Trends in brain-dead organ donor characteristics

Recommendations for surgical safety checklist use in Canadian children’s hospitals

The impact of adverse events on health care costs for older adults undergoing nonelective abdominal surgery

Diagnostic imaging for inpatients with pancreatic conditions: How much ionizing radiation are we using?
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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EDITORIAL • ÉDITORIAL

Continuous quality improvement in orthopedic surgery: changes and implications with health system funding reform

This guest editorial on quality control measures in orthopedic surgery was invited, as the time has come where we need to look at better quality improvement measures that are meaningful and physician-based. We do not want to have measures imposed that we have had no hand in designing or approving. All surgical specialties — not just orthopedic surgery — will need to be involved in this effort.

Total health expenditure was expected to reach $219.1 billion or $6105 per Canadian in 2015, with orthopedic care accounting for approximately 12% of total hospital acute care costs. In 2012–13, providing health care in Ontario consumed 42 cents of every tax dollar. Without modification, health spending would account for up to 70 per cent of the provincial budget by 2025. In an effort to stem the tide, health system funding reform (HSFR) was implemented in April 2012 as part of Ontario’s Action Plan for Health Care. A major constituent was the introduction of standardized bundled payments for quality-based procedures (QBP), which serve to reward care that improves patient outcomes. The United States and other countries are also moving toward bundled pricing. Of the QBPs currently in place in Ontario, 20% (4 of 20) involve orthopedic surgical procedures.

The principle behind HSFR, and the ethos for establishing mandated QBPs, is to improve the quality of health care. The adage goes, “improve the quality of care, enhance patient satisfaction, and thereby improve patient outcomes and lower costs.” However, what is quality improvement, and how is it best enacted and then measured?

Quality: What does it mean in today’s health care landscape?

According to the Institute of Medicine, quality health care should be safe, effective, patient-centred, timely, efficient and equitable. Quality does not necessarily improve by spending more money; quality could be a means to save money, as better coordinated care can lead to lower complication rates, shorter lengths of stay, reduced readmissions, and reduced use of health services after surgery. Quality of care can be assessed and improved through 3 sequential and interrelated dimensions: structures, processes and outcomes.

Increasingly, data collected through local data sets are being contributed to provincial and national registries in order to help quality-improvement initiatives. The American College of Surgeons’ National Surgical Quality Improvement Program (NSQIP) measures and compares the quality of surgical care across North America to enhance a hospital’s ability to zero in on preventable complications. As health care is always evolving with advances in technology, procedures and medical knowledge, the need for a “plan, do, study, act” (PDSA) cycle is necessary whereby data can be analyzed instantly and feedback provided constantly in order to continuously revise and improve.

The PDSA cycle forms the basis for continuous quality improvement (CQI), which encompasses processes associated with providing a product or service to meet or exceed customer expectations. The key to any CQI initiative is using a structured planning approach to evaluate current health care structures and processes and improve upon them to achieve the desired outcome and vision. To study and improve structures and processes, time-driven activity-based costing (TDABC) is becoming more frequently used in health care, including orthopedic surgery.

CQI and orthopedic surgery

Core aspects of most CQI programs include collection of data that allow assessment of health care structures, processes and patient-centred outcomes; feedback of performance and outcomes data to surgeons and stakeholders, ideally with risk adjustment and benchmarking of the data; and implementation of appropriate interventions to promote reduction in wasteful and inefficient variation in care while simultaneously improving performance.

Despite their relative infancy in health care, CQI programs have proven valuable at improving patient outcomes in orthopedic surgery, one of which was spearheaded by the Alberta Bone and Joint Health Institute. There have also been examples in subspecialties of orthopedic surgery looking at various quality end points, including fall prevention, antibiotic delivery in the emergency department and use of stat MRI for acute spine injuries.

Quality improvement plans in Ontario are now a formal commitment aligned with system and provincial priorities. Surgeons must become active participants in the quality movement by understanding the basic principles of CQI and how they apply to patient care. Only through
collaboration and integration can health care incorporate a
culture for improving quality and patient safety. Truly
improving performance is difficult, though, owing to ques-
tions about quality, design care processes, measure inputs
and outputs, multistakeholder collaborations, and incentive
programs. Major obstacles commonly reported are lack of
time, limited resources, lack of training, and pressures to
deal with other changes.26–29 Future efforts in developing
quality improvement require strong physician leadership in
helping to develop an optimal care team that is as patient-
centred as possible.9

In summary, CQI programs evaluating health care ser-
ices can inform choices to optimize care and improve ef-
ciciencies through knowledge translation. Successful end
products may include better patient satisfaction, improved
patient-reported outcomes, highly efficient care pathways,
and overall cost savings.

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Amélioration continue de la qualité en chirurgie orthopédique : modifications et répercussions de la réforme du financement du système de santé

Fruit d'une collaboration spéciale, cet éditorial sur les mesures de contrôle de la qualité en chirurgie orthopédique arrive à point nommé : en effet, il est grand temps que des mesures d'amélioration de la qualité utiles et élaborées par des médecins soient adoptées. Nous ne voulons plus nous voir imposer des mesures élaborées et approuvées sans notre concours. Et pour que les choses changent, toutes les spécialités chirurgicales devront mettre la main à la pâte.

Au Canada, les dépenses totales en santé prévues pour 2015 s'élevaient à 219,1 milliards de dollars, soit 6105 dollars par habitant. Les soins orthopédiques comprenaient pour environ 12 % des dépenses associées aux soins actifs dans les hôpitaux. En 2012–2013, pour chaque dollar fiscal, 42 cents ont servi à financer les soins de santé en Ontario. Si rien ne change, les dépenses en santé pourraient représenter jusqu'à 70 % du budget provincial d'ici 2025.

C'est pour freiner cette augmentation que la réforme du financement du système de santé (RFSS) a été implantée en avril 2012 dans le cadre du Plan d'action de l'Ontario en matière de soins de santé. Parmi les principaux éléments de cette réforme, notons la mise en place d'un modèle normalisé de paiement regroupé pour les actes médicaux fondés sur la qualité (AMFQ) visant à encourager les soins qui améliorent les résultats pour les patients. D'autres pays, dont les États-Unis, tendent également vers l'adoption de modèles semblables. Parmi les AMFQ actuallement posés en Ontario, 20 % (c.-à-d. 4 sur 20) sont des interventions en chirurgie orthopédique.

L'objectif derrière l'implantation de la RFSS et l'imposition d'AMFQ est le même : améliorer la qualité des soins de santé. C'est bien connu : en améliorant la qualité des soins et la satisfaction des patients, on obtient de meilleurs résultats pour les patients et une diminution des coûts. Mais en quoi consiste l'amélioration de la qualité? Quelle est la meilleure méthode pour la mettre en œuvre et l'évaluer?

Quelle est la place de la qualité dans le contexte actuel des soins de santé?

Selon l'Institute of Medicine, des soins de qualité doivent être sécuritaires, efficaces, axés sur le patient, efficaces, équitables et fournis dans des délais raisonnables. L'amélioration de la qualité ne passe pas nécessairement par une augmentation des dépenses : elle peut même servir à économiser de l'argent. En effet, une meilleure coordination des soins peut se traduire par une diminution du taux de complications, de la durée des séjours, des réadmissions et de l'utilisation des services de santé après une chirurgie. L'évaluation et l'amélioration de la qualité des soins reposent sur 3 dimensions séquentielles et inter reliées, soit les structures, les processus et les résultats.

De plus en plus, les données recueillies au moyen d'ensembles de données locaux sont transmises à des registres provinciaux et nationaux afin de favoriser les initiatives d'amélioration de la qualité. Dans le cadre du National Surgical Quality Improvement Program de l'American College of Surgeons, on évalue et compare la qualité des soins chirurgicaux offerts en Amérique du Nord pour aider les hôpitaux à cibler certaines complications évitables. Compte tenu de l'évolution constante des soins de santé attributable aux diverses percées dans les technologies, les procédés et les connaissances médicales, il devient essentiel d'adopter un cycle de type «Planification–Exécution–Étude–Action », au moyen duquel il sera possible d'analyser instantanément les données et de fournir constamment de la rétroaction aux fins de révision et d'amélioration continues.

L'amélioration continue de la qualité (ACQ) repose directement sur ce type de cycle. Elle s'applique à tous les processus visant à fournir un produit ou un service à un consommateur de façon à combler ou à dépasser ses attentes. Toute initiative d'ACQ doit reposer sur une stratégie de planification cohérente servant à évaluer les structures et les processus actuels et à les améliorer pour atteindre la vision et les résultats souhaités. Pour ce faire, il est de plus en plus fréquent dans le secteur des soins de santé, notamment en chirurgie orthopédique, d'avoir recours à la méthode des coûts par activités tout en tenant compte du temps requis.

**ACQ et chirurgie orthopédique**

Parmi les principaux aspects de la plupart des programmes d'ACQ, notons : la collecte de données permettant l'évaluation des structures, des processus et des résultats pour les patients; le transfert aux chirurgiens et aux intervenants des données sur le rendement et les résultats, de préférence après qu'elles aient été ajustées en fonction du risque et étalonnées; la mise en œuvre d’interventions appropriées pour atténuer les variations inutiles entre les soins tout en améliorant le rendement.
ÉDITORIAL

Même si leur utilisation dans le secteur des soins de la santé est relativement récente, les programmes d’ACQ ont fait leurs preuves pour améliorer les résultats pour des patients en chirurgie orthopédique, notamment dans le cadre d’une initiative dirigée par l’Alberta Bone and Joint Health Institute21,22. Dans certaines surspécialités de la chirurgie orthopédique, d’autres indicateurs de qualité ont également été recensés, comme la prévention des chutes23, l’administration d’antibiotiques au service des urgences24 et l’utilisation immédiate de l’IRM en cas de lésions médulaires graves25.


En résumé, les programmes d’ACQ visant des services de soins de santé peuvent orienter la prise de décisions et, grâce à l’application des connaissances, optimiser les soins et améliorer l’efficacité. Parmi les résultats potentiels, soulignons une plus grande satisfaction des patients, une amélioration des résultats déclarés par les patients, des plans d’interventions plus efficaces et des économies globales.

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Trends in brain-dead organ donor characteristics: a 13-year analysis

Background: Driven by disease trends, such as obesity and metabolic syndrome, that are increasingly prevalent in the general population, we aimed to evaluate the comorbidities and attributes of the brain-dead organ donor population over time in a longitudinal study.

Methods: We compared overall health and baseline attributes of organ donors between 2000–2005 and 2006–2012 using our prospective transplant database. Descriptive and comparative analyses of the 2 historical cohorts were performed.

Results: A total of 1040 brain-dead organ donors were included in our analysis: 496 from the 2000–2005 period and 544 from the 2006–2012 period. Our analysis revealed that donors from the recent (2006–2012) period were more likely to have increased body mass index (26.4 ± 6.0 v. 25.0 ± 4.8, p = 0.003), smoking history (57.0% v. 27.2%, p < 0.001), coronary artery disease (14.3% v. 3.2%, p = 0.015) and dyslipidemia (19.1% v. 4.2%, p < 0.001), but less likely to have concurrent infection (1.1% v. 7.9%, p < 0.001) than those from the earlier period.

Conclusion: Our data suggest that the characteristics and comorbidities of brain-dead organ donors have somewhat deteriorated over the last decade. Further studies are needed to evaluate the impact of these health attributes on donated organ utilization and outcomes.

Despite the efforts of the transplant community to address the urgent need for donor organs, the disparity between the number of patients on the waiting list and available donor organs remains substantial.1 It is now well recognized that solid organ transplantation is the most definitive and effective treatment for end-stage liver disease and kidney failure. Innovative measures, such as the use of split livers2–4 and living-related donation,5,6 have been
developed to try to reduce the gap between transplantable organ supply and demand. In fact, in 2001 in the United States, the use of living-related donor organs increased considerably to surpass the number of deceased organ donor procurements (52% v. 48%). Evidently the donation patterns of transplant centres are influenced by many factors, such as death and donation rates, allocation policy, listing regulations and usage of expanded criteria donors (ECD). Recently, Redelmeier and colleagues7 reported on the organ donation trends in Ontario, Canada. This population-based cohort study reported a small donation rate, yet noted a significant increase in deceased donors over a 16-year period.

On the other hand, population-based epidemiological studies from North American data suggest a persistent growth in the prevalence of certain disease states, such as metabolic syndrome.8 For instance, metabolic syndrome is defined by the presence of several risk factors, such as obesity, hyperlipidemia, diabetes and hypertension, all of which have their own negative impact on morbidity and mortality.9,10 Moreover, metabolic syndrome has been associated with fatty liver disease, steatosis and liver fibrosis11–13 as well as chronic kidney disease.14–16 Since deceased donors consist of a portion of the general population, such epidemiological changes and disease trends could potentially be reflected into the organ donor pool. Multiple clinical, biochemical, technical and ethical factors already play a role in organ donation discussions, but worse comorbidities and unfavourable metabolic profiles may potentially further challenge the decision to consider organ donation. Although multiple national reports on organ donation trends exist,17,18 data on specific characteristics and comorbidities of deceased donors are scarce.

We postulated that as some disease trends, such as metabolic syndrome, are increasingly prevalent in the general population, demographic characteristics of brain-dead organ donors might also be affected. We thus aimed to evaluate the changes in brain-dead organ donor characteristics in a longitudinal study over a period of 13 years, using the registry of deceased donors procured by our institution.

METHODS

Organ donor population

This study was approved by the McGill University Health Center (MUHC) and the Transplant Quebec Research Ethics Boards (REBs). All eligible brain-dead organ donors identified between January 2000 and December 2012 who donated 1 or more organs to a patient from the MUHC were included in the study. The donor inclusion criteria included only brain-dead donors who were 18 years of age or older. For the purpose of this study, living-related donors and donation after cardiac death (DCD) were excluded from the analysis. The extracted data from our prospective transplant database were limited to organ donor characteristics, such as donor age; sex; race; cause of death; ABO group; body mass index (BMI); glomerular filtration rate (GFR) before procurement; history of smoking, coronary artery disease, hypertension, diabetes or dyslipidemia; history of malignancy or drug abuse; and presence of an active infection.

Brain death was declared as standard and defined as complete loss of motor or respiratory drive, absence of brainstem reflexes in the context of an irreversible injury and absence of metabolic or contributing reversible injuries.19–22 The donor GFR was calculated using the 4 variables in the Modification of Diet in Renal Disease (MDRD) Study:23 serum creatinine, age, race and sex. For the causes of brain death, anoxic brain injury included brain death after events like respiratory or cardiac arrest, poisoning (e.g., carbon monoxide), drug overdose or drowning. Traumas causing brain death included motor vehicle accidents as well as penetrating and blunt traumatic head injuries. Although florid septicemia and severe infections were a contraindication to organ donation, presence of an infectious source (bacteremia, fungemia) did not preclude organ donation candidacy.24 Expanded criteria donors are defined as those aged 60 years or older, or older than 50 years with at least 2 of the following conditions: hypertension history, serum creatinine > 1.5 mg/dL, or death due to stroke, which are the criteria used by the United Organ Sharing Network (UNOS).25

Statistical analysis

Categorical and continuous variables are expressed as summary statistics (number, percentage, median, range, mean, standard deviation); all comparisons between groups were carried out using a 2-sided test. We used the Fisher exact test or the χ2 test (for categorical variables) and the Wilcoxon rank-sum test (for continuous non-normally distributed variables) to assess differences between the groups. To identify variables independently associated with a time period (recent 2006–2012 v. remote 2000–2005), we performed multivariable logistic regression analyses. We considered results to be significant at p < 0.05. All analyses were performed using JMP statistics software version 11.0 (SAS).

RESULTS

Characteristics of organ donors

After excluding living-related donations and DCD donors, a total of 1040 brain-dead organ donors were included in this study (Fig. 1). A median of 84 (range 79–87) organ donor procurements were performed yearly during the study period. The median age of donors was 47 (range 31–58) years, and 586 (56.3%) were men. Donor BMI was greater than 50 years with at least 2 of the following conditions: hypertension history, serum creatinine > 1.5 mg/dL, or death due to stroke, which are the criteria used by the United Organ Sharing Network (UNOS).25
followed by trauma (241, 23.2%) and anoxic brain injury (133, 12.8%). The ratio of expanded criteria donors over standard criteria donors significantly increased over time, (Fig. 3).

Comparison of organ donor characteristics over time

The cohort was divided into 2 time periods — remote (2000–2005) and recent (2006–2012) — to evaluate changes over time in organ donor demographic profile and comorbidities. Baseline characteristics and comorbidities of the 2 groups are detailed and compared in Table 1. In fact, significant differences were noted between the 2 time periods in terms of donor age, BMI, history of smoking, hypertension, hyperlipidemia, diabetes and coronary artery disease (Table 1). Interestingly, there were fewer donors with documented infection at the time of procurement in the recent period (1.1% v. 7.9%, p < 0.001). The causes of death were also significantly different between the 2 time periods: in the recent period, fewer donors died as a result of trauma (19.7% v. 27.0%, p < 0.001), and more died from anoxic brain injury (17.3% v. 8.1%, p < 0.001), consistent with previously published North American data.17 Moreover, although the distribution of donors’ average BMI did not demonstrate a steady slope year after year, there was increasing risk of BMI above 30 compared with the baseline period (Fig. 3A) and a significant increase in BMI above 30 over time (Fig. 3B).

Analysis of significant donor characteristics related to period of procurement

Since many of the variables analyzed were potentially related and concomitantly present as comorbidities, we wanted to ascertain independent predictors of the recent time period (2006–2012) compared with the remote period (2000–2005). The initial descriptive analysis demonstrated significantly greater associations of BMI, smoking history, coronary artery disease, hyperlipidemia and infection with procurements performed in the recent years. The multivariable logistic regression (Table 2) confirmed that several variables were independently predictive of the recent time period: BMI, smoking history, coronary artery disease, hyperlipidemia (more likely in the recent time period) and presence of infection (less likely in the recent time period). In addition, there were more women and better renal function among donors in the recent time period.

DISCUSSION

Organ transplantation is a life-saving treatment for many patients with acute or chronic solid organ failures. As a result of this ultimate and definitive therapy, more patients are considered eligible for organ transplantation, contributing to the persistent discrepancy between potential recipients and
available donated organs. The usage of ECD in kidney transplantation was an attempt to counterbalance the organ shortage crisis, and although initial studies reported lower survival after transplantation from ECD than from standard donors,26–28 some recent studies have reported more encouraging results.29,30 In parallel to these facts occurring in the transplant community, statistics resulting from public health surveillance institutes are all pointing toward a growing prevalence of chronic diseases, such as obesity, diabetes, hypertension, dyslipidemia and coronary artery disease; all of which contribute to an overall worsening health status among the general population, and hence the deceased standard criteria donor pool as well. Our aim was to characterize the trends in comorbidities and physical health attributes of organ donors over more than a decade. Our results indicate that there is a statistically significant increase in comorbidities, such as increased obesity, hyperlipidemia, smoking history and coronary artery disease, suggestive of an overall poorer health status. It may be argued that some of the significant variables probably reflect an increase in the use of ECD by the transplant centres and especially that the ratio of ECD increased over time. However, the situation in our centre may reflect that the increase in comorbidities among donors is associated with the increase in comorbidities in the general population, and this is evidenced by the stability of organs donated over time. There are 2 liver transplantation centres in the province of Quebec, and ours is the only multiorgan site. We share the brain death donors under the management of Transplant Quebec. Our centre receives organs from about 75% of the donors, and our provincial donation rate has been stable over the last decade (around 120–130 donors each year); therefore, our data at least represent the situation of the whole province. We therefore are confident that there was no donor selection bias in our cohort and that the application of ECD worldwide did not affect our donor selections.

Also, because the rate of ECD use has been increasing29,31 and the total number of eligible donors increases at a slower rate,18 this suggests that the proportion of eligible donors with “bad” criteria has been rising at the expense of more healthy donors. Therefore, the worsening donor characteristics are most likely not related to surgeons’ willingness to procure organs from ECD, but rather to a donor pool of gradually poorer quality. Most of the variables we describe in the present study have been previously found to be associated with worse outcomes after transplantation.32,33 For instance, obesity has been reported to be associated with inflammation and modified immune responses,32 potentially impacting allorecognition and alloimmunity. Another argument may be that the difference in BMI between the remote and recent periods in our study was only 1.4 and that we may have overestimated the role

Fig. 2. Organ donors by period and donor category. 0 = standard criteria donors; 1 = expanded criteria donors.
of BMI. However, although such a difference might not be significant in general population, the higher BMI in the recent period of our study impacted the organ quality of the donors. Increasing obesity in the general population affects the BMI of organ donors, which causes problems for transplantation. Orman and colleagues analyzed BMI over 15 years (1995–2010) and found that BMI increased significantly in the past 15 years in the United States, which is consistent with our results. They also reported that obesity might not only affect the quality of the donated livers, but also of donated pancreas. Declining health characteristics of the donor population may consequently have a negative impact on multiple potential solid organs.

**Fig. 3.** (A) Risk of body mass index (BMI) > 30 of organ donors procured by time period. (B) Percentage of organ donors by BMI category and time period. CI = confidence interval.
Limitations

We acknowledge that our study has some limitations. First, the data were derived from a single institution’s transplant centre, which poses a limitation in terms of sample size and selection bias. Our centre’s expertise lies in kidney, liver and pancreas transplantation, therefore the organ donation attributes will correspond to the recipients treated at our centre who required those donated organs. Although the number of organ procurements performed

<table>
<thead>
<tr>
<th>Table 1. Baseline characteristics and comorbidities of organ donor population by time period (n = 1040)</th>
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<tr>
<td><strong>Time period; no. (%)</strong>*</td>
</tr>
<tr>
<td>Age, median (IQR), yr</td>
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<tr>
<td>Sex</td>
</tr>
<tr>
<td>Male</td>
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<tr>
<td>Female</td>
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<td>Race</td>
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<tr>
<td>White</td>
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<tr>
<td>Black</td>
</tr>
<tr>
<td>Cause of death</td>
</tr>
<tr>
<td>Cerebrovascular/stroke</td>
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<tr>
<td>Trauma†</td>
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<tr>
<td>Anoxic brain injury‡</td>
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<tr>
<td>Tumour</td>
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<tr>
<td>Other/unknown</td>
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<td>ABO group§</td>
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<td>A</td>
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<td>AB</td>
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<tr>
<td>O</td>
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<tr>
<td>BMI, mean ± SD</td>
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<td>GFR, median (IQR), mL/min/1.73 m²</td>
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<tr>
<td>Smoking history</td>
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<td>Hypertension history</td>
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<td>Hyperlipidemia</td>
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<td>Diabetes mellitus</td>
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<td>CAD history</td>
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<tr>
<td>History of malignancy</td>
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<td>Presence of infection</td>
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</table>

BMI = body mass index; CAD = coronary artery disease; GFR = glomerular filtration rate; IQR = interquartile range; SD = standard deviation.
*Unless indicated otherwise.
†Includes motor vehicle accidents and other penetrating/blunt traumatic injury.
‡Includes drug intoxication and drowning.
§Based on n = 1038 (missing data for 1 donor per group).

<table>
<thead>
<tr>
<th>Table 2. Forward stepwise multivariable logistic regression analyses depicting independent donor characteristics predicting their odds in the recent time period compared with the remote time period</th>
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<tbody>
<tr>
<td><strong>Donor characteristic</strong></td>
</tr>
<tr>
<td>Smoker</td>
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<tr>
<td>Hyperlipidemia</td>
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<tr>
<td>Infection</td>
</tr>
<tr>
<td>BMI &gt; 30</td>
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<tr>
<td>4th quartile (good) renal function</td>
</tr>
<tr>
<td>CAD</td>
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<tr>
<td>Female</td>
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</tbody>
</table>

BMI = body mass index; CAD = coronary artery disease; CI = confidence interval; OR = odds ratio; SE = standard error.
by our centre constitutes 75% of the total provincial donor pool, our results can still not be generalized to a national level. Moreover, the impact of the deteriorating quality of deceased donors on the organ recovery and discard rate is still unclear. It has been previously shown that some donor attributes, notably older donor age, higher BMI, diabetes and DCD, are all independently associated with organ nonrecovery. Although these data could be extrapolated to our findings, further research would be required to correlate the physical attributes and comorbidities of deceased donors to organ utilization.

**CONCLUSION**

The present longitudinal analysis of 1040 brain-dead organ donors demonstrates overall worsening of general health attributes and comorbidities in this population. More research is required to evaluate the impact of these findings on organ utilization patterns and recipient outcomes.

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**Competing interests:** None declared.

**Contributors:** P. Metrakos designed the study. M. Hassanain, M. Aljiffry, A. Aloraini and A. Madkhali acquired the data, which E. Simonneau and S. Doi analyzed. M. Hassanain, E. Simonneau, A. Aloraini and A. Madkhali wrote the article, which all authors reviewed and approved for publication.

**References**

Recommendations for surgical safety checklist use in Canadian children’s hospitals

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Background: There is ample evidence that avoidable harm occurs in patients, including children, who undergo surgical procedures. Among a number of harm mitigation strategies, the use of surgical safety checklists (SSC) is now a required organizational practice for accreditation in all North American hospitals. Although much has been written about the effects of SSC on outcomes of adult surgical patients, there is a paucity of literature on the use and role of the SSC as an enabler of safe surgery for children.

Methods: The Pediatric Surgical Chiefs of Canada (PSCC) advocates on behalf of all Canadian children undergoing surgical procedures. We undertook a survey of the use of SSC in Canadian children’s hospitals to understand the variability of implementation of the SSC and understand its role as both a measure and driver of patient safety and to make specific recommendations (based on survey results and evidence) for standardized use of the SSC in Canadian children’s hospitals.

Results: Survey responses were received from all 15 children’s hospitals and demonstrated significant variability in how the checklist is executed, how compliance is measured and reported, and whether or not use of the checklist resulted in specific instances of error prevention over a 12-month observation period. There was near unanimous agreement that use of the SSC contributed positively to the safety culture of the operating room.

Conclusion: Based on the survey results, the PSCC have made 5 recommendations regarding the use of the SSC in Canadian children’s hospitals.

Contexte : Il a été prouvé maintes fois que les patients, y compris les enfants, sur qui des interventions chirurgicales sont pratiquées peuvent subir des méfaits évitables. Les normes d’agrément exigent dorénavant de tous les hôpitaux d’Amérique du Nord qu’ils utilisent une liste de contrôle de la sécurité chirurgicale, l’une des stratégies susceptibles de réduire ces méfaits. Si de nombreux articles portent sur l’efficacité d’une telle liste lors d’interventions chirurgicales sur des patients adultes, peu d’études ont été publiées sur l’utilisation et le rôle de ces listes dans le contexte de la sécurité des interventions chirurgicales effectuées sur des enfants.

Méthodes : L’organisme Pediatric Surgical Chiefs of Canada (PSCC) représente tous les enfants canadiens qui subissent des interventions chirurgicales. Nous avons mené un sondage auprès des hôpitaux canadiens pour enfants pour déterminer le degré de mise en œuvre de la liste de contrôle d’un endroit à l’autre, pour comprendre son rôle dans l’évaluation et l’amélioration de la sécurité des patients et pour formuler des recommandations précises (d’après les données probantes et les résultats obtenus) afin d’en normaliser l’utilisation dans les hôpitaux pour enfants du Canada.

Résultats : Les 15 hôpitaux pour enfants ont tous répondu à notre sondage. Leurs réponses étaient très variées en ce qui concerne la mise en œuvre de la liste de contrôle, la façon dont ils évaluent et documentent le respect de la liste et l’efficacité de celle-ci à prévenir des erreurs concrètes pendant la période de 12 mois à l’étude. Les répondants ont indiqué presque à l’unanimité que la liste de contrôle favorisait grandement une culture de sécurité en salle d’opération.

Conclusion : À partir de ces résultats, le PSCC a formulé 5 recommandations concernant l’utilisation de la liste de contrôle dans les hôpitaux pour enfants du Canada.
Implementation.8 Implementation without careful attention given to stakeholder engagement and education (the “why”), without clear guidelines or recommendations for checklist format (the “what”), and without formal team training or guidelines for compliance measurement (the “how”) may at least in part, explain the phenomenon observed in the Ontario hospitals report.

The goal of the present study was to obtain a snapshot of surgical checklist use in all 15 Canadian hospitals that provide tertiary subspecialty surgical care for children to understand how the checklist has been implemented and used, how compliance is measured and reported, and the perceived value in preventing errors and contributing positively to a culture of safety in the pediatric OR. Using these data as justification to optimize implementation fidelity, the Pediatric Surgical Chiefs of Canada (PSCC) have made recommendations for standardized use of a pediatric SSC in support of safe and high-quality surgical care for children.

**Methods**

**Setting**

We surveyed all children’s hospitals in Canada \( n = 15 \) that provide subspecialty children’s surgery with full-time availability of fellowship-trained pediatric anesthesiologists. These include 9 “free-standing” children’s hospitals and 6 children’s hospitals that have some shared services with an adjacent general hospital.

**Survey tool**

The questionnaire (Appendix 1, available at cansurg.ca) was developed collaboratively by the PSCC. The questions sought to determine the attributes of the surgical checklist in use at each children’s hospital: its structure, details of how the checklist is executed, how compliance is measured and reported, the role of the SSC in performance measurement and improvement, and stakeholder (physician, parent) assessment of the value of the checklist and its impact on the safety culture of the OR.

**Results**

All 15 questionnaires were returned, yielding a complete representation of the use of surgical checklists in Canadian children’s hospitals. The survey permitted free text comments, some of which are excerpted below. The aggregate data were distributed in electronic format, and presented and discussed at the annual general meeting of the PSCC.

**Surgical checklist structure**

All 15 children’s hospitals reported using the same 3-phase communication structure described in the original WHO SSC. In all hospitals, the WHO checklist has been modified to meet the needs of the local environment.

**Sign in**

The sign in, performed immediately after the child is brought into the OR (often in the company of a parent), but before administration of anesthesia, consists of a team discussion verifying the patient’s identification, weight, and presence of allergies; the planned operative procedure (site and side); and confirmation of surgical site marking, if indicated.
Time out
The time out, performed after administration of anesthesia, but just before the surgical incision, verifies the patient’s identification; the planned procedure (site and side); the need for and time of administration of prophylactic antibiotics; and whether special equipment, implants, or blood are required and immediately available.

Sign out
The sign out, performed at the end of the operation, confirms the operative procedure performed, whether final counts (sponge, needle, instruments) were correct, whether any surgical specimens were submitted, and the estimated blood loss for the procedure. Note may be made of any communication, equipment or process failures, and required remediation steps.

Huddle
In addition to the sign in, time out and sign out phases, 6 of 15 (40%) hospitals use a morning “huddle” (also referred to as the “7:35 huddle”). The huddle is a meeting among the anesthesiology, nursing and surgery staff that occurs 10 minutes before the first case of an elective surgical slate. The discussion is usually led by the surgeon and anesthesiologist and includes a brief oral confirmation of all the scheduled cases, equipment or blood product requirements, need for antibiotic prophylaxis, and the potential for any specific anesthesia needs (e.g., epidural anesthesia). One respondent explained, “the huddle gets everyone on the same page and reminds us of our shared responsibility to ensure that all patients have a safe procedure.”

Executing the SSC
There is considerable variation across Canadian Children’s Hospitals as to how the individual disciplines (i.e., anesthesiology, nursing and surgery) participate in the surgical checklist. In 5 of 15 hospitals, the attending anesthesiologist and surgeon and a member of the nursing team are required to be present for all 3 phases, while in another 7 hospitals, the roles of the anesthesiologist and surgeon may be represented by residents or fellows, provided they are familiar with the patient and the planned procedure.

There is also variability in how the elements of the checklist are discussed and who leads each step. For example, in 3 hospitals, all 3 phases follow a fixed script that is read aloud. However, in 4 hospitals, the surgical checklist consists of free-flowing conversation at each stage, whereas in the remaining 5 hospitals, a partially scripted checklist is used. There are no set requirements for who leads the performance of the checklist at any of the hospitals. Introduction of the members of the team was part of the time out phase in the WHO SSC. This step is often omitted if the team members know each other. One respondent explained, “we use a white board with everyone’s name written on it.”

Eight of 15 Canadian children’s hospitals use a modified surgical checklist for anesthesia or sedation procedures performed outside the OR.

Measuring and reporting compliance
Surgical checklist compliance is tracked in 14 of 15 (93%) Canadian children’s hospitals. In more than half of hospitals, compliance is recorded manually on the OR record, which subsequently gets uploaded into a hospital information system. Other means of measuring compliance include periodic OR record or direct observer audits. In 7 of 15 children’s hospitals (representing British Columbia, Alberta and Ontario) SSC compliance is identified as a quality indicator with mandatory reporting to the hospital executive, Board of Directors and the Ministry of Health. In 13 hospitals SSC compliance is reported internally to clinical leadership and the hospital executive. In 7 of 15 hospitals a quality improvement project targeting improved compliance with the SSC had been undertaken in the 12 months preceding the survey. One respondent explained, “we’ve tried to increase compliance to as close to 100% as possible by presenting our data at Department of Surgery rounds and divisional monthly meetings, and at our perioperative nurses’ weekly education conference.”

Value proposition and the SSC
The contribution of the surgical checklist to the safety and quality of surgical encounters at each of the 15 hospitals was assessed from a number of perspectives. One was the value (perceived by the OR team) of having parents as observers during the sign in phase for their children in those children’s hospitals that permit parental presence at administration of anesthesia (12 of 15 hospitals). The perception in 6 of these 12 hospitals (50%) was that parental presence added value, while the remainder felt there was little or no added value. One respondent explained, “the view of value of parental presence is mixed. We have researchers looking specifically at this question. They have not demonstrated significant benefit, but there is perception of benefit in select cases.”

Another “value” question asked whether or not the SSC had identified and prevented any errors (“near misses”) within the previous 12 months. Six of 15 (40%) hospitals reported having 1 or more errors identified by the surgical checklist; 5 potential “never events” (i.e., wrong side, wrong procedure, wrong patient) were identified and prevented. One respondent commented, “the SSCL prevented at least 1 wrong side cochlear implant
operation.” Other errors recognized included 4 patients who did not have the side or site of surgery marked (despite a policy that requires this), and 1 patient each for whom equipment deficiencies or a failure to administer prophylactic antibiotics was realized. However, at least 1 “never event” did occur, despite an appropriately executed checklist. One respondent commented, “despite an SSC being properly completed, we did have an occurrence of a wrong-sided incision in 1 case.”

Surgeons in chief were asked to assess whether OR efficiency had improved, diminished or remained unchanged since implementation of the surgical checklist. Four of 15 felt it had improved, while the remainder felt that it had diminished (n = 3) or had no effect (n = 8). Finally, the last question inquired about the impact of the SSC on the safety culture in the OR. In the majority of children’s hospitals (13 of 15), the perception of the surgeons in chief was that the checklist had a positive influence on the safety culture, but there was still a need for constant vigilance. One respondent commented, “we are still having some trouble instituting all aspects of the SSCL with emergency cases after regular OR hours and we need to instill a culture of safety for all cases at all times.”

**DISCUSSION**

The use of a surgical checklist or some other standardized communication tool to facilitate team-based collaboration and critical task completion leading to early recognition of “near misses” and prevention or early recognition of complications represents one of the most important changes in surgical care over the past decade. Borrowed from other high-risk industries, such as aviation, and used successfully for error reduction in other complex patient care environments, including intensive care units, procedural checklists permit structuring of the communication of critical information. Explicit information sharing among all team members across nonhierarchical disciplines encourages cross-checking for accuracy and supplements traditional paths of communication within disciplines (e.g., nurse to nurse, surgeon to surgical resident). Prior to the development of the WHO SSC, the Joint Commission developed a Universal protocol for preventing wrong site, wrong procedure, wrong person surgery. This protocol, which became a U.S. hospital accreditation criterion in 2008, mandates a preoperative verification process, unambiguous surgical site marking, and a surgical pause or “time out” to be performed immediately before the start of the procedure. Another type of procedural checklist shown to be successful in reducing postoperative morbidity and mortality is the Surgical Patient Safety System (SURPASS), which utilizes a comprehensive, multidisciplinary SSC that follows the patient from admission to surgery to discharge. This checklist incorporates existing protocols and checks to create a comprehensive framework for the surgical pathway and minimize errors during transfers from one stage of the pathway to the next.

Although use of an SSC is an accreditation requirement in Canadian hospitals, there are no standards for compliance documentation or reporting. Within the province of British Columbia, for example, surgical checklist compliance is a mandatory performance measurement reported to the Ministry of Health, with a minimum expectation threshold of 80%. However, the definitions of whether the checklist was used for a given surgical encounter vary among hospitals, ranging from a qualitative “yes” or “no” to a 9-point (3 disciplines present for all 3 phases) quantitative score for which all 9 “ticks” are necessary to achieve compliance. There is also variation in how the data are collected, ranging from third party observation to surgical record audits to self reporting. These factors all serve to confound the reliability of compliance data and may contribute to the phenomenon of very high rates of checklist compliance (> 95%) without evidence of improvement in outcome following checklist implementation. An emerging theme in checklists as process improvement tools is the importance of “implementation fidelity” and the need to measure not only adherence to the tool, but also the support domains (e.g., education, resourcing, role of “champions,” staff engagement, incentives, safety culture) that would be expected to influence checklist adherence.

Children’s hospitals differ from hospitals for adults or community hospitals that treat adults and some children owing to their focus on delivering health services that are unique to the clinical, developmental and psychosocial needs of children and their families. In comparison to adults, the experiences of children undergoing surgery can vary dramatically based on the child’s age, developmental stage and health status; therefore, it is reasonable to assume that some modifications of a checklist that was developed primarily for use in adults might be necessary. With few exceptions, children undergoing surgery are more likely to be healthy, more likely to undergo an outpatient surgical procedure and more likely to be accompanied to the OR by a parent who will be present during anesthetic induction. Although rates of postoperative adverse events (mortality and morbidity) are lower in children than in adults, children do experience life-threatening complications after surgery and are not immune to “never events.”

Given that children appear to have an equivalent vulnerability to surgical harm, there is surprisingly little information on how surgical checklists have been implemented in tertiary care children’s hospitals. Reports from 2 American children’s hospitals describe the adaptation of the original WHO SSC to a 3-phase procedural checklist with some customization of steps to match the unique attributes of the procedures (e.g., a modified
checklist for short procedures) or the surgical team (e.g., large posters in every OR that the team could view simultaneously).26,27 A large Canadian children’s hospital described the addition of a “7:35 huddle” — a meeting of the surgical team before the start of an elective slate where all the day’s cases were briefly discussed to enable team preparedness.28

Draft recommendations arising from the PSCC’s discussion of aggregate survey data were modified until unanimous consensus was reached. In recognition of the need for an SSC that meets the unique needs of children and families, the PSCC makes the following observations and recommendations.

**Checklist implementation**

**Recommendation:** Although all Canadian children’s hospitals are currently using an SSC, change management must be undertaken with “implementation fidelity” as a primary objective. A poorly conceived change management strategy (i.e., without proper education, justification, adequate implementation resources, or perceived lack of clinical champions) may do more harm than good, and should be avoided. The surgeon in chief, in collaboration with a senior manager or director with oversight for perioperative services, should oversee any change implementation related to the SSC.

**Checklist structure**

**Recommendation:** Children’s hospitals should use a surgical checklist adapted to the needs of patients and the surgical teams. A “7:35 huddle” adds an additional element of planning and instills a strong sense of shared responsibility for patient safety and should be officially considered part of the checklist. For slates of repetitive, short-duration “sided” procedures, the focus of the huddle should be on patient identification, confirmation of site and side, and plans for regional anesthesia, with complementary goals of room efficiency and patient safety. For longer, complex procedures, the huddle should include a specific discussion of personnel roles, special equipment, blood product or implant needs and any special requirements for tissue handling (e.g., frozen sections).

**Executing the surgical checklist**

**Recommendation:** All 3 disciplines (anesthesiology, nursing and surgery) must be present for all phases (including the 7:35 huddle), and the representative of the physician disciplines must be sufficiently experienced and know the individual patients and procedures well enough to be authoritative in these discussions (i.e., either the staff surgeon and anesthesiologist, or a subspecialty fellow). Team member introductions may be unnecessary when everyone knows one another (as in the context of dedicated specialty OR nursing teams), but is essential when new staff (nursing or physician) are present. There must be consistency in discipline representation between the 7:35 huddle and sign in for each case. Flexibility in who leads the oral communication of each phase is appropriate, and whether conversation is free-flowing or scripted should be decisions of the surgical teams, guided by preference and experience. Because the sign in phase will often be performed in the presence of a parent, consideration should be given to introductions, although this must not alter the intent of this step, which is identity and procedure verification for the child.

**Use of the surgical checklist outside of the OR**

**Recommendation:** The surgical checklist should be used for procedures requiring sedation or general anesthesia outside of the OR (e.g., cardiac catheterization or interventional radiology suites), and operational governance structures should make checklist compliance a requirement in any part of the hospital where procedural sedation or anesthesia is provided.

**Measuring and reporting surgical checklist compliance**

**Recommendation:** The process used for compliance documentation should have face validity, should be collected in real time (i.e., not subject to recall bias) and should not have unintended consequences (i.e., significantly disrupt workflow or be a source of distraction to the surgical team). Recording of compliance should be integrated in the operative record (electronically, where feasible), and should minimize extra work for nurses, who are already heavily burdened with documentation during and after surgery.

Ideally, the surgical checklist should be viewed as a safety conversation that occurs within an integrated, high-functioning team with surgical patient safety as a shared core value — not as a “tick box” exercise necessary to keep administrators happy. A critical determinant of success of the surgical checklist, or any other process improvement measure in the OR, is the response of the prevailing culture to its implementation.

Children’s hospitals should have flexibility in how they interpret and document checklist compliance, but must be committed to validity and transparency. Checklist compliance should be reported internally as a perioperative services quality indicator, and noncompliance should be discernable at several levels, including the surgical specialty, the individual surgeon (or anesthesiologist), and even the room and slate, to enable data “drill downs” when undertaking performance improvement activities.
CONCLUSION

Many children experience preventable adverse events in Canadian children’s hospitals, and the OR is a high-risk area for these events. A standardized, appropriately implemented surgical checklist that is sensitive to the unique needs of children and their families is an integral element within a comprehensive strategy targeting harm reduction in hospitalized children.

Acknowledgments: The planning and data provision for this study reflects the collective effort of the Pediatric Surgical Chiefs of Canada (PSCC). The PSCC extend their thanks to the Executive Board of the Canadian Pediatric Anesthesia Society (CPAS), who reviewed and endorsed these recommendations.

Affiliations: From the Pediatric Surgical Chiefs of Canada (PSCC).

Competing interests: None declared.

References

Making the transition from video-assisted thoracoscopic surgery to chest tube with fibrinolytics for empyema in children: Any change in outcomes?

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Background: There is ongoing variation in the use of video-assisted thoracoscopic surgery (VATS) and chest tube with fibrinolytics (CTWF) for empyema in children. Our objective was to report outcomes from a centre that recently made the transition from VATS to CTWF as the primary treatment modality.

Methods: We conducted a historical cohort study of children with empyema treated with either primary VATS (between 2005 and 2009) or CTWF (between 2009 and 2013).

Results: Sixty-seven children underwent pleural drainage for empyema during the study period: 28 (42%) were treated with primary VATS, and 39 (58%) underwent CTWF. There were no significant differences between the VATS and CTWF groups for length of stay (8 v. 9 d, p = 0.61) or need for additional procedures (4% v. 13%, p = 0.19). Length of stay varied widely for both VATS (4–53 d) and CTWF (5–46 d). Primary VATS failed in 1 (4%) patient, who required an additional chest tube, and CTWF failed in 5 (13%) patients. Additional procedures included 3 rescue VATS, 2 additional chest tubes and 1 thoracotomy. All patients recovered and were discharged home.

Conclusion: Primary VATS and CTWF were associated with similar outcomes in children with empyema. There appears to be a subset of children at risk for treatment failure with CTWF. Further research is needed to determine if these patients would benefit from primary VATS.

Contexte : Il existe une certaine variation dans le choix de l’intervention chirurgicale thoracoscopique assistée par vidéo (CTAV) ou de l’installation d’un drain thoracique accompagné de fibrinolytiques (DTIF) pour traiter la pleurésie purulente chez les enfants. L’objectif de cette étude était de décrire les résultats observés dans un centre ayant récemment remplacé la CTAV par le DTIF comme traitement de première intention.

Méthodes : Nous avons mené une étude de cohorte rétrospective auprès d’enfants atteints de pleurésie purulente, qui ont été traités soit par CTAV (entre 2005 et 2009), soit par l’installation d’un DTIF (entre 2009 et 2013).

Résultats : Pendant la période à l’étude, 67 enfants ont subi un drainage pleural. De ce nombre, 28 (42 %) ont été traités par CTAV, et 39 (58 %) par DTIF. Aucune différence significative n’a été observée entre ces 2 groupes sur le plan de la durée du séjour (8 [CTAV] contre 9 [DTIF], p = 0,61) et du recours à des interventions supplémentaires (4 % [CTAV] contre 13 % [DTIF], p = 0,19). La durée du séjour était toutefois très variable dans les 2 cas : entre 4 et 53 jours dans le groupe de la CTAV, et entre 5 et 46 jours dans celui du DTIF. La CTAV a échoué dans un cas (4 %), et un drain thoracique supplémentaire a dû être installé. La pose d’un DTIF s’est soldée par un échec dans 5 cas (13 %), qui ont nécessité 3 CTAV d’urgence, l’installation de 2 drains thoraciques additionnels et une thoracotomie. Tous les patients se sont rétablis et ont obtenu leur congé.

Conclusion : La CTAV et le DTIF employés comme traitements de première intention sont associés à des résultats semblables chez les enfants atteints de pleurésie purulente, mais l’installation d’un DTIF semble être plus susceptible d’échouer chez un sous-ensemble d’enfants. D’autres recherches seront nécessaires pour déterminer s’il serait préférable d’avoir recours à la CTAV comme traitement de première intention.
A recent survey of pediatric hospitals in the United States demonstrated that the incidence of empyema in children nearly doubled from 3.1 to 6.0 per 100,000 between 1997 and 2009. Changes during this time period also demonstrated increased use of pleural drainage procedures. Prior to the advent of minimally invasive surgery, pleural drainage could be accomplished only via thoracostomy, chest tube insertion, or thoracotomy. The emergence of video-assisted thoracoscopic surgery (VATS) in the 1990s provided clinicians with a new approach that permitted mechanical débridement and drainage of the pleural space without the need for a thoracotomy. With primary VATS, the majority of patients experience a complete resolution of symptoms, with decreased chest tube duration, duration of antibiotics, need for repeat procedures, length of stay in hospital and mortality.

Over the past decade, the popularity of primary VATS has been challenged by the increasing use of chest tube with fibrinolytics (CTWF). With this technique, children undergo chest tube insertion in the operating room (or in the interventional radiology suite) under general anesthesia (or conscious sedation). These patients then receive intrapleural fibrinolytics administered through the chest tube for 3 days to break down fibrin adhesions and facilitate pleural drainage. A systematic review from 2010 of 3 small, randomized controlled trials (RCTs) comparing VATS and CTWF revealed no significant differences in outcomes.

Both approaches were associated with similar length of stay in hospital and rates of treatment failure, defined as the need for additional chest tubes or surgery. Since then, a fourth single-centre RCT comparing VATS and CTWF was published. That study found that VATS was associated with earlier chest tube removal, shorter length of stay and faster resolution of symptoms. While hospital costs were higher with VATS in 3 of these 4 trials, an economic analysis demonstrated that primary VATS was more cost-effective when length of stay was longer than 10 days.

In 2012, the American Pediatric Surgical Association (APSA) Outcomes and Clinical Trials Committee performed an extensive review on the management of empyema in children. They concluded that the best available evidence suggests that VATS is neither superior nor inferior to CTWF and that both treatment modalities remain clinically equivalent. Since primary VATS appears to be more expensive, the committee recommended that CTWF be used as first-line therapy and that VATS should be reserved as a rescue treatment for the subset of patients in whom CTWF fails.

Recommendations from APSA were further strengthened by results from the first multicentre RCT published in 2014. This study once again demonstrated no statistically significant differences in clinical outcomes between children treated with primary VATS ($n = 50$) and those treated with primary CTWF ($n = 53$), including median length of stay (14 v. 13 d), median postoperative stay (10 v. 9 d), days of fever after treatment (4 v. 6 d), or need for a second drainage procedure (15% v. 10%, $p = 0.47$). There was a statistically significant difference in terms of chest tube duration ($p < 0.001$), but the magnitude was small (median 5 d for CTWF v. 4 d for VATS).

The best available evidence suggests that although primary VATS and CTWF are clinically equivalent, CTWF is less expensive, less invasive (since it involves 1 small incision for chest tube insertion rather than the 2 or 3 incisions required for primary VATS), and can often be performed with conscious sedation rather than a general anesthetic. Despite these advantages, many centres continue to use VATS as their primary treatment modality.

The purpose of this study was to determine if switching from VATS to CTWF within a single institution was associated with improved outcomes among children with empyema. While systematic reviews of RCTs represent the highest level of evidence, the trials reported to date for VATS and CTWF have not included all subgroups of patients, such as those with certain pre-existing comorbidities. Our centre switched from using primary VATS to CTWF in 2009. As such, we decided to review our experience and report the clinical outcomes associated with each treatment strategy.

**METHODS**

After obtaining ethics approval (REB#16987), we identified all pediatric patients (age < 18 yr) who presented to the Children’s Hospital at London Health Sciences Centre with a diagnosis of pleural empyema between November 2005 and April 2013. Our hospital is the sole pediatric referral centre for a catchment area of 1.7 million people, with approximately 10–20 cases of empyema per year. Participants in this study were sequentially identified using a prospective database as well as a retrospective review of diagnostic codes from our centre’s medical records. We excluded those who underwent chest tube insertion alone (and did not receive intrapleural fibrinolytics) or primary thoracotomy performed by a thoracic surgeon who primarily treated adults. All children in this study had stage II empyema, confirmed by the presence of septations and loculated fluid on ultrasound.

Baseline variables included demographic data, the type of initial treatment, oxygen requirements, admission to the intensive care unit upon presentation to our centre, initial ultrasound findings and presence of necrosis on any imaging before pleural drainage. Outcomes included timing of pleural drainage, length of stay in hospital, readmission to hospital and need for additional procedures. All VATS procedures were performed by a single pediatric surgeon (A.B.) and typically involved 2 incisions of 5 mm.
Patients treated with CTWF underwent chest tube insertion with conscious sedation or general anesthesia. This procedure was typically performed in the interventional radiology suite under ultrasound and fluoroscopic guidance. After insertion, pleural fluid was allowed to drain, and tissue plasminogen activator (tPA) was administered within 12 hours. Typically, 4 mg of tPA was dissolved in 40 mL of normal saline and inserted directly through the chest tube. After administration, the chest tube was clamped for 1 hour, and the patient was placed in 3 different positions for 20 minutes each (left lateral decubitus, right lateral decubitus, and supine). Patients received tPA once daily for 3 days, and chest tube drainage was monitored closely. The chest tube was left in place until completion of the 3-day course, pleural drainage was less than 50 mL in a 24-hour period and the patient was asymptomatic. A chest radiograph was obtained to confirm radiologic improvement before chest tube removal. Patients who had ongoing symptoms underwent placement of a second chest tube or rescue VATS (at the discretion of the treating surgeon).

Statistical analysis

We analyzed the data using the Statistical Package for the Social Sciences version 21. Descriptive statistics included median, range and frequency. Analytical statistics included t tests for independent means for continuous data and \( \chi^2 \) tests for categorical data. We used Yates correction when applying the \( \chi^2 \) test to all 2 \times 2 contingency tables with cells containing expected values of less than 5.

RESULTS

We identified 67 infants, children and adolescents who underwent pleural drainage between November 2005 and April 2013. Twenty-eight (42%) were treated with primary VATS between November 2005 and July 2009 by a single pediatric surgeon. Thirty-nine (58%) underwent CTWF between August 2009 and April 2013. We excluded children who were treated with chest tube insertion alone and did not receive intrapleural fibrinolitics \( (n = 9) \) or who underwent primary thoracotomy performed by a thoracic surgeon who primarily treated adults \( (n = 8) \).

Baseline demographic and clinical characteristics are summarized in Table 1. Mean age was similar between the groups: 5.2 years (range 2 mo to 16 yr) for VATS versus 6.1 years (range 6 mo to 17 yr) for CTWF \( (p = 0.39) \). The groups were also similar in terms of sex (46% v. 38% boys, \( p = 0.62 \)), need for supplemental oxygen (7% v. 15%, \( p = 0.52 \)), immediate admission to the intensive care unit (18% v. 28%, \( p = 0.49 \)), and ultrasound findings and presence of lung necrosis on initial imaging (21% v. 10%, \( p = 0.36 \)).

The timing of the procedure was slightly earlier for CTWF than primary VATS (median 1 d v. 2 d after admission), but this trend did not achieve statistical significance \( (p = 0.07) \). Similarly, more patients appeared to undergo drainage within 48 hours of admission with CTWF than VATS (79% v. 57%, \( p = 0.06 \)). There were no significant differences between VATS and CTWF for overall length of stay (median 8 d v. 9 d, \( p = 0.61 \)), length of stay postprocedure (6 d v. 8 d, \( p = 0.28 \)) and frequency of hospital stay longer than 10 days (29% v. 44%, \( p = 0.21 \)). Furthermore, overall length of stay varied widely for both VATS (4–53 d) and CTWF (5–46 d).

Outcomes associated with each treatment modality are summarized in Table 2. There were no significant differences between the 2 treatment modalities in terms of treatment failure, as defined by the need for additional procedures (4% v. 13%, \( p = 0.19 \)). There were also no conversions to thoracotomy with primary VATS, but 1 (4%) patient required an additional chest tube postoperatively. Primary CTWF failed in 5 (13%) patients: 2 (5%) required a second chest tube and 3 (8%) underwent rescue VATS. One of the patients who required a second chest tube eventually proceeded to thoracotomy and open decortication performed by a thoracic surgeon who primarily treated adults.

One child treated with primary VATS and 1 who underwent CTWF experienced symptomatic anemia and required transfusion of packed red blood cells. In both patients, there was no hemodynamic instability, and no additional procedures were required. All children in both treatment groups recovered and were discharged home. There was 1 readmission to hospital in each group.

DISCUSSION

The purpose of this study was to explore how changing from primary VATS to CTWF affects clinical outcomes among children with empyema treated at a single institution. Our centre experienced similar length of stay, rates of treatment failure and complications with each approach. Primary VATS and CTWF were used to treat children of all ages, ranging from infants to fully grown adolescents. Complications were rare for both strategies, with postprocedural bleeding requiring transfusion occurring in less than 5% of patients and not resulting in the need for additional interventions. Furthermore, while...
most children were discharged home within 10 days, both treatment modalities were associated with some children having a length of stay beyond 1 month.

None of the outcomes assessed demonstrated statistically significant differences between VATS and CTWF. There was a trend toward earlier pleural drainage with CTWF (by 1 d) and shorter length of stay postprocedure with VATS (by approximately 2 d). There are several possible reasons for this finding. First, competition for operating room time may have meant that pleural drainage was achieved slightly earlier with CTWF (which was performed in the interventional radiology suite) than with primary VATS. Second, clinicians and parents may have been more willing to proceed with early pleural drainage via CTWF because it is less invasive and may not require a general anesthetic. Finally, the 3-day course of intrapleural fibrinolytics after chest tube insertion may explain why length of stay postprocedure was slightly higher with CTWF. Despite these trends, the overall length of stay was not significantly different between the approaches. This finding is similar to that reported by the systematic review of 3 RCTs and the recent multicentre RCT.

**Limitations**

There are several limitations to this study. First, there were a small number of participants, and as such, most statistical comparisons were underpowered. Second, this study used historical rather than contemporary groups, and so the results may have been biased by factors other than the 2 treatment modalities. For example, there may have been baseline differences between the treatment groups that were not captured in the data reported here (e.g., increased duration of symptoms before presentation in 1 group compared with the other). There may also have been important changes over time in terms of disease itself (e.g., increased virulence of micro-organisms in the more recent cohort treated with CTWF) or clinical management (e.g.,

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**Table 1. Baseline characteristics of patients who underwent pleural drainage via video-assisted thoracoscopic surgery versus chest tube with fibrinolytics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>VATS, n = 28</th>
<th>CTWF, n = 39</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time period</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2005–2009</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009–2013</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, mean [range], yr</td>
<td>5.2 [2 mo–17 yr]</td>
<td>6.1 [6 mo–17 yr]</td>
<td>0.39</td>
</tr>
<tr>
<td>Male sex</td>
<td>13 (46)</td>
<td>15 (38)</td>
<td>0.62</td>
</tr>
<tr>
<td>Female sex</td>
<td>15 (54)</td>
<td>24 (62)</td>
<td></td>
</tr>
<tr>
<td>Supplemental oxygen on admission to hospital</td>
<td>2 (7)</td>
<td>6 (15)</td>
<td>0.52</td>
</tr>
<tr>
<td>Immediate admission to ICU</td>
<td>5 (18)</td>
<td>11 (28)</td>
<td>0.49</td>
</tr>
<tr>
<td>Ultrasound findings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simple septations</td>
<td>5 (18)</td>
<td>10 (26)</td>
<td>0.59</td>
</tr>
<tr>
<td>Complex septations</td>
<td>22 (79)</td>
<td>24 (74)</td>
<td></td>
</tr>
<tr>
<td>Pleural thickening</td>
<td>5 (18)</td>
<td>5 (13)</td>
<td></td>
</tr>
<tr>
<td>Ultrasound not performed</td>
<td>3 (11)</td>
<td>2 (5)</td>
<td></td>
</tr>
<tr>
<td>Necrosis on imaging</td>
<td>6 (21)</td>
<td>4 (10)</td>
<td>0.36</td>
</tr>
</tbody>
</table>

CTWF = chest tube with fibrinolytics; ICU = intensive care unit; VATS = video-assisted thoracoscopic surgery.

*Unless indicated otherwise.

**Table 2. Outcomes of patients who underwent pleural drainage via video-assisted thoracoscopic surgery versus chest tube with fibrinolytics**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>VATS, n = 28</th>
<th>CTWF, n = 39</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days to procedure, median [range]</td>
<td>2 [0–10]</td>
<td>1 [0–13]</td>
<td>0.07</td>
</tr>
<tr>
<td>Procedure within 48 h of admission</td>
<td>16 (57)</td>
<td>31 (79)</td>
<td>0.06</td>
</tr>
<tr>
<td>LOS postprocedure, median [range], d</td>
<td>6 [3–48]</td>
<td>8 [3–45]</td>
<td>0.28</td>
</tr>
<tr>
<td>LOS, median [range], d</td>
<td>8 [4–53]</td>
<td>9 [5–46]</td>
<td>0.61</td>
</tr>
<tr>
<td>Participants with LOS &gt; 10 d</td>
<td>8 (29)</td>
<td>17 (44)</td>
<td>0.21</td>
</tr>
<tr>
<td>Total additional procedures</td>
<td>1 (4)</td>
<td>5 (13)</td>
<td>0.19</td>
</tr>
<tr>
<td>Additional chest tube</td>
<td>1 (4)</td>
<td>2 (5)</td>
<td></td>
</tr>
<tr>
<td>Rescue thoracoscopic surgery</td>
<td>0 (0)</td>
<td>3 (8)</td>
<td></td>
</tr>
<tr>
<td>Rescue thoracotomy</td>
<td>0 (0)</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Transfusion for bleeding postprocedure</td>
<td>1 (4)</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Readmission to hospital</td>
<td>1 (4)</td>
<td>1 (3)</td>
<td></td>
</tr>
</tbody>
</table>

CTWF = chest tube with fibrinolytics; LOS = length of stay; VATS = video-assisted thoracoscopic surgery.

*Unless indicated otherwise.
increased recognition of the need for early pleural drainage in more recent years).

Finally, this study relied partly on retrospective data, and as such, we were unable to assess the experiences of patients and their families in a prospective fashion. Randomized controlled trials in this area have similar limitations, with the primary focus being on objective outcomes, such as length of stay, cost and need for additional procedures. Three of the single-centre trials reported the use of pain medication after each procedure, but none assessed patient-reported pain using validated questionnaires or other assessments. One of the trials noted decreased duration of narcotic use with VATS compared with CTWF (2.2 d v. 7.6 d, p = 0.043), but 2 others did not report any differences. Outcomes related to pain were not reported in the recent multicentre RCT.

CONCLUSION

Clinicians, parents, and hospital administrators should bear in mind that the only consistent benefits of CTWF over VATS are related to the procedure itself: CTWF costs less, results in fewer scars and may be performed under conscious sedation rather than general anesthesia. While these advantages are not insignificant, they do not appear to consistently translate into decreased use of pain medication or length of stay in hospital. Furthermore, there appears to be a subset of children with empyema who are at risk for treatment failure with CTWF. In the present study, the frequency of additional procedures following CTWF was 13% compared with 4% with VATS.

The current recommendation from the APSA Clinical Trials and Outcomes Committee is that all patients be offered a trial of CTWF followed by rescue VATS in cases of failure of nonoperative management. A superior approach might be to offer primary VATS to children who are identified as being at high risk for treatment failure with CTWF. Using primary VATS in a targeted fashion would necessitate the development of a prognostic score based on a large sample of children treated with CTWF. This strategy is currently being explored in adults through the development of the “RAPID” score. This tool identifies high-risk adult patients with empyema using the following baseline characteristics: renal impairment (R), age older than 70 years (A), purulent pleural fluid on thoracentesis (P), hospital-acquired infection (I) and poor diet as measured by low albumin (D).

We are in the process of developing a similar score for children by pooling data from 3 children’s hospitals from the past decade. In doing so, our hope is to identify baseline characteristics (including clinical, demographic, radiologic and laboratory variables) that predict treatment failure with CTWF. This may lead to the development of a combined treatment strategy where low-risk patients are given a trial of CTWF, whereas those identified as high-risk are treated with primary VATS.

Affiliations: From the Division of General Surgery, Western University (Livingston, Vogt, Merritt, Bütter); the Schulich School of Medicine & Dentistry, Western University (Colozza); and the Division of Pediatric Surgery, Western University (Merritt, Bütter), London, Ont.

Competing interests: None declared

Contributors: M. Livingston, K. Vogt, N. Merritt and A. Bütter designed the study. M. Livingston, S. Colozza, and K. Vogt acquired and analyzed the data. M. Livingston and A. Bütter wrote the article, which all authors reviewed and approved for publication.

References

The impact of adverse events on health care costs for older adults undergoing nonelective abdominal surgery

Background: Postoperative complications have been identified as an important and potentially preventable cause of increased hospital costs. While older adults are at increased risk of experiencing complications and other adverse events, very little research has specifically examined how these events impact inpatient costs. We sought to examine the association between postoperative complications, hospital mortality and loss of independence and direct inpatient health care costs in patients 70 years or older who underwent nonelective abdominal surgery.

Methods: We prospectively enrolled consecutive patients 70 years or older who underwent nonelective abdominal surgery between July 1, 2011, and Sept. 30, 2012. Detailed patient-level data were collected regarding demographics, diagnosis, treatment and outcomes. Patient-level resource tracking was used to calculate direct hospital costs (2012 $CDN). We examined the association between complications, hospital mortality and loss of independence cost using multiple linear regression.

Results: During the study period 212 patients underwent surgery. Overall, 51.9% of patients experienced a nonfatal complication (32.5% minor and 19.4% major), 6.6% died in hospital and 22.6% experienced a loss of independence. On multivariate analysis nonfatal complications \( p < 0.001 \), hospital mortality \( p = 0.021 \) and loss of independence at discharge \( p < 0.001 \) were independently associated with health care costs. These adverse events respectively accounted for 30%, 4% and 10% of the total costs of hospital care.

Conclusion: Adverse events were common after abdominal surgery in older adults and accounted for 44% of overall costs. This represents a substantial opportunity for better patient outcomes and cost savings with quality improvement strategies tailored to the needs of this high-risk surgical population.

Contexte : Les complications postopératoires sont une cause évitable qui contribue grandement aux coûts hospitaliers élevés. Malgré le fait que les personnes âgées courent un risque accru de subir des complications ou des événements indésirables, peu de recherches ont étudié l’incidence de ces éléments sur les coûts d’hospitalisation. Nous nous sommes penchés sur la relation entre les coûts des soins de santé assumés par les malades hospitalisés et les complications postopératoires, la mortalité hospitalière et la perte d’autonomie auprès d’une population de patients de 70 ans et plus ayant subi une intervention chirurgicale abdominale non facultative.

Méthodes : La cohorte prospective a été formée de patients consécutifs âgés de 70 ans et plus ayant subi une intervention chirurgicale abdominale non facultative entre le 1er juillet 2011 et le 30 septembre 2012. Des données détaillées concernant leur profil démographique, leur diagnostic, leur traitement et leurs résultats ont été recueillies. Le calcul des coûts hospitaliers directs est basé sur un suivi des ressources utilisées par les patients (en dollars canadiens, 2012). Au moyen d’une régression linéaire multiple, nous avons analysé la relation entre les complications, la mortalité hospitalière et la perte d’autonomie.

Résultats : Pendant la période à l’étude, 212 patients ont subi une intervention chirurgicale. Parmi eux, 51,9 % ont subi une complication non mortelle (mineure dans 32,5 % des cas; majeure dans 19,4 % des cas), 6,6 % sont décédés à l’hôpital, et 22,6 % ont subi une perte d’autonomie. Une analyse multivariable a permis de conclure que les complications non mortelles \( p < 0,001 \), la mortalité hospitalière \( p = 0,021 \) et la perte d’autonomie à la sortie de l’hôpital \( p < 0,001 \) étaient indépendamment associées aux coûts des soins de santé et qu’elles représentaient respectivement 30 %, 4 % et 10 % des coûts d’hospitalisation totaux.
The Canadian population is aging, and by 2050 the proportion of adults aged 65 and older is expected to double and the proportion aged 80 years and older is expected to triple. These demographic changes may place a considerable financial burden on the health care system as a substantial proportion of the health care budget is allocated to the care of older adults. In 2009, 44% of the total Canadian health care budget was spent on the care of people aged 65 years and older, although they accounted for only 14% of the population. With health care expenses increasing faster than the gross domestic product, effective strategies to control costs are needed.

Among surgical patients, postoperative complications have been identified as an important and potentially preventable cause of increased health care costs. However, very little research has specifically studied this association in older patients. Compared with younger individuals, postoperative adverse events are more common in older adults after abdominal surgery, and some patients are at exceptionally high risk for complications. For example, emergency abdominal surgery in older adults is associated with mortality exceeding that for cardiac procedures and complication rates as high as 50%. This has broad implications given that emergency abdominal surgery is routinely performed in most acute care hospitals and the need for these services is expected to increase with the aging of the general population.

The increased frequency of complications among older surgical patients is likely an important component of health care costs; however, the magnitude of this association is not well established. Furthermore, other postoperative adverse events, such as perioperative mortality and loss of independence, may also impact the cost of care. A clear understanding of the various factors that contribute to the increased costs among older surgical patients is needed to guide cost containment strategies and resource allocation. The primary purpose of this study was to examine the association between adverse events (postoperative complications, hospital mortality and loss of independence) and direct inpatient health care costs in patients older than 70 years who underwent nonelective abdominal surgery in a tertiary care teaching hospital.

**METHODS**

We prospectively enrolled all patients aged 70 years and older who were admitted to an acute care surgery service at a tertiary care teaching centre and underwent non-elective abdominal surgery between July 1, 2011, and Sept. 30, 2012. We chose this age group because acuity, complications and cost increase dramatically in patients older than 70 years. Only patients with intra-abdominal or abdominal wall conditions were included. Patients were excluded if they were admitted for treatment of a complication resulting from a prior elective procedure, or if they were transferred from an outpatient hospital, owing to the inability to track resource utilization.

The episode of care used for analysis in this study was from the time of admission to the acute care surgical service until discharge from hospital or 90 days following admission, whichever occurred first. Patients were enrolled within 48 hours of the index admission. At the time of enrolment, one of us (J.G.B. or P.J.B.D.) interviewed and examined each patient, and a comprehensive geriatric assessment (CGA) was completed. The CGA is a validated multidisciplinary diagnostic tool that expands on the standard medical history and physical examination, including aspects of health important for older adults. It includes an assessment of mobility, activities of daily living, residential status, cognition, mood, self-rated health, strength, sleep and social supports. The CGA includes a review of systems, a review of medications and medical history. The information from the CGA can be used to calculate a frailty index (FI-CGA). The FI-CGA is calculated by dividing the number of health deficits a patient has accumulated by all measured deficits. Therefore, possible scores range from 0.00 to 1.00 on a continuous scale. For example, mean index scores of 0.22, 0.36 and 0.43 indicate apparent vulnerability, moderate frailty and severe frailty, respectively.

We performed a standardized, comprehensive review of the patients’ medical records to collect data regarding the following variables: American Society of Anesthesiologists (ASA) classification, operative severity (OS), postoperative complications and resource utilization. The ASA classification was taken from the anesthesiologist’s preoperative assessment. We categorized OS on a 3-level ordinal scale: 1) laparoscopic surgery for benign disease, 2) open surgery for benign disease and 3) open or laparoscopic surgery for malignant disease.

Hospital complications were categorized by severity using the Clavien–Dindo (CD) classification: nonfatal complications were defined as minor (CD level I and II) and major (CD level III and IV), and fatal complications were categorized as CD level V. Consensus was reached among the investigators when there were discrepancies in grading complications. If a patient experienced more than 1 complication, the most severe was used for analysis. Only deaths that occurred during admission to hospital were included in this analysis, defined here as hospital mortality.
We divided preadmission residential status into 5 categories: living alone, living with others, semi-independent housing, nursing home and inpatient longer than 2 weeks. Residential status at discharge was divided into 6 categories: living alone, living with others, semi-independent housing, nursing home, restorative care (inpatient physiotherapy/occupational therapy) and continued hospitalization. Loss of independence was defined as inability to return to the preadmission residential status.

**Cost calculation**

Direct costs were calculated from the perspective of the hospital (payer). We estimated costs by tracking resource utilization and multiplying by the cost of each resource. For patients who remained in hospital for more than 90 days, the costs incurred after 90 days were truncated. Since health care costs are typically high right-skewed, we truncated costs to limit the influence of outliers and avoid severely skewed data. To limit measurement bias, we used only the costs from the index hospitalization; the costs of readmission at outlying hospitals were excluded owing to the potential bias and complexity of estimating costs incurred in other institutions. All costs were calculated in 2012 Canadian dollars.

The majority of unit cost estimates were based on an exact count. When this was not feasible, cost estimates were based on time intervals. We counted the exact number of resources used in each of the following categories: diagnostic imaging, laboratory investigations, nonoperative interventional procedures, blood products, consultations, physician fees, antibiotics, anticoagulants and operative disposables. These counts were double-checked for errors in extraction or transcription.

Cost estimates for hospital beds and the operating room were assigned based on units of time rather than the number of resources used. Bed costs for ward, intermediate and intensive care were assigned on a daily basis. Bed costs included direct supplies and staff compensation. Operating room facility costs were assigned using a base rate (for preoperative nursing, the patient attendant, the anesthesia technician, anesthesia supplies and postanesthetic care unit nursing) and an hourly rate (for intraoperative nursing). Medication costs for analgesics and antiemetics outside of the operating room as well as intensive care infusions were assigned on a daily basis. We calculated daily averages for these medications by performing an exact count of medication dosages for the first 25 patients and applying these to subsequent patients. The subset of patients that we used to calculate the costs of medications did not differ significantly from the study population in terms of age, sex, body mass index, ASA classification, frailty index, Charlson comorbidity score, OS or length of stay in hospital. Sources for unit cost estimates are listed in Appendix 1, available at canjsurg.ca.

The cost of unnecessary patient days was also estimated. The number of unnecessary days in hospital was defined as the difference between the actual discharge date and the date when health care providers documented in the chart that the patient was medically ready to leave hospital. Unnecessary days in the intermediate care unit (IMCU) or intensive care unit (ICU) were defined as the difference between the date that the patient was declassified and the date that they actually left the IMCU or ICU. We estimated the excess cost of unnecessary days on the ward by multiplying the number of patient days by the ward bed costs. We estimated the excess cost for unnecessary IMCU and ICU patient days using the difference between IMCU or ICU bed costs and costs at the next lower level of care.

**Statistical analysis**

Univariate differences in cost were compared using nonparametric tests (Wilcoxon rank-sum test or Kruskal-Wallis test). To assess the multivariate association between cost and postoperative complications, loss of independence and hospital mortality, we performed a multiple linear regression, controlling for age, ASA, OS and FI-CGA. These factors have been associated with health care costs in previous research. Even after truncating the data, the data continued to be right-skewed. The cost data were logarithmically transformed to adjust for the skewness. Log-transforming the data improved the fit diagnostics of the models, demonstrated by more homogeneous, random residuals plots. Additionally, the $R^2$ value of the cost model increased from 0.3554 to 0.5735 with log-transformation of cost data, indicating better fit to the regression line. We calculated adjusted median costs by exponentiating the least squares means of the log-transformed total costs using general linear models.

The increase in cost associated with each level of an ordinal factor was calculated by exponentiating the $\beta$ coefficient (e.g., x unit increase in complication severity results in exp [coefficient] increase in cost). We calculated the costs attributable to adverse events (most severe postoperative complication, hospital mortality and loss of independence) using a regression-based approach.

**RESULTS**

During the 15-month study period 212 patients underwent nonelective abdominal surgery and formed the study cohort (Fig. 1). Patient characteristics are summarized in Table 1. The median length of stay was 8.0 (interquartile range [IQR] 4.0–16.5) days. The length of stay was truncated for 7 (3.3%) patients in the study. Eighty-eight percent of patient-days in hospital were spent in a ward bed, 7% were in the IMCU and 5% were in the ICU. Overall, 110 (51.9%) patients experienced at least 1 nonfatal complication. Of these, 69 (32.5%) experienced a minor complication and...
41 (19.4%) a major complication. The 3 most common complications are listed by grade for all patients in Table 2. See Appendix 1 for a complete list of complications, using the most severe complication experienced by each patient. Hospital mortality was 6.6%. Of the 14 patients who died, 12 died from complications directly related to their surgeries. The remaining 2 patients died from a combination of pre-existing comorbidities and progression of the presenting disease. Major complications were more common among the patients who died in hospital than among patients who survived (43% v. 18%, p = 0.033). Patients who died in hospital were more likely than those who survived to require admission to the ICU (93% v. 17%, p < 0.001), where they spent a median of 2.0 (range 0–16) days.

Table 3 shows preadmission and discharge residential status for the study cohort. Overall, 22.6% of patients experienced a loss of independence. Patients who had a loss of independence at discharge spent a longer time in hospital (median stay 19.0 d v. 6.5 d, p < 0.001) and had a higher number of unnecessary days in hospital (median 1.5 d v. 0.0 d, p < 0.001) than patients who returned to their preadmission residential status.

The median total direct hospital costs were $9166 per patient (range $1993–$104 403). Hospital costs for the entire cohort of 212 patients totaled $3 378 132 (for a breakdown of mean, median and total direct hospital costs by category, see Appendix 1). The severity of complications was associated with increased health care costs (Table 4). The median cost of care was also significantly greater for patients who died in hospital and for those who experienced a loss of independence (Table 4). Forty-seven (22.2%) patients stayed in hospital at least 1 day that was medically unnecessary. The total number of medically unnecessary days for all patients in ward, IMCU and ICU beds were 386 (12%), 12 (< 1%) and 8 (< 1%), respectively. Unnecessary days in ward, IMCU and ICU beds accounted for estimated costs of $170 226 (5.0%), $3708 (0.1%) and $10 800 (0.3%), respectively.

On multivariate analysis, age was not independently associated with costs (p = 0.28), whereas ASA score (p = 0.001), OS (p < 0.001), frailty index (p < 0.001), complication severity (p < 0.001), loss of independence (p < 0.001) and hospital mortality (p = 0.021) were significantly associated with health care resource utilization. The costs attributable to experiencing a complication, hospital mortality or loss of independence are listed in Table 5. Each increasing level of the Clavien–Dindo classification of complications was associated with a 28% increase in total health care costs. Hospital mortality was associated with a 50% increase in costs, and a loss of independence was associated with a 46% increase.

**DISCUSSION**

In the present study, postoperative complications, hospital mortality and loss of independence collectively accounted for 44% of direct inpatient health care costs among older adults who underwent nonelective abdominal surgery.

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**Fig. 1.** Recruitment and selection of elderly patients (age ≥ 70 yr) admitted to the acute care surgery service between July 1, 2011 and Sept. 30, 2012.
While the finding that postoperative complications are associated with increased costs is not new, this study was unique in that it focused specifically on high-risk older adults and used detailed patient-level data. This allowed us to control for relevant patient factors and to accurately categorize complications.\(^2\) Furthermore, costs were calculated by counting resources, which is the most accurate method, but is uncommonly performed. Patient age was not associated with costs, suggesting that other factors, such as comorbidities and performance status (included in the frailty index and ASA class), might play a more important role in predicting resource utilization in older surgical patients. Increasing frailty was associated with costs, and this is consistent with the findings of previous studies that have reported an association between frailty and various outcomes in older surgical patients.\(^2\)\(^,\)\(^2\)\(^7\)

Nonfatal complications occurred in more than 50% of patients and accounted for 30% of the overall costs. Recognition of the high costs and poor outcomes associated with complications has led to quality improvement initiatives, such as the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP). While some studies have reported a decrease in morbidity and mortality associated with NSQIP participation,\(^2\)\(^8\)\(^,\)\(^2\)\(^9\) others have failed to demonstrate any improvements.\(^3\)\(^0\)\(^,\)\(^3\)\(^1\) Osborne and colleagues\(^3\)\(^0\) specifically compared outcomes between older adult surgical patients who were treated at NSQIP hospitals and those who were not, and reported that there was no difference in morbidity, mortality or costs.

While quality reporting systems like NSQIP are important, quality improvement requires specific interventions. Additionally, quality improvement is unlikely to be successful with a one size fits all approach. Research has suggested that older patients are more likely to experience cardiac, pulmonary and urologic complications, falls and adverse drug events than younger patients.\(^7\)\(^,\)\(^9\)\(^,\)\(^2\)\(^4\)\(^,\)\(^3\)\(^2\)\(^–\)\(^3\)\(^4\) Accordingly, interventions to improve outcomes and reduce costs need to be tailored to the population at risk. For example, several surgical and anesthetic strategies have been described to reduce pulmonary complications in older adults;\(^3\)\(^5\)\(^,\)\(^3\)\(^6\) these were the most common life-threatening complications (grade IV) in the present study and were associated with a 274% increase in costs. Other complications that were common in the patient population that could also be modified were delirium and urinary tract infections. These also represent potential areas for cost reduction. Whether or not these interventions or other quality improvement initiatives will be both successful and cost-effective will require careful evaluation.

Postoperative mortality is an inherent risk associated with emergency surgical care of older adults. Previous research has reported that acute care hospital admissions at the end of life contribute to increased costs of death.\(^3\)\(^7\) However, very little research has specifically examined the impact of death

### Table 1. Characteristics of 212 patients aged 70 years and older who underwent nonelective abdominal surgery

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (range), yr</td>
<td>78 (70–97)</td>
</tr>
<tr>
<td>Female sex</td>
<td>112 (52.8)</td>
</tr>
<tr>
<td>Frailty index at admission, median (range)</td>
<td>0.3 (0.16–0.51)</td>
</tr>
<tr>
<td>ASA classification</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>5 (2.4)</td>
</tr>
<tr>
<td>II</td>
<td>82 (38.7)</td>
</tr>
<tr>
<td>III</td>
<td>99 (46.7)</td>
</tr>
<tr>
<td>IV</td>
<td>22 (10.4)</td>
</tr>
<tr>
<td>V</td>
<td>4 (1.9)</td>
</tr>
<tr>
<td>Operative severity</td>
<td></td>
</tr>
<tr>
<td>Grade 1</td>
<td>77 (36.3)</td>
</tr>
<tr>
<td>Grade 2</td>
<td>108 (50.9)</td>
</tr>
<tr>
<td>Grade 3</td>
<td>27 (12.7)</td>
</tr>
<tr>
<td>Common diagnoses</td>
<td></td>
</tr>
<tr>
<td>Biliary tract disease</td>
<td>62 (29.2)</td>
</tr>
<tr>
<td>Small bowel obstruction</td>
<td>59 (27.8)</td>
</tr>
<tr>
<td>Large bowel obstruction (malignant)</td>
<td>18 (8.5)</td>
</tr>
<tr>
<td>Incarcerated hernia without obstruction</td>
<td>18 (8.5)</td>
</tr>
<tr>
<td>Colitis (including diverticulitis)</td>
<td>15 (7.1)</td>
</tr>
<tr>
<td>Appendicitis</td>
<td>7 (3.3)</td>
</tr>
<tr>
<td>Common procedures</td>
<td></td>
</tr>
<tr>
<td>Cholecystectomy</td>
<td>59 (27.8)</td>
</tr>
<tr>
<td>Segmental colon resection</td>
<td>39 (18.4)</td>
</tr>
<tr>
<td>Hernia without bowel resection</td>
<td>27 (12.7)</td>
</tr>
<tr>
<td>Lysis of adhesions</td>
<td>22 (10.4)</td>
</tr>
<tr>
<td>Small bowel resection</td>
<td>11 (5.2)</td>
</tr>
<tr>
<td>Hernia repair with bowel resection</td>
<td>9 (4.2)</td>
</tr>
<tr>
<td>Appendectomy</td>
<td>7 (3.3)</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists.

*Unless indicated otherwise.

### Table 2. Three most common hospital complications among patients aged 70 years and older who underwent nonelective abdominal surgery

<table>
<thead>
<tr>
<th>Clavien–Dindo classification; description</th>
<th>Complication*</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any deviation from the normal postoperative course, without specific intervention</td>
<td>Delirium</td>
<td>12 (35)</td>
</tr>
<tr>
<td></td>
<td>Wound infection</td>
<td>6 (18)</td>
</tr>
<tr>
<td></td>
<td>Ileus</td>
<td>4 (12)</td>
</tr>
<tr>
<td>Grade II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requiring specific pharmacological intervention</td>
<td>Urinary tract infection</td>
<td>10 (29)</td>
</tr>
<tr>
<td></td>
<td>Atrial fibrillation</td>
<td>8 (24)</td>
</tr>
<tr>
<td></td>
<td>Pneumonia</td>
<td>6 (18)</td>
</tr>
<tr>
<td>Grade III</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requiring surgical, endoscopic or radiological intervention</td>
<td>Dehiscence</td>
<td>2 (17)</td>
</tr>
<tr>
<td></td>
<td>Postoperative bleeding</td>
<td>2 (17)</td>
</tr>
<tr>
<td></td>
<td>Urinary tract infection</td>
<td>2 (17)</td>
</tr>
<tr>
<td>Grade IV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life-threatening complication involving organ dysfunction</td>
<td>Respiratory failure</td>
<td>16 (64)</td>
</tr>
<tr>
<td></td>
<td>Acute renal failure</td>
<td>2 (8)</td>
</tr>
<tr>
<td></td>
<td>Pneumonia</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Grade V</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complication resulting in death</td>
<td>Intra-abdominal sepsis</td>
<td>4 (33)</td>
</tr>
<tr>
<td></td>
<td>Pneumonia</td>
<td>2 (17)</td>
</tr>
<tr>
<td></td>
<td>Ischemic bowel</td>
<td>2 (17)</td>
</tr>
</tbody>
</table>

*Includes only the most severe complication experienced by each patient.
on inpatient costs, which accounted for 4% of overall costs in the present study. Ideally, aggressive and expensive interventions, like surgery, should be avoided when they are likely to be futile. The ability of health care providers to predict death before surgery is inadequate.38,39 Decisions to withhold care at the time of presentation may be appropriate for only a small proportion of older adults with advanced frailty or severe comorbidities. Research is needed to develop strategies, such as time-limited trials of care,40 to minimize the occurrence of high-cost inpatient deaths. These will help patients, families and physicians make sound decisions regarding appropriateness of care and resource utilization.

Hospitalization and treatment of older adults can result in a functional decline and loss of independence. This has important implications not only for patients, but also for their families and the health care system in general.41 While nursing home care has been associated with increased costs compared with home- or community-based care, the influence of a loss of independence on inpatient health care costs has not been described.42,43 A change in residential status at discharge in the present study was associated with significantly more medically unnecessary days in hospital and increased costs. This suggests that time spent in hospital waiting for appropriate institutional or community-based discharge care contributed, at least in part, to these costs. This emphasizes the need for adequate rehabilitation and nursing home resources to meet the future demand for such facilities. A chronic shortage of nursing home beds has been a problem in both Canada and the United Kingdom.44,45 Changing demographics may place increasing pressure on beds in acute care facilities.

**Limitations**

Several limitations associated with this study should be considered. While the sample size was small in contrast to other investigations of a similar nature, it allowed for collection of detailed information regarding the patients, complications and resource utilization. In addition, we excluded patients transferred from outlying hospitals (5.2%) owing to inability to access cost data. Patients are typically transferred from other hospitals if they require a subspecialty surgeon or if they require intensive care that is not available at the referring hospital. Since these situations represent

<p>| Table 3. Preadmission and discharge residential status for patients aged 70 years and older who underwent nonelective abdominal surgery |</p>
<table>
<thead>
<tr>
<th>Preadmission residential status</th>
<th>Nursing home</th>
<th>Restorative care</th>
<th>Continued hospitalization</th>
<th>Deceased</th>
<th>Total no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living alone</td>
<td>31 (53)</td>
<td>12 (20)*</td>
<td>2 (3)*</td>
<td>5 (8)*</td>
<td>5 (8)*</td>
</tr>
<tr>
<td>Living with others</td>
<td>3 (2)</td>
<td>103 (76)</td>
<td>—</td>
<td>14 (10)*</td>
<td>4 (3)*</td>
</tr>
<tr>
<td>Semi-independent housing</td>
<td>—</td>
<td>—</td>
<td>6 (60)</td>
<td>2 (20)*</td>
<td>1 (10)*</td>
</tr>
<tr>
<td>Nursing home</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1 (14)*</td>
<td>—</td>
</tr>
<tr>
<td>Inpatient &gt; 2 wk</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1 (103)</td>
<td>—</td>
</tr>
</tbody>
</table>

*Change in residential status where available care was increased, representing a loss of independence.

<p>| Table 4. Univariate comparison of costs (2012 CDN) between patients aged 70 years and older who did and did not experience an adverse event after undergoing nonelective abdominal surgery |</p>
<table>
<thead>
<tr>
<th>Adverse event*</th>
<th>No. (%)</th>
<th>Hospital costs, median (IQR) [range], CDN</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>No 198 (93)</td>
<td>7926 (5043–17 880) [1993–104 003]</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Clavien–Dindo complication</td>
<td>None 102 (48)</td>
<td>6030 (4010–9570) [1993–37 036]</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Grade I 34 (16)</td>
<td>9459 (6554–16 126) [2975–47 427]</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Grade II 35 (17)</td>
<td>17 366 (16 605–23 456) [3513–78 080]</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Grade III 12 (6)</td>
<td>16 151 (11 028–19 566) [5973–64 253]</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Grade IV 29 (14)</td>
<td>30 660 (16 810–66 427) [9497–104 043]</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Loss of independence</td>
<td>No 164 (77)</td>
<td>7248 (4851–15 611) [1993–97 568]</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Yes 48 (23)</td>
<td>19 872 (9674–32 452) [3753–104 043]</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

IQR = Interquartile range.  
*The most severe complication experienced by each patient was used in this analysis.  
†Wilcoxon rank-sum test.  
‡Kruskal–Wallis test.
more severe cases, the study population was likely typical of patients who would be seen for emergency abdominal surgery in most acute care hospitals. Readmission to hospital has been associated with increased health care costs but was not included in this study to avoid a measurement bias associated with inability to track costs at outside institutions. Overall, only 3.8% of patients were readmitted within 6 months for reasons related to their initial hospital stays. Finally, our results may not be applicable to care settings outside of Canada given the differences in practice patterns and costs. Although health care costs in the United States are higher than those in other countries, research suggests that proportionate cost associations appear to be similar across different health care systems.

**CONCLUSION**

Adverse events were common among older patients who underwent nonelective abdominal surgery and accounted for 44% of inpatient health care costs. This represents a substantial opportunity for better patient outcomes and cost savings. Given the substantial costs attributable to adverse events, savings may be possible with effective quality improvement programs even if large implementation costs are required. Developing such programs tailored to the needs of high-risk surgical populations should be a priority for clinicians and policy-makers.

**Affiliations:** From the Division of General Surgery, Dalhousie University, Halifax, NS (Bailey, Davis, Molinari, Johnson); and the Department of Community Health and Epidemiology, Dalhousie University, Halifax, NS (Bailey, Davis, Molinari, Johnson); and the Department of Surgery, Dalhousie University, Halifax, NS (Levy, Molinari, Johnson).

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**Competing interests:** None declared.

**Contributors:** All authors designed the study. J. Bailey and P. Davis acquired the data, which J. Bailey, A. Levy, M. Molinari and P. Johnson analyzed. J. Bailey and P. Johnson wrote the article, which all authors reviewed and approved for publication.

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**Table 5. Adjusted and attributable costs (2012 CDN) associated with hospital mortality, complication severity and loss of independence among patients aged 70 years and older who underwent nonelective abdominal surgery**

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>No. (%)</th>
<th>Adjusted costs, median (IQR)*</th>
<th>Attributable costs, median (IQR)†</th>
<th>p value‡</th>
<th>Total attributable costs for all patients (%)†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospital death</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>198 (93)</td>
<td>9924 (9179–10 730)</td>
<td>—</td>
<td>0.021</td>
<td>135 043 (4)</td>
</tr>
<tr>
<td>Yes</td>
<td>14 (7)</td>
<td>14 866 (10 713–20 629)</td>
<td>7535 (5156–14 003)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Complication severity§</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>102 (48)</td>
<td>7745 (6893–8702)</td>
<td>—</td>
<td>&lt; 0.001</td>
<td>1 016 668 (30)</td>
</tr>
<tr>
<td>Grade I</td>
<td>34 (16)</td>
<td>8858 (7283–10 772)</td>
<td>2364 (1959–3521)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade II</td>
<td>35 (17)</td>
<td>12 838 (10 625–15 512)</td>
<td>5800 (3911–7390)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade III</td>
<td>12 (6)</td>
<td>13 851 (10 079–19 034)</td>
<td>8692 (6268–12 294)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade IV</td>
<td>29 (14)</td>
<td>21 230 (17 115–26 334)</td>
<td>19 092 (14 302–23 641)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Loss of independence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>164 (77)</td>
<td>9353 (8572–10 205)</td>
<td>—</td>
<td>&lt; 0.001</td>
<td>343 155 (10)</td>
</tr>
<tr>
<td>Yes</td>
<td>48 (23)</td>
<td>13 691 (11 534–16 251)</td>
<td>6090 (3809–9284)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; IQR = interquartile range; OS = operative severity.

*Adjusted for age, ASA classification, frailty index based on a comprehensive geriatric assessment and OS.

†Estimated based on predicted values using multiple linear regression (log costs = age + ASA classification + frailty index based on a comprehensive geriatric assessment + OS + Clavien-Dindo classification + change in residential status + in-hospital mortality).

§Multiple linear regression adjusting for age, ASA classification, frailty index based on a comprehensive geriatric assessment, OS, Clavien-Dindo classification, loss of independence, and in-hospital mortality.

The most severe complication experienced by each patient was used in this analysis.

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Creation of the sole regional laser lead extraction program serving Atlantic Canada: initial experience

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DOI: 10.1503/cjs.011115

Background: An increasing need for laser lead extraction has grown in parallel with the increase of implantation of pacing and defibrillating devices. We reviewed the initial experience of a regional laser-assisted lead extraction program serving Atlantic Canada.

Methods: We retrospectively reviewed the cases of all consecutive patients who underwent laser lead extraction at the Maritime Heart Centre in Halifax, NS, between 2006 and 2015. We conducted univariate and Kaplan–Meier survivorship analyses.

Results: During the 9-year study period, 108 consecutive patients underwent laser lead extractions (218 leads extracted). The most common indication for extraction was infection (84.3%). Most patients were older than 60 years (73.1%) and had leads chronically implanted; the explanted leads were an average of 7.5 ± 6.8 years old. Procedural and clinical success (resolution of preoperative symptoms) rates and mortality were 96.8%, 97.2%, and 0.9%, respectively. Sternotomy procedures were performed in 3 instances: once for vascular repair due to perforation and twice to ensure that all infected lead material was removed. No minor complications required surgical intervention. Survival after discharge was 98.4% at 30 days and 94% at 12 months.

Conclusion: Atlantic Canada’s sole surgical extraction centre achieved high extraction success with a low complication rate. Lead extraction in an operative setting provides for immediate surgical intervention and is essential for the survival of patients with complicated cases. Surgeons must weigh the risks versus benefits in patients older than 60 years who have chronically implanted leads (> 1 yr) and infection.

Contexte : La demande en matière d’extraction de sondes par laser a augmenté parallèlement à l’installation de stimulateurs et de défibrillateurs cardiaques. Nous nous sommes penchés sur les débuts d’un programme d’extraction de sondes par laser dans les provinces de l’Atlantique.

Méthodes : Nous avons étudié rétrospectivement les dossiers de tous les patients consécutifs ayant subi une extraction de sondes par laser au Maritime Heart Centre à Halifax (N.-É), entre 2006 et 2015. Nous avons mené une analyse unidimensionnelle et une analyse de survie selon la méthode de Kaplan–Meier.

Résultats : Pendant les 9 années à l’étude, 108 patients consécutifs ont subi une extraction de sondes par laser (218 sondes retirées). La cause d’extraction la plus fréquente était l’infection (84,3 %). La plupart des patients étaient âgés de plus de 60 ans (73,1 %), et leurs sondes avaient été installées de façon permanente. Les sondes extraites avaient été installées en moyenne 7,5 ± 6,8 ans plus tôt. Le taux de réussite de l’intervention, le taux de réussite clinique (soulagement des symptômes préopératoires) et le taux de mortalité se chiffraient respectivement à 96,8 %, à 97,2 % et à 0,9 %. Trois sternotomies ont dû être effectuées, dans 1 cas pour réparer les parois vasculaires à la suite d’une perforation, et dans les 2 autres cas pour s’assurer du retrait de tous les éléments infectés de la sonde. Aucune complication mineure n’a nécessité d’intervention chirurgicale. Le taux de survie après 30 jours et 12 mois suivant le congé des patients étaient de 98,4 % et de 94 %, respectivement.

Conclusion : Le seul centre d’extraction de sondes dans les provinces de l’Atlantique obtient un taux élevé de réussite et un faible taux de complications. L’extraction de sondes en milieu opératoire permet de pratiquer immédiatement des interventions chirurgicales et est essentielle à la survie des patients dont les cas sont complexes. Les chirurgiens doivent évaluer les risques et les avantages pour les patients de plus de 60 ans qui montrent des signes d’infection et chez qui les sondes ont été installées depuis un certain temps (> 1 an).
The rate of internal cardiac pacemaker implantation has accelerated in recent years with more than 200,000 patients living with pacemakers in Canada (2012). The complexity of the implanted hardware has also increased; single-chamber pacemakers are being replaced by multichamber, rate-responsive pacemakers, which are capable of both pacing and cardioversion as well as cardiac resynchronization therapy. Similarly, the number of implantable cardioverter defibrillator (ICD) implantations has increased in parallel with pacemaker implantations in recent years (increase of 160% for ICDs v. 31% for pacemakers, 1993–2009) as a result of increased understanding of cardiac arrhythmia in the population.

The increasing number of implantations has also resulted in a huge growth in the number of indications for explanting pacemaker and ICD devices. The most common indication for device and/or lead extraction remains device-related infection (≥60%), with the most commonly associated pathogen belonging to the Staphylococcus genus of bacteria. Other common indications for extraction are lead or device malfunction, device upgrade, pain and/or discomfort associated with the cardiac implanted electronic device (CIED) as well as congestion (i.e., a large number of electrodes in the heart and surrounding vasculature, which hamper both the insertion and removal of leads).

Lead and device extraction has been associated with potentially serious major and minor complications. Major complications include death and cardiac or vascular perforation resulting in a sternotomy. Minor complications include, but are not limited to, pericardial effusion, hemothorax, hematoma, thrombosis, lead migration, pneumothorax and pulmonary embolism, with some requiring surgical intervention.

Given the above risks, CIED lead extraction procedures are routinely conducted in specialized cardiac centres, specifically in either an operating room (OR) by an experienced surgeon or in an electrophysiology (EP) laboratory with a team of cardiologists along with support staff as well as a cardiac surgical unit in case of serious complications. Traditional traction-only extractions are effective for cases of acutely implanted leads (<1 yr); however, such extractions have exhibited limited effectiveness for chronically implanted leads (>1 yr). Laser-power sheaths with a locking style are increasingly implemented to facilitate highly effective procedures with low complication rates (complete success: 94% with laser-assisted extraction v. 64% with simple traction).

The present study examined the initial experience of all consecutive patients undergoing lead extraction using a laser-powered system within a regional program serving Atlantic Canada. We provide a comprehensive analysis of the outcomes and benefits associated with performing the laser lead extraction procedure at the sole referral centre serving Canada’s 4 Atlantic provinces, New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland and Labrador.

**METHODS**

**Patient population**

The patient population analyzed consisted of all consecutive patients who underwent pacemaker or ICD laser lead extraction procedures at the Halifax Infirmary between Sept. 1, 2006, and May 31, 2015. This included only extraction in which a laser-powered system was needed. As such, all extraction procedures using manual only traction and those that did not use any powered extraction sheath(s) were excluded from the study. All patients were identified using a mandatory record of use of the laser system. The study was approved by the institution research ethics review board and followed all usual standard guidelines.

**Lead extraction procedure**

All extraction procedures at the Halifax Infirmary were conducted in a cardiac surgery operating room with the primary operator being a cardiac surgeon specializing in arrhythmia and CIED surgery. All interventions were conducted using general anesthesia with central venous access, continuous transesophageal echocardiography and continuous blood pressure monitoring. All surgeons gained expertise in this operation by visiting 2 high-volume centres, the Montreal Heart Institute and the Cleveland Clinic, as both perform this procedure frequently. The Spectronetics Company provided clinical support during the initial cases to allow experience to be gained. The electrophysiologists do not have an active role in the extraction program, but provide invaluable expertise in device system management and work collaboratively with many of these patients.

Lead extractions at the Halifax Infirmary were conducted using a stepwise approach, where extraction via simple traction was initially attempted. If simple traction was not sufficient, a locking stylet (LLD Spectronetics) was then used for assistance. This was followed by the use of an appropriately sized laser manual dissection sheath (Spectronetics) under fluoroscopic guidance. All extraction procedures aimed for the complete removal of all targeted leads. If a fragment of lead remained mobile, an additional approach, such as a snare catheter, was used.

In patients who were pacemaker-dependent, a temporary pacemaker was positioned from the right internal jugular vein, or a single lead active fixation permanent pacemaker was placed on the opposite side; the choice was left to surgeon preference.

**Definitions**

Clinical and procedural criteria were defined according to the LExICon lead extraction study. Procedural success was divided into 2 subcategories: complete and partial. Complete success was defined as the total removal of all...

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lead material from a patient’s vascular space. Partial success was defined as the removal of all lead material except for a small portion of the lead; retained lead material could incorporate the lead tip (electrode) and 4 cm or less of lead coil and/or insulation. Procedural failure was defined as the retention of more than 4 cm of lead material that could not be removed safely. Clinical success was defined as the resolution of all preoperative indications and symptoms associated with lead removal and the absence of major complications and/or lack of pacing control. Clinical failure was defined as the inability to resolve preoperative lead extraction indications and/or the development of major complications; specifically, the occurrence of in-hospital death and the necessity for a sternotomy were considered the criteria for clinical failure.

Complications were defined using the laser lead extraction guidelines of the Canadian Heart Rhythm Society Device Advisory Committee. A complication was classified as major if the outcome or potential outcome was directly life-threatening, including death, surgical intervention (i.e., sternotomy) and/or an acute or chronic disability. Any suboptimal event that was not immediately or directly life-threatening was deemed to be a minor complication, including the development of cardiac arrhythmia, arm swelling, pericardial effusion or pulmonary embolism not requiring surgical intervention.

Data collection and characteristics

We retrospectively collected lead extraction data from the Central District Health Authority’s patient medical database (Horizon Patient Folder). The specific data collected pertained to the patients’ demographic characteristics, clinical presentation and characteristics, extraction processes and procedural complications.

Statistical analysis

We performed a univariate analysis of pertinent patient variables. Additionally, a Kaplan–Meier survivorship analysis was conducted using Prism software version 6 (GraphPad Software Inc.).

RESULTS

Patient population

In a study population of 108 consecutive patients, a total of 218 leads were extracted in 111 consecutive primary procedures using a laser sheath and locking stylet between Sept. 1, 2006, and May 31, 2015. All 111 procedures were performed in an operating room setting with transesophageal echocardiography guidance and fluoroscopy. The mean age of patients was 67.2 ± 12.8 years, with the majority of patients (40.7%) between 70 and 79 years of age. The explanted leads were on average 7.5 ± 6.8 years old, and the average number of leads explanted per patient was 2.1 ± 1.0. The majority of patients were from Nova Scotia (47.2%), followed by New Brunswick (39.8%), Newfoundland and Labrador (8.3%), Prince Edward Island (4.7%), and from outside of Atlantic Canada (0.9%). Patient demographic characteristics are summarized in Table 1. The most common indication for extraction was infection (84.3%) and included patients with endocarditis (9.2%), pocket infection (3.7%) or erosion (56.5%). Additional indications included nonfunctional devices or leads (4.6%), elective or required upgrade (13.0%), and pain or associated device irritation (0.9%).

Procedural success

The overall procedural success with respect to extracted leads was 96.8%, with a total of 203 (93.1%) targeted leads completely extracted and 8 (3.7%) leads partially extracted; 7 leads (3.2%) failed to be extracted. Procedural success was 93.5%, with a total removal rate of 89.8% (97 patients) and a partial removal rate of 3.7% (4 patients); the procedure failure rate was 6.5% (7 failures; Table 2). Clinically, 105 (97.2%) procedures resulted in favourable outcomes, with complete resolution of preoperative indications in which the extraction indication was predominantly infection (i.e., all infected device material was extracted without complication; Table 2). In the present study, 3 (2.8%) patients had unfavourable procedure outcomes, which we defined as the need or decision to perform a sternotomy to complete the extraction or to deal with a life-threatening procedural complication (Table 2). One patient required sternotomy due to vascular perforation of the innominate vein (or brachiocephalic vein) and hemodynamic instability. In contrast, an elective sternotomy was performed in 2 patients electively owing to inability to remove all infected lead material. A single patient died in hospital several days postoperatively due to arrhythmia-related complications. Therefore, in-hospital mortality was less than 1%.

The most common minor complications were pleural effusion (21.3%), pneumothorax (4.6%) and pocket hematoma (2.8%), none of which required interventions, such as drainage or tube placement. Ventricular arrhythmias occurred postoperatively in 7 patients, with 2 (1.9%) instances of ventricular fibrillation; a single patient died in hospital 9 days postoperatively following a ventricular tachycardia (VT) arrest. There were 3 (2.8%) instances of lead fragment migration that did not require further intervention. Median length of hospital stay for all consecutive patients was 5 (range 2–7.25) days. Major and minor complications are summarized in Table 3. Of the 3 cases of major complications in which further surgical intervention
was required, 2 patients initially presented with device-related infections, whereas the third patient required a device upgrade owing to a nonfunctioning lead. The single patient who died in hospital presented with device-associated infection and underwent laser lead extraction, but uncontrollable VT developed and the patient died 9 days postoperatively. One should note that all major adverse events, including lead extraction failures, occurred in the earlier part of the study (2007–2011), with no cases of major adverse events occurring from 2012 onward. Specific characteristics of procedural failure cases are detailed in Table 4 to provide some insight into the characteristics that may predict failures.

### Device and lead characteristics

Of the 105 devices explanted from 108 patients that had available designations, the vast majority were pacemaker devices (70.5%), followed by ICDs (23.0%) and biventricular devices (6.7%). Of the 218 leads extracted, 214 (97.2%) leads had available information pertaining to the duration of implantation: 65 (30.4%) leads were 5–10 years old and 46 (21.5%) leads were older than 10 years (Table 5). The leads were on average 7.5 ± 6.8 years old (median 6 [interquartile range 2–10] years old).

Patient age versus the duration of implanted devices is represented in Figure 1, where the previously stated characteristics are demonstrated visually. This figure illustrates

### Table 1. Demographic and clinical characteristics of study patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td></td>
</tr>
<tr>
<td>&lt; 60</td>
<td>29 (26.9)</td>
</tr>
<tr>
<td>60–69</td>
<td>21 (19.4)</td>
</tr>
<tr>
<td>70–79</td>
<td>44 (40.7)</td>
</tr>
<tr>
<td>≥ 80</td>
<td>14 (13.0)</td>
</tr>
<tr>
<td>Female sex</td>
<td></td>
</tr>
<tr>
<td></td>
<td>29 (26.9)</td>
</tr>
<tr>
<td>BMI, mean ± SD</td>
<td>30.5 ± 13.1</td>
</tr>
<tr>
<td>Province</td>
<td></td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>51 (47.2)</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>43 (39.8)</td>
</tr>
<tr>
<td>Newfoundland and Labrador</td>
<td>9 (8.3)</td>
</tr>
<tr>
<td>Prince Edward Island</td>
<td>3 (4.7)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Medical history</td>
<td></td>
</tr>
<tr>
<td>EF &lt; 50%†</td>
<td>49 (46.8)</td>
</tr>
<tr>
<td>Renal insufficiency (Cr &gt; 176)</td>
<td>6 (5.6)</td>
</tr>
<tr>
<td>Diabetes mellitus‡</td>
<td>45 (42.7)</td>
</tr>
<tr>
<td>Hypertension‡</td>
<td>56 (54.9)</td>
</tr>
<tr>
<td>COPD†</td>
<td>8 (7.8)</td>
</tr>
<tr>
<td>CAD‡</td>
<td>7 (6.8)</td>
</tr>
<tr>
<td>CHF‡</td>
<td>23 (22.6)</td>
</tr>
<tr>
<td>Myocardial infarction‡</td>
<td>26 (25.5)</td>
</tr>
<tr>
<td>Atrial Fibrillation‡</td>
<td>47 (46.1)</td>
</tr>
<tr>
<td>Pacemaker dependence§</td>
<td>69 (66.3)</td>
</tr>
</tbody>
</table>

*BMI = body mass index; CAD = coronary artery disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; Cr = creatinine; EF = ejection fraction; SD = standard deviation.
*Unless indicated otherwise.
†Data available for 94% of the sample.
‡Data available for 95% of the sample.
§Data available for 96% of the sample.

### Table 2. Procedural and clinical outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No. (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural success (per lead, n = 218), %</td>
<td>96.8</td>
</tr>
<tr>
<td>Complete</td>
<td>203 (93.1)</td>
</tr>
<tr>
<td>Partial</td>
<td>8 (3.7)</td>
</tr>
<tr>
<td>Failure</td>
<td>7 (3.2)</td>
</tr>
<tr>
<td>Procedural success (per patient, n = 108), %</td>
<td>93.5</td>
</tr>
<tr>
<td>Complete</td>
<td>97 (89.8)</td>
</tr>
<tr>
<td>Partial</td>
<td>4 (3.7)</td>
</tr>
<tr>
<td>Failure</td>
<td>7 (6.5)</td>
</tr>
<tr>
<td>Number of equipment failures (per patients, n = 108)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Clinical success at procedure (per patient, n = 108)</td>
<td>105 (97.2)</td>
</tr>
<tr>
<td>Success</td>
<td></td>
</tr>
<tr>
<td>Failure</td>
<td>3 (2.8)</td>
</tr>
<tr>
<td>Major adverse events, no. (n = 4)</td>
<td></td>
</tr>
<tr>
<td>In-hospital death</td>
<td>1</td>
</tr>
<tr>
<td>Conversion to sternotomy</td>
<td>3</td>
</tr>
</tbody>
</table>

*Unless indicated otherwise.

### Table 3. Complications associated with extraction of cardiac implantable electronic device and leads

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complications</td>
<td></td>
</tr>
<tr>
<td>Major</td>
<td>4 (3.7)</td>
</tr>
<tr>
<td>In-hospital death</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Required sternotomy</td>
<td>3 (2.8)</td>
</tr>
<tr>
<td>Minor</td>
<td>55 (50.9)</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>23 (21.3)</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>5 (4.6)</td>
</tr>
<tr>
<td>Ventricular tachycardia</td>
<td>5 (4.6)</td>
</tr>
<tr>
<td>Arm swelling</td>
<td>5 (4.6)</td>
</tr>
<tr>
<td>Venous thrombosis</td>
<td>4 (3.7)</td>
</tr>
<tr>
<td>Subclavian</td>
<td>1</td>
</tr>
<tr>
<td>Internal jugular</td>
<td>2</td>
</tr>
<tr>
<td>Basilic</td>
<td>1</td>
</tr>
<tr>
<td>Hematoma at extraction site</td>
<td>3 (2.8)</td>
</tr>
<tr>
<td>Drainage intervention</td>
<td>0</td>
</tr>
<tr>
<td>DVT§</td>
<td>2 (1.9)</td>
</tr>
<tr>
<td>Upper extremities</td>
<td>1</td>
</tr>
<tr>
<td>Lower extremities</td>
<td>1</td>
</tr>
<tr>
<td>Lead fragment migration</td>
<td>3 (2.8)</td>
</tr>
<tr>
<td>Ventricular fibrillation</td>
<td>2 (1.9)</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>TIA§</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Hemotherox</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>7 (6.5)</td>
</tr>
<tr>
<td>LOS, mean ± SD, d</td>
<td>8.2 ± 11.1</td>
</tr>
</tbody>
</table>

*DVT = deep vein thrombosis; LOS = length of stay in hospital; SD = standard deviation; TIA = transient ischemic attack.
*Unless indicated otherwise.
how a significant number of leads were more than 10 years old, with some as old as 20–30 years.

**Long-term outcomes**

Follow-up after discharge was available for all patients in the first 12 months postoperatively, but for only 32 (29.63%) patients beyond 12 months postoperatively. The median follow-up after extraction in our study was 14 (range 6–16) months. Using Kaplan–Meier analysis the 30-day survival was 98.4% and 1-year survival was 94.0% (Fig. 2).

**DISCUSSION**

The aim of the present study was to illustrate the initial experience of a laser lead extraction program at the low-volume Maritime Heart Centre, which is the only referral centre for this procedure for Atlantic Canada and serves a population of approximately 2.4 million. Laser lead extraction is an increasingly common procedure throughout the world, but it is associated with potentially life-threatening complications (e.g., cardiovascular perforations, arrhythmias and death). Therefore, it was important for the Atlantic provinces to develop a program that consisted of experienced surgeons and support staff who could provide a superior standard of care in a timely manner — especially as the Atlantic provinces have the most elderly population and a large proportion of patients with chronically implanted leads and multiple simultaneous implanted leads, which are serious comorbidities in laser lead extraction patients.

Together, our findings suggest that acceptable outcomes could be achieved in a low-volume centre using a standardized superior (subclavian) approach and concentrating the expertise to a limited number of operators. Similar procedural and clinical results have been reported in larger, multi-institutional studies, such as the LExICon study (n = 1449), which had procedural and clinical success rates of 96.5% and 97.7%, respectively. Likewise, a Canadian registry (n = 684) reported procedural and clinical success rates of 91.4% and 93.1%, respectively. Although it is difficult to compare our results to those of these large studies owing to the limited number of patients in our cohort, notably, we report consistent positive findings from patients who had leads in place for longer periods of time than those in other studies, and extended implantation periods is a known predictor of procedural failure or major complications. We reported an average duration of chronically implanted leads of 7.1 ± 6.0 years, with 51.9% of patients having leads older than 5 years and

<table>
<thead>
<tr>
<th>Year of operation</th>
<th>Final outcome</th>
<th>No. of leads</th>
<th>Patient age, yr</th>
<th>Duration of lead, yr</th>
<th>LOS, d</th>
<th>Procedural and treatment details</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>Major adverse event: death</td>
<td>2</td>
<td>70</td>
<td>9</td>
<td>9</td>
<td>Presented with RV lead infection. Postoperatively patient enter MODS, and was intubated, given antibiotics, inotropes, and dialysis. Patient expired 9 days following OR date</td>
</tr>
<tr>
<td>2011</td>
<td>Major adverse event: vascular perforation leading to emergent sternotomy</td>
<td>2</td>
<td>61</td>
<td>20, 6</td>
<td>10</td>
<td>Non-functioning lead requiring replacement with prior-history of congenital heart defect repair. Intraoperatively, perforation at the SVC/innominate junction promoted the surgical team to immediately perform an emergency sternotomy to repair the perforation with a large piece of bovine pericardium patch. All leads were completely removed following vascular repairs. The patient did recover, and was discharged.</td>
</tr>
<tr>
<td>2008</td>
<td>Major adverse event: laser lead extraction failure requiring a sternotomy</td>
<td>3</td>
<td>71</td>
<td>12, 30</td>
<td>12</td>
<td>Device pocket infection, in which infectious leads could not be fully removed. All the leads were completely removed after sternotomy and the patient was closed and released to the floor in stable condition. There was no adverse complications postoperatively.</td>
</tr>
<tr>
<td>2007</td>
<td>Major adverse event: laser lead extraction failure requiring a sternotomy</td>
<td>2</td>
<td>80</td>
<td>18</td>
<td>21</td>
<td>Device pocket infection with chronic draining sinus. Intraoperatively, the surgical team attempted to remove the 3 leads unsuccessfully. After completion of sternotomy, all leads were removed. Patient tolerated procedure and was discharged home after subsequent reimplantation of a new pacemaker.</td>
</tr>
</tbody>
</table>

**Table 5. Explanted device (n = 105) and lead characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explanted device†</td>
<td>Pacemaker</td>
</tr>
<tr>
<td></td>
<td>ICD</td>
</tr>
<tr>
<td></td>
<td>Bi-Ventricular</td>
</tr>
<tr>
<td>Lead duration, yr†</td>
<td>≤ 1</td>
</tr>
<tr>
<td></td>
<td>&gt; 1 to ≤ 5</td>
</tr>
<tr>
<td></td>
<td>&gt; 5 to ≤ 10</td>
</tr>
<tr>
<td></td>
<td>&gt; 10</td>
</tr>
<tr>
<td>Lead duration, mean ± SD, yr†</td>
<td>7.1 ± 6.0</td>
</tr>
</tbody>
</table>

SD = standard deviation. *Unless indicated otherwise. †Data available for 97% of the sample. ‡Data available for 98% of the sample.
21% having leads older than 10 years. This contrasts with the extracted lead duration of 5.7 ± 0.2 years reported in larger studies. The duration of a lead has been clearly shown to correlate with potentially difficult extractions and major adverse events, or to result in extraction failure. A single patient in our series sustained a major vascular injury (perforation of the innominate vein, or brachiocephalic vein) during an attempt to extract a 20-year-old lead, requiring an emergency sternotomy. An additional 2 patients had elective sternotomies because of the inability to extract all infected lead material in 18- and 30-year-old leads. The incidence of procedure-related

![Fig. 1. Lead implant duration versus respective patient age. Light grey circles represent leads that were successfully extracted without complication, dark grey circles represent leads for which major complications occurred during extraction, and black circles represent targeted leads that were not extracted.](image1)

![Fig. 2. Kaplan–Meier analysis of 12-month survivorship among patients who underwent lead extraction.](image2)
minor complications was frequent, occurring in 50.9% of patients; however, none of these patients required additional interventions.

Device-related infection was the most common indication for laser lead extractions in our series.\(^5,16,18\) We found that 84.3% of patients had some form of device-related infection ranging from localized pocket infection to systemic infection, such as endocarditis. This finding contrasts those of many larger series in which infection was present in only 35%–62% of the patient population, making our study population unique.\(^3,16,19\) Nevertheless, infection is the leading indication for laser lead extraction in North America, with significant increases in the incidence of infection during the past several years.\(^20\) Device-related infection has been shown to be an important indicator of higher mortality, with a mortality as high as 66% reported in untreated patients versus 18% following extraction and antibiotic treatment.\(^21\) This potentially high mortality explains the drive behind the 2 patients in our series who underwent elective sternotomies to ensure complete removal and improve long-term survival.\(^19,20\) The removal of all infected devices and proximal material is vital to prevent reoccurrence of bacteremia or the development of endocarditis.\(^21\) To the best of our knowledge we have not seen long-term recurrence of infection in patients who underwent partial lead extraction, particularly patients in whom a small piece of lead material was left in the cardiac tissue or vasculature (\(n = 8\)). The median follow-up after extraction in our study was 14 (range 6–16) months, with 98.6% 30-day survival and 94% 1-year survival.

Our study has reported an in-hospital mortality of 0.9%, which is similar to that reported in previous studies (0.7%–1.9%).\(^5,7,9\) What is unique about our program is that all procedures were performed by a cardiovascular surgeon in a dedicated operating room setting. This meant that all patients were ready for emergent sternotomy and extracorporeal bypass system on standby, as well as hemodynamic stability monitoring via atrial pressure and transesophageal echocardiography to facilitate rapid diagnosis of procedural complications. The present study was in no way designed to validate the use of an operating room with a surgeon present as opposed to a procedure room, such as catheterization laboratory (EP laboratory), without a surgeon. Operating room versus catheterization laboratory extraction outcomes have been examined and have been found to produce similar results.\(^9\) One should note that our standardized approach allowed for an efficient transition (without delay) from the lead extraction to emergent sternotomy in the patient who experienced a life-threatening perforation of the innominate vein, leading to sudden cardiovascular collapse. The patient had had previous coronary artery bypass graft, which increased the difficulty of the repeat sternotomy owing to the presence of scar tissue as well as blood loss. The success of her restorative surgery was possible only given the readiness of the surgical team (i.e., nursing, perfusion, anesthesiologist and surgeon) in the room. The patient survived without major sequelae. The length of stay in hospital after the procedure in our study was 8.2 ± 11.1 (median 5, range 2–7.25) days, which was longer than the typical 5–7 days reported previously.\(^16,22\) We speculate that the extended in-hospital period in our patient population correlates with the finding that most of the patients’ primary extraction indications had been infection (84.3%), which subsequently meant extended antibiotic treatment or wound care before discharge.\(^4,20,22\)

We hope that this study serves as a stepping stone in terms of improving this program not only at the Maritime Heart Centre, but also at low-volume centres across Canada. Furthermore, following the promising results of this study, we also hope to expand our program by including more than only patients with class I indications and by incorporating different extraction techniques, such as a femoral extraction approach. This approach has been demonstrated to allow procedural and clinical success when a superior (subclavian) approach has failed and may allow the program to reduce the number of sternotomies for nonperforation-related complications (i.e., lead migration, lead fragmentation, or a congested heart).\(^23,24\) Additionally, as members of our operative team are currently collaborating to create a national registry for lead extraction, and as both surgeons and EP physicians are collaborating on uniquely Canadian laser lead extraction guidelines, it is our hope that our program will stay among the institutions at the forefront of medical innovation in Canada and provide the best possible care for patients with complex lead issues.

Limitations

An important limitation of this study is its small sample size. We specifically examined only patients who underwent laser-assisted extractions, excluding patients whose leads were removed via nonpowered countertraction. As such, the present study focused only on leads that could not be removed by simple traction and focused on leads that were technically more challenging, which may explain why infection was a predominant indication.\(^11,19\) This study may not truly evaluate the clinical needs for lead extraction in Atlantic Canada, but it provides some insight into the incidence of device-related infections that require extraction for a particular patient population.

Compared with other extraction studies,\(^17,25\) our study tended to look at an exhaustive list of possible minor complications. Subsequently, the larger number of complication variables examined produced a higher minor complication rate than those reported in other studies.
One should note that none of the minor complications reported resulted in additional interventions.

**CONCLUSION**

The impetus for the creation of the laser lead extraction program was based on a clinical need and the desire to avoid transferring patients to larger institutions in Montreal, Que. This study showed that a high success rate with a low complication rate and low mortality can be achieved in a low-volume centre serving a large geographical area. Patient comorbidities, such as chronically (>1 yr) implanted leads, advanced patient age and arrhythmia, and complications, such as perforation and postoperative arrhythmia, were overcome by concentrating the technical expertise to a limited number of surgeons and dedicated cardiac nursing staff.

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Temporal trends in the use of diagnostic imaging for inpatients with pancreatic conditions: How much ionizing radiation are we using?

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Background: Low-dose ionizing radiation from medical imaging has been indirectly linked with subsequent cancer and increased costs. Computed tomography (CT) is the gold standard for defining pancreatic anatomy and complications. Our primary goal was to identify the temporal trends associated with diagnostic imaging for inpatients with pancreatic diseases.

Methods: Data were extracted from the Healthcare Cost and Utilization Project Nationwide Inpatient Sample (NIS) database from 2000 to 2008. Pancreas-related ICD-9 diagnostic codes were matched to all relevant imaging modalities.

Results: Between 2000 and 2008, a significant increase in admissions (p < 0.001), but decrease in overall imaging procedures (p = 0.032), for all pancreatic disorders was observed. This was primarily a result of a reduction in the number of CT and endoscopic retrograde cholangiopancreatography examinations (i.e., reduced radiation exposure, p = 0.008). A concurrent increase in the number of inpatient magnetic resonance cholangiopancreatography/magnetic resonance imaging performed was observed (p = 0.040). Intraoperative cholangiography and CT remained the dominant imaging modality of choice overall (p = 0.027).

Conclusion: Inpatients with pancreatic diseases often require diagnostic imaging during their stay. This results in substantial exposure to ionizing radiation. The observed decrease in the use of CT may reflect an improved awareness of potential stochastic risks.

Contexte: Les faibles doses de rayonnement ionisant associées à l’imagerie médicale ont été indirectement associées à des cas subséquents de cancer et à une augmentation des coûts. Considérée comme la norme dans le domaine, la tomographie par ordinateur est utilisée pour étudier l’anatomie et les complications pancréatiques. Notre principal objectif consistait à dégager les tendances temporelles associées à l’utilisation de l’imagerie diagnostique chez des patients hospitalisés atteints de maladies pancréatiques.


Résultats: De 2000 à 2008, une hausse importante du nombre d’admissions (p < 0,001) a été observée pour l’ensemble des maladies pancréatiques, parallèlement à une baisse du nombre total d’examens d’imagerie (p = 0,032). Ces changements sont principalement attribuables à une diminution du nombre de tomographies par ordinateur et de cholangiopancréatographies rétrogrades endoscopiques effectuées (donc à une diminution de l’exposition au rayonnement, p = 0,008). Par ailleurs, une augmentation du nombre de tomographies et de cholangio-pancréatographies par résonance magnétique effectuées sur des patients hospitalisés (p = 0,040) a également été observée. Dans l’ensemble, les cholangio-pancréatographies et les tomographies peropératoires demeurent les techniques d’imagerie les plus utilisées (p = 0,027).

Conclusion: Les patients atteints de maladies pancréatiques ont généralement besoin de subir un examen d’imagerie médicale pendant leur séjour à l’hôpital, et peuvent donc être exposés à une dose substantielle de rayonnement ionisant. La baisse observée du nombre de tomographies par ordinateur pourrait témoigner d’une sensibilisation améliorée aux risques stochastiques potentiels.
Pancreatic diseases include, but are not limited to, both acute and chronic pancreatitis as well as pancreatic neoplasia. These conditions represent some of the most debilitating and life-threatening diagnoses in all of surgery. As a result, pancreatic diseases challenge our clinical, social and financial resources. Not surprisingly, this patient population is at significant risk for perioperative morbidity and postoperative mortality during their time as inpatients. They also often undergo extensive outpatient imaging surveillance protocols for years of follow-up.\(^1\)

The current noninvasive, gold standard modality for the detection and assessment of nearly all pancreatic diseases is computed tomography (CT) with intravenous contrast medium.\(^2\) Although pancreatic ductal anatomy is better evaluated with magnetic resonance cholangiopancreatography (MRCP), and fluid analysis is clearly superior via endoscopic ultrasonography, high-fidelity CT remains the dominant workhorse in high-volume pancreatic centres. In addition to the inherent risk of contrast-associated nephropathy, CT imaging exposes patients to a measurable dose of ionizing radiation.\(^3\)–\(^6\) Considering the frequent need for multiple CT scans during the course of their inpatient care (i.e., necrotizing pancreatitis or postoperative complications after pancreatic procedures), a patient’s radiation exposure can be substantial. The increasing use of CT imaging\(^7\)–\(^12\) coupled to the growing incidence of both pancreatitis\(^13\)–\(^17\) and pancreatic tumours (i.e., intraductal papillary mucinous neoplasm [IPMN]), makes this public health issue especially topical.

The primary aim of this study was to identify temporal trends in diagnostic imaging procedures for patients with diseases of the pancreas using a large national database.

**Methods**

**Data source**

All data were collected from the Healthcare Cost and Utilization Project central distributor via the National Inpatient Sample (HCUP-NIS) database (2000–2008). The HCUP-NIS represents the largest publicly available database of hospital admissions in the United States, with all-payer sources (Medicaid, Medicare, privately insured, and uninsured). It is a discharge-based registry (i.e., each entry represents a single hospital admission) that contains primary and secondary diagnoses and procedures, patient demographic characteristics, and other clinical and nonclinical data elements of inpatient discharge records from community hospitals in participating states. The individual state inpatient databases are uniformly formatted to allow representative sampling into NIS and multistate analyses. Progressive increases in sampling frame (from 8 states in 1988 to 48 at present) and constant review of sampling design have optimized U.S. population representativeness over the years. The HCUP-NIS currently approximates a 20% stratified sample of discharges from community hospitals in the United States, representing more than 95% of the U.S. population. All available information is de-identified, and different admissions for the same patient are registered as distinct entries. Accounting for changes in NIS design over the years, NIS supplemental files containing revised discharge weights were used to consistently represent United States nationwide data trends.

**Study population**

We used ICD-9-CM codes to define eligible participants and for data abstraction from the HCUP-NIS. All hospitalizations from 2000 to 2008 with a primary diagnosis of acute pancreatitis (code 577.0); chronic pancreatitis (code 577.1); or neoplasia of the head (code 157.1), body (code 157.0), or tail (code 157.2) of the pancreas were included. A search of the ICD-9-CM code conversion table revealed no changes to the included codes during the study period (i.e., ICD-9-CM diagnostic terminology consistently represents this subpopulation of discharges throughout the study period).

**Data elements**

The number of imaging procedures performed during hospitalization was abstracted and computed separately for distinct imaging modalities under each primary diagnosis group. Imaging modalities were selected according to clinical relevance based on the primary diagnosis (acute and chronic pancreatitis; neoplasia of the head, body and tail):

- diagnostic ultrasonography of the abdomen (codes 88.76 and 88.76)
- axial CT of the abdomen (code 88.01)
- magnetic resonance imaging (MRI) of the abdomen (code 88.87)
- endoscopic retrograde colangiopancreatography (ERCP; codes 51.10, 51.11, and 52.13)
- intraoperative cholangiography (IOC; code 87.53)
- percutaneous hepatic cholangiography (PTC; code 87.51), and
- endoscopic ultrasonography of the abdomen (211.1)

**Analysis**

We assessed and analyzed primary diagnosis groups independently, except for neoplasm of the body and tail of the pancreas. These were considered together as neoplasm of the distal/left pancreas.

The frequency of each imaging modality was computed for the entire population during the study period. U.S. nationwide estimates of the number of discharges and imaging procedures were obtained using revised NIS discharge weights.
We calculated the proportion of hospitalizations, including imaging procedures, for each imaging modality as annual utilization percentages. The total number of discharges in a specific calendar year with at least 1 imaging procedure performed was ascertained as the numerator, whereas the denominator corresponds to the total number of discharges in the respective year.

Count data were summarized as frequencies or proportions. A combination of descriptive statistics with linear regression adjusted per year was used to analyze the data. We considered 2-sided $p$ values < 0.05 to represent statistical significance for all evaluations. Two-way plots were used to illustrate the temporal change in the proportion of NIS admissions over time. All statistical testing was performed using Stata/IC software version 12.0 (Stata Corp.).

**RESULTS**

**Acute and chronic pancreatitis**

From 2000 to 2008, we noted an increase of 34.2% in hospital admissions attributed to the primary diagnosis of acute pancreatitis (284 718–382 038 hospitalizations) and 65.7% for chronic pancreatitis (82 176–136 198 hospitalizations) ($p < 0.001$). Described as a ratio of all inpatient admissions, this increased from 2.85 to 3.82 per 100 000 NIS admissions for acute pancreatitis and 0.82 to 1.36 per 100 000 NIS admissions for chronic pancreatitis ($p < 0.001$). This totals 3.9 million hospitalizations for pancreatitis in the United States over the 9-year study interval (3 028 128 acute pancreatitis; 901 549 chronic pancreatitis; Fig. 1).

We observed a reduction in the overall use of imaging procedures (1 imaging procedure per 4.3 patients admitted with pancreatitis in 2000 to 1 per 6.7 patients in 2008, $p < 0.001$). During the study period, 68 647 diagnostic abdominal ultrasounds, 136 285 CT scans; 126 501 ERCPs, 254 185 IOCs, 23 030 MRCP/MRIs and 6485 PTCs were performed for patients admitted with a primary diagnosis of pancreatitis.

**Trends in imaging modality utilization — acute pancreatitis**

The IOC remained the most common imaging procedure, with an average annual utilization of 8.4%. The utilization of MRI increased from 0.3% in 2000 to 1.0% in 2008 ($p < 0.001$). There was a progressive reduction in the use of CT from 5.3% in 2000 to 3.0% in 2008 ($p = 0.022$). The use of ultrasonography decreased from 3.6% in 2000 to 1.7% in 2008 ($p = 0.019$). The largest observed decrease occurred with ERCP (6.3% in 2000 to 2.3% in 2008, $p < 0.001$; Fig. 2A).

**Trends in imaging modality utilization — chronic pancreatitis**

Magnetic resonance imaging was the only modality noted to increase for hospitalized patients with chronic pancreatitis (0.3% in 2000 to 0.7% in 2008, $p = 0.034$). All other imaging modalities showed a reduction in use, particularly ERCP (4.7% in 2000 to 1.9% in 2008) and CT (4.3% in 2000 to 2.5% in 2008, $p = 0.007$; Fig. 2B).

![Fig. 1. National trends over the study period (2000–2008) in number of hospitalizations with primary diagnosis of acute and chronic pancreatitis.](image-url)
Pancreatic neoplasia

Pancreatic neoplasia resulted in a total of 244,220 hospitalizations, with an increase of 35.6% between 2000 and 2008 (24,244 to 32,869 admissions, \( p < 0.001 \)). Described as a ratio of all inpatient admissions, this increased from 0.24 to 0.33 per 100,000 NIS admissions (\( p < 0.001 \)). The most common tumour site (75.9%) was the head of the pancreas (185,463 admissions; Fig. 3). Hospital admissions for pancreatic neoplasia resulted in a total of 50,839 imaging procedures (3,554 ultrasounds, 13,508 CT scans, 21,235 ERCPs, 1,478 MRIs and 11,064 PTCs).

Trends in imaging modality utilization — pancreatic neoplasia

From 2000 to 2008, there was a consistent reduction in the utilization of ERCP for patients admitted with neoplasia of both the pancreatic head (11.0% to 8.2%) and distal gland (3.8% to 1.3%) (\( p = 0.044 \)). Utilization of CT also decreased from 6.6% to 3.1% for neoplasia of the pancreatic head and from 6.7% to 2.8% for the left pancreas (\( p = 0.003 \)). Ultrasonography and MRI utilization remained below 2.0% of hospital admissions for pancreatic neoplasms of the head and distal pancreas.

Fig. 2. National trends over the study period (2000–2008) in utilization of imaging modalities for patients admitted with primary diagnosis of (A) acute pancreatitis and (B) chronic pancreatitis. CT = computed tomography; ERCP = endoscopic retrograde cholangiopancreatography; IOC = intraoperative cholangiography; MRI = magnetic resonance imaging; US = ultrasonography.
Utilization of PTC in patients admitted with pancreatic head neoplasia remained unchanged, with an average annual utilization of 5.3% ($p = 0.23$; Fig. 4A and Fig. 4B).

**DISCUSSION**

From 2000 to 2008, the total volume of admissions for pancreatic diseases increased significantly. Whether discussing raw admission numbers or ratios per 100 000 NIS admissions, the observed 34.2%, 65.7% and 35.6% increases for acute pancreatitis, chronic pancreatitis, and pancreatic cancer, respectively, strongly suggest a true increase in the incidence of each of these diseases. Given that this total inpatient volume approaches 39 million visits, the hospital and physician resources required to care for this patient population are extensive. To our knowledge, this study is the first modern population-based description of increasing pancreatic volumes.

Although CT remains the single most important imaging modality for pancreatic diseases (diagnosis and prognosis), additional tests are also frequently required. These include transabdominal ultrasonography and MRCP. Invasive tests are also not uncommon and incorporate ERCP (i.e., biliary stent placement), IOC (i.e., define retained choledocholithiasis) and endoscopic ultrasonography (i.e., characterization and/or biopsy of lesions). While ultrasonography, MRCP and endoscopic ultrasonography have the benefit of avoiding the delivery of ionizing radiation to patients, CT and the fluoroscopy associated with ERCP and IOC carry potential stochastic risks. Given the explosion in CT scanner use and indications1,4,18–28 (3 million CTs performed in 1980 v. 62 million in 2006), radiation exposure is always a public health concern. This is evident in the nearly 6-fold increase in the per capita radiation exposure delivered from medical imaging. More specifically, while the majority (80% to 85%) of human radiation exposure arises from equal amounts of solar and radon sources (background dose 1–3 mSv/yr), medical imaging creates most of the remaining 15% to 20%. Furthermore, abdominal CT imaging accounted for up to 31% of the annual cumulative effective dose from medical imaging procedures in a study of nearly 1 million nonelderly adults.

Although many clinicians would argue that the vast majority of inpatient imaging is necessary to the care of pancreatic patients, it is clearly important that as physicians we evaluate both the volume of our imaging, as well as its true utility (i.e., ability to alter care). The essential nature of this issue is supported by the observation that at least 75% of CT imaging is obtained in a hospital setting, with up to half being scans of the torso. This was noted to be even higher (89%) in a recent postresection pancreatic cancer–specific study. Furthermore, in an evaluation of the impact of CT-based ionizing radiation on patients with pancreatitis, less than 31% had subsequent alterations in their care. It has also been recently reported in a large registry-based study of pancreatic cancer that no benefit in survival was noted with scheduled or routine CT scans in the postoperative/postdischarge period. These data...
surrounding the issue of appropriate diagnostic tests do not begin to account for the costs associated with overly liberal imaging policies.\textsuperscript{1,32}

While the true stochastic risks of DNA mutations and therefore carcinogenesis following exposure to medical imaging are unknown\textsuperscript{1} (i.e., absence of large-scale epidemiologic data),\textsuperscript{33} the potential life expectancy of the patient population must be considered. The effective dose of 40 mSv among patients with acute pancreatitis\textsuperscript{1} is identical to that reported for patients with pancreatic cancer during their first year (40.1 mSv).\textsuperscript{6} Unfortunately, patients with pancreatic cancer have substantially shorter life expectancy as evidenced by an overall 5-year exposure of only 68.8 mSv per patient.\textsuperscript{6} Given the known challenge of recovering well enough from postoperative complications to receive adjuvant chemotherapy, it can easily be argued that the radiation exposure associated with multiple CT scans in this scenario is irrelevant from a stochastic standpoint. When this concept is applied to our data set, the observed reduction in CT imaging over the study interval would have resulted in a theoretical reduction in the absolute number of patients who developed a radiation-induced

![Graph A](image-url)

**Fig. 4.** National trends over the study period (2000–2008) in utilization of imaging modalities for patients admitted with primary diagnosis of neoplasia of the (A) pancreatic head and (B) distal pancreas. CT = computed tomography; ERCP = endoscopic retrograde cholangiopancreatography; IOC = intraoperative cholangiography; MRI = magnetic resonance imaging; US = ultrasonography.
fatal cancer per year of 3 for acute pancreatitis and 1 for both chronic pancreatitis and pancreatic neoplasia. As a result, the core of this issue lies in the specific discussion surrounding both benign diseases, such as pancreatitis, as well as in the frequency of altering treatment regimes based on additional imaging tests (Table 1).1

Given the highly publicized nature of exposure to medical radiation,1,14 it was interesting to note the significant decrease in the volume of CT scans performed for patients with both pancreatitis and neoplasia. Upon discussing this observation at an international panel, audience members anecdotally felt that their own practice reflected this reality.15 This decrease in the frequency of CT clearly resulted in fewer overall diagnostic imaging tests for patients as a whole. A significant increase in the use of MRCP/MRI (3-fold) was also noted and likely reflects a move away from modalities associated with ionizing radiation (i.e., particularly benign conditions). Similar arguments can be made for the impact of endoscopic ultrasonography. Not surprisingly, given that the majority of cases of acute pancreatitis are biliary-related (choledocholithiasis), IOC remained the most common imaging modality overall. Furthermore, despite ultrasonography being the most frequent initial diagnostic test for cases of acute pancreatitis, its observed decrease may reflect an increased volume of outpatient ultrasonography performed before acute attacks requiring hospital admission.

It was also interesting to note that the frequency of ERCP decreased significantly. Given the strong evidence that most (75.9%) cancers are located in the head of the pancreas and that preoperative ERCP and biliary stent placement increases the risk of postoperative complications,16 this observation is likely reflective of evidence-based changes in practice over time. More specifically, in a country with rapid access to the operating theatre for resective procedures (e.g., Whipple), preoperative biliary stents have become relatively contraindicated. In the context of prolonged wait times, Canadian surgeons continue to struggle with this issue. This pattern also reflects strong evidence against the use of ERCP in patients with acute pancreatitis in the absence of persistent biliary obstruction or cholangitis.17 It is furthermore evident that the overall frequency of diagnostic ERCP has decreased substantially in the context of acute biliary diseases in a large U.S. database study.18

**Limitations**

This study has several limitations. First, as a result of the aggregated or ecological nature of the data, our results can be interpreted only as associations on a population level, and therefore not causative at the individual level. This limitation extends to deriving any individual level patient conclusions. Second, although the HCUP-NIS database leads to strong observations based on the volume of data, there is no specific confirmation of compliance in reporting of a particular data field by a given centre. As a result, while the pattern of change in diagnostic tests remains reliable over time, the reported specific incidence is subject to error. Third, the NIS data set is limited to inpatient admissions, and as a result does not allow commentary on the volume or frequency of outpatient CT imaging that likely occurs and potentially predominates the care of patients with neoplastic pancreatic diseases. Fourth, the inability of this data set to discriminate between mild and severe/critical acute pancreatitis also limits the interpretation of the rate of CT imaging. A higher rate of CT examinations would clearly be expected for more severe variants of pancreatitis. Similarly, patients with pancreatic neoplasia would also be expected to display a higher rate of CT imaging following resection compared with nonresection admissions. Finally, extrapolation of the specific ionizing radiation exposure to a patient group is difficult given the population-based nature of the data. The delivered effective dose can vary significantly based on the individual CT scanner (i.e., number of
slices). The reported effective dose for single-phase abdominal CT scan ranges from 1.5 to 10 mSv depending on the number of channels, although the generally recognized average effective dose is 8 mSv (Table 1). In comparison, exposure for both pilots/flight crews (1000 flight h/yr) and occupational radiation workers approximate 5 mSv per year. Recent estimates of the lifetime risk of radiation-induced cancer approximate 1 person in 100 for those exposed to 100 mSv (relative risk 1.024; Table 1). 9 The lifetime risk of cancer from all other causes is 42 in 100, and the risk of dying from a motor vehicle crash in the United States is 1 in 77. 28-40-42

CONCLUSION

In summary, despite an increasing overall volume of admissions for pancreatic diseases, the frequency of inpatient CT imaging is decreasing while the use of MRCP/MRI is increasing. This observation is notable in the context of potential patient and physician concerns regarding the stochastic risks of ionizing radiation. The observed reduction in ERCP use among patients with pancreatic neoplasia is likely a reflection of the strong evidence favouring the avoidance of preoperative biliary stenting and therefore proceeding directly to operative resection in a timely manner.

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Contributors: J.-F. Ouellet, E. Dixon, S. Grondin, R. Myers, R. Mohamed and C. Ball designed the study. J.-F. Ouellet, D. Tanyingoh, G. Kaplan and C. Ball acquired the data, which A. Bressan, J.-F. Ouellet, D. Tanyingoh, G. Kaplan, R. Myers and C. Ball analyzed. A. Bressan, S. Grondin and C. Ball wrote the article, which all authors reviewed and approved for publication.

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Understanding the complexities of shared decision-making in cancer: a qualitative study of the perspectives of patients undergoing colorectal surgery

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Background: Decisions leading up to surgery are fraught with uncertainty owing to trade-offs between treatment effectiveness and quality of life. Past studies on shared decision-making (SDM) have focused on the physician–patient encounter, with little emphasis on familial and cultural factors. The literature is scarce in surgical oncology, with few studies using qualitative interviews. Our objective was to explore the complexities of SDM within the setting of colorectal cancer (CRC) surgery.

Methods: An interdisciplinary team developed a semistructured questionnaire. Telephone interviews were conducted with CRC patients in the practice of 1 surgical oncologist. Data saturation was achieved and a descriptive thematic analysis was performed.

Results: We interviewed 20 patients before achieving data saturation. Three major themes emerged. First, family was considered as a crucial adjunct to the patient–provider dyad. Second, patients identified several facilitators to SDM, including a robust social support system and a competent surgical team. Although language was a perceived barrier, there was no difference in level of involvement in care between patients who spoke English fluently and those who did not. Finally, patients perceived a lack of choice and control in decision-making, thus challenging the very notion of SDM.

Conclusion: Surgeons must learn to appreciate the role of family as a vital addition to the patient–provider dyad. Family engagement is crucial for CRC patients, particularly those undergoing surgical resection of late-stage disease. Surgeons must be aware of the uniqueness of decision-making in this context to empower patients and families.


Méthodes : Une équipe interdisciplinaire a conçu un questionnaire semi-structuring au moyen duquel nous avons interviewé par téléphone des patients atteints d’un cancer colorectal et suivis par le même chirurgien oncologue. Nous avons atteint le seuil de saturation des données, puis réalisé une analyse thématique descriptive.

Résultats : Pour atteindre la saturation, nous avons interrogé 20 patients. Trois thèmes principaux sont ressortis. D’abord, la famille était considérée comme un précieux ajout au tandem patient–médecin. Ensuite, les patients ont énuméré quelques éléments qui facilitent la prise de décision partagée, notamment la présence d’un bon réseau de soutien social et d’une équipe de professionnels compétente. À noter : même si la langue était perçue comme un obstacle, nous n’avons observé aucune différence entre les patients qui maîtrisent bien l’anglais et les autres en ce qui concerne l’engagement. Enfin, les patients ne sentaient pas que leur opinion comptait pour beaucoup dans la prise de décision, ce qui remet en question la notion même de prise de décision partagée.

Conclusion : Les chirurgiens doivent voir la famille comme un acteur de soutien essentiel au tandem patient–médecin. La participation de la famille est cruciale pour les patients atteints d’un cancer colorectal, surtout pour ceux qui subissent une résection chirurgicale à un stade avancé de la maladie. Les chirurgiens ne doivent pas oublier que chaque cas est unique, afin d’autonomiser les patients et leur famille.
Treatment decision-making is particularly challenging for patients with colon cancer owing to the presence of substantial trade-offs between therapeutic effectiveness and post-treatment quality of life in addition to the inherent risks associated with complex surgical procedures.

When patients arrive at a crossroads of medical or surgical options, most wish to participate alongside their clinicians in making decisions. In fact, various studies have investigated the shared decision-making (SDM) process between the physician and patient across different clinical settings. For instance, Bélanger and colleagues elucidated the concept in palliative care using narrative synthesis, exploring patient preferences for SDM, the level of patient participation in decision-making and the barriers and facilitators to SDM. In the field of cancer care specifically, the evidence suggests that critically ill patients generally prefer to be involved in decision-making with the health care team and that providing information about care options and maintaining realistic expectations may increase patient engagement.

While the literature on SDM focuses on the patient’s direct encounter with the physician and health care team, there is little to no emphasis on the interplay between familial and cultural influences and decision-making within a model of patient-centred care. Research on this topic is especially scarce in the field of surgical oncology, with a lack of studies using qualitative interviews to explore these issues from the patient’s perspective. Therefore, the objective of this study was to examine the complexities of the longitudinal and interactive process of SDM among patients, their families and the health care team in colorectal cancer (CRC) surgery.

Methods

Participants

Adult patients (≥ 18 yr) who underwent surgical resection for suspected or pathologically confirmed CRC and who were in early postoperative follow-up (< 3 mo) in the Gastrointestinal Oncology Clinic at Princess Margaret Cancer Centre or Toronto Western Hospital (part of the University Health Network in Toronto, Ont.) were eligible to participate. The University Health Network is a multi-institution tertiary academic centre located in a large urban city, serving a culturally diverse and complex patient population.

We used convenience sampling, a form of nonprobability sampling, to identify patients for prospective recruitment from a single surgeon’s (F.A.Q.) clinical practice. All patients approached to take part in the study were fully aware of their diagnosis and were considered physically and psychologically able to cope with the interview process. We obtained informed consent from all patients before their participation in the study. The protocol was approved by the University Health Network Research Ethics Board before study initiation.

Data collection

An interdisciplinary team consisting of a psychiatrist, surgical oncologist and nurse navigator developed a semi-structured interview guide that addressed 3 broad areas: history of illness, participation in treatment decisions and demographic characteristics. The interview guide, consisting of both open-ended questions and question probes used to facilitate the discussion, allowed flexibility to elicit individual views and descriptions of experiences.

All interviews were conducted by telephone. Patients were first asked to briefly recount their health care experiences since receiving the diagnosis of CRC. This provided an overview of preoperative and postoperative care, including therapies received, and enabled subsequent in-depth exploration of participation in treatment decision-making. Several open-ended questions were used to ascertain perceptions of choice, preferences for participation in decision-making, and factors that helped or hindered decision-making, including the following:

- “Can you tell me about your decision-making process leading up to surgery?”
- “Can you tell me about the information that was given to you during the decision-making process?”
- “Can you identify any factors that played a role (good or bad) in this decision-making process?”

These questions were followed by a series of probing questions used when necessary to stimulate deeper thinking about the issues. Demographic data were also collected from patients, and specific tumour staging information and surgical procedure type were obtained from electronic patient records.

Data analysis

Interviews were audio-recorded and transcribed verbatim by an independent transcriptionist. All identifying information was removed from transcripts before analysis to maintain anonymity. Transcripts were hand-coded following each interview to allow iterative data collection and analysis, whereby new and emerging concepts could be further explored in subsequent interviews. Descriptive coding was used to identify distinct concepts, which were later grouped into categories. The research team met consistently to discuss emerging ideas and categories. Upon achieving data saturation (the point at which no new information that was relevant to the research question emerged), these categories were further analyzed and refined to identify overarching themes in the attitudes, perceptions and experiences of patients. Sociodemographic and clinical data were summarized using descriptive statistics.
RESULTS

Sociodemographic characteristics

The patient sample (n = 20) included 11 men (55%) and 9 women (45%; Table 1). Eleven patients were 70 years of age or older. The mean age of the sample was 71.5 (range 42–88) years. Eleven patients had colon cancer and 9 patients had rectal cancer, with all stages of disease represented from carcinoma in situ (stage 0) to stage IV cancer. Almost half of the patient cohort received neoadjuvant chemotherapy/radiotherapy in addition to surgery. Fifty percent of patients reported English as their primary language. Patients came from a variety of backgrounds, including Canadian, European, Southeast Asian and Latin American descent. Patient education ranged from none to a graduate or postgraduate degree, with 55% completing up to elementary or high school. The vast majority of patients were either retired or currently unemployed, which may be a reflection of the age distribution, as most patients were older than retirement age (≥65 yr).

Complexities of shared decision-making

We identified 3 major themes or factors that appeared to shape decision-making in this context: the role of family and social support, facilitators and barriers to patient confidence and informed decision-making, and perceived lack of control and choice.

The role of family and social support

Family is a crucial adjunct to the physician–patient interaction. Specifically, family members may assume 1 (or more) of 3 roles in SDM. First, a patient’s family may offer opinions and ideas toward treatment or collaborate with patients when making decisions about their care, and therefore ultimately influence decisions. This can also impact motivation toward treatment. Patients 5 and 7, respectively, stated,

It was my decision and my family’s decision. When we knew that I had cancer, we immediately followed this up. We discussed all the options together and I considered what my

| Table 1. Demographic and clinical characteristics of the patient cohort |
|-----------------------------|-----------------------------|
| Characteristic              | No. (%) of patients         |
| Sex                         |                             |
| Male                        | 11 (55)                     |
| Female                      | 9 (45)                      |
| Age, yr                     |                             |
| 50–59                       | 7 (35)                      |
| ≥ 70                        | 11 (55)                     |
| Primary language            |                             |
| English                     | 10 (50)                     |
| Portuguese                  | 5 (25)                      |
| Arabic                      | 1 (5)                       |
| Filipino                    | 1 (5)                       |
| Polish                      | 1 (5)                       |
| Russian                     | 1 (5)                       |
| Spanish                     | 1 (5)                       |
| Race                        |                             |
| African                     | 2 (10)                      |
| British                     | 1 (5)                       |
| White Canadian              | 1 (5)                       |
| Jewish Canadian             | 1 (5)                       |
| Ecuadorian                  | 1 (5)                       |
| Filipinos                   | 1 (5)                       |
| Israeli Muslim              | 1 (5)                       |
| Latin American              | 1 (5)                       |
| Polish European             | 1 (5)                       |
| Russian European            | 1 (5)                       |
| Spanish European            | 1 (5)                       |
| Employment status           |                             |
| Unemployed/retired          | 18 (90)                     |
| Employed                    | 2 (10)                      |
| Tumour site                 |                             |
| Colon                       | 11 (55)                     |
| Rectum                      | 9 (45)                      |
| Cancer stage                | 9 (45)                      |
| 0 (carcinoma in situ)       | 1 (5)                       |
| I                           | 4 (20)                      |
| IV                          | 5 (25)                      |
| Surgical procedure          |                             |
| Lower anterior resection    | 10 (50)                     |
| Hernicolectomy              | 5 (25)                      |
| Abdominoperineal resection  | 2 (10)                      |
| Subtotal colectomy          | 2 (10)                      |
| Total colectomy             | 1 (5)                       |
| Neoadjuvant therapy         | 9 (45)                      |
| *One participant completed only the first year of university.
children were telling me. Sometimes they knew more about the benefits of surgery or chemotherapy than I did.

It's my kids, my kids they want me to live and so does my wife. My kids say 'Daddy, we don't want you to die.' And this played a big role in my decision-making process.

Second, family members can function as interpreters for patients whose primary language is not English, obviating the need for third-party translators. This may result in greater patient honesty, trust and comfort, and thus serve to support patient decision-making. One patient's son said,

There is a language barrier so at all times, it would be either myself or my sister with him while he's speaking with the physician or any health care team member, and as such, we would do our best to give him all of the relevant information that they shared with us. He would often take the initiative to make decisions on his own.

Finally, family and friends are a source of practical, emotional and psychological support for patients. Patients 19 and 16, respectively, stated,

Even my daughter-in-law comes, she drives me down to clinic, my son too, and oftentimes my daughter. As a family, we are together.

I have a lot of friends in and around the community. And they're very supportive, always there to give encouraging words of support.

Furthermore, having a robust social support network reduces the burden of decision-making, eases uncertainty and improves patient experience. Patients 8 and 13, respectively, stated,

I think the whole thing was not knowing what the outcome was going to be, whether I was going to be okay after having the surgery. But I had excellent support from my husband and my family so that helped mitigate some of the anxiety.

My family and friends are my go-to source for emotional and psychological comfort. I can't imagine how I'd deal with a diagnosis like stage III colon cancer without their everlasting support. They keep me sane and most importantly, they make me happy, even when everything else is not going my way.

Facilitators and barriers to decision-making
Facilitators and barriers in the decision-making process affect patient confidence in their care and ability to make informed decisions. For instance, patient perception of quality and staff characteristics can strengthen trust. Patients 2 and 3, respectively, stated,

I'm so lucky because I have very good doctors. I am glad I went to the right hospital and received treatment from an excellent team of surgeons and nurses. They treated me, they made sure I lived as long as possible.

I know I am going for a big surgery and I only believe in you. I believe in your books, I believe in your education, and I believe that you are a good doctor. I don't believe in anything else.

Moreover, patients rely on the information they receive from providers in order to make decisions. Patients 7 and 14, respectively, stated,

We definitely trusted the information. We relied on the doctors and the staff. Our surgeon was very reassuring. He said that he would have treated his dad in the same way, you know? And the fact he was confident in his approach, it made us feel very comfortable and safe.

I felt very secure, in his explanation of what he was going to do. I was very confident in him, as it seemed like he had a good handle on what I was going through. He's a fabulous doctor, I can tell you that!

Additionally, personal beliefs and convictions can help patients cope through the decision-making process. Patients 20 and 1, respectively, stated,

I rely on the specialist. I have faith and they are the experts so I put myself in their hands. And the hands of God of course."

I know it's a little hard for me, but what can I do? I try to survive. I don't want to die yet. I don't want to give up, I want to go all the way. I hope I can stay in this world a little bit more.

However, language is a potential barrier to the SDM process. Patient 11's family and Patient 8, respectively, stated,

Certainly the language barrier is there. Another barrier I would identify is the lack of educational resources on his particular type of cancer that he can read and understand, like in his language.

Although we were happy with the care we received, it made it tough at times to really understand what my options were. I can manage with English, but getting information in Spanish definitely would have made a big difference in the decision-making process.

Lack of choice and control in decision-making
Many patients feel a limited sense of control over decisions and that there are limited alternatives for treatment. This
is particularly true if patients are admitted to hospital on an emergency basis. Patients 18, 16 and 7, respectively, stated,

It was done so quickly I did not really have a chance to make any decisions. I just did exactly what they told me to do.

On Tuesday I got a phone call and on Thursday I was on the operating table. There weren’t any real decisions to make. It was made for me.

I do whatever they tell me to do. It’s not like I was given much of a choice or menu of options anyways!

Furthermore, the life-threatening nature of the initial cancer diagnosis leads patients to believe that surgical intervention is inevitable and that there are few, if any, decisions to be made. This perception of lack of choice and control in decision-making is held by patients across all cancer stages. Patient 9 stated,

(…) he told me the most is 3 months if you don’t get the surgery. In my mind, this meant that I really didn’t have much of a choice. I had to get this thing out of me, otherwise, it will take my life.

In fact, many patients in our study were given limited options. They were told or advised what treatment course would be taken (and patients generally accepted this).

Influence of sociodemographic and cultural factors

It is important to recognize that all 3 themes transcended differences in sociodemographic variables, such as age, language, race and education. Patient 3 stated,

Finding support in your family and friends is a lot more important than cultural background I think. Background, we are all the same. Whether we are born in a different country, raised to a different value, but if you have these values I think you go through life a little easier.

While several patients identified language as a potential barrier to the SDM process, their level of involvement in decision-making, as measured using a 10-point Likert scale, did not differ from that among patients who spoke English as a primary language (Table 2). The number of family members present in clinic was also similar between the groups. When patients were stratified based on race, there was no difference in level of involvement in care or familial support.

DISCUSSION

Using a qualitative research design, we studied the complexities of SDM for patients undergoing a major operation for CRC. Three major themes were identified that represent factors shaping decision-making in this setting: 1) family plays a central role in supporting patients, and social support reduces patient burden; 2) patient confidence in care and the decision-making process is influenced by facilitators and barriers, such as provider communication and information; and 3) patients experience a lack of control and limited choice in treatment decisions. These findings persisted across race and disease stage, which suggests that cultural influences may be less important in patient decision-making than family engagement and social network. More importantly, this calls into question the very notion of SDM in colorectal surgical oncology.

A total of 20 patient interviews were completed, at which time data saturation was achieved. A recent experiment using 60 qualitative interviews found that saturation occurred within the first 12 interviews and that elements for meta-themes were present as early as the first 6 interviews. Therefore, we believe that our sample size was sufficient for thematic exploration of this topic.

The findings from our study add meaningful substance to the existing, yet very limited, body of literature on SDM among patients with CRC undergoing surgery. Previous studies have focused almost exclusively on the physician–patient interaction, with little, if any, emphasis on the impact of familial or cultural factors in the SDM process. Patients in our cohort valued family as a crucial adjunct to the health care team, recognizing 3 specific roles for family members (collaborators, interpreters and supporters) that enable and influence decision-making while reducing the burden on patients and enhancing their overall experience. Consequently, within a model of patient-centred care, the involvement of family in patient decision-making is an important consideration for surgeons and other health care providers involved in their cancer care. Moreover, family engagement appears to be important despite race, and level of involvement in decision-making is similar between patients who speak English as a primary language and those who do not (likely owing to the presence of family members in clinic who provided translation). Although family members may not have the same level of health

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Table 2. Level of involvement in care and social support by primary language and race*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Factor; mean (median)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Level of involvement</td>
</tr>
<tr>
<td>English as primary</td>
<td>9 (10)</td>
</tr>
<tr>
<td>language (n = 10)</td>
<td></td>
</tr>
<tr>
<td>English as secondary</td>
<td>8 (10)</td>
</tr>
<tr>
<td>language (n = 10)</td>
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</tr>
<tr>
<td>European (n = 11)</td>
<td>8.2 (10)</td>
</tr>
<tr>
<td>Non-European (n = 9)</td>
<td>8.9 (10)</td>
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</tbody>
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*Rated on a 10-point Likert scale.
literacy as professional interpreters, they may be able to facilitate understanding by serving as a cultural advisor or advocate for the patient. While it is essential to make professional interpreters available, family involvement is often important to a patient’s identity and can facilitate informed and autonomous decision-making. Psychosocial oncology services should be used to augment emotional and psychological support, especially for patients who do not have a strong social support network.

Furthermore, favourable surgeon characteristics and adequate patient education can improve perception of quality and confidence in the care being delivered. Seriously ill patients tend to value a surgeon who is capable of balancing honesty and open communication with hope and empathy. A confident and compassionate surgeon must also strive to educate patients about their disease, as patients who are psychologically prepared for surgery tend to have better surgical outcomes. Meeting the patient’s need for information regarding the surgical experience can also alleviate certain fears and misunderstandings about care. Patients who are more knowledgeable about what to expect after surgery and who have an opportunity to express their goals and opinions often cope better in the postoperative period.

A humanistic bedside manner, therefore, goes a long way in fostering a strong doctor–patient relationship, which ultimately empowers patients and their families to make informed treatment decisions with a high degree of satisfaction.

A limited sense of control over decisions and a perception of lack of choice were also pervasive in the patient interviews. A majority of patients expressed an increased sense of vulnerability. Patients, particularly those admitted to hospital on an emergency basis or with end-stage disease, felt helpless as they believed that progression of disease was out of their hands. Despite being informed about treatment alternatives, the life-threatening nature of CRC led patients to believe that surgical intervention was inevitable. In the future, informing patients about genetic predisposition and the role of lifestyle factors in cancer may reduce fatalistic attitudes and increase their sense of control over their diagnosis.

Although SDM among patients, families and health professionals is increasingly advocated as optimal, there is contradictory evidence as to what role patients with cancer prefer to play in the decision-making process. A previous study reported that patients with CRC wanted to be informed and involved in their care, but did not necessarily want to make any decisions. Another small pilot study of patients with CRC found that more than two-thirds of participants preferred a passive decision-making role; however, 80% of patients in the study said that they had not been presented with any treatment alternatives. We found similar results. Although patients in our study were educated about their diagnosis and treatment options — surgery, radiation, chemotherapy, and watchful waiting — a majority were comfortable with deferring the final decision and treatment plan to the “expert” members of the health care team. Notably, surgery remains the primary curative treatment for CRC, and so it is understandable that many patients may believe it to be their only option.

This preference for passive decision-making has also been observed in patients with different cancers. A UK study of 150 women with newly diagnosed breast cancer reported that 52% relied on doctors to make decisions about their care, preferring instead to be involved passively in decision-making. Similarly, a study involving 57 Canadian men with prostate cancer found that 58% favoured the same. Patient acceptance of passive decision-making in cancer care might be reflective of their limited medical knowledge and general trust in medical expertise. This exemplifies the concept of “entrustment” described by McKneally and colleagues, who interviewed patients after major surgery. The patients they interviewed rejected the concept of weighing risks and benefits and other processes aimed to maximize their autonomy. They were also resigned to the risks of treatment and accepted the expert recommendation to consent to surgery. In essence, the patients in the study universally trusted “the competence and willingness of their surgeons to make good treatment decisions on their behalf.” Surgeons and other health care providers must strive toward cultivating a sense of trust and open communication with their patients in order to foster trust and further enrich the doctor–patient relationship.

There is a tremendous focus on cancer in the media and a relentless effort to fight advanced stages of the disease, which ultimately shapes public opinion and in turn patient motivation toward treatment in clinical practice. Patients are often willing to undergo aggressive treatments with small benefits in spite of major toxicity and treatment-related morbidity. Surgeon bias toward surgery may also contribute to patient interest in surgery. However, in an era of conscious health spending, increased awareness of treatment options and the evidence surrounding each is important to improve public understanding of disease course. Furthermore, critical discussions among patients, families and providers about available treatment options are needed to prevent unnecessary intervention, as there is growing evidence that surgery may not add benefit in patients with some advanced cancers; for example, surgical resection of metastatic CRC in a patient with minimal symptoms attributable to the primary tumour often does not improve outcome and may delay systemic therapy. Thus, there may also be a role for surgical oncologists in initiating early conversations about palliative care with patients and their families in select cases; SDM can serve as a platform to promote these discussions in the clinical setting.
Limitations

The results of our study are subject to several limitations. The findings represent the views of patients under the care of a single surgical oncologist. The use of convenience sampling, resulting in a cohort with 90% of patients older than 65 years, may also limit the generalizability of our results. Future studies should aim to recruit a diverse cross-section of patients undergoing CRC surgery with unique treatment experiences to further explore the themes presented in this study. Moreover, we focused on the disease-directed treatment decision-making process from the patient’s perspective. Additional research that examines surgeon and other health care provider perspectives as well as other aspects of care would provide a more comprehensive picture of SDM in this context. For instance, it would be beneficial to explore the perspectives of patients who declined surgery and the decision-making process that results in a nonsurgical approach to CRC. Finally, although patients were in the early postoperative phase (within 3 mo of surgery) during interviews, some of our results may be limited by recall bias. In retrospect, postoperative patients may see their choice to undergo surgery as inevitable, thereby conveying a relative lack of choice or control in the decision-making process. This underscores the importance of future prospective studies to further elucidate the intricacies of SDM among patients with CRC.

Nonetheless, this study expands our understanding of the current milieu of SDM in CRC surgery. Surgeons and other health care providers must learn to appreciate the role of family as a vital addition to the patient–provider dyad and that familial influences are integral to SDM, patient satisfaction and empowerment. Physicians must also remain sensitive to each patient’s unique preferences, as the term “decision-making” can be a potential misnomer, particularly for patients undergoing surgical resection of late-stage disease.

CONCLUSION

Sociodemographic factors, including age, culture and education, may be less important than family engagement and social support for patients who require surgical treatment for CRC. Health care providers must be aware of the uniqueness of decision-making in this context in order to empower patients and their families. Institutional measures must be undertaken to enhance patient education about SDM. Instructive resources, including information packages and brochures in a patient’s primary language, can help patients and their families make informed and meaningful treatment decisions.

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Competing interests: None declared.

Contributors: All authors designed the study. D. Hirpara acquired and analyzed the data, which M. Cleghorn and F. Quereshy also analyzed. D. Hirpara and M. Cleghorn wrote the article, which all authors reviewed and approved for publication.

References

Traumatic spinal injuries in children at a single level 1 pediatric trauma centre: report of a 23-year experience

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Background: With a reported incidence of up to 10% compared to all spinal trauma, spinal injuries in children are less common than in adults. Children can have spine fractures with or without myelopathy, or spinal cord injuries without radiological abnormalities (SCIWORA).

Methods: We retrospectively reviewed the cases of children with spinal injuries treated at a level 1 pediatric trauma centre between 1990 and 2013.

Results: A total of 275 children were treated during the study period. The mean age at admission was 12 ± 4.5 years, and the male:female ratio was 1.4:1. Spinal injuries were more common in children of ages 12–16 years, with most injuries among ages 15–16 years. The top 3 mechanisms of spinal injury were motor vehicle–related trauma (53%), sports (28%) and falls (13%). Myelopathy occurred in 12% and SCIWORA occurred in 6%. The most common spine levels injured were L2–sacrum, followed by O–C2. Associated injuries, including head injuries (29%), and fractures/dislocations (27%) occurred in 55% of children. Overall mortality was 3%. Surgical intervention was required in 14%.

Conclusion: The creation of a pediatric spinal injury database using this 23-year retrospective review helped identify important clinical concepts; we found that active adolescent boys had the highest risk of spine injury, that noncontiguous spine injuries occurred at a rate higher than reported previously and that nonaccidental spine injuries in children are under-reported. Our findings also emphasize the importance of maintaining a higher index of suspicion with trauma patients with multiple injuries and of conducting detailed clinical and radiographic examinations of the entire spine in children with a known spinal injury.
Although traumatic spinal injuries in pediatric patients are relatively rare, accounting for only 1%–10% of all reported spinal injuries, these injuries may contribute to substantial morbidity and mortality in children. The overall incidence of spinal injuries among children in the United States is 7.41 per 100 000. Another study reported that the incidence of spinal cord injury in the pediatric population within the United States is 18.1 injuries per 1 million children, representing approximately 1300 new cases per year. The true incidence may be underestimated, because spinal injuries can be masked by other features of trauma. Therefore, a thorough understanding of spinal injuries is essential so that they are not overlooked. Different specialists involved in the care of children with spinal injuries should be aware of these findings. The aim of this study was to review spinal injuries in children admitted to a level 1 pediatric trauma centre by both the orthopedic and neurosurgery services at the Children’s Hospital of Eastern Ontario (CHEO) in Ottawa, Ont. We investigated the epidemiology, mechanisms of injury, levels of the spinal injuries and types of injury as well as the morbidity and mortality associated with spinal injuries. Population-based, disease-specific surveillance data on injury are the hallmark of the public health approach to all burden of disease, including surgical trauma, and are required for the development of treatment and prevention strategies for traumatic spinal injuries.

METHODS

Retrospective chart review

This study was approved by the research ethics board at CHEO. We performed a retrospective chart review of consecutive patients admitted to hospital with spinal injury using a 3-pronged approach to identify all spinal injuries over the defined study period of 1990–2013. First, we used ICD-10 codes (Appendix 1, available at canjsurg.ca) to identify hospital charts through the medical records department for the study period. Second, a hospital-based trauma registry was developed in 2000, and this was also used as a source to identify study patients. Finally, a fracture database maintained independently by the Division of Pediatric Orthopedics for research purposes was also used.

Spinal injuries included all spinal fractures, subluxations or dislocations with or without myelopathy, and spinal cord injury without radiologic abnormality (SCIWORA). Minor spinal fractures, such as spinous process and transverse process fractures, were considered spinal injuries and were also included in this study as they were referred to the surgical service (either orthopedic or neurosurgery). Data collection included patient demographics, mechanism of injury, levels of injury, extent of neurologic injury and recovery, associated injuries, treatment and follow-up. Children were grouped by age in our analyses: infants (0–1 yr), toddlers (2–4 yr), school age (5–13 yr) and adolescents (14–18 yr).

RESULTS

Study sample

A total of 275 children were admitted to CHEO with spine injuries during the 23-year study period (1990–2013). The mean age was 12 ± 4.5 years (range 2 mo to 18 yr). Spinal injuries were most common in older children and teens aged 12–16 years, with the highest incidence in the 15–16 year age group; among younger children, injuries were most common in 4- and 6-year-olds (Fig. 1). The overall male:female ratio was 1.4:1. For injuries related to sports and falls, boys outnumbered girls 2.9:1 and 1.9:1, respectively. For fractures of the spine related to nonaccidental injuries in children, all 6 cases in our series involved boys, and for spine fractures related to other etiologies the ratio was equal. For motor vehicle–related injuries, the male:female ratio was 1:1.2.

Etiology of injury

Among all age groups, the predominant etiology of spinal injury was motor vehicle–related (53%). Of these, 38% were motor vehicle crashes (MVC), 5% involved motor vehicles and either bicycles or pedestrians, 4% involved recreational vehicles (e.g., dirt bike, snowmobile, all-terrain vehicle [ATV]), and 1% involved motor vehicles and motorcycles. Sports injuries accounted for 28% of all injuries, followed by falls (13%), other etiologies (4%) and child abuse (2%; Table 1).

The mean age of children with motor vehicle–related spinal injuries was 11.6 ± 4.7 years (range 10 mo to 18 yr). Of the 146 motor vehicle–related injuries, 72 (49%) involved adolescents, 54 (37%) involved school age children, 18 (12%) involved toddlers and 2 (1%) involved infants. The mean age of children with sports–related spinal injuries was 14.0 ± 2.3 years (range 4–18 yr). Of the 78 sports–related injuries, 51 (65%) involved adolescents, 26 (33%) involved school age children and 1 (1%) involved a toddler; no infants had sports-related injuries. More than one-fifth (22%) of sports-related injuries occurred while playing hockey (n = 17). Snowboarding (n = 10), diving (n = 8), biking (n = 7), football (n = 6) and skiing (n = 6) were the next most frequent sports-related mechanisms of injury, followed by tobogganing (n = 5), horseback riding (n = 5), trampoline (n = 3), gymnastics (n = 2) and wrestling (n = 2). Only 1 child in each of the following sports experienced a spinal injury: soccer, track and field, cheerleading, parkour, basketball, rugby and skateboarding.

The mean age of children whose spinal injuries were due to falls was 10.3 ± 4.6 years (range 6 mo to 17 yr). More than half of these injuries (51%) occurred in school age children, 34% occurred in adolescents, 11% occurred in toddlers and 3% occurred in infants. About one-third (31%) of these children fell out of a tree, 14% fell out of a window, 9% fell off playground equipment and the remainder fell from other surfaces (e.g., from a balcony, ladder, roof, cliff, urinal, farming equipment, stairs).
The mean age of children with spinal injuries due to other etiologies was $13 \pm 2.6$ years (range 9–16 yr). Half of these injuries occurred in school age children and the other half occurred in adolescents; 30% occurred while playfighting and the rest occurred in other circumstances (e.g., jumping off a railing, jumping out of a window, being pushed into lockers, running into a post, receiving a gunshot wound, falling on ice and falling off a deck).

The mean age of children with spinal injuries due to child abuse was $6.6 \pm 3.8$ months (range 2–10 mo).

**Level of injury**

The most commonly injured region of the vertebral column or spinal cord in all age groups was L2–sacrum ($n = 72$), followed by O–C2 ($n = 46$), T11–L1 ($n = 44$), C3–C7 ($n = 42$), T1–T10 ($n = 39$) and noncontiguous spinal levels ($n = 32$; Table 2). Of the 32 (12%) children with noncontiguous spinal injuries (NCSI), the mean age was $11.3 \pm 4.9$ years (range 10 mo to 17 yr), and overall male:female ratio was 1.1:1.

**Myelopathy/clinical spinal cord injury**

Spinal injury with myelopathy accounted for 12% of all injuries in this study. The mean age of children with myelopathy was $12.2 \pm 4.1$ years (range 2–17 yr). Myelopathy occurred most commonly in older children; approximately 74% of children with myelopathy were aged 12 years or older. The overall male:female ratio of these children was 1.6:1; the ratio in children younger than 12 years was 1.3:1, and that in children aged 12 years and older was 1.8:1. Spinal cord injuries in children most often occurred as a result of motor vehicle–related trauma ($n = 16$), sports-related injuries ($n = 15$), falls ($n = 2$) and a gunshot wound ($n = 1$; Table 3). In children younger than 12 years, the most common causes were motor vehicle–related trauma, followed by a fall and gunshot wound. In older children, the most common causes were sports-related injuries, followed by motor vehicle–related traumas and a fall.

All children with myelopathy ($n = 34$) presented with a range of neurologic deficits extending from transient paraesthesias or paresis to permanent hemiplegia or paraplegia. Of these children, 19 presented with transient and 15 with permanent neurologic deficits. Eight had sensory deficits only, 7 had motor deficits only, and 19 had both sensory and motor symptoms. There were 2 SCIWORAs, 23 spinal cord injuries with fractures and 9 SCIWORAs other than fractures. Of the 15 children with permanent neurologic deficits, 10 were paraplegic (7 owing to MVCs, 2 owing to sports-related injuries and 1 owing to a gunshot wound), 2 were quadriplegic (both owing to sports-related injuries), 2 were hemiplegic (both owing to MVCs) and 1 had

![Fig. 1. Age distribution of children with spine injuries at all levels.](image-url)
sensory deficits only (owing to an MVC). Numerous long-term complications were observed during follow-up for the patients with permanent neurologic deficits. Among the 10 paraplegic patients, all 10 had lower extremity weakness, 9 had neurogenic bladders, 2 had scoliosis, 1 was kyphotic and 1 had chronic autonomic dysreflexia. The quadriplegic patients had decreased sensation and motor function of the upper and lower extremities and no fine motor movement. The children with hemiplegia had upper and lower extremity weakness.

The most commonly injured regions in children with myelopathy were C3–C7 and NCSI, followed by O–C2, L2–S, T1–T10 and T11–L1 regions (Table 2). There were no deaths attributable to myelopathy (Table 3).

**SCIWORA**

In total, SCIWORA occurred in 2 (6%) patients with myelopathy, whose mean age was 13.5 ± 2.1 years. Both patients were boys, and the mechanisms of injury were

<table>
<thead>
<tr>
<th>Table 1. Etiology of injury</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age group; no. of patients</strong></td>
</tr>
<tr>
<td><strong>Mechanisms of injury</strong></td>
</tr>
<tr>
<td>Motor vehicle crash</td>
</tr>
<tr>
<td>Accident</td>
</tr>
<tr>
<td>Pedestrian</td>
</tr>
<tr>
<td>Bicycle</td>
</tr>
<tr>
<td>Recreational*</td>
</tr>
<tr>
<td>Motorcycle</td>
</tr>
<tr>
<td>Sports-related</td>
</tr>
<tr>
<td>Hockey</td>
</tr>
<tr>
<td>Snowboarding</td>
</tr>
<tr>
<td>Diving</td>
</tr>
<tr>
<td>Biking</td>
</tr>
<tr>
<td>Football</td>
</tr>
<tr>
<td>Skiing</td>
</tr>
<tr>
<td>Tobogganing</td>
</tr>
<tr>
<td>Horseback riding</td>
</tr>
<tr>
<td>Trampoline</td>
</tr>
<tr>
<td>Gymnastics</td>
</tr>
<tr>
<td>Wrestling</td>
</tr>
<tr>
<td>Soccer</td>
</tr>
<tr>
<td>Track and Field</td>
</tr>
<tr>
<td>Cheerleading</td>
</tr>
<tr>
<td>Parkour</td>
</tr>
<tr>
<td>Basketball</td>
</tr>
<tr>
<td>Rugby</td>
</tr>
<tr>
<td>Skating</td>
</tr>
<tr>
<td>Falls</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Nonaccidental Injury</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

*Includes dirt bike (n = 1), snowmobile (n = 5) and all-terrain vehicle (n = 6).

<table>
<thead>
<tr>
<th>Table 2. Levels of injury in all age groups</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level of injury to vertebral column or spinal cord</strong></td>
</tr>
<tr>
<td><strong>Age group</strong></td>
</tr>
<tr>
<td>Infant</td>
</tr>
<tr>
<td>Toddler</td>
</tr>
<tr>
<td>School age</td>
</tr>
<tr>
<td>Adolescent</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

C = cervical; O = occipital; L = lumbar; NCSI = noncontiguous spinal injuries; S = sacral; T = thoracic.
MVCs and sports. The school age patient (12 yr) sustained injury in the T1–T10 region, specifically at the T1–T3 level. The specific mechanism of injury in this patient was an unbelted MVC. The patient presented with both sensory and motor deficits, and initial magnetic resonance imaging (MRI) revealed a contusion or hematoma of the spinal cord at the T1–T3 level; the thoracic spine radiograph was normal. The patient was treated with methylprednisolone and a neck and thoracic brace. He had a complete spinal cord injury with complete loss of motor function below the middle thoracic region. He was paraplegic with a neurogenic bladder. The second patient with a SCIWORA was an adolescent (15 yr) who sustained an injury in the subaxial cervical region (C4–C5). The etiology was identified as a football injury. The patient presented with temporary lower extremity sensory deficits that lasted for 2 days. Positive MRI findings showed a focal central disc herniation, and the cervical spine radiograph was normal. The patient was treated with methylprednisolone, bed rest and a soft cervical collar. He made a complete neurologic recovery.

**Associated Injuries**

In total, 45% of children had isolated spinal injuries. Of the 151 (55%) children who had other associated injuries, the most commonly associated injuries were head (29%), orthopedic (27%), visceral (13%) and other body systems injuries (Table 4). Children with NCSI had associated injuries in 56% of cases, those with myelopathy had associated injuries in 65% of cases, and patients who died had associated injuries in 89% of cases.

**Table 3. Patient and injury characteristics in all spinal injury patients and subgroups**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All spinal injuries (n = 275)</th>
<th>Myelopathy (n = 34)</th>
<th>Permanent neurological injuries (n = 15)</th>
<th>Mortality (n = 9)</th>
<th>SCIWORA (n = 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD, yr</td>
<td>12 ± 4.5</td>
<td>12.2 ± 4.1</td>
<td>11.1 ± 5.0</td>
<td>9.3 ± 5.3</td>
<td>13.5 ± 2.1</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>158</td>
<td>21</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>117</td>
<td>13</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Mechanism of injury</td>
<td>Motor vehicle–related</td>
<td>146</td>
<td>16</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Sports-related</td>
<td>78</td>
<td>15</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Falls</td>
<td>35</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>10</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Child abuse</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Injury level</td>
<td>O–C2</td>
<td>46</td>
<td>5</td>
<td>1</td>
<td>6</td>
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<tr>
<td></td>
<td>C3–C7</td>
<td>42</td>
<td>8</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>T1–T10</td>
<td>39</td>
<td>4</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>T11–L1</td>
<td>44</td>
<td>4</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>L2–S</td>
<td>72</td>
<td>5</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>NCSI</td>
<td>32</td>
<td>8</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>SCIWORA</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Associated injury</td>
<td>None</td>
<td>124</td>
<td>12</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Head injury</td>
<td>81</td>
<td>11</td>
<td>5</td>
<td>8</td>
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<tr>
<td></td>
<td>Orthopedic injury</td>
<td>73</td>
<td>10</td>
<td>5</td>
<td>2</td>
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<tr>
<td></td>
<td>Visceral injury</td>
<td>35</td>
<td>7</td>
<td>6</td>
<td>3</td>
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<tr>
<td></td>
<td>Chest injury</td>
<td>28</td>
<td>3</td>
<td>2</td>
<td>3</td>
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<tr>
<td></td>
<td>Genitourinary injury</td>
<td>14</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Maxillofacial injury</td>
<td>23</td>
<td>3</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Treatment</td>
<td>Conservative</td>
<td>150</td>
<td>9</td>
<td>6</td>
<td>7</td>
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<tr>
<td></td>
<td>Collar or brace</td>
<td>67</td>
<td>10</td>
<td>0</td>
<td>2</td>
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<tr>
<td></td>
<td>Halo Vest</td>
<td>19</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Surgery</td>
<td>39</td>
<td>14</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Death</td>
<td>9</td>
<td>0</td>
<td>0</td>
<td>9</td>
</tr>
</tbody>
</table>

C = cervical; O = occipital; L = lumbar; NCSI = noncontiguous spinal injuries; S = sacral; SCIWORA = spinal cord injuries without radiological abnormalities; SD = standard deviation; T = thoracic.

*Unless indicated otherwise.
Mortality

Overall, 9 (3%) children with spinal injuries died. The mean age of these children was 9.3 ± 5.3 years (range 2–16 yr); 7 were boys. All deaths were motor vehicle–related, 1 of which involved a snowmobile. Six children died with O–C2 spine injuries, 2 with NCSI and 1 with an L2–S injury following a motor vehicle–pedestrian collision. Both of the children who died with NCSI had a section of their cervical spine involved. Eight of the 9 deceased children had closed head injuries (CHI); however, only 3 children died exclusively from CHI. Another 3 of the children with CHI had associated injuries: 1 had multiple traumatic injuries on autopsy, including fracture/dislocation and transection of the spinal cord at the C6–C7 and L1–L2 levels, and severe abdominal and cardiothoracic injuries; 1 had distraction at the C6–C7 level; and 1 had distraction at the C1–C2 level. Of the other 3 children who died, 1 had a complete C1 dislocation, 1 had a complex fracture of C3 and distraction at the C2–C3 level, and 1 died of a second MVC after recovering from the first one, but this child had no follow up at CHEO.

Treatment

Thirty-nine of 275 (14%) children with spinal injuries required operative treatment. Of these, 33 patients underwent posterior spinal fusion and 6 had open reduction and internal fixation. Fourteen of 34 children with myelopathy required operative intervention (Table 4).

Use of injury prevention devices

Of the 103 children injured in MVCs, 80 (78%) were reported to be appropriately restrained, whereas 23 (22%) were unrestrained. Of the 9 children who died after MVCs, 5 were appropriately restrained and 4 were unrestrained.

DISCUSSION

Pediatric spine injuries are relatively rare events; however, their clinical outcomes can be devastating. The actual incidence of pediatric spine trauma may be under-reported. Außermair found evidence of fractures of the spine at autopsy in 12 of 100 children over an 8-year period; however, only 1 of the 12 children was thought to have a spine fracture before autopsy. As such, a high index of suspicion is always warranted, especially in light of distracting injuries (i.e., associated injuries, such as abdominal, chest or head injuries seen in seriously traumatized children and adolescents).

Pediatric series on spine fractures have typically been small because of the nature of pediatric centres with small numbers. Few large, multicentre series exist. At many centres the care of spinal injuries may be shared between the orthopedic service and the neurosurgical service, further diluting reported series, which may not be multidisciplinary. Our series reports the combined pediatric spinal injury referrals of 275 children to the orthopedic and neurosurgical services at a single level 1 pediatric trauma centre over a 23-year period. The Trauma Association of Canada (TAC), a multidisciplinary association of health care professionals committed to promoting injury control and excellence in trauma care throughout Canada, mandate provincial and regional injury surveillance and reporting via a trauma registry or database from participating trauma centres. Recently, the Canadian Pediatric Spine Society (CPSS) discussed the further development of a pediatric module for a national Canadian Spine Society registry to promote an evidence-based approach to clinical care, patient safety and quality assurance. Presently, there is no Canadian pediatric spine trauma registry.

The demographic characteristics of our patient population were similar to those of other studies with pediatric patients sustaining only cervical spine injuries. Similar to Brown and colleagues and Orenstein and colleagues, we found a bimodal age distribution, with the highest number of injuries in occurring in children aged 12–16 years and a smaller increase around the ages of 4 and 6 years. There were no differences in the age distribution between our study, which included injuries to all regions of the spinal cord, and studies investigating only cervical spine injuries. Like most other series in the literature, our study shows that spinal injury occurs more commonly in adolescents than in children aged 8 years or younger. Likewise, we found that boys were more commonly injured than girls, with an overall male:female ratio of 1.4:1.

Similar to other studies, we found that the most frequent etiology of spinal injury in children overall was MVCs. Hamilton and colleagues, Martin and colleagues, Mann and colleagues and Osenbach and colleagues reported that nearly half of all their patients with spinal injuries were caused by MVCs (50%, 46%, 52% and 50% of all injuries, respectively). In our study, more than half (53%) of all spinal injuries were motor vehicle–related. More specifically, studies have reported that the most common mechanisms of injury in young children are MVCs, pedestrian–motor vehicle collisions or falls and in older children are sports-related injuries, diving accidents and gunshot injuries. In our series, the most common mechanism of injury in young children was MVCs, followed by an even distribution of sports-related injuries and falls. In our older children, the most frequent

| Table 4. Associated injury distribution in spinal trauma patients |
|-----------------|------------------|
| Associated injury | No. (%) of patients |
| None            | 124 (45)         |
| Head injury     | 81 (29)          |
| Orthopedic injury | 73 (27)       |
| Visceral injury | 35 (13)          |
| Chest injury    | 28 (10)          |
| Maxillofacial injury | 23 (8)       |
| Genitourinary injury | 14 (5)      |
mechanism of injury was sports-related injuries. Sports-related injuries accounted for 28% of all injuries in our study. In a retrospective study of 103 consecutive cervical spine injuries treated in a single level 1 pediatric trauma centre, Brown and colleagues\textsuperscript{8} reported that sports-related injuries accounted for 27%; of these, 29% were associated with football.\textsuperscript{8} In our study, 22% of sports-related injuries occurred while playing hockey, and these were the leading cause of sports-related injuries in our adolescent group. We believe this reflects the popularity of ice hockey in Canada.

The thoracolumbar injury classification and severity score (TLICS) was established to facilitate communication among surgeons and serve as a guideline for treating thoracolumbar injuries. The classification system is based on 3 major categories: morphology of the injury, integrity of the posterior ligamentous complex and neurologic status of the patient. The 4 major morphologic subcategories are compression injuries, burst injuries, translational/rotational injuries and distraction injuries.\textsuperscript{11} Among the 155 children in our series who sustained thoracolumbar injuries, 93 had compression injuries, 14 had burst injuries, 1 had a translational/rotational injury, 23 had distraction injuries and 24 had injuries that did not fit into 1 of the 4 TLICS morphologic subcategories (minor spinal fractures, spinous process fractures, transverse process fractures, SCIWORA). Consistent with several studies\textsuperscript{1,10} there was a marked association between flexion–distraction injuries and abdominal injury. In our study, 23 children sustained distraction injuries, and 15 of them had abdominal visceral injuries.

Intentional injury in infants is an increasingly recognized cause of injury to the spine.\textsuperscript{14} Avulsion fractures of the spinous process, fractures of the pars or pedicles or compression fractures of multiple vertebral bodies are the most common patterns of injury and may result from severe shaking or battering.\textsuperscript{15} All of the infants in this series had compression fractures of vertebral bodies in the thoracic, lumbar or multiple regions of the thoracic and lumbar spine. These injuries were often associated with other common signs of intentional injury to children, including head injury and fractures of the skull, ribs or long bones.

Like other studies of pediatric spinal trauma, we reported that spine fracture without spinal cord injury was more common than fracture with spinal cord injury.\textsuperscript{1,8,10} In addition, young children seem to sustain more cervical spine injuries, whereas adolescents tend to sustain more thoracic and lumbar injuries.\textsuperscript{11,16} In our study, the most common spinal levels injured were the L2–sacrum followed by the O–C2 regions. An O–C2 spine injury was the leading cause of death in our study. We believe that this reflects the anatomic features of these segments and that thoracic and lumbar spine injuries increase proportionally with the age of the child.\textsuperscript{17} Pang and Wilberger\textsuperscript{18} originally defined SCIWORA as spinal cord injury without evidence of radiographic abnormality. We defined SCIWORA as an acute spinal cord injury associated with a sensory or motor deficit or both,\textsuperscript{8} with a symptom duration of at least 24 hours and without evidence of injury on plain radiographs or computed tomography scans.\textsuperscript{19} We identified 2 (6%) cases of SCIWORA in the patients with myelopathic changes ($n=34$), which is within the wide range of published estimates of SCIWORA in the pediatric population with reported ranges of 1.3%–38%.\textsuperscript{1,8,11,20} The positive MRI results of these 2 patients assisted in the identification and prognosis of their injuries.

The location of injury in patients with SCIWORA commonly involves the cervical cord,\textsuperscript{20,21} but may also occur in the thoracic spine in association with high-energy trauma,\textsuperscript{22,23} such as MVCs. Trigylidas and colleagues\textsuperscript{20} found that 10% of myelopathic patients presented with associated head injuries and that 50% of these head injuries occurred in patients with SCIWORA.

Spine trauma in children and adolescents is frequently accompanied by associated injuries. In this series, we report a prevalence of associated injuries of 55%, which is similar to reported ranges in other series (42%–65%). Rush and colleagues\textsuperscript{24} found associated injury frequency to be the highest among children aged 13–19 years (64%), but not much lower than in those aged 0–3 years (57%) or 4–12 years (52%).\textsuperscript{24} They also reported spine injuries to be the most frequent in the older age group, similar to our results.

The incidence of NCSI reported in the literature over the last decade has been in the range of 6%–7%,\textsuperscript{25,26} although a large pediatric series recently reported an incidence of 17%.\textsuperscript{24} Our results also reflected a higher rate, with NCSI in 32 (12%) children; we defined NSCI as 1 intact vertebral segment between separate spinal injury levels. A significant rate of NCSI in children is an important finding that requires dissemination especially to front-line emergency workers who must maintain a high index of clinical suspicion when evaluating and imaging traumatized children. Our findings of a higher incidence than that reported a decade ago but in agreement with more recent and larger pediatric series may indicate a previous under-reporting of pediatric NCSI.

Rush and colleagues\textsuperscript{24} found that 74% of NCSI in pediatric patients occurred in a different radiographic spinal region than the index fracture, with the most common divergence being between the cervical and thoracic regions. The implication here is that the emergency physicians would need to image a separate spine region in order to make the second fracture diagnosis. Firth and colleagues\textsuperscript{27} found thoracic–thoracacic NCSI to be the most frequent, with a median vertebral divergence of 4 vertebral segments. With an average of 4 vertebral segments between NCSI, we support the idea of full radiographs of the hypermobile pediatric spine to clear NCSI, especially in children with high-impact injuries in which the distance between NSCI fractures can increase.\textsuperscript{27} This would be especially true in unconscious children in the presence of associated injuries, which we believe can distract from clinical examination of the injured spine.

We found NSCI primarily in the mean age-group of $11.3 \pm 4.9$ years. Rush and colleagues\textsuperscript{24} found the rate of
NCSI was highest in children aged 13–19 years, likely owing to the higher kinetic energies from MVCs and high-impact sports seen in the older age groups.

CONCLUSION

This study has added to the limited literature on children and adolescents with traumatic injuries that involve the spine, and it is important in that it represents the complete experience of a level 1 pediatric trauma centre over a prolonged period of time and includes children seen by the orthopedics and neurosurgery services. The population-based surveillance of the burden of surgical disease at referral centres such as ours has contributed literature on important clinical subgroups, such as children with NCSI and how the rates of such subgroups may have been previously underestimated. Moreover, our data underline another important and under-reported problem, that of spine injury in child abuse.

Our data also underscore how trauma patients with multiple injuries present a diagnostic and therapeutic problem. Physicians should perform detailed clinical and radiographic examinations of the entire spine, and we recommend that if 1 spine injury is found then the entire spine should be imaged to rule out a second clinically important spinal injury distant from the first. Use of MRI should be considered in patients presenting with neurologic deficits after spine trauma, with or without plain radiograph findings of a boney spinal injury.

In a recent systematic review of pediatric spinal cord injuries, Parent and colleagues concluded that traumatic spinal cord injuries should be highly suspected in the presence of abnormal neck or neurologic examinations, a high-risk etiology of injury or a distracting injury, even without radiologic abnormality. Finally, future efforts should continue to educate children, especially teenagers, about injury prevention.

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Contributors: M. Vassilyadi and P. Moroz designed the study. All authors acquired and analyzed the data. C. Kim, M. Vassilyadi, N. Moroz and P. Moroz wrote the article, which all authors reviewed and approved for publication.

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Clinical importance of bilateral disease in patients with papillary thyroid cancer

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A cancer-related factor that is not included in papillary thyroid cancer (PTC) prognostic scoring systems is bilaterality. While it may seem that bilaterality should be considered during the management of PTC, its clinical importance has been debated. This controversy exists because the extent of surgery for PTC has not been found to affect survival in low-risk individuals, despite their potential for PTC bilaterality. We sought to determine if PTC bilaterality is a cancer prognosticator based upon its association with known clinical and pathological PTC prognosticators, and MACIS scores. In this article we discuss our findings and their potential clinical implications.

Papillary thyroid cancer (PTC) is a highly prevalent endocrine malignancy with low recurrence rates and excellent prognosis. Many different prognostic scoring systems have been developed to predict outcomes for patients with PTC. One cancer-related factor that is not included in PTC prognostic scoring systems is the presence of PTC bilaterality. Although intuitively it seems that PTC bilaterality should be a consideration during PTC management, its clinical significance has remained controversial. This debate exists because the extent of surgery for PTC (i.e., lobectomy v. total thyroidectomy) has not been found to affect survival in low-risk individuals, despite their potential for PTC bilaterality. We sought to determine if PTC bilaterality is a cancer prognosticator based upon its association with known clinical and pathological predictors of PTC prognosis and MACIS scores.

We retrospectively reviewed all sequential PTC patients who underwent either total thyroidectomy or thyroid lobectomy and subsequent completion thyroid lobectomy at St. Paul’s Hospital, Vancouver, Canada, between 2000 and 2012. Demographic and histopathological risk factors and MACIS scores were compared between patients with unilateral and bilateral PTC, and statistical significance was determined using χ² analysis.

Our study population consisted of 203 PTC patients. Of these individuals, 82 (40.4%) had bilateral PTC, and 121 (59.6%) had unilateral PTC. Several clinical and histopathological PTC characteristics that are known to correlate with cancer prognosis were investigated using χ² analysis and are presented in Table 1. By definition, all patients with bilateral PTC were also considered to have multifocal PTC. Only 3 patients in the unilateral PTC group (2.5%) had evidence of multifocal disease within their involved thyroid lobe.

Of the 8 clinicopathological characteristics studied, only PTC size and the presence of lymphovascular invasion correlated with cancer bilaterality (Table 1). Not surprisingly, PTC multifocality was significantly different between the 2 groups since all patients diagnosed with PTC bilaterality had more than 1 focus of PTC, and thus harbored multifocal disease (Table 1).

Multifocality, defined as the presence of greater than a single intrathyroidal PTC focus, was further studied to determine if the principal site of multifocal PTC in the bilateral cases was ipsilateral or contralateral to the largest PTC focus. The mean size and number of multifocal lesions were 0.7 cm and 2.2 cm,
DISCUSSIONS EN CHIRURGIE

respectively. Out of 81 bilateral PTC cases, the majority of patients had their principal site of cancer multifocality ipsilateral to their largest cancer focus, a significant observation (50 cases, 61.7%, \( p = 0.035 \)). When individuals with predominantly ipsilateral multifocal PTC were compared with individuals with predominantly contralateral multifocal PTC, there were no significant differences observed. This finding is consistent with observations made by Hay and colleagues\(^1\) from the Mayo Clinic during the development of the MACIS prognostic scoring. Multicentricity was not found to predict risk of thyroid cancer mortality, and was therefore not incorporated into the MACIS score.\(^1\) Multicentricity was not found to predict risk of thyroid cancer mortality, and was therefore not incorporated into the MACIS score.\(^1\)

Perhaps the most surprising finding in our study was the association we observed between cancer size and lateralization. Specifically, PTC unilaterality was associated with larger cancer size (> 1 cm), and there also was a significantly higher proportion of individuals harbouring small PTCs in the bilateral group than in the unilateral group (26.8% v. 0%, \( p < 0.001 \)). In addition, the majority of individuals with multifocal PTC in the bilateral group had their principal site of multifocality within the same lobe as the largest PTC focus (61.7%, \( p = 0.035 \)). This is an important observation, because prior work has suggested that the presence of multifocal PTC predicts the presence of bilateral PTC, and thus suggests potential benefit from total thyroidectomy.\(^1\) Based on our observations, individuals harbouring small and otherwise low-risk PTCs, if treated with lobectomy alone, may have residual PTC foci present in the remnant lobe up to 26.8% of the time.

A recent population-level analysis confirmed previous findings that total thyroidectomy for PTC resulted in a higher 10-year overall survival, and a lower 10-year recurrence risk than lobectomy alone. In this study, it was shown that after adjusting for variables related to complexity of disease, the apparent overall survival advantage attributable to total thyroidectomy was not reproducible.\(^2\) Thus, even though current American Thyroid Association guidelines acknowledge that PTC has a predisposition for being both multifocal and/or bilateral, they stipulate that for cancers smaller than 4 cm with no evidence of gross extrathyroidal extension and no evidence of lymph node or distant metastatic disease, either near-total or total thyroidectomy or thyroid lobectomy may be considered adequate initial surgical treatment.\(^4\)

An important consideration is the underlying mechanisms that lead to PTC multifocality. It has been postulated that multifocal PTCs either represent multiple synchronous primary cancers that arise from independent clones, or that they are the consequence of intraglandular dissemination of a single malignant clone.\(^5\) The associations we observed between small PTC size, the presence of lymphovascular invasion and PTC bilaterality suggest we are either observing small, locally aggressive but independent cancer foci, or that they represent a single primary cancer that spreads early, through lymphovascular invasion, into the contralateral lobe. Even though the underlying pathophysiology of PTC bilaterality is currently controversial and further research is required, limited study of this question at the molecular level has supported the former theory.\(^5\)

The incidence of bilateral PTC in our study population was 40.4%, which is consistent with prior reports in the current literature.\(^3\) We found PTC bilaterality was associated with smaller cancer size and the presence of lymphovascular invasion. These observations suggest that the development of PTC bilaterality, regardless of the underlying mechanism, likely represents an early event that occurs during thyroid cancer development and progression. While our study does not necessarily suggest that individuals with small, otherwise low-risk PTCs should mandatorily undergo a total thyroidectomy, we believe that the propensity for bilateral disease should be clearly addressed in the discussion with thyroid cancer patients when planning the extent of their thyroid operation.

<table>
<thead>
<tr>
<th>Group, no. (%)</th>
<th>Bilateral</th>
<th>Unilateral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>0.52</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>55 (67.1)</td>
<td>90 (74.4)</td>
</tr>
<tr>
<td>Male</td>
<td>27 (32.9)</td>
<td>31 (25.6)</td>
</tr>
<tr>
<td>Age, yr</td>
<td>0.36</td>
<td></td>
</tr>
<tr>
<td>&lt; 45</td>
<td>31 (37.8)</td>
<td>59 (48.8)</td>
</tr>
<tr>
<td>≥ 45</td>
<td>51 (62.2)</td>
<td>62 (51.2)</td>
</tr>
<tr>
<td>Extrathyroidal extension</td>
<td>0.78</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>49 (61.2)</td>
<td>78 (65.0)</td>
</tr>
<tr>
<td>Yes</td>
<td>31 (38.8)</td>
<td>42 (35.0)</td>
</tr>
<tr>
<td>Size, cm</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>≤ 1</td>
<td>22 (26.8)</td>
<td>0</td>
</tr>
<tr>
<td>&gt; 1</td>
<td>60 (73.1)</td>
<td>121 (100)</td>
</tr>
<tr>
<td>Vascular extension</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>66 (80.5)</td>
<td>119 (98.3)</td>
</tr>
<tr>
<td>Yes</td>
<td>16 (19.5)</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>Multifocal disease</td>
<td>&lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>118 (97.5)</td>
</tr>
<tr>
<td>Yes</td>
<td>82 (100)</td>
<td>3 (2.5)</td>
</tr>
<tr>
<td>Lymph node metastases</td>
<td>0.36</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>46 (56.8)</td>
<td>82 (67.8)</td>
</tr>
<tr>
<td>Yes</td>
<td>35 (43.2)</td>
<td>39 (32.2)</td>
</tr>
<tr>
<td>Distant metastases</td>
<td>0.52</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>77 (96.3)</td>
<td>120 (99.2)</td>
</tr>
<tr>
<td>Yes</td>
<td>3 (3.8)</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>MACIS score</td>
<td>0.78</td>
<td></td>
</tr>
<tr>
<td>&lt; 6</td>
<td>65 (82.3)</td>
<td>92 (76.7)</td>
</tr>
<tr>
<td>6–6.99</td>
<td>7 (8.9)</td>
<td>17 (14.2)</td>
</tr>
<tr>
<td>7–7.99</td>
<td>4 (5.1)</td>
<td>6 (5.0)</td>
</tr>
<tr>
<td>&gt; 8</td>
<td>3 (3.8)</td>
<td>5 (4.2)</td>
</tr>
<tr>
<td>MACIS score</td>
<td>&gt; 0.99</td>
<td></td>
</tr>
<tr>
<td>&lt; 7</td>
<td>72 (91.1)</td>
<td>109 (90.8)</td>
</tr>
</tbody>
</table>
Affiliations: From the Department of Surgery, St. Paul’s Hospital and University of British Columbia, Vancouver, BC (Moore, Meleck, Wiseman); the Michael Smith Genome Sciences Centre, British Columbia Cancer Research Centre, Vancouver, BC (Kasaian, Jones); and the Department of Medical Genetics, University of British Columbia, Vancouver, BC (Jones).

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.

References

GPs with enhanced surgical skills: a questionable solution for remote surgical services

I respond to arguments by Drs. Vinden and Ott in “GPs with enhanced surgical skills: a questionable solution for remote services” (December 2015). We welcome an evidence-based debate on how to best meet the surgical needs of rural residents in Canada.

The definition of safety in surgery has focused on hospital-based activity related to procedural interventions. However, quality of care must also include dimensions of acceptability, accessibility, appropriateness, effectiveness and efficiency. Our patients’ definition, similarly, will include impact of travel on finances, loss of supportive relationships, and sense of “community belonging.”

As for the breadth of the skill set proposed, rural population distribution matters. The degree of generalization required to practise in any given setting is inversely proportional to the human resources available. This means that in rural Canada, with its low physician numbers, a broad skill set is necessary and will continue to be practised. The ESS physician crosses one of these gaps.

Any critique around competency-based training must be given within the context of the current curricula redefinition for general surgeons. The published draft was a scaled-down version, designed to convey the procedural content. The program itself provides foundational content, milestones, etc.

Disparity of time frames in training, although less relevant in a Competence by Design (CBD) framework, is offered as evidence of the inadequacy of the ESS training program. Unlike the vast majority of “rookie” R1 surgical residents, however, ESS residents are not postgraduate year (PGY)1s, but are licensable physicians, with at least 2 years of clinical knowledge and skill acquisition, often acquired in low-resource settings where decision-making skills have been well tested.

Regarding gastrointestinal endoscopy training, the American Board of Surgery (similar to CAGS’s) reiterates the importance of rural care and of de-emphasizing specialty designation, stating that “patients will be best served by establishing validated quality indicators for proficiency, (...)using these more objective standards.”

How does centralization of care affect care delivery? Malik and colleagues argue that a massive shift toward geographically centralized care would imperil a host of other services, and thus argue strongly against such centralization (despite demonstrably worse outcomes). Safety and quality must have a broader context than hospital statistics.

Finally, will the current “surplus” of surgical human resources solve rural surgical issues? New general surgeons who are prepared for rural practice are rare, but even those who are will bring with them substantial resource requirements. Rural places would welcome such an influx, but for now will continue to provide the best possible care with the available resources.

Randall Friesen, MD
From the Department of Surgery, University of Saskatchewan, Saskatoon, Sask.
DOI: 10.1503/cjs.001616

References
The Regina Qu’Appelle Health Region (RQHR) is seeking a dynamic and effective leader to join our administrative and clinical team as the DEPARTMENT HEAD OF SURGERY.

The Department Head provides leadership on behalf of RQHR to operationalize the interests and ensure the integrity of the RQHR Strategic Plan in all deliberations.

The Department Head will work together with a multidisciplinary team to deliver and foster the highest standards of practice in accordance with the statement of purpose, principal functions, values, philosophy, principles, goals and objectives of the Department of Surgery. The Department Head supports and actively pursues the Patients First Philosophy.

The Department Head will be a strong leader, with effective organizational, team building, administrative, interpersonal and collaborative skills, who is able to engage, inspire, and motivate the Department to be full participants in the continuous improvement and development of a vibrant and academic clinical department and to be actively engaged in the particular patient value stream in which they participate. Such shall be undertaken in a manner consistent with the strategic plan, vision, values and mission of the Regina Qu’Appelle Regional Health Authority.

Qualifications:
The successful candidate will hold certification or be eligible for certification from the Royal College of Physicians and Surgeons of Canada and be eligible for licensure to practice in Saskatchewan. In accordance with immigration requirements, preference will be given to Canadian citizens, and residents of Canada.

For information or to submit curriculum vitae, before June 23, 2016, please contact:
Cheryl Isted, Manager, Physician Privileges and Performance
Regina Qu’Appelle Health Region
Tel 306 766-0727
Email cheryl.isted@rqhealth.ca
www.rqhealth.ca/careers Twitter@RQHRdocs

The Division of General Surgery at Mount Sinai Hospital and the University of Toronto are searching for an academic colorectal surgeon with a special interest and planned focus in the management of inflammatory bowel disease. The ideal candidate should be eligible for a full-time clinical academic appointment at the rank of Assistant, Associate or Full Professor at the University of Toronto. The start date will be mutually agreed upon.

The successful candidate should have completed a general surgery residency and colorectal fellowship, and should have completed or be registered in a program to complete a graduate degree (MSc or PhD) in clinical epidemiology, education or other academic discipline. In addition, the candidate should have a track record of research activity and ongoing productivity, with clinical and research training including experience and interest in the field of colorectal surgery – specifically inflammatory bowel disease. He/she must have extensive practical experience in minimally invasive and open surgical approaches to complex inflammatory bowel disease and its complications. He/she should show demonstrated ability to work within a multidisciplinary team and to teach trainees at all levels. Evidence of excellence in teaching and research is required.

The successful applicant will join the faculty of the Department of Surgery at the University of Toronto. Candidates must be eligible for certification with the Royal College of Physicians and Surgeons of Canada and be licensed in the Province of Ontario.

Salary will be in the range of $200,000 - $400,000 commensurate with qualifications and experience. This estimate is based on fee for service billings. The successful candidate will be a member of the Mount Sinai Hospital Department of Surgery Financial Sharing Agreement.

Please submit a letter of intent, names of three referees and CV by June 30, 2016 to:
Dr. Carol Swallow, Head, Division of General Surgery, Mount Sinai Hospital
Suite 1225, 600 University Avenue, Toronto, Ontario, Canada MSG 1X5
Email cs swallow@mtsinai.on.ca

Correspondence in this regard may be directed to:
Faryal Esmail
Fax 416 586-8392 • Email femail@mtsina on.ca

For more information about the Faculty of Medicine/Department of Surgery, please visit our home page at http://surgery.utoronto.ca

The University of Toronto is strongly committed to diversity within its community and especially welcomes applications from visible minority group members, women, Aboriginal persons, persons with disabilities, members of sexual minority groups, and others who may contribute to the further diversification of ideas. All qualified candidates are encouraged to apply; however, Canadians and permanent residents will be given priority.

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THORACIC SURGERY POSITION
Moncton, New Brunswick

The Moncton Hospital is recruiting a full-time Thoracic Surgeon to begin practice immediately. The department at present consists of five and a half general surgeons, one thoracic and two vascular surgeons. Applicants must be eligible for licensure in New Brunswick and hold subspecialty certification in Thoracic Surgery. Applicants will be expected to participate in the call schedule and teaching of residents. We are NCIC affiliated and opportunities exist for research. The hospital has two state-of-the-art MIS suites as well as a new outpatient complex including an up-to-date GI/endoscopy suite, clinics and minor OR suites.

The Moncton Hospital is a 380-bed tertiary and critical care facility within Horizon Health Network. It is a major referral hospital which serves communities throughout New Brunswick, Prince Edward Island and northern Nova Scotia. It is a Level II Trauma Centre which offers tertiary services in neurosurgery, oncology and neonatal care and includes all other major services and subspecialties.

The Moncton Hospital offers excellent opportunities for teaching and clinical research and has academic affiliation with Dalhousie University. The hospital is one of the largest employers within metro Moncton, employing 3,000 staff and physicians.

The city, with adjoining municipalities, has a population of more than 138,000, and was ranked as one of the best Canadian cities for quality of community life. There is an abundance of educational, cultural and recreational opportunities including easy access to warm water beaches of the Northumberland Strait, and also the scenic Bay of Fundy area. Visit the City’s website at www.moncton.ca

Requirements:
The Department of Surgery requires that their members have passed the examination of the Royal College of Physicians and Surgeons of Canada in their specialty or equivalent, in order to be eligible for active membership.

Remuneration:
Standard remuneration is fee-for-service which is a direct compensation between the physician and Medicare of New Brunswick. No source deductions can be provided. However, under special circumstances, with approval from the Department of Health of New Brunswick, a salaried model may be available. This may range between a minimum of $243,204 to a maximum of $268,788 annually (excluding benefits and source deductions) based on qualifications and experience. On call remuneration is fee for service.

Applicants are invited to forward their CV to:

Dr. Ken Mitton, Medical Director
135 MacBeath Ave., Moncton NB E1C 6Z8
Fax 506 857-5545
Email medical.staff@horizonnb.ca