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Canadian Journal of Surgery

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Incremental value and clinical impact of neck sonography for primary hyperparathyroidism: a risk-adjusted analysis

Complications associated with laparoscopic sleeve gastrectomy for morbid obesity: a surgeon’s guide

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Resident work conditions under the microscope

This edition of CJS has a commentary by Imrie and colleagues1 from the Royal College of Physicians and Surgeons of Canada referencing the report *Fatigue, Risk and Excellence: Towards a Pan-Canadian Consensus on Resident Duty Hours*’ that has recently been released by the National Steering Committee on Resident Duty Hours. A large group of engaged physicians and other experts have reviewed literature on the effect of resident duty hour restrictions in relation to patient safety, resident wellness, training and educational outcomes and the educational needs of surgeons. The working group highlighted evidence suggesting bad outcomes in care delivery and training — particularly for surgical specialties — when total or consecutive hours of resident duty are mandated. Restricting the number of hours, which in reality may be a reflection of an increase in the number of handovers in patient care, seems to have resulted in some bad outcomes. Imrie and colleagues comment on recent studies that reported more complications in high-acuity surgical patients and increasing failures in certification examinations with rigid resident hours.

The actual conclusions of this report, as I interpret it, are that a tired doctor may not necessarily be a bad doctor, that there are no conclusive data to show that restrictions on consecutive resident duty hours are necessary for patient safety, that there is no clear evidence that resident duty hour hours have an overall cross-medicine impact on academic performance, and that there is evidence suggesting suboptimal patient care and educational outcomes in surgery resulting from the restriction of resident duty hours. There have been observations that resident wellness suffered owing to longer hours under previous training schemes and that any changes in hours need to incorporate “other” metrics. The National Steering Committee on Resident Duty Hours report is timely, as we enter a phase of determining what is appropriate training or even what defines a normal practice after residency. Closer to home, *Maclean’s* ran a story on a similar subject with an emphasis on the fact that changing the hours worked might have increased errors.4

We definitely need to look at how these observations and this landmark report should change the way we design training programs, especially in surgery. I think adding yet another novel layer, such as competency-based training, on top of restricted resident hours will not mitigate the shortcomings of the current system. But something has to be reconfigured. It may be that we need better studies and that the current results reflect inherent bias. However, we need to step up and do something quickly because it seems the patients may be paying a price for our new programs.

Edward J. Harvey, MD
Coeditor, *Canadian Journal of Surgery*

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Les conditions de travail des résidents sous le microscope

Dans ce numéro du *JCC* figure un commentaire du Dr Imrie et de ses collaborateurs du Collège royal des médecins et chirurgiens du Canada concernant le rapport *Fatigue, risque et excellence : A la recherche d’un consensus pancanadien sur les heures de travail des résidents* récemment publié par le Comité directeur national sur les heures de travail des résidents. Un grand nombre de médecins et autres experts ont passé en revue la littérature sur l’effet des restrictions des heures de travail des résidents sur la sécurité des patients et le mieux-être des résidents, ainsi que sur les résultats de la formation des chirurgiens et les besoins à cet égard. Le groupe de travail a mis en évidence des preuves suggérant que lorsque les heures de travail totales ou consécutives des résidents sont imposées, cela entraîne de mauvais résultats dans la prestation de soins et la formation — en particulier pour les spécialités chirurgicales. Limiter le nombre d’heures, ce qui en réalité peut refléter une augmentation du nombre de transferts des soins, semble avoir donné de mauvais résultats. Le Dr Imrie et ses collaborateurs commentent de récentes études qui ont signalé un nombre accru de complications chez les patients à la suite d’interventions chirurgicales d’urgence et des taux de plus en plus élevés d’échec des examens de certification en raison des heures de travail inflexibles des résidents.

Selon mon interprétation, les conclusions réelles de ce rapport sont qu’un médecin fatigué n’est pas nécessairement un mauvais médecin, qu’il n’y a pas de données concluantes pour prouver qu’il est nécessaire de restreindre les heures de travail consécutives des résidents pour assurer la sécurité des patients, qu’il n’y a pas de données claires démontrant que la réglementation des heures de travail des résidents a une incidence négative sur les résultats scolaires de leurs étudiants, et qu’il existe des preuves suggérant que la restriction des heures de travail des résidents a un effet négatif sur le soin des patients et le rendement académique en chirurgie. On a observé que les longues heures passées dans les programmes de formation antérieurs avaient eu un effet négatif sur le mieux-être des résidents et que tout changement dans les heures de travail doit intégrer « d’autres » mesures. Le rapport du Comité directeur national sur les heures de travail des résidents arrive à point nommé, car nous entreprenons une phase de détermination de ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Notre association nationale a certes de la difficulté à définir ce qui constitue une formation appropriée, voire même ce qui constitue une pratique normale après la résidence. Nous devons absolument regarder comment ces observations et ce rapport déterminant devraient changer la façon dont nous concevons des programmes de formation, en particulier dans les disciplines chirurgicales. Je pense qu’ajouter un autre élément, tel que la formation axée sur les compétences, à la restriction des heures de travail des résidents n’atténuerait pas les lacunes du système actuel. Mais il faut reconfigurer quelque chose. Il se peut que nous devions réaliser de meilleures études et que les résultats actuels reflètent un biais inhérent. Nous devons cependant agir sans plus tarder, car il semble que les patients payent un prix pour nos nouveaux programmes.

Edward J. Harvey, MD
Co-rédacteur, *Journal canadien de chirurgie*

Intérêts concurrents: Aucuns déclarés.

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Références


COMMENTARY • COMMENTAIRE

A new era for resident duty hours in surgery calls for greater emphasis on resident wellness

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In Canada, physicians and surgeons in training have dual roles as learners and care providers. While they have graded responsibility for the provision of patient care, they are also training for independent practice. Over the last several decades and against the backdrop of rapid changes in patient care and surgical practice, there has been ongoing discussion and evolution in the residency education system and in residents’ schedules. Historically, residents literally resided within the hospitals in which they provided care and received training. Today’s health care and medical education systems are marked by shifts and broader changes in the characteristics of patient care, workflow and scheduling of residents and by an increasing professional diversity in the health care team. While residents of the 21st century do not live in the hospitals in which they work and train, they are nevertheless key members of health care delivery teams in our busiest hospitals, and it is in these hospitals that faculty members and training programs are tasked with ensuring the safe maturation of residents into independent physicians and surgeons.

The ongoing dialogue surrounding resident duty hours has led to an important debate in residency education worldwide. Until recently, there has been no cohesive approach, inclusive of multiple stakeholders, toward issues surrounding the regulation of resident duty hours in Canada. However, over the last 16 months, a new era of the resident duty hours debate has begun. Since March 2012, supported with funding from Health Canada, concerted efforts have been made to arrive at a pan-Canadian consensus on this important topic. This work has resulted in an unprecedented report, entitled Fatigue, Risk and Excellence: Towards a Pan-Canadian Consensus on Resident Duty Hours, launched earlier this month.

The project was directed by a senior consortium, the National Steering Committee on Resident Duty Hours, comprising stakeholders from Canadian postgraduate medical education and representatives from collaborating partner organizations, including the Association of Canadian Academic Healthcare Organizations; the Association of Faculties of Medicine of Canada; the Canadian Association of Internes and Residents; the Canadian Medical Association; the Collège des Médecins du Québec; the Federal, Provincial, and Territorial Committee on Health Workforce; the Fédération des Médecins Résidents du Québec; and the Royal College of Physicians and Surgeons of Canada.

From the time of the project’s inception, the National Steering Committee recognized the importance of identifying and addressing the challenges posed by resident duty hour regulations for training in surgical and procedural disciplines. To do so, the committee established a working group to review and compile the evidence related to the unique issues and challenges faced in surgical and procedural disciplines and the training of residents within such specialties. Chaired by a trauma and acute care surgeon who is the program director of the general surgery residency training program at the University of Toronto (N.A.), the group reviewed a large volume of research related to the effect of resident duty hour restrictions on the inter-related domains of patient safety, resident wellness and training and educational outcomes, as well as the
varying educational needs of surgeons who provide patient care across the large and diverse landscape of Canada. In addition to the Special Considerations for Procedural Disciplines working group, 5 other expert working groups (Patient Safety, Medical Education, Resident and Faculty Health and Wellness, Professionalism, and Health Systems Performance and Health Economics) were created to explore themes across all medical disciplines.

One of the key findings articulated in the project’s final report pertains to the unique challenges faced by the surgical and procedural disciplines in an environment of strictly regulated resident duty hours. The literature reviewed by the Special Considerations for Procedural Disciplines working group highlighted a body of evidence suggesting suboptimal outcomes in surgical care delivery and surgical training when total or consecutive hours of resident duty are rigidly restricted, such as they have been in the United States and the European Union. Recent studies suggest increased complications in high-acuity surgical patients and declining performance on some certification examinations as a result of rigidly controlled resident duty hours. The working group’s analysis of the literature led to their conclusion that there is a vital need for more research on the effect of duty hours on surgical and procedural skills acquisition and performance and for the development of training and care delivery paradigms appropriate for higher-acuity patient care areas, where such research findings more frequently emerge. It would seem appropriate that procedural and surgical training programs work collaboratively with all stakeholder organizations to develop strategies that support excellent training outcomes, resident wellness and patient safety among these disciplines.

The final project report outlines a series of 5 principles and 5 recommendations for the future direction of resident duty hours in Canada with implications for all disciplines and residency programs. Rather than outlining specific restrictions regarding a set number of hours or shift length, chief in the National Steering Committee proposal is the need for a comprehensive, rigorous and tailored approach to the management and mitigation of physician and surgeon fatigue and burnout. Neither role — learner or health care provider — is well served if unchecked fatigue impairs cognitive functions or threatens professional satisfaction or health.

The Royal College of Physicians and Surgeons of Canada is dedicated to facilitating the implementation and supporting the launch of all recommendations proposed by the National Steering Committee across all residency programs and all disciplines. Such changes focus on fatigue mitigation and stress management during residency and highlight strategies that could involve new models of scheduling; greater protection for sleep at night; adjustments to resident workload; and broader, educational innovations, such as competency-based training and evaluation, that echo changes across the continuum of medical education. Also included as a key recommendation is the proposed development of a national consortium to study and disseminate new knowledge related to resident duty hour regulation. These and other innovations will support a transition to a new era of resident duty hours that maximizes education and patient care outcomes in the 21st century.

References


Laparoscopic versus open surgery for the treatment of colorectal cancer: a literature review and recommendations from the Comité de l’évolution des pratiques en oncologie

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Rasmy Lougnarath, MD¶
Claude Thibault, MD**
Normand Gervais, MD††
For the Comité de l’évolution des pratiques en oncologie

Background: Adoption of the laparoscopic approach for colorectal cancer treatment has been slow owing to initial case study results suggesting high recurrence rates at port sites. The use of laparoscopic surgery for colorectal cancer still raises a number of concerns, particularly with the technique’s complexity, learning curve and longer duration. After exploring the scientific literature comparing open and laparoscopic surgery for the treatment of colorectal cancer with respect to oncologic efficacy and short-term outcomes, the Comité de l’évolution des pratiques en oncologie (CEPO) made recommendations for surgical practice in Quebec.

Methods: Scientific literature published from January 1995 to April 2012 was reviewed. Phase III clinical trials and meta-analyses were included.

Results: Sixteen randomized trials and 10 meta-analyses were retrieved. Analysis of the literature confirmed that for curative treatment of colorectal cancer, laparoscopy is not inferior to open surgery with respect to survival and recurrence rates. Moreover, laparoscopic surgery provides short-term advantages, including a shorter hospital stay, reduced analgesic use and faster recovery of intestinal function. However, this approach does require a longer operative time.

Conclusion: Considering the evidence, the CEPO recommends that laparoscopic resection be considered an option for the curative treatment of colon and rectal cancer; that decisions regarding surgical approach take into consideration surgeon experience, tumour stage, potential contraindications and patient expectations; and that laparoscopic resection for rectal cancer be performed only by appropriately trained surgeons who perform a sufficient volume annually to maintain competence.

Contexte : L’adoption de la laparoscopie pour traiter le cancer colorectal se fait lentement à cause des résultats des premières études de cas qui indiquent des taux élevés de récidive aux sites d’intervention. La laparoscopie pour traiter le cancer colorectal soulève toujours de nombreuses préoccupations, particulièrement en raison de la complexité de la technique, de la courbe d’apprentissage, et de la durée de la chirurgie. Après avoir étudié les publications scientifiques comparant l’efficacité oncologique et les résultats à court terme de la laparoscopie à ceux de la chirurgie ouverte pour le traitement du cancer colorectal, le Comité de l’évolution des pratiques en oncologie (CEPO) a formulé des recommandations pour la pratique chirurgicale au Québec.


Résultats : Seize essais randomisés et 10 méta-analyses ont été retenus. L’analyse des publications a confirmé que pour le traitement curatif du cancer colorectal, la laparoscopie n’est pas inférieure à la chirurgie ouverte pour ce qui est des taux de survie et de récidive. La laparoscopie offre de plus des avantages à court terme, y compris une hospitalisation de moins longue durée, une réduction de l’usage d’analgésiques et un rétablissement plus rapide de la fonction intestinale. Cette intervention prend toutefois plus de temps.

Conclusion : Compte tenu des données probantes, le CEPO recommande d’envisager la résection laparoscopique comme technique curative possible du cancer colorectal et que les décisions sur la méthode chirurgicale tiennent compte de l’expérience du chirurgien, du stade de la tumeur, des contre-indications possibles et des attentes du patient. Dans le cas de la résection laparoscopique du cancer du rectum, le CEPO recommande qu’elle ne soit pratiquée que par des chirurgiens ayant reçu la formation nécessaire et qui pratiquent suffisamment d’interventions par année pour maintenir leur compétence.
C olorectal cancer is the third most commonly diagnosed cancer and the second leading cause of cancer-related death in Canada. The Canadian Cancer Society estimated that approximately 23,800 new colorectal cases will be diagnosed in Canada in 2013 (6,300 in Quebec), and that 9,200 related deaths will be reported (2,450 in Quebec).

Surgery is the only curative treatment for colorectal cancer. Curative surgery requires resection of the primary tumour with negative margins and a complete oncologic lymphadenectomy. The resected colic segment depends on vascularization and lymphatic drainage at the tumour site and, according to the American Joint Committee on Cancer, a minimum of 12 lymph nodes should be retrieved in surgical specimens. Otherwise, tumour stage could be underestimated, and a suboptimal treatment could be offered.1

The surgical approach for rectal cancer is affected by tumour stage and localization.1 Generally, 5 types of resection can be performed: local excision of the tumour, anterior resection of the rectum, proctectomy with coloanal anastomosis or with terminal colostomy (Hartmann), and abdominoperineal resection. A major improvement in surgical technique was achieved in 1982 when total mesorectal excision was first described and resulted in a substantial reduction in recurrence rates.2

Traditionally, colorectal cancer resection has been performed exclusively through open surgery. However, following successful laparoscopic procedures, such as cholecystectomy, appendectomy and treatment of incisional hernias, this surgical approach has gradually been introduced first in the treatment of colon cancer and then in the treatment of rectal cancer.1 Surgical preparation for laparoscopy is similar to that for open surgery. However, small lesions need to be carefully localized preoperatively by means of colonoscopy (with a tattoo or clip) or barium enema. Laparoscopic resection should result in the removal of the colon or rectal segment containing the tumour and associated lymphatic drainage to the same extent as open surgery. Surgery can be performed entirely by laparoscopy, be laparoscopy-assisted (anastomosis is then performed extracorporally) or be hand-assisted (in which case a sufficiently long incision is made to allow the surgeon’s hand to enter the abdominal cavity). For all 3 strategies, the abdominal wall incision should be protected to prevent tumour dissemination.4

Laparoscopic resection of the sigmoid colon was first described by Jacobs and colleagues1 in 1991. However, generalized adoption of the laparoscopic procedure was slower for colorectal cancer than for other pathologies. This can be explained by the disappointing results of initial case studies on laparoscopic colon cancer resection, which revealed high recurrence rates at port sites.5–3 Despite the fact that more recent studies did not reproduce these results,13,14 many concerns still persist about the use of laparoscopic surgery in colon and rectal cancer treatment, notably with respect to the technique’s complexity, the associated learning curve and the longer operative time.5

About half the general surgeons in Canada perform laparoscopic colorectal surgery. The highest rate of adoption of laparoscopic surgery is in Quebec, where it is estimated at 67%. Significant predictors for offering a laparoscopic approach are recent graduation, male sex, province of practice, university affiliation and minimally invasive surgery training, whereas constraints for adoption of this technique include the lack of available operative time and lack of formal training programs.12

The present review explores the relevant scientific literature comparing open and laparoscopic surgery in the treatment of colon and rectal cancer with respect to oncologic efficacy and short-term risks and benefits. Based on the best available evidence, recommendations have been made for surgical practice in Quebec.

M ETHODS

Published clinical trials comparing open and laparoscopic surgery in colon and rectal cancer treatment were retrieved using the medical subject headings “colorectal neoplasms,” “rectal neoplasms,” “general surgery,” “colorectal surgery,” “laparoscopy” and “colectomy” as well as the keywords “colorectal cancer,” “colon cancer,” “rectal neoplasms,” “rectal cancer,” “open surgery,” “resection,” “laparoscopy,” “colectomy,” “rectal surgery” and “total mesorectal excision.” Only English- and French-language phase III randomized trials and meta-analyses were selected. Specifically for colon cancer, in light of the large number of studies retrieved and the variations in study quality, only trials involving more than 200 patients were retained. The period covered was from January 1995 to April 2012, inclusively. Studies reporting data on colorectal cancer were considered only if specific data on colon and rectal cancer were presented separately. Economic studies, trials pertaining to metastatic disease of the colon or rectum and trials addressing chemotherapy- or radiotherapy-based treatments were excluded. Abstracts presented at the American Society of Clinical Oncology (ASCO) and European Society for Medical Oncology (ESMO) meetings from 2008 to 2012 were also reviewed, and only those reporting phase III trial results were included.

The level of evidence of selected studies and the strength of recommendation were evaluated using the ASCO and ESMO gradation system (Table 1).15 The original guideline was developed by a CEPO subcommittee, reviewed by independent experts and, finally, adopted by the CEPO by consensus.

R ESULTS

Eight phase III randomized clinical trials10,11,14–27 and 5 meta-analyses28–32 comparing laparoscopy and open
### Table 1. Levels of evidence and grades of recommendations

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence demonstrated by means of meta-analyses of well-designed controlled trials or large randomized trials with clear-cut results (low rate of false-positive and false-negative errors, high power)</td>
</tr>
<tr>
<td>II</td>
<td>Evidence demonstrated by means of small randomized trials with uncertain results (high rate of false-positive and false-negative errors, low power)</td>
</tr>
<tr>
<td>III</td>
<td>Evidence demonstrated by means of nonrandomized concurrent cohort comparisons with contemporaneous controls</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence demonstrated by means of nonrandomized historical cohort comparisons</td>
</tr>
<tr>
<td>V</td>
<td>Evidence demonstrated by means of case series without controls</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Grade of recommendation</th>
<th>Description</th>
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<tbody>
<tr>
<td>A</td>
<td>Supported by Level I evidence or multiple Level II, III or IV trials presenting concordant observations</td>
</tr>
<tr>
<td>B</td>
<td>Supported by Level II, III or IV trials presenting generally concordant observations</td>
</tr>
<tr>
<td>C</td>
<td>Supported by Level II, III or IV trials presenting nonconcordant observations</td>
</tr>
<tr>
<td>D</td>
<td>Supported by few trials or no empiric evidence</td>
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Adapted from Cook and colleagues with permission from the American College of Chest Physicians.

### Table 2. Main characteristics of randomized clinical trials on colon cancer

<table>
<thead>
<tr>
<th>Variable</th>
<th>COLOR10,14</th>
<th>COST16,17</th>
<th>CLASICC11,20,21*</th>
<th>L A P K O N II26</th>
<th>A L C C a S 52</th>
<th>Barcelona10,20,21</th>
<th>Liang63</th>
<th>L A F A-study47†</th>
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<td>Centralized by telephone</td>
<td>Centralized by telephone Revealed during operation</td>
<td>Centralized</td>
<td>Sealed envelopes</td>
<td>Random-sized blocks 2×10</td>
<td>2×2 Internet randomization module</td>
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<td>3-year DFS</td>
<td>Time to recurrence</td>
<td>3-year DFS 3-year OS LR</td>
<td>3-year DFS 3-year OS LR</td>
<td>3-year DFS 3-year OS LR</td>
<td>3-year DFS 3-year OS LR</td>
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<td>I</td>
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<td>35% (LAP)</td>
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<td>23%</td>
<td>22%</td>
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<tr>
<td>II</td>
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<td>34% (OP)</td>
<td>31% (LAP)</td>
<td>38% (OP) 32% (LAP)</td>
<td>40%</td>
<td>43%</td>
<td>49%</td>
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<tr>
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<td>28% (OP)</td>
<td>26% (LAP)</td>
<td>33% (OP) 33% (LAP)</td>
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<td>35%</td>
<td>51%</td>
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<tr>
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<td>2%</td>
<td>—</td>
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<td>According to surgeon (p = 0.99)</td>
<td>According to surgeon</td>
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<td>NA</td>
<td>55% (OP) 61% (LAP)</td>
<td>For stage III patients NA</td>
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<tr>
<td>Right</td>
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<td>54%</td>
<td>45%</td>
<td>29%</td>
<td>58%</td>
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<td>—</td>
<td>48%</td>
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<tr>
<td>Left</td>
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<td>7%</td>
<td>13%</td>
<td>1%</td>
<td>4%</td>
<td>2%</td>
<td>70%</td>
<td>49%</td>
</tr>
<tr>
<td>Sigmoid</td>
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<td>38%</td>
<td>21%</td>
<td>1%</td>
<td>—</td>
<td>45%</td>
<td>30%</td>
<td>—</td>
</tr>
<tr>
<td>Anterior</td>
<td>—</td>
<td>—</td>
<td>11%</td>
<td>—</td>
<td>38%</td>
<td>5%</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Conversion rate</td>
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<td>21%</td>
<td>25%</td>
<td>11%</td>
<td>15%</td>
<td>11%</td>
<td>3%</td>
<td>11%</td>
</tr>
<tr>
<td>Surgeon experience</td>
<td>≥ 20 LAP colectomies ≥ 20 LAP resections ≥ 20 LAP colectomies ≥ 20 LAP colectomies 52% surgeons treated &gt; 10 patients Experienced team Experienced surgeon ≥ 20 LAP for benign disease</td>
<td></td>
<td></td>
<td></td>
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</table>

CLASICC = Conventional Versus Laparoscopic-Assisted Surgery in Patients with Colorectal Cancer; COLOR = Colon Cancer Laparoscopic or Open Resection; COST = Clinical Outcomes of Surgical Therapy; DFS = Disease-free survival; LAP = laparoscopy; LR = local recurrence; multi = multicentred; NA = not available; OP = open surgery; OS = overall survival; single = single-centred. *This trial included patients with colon and rectum cancers. When available, only data specific to colon cancer are presented. †This trial evaluated fast-track versus standard care and LAP versus OP (4 arms). Only the 2 arms with standard care (LAP v. OP) are presented. ‡As evaluated according to the American Society of Clinical Oncology and European Society for Medical Oncology grading system (see Table 1). §Only short-term outcomes are published. ¶71% for left plus rectosigmoid.
surgery for the treatment of colon cancer were identified. For rectal cancer, 9 phase III randomized clinical trials and 7 meta-analyses were selected. No meeting abstracts satisfied the inclusion criteria. The main design characteristics of each randomized trial are summarized in Table 2 for colon cancer and in Table 3 for rectal cancer.

Oncologic outcomes: colon cancer

Phase III randomized trials

In 2009, Buunen and colleagues10 presented the long-term results of the Colon cancer Laparoscopic or Open Resection (COLOR) noninferiority trial. The primary outcome was 3-year disease-free survival, which was 74.2% with the laparoscopic procedure and 76.2% with open surgery. Noninferiority thresholds were set at a 7% difference between the 2 procedures at a level of significance of \( p = 0.025 \). These 2 criteria were not met, since the superior limit of the 95% confidence interval (CI) of the observed difference reached 7.2% (\( p = 0.03 \)). Three-year overall survival was 81.8% after laparoscopy and 84.2% after open surgery (\( p = 0.45 \)).

In 2004, the long-term results of the Clinical Outcomes of Surgical Therapy (COST) noninferiority trial 16 were presented. The cut-offs to declare the laparoscopic procedure noninferior to open surgery regarding time to recurrence at 3 years were set at a hazard ratio (HR) of less than 1.23 and \( p \geq 0.41 \). According to these criteria, the laparoscopic procedure was not inferior to open surgery (\( p = 0.83 \)). The cumulative incidence of recurrence did not significantly differ between the 2 procedures (HR 0.86, 95% CI 0.63–1.17, \( p = 0.32 \)). No differences in overall survival (HR 0.91, 95% CI 0.68–1.21, \( p = 0.51 \)) or disease-free survival (HR 0.95, 95% CI 0.74–1.23, \( p = 0.70 \)) were observed. In 2007, Fleshman and colleagues 17 published updated results after 5 years of follow-up and confirmed the noninferiority of laparoscopy in terms of time to recurrence.

### Table 3. Main characteristics of randomized clinical trials on rectal cancer

<table>
<thead>
<tr>
<th>Variable</th>
<th>Liang13,16</th>
<th>COREAN14</th>
<th>CLASICC11,20,21*</th>
<th>Lujan17</th>
<th>Ng18,19</th>
<th>Ng20</th>
<th>Pechlivanides15</th>
<th>Braga41*</th>
<th>Zhou42</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design, Phase III</td>
<td>single</td>
<td>multi</td>
<td>multi</td>
<td>single</td>
<td>single</td>
<td>multi</td>
<td>single</td>
<td>single</td>
<td></td>
</tr>
<tr>
<td>Median follow-up, mo.</td>
<td>44</td>
<td>NA</td>
<td>37</td>
<td>34 (OP)</td>
<td>113 (OP)</td>
<td>91 (OP)</td>
<td>54</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>3-year OS</td>
<td>DFS</td>
<td>5-year DFS, 5-year OS, LR</td>
<td>No. lymph nodes retrieved, integrity of mesorectal resection margin</td>
<td>Long-term morbidity</td>
<td>Postoperative recovery</td>
<td>No. lymph nodes retrieved</td>
<td>Short-term postoperative bility</td>
<td>Short-term results</td>
</tr>
<tr>
<td>Level of evidence†</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
</tr>
<tr>
<td>Population, no</td>
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<td>170</td>
<td>128</td>
<td>103</td>
<td>77</td>
<td>48</td>
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<td>89</td>
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<td>LAP</td>
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<td>170</td>
<td>253</td>
<td>101</td>
<td>76</td>
<td>51</td>
<td>34</td>
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<td>82</td>
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<td>Tumour stage</td>
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<td>NA</td>
<td>15% (OP)</td>
<td>15% (OP)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>II</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>38% (OP)</td>
<td>38% (OP)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>III</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>43% (OP)</td>
<td>26% (OP)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>IV</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>5% (OP)</td>
<td>21% (OP)</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td>Postoperative chemotherapy</td>
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<td>NA</td>
<td>NA</td>
<td>29% (OP)</td>
<td>33% (OP)</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td>Stage III or IV disease</td>
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<td></td>
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<td>Stage III or IV disease</td>
<td>Stage III or IV disease</td>
<td>Stage III or IV disease</td>
<td>Stage III or IV disease</td>
<td>Stage III or IV disease</td>
<td>Stage III or IV disease</td>
</tr>
<tr>
<td>Tumour distance from AV, cm</td>
<td>NA</td>
<td>5.3 (OP)</td>
<td>6.2 (OP)</td>
<td>12–15 cm</td>
<td>≥ 5 cm</td>
<td>8 (OP)</td>
<td>8.6 (OP)</td>
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<td>3%</td>
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<tr>
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<td>28–150</td>
<td>≥ 20 LAP</td>
<td>Experienced surgeon</td>
<td>Experienced surgeon</td>
<td>Experienced surgeon</td>
<td>Experienced surgeon</td>
<td>Experienced surgeon</td>
<td>Experience</td>
</tr>
</tbody>
</table>
| AV = anal verge; CLASICC = Conventional Versus Laparoscopic-Assisted Surgery in Patients with Colorectal Cancer; COREAN = Comparison of Open versus laparoscopic surgery for mid and low Rectal Cancer After Neoadjuvant chemo-radiotherapy; DFS = disease-free survival; LAP = laparoscopy; LR = local recurrence; NA = not available; OP = open surgery; OS = overall survival. *This trial included patients with colon and rectum cancers. When available, data specific to rectal cancer are presented. †As evaluated according to the American Society of Clinical Oncology and European Society for Medical Oncology gradation system (Table 1).
(p = 0.75) and cumulative incidence of recurrence (HR 0.84, 95% CI 0.62–1.13, p = 0.25).

In 2007, Jayne and colleagues11 presented the long-term results of the Conventional versus Laparoscopic-Assisted Surgery in Colorectal Cancer (CLASICC) trial. The objective was to assess overall survival, disease-free survival and local recurrence at 3 years in patients with colon or rectal cancer treated with laparoscopic or open surgery. For colon cancer, the local recurrence rates were 7.3% with laparoscopy and 6% with open surgery (p = 0.68). Differences between the 2 approaches with respect to 3-year overall survival (p = 0.51) and disease-free survival (p = 0.75) were not significant. Updated data showed similar results between groups assigned to laparoscopy and open surgery for 5-year overall survival (55.7% v. 62.7%, p = 0.25) and disease-free survival (57.6% v. 64%, p = 0.20).

In 2008, Lacy and colleagues28 presented long-term results of a phase III randomized trial conducted in Barcelona, Spain, updating data initially published in 2002.24 The primary outcome was cancer-related mortality. After 3.5 years of follow-up, cancer-related mortality was 9% with laparoscopy and 21% with open surgery (p = 0.03); after a median follow-up of 8 years, the rate was 16% and 27%, respectively, (p = 0.07). Recurrence rates of 18% with laparoscopy and 28% with open surgery were also observed (p = 0.07).

In 2007, Liang and colleagues24 published results of a randomized trial conducted in Taiwan by a single surgeon. Time to recurrence after colon cancer resection was not significantly different between the laparoscopic and open procedure (p = 0.36). The cumulative incidence of recurrence was 17% with laparoscopy and 21.6% with open surgery.

In 6 trials, the extent of resection, as measured by resection margins and the number of lymph nodes harvested, did not significantly differ between laparoscopic and open surgery. The number of lymph nodes harvested varied between 10 and 17.14,16,21,22,23,24 In the studies reporting recurrence rates at wound or port sites, the rates were not statistically different between the groups (1.3% v. 0.4%, p = 0.09; 0.9% v. 0.5%, p = 0.43; 0.9% v. 0%, p value not available;22 and 0.7% v. 0.7%, p value not available,24 for the laparoscopic and open procedures, respectively).

Meta-analyses
In 2011, Ma and colleagues25 conducted a meta-analysis comparing laparoscopy with open resection for colorectal cancer. Data from 6 studies (n = 1800) specific to colon cancer showed that cancer-related mortality was 17.7% with laparoscopy and 19.7% with open surgery (odds ratio [OR] 0.85, 95% CI 0.66–1.09, p = 0.20).

In 2010, Bai and colleagues26 conducted a meta-analysis including 3 trials (n = 2147)17,32 that reported long-term outcome data following laparoscopic and open colon resection. Overall mortality was similar for laparoscopic and open surgery (24.9% v. 26.4%, OR 0.92, 95% CI 0.76–1.12, p = 0.41). Overall recurrence rates of 19.3% and 20% (OR 0.96, 95% CI 0.78–1.19, p = 0.71), local recurrence rates of 4% and 4.4% (OR 0.91, 95% CI 0.59–1.39, p = 0.66) and distal recurrence rates of 12.8% and 14% (OR 0.90, 95% CI 0.70–1.16, p = 0.41) were also observed with laparoscopic and open surgery, respectively.

In 2008, Kuhry and colleagues31 conducted a Cochrane collaboration meta-analysis comparing survival and recurrence rates in patients with colorectal cancer treated with laparoscopic or open surgery. This meta-analysis included 12 trials. Four trials (n = 938) presented results of recurrence in patients with colon cancer. The local recurrence rate was 5.2% with laparoscopic surgery and 5.6% with open resection (OR 0.84, p = 0.57), whereas distant recurrence was 11.3% and 13.6%, respectively (OR 0.82, p = 0.32). In 5 trials (n = 1575), cancer-related mortality was 14.6% with laparoscopy and 16.4% with open surgery (OR 0.80, p = 0.12). The combined results of 4 trials (n = 1162) showed overall mortality of 20.4% with laparoscopy and 23.6% with open surgery (OR 0.82, p = 0.17).

In 2007, Bonjer and colleagues32 presented a meta-analysis combining individual data on patients recruited before March 2000 in the COLOR, COST, CLASICC and Barcelona trials (n = 1536). The 3-year overall survival (82.2% v. 83.5%, p = 0.56) and disease-free survival (75.8% v. 75.3%, p = 0.83) were similar between laparoscopic and open colectomy, respectively.

A recent meta-analysis33 showed that the number of lymph nodes harvested was similar with laparoscopic and open colon resection (weighted mean difference [WMD] –0.18, p = 0.82).

Oncologic outcomes: rectal cancer

Phase III randomized trials
In 2011, Liang and colleagues34 presented results of a randomized trial conducted in a single centre in China to evaluate 3-year overall survival following laparoscopic or open surgery for rectal cancer. After a median follow-up of about 44 months, overall survival was similar for laparoscopic and open surgery (76% v. 82.8%, p = 0.46). There was no difference between these 2 procedures in the median number of lymph nodes harvested (7.1 v. 7.4, p = 0.47) or the distance between the inferior border of the tumour and the incised margin in the lower anterior resection operation (3.2 cm v. 3.1 cm, p = 0.15).

In 2010, Kang and colleagues35 presented the short-term oncologic results of the Comparison of Open versus Laparoscopic surgery for mid and low REctal cancer After Neoadjuvant chemoradiotherapy (COREAN) trial. The tumour had to be localized at no more than 9 cm from the anal verge. No difference was shown between laparoscopic and open surgery with respect to the macroscopic quality of the resected mesorectum (complete 72.4% v. 74.7%)}
almost complete 19.4% v. 13.5%; incomplete 4.7% v. 6.5%; p = 0.41, the median number of lymph nodes harvested (17 v. 18, p = 0.09), the negative circumferential margins (97.1% v. 95.5%, p = 0.77) and the rate of negative proximal, distal and radial margins (p = 0.44, p = 0.54 and p = 0.31, respectively).

In 2010, Jayne and colleagues30 presented updated results of the CLASICCC trial after a median follow-up of 56.3 months. For rectal cancer, overall survival (60.3% v. 59.9%, p = 0.13) and disease-free survival (53.2% v. 52.1%, p = 0.95) were similar for laparoscopic and open surgery, respectively. No difference was observed between laparoscopic and open procedures in local and distal recurrence rates. Distal recurrence rates were 21.9% with both laparoscopic and open anterior resection, whereas they were 35.7% with laparoscopic abdominoperineal resection and 40.8% with open abdominoperineal resection. Local recurrence rates were 9.4% with laparoscopic and 7.6% with open anterior resection. Positive resection margins were more frequent with laparoscopic than open anterior resection (12.4% v. 6.3%, p = 0.01), but not with abdominoperineal resection (20% v. 26%, p value not available).

In 2009, Lujan and colleagues31 presented results of a noninferiority randomized trial that evaluated efficacy of laparoscopy compared with open resection of the low or mid rectum. Five-year disease-free survival (84.8% v. 81%, p = 0.90), overall survival (72.1% v. 73.3%, p = 0.98) and local recurrence (4.8% v. 5.3%, p = 0.78) were similar with laparoscopic and open surgery, respectively. The mean number of lymph nodes harvested was greater with laparoscopy (13.6 v. 11.6, p = 0.03). Integrity of the resection margins was similar with laparoscopic and open procedures (2.8% v. 4%, p = 0.42).

In 2009, Ng and colleagues32 presented results of a randomized trial conducted in a single centre in Hong Kong to evaluate long-term oncologic efficacy of laparoscopic surgery for proximal rectal cancer (12–15 cm from the anal verge). After a median follow-up of about 110 months, no difference was observed between laparoscopic and open surgery for 5-year overall survival (75.2% v. 76.5%, p = 0.20) and disease-free survival (78.1% v. 73.6%, p = 0.55) in patients with stage I–III rectal cancer. In patients with stage IV disease, mean survival was 32.6 months after laparoscopy and 13.9 months after open surgery (p = 0.05). During the follow-up period, 30% of patients assigned to laparoscopy and 47.2% of patients assigned to open surgery died; 15% and 22.2%, respectively, were cancer-related deaths. Recurrence rates were similar with laparoscopic and open surgery (p = 0.60), as were the mean number of lymph nodes harvested (12.4 v. 13, p = 0.72) and the positive resection margins rate (6.3% v. 3.9%).

In 2007, Pechlivanides and colleagues33 presented the results of a randomized trial conducted by a single surgeon to compare laparoscopic and open surgeries in the treatment of rectal cancer localized at less than 12 cm from the anal verge. The mean number of lymph nodes harvested was 19.2 in both groups (p = 0.2). No data on survival or recurrence were presented.

In 2007, Braga and colleagues34 presented results of a randomized trial, conducted in Italy by a single team, after a median follow-up of 53.6 months. No difference was observed between groups assigned to laparoscopy or open surgery for 5-year overall survival (stage I: p = 0.93, II: p = 0.37, III: p = 0.98, and IV: p = 0.95), 3-year local recurrence (4% v. 5.2%, p = 0.97) and mean number of lymph nodes harvested (12.7 v. 13.6, p value not available). The distal margins were negative in all patients whereas positive circumferential margins were observed in 1 patient treated with laparoscopy (1.3%) and 2 patients treated with open surgery (2.4%).

Meta-analyses
In 2011, Huang and colleagues35 conducted a meta-analysis including 6 clinical trials (n = 1033) that evaluated efficacy of laparoscopic surgery in rectal cancer treatment. Three-year overall survival (p = 0.11, 4 trials) and disease-free survival (p = 0.11, 3 trials) were not significantly different after

### Table 4: Comparison of oncologic results in rectal cancer

<table>
<thead>
<tr>
<th>Result</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progression-free survival</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-year</td>
<td>0.90 (0.66–1.24)</td>
<td>0.53</td>
</tr>
<tr>
<td>5-year</td>
<td>1.17 (0.85–1.61)</td>
<td>0.35</td>
</tr>
<tr>
<td>Recurrence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>0.93 (0.68–1.25)</td>
<td>0.61</td>
</tr>
<tr>
<td>Local</td>
<td>0.83 (0.52–1.31)</td>
<td>0.41</td>
</tr>
<tr>
<td>Wound sites</td>
<td>1.34 (0.07–24.10)</td>
<td>0.84</td>
</tr>
<tr>
<td>Distal metastasis</td>
<td>0.89 (0.63–1.27)</td>
<td>0.52</td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>0.80 (0.60–1.07)</td>
<td>0.13</td>
</tr>
<tr>
<td>Cancer-related</td>
<td>0.71 (0.45–1.12)</td>
<td>0.14</td>
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</table>

CI = confidence interval; OR = odds ratio.
laparoscopy or open surgery. After a follow-up ranging from 32.8 to 112.5 months, local recurrence rates after laparoscopic and open surgery were not statistically different ($p = 0.21$, 4 trials). No difference was observed between laparoscopic and open surgery for the mean number of lymph nodes harvested ($p = 0.43$, 5 trials); positive circumferential resection margins were also similar (7.9% v. 5.4%, $p = 0.63$, 5 trials).

In 2011, Ohtani and colleagues 44 conducted a meta-analysis comparing the oncologic efficacy of laparoscopic and open surgery for rectal cancer. Twelve trials were included ($n = 2095$), and results showed no difference between the 2 procedures for the oncologic outcomes measured (Table 4).

In the meta-analysis comparing laparoscopy with open resection for colorectal cancer by Ma and colleagues 29 in 2011, data specific to rectal cancer from 5 studies were presented ($n = 991$). Cancer-related mortality was 13.1% with laparoscopy and 15.3% with open surgery (OR 0.76, 95% CI 0.53–1.11, $p = 0.16$).

In 2008, Anderson and colleagues 45 conducted a meta-analysis including 22 clinical trials that evaluated the efficacy of laparoscopic surgery in rectal cancer treatment. After 4.4 years of follow-up (13 trials), overall survival was 72% with laparoscopy and 65% with open surgery ($p = 0.5$). At a median follow-up of 35 months, local recurrence rates after laparoscopic and open surgery were 7% and 8%, respectively (16 trials), whereas distal recurrence rates were 12% and 14%, respectively ($p = 0.54$, 9 trials). The mean number of lymph nodes harvested was lower with laparoscopy than with open surgery (10 v. 12, $p = 0.001$, 17 trials); however, 3 trials showed that more lymph nodes were harvested with laparoscopy. The rate of positive resection margins was similar with laparoscopic and open surgery (5% v. 8%, 10 trials).

Three additional meta-analyses compared short-term oncologic outcomes after laparoscopic and open surgery for rectal cancer and showed no difference between the procedures in terms of the mean number of lymph nodes harvested and the rate of positive resection margins.28,46,47

### Short-term outcomes

#### Duration of operation

Thirteen trials presented data on the duration of surgery for colon and rectal cancer (Table 5). In all but 1 study, operative time was longer for laparoscopic than for open surgery. The COLOR trial investigators showed that differences in operative time between the 2 procedures for colon cancer tended to be smaller in centres with high volumes ($p = 0.027$).14

#### Intraoperative blood loss

Five trials assessed median intraoperative blood loss during laparoscopic and open surgeries for colon cancer.10,23–25,27 Four trials observed less blood loss during laparoscopy: COLOR (100 mL v. 175 mL, $p = 0.003$),10 Barcelona (105 mL v. 193 mL, $p = 0.001$),23 Liang and colleagues (54 mL v. 240 mL, $p < 0.001$) and LAFA-study (100 mL v. 200 mL, $p < 0.001$).25 Only the Australasian Laparoscopic Colon Cancer Study (ALCCaS) trial showed no significant difference between the 2 procedures (median blood loss of 100 mL in both cases, $p = 0.17$).27

Six trials assessed intraoperative blood loss during rectal cancer surgery.13,16,17,19,41,42 All trials showed a trend toward less blood loss with laparoscopy; this trend was significant.
in 4 trials: COREAN (200 mL v. 217.5 mL, \(p = 0.006\)), Lujan and colleagues\(^\text{10}\) (127.8 mL v. 234.2 mL, \(p < 0.001\)), Braga and colleagues\(^\text{11}\) (150 mL v. 350 mL, \(p < 0.001\)) and Zhou and colleagues\(^\text{12}\) (20 mL v. 92 mL, \(p = 0.05\)). Two trials compared transfusion use during laparoscopic and open surgeries for the treatment of colon cancer:\(^\text{4,10}\) Sixteen patients undergoing laparoscopy (5.4%) versus 18 patients undergoing open surgery (6%) received a transfusion in the ALCCaS trial,\(^\text{27}\) whereas 11.6% and 17.6% of patients assigned to laparoscopic and open surgery, respectively, received transfusion in LAPKON II.\(^\text{26}\) Three trials evaluated transfusion rates during rectal cancer resection.\(^\text{10,33,41}\) Only 1 patient, assigned to open surgery, needed a transfusion in the COREAN trial (\(p > 0.99\)),\(^\text{14}\) whereas 4 patients (2.4%) assigned to laparoscopy and 8 patients (4.6%) assigned to open surgery needed a transfusion in the trial by Liang and colleagues\(^\text{33}\) (\(p = 0.38\)). Braga and colleagues\(^\text{41}\) observed transfusion rates of 7.2% with laparoscopy and 26.8% with open surgery (\(p = 0.002\)).

**Postoperative pain**

Liang and colleagues\(^\text{24}\) measured postoperative pain using a visual analogue scale of 0–10. Less pain was recorded after laparoscopy than open surgery for colon cancer (median 3.5 v. 8.6, \(p < 0.001\)). In the COREAN trial, mean postoperative pain was less after laparoscopy than open surgery up to 3 days after surgery for rectal cancer (\(p < 0.05\)). Ng and colleagues\(^\text{14}\) reported no difference in pain, according to the visual analogue scale, on the first day after laparoscopic and open surgery for rectal cancer (\(p = 0.41\)).

In 2 trials, less analgesic use was reported after laparoscopy than open surgery for colon cancer. In the COLOR trial, 8%–14% fewer patients needed analgesics in the first 3 days after laparoscopy than open surgery (\(p < 0.001\) to \(p = 0.008\)).\(^\text{14}\) In the COST trial, this difference corresponded to a median of 1 day less needing analgesics.\(^\text{14}\) There was also less analgesic use after laparoscopy than open surgery for rectal cancer, according to 4 trials. In these trials, lower doses of morphine (median 107.2 mg v. 156.9 mg, \(p < 0.001\)),\(^\text{14}\) and fewer injections of analgesics (mean 6 v. 11.4, \(p = 0.007\) and 4.9 v. 8.3, \(p = 0.001\))\(^\text{14,33}\) were used by patients assigned to laparoscopy than open surgery. The median duration of analgesic treatment was also shorter (3.9 d v. 4.1 d, \(p = 0.23\)).\(^\text{42}\)

**Recovery of intestinal function**

For colon cancer, Liang and colleagues\(^\text{24}\) found that postoperative ileus lasted for a mean of 48 hours after laparoscopy compared with 96 hours after open surgery (\(p < 0.001\)). In the Barcelona trial, peristalsis began at a mean of 36 hours after laparoscopic surgery compared with 55 hours after open surgery (\(p = 0.001\)).\(^\text{21}\) In the ALCCaS trial, the mean time to passing first flatus was 3.2 days after laparoscopy compared with 3.5 days after open surgery (\(p = 0.027\)).\(^\text{27}\) Finally, 3 trials measured time to first bowel movement: 3.6, 4.0 and 4.4 days, respectively, after laparoscopy and 4.6, 6.0 and 4.9 days, respectively, after open surgery (\(p < 0.001\), \(p\) value not available\(^\text{14}\) and \(p = 0.011\).\(^\text{27}\) respectively).

For rectal cancer, peristalsis also began sooner after laparoscopy than open surgery, as found in 5 trials: Liang and colleagues\(^\text{33}\) (3.9 d v. 4.2 d, \(p < 0.001\)), Ng and colleagues\(^\text{27}\) (4.3 d v. 6.3 d, \(p < 0.001\)), Ng and colleagues\(^\text{42}\) (4.1 d v. 4.7 d, \(p = 0.06\)), CLASICC (5 d v. 6 d, \(p\) value not available\(^\text{33}\) and Zhou and colleagues\(^\text{26}\) (1.5 d v. 2.7 d, \(p = 0.009\)). This conclusion is supported in a meta-analysis (WMD –1.52 d, 95% CI –2.20 to –1.01).\(^\text{46}\) The mean time to passing first flatus was also shorter after laparoscopy (38.5 hr v. 60 hr, \(p < 0.001\)\(^\text{14}\) and 3.1 d v. 4.6 d, \(p < 0.001\))\(^\text{33}\), as was the mean time for first stool (3 d v. 3.3 d, \(p < 0.001\)\(^\text{14}\) and 96.5 hr v. 123 hr, \(p < 0.001\)).

Return to normal diet after laparoscopic and open surgery for rectal cancer was evaluated in 4 trials: COREAN (85 hr v. 93 hr, \(p < 0.001\)),\(^\text{27}\) Ng and colleagues\(^\text{24}\) (4.3 d v. 6.3 d, \(p = 0.001\)), Ng and colleagues\(^\text{33}\) (4.3 d v. 4.9 d, \(p = 0.001\)) and CLASICC (6 d v. 6 d; \(p\) value not available).\(^\text{27}\) Faster return to normal diet after laparoscopy was confirmed in a meta-analysis (WMD –0.92 d, 95% CI –1.35 to –0.50).\(^\text{46}\)

**Length of hospital stay**

Seven trials presented data on length of hospital stay after colon cancer surgery (Table 6). In all cases, patients treated with laparoscopy had a shorter hospital stay than patients treated with open surgery. However, the ALCCaS trial showed that among laparoscopy-treated patients, those who were converted to open surgery had a significantly longer hospital stay than those who were not converted (14.6 d v. 8.6 d, \(p < 0.001\)).\(^\text{27}\) As for rectal cancer, 7 trials presented data on length of hospital stay (Table 6). Although all trials reported a shorter hospital stay after laparoscopy than open surgery, the difference was significant in only 3 trials. In addition, a meta-analysis showed that hospital stay was shorter after laparoscopy than open surgery for rectal cancer (WMD –2.67 d, 95% CI –3.81 to –1.54).\(^\text{46}\)

**Morbidity and mortality**

Overall complication rates following colon cancer resection were evaluated in 4 trials. Only in the Barcelona trial was the complication rate lower for laparoscopy than open surgery (11% v. 29%, \(p = 0.001\)),\(^\text{21}\) whereas COLOR,\(^\text{14}\) LAFA-study\(^\text{21}\) and the study by Liang and colleagues\(^\text{24}\) reported no significant difference after laparoscopic or open procedures (\(p = 0.88\), \(p = 0.20\) and \(p = 0.15\), respectively). Reported intraoperative complications included hemorrhage, cardiac or pulmonary insufficiency, adverse anesthetic events and injury of bowel or adjacent organs. The intraoperative complication rate was statistically higher following laparoscopy in 1 trial (10.5% v. 3.7%, \(p = 0.001\)),\(^\text{27}\) whereas 3 trials showed no difference between laparoscopic and open procedures (4% v. 2%, \(p = 0.10\),\(^\text{16}\) 7% v. 8%, \(p\) value not available,\(^\text{21}\) and 5.6% v. 2.3%, \(p = 0.10\)).\(^\text{46}\) No difference in postoperative complication rates
was found in these 4 trials between laparoscopic and open surgery (37.8% v. 45.3%, \( p = 0.06 \), 19% v. 19%, \( p = 0.98 \), 26% v. 27%, \( p \) value not available, and 25.2% v. 23.9%, \( p = 0.75 \)). Wound or urinary tract infections, Anastomotic leakage, prolonged ileus, hemorrhage, and various cardiac, pulmonary or vascular complications were the most frequent postoperative complications reported.

Complication rates following rectal cancer resection were presented in 7 trials.21,34,36,37,39,41,42 The intraoperative complication rates ranged from 6.1% to 21.2% for laparoscopy and from 12.4% to 23.5% for open surgery (\( p = 0.016 \) to \( p = 0.60 \)).21,34,42 and the postoperative complication rates ranged from 2.4% to 45.1% and from 10.6% to 52.1%, respectively (\( p = 0.012 \) to \( p = 0.96 \)).36,37,39,41 Results of a meta-analysis showed that patients assigned to laparoscopy presented less morbidity than those assigned to open surgery (OR 0.63, 95% CI 0.41–0.96, \( p \) value not available,21 and 25.2% v. 27%, \( p = 0.046 \),41 whereas only the global quality of life score (\( p = 0.05 \)) and the subdomain of outlook (\( p = 0.021 \)) were better following laparoscopy than open surgery.13 In the COST trial (\( n = 428 \)), only the global quality of life score 2 weeks after surgery was higher following laparoscopy (80 v. 75, \( p \) value not available),13 whereas only the global quality of life score (\( p = 0.05 \)) and the subdomain of outlook (\( p = 0.021 \)) were improved 18 months after surgery.13 The LAFA-study showed no statistically significant differences on any of the scales evaluated between laparoscopic and open surgery at any time point.13

For rectal cancer, 3 trials evaluated quality of life following laparoscopic and open surgery. The COREAN trial showed that sleep (\( p = 0.004 \)), physical condition (\( p = 0.007 \)) and fatigue (\( p = 0.021 \)) were better 3 months after laparoscopy than open surgery. A greater frequency of sexual problems after surgery than before the intervention was

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<th>Table 6. Length of hospital stay following open and laparoscopic surgeries</th>
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<td>Lujan et al.24</td>
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<td>Braga et al.31</td>
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ALCCaS = Australasian Laparoscopic Colon Cancer Study; CLASICC = Conventional Versus Laparoscopic-Assisted Surgery in Patients with Colorectal Cancer; COLOR = Colon cancer Laparoscopic or Open Resection; COREAN = Comparison of Open versus Laparoscopic surgery for mid and low Rectal cancer After Neoadjuvant ChemoRadiotherapy; COST = Clinical Outcomes of Surgical Therapy; IQR = interquartile range; NA = not available; SD = standard deviation.
observed for both groups \((p < 0.001)\), with no difference between groups \((p = 0.29)\). More miction problems were observed after laparoscopy than open surgery \((p < 0.001)\), Braga and colleagues41 showed better general health status \((p < 0.001)\), physical condition \((p < 0.001)\) and social function \((p = 0.003)\) with laparoscopy than open surgery, but only in the first year after the operation. In the CLASICC trial, it was shown that men treated with laparoscopy tended to have worse global sexual \((p = 0.06)\) and erectile function \((p = 0.07)\); however, this difference was not significant. Conversion and total mesorectal excision were identified as prognostic factors negatively affecting sexual function. Although a decrease in global sexual function was generally observed in women following surgery, no difference was noted between groups. Urinary function was also similar following laparoscopic and open surgery in both men and women.15

**DISCUSSION**

**Oncologic outcomes**

The first case series comparing laparoscopic and open surgeries for colon cancer treatment reported high recurrence rates at wound and port sites, raising doubts as to the oncologic efficacy of laparoscopy. Large randomized trials that followed were therefore attentive to oncologic outcomes, such as positive resection margins, number of lymph nodes harvested and recurrence rates at port sites. None of the trials included in this review showed any difference between open and laparoscopic procedures regarding these outcomes. Only in the COLOR trial were there more recurrences in the abdominal wall observed following laparoscopy than open surgery for colon cancer \((5 \text{ at the port site and } 2 \text{ at the tumour extraction site}), but the difference was not significant \((p = 0.09)\).10 Three trials presented data on recurrence at trocar and scar sites following surgery for rectal cancer and reported only 1 recurrence \(\text{in the open surgery group})31,37,39. Thus, it appears that initial concerns were not justified.

All but 1 trial studying colon cancer concluded that laparoscopy is noninferior to open surgery in terms of overall survival, disease-free survival and recurrence rate. The COLOR study group had set the noninferiority threshold at 7\%, and the upper limit of the 95\% CI for the 3-year disease-free survival difference just exceeded this, at 7.2\%.10 Though they could not totally exclude the possibility of inferiority, the authors still concluded that laparoscopy could be performed safely for the treatment of colon cancer. Moreover, when data are analyzed according to treatment received, as recommended in the CONSORT statement,48 the noninferiority of laparoscopy is statistically confirmed.10 On the other hand, only 1 trial concluded that laparoscopy was superior to open surgery for colon cancer treatment.22 However, a number of biases were identified in that trial. First, trial design was based on the hypothesis that noninferiority would be declared if cancer-related survival after laparoscopy was less than 15\% inferior to that after open surgery, which is a clinically unacceptable threshold according to the oncologic experts consulted. Second, equivalence of the 2 groups must be questioned, since the group assigned to laparoscopy received more postoperative chemotherapy than the group assigned to open surgery \((61\% \text{ v. } 55\%).\) It therefore seems inappropriate to conclude, based on the results of this single trial, that long-term outcomes of patients with colon cancer after laparoscopic resection are superior to those after open surgery.

The combined results of the 5 randomized trials included in this review confirm that laparoscopy is noninferior to open surgery for colon cancer treatment with respect to overall survival, disease-free survival and disease recurrence.20,21,22,24 Results presented in 3 meta-analyses also strongly support these conclusions.30–32 Trials evaluating the laparoscopic procedure for rectal cancer had generally lower power than those evaluating laparoscopic colon cancer resection, thus explaining why trials accruing fewer than 200 patients were included in this review. Consequently, 6 randomized trials presenting data on survival and recurrence were retrieved and showed noninferiority of laparoscopic compared with open resection for rectal cancer in terms of overall and disease-free survival.20,23,24,35 The equivalence of these 2 procedures is supported by 3 meta-analyses,41–43 and was confirmed for both anterior and abdominoperineal resections.20

All trials retrieved included resections of the left, right or sigmoid colon for adult patients with stage I, II or III colon cancer or anterior or abdominoperineal resection of rectal cancer of any stage. A laparoscopic procedure is thus appropriate for these populations. In contrast, patients presenting with 1 or more of the following conditions were generally excluded: transverse colon cancer; morbid obesity; adjacent organ invasion; metastatic disease; cardiovascular, pulmonary or hepatic disease; inflammatory bowel disease; or need for emergency surgery. These conditions can be considered potential contraindications for laparoscopy, depending on the surgeon’s experience. Notably, transverse colon resection poses many challenges, such as resection of the colic vessels and mobilization of the 2 colic segments before anastomosis. For these reasons, laparoscopic transverse colon resection should only be performed by surgical teams with extensive experience in laparoscopic colon resections. On the other hand, while patients with metastatic disease have generally been excluded from trials to avoid survival bias, clinical experience shows that laparoscopy can successfully be performed in some symptomatic patients presenting with obstruction or bleeding.

**Short-term outcomes**

Selected trials showed some short-term benefits of laparoscopy compared with open colorectal cancer...
Conversion to open surgery is believed to have a negative impact on survival and morbidity outcomes. A subgroup analysis performed by the authors of the COST study showed that patients who underwent conversion experienced more complications than those whose colon surgery had been completed laparoscopically (7.8% v. 2.9%). Five-year overall survival was also lower in these patients (69% v. 80%). In the CLASICC trial, converted surgery was associated with a hospital stay of up to 2 weeks longer than laparoscopy and with a higher complication rate (93% v. 50% following open surgery and 59% following laparoscopy). On intention-to-treat analysis, patients who were converted intraoperatively to open surgery were appropriately included in the laparoscopic group. Conversion is a reality of normal practice and thus has to be considered in the evaluation of the safety of laparoscopy. Nevertheless, surgeries most susceptible to being converted should be identified preoperatively whenever possible so that these patients can be treated with open surgery to reduce the likelihood of complications.

**Minimum training requirements**

No randomized clinical trial has evaluated the minimum training requirements for safely performing laparoscopy for colon cancer treatment, despite the need to better inform surgeons in this regard. Most practice guidelines and consensus statements agree that surgeons need to...
acquire a certain level of training. In 2 trials, surgeons were required to have performed at least 20 laparoscopic colectomies in order to be recruited. A few trials have tried to define the learning curve of laparoscopic colon resection, but these are primarily case series constituting a low level of evidence. Despite the absence of evidence, it is reasonable to assume that the skills acquired from performing simple laparoscopic procedures are transferable to more complex surgeries. In this sense, surgeons should first acquire experience through simple laparoscopic resections of benign lesions and then progressively integrate more complex procedures into their practices, including those involving cancer.

One prospective and 3 retrospective trials evaluated the impact of surgeon experience on oncologic outcomes following rectal cancer resection. Three of them showed that operative duration decreased significantly with the number of interventions performed. Park and colleagues observed a plateau after 90 interventions followed by a decrease in operative duration, whereas Ito and colleagues reported that operative duration decreased from 228 to 179 minutes after more than 40 interventions had been performed. All 4 trials also showed a significant decrease in postoperative morbidity as the surgeon gained more experience (after 30–60 interventions had been performed, depending on the trial). Since inclusion criteria for patients and for surgeons were not the same for all trials, a general conclusion regarding the minimum number of cases to be performed to gain sufficient experience cannot be drawn. Nonetheless, the available evidence undoubtedly shows that surgeon experience and competence in laparoscopy for rectal cancer have a major impact on outcome.

**CONCLUSION**

Analysis of the scientific literature confirmed that for the curative treatment of colon and rectal cancer, laparoscopy is not inferior to open surgery with respect to overall survival, disease-free survival and rate of recurrence. In addition, laparoscopic surgery provides short-term advantages over open surgery, particularly a shorter hospital stay, reduced need for analgesics, faster recovery of intestinal function, and an earlier return to activities of daily life. In contrast, laparoscopic surgery requires a longer operative time.

Considering the evidence currently available, the CEPO recommends that laparoscopic resection be considered an option for the curative treatment of colon and rectal cancer (grade A recommendation); that decisions regarding surgical approach (laparoscopic or open surgery) for the curative treatment of colon cancer take into consideration the surgeon's experience, tumour stage, potential contraindications and patient expectations (grade D recommendation); and that laparoscopic resection for rectal cancer be performed only by appropriately trained surgeons who perform a sufficient volume annually to maintain competence (grade D recommendation).

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**References**


41. Braga M, Frasson M, Vignali A, et al. Laparoscopic resection in rectal...


Comparison of the major intraoperative and postoperative complications between unilateral and sequential bilateral total knee arthroplasty in a high-volume community hospital

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Background: Total knee arthroplasty (TKA) is a common surgical treatment for arthritis. In the event of bilateral knee symptoms, a patient may elect for bilateral TKA (BTKA) under 1 anesthetic or 2 separate unilateral TKAs (UTKA). Controversy exists in the literature regarding the safety of BTKA versus UTKA. We compared the rate of major intraoperative and postoperative complications for BTKA versus UTKA at a high-volume community hospital.

Methods: We compared 373 patients who underwent BTKA with 966 who underwent UTKA between May 2008 and May 2011. Health records were used to determine patient characteristics and major intraoperative and postoperative complications. The BTKA and UTKA cohorts were matched for demographic characteristics and comorbidities with the exception of previous transient ischemic attack and previous knee surgery (UTKA > BTKA).

Results: Rates of intraoperative and postoperative complications, including cardiovascular, thromboembolic and neurologic complications; deep wound infections; and mortality, did not differ significantly between groups. Bilateral TKA was associated with a greater proportion of patients requiring blood transfusion than UTKA (29.8% v. 8.9%, p < 0.001). Among those transfused, there was no significant difference between the groups in the mean number of units required (1.72 ± 0.77 v. 1.53 ± 0.85 units, p = 0.68).

Conclusion: Bilateral TKA was not associated with statistically greater rates of intraoperative and postoperative complications than UTKA, barring the proportion of patients requiring transfusion. Our results support the use of BTKA to treat bilateral knee arthritis in a high-volume community hospital setting.

Contexte : La prothèse (ou arthroplastie) totale du genou (PTG) est un traitement chirurgical courant contre l’arthrite. Quand les 2 genoux sont atteints, le patient peut choisir entre une PTG bilatérale (PTGB), qui ne nécessitera qu’une seule anesthésie, ou 2 interventions unilatérales distinctes (PTGU). Dans la littérature, on ne semble pas s’entendre sur l’innocuité de la PTGB contre la PTGU. Nous avons comparé les taux de complications peropératoires et postopératoires majeures associées aux PTGB et aux PTGU dans un hôpital communautaire où s’effectue un volume élevé de telles interventions.

Méthodes : Nous avons comparé 373 patients qui ont subi une PTGB à 966 qui ont subi une PTGU entre mai 2008 et mai 2011. Nous avons consulté les dossiers médicaux pour établir les caractéristiques des patients et relever les complications peropératoires et postopératoires majeures. Les cohortes soumises à la PTGB et à la PTGU ont été assorties en fonction des caractéristiques démographiques et des comorbidités, à l’exception des antécédents d’accidents ischémiques transitoires et d’interventions chirurgicales du genou (PTGU > PTGB).

Résultats : Les taux de complications peropératoires et postopératoires, y compris cardiovasculaires, thromboemboliques et neurologiques, les infections de plaies profondes et la mortalité n’ont pas varié significativement entre les groupes. Une proportion plus grande de patients soumis à la PTGB a nécessaire une transfusion sanguine comparative-ment aux patients soumis à la PTGU (29.8% c. 8.9%, p < 0.001), Parmi les receveurs de transfusions, on n’a noté aucune différence significative entre les groupes quant au nombre moyen d’unités requises (1.72 ± 0.77 c. 1.53 ± 0.85 unité, p = 0.68).
RECHERCHE

Conclusion : La PTGB n’a pas été associée à des taux statistiquement plus élevés de complications peropératoires et postopératoires comparativement à la PTGU, à l’exception de la proportion de patients ayant nécessité une transfusion. Nos résultats appuient le recours à la PTGB pour traiter l’arthrite bilatérale du genou dans le contexte d’un hôpital communautaire ou le volume de ces interventions est élevé.

Total knee arthroplasty (TKA) is the most commonly performed joint replacement surgery in Canada.1,2 It is considered a safe and reliable procedure for providing pain relief, correcting limb alignment and improving quality of life in patients with moderate to severe arthritis.3 A substantial proportion of these patients present with bilateral symptomatic joint disease and may benefit from bilateral replacements. In these circumstances, the patient and orthopaedic surgeon must together decide whether to pursue a bilateral knee replacement under a single anesthetic (BTKA) or 2 separate unilateral TKAs (UTKA).4

Critics of BTKA argue that the procedure increases the risk for serious complications.5–8 The TKA complications most often referenced in the literature are cardiovascular (i.e., new-onset arrhythmia, myocardial infarction, congestive heart failure), thromboembolic (i.e., deep vein thrombosis, pulmonary embolism), neurologic (i.e., transient ischemic attack, stroke, delirium), blood loss measured directly or indirectly through blood transfusion requirements and mortality.9 The true risk associated with BTKA remains controversial, as many studies opposing the procedure have reported predominantly nonstatistical differences in complication rates between BTKA and UTKA.10–13

Proponents of BTKA, however, report numerous advantages, including decreased total anesthetic, total rehabilitation time, length of hospital stay and institution costs. These patients have also been found to have lower rates of superficial wound infections and to report increased convenience and satisfaction.14–16 One study also found that at 10 years postoperatively the BTKA group had a significantly higher rate of survival than the UTKA group, independent of other contributing factors.17

The number of TKAs being performed in Canada is projected to continue rising given the prevalence of degenerative osteoarthritis in the aging population. While most TKAs are performed in community hospitals, we are not aware of any literature comparing the rates of major complications of BTKA with UTKA within the context of a community hospital.18

Our objective was to compare the rates of major intraoperative and postoperative complications between patients undergoing BTKA and those undergoing UTKA at a high-volume community hospital.

METHODS

Study population

We searched the surgical database to retrospectively identify all patients who had undergone a BTKA or a UTKA between May 2008 and May 2011. Patients who had an incomplete charted medical history, multiple procedures under the same anesthetic or a revision TKA were excluded from the analysis. Patients who underwent staged TKA (2 distinct surgeries on both knees within a 1-year period) were excluded from the study because of the small population size and owing to suggestions in the literature that retrospective analysis of staged procedures can be misleading.21 Furthermore, patients who were subject to blood conservation techniques, including autologous blood transfusion, erythropoietin, and tranexamic acid (TXA) were excluded from the study. All patients underwent a preoperative assessment by an anesthesiologist to ensure suitability for surgery, and those patients who were found to need optimization of their comorbidities were referred to internal medicine. All candidates with bilateral knee symptoms who were deemed eligible for surgery were given the option of BTKA or 2 UTKAs. Our institution’s research ethics board approved our study protocol.

Operative and postoperative procedures

A pool of 7 staff surgeons performed the TKAs using a standardized approach. Whereas in some centres, 2 surgeons operate in parallel in patients undergoing BTKA,22 the BTKAs in our study were performed sequentially by a single surgeon, with the patient under a single anesthetic. The patients received either general or regional anesthetic with sedation and were given routine preoperative intravenous antibiotics. Procedures were performed under tourniquet control. All TKAs were done with intramedullary femoral alignment and extramedullary tibial alignment. The prostheses were produced by Zimmer or Biomet and were either cruciate-sparing or posterior stabilized.

Postoperatively, all patients were under the care of the same hospitalist. Supplemental oxygen was administered until oxygen saturation was maintained at a minimum of 92% on room air. Pain control was achieved using oral analgesics supplemented by patient-controlled analgesia. All patients received routine thromboprophylaxis for 2–3 weeks. Continuous passive motion was started within 24 hours of surgery. On the first postoperative day, patients were mobilized, fully weight bearing, under the supervision of physiotherapists. Patients were typically discharged by the fourth day or transferred to a rehabilitation institution as required.
Medical records

Two of us (E.S. and G.R.T.) collected and independently reviewed and verified all data from the patients’ hospital records. Patient demographic characteristics and medical history were determined by reviewing all standard preoperative orthopedic, anesthesiology and internal medicine records. Intraoperative complications, if any, were identified in operative and/or consultation notes. Patient progress notes, consultation notes, discharge summaries, readmission records and follow-up appointment notes for up to 3 months were screened to identify any postoperative complications. Transfusion data were obtained from the institution blood bank records.

Statistical analysis

Continuous variables are expressed as means ± standard deviation. We compared these data with an unpaired, 2-tailed Student t test using Microsoft Excel software. Dichotomous variables are expressed as numbers and percentages, and we analyzed these data with a 2-tailed Fisher exact test using GraphPad Prism. We considered results to be significant at p < 0.05. We calculated odds ratios (OR) and 95% confidence intervals (CIs) for all data.

RESULTS

Based on our study criteria, we excluded 36 patients from the UTKA group and 12 from the BTKA group. Of those patients who met our inclusion criteria, 966 underwent UTKA (65.9% women v. 34.1% men, mean age 69.6 ± 10.2 yr) and 373 underwent BTKA (71.0% women v. 29.0% men, mean age 69.1 ± 9.1 yr). No patients were lost to follow-up. There were no significant differences between the cohorts in terms of sex, age, body mass index (BMI) or smoking history. In both cohorts, there were nearly twice as many women as men (Table 1).

We compared the groups for preoperative comorbidities, including hypertension, arrhythmia, coronary artery disease (CAD), myocardial infarction (MI), congestive heart failure (CHF), deep vein thrombosis (DVT), pulmonary embolism (PE), stroke, transient ischemic attack (TIA), dementia, asthma, chronic obstructive pulmonary disease (COPD), renal disease, diabetes mellitus, previous knee surgery, preoperative hemoglobin and anemia (hemoglobin < 130 g/L). No significant differences existed between cohorts except for incidence of TIA and previous knee surgery. A greater proportion of patients undergoing UTKA had a history of TIA than those undergoing BTKA (3.4% v. 1.1%, p = 0.015). The patients undergoing UTKA had significantly more previous knee operations, including arthroscopic débridement, than patients undergoing BTKA (20.3% v. 5.6%, p < 0.001; Table 2).

There were no significant differences between the UTKA and BTKA cohorts for intraoperative and postoperative cardiovascular, thromboembolic or neurologic complications; deep wound infections; or mortality. In addition, there were no significant differences in the rates of respiratory failure, renal failure or length of hospital stay between cohorts. The sole significant difference identified between cohorts was the greater proportion of BTKA patients requiring blood transfusions (29.8% v. 8.9%, p < 0.001). Among those patients in the BTKA and UTKA cohorts who were transfused, there was no significant difference in the number of blood units required (1.72 ± 0.77 v. 1.53 ± 0.85 units, p = 0.68; Table 3).

As part of a further analysis, we assessed the UTKA and BTKA cohorts to identify factors that may have predisposed patients to transfusion. All patients who received transfusion had preoperative anemia (p < 0.001). Previous MI was significantly more common among transfused than nontransfused patients in the UTKA cohort (14.0% v. 5.5%, p = 0.008); we did not observe a similar trend in the BTKA cohort. Transfused patients were significantly older than nontransfused patients in the UTKA cohort (76.1 ± 8.60 yr v. 69.2 ± 10.12 yr, p < 0.001); again, we did not observe a similar trend in the BTKA cohort.

DISCUSSION

The number of TKAs being performed in Canada is projected to continue rising, given the aging population. The literature regarding the relative safety of BTKA remains controversial. While some studies supporting the use of BTKA have shown comparable complication rates to that...
of UTKA, critics of BTKA maintain that the procedure increases the risk of serious complications, including cardiovascular, thromboembolic and neurologic events and death. Therefore, we conducted the present study to determine whether it is safe to perform BTKA at a high-volume community hospital.

Our study demonstrated no significant differences in intraoperative and postoperative complications between patients undergoing BTKA and those undergoing UTKA with the exception of an increased proportion of patients in the BTKA cohort requiring blood transfusions. It has been suggested that patients undergoing BTKA are at increased risk for cardiovascular complications due to greater intraoperative blood loss leading to substantial hemodynamic shifts and ischemia. A potential explanation for the comparable cardiovascular outcomes between cohorts in our study may be that the blood loss experienced by patients in the BTKA group was not substantial enough to precipitate more cardiovascular events. Support for this explanation may lie in the fact that the mean transfusion requirement for our patients undergoing BTKA was 1.72 ± 0.77 units, whereas the literature reports requirements of 3.9 units for these patients. Furthermore, a study that identified a greater proportion of postoperative CHF in the BTKA cohort examined a population aged older than 80 years, which was markedly older than the mean age of both cohorts in the present study (69.6 ± 10.2 yr in the UTKA group and 69.1 ± 9.1 yr in the BTKA group).

The reported incidence of thromboembolic events following a TKA procedure varies widely in the literature, ranging from 0.4% to 71% for DVT and 0% to 3% for PE. Studies demonstrating high rates, however, used radiological imaging to detect thromboembolism. Radiological imaging often detects clinically asymptomatic thrombosis, whereas our study considered only symptomatic events. Consistent with our findings, several studies considering only symptomatic DVT or PE have demonstrated no statistically significant differences between UKTA and BTKA cohorts. One possible explanation for this may be that while BTKA increases recovery time and predisposes patients to immobility-related thromboembolic risk, patients undergoing BTKA tend to be more hypocoagulable in the postoperative period due to a greater intraoperative consumption of coagulation factors.

The literature reports a 3-month mortality of 0.46% associated with TKA. In addition, 1 study of in-hospital mortality found that 0.5% of patients who had BTKA died compared with 0.3% of patients who had UTKA. In contrast, our study identified lower mortality among patients who had UTKA, with no significant difference between cohorts (0.3% in the BTKA group v. 0.1% in the UTKA group, p = 0.48). Although the literature predominantly reflects higher mortality in patients who had BTKA, many

<table>
<thead>
<tr>
<th>Table 2. Comorbidities of patients undergoing bilateral or unilateral total knee arthroplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group, no. (%)*</td>
</tr>
<tr>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Arrhythmia</td>
</tr>
<tr>
<td>Coronary artery disease</td>
</tr>
<tr>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>Chronic heart failure</td>
</tr>
<tr>
<td>Thromboembolic</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
</tr>
<tr>
<td>Neurologic</td>
</tr>
<tr>
<td>Transient ischemic attack</td>
</tr>
<tr>
<td>Stroke</td>
</tr>
<tr>
<td>Dementia</td>
</tr>
<tr>
<td>Respiratory</td>
</tr>
<tr>
<td>Asthma</td>
</tr>
<tr>
<td>COPD</td>
</tr>
<tr>
<td>Renal failure</td>
</tr>
<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>Previous knee surgery</td>
</tr>
<tr>
<td>Preop HB status</td>
</tr>
<tr>
<td>Preop HB, mean ± SD, g/L</td>
</tr>
<tr>
<td>Preop anemia, † mean ± SD, g/L</td>
</tr>
</tbody>
</table>

BTKA = bilateral total knee arthroplasty; CI = confidence interval; COPD = chronic obstructive pulmonary disease; HB = hemoglobin; OR = odds ratio; SD = standard deviation; UTKA = unilateral total knee arthroplasty.

*Unless otherwise indicated.
†Hb < 130 g/L.
authors have acknowledged that there may be no difference between procedures if performed at high-volume institutions with specialized TKA surgeons. At our institution, 500–600 BTKAs and UTKAs are collectively performed each year, making it a high-volume, specialized facility. Furthermore, critics of BTKA claim that the studies demonstrating no difference in mortality between cohorts are misleading, as BTKA candidates are often selected for their benign medical history, thereby introducing a selection bias. Both populations in the present study, however, were comparable in terms of demographic characteristics and comorbidity profiles. In addition, our patients were not assigned to a particular procedure based on comorbidities; rather, they chose the procedure they would undergo.

The only significant difference between the BTKA and UTKA cohorts in the present study was the proportion of patients requiring blood transfusion of at least 1 unit (8.9% v. 29.8%, p < 0.001). All transfused patients, regardless of cohort, had preoperative anemia, which is the strongest predictor of transfusion. Studies show that the blood loss associated with TKA can be as high as 2.2 units per knee replaced due to extensive bone and soft tissue cuts; therefore, it would be expected that operating on 2 knees rather than 1 knee predisposes the patient to a greater risk of blood loss and the need for transfusion. In fact, it has been reported that during BTKA, the blood loss from the second knee replacement is greater than that from the first, likely due to decreased tissue clotting factors associated with intraoperative tissue trauma, hypothermia or hypoxemia. Interestingly, our study demonstrated that among patients being transfused, those in the BTKA cohort required a greater number of blood units than those in the UTKA cohort, but this finding was not significant (1.72 ± 0.77 v. 1.53 ± 0.85 units, p = 0.68). While this outcome may seem paradoxical, it is important to note that transfusion requirement is a useful, albeit imperfect, substitute measurement for blood loss. Blood transfusion is a second line treatment for hemodynamically unstable patients owing to transfusion-related risks; therefore, the trigger for transfusion is often reserved for patients with a hemoglobin level of less than 70 g/L, and patients are often transfused until stable rather than euvolemic. Prophylactically, the use of antifibrinolytics has been shown to markedly reduce blood loss and transfusion requirements during TKA. Intraoperative use of antifibrinolytic TXA has recently been incorporated into the TKA procedures at our institution to address the need for blood transfusion, particularly in patients undergoing BTKA. Preliminary data demonstrate that use of TXA has resulted in lowered transfusion rates for patients undergoing BTKA.

In contrast to the present study, several larger bodies of work have found that while the absolute number of complications associated with any TKA procedure is small, the relative risk of cardiovascular complications, PE and death is greater for BTKA. The results of our community

<table>
<thead>
<tr>
<th>Complication</th>
<th>UTKA, n = 966</th>
<th>BTKA, n = 373</th>
<th>p value</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arhythmia</td>
<td>8 (0.8)</td>
<td>1 (0.3)</td>
<td>0.46</td>
<td>3.1 (0.4–24.9)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>4 (0.4)</td>
<td>4 (1.0)</td>
<td>0.23</td>
<td>0.4 (0.1–1.5)</td>
</tr>
<tr>
<td>Chronic heart failure</td>
<td>10 (1.0)</td>
<td>0 (0)</td>
<td>0.07</td>
<td>NA</td>
</tr>
<tr>
<td>Total</td>
<td>22 (2.3)</td>
<td>5 (1.3)</td>
<td>0.39</td>
<td>1.7 (0.6–4.6)</td>
</tr>
<tr>
<td>Thromboembolic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>5 (0.5)</td>
<td>2 (0.5)</td>
<td>&gt; 0.99</td>
<td>1.0 (0.2–5.0)</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>3 (0.3)</td>
<td>1 (0.3)</td>
<td>&gt; 0.99</td>
<td>1.2 (0.1–11.2)</td>
</tr>
<tr>
<td>Total</td>
<td>8 (0.8)</td>
<td>3 (0.8)</td>
<td>&gt; 0.99</td>
<td>1.0 (0.3–3.9)</td>
</tr>
<tr>
<td>Neurologic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TIA/stroke</td>
<td>2 (0.2)</td>
<td>0 (0.0)</td>
<td>&gt; 0.99</td>
<td>NA</td>
</tr>
<tr>
<td>Delirium</td>
<td>12 (1.2)</td>
<td>3 (0.8)</td>
<td>0.77</td>
<td>1.6 (0.4–5.5)</td>
</tr>
<tr>
<td>Total</td>
<td>14 (1.4)</td>
<td>4 (1.1)</td>
<td>0.79</td>
<td>1.4 (0.4–4.1)</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>4 (0.4)</td>
<td>2 (0.5)</td>
<td>0.67</td>
<td>0.8 (0.1–4.2)</td>
</tr>
<tr>
<td>Renal failure</td>
<td>1 (0.1)</td>
<td>0 (0.0)</td>
<td>0.28</td>
<td>NA</td>
</tr>
<tr>
<td>Deep infection</td>
<td>4 (0.4)</td>
<td>1 (0.3)</td>
<td>&gt; 0.99</td>
<td>1.5 (0.2–13.9)</td>
</tr>
<tr>
<td>Mortality</td>
<td>1 (0.1)</td>
<td>1 (0.3)</td>
<td>0.48</td>
<td>0.4 (0.6–2)</td>
</tr>
<tr>
<td>Hospital stay, mean ± SD, d</td>
<td>4.9 ± 2.9</td>
<td>5.3 ± 2.1</td>
<td>0.36</td>
<td>0.92 (0.88–0.98)</td>
</tr>
<tr>
<td>Transfusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfused</td>
<td>86 (8.9)</td>
<td>111 (29.8)</td>
<td>&lt; 0.001</td>
<td>0.2 (0.2–0.3)</td>
</tr>
<tr>
<td>Units, mean ± SD</td>
<td>1.53 ± 0.85</td>
<td>1.72 ± 0.77</td>
<td>0.68</td>
<td>0.89 (0.84–0.94)</td>
</tr>
</tbody>
</table>

BTKA = bilateral total knee arthroplasty; CAD = coronary artery disease; CI = confidence interval; NA = not available; OR = odds ratio; SD = standard deviation; TIA = transient ischemic attack; UTKA = unilateral total knee arthroplasty.

*Unless otherwise indicated.
hospital-based study may therefore not be universally applicable to all centres where BTKA is performed. Given the controversial status of BTKA safety in the literature, patients should be made aware of the major intraoperative and postoperative complications identified in the larger cohort studies when deciding whether to undergo elective bilateral or unilateral knee replacement surgery.

Limitations

Our study had several limitations that should be acknowledged. First, despite having a standard TKA approach at our institution, our study was based on the data of 7 surgeons, each of whom may have introduced a minor degree of procedure variability. Nevertheless, we felt that combining the results from different surgeons yielded a more accurate representation of TKA outcomes at a community hospital and would enhance the external validity of our study. Second, reviewing only hospital records may not identify all patient complications that occurred after discharge. For instance, if a patient visited another hospital with an acute complication, our institution database may not have a record of that visit. The potential for this error was minimized, however, as no study patient was lost to follow-up and all patients were seen within the first 3 postoperative months to monitor knee progress and screen for complications. Finally, it may be suggested that a comparison between BTKA and staged TKA is more valuable than a comparison of BTKA and UTKA. We initially incorporated staged TKA, but the sample size was too small for the analysis to have adequate statistical power. In addition, staged TKA introduces confounding factors, such as 2 distinct anesthetic exposures and 2 distinct postoperative recovery periods, that do not exist in a comparison between BTKA and UTKA. In addition, the literature suggests that the operative risk of staged TKA is underestimated in retrospective studies, as patients who experience complications during the first surgery may be unlikely to participate in a second surgery and thereby become a UTKA patient. Individuals who decline the second operation are likely to continue experiencing symptoms of arthritis, which suggests that they may have been better served by a 1-step BTKA.

This study has several strengths compared with the existing body of literature. First, having the study based at a high-volume hospital generated a large number of eligible patients in both cohorts for comparison. Second, this study uniquely examined the TKA outcomes at a community institution where all surgeries are performed by staff surgeons, whereas most studies in the literature were conducted at academic centres where trainees also participated in operations. Finally, the same hospitalist managed all patients in the postoperative setting at our institution, minimizing the possibility that variability in postoperative care influenced complication rates.

Conclusion

The purpose of our study was to determine the safety of performing BTKA procedures at a high-volume community hospital. While several large scale studies, which used data from academic centres, have identified relative risks correlated with BTKA, our study did not find BTKA to be associated with increased cardiovascular, thromboembolic, or neurologic complications; deep wound infection; or death compared with UTKA. The proportion of patients requiring blood transfusions was significantly greater in the BTKA cohort, but the number of units required per transfused patient was not significantly different. Recent efforts have been made at our institution to effectively reduce the need for transfusion by introducing the use of TXA. We conclude that BTKA can be a safe treatment for bilateral knee arthritis in the context of a high-volume community hospital with experienced TKA surgeons, hospitalists, paramedical staff and ready access to postoperative inpatient rehabilitation.

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Competing Interests: None declared.

Contributors: E. Spicer and G.R. Thomas contributed to all aspects of this work. E.J. Rumble designed the study, analyzed the data, reviewed the article and approved the final version for publication.

References


Impact of a regional acute care surgery model on patient access and outcomes

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Background: The consolidation of acute care surgery (ACS) services at 3 of 6 hospitals in a Canadian health region sought to alleviate a relative shortage of surgeons able to take emergency call. We examined how this affected patient access and outcomes.

Methods: Using the generalized linear model and statistical process control, we analyzed ACS-related episodes that occurred between 39 months prior to and 17 months after the model’s implementation (n = 14 713).

Results: Time to surgery increased after the consolidation. Wait times increased primarily for patients presenting at nonreferral hospitals who were likely to require transfer to a referral hospital. Although ACS teams enabled referral hospitals to handle a much higher volume of patients without increasing within-hospital wait times, overall system wait times were lengthened by the growing frequency of patient transfers. Wait times for inpatient admission were difficult to interpret because there was a trend toward admitting patients directly to the ACS service, bypassing the emergency department (ED). For patients who did go through the ED, wait times for inpatient admission increased after the consolidation; however, this trend was cancelled out by the apparently zero waits of patients who bypassed the ED. Regionalization showed no impact on length of stay, readmissions, mortality or complications.

Conclusion: Consolidation enabled the region to ensure adequate surgical coverage without harming patients. The need to transfer patients who presented at nonreferral hospitals led to longer waits.

Contexte : Le regroupement des services chirurgicaux d’urgence (SCU) dans 3 hôpitaux sur 6 d’une région sanitaire canadienne visait à contrecarrer une relative pénurie de chirurgiens capables d’effectuer les interventions d’urgence. Nous en avons analysé l’impact sur l’accessibilité des services et sur les résultats chez les patients.

Méthodes : À l’aide du modèle linéaire généralisé et d’un contrôle statistique des procédés, nous avons analysé les cas adressés aux SCU entre 39 mois précédant et 17 mois suivant l’entrée en vigueur du regroupement des services (n = 14 713).

Résultats : L’intervalle avant l’intervention chirurgicale s’est allongé après le regroupement des services. Les temps d’attente ont principalement augmenté pour les patients qui consultaient dans un hôpital de premier recours d’où ils étaient susceptibles d’être réorientés vers un hôpital de référence. Même si les équipes des SCU ont permis aux hôpitaux de référence de gérer un volume beaucoup plus important de patients sans augmentation du temps d’attente à l’hôpital même, le temps d’attente dans son ensemble s’est prolongé à l’échelle du système en raison de l’accroissement du nombre de transferts. Les temps d’attente pour les hospitalisations ont été difficiles à interpréter parce qu’on avait tendance à admettre les patients directement aux SCU, en contournant les services d’urgences. Pour les patients qui passaient par les urgences, les temps d’attente pour une hospitalisation ont augmenté après le regroupement; toutefois, cette tendance a été compensée par l’attente pour ainsi dire nulle des patients qui contournaienlales services d’urgence. La régionalisation n’a exercé aucun impact sur la durée du séjour, les réadmissions, la mortalité ou les complications.

Conclusion : Le regroupement a permis à la région d’assurer une couverture chirurgicale adéquate sans nuire aux patients. La nécessité de réorienter des patients vers les hôpitaux de référence a contribué à prolonger les temps d’attente.
Access to emergency or urgent surgery has become a serious concern across North America and beyond. With the evolution of surgical subspecialties there has been a relative decline in the availability of surgeons who provide emergency care, particularly after hours. Many health care organizations and systems have sought to cope with this problem by consolidating surgical services. There is growing international interest in the acute care surgery (ACS) model, in which designated resources, including the time of designated surgeons, are set aside for emergency and/or urgent surgery. The model may be implemented within a hospital, among hospitals (regionalization), or both.

Past research has suggested that within-hospital ACS consolidation can reduce wait times for emergency surgery, and may sometimes improve patient outcomes. However, the literature is dominated by uncontrolled pre–post studies, which cannot rule out secular trends and other confounders, such as adoption of new surgical practices, as explanations for the observed results. Very few studies have evaluated ACS consolidation on a regional level involving multiple institutions. One study found that mortality and length of stay (LOS) decreased over time within a regionalized ACS service, but it did not compare these rates with those observed before regionalization. Another study found no significant change in mortality when high-acute surgery (including many procedures outside the scope of emergency general surgery) was regionalized; there was an ongoing decline in LOS, but this decline had begun before regionalization. To our knowledge, no study has examined wait times at the pan-regional level, taking into account how transfers affect the patient journey. As the ACS model becomes increasingly widespread, there is an urgent need for further evidence on the impacts of ACS consolidation, especially regional consolidation.

The Winnipeg Regional Health Authority (WRHA), an urban health region in Western Canada (catchment population 1.2 million), implemented the ACS model to stabilize and sustain call schedules. The region had been unable to fill the gaps through recruitment because there was neither the volume of work nor the resources to support new recruits. This 6-hospital system consolidated emergency general surgery at 3 referral sites, each of which now includes a designated ACS team. A clinical lead or service chief (funded position) is responsible for addressing administrative needs and maintaining call schedules. One surgeon covers the day shift (7:30–16:30) from Monday to Sunday, providing continuity throughout the week. The night shift (16:30–7:30, home-call) rotates among participating surgeons on a daily basis. Remuneration is a blended model of a day and night stipend and fee-for-service. A hospitalist was added to the ACS team at the nonteaching site; hospitalists and/or physician assistants play a smaller role at the teaching sites. The referral hospitals have added daytime ACS slates, but not dedicated emergency operating rooms (ORs). To offset the increased volume of ACS patients at the referral hospitals, both elective general surgery and orthopedic surgery cases have been relocated to the nonreferral hospitals.

One hospital became a referral centre in April 2008, another in December 2008. A third offered ACS throughout the study period but did not invite additional referrals.) The consolidation succeeded in filling call schedules and ensuring reliable access to an on-call surgeon. This study sought to determine the impact of consolidation on patient access and outcomes.

**Methods**

Our analyses of administrative data included all adult patients (aged 20 years and older) with an ACS-related inpatient stay at a WRHA hospital between 2005 and 2009. The University of Manitoba Health Research Ethics Board approved our use of this deidentified data for research purposes. We defined “ACS-related” as an emergent admission to the general surgery service, where the most responsible diagnosis was gastrointestinal (GI)-related (ICD-10 K codes [diseases of the GI system] or R10 codes [abdominal pain]). This criterion was used because the most common acute surgical conditions are GI-related (e.g., appendicitis, cholecystitis), whereas the most common types of emergency general surgery outside the scope of the ACS consolidation (trauma and cancer-related surgery) are not. We defined an “episode of care” as an acute care admission with an eligible diagnosis and emergency department (ED) visit that occurred within 24 hours (or, if a patient transfer was reported, within 72 h) of another admission or visit. Based on these criteria, we arrived at a sample of 14,735 episodes of care. In the interest of statistical independence of observations, we then excluded episodes where the patient had a recent prior episode. For tests of system responsiveness (time to surgery, time to inpatient admission) and complications, we considered a recent episode to have occurred in the previous 72 hours; for other tests of patient management, we considered a recent episode to have occurred in the previous 30 days.

The dependent variables included time to surgery (time from first presentation at a WRHA hospital to first surgery), time to inpatient admission (time from first presentation at a WRHA hospital to first inpatient admission), LOS (total time from first inpatient admission to last inpatient discharge), readmission (all-cause readmission to any WRHA hospital within 30 d of being discharged alive), death (in hospital or within 30 d of discharge) and complications (presence of 1 or more complications in surgical patients; the data source included generalized complications, such as infection, hemorrhage and iatrogenic injury, but not disease-specific issues, such as ruptured appendix).

The intervention period began on Apr. 1, 2008, with the creation of the first referral site. Given the stepped nature of patients (aged 20 years and older) with an ACS-related inpatient stay at a WRHA hospital between 2005 and 2009. The University of Manitoba Health Research Ethics Board approved our use of this deidentified data for research purposes. We defined “ACS-related” as an emergent admission to the general surgery service, where the most responsible diagnosis was gastrointestinal (GI)-related (ICD-10 K codes [diseases of the GI system] or R10 codes [abdominal pain]). This criterion was used because the most common acute surgical conditions are GI-related (e.g., appendicitis, cholecystitis), whereas the most common types of emergency general surgery outside the scope of the ACS consolidation (trauma and cancer-related surgery) are not. We defined an “episode of care” as an acute care admission with an eligible diagnosis and emergency department (ED) visit that occurred within 24 hours (or, if a patient transfer was reported, within 72 h) of another admission or visit. Based on these criteria, we arrived at a sample of 14,735 episodes of care. In the interest of statistical independence of observations, we then excluded episodes where the patient had a recent prior episode. For tests of system responsiveness (time to surgery, time to inpatient admission) and complications, we considered a recent episode to have occurred in the previous 72 hours; for other tests of patient management, we considered a recent episode to have occurred in the previous 30 days.

The dependent variables included time to surgery (time from first presentation at a WRHA hospital to first surgery), time to inpatient admission (time from first presentation at a WRHA hospital to first inpatient admission), LOS (total time from first inpatient admission to last inpatient discharge), readmission (all-cause readmission to any WRHA hospital within 30 d of being discharged alive), death (in hospital or within 30 d of discharge) and complications (presence of 1 or more complications in surgical patients; the data source included generalized complications, such as infection, hemorrhage and iatrogenic injury, but not disease-specific issues, such as ruptured appendix).

The intervention period began on Apr. 1, 2008, with the creation of the first referral site. Given the stepped nature of
of implementation, we considered dividing the intervention period into 2 phases; however, phase 2 and its interaction with linear time never reached significance in any model and were therefore removed. Covariates included month of last hospital discharge, sex, age, diagnostic category (appendicitis, cholecystitis, intestinal obstruction, pancreatitis, diverticulitis, other), operative status (undergoing an ACS-related procedure within 7 d of the start of the episode; the list of eligible procedures was determined by a surgeon who was blind to all other data), non-WRHA facility (transfer to or from out-of-region facility during the episode) and referral hospital (presenting at a hospital that was or became a referral centre). The inclusion and exclusion criteria and related sample sizes for each analysis are provided in Table 1, and characteristics of the sample are summarized in Table 2.

Statistical analysis
Analytic methods included statistical process control and regression modelling. Statistical process control (SPC) involves plotting the data on a control chart to examine the timing and magnitude of any changes. Results are tested for significance according to rules that include 1 data point outside the upper and lower control limits, 6 consecutive data points ascending or descending and 9 consecutive data points above or below the mean. On the control charts, the solid line represents the mean and the dotted lines represent the upper and lower control limits. We calculated these values based on the preintervention period.

We used multiple linear regression for continuous (log-transformed) variables and logistic regression for binary variables. Before choosing this method, we used the Durbin–Watson test to check for autocorrelation of errors, using data at the levels of both individual cases and monthly aggregates. These tests did not show significant results (the Durbin–Watson statistic approached 2), indicating that it was unnecessary to use a procedure, such as ARIMA, to control for autocorrelation.

RESULTS
Implementation of ACS
Between 2007 and 2009, ACS all but stopped at the 3 non-referral centres, while the proportion of ACS episodes handled at the 2 new referral centres increased by 71.5%. The overall volume of general surgery patients rose permanently at 1 referral centre and temporarily at the other (it should be noted that the consolidation also redistributed non–general surgery patients). A 4.5-fold increase was observed in patient transfers among WRHA hospitals for surgical consultation or treatment. Ambulance data suggested that this increase was somewhat, but not fully offset by a decrease in the number of there-and-back transfers for tests, such as computed tomography (see the Appendix, Figs. S1 and S2, available at cma.ca/cjs).

Time to surgery
Our SPC analysis suggested some increase in wait times after the intervention, although this trend did not reach significance (Fig. 1). However, Figure 2 shows that when the analysis was repeated for patients within the WRHA, the finding clearly reached significance (more than 9 points above the preintervention mean, with the rise beginning around December 2008). This finding was explained by the observation that the vast majority of non-WRHA patients presented to 1 of the 3 ACS referral hospitals directly, whereas about one-third of WRHA patients presented to a non-ACS site (both before and after the intervention). Further analysis confirmed that, whereas wait times stayed fairly constant at referral hospitals, they rose sharply at feeder hospitals after the intervention began (see the Appendix, Figs. S3 and S4). This rise appeared to reflect

<table>
<thead>
<tr>
<th>Table 1. Inclusion and exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description; inclusion criteria No.</td>
</tr>
<tr>
<td>Total potential sample</td>
</tr>
<tr>
<td>All ACS episodes of care</td>
</tr>
<tr>
<td>Descriptive analyses</td>
</tr>
<tr>
<td>No ACS hospital stays within the past 72 h</td>
</tr>
<tr>
<td>Time to surgery, log</td>
</tr>
<tr>
<td>No ACS hospital stays within the past 72 h</td>
</tr>
<tr>
<td>ACS episode is not incidental</td>
</tr>
<tr>
<td>Surgical patient</td>
</tr>
<tr>
<td>Date and time of surgery available</td>
</tr>
<tr>
<td>Surgery occurred during the recorded episode</td>
</tr>
<tr>
<td>Surgery occurred fewer than 7 d after start of episode</td>
</tr>
<tr>
<td>No missing “transfer from” visit</td>
</tr>
<tr>
<td>Time to inpatient, log</td>
</tr>
<tr>
<td>No ACS hospital stays within the past 72 h</td>
</tr>
<tr>
<td>ACS episode is not incidental</td>
</tr>
<tr>
<td>No missing “transfer from” visit</td>
</tr>
<tr>
<td>Length of stay, log</td>
</tr>
<tr>
<td>No ACS hospital stays within the past 30 d</td>
</tr>
<tr>
<td>ACS episode is not incidental</td>
</tr>
<tr>
<td>No missing “transfer to” visit</td>
</tr>
<tr>
<td>30-d readmission</td>
</tr>
<tr>
<td>No ACS hospital stays within the past 30 d</td>
</tr>
<tr>
<td>Discharge prior to the last month of data collection</td>
</tr>
<tr>
<td>Discharged alive</td>
</tr>
<tr>
<td>30-d mortality (includes inhospital)</td>
</tr>
<tr>
<td>No ACS hospital stays within the past 30 d</td>
</tr>
<tr>
<td>Discharge prior to the last month of data collection</td>
</tr>
<tr>
<td>Complications</td>
</tr>
<tr>
<td>No ACS hospital stays within the past 72 h</td>
</tr>
<tr>
<td>Surgical patient</td>
</tr>
<tr>
<td>Surgery occurred during the recorded episode</td>
</tr>
<tr>
<td>Surgery occurred fewer than 7 d after start of episode</td>
</tr>
</tbody>
</table>

ACS = acute-care surgery.
the increasing proportion of patients who were transferred (from 18.8% to 70.6% of surgical patients presenting at nonreferral hospitals), not an increase in the length of time associated with a transfer (which did not change over the study period). Supplementary analyses indicated that transferred patients waited a median of 5.5 hours longer than nontransferred patients; depending on whether the patient travelled by ambulance, 2–3 of these hours could be accounted for by the transfer process. The remaining time appeared to reflect pre- and posttransfer delays, such as waiting for access to a bed or OR suite. The increased wait did not seem to occur as a result of arriving at a particular hospital (patients arriving at all nonreferral hospitals had similar wait times), nor as a result of delays in being admitted to a referral hospital (transfer patients were admitted quickly and were fast-tracked to surgery). The region-wide impact was a 1- to 2-hour increase in median wait times every half-year after the consolidation.

Multiple linear regression confirmed these results (see the Appendix, Table S1). Both for the sample as a whole and more strongly for WRHA patients, there was a significant interaction between the intervention and the episode date. This indicated that time to surgery began to get longer after the intervention was implemented. Significant intervention effects were apparent at 12 and 18 months. There was also a significant interaction between the intervention and type of hospital: after the intervention, waits became longer at feeder hospitals and slightly and temporarily shorter at referral hospitals. When the analysis was restricted to patients who presented at referral hospitals (99% of whom remained there), no intervention effect appeared. To ensure that missing data for “time to surgery” had not biased our results, we performed a Poisson regression using days to surgery as the dependent variable. The effects for intervention and month as well as the interaction between them remained in the same direction and reached significance in the WRHA subsample ($p = 0.041$). The significant result is striking, considering the imprecision of the dependent variable, days to surgery, whose value was 0 or 1 for 72% of episodes.

**Time to inpatient admission**

Wait times for inpatient admission were difficult to interpret because the study period coincided with a trend toward

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**Table 2. Characteristics of the study sample**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group; no. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre–model implementation</td>
</tr>
<tr>
<td></td>
<td>$n = 8994$</td>
</tr>
<tr>
<td>Total, $n = 14713$</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>4175 (46.4)</td>
</tr>
<tr>
<td>Female</td>
<td>4819 (53.6)</td>
</tr>
<tr>
<td>Age, yr</td>
<td></td>
</tr>
<tr>
<td>20–34</td>
<td>1876 (20.9)</td>
</tr>
<tr>
<td>35–49</td>
<td>2140 (23.8)</td>
</tr>
<tr>
<td>50–64</td>
<td>2109 (23.4)</td>
</tr>
<tr>
<td>65–79</td>
<td>1841 (20.5)</td>
</tr>
<tr>
<td>≥80</td>
<td>1028 (11.4)</td>
</tr>
<tr>
<td>Operative status*</td>
<td></td>
</tr>
<tr>
<td>Nonsurgical</td>
<td>3478 (38.7)</td>
</tr>
<tr>
<td>Surgical</td>
<td>5516 (61.3)</td>
</tr>
<tr>
<td>Diagnostic category</td>
<td></td>
</tr>
<tr>
<td>Appendicitis</td>
<td>1433 (15.9)</td>
</tr>
<tr>
<td>Cholecystitis</td>
<td>1561 (17.4)</td>
</tr>
<tr>
<td>Intestinal obstruction</td>
<td>1075 (12.0)</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>586 (6.5)</td>
</tr>
<tr>
<td>Diverticulitis</td>
<td>555 (6.2)</td>
</tr>
<tr>
<td>Other</td>
<td>3784 (42.1)</td>
</tr>
<tr>
<td>Origin</td>
<td></td>
</tr>
<tr>
<td>WRHA</td>
<td>7915 (88.0)</td>
</tr>
<tr>
<td>Non-WRHA</td>
<td>1079 (12.0)</td>
</tr>
</tbody>
</table>

WRHA = Winnipeg Regional Health Authority.
*In this table, patients who had surgery at any time are counted as operative.
admitting selected patients directly to the inpatient surgery ward, bypassing the ED. There was no apparent wait time for such patients, but this would seem to be an underestimate, since we do not know when they really presented in the system. To avoid underestimating postintervention wait times, we ran the analyses twice: once for patients who went through the ED and again for the full sample.

For patients admitted through the ED, SPC analysis showed an unmistakable increase in time to inpatient admission (Fig. 3). The most dramatic increase coincided with the jump in direct admissions, but some increase had already become apparent by early 2008, before the intervention period. However, the full-sample analysis suggested a possible decrease in wait times during the intervention period (Fig. 4).

The regression models echoed the findings that after the intervention, wait times increased for admissions through the ED but decreased for admissions as a whole, although these effects varied in significance between WRHA patients and the full sample (see the Appendix, Table S2). As with time to surgery, the increased waits for admissions through the ED were more apparent for patients who presented to a nonreferral hospital (data not shown). Decreased waits for overall admissions were more apparent at referral hospitals, because only these hospitals adopted a policy of bypassing the ED.

These results imply that ACS patients who visited the ED postconsolidation spent longer there than they would preconsolidation. However, an increasing number of ACS patients spent no time in the ED at all. The 2 trends

Fig. 1. Time to surgery (log) for all patients.

Fig. 2. Time to surgery (log) for Winnipeg Regional Health Authority (WHRA) patients.

Fig. 3. Time to inpatient admission (log) for patients admitted from the emergency department (ED).

Fig. 4. Time to inpatient admission (log) for all patients.

Fig. 5. Length of stay (log) for all patients.
patients do appear to have helped. The new referral hospital level, strategies to improve access for ACS consolidation on non-ACS patients. Benchmarking data collected annually from 2007/08 through 2010/11 detected no significant changes in adverse outcomes (readmission, in-hospital mortality) for acute myocardial infarction or stroke patients at the referral hospitals, nor was there an increase in the number of hospital admissions for ambulatory care–sensitive conditions. These data provide no a priori evidence of patient harm, but firm conclusions cannot be drawn without more sensitive and frequent measures of emergency patient outcomes.

CONCLUSION

Our findings suggest that a regional ACS model can ensure adequate emergency surgical coverage without
threatening patient outcomes. This makes it a viable solution to a health human resources problem that has become increasingly serious in Canada, the United States and elsewhere. Patient outcomes were not impacted; however, the growing number of patient transfers brought an overall increase in wait times. The WRHA has recognized a need to improve the current system so that all patients experience a smooth journey without delays; it is currently working to streamline the transfer process while also reducing surgical volume at referral hospitals by redirecting other types of surgery. The system is still evolving, and benefits may be realized as it develops. With time, ACS patients may gravitate and be directed toward the referral sites, with a lower proportion presenting at non-ACS facilities. What is clear, however, is that regionalization brings its own challenges, and evidence on the outcomes of within-hospital ACS consolidation cannot necessarily be generalized to the regional level. Returning to a model with unpredictable gaps in the emergency call schedule would not be an option for the WRHA, nor for other regions in similar situations; however, our findings do not provide grounds for wholesale adoption of the model regardless of context. It remains essential for jurisdictions that implement a regional ACS model to carefully monitor its impacts — both intended and unintended.

Acknowledgements: This research was undertaken as part of an evaluation of the Winnipeg Regional Health Authority (WRHA) Acute-Care Surgical Service. We thank Trevor Strome, Miroslava Svitlica, Jill Evison, Trudy Wilgosh, Ray Larkins, Cameron Robertson, Susan Gerlach, Wendy Rogoski, Evelyn Fondse, Anne Haknasson, Crystal Letain, Victor Cho and Elaine Pelletier for their help with data acquisition. We also appreciate the suggestions we received from the MNU/WRHA Working Group and from Dr. David Hochman.

Competing interests: None declared.

Contributors: S.A. Kreindler, C.J. Metge, R.W. Nason and M.E.K. Moffatt designed the study. L. Zhang acquired the data, which all authors interpreted and analyzed. S.A. Kreindler wrote the article, which all authors reviewed and approved for publication.

References
Incremental value and clinical impact of neck sonography for primary hyperparathyroidism: a risk-adjusted analysis

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Background: Despite the different preoperative imaging modalities available for parathyroid adenoma localization, there is currently no uniform consensus on the most appropriate preoperative imaging algorithm that should be routinely followed prior to the surgical management of primary hyperparathyroidism (PHPT). We sought to determine the incremental value of adding neck ultrasonography to scintigraphy-based imaging tests.

Methods: In a single institution, surgically naive patients with PHPT underwent the following localization studies before parathyroidectomy: 1) Tc-99m sestamibi imaging with single photon emission computed tomography/computed tomography (SPECT/CT) or Tc-99m sestamibi imaging with SPECT alone, or 2) ultrasonography in addition to those tests. We retrospectively collected data and performed a multivariate analysis comparing group I (single study) to group II (addition of ultrasonography) and risk of bilateral (BNE) compared with unilateral (UNE) neck exploration.

Results: Our study included 208 patients. Group II had 0.45 times the odds of BNE versus UNE compared with group I (unadjusted odds ratio [OR] 0.45, 95% confidence interval [CI] 0.25–0.81, p = 0.008). When adjusting for patient age, sex, preoperative calcium level, use of intraoperative PTH monitoring, preoperative PTH level, adenoma size, and number of abnormal parathyroid glands, Group II had 0.48 times the odds of BNE versus UNE compared with group I (adjusted OR 0.48, 95% CI 0.23–1.03, p = 0.06). In a subgroup analysis, only the addition of ultrasonography to SPECT decreased the risk of undergoing BNE compared with SPECT alone (unadjusted OR 0.40, 95% CI 0.19–0.84, p = 0.015; adjusted OR 0.38, 95% CI 0.15–0.96, p = 0.043).

Conclusion: The addition of ultrasonography to SPECT, but not to SPECT/CT, has incremental value in decreasing the extent of surgery during parathyroidectomy, even after adjusting for multiple confounding factors.

Contexte : Malgré l’existence de diverses modalités d’imagerie préopératoire pour la localisation de l’adénome parathyroïdien, on déplore actuellement l’absence de consensus en ce qui concerne l’algorithme le plus approprié à suivre au chapitre de l’imagerie préopératoire à une prise en charge chirurgicale de l’hyperparathyroïdie primaire (HPTP). Nous avons voulu vérifier si l’ajout de l’échographie au cours des explorations d’imagerie scintigraphique offrait une valeur ajoutée.

Méthodes : Dans un établissement, des patients atteints d’HPTP n’ayant jamais subi d’intervention chirurgicale ont été soumis à des examens de localisation préparathyroïdectomie : 1) imagerie au moyen du sestamibi marqué au Tc-99m avec tomographie par émission monophotonique/tomodensitométrie (SPECT/CT), ou imagerie au moyen du sestamibi marqué au Tc-99m avec SPECT seule, ou 2) échographie en plus de ces tests. Nous avons recueilli les données rétrospectivement et effectué une analyse multivariée pour comparer le Groupe I (examen seul) au Groupe II (ajout de l’échographie) et la probabilité qu’ils subissent une exploration cervicale bilatérale (ECB) plutôt qu’unilatérale (ECU).

Résultats : Notre étude a recruté 208 patients. Le Groupe II s’est trouvé exposé à un risque 0,45 fois plus grand d’être soumis à une ECB plutôt qu’à une ECU, comparativement au Groupe I (rapport des cotes [RC] non ajusté 0,45, intervalle de confiance [IC] de 95 % 0,25–0,81, p = 0,008). Après ajustement pour tenir compte de l’âge et du sexe des patients, de leur taux préopératoire de calcium, de la surveillance peropératoire de l’HPT, du taux préopératoire de l’HPT, de la taille de l’adénome et du nombre de ganglions parathyroïdiens anormaux, le Groupe II s’est révélé exposé à un risque 0,48 fois plus grand à l’égard de l’ECB plutôt que de
Primary hyperparathyroidism (PHPT) is a common endocrine disorder characterized by an elevated parathyroid hormone (PTH) level and hypercalcemia.1–3 Currently, the most common presentation of PHPT is an asymptomatic individual who is incidentally identified through routine biochemical laboratory testing.3,4 When PHPT is symptomatic, its most prevalent clinical presentations is nephrolithiasis, followed by musculoskeletal complaints, neuropsychiatric disorders and abdominal symptoms.1–3 With an incidence of about 1% in the adult population, increasing to 2% in adults aged 55 years and older, PHPT tends to be a disease of middle-aged women.1,5

The most common cause of PHPT is a solitary parathyroid adenoma, which accounts for up to 90% of cases.2,6 Approximately 2% of these adenomas may be found in ectopic locations, including within the mediastinum, carotid sheath or thyroid gland.1,5 Other causes of PHPT include multiple parathyroid adenomas (5%), 4 gland hyperplasia (5%) and parathyroid carcinoma (<1%).1,3,5 Parathyroidectomy is the treatment of choice for PHPT and offers an enduring cure.1,3,5,6

Historically, the gold standard approach to parathyroidectomy has been a bilateral neck exploration.3 However, the advent of increasingly available and accurate preoperative imaging, along with intraoperative PTH measurement, has allowed surgeons to carry out a more focused surgical approach, especially since the vast majority of PHPT cases are caused by a single adenoma.2,4,7 Combined with other tools, such as the intraoperative parathyroid hormone assay, there has been an increasing number of surgeons advocating for focused parathyroidectomy, such as unilateral neck exploration and minimally invasive parathyroidectomy.8–14 Moreover, focused parathyroidectomy is associated with decreased surgical dissection and risk of bilateral recurrent laryngeal nerve injury, minimized postoperative pain and shortened length of stay in hospital.8,15

Accurate preoperative imaging has facilitated the use of focused parathyroidectomy.15 Several imaging modalities are available for preoperative localization, including Tc-99m sestamibi imaging (with planar and single photon emission computed tomography; SPECT), neck ultrasonography, and combined Tc-99m sestamibi single photon emission computed tomography with computed tomography (SPECT/CT).11 Other imaging modalities being studied for parathyroid preoperative localization include magnetic resonance imaging (MRI), positron emission tomography combined with CT (PET/CT), and 4-dimensional angiography-enhanced CT.16,17

However, despite the different preoperative imaging tests available for parathyroid adenoma localization, there is currently no uniform consensus on the most appropriate preoperative imaging algorithm that should be routinely followed before the surgical management of PHPT. Moreover, the literature regarding preoperative imaging of PHPT has been primarily focused on the sensitivity and specificity of each imaging test.1,18 Several studies have examined performance of multiple preoperative imaging tests compared with a single imaging test and have focused their analysis on sensitivity and specificity rather than actual clinical outcomes.14,19–21 Therefore, the objective of this study was to evaluate whether there is incremental value in adding ultrasonography to a functional imaging test, such as SPECT or SPECT/CT, in reducing the risk of carrying out a bilateral (BNE) versus unilateral (UNE) neck exploration at the time of parathyroidectomy.

**Methods**

**Study hypothesis and objective**

We hypothesized that there was an association between preoperative imaging test for localization of parathyroid adenoma in PHPT and extent of surgery. The intervention of interest was the addition of ultrasonography to scintigraphy-based imaging (group II) compared with only scintigraphy-based imaging (group I). The outcome of interest was the relative risk of BNE versus UNE. To account for spurious associations brought on by confounding factors, we used multivariate logistic regression analysis to evaluate this intervention–outcome relationship.

**Participants**

We retrospectively reviewed all operations carried out for treatment of PHPT between January 2002 and August 2011 at a single Canadian tertiary care centre. St. Paul's
Hospital (Vancouver, BC) is a referral centre for head and neck endocrine surgery, and subspecialty-trained head and neck surgeons performed all operations. There is no formal guideline for preoperative imaging for PHPT at our centre, and there has generally been an even distribution of ultrasonography, SPECT and SPECT/CT for preoperative localization. Frequently, patients undergo either SPECT or SPECT/CT, and some of these patients also undergo ultrasonography of the neck. Our operative approach to PHPT is to begin with a UNE for cases that have localized preoperatively and to proceed with a BNE if a UNE does not identify the adenoma.

For cases that do not localize with preoperative imaging, a BNE is carried out if an adenoma is not on the side of the neck initially explored. Inclusion in the study cohort required the patient to have met diagnostic criteria for PHPT, undergo preoperative localization imaging and undergone neck exploration with pathological confirmation of parathyroid adenoma removal. Individuals who underwent a prior surgical parathyroid exploration and had persistent or recurrent PHPT were excluded. There were 268 cases of PHPT that were reviewed. Nine patients who did not undergo preoperative imaging were excluded. Two patients who did not have an adenoma identified at surgery were also excluded, as were 11 patients who had prior neck explorations. Thirty-eight patients were excluded as they underwent imaging tests in addition to SPECT, SPECT/CT, and/or ultrasonography.

We reviewed patient demographic characteristics, preoperative laboratory studies, imaging findings, operative findings (including intraoperative PTH measurements), extent of operative exploration (UNE v. BNE), adenoma size, postoperative laboratory studies and pathologic diagnoses. We obtained the data by retrospectively reviewing patient charts; imaging, biochemical and pathology results; and operative records. Operative identification of a parathyroid adenoma with pathologic confirmation determined whether a preoperative imaging test resulted in correct preoperative lateralization (left v. right). Cure of PHPT was confirmed by normalization of serum calcium levels within 30 days postoperatively.

Patient information was collected and stored in a deidentified database for data analysis. The study was approved by our institutional review board.

Imaging protocols

The protocols for SPECT (comprising planar and SPECT imaging) and SPECT/CT (comprising planar and SPECT/CT imaging) at our centre have been previously described. Imaging of the neck and upper thorax is obtained in the supine position with a low-energy, high-resolution collimator, 10 minutes after intravenous injection of 700 MBq Tc-99m sestamibi. Planar images are obtained over 5 minutes, both immediately and 2 hours postinjection, using a 128-square matrix. Noncircular orbit SPECT is obtained immediately and at 2 hours postinjection using a 128-square matrix with 128 stops, 15 seconds per stop for the early acquisition and 20 seconds per stop for the delayed acquisition. For patients undergoing SPECT/CT, a volumetric CT acquisition is obtained after the delayed SPECT through the same anatomic region (80 kVp, 60 mAs, using CAREDOSE dose modulation). Sets of 1 mm thick contiguous slices are acquired and reconstructed as contiguous 1.25 mm thick slices using a medium-smooth reconstruction kernel. The SPECT/CT images are then generated using iterative reconstruction with 8 subsets and 12 iterations. All imaging was carried out with a Siemens Symbia T6 hybrid SPECT/CT scanner. Finally, the SPECT/CT fused multiplanar images are reviewed on a Siemens Leonardo workstation (Siemens Medical Systems) by a nuclear medicine/radiology dual certified physician.

Statistical analysis

As the outcome of interest was the extent of surgical exploration based on UNE versus BNE, we chose our definition of correct localization based on correct lateralization. We evaluated the proportion of correct lateralization in group I (SPECT v. SPECT/CT) compared with group II (1 of these tests with the addition of ultrasonography) using a Fisher exact test. We used multivariate logistic regression to determine the odds of BNE versus UNE for group I (1 imaging test) compared with group II (addition of ultrasonography to the imaging test). We controlled for the following covariates: age, sex, preoperative calcium, preoperative PTH, use of intraoperative PTH assay, adenoma size (greatest dimension) and number of abnormal parathyroid glands (solitary adenomas v. abnormal parathyroid glands). All data analyses were performed using Stata software version 11.2 (Stata Corp.).

Results

Patients

We reviewed 268 cases of PHPT. Nine patients who did not undergo preoperative imaging were excluded. Two patients who did not have an adenoma identified at surgery were also excluded, as were 11 patients who had prior neck explorations. We excluded a further 38 patients because they underwent imaging tests in addition to SPECT, SPECT/CT and/or ultrasonography. Our final cohort consisted of 208 patients who had undergone SPECT, SPECT/CT or the addition of ultrasonography to these tests preoperatively.

The clinical and pathological characteristics of patients are summarized in Table 1. There were 156 (75.0%) women and 52 (25.0%) men. The mean age was 58.6 ±
13.6 years. There were 8 (3.8%) cases of multiglandular disease (5 double adenomas and 3 sporadic 4-gland hyperplasias) and 2 (1.0%) cases of parathyroid carcinoma. Ectopic adenomas accounted for 7 (3.4%) cases, and all were solitary. Excluding the para thyroid carcinomas and ectopic adenomas, there were 191 (91.8%) cases with a pathological diagnosis of solitary parathyroid adenoma. The mean patient follow-up, as defined by the date of the last serum calcium measurement, was 140 days.

Baseline preoperative laboratory data were collected and all patients underwent biochemical testing postoperatively. Ionized calcium levels were corrected for the patients’ blood pH. The preoperative calcium levels were 2.75 ± 0.19 mmol/L for total calcium level (reference range 2.18–2.58 mmol/L) and 1.52 ± 0.13 mmol/L for ionized calcium level (reference range 1.17–1.29 mmol/L). Postoperative follow-up calcium levels were 2.33 ± 0.17 mmol/L for total calcium level and 1.26 ± 0.09 mmol/L for ionized calcium level.

The majority of study patients (67.4%) underwent parathyroidectomy with intraoperative parathyroid hormone measurement during which a 50% drop at 5 or 10 minutes after adenoma removal, from baseline or preexcision levels, was considered predictive of cure. Baseline PTH measurements were 19.8 ± 25.9 pmol/L (reference range 1.3–6.8 pmol/L). Intraoperative PTH measurements were 22.9 ± 28.9 pmol/L, 19.0 ± 20.9 pmol/L, 8.5 ± 8.9 pmol/L and 6.3 ± 6.4 pmol/L for baseline pre-excision at 0 minutes, 5 minutes and 10 minutes after adenoma resection, respectively.

Correct localization by imaging tests

We evaluated the incremental value of ultrasonography with respect to proportion of correct localization in patients who underwent only 1 preoperative imaging test (group I) versus patients who had the addition of ultrasonography to a preoperative imaging test (group II). There were 75 patients in group I and 133 patients in group II. Group II had 78.9% correctly localized parathyroid adenomas compared with only 54.7% in group I (p < 0.001). In a subgroup analysis, the addition of ultrasonography to SPECT improved correct localization from 45.9% to 75.8% (p < 0.001). The addition of ultrasonography to SPECT/CT, however, did not significantly improve correct preoperative localization (p = 0.30; Table 2).

Impact of preoperative imaging test on extent of surgery

We assessed the clinical impact of adding ultrasonography to a preoperative imaging test using logistic regression models evaluating the odds of BNE versus UNE during parathyroidectomy. These results are summarized in Table 3. Univariate analyses are illustrated as unadjusted

### Table 1. Descriptive statistics for unilateral (UNE) versus bilateral (BNE) neck exploration

<table>
<thead>
<tr>
<th>Group; mean ± SD or no. (%)</th>
<th>Overall, n = 208</th>
<th>UNE, n = 138</th>
<th>BNE, n = 70</th>
<th>p value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>58.6 ± 13.5</td>
<td>59.3 ± 14.2</td>
<td>57.1 ± 12.2</td>
<td>0.26</td>
</tr>
<tr>
<td>Sex, female</td>
<td>156 (75.0)</td>
<td>103 (74.6)</td>
<td>53 (74.7)</td>
<td>0.87</td>
</tr>
<tr>
<td>Preoperative Ca, mmol/L</td>
<td>2.75 ± 0.19</td>
<td>2.76 ± 0.18</td>
<td>2.73 ± 0.19</td>
<td>0.19</td>
</tr>
<tr>
<td>Intraoperative PTH assay</td>
<td>139 (66.8)</td>
<td>101 (73.2)</td>
<td>38 (54.3)</td>
<td>0.008</td>
</tr>
<tr>
<td>PTH, nmol/L</td>
<td>19.8 ± 25.9</td>
<td>22.6 ± 28.9</td>
<td>14.4 ± 17.5</td>
<td>0.032</td>
</tr>
<tr>
<td>Greatest dimension, cm</td>
<td>1.76 ± 1.02</td>
<td>1.91 ± 1.17</td>
<td>1.50 ± 0.61</td>
<td>0.011</td>
</tr>
<tr>
<td>Adenoma type</td>
<td></td>
<td></td>
<td></td>
<td>0.002</td>
</tr>
<tr>
<td>Solitary</td>
<td>191 (91.8)</td>
<td>133 (96.3)</td>
<td>58 (82.9)</td>
<td>—</td>
</tr>
<tr>
<td>Double</td>
<td>5 (2.4)</td>
<td>0 (0)</td>
<td>5 (7.1)</td>
<td>—</td>
</tr>
<tr>
<td>Ectopic</td>
<td>7 (3.4)</td>
<td>4 (3.0)</td>
<td>3 (4.3)</td>
<td>—</td>
</tr>
<tr>
<td>Hyperplasia</td>
<td>3 (1.4)</td>
<td>0 (0)</td>
<td>3 (4.3)</td>
<td>—</td>
</tr>
<tr>
<td>Carcinoma</td>
<td>2 (1.0)</td>
<td>1 (0.7)</td>
<td>1 (1.4)</td>
<td>—</td>
</tr>
<tr>
<td>Imaging studies</td>
<td></td>
<td></td>
<td></td>
<td>0.007</td>
</tr>
<tr>
<td>Group I</td>
<td>75 (36.0)</td>
<td>41 (29.7)</td>
<td>34 (48.6)</td>
<td>—</td>
</tr>
<tr>
<td>SPECT only</td>
<td>61 (29.3)</td>
<td>28 (20.3)</td>
<td>33 (47.2)</td>
<td>—</td>
</tr>
<tr>
<td>SPECT/CT</td>
<td>14 (6.7)</td>
<td>13 (9.4)</td>
<td>1 (1.4)</td>
<td>—</td>
</tr>
<tr>
<td>Group II</td>
<td>133 (64.0)</td>
<td>97 (70.3)</td>
<td>36 (51.4)</td>
<td>—</td>
</tr>
<tr>
<td>SPECT+ ultrasonography</td>
<td>62 (29.8)</td>
<td>42 (30.4)</td>
<td>20 (28.6)</td>
<td>—</td>
</tr>
<tr>
<td>SPECT/CT+ ultrasonography</td>
<td>71 (34.1)</td>
<td>55 (39.9)</td>
<td>16 (22.8)</td>
<td>—</td>
</tr>
</tbody>
</table>

BNE = bilateral neck exploration; Ca = calcium; CT = computed tomography; PTH = parathyroid hormone; SD = standard deviation; SPECT = single photon emission computed tomography; UNE = unilateral neck exploration.

*Unless otherwise indicated.

†The p value for differences between UNE and BNE was calculated using a 2-sided t test (continuous data) and χ² test (categorical data).
odds ratios (ORs) with associated 95% confidence intervals (CIs) and p values for association. Parallel representation is demonstrated for multivariate analyses, which have been adjusted for the following confounders: age, sex, preoperative serum calcium, intraoperative PTH assay, preoperative PTH levels, size of adenoma and number of abnormal parathyroid glands (s solitary v. multiple).

Group II had 0.45 times the odds of BNE versus UNE compared with group I (unadjusted OR 0.45, 95% CI 0.25–0.81, p = 0.008). The adjusted analysis demonstrates that group II had 0.48 times the odds of BNE versus UNE compared with group I (adjusted OR 0.48, 95% CI 0.23–1.03, p = 0.06). We performed a subgroup analysis to determine the incremental value of ultrasonography to SPECT and to SPECT/CT. Adding ultrasonography to SPECT for preoperative imaging of PHPT reduces the odds of BNE by 62% compared with SPECT alone (adjusted OR 0.38, 95% CI 0.15–0.96, p = 0.043). However, the addition of ultrasonography to SPECT/CT for preoperative localization of PHPT does not reduce the odds of undergoing BNE compared with SPECT/CT alone (adjusted OR 2.93, 95% CI 0.18–46.5, p = 0.31).

**DISCUSSION**

The present study evaluates the incremental value of ultrasonography on preoperative parathyroid adenoma localization tests in terms of correct lateralization and clinical impact on extent of parathyroid surgery (BNE v. UNE). The overall results suggest that there is incremental value in adding ultrasonography to an imaging test to localize a parathyroid adenoma preoperatively, as well as to reduce the risk of BNE and the extent of operative neck exploration. Interestingly, a subgroup analysis demonstrated that ultrasonography provides added value in correctly localizing a parathyroid adenoma preoperatively and reduces the chance of BNE when combined with SPECT but not when combined with SPECT/CT.

Other studies have also reported incremental value when combining preoperative localization studies. Parcell and colleagues evaluated ultrasonography and planar scintigraphy (conventional 2-dimensional imaging without SPECT) for parathyroid localization and found that their sensitivity was 57% and 54% for the tests, respectively, but that combining the tests increased the sensitivity to 78%. In a prospective clinical study, the combination of ultrasonography and planar scintigraphy had 96% sensitivity, 83% specificity, 88% positive predictive value and 94% negative predictive value. A recent review by Johnson and colleagues also concluded that preoperative PHPT patient imaging with ultrasonography and planar scintigraphy most accurately predicted the location of solitary adenomas when compared with either imaging test alone. These findings are consistent with the results of the present study, although our study further validated the value added of combining ultrasonography and planar imaging with either SPECT or SPECT/CT scintigraphy by evaluating the impact on the extent of parathyroid exploration.

The protection against BNE afforded by ultrasonography is supported by reports of surgeon-performed ultrasonography for preoperative parathyroid adenoma localization. These studies underscore the importance of operator experience for clinically informative neck ultrasonography and suggest that the selective addition of sestamibi imaging (for cases in which the ultrasound was negative or equivocal) is the most cost-effective preoperative approach and the most protective against BNE. Our results echo the utility of ultrasonography in preoperative imaging for PHPT, especially for imaging modalities that alone may not adequately facilitate a focused neck exploration.

A retrospective case series recently evaluated the incremental value of combining ultrasonography and SPECT/CT with software fusion for preoperative localization of parathyroid adenomas. Fifty-nine patients were evaluated in this study, and the sensitivity of ultrasonography and SPECT/CT was 64% and 90%, respectively, with concordant localization. The sensitivity of ultrasonography alone was 59%, but when combined with SPECT/CT, the sensitivity increased to 79%.

**Table 2. Degree of correct lateralization, by imaging test**

<table>
<thead>
<tr>
<th>Imaging test</th>
<th>Group I, n = 75 (55)</th>
<th>Group II, n = 133 (79)</th>
<th>Group I v. Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPECT only, n = 61 (48)</td>
<td>28 (84)</td>
<td>47 (76)</td>
<td>0.40 (0.19-0.84)</td>
</tr>
<tr>
<td>SPECT/CT, n = 14 (93)</td>
<td>13 (93)</td>
<td>105 (79)</td>
<td>0.38 (0.15-0.96)</td>
</tr>
<tr>
<td>SPECT + ultrasonography, n = 62</td>
<td>47 (76)</td>
<td>58 (82)</td>
<td></td>
</tr>
</tbody>
</table>

**Table 3. Odds of bilateral versus unilateral neck exploration**

<table>
<thead>
<tr>
<th>Model*</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I v. group II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group I</td>
<td>0.45 (0.25-0.81)</td>
<td>0.008</td>
</tr>
<tr>
<td>Group II</td>
<td>0.48 (0.23-1.03)</td>
<td>0.06</td>
</tr>
<tr>
<td>SPECT v. SPECT + ultrasonography</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPECT</td>
<td>0.40 (0.19-0.84)</td>
<td>0.015</td>
</tr>
<tr>
<td>SPECT + ultrasonography</td>
<td>0.38 (0.15-0.96)</td>
<td>0.043</td>
</tr>
<tr>
<td>SPECT/CT v. SPECT/CT + ultrasonography</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPECT/CT</td>
<td>3.78 (0.46-31.1)</td>
<td>0.22</td>
</tr>
<tr>
<td>SPECT/CT + ultrasonography</td>
<td>2.93 (0.18-46.5)</td>
<td>0.31</td>
</tr>
</tbody>
</table>

CI = confidence interval; CT = computed tomography; OR = odds ratio; SPECT = single photon emission computed tomography.

*Model adjusted for age, sex, preoperative calcium, intraoperative parathyroid hormone (PTH) monitoring, preoperative PTH level, size of adenoma, and type of adenoma (solitary v. nonsolitary).
ultrasonography and SPECT/CT findings in 59% of cases. The observation that combined ultrasonography and SPECT/CT had an overall sensitivity of 95% and accuracy of 91% led this group to conclude that there was incremental value in combining these tests for preoperative localization. Our findings are not entirely consistent with this group’s observations, as we did not observe any significantly increased value added in combining SPECT/CT with ultrasonography. A potential reason for this difference might be the fairly high rate at which SPECT/CT was able to correctly localize a parathyroid adenoma preoperatively (92.8%).

The risk of ionizing radiation from SPECT/CT must be considered. A recent study quantified the radiation exposure associated with SPECT/CT of the neck and postulated that it would take anywhere from 2390 to 8030 scans to cause 1 case of radiation-induced cancer, depending on patient age and sex. Thus, the most appropriate role for SPECT/CT may be as part of the preoperative evaluation of complex PHPT. Several recent studies have supported SPECT/CT as a valuable preoperative imaging modality for PHPT, particularly in cases of multi-glandular disease and ectopic parathyroid adenoma. Case series have suggested promise for this technique as an evolving method of preoperative localization for PHPT. Our results are consistent with these findings.

Despite the value in combining preoperative imaging studies, there is also evidence to support the use of a single preoperative imaging test. Moure and colleagues evaluated the utility of planar scintigraphy alone in localizing parathyroid adenomas and guiding UNE. The results of their study suggested that patients with PHPT and unequivocally positive planar scintigraphy scans may safely undergo a focused parathyroidectomy without additional preoperative imaging. In contrast, our results suggest that by adding ultrasonography to SPECT, there is an increased probability of accurate preoperative parathyroid localization, and we have demonstrated that this will lead to decreased extent of neck exploration during parathyroidectomy.

While several outcomes (e.g., cure of PHPT) could have been evaluated, we specifically chose extent of parathyroid surgery. This is an important outcome to evaluate, as it is clinically relevant for both surgeons and patients, does not depend on complete 1-year follow-up and is not subject to censoring of data as a result of cases being lost to follow-up.

One of the strengths of the present study is our 100% complete data on the primary outcome of interest. Perhaps the most important contribution of the present report is translating the impact of preoperative imaging tests on clinically relevant outcomes, specifically the extent of parathyroid surgery that must be carried out for a successful parathyroidectomy. Our results suggest that combining SPECT with ultrasonography is a safe and informative preoperative imaging practice for PHPT that reduces the risk of BNE and helps facilitate a focused parathyroid operation.

Limitations

The present study has several limitations. Two are its relatively small sample size and its retrospective nature. The retrospective nature of our study did not allow for implementation of a standardized protocol for preoperative imaging in PHPT. We attempted to account for this type of bias by incorporating the type of imaging test ordered into our multivariate model and the effect on extent of surgery. While this approach is reasonable in most instances, we had a relatively small sample size (n = 208) with only 70 outcomes of interest (BNE). Given the number of covariates in our multivariate analysis, our adjusted model may be susceptible to being overfitted. We also did not validate our model, as we could not stably model our outcome of interest by splitting our database into test and validation subsets.

Conclusion

We examined the clinical utility of adding ultrasonography to 2 commonly performed preoperative imaging investigations for PHPT — SPECT and SPECT/CT — assessed on the basis of accuracy of preoperative localization and the extent of surgical exploration subsequently required. Our analysis demonstrates that greater incremental value is gained by adding ultrasonography to SPECT rather than to SPECT/CT. Further study of techniques for accurately localizing abnormal parathyroid glands preoperatively, particularly in a prospective or randomized controlled study design, is an important future direction that will ultimately lead to improved outcomes for individuals with PHPT.

Competing interests: None declared.


References


Total hip arthroplasty using a combined anterior and posterior approach via a lateral incision in patients with ankylosed hips

**Background:** For most patients with severely ankylosed hips, traditional surgical approaches do not provide sufficient exposure during THAs. We report our experience with a combined anterior and posterior approach using a lateral incision for total hip arthroplasty (THA) in patients with severe, spontaneous bony hip ankylosis.

**Methods:** Between January 2004 and December 2008, patients with severe, spontaneous bony hip ankylosis underwent THA via a combined anterior and posterior approach using a lateral incision.

**Results:** We included 47 patients (76 hips) with a mean age of 53 (range 22–72) years in our study. All surgeries were successful, and no significant postoperative complications occurred. The mean operative duration was 1.5 (range 1.3–1.7) hours, and mean blood loss was 490 (range 450–580) mL. The mean duration of follow-up was 5.5 (range 2–11) years. Harris hip score improved from 53 to 88 points postoperatively, and the outcome was good to excellent in 88.37% of cases. Heterotopic ossification occurred in 6 hips, and infection, which resolved with antibiotics, occurred in 1 patient.

**Conclusion:** This combined anterior and posterior approach to THA using a lateral incision in patients with severe, spontaneous ankylosis provides very good exposure, protects the abduction unit and results in good to excellent postoperative recovery.

Ankylosis, spontaneous fusion of a joint after injury or disease, is caused by a number of conditions, including rheumatoid arthritis, tuberculosis, septic arthritis, ankylosing spondylitis, severe osteoarthritis and hip trauma. Regardless of whether a patient has fibrous or bony ankylosis, the clinical manifestation is complete loss of both active and passive motion of the hip joint. Considering the negative impact on quality of life, an appropriate
surgical intervention should be considered. Total hip arthroplasty (THA) has become the most common surgical procedure performed in developed nations. Good outcomes are reported following THA in patients with ankylosed hips; however, the procedure is technically demanding, and postoperative complications are not uncommon, particularly when compared with primary THAs.

Common approaches to the nonankylosed hip include the anterior, posterior and lateral approaches. Each has its own advantages and disadvantages. For example, the Smith–Peterson approach cannot ideally expose the hip joint unless either the gluteus medius is partially detached from the greater trochanter or an additional trochanteric osteotomy is performed. The Watson–Jones approach offers poor operative exposure and requires partial destruction of the abductors, and the space posterior to the acetabulum is limited for intraoperative manipulation. The Hardinge approach provides limited exposure and thus is not suitable for patients with bony hip ankylosis, especially for those in whom there is difficulty exposing the posterior margin of the acetabulum. Finally, with the posterolateral approach, abduction of the hip is limited and anterior exposure of the acetabulum is relatively difficult.

For most patients with severely ankylosed hips, traditional surgical approaches do not provide sufficient exposure during THAs. Femoral external rotation or adduction deformities are common with ankylosed hips, and thus a simple anterior or posterior approach cannot satisfactorily expose the surgical field. The purpose of this report is to relay our experience with a combined anterior and posterior approach using a lateral incision for THA in patients with severely ankylosed hips. We hypothesized that this combined approach would improve exposure of the hip joint capsule compared with both the posterior and anterior approaches and that it would result in good to excellent clinical outcomes.

**METHODS**

**Patient selection**

Between January 2004 and December 2008, patients with spontaneous bony hip ankylosis undergoing THA were treated using a combined anterior and posterior approach by the same group of orthopedic surgeons at the Chang-hai Hospital, Shanghai, China. Surgical indications for THA included persistent low back pain, ipsilateral knee pain and instability, contralateral hip pain, nonfunctional hip fusion preventing ipsilateral knee arthroplasty, flexion deformity greater than 30°, adduction deformity greater than 10° and heterotopic fusion. Young patients requiring aesthetic or functional correction were also included. We excluded patients if there was either absence or severe fibrosis of the abductors owing to prior surgeries, recent signs of infection or marked atrophy of the quadriceps and/or abductors. We also excluded patients with fibrous ankylosis. Patients were consecutively enrolled, and they all provided informed consent. The ethics committee of the hospital approved our study protocol.

We calculated Harris hip scores for all patients both pre- and postoperatively (at the time of last follow-up). A score of 90–100 points was considered excellent, 80–89 points was considered good, 70–79 points was considered fair and a score of less than 70 points was considered poor.

**Surgical procedure**

Patients were placed in the lateral recumbent position (Fig. 1A). The surgeon made a skin incision along the centre of the femoral shaft, with the superior end 8 cm above the tip of the greater trochanter and the inferior end 7 cm below the tip of the greater trochanter (Fig. 1B). Thus, the total incision length was 15 cm. The subcutaneous tissues...
were dissected to expose the fascia lata, which was then longitudinally split distally to proximally. The trochanteric bursa over the greater trochanter was incised, and then the gluteus maximus was cut proximally along the interval between the gluteus maximus and the tensor fascia lata to the proximal skin incision. The surgeon then made a 2 cm incision and bluntly dissected the fascia lata superiorly and inferiorly. Two thyroid retractors were used to slightly pull the tensor fascia lata to maintain tension. The posterior side was exposed first (Fig. 2A). The operating table was rotated toward the prone position (away from the surgeon) by 15°, and gauze was packed inside the deep surface of the gluteus maximus to control bleeding. The gluteus maximus and fascia lata were retracted posteriorly to expose the gluteus medius and external rotators. In patients with ankylosed hips, it is not possible to flex the knee joint to 90° and internally rotate the hip joint to make the external rotators tense. Therefore, the piriformis tendon was carefully elevated with a long, curved vascular clamp at the junction of the posterior margin of the insertion site of the gluteus medius and the greater trochanter. The piriformis was then incised at the insertion site of the tendon. Along the intertrochanteric fossa and the posterior side of the greater trochanter, the superior gemellus, obturator internus, inferior gemellus and the insertion site of the quadratus femoris were cut close to the bone with an electric scalpel. The surgeon further dissected the external rotators on the posterior and inferior surface of the joint capsule with a long-handled periosteal elevator. The retractor was adjusted to expose the posterior and inferior joint capsule. The junction between the deep part of the gluteus minimus and the superficial surface of the upper joint capsule was bluntly dissected with a long-handled periosteal elevator, and the gluteus minimus and the gluteus medius were retracted superiorly with a Hoffmann retractor. Most parts of the superior, posterior and inferior joint capsule were removed, and the attached soft tissues were removed with an electric scalpel along the femoral neck. Large gauze was used to pack the incision site to complete the posterior exposure.

To expose the anterior joint capsule, the operating table was rotated toward the supine position (toward the surgeon) by 15°, and the fascia lata was retracted anteriorly and posteriorly. An incision was made along the junction between the tensor fascia lata and the gluteus medius (Fig. 2B). The gluteus medius was retracted posteriorly, the fascia lata was pulled anteriorly, and the anterior part of the joint capsule was exposed after releasing the soft tissue adhering to the femoral side of the joint capsule. Dissection was performed along the space between the gluteus medius and tensor fascia lata toward the joint capsule (Fig. 2C). The soft tissue on the anterior joint capsule was then dissected with a periosteal elevator, and the anterior and inferior aspect of the joint capsule was exposed completely by adjusting the position of the retractors. A Hoffmann retractor was inserted between the deep part of the gluteus minimus and the superficial surface of the upper joint capsule to pull the gluteus minimus and the gluteus medius superiorly. Injury to the superior gluteal nerve due to excessive retraction was avoided. The anterior joint capsule and remnants of the superior and inferior joint capsule were removed. To improve exposure, the femoral vastus lateralis was split in the direction of the femur. The ankylosed hip joint was totally exposed and the external abductors (i.e., gluteus medius and minimus) were preserved.

The femoral neck osteotomy (Figs. 3 and 4) was achieved in 2 steps. First, via the anterior approach, the osteotomy was performed 2 cm posteroinferior to the junction of the femoral head and neck with an oscillating saw. Via the posterior approach, the osteotomy was performed 2 cm interoinferior to the junction of the femoral head and neck. A V shape was formed by the anterior and posterior clefs to make the previously ankylosed hip a mobile hip. Then, a standard femoral neck osteotomy was performed 1 cm superior to the lesser trochanter. The sciatic nerve (identified via the loosely packed adipose tissue

![Fig. 2. (A)](image1.png) The operating table was rotated away from the surgeon by 15°, and the posterior joint capsule of the hip joint was exposed. (B) The operating table was then rotated toward the surgeon by 15° to allow access to the anterior structures of the hip joint. (C) The anterior hip joint capsule was exposed by approaching the spatium intermusculare between the gluteus medius and tensor fascia lata.)

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surrounding the nerve) was located in the gap between the gluteus maximus and the group of external rotation muscles. Under normal circumstances, no routine release was performed; however, for patients with severely contracted joint capsules, the soft tissue surrounding the sciatic nerve was released by 4–5 cm along the nerve to provide additional room. The newly formed hip joint was moved repeatedly and the tense soft tissue, particularly the inferior and medial soft tissue, around the hip joint was released.

The exact location of the acetabulum was identified with the assistance of preoperative radiographs and remaining stumps following the femoral neck osteotomy. This is an important step for ankylosed hips with in situ fusion; however, it does not work for the ankylosed hip with deformed fusions. A small curved osteotome was then inserted approximately 2 cm posterior and inferior to the junction of the femoral head and neck in the anterior surgical field. Preoperative radiographs facilitated proper positioning. The knee joint was flexed 90°, and the hip joint was internally rotated to expose the acetabulum. The acetabulum was reamed at 45° inclination and 15° anteversion, and an acetabular trial insert was placed. Next, the femoral canal was reamed and a suitable femoral neck prosthesis was selected. The femoral components used were coated anatomic medullary locking (DePuy), and the acetabular components used were Duraloc (Depuy). Of the implants, 9 were cemented and 67 were noncemented. Hip joint range of motion and soft tissue tension were observed after reduction. If the soft tissue, especially the gluteus medius, was tense, then a secondary release was made along the superior margin of the acetabulum until the result was satisfactory. Hip joint reduction was performed, and again the hip joint range of motion and soft tissue tension were assessed. The surgical wound was closed via a layer-by-layer method, and continuous drainage with negative pressure was applied.

We defined blood loss as the volume of intraoperative suction plus the change in weight of the sponges used (postoperative sponge weight – preoperative sponge weight), with the sum divided by the density of blood (1.055 g/cm³). Postoperative blood loss through drainage was not included.

Postoperative management and follow-up

Preoperative parenteral antibiotics and prophylaxis for deep vein thrombosis (4 mg/d of fraxiparine, subcutaneous) were administered to all patients. Postoperatively, the affected limb was placed in a neutral abduction position and a special shoe was applied to avoid adduction and internal rotation, as this can lead to the development of early postoperative hip joint dislocation. A pillow was

Fig. 3. Result of the femoral neck exposure. The abductors were preserved after exposing the femoral neck by gently applying retractors after the combined anterior and posterior approach. There was no need to perform an osteotomy of the greater trochanter in any of the included patients.

Fig. 4. (A) The femoral neck was exposed via a combined anterior and posterior approach. (B) The femoral head has been amputated.
placed under the knee to flex the knee joint 30°, and a triangular pillow was placed between the legs. The drain was removed 24–48 hours postoperatively.

Non-weight bearing exercise and crutch ambulation were initiated 1 and 2 weeks postoperatively, respectively. Partial weight-bearing began 6–8 weeks postoperatively; it was delayed to provide sufficient time to ensure maximal soft-tissue healing because the extent of the soft-tissue dissection in ankylosed hips is greater than in healthy hips. We obtained radiographs before discharging the patients.

All patients underwent follow-up examination 1, 3 and 6 months after discharge and yearly thereafter. Two independent observers, 1 surgeon and 1 physician not involved in the arthroplasty, performed the follow-up examinations. Pain, function, deformities and range of motion using the Harris hip score were assessed at the last follow-up, and the sum range of motion was measured based on flexion, extension, abduction, internal adduction internal and external rotation movements.

**RESULTS**

We included 47 patients (76 hips) in our study: 29 (48 hips) were men, and the mean patient age was 53 (range 22–72) years. Patient characteristics are summarized in Table 1. All cases were primary THAs in patients with severe, spontaneous ankylosed hip joints. A representative case is shown in Figure 5. The mean operative duration was 1.5 (range 1.3–1.7) hours, and mean blood loss was 490 (range 450–580) mL. Fractures limited to the proximal femoral metaphysis occurred in 5 patients, and wiring was required in 2 of them. Immediate postoperative radiographs revealed excellent location of all prostheses, as the rotation centre of the hip joints were reconstructed and the fixation status of the prostheses was deemed acceptable.

The mean duration of follow-up was 5.5 (range 2–11) years. Four patients (6 hips) were lost to follow-up after discharge. In the remaining 43 patients, there were no postoperative dislocations or hip impingements. The mean Harris hip score increased from 53 points preoperatively to 88 points postoperatively. The outcome was excellent in 14 patients, good in 24, fair in 4 and poor (because of infection) in 1 patient. In total, 88.37% of the outcomes were considered good to excellent.

Postsurgically, 4 hips were associated with mild pain and

<p>| Table 1. Demographic and clinical characteristics of patients undergoing total hip arthroplasty for ankylosed hip joints |</p>
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients (no. of hips)</td>
<td>47 (76)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>29 (62)</td>
</tr>
<tr>
<td>Female</td>
<td>18 (38)</td>
</tr>
<tr>
<td>Affected side</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>36 (77)</td>
</tr>
<tr>
<td>Left</td>
<td>40 (85)</td>
</tr>
<tr>
<td>Age, mean (range) yr</td>
<td>53 (22–72)</td>
</tr>
<tr>
<td>Duration of disease at time of surgery, mean (range) yr</td>
<td>7.5 (5–9)</td>
</tr>
<tr>
<td>Patient follow-up time, mean (range) yr</td>
<td>5.5 (2–11)</td>
</tr>
<tr>
<td>Presence of hip flexion contracture</td>
<td>67 (88)</td>
</tr>
<tr>
<td>Cause of ankylosis</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>9 (19.1)</td>
</tr>
<tr>
<td>Tuberculosis of the hip</td>
<td>6 (12.9)</td>
</tr>
<tr>
<td>Sequela of the septic arthritis</td>
<td>7 (14.9)</td>
</tr>
<tr>
<td>Ankylosing spondylitis</td>
<td>16 (34.0)</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>5 (10.6)</td>
</tr>
<tr>
<td>Hip trauma</td>
<td>4 (8.5)</td>
</tr>
</tbody>
</table>

*Unless otherwise indicated.

Fig. 5. (A) Preoperative radiographs of a 35-year-old man. He had ankylosing spondylitis associated with bilateral ankylosed hip joints. Because the patient had lower extremity deformities, the pelvis could not be oriented in an ideal anteroposterior position for radiographs. The range of motion in every direction was 0 in both hip joints and the patient experienced severe pain in both hip joints. (B) Anteroposterior radiographs of the same patient 3 years postoperatively. The position of the prosthesis was excellent. The pain in both hip joints was completely resolved, and 89° and 100° flexion was achieved in the left and right hip joints, respectively. The patient's gait was normal postoperatively.
discomfort, which was successfully managed via patient-controlled analgesia. In 1 case there was pain in the middle and upper thigh, which gradually improved over 3–4 weeks. Heterotopic ossification occurred in 6 hips: 3 were grade I and the rest were grade II according to the Brooker classification. Hip function was not affected in any of these patients. Mild nerve traction injury occurred in 2 patients; it presented as numbness of the skin over the lateral aspect of the limb and foot on the operated side. Nonsteroidal anti-inflammatory drugs and vitamin B were prescribed, and the condition resolved in both patients within 6 months of surgery. Neither patient had evidence of motor neuron injury.

Postoperative measurements of the leg revealed a leg length difference of ≤ 1 cm in all but 1 patient, in whom 1 limb was lengthened by 1.3 cm and the other limb shortened by 0.9 cm. The patient had difficulty walking, which was resolved by adjusting the patient’s shoes. The main type of nerve injury was sciatic nerve palsy, and all patients were negative for Trendelenburg gait during the last follow-up visit. Preoperatively, flexion contracture was noted in 67 (88%) hips, the mean deformity angle was 37° (range 12°–89°), and range of motion was 0°. At the last follow-up, mean range of motion was 119.7° (range, 100°–135°) in the replaced joints (Table 2).

**DISCUSSION**

This report describes the results of a THA technique in 47 patients with severe, spontaneous ankylosed hip joints using a combined anterior and posterior approach via a lateral incision. This combined approach preserves the abductors with no damage to either the gluteus medius or gluteus minimus, thereby improving postoperative joint function; does not increase the length of the surgical incision, but rather alters the position of the surgical field for performing both the anterior and posterior procedures; clearly exposes the acetabulum and adjacent tissues; and allows the incision to be extended superiorly or inferiorly at any time during the surgery, if indicated.

This approach is markedly different from the standard surgical approaches to THA. Two common approaches for THAs are a posterolateral approach (e.g., the Gibson or Osborne approaches) and a lateral approach (e.g. the Ollier approach).2,5 When performing a primary THA, these approaches are simple and convenient, the anatomic structures are distinct and surgical exposure is sufficient to achieve a satisfactory outcome. In ankylosed hip joints, however, these approaches are not optimal. The Gibson approach easily exposes the femoral side, but the external rotators and posterior joint capsule are difficult to expose if the ankylosis is associated with an external rotation deformity of the femur. Furthermore, the exposure and release of the anterior joint capsule is difficult if an adduction deformity exists. The Watson–Jones approach does not clearly expose the medial and inferior margin of the acetabulum. Thus, extensive soft tissue release (removing most parts of the insertion site of the gluteus medius) or a greater trochanter osteotomy are often inevitable, which can contribute to the development of postoperative complications, such as muscle weakness in the abductors, superior gluteal nerve injury (innervating the tensor fascia lata, gluteus medius and minimus) and greater trochanter nonunion.11 The Hardinge approach requires no greater trochanter osteotomy, and the approach maintains the integrity of the gluteus medius. However, the approach provides limited exposure, and thus is not suitable for patients with bony hip ankylosis, especially for those in whom there is difficulty exposing the posterior margin of the acetabulum, which would affect placement of the acetabular prosthesis.

A transtrochanteric approach is the most commonly used approach for ankylosed hips.12,13 However, it can result in massive bleeding and has a relatively long operative duration. Furthermore, fixation of the greater trochanter is difficult, heterotopic ossification is severe, postoperative local pain occurs, bursitis of the greater trochanter can develop, and the rate of trochanteric nonunion following the transtrochanteric approach has been reported to be 0.8%–5%.14,11

### Table 2. Mean patient hip movements at various time points postoperatively

<table>
<thead>
<tr>
<th>Function</th>
<th>Postoperative time; mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8 wk</td>
</tr>
<tr>
<td>Flexion, °</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>65.08 ± 8.16</td>
</tr>
<tr>
<td>Right</td>
<td>68.13 ± 7.09</td>
</tr>
<tr>
<td>Extension, °</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>7.97 ± 1.91</td>
</tr>
<tr>
<td>Right</td>
<td>8.41 ± 2.01</td>
</tr>
<tr>
<td>Abduction, °</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>24.38 ± 4.52</td>
</tr>
<tr>
<td>Right</td>
<td>24.09 ± 4.11</td>
</tr>
</tbody>
</table>

SD = standard deviation.
Table 3. Summary of key studies of total hip arthroplasty in patients with ankylosed hips

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients</th>
<th>Surgical approach</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present study</td>
<td>47 patients (76 hips) with spontaneous ankylosis.</td>
<td>A combined anterolateral and posterolateral approach via a lateral incision. Mean follow-up was 5.5 years.</td>
<td>Harris hip score improved from 53 to 88 points postoperatively. The outcome was excellent to good in 88.37% of cases. Femoral prosthesis subsidence occurred in 3 hips. The maximum subsidence was 2 mm. No treatment was required. Heterotopic ossification occurred in 6 hips.</td>
</tr>
<tr>
<td>Bhan et al.16</td>
<td>Retrospective review of 54 patients (92 hips) who underwent cementless THA for bony ankylosis due to ankylosing spondylitis.</td>
<td>Posterior approach. Mean follow-up was 8.5 years.</td>
<td>Harris hip scores improved from 49.5 to 82.6. Complications included pain (n = 10), anterior dislocation (n = 4), sciatic nerve palsy (n = 1), revision arthroplasty due to aseptic loosening (n = 13).</td>
</tr>
<tr>
<td>Kim et al.18</td>
<td>12 patients with bilateral ankylosis (24 hips).</td>
<td>All surgeries performed by a single surgeon via the standard transtrochanteric approach.</td>
<td>Harris hip scores increased from 55.4 to 82.3. Complications included osteolysis (n = 3) and loosening (n = 2), and 11 cups were outside the safe ranges of Lewinnek.</td>
</tr>
<tr>
<td>Abdel-Aal et al.19</td>
<td>12 patients (15 hips) with surgically and spontaneously fused hips.</td>
<td>Hardinge approach.</td>
<td>Harris hip scores in all patients improved from 42 preoperatively to 76 postoperatively. Complications included femoral artery injury due to Hofmann retractors in front of the acetabulum, 1 failed THA.</td>
</tr>
<tr>
<td>Joshi et al.5</td>
<td>103 patients underwent 181 THAs for ankylosing spondylitis.</td>
<td>Either direct lateral approach via trochanteric osteotomy or the Hardinge approach. All patients received cemented low-friction THAs.</td>
<td>No Harris hip scores were reported. Instead, authors indicated that 96% of hips had an excellent (low) pain score and 29.25 of the hips had normal or near-normal function.</td>
</tr>
<tr>
<td>Rutz et al.20</td>
<td>22 patients (22 ankylosed hips) secondary to posttraumatic osteoarthritis, coxitis, hip dysplasia and primary osteoarthritis.</td>
<td>19 conversions were via a lateral approach and 3 via an enhanced posterior repair; 20 patients were available at a mean follow-up of 13.2 years.</td>
<td>Harris hips scores postoperatively were 84.9. Thrombolytic scores were not obtained. No complications were reported.</td>
</tr>
<tr>
<td>Hamadouche et al.21</td>
<td>45 patients (45 hips) underwent THA for treatment of spontaneous ankylosis (n = 20) and postoperative ankylosis.</td>
<td>Lateral approach with a standard trochanteric osteotomy. Harris score improved from 11.3 points preoperatively to 16.5 points at the time of last follow-up. Satisfactory hip function was achieved in 41 (91%) patients. Complications included deep vein thrombosis (n = 2), common peroneal nerve palsy (n = 1), and periarticular and inguinal abscess 1 year postoperatively (n = 1).</td>
<td></td>
</tr>
<tr>
<td>Rajaratnam et al.22</td>
<td>15 patients (16 hips) undergoing cementless THA to treat spontaneous ankylosis (including ankylosing spondylitis) or surgical arthrodesis.</td>
<td>Hardinge approach in 5 patients and the remaining patients had a posterior approach with an enhanced posterior repair. Median follow-up was 10.75 years. Harris hip scores improved from 70 to 83 and Merle d'Aubigné hip scores had a score of 4.8 for pain, 3.9 for mobility, and 4.4 for function. The overall Merle d'Aubigné hip score postoperatively was a mean of 13. Aseptic loosening requiring acetabular cup revision occurred in one patient, and deep vein thrombosis occurred in another.</td>
<td></td>
</tr>
<tr>
<td>Bangjian et al.23</td>
<td>12 patients with bilateral ankylosed hip joints (24 hips) caused by late ankylosing spondylitis.</td>
<td>The most appropriate approach depending on patient anatomy and the condition was via the posterolateral approach. Mean follow-up was 4.2 years. Harris hip scores improved from 10 to 87 (mean 41.4), and extension ranges were 10 to 20° (mean 10.75). No complications were reported. No patient experienced hip pain postoperatively.</td>
<td></td>
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</table>

THA = total hip arthroplasty.
The combined approach presented herein may appear similar to the technique described for periacetabular osteotomies and to some of the surgeries retrospectively reviewed by Bhan and colleagues, and to the “minimally invasive 2-incision approach” described by Berger; however, there are some major differences. The Berger method approaches the hip between the tensor fascia lata and the sartorius muscle, and the rectus femoris is pulled inwardly to expose the capsula articularis coxae. This method does not adequately expose the acetabulum in patients with severely ankylosed hips. In addition, Bhan and colleagues and Berger reported the use of fluoroscopy and 2 skin incisions for each hip.

As our study was not a controlled clinical trial, directly comparing these results with a similar group of patients treated via alternate approaches is difficult. As demonstrated in Table 3, the published studies on THA in patients with ankylosed hips include variable etiologies of the ankylosis and variable outcome measures, use different types of prostheses and may or may not involve performing a trochanteric osteotomy. Nonetheless, some comparisons can be made, as Harris hip scores have been reported in several studies. In our study, the Harris hip score improved by a mean of 35 points. This is marginally greater than the improvement reported by Bhan and colleagues (33.1), Kim and colleagues (26.9) and Abdel-Aal and colleagues (34), and markedly greater than the improvement reported by Rajaratnam and colleagues (13). However, the improvement in our study is notably lower than that reported by Bangjian and colleagues (71). In addition, postoperative complications in our study were minimal compared with those noted in the other published studies. For example, nerve injury to the sciatic, femoral and common peroneal nerves were reported in a number of studies, as were deep vein thrombosis, aseptic loosening and deep infections.

The mean range of motion (119.7°) in our study is better than that reported in many primary THA studies. This may be because of differences in the procedures and the subjectivity in measurements. In our practice, range of motion is in part evaluated by determining what kinds of daily activities the patients can perform. For patients who could squat for toileting (and in this study all patients could do so), performing such action would require at least 120° of hip flexion. After a primary THA, patients would likely be able to satisfy the criterion of sitting on stools, which typically requires 100°–120° range of motion.

Despite being unable to directly compare the published studies on THA in ankylosed hips, our study presents superior outcomes in terms of low dislocation rate, good hip abduction function and full correction of preoperative hip deformities than the other series listed in Table 3. Furthermore, the approach described herein optimizes the prosthetic insertion by fully exposing the acetabular and femoral sides of surgical fields and prevents excessive soft tissue traction that could lead to blunt soft tissue injury. Finally, this approach avoids injuring the gluteal musculature that are essential in postoperative recovery of gait and hip abduction.

To ensure successful outcomes using this approach, a number of key points should be considered. First, be particularly diligent about protecting the gluteus medius and minimus and avoiding excessive traction of the gluteus medius and minimus to protect the superior gluteal nerve. Next, during the femoral neck osteotomy, protect the peripheral soft tissue. Third, repair the anterior and posterior soft tissues around the hip joint carefully, as surgical release leads to the loss of the stabilizing tissues, such as the joint capsule and tendons. Finally, when preparing the acetabulum and femur, protect the peripheral muscles by packing with gauze to avoid seeding bone marrow components into the peripheral muscles. This may decrease the incidence of heterotopic ossification.

**Limitations**

As noted, a limitation of this study is that it lacked a control group. In addition, the sample was relatively small and the follow-up relatively short. Finally, the Harris hip score, although commonly used, has many limitations as a research tool. However, any scoring method has limitations, and the Harris hip score has been adopted by our institution as a standard for assessment. Therefore, we used this method for the purpose of standardization and uniformity in our collected data.

**Conclusion**

This combined anterior and posterior approach using a lateral incision provides very good exposure of ankylosed hip joints, protects the abduction unit and results in good to excellent postoperative recovery. This THA approach should be considered in the management of patients with 1 or more naturally ankylosed hips.

**Competing interests:** None declared.

**Contributors:** Zhiwei Wang designed the study. J. Li, Zhiwei Wang, Y. Wu and W. Xu acquired the data, which Zhiwei Wang, M. Li, Y. Wu and Zimin Wang analyzed. J. Li and Zimin Wang wrote the article, which all authors reviewed and approved for publication.

**References**


Clinical outcomes compared between laparoscopic and open appendectomy in pregnant women

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Background: Despite the initial absolute or relative contraindication of laparoscopic surgery during pregnancy, in the last decade, laparoscopic appendectomy (LA) has been performed in pregnant women. But few studies compare the outcomes of LA compared with open appendectomy (OA). We investigated clinical outcomes to evaluate the safety and efficacy of LA compared with OA in pregnant women.

Methods: We recruited consecutive pregnant patients with a diagnosis of acute appendicitis who were undergoing LA or OA between May 2007 and August 2011 into the study.

Results: Sixty-one patients (22 LA and 39 OA) enrolled in our study. There were no significant differences in duration of surgery, postoperative complication rate and obstetric and fetal outcomes, including incidence of preterm labour, delivery type, gestation age at delivery, birth weight and APGAR scores between the 2 groups. However, the LA group had shorter time to first flatus (2.4 ± 0.4 d v. 4.0 ± 1.7 d, p = 0.034), earlier time to oral intake (2.3 ± 1.6 d v. 4.1 ± 1.9 d, p = 0.023) and shorter postoperative hospital stay (4.2 ± 2.9 d v. 6.9 ± 3.7 d, p = 0.043) than the OA group.

Conclusion: Laparoscopic appendectomy is a clinically safe and effective procedure in all trimesters of pregnancy and should be considered as a standard treatment alternative to OA. Further evaluation including prospective randomized clinical trials comparing LA with OA are needed to confirm our results.


Méthodes : Pour la présente étude, nous avons recruté des patientes enceintes consécutives portant un diagnostic d’appendicite aiguë qui ont dû subir une AL ou une AO entre mai 2007 et août 2011.

Résultats : Soixante-et-une patientes (22 soumises à l’AL et 39 à l’AO) ont été inscrites à notre étude. Nous n’avons noté aucune différence significative pour ce qui est de la durée de l’intervention chirurgicale, du taux de complications postopératoires et des résultats obstétricaux et fœtaux, y compris l’incidence du travail prématuré, le type d’accouchement, l’âge gestationnel et le poids à la naissance et les indices d’APGAR entre les 2 groupes. Toutefois, le groupe soumis à l’AL a moins tardé à présenter des flatuosités (2.4 ± 0.4 j c. 4.0 ± 1.7 j, p = 0.034), a commencé à s’alimenter par la bouche plus tôt (2.3 ± 1.6 j c. 4.1 ± 1.9 j, p = 0.023) et a connu un séjour hospitalier postopératoire plus bref (4.2 ± 2.9 j c. 6.9 ± 3.7 j, p = 0.043) comparativement au groupe soumis à l’AO.

Conclusion : L’appendicectomie laparoscopique est une intervention sécuritaire et efficace au plan clinique durant les 3 trimestres de la grossesse, et il faut l’envisager comme solution de rechange thérapeutique standard à l’AO. Il faudra une évaluation plus approfondie pour confirmer nos résultats, y compris au moyen d’essais cliniques randomisés prospectifs comparant l’AL à l’AO.

Acute appendicitis is the most common nonobstetric condition requiring emergency surgery during pregnancy, with an estimated incidence between 0.05% and 0.13%. Although the incidence of acute appendicitis during pregnancy is similar to that in nonpregnant women, the rate of...
complicated appendicitis is much higher in pregnant women.\textsuperscript{2} Delay in diagnosis increases the risk of complications in the mother and fetus. When acute appendicitis is suspected, an aggressive approach is recommended.\textsuperscript{3} In nonpregnant patients, the advantages of laparoscopic appendectomy (LA), including reduced postoperative pain, fewer wound infections, earlier hospital discharge and faster return to work, are widely accepted.\textsuperscript{4} Despite the initial absolute or relative contraindication of laparoscopic surgical procedures during pregnancy, in the last decade LA has been performed in pregnant women.\textsuperscript{5} Although there have been no prospective randomized controlled trials studying LA in pregnant women, several reports have documented the feasibility, safety and effectiveness of LA in this population.\textsuperscript{1,2,4–9} However, these reports include case reports and small series, so their results are limited. In particular, there is very limited information on the outcomes of LA compared with open appendectomy (OA). Therefore, we investigated clinical outcomes to evaluate the safety and efficacy of LA compared with OA in pregnant women.

METHODS

We recruited consecutive pregnant women with a diagnosis of acute appendicitis who underwent LA (study cohort) or OA (control cohort) between May 2007 and August 2011. Ultrasounds and complete blood counts (CBC) were routinely obtained preoperatively. We confirmed the diagnosis of acute appendicitis by clinical examination and ultrasonography. All patients received preoperative and postoperative obstetric consultations and fetal monitoring. We retrospectively analyzed the medical records to compare the 2 groups. Preoperative clinical data included age, body mass index (BMI), gestation age at operation, incidence of previous Caesarean section and accuracy of the diagnostic ultrasound. Perioperative data included the duration of surgery, return to normal bowel movement, return to adequate oral intake, length of stay in hospital (LOS), postoperative complications and final pathology. Obstetric and fetal data included gestation age at delivery, incidence of preterm labour, delivery type, birth weight, APGAR scores at 1 minute and 5 minutes, and fetal mortality.

Laparoscopic appendectomy technique in pregnant women

The patient was placed on the table in the supine position with a slight left side tilt (20\degree–30\degree). We performed the procedure with the patient under general anesthesia and maintained continuous end-tidal CO\textsubscript{2} monitoring within the physiologic range (30–40 mm Hg). Routinely, we inserted a Foley catheter, used pneumatic compression devices on the legs and administered prophylactic antibiotics intravenously before the incision. In all patients, we entered the peritoneal cavity using the Hasson open technique, and the procedure was performed using 3 ports. First, we inserted a 10 mm balloon trocar (telescope route) supraumbilically according to the size of the uterus (3–4 cm above the uterine fundus), and pneumoperitoneum (10–12 mm Hg) was achieved by CO\textsubscript{2} insufflation. Subsequently, 2 working 5 mm trocars were inserted, depending on the gestation age (Fig. 1). The appendix was then elevated using a left-handed forceps, and the mesoappendix was divided using a harmonic scalpel (Ethicon). The appendiceal stump was ligated using endoloop (Ethicon) and transected using endo-scissors. The specimen was then placed in a Lap Bag\textsuperscript{\textregistered} (SJM) and removed through the umbilical port site. One closed suction drain was left next to the appendiceal stump.

Statistical analysis

Data are presented as means ± standard deviations. We compared the groups using the Mann–Whitney U test or $\chi^2$ test, as appropriate. We used SPSS version 14.0 for Windows for all statistical comparisons, and we considered results to be significant at \( p < 0.05 \).

RESULTS

Participants

Sixty-one patients enrolled in our study. In all 22 patients who had LA, the procedure was completed laparoscopically.
without conversion, and 39 OAs were performed in patients who refused LA. The mean age of the LA group was 29.3 ± 3.1 years, and that of the OA group was 31.4 ± 4.3 years (p = 0.45). There were no significant differences in BMI (22.7 ± 2.8 v. 22.8 ± 3.6, p = 0.83) or the gestation age at operation (16.4 ± 5.7 wk v. 16.7 ± 4.8 wk, p = 0.80) between the groups. In the LA group, 6 (27.3%) patients were in the first trimester, 13 (59.1%) were in the second trimester and 3 (13.6%) were in the third trimester. In the OA group, 8 (20.5%) patients were in the first trimester, 20 (51.3%) were in the second trimester and 11 (28.2%) were in the third trimester. The rate of previous Caesarean section in the LA group was 18.2%, and that of the OA group was 20.5% (p = 0.64). In all patients, we obtained an ultrasound preoperatively to clarify the diagnosis of acute appendicitis. There were no significant differences in the rate of false positive (9.1 v. 10.3%, p = 0.65) and false negative results (22.7 v. 17.9%, p = 0.16) between the groups (Table 1). Table 2 demonstrates the postoperative histopathological diagnoses in both groups. In the LA group, 2 (9.1%) patients had a normal appendix, 12 (54.6%) had focal appendicitis, 7 (31.8%) had suppurative appendicitis and 1 (4.5%) had gangrenous appendicitis. In the OA group, 4 (10.3%) patients had a normal appendix, 19 (48.7%) had focal appendicitis, 10 (25.6%) had suppurative appendicitis and 6 (15.4%) had gangrenous appendicitis.

**Perioperative outcomes**

The mean duration of surgery in the LA group was 44.2 ± 16.4 minutes, and that in the OA group was 47.3 ± 14.7 minutes. The mean time to normal bowel movement in the LA group was significantly shorter than that in the

<table>
<thead>
<tr>
<th>Table 1. Demographic and clinical characteristics of pregnant women undergoing laparoscopic or open appendectomy</th>
</tr>
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<tbody>
<tr>
<td>Characteristic</td>
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<tr>
<td></td>
</tr>
<tr>
<td>Age, yr</td>
</tr>
<tr>
<td>BMI</td>
</tr>
<tr>
<td>Gestation age at operation, wk</td>
</tr>
<tr>
<td>First trimester</td>
</tr>
<tr>
<td>Second trimester</td>
</tr>
<tr>
<td>Third trimester</td>
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<tr>
<td>Previous Caesarean section</td>
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<tr>
<td>Preoperative ultrasonography</td>
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<tr>
<td>False-positive ultrasound</td>
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<tr>
<td>False-negative ultrasound</td>
</tr>
</tbody>
</table>

BMI = body mass index; LA = laparoscopic appendectomy; OA = open appendectomy; SD = standard deviation.

<table>
<thead>
<tr>
<th>Table 2. Final histopathological diagnosis after operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage; diagnosis</td>
</tr>
<tr>
<td></td>
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<tr>
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<tr>
<td>Suppurative appendicitis</td>
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<tr>
<td>Gangrenous appendicitis</td>
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<tr>
<td>Second trimester</td>
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<tr>
<td>Normal appendix</td>
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<tr>
<td>Focal appendicitis</td>
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<tr>
<td>Suppurative appendicitis</td>
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<tr>
<td>Gangrenous appendicitian</td>
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<tr>
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<tr>
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<tr>
<td>Suppurative appendicitian</td>
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<tr>
<td>Gangrenous appendicitian</td>
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LA = laparoscopic appendectomy; OA = open appendectomy.
RECHERCHE

OA group (2.4 ± 0.4 d v. 4.0 ± 1.7 d, p = 0.034). Also, the mean time to adequate oral intake in the LA group was earlier than in the OA group (2.3 ± 1.6 d v. 4.1 ± 1.9 d, p = 0.023). The mean LOS in the LA group was 4.2 ± 2.9 days, and that of the OA group was 6.9 ± 3.7 days (p = 0.043). Three patients experienced complications, including intra-abdominal abscess and wound infection. In the LA group, an intra-abdominal abscess developed in 1 (4.5%) patient after surgery. This 29-year-old woman with a gestation age of 18 weeks was treated successfully with antibiotics and delivered a healthy boy weighing 3720 g at a gestation age of 40 weeks. In the OA group, 2 (5.1%) patients experienced complications (intra-abdominal abscess, wound infection) after surgery. The intra-abdominal abscess developed in a 33-year-old woman at 28 weeks’ gestation. She was treated successfully with percutaneous drainage and delivered a healthy girl weighing 2670 g at a gestation age of 37 weeks. Wound infection was treated conservatively. No statistical difference was observed in the rate of the complication between the groups (Table 3).

Obstetric and fetal outcomes

No patients were lost to follow-up, and they all had uncomplicated deliveries. There were no significant differences in the incidence of preterm labour (9.1 v. 10.3%, p = 0.66) or delivery type (p = 0.41) between the groups. The LA and OA groups had equivalent fetal outcomes, as demonstrated by gestational age at delivery, birth weight and APGAR scores (Table 4).

DISCUSSION

Although acute appendicitis is the most common cause of nonobstetric abdominal surgery during pregnancy and its incidence is similar to that in nonpregnant women, the diagnosis is difficult because of the anatomic and physiologic changes that occur during pregnancy. The risk for appendicitis does not appear to be increased by pregnancy, but the incidence of perforated appendicitis in pregnant women is much higher than in the general population. The reported rate of appendiceal perforation during pregnancy can be as high as 43%, compared with 19% in the general population. Complicated appendicitis can lead to maternal and fetal morbidity and even fetal loss, so pregnant women with suspected appendicitis should undergo surgery immediately, regardless of the gestation age of the fetus. The number of negative laparoscopic and open exploration rates during pregnancy ranges from 0% to 50% and 15% to 50%, respectively. In our study, the overall negative appendectomy rate was 9.8% (9.1% for the LA group and 10.3% for the OA group).

Diagnostic imaging studies are often used to clarify a confusing clinical picture. Ultrasonography is widely used

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**Table 3. Perioperative outcomes of laparoscopic or open appendectomy in pregnant women**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group (mean ± SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time, min</td>
<td>LA, n = 22</td>
<td>OA, n = 39</td>
</tr>
<tr>
<td>Time to first flatus, d</td>
<td>44.2 ± 16.4</td>
<td>47.3 ± 14.7</td>
</tr>
<tr>
<td>Time to oral intake, d</td>
<td>2.4 ± 0.4</td>
<td>4.0 ± 1.7</td>
</tr>
<tr>
<td>Postoperative LOS, d</td>
<td>4.2 ± 2.9</td>
<td>6.9 ± 3.7</td>
</tr>
<tr>
<td>Complication rate, n (%)</td>
<td>1 (4.5)</td>
<td>2 (5.1)</td>
</tr>
</tbody>
</table>

**Table 4. Obstetric and fetal outcomes of laparoscopic or open appendectomy in pregnant women**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group (mean ± SD or no., %)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestation age at delivery, wk</td>
<td>LA, n = 22</td>
<td>OA, n = 39</td>
</tr>
<tr>
<td>Preterm labour</td>
<td>37.1 ± 1.7</td>
<td>38.2 ± 3.5</td>
</tr>
<tr>
<td>Delivery type</td>
<td>2 (9.1)</td>
<td>4 (10.3)</td>
</tr>
<tr>
<td>Vaginal delivery</td>
<td>16 (72.7)</td>
<td>25 (64.1)</td>
</tr>
<tr>
<td>Caesarean section</td>
<td>6 (27.3)</td>
<td>14 (35.9)</td>
</tr>
<tr>
<td>Birth weight, g</td>
<td>2810 ± 293</td>
<td>2790 ± 312</td>
</tr>
<tr>
<td>APGAR score, 1 min</td>
<td>9.2 ± 0.1</td>
<td>9.3 ± 0.2</td>
</tr>
<tr>
<td>APGAR score, 5 min</td>
<td>9.8 ± 0.2</td>
<td>9.9 ± 0.1</td>
</tr>
<tr>
<td>Fetal loss</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

LA = laparoscopic appendectomy; OA = open appendectomy; SD = standard deviation.

*Unless otherwise indicated.
as a first-line diagnostic test because of its safety for the mother and fetus and its relatively high sensitivity and specificity for many intra-abdominal processes. In our study, ultrasonography was performed in all patients; acute appendicitis was found in 15 (68.2%) patients in the LA group and 28 (71.8%) in the OA group.

Conventionally, the treatment of choice for acute appendicitis during pregnancy has been OA. But there is no evidence that the benefits of OA outweigh those of LA in pregnant women with respect to perioperative morbidity and mortality. In the present study, the absence of significant differences in the analysis of clinical details suggests that our 2 groups had relatively similar preoperative conditions. Our study also supports the safety of LA because we found no differences in perioperative morbidity and mortality compared with OA. Moreover, some proven advantages of LA, including better intraoperative visualization, decreased surgical trauma, decreased gravid uterine manipulation, shorter postoperative LOS and faster return to work, may be even more important in pregnant women.

In our study, the LA group had significantly shorter postoperative LOS, earlier recovery of bowel function and shorter time to oral intake than the OA group.

It has been recommended to position the patient on her left side during surgery to prevent uterine compression of the inferior vena cava and to facilitate access to the appendix. Morrell and colleagues have suggested lateral rotation of the operating table to displace the uterus for better venous return. In our hospital, all pregnant patients were placed in a supine position with a slight left side tilt (20°–30°).

There is consensus that laparoscopic procedures are safest in the second trimester of pregnancy because the uterus, owing to its small size, is less susceptible to traumatic injuries. Some authors have suggested that laparoscopic procedures performed during the first trimester are usually associated with greater risk for fetal loss because of teratogenicity of medications and decreased uterine blood flow due to the pneumoperitoneum. An advanced gestational age was previously regarded as a contraindication for LA because of expected technical difficulties. However, Upadhyay and colleagues demonstrated that laparoscopic surgery in the third trimester of pregnancy is feasible and can be performed safely, and they recommended laparoscopic surgery in all 3 trimesters. In our study, LA was performed safely in all 3 trimesters without fetal mortality.

One of the most important concerns during LA in pregnancy is the potential risk of injury to the gravid uterus. Some debate exists about the best method to access the abdomen. The Veress needle or the Hasson open technique, and there was no injury to the gravid uterus. We consider the Hasson open technique to be completely safe and suggest that it should be the standard method in pregnant women, in accordance with the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) guidelines.

Achieving pneumoperitoneum during laparoscopy is another concern. The CO2 used for pneumoperitoneum is associated with pulmonary effects in pregnant women and a potential risk for acidosis in the fetus. It has been recommended that intra-abdominal pressure should be maintained at less than 12 mm Hg to avoid worsening pulmonary physiology in pregnant women. Previously published animal studies reported no adverse fetal effects of CO2 insufflation when the maximal intra-abdominal pressure was limited to 10–12 mm Hg for less than 60 minutes. Although studies have demonstrated that laparoscopic surgery can be performed safely during any trimester with good maternal and fetal outcomes, the long-term effects on the child after delivery have not been well studied. In the present study, intra-abdominal pressure was maintained at 10–12 mm Hg and the duration of surgery was less than 60 minutes (mean duration of LA 44.2 ± 16.4 min).

Stasis of blood in the lower extremities is common during pregnancy, so pregnant women are at high risk for thromboembolic complications. According to the SAGES guidelines, intraoperative and postoperative pneumatic compression devices and early postoperative ambulation are recommended to prevent deep vein thrombosis in pregnant patients. In the present study, we routinely used pneumatic compression devices, and there were no thromboembolic complications.

CONCLUSION

Our results show that LA is safe and effective in all trimesters and that it is associated with good maternal and fetal outcomes similar to those of OA. In addition, LA is associated with shorter postoperative LOS, earlier recovery of bowel function and shorter time to oral intake. On the basis of our results and considering the general advantages of laparoscopic surgery, LA in pregnant women should be considered as a standard treatment alternative to OA. Further evaluation, including prospective randomized clinical trials comparing LA with OA, are needed to confirm these results.

Competing interests: None declared.

Contributors: J.C. Chung designed the study and wrote the article. G.S. Cho and H.C. Kim acquired the data, which J.C. Chung, E.J. Shin and O.P. Song analyzed. All authors reviewed the article and approved it for publication.
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References


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Votre participation peut faire la différence.
Nous espérons avoir de vos nouvelles !
Adding an endovascular aortic surgery program to a rural regional medical centre

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Edward Woo, MD†
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Paul Fedalen, MD*
Grace Wang, MD†
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**Background:** Abdominal aortic aneurysms requiring surgical intervention are generally treated by endovascular means. Such procedures are not always offered in rural hospitals, possibly leaving patients underserved. We reviewed our experience initiating an endoaortic surgery program.

**Methods:** A surgeon in a rural centre was credentialed to perform endovascular aortic aneurysm repair through collaboration with a university centre and was proctored locally for the first 5 abdominal aneurysm repairs. Web-based image storage was used to review complex cases as part of an ongoing partnership. Referred patients were screened for multiple aneurysms and underwent long-term monitoring.

**Results:** In all, 160 patients were evaluated for 176 aortic pathologies. Twenty-five patients (17 men) aged 55–89 years underwent 26 endovascular abdominal (n = 23) or thoracic (n = 3) aortic procedures. Emergent endovascular procedures were not performed. There were no operative deaths, requirements for dialysis or conversions to open repair. Two endoleaks required early reintervention. The median length of stay in hospital for endovascular procedures was 2.5 days. Chronic endoleaks were observed in 7 patients. An additional 8 patients underwent open abdominal aneurysm repair locally and 15 patients were referred to the university program.

**Conclusion:** Creation of an endovascular aortic surgery program in a rural hospital is feasible through collaboration with a high-volume centre. Patient safety is enhanced by obtaining second opinions using web-based image review. Most interventions are for abdominal aortic aneurysms, but planning for a comprehensive aortic clinic is preferable.

**Contexte :** Les anévrismes de l’aorte abdominale justiciables d’une intervention chirurgicale sont généralement traités par voie endovasculaire. Ce type d’intervention n’est toutefois pas toujours pratiqué dans les hôpitaux ruraux. Les patients peuvent donc s’en trouver moins bien desservis. Nous avons passé en revue notre expérience après la mise sur pied d’un programme de chirurgie endoaortique.

**Méthodes :** Grâce à une collaboration avec un centre universitaire, un chirurgien d’un centre rural a reçu l’agrément nécessaire pour effectuer la réparation endovasculaire des anévrismes de l’aorte et il a été supervisé localement pour les 5 premières réparations d’anévrisme de l’aorte abdominale. Une banque d’images sur le Web a permis de passer en revue des cas complexes dans le cadre d’un partenariat continu. On a fait subir aux patients adressés en consultation un dépistage d’anévrismes multiples et ils ont fait l’objet d’un suivi à long terme.

**Résultats :** En tout, 160 patients ont été examinés pour 176 anomalies aortiques. Vingt-cinq patients (17 hommes) âgés de 55 à 89 ans ont subi 26 interventions endovasculaires de l’aorte abdominale (n = 23) ou thoracique (n = 3). Aucune autre intervention endovasculaire n’a été effectuée. On n’a eu à déplorer aucun décès en lien avec les interventions, aucun recours à la dialyse ni conversion vers une chirurgie ouverte. Deux endofuites ont nécessité une réintervention précoce. La durée médiane du séjour hospitalier dans les cas d’intervention endovasculaire a été de 2,5 jours. Des endofuites chroniques ont été observées chez 7 patients. Huit autres patients ont subi une réparation ouverte d’anévrisme abdominal localement et 15 patients ont été référés au programme universitaire.

**Conclusion :** La création d’un programme de chirurgie de l’aorte endovasculaire dans un hôpital rural est réalisable grâce à une collaboration avec un centre dont le volume d’interventions est élevé. La sécurité des patients est renforcée par l’obtention de secondes opinions facilitées par une banque d’images sur le Web. La plupart des interventions concernent des anévrismes de l’aorte abdominale, mais il est préférable de planifier la mise en place d’une clinique où on pourrait intervenir sur toutes les portions de l’aorte.
Open aortic aneurysm repairs can have high complication rates because many patients undergoing this type of surgery have comorbidities, mostly related to advanced age. Since Parodi and colleagues reported their experience using intraluminal graft implants to treat aortic aneurysms, less invasive endovascular aortic aneurysm repair (EVAR) of abdominal aortic aneurysms (AAA) has become applicable in up to 75% of cases requiring intervention. Such technology is also applicable, albeit to a lesser extent, for thoracic endovascular aortic aneurysm repair (TEVAR). Despite questions about long-term benefit and potentially higher up-front costs, these procedures are more appealing because they have significantly lower 30-day morbidity and mortality.

Adding an endovascular aortic repair program to an existing surgical product line may not be possible because there could be too few vascular cases to attract a vascular surgeon. In such instances, local general surgeons often have provided open vascular surgery services, including abdominal aortic aneurysm repair. These vascular services may be complemented by interventional radiology and cardiology for catheter-based treatment of ilioc and lower extremity arterial disease. Alternatively, a rural hospital may try to attract a dually specialized surgeon who has qualified in both general and vascular surgery. Such surgeons, however, frequently wish to limit their practices to vascular surgery. The majority of general surgeons do not receive sufficient vascular training to provide endovascular aortic aneurysm repairs.

Under these circumstances, rural physicians must refer patients requiring treatment for aortic aneurysm disease to distant hospitals. Unless a local physician or surgeon is motivated to regularly follow such patients before and after intervention, there is a risk of creating an underserved population. An appropriately qualified surgeon at a rural medical center would allow the hospital to manage these patients comprehensively. In this paper we describe how a regional hospital serving a population of 250 000–500 000, Bayhealth Medical Center (BMC), implemented such an aortic clinic and stent graft surgery program. A partnership with a distant university medical center, the Hospital of the University of Pennsylvania (HUP), was initiated to facilitate the introduction of endovascular aortic procedures.

**Methods**

An accredited institutional review board approved this retrospective study and waived the requirement for patient consent.

**Endovascular working group and timeline**

Before creation of the endovascular surgery program, it was necessary to establish a hospital working group. An administrator oversaw representatives from surgery, anesthesia, clinical engineering, the cardiovascular operating room and diagnostic imaging. The group was tasked with the generation of a timeline, credentialing guidelines and contracting with a high-volume vascular surgery program. Credentialing guidelines were developed with the guidance of the director of the local cardiac catheterization laboratory. An 8-month timeline laid out monthly goals for the endovascular working group. It included the credentialing process, the purchase of a new C-arm fluoroscopy machine, training the operating room (OR) nursing staff and ordering necessary endovascular inventory items. The inventory list was compiled by the surgeon being credentialed (D.M.). Our timeline is presented in the Appendix (available at cms.ca/cjs). The working group met every 2 weeks and reported its progress toward starting the endovascular service.

**Joint venture with high-volume vascular surgery service**

The BMC is in a county that is code 3 on the U.S. Department of Agriculture’s census-based Rural–Urban Continuum Codes (RUCC) and serves a small metro area with a population of about 250 000; BMC also partially serves an adjacent county that is code 4. The HUP is in a county that is code 1 on the RUCC system. It is in a large, metro area with a population of about 6 million and

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Assist at HUP</th>
<th>Operator at HUP</th>
<th>Operator at BMC</th>
<th>Total procedures</th>
<th>Required total</th>
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<tr>
<td>EVAR procedures</td>
<td>9</td>
<td>2</td>
<td>5*</td>
<td>9 assist</td>
<td>5 assist</td>
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<td>4</td>
<td>2 suggested</td>
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<tr>
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<td>20</td>
<td>10*</td>
<td>41 assist</td>
<td>15 assist</td>
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<tr>
<td>Interventional aortoiliac procedures</td>
<td>20</td>
<td>9</td>
<td>10*</td>
<td>20 assist</td>
<td>15 assist</td>
</tr>
<tr>
<td>TEVAR procedures</td>
<td>6</td>
<td></td>
<td></td>
<td>6</td>
<td>10</td>
</tr>
</tbody>
</table>

*AAA = abdominal aortic aneurysm; BMC = Bayhealth Medical Center; EVAR = endovascular aortic aneurysm repair; HUP = Hospital of the University of Pennsylvania; TEVAR = thoracic endovascular aortic aneurysm repair.

*Cases completed during the first 5 proctored cases at BMC.
is located about 80 miles from BMC. The HUP has made a major commitment to heart and vascular care. The partnership between BMC and HUP increases their outreach and facilitates the referral of BMC patients with complex aortic pathology to be treated at HUP. These patients can then be treated by specialized surgeons with state-of-the-art equipment that is not available at BMC. An example of this would be a hybrid operating room suite. Such a suite can have better imaging equipment and usually has a larger inventory of specialized catheters needed for unusual and complex cases. In return for financial compensation, BMC may use HUP’s brand identity in advertisements and community outreach. The HUP surgeons obtained credentials that allow them to assist or proctor up to 6 cases per year at BMC. The BMC surgeons may also work in partnership with HUP surgeons on complex cases by having privileges at both hospitals. The BMC surgeons can consult rapidly with HUP surgeons on complex cases using web-based imaging services, deciding whether to treat patients locally or refer them.

**Credentialing guidelines and process**

Patient evaluation and selection started 6 months before the first expected EVAR procedure during the credentialing period. During this time, urgent, emergent and more complex cases were referred to the university centre for earlier treatment or enrolment into newer graft trials. A BMC cardiac surgeon (D.M.) spent 3 days per week at HUP assisting in or performing endovascular procedures. During the 6-month training period, a list of usual wire and catheters needed for EVAR and TEVAR procedures was developed so that the working group could make contact with vendors.

Because endovascular aortic surgery was a new procedure for our hospital, there was no established credentialing policy. We therefore developed a credentialing policy for EVAR and TEVAR. The policy included both a didactic and procedural portion. The didactic portion included reading a relevant textbook and taking an accredited or approved education program on EVAR procedures. For the procedural portion, the surgeon was required to participate in a specified number of endovascular procedures. The number and type of required procedures for each module are listed in Table 1. These were based on Society of Vascular Surgeons and American College of Cardiology guidelines.

The surgeon must act as operator (while proctored by a qualified surgeon) in at least half of the required procedures (excluding TEVAR procedures). Each endovascular abdominal aneurysm repair case was counted as 1 EVAR procedure, 2 aortoiliac intervention procedures and 2 aortoiliac diagnostic procedures. The TEVAR cases counted similarly, but without aortoiliac intervention. The surgeon (D.M.) satisfied most of the procedural credentialing requirements on cases at HUP then completed these requirements in the first 5 cases at BMC. These were pre-planned with an HUP surgeon (E.W.) acting as a proctor. This satisfied the standard focused professional practice evaluation (FPPE) required by the BMC medical staff office. A detailed count of completed cases is presented in Table 1. Collaboration with HUP surgeons allowed the surgeon to complete his training and fulfill his procedural credentialing requirements. The TEVAR credentials were not rigorously met, but the hospital credentialing committee felt the overall experience was sufficient to sign off.

**Imaging**

Because of the intensive planning required before an endovascular procedure, high-quality computed tomography (CT) imaging studies are essential to the surgeon. The collaborative nature of the BMC endovascular service line necessitated rapid sharing of imaging studies with HUP surgeons. When starting our endovascular service line, we considered several imaging programs. One of the most important criteria for our imaging system was that it must allow for easy and seamless remote image sharing. We chose the PEMS software package (M2S). With this software, BMC computed tomography angiography (CTA) films can be uploaded and processed into 3-dimensional (3D) images upon email request. Viewing software can be downloaded on any computer, and M2S-generated 3D images can be easily downloaded and stored locally for physician evaluation. M2S acts as an intermediary between vendors and hospitals, facilitating the rapid and secure sharing of images.

![Fig. 1. Example images from the M2S software package. (A) A patient who will undergo endovascular aortic aneurysm repair (EVAR) at Bayhealth Medical Center. (B) A high-risk EVAR due to thrombus in the proximal neck. This patient would be referred to the Hospital of the University of Pennsylvania. Note how a tomographic slice can be placed onto the aortic contour, orthogonal to the bloodpath. (C) Anatomy requiring open repair or a new generation graft adapted to severe neck angulation. All patients were screened for multiple aneurysms with chest, abdomen and pelvis imaging.](image-url)
BMC and HUP surgeons, as BMC films can be dropped directly into a HUP surgeon’s (E.W.) folder, upon request. Isolated surgeons can then view the same film from their respective login points. This avoids having to physically send and receive films, which can be costly and time-consuming. Another important criterion for the imaging program is high-quality image reformatting. The program we chose has the ability to map thrombus and calcium along blood-paths. This feature facilitates endovascular graft planning, as seen in Figure 1.

Local surgeon partnership

Before starting this program, patients with AAA were referred by primary care physicians to the local private general surgery groups for open repair or were referred to various city hospitals. After instituting this program, many patients underwent endovascular repair by the BMC (D.M.) or HUP surgeons. The ability of the endovascular program to treat simple cases has left the more complex cases for open repair. Partnering with a local general surgeon became important to treat complicated cases requiring open repair. This has helped refine surgical techniques for open AAA repair.

Clinical pathway and operative technique

A complete clinical pathway was an integral part of starting the aortic service. One midlevel practitioner (M.S.) assisted the BMC surgeon (D.M.) on all aspects of the aortic clinic and surgery. Patients referred to this service have an initial consult and are counselled on aortic aneurysms or other pathology for which they were referred. The patient’s aortic disease is then broadly classified as sporadic, degenerative, syndromic or familial. In cases of suspected hereditary aortic disease, patients’ family members are also urged to undergo screening. All patients are screened for multiple aneurysms and undergo lifelong monitoring before and after surgical treatment. Patients with less severe disease and those who are unfit for surgery are also followed long-term. Based on each patient’s needs and the extent of disease, a course of intervention is chosen as either medical treatment with β blockers17,18 and angiotensin converting enzyme inhibitors19 or surgical treatment, when required. Aneurysms and intramural hematomas distal to the aortic arch were evaluated with an intention to treat by endovascular means as a first choice. In the thoracic aorta, ideal candidates had ulcers with large intramural hematoma or a saccular aneurysm. In the abdominal aorta, ideal candidates had an infrarenal aneurysm with an adequate neck. In all cases, we looked for a 20 mm proximal and distal seal. All borderline cases were reviewed with HUP surgeons using web-based image sharing. A representative from the graft vendor brought in the stent grafts on a per case basis and was present as a resource throughout the operative procedure.

Prior to surgical treatment, preoperative evaluation for all patients included echocardiography, nuclear medicine-based stress testing and anesthesia consultation. Patients were admitted on the day of surgery and acetylsalicylic acid and β blockers were continued perioperatively. The EVAR procedures were carried out with bilateral open common femoral artery access. The EVAR planning was done preoperatively using 3D image processing to evaluate the aneurysm as well as iliac and femoral access size. All patients received general anesthesia and underwent comparison of upper body and lower extremity arterial line tracing after repair of femoral artery access. The TEVARs were carried out with unilateral open femoral or common iliac artery access and contralateral percutaneous access. Depending on the degree of calcification, superficial femoral artery access was occasionally preferred. In all cases, a purse string suture consisting of 4–0 polypropylene with a small red tourniquet was used to encircle the entry site (Fig. 2). This minimized blood loss and permitted downsizing access when exchanging the delivery system sheath for a moulding balloon access sheath. The purse string suture is removed at the end of the operation and the femoral artery is repaired with interrupted 5–0 polypropylene sutures. All cases were completed using Cook Zenith (Cook Medical) or Endurant (Medtronic) graft systems. Postoperatively, all patients went to the cardiovascular surgical care unit, which has the ability to list patients as intensive, intermediate or surgical care. Patients could be discharged home or to a rehabilitation facility from the unit without first going to a different hospital. Follow-up CTA with 2- and 5-minute delay films were obtained 4–8 weeks postoperatively and at 6–12 month
intervals thereafter. Ultrasonography was used selectively to monitor aneurysm sac size when appropriate to decrease the risk of radiation exposure.20,21

Community awareness

To increase awareness of the new endovascular service, we used a variety of outreach programs. These included mass mailings, meet and greet lunches with primary care physicians and senior citizen education at community centers. Special emphasis was placed on the importance of aortic aneurysm screening for high-risk patients. Patient recruitment increased community awareness about the dangers of aortic aneurysm, the benefits of early detection, and possible options for AAA repair.

Statistical analysis

Data were collected and analyzed with Microsoft Excel 2010. We compared continuous variables using a Student t test, when appropriate.

Results

In all, 160 patients in the BMC aortic clinic were evaluated and followed for a total of 176 aortic pathologies over 46 months. Of these pathologies, 155 were aneurysms. Table 2 shows the anatomic distribution of these 155 aneurysms and the average age of the corresponding

<table>
<thead>
<tr>
<th>Pathology</th>
<th>No. patients (male)</th>
<th>Age, median (range) yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAA ascending</td>
<td>55 (42)</td>
<td>66 (47–88)</td>
</tr>
<tr>
<td>TAAA descending</td>
<td>8 (3)</td>
<td>67 (47–76)</td>
</tr>
<tr>
<td>Type I/II TAAA</td>
<td>2 (1)</td>
<td>66.5 (66–67)</td>
</tr>
<tr>
<td>Abdominal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AAA</td>
<td>79 (62)</td>
<td>75 (51–90)</td>
</tr>
<tr>
<td>Type III TAAA</td>
<td>6 (2)</td>
<td>65 (60–77)</td>
</tr>
<tr>
<td>Type IV TAAA</td>
<td>5 (0)</td>
<td>73 (66–73)</td>
</tr>
</tbody>
</table>

AAA = abdominal aortic aneurysm; TAA = thoracic aortic aneurysm; TAAA = thoracoabdominal aortic aneurysm.

Fig. 3. Patients evaluated and treated in the aortic clinic at Bayhealth Medical Center (BMC). AAA = abdominal aortic aneurysm; EVAR = endovascular aortic aneurysm repair; HUP = Hospital of the University of Pennsylvania; TAA = thoracic aortic aneurysm; TAAA = thoracoabdominal aortic aneurysm; TEVAR = thoracic endovascular aortic aneurysm repair.
patients. Other pathologies included dissection, intramural hematoma and mesenteric ischemia. Figure 3 shows the number of patients evaluated for aneurysm surgery who had open repair, had endovascular repair, were referred to HUP or underwent further surveillance. Of the 90 abdominal aortic pathologies, 23 were treated with EVAR and 8 were treated with open repair. Of the 65 thoracic aortic pathologies, 3 were treated with TEVAR and 29 were treated with open repair.

Overall, 9.7% of pathologies (15 of 155) were referred to HUP for treatment. Two of these were for persistent endoleaks and growing aneurysm sacs in patients previously treated with EVAR at other hospitals. In total, 49.7% of evaluated aortic pathologies (77 of 153) underwent further surveillance, with 16 of these patients deemed unsuitable for EVAR or open repair. Many of these patients had advanced frailty or dementia.

A total of 23 EVAR and 3 TEVAR procedures were carried out at BMC. None was emergent. Iliac artery access was required in 4 cases because of small femoral artery size. One patient with an aortoiliac aneurysm required hypogastric artery coiling, which was performed by an interventional cardiologist 1 week before surgery. Table 3 shows the results of endovascular and open abdominal aortic aneurysm repair at BMC during the study period. All 8 open abdominal procedures involved a retroperitoneal approach with suprapenal or supraceliac clamping. Three were for the diagnosis of type III (n = 2) or IV (n = 1) thoracoabdominal aortic aneurysms (TAAA).

These patients were treated with adjunct distal perfusion, when appropriate. In this study, perioperative morbidities were considered separate from endoleaks. The mean size of aneurysms operated on for both EVAR and open repair was comparable (mean 5.6 ± 0.8 cm v. 5.6 ± 0.9 cm; p = 0.97) and there was no significant difference in the average age of patients who underwent each procedure (mean 71.7 ± 9.0 yr v. 74.4 ± 7.7 yr, p = 0.46). The length of stay in hospital of patients undergoing EVAR was significantly shorter than that of patients undergoing open repair (mean 3.0 ± 1.3 d v. 9.8 ± 3.8 d, p = 0.002). There were no conversions to open surgery during the study period. Vascular morbidities are summarized in Table 4. Two patients required femorofemoral bypass perioperatively. In 1 case, this was because of the inability to cannulate the contralateral main body gate, causing conversion to auni-iliac stent graft repair. In another, it was because of iliac artery stenosis that was aggravated by the stent graft. Three patients required iliac artery angioplasty, 2 of which included stent placement. There were no perioperative deaths in both EVAR and open repair groups. Instances of perioperative morbidity occurred in 4 of 23 EVAR repairs, including a patient with a postoperative ileus, a patient in whom renal dysfunction developed because pre-existing artery stenosis became occluded due to plaque shift, a patient with graft infection and a patient in whom a GI bleed developed 2 weeks postoperatively due to clopidogrel being taken for a previous carotid artery stent. The graft infection required excision and extra-anatomical reconstruction after referral to HUP. A pre-existing aortoduodenal fistula was suspected. Perioperative morbidity occurred in 2 of 8 open repairs, including a patient who experienced renal dysfunction and another patient who experienced dialysis-dependent renal failure. The latter patient had a pararenal abdominal aortic aneurysm. There were no perioperative deaths or morbidities in the TEVAR group.

Endoleaks were classified as types I, II or III. These represent seal area, retrograde fill and graft overlap area leaks, respectively. Reintervention for endoleak was required within 30 days in 2 patients. One, a type I, was post-TEVAR and presented with sudden back pain before discharge. The other, a type III, was post-EVAR and presented with paroxysmal tachycardia and mild anemia before discharge. Both patients underwent uneventful reintervention with additional stent graft placement. Five patients had type II endoleaks. Late type III endoleaks were suspected in another 2 EVAR patients, but these were not confirmed by brachial access angiograms, and there has been no sac growth on follow-up imaging to date. One TEVAR patient had a late aortic dissection distal to the graft within 1 year of treatment.

No patient in this series required reintervention for late endoleaks to date. Type II endoleaks are evaluated with serial CTA and managed conservatively as long as the aneurysm sac size is stable or shrinking. Complex type II leaks that seem progressive or that could be confused with type III leaks were reviewed with a university surgeon.

---

Table 3. Results of abdominal aneurysm repair

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Aneurysm size, mean ± SD, cm</th>
<th>Age, mean ± SD, yr</th>
<th>No. patients (male)</th>
<th>LOS, mean ± SD, d</th>
<th>Perioperative morbidity*</th>
<th>Follow-up time, median (range) mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVAR, n = 23</td>
<td>5.6 ± 0.8</td>
<td>71.7 ± 9.0</td>
<td>23 (17)</td>
<td>3.0 ± 1.3</td>
<td>47</td>
<td>6.7 (1.0–22.7)</td>
</tr>
<tr>
<td>Open repair, n = 8</td>
<td>5.6 ± 0.9</td>
<td>74.4 ± 7.7</td>
<td>8 (4)</td>
<td>9.8 ± 3.8</td>
<td>23</td>
<td>4.0 (1.7–37.6)</td>
</tr>
</tbody>
</table>

EVAR = endovascular aortic aneurysm repair; LOS = length of stay; SD = standard deviation.

*There were no deaths. Endoleaks were considered separately from perioperative morbidities.

†The instances of morbidity include a patient with a postoperative ileus, a patient with renal dysfunction due to plaque shift, a patient with graft infection and a patient with a gastrointestinal bleed 2 weeks postoperatively due to clopidogrel being taken for a previous carotid artery stent.

*One patient had renal dysfunction while another patient had dialysis-dependent renal failure postoperatively.
DISCUSSION

The BMC created its heart program because of a need to serve a growing regional population in the range of 250 000–500 000. Until we initiated this program, abdominal aneurysm care was provided by the general surgeons. Patients underwent open repair or were referred for endovascular stent grafting. The local interventional cardiologists serve most of the peripheral vascular needs for the community. The local general surgeons treat the remaining patients who require open surgery for peripheral arterial or venous pathology, including emergent thromboembolectomy and femorofemoral bypass of the lower extremity. There is no local vascular surgeon. The BMC endoaortic program was established by a cardiac surgeon. However, the present model could be established by a general or older vascular surgeon willing to undergo training and credentialing, as described in the Methods section. In addition, the model we describe for a comprehensive aortic clinic can be used by a vascular surgeon wishing to partner with a distant university program. Clearly, hospital or health system support is required to ensure that incentives and goals of all parties involved are aligned. The purpose of this article was to describe how a region that was under-served for aortic care could become partially or mostly served locally. We noted that more than 80%–90% of the pathology we evaluated was aneurysmal disease.

The majority of patients requiring endovascular treatment had infrarenal AAAs. There were no conversions to open surgery, reflecting careful patient selection. Initially, almost all cases were reviewed with the university surgeons preoperatively. With time this proportion fell to about 1 in 4. Adjunct surgical procedures commonly used were femoral artery exposure, iliac artery exposure via the retroperitoneum and femorofemoral bypass. Along with catheter and wire skills, such procedures can be performed by general surgeons willing to undergo a short training period. The cognitive requirements for clinical evaluation and follow-up are also within the reach of the general surgery knowledge base. Most abdominal aortic aneurysms are currently treated by endovascular repair, which has less perioperative morbidity and shorter hospital stay.7–9 Open aneurysm cases have more complex neck anatomy and may require referral to a university centre, depending on the local surgery team. At BMC, this was not always necessary, as the surgeon (D.M.) had previous experience with retroperitoneal exposures, which is more commonly needed with complex neck anatomy.

The initial results of this small data set show that, through collaboration with a university hospital, starting such a program at a rural regional medical centre can be successful. The results of AAA repair by both endovascular and open means at BMC are similar to results reported in major studies and reviews.7–11 The patient population for our study was similar to that in these trials. These studies report 30-day mortality of 0.5%–1.2% for endovascular repair and 3.0%–4.8% for open repair. Although the operative mortality at BMC (0% for both endovascular and open repair) was lower than these findings, this could be because of our relatively small number of procedures as well as our affiliation with a major university centre, which tends to take on our higher-risk or atypical anatomy patients. For our study, the mean length of stay in hospital for endovascular and open repairs was also similar to that of other studies.7–11 The rate of morbidities and endoleaks in our study was similar to results of these other trials.

To date, reintervention was required in 3 of 26 (11.5%) endoaortic procedures. These were early reinterventions, and there have been no late reinterventions to date. This could be because of the use of newer generation stent grafts, which have improved fixation. We also found that as our experience grew we became more comfortable with iliac artery stent angioplasty to treat residual stenosis after EVAR, reducing the risk of unplanned femorofemoral bypass. Similarly we had 1 conversion to uni-iliac repair early in our experience because we could not cannulate the contralateral limb gate. We have since learned to capture a wire from the ipsilateral side with a snare and pull it down through the contralateral gate as an alternative.

Although the endovascular surgery program was created to fill a need, it has led to the creation of an aortic disease clinic. Patients are therefore followed from initial consult to intervention and screened in a lifelong monitoring program. Hopefully this will impact AAA-related mortality in the BMC service area. There have been 160 patients evaluated in the clinic within a 46-month period. This has led to an increased expertise in imaging of aortic pathologies and collaboration with local radiologists. It was necessary to use many imaging modalities, depending on purpose of the imaging study. For example, noncontrast CT or magnetic resonance angiography (MRA) studies were used mainly for aneurysm screening and monitoring and contrast-enhanced CT studies with 3D image reconstruction were used for all patients needing surgery.

We tried to base our approach to patient selection on guidelines as well as common community practice. In the case of thoracic aortic aneurysms, this meant limiting our
selection to intamural hematoma with ulcer or saccular aneurysm. Our series included 1 of each and 1 reintervention, as noted previously. More complex or trauma cases were referred to the university centre for enrolment in trials or received surgery via a conventional open approach. This was in keeping with the 2010 American Heart Association guidelines on thoracic aortic disease. In the case of abdominal aortic aneurysms our patients usually had the expectation of endovascular repair. Randomized trials have demonstrated the safety of EVAR versus open repairs with lower early mortality, but some of the data remain controversial as to overall superiority in patients younger than 65 years. Our patient selection (average age 71.7 yr) was in keeping with this as well as the 2009 Society of Vascular Surgery guidelines. More than half the abdominal aneurysm repairs in the United States are currently treated by endovascular means. This trend has been correlated with the observation that the number of annual deaths from intact and ruptured AAA has substantially decreased in the United States. This has coincided with an increase in elective AAA repair after the introduction of EVAR and a decrease in the diagnosis and repair of ruptured AAA. The question of treating infrarenal aneurysms with contained ruptures merits consideration. In our hospital, such patients are treated by the on-call general surgeon with an open operation or are referred. As we gain experience and as newer generation ruptured aneurysm uni-iliac kits become available, it may be possible for our centre to offer emergent EVAR to such patients. The limitation that we face is that it is not cost-effective for a small program to stock stent grafts in all sizes locally. A vendor representative must be brought in for every case at this stage. We have been able to offer urgent EVAR (within several days) for symptomatic aneurysms. We also found that there are fewer TEVAR operations needed than EVARs. Our hospital is unique since we have perfusion services to back up TEVAR procedures should open conversion be needed. Even with such backup available, we carefully select only the most simple TEVAR operations, typically intramural hematoma or saccular aneurysms meeting criteria for intervention. It can be expected that many similar sized centres would not have such a service and would be referring TEVARs to the university centre. Such patients could still be followed in a local aortic clinic. This illustrates the notion that a comprehensive aortic clinic that partners with a university centre is preferable.

Some reports suggest that many rural centres refer their aortic aneurysm cases to high-volume, urban centres. However, it has been shown that patients prefer to see physicians closer to home, despite a possibly higher mortality. Primary care physicians may also wish to refer patients to specialists based on qualities such as appointment timeliness and communication. There is a possibility that rural patients are underserved by urban centres despite idealistic intentions. We overcame these obstacles through the use of a “hub-and-spoke” model in which patients are able to access a single, local aortic clinic. Patients at the clinic are either referred to the high-volume university centre or treated and followed locally. In cases where patients require referral, they are counselled locally. Their films are prereviewed by the university surgeon and discussed with the local surgeon. The local surgeon can communicate with local primary care physicians and provide follow-up after surgery for the university centre. Also, in this way, referrals are screened for fitness for surgery before being seen at the university centre, preventing patients from travelling unnecessarily. Cardiology clearance is obtained locally before referral by the comprehensive aortic clinic, assisting the local primary care physician with this potentially complex decision tree. This model is also advantageous for the high-volume university centre. Treatment is streamlined because patients are essentially ready for surgery when they are seen by accepting surgeons. The “hub-and-spoke” model described here is really a double “hub-and-spoke” model and is illustrated in Figure 4.

Other literature describes the introduction of an endovascular aortic surgery program into a nonuniversity hospital using vascular surgeons and interventional radiologists. In our model, a surgeon spent 3 days per week over a 6-month period at the university hospital. This allowed the surgeon to receive the necessary training and experience without unacceptably disrupting local services. The BMC nursing and endovascular team also travelled to HUP to observe cases intermittently. This was then crystallized by having a HUP surgeon proctor the BMC team for its first 5 cases and sign off on their competency. Credentialing...
policies must be set by the appropriate hospital committee using nationally recognized guidelines. In our case, we set the bar fairly high for initial credentialing. Recredentialing guidelines are not as well defined. Our team found that trying to do at least 1 case per month was a comfortable pace for familiarity. As patient load grew, the comprehensive approach we strived for required additional personnel, such as a physician assistant or nurse practitioner, to consolidate care and assist in seeing patients.

**CONCLUSION**

Creation of the endovascular aneurysm repair program at BMC allowed for many of the less complicated cases to be treated with EVAR, where they previously would have been treated with open repair or referred. As experience was gained with endovascular procedures, more complex cases were treated at BMC rather than referred to HUP. The collaboration also facilitated BMC patient access to new graft trials at HUP. The BMC gained brand recognition with a renowned medical centre, while the high-volume centre broadened its outreach.

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**Competing interests:** None declared.

**Contributors:** Each author helped design the study, reviewed the article and approved its publication. D. Marelli, M. Watson, M. Stallings acquired the data. D. Marelli and M. Watson analyzed the data and wrote the article.

**References**


Development and preliminary validation of a Function IndeX for Trauma (FIX-IT)

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Background: Assessing fracture healing in clinical trials is subjective. The new Function IndeX for Trauma (FIX-IT) score provides a simple, standardized approach to assess weight-bearing and pain in patients with lower extremity fractures. We conducted an initial validation of the FIX-IT score.

Methods: We conducted a cross-sectional study involving 50 patients with lower extremity fractures across different stages of healing to evaluate the reliability and preliminary validity of the FIX-IT score. Patients were independently examined by 2 orthopedic surgeons, 1 orthopedic fellow, 2 orthopedic residents and 2 research coordinators. Patients also completed the Short Form-36 version 2 (SF-36v2) questionnaire, and convergent validity was tested with the SF-36v2.

Results: For interrater reliability, the intraclass correlation coefficients ranged from 0.637 to 0.915. The overall interrater reliability for the total FIX-IT score was 0.879 (95% confidence interval 0.828–0.921). The correlations between the FIX-IT score and the SF-36 ranged from 0.682 to 0.770 for the physical component summary score, from 0.681 to 0.758 for the physical function subscale, and from 0.677 to 0.786 for the role–physical subscale.

Conclusion: The FIX-IT score had high interrater agreement across multiple examiners. Moreover, FIX-IT scores correlate with the physical scores of the SF-36. Although additional research is needed to fully validate FIX-IT, our results suggest the potential for FIX-IT to be a reliable adjunctive clinician measure to evaluate healing in lower extremity fractures.

Level of evidence: Diagnostic Study Level I.
The clinical assessment of fracture healing is a largely subjective process without a gold standard.1,2 Although measures have been developed for hip and ankle fractures,3 there is no validated measure that adequately describes functional healing for tibial fractures. A recently published systematic review that evaluated variability in the assessment of fracture healing in orthopedic trauma studies reported that the 3 most commonly used clinical criteria were the absence of pain or tenderness on palpation or examination, the absence of pain or tenderness when bearing weight and the ability to bear weight.4 Similarly, another review evaluating the clinical criteria used to define fracture union found that the 4 most common criteria were the absence of pain or tenderness when bearing weight, the absence of pain or tenderness on palpation or examination, the ability to bear weight and the ability to walk or perform activities of daily living with no pain.5

Pain at the fracture site is commonly regarded as a sign that a fracture has not yet healed.1,2 However, some patients may have persistent pain despite evidence of healing, whereas others may have no pain without evidence of healing.2 Consequently, pain alone may be an inadequate measure to determine if a fracture has healed. The ability to bear weight on injured appendages has been suggested to serve as an objective measure for healing of tibial fractures treated by external fixation1 because weight-bearing ability has been shown previously to increase with time postfracture2,6 and has been found to correlate well with bone stiffness.8 In tibial shaft fractures treated with intramedullary nailing, weight-bearing is possible from the day after surgery. Therefore, early weight-bearing in this context may not represent a healed fracture, and other dimensions, such as pain, should be considered when assessing fracture healing.

The Function IndeX for Trauma (FIX-IT) assessment provides a simple standardized approach to the measurement of weight-bearing and pain assessment in patients with lower extremity fractures, specifically tibia and femoral fractures. The FIX-IT score is a clinical outcomes assessment measure ranging from 0 to 12 points in 2 domains: the ability to bear weight (maximum 6 points) and pain at the fracture site (maximum 6 points; see the Appendix, available at cma.ca/cjs). The ability to bear weight is assessed through the single-leg stand and ambulation procedures. Pain is assessed through palpation and stress procedures. The scores in both domains, which are weighted equally, are summed to obtain the final total score; the maximum score of 12 indicates the highest level of function. The measure was developed based on a review of published literature on the assessment of tibial fracture healing and discussion with regulatory professionals and content experts in orthopedic trauma surgery. The objective of the present study was to evaluate the face validity, content validity, external validity, overall physician satisfaction, interrater reliability and convergent validity of the FIX-IT measure.

Methods

Overview of the study design

To assess face and content validity, the FIX-IT measure was independently evaluated by 5 orthopedic trauma surgeons before the clinical study. We conducted a cross-sectional study of patients with lower extremity fractures across different stages of healing to evaluate the interrater reliability of the FIX-IT measure. We obtained research ethics board approval before initiating the study. Patients were enrolled from Hamilton Health Sciences — General Site in Hamilton, Ont., and the sample was a nonrandom, convenience sample of patients with tibial or femoral fractures presenting to a fracture clinic. To assess interrater reliability, patients were independently examined by 7 reviewers. Prior to performing the FIX-IT assessments, we recorded the demographic and fracture characteristics of patients, and the patients completed the Short-form 36, version 2 (SF-36v2) questionnaire.

Assessment of face and content validity

To assess face validity, 5 orthopedic trauma surgeons from North America, Europe and Asia independently reviewed the FIX-IT measure and determined whether it looked like it was going to measure what it was supposed to measure. Specifically, the surgeons were asked to rate on a scale of 1–5 the overall agreement with the validity of this measure for understanding functional healing in patients with fractures.

We assessed content validity qualitatively by asking each of the 5 surgeons to determine whether each item was “essential,” “useful, but not essential” or “not necessary” to the performance of the construct. Each surgeon also rated their overall satisfaction with the administration of the measure and completed an open-ended question asking whether any item essential for the performance of the construct was currently missing from the existing measure.

Assessment of interrater reliability

We assessed consecutive patients with lower extremity fractures attending a fracture clinic for inclusion in our study. The inclusion criteria were lower extremity long-bone fracture, age 18 years or older, English language, ability to ambulate before the fracture and provision of informed consent. The exclusion criteria were bilateral lower extremity fractures, fractures of the axial skeleton limiting weight-bearing, inability to complete questionnaires or comply with functional tests, presence of pre-injury lower extremity pain syndrome, paralysis or sensory...
deficit and prefracture use of assistive devices. We obtained informed consent from all participants, and baseline and fracture characteristics were recorded.

Two orthopedic surgeons, 1 orthopedic fellow, 2 orthopedic surgical trainees and 2 research coordinators independently assessed patient function using the FIX-IT measure. Raters were selected before the study and each rater participated in a training session on how to use the FIX-IT measure. The team then evaluated each patient, and each rater, unaware of the other raters’ responses, scored patient function in all participants.

**Assessment of convergent validity**

Each eligible patient completed the SF-36v2, which is a health-related quality of life measure. The SF-36v2 dimensions were scored separately and transformed to a 0–100 scale. Domains were also grouped into the physical component summary (PCS) score and the mental component summary (MCS) score, as recommended by the SF-36v2 scoring manual. We chose to use the SF-36v2 rather than other available instruments because of its use in previous studies evaluating fracture outcomes and the hypothesis that the FIX-IT measure would correlate with the SF-36v2 physical functioning scale, role-physical scale and physical health component summary measure scores.

**Sample size considerations**

The sample size is controlled in reliability studies by varying the number of raters and the number of patients. Although increasing the number in either group will yield a more precise reliability estimate, the number of participants has a much greater impact on the precision than the number of raters. The number of raters was chosen based on generalizability and feasibility. Using 2 orthopedic surgeons, 1 orthopedic fellow, 2 orthopedic residents and 2 research coordinators as raters, we determined that a sample of 50 patients would provide sufficient precision for meaningful analysis of the FIX-IT measure. Assuming an expected intraclass correlation (ICC) of 0.8, a sample size of 50 patients and 7 raters, the expected half width of the 95% confidence interval (CI) for the estimated ICC was approximately 0.10.

**Statistical analysis**

Reviewer assessment of face and content validity and overall satisfaction with the administration of FIX-IT was assessed with 5-point Likert-type scales ranging from 1 (completely disagree) to 5 (completely agree). Scores were summarized qualitatively for each assessment.

We used ICCs with 95% CIs to measure agreement in the rater’s overall FIX-IT scores, including the 4 component scores. The ICC, used to quantify agreement for a continuous variable, is equivalent to the quadratically weighted $\kappa$ for categorical data. The weighted $\kappa$, as described by Fleiss, adjusts the observed proportion of agreement by correction for the proportion of agreement that could have occurred by chance alone. As they are numerically equivalent, similar guidelines for interpretation of $\kappa$ values can be applied to the ICC. Landis and Koch suggest that $\kappa$ of 0–0.2 represents slight agreement, 0.21–0.40 fair agreement, 0.41–0.60 moderate agreement, and 0.61–0.80 substantial agreement. A $\kappa$ value above 0.80 is considered almost perfect agreement. The value of the ICC ranges from +1, representing perfect agreement, to −1, representing absolute disagreement.

In addition, FIX-IT was compared with similar domains of a frequently used patient-reported outcomes scale. Specifically, the association between the FIX-IT

<table>
<thead>
<tr>
<th>Table 1. Content and face validity of the FIX-IT measure</th>
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<tbody>
<tr>
<td>Question; responses</td>
</tr>
<tr>
<td>How would you rate your overall agreement with the validity of this measure for understanding functional healing for fracture patients?</td>
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<tr>
<td>How satisfied are you with the administration of the measure?</td>
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<tr>
<td>How important is the ability measured by the single-leg stand score for understanding functional healing for fracture patients?</td>
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<tr>
<td>How important is the ability measured by the ambulation score for understanding functional healing for fracture patients?</td>
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<tr>
<td>How important is tolerance measured by the palpation score for understanding functional healing for fracture patients?</td>
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<tr>
<td>How important is the tolerance measured by the stress score for understanding functional healing for fracture patients?</td>
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</tbody>
</table>

FIX-IT = Function IndeX for Trauma.
scores and the SF-36v2 physical functioning scale, role-physical scale, and physical health component summary measure scores were assessed using Pearson correlation. The SF-36v2 was scored according to the SF-36v2 version 2.0 scoring manuals.9

RESULTS

Assessment of face and content validity

The FIX-IT instrument demonstrated acceptable face and content validity, as measured by 5 experts who determined that the items were all either useful or essential (Table 1). When asked if there were any additional items to consider including in the FIX-IT measure, 2 reviewers suggested including return to work, a patient-important outcome that indicates the ability to resume both physical and mental activities.17 As a substantial proportion of patients will not return to work even 2 years after the fracture occurs,18 return to work as a measure of fracture healing may not be very responsive to change.17 Therefore, the developers opted not to incorporate questions on return to work.

Patient characteristics

Of the 50 patients enrolled in the study, 42 (84%) had tibia fractures and 8 (16%) had femur fractures (Table 2). The mean time from injury to assessment for the study was 34 (range 0.5–555) months. The majority of the patients evaluated had already established problems with their fracture healing (Table 2).

<table>
<thead>
<tr>
<th>Table 2. Participant and fracture characteristics</th>
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</thead>
<tbody>
<tr>
<td>Participant characteristic</td>
</tr>
<tr>
<td>Age, yr (mean ± SD)</td>
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<td>Sex</td>
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<td>Male</td>
</tr>
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<td>Female</td>
</tr>
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<tr>
<td>Time from injury, mo., mean ± SD (range)</td>
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<tr>
<td>&lt; 6</td>
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</tr>
<tr>
<td>12–24</td>
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<tr>
<td>&gt; 24</td>
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<tr>
<td>Mechanism of injury</td>
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<td>Fall</td>
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<td>Motor vehicle accident</td>
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<td>Total of 33 additional injuries†</td>
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</tr>
<tr>
<td>Other lower extremity injury</td>
</tr>
<tr>
<td>Spinal injury</td>
</tr>
<tr>
<td>Head/face injury</td>
</tr>
<tr>
<td>Thoracic injury</td>
</tr>
<tr>
<td>Location of fracture</td>
</tr>
<tr>
<td>Tibia</td>
</tr>
<tr>
<td>Femur</td>
</tr>
</tbody>
</table>

SD = standard deviation.

*Unless otherwise indicated.

†Patients may have had more than 1 additional injury.

‡Patients may have had multiple complications and reoperations.
Functional status

The mean SF-36v2 PCS score was 35.06 ± 9.77, and the mean SF-36v2 MCS score was 43.73 ± 15.55 (Fig. 1). The mean SF-36v2 physical functioning scale score was 39.32 ± 29.23, the mean role–physical scale score was 33.92 ± 34.09, and the mean bodily pain scale score was 42.94 ± 24.00.

The FIX-IT measure and assessment of interrater reliability

The mean overall FIX-IT score was 7.97 ± 2.73 (Table 3). The overall interrater reliability for the FIX-IT score was 0.879 (95% CI 0.828–0.921; Table 4). The interrater reliability was 0.860 (95% CI 0.787–0.913) between the 2 orthopedic surgeons and the orthopedic fellow, 0.878 (95% CI 0.793–0.929) between the 2 residents and 0.893 (95% CI 0.819–0.938) between the 2 research coordinators.

Assessment of convergent validity

The correlations between the FIX-IT score and the SF-36v2 PCS score ranged from 0.682 to 0.770 (Table 5). The correlations between the FIX-IT score and the SF-36v2 physical functioning scale ranged from 0.681 to 0.758, and the correlation between the FIX-IT score and the SF-36v2 role-physical scale ranged from 0.677 to 0.786. The correlations between each procedure in the FIX-IT score and the SF-36v2 PCS are summarized in Table 5.

DISCUSSION

The use of a reliable, valid and responsive measure of fracture healing is essential for precisely estimating treatment effects in clinical trials. The FIX-IT measure is a recently developed, simple fracture healing assessment tool emphasizing outcomes that are likely important to patients. This preliminary study has demonstrated the FIX-IT measure has acceptable face and content validity and has shown that overall interrater reliability for the FIX-IT score among all 7 reviewers was 0.879 (95% CI 0.828–0.921), which demonstrates excellent agreement. The interrater reliability was above 80% among the 2 orthopedic surgeons and the orthopedic fellow, between the 2 residents,

![Fig. 1. Comparison of Short Form-36, version 2 (SF-36v2) scores from the study sample with the American population norms.](Image)

### Table 3. FIX-IT scores, n = 50

<table>
<thead>
<tr>
<th>Score, minimum: 0, maximum: 3*</th>
<th>Mean ± SD</th>
<th>Median</th>
<th>Min–max</th>
<th>Quartiles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-leg stand score</td>
<td>1.63 ± 1.19</td>
<td>2</td>
<td>0–3</td>
<td>25 1 50 2 75 3</td>
</tr>
<tr>
<td>Ambulation score</td>
<td>2.09 ± 0.93</td>
<td>2</td>
<td>0–3</td>
<td>25 2 50 2 75 3</td>
</tr>
<tr>
<td>Total score for ability to bear weight on fractured limb Minimum: 0, maximum: 6</td>
<td>3.72 ± 1.95</td>
<td>4</td>
<td>0–6</td>
<td>25 2 50 4 75 6</td>
</tr>
<tr>
<td>Palpation score</td>
<td>1.91 ± 0.75</td>
<td>2</td>
<td>1–3</td>
<td>25 1 50 2 75 2</td>
</tr>
<tr>
<td>Stress score</td>
<td>2.33 ± 0.80</td>
<td>3</td>
<td>0–3</td>
<td>25 2 50 3 75 3</td>
</tr>
<tr>
<td>Total score for pain at the fracture site Minimum: 0, maximum: 6</td>
<td>4.25 ± 1.35</td>
<td>4</td>
<td>1–6</td>
<td>25 3 50 4 75 5</td>
</tr>
<tr>
<td>Overall FIX-IT score Minimum: 0, maximum: 12</td>
<td>7.97 ± 2.73</td>
<td>8</td>
<td>1–12</td>
<td>25 6 50 8 75 10</td>
</tr>
</tbody>
</table>

*Unless otherwise indicated.
and between the 2 research coordinators. This demonstrates that the FIX-IT measure has excellent reliability across different raters with different levels of clinical assessment skills and suggests that FIX-IT can be consistently administered by surgical trainees in clinical practices and in clinical studies by research coordinators.

Although the FIX-IT measure has adequate convergent validity with the SF-36v2, there are a couple of reasons that the correlation may not be perfect. First, generic health-related quality of life measures often lack sensitivity to detect smaller functional changes that may be affected by an orthopedic injury; and it is possible that the FIX-IT measure better captured the patient’s abilities than the SF-36v2. Also, the SF-36v2 elicits the patient’s perspective on physical function whereas FIX-IT elicits the clinician’s perspective on fracture healing. The expectation of healing may be different for the patient and the clinician, possibly impacting the ratings of their functioning.

Limitations

As the present study was a preliminary evaluation of the FIX-IT assessment, it had limitations. First, in the initial surgeon assessment of content, it may have been unclear to expert reviewers that the goal was not to further reduce the items on the FIX-IT assessment. Surgeons may have felt that they had to indicate that at least something was not essential. Second, this was a convenience sample of patients from 1 surgeon’s fracture clinic, limiting the generalizability of the findings. Third, the majority of the patients included in this study were assessed at least 12 months after the fracture, and many patients were being seen at the fracture clinic for complications. This is also evident in the patients’ SF-36v2 scores, as they were lower than anticipated. The SPRINT study, a large randomized controlled trial evaluating reamed versus unreamed intramedullary nails, reported a physical component score of 42.9 ± 11 in the reamed group and 43.5 ± 11 in the unreamed group 1 year postinjury. This score is higher than the physical component score of 35.06 ± 9.77 found in the present study, indicating that patients in our study likely experienced more complications than the typical patient with a lower extremity fracture. Fourth, patients were only assessed once in our study, as opposed to being assessed over time to measure the progression of fracture healing, as in clinical practice or in a prospective clinical trial.

A strength of this study is that multiple raters with different clinical backgrounds and training levels independently assessed each included patient. The intrarater agreement was acceptable among all raters, implying that the

Table 4. Interrater reliability of the FIX-IT measure

<table>
<thead>
<tr>
<th>Item</th>
<th>Overall, n = 7</th>
<th>Surgeons and orthopaedic fellow, n = 3</th>
<th>Residents, n = 2</th>
<th>Research coordinators, n = 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-leg stand score</td>
<td>0.834 (0.769–0.890)</td>
<td>0.811 (0.717–0.890)</td>
<td>0.825 (0.712–0.897)</td>
<td>0.805 (0.624–0.896)</td>
</tr>
<tr>
<td>Ambulation score</td>
<td>0.854 (0.795–0.904)</td>
<td>0.857 (0.784–0.911)</td>
<td>0.893 (0.819–0.938)</td>
<td>0.856 (0.760–0.916)</td>
</tr>
<tr>
<td>Total score, ability to bear weight on fractured limb</td>
<td>0.897 (0.852–0.933)</td>
<td>0.890 (0.831–0.932)</td>
<td>0.915 (0.855–0.951)</td>
<td>0.874 (0.763–0.931)</td>
</tr>
<tr>
<td>Palpation score</td>
<td>0.714 (0.620–0.803)</td>
<td>0.637 (0.494–0.759)</td>
<td>0.701 (0.529–0.818)</td>
<td>0.751 (0.599–0.851)</td>
</tr>
<tr>
<td>Stress score</td>
<td>0.725 (0.633–0.810)</td>
<td>0.685 (0.552–0.793)</td>
<td>0.737 (0.580–0.841)</td>
<td>0.771 (0.628–0.864)</td>
</tr>
<tr>
<td>Total score, pain at the fracture site</td>
<td>0.784 (0.705–0.854)</td>
<td>0.732 (0.612–0.827)</td>
<td>0.763 (0.618–0.858)</td>
<td>0.827 (0.716–0.898)</td>
</tr>
<tr>
<td>Total FIX-IT score</td>
<td>0.879 (0.828–0.921)</td>
<td>0.860 (0.787–0.913)</td>
<td>0.878 (0.793–0.929)</td>
<td>0.893 (0.819–0.939)</td>
</tr>
</tbody>
</table>

CI = confidence interval; FIX-IT = Function Index for Trauma; ICC = intraclass correlation coefficient.

Table 5. Correlation of the FIX-IT measure with the SF-36v2 and correlation of each procedure in the FIX-IT measure with the SF-36v2 — physical health component summary score

<table>
<thead>
<tr>
<th>Item</th>
<th>Pearson correlation, values across individual assessors, range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correlation of the FIX-IT measure with the SF-36v2</td>
<td></td>
</tr>
<tr>
<td>SF-36v2 physical health component summary score (range)</td>
<td>0.682–0.770</td>
</tr>
<tr>
<td>SF-36v2 physical function scale score (range)</td>
<td>0.681–0.758</td>
</tr>
<tr>
<td>SF-36v2 role-physical scale score (range)</td>
<td>0.677–0.786</td>
</tr>
<tr>
<td>Correlation of each procedure in the FIX-IT measure with the SF-36v2 physical health component summary score (range)</td>
<td></td>
</tr>
<tr>
<td>Single-leg stand score</td>
<td>0.499–0.584</td>
</tr>
<tr>
<td>Ambulation score</td>
<td>0.549–0.711</td>
</tr>
<tr>
<td>Palpation score</td>
<td>0.309–0.506</td>
</tr>
<tr>
<td>Stress score</td>
<td>0.444–0.503</td>
</tr>
</tbody>
</table>

FIX-IT = Function Index for Trauma; SF-36v2 = Short-form 36 version 2.
FIX-IT measure can be administered by study personnel or surgical trainees, reducing the demands of a clinical trial on the orthopedic surgeon.

**CONCLUSION**

The FIX-IT measure incorporates common clinical criteria into a simple assessment tool. The developers did not include questions about activities of daily living or return to work into the tool. Such questions were excluded in the FIX-IT measure because it was developed to be a simple index, and these questions are often included in other validated measures that are administered in patients participating in clinical trials.17 The developers also did not incorporate radiographic parameters into the assessment tool. As radiographic parameters are subjective, adjudication of these outcomes is becoming the gold standard,17 thus the developers opted to exclude radiographic outcomes from the FIX-IT measure.

Future research on the FIX-IT assessment should be conducted at multiple centres in larger numbers of patients, should include patients with fresh fractures and should measure the evaluation of fracture healing progression over time.

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**Contributors:** M. Bhandari, S.M. Wasserman, N. Yurgin, S. Sprague and R.E. Dent designed the study. M. Bhandari, S.M. Wasserman, B. Petrisor and S. Sprague acquired the data, which M. Bhandari, S.M. Wasserman, N. Yurgin, S. Sprague and R.E. Dent analyzed. M. Bhandari, S.M. Wasserman and S. Sprague wrote the article. M. Bhandari, S.M. Wasserman, N. Yurgin, B. Petrisor and R.E. Dent reviewed the article. All authors approved its publication.

**References**


Quality of narrative operative reports in pancreatic surgery

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Quality of narrative operative reports in pancreatic surgery

Background: Quality in health care can be evaluated using quality indicators (QIs). Elements contained in the surgical operative report are potential sources for QI data, but little is known about the completeness of the narrative operative report (NR). We evaluated the completeness of the NR for patients undergoing a pancreaticoduodenectomy.

Methods: We reviewed NRs for patients undergoing a pancreaticoduodenectomy over a 1-year period. We extracted 79 variables related to patient and narrator characteristics, process of care measures, surgical technique and oncology-related outcomes by document analysis. Data were coded and evaluated for completeness.

Results: We analyzed 74 NRs. The median number of variables reported was 43.5 (range 13–54). Variables related to surgical technique were most complete. Process of care and oncology-related variables were often omitted. Completeness of the NR was associated with longer operative duration.

Conclusion: The NRs were often incomplete and of poor quality. Important elements, including process of care and oncology-related data, were frequently missing. Thus, the NR is an inadequate data source for QI. Development and use of alternative reporting methods, including standardized synoptic operative reports, should be encouraged to improve documentation of care and serve as a measure of quality of surgical care.

Contexte : Il est possible d’évaluer la qualité des soins de santé au moyen d’indicateurs de qualité (IQ). Les éléments contenus dans les notes opératoires (NO) sont une source potentielle de renseignements pouvant servir d’IQ, mais on en sait peu sur leur exhaustivité. Nous avons voulu évaluer l’ exhaustivité des NO dans les dossiers de patients soumis à une pancréatodudénectomie.

Méthodes : Nous avons passé en revue les NO dans les dossiers de patients soumis à une pancréatodudénectomie sur une période d’un an. Par analyse des documents, nous avons extrait 79 variables liées aux caractéristiques des patients et aux rédacteurs des NO, aux mesures des protocoles opératoires, à la technique chirurgicale et aux résultats oncologiques. Nous avons encodé et évalué ces données en fonction de leur exhaustivité.

Résultats : Nous avons analysé les NO pour 74 interventions. Le nombre médian de variables relevées était de 43,5 (entre 13 et 54). Les variables liées au protocole de soins et les variables oncologiques étaient souvent omises. L’ exhaustivité des NO était proportionnelle à la durée de l’intervention.

Conclusion : Les NO sont souvent incomplètes et leur qualité laisse à désirer. Des éléments importants, dont le protocole opératoire et les données oncologiques, étaient souvent manquants. Ainsi, les NO constituent une source inadéquate de données en ce qui concerne les IQ. Il faudra encourager la mise au point et l’utilisation d’autres types de rapports, dont des synopsis opératoires standardisés, pour mieux documenter les soins chirurgicaux prodigués et pour en évaluer la qualité.

Quality improvement is an important component of health care systems. Quality in health care can be evaluated in terms of the structures, processes and outcomes of care.1 Process and/or outcome data are used as quality indicators (QIs) for performance management. Outcome data, such as survival time, complication rates or quality of life data, are often difficult to obtain or take a long time to mature. As a result, process of care
data are frequently used as a surrogate for outcome data when measuring the quality of a health care system because process of care data are often available from administrative data sources.

At present, few QIs are available that measure the processes of care that occur during a surgical procedure. There is interest in measuring components of the operative report as a potential source of data for QIs. Completeness and accuracy of an operative report may be a means to assess the quality of care delivery and to identify opportunities for new quality initiatives. Thus, elements of the operative report have the potential to be used as QIs, but to our knowledge, this has not yet been established in the literature.

A narrative operative report (NR) is currently the standard documentation method used for the vast majority of surgical procedures in North America. It is an open format description of the operative steps performed during a surgical procedure dictated by a surgeon in narrative form. The content of the NR is not standardized or regulated. The primary function of the NR is to document procedural events for clinical and medicolegal reasons. An NR may potentially be used to measure the quality of the surgical procedure if intraoperative process of care measures can be extracted in a robust manner. But, at the present time little is known about the quality or the completeness of the NR. A study by Govindarajan and colleagues found that NRs can be used to extract data about nontechnical competencies of a surgical procedure, but the authors did not address issues related to the quality of health care. Others have reported that NRs are of variable quality owing to incomplete and/or inadequate reporting. For patients with cancer, Edhemovic and colleagues reported that NRs failed to adequately document the oncologically relevant elements that occur in rectal cancer procedures. Incomplete and inconsistent documentation in the NR may compromise the ability of physicians to make optimal decisions regarding further treatment.

Newer documentation methods have been developed that allow for standardized reporting of operative procedures. Proponents of standardized operative reports, also known as synoptic operative reports (SRs), point to more complete documentation with fewer omissions in SRs than NRs, resulting in higher quality data, as reasons to adopt the SR. Data from SRs may be used to improve communication between different health care providers to optimize clinical care, resulting in higher quality of care. For example, SRs that include details regarding the margin status of a procedure (i.e., R0, R1 or R2) may help inform the planning of postoperative adjuvant therapy, such as external beam radiotherapy. Also, data from an SR can be used for performance evaluation, quality improvement and research purposes.

Pancreaticoduodenectomy is performed for pancreatic cancer. Institutions that perform a high volume of pancreaticoduodenectomies have better outcomes than centres that perform only a few procedures per year. However, surgeon-specific processes account for a substantial component of the observed volume–outcomes association for pancreaticoduodenectomy. It is postulated that processes related to the technical proficiency and adherence to oncologic principles during the pancreaticoduodenectomy contribute to the improved outcomes observed. Thus, operative notes may be a useful source of intraoperative process of care data for this procedure.

The objective of our study was to evaluate the potential of the NR as a possible source of quality improvement data. Using document analysis, we assessed the completeness of reporting of data in NRs from pancreaticoduodenectomy procedures to evaluate the quality of data available in NRs.

**Methods**

We identified the NRs of patients who underwent a pancreaticoduodenectomy between Jan. 1, 2008, and Dec. 31, 2008, from a prospective maintained database at the University Health Network, Toronto, Ont. This academic institution has a high volume of hepatopancreato-biliary (HPB) procedures yearly, performed by 10 subspecialty-trained surgeons. We obtained ethics approval from the institutional research ethics board before the study commencement.

We analyzed the contents of dictated NRs. A draft framework of data elements considered important for an NR for pancreaticoduodenectomy was developed based on a literature review of outcomes following pancreaticoduodenectomy, operative variables that were collected in an existing provincial clinical database and input from general surgeons with content expertise. Potential data elements were pilot-tested for face validity by 5 surgical oncologists, including HPB surgical oncologists, and modified based on expert input to create a final set of variables.

We evaluated 79 variables covering 3 domains of interest: process of care, surgical manoeuvres and oncology-related variables. Of the 79 variables, 60 were considered mandatory and 19 were deemed optional.

The standard NR consists of a verbatim transcribed account of the procedure narrated by a physician member of the surgical team. This document is created free-form and is unstructured in format and content. We analyzed dictated NRs from the patients’ electronic medical records; handwritten notes in the paper chart were excluded. Data were extracted from the NRs by an independent data extractor. Demographic and clinical characteristics of the patients and the characteristics of the physician narrator were also recorded.

**Statistical analysis**

We calculated summary statistics for patient demographic information and the level of training of the individual who narrated the report. The variables were grouped into data
elements, and we calculated the median number of variables reported for each data element. Data pertaining to concomitant procedures performed at the same time as the pancreaticoduodenectomy were excluded from analysis, as these elements were unique to each situation and the content was nonstandard.

We performed univariate analysis using the Mann–Whitney U test, $\chi^2$ test or Fisher exact test, as appropriate. The data were analyzed using SPSS 15.0. In addition, we performed comparative analysis of the 5 most and least complete dictated NRs for variables of interest as a form of sensitivity analysis.

**RESULTS**

A total of 78 pancreaticoduodenectomies were performed, and 74 NRs were available for data extraction. In 4 cases, an NR was not dictated and was absent from the electronic medical record. These cases were excluded from our analysis.

**Patient characteristics**

There were 74 patients analyzed. In 61 patients (82%), a standard Whipple type pancreaticoduodenectomy was performed. Thirteen patients also underwent concomitant vascular procedures including portal vein resections (13 of 74) and/or arterial resections (2 of 74). Twenty-one patients had additional non-HPB procedures.

The majority of patients were men (43 of 74, 58%) and older than 60 years (45 of 74, 61%; Table 1).

**Narrative report characteristics**

The average time to dictation of the NRs was 1.5 days. The physician team member who dictated the NR was the attending surgeon (14 of 74, 19%), clinical fellow (43 of 74, 58%) or senior surgical resident (16 of 74, 22%; Table 1). There were no instances of duplicate NRs. None of the NRs was reviewed or verified by the staff surgeon via the electronic records system.

The median number of variables reported was 43.5 (range 13–54; Tables 2–4). No NR was complete for all 60 mandatory variables. The processes of care and oncologic variables were least complete, with several omissions (Tables 2 and 4). A median of 3 of 9 (range 0–7) processes of care variables were reported. No procedure was complete for all process of care variables. The most commonly omitted process of care variables were urgency of surgery (13 of 74, 18%), time out performed (11 of 74, 15%) and American Society of Anesthesiologists (ASA) status (0%; Table 2).

Oncology-specific findings were reported for a median of 5 of 9 (range 0–9) variables. Tumour size (38 of 74, 51%), lymphadenectomy performed (29 of 68, 43%), clinical resection and/or margin status reported (18 of 74, 24%) and lymphadenopathy (22 of 74, 30%) were the least frequently reported oncologic variables (Table 4).

Administrative variables and surgical technique variables were most commonly complete and were reported a for

<table>
<thead>
<tr>
<th>Table 2. Note and procedures process characteristics, $n = 74$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristic</td>
</tr>
<tr>
<td>Administrative</td>
</tr>
<tr>
<td>Chart no.</td>
</tr>
<tr>
<td>Date of surgery</td>
</tr>
<tr>
<td>Date of dictation</td>
</tr>
<tr>
<td>Dictating physician</td>
</tr>
<tr>
<td>Median (range)</td>
</tr>
<tr>
<td>Procedure</td>
</tr>
<tr>
<td>Surgeon</td>
</tr>
<tr>
<td>Incision</td>
</tr>
<tr>
<td>Preoperative diagnosis</td>
</tr>
<tr>
<td>Assistants</td>
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<tr>
<td>Procedure performed</td>
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<tr>
<td>Postoperative diagnosis</td>
</tr>
<tr>
<td>Proposed procedure</td>
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<td>Position</td>
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<td>Median (range)</td>
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<tr>
<td>Clinical information</td>
</tr>
<tr>
<td>Indication for surgery listed</td>
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<tr>
<td>Comorbidities listed</td>
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<tr>
<td>Median (range)</td>
</tr>
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<td>Process</td>
</tr>
<tr>
<td>Patient disposition</td>
</tr>
<tr>
<td>Sponge/instrument count reported</td>
</tr>
<tr>
<td>Consent obtained</td>
</tr>
<tr>
<td>Specimen disposition</td>
</tr>
<tr>
<td>Preoperative antibiotics</td>
</tr>
<tr>
<td>DVT prophylaxis</td>
</tr>
<tr>
<td>Urgency of surgery</td>
</tr>
<tr>
<td>Time out performed</td>
</tr>
<tr>
<td>ASA status</td>
</tr>
<tr>
<td>Median (range)</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; DVT = deep vein thrombosis.

*Unless otherwise indicated.
median of 4 of 4 (range 3–4) and 20 of 28 (range 1–26) variables, respectively. All identifying patient information was reported. The procedure performed was reported in 66 (89%) of the cases. Variables associated with surgical technique most commonly reported were those related to pancreatic mobilization and resection with a median of 5 of 6 variables (range 1–6; Table 3).

Narrative report completeness and physician dictator characteristics

The \( \chi^2 \) tests revealed no significant results when comparing narrator type (attending surgeon, clinical fellow, senior surgical resident) for each of the reported variables, except for time out performed, bile duct anastomosis type and specimen disposition (all \( p < 0.05 \)). Fellows reported time out performed more often, surgical house staff (clinical fellows or residents) reported the bile duct anastomosis type more often, and senior residents reported specimen disposition more often than the other narrator types.

Sensitivity analysis was performed for comparative analysis. The 5 most and least complete NRs were identified and compared. The 5 most complete NRs included 54 (87%) variables. These NRs were all dictated by the same clinical fellow within a week of the procedure date. The 5 least complete NRs included 36 (<58%) variables. These NRs were dictated by surgical house staff within a week of the procedure date. None of the most or least complete reports was dictated by attending surgeons.

Narrative report completeness and perioperative outcomes

We evaluated the association between perioperative outcomes and completeness of NRs. Completeness was divided into quartiles. Perioperative outcomes of the least and most complete NRs were compared (Table 5) by univariate analysis. Completeness of the NR was positively associated with operating room (OR) times (\( p = 0.048 \)). In the most complete NR quartile, a median of 48 variables were present and the median OR time was 396 (unknown–800) minutes versus the least complete quartile, which had a median of 39.5 variables present and a median OR time.

### Table 3. Surgical manoeuvres, \( n = 74 \)

<table>
<thead>
<tr>
<th>Manoeuvre</th>
<th>No. present (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic mobilization</td>
<td></td>
</tr>
<tr>
<td>Duodenum kocherized</td>
<td>70 (95)</td>
</tr>
<tr>
<td>Lesser sac opened</td>
<td>67 (91)</td>
</tr>
<tr>
<td>Tunnel created under pancreatic neck</td>
<td>67 (91)</td>
</tr>
<tr>
<td>GDA identified/divided</td>
<td>65 (88)</td>
</tr>
<tr>
<td>Cholecystectomy performed</td>
<td>64 (86)</td>
</tr>
<tr>
<td>Colon mobilized</td>
<td>50 (68)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>5 (1–6)</td>
</tr>
<tr>
<td>Resection</td>
<td></td>
</tr>
<tr>
<td>Pancreas divided</td>
<td>71 (96)</td>
</tr>
<tr>
<td>Distal GI margin divided</td>
<td>69 (93)</td>
</tr>
<tr>
<td>Common bile duct divided</td>
<td>69 (93)</td>
</tr>
<tr>
<td>Proximal GI margin divided</td>
<td>66 (89)</td>
</tr>
<tr>
<td>Level of bile duct division reported</td>
<td>52 (70)</td>
</tr>
<tr>
<td>Uncinate process divided</td>
<td>49 (66)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>5 (0–6)</td>
</tr>
<tr>
<td>Anastomosis</td>
<td></td>
</tr>
<tr>
<td>Pancreatic anastomosis type</td>
<td>67 (91)</td>
</tr>
<tr>
<td>Sutures used</td>
<td>73 (99)</td>
</tr>
<tr>
<td>GI anastomosis type</td>
<td>60 (81)</td>
</tr>
<tr>
<td>Pancreatic texture</td>
<td>43 (58)</td>
</tr>
<tr>
<td>Bile duct anastomosis type</td>
<td>38 (52)</td>
</tr>
<tr>
<td>Sutures used</td>
<td>69 (93)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>5 (0–6)</td>
</tr>
<tr>
<td>Closure/other details</td>
<td></td>
</tr>
<tr>
<td>Wound closure, type</td>
<td>73 (99)</td>
</tr>
<tr>
<td>Other procedures described, if performed</td>
<td>20/21 (95)</td>
</tr>
<tr>
<td>Intraoperative consult obtained, applicable only</td>
<td>8/9 (89)</td>
</tr>
<tr>
<td>Hemostasis performed</td>
<td>65 (88)</td>
</tr>
<tr>
<td>Patient condition at end of case</td>
<td>59 (80)</td>
</tr>
<tr>
<td>Drains left</td>
<td>52 (70)</td>
</tr>
<tr>
<td>Estimated blood loss</td>
<td>44 (59)</td>
</tr>
<tr>
<td>Complications, intraoperative</td>
<td>24 (32)</td>
</tr>
<tr>
<td>Transfusions received</td>
<td>21 (28)</td>
</tr>
<tr>
<td>Transfusion type, applicable only</td>
<td>10/66 (15)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>5 (0–8)</td>
</tr>
</tbody>
</table>

GDA = gastroduodenal artery; GI = gastrointestinal.

### Table 4. Operative variables, \( n = 74 \)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Present (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adhesions described, if present</td>
<td>24/25 (96)</td>
</tr>
<tr>
<td>Exploratory laparotomy performed</td>
<td>70 (95)</td>
</tr>
<tr>
<td>Frozen section, if performed</td>
<td>14/15 (93)</td>
</tr>
<tr>
<td>Tumour location</td>
<td>66 (89)</td>
</tr>
<tr>
<td>Tumour extension</td>
<td>64 (86)</td>
</tr>
<tr>
<td>Tumour size</td>
<td>38 (52)</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>18 (24)</td>
</tr>
<tr>
<td>Lymphadenectomy performed, applicable only</td>
<td>29/68 (43)</td>
</tr>
<tr>
<td>Clinical resection/margin status reported</td>
<td>22 (30)</td>
</tr>
<tr>
<td>Median (range)</td>
<td>5 (0–9)</td>
</tr>
</tbody>
</table>

*Unless otherwise indicated.

### Table 5. Narrative operative report completeness and perioperative outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Completeness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative duration, mean (range) min</td>
<td></td>
</tr>
<tr>
<td>Lowest quartile</td>
<td>347 (251–495)</td>
</tr>
<tr>
<td>Highest quartile</td>
<td>396 (unk.–800)</td>
</tr>
<tr>
<td>p value</td>
<td>0.048</td>
</tr>
<tr>
<td>Length of stay, mean (range) d</td>
<td></td>
</tr>
<tr>
<td>9 (5–33)</td>
<td>10 (6–22)</td>
</tr>
<tr>
<td>Perioperative complications, no. (%)</td>
<td></td>
</tr>
<tr>
<td>4/16 (20)</td>
<td>6/19 (32)</td>
</tr>
<tr>
<td>p value</td>
<td>0.42</td>
</tr>
</tbody>
</table>

Unk. = unknown.
of 347 (251–495) minutes. There was no association between the completeness of the NR and length of stay in hospital ($p = 0.96$) or major perioperative complications ($p = 0.42$).

**DISCUSSION**

The NRs are the usual form of documentation used to record the details of a surgical procedure. The purpose of our study was to examine the completeness of NRs in order to evaluate their potential as a source of quality assurance data.

Our results demonstrate that NRs are frequently incomplete. Variables related to surgical technique and administrative details were often present, whereas oncology-related and process of care details were commonly omitted in the majority of NRs. Thus, NRs are a poor source for quality assurance data.

We found that narrator characteristics were associated with NR completeness. When we compared the 5 most and least complete NRs, the 5 most complete NRs were all dictated by the same clinical fellow, whereas the least complete NR (13 variables reported, 16%) was dictated by the least experienced narrator, a senior surgical resident. This suggests that narrator training affects the quality of NRs. To date, surgical education places little, if any, emphasis on teaching trainees how to dictate NRs, and as a result the quality of NRs are expectedly variable.

Also, we report on an association between the completeness of NRs and operative duration. The longer the procedure time, the more likely that the NRs were more complete. Longer operative durations may be associated with more complex procedures, suggesting that the completeness of the NRs may be associated with procedure complexity. This finding is consistent with the results of previous work by Stewart and colleagues, who reported that procedural quality was directly related to the operative documentation. We did not find a significant association between NR completeness and patient-related outcomes, such as length of stay in hospital or perioperative complications. However, our study was underpowered to explore this question.

There is scant literature on the quality of operative documentation in surgery. Edhemovic and colleagues demonstrated that the most complete parts of NRs contained the least important information (patient information, indication for the procedure and closure technique). Our findings were similar. Information on elements without long-term implications (e.g., incision type, anastomotic suture technique) was virtually always complete, whereas information on oncology-related variables (e.g., clinical margin status, extent of lymphadenectomy performed) was often omitted.

To our knowledge, our study is the first evaluation of the NR for the pancreaticoduodenectomy operation. Strengths of this study are that the documents analyzed reflect NRs from a large contemporaneous sample of an experienced group of HPB surgical oncologists with a uniform approach to the pancreaticoduodenectomy. Thus, the variations that we identified reflect variations in the quality of the NRs rather than substantial variations in the procedure.

**Limitations**

A limitation of our study is its retrospective nature. In particular, we excluded 4 procedures for which no NR was dictated. Thus, our results are skewed in the direction of NRs being more complete than in the real-world setting.

Another limitation of this study is that we did not perform veracity checks of the variables studied, as NR completeness rather than NR correctness was the focus of this study. Thus, the fidelity of the NR as a reflection of the actual conduct of the procedure could not be assessed in our study. However, other authors have examined this association using cognitive task analysis. Stewart and colleagues found differences in the reporting of key steps of laparoscopic cholecystectomy in the NRs of patients who underwent laparoscopic cholecystectomy and in whom bile duct injury occurred. In patients who had a bile duct injury — a “bad” outcome — key elements of the surgical procedure were omitted, suggesting that the completeness of NRs reflects differences in the quality of the procedure performed.

**Implications**

Owing to the inadequacies of NRs that we have reported, we recommend the use of SRs to complement or replace NRs as a quality initiative. An SR may improve the completeness and quality of reports by minimizing inconsistent, inaccurate or missing information transfer between care providers, which can lead to suboptimal patient care. Several studies report that SRs provide more complete information than the NRs. There is wide acceptance of SRs by clinicians who prefer the readability of SRs over NRs. Further structured synoptic reporting results promote quality by standardizing the reporting processes among patients and institutions. Several jurisdictions mandate the use of synoptic pathology reports as a performance indicator.

Little research has been conducted to evaluate the potential benefits and/or limitations of synoptic reporting of operative procedures. However, owing to the potential benefits of SRs, many groups are developing and using SRs at the institutional level as quality assurance data.

To our knowledge, our study is the first evaluation of the NR for the pancreaticoduodenectomy operation.
improvement strategies. But there are also potential problems with SRs.

A major objection is that SRs, with their pro forma structure, may not be flexible enough for some procedures, particularly complex cancer procedures, that do not lend themselves to standardization. For these cases, SRs may not be able to accurately reflect the details of the procedure. However, Park and colleagues have recently developed and implemented an electronic SR for pancreaticectomy. They established that an SR is feasible and acceptable to surgeons, even for this complex, multistep procedure. In their study, the mean time for SR completion was only 4 ± 1.6 minutes per case. Furthermore, the SR document was more complete and reliable than NRs. A possible remedy to the structure of the SR is to include an optional free text field. This would allow nonstandardizable information to be included within an SR.

Other objections to SRs that have been suggested is that they can be difficult to complete, take longer to complete than NRs and add to the surgeon’s workload. However, several studies have reported that SRs take less time to complete than NRs. This suggests that the surgeon’s workload is actually decreased with SRs. Thus, the perception of SRs being more work is likely related to poor implementation strategies and/or existing knowledge gaps rather than being an intrinsic property of SRs.

In addition, the associations between SRs and patient outcomes, such as complication rate, positive margin rate and/or survival, have not yet been established. A few studies suggest that the quality of documentation is directly related to the quality of surgery, but the more likely mechanism for quality improvement is through more efficient communication of information among care providers, which allows for optimal treatment recommendations. However, more research should be done in this area. This topic was beyond the scope of this present study, which focused on the completeness of NRs. However, in future work, we will examine the association between the format (NR v. SR), quality of documentation and patient-related outcomes.

CONCLUSION

Unstructured NRs for cancer surgery are seldom complete and are of poor quality. Clinically important variables are frequently missing from NRs. As a result, an NR cannot be used as a data source for quality assurance purposes. Similar considerations also limit the use of the NR for research and medicolegal applications. Development and use of an SR should be encouraged to improve documentation of care and serve as a measure of quality of surgical care.

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Contributors: M.E. Wiebe, L. Sandhu, E.D. Kennedy, N.N. Baxter, A.R. Gagliardi, D.R. Urbach and A.C. Wei designed the study. M.E. Wiebe, L. Sandhu and A.C. Wei acquired the data. M.E. Wiebe, J.L. Takata and A.C. Wei analyzed the data. M.E. Wiebe and A.C. Wei wrote the article. All authors reviewed the article and approved its publication.

References


The impact of a massive transfusion protocol (1:1:1) on major hepatic injuries: Does it increase abdominal wall closure rates?

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Background: Massive transfusion protocols (MTPs) using high plasma and platelet ratios for exsanguinating trauma patients are increasingly popular. Major liver injuries often require massive resuscitations and immediate hemorrhage control. Current published literature describes outcomes among patients with mixed patterns of injury. We sought to identify the effects of an MTP on patients with major liver trauma.

Methods: Patients with grade 3, 4 or 5 liver injuries who required a massive blood component transfusion were analyzed. We compared patients with high plasma:red blood cell:platelet ratio (1:1:1) transfusions (2007–2009) with patients injured before the creation of an institutional MTP (2005–2007).

Results: Among 60 patients with major hepatic injuries, 35 (58%) underwent resuscitation after the implementation of an MTP. Patient and injury characteristics were similar between cohorts. Implementation of the MTP significantly improved plasma:red blood cell:platelet ratios and decreased crystalloid fluid resuscitation (p = 0.026). Rapid improvement in early acidosis and coagulopathy was superior with an MTP (p = 0.009). More patients in the MTP group also underwent primary abdominal fascial closure during their hospital stay (p = 0.021). This was most evident with grade 4 injuries (89% vs. 14%). The mean time to fascial closure was 4.2 days. The overall survival rate for all major liver injuries was not affected by an MTP (p = 0.61).

Conclusion: The implementation of a formal MTP using high plasma and platelet ratios resulted in a substantial increase in abdominal wall approximation. This occurred concurrently to a decrease in the delivered volume of crystalloid fluid.
Recent excitement surrounding the use of massive transfusion protocols (MTPs) with high plasma and platelet concentrations for injured patients in physiologic extremis is substantial. While the effect on overall mortality in the civilian population is still debated, massive resuscitations with high plasma:packed red blood cell (RBC) ratios remain promising for addressing the early coagulopathy and acidosis frequently associated with life-threatening injury. Additional benefits of a formal MTP include earlier administration of blood products during the resuscitation phase, improved overall efficiency, decreased total blood product use during a patient’s hospital stay and a substantial economic savings.

Concurrent to the initiation of MTP blood component therapy, the concept of damage control resuscitation also incorporates principles of reduced crystalloid delivery, permissive hypotension and immediate operative and/or angiographic hemorrhage control. This constellation of techniques is directed at patients who present in physiologic extremis (pH ≤ 7.1, base deficit ≥ 12.5, and/or core temperature ≤ 34°C). Interestingly, these parameters are nearly identical to the risk factors for the development of primary abdominal compartment syndrome (ACS), as a result of improved recognition of the ACS phenomenon as well as the widespread application of temporary abdominal closures (silo) as a preventative measure, the incidence of primary ACS has decreased substantially over the past 5 years. Unfortunately, the resultant “open” abdomen remains fraught with considerable short and long-term morbidity. In the best case scenario this includes a poor quality of life and the need for major reconstructive surgery.

In addition to its effect on acidosis and coagulopathy, MTPs have also been shown to substantially reduce the volume of crystalloid fluid delivered during the initial resuscitation period. Uncontrolled/excessive resuscitation is a clear risk factor for the development of ACS as well as a major obstacle to obtaining definitive fascial closure of the abdominal wall (visceral edema). As a result, it can be postulated that the incidence of both primary ACS and the open abdomen in severely injured patients may be reduced with the use of a formal 1:1:1 ratio MTP. Anecdotally, this appeared to be particularly evident in patients with high-grade hepatic injuries at our institution. As a result, the primary goal of our study was to identify the effects of a mature MTP on patients with major liver injuries by comparing them to a control group who underwent massive transfusions before initiation of a formalized high plasma protocol.

**Methods**

The primary study population consisted of all patients with a high grade liver injury (grade 3, 4 or 5), who presented to Grady Memorial Hospital (GMH), after the implementation of a formal MTP (Feb. 1, 2007, to Feb. 1, 2009; Table 1). The hospital is a level 1 trauma centre located in an urban setting. Massive transfusion was defined as transfusion of ≥ 10 units of RBCs in any 24-hour period during a patient’s hospital stay. We compared this population with a cohort with high-grade hepatic injuries who also underwent a massive transfusion (≥ 10 units of RBCs) prior to the initiation of the formal MTP (Jan. 1, 2005, to Jan. 31, 2007). The massive transfusion prospective registry, the trauma patient registry and chart reviews supplied all data. Although our institution does not have a formal protocol for management of the open abdomen, individual clinical practice was essentially identical. All management and challenges were also discussed daily at “Morning Report” by the faculty and senior leadership.

The MTP at GMH is initiated for patients who present in physiologic extremis (acidosis, coagulopathy, hypothermia) as a result of high-grade injuries. It is designed to ensure immediate availability of aggressive and early component therapy and is activated with a phone call to the blood bank. This activation is restricted to an attending physician or fellow from the departments of surgery, anesthesia, emergency medicine or critical care. Efforts are made by clinical personnel to obtain and deliver a sample of the patient’s blood to the blood bank for blood typing. The blood bank responds to the call for protocol activation by immediately placing 6 units of group O or type-specific RBCs and 6 units of group AB fresh packed red blood cells; TS = type-specific; UD = universal donor. *PRBCs and plasma can be doubled to 12 units each per cycle by request.

<table>
<thead>
<tr>
<th>Package</th>
<th>PRBCs</th>
<th>Plasma</th>
<th>Platelets</th>
<th>Cryoprecipitate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation</td>
<td>6 units (UD/TS)</td>
<td>6 units (UD)</td>
<td>1 apheresis§</td>
<td></td>
</tr>
<tr>
<td>1 (0.5 h)</td>
<td>6 units (UD/TS)</td>
<td>6 units (UD)</td>
<td>1 apheresis§</td>
<td></td>
</tr>
<tr>
<td>2 (1 h)</td>
<td>6 units (UD/TS)</td>
<td>6 units (TS)</td>
<td>20 units</td>
<td></td>
</tr>
<tr>
<td>3 (1.5 h)†</td>
<td>6 units (UD/TS)</td>
<td>6 units (TS)</td>
<td>1 apheresis§</td>
<td></td>
</tr>
<tr>
<td>4 (2 h)</td>
<td>6 units (UD/TS)</td>
<td>6 units (TS)</td>
<td>10 units</td>
<td></td>
</tr>
<tr>
<td>5 (2.5 h)</td>
<td>6 units (UD/TS)</td>
<td>6 units (TS)</td>
<td>1 apheresis§</td>
<td></td>
</tr>
<tr>
<td>6 (3 h)†</td>
<td>6 units (UD/TS)</td>
<td>6 units (TS)</td>
<td>10 units</td>
<td></td>
</tr>
</tbody>
</table>

| PRBCs = packed red blood cells; TS = type-specific; UD = universal donor. *PRBCs and plasma can be doubled to 12 units each per cycle by request. †Recombinant Factor VIIa may be used at attending physician discretion (dose: 3.6 mg, 1 repeat dose as needed in 30 minutes). HI MTP is still active, alternate packages identical to packages 5 and 6 until protocol terminated. §A single apheresis unit of platelets is considered to equal 6–10 standard units. |
frozen plasma (FFP) in a cooler as the “initiation package.” For this purpose, the blood bank maintains an adequate inventory of thawed plasma products for immediate distribution. The blood bank then continues to prepare predesignated packages of components to be picked up every 30 minutes with a goal ratio of RBC:FFP:platelets of 1:1:1 (Table 1). The blood bank continues to issue group O RBCs, but, owing to limited group AB plasma inventory, will issue ABO type compatible FFP once the patient’s blood type is known. If requested, the blood bank is able to double up the protocol to allow for 12 units of RBCs and 12 units of FFP to be delivered every 30 minutes. In addition, if bleeding is uncontrolled, the clinical service can request a 3.6 mg dose of rFVIIa after package 2 (18 units of RBCs), with an identical second dose, if needed, distributed 30 minutes later. The charge nurse in the area of resuscitation is responsible for designating a “runner,” who picks up a cooler every 30 minutes from the blood bank, returns used coolers and delivers product to the patient area. In addition to hemorrhage control, the attending physician is responsible for starting and stopping the protocol and for activating rFVIIa use.

The protocol dictates performing coagulation parameters and blood gases at least every other hour to monitor the patient’s response to therapy. The blood bank medical director, through the transfusion committee of the hospital, reviews the MTP quality indicators: 90% or higher percentage of MTP cycles in which blood products are available within 30 minutes and delivered to the resuscitation area in a timely manner; 100% of MTPs in which blood typing specimen was received by the blood bank before the second cycle; 5% or less waste of blood products; and 0% incidence of transfusion reactions.

Exclusion criteria for the study were limited to patients who did not undergo a massive transfusion following a high-grade liver injury. Liver injuries were graded using the American Association for the Surgery of Trauma grading system.37,38

**Statistical analysis**

We performed our statistical analyses using Stata version 8.0 (Stata Corp). 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. Differences in proportions among categorical data were assessed using the Fisher exact test. We considered results to be significant at $p < 0.05$ for all comparisons.

**Results**

A total of 35 and 25 patients with major liver injuries underwent a massive RBC transfusion before and after the initiation of a formal (1:1:1) MTP, respectively. For all grades of major hepatic trauma, patient demographics, injury characteristics, mechanisms, initial hemodynamic status and presenting base deficits were similar between the groups (Tables 2–4).

The overall survival rate for all patients with major liver injuries (grades 3, 4, and 5) was not affected by the implementation of a formal MTP (18 of 35 in the MTP group v. 11 of 25 pre-MTP, $p = 0.61$). Most patients in the MTP cohort died of massive exsanguinating hemorrhage and physiologic exhaustion (33% of grade 3, 86% of grade 4, 88% of grade 5 patients). The rate of primary abdominal fascial closure prior to discharge was significantly higher in the patient cohort who received a higher FFP:RBC ratio (12 of 18 in the MTP group v. 3 of 11 in the pre-MTP group, $p = 0.02$). This was a result of the large difference between patients with grade 4 injuries (8 in the MTP group v. 1 in the pre-MTP group; Table 3). Of the 6 patients who did not achieve fascial closure prior to discharge, 5 had prolonged mechanical limitations of the abdominal wall following a massive crystalloid-based resuscitation. The remaining patient required multiple operative interventions for concurrent injuries and displayed moderate intraperitoneal sepsis as a driving factor. Of the 8 patients with grade 4 liver injuries in the MTP

**Table 2. Comparison of patients with grade 3 liver injuries after massive transfusion**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group; mean (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTP</td>
<td>Pre-MTP</td>
</tr>
<tr>
<td>Total patients</td>
<td>9</td>
</tr>
<tr>
<td>Age, median, yr</td>
<td>30</td>
</tr>
<tr>
<td>Male sex</td>
<td>100</td>
</tr>
<tr>
<td>Penetrating mechanism</td>
<td>56</td>
</tr>
<tr>
<td>Injury severity score</td>
<td>31</td>
</tr>
<tr>
<td>Hemodynamic instability</td>
<td>44</td>
</tr>
<tr>
<td>Presenting base deficit</td>
<td>−13.3</td>
</tr>
<tr>
<td>Concurrent injuries</td>
<td>3.3</td>
</tr>
<tr>
<td>Mechanical ventilation, d</td>
<td>16</td>
</tr>
<tr>
<td>LOS, d</td>
<td>32</td>
</tr>
<tr>
<td>Overall mortality</td>
<td>3 (33)</td>
</tr>
<tr>
<td>Initial damage control procedure</td>
<td>6 (66)</td>
</tr>
<tr>
<td>No. of operations among all patients</td>
<td>4</td>
</tr>
<tr>
<td>Primary abdominal fascial closure</td>
<td>2 (2) (2)</td>
</tr>
<tr>
<td>Achieved by survivors prior to discharge</td>
<td>1.28</td>
</tr>
<tr>
<td>PRBC:FFP transfusion</td>
<td>1.12</td>
</tr>
<tr>
<td>PRBC:platelets transfusion</td>
<td>26</td>
</tr>
<tr>
<td>Total PRBC units, &lt; 6 h</td>
<td>25</td>
</tr>
<tr>
<td>Crystalloid infusion, L</td>
<td>6</td>
</tr>
<tr>
<td>Factor Vlla</td>
<td>5 (56)</td>
</tr>
<tr>
<td>Postoperative INR</td>
<td>1.26</td>
</tr>
<tr>
<td>Postoperative base deficit</td>
<td>−7.1</td>
</tr>
</tbody>
</table>

FFP = fresh frozen plasma; INR = international normalized ratio; LOS = length of stay in hospital; MTP = massive transfusion protocol; PRBC = packed red blood cells. *Unless otherwise indicated. †$p < 0.05$. 

---
group who underwent successful abdominal fascial closure during their initial hospital stay, 4 were closed during the initial operative procedure and 4 underwent primary fascial approximation at a mean of 4.2 days after admission.

Most patients in the MTP group underwent initial perihepatic packing (66% of grade 3, 47% of grade 4, 73% of grade 5 patients). This was comparable to patients in the pre-MTP group (60% of grade 3, 77% of grade 4, 86% of grade 5 patients; $p = 0.048$).

**Discussion**

Major hepatic trauma consists of large parenchymal lacerations, hematomas, juxtahepatic venous injuries and complete hepatic avulsions. Accordingly, these patients often require substantial transfusions, and high associated mortality correlates with the grade of injury. When operative therapy is required, major liver injuries can also be described as some of the most challenging cases. Because all current massive transfusion literature describes patient morbidity and mortality following generalized injuries, the primary goal of our study was to evaluate the influence of a high plasma ratio MTP on the outcomes of patients with major hepatic trauma.

Injured military and civilian patients classically require massive transfusion of blood products in approximately 8% and 3% of cases, respectively. These patients most often present to the hospital in physiologic extremis. As a result, acidosis was predictably impressive in our patient cohort, with mean base deficits ranging from –13.3 to –16.4, depending on the hepatic grade of injury (Tables 2–4). The severity of their injuries was also evident in the high mean injury severity score (ISS), duration of mechanical ventilation and hospital stay as well as the rate of hemodynamic instability at admission. The observation that 66%–100% of patients required an emergent damage control operative procedure also highlights the extremis in this cohort. When taken as a collective, these patients epitomize the requirement for massive blood product resuscitation and immediate hemorrhage control via damage control principles.

Although there appears to be a clear reduction in mortality for injured soldiers, this finding has recently been questioned within the civilian cohort. Prior to the implementation of a formalized high plasma MTP (Table 1), mortality for patients who required a massive transfusion (≥ 10 units of RBCs) following grade 3, 4 or 5 hepatic injuries at our institution was 60%, 46% and 71%, respectively. Given associated patient ISS of 31, 26 and 29,

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group; mean (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients</td>
<td>11</td>
</tr>
<tr>
<td>Age, yr median</td>
<td>29</td>
</tr>
<tr>
<td>Male sex (82)</td>
<td>(88)</td>
</tr>
<tr>
<td>Penetrating mechanism (64)</td>
<td>(69)</td>
</tr>
<tr>
<td>Injury severity score (29)</td>
<td>(26)</td>
</tr>
<tr>
<td>Hemodynamic instability (91)</td>
<td>(71)</td>
</tr>
<tr>
<td>Presenting base deficit –15.2</td>
<td>–16.4</td>
</tr>
<tr>
<td>Concurrent injuries</td>
<td>2.9</td>
</tr>
<tr>
<td>Mechanical ventilation, d</td>
<td>3</td>
</tr>
<tr>
<td>LOS, d</td>
<td>15</td>
</tr>
<tr>
<td>Overall mortality, no.</td>
<td>8 (73)</td>
</tr>
<tr>
<td>Initial damage control procedure, no.</td>
<td>9 (82)</td>
</tr>
<tr>
<td>No. of operations among all patients</td>
<td>1</td>
</tr>
<tr>
<td>Primary abdominal fascial closure</td>
<td>2/3 (67)</td>
</tr>
</tbody>
</table>

Achieved by survivors prior to discharge
PRBC:FFP transfusion 1.56 10.9
PRBC:platelets transfusion 1.23 16
Total PRBC units, 24 h 31 24
Total PRBC units, < 6 h 28 20
Crystalloid infusion, L 6 131
Factor VIIa 6 (40) 2 (15)
Postoperative INR 1.19 1.99
Postoperative base deficit –4.9 –10.6

Table 4. Comparison of patients with grade 5 liver injuries after massive transfusion

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group; mean (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients</td>
<td>11</td>
</tr>
<tr>
<td>Age, yr median</td>
<td>29</td>
</tr>
<tr>
<td>Male sex (82)</td>
<td>(88)</td>
</tr>
<tr>
<td>Penetrating mechanism (64)</td>
<td>(69)</td>
</tr>
<tr>
<td>Injury severity score (29)</td>
<td>(26)</td>
</tr>
<tr>
<td>Hemodynamic instability (91)</td>
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<td>Primary abdominal fascial closure</td>
<td>2/3 (67)</td>
</tr>
</tbody>
</table>

Achieved by survivors prior to discharge
PRBC:FFP transfusion 1.65 6.1
PRBC:platelets transfusion 2.03 3.8
Total PRBC units, 24 h 23 37
Total PRBC units, < 6 h 17 29
Crystalloid infusion, L 6 11
Factor VIIa 2 (18) 2 (29)
Postoperative INR 1.31 1.49
Postoperative base deficit –13.4 –14.6

FFP = fresh frozen plasma; INR = international normalized ratio; LOS = length of stay in hospital; MTP = massive transfusion protocol; PRBC = packed red blood cells.

*Unless otherwise indicated.

$^{†}p < 0.05$. 

Can J Surg, Vol. 56, No. 5, October 2013 E131
To this end, 4 patients with grade 4 trauma even and blood products are delivered via a crystalloid sparing that generalized visceral edema is reduced when plasma was also striking. This supports the anecdotal observation in the remaining patients who had successful approximation use of an MTP in patients with grade 4 injuries (13 v. 6 L) observed decrease in crystalloid resuscitation following the respective procedure. This compares to a mean wait of 4.2 days.

This philosophy was then coined “damage control” by Rotondo and colleagues, given its obvious conceptual similarity to the Navy’s use of the same term. Although this concept has resulted in a substantial improvement in mortality when applied to the correct patient population, it also commits the patient to a series of subsequent operative procedures aimed at restoring gastrointestinal continuity and abdominal wall closure. Unfortunately, many patients are eventually left with “open” abdomens because of generalized visceral edema caused by their initial resuscitation and the prevention of ACS. Although these abdomens are covered by a skin graft, the short and long-term morbidity, economic and resource cost are substantial and mortality is high.

The abdominal wall closure rate associated with the implementation of a 1:1:1 MTP was higher than in patients who received a low plasma massive transfusion (67% v. 27%) despite the use of similar intraoperative techniques. While these rates did not vary in patients with either grade 3 or 5 liver trauma, a large improvement was noted in patients with grade 4 injuries (14% v. 89%; Table 3). The observed decrease in crystalloid resuscitation following the use of an MTP in patients with grade 4 injuries (13 v. 6 L) was also striking. This supports the anecdotal observation that generalized visceral edema is reduced when plasma and blood products are delivered via a crystalloid sparing MTP.

To this end, 4 patients with grade 4 trauma even underwent immediate fascial closure during the initial operative procedure. This compares to a mean wait of 4.2 days in the remaining patients who had successful approximation of their abdominal wall during the initial hospital stay. We believe this decrease in both visceral and abdominal wall edema played an important role in achieving higher rates of definitive abdominal fascial closure. The 54% reduction to 6 L of administered crystalloids is also interesting, given that the published threshold for increasing the risk for ACS is 7.5 L. The same statistical decrease in crystalloid resuscitation was not observed in patients with grade 3 injuries, who failed to show an increase in closure rates despite implementation of the formal MTP (Table 2). This potential link has recently been suggested elsewhere. Unfortunately, most patients with grade 5 hepatic injuries died of exsanguinating hemorrhage (Table 4), likely obscuring any potential improvement in abdominal closure associated with a crystalloid sparing MTP.

Limitations

Limitations in this study are multiple. First, it was retrospective; therefore, the possibility of bias cannot be eliminated. Second, although mortality among patients with grade 4 and 5 liver injuries pre- and post-MTP were nearly identical, our study was substantially underpowered to assess overall mortality. While our primary goal was to descriptively evaluate the impact of an MTP on major liver injuries, small sample size (grade 3 injuries) may have obscured improvements in mortality. Finally, although an increased abdominal fascial closure rate was evident, observed decreases in visceral and abdominal wall edema were anecdotal. As a result, confirmatory abdominal wall measurements and intra-abdominal pressures would be helpful in future studies.

Conclusion

The implementation of a formal MTP using high plasma and platelet ratios resulted in a substantial increase in abdominal wall approximation. This occurred concurrently to a decrease in the volume of crystalloid fluid delivered during the initial resuscitation for massive hemorrhage. We hypothesize that this improvement was related to an overall decrease in generalized edema of both the viscera and abdominal wall. It was particularly pronounced in patients with grade 4 injuries. Given the rapid adoption and initiation of modern 1:1:1 MTPs across the globe, the targeted effects of this strategy...
Comparing interests: D.V. Feliciano declares having received speaker fees. No other competing interests declared.

Contributors: C.G. Ball, C.J. Dente, B. Shaz, A.D. Wyrzykowski, J.M. Nicholas and D.V. Feliciano designed the study. C.G. Ball, C.J. Dente, B. Shaz, A.D. Wyrzykowski acquired and analyzed the data. D.V. Feliciano also acquired the data, and A.W. Kirkpatrick also participated in data analysis. C.G. Ball, C.J. Dente, B. Shaz, A.D. Wyrzykowski and D.V. Feliciano wrote the article, which all authors reviewed and approved for publication.

References


Background: In Canada, provincial cancer registries have been established to provide rigorous population-based data for patients with colorectal cancer. Databases maintained by regional cancer agencies contain a broader scope of information and have been used as a surrogate source of information for colorectal cancer research. It is unclear whether these data can be reliably extrapolated to all patients affected by colorectal cancer. We sought to determine whether patients included in a referral-based database are systematically different from patients who are not included.

Methods: We conducted a retrospective cohort study to compare patients referred to the British Columbia Cancer Agency with those who were not referred. Comparison was based on age, sex and geographic location. We used univariate and logistic regression analysis to identify significant differences between the cohorts.

Results: Univariate analysis demonstrated that the referral and nonreferral cohorts differed in sex, age and geographic location. For patients with rectal cancer, the referral and nonreferral cohorts varied in age and geographic location. Multivariate analysis demonstrated significant differences in age and geographic location but not sex for patients with colon and rectal cancer.

Conclusion: Patients included in the referral database differed in age and geographic location from those included only in the provincial database. Studies using large data sets from referral centres must be interpreted with caution and may not be representative of the entire patient population.
cancer on population health, provincial cancer registries have been established.1

To best treat patients with cancer, specialized cancer centres are established in most jurisdictions. In British Columbia, branches of the British Columbia Cancer Agency (BCCA) are the sole providers of radiotherapy and a major provider of chemotherapy for citizens of the province. Research based at these cancer centres is often used to guide cancer treatment for all patients with cancer based on the assumption that the data can be extrapolated to all patients. However, it is unclear whether these data can be used as a substitute for population-based cancer registries owing to health care access bias.6 The primary goal of the present study was to determine whether patients with colorectal cancer who are referred to the BCCA are systematically different from those who are not referred and are therefore not captured within the cancer agency database.

METHODS

Cancer databases in British Columbia

In British Columbia, a registry of all patients with a confirmed tissue diagnosis of cancer is maintained by the British Columbia Cancer Registry (BCCR) and is mandated by provincial law. The scope of data contained within the registry is limited, and no stage-specific data are recorded. To address this, the BCCA established the Gastrointestinal Cancer Outcomes Unit in 2002. This unit maintains a colorectal cancer outcomes database (CRC database), which captures additional disease information, including stage, and treatment information for all patients with colorectal cancer who have been referred to the BCCA. The CRC database has been used in previous cancer outcome research and has been considered a reasonable approximation of population-based data.7–10

Data set comparison

We obtained institutional ethics review board approval from the BCCA. We queried the BCCR to identify all patients in the province with colon, rectosigmoid and rectal cancer diagnosed between January 2002 and December 2004. Patients included in the BCCR represent the entire population of patients with colorectal cancer in British Columbia during the study period. The CRC database solely captures data for patients who have been referred to and used the BCCA. Cross-referencing the BCCR and CRC databases formed a cohort of patients who had used the BCCA (the referred cohort) and a second cohort of patients who had not used the BCCA (nonreferred cohort).

We collected demographic information, including age, sex and regional health authority (representing geographic region within British Columbia), for all patients in each cohort. All adult patients who were residents of British Columbia at the time of colorectal cancer diagnosis were included in the study. Patients who were identified as having rectosigmoid cancer were grouped with patients with colon cancer for the analysis. The rationale for combining patients with rectosigmoid and colon cancer was that these 2 groups of patients were most frequently treated with surgery and chemotherapy and rarely received radiation therapy, suggesting these were not true rectal cancers. We determined and compared rates of chemotherapy between cohorts by reviewing the records of the BCCA pharmacy, which maintains a record of all chemotherapy administered within the province.

Statistical analysis

We initially recorded data in contingency tables and performed univariate analysis. Statistical analysis involved Student t tests to compare continuous variables and the χ² test to assess categorical variables. We considered a 2-sided p value of 0.05 to be statistically significant for all comparisons. To account for confounding between variables, we performed logistic regression analysis. The covariates selected for analysis were limited to those for which data were available from both the provincial cancer registry and the Gastrointestinal Cancer Outcomes Unit. Age at diagnosis, sex and regional health authority were the only covariates for which comparative data were available. Age was entered as a continuous variable, whereas sex and health authority were analyzed as categorical variables. We used regression coefficients to determine the odds ratio for capture in the CRC database for each covariate entered in the model.

RESULTS

We identified 7305 cases of colorectal carcinoma diagnosed between 2002 and 2004 in the BCCR. There were 6749 cases of colorectal adenocarcinoma that met the inclusion criteria and were included in the analysis. The referred cohort comprised 3651 patients from the BCCR who had used the BCCA. The remaining 3098 patients from the BCCR had not used the BCCA and were not in the CRC database, thus forming the nonreferred cohort (Fig. 1).

There were 4940 patients with colon cancer diagnosed during the years of the study. Overall, we included 2302 (46.6%) patients with colon cancer in the referred cohort and 2638 (53.4%) in the nonreferred cohort. A total of 1809 patients with rectal cancer were identified, with 1349 (74.6%) in the referred and 460 (25.4%) in the nonreferred cohorts.

For patients with colon cancer, univariate analysis demonstrated significant differences in sex, age and geographic location. As demonstrated in Table 1, 1071 (44.8%) women with colon cancer were referred to the BCCA
compared with 1231 (48.2%) men ($p = 0.017$). With increasing age, the likelihood of referral to the BCCA decreased; 44 (75.9%) patients younger than 40 years were included in the referred cohort compared with 327 (25.0%) of octogenarians ($p < 0.001$). Referral rates ranged from 61 (26.6%) to 689 (60.3%) based on geographic location within the province ($p < 0.001$). The percentage of patients referred to the BCCA increased from 2002 to 2003; a similar increase was not observed between 2003 and 2004.

The univariate analysis for patients with rectal cancer showed significant differences between cohorts with respect to age and regional health authority (Table 2). There was no difference in rates of referral by sex ($p = 0.23$). In this group, 855 (75.5%) men and 494 (73.0%) women with rectal cancer were included in the referred cohort. With respect to age, a similar trend to that seen among patients with colon cancer emerged; as age increased, rates of referral decreased. Of patients aged younger than 40 years, 24 (85.7%) were included in the CRC database compared with 184 (54.3%) of patients older than 80 years. Referral rates ranged from 74 (67.3%) to 304 (81.7%) based on geographic location within the province ($p = 0.007$). The rate of patient inclusion in the CRC database increased from 2002 to 2004.

The results of the logistic regression analysis for patients with colon cancer revealed no significant difference in rate of inclusion in the provincial cancer agency database based on sex, accounting for geographic location and inspection.
age ($p = 0.33$; Table 3). Variation in rates of referral based on geographic location was noted ($p < 0.001$). The interaction of age at diagnosis and health region was significant, indicating that rates of referral by age were different among the regions.

For patients with rectal cancer, the logistic regression analysis demonstrated no significant difference in rate of referral based on sex while adjusting for health region and age at diagnosis ($p = 0.50$; Table 4). For every 5-year increase in age above 60 years at diagnosis, referral rates were estimated to decrease by 30% ($p < 0.001$). Accounting for age at diagnosis and sex, significant differences in rates of referral were noted for different geographic regions ($p < 0.001$).

Across each health authority, patients in the referred cohort were more likely to receive chemotherapy than patients in the nonreferred cohort (Table 5). For patients in the nonreferred cohort, the rate of chemotherapy was highest in the Northern Health Authority and the Vancouver Coastal Health Authority for patients with colon and rectal cancer. Figures 2 and 3 demonstrate the variation in chemotherapy rates for patients with colon and rectal cancers, respectively, across regional health authorities in the province of British Columbia.

**DISCUSSION**

A major strength of population-based research is the external validity of conclusions based on study results. The collection of population-based, stage-specific, cancer data requires substantial resources and is currently not available for patients with colorectal cancer in the province of British Columbia. Therefore, much of the research regarding colorectal cancer in British Columbia has relied on analysis of data collected on patients referred to the BCCA. Referral-based data can be a robust source of information for health care research because of the broad scope of data collected. However, conclusions based exclusively on analysis of referral-based data are subject to health care access bias, whereby referred patients may not be representative of the entire patient population.

Our study demonstrates that patients referred to the BCCA, and therefore captured in the CRC database, are systematically different from those patients who are not referred. The results of this study are important in that they demonstrate that patients of advanced age and those living in different regions of the province are not uniformly included in the CRC database. Conclusions based solely on analysis of referral-based data are therefore not necessarily generalizable to the entire population of patients with colorectal cancer in the province.

Previous studies have demonstrated conflicting results in determining the effect of sex on referral to regional cancer centres. In our study, the univariate analysis suggested

<table>
<thead>
<tr>
<th>Table 3. Logistic regression analysis for patients with colon cancer demonstrating the adjusted effects of each covariate on rate of referral to the BCCA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effect</strong></td>
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<tr>
<td>Odds of referral for a 5-yr increase in age</td>
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<tr>
<td>Vancouver Island</td>
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<tr>
<td>Fraser</td>
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<tr>
<td>Vancouver Coastal</td>
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<tr>
<td>Interior</td>
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<tr>
<td>Health authority</td>
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<tr>
<td>Odds of referral with mean age 70 yr</td>
</tr>
<tr>
<td>Northern</td>
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<tr>
<td>Vancouver Island</td>
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<td>Fraser</td>
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<tr>
<td>Interior</td>
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<tr>
<td>Sex</td>
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<tr>
<td>Interaction between age at diagnosis and health authority</td>
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<th>Table 4. Logistic regression analysis demonstrating the adjusted effects of each covariate on rate of referral to the BCCA for patients with rectal cancer</th>
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<tbody>
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<td>Factor</td>
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<td>Increase in 5-yr for age at diagnosis</td>
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<td>Health authority</td>
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<tr>
<td>Sex</td>
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<th>Table 5. Chemotherapy treatment by health authority for patients in the referred and nonreferred cohorts</th>
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<td>Cancer; health authority</td>
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<tr>
<td>Fraser</td>
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<tr>
<td>Interior</td>
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<td>Northern</td>
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<td>Vancouver Coastal</td>
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<td>Vancouver Island</td>
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<td>Rectal cancer</td>
</tr>
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<td>Fraser</td>
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<tr>
<td>Interior</td>
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<tr>
<td>Northern</td>
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<tr>
<td>Vancouver Coastal</td>
</tr>
<tr>
<td>Vancouver Island</td>
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</tbody>
</table>

BCCR = BC Cancer Registry; CRC = colorectal cancer outcomes database.
that rates of referral to the BCCA were significantly lower for women with colon cancers than men. However, when these data were corrected for age at diagnosis and health care region, the effect of sex was no longer significant. For patients with rectal cancer, there was no significant difference in rates of capture based on sex in the univariate or logistic regression analysis.

Our study demonstrates that with advanced age, referral to the BCCA decreased. This finding is consistent with previous research showing that patients with advanced age were less likely to be referred to regional cancer centres for multidisciplinary assessment and treatment and that even when referred they were less likely to use available cancer resources than younger patients. As nonreferred patients do not have stage-specific data, it was not possible to determine whether lower rates of referral with advanced age was owing to stage, comorbidity or physician and patient attitudes. Recent research has shown a trend toward more advanced age at initial colorectal cancer diagnosis. Thus, research based on referral centres may not appropriately inform treatment of elderly patients.

Within the province of British Columbia, regional health authorities have been established to administer health care resources over the large geographic area of the province. In our analysis, we determined that rates of referral to the BCCA were significantly different among the province’s 5 regional health authorities. Previous research has determined that geographic barriers prevent effective use of available health care resources. Differences in access to cancer care have been shown to vary with rural and urban status. Previous reports have demonstrated that patients living in rural areas have delayed initiation of chemotherapy and radiation therapy compared with those living in urban areas. Travel distance invariably contributes to the discrepancy. Rural status may influence access to cancer screening, cancer care and follow-up. Further research can help quantify the effect of rural status on colorectal cancer outcomes within British Columbia. To serve the vast geographic area of the province, the BCCA has developed satellite sites at regional and community hospitals where patients may access adjuvant therapy. Despite these efforts, the main centres of the BCCA and most of the resources are located in major urban areas. Patients living in more remote regions of the province may be less likely to access these resources and would be less likely to be captured within the CRC database. In addition to potential geographic barriers to assessment at regional cancer centres, the available resources in each health authority may influence rates of BCCA referral and inclusion in the CRC database. Oncologists not affiliated with

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**Fig. 2.** Geographic variation in chemotherapy rates for patients with colon cancer in the province of British Columbia.

**Fig. 3.** Geographic variation in chemotherapy rates for patients with rectal cancer in the province of British Columbia.
the BCCA manage patients with colorectal cancer and prescribe chemotherapy in certain health authorities; these regions may have lower rates of patient inclusion in the CRC database but similar overall therapeutic options for patients with colon cancer. Our results suggest potential geographic influence on referral to regional cancer centres, but further research is required to test this hypothesis.

Previous studies have noted that rates of referral to regional cancer centres have increased over time, possibly related to increased compliance with recommendations for chemotherapeutic agents and radiotherapy for certain stages of colon and rectal cancer, or perhaps owing to educational programs. We noted that referral rates varied over the 3-year period of our study, but an increased rate of referral was not observed. To determine conclusively whether patient capture into the CRC database has increased over time, analysis over a longer period is required.

As expected, patients referred to the BCCA had higher rates of chemotherapy across all health care authorities in the province. For patients who were not referred to the BCCA, rates of chemotherapy were highest in the Northern Health Authority and the Vancouver Coastal Health Authority. The higher rates of chemotherapy among nonreferred patients within the Northern and Vancouver Coastal Health Authorities may be explained by medical oncologists not affiliated with the BCCA administering adjuvant therapy in these regions. As information on cancer stage is unavailable for the patients included only in the BCCR, it was not possible to determine the effect of cancer stage on chemotherapy rates. The low rates of chemotherapy in the BCCR cohort may be explained by patients having early-stage disease and therefore not requiring chemotherapy. This is unlikely, and previous research has demonstrated that substantial numbers of patients with stage III colon cancer were not referred for chemotherapy. The inability to collect stage-specific information from the provincial cancer registry limits the ability to interpret the difference in chemotherapy rates between the 2 cohorts. The BCCR is currently involved in the Canadian Partnership Against Cancer National Cancer Staging Initiative, which has a mandate to capture population-based stage information for major cancers, including colorectal cancer, for cases diagnosed from 2010 onward. The implementation of this initiative in British Columbia is planned for late 2011.

Limitations

The results of this study are subject to potential limitations that must be considered when interpreting our results. Incorrect entry of patient information or miscoding of diagnosis is possible and can lead to misclassification bias. The study was limited to a single Canadian province, and the results may not be generalizable to other provinces. As stage-specific information is not available for patients in the BCCR cohort, it was not possible to determine the influence of cancer stage on patient inclusion in the CRC database.

Conclusion

Our results demonstrate that patients included in the referral database are systematically different from the overall population of patients with colorectal cancer in British Columbia with respect to age and geographic location. Patients of advanced age were less likely to be included in the CRC database than younger patients. In addition, geographic variation in rates of inclusion within the CRC database was demonstrated for both colon and rectal cancer. Studies using large data sets at tertiary referral centres, even in places that have consolidated care at these centres, must be interpreted with caution. Our results suggest that health care access bias related to patient age and location within the province influences the validity of the referral database. Expansion of the provincial cancer registry to include stage-specific information as part of the National Staging Initiative will greatly improve the ability to analyze care provided to all patients with colorectal cancer and help with health care resource management and clinical research.

Competing interests: None declared.

Contributors: J. Faulds, P.T. Phang and C.J. Brown designed the study. C.E. McGahan and C.J. Brown acquired and analysed the data, which J. Faulds, P.T. Phang and M.J. Raval also analysed. J. Faulds, M.J. Raval and C.J. Brown wrote the article, which C.E. McGahan, P.T. Phang, M.J. Raval and C.J. Brown reviewed. All authors approved the final version for publication.

References


Complications associated with laparoscopic sleeve gastrectomy for morbid obesity: a surgeon’s guide

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Obesity is a common disease affecting adults and children. The incidence of obesity in Canada is increasing. Laparoscopic sleeve gastrectomy (LSG) is a relatively new and effective procedure for weight loss. Owing to an increase in the number of bariatric surgical procedures, general surgeons should have an understanding of the complications associated with LSG and an approach for dealing with them. Early postoperative complications following LSG that need to be identified urgently include bleeding, staple line leak and development of an abscess. Delayed complications include strictures, nutritional deficiencies and gastresophageal reflux disease. We discuss the principles involved in the management of each complication.
REVUE

increased incidence of complications associated with such procedures. It is therefore essential for all general surgeons, including those practising in smaller communities, to be aware of these potential complications and to have a basic understanding of how to manage them and when to ask for guidance from a bariatric surgeon. The purpose of this article is to shed some light on basic principles in the management of complications after LSG. We present our operative approach to LSG and review the major acute (within 2 wk of surgery) and late complications that can arise in patients following LSG (Table 1).

**Operative Technique**

The patient is placed in a supine position with the arms spread apart. Pneumoperitoneum is achieved using a closed technique with a Veress needle placed in the left subcostal area of the abdomen. Two 10 mm ports are placed in the supraumbilical and left midabdominal areas. An additional 15 mm port is placed in the right midabdomen to pass the stapler. Finally, 2 additional 5 mm ports are placed in the left and right upper quadrants of the abdomen. The left lobe of the liver is retracted medially using a Nathanson retractor placed in the subxiphoid area.

The stomach is decompressed at the beginning of the operation by placing an orogastric tube. The surgeon stands to the patient’s right with the first assistant standing to the patient’s left. The angle of His is taken down bluntly using the Goldfinger dissector (Ethicon Endo-Surgery), exposing the left crus of the diaphragm. Dissection is started about 6 cm proximal to the pylorus by taking down the gastrocolic ligament using the Harmonic Scalpel (Ethicon Endo-Surgery). Dissection is carried out proximally toward the short gastric vessels. This releases attachments to the greater curvature of the stomach and gastric fundus. The orogastric tube is then removed and replaced by a 50-French bougie placed in the stomach by the anesthesiologist and guided laparoscopically to sit in the lesser curvature of the stomach just distal to the pylorus. A 60 mm Endo GIA tri-stapler is then used to divide the stomach. We use 2 black cartridges initially to divide the distal stomach, starting 6 cm proximal to the pylorus. Next, 4–6 60 mm purple cartridges are used to complete the division of the remainder of the stomach. The specimen is then taken out of the abdominal cavity through the 15 mm port.

The bougie is then removed, and intraoperative gastroscopy is performed with air insufflation and methylene blue to rule out any leaks. We routinely close our 15 mm port fascia under direct vision before exsufflation of the abdomen. Patients receive nothing by mouth after surgery. On postoperative day 1, an upper gastrointestinal study is done using gastrografin to rule out staple line leakage (Fig. 2). A clear fluids diet is subsequently initiated.

**Acute Complications**

**Hemorrhage**

The risk of postoperative bleeding has been reported to be between 1% and 6% after LSG. The source of bleeding can be intra- or extraluminal. Intraluminal bleeding from the staple line usually presents with an upper gastrointestinal bleed. Common symptoms include hematemesis or melena stools. Diagnosis and management of intraluminal bleeding follow the common algorithm taken for an

<table>
<thead>
<tr>
<th>Complication</th>
<th>Chronicity</th>
<th>Diagnosis</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemorrhage</td>
<td>Acute</td>
<td>Physical findings, serial CBC</td>
<td>Transfusion with or without laparoscopy/laparotomy</td>
</tr>
<tr>
<td>Leaks</td>
<td>Acute/chronic</td>
<td>Physical findings, UGI series</td>
<td>Drainage (infrared laparoscopy), antibiotics with or without stenting and/or repair</td>
</tr>
<tr>
<td>Abscess</td>
<td>Chronic</td>
<td>CT scan, ultrasound</td>
<td>Drainage, antibiotics</td>
</tr>
<tr>
<td>Stricture</td>
<td>Chronic</td>
<td>Endoscopy, UGI series</td>
<td>Endoscopy (dilatation), surgery (seroryotomy)</td>
</tr>
<tr>
<td>Nutrient deficiency</td>
<td>Chronic</td>
<td>Physical findings, blood work</td>
<td>Nutritional supplements</td>
</tr>
<tr>
<td>GERD</td>
<td>Chronic</td>
<td>History, endoscopy</td>
<td>Treatment with proton pump inhibitor</td>
</tr>
</tbody>
</table>

CBC = complete blood count; CT = computed tomography; GERD = gastroesophageal reflux disease; UGI = upper gastrointestinal.
upper gastrointestinal bleed. This includes establishment of large bore intravenous lines for fluid resuscitation, administration of packed red blood cells if necessary, accurate measurement of urine output with insertion of a Foley catheter and an urgent gastroscopy to diagnose and control the source of bleeding.

Extraluminal bleeding usually presents with a serial drop in serum hemoglobin levels or signs of tachycardia or hypotension. Common sources for extraluminal bleeding include the gastric staple line, spleen, liver or abdominal wall at the sites of trocar entry. We suggest a second-look laparoscopy in any patient who presents with extraluminal bleeding with a sustained heart rate greater than 120 beats per minute and a drop in hemoglobin of more than 10 g/L postoperatively. Urgent laparoscopy facilitates a diagnosis and allows evacuation of the clot as well as surgical control of the source of bleeding. Many times the actual source cannot be identified, but we believe that evacuation of the hematoma and placement of a closed suction drain often serves as a helpful adjunct to patient resuscitation.

A number of buttressing materials are commercially available to attempt to reduce the rate of bleeding from the staple line. These include glycolide trimethylene carbonate copolymer (Gore Seamguard; W.L. Gore and Associates), bovine pericardium strips (Synovis Surgical Innovations) or porcine small intestinal submucosa (Surgisis Biodesign, Cook Medical). Whether the use of buttressing material reduces the rate of bleeding remains controversial. In a recent prospective randomized trial, Dapri and colleagues\textsuperscript{13} compared the rate of staple line bleeding after LSG using 3 different techniques: stapling the stomach with no reinforcement, or reinforcement with either suturing or buttressing with Gore Seamguard. These investigators observed a significantly lower rate of bleeding with the use of buttressing material. There was no difference in the incidence of a leak. Albanopoulos and colleagues,\textsuperscript{14} however, did not observe a significant difference in their rate of postoperative bleeding between patients with staple line suturing or buttressing with Gore Seamgard after LSG. These investigators had a 6% and 0% complication rate (bleeding and leak) in their suturing and Seamgard arms, respectively, but this did not reach significance. Therefore at our institution we do not routinely use any reinforcement materials (sutures or buttresses) for LSG.

\textbf{Staple line leak}

Gastric leak is one of the most serious and dreaded complications of LSG (Fig. 3). It occurs in up to 5% of patients following LSG.\textsuperscript{8,12} Several classifications exist...
Based on the radiologic findings and time of diagnosis. Based on upper gastrointestinal contrast study, gastric leak can be classified into 2 types. A type I or subclinical leak is controlled either through a surgical drain or through a fistulous tract into the abdominal or chest cavity. A type II or clinical leak is a disseminated leak with diffusion of the contrast into the abdominal or chest cavities. Based on the time of diagnosis, gastric leaks are classified as early or late. An early leak is generally diagnosed within the first 3 days after surgery, whereas a delayed leak is usually diagnosed more than 8 days after surgery.

Gastric leaks can be diagnosed either incidentally on a routine upper gastrointestinal series performed postoperatively without any clinical signs or during exploratory laparoscopy/laparotomy performed owing to unexplained tachycardia. In a study by Kolakowski and colleagues, a combination of clinical signs of fever, tachycardia and tachypnea was found to be 58.33% sensitive and 99.75% specific for detection of anastomotic leaks. Diabetes mellitus and sleep apnea were associated with a greater incidence of anastomotic leak. Therefore, we suggest an exploratory laparoscopy for diagnosis in patients who show these signs in the early postoperative period. In the presence of a leak, an abdominal washout with surgical repair of the leak (if technically feasible) and establishment of an enteral feeding route should be performed. Because the stomach is limited in size, the preferred choice for enteral feeding is typically a feeding jejunostomy.

In contrast, treatment of a delayed gastric leak is more challenging surgically owing to the presence of an inflammatory reaction. In this setting, attempts to repair the leak are usually futile. Treatment options include conservative or surgical management. This depends on the patient’s hemodynamic condition and on physical and radiologic findings. In the absence of hemodynamic instability and physical findings suggestive of peritonitis, conservative management may be initiated. This entails fluid resuscitation, initiation of intravenous antibiotics, nothing by mouth, percutaneous drainage of intra-abdominal collections (if drainable) and intraluminal stenting. In a septic patient with radiological evidence of a leak with diffuse intra-abdominal fluid collections, surgical drainage of the fluid collection is warranted.

At our institution, we have successfully managed delayed gastric leaks with drainage (either surgical or percutaneous), establishment of a feeding route (enteral or parenteral) and placement of gastric stents for approximately 2–4 weeks (Fig. 4). Other investigators have also used intraluminal stents for the management of gastric leaks. Himpens and colleagues reported their experience in the management of 29 patients with gastric leak after sleeve gastrectomy with stenting. These investigators left the stents in situ on average for 7 weeks. Immediate success was observed in 19 patients after placement of the first stent, whereas 5 patients required placement of a second stent. Two patients had persistent leaks requiring a surgical intervention.

Abscess

Intra-abdominal abscess is another possible complication after LSG. It usually presents with symptoms of abdominal pain, fever/chills or nausea and vomiting. If there are clinical suspicions, one should obtain a computed tomography scan of the abdomen to rule out the presence of intra-abdominal abscess. In a series of 164 patients undergoing LSG, Lalor and colleagues reported 1 patient with an abscess (0.7%). Treatment includes percutaneous drainage and antibiotics.

Chronic Complications

Stricture

Formation of stricture is another potential complication occurring after LSG. It could present either acutely after surgery due to tissue edema or more commonly in a delayed fashion. Presenting symptoms include food intolerance, dysphagia or nausea and vomiting. Although kinking of the stomach following LSG has been reported, the most common site of stenosis is at the incisura angularis. An upper gastrointestinal study or endoscopy is usually diagnostic.

Treatment options depend on the time of presentation. A stricture diagnosed acutely after surgery can sometimes be treated conservatively with bowel rest (nothing by
mouth), rehydration with intravenous fluids and close observation. In the absence of other pathologies (e.g., abscess, leak), these strictures will spontaneously resolve with no need for further intervention. Failure of conservative management warrants endoscopic dilation.

In contrast, chronic strictures usually require further intervention. These include either endoscopic or surgical treatments. Treatment options depend on the length of stenosis. Endoscopic dilatation is an invaluable tool used in this setting of a short segment stenosis.23 Successive treatments in 4- to 6-week intervals are adequate to treat strictures and ameliorate patient symptoms. In contrast, long segment stenosis and failure of endoscopic management demands a surgical intervention. Options include laparoscopic or open seromyotomy or conversion to Roux-en-Y gastric bypass. Dapri and colleagues26 reported their experience with laparoscopic seromyotomy in patients who had LSG. These investigators reported successful results with this treatment. Parikh and colleagues25 reported an incidence of 3.5% of symptomatic stenosis following LSG in their series of 230 patients; 2 patients required conversion to a Roux-en-Y gastric bypass owing to failure of endoscopic management.

Nutritional deficiencies

Nutritional deficiencies are common after bariatric surgery. The etiology is multifactorial owing to impaired absorption and decreased oral intake. In a recent study by Gehrer and colleagues,27 the prevalence of vitamin B12, vitamin D, folate, iron and zinc deficiency were reported to be 3%, 23%, 3%, 3% and 14%, respectively, after LSG. In general, these investigators found micronutrient deficiencies to be less prevalent after LSG than Roux-en-Y gastric bypass; however, folate deficiency was slightly more common after LSG than Roux-en-Y gastric bypass (22% v. 12%). Routine blood work is therefore warranted after LSG to diagnose vitamin and mineral deficiencies. At our institution, we routinely monitor patients’ serum vitamin B12, vitamin D, folate, iron and calcium levels at 3, 6 and 12 months after surgery and treat them accordingly, if necessary.

Gastroesophageal reflux disease

Gastroesophageal reflux disease (GERD) is a condition seen commonly in the bariatric surgery population. Although some operations, such as Roux-en-Y gastric bypass, are known to be associated with a reduced incidence of reflux postoperatively, this is controversial for LSG. In a recent systematic review by Chiu and colleagues,28 the authors found the data to be inconclusive with respect to the effect of LSG on GERD. Of the included studies, 4 showed an increased incidence of GERD postoperatively, whereas 7 showed a decrease in the incidence of GERD. Carter and colleagues29 performed a retrospective study on patients who underwent LSG and found 47% of their patients to have persistent (> 30 d) GERD symptoms. The most common reported symptoms included heartburn (46%) and regurgitation (24%). Management of patients with persistent GERD involves treatment with proton pump inhibitors. These patients require close clinical follow-up. If their symptoms persist despite the use of proton pump inhibitors, we usually perform a gastroscopy for diagnosis.

CONCLUSION

Laparoscopic sleeve gastrectomy is a new and effective procedure for the surgical management of morbid obesity. Therefore, the number of patients undergoing this procedure will continue to rise. Basic understanding of common complications and available treatment options is essential for all practising general surgeons. This paper offers basic management guidelines for the treatment of complications after LSG. By early diagnosis and treatment of these complications, patient morbidity and mortality might be reduced.

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Contributors: All authors designed the study. K. Sarkhosh acquired the data, which K. Sarkhosh and A. Sharma analyzed. K. Sarkhosh and S. Karmali wrote the article, which all authors reviewed and approved for publication.

References


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Cost-effectiveness of bariatric surgery for severely obese adults with diabetes

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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) and is supported by an educational grant from ETHICON and ETHICON ENDO-SURGERY, both units of Johnson & Johnson Medical Products, a division of Johnson & Johnson and ETHICON Inc. and ETHICON ENDO-SURGERY Inc., divisions of Johnson & Johnson Inc. 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**

**Objective:** To analyze the cost-effectiveness of bariatric surgery in severely obese adults who have diabetes. **Base case:** Patients with body mass index (BMI) ≥ 35 who have diabetes. **Methods:** The Centre for Disease Control (CDC)-RTI Diabetes Cost-Effectiveness Model, which is a Markov simulation model of disease progression and cost-effectiveness for type 2 diabetes, was expanded to consider the effects of bariatric surgery. **Interventions considered:** Gastric bypass and gastric banding compared with usual diabetes care. **Outcomes considered:** Diabetes-related and surgical complications, diabetes remission and relapse rates, deaths, costs and quality of life. **Results:** Bariatric surgery increased quality-adjusted life years (QALYs) and decreased costs. Bypass surgery had cost-effectiveness ratios of $7 000 per QALY and $12 000 per QALY for severely obese patients with newly diagnosed and established diabetes, respectively. Gastric banding had cost-effectiveness ratios of $11 000 per QALY and $13 000 per QALY, respectively. In sensitivity analyses, the cost-effectiveness ratios were most affected by assumptions about the direct gain in quality of life and by BMI reduction following surgery. **Conclusion:** The analysis indicates that gastric bypass and gastric banding are cost-effective methods of reducing mortality and diabetes-related complications in severely obese adults with diabetes.

**COMMENTARY**

Bariatric surgery has a well-established role in the management of obesity. Procedures such as gastric banding, gastric bypass and gastric sleeve resection have been shown to result in sustained weight loss where medical management has failed. There are approximately 2 million people in Canada and 20 million people in the United States who have type 2 diabetes. Of these, approximately 80%–90% are obese. Bariatric surgery has been shown to reverse type 2 diabetes by a mechanism that is unclear in a substantial number of patients. This effect can be independent of weight loss.

The study by Horerger and colleagues attempts to measure the cost-effectiveness of bariatric surgery compared with medical management of diabetes. It takes an established model of cost-effectiveness simulating diabetes progression that was developed by the Centers for Disease Control (CDC) and adds the costs and outcomes associated with bariatric surgery. This model measures costs and outcomes in patients with type 2 diabetes from diagnosis to death and simulates the development of diabetic complications along 3 microvascular pathways (nephropathy, neuropathy and retinopathy) and 2 macrovascular pathways (coronary heart disease and stroke). The important outcomes related to surgery are the probability of remission of disease (complete and partial), the probability of relapse and the probability of complications related to the surgery. Reported costs are in 2005 US dollars and are discounted at a rate of 3% per year, as is usually done in an economic analysis. Costs associated with usual diabetic care were derived from the UK Prospective Diabetes study.

The study population is diabetic patients with a BMI of 35 or more. This is the group that qualifies for bariatric surgery under current National Institutes of Health guidelines.

The authors performed a comprehensive analysis of medical costs using U.S. data that include the upfront costs of surgery as well as the costs associated with subsequent years of care and the need for revision surgery (e.g., cholecystectomy, pancreatectomy). They compare the costs of gastric bypass and gastric banding, which are the 2 most common procedures performed in the United States, although sleeve gastrectomy is being performed more commonly now. Unfortunately, the exact derivation of the costs is only available in an online appendix to the paper and cannot be easily reviewed. It is not clear if the authors studied costs from a societal perspective and included time off work and patient costs.

The authors modelled the outcomes of surgery based on 2 meta-analyses that included 982 published studies. It should be noted, however, that only 5% of the publications were randomized controlled trials (RCTs). The authors determined the rate of remission of diabetes in patients with new onset (56.7%–80.3%) or established diabetes (40%) for both gastric banding and gastric bypass. They were also able to model the complications of surgery with data derived from the same studies. Bariatric surgery had cost-effectiveness ratios ranging between $7 000 and $13 000 per QALY. Patients with new onset diabetes gained more QALYs after surgery than those with established diabetes, and they gained more QALYs from bypass surgery than gastric banding but had a higher surgical cost. To put these costs in context, it is generally considered that interventions with a cost of less than $50 000 per QALY are cost-effective.

Most importantly in this type of study, the authors went on to perform sensitivity analyses. They varied the possible outcomes of surgery from one-half to 2 times the observed rates to see if this affected the cost-effectiveness of surgery. They found that the incremental cost-effectiveness of surgery did not change much unless they varied the QALY improvement or the weight loss associated with surgery. Finding an operation to be cost-effective even when the outcomes vary widely strongly suggests that the findings are robust.

Unfortunately the authors did not find surgery to be cheaper overall than medical management. However, they modelled only the costs of diabetic care and did not factor in potential cost savings for other conditions related to weight loss. For example, decreasing blood pressure or decreasing the need for joint replacement could definitely reduce costs for surgical patients.
Bariatric surgery has become an important option in the management of diabetes and should be considered in obese patients with this disease. The study by Horger and colleagues provides a thorough analysis of the costs and benefits of gastric bypass and gastric banding and finds the procedures to be cost-effective. In addition, three recent RCTs of bariatric surgery versus medical management in obese patients with type 2 diabetes have been published. The one by Dixon and colleagues showed that gastric banding is superior to medical management at 2 years. Mingrone and colleagues compared gastric bypass and biliopancreatic diversion to medical management. No patients in the medically managed arm had remission of diabetes at 2 years, while 75% of those who underwent biliopancreatic diversion were in remission. Schauer and colleagues compared gastric bypass and gastric sleeve to intensive medical management. At 1 year, 12% of the medically managed patients, 42% in the gastric bypass group and 37% in the gastric sleeve group had a hemoglobin A1C of 6.0% or less. Thus, all of the commonly performed bariatric procedures have been shown to be effective in the short term for the management of type 2 diabetes.

What remains to be further defined is the most appropriate time to intervene surgically in patients with type 2 diabetes (at what BMI, at what illness duration, and at what age?). Also to be defined is the most appropriate procedure (gastric band, gastric bypass, biliopancreatic diversion, or gastric sleeve). While this will take some time to assess, it is clear that bariatric surgery should be discussed with patients as an option for treatment of type 2 diabetes and obesity. The results of the study by Horger and colleagues should encourage surgeons, physicians, insurers and policy makers to improve access to bariatric/metabolic surgery for morbidly obese patients with type 2 diabetes.

The importance and relevance of this cost-effectiveness study lies in the way in which it promotes a unique opportunity for general surgeons to play a pivotal role in the definitive management of diabetes. Departments of surgery will have to prepare for a further increase in demand for a procedure with already long wait lists and limited access.

Competing interests: None declared.

References

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.

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IDENTIFICATION AND USE OF OPERATING ROOM EFFICIENCY INDICATORS: THE PROBLEM OF NOT PERFORMING THE RIGHT SEARCH WITHIN PUBMED

Drs. Fixler and Wright¹ should be commended for demonstrating that operating room (OR) performance indicator definitions vary in literature and among children’s hospitals. Unfortunately, I do not agree with their conclusion that the most logical course would be for professional associations to agree upon and develop common metrics and definitions. Their conclusion is based on a limited review of papers that are not always relevant.

First, the Procedural Times Glossary has been the leading source for OR definitions since 1997.² Papers describing operational research in ORs use this glossary.³ Papers concerning operational research within the OR can be found online (http://www.franklindexter.net/bibliography_TOC.htm).

Based on this evidence, I conclude that there are clear definitions for monitoring OR performance indicators. An additional conclusion is that hospitals continue to use their own definitions. This needs to be solved by sending surgeons, anesthesiologists and managers of ORs to courses where they can learn which indicators to use and how to use them.

Fixler and Wright call for us to use the OR resources in both an efficient and effective way. Here they make a mistake. Indeed, monitoring the operational performance of the OR may contribute to the use of OR resources in an efficient way. However, the call to use OR resources in an effective way is a faulty statement. According to the Institute of Medicine’s Committee on Quality Health Care in America, effective care “is based on providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).”⁴ Here the patient clinical parameters are of interest and not, for example, the utilization rate of the OR.

In conclusion, performing an accurate search in PubMed will show that the actual problem of agreed-upon definitions in literature, as described by the authors, does not exist.

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References

COMMENT ON “IDENTIFICATION AND USE OF OPERATING ROOM EFFICIENCY INDICATORS: THE PROBLEM OF DEFINITION”

It was with profound interest that we read the commentary written by Tamas Fixler and James G. Wright in the August 2013 issue of the Canadian Journal of Surgery. The commentary deals with the identification and measurement of operating room (OR) performance indicators, addressing the variation among hospitals in terms of which indicators are collected and analyzed.

Common definitions among hospitals are essential for external benchmarking. Although the authors identified 8 indicators as the most critical for monitoring OR performance in 15 children’s hospitals in Canada, definitions for these indicators vary in literature and across hospitals.

In the Netherlands, OR departments of all 8 university medical centres (UMCs) established a nationwide benchmarking collaboration in 2005 that is still active today. The objective of the collaboration is to improve OR performance by learning from each other through exchanging best practices. Each UMC provides records for all performed surgical cases to a central OR benchmark database. This extensive database, presently comprising more than 1 million surgical case records, is used to calculate key performance indicators related to the utilization of OR capacity. The database is also used for multicentre research on OR scheduling topics and OR efficiency.

At the start of this collaboration, a set of performance indicators, particularly from a utilization perspective, was identified. Next, data definitions of time periods and methods of registration, as well as definitions of performance indicators, were harmonized among all benchmarking participants, a process that took nearly 2 years. An independent data management centre enters the longitudinal data collection in the central OR benchmark database. This centre provides professional expertise by facilitating and processing data, and by performing reliability checks before data are deemed ready for analysis.
Our collaboration frequently meets to discuss data analysis results and explore processes and practices beyond the data. Through promoting dialogue among UMCs, a learning environment has been created.

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THE AUTHORS RESPOND

We thank Dr. Stepaniak for his interest in our commentary on the identification and use of operating room (OR) efficiency indicators. While the Procedural Times Glossary, developed by the Association of Anesthesia Clinical Directors (AACD), is a leading source of procedural time definitions in support of economic and efficiency analyses within the OR, this does not negate the fact that variable performance indicator definitions nonetheless exist in the body of OR efficiency literature. Moreover, despite the availability of leading sources of definitions such as the Procedural Times Glossary, differences in how hospitals define key OR performance indicators persist.

Furthermore, even the AACD’s Procedural Times Glossary may not always be adequate if one wants to ensure consistent performance indicator data collection across multiple hospitals. For example, the AACD defines “turnover time” as the “time from prior patient out of room to succeeding patient in room time for sequentially scheduled cases.” However, while this definition is clearly meant to exclude idle time between nonsequentially scheduled cases, it does not entirely address potential exclusions, such as delays between sequentially scheduled cases unrelated to room cleaning and preparation (e.g., patient arrives late); how these situations are handled varies significantly across hospitals and materially impacts how the indicator is collected.

Another example is the definition of “on-time starts,” defined as the patient being in the OR at the scheduled time. This does not consider, however, whether certain late starts should be excluded (e.g., owing to delayed access to postoperative beds, as is the case at some hospitals).

Thus, we do believe that there is room for professional associations to agree to develop common metrics and operational definitions, perhaps using the AACD’s Procedural Times Glossary (or an equivalent source) as a starting point, closing any gaps from there.

Regarding Dr. Stepaniak’s second point, while performance indicators may not contribute to the effective use of resources as defined by the Institute of Medicine’s Committee on Quality Health Care in America, they may do so under another definition, such as the Oxford English Dictionary, which defines “effective” as “having an intended or expected effect.” If using resources efficiently leads to the most patients having surgery in the best way (i.e., on time starts, no delays, no cancellations), then use of OR performance indicators to monitor operational performance can indeed lead to the effective use of resources.

In addition, we also thank Dr. Kazemier and Ms. van Veen-Berkx for their interest in our commentary and note that the Dutch experience, whereby it took 2 years to harmonize OR performance indicator definitions and reporting across 8 university medical centres, speaks to the complexity of the undertaking and the continuing lack of universal standards for indicator definitions.

Moreover, some Canadian provinces have also had some success in harmonizing OR performance indicators, such as the OR Benchmarks Collaborative in Ontario. As our commentary has demonstrated, though, variable indicator definitions persist and harmonizing them nationally may be particularly challenging due to the provincial delivery of health care.

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Reference

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Authorship credit will be assigned only to individuals who meet ALL of the following criteria. Each author must have

• contributed to study conception and design OR data acquisition OR data analysis
• contributed to writing OR critically reviewing the article
• approved the final version of the article submitted for publication

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The CJS endorses the statement of the International Committee of Medical Journal Editors (available at www.icmje.org) concerning the registration of clinical trials. In brief, the journal requires, as a condition of consideration for publication, registration of clinical trials in a public trials registry at or before the onset of patient enrollment. For CJS, this policy applies to any clinical trial that starts enrolment after Jul. 1, 2006. A clinical trial is defined as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relation between a medical intervention and a health outcome. Studies designed for other purposes (e.g., Phase I trials) are exempt. The journal does not endorse a specific registry but, when selecting a registry, authors should use the criteria mentioned in the statement of the International Committee of Medical Journal Editors.
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Les auteurs sont priés de consulter les « Exigences uniformes pour les manuscrits présentés aux revues biomédicales ». Il faut toutefois retenir qu’en général, il faut présenter un matériel original, utiliser des méthodes appropriées et présenter des données valides pour étayer les conclusions. Le sujet devra intéresser les chirurgiens et les chirurgiens en formation du Canada. Il faut rédiger le manuscrit le plus brièvement possible et ajouter des tableaux et illustrations uniquement s’ils ajoutent au texte.

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- les coordonnées de l’auteur correspondant (adresse postale, numéros de téléphone et de télécopieur et adresse électronique)

Résumé

Tous les articles sauf les séries de cas doivent comporter un résumé de 150 à 250 mots, de préférence structuré, avec les mêmes rubriques qui apparaissent dans le corps du texte, comme suit :
- Contexte
- Méthodes
- Résultats
- Conclusion

S’il ne convient pas d’utiliser ces titres dans l’article, fournir un résumé non structuré à la fois descriptif et informatif.

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