Teaching surgery takes time: the impact of surgical education on time in the operating room

A Canadian population-based description of the indications for lower-extremity amputations and outcomes

The relevance of preoperative ultrasound cervical mapping in patients with thyroid cancer

Very early initiation of chemical venous thromboembolism prophylaxis after blunt solid organ injury is safe
HIDRADENITIS SUPPURATIVA

Dr. Shear, Dr. Tran and Dr. George discuss Hidradenitis Suppurativa.

Q. WHAT IS HS?
A. Hidradenitis Suppurativa (HS) is a chronic, painful, inflammatory skin disease which affects 1-4% of the general adult population.1,4 It is characterized by boils usually occurring where certain sweat glands are located, such as under the breasts, buttocks and inner thighs. The boils can develop and connect, forming draining sinuses which discharge foul-smelling pus.1,2,4

Q. WHAT CAUSES HS?
A. The cause of HS is unclear. It is thought that certain genetic markers and defects within hair follicles are at the root of the disease.2 Risk factors include smoking and obesity.1 About one-third of patients report a family history of HS.1 HS has been reported to co-occur with several comorbid conditions—mostly, inflammatory bowel disease.1

Q. HOW DOES HS IMPACT QUALITY OF LIFE?
A. HS is often undiagnosed or misdiagnosed.2,3,4 It interferes with social interactions, job performance and intimate relationships—often leading to isolation.1 It is painful and causes embarrassment.1

Q. DO PEOPLE SUFFERING FROM HS GO TO THE ER FOR TREATMENT?
A. People with HS come to the emergency room in severe pain and discomfort requiring assistance with the draining of the boils during a flare-up.4 It's not unusual for patients to go home undiagnosed.4

Q. IS THERE A CURE FOR HS?
A. There is currently no cure for HS.4,5 Early diagnosis and proper management is important for a patient’s quality of life.1 The first step for those with HS is to speak to their dermatologist to get an accurate diagnosis.1

Q. HOW CAN HS BE TREATED?
A. Medical treatments for HS have included antibacterial washes, topical clindamycin, various systemic antibiotics, hormonal therapies, systemic retinoids, laser treatment, intralesional steroid injections and biologics.3 Surgical de-roofing or wide excision procedures have long been the definitive treatment for severe HS.3 There is no guarantee that HS will not recur in the previously excised areas.3

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Caregiver fatigue and surrogate end-of-life decision making

The Supreme Court of Canada ruling in the case of Carter versus Canada (2015 SCC 5) concerns the right of a competent adult to a physician-assisted death if his or her suffering from a grievous and irremediable medical condition is intolerable. Discussions of the ruling have extended the parameters to include competent minors and advanced directives. They may also have altered the way we look at a separate but related end-of-life scenario, withdrawal of life-support; the number of anesthetic agents used to cover a patient during the withdrawal of life-support appear to have increased recently.

How is it that all our legal and religious traditions imply that an abhorrence of terminating life is built into civilization, and yet a group of empathetic citizens believe that it may have a role in caring for the seriously ill? Can the decision to end the life of a patient be made impartially?

The clinical situation described in the ruling is rare in the spectrum of end-of-life scenarios. The vast majority of patients will not be able to communicate their consent to termination. Most of us chose our life’s companion to be the person who will make our critical decisions when we are incapable. Even though we might hope to guide them by making our wishes known in advance, all decisions are made in their own moment, and upon these delegates we impose the full responsibility of deciding.

While most patients prefer their next-of-kin to be their substitute decision maker, lawyers recommend a third party who will not benefit financially or otherwise by the patient’s death. Having a State or hospital committee decide is not acceptable because of past errors made with respect to forced sterilization or memories of Nazi euthanasia programs. However, even an acceptable third party may not be able to remain impartial.

Two doctors would probably be required to determine medical issues in end-of-life protocols. The duplication is an acknowledgement of the subjective nature of such issues and of the risk of conflicts of interest. The strategy of using 2 doctors’ opinions originated in France to allow autopsies within 24 hours of death and was later applied to committing patients for psychiatric treatment and to the declaration of brain death for transplantation. Should the patient’s own doctor be 1 of the 2? While a doctor’s opinion is unlikely to be influenced by the loss or gain of fees, doctors may share with the patients’ representatives a different conflict of interest: the risk of caregiver fatigue.

It is well known that the neural networks stimulated by fear and pain are also activated by observing, or even imagining, the events that cause the fear or the pain. Caregivers suffer with those for whom they care. Loved ones who vicariously experience pain and suffering in ultimately futile care have difficulty coping. Wanting to prevent it from happening again is a natural aspiration. Surgeons try to learn from the experience in order to make the care easier on future patients and to make the outcomes more successful. For others, termination of that phase of life might be considered a better option to prevent futile suffering. There are some diseases, such as advanced amyotrophic lateral sclerosis (ALS), where the prospect of progress appears remote, reinforcing the urge to end the hopeless phase “with dignity.”

The stress of care and prolonged exposure to suffering affect family and professional caregivers. Different forms of caregiver fatigue are known, but poorly defined. The ALS Society of Canada believes compassion fatigue occurs when caregivers begin to feel the pain and suffering of the patient so that they lose a sense of themselves and their role in the patient’s care. Sixteen symptoms are listed. Some of these symptoms are similar to those of people with depression, such as difficulty concentrating or sleeping; others are similar to those of people with addiction, such as obsession or difficulties at work. Irritability and difficulty making decisions are hallmarks of compassion fatigue.

Caregiver fatigue may be worsened by the roller coaster of life-saving procedures followed by complications and the inevitable hurdles before recovery. Most surgeons have watched families go from wanting everything done to despair regarding any treatment and then back again — all within hours or days. Surgeons who have invested a lot of effort trying to save a patient risk the same emotional confusion. To build resilience to caregiver fatigue, surgeons need to recognize warning signs and seek a colleague’s support in the patient’s care. The modern trend to rotating team care inhibits the guidance a surgeon can offer families. All of this may

The views expressed in this editorial are those of the author and do not necessarily reflect the position of the publisher.
result in a premature decision to withdraw life support. It also prevents an impartial decision to terminate life.

The empathy that professional and family caregivers have for seriously ill patients is hard-wired into our brains. The same neural networks are stimulated in third parties reviewing evidence of a patient’s suffering. This neurologic mechanism makes us want to end suffering, even if it means terminating life. However, it is the same mechanism that prevents us from making the truly impartial decision necessary to terminate life. An innate understanding of this dilemma is the basis for our customary prohibition on terminating life. It is a dilemma that we may never be able to solve.

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Coeditor, Canadian Journal of Surgery
Competing interests: None declared.
DOI: 10.1503/cjs.002616

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La fatigue des aidants et la prise de décisions en fin de vie par autrui

Les opinions exprimées dans cet éditorial sont celles de l’auteur et ne reflètent pas nécessairement la position de l’éditeur.

La décision de la Cour suprême du Canada dans l’affaire Carter c. Canada (2015 CSC 5) concerne le droit d’un adulte capable de décision à recourir à l’aide médicale à mourir si ses souffrances, dues à un problème de santé grave et irréparable, lui sont intolérables. En plus d’avoir élargi les paramètres pour inclure les mineurs capables de décision et les directives préalables, les discussions sur la décision pourraient aussi avoir influencé notre vision d’un scénario de fin de vie distinct mais relié : le retrait du maintien des fonctions vitales. Le nombre d’agents anesthésiants utilisés pour soulager un patient durant le retrait semble d’ailleurs avoir augmenté récemment.

Comment concilier le fait que, d’une part, toutes nos traditions juridiques et religieuses supposent que l’aversão à mettre fin à la vie est intrinsèque à la civilisation et que, d’autre part, un groupe de citoyens empathiques croit que l’aide à mourir pourrait avoir un rôle dans les soins aux personnes gravement malades? Une décision de mettre fin à la vie d’un patient peut-elle être impartiale?

La situation clinique décrite dans la décision survient rarement dans le continuum des scénarios de fin de vie. La vaste majorité des patients ne sont pas en mesure de communiquer leur consentement à mourir, et la plupart désignent leur partenaire de vie pour prendre des décisions essentielles à leur place lorsqu’ils en seront incapables. Même si les patients espèrent guider leurs proches en leur faisant connaître leurs volontés à l’avance, chaque décision doit être prise dans un contexte unique, et c’est sur les épaules de ces délégués que reposera la pleine responsabilité du choix.

Bien que la plupart des patients préfèrent que leur plus proche parent prenne les décisions à leur place, les avocats recommandent de faire appel à un tiers qui ne profitera ni financièrement ni autrement du décès du patient. Par ailleurs, il ne serait pas acceptable de confier ces décisions à l’État ou à un comité d’hôpital en raison des erreurs survenues dans le passé, notamment la stérilisation forcée et les programmes d’euthanasie instaurés sous le régime nazi. Cependant, même un tiers pourrait être incapable de rester impartial.

Les protocoles de fin de vie exigeront probablement l’intervention de 2 médecins pour cerner les problèmes médicaux. Cette redondance confirme la nature subjective de ces questions et le risque de conflit d’intérêts. Utilisée pour la première fois en France pour rendre possibles les autopsies moins de 24 heures après le décès, la stratégie du recours à 2 médecins a ensuite été appliquée à la décision d’interner des patients pour un traitement psychiatrique et à la déclaration de mort cérébrale aux fins de transplantation. Le médecin du patient devrait-il compter parmi les décideurs? Bien que leur opinion risque peu d’être influencée par la perte ou le gain d’argent, les médecins peuvent partager avec les représentants des patients un autre type de conflit d’intérêts : le risque de fatigue des aidants.

On a déjà démontré que les réseaux de neurones stimulés par la peur et la douleur sont aussi activés par l’observation, ou même l’imagination, d’événements qui
causent ces réponses. Les aidants souffrent avec ceux dont ils prennent soin. Les proches qui vivent par procuration la douleur et la souffrance causées par des soins ultimement futiles ont de la difficulté à résister à la pression. Le désir d’empêcher que la souffrance se reproduise est naturel. Les chirurgiens essaient d’en tirer des leçons afin d’améliorer les soins qu’ils donneront à leurs futurs patients et les résultats qu’ils obtiendront. Pour d’autres, l’interruption de la vie à cette étape peut être considérée comme une option préférable pour prévenir des souffrances inutiles. Pour certaines maladies, comme la sclérose latérale amyotrophique (SLA) avancée, les perspectives de progrès semblent éloignées, ce qui renforce le désir de mettre fin « avec dignité » à une phase qui ne permet aucun espoir.

Le stress lié aux soins et l’exposition prolongée à la souffrance ont des répercussions sur les aidants familiaux et professionnels. On a recensé plusieurs formes de fatigue des aidants, mais elles sont mal définies. La Société canadienne de la SLA croit que la fatigue de compassion survient quand les aidants commencent à ressentir la douleur et la souffrance du patient et perdent de vue leur identité et leur rôle dans les soins. L’organisme a répertorié 16 symptômes : certains ressemblent à ceux de la dépression, comme la difficulté à se concentrer ou à dormir; d’autres se rapprochent de ceux de la dépendance, comme l’obsession ou les problèmes au travail. L’irritabilité et la difficulté à prendre des décisions sont des traits distinctifs de la fatigue de compassion.

La fatigue des aidants peut être aggravée par le maélstrom des interventions salvatrices suivies de complications et des inévitables obstacles qui précèdent le rétablissement. La plupart des chirurgiens ont vu des familles alterner entre le désir de tout tenter et le désespoir face à tout traitement, et ce, en quelques heures ou quelques jours. Les chirurgiens qui ont multiplié les efforts pour sauver un patient risquent la même confusion émotionnelle. Pour accroître leur résilience, ils doivent reconnaître les signaux d’alarme et chercher l’aide d’un collègue pour soigner le patient. Par ailleurs, la tendance moderne à la rotation des équipes de soins limite le soutien que peut offrir un chirurgien aux familles. Tous ces facteurs risquent de mener à un retrait prématuré du maintien des fonctions vitales. Ils mettent aussi en jeu l’impartialité d’une décision concernant l’interruption de la vie.

L’empathie qu’eprouvent les aidants professionnels et familiaux pour les patients gravement malades est bien ancrée dans nos cerveaux. Les mêmes réseaux de neurones sont stimulés chez des tiers qui étudient le cas d’un patient souffrant. Ce mécanisme neurologique nous pousse à vouloir mettre fin à la souffrance, même s’il faut abréger la vie. Cependant, ce même mécanisme nous empêche de faire preuve de l’impartialité nécessaire pour prendre la décision de mettre fin à une vie. C’est une compréhension innée de ce dilemme qui nous pousse conventionnellement à interdire de mettre fin à la vie. Voilà un dilemme qu’il ne nous sera peut-être jamais donné de résoudre.

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Intérêts concurrents: Aucun déclaré.

DOI: 10.1503/cjs.003616

Références

Trauma simulation in bilingual Canada: Insurmountable barrier or unexpected strength? Insights from the first bilingual S.T.A.R.T.T. course

The Standardized Trauma and Resuscitation Team Training (S.T.A.R.T.T.) course focuses on training multidisciplinary trauma teams: surgeons/physicians, registered nurses (RNs), respiratory therapists (RTs) and, most recently, prehospital personnel. The S.T.A.R.T.T. curriculum highlights crisis management (CRM) skills: communication, teamwork, leadership, situational awareness and resource utilization. This commentary outlines the modifications made to the course curriculum in order to satisfy the learning needs of a bilingual audience. The results suggest that bilingual multidisciplinary CRM courses are feasible, are associated with high participant satisfaction and have no clear detriments.

SUMMARY

The Standardized Trauma and Resuscitation Team Training (S.T.A.R.T.T.) course focuses on training multidisciplinary trauma teams: surgeons/physicians, registered nurses (RNs), respiratory therapists (RTs) and, most recently, prehospital personnel. The S.T.A.R.T.T. curriculum highlights crisis management (CRM) skills: communication, teamwork, leadership, situational awareness and resource utilization. S.T.A.R.T.T. was designed to meet the needs of each participant discipline while bolstering common skills required by all team members.

Previously, the course has been delivered only in English; however, the opportunity of a national conference in Quebec spurred its next evolution: to teach simultaneously in English and French and to address language barriers. To our knowledge there are no other published reports concerning the challenges and successes associated with bilingual simulation courses.

S.T.A.R.T.T. is typically held alongside national meetings of the Canadian Surgery Forum (CSF) and the Trauma Association of Canada (TAC). Unlike multidisciplinary TAC meetings, the CSF is typically for surgeons only. Therefore the physicians participating in the S.T.A.R.T.T. course at this meeting generally come from across Canada and speak only English. On the other hand, the RNs and RTs who participate are generally recruited locally. For this particular course in French-speaking Quebec, the RNs and RTs were again recruited locally, and all were primary French speakers professionally (though many could communicate to some degree in English). There was concern about teaching a course that promotes realistic teamwork and communication but not doing so in all attendees’ working language. This led to extensive efforts to ensure that S.T.A.R.T.T not only bridged the discipline gap, but also the language gap.

First, the conference was co-hosted by an English- and a French-speaker, who co-introduced each session. Introductory lectures on CRM and trauma teams were then accompanied by printed slides offered in both English and French.
Next, participants were divided into mixed-language trauma teams for introductory “icebreaker” simulations. These simulations were deliberately low-fidelity (to avoid cognitive overload) and nonmedical (to focus on relationship building and team communication). Specifically, this exercise consisted of teams building paper chains of varying design complexity and following instructions of varying complexity. Such exercises can illustrate key aspects of teamwork, including the need to communicate clearly, to cite names, to close the loop (i.e., all instructions are confirmed as received and confirmed when completed), to ensure a shared mental model (i.e., everyone is “on the same page”), to establish a leader and to decide whether tasks can be broken into parts. These exercises allow team members to bond, gain empathy and foster trust before applying medical knowledge or manual skills.

The course then progressed to more complex high-fidelity trauma simulations. Our usual format has senior instructors/expert debriefers spend the day as “team coaches” with their assigned teams. This avoids duplication of teaching points and gradually builds the teams’ sophistication in terms of communication and teamwork. We maintained this structure but provided 2 coaches (1 English and 1 bilingual) to each team.

Many CRM ideas originate with aviation. Pilots refer to “flying by voice” as much as “flying by instruments.” Similarly, trauma teams may “resuscitate by voice” as much as by drugs or equipment. Therefore, we added simulations of telephone calls to the S.T.A.R.T.T. course. These simulations further highlighted communication as an essential trauma skill separate from factual recall or manual dexterity. They also allowed participants working in their second languages to focus purely on communication. However, we discovered unique benefits of these telephone simulations. They were inexpensive and logistically simple; all that was needed were telephones in different rooms and an instructor assuming the role of a geographically distant doctor. This exercise also prompted a discussion about how telephone referrals differ across Canada, which further led to discussions about how they might be improved, the need for practitioners to understand their local systems and how urban health care workers can support those in relatively underserviced areas.

We expected course feedback to focus on the language issue. Interestingly, it did not; as with previous courses, comments focused on course content. This may explain why we received predominantly positive feedback and why it was largely identical to that from previous courses. Because participants did not even comment on language, it may have been a nonissue for attendees, meaning faculty concerns were unfounded. Alternatively, the lack of feedback on language may mean that the extra efforts were worthwhile.

![Fig. 1. Participant responses to satisfaction survey by first language of participant, compared with historical data from previous courses.](image-url)
Language gaps likely exist across specialties, even when all specialists speak the same root language. The term “Tower of Babel syndrome” has been coined to describe situations when, for example, the same patient is identified by nurses as “bed 4,” by surgeons as “the perforated bowel,” by intensivists as “the septic shock,” and by anesthesiologists as “the difficult airway.” By having health care professions separated by actual languages, we were able to illustrate the potential dangers inherent in our medical dialects.

The language gap appeared to reinforce the CRM teaching points by emphasizing that communication is more than just what you say. While verbal communication refers to the words spoken, paraverbal communication refers to how loud, emotional or rushed that communication is, and nonverbal communication refers to eye contact, hand gestures, body language and facial expressions. Communication courses typically focus solely on verbal communication even though other forms are just as important or more important if verbal and nonverbal communication are discordant (e.g., you say, “I don’t need help,” but your facial expressions suggest otherwise). Our language gap spurred a greater discussion of verbal, paraverbal and nonverbal communication.

Despite the limitations of participant course evaluations, there was no evidence that the language gap was a hindrance to the course. The bilingual format may have helped both attendees and faculty understand the importance of communication and team empathy. The format provided a “disruptive innovation” that helped the S.T.A.R.T.T. course to evolve further. Bilingual simulation also provided the stimulus to test novel ideas that can supplement the course, regardless of future location or language.

While the course was objectively and subjectively successful, it had limitations. Preparation time was longer, instructors were selected for language ability as well as content expertise, and, while perhaps not necessary, we pre-emptively reduced attendee numbers. Because instruction and debriefing occurred in both languages, extra time was spent translating, repeating and speaking more slowly. This presumably meant less content was covered overall, duplication for bilingual participants and periodic disengagement for unilingual participants.

Our results suggest that bilingual multidisciplinary CRM courses are feasible, are associated with high participant satisfaction and have no clear detriments. However, this high satisfaction was associated with extra preparation and additional human resources. The increased focus on communication did not obviously detract from other learning objectives. Instead, 2 languages may have been an unexpected plus.

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Competing interests: None declared.

Contributors: All authors contributed substantially to the conception, writing and revision of this article and approved the final version for publication.

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Canadian Association of General Surgeons position statement: recommendations for surgeons with blood-borne communicable diseases

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Accepted for publication
Nov. 16, 2015

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DOI: 10.1503/cjs.007615

SUMMARY

The potential for transmission of hematogenously transmitted pathogens during exposure-prone procedures is a clinically important concern to both patients and surgeons. There is inconsistency among regulatory bodies in Canada regarding the management of infection risk among surgeons, particularly with regard to screening and the postexposure management of infected surgeons. The Canadian Association of General Surgeons commissioned a task force to review the evidence regarding the management of blood-borne pathogens and transmission risk during surgical procedures. The results of this review indicate a need for several jurisdictions to update their guidelines to reflect current evidence-based practices.

Exposure-prone procedures (EPPs) are those in which the surgeon is exposed to the tissues in a patient’s body cavity and there is a possibility of blood contamination via sharp objects/instruments or sharp tissues (e.g., bone). An overwhelming concern during EPPs is the potential for transmission of hematogenously transmitted pathogens between patients and surgeons. The guidelines adopted by provincial regulatory authorities with regard to EPPs are relevant and of great importance to general surgeons in Canada, who routinely perform these procedures. While surgeons consider it their professional and moral obligation to provide medical care to patients regardless of the risk for infection, there is an equal obligation to protect patients from the risk of transmission of blood-borne viruses (BBVs) from surgeons. In developing this position statement, the primary consideration of CAGS and its members was the protection and minimization of risk to patients.

In 1991 the Centers for Disease Control (CDC) published recommendations to prevent the transmission of BBVs from infected health care providers to patients during the performance of EPPs. These recommendations advocated that there be no restrictions for BBV-positive physicians who do not perform EPPs; that providers who perform EPPs should be aware of their hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) status; that BBV-positive providers should have their activities guided by expert panels; and that BBV-positive providers who perform EPPs should notify patients in advance of their seropositivity. Based on the CDC and the Public Health Agency of Canada (PHAC) guidelines and the desire for regulatory bodies to adopt a “zero-risk” model, several provincial colleges advocated mandatory testing for BBVs as well as restrictive and punitive measures for physicians who tested positive for BBVs, including mandatory disclosure to patients and restriction of practice. Regulatory bodies also selected thresholds of viral activity (i.e., HBeAg positivity or viral DNA/RNA levels) for EPP restrictions without appropriate evidence.

In recent years, the CDC and the Society for Healthcare Epidemiology of America (SHEA) have issued up-to-date evidence-based guidelines for
the management of health care workers infected with BBVs, including HBV, HCV and HIV. These have been recognized and adopted by some licensing bodies, including the College of Physicians and Surgeons of Ontario. However, the PHAC and many other provincial regulatory bodies have failed to update their policies on this matter.

In Canada there is a lack of synchronization and transparency regarding the issue of BBV-infected health care workers across provinces and territories. Not all jurisdictions have published guidelines, and in some provinces it is the regulatory colleges that have addressed this issue, while in others it is individual institutions and/or organizations that have addressed it. As the Canadian Association of General Surgeons (CAGS) represents surgeons who routinely perform EPPs, the elimination of transmission of BBVs between general surgeons and their patients and the management of BBV-infected surgeons has been identified as a relevant concern of the association. The recommendations provided by CAGS are informed by previous publications on the topic, including those recently published by the Canadian Medical Protective Association (CMPA). CAGS calls on all provincial Colleges to update their guidelines and policies on this matter to reflect the current evidence and understanding of the risk of transmission.

RECOMMENDATIONS

There is currently a lack of consistency across Canada in the management of surgeons found to be infected with BBVs, with many jurisdictions publishing guidelines that are not based on evidence. The primary concern must be the protection of patients; however, policies that are not evidence-based and too restrictive can have negative implications for surgeons and the public. CAGS proposes the following principles in the management of surgeons who perform EPPs and are infected with BBVs, and provides specific suggestions for HBV, HCV and HIV based on the current evidence of risk of transmission.

Recommendations for the management of risk of BBV infection in surgeons who perform EPPs

1. All surgeons performing EPPs should be vaccinated against BBVs when effective vaccines exist.
2. All surgeons performing EPPs (including abdominal, thoracic, breast, head and neck surgery) should be aware of their BBV status.
3. Screening of surgeons for BBVs should occur before potential or presumed exposure. Recommendations on routine screening for surgeons should be evidence-based. There is currently no evidence to support the mandatory or regular, intensive (i.e., yearly) screening advocated by some jurisdictions.
4. Surgeons should at all times observe standard universal precautions when performing an EPP in any patient.
5. Endoscopy and robotic surgery are considered minimal-risk procedures and should not be classified as EPPs.
6. Surgeons should consult with an infectious disease expert and/or their hospital/regional workplace health and safety (WHS) department if they have been exposed to blood or body fluids by percutaneous (e.g., needle stick) or mucosal routes for the purpose of testing and potential prophylaxis. Unless there is clear evidence of risk to patients, surgeons should be permitted to perform EPPs until definitive postexposure testing is performed.
7. Following exposure to potential infection, surgeons should consult with the appropriate hospital and infectious disease resources and comply with prophylaxis treatment, where available.

Principles for the management of surgeons who perform EPPs and are infected with BBVs

1. Surgeons infected with BBVs (HBV, HCV, HIV) should receive support, their privacy should be respected, and they should be encouraged to seek expert advice and treatment.
2. Evidence-based policies should require “reasonable measures” to minimize the risk of transmission to patients during EPPs. Procedures should be stratified according to perceived risk of transmission according to SHEA guidelines.
3. Surgeons infected with BBVs should not be restricted from performing category 1 and 2 EPPs as long as the risk of transmission is considered to be negligible.
4. Restrictions should be placed on BBV-infected surgeons performing category 3 EPPs if their viral activity is above a threshold that indicates a risk for transmission. The threshold at which surgeons should be restricted depends on the specific infection (see the sections that follow) and should be based on evidence of risk for transmission to patients.
5. The degree of restrictions depends on accurate and expert assessment of the surgeons’ infectivity and the surgical procedures performed.
6. Surgeons should be allowed to resume performing category 3 EPPs once their viral load falls or once it is maintained below an approved threshold with appropriate antiviral therapy, where the risk for transmission is considered to be minimal.
7. Programs should be in place to retrain surgeons who cannot control their infection below the risk threshold with treatment or to assist them to refocus their practices on non-EPP activities (e.g., endoscopy). Surgeons should not be required to disclose their infection status to patients in advance except in
circumstances where documented transmission from that surgeon to a patient has occurred.

**Hepatitis B**

There are approximately 350 million people with chronic HBV infection worldwide; however, the prevalence in Canada is quite low, with HBV infection rates estimated at 0.1%–0.5% of the general population. Since 1990 the rate of new HBV infection has decreased 5-fold owing to initiatives to prevent person to person and perinatal transmission and owing to vaccination programs. Nonetheless, the prevalence of HBV infection in Canada has been increasing owing to immigration from areas of endemic HBV infection. Physicians may acquire HBV through occupational exposure, or physicians born in endemic regions may have acquired the virus through vertical or early horizontal childhood transmission.

There have been substantial developments in understanding the risk of transmission to patients from HBV-infected health care providers. In addition, the general adoption of universal precautions, the declining prevalence of HBV, and the development of effective antiviral therapy have significantly altered our understanding of the HBV transmission risk. Furthermore, there is an enhanced understanding that non–evidence based punitive measures by regulatory bodies may lead surgeons to avoid HBV testing, conceal positive tests and delay or decline HBV treatment, which places both patients and physicians at increased risk.

The risk of transmission from an HBV-infected surgeon to a patient has been estimated by PHAC at between 24 and 2400 transmissions per 1 million procedures. Since 1992 there has been only 1 reported case in Canada and 1 case in the United States of transmission of HBV from an infected surgeon to patients. Transmission has occurred from both HBeAg-positive and negative physicians and most implicated health care workers had high viral DNA levels (i.e., above 1 × 10⁵ general equivalents [GE] or 20 000 IU/mL). Disclosure of a physician’s HBV serology has never been demonstrated to reduce the risk of transmission. Despite its rare occurrence, the infection of a patient with HBV from an infected surgeon is a devastating occurrence and should be avoided at all costs.

**Principles for the management of surgeons exposed to or infected with HBV**

1. All surgeons should be vaccinated against HBV and have postvaccination serology performed to document immunity.

2. Surgeons known to be infected with HBV should be encouraged to seek antiviral therapy to reduce the risk of transmission and for personal health reasons.

3. The monitoring of treatment response and thresholds to perform EPPs should be based on HBV DNA levels obtained using the current standard sensitive polymerase chain reaction assay.

4. Surgeons with HBV DNA levels < 1 × 10⁴ GE/mL (2000 IU/mL) should not be subjected to any restrictions on their practice of EPPs.

5. Surgeons with HBV DNA levels < 1 × 10⁵ GE/mL (20 000 IU/mL) but > 1 × 10⁴ GE/mL (2000 IU/mL) should be allowed to perform lower-risk (category 2) procedures, including laparoscopic, thyroid/parathyroid, thoracoscopic, minor vascular and cutaneous procedures.

6. HBV DNA levels should be checked every 6 months in surgeons with known chronic HBV infection. Transient elevations in HBV DNA can represent spontaneous fluctuations and may not represent increased infectivity in those not undergoing therapy. In those who are receiving therapy, this may represent virologic breakthrough due to nonadherence. A single reading above threshold (> 1 × 10⁴ GE/mL or 2000 IU/mL) should prompt more frequent follow-up of HBV DNA levels until levels fall below threshold or until therapy is altered or introduced.

**Hepatitis C Virus**

HCV infection is a global health concern. The primary means of exposure is parenteral; although historically infecion was most commonly due to blood products transfused before 1990, now the most common causes are intravenous drug use and, in the developing world, percutaneous health care–associated exposure. Therapy for HCV continues to improve rapidly. The newest antiviral agents (sustained viral response) can achieve cure rates of 90%–100% (i.e., HCV viremia undetectable in plasma). The risk of transmission of HCV from an infected physician to a patient is extremely low (< 0.0025%).

**Principles for the management of surgeons exposed or infected with HCV**

1. There is currently no good evidence that mandatory testing of surgeons for HCV infection reduces risks to patients. If testing is performed, HCV antibody negativity is adequate to exclude HCV infection. Conversely, both HCV antibody and HCV RNA positivity should be used to indicate infection.

2. Surgeons in whom HCV infection is confirmed should be encouraged to seek medical assistance and should strongly consider undergoing antiviral therapy.

3. Surgeons infected with HCV who have measurable levels of HCV RNA above a threshold of 1 × 10⁴ GE or virus copies/mL should be restricted from performing category 3 EPPs, but should be permitted to resume
There is currently no good evidence on which to base infected surgeons to their patients, and concerns for should be made to prevent transmission of BBVs from tissue//fluid during surgery or other duties in the provision of medical care. At the same time, every effort is an important concern. Policies regarding BBV testing and the management of BBV-infected surgeons by professionals. Restrictions in scope of practice for BBV-infected surgeons should be guided by evidence-based risk for transmission based on viral activity levels and response to therapy. Surgeons should be allowed to resume a full scope of practice once viral levels have fallen below an evidence-based threshold on appropriate antiviral therapy.

**HUMAN IMMUNODEFICIENCY VIRUS**

Since its original detection there have been great strides made in the detection and treatment of HIV. Combination antiretroviral therapies can suppress the viral levels of HIV to below what is currently detectable in virtually all patients. There have been only 2 cases of surgeon to patient transmission of HIV; both surgeons were not aware of their infections and consequently were not undergoing any therapy. The estimated risk of transmission to a patient is between 1 in 2.69 million and 1 in 26.88 million.

**Principles for the management of surgeons exposed to or infected with HIV**

1. Surgeons infected with HIV with viral levels above a threshold of $5 \times 10^6$ GE/mL should be restricted from performing category 3 EPPs, but should be permitted to resume performing category 3 EPPs while undergoing antiretroviral therapy when their HIV RNA levels fall below $5 \times 10^6$ GE/mL.

2. Regular testing (every 4–6 mo) to ensure that viral load remains below the acceptable threshold should be considered under the supervision of a qualified physician.

**CONCLUSION**

Transmission of BBV between patients and physicians is an important concern. Policies regarding BBV testing and the management of BBV-infected surgeons by provincial regulatory bodies are inconsistent and often are not evidence-based. Surgeons should at all times observe universal precautions to reduce the risk of transmission of BBVs through exposure to infective tissues/fluid during surgery or other duties in the provision of medical care. At the same time, every effort should be made to prevent transmission of BBVs from infected surgeons to their patients, and concerns for public safety must be paramount. Surgeons should be vaccinated against BBVs when effective vaccines exist, and they should be encouraged to report and seek out medical assistance following potential exposure to BBVs so that prophylactic measures can be taken. There is currently no evidence to support routine (i.e., annual) BBV testing for physicians. Surgeons known to be infected with BBVs should be encouraged to disclose their status without fear of reprisals and should be provided with appropriate medical care and support. BBV-infected surgeons with high viral activity that indicates a risk for transmission to patients should be restricted from performing category 3 invasive procedures but should be allowed to perform category 1 and 2 procedures. Restrictions in scope of practice for BBV-infected surgeons should be guided by evidence-based risk for transmission based on viral activity levels and response to therapy. Surgeons should be allowed to resume a full scope of practice once viral levels have fallen below an evidence-based threshold on appropriate antiviral therapy.

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**Competing interests:** None declared.

**Contributors:** All authors contributed substantially to the conception, writing and revision of this commentary and approved the final version for publication.

**References**


Teaching surgery takes time: the impact of surgical education on time in the operating room

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Accepted for publication Dec. 23, 2015

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DOI: 10.1503/cjs.017515

Background: It is generally accepted that surgical training is associated with increased surgical duration. The purpose of this study was to determine the magnitude of this increase for common surgical procedures by comparing surgery duration in teaching and nonteaching hospitals.

Methods: This retrospective population-based cohort study included all adult residents of Ontario, Canada, who underwent 1 of 14 surgical procedures between 2002 and 2012. We used several linked administrative databases to identify the study cohort in addition to patient-, surgeon- and procedure-related variables. We determined surgery duration using anesthesiology billing records. Negative binomial regression was used to model the association between teaching versus nonteaching hospital status and surgery duration.

Results: Of the 713,573 surgical cases included in this study, 20.8% were performed in a teaching hospital. For each procedure, the mean surgery duration was significantly longer for teaching hospitals, with differences ranging from 5 to 62 minutes across individual procedures in unadjusted analyses (all p < 0.001). In regression analysis, procedures performed in teaching hospitals were associated with an overall 22% (95% confidence interval 20%–24%) increase in surgery duration, adjusting for patient-, surgeon- and procedure-related variables as well as the clustering of patients within surgeons and hospitals.

Conclusion: Our results show that a wide range of surgical procedures require significantly more time to perform in teaching than nonteaching hospitals. Given the magnitude of this difference, the impact of surgical training on health care costs and clinical outcomes should be a priority for future studies.

Contexte : Il est généralement admis que la formation chirurgicale est associée à des interventions plus longues. L’objectif de la présente étude était de déterminer l’ampleur de cette augmentation pour les chirurgies courantes en comparant la durée des interventions dans les hôpitaux universitaires et les autres hôpitaux.

Méthodes : Dans le cadre d’une étude de cohorte rétrospective basée sur la population, nous avons recensé tous les résidents adultes de l’Ontario (Canada) qui ont subi une intervention chirurgicale parmi une liste de 14 entre 2002 et 2012. À l’aide de plusieurs bases de données administratives reliées, nous avons constitué la cohorte de l’étude et recueilli des variables associées aux patients, aux chirurgiens et aux interventions. Nous avons déterminé la durée des opérations à partir des dossiers de facturation d'anesthésiologie. Une régression binomiale négative a été utilisée pour modéliser le lien entre le statut des hôpitaux — universitaires ou non — et la durée.

Résultats : Des 713 573 chirurgies à l’étude, 20,8 % ont eu lieu dans un hôpital universitaire. Dans tous les cas, la durée moyenne était significativement plus longue dans les hôpitaux universitaires, les écarts variant de 5 à 62 minutes pour chaque intervention dans les analyses non corrigées (p < 0,001 dans tous les cas). Selon l’analyse de régression, les chirurgies effectuées dans les hôpitaux universitaires étaient associées à une augmentation globale de la durée de 22 % (intervalle de confiance à 95 %, 20 %–24 %), après ajustement pour les variables liées aux patients, aux chirurgiens et aux interventions ainsi que pour la densité de patients pris en charge par les chirurgiens et les hôpitaux.

Conclusion : Nos résultats montrent que de nombreuses interventions chirurgicales durent considérablement plus longtemps dans les hôpitaux universitaires que dans les autres hôpitaux. Étant donné l’ampleur de cet écart, l’étude de l’incidence de la formation chirurgicale sur les coûts des soins de santé et les résultats cliniques devrait être une priorité pour les recherches futures.
Training the next generation of surgeons is an integral part of a sustainable health care system. Surgical training is associated with decreased operative efficiency owing to the time required for instruction in addition to the slower operative speed of trainees compared with senior surgeons. Given the long duration of surgical residency, surgical training can result in substantial cumulative inefficiency, which impacts cost as well as access to limited surgical resources. Previous research has also demonstrated a consistent association between prolonged surgery duration and adverse patient outcomes across a wide range of procedures.

Although previous research has shown that trainee involvement is associated with prolonged surgical duration, the magnitude of this increase has not been estimated at a population level, nor has previous research adjusted for patient- and surgeon-related factors, such as experience of the attending surgeon. Administrative data from the province of Ontario are ideal to address this research question because surgical training in Ontario is concentrated within a limited number of teaching hospitals, such that the impact of training on surgery duration can be estimated by comparing teaching and nonteaching hospitals.

The objective of this study was to establish robust, population-based estimates of the time premium associated with operative training for a variety of common surgical procedures, adjusting for patient-, surgeon- and procedure-related variables. Results from this study can be used by administrators, policy-makers and legislators to make informed decisions about sustainable funding for surgical education and will provide a benchmark for surgical educators as they balance operative efficiency and trainee participation with the potential for adverse time-dependent surgical outcomes.

**Methods**

**Study setting and design**

Residents of the province of Ontario, Canada, (population 13.4 million in 2012) have universal access to hospital care and physician services. Private delivery of such services is prohibited, meaning that all eligible procedures performed in the province are recorded in administrative databases. Relevant data sets were linked using unique, encoded identifiers and analyzed at ICES Western, a satellite site for the Institute for Clinical Evaluative Sciences (ICES) in Toronto, Ont.

In Ontario, surgical and anesthesiology training is concentrated in hospitals associated with 6 medical schools. Nonteaching services in teaching hospitals are rare, and in most programs residents outnumber staff, meaning that it is reasonable to assume that a resident will be present at almost all procedures performed in a teaching hospital. Residents rotate through community hospitals for a small proportion of their overall training. When present in a community hospital, residents would typically replace a surgical assistant.

In this retrospective, multicentre, population-based cohort study, all adult residents of Ontario who underwent any of the index procedures (see the section on procedures and data sources) between Apr. 1, 2002, and Mar. 31, 2012, were included. Cases were excluded if the patient was younger than 18 years, if the procedure was performed emergently or during out-of-office hours (evening, weekend, or holiday; not for appendectomy or hip fracture), if the surgery was for a recurrent condition, if the attending surgeons’ main specialty was atypical for the procedure, or if the surgery was performed without an anesthesiologist (involvement of anesthesiology was required to calculate the outcome). Elective procedures (except tonsillectomy, which is rarely performed with an assistant) performed in nonteaching hospitals were excluded if an assistant did not submit a valid payment claim for the surgery because it was thought that such surgeries may be more likely to include resident assistants. Finally, 2 geographic areas encompassing less than 1.5% of the Ontario population were excluded owing to concerns regarding procedure coding accuracy in those areas. The number of cases excluded at each step is presented in Appendix 1, Table S1 (available at canjsurg.ca).

**Procedures and data sources**

A panel of experts selected procedures from various surgical specialties that represent common procedures that are often managed in both teaching and community settings, but rarely require referral to tertiary care centres. Procedures included laparoscopic cholecystectomy, right hemicolecctiony, appendectomy, unilateral inguinal hernia repair, hysterectomy, hip hemiarthroplasty, open reduction and internal fixation (ORIF) for hip fracture, hip and knee arthroplasty, and tonsillectomy (see Appendix 1, Table S2 for coding information); where applicable, open and laparoscopic procedures were considered separately.

Surgeon and patient characteristics were ascertained from 5 linked health care administrative databases: the Canadian Institute for Health Information (CIHI) Discharge Abstract Database (DAD) and Same Day Surgery (SDS) databases (includes diagnostic, procedural and clinical patient data), the Ontario Health Insurance Plan (OHIP) database (contains health claims), the Registered Persons Database (vital statistics for all residents of Ontario) and the ICES Physician Database (information for all physicians practising in Ontario).

We created exposure groups based on the type of hospital (teaching v. nonteaching) in which the index procedure was performed. Hospital type was determined using a list of academic hospitals published by Health Force Ontario, all of which have surgical training programs. The number of hospitals in each group fluctuated slightly over time.
owing to openings, closures and mergers. In the final year (2012) we identified 19 teaching hospitals and 159 non-teaching hospitals. Although 1 medical school (Northern Ontario School of Medicine) began providing postgraduate training during the study period, the 2 hospitals associated with this program were classified as nonteaching because of the very small number of residents enrolled during the timeframe of this study. The impact of this decision should be minimized by the exclusion of procedures performed at nonteaching hospitals without an assistant. There are no known surgical training programs at any other nonteaching hospitals included in the study.

**Variable definitions**

Duration of surgery was determined on the basis of anesthesiology billing records, using the methodology validated by Redelmeier and colleagues.\(^2^3\) In Ontario, anesthesiologists submit fee-for-service billings through OHIP, with fees calculated according to a standardized algorithm based on service units. Service units related to surgery duration represent the entire time that the anesthesiologist is in attendance with the patient and are recorded in 15-minute intervals; therefore, times calculated based on these units should include all physician teaching activities that occur during the encounter.

We determined patient complexity using the Johns Hopkins ACG (adjusted clinical group; ACG software version 10) methodology.\(^2^4\) This method of case-mix grouping captures all morbidities for which a patient receives care during a defined period — in this case, 3 years before the procedure date. The ACGs can be collapsed into 6 resource utilization bands (RUBs) on the basis of expected use of health care resources. In the present study, we used the CIHI-DAD, CIHI-SDS, CIHI–National Ambulatory Care Reporting System (NACRS) and OHIP databases to calculate RUBs, which were summarized as a 3-point ordinal variable: 1 = low (RUB = 0–3), 2 = moderate (RUB = 4) and 3 = high (RUB = 5).

**Statistical analysis**

We conducted all analyses using SAS software version 9.3 (SAS Institute). Differences in baseline variables between teaching and nonteaching hospitals were assessed using standardized differences, with an effect size threshold of > 0.2 used to identify meaningful differences. We assessed differences in mean surgery duration using \(t\) tests. As surgery duration is a non-negative integer, it is appropriate to model it using a count data model, such as Poisson or negative binomial regression. In this case, where overdispersion was present, we used negative binomial regression to assess the association between surgery duration and teaching hospital status, controlling for patient age, sex, obesity (body mass index [BMI] > 40), complexity (RUB), anesthetic technique, procedure year and procedure type (only for analyses involving multiple procedures). We additionally controlled for surgeon-related variables, including age, sex and annual procedure-specific volume (determined using the OHIP database). To account for the clustering effect of patients within surgeons and hospitals, we used the generalized estimating equations approach.

We conducted 3 additional sensitivity analyses to assess the presence of referral bias, whereby more difficult, potentially longer-duration cases are referred to teaching hospitals. Two of these analyses used the Ontario Multi-specialty Network (OMN) database\(^2^5\) to identify each patient’s expected admitting hospital. The OMN assigns Ontario residents to an expected admitting hospital using a 2-step process: individuals are linked to a “usual provider of care,” and providers are linked to hospitals. The OMN also aggregates select hospitals into hospital networks, such that the expected place of admission can be 1 of several individual hospitals within the network (i.e., the patient’s expected admitting hospital network). In the first sensitivity analysis, the cohort was limited to procedures performed at the patient’s expected admitting hospital, whereas the second was limited to procedures performed within the patient’s expected admitting hospital network. In the final sensitivity analysis, the cohort was limited to patients defined as having a low level of complexity (RUB = 1). All 3 sensitivity analyses involved the same statistical approach used for the primary analyses.

**Results**

Of the 713 573 surgical procedures included in this study, 148 538 (20.8%) were performed in a teaching hospital, representing 11.7%–39.8% across the individual procedures. Across all procedures, the mean duration of surgery was significantly longer for procedures performed in teaching than nonteaching hospitals, with mean differences ranging from 5 to 62 minutes across the individual procedures and all comparisons significant at \(p < 0.001\) (Table 1). In negative binomial regression analyses adjusting for patient-, surgeon- and procedure-related variables, teaching hospitals were associated with significantly longer surgery durations than nonteaching hospitals for all of the procedures studied (Fig. 1). Across the 14 procedures, teaching hospitals were associated with an overall 22% (95% confidence interval [CI] 20%–24%) increase in surgery duration, ranging from 8% for hip arthroplasty to 33% for open right colectomy.

Patients treated in teaching and nonteaching hospitals were similar in regards to baseline characteristics (Appendix 1, Table S3a–c). While a slightly higher proportion of complex patients (as ascertained by the RUBs) were treated in teaching hospitals than nonteaching hospitals (26.0% v. 21.5%), most of the baseline differences identified were not clinically significant. Similarly, surgeons operating in...
teaching and nonteaching hospitals did not meaningfully differ, with the exception that surgeons operating in teaching hospitals tended to perform a greater number of the index procedures per year (mean total of $51.8 \pm 43.6$ v. $43.3 \pm 41.3$ procedures).

An increase in surgical duration was evident over the study period in both teaching and nonteaching hospitals for all procedures except elective hip and knee arthroplasty. Overall mean duration increased from 114 minutes in 2002 to 125 minutes in 2011 across the 14 procedures. Post hoc analysis of this unexpected finding suggests that this increase is largely explained by the transition from open to laparoscopic techniques over the study period for several of the included procedures (data not shown).

We conducted 3 sensitivity analyses to investigate the potential impact of referral bias using the same analytic methods used for the main analysis and adjusting for the same covariates. Exclusion of patients who were not admitted to their expected hospital and/or hospital network (on the basis of OMA hospital assignment) did not change our findings, with teaching hospitals remaining significantly associated with increased duration for each procedure type. Again, we obtained similar findings when the cohort was restricted to patients with a low level of complexity. Results

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No.</th>
<th>Nonteaching Mean ± SD</th>
<th>Teaching Mean ± SD</th>
<th>Mean difference (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic cholecystectomy</td>
<td>129,369</td>
<td>97 ± 29.9</td>
<td>119 ± 43.2</td>
<td>23 (23.3%)</td>
</tr>
<tr>
<td>Laparoscopic right hemicolecotomy</td>
<td>4538</td>
<td>200 ± 63.3</td>
<td>238 ± 65.2</td>
<td>38 (19.3%)</td>
</tr>
<tr>
<td>Open right hemicolecotomy</td>
<td>6584</td>
<td>165 ± 62.3</td>
<td>226 ± 92.3</td>
<td>62 (37.5%)</td>
</tr>
<tr>
<td>Laparoscopic appendectomy</td>
<td>34,404</td>
<td>98 ± 29.3</td>
<td>127 ± 36.7</td>
<td>29 (29.5%)</td>
</tr>
<tr>
<td>Open appendectomy</td>
<td>24,106</td>
<td>89 ± 33.7</td>
<td>109 ± 46.3</td>
<td>20 (21.9%)</td>
</tr>
<tr>
<td>Laparoscopic inguinal hernia repair</td>
<td>6705</td>
<td>87 ± 24.9</td>
<td>105 ± 35.7</td>
<td>19 (21.3%)</td>
</tr>
<tr>
<td>Open inguinal hernia repair</td>
<td>65,904</td>
<td>82 ± 22.1</td>
<td>95 ± 35.1</td>
<td>14 (16.7%)</td>
</tr>
<tr>
<td>Laparoscopic hysterectomy</td>
<td>4400</td>
<td>177 ± 60.8</td>
<td>217 ± 62.9</td>
<td>40 (22.6%)</td>
</tr>
<tr>
<td>Open hysterectomy</td>
<td>59,381</td>
<td>127 ± 36.1</td>
<td>154 ± 53.7</td>
<td>27 (21.4%)</td>
</tr>
<tr>
<td>ORIF for hip fracture</td>
<td>33,674</td>
<td>118 ± 35.6</td>
<td>154 ± 55.0</td>
<td>36 (30.4%)</td>
</tr>
<tr>
<td>Hip hemiarthroplasty</td>
<td>19,872</td>
<td>138 ± 37.0</td>
<td>173 ± 47.3</td>
<td>35 (25.2%)</td>
</tr>
<tr>
<td>Hip arthroplasty</td>
<td>53,000</td>
<td>152 ± 36.8</td>
<td>157 ± 39.2</td>
<td>5 (3.2%)</td>
</tr>
<tr>
<td>Knee arthroplasty</td>
<td>96,559</td>
<td>149 ± 33.1</td>
<td>158 ± 39.5</td>
<td>9 (6.3%)</td>
</tr>
<tr>
<td>Tonsillectomy</td>
<td>26,539</td>
<td>60 ± 16.0</td>
<td>68 ± 25.7</td>
<td>8 (13.0%)</td>
</tr>
<tr>
<td>Overall</td>
<td>56,5035</td>
<td>115 ± 43.7</td>
<td>144 ± 54.7</td>
<td>29 (25.0%)</td>
</tr>
</tbody>
</table>

ORIF = open reduction and internal fixation; SD = standard deviation.

*Mean time in teaching – mean time in nonteaching hospitals. Significant at $p < 0.001$ for each procedure.

**Table 1. Mean duration of surgery by hospital type and unadjusted difference in surgery duration comparing teaching to nonteaching hospitals (in minutes)**

![Fig. 1. Operative time ratio comparing surgery duration in teaching and nonteaching hospitals, adjusted for patient-, surgeon- and procedure-related variables (see the Statistical analysis section for a complete description of covariate adjustment). CI = confidence interval; Lap = laparoscopic; ORIF = open reduction and internal fixation.](image)
for the sensitivity analyses are presented in Appendix 1, Figs. S1–S3.

**DISCUSSION**

This robust analysis of more than 700 000 cases demonstrates that surgery duration is prolonged in teaching compared with nonteaching hospitals over a wide range of commonly performed procedures. On average, procedures performed in teaching hospitals take 22% longer to complete, with an even greater increase for more complex procedures. The magnitude of this difference suggests a negative impact on both patient outcomes and clinical efficiency. There are many differences between teaching and nonteaching hospitals, with teaching hospitals tending to have larger volume, higher acuity and a greater focus on research. Beyond the impact of these disparities, we propose that factors associated with surgical training likely account for the vast majority of the observed increase in surgery duration.

Prolonged surgery duration has been linked previously to surgical training, yet few studies have controlled for patient or surgeon factors. Our study confirms these findings by accounting for a wide range of patient and surgeon factors and by generating a robust estimate of the time premium associated with surgical training. This study also differs from previous literature in that we looked at total duration of surgery, defined as the duration of involvement by anesthesiologists, rather than the time from incision to skin closure. Our definition includes all aspects of the operative intervention, including positioning, prepping, draping and insertion of monitoring catheters and lines within the operating suite. Moreover, this definition accounts for all teaching activities that occur within the operating suite, including training of surgical and anesthesiology residents. This metric is potentially more useful from the perspective of both patients and policy-makers, as it encompasses the entire case and all associated resources.

The difference in surgery duration between teaching and nonteaching hospitals was much lower for elective hip and knee arthroplasty than for other procedures, with increases of 8% and 9% in adjusted analyses, respectively. We speculate that specialization within dedicated arthroplasty teams may partly explain this finding. Within Ontario teaching centers, arthroplasty procedures are predominantly performed by surgeons who specialize in arthroplasty and work with dedicated teams, whereas community-based arthroplasty is typically performed by general orthopedic surgeons in nondenominated units. This contrasts with the other procedures we studied, which are often performed by generalists and, although common, rarely dominate a surgeon’s practice in either teaching or nonteaching settings. Whether such efficiencies can be achieved by adopting specialized units for other common procedures is an obvious question posed by this research.

Although investigation of surgical outcomes was beyond the scope of the present study, previous research has demonstrated a consistent association between surgery duration and adverse surgical outcomes. This association likely reflects multiple confounding factors, including the observation that complex and challenging cases take longer and are associated with higher complication rates. Disentangling the impact of teaching time from other factors that increase surgical duration will be a considerable challenge for future research to address. Quantifying the added operative time that is an inherent component of surgical training represents an important contribution to the debate regarding the effect of trainees on patient outcomes. Future research should aim to identify thresholds that are indicative of excess risk of complications across various surgical procedures.

**Limitations**

As a large, population-based study, the present study allows for precise estimates and wide generalizability. However, because this study was limited to the data available within administrative databases, it was not possible to adjust for some of the variables known to contribute to surgery duration, such as procedure complexity (e.g., size of hernia). Similarly, no information was available regarding the resident’s experience level or extent of participation, nor was it possible to confirm resident involvement in individual cases. Although this study encompassed the entire training period of several annual cohorts of residents, we were also unable to assess the impact of trainee seniority. Another potential weakness is that we estimated surgery duration on the basis of billing data rather than direct measurement; however, it is unlikely that any bias introduced using this method would have a differential impact on estimates for teaching and nonteaching hospitals.

**CONCLUSION**

This population-based study of more than 700 000 cases suggests that trainee involvement significantly increases surgery duration. The magnitude of this increase is large enough to potentially affect direct and indirect costs, institution and surgeon efficiency, and possibly impact surgical outcomes. Our findings with respect to arthroplasty further suggest that the impact of teaching may be reduced when surgical training is delivered in the context of procedure-specific teams. These data provide a benchmark for surgical educators as they strive to meet the needs of their trainees without compromising efficiency or safety. Finally, our study provides robust population-level data allowing policymakers to include the time costs of surgical training into funding models.
Acknowledgements: The authors thank Drs. Amit Garg, David Urbach and Salimah Shariff for their support and input throughout the study process and Kathryn Barber for providing insight regarding hospital coding procedures. This study was funded in part by the Academic Medical Organization of Southwestern Ontario (AMOSO) AHSC AFP Innovation Fund and the London Health Sciences Centre Department of Surgery. This study was supported by the ICES Western site. ICES is funded by an annual grant from the Ontario Ministry of Health and Long-Term Care (MOHLTC). Core funding for ICES Western is provided by AMOSO, the Schulich School of Medicine and Dentistry (SSMD), Western University, and the Lawson Health Research Institute (LHRI). The opinions, results and conclusions reported in this paper are those of the authors and are independent from the funding sources. No endorsement by ICES, AMOSO, SSMD, LHRI, or the Ontario MOHLTC is intended or should be inferred. Parts of this material are based on data and information compiled and provided by CIHI. However, the analyses, conclusions, opinions and statements expressed herein are those of the author, and not necessarily those of CIHI.

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Competing interests: None declared.

Contributors: All authors designed the study and interpreted the results. J. Winick-Ng was responsible for data extraction and analysis. C. Vinden wrote the article, which all authors reviewed and approved for publication.

References

Laparoscopic sleeve gastrectomy at a new bariatric surgery centre in Canada: 30-day complication rates using the Clavien–Dindo classification

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Accepted for publication Dec. 22, 2015

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DOI: 10.1503/cjs.016815

Background: Newfoundland and Labrador (NL) has the highest rate of obesity in Canada, prompting the establishment of a bariatric surgery program at the Health Sciences Centre in NL. This retrospective study examined 30-day complication rates in more than 200 consecutive patients who underwent laparoscopic sleeve gastrectomy (LSG) between May 2011 and February 2014.

Methods: We performed a chart review and collected data on 30-day postoperative complications. Complications were graded and reported using the Clavien–Dindo classification. Grades I and II were defined as minor and grades III and higher were defined as major complications.

Results: We reviewed the charts of the first 209 patients to undergo LSG. The mean body mass index was 49.2, 81% were women and the average age was 43 years. Comorbidities included hypertension (55.0%), obstructive sleep apnea (46.4%), dyslipidemia (42.1%), diabetes (37.3%), osteoarthritis (36.4%) and cardiovascular disease with previous cardiac stents (5.3%). Furthermore, 38.3% of patients reported psychiatric diagnoses, such as depression and anxiety. The overall 30-day complication rate was 15.3%. The complication rate for minor complications was 13.4% and for major complications was 1.9% (2 leaks, 1 stricture and 1 fistula).

Conclusion: Our results support the feasibility of safely performing LSG surgery at bariatric centres completing fewer than 125 procedures annually.

Obesity, defined as a body mass index (BMI) of 30 or higher, has been associated with comorbidities, such as diabetes, obstructive sleep apnea, cardiovascular disease, hypertension and dyslipidemia, as well as an increased incidence of certain cancers. Although numerous treatment options exist for obesity, bariatric surgery has proven to be the only effective treatment...
resulting in substantial and sustainable weight loss, substantial improvement in comorbid conditions and quality of life, and reduction in the risk of death. According to Canadian guidelines, surgical treatment of adult obesity is indicated in medical refractory patients with a BMI of 40 or higher or with a BMI of 35 or higher combined with at least 1 comorbid condition. Newfoundland and Labrador (NL) has the highest rates of obesity in Canada, with estimated increases projected. In 2011, Eastern Health established a provincial bariatric surgery program in NL at the Health Science Centre. This multidisciplinary program consists of 3 surgeons, a nurse practitioner and a dietician, with referral to other allied health professionals if required. Laparoscopic sleeve gastrectomy (LSG) is the primary bariatric procedure (96%) performed at this centre.

Laparoscopic sleeve gastrectomy originated as an initial step of a 2-step procedure known as the biliopancreatic bypass. It has gained popularity and is currently the second most commonly performed bariatric surgery in Canada. Its relatively short duration of surgery, shorter learning curve and lower complication rates make it an increasingly popular alternative to the laparoscopic Roux-en-Y gastric bypass (LRYGB).

Current literature provides evidence that supports lower complication rates with LSG than with LRYGB. A 2010 systematic review of 15 studies including 940 patients analyzed the clinical outcomes and operational impact of LSG. The authors reported a major complication rate (e.g., staple line leakage and internal bleeding) ranging from 0% to 29%. The range was 0%–5.5% for leakage and 0%–15.8% for bleeding. Mortality ranged from 0% to 3.3%. In the systematic review some studies reported all minor complications (e.g., vomiting, nausea and diarrhea), and others did not, confounding the analysis. In a more recent systematic review and meta-analysis on the effectiveness and risks of bariatric surgery, Chang and colleagues reported complication rates associated with LSG from both randomized controlled trials (RCTs) and observational studies. The meta-analytic results from the 10 observational studies (n = 3647 patients) reported perioperative and postoperative mortality for LSG as 0.29% and 0.34%, respectively. The complication rate after LSG ranged from 8.9% (8 observational studies, n = 4987 patients) to 13% (2 RCTs, n = 137 patients).

In response to a growing number of people living with obesity, specifically those with severe obesity (BMI ≥ 35), there has been an increase in the volume of bariatric surgeries performed in many Canadian provinces. In Canada, 28% of bariatric procedures performed between 2012 and 2013 were LSG. With the increasing number of LSG procedures being performed, outcome assessment is of utmost importance.

The Surgical Review Corporation (SRC), American Society of Bariatric Surgery (ASBS) and Bariatric Surgery Center of Excellence (BSCOE) established guidelines to ensure patient safety and operative quality. While the NL program complies with some of the criteria (i.e., including a dedicated bariatric team and long-term patient follow-up) for a BSCOE, operative volumes are less than the minimum annual 125 bariatric procedures required to be classified as a COE. The purpose of this study was to assess 30-day complication rates and mortality in the first 209 consecutive patients undergoing LSG. We used the Clavien–Dindo classification system to grade and report surgical complications in a standard and comparable format to allow valid and reliable comparisons.

**METHODS**

**Study setting**

The Provincial Bariatric Surgery Program was established in May 2011. This multidisciplinary team consists of 3 surgeons trained in bariatric surgery, a nurse practitioner and a dietician. The 3 surgeons (D.P., D.B., C.S.), who performed all procedures in this study, have advanced laparoscopic skills. Two of the surgeons (D.P. and C.S.) are fellowship-trained in minimally invasive and bariatric surgery.

**Study design**

We conducted a cross-sectional study of all patients who underwent LSG between May 2011 and February 2014 in the NL Bariatric Surgery Program. Newfoundland’s Health Research Ethics Authority approved this study.

The eligible population consisted of all patients meeting the Canadian clinical practice guidelines’ criteria for the surgical treatment of obesity (BMI ≥ 35 with risk factors, or BMI ≥ 40) who were referred by their primary care provider to the bariatric team using a standardized referral form submitted to a central intake system and who underwent preliminary eligibility screening with the nurse practitioner. Following mandatory attendance at a presurgical bariatric surgery general orientation and an education session provided either face-to-face or via webinar, patients were required to undergo extensive preoperative work-up, including a 2-week diet trial (1 wk full-fluid diet and 1 wk healthy eating), and to complete a food journaling activity. All patients met with the nurse practitioner one-on-one or via Telehealth for further assessment, including a detailed review of their weight history and past weight loss attempts, bloodwork and a sleep study to identify and treat any sleep-disordered breathing, as necessary. If any other medical concerns were identified, patients were referred for consultation with the appropriate specialist (e.g., cardiologist, endocrinologist, respirologist) based on the comorbid condition. An appointment with 1 of the 3 bariatric surgeons in the bariatric surgery clinic was arranged to obtain formal surgical consent.

**Participants**

We included patients aged 19–70 years with a BMI ≥ 40 or ≥ 35 as well as severe obesity-related comorbidities who...
had attempted nonsurgical weight loss in the past and who were deemed medically, psychologically, and emotionally stable to consent to surgery and partake in a diet and lifestyle modification regimen. We excluded patients who were pregnant or planning a pregnancy within 2 years of surgical treatment, who had a medical condition that would make surgery too risky (i.e., not fit for surgery), and who had a BMI > 60.

Operative procedure

Two surgeons were present for all LSG procedures. All cases involved a 5- or 6-port approach. The vascular supply of the stomach was divided along the greater curve, starting 5 cm proximal to the pylorus and carried to the angle of His. A gastric sleeve was created using 60 mm linear staplers along with a 42-Fr bougie, which was advanced via the oropharynx into the stomach by the anesthesiologist. The gastric specimen was removed via the left upper quadrant port site. The staple line was leak-tested with a gastroscope. On postoperative day 1, all patients underwent a gastrografin swallow to assess for a leak from the gastric staple line and to ensure patency on the sleeve. If no problem was identified, patients were started on a clear liquid diet and generally discharged home on postoperative day 2 with dietary instructions. Follow-up visits with the multidisciplinary team were scheduled at 1, 3, 6, 12, 18 and 24 months and annually thereafter. Patients followed up with their surgeon at 6 weeks and as needed from then on.

Data collection

We reviewed the charts of all patients included in our study. For each chart, a single data collector (V.F.) reviewed preoperative and postoperative clinic visit records, relevant laboratory investigations and hospital discharge summaries. We collected data on patient demographics, postoperative complications and mortality. We used the Clavien–Dindo (CD) Classification (Table 1) to grade the complications, and we then grouped the complications as minor and major. Minor complications were defined as CD grades I and II, and major complications were defined as CD grades III–V. All complications were independently reviewed by the data collector (V.F.) and 1 of the surgeons (D.P.); inter-rater agreement was 100%.

Statistical analysis

We conducted our analyses using SPSS for Windows version 21 (IBM). Categorical variables are described using frequencies and percentages. Continuous variables are described using means and standard deviations if they were normally distributed or medians and interquartile ranges if they were not normally distributed.

RESULTS

Between May 2011 and February 2014, 209 patients underwent LSG at our centre. The mean preoperative BMI was 49.2 (range 35.0–67.4), 81% of patients were women, and the average age was 43.4 (range 22–70) years. The 4 most common obesity-related comorbidities among the patients were hypertension (55.0%), obstructive sleep apnea (46.4%), dyslipidemia (42.1%) and diabetes (37.3%) (Table 2). All procedures were successfully completed laparoscopically. Data on the duration of surgery were available for 206 patients and ranged from 40 to 177 min (mean 78.63 ± 23.43 min). Mean hospital length of stay

| Table 1. Clavien–Dindo classification of surgical complications |
|--------------------------|---------------------------------|
| Grade | Description |
| I | Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiologic interventions. Acceptable therapeutic regimens are drugs, such as antiemetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside. |
| II | Requires pharmacological treatment with drugs other than those allowed for grade I complications. Blood transfusions, antibiotics and total parenteral nutrition are also included. |
| III | Requires surgical, endoscopic or radiological intervention. |
| IIIa | Intervention under regional/local anesthesia. |
| IIIb | Intervention under general anesthesia. |
| IV | Life-threatening complication requiring intensive care/ intensive care unit management. |
| IVa | Single-organ dysfunction. |
| IVb | Multiorgan dysfunction. |
| V | Patient demise. |

| Table 2. Characteristics of first 209 patients undergoing LSG |
|--------------------------|--------------------------|
| Characteristic | Mean ± SD [range] or no. (%) |
| Age, yr | 43.4 ± 9.55 (22–70) |
| Female sex | 169 (80.9) |
| Preoperative weight, kg | 134.3 ± 23.31 |
| Preoperative BMI | 49.2 ± 6.72 |
| Duration of surgery, min | 78.63 ± 23.43 (40–177) |
| LOS, d | 2.2 ± 1.26 (1–16) |
| Comorbidity | |
| HTN | 115 (55.0) |
| OSA | 97 (46.4) |
| Diabetes | 78 (37.3) |
| GERD | 76 (36.4) |
| CVD | 11 (5.3) |
| OA | 76 (36.4) |
| DLD | 88 (42.1) |
| Anxiety/depression | 80 (38.3) |

BMI = body mass index; CVD = cardiovascular disease; DLD = dyslipidemia; GERD = gastroesophageal reflux disease; HTN = hypertension; LOS = length of stay; LSG = laparoscopic sleeve gastrectomy; OA = osteoarthritis; OSA = obstructive sleep apnea; SD = standard deviation.
was 2.2 ± 1.26 (range 1–16) days. There was no 30-day postoperative mortality.

Eight (3.8%) patients experienced CD grade I complications: 4 required intravenous fluid rehydration, 2 had a rash requiring antihistamines, 1 had urinary retention, and 1 had a substantial drop in hemoglobin leading to prolonged LOS but not transfusion. Grade II complications occurred in 20 (9.6%) patients: 6 experienced a postoperative drop in hemoglobin requiring blood transfusion, 2 had a pulmonary embolism (PE) and were started on anticoagulation therapy, and 12 had minor infections requiring oral antibiotics. Two (1.0%) patients experienced a grade IIIa complication: 1 experienced a gastric fistula treated with percutaneous drainage and 1 had a stricture requiring endoscopic bougie dilation. Two (1.0%) leaks occurred, requiring intervention under general anesthesia (grade IIIB). One of these patients required percutaneous drainage as well as placement of an endoscopic stent under general anesthesia. The other patient experienced an almost immediate postoperative leak treated with reoperation on postoperative day 1 (Table 3). The overall minor complication rate was 13.4%, and the major complication rate was 1.9%.

**DISCUSSION**

Laparoscopic sleeve gastrectomy has been shown to be an effective stand-alone bariatric procedure. It generally has a shorter duration and easier learning curve than the current gold standard, LRYGB. With the increasing number of Canadians living with severe obesity and the increased volume of LSG surgeries being performed in Canada, the safety of LSG as a treatment for severe obesity must be examined.

Our institution is a newly established bariatric surgery centre comprising 3 bariatric surgeons who collectively perform fewer than 125 procedures annually. Our study population demographics and comorbidity profile are similar to those of other bariatric surgery populations (e.g., average age 43 yr, > 80% women, average presurgery BMI 49). More than one-third of our patients had comorbid type 2 diabetes, gastroesophageal reflux disease and dyslipidemia, close to half had obstructive sleep apnea, and more than half had hypertension.

We compared our study results with those of other studies that used the CD classification (Table 3). In the study by Vidal and colleagues, minor complications were reported in 5 (4.4%) patients: urinary tract infection (n = 2), pseudomembranous colitis (n = 1), hypertensive crisis (n = 1) and subphrenic abscess (n = 1). Major complications were reported in 5 (4.4%) patients: gastric leak (n = 2), bleeding from the port site (n = 2) and acute myocardial infarction resulting in death (n = 1).

In the study by Peterli and colleagues, minor complications were reported in 7.5% of patients, 3 of which were nonsurgical, 1 was surgical and 3 were due to dysphagia. Obstruction (n = 1) and infection (n = 1) were identified as major complications, for a rate of 0.9%.

Lemanu and colleagues reported 38 minor complications and 29 major complications. The 28 major complications included 23 grade III, 5 grade IV and 1 grade V. The authors reported staple line leakage (2%), staple line bleeding (2.5%) and 1 death (0.3%).

Goiten and colleagues also used the CD classification and reported an overall complication rate of 4.1%. Sixty-two (2.3%) patients experienced minor complications and 48 (1.8%) experienced major complications. Absolute 30-day complication rates were reported as follows: bleeding 2.5% (n = 66), leakage 0.8% (n = 22), venous thromboembolism 0.2% (n = 4) and obstruction 0.1% (n = 3).

**Table 3. Thirty-day complication rates associated with LSG using the Clavien–Dindo classification and categorized as major and minor complications**

<table>
<thead>
<tr>
<th>Clavien–Dindo grade</th>
<th>Present study (n = 209)</th>
<th>Lemanu et al. (n = 400)</th>
<th>Vidal et al. (n = 114)</th>
<th>Peterli et al. (n = 107)</th>
<th>Goiten et al. (n = 2651)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>8 (3.8)</td>
<td>20 (5)</td>
<td>—</td>
<td>5 (4.7)</td>
<td>19 (0.7)</td>
</tr>
<tr>
<td>II</td>
<td>20 (9.6)</td>
<td>18 (4.5)</td>
<td>5 (4.4)</td>
<td>3 (2.8)</td>
<td>43 (1.6)</td>
</tr>
<tr>
<td>Minor complication rate</td>
<td>28 (13.4)</td>
<td>38 (9.5)</td>
<td>5 (4.4)</td>
<td>8 (7.5)</td>
<td>62 (2.3)</td>
</tr>
<tr>
<td>Major</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>—</td>
<td>23 (5.6)</td>
<td>—</td>
<td>1 (0.9)</td>
<td>—</td>
</tr>
<tr>
<td>IIIa</td>
<td>2 (1.0)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>18 (0.7)</td>
</tr>
<tr>
<td>IIIb</td>
<td>2 (1.0)</td>
<td>—</td>
<td>4 (3.5)</td>
<td>—</td>
<td>22 (0.8)</td>
</tr>
<tr>
<td>IV</td>
<td>—</td>
<td>5 (1.3)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>IVa</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>5 (0.2)</td>
</tr>
<tr>
<td>IVb</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>2 (0.07)</td>
</tr>
<tr>
<td>V</td>
<td>—</td>
<td>1 (0.3)</td>
<td>1 (0.9)</td>
<td>—</td>
<td>1 (0.04)</td>
</tr>
<tr>
<td>Major complication rate</td>
<td>4 (1.9)</td>
<td>29 (7.3)</td>
<td>5 (4.4)</td>
<td>1 (0.9)</td>
<td>48 (1.8)</td>
</tr>
<tr>
<td>Overall complication rate</td>
<td>32 (15.3)</td>
<td>67 (16.8)</td>
<td>10 (8.8)</td>
<td>9 (8.4)</td>
<td>110 (4.1)</td>
</tr>
</tbody>
</table>

LSG = laparoscopic sleeve gastrectomy.
In our study, the major complication rate was 1.9%. This finding falls in the range reported by the other comparable studies that used the CD classification (range 0.9%–7.3%; Table 3). The minor complication rate of 13.4% found in our study is higher than those of the other studies that reported minor complication rates (range 2.3%–9.5%; Table 3). Our overall complication rate of 15.3% falls within the range of 4.1%–16.8% reported by the other comparable studies. In the present study there was no 30-day mortality. Mortality was also low in the comparable studies and ranged from 0%–0.9%.

**Strengths and limitations**

This study has a number of strengths. First, we used a reliable and valid classification system to grade and report surgical complications following LSG. Second, we had complete follow-up data on our first 209 patients. Third, all procedures were performed by surgeons at the same academic-affiliated health care institution using 2 surgeons per case approach. Finally, we conducted a comprehensive chart review, which is more likely to capture all major complications (e.g., rash, dehydration), thus describing the morbidity associated with LSG more accurately.

Our study also has some limitations: its retrospective, observational design and its focus on 30-day complication rates only; we did not capture potential complications known to occur long after LSG, such as gastroesophageal reflux disease, hernia and gastric fistula.

This study suggests that an annual bariatric surgery procedure volume of 125 cases is not required. Although the rationale for this guideline is clear, our results suggest that a lower number is acceptable. This may be explained by the fact that all cases in this study were performed with 2 surgeons present, with at least 1 of the surgeons involved being fellowship-trained in bariatric surgery. Also, before starting the program, the first 2 cases were proctored by an experienced visiting surgeon who had performed several hundred LSGs.

In order to standardize grading and reporting of complications following bariatric surgery, future studies should use the CD classification. In addition, future research should include an examination of long-term complications, such as nutritional deficiencies after LSG. Finally, identifying predictors of complications after LSG and the potential contribution complications make to unsuccessful weight loss after surgery may help to inform clinical decision-making.

**CONCLUSION**

A new, low-volume bariatric centre can safely perform LSG if steps are taken to ensure that the surgeons are appropriately trained and patients have access to a dedicated bariatric health team. The CD classification system appears to be a useful, standardized method for comparing 30-day complication rates following LSG.

**Affiliations:** All authors are from the Faculty of Medicine, Memorial University, Health Sciences Centre, St. John’s, NL.

**Competing interests:** None declared.

**Contributors:** V. Falk, L. Twells and C. Smith designed the study. V. Falk and R. Murphy acquired the data, which V. Falk, L. Twells, D. Gregory and D. Pace analyzed. V. Falk, L. Twells, D. Gregory, D. Boone and D. Pace wrote the article, which all authors reviewed and approved for publication.

**References**


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UNCOVERING HIDRADENITIS SUPPURATIVA

Dr. Shear, Dr. Tran and Dr. George discuss Hidradenitis Suppurativa.

Q. WHAT IS HS?
A. Hidradenitis Suppurativa (HS) is a chronic, painful, inflammatory skin disease which affects 1-4% of the general adult population.\(^1,4\) It is characterized by boils usually occurring where certain sweat glands are located, such as under the breasts, buttocks and inner thighs. The boils can develop and connect, forming draining sinuses which discharge foul-smelling pus.\(^1,2,4\)

Q. HOW DOES HS IMPACT QUALITY OF LIFE?
A. HS is often undiagnosed or misdiagnosed.\(^2,3,4\) It interferes with social interactions, job performance and intimate relationships—often leading to isolation.\(^1\) It is painful and causes embarrassment.\(^1\)

Q. WHAT CAUSES HS?
A. The cause of HS is unclear. It is thought that certain genetic markers and defects within hair follicles are at the root of the disease.\(^2\) Risk factors include smoking and obesity.\(^1\) About one-third of patients report a family history of HS.\(^1\) HS has been reported to co-occur with several comorbid conditions—mostly, inflammatory bowel disease.\(^3\)

Q. HOW CAN HS BE TREATED?
A. Medical treatments for HS have included antibacterial washes, topical clindamycin, various systemic antibiotics, hormonal therapies, systemic retinoids, laser treatment, intralesional steroid injections and biologics.\(^3\) Surgical de-roofing or wide excision procedures have long been the definitive treatment for severe HS.\(^3\) There is no guarantee that HS will not recur in the previously excised areas.\(^3\)

Q. IS THERE A CURE FOR HS?
A. There is currently no cure for HS.\(^4,5\) Early diagnosis and proper management is important for a patient’s quality of life.\(^1\) The first step for those with HS is to speak to their dermatologist to get an accurate diagnosis.\(^1\)

Q. DO PEOPLE SUFFERING FROM HS GO TO THE ER FOR TREATMENT?
A. People with HS come to the emergency room in severe pain and discomfort requiring assistance with the draining of the boils during a flare-up.\(^4\) It’s not unusual for patients to go home undiagnosed.\(^4\)

References:
A Canadian population-based description of the indications for lower-extremity amputations and outcomes

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Thomas L. Forbes, MD
Graham Roche-Nagle, MD, MBA

Presented at the plenary session of the 2013 meeting of the Canadian Society for Vascular Surgery in Edmonton, Alta., Canada.

Background: To our knowledge, there have been no previously published reports characterizing lower-extremity amputations in Canada. The objective of this study was to describe the indications and outcomes of lower-extremity amputations in the Canadian population.

Methods: We performed a retrospective cohort study of all adult patients who underwent lower-extremity amputation in Canada between 2006 and 2009. Patients were identified from the Canadian Institute for Health Information’s Discharge Abstract Database, which includes all hospital admissions across Canada with the exception of the province of Quebec. Pediatric, trauma, and outpatients were excluded.

Results: During the study period, 5342 patients underwent lower-extremity amputations in 207 Canadian hospitals. The mean age was 67 ± 13 years, and 68% were men. Amputations were most frequently indicated after admission for diabetic complications (81%), cardiovascular disease (6%), or cancer (3%). In total, 65% of patients were discharged to another inpatient or long-term care facility, and 26% were discharged home with or without support. Most patients were diabetic (96%) and most (65%) required a below-knee amputation. Predictors of prolonged (>7 d) hospital stay included amputation performed by a general surgeon; cardiovascular risk factors, such as diabetes, hypertension, ischemic heart disease, congestive heart failure, or hyperlipidemia; and undergoing the amputation in the provinces of Newfoundland and Labrador, New Brunswick, or British Columbia.

Conclusion: There is variability in the delivery of lower-extremity amputations and postoperative hospital discharges among surgical specialists and regions across Canada. Future work is needed to investigate the reasons for this variability and to develop initiatives to shorten postoperative hospital stays.

Contexte: À notre connaissance, aucun rapport caractérisant les amputations des membres inférieurs n’a été publié au Canada à ce jour. L’objectif de la présente étude était de décrire les indications et les résultats de ces amputations dans la population canadienne.

Méthodes: Nous avons effectué une étude de cohorte rétrospective portant sur tous les patients adultes ayant subi l’amputation d’un membre inférieur au Canada entre 2006 et 2009. Les patients ont été sélectionnés à partir de la Base de données sur les congés des patients de l’Institut canadien d’information sur la santé, qui comprend toutes les hospitalisations au Canada, à l’exception du Québec. Les cas pédiatriques, les traumatismes et les patients externes ont été exclus.

Résultats: Durant la période à l’étude, 5342 patients ont subi l’amputation d’un membre inférieur dans 207 hôpitaux canadiens. L’âge moyen était de 67 ± 13 ans, et 68 % des patients étaient des hommes. Les amputations étaient principalement recommandées après l’hospitalisation pour des complications du diabète (81 %), une maladie cardiovasculaire (6 %) ou un cancer (3 %). Au total, 65 % des patients ont été transférés vers un autre établissement hospitalier ou de soins de longue durée après leur congé, et 26 % sont retournés à la maison avec ou sans soutien supplémentaire. La plupart des patients étaient diabétiques (96 %), et la plupart (65 %) ont subi une amputation sous le genou. Les indicateurs d’hospitalisation longue (> 7 jours) comprenaient l’amputation par un chirurgien généraliste; les facteurs de risque cardiovasculaires, comme le diabète, l’hypertension, la cardiopathie ischémique, l’insuffisance cardiaque congestive ou l’hyperlipidémie; et le fait d’avoir subi l’amputation à Terre-Neuve-et-Labrador, au Nouveau-Brunswick ou en Colombie-Britannique.
Despite advancements in limb salvage treatments, lower-extremity amputations continue to pose a substantial health care challenge. In the United States, for example, there are more than 1.6 million amputees, and that number is projected to double to 3.6 million by the year 2050.¹ There is a large variability in the annual global incidence of amputations, which varies between 0.4 and 116 amputations per 10,000 people.² Reassuringly, however, amputation rates have not increased in several decades, possibly because of better surgical and medical preventative strategies.³

Of the many risk factors that result in a patient requiring an amputation, diabetes is the most prominent, and affects 1 in 3 British and almost half of Australian amputees.⁴ Diabetic amputees have a greater risk of heart failure, further amputation and death than nondiabetic amputees.⁵

To our knowledge, there have been no previously published reports characterizing lower-extremity amputations in Canada. The aim of this study was to investigate the trends in lower-extremity amputations among Canadian patients and describe their associated clinical outcomes.

**METHODS**

We analyzed the Canadian Institute for Health Information (CIHI) Discharge Abstract Database for the years 2006–2009 to identify all lower-extremity amputations.

**Inclusion and exclusion criteria**

The analysis included acute inpatient records of adult patients (age ≥ 18 yr) who received an above- or below-knee amputation for ischemia or malignancy in a Canadian hospital (excluding the province of Quebec, which does not participate in the CIHI database). Only the index admission for amputation was included in the analysis. The analysis excluded pediatric and trauma patients and outpatient encounters.

**Patient identification**

To identify the patients, we queried the CIHI database for the Canadian Classification of Health Interventions (CCI) codes “1.VC.93” (femoral amputations, which include all above-knee amputations) or “1.VQ.93” (tibial and fibular amputations, which include all below-knee, foot and toe amputations) in any position within the intervention fields, and the International Statistical Classification of Diseases and Related Health Problems, 10th Canadian Revision (ICD-10-CA) codes “E10-E14” (diabetes mellitus) or “C00-C97” (malignant neoplasms) in any position within the diagnosis fields.

**Statistical analysis**

Descriptive statistics were generated for continuous and categorical variables. Where appropriate, we stratified the analysis by the type of surgeon who performed the initial amputation: vascular, orthopedic, general, or “other” surgeon. The “other” category mostly comprised plastic surgeons and podiatrists.

We developed multivariable logistic regression models to identify factors associated with prolonged (> 7 d) hospital stay after an index amputation, discharge home and death in hospital. The regression models controlled for the type of surgeon who performed the initial amputation (reference category: vascular surgeon), female sex, the type of hospital (academic v. community), age, province (reference category: province of Ontario), type of amputation (reference category: below-knee amputation), diabetes mellitus, hypertension, ischemic heart disease (IHD), congestive heart failure (CHF), hyperlipidemia and whether the patient underwent a reamputation on the same admission. Owing to their relatively small numbers, we analyzed patients from the Yukon, Northwest Territories and Nunavut as part of a single “northern territories” category. We considered results to be significant at p < 0.05.

All analyses were carried out using SAS statistical software version 9.3 (SAS Institute Inc.). We obtained approval for this study from CIHI’s Privacy, Confidentiality and Security Committee and the research ethics board of the University of Toronto’s University Health Network. The research was conducted using an anonymized database of thousands of amputees, and so obtaining consent from individual patients was not deemed necessary.

**RESULTS**

A total of 5342 index lower-extremity amputations were identified in our data set. Of those, 1382 amputations were performed in 2006, 1382 in 2007, 1288 in 2008 and 1290 in 2009. Patients were treated in 207 different hospitals across Canada. Most amputations (53%) took place in Ontario, Canada’s most populous province, followed by British Columbia (12%) and Alberta (10%). Baseline patient characteristics are outlined in Table 1. Most patients were men and older than 65 years. Most (96%) were diabetic and most (65%) underwent a below-knee...
amputation. Amputations took place a median of 3 days after patients were admitted to hospital.

Diabetic complications accounted for most hospital admissions (Table 2). Those included ischemic and neuropathic ulcers secondary to type 2 diabetes in 81% of patients, followed by type 1 and “unspecified” diabetic ulcers in the remainder of patients. While lower-extremity tumours accounted for only 3% of all lower-extremity amputations, the majority of those (88%) were carried out by orthopedic surgeons.

Patients who required a reamputation most commonly underwent a below-knee amputation (61%). An above-knee amputation was performed in 22% and a foot amputation in 14% of reamputation patients (Fig. 1). Further amputations on the same admission were required in 537 (10%) patients.

The median length of stay in hospital varied by the type of surgeon performing the procedure. Vascular surgery patients were admitted for a median of 16 days, orthopedic patients 17 days, general surgery patients 19 days and other patients 21 days. Patients requiring reamputation spent a median of 37 days in hospital.

A greater proportion of patients (44%) were discharged to a long-term care facility, whereas 21% were discharged to another inpatient facility (Fig. 2) and 27% were discharged home. Overall hospital mortality was 9%. Patients who required a reamputation and those who did not require reamputation both had a 9% mortality.

Factors associated with a prolonged (> 7 d) hospital stay are listed in Table 3. Undergoing amputation by a general surgeon; undergoing amputation in the provinces of Newfoundland and Labrador, New Brunswick, or British Columbia; having a history of diabetes, hypertension, IHD, CHF or hyperlipidemia; and undergoing a reamputation on the same admission all predicted a longer

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### Table 1. Patient characteristics stratified by the type of surgeon performing the amputation

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Type of surgeon; no. (%) of patients*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VS</td>
</tr>
<tr>
<td>Age, mean ± SD, yr</td>
<td>68 ± 12</td>
</tr>
<tr>
<td>Male sex, %</td>
<td>68</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1840 (98)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>683 (36)</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>346 (18)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>184 (10)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>90 (5)</td>
</tr>
<tr>
<td>Teaching hospital</td>
<td>1263 (67)</td>
</tr>
<tr>
<td>Type of amputation</td>
<td></td>
</tr>
<tr>
<td>Above-knee</td>
<td>663 (35)</td>
</tr>
<tr>
<td>Below-knee</td>
<td>1083 (58)</td>
</tr>
<tr>
<td>Ankle</td>
<td>34 (2)</td>
</tr>
<tr>
<td>Foot</td>
<td>78 (4)</td>
</tr>
<tr>
<td>Toe</td>
<td>21 (1)</td>
</tr>
</tbody>
</table>

*GS = general surgeon; OS = orthopedic surgeon; SD = standard deviation; VS = vascular surgeon.

### Table 2. Admitting diagnosis stratified by the type of surgeon performing the amputation

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Type of surgeon; no. (%) of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VS</td>
</tr>
<tr>
<td>Diabetic complications</td>
<td>1622 (86)</td>
</tr>
<tr>
<td>Lower-extremity tumour</td>
<td>2 (0.1)</td>
</tr>
<tr>
<td>Musculoskeletal disease</td>
<td>30 (2)</td>
</tr>
<tr>
<td>Skin disease</td>
<td>30 (2)</td>
</tr>
<tr>
<td>Convalescence and physiotherapy</td>
<td>20 (1)</td>
</tr>
<tr>
<td>Infection</td>
<td>17 (1)</td>
</tr>
<tr>
<td>Unspecified pain and discomfort</td>
<td>5 (0.3)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>6 (0.3)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>6 (0.3)</td>
</tr>
<tr>
<td>Other cardiovascular disease</td>
<td>126 (7)</td>
</tr>
<tr>
<td>Other diseases</td>
<td>17 (1)</td>
</tr>
</tbody>
</table>

*GS = general surgeon; OS = orthopedic surgeon; VS = vascular surgeon.
Fig. 1. Type of reamputation performed on same admission stratified by the type of surgeon performing the amputation. GS = general surgeon; OS = orthopedic surgeon; VS = vascular surgeon.

Fig. 2. Patient discharge destination stratified by the type of surgeon performing the amputation. GS = general surgeon; OS = orthopedic surgeon; VS = vascular surgeon.
hospital stay. Factors protective against a prolonged hospital stay included undergoing the procedure in the province of Saskatchewan and undergoing an above-knee amputation.

Factors associated with discharge home rather than to another health care facility after lower-extremity amputation included being a general surgery patient (odds ratio [OR] 1.2, 95% confidence interval [CI] 1.02–1.5), undergoing the amputation in the provinces of Newfoundland and Labrador (OR 3, 95% CI 2.2–4.2), Nova Scotia (OR 1.5, 95% CI 1.2–2.1), New Brunswick (OR 1.5, 95% CI), Manitoba (OR 1.7, 95% CI 1.3–2.1), Saskatchewan (OR 2.7, 95% CI 2.3–3.3); prolonged length of stay (OR 1.7, 95% CI 1.5–2); and a history of diabetes (OR 1.2, 95% CI 1.4–2.8).

Factors associated with death in hospital after lower-extremity amputation included being an orthopedic surgery patient (OR 1.4, 95% CI 1.1–1.8); older age (OR 1.02, 95% CI 1.01–1.03); undergoing the amputation in the provinces of Newfoundland and Labrador (OR 1.7, 95% CI 1–2.8), Prince Edward Island (OR 2.7, 95% CI 1.1–6.9), Nova Scotia (OR 1.7, 95% CI 1.1–2.6), New Brunswick (OR 2, 95% CI 1.2–3.3), or British Columbia (OR 1.6, 95% CI 1.2–2.1); having an above-knee amputation (OR 2.1, 95% CI 1.7–2.6); and a history of IHD (OR 3, 95% CI 2.4–3.7) and CHD (OR 2.5, 1.9–3.2).

**DISCUSSION**

Our results demonstrate a regional and surgeon-dependent variability in the delivery and outcomes associated with lower-extremity amputations across Canada.

**Indications for amputation**

Eighty-one percent of the patients in our data set underwent lower-extremity amputation during a hospital admission for diabetic complications. The actual number, however, is likely higher, as other admitting diagnoses, such as skin disease, infection and cardiovascular disease, may also be secondary to diabetes. Our finding is consistent

| Table 3. Predictors of prolonged (> 7 d) hospital stay after an index amputation |
|-----------------------------|--------|----------|
| Characteristic              | OR     | 95% CI   |
| Type of surgeon             |        |          |
| Vascular surgeon Reference  | 1.00   |          |
| Orthopedic surgeon          | 1.14   | 0.96–1.36|
| General surgeon             | 1.51   | 1.21–1.87|
| Other surgeon               | 0.96   | 0.96–1.57|
| Female sex                  | 0.97   | 0.83–1.12|
| Community (v. teaching) hospital | 0.98 | 0.83–1.16|
| Age                         | 1      | 0.99–1.00|
| Province or territory       |        |          |
| Newfoundland and Labrador  | 3.50   | 1.99–6.15|
| Prince Edward Island        | 1.19   | 0.44–3.18|
| Nova Scotia                 | 1.18   | 0.86–1.64|
| New Brunswick               | 1.83   | 1.12–2.99|
| Manitoba                    | 0.78   | 0.60–1.02|
| Saskatchewan                | 0.51   | 0.38–0.70|
| Alberta                     | 1.09   | 0.84–1.42|
| British Columbia            | 1.62   | 1.25–2.08|
| Northern territories        | 0.34   | 0.06–1.96|
| Type of amputation          |        |          |
| Below-knee                  | 0.71   | 0.61–0.83|
| Above-knee                  | 4.62   | 0.57–37.30|
| Foot                        |        |          |
| Cardiovascular risk factors |        |          |
| Diabetes                    | 1.39   | 1.02–1.90|
| Hypertension                | 1.34   | 1.13–1.58|
| Ischemic heart disease      | 1.54   | 1.24–1.91|
| Congestive heart failure    | 2.60   | 1.86–3.03|
| Hyperlipidemia              | 2.10   | 1.33–3.42|
| Reamputation on same admission | 10.50 | 5.16–21.35|

CI = confidence interval; OR = odds ratio.
with previously reported proportions of amputations due to diabetic complications ranging between 25% and 90% globally. As such, the importance of appropriate outpatient support for these patients cannot be overstated. A recent report by Brooke and colleagues demonstrated that patients who received high-quality outpatient diabetic management had superior limb-salvage and lower readmission rates postamputation.

Approximately 3% of patients underwent amputation for lower-extremity malignancy. The most frequent malignancy-related admitting diagnoses were “malignant neoplasm of connective and soft tissue of lower limb, including hip” (34%), “malignant neoplasm long bones of lower limb” (21%), “malignant neoplasm skin of lower limb, including hip” (10%) and “secondary malignant neoplasm of bone and bone marrow” (10%). The actual number of lower-extremity amputations performed for malignancy is probably higher, however, as our database did not include pediatric amputations. Malignant bone tumours, such as osteosarcoma and Ewing sarcoma, account for 6% of all malignancies diagnosed in patients younger than 20 years, and two-thirds of those occur in the lower extremities.

Most of the amputations performed by general (81%) and orthopedic surgeons (58%) were done in community hospitals, whereas most of the amputations performed by vascular surgeons (67%) were done in academic centres. This is likely because vascular surgery in Canada is increasingly concentrated in tertiary hospitals and large referral-centres, many of which are university-affiliated. As such, in community hospitals with no readily available vascular surgery support, amputations are more likely to be performed by general and orthopedic surgeons.

Reamputation on the same admission

Approximately 10% of patients required further amputations on the same admission. Of those, 41% were vascular surgery patients, while orthopedic and general surgery patients each accounted for 28% of reamputations. In the absence of patient morbidity scores within our data set, we hypothesize that this is likely reflective of a worse health state among vascular surgery amputees rather than any significant differences in technical outcomes between the various surgical specialties.

Our results are slightly lower than the 13% early reoperation rate reported by Aulivola and colleagues in a population of lower-extremity amputees. Previously described predictors of below-knee amputation stump failure include the absence of a popliteal pulse and the presence of calf rest pain, feet tissue loss, postoperative stump trauma and wound infection. Similarly, a history of coronary artery disease, cerebrovascular disease and impaired ambulation also predict lack of success after below-knee amputation.

Hospital length of stay

Numerous factors predicted a prolonged (> 7 d) stay in hospital after lower-extremity amputation. General surgery patients were 1.5 times as likely to stay longer in hospital than vascular surgery patients. We hypothesize that this is because amputations comprise a smaller proportion of a Canadian general surgeon’s practice than of vascular and orthopedic surgeons’ practices. As such, general surgery teams are probably less experienced with the complex discharge requirements of amputees, which may explain why their patients spend more time in hospital postoperatively. Furthermore, general surgeons might be performing amputations in smaller hospitals without access to the discharge resources available at larger centres.

Amputations performed in certain provinces were predictive of a longer or shorter hospital stay than those performed in Ontario. This trend may be explained by regional variations in access to hospital and postdischarge resources, such as rehabilitation facilities and postdischarge community supports, as the provision of health care is primarily the responsibility of the provinces in Canada.

The trend may also be explained by differences in the demographic and socioeconomic characteristics across the country. First Nations Canadians, for example, form a greater proportion of the population in the central and western provinces and have a disproportionate burden of social issues and ill health compared with the rest of the population. Conversely, most recent immigrants to Canada settled in Ontario and hailed from southeast Asia and the Indian subcontinent, where the incidence of diabetes and other cardiovascular risk factors differs from that in the rest of the Canadian population.

Unsurprisingly, patients in our study with a history of diabetes, hypertension, IHD, CHF or hyperlipidemia were more likely to have a prolonged hospital stay than other patients. Those risk factors are probably markers for poorer patient health that predict worse postamputation outcomes. A study by Hasanadka and colleagues found that medical comorbidities, such as a history of myocardial infarction, CHF, chronic obstructive sleep apnea and dialysis use, predicted postoperative complications and mortality after above- and below-knee amputations.

Interestingly, above-knee amputees were more likely to be discharged earlier from hospital than below-knee amputees. This may in part be because those patients are less likely to have postoperative wound complications impacting their length of stay in hospital. Several studies have shown that above-knee amputations are associated with fewer postoperative wound healing issues than below-knee amputations.

Discharge destination

Most patients (65%) were discharged to a long-term care or another inpatient facility, whereas a minority were
discharged home (27%). A multicentre American study similarly reported that approximately 76% of amputees were discharged to an inpatient rehabilitation or skilled nursing facility, whereas approximately 24% were discharged home.\textsuperscript{18} The authors found that while patient sex and race did not impact discharge destination, predictors of discharge home versus a long-term care facility included younger age, being married, not having previously resided in a nursing home, and not having experienced any postoperative complications while still in hospital.

We found that general surgery amputees were more likely to be discharged home than other patients. We hypothesize that this is because of the lower burden of disease in those patients compared with vascular surgery amputees, although this could not be demonstrated using this database. Compared with patients in Ontario, patients in several other provinces were also more likely to be discharged home. The reasons for this are unclear and are likely secondary to several systemic factors that merit future investigation. Finally, patients who spent more than 7 days in hospital were more likely to be discharged home than to a rehabilitation facility. This may be because some hospitals rehabilitated amputees as inpatients in their facilities rather than transfer them to another institution, and those amputees were then discharged home after completion of their rehabilitation.

**Mortality**

Nine percent of patients died in hospital on the same admission after undergoing a lower-extremity amputation. It was not possible to determine the reasons for death in our database, but previous studies have reported a 6\%–10\% 30-day mortality in this patient population.\textsuperscript{19–21} Mortality among lower-extremity amputees has been shown to increase with the degree of renal dysfunction and is greatest in dialysis-dependent patients, who have a reported 30-day mortality of 16\%.\textsuperscript{22} Patients with diabetes have also been shown to have twice the risk of postoperative mortality after lower-extremity amputation compared with nondiabetic patients.\textsuperscript{5} We found that orthopedic surgery amputees were more likely to die in hospital than other patients. Unfortunately, it is not possible to adequately explain this finding given the lack of detailed patient comorbidity and hospital admission details, such as postoperative complications. Predictably, older patients were also more likely to die in hospital than younger patients. We found a higher mortality in several provinces compared with Ontario, which cannot be explained by our data set. Having an above-knee amputation was also associated with greater risk of death, likely because of the progression of atherosclerotic and diabetic disease in those vulnerable patients.

**Limitations**

Several considerations limit the generalizability of our findings. Our database did not include amputations for blunt or penetrating trauma or pediatric amputations. We also did not have data on minor amputations, such as toe amputations, which were performed as day surgeries or in physician offices. The annual number of minor amputations across Canada is certainly larger than what was reported in the present study, but we captured only minor amputations when a patient was admitted to an acute care hospital primarily to undergo this procedure, which excluded from the analysis a large number of patients who underwent the procedure as outpatients.

Furthermore, patients from Quebec, Canada’s second most populous province, were also not included. We unfortunately had very limited data on the patients’ course in hospital, including operative details or complications that developed during the admission, or whether the patients had undergone any previous revascularization attempts.

Finally, our length of stay analysis must be interpreted with caution, as it was not possible to determine whether the amputations in our data set were performed electively or secondary to complications that developed during a hospital admission for another condition, which would likely have resulted in a longer hospital stay.

These limitations notwithstanding, this to the best of our knowledge is the first report on lower-extremity amputations across Canada, and our results might be helpful in providing a future direction for more detailed studies to better explain regional and surgeon-dependent variability in outcomes after lower-extremity amputations.

**Future work**

In the current political climate in the United States and Canada, where the performance of health care systems is subject to increasing scrutiny by government agencies, private insurers and the general public, several factors, such as in-hospital mortality and length of stay, have emerged as important performance indicators to measure the quality of health care delivery.

Our study has identified several avenues for future research on patients undergoing lower-extremity amputations. From a health care delivery systems standpoint, it would be useful to analyze the highest-performing hospitals where patients experienced the fewest postoperative complications and were discharged in a timely manner to glean any lessons that are generalizable to other institutions. A study from Britain demonstrated that factors such as the patient’s type of admission, discharge destination, hospital type, specialty of the admitting physician and geographical region were all significant predictors of length of stay.\textsuperscript{23}
CONCLUSION

Most nontraumatic lower-extremity amputations in Canada are performed for diabetic complications, but the delivery and outcomes after amputation vary according to the region and the type of surgeon performing the amputation. Future work is needed to investigate the reasons for this variability and to develop initiatives to improve the quality of health care delivery to this vulnerable patient population.

Acknowledgments: The authors thank Mrs. Sandra Blirtz and Ms. Janice Montbriand for their advice with the statistical analysis.

Affiliations: All authors are from the Division of Vascular Surgery, University Health Network, University of Toronto, Toronto, Ont.

Competing interests: None declared.

Contributors: A. Kayssi and G. Roche-Nagle designed the study and acquired the data. All authors analyzed the data, wrote and reviewed the article and approved the final version for publication.

References

Are patients willing to pay for total shoulder arthroplasty? Evidence from a discrete choice experiment

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Accepted for publication
Jan. 5, 2015

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Background: Total shoulder arthroplasty (TSA) is a common treatment to decrease pain and improve shoulder function in patients with severe osteoarthritis (OA). In Canada, patients requiring this procedure often wait a year or more. Our objective was to determine patient preferences related to accessing TSA, specifically comparing out-of-pocket payments for treatment, travel time to hospital, the surgeon’s level of experience and wait times.

Methods: We administered a discrete choice experiment among patients with end-stage shoulder OA currently waiting for TSA. Respondents were presented with 14 different choice sets, each with 3 options, and they were asked to choose their preferred scenario. A conditional logit regression model was used to estimate the relative preference and willingness to pay for each attribute.

Results: Sixty-two respondents completed the questionnaire. Three of the 4 attributes significantly influenced treatment preferences. Respondents had a strong preference for an experienced surgeon (mean 0.89 ± standard error [SE] 0.11), while reductions in travel time (–0.07 ± 0.04) or wait time (–0.04 ± 0.01) were of less importance. Respondents were found to be strongly averse (–1.44 ± 0.18) to surgical treatment by a less experienced surgeon and to paying out-of-pocket for their surgical treatment (–0.56 ± 0.05).

Conclusion: Our results suggest that patients waiting for TSA to treat severe shoulder OA have minimal willingness to pay for a reduction in wait time or travel time for surgery, yet will pay higher amounts for treatment by an experienced surgeon.
shoulder osteoarthritis (OA) is a debilitating disease present in approximately one-third of patients older than 60 years. Pain and loss of function from shoulder OA have a substantial impact on these patients’ lives. Recent studies have demonstrated decreased health-related quality of life (HRQoL) scores for patients with shoulder OA when compared with population norms.

In less severe cases of shoulder OA, nonoperative treatments, such as physiotherapy, analgesics and non-steroidal anti-inflammatory drugs, may be effective in reducing pain. Less invasive surgical procedures, such as arthroscopic débridement, have also been used for less severe stages of shoulder OA. However, once the patient progresses to end-stage shoulder OA, the recommended treatment is total shoulder arthroplasty (TSA). A recent meta-analysis found that treatment of shoulder arthritis with TSA leads to significant improvement in both generic and joint-specific HRQoL scores.

Owing to budget constraints in the publicly funded Canadian health care system, operating room access and costly surgical implants are frequently rationed. These constraints can cause patients with shoulder OA to wait more than a year to receive this effective surgery. Unfortunately, it has been demonstrated in other arthritic populations that a patient’s condition and quality of life deteriorate while on a wait list. Additionally, the eventual outcome of the TSA may be compromised by progressive joint stiffness and muscle atrophy. When faced with substantial wait times, patients may consider other options for accessing necessary surgical care.

The objective of this study was to determine patient preferences for accessing TSA surgery in Ontario, Canada. Specifically, we sought to determine preferences toward paying out of pocket for surgery, travelling increased distances, or being treated by surgeons with varying levels of experience in exchange for a shorter wait time to receive a TSA.

**Methods**

**Study design**

The study used a discrete choice experiment (DCE) to estimate the access to treatment preferences of patients waiting for an elective TSA. The methodology is based on random utility theory, which states that consumers have a preference for and derive utility from underlying attributes rather than the specific good or service. Discrete choice experiments are becoming increasingly popular in health services research, with the recognition that the attractiveness of health interventions for a patient often depend on more than just the possible health outcome.

These experiments have also been proven to be an effective tool in accounting for patient preferences when allocating scarce health care resources.

**Attributes and levels**

The attributes and corresponding levels (Table 1) used in this study were developed using qualitative methods. We conducted semistructured interviews among patients with shoulder OA who were currently waiting for TSA treatment until data redundancy was obtained. Four attributes and their corresponding levels were then selected through a consensus process with patients and orthopedic surgeons to ensure content validity. The designated attributes included travel time to the hospital for surgical treatment, the wait time for surgical treatment, the surgeon’s experience level and a potential out-of-pocket cost for surgical treatment. The travel time attribute levels were selected to reflect current referral patterns and patient proximity to alternative treatments.
We used willingness to pay thresholds described in elective surgery literature to develop the out-of-pocket payment levels. The surgeon’s level of experience was a common theme noted in the semi-structured interviews. The wait list levels were based on the experience of current patients. By changing the attribute levels in the 14 hypothetical comparisons, we were able to use the respondents’ stated choices in each question to estimate their underlying relative preference for the included attributes.

**Participants**

We recruited adult patients with end-stage shoulder OA waiting for TSA surgery to complete the DCE questionnaire. All participants were recruited from a single surgeon’s practice located in metropolitan Ontario. Participants were mailed the DCE questionnaire along with demographic and clinical outcome questionnaires. Health-related quality of life was measured with the Euroqol-5D (EQ-5D) instrument, and shoulder function was assessed with the Quick Disabilities of Arm, Shoulder, and Hand (quickDASH) questionnaire. We obtained informed consent from all study participants, and the study protocol was approved by the St. Michael’s Hospital Research Ethics Board.

**Questionnaire development**

We used Sawtooth CBC/SSI Web version 6.4.2 software (Sawtooth Software, Inc.) to develop the DCE questionnaire. In each choice set, study participants were asked to choose 1 of 3 options: 2 different hypothetical scenarios to receive TSA or a status quo option where TSA treatment is declined. A sample choice set is available in Figure 1. The status quo option was included to account for individuals who did not prefer either of the 2 alternatives presented in the choice set and would rather continue to live with their shoulder OA. Each hypothetical scenario included varying levels of the 4 attributes. Each respondent was asked to complete 14 choice sets.

**Statistical analysis**

We analyzed the DCE responses using a conditional logit model (STATA software version 13.1, StataCorp).

<table>
<thead>
<tr>
<th>Table 1. Attributes and attribute levels</th>
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<tr>
<td>Attribute</td>
</tr>
<tr>
<td>Travel time to the hospital for surgery, h</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Wait time from deciding to have surgery to the day of surgery, mo</td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
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<tr>
<td></td>
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<tr>
<td>Surgeon’s level of experience</td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
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<tr>
<td>Out-of-pocket cost for surgical treatment, Can$</td>
</tr>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Table 2. Characteristics of questionnaire respondents (n = 62)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristic</td>
</tr>
<tr>
<td>Female sex</td>
</tr>
<tr>
<td>Age, mean ± SD</td>
</tr>
<tr>
<td>Home region</td>
</tr>
<tr>
<td>Toronto</td>
</tr>
<tr>
<td>York</td>
</tr>
<tr>
<td>Peel</td>
</tr>
<tr>
<td>Nipissing</td>
</tr>
<tr>
<td>Peterborough</td>
</tr>
<tr>
<td>Simcoe</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Marital status</td>
</tr>
<tr>
<td>Married</td>
</tr>
<tr>
<td>Widowed</td>
</tr>
<tr>
<td>Separated/divorced</td>
</tr>
<tr>
<td>Single (never married)</td>
</tr>
<tr>
<td>Not disclosed</td>
</tr>
<tr>
<td>Education</td>
</tr>
<tr>
<td>Elementary</td>
</tr>
<tr>
<td>Some secondary</td>
</tr>
<tr>
<td>Completed secondary</td>
</tr>
<tr>
<td>Some postsecondary</td>
</tr>
<tr>
<td>Completed postsecondary</td>
</tr>
<tr>
<td>Completed graduate degree</td>
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<tr>
<td>Not disclosed</td>
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<tr>
<td>Employment status</td>
</tr>
<tr>
<td>Full-time</td>
</tr>
<tr>
<td>Part-time</td>
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<tr>
<td>Homeworker</td>
</tr>
<tr>
<td>Retired</td>
</tr>
<tr>
<td>Not disclosed</td>
</tr>
<tr>
<td>Annual household income, $</td>
</tr>
<tr>
<td>&lt; 20 000</td>
</tr>
<tr>
<td>20 000–39 999</td>
</tr>
<tr>
<td>40 000–59 999</td>
</tr>
<tr>
<td>60 000–79 999</td>
</tr>
<tr>
<td>80 000–99 999</td>
</tr>
<tr>
<td>&gt; 100 000</td>
</tr>
<tr>
<td>Not disclosed</td>
</tr>
<tr>
<td>Clinical characteristics and history</td>
</tr>
<tr>
<td>Duration on wait list, mean ± SD, yr</td>
</tr>
<tr>
<td>Duration of shoulder pain, median [IQR], yr</td>
</tr>
<tr>
<td>EQ-5D score, median [IQR]</td>
</tr>
<tr>
<td>QuickDASH score, mean ± SD</td>
</tr>
</tbody>
</table>

IQR = interquartile range; SD = standard deviation.

*Unless indicated otherwise.
Travel time (in h), wait time (in mo) and cost (per $1000) were entered into the model as continuous variables and were assumed to be linear. The surgeon’s level of experience was coded using effect coding. The reference level for the model was the status quo option (no surgical treatment). The respondents’ relative preferences (or utility) for each of the attributes are represented by the magnitude and direction of the regression coefficients. The ratio of the coefficients (marginal rate of substitution) shows trade-offs that the respondents would be willing to make between the attributes. We calculated willingness to pay for each attribute using the ratio of the attribute’s coefficient to the cost coefficient. Willingness to pay can provide useful interpretations for the preference estimates, as they indicate how much the respondents, on average, are willing to pay for a marginal change in 1 of the attribute levels.

**RESULTS**

Of the 137 patients who met the eligibility criteria, 62 (45%) respondents completed the questionnaire. The mean age of participants was 70.9 ± 9.62 years. Fifty-three percent of participants were women, 44% resided within the city of Toronto, 26% had completed post-secondary education, 47% were retired and 18% had an annual household income of more than $100 000 (Table 2). Respondents had been on the wait list for surgery for an average of 16.8 months and had experienced shoulder pain for an average of 6.14 years. The median HRQoL EQ-5D score of the participants was 0.61 (interquartile range [IQR] 0.51–0.80), and the mean QuickDASH score was 50.9 ± 18.11, denoting significant disability.

We used a conditional logit model to determine the mean preference estimates of each attribute (Table 3). The preference estimates for cost, surgeon experience and wait time were statistically different from zero at $\alpha = 0.01$. Respondents had a strong positive preference for treatment by an experienced surgeon (mean 0.89 ± standard error [SE] 0.11), while reductions in travel time to the hospital for treatment (–0.07 ± 0.04) or time on the surgical wait list (–0.04 ± 0.01) were of less importance. Respondents were found to be strongly averse (–1.44 ± 0.18) to surgical treatment by a surgeon with less than average experience and to paying out of pocket for their surgical treatment (–0.56 ± 0.05).

The willingness to pay value enables potential trade-offs to be analyzed using marginal rates of substitution. For our analysis, cost is coded as a continuous variable and assumed to be linear. The reference level for the cost variable in our model was set to $1000 for coherent framing of the comparisons. The results suggest that respondents were willing to pay $128.50 to reduce their travel time to the hospital for surgical treatment by 1 hour and $76.40 to have their wait time for surgical treatment decreased by 1 month. All else being equal, respondents preferred to drive more than 7 hours to the hospital for surgical treatment or wait more than 13 months than pay $1000 out of pocket for their surgical treatment. Respondents were willing to drive an additional 3 hours to the hospital for surgical treatment or wait an additional 5.5 months to have their treatment performed by an experienced surgeon as opposed to treatment by a surgeon of average experience.

**DISCUSSION**

This study sought to evaluate patient preferences for accessing TSA in Ontario, Canada. Our results suggest that patients waiting for TSA to treat severe shoulder OA are generally unwilling to pay for a reduction in their wait time or travel time for surgery. Patients are willing to pay a 33% premium for surgical treatment by an experienced surgeon. It should also be noted that patients demonstrated a strong aversion to treatment from a less experienced surgeon, preferring to opt out of surgical treatment entirely.

Our findings are consistent with those of previous research, which found that Canadians are relatively unwilling to pay to decrease their wait times for elective surgical procedures. Our findings also support claims that, on average, Canadians place tremendous value on equity in the health care system. It has been suggested

### Table 3. Conditional logit model relative preference estimates for each attribute*

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Coefficient</th>
<th>SE</th>
<th>p value</th>
<th>95% CI</th>
<th>WTP (Can$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travel time, hr</td>
<td>–0.0719</td>
<td>0.0377</td>
<td>0.06</td>
<td>–0.1459 to 0.0020</td>
<td>–128.50</td>
</tr>
<tr>
<td>Wait time, mo</td>
<td>–0.0428</td>
<td>0.0080</td>
<td>&lt; 0.001</td>
<td>–0.0584 to –0.0271</td>
<td>–76.40</td>
</tr>
<tr>
<td>Surgeon’s level of experience</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less</td>
<td>–1.4463</td>
<td>0.1796</td>
<td>&lt; 0.001</td>
<td>–1.7963 to –1.0962</td>
<td>–2583.34</td>
</tr>
<tr>
<td>Similar</td>
<td>0.6548</td>
<td>0.1199</td>
<td>&lt; 0.001</td>
<td>0.4197 to 0.8898</td>
<td>1169.53</td>
</tr>
<tr>
<td>More</td>
<td>0.8907</td>
<td>0.1071</td>
<td>&lt; 0.001</td>
<td>0.6809 to 1.1005</td>
<td>1590.99</td>
</tr>
<tr>
<td>Cost (Can$ 1000)</td>
<td>–0.5599</td>
<td>0.0548</td>
<td>&lt; 0.001</td>
<td>–0.6672 to –0.4525</td>
<td>Reference</td>
</tr>
</tbody>
</table>

CI = confidence interval; SE = standard error; WTP = willingness to pay.

*Log-likelihood = –632.3631, number of observations = 2604.
that patients are willing to wait, as long as all Canadians wait the same amount of time.

When compared with other studies that have investigated the willingness to pay among orthopedic patients,17–20 our results stand out as an outlier. Even when compared with patients in other health systems with universally available publicly funded treatments,15 the respondents in our study demonstrated far less willingness to pay for treating their severe shoulder OA. The willingness among study respondents to pay for treatment by a surgeon of average experience would fall short of covering the anesthesiologist and surgeon billing costs in Ontario and would cover less than one-tenth of the total treatment costs, including the implant, sundries and hospitalization expense.21,22

At the time of completing the questionnaire, our study respondents had been on the surgical wait list for an average of 16.8 months, had experienced shoulder pain for more than 6 years and experienced considerable disability (EQ-5D score of 0.61). Despite the profound disability and duration of shoulder pain, we were surprised that the willingness to pay for a decreased surgical wait time was relatively negligible. The rationale for this observation is not entirely clear and may represent the Canadian values already discussed; however, from a clinical perspective, it is possible that the arthritic shoulder was on the patients' nondominant limb or that they had become adept at performing most activities of daily living with their contralateral extremity. Furthermore, it is also possible that respondents had been disabled for such a long time and had subsequently been waiting for more than 1 year that they did not feel there was value in paying to reduce their surgical wait time.

Limitations

The results of this study must be interpreted in the context of the study design. Participants were recruited from the wait list of a single surgeon based in a major urban centre with a high-volume upper-extremity referral practice; therefore, this sample may not be representative of patients on the surgical wait lists of community hospitals or of other surgeons. In addition, the DCE findings are based on the attributes included in the questionnaire. Although our attribute development process suggested these are important attributes to this study population, there may be other attributes of importance that were not included in the questionnaire design and therefore not accounted for in the final model. Finally, the study’s sample size was unfortunately prohibitive in investigating the effect of time on a surgical wait list, time with shoulder pain, the level of disability and demographic characteristics on patient preferences for accessing surgical treatment. We suspect that variables such as age, employment status and income may affect patient preferences for surgical treatment, but we were unable to fully explore preference heterogeneity in this study. We recognize that this insight is of interest to providers and policy-makers, and further research in this area is required.

Strengths

The strengths of our study include its novel design, its patient-centred focus and its relevance to policy-makers tasked with allocating surgical resources in Canada. The effective allocation of surgical resources continues to be a contentious issue. Our study applies a unique approach rooted in behavioural economics and market research to quantify the relative preferences of this patient population.

CONCLUSION

The results of this study represent noteworthy findings for both surgeons and policy-makers. Significant surgical wait times continue to plague the Canadian health care system. The concept of surgical “centres of excellence” garners much attention as a mechanism for providing high-volume surgical output and expert care for common surgical procedures. Discussions have speculated whether Canadians would be willing to co-pay or travel a greater distance for an elective surgical procedure provided by a surgeon with procedural-specific expertise or minimal wait time. The results of our study suggest that patients value surgeon expertise, but wait time may not be as important to patients waiting for TSA. Our findings represent insight into patient preferences for a common elective surgical procedure. Our methodology is a valuable tool to align resources with patient preferences, and efforts to create strategies to provide patients with timely access to surgical care must be continued.

Affiliations: From the R Adams Cowley Shock Trauma Center, Department of Orthopaedics, University of Maryland School of Medicine, Baltimore, MD (O’Hara, Slobogean); the Centre for Health Evaluation and Outcome Sciences, University of British Columbia, St. Paul’s Hospital, Vancouver, BC (Mohammadi); the School of Pharmacy, Memorial University, St. John’s, NF (Marra); the Department of Orthopaedics, St. Michael’s Hospital, Toronto, Ont. (Vicente, McKee); and the Collaboration for Outcomes Research and Evaluation, Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, BC (Khakban).

Competing interests: M. McKee is paid as a consultant by Zimmer and Stryker, who produce total shoulder arthroplasty implants. No other competing interests declared.

Contributors: G. Slobogean, T. Mohammadi, C. Marra, M. Vicente, A. Khakban and M. McKee designed the study. N. O’Hara, G. Slobogean, M. Vicente and M. McKee acquired the data, which N. O’Hara, G. Slobogean, T. Mohammadi, C. Marra, A. Khakban and M. McKee analyzed. N. O’Hara, G. Slobogean, T. Mohammadi, C. Marra and M. McKee wrote the article, which all authors reviewed and approved for publication.
References


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The relevance of preoperative ultrasound cervical mapping in patients with thyroid cancer

Davit Kocharyan, MD, MSc (cand)
Frank Schwenter, MD, PhD
Manon Bélair, MD
Edgard Nassif, MD, MBA

Background: Cervical lymph node involvement in thyroid cancer is associated with locoregional recurrence and decreased disease-free survival. Preoperative lymph node mapping helps in planning surgery for neck dissection and improves patient outcomes. We sought to perform a qualitative and quantitative analysis of ultrasound mapping for thyroid cancer and evaluate the clinical importance of this exam in terms of identifying the group of patients who would benefit most from subsequent surgical dissection.

Methods: We retrospectively reviewed the cases of 263 patients who underwent thyroid surgery between 2009 and 2013. We calculated the positive predictive values (PPVs) of ultrasound mapping of both the lateral and central compartments together and the lateral or central compartment individually. A quantitative analysis was performed by comparing the number of positive lymph nodes at ultrasound imaging with histopathologic evaluation.

Results: A total of 136 cases of thyroid cancer in 120 patients met the inclusion criteria for ultrasound mapping analysis. The PPVs (and 95% confidence intervals) were 83.82% (0.76–0.89) for the lateral and central compartments, 85.39% (0.76–0.91) for the lateral compartment, and 80.48% (0.7–0.87) for the central compartment. When comparing the positive lymph nodes at ultrasound imaging with histopathologic evaluation, the result was $\chi^2 = 10.33$ ($p = 0.006$).

Conclusion: This single-institution study indicated that preoperative ultrasound mapping is an accurate imaging procedure for predicting lymphatic spread in differentiated and medullary thyroid cancer. Ultrasound mapping can be used as an efficient tool for surgical planning and prognosis determination, as well as for identifying the group of patients who would benefit most from subsequent surgical intervention.
Differentiated thyroid carcinomas are the most common types of thyroid malignancies. Papillary thyroid carcinoma (PTC) accounts for approximately 80% of all thyroid neoplasms and has shown a permanent increase in its incidence. The fastest increase has been in women, making PTC now the sixth most common cancer among women. There are several major risk factors for PTC, such as exposure to ionizing radiation and a family history of thyroid cancer. Papillary carcinoma is also associated with mutations of oncogenes, such as BRAF, RET/PTC, RAS and TRK.

Despite a high survival rate (5- and 10-year overall survival of 90% and 95%, respectively), about 20%–50% of patients require additional treatments for lymph node (LN) metastasis. In 80%–90% of patients, micrometastasis can be found with meticulous bilateral neck dissection. Although cervical LN metastasis has almost no impact on short-term survival, it greatly affects long-term survival, as it is a major risk factor for locoregional tumour recurrence. Lymph node metastasis is associated with several predisposing risk factors, such as male sex, age older than 45 years, tumour size greater than 1 cm and lymphovascular and extrathyroidal invasions. Moreover, PTC located in the upper neck has been shown to present a higher rate of lateral neck metastasis than PTC in the lower neck.

Despite an increased rate of recurrence in patients with PTC and LN metastasis, there is no evidence that radical neck or routine central compartment dissection can improve disease-free survival, particularly in patients with papillary thyroid microcarcinomas measuring less than 10 mm. Central neck dissection is even associated with a higher rate of complications, such as hypocalcemia, recurrent laryngeal nerve palsy, hematoma, chyle leakage and spinal accessory nerve dysfunction.

Lymph node involvement can be detected by physical examination, which has a sensitivity as low as 15%–30%, whereas neck imaging is highly efficient; high-resolution ultrasonography (US) in particular is able to detect nodules as small as 5 mm. In addition, computed tomography (CT) can be used for staging LNs in patients with thyroid carcinoma. Although most studies agree that US is the first choice, some investigators have reported comparable sensitivity with CT and that sensitivity was even slightly higher with CT than US for the central compartment.

In these studies, it is interesting to observe that the sensitivity of US is lower (< 80%) than previously reported. Computed tomography necessitates the injection of a high quantity of iodine contrast, which could interfere in the follow-up investigation and treatment of the patient. After receiving iodine contrast, patients must wait 3–4 months before being able to receive radioactive iodine treatment or a thyroid iodine uptake scan. It is important to be aware of the patient therapy and coordinate CT with the medical team; this is clearly a disadvantage of this modality. Using US also gives the opportunity to practice fine needle aspiration (FNA) on LNs that are undetermined and influence the extent of the dissection.

A US-based preoperative evaluation of the primary tumour’s extent as well as LN involvement has become an essential procedure, which can modify the overall surgical approach in up to 40% of cases. This approach is recommended in the guidelines of the American Thyroid Association.

The aim of this study is to evaluate the diagnostic reliability of preoperative US mapping of thyroid cancers in our institution by calculating the positive predictive value (PPV) of the test and trying to determine whether there is a quantitative association between US mapping and pathological analysis. The interpretation of such an association may help to target the group of patients who would benefit most from the subsequent surgical procedure and at the same time help avoid unproductive surgical dissection in patients with minimal risk of disease recurrence. To our knowledge, no study has been done to evaluate the existence of such a quantitative association between cervical LN mapping and pathological results.

**METHODS**

The medical records of 263 patients who underwent surgery for thyroid cancer at the Centre hospitalier de l’Université de Montréal (CHUM) between 2009 and 2013 were retrospectively reviewed. The only exclusion criterion was the absence of US mapping. We used the electronic institutional database and Microsoft Access software for data collection. Surgeries were performed by 9 surgeons (1 endocrine surgeon and 8 otorhinolaryngologists). Ten radiologists were involved in the study, but more than 80% of cases were examined by 1 radiologist with advanced skills in US mapping of thyroid cancer. A US system equipped with a high-resolution (13 MHz) linear probe was used. Parameters including operative procedures, pathological analyses and mapping results according to neck compartments were collected.

For the purpose of quantitative analysis, patients were divided into 2 groups based on the number of suspicious LNs at US mapping (group A: 1 or 2 suspicious LNs; group B: ≥ 3 suspicious LNs). Concerning the histopathological results, we created 3 groups according to the number of positive LNs (group 1: 0 positive LNs; group 2: 1 or 2 positive LNs; group 3: ≥ 3 positive LNs). The LN location in the neck was divided into central (CC) and lateral compartments (LC). The CC was defined as the space between the medial margins of bilateral carotid arteries, corresponding to level VI, whereas the LC extends from the carotid arteries to the medial border of the trapezius muscle and involves levels II, III, IV and V, according to the definitions of the American Head and Neck Society and the American Academy of Otolaryngology — Head and Neck Surgery.
The imaging suspicion of LN involvement was based on various criteria, such as cystic changes, hyperechogenicity, loss of hilar echogenicity (fat centre), internal microcalcifications, poorly defined irregular borders, shape/dimension ratio, compressibility, vascularity, size > 5 mm in its shortest diameter and round shape (Fig. 1). In our study, we considered a node to be suspicious if at least 1 of these criteria was met. As for loss of hilar echogenicity on nodes smaller than 5 mm, an additional criterion was needed to reach the level of suspicious LN. The surgical exploration was guided by US mapping. Suspicious LNs were removed based on the compartment-oriented approach without further dissection. On histopathology, LNs with a diameter less than 5 mm were examined by 1-sliced specimen. We used 2-sliced specimen examination for the LNs with a diameter greater than 5 mm.

**Statistical analysis**

We performed our statistical analyses using SPSS software, version 20. Continuous variables were analyzed as means ± standard deviations, and we used the χ² test for categorical data.

**RESULTS**

Among the 263 patients who underwent thyroid surgery, 261 had undergone US mapping, and suspicious LNs were found in 154 cases. Despite positive US mapping, 18 cases were excluded from the study owing to the absence of LNs in the surgical specimen (3 patients), the absence of pathological results (1 patient), the absence of neck compartment dissection (11 patients), and a change in surgical planning in favour of palliative tracheotomy (1 patient) and hemithyroidectomy (2 patients). Therefore, results were obtained after analyzing 136 cases of positive US mapping in 120 patients (Table 1).

The patients’ mean age was 49.9 ± 16.2 (range 16–90) years. Of the 120 patients, 89 (74.1%) were women and 31 (25.9%) were men. Nine patients had been operated twice, 2 patients 3 times, and 1 patient 4 times. Among the 120 patients, histopathological analysis indicated 110 PTCs, 8 medullary cancers, 1 follicular cancer and 1 Hurthle cell tumour. In 87 cases, compartment-oriented surgical excision of suspected LNs along with thyroidectomy had been performed (primary surgeries) and 49 procedures had been carried out for recurrent disease (secondary surgeries). Three postsurgical complications had been recorded: 1 bilateral chylothorax, 1 hematoma in thyroid bed, and 1 case of bleeding from the innominate artery. During the data collection period (February to September 2014), radiological findings of locoregional recurrent disease were noted in 26 (21.6%) patients. On US mapping, there were 40 (29.4%) cases in group A and 96 (70.6%) cases in group B. On histopathology, there were 22 (16.2%) cases in group 1, 41 (31.1%) cases in group 2 and 73 (53.7%) cases in group 3 (Table 2). When comparing these groups using the χ² test, the results were significant (χ² = 10.33, p = 0.006).

We calculated the PPVs of ultrasound mapping for LC alone, CC alone and both LC and CC. For LC, 76 of 89 cases were confirmed positive on pathological examination, resulting in a PPV of 85.39% (95% confidence interval [CI] 0.76–0.91). For CC, 66 of 82 cases were confirmed positive, resulting in a PPV of 80.48% (95% CI...
DISCUSSION

This study examined the qualitative and quantitative reliability of US mapping of thyroid cancer in a single institution. Our results confirmed that US mapping is a reliable tool for detecting affected LNs. With an PPV of 83.82% for the LC and CC together with advantages, such as simplicity, ease in terms of performance, wide availability, comparatively low price, noninvasiveness and lack of radiation,12 US mapping is an excellent tool for surgery guidance. The relatively low rate of detection of metastatic LNs in the CC might be explained by anatomic limitations in that area of the neck, such as the clavicle, sternum and tracheal air shadow.1,20

Micrometastases (< 2 mm) in patients undergoing prophylactic LN dissection were found in up to 80% of individuals.12,25 Nevertheless, such micrometastases are not clinically relevant, as palpable lymphadenopathies do not develop in most patients with PTC. On the contrary, patients presenting with macrometastases (> 2 mm) have 5%–40% persistent/recurrent (P/R) disease after surgery,26,27 which has a tremendous impact on quality of life, and despite the additional therapeutic interventions, 10% of patients die from the disease.28 Reoperation of P/R disease involves many difficulties because the extensive scarring from previous surgery can obscure normal anatomy, which in turn contributes to longer surgeries and increased morbidity.29

Ultrasound mapping guides the surgeon for precise neck dissection, resulting in decreased locoregional tumour recurrence and lower risk of postsurgical complications due to reoperation. To analyze this test more thoroughly, we decided to go a step further in our study by evaluating not only PPV, but also the quantitative reliability of the test, which, to our knowledge, had not been done before. Such an approach seemed highly valuable as patients with multiple positive LNs have been shown to be at greater risk of recurrence.30 Based on the quantitative results of US mapping, patients can be stratified according to the level of risk of recurrent disease, which in turn will help to better select surgical candidates. The use of US mapping to plan compartment-oriented LN dissection could therefore benefit patients undergoing thyroid cancer surgery, as recognized by the American Thyroid Association.30

Limitations

Our results showed a statistically significant association between US mapping analysis and LN pathological examination, indicating that US mapping is an effective tool in the armamentarium of quantitative prediction for lymphatic spread in thyroid cancer. Another notable observation was derived by analyzing the false-positive cases on US mapping. In 10 of 22 cases (45.4%), patients had Hashimoto’s thyroiditis, which was mimicking affected LNs in thyroid cancer. The retrosternal localization and small size (< 5 mm) of the affected LNs made it extremely difficult to distinguish them from metastatic LNs. Consequently, we believe that Hashimoto’s thyroiditis might be considered a limiting factor for US mapping in patients with suspicion of thyroid cancer.

Another major subject of discussion is the test’s specificity and sensitivity. In fact, it is impossible to calculate either sensitivity or specificity because negative findings on US cannot be considered true negatives

Table 1. Surgical and histopathological characteristics of patients who underwent ultrasound mapping followed by neck dissection

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients/cases</td>
<td>120/136</td>
</tr>
<tr>
<td>Sex, F/M</td>
<td>89 (74.1%)/31 (25.9%)</td>
</tr>
<tr>
<td>Age, mean ± SD [range], yr</td>
<td>49.9 ± 16.2 [16–90]</td>
</tr>
<tr>
<td>No. of primary/secondary surgeries</td>
<td>87/49</td>
</tr>
<tr>
<td>No. of postsurgical complications</td>
<td>3</td>
</tr>
<tr>
<td>Locoregional recurrence on US follow-up</td>
<td>26 (21.6%)</td>
</tr>
<tr>
<td>Histopathology, no. patients</td>
<td>110 papillary</td>
</tr>
<tr>
<td></td>
<td>8 medullary</td>
</tr>
<tr>
<td></td>
<td>1 follicular</td>
</tr>
<tr>
<td></td>
<td>1 Hurthle cell</td>
</tr>
</tbody>
</table>

F = female; M = male; SD = standard deviation; US = ultrasound.

*Unless indicated otherwise.

Table 2. Cross-tabulation of the results among the groups of US mapping and histopathology

<table>
<thead>
<tr>
<th>Mapping; group</th>
<th>Histopathology; group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 (0 PLN)</td>
</tr>
<tr>
<td>A (1 or 2 SLN)</td>
<td>10</td>
</tr>
<tr>
<td>B (≥ 3 SLN)</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>22</td>
</tr>
</tbody>
</table>

PLN: positive lymph nodes; SLN = suspicious lymph nodes; US = ultrasound.

Table 3. Descriptive statistics of the removed LNs according to compartments

<table>
<thead>
<tr>
<th>No. LNs</th>
<th>LC, n = 91</th>
<th>CC, n = 93</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. LNs</td>
<td>Positive LNs</td>
<td>Total LNs</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>4.21 ± 0.66</td>
<td>19.41 ± 1.6</td>
</tr>
<tr>
<td>Median [range]</td>
<td>2 [0–49]</td>
<td>17 [1–72]</td>
</tr>
<tr>
<td>Sum</td>
<td>383</td>
<td>1766</td>
</tr>
</tbody>
</table>

CC = central compartments; LC = lateral compartment; LN = lymph node; SD = standard deviation.
owing to the lack of supporting “gold standard” results. In the literature, these 2 values have a very wide range (29%–100%) depending on the study design and chosen “gold standard” methods, as shown in the meta-analysis by Wu and colleagues.11 We therefore believe that the best way to solve this contradiction is to conduct a prospective study with long-term follow-up of negative cases on US mapping.

CONCLUSION

Ultrasound mapping is a reliable tool for guiding surgical dissection of the neck, both for a primary tumour and for P/R disease. It has a sufficiently high PPV and strong quantitative association with histopathological analysis, which makes it possible to focus on patients with higher risk of recurrent disease. Meanwhile, there may be some limitations to the test in cases such as thyroiditis, and further research needs to be conducted to obtain more reliable values for both sensitivity and specificity.

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Competing interests: None declared.

Contributors: D. Kocharyan and E. Nassif designed the study, acquired and analyzed the data, which F. Schwenter and M. Bélair also analyzed. D. Kocharyan and E. Nassif wrote the article, which all authors reviewed and approved for publication.

References

Very early initiation of chemical venous thromboembolism prophylaxis after blunt solid organ injury is safe

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Accepted for publication  
Dec. 7, 2015

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DOI: 10.1503/cjs.010815

Background: The optimal timing of initiating low–molecular weight heparin (LMWH) in patients who have undergone nonoperative management (NOM) of blunt solid organ injuries (SOIs) remains controversial. We describe the safety of very early initiation of chemical venous thromboembolism (VTE) prophylaxis among patients undergoing NOM of blunt SOIs.

Methods: We retrospectively studied severely injured adults who sustained blunt SOI without significant intracranial hemorrhage and underwent an initial NOM at a Canadian lead trauma hospital between 2010 and 2014. Safety was assessed based on failure of NOM, defined as the need for operative intervention, in patients who received early (< 48 h) or late LMWH (≥ 48 h, or early discharge [≤ 72 h] without LMWH).

Results: We included 162 patients in our analysis. Most were men (69%), and the average age was 42 ± 18 years. The median injury severity score was 17, and splenic injuries were most common (97 [60%], median grade 2), followed by liver (57 [35%], median grade 2) and kidney injuries (31 [19%], median grade 1). Combined injuries were present in 14% of patients. A total of 78 (48%) patients received early LMWH, while 84 (52%) received late LMWH. The groups differed only in percent of high-grade splenic injury (14% v. 32%). Overall 2% of patients failed NOM, none after receiving LMWH. Semielective angiography was performed in 23 (14%) patients. The overall rate of confirmed VTE on imaging was 1.9%.

Conclusion: Early initiation of medical thromboembolic prophylaxis appears safe in select patients with isolated SOI following blunt trauma. A prospective multicentre study is warranted.

Contexte : Le moment optimal pour commencer le traitement à l’héparine de bas poids moléculaire (HBPM) chez les patients ayant subi un traumatisme fermé à un organe plein (TFOP) avec prise en charge non chirurgicale (PCNC) demeure un sujet controversé. Nous décrivons l’innocuité d’une initiation hâtive de la chimiprophylaxie de la thromboembolie veineuse (TEV) chez les patients dont le TFOP est pris en charge de façon non chirurgicale.

Méthodes : Nous avons étudié rétrospectivement les cas d’adultes gravement blessés ayant subi un TFOP sans hémorragie intracrânienne importante pris en charge de façon non chirurgicale dans un hôpital canadien de premier plan spécialisé en traumatologie entre 2010 et 2014. L’innocuité a été évaluée en fonction du taux d’échec de la PCNC, défini comme la nécessité de recourir à une intervention chirurgicale, chez des patients qui ont reçu de l’HBPM plus tôt (< 48 h) ou plus tard (≥ 48 h, ou qui ont reçu un congé précoce [≤ 72 h]).

Résultats : Pour notre analyse, nous avons retenu 162 patients, en majorité des hommes (69 %), dont l’âge moyen était de 42 ± 18 ans. L’indice médian de gravité de la blessure était de 17; les lésions à la rate étaient les plus fréquentes (97 [60 %], stade médian 2), suivies des lésions du foie (57 [35 %], stade médian 2) et des lésions du rein (31 [19 %], stade médian 1). Il y avait présence de lésions combinées chez 14 % des patients. Au total, 78 patients (48 %) ont reçu de l’HBPM plus tôt, comparativement à 84 (52 %) qui en ont reçu plus tard. Seul le pourcentage de lésions spléniques graves était différent chez les 2 groupes (14 % comparativement à 32 %). La PCNC a échoué chez 2 % des patients, et chez aucun patient après l’administration d’HBPM. Une angiographie semi-urgente a été réalisée chez 23 patients (14 %). Le taux global de TEV confirmé par imagerie était de 1,9 %.

Conclusion : L’initiation hâtive de la prophylaxie de la TEV semble être sans danger chez certains patients ayant subi un traumatisme fermé et isolé à un organe plein. Il y a lieu de réaliser une étude multicentrique prospective.
Trauma patients are at high risk of venous thromboembolism (VTE). Without any prophylaxis, more than 50% may experience deep vein thrombosis (DVT), which substantially increases the risk of pulmonary embolism (PE).\(^1,2\) In trauma patients who survive 24 hours, PE is the third leading cause of death.\(^3\) Even with chemical prophylaxis, DVT can be detected in 15% of patients when screened with duplex ultrasonography.\(^4\)

Trauma patients can be one of the most difficult populations in which to initiate chemical prophylaxis. Typically an initial coagulopathic state transitions to a hypercoagulable state within 48 hours of injury.\(^5\) Both the American College of Chest Physicians\(^6\) and the Eastern Association for the Surgery of Trauma\(^7\) have released guidelines regarding chemical VTE prophylaxis following trauma and recommend early chemical VTE prophylaxis. While this is an achievable goal in many patients, those with solid organ injuries (SOIs) represent a unique challenge, especially in the presence of head injury. Nonoperative management (NOM) of blunt SOIs is becoming more common, and the safety of early initiation of chemical VTE prophylaxis in this unique population remains unclear.\(^8\)

The goal of our study was to determine the rate of failure of NOM with early initiation of chemical VTE prophylaxis in patients with isolated blunt SOIs who undergo an initial trial of NOM.

**Methods**

The London Health Sciences Centre (LHSC) is a lead trauma centre in Southwestern Ontario, Canada, with an approximate catchment of 1.5 million people. The LHSC maintains a trauma database for all trauma activations or patients with an injury severity score (ISS) greater than 12. The information in the locally maintained trauma database is collected prospectively, with less than 1% of data missing. The LHSC admits approximately 360 patients per year with an ISS greater than 12.

We queried the database to identify all adult patients (≥ 18 yr) with blunt splenic, liver, or kidney injuries, or any combination thereof, treated at the LHSC between April 2010 and February 2014. We excluded patients with a significant head injury (Maximum Abbreviated Injury Score [MAIS] of the head > 2), patients with penetrating trauma, those who died within 24 hours of presentation and those who were injured more than 24 hours before presentation to hospital.

We defined operative management based on the initial treatment plan from reviewing the trauma team leader and general surgery documentation. We considered patients to have undergone NOM if they did not receive an operation as part of their initial treatment plans or if they underwent angiography urgently or electively for embolization. The use of NOM for blunt SOI at LHSC is not based on a protocol. Patients with a splenic injury undergo follow-up computed tomography (CT) at 48 hours to assess for pseudoaneurysms. When splenic pseudoaneurysms are found, patients receive elective embolization before discharge. A similar strategy exists for high-grade liver injuries. Based on our prior work,\(^9\) routine repeat imaging is performed in all patients with liver injuries classified as grade 3 or greater to assess for the presence of pseudoaneurysm. Repeat imaging for low-grade liver injuries and all grades of kidney injuries are left to the discretion of the attending trauma physician. Venous thromboembolism prophylaxis includes low–molecular weight heparin (LMWH; dalteparin 5000 IU subcutaneous injections daily), sequential compression devices and thromboembolism-deterrent stockings at the discretion of the attending trauma physician. There is no routine screening for DVT or PE.

We divided the study cohort into 2 groups: patients who received LMWH within 48 hours of admission (early) and patients who received LMWH more than 48 hours after admission or who did not receive LMWH but were discharged after less than 72 hours (late).

We reviewed the electronic and paper medical records of all included patients. The primary outcome of interest was failure of NOM, defined as an abdominal operation while in hospital after an initial trial of NOM based on a review of documentation from the trauma and general surgery services. Elective (≥ 24 h) or urgent (< 24 h) angiography was not defined as failure of NOM, but was recorded. Timing of failure of the intervention in relation to initiation of chemical VTE prophylaxis was also recorded. Secondary outcomes included the need for blood transfusion. Additional data collected included demographic characteristics, ISS, MAIS, Glasgow Coma Scale (GCS) score, grade of solid organ injury, hemodynamics on arrival to the trauma centre and length of stay in hospital. Grade of injury was classified according to the American Association for the Surgery of Trauma. Injuries were classified based on a review of CT findings as dictated by the attending board-certified radiologist, and those that were grade 3 and higher were considered to be high-grade. Deep vein thrombosis and PE were recorded if they were identified in the final dictated report for the ultrasound and CT pulmonary angiogram, respectively.

Approval for this study was obtained from the Research Ethics Board at Western University (REB Number 106030).

**Statistical analysis**

We analyzed the data using SPSS software version 22. Data are presented as means with standard deviations for normally distributed continuous variables, medians with interquartile ranges (IQR) for non-normally distributed continuous variables, and frequencies with percentages for categorical variables. We compared the continuous...
variables using the Student t test or the Mann–Whitney U test and categorical variables using the Pearson χ² or Fisher exact test, as appropriate. We considered results to be significant at p < 0.05.

**RESULTS**

From April 2010 to March 2014 there were 287 patients with splenic, liver, kidney injuries or a combination thereof admitted to the LHSC trauma centres. Of the 287 patients there were 44 patients younger than 18 years, 20 who presented to hospital more than 24 hours after trauma, 18 who had a component of penetrating trauma and 4 who died within 24 hours. None of the patients who died within 24 hours received LMWH. These patients were excluded from our analysis, leaving 201 adults with blunt splenic, liver and/or kidney injuries available for analysis. Of these 201 patients, 24 (12%) were initially managed with operative exploration; therefore our final cohort included 162 patients. Seventy-eight patients received LMWH within 48 hours (early group). The mean time to initiation of LMWH in this group was 23 ± 12 hours. The late LMWH group comprised 84 patients. Fifteen patients had a length of stay longer than 72 hours and did not receive LMWH at the discretion of the attending trauma physician; they were excluded from further analysis. The demographic characteristics of the overall population and univariate comparisons between the early and late LMWH groups can be found in Table 1. Overall, the population was moderately injured with a mean ISS of 19 ± 9. The average patient age was 42 ± 18 years, and 69% were men. Baseline characteristics were similar between the 2 groups. The only significant difference was a higher proportion of high-grade splenic injuries in the late LMWH group (14% v. 32%, p = 0.007).

Of the 162 patients with an initial management plan of nonoperative management, 17 (10.5%) were managed with urgent angiography for active extravasation; NOM failed in 1 of these patients, who required operative intervention (Table 2). Two additional patients required operative intervention, without an attempt of angioembolization, giving a failure rate of 1.9%. No patient failed NOM after receiving LMWH. Semiurgent angiography was performed in 23 (15.9%) patients for pseudoaneurysms. The majority (136 [84%]) of patients required no angiographic or operative intervention. While there was no difference in the need for transfusion between groups (33% v. 30%, p = 0.74), more patients in the early LMWH group required transfusion after initiation of LMWH (21% v. 5%, p = 0.005). Further, among patients who required a blood transfusion, a median of 4.5 units of blood (IQR 2–8) were required during the hospital stay in the early LMWH group compared with a median of 2 units (IQR 2–4) in the late LMWH group (p = 0.08).

Three patients were confirmed to have VTE on imaging: 1 with a DVT and 2 with a PE, giving an overall VTE rate of 1.9%. All patients with a symptomatic VTE were treated with LMWH. Semiurgent angiography was performed in 23 (14%) patients for pseudoaneurysms. The majority (19 [22%]) of patients had a successful outcome, with 18 of these 23 patients having a single pseudoaneurysm. The average time to initial pseudoaneurysm treatment was 18 ± 11 days. Of the 18 pseudoaneurysms treated with NOM, 15 (83%) were successfully treated, giving an overall failure rate of 1.9%. No patient failed NOM after receiving LMWH. Semiurgent angiography was performed in 23 (14%) patients for pseudoaneurysms. The majority (136 [84%]) of patients required no angiographic or operative intervention. While there was no difference in the need for transfusion between groups (33% v. 30%, p = 0.74), more patients in the early LMWH group required transfusion after initiation of LMWH (21% v. 5%, p = 0.005). Further, among patients who required a blood transfusion, a median of 4.5 units of blood (IQR 2–8) were required during the hospital stay in the early LMWH group compared with a median of 2 units (IQR 2–4) in the late LMWH group (p = 0.08).

### Table 1. Demographic characteristics of patients with blunt SOI undergoing NOM

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group, mean ± SD*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>Total, n = 162</td>
</tr>
<tr>
<td></td>
<td>Early, n = 78</td>
</tr>
<tr>
<td></td>
<td>Late, n = 84</td>
</tr>
<tr>
<td>Age, yr</td>
<td>42 ± 18</td>
</tr>
<tr>
<td>Sex, no. (%)</td>
<td>111 (69)</td>
</tr>
<tr>
<td>ISS</td>
<td>19 ± 9</td>
</tr>
<tr>
<td>SBP, mm Hg</td>
<td>128 ± 22</td>
</tr>
<tr>
<td>Heart rate, bpm</td>
<td>91 ± 18</td>
</tr>
<tr>
<td>Temperature, °C</td>
<td>36.6 ± 0.8</td>
</tr>
</tbody>
</table>

### Table 2. Characteristics of NOM and failure of NOM and transfusions

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group, no. (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No intervention</td>
<td>Total, n = 162</td>
</tr>
<tr>
<td></td>
<td>Early, n = 78</td>
</tr>
<tr>
<td></td>
<td>Late, n = 84</td>
</tr>
<tr>
<td>No intervention</td>
<td>145 (90)</td>
</tr>
<tr>
<td></td>
<td>73 (94)</td>
</tr>
<tr>
<td></td>
<td>72 (86)</td>
</tr>
<tr>
<td>Urgent embolization</td>
<td>17 (10)</td>
</tr>
<tr>
<td></td>
<td>5 (6)</td>
</tr>
<tr>
<td></td>
<td>12 (14)</td>
</tr>
<tr>
<td>Elective embolization</td>
<td>23 (14)</td>
</tr>
<tr>
<td></td>
<td>6 (8)</td>
</tr>
<tr>
<td></td>
<td>17 (20)</td>
</tr>
<tr>
<td>After LMWH</td>
<td>8 (55)</td>
</tr>
<tr>
<td></td>
<td>6 (100)</td>
</tr>
<tr>
<td>Failure of NOM</td>
<td>3 (4)</td>
</tr>
<tr>
<td></td>
<td>2 (3)</td>
</tr>
<tr>
<td></td>
<td>1 (1)</td>
</tr>
<tr>
<td>After LMWH</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Transfusion</td>
<td>51 (32)</td>
</tr>
<tr>
<td></td>
<td>26 (33)</td>
</tr>
<tr>
<td></td>
<td>25 (30)</td>
</tr>
<tr>
<td>pRBC &lt; 24 h, median (IQR)*</td>
<td>2 (0–4)</td>
</tr>
<tr>
<td></td>
<td>2 (0–6)</td>
</tr>
<tr>
<td></td>
<td>2 (0.5–3.5)</td>
</tr>
<tr>
<td>Total pRBC, median (IQR)*</td>
<td>3 (2–6)</td>
</tr>
<tr>
<td></td>
<td>4.5 (2–8.25)</td>
</tr>
<tr>
<td></td>
<td>2 (2–4)</td>
</tr>
<tr>
<td>After LMWH</td>
<td>21 (13)</td>
</tr>
<tr>
<td></td>
<td>16 (21)</td>
</tr>
<tr>
<td></td>
<td>5 (5)</td>
</tr>
<tr>
<td>LOS, median (IQR)</td>
<td>5 (3–8)</td>
</tr>
<tr>
<td></td>
<td>7 (4–9)</td>
</tr>
<tr>
<td></td>
<td>4 (3–7)</td>
</tr>
<tr>
<td>SCU, median (IQR)</td>
<td>3 (1–6)</td>
</tr>
<tr>
<td></td>
<td>3 (1–6)</td>
</tr>
<tr>
<td></td>
<td>3 (2–4)</td>
</tr>
<tr>
<td>VTE</td>
<td>0.10</td>
</tr>
<tr>
<td>PE, no.</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>DVT, no.</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

DVT = deep vein thrombosis; IQR = interquartile range; LMWH = low-molecular weight heparin; LOS = length of stay; NOM = nonoperative management; pRBC = packed red blood cells; SCU = special care unit; VTE = venous thromboembolism; PE = pulmonary embolism.

*Unless indicated otherwise.

*Median number of blood products in patients who received a transfusion.
received LMWH less than 48 hours after admission and went on to receive appropriate therapeutic anticoagulation. Only 1 patient in this cohort died; this patient was infected with *Clostridium difficile* after an extended stay in the intensive care unit.

**DISCUSSION**

The challenge of chemical VTE prophylaxis lies in the balance of hemorrhage and hypercoagulability unique to traumatically injured patients. This is particularly true in patients managed nonoperatively where supportive, largely noninvasive treatments are favored instead of definitive surgical management. Fears of early hemorrhagic complications have historically limited early initiation of chemical VTE prophylaxis. More recently, however, limited evidence has come out supporting the safety of early initiation of chemical VTE prophylaxis.10–12 Our study adds further support for the safety of early (<48 h) initiation of LMWH for VTE prophylaxis in patients with blunt SOIs and no significant intracranial pathology. The overall rate of failure of NOM was very low in this study, and suggests we are correctly identifying appropriate patients for a trial of NOM. Nonetheless, we found no difference in the failure rate of NOM between patients who received early or late LMWH. The incidence of VTE was similar to that in other cohorts; however, all instances of VTE in this study were in patients receiving early rather than late chemical VTE prophylaxis.10–12

Current guidelines highlight a lack of evidence for or against early initiation of chemical VTE prophylaxis in patients undergoing NOM of blunt SOIs and have in particular stressed the unique challenge of managing these patients. A lack of evidence precluded recommendations on this specific patient population particularly regarding the timing of chemical VTE prophylaxis by the Eastern Association for the Surgery of Trauma.13,14 Four recent retrospective studies have attempted to address this problem. Similar to our work, a Canadian multicentre study reported in 2009 reviewed 72 patients with blunt hepatic injuries and found that those receiving delayed chemical VTE prophylaxis were more likely to have a high-grade injury.15 In this study, it was demonstrated that a greater number of blood transfusions were given to the delayed group, with 44% of patients requiring transfusion compared with 26% in the early group. The authors concluded that early chemical VTE prophylaxis is safe, and they reported standardizing early administration at the study institution.15 In 2002, Alejandro and colleagues10 reported on 114 patients with blunt splenic injury. Failure rates of nonoperative management (5%) were no different between early and late chemical VTE prophylaxis and were similar to our reported rates. Eberle and colleagues11 reviewed the cases of 312 patients undergoing NOM of SOIs and did not exclude those with head injuries. More than two-thirds of the patients did not receive chemical VTE prophylaxis, leaving a sample size of 111 patients. Compared with our population, their patients had higher ISS scores and a larger number of high-grade injuries. Again, failure rates of 5% were reported, particularly in those patients with high-grade spleen injuries; however, there was no difference between early and late groups. Joseph and colleagues12 performed propensity score matching on 116 patients receiving early, intermediate and late chemical VTE prophylaxis and who did not have significant head injuries. By matching for confounding factors such as age, sex, systolic blood pressure, GCS score, ISS and grade of organ injury, bias was certainly limited. No patient failed NOM and only 3 patients required embolization, which is substantially fewer patients than in our cohort. This difference can likely be explained by our institutional practice of re-imaging at 48 hours to assess for pseudoaneurysms. Furthermore, only 2% of patients in the study by Joseph and colleagues received blood products postprophylaxis compared with 13% in our study.

While the transfusion rate did not differ between groups in our study, significantly more units were given to the group receiving early prophylaxis. None of the aforementioned studies demonstrated any significant increase in total blood products given to the early LMWH group as compared with the late LMWH group. Indeed Eberle and colleagues11 and Datta and colleagues15 found that those receiving late chemical VTE prophylaxis received more blood products but attributed this to a more injured group at baseline. Our study raises the important issue that patients receiving early chemical VTE prophylaxis may require more blood products than similarly injured patients. It is, however, beyond the scope of a retrospective review to determine the impact of LMWH on the amount of blood transfused, and unknown confounding factors may be present, highlighting the need for a prospective study. The lack of transfusion difference found by Joseph and colleagues12 is perplexing as our cohorts were very similar in age, sex, ISS and grade of SOL. Therefore, it is unlikely that our study was biased toward sicker patients who may require more supportive care. The patients included in the study by Joseph and colleagues12 required an average of 2 units (early group) compared with zero units in the intermediate and late groups. This difference was not significant, but the sample size was small. Further the overall use of blood transfusion in the cohort was low at only 2%. Despite this finding, our study adds to the reported literature, suggesting that early chemical VTE prophylaxis is safe in select patients following blunt SOL, as measured by failure of NOM.

The strengths of our study include a relatively large sample size compared with those of other studies in the existing literature and the homogeneous patient population studied, namely patients with blunt SOIs but without significant head injuries. Although the use of
Limitations

Limitations of our study are related to the retrospective nature and lack of controlled protocol for chemical VTE initiation at our centre. While patients were similar in age, sex and injury scores, there was a significant difference in the percentage of high-grade splenic injuries, which could be a confounding factor and may highlight a reluctance to initiate chemical VTE prophylaxis in this particular subset of patients, leading to a selection bias that was unlikely to be overcome by using a larger sample size. The event rate for the primary outcome, failure NOM, was low and represents an important limitation. However, our event rate is in keeping with those reported in the other literature on the topic.10,11,12 The low event rate limits the robustness of our conclusions, but suggests that patient selection for VTE prophylaxis is currently reasonable at our centre with respect to failure of NOM. The rate of VTEs was also low (1.9%) and was similar to those reported in other cohorts, but we do not routinely screen for DVT and PE, and the rate was determined based on confirmed imaging studies. The small number of outcomes (n = 3) makes it challenging to draw meaningful statistical conclusions, but emphasizes the fact that chemical VTE prophylaxis is not 100% effective at prevention. Finally we did not assess the role of mechanical VTE prophylaxis in this study. Limitations with regards to blood transfusion require caution in interpreting a greater need in the early group. When measured relative to initiation of chemical VTE prophylaxis, those receiving early therapy appeared to receive more total transfusions, but this may be owing to a lead-time bias.

CONCLUSION

Our study adds to the literature supporting early chemical VTE prophylaxis with LMWH in patients with blunt SOIs in the absence of significant head injury. This study showed no difference in NOM failure rates nor any difference in the use of transfusion. The finding that more units of blood may be transfused in patients who receive early VTE is intriguing, and further work to elucidate this association is required. Given this finding and the limitations inherent with retrospective cohort studies, a multicentred prospective study is warranted.

Contributors: P. Murphy, N. Sothilingam, N. Parry and K. Vogt designed the study. P. Murphy, N. Sothilingam, T. Charyk Stewart, B. Batey and K. Vogt acquired the data, which P. Murphy, N. Sothilingam, T. Charyk Stewart, B. Moffat, D. Gray, N. Parry and K. Vogt analyzed. P. Murphy and K. Vogt wrote the article, which all authors reviewed and approved for publication.

Competing interests: None declared.

References

Cross-cultural adaptation and validation of the Ankle Osteoarthritis Scale for use in French-speaking populations

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Accepted for publication Dec. 22, 2015

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Background: The Ankle Osteoarthritis Scale (AOS) is a self-administered score specific for ankle osteoarthritis (OA) with excellent reliability and strong construct and criterion validity. Many recent randomized multicentre trials have used the AOS, and the involvement of the French-speaking population is limited by the absence of a French version. Our goal was to develop a French version and validate the psychometric properties to assure equivalence to the original English version.

Methods: Translation was performed according to American Association of Orthopaedic Surgeons (AAOS) 2000 guidelines for cross-cultural adaptation. Similar to the validation process of the English AOS, we evaluated the psychometric properties of the French version (AOS-Fr): criterion validity (AOS-Fr v. Western Ontario and McMaster Universities Arthritis Index [WOMAC] and SF-36 scores), construct validity (AOS-Fr correlation to single heel-lift test), and reliability (AOS-Fr test–retest). Sixty healthy individuals tested a pre-final version of the AOS-Fr for comprehension, leading to modifications and a final version that was approved by C. Saltzman, author of the AOS. We then recruited patients with ankle OA for evaluation of the AOS-Fr psychometric properties.

Results: Twenty-eight patients with ankle OA participated in the evaluation. The AOS-Fr showed strong criterion validity (AOS:WOMAC \( r = 0.709 \) and AOS:SF-36 \( r = -0.654 \)) and construct validity (\( r = 0.664 \)) and proved to be reliable (test–retest intraclass correlation coefficient = 0.922).

Conclusion: The AOS-Fr is a reliable and valid score equivalent to the English version in terms of psychometric properties, thus is available for use in multicentre trials.

Contexte : L’Ankle Osteoarthritis Scale (AOS) est une échelle d’auto-évaluation de l’arthrose de la cheville très fiable, et dont la validité conceptuelle et critérielle est élevée. De nombreux essais multicentriques randomisés récents ont utilisé l’AOS, mais faute d’une version française, la participation de la population francophone est limitée. Notre objectif était donc de créer une version française et d’en valider les propriétés psychométriques pour veiller à ce qu’elle soit équivalente à la version anglaise originale.


Résultats : Vingt-huit patients atteints d’arthrose à la cheville ont participé à l’évaluation. Une forte validité critique (AOS-WOMAC : \( r = 0.709 \) et AOS-SF-36 : \( r = -0.654 \)) et conceptuelle (\( r = 0.664 \)) a été mise en évidence, et l’échelle s’est avérée fiable (coefficient de corrélation intraclasse = 0,922 pour le test–retest).

Conclusion : L’AOS-Fr est une échelle fiable et valide équivalente à la version anglaise sur le plan des propriétés psychométriques; elle peut donc être utilisée pour les essais multicentriques.
ANKLE OSTEOARTHRITIS (OA) IS DEFINED AS DEGENERATIVE CHANGES OF THE TIBIOTALAR JOINT. IT IS LESS COMMON THAN HIP AND KNEE OA, AND AS OPPOSED TO THOSE LARGER JOINTS, LESS THAN 10% OF CASES OF OA ARE PRIMARY CASES OF ANKLE OA.1 AS THE MOST COMMON CAUSE OF ANKLE OA IS POST-TRAUMATIC, MANY YOUNG PATIENTS ARE AFFECTED BY THIS CONDITION, AND IN THIS OTHERWISE ACTIVE POPULATION, ANKLE OA TREATMENT CAN BE CHALLENGING.2 THE PROGRESSION OF ANKLE OA LEADS TO INVALIDITY AND REMAINS DIFFICULT TO TREAT WITHOUT CAUSING FUNCTIONAL LIMITATION.1 A STUDY BY GLAZE BROOK AND COLLEAGUES4 IN 2008 DEMONSTRATED THAT DISABILITY ASSOCIATED WITH ANKLE OA WAS AT LEAST AS SEVERE AS THAT ASSOCIATED WITH HIP OA.

ONE OF THE MAIN TREATMENT OPTIONS FOR ANKLE OA IS ANKLE ARTHRODESI S. HOWEVER, LONG-TERM STUDIES HAVE REPORTED SECONDARY SUBTALAR ARTHROSI S IN AS MANY AS 50% OF PATIENTS AT 10 YEARS.5 WHILE EARLY TOTAL ANKLE ARTHROPLASTY (TAA) DESIGNS WERE ASSOCIATED WITH HIGH FAILURE RATES AND COMPLI CATIONS, BIO-MECHANICAL PROGRESS BROUGHT FORWARD A NEW GENERATION OF TAA DESIGNS WITH GOOD TO EXCELLENT RESULTS IN THE INTERMEDIATE TERM.6 THIS RENEWAL IN INTEREST FOR TAA LED SURGEONS TO PERFORM THIS PROCEDURE MORE OFTEN. LONG-TERM MULTICENTRE STUDIES ARE REQUIRED TO HELP SURGEONS DECIDE WHETHER FUSION OR TAA IS THE BEST TREATMENT OPTION FOR THEIR PATIENTS. GOOD RANDOMIZED CONTROLLED TRIALS RELY ON THE USE OF GOOD FUNCTIONAL OUTCOME EVALUATION TOOLS TO PROVIDE HIGH-QUALITY AND VALID RESULTS.

THE ANKLE OSTEOARTHRITIS SCALE (AOS) IS AN ADAPTATION OF THE FOOT FUNCTION INDEX, MODIFIED SPECIFICALLY FOR ANKLE OA, AND IS OFTEN USED FOR RESEARCH PURPOSES.7,8 THE AOS IS A SELF-ADMINISTERED SCORE DIVIDED IN 2 SUBSCALES OF 9 ITEMS. THE FIRST SECTION EVALUATES PAIN, WHILE THE OTHER IS DESIGNED TO EVALUATE FUNCTIONAL LIMITATIONS. EACH ITEM IS ANSWERED USING A VISUAL ANALOGUE SCALE. THE SCORE IS KNOWN FOR EXCELLENT RELIABILITY AND STRONG CONSTRUCT AND CRITERION VALIDITY.6 THE AOS HAS BEEN RECOMMENDED FOR USE IN CONJUNCTION WITH THE SF-36 FOR THE EVALUATION OF END-STAGE ANKLE OA OWING TO ITS LEVEL OF RESPONSIVENESS AND LACK OF CONSTRAINT OF PATIENT RESPONSES.9 NOTABLY, MANY RECENT RANDOMIZED MULTICENTRE TRIALS HAVE USED THE AOS AS A MEASURE OF ANKLE OA.6,10

THE USABILITY AND VALIDITY OF ANY FUNCTIONAL SCALE IS ONLY AS GOOD AS ITS ABILITY TO EVALUATE PATIENTS CROSS-CULTURALLY. IN ORDER TO EVALUATE A NON-ENGLISH-SPEAKING POPULATION, FUNCTIONAL SCORE QUESTIONNAIRES IN THE PATIENTS’ NATIVE LANGUAGE SHOULD BE CREATED AND VALIDATED.9,11,12 AT THIS TIME, THE PARTICIPATION OF FRENCH-SPEAKING ORTHOPEDIC PATIENTS IN MULTICENTRE STUDIES IS LIMITED BY THE ABSENCE OF A FRENCH VERSION OF THE AOS. OUR GOAL WAS TO TRANSLATE THE AOS INTO FRENCH AND VALIDATE THE FRENCH VERSION BY EVALUATING ITS PSYCHOMETRIC PROPERTIES.

METHODS

Translation

The study was approved by the ethics committee of the Centre intégré universitaire de santé et de services sociaux de l’Estrie — Centre hospitalier universitaire de Sherbrooke (CIUSSS de l’Estrie CHUS; protocol #09–130). Following the guidelines for the cross-cultural adaptation process written by the American Association of Orthopaedic Surgeons (AAOS) in 2000, the translation was performed using a 6-step process:6 initial translation, synthesis, back translation, expert committee, test of the prefinal version and submission of the document to the developer. For the initial translation, 2 independent translators whose mother tongue was French translated the scale from English to French. The synthesis step required these 2 translators to meet, discuss and compose a synthesized version of the translated AOS. Two independent translators, blind to the original scale, whose native language was English then translated the synthesized version back to English. An expert committee composed of a linguist, 2 orthopedic surgeons and the 4 translators revised the whole process and consolidated the prefinal version. Sixty individuals without ankle OA then tested the prefinal version by answering the questionnaire and evaluating their comprehension of each item. From the data collected in this step, some sections of the test were changed to improve comprehension and readability. For the final step, the methods for obtaining the corrected French version (AOS-Fr) were submitted to Dr. Charles Saltzman, the developer of the English version, who approved the methodology and use (Appendix 1, available at canjsurg.ca).

Evaluation of psychometric properties

In order to validate the use of the AOS-Fr, we set out to evaluate the psychometric properties of the test among patients with ankle OA using the same process as the original study validating the English version of the AOS.7 We recruited patients with degenerative changes isolated to the ankle at the outpatient orthopedic clinic of CIUSSS de l’Estrie CHUS, Sherbrooke, Que. Most patients were seen for a follow-up of their ankle OA, but a few of them were new consultations. The diagnosis of ankle OA was based on the presence of degenerative changes evident on weight-bearing radiographs. To be included, patients had to consider French as their mother tongue and be able to read and write in French. Patients younger than 18 years and those with additional foot and/or ankle pathologies were excluded.

At the first visit, we collected sociodemographic data (age, sex, body mass index [BMI], occupation) and pertinent medical history (diabetes, neuropathy, ankle or foot fractures), and patients were asked to perform single heel-lift tests of both the affected and unaffected sides. The participants completed 3 questionnaires: the AOS-Fr, SF-36 and Western Ontario and McMaster Universities Arthritis Index (WOMAC). We assessed criterion validity by comparing the AOS-Fr to the WOMAC and the SF-36 scores, as was done in the original validation of the AOS.7 A research assistant gave participants instructions for
Completing the questionnaires, and the patients were left to complete the questionnaires alone. Construct validity was established by examining the correlation between the AOS-Fr scores and the single heel-lift test. Finally, to measure test–retest reliability, patients were asked to complete the AOS-Fr a second time and to complete a small questionnaire detailing any modification to the treatment (shoes, orthotics, medication, surgery, injection) 1 week after the first visit and return the questionnaire by mail. Any modification to their treatment between the completion of the 2 AOS-Fr questionnaires would nullify the test–retest reliability, so these patients would be excluded from the analysis.

**Power and sample size calculation**

The required number of patients was estimated based on properties to assess. The reproducibility (test–retest) of the questionnaire is an important property to assess. Its lower acceptable limit is 0.85. Because the reproducibility of the English version would require at least 0.97, we estimated that the French version would be at least 0.90. A sample of 10 patients was therefore sufficient to obtain a power of 99% with a reproducibility of 0.90. Concerning validity, our goal was to obtain a statistically significant correlation with the 3 selected tests. We hypothesized that we would obtain the lowest correlation between the AOS-Fr and the SF-36 questionnaire, as the SF-36 is not specific to ankle OA. By estimating an average correlation of 0.50, a sample of 30 patients was required to obtain a significant correlation with a power of 80% and \( p < 0.05 \).

**RESULTS**

**Population**

A total of 28 patients were included in the study: 18 men and 10 women. Thirteen patients had OA of the right ankle, 12 patients had OA of the left ankle, and 3 patients had bilateral ankle involvement. The mean age was 61 (range 25–83) years, and the mean BMI was 31.2 (range 22.7–46.9; Table 1).

**Test–retest reliability**

To determine reliability of the AOS-Fr, we compared the scores of the 2 AOS tests completed by the participants, excluding those whose treatments were modified between the tests, as modification may have led to a difference in functional outcome. Between the first visit and the second time answering the AOS-Fr 1 week later, treatment was modified in 9 patients. One patient had an ankle surgery, 2 received a cortisone ankle injection, 3 began wearing orthotics and 3 modified their shoe wear. All of these patients were excluded from the test–retest analysis, leaving 19 patients (Fig. 1). The intraclass correlation coefficient (ICC) between the AOS-Fr at first visit and after 1 week was excellent. The ICC for the entire score was 0.922 (95% confidence interval [CI] 0.8–0.97), with 0.895 (95% CI 0.729–0.96) for the pain subscale and 0.915 (95% CI 0.779–0.967) for the disability subscale (Table 2).

**Criterion validity**

We used the examination of the WOMAC correlation to the AOS-Fr completed at the first visit to measure criterion validity. Two patients didn’t complete the WOMAC properly and were excluded, leaving 26 patients for the analysis (Fig. 1). The Pearson correlation coefficient between the global AOS-Fr and the WOMAC scores was \( r = 0.709 \) (\( p < 0.001 \)). When comparing the WOMAC scores with the AOS-Fr pain and disability subscale scores, the correlation coefficients were \( r = 0.677 \) (\( p < 0.001 \)) and \( r = 0.698 \) (\( p < 0.001 \)), respectively (Table 2).

We then proceeded to calculate the correlation between the AOS-Fr and SF-36 scores. As described in the original publication of the AOS, we expected a negative correlation between the AOS-Fr and SF-36 scores since an increase in the SF-36 score represents a better function, while a high AOS score suggests poor function. Indeed, the correlation coefficient obtained between the AOS-Fr and SF-36 scores was \( r = –0.654 \) (\( p = 0.001 \)). When evaluated separately, the SF-36 strongly correlated with the pain section (\( r = –0.620 \), \( p = 0.003 \)) and with the disability section (\( r = –0.618 \), \( p = 0.003 \)) of the AOS-Fr (Table 2).

**Construct validity**

Since the single heel-lift ratio is influenced by the results of both ankles, we excluded 3 patients who had bilateral ankle OA, leaving 25 patients for the analysis (Fig. 1). Similar to the SF-36, the single heel-lift is reciprocal to the AOS score, giving a negative correlation. The ICCs between the AOS-Fr and the single heel-lift were \( r = –0.664 \) (\( p < 0.001 \)) overall, \( r = –0.664 \) (\( p < 0.001 \)) for the global score, \( r = –0.542 \) (\( p < 0.001 \)) for the pain score and \( r = –0.628 \) (\( p < 0.001 \)) for the disability score (Table 2).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, male:female</td>
<td>18:10</td>
</tr>
<tr>
<td>Age, mean ± SD, yr</td>
<td>61 ± 16.5</td>
</tr>
<tr>
<td>Age, range, yr</td>
<td>25–83</td>
</tr>
<tr>
<td>BMI, mean ± SD</td>
<td>31.2 ± 6.35</td>
</tr>
<tr>
<td>BMI, range</td>
<td>22.7–46.9</td>
</tr>
<tr>
<td>Affected ankle, right:left:bilateral</td>
<td>13:12:3</td>
</tr>
</tbody>
</table>

BMI = body mass index; OA = osteoarthritis; SD = standard deviation.

---

Consultation visit with orthopedic surgeon for ankle OA
n = 37

Exclusions (patients lost to follow-up, missing questionnaires)
n = 9

Completed AOS questionnaires at 1 week returned by mail
n = 28

AOS test–retest
n = 19

Criterion validity
n = 26

Construct validity
n = 25

Patients with a modification in treatment (excluded)
n = 9

Patients with incomplete questionnaires (excluded)
n = 2

Patients with bilateral ankle OA (excluded)
n = 3

Table 2. Validity of the AOS-Fr

<table>
<thead>
<tr>
<th>Comparison</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test–retest validity*</td>
<td></td>
</tr>
<tr>
<td>AOS-Fr v. AOS-Fr 1-wk</td>
<td>0.922 (95% CI 0.800–0.970)</td>
</tr>
<tr>
<td>AOS-Fr v. AOS-Fr 1-wk, pain subscale</td>
<td>0.895 (95% CI 0.729–0.960)</td>
</tr>
<tr>
<td>AOS-Fr v. AOS-Fr 1-wk, disability subscale</td>
<td>0.915 (95% CI 0.779–0.967)</td>
</tr>
<tr>
<td>Criterion validity†</td>
<td></td>
</tr>
<tr>
<td>AOS-Fr v. WOMAC</td>
<td>0.709†</td>
</tr>
<tr>
<td>AOS-Fr/PAIN vs WOMAC</td>
<td>0.677†</td>
</tr>
<tr>
<td>AOS-Fr, disability subscale v. WOMAC</td>
<td>0.698</td>
</tr>
<tr>
<td>AOS-Fr v. SF-36</td>
<td>-0.654§</td>
</tr>
<tr>
<td>AOS-Fr, pain subscale v. SF-36</td>
<td>-0.620§</td>
</tr>
<tr>
<td>AOS-Fr, disability subscale v. SF-36</td>
<td>-0.618§</td>
</tr>
<tr>
<td>Construct validity‡</td>
<td></td>
</tr>
<tr>
<td>AOS-Fr v. single heel-lift ratio</td>
<td>-0.664§</td>
</tr>
<tr>
<td>AOS-Fr, pain subscale v. single heel-lift ratio</td>
<td>-0.542§</td>
</tr>
<tr>
<td>AOS-Fr, disability subscale v. single heel-lift ratio</td>
<td>-0.628§</td>
</tr>
</tbody>
</table>

AOS-Fr = Ankle Osteoarthritis Scale, French version; CI = confidence interval; ICC = intraclass correlation coefficient; WOMAC = Western Ontario and McMaster Universities Arthritis Index.

*Calculated using ICC.
†Measured using the Pearson correlation coefficient comparing the WOMAC and SF-36 to the AOS-Fr at the same visit.
‡Calculated using the Pearson correlation coefficient between the AOS-Fr and the single heel-lift ratio at the same visit.
§Significant at p < 0.01, 2-tailed.

Fig. 1: Breakdown of the 37 participants recruited for the study. Owing to different factors (loss to follow-up, incomplete questionnaires, and treatment modifications between visits), some participants were not included in our analyses. AOS = Ankle Osteoarthritis Scale; OA = osteoarthritis.
DISCUSSION

The purpose of this study was to produce a valid French version of the AOS that is equivalent to the English version. The final AOS-Fr was validated for reliability, construct validity and criterion validity. The result of the test–retest reliability showed an excellent ICC of 0.922, which was almost equal to the original version (ICC = 0.97). However, we detected a stronger correlation with the pain subscale ($r = -0.620, p = 0.003$) than that calculated in the original version ($r = -0.34, p < 0.20$). When studying the correlation between WOMAC and the AOS-Fr pain and disability subscale scores we obtained correlations of 0.667 and 0.698, respectively, which is in line with the results of the English version (0.65 and 0.79, respectively). Examination of the construct validity by calculation of the correlation between the single heel-lift ratio and the AOS-Fr demonstrated less correlation than the original version but still a strong and significant correlation (AOS-Fr: $r = -0.664, p < 0.001$ v. original: $r = 0.88$ for the global score; AOS-Fr: $r = -0.542, p = 0.003$ v. original: $r = 0.90$ for the pain score; AOS-Fr: $r = -0.628, p < 0.001$ v. original: $r = 0.63$ for the pain score). Although our study included slightly fewer patients than required in our sample size calculation, we obtained strong and significant correlations with all of our tests.

CONCLUSION

The AOS-FR is a reliable and valid score. It is equivalent to the original English version in terms of psychometric properties.

Acknowledgements: The authors thank the Université de Sherbrooke medical students for their help with data collection and the Fondation de recherché et enseignement en orthopédie de Sherbrooke for funding this study.

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Competing interests: None declared.

Contributors: M. Angers, F. Balg and J.-P Allard designed the study. M. Angers, A. Svotelis and J.-P Allard acquired the data, which M. Angers and A. Svotelis analyzed. M. Angers, A. Svotelis and F. Balg wrote the article, which all authors reviewed and approved for publication.

References

Clinical practice guideline: management of acute pancreatitis

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Presented in part at the Canadian Surgery Forum, Sept. 21, 2014, Vancouver, BC.

Accepted for publication
Dec. 7, 2015

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DOI: 10.1503/cjs.015015

There has been an increase in the incidence of acute pancreatitis reported worldwide. Despite improvements in access to care, imaging and interventional techniques, acute pancreatitis continues to be associated with significant morbidity and mortality. Despite the availability of clinical practice guidelines for the management of acute pancreatitis, recent studies auditing the clinical management of the condition have shown important areas of noncompliance with evidence-based recommendations. This underscores the importance of creating understandable and implementable recommendations for the diagnosis and management of acute pancreatitis. The purpose of the present guideline is to provide evidence-based recommendations for the management of both mild and severe acute pancreatitis as well as the management of complications of acute pancreatitis and of gall stone–induced pancreatitis.

Acute pancreatitis can range from a mild, self-limiting disease that requires no more than supportive measures to severe disease with life-threatening complications. The most common causes of acute pancreatitis are gallstones and binge alcohol consumption. There has been an increase in the incidence of acute pancreatitis reported worldwide. Despite improvements in access to care, imaging and interventional techniques, acute pancreatitis continues to be associated with significant morbidity and mortality.

A systematic review of clinical practice guidelines for the management of acute pancreatitis revealed 14 guidelines published between 2004 and 2008 alone. Although these guidelines have significant overlap in their recommendations for diagnosing and managing acute pancreatitis, there is disagreement in some aspects of both the timing and types of interventions that should be used for both mild and severe acute pancreatitis. The availability of new imaging modalities and noninvasive therapies has also changed clinical practice. Finally, despite the availability of guidelines, recent studies auditing clinical management of acute pancreatitis have shown important areas of noncompliance with evidence-based recommendations. This underscores the importance of creating understandable and implementable recommendations for the diagnosis and management of acute pancreatitis and emphasizes the need for regular audits of clinical practice within a given hospital to ensure compliance.

The purpose of the present guideline is to provide evidence-based recommendations for the management of both mild and severe acute pancreatitis as well as the management of complications of acute pancreatitis and of gall stone–induced pancreatitis.
METHODOLOGY

The guideline was developed under the auspices of the Best Practice in General Surgery group at the University of Toronto. Best Practice in General Surgery is a quality initiative aimed to provide standardized evidence-based care to all general surgery patients treated at the University of Toronto adult teaching hospitals. A working group consisting of general surgeons, critical care intensivists and a gastroenterologist led the development of these recommendations. The working group established the research questions, the analytical framework and clinically relevant outcomes for the guideline. The recommendations pertain to patients with a new presentation of suspected acute pancreatitis. Primary outcomes are complications, both infectious and noninfectious; mortality; length of hospital stay; and readmissions associated with acute pancreatitis. Definitions of key terms were based on the 2012 Atlanta Classification of Acute Pancreatitis10 (Box 1).

Initially, we performed a scoping review to identify clinical practice guidelines related to the management of acute pancreatitis. We then searched Medline for guidelines published between 2002 and 2014 using the Medical Subject Headings “pancreatitis,” “acute necrotizing pancreatitis,” “alcoholic pancreatitis,” and “practice guidelines” to update the systematic review. The results were limited to articles published in English between January 2007 and January 2014. The references of relevant guidelines were reviewed. Up-to-date articles on acute pancreatitis diagnosis and management were also reviewed for their references11 (as of January 2014).

The working group developed the guideline recommendations based on evidence as well as consensus. Then the guideline recommendations were circulated to all general surgeons, gastroenterologists and critical care intensivists at the University of Toronto for feedback.

GUIDELINE RECOMMENDATIONS

Table 1 summarizes the guideline recommendations and grading.

1. Diagnosis of acute pancreatitis

1.1 A serum lipase test should be performed in all patients with a suspected diagnosis of acute pancreatitis. A 3-fold elevation of serum lipase from the upper limit of normal is required to make the diagnosis of acute pancreatitis.

1.2 Ultrasonography should be performed in all patients at baseline to evaluate the biliary tract and in particular to determine if the patient has gallstones and/or a stone in the common bile duct (CBD).

1.3 Magnetic resonance cholangiopancreatography (MRCP) is recommended only in patients in whom there is elevation of liver enzymes and in whom the CBD is either not visualized adequately or is found to be normal on ultrasound.

1.4 Computed tomography (CT) should be performed selectively when 1) a patient presents with substantial abdominal pain and a broad differential diagnosis that includes acute pancreatitis, or 2) in patients with suspected local complications of acute pancreatitis (e.g., peritonitis, signs of shock, suggestive ultrasound findings). Computed tomography for the assessment of local complications is most useful 48–72 hours after the onset of symptoms rather than at the time of admission. Unless contraindicated (e.g., renal dysfunction), intravenous contrast should be given in order to assess for pancreatic necrosis once patients are adequately fluid resuscitated and normovolemia is restored.
### Table 1. Summary and grading of recommendations

<table>
<thead>
<tr>
<th>Guideline recommendation</th>
<th>Strength of evidence</th>
<th>Guideline recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A serum lipase test should be performed in all patients with a suspected diagnosis of acute pancreatitis.</td>
<td>Moderate-high</td>
<td>Strong</td>
</tr>
<tr>
<td>Ultrasonography should be performed in all patients at baseline to evaluate the biliary tract to determine if the patient has gallstones and/or a stone in the common bile duct.</td>
<td>High</td>
<td>Strong</td>
</tr>
<tr>
<td>Magnetic resonance cholangiopancreatography (MRCP) is recommended only in patients in whom there is elevation of liver enzymes and the common bile duct is either not visualized adequately or is found to be normal on ultrasound.</td>
<td>High</td>
<td>Strong</td>
</tr>
<tr>
<td>Computed tomography should be performed selectively when 1) a broad differential diagnosis that includes acute pancreatitis must be narrowed, or 2) in patients with acute pancreatitis and a suspected local complication (e.g., peritonitis, signs of shock, suggestive ultrasound findings).</td>
<td>Low–moderate</td>
<td>Strong</td>
</tr>
<tr>
<td>Creactive protein (CRP) should be assessed at admission and daily for the first 72 h after admission.</td>
<td>Low–moderate</td>
<td>Weak</td>
</tr>
<tr>
<td>Acute Physiologic Assessment and Chronic Health Evaluation (APACHE II) Scores should be calculated on admission and daily for the first 72 h after admission.</td>
<td>Moderate</td>
<td>Weak</td>
</tr>
<tr>
<td>The diagnosis of severe acute pancreatitis should be made if the patient has a serum CRP &gt; 14,286 nmol/L (150 mg/dL) at baseline or in the first 72 h; APACHE Score &gt; 8 at baseline or in the first 72 h; or exhibits signs of persistent organ failure for &gt; 48 h despite adequate intravenous fluid resuscitation.</td>
<td>Moderate</td>
<td>Strong</td>
</tr>
<tr>
<td>Supportive care, including resuscitation with isotonic intravenous fluids like Ringer’s Lactate, pain control and mobilization, should be the mainstay of treatment for patients with mild acute pancreatitis.</td>
<td>Low</td>
<td>Strong</td>
</tr>
<tr>
<td>Careful consideration of transfer to a monitored unit should be made in patients with:</td>
<td>Low</td>
<td>Strong</td>
</tr>
<tr>
<td>- Severe acute pancreatitis based on APACHE II Score &gt; 8, CRP &gt; 14,286 nmol/L (150 mg/dL), or organ dysfunction &gt; 48 h despite adequate resuscitation;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Evidence of present or evolving organ dysfunction;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Need for aggressive, ongoing fluid resuscitation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with mild acute pancreatitis should receive a regular diet on admission. If patients initially are unable to tolerate an oral diet owing to abdominal pain, nausea, vomiting, or ileus, they may be allowed to self-advance their diet from withholding oral food and liquid to a regular diet as tolerated.</td>
<td>High</td>
<td>Strong</td>
</tr>
<tr>
<td>In patients with severe acute pancreatitis, enteral nutrition should be commenced as soon as possible following admission (within 48 h).</td>
<td>High</td>
<td>Strong</td>
</tr>
<tr>
<td>Prophylactic antibiotics are not recommended.</td>
<td>High</td>
<td>Strong</td>
</tr>
<tr>
<td>Patients with 1) extensive necrotizing acute pancreatitis, 2) who show no clinical signs of improvement following appropriate initial management, or 3) who experience other complications should be managed in institutions that have on-site or access to therapeutic endoscopy, interventional radiology, surgeons and intensivists with expertise in dealing with severe acute pancreatitis.</td>
<td>Moderate</td>
<td>Weak</td>
</tr>
<tr>
<td>Follow-up computed tomography should be based on the clinical status of the patient and not performed routinely at regular intervals.</td>
<td>Low</td>
<td>Strong</td>
</tr>
<tr>
<td>Patients with acute peripancreatic fluid collections with no radiological or clinical suspicion of sepsis should be observed, and image-guided fine needle aspiration (FNA) should be avoided owing to the risk of introducing infection into a sterile collection.</td>
<td>Moderate</td>
<td>Weak</td>
</tr>
<tr>
<td>Sterile necrosis based on negative FNA and/or stable clinical picture should be managed nonoperatively, and antibiotics are not indicated. For unstable patients in whom sepsis is suspected but no source has been identified, treatment with broad spectrum antibiotics on speculation may be indicated while an appropriate work up (bacterial and fungal cultures, CT scan) is carried out.</td>
<td>Moderate</td>
<td>Weak</td>
</tr>
<tr>
<td>In patients with FNA-confirmed infections of ANCs or WOPN, a step-up approach of antibiotics, image-guided drainage, followed by surgical intervention, if necessary, is indicated.</td>
<td>Moderate</td>
<td>Strong</td>
</tr>
<tr>
<td>Pancreatic pseudocysts that are asymptomatic should be managed nonoperatively. Intervention is indicated in pseudocysts that are symptomatic, infected, or increasing in size on serial imaging.</td>
<td>Moderate</td>
<td>Strong</td>
</tr>
<tr>
<td>Endoscopic retrograde cholangiopancreatography (ERCP) should be performed early (within 24–48 h) in patients with acute gallstone pancreatitis associated with bile duct obstruction or cholangitis. In unstable patients with severe acute gallstone pancreatitis and associated bile duct obstruction or cholangitis, placement of a percutaneous transhepatic gallbladder drainage tube should be considered if ERCP is not safely feasible.</td>
<td>Moderate-high</td>
<td>Strong</td>
</tr>
<tr>
<td>Cholecystectomy should be performed during the index admission in patients who have mild acute pancreatitis and delayed until clinical resolution in patients who have severe acute pancreatitis.</td>
<td>Moderate</td>
<td>Strong</td>
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<tr>
<td>If cholecystectomy cannot be performed during the index admission owing to medical comorbidities, patients with acute gallstone pancreatitis should undergo ERCP with sphincterotomy before discharge.</td>
<td>Low</td>
<td>Weak</td>
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2. Assessment of severity

2.1 A serum C-reactive protein (CRP) level of 14 286 nmol/L (150 mg/dL) or greater at baseline or in the first 72 hours is suggestive of severe acute pancreatitis and is predictive of a worse clinical course. Thus, CRP should be assessed at admission and daily for the first 72 hours after admission.

2.2 Acute Physiologic Assessment and Chronic Health Evaluation (APACHE) II Scores should be calculated on admission and daily for the first 72 hours after admission. An APACHE II Score of 8 or higher at baseline or in the first 72 hours is suggestive of severe acute pancreatitis and is predictive of a worse clinical course.

2.3 Severe acute pancreatitis should be diagnosed if a patient exhibits signs of persistent organ failure for more than 48 hours despite adequate intravenous fluid resuscitation.

3. Supportive care

3.1 Supportive care, including resuscitation with isotonic intravenous fluids (e.g., Ringer’s Lactate solution), pain control and mobilization should be the mainstay of treatment of patients with mild acute pancreatitis.

3.2 Careful consideration of transfer to a monitored unit should be made in patients with 1) severe acute pancreatitis based on an APACHE II Score greater than 8, CRP greater than 14 286 nmol/L (150 mg/L), or organ dysfunction for more than 48 hours despite adequate resuscitation; 2) evidence of present or evolving organ dysfunction defined as follows

- Respiratory (PaO₂/FiO₂ < 300 or respiratory rate > 20 breaths per min)
- Cardiovascular (hypotension despite aggressive fluid resuscitation [systolic blood pressure (sBP) < 90 mm Hg off of inotropic support or drop of sBP > 40], need for vasopressors [not fluid responsive], or pH < 7.3)
- Renal (≥ 1.5-fold increase in serum creatinine over 7 d, increase of ≥ 26.5 μmol in serum creatinine over 48 h, urine output < 0.5mL/kg/h for ≥ 6 h);

and/or 3) the need for aggressive, ongoing fluid resuscitation defined as evidence of severe hemococoncentration (hemoglobin [Hb] > 160, hematocrit [HCT] > 0.500). Patients with 1 or more of the above criteria and a body mass index (BMI) above 30 (or BMI > 25 in Asian populations) should be monitored carefully, with a lower threshold for transfer to a monitored unit given the worse course of disease in the obese patient population.

4. Nutrition

4.1 Patients who present with mild acute pancreatitis should receive a regular diet on admission. If patients are unable to tolerate an oral diet owing to abdominal pain, nausea, vomiting, or ileus, they may be allowed to self-advance their diet from withholding oral food and fluids (NPO) to a regular diet as tolerated.

4.2 In patients with severe acute pancreatitis, enteral nutrition should be commenced as soon as possible following admission (within 48 h). A nasojejunal tube is not superior to a nasogastric feeding tube; thus commencement of feeds should not be delayed for the purpose of placing a nasojejunal feeding tube. Enteral feeding is recommended over parenteral nutrition.

5. Prophylactic antibiotics

5.1 Prophylactic antibiotics are not recommended in patients with mild or severe acute pancreatitis.

6. Diagnosis and management of local complications of acute pancreatitis

6.1 Repeat CT should be considered with new (or unresolving) evidence of infection (e.g., leukocytosis, fever) without a known source, new inability to tolerate oral/enteral feeds, change in hemodynamic status, or evidence of bleeding.

6.2 Patients who have extensive necrotizing acute pancreatitis, who show no clinical signs of improvement following appropriate initial management, or in whom other complications develop should be managed in consultation with, or at institutions with therapeutic endoscopy, interventional radiology, surgical and intensive care expertise in dealing with severe acute pancreatitis.

6.3 Patients with acute peripancreatic fluid collections with no radiological or clinical suspicion of sepsis should be observed, and image-guided fine needle aspiration (FNA) should be avoided owing to the risk of introducing infection into a sterile collection.

6.4 When there is radiological or clinical suspicion of infected necrosis in patients with acute necrotic collections (ANCs) or walled-off pancreatic necrosis (WOPN), image-guided FNA with culture should be performed to distinguish infected from sterile necrosis.

6.5 Sterile necrosis based on negative FNA and/or stable clinical picture should be managed nonoperatively, and antibiotics are not indicated. The exception is unstable patients in whom sepsis is suspected but no source has been identified; in these patients, treatment...
with broad-spectrum antibiotics on speculation may be indicated while an appropriate workup (bacterial and fungal cultures, CT) is carried out.

6.6 Antibiotics should be prescribed only in patients with infected necrosis confirmed by FNA or if there is gas within a collection visualized on CT scan. Antimicrobial therapy should be tailored to FNA culture speciation and sensitivities; however, empiric treatment with antibiotics active against the most common pathogens in infected pancreatic necrosis (*Escherichia coli*, *Bacteroides* species, *Enterobacter* species, *Klebsiella* species and *Streptococcus faecalis* as well as other gram positive organisms, such as *Staphylococcus epidermidis* and *Staphylococcus aureus*) may be considered until final culture results are available.

6.7 In patients with FNA-confirmed infections of ANCs or WOPN, a step-up approach of antibiotics and image-guided drainage, followed by surgical intervention if necessary, is indicated. Surgical consultation should occur early; however, surgical intervention should be delayed until later in the course of disease whenever possible. Minimally invasive image-guided or endoscopic drainage is recommended as first line therapy, and multiple drains may be necessary. Surgery should be considered for patients in whom less invasive approaches fail, but should be delayed long enough to allow demarcation of necrotic pancreatic tissue.

6.8 Pancreatic pseudocysts that are asymptomatic should be managed nonoperatively. Intervention is indicated in pseudocysts that are symptomatic, infected, or increasing in size on serial imaging, and should be performed in a high-volume centre.

7. Management of patients with acute gallstone pancreatitis

7.1 Endoscopic retrograde cholangiopancreatography (ERCP) should be performed early (within 24–48 h) in patients with acute gallstone pancreatitis associated with bile duct obstruction or cholangitis. In unstable patients with severe acute gallstone pancreatitis and associated bile duct obstruction or cholangitis, placement of a percutaneous transhepatic gallbladder drainage tube should be considered if ERCP is not safely feasible.

7.2 Cholecystectomy should be performed during the index admission in patients who have mild acute pancreatitis and should be delayed until clinical resolution in patients who have severe acute pancreatitis.

7.3 If cholecystectomy is contraindicated in patients because of medical comorbidities, ERCP and sphincterotomy should be considered prior to discharge in patients with acute gall stone pancreatitis.

**SUMMARY OF THE EVIDENCE**

**Diagnosis of acute pancreatitis**

Serum lipase has a slightly higher sensitivity for detection of acute pancreatitis, and elevations occur earlier and last longer than with elevations in serum amylase. One study demonstrated that at day 0–1 from onset of symptoms, serum lipase had a sensitivity approaching 100% compared with 95% for serum amylase. For days 2–3 at a sensitivity set to 85%, the specificity of lipase was 82% compared with 68% for amylase. Serum lipase is therefore especially useful in patients who present late to hospital. Serum lipase is also more sensitive than serum amylase in patients with acute pancreatitis secondary to alcohol overuse. Furthermore, simultaneous determination of serum lipase and amylase only marginally improve the diagnosis of acute pancreatitis in patients with acute abdominal pain.

Biliary stones and alcohol overuse are the causes of acute pancreatitis in 70%–80% of cases. It is important to distinguish between these etiologies owing to differences in management. Right upper quadrant ultrasonography is the primary imaging modality for suspected acute biliary pancreatitis owing to its low cost, availability and lack of associated radiation exposure. Ultrasonography has a sensitivity and specificity greater than 95% in the detection of gallstones, although the sensitivity may be slightly lower in the context of ileus with bowel distension, commonly associated with acute pancreatitis. Ultrasoundography can also identify gallbladder wall thickening and edema, gallbladder sludge, pericholecystic fluid and a sonographic Murphy sign, consistent with acute cholecystitis. When these signs are present, the positive predictive value of ultrasonography in the diagnosis of acute cholecystitis is greater than 90%, and additional studies are rarely needed.

Magnetic resonance cholangiopancreatography is useful in identifying CBD stones and delineating pancreatic and biliary tract anatomy. A systematic review that included a total of 67 studies found that the overall sensitivity and specificity of MRCP to diagnose biliary obstruction were 95% and 97%, respectively. Sensitivity was slightly lower, at 92%, for detection of biliary stones. However, the cost of MRCP should limit its use in the diagnosis of gallstones or acute cholecystitis especially with the availability and utility of ultrasonography for the same purpose.

In severe disease, CT is useful to distinguish between interstitial acute pancreatitis and necrotizing acute pancreatitis and to rule out local complications. However, in acute pancreatitis these distinctions typically occur more than 3–4 days from onset of symptoms, which makes CT of limited use on admission unless there is a broad differential diagnosis that must be narrowed.
**Assessment of Severity**

Levels of serum CRP above 14,286 nmol/L (150 mg/dL) at 48 hours from admission help discriminate severe from mild disease. At 48 hours, serum CRP levels above 14,286 nmol/L (150 mg/dL) have a sensitivity, specificity, positive predictive value and negative predictive value of 80%, 76%, 67%, and 86%, respectively, for severe acute pancreatitis. Levels greater than 17,143 nmol/L (180 mg/dL) within the first 72 hours of disease onset have been correlated with the presence of necrosis with the sensitivity and specificity both greater than 80%. Serum CRP generally peaks 36–72 hours after disease onset, so the test is not helpful in assessing severity on admission. C-reactive protein rises steadily in relation to the severity of acute pancreatitis and is inexpensive to measure, and testing is readily available.

A variety of reports have correlated a higher APACHE II Score at admission and during the first 72 hours with a higher mortality (< 4% with an APACHE II Score < 8 and 11%–18% with an APACHE II Score ≥ 8). The advantage of using the APACHE II Score is the availability of this information within the first 24 hours and daily thereafter. In general, an APACHE II Score that increases during the first 48 hours is strongly predictive of the development of severe acute pancreatitis, whereas an APACHE II Score that decreases within the first 48 hours strongly predicts mild acute pancreatitis. There are some limitations in the ability of the APACHE II Score to stratify patients for disease severity. For example, studies have shown that it has limited ability to distinguish between interstitial and necrotizing acute pancreatitis, which confer different prognoses.

At 24 hours, the Score also has limited utility. In a recent report, APACHE II Scores generated within the first 24 hours had a positive predictive value of only 43% and negative predictive value of 86% for severe acute pancreatitis. Even with its limitations, a study of 49 patients found that generic measures of disease severity like the APACHE II Score were superior to disease-specific scoring systems in predicting mortality. For instance, the Ranson score was found to be a poor predictor of severity in a meta-analysis of 110 studies. The organ failure–based criteria for the prediction of severity in acute pancreatitis are taken, in part, from the modified Multiple Organ Dysfunction Score presented by Banks and colleagues in their revision of the Atlanta Classification. A diagnosis of severe acute pancreatitis should also be made if a patient exhibits signs of persistent organ failure for more than 48 hours despite adequate intravenous fluid resuscitation. In a study of 174 patients who experienced early (within the first week) organ failure due to acute pancreatitis, Johnson and Abu-Hilal examined the mortality and morbidity associated with transient organ failure (resolving in < 48 h) and persistent organ failure (lasting ≥ 48 h). In the transient organ failure group (n = 71) mortality was 1%, and 29% of these patients went on to experience local complications of acute pancreatitis; in the persistent organ failure group (n = 103) mortality was 35%, and 77% of patients experienced a local complication. In a study of 759 patients with acute pancreatitis, patients with systemic inflammatory response syndrome (SIRS) lasting for more than 48 hours were demonstrated to have a significantly higher rate of multigorgan dysfunction (as determined by the mean Marshall Score) and death than those with transient SIRS lasting less than 48 hours (4 [25.4%] vs. 3 [8%], p < 0.001).

In a recent meta-analysis of 12 clinical studies examining the impact of obesity on severity of acute pancreatitis, Chen and colleagues demonstrated a significantly increased risk of severe acute pancreatitis (relative risk [RR] 2.20, 95% confidence interval [CI] 1.82–2.66), local complications (RR 2.68, 95% CI 2.09–3.43), systemic complications (RR 2.14, 95% CI 1.42–3.21) and in-hospital mortality (RR 2.59, 95% CI 1.66–4.03) in obese compared with nonobese patients. Owing to these increased risks, special consideration should be given to patients with suspected severe acute pancreatitis who have a BMI greater than 30 (or a BMI > 25 in Asian populations).

**Supportive Care**

Animal studies have shown that aggressive fluid replacement supports pancreatic microcirculation and prevents necrosis. There have been no high-quality trials to test the effectiveness of aggressive fluid resuscitation in patients with acute pancreatitis, and the approach to fluid resuscitation in these patients remains an under-investigated topic. However, poor outcomes, including more deaths and necrosis, have been reported in patients in whom there was hemococoncentration. In an observational study, necrotizing acute pancreatitis developed in all patients who received inadequate fluid replacement as measured by a rise in hematocrit at 24 hours. Further, a recent randomized controlled trial (RCT) compared the use of normal saline versus Ringer's Lactate in goal-directed and standard fluid resuscitation in patients with acute pancreatitis. In this RCT (n = 40), Wu and colleagues found that after 24 hours of resuscitation there was an 84% reduction in the incidence of SIRS in patients resuscitated with Ringer's Lactate (p = 0.035) as well as a significant reduction in CRP from 9905 nmol/L (104 mg/dL) to 5143 nmol/L (54 mg/dL) when Ringer's Lactate was selected over normal saline (p = 0.02).

Pain control is an important part of the supportive management of patients with acute pancreatitis. Therefore, in the absence of any patient-specific contraindications, a multimodal analgesic regimen is recommended, including narcotics, nonsteroidal anti-inflammatories and acetaminophen.

There are no studies assessing the impact of different models of critical care delivery and outcomes in patients with severe acute pancreatitis. However, a systematic review of 26 observational studies showed that critically ill patients cared for by an intensivist or using an intensivist...
consultant model in a closed intensive care unit (ICU) had a shorter stay in the ICU and lower mortality than similar patients cared for in units without such staffing patterns.54

NUTRITION

The underlying pathogenesis of acute pancreatitis is the premature activation of proteolytic enzymes resulting in the autodigestion of the pancreas. In the past, it was accepted practice that bowel rest would limit the inflammation associated with this process.55 Recently, however, a series of RCTs have convincingly shown that early oral/enteral feeding in patients with acute pancreatitis is not associated with adverse effects and may be associated with substantial decreases in pain, opioid usage and food intolerance.56–58 Furthermore, Eckerwall and colleagues59 demonstrated that oral feeding on admission for mild acute pancreatitis was associated with a significant decrease in length of stay from 6 to 4 days (p = 0.047) compared with withholding oral food and fluids.60 The major benefits from early feeding appear to be effective only if feeding is commenced within the first 48 hours following admission,61 and the current recommendation based on a 2010 meta-analysis of 32 RCTs is to commence oral feeding at the time of admission if tolerated or within the first 24 hours.62 Finally, a low-fat diet was shown to be preferable to clear fluids on admission for mild acute pancreatitis owing to a higher caloric intake with no associated adverse effects.57,58 There is no evidence to suggest that a low-fat diet is preferable to a regular diet.

A 2010 Cochrane meta-analysis of 8 RCTs involving 348 patients comparing enteral nutrition to total parenteral nutrition for acute pancreatitis showed reduced mortality (RR 0.50, 95% CI 0.28–0.91), multiorgan failure (RR 0.55, 95% CI 0.37–0.81), systemic infection (RR 0.39, 95% CI 0.23–0.65), operative interventions (RR 0.44, 95% CI 0.29–0.67), local septic complications (RR 0.74, 95% CI 0.40–1.35), and other local complications (RR 0.70, 95% CI 0.43–1.13).62 Mean length of hospital stay was reduced by 2.37 days in the enteral nutrition compared with the total parenteral nutrition group (95% CI −7.18 to 2.44). Furthermore, a subgroup analysis of enteral versus total parenteral nutrition in patients with severe acute pancreatitis showed an RR for death of 0.18 (95% CI 0.06–0.58) and an RR for multiorgan failure of 0.46 (95% CI 0.16–1.29). Several meta-analyses have shown similar results, with significant reductions in infectious complications, mortality and multiorgan dysfunction when enteral nutrition is commenced within the first 48 hours following admission.53,63,64

A meta-analysis65 of 4 prospective studies of patients with predicted severe acute pancreatitis (n = 92) demonstrated no change in intolerance of feeding (RR 1.09, 95% CI 0.46–2.59, p = 0.84) or in mortality (RR 0.77, 95% CI 0.37–1.62, p = 0.5) when given enteral feeds by nasogastric feeding tube versus nasojunal feeding tube. In a more recent meta-analysis of 3 RCTs (n = 157), Chang and colleagues66 found no significant differences in mortality (RR 0.69, 95% CI 0.37–1.29, p = 0.25), tracheal aspiration (RR 0.46, 95% CI 0.14–1.53, p = 0.20), diarrhea (RR 1.43, 95% CI 0.59–3.45, p = 0.43), exacerbation of pain (RR 0.94, 95% CI 0.32–2.70, p = 0.90) and meeting energy balance (RR 1.00, 95% CI 0.92–1.09, p = 0.97) between patients fed through nasogastric and nasojejunal feeding tubes. While no high-quality RCTs exist on this topic, to date there has been no evidence to suggest that enteral feeds should be delayed for the purposes of acquiring a nasojejunal feeding tube, especially in light of morbidity and mortality benefits of commencing enteral feeds within the first 48 hours.

Although semi-elemental, immune-enhanced and probiotic enteral feeds showed initial promise in the management of severe acute pancreatitis, meta-analyses still indicate that there is insufficient evidence to recommend the use of any of these nutritional formulations at this time.61,67,68 Given its promise in the context of other critically ill and septic patients,69–71 the use of probiotics in the management of acute pancreatitis may yet prove effective as research continues.

PROPHYLACTIC ANTIBIOTICS

A 2010 meta-analysis of 7 RCTs involving 404 patients comparing prophylactic antibiotics versus placebo in CT-proven necrotizing acute pancreatitis concluded that there was no statistically significant reduction of mortality with therapy (8.4% in the antibiotic group vs. 14.4% in controls, p = 0.07), nor a significant reduction in infection rates of pancreatic necrosis (19.7% in the antibiotic group vs. 24.4% in controls, p = 0.47). Nonpancreatic infection rates (23.7% in the antibiotic group vs. 36% in controls, p = 0.08) and overall infections (37.5% in the antibiotic group vs. 51.9% in controls, p = 0.12) were not significantly reduced with prophylactic antibiotics. The need for operative treatment and fungal infections were not significantly different.72

Similar results were found in a 2008 meta-analysis of 7 RCTs involving 467 patients with CT-proven necrotizing acute pancreatitis comparing prophylactic antibiotics with placebo or no treatment. The rate of infected pancreatic necrosis was not significantly different (17.8% in the antibiotic group vs. 22.9% in controls, RR 0.81, 95% CI 0.54–1.22). There was a nonsignificant decrease in mortality in the antibiotic group compared with the control group (9.3% v. 15.2%, RR 0.54–1.22). Subsequent subgroup analysis confirmed that antibiotics were not significantly superior to placebo or no treatment in reducing the rate of infected necrosis or mortality.73

A 2012 meta-analysis of 11 RCTs looking at the efficacy of prophylactic antibiotics in acute pancreatitis calculated the number needed to treat to be 1429,74 and yet another meta-analysis of 14 RCTs (n = 841) showed no statistically significant reduction in mortality (RR 0.74, 95% CI 0.50–1.07), incidence of infected pancreatic necrosis (RR 0.78, 95% CI 0.60–1.02), incidence of nonpancreatic infections
In light of the lack of demonstrated benefit of prophylactic antibiotics in the treatment of acute pancreatitis, the adverse effects of this practice must be carefully considered. In a prospective, randomized controlled trial (n = 92), Maravi-Poma and colleagues\(^76\) demonstrated a 3-fold increase in the incidence of local and systemic fungal infection with *Candida albicans* (from 7% to 22%) in patients with prolonged treatment with prophylactic antibiotics, a finding consistent with those of other similar studies.\(^77\)-\(^79\)

In addition, overuse of antibiotics is associated with the increased risk of antibiotic-associated diarrhea and *Clostridium difficile* colitis\(^80\) and with the selection of resistant organisms,\(^81\) all of which suggest that the adverse effects of prophylactic antibiotic coverage outweigh any benefit offered by the practice.

**Diagnosis and Management of Local Complications of Acute Pancreatitis**

Two recent review articles on acute pancreatitis have summarized the importance of managing patients with complications of acute pancreatitis at high-volume centers in which all services are well versed in the multidisciplinary step up approach to severe and/or complicated disease.\(^82\),\(^83\)

Computed tomography evidence of necrosis has been shown to correlate with the risk of other local and systemic complications.\(^83\)-\(^85\) Local complications that can be recognized on abdominal CT scans include peripancreatic fluid collections, gastrointestinal and biliary complications (e.g., obstructions), solid organ involvement (e.g., splenic infarct), vascular complications (e.g., pseudoaneurysms, splenic vein thrombosis) and pancreatic ascites.\(^86\)-\(^88\)

Fine needle aspiration has been established as an accurate, safe and reliable technique for identification of infected acute peripancreatic fluid collections (APFCs), pancreatic pseudocysts, ANCs and WOPN.\(^84\),\(^89\)-\(^91\) However, FNA of pancreatic pseudocysts, APFCs, ANCs and WOPN should not be performed in the absence of a clinically or radiologically suspected infection owing to the small but documented risk of introducing an FNA-associated infection into a previously sterile collection.\(^92\),\(^93\)

Elevations in white blood cell count and temperature may occur in the context of sterile necrosis and be similar to those seen in patients with infected necrosis;\(^86\) therefore, it is difficult to distinguish between these conditions clinically. Fine needle aspiration has been established as an accurate, safe and reliable technique for identification of infected necrosis.\(^84\),\(^89\)-\(^91\) A 1995 retrospective observational study\(^90\) assessed the value of CT-guided FNA in 104 patients with acute pancreatitis suspected of having pancreatic infection on the basis of systemic toxicity and CT evidence of severe acute pancreatitis. Cultures were positive in 58 out of 58 aspirates from the 51 patients with CT scans suggestive for infection, all but 2 of which were confirmed surgically (2 patients died without confirmation). Of the 53 patients with CT imaging suggestive of sterile acute pancreatitis, all but 2 aspirates judged to be sterile by FNA were validated on the basis of negative cultures obtained surgically or by clinical resolution of acute pancreatitis without the need for surgery (2 patients died without confirmation). There were no complications. These findings are consistent with those of other studies.\(^84\),\(^89\),\(^91\)

Elevations in white blood cell count and temperature may occur in sterile necrosis and be similar to those seen in patients with infected necrosis.\(^86\) Therefore, it is difficult to distinguish between these conditions clinically, and if infected necrosis is suspected, an FNA is indicated to rule out infection. Most patients with sterile necrosis respond to conservative medical management.\(^84\),\(^94\) For these patients, there have been several retrospective reports suggesting that a delay in surgical necrosectomy and at times a total avoidance of surgery results in less morbidity and mortality than early surgical débridement.\(^95\)-\(^101\) Second, when sterile necrosis is debrided surgically, a common sequela is the development of infected necrosis and the need for additional surgery.\(^96\),\(^101\)-\(^103\) In at least 1 report, patients so treated had a very high mortality.\(^101\) Finally, in a randomized controlled trial\(^95\) that compared early to late surgery in a small number of patients with sterile necrosis, there was a trend toward greater mortality among those operated within the first 3 days after admission.

Antibiotics should be prescribed only in patients with infected necrosis confirmed by FNA or if there is gas within a collection visualized on CT scan. Antimicrobial therapy should be tailored to FNA culture speciation and sensitivities; however, empiric treatment with antibiotics active against the most common pathogens in infected pancreatic necrosis (*E. coli, Bacteroides species, Enterobacter species, Klebsiella species* and *S. faecalis* as well as other gram-positive organisms such as *S. epidermidis* and *S. aureus*) may be considered until final culture results are available.

Although insufficient evidence exists to make definitive recommendations regarding empiric antimicrobial therapy choices in infected pancreatic necrosis, a number of studies have looked at the pancreatic penetration of various antibiotics. Imipenem and ertapenem have both been shown to penetrate pancreatic tissue and pancreatic fluid at levels exceeding the minimum inhibitory concentration (MIC\(_{90}\)) for the most commonly seen bacteria after as little as a single intravenous dose.\(^105\),\(^106\) Similar findings were documented for moxifloxacin, with concentrations greater than the MIC\(_{90}\) after a dose of 400 mg, either oral or intravenous.\(^107\) An in vitro study of the most commonly isolated bacteria from pancreatic necrosis — *E. coli, Enterobacter cloacae, Enterococcus faecalis, Bacteroides fragilis* — compared the effectiveness of imipenem, ertapenem and moxifloxacin against these pathogens. While all 3 antibiotics demonstrated good coverage in this in vitro acute pancreatitis...
A pancreatic pseudocyst is a collection of pancreatic fluid (either direct leakage from the inflamed gland or disruption of the pancreatic duct) enclosed by a nonepithelialized wall of granulation or fibrous tissue. They usually evolve more than 4 weeks after the onset of acute pancreatitis and contain pancreatic enzyme-rich fluid. They are most often sterile but can become infected.44,120 Half of all pseudocysts resolve spontaneously.121,122 Neither size nor duration of the pseudocyst are predictive of the natural course.123,124 Clinical signs of sepsis or the presence of air bubbles in a pseudocyst indicate potential infection. At this point, aspiration of the fluid with gram stain, culture and sensitivities is indicated. The most common bacteria cultured in an infected pseudocyst are enteric microorganisms, such as E. coli, Bacteroides species, Enterobacter species, Klebsiella species and S. faecalis as well as other gram-positive organisms, such as S. epidermidis and S. aureus.103,104 General indications for intervention are symptomatic pseudocysts, complications or infection of a pseudocyst, or increasing size on serial imaging.125-129 Many options are available for the management of pancreatic pseudocysts, including percutaneous, endoscopic or surgical drainage (open and laparoscopic) and creation of a cystogastrostomy (endoscopically or surgically). These procedures should be performed at high-volume centres with integrated multidisciplinary teams.

MANAGEMENT OF ACUTE GALLSTONE PANCREATITIS

A 2012 Cochrane meta-analysis129 included RCTs comparing early routine ERCP versus early conservative management with or without selective use of ERCP in patients with suspected acute gallstone pancreatitis. There were 5 RCTs with a total of 644 patients. Overall, there were no statistically significant differences between the 2 treatment strategies in mortality (RR 0.74, 95% CI 0.18–3.03), local (RR 0.86, 95% CI 0.52–1.43) or systemic complications (RR 0.59, 95% CI 0.31–1.11) as defined by the Atlanta Classification. Among trials that included patients with cholangitis, the early routine ERCP strategy significantly reduced mortality (RR 0.20, 95% CI 0.06–0.68), local (RR 0.45, 95% CI 0.20–0.99) and systemic complications (RR 0.37, 95% CI 0.18–0.78) as defined by the Atlanta Classification. Among trials that included patients with biliary obstruction, the early routine ERCP strategy was associated with a significant reduction in local complications as defined by authors of the primary study (RR 0.54, 95% CI 0.32–0.91), and a nonsignificant trend toward reduction of local (RR 0.53, 95% CI 0.26–1.07) and systemic complications (RR 0.56, 95% CI 0.30–1.02) as defined by the Atlanta Classification. Complications of ERCP were infrequent.

In an RCT from China (n = 101),130 patients with severe acute gallstone pancreatitis were randomized to early treatment (within 72 h of onset) with ERCP or image-guided...
percutaneous transhepatic gallbladder drainage (PTGD). Success rates were comparable between the ERCP and PTGD (92% v. 96%, respectively), and 4-month mortality (p = 0.80), local complications (p = 0.59) and systemic complications (p = 0.51) did not differ significantly. The author concluded that PTGD is a safe, effective and minimally invasive option that should be considered for all patients with severe acute gallstone pancreatitis who are poor candidates for or who are unable to tolerate ERCP.130

A systematic review131 of 8 cohort studies (n = 948) and 1 RCT (n = 50) revealed that while the readmission rate for gallstone disease in patients admitted for acute gallstone pancreatitis and discharged without cholecystectomy was 18% within the first 58 days after discharge, it was 0% in the cohort that underwent index admission cholecystectomy (p < 0.001). These results are supported by several retrospective studies that also cited significantly higher recurrence rates of gallstone disease (15%–32%) in patients who did not undergo index admission cholecystectomy.132–134 The majority of these recurrent attacks occurred before the time of interval cholecystectomy.133,134

In an RCT that included 50 patients with mild acute gallstone pancreatitis, laparoscopic cholecystectomy performed within 48 hours of admission resulted in a shorter hospital stay (mean 3.5 [95% CI 2.7–4.3] d, median 3 [IQR 2–4] d) than one performed after resolution of pain and laboratory abnormalities (mean 5.8 [95% CI 3.8–7.9] d, median 4 [IQR 4–6] d, p = 0.002).135 A second study demonstrated similar findings, with a significant reduction in the mean total length of stay from 7 to 5 days (p < 0.001).134

While studies have demonstrated no increase in complication rates or mortality in patients with acute gallstone pancreatitis who underwent early versus late cholecystectomy,131,136 special consideration should be given to patients admitted for severe necrotizing acute pancreatitis and/or requiring ICU admission. In this patient population, delaying cholecystectomy for at least 3 weeks may be reasonable because of an increased risk of infection.137

High recurrence rates of gallstone disease in patients admitted for acute gallstone pancreatitis and discharged without cholecystectomy has prompted several studies addressing the effectiveness of ERCP and sphincterotomy to reduce this risk. In a prospective study of 233 patients with acute gallstone pancreatitis, a subgroup analysis of patients discharged without undergoing cholecystectomy revealed that 37% of patients discharged with no intervention had recurrent gallstone disease within 30 days compared with 0% of patients who underwent ERCP and sphincterotomy alone (p = 0.019).132 In a retrospective analysis of 1119 patients admitted for acute gallstone pancreatitis, Hwang and colleagues133 reported a reduction of recurrent gallstone disease from 17% to 8% (p < 0.001) with ERCP and sphincterotomy alone, as opposed to no intervention in individuals discharged home without cholecystectomy.133 A systematic review of 8 cohort studies and 1 RCT demonstrated a similar reduction in biliary events from 24% to 10% (p < 0.001) when patients not undergoing index admission cholecystectomy underwent ERCP and sphincterotomy before discharge.131 These data strongly support the consideration of ERCP with sphincterotomy for patients unable to tolerate surgery on the index admission owing to comorbidities or deconditioning.

All data regarding the use of ERCP with sphincterotomy to prevent recurrent complications of gallstone disease have been generated in patients with mild to moderate acute gallstone pancreatitis, and currently, there is a lack of evidence on which to base definitive recommendations for the management of patients with severe and complicated acute gallstone pancreatitis.

Acknowledgements: R. McLeod holds the Angelo and Alfredo De Gasperis Chair in Colorectal Cancer and IBD Research. N. Coburn holds the Hanna Family Research Chair in Surgical Oncology. A. Nathens holds the Canada Research Chair in Systems of Trauma Care.

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Competing interests: None declared.

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Surgeon unemployment: Would practice sharing be a viable solution?

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Accepted for publication
Nov. 9, 2015

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DOI: 10.1503/cjs.014015

SUMMARY

Surgeon unemployment has become a crisis within Canadian surgery in recent years. Without dedicated governmental workforce planning, ensuring that new residency graduates can find employment will require new models of employment. Practice sharing, whereby a new graduate and a senior surgeon partner to divide their practices, allows the senior surgeon to wind down and the newer surgeon to ramp up. Importantly, this arrangement builds in formal mentoring, which is so important in the early years of starting a surgical practice. Practice sharing may be a solution for the workforce issues currently afflicting new surgical graduates across Canada.

Canadian health care faces many challenges, such as the rising cost of care and an aging population. Provincial government payers in particular struggle to foot the bill for substantial health care costs — just over 12% of gross domestic product in provinces such as Ontario and about half of the government budgets in many provinces. Despite an investment of this magnitude, our outcomes lag when compared with those of other developed nations.1 Surgery is no exception, with long wait times being the most frequently cited evidence of a costly system that is failing to bring sufficient access to its citizens.2

These are the problems that we most often hear about, but surgical trainees in this country are most likely to hear about another problem: unemployment. It is not an issue that the general public associates with the medical profession or is even aware of, but across the country the issue is unrelenting. Young graduates of our surgical programs languish, taking locum jobs or moving great distances and even countries to find work, or retraining in more employable specialties. Cardiac surgeons were the first ones affected; many have been under- or unemployed since the decline in open bypass surgeries led to a decreasing need for cardiac surgeons. Next came difficulties for orthopedic surgery graduates, and most recently general surgeons have had difficulty finding work. This is extraordinary and unprecedented though it has largely gone unnoticed by the general public. Some surgeons have left the country — not for more lucrative jobs as in days past, but rather for any permanent job at all.

The overall feeling among trainees is that this lack of opportunity represents a major deficiency in our health care system, and many feel justifiably angry at a system that demanded so much of them during their training. Although none of these individuals are “owed” anything, including a job, the society that paid to train them certainly is. It is hard to quantify the wasted resources that are consumed by an unemployed surgeon — our tax dollars subsidized a decade of medical and residency training for each trainee, and that subsidized training must be added to the cost of future productivity lost. Further, unemployment wastes the talent and time of some of the most educated, skilled workers in the country.
Moreover, we owe it to our patients to address this issue. Day in and day out, patients allow residents to care for them with graduated levels of supervision. Undoubtedly, these patients accept the risk of being cared for by trainees in exchange for its equal benefit — doctors on hand during the night, for example — but they do this with a certain unstated understanding that this training yields expertise that will benefit society for decades to come. The eventual unemployment of these physicians not only wastes extraordinary amounts of money, resources and the time of clinical teachers, but also breaks this implicit social contract. All patients who are cared for by trainees should be concerned that these surgeons they are helping to train may not have a place to practise the skills they have acquired after they graduate.

Are there any solutions to this growing problem? One promising concept is that of practice sharing. That is, as senior surgeons begin to wind their practices down, they partner with young surgeons starting out. Operating times can be split, with the elder surgeons taking progressively less time going forward. This model has several advantages. First, in hospitals where resources are limited, the senior surgeons do not “tie up” positions until formal retirement, allowing the younger surgeons the prospect of some future stability. There is a huge benefit to providing a smooth transition to new staff members. As the work curve of the senior surgeons winds down, the younger colleagues wind up. One of the challenges for senior surgeons is the burden of call responsibilities as they age, which could be eased by practice sharing with junior colleagues. Many recently certified surgeons are in the early stages of starting a family, and another potential personal benefit of practice sharing for junior surgeons is that it would enable them to spend more time with their families during this crucial phase of family life.

Of critical importance is the role of mentoring. The practice sharing model builds in strong mentoring for junior surgeons. Many surgeons, as they look back on their first several years in practice, realize that they needed mentoring during this important phase, in which a great deal is learned about surgical judgment, patient selection and technical approaches to difficult cases. Practice sharing would provide a formal structure for mentoring these new surgeons, complementing the informal and ad hoc way in which senior mentors are identified and used at present. Ultimately, this may also lead to better patient outcomes, whereby better mentoring encourages better decision making in patient care.

So how can hospitals begin to use this new model? Certainly leadership at the hospital level is essential for the success of this new model. From an administration standpoint, arranging practice sharing should require little in the way of additional resources, as the senior and junior surgeons would be sharing operating time and potentially other secondary support staff as well.

Ultimately, leadership at the provincial and federal levels is critical to address the root cause of the employment crisis in surgery. Rigorous evaluation of the numbers and of the specialty requirements needed to provide adequate surgical care across the country is long overdue. If there are mismatches in demand, the numbers of trainees should be adjusted to fit the projected workforce needs. Traditionally, academic health centres have relied on resident house staff. However, as physician extenders like nurse practitioners and physician assistants become more common, academic centres may instead be able to reduce the service roles currently filled by superfluous trainees. This would allow educational centres to focus on trainee education and experience while at the same time reducing the numbers of eventual graduates who are unemployable given projected national and provincial needs.

Our government needs to make a serious effort to address unemployment. It is not ethical for the system to put highly talented individuals through 5–10 years of rigorous clinical and research training to have little prospect of permanent appointment at the end. It will erode morale and collegiality. Practice sharing presents a viable alternative that can benefit all involved. We all owe it to our patients to improve our health care system, and planning for the employment of young surgeons is an important part of this.

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Competing interests: None declared.

Contributors: Both authors contributed substantially to the conception, writing and revision of this commentary and approved the final version for publication.

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Dr. William Waugh (1851–1936): promoter of change in nineteenth century medical education and practice

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Presented in part as the 2015 Harvey Oration to the Harvey Club of London, Canada

DOI: 10.1503/cjs.002416

SUMMARY

Dr. William E. Waugh (1851–1936) witnessed and actively participated in many changes in medical education and practice during his 60-year decades in medicine. Trained as a surgeon and general practitioner, Waugh practised medicine in London, Ont., during the late nineteenth and early twentieth centuries. Early in his career, he embraced the new field of microbiology; refused outdated practices, such as bleeding; and dared to form a medical school despite strong criticism. Waugh was one of the founders of the Western University medical school, and he served various teaching and administrative roles in addition to maintaining a successful practice. He reminded students of the role of the physician’s senses, which he cautioned were in danger of being eclipsed, rather than supplemented, by the diagnostic instruments being adopted into clinical practice.

Dr. William Waugh (1851–1936), Western University Archives, A00-071-003.

Dubbed the “grand old man” of surgery by his junior medical colleagues, William Ebenezer Waugh (1851–1936) witnessed and actively participated in many changes in medical education and practice during his 60 decades in medicine. Trained as a surgeon and general practitioner, Waugh practised medicine in London, Ont., during the late nineteenth and early twentieth centuries. Early in his career, he embraced the new field of microbiology; refused outdated practices, such as bleeding; and dared to form a medical school despite strong criticism. It was Waugh who, arriving by horse and buggy on Oct. 1, 1882, delivered the first lecture in Western University’s medical program in a converted cottage that became the original medical school building. Serving multiple faculty and administrative posts, Waugh maintained the longest connections with the university among its elite group of medical school founders.1

At a time when individuals practised medicine after having undergone various types of education, Waugh pursued training as a regular or allopathic physician. In 1868, he apprenticed locally with Alexander Anderson, who had trained in Scotland and was a member of the Royal College of Surgeons of England. One year later, Waugh headed to medical school at McGill University for 3 years. One of his classmates at McGill was William Osler, who strongly encouraged fellow students to use the microscope, a somewhat new instrument in medical schools at this time. Osler regularly came to class with new specimens for demonstration, to the benefit of his peers, after which Waugh maintained a lifelong advocacy of its use. While they were medical students, Osler received a special prize for his work with the microscope, and Waugh, as a student prosector in anatomy, won a prize for dissection. Graduating alongside Osler in 1872, Waugh left McGill as the silver medalist of his medical class. What was it like to be a classmate of William Osler, who many would soon idolize as the “Father of modern medicine”? Reflecting on this 60 years later, Waugh stated, “Osler seemed to us, just an ordinary student and his later work was, I think more or less of a surprise to us who were his contemporaries … no one dreamed that he would become so important a person.”2

With medical degree in hand, Waugh returned to London, Ont., with his microscope and dissection prize bust to practise medicine. The city’s population of about 20 000 people were served by roughly 20 physicians, several of whom were homeopathic practitioners, all with reportedly busy practices. During the latter part of the nineteenth century, Londoners faced problems with diphtheria, typhoid fever and periodic malaria bouts in addition to ongoing cases of flu, fevers, respiratory and abdominal problems, farming injuries, and so forth. Waugh spoke out against the practice of bleeding, an outdated belief in removing excess blood to
rebalance body fluids as a means to restore health, which apparently a handful of London physicians still performed as a “cure-all” treatment. Waugh’s training at McGill made him a firm believer in the germ theory that was shaping medical practice. The 1869 Ontario Medical Act set up a new College of Physicians and Surgeons of Ontario that, through examining would-be practitioners and university graduates before granting medical licenses, contributed to higher (and safer) scientific standards in medicine.

During his career, Waugh witnessed the introduction of many new diagnostic instruments into medical practice, and this seemed to worry him. On the one hand, it was Waugh who encouraged the use of the microscope when many London physicians did not own one. The stethoscope remained the sole diagnostic aid for the physician for many years, until the greater use of the clinical thermometer during the 1870s. Over the next 60 years, clinicians adopted and used a growing number of diagnostic instruments, such as ophthalmoscopes, blood pressure kits, radiography machines, bronchoscopes, electrocardiography machines and more. Waugh lamented how the senses were not being used in diagnosis in the same way. In 1932, he stated that “the older physicians could see more, hear more and especially feel more than the generations that came later because they, in their training, had not had the use of the instruments of precision which are so common today.” He certainly did not suggest that physicians not use these diagnostic tools, but quietly reminded students of the role of the physician’s senses.

In 1936, Waugh died at the age of 85. His funeral was a “Who’s Who” of the London medical community, attended by Drs. Edwin Seaborn, J.A. Macgregor, W.J. Weekes, George Ramsay, and others. Predeceased by his wife Margaret, Waugh left his estate to their only child, Jean, who later donated the family house to the university in recognition of her father’s long service and connections to the medical school. A calm, determined man, Waugh was well liked by colleagues and students. He received various medical society honours during his lifetime, and thereafter was warmly remembered as a distinguished surgeon, medical practitioner and pioneer teacher of Western University’s medical school.

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APPLES AND ORANGES

In the February 2016 issue of the *CJS*, Malik and colleagues present data comparing recurrence rates for inguinal hernia repairs done in Ontario general hospitals to those done at the Shouldice Hospital. The Ontario Association of General Surgeons has several concerns about this paper, especially about the issue of selection bias and fair up-to-date comparison.

The Shouldice Hospital is a controversial entity among Ontario general surgeons, who generally consider them to be “cherry picking” the easiest hernias. Malik and colleagues acknowledged the potential for selection bias and that their databases lacked detailed clinical information on smoking; obesity; and hernia characteristics, such as size, which would allow for fair comparison. The authors attempted to measure selection bias indirectly by comparing outcomes of a small subgroup of patients who had a consultation at the Shouldice Hospital between 2004 and 2006 and then had their surgeries elsewhere.

The recurrence rate in this group was 3%, which the authors felt was insufficient to explain the large difference in recurrence rate. We, however, beg to differ and would argue that the presented data suggest a large selection bias. Since this study ended in 2007, the subgroup had an average of only 2 years of follow-up, and their 3% early recurrence rate is approximately double the 2-year recurrence rate when data from all years is considered (see Fig. 1 of their study). If one adjusted for secular trends, where the recurrence risk for hernias done from 2003–2007 was half that of the reference range of 1993–1997 (see Table 3 of their study), it would make the recurrence rate in those rejected several times above the concurrent provincial average and in the range where selection bias could account for a significant portion of the results.

The authors’ estimate of a 10% rejection rate based on consultation rates is also highly contentious.

Shouldice promotes itself as not requiring a referral (only one-third of their patients in 2004–2006 had a referral and consultation), so a huge proportion of their selection and rejection process would be completely invisible to the databases used by these researchers. The selection process at Shouldice has a significant emphasis on ideal body weight, and many patients are rejected owing to failure to achieve weight loss goals that are not imposed by most other surgeons. When one considers that 72% of middle-aged men in Ontario are obese or overweight, a large proportion of these patients would be ineligible for surgery at the Shouldice Hospital despite its publicly funded status. This is a level of discrimination not seen at other Ontario hospitals.

We would also point out that there have been at least 16 randomized controlled trials of the Shouldice repair wherein selection bias is implicitly eliminated by randomization. A meta-analysis and Cochrane review of these trials clearly shows a strong advantage for mesh repairs, essentially showing the exact opposite of what Malik and colleagues reported, with mesh-based repairs being 4 times less likely to recur. In short, Malik and colleagues report an effect that is 16 times better than what the randomized literature shows. We also criticize the study for focusing on hospital volume rather than surgeon volume or technique, both of which were tracked in the databases used. The impact of hospital volume would be expected to influence only cases requiring complex hospital care and, indeed, this study found no trend between high- and low-volume general hospitals. Surgical technique, particularly the use of mesh, has been shown in multiple studies to have a significant impact, yet it was not adjusted for.

We also criticize the study for presenting aggregate data that clearly span a transitional period in hernia repair, where most surgeons made an appropriate evidence-based shift away from tension-based tissue repairs to tension-free mesh repairs. The overall 50% reduction in recurrence rate over the course of this study is hidden in the fine print and is probably due to technique. A comparison with an old technique that is largely abandoned only magnifies the difference in recurrence rates and doesn’t inform about current practice.

The study does raise the interesting question as to whether extremely high surgeon volume can impact results. A population-based study from Sweden found very little impact of surgeon volume, with recurrence rates generally plateauing at an annual rate of only 10 per year and, though volumes did not approach those of the Shouldice hospital, there was no trend toward better outcomes with higher volumes.

Finally, we point out that the fee code for recurrence is essentially a self-reported variable that is unvalidated in the setting of a private company with a marketing strategy that is based on low recurrence rates.

We feel that this paper gives a misleading picture of the current status of inguinal hernia surgery in Ontario and would caution health care planners that selection bias rather than process issues are by far the most likely explanation of the results presented. We do acknowledge that its publication will hopefully stimulate an important debate about the quality of hernia surgery in Ontario and the importance of measuring adjusted outcomes, of which recurrence is but one.

Chris Vinden, MD
From the Ontario Association of General Surgeons, Ontario, Canada.
It is true that randomized trials do not support the use of the Shouldice technique for inguinal hernia repair, especially when compared to modern, tension-free repairs. Like Dr. Vinden, we do not believe that general surgeons should stop performing their usual technique of hernia repair — with which they are most skilled and confident — in favour of a repair that is notoriously difficult to perform well in typical practice settings. We also agree that it is neither advisable nor feasible to regionalize a procedure as common as inguinal hernia repair to specialty hospitals.

On the other hand, it appears that much may be learned about inguinal hernia repair from large specialty hospitals — even if those lessons relate to issues such as how patient selection and preparation influence outcomes, and the value of focused expertise even in a relatively minor surgical procedure.

**LETTER TO THE EDITOR**

We are writing to respond to Drs. Vinden and Ott’s commentary, “GPs with enhanced surgical skills: a questionable solution for remote services.” We commend the authors for appealing to research data to inform the discussion of the need for a standardized curriculum by considering the efficacy of family physicians with enhanced surgical skills (FPRESS) in meeting the health care needs of rural Canadians. However, we feel some of the data referenced has been misconstrued and would like to contribute to this discussion, focusing primarily on data regarding maternity services and operative delivery.

Regarding the volume-to-outcomes data cited, the context of the data was analysis of outcomes from 3 major hospital systems in the United States who committed to a volume threshold for 10 high-complexity surgeries. The author explains why volume is traditionally used instead of outcomes in the evaluation of surgical competence (to account for the procedure selection bias of surgeons and ease of data access) but concludes that “the mechanism underlying volume–outcomes relationships remain unknown.” Further, he argues that if the underlying mechanism is one of increased practice leading to better outcomes, support for best practice models and quality improvement — not volume thresholds — is the most appropriate response. As the author notes,

if, on the other hand, outcomes improve because hospitals and surgeons gain expertise with incremental experience through a “practice makes perfect” mechanism, then the focus should be on dissemination of best practices and quality improvement.

Additionally — and more pertinent to the current discussion — an earlier study by Urbach and colleagues comparing volume studies from Canada and the United States found:

(...)that volume–outcome associations are much less common in Canada than in the United States, perhaps because different models of health care financing and delivery affect patterns of procedure volumes and volume–outcome associations. Market-based models promote competition between hospitals and providers, which may exacerbate existing variations in quality of care. The extent to which models of health care financing and organization cause variation in health outcomes across hospitals, and contribute to volume–outcome associations, has not been fully appreciated or examined.

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DOI: 10.1503/cjs.001916

**AUTHOR RESPONSE**

We don’t know exactly why people who had an inguinal hernia repair at the Shouldice Hospital had a much lower rate of surgery for recurrence than those who had hernias repaired elsewhere in Ontario. Ultimately, there are only 3 possible explanations: patient selection, surgical technique, or perioperative care. Most likely, it is some combination of these factors.

Dr. Vinden suggests that patient selection largely explains the difference, and he may be correct. However, for selection alone to account for the extraordinary difference in surgical recurrences we observed, the influence of selection must be enormous. Even assuming that 30% of all patients seen at the Shouldice Hospital are rejected for surgery and have their hernia repairs done elsewhere, the recurrence rate among those patients would have to be nearly 14% to mask a “true” risk of recurrence that is equivalent to the surgical recurrence risk in general hospitals.

David R. Urbach; Atíqa Malik; Thérèse A. Stukel; Chaim M. Bell

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DOI: 10.1503/cjs.003416
Jurisdictions outside of the United States have witnessed their volume–outcomes associations disappear with improving prenatal screening, regionalization and formalized referral systems. No international data after 1996 outside the United States have shown a volume–outcome association in maternity care. The mid-1990s is recognized as a watershed date for advances in prenatal screening, influencing appropriate triage for those cases likely to require higher levels of care. For example, Lasswell and colleagues\(^6\) found an undisputed volume–outcome association for very low–birth weight and very premature infants (those who would be risked out for delivery at a hospital without a neonatal intensive care unit and attendant pediatric specialist). Heller and colleagues\(^5\) in Germany showed no association between volume and outcomes after 1996. Two large studies in Norway showed a volume–outcome association in data up to 1995,\(^5\)\(^6\) as did a study in Sweden with data to the same date.\(^6\) In Australia, a study replicating the procedures of Moster and colleagues\(^6\) but using Australian data from 1999–2001 found no volume association.\(^9\)

Taken together, the weight of evidence for rural obstetrical care suggests that that distance to care has a greater clinical effect than does volume. Not taking into account reported psychosocial stress, sense of belonging and community, Aboriginal claim to birthings in their home territories and other qualitative evidence, BC and Canada-wide population data demonstrate that those women without local services have far worse outcomes that those with primary only (no surgical) services or those with FPRESS-supported surgical services.\(^10\),\(^11\) Further, a positive correlation between increasing adverse maternal–newborn outcomes and distance to services (1–4+ h) has been demonstrated.\(^11\) In international data, a study from the Netherlands showed that each minute of travel time is associated with an increased risk of neonatal mortality (odds ratio 1.01).\(^12\) In Australia, remoteness was found to be an independent factor in birth outcomes.\(^13\) In France, greater distance was associated with worse outcomes.\(^14\) In Wales, greater distance to hospital was associated with higher risk of neonatal mortality.\(^15\)

Finally, the authors cite the Canadian Institute for Health Information report on “Hospital births in Canada: a focus on women living in rural and remote areas.”\(^16\) Although we applaud the spotlight on rural outcomes that this report brings, it must be noted that “rural” was defined as communities with a population of less than 10,000 not stratified by service delivery level. The influence of poor outcomes from communities with no access to services as noted above would be a primary determinant of the overall poor health outcomes of rural women. This, as much as anything, should be an indicator of the need for finding innovative and safe solutions to meet the perinatal — and other — surgical needs of rural residents. Although we agree with the authors that a pluralistic view of solutions is needed in rural Canada, the available evidence would suggest that the solutions must involve the contribution of FPRESS.

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DOI: 10.1503/cjs.001016

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