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Consensus ad idem: a protocol for development of consensus statements

No single group has the right to ignore a consensus of thoughtful opinion.
Mollie Hunter (1922–2012)

In this issue, we publish a consensus report from the Clinical Practice Committee of the Canadian Association of General Surgeons regarding Clostridium difficile.1 Medical use of the word “consensus” is evolving. Its 19th century meaning — the harmony between physiologic systems — has faded in most areas of medicine, with the possible exception of the field of genetics in which consensus may refer to conserved sequences of DNA. The specific physiologic term has been replaced in medicine by a vaguer popular meaning, often used to confer authority upon a statement or process — authority that it might otherwise possess. Popular use is derived from the legal term consensus ad idem, which originated in Roman law as an informal contract based on mutual consent. The element of consent has persisted in its legal use, but the emphasis has changed in popular and medical use to denote agreement not just between parties, but general acceptance.

While we have become increasingly precise about grades of medical evidence, interpretation of these units of evidence in complex pathophysiological systems remains less structured. The outcome is more often decided by regulators and insurers than by agreement among practitioners. The National Institutes of Health (NIH) distinguishes consensus statements from clinical practice guidelines (CPGs) as the synthesis of new information from recent research. Standardization policies by jurisdictions such as the European Union are vague with respect to methods of consensus development, but they are prescriptive with respect to CPGs, stating they may be used in litigation as a standard of practice.2 This is particularly true of cancer care in Canada.3 The NIH Consensus Development Program attempts to address some of these issues, but topic selection is very restrictive and the conference approach is limiting.4

The Delphi procedure for deriving consensus is said to have originated as a method used by the military after World War II to brainstorm about the capabilities and future actions of the enemy. Developed later for public policy creation, the procedure attempted to include and protect all points of view in iterative cycles of facilitated refinement. The nominal group method assigns fundamental aspects of complex problems to groups using techniques intended to prevent domination by a single opinion, with voting to determine priorities. The nominal group method was used recently to determine waiting time targets for pediatric surgery in Canada.5 The Delphi procedure is more often used for distant communication, and the nominal group method is favoured by consensus conferences. With modern communication systems, these procedures may be blended.

Consensus ad idem implies agreement not only about the answer, but also about the question. CJ S protocol for publishing consensus-based articles will require the authors to be selected by a representative group or society. The subject, topic or question addressed by the statement should be validated by a committee of that group. Composition of the report should use the procedures outlined here so that research tasks are shared productively among subgroups and opinions, including a patient perspective if possible, are debated. The initial draft should be circulated among the general membership of the society, whose comments should be considered in revisions before confirmation by a committee or executive of the sponsoring society. When the final draft is submitted to the journal, it will undergo independent peer review. Those accepted for publication will include a footnote confirming compliance with CJ S protocol for consensus development. In the end, the weight accorded to a consensus report will depend on the validity of the process it uses to distill the thoughtful opinion it appraises.

Vivian McAlister, MB
Coeditor, Canadian Journal of Surgery

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Consensus ad idem : une démarche pour la formulation de déclarations de consensus

Aucun groupe n’a le droit d’ignorer un consensus d’opinion réfléchie.
Mollie Hunter (1922–2012)

Dans ce numéro, nous publions un rapport de consensus du Comité de pratique clinique de l’Association canadienne des chirurgiens généraux au sujet de Clostridium difficile. L’usage médical du terme « consensus » a évolué au fil des siècles. Au 19e siècle, il signifiait « harmonie entre les systèmes physiologiques ». Ce sens a disparu dans la plupart des domaines médicaux, à l’exception possible du domaine de la génétique, dans lequel un consensus peut faire référence à des séquences conservées d’ADN. Le sens physiologique précis a été remplacé en médecine par un sens populaire plus vague, souvent utilisé pour conférer une autorité à un énoncé ou un processus — autorité qu’il pourrait ne pas détériorer autrement. L’usage populaire est dérivé du terme juridique consensus ad idem, notion issue du droit romain signifiant un « contrat informel fondé sur le consentement mutuel ». L’élément de consentement a persisté dans son utilisation légale, mais le sens a changé dans l’usage populaire et médical pour désigner un accord non seulement entre les parties, mais une acceptation générale.

Bien que nous soyons devenus plus précis au sujet des degrés de qualité des preuves médicales, l’interprétation de ces unités de données dans les systèmes physiopathologiques complexes demeure moins structurée. Le résultat est souvent décidé davantage par les organismes de réglementation et les assureurs que par un accord entre les praticiens. Les National Institutes of Health (NIH) des États-Unis font une distinction entre les déclarations de consensus et les guides de pratique clinique (GPC), les définissant comme la synthèse de nouvelles informations issues de la recherche récente. Les politiques de normalisation par les administrations comme l’Union européenne sont vagues en ce qui concerne les méta-analyses ou les guides de pratique clinique, les définissant comme la synthèse de nouvelles informations issues de la recherche récente. Les politiques de normalisation par les administrations comme l’Union européenne sont vagues en ce qui concerne les méthodes d’élaboration d’un consensus, alors qu’elles ont des normatives à l’égard des GPC, affirmant qu’ils peuvent être utilisés dans des litiges en tant que norme de pratique. Cela est particulièrement vrai dans le cas des soins du cancer au Canada. Le Programme d’élaboration de consensus des NIH tente de résoudre certaines de ces questions, mais le choix des sujets est très restrictif et l’approche par conférence est également restrictive.

La méthode Delphi utilisée pour dégager un consensus tire son origine d’une méthode employée par les militaires après la Seconde Guerre mondiale. Ils tenaient des séances de remue-méninges sur les capacités et les actions futures de l’ennemi. Développée plus tard pour la création de politiques publiques, la méthode Delphi a tenté d’inclure et de protéger tous les points de vue en utilisant des cycles itératifs pour préciser l’opinion consensuelle. Par ailleurs, la technique du groupe nominal attribue des aspects fondamentaux de problèmes complexes à des groupes en utilisant des techniques destinées à empêcher la domination par une seule opinion par un scrutin sur le choix des priorités. La technique du groupe nominal a été utilisée récemment pour déterminer les objectifs de temps d’attente pour la chirurgie pédiatrique au Canada. La méthode Delphi est l’approche la plus souvent utilisée pour la communication à distance alors que la technique du groupe nominal est la préférée pour les conférences de consensus. Grâce aux systèmes de communication modernes, on peut combiner ces méthodes.

Le consensus ad idem suppose un accord non seulement sur la réponse, mais aussi sur la question. Le protocole JCC pour la publication d’articles fondés sur un consensus exige que les auteurs soient choisis par une société ou un groupe représentatif. Le sujet ou la question posée par l’énoncé doit être validé par un comité de ce groupe ou de cette société. La composition du rapport devrait utiliser les procédures décrites ici afin que les tâches de recherche soient réparties de manière productive entre les sous-groupes et que les opinions, y compris le point de vue du patient si possible, fassent l’objet de discussions. L’ébauche initiale du manuscrit devrait être distribuée à l’ensemble des membres de la société, dont les commentaires doivent être pris en compte dans les révisions avant la confirmation par un comité ou par l’Exécutif de la société commanditaire. Lorsque le manuscrit final est présenté au journal, il sera soumis à un examen indépendant par les pairs. Les articles acceptés pour publication inclureront une note de bas de page confirmant la conformité au protocole du JCC pour l’élaboration d’un consensus. Au final, le poids accordé à un rapport de consensus dépendra de la validité du processus utilisé pour extraire l’opinion réfléchie qu’il évalue.

Vivian McAlister, MB
Co-rédacteur, Journal canadien de chirurgie

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Références
Clostridium difficile is emerging as a major infectious disease threat worldwide. The incidence of C. difficile infection (CDI) has exponentially increased globally, and the profile of patients at risk has changed in the past decade. Severe CDI outbreaks due to new, hypervirulent strains have emerged and inflicted significant morbidity on low-risk patients. In the United States, CDI rates have doubled, with 76.9 episodes of CDI per 10,000 hospital discharges in 2005. The alarming prevalence of CDI was exemplified in a recent report from the Association of Professionals in Infection Control and Epidemiology, who identified that more than 12 of every 1,000 inpatients in the United States have been infected and are experiencing symptoms of CDI. Therefore, it is not surprising that CDI colitis has been identified as the direct cause of death in 1%–2% of affected patients, with the estimated annual cost per year per facility for nosocomial CDI estimated at $128,200. Containment and treatment of individuals afflicted with CDI was estimated at more than $3 billion in the United States alone. It is critical that health care providers understand this emerging infectious disease and develop strategies to limit its destructive impact on the population.

**History**

In 1935, Hall and O'Toole, in an attempt to understand the development of normal bacterial flora in neonates, identified a new anaerobe, which they initially called Bacillus difficilis. Interestingly, this bacterium was not clinically infectious in newborns but was pathogenic in guinea pigs via a fierce exotoxin. It was not until 1977 that Bartlett and colleagues identified that this anaerobic bacterium was a potent human pathogen and the etiologic agent responsible for antibiotic associated pseudomembranous colitis. The bacillus was aptly moved to the genus Clostridium, secondary to its obligate anaerobic status and its capability of producing endospores. The species name “difficile” remained owing to the difficulty involved in its isolation and study. Since then, C. difficile has evolved and is recognized as an important nosocomial pathogen, inflicting significant morbidity in infected individuals.

**Disease characteristics**

The virulence of C. difficile varies by patient. In its most benign cases C. difficile is associated with no symptoms, and individuals serve only as a reservoir for the disease. Symptomatic patients often report only mild abdominal pain and diarrhea. Others experience leukocytosis, fever, copious volumes of diarrhea and severe abdominal pain. Fulminant colitis develops in approximately 3% of these patients and is associated with a profound inflammatory response and considerable morbidity. The pertinent features of the various clinical presentations are summarized in Box 1.

To appreciate the spectrum of clinical disease caused by this microbe, it is important to understand its biology and the pathogenesis of disease. C. difficile is an anaerobic, gram-positive bacillus. It reproduces by the process of binary fission and is motile through the presence of peritrichous flagella. C. difficile exists...
COMMENTAIRE

in 1 of 2 forms: a vegetative form (sensitive to oxygen) and a spore form (heat-stable and able to survive in a variety of environments).\(^7\) In its vegetative state the bacterium is able to use nutrients to grow and divide. However, when conditions become unfavourable (e.g., acidic environment, high temperature), this microbe is able to enter a dormant state and form a highly resistant spore. The ability of \textit{C. difficile} to form these endospores is a key survival feature that allows it to persist both in patients and on inanimate objects (where it can survive up to 2 yr), making it very difficult to eradicate and easy to transmit.\(^7\) Interestingly, when the bacterium is faced with stress and unfavourable conditions, its ability to adhere to human intestinal cells increases, making colonization easier. Its ability to form spores enables its survival through the human digestive system and out into the oxygenated environment until it returns to its human host and vegetative state.\(^7\)

The natural habitat for this organism is the microflora of human intestines. Around 3% of healthy adults and up to 70% of infants have \textit{C. difficile} bacteria in their guts.\(^7\) Natural gut flora acts as a barrier that protects against colonization by this microbe.\(^7\) While this organism also exists in the gastrointestinal system of pets and livestock, human CDI is not considered a zoonotic or food-borne disease.\(^7\) \textit{C. difficile} is spread via the fecal–oral route, where the organism is ingested in either the vegetative or spore form. Once ingested, the spore form is acid-resistant and passes readily through the stomach; it may germinate into the vegetative form in the alkaline small bowel environment and then travel to the capacious large intestine.\(^1\) In most individuals, the normal ubiquitous microflora of the intestine prevents \textit{C. difficile} from growing owing to limited space and resources. However, if the normal microflora of a person infected with \textit{C. difficile} has been disrupted by antibiotic therapy, these microbes are able to multiply and colonize within the intestinal crypts.\(^7\)

The most common risk factor for colonization is exposure to antibiotics, particularly those with broad-spectrum activity (e.g., clindamycin, penicillin, some cephalosporins).\(^10\) Other described risk factors include immunosuppressive agents, increasing age, severe underlying illness, gastrointestinal surgery and use of antiperistaltic and antacid medications.\(^10\)

After colonization, \textit{C. difficile} generates and releases its main virulence factors: 2 large clostridial exotoxins, toxins A and B.\(^7\) These toxins are encoded by the \textit{tcdA} and \textit{tcdB} genes. Toxins A and B act as potent exotoxins that work by binding to human intestinal epithelial cells and inducing inflammation, mucopurulent secretions and damage to mucosal structures.\(^7\) The process begins with toxin A binding to the apical side of the cell, which, after internalization, causes cytoskeletal changes that result in disruption of tight junctions and loosening of the epithelial barrier.\(^7\) This disruption allows both toxins to then cross the epithelium, where toxin B binds preferentially to the basolateral cell membrane.\(^11\) Both toxins are cytotoxic and induce the release of various immunomodulatory mediators. Toxin A works specifically by activating and recruiting important inflammatory mediators (interleukin [II]-6, IL-8, IL-1, tumour necrosis factor [TNF]-\(\alpha\)) to the site of colonization, while toxin B demonstrates direct cytotoxic effects.\(^7\) Only toxigenic strains of \textit{C. difficile} are able to produce clinically symptomatic CDI. In the asymptomatic carrier state, these toxins are found less frequently.\(^11\) Further, asymptomatic carriers show a propensity to produce a protective IgG response to the \textit{C. difficile} enterotoxin.\(^7\) Toxin A, although not essential for virulence, plays a more critical role than toxin B in the development of \textit{C. difficile} diarrhea, as animal models have demonstrated it is solely associated with tissue damage and fluid accumulation in intestinal cells.\(^7\) Toxin B has no direct enterotoxic effect and plays a role after the intestinal wall has been damaged by toxin A.\(^7\) Interestingly, a recent study examining the change in CDI epidemiology has identified the existence of a new hypervirulent and epidemic strain of \textit{C. difficile}.\(^7\) It has been suggested that the

Box 1. Clinical presentation and features of \textit{Clostridium difficile} infection\(^7,8\)

**Asymptomatic carrier state**

- Up to 20% of patients are colonized with CDI but do not have any clinical symptoms of CDI
- Individuals serve as an important reservoir for environmental contamination
- Host immune response to CDI may play a role in determining individuals’ carrier state

**\textit{C. difficile} diarrhea**

- Mild to moderate nonbloody, watery diarrhea with or without abdominal cramps
- Symptoms usually begin during or shortly after antibiotic therapy
- Diarrhea resolves with discontinuation of antibiotics
- Toxins can be detected from fecal specimens
- Endoscopy results are often normal

**\textit{C. difficile} colitis**

- Fever, malaise, abdominal pain, high-volume watery diarrhea in which stools can have some trace blood
- Leukocytosis is common
- Patchy erythematous colitis without pseudomembranes visible on endoscopy scan

**Pseudomembranous colitis (PMC)**

- Systemic illness, including abdominal pain, tenderness, fever and severe diarrhea that may be bloody
- Severe leukocytosis and hypoaalbuminemia can be seen
- Pseudomembranes (raised yellow plaques on colonic mucosa), most commonly in rectogastrointestinal area visible on endoscopy scan
- Increased colonic thickening visible on computed tomography scan

**Fulminant colitis**

- Occurs in approximately 3% of patients
- Associated with serious complications (perforation, prolonged ileus, toxic megacolon, death)
- Systemic inflammatory condition involving severe abdominal pain with or without diarrhea, high fever, chills, hypotension, tachypnea and marked leukocytosis
- Surgical intervention often necessary

CDI = \textit{C. difficile} infection.
emergence of these hypervirulent strains has been driven by overuse and misuse of antibiotics. The epidemic strain (toxinotype 3, strain 027) has been shown to produce higher levels of toxins A and B (16–23 times higher) than the usual toxinotype 0. Further, this strain produces a binary toxin, CDT, which potentiates the toxic effects of toxins A and B.

DIAGNOSIS

The enterotoxins produced by C. difficile represent the major virulence factors causing CDI. Diagnostic tools use this production to help health care providers diagnose the presence of this infectious scourge. Clinically, the diagnosis should be considered in any patient with new onset diarrhea with risk factors (primarily previous antibiotic exposure), especially if the diarrhea was contracted nosocomially. Laboratory diagnosis is made based on the detection of toxin A or B in a stool specimen. The gold standard test for diagnosis is the cytotoxin assay, which has a sensitivity of 80%–90% and a specificity of 99%–100%. This test is based on identification of toxin B in a cell culture. The main disadvantage with this test is that results take 1–3 days. To speed up results, rapid enzyme immunoassay tests have been developed to detect toxin A or both toxins A and B in the stool specimen. This enzyme-linked immunosorbent assay produces a reduced sensitivity (65%–85%) and specificity (95%–100%) compared with the cytotoxicity assay but allows results to be available within hours rather than days. Other less commonly used tests include anaerobic stool culture isolation of C. difficile. Stool culture for C. difficile is rarely performed in clinical microbiology laboratories because of inconvenience compared with the toxin assays and because the test, while very sensitive (90%–100%), fails to distinguish between toxigenic and nontoxigenic strains. This can be distinguished if a toxin assay is added as a second step in the test. A new investigational method is the polymerase chain reaction assay for C. difficile toxins. This test is sensitive (92%–97%) and specific (100%). Commercial availability is pending. In some situations, endoscopy has been used when a rapid diagnosis is required (e.g., a patient has ileus and cannot produce stool specimens). Sigmoidoscopy or colonoscopy is used to visualize and biopsy the colonic mucosa to diagnose pseudomembranous colitis. Endoscopy carries a risk of perforation, so it should be used judiciously. Finally, imaging, such as computed tomography, can be useful in demonstrating thumbprinting of the colonic mucosa (suggestive of edema), but these changes are not specific and cannot be used as the sole diagnostic tool.

TREATMENT

Once a diagnosis has been established treatment should be initiated for CDI. The key first step in treatment is to identify and eliminate the inciting agent (most commonly an antibiotic) as soon as possible. Thereafter supportive measures, such as fluid resuscitation and electrolyte correction should be initiated. These 2 measures are often sufficient for early mild disease. For mild to moderate cases, the mainstay of therapy is targeted antimicrobial treatment against C. difficile. The Infectious Disease Society of America recommends metronidazole (oral administration of 500 mg twice daily for 10–14 d) as the first line therapy. Vancomycin (oral administration of 125 mg 4 times daily for 10–14 d) is the drug of choice for severe CDI. If a prior underlying infection requires a prolonged course of antibiotics, anti-CDI therapy should be extended to 1 week past the concomitant antimicrobial’s conclusion. In patients with the most severe and complicated infections (e.g., toxic megacolon), a combination of intravenous metronidazole (500 mg 3 times daily) and oral vancomycin (500 mg 4 times daily) is recommended.

The wide spectrum of illness caused by C. difficile is mirrored by an equally broad approach to following the disease’s progression. In patients with mild disease, serial examination, regular bloodwork and symptom reporting are the mainstays of monitoring. Patients with more severe manifestations of the disease, including increasing abdominal pain and distention or an impressive and increasing leukocytosis, may benefit from daily radiography of the abdomen to monitor for colonic dilatation, the development of toxic megacolon and perforation. Some suggest that genotyping C. difficile infections at disease onset may help predict disease severity. Clinicians armed with data regarding the genotype of C. difficile in instances of outbreak have felt that the information helped the management of these clusters, but these feelings were not reflected by clinical outcomes.

There is uncertainty regarding 2 major issues in the surgical management of CDI: timing and choice of procedure. Surgical intervention is common in severely ill patients with peritonism, perforation, necrotizing colitis or multi-organ dysfunction syndrome. Attempts to standardize timing of colectomy have been made on the basis of laboratory values (e.g., white blood cell count of 20–50 x 10^9/L, a serum lactate of 2.2–5.0 mmol/L), patient demographics (e.g., age > 74 yr), and clinical status (e.g., the need for vasoactive medications). The question of timing is further complicated by an emerging alternative procedure to colectomy: diverting loop ileostomy with colonic lavage, whose promising early results may lead to earlier operative intervention given the theoretical minimization of systemic insult owing to the decreased extent of the operation. However, the information obtained by Neal and colleagues regarding this technique is limited largely by its current versus historical cohort design.

Apart from metronidazole and vancomycin, several new therapeutic agents have been tested or are being researched as potential options. One of these is fidazomycin, a macrocyclic antibiotic that, in vitro, has demonstrated...
higher activity against \textit{C. difficile}, including the hypervirulent type 027, than vancomycin.\cite{1} Large, multicentre randomized clinical trials continue to study the efficacy of this drug, and it appears to be a potent future weapon to combat \textit{C. difficile}. In addition to studies on antimicrobial treatments for CDI, there have also been studies of the use of intravenous immunoglobulin (IVIG) in patients with severe or recurrent CDI. The IVIG contains \textit{C. difficile} antitoxins, and small case series have demonstrated benefit, but comparative studies are still required before any treatment recommendations can be made.\cite{1} Dating back to 1958, intestinal microbiota transplantation (fecal bacterotherapy) has been outlined as a potential treatment modality.\cite{7,15} In an attempt to restore normal intestinal flora (limiting colonization by \textit{C. difficile}), microorganisms can be transplanted from healthy individuals via infusion of liquid suspension of stool. Systematic reviews have demonstrated this modality to be highly effective, and it led to resolution in 92% of patients.\cite{1} Clinical trials providing recommendations and guidance are still not available.\cite{1} Future possibilities include vaccination against \textit{C. difficile}. Currently, a parenteral \textit{C. difficile} toxoid vaccine, which induces high levels of antitoxin A immunoglobulin G, is in phase 2 clinical trials.\cite{1} Despite all of these treatment options, about 20% of patients with a single episode of CDI will relapse.\cite{1} Relapse is related to spore persistence and is caused by the same strain that caused the initial infection. Metronidazole remains the primary drug of choice for recurrence.\cite{1} If treatment with metronidazole alone fails, tapered and pulsed therapy with metronidazole and vancomycin is suggested.\cite{1} In addition, individuals with recurrent CDI tend to be very strong candidates for adjunctive therapy with probiotic agents, such as \textit{Saccharomyces boulardii} and \textit{Lactobacillus GG}.\cite{4} These probiotics are live microbes that help upregulate the host flora’s composition and thus out-compete \textit{C. difficile} for colonizing real estate.

\section*{Prevention}

Prevention strategies remain one of the most important methods that health care providers must use to limit the spread and pestilence caused by \textit{C. difficile}. Clinical practice guidelines for CDI prevention were published by the Society for Healthcare Epidemiology of America and the Infectious Disease Society of America in 2010.\cite{6} The key points include the strict isolation of infected patients in private rooms, proper use of gown and gloves and proper handwashing procedures for health care workers, environmental cleaning and disinfection using chlorine-based cleaning agents and implementation of antibiotic stewardship programs.\cite{7,23} Special attention should be paid to improving antibiotic usage by clinicians. A stepwise reduction in the use of clindamycin, broad-spectrum cephalosporins and fluoroquinolones, with an associated decrease in total frequency and duration of exposure, is one of the most effective methods of reducing the incidence of CDI according to the Centers for Disease Control.\cite{25}

Since its initial isolation in 1935, \textit{C. difficile} has swiftly taken its position as one of the most common nosocomial pathogens causing significant morbidity and mortality worldwide. As we have learned from the pathogenesis of CDI, \textit{C. difficile} is an extremely persistent organism with an ability to survive for long periods in a variety of environmental conditions. Further, it is highly adaptive, and in the past decade severe outbreaks due to hypervirulent strains have emerged.\cite{7} It is important to understand both the factors associated with the emergence of this disease and the modalities we can use to manage and prevent its effects. The injudicious use of antibiotics has been identified as one of the most important etiologic factors in promoting an antecedent disruption of normal colonic flora, which is a necessary first step in the pathogenesis of disease.\cite{7} Ergo, it will take a dedicated effort by all health care providers both to accept our role in promoting the proliferation of CDI and to use this knowledge to implement important strategies, such as proper handwashing and detailed antibiotic stewardship programs, to control and hopefully eliminate this emerging infectious scourge.

\section*{Conclusions}

The Canadian Association of General Surgeons Clinical Practice Committee encourages Canadian surgeons to be aware of the science of \textit{C. difficile} infection and its pathogenesis in order to be better equipped to deal effectively with the condition.

\section*{References}

The reliability of differentiating neurogenic claudication from vascular claudication based on symptomatic presentation

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Background: Intermittent claudication can be neurogenic or vascular. Physicians use a profile based on symptom attributes to differentiate the 2 types of claudication, and this guides their investigations for diagnosis of the underlying pathology. We evaluated the validity of these symptom attributes in differentiating neurogenic from vascular claudication.

Methods: Patients with a diagnosis of lumbar spinal stenosis (LSS) or peripheral vascular disease (PVD) who reported claudication answered 14 questions characterizing their symptoms. We determined the sensitivity, specificity and positive and negative likelihood ratios (PLR and NLR) for neurogenic and vascular claudication for each symptom attribute.

Results: We studied 53 patients. The most sensitive symptom attribute to rule out LSS was the absence of “triggering of pain with standing alone” (sensitivity 0.97, NLR 0.050). Pain alleviators and symptom location data showed a weak clinical significance for LSS and PVD. Constellation of symptoms yielded the strongest associations: patients with a positive shopping cart sign whose symptoms were located above the knees, triggered with standing alone and relieved with sitting had a strong likelihood of neurogenic claudication (PLR 13). Patients with symptoms in the calf that were relieved with standing alone had a strong likelihood of vascular claudication (PLR 20.0).

Conclusion: The classic symptom attributes used to differentiate neurogenic from vascular claudication are at best weakly valid independently. However, certain constellation of symptoms are much more indicative of etiology. These results can guide general practitioners in their evaluation of and investigation for claudication.

Contexte : La claudication intermittente peut avoir une étiologie neurogène ou vasculaire. Les médecins utilisent un profil fondé sur les particularités des symptômes pour distinguer l’une de l’autre et ceci oriente leur choix des méthodes de diagnostic de la pathologie sous-jacente. Nous avons évalué la validité de ces particularités des symptômes utilisées pour distinguer la claudication d’origine neurogène de la claudication d’origine vasculaire.

Méthodes : Des patients atteints d’une sténose spinale lombaire (SSL) ou d’une maladie vasculaire périphérique (MVP) avaient chaque fois répondu à 14 questions afin de caractériser leurs symptômes. Nous avons déterminé la sensibilité, la spécificité et les rapports de probabilité positifs et négatifs (RPP et RPN) de la claudication neurogène ou vasculaire par constelation des symptômes. Les résultats peuvent guider l’omnipraticien dans son examen et dans son diagnostic de la claudication.

Résultats : Notre étude a regroupé 53 patients. La particularité des symptômes dotée de la sensibilité la plus élevée pour ce qui est d’écarter le diagnostic de SSL a été l’absence de « déclenchement de douleur à la simple station debout » (sensibilité 0,97; NLR 0,050). Les données sur ce qui soulageait la douleur et sur la localisation des symptômes ont eu une faible portée clinique en ce qui a trait à la SSL et à la MVP. La présence d’une constellation de symptômes a donné lieu aux associations les plus solides : les patients qui manifestaient un signe du « panier d’épicerie » positif et dont les symptômes étaient localisés au-dessus du genou, déclenchés par la station debout seule et soulagés en position assise présentaient une forte probabilité de claudication d’origine neurogène (RPP 13). Chez les patients dont les symptômes étaient localisés au mollet et qui étaient soulagés par la station debout, on notait une forte probabilité de claudication d’origine vasculaire (RPP 20.0).

Conclusion : Considérés individuellement, les attributs classiques des symptômes utilisés pour distinguer la claudication d’origine neurogène de la claudication d’origine vasculaire sont au mieux faiblement valides. Toutefois, certaines constellations de symptômes éclairaient bien davantage l’étiologie. Ces résultats peuvent guider l’omnipraticien dans son examen et dans son diagnostic de la claudication.
**Methods**

This was an observational cohort study approved by our institution research ethics review board. A research associate explained the study and provided a letter of information to every patient who fulfilled the inclusion and exclusion criteria described the next section. We obtained written consent from each patient enrolled in the study.

**Selection and description of participants**

We recruited patients attending the spine or vascular clinics at a tertiary care centre between July 2008 and July 2011 who reported intermittent claudication. Our inclusion criteria were a 6-month history of intermittent claudication symptoms (defined as “induction of pain in the legs and/or buttocks with walking, alleviated with standing or sitting”) and either clinically important LSS or PVD diagnosed by a fellowship-trained orthopedic spine surgeon or vascular surgeon, respectively. The exclusion criteria were concurrent PVD and LSS, nondegenerative LSS (e.g., congenital, traumatic), mechanical back pain equal to or greater than claudication symptoms, radicular pain due to foraminal stenosis, previous back or vascular surgery, type 1 diabetes, lower extremity peripheral neuropathy, symptomatic hip or knee osteoarthritis, total hip or knee arthroplasty, inability to read/write English, inability to provide informed consent, substance abuse and/or mental illness.

To confirm that every patient had a single pathology, either LSS or PVD, each patient underwent MRI of the lumbar spine and had their ABI measured with Doppler ultrasonography. A fellowship-trained orthopedic spine surgeon (C.S.B.) reviewed the MRI scans in a blinded fashion to determine if severe central canal stenosis (LSS) was present. Certified ultrasonography technicians performed the ABI measurements. Values less than 0.9 were labelled as positive for PVD.\textsuperscript{19,20} Patients with findings positive for one test and negative for the other were enrolled in the appropriate group. No patients had positive results for both LSS and PVD.

**Outcome measures**

Patients completed a questionnaire (see the Appendix, available at cma.ca/cjs) pertaining to their claudication symptoms. This was completed with the assistance of a research associate or surgical resident to ensure proper understanding of the questions. All questions addressed different symptom attributes, including symptom triggers and predictability of onset, symptom alleviators and time for relief, symptom location, nature of the symptoms and association between symptoms and body posture. Each question elicited a response of “yes” or “no.”
Statistical analysis

We tested each question for its sensitivity, specificity, PLR and NLR (Table 1) for both the neurogenic and vascular groups. If a test item (i.e., symptom attribute) has a high sensitivity, a negative response can be useful in ruling out a disease; conversely, if a test item (or symptom attribute) has a high specificity, a positive response indicates a high probability of the presence of the disease. Because the prevalence of each pathology is unclear, sensitivity and specificity are less valid in determining clinical relevance. On the other hand, likelihood ratios are not affected by prevalence, and are therefore more valid in this context. They indicate how much the odds of having the disease increase when the test is positive (PLR) or decrease when the test is negative (NLR; Table 2). We began by calculating these values for individual symptom attributes. This yielded weak clinical significance only; therefore, we performed the same statistical analysis using combinations of symptoms attributes. To do this, we combined in a stepwise fashion the attributes with the highest PLR values whose 95% confidence interval (CI) did not include 1 until we reached a PLR greater than 10, indicating a strong evidence for the pathology in question (LSS or PVD).

RESULTS

We enrolled 53 patients (12 women and 18 men, with an average age of 65 ± 7.6 yr in the neurogenic group and 8 women and 15 men with an average age of 61 ± 8.1 yr in the vascular group). The sensitivity, specificity, PLR, and NLR are provided for each symptom attribute classically associated to the neurogenic and vascular groups (Tables 3 and 4, respectively). We analyzed every attribute for both groups. All PLRs obtained were less than 5 for any of the individual symptom attributes investigated (Tables 3 and 4). This implies that a single symptom attribute represents weak evidence for one type of claudication over the other (Table 2). This result led us to create constellations of symptom attributes; these are presented in Tables 3 and 4.

Neurogenic claudication

The symptom attribute best able to rule out intermittent neurogenic claudication (i.e., high sensitivity) was the absence of "triggering of pain with standing alone" (sensitivity 0.97, NLR 0.050; Table 3). The 3 largest PLR values were the alleviation of symptoms when sitting (PLR 3.8), triggering of symptoms when standing alone (rather than walking; PLR 3.2) and symptoms located above the knee (PLR 2.3; Table 3). In addition, the NLR values for these 3 symptom attributes were the smallest (0.21, 0.04 and 0.31, respectively), meaning that not only are these attributes most closely associated with neurogenic claudication, they are also the ones least closely associated with vascular claudication. Furthermore, despite small sample numbers, the 95% CI for the PLR and NLR values of each of these 3 symptom attributes did not include 1. However, because the PLR and NLR values were less than 5, they individually represented only weak evidence of neurogenic claudication.

Certain constellations of symptoms yielded stronger associations and, therefore, more clinically relevant results. The constellation consisting of triggering of symptoms with standing, relief with sitting, symptoms located above the knees and a positive shopping cart sign yielded a PLR of 13 (Table 2).

Vascular claudication

The absence of the triggering of pain with walking was the most sensitive symptom with which to rule out vascular claudication in this cohort (sensitivity 0.96). However,

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**Table 1. Statistical calculations used for analysis**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>Likelihood that the diagnostic test will indicate the presence of disease when the disease is actually present</td>
<td>( T_+ \div (T_+ + F_-) )</td>
</tr>
<tr>
<td>Specificity</td>
<td>Likelihood that the diagnostic disease will indicate the absence of disease when the disease is actually absent</td>
<td>( T_- \div (T_- + F_+) )</td>
</tr>
<tr>
<td>Positive likelihood ratio</td>
<td>Indicates how much more likely it is to get a positive test in a person with than without the disease</td>
<td>Sensitivity ( \div (1 - \text{Specificity}) )</td>
</tr>
<tr>
<td>Negative likelihood ratio</td>
<td>Indicates how much more likely it is to get a negative test in a person without than with the disease</td>
<td>( (1 - \text{Sensitivity}) \div \text{Specificity} )</td>
</tr>
</tbody>
</table>

**F_+** = false positive; **F_-** = false negative; **T_+** = true positive; **T_-** = true negative.

---

**Table 2. Interpretation of likelihood ratio values for clinical application**

<table>
<thead>
<tr>
<th>Likelihood ratio</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 10</td>
<td>Strong evidence to rule in the disease</td>
</tr>
<tr>
<td>5–10</td>
<td>Moderate evidence to rule in the disease</td>
</tr>
<tr>
<td>2–5</td>
<td>Weak evidence to rule in the disease</td>
</tr>
<tr>
<td>0.5–2</td>
<td>No significant change in the likelihood of the disease</td>
</tr>
<tr>
<td>0.2–0.5</td>
<td>Weak evidence to rule out the disease</td>
</tr>
<tr>
<td>0.1–0.2</td>
<td>Moderate evidence to rule out the disease</td>
</tr>
<tr>
<td>&lt; 0.1</td>
<td>Strong evidence to rule out the disease</td>
</tr>
</tbody>
</table>
Table 3. Symptom attributes for neurogenic intermittent claudication

<table>
<thead>
<tr>
<th>Attribute*</th>
<th>Measure (95% CI)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PLR</th>
<th>NLR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single symptom attributes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trigger</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standing (1)</td>
<td>0.97 (0.81–1.0)</td>
<td>0.70 (0.47–0.98)</td>
<td>3.2 (1.7–6.9)†</td>
<td>0.04 (0.0067–0.34)†</td>
<td></td>
</tr>
<tr>
<td>Walking (2)</td>
<td>0.90 (0.72–0.97)</td>
<td>0.04 (0.0023–0.24)</td>
<td>0.94 (0.81–1.1)</td>
<td>2.30 (0.12–43)</td>
<td></td>
</tr>
<tr>
<td>Alleviator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sitting (3a)</td>
<td>0.83 (0.65–0.94)</td>
<td>0.78 (0.56–0.92)</td>
<td>3.80 (1.7–8.5)†</td>
<td>0.21 (0.083–0.44)†</td>
<td></td>
</tr>
<tr>
<td>Posture</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shopping cart sign (4)</td>
<td>0.80 (0.61–0.92)</td>
<td>0.52 (0.31–0.73)</td>
<td>1.70 (1.1–2.7)†</td>
<td>0.38 (0.17–0.85)†</td>
<td></td>
</tr>
<tr>
<td>Walking uphill (7)</td>
<td>0.23 (0.11–0.43)</td>
<td>0.78 (0.55–0.92)</td>
<td>1.07 (0.39–2.9)</td>
<td>0.98 (0.79–1.2)</td>
<td></td>
</tr>
<tr>
<td>Nature</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Numbness (8)</td>
<td>0.75 (0.55–0.89)</td>
<td>0.41 (0.21–0.63)</td>
<td>1.30 (0.84–1.9)</td>
<td>0.61 (0.28–1.3)</td>
<td></td>
</tr>
<tr>
<td>Cramping (9)</td>
<td>0.53 (0.35–0.71)</td>
<td>0.35 (0.17–0.57)</td>
<td>0.82 (0.52–1.3)</td>
<td>1.30 (0.78–2.3)</td>
<td></td>
</tr>
<tr>
<td>Burning pain (10)</td>
<td>0.62 (0.42–0.79)</td>
<td>0.52 (0.31–0.73)</td>
<td>1.30 (0.78–2.2)</td>
<td>0.73 (0.42–1.3)</td>
<td></td>
</tr>
<tr>
<td>Weakness (11)</td>
<td>0.43 (0.25–0.63)</td>
<td>0.59 (0.37–0.79)</td>
<td>1.00 (0.54–2.0)</td>
<td>0.97 (0.66–1.4)</td>
<td></td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Above the knees (5)</td>
<td>0.80 (0.61–0.92)</td>
<td>0.65 (0.43–0.83)</td>
<td>2.30 (1.3–4.1)†</td>
<td>0.31 (0.14–0.66)†</td>
<td></td>
</tr>
<tr>
<td>Time for relief</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 10 min</td>
<td>0.30 (0.15–0.50)</td>
<td>0.78 (0.56–0.92)</td>
<td>1.40 (0.53–3.6)</td>
<td>0.89 (0.69–1.1)</td>
<td></td>
</tr>
<tr>
<td>Constellation of symptom attributes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triggered with standing (1), alleviated with sitting (3a)</td>
<td>0.80 (0.61–0.92)</td>
<td>0.87 (0.65–0.97)</td>
<td>6.10 (2.1–18)†</td>
<td>0.23 (0.11–0.48)†</td>
<td></td>
</tr>
<tr>
<td>Triggered with standing (1), alleviated with sitting (3a), located above the knees (5)</td>
<td>0.67 (0.47–0.82)</td>
<td>0.91 (0.70–0.98)</td>
<td>7.70 (2.0–30)†</td>
<td>0.37 (0.22–0.61)†</td>
<td></td>
</tr>
<tr>
<td>Triggered with standing (1), alleviated with sitting (3a), located above the knees (5), positive shopping cart sign (4)</td>
<td>0.57 (0.38–0.74)</td>
<td>0.96 (0.76–1.0)</td>
<td>13.00 (1.9–91)†</td>
<td>0.45 (0.30–0.68)†</td>
<td></td>
</tr>
</tbody>
</table>

CI = confidence interval; NLR = negative likelihood ratio; PLR = positive likelihood ratio.
*Numbers in brackets represent the corresponding question number in the questionnaire (see the Appendix, available at cma.ca/cjs).
†Numbers whose values represent clinical significance.

Table 4. Symptom attributes for vascular intermittent claudication

<table>
<thead>
<tr>
<th>Attribute*</th>
<th>Measure (95% CI)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PLR</th>
<th>NLR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single symptom attributes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trigger</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking (2)</td>
<td>0.96 (0.76–1.00)</td>
<td>0.10 (0.03–0.28)</td>
<td>1.10 (0.92–1.2)</td>
<td>0.43 (0.04–5.3)</td>
<td></td>
</tr>
<tr>
<td>Symptom onset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Predictable (2a)</td>
<td>0.87 (0.65–0.97)</td>
<td>0.37 (0.21–0.56)</td>
<td>1.37 (1.0–1.9)</td>
<td>0.36 (0.11–1.1)</td>
<td></td>
</tr>
<tr>
<td>Alleviator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standing (3)</td>
<td>0.78 (0.56–0.92)</td>
<td>0.90 (0.72–0.97)</td>
<td>7.80 (2.6–23)†</td>
<td>0.24 (0.11–0.53)†</td>
<td></td>
</tr>
<tr>
<td>Nature</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Numbness (8)</td>
<td>0.59 (0.37–0.79)</td>
<td>0.25 (0.11–0.45)</td>
<td>0.79 (0.52–1.2)</td>
<td>1.60 (0.80–3.3)</td>
<td></td>
</tr>
<tr>
<td>Cramping (9)</td>
<td>0.65 (0.43–0.83)</td>
<td>0.47 (0.29–0.65)</td>
<td>1.20 (0.78–1.9)</td>
<td>0.75 (0.40–1.9)</td>
<td></td>
</tr>
<tr>
<td>Burning pain (10)</td>
<td>0.47 (0.27–0.69)</td>
<td>0.38 (0.21–0.58)</td>
<td>0.77 (0.46–1.3)</td>
<td>1.37 (0.83–2.3)</td>
<td></td>
</tr>
<tr>
<td>Weakness (11)</td>
<td>0.41 (0.21–0.63)</td>
<td>0.57 (0.37–0.75)</td>
<td>0.95 (0.49–1.8)</td>
<td>1.00 (0.69–1.5)</td>
<td></td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Calves (6)</td>
<td>0.78 (0.56–0.92)</td>
<td>0.73 (0.54–0.87)</td>
<td>2.90 (1.6–5.5)†</td>
<td>0.30 (0.13–0.66)†</td>
<td></td>
</tr>
<tr>
<td>Time for relief</td>
<td></td>
<td></td>
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<tr>
<td>1–2 min (11a)</td>
<td>0.57 (0.35–0.76)</td>
<td>0.57 (0.38–0.74)</td>
<td>1.30 (0.76–2.2)</td>
<td>0.77 (0.46–1.3)</td>
<td></td>
</tr>
<tr>
<td>Constellation of symptom attributes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alleviated with Standing (3), located in the calves (6)</td>
<td>0.65 (0.43–0.83)</td>
<td>0.97 (0.81–1.0)</td>
<td>20.00 (2.8–140)†</td>
<td>0.36 (0.21–0.63)†</td>
<td></td>
</tr>
</tbody>
</table>

CI = confidence interval; NLR = negative likelihood ratio; PLR = positive likelihood ratio.
*Numbers in brackets represent the corresponding question number in the questionnaire (see the Appendix, available at cma.ca/cjs).
†Numbers whose values represent clinical significance.
the specificity of this attribute was 0.10, and both the PLR and NLR were very close to 1 (PLR 0.99; NLR 1.1), indicating that patients with neurogenic claudication experience pain with walking almost as frequently as those with vascular claudication. Therefore this symptom cannot be used as a positive discriminator for vascular claudication.

The alleviation of pain with standing alone (i.e., standing still/no walking) represents moderate evidence for vascular claudication (PLR 7.8). Symptoms located below the knees had a weak association with this etiology (PLR 2.9). The 95% CIs for both values did not include 1.

As in the neurogenic group, combination of symptom attributes led to stronger associations. The constellation consisting of alleviation of symptoms with standing alone, and symptoms located below the knees yielded a PLR of 20, which represents strong evidence for vascular claudication.

**DISCUSSION**

In 1858, Charcot described vascular claudication as “weakness, numbness, cramping and stiffness of the legs with walking, and prompt relief with rest.” It was not until almost a century later, in 1954, that Verbiest recognized the clinical syndrome of LSS. He claimed “the most typical symptoms are tiredness and loss of power in the legs, anaesthesia and a feeling of numbness in the sacral dermatomes, and bilateral sciatica.” Relevant to the findings of our study, he stated, “the symptoms are present only on standing or walking.” He noted the resemblance to vascular claudication and recognized the clinical equipoise that this posed. Subsequent publications have attempted to differentiate neurogenic from vascular claudication, but relied on clinical impression rather than quantitative assessment. This has led to the classic associations of certain symptom attributes with either neurogenic or vascular claudication, yet the validity of these associations remains unclear. The present study established the validity of specific symptoms in differentiating neurogenic from vascular claudication.

Our study demonstrates that use of symptom attributes in isolation to differentiate between neurogenic and vascular claudication is weak at best. These attributes include the location of the symptoms (above the knees for neurogenic claudication; below the knees for vascular claudication) as well as the symptom alleviators (sitting for neurogenic claudication; standing for vascular claudication). However, alleviation of symptoms with standing alone has a moderate correlation with vascular claudication; its presence could direct physicians toward a vascular workup rather than neurogenic investigations.

Certain constellations of symptom attributes are more strongly associated with each type of claudication. We found that the presence of symptoms that are triggered with standing, relieved with sitting, located above the knees and have a positive shopping cart sign represent strong evidence that a patient has intermittent neurogenic claudication rather than vascular claudication. On the other hand, a patient with symptoms that are relieved with standing alone and located below the knees is much more likely to have vascular than neurogenic claudication.

In 1978, Hawkes and Roberts compared the clinical history and examination between patients with degenerative LSS and those with PVD. They found that the vascular group had relief of symptoms when standing and a constant claudication distance and that the neurogenic group had pain with standing and variable claudication distance. Our study demonstrated similar findings regarding the dependence of symptoms with respect to standing, but we found that symptom onset with “constant claudication distance” was not predictive of the claudication type.

Dodge and colleagues reviewed a series of patients with LSS who were treated with decompressive lumbar spine surgery. They found that some patients had persistent symptoms postoperatively due to a secondary vascular etiology contributing to their claudication. They noted that a cramping type of discomfort can be associated with both types of claudication, but that a motor deficit can usually be attributed to LSS. While our study supports their observation with respect to the cramping nature of the pain, we did not find a greater prevalence of subjective weakness in the neurogenic group, which differs from their suggested association with objective weakness.

Four recent studies have examined symptomatic presentation of patients with LSS, and the results of these studies were reviewed in a meta-analysis (n = 741) by Suri and colleagues. The study population was not limited to patients with specific reports of intermittent claudication; rather, patients presenting with LBP and/or lower extremity pain were included. The meta-analysis concluded that the symptoms most commonly associated with LSS were absence of pain when seated, improvement of symptoms when bending forward and presence of bilateral buttock or leg pain. They also suggested that most of the symptom attributes classically associated with LSS were not specific to neurogenic claudication. Importantly, our data are in agreement with the results of the meta-analysis with respect to the positional influence of symptoms in patients with LSS.

**Strengths and limitations**

Strengths of our study include its prospective design and the fact that all patients were assisted by 1 of 2 health care staff members in a single institution, ensuring proper, consistent interpretation and understanding of every item on the questionnaire. Also, our cohorts comprised patients whose mainly reported lower extremity claudication symptoms rather than nonspecific low back pain or lower extremity symptoms.

Our study is limited by the size of our patient cohorts.
Despite this limitation, we did obtain statistically significant results, as demonstrated by 95% CIs. Furthermore, it would have been useful to include physical examination findings in our analysis.

CONCLUSION

Our results indicate that most symptom attributes in isolation have limited reliability in diagnosing neurogenic or vascular claudication. However, there is a specific constellation of symptoms that can significantly increase the likelihood of accurately predicting the underlying etiology of claudication. For neurogenic claudication, the constellation consists of symptoms that are triggered with standing, relieved with sitting and located above the knees and that have a positive shopping cart sign. For vascular claudication, the constellation consists of symptoms that are relieved with standing alone and located below the knees. Our results can guide physicians and surgeons in their evaluation of patients reporting intermittent claudication and encourage the appropriate use of health care resources.

Competing interests: None declared.

Contributors: M. Nadeau, M. Rosas-Arellano, K. Gurr, S. Bailey and C. Bailey designed the study. M. Nadeau, M. Rosas-Arellano, K. Gurr, S. Bailey, D. Taylor, K. Lawlor and C. Bailey acquired the data, which M. Nadeau, M. Rosas-Arellano, K. Gurr, R. Grewal and C. Bailey analyzed. M. Nadeau and C. Bailey wrote the article, which all authors reviewed and approved for publication.

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Functional outcomes and cost estimation for extra-articular and simple intra-articular distal radius fractures treated with open reduction and internal fixation versus closed reduction and percutaneous Kirschner wire fixation

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Background: We sought to compare direct costs and clinical and radiographic outcomes for distal radius fractures (DRF) treated with open reduction internal fixation with volar locking plates (VLP) versus closed reduction and percutaneous pinning (CRPP).

Methods: We identified patients with AO-type A and C1 DRFs from a prospective database. Outcomes were assessed at 6 weeks and at 3, 6 and 12 months, and surgical care costs were estimated.

Results: Twenty patients were treated with CRPP and 24 with VLP. There were no significant differences in patient-rated wrist evaluation (PRWE) scores between the 2 groups at any time point (mean 16.2 ± 23.1 in the CRPP group v. 21.5 ± 23.6 in the VLP group, $p = 0.91$). Overall alignment was maintained in both groups; however, there was a greater loss of radial height over time with CRPP than VLP (0.97 mm v. 0.25 mm, $p = 0.018$). The mean duration of surgery was longer for VLP than CRPP (113.9 ± 39.5 min v. 86.5 ± 7.8 min, $p = 0.029$), but there were fewer clinic visits (5.2 ± 1.4 v. 7.8 ± 1.3, $p < 0.001$) and fewer radiographs (7.4 ± 2.7 v. 9 ± 2.4, $p = 0.031$). The total cost per case was greater for VLP than CRPP ($1637.27 v. $733.91$).

Conclusion: Based on PRWE scores, VLPs did not offer any significant advantage over CRPP in patients with simple fracture types between 3 and 12 months, but they were much more costly. Whether VLP offers any functional advantage earlier in recovery, thereby justifying their expense, requires further investigation in the form of a prospective randomized trial with a detailed cost analysis.

Contexte : Nous avons voulu comparer les coûts directs et l’issue clinique et radiographique du traitement des fractures du radius distal (FRD) au moyen d’une technique de réduction ouverte avec fixation interne par plaques palmaires de stabilisation (PPS) par rapport à la méthode par réduction fermée et enclouage percutané (RFEP).

Méthodes : Nous avons recensé les patients victimes d’une FRD de type AO et de type C1 à partir d’une base de données prospectives. L’issue de ces fractures a été évaluée après 6 semaines, puis après 3, 6 et 12 mois et nous avons estimé les coûts des soins chirurgicaux.

Résultats : Vingt patients ont été traités par RFEP et 24 par PPS. On n’a noté aucune différence significative entre les 2 groupes quant aux scores d’évaluation des poignets par les patients eux-mêmes, peu importe le moment de l’évaluation (moyenne 16,2 ± 23,1 dans le groupe traité par RFEP c. 21,5 ± 23,6 dans le groupe traités par PPS, $p = 0,91$). L’alignement global a été maintenu dans les 2 groupes; toutefois, on a observé une diminution plus marquée de la longueur du radius avec le temps dans les cas de RFEP que dans les cas de PPS (0,97 mm c. 0,25 mm, $p = 0,018$). La durée moyenne de la chirurgie a été plus longue avec la PPS qu’avec la RFEP (113,9 ± 39,5 min c. 86,5 ± 7,8 min, $p = 0,029$), mais si les visites à la clinique et les radiographies ont été moins nombreuses (respectivement, 5,2 ± 1,4 c. 7,4 ± 2,7 c. 9 ± 2,4, $p = 0,031$), le coût total par cas a été plus élevé avec la PPS qu’avec la RFEP (1637,27 S. c. 733,91 S.).

Conclusion : Compte tenu des scores d’évaluation du poignet par les patients eux-mêmes, la PPS n’a pas sembler offrir d’avantages significatifs par rapport à la RFEP après 3 et 12 mois chez les patients présentant des types de fractures simples, mais elle s’est révélée beaucoup plus coûteuse. Il reste encore à vérifier, au moyen d’un essai prospectif randomisé assorti d’une analyse de coûts détaillée, si la PPS offre des avantages fonctionnels plus tôt lors du rétablissement, ce qui en justifierait le coût.
The introduction of locking plate technology has greatly influenced treatment of distal radius fractures (DRFs) in recent years. In the last decade, there has been an exponential increase in the number of DRFs treated with locking plates. In 1999, trainees in the United States preparing for board certification treated 58% of DRFs with closed reduction and percutaneous pinning (CRPP), whereas in 2007 only 19% of these injuries were treated with CRPP. Even in older patients in whom the use of internal fixation has generally been less frequent, the use of internal fixation has increased in recent years. In 2005, 16% of all DRFs were treated with internal fixation compared with 3% in 1997. In 2007, United States Medicare payments were $170 million for the management of DRFs. It has been estimated that if the use of internal fixation to treat DRFs increases to 50%, DRF-attributable payments could be nearly $240 million.

Many surgeons assume that volar locking plates (VLPs) are associated with fewer complications, better function and improved patient satisfaction than other treatment methods. Kreder and colleagues studied displaced intra-articular fractures and found that patients who underwent indirect reduction and percutaneous fixation had a more rapid return of function and a better functional outcome than those who underwent open reduction and internal fixation (ORIF; although the authors did not study locking plate technology). They recommended that ORIF be preceded by an attempt at minimally invasive percutaneous reduction. This finding contrasts with those of Rozental and colleagues, who studied unstable extra-articular or simple intra-articular fractures treated with ORIF or CRPP. They concluded that both are effective methods for treatment of these injuries; however, they reported that better functional results could be expected in the early postoperative period with ORIF. McCayden and colleagues also reported improved clinical outcomes in the early postoperative course when comparing VLPs with percutaneous fixation for unstable extra-articular fractures. They concluded their follow up at 6 months, so it is difficult to determine if any long-term differences exist. Leung and colleagues found that at 24 months, results for plate fixation were significantly better than percutaneous pin fixation for intra-articular fractures.

Studies on the treatment of DRFs are difficult to compare, as different outcome tools are used, different plates are used for fixation and the complexity of included fractures varies widely. Because complex fractures are also included, many patients treated with percutaneous pinning also required supplementation with external fixation. For these reasons, despite the vast amount of literature available, clear recommendations cannot be made for simple fracture types based on validated patient-rated outcomes. The most recent review by the American Academy of Orthopaedic Surgeons (AAOS) lists several recommendations with respect to treatment of these injuries, but does not recommend the type of fixation to use for specific fracture types.

In most of the studies mentioned previously, the cost of the different treatment modalities is ignored. Given the widespread problem of rapidly escalating health care costs, the cost of these interventions must be considered, particularly when outcomes are similar between 2 choices. Shauver and colleagues stated that despite the increased price of these implants, cost–utility calculations have shown that from a societal perspective, ORIF is considered a worthwhile alternative to casting. They concluded that there was a slight preference for ORIF compared with casting for faster return to minimally restricted activity. For patients treated surgically, cost and long-term outcomes were similar regardless of fixation type, and as a result the study found that patients showed little preference for one treatment type over the other. Looking at VLP more specifically, to our knowledge, only 1 study has compared the cost of VLP to CRPP. Shyamalan and colleagues reported that treatment of a DRF with VLP cost 3 times more than treatment with Kirschner wire fixation (k-wires) and casting (£2212 v. £662). Unfortunately, their study had a small sample size (n = 20), was retrospective and did not include any clinical or radiographic outcomes, making it difficult to put the cost comparison into context.

Although VLP likely offers an advantage over CRPP in patients with fractures that are comminuted or complex, we questioned whether VLPs are being overused in patients with simple fracture types that would have been traditionally treated with percutaneous pins and plaster, thus contributing to escalating health care costs. The purpose of this study was to compare clinical and radiographic outcomes in a prospective cohort of patients with extra-articular or simple intra-articular DRFs treated with VLP or CRPP and to compare the costs of these 2 techniques.

**Methods**

We identified patients with DRFs treated at a tertiary care centre between 1997 and 2009 from an existing prospective database. Surgeon preference dictated the type of surgery these patients received; the patients were not involved in other studies and therefore were not randomized. Our inclusion criteria were AO type A extra-articular or type C1 simple intra-articular DRFs treated with either percutaneous k-wire fixation or VLP in skeletally mature individuals. One year of follow-up data was also required. We excluded patients with any complex or comminuted intra-articular fracture types (AO type C2 or more complex). We also excluded patients who underwent methods of fixation other than CRPP or VLP.

The primary outcome was the patient-rated wrist evaluation (PRWE) score. The PRWE is a reliable, valid measure...
of patient-rated pain and disability. Secondary outcomes included range of motion and grip strength. Patients were evaluated prospectively at 6 weeks and at 3, 6 and 12 months postoperatively. Radiographs were reviewed by at least 2 individuals: a fellowship-trained orthopaedic surgeon (R.G.) and a senior-level orthopaedic resident (I.D.). We assessed change in ulnar variance, radial inclination, and volar tilt by comparing the earliest posttreatment radiograph with radiographs taken at the 1-year follow-up. Complications associated with each treatment were also identified.

We estimated the cost of each treatment arm retrospectively. To estimate surgical costs, we reviewed patients’ health care records to determine the length of time each patient spent in the operating room (OR). We estimated the OR cost at $121/h (i.e., 2.5 registered nurses at $40/h, and 1 attendant at $21/h). In addition, we estimated the cost of hardware based on current institutional costs of VLP ($750: cost of plate + 5 locking screws + 1 cortical screw) and k-wires ($40: cost of 4 k-wires). We estimated other direct health care costs by evaluating the number of clinic visits and radiographs taken throughout the duration of treatment. Nursing cost at the first postoperative visit was estimated at $9 (chart review, filling in radiography requisitions, set-up of patient, suture removal and pin site care for a total estimated time of 20 minutes). Subsequent visits were estimated to cost $5 each with an estimated time of 10 minutes per patient. Estimated costs for each radiograph taken included $21.05, billed to the Ontario Health Insurance Plan (OHIP), for a standard wrist radiograph with 2 views and $7 for technician time (average of 4–7 minutes) for a total cost of $28.05 for each radiograph taken. According to the Ontario Ministry of Health and Long-Term Care Schedule of Benefits, the surgeon fee for open reduction (F030) is $420, and the surgeon fee for closed reduction plus 50% for percutaneous pinning is $224.02.

Statistical analysis

We analyzed categorical variables using the $\chi^2$ test, and continuous variables were compared using a 2-tailed Student $t$ test.

### Results

#### Participants

Forty-four patients satisfied the inclusion criteria. A total of 20 patients (90% of them having intra-articular DRFs) were treated with CRPP, and 24 (87.5% of them having intra-articular DRFs) were treated with ORIF using a VLP. We compared the 2 groups on the basis of age, sex, handedness, and workers’ compensation benefits (Table 1). The only significant difference between the groups was age (mean 40.3 ± 12.4 yr for patients in the CRPP group v. 50.3 ± 14.7 yr for patients in the VLP group, $p = 0.009$).

#### Patient-reported outcomes

Comparing the PRWE scores between the 2 groups yielded no significant difference at any time point between 6 weeks and 1 year ($p = 0.91$, mean difference 3.0 out of a total possible score of 100 for PRWE; Fig. 1A).

#### Objective outcomes

Grip strength and range of motion (specifically flexion, extension, supination, pronation, radial deviation, and ulnar deviation) were assessed at 3, 6, and 12 months. The VLP group showed improved flexion at 6 months compared with the CRPP group (63° v. 51°, $p = 0.022$; Fig. 1B). The CRPP group showed improved extension at 1 year compared with the VLP groups (55° v. 44°, $p = 0.008$; Fig. 1C). Supination was greater in the VLP group than the CRPP group at 3 months (66° v. 50°, $p = 0.021$) and 6 months (75° v. 61°, $p = 0.018$; Fig. 1D). We found no significant differences between the groups for pronation, radial deviation, ulnar deviation, or grip strength (Table 2).

#### Radiographic outcomes

Both groups had similar fracture types and had excellent reductions with no significant loss of alignment over time. When comparing preoperative to postoperative images

| Table 1. Demographic and clinical characteristics of patients who underwent closed reduction with percutaneous pinning or open reduction and internal fixation with volar locking plates to treat distal radius fractures |
|----------------------------------------|-----------------|-----------------|-----------------|
| Variable                         | CRPP, n = 20    | VLP, n = 24     | $p$ value       |
| Age, yr; mean ± SD               | 40.3 ± 12.4     | 50.3 ± 14.7     | 0.009           |
| Sex, female                      | 15 (75)         | 17 (70.8)       | 0.76            |
| Fracture distribution (% intra-articular) | 18 (90) | 21 (87.5)       | 0.72            |
| Dominant hand involved           | 9 (45)          | 11 (47.8)       | 0.96            |
| WSIB involvement                 | 2 (8.3)         | 2 (8.3)         | 0.66            |

CRPP = closed reduction and percutaneous pinning; SD = standard deviation; VLP = volar locking plates; WSIB = Workplace Safety and Insurance Board.
*Unless otherwise indicated.
taken at 1 year, we found no significant differences between the groups for change in radial inclination ($p = 0.09$) or volar tilt ($p = 0.29$). The CRPP group experienced a greater loss of radial height over time than the VLP group (0.97 mm v. 0.25 mm, $p = 0.018$).

**Complications**

There was no significant difference in the complication rate between the 2 groups ($p = 0.24$). Three (15%) patients in the CRPP group and 1 (4.2%) patient in the VLP group experienced complications. In the CRPP group, 1 patient had mild, transient median nerve compression, which resolved without any specific treatment. Another patient had complex regional pain syndrome, which also resolved without any specific therapy. One patient had a superficial pin site infection that resolved with oral antibiotics. In the VLP group, 1 patient experienced mild, transient median nerve symptoms that resolved without any specific intervention.

![Graphs showing PRWE score, flexion, extension, and supination over time for CRPP and VLP](image)

**Fig. 1.** Comparison of (A) patient-rated wrist evaluation (PRWE) scores, (B) flexion, (C) extension and (D) supination in patients who underwent closed reduction and percutaneous pinning (CRPP) or open reduction and internal fixation with volar locking plates (VLP) to treat distal radial fractures. *$p < 0.05$.*
Cost estimation

Total cost was estimated based on OR cost, cost per clinic visit, cost for each radiograph taken, cost of the implant, and surgeon billing. The VLP group required 27 more minutes of operative time than the CRPP group \( (p = 0.029) \). The OR cost associated with CRPP was $174.44 compared with a VLP cost of $229.70 (Table 3).

We also estimated costs associated with clinic visits. The CRPP group had more clinic visits than the VLP group (7.8 v. 5.2, \( p < 0.001 \)), for a greater cost ($43 v. $30). The CRPP group also had more radiographs taken than the VLP group (9 v. 7.4, \( p = 0.031 \)), for a cost of $252.45 versus $207.57 (Table 3).

Implant costs for the VLP group were also substantially higher than those for the CRPP group. The estimated cost of a 5 hole locking plate with 5 locking screws and 1 cortical screw is approximately $750. This is in comparison to the estimated cost of an individual k-wire, which is approximately $10 (Table 3). According to the Ontario Ministry of Health and Long-Term Care Schedule of Benefits, the surgeon fee for open reduction (F030) is $420, whereas the fee for closed reduction (F046) plus 50% for percutaneous pinning is $224.02. Taking all the above components together, the overall cost estimation for treatment with CRPP was $733.91 versus a cost of $1637.27 for VLP (Fig. 2).

DISCUSSION

Distal radius fractures are extremely common injuries. Many different treatment methods have been advocated, including CRPP, external fixation and ORIF. Recent advances in plate design have certainly impacted treatment of these injuries. With the introduction of locking plate technology, greater portions of patients with these injuries have been treated with ORIF in recent years. Even within our own institution, there has been an exponential increase in the use of VLPs leading to substantially higher costs. Despite the obvious shift in treatment modality, the literature suggests no long-term difference between the 2 treatment strategies and remains inconsistent in support of short-term advantages.

Studies suggest that differences between fixation types may be short-lived and that long-term outcomes are similar. Wei and colleagues compared results for unstable DRFs treated with external fixation, VLPs or radial column plates. At 6 months and 1 year, outcomes for each group were found to be excellent, with minimal differences in strength, motion and radiographic alignment. Similarly, Egol and
colleagues\textsuperscript{11} compared external fixation with supplementary k-wire fixation to VLPs for unstable DRFs. Although the VLP group experienced a significant early improvement in range of motion, this advantage diminished over time.\textsuperscript{11} In our patient population, VLP fixation did not provide any clear advantage over CRPP for the clinical outcomes measured. Our study did not identify any significant difference in overall PRWE scores.

Similarly, the long-term radiographic parameters we assessed also were similar between the 2 groups. There was no significant difference in radial inclination or volar tilt. The CRPP group did, however, experience a greater loss in radial height than the VLP group (0.97 mm v. 0.25 mm), which we found to be statistically significant. Whether this small a difference has any clinical relevance is unknown. The similar outcomes in PRWE scores with a similar range of motion would indicate that this difference in radial height did not impact clinical outcomes. The complication rate for each group was also low and compared favourably with the rates reported in the literature.

Despite long-term results showing similar outcomes, some studies reported differences in short-term outcomes. Rozental and colleagues\textsuperscript{4} compared VLP fixation to percutaneous fixation and casting or external fixation and found better functional results in the early postoperative period with ORIF. This difference was particularly pronounced at 6 weeks and 9 weeks after the injury and then decreased over time. They recommended that this form of treatment be considered for patients requiring a faster return to function after injury.\textsuperscript{1} Kreder and colleagues\textsuperscript{3} compared internal fixation with indirect percutaneous reduction and external fixation for displaced intra-articular fractures and found that patients who underwent indirect reduction and percutaneous fixation had a more rapid return to function and a better functional outcome.\textsuperscript{1} Although they did not include a formal cost comparison, our estimation of cost of internal fixation would give added incentive to attempt percutaneous fixation according to the superior results of Kreder and colleagues.

With no long-term difference, selecting a particular method of fixation might be justified if improved results could be found early in the postoperative course. Improved results in the short term could be in the form of subjective symptom relief or they could be economic in nature. Economic analyses that include the patient perspective or that consider disability costs would improve our understanding of the overall economic benefit of fracture management. In a previous study,\textsuperscript{12} we demonstrated that 20\% of patients were able to return to work immediately after fracture treatment and that median time off work was 8 weeks. Occupational demands and self-reported disability were predictive of the length of time patients were absent from work, whereas radiographic parameters were not. Thus, future studies would need to determine whether earlier recovery of motion equates to earlier return to work.

Given the economic constraints in health care, cost should be considered when deciding on a treatment strategy. None of the studies mentioned previously took into account the cost of the implants they used. To date, the only known cost analysis of treating DRFs is the one performed by Shyamalan and colleagues.\textsuperscript{7} They reported that treatment of a DRF with VLP cost 3 times more than treatment with CRPP and casting (£2212 v. £662).\textsuperscript{9} Similarly, our estimations demonstrate that treatment with VLP fixation more than doubles the cost associated with CRPP ($1217.27 v. $509.89). Shyamalan and colleagues focused on a cost analysis and did not include clinical or radiographic outcomes, an important weakness of their study. In the absence of any clear clinical benefit, cost should be considered in the decision on how to treat these common injuries.

Limitations

The present study had several limitations. Our sample size was small and may have been underpowered to detect treatment differences. A small sample size would not have affected the large difference we saw in our cost estimation, but may have played a role in identifying significant differences in clinical outcomes given that these differences were quite small. In addition, our cohort was not randomized and was therefore subject to potential biases. Although the data were collected prospectively, the study question was posed retrospectively. In performing a cost analysis, it would be ideal to include hospital, patient and societal costs; a limitation of our study was that we were unable to include societal (e.g., work disability) or patient costs (e.g., cost of therapy) in our estimation. Finally, the earliest outcome evaluations had already been prespecified at 3 months. Therefore, we are unable to determine whether there were any short-term benefits to patients in terms of pain and disability earlier in the postoperative period.

Strengths of our study included the fact that only patients with simple fracture types were included. By not combining populations with simple and complex fracture types, we were able to draw specific conclusions with respect to simple fracture types. In addition, to our knowledge, no other study published thus far has included both radiographic and clinical outcomes combined with a cost analysis.

A larger, more detailed economic analysis that considers the cost perspective of patients and society, including costs of lost productivity, in the early phases of recovery would be warranted given that there is no current long-term advantage demonstrated for VLP. If future studies were to report that patients could return to work safely and sooner with VLP than CRPP, the increased cost associated with VLPs could be justified.
CONCLUSION

Despite the substantially greater cost, no significant long-term advantages were identified in patients with simple DRFs treated with VLP versus CRPP. It is unknown whether treatment with VLP offers an advantage in the short term (< 3 mo). Until future studies can demonstrate a more clear advantage of using VLP, CRPP continues to provide a safe and cost-effective option for treating extra-articular or simple intra-articular DRFs.

Competing interests: None declared.

Contributors: I. Dzaja and R. Grewal designed the study. I. Dzaja and J.C. MacDermid acquired the data, which I. Dzaja, J.H. Roth and R. Grewal analyzed. I. Dzaja, J.C. MacDermid and R. Grewal wrote the article, which all authors reviewed and approved for publication.

References


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   Steinitz et al.
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Limited adequacy of thyroid cancer patient follow-up at a Canadian tertiary care centre

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Background: We sought to evaluate the adequacy of follow-up of thyroid cancer patients at a Canadian centre.

Methods: We mailed a survey to the family physicians of thyroid cancer patients and analyzed the findings relative to follow-up guidelines published by the American Thyroid Association (ATA). Statistical significance between early and late follow-up patterns was analyzed using the $\chi^2$ test.

Results: Our survey response rate was 56.2% (91 of 162). The time from operation ranged from 1.24–7.13 (mean 3.96) years, and 87.9% of patients had undergone a physical exam within the previous year. Only 37.4% and 14% of patients had a serum thyroglobulin measurement within 6 and between 6 and 12 months before the survey, respectively. Thyroid stimulating hormone (TSH) levels were measured within the prior 6 months in 67% of patients and between 6 and 12 months in 13.2%. The TSH levels were suppressed (<0.1 µIU/L) in 24.2% of patients, 0.1–2 µIU/L in 44% and greater than 2 µIU/L in 17.6%. Ultrasonography was the most common imaging test performed.

Conclusion: There is significant variation in the follow-up patterns of patients with thyroid cancer, and there is considerable deviation from current ATA guidelines.

The incidence of thyroid cancer has been steadily increasing over the past 3 decades.¹² In the United States, the incidence in 1975 was 4.9 per 100 000 and increased to 12.0 per 100 000 in 2007, which represents a 2.4-fold increase.¹ This has been largely attributed to increased detection of differentiated thyroid carcinoma (DTC), specifically papillary thyroid carcinoma (PTC).¹ Differentiated thyroid carcinoma includes the histologic diagnoses of PTC, follicular thyroid carcinoma (FTC) and Hurthle
cell carcinoma (HCC). Although thyroid cancer is relatively uncommon, it is the most common endocrine cancer and accounts for 95% of all endocrine malignancies. Prognosis for DTC is generally favourable, with its 5-year relative survival being 99.8% for localized disease and 97.1% when regional metastases to lymph nodes are present. However, thyroid cancer may recur and lead to morbidity and mortality as remotely as 30 years after primary disease treatment. Thus, patients with diagnosed thyroid cancer require diligent long-term follow-up and surveillance. In addition to disease surveillance, follow-up is important for monitoring thyroxine suppression therapy after surgical resection.

There is controversy in the literature regarding follow-up and surveillance practices for thyroid cancer patients, with different guidelines published by different medical societies. Guidelines were initially published by the American Thyroid Association (ATA) in 1996 and revised in 2006 and in 2009 to assist physicians in developing an evidence-based treatment and follow-up algorithm for DTC. Other guidelines with different recommendations have been published by the National Comprehensive Cancer Network (NCCN) and the European Thyroid Association. With the rising incidence of DTC, it is essential to ensure that evidence-based practices for treatment and follow-up are followed and uniformly applied to ensure that patients with thyroid cancer are receiving appropriate medical care. Adequate follow-up practices facilitate early detection of disease recurrence and also ensure appropriate monitoring of TSH levels. Furthermore, adequate follow-up helps to avoid overly aggressive TSH suppression and its associated morbidities, including an increased risk of osteoporosis in postmenopausal women, or undersupplementation and the associated morbidities related to hypothyroidism. Previous studies have identified substantial variability in practice patterns regarding treatment and follow-up of patients with thyroid cancer. A study by Famakinwa and colleagues benchmarked national practice patterns in the United States against ATA guidelines using results obtained from cross-sectional analysis of surveillance, epidemiology and end results (SEER) for thyroidectomy, lymphadenectomy and radioactive iodine therapy of DTC. They reported significant variation in adherence to treatment guidelines by health care practitioners. These observations suggest that there is variation in the quality of care for DTC patients, especially elderly patients and minorities.

At our institution, postsurgical follow-up of patients with thyroid cancer is not standardized, but it is always multidisciplinary. Surgeons provide initial short-term postsurgical follow-up, most patients are followed by an endocrinologist for a variable length of time postoperatively, and some patients may be followed by a radiation oncologist depending on the use of adjuvant radioactive iodine therapy and, less commonly, external beam radiation therapy. As is the case for most cancer types, at our institution the long-term follow-up and surveillance of patients with thyroid cancer is the responsibility of primary care physicians. Given the relative rarity of thyroid cancer and the complexities of its follow-up it is our hypothesis that there are limitations in the adequacy of postoperative follow-up and surveillance of this patient population. We have been unable to identify any prior studies that have examined “real world” follow-up practices for patients with DTC in Canada. The objective of this study was to determine whether individuals treated for DTC at our centre received adequate postoperative follow-up care in accordance with current guidelines.

METHODS

We performed a retrospective, cross-sectional study of all individuals with diagnosed DTC larger than 1 cm who underwent an operation at a single tertiary care centre (St. Paul’s Hospital, Vancouver, BC) between 2003 and 2007. The histologic subtypes of PTC, FTC and HCC were included. We identified patients with thyroid cancer diagnoses through the hospital pathology information system, and the treating primary care physicians were identified through retrospective chart review. Our institutional research ethics board approved the study protocol.

In addition to providing first-line medical care, at our institution, primary care physicians facilitate specialist referrals, and collaborate with specialists and other health care professionals to provide comprehensive longitudinal health care and post-treatment follow-up for individuals in their care. Primary care physicians provide continuity of care and receive all consultation letters, clinical correspondences, test results and operative and treatment reports regarding their patients. Thus, at our centre, primary care physicians are responsible for providing long-term follow-up and surveillance and serve as a “home base” for patients receiving multidisciplinary cancer care. Therefore, for the thyroid cancer patient population treated at our centre, it is the primary care physicians who are ultimately responsible for their long-term follow up and have the most complete information on their long-term postoperative management. It was for these reasons that the primary care physicians were the source of follow-up information for the present study.

The primary care physicians of individuals who underwent surgery at our centre were contacted by mail with a survey package that consisted of a cover letter describing the study and a questionnaire. The survey packages were resent to primary care physicians who didn’t respond to the initial survey 6 months later to encourage a high level of study participation. The questionnaire requested information about their patients’ disease status (i.e., no recurrence, death from other
cause, lost to follow-up); the timing of the most recent physical exam; results of laboratory investigations, including serum thyroglobulin (Tg) level, antithyroglobulin antibody (anti-Tg Ab) level, thyroid stimulating hormone (TSH), T4; and other relevant radiologic examinations, including ultrasonography, computed tomography (CT), diagnostic whole body radioiodine scan (DxWBS), magnetic resonance imaging (MRI) and positron emission tomography (PET). A description of the findings from the most recent physical exam; specific levels of Tg, anti-Tg Ab, TSH and T4; and the presence of normal or abnormal findings on the most recent imaging studies were also requested. Surveyed physicians were asked to specify whether Tg measurements were drawn while their patient was undergoing TSH suppression with thyroid hormone or while undergoing TSH stimulation through withholding levothyroxine or using recombinant human thyrotropin (rhTSH). We compared the survey results with recommendations from the ATA according to the revised management guidelines. Findings were also reviewed in the context of the local thyroid cancer follow-up recommendations published online by the British Columbia Cancer Agency (BCCA). The BCCA is responsible for establishing a coordinated, province-wide program of cancer control and management for residents of British Columbia and publishes online cancer management guidelines based on its accumulated experiences with best practice evidence derived from major cancer centres worldwide.

**Statistical analysis**

All results were expressed as proportions of total patients. We used the \( \chi^2 \) test to compare follow-up patterns between early and later follow-up duration (less than 2 yr v. \( \geq \) 2 yr). The BCCA recommends scheduled follow-up visits every 3–4 months for the first 2 years after treatment, every 6 months for the next 2 years after treatment if there is no evidence of recurrence, and annual visits thereafter. Early follow-up was therefore defined as less than 2 years from thyroid cancer treatment, as this was the time period with the most frequently recommended follow-up visits. The late follow-up time period was defined as 2 years or longer from thyroid cancer treatment. We compared patients who were followed for less than 2 years with those who received longer-term follow-up for 2 years or more after treatment. The frequency of follow-up testing based on the surveyed time intervals for each follow-up test were treated as categorical data. We assessed patterns of follow-up testing frequency using the \( \chi^2 \) test. We considered results to be significant if \( p < 0.05 \). Statistical testing was 2-sided. We carried out statistical analyses using SPSS software.

**RESULTS**

Of the 162 surveys mailed to primary care physicians, 91 (56.2%) were returned with adequate information for evaluation. Each survey was returned by a different primary care physician. (i.e., no physician had more than 1 patient in the study population). Twenty (12.3%) surveys were returned with no information for analysis because the patient was deceased, the physician was unwilling to complete the survey, the patient was no longer in the care of the physician, or the patient had moved or was lost to follow-up. Seven (4.3%) surveys were returned undelivered because the primary care physician had moved his/her practice or retired, or because the survey was sent to the incorrect physician. The primary care physicians who completed the surveys answered most of the questions. We considered a survey to be adequate if a response was provided for more than two-thirds (66%) of the questions. Forty-four (27.2%) surveys were not returned.

The histologic type of DTC in all 91 patients for whom the survey was returned and adequate for evaluation was PTC. In all, 74 (81.3%) of these patients were women and 17 (18.7%) were men. The mean age of patients was 45.8 (range 21–75) years, and the mean MACIS (distant metastasis, patient age, completeness of resection, local invasion and tumour size) score was 4.81 (range 3.25–8.84) based on 88 of 91 patients; sufficient information to calculate the MACIS score was unavailable for the remaining 3 patients. Ninety surveys reported follow-up duration; the mean follow-up duration was 3.96 (median 3.66, range 1.24–7.13) years.

The disease status of the patients was recorded at the time the surveys were filled out by the primary care physicians. It was noted that 83 of the 91 (91.2%) patients were cured with no known recurrence; 3 (3.3%) had active thyroid cancer or cancer recurrence, 2 (2.2%) died from causes other than thyroid cancer and 2 (2.2%) were lost to clinical follow-up. The remaining survey (1.1%) did not include an answer to this question. The extent of thyroid surgery for the study population is summarized in Table 1. All individuals who underwent a thyroid lobectomy with a final pathological cancer diagnosis (\( n = 17 \)) subsequently underwent completion thyroid lobectomy.

<table>
<thead>
<tr>
<th>Table 1. Thyroid operations that yielded cancer diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation No. (%) ( n = 91 )</td>
</tr>
<tr>
<td>Left lobectomy* ( n = 8 )</td>
</tr>
<tr>
<td>Right lobectomy* ( n = 9 )</td>
</tr>
<tr>
<td>Total or near total thyroidectomy</td>
</tr>
</tbody>
</table>

*All 17 patients who underwent lobectomy subsequently underwent removal of the remaining thyroid lobe.
Physical examination

No specific recommendations have been made by the ATA regarding the appropriate frequency of physical examination after treatment of thyroid cancer. However, the BCCA recommends physical examination of the thyroid bed, lymph nodes of the neck and other symptomatic areas as a part of postoperative disease surveillance.14 Most of the study patients (67%) had undergone a physical examination within the 6 months before the survey, 20.9% between 6 and 12 months, 5.5% between 1 and 2 years, and 4.4% between 2 and 5 years. Two (2.2%) surveys had no response to this question. In their most recent physical exam, 74 (81.3%) patients had a normal physical exam with no evidence of recurrence and 3 (3.3%) patients had abnormal findings that were concerning for possible cancer recurrence (Table 2). These 3 patients specifically had a new neck mass identified. Two (2.2%) surveys had no responses.

Serum Tg and anti-Tg Ab measurements

According to the current ATA guidelines, serum Tg should be measured every 6–12 months after treatment of DTC (Recommendation 43 A).7 A serum Tg measurement was available for 68.1% of patients in our study. Only 37.4% of patients had a serum Tg measurement within the prior 6 months and 15.4% between 6 and 12 months after treatment, in accordance with the ATA guidelines. The remaining 29.7% of patients underwent serum Tg measurements less frequently than recommended (Table 2). No responses were available for this question for 17.6% of the patients.

According to the ATA, anti-Tg antibodies should be quantitatively assessed with every serum Tg measurement (Recommendation 43 A). Most patients (61.5%) in our study had at least 1 serum anti-Tg Ab measurement; 29.7% of patients had an anti-Tg Ab measurement within the prior 6 months, 12.1% between 6 and 12 months, 12.1% measured between 1 and 2 years, and 7.7% measured between 2 and 5 years. Roughly 30.8% of patients have never had an anti-Tg Ab measurement. No data were available for 7.7% of patients, and 53.8% had negative anti-Tg Ab levels (< 41 kIU/L).

The highest sensitivity for serum Tg measurement for identifying thyroid cancer recurrence is obtained following thyroid hormone withdrawal or stimulation using rhTSH.7 Nine of 91 (9.9%) patients in our study had serum Tg measurements with TSH stimulation either by withholding thyroid hormone or by administering rhTSH. Roughly 40.7% of patients had serum Tg measurements while their TSH was suppressed when receiving thyroid hormone. There were no responses to this survey question for 49.5% of patients.

The ATA recommends that for low-risk patients who have undergone remnant ablation and who have a negative cervical ultrasound and an undetectable TSH-suppressed Tg within the first year after treatment, serum Tg should be measured after thyroxine withdrawal or rhTSH stimulation approximately 12 months after the ablation to confirm absence of disease (Recommendation 45 A). These patients can subsequently be followed with yearly clinical examination and Tg measurements while on thyroid hormone replacement (B). Compliance with these guidelines could not be determined in our study because there was insufficient data to determine which patient risk stratification system was used by the treating physicians. In addition, remnant ablation therapy information was also not available for the study cohort.

TSH and T4 levels

One of the goals of long-term follow-up of thyroid cancer patients is to monitor thyroxine suppression or replacement therapy to avoid both under-replacement and overly

<p>| Table 2. Frequency of follow-up modalities expressed as percentage (%) of total patients* |
|-----------------------------------------------|----------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Follow-up modality</th>
<th>Total performed†</th>
<th>Within 6 mo</th>
<th>Within 12 mo</th>
<th>Within 2 yr</th>
<th>Within 5 yr</th>
<th>Never performed</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical examination</td>
<td>97.8</td>
<td>67.0</td>
<td>20.9</td>
<td>5.5</td>
<td>4.4</td>
<td>0</td>
<td>2.2</td>
</tr>
<tr>
<td>Serum Tg</td>
<td>68.1</td>
<td>37.4</td>
<td>15.4</td>
<td>11.0</td>
<td>4.4</td>
<td>14.3</td>
<td>17.6</td>
</tr>
<tr>
<td>Anti-Tg Ab</td>
<td>61.5</td>
<td>29.7</td>
<td>12.1</td>
<td>12.1</td>
<td>7.7</td>
<td>30.6</td>
<td>7.7</td>
</tr>
<tr>
<td>TSH</td>
<td>88.8</td>
<td>67.0</td>
<td>13.2</td>
<td>4.4</td>
<td>2.2</td>
<td>3.3</td>
<td>9.9</td>
</tr>
<tr>
<td>T4</td>
<td>68.1</td>
<td>49.5</td>
<td>14.3</td>
<td>3.3</td>
<td>1.1</td>
<td>15.4</td>
<td>16.5</td>
</tr>
<tr>
<td>Cervical ultrasonography</td>
<td>57.1</td>
<td>25.3</td>
<td>9.9</td>
<td>11.0</td>
<td>11.0</td>
<td>39.6</td>
<td>3.3</td>
</tr>
<tr>
<td>DxWBS</td>
<td>35.2</td>
<td>7.7</td>
<td>4.4</td>
<td>11.0</td>
<td>12.1</td>
<td>56.0</td>
<td>8.8</td>
</tr>
<tr>
<td>PET</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>82.9</td>
<td>12.1</td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>12.1</td>
<td>4.4</td>
<td>1.1</td>
<td>3.3</td>
<td>3.3</td>
<td>82.4</td>
<td>5.5</td>
</tr>
<tr>
<td>MRI</td>
<td>2.2</td>
<td>0</td>
<td>1.1</td>
<td>1.1</td>
<td>82.4</td>
<td>15.4</td>
<td></td>
</tr>
</tbody>
</table>

CT = computed tomography; DxWBS = diagnostic whole body iodine scan; MRI = magnetic resonance imaging; PET = positron emission tomography; TSH = thyroid stimulating hormone.

* n = 91.
† Total performed represents total number and proportion of patients who received at least 1 of the follow-up modality.
aggressive treatment. Most study patients (86.8%) underwent a TSH level measurement; 67.0% of patients had a TSH measurement within the prior 6 months, 13.2% between 6 and 12 months, 4.4% between 1 and 2 years, and 2.2% between 2 and 5 years. Roughly 3.3% of patients never underwent a TSH measurement. No data were available for 9.9% of patients. Roughly 68.1% of patients underwent a T4 level measurement: 49.5% within the prior 6 months, 14.3% between 6 and 12 months, 3.3% between 1 and 2 years, and 1.1% between 2 and 5 years. No T4 levels were measured in 15.4% of patients, and T4 measurement data were not available for 16.5% of patients (Table 2).

The ATA guidelines recommend that serum TSH may be kept within the low normal range (0.3–2 µIU/L) for individuals with no evidence of disease, especially those at low risk for recurrence (Recommendation 49 B). For higher-risk patients who clinically and biochemically have no evidence of disease, consideration should be given to maintaining TSH levels at 0.1–0.5 µIU/L for 5–10 years after treatment (Recommendation 49 C). For patients with persistent disease, the serum TSH should be maintained below 0.1 µIU/L indefinitely (Recommendation 49 B). In our study population, 68.1% of patients had serum TSH levels lower than or equal to 2 µIU/L, as recommended for low-risk patients who are free of disease, and 17.6% of patients had a serum TSH level above 2 µIU/L, which is higher than the minimum level of suppression recommended for disease-free or low-risk patients (Fig. 1). No data were available for 9.9% of patients (Fig. 1).

**Neck ultrasonography**

According to the ATA, cervical ultrasonography to evaluate the thyroid bed and central and lateral cervical neck compartments should be carried out 6–12 months postoperatively (Recommendation 48 B). Subsequent imaging with ultrasonography should be performed periodically depending on the patient’s risk of recurrent disease and Tg status (Recommendation 48 B). In our study it was difficult to determine whether ultrasonography was carried out in accordance with this guideline since the data collected were cross-sectional. However, more than half (57.1%) of the patients underwent cervical ultrasonography at least once: 25.3% of patients within the prior 6 months, 9.9% between 6 and 12 months, 11% between 1 and 2 years, and 11% between 2 and 5 years. Roughly 39.6% of patients did not undergo cervical ultrasonography, and data were unavailable for 3.3% of patients. Of the 32 patients who underwent ultrasonography, 84.6% had normal results and 13.5% had abnormal results; 3.3% of surveys did not provide information on ultrasonography results.

**Diagnostic whole-body radioiodine scans**

The ATA guidelines state that 6–12 months after remnant ablation, DxWBS may be useful for patients at high or intermediate risk for recurrent disease either after thyroid hormone withdrawal or rhTSH treatment (Recommendation 47 C). However, low-risk individuals who have had a first post-radioactive iodine remnant ablation whole body scan (WBS) with an undetectable Tg level and a negative anti-Tg antibody level as well as a negative neck ultrasound do not require routine follow-up DxWBS (Recommendation 46 F). In our study population 32 (35.2%) patients underwent a radioiodine scan and 56% did not; no response was provided in 8.8% of surveys. Of the 32 patients who underwent DxWBS, 27 (84.4%) had a normal result and 4 (12.5%) had an abnormal result (Table 2). No data were available for 8.8% of patients.

**PET/PET-CT**

According to the ATA guidelines, it is unlikely that low-risk patients require a PET scan as part of their initial follow-up. However, PET scans do play a role in localizing disease for Tg-positive (> 10 ng/mL) patients and patients with negative DxWBS (Recommendation 48 C). In addition, PET scans may be used as part of the initial staging of poorly differentiated thyroid cancers, as a prognostic tool for patients with metastatic disease, or to evaluate response following systemic or local therapy of metastatic or locally invasive disease (C). No patients in the present study were reported to have undergone PET.

**CT and MRI**

No specific recommendations have been given by the ATA regarding the role of CT or MRI in the postoperative follow-up of DTC patients. In the present study, 12.1% of patients underwent CT of the neck, and 82.4% did not; no data were available for 5.5%. Of the 11 patients who underwent CT, 9 (81.8%) had normal results and 2 (18.2%) had abnormal results.
In all 2.2% of patients underwent MRI and 82.4% did not; no data were available for 15.4% of patients. Both patients who underwent MRI had normal results.

**Early versus late follow-up**

There were no statistically significant differences when comparing early (<2 yr from thyroid cancer treatment) to late (≥2 yr from thyroid cancer treatment) follow-up groups (Table 3).

**DISCUSSION**

An important goal of long-term follow-up of thyroid cancer patients is to monitor for local disease recurrence and the development of regional or distant metastasis. No specific recommendations regarding the frequency of physical examination have been suggested by the ATA. The current BCCA guidelines recommend visits and evaluation by the most responsible physician every 3–4 months for the first 2 years after treatment, every 6 months for the following 2 years and annually thereafter. More frequent visits may be necessary if cancer recurrence is diagnosed or if there are complications. In the present study, 87.9% of patients underwent a physical examination in the year before the survey, in accordance with the minimum recommendation.

Without antibody interference, serum Tg has a high sensitivity and specificity for detecting thyroid cancer recurrence. A meta-analysis reported by Eustatia-Rutten and colleagues found that higher sensitivities for detecting disease recurrence were observed after total thyroidectomy and remnant ablation and that the highest sensitivities for recurrence were observed when measured after TSH stimulation using withdrawal of thyroid hormone therapy or rhTSH treatment than when measured with unstimulated postoperative Tg levels. About half (52.7%) of the patients in our study underwent an annual Tg measurement in accordance with the minimum recommended frequency by the ATA. A minority (9.9%) of patients underwent a serum Tg measurement with TSH stimulation. Anti-Tg antibodies should also be measured with every Tg level measurement, as they interfere with the immunometric Tg assay and spuriously lower serum Tg measurements. Only 61.5% of patients underwent at least 1 serum anti-Tg Ab measurement. The BCCA also recommends measurement of serum Tg as a useful marker for recurrence when levels rise in specimens drawn under the same conditions. A rising titre of anti-Tg antibodies may also suggest an increased risk of cancer recurrence.

Several types of imaging tests are available for postoperative DTC disease surveillance. Ultrasonography has been shown to be superior to clinical examination for detecting local or regional recurrence and may be used to guide fine needle aspiration biopsy of lesions as small as 5 mm. The ATA recommends that cervical ultrasonography be carried out every 6 to 12 months after thyroid surgery, with subsequent ultrasonography carried out based on patient risk status and Tg level. It is difficult to determine whether ultrasonography was carried out in accordance with this guideline since the data collected were cross-sectional. However, 57.1% of patients in the present study underwent postsurgical cervical ultrasonography at least once.

Whole body radioiodine scans have several limitations that impact their utility for long-term follow-up of DTC patients. Radioiodine ablation decreases the sensitivity of a WBS, and WBS provides little anatomic detail and has virtually no diagnostic yield in the setting of a negative Tg test result. The combination of ultrasonography and Tg measurement is more sensitive and specific for detection of local DTC recurrence than the combination of WBS and Tg measurement. The ATA does not recommend WBS for follow-up of low-risk thyroid cancer patients who have no other laboratory evidence of recurrence after remnant ablation. The BCCA guidelines specify that WBS should be continued until there is no evidence of uptake in the neck or elsewhere and then should be repeated only if the Tg level rises or if disease recurrence is detected clinically. In our study population 35.2% of patients underwent a radioiodine scan. However, it is unclear whether these were part of the initial post-ablation WBS or later DxWBS.

Positron emission tomography scanning has been used primarily to localize disease in Tg-positive, radioactive iodine scan–negative patients and patients with negative DxWBS. According to the ATA guidelines, it is unlikely that low-risk patients would require PET as part of their initial cancer surveillance. No patients in our study population underwent PET.

The availability, cost and accuracy of ultrasonography for detecting local and regional cancer recurrence, and the utility of PET/PET-CT for detecting WBS-negative local recurrence and metastatic disease, have led to limited use.
of CT and MRI for thyroid cancer surveillance. Furthermore, it is preferable to avoid the iodinated contrast agents used for CT in patients with DTC because they interfere with radiiodine scanning or therapy. However, CT may still have a role in detecting distant metastases, and MRI may be useful in evaluating invasion of adjacent structures. No specific recommendations have been given by the ATA regarding the role of CT or MRI in the postoperative follow-up of patients with a history of DTC. Only a minority of patients in our study underwent CT (12.1%) or MRI (2.2%).

A second goal of long-term thyroid cancer surveillance is monitoring of thyroxine suppression or replacement therapy to avoid under-replacement or overly aggressive treatment. Periodic TSH and T4 measurements are also recommended by the BCCA. Accordingly, 86.8% of patients in our study underwent a TSH level measurement, and 68.1% underwent a T4 level measurement. The TSH receptors are expressed on the cell membranes of DTC cells, and TSH stimulation leads to increased cell growth, invasion, angiogenesis, expression of thyroid specific proteins and inhibition of apoptosis of thyroid cancer cells. A meta-analysis reported by McGuff and colleagues suggested that suppression of TSH resulted in a significant reduction in major adverse clinical events, including disease progression, recurrence and death. In our study, 68.1% of patients had serum TSH levels lower than or equal to 2 μIU/L, as is recommended by current ATA guidelines for maintenance of patients who are free of disease, especially for those individuals who are at low risk of recurrence. Suppression to lower levels is recommended for individuals who are at a higher risk of disease recurrence or who have evidence of disease, though sufficient data are not available to determine how patients in the present study were risk stratified.

We compared early (<2 yr after treatment) and late (≥2 yr after treatment) follow-up to determine whether follow-up practices deteriorated over time. There were no significant differences between these 2 groups in follow-up patterns identified with respect to frequency of physical examination, laboratory investigation or imaging.

**Limitations**

One limitation of the present study was that only 91 of 162 (56.2%) surveys were returned with sufficient information for analysis. This may reflect a nonresponse bias in which physicians with a particular interest in thyroid cancer follow-up or, conversely, physicians who may be less familiar with thyroid cancer follow-up or who have encountered more problems with follow-up procedures may have been more likely to respond to the survey. This resulted in a relatively small study population, which may not completely reflect the state of follow-up practices of patients who were surgically treated at our institution. In addition, not all surveys had complete answers for all the questions, and this may bias our results toward patients who received more complete follow-up. In addition, the data collected on follow-up were cross-sectional and did not allow evaluation of trends in follow-up over time for individual patients. Finally, information bias may also have limited our study because primary care physicians were the source of patient data, and we assumed that the primary care physicians had complete records on all procedures, tests and follow-up investigations for their patients. However, this assumption may have been incorrect; some information may not have been copied to the primary care physician, and follow-up investigations may have been carried out but the records may not have been available to the primary care physician. Such occurrences would bias our observations toward more incomplete follow-up trends.

A previous study by Van den Bruel and colleagues assessed thyroid cancer treatment and follow-up practices in Belgium through a survey that addressed the management of an index case with clinical variations and compared the responses with recommendations from the European Thyroid Association (ETA) Consensus Guidelines and ATA Guidelines. This study found variations in TSH suppression therapy practices for a good prognosis index case, and these differences reflected the differences in therapeutic goals proposed by the ATA and the ETA. The ETA recommends that TSH be maintained at ≤ 0.1 μIU/L, whereas the ATA recommends that the suppression level should be kept between 0.1 and 0.5 μIU/L. However, there was a clear indication for TSH suppression therapy in a poor prognosis case that was also presented, and the surveyed clinicians responded appropriately. In our study, there was insufficient data to risk-stratify the patients and thus determine their exact recommended level of TSH suppression. However, 68.1% of patients had serum TSH levels of 2 μIU/L or less, as is recommended for patients who are free of disease, especially those who are at low risk for thyroid cancer recurrence.

There may be barriers for primary care physicians to access certain tests, such as high-resolution ultrasonography of the neck, that may impact their ability to provide complete thyroid cancer follow-up. In addition, thyroid cancer is relatively uncommon, and educational opportunities in this area may be limited for primary care physicians. Educational interventions for primary care physicians, which include providing updated guidelines directly or in relevant journals and conducting educational seminars at appropriate conferences, are possible strategies that may improve primary care follow-up of patients with thyroid cancer in British Columbia and elsewhere. Another method for providing recommendations for thyroid cancer follow-up investigation may be through a standardized letter sent by the treatment team (ie. surgeon, endocrinologist, radiation oncologist) to the family physician after treatment is completed.
CONCLUSION

Our study suggests that there are considerable variations in follow-up practices for DTC patients who are treated at our centre. Currently, some individuals receive less intensive surveillance than recommended for the lowest risk population. Thus, these individuals are not undergoing adequate thyroid cancer surveillance in accordance with current guidelines. It is also interesting to note that 91% of patients with returned surveys were thought to be cured by their primary care physicians despite inadequate follow-up investigation. These results emphasize the need for more standardized and coordinated follow-up and surveillance practices and for better dissemination of information and education on follow-up guidelines for primary care physicians who provide care for thyroid cancer patients. Such strategies are currently underway at our centre. Given the current availability of evidence-based guidelines, prospective study of interventions that may improve follow-up of patients with thyroid cancer are warranted and may eventually lead to improved outcomes for individuals in whom this common endocrine malignancy is diagnosed.

Competing interests: None declared.

Contributors: S.M. Wiseman designed the study. E. Lam, S. Strugnell and S.M. Wiseman acquired the data, which E. Lam, C. Bajdik, D. Holmes and S.M. Wiseman analyzed. S.M. Wiseman wrote the article, which all authors reviewed and approved for publication.

References

Quality of inguinal hernia operative reports: room for improvement

Background: Operative reports (ORs) serve as the official documentation of surgical procedures. They are essential for optimal patient care, physician accountability and billing, and direction for clinical research and auditing. Nonstandardized narrative reports are often of poor quality and lacking in detail. We sought to audit the completeness of narrative inguinal hernia ORs.

Methods: A standardized checklist for inguinal hernia repair (IHR) comprising 33 variables was developed by consensus of 4 surgeons. Five high-volume IHR surgeons categorized items as essential, preferable or nonessential. We audited ORs for open IHR at 6 academic hospitals.

Results: We audited 213 ORs, and we excluded 7 femoral hernia ORs. Tension-free repairs were the most common (82.5%), and the plug-and-patch technique was the most frequent (52.9%). Residents dictated 59% of ORs. Of 33 variables, 15 were considered essential and, on average, 10.8 ± 1.3 were included. Poorly reported elements included first occurrence versus recurrent repair (8.3%), small bowel viability in incarcerated hernias (10.7%) and occurrence of intraoperative complications (32.5%). Of 18 nonessential elements, deep vein thrombosis prophylaxis, preoperative antibiotics and urgency were reported in 1.9%, 11.7% and 24.3% of ORs, respectively. Repair-specific details were reported in 0 to 97.1% of ORs, including patch sutured to tubercle (55.1%) and location of plug (67.0%).

Conclusion: Completeness of IHR ORs varied with regards to essential and nonessential items but were generally incomplete, suggesting there is opportunity for improvement, including implementation of a standardized synoptic OR.
RECHERCHE

The operative report (OR) has traditionally been in the form of a narrative, which is dictated after the surgical procedure by either a surgeon or resident. Its role is multifaceted: it serves as both documentation of the procedure and as communication between health care providers in the perioperative and postoperative period. It is also essential for medicolegal purposes, quality assurance, research into practice patterns and patient outcomes, and for compensation in some jurisdictions.

In recent years, ORs have been examined and shown to be lacking in quality, completeness, timeliness and consistency. While several studies have assessed the quality and completeness of ORs in the areas of surgical oncology, bariatric surgery, obstetrical/gynecological surgeries, Mohs micrographic surgery and orthopedic procedures, ORs for common general surgery procedures have not been examined in great detail. To our knowledge, the quality of narrative ORs for inguinal hernia repairs (IHRs) has not been studied to date even though IHRs are among the most commonly performed procedures by general surgeons. The purpose of this study was to examine the completeness of IHR narrative ORs in a large academic centre across 6 teaching hospitals.

METHODS

Four surgeons (a high-volume hernia surgeon, 2 general surgeons and a surgical resident) developed a standardized checklist for IHR by consensus. The checklist included elements pertinent to demographics (date of operation, date of dictation, person dictating, surgeon, assistants, date of birth and sex of patient), intraoperative details (deep vein thrombosis [DVT], prophylaxis, preoperative antibiotics, type of anesthesia, operative urgency, complications, skin closure) and hernia details (preoperative diagnosis, procedure, side, postoperative diagnosis, hernia type, occurrence, type of repair, hernia sac, cord explored, cord structures identified, division of round ligament, fixation of round ligament, exterior oblique closed, method of fixation, ilioinguinal nerve identified or divided, testicle pulled down at end of case, ilioinguinal nerve block, ligation of round ligament, exterior oblique closed, cord explored, cord structures identified, division of round ligament, fixation of round ligament, exterior oblique closed, method of fixation, ilioinguinal nerve identified or divided, testicle pulled down at end of case, ilioinguinal nerve block, hernia incarcerated). In addition, 1–7 variables unique to 6 different types of hernia repairs (prolene hernia system, Lichtenstein, plug-and-patch, Bassini, McVay, Shouldice) were included. Thus, in total 34–40 items were included in the checklist, depending on the type of repair.

Five high-volume hernia surgeons then evaluated the checklist and classified each element as essential, preferable or nonessential. Fifteen general items were determined to be essential by majority vote (agreement among at least 3 surgeons). All repair-specific items were classified as essential using the same method.

We conducted an audit of narrative ORs performed in 2009 at 6 teaching hospitals affiliated with the University of Toronto. Inclusion criteria for the study were patients undergoing elective or emergent open IHRs by any technique. A list of patients fitting the study criteria was generated by the Medical Records Department at each site. We reviewed the charts consecutively and retroactively, starting with procedures performed in November 2008 and continuing until we had reviewed the charts of approximately 50 patients at each site or all charts over the course of 2.5 years. Two medical students extracted the data from the patient charts on a pilot-tested data abstraction sheet. A senior author later reviewed all data.

We determined a completeness score for each OR according to both the checklist and the essential items list (Appendix, Table S1, available at cma.ca/cjs), and we assessed the OR based on the dictator (staff, senior resident, junior resident, dictator not specified) and repair type.

RESULTS

Of the charts reviewed, we selected 213 ORs (range 3–45 per hospital) for audit. Of these, 7 ORs were for femoral hernia repairs and were excluded from the study. Details regarding patient and hernia characteristics are shown in Table 1. The level of training of the person dictating the OR was also recorded: 82 (39.8%) staff surgeons, 33 (16.0%) senior residents, 26 (12.6%) junior residents, 62 (30.1%) residents (year not specified) and 3 (1.4%) level of training (staff surgeon v. resident) not specified.

Completeness of demographic information ranged from 48.5% for date of birth to 100% for date of dictation, person

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)</th>
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<tbody>
<tr>
<td>Sex</td>
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</tr>
<tr>
<td>Male</td>
<td>167</td>
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</tr>
<tr>
<td>Female</td>
<td>17</td>
<td>(8.3)</td>
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<tr>
<td>Not specified</td>
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<td>(10.7)</td>
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<tr>
<td>Type of hernia</td>
<td></td>
<td></td>
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<tr>
<td>Indirect</td>
<td>90</td>
<td>(43.7)</td>
</tr>
<tr>
<td>Direct</td>
<td>59</td>
<td>(28.6)</td>
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<tr>
<td>Pantaloon</td>
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<td>(5.3)</td>
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<tr>
<td>Not specified</td>
<td>46</td>
<td>(22.3)</td>
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<tr>
<td>Side of hernia</td>
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<tr>
<td>Right</td>
<td>103</td>
<td>(50.0)</td>
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<tr>
<td>Left</td>
<td>85</td>
<td>(41.3)</td>
</tr>
<tr>
<td>Bilateral</td>
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<td>(7.8)</td>
</tr>
<tr>
<td>Not specified</td>
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<td>(1.0)</td>
</tr>
<tr>
<td>Urgency of operation</td>
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<tr>
<td>Urgent</td>
<td>14</td>
<td>(6.8)</td>
</tr>
<tr>
<td>Elective</td>
<td>36</td>
<td>(17.5)</td>
</tr>
<tr>
<td>Not specified</td>
<td>156</td>
<td>(75.7)</td>
</tr>
<tr>
<td>Type of repair</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolene hernia system</td>
<td>35</td>
<td>(17.0)</td>
</tr>
<tr>
<td>Lichtenstein</td>
<td>26</td>
<td>(12.6)</td>
</tr>
<tr>
<td>Plug-and-patch</td>
<td>109</td>
<td>(52.9)</td>
</tr>
<tr>
<td>Bassini</td>
<td>2</td>
<td>(1.0)</td>
</tr>
<tr>
<td>McVay</td>
<td>4</td>
<td>(1.9)</td>
</tr>
<tr>
<td>Shouldice</td>
<td>23</td>
<td>(11.2)</td>
</tr>
<tr>
<td>Not specified</td>
<td>7</td>
<td>(3.4)</td>
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</table>
dictating and operating surgeon. Completeness of intraoperative details ranged from 1.5%–97.1%. The most poorly reported details were occurrence of complications (32.5%) and administration of DVT prophylaxis (1.9%). The most frequently reported details were type of anesthesia (96.6%) and skin closure method (97.1%; Appendix, Table S1).

Hernia-specific details were reported in 8.5%–99.0% of ORs. The most poorly reported detail was the occurrence of the hernia (recurrent or not; 8.5%). The most frequently reported details were the side of the repair (99.0%) and the type of procedure performed (97.1%). Twenty-six (12.6%) reports did not state that the external oblique was closed, and 21 (10.2%) did not specify the type of suture used for repair. Whether the ilioinguinal nerve was identified was dictated in 46.6% of reports and whether the nerve was divided was reported in only 36.4%. The hernia sac was mentioned in 74.8%. Cord exploration was dictated in 32.0%, and identification of cord structures was mentioned in 37.9%. In the ORs of female patients, division of the round ligament was mentioned in 23.5%.

Tension-free repairs (82.5% of repairs) were the most common type of repair performed and were further categorized into prolene hernia system, Lichtenstein and plug-and-patch repairs. The tissue repairs in the audit consisted of the Bassini, McVay and Shouldice repairs. The most common repair was the plug-and-patch method (n = 109), and completeness scores ranged from 36.7% (mention of recreated ring) to 96.3% (reporting tacking of the patch). The prolene hernia system ORs had the highest completeness scores, ranging from 74.3% (mesh was tacked to the inguinal ligament and conjoint tendon) to 97.1% (onlay mesh mentioned). Of the tissue repairs, the most poorly reported was the McVay with no ORs mentioning a transition stitch and no dictations indicating that the conjoint tendon was sutured to the inguinal ligament.

The overall completeness score for essential items was 71.7%, with an average of 10.8 ± 1.3 of essential elements included in dictated ORs. Of the 15 essential items (Table 2), the most poorly reported item was whether the hernia was recurrent (8.3% complete). The individual items ranged from 8.3% to 100% completeness for date of dictation, person dictating and operating surgeon.

**DISCUSSION**

Narrative reports have traditionally been the standard of care for documenting procedures and examinations performed on patients. In the past decade, studies have shown that these dictations are inadequate and that synoptic reports have been adopted in pathology, radiology, internal medicine, pediatrics and surgery.1–5,7–14

In Ontario, Cancer Care Ontario implemented the College of American Pathologists (CAP) standardized checklists for cancer pathology across 14 regional health integration networks in an electronic form with discrete data fields. Srigley and colleagues15 reported that this implementation was associated with increased completeness rates (39.3% in narrative reports vs. 93.0% in synoptic reports for colorectal tumour pathology). Other studies in pathology have reported similar results with the use of synoptic reports.8,14 Synoptic reports have also been shown to increase the quality of disability exams,9 improve quality assurance participation in interventional radiology procedures10 and improve timeliness and completeness of neonatal discharge summaries.11 Computerized discharge summaries on medical and surgical services were shorter, contained more information, were faster to generate (at discharge vs. up to 26-week delay) and were more likely to be created (98% vs. 71%).12,13 Synoptic reports were found in general to be of similar quality to narrative reports,14 and they were preferred by general practitioners.7

It is not surprising that the synoptic report has been adopted in surgical reporting. Operative reports have been found to be lacking in consistency, quality and completeness and are frequently dictated after a significant delay.6,8–10 In a study of 250 laparoscopic cholecystectomy ORs, Stewart and colleagues8 showed that there was a large variation in the content of reports and that key elements, such as adequate dissection of the Calot triangle, were often omitted (present in 24.8% of ORs). Several studies have reported significant delays in the dictation of ORs: 55% were dictated more than 24 hours after surgery in one study17 and 33% after more than 48 hours in another study.18 Sixty-seven percent of delayed dictations (>24h) in a study of resident dictations were noted to be incomplete.19 Flynn and Allen11 reported that incomplete description of surgical procedures led to delayed reimbursement in 76% of 550 ORs, which was the equivalent of $1 300 000. In a study of resident dictations by Novisky and colleagues,19 9.7% of 97 ORs had deficiencies accounting for loss of $18 200 of reimbursement if audited. Factors that were identified as affecting the quality of

<table>
<thead>
<tr>
<th>Table 2. Essential elements to be included in the operative report</th>
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<tbody>
<tr>
<td><strong>Element</strong></td>
</tr>
<tr>
<td>Date of operation</td>
</tr>
<tr>
<td>Date of dictation</td>
</tr>
<tr>
<td>Person dictating the operative report</td>
</tr>
<tr>
<td>Preoperative diagnosis</td>
</tr>
<tr>
<td>Procedure (e.g., hernia repair)</td>
</tr>
<tr>
<td>Site</td>
</tr>
<tr>
<td>Postoperative diagnosis</td>
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<tr>
<td>Surgeon</td>
</tr>
<tr>
<td>Sex of patient</td>
</tr>
<tr>
<td>Occurrence (first repair v. recurrent)</td>
</tr>
<tr>
<td>Type of repair</td>
</tr>
<tr>
<td>Cord explored</td>
</tr>
<tr>
<td>Complications</td>
</tr>
<tr>
<td>Iliotibial nerve block</td>
</tr>
<tr>
<td>Incarcerated hernia</td>
</tr>
</tbody>
</table>
dictations were the delay between the procedure and dictation, the level of training of the person dictating and lack of awareness of data that are important from medical, medicolegal or scientific standpoints. Some studies assessing ORs in Mohs micrographic surgery and obstetric/gynecological procedures (including cesarean section, postpartum tubal ligation, total abdominal hysterectomy, vaginal hysterectomy and laparoscopic tubal ligation) have shown improvement in completeness and quality. In general surgery, most studies on OR quality have been conducted in the subspecialty of surgical oncology. One of the early studies, conducted by Edhemovic and colleagues, assessed ORs for rectal cancer surgery. They examined the completeness of intraoperative data reporting, including resection method, clinical margins and node status in standard versus computerized synoptic ORs. They showed that the narrative OR contained 45.9% of the specified data elements with the most important data present in only 33.5%–47.5% of dictations; after development of a web-based synoptic reporting tool, 99% of the data elements were captured. The authors recommended that the synoptic format be adopted as a standard for rectal cancer surgery reporting and serve as an educational tool to remind the surgeon of essential steps of the operation.

In the area of surgical oncology, there have also been publications on synoptic ORs for thyroidectomy, breast cancer procedures and pancreatic resection. The completeness of narrative vs. synoptic thyroidectomy ORs were compared in the study by Chambers and colleagues, where no narrative reports (v. 100% of synoptic reports) contained adequate information to calculate the MACIS (distant metastasis, patient age, completeness of resection, local invasion, and tumour size) score, which is used for prognostication and risk stratification. Essential elements, such as presence of invasion, completeness of resection, and preoperative vocal cord assessment were poorly reported in narrative reports, whereas they were mandatory fields in the web-based template. In a large-scale study on pancreatic resections, synoptic ORs were associated with significantly higher completeness scores, quicker availability in patient charts and good interobserver agreement. The study suggested that electronic synoptic ORs could decrease errors in transcription, reduce costs and provide faster turnaround time. Another study examined the use of a synoptic reporting tool for breast cancer procedures and concluded that the tool was associated with quality improvement, increased efficiency and decreased costs. The study quoted benefits with the new tool, including easy outcomes analysis and assessment of success of breast cancer screening programs, and it also served an ongoing educational purpose. A separate study was conducted on residents’ use of computerized synoptic ORs for breast cancers and showed higher completeness scores and better understanding of the operative procedure and perioperative preparations.

Operative reports for common general surgery procedures have not been examined in great detail. To our knowledge, the quality of narrative ORs for IHRs has not been studied to date even though IHRs are among the most common procedures performed by general surgeons. In our own study we reviewed 206 open IHRs dictated by individuals with various levels of training. The completeness scores ranged from 1.9% (DVT prophylaxis) to 100% for individual elements on the checklist. Essential elements were dictated with an inclusion rate of 71.7%. When all elements were considered, however, completeness of ORs scored between 59.2% and 69.0% depending on the level of training of the person dictating the OR. This calculation was limited because of missing data on sex and sex-specific elements. For example, completeness of spermatic cord exploration may have been inaccurately calculated because we included it into the completeness calculation when sex was not specified despite the possibility that the patient could have been a woman. Repair-specific detail scores also varied among the types of repairs. Although our study examined factors such as turnover time for dictation, resident comfort with dictation and cost of dictated reports, our low completeness scores were consistent with those reported in other studies reviewing narrative ORs and showed substantial room for improvement.

The University of Toronto has implemented a synoptic template for laparoscopic cholecystectomy for residents but has yet to conduct a quality study of subsequent dictations. We have yet to develop a web-based synoptic reporting tool, but this is our ultimate goal. The studies we discussed demonstrate that this method would allow real-time entry of pertinent operative information and immediate generation of a synoptic OR for inclusion in the patient’s chart upon their transfer out of the operating room, improving communication and continuity of care between hospital teams. The addition of discrete data fields also allows for easy extraction of data for use in quality assessment and for research purposes. Several studies from Alberta have reported success with implementation of a web-based system for oncologic operative reporting (the WebSMR). In a recent publication studying implementation and ease of use of the system, 75% of staff surgeons were moderately or highly satisfied, and 80% said they would recommend the system to surgeons at other sites.

There are important hurdles to changing the status quo regarding dictation of general surgical procedures. These include accessibility and ease of use, privacy issues and technical aspects of implementing a web-based application. There is always a learning curve associated with new tools in health care, and residents and surgeons alike require training on a new system that could be time-consuming in an already busy timetable. Eventually the goal would be for a net decrease in the amount of time required to record operative details in a new system. Privacy issues surrounding personal health information is always an area of concern when a patient’s medical record is available on a computer connected to the Internet or intranet. Specific security measures would have to be in place to prevent external or inappropriate access to the synoptic reports. Appropriate consultation with information
technology professionals who, as most hospitals already have electronic medical records with similar security requirements. Technical difficulties include design of a user-friendly, efficient application requiring close interaction among surgeons, health records and computer programmers. However, there are important potential benefits of implementing a computerized synoptic OR, including decreased transcription costs, faster and greater completion of ORs and prevention of duplication of information on the electronic health record and the electronic OR.

One topic of discussion in studies comparing narrative reports with synoptic reports is the high correlation between the list of essential items and the elements included in a synoptic report. It is possible that the same surgeon provides input into creation of a synoptic report and subsequently participates in the creation of an audit checklist, skewing the results in favour of synoptic reports. To minimize this concern, our checklist for data extraction was based on a consensus committee among a group of academic surgeons at the University of Toronto. In addition, no other validated checklists in the literature nor publications on essential elements of an IHR were available. Neither the initial checklist nor the selection of essential elements were based on precedent evidence. However, one source of bias is that the checklist was created by some surgeons who were also audited in this study.

Limitations

A limitation to our study was the lack of random selection of ORs. The records were all selected in retrospective sequence from a specified date with no randomization for patient parameters, surgical teams or surgical procedure. This led to uneven distribution in the data, especially regarding the location of types of repair; 1 institution carried out most prolate hernia system repairs (27 of 35, 77.1%), and another institution carried out most Shouldice repairs (19 of 23, 82.6%).

CONCLUSION

Accurate and comprehensive operative notes are essential to patient care, surgeon accountability, resident training and database compilation. Many of the narrative ORs for IHRs are missing key information, and our study suggests there is an opportunity for improvement in the completeness of ORs. One method for improvement lies in standardized synoptic reports, which have been reported to have higher completeness scores and shorter turnover time. Our institution has already initiated synoptic checklists and is in the process of developing a web-based tool for real-time composition of a synoptic operative record.

Competing interests: F. Brenneman has received consultant fees and speaker fees from Johnson & Johnson Inc. No other competing interests declared.

Contributors: S. Forbes, C. Eskcioğlu, F. Brenneman and R. McLeod designed the study. A. Pooni, S. Forbes and C. Eskcioğlu acquired the data, which G. Ma, E. Pearsall and R. McLeod analyzed. G. Ma and R. McLeod wrote the article, which all authors reviewed and approved for publication.

References

On-pump beating-heart versus conventional coronary artery bypass grafting for revascularization in patients with severe left ventricular dysfunction: early outcomes

Background: We sought to evaluate the effects of on-pump beating-heart versus conventional coronary artery bypass grafting techniques requiring cardioplegic arrest in patients with coronary artery disease with left ventricular dysfunction.

Methods: We report the early outcomes associated with survival, morbidity and improvement of left ventricular function in patients with low ejection fraction who underwent coronary artery bypass grafting between August 2009 and June 2012. Patients were separated into 2 groups: group I underwent conventional coronary artery bypass grafting and group II underwent an on-pump beating-heart technique without cardioplegic arrest.

Results: In all, 131 patients underwent coronary artery bypass grafting: 66 in group I and 65 in group II. Left ventricular ejection fraction was 26.6% ± 3.5% in group I and 27.7% ± 4.7% in group II. Left ventricular end diastolic diameter was 65.6 ± 3.6 mm in group I and 64.1 ± 3.2 mm in group II. There was a significant reduction in mortality in the conventional and on-pump beating-heart groups (p < 0.001). Perioperative myocardial infarction and low cardiac output syndrome were higher in group I than group II (both p < 0.05). Improvement of left ventricular function after the surgical procedure was better in group II than group I.

Conclusion: The on-pump beating-heart technique is the preferred method for myocardial revascularization in patients with left ventricular dysfunction. This technique may be an acceptable alternative to the conventional technique owing to lower postoperative mortality and morbidity.

Contexte : Nous avons voulu comparer les effets du pontage coronarien sur cœur battant sous CEC (circulation extracorporelle) et ceux du pontage coronarien classique exigeant un arrêt cardioplégique chez des patients atteints de coronaropathie et de dysfonction ventriculaire gauche.

Méthodes : Nous faisons état des premiers résultats aux plans de la survie, de la morbidité et de l’amélioration de la fonction ventriculaire gauche chez des patients qui avaient une fraction d’éjection faible et qui ont reçu un pontage coronarien entre août 2009 et juin 2012. Les patients ont été répartis en 2 groupes: le groupe I a été soumis à la technique de pontage coronarien classique et le groupe II a été soumis à la technique à cœur battant sous CEC sans arrêt cardioplégique.

Résultats : En tout, 131 patients ont reçu un pontage coronarien : 66 dans le groupe I et 65 dans le groupe II. La fraction d’éjection ventriculaire gauche était de 26,6 % ± 3,5 % dans le groupe I et de 27,7 % ± 4,7 % dans le groupe II. Le diamètre télediastolique ventriculaire gauche était de 65,6 ± 3,6 mm dans le groupe I et de 64,1 ± 3,2 mm dans le groupe II. On a noté une réduction significative de la mortalité dans les groupes soumis à l’intervention classique et à l’intervention à cœur battant sous CEC (p < 0,001). L’infarctus du myocarde peropératoire et le syndrome de faible débit cardiaque ont été plus fréquents dans le groupe I que dans le groupe II (tous deux p < 0,05). L’amélioration de la fonction ventriculaire gauche après l’intervention chirurgicale a été plus marquée dans le groupe II que dans le groupe I.

Conclusion : La technique à cœur battant sous CEC est la méthode préférée de revascularisation myocardique chez les patients atteints d’une dysfonction ventriculaire gauche. Cette technique peut être une solution de rechange acceptable à la technique classique en raison des taux de mortalité et de morbidity postopératoires plus faibles qui y sont associés.
Conventional coronary artery bypass grafting (CABG) is routinely used worldwide to treat patients with coronary artery disease. The procedure is associated with several side effects mostly due to the use of aortic cross-clamping, cardioplegic arrest and cardiopulmonary bypass (CPB). In the last 20 years, many efforts have been undertaken to reduce the incidence of major intraoperative and postoperative complications related to the procedure.

Myocardial revascularization in patients with left ventricular dysfunction is often performed to alleviate symptoms, to prevent future ischemic events and to increase survival. Improvement in myocardial protection techniques and complete revascularization procedures has reduced the morbidity and mortality associated with CABG. However, perioperative morbidity and mortality remain high in patients with severe left ventricular dysfunction who undergo this procedure. Recently, beating-heart and noncardioplegic CABG without cross-clamping have been used as alternative surgical techniques in high-risk patients. Patients with left ventricular dysfunction who have extensive areas of hibernating myocardium might be expected to derive the greatest benefits from CABG in terms of left ventricular function improvement. Randomized trials have demonstrated an important survival benefit in patients with low left ventricular ejection fraction who undergo surgical revascularization.

In the present study, we compared improvement of left ventricular function and the early clinical outcomes in patients with left ventricular dysfunction undergoing conventional versus on-pump beating-heart techniques.

METHODS

We conducted this study to determine the early outcomes of consecutive patients who underwent isolated coronary artery bypass surgery between August 2009 and June 2012. We selected patients based initially on their ejection fraction who undergo surgical revascularization. Randomized trials have demonstrated an important survival benefit in patients with low left ventricular ejection fraction who undergo surgical revascularization.

In the present study, we compared improvement of left ventricular function and the early clinical outcomes in patients with left ventricular dysfunction undergoing conventional versus on-pump beating-heart techniques.

**Conventional CABG**

Cardiopulmonary bypass was established with aortic cannulation and bicaval venous drainage. Systemic temperature was kept between 30° and 32°C (middle hypothermic). The aorta was cross-clamped, and myocardial protection was achieved with intermittent antegrade and retrograde blood cardioplegia. The distal anastomoses were constructed with running sutures of 7-0 or 8-0 polypropylene, and the proximal anastomoses were connected to the ascending aorta with 5-0 or 6-0 polypropylene sutures during a single cross-clamping period. Cumulative regional ischemic times were between 9.1 and 14.2 min. for each anastomosis during cross-clamping. After the patient was weaned from CPB and decannulated, the heparin was reversed with protamine infusion (1/1.5 rate).

**On-pump beating-heart CABG**

The CPB circuit was the same as that for conventional CABG. The operation was continued with the assisted beating heart. The temperature of patients was kept approximately 36°C without cooling (normothermic). The distal anastomoses were constructed before the proximal anastomoses. The left anterior descending artery (LAD) was revascularized first with the internal thoracic artery.
(ITA), followed by the circumflex (Cx) and right coronary arteries (RCA). Regional myocardial immobilization was achieved with a suction stabilizer (Octopus, Medtronic; Guidant Acrobat, Guidant). We did not use an apical suction cardiac positioning device for revascularization. During anastomoses, target vessel homeostasis was obtained with temporary occlusion of the proximal coronary artery, and/or a humidified carbon dioxide blower was used for better visualization. Distal anastomoses were made with running sutures of 7–0 or 8–0 polypropylene. Cumulative regional ischemic times were between 8.7–15.9 min for each anastomosis during beating. After each distal anastomosis, perfusion was maintained with warm blood through the pump using anastomosed saphenous veins. The proximal anastomoses were created with 5–0 or 6–0 polypropylene sutures under a partial occlusion clamp. After weaning from CPB and decannulation, the heparin was reversed with protamine infusion (1/1.5 rate).

### Definition and follow-up

We defined in-hospital mortality as death for any reason occurring within 30 days after the operation. Perioperative acute myocardial infarction was defined as the appearance of new Q-waves or a marked loss of R-wave forces and peak creatine phosphokinase (CK-MB) fractions greater than 10% of total creatine kinase. Low cardiac output syndrome (LCOS) was defined as a cardiac index lower than 2.0 L/min/m² requiring pharmacologic support and/or IABP insertion. Postoperative renal dysfunction referred to an increment of creatinine levels of 1 mg/dL compared with the preoperative value. Neurological complications referred to any transient or permanent neurologic deficit that developed after surgery. Gastrointestinal complications included confirmed diagnosis of upper and lower gastrointestinal hemorrhage, intestinal ischemia, acute cholecystitis and pancreatitis. We recorded mortality; perioperative acute myocardial infection; IABP usage; incidence of LCOS; renal failure; use of an inotropic agent; intensive care unit and hospital stay; cardiac hemodynamic changes; bleeding; revision rates; gastrointestinal, pulmonary and neurologic complications; infections; and survival rates. All surviving patients underwent postoperative echocardiography within 3 months after the surgical procedure. We determined survival status by contacting all patients or their next of kin by telephone.

### Statistical analysis

Group statistics are expressed as means ± standard deviation. We performed the Mann–Whitney *U* test for continuous variables and the Wilcoxon signed rank test to compare pre- and postoperative within-group variables. We used the Fisher exact test for nonparametric variables. Survival was calculated using the Kaplan–Meier method. Statistically significant differences are noted for each analysis, and we considered results to be significant at *p* < 0.05.

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**Table 1. Preoperative data of patients with low ejection fraction undergoing coronary artery bypass graft**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group I</th>
<th>Group II</th>
<th><em>p</em> value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, M:F</td>
<td>34:22</td>
<td>32:23</td>
<td>0.66</td>
</tr>
<tr>
<td>Age, mean ± SD, yr</td>
<td>65.3 ± 4.5</td>
<td>68.1 ± 4.8</td>
<td>0.44</td>
</tr>
<tr>
<td>Hypertension</td>
<td>34</td>
<td>31</td>
<td>0.73</td>
</tr>
<tr>
<td>Smoker</td>
<td>76</td>
<td>70</td>
<td>0.57</td>
</tr>
<tr>
<td>Diabetes</td>
<td>24</td>
<td>22</td>
<td>0.73</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>50</td>
<td>45</td>
<td>0.47</td>
</tr>
<tr>
<td>Creatinine level &gt; 1.6 mg/dL</td>
<td>11</td>
<td>10</td>
<td>0.51</td>
</tr>
<tr>
<td>CK-MB mean (range), IU/L</td>
<td>66.8 (33–277)</td>
<td>67.1 (44–450)</td>
<td>0.21</td>
</tr>
<tr>
<td>COPD</td>
<td>28</td>
<td>24</td>
<td>0.64</td>
</tr>
<tr>
<td>CVD</td>
<td>7</td>
<td>6</td>
<td>0.88</td>
</tr>
<tr>
<td>PVD</td>
<td>13</td>
<td>12</td>
<td>0.36</td>
</tr>
<tr>
<td>arrhythmias</td>
<td>18</td>
<td>16</td>
<td>0.57</td>
</tr>
<tr>
<td>NYHA class, mean ± SD</td>
<td>3.3 ± 0.45</td>
<td>3.2 ± 0.5</td>
<td>0.59</td>
</tr>
<tr>
<td>Preoperative PTCA</td>
<td>20</td>
<td>15</td>
<td>0.64</td>
</tr>
<tr>
<td>Preoperative IABP</td>
<td>21</td>
<td>17</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Stable angina</td>
<td>55</td>
<td>56</td>
<td>0.82</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>11</td>
<td>8</td>
<td>0.56</td>
</tr>
<tr>
<td>LVEF, mean ± SD, mm</td>
<td>26.6 ± 3.5</td>
<td>27.7 ± 4.7</td>
<td>0.33</td>
</tr>
<tr>
<td>LVEDD, mean ± SD, mm</td>
<td>65.6 ± 3.6</td>
<td>64 ± 3.2</td>
<td>0.62</td>
</tr>
</tbody>
</table>

**Notes:**
- CABG = Coronary artery bypass graft; CK = creatine kinase; COPD = chronic obstructive pulmonary disease; CVD = cerebrovascular disease; F = female; IABP = intra-aortic balloon pump; LVEDD = left ventricle end-diastolic diameter; LVEF = left ventricular ejection fraction; M = male; NYHA = New York Heart Association; PTCA = percutaneous transluminal coronary angioplasty; PVD = peripheral vascular disease; SD = standard deviation.
- *Unless otherwise indicated.*
- †Conventional CABG.
- ‡On-pump beating-heart CABG.
**RESULTS**

We included 131 consecutive patients in our study: 66 patients in group I and 65 patients in group II. The mean follow-up time was 13 (range 3–18) months. The mean age of patients in group I was 65.3 ± 4.5 (range 52–81) years compared with 68.1 ± 4.8 (range 55–77) years in group II. New York Heart Association classifications were 3.3 ± 0.45 and 3.2 ± 0.6 in groups I and II, respectively. By transthoracic echocardiography, left ventricular ejection fraction was 26.6% ± 3.5% in group I and 27.7% ± 4.7% in group II. Left ventricular end diastolic diameter (LVEDD) was 65.6 ± 3.6 mm in group I and 64 ± 3.2 mm in group II. In group I, 19 (14.5%) patients had IABP preoperatively compared with 17 (12.9%) patients in group II. The enzymatic evidence of possible myocardial infarction was considered when CK-MB values were greater than 10% of creatine kinase values and when CK-MB values were greater than 25 IU/mL. The preoperative data are summarized in Table 1. There were no differences between the groups in preoperative characteristics. Moreover, the preoperative use of IABP was similar between groups. The time interval from the onset of acute myocardial infarction to CABG was similar between the groups (11 h ± 2.7 v. 10 h ± 2.2).

Table 2 shows the intraoperative characteristics of the patients. The CPB time was similar between the groups. The mean overall number of distal anastomoses was 3.1 ± 0.7 versus 3.0 ± 0.6 (p = 0.76). There was no difference in the number of bypassed vessels, in type of arterial conduits or in the sites of surgical anastomoses between the groups. Some patients (5 in group I and 4 in group II) required 2 anastomoses to the LAD artery owing to multiple stenoses. There was no difference between the groups in use of ITA. The ITA could not be used in 4 patients owing to failure or lack of ITA flow. The details on the extent of coronary artery disease are shown in Table 2.

We analyzed data on postoperative survival and complications between the groups (Table 3). Twenty-two patients in the conventional CABG group required new insertion of an IABP compared with 4 patients in the on-pump beating-heart CABG group (p = 0.023). The reason for new IABP insertion was failure to wean from bypass owing to low cardiac output. Although the pulmonary, neurologic, gastrointestinal and infectious complications were identified postoperatively in both groups in our series, the incidence was significantly lower in the on-pump beating-heart group.

Rates of perioperative acute myocardial infarction, new IABP insertion and LCOS were lower in the on-pump beating-heart than the conventional group (all p < 0.05). The increment of postoperative creatinine level greater than 1.5 mg/dL (postoperative renal dysfunction) compared with the preoperative value was notably lower in group II (p < 0.001). Three patients in group I required postoperative ultrafiltration and hemodialysis. In-hospital mortality was 12.7% (14 patients) in group I versus 1.8% (2 patients) in group II (p < 0.001). Operative mortality was also higher in the conventional
The cause of intraoperative deaths was low cardiac output. In the conventional group, 4 patients died within 48 hours compared with no patients in the on-pump CABG group. The cause of early deaths was progressive cardiac failure unresponsive to inotropic agents and/or IABP support resulting in multiple organ failure. Three patients in group I died later in the postoperative term; the causes of death were renal insufficiency in 2 patients (postoperative days 18 and 25) and recurrent ventricular arrhythmia in 1 patient (postoperative day 3).

The echocardiographic examination within 3 months of surgery revealed improvement of left ventricle function in groups I and II after CABG. The LVEDD also decreased in the 2 groups according to preoperative data. The ejection fraction increase and LVEDD decrease were higher in group II than group I; however, these differences were not significant.

Mean follow-up ranged from 3 to 18 months. The actuarial survival at 1, 12 and 18 months, taking into account all deaths in group I, was 92%, 82% and 70% compared with 97%, 84% and 77%, respectively, in group II (all p > 0.05).

There was an important difference between the groups in terms of intensive care unit and hospital stay; these were significantly shorter in group II than group I (p = 0.032 and p = 0.019, respectively).

**DISCUSSION**

A dysfunctional left ventricle with low ejection fraction is one of the most important factors for increased morbidity and mortality after and during cardiac surgery. One of the main surgical issues in these patients is myocardial protection. Despite new myocardial protection techniques, anesthesia and surgical techniques, postoperative adverse events related to intraoperative protection have not been completely eliminated.4–5 Theoretically, the ideal solution to this problem is alternative techniques, such as an off-pump beating-heart technique without CPB or an on-pump beating-heart technique with CPB.

Various studies have shown that an off-pump beating-heart technique is safe and has satisfactory short-term clinical outcomes compared with conventional CABG.4–9 Despite the efficiency and safety of off-pump techniques over conventional CPB, some critics may argue that patients treated with an off-pump technique are undergoing incomplete revascularization. Although incomplete revascularization has not been reported to increase early risk, it may cause recurrent angina, decrease late survival and require reintervention in the long term.10–11 Furthermore, one of the important drawbacks of this technique is the hemodynamic deterioration that can occur during manipulation of the heart, which entails urgent conversion to conventional CPB. Conversion from off-pump to
on-pump bypass has been associated with poor prognosis and may increase in-hospital mortality.\textsuperscript{12-17} Owing to the increased cardiac and hemodynamic instability, incomplete revascularization and repeated surgical interventions associated with the off-pump technique, an alternative technique that does not involve aortic cross-clamping with CPB has been developed. We have researched the effectiveness of an on-pump beating-heart technique in reducing both mortality and morbidity in patients with left ventricular dysfunction.

There is evidence that with conventional CABG the arrested heart may not be as well protected from ischemia as the beating-heart. Kreja and colleagues\textsuperscript{19} found that troponin T levels were higher with conventional CABG than with on- or off-pump beating-heart techniques. Patients with left ventricular dysfunction may be unable to sustain an adequate intraoperative cardiac output during the beating-heart technique; hence, the theoretical need exists for mechanical support from a CPB circuit as a hybrid procedure. It has been demonstrated that an on-pump beating-heart technique reduces the release of CK-MB and myocardial injury compared with conventional CABG.\textsuperscript{12,13,15,17,20} Early surgical outcomes were better in the on-pump beating-heart group in our study, and this result is consistent with those reported in several studies.\textsuperscript{18-21} Postoperative LCOS ratios, perioperative infarction, new IABP insertion (for weaning from the CPB), and duration of inotropic support were significantly lower in the on-pump beating-heart group than the conventional group. Postoperatively, intensive care unit and hospital stay as well as hospital costs decreased in the on-pump beating-heart group. The mortality of patients with left ventricular dysfunction undergoing an on-pump beating-heart technique varies from 2\%–8\%.\textsuperscript{1,5,11} In-hospital mortality was significantly lower in the on-pump beating-heart group than in the conventional group. In our study, mortality was 0.3\%, which was low compared with that reported in other studies. These considerations may all be related to the elimination of cardioplegic arrest, which is the main difference between the techniques. No significant differences were detected between the groups in relation to morbidity, including the incidence of stroke, gastrointestinal problems, pulmonary complications, bleeding, mediastinitis and prolonged mechanical ventilation, which are all believed to be related to the use of CPB itself.

Mizutani and colleagues\textsuperscript{11} have indicated that the on-pump beating-heart technique may increase the risk for incomplete revascularization due to shorter duration of surgery and CPB time. But we agree with the conclusions of previous studies that the on-pump beating-heart technique is associated with an adequate number of grafts performed and complete revascularization.\textsuperscript{15,22} The on-pump beating-heart technique allows optimal exposure of the coronary arteries. This avoids extreme upward retraction of the heart, especially during revascularization of the Cx branch, which might contribute to better myocardial protection.\textsuperscript{11,21}

Renal failure is a frequent complication in patients who have experienced hemodynamic failure or who have undergone conventional CABG. Most authors have shown that on-pump beating-heart CABG presents a low risk for systemic hypoperfusion during surgery and better renal protection, as demonstrated by a low incidence of postoperative renal complications.\textsuperscript{12,21} Because most patients with left ventricular dysfunction are hemodynamically unstable and have poor perfusion of their visceral organs, the appropriate circulatory support system, such as CPB, should be applied to improve their hemodynamic status and compensate for visceral organ perfusion.\textsuperscript{3,14,16,20,21} Therefore, the on-pump beating-heart technique offers a lower risk of systemic hypoperfusion during surgery and, as a consequence, superior renal protection.\textsuperscript{3,14,20} Although postoperative renal dysfunction was identified in both groups in our series, the incidence was significantly lower in the on-pump beating-heart group. Furthermore, there was no renal dysfunction requiring hemodialysis in the on-pump beating-heart technique group in our series. Despite the use of CPB in both groups, CPB time was shorter in the on-pump beating-heart group. Shortening of the duration of CPB may reduce the renal and visceral injury. In addition, the systemic heat of patients was approximately 36°C in the on-pump beating-heart group, whereas the patients were cooled to 30°C in the conventional group. Therefore, the renal and visceral damage that may have occurred due to systemic cooling would have been more significant in the conventional group.

Limitations

There are some limitations to the present study. First, the sample was nonrandomized. However, using specific statistical evaluations allowed for relatively precise risk and outcome assessment and comparison. Second, its retrospective nature and small sample limited the validity of the clinical results. Further studies are needed, particularly to determine the benefit achieved by increasing myocardial revascularization among patients who underwent on-pump beating-heart CABG. Finally, although a larger number of patients would be needed to guarantee more significant results, we believe that our study already shows interesting short-term results.

Conclusion

We performed an on-pump beating-heart technique to revascularize the myocardium in patients with left ventricular dysfunction and compared the early outcomes with those of conventional CABG. Our experience
RECHERCHE

suggests that an on-pump beating-heart technique is the preferable method of myocardial revascularization for patients with acute myocardial infarction and low ejection fraction who might tolerate cardioplegic arrest poorly. The main advantages of the on-pump beating-heart technique are complete revascularization without hemodynamic instability and low morbidity and mortality in patients with left ventricular dysfunction.

Competing interests: None declared.


References

Validity of vascular trauma codes at major trauma centres

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Background: The use of administrative databases in vascular injury research has been increasing, but the validity of the diagnosis codes used in this research is uncertain. We assessed the positive predictive value (PPV) of International Classification of Diseases, tenth revision (ICD-10), vascular injury codes in administrative claims data in Ontario.

Methods: We conducted a retrospective validation study using the Canadian Institute for Health Information Discharge Abstract Database, an administrative database that records all hospital admissions in Canada. We evaluated 380 randomly selected hospital discharge abstracts from the 2 main trauma centres in Toronto, Ont., St. Michael’s Hospital and Sunnybrook Health Sciences Centre, between Apr. 1, 2002, and Mar. 31, 2010. We then compared these records with the corresponding patients’ hospital charts to assess the level of agreement for procedure coding. We calculated the PPV and sensitivity to estimate the validity of vascular injury diagnosis coding.

Results: The overall PPV for vascular injury coding was estimated to be 95% (95% confidence interval [CI] 92.3–96.8). The PPV among code groups for neck, thorax, abdomen, upper extremity and lower extremity injuries ranged from 90.8 (95% CI 82.2–95.5) to 97.4 (95% CI 91.0–99.3), whereas sensitivity ranged from 90% (95% CI 81.5–94.8) to 98.7% (95% CI 92.9–99.8).

Conclusion: Administrative claims hospital discharge data based on ICD-10 diagnosis codes have a high level of validity when identifying cases of vascular injury.

Level of evidence: Observational Study Level III.

Contexte : L’utilisation des bases de données administratives pour la recherche sur les lésions vasculaires est en hausse, mais la validité des codes diagnostiques utilisés dans ces recherches est incertaine. Nous avons évalué la valeur prédictive positive (VPP) des codes de lésions vasculaires de la dixième édition de la Classification internationale des maladies (CIM-10) qui figurent dans une base de données administrative ontarienne.

Méthodes : Nous avons réalisé une étude de validation rétrospective à partir de la base de données de l’Institut canadien d’information sur la santé (ICIS) sur les congés des patients, une base de données administrative qui enregistre toutes les hospitalisations au Canada. Nous avons évalué 380 congés hospitaliers de 2 grands centres de traumatologie de Toronto, en Ontario, soit l’Hôpital St. Michael’s et le Centre des sciences de la santé Sunnybrook, entre le 1er avril 2002 et le 31 mars 2010. Nous avons ensuite comparé ces dossiers aux dossiers hospitaliers des patients correspondants pour vérifier la concordance des codes attribués aux interventions. Nous avons calculé la VPP et la sensibilité pour estimer la validité des codes diagnostiques appliqués aux lésions vasculaires.

Résultats : La VPP globale pour les codes de lésions vasculaires a été estimée à 95 % (intervalle de confiance [IC] de 95 % 92,3–96,8). Parmi les groupes de codes attribués aux lésions affectant le cou, le thorax, l’abdomen, les membres supérieurs et inférieurs, la VPP a varié de 90,8 (IC de 95 % 82,2–95,5) à 97,4 (IC de 95 % 91,0–99,3), tandis que la sensibilité a varié de 90 % (IC de 95 % 81,5–94,8) à 98,7 % (IC de 95 % 92,9–99,8).

Conclusion : Les données administratives sur les congés hospitaliers basées sur les codes diagnostiques de la CIM 10 ont un degré de validité élevé pour ce qui est des lésions vasculaires.

Niveau de preuve : Étude d’observation Niveau III.
A

methods

Results

Discussion

Given the importance of administrative databases as a source of data for epidemiological, prospective and evidence-based medicine studies, examining the validity of diagnostic codes
RESEARCH

in administrative databases highlights how the accuracy of these codes is important and has a significant effect on the study results.

To our knowledge, our study is the first to assess the validity of diagnosis (ICD-10) codes for vascular injury in administrative claims data. Our findings suggest an overall PPV of 95% (95% CI 92.3–96.8) and a sensitivity ranging from 90.0% to 98.7% for individual code groups.

Limitations

Our study was limited to only 2 trauma centres in Toronto, Ont., which may limit the generalizability of our findings. In addition, vascular injury subcodes, which differentiate between arterial and venous injuries and among anatomic regions, were not identified in this validation study.

CONCLUSION

Despite its limitations, our study suggests that administrative claims hospital discharge data have a high level of validity when identifying cases of vascular injury. Given that our results showed such a high level of accuracy, we anticipate that the number of vascular injury cases we may have missed by using those 8 major vascular trauma ICD-10 codes would be low. As such, usage of a particular database becomes further feasible and valuable, even for advanced retrospective vascular injury studies.

Acknowledgements: We thank Dr. Andrew Dueck for assisting us in supervising the chart review process at the Sunnybrook Health Sciences Centre.

Competing interests: None declared.

Contributors: A. Altojiry, M. Melo and M. Mamdani designed the study. A. Altojiry and M. Al-Omran, T.F. Lindsay, K.W. Johnston and M. Mamdani analyzed. A. Altojiry wrote the article, which all authors reviewed and approved for publication.

References

Canadian Surgery FORUM

The Canadian Surgery FORUM canadien de chirurgie will hold its annual meeting Sept. 18–21, 2014, in Vancouver, British Columbia. This interdisciplinary meeting provides an opportunity for surgeons across Canada with shared interests in clinical practice, continuing professional development, research and medical education to meet in a collegial fashion. The scientific program offers material of interest to academic and community surgeons, residents in training and students.

The major sponsoring organizations include the following:

- The Canadian Association of General Surgeons
- The Canadian Society of Colon and Rectal Surgeons
- The Canadian Association of Thoracic Surgeons
- The Canadian Society of Surgical Oncology

Other participating societies include the American College of Surgeons, the Canadian Association of Bariatric Physicians and Surgeons, the Canadian Association of University Surgeons, the Canadian Hepato-Pancreato-Biliary Society, the Canadian Undergraduate Surgical Education Committee, the James IV Association of Surgeons, the Québec Surgical Association and the Trauma Association of Canada.

For registration and further information visit www.cags-accg.ca.

FORUM canadien de chirurgie

La réunion annuelle du FORUM canadien de chirurgie aura lieu du 18 au 21 septembre 2014 à la Ville de Vancouver, Colombie-Britannique. Cette réunion interdisciplinaire permet aux chirurgiens de toutes les régions du Canada qui s’intéressent à la pratique clinique, au perfectionnement professionnel continu, à la recherche et à l’éducation médicale d’échanger dans un climat de collégialité. Un programme scientifique intéressera les chirurgiens universitaires et communautaires, les résidents en formation et les étudiants.

Les principales organisations qui parrainent cette réunion sont les suivantes :

- L’Association canadienne des chirurgiens généraux
- La Société canadienne des chirurgiens du cölon et du rectum
- La Société canadienne de chirurgie thoracique
- La Société canadienne d’oncologie chirurgicale

Le American College of Surgeons, l’Association canadienne des médecins et chirurgiens spécialistes de l’obésité, l’Association québécoise de chirurgie, le Canadian Association of University Surgeons, le Canadian Hepato-Pancreato-Biliary Society, le Canadian Undergraduate Surgical Education Committee, le James IV Association of Surgeons et l’Association canadienne de traumatologie sont au nombre des sociétés qui appuient cette activité.

Pour vous inscrire ou pour plus de renseignements, veuillez consulter le site www.cags-accg.ca.
Jejunostomy tube feeding in patients undergoing esophagectomy

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Background: Surgical jejunostomy tubes are a routine part of elective esophagectomies in patients with carcinomas and provide a route for nutritional support in those who experience complications. We wished to determine how frequently oral intake is delayed and the amount of nutrition delivered via the jejunostomy tube.

Methods: We reviewed the charts of all adults undergoing esophagectomy for carcinoma between January 2000 and June 2008. We determined the proportion of patients unable to resume oral nutrition after 8 days and the amount of nutrition delivered in each of the 8 days.

Results: In all, 111 patients underwent elective esophagectomy for carcinoma, and 103 had a jejunostomy tube placed. The mean age was 67 ± 10.8 years. The median time to oral intake was 7 (interquartile range 7–11) days. Seventy-four (67%) patients resumed oral intake within 8 days. The mean nutrition delivered by jejunostomy within the first 8 days as a percentage of the target was 45.6% (95% confidence interval 41.2%–49.9%). Six (5.4%) patients experienced complications attributable solely to the jejunostomy tube; 3 (2.9%) required surgery. Forty (38.8%) patients had abdominal issues serious enough to warrant delaying the progression of feeding.

Conclusion: Two-thirds of patients undergoing elective esophagectomy were tolerating oral intake by the end of the eighth postoperative day, and less than half of the target nutrition was delivered over the first 8 days. We now selectively place surgical jejunostomy tubes in patients undergoing elective esophagectomies.

Conte: Des cathéters de jéjunostomie chirurgicale sont d’emblée posés lors des cesophagectomies non urgentes chez les patients atteints de cancer et procurent une voie d’administration du soutien nutritionnel chez les patients qui présentent des complications. Nous avons voulu déterminer la fréquence à laquelle la prise orale est retardée et la quantité de solution pour nutrition parentérale administrée par le cathéter de jéjunostomie.

Méthodes : Nous avons analysé les dossiers de tous les adultes soumis à une cesophagectomie pour un cancer entre janvier 2000 et juin 2008. Nous avons calculé la proportion de patients incapables de recommencer à se nourrir par la bouche après 8 jours et la quantité de solution administrée à chacun des 8 jours.

Résultats : En tout, 111 patients ont subi une cesophagectomie non urgente pour un cancer et on a posé un cathéter de jéjunostomie à 103 d’entre eux. L’âge moyen était de 67 ± 10,8 ans. L’intervalle médian avant le début des prises orales a été de 7 jours (fourchette interquartile de 7–11). Soixante-quatorze patients (67 %) ont recommencé à s’alimenter par la bouche dans l’espace de 8 jours. La quantité moyenne de solution pour nutrition parentérale administrée par jéjunostomie au cours des 8 premiers jours en pourcentage de l’objectif cible a été de 45,6 % (intervalle de confiance [IC] de 95 %, 41,2 %–49,9 %). Six patients (5,4 %) ont présenté des complications attribuables uniquement au cathéter de jéjunostomie; 3 (2,9 %) ont eu besoin d’une chirurgie. Quarante patients (38,8 %) ont présenté des symptômes abdominaux suffisamment graves pour retarder la progression de l’alimentation.

Conclusion : Les deux tiers des patients soumis à une cesophagectomie non urgente toléraient la prise orale à la fin du huitième jour postopératoire et moins de la moitié de la nutrition cible a été administrée au cours des 8 premiers jours. Nous plaçons maintenant des cathéters de jéjunostomie chirurgicale de façon sélective chez les patients qui subissent des cesophagectomies non urgentes.
n Canada, surgical jejunostomy tubes are routinely placed at the time of elective esophagectomy when oral nutrition is expected to be commenced after the first postoperative week. A potential benefit of placing a surgical jejunostomy tube is to provide a “safety valve” in case of delay in the resumption of oral intake. Another reason is to provide early enteral nutrition to reduce perioperative complications. Therefore, surgical jejunostomy is a prophylactic intervention analogous to perioperative antibiotics or anticoagulation.

However, as for any prophylactic procedure, there will be patients who receive the intervention in whom no benefit is expected but who are nevertheless exposed to the risk of the intervention. We sought to understand the possible benefits and risks associated with the routine insertion of surgical jejunostomy tubes in patients undergoing elective esophagectomy for carcinoma.

We conducted a retrospective cohort study to determine first, the frequency of delayed oral intake (i.e., how often did the jejunostomy serve as the “safety valve”?); second, how much nutrition was actually delivered within the first 8 postoperative days; and third, the frequency and nature of adverse events associated with jejunostomy tubes.

METHODS

Clinical protocol

At the Health Sciences Centre in Winnipeg, Man., we generally perform a transhiatal procedure and place a jejunostomy tube using a Witzel technique and a 10 or 12 F soft silicone catheter. Other procedures, such as thoracoabdominal or Ivor-Lewis procedures, are performed if deemed more suitable.

For patients having a surgical jejunostomy tube placed, dextrose solution is infused through the jejunostomy tube starting at a rate of 25 mL/h on postoperative day 1. On postoperative day 2, a standard polymeric formula is started at a rate of 25 mL/h administered by continuous infusion via automated Kangaroo ePump (Covidien) and advanced at a rate of 10–15 mL every 8–10 hours up to the target rate for that patient, depending on patient tolerance. The surgical team, in consultation with the dietician, determines the rate of advance.

On postoperative day 6 or 7, anastomotic integrity is confirmed with a contrast study. Tube feeding is decreased when the diet is advanced to full fluid consistency and is discontinued before the patient is discharged from hospital.

Study protocol

After obtaining University of Manitoba Health Research Ethics Board approval, we consulted hospital records to identify patients who had undergone surgical procedures on the esophagus at the Winnipeg Health Sciences Centre between Jan. 1, 2000, and June 30, 2008. Adults older than 18 years who underwent an elective esophagectomy for carcinoma were included.

Data collection

From the patient notes, we collected details of preoperative status, disease characteristics and operative details. For each patient, we calculated the daily delivered volume of tube feed and their target volumes.

Definitions

We classified dysphagia as none or minimal, tolerating liquids or obstructed. Because we were not confident in deriving a formal dysphagia score from the chart, we did not do so. Weight loss was determined at the time of the dietician assessment and recorded in the patient’s chart; however, the information in the chart did not allow for an accurate determination of the time period in which weight loss occurred.

We considered the time to oral intake to be the date of operation to commencement of any oral intake.

Statistical analysis

All patients were classified as having commenced oral intake by the end of postoperative day 8 (early) or not (delayed). We compared these 2 groups according to routinely measured perioperative factors. In those with jejunostomy tubes, the amount of nutrition delivered is expressed as a percentage of the target volume required for each patient, as determined by the Harris–Benedict equation and the specific nutritional formula used. The amount delivered each day during the first 8 postoperative days and the total amount delivered during this period is presented. We calculated 95% confidence intervals (CIs) for estimates of amount of nutrition delivered and proportions of patients who were unable to take oral intake by day 8. We did not undertake formal tests of significant differences between groups.

RESULTS

From Jan. 1, 2000, to June 30, 2008, 111 patients underwent an elective esophagectomy (95 men and 16 women). The type of operations performed were transhiatal esophagectomy (n = 64), thoracoabdominal or combined abdominal and thoracic (n = 44) and Ivor Lewis procedure with a neck anastomosis (n = 3). There were 69 patients who had the anastomosis placed in the neck and 42 had the anastomosis placed in the chest.

The mean body mass index was 26.9 ± 4.5, and the mean weight loss was 9.1% ± 8.1% of the usual weight. Before the operation, 59 patients had normal oral intake, 35 could manage only liquids and 10 were obstructed; we
were unable to determine preoperative oral intake status in 7 patients (Table 1).

Of the 111 patients, 103 had a surgical jejunostomy tube placed at the time of esophagectomy. The 8 patients without a jejunostomy tube received total parenteral nutrition (TPN) for nutritional support.

The median time to oral intake in all esophagectomy patients was 7 (interquartile range 7–11) days.

There were 74 patients (67%, 95% CI 57%–75%) who resumed oral intake by postoperative day 8 (Table 2). In the 37 patients in whom oral intake was delayed, 23 had a documented anastomotic leak and 14 had other complications, such as respiratory failure, gastric dilatation or sepsis. Of these 37 patients with delayed oral intake, 28 received prolonged nutritional support via their jejunostomy tubes and 9 commenced TPN owing to complications, including jejunostomy tube failure.

In the 103 patients who had a jejunostomy tube placed at operation, the overall nutritional intake through the jejunostomy tube was a mean of 45.6% (95% CI 41.2%–49.9%) of the target. In the early group, the mean nutrition delivered during the first 8 days was 41.0% (95% CI 32.6%–49.5%) of the target. In the delayed group, the mean nutrition delivered during the first 8 days was 47.9% (95% CI 42.8%–52.9%) of the target and in the overall population, the mean nutrition delivered during the first 8 days was 41.0% (95% CI 32.6%–49.5%) of the target.

The pattern of nutritional delivery was variable for both groups, but overall there was a slow increase toward the target. In other words, for every 100 patients who undergo an elective esophagectomy for cancer, 66 will have undergone a surgical procedure that was unnecessary as a “safety valve.” In addition, those patients who had a jejunostomy tube placed received less than half of the target nutrition. During this time period, 47.9% of the target nutrition was actually delivered.

Six patients, 3 of whom were in the early group, experienced complications attributable to the jejunostomy tube itself. Of the 6 patients, 3 required surgery for these complications (Tables 3 and 4). In addition to the observed complications attributable to the jejunostomy tube, the tube was blocked in 7 patients and dislodged in 2 patients. Forty patients (38.8%, 95% CI 29.3%–48.9%) reported abdominal issues serious enough to warrant withholding the progression of feeding.

**Discussion**

Our study found that 66% of patients were able to commence oral intake by the end of 8 postoperative days. During this time period, 47.9% of the target nutrition was actually delivered.

In other words, for every 100 patients who undergo an elective esophagectomy for cancer, 66 will have undergone a surgical procedure that was unnecessary as a “safety valve.” In addition, those patients who had a jejunostomy tube placed received less than half of the target nutrition, calling into question our success in actually providing early enteral nutrition.

Overall 40 patients had abdominal pain, diarrhea or other issues serious enough to warrant withholding their tube feeds, and 3 patients experienced jejunostomy complications severe enough to require reoperation.

Table 1. Characteristics of patients who underwent elective esophagectomy for carcinoma and who did or did not receive a jejunostomy tube

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total</th>
<th>Tube</th>
<th>No tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. (%)</td>
<td>111</td>
<td>103</td>
<td>8</td>
</tr>
<tr>
<td>Age, mean ± SD, yr</td>
<td>64.7 ± 10.8</td>
<td>64.5 ± 11</td>
<td>66.4 ± 9.4</td>
</tr>
<tr>
<td>Sex, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16 (14.4)</td>
<td>16 (15.5)</td>
<td>0</td>
</tr>
<tr>
<td>Male</td>
<td>95 (85.6)</td>
<td>87 (84.5)</td>
<td>8 (100)</td>
</tr>
<tr>
<td>Body mass index, mean ± SD</td>
<td>26.9 ± 4.5</td>
<td>26.9 ± 4.5</td>
<td>27.1 ± 5.3</td>
</tr>
<tr>
<td>Dysphagia, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None/minimal</td>
<td>59 (53.2)</td>
<td>53 (51.3)</td>
<td>6 (75.0)</td>
</tr>
<tr>
<td>Fluid only</td>
<td>35 (31.5)</td>
<td>34 (33.0)</td>
<td>1 (12.5)</td>
</tr>
<tr>
<td>Obstructed</td>
<td>10 (9.0)</td>
<td>9 (8.7)</td>
<td>1 (12.5)</td>
</tr>
<tr>
<td>Unable to determine</td>
<td>7 (6.3)</td>
<td>7 (6.8)</td>
<td>0</td>
</tr>
<tr>
<td>Weight loss, mean ± SD, %</td>
<td>--9.1 ± 8.1</td>
<td>--9.3 ± 7.9</td>
<td>--6.3 ± 10.9</td>
</tr>
<tr>
<td>Stage, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 0</td>
<td>2 (1.8)</td>
<td>2 (2)</td>
<td>0</td>
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<tr>
<td>Stage 1</td>
<td>7 (6.4)</td>
<td>6 (5.9)</td>
<td>1 (12.5)</td>
</tr>
<tr>
<td>Stage 2a</td>
<td>9 (8.2)</td>
<td>8 (7.6)</td>
<td>1 (12.5)</td>
</tr>
<tr>
<td>Stage 2b</td>
<td>29 (26.4)</td>
<td>26 (25.5)</td>
<td>3 (37.5)</td>
</tr>
<tr>
<td>Stage 3</td>
<td>53 (48.2)</td>
<td>50 (49.0)</td>
<td>3 (37.5)</td>
</tr>
<tr>
<td>Stage 4</td>
<td>10 (9.1)</td>
<td>10 (9.8)</td>
<td>0</td>
</tr>
<tr>
<td>Operation performed, no. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>THE/laparotomy</td>
<td>64 (57.7)</td>
<td>60 (58.3)</td>
<td>4 (50)</td>
</tr>
<tr>
<td>Thoracoabdominal/thoracotomy</td>
<td>44 (39.6)</td>
<td>40 (38.8)</td>
<td>4 (50)</td>
</tr>
<tr>
<td>Ivor Lewis McKeown</td>
<td>3 (2.7)</td>
<td>3 (2.9)</td>
<td>0</td>
</tr>
</tbody>
</table>

SD = standard deviation; THE = transhiatal esophagectomy.

Table 2. Characteristics of patients who underwent elective esophagectomy for carcinoma and who did or did not resume oral intake within 8 postoperative days

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Oral intake within 8 days</th>
<th>Oral intake after 8 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. (%)</td>
<td>74 (67)</td>
<td>37 (33)</td>
</tr>
<tr>
<td>Age, mean ± SD, yr</td>
<td>64.4 ± 11</td>
<td>65.3 ± 10.7</td>
</tr>
<tr>
<td>Sex, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10 (11.5)</td>
<td>6 (16.2)</td>
</tr>
<tr>
<td>Male</td>
<td>64 (86.5)</td>
<td>31 (83.8)</td>
</tr>
<tr>
<td>Body mass index, mean ± SD</td>
<td>26.4 ± 4.3</td>
<td>27.9 ± 4.8</td>
</tr>
<tr>
<td>Dysphagia, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None/minimal</td>
<td>38 (51.3)</td>
<td>21 (58.3)</td>
</tr>
<tr>
<td>Fluid only</td>
<td>25 (33.8)</td>
<td>10 (27.8)</td>
</tr>
<tr>
<td>Obstructed</td>
<td>4 (8.7)</td>
<td>5 (13.9)</td>
</tr>
<tr>
<td>Unable to determine</td>
<td>7 (6.8)</td>
<td>0</td>
</tr>
<tr>
<td>Weight loss, mean ± SD, %</td>
<td>--8.8 ± 7.8</td>
<td>--9.7 ± 8.8</td>
</tr>
<tr>
<td>Stage, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 0</td>
<td>1 (1.4)</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>Stage 1</td>
<td>4 (5.4)</td>
<td>3 (8.3)</td>
</tr>
<tr>
<td>Stage 2a</td>
<td>7 (9.5)</td>
<td>2 (5.6)</td>
</tr>
<tr>
<td>Stage 2b</td>
<td>20 (27.0)</td>
<td>9 (25.0)</td>
</tr>
<tr>
<td>Stage 3</td>
<td>35 (47.3)</td>
<td>18 (50.0)</td>
</tr>
<tr>
<td>Stage 4</td>
<td>7 (9.5)</td>
<td>3 (8.3)</td>
</tr>
<tr>
<td>Operation performed, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>THE/laparotomy</td>
<td>40 (54.1)</td>
<td>24 (64.9)</td>
</tr>
<tr>
<td>Thoracoabdominal/thoracotomy</td>
<td>31 (41.9)</td>
<td>13 (35.1)</td>
</tr>
<tr>
<td>Ivor Lewis McKeown</td>
<td>3 (4.1)</td>
<td>0</td>
</tr>
</tbody>
</table>

SD = standard deviation; THE = transhiatal esophagectomy.
The jejunostomy tube complication rates and the rate of gastrointestinal symptoms, which limit tube feed delivery, observed in our study are in keeping with the rates reported in the literature.2–6 Our findings that only half the intended nutrition is actually delivered are similar to those of many authors who report a high incidence of difficulties meeting targets,7–15 although isolated reports of very high success rates exist.3,16,17 Mechanical difficulties and symptoms, such as diarrhea and abdominal pain, that limit advancement of tube feeds and subsequent delivery of nutrition are responsible for the generally limited success in achieving targets. Given that close to 40% of patients had gastrointestinal symptoms severe enough to decrease feed rates or stop feeding altogether (as recorded in their charts), this is a plausible reason for the total delivery of nutrition in our study population.

The variation in success with tube feeding across studies could be due to the specifics of the protocol, such as the use of rest periods and rate of advancement. The timing and rate of advancement that we used was in keeping with protocols used in other centres in Canada and worldwide. We did not use rest periods during feeding, whereas others have.13,17 Lobo and colleagues11 reported achieving 77%–95% of the target on postoperative day 3 in the 2 arms of their trial of immune modulated nutrition. Ryan and colleagues17 reported 96%–98% of the target reached in the 2 arms of their study. Even in these studies, the target was not reached until postoperative day 3, and our patients started oral intake 4 days after.

It could be argued that even a small amount of nutrition is better than none, but the evidence for the effectiveness of early nutrition in postoperative patients is poor. A number of randomized trials have compared small bowel feeding to hydration alone or to parenteral nutrition in patients undergoing esophageal or gastric surgery. No trials enrolling patients with predominantly upper gastrointestinal surgery have shown a benefit in septic complications, anastomotic failure or any other clinical measures.8–11,16 In 2001, Lewis and colleagues18 performed a systematic review of randomized trials comparing enteral feeding to nil by mouth and concluded that there was insufficient evidence for the benefit of early small bowel feeding. Although some reports maintain that there is improvement in measures of gut function, it has not resulted in clinical differences. In a more recent meta-analysis comparing enteral to parenteral

Fig. 1. Patients who started eating by mouth (PO) (A) by postoperative day 8 and (B) after postoperative day 8. Values shown are means and interquartile ranges.
nutrition, Mazaki and Ebisawa\textsuperscript{19} reported possible benefits of enteral nutrition over parenteral nutrition in surgical patients, but they raised a note of caution in their findings because of the incidence of adverse events, which was similar to that in our study. These adverse events included leaking tubes, vomiting, diarrhea and abdominal distention. Observational studies have also documented complications associated with early enteral nutrition, including rare but very serious events (perforation of the small bowel, small bowel necrosis),\textsuperscript{20} and less serious but common events (vomiting, diarrhea, bloating, abdominal pain).\textsuperscript{20–23}

It has been argued that routine jejunostomy tubes provide a “safety valve” in case of complications precluding timely commencement of oral intake. However, this policy subjects patients who may never require prolonged nutritional support (67% in our study) to the risks and discomforts of the intervention. If jejunostomy tubes rarely caused adverse events, this policy could be justified; however, adverse events occurred frequently in our study and in virtually every other study published.

**Strengths**

We have presented an estimate of the frequency of delayed oral intake and a detailed description of tube feeding, including the extent of meeting nutritional targets and the adverse events associated with the use of jejunostomy tubes. We have presented quantitative information that may help surgeons decide whether to continue using jejunostomy feeds early in the postoperative course.

**Limitations**

We cannot make a definitive statement about the overall benefit of routine feeding jejunostomy compared with an alternative in these patients. The present study was not a comparative study about the efficacy of jejunostomy tubes, nor was it designed to determine whether patients with jejunostomy tubes fared better than those without. Only a clinical trial can answer this question.

Given the goal of our study, its major weakness is that we had to limit the data of interest to those that were not only measured but also recorded in a reliable manner. It is likely that some complications, such as abdominal discomfort insufficient to warrant adjusting feed rates, have been under-reported.

In calculating the amount of nutrition delivered, we had to make a number of assumptions, the main one being that there was a constant rate of tube feeding between measurements. It is unclear how this assumption may have altered our findings.

**Implications**

The patients, the type of operation and the main outcomes in our study were similar to those in other reports. This suggests that our findings are likely to be generalizable to other settings with similar strategies of managing postoperative esophagectomy patients. Our results highlight that a feeding jejunostomy is not a benign surgical intervention. The jejunostomy tube itself is a source of complications, which at times can be life-threatening but more frequently a source of discomfort and distress.

The clinical benefit of routine tube feeding in the typical patient remains uncertain, but it is clear that complications, such as intraperitoneal leak or bowel necrosis,\textsuperscript{20} can occur. A major complication rate of 3% is clinically important in the face of unproven benefits from an essentially prophylactic intervention. In the absence of reasonable evidence of benefit from an intervention, we maintain that it is unreasonable to put patients at risk of well-documented harms. Further, episodes of diarrhea, pain and nausea after patients have undergone surgery as demanding as an esophagectomy should not simply be dismissed as minor discomforts. We

\begin{table}
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Oral intake within 8 days</th>
<th>Oral intake after 8 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days to start oral intake, median (interquartile range)</td>
<td>7 (7–7)</td>
<td>15 (11–23)</td>
</tr>
<tr>
<td>Complications, no.</td>
<td>29/74</td>
<td>36/37</td>
</tr>
<tr>
<td>Anastomotic leaks, no.</td>
<td>4/74</td>
<td>23/37</td>
</tr>
<tr>
<td>Days of tube feeding, median (interquartile range)</td>
<td>6 (5–7)</td>
<td>14.5 (8–21)</td>
</tr>
<tr>
<td>Abdominal issues requiring feeding to be withheld, no.</td>
<td>23/68</td>
<td>17/35</td>
</tr>
</tbody>
</table>
\end{table}

\begin{table}
<table>
<thead>
<tr>
<th>Patient</th>
<th>Days to oral intake</th>
<th>Days to jejunostomy tube complication</th>
<th>Complication</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12</td>
<td>7</td>
<td>Jejunal ischemia</td>
<td>Localized resection</td>
</tr>
<tr>
<td>2</td>
<td>62</td>
<td>8</td>
<td>Bowel obstruction and perforated jejunum</td>
<td>Localized resection</td>
</tr>
<tr>
<td>3</td>
<td>NA*</td>
<td>13</td>
<td>Small bowel leak and localized abscess</td>
<td>Repair of jejunum</td>
</tr>
<tr>
<td>4</td>
<td>11</td>
<td>10</td>
<td>Jejunal site infection</td>
<td>Tube removed</td>
</tr>
<tr>
<td>5</td>
<td>52</td>
<td>49</td>
<td>Jejunal site infection</td>
<td>Tube removed</td>
</tr>
<tr>
<td>6</td>
<td>8</td>
<td>6</td>
<td>Jejunal site infection</td>
<td>Antibiotics</td>
</tr>
</tbody>
</table>

NA = not applicable.

*Patient died on postoperative day 27 without having resumed oral intake.

Can J Surg, Vol. 56, No. 6, December 2013
believe that the instruction to “first do no harm” holds true. Given our findings, it seems reasonable to adopt the practice of using feeding jejunostomy tubes in patients who the surgeon feels are at elevated risk for anastomotic failure, which will delay commencement of oral intake. In patients who require nutritional support, the options of a nasojejunal tube, TPN or postoperative insertion of a jejunostomy tube remain. These alternative interventions have their own associated complications, but in contrast to their routine use in all patients undergoing esophagectomy, these complications will be limited to the minority of patients who have a therapeutic need for the intervention. It is possible that the routine use of a jejunostomy tube in patients undergoing elective esophagectomy is in fact justified to reduce postoperative complications, such as anastomotic failure and sepsis. It is also possible that for those centres that believe in prolonged limitation of oral intake after surgery and in use the jejunostomy tube for nutritional support during this time, the trade-off of complications to benefits may be reasonable. But determining the overall balance of risks and benefits of routine jejunostomy tube feeding in the immediate postoperative period requires a randomized trial powered to detect differences in mortality and that will carefully account for all complications and adverse events, including “minor” ones, such as pain and diarrhea. Such a study must consider the extent and timing of weight loss in the participating patients, the type of surgery they undergo and the extent to which they actually receive the intended amount of nutrition, since it remains unknown how much nutrition is actually “enough” to bring about a benefit.

**CONCLUSION**

We have demonstrated that among patients who underwent elective esophagectomy for cancer and received a jejunostomy tube, two-thirds did not require the tube as a “safety valve.” Tube feeding provides less than half of the target nutrition we wish to deliver. For certain patients, such as those with substantial weight loss before surgery, a jejunostomy tube may be reasonable. In patients unable to take oral nutrition after a week owing to a complication, many options remain.

Jejunostomy tubes can lead to serious complications and frequent but less serious adverse events in a group of patients already at high risk for complications. We feel that it is unreasonable to subject two-thirds of patients to a procedure that has been proven to cause harm in the absence of convincing evidence in the literature that this intervention is of clinical benefit.

**Acknowledgments:** This work was carried out as part of a Masters thesis at McMaster University. The contributions of Drs. Gail Darling and Mohit Bhandari, who served on the thesis committee, are greatly appreciated.

**Competing interests:** None declared.

**Contributors:** S.K. Srinathan designed the study. S.K. Srinathan, T. Hamin and A.L. Tan acquired the data, which S.K. Srinathan, S. Walter, H.W. Unruh and G. Guyatt analyzed. S.K. Srinathan and S. Walter wrote the article. All authors reviewed the article and approved its publication.

**References**

Uptake of an innovation in surgery: observations from the cluster-randomized Quality Initiative in Rectal Cancer trial

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DOI: 10.1503/cjs.019112

Background: Theory suggests the uptake of a medical innovation is influenced by how potential adopters perceive innovation characteristics and by characteristics of potential adopters. Innovation adoption is slow among the first 20% of individuals in a target group and then accelerates. The Quality Initiative in Rectal Cancer (QIRC) trial assessed if rectal cancer surgery outcomes could be improved through surgeon participation in the QIRC strategy. We tested if traditional uptake of innovation concepts applied to surgeons in the experimental arm of the trial.

Methods: The QIRC strategy included workshops, access to opinion leaders, intraoperative demonstrations, postoperative questionnaires, and audit and feedback. For intraoperative demonstrations, a participating surgeon invited an outside surgeon to demonstrate optimal rectal surgery techniques. We used surgeon timing in a demonstration to differentiate early and late adopters of the QIRC strategy. Surgeons completed surveys on perceptions of the strategy and personal characteristics.

Results: Nineteen of 56 surgeons (34%) requested an operative demonstration on their first case of rectal surgery. Early and late adopters had similar perceptions of the QIRC strategy and similar characteristics. Late adopters were less likely than early adopters to perceive an advantage for the surgical techniques promoted by the trial ($p = 0.023$).

Conclusion: Most traditional diffusion of innovation concepts did not apply to surgeons in the QIRC trial, with the exception of the importance of perceptions of comparative advantage.

Contexte : Selon une théorie, 2 facteurs influencent l’adoption de nouvelles pratiques en médecine, soit la façon dont les adeptes potentiels perçoivent les caractéristiques novatrices et les caractéristiques propres aux adeptes potentiels eux-mêmes. L’adoption des nouvelles pratiques se fait lentement chez les premiers 20 % des individus d’un groupe cible, puis va en s’accélérant. L’étude QIRC (Quality Initiative in Rectal Cancer) a voulu vérifier si la participation des chirurgiens à la stratégie QIRC pouvait améliorer l’issue de la chirurgie pour cancer du rectum. Nous avons vérifié si les modes habituels d’adoption des nouvelles pratiques s’appliquaient aux chirurgiens dans le groupe expérimental de l’étude.

Méthodes : La stratégie QIRC incluait des ateliers, l’accès à des meneurs d’opinion, des démonstrations peropératoires et des questionnaires postopératoires, suivis de vérifications et de commentaires. Pour les démonstrations peropératoires, un chirurgien participant invitait un chirurgien de l’extérieur à faire une démonstration de techniques chirurgicales rectales optimales. Nous avons utilisé les délais d’adoption des nouvelles pratiques par les chirurgiens pour faire ressortir la distinction entre les adeptes précoces et tardifs de la stratégie QIRC. Les chirurgiens ont répondu à des questionnaires sur leurs perceptions à l’endroit de la stratégie et sur leurs caractéristiques personnelles.

Résultats : Dix-neuf chirurgiens sur 56 (34 %) ont demandé une démonstration opératoire lors de leur premier cas de chirurgie rectale. Les adeptes précoces et tardifs avaient des perceptions similaires de la stratégie QIRC et des caractéristiques personnelles similaires. Les adeptes tardifs étaient moins susceptibles que les adeptes précoces de percevoir l’avantage des techniques chirurgicales préconisées dans le cadre de l’étude ($p = 0.023$).

Conclusion : La plupart des modes habituels de diffusion des nouvelles pratiques ne s’appliquaient pas aux chirurgiens de l’essai QIRC, à l’exception de l’importance des perceptions à l’endroit des avantages comparatifs.
RECHERCHE

Researchers suggest that the uptake of a medical innovation depends on how potential adopters perceive the characteristics of the innovation, the characteristics of the potential adopters and contextual factors that act as barriers or facilitators to the diffusion of the innovation. Characteristics of an innovation that can reportedly influence uptake (e.g., use of a new drug) are comparative advantage, compatibility with adopter values, complexity of use and ability to observe or trial use of the innovation. Characteristics that can reportedly differentiate early and late adopters, respectively, include higher resource levels, a cosmopolitan nature, higher education levels and a more positive attitude. Other research suggests that the rate of innovation adoption is slow among the first 20% of individuals in a target group and then accelerates. Figure 1 presents a typical diffusion of innovation curve.

There is a remarkable paucity of quantitative data supporting the above concepts on clinical innovation adoption in the medical realm. Most papers commenting on the uptake of medical innovations are theoretical or rely on survey or qualitative data. Such studies do not correlate survey or interview results with actual rates of innovation uptake. We could find only 1 relevant medical study with quantitative data that measured rates of uptake of a medical innovation among individual physicians concurrently with diffusion of innovation factors.

The Quality Initiative in Rectal Cancer (QIRC) trial involved 5 interventions: workshops, intraoperative demonstrations, access to opinion leaders, postoperative questionnaires, and audit and feedback. Workshops reviewed surgical techniques and principles of quality improvement. During the workshops, participating surgeons selected a local opinion leader using a validated methodology. For the intraoperative demonstrations, a participating surgeon could invite another surgeon to the operating room to demonstrate total mesorectal excision techniques. The postoperative questionnaire was designed to prompt surgeons to re-examine key intraoperative steps of total mesorectal excision. Hospitals were the unit of study randomization. It is thus important to emphasize that individual surgeons in the experimental arm were free to use any or none of the QIRC strategy interventions. In addition, patients in control arm hospitals received no interventions, and thus data from this group are not relevant to the current assessment of innovation uptake.

**METHODS**

The QIRC trial

We have reported the methods and primary results of the QIRC trial previously. Briefly, we cluster-randomized 16 Ontario hospitals and their respective groups of surgeons to the QIRC strategy (i.e., 8 experimental arm sites with 56 surgeons) versus no intervention (i.e., 8 control arm sites with 49 surgeons). The primary study outcomes were rates of permanent colostomy and local tumour recurrence. The trial was closed after 1015 patients were enrolled.

The QIRC strategy involved 5 interventions: workshops, intraoperative demonstrations, access to opinion leaders, postoperative questionnaires, and audit and feedback. Workshops reviewed surgical techniques and principles of quality improvement. During the workshops, participating surgeons selected a local opinion leader using a validated methodology. For the intraoperative demonstrations, a participating surgeon could invite another surgeon to the operating room to demonstrate total mesorectal excision techniques. The postoperative questionnaire was designed to prompt surgeons to re-examine key intraoperative steps of total mesorectal excision. Hospitals were the unit of study randomization. It is thus important to emphasize that individual surgeons in the experimental arm were free to use any or none of the QIRC strategy interventions. In addition, patients in control arm hospitals received no interventions, and thus data from this group are not relevant to the current assessment of innovation uptake.

Study groups: defining early and late adopters of the QIRC strategy in the intervention arm

For the 56 experimental arm surgeons, we used participation in an intraoperative demonstration to differentiate early and late adopters of the QIRC strategy. While we considered all 5 of the strategy interventions important, we hypothesized that a request for an intraoperative demonstration required the greatest change in traditional
practice. Such a demonstration involved the entry of an outside surgeon (i.e., operative demonstrator) being invited into the home operating theatre of a participating surgeon. The participating surgeon and support staff in the operating room would all be aware that the operative demonstrator was in attendance to demonstrate a potentially improved method of rectal surgery. By extension, this raised the possibility that the provision of rectal surgery to date by the respective surgeon could be perceived as suboptimal. For statistical robustness, we decided a priori that early and late adopters would be divided into 2 approximately equal-sized groups based on the timing of requests for a demonstration.

**Data sources**

**Study team notes and completion of patient accrual**
The study team recorded surgeon consent rates, timing and participation in workshops, intraoperative demonstrations and completion of postoperative questionnaires. Data on the number and timing of rectal cancer surgeries performed by all surgeons and on the number and timing of requests for an intraoperative demonstration were available.

**Surgeon survey**
At the completion of patient accrual, experimental arm surgeons were mailed a survey related to the QIRC trial. The survey was pilot tested for readability and comprehensiveness by surgeons from hospitals not involved in the QIRC trial. We used the Dillman method of repeated requests to maximize survey response rates among surgeons. Respondents were given the option to identify themselves or to remain anonymous. Subjective responses were scored on a 5-point Likert scale.

**Study end points**

**Participation rates**
We calculated rates of consent and participation in workshops, postoperative questionnaires and operative demonstrations. We measured rates of participation in the intraoperative demonstrations overall (i.e., x% of surgeons requested a demonstration) and by time (e.g., x% of surgeons requested a demonstration by their third case of rectal cancer surgery). We did not measure participation in the opinion leader or in the audit and feedback intervention, since all sites selected an opinion leader and feedback was mailed to all surgeons.

**Surgeon perceptions of total mesorectal excision and the QIRC strategy**
From the surveys, we gathered data on the following surgeon perceptions: 1) comparative advantage of total mesorectal excision versus traditional techniques and of the QIRC strategy interventions versus other continuing education initiatives, and of the surgical techniques promoted by the QIRC strategy versus pretrial techniques; 2) compatibility with values of total mesorectal excision with a desire to cure patients; and 3) complexity of total mesorectal excision as a surgical technique and of participation in the overall QIRC strategy and the intraoperative demonstration intervention. These are the key perceptions thought to drive adoption of innovation.

**Surgeon characteristics**
We collected data on the following surgeon characteristics: year of graduation; resource levels (i.e., hours of operating room and endoscopy time); cosmopolitan nature (i.e., attendance at regional and national or international surgical meetings); willingness to adopt other surgical innovations (i.e., laparoscopic surgery for colon surgery); and positive attitude (i.e., attitude to health care in Ontario and the direction of colorectal cancer surgery care in Ontario). Such characteristics have been found in other areas to predict rates of adoption of an innovation.

**Statistical analyses**

We used descriptive and univariate (unadjusted) analyses of study end points. We used the Mann–Whitney U and Fisher exact tests for continuous and categorical variables, respectively. The criterion for statistical significance was set at $\alpha = 0.05$. Since these analyses were primarily exploratory to generate hypotheses, we did not adjust the overall level for multiple testing. Five-point Likert scale survey responses were categorized as negative (score of 1 or 2), neutral (score of 3) or positive (score of 4 or 5) to assist with interpretation and analyses. We performed sensitivity analyses by repeating relevant analyses after excluding data from surgeons who began working at study hospitals after the initiation of the trial, since we surmised that such surgeons would be less likely to participate in all aspects of the study. All analyses were performed using SPSS version 16. The Ethics Review Board of the Hamilton Health Sciences Centre/McMaster University approved the protocol.

**RESULTS**

**Overall participation rates**
The consent rate for the trial was 96 of 105 (91%) surgeons for both arms of the trial, and 51 of 56 (91%) and 45 of 49 (92%) in the experimental and control arms, respectively. Consenting surgeons treated 97% of the study population. At the 8 experimental arm sites, 39 of 56 (70%) surgeons attended a workshop, 40 of 56 (71%) surgeons requested an operative demonstration, and 44 of 56 (79%) surgeons completed at least 1 postoperative
questionnaire. The 40 surgeons who requested an operative demonstration treated 86% of the patients accrued in the experimental arm.

**Uptake of operative demonstrations and defining early and late adopters of the QIRC strategy**

The curve for uptake over time for the operative demonstrations is presented in Figure 2. Nineteen of 56 (34%) surgeons requested an operative demonstration on their first case of rectal cancer surgery after site randomization. By the fourth case (i.e., the fourth potential opportunity for participation), 75% of surgeons had requested an operative demonstration, and by the tenth case the participation rate was 100%.

Among the 56 experimental arm surgeons, early adopters requested an operative demonstration on their first or second case of rectal cancer surgery. Thus, late adopters requested an operative demonstration only after their second case of rectal cancer surgery or not at all. This followed our a priori decision to create 2 approximately equal-sized groups based on timing of participation in the operative demonstration intervention. The resulting 27 early and 29 late adopters performed 52% and 48% of all cases in the experimental arm, respectively.

**Comparing early and late adopters of the QIRC strategy**

**QIRC strategy participation rates**

For the 56 experimental arm surgeons, there were marked differences in rates of participation for the 27 early versus 29 late adopters. The participation rates for early and late adopters, respectively, were 100% and 83% (p = 0.024) for trial consent, 89% and 52% (p = 0.003) for the workshops, 100% and 45% (p < 0.001) for intraoperative demonstrations, and 89% and 69% (p = 0.07) for completion of a postoperative questionnaire (Table 1).

**Survey participation rates**

Thirty-three of 56 (59%) surgeons returned a completed survey, and 2 of them wished to remain anonymous. We therefore compared survey results for 18 early and 13 late adopters of the operative demonstration. These 31 surgeons performed 65% of all experimental arm cases.

**Perceptions of total mesorectal excision and the QIRC strategy**

There were few differences between early and late adopters in their perceptions of total mesorectal excision surgery or the QIRC strategy (Table 2). For comparative advantage, 83% and 69% of early and late adopters, respectively, rated the QIRC strategy as more effective than other continuing medical education activities (p = 0.30), and 78% and 80%, respectively, perceived an advantage of total mesorectal excision versus traditional surgical techniques (p = 0.31). The 1 difference in perceived comparative advantage was that 18% and 62% of early and late adopters, respectively, reported no improvement with the techniques promoted in the QIRC trial versus the respective surgeon's pretrial techniques (p = 0.023). For compatibility with values, 90% of respondents overall indicated that total mesorectal excision was more compatible than traditional techniques for achieving cure. For complexity, 90% of surgeons found their personal involvement in the QIRC trial to be not at all burdensome.

![Fig. 2. Curve for uptake over time for the operative demonstrations.](image_url)
Table 3. Surgeon characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Early adopters, n = 18</th>
<th>Late adopters, n = 13</th>
<th>Overall</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year of graduation, median</td>
<td>1984</td>
<td>1988</td>
<td>1984</td>
<td>0.13</td>
</tr>
<tr>
<td>Resources</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating room hours per wk, median</td>
<td>10</td>
<td>9</td>
<td>10</td>
<td>0.26</td>
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<tr>
<td>Endoscopy hours per wk, median</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>0.73</td>
</tr>
<tr>
<td>Cosmopolitan nature</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annually attend 6–10 surgical conferences inside Ontario, %</td>
<td>28</td>
<td>31</td>
<td>29</td>
<td>0.46</td>
</tr>
<tr>
<td>Annually attend 1–5 surgical conferences outside Ontario, %</td>
<td>78</td>
<td>69</td>
<td>74</td>
<td>0.66</td>
</tr>
<tr>
<td>Other surgical innovations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attempted or performed a laparoscopic colon resection for benign or malignant disease in the last 12 months, %</td>
<td>56</td>
<td>62</td>
<td>58</td>
<td>0.74</td>
</tr>
<tr>
<td>Attitude*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive opinion on the current direction of the health care system in Ontario, %</td>
<td>11</td>
<td>23</td>
<td>16</td>
<td>0.37</td>
</tr>
<tr>
<td>Positive opinion on the current direction of colorectal cancer surgery in Ontario, %</td>
<td>56</td>
<td>85</td>
<td>68</td>
<td>0.09</td>
</tr>
</tbody>
</table>

*Respondents answered using a 5-point Likert scale. Codes were collapsed for the analyses. Percentages based on positive responses (codes 1 and 2) versus neutral or negative responses (codes 3, 4 and 5).
RECHERCHE

Surgeon characteristics
There were no differences between early and late adopters in median year of graduation, resource levels (i.e., hours of operating room and endoscopy time), cosmopolitan nature (i.e., frequency of attendance at regional, national or international meetings), willingness to adopt other surgical innovations (i.e., laparoscopic surgery for colon surgery) and positive attitude (i.e., attitude to health care in Ontario and attitude to the direction of colorectal cancer surgery care in Ontario; Table 3). For example, 56% and 62% of early and late adopters, respectively, had attempted a laparoscopic colon resection ($p = 0.74$), while 56% and 85% had a positive opinion on the current direction of colorectal cancer surgery in Ontario.

DISCUSSION

Our results from a substudy of a randomized surgical trial do not support traditional diffusion of innovation concepts. The rate of uptake of the operative demonstrations — a proxy for the entire QRC strategy — occurred more quickly than expected. Instead of uptake accelerating only after a 20% adoption rate threshold, a remarkable 34% of surgeons requested a demonstration at the first opportunity. In addition, early and late adopters had similar perceptions of the QIRC strategy and similar surgeon characteristics. These observations, if corroborated in other surgical areas, have important implications for stakeholders interested in the appropriate uptake of surgical innovations or new techniques. Overall, surgeons should not be viewed as a source of resistance to innovation uptake, and traditional characteristics differentiating individual adoption patterns in other areas may not apply to surgeons.

Early and late adopters of the operative demonstrations had similar perceptions of the QIRC strategy and of total mesorectal excision surgery, with 1 exception: late adopters were more likely than early adopters to perceive no advantage for the surgical techniques promoted by the strategy compared with their pretrial techniques (62% v. 18%, $p = 0.023$). Early and late adopters did feel that total mesorectal excision techniques were superior to traditional techniques. Thus, on average, late adopters likely accepted the advantage of total mesorectal excision techniques, but were confident they were already optimally providing such techniques before the QIRC trial. It is logical that late adopters of an innovation would perceive relatively less advantage than early adopters for the techniques promoted by the QIRC strategy. These findings also mesh with those from a survey study of laparoscopic surgeons in the Netherlands.11 Participants were asked to provide responses on factors that influenced their adoption of laparoscopic techniques for various procedures. Additional benefit was the strongest predictor of uptake, with technical factors playing a minor role.

Of note, rates of local recurrence and permanent colostomy — the primary outcomes of the QIRC trial — did not vary between early and late adopters. This was expected given similar outcomes in both arms of the overall QIRC trial; participation in the QIRC strategy did not lead to improved patient outcomes; thus, one would not expect that early or late adoption of a noneffective intervention would result in improved patient outcomes.

Our findings on surgeon perceptions of the QIRC strategy have implications for quality improvement efforts.14 We hypothesize that in the face of persistent quality gaps stakeholders may wish to target clinician perceptions of the comparative advantage of the intended practice change. The production and effective presentation of high-quality evidence demonstrating the advantage of specific practice changes may be an efficient initial focus of quality improvement. As well, if clinicians perceive a comparative advantage for a particular practice and there is still slow adoption, then related quality gaps should not be attributed to recalcitrant clinicians, but rather to other barriers to optimal care.

Most research on factors driving the uptake of medical innovations involves surveys or qualitative interviews.7-11 Results are not correlated with the actual uptake rate of an innovation, or quantitative data, as was done in the present study. In the 1 study we could identify that measured diffusion rates among individual clinicians, the uptake of a new antibiotic (i.e., tetracycline) among family physicians was rapid and followed a curve remarkably similar to the uptake curve seen in the present study.13 Both studies provide limited evidence that rapid medical practice change can occur. The paucity of rigorous diffusion of innovation studies that contain quantitative data precludes a conclusion that this is the norm for adoption of clinical innovation. We encourage related research.

Limitations

There are limitations to the present study. First, some may not consider participation in an intraoperative demonstration as the uptake of a medical innovation. However, as discussed, a request for an intraoperative demonstration required a marked change in traditional surgeon practice and was completely voluntary. In addition, our a priori rules to identify early and late adopters based on timing of an operative demonstration did result in 2 groups with significantly different rates of participation in other parts of the QIRC trial, including trial consent, attendance at workshops and completion of postoperative questionnaires. Second, the study relied on data from a small number of surgeons and survey responses. But the hospitals involved in the QIRC trial treat an estimated 25% of all patients with rectal cancer in Ontario (population 13 million), and the 31 surgeons who completed study
surveys performed 65% of the cases in the experimental arm.\footnote{Simunovic M, Coates A, Goldsmith C, et al. The cluster-randomized Quality Initiative in Rectal Cancer (QIRC) trial: study protocol of a cluster randomized controlled trial in surgery. \textit{Int J Qual Health Care} 2008;20:529-36.} Thus, survey responses likely represent perceptions and characteristics among a large percentage of surgeons treating rectal cancer patients in Ontario. As well, it is important to reiterate that there is an incredible paucity of quantitative data correlating the uptake of clinical innovations with the personal characteristics or perceptions of the involved clinicians. Finally, we did not account for multiple testing. But as discussed in the Methods section, we considered the present study to be mainly hypothesis-generating. We believe that sharing our results with the wider community is important given the current lack of quantitative data on the diffusion of surgical innovations.

**CONCLUSION**

Overall, traditional diffusion of innovation concepts did not apply to surgeons in the QIRC trial, with the exception of perceptions of comparative advantage. Our findings should be quantitatively tested in other clinical areas and among other physician groups.

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**Competing interests:** None declared.

**Contributors:** M. Simunovic, A. Coates, A. Smith, C.H. Goldsmith, L. Thahane and M.N. Levine designed the study. M. Simunovic, A. Coates, C.H. Goldsmith and L. Thahane acquired the data. Data analysis and interpretation was done by M. Simunovic, A. Coates, C.H. Goldsmith, L. Thahane and M.N. Levine, who also wrote the article. All authors reviewed and approved the final version for publication.

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Background: The use of hip arthroscopy has been steadily rising as technology, experience and surgical education continue to advance. Previous reports of the complication rate associated with hip arthroscopy have varied. The purpose of this study was to report our experience with hip arthroscopy complications at a single Canadian institution (McMaster University).

Methods: We performed a retrospective chart review of 2 hip arthroscopists at the same institution to identify patients who had undergone the index surgery and had been followed for a minimum of 6 months postoperatively. We used a standard data entry form to collect information on patient demographic and clinical characteristics, including age, sex, surgical indication and type of complication if any.

Results: A total of 211 patients underwent 236 hip arthroscopies. The mean age at time of surgery was 37 ± 13 years and mean follow-up was 394 ± 216.5 days. The overall complication rate associated with hip arthroscopy was 4.2% (95% confidence interval 2.3%–7.6%). We identified 4 major and 6 minor complications.

Conclusion: Overall, hip arthroscopy appears to be safe, with minor complications occurring more frequently than major ones. However, surgeons should recognize the possibility of serious complications associated with this procedure. Future research should focus on prospective designs looking for potential prognostic factors associated with hip arthroscopy complications.

Contexte : Le recours à l’arthroscopie de la hanche augmente de manière constante, au rythme des progrès réalisés aux plans de la technologie, de l’expérience et de l’enseignement de la chirurgie. Les rapports précédents sur les taux de complications associés à l’arthroscopie de la hanche ont varié. Le but de cette étude était de faire état de notre expérience en ce qui concerne les complications de l’arthroscopie de la hanche dans un établissement canadien (Université McMaster).

Méthodes : Nous avons procédé à une analyse rétrospective des dossiers de 2 spécialistes de l’arthroscopie de la hanche d’un même établissement pour recenser les patients qui ont subi une première chirurgie et qui ont été suivis pendant au moins 6 mois après leur intervention. Nous avons utilisé un formulaire standard d’entrée de données pour recueillir des renseignements sur les caractéristiques démographiques et cliniques des patients, notamment l’âge, le sexe, l’indication de la chirurgie et le type de complication, le cas échéant.

Résultats : En tout, 211 patients ont subi 236 arthroscopies de la hanche. L’âge moyen au moment de la chirurgie était de 37 ± 13 ans et le suivi moyen a été de 394 ± 216,5 jours. Le taux global de complications associées à l’arthroscopie de la hanche a été de 4,2% (intervalle de confiance de 95%, 2,3 %–7,6 %). Nous avons recensé 4 complications majeures et 6 mineures.

Conclusion : Dans l’ensemble, l’arthroscopie de la hanche semble sécuritaire, les complications mineures étant survenues plus souvent que les complications majeures. Toutefois, les chirurgiens doivent reconnaître le risque de complications graves associées à cette intervention. La recherche à venir devra s’attarder à des modèles prospectifs pour déceler les facteurs pronostiques potentiellement associés aux complications de l’arthroscopie de la hanche.
The use of hip arthroscopy has been steadily increasing. A recent review of the American Board of Orthopaedic Surgeons (ABOS) database showed an 18-fold increase in the number of hip arthroscopies performed from 1999 through 2009. This dramatic rise is likely related to the appeal of a minimally invasive surgical approach and the increasing availability of formal training in hip arthroscopy. Despite its popularity, hip arthroscopy presents a unique set of technical challenges and considerations. These include the deep-seated nature of the ball-and-socket hip joint and the dense surrounding soft tissues that ultimately limit maneuverability of surgical tools, requiring longer instruments and specialized equipment for distraction.

Reports of the complication rates associated with hip arthroscopy have varied in the literature. In 2001, Sampson reported a complication rate of 6.4% for 530 hip arthroscopies. Clarke and colleagues reviewed 1054 cases between 1989 and 2001 and reported a complication rate of 1.4%. Such variability is likely related to multiple factors, including patient selection, surgeon experience, and a lack of a universal definition of complications.

The goal of the present study was to report our experience with hip arthroscopy at McMaster University. Specifically, we documented the complication rate following hip arthroscopy at our institution.

**METHODS**

**Study design**

We performed a single-centre retrospective chart review of patients who underwent hip arthroscopy between September 2009 and January 2012. The protocol for the conduct and analysis of the study was created a priori. The research ethics board at McMaster University approved this study.

**Eligibility criteria**

All patients who underwent hip arthroscopy at our institution were identified by contacting 2 arthroscopists (O.A., I.W.) and reviewing their patient roster. Patients were included if they attained at least 6 months' follow-up.

**Intervention**

**Surgical indications**

Patients undergoing hip arthroscopy had a history of groin and/or hip pain for a minimum of 3 months and failed nonoperative management (physiotherapy, oral anti-inflammatories). Physical examinations involving the anterior impingement test and log-roll tests confirmed intra-articular hip disorders. Radiographic imaging was used to assess bony morphology (femoroacetabular impingement [FAI], hip dysplasia, osteoarthritis) of the hip, and magnetic resonance imaging (MRI) confirmed the presence or absence of intra- and extra-articular hip disorders (e.g., FAI, labral tears, loose bodies). In patients for whom there was an unclear diagnosis, an intra-articular injection was used to delineate the source of hip pain. Those with clearly identified pathology (history, physical, imaging, injection) were offered hip arthroscopy.

**Surgical procedure**

All patients had hip arthroscopy in the supine position and received intravenous antibiotics under general anesthesia with longitudinal traction applied to the operative limb. Standard portals included anterior, anterolateral and distal anterolateral portals. Once the central compartment of the hip (cartilage, labrum, ligamentum, capsule) was evaluated and treated appropriately, the peripheral compartment (head and neck junction of hip, ligaments, capsule) was evaluated and treated. The distal anterolateral portal was used for bony debridement when osseous lesions, such as a cam lesion were present. Fluoroscopy was used to assist the procedures in all cases.

**Postoperative rehabilitation**

All patients were limited to protected weight-bearing with crutches for 2–6 weeks, depending on the extent of the surgery. Patients who had surgery for FAI were restricted for 6 weeks. Patient follow-up visits occurred at 2, 6 and 12 weeks and at 6 and 12 months. All patients received supervised physical therapy for up to 12 weeks. The focus of physical therapy was gait training and range of motion during the first 6 weeks, then range of motion and proprioceptive training for the subsequent 6 weeks and, finally, strengthening for the following 6 weeks. The therapy was altered based on each patient's progress.

**Outcomes**

The primary outcome measure was the occurrence of a complication after hip arthroscopy. After a discussion with a focus group including 3 surgeons (S.B., O.R.A. and M.B.), we chose to define a complication as an event that resulted in a prolonged recovery from surgery (> 6 additional mo) or required a secondary intervention (medical or surgical treatment, including revisions of the index procedure). Major complications were further defined as those that had life-threatening sequelae or endangered the viability of the limb involved.

To determine the complication rate, we used a standard data entry form to collect patient demographic and clinical characteristics, including age, sex, surgical indication and type of complication. When possible, we also collected data on the presence of comorbidities, namely, diabetes mellitus, tobacco use, osteoporosis or immunocompromised status (HIV, AIDS, high-dose steroid use, rheumatoid arthritis, active cancer). Discrepancies in the
data were resolved by consultation with the surgeon who performed the procedure (O.A. or I.W.).

**Sample size**

The primary outcome for this study was the incidence of complications in patients who underwent hip arthroscopy. From a previous meta-analysis, the weighted incidence of complications in the literature was 4.0%. We hypothesized that a 95% confidence interval (CI) of ± 3% around the complication rate would have high precision. Using normal approximation to binomial distribution, we calculated that a sample size of 172 patients would be required to produce a 95% CI ± 3%, with an α level of 0.05. Thus, we planned to recruit all eligible patients to increase precision. Our sample size of 236 would allow a 95% CI of ±2.6%. We used StatsDirect software (www.statsdirect.com) for sample size calculation.

**Statistical analysis**

We performed a univariable analysis of complication. Categorical variables are reported as counts and percentages, and continuous variables are reported as means ± standard deviation (SD). The proportion of complication rates are reported with 95% CIs. We considered results to be significant at \( p < 0.05 \). We used SPSS version 20.0 software for statistical analysis.

**RESULTS**

**Patients**

We identified a total of 211 patients undergoing 236 hip arthroscopies: 97 (46%) men and 114 (54%) women. The mean age at time of surgery was 37 ± 13 years, and the mean follow-up was 394 ± 216.5 days. Three patients had diabetes, 2 were immunocompromised (active cancer, chronic steroid use) and 13 were smokers. Table 1 lists the surgical indications for hip arthroscopy. The most common indication was FAI and labral tear, accounting for 127 (53.8%) hips, followed by labral tears alone (48 hips, 20.3%) and FAI alone (46 hips, 19.5%).

**Complications**

Based on our definition, a total of 10 complications occurred in 9 patients, for an overall complication rate of 4.2% (95% CI 2.3%–7.6%; Box 1). Four major complications occurred in 3 patients.

One patient had an anterior dislocation secondary to a fall after an uncomplicated treatment for a mixed FAI deformity. This patient did not have any signs of joint hypermobility or laxity. Her centre edge angle was on the lower range of normal (25°), which suggested mild dysplasia. She was treated with an urgent closed reduction under general anesthesia and subsequent hip spica bracing for 6 weeks. Her rehabilitation restarted after the bracing period of 6 weeks in an uncomplicated fashion. During bracing, hip flexion (> 60°) and all rotational movements were limited. Serial MRIs did not reveal avascular necrosis at the latest follow-up, and the patient made a full recovery.

In the second patient, after an identical FAI procedure, deep vein thrombosis (DVT) developed 6 weeks postoperatively and was treated with oral anticoagulants. This patient remained symptom-free after treatment of DVT; another physician, whose medical records could not be accessed retrospectively, treated the DVT, thus we were unable to specify the duration of anticoagulation.

Finally, a third patient experienced both a deep wound infection with *Staphylococcus aureus* and DVT shortly thereafter. Initial treatment consisted of irrigation and débridement of the wound followed by long-term intravenous and oral antibiotics (12 weeks) and oral anticoagulants. Follow-up MRI of the hip showed secondary osteomyelitis of the acetabulum. Secondary arthritis developed over a 6-month course, and this patient is now under consideration for hip arthroplasty. The patient’s DVT resolved with oral anti-coagulation therapy.

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**Box 1. Summary of complications**

<table>
<thead>
<tr>
<th>Major</th>
<th>Minor</th>
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<tbody>
<tr>
<td>Hip dislocation (n = 1)</td>
<td>Neuropathy (n = 2)</td>
</tr>
<tr>
<td>Deep vein thrombosis (n = 2)</td>
<td>Superficial wound infection (n = 1)</td>
</tr>
<tr>
<td>Septic joint (n = 1)</td>
<td>Heterotopic ossification (n = 2)</td>
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<tr>
<td></td>
<td>Capsular adhesion (n = 1)</td>
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</table>
No patients who experienced major complications had a history of predisposing conditions, such as coagulopathy or immunocompromised status.

Six patients experienced minor complications: 1 patient had mild paresthesias to the anterolateral thigh that was followed with serial observations, 2 patients had symptomatic heterotopic ossification treated nonoperatively, 1 patient had a superficial wound infection that was treated with a course of oral antibiotics, and 1 patient had a symptomatic capsular adhesion treated with an arthroscopic débridement. This patient received the diagnosis after having experienced ongoing hip pain following arthroscopic surgery for FAI and labral tear; repeat arthroscopy 8 months later identified extensive capsular adhesions. Finally, 1 patient experienced generalized leg numbness and difficulty moving the second, third and fifth toes about 6 weeks postoperatively. This patient was referred to Neurology, where a specific etiology could not be identified. The symptoms gradually resolved.

**DISCUSSION**

Our results revealed an overall complication rate of 4.2% following hip arthroscopy. We identified 4 major and 6 minor complications. Hip arthroscopy appears to be safe, with the majority of complications being non-life or limb threatening. However, we caution against considering hip arthroscopy a benign procedure. In our series, a deep wound infection and secondary osteomyelitis with consequent premature osteoarthritis developed postoperatively in 1 patient, who then required irrigation, débridement and intravenous antibiotics. Furthermore, DVT developed in 2 patients. Surgeons who perform hip arthroscopies should remain mindful of the infrequent, but serious complications that can occur. Patients considering the procedure should be thoroughly counselled regarding these adverse events. A careful discussion should occur to weigh the risks against the benefits of improved functional outcomes supported by current evidence.

The results from our series are in keeping with the complication rates reported in the literature. Sampson suggested that hip arthroscopy was associated with a complication rate ranging from 1.6% to 5%. A recent systematic review of 66 articles representing 6962 hip arthroscopies performed between 2000 and 2011 also found an overall complication rate of 4.0% (95% CI 2.9%–5.2%); 20 (0.3%) of the complications reported were severe. The authors concluded that hip arthroscopy was generally safe, but that larger prospective studies were needed.

In reviewing the literature, traction injuries and secondary neurapraxias are thought to be the most common complication associated with hip arthroscopy. Clarke and colleagues suggested a rate ranging from 2.6% to 20%. In the present series, we identified 1 patient with mild paresthesias to the anterolateral thigh, likely representing a neurapraxia of the lateral femoral cutaneous nerve, and another patient with generalized nonanatomic sensation and motor disturbances in the lower extremity. This lower rate in our series may represent technological advances in surgical therapy (e.g., dedicated traction tables) or the advancement in surgical training, as both participating surgeons obtained dedicated fellowship training in hip arthroscopy.

Two patients in our series experienced postoperative infections. Owing to the limited occurrence of this outcome, it is difficult to statistically analyze for potential risk factors. It remains unclear whether certain high-risk patients can be identified preoperatively and counselled regarding the incidence of infections after hip arthroscopy. Even less is known about the possible contribution of diagnostic intra-articular hip injections to the risk of postoperative infections. Further studies are needed to adequately identify potential predictors of this serious complication.

Two interesting trends emerged in our retrospective case review. First, we noticed that 6 of the 9 patients (67%) who had a complication were treated surgically for FAI (compared with 33% of complications in non-FAI surgery). It is possible that these patients were at risk for postoperative complications because treating FAI required more extensive bony surgery (e.g., rim trimming and osteoplasty) and longer traction and operative times. Further studies are required to determine whether FAI is a risk factor for postoperative complications.

In addition, DVT developed in 2 patients (0.8%), requiring anticoagulation. Salvo and colleagues recently studied 81 hip arthroscopy patients and found a DVT incidence of 3.7%. Bushnell and colleagues performed a non-systematic review of the literature and identified 27 studies of hip arthroscopy, including 5534 patients; the overall reported DVT rate was 0%. Guidelines, including the current American College of Chest Physicians (ACCP) guidelines on prevention of venous thromboembolic (VTE) events in orthopaedics, have not included specific recommendations on thromboprophylaxis for patients undergoing hip arthroscopy. However, extrapolating from patients who have had knee arthroscopy, the ACCP guidelines recommend no thromboprophylaxis in those without a history of venous thromboembolism. At our institution, we do not currently administer routine perioperative thromboprophylaxis in patients undergoing elective outpatient hip arthroscopy. Until further studies identify a clear benefit, a decision to provide anticoagulation prophylaxis should be made on an individual patient basis.

The strengths of the current study are that we included every eligible patient from 2 surgeons performing a high volume of hip arthroscopies. We used consistent criteria to identify all complications, and the definition was constructed a priori in consultation with several orthopaedic
surgeons. Information about complications relating to this procedure will be directly helpful to all decision-makers, including patients and their treating physicians. This series is applicable to those in academic practice and relevant to the Canadian health care environment.

Limitations

Our findings need to be interpreted within the inherent limitations of a retrospective chart review, which is prone to data inaccuracies and missing data. Surgeon experience is also an important consideration in our study. The 2 hip arthroscopists (O.A., I.W.) at our institution are within their first 5 years of practice. Complication rates are expected to decrease with surgeon experience. Sampson described his complication rate decline from 15% in the first 60 cases to 6.2% in the next 500 cases, and 0.5% in his last 500 cases. Similarly, Bellotti and colleagues reported 5 complications in their first 30 cases and only 2 in 67 subsequent cases. A combination of patient selection bias and surgeon experience likely contributed to this decline. In addition, the lack of a universally accepted definition of what constitutes a surgical complication can lead to the over- or under-reporting of complications by individual authors. Finally, another limitation of this study is the small number of events (10 complications) and lack of power to conduct multivariable regression analysis to explore the predictors of the complication. We would need at least 10 events per covariable to avoid poor estimation of Wald-based coefficients and their corresponding CIs.

CONCLUSION

Overall, hip arthroscopy appears to be safe, but surgeons need to consider the possibility of serious complications in the postoperative period. Future studies should focus on rigorous designs looking for potential predictors of complications that would allow a more thorough risk assessment in the preoperative setting.

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Competing interests: None declared.

Contributors: F. Farrokhyar, S. Burrow and M. Kowalczuk designed the study. M. Kowalczuk acquired the data, which K. Chan, F. Farrokhyar, M. Kowalczuk, M. Bhandari and O.R. Ayeni analyzed. K. Chan wrote the article, which all authors reviewed and approved for publication.

References

Self-directed practice schedule enhances learning of suturing skills

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Portions of this work have been previously presented at the Annual Meeting of the Royal College of Physicians and Surgeons of Canada in Ottawa, Ont., September 2008, and the Annual Meeting of the Association for Surgical Education in Salt Lake City, Utah, Apr. 28–May 2, 2009.

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Background: Most preoperative surgical training programs experience challenges with the availability of expert surgeons to teach trainees. Some research suggests that trainees may benefit from being allowed to actively shape their learning environments, which could alleviate some of the time and resource pressures in surgical training. The purpose of this study was to investigate the effects of self-directed or prescribed practice schedules (random or blocked) on learning suturing skills.

Methods: Participants watched an instructional video for simple interrupted, vertical mattress and horizontal mattress suturing then completed a pretest to assess baseline skills. Participants were assigned to 1 of 4 practice groups: self-directed practice schedule, prescribed blocked practice schedule, prescribed random practice schedule or matched to the self-directed group (control). Practice of the skill was followed by a delayed (1 h) posttest. Improvement from pretest to posttest was determined based on differences in performance time and expert-based assessments.

Results: Analyses revealed a significant effect of group for difference in performance time of the simple interrupted suture. Random practice did not show the expected advantage for skill learning, but there was an advantage of self-directed practice.

Conclusion: Self-directed practice schedules may be desirable for optimal learning of simple technical skills, even when expert instruction is available. Instructors must also take into account the interaction between task difficulty and conditions of practice to develop ideal training environments.

Contexte : La plupart des programmes de formation préopératoire en chirurgie ont du mal à trouver des experts pour enseigner la chirurgie aux stagiaires. Selon certaines recherches, il pourrait être utile de permettre aux stagiaires de structurer eux-mêmes leurs milieux d’apprentissage, ce qui pourrait se révéler avantages compte tenu des contraintes de temps et de ressources. Le but de cette étude était de mesurer les effets de différents horaires d’exercices, autodirigés ou prescrits (aléatoires ou fixes), sur l’apprentissage des techniques de sutures.

Méthodes : Les participants ont regardé une vidéo de formation sur les sutures uniques interrompues de type matelassier verticales et horizontales, avant de subir un prétest pour évaluer leurs compétences de base. Les participants ont ensuite été assignés à 1 de 4 groupes de pratique : horaires d’exercices autodirigés, fixes prescrits, aléatoires prescrits ou assortis au groupe « autodirigé » (témoin). La période d’exercices était suivie d’un post-test administré après un délai d’une heure. L’amélioration des résultats entre le prétest et le post-test a été déterminée par les différences de temps d’exécution et l’évaluation d’un expert.

Résultats : Les analyses ont révélé un effet significatif selon le groupe en ce qui a trait aux différences de temps d’exécution pour la suture simple interrompue. Les horaires d’exercices aléatoires ne se sont pas accompagnés de l’avantage attendu pour ce qui est de l’apprentissage de la technique, mais on a noté un avantage associé aux horaires d’exercices autodirigés.

Conclusion : Les horaires d’exercices autodirigés pourraient être souhaitables pour un apprentissage optimal des habiletés techniques simples, même lorsqu’un enseignement par les experts est disponible. Les instructeurs doivent aussi tenir compte de l’interaction entre la difficulté de la tâche et les conditions dans lesquelles se font les exercices pour améliorer les milieux de formation.
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Surgical instructors often predetermine the details of training sessions, such as the order of practised tasks, the duration of practice, and timing and type of feedback, while the trainee remains relatively passive. Such training environments are often not tailored to the informational needs of individual learners and, as such, are likely to be suboptimal learning environments. However, as surgical training programs contend with limited instructor availability and time allotted to teach fundamental technical skills, there is a trend toward the use of self-directed learning modules (e.g., CD-ROM and online programs) that require learners to be more active and independent. Recent research suggests that self-directed practice might assist surgical educators in creating learning environments that better support trainees’ motivation to practise by meeting changing informational needs. A study conducted by Jowett and colleagues demonstrated that skill performance for tying knots was unaffected by practice enforced after trainees decided they had reached proficiency and did not require further practice. These researchers speculated that the learning environment (e.g., simulation model and instructions) remained unchanged after the trainees reached a certain proficiency on the skill and therefore did not provide any additional benefit to learning. Studies using laboratory, sporting and surgical tasks have shown that motor learning can be facilitated if the learner is able to self-direct various aspects of their training experience, such as frequency of feedback, access to video instructions and order of practised tasks.

Surgical educators have also begun to consider how other aspects of the training environment, such as distribution and schedule of practice, can be optimized to enhance motor learning within time constraints. With respect to practice schedules, the literature has shown that performance during acquisition of related tasks practised in a random or unsystematic order (e.g., ACB, BAC, ABC) is impaired compared with performance of tasks in blocked or drill-type order (e.g., AAA, BBB, CCC). Interestingly, however, after a rest period, performance is better on a delayed test for random practice compared with blocked practice. This phenomenon is referred to as the contextual interference effect and is often explained by the forgetting hypothesis, which suggests that practice that forces the learner to repetitively forget and recall the required skills, such as random practice, will enhance delayed performance. This is important because, unlike immediate postpractice performance, which often represents transient practice effects, delayed tests are more likely to reflect relatively permanent improvement in ability.

Since the motor learning literature has shown the contextual interference effect to be greatest for simple laboratory tasks, researchers have begun to explore its applicability to more complex tasks in the surgical domain. While these studies have shown divergent results, they highlight the fact that, in the surgical domain, interactions between performance and practice variability can be affected by task difficulty.

While there is some evidence supporting random and self-directed practice in the surgical domain, to our knowledge, no studies have examined both practice schedule and the selection of practice schedule for the same surgical skill. The purpose of this study was to determine how practice schedule (random or blocked) and selection of practice schedule (self-directed or prescribed) contribute to learning of suture skills. We hypothesized that self-directed and random practice schedules would produce better postpractice performance than the other prescribed practice schedules.

**Methods**

**Participants**

We recruited first- and second-year medical students from the University of Toronto to participate in our study. The University of Toronto and Mount Sinai Hospital Research Ethics Boards approved the research protocol, and all participants provided voluntary informed consent.

**Procedure**

Each participant viewed an 8-minute instructional video of an expert demonstration of 3 types of wound closure skills: simple interrupted, vertical mattress and horizontal mattress. Using Sofsilk 3–0 silk sutures (United States Surgical Corporation, Covidien), a synthetic skin pad (Limbs & Things), curved needle, forceps and a needle driver, all participants performed a pretest consisting of 1 trial of each of the 3 sutures without any feedback or access to the instructional video. Each participant was then randomly assigned to 1 of 4 practice schedule groups: self-directed, random, blocked or matched control. Participants in the self-directed group were free to choose their practice schedules with the constraint that by the end of practice they had performed 5 trials of each suture type. The random and blocked groups received prescribed practice protocols and practised the 3 suture types in the orders outlined in Table 1. Participants in the matched control group served as a control, such that each participant in this group was prescribed exactly the same practice schedule as 1 participant from the self-directed group. The difference between the random and self-directed groups (other than the prescription of the practice schedule) is that the random group had a truly random schedule whereas the self-directed group may have selected elements of both blocked and random patterns in their schedules. During practice, all participants were free to review the instructional video as frequently as they wished. After the practice session there was a rest interval of 1 hour followed by a posttest administered in the same manner as the pretest.
Statistical analysis

The pretest and posttest performances were videotaped and used to obtain measures of performance to assess learning. First, total time to complete each suture (performance time), from the first needle puncture in the skin pad to cutting of the final sutures, was extracted from each video. Second, the pretest videos were independently assessed by 2 experts blinded to the experimental condition or group. The expert observers used 3 validated measures to assess performance across all 3 suture techniques: a global rating scale of operative performance (maximum score 35), a checklist for suture of skin laceration (maximum score 11) and a final product analysis (maximum score 4). These scores were used to assess interrater agreement and consistency by calculating single-measures intra class correlation coefficients (ICCs) with 95% confidence intervals (CIs) using a 2-way, random-effects model with both absolute agreement and consistency methods. Absolute agreement implies that the raters assigned similar scores (absolute values) for similar performances, whereas consistency means that the raters’ scores followed similar trends for the performances even if the absolute scores were not the same. For formative or summative classroom-type assessment, reliability is expected to be in the range of 0.70–0.79 or lower depending on the length of the test/number of test items.

One rater then went on to score the posttest videos using the same measures. Difference scores were calculated for performance time and each of the validated measures by subtracting the pretest score from the posttest score. The difference scores were analyzed in separate 4-group 1-way analyses of variance. We considered effects to be significant at \( p < 0.05 \), and they were further analyzed using the Tukey honestly significant difference method for post hoc comparison of means. We also calculated Cohen’s \( d \) effect sizes (using average standard deviations) to help determine the importance of group effects independent of sample size. Effect sizes at 0.2, 0.5 and 0.8 were considered small, medium and large, respectively.

RESULTS

Thirty-eight first- and second-year medical students (20 women and 18 men with a mean age of 23 yr) from the University of Toronto participated in our study. Ten participants were randomly assigned to the self-directed group, 9 to the random group, 10 to the blocked group and 9 to the matched control group. Inspection of the practice schedules selected by the participants in the self-directed group showed that 7 of 10 participants chose a blocked practice schedule. The order of the blocks was the same as the order of suture types demonstrated on the instructional video. The remaining 3 participants chose a hybrid schedule that was predominantly blocked, but had some elements of randomization that appeared later in practice.

Interrater consistency and agreement

Intraclass correlations were calculated for the 2 raters who viewed the pretest videos to determine whether scores from 2 independent raters were consistent and/or in agreement. As seen in Table 2, the ICCs indicated that there was moderate agreement and consistency between the raters for each measurement tool (global rating scale, checklist, final product analysis). The global rating scale had the highest agreement and consistency, followed by the checklist and the final product analysis. However, overlap among the CIs suggests that there were no significant differences in agreement or consistency among the measurement tools.

### Table 1. Practice schedules used by participants in each group

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<td>S</td>
</tr>
<tr>
<td>14</td>
<td>H</td>
<td>H</td>
<td>V</td>
<td>H</td>
<td>H</td>
<td>H</td>
<td>H</td>
<td>H</td>
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<td>15</td>
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</tr>
</tbody>
</table>

H = horizontal mattress suture; S = simple interrupted suture; V = vertical mattress suture.
tools. The ICCs were all in the range 0.50–0.70, which we believe is acceptable considering the number of items used for each measurement tool. Since we determined that the scores were fairly stable across raters, only 1 rater continued evaluation of the posttest videos.

**Performance time**

Means and standard errors for differences in performance time from pretest to posttest are shown in Figure 1. The analysis of performance time showed a main effect of group for the simple suture ($F_{3,27} = 4.04, p = 0.017$). Tukey post hoc comparisons indicated that self-directed participants decreased their performance time significantly more than both the blocked ($p = 0.036$) and matched control ($p = 0.040$) groups. Further, the effect sizes for both these comparisons ($d = 1.2$ and $d = 1.3$, respectively) exceeded Cohen’s convention for a large effect. Performance times for the other 2 suture techniques (horizontal and vertical mattress) showed similar patterns, but these effects were not significant.

**Expert ratings**

The analyses of the expert ratings did not show any significant effects of group. However, as seen in Figure 2, the trends suggest that on average the self-directed group demonstrated greater or similar improvements from pretest to posttest, particularly using the global rating scale. These results are similar to those for performance time of the simple suture. In fact, since these trends were similar, we calculated Cohen $d$ effect sizes to compare each group to the self-directed group. The effect sizes were $d = 1.1$, $d = 1.3$ and $d = 0.8$ for comparisons of the self-directed group with the random, blocked and matched control groups, respectively.

### Table 2. Summary of intraclass correlation coefficients* indicating agreement and consistency between 2 expert raters for pretest scores

<table>
<thead>
<tr>
<th>Measurement tool</th>
<th>Absolute agreement</th>
<th>Consistency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global rating scale</td>
<td>0.64 (0.20–0.84)</td>
<td>0.73 (0.51–0.87)</td>
</tr>
<tr>
<td>Checklist</td>
<td>0.55 (0.21–0.77)</td>
<td>0.61 (0.32–0.80)</td>
</tr>
<tr>
<td>Final product analysis</td>
<td>0.50 (0.20–0.71)</td>
<td>0.55 (0.27–0.74)</td>
</tr>
</tbody>
</table>

CI = confidence interval; ICC = intraclass correlation coefficient.

*Single measures ICC based on 2 raters; 95% CI for estimate of ICC.

**DISCUSSION**

Our results demonstrate that when compared with the blocked and matched control groups, the self-directed group experienced a significant improvement in performance time for the simple interrupted suture. Furthermore, both these effect sizes were large, suggesting that these effects may have practical importance for training of suturing skills. Our analysis of expert evaluations using a global rating scale, checklist and final product analysis yielded no significant group effects, but trends were similar to those observed for performance time. In addition, effect size calculations for the global ratings showed large effects for comparisons between the self-directed group and all other practice groups, suggesting that these results are also important for future research in this area.

Unlike most studies in the basic motor control literature but in line with the surgical training literature, our results do not support the contextual interference effect; that is, they do not show a learning advantage for random compared with blocked practice. This suggests that random
practice does not facilitate improved performance for this particular skill (suturing) and adds support to the idea that random practice does not always confer an advantage for learning, particularly for more complex skills like those often explored in the surgical domain. One may argue that the 3 suture types used were quite similar, with only minor variations in the details of the general suturing task. It is then possible that these small variations may not be enough to force the learner to forget and recall the skills; hence, not enough to produce the contextual interference effect. However, in a recent review, Merbah and Meulemans conclude that for more complex applied tasks, the contextual interference effect can appear even when there are variations only within the same type of task. This notion of task complexity and its interactions with motor learning effects should always be considered and is addressed in the challenge point framework, described by Guadagnoli and Lee. They proposed that the effectiveness of a particular practice condition depends on an interaction between the difficulty of the task and the expertise of the learner. It is possible that, for the medical students who participated in the present study, the psychomotor demands of learning 3 suturing techniques, as well as the difficulty of each technique, already taxed their cognitive and attentional resources such that the added cognitive demands imposed by random practice did not help learning.

Consistent with the challenge point framework, our results also showed a learning advantage for individuals who practised using a self-directed schedule. This advantage over a matched control group has been previously shown for various aspects of practice and can be ascribed to increased autonomy, which likely allows the participant to adapt the learning experience to his or her specific needs and may also result in increased motivation, more instances of deliberate practice and improved motor learning. However, the advantage of a self-directed practice schedule over prescribed random and blocked practice is particularly interesting. Despite having chosen predominantly blocked schedules and changing to a random schedule later in the training phases, the self-directed group experienced superior learning. Furthermore, since the benefit of a self-directed practice schedule was significant only for the simplest suture technique, it is possible that increased task difficulty (and greater cognitive load) imposed by more difficult suture techniques reduced the advantage of a self-directed practice schedule for the horizontal and vertical mattress suture techniques. This emphasizes the complex interaction of task difficulty and training conditions that are required for optimal learning. Nonetheless, the self-directed learning advantage that we observed is consistent with the literature that has been produced using basic laboratory tasks and now adds to the emerging work in the clinical skills domain, particularly for self-directed practice schedules as opposed to self-directed feedback or access to instructional materials.

Limitations

While this study is an important first step in understanding the role of practice schedules and instructional methods in learning surgical skills, we believe that more research is required to examine the impact of practice schedules for a variety of surgical tasks performed by surgeons with various skill levels. Furthermore, the generalizability of our results is limited to this particular skill, the population that was tested and the short time period over which we assessed learning effects. We are currently looking at similar processes in surgical residents to examine whether increased skill levels have any interaction with the already reported benefits to self-directed practice. Since our results were different across suturing techniques, we believe that in future studies and in practice, researchers and trainers should take care to examine component skills in a training program and so identify specific areas where trainees may require extra practice or instruction.

CONCLUSION

Many surgical skill centres are now offering 24-hour access to their facilities; however, instructors are often not available to provide expert direction during off-hours, leaving trainees to manage their own practice sessions. Our findings suggest that self-directed practice schedules within a curriculum may contribute to optimal learning of basic technical skills, such as simple suturing.

Competing interests: None declared.

Contributors: O. Safir, A. Dubrowski, D. Backstein and H. Carnahan designed the study. O. Safir acquired and analyzed the data, which was also analyzed by C.K. Williams. O. Safir, C.K. Williams, A. Dubrowski and H. Carnahan wrote the article. C.K. Williams, D. Backstein and H. Carnahan reviewed the article. All authors approved its publication.

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References

Patterns of use and outcomes for radiation therapy in the Quality Initiative in Rectal Cancer (QIRC) trial

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Background: The Quality Initiative in Rectal Cancer (QIRC) trial targeted surgeon intraoperative technique and not radiation therapy (RT) use. We performed a post hoc analysis of RT use among patients in the QIRC trial, not by arm of trial but rather for the entire group. We wished to identify associations between local recurrence risk and use of preoperative, postoperative or no RT

Methods: We compared demographic, tumour and process of care measures among patients receiving preoperative, postoperative or no RT. A multivariable Cox regression model assessed local recurrence risk.

Results: The QIRC trial enrolled 1015 patients at 16 hospitals between 2002 and 2004. Radiation therapy use did not differ between trial arms, and median follow-up was 3.6 years. For the preoperative, postoperative and no RT groups, respectively, the percentage of patients was 12.8%, 19.3% and 67.9%; the percentage of stage II/III tumours was 57.0%, 88.7% and 48.1%; and the local recurrence rate was 5.3%, 10.2% and 5.5% (\( p = 0.05 \)). After controlling for patient and tumour characteristics, including tumour stage, the hazard ratio (HR) for local recurrence was increased in the postoperative RT versus the no RT group (HR 1.64, 95% confidence interval 1.04–2.58, \( p = 0.027 \)).

Conclusion: Use of preoperative RT was low; most patients with stage II/III disease did not receive RT and, as expected, the postoperative RT group had the highest risk of local recurrence. Our results suggest opportunities to improve rectal cancer RT use in Ontario.

Contexte : L’essai QIRC (Quality Initiative in Rectal Cancer) portait sur la technique peropératoire des chirurgiens et non sur l’utilisation de la radiothérapie (RT). Nous avons effectué une analyse rétrospective de l’utilisation de la RT chez les patients inclus dans l’essai QIRC, non pas en fonction des différents groupes de l’essai, mais en fonction de sa population entière. Nous avons voulu vérifier les liens entre le risque de récurrences locales et l’utilisation préopératoire ou postopératoire de la RT ou l’abstention de toute RT.

Méthodes : Nous avons comparé les paramètres démographiques, les caractéristiques de la tumeur et le processus de soins chez les patients soumis à une RT préopératoire ou postopératoire, ou non traités par RT. Un modèle de régression multivariée de Cox a permis d’évaluer le risque de récurrences locales.

Résultats : L’essai QIRC a regroupé 1015 patients de 16 hôpitaux entre 2002 et 2004. Le recours à la radiothérapie n’a pas différé entre les groupes de l’essai, et le suivi médian a été de 3,6 ans. Pour ce qui est des groupes soumis à une RT préopératoire ou postopératoire, ou non soumis à la RT, respectivement, le pourcentage de patients était de 12,8 %, 19,3 % et 67,9 %; le pourcentage de tumeurs de stade II/III était de 57,0 %, 88,7 % et 48,1 %, et le taux de récurrences locales, de 5,3 %, 10,2 % et 5,5 % (\( p = 0,05 \)). Après ajustement pour tenir compte des caractéristiques des patients et des tumeurs, y compris le stade de la tumeur, le risque relatif (RR) de récurrences locales a augmenté dans le groupe soumis à une RT postopératoire par rapport au groupe non soumis à la RT (RR 1,64; intervalle de confiance de 95 %, 1,04–2,58, \( p = 0,027 \)).

Conclusion : Le recours à la RT préopératoire a été faible; la plupart des patients atteints d’une maladie de stade II/III n’ont pas reçu de RT et comme prévu, le groupe soumis à une RT postopératoire a présenté le risque le plus élevé de récurrences locales. Nos résultats indiquent qu’il serait possible d’améliorer l’utilisation de la RT pour le cancer rectal en Ontario.
A negative outcome following rectal cancer surgery is local tumour recurrence in the pelvis. Prospective randomized trials have demonstrated that pelvic radiation can reduce post-surgical rates of local recurrence and that radiation is more effective when given in the preoperative versus the postoperative setting. However, an improvement in survival has not been consistently shown. The introduction of improved surgical techniques known as total mesorectal excision (TME) has led to marked reductions in the risks of local recurrence. The recent MRC-CR07 trial showed that patients receiving preoperative radiation therapy (RT) and high-quality surgery had a local recurrence rate of only 1%. Clinical leaders in jurisdictions around the world have integrated the results of rectal cancer radiotherapy trials in different ways. For example, for most patients with stage II or III rectal cancer, guidelines in Ontario encourage the use of preoperative or postoperative long-course chemoradiation. In British Columbia, the preference is for patients with stage II or III rectal cancer to receive preoperative short-course RT (i.e., delivered over 1 wk). In Sweden, most patients with rectal cancer are deemed appropriate for preoperative short-course RT, whereas in Norway only a minority of patients receive any form of RT.

The Quality Initiative in Rectal Cancer (QIRC) trial tested if a quality improvement strategy would lead to improvements in hospital rates of local recurrence and permanent stoma among patients undergoing rectal cancer surgery. Surgeon-directed interventions included workshops, access to opinion leaders, operative demonstrations, audit and feedback, and postoperative questionnaires. Despite excellent participation, the trial results were negative (i.e., results in the intervention and control arms were similar). The interventions were designed to optimize surgeon intraoperative technique, not to optimize other surgical decisions, such as the use of RT.

For the present study we assessed factors influencing RT use, and we correlated patterns of RT use (e.g., preoperative, postoperative, no RT) to rates of local recurrence and permanent stoma at initial surgery. We assessed RT use among the entire study group, not by trial arm. Of note, during the period of study accrual, approximately 25% of all patients undergoing rectal cancer surgery in Ontario did so at trial hospitals. Thus, our findings likely reflect how RT is used across the province for patients with rectal cancer.

**METHODS**

The study received ethics approval from the Hamilton Health Sciences Research Ethics Board.

**The QIRC trial**

The QIRC trial protocol and primary results have been published elsewhere. Patients were eligible for trial inclusion if they underwent major surgery for rectal cancer. Rectal tumours were located within 15 cm of the anal verge by rigid sigmoidoscopy, or were at or below the level of the sacral promontory. All patients with stage II or III tumours would have been eligible to receive pre- or postoperative RT according to Ontario guidelines. Consecutive patients at each site were accrued to avoid the potential bias of excluding patients with tumours at relatively greater risk for negative outcomes.

Sixteen hospitals were cluster-randomized to the QIRC strategy (experimental arm) or to continue with routine practice (control arm). The surgeon-directed QIRC strategy consisted of workshops, access to opinion leaders, operative demonstrations, postoperative questionnaires, and audit and feedback. Eight experimental arm hospitals and 8 control arm hospitals enrolled patients between May 2002 and December 2004. Use of the QIRC strategy did not decrease rates of local recurrence or permanent stoma. Hospital charts were reviewed within 2 weeks of surgery and every 3 months thereafter. In Ontario, all RT is delivered at a small number of regional cancer centres. We reviewed charts from regional cancer centres to collect data on patient adjuvant treatments (RT and chemotherapy) and study outcomes. Data were collected for a minimum of 30 months; follow-up was longer for patients who enrolled near the beginning of the trial. Data collected included patient (age, sex, comorbidities), tumour (distance from the anal verge; size; tumour-node-metastasis [TNM] staging; differentiation; presence of vascular, lymphatic or perineural invasion) and process of care (number of lymph nodes counted, mesorectal margin status, use of preoperative pelvic computed tomography [CT]) measures. For staging data, postoperative pathology reports were used to determine T and N categories. Thus, there was likely some under-staging in the preoperative RT group.

**Study groups and outcomes**

Patients from the 2 arms of the trial were combined, and then divided into 3 groups: patients receiving preoperative RT, postoperative RT or no RT. We compared rates of local recurrence and permanent stoma among these groups. Many patients in routine practice may end up with a permanent stoma despite this not being the expected result of the original surgery.
However, we were most interested in how surgeons approached their choice of initial surgical procedure and use of RT. Thus we defined permanent stoma as an abdominoperineal resection at initial surgery. Local recurrence in the pelvis was ideally confirmed by biopsy, but any pelvic mass on cross-sectional imaging with associated worsening symptoms of pain or pressure, or deteriorating bowel, bladder or sexual function was classified as a local recurrence. The QIRC trial did not mandate specific follow-up tests. However, a local rectal cancer recurrence inevitably results in a return visit to a regional cancer centre for palliative radiation, chemotherapy, or another hospital-based service. Ongoing chart reviews at hospitals and cancer centres ensured that data from such interactions would be abstracted.

**Statistical analysis**

We used the $\chi^2$ test for categorical variables and the Student $t$ test for continuous variables to assess differences among the 3 groups in patient and tumour variables and in treatment and outcome measures. We used a proportional hazards Cox regression model to assess the risk of local recurrence over time while controlling for patient and tumour variables, arm of trial and the clustering of data at the hospital level. We did not consider chemotherapy in our multivariable model since previous QIRC trial analyses demonstrated a marked correlation between use of RT and use of chemotherapy.16 For all tests, we considered results to be significant at $p < 0.05$. Analyses were conducted using SAS, SPlus and StatXact software.

**RESULTS**

The QIRC trial involved 8 experimental arm hospitals (56 surgeons, 558 patients) and 8 control arm hospitals (49 surgeons, 457 patients).16 Patients were followed for a median of 3.6 years. For the experimental and control arms, respectively, the rate of permanent stoma was 39% and 41% (odds ratio [OR] 0.97, 95% confidence interval [CI] 0.63–1.48, $p = 0.88$) and the rate of local recurrence was 7% and 6% (OR 1.06, 95% CI 0.68–1.64, $p = 0.80$). For the entire study cohort, the percentages of patients in the preoperative, postoperative and no RT groups were 12.8%, 19.3% and 67.9%, respectively (Table 1). Preoperative RT was usually delivered using long-course protocols, with only 15% of preoperative cases receiving the short-course 5-day protocol favoured in many European centres. Patients who received RT were younger ($p < 0.001$), more likely to be male ($p = 0.009$) and less likely to have comorbidities ($p = 0.011$).

Patients who received preoperative RT had tumours significantly closer to the anal verge (median distance 5 cm from the verge) than patients receiving postoperative or no RT (median distance 10 cm from the verge, $p < 0.001$; Table 2). Nearly all patients in the postoperative RT group had stage II or III tumours, while nearly one-third of patients in the no RT group had stage I tumours ($p < 0.001$). Of note, most (57.2%) patients with stage II or III tumours were in the no RT group. In Ontario, such patients would have been eligible for consideration of some form of RT. Patients in the postoperative RT group had tumours with less favourable characteristics, such as presence of vascular, lymphatic or neural invasion ($p < 0.001$) and moderate to poor differentiation ($p < 0.001$).

Most (73.1%) patients in the preoperative RT group received a preoperative pelvic CT scan compared with only about half in the postoperative and no RT groups.

**Table 1. Characteristics of patients with rectal cancer**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Preoperative radiation</th>
<th>Postoperative radiation</th>
<th>No radiation</th>
<th>$p$ value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients</td>
<td>130 (12.8)</td>
<td>196 (19.3)</td>
<td>689 (67.9)</td>
<td></td>
</tr>
<tr>
<td>Age, median, yr</td>
<td>65</td>
<td>65</td>
<td>71</td>
<td>&lt; 0.001‡</td>
</tr>
<tr>
<td>Male sex</td>
<td>89 (68.5)</td>
<td>136 (69.4)</td>
<td>407 (59.1)</td>
<td>0.009</td>
</tr>
<tr>
<td>Comorbidities ≥1</td>
<td>23 (17.7)</td>
<td>42 (21.4)</td>
<td>194 (28.2)</td>
<td>0.011</td>
</tr>
</tbody>
</table>

*Unless otherwise indicated.
†Mann–Whitney U test.
‡Mann–Whitney U test.

**Table 2. Tumour characteristics of patients with rectal cancer**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Preoperative radiation</th>
<th>Postoperative radiation</th>
<th>No radiation</th>
<th>$p$ value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance from anal verge, median cm</td>
<td>5.0</td>
<td>10.0</td>
<td>10.0</td>
<td>&lt; 0.001‡</td>
</tr>
<tr>
<td>Tumour size, median cm</td>
<td>2.7</td>
<td>4.5</td>
<td>4.0</td>
<td>&lt; 0.001‡</td>
</tr>
<tr>
<td>TNM stage‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage I</td>
<td>28 (21.5)</td>
<td>6 (3.1)</td>
<td>221 (32.1)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Stage II</td>
<td>37 (28.5)</td>
<td>62 (31.6)</td>
<td>150 (21.8)</td>
<td></td>
</tr>
<tr>
<td>Stage III</td>
<td>37 (28.5)</td>
<td>112 (57.1)</td>
<td>161 (26.3)</td>
<td></td>
</tr>
<tr>
<td>Stage IV</td>
<td>13 (10.0)</td>
<td>13 (6.6)</td>
<td>86 (12.5)</td>
<td></td>
</tr>
<tr>
<td>Unable to stage</td>
<td>15 (11.5)</td>
<td>3 (1.5)</td>
<td>51 (7.4)</td>
<td></td>
</tr>
<tr>
<td>Vascular, lymphatic, neural invasion</td>
<td>25 (19.2)</td>
<td>81 (41.3)</td>
<td>174 (25.3)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Histologic grade</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate or poor</td>
<td>96 (73.8)</td>
<td>181 (92.3)</td>
<td>555 (80.6)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Positive circumferential radial margin§</td>
<td>13 (10.0)</td>
<td>24 (12.2)</td>
<td>48 (7.0)</td>
<td>0.048</td>
</tr>
</tbody>
</table>

TNM = tumour-node-metastasis.
†Unless otherwise indicated.
‡$t$ test.
§Comparison of postoperative and no radiation only, owing to possible downsizing in preoperative radiation group.
¶Positive circumferential radial margin = distance ≤ 1 mm.
For patients in the preoperative, postoperative and no RT groups, respectively, the rate of permanent stoma was 53.8%, 27.0% and 22.5% (p < 0.001), while the rate of local recurrence was 5.4%, 10.2% and 5.5% (p = 0.05). The higher stoma rate in the preoperative group is not surprising given the much lower median tumour location in this group. For these same groups, and considering only patients with stage II or III tumours, the rates of local recurrence changed little: 5.3%, 9.8% and 7.0%, respectively (p = 0.39).

Controlling for arm of trial; relevant patient and tumour variables, including tumour stage; and the clustering of data at the hospital level, compared with the no RT group, the risk of local recurrence was similar in the preoperative group (hazard ratio [HR] 0.92, 95% CI 0.37–2.33, p = 0.027; Table 4). The median number of lymph nodes examined was lowest at 8 in the preoperative RT group compared with 12 and 10 in the postoperative RT and the no RT groups, respectively (p < 0.001). It is known that preoperative RT will lower lymph node counts.18

For these same groups, and considering only patients with stage II or III tumours, the rates of local recurrence changed little: 5.3%, 9.8% and 7.0%, respectively (p = 0.027; Table 4).

**DISCUSSION**

The QIRC trial tested whether surgeon-directed interventions could improve patient outcomes by encouraging optimal intraoperative techniques for rectal cancer surgery. The QIRC strategy did not attempt to influence surgeons on their use of RT. The present study is a secondary analysis of RT use and patient outcomes among all QIRC trial patients. The results are presented by mode of RT delivery and thus should not be viewed as reflecting the utility of RT. Rather, they likely reflect the decision-making of surgeons before or after surgery in response to information that may not have been available for our analyses. Therefore, it is inappropriate to infer causality between study results and study group (e.g., postoperative RT leads to a higher risk of local recurrence, or preoperative RT leads to a higher risk of permanent stoma). However, our findings do suggest opportunities to improve RT use in Ontario in patients with rectal cancer.

Studies have shown that RT is more effective in the pre- versus the postoperative setting.1,2,4 This may be because of a greater probability of patients completing planned treatment, improved effectiveness of RT in tissues that are optimally oxygenated and the absence of scar tissue, which may protect sequestered cancer cells from radiation. Yet in the QIRC trial only 12.8% of patients received preoperative RT, representing only 39.9% of all patients receiving RT. In addition, patients in the preoperative RT group were more likely to have tumours close to the anal verge, and more than half received an abdomino-perineal resection at initial surgery—a higher percentage than patients receiving postoperative or no RT. We do not suggest that preoperative RT increases the risk of permanent stoma. Rather, our results suggest that tumour location, not tumour stage, largely drove the use of preoperative RT in the QIRC trial.

We also observed that 21.5% of patients in the preoperative RT group had stage I tumours at final pathology. While tumour downsizing may have occurred in some patients, it is unlikely that this occurred in one-fifth of patients in the preoperative group, as we observed. A recent trial from Germany randomly assigned patients with stage II or III tumours to pre- or postoperative chemoradiation.2 After surgery, 18% of patients in the postoperative therapy arm were found to actually have stage I tumours and thus were incorrectly assessed for trial eligibility. It is likely that reserving preoperative RT for patients with stage II or III tumours will result in a substantial number of patients with stage I tumours receiving RT. Stakeholders should consider strategies to increase the percentage of patients receiving preoperative RT while improving staging accuracy. The routine use of preoperative magnetic resonance imaging (MRI) should help.19

**Table 3. Process of care and outcome measures**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group, no. (%)</th>
<th>p value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients</td>
<td>130 (12.8)</td>
<td>196 (19.3)</td>
</tr>
<tr>
<td>Process of care measures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative CT</td>
<td>95 (73.1)</td>
<td>102 (52.0)</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>No. lymph nodes examined, median</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Permanent colostomy at initial</td>
<td>70 (53.8)</td>
<td>53 (27.0)</td>
</tr>
<tr>
<td>surgery</td>
<td>7 (5.4)</td>
<td>20 (10.2)</td>
</tr>
<tr>
<td>Local recurrence</td>
<td>4/74 (5.4)</td>
<td>17/174 (9.8)</td>
</tr>
<tr>
<td>for stage II/III</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CT = computed tomography.
*Unless otherwise indicated.
†Analysis of variance (ANOVA).
‡Mann–Whitney U test.

**Table 4. Multivariable clustered analysis of risk of local recurrence**

<table>
<thead>
<tr>
<th>Group</th>
<th>HR (95% CI)</th>
<th>p value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm of trial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control group</td>
<td>1.00</td>
<td>Reference group</td>
</tr>
<tr>
<td>Experimental group</td>
<td>0.99 (0.61–1.61)</td>
<td>0.98</td>
</tr>
<tr>
<td>Radiation group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No RT</td>
<td>1.00</td>
<td>Reference group</td>
</tr>
<tr>
<td>Preoperative RT</td>
<td>0.92 (0.37–2.33)</td>
<td>0.88</td>
</tr>
<tr>
<td>Postoperative RT</td>
<td>1.64 (1.04–2.58)</td>
<td>0.027</td>
</tr>
</tbody>
</table>

CI = confidence interval; HR = hazard ratio; RT = radiation therapy.
*Adjusted for data at hospital level. Controlling for age; sex; comorbidities; stage; distance of tumour from anal verge; tumour size; histologic grade; any vascular, lymphatic, neural invasion; and positive circumferential radial margin.

*Unless otherwise indicated.
Patients receiving postoperative RT were more likely to have tumours with moderate/poor differentiation, lympho-vascular or neural invasion and a positive circumferential radial margin. Such factors may indicate a more aggressive cancer and may act as prompts for surgeons to consider postoperative RT. In addition, nearly all patients receiving postoperative RT had stage II or III tumours, in concordance with provincial guidelines. These observations may explain why the post-RT group had the higher risk of local recurrence (10%). However, in the no RT group, the rate of local recurrence among patients with stage II or III tumours was only 7%. It may be that patients who received postoperative RT had other negative prognostic indicators that were obvious to the involved surgeon but not to the investigators after data abstraction from pathology and other patient reports. Such confounding variables could include final appearance or overall quality of the TME specimen, a likely reflection of the difficulty of surgery. But if such difficult operations could be anticipated through preoperative imaging and physical findings (i.e., threatened mesorectal margin), RT would ideally be provided preoperatively. Again, our concern is not that there was higher risk of local recurrence in the postoperative RT group, but rather that stakeholders should devise strategies to minimize the use of postoperative RT overall and increase the use of preoperative RT for appropriate patients.

Findings in the no RT group are in keeping with those of previously published work. Patients in this group were more likely to be older, to have more comorbidities, to be women and to have a stage I tumour. Radiation therapy has associated short-term morbidities and long-term risks and is more likely to be avoided in older patients or in those with more comorbidities. Men may be more likely to receive RT than women owing in part to the expected difficulty with the narrow male pelvis and concerns of close radial margins. In Ontario, it is not recommended that patients with stage I rectal cancer receive RT.

There was an inadequate use of preoperative cross-sectional imaging. Such imaging can assess the local extent of the tumour, especially for rectal tumours beyond the reach of the digital rectal examination, and can also assess metastatic disease. Findings should influence discussions on the role of surgery and RT. Such imaging of the abdomen and pelvis was used in 73.1%, 52.0% and 49.3% of patients in the preoperative, postoperative and no RT groups, respectively. Of note, during the years of the trial there was no use of preoperative pelvic MRI, something that is quickly becoming a standard of care.

In our multivariable model assessing 3 study groups demarcated by mode of RT delivery, controlling for tumour, trial arm and study group variables, tumour stage did not influence the risk of local recurrence. This parallels the primary analyses of the QIRC trial, where stage of tumour did not impact risk of local recurrence. This finding challenges the current Ontario paradigm that all patients with stage II and III tumours should receive some form of RT. Of note, 57.2% of all patients with stage II or III tumours did not receive RT, and the rate of local recurrence among these patients was only 7.0%. It is possible that in the setting of high-quality surgery, the use of RT can be reserved for patients with a threatened mesorectal margin and less influence attributed to tumour stage.

**Limitations**

The limitations of this study include the fact that the QIRC trial was not designed specifically to look at RT use, and there is the possibility that relevant factors were not assessed or considered. For example, surgeon preferences and recommendations to patients may have been based on personal expertise and experiences. Also, we were not able to account for patient choice. In addition, complications related to surgery were not captured, which may also affect discussions on the use of postoperative RT. The present study followed patients for a median of only 3.6 years; however, it is known that RT can delay the appearance of local recurrences. Thus a longer follow-up period in our study may have revealed more patients with local recurrence in the 2 RT groups only, a finding that would not substantively change our observations or conclusions. Finally, only 16 hospitals were involved in the trial, and only 2 sites were teaching hospitals. Thus, our data may not be representative of RT use in patients with rectal cancer across the province. However, in Ontario, 70% of rectal surgery is performed at nonteaching hospitals and, as mentioned, sites participating in the QIRC trial treated approximately 25% of all patients with rectal cancer in the province. In addition, previous research using Ontario data has demonstrated similar outcomes following colorectal cancer surgery at teaching versus nonteaching hospitals. Thus our findings are likely representative of RT use across the province.

**Conclusion**

In the present study, use of preoperative RT was low and was largely reserved for patients with tumours relatively near the anal verge. Most patients with stage II or III rectal cancer did not receive pre- or postoperative RT, and patients who received postoperative RT had the highest risk of local recurrence. Our results suggest opportunities to improve RT use in patients with rectal cancer in Ontario.

**Competing interests:** None declared.

**Contributors:** M. Levine and M. Simunovic designed the study. A. Coates, L. Thabane and M. Simunovic acquired the data, which V. Francescuzzi, A. Coates, L. Thabane, C.H. Goldsmith and M. Simunovic analyzed. V. Francescuzzi and M. Simunovic wrote the article. All authors reviewed the article and approved its publication.

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References

Timeliness in obtaining emergent percutaneous procedures in severely injured patients: How long is too long and should we create quality assurance guidelines?

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Background: Modern trauma care relies heavily on nonoperative, emergent percutaneous procedures, particularly in patients with splenic, pelvic and hepatic injuries. Unfortunately, specific quality measures (e.g., arrival to angiography times) have not been widely discussed. Our objective was to evaluate the time interval from arrival to initiation of emergent percutaneous procedures in severely injured patients.

Methods: All severely injured trauma patients (injury severity score [ISS] > 12) presenting to a level 1 trauma centre (2007–2010) were analyzed with standard statistical methodology.

Results: Among 60 severely injured patients (mean ISS 31, hypotension 18%, mortality 12%), the median time interval to the initiation of an angiographic procedure was 270 minutes. Of the procedures performed, 85% were therapeutic embolizations and 15% were diagnostic procedures. Splenic (median time 243 min, range 32–801 min) and pelvic (median time 278 min, range 153–466 min) embolizations accounted for 43% and 25% of procedures, respectively. The median embolization procedure duration for the spleen was 28 (range 15–153) minutes compared with 59 (range 34–171) minutes for the pelvis. Nearly 22% of patients required both an emergent percutaneous and subsequent operative procedure. Percutaneous therapy typically preceded open operative explorations.

Conclusion: The time interval from arrival at the trauma centre to emergent percutaneous procedures varied widely. Improved processes emphasizing patient transition from the trauma bay to the angiography suite are essential. Discussion regarding the appropriate time to angiography is needed so this marker can be used as a quality outcome measure for all level 1 trauma centres.

Contexte : De nos jours, en traumatologie, les soins reposent largement sur des interventions non chirurgicales percutanées d’extrême urgence, particulièrement chez les patients blessés à la rate, au bassin et au foie. Malheureusement, les indices de qualité spécifiques (p. ex., temps écoulé entre l’arrivée et l’angiographie) n’ont pas fait l’objet de discussions approfondies. Notre objectif était de mesurer le temps écoulé entre l’arrivée et l’instauration des interventions percutanées d’extrême urgence chez les grands blessés.


Résultats : Pour 60 patients gravement blessés (IGB moyen 31, hypotension 18 %, mortalité 12 %), le temps écoulé avant l’instauration d’une intervention angiographique a été de 270 minutes. Parmi les interventions effectuées, 85 % ont été des embolisations thérapeutiques et 15 % des interventions diagnostiques. Les embolisations spléniques (temps écoulé médian 243 minutes, intervalle 32–801 minutes) et pelviennes (temps écoulé médian 278 minutes, intervalle 153–466 minutes) ont représenté 43 % et 25 % des interventions, respectivement. La durée médiane de l’intervention d’embolisation dans le cas de la rate a été de 28 (intervalles 15–153) minutes, contre 59 (intervalles 34–171) minutes pour les blessures touchant le bassin. Près de 22 % des patients ont eu besoin d’une intervention percutanée d’extrême urgence et d’une intervention chirurgicale par la suite. Les explorations chirurgicales ouvertes ont généralement été précédées d’un traitement percutané.

Conclusion : Le temps écoulé entre l’arrivée au centre de traumatologie et les interventions percutanées d’extrême urgence varie beaucoup. Il faut, sans contredit, améliorer les processus en soulignant l’importance du transfert des patients de la salle de traumatologie à la salle d’angiographie et poursuivre la discussion sur le temps écoulé avant l’angiographie pour que ce marqueur puisse servir comme paramètre de mesure de la qualité dans tous les centres de traumatologie de niveau 1.
ost preventable deaths from trauma are a consequence of untreated hemorrhage and subsequent early exsanguination. Treatment modalities range from minimally invasive percutaneous techniques to invasive open procedures.

Angiography has emerged as a vital adjunct in the resuscitation of injured patients. As a tool in the armamentarium of trauma care, the role of interventional radiology is no longer purely diagnostic, but instead has evolved into a predominantly therapeutic endeavour. Modern trauma care relies heavily on nonoperative, emergent percutaneous techniques in the management of injured patients with substantial hemorrhage, particularly in patients with splenic, pelvic and hepatic injuries. Furthermore, the American College of Surgeons Committee on Trauma states that both level I and II trauma centres should have timely availability to conventional angiography and to radiology staff with the ability to oversee therapeutic procedures.

Unfortunately, general consensus guidelines are not currently available to define “timeliness” for percutaneous procedures aimed at hemorrhage control. This contrasts both neurologic (stroke) and cardiac (myocardial infarction) sciences, where strict time-based protocols have been in place for years. Furthermore, these guidelines act as important quality metrics.

The primary objective of the present study was to evaluate the waiting time from patient arrival to initiation of any urgent percutaneous procedure in severely injured patients at a level I trauma centre. The secondary goal was to define the type and pattern of percutaneous interventions.

METHODS

We identified all severely injured patients (injury severity score [ISS] ≥ 12) presenting to the Foothills Medical Centre (FMC) between Feb. 1, 2007, and Jan. 31, 2010. The FMC is a Trauma Association of Canada–accredited, level 1 trauma centre serving as the trauma referral facility for southern Alberta, southwestern Saskatchewan and southeastern British Columbia. As a result, more than 2 million people with severe injuries receive care at our centre, which admits more than 1100 of these patients annually. The Alberta Trauma Registry provided data on all patients (age, sex, comorbidities, date of injury, mechanism of injury, length of hospital and ICU stay, type of injuries, ISS, discharge destination, operative and percutaneous procedures, vital signs and mortality). Fidelity was ensured by additional searches of the Alberta Health Services electronic patient medical records; we obtained the waiting times and specific details for all percutaneous procedures from these medical records. The FMC angiography suite is located only a few metres from the trauma bays. We defined hypotension as persistent (at least 2 measurements < 90 mm Hg, measured at any point in the presurgical/angiographic care of the patient [i.e., prehospital or trauma bay]). These hypotensive measurements were taken at a mean interval of 16 minutes. This study was approved by the University of Calgary institutional review board.

Statistical analysis

All analyses were performed using Stata version 12.0 (Stata Corporation). Normally or near-normally distributed variables are reported as means, and non-normally distributed variables are reported as medians. We compared means using the Student t test and medians using the Mann–Whitney U test. We assessed differences in proportions for categorical data using the Fisher exact test. We considered results to be significant at \( p < 0.05 \).

RESULTS

A total of 60 injured patients underwent urgent percutaneous procedures between Feb. 1, 2007, and Jan. 31, 2010. Patient, injury and outcome characteristics are summarized in Table 1. Blunt mechanisms accounted for most (94%) injuries (motor vehicle crashes 65%, falls 22%, assault 7%). Urgent percutaneous procedures were primarily therapeutic, with splenic and pelvic injuries representing the dominant targets (Table 2).

The overall median time from patient arrival to urgent percutaneous procedure was 270 minutes. The median time for urgent percutaneous procedures involving splenic and pelvic arterial embolizations was 243 and 278 minutes, respectively. The median procedure time of splenic embolizations was 28 minutes, while the median duration of pelvic embolizations was 59 minutes. Eleven (18%) injured patients requiring an urgent percutaneous procedure

Table 1. Patients demographic characteristics and outcomes

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients</td>
<td>60</td>
</tr>
<tr>
<td>Age mean (range) yr</td>
<td>36 (15–84)</td>
</tr>
<tr>
<td>Male sex</td>
<td>50 (73)</td>
</tr>
<tr>
<td>ISS</td>
<td>31</td>
</tr>
<tr>
<td>Hypotension at admission (sBP &lt; 90 mm Hg)</td>
<td>11 (18)</td>
</tr>
<tr>
<td>ICU admission</td>
<td>31 (52)</td>
</tr>
<tr>
<td>ICU stay mean (range) d</td>
<td>7 (1–24)</td>
</tr>
<tr>
<td>Mortality</td>
<td>7 (12)</td>
</tr>
<tr>
<td>Discharge status</td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>30 (50)</td>
</tr>
<tr>
<td>Rehabilitation</td>
<td>23 (38)</td>
</tr>
<tr>
<td>Analyte</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>7.26</td>
</tr>
<tr>
<td>Base deficit</td>
<td>–7</td>
</tr>
<tr>
<td>Lactate, mg/dL</td>
<td>2.4</td>
</tr>
<tr>
<td>Massive transfusion protocol employed</td>
<td>5 (8)</td>
</tr>
<tr>
<td>CT before angiography</td>
<td>57 (95)</td>
</tr>
<tr>
<td>Mean RBC transfusion units &lt; 24 h</td>
<td>1.4</td>
</tr>
<tr>
<td>Mean crystalloid resuscitation, L &lt; 24 h</td>
<td>4.45</td>
</tr>
<tr>
<td>Referred from a preceding centre</td>
<td>14 (23)</td>
</tr>
</tbody>
</table>

*Unless otherwise indicated.

CT = computed tomography; ICU = intensive care unit; ISS = injury severity score; RBC = red blood cells; sBP = systolic blood pressure.
presented to the hospital with a systolic blood pressure (sBP) less than 90 mm Hg. The median time to percutaneous procedure in this group of patients was 212 minutes. The rest of the injured trauma patients with an sBP greater than 90 mm Hg had a median time to percutaneous procedure of 259 minutes. Of the patients who presented with hypotension, 8 (73%) responded to fluid resuscitation. The median time to angiography in this subset was 253 minutes. In those who did not respond but who were transferred to the angiography suite (i.e., instead of directly to the operating theatre), the median door to needle time was 49 minutes.

Door to needle times were longer between midnight and 7 am. The overall mean time to percutaneous procedure from 7 am to 5 pm was 299 minutes. This compares to 298 minutes for procedures between 5 pm and midnight, as well as 357 minutes for angiography between midnight and 7 am ($p = 0.041$).

Thirteen (21.7%) injured trauma patients required both an emergent percutaneous and a subsequent open operative procedure. All patients except 1 underwent the percutaneous procedure before the operative intervention (the exception involved preperitoneal pelvic packing followed by embolization). The median time from the percutaneous procedure to the operative intervention in these patients was 2 days. This cohort includes 2 (7.7%) patients who initially underwent splenic artery embolization, 7 (50%) who received pelvic embolization, 1 who underwent internal mammary artery embolization (associated sternal fracture that eventually required a median sternotomy to decompress a mediastinal hematoma) and 1 who received an axillary artery embolization (axillary artery transection that was subsequently treated with an axillobrachial bypass). Patients undergoing splenic artery embolization and operative intervention had a median time of 4 days from the percutaneous procedure to operation. It should be noted that 1 patient underwent repair of a complex acetabular fracture while the other patient had a delayed repair of a missed diaphragmatic injury. The patients undergoing pelvic embolization and subsequent operative intervention also had a median time of 4 days from the percutaneous procedure to operation. All but 1 patient underwent orthopedic fixation of their pelvic fractures after embolization at the discretion of the orthopedic surgery service.

Table 2. Emergent percutaneous procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous</td>
<td></td>
</tr>
<tr>
<td>Diagnostic</td>
<td>9 (15)</td>
</tr>
<tr>
<td>Therapeutic</td>
<td>51 (85)</td>
</tr>
<tr>
<td>Therapeutic target organ</td>
<td></td>
</tr>
<tr>
<td>Spleen</td>
<td>26 (43)</td>
</tr>
<tr>
<td>Pelvis</td>
<td>15 (25)</td>
</tr>
<tr>
<td>Other</td>
<td>10 (17)</td>
</tr>
</tbody>
</table>

**Discussion**

Our study reveals a wide range in waiting times for urgent angiographic procedures in severely injured patients presenting to our trauma centre. It also represents the first time, to our knowledge, that a tertiary referral trauma centre has audited the overall timeliness of obtaining urgent percutaneous procedures in potentially hemorrhaging patients with all types of injury patterns. Although a select few North American centres have suggested local door to needle response times, there is no commonly agreed upon target threshold or quality measure. This fundamentally differs from neurologic and cardiac sciences (90 min). It is also problematic given that delays in angiography have been shown to lead to a 2-fold higher risk of death in injured patients (47% increase with each hour of delay).

While there is a paucity of literature surrounding overall door to needle times, reasonable data exist with regard to pelvic fractures. Tai and colleagues commented that retroperitoneal pelvic packing was as clinically effective as angiography and significantly reduced the 140-minute delay to achieving embolization. Similarly, Osborn and colleagues noted a reduction to hemorrhage control within 45 minutes for pelvic packing compared with 130 minutes for angiography. Finally, although door to needle times are inadequately discussed, Cothren and colleagues also advocate routine peritoneal pelvic packing with a combined operative and subsequent angiography time of 164 minutes. It is interesting to note that although these delays appear much shorter than our overall pelvic fracture door to needle times (median 278 min), the mean time for patients with pelvic fractures and concurrent hypotension that was not responsive to resuscitation in our audit was only 41 min. Certainly the slower percutaneous response times between midnight and 7 am noted in our centre reflect a need for improvement.

We hypothesize that the wide range in waiting times for obtaining emergent percutaneous procedures for injured patients is multifactorial. Clearly a substantial proportion of this time involves activation of the interventional radiology team comprising a radiologist and 2 nurse specialists/technicians. Although the trauma team is onsite 24 hours per day, the door to decision time is entirely under the control of the attending trauma surgeon. This clearly represents an important factor in potential delays and may include variables such as waiting for computed tomography (i.e., to detect vascular extravasation in a hemodynamically stable patient), evaluating a patient’s response to ongoing resuscitation and/or individual surgeon experience and training. Unfortunately, the precise time point at which a trauma surgeon makes the decision to proceed to angiography is not possible to discern in a retrospective audit. Because the door to needle time remains a very crude quality measure, our future prospective study will capture all potential details, including what we believe may be the most important factor: door to decision time.
The subset of injured trauma patients requiring both an emergent percutaneous procedure and an operative intervention requires special mention. Given the liberal access to interventional radiology procedures at our institution (both geographically and personnel-wise), injured patients with splenic and/or pelvic trauma are typically selected on an aggressive basis to undergo emergent embolization. As outlined, there were no observed failures in splenic or pelvic embolizations that required a subsequent operative procedure. Lone “failures” were related to an eventual mediastinal hematoma after an internal mammary arterial laceration and a vascular bypass after arrest of axillary hemorrhage with embolization.

To further improve the response times for obtaining emergent percutaneous procedures in severely injured patients, the concept of a single, hybrid operating suite is becoming more popular. This technology allows emergent percutaneous interventions to be performed in the same physical location as open procedures, resuscitations, general anesthesia and critical care. This advanced resuscitation with angiography, percutaneous techniques and operative repair (RAPTOR) suite would prevent timely delays in transporting injured patients between the trauma bay, operating theatre and/or interventional radiology suite.25

A benefit of this study will be the ability to use waiting times as a quality metric for the performance of our trauma and radiology teams as well as for the planned implementation of the RAPTOR suite. Furthermore, we hope to use these door to needle metrics in future iterations of the Trauma Association of Canada’s trauma centre accreditation process.

CONCLUSIONS

To our knowledge, this is the first formal audit of waiting times for obtaining all urgent percutaneous procedures in severely injured patients. Despite the effectiveness of therapeutic angiography, wide variations in waiting times remain problematic. This data has served as an initial foundation for a prospective waiting time tracking study that we hope can be used as a quality benchmark for both continuous quality improvement and evaluation of the RAPTOR suite.

Competing interests: None declared.

Contributors: J.-F. Ouellet and C. Ball designed the study. A. Smith, J.-F. Ouellet and C. Ball acquired the data, which all authors analyzed. A. Smith, J.-F. Ouellet and C. Ball wrote the article, which all authors reviewed and approved for publication.

References

Comparison of laparoscopic Roux-en-Y gastric bypass with laparoscopic sleeve gastrectomy for morbid obesity or type 2 diabetes mellitus: a meta-analysis of randomized controlled trials

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Background: Laparoscopic Roux-en-Y gastric bypass (LRYGB) is one of the most widely used bariatric procedures, and laparoscopic sleeve gastrectomy (LSG) as a single-stage procedure for treating morbid obesity is becoming more popular. We compared both techniques to evaluate their efficacy in treating morbid obesity or type 2 diabetes mellitus (T2DM).

Methods: We searched the Cochrane Controlled Trials Register databases, Medline, Embase, ISI databases and the Chinese Biomedical Literature Database to identify randomized controlled trials (RCTs) of LRYGB and LSG for morbid obesity or T2DM published in any language. Statistical analyses were carried out using RevMan software.

Results: Five worldwide RCTs with 196 patients in the LRYGB group and 200 in the LSG group were included in our analysis. Compared with patients who had LSG, those who had LRYGB had a higher remission rate of T2MD, lost more weight and had lower low-density lipoprotein, triglycerides, homeostasis model assessment index and insulin levels. There was no difference in the reoperation rate between the groups. However, patients treated with LRYGB had a higher incidence of complication than those treated with LSG.

Conclusion: Our meta-analysis demonstrates that LRYGB is more effective than LSG for the surgical treatment of T2DM and control of metabolic syndrome. However, LSG is safer and has a reduced rate of complications. Further high-quality RCTs with long follow-up periods are needed to provide more reliable evidence.
Obesity and type 2 diabetes mellitus (T2DM) are currently 2 of the most common chronic diseases in Western countries.\textsuperscript{1,2} The growing incidence of obesity and T2DM globally is widely recognized as one of the most challenging contemporary threats to public health.\textsuperscript{3} Uncontrolled diabetes can eventually lead to macrovascular and microvascular complications, including myocardial infarction, stroke, blindness, neuropathy and renal failure in many patients. Obesity and T2DM are closely related and difficult to control by current medical treatment, including diet, drug therapy and behavioural modification.\textsuperscript{4-6} Bariatric surgery is the most effective treatment of morbid obesity and, depending on the type of operation, is also very effective in the resolution of diabetes.\textsuperscript{7} This effect usually occurs even before the start of weight loss owing to changes in the gut hormones and the patient’s diet.\textsuperscript{8}

Laparoscopic Roux-en-Y gastric bypass (LRYGB), currently the preferred bariatric operation, involves 2 surgical alterations: restriction of the gastric volume and diversion of the ingested nutrients away from the proximal small intestine.\textsuperscript{9} In contrast, laparoscopic sleeve gastrectomy (LSG) preserves the integrity of the pylorus and does not include the intestinal bypass. Laparoscopic sleeve gastrectomy is the restrictive part of the biliopancreatic diversion and was initially applied as an isolated operation for super-obese patients with severe comorbidities as a staged concept.\textsuperscript{10} It is mainly a restrictive operation with no mal-absorptive effect. The long-term efficacy of the LSG procedure as a treatment of morbid obesity or T2DM has not been demonstrated; however, it is promising to observe weight loss in the first year after operation.\textsuperscript{11,12} At present, to our knowledge, there is no evidence to demonstrate whether LRYGB or LSG is superior for treating morbid obesity or T2DM.

Meta-analysis is a statistical tool that can be used to evaluate the literature qualitatively and quantitatively, accounting for variations in characteristics that can influence overall estimates of outcomes of interest. To our knowledge, meta-analysis of LRYGB versus LSG for morbid obesity or T2DM has not been performed previously. As deciding what kind of surgery to recommend to patients remains an important issue, we performed a meta-analysis of randomized controlled trials (RCTs) comparing LRYGB with LSG for the treatment of morbid obesity or T2DM.

**Methods**

**Study selection**

We searched the Cochrane Central Register of Controlled Trials, Medline, Embase, ISI databases and the Chinese Biomedical Literature Database for RCTs published in any language between January 1966 and November 2012. Our search terms were “gastric bypass,” “sleeve gastrectomy” and “bariatric surgery.” We manually searched the reference lists of pertinent articles to identify any additional studies relevant to our analysis. Two independent investigators (B.N. and K.-X.S.) reviewed all articles from the previous search based on the following selection criteria. Included studies must have been prospective RCTs comparing gastric bypass with sleeve gastrectomy for morbid obesity or T2DM. Quasirandomized trials, nonrandomized studies, nonhuman studies, nonsurgical interventions, case reports, letters and comments were excluded from our analysis. Finally, when the results of a single study were reported in more than 1 publication, only the most recent and complete data were included in our meta-analysis. Included trials were chosen by the 2 nonblinded authors (J.-F.L. and D.-D.L.). Disagreements were resolved by discussion.

**Assessment of study quality**

The quality of included reports was scored using the Jadad composite scale,\textsuperscript{13} which assesses descriptions of randomization, blinding and dropouts (withdrawals). The quality scale ranges from 0 to 5 points, with a low-quality report receiving a score of 2 points or less and a high-quality report receiving a score of at least 3 points.

**Statistical analysis**

All available trials with reporting data were summarized. Results for continuous outcomes are reported as weighted mean difference (WMD) or standard mean difference, and dichotomous outcomes are reported as odds ratios (ORs) with 95% confidence intervals (CIs). We performed all statistical analyses with RevMan version 5.0. We used the $\chi^2$ statistic to assess heterogeneity among the trials and the $F$ statistic to assess the extent of inconsistency. If there was a significant heterogeneity, we used a random-effects model to confirm the case results. A fixed-effect model for calculations of summary estimates and their 95% CIs was also applied unless there was significant heterogeneity. We considered results to be significant at $p < 0.05$.

**Results**

**Included studies**

Figure 1 shows the selection process from initial review to the inclusion in our meta-analysis. The initial search identified 581 publications, of which 576 were excluded, leaving 5 publications for analysis.\textsuperscript{14-18} One study,\textsuperscript{19} which was the subset of another study,\textsuperscript{14} was excluded; another study\textsuperscript{20} was the republication of the trial by Woelnerhanssen and colleagues\textsuperscript{15} and was also...
excluded. The 5 trials of LRYGB and LSG for morbid obesity or T2DM with a total of 396 patients that we included in our analysis were retrieved from the electronic databases. The study by Lee and colleagues\(^{14}\) was the only trial to study surgical treatment of nonmorbidly obese patients (BMI < 35) with poorly controlled T2DM; the other 4 studies\(^{15–18}\) evaluated surgical treatment of morbidly obese patients (BMI > 35) with or without T2DM. There were 196 patients in the LRYGB group and 200 patients in the LSG group. Standard deviations were not reported in most studies; however, they were estimated either by means of ranges or \(p\) values. The characteristics and quality of each selected study are demonstrated in Table 1, and the outcome variables extracted from these trials are shown in Table 2. The studies were homogeneous in terms of clinical and methodological criteria.

**Remission of T2DM**

Remission of T2DM is defined as fasting plasma glucose levels less than 126 mg/dL in addition to HbA1c values less than 6.5% without the use of oral hypoglycemics or insulin. Three trials\(^{14,15,18}\) reported the remission of T2DM, which was much better in the LRYGB group than in the LSG group (WMD \(-0.42, 95\% CI -0.63 to -0.22, p < 0.001; Fig. 2\)).

**HOMA index**

Insulin resistance was estimated by the HOMA index. Two trials\(^{14,15}\) that reported this outcome demonstrated the LRYGB group had a significantly lower HOMA index than the LSG group (WMD \(-0.42, 95\% CI -0.63 to -0.22, p < 0.001; Fig. 2\)).

**Insulin level**

Two trials\(^{14,15}\) reported insulin level, which was significantly lower in the LRYGB group than in the LSG group (WMD \(-1.27, 95\% CI -2.06 to -0.48, p = 0.002; Fig. 3\)).

**Percent excess weight loss**

Weight loss outcome was defined by percent excess weight loss (%EWL). For all studies, weight loss was reported as mean %EWL\(_d\), defined as (weight loss ÷ excess weight) \times 100. Meta-analyses were performed to examine mean %EWL outcomes separately for the LRYGB and LSG groups. Two studies\(^{14,15}\) reported weight loss. The LRYGB group experienced greater weight loss than the LSG group (WMD 6.76, 95\% CI 4.61–8.91, \(p < 0.001; Fig. 4\)).

**Reoperation**

Two studies\(^{16,17}\) reported reoperation rates; there was no significant difference in reoperation between the groups (OR 1.24, 95\% CI 0.37–4.16, \(p = 0.73; Fig. 2\)).

**Complications**

Three studies\(^{14,16,17}\) reported complications; the LRYGB group had a higher incidence of complications than the LSG group (OR 1.89, 95\% CI 1.07–3.33, \(p = 0.030; Fig. 2\)).

**Triglycerides**

Bariatric surgery had a marked reduction in body weight and improvement of other associated metabolic disorders, including reduction of blood lipid levels. Two studies\(^{14,17}\) reported that the triglycerides level decreased after bariatric surgery, and the LRYGB group had a significantly lower triglycerides level than the LSG group after surgery (WMD \(-0.23, 95\% CI -0.35 to -0.11, p < 0.001; Fig. 3\)).

**Low-density lipoprotein**

Two studies\(^{14,17}\) reported low-density lipoprotein (LDL) level. There was statistical heterogeneity among studies (\(I^2 = 79\%, p = 0.030\)); random-effects models were used in the analysis. The LRYGB group had a significantly lower LDL level than the LSG group (WMD \(-0.73, 95\% CI -1.25 to -0.22, p = 0.005; Fig. 5\)).

---

**Table 1.**

<table>
<thead>
<tr>
<th>Category</th>
<th>Included Studies, (n = 5) (randomized controlled trials)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 2.**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>LRYGB group</th>
<th>LSG group</th>
<th>WMD</th>
<th>95% CI</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remission of T2DM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HOMA index</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent excess weight loss</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reoperation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triglycerides</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low-density lipoprotein</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Despite the large volume of literature devoted to bariatric surgery and diabetes, only a small number of studies have been performed in a comparative way, with a level of evidence of 3 or higher. However, a meta-analysis is a design that allows merging results of small RCTs, increasing the possibility of detecting an intervention effect. To our knowledge, this is the first meta-analysis to date that evaluates data from multiple studies to assess RCTs on LRYGB and LSG for morbid obesity or T2DM.

Our results showed that LRYGB was associated with a higher remission rate of T2DM and that patients who underwent this procedure lost more weight than those who had LSG; gastric bypass may be a better choice for patients with metabolic syndrome or hyperlipidemia. However, the LSG procedure is safer than the more complex LRYGB and avoids the long-term sequela of micronutrient deficiency after duodenum exclusion.

Our meta-analysis revealed that both LRYGB and LSG were effective in the treatment of patients with T2DM in whom current medical treatment had failed. However, the remission rate of T2DM in the LRYGB group was much higher than that in the LSG group. These results corroborate previous reports that gastric bypass may achieve an 80% T2DM remission and that purely restrictive procedures may achieve a rate of about 50%. Besides weight loss, the LRYGB group also achieved a lower blood lipid level. That is why the LRYGB group had a higher metabolic syndrome remission rate than the LSG group. Schauer and colleagues found that obese patients with poorly controlled diabetes treated by either gastric bypass or sleeve gastrectomy combined with medical therapy were significantly more likely to achieve a glycated hemoglobin level of 6.0%. 

### Table 1. Study characteristics and quality evaluation of each selected study

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Jadad score</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Double blind</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
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<tr>
<td>Randomization</td>
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<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Country</td>
<td>Taiwan</td>
<td>Switzerland</td>
<td>Finland</td>
<td>Greece</td>
<td>Spain</td>
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<td>NCT00540462</td>
<td>NCT00356213</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>No. patients</td>
<td>60</td>
<td>23</td>
<td>238</td>
<td>60</td>
<td>15</td>
</tr>
<tr>
<td>LRYGB</td>
<td>30</td>
<td>12</td>
<td>117</td>
<td>30</td>
<td>7</td>
</tr>
<tr>
<td>LSG</td>
<td>30</td>
<td>11</td>
<td>121</td>
<td>30</td>
<td>8</td>
</tr>
<tr>
<td>Follow-up, mo</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>36</td>
<td>12</td>
</tr>
<tr>
<td>BMI</td>
<td>30.3 (25–34)</td>
<td>&gt; 40, with comorbidity</td>
<td>44.6 (35–66)</td>
<td>&lt; 50</td>
<td>&gt; 40 or BMI &gt; 35 with comorbidity</td>
</tr>
<tr>
<td>Condition</td>
<td>T2DM</td>
<td>Nondiabetic morbidity obese</td>
<td>Morbid obesity</td>
<td>Nonsuperobese</td>
<td>Nonsuperobese</td>
</tr>
<tr>
<td>Age, yr</td>
<td>45 (34–58)</td>
<td>&lt; 60</td>
<td>49 (23–67)</td>
<td>NR</td>
<td>18–60</td>
</tr>
<tr>
<td>Deaths</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>NR</td>
</tr>
</tbody>
</table>

BMI = body mass index; LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; NR = not reported; T2DM = type 2 diabetes mellitus.

### Table 2. Outcome measures of included randomized trials

<table>
<thead>
<tr>
<th>Trials</th>
<th>Treatment</th>
<th>Complication</th>
<th>Operation time, median (range) or mean (SD) min</th>
<th>Hospital stay, d</th>
<th>Reoperation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee et al.</td>
<td>LRYGB</td>
<td>4</td>
<td>117</td>
<td>2.2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>LSG</td>
<td>4</td>
<td>127</td>
<td>2.1</td>
<td>0</td>
</tr>
<tr>
<td>Woelnerhanssen et al.</td>
<td>LRYGB</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>LSG</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>0</td>
</tr>
<tr>
<td>Helmiö et al.</td>
<td>LRYGB</td>
<td>31</td>
<td>94 (52–195)</td>
<td>4 (3–16)</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>LSG</td>
<td>16</td>
<td>66 (40–188)</td>
<td>4 (1–22)</td>
<td>3</td>
</tr>
<tr>
<td>Kehagias et al.</td>
<td>LRYGB</td>
<td>3</td>
<td>186 (34.4)</td>
<td>NR</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>LSG</td>
<td>3</td>
<td>126.5 (34.1)</td>
<td>NR</td>
<td>1</td>
</tr>
<tr>
<td>Ramón et al.</td>
<td>LRYGB</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>LSG</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; NR = not reported; SD = standard deviation.
**Fig. 2.**Meta-analysis of studies comparing remission of type 2 diabetes mellitus (T2DM), reoperation and complication rates between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.

**Fig. 3.**Meta-analysis of studies comparing homeostasis model assessment (HOMA) index, insulin, and triglycerides between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.
or less 1 year after randomization than those patients receiving medical therapy alone. Notably, many patients in the surgical group, particularly those in the gastric bypass group, achieved glycemic control without the use of diabetes medications. Although more clinical trials are needed, this meta-analysis and other studies have strongly recommended that LRYGB as a metabolic surgery should be included in the armament of T2DM treatments.

The underlying mechanism for T2DM remission after gastric bypass surgical procedures is intriguing. Four possible mechanisms have been proposed, including the starvation followed by weight loss hypothesis, the ghrelin hypothesis, the upper intestinal (foregut) hypothesis and the lower intestinal (hindgut) hypothesis. None of these theories necessarily precludes the others, so any combination may be operational to some extent; therefore, it is difficult to design a study to elucidate the exact mechanism. The results of our meta-analysis strongly support the finding that the duodenum may play a role in T2DM resolution after bariatric surgery. The rapid postoperative remission of T2DM is primarily related to an improvement in insulin resistance rather than increasing insulin secretion. The difference in insulin resistance in the postoperative period between the 2 procedures found in this meta-analysis also supports the theory that duodenum exclusion is helpful for the reduction of insulin resistance. In recent studies, Korner and colleagues found that reduction of insulin resistance correlated significantly with weight loss only in patients who underwent gastric banding, not in those who had gastric bypass, and Bikman and colleagues found that improved insulin sensitivity after gastric bypass was due to something other than weight loss. Because the duodenum was recently found to have a novel intestine–brain–liver neurocircuit to increase hepatic insulin sensitivity, it is possible that gastrointestinal surgery may help mediate antidiabetes effects, although this is currently unclear. More elaborate studies are needed to elucidate the underlying complex mechanism of T2DM resolution after gastric bypass surgery.

**Limitations**

The main limitation of this meta-analysis is the lack of RCTs with large sample sizes. Another limitation is the lack of long-term follow-up. Without long-term follow-up, we cannot confirm the durability of T2DM remission after surgery and the influence of possible weight change in the future. More elaborate clinical studies are indicated to elucidate this issue.

**CONCLUSION**

In summary, our meta-analysis has demonstrated that LRYGB is more effective than LSG for the surgical treatment of T2DM and control of metabolic syndrome. Patients treated with LRYGB lost more weight than those

---

**Table:**

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>LRYGB</th>
<th>LSG</th>
<th>Mean difference, 95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee 2011</td>
<td>94.4</td>
<td>33.1</td>
<td>18.10 (–0.18, 36.38)</td>
</tr>
<tr>
<td>Woelnerhanssen 2011</td>
<td>34.5</td>
<td>2.7</td>
<td>6.60 (4.43, 8.77)</td>
</tr>
<tr>
<td>Total, 95% CI</td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
</tr>
<tr>
<td>Heterogeneity:</td>
<td>χ² = 1.50, p = 0.22; F = 33%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Fig. 4.** Meta-analysis of studies comparing percent excess weight loss (%EWL) between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>LRYGB</th>
<th>LSG</th>
<th>Mean difference, 95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee 2011</td>
<td>2.51</td>
<td>0.56</td>
<td>–1.03 (–1.46, –0.60)</td>
</tr>
<tr>
<td>Woelnerhanssen 2011</td>
<td>2.6</td>
<td>0.2</td>
<td>–0.50 (–0.71, –0.29)</td>
</tr>
<tr>
<td>Total, 95% CI</td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
</tr>
<tr>
<td>Heterogeneity:</td>
<td>χ² = 0.11; χ² = 4.73, p = 0.22; F = 79%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Fig. 5.** Meta-analysis of studies comparing low-density lipoprotein between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.
treated with LSG. Further high-quality RCTs with large sample sizes and long follow-up periods are needed to provide more reliable evidence.

Competing interests: None declared.

Contributors: J.-F. Li and D.-D. Lai designed the study, acquired the data and wrote the article. B. Ni and K.-X. Sun analyzed the data. J.-F. Li, D.-D. Lai, B. Ni and K.-X. Sun reviewed the article. All authors approved its publication.

References

2. Garber AJ. Obesity and type 2 diabetes: Which patients are at risk? Diabetes Obes Metab 2012;14:399-408.
Outcomes: wedge resection versus lobectomy for non–small cell lung cancer at the Cancer Centre of Southeastern Ontario 1998–2009

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Background: Sublobar resection for non–small cell lung cancer (NSCLC) remains controversial owing to concern about local recurrence and long-term survival outcomes. We sought to determine the efficacy of wedge resection as an oncological procedure.

Methods: We analyzed the outcomes of all patients with NSCLC undergoing surgical resection at the Cancer Centre of Southeastern Ontario between 1998 and 2009. The standard of care for patients with adequate cardiopulmonary reserve was lobectomy. Wedge resection was performed for patients with inadequate reserve to tolerate lobectomy. Predictors of recurrence and survival were assessed. Appropriate statistical analyses involved the $\chi^2$ test, an independent samples $t$ test and Kaplan–Meier estimates of survival. Outcomes were stratified for tumour size and American Joint Committee on Cancer seventh edition TNM stage for non–small cell lung cancer.

Results: A total of 423 patients underwent surgical resection during our study period: wedge resection in 71 patients and lobectomy in 352. The mean age of patients was 64 years. Mean follow-up for cancer survivors was 39 months. There was no significant difference between wedge resection and lobectomy for rate of tumour recurrence, mortality or disease-free survival in patients with stage IA tumours less than 2 cm in diameter.

Conclusion: Wedge resection with lymph node sampling is an adequate oncological procedure for non–small cell lung cancer in properly selected patients, specifically, those with stage IA tumours less than 2 cm in diameter.

Contexte : La résection sous-lobaire pour le cancer du poumon non à petites cellules (CPNPC) demeure controversée en raison du risque de récurrence locale et des perspectives de survie à long terme. Nous avons voulu déterminer l’efficacité de la résection cunéiforme en tant qu’intervention oncologique.

Méthodes : Nous avons analysé les résultats pour tous les patients atteints d’un CPNPC soumis à une résection chirurgicale au Centre oncologique du Sud-Est de l’Ontario entre 1998 et 2009. Chez les patients qui présentaient une réserve cardiaque ou pulmonaire insuffisante, la norme thérapeutique était la lobectomie. Les patients dont la réserve était insuffisante pour tolérer une lobectomie ont subi une résection cunéiforme. Les prédicteurs de récurrences et de survie ont été évalués. Les analyses statistiques appropriées ont inclus le test $\chi^2$, le test $t$ et les estimations de Kaplan–Meier de la survie. Les résultats ont été stratifiés en fonction de la taille et du stade de la tumeur selon la septième édition de la classification TNM de l’American Joint Committee on Cancer pour le CPNPC.

Résultats : En tout, 423 patients ont subi une résection chirurgicale au cours de la période couverte par notre étude : résection cunéiforme chez 71 patients et lobectomie chez 352 patients. L’âge moyen des patients était de 64 ans. Le suivi moyen pour les survivants du cancer a été de 39 mois. On n’a noté aucune différence significative entre la résection cunéiforme et la lobectomie aux plans des récurrences tumorales, de la mortalité ou de la survie sans maladie chez les patients qui présentaient des tumeurs de stade IA de moins de 2 cm de diamètre.

Conclusion : La résection cunéiforme avec exérèse des ganglions lymphatiques est une intervention oncologique appropriée pour le CPNPC chez les patients adéquatement sélectionnés, plus précisément, chez ceux qui ont des tumeurs de stade IA de moins de 2 cm de diamètre.
Surgical resection in the form of lobectomy or pneumonectomy remains the standard of care for stage I and II non–small cell lung carcinoma (NSCLC) despite advances in chemotherapy and radiation therapy. Owing to the primary causative relationship of smoking to NSCLC and associated cardiopulmonary comorbidities, many patients are deemed medically unfit to withstand full lobectomy. The best management for these patients remains controversial; many modalities are available, necessitating further investigation on this topic. These modalities include sublobar resection (wedge resection or anatomic segmental resection), observation, conventional fractionated or stereotactic body radiotherapy (SBRT) and radiofrequency ablation. Many surgeons still prefer sublobar resections over SBRT and ablative therapies despite successful local control rates having been reported with SBRT, particularly by Timmerman and colleagues. Controversy remains as to whether sublobar resections are adequate oncologic procedures for patients with severely impaired pulmonary function who could not withstand lobectomy. This relates to concern that despite preservation of pulmonary function, tumour resection margins may be compromised with inadequate nodal sampling, possibly understaging the primary tumour. This could lead to increased rates of local and systemic recurrence and decrease disease-free and overall survival.

All but 1 previous study examining sublobar resections for NSCLC have been retrospective in nature, many revealing conflicting results. The prospective trial by Ginsberg and Rubinstein concluded that lobectomy was preferred over limited resections owing to decreased rates of local recurrence. This landmark study did not account for tumour diameter or location of the early-stage lesions. It has since been postulated that sublobar resection is an adequate oncologic surgery for peripheral lesions less than 2 cm in diameter, especially in the setting of a second primary lung cancer, adenocarcinoma in situ, or ground-glass opacities. All previous studies have used the sixth edition American Joint Committee in Cancer (AJCC) tumour-node-metastasis (TNM) classification and focused on comparing outcomes of segmental resection to lobectomy. Only 1 previous non–Canadian study has focused on comparing outcomes of wedge resection to lobectomy; however, this study also used the sixth edition AJCC TNM classification. The purpose of the present study was to determine whether there is a significant difference in tumour recurrence and survival in patients who undergo wedge resections versus lobectomy for NSCLC based on the seventh edition AJCC TNM classification and thus to determine whether wedge resection is an adequate oncologic procedure to offer patients.

METHODS

This was a retrospective analysis of all patients who underwent lung resection for NSCLC at the Cancer Centre of Southeastern Ontario for the fiscal years 1998 to 2009. All patients were pathologically staged according to the seventh edition AJCC TNM classification. Lobectomy or pneumonectomy was the standard of care performed for patients with adequate pulmonary function. Sublobar resection was reserved for patients with cardiopulmonary comorbidities precluding lobectomy. We compared the outcomes of patients who underwent either of these 2 procedures during the study period. This study received research ethics board approval from the research ethics board at Queen’s University in Kingston, Ont.

We collected data on basic demographics (age, sex), patient comorbidities (coronary artery disease, chronic obstructive pulmonary disease [COPD], diabetes), operative details (type of surgery, anatomic location), tumour pathological characteristics (margin status, histology, differentiation, presence of lymphatic or vascular invasion), disease recurrence, mortality (including cause of death) and morbidity (prolonged air leak, cardiac arrhythmia).

Primary outcomes included incidence of local–regional and distant recurrence, disease-free survival and overall survival. Disease recurrence was defined as the incidence of recurrent carcinoma (local–regional or distant), disease-free survival was the time from surgery to diagnosis of recurrent carcinoma, and overall survival was the time from surgery to death or last known follow-up. Secondary outcomes included length of hospital stay and postoperative complications, including prolonged air leak and cardiac arrhythmia. Prolonged air leak was defined as an air leak from the chest tube lasting more than 5 days. Cardiac arrhythmia was defined as an acute change in the patients’ electrocardiogram to display atrial fibrillation, atrial flutter or multifocal atrial tachycardia (MAT).

Statistical analysis

Data were entered in Excel and imported into PASW Statistics (SPSS Inc.) for analysis. Following a descriptive analysis (means, standard deviations and medians for continuous data, frequencies for categorical data), continuous data were plotted to assess the normality of the distribution. We used χ² tests (Pearson or Fisher exact, as appropriate) to compare the lobectomy and wedge groups on categorical data, such as sex, comorbidities and complications. We performed independent samples t tests to compare the groups on age and tumour diameter and the nonparametric Mann–Whitney U test to compare the groups on length of stay in hospital. We used Kaplan–Meier analysis to compare the groups on time to recurrence. We also performed subset analyses for cancer stage, tumour stage and smoking status.

RESULTS

A total of 352 patients underwent lobectomy and 71 patients underwent wedge resection. Clinical outcomes were balanced between the cohorts for age, sex, smoking,
neoadjuvant and adjuvant chemoradiotherapy (Table 1). The mean time to recurrence was 22 months in patients who underwent lobectomy and 21 months in those who underwent wedge resection; mean follow-up after surgery was 39 months and 37 months, respectively, and mean follow-up after recurrence was 14 months and 13 months, respectively. The mean age of patients was 64.7 (range 28–82) years. Most patients were smokers (388, 91.7%). Patient who underwent wedge resections were more likely to have COPD by spirometry than those who underwent lobectomy (46.5% v. 28.9%, p = 0.004). The groups were balanced with respect to the presence of other significant comorbidities, such as coronary artery disease, diabetes and substance abuse (Table 1).

With respect to pathological outcomes, distribution of tumour histology, margin status, differentiation and presence of lymphatic or vascular invasion were also balanced between cohorts (Table 2). Patients who underwent wedge resection were more likely than those who underwent lobectomy to have a smaller tumour diameter (p < 0.001) and to have a tumour less than 2 cm in size (p = 0.009). They also tended to have stage IA disease (p = 0.021).

Table 3 shows the disease-free survival and overall survival, by tumour stage and by cancer stage, for patients in the lobectomy and wedge resection groups. Between-group differences in disease-free survival existed for both tumour stage and cancer stage (p = 0.043 and p = 0.008, respectively), but between-group differences in overall survival fell short of significance (p = 0.08 and p = 0.09, respectively).

In comparing surgical outcomes between the 2 cohorts there was a trend that patients who underwent lobectomy had a longer stay in hospital than those who underwent wedge resection (7.7 d v. 6.8 d, p = 0.09), although the median values (6 d) were the same. There was no significant difference in 30-day mortality (4 deaths in the lobectomy group v. 2 in the wedge resection group). There were higher rates of prolonged air leak in the lobectomy group than the wedge resection group (12.5% v. 7%, p = 0.19), but the sample was too small to reach statistical significance. Similarly there were higher rates of atrial fibrillation, flutter and MAT in the lobectomy group than the wedge resection group (6% v. 1.4%); however, this difference did not attain statistical significance.

For disease-free survival there was no significant difference between wedge resection and lobectomy (p = 0.59).

### Table 1. Clinical characteristics of patients undergoing surgical resection for non–small cell lung cancer, by surgical procedure

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group; no (%)*</th>
<th>Lobectomy</th>
<th>Wedge resection</th>
<th>p value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age mean, yr</td>
<td></td>
<td>64.7</td>
<td>64.9</td>
<td>0.78</td>
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<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td>0.48</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td>165 (46.9)</td>
<td>30 (42.3)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>187 (53.1)</td>
<td>41 (57.7)</td>
<td></td>
</tr>
<tr>
<td>Smoker</td>
<td></td>
<td>323 (96.1)</td>
<td>65 (88.5)</td>
<td>0.48</td>
</tr>
<tr>
<td>Comorbidities</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Coronary artery disease</td>
<td></td>
<td>87 (24.9)</td>
<td>19 (26.8)</td>
<td>0.74</td>
</tr>
<tr>
<td>COPD</td>
<td></td>
<td>101 (28.9)</td>
<td>33 (46.5)</td>
<td>0.004</td>
</tr>
<tr>
<td>Psychiatric</td>
<td></td>
<td>33 (9.4)</td>
<td>6 (8.4)</td>
<td>0.80</td>
</tr>
<tr>
<td>Type II diabetes</td>
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<td>34 (9.7)</td>
<td>6 (8.5)</td>
<td>0.74</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Adjuvant</td>
<td></td>
<td>57 (16.9)</td>
<td>10 (14.9)</td>
<td>0.70</td>
</tr>
<tr>
<td>Neoadjuvant</td>
<td></td>
<td>7 (2.1)</td>
<td>1 (1.5)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Tumour stage</td>
<td></td>
<td></td>
<td></td>
<td>0.007</td>
</tr>
<tr>
<td>T1a</td>
<td></td>
<td>96 (27.3)</td>
<td>27 (38.9)</td>
<td></td>
</tr>
<tr>
<td>T1b</td>
<td></td>
<td>86 (24.4)</td>
<td>16 (22.5)</td>
<td></td>
</tr>
<tr>
<td>T2a</td>
<td></td>
<td>117 (33.2)</td>
<td>18 (25.4)</td>
<td></td>
</tr>
<tr>
<td>T2b</td>
<td></td>
<td>23 (6.5)</td>
<td>2 (2.8)</td>
<td></td>
</tr>
<tr>
<td>T3</td>
<td></td>
<td>28 (8.0)</td>
<td>4 (5.6)</td>
<td></td>
</tr>
<tr>
<td>T4</td>
<td></td>
<td>2 (0.6)</td>
<td>2 (2.8)</td>
<td></td>
</tr>
<tr>
<td>Cancer stage; AJCC seventh ed.</td>
<td></td>
<td></td>
<td></td>
<td>0.020</td>
</tr>
<tr>
<td>IA</td>
<td></td>
<td>146 (41.5)</td>
<td>35 (49.3)</td>
<td></td>
</tr>
<tr>
<td>IB</td>
<td></td>
<td>68 (19.3)</td>
<td>16 (22.5)</td>
<td></td>
</tr>
<tr>
<td>II A</td>
<td></td>
<td>81 (23.0)</td>
<td>4 (5.6)</td>
<td></td>
</tr>
<tr>
<td>IIB</td>
<td></td>
<td>29 (8.2)</td>
<td>5 (7.0)</td>
<td></td>
</tr>
<tr>
<td>III A</td>
<td></td>
<td>26 (7.4)</td>
<td>11 (15.5)</td>
<td></td>
</tr>
<tr>
<td>III B</td>
<td></td>
<td>1 (0.3)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td></td>
<td>1 (0.3)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

AJCC = American Joint Committee in Cancer; COPD = chronic obstructive pulmonary disease.

*Unless otherwise indicated.
†All tests are χ² tests (Pearson or Fisher exact, as appropriate) with the exception of age, which was based on a t test.

### Table 2. Pathological characteristics of patients undergoing surgical resection for non–small cell lung cancer, by surgical procedure

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group; no (%)*</th>
<th>Lobectomy</th>
<th>Wedge resection</th>
<th>p value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumour size, mean, cm</td>
<td></td>
<td>3.3</td>
<td>2.5</td>
<td>0.002</td>
</tr>
<tr>
<td>T1a; AJCC seventh ed.</td>
<td></td>
<td>96 (27.3)</td>
<td>27 (38)</td>
<td>0.007</td>
</tr>
<tr>
<td>Stage IA; AJCC seventh ed.</td>
<td></td>
<td>146 (41.5)</td>
<td>35 (49.3)</td>
<td>0.021</td>
</tr>
<tr>
<td>Histology, no (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.44</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td></td>
<td>230 (65.5)</td>
<td>53 (74.6)</td>
<td></td>
</tr>
<tr>
<td>Squamous cell</td>
<td></td>
<td>94 (26.7)</td>
<td>15 (21.1)</td>
<td></td>
</tr>
<tr>
<td>Adenosquamous</td>
<td></td>
<td>9 (2.6)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Large cell</td>
<td></td>
<td>12 (3.4)</td>
<td>3 (4.2)</td>
<td></td>
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<tr>
<td>Other</td>
<td></td>
<td>5 (1.4)</td>
<td>0</td>
<td></td>
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<tr>
<td>Tumour differentiation</td>
<td></td>
<td></td>
<td></td>
<td>0.38</td>
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<tr>
<td>Well</td>
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<td>46 (13.3)</td>
<td>11 (16.2)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td></td>
<td>134 (38.7)</td>
<td>19 (27.9)</td>
<td></td>
</tr>
<tr>
<td>Poor</td>
<td></td>
<td>154 (44.5)</td>
<td>36 (52.9)</td>
<td></td>
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<tr>
<td>Undifferentiated</td>
<td></td>
<td>12 (3.5)</td>
<td>2 (2.9)</td>
<td></td>
</tr>
<tr>
<td>Invasion present</td>
<td></td>
<td></td>
<td></td>
<td>0.038</td>
</tr>
<tr>
<td>Lymphatic</td>
<td></td>
<td>87 (25.3)</td>
<td>21 (30.4)</td>
<td>0.38</td>
</tr>
<tr>
<td>Vascular</td>
<td></td>
<td>101 (29.4)</td>
<td>18 (26.5)</td>
<td>0.63</td>
</tr>
</tbody>
</table>

AJCC = American Joint Committee in Cancer.

*Unless otherwise indicated.
†All tests are χ² other than tumour size, which was assessed using a t test.
There was also no difference in overall tumour recurrence (36.8% v. 35%, respectively, \( p = 0.78 \)) or in overall mortality (37.3% v. 32.7%, respectively, \( p = 0.46 \)).

When the cohorts were stratified by tumour size, there was no significant difference in disease-free survival for patients with tumours less than 2 cm in diameter (\( p = 0.65 \); Fig. 1). There was, however, a significant difference in disease-free survival in favour of lobectomy for patients with tumours larger than 5 cm in diameter (\( p = 0.001 \)). For patients with tumours less than 2 cm, the hospital stay was significantly longer for those who underwent lobectomy than those who underwent wedge resection (7.9 d v. 6.2 d, \( p = 0.043 \)), which was also reflected in the median values (6 d and 5 d, respectively). We observed a trend toward higher rates of prolonged air leak in the lobectomy group compared with the wedge resection group (18.9% v. 6.1%, respectively, \( p = 0.10 \)). There was no significant difference between the lobectomy and wedge resection cohorts for

### Table 3. Tumour and cancer stage–specific disease-free survival and overall survival rates

<table>
<thead>
<tr>
<th>Stage*</th>
<th>Group; no. (%)</th>
<th>Disease-free survival</th>
<th>Overall survival</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lobectomy, ( n = 223 )</td>
<td>Wedge resection, ( n = 43 )</td>
<td>( p ) value†</td>
</tr>
<tr>
<td>T1a</td>
<td>67 (30.0)</td>
<td>18 (41.9)</td>
<td>0.043</td>
</tr>
<tr>
<td>T1b</td>
<td>58 (26.0)</td>
<td>9 (20.9)</td>
<td>75 (24.5)</td>
</tr>
<tr>
<td>T2a</td>
<td>67 (30.0)</td>
<td>11 (25.6)</td>
<td>73 (31.3)</td>
</tr>
<tr>
<td>T2b</td>
<td>15 (6.8)</td>
<td>1 (2.3)</td>
<td>12 (5.1)</td>
</tr>
<tr>
<td>T3</td>
<td>14 (6.3)</td>
<td>3 (7.0)</td>
<td>20 (9.0)</td>
</tr>
<tr>
<td>T4</td>
<td>2 (0.9)</td>
<td>0</td>
<td>2 (0.9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cancer stage</th>
<th>Group; no. (%)</th>
<th>Disease-free survival</th>
<th>Overall survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>I A</td>
<td>110 (49.3)</td>
<td>107 (45.9)</td>
<td>23 (53.5)</td>
</tr>
<tr>
<td>IB</td>
<td>43 (19.2)</td>
<td>45 (19.3)</td>
<td>9 (20.9)</td>
</tr>
<tr>
<td>II A</td>
<td>39 (17.5)</td>
<td>46 (19.8)</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>II B</td>
<td>19 (8.5)</td>
<td>22 (9.5)</td>
<td>2 (4.7)</td>
</tr>
<tr>
<td>II A</td>
<td>10 (4.5)</td>
<td>11 (4.7)</td>
<td>8 (18.6)</td>
</tr>
<tr>
<td>II B</td>
<td>1 (0.5)</td>
<td>1 (0.4)</td>
<td>0</td>
</tr>
<tr>
<td>IV</td>
<td>1 (0.5)</td>
<td>1 (0.4)</td>
<td>0</td>
</tr>
</tbody>
</table>

AJCC = American Joint Committee on Cancer.
* Tumour stage and cancer stage are based on the AJCC, seventh edition.
† \( p \) values are based on the Pearson \( \chi^2 \) test.

### Table 4. Outcomes for patients with tumours smaller than 2 cm in diameter

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group; no. (%)*</th>
<th>Disease-free survival</th>
<th>Overall survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumour recurrence</td>
<td>Lobectomy, ( n = 96 )</td>
<td>Wedge resection, ( n = 33 )</td>
<td>( p ) value†</td>
</tr>
<tr>
<td>Distant, brain, bone, adrenal</td>
<td>26 (27.7)</td>
<td>8 (26.7)</td>
<td>0.92†</td>
</tr>
<tr>
<td>Regional; mediastinal or hilar lymph nodes</td>
<td>11</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Local; within lung parenchyma</td>
<td>6</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Overall mortality</td>
<td>24 (25)</td>
<td>6 (19.4)</td>
<td>0.52†</td>
</tr>
<tr>
<td>Complication; prolonged air leak</td>
<td>18 (19.9)</td>
<td>2 (6.1)</td>
<td>0.10†</td>
</tr>
<tr>
<td>Length of hospital stay, mean d</td>
<td>7.9</td>
<td>6.2</td>
<td>0.043†</td>
</tr>
<tr>
<td>Tumour diameter, mean cm</td>
<td>1.6</td>
<td>1.5</td>
<td>0.13†</td>
</tr>
</tbody>
</table>

* Unless otherwise indicated.
† \( \chi^2 \) test.
‡ Mann–Whitney U test.

![Fig. 1. Kaplan–Meier estimates of disease-free survival in patients who underwent lobectomy compared with those who underwent wedge resection for tumours smaller than 2 cm in diameter (\( p = 0.65 \)).](image)
patients with tumours smaller than 2 cm for recurrence (27.7% v. 26.7%, respectively, p = 0.92) or overall mortality (25% v. 19.4%, respectively, p = 0.52; Table 4). When tumours were stratified based on the seventh edition AJCC TNM classification, there were no significant differences in outcomes encountered for tumour stage and overall stage IA and IB disease.

**DISCUSSION**

This Canadian study carried out at a tertiary care university hospital is unique in that it predominantly compares wedge resection (as opposed to segmental resection) with lobectomy for the surgical management of NSCLC. In addition, the groups were stratified by tumour size and based on the seventh edition AJCC TNM classification. We observed similar rates of disease-free and overall survival for patients with early-stage NSCLC undergoing lobectomy and wedge resection.

**Limitations**

The limitations of this study arise primarily from its retrospective nature and 11-year duration. Some patient data on preoperative cardiopulmonary assessment (pulmonary function and echocardiography test results) were simply not available. However, given our institution’s adherence to widely accepted guidelines (Cancer Care Ontario, American College of Chest Physicians and National Comprehensive Cancer Network guidelines) for the conduct of preoperative assessment and pulmonary resection, along with the demographic and comorbidity data provided, readers are still able to extrapolate the applicability of these results to their own patients. In addition, during the 11-year course of this study, practice standards regarding lymph node assessment and adjuvant therapy protocols changed. We strongly feel that this would not have affected the results substantially, given that only those patients with the smallest tumours (≤ 2 cm) who underwent wedge resection had similar survival to those who underwent lobectomy. These patients would have been unlikely to receive chemotherapy, even with the new standard of care.

It is important to recognize that patients with compromised pulmonary reserve may be more likely to die sooner than those without compromised pulmonary reserve of causes other than lung cancer recurrence, thus potentially decreasing overall survival and artificially inflating the disease-free survival in this group. Furthermore, patients who underwent wedge resection were more likely to have documented COPD than those who underwent lobectomy. In addition, the wedge resection cohort was selected to have smaller (< 2 cm), earlier staged tumours (stage IA or IB) than the lobectomy cohort. For tumours smaller than 2 cm in size, patients who underwent lobectomy had a significantly increased length of hospital stay. This may be due to the complication of prolonged air leak, for which we observed a trend toward higher rates.

**CONCLUSION**

These data demonstrate that in properly selected patients wedge resection for NSCLC has the potential to be an adequate oncologic procedure. Specifically, the eligible patient groups include those with small tumours (< 2 cm in diameter) and seventh edition AJCC stage IA or IB disease. This is supported by similar rates of disease-free and overall survival observed in these cohorts. Furthermore, we await the results of the ongoing National Cancer Institute of Canada Clinical Trials Group phase III randomized trial of lobectomy versus sublobar resection for tumours smaller than 2 cm in patients with peripheral NSCLC (BRC.5 CALGB 140503) to learn whether similar survival outcomes to those in our retrospective analysis can be observed in the prospective setting.

**Competing interests:** None declared.

**Contributors:** A. McGuire designed the study and acquired the data, which all authors analyzed. A. McGuire and W. Hopman wrote the article, which all authors reviewed and approved for publication.

**References**


Surgical instructors often predetermine the details of training sessions, such as the order of practised tasks, the duration of practice, and timing and type of feedback, while the trainee remains relatively passive. Such training environments are often not tailored to the informational needs of individual learners and, as such, are likely to be suboptimal learning environments. However, as surgical training programs contend with limited instructor availability and time allotted to teach fundamental technical skills, there is a trend toward the use of self-directed learning modules (e.g., CD-ROM and online programs) that require learners to be more active and independent. Recent research suggests that self-directed practice might assist surgical educators in creating learning environments that better support trainees’ motivation to practise by meeting changing informational needs. A study conducted by Jowett and colleagues demonstrated that skill performance for tying knots was unaffected by practice enforced after trainees decided they had reached proficiency and did not require further practice. These researchers speculated that the learning environment (e.g., simulation model and instructions) remained unchanged after the trainees reached a certain proficiency on the skill and therefore did not provide any additional benefit to learning. Studies using laboratory, sporting and surgical tasks have shown that motor learning can be facilitated if the learner is able to self-direct various aspects of their training experience, such as frequency of feedback, access to video instructions and order of practised tasks.

Surgical educators have also begun to consider how other aspects of the training environment, such as distribution and schedule of practice, can be optimized to enhance motor learning within time constraints. With respect to practice schedules, the literature has shown that performance during acquisition of related tasks practised in a random or unsystematic order (e.g., ACB, BAC, ABC, for 3 tasks A, B and C) is impaired compared with performance of tasks in blocked or drill-type order (e.g., AAA, BBB, CCC). Interestingly, however, after a rest period, performance is better on a delayed test for random practice compared with blocked practice. This phenomenon is referred to as the contextual interference effect and is often explained by the forgetting hypothesis, which suggests that practice that forces the learner to repetitively forget and recall the required skills, such as random practice, will enhance delayed performance. This is important because, unlike immediate postpractice performance, which often represents transient practice effects, delayed tests are more likely to reflect relatively permanent improvement in ability (i.e., learning). Since the motor learning literature has shown the contextual interference effect to be greatest for simple laboratory tasks, researchers have begun to explore its applicability to more complex tasks in the surgical domain. While these studies have shown divergent results, they highlight the fact that, in the surgical domain, interactions between performance and practice variability can be affected by task difficulty.

While there is some evidence supporting random and self-directed practice in the surgical domain, to our knowledge, no studies have examined both practice schedule and the selection of practice schedule for the same surgical skill. The purpose of this study was to determine how practice schedule (random or blocked) and selection of practice schedule (self-directed or prescribed) contribute to learning of suturing skills. We hypothesized that self-directed and random practice schedules would produce better postpractice performance than the other prescribed practice schedules.

**METHODS**

**Participants**

We recruited first- and second-year medical students from the University of Toronto to participate in our study. The University of Toronto and Mount Sinai Hospital Research Ethics Boards approved the research protocol, and all participants provided voluntary informed consent.

**Procedure**

Each participant viewed an 8-minute instructional video of an expert demonstration of 3 types of wound closure skills: simple interrupted, vertical mattress and horizontal mattress. Using Sofsilk 3–0 silk sutures (United States Surgical Corporation, Cvidien), a synthetic skin pad (Limbs & Things), curved needle, forceps and a needle driver, all participants performed a pretest consisting of 1 trial of each of the 3 sutures without any feedback or access to the instructional video. Each participant was then randomly assigned to 1 of 4 practice schedule groups: self-directed, random, blocked or matched control. Participants in the self-directed group were free to choose their practice schedules with the constraint that by the end of practice they had performed 5 trials of each suture type. The random and blocked groups received prescribed practice protocols and practised the 3 suture types in the orders outlined in Table 1. Participants in the matched control group served as a control, such that each participant in this group was prescribed exactly the same practice schedule as 1 participant from the self-directed group. The difference between the random and self-directed groups (other than the prescription of the practice schedule) is that the random group had a truly random schedule whereas the self-directed group may have selected elements of both blocked and random patterns in their schedules. During practice, all participants were free to review the instructional video as frequently as they wished. After the practice session there was a rest interval of 1 hour followed by a posttest administered in the same manner as the pretest.
 Statistical analysis

The pretest and posttest performances were videotaped and used to obtain measures of performance to assess learning. First, total time to complete each suture (performance time), from the first needle puncture in the skin pad to cutting of the final sutures, was extracted from each video. Second, the pretest videos were independently assessed by 2 experts blinded to the experimental condition or group. The expert observers used 3 validated measures to assess performance across all 3 suture techniques: a global rating scale of operative performance $^{17}$ (maximum score 35), a checklist for suture of skin laceration $^{17}$ (maximum score 11) and a final product analysis $^{18}$ (maximum score 4). These scores were used to assess interrater agreement and consistency by calculating single-measures intra class correlation coefficients (ICCs) with 95% confidence intervals (CIs) using a 2-way, random-effects model with both absolute agreement and consistency methods. Absolute agreement implies that the raters assigned similar scores (absolute values) for similar performances, whereas consistency means that the raters’ scores followed similar trends for the performances even if the absolute scores were not the same. For formative or summative classroom-type assessment, reliability is expected to be in the range of 0.70–0.79 or lower depending on the length of the test/number of test items.$^{19}$

One rater then went on to score the posttest videos using the same measures. Difference scores were calculated for performance time and each of the validated measures by subtracting the pretest score from the posttest score. The difference scores were analyzed in separate 4-group 1-way analyses of variance. We considered effects to be significant at $p < 0.05$, and they were further analyzed using the Tukey honestly significant difference method for post hoc comparison of means. We also calculated Cohen $d$ effect sizes (using average standard deviations) to help determine the importance of group effects independent of sample size. Effect sizes at 0.2, 0.5 and 0.8 were considered small, medium and large, respectively.

Results

Thirty-eight first- and second-year medical students (20 women and 18 men with a mean age of 23 yr) from the University of Toronto participated in our study. Ten participants were randomly assigned to the self-directed group, 9 to the random group, 10 to the blocked group and 9 to the matched control group. Inspection of the practice schedules selected by the participants in the self-directed group showed that 7 of 10 participants chose a blocked practice schedule. The order of the blocks was the same as the order of suture types demonstrated on the instructional video. The remaining 3 participants chose a hybrid schedule that was predominantly blocked, but had some elements of randomization that appeared later in practice.

Interrater consistency and agreement

Intraclass correlations were calculated for the 2 raters who viewed the pretest videos to determine whether scores from 2 independent raters were consistent and/or in agreement. As seen in Table 2, the ICCs indicated that there was moderate agreement and consistency between the raters for each measurement tool (global rating scale, checklist, final product analysis). The global rating scale had the highest agreement and consistency, followed by the checklist and the final product analysis. However, overlap among the CIs suggests that there were no significant differences in agreement or consistency among the measurement

<table>
<thead>
<tr>
<th>Trial</th>
<th>Random</th>
<th>Blocked</th>
<th>P1</th>
<th>P2</th>
<th>P3</th>
<th>P4</th>
<th>P5</th>
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H = horizontal mattress suture; S = simple interrupted suture; V = vertical mattress suture.
tools. The ICCs were all in the range 0.50–0.70, which we believe is acceptable considering the number of items used for each measurement tool. Since we determined that the scores were fairly stable across raters, only 1 rater continued evaluation of the posttest videos.

**Performance time**

Means and standard errors for differences in performance time from pretest to posttest are shown in Figure 1. The analysis of performance time showed a main effect of group for the simple suture \( F_{3,27} = 4.04, p = 0.017 \). Tukey post hoc comparisons indicated that self-directed participants decreased their performance time significantly more than both the blocked \( p = 0.036 \) and matched control \( p = 0.040 \) groups. Further, the effect sizes for both these comparisons \( d = 1.2 \) and \( d = 1.3 \), respectively, exceeded Cohen’s convention for a large effect. Performance times for the other 2 suture techniques (horizontal and vertical mattress) showed similar patterns, but these effects were not significant.

**Expert ratings**

The analyses of the expert ratings did not show any significant effects of group. However, as seen in Figure 2, the trends suggest that on average the self-directed group demonstrated greater or similar improvements from pretest to posttest, particularly using the global rating scale. These results are similar to those for performance time of the simple suture. In fact, since these trends were similar, we calculated Cohen’s \( d \) effect sizes to compare each group to the self-directed group. The effect sizes were \( d = 1.1, d = 1.3 \) and \( d = 0.8 \) for comparisons of the self-directed group with the random, blocked and matched control groups, respectively.

**DISCUSSION**

Our results demonstrate that when compared with the blocked and matched control groups, the self-directed group experienced a significant improvement in performance time for the simple interrupted suture. Furthermore, both these effect sizes were large, suggesting that these effects may have practical importance for training of suturing skills. Our analysis of expert evaluations using a global rating scale, checklist and final product analysis yielded no significant group effects, but trends were similar to those observed for performance time. In addition, effect size calculations for the global ratings showed large effects for comparisons between the self-directed group and all other practice groups, suggesting that these results are also important for future research in this area.

Unlike most studies in the basic motor control literature but in line with the surgical training literature, our results do not support the contextual interference effect; that is, they do not show a learning advantage for random compared with blocked practice. This suggests that random

![Table 2. Summary of intraclass correlation coefficients* indicating agreement and consistency between 2 expert raters for pretest scores](image)

**Table 2. Summary of intraclass correlation coefficients* indicating agreement and consistency between 2 expert raters for pretest scores**

<table>
<thead>
<tr>
<th>Measurement tool</th>
<th>Absolute agreement</th>
<th>Consistency</th>
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<tbody>
<tr>
<td>Global rating scale</td>
<td>0.64 (0.20–0.84)</td>
<td>0.73 (0.51–0.87)</td>
</tr>
<tr>
<td>Checklist</td>
<td>0.55 (0.21–0.77)</td>
<td>0.61 (0.32–0.80)</td>
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<tr>
<td>Final product analysis</td>
<td>0.50 (0.20–0.71)</td>
<td>0.55 (0.27–0.74)</td>
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CI = confidence interval; ICC = intraclass correlation coefficient.

*Single measures ICC based on 2 raters; 95% CI for estimate of ICC.

![Fig. 1. Comparison of means (with standard errors) for differences in performance time (posttest – pretest) for each practice group performing each type of suture.](image)

![Fig. 2. Comparison of means (with standard errors) for differences in expert evaluation scores (posttest – pretest) using the global rating scale, checklist and final product analysis for each practice group.](image)
**IS THE CULTURE OF SURGERY STILL A GENDER ISSUE?**

We read Brown and colleagues’ recent article on culture transition in surgery with interest. We agree with the accompanying editorial by Harvey; that this is an important addition to the literature and that open, frank discussion is needed from the profession. We feel that some of their points merit further exploration.

The authors highlight 2 key factors influencing the culture and future of our profession: the (slow) movement toward gender balance and a generationally driven attitudinal shift. They study how “new” recruits perceive these changes by interviewing 17 surgeons (9 women, 8 men), all of whom are assistant professor level or higher; have a mean age of 38 years; and are in heterosexual relationships. The ethnic profile of the sample was not reported.

We would suggest that interviewing this sample, though of interest, might in fact miss the point; the authors have sought the views of the “new establishment.” All of the participants of the study have become established academic surgeons, some against well-defined, albeit diminishing, barriers. They have opted to stay in the profession, in some cases alongside the added commitments of motherhood. In the UK, 90% of those in surgical training decide on this path during their first year postqualification with a similar gender ratio, yet far fewer women ultimately achieve their goal. Women initially attracted to surgery move away from this career option during their postgraduate education; this attrition was previously attributed to lifestyle considerations. We would postulate that the same may be true of some black and minority ethnic groups, and possibly also lesbian, gay, bisexual and transgendered surgical trainees. Interviewing a cohort from these groups — those who chose not to enter the profession they were initially drawn to — may cast further light on gender and cultural issues within surgery and underscore why it has been perceived for so long as an “old boys’ club” with ongoing discrimination.

Brown and colleagues cite a lack of mentoring as 1 potential reason for our profession’s loss of talent. We would support this claim. In our experience and the experience of others, access to mentors is limited not only for women but also for other minorities in this professional arena. Formalized mentoring programs that seek to pair candidates with suitably matched (but not necessarily demographically similar) mentors, and the use of mentoring frameworks, may help people to achieve successful mentoring relationships. Raising awareness for mentoring and mentor acquisition as early as possible in surgical careers (i.e., medical school) may also benefit potential surgeons.

Positive role models have been shown to significantly impact career choices. From our personal experience, role models are limited for Generation Y female potential surgeons. We agree with the study, that increasingly this is not a gender issue; men, too, want a better work–life balance to pursue portfolio careers while having flexibility for more time at home and the opportunity to travel. Certain aspects of surgery as a career (e.g., emergency work, management of complications, unpredictability of surgical pathology, competition for attaining training posts) inherently clash with these aspirations; however, we believe that broad-minded individuals with ambition within and outside of medicine are assets to any workforce.

Surgical trainees with the Generation Y value set should be encouraged into, not dissuaded from, surgical specialties. This will not happen passively; it requires a strategic approach involving enhanced child care options, job sharing and flexible contracts, and signposting of role models and mentoring opportunities. It requires a culture change within our profession.

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DOI: 10.1503/cjs.021213

**References**


**THE AUTHORS RESPOND**

We appreciate the thoughtful response from McGrath, Brew and Warren. We acknowledge that we interviewed those who overcame the
challenges of postgraduate training and became academic surgeons. We question whether they would perceive themselves as the “new establishment,” though we will concede that to be successful these individuals have agreed to the expectations of their department and their academic institution. We recognize that many surgical trainees leave training programs and many academic surgeons leave university departments to go into community practice because they cannot, or will not, make the compromises required to deal with the demands of their roles. We agree that many capable women leave surgical training or drop out of academic surgery because of the difficulty of combining family and professional roles.

We also acknowledge the limitations of our study group. We were interested in the case study represented by a department of surgery that intentionally set out to change the gender mix and to change policies to be more “family friendly.” We would contend that departments of surgery can make choices about how to support women and men during their training and as faculty members, and these choices will make trainees more likely to be successful. This is an evolutionary rather than a revolutionary approach.

Our paper indicates the critical importance of mentorship. If mentors are not assigned or identified in one’s own department, individuals need to look elsewhere—to national surgery organizations or other national organizations such as the Canadian Medical Association, which has a mentorship program to faculty members outside of surgery.

Again, we thank the authors for their comments and observations, all directed at inclusiveness in surgical training and academic pursuits.

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COMMENT ON “COMPARISON OF THE MAJOR INTRAOPERATIVE AND POSTOPERATIVE COMPlications BETWEEN UNILATERAL AND SEQUENTIAL BILATERAL TOTAL KNEE ARTHROPLASTY IN A HIGH-VOLUME COMMUNITY HOSPITAL”

It was with great interest that we read the recent article by Spicer, Thomas and Rumble, which provides an insight into the safety of unilateral total knee arthroplasty (UTKA) versus sequential or simultaneous bilateral total knee arthroplasty (BTKA) in a high-volume community hospital. The authors excluded from their study patients who underwent staged TKA, defined as “2 distinct surgeries on both knees within a 1-year period.” Instead, candidates with bilateral knee symptoms who were deemed eligible for surgery were given the option of BTKA or 2 UTKAs.

In our experience with patients who present with bilateral fixed flexion deformities, even if a UKA is initially successful, it may develop stiffness and adopt the fixed flexion of the contralateral knee if the latter is not likewise replaced within a few months. Residual flexion contractures after knee replacement have been associated with poor outcomes.

The limitation of movement and impact on quality of life caused by a residual flexion contracture should be considered a complication in itself. This complication might be avoided by performing a BTKA or careful pre- and postoperative management to safely complete staged TKA procedures in considerably less than 1 year. Although it seems reasonable that “individuals who decline the second operation may have been better served by a 1-step BTKA,” the alternative is perhaps more relevant to orthopedic departments where there is less experience and expertise in performing BTKAs.

The merits of BTKA versus staged TKA have been extensively discussed in the literature. Reduced costs, single anesthetic and decreased total recovery time have been highlighted as advantages of BTKA, but an increased risk of serious postoperative complications have also been reported. We hope that future studies will continue to objectively evaluate the risks and benefits of each, and identify which patients might be more suited to a particular method.

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DOI: 10.1503/cjs.027313

References


THE AUTHORS RESPOND

We thank Razii and Morgan-Jones for their comments regarding our study that compared the incidence of serious perioperative complications between unilateral and bilateral total knee replacements.

They make the additional observation that replacing 1 knee when the patient has a deformity in both knees presents difficulties with rehabilitation and may compromise the outcome for the knee. We agree that this may very well be the case, though it was not the focus of our study.

They also comment on the omission of staged procedures, in which the 2 knees are replaced on separate occasions within the first year. In our hospital there were only 69 such patients during the time frame of our study, which did not reach statistical significance; hence, we omitted them.

They encourage further study to “identify which patients might be more suited to a particular method.” This may be useful to surgeons in different settings. In our case, we found that replacing both knees under 1 anesthetic was safe in the setting of a high-volume community hospital.

Once again, we appreciate the feedback.

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practice does not facilitate improved performance for this particular skill (suturing) and adds support to the idea that random practice does not always confer an advantage for learning, particularly for more complex skills like those often explored in the surgical domain. One may argue that the 3 suture types used were quite similar, with only minor variations in the details of the general suturing task. It is then possible that these small variations may not be enough to force the learner to forget and recall the skills; hence, not enough to produce the contextual interference effect. However, in a recent review, Merbah and Meulemans conclude that for more complex applied tasks, the contextual interference effect can appear even when there are variations only within the same type of task. This notion of task complexity and its interactions with motor learning effects should always be considered and is addressed in the challenge point framework, described by Guadagnoli and Lee. They proposed that the effectiveness of a particular practice condition depends on an interaction between the difficulty of the task and the expertise of the learner. It is possible that, for the medical students who participated in the present study, the psychomotor demands of learning 3 suturing techniques, as well as the difficulty of each technique, already taxed their cognitive and attentional resources such that the added cognitive demands imposed by random practice did not help learning.

Consistent with the challenge point framework, our results also showed a learning advantage for individuals who practised using a self-directed schedule. This advantage over a matched control group has been previously shown for various aspects of practice and can be ascribed to increased autonomy, which likely allows the participant to adapt the learning experience to his or her specific needs and may also result in increased motivation, more instances of deliberate practice and improved motor learning. However, the advantage of a self-directed practice schedule over prescribed random and blocked practice is particularly interesting. Despite having chosen predominantly blocked schedules and changing to a random schedule later in the training phases, the self-directed group experienced superior learning. Furthermore, since the benefit of a self-directed practice schedule was significant only for the simplest suture technique, it is possible that increased task difficulty (and greater cognitive load) imposed by more difficult suture techniques reduced the advantage of a self-directed practice schedule for the horizontal and vertical mattress suture techniques. This emphasizes the complex interaction of task difficulty and training conditions that are required for optimal learning. Nonetheless, the self-directed learning advantage that we observed is consistent with the literature that has been produced using basic laboratory tasks and now adds to the emerging work in the clinical skills domain, particularly for self-directed practice schedules as opposed to self-directed feedback or access to instructional materials.

Limitations

While this study is an important first step in understanding the role of practice schedules and instructional methods in learning surgical skills, we believe that more research is required to examine the impact of practice schedules for a variety of surgical tasks performed by surgeons with various skill levels. Furthermore, the generalizability of our results is limited to this particular skill, the population that was tested and the short time period over which we assessed learning effects. We are currently looking at similar processes in surgical residents to examine whether increased skill levels have any interaction with the already reported benefits to self-directed practice. Since our results were different across suturing techniques, we believe that in future studies and in practice, researchers and trainers should take care to examine component skills in a training program and so identify specific areas where trainees may require extra practice or instruction.

CONCLUSION

Many surgical skill centres are now offering 24-hour access to their facilities; however, instructors are often not available to provide expert direction during off-hours, leaving trainees to manage their own practice sessions. Our findings suggest that self-directed practice schedules within a curriculum may contribute to optimal learning of basic technical skills, such as simple suturing.

Competing interests: None declared.

Contributors: O. Safir, A. Dubrowski, D. Backstein and H. Carnahan designed the study. O. Safir acquired and analyzed the data, which was also analyzed by C.K. Williams. O. Safir, C.K. Williams, A. Dubrowski and H. Carnahan wrote the article. C.K. Williams, D. Backstein and H. Carnahan reviewed the article. All authors approved its publication.

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References

Patterns of use and outcomes for radiation therapy in the Quality Initiative in Rectal Cancer (QIRC) trial

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Lehana Thabane, PhD‡§
Charles H. Goldsmith, PhD‡§
Mark N. Levine, MD†‡¶
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Background: The Quality Initiative in Rectal Cancer (QIRC) trial targeted surgeon intraoperative technique and not radiation therapy (RT) use. We performed a post hoc analysis of RT use among patients in the QIRC trial, not by arm of trial but rather for the entire group. We wished to identify associations between local recurrence risk and use of preoperative, postoperative or no RT

Methods: We compared demographic, tumour and process of care measures among patients receiving preoperative, postoperative or no RT. A multivariable Cox regression model assessed local recurrence risk.

Results: The QIRC trial enrolled 1015 patients at 16 hospitals between 2002 and 2004. Radiation therapy use did not differ between trial arms, and median follow-up was 3.6 years. For the preoperative, postoperative and no RT groups, respectively, the percentage of patients was 12.8%, 19.3% and 67.9%; the percentage of stage II/III tumours was 57.0%, 88.7% and 48.1%; and the local recurrence rate was 5.3%, 10.2% and 5.5% (p = 0.05). After controlling for patient and tumour characteristics, including tumour stage, the hazard ratio (HR) for local recurrence was increased in the postoperative RT versus the no RT group (HR 1.64, 95% confidence interval 1.04–2.58, p = 0.027).

Conclusion: Use of preoperative RT was low; most patients with stage II/III disease did not receive RT and, as expected, the postoperative RT group had the highest risk of local recurrence. Our results suggest opportunities to improve rectal cancer RT use in Ontario.

Contexte : L’essai QIRC (Quality Initiative in Rectal Cancer) portait sur la technique peropératoire des chirurgiens et non sur l’utilisation de la radiothérapie (RT). Nous avons effectué une analyse rétrospective de l’utilisation de la RT chez les patients inclus dans l’essai QIRC, non pas en fonction des différents groupes de l’essai, mais en fonction de sa population entière. Nous avons voulu vérifier les liens entre le risque de récurrences locales et l’utilisation préopératoire ou postopératoire de la RT ou l’abstention de toute RT.

Méthodes : Nous avons comparé les paramètres démographiques, les caractéristiques de la tumeur et le processus de soins chez les patients soumis à une RT préopératoire ou postopératoire, ou non traités par RT. Un modèle de régression multivariée de Cox a permis d’évaluer le risque de récurrences locales.

Résultats : L’essai QIRC a regroupé 1015 patients de 16 hôpitaux entre 2002 et 2004. Le recours à la radiothérapie n’a pas différé entre les groupes de l’essai, et le suivi médian a été de 3,6 ans. Pour ce qui est des groupes soumis à une RT préopératoire ou postopératoire, ou non soumis à la RT, respectivement, le pourcentage de patients était de 12,8 %, 19,3 % et 67,9 %; le pourcentage de tumeurs de stade II/III était de 57,0 %, 88,7 % et 48,1 %, et le taux de récurrences locales, de 5,3 %, 10,2 % et 5,5 % (p = 0,05). Après ajustement pour tenir compte des caractéristiques des patients et des tumeurs, y compris le stade de la tumeur, le risque relatif (RR) de récurrences locales a augmenté dans le groupe soumis à une RT postopératoire par rapport au groupe non soumis à la RT (RR 1,64; intervalle de confiance de 95 %, 1,04–2,58, p = 0,027).

Conclusion : Le recours à la RT préopératoire a été faible; la plupart des patients atteints d’une maladie de stade II/III n’ont pas reçu de RT et comme prévu, le groupe soumis à une RT postopératoire a présenté le risque le plus élevé de récurrences locales. Nos résultats indiquent qu’il serait possible d’améliorer l’utilisation de la RT pour le cancer rectal en Ontario.
A negative outcome following rectal cancer surgery is local tumour recurrence in the pelvis. Prospective randomized trials have demonstrated that pelvic radiation can reduce post-surgical rates of local recurrence and that radiation is more effective when given in the preoperative versus the postoperative setting. However, an improvement in survival has not been consistently shown. The introduction of improved surgical techniques known as total mesorectal excision (TME) has led to marked reductions in the risks of local recurrence. The recent MRC-CR07 trial showed that patients receiving preoperative radiation therapy (RT) and high-quality surgery had a local recurrence rate of only 1%. Clinical leaders in jurisdictions around the world have integrated the results of rectal cancer radiotherapy trials in different ways. For example, for most patients with stage II or III rectal cancer, guidelines in Ontario encourage the use of preoperative or postoperative long-course chemoradiation. In British Columbia, the preference is for patients with stage II or III rectal cancer to receive preoperative short-course RT (i.e., delivered over 1 wk). In Sweden, most patients with rectal cancer are deemed appropriate for preoperative short-course RT, whereas in Norway only a minority of patients receive any form of RT.

The Quality Initiative in Rectal Cancer (QIRC) trial tested if a quality improvement strategy would lead to improvements in hospital rates of local recurrence and permanent stoma among patients undergoing rectal cancer surgery. Surgeon-directed interventions included workshops, access to opinion leaders, operative demonstrations, audit and feedback, and postoperative questionnaires. Despite excellent participation, the trial results were negative (i.e., results in the intervention and control arms were similar). The interventions were designed to optimize surgeon intraoperative technique, not to optimize other surgical decisions, such as the use of RT.

For the present study we assessed factors influencing RT use, and we correlated patterns of RT use (e.g., preoperative, postoperative, no RT) to rates of local recurrence and permanent stoma at initial surgery. We assessed RT use among the entire study group, not by trial arm. Of note, during the period of study accrual, approximately 25% of all patients undergoing rectal cancer surgery in Ontario did so at trial hospitals. Thus, our findings likely reflect how RT is used across the province for patients with rectal cancer.

**Methods**

The study received ethics approval from the Hamilton Health Sciences Research Ethics Board.

**The QIRC trial**

The QIRC trial protocol and primary results have been published elsewhere. Patients were eligible for trial inclusion if they underwent major surgery for rectal cancer. Rectal tumours were located within 15 cm of the anal verge by rigid sigmoidoscopy, or were at or below the level of the sacral promontory. All patients with stage II or III tumours would have been eligible to receive pre- or postoperative RT according to Ontario guidelines. Consecutive patients at each site were accrued to avoid the potential bias of excluding patients with tumours at relatively greater risk for negative outcomes.

Sixteen hospitals were cluster-randomized to the QIRC strategy (experimental arm) or to continue with routine practice (control arm). The surgeon-directed QIRC strategy consisted of workshops, access to opinion leaders, operative demonstrations, postoperative questionnaires, and audit and feedback. Eight experimental arm hospitals and 8 control arm hospitals enrolled patients between May 2002 and December 2004. Use of the QIRC strategy did not decrease rates of local recurrence or permanent stoma.

**Data collection and follow-up**

Hospital charts were reviewed within 2 weeks of surgery and every 3 months thereafter. In Ontario, all RT is delivered at a small number of regional cancer centres. We reviewed charts from regional cancer centres to collect data on patient adjuvant treatments (RT and chemotherapy) and study outcomes. Data were collected for a minimum of 30 months; follow-up was longer for patients who enrolled near the beginning of the trial. Data collected included patient (age, sex, comorbidities), tumour (distance from the anal verge; size; tumour-node-metastasis [TNM] staging; differentiation; presence of vascular, lymphatic or perineural invasion) and process of care (number of lymph nodes counted, mesorectal margin status, use of preoperative pelvic computed tomography [CT]) measures. For staging data, postoperative pathology reports were used to determine T and N categories. Thus, there was likely some understaging in the preoperative RT group.

**Study groups and outcomes**

Patients from the 2 arms of the trial were combined, and then divided into 3 groups: patients receiving preoperative RT, postoperative RT or no RT. We compared rates of local recurrence and permanent stoma among these groups. Many patients in routine practice may end up with a permanent stoma despite this not being the expected result of the original surgery.
However, we were most interested in how surgeons approached their choice of initial surgical procedure and use of RT. Thus we defined permanent stoma as an abdominoperineal resection at initial surgery. Local recurrence in the pelvis was ideally confirmed by biopsy, but any pelvic mass on cross-sectional imaging with associated worsening symptoms of pain or pressure, or deteriorating bowel or sexual function was classified as a local recurrence. The QIRC trial did not mandate specific follow-up tests. However, a local rectal cancer recurrence inevitably results in a return visit to a regional cancer centre for palliative radiation, chemotherapy, or another hospital-based service. Ongoing chart reviews at hospitals and cancer centres ensured that data from such interactions would be abstracted.

**Statistical analysis**

We used the $\chi^2$ test for categorical variables and the Student $t$ test for continuous variables to assess differences among the 3 groups in patient and tumour variables and in treatment and outcome measures. We used a proportional hazards Cox regression model to assess the risk of local recurrence over time while controlling for patient and tumour variables, arm of trial and the clustering of data at the hospital level. We did not consider chemotherapy in our multivariable model since previous QIRC trial analyses demonstrated a marked clustering of data at the hospital level. We did not consider chemotherapy in our multivariable model since previous QIRC trial analyses demonstrated a marked correlation between use of RT and use of chemotherapy. For all tests, we considered results to be significant at $p < 0.05$. Analyses were conducted using SAS, SPlus and StatXact software.

**RESULTS**

The QIRC trial involved 8 experimental arm hospitals (56 surgeons, 558 patients) and 8 control arm hospitals (49 surgeons, 457 patients). Patients were followed for a median of 3.6 years. For the experimental and control arms, respectively, the rate of permanent stoma was 39% and 41% (odds ratio [OR] 0.97, 95% confidence interval [CI] 0.63–1.48, $p = 0.88$) and the rate of local recurrence was 7% and 6% (OR 1.06, 95% CI 0.68–1.64, $p = 0.80$). For the entire study cohort, the percentages of patients in the preoperative, postoperative and no RT groups were 12.8%, 19.3% and 67.9%, respectively (Table 1). Preoperative RT was usually delivered using long-course protocols, with only 15% of preoperative cases receiving the short-course 5-day protocol favoured in many European centres. Patients who received RT were younger ($p < 0.001$), more likely to be male ($p = 0.009$) and less likely to have comorbidities ($p = 0.011$).

Patients who received preoperative RT had tumours significantly closer to the anal verge (median distance 5 cm from the verge) than patients receiving postoperative or no RT (median distance 10 cm from the verge, $p < 0.001$; Table 2). Nearly all patients in the postoperative RT group had stage II or III tumours, while nearly one-third of patients in the no RT group had stage I tumours ($p < 0.001$). Of note, most (57.2%) patients with stage II or III tumours were in the no RT group. In Ontario, such patients would have been eligible for consideration of some form of RT. Patients in the postoperative RT group had tumours with less favourable characteristics, such as presence of vascular, lymphatic or neural invasion ($p < 0.001$) and moderate to poor differentiation ($p < 0.001$).

Most (73.1%) patients in the preoperative RT group received a preoperative pelvic CT scan compared with only about half in the postoperative and no RT groups.

### Table 1. Characteristics of patients with rectal cancer

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Preoperative radiation</th>
<th>Postoperative radiation</th>
<th>No radiation</th>
<th>$p$ value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients</td>
<td>130 (12.8)</td>
<td>196 (19.3)</td>
<td>689 (67.9)</td>
<td></td>
</tr>
<tr>
<td>Age, median, yr</td>
<td>65</td>
<td>65</td>
<td>71</td>
<td>&lt; 0.001‡</td>
</tr>
<tr>
<td>Male sex</td>
<td>89 (68.5)</td>
<td>136 (69.4)</td>
<td>407 (59.1)</td>
<td>0.009</td>
</tr>
<tr>
<td>Comorbidities ≥1</td>
<td>23 (17.7)</td>
<td>42 (21.4)</td>
<td>194 (28.2)</td>
<td>0.011</td>
</tr>
</tbody>
</table>

†Comparison of postoperative and no radiation only, owing to possible downsizing in preoperative radiation group.

### Table 2. Tumour characteristics of patients with rectal cancer

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group, no. (%)*</th>
<th>Preoperative radiation</th>
<th>Postoperative radiation</th>
<th>No radiation</th>
<th>$p$ value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients</td>
<td>130 (12.8)</td>
<td>196 (19.3)</td>
<td>689 (67.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance from anal verge, median cm</td>
<td>5.0</td>
<td>10.0</td>
<td>10.0</td>
<td>&lt; 0.001‖</td>
<td></td>
</tr>
<tr>
<td>Tumour size, median cm</td>
<td>2.7</td>
<td>4.5</td>
<td>4.0</td>
<td>&lt; 0.001‖</td>
<td></td>
</tr>
<tr>
<td>TNM stage‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage I</td>
<td>28 (21.5)</td>
<td>6 (3.1)</td>
<td>221 (32.1)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Stage II</td>
<td>37 (28.5)</td>
<td>62 (31.6)</td>
<td>150 (21.8)</td>
<td></td>
<td></td>
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<tr>
<td>Stage III</td>
<td>37 (28.5)</td>
<td>112 (57.1)</td>
<td>161 (26.3)</td>
<td></td>
<td></td>
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<tr>
<td>Stage IV</td>
<td>13 (10.0)</td>
<td>13 (6.6)</td>
<td>86 (12.5)</td>
<td></td>
<td></td>
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<tr>
<td>Unable to stage</td>
<td>15 (11.5)</td>
<td>3 (1.5)</td>
<td>51 (7.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vascular, lymphatic, neural invasion</td>
<td>25 (19.2)</td>
<td>81 (41.3)</td>
<td>174 (25.3)</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Preoperative radiation</th>
<th>Postoperative radiation</th>
<th>No radiation</th>
<th>$p$ value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histologic grade</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate or poor</td>
<td>96 (73.8)</td>
<td>181 (92.3)</td>
<td>555 (80.6)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Positive circumferential radial margin‡</td>
<td>13 (10.0)</td>
<td>24 (12.2)</td>
<td>48 (7.0)</td>
<td>0.048</td>
</tr>
</tbody>
</table>

†Mann–Whitney U test.

‡Comparison of postoperative and no radiation only, owing to possible downsizing in preoperative radiation group.

§Positive circumferential radial margin = distance ≤ 1 mm.

¶Mann–Whitney U test.

‖Chi-square.
(p < 0.001; Table 3). The median number of lymph nodes examined was lowest at 8 in the preoperative RT group compared with 12 and 10 in the postoperative RT and the no RT groups, respectively (p < 0.001). It is known that preoperative RT will lower lymph node counts.15

For patients in the preoperative, postoperative and no RT groups, respectively, the rate of permanent stoma was 53.8%, 27.0% and 22.5% (p < 0.001), while the rate of local recurrence was 5.4%, 10.2% and 5.5% (p = 0.05). The higher stoma rate in the preoperative group is not surprising given the much lower median tumour location in this group. For these same groups, and considering only patients with stage II or III tumours, the rates of local recurrence changed little: 5.3%, 9.8% and 7.0%, respectively (p = 0.39).

Controlling for arm of trial; relevant patient and tumour variables, including tumour stage; and the clustering of data at the hospital level, compared with the no RT group, the risk of local recurrence was similar in the preoperative group (hazard ratio [HR] 0.92, 95% CI 0.37–2.33, p = 0.88) and higher in the postoperative group (HR 1.64, 95% CI 1.04–2.58, p = 0.027; Table 4).

**Discussion**

The QIRC trial tested whether surgeon-directed interventions could improve patient outcomes by encouraging optimal intraoperative techniques for rectal cancer surgery. The QIRC strategy did not attempt to influence surgeons on their use of RT. The present study is a secondary analysis of RT use and patient outcomes among all QIRC trial patients. The results are presented by mode of RT delivery and thus should not be viewed as reflecting the utility of RT. Rather, they likely reflect the decision-making of surgeons before or after surgery in response to information that may not have been available for our analyses. Therefore, it is inappropriate to infer causality between study results and study group (e.g., postoperative RT leads to a higher risk of local recurrence, or preoperative RT leads to a higher risk of permanent stoma). However, our findings do suggest opportunities to improve RT use in Ontario in patients with rectal cancer.

Studies have shown that RT is more effective in the pre- versus the postoperative setting.1,2,4 This may be because of a greater probability of patients completing planned treatment, improved effectiveness of RT in tissues that are optimally oxygenated and the absence of scar tissue, which may protect sequestered cancer cells from radiation. Yet in the QIRC trial only 12.8% of patients received preoperative RT, representing only 39.9% of all patients receiving RT. In addition, patients in the preoperative RT group were more likely to have tumours close to the anal verge, and more than half received an abdominopерineal resection at initial surgery—a higher percentage than patients receiving postoperative or no RT. We do not suggest that preoperative RT increases the risk of permanent stoma. Rather, our results suggest that tumour location, not tumour stage, largely drove the use of preoperative RT in the QIRC trial.

We also observed that 21.5% of patients in the preoperative RT group had stage I tumours at final pathology. While tumour downstaging may have occurred in some patients, it is unlikely that this occurred in one-fifth of patients in the preoperative group, as we observed. A recent trial from Germany randomly assigned patients with stage II or III tumours to pre- or postoperative chemoradiation.2 After surgery, 18% of patients in the postoperative therapy arm were found to actually have stage I tumours and thus were incorrectly assessed for trial eligibility. It is likely that reserving preoperative RT for patients with stage II or III tumours will result in a substantial number of patients with stage I tumours receiving RT. Stakeholders should consider strategies to increase the percentage of patients receiving preoperative RT while improving staging accuracy. The routine use of preoperative magnetic resonance imaging (MRI) should help.19

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**Table 3. Process of care and outcome measures**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group</th>
<th>No. (%)</th>
<th>p value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients</td>
<td>130 (12.8)</td>
<td>196 (19.3)</td>
<td>689 (67.9)</td>
</tr>
<tr>
<td>Process of care measures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative CT</td>
<td>95 (73.1)</td>
<td>102 (52.0)</td>
<td>340 (49.3)</td>
</tr>
<tr>
<td>No. lymph nodes examined, median</td>
<td>8</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Permanent colostomy at initial surgery</td>
<td>70 (53.8)</td>
<td>53 (27.0)</td>
<td>155 (22.5)</td>
</tr>
<tr>
<td>Local recurrence</td>
<td>7 (5.4)</td>
<td>20 (10.2)</td>
<td>38 (5.5)</td>
</tr>
<tr>
<td>Local recurrence for stage II/III</td>
<td>4/74 (5.4)</td>
<td>17/174 (9.8)</td>
<td>23/331 (6.9)</td>
</tr>
</tbody>
</table>

CT = computed tomography.  
*Unless otherwise indicated.  
†Mann–Whitney U test.

---

**Table 4. Multivariable clustered analysis of risk of local recurrence**

<table>
<thead>
<tr>
<th>Group</th>
<th>HR (95% CI)</th>
<th>p value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>1.00</td>
<td>Reference group</td>
</tr>
<tr>
<td>Experimental group</td>
<td>0.99 (0.61–1.61)</td>
<td>0.98</td>
</tr>
<tr>
<td>Radiation group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No RT</td>
<td>1.00</td>
<td>Reference group</td>
</tr>
<tr>
<td>Preoperative RT</td>
<td>0.92 (0.37–2.33)</td>
<td>0.88</td>
</tr>
<tr>
<td>Postoperative RT</td>
<td>1.64 (1.04–2.58)</td>
<td>0.027</td>
</tr>
</tbody>
</table>

CI = confidence interval; HR = hazard ratio; RT = radiation therapy.
*Adjusted for data at hospital level. Controlling for age; sex; comorbidities; stage; distance of tumour from anal verge; tumour size; histologic grade; any vascular, lymphatic, neural invasion; and positive circumferential radial margin.
Patients receiving postoperative RT were more likely to have tumours with moderate/poor differentiation, lymphovascular or neural invasion and a positive circumferential radial margin. Such factors may indicate a more aggressive cancer and may act as prompts for surgeons to consider postoperative RT. In addition, nearly all patients receiving postoperative RT had stage II or III tumours, in concordance with provincial guidelines. These observations may explain why the post-RT group had the higher risk of local recurrence (10%). However, in the no RT group, the rate of local recurrence among patients with stage II or III tumours was only 7%. It may be that patients who received postoperative RT had other negative prognostic indicators that were obvious to the involved surgeon but not to the investigators after data abstraction from pathology and other patient reports. Such confounding variables could include final appearance or overall quality of the TME specimen, a likely reflection of the difficulty of surgery. But if such difficult operations could be anticipated through preoperative imaging and physical findings (i.e., threatened mesorectal margin), RT would ideally be provided preoperatively.

Again, our concern is not that there was higher risk of local recurrence in the postoperative RT group, but rather that stakeholders should devise strategies to minimize the use of postoperative RT overall and increase the use of preoperative RT for appropriate patients.

Findings in the no RT group are in keeping with those of previously published work. Patients in this group were more likely to be older, to have more comorbidities, to be women and to have a stage I tumour. Radiation therapy has associated short-term morbidities and long-term risks and is more likely to be avoided in older patients or in those with more comorbidities. Men may be more likely to receive RT than women owing in part to the expected difficulty with the narrow male pelvis and concerns of close radial margins. In Ontario, it is not recommended that patients with stage I rectal cancer receive RT.

There was an inadequate use of preoperative cross-sectional imaging. Such imaging can assess the local extent of the tumour, especially for rectal tumours beyond the reach of the digital rectal examination, and can also assess metastatic disease. Findings should influence discussions on the role of surgery and RT. Such imaging of the abdomen and pelvis was used in 73.1%, 52.0% and 49.3% of patients in the preoperative, postoperative and no RT groups, respectively. Of note, during the years of the trial there was no use of preoperative pelvic MRI, something that is quickly becoming a standard of care.

In our multivariable model assessing 3 study groups demarcated by mode of RT delivery, controlling for tumour, trial arm and study group variables, tumour stage did not influence the risk of local recurrence. This parallels the primary analyses of the QIRC trial, where stage of tumour did not impact risk of local recurrence. This finding challenges the current Ontario paradigm that all patients with stage II and III tumours should receive some form of RT. Of note, 57.2% of all patients with stage II or III tumours did not receive RT, and the rate of local recurrence among these patients was only 7.0%. It is possible that in the setting of high-quality surgery, the use of RT can be reserved for patients with a threatened mesorectal margin and less influence attributed to tumour stage.

Limitations

The limitations of this study include the fact that the QIRC trial was not designed specifically to look at RT use, and there is the possibility that relevant factors were not assessed or considered. For example, surgeon preferences and recommendations to patients may have been based on personal expertise and experiences. Also, we were not able to account for patient choice. In addition, complications related to surgery were not captured, which may also affect discussions on the use of postoperative RT. The present study followed patients for a median of only 3.6 years; however, it is known that RT can delay the appearance of local recurrences. Thus a longer follow-up period in our study may have revealed more patients with local recurrence in the 2 RT groups only, a finding that would not substantively change our observations or conclusions. Finally, only 16 hospitals were involved in the trial, and only 2 sites were teaching hospitals. Thus, our data may not be representative of RT use in patients with rectal cancer across the province. However, in Ontario, 70% of rectal surgery is performed at nonteaching hospitals and, as mentioned, sites participating in the QIRC trial treated approximately 25% of all patients with rectal cancer in the province. In addition, previous research using Ontario data has demonstrated similar outcomes following colorectal cancer surgery at teaching versus nonteaching hospitals. Thus our findings are likely representative of RT use across the province.

Conclusion

In the present study, use of preoperative RT was low and was largely reserved for patients with tumours relatively near the anal verge. Most patients with stage II or III rectal cancer did not receive pre- or postoperative RT, and patients who received postoperative RT had the highest risk of local recurrence. Our results suggest opportunities to improve RT use in patients with rectal cancer in Ontario.

Competing interests: None declared.

Contributors: M. Levine and M. Simunovic designed the study. A. Coates, L. Thabane and M. Simunovic acquired the data, which V. Francescutti, A. Coates, L. Thabane, C.H. Goldsmith and M. Simunovic analyzed. V. Francescutti and M. Simunovic wrote the article. All authors reviewed the article and approved its publication.

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References

Timeliness in obtaining emergent percutaneous procedures in severely injured patients: How long is too long and should we create quality assurance guidelines?

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Daniel Niven, MD‡
Andrew W. Kirkpatrick, MD**†‡
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Background: Modern trauma care relies heavily on nonoperative, emergent percutaneous procedures, particularly in patients with splenic, pelvic and hepatic injuries. Unfortunately, specific quality measures (e.g., arrival to angiography times) have not been widely discussed. Our objective was to evaluate the time interval from arrival to initiation of emergent percutaneous procedures in severely injured patients.

Methods: All severely injured trauma patients (injury severity score [ISS] > 12) presenting to a level 1 trauma centre (2007–2010) were analyzed with standard statistical methodology.

Results: Among 60 severely injured patients (mean ISS 31, hypotension 18%, mortality 12%), the median time interval to the initiation of an angiographic procedure was 270 minutes. Of the procedures performed, 85% were therapeutic embolizations and 15% were diagnostic procedures. Splenic (median time 243 min, range 32–801 min) and pelvic (median time 278 min, range 153–466 min) embolizations accounted for 43% and 25% of procedures, respectively. The median embolization procedure duration for the spleen was 28 (range 15–153) minutes compared with 59 (range 34–171) minutes for the pelvis. Nearly 22% of patients required both an emergent percutaneous and subsequent operative procedure. Percutaneous therapy typically preceded open operative explorations.

Conclusion: The time interval from arrival at the trauma centre to emergent percutaneous procedures varied widely. Improved processes emphasizing patient transition from the trauma bay to the angiography suite are essential. Discussion regarding the appropriate time to angiography is needed so this marker can be used as a quality outcome measure for all level 1 trauma centres.

Contexte : De nos jours, en traumatologie, les soins reposent largement sur des interventions non chirurgicales percutanées d’extrême urgence, particulièrement chez les patients blessés à la rate, au bassin et au foie. Malheureusement, les indices de qualité spécifiques (p. ex., temps écoulé entre l’arrivée et l’angiographie) n’ont pas fait l’objet de discussions approfondies. Notre objectif était de mesurer le temps écoulé entre l’arrivée et l’instauration des interventions percutanées d’extrême urgence chez les grands blessés.


Résultats : Pour 60 patients gravement blessés (IGB moyen 31, hypotension 18 %, mortalité 12 %), le temps écoulé avant l’instauration d’une intervention angiographique a été de 270 minutes. Parmi les interventions effectuées, 85 % ont été des embolisations thérapeutiques et 15 % des interventions diagnostiques. Les embolisations spléniennes (temps écoulé médian 243 minutes, intervalle 32–801 minutes) et pelviennes (temps écoulé médian 278 minutes, intervalle 153–466 minutes) ont représenté 43 % et 25 % des interventions, respectivement. La durée médiane de l’intervention d’embolisation dans le cas de la rate a été de 28 (intervalle 15–153) minutes, contre 59 (intervalle 34–171) minutes pour les blessures touchant le bassin. Près de 22 % des patients ont eu besoin d’une intervention percutanée d’extrême urgence et d’une intervention chirurgicale par la suite. Les explorations chirurgicales ouvertes ont généralement été précédées d’un traitement percutané.

Conclusion : Le temps écoulé entre l’arrivée au centre de traumatologie et les interventions percutanées d’extrême urgence varie beaucoup. Il faut, sans contredit, améliorer les processus en soulignant l’importance du transfert des patients de la salle de traumatologie à la salle d’angiographie et poursuivre la discussion sur le temps écoulé avant l’angiographie pour que ce marqueur puisse servir comme paramètre de mesure de la qualité dans tous les centres de traumatologie de niveau 1.
Most preventable deaths from trauma are a consequence of untreated hemorrhage and subsequent early exsanguination. Treatment modalities range from minimally invasive percutaneous techniques to invasive open procedures.

Angiography has emerged as a vital adjunct in the resuscitation of injured patients. As a tool in the armamentarium of trauma care, the role of interventional radiology is no longer purely diagnostic, but instead has evolved into a predominantly therapeutic endeavour. Modern trauma care relies heavily on nonoperative, emergent percutaneous techniques in the management of injured patients with substantial hemorrhage, particularly in patients with splenic, pelvic and hepatic injuries. Furthermore, the American College of Surgeons Committee on Trauma states that both level I and II trauma centres should have timely availability to conventional angiography and to radiology staff with the ability to oversee therapeutic procedures.

Unfortunately, general consensus guidelines are not currently available to define “timeliness” for percutaneous procedures aimed at hemorrhage control. This contrasts both neurologic (stroke) and cardiac (myocardial infarction) sciences, where strict time-based protocols have been in place for years. Furthermore, these guidelines act as important quality metrics.

The primary objective of the present study was to evaluate the waiting time from patient arrival to initiation of any urgent percutaneous procedure in severely injured patients at a level I trauma centre. The secondary goal was to define the type and pattern of percutaneous interventions.

**METHODS**

We identified all severely injured patients (injury severity score [ISS] ≥ 12) presenting to the Foothills Medical Centre (FMC) between Feb. 1, 2007, and Jan. 31, 2010. The FMC is a Trauma Association of Canada–accredited, level 1 trauma centre serving as the trauma referral facility for southern Alberta, southwestern Saskatchewan and southeastern British Columbia. As a result, more than 2 million people with severe injuries receive care at our centre, which admits more than 1100 of these patients annually. The Alberta Trauma Registry provided data on all patients (age, sex, comorbidities, date of injury, mechanism of injury, length of hospital and ICU stay, type of injuries, ISS, discharge destination, operative and percutaneous procedures, vital signs and mortality). Fidelity was ensured by additional searches of the Alberta Health Services electronic patient medical records; we obtained the waiting times and specific details for all percutaneous procedures from these medical records. The FMC angiography suite is located only a few metres from the trauma bays. We defined hypotension as persistent (at least 2 measurements < 90 mm Hg, measured at any point in the presurgical/angiographic care of the patient [i.e., prehospital or trauma bay]). These hypotensive measurements were taken at a mean interval of 16 minutes. This study was approved by the University of Calgary institutional review board.

**Statistical analysis**

All analyses were performed using Stata version 12.0 (Stata Corporation). Normally or near-normally distributed variables are reported as means, and non-normally distributed variables are reported as medians. We compared means using the Student t test and medians using the Mann–Whitney U test. We assessed differences in proportions for categorical data using the Fisher exact test. We considered results to be significant at p < 0.05.

**RESULTS**

A total of 60 injured patients underwent urgent percutaneous procedures between Feb. 1, 2007, and Jan. 31, 2010. Patient, injury and outcome characteristics are summarized in Table 1. Blunt mechanisms accounted for most (94%) injuries (motor vehicle crashes 65%, falls 22%, assault 7%). Urgent percutaneous procedures were primarily therapeutic, with splenic and pelvic injuries representing the dominant targets (Table 2).

The overall median time from patient arrival to urgent percutaneous procedure was 270 minutes. The median time for urgent percutaneous procedures involving splenic and pelvic arterial embolizations was 243 and 278 minutes, respectively. The median procedure time of splenic embolizations was 28 minutes, while the median duration of pelvic embolizations was 59 minutes. Eleven (18%) injured patients requiring an urgent percutaneous procedure

<table>
<thead>
<tr>
<th>Table 1. Patients demographic characteristics and outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristic</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>No. patients</td>
</tr>
<tr>
<td>Age mean (range) yr</td>
</tr>
<tr>
<td>Male sex</td>
</tr>
<tr>
<td>ISS</td>
</tr>
<tr>
<td>Hypotension at admission (sBP &lt; 90 mm Hg)</td>
</tr>
<tr>
<td>ICU admission</td>
</tr>
<tr>
<td>ICU stay mean (range) d</td>
</tr>
<tr>
<td>Mortality</td>
</tr>
<tr>
<td>Discharge status</td>
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<tr>
<td>Rehabilitation</td>
</tr>
<tr>
<td>Analyte</td>
</tr>
<tr>
<td>pH</td>
</tr>
<tr>
<td>Base deficit</td>
</tr>
<tr>
<td>Lactate, mg/dL</td>
</tr>
<tr>
<td>Massive transfusion protocol employed</td>
</tr>
<tr>
<td>CT before angiography</td>
</tr>
<tr>
<td>Mean RBC transfusion units &lt; 24 h</td>
</tr>
<tr>
<td>Mean crystalloid resuscitation, L &lt; 24 h</td>
</tr>
<tr>
<td>Referred from a preceding centre</td>
</tr>
</tbody>
</table>

*Unless otherwise indicated. CT = computed tomography; ICU = intensive care unit; ISS = injury severity score; RBC = red blood cells; sBP = systolic blood pressure.
presented to the hospital with a systolic blood pressure (sBP) less than 90 mm Hg. The median time to percutaneous procedure in this group of patients was 212 minutes. The rest of the injured trauma patients with an sBP greater than 90 mm Hg had a median time to percutaneous procedure of 259 minutes. Of the patients who presented with hypotension, 8 (73%) responded to fluid resuscitation. The median time to angiography in this subset was 253 minutes. In those who did not respond but who were transferred to the angiography suite (i.e., instead of directly to the operating theatre), the median door to needle time was 49 minutes.

Door to needle times were longer between midnight and 7 am. The overall mean time to percutaneous procedure from 7 am to 5 pm was 299 minutes. This compares to 298 minutes for procedures between 5 pm and midnight, as well as 357 minutes for angiography between midnight and 7 am (p = 0.041).

Thirteen (21.7%) injured trauma patients required both an emergent percutaneous and a subsequent open operative procedure. All patients except 1 underwent the percutaneous procedure before the operative intervention (the exception involved preperitoneal pelvic packing followed by embolization). The median time from the percutaneous procedure to the operative intervention in these patients was 2 days. This cohort includes 2 (7.7%) patients who initially underwent splenic artery embolization, 7 (50%) who received pelvic embolization, 1 who underwent internal mammary artery embolization (associated sternal fracture that eventually required a median sternotomy to decompress a mediastinal hematoma) and 1 who received an axillary artery embolization (axillary artery transection that was subsequently treated with an axillobrachial bypass). Patients undergoing splenic artery embolization and operative intervention had a median time of 4 days from the percutaneous procedure to operation. It should be noted that 1 patient underwent repair of a complex acetabular fracture while the other patient had a delayed repair of a missed diaphragmatic injury. The patients undergoing pelvic embolization and subsequent operative intervention also had a median time of 4 days from the percutaneous procedure to operation. All but 1 patient underwent orthopedic fixation of their pelvic fractures after embolization at the discretion of the orthopedic surgery service.

**Table 2. Emergent percutaneous procedures**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous</td>
<td></td>
</tr>
<tr>
<td>Diagnostic</td>
<td>9 (15)</td>
</tr>
<tr>
<td>Therapeutic</td>
<td>51 (85)</td>
</tr>
<tr>
<td>Therapeutic target organ</td>
<td></td>
</tr>
<tr>
<td>Spleen</td>
<td>26 (43)</td>
</tr>
<tr>
<td>Pelvis</td>
<td>15 (25)</td>
</tr>
<tr>
<td>Other</td>
<td>10 (17)</td>
</tr>
</tbody>
</table>

**Discussion**

Our study reveals a wide range in waiting times for urgent angiographic procedures in severely injured patients presenting to our trauma centre. It also represents the first time, to our knowledge, that a tertiary referral trauma centre has audited the overall timeliness of obtaining urgent percutaneous procedures in potentially hemorrhaging patients with all types of injury patterns. Although a select few North American centres have suggested local door to needle response times, there is no commonly agreed upon target threshold or quality measure. This fundamentally differs from neurologic and cardiac sciences (90 min). It is also problematic given that delays in angiography have been shown to lead to a 2-fold higher risk of death in injured patients (47% increase with each hour of delay).21

While there is a paucity of literature surrounding overall door to needle times, reasonable data exist with regard to pelvic fractures. Tai and colleagues,22 commented that retroperitoneal pelvic packing was as clinically effective as angiography and significantly reduced the 140-minute delay to achieving embolization. Similarly, Osborn and colleagues23 noted a reduction to hemorrhage control within 45 minutes for pelvic packing compared with 130 minutes for angiography. Finally, although door to needle times are inadequately discussed, Cothren and colleagues24 also advocate routine peritoneal pelvic packing with a combined operative and subsequent angiography time of 164 minutes. It is interesting to note that although these delays appear much shorter than our overall pelvic fracture door to needle times (median 278 min), the mean time for patients with pelvic fractures and concurrent hypotension that was not responsive to resuscitation in our audit was only 41 min. Certainly the slower percutaneous response times between midnight and 7 am noted in our centre reflect a need for improvement.

We hypothesize that the wide range in waiting times for obtaining emergent percutaneous procedures for injured patients is multifactorial. Clearly a substantial proportion of this time involves activation of the interventional radiology team comprising a radiologist and 2 nurse specialists/technicians. Although the trauma team is onsite 24 hours per day, the door to decision time is entirely under the control of the attending trauma surgeon. This clearly represents an important factor in potential delays and may include variables such as waiting for computed tomography (i.e., to detect vascular extravasation in a hemodynamically stable patient), evaluating a patient’s response to ongoing resuscitation and/or individual surgeon experience and training. Unfortunately, the precise time point at which a trauma surgeon makes the decision to proceed to angiography is not possible to discern in a retrospective audit. Because the door to needle time remains a very crude quality measure, our future prospective study will capture all potential details, including what we believe may be the most important factor: door to decision time.
The subset of injured trauma patients requiring both an emergent percutaneous procedure and an operative intervention requires special mention. Given the liberal access to interventional radiology procedures at our institution (both geographically and personnel-wise), injured patients with splenic and/or pelvic trauma are typically selected on an aggressive basis to undergo emergent embolization. As outlined, there were no observed failures in splenic or pelvic embolizations that required a subsequent operative procedure. Lone “failures” were related to an eventual mediastinal hematoma after an internal mammary arterial laceration and a vascular bypass after arrest of axillary hemorrhage with embolization.

To further improve the response times for obtaining emergent percutaneous procedures in severely injured patients, the concept of a single, hybrid operating suite is becoming more popular. This technology allows emergent percutaneous interventions to be performed in the same physical location as open procedures, resuscitations, general anesthesia and critical care. This advanced resuscitation with angiography, percutaneous techniques and operative repair (RAPTOR) suite would prevent timely delays in transporting injured patients between the trauma bay, operating theatre and/or interventional radiology suite.

A benefit of this study will be the ability to use waiting times as a quality metric for the performance of our trauma and radiology teams as well as for the planned implementation of the RAPTOR suite. Furthermore, we hope to use these door to needle metrics in future iterations of the Trauma Association of Canada’s trauma centre accreditation process.

CONCLUSIONS

To our knowledge, this is the first formal audit of waiting times for obtaining all urgent percutaneous procedures in severely injured patients. Despite the effectiveness of therapeutic angiography, wide variations in waiting times remain problematic. This data has served as an initial foundation for a prospective waiting time tracking study that we hope can be used as a quality benchmark for both continuous quality improvement and evaluation of the RAPTOR suite.

Competing interests: None declared.

Contributors: J.-F. Ouellet and C. Ball designed the study. A. Smith, J.-F. Ouellet and C. Ball acquired the data, which all authors analyzed. A. Smith, J.-F. Ouellet and C. Ball wrote the article, which all authors reviewed and approved for publication.

References

Comparison of laparoscopic Roux-en-Y gastric bypass with laparoscopic sleeve gastrectomy for morbid obesity or type 2 diabetes mellitus: a meta-analysis of randomized controlled trials

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Background: Laparoscopic Roux-en-Y gastric bypass (LRYGB) is one of the most widely used bariatric procedures, and laparoscopic sleeve gastrectomy (LSG) as a single-stage procedure for treating morbid obesity is becoming more popular. We compared both techniques to evaluate their efficacy in treating morbid obesity or type 2 diabetes mellitus (T2DM).

Methods: We searched the Cochrane Controlled Trials Register databases, Medline, Embase, ISI databases and the Chinese Biomedical Literature Database to identify randomized controlled trials (RCTs) of LRYGB and LSG for morbid obesity or T2DM published in any language. Statistical analyses were carried out using RevMan software.

Results: Five worldwide RCTs with 196 patients in the LRYGB group and 200 in the LSG group were included in our analysis. Compared with patients who had LSG, those who had LRYGB had a higher remission rate of T2DM, lost more weight and had lower low-density lipoprotein, triglycerides, homeostasis model assessment index and insulin levels. There was no difference in the reoperation rate between the groups. However, patients treated with LRYGB had a higher incidence of complication than those treated with LSG.

Conclusion: Our meta-analysis demonstrates that LRYGB is more effective than LSG for the surgical treatment of T2DM and control of metabolic syndrome. However, LSG is safer and has a reduced rate of complications. Further high-quality RCTs with long follow-up periods are needed to provide more reliable evidence.


Méthodes : Nous avons interrogé les bases de données du Registre des essais cliniques contrôlés de la Collaboration Cochrane, de même que les bases de données Medline, Embase, ISI et la base de données de la littérature biomédicale chinoise pour recenser les essais randomisés et contrôlés (ERC) publiés dans toutes les langues sur la DGRY et la GLL dans les cas d’obésité morbide ou de DT2. Les analyses statistiques ont été effectuées au moyen du logiciel RevMan.

Résultats : Cinq ERC ont été recensés dans le monde et ont été inclus dans notre analyse, totalisant 196 patients soumis à la DGRY et 200 soumis à la GLL. Comparativement aux patients soumis à la GLL, les patients soumis à la DGRY ont présenté des taux de rémission plus élevés de leur DT2, ils ont perdu plus de poids et ont présenté des taux plus faibles de lipoprotéines de faible densité et de triglycérides, une baisse de leur indice d’évaluation du modèle d’homéostasie) et de leur taux d’insuline. On n’a noté aucune différence entre les groupes pour ce qui est du taux de réintervention. Toutefois, l’incidence des complications a été plus élevée chez les patients traités par DGRY que chez ceux traités par GLL.

Conclusion : Notre méta-analyse démontre que la DGRY est plus efficace que la GLL pour le traitement chirurgical du DT2 et le contrôle du syndrome métabolique. Toutefois, la GLL est plus sécuritaire et s’accompagne d’un taux moindre de complications. Il faudra procéder à d’autres ERC de grande qualité comportant des suivis prolongés pour amasser des preuves plus fiables.
Obesity and type 2 diabetes mellitus (T2DM) are currently 2 of the most common chronic diseases in Western countries. The growing incidence of obesity and T2DM globally is widely recognized as one of the most challenging contemporary threats to public health. Uncontrolled diabetes can eventually lead to macrovascular and microvascular complications, including myocardial infarction, stroke, blindness, neuropathy and renal failure in many patients. Obesity and T2DM are closely related and difficult to control by current medical treatment, including diet, drug therapy and behavioural modification. Bariatric surgery is the most effective treatment of morbid obesity and, depending on the type of operation, is also very effective in the resolution of diabetes. This effect usually occurs even before the start of weight loss owing to changes in the gut hormones and the patient’s diet.

Laparoscopic Roux-en-Y gastric bypass (LRYGB), currently the preferred bariatric operation, involves 2 surgical alterations: restriction of the gastric volume and diversion of the ingested nutrients away from the proximal small intestine. In contrast, laparoscopic sleeve gastrectomy (LSG) preserves the integrity of the pylorus and does not include the intestinal bypass. Laparoscopic sleeve gastrectomy is the restrictive part of the biliopancreatic diversion and was initially applied as an isolated operation for superobese patients with severe comorbidities as a staged concept. It is mainly a restrictive operation with no malabsorptive effect. The long-term efficacy of the LSG procedure as a treatment of morbid obesity or T2DM has not been demonstrated; however, it is promising to observe weight loss in the first year after operation. At present, to our knowledge, there is no evidence to demonstrate whether LRYGB or LSG is superior for treating morbid obesity or T2DM.

Meta-analysis is a statistical tool that can be used to evaluate the literature qualitatively and quantitatively, accounting for variations in characteristics that can influence overall estimates of outcomes of interest. To our knowledge, meta-analysis of LRYGB versus LSG for morbid obesity or T2DM has not been performed previously. As deciding what kind of surgery to recommend to patients remains an important issue, we performed a meta-analysis of randomized controlled trials (RCTs) comparing LRYGB with LSG for the treatment of morbid obesity or T2DM.

**Methods**

**Study selection**

We searched the Cochrane Central Register of Controlled Trials, Medline, Embase, ISI databases and the Chinese Biomedical Literature Database for RCTs published in any language between January 1966 and November 2012. Our search terms were “gastric bypass,” “sleeve gastrectomy” and “bariatric surgery.” We manually searched the reference lists of pertinent articles to identify any additional studies relevant to our analysis. Two independent investigators (B.N. and K.-X.S.) reviewed all articles from the previous search based on the following selection criteria. Included studies must have been prospective RCTs comparing gastric bypass with sleeve gastrectomy for morbid obesity or T2DM. Quasirandomized trials, nonrandomized studies, nonhuman studies, nonsurgical interventions, case reports, letters and comments were excluded from our analysis. Finally, when the results of a single study were reported in more than 1 publication, only the most recent and complete data were included in our meta-analysis. Included trials were chosen by the 2 nonblinded authors (J.-F.L. and D.-D.L.). Disagreements were resolved by discussion.

**Assessment of study quality**

The quality of included reports was scored using the Jadad composite scale, which assesses descriptions of randomization, blinding and dropouts (withdrawals). The quality scale ranges from 0 to 5 points, with a low-quality report receiving a score of 2 points or less and a high-quality report receiving a score of at least 3 points.

**Statistical analysis**

All available trials with reporting data were summarized. Results for continuous outcomes are reported as weighted mean difference (WMD) or standard mean difference, and dichotomous outcomes are reported as odds ratios (ORs) with 95% confidence intervals (CIs). We performed all statistical analyses with RevMan version 5.0. We used the χ² statistic to assess heterogeneity among the trials and the F statistic to assess the extent of inconsistency. If there was a significant heterogeneity, we used a random-effects model to confirm the case results. A fixed-effect model for calculations of summary estimates and their 95% CIs was also applied unless there was significant heterogeneity. We considered results to be significant at p < 0.05.

**Results**

**Included studies**

Figure 1 shows the selection process from initial review to the inclusion in our meta-analysis. The initial search identified 581 publications, of which 576 were excluded, leaving 5 publications for analysis. One study, which was the subset of another study, was excluded; another study was the republication of the trial by Woelnerhanssen and colleagues and was also
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excluded. The 5 trials of LRYGB and LSG for morbid obesity or T2DM with a total of 396 patients that we included in our analysis were retrieved from the electronic databases. The study by Lee and colleagues14 was the only trial to study surgical treatment of nonmorbidly obese patients (BMI < 35) with poorly controlled T2DM; the other 4 studies15–18 evaluated surgical treatment of morbidly obese patients (BMI > 35) with or without T2DM. There were 196 patients in the LRYGB group and 200 patients in the LSG group. Standard deviations were not reported in most studies; however, they were estimated either by means of ranges or pvalues.

The characteristics and quality of each selected study are demonstrated in Table 1, and the outcome variables extracted from these trials are shown in Table 2. The studies were homogeneous in terms of clinical and methodological criteria.

Remission of T2DM

Remission of T2DM is defined as fasting plasma glucose levels less than 126 mg/dL in addition to HbA1c values less than 6.5% without the use of oral hypoglycemics or insulin. Three trials14,16,17 reported the remission of T2DM, which was much better in the LRYGB group than in the LSG group (WMD –0.42, 95% CI –0.63 to –0.22, p < 0.001; Fig. 3).

HOMA index

Insulin resistance was estimated by the HOMA index. Two trials14,15 that reported this outcome demonstrated the LRYGB group had a significantly lower HOMA index than the LSG group (WMD –0.42, 95% CI –0.63 to –0.22, p < 0.001; Fig. 3).

Insulin level

Two trials14,15 reported insulin level, which was significantly lower in the LRYGB group than in the LSG group (WMD –1.27, 95% CI –2.06 to –0.48, p = 0.002; Fig. 3).

Percent excess weight loss

Weight loss outcome was defined by percent excess weight loss (%EWL). For all studies, weight loss was reported as mean %EWL, defined as (weight loss ÷ excess weight) × 100. Meta-analyses were performed to examine mean %EWL outcomes separately for the LRYGB and LSG groups. Two studies14,15 reported weight loss. The LRYGB group experienced greater weight loss than the LSG group (WMD 6.76, 95% CI 4.61–8.91, p < 0.001; Fig. 4).

Reoperation

Two studies16,17 reported reoperation rates; there was no significant difference in reoperation between the groups (OR 1.24, 95% CI 0.37–4.16, p = 0.73; Fig. 2).

Complications

Three studies14,16,17 reported complications; the LRYGB group had a higher incidence of complications than the LSG group (OR 1.89, 95% CI 1.07–3.33, p = 0.030; Fig. 2).

Triglycerides

Bariatric surgery had a marked reduction in body weight and improvement of other associated metabolic disorders, including reduction of blood lipid levels. Two studies14,15 reported that the triglycerides level decreased after bariatric surgery, and the LRYGB group had a significantly lower triglycerides level than the LSG group after surgery (WMD –0.23, 95% CI –0.35 to –0.11, p < 0.001; Fig. 3).

Low-density lipoprotein

Two studies14,15 reported low-density lipoprotein (LDL) level. There was statistical heterogeneity among studies (I² = 79%, p = 0.030); random-effects models were used in the analysis. The LRYGB group had a significantly lower LDL level than the LSG group (WMD –0.73, 95% CI –1.25 to –0.22, p = 0.005; Fig. 5).
**Discussion**

Despite the large volume of literature devoted to bariatric surgery and diabetes, only a small number of studies have been performed in a comparative way, with a level of evidence of 3 or higher. However, a meta-analysis is a design that allows merging results of small RCTs, increasing the possibility of detecting an intervention effect. To our knowledge, this is the first meta-analysis to date that evaluates data from multiple studies to assess RCTs on LRYGB and LSG for morbid obesity or T2DM.

Our results showed that LRYGB was associated with a higher remission rate of T2DM and that patients who underwent this procedure lost more weight than those who had LSG; gastric bypass may be a better choice for patients with metabolic syndrome or hyperlipidemia. However, the LSG procedure is safer than the more complex LRYGB and avoids the long-term sequela of micronutrient deficiency after duodenum exclusion.

Our meta-analysis revealed that both LRYGB and LSG were effective in the treatment of patients with T2DM in whom current medical treatment had failed. However, the remission rate of T2DM in the LRYGB group was much higher than that in the LSG group. These results corroborate previous reports that gastric bypass may achieve an 80% T2DM remission and that purely restrictive procedures may achieve a rate of about 50%. Besides weight loss, the LRYGB group also achieved a lower blood lipid level. That is why the LRYGB group had a higher metabolic syndrome remission rate than the LSG group. Schauer and colleagues found that obese patients with poorly controlled diabetes treated by either gastric bypass or sleeve gastrectomy combined with medical therapy were significantly more likely to achieve a glycated hemoglobin level of 6.0%.

<table>
<thead>
<tr>
<th>Table 1. Study characteristics and quality evaluation of each selected study</th>
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</thead>
<tbody>
<tr>
<td><strong>Characteristic</strong></td>
</tr>
<tr>
<td>Jadad score</td>
</tr>
<tr>
<td>Double blind</td>
</tr>
<tr>
<td>Randomization</td>
</tr>
<tr>
<td>Lost to follow-up</td>
</tr>
<tr>
<td><strong>Country</strong></td>
</tr>
<tr>
<td><strong>Clinical trial registration</strong></td>
</tr>
<tr>
<td><strong>Publication year</strong></td>
</tr>
<tr>
<td><strong>No. patients</strong></td>
</tr>
<tr>
<td><strong>LRYGB</strong></td>
</tr>
<tr>
<td><strong>LSG</strong></td>
</tr>
<tr>
<td><strong>Follow-up, mo</strong></td>
</tr>
<tr>
<td><strong>BMI</strong></td>
</tr>
<tr>
<td><strong>Condition</strong></td>
</tr>
<tr>
<td><strong>Age, yr</strong></td>
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<tr>
<td><strong>Deaths</strong></td>
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</tbody>
</table>

**BMI** = body mass index; LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; NR = not reported; T2DM = type 2 diabetes mellitus.

<table>
<thead>
<tr>
<th>Table 2. Outcome measures of included randomized trials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trials</strong></td>
</tr>
<tr>
<td>Lee et al.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Woelnerhanssen et al.</td>
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<tr>
<td></td>
</tr>
<tr>
<td>Helmiö et al.</td>
</tr>
<tr>
<td></td>
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<tr>
<td>Kehagias et al.</td>
</tr>
<tr>
<td></td>
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<tr>
<td>Ramón et al.</td>
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<td></td>
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</tbody>
</table>

**LRYGB** = laparoscopic Roux-en-Y gastric bypass; **LSG** = laparoscopic sleeve gastrectomy; NR = not reported; SD = standard deviation.
### Table 1: Weight Loss after LRYGB and LSG

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>LRYGB</th>
<th>LSG</th>
<th>Weight, %</th>
<th>Odds ratio</th>
<th>Odds ratio, 95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mean difference</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>95% CI</strong></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 2.1.1 HOMA index

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>LRYGB</th>
<th>LSG</th>
<th>Weight, %</th>
<th>Odds ratio</th>
<th>Odds ratio, 95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee 2011</td>
<td>1.2</td>
<td>30</td>
<td>2.5</td>
<td>1.00</td>
<td>(0.05, 22.18)</td>
</tr>
<tr>
<td>Woelnerhanssen</td>
<td>2.9</td>
<td>12</td>
<td>3.3</td>
<td>1.00</td>
<td>(0.13, 7.60)</td>
</tr>
<tr>
<td><strong>Subtotal, 95% CI</strong></td>
<td>4.1</td>
<td>42</td>
<td>100.0</td>
<td>1.00</td>
<td>(0.37, 4.16)</td>
</tr>
</tbody>
</table>

#### 2.1.2 Insulin

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>LRYGB</th>
<th>LSG</th>
<th>Weight, %</th>
<th>Odds ratio</th>
<th>Odds ratio, 95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee 2011</td>
<td>4.9</td>
<td>30</td>
<td>4.7</td>
<td>1.00</td>
<td>(0.19, 5.40)</td>
</tr>
<tr>
<td>Woelnerhanssen</td>
<td>13.1</td>
<td>12</td>
<td>14.8</td>
<td>1.00</td>
<td>(0.23, 4.43)</td>
</tr>
<tr>
<td><strong>Subtotal, 95% CI</strong></td>
<td>17.7</td>
<td>42</td>
<td>100.0</td>
<td>1.00</td>
<td>(0.37, 4.16)</td>
</tr>
</tbody>
</table>

#### 2.1.3 Triglycerides

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>LRYGB</th>
<th>LSG</th>
<th>Weight, %</th>
<th>Odds ratio</th>
<th>Odds ratio, 95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee 2011</td>
<td>1.19</td>
<td>30</td>
<td>1.63</td>
<td>1.00</td>
<td>(0.19, 5.40)</td>
</tr>
<tr>
<td>Woelnerhanssen</td>
<td>1</td>
<td>12</td>
<td>1.2</td>
<td>1.00</td>
<td>(0.23, 4.43)</td>
</tr>
<tr>
<td><strong>Subtotal, 95% CI</strong></td>
<td>2.1</td>
<td>42</td>
<td>100.0</td>
<td>1.00</td>
<td>(0.37, 4.16)</td>
</tr>
</tbody>
</table>

### Fig. 2: Meta-analysis of studies comparing remission of type 2 diabetes mellitus (T2DM), reoperation and complication rates between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.

### Fig. 3: Meta-analysis of studies comparing homeostasis model assessment (HOMA) index, insulin, and triglycerides between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.
or less 1 year after randomization than those patients receiving medical therapy alone. Notably, many patients in the surgical group, particularly those in the gastric bypass group, achieved glycemic control without the use of diabetes medications. Although more clinical trials are needed, this meta-analysis and other studies have strongly recommended that LRYGB as a metabolic surgery should be included in the armament of T2DM treatments.

The underlying mechanism for T2DM remission after gastric bypass surgical procedures is intriguing. Four possible mechanisms have been proposed, including the starvation followed by weight loss hypothesis, the ghrelin hypothesis, the upper intestinal (foregut) hypothesis and the lower intestinal (hindgut) hypothesis. None of these theories necessarily precludes the others, so any combination may be operational to some extent; therefore, it is difficult to design a study to elucidate the exact mechanism. The results of our meta-analysis strongly support the finding that the duodenum may play a role in T2DM resolution after bariatric surgery. The rapid postoperative remission of T2DM is primarily related to an improvement in insulin resistance rather than increasing insulin secretion. The difference in insulin resistance in the postoperative period between the 2 procedures found in this meta-analysis also supports the theory that duodenum exclusion is helpful for the reduction of insulin resistance. In recent studies, Korner and colleagues found that reduction of insulin resistance correlated significantly with weight loss only in patients who underwent gastric banding, not in those who had gastric bypass, and Bikman and colleagues found that improved insulin sensitivity after gastric bypass was due to something other than weight loss. Because the duodenum was recently found to have a novel intestine–brain–liver neurocircuit to increase hepatic insulin sensitivity, it is possible that gastrointestinal surgery may help mediate antidiabetes effects, although this is currently unclear. More elaborate studies are needed to elucidate the underlying complex mechanism of T2DM resolution after gastric bypass surgery.

**Limitations**

The main limitation of this meta-analysis is the lack of RCTs with large sample sizes. Another limitation is the lack of long-term follow-up. Without long-term follow-up, we cannot confirm the durability of T2DM remission after surgery and the influence of possible weight change in the future. More elaborate clinical studies are indicated to elucidate this issue.

**CONCLUSION**

In summary, our meta-analysis has demonstrated that LRYGB is more effective than LSG for the surgical treatment of T2DM and control of metabolic syndrome. Patients treated with LRYGB lost more weight than those

---

**Table 1**

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>LRYGB</th>
<th>LSG</th>
<th>Mean difference, 95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
</tr>
<tr>
<td>Lee 2011</td>
<td>94.4</td>
<td>33.1</td>
<td>30</td>
</tr>
<tr>
<td>Woelnerhanssen 2011</td>
<td>34.5</td>
<td>2.7</td>
<td>12</td>
</tr>
<tr>
<td>Total, 95% CI</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: $\chi^2 = 1.50, p = 0.22$; $I^2 = 33%

Test for overall effect: $z = 6.16, p < 0.00001$

CI = confidence interval; LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; SD = standard deviation.

*Inverse variance, fixed.

---

**Fig. 4.** Meta-analysis of studies comparing percent excess weight loss (%EWL) between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.

---

**Table 2**

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>LRYGB</th>
<th>LSG</th>
<th>Mean difference, 95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
</tr>
<tr>
<td>Lee 2011</td>
<td>2.51</td>
<td>0.56</td>
<td>30</td>
</tr>
<tr>
<td>Woelnerhanssen 2011</td>
<td>2.6</td>
<td>0.2</td>
<td>12</td>
</tr>
<tr>
<td>Total, 95% CI</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: $t^2 = 0.11; \chi^2 = 4.73, p = 0.22$; $F = 79%$

Test for overall effect: $z = 2.78, p < 0.005$

CI = confidence interval; LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; SD = standard deviation.

*Inverse variance, fixed.

---

**Fig. 5.** Meta-analysis of studies comparing low-density lipoprotein between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.
treated with LSG. Further high-quality RCTs with large sample sizes and long follow-up periods are needed to provide more reliable evidence.

Competing interests: None declared.

Contributors: J.-F. Li and D.-D. Lai designed the study, acquired the data and wrote the article. B. Ni and K.-X. Sun analyzed the data. J.-F. Li, D.-D. Lai, B. Ni and K.-X. Sun reviewed the article. All authors approved its publication.

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Outcomes: wedge resection versus lobectomy for non–small cell lung cancer at the Cancer Centre of Southeastern Ontario 1998–2009

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Background: Sublobar resection for non–small cell lung cancer (NSCLC) remains controversial owing to concern about local recurrence and long-term survival outcomes. We sought to determine the efficacy of wedge resection as an oncological procedure.

Methods: We analyzed the outcomes of all patients with NSCLC undergoing surgical resection at the Cancer Centre of Southeastern Ontario between 1998 and 2009. The standard of care for patients with adequate cardiopulmonary reserve was lobectomy. Wedge resection was performed for patients with inadequate reserve to tolerate lobectomy. Predictors of recurrence and survival were assessed. Appropriate statistical analyses involved the\(^2\) test, an independent samples t test and Kaplan–Meier estimates of survival. Outcomes were stratified for tumour size and American Joint Committee on Cancer seventh edition TNM stage for non–small cell lung cancer.

Results: A total of 423 patients underwent surgical resection during our study period: wedge resection in 71 patients and lobectomy in 352. The mean age of patients was 64 years. Mean follow-up for cancer survivors was 39 months. There was no significant difference between wedge resection and lobectomy for rate of tumour recurrence, mortality or disease-free survival in patients with stage IA tumours less than 2 cm in diameter.

Conclusion: Wedge resection with lymph node sampling is an adequate oncological procedure for non–small cell lung cancer in properly selected patients, specifically, those with stage IA tumours less than 2 cm in diameter.

Contexte : La résection sous-lobaire pour le cancer du poumon non à petites cellules (CPNPNC) demeure controversée en raison du risque de récurrence locale et des perspectives de survie à long terme. Nous avons voulu déterminer l’efficacité de la résection cunéiforme en tant qu’intervention oncologique.

Méthodes : Nous avons analysé les résultats pour tous les patients atteints d’un CPNPNC soumis à une résection chirurgicale au Centre oncolgique du Sud-Est de l’Ontario entre 1998 et 2009. Chez les patients qui présentaient une réserve cardiaque suffisante, la norme thérapeutique était la lobectomie. Les patients dont la réserve était insuffisante pour tolérer une lobectomie ont subi une résection cunéiforme. Les prédicteurs de récurrences et de survie ont été évalués. Les analyses statistiques appropriées ont inclu le test\(^2\), le test t et les estimations de Kaplan–Meier de la survie. Les résultats ont été stratifiés en fonction de la taille et du stade de la tumeur selon la septième édition de la classification TNM de l’American Joint Committee on Cancer pour le CPNPNC.

Résultats : En tout, 423 patients ont subi une résection chirurgicale au cours de la période couverte par notre étude : résection cunéiforme chez 71 patients et lobectomie chez 352 patients. L’âge moyen des patients était de 64 ans. Le suivi moyen pour les survivants du cancer a été de 39 mois. On n’a noté aucune différence significative entre la résection cunéiforme et la lobectomie aux plans des récurrences tumorales, de la mortalité ou de la survie sans maladie chez les patients qui présentaient des tumeurs de stade IA de moins de 2 cm de diamètre.

Conclusion : La résection cunéiforme avec exérèse des ganglions lymphatiques est une intervention oncologique appropriée pour le CPNPNC chez les patients adéquatement sélectionnés, plus précisément, chez ceux qui ont des tumeurs de stade IA de moins de 2 cm de diamètre.
Surgical resection in the form of lobectomy or pneumonectomy remains the standard of care for stage I and II non–small cell lung carcinoma (NSCLC) despite advances in chemotherapy and radiation therapy. Owing to the primary causative relationship of smoking to NSCLC and associated cardiopulmonary comorbidities, many patients are deemed medically unfit to withstand full lobectomy. The best management for these patients remains controversial; many modalities are available, necessitating further investigation on this topic. These modalities include sublobar resection (wedge resection or anatomic segmental resection), observation, conventional fractionated or stereotactic body radiotherapy (SBRT) and radiofrequency ablation. Many surgeons still prefer sublobar resections over SBRT and ablative therapies despite successful local control rates having been reported with SBRT, particularly by Timmerman and colleagues. Controversy remains as to whether sublobar resections are adequate oncologic procedures for patients with severely impaired pulmonary function who could not withstand lobectomy. This relates to concerns that despite preservation of pulmonary function, tumour resection margins may be compromised with inadequate nodal sampling, possibly understaging the primary tumour. This could lead to increased rates of local and systemic recurrence and decreased disease-free and overall survival.

All but 1 previous study examining sublobar resections for NSCLC have been retrospective in nature, many revealing conflicting results. The prospective trial by Ginsberg and Rubinstein concluded that lobectomy was preferred over limited resections owing to decreased rates of local recurrence. This landmark study did not account for tumour diameter or location of the early-stage lesions. It has since been postulated that sublobar resection is an adequate oncologic surgery for peripheral lesions less than 2 cm in diameter, especially in the setting of a second primary lung cancer, adenocarcinoma in situ, or ground-glass opacities. All previous studies have used the sixth edition American Joint Committee in Cancer (AJCC) tumour-node-metastasis (TNM) classification and focused on comparing outcomes of segmental resection to lobectomy. Only 1 previous non-Canadian study has focused on comparing outcomes of wedge resection to lobectomy; however, this study also used the sixth edition AJCC TNM classification. The purpose of the present study was to determine whether there is a significant difference in tumour recurrence and survival in patients who undergo wedge resections versus lobectomy for NSCLC based on the seventh edition AJCC TNM classification and thus to determine whether wedge resection is an adequate oncologic procedure to offer patients.

METHODS

This was a retrospective analysis of all patients who underwent lung resection for NSCLC at the Cancer Centre of Southeastern Ontario for the fiscal years 1998 to 2009. All patients were pathologically staged according to the seventh edition AJCC TNM classification. Lobectomy or pneumonectomy was the standard of care performed for patients with adequate pulmonary function. Sublobar resection was reserved for patients with cardiopulmonary comorbidities precluding lobectomy. We compared the outcomes of patients who underwent either of these 2 procedures during the study period. This study received research ethics board approval from the research ethics board at Queen’s University in Kingston, Ont.

We collected data on basic demographics (age, sex), patient comorbidities (coronary artery disease, chronic obstructive pulmonary disease [COPD], diabetes), operative details (type of surgery, anatomic location), tumour pathological characteristics (margin status, histology, differentiation, presence of lymphatic or vascular invasion), disease recurrence, mortality (including cause of death) and morbidity (prolonged air leak, cardiac arrhythmia).

Primary outcomes included incidence of local–regional and distant recurrence, disease-free survival and overall survival. Disease recurrence was defined as the incidence of recurrent carcinoma (local–regional or distant), disease-free survival was the time from surgery to diagnosis of recurrent carcinoma, and overall survival was the time from surgery to death or last known follow-up. Secondary outcomes included length of hospital stay and postoperative complications, including prolonged air leak and cardiac arrhythmia. Prolonged air leak was defined as an air leak from the chest tube lasting more than 5 days. Cardiac arrhythmia was defined as an acute change in the patients’ electrocardiogram to display atrial fibrillation, atrial flutter or multifocal atrial tachycardia (MAT).

Statistical analysis

Data were entered in Excel and imported into PASW Statistics (SPSS Inc.) for analysis. Following a descriptive analysis (means, standard deviations and medians for continuous data, frequencies for categorical data), continuous data were plotted to assess the normality of the distribution. We used $\chi^2$ tests (Pearson or Fisher exact, as appropriate) to compare the lobectomy and wedge groups on categorical data, such as sex, comorbidities and complications. We performed independent samples $t$ tests to compare the groups on age and tumour diameter and the nonparametric Mann–Whitney $U$ test to compare the groups on length of stay in hospital. We used Kaplan–Meier analysis to compare the groups on time to recurrence. We also performed subset analyses for cancer stage, tumour stage and smoking status.

RESULTS

A total of 352 patients underwent lobectomy and 71 patients underwent wedge resection. Clinical outcomes were balanced between the cohorts for age, sex, smoking,
neoadjuvant and adjuvant chemoradiotherapy (Table 1). The mean time to recurrence was 22 months in patients who underwent lobectomy and 21 months in those who underwent wedge resection; mean follow-up after surgery was 39 months and 37 months, respectively, and mean follow-up after recurrence was 14 months and 13 months, respectively. The mean age of patients was 64.7 (range 28–82) years. Most patients were smokers (388, 91.7%). Patient who underwent wedge resections were more likely to have COPD by spirometry than those who underwent lobectomy (46.5% v. 28.9%, \( p = 0.004 \)). The groups were balanced with respect to the presence of other significant comorbidities, such as coronary artery disease, diabetes and substance abuse (Table 1).

With respect to pathological outcomes, distribution of tumour histology, margin status, differentiation and presence of lymphatic or vascular invasion were also balanced between cohorts (Table 2). Patients who underwent wedge resection were more likely than those who underwent lobectomy to have a smaller tumour diameter (\( p < 0.001 \)) and to have a tumour less than 2 cm in size (\( p = 0.009 \)). They also tended to have stage IA disease (\( p = 0.021 \)).

Table 3 shows the disease-free survival and overall survival, by tumour stage and by cancer stage, for patients in the lobectomy and wedge resection groups. Between-group differences in disease-free survival existed for both tumour stage and cancer stage (\( p = 0.043 \) and \( p = 0.008 \), respectively), but between-group differences in overall survival fell short of significance (\( p = 0.08 \) and \( p = 0.09 \), respectively).

In comparing surgical outcomes between the 2 cohorts there was a trend that patients who underwent lobectomy had a longer stay in hospital than those who underwent wedge resection (7.7 d v. 6.8 d, \( p = 0.09 \)), although the median values (6 d) were the same. There was no significant difference in 30-day mortality (4 deaths in the lobectomy group v. 2 in the wedge resection group). There were higher rates of prolonged air leak in the lobectomy group than the wedge resection group (12.5% v. 7%, \( p = 0.19 \)), but the sample was too small to reach statistical significance. Similarly there were higher rates of atrial fibrillation, flutter and MAT in the lobectomy group than the wedge resection group (6% v. 1.4%); however, this difference did not attain statistical significance.

For disease-free survival there was no significant difference between wedge resection and lobectomy (\( p = 0.59 \)).

### Table 1. Clinical characteristics of patients undergoing surgical resection for non–small cell lung cancer, by surgical procedure

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Lobectomy Group, no (%)</th>
<th>Wedge resection Group, no (%)</th>
<th>( p ) value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age mean, yr</td>
<td>64.7</td>
<td>64.9</td>
<td>0.78</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td>0.48</td>
</tr>
<tr>
<td>Male</td>
<td>165 (46.9)</td>
<td>30 (42.3)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>187 (53.1)</td>
<td>41 (57.7)</td>
<td></td>
</tr>
<tr>
<td>Smoker</td>
<td>323 (96.1)</td>
<td>65 (98.5)</td>
<td>0.48</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>87 (24.9)</td>
<td>19 (26.8)</td>
<td>0.74</td>
</tr>
<tr>
<td>COPD</td>
<td>101 (28.9)</td>
<td>33 (46.5)</td>
<td>0.004</td>
</tr>
<tr>
<td>Psychiatric</td>
<td>33 (9.4)</td>
<td>6 (8.4)</td>
<td>0.80</td>
</tr>
<tr>
<td>Type II diabetes</td>
<td>34 (9.7)</td>
<td>6 (8.5)</td>
<td>0.74</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjuvant</td>
<td>57 (16.9)</td>
<td>10 (14.9)</td>
<td>0.70</td>
</tr>
<tr>
<td>Neoadjuvant</td>
<td>7 (2.1)</td>
<td>1 (1.5)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Tumour stage</td>
<td></td>
<td></td>
<td>0.007</td>
</tr>
<tr>
<td>T1a</td>
<td>96 (27.3)</td>
<td>27 (38.0)</td>
<td></td>
</tr>
<tr>
<td>T1b</td>
<td>86 (24.4)</td>
<td>16 (22.5)</td>
<td></td>
</tr>
<tr>
<td>T2a</td>
<td>117 (33.2)</td>
<td>18 (25.4)</td>
<td></td>
</tr>
<tr>
<td>T2b</td>
<td>23 (6.5)</td>
<td>2 (2.8)</td>
<td></td>
</tr>
<tr>
<td>T3</td>
<td>28 (8.0)</td>
<td>4 (5.6)</td>
<td></td>
</tr>
<tr>
<td>T4</td>
<td>2 (0.6)</td>
<td>4 (5.6)</td>
<td></td>
</tr>
<tr>
<td>Cancer stage; AJCC seventh ed.</td>
<td></td>
<td></td>
<td>0.020</td>
</tr>
<tr>
<td>IA</td>
<td>146 (41.5)</td>
<td>35 (49.3)</td>
<td></td>
</tr>
<tr>
<td>IB</td>
<td>68 (19.3)</td>
<td>16 (22.5)</td>
<td></td>
</tr>
<tr>
<td>IIA</td>
<td>81 (23.0)</td>
<td>4 (5.6)</td>
<td></td>
</tr>
<tr>
<td>IIB</td>
<td>29 (8.2)</td>
<td>5 (7.0)</td>
<td></td>
</tr>
<tr>
<td>IIIA</td>
<td>26 (7.4)</td>
<td>11 (15.5)</td>
<td></td>
</tr>
<tr>
<td>IIIB</td>
<td>1 (0.3)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>1 (0.3)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

AJCC = American Joint Committee in Cancer; COPD = chronic obstructive pulmonary disease.

†All tests are \( \chi^2 \) tests (Pearson or Fisher exact, as appropriate) with the exception of age, which was based on a \( t \) test.

### Table 2. Pathological characteristics of patients undergoing surgical resection for non–small cell lung cancer, by surgical procedure

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Lobectomy Group, no (%)</th>
<th>Wedge resection Group, no (%)</th>
<th>( p ) value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumour size, mean, cm</td>
<td>3.3</td>
<td>2.5</td>
<td>0.002</td>
</tr>
<tr>
<td>T1a; AJCC seventh ed.</td>
<td>96 (27.3)</td>
<td>27 (38.0)</td>
<td>0.007</td>
</tr>
<tr>
<td>Stage IA; AJCC seventh ed.</td>
<td>146 (41.5)</td>
<td>35 (49.3)</td>
<td>0.021</td>
</tr>
<tr>
<td>Histology, no (%)</td>
<td></td>
<td></td>
<td>0.44</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>230 (65.5)</td>
<td>53 (74.6)</td>
<td></td>
</tr>
<tr>
<td>Squamous cell</td>
<td>94 (26.7)</td>
<td>15 (21.1)</td>
<td></td>
</tr>
<tr>
<td>Adenosquamous</td>
<td>9 (2.6)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Large cell</td>
<td>12 (3.4)</td>
<td>3 (4.2)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5 (1.4)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Tumour differentiation</td>
<td></td>
<td></td>
<td>0.38</td>
</tr>
<tr>
<td>Well</td>
<td>46 (13.3)</td>
<td>11 (16.2)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>134 (38.7)</td>
<td>19 (27.9)</td>
<td></td>
</tr>
<tr>
<td>Poor</td>
<td>154 (44.5)</td>
<td>36 (52.9)</td>
<td></td>
</tr>
<tr>
<td>Undifferentiated</td>
<td>12 (3.5)</td>
<td>2 (2.9)</td>
<td></td>
</tr>
<tr>
<td>Invasion present</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymphatic</td>
<td>87 (25.3)</td>
<td>21 (30.4)</td>
<td>0.38</td>
</tr>
<tr>
<td>Vascular</td>
<td>101 (29.4)</td>
<td>18 (26.5)</td>
<td>0.63</td>
</tr>
</tbody>
</table>

AJCC = American Joint Committee in Cancer.

*All tests are \( \chi^2 \) other than tumour size, which was assessed using a \( t \) test.
There was also no difference in overall tumour recurrence (36.8% v. 35%, respectively, \( p = 0.78 \)) or in overall mortality (37.3% v. 32.7%, respectively, \( p = 0.46 \)).

When the cohorts were stratified by tumour size, there was no significant difference in disease-free survival for patients with tumours less than 2 cm in diameter (\( p = 0.65 \); Fig. 1). There was, however, a significant difference in disease-free survival in favour of lobectomy for patients with tumours larger than 5 cm in diameter (\( p = 0.001 \)). For patients with tumours less than 2 cm, the hospital stay was significantly longer for those who underwent lobectomy than those who underwent wedge resection (7.9 d v. 6.2 d, \( p = 0.043 \)), which was also reflected in the median values (6 d and 5 d, respectively). We observed a trend toward higher rates of prolonged air leak in the lobectomy group compared with the wedge resection group (18.9% v. 6.1%, respectively, \( p = 0.10 \)). There was no significant difference between the lobectomy and wedge resection cohorts for

### Table 3. Tumour and cancer stage–specific disease-free survival and overall survival rates

<table>
<thead>
<tr>
<th>Stage*</th>
<th>Disease-free survival</th>
<th>Overall survival</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lobectomy, ( n = 223 )</td>
<td>Wedge resection, ( n = 43 )</td>
</tr>
<tr>
<td>T1a</td>
<td>67 (30.0)</td>
<td>18 (41.9)</td>
</tr>
<tr>
<td>T1b</td>
<td>58 (26.0)</td>
<td>9 (20.9)</td>
</tr>
<tr>
<td>T2a</td>
<td>67 (30.0)</td>
<td>11 (25.6)</td>
</tr>
<tr>
<td>T2b</td>
<td>15 (6.8)</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>T3</td>
<td>14 (6.3)</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>T4</td>
<td>2 (0.9)</td>
<td>3 (7.0)</td>
</tr>
<tr>
<td>Cancer stage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IA</td>
<td>110 (49.3)</td>
<td>107 (45.9)</td>
</tr>
<tr>
<td>IB</td>
<td>43 (19.2)</td>
<td>45 (19.3)</td>
</tr>
<tr>
<td>IIA</td>
<td>39 (17.5)</td>
<td>46 (19.8)</td>
</tr>
<tr>
<td>IIB</td>
<td>19 (8.5)</td>
<td>22 (9.5)</td>
</tr>
<tr>
<td>IIIA</td>
<td>10 (4.5)</td>
<td>11 (4.7)</td>
</tr>
<tr>
<td>IIIB</td>
<td>1 (0.5)</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>IV</td>
<td>1 (0.5)</td>
<td>1 (0.4)</td>
</tr>
</tbody>
</table>

AJCC = American Joint Committee on Cancer.
* Tumour stage and cancer stage are based on the AJCC, seventh edition.
† \( p \) values are based on the Pearson \( \chi^2 \) test.

### Table 4. Outcomes for patients with tumours smaller than 2 cm in diameter

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group; no. (%)*</th>
<th>( \chi^2 ) test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumour recurrence</td>
<td>26 (27.7)</td>
<td>8 (26.7)</td>
</tr>
<tr>
<td>Distant, brain, bone, adrenal</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Regional; mediastinal or hilar lymph nodes</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Local; within lung parenchyma</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Overall mortality</td>
<td>24 (25)</td>
<td>6 (19.4)</td>
</tr>
<tr>
<td>Complication; prolonged air leak</td>
<td>18 (19.9)</td>
<td>2 (6.1)</td>
</tr>
<tr>
<td>Length of hospital stay, mean d</td>
<td>7.9</td>
<td>6.2</td>
</tr>
<tr>
<td>Tumour diameter, mean cm</td>
<td>1.6</td>
<td>1.5</td>
</tr>
</tbody>
</table>

* Unless otherwise indicated.
† \( \chi^2 \) test.
‡ Mann–Whitney \( U \) test.
patients with tumours smaller than 2 cm for recurrence (27.7% v. 26.7%, respectively, \( p = 0.92 \)) or overall mortality (25% v. 19.4%, respectively, \( p = 0.52 \); Table 4). When tumours were stratified based on the seventh edition AJCC TNM classification, there were no significant differences in outcomes encountered for tumour stage and overall stage IA and IB disease.

**DISCUSSION**

This Canadian study carried out at a tertiary care university hospital is unique in that it predominantly compares wedge resection (as opposed to segmental resection) with lobectomy for the surgical management of NSCLC. In addition, the groups were stratified by tumour size and based on the seventh edition AJCC TNM classification. We observed similar rates of disease-free and overall survival for patients with early-stage NSCLC undergoing lobectomy and wedge resection.

**Limitations**

The limitations of this study arise primarily from its retrospective nature and 11-year duration. Some patient data on preoperative cardiopulmonary assessment (pulmonary function and echocardiography test results) were simply not available. However, given our institution’s adherence to widely accepted guidelines (Cancer Care Ontario, American College of Chest Physicians and National Comprehensive Cancer Network guidelines) for the conduct of preoperative assessment and pulmonary resection, along with the demographic and comorbidity data provided, readers are still able to extrapolate the applicability of these results to their own patients. In addition, during the 11-year course of this study, practice standards regarding lymph node assessment and adjuvant therapy protocols changed. We strongly feel that this would not have affected the results substantially, given that only those patients with the smallest tumours (≤ 2 cm) who underwent wedge resection had similar survival to those who underwent lobectomy. These patients would have been unlikely to receive chemotherapy, even with the new standard of care.

It is important to recognize that patients with compromised pulmonary reserve may be more likely to die sooner than those without compromised pulmonary reserve of causes other than lung cancer recurrence, thus potentially decreasing overall survival and artificially inflating the disease-free survival in this group. Furthermore, patients who underwent wedge resection were more likely to have documented COPD than those who underwent lobectomy. In addition, the wedge resection cohort was selected to have smaller (< 2 cm), earlier staged tumours (stage IA or IB) than the lobectomy cohort. For tumours smaller than 2 cm in size, patients who underwent lobectomy had a significantly increased length of hospital stay. This may be due to the complication of prolonged air leak, for which we observed a trend toward higher rates.

**CONCLUSION**

These data demonstrate that in properly selected patients wedge resection for NSCLC has the potential to be an adequate oncologic procedure. Specifically, the eligible patient groups include those with small tumours (< 2 cm in diameter) and seventh edition AJCC stage IA or IB disease. This is supported by similar rates of disease-free and overall survival observed in these cohorts. Furthermore, we await the results of the ongoing National Cancer Institute of Canada Clinical Trials Group phase III randomized trial of lobectomy versus sublobar resection for tumours smaller than 2 cm in patients with peripheral NSCLC (BRC.5 CALGB 140503) to learn whether similar survival outcomes to those in our retrospective analysis can be observed in the prospective setting.

**Competing interests:** None declared.

**Contributors:** A. McGuire designed the study and acquired the data, which all authors analyzed. A. McGuire and W. Hopman wrote the article, which all authors reviewed and approved for publication.

**References**


Does the long-term use of aspirin decrease the risk of death due to cancer?

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The term “evidence-based medicine” was first coined by Sackett and colleagues as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.” The key to practising evidence-based medicine is applying the best current knowledge to decisions in individual patients. Medical knowledge is continually and rapidly expanding. For clinicians to practise evidence-based medicine, they must have the skills to read and interpret the medical literature so that they can determine the validity, reliability, credibility and utility of individual articles. These skills are known as critical appraisal skills, and they require some knowledge of biostatistics, clinical epidemiology, decision analysis and economics, and clinical knowledge.

Evidence Based Reviews in Surgery (EBRS) is a program jointly sponsored by the Canadian Association of General Surgeons (CAGS) and the American College of Surgeons (ACS). The primary objective of EBRS is to help practising surgeons improve their critical appraisal skills. During the academic year, 8 clinical articles are chosen for review and discussion. They are selected for their clinical relevance to general surgeons and because they cover a spectrum of issues important to surgeons, including causation or risk factors for disease, natural history or prognosis of disease, how to quantify disease, diagnostic tests, early diagnosis and the effectiveness of treatment. A methodological article guides the reader in critical appraisal of the clinical article. Methodological and clinical reviews of the article are performed by experts in the relevant areas and posted on the EBRS website, where they are archived indefinitely. In addition, a listserv allows participants to discuss the monthly article. Surgeons who participate in the monthly packages can obtain Royal College of Physicians and Surgeons of Canada Maintenance of Certification credits and/or continuing medical education credits for the current article only by reading the monthly articles, participating in the listserv discussion, reading the methodological and clinical reviews and completing the monthly online evaluation and multiple choice questions.

We hope readers will find EBRS useful in improving their critical appraisal skills and in keeping abreast of new developments in general surgery. Four reviews are published in condensed versions in the Canadian Journal of Surgery and 4 are published in the Journal of the American College of Surgeons. For further information about EBRS, please refer to the CAGS or ACS websites. Questions and comments can be directed to the program administrator, Marg McKenzie, at mmckenzie@mtsinai.on.ca.

Reference

Selected article

ABSTRACT

Question: Does the long-term use of acetylsalicylic acid (ASA) decrease the risk of death due to cancer? Design: Pooled analysis. Data source: Cochrane Collaboration, Database of Systematic reviews, PubMed and Embase. Study selection: Individual patient data from all randomized trials of daily ASA versus no ASA with a mean duration of scheduled trial treatment of 4 years or longer were used to determine the effect of allocation to ASA on risk of cancer death in relation to scheduled duration of trial treatment for gastrointestinal (GI) and non-GI cancers. Results: In 8 eligible trials (25 570 patients, 674 cancer-related deaths), allocation to ASA reduced the risk of death due to cancer (pooled odds ratio [OR] 0.79, 95% confidence interval [CI] 0.68–0.92, p = 0.003). On analysis of individual patient data, which were available from 7 trials (23 535 patients, 657 cancer-related deaths), the benefit was apparent only after 5 years’ follow-up (all cancers, hazard ratio [HR] 0.66, 95% CI 0.50–0.87; GI cancers, 0.46, 95% CI 0.27–0.77; both p = 0.003). The 20-year risk of cancer death (deaths in 12 659 patients in 3 trials) remained lower in the ASA groups than in the control groups (all solid organ cancers, HR 0.80, 95% CI 0.72–0.88, p < 0.001; GI cancers, HR 0.65, 95% CI 0.54–0.78, p < 0.001), and benefit increased (interaction p = 0.01) with scheduled duration of trial treatment (≥7.5 years: all solid cancers, HR 0.69, 95% CI 0.54–0.88, p = 0.003; GI cancers, HR 0.41, 95% CI 0.26–0.66, p < 0.001). The latent period before an effect on deaths could be observed was about 5 years for esophageal, pancreatic, brain and lung cancer, but was longer for stomach, colorectal and prostate cancer. For lung or esophageal cancer, the benefit was confined to adenocarcinomas, and the overall effect on 20-year risk of cancer-related death was greatest for adenocarcinomas (HR 0.66, 95% CI 0.56–0.77, p < 0.001). The benefit was unrelated to ASA dose (75 mg or higher), sex or smoking, but was increased with age; the absolute reduction in 20-year risk of cancer-related death reached 7.08% at age 65 years and older. Conclusion: Daily ASA reduced deaths due to several common cancers during and after the trials. The benefit increased with duration of treatment and was consistent across the different study populations. These findings have implications for guidelines on use of ASA and for understanding carcinogenesis and its susceptibility to drug intervention.

COMMENTARY

Cancer is one of the leading causes of death in the developed world, with the lifetime risk approaching 40%. Although great strides have been made in cancer treatment, there has been relatively little progress in terms of primary cancer prevention. There is some evidence, both from observational trials and animal models, suggesting that long-term ASA use may reduce the risk of cancer, particularly cancers of the GI tract. The effect of ASA is hypothesized to be due to cyclo-oxygenase inhibition and to decreased production of prostaglandins and inflammatory mediators. Although the mechanism of action is not yet clear, data from several trials support the role of daily ASA use in reducing the incidence of colorectal cancers.

Rothwell and colleagues performed a pooled analysis of randomized controlled trials of ASA versus control with a mean treatment duration of at least 4 years. The study design was a variant of a systematic review and meta-analysis. This study design is a variant of a systematic review and meta-analysis called a “pooled analysis,” whereby individual patient data from multiple studies are combined and analyzed. Individual patient-level data are required, thus it is usually not possible to perform with standard aggregated data available in published trials. Instead, patient-level data usually have to be requested from the original investigators.

Pooled analyses are usually considered more rigorous than meta-analyses. First the researcher has the raw data and is not relying on the assumptions written in a previously published paper (some of which may not be apparent in the paper). Second, the researcher can impose common inclusion and exclusion criteria, statistical methods and other methods across all data. For example, rather than including patients 25 years and older from one study and patients 18 years and older from a second study, if the researcher has the raw data, he/she can exclude the 18- to 24-year-olds from the first study to make the data consistent. Third, when working with raw data, the statistic may be more accurate because in a meta-analysis, means are rounded and sometimes the data must be approximated by looking at graphs. Finally, the researcher often can control for publication bias if the data were not chosen based on publications, but rather based on knowledge of existing trials.

On the other hand, one cannot just pool all data together and use standard statistics. Because the patients from the different studies were not accrued from the same sampling frame, it is best to use a random-effects model in which “the study” is modelled/controlled for as a random effect. This method is akin to the issue of clustering of centres in randomized controlled trials.

The major advantage to meta-analysis is that the author can use data from many studies for which one would not necessarily have access to the data. Finally, not all pooled analyses are performed rigorously. “Sample pooling” of data where there is no adjustment for the fact that the data come from different trials (i.e., sampling frames) should not be performed.

The pooled analysis of the 8 studies included in the study by Rothwell and colleagues demonstrated that in the patients receiving ASA, cancer-related deaths were significantly reduced (OR 0.79, 95% CI 0.68–0.92, p = 0.003). On analysis of individual patient data, the benefit became
apparent only after 5 years of follow-up. A significantly decreased HR was observed for all solid organ cancers.

The findings of Rothwell and colleagues are consistent with those of many previous studies assessing the effect of ASA on cancer prevention, particularly the prevention of colorectal cancer. Unique in this study was the long follow-up and the finding of risk reduction for several cancers not previously shown to be impacted by ASA use. Although this pooled analysis supports the cancer reduction effects of daily ASA, conflicting results have been reported: the Women’s Health Study, a large 10-year trial of 100 mg of ASA taken every other day, reported no reduction in cancer incidence or mortality.1

Rothwell and colleagues conclude, “Daily aspirin reduced deaths due to several common cancers during and after the trials. The benefit increased with duration of treatment and was consistent across the different study populations. These findings have implications for guidelines on use of aspirin and for understanding of carcinogenesis and its susceptibility to drug intervention.”

Although the data presented cannot be considered strong enough to make a broad recommendation on the use of ASA in the chemoprophylaxis of cancer, there consistently seems to be a signal that ASA use decreases cancer-related mortality, and it is time that this be investigated directly.

References
IS THE CULTURE OF SURGERY STILL A GENDER ISSUE?

We read Brown and colleagues’ recent article1 on culture transition in surgery with interest. We agree with the accompanying editorial by Harvey,2 that this is an important addition to the literature and that open, frank discussion is needed from the profession. We feel that some of their points merit further exploration.

The authors highlight 2 key factors influencing the culture and future of our profession: the (slow) movement toward gender balance and a generationally driven attitudinal shift. They study how “new” recruits perceive these changes by interviewing 17 surgeons (9 women, 8 men),3 all of whom are assistant professor level or higher; have a mean age of 38 years; and are in heterosexual relationships. The ethnic profile of the sample was not reported.

We would suggest that interviewing this sample, though of interest, might in fact miss the point; the authors have sought the views of the “new establishment.” All of the participants of the study have become established academic surgeons, some against well-defined, albeit diminishing, barriers. They have opted to stay in the profession, in some cases alongside the added commitments of motherhood. In the UK, 90% of those in surgical training decide on this path during their first year postqualification with a similar gender ratio, yet far fewer women ultimately achieve their goal.4 Women initially attracted to surgery move away from this career option during their postgraduate education; this attrition was previously attributed to lifestyle considerations.5,6 We would postulate that the same may be true of some black and minority ethnic groups, and possibly also lesbian, gay, bisexual and transgendered surgical trainees. Interviewing a cohort from these groups — those who chose not to enter the profession they were initially drawn to — may cast further light on gender and cultural issues within surgery and underscore why it has been perceived for so long as an “old boys’ club” with ongoing discrimination.

Brown and colleagues1 cite a lack of mentoring as 1 potential reason for our profession’s loss of talent. We would support this claim. In our experience7 and the experience of others, access to mentors is limited not only for women but also for other minorities in this professional arena. Formalized mentoring programs that seek to pair candidates with suitably matched (but not necessarily demographically similar) mentors, and the use of mentoring frameworks, may help people to achieve successful mentoring relationships.8 Raising awareness for mentoring and mentor acquisition as early as possible in surgical careers (i.e., medical school) may also benefit potential surgeons.

Positive role models have been shown to significantly impact career choices.9 From our personal experience (H.M., T.B.), role models are limited for Generation Y female potential surgeons. We agree with the study, that increasingly this is not a gender issue; men, too, want a better work–life balance9 to pursue portfolio careers while having flexibility for more time at home and the opportunity to travel. Certain aspects of surgery as a career (e.g., emergency work, management of complications, unpredictability of surgical pathology, competition for attaining training posts) inherently clash with these aspirations; however, we believe that broad-minded individuals with ambition within and outside of medicine are assets to any workforce.

Surgical trainees with the Generation Y value set should be encouraged into, not dissuaded from, surgical specialties. This will not happen passively; it requires a strategic approach involving enhanced child care options, job sharing and flexible contracts, and signposting of role models and mentoring opportunities. It requires a culture change within our profession.

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References


THE AUTHORS RESPOND

We appreciate the thoughtful response from McGrath, Brew and Warren. We acknowledge that we interviewed those who overcame the
challenges of postgraduate training and became academic surgeons. We question whether they would perceive themselves as the “new establishment,” though we will concede that to be successful these individuals have agreed to the expectations of their department and their academic institution. We recognize that many surgical trainees leave training programs and many academic surgeons leave university departments to go into community practice because they cannot, or will not, make the compromises required to deal with the demands of their roles. We agree that many capable women leave surgical training or drop out of academic surgery because of the difficulty of combining family and professional roles.

We also acknowledge the limitations of our study group. We were interested in the case study represented by a department of surgery that intentionally set out to change the gender mix and to change policies to be more “family friendly.” We would contend that departments of surgery can make choices about how to support women and men during their training and as faculty members, and these choices will make trainees more likely to be successful. This is an evolutionary rather than a revolutionary approach.

Our paper indicates the critical importance of mentorship. If mentors are not assigned or identified in one’s own department, individuals need to look elsewhere—to national surgery organizations or other national organizations such as the Canadian Medical Association, which has a mentorship program to faculty members outside of surgery.

Again, we thank the authors for their comments and observations, all directed at inclusiveness in surgical training and academic pursuits.

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COMMENT ON “COMPARISON OF THE MAJOR INTRAOPERATIVE AND POSTOPERATIVE COMPLICATIONS BETWEEN UNILATERAL AND SEQUENTIAL BILATERAL TOTAL KNEE ARTHROPLASTY IN A HIGH-VOLUME COMMUNITY HOSPITAL”

It was with great interest that we read the recent article by Spicer, Thomas and Rumble, which provides an insight into the safety of unilateral total knee arthroplasty (UTKA) versus sequential or simultaneous bilateral total knee arthroplasty (BTKA) in a high-volume community hospital. The authors excluded from their study patients who underwent staged TKA, defined as “2 distinct surgeries on both knees within a 1-year period.” Instead, candidates with bilateral knee symptoms who were deemed eligible for surgery were given the option of BTKA or 2 UTKAs.

In our experience with patients who present with bilateral fixed flexion deformities, even if a UKA is initially successful, it may develop stiffness and adopt the fixed flexion of the contralateral knee if the latter is not likewise replaced within a few months. Residual flexion contractures after knee replacement have been associated with poor outcomes.

The limitation of movement and impact on quality of life caused by a residual flexion contracture should be considered a complication in itself. This complication might be avoided by performing a BTKA or careful pre- and postoperative management to safely complete staged TKA procedures in considerably less than 1 year. Although it seems reasonable that “individuals who decline the second operation may have been better served by a 1-step BTKA,” the alternative is perhaps more relevant to orthopedic departments where there is less experience and expertise in performing BTKAs.

The merits of BTKA versus staged TKA have been extensively discussed in the literature. Reduced costs, single anesthetic and decreased total recovery time have been highlighted as advantages of BTKA, but an increased risk of serious postoperative complications have also been reported. We hope that future studies will continue to objectively evaluate the risks and benefits of each, and identify which patients might be more suited to a particular method.

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References


THE AUTHORS RESPOND

We thank Razii and Morgan-Jones for their comments regarding our study that compared the incidence of serious perioperative complications between unilateral and bilateral total knee replacements.

They make the additional observation that replacing 1 knee when the patient has a deformity in both knees presents difficulties with rehabilitation and may compromise the outcome for the knee. We agree that this may very well be the case, though it was not the focus of our study.

They also comment on the omission of staged procedures, in which the 2 knees are replaced on separate occasions within the first year. In our hospital there were only 69 such patients during the time frame of our study, which did not reach statistical significance; hence, we omitted them.

They encourage further study to “identify which patients might be more suited to a particular method.” This may be useful to surgeons in different settings. In our case, we found that replacing both knees under 1 anesthetic was safe in the setting of a high-volume community hospital.

Once again, we appreciate the feedback.

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Le *Journal canadien de chirurgie* (JCC) publie des articles de recherche originale et des articles de revue sur tous les aspects de la technique et la pratique chirurgicales (y compris la chirurgie fondée sur les données probantes, la chirurgie à l’étranger, la biologie chirurgicale pour le clinicien, les soins des traumatisés et les soins critiques), de même que des éditoriaux, commentaires et les séries de cas.

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GENERAL SURGEON

The Department of Surgery, Alberta Health Services – Calgary Zone and the University of Calgary invite applications for the position of General Surgeon.

Qualifications include an MD, a Fellowship in the Royal College of Physicians and Surgeons of Canada in General Surgery with additional fellowship training and eligibility for licensure in the province of Alberta. Candidates are expected to have two additional skill sets on top of their general surgery training (Masters’ Degree preferred).

Teaching at the undergraduate and postgraduate level will be required. Participation in research related to clinical outcomes or medical education is expected. Committee duties will be expected as the need arises. The successful candidate will take call according to the site and Alberta Health Services policies.

In accordance with Canadian immigration requirements, priority will be given to Canadian citizens and permanent residents of Canada. Alberta Health Services and the University of Calgary are committed to employment equity.

Please submit your curriculum vitae and the names and addresses of three referees to:

Dr. Francis Sutherland
Section Head General Surgery, Calgary Zone
Foothills Medical Centre
1403 - 29 Street NW
Calgary, Alberta T2N 2T9

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Dr. S. Widder
2D4.27 Walter Mackenzie Centre
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