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Physician burnout is the new catch phrase. Recognized as a problem for years, burnout has now become more relevant. It is the sheer volume of cases that has become a threat to the medical profession. Annually, about 400 physicians take their own lives in the United States. We do not have hard numbers for Canada.

The Mayo Clinic published its survey-based work on burnout in 2016. It reported that physicians with at least 1 symptom of burnout had increased to 54% from 46% the previous year. The Canadian Medical Association released data in the last year on the Canadian experience. One in 3 physicians reported signs of depression. Residents seemed more at risk (95%) of depression, but were also more likely to report it. In Quebec, the PAMQ (Quebec physician assistance program) has existed since 1990. New cases are threatening to overwhelm the program. Last year there was a 20% increase in new cases among specialists and 12% among family physicians.

The complaints to the PAMQ are varied, but seem to be related to a number of environmental factors. Doctors feel they are confined, with no viable exits, leading to early retirement or shutdown of their practices for an indefinite period. They also claim that changes in the system have left them overloaded in a dysfunctional workplace and without control. The most affected are younger than the average physician (43 v. 52 yr).

We have seen active demeaning of physicians in the media by government spokespeople as well as increasing rationing of care by ministries of health and hospital administrators. The rationing has government origins, but the physicians are perceived as the culprits. There are complaints of time pressure, declining pay and umpteen unproductive paperwork tasks required by administration that either don’t improve or actually inhibit patient care. Physician-oriented investigations by peer regulatory bodies and lawsuits are also a huge stress factor. And electronic health record migration has not facilitated patient care.

Certainly, medical graduates are under more pressure than ever to adapt to a new work environment, and debt load and job uncertainty from lack of resources are enough to cause concern. But what has made this generation of physicians more prone to burnout? It may be just a heightened sensitivity to hardship combined with a decreased stigma for speaking out. But that would mean the environment is about the same, with a more sensitive measuring stick.

Work conditions have improved. Residents no longer exit a 5-year program of 1 in 2 in-house call. New staff have support programs and generally are not working more hours than their predecessors. However, patient care has become more complex, with more tests required and attendant comorbidities. But limited employment opportunities and residency spots in specialties combined with a need for a different work–life balance has made working more pressure filled. Unfortunately, burnout requests seem to have funny parameters in some cases. I have seen staff claim they are too tired to do call but have no problem increasing their elective lists. Ideally, like with other disabilities, we need more objective qualifications for diagnosis and treatment of burnout. Burnout is a real problem that needs better definition.

Currently, the plan for therapy varies greatly among cases, with no agreed-upon recovery program. Treatment protocols are not unified and definitely need to be. Like all other epidemics, we need to recognize the importance of physician burnout and meet the problem head-on. However, all these issues combined seem to indicate that in the future, we are going to have to train more physicians to meet our needs.

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Competing interests: E.J. Harvey is the chief medical officer of Greybox Solutions, the co-founder and head of medical innovation of NXTSens Inc., the co-founder and chief medical officer of MY01 Inc., and the co-founder and director of Strathera Inc. He receives institutional support from J & J DePuy Synthes, Stryker and Zimmer, and he is a board member of the Orthopedic Trauma Association and the Canadian Orthopaedic Association.

DOI: 10.1503/cjs.000819
D’epuis peu, l’épuisement professionnel des médecins est sur toutes les lèvres. Problème connu depuis des années, le burn-out sort maintenant de l’ombre. Et en soi, le nombre de cas pose une menace pour la profession médicale. Aux États-Unis, on déplore environ 400 suicides de médecins chaque année. On ignore quel en est le nombre au Canada.

La Clinique Mayo a publié les résultats de son enquête sur l’épuisement professionnel en 2016. Ce rapport révèle que la proportion de médecins présentant au moins 1 symptôme de burn-out était passée de 46 % à 54 % par rapport à l’année précédente. L’Association médicale canadienne a pour sa part diffusé des données sur l’expérience canadienne au cours de la dernière année. Un médecin sur 3 faisait état de signes de dépression. Les résidents semblaient plus à risque (95 %) à l’égard de la dépression, mais était également plus susceptibles d’en parler. Le Programme d’aide aux médecins du Québec (PAMQ) existe depuis 1990. Les nouveaux cas sont sur le point de créer une congestion au sein du programme. L’an dernier leur nombre a augmenté de 20 % chez les spécialistes et de 12 % chez les médecins de famille.

Les motifs de consultation au PAMQ varient, mais semblent liés à plusieurs facteurs environnementaux. Les médecins se sentent coincés dans une situation sans issue qui les pousse vers la retraite ou la fermeture de leurs cabinets pour des périodes indéterminées. Ils affirment aussi que les changements apportés au système ont allongé leur tâche et rendu leurs milieux de travail dysfonctionnels; ils n’ont de contrôle sur rien. Les plus affectés sont moins âgés que la moyenne des médecins (43 ans c. 52)\textsuperscript{2,3}.

On a assisté au dénigrement des médecins par des porte-paroles gouvernementaux dans les médias, ainsi qu’à une rationalisation des soins par les ministères de la Santé et les administrations hospitalières. La rationalisation émane du gouvernement, mais ce sont les médecins qui en portent l’odieux. Leur plaintes concernent les contraintes de temps, le déclin des salaires et la multiplication des tracasseries bureaucratiques imposées par l’administration, qui ne font rien pour améliorer les soins. Les enquêtes menées par les ordres professionnels sur leurs membres et les poursuites constituent d’autres importants facteurs de stress. La mise en place des dossiers médicaux électroniques n’a pas non plus facilité la prestation des soins.

Les diplômés en médecine subissent sans contredit une pression inégalée pour s’adapter à un nouveau milieu de travail, sans compter l’endettement et l’insécurité professionnelle inhérente aux restrictions budgétaires. Mais qu’est-ce qui rend cette génération de médecins plus sujette à l’épuisement professionnel? Ce pourrait être simplement une sensibilité exacerbée aux difficultés de la vie, combinée à une moindre stigmatisation de ceux qui les dénoncent. Cela pourrait signifier que l’environnement est relativement le même, mais qu’on l’évalue avec des instruments plus précis.

Les conditions de travail se sont améliorées. Les résidents ne sortent plus d’un programme de 5 ans où ils ont fait 1 garde sur 2. Les nouveaux médecins disposent de programmes de soutien et ne travaillent pas plus d’heures que leurs prédécesseurs. Par contre, les soins aux patients se sont complexifiés, les tests se sont multipliés, tout comme les comorbidités. Mais la diminution des possibilités d’emploi et des postes de résidents en spécialité alliée à la recherche d’une meilleure conciliation travail–vie personnelle ajoute un élément de stress. Malheureusement, les réclamations pour burn-out semblent avoir parfois d’étranges paramètres.
J’ai entendu des gens se plaindre d’être trop fatigués pour faire une garde, tout en augmentant leurs listes de stages. Idéalement, comme avec toute autre invalidité, il faut des paramètres diagnostiques et thérapeutiques plus objectifs pour le burn-out. C’est un problème réel qui se doit d’être mieux défini.

À l’heure actuelle, les plans de traitement varient énormément d’un cas à l’autre, sans règle. Les protocoles thérapeutiques sont disparates alors qu’ils devraient être standardisés. Comme toute autre épidémie, nous devons reconnaître l’importance de l’épuisement professionnel chez les médecins et s’y attaquer. Par contre, si on considère les diverses composantes du problème, on conclut qu’à l’avenir, il faudra former plus de médecins pour répondre à nos besoins.

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DOI: 10.1503/cjs.000919

Références

Online manuscript submission and peer review
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http://mc.manuscriptcentral.com/cjs
Reinventing the wheel in scoliosis surgery: effective strategies for safely improving efficiency

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Accepted June 4, 2018

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DOI: 10.1503/cjs.019317

As interest in technological advancements continues to grow, the surgical treatment of adolescent idiopathic scoliosis (AIS) is constantly evolving. Some innovations are implemented at a hefty cost, thus raising questions regarding added value of care. In fact, costs associated with the surgical treatment of AIS have recently been estimated to be more than $1.1 billion annually in the United States alone.1 The main drivers of costs are associated with the implants used to achieve deformity correction and the time-consuming nature of the surgery.2

This commentary discusses 2 surgical strategies, intraoperative skull femoral traction (IOSFT) and navigated sequential drilling (NSD), which have been systematically implemented at our academic children’s hospital with the aim of safely improving efficiency in scoliosis surgery. Both techniques are modifications of previously described surgical techniques using current technology to improve procedural safety as compared with the original descriptions.

Intraoperative skull femoral traction

The IOSFT strategy was first described by Cotrel and colleagues.3 The pediatric spine surgery team at our institution introduced the systematic use of IOSFT for posterior spinal instrumentation and fusion (PSIF) in 2010. Our technique, compared with the original description, is used in conjunction with real-time neurophysiological monitoring. The benefit of this is twofold. First, IOSFT safely straightens the spine before definitive deformity correction. In fact, IOSFT has been shown to reduce scoliosis by 30%–50% before instrumentation.4 Second, neurophysiological monitoring informs the surgeons of impending intraoperative neurologic injury. The systematic implementation of IOSFT has led us to reduce our average operating time by more than 1 hour and altogether reduced our cost per case by $3972. In addition, we found that traction protected against requiring blood transfusions, with an absolute risk reduction of 31% and a number needed to treat of 3.5

Navigated sequential drilling

In 2013, we piloted in a laboratory and introduced the routine use of NSD for preparing pilot holes for pedicle screw instrumentation. This technique is

SUMMARY

Posterior spinal instrumentation and fusion (PSIF) has been the standard operative treatment for adolescent idiopathic scoliosis (AIS) and is one of the most frequently performed elective pediatric surgeries in North America, incurring an expenditure of more than $1.1 billion annually in the United States alone. This commentary reflects on the outcomes of systematically implementing intraoperative skull femoral traction (IOSFT) combined with navigated sequential drilling (NSD) during PSIF for AIS as strategies for quality improvement at our tertiary children’s hospital.
a modification of the original technique by Roy-Camille and colleagues.\(^5\) With NSD, all pedicle pilot holes are drilled sequentially using a slow-speed oscillating battery-powered drill and 3.2 mm drill bit with a safety stop at 25 mm. With this strategy, we have safely improved surgical efficiency and significantly reduced the need for blood transfusion. The NSD technique creates smaller pilot holes than the conventional awl technique, therefore reducing bleeding. Because there is less bleeding, we can sequentially drill all pilot holes before pedicle screw instrumentation, thereby safely accelerating the pace of this surgical step. Accordingly, our blood transfusion requirements, including the use of cell saver, dropped from 33% to nearly zero. This is in contrast with the transfusion rates of 24%\(^7\) and 67.6%\(^8\) previously reported from 33% to nearly zero. This is in contrast with the requirements, including the use of cell saver, dropped this surgical step. Accordingly, our blood transfusion instrumentation, thereby safely accelerating the pace of reducing bleeding. Because there is less bleeding, we can pilot holes than the conventional awl technique, therefore blood transfusion. The NSD technique creates smaller surgical efficiency and significantly reduced the need for 25 mm. With this strategy, we have safely improved surgery duration.

**Development**

Our team has recently performed a retrospective quality improvement study of 125 patients who underwent single-stage PSIF for AIS between January 2008 and December 2015 at our institution.\(^9\)

Three cohorts were defined based on the intraoperative surgical strategies used. Twenty-eight patients underwent PSIF without either IOSFT or NSD, while 45 patients underwent PSIF with IOSFT alone. All these patients had their pedicle pilot holes prepared with a navigated awl. A third cohort of 52 patients underwent PSIF using both IOSFT and NSD. The primary outcome measures were classified by reportable indicators according to our regional health care system quality framework: median operative time, prevalence of cases requiring extended operating room time (finishing after 15:45 h), need for blood transfusion (cell saver or allogenic) and total cost per case.

Our findings suggest that the systematic use of IOSFT and NSD improved safety, efficiency and value-of-care in PSIF for AIS. Combined, IOSFT and NSD have reduced operating times by 59%, decreased the need for blood transfusions from 64% to 1.9% and reduced median cost per case by $8500 (24%) from cohort A to cohort C.

The efficiencies facilitated by using IOSFT and NSD systematically have had other important ramifications at our institution. In our setting, shorter operating time increases the value of care by reducing cost and improving access to health care. With improved efficiency, we have been able to accommodate larger volumes of pediatric spine surgeries during normal operating days. Shorter operating times have allowed for improved utilization of operating room resources, ultimately resulting in shorter wait times for patients and reduced length of hospital stay.

During the same time frame (2010–2015), an independent audit of surgical site spinal infections at our institution showed a relatively lower incidence of infections than reported in the current literature.\(^5\)

**Conclusion**

The combination of IOSFT and NSD for AIS surgery has, to our knowledge, never been reported, and its external validity has yet to be evaluated. If reproducible, the use of IOSFT and NSD during surgical treatment of scoliosis could have significant implications for health resource utilization across health care systems. We understand that the quality improvements reported here reflect the experience of 2 surgeons and their trainees in a single high-volume tertiary pediatric health care setting and thus may not be generalizable. However, this is a hypothesis-generating commentary, which invites further prospective investigation accounting for other plausible confounding variables. Such prospective study would represent an ethical challenge in our institution, given the overall quality improvements with the implemented strategies. We have taken the first step by studying NSD in a simulation laboratory, and our pilot data support our clinical findings.\(^1\)

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**Competing interests:** None declared.

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

**References**

Concordance between laboratories in metal ion testing in patients with metal-on-metal hip implants

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Accepted Feb. 15, 2018; Published online Oct. 1, 2018  

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Background: Testing of whole blood or serum metal ion levels has become an important part of assessing and monitoring the performance of metal-on-metal bearings, both in hip resurfacing arthroplasty and in total hip replacement. The aim of this study was to determine the concordance between 2 laboratories testing cobalt and chromium ion levels in patients with metal-on-metal bearings.

Methods: Serum and whole blood samples from patients who had undergone metal-on-metal resurfacing or large-diameter total hip arthroplasty were tested for cobalt and chromium ions in laboratory A (a recognized laboratory) and laboratory B (tasked with testing clinical specimens). Laboratory A performed cobalt and chromium testing on whole blood, and laboratory B performed cobalt testing on whole blood and chromium testing on serum.

Results: Samples from 104 patients were tested. Laboratory B reported lower whole blood cobalt levels than laboratory A. Furthermore, laboratory A reported that all patients had elevated whole blood cobalt ion levels compared to the normal reference values for the laboratory, whereas laboratory B reported that 46 patients (44.2%) had whole blood cobalt ion levels within the normal reference range for the laboratory.

Conclusion: This comparative study highlights the importance of using a single laboratory for metal ion testing, as values generated from different laboratories may not be directly comparable. With recent literature suggesting that whole blood cobalt levels as low as 1 ppb may be a predictor of adverse reactions to metal debris, accurate clinical measurement needs to be increasingly exact.

Contexte : Le dosage sanguin ou sérique d’ions métalliques est devenu une étape importante de l’évaluation et du suivi des prothèses à couple de frottement métal-métal utilisées en arthroplastie de resurfaçage ou totale de la hanche. La présente étude visait à évaluer la concordance entre les résultats de 2 laboratoires pour le dosage du cobalt et du chrome chez des patients porteurs de ces prothèses.

Méthodes : Des prélèvements de sérum et de sang entier de patients porteurs d’une prothèse de resurfaçage ou d’une prothèse totale de hanche à couple métal-métal ont été expédiés au laboratoire A (un laboratoire reconnu) et au laboratoire B (spécialisé en analyse d’échantillons cliniques) pour le dosage des ions cobalt et chrome. Le laboratoire A a effectué toutes ses analyses sur des prélèvements de sang entier, et le laboratoire B a utilisé le sang entier pour le dosage du cobalt et le sérum pour le dosage du chrome.

Résultats : Les prélèvements de 104 patients ont été analysés. Le laboratoire B a détecté des taux sanguins de cobalt inférieurs à ceux du laboratoire A. De plus, le laboratoire A a indiqué que tous les patients présentaient des taux de cobalt sanguins élevés par rapport à ses valeurs de référence, alors que le laboratoire B a déterminé que le taux de cobalt sanguin de 46 patients (44,2 %) se trouvait dans sa fourchette de valeurs de référence normales.

Conclusion : Cette étude comparative vient souligner l’importance de choisir un seul laboratoire pour le dosage des ions métalliques, car les valeurs générées par des établissements différents pourraient ne pas être directement comparables. Comme des études récentes semblent indiquer que des taux de cobalt sanguins aussi faibles que 1 p. p. milliard pourraient être des prédicteurs de réaction indésirable aux débris métalliques, la précision et l’exactitude des mesures cliniques revêtent une importance croissante.
Testing of whole blood or serum metal ion levels has become an important part of assessing and monitoring the performance of metal-on-metal bearings, both in hip resurfacing arthroplasty and in total hip replacement. In most cases, metal ion testing involves testing of cobalt and chromium ion levels. Keegan and colleagues looked at cut-off thresholds that are an indication of potential bearing failure. More recently, Kwon and colleagues recommended a lower threshold of 4 µg/L for further investigation of painless metal-on-metal hip arthroplasty as a part of an orthopedic evaluation and management algorithm.

In addition, cobalt can cause systemic toxicity, which can result in serious consequences like blindness, hearing loss, memory loss and cardiomyopathy; cardiomyopathy has caused death in 2 patients. Therefore, accurate measurement of cobalt ion levels in this rare but serious situation is key.

More recently, failure of total hip prostheses as a consequence of trunnion wear has been reported. Fillingham and colleagues underlined the importance of accurate testing of metal ion levels to help establish the likelihood of an adverse metal reaction as a consequence of trunnion wear. They concluded that measurement of the serum cobalt level, with a threshold value of 17 nmol/L (1.0 µg/L), is the best test for identifying the presence of adverse local tissue reactions in patients with a metal-on-polyethylene total hip arthroplasty prostheses.

Different analytical methods have been used to determine metal ion levels in whole blood or serum. Inductively coupled plasma mass spectrometry (ICPMS) is one of the most sensitive techniques for this purpose: it can detect metal ions at concentrations as low as 1 part per quadrillion. Several investigators have emphasized the importance of using recognized laboratories to ensure accurate levels. Pei and colleagues confirmed the concordance of metal ion testing results between a recognized reference laboratory in London, Ontario, and the Alberta Centre for Toxicology, Calgary, both of which used ICPMS. However, Rahmé and colleagues concluded that there was a clinically significant absolute difference in chromium and cobalt ion levels between 2 laboratories. Vials used for sample collection and the method of sample preparation were different in the 2 laboratories, which might have affected the results.

In an effort to determine the accuracy of testing, we performed an audit comparing the results of a new laboratory (laboratory B) tasked with testing clinical specimens with those of a recognized laboratory (laboratory A), whose results have previously been reported.

### Methods

Whole blood and serum samples from consecutive patients who had undergone metal-on-metal hip resurfacing or large-diameter total hip arthroplasty performed by 1 surgeon (J.N.P.) were tested for cobalt and chromium concentrations at both laboratory A and laboratory B. As the study was conducted as an audit, there was an agreement with the laboratory that 100 patients would represent a reasonable sample. The data were collected between June 2015 and June 2017. Specimens were collected in 1 clinical laboratory by a single venipuncture as per Clinical and Laboratory Standards Institute guidelines. Specimen collection was performed as per the specimen requirements provided by each laboratory. Specimens were stored at 2°C–6°C and were shipped to the laboratories on ice.

Laboratory A performed cobalt and chromium testing on whole blood, which was collected in a single 6-mL royal blue top trace element Vacutainer tube containing K2-ethylenediaminetetraacetic acid (EDTA) (Becton, Dickinson and Company). Reference intervals provided for laboratory A were 2.3–7.7 nmol/L (0.12–1.40 µg/L) for whole blood chromium level and 1.9–6.6 nmol/L (0.11–0.39 µg/L) for whole blood cobalt level.

Laboratory B performed cobalt testing on whole blood and chromium testing on serum. Whole blood specimens were collected in a 6-mL Monoject royal blue top tube containing Na2-EDTA (Covidian [now Medtronic Minimally Invasive Therapies]). Serum specimens were collected in a 6-mL BD royal blue top Vacutainer tube with no additive (Becton, Dickinson and Company). Reference intervals provided by laboratory B were 0.0–10.0 nmol/L (0.0–0.52 µg/L) for serum chromium level and 0–20 nmol/L (0–1.2 µg/L) for whole blood cobalt level.

Both laboratories used laboratory-developed ICPMS methods for cobalt and chromium analyses.

### Statistical analysis

We performed data analysis using Microsoft Excel 2013. We graphed and compared correlations between the metal ion results from each set of paired samples using a linear regression line. In addition, we generated Bland–Altman graphs to assess the absolute and percent bias between the 2 laboratories. Because the study was conducted as an audit and patient information was blinded, approval was deemed unnecessary by the institutional ethics review board.

### Results

Specimens from 104 patients were tested. Laboratory A reported that all patients had elevated whole blood cobalt ion levels compared to the normal reference values for the laboratory, whereas laboratory B reported that 46 patients (44.2%) had whole blood cobalt ion levels within the normal reference range for the laboratory. Laboratory A reported elevated chromium ion levels in all patients, and laboratory B reported elevated chromium ion levels in all but 1 patient (Fig. 1B).
There was good correlation for the results of cobalt ion testing between the 2 laboratories ($R^2 = 0.9924$) (Fig. 1A). However, a bias toward laboratory A was observed that increased through the concentration range (Fig. 1B). Above 200 nmol/L (11.8 $\mu$g/L), the observed percent bias was fairly consistent, around 20% (Fig. 1C).

There was also good correlation for the results of chromium ion testing between the 2 laboratories, with an $R^2$ of 0.9883, with a bias toward laboratory B (Fig. 2A). A proportional absolute bias was observed for chromium (Fig. 2B), and a percent bias of 60% was observed for values over 175 nmol/L (9.1 $\mu$g/L) (Fig. 2C).

**DISCUSSION**

The importance of monitoring patients who have undergone metal-on-metal hip resurfacing or total hip arthroplasty for chromium and cobalt ions to enable early detection of local tissue adverse reactions and pseudotumour formation is well documented.1–7 These are important causes of painful hips in such patients and may necessitate revision surgery. Furthermore, acute systemic toxic effects of chromium ions can result in renal, hematological, hepatobiliary and respiratory disorders, and chronic elevated chromium ion levels are known to be allergenic and carcinogenic.6,15 Similarly, elevated levels of cobalt ions can present with polycythemia, hypothyroidism, cardiomyopathy and neurologic manifestations such as parasthesia, numbness, memory loss, vision loss and hearing loss.9–15

Although there was good correlation for the results of both chromium and cobalt ion testing between the 2 laboratories in the current study, the absolute value for both analytes differed substantially at higher concentrations. The 2 laboratories used the same gold standard technique, ICPMS; however, these differences in absolute values for cobalt and chromium reflect differences in calibration between the 2 assays. This is an issue faced by all laboratory assays that are not standardized to a primary reference material and presents a challenge to clinicians in interpreting results produced by different laboratories. This highlights the need to have results generated by 1 laboratory in order to allow for result trending.

A second issue encountered in our study was that, despite the good correlation for cobalt ion testing, 44% of the specimens tested for cobalt by laboratory B were reported as being in the normal reference range. Previous experience with metal ion testing and a review of the literature show that patients with metal-on-metal bearing surfaces have elevated serum or whole blood levels of both chromium and cobalt.17–20 This suggests that laboratory B’s reference interval for cobalt may have included patients with metal-on-metal hip implants. When clinical decision-making may involve options as complex and challenging as revision hip arthroplasty, it also creates concerns for clinical interpretation when more than 40% of patients fall within the normal...
These issues with laboratory B lead us to conclude that changing testing to laboratory B could cause confusion when interpreting results, making it extremely difficult for clinicians involved in making treatment decisions.

**Strengths and limitations**

One of the strengths of our study is that it involved prospectively collected data. In addition, samples were collected in similar EDTA vials for whole blood analysis, and the method of sample preparation before analysis was similar for the 2 laboratories. Both laboratories validated the stability of samples used for analysis. These similarities strengthen our findings. One factor that could have a bearing on correlation of the chromium results is that laboratory A used whole blood samples, whereas laboratory B used serum samples. Smoulders and colleagues\(^2\) compared whole blood and serum chromium levels and reported that serum results were higher than whole blood results, similar to our findings.

**Conclusion**

Clinicians usually encounter challenging scenarios when choosing options such as revision surgery for patients with metal-on-metal hip resurfacing and total hip arthroplasty, especially when patients have nonpainful hips and raised levels of metal ions. Accuracy and reliability of laboratory testing are very important for absolute metal ions results to be accurate. In such situations, it is critical for treating clinicians who are relying on metal ion values to be aware that there are substantial differences between laboratories. The use of laboratories with good accuracy and reproducibility is important for clinical decision-making. Given the results of the current study, we no longer send specimens to laboratory B for metal ion testing. We also recommend that, until there is reliable standardization between laboratories, patients be followed using results generated by a single laboratory.

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**Competing interests:** None declared.

**Contributors:** J. Powell, J. Boyd, P. Railton and H. Sadrzadeh designed the study. J. Powell and P. Railton acquired the data, which J. Powell, R. Saini, J. Boyd and H. Sadrzadeh analyzed. J. Powell, R. Saini, J. Boyd and P. Railton wrote the article, which all authors reviewed and approved for publication.

**References**


Results of Octaplex for reversal of warfarin anticoagulation in patients with hip fracture

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Accepted Mar. 21, 2018; Published online Oct. 1, 2018

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DOI: 10.1503/cjs.018017

Background: Patients with hip fracture who present anticoagulated with warfarin often require reversal of anticoagulation for safe hip fracture surgery. Vitamin K is typically administered for this, but requires 24–48 hours for maximal effect. These patients have an increased delay to surgery and increased mortality. Octaplex is a prothrombin complex concentrate (PCC) that reverses warfarin anticoagulation in less than an hour. This study assesses the effectiveness and safety of Octaplex for reversal of warfarin anticoagulation for hip fracture surgery.

Methods: We reviewed the medical records of all patients with hip fracture in Calgary who received Octaplex between 2009 and 2015. Timing of admission, Octaplex administration and hip fracture surgery were recorded. Mortality and cardiac, thrombotic and orthopedic complications were assessed.

Results: Median time from Octaplex administration to an international normalized ratio of 1.4 or lower was 1.1 hours. The median time from admission to surgery was 22 hours. Thirty-day mortality was 15.2%, with 4 cases of cardiac arrest and 1 respiratory arrest. Patients who received both Octaplex and fresh frozen plasma (FFP) had a lower rate of 30-day survival than those who received only Octaplex (95.7% v. 60.0%, \(p = 0.002\)).

Conclusion: There were significant rates of cardiac events and 30-day mortality among patients who received Octaplex, but this is unsurprising in this population with multiple medical comorbidities. We caution against administering both FFP and a PCC in patients for warfarin reversal. Octaplex is effective for rapidly reversing warfarin anticoagulation and reducing delays to hip fracture surgery. Further study comparing Octaplex to reversal using only vitamin K is required.

Contexte : Les patients avec fracture de la hanche qui sont sous anticoagulothérapie par warfarine au moment de consulter ont souvent besoin qu’on inverse leur anticoagulation pour être opérés sans danger. La vitamine K est généralement administrée à cette fin, mais il lui faut de 24 à 48 heures pour exercer son plein effet. Chez ces patients, le délai est plus long avant la chirurgie et la mortalité est plus élevée. Octaplex est un concentré de complexe prothrombine (CCP) qui inverse l’anticoagulation due à la warfarine en moins d’une heure. Cette étude évalue l’efficacité et l’innocuité d’Octaplex pour l’inversion de l’anticoagulation due à la warfarine lors d’une chirurgie pour fracture de la hanche.


Résultats : L’intervalle médian entre l’administration d’Octaplex et l’obtention d’un ratio international normalisé de 1,4 ou moins a été de 1,1 heure. L’intervalle médian entre l’admission et la chirurgie a été de 22 heures. La mortalité à 30 jours a été de 15,2 %, incluant 4 arrêts cardiaques et 1 arrêt respiratoire. Les patients qui ont reçu Octaplex et du plasma frais congelé (PFC) ont eu un taux de survie à 30 jours moins élevé que ceux qui ont reçu Octaplex seulement (95,7 % c. 60,0 %, \(p = 0,002\)).

Conclusion : On a observé des taux significatifs d’événements cardiaques et de mortalité à 30 jours chez les patients traités par Octaplex, mais cela est peu surprenant dans cette population présentant plusieurs comorbidités médicales. Nous formulons une mise en garde contre l’utilisation de PFC et d’un CCP chez les patients soumis à une inversion de l’effet de la warfarine. Octaplex est efficace pour inverser rapidement l’anticoagulation due à la warfarine et accélérer l’accès à la chirurgie pour fracture de la hanche. Il faudra approfondir la recherche et comparer l’inversion par Octaplex plutôt que par la vitamine K seulement.
Hip fractures are a common cause of morbidity and mortality in elderly patients; more than 2400 hip fracture surgeries are performed per year in Alberta. A substantial number of patients with hip fracture present anticoagulated with a vitamin K antagonist (e.g., warfarin) for a number of medical conditions, including atrial fibrillation, venous thromboembolism and mechanical heart valves. Reversal of warfarin anticoagulation is necessary for adequate hemostasis during and after hip fracture surgery. An international normalized ratio (INR) of 1.4 or lower permits safe neuroaxial anesthesia and is associated with lower intraoperative and postoperative bleeding risks.

Reversal of anticoagulation from warfarin using oral or intravenous vitamin K is superior to simply withholding warfarin in patients with hip fracture. However, the effect of vitamin K on the normalization of INR is not seen until at least 4 hours after administration, and 24–48 hours are required for maximal effect. However, delays to hip fracture surgery have been shown in multiple studies to increase patient pain, length of stay (LOS), morbidity and mortality. Furthermore, patients with hip fracture who are on warfarin therapy have been shown to have a longer time to surgery, a longer LOS and higher mortality. Fresh frozen plasma (FFP) allows for more rapid reversal of warfarin anticoagulation, but carries significant risks, including fluid overload, transfusion-related acute lung injury and transmission of blood-borne illness.

Octaplex is a prothrombin complex concentrate (PCC) used for emergent reversal of warfarin therapy in patients exhibiting serious or life-threatening bleeding manifestations or patients requiring unplanned/urgent (< 6 h) interventions with risk of bleeding. Octaplex and other PCCs provide rapid reversal of INR (within 15–60 min) with maximal effect for 4–6 hours. With a concentration of clotting factors more than 25 times higher than FFP, Octaplex requires a low volume to be infused (1–2 mL/kg), minimizing the risk of fluid overload and reducing the time required for infusion. As a pasteurized product, Octaplex poses an extremely low risk of disease transmission. Octaplex contains human coagulation factors II, VII, IX and X and proteins C and S, and has been shown to be safe and effective in multiple clinical trials in patients with life-threatening bleeding. Other studies have demonstrated the safety of PCCs in other applications including intracranial bleeding and before urgent cardiac surgery. Compared with FFP, PCCs more rapidly and completely reverse warfarin anticoagulation while reducing the risk of fluid overload. Although the overall rate of reported thrombotic events has been low, complications of PCC administration, including deep vein thrombosis (DVT), myocardial infarction (MI) and thrombotic stroke, have been reported previously. However, most patients who had adverse thrombotic events had comorbidities that may have contributed to their thrombotic risk.

Prothrombin complex concentrate has been recommended for more rapidly reversing warfarin anticoagulation to reduce delays in hip fracture surgery, particularly in patients at risk of volume overload. However, patients with hip fracture are a particularly high-risk group, with high mortality and rates of complications including heart failure, DVT, pulmonary embolism (PE), MI and stroke. To our knowledge, there are no studies on the use of Octaplex in patients with hip fracture. Although there is a study showing the effectiveness of PCCs for reversal of acute traumatic coagulopathy in orthopedic trauma patients, it specifically excluded patients taking warfarin before their injury. In the present study, we sought to characterize the effectiveness of Octaplex for the reversal of warfarin anticoagulation in patients with hip fracture.

**METHODS**

We performed a retrospective chart review of all cases of Octaplex use in patients with hip fractures treated in Calgary, Alta., between December 2009 and February 2015. We included patients who had a femoral neck, peritrochanteric, or subtrochanteric hip fracture; presented to hospital with an INR of 1.6 or higher; were taking warfarin for anticoagulation before presentation; were given Octaplex for reversal of INR before hip fracture surgery; and were scheduled to undergo surgery for hip fracture treatment (screw fixation, sliding hip screw, cephalomedullary nail, hemiarthroplasty, or total hip arthroplasty). We excluded patients younger than 18 years and those who had open injuries, neurologic or vascular injury in the affected limb, or pathologic or periprosthetic fractures. We obtained the patient list from a transfusion medicine database of patients who received Octaplex in association with hip or femur fracture surgery or admission. Inpatient paper and electronic medical records as well as initial radiographs were reviewed to remove patients who did not meet the inclusion and exclusion criteria.

The primary outcome measure was the time from Octaplex administration to a measured INR of 1.4 or lower. Other outcome measures assessed are listed in Box 1.

**Statistical analysis**

Statistical calculations, including Kaplan–Meier survival analysis, were performed using IBM SPSS version 24. We considered results to be significant at $p < 0.05$. 

RESULTS

We identified 33 patients who met our inclusion criteria (Fig. 1). Their demographic and comorbidity data are shown in Table 1. Fracture type and treatment are shown in Table 2. All patients were taking warfarin preoperatively: 26 (82%) for atrial fibrillation and 6 (18%) for previous DVT and/or PE. It is important to note that many of these patients had multiple pre-existing comorbidities, particularly coronary artery disease (55%), congestive heart failure (CHF; 45%) and chronic obstructive pulmonary disease (39%). The mean Charlson Comorbidity Index (CCI) score was 2.82.

The median time from Octaplex administration to a measured INR of 1.4 or lower was just over 1 hour. This is indicative of the time required for Octaplex infusion and the process of obtaining a repeated coagulation study — theoretically, the onset of action of Octaplex may be as fast as 10 minutes.15 Table 3 and Table 4 show the results of Octaplex on the INR and time to surgery for our population. A single dose of Octaplex was effective in correcting the INR to 1.4 or lower in 29 patients (88%), with an average dose of 1470 units of Octaplex. Of the 4 remaining patients, 2 required a second dose of Octaplex; 1 underwent surgery with an INR of 1.5 and 1 passed away before surgery. All patients received oral or intravenous vitamin K before surgery, with a mean dose of 19.5 mg (range 5–55 mg) given. Two patients had Octaplex administered after they were brought to the operating room to minimize delays to surgery; therefore, zero hours passed from Octaplex administration to the start of surgery. The median delay from time of admission to surgery was 22 hours.

Spinal anesthesia was used in 20 patients (63%), without any cases of postoperative epidural hematoma. Intraoperative estimated blood loss (EBL) was less than 300 mL in nearly all patients, except for an EBL of 400 mL for a patient undergoing hemiarthroplasty...
and an EBL of 800 mL in a patient undergoing cephalomedullary fixation of a subtrochanteric fracture that required open reduction. The overall mean EBL was 244 ± 150.5 mL. Transfusion of packed red blood cells was required intraoperatively or postoperatively in 11 patients (33%), with a range of 0–3 units of blood administered. The median LOS was 11 (range 2–62) days before discharge home or to a rehabilitation facility.

Five out of 33 patients (15.2%) died within 30 days of Octaplex administration or hip fracture surgery, with an overall 30-day survival of 84.8% ± 6.2%. Two patients died before their hip fracture surgery after receiving Octaplex. The first developed electrocardiogram changes consistent with an inferior MI immediately after administration of Octaplex and died shortly thereafter. The second sustained an intraoperative cardiac arrest and died during administration of a spinal anesthetic 6 hours after she received Octaplex. Three patients died within 30 days after hip fracture surgery. Two deaths occurred at 3 and 21 days from a presumed fatal MI or arrhythmia. The final death occurred after the patient experienced a respiratory arrest at their care home 28 days postoperatively. Of these 5 patients who died within 30 days, 4 received both Octaplex and FFP preoperatively.

Ten patients (31%) preoperatively received FFP in addition to Octaplex, and the survival of this subgroup was significantly worse. Seven patients received Octaplex after FFP because of insufficient INR reversal. One

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### Table 1. Demographic and clinical characteristics of the study sample

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>14 (42)</td>
</tr>
<tr>
<td>Female</td>
<td>19 (58)</td>
</tr>
<tr>
<td>Age, yr; mean ± SD (range)</td>
<td>81 ± 7 (65–95)</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>18 (55)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>15 (45)</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>13 (39)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>8 (24)</td>
</tr>
<tr>
<td>Dementia</td>
<td>7 (21)</td>
</tr>
<tr>
<td>Diabetes without complications</td>
<td>6 (18)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>5 (15)</td>
</tr>
<tr>
<td>Diabetes with complications</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Severe renal disease</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Connective tissue disease</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Peptic ulcer disease</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Hemiparesis</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Moderate or severe liver disease</td>
<td>1 (3)</td>
</tr>
</tbody>
</table>

SD = standard deviation. *Unless indicated otherwise.

### Table 2. Classification and treatment of hip fractures

<table>
<thead>
<tr>
<th>Fracture</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
<td></td>
</tr>
<tr>
<td>Femoral neck fracture</td>
<td>14 (42)</td>
</tr>
<tr>
<td>Intertrochanteric fracture</td>
<td>18 (55)</td>
</tr>
<tr>
<td>Subtrochanteric fracture</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
</tr>
<tr>
<td>Cephalomedullary nail</td>
<td>15 (45)</td>
</tr>
<tr>
<td>Hemiarthroplasty</td>
<td>12 (36)</td>
</tr>
<tr>
<td>Sliding hip screw</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Cannulated screw</td>
<td>1 (3)</td>
</tr>
<tr>
<td>No surgery</td>
<td>2 (6)</td>
</tr>
</tbody>
</table>

### Table 3. INR at critical time points during admission

<table>
<thead>
<tr>
<th>Time point</th>
<th>INR; mean ± SD (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation</td>
<td>3.1 ± 1.5 (1.6–9.0)</td>
</tr>
<tr>
<td>Before Octaplex administration</td>
<td>2.3 ± 1.6 (1.4–9.0)</td>
</tr>
<tr>
<td>After Octaplex administration</td>
<td>1.3 ± 0.2 (1.0–1.9)</td>
</tr>
<tr>
<td>Mean change in INR</td>
<td>1.0 ± 1.5 (0.1–7.6)</td>
</tr>
</tbody>
</table>

INR = international normalized ratio; SD = standard deviation.

### Table 4. Time course of patients from Octaplex administration to INR reversal and hip fracture surgery

<table>
<thead>
<tr>
<th>Time course</th>
<th>Mean ± SD (range), h</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Octaplex to INR ≤ 1.4</td>
<td>2.2 ± 3.1 (0.5–14.9)</td>
<td>1.1</td>
</tr>
<tr>
<td>Octaplex to surgery</td>
<td>8.5 ± 15.8 (0–60.4)</td>
<td>2.6</td>
</tr>
<tr>
<td>Admission to surgery</td>
<td>32.5 ± 23.2 (8.4–106.0)</td>
<td>22.0</td>
</tr>
</tbody>
</table>

INR = international normalized ratio; SD = standard deviation.
patient received Octaplex and FFP simultaneously, and 2 patients received FFP after Octaplex despite a post-Octaplex INR of 1.4 or lower, all for undocumented reasons. In patients who received Octaplex but no FFP, 30-day survival was 95.7% ± 4.3%. However, in patients who received both Octaplex and FFP, 30-day survival was 60.0% ± 15.5%. This difference was statistically significant using a log-rank comparison (p = 0.002). The survival curves are shown in Figure 2. However, these 2 groups are dissimilar in age and comorbidities, as patients who received both Octaplex and FFP were older (mean age 84.1 v. 79.4, p = 0.09) and had more comorbidities (mean CCI score 3.90 v. 2.35, p = 0.049) than those who received only Octaplex.

Aside from the deaths described previously, no other cardiac events were noted postoperatively. No patients experienced CHF between the time of Octaplex administration and their hip fracture surgery. Five patients experienced CHF postoperatively within 30 days of Octaplex administration. Three of these patients were treated with furosemide during their postoperative hospital stay, and 2 required readmission for management of CHF at 20 and 29 days postoperatively. The only venous thromboembolic complication identified was a single case of DVT diagnosed at 7 days postoperatively. No strokes, PEs, or arterial thrombi were identified within 30 days after Octaplex administration.

Three patients experienced orthopedic complications within 30 days of surgery. Two patients had persistent drainage from their surgical wounds after resumption of anticoagulation therapy and were treated with negative pressure wound therapy. This was successful in 1 patient, but the other was readmitted to hospital 22 days postoperatively for a deep infection that required surgical irrigation and débridement followed by home intravenous antibiotic therapy. The organisms identified were Propionium acnes and Staphylococcus aureus (coagulase negative). The third orthopedic complication involved a patient who had a ground-level fall 29 days after discharge and sustained a periprosthetic fracture around the tip of his long cephalomedullary nail. His fracture was stabilized with a distal femoral locking plate after his anticoagulation was reversed without the use of Octaplex.

DISCUSSION

This case series highlights that patients with hip fracture who receive Octaplex often have a very high perioperative risk profile, with many of our patients having pre-existing coronary artery disease, CHF, or chronic obstructive pulmonary disease. Octaplex provides a rapid and effective method of reversing warfarin anticoagulation, as reflected in previous studies. In this study, Octaplex rapidly corrected the INR to 1.4 or lower in nearly all patients. This allowed for expedited surgery, as shown by a median delay to surgery of less than 24 hours from admission and a median time of 2.6 hours from Octaplex administration to surgery.

Unfortunately a small number of patients in this series had their surgery delayed despite Octaplex administration and INR reversal, usually until the next day to allow for surgeon or operating room availability. Policies to minimize these delays have been enacted in our health region, including better communication between surgical and anesthetic teams to ensure optimal timing for Octaplex administration. As clinician comfort with the use of Octaplex increased during this series, patients were brought to the operating room before or immediately after Octaplex infusion, often without waiting for a repeat INR. This did not result in an increase in intraoperative blood loss or transfusion requirements.

Previous studies have shown the high morbidity and mortality associated with hip fractures.23,25 The 30-day mortality in the subgroup that received Octaplex but no FFP was 4.3%, which compares favourably to the literature. However, the overall 30-day mortality in this study of 15.2% is higher than previously published in other studies. Nevertheless, our population in this study is particularly high risk, with a very high rate of comorbidities, which may have contributed to the high mortality. We have identified a significantly higher mortality in the subgroup of patients who received both Octaplex and FFP, with a high rate of cardiac events. This may be partially attributed to the older age and increased comorbidities in this subgroup, but we advise caution in administering both a PCC and FFP in patients for warfarin reversal, as this may be associated with higher morbidity and mortality.

Limitations

The primary limitation of this study is the lack of a comparison cohort — a group of patients with hip fracture who did not receive Octaplex for reversal of warfarin anticoagulation. Such a cohort would permit a comparison of time to surgery, morbidity and mortality in patients who did or did not receive Octaplex. In addition, the inpatient and electronic chart review allowed us to identify complications that occurred during the inpatient hospital stay or at another hospital in the local region. However, complications that occurred after the patient was discharged to a remote care facility and that were managed outside of Calgary would not have been identified in this review.

We hope that the results of this study will assist in guiding the conduct of future studies comparing the use of Octaplex to vitamin K with or without FFP for the reversal of warfarin anticoagulation in patients with hip fracture. Using Octaplex will permit much more rapid reversal of warfarin anticoagulation and earlier hip fracture surgery, potentially reducing patient suffering, cost, morbidity and mortality.
CONCLUSION

Octaplex is quick, safe and effective for the reversal of warfarin anticoagulation in patients with hip fracture. Octaplex reduced delays to hip fracture surgery in these patients, many of whom presented with multiple significant medical comorbidities. Nevertheless these patients remained at high risk, with an overall 30-day mortality of 15.2%. Survival was significantly lower in patients who received both FFP and Octaplex for warfarin reversal, suggesting that coadministration of both FFP and a PCC may be associated with a higher rate of complications. Further study comparing the reversal of warfarin anticoagulation by Octaplex to reversal using only vitamin K will be valuable. Octaplex facilitates earlier surgery in patients with hip fracture with warfarin anticoagulation, potentially reducing morbidity and mortality in this challenging population.

Acknowledgements: The authors thank Charles MacAdams, who passed away during the conduct of this study, for his contributions to developing a database for the use of PCCs in Calgary and in designing this study.

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Competing interests: None declared.

Contributors: Both authors designed the study. M.-T. Shabani-Rad acquired the data, which both authors analyzed. R. Ng wrote the article, which both authors reviewed and approved for publication.

References

Significant cost savings and similar patient outcomes associated with early discharge following total knee arthroplasty

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Accepted Mar. 27, 2018; Published online Oct. 1, 2018

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DOI: 10.1503/cjs.002118

Background: A substantial portion of the cost of total knee arthroplasty (TKA) results from the postoperative inpatient length of stay (LOS). Considering the annual increase in TKAs, reducing LOS represents a potential for cost savings. We sought to compare in-hospital costs and patient-reported outcomes for an early discharge protocol compared with the standard LOS following TKA.

Methods: We conducted a retrospective matched cohort study, matching patients on age, sex, body mass index and preoperative Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) score. We compared costs associated with time in the operating room, intraoperative pain control and inpatient stay as well as 1-year postoperative patient-reported outcomes between early discharge and standard LOS groups.

Results: We included 50 patients in our study (25 per group). The average LOS in the early discharge group was 26.5 hours, compared with 48.9 hours in the standard care group. The early discharge group had higher intraoperative costs associated with pain control (mean difference 26.98, 95% confidence interval 14.41–37.90, \( p < 0.01 \)); however, this difference was offset by substantial savings associated with the reduced LOS. The mean total cost for the early discharge group was $649.62 ± $281.71 versus $1279.71 ± $515.98 for the standard care group. There were no significant differences in SF12 or WOMAC scores between groups at 1 year postoperative.

Conclusion: In-hospital costs were significantly lower with a postoperative day 1 discharge protocol than with standard LOS following TKA, with no difference in patient-reported outcomes.

Contexte : Une portion substantielle du coût de l’arthroplastie pour prothèse totale du genou (PTG) est liée à la durée du séjour postopératoire. Compte tenu de l’augmentation annuelle des cas de PTG, abréger les séjours représente une source potentielle d’économies. Nous avons comparé les coûts hospitaliers et les résultats signalés par les patients avec un protocole de congé rapide et avec le séjour de durée standard après la PTG.

Méthodes : Nous avons procédé à une étude de cohorte rétrospective appariée, où les patients étaient assortis selon le l’âge, le sexe, l’indice de masse corporelle et le score WOMAC (Western Ontario & McMaster Universities Osteoarthritis) préopératoire. Nous avons comparé les coûts associés au temps passé au bloc opératoire, au contrôle de la douleur peropératoire et au séjour hospitalier, de même que les résultats signalés par les patients 1 an après l’intervention entre les 2 groupes (congé rapide et séjour standard).

Résultats : Nous avons inclus 50 patients dans notre étude (25 par groupe). Le séjour moyen du groupe soumis au congé rapide a été de 26,5 heures, contre 48,9 heures pour le séjour standard. Le groupe soumis au congé rapide a présenté des coûts peropératoires plus élevés associés au contrôle de la douleur (différence moyenne 26,98, intervalle de confiance de 95 % 14,41–37,90, \( p < 0,01 \)); par contre, cette différence a été compensée par d’importantes économies associées à des séjours plus courts. Le coût total moyen pour le groupe soumis au congé rapide a été de $649,62 ± $281,71 contre $1279,71 ± $515,98 pour le séjour standard. On n’a noté aucune différence significative pour ce qui est des scores SF12 ou WOMAC entre les groupes 1 an après l’intervention.

Conclusion : Les coûts perhospitaliers ont été significativement moindres avec le protocole de congé postopératoire rapide (après 1 jour), comparativement au séjour standard après la PTG, sans différence en ce qui concerne les résultats signalés par les patients.
Total knee arthroplasty (TKA) is an established, effective intervention for advanced osteoarthritis (OA) of the knee. The prevalence of knee OA is rapidly increasing, resulting in a rising demand for care and contributing to substantial strains on the health care system. The number of TKA procedures is expected to grow by 48% by 2020. The procedure has a substantial economic impact, costing approximately $500 million annually in Ontario alone. These numbers highlight the critical need to identify more efficient methods of care delivery while maintaining safety and patient outcomes.

Historically, standard practice following TKA involved an inpatient hospital stay of 2.5–3 weeks; however, the introduction of less invasive surgical techniques, improved management and comprehensive rehabilitation have enabled shorter inpatient stays. Today, the average inpatient stay following surgery is 2–4 days.

A substantial portion of the overall cost of TKA results from the inpatient hospital length of stay (LOS) following the procedure. Considering the large and increasing number of these procedures performed annually, further reducing the LOS through an accelerated discharge model of care represents a potential for significant cost savings. Although decreasing LOS is a novel opportunity to improve economic efficiency, high-quality, evidence-based comparisons to traditional inpatient models of both costs and patient outcomes are lacking. Furthermore, accelerated discharge protocols involve substantial changes to current practice, therefore an evaluation of potential barriers to adopting an early discharge program is warranted.

The objective of this study was to compare in-hospital costs and patient-reported outcomes associated with an early discharge protocol compared with the standard LOS following TKA. Our secondary objective was to demonstrate some of the challenges associated with adopting an early discharge program and discuss potential solutions.

Methods

We conducted a retrospective matched comparative cohort study. We compared an early discharge patient care pathway group to a group of patients who had the standard LOS following TKA. Patients were matched on age, sex, body mass index (BMI) and preoperative Western Ontario and McMaster University Osteoarthritis Index (WOMAC) score. We obtained approval from our institution’s research ethics board to conduct this study.

Interventions

Patients in the early discharge group received an accelerated discharge protocol. Prior to surgery, patients were informed of the anesthesia protocols as well as expectations around the enhanced discharge program. The patient and caregiver were informed of the projected care pathway details. Potential complications were also discussed so that the patient understood the normal course of recovery as well as signs or symptoms that would be cause for concern and require additional consultation. The patients received a spinal anesthetic as well as a periarticular multimodal injection. Sedation used intraoperatively was left to the discretion of the anesthesiologist. Patients also received a nerve block for pain and were sent home with a pain pump connected to the intra-articular catheters with continuous ropivacaine infusion. These catheters were removed at 72 hours by the patient.

Patients in the usual care group did not receive any additional analgesics and were discharged according to current, standard protocols for TKA. At our institution the standard of care LOS is 2–3 days following the procedure; our standard is shorter than the provincial guideline of 4 days.

Discharge criteria were similar in both groups: demonstrated ability to use the required gait aids, appropriate pain control, control or absence of nausea and vomiting, hemostasis at the surgical wound, hemodynamic stability with appropriate laboratory values, alertness and orientation, ability to use the bathroom, standard targets from physiotherapy for discharge, take-home medications and availability of a caregiver.

Eligibility criteria

Patients were eligible for the early discharge protocol if they were undergoing primary TKA for knee OA, had an American Society of Anesthesiologists (ASA) score ≤ 3, and were able to read and understand English. They were also required to live within a 60-minute drive of the hospital, have access to a phone, and have sufficient caregiver support at home. We excluded patients with a history of anesthesia-related complications, narcotic dependency, reliance on a walker and/or wheelchair for mobility, anaphylaxis to penicillin, psychosocial issues that may influence safety, or cognitive issues that precluded the ability to understand instructions. Consenting patients who met the eligibility criteria were included in the study; however, these patients were not a sequential cohort based on patient eligibility and resource needs. Both the anesthesiologist and surgeon discussed whether the patient was an appropriate candidate for early discharge before enrolling them in that group.

In-hospital resource use

We recorded all costs associated with each procedure during the in-hospital stay, including length of time in the operating room, anesthesia-related costs, intraoperative pain medication, LOS (including both time in postanesthesia recovery unit and on the inpatient floor until discharge), as well as physiotherapy consultations, medication use and
any other inpatient resource use (including those associated with complications) up until discharge. We did not include procedure-related equipment and implant costs, as these were assumed to be identical between groups. We obtained unit costs for each item of resource use from the case costing department at our institution. All costs are reported in 2017 Canadian dollars.

**Patient-reported outcomes**

All patients prospectively completed the SF-12 and the WOMAC questionnaires preoperatively and 1 year postoperatively.

**Statistical analysis**

We used descriptive statistics to summarize baseline characteristics of the study participants. We compared costs associated with time in the operating room, intraoperative pain control, inpatient stay and the total overall cost between groups. We compared costs and 1-year quality of life outcomes between groups using an independent sample t test. If the data did not meet the assumptions of a t test, we conducted nonparametric bootstrapping to compare the mean differences between groups.

**RESULTS**

There were 25 patients who underwent primary TKA with the early discharge protocol at our institution between 2015–2016. They were matched to 25 patients who underwent a primary TKA during the same time period and received the standard of care treatment and LOS. Patients were similar in baseline characteristics and preoperative WOMAC scores (Table 1).

The average LOS in the early discharge group was 26.5 hours, compared with 48.9 hours in the usual care group. Seven patients in the early discharge group experienced a delayed discharge resulting in an LOS longer than 24 hours (catheter leakage $n=4$, pain control $n=1$, vasovagal $n=1$, urinary retention $n=1$).

The early discharge group had higher intraoperative costs associated with pain control (mean difference 26.98, 95% confidence interval [CI] 14.41 to 37.90, $p<0.01$); however, these differences were offset by significant savings from the reduced LOS. The mean total cost for the early discharge group was $649.62 ± 281.71 versus $1279.71 ± 515.98 for the standard care group (mean difference $-934.44$, 95% CI $-1453.16$ to $-483.54$, $p<0.01$; Table 2).

Patients in both groups reported similar quality of life and function following surgery. There were no significant differences in the SF12 mental and physical component scores or WOMAC total score between the 2 groups 1 year postoperatively (Table 3).

**DISCUSSION**

We found significantly lower in-hospital costs with a postoperative day 1 discharge protocol than with the standard LOS following TKA, with no difference in patient-reported outcomes 1 year following surgery. At our institution, the standard of care LOS is an average of 2–3 days, which is even lower than the suggested provincial guideline of 4 days, therefore even greater cost savings may be realized with an early discharge protocol at other institutions.

Previous studies have evaluated the impact of reduced LOS on clinical outcomes and found that an earlier discharge is a feasible alternative to traditional inpatient TKA. For example, Raphael and colleagues evaluated a reduced LOS protocol (average length of stay of 47 h v. 116 h) and found no increase in complication or readmission rates.

**Table 1. Demographic and clinical characteristics of the study sample**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group; mean ± SD*</th>
<th>Early discharge</th>
<th>Standard care</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td></td>
<td>63.5 ± 4.1</td>
<td>65.4 ± 4.4</td>
<td>0.10</td>
</tr>
<tr>
<td>Male sex; no. (%)</td>
<td></td>
<td>13 (50)</td>
<td>13 (50)</td>
<td>—</td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td>29.7 ± 4.3</td>
<td>30.7 ± 4.5</td>
<td>0.41</td>
</tr>
<tr>
<td>SF12 MCS</td>
<td></td>
<td>58.3 ± 6.2</td>
<td>59.4 ± 7.6</td>
<td>0.59</td>
</tr>
<tr>
<td>SF12 PCS</td>
<td></td>
<td>32.3 ± 6.2</td>
<td>31.6 ± 8.5</td>
<td>0.75</td>
</tr>
<tr>
<td>WOMAC total score</td>
<td></td>
<td>51.6 ± 15.6</td>
<td>51.3 ± 14.7</td>
<td>0.94</td>
</tr>
</tbody>
</table>

BMI = body mass index; MCS = mental component score; PCS = physical component score; SD = standard deviation; WOMAC = Western Ontario & McMaster Universities Osteoarthritis Index.

*Unless indicated otherwise.

**Table 2. In-hospital costs**

<table>
<thead>
<tr>
<th>Cost</th>
<th>Group; mean ± SD</th>
<th>Early discharge</th>
<th>Standard care</th>
<th>Mean difference (95% CI)</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating room</td>
<td></td>
<td>1438.85 ± 275.62</td>
<td>1622.77 ± 484.51</td>
<td>$-183.91$ (–395.17 to 53.31)</td>
<td>0.09</td>
</tr>
<tr>
<td>Intraoperative medications</td>
<td></td>
<td>104.36 ± 13.09</td>
<td>77.38 ± 21.76</td>
<td>26.98 (14.41 to 37.90)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Inpatient stay</td>
<td></td>
<td>649.62 ± 281.71</td>
<td>1279.71 ± 515.98</td>
<td>$-630.09$ (–864.47 to –413.44)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Total cost*</td>
<td></td>
<td>2563.48 ± 396.48</td>
<td>3497.92 ± 916.27</td>
<td>$-934.44$ (–1453.16 to –483.54)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

CI = confidence interval; SD = standard deviation.

*The total cost does not include procedure-related equipment and implant costs, as these were assumed to be similar between groups.
Similarly, Kolisek and colleagues\(^6\) compared patients who underwent TKA with an accelerated pathway (discharged within 23 h of surgery) to those who followed a standard inpatient protocol with a mean hospital stay of 2–4 days. They found no differences in perioperative complications, returns to hospital or Knee Society scores at a mean follow up of 24 months. Finally, a retrospective analysis of more than 50,000 total hip arthroplasties (THA) and TKAs found no differences in 30-day major complications or readmissions among patients with a 0–2 day hospital stay compared with those discharged on postoperative day 3 or 4.\(^7\) Although these findings are encouraging, the validity and generalizability of the results are limited by the retrospective nature of the studies and the carefully selected patient cohorts. Furthermore, these studies did not evaluate the economic impact of those results.

Considering the large and increasing number of TKAs performed annually, there is a need to evaluate the economic efficiency of current models of care. This has led some clinicians to perform arthroplasty as an outpatient procedure, where eligible patients are discharged home on the same day as their surgery. Eliminating the overnight hospital stay is a novel opportunity to improve economic efficiency, yet large, high-quality, evidenced-based comparisons to traditional inpatient models are lacking.

A retrospective study by Lovald and colleagues\(^8\) estimated that outpatient TKA compared with an inpatient stay of 3–4 days resulted in cost savings of $8327. Huang and colleagues\(^9\) conducted a case–control study comparing the costs among 20 patients who were discharged the same day of surgery to 20 inpatients who underwent TKA. They found that the same-day discharge resulted in a median cost savings of approximately 30%. At 1 year postoperative, there were no major complications and no returns to hospital or readmissions for either group.\(^9\)

Although these results are encouraging, future study is warrantied to determine if similar results can be found in a randomized controlled trial adequately powered to detect differences in adverse event rates between groups, incorporating a full economic evaluation. Importantly, evaluation of barriers to implementation of outpatient pathways is necessary, as an abrupt change in practice to current TKA care pathways may be hindered by changes to both clinical practice and current funding models. For example, in Ontario, although physicians are reimbursed the same amount for outpatient and inpatient procedures, outpatient TKA is not incorporated into current Quality-Based Procedures (QBP) indicators, therefore hospitals are not compensated for outpatient arthroplasty unless covered under another global funding budget other than the QBP.\(^3\) Furthermore, postoperative physical therapy is covered by public funding only following an overnight stay in hospital.\(^10\)

As part of the transition of care, first moving to a postoperative day 1 discharge may enable a smoother, more appropriate transition to outpatient care, allowing sufficient evidence to be generated to inform future funding models and care pathways.

The transition to implementing outpatient THA has followed a similar pathway. Prior studies have reported patient-reported, clinical and cost outcomes following outpatient THA as well as an evaluation of barriers encountered with the accelerated discharge protocols.\(^11,12\) Similarly, the transition of care to reduced LOS in TKA requires changes in practice among all health care providers involved in the care of the patient. This includes changes in surgical approach, such as greater care of soft tissue management, decreased blood loss and reduced tourniquet time. It also may require new anesthesia techniques.

Although our initial intention of the early discharge protocol in the present study was to enable an LOS shorter than 24 hours, the average LOS of patients in the early discharge group was longer than 24 hours. The most common reason for a delay in discharge was complications of the intra-articular catheters used to deliver analgesics. The mode of failure was leakage, demonstrating that newer anesthesia techniques allow pain control issues to be addressed, but may introduce additional complications that affect time to discharge. Our experience highlights several aspects to consider and address when implementing and evaluating an early discharge protocol: the learning curve associated with the changes in the care pathway, effective communication strategies among the entire care team, patient satisfaction with postoperative pain control, and evaluation of the patient and caregiver experience with the new care pathway.

**Limitations**

Strengths of this study include a prospective cohort of patients undergoing the postoperative day 1 discharge protocol, with detailed patient-level costing of in-hospital and procedure-related resource use. Although our results may be limited by the small sample size and retrospective comparison group, we matched groups on several characteristics known to influence LOS and outcomes to

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**Table 3. Patient-reported outcomes 1 year postoperative**

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Group; mean ± SD</th>
<th>Mean difference (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF12 MCS</td>
<td>61.4 ± 9.5</td>
<td>58.4 ± 9.9</td>
<td>2.7 (–2.3 to 7.8)</td>
</tr>
<tr>
<td>SF12 PCS</td>
<td>47.4 ± 11.4</td>
<td>49.5 ± 11.8</td>
<td>-1.8 (–8.3 to 4.7)</td>
</tr>
<tr>
<td>WOMAC Total</td>
<td>81.3 ± 13.5</td>
<td>80.4 ± 23.3</td>
<td>0.92 (–10.3 to 14.7)</td>
</tr>
</tbody>
</table>

CI = confidence interval; MCS = mental component score; PCS = physical component score; SD = standard deviation; WOMAC = Western Ontario & McMaster Universities Osteoarthritis Index.
minimize the risk of bias. Our preliminary evaluation of the feasibility, costs and clinical outcomes associated with early discharge will enable us to further refine the early discharge protocol, ensuring a smooth transition to outpatient care, and evaluate the cost-effectiveness of outpatient TKA.

**Conclusion**

Our results suggest that discharge on postoperative day 1 following TKA is a feasible, cost-saving alternative, with no change in patient outcomes. Potential challenges to a successful early discharge must be considered and addressed before implementation as our health care system progresses toward shorter LOS. Future study should investigate adverse events in the immediate postoperative period and any associated costs as well as additional health care resource use, both direct and indirect, over the entire first year after surgery through a full economic evaluation.

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**Competing interests:** None declared.

**Contributors:** J. Howard and B. Lanting designed the study. J. Marsh, L. Somerville and B. Lanting acquired the data, which J. Marsh and B. Lanting analyzed. J. Marsh, L. Somerville and B. Lanting wrote the article, which all authors reviewed and approved for publication.

**References**

Impact of sequential implementation of multimodal perioperative care pathways on colorectal surgical outcomes

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This paper was presented at the Canadian Surgery Forum, Toronto, Sept. 8–11, 2016, and the WB and MH Chung Research Day, Department of Surgery, University of British Columbia, Vancouver, Nov. 7, 2016.

Accepted Apr. 13, 2018; Published online Dec. 1, 2018

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DOI: 10.1503/cjs.015617

Background: Standardized care protocols offer the potential to reduce postoperative complication rates. The purpose of this study was to determine whether there was an additive benefit associated with the sequential implementation of the evidence-based surgical site infection bundle (SSIB) and enhanced recovery after surgery (ERAS) protocols for patients undergoing colorectal surgery in a community hospital.

Methods: Patients at a single institution who underwent elective colorectal surgery between Apr. 1, 2011, and Dec. 31, 2015, were identified by means of American College of Surgeons National Surgical Quality Improvement Program data. Patients were stratified into 3 groups according to the protocol implementation dates: pre-SSIB/pre-ERAS (control), post-SSIB/pre-ERAS and post-SSIB/post-ERAS. Primary outcomes assessed were length of stay and wound complication rates. We used inverse proportional weighting to control for possible differences between the groups.

Results: There were 368 patients included: 94 in the control group, 95 in the post-SSIB/pre-ERAS group and 179 in the post-SSIB/post-ERAS group. In the adjusted analyses, mean length of stay (control group 7.6 d, post-SSIB/post-ERAS group 5.5 d, \(p = 0.04\)) and overall wound complication rates (14.7% and 6.5%, respectively, \(p = 0.049\)) were reduced after sequential implementation of the protocols.

Conclusion: Sequential implementation of quality-improvement initiatives yielded additive benefit for patients undergoing colorectal surgery in a community hospital, with a decrease in length of stay and wound complication rates. The amount of improvement attributable to either initiative is difficult to define as they were implemented sequentially. The improved outcomes were realized after the introduction of the ERAS protocol in adjusted analyses.

Contexte : Les protocoles de soins standardisés offrent la possibilité de réduire les taux de complications postopératoires. Le but de cette étude était de déterminer s’il y a un avantage additif associé à l’application séquentielle des protocoles fondés sur des données probantes SSIB (surgical site infection bundle) et ERAS (enhanced recovery after surgery) chez des patients soumis à une chirurgie colorectale dans un hôpital communautaire.


Résultats : Nous avons inclus 368 patients, 94 dans le groupe témoin, 95 dans le groupe post-SSIB/pré-ERAS et 179 dans le groupe post-SSIB/post-ERAS. Dans les analyses ajustées, la durée moyenne des séjours (groupe témoin 7.6 j, groupe post-SSIB/post-ERAS 5.5 j, \(p = 0.04\)) et les taux globaux de complications de plaies (14.7 % et 6.5 % respectivement, \(p = 0.049\)) ont diminué après l’application séquentielle des protocoles.

Conclusion: L’application séquentielle des initiatives d’amélioration de la qualité a donné lieu à des bienfaits additifs chez les patients soumis à une chirurgie colorectale dans un hôpital communautaire, avec abrègement du séjour hospitalier et diminution du taux de complications de plaies. Le degré d’amélioration attributable à chacune des initiatives est difficile à préciser puisqu’elles ont été appliquées séquentiellement. L’amélioration des paramètres a été obtenue après l’introduction du protocole ERAS dans des analyses ajustées.
Surgery for resection of the colon or rectum is traditionally associated with a high risk of complications. Historically, patients undergoing colorectal resection could expect a 20%–25% risk of complications along with the prospect of a postoperative hospital stay of 7–10 days. Recognizing an opportunity for improved care, many institutions have introduced standardized care protocols to decrease postoperative complication rates, reduce length of stay and provide cost-effective care without compromising patient safety. Two such protocols are the enhanced recovery after surgery (ERAS) and the surgical site infection bundle (SSIB). These protocols show promising results in reducing morbidity and length of stay after colorectal procedures.

The ERAS pathway is an evidence-based initiative developed to promote rapid recovery and decrease postoperative complication rates. This multimodal intervention was first introduced by Kehlet, in 1990, and is now recognized as the gold standard for perioperative care management in patients undergoing colonic or rectal surgery. The ERAS pathway aims to optimize recovery by modifying physiological and psychological responses to major surgery. Studies evaluating patient outcomes after implementation of ERAS have shown reduced complication rates and length of stay, improvements in cardiopulmonary function, earlier mobilization and return of bowel function, and overall reduction of cost to the healthcare system. The SSIB protocol.

The NSQIP system of data sampling has been validated and allows for comparison of risk-adjusted surgical outcomes among all participating hospitals. We used a procedure-targeted NSQIP module to ensure that all relevant cases were captured. Inclusion criteria were based on pre-defined NSQIP Current Procedural Terminology codes for colorectal resection. Procedures were elective, open or laparoscopic, and included abdominoperineal resection, partial colectomy, total abdominal colectomy with or without proctectomy, proctectomy and low anterior resection. Patients younger than 18 years were excluded as per NSQIP guidelines. In addition, patients who had emergency colorectal procedures were excluded, as the perioperative care pathways could not be applied in the same way to this patient population owing to the expediency of care required. No patients were lost to follow-up. Processes within the quality-improvement initiatives were applied to all eligible patients, at reported compliance rates, as per their cohort, and follow-up data were obtained for all these patients as per the NSQIP protocol.

**Perioperative quality-improvement pathways**

The SSIB and ERAS interventions were a multidisciplinary effort that required the participation and compliance of surgeons, operating room nurses, anesthesiologists, ward nurses, enterostomal therapists, clinical practice educators, patient care coordinators and other allied health care professionals. Implementation of the perioperative care pathways was a team effort coordinated by a team of front-line providers. The SSIB and ERAS elements were selected based on established, evidence-based, best-practice guidelines as reviewed by the local team. Our site participated in Health Authority and provincial ERAS collaboratives, and this also influenced pathway design. Compliance with the components of the perioperative quality-improvement programs was tracked and reported quarterly. The target compliance for each component throughout all study periods was set at 80% for our site.

**METHODS**

**Study population and data collection**

This was a retrospective cohort study approved by the Interior Health Research Ethics Board. The study was completed at Royal Inland Hospital, a tertiary referral community hospital with 245 acute care beds located in Kamloops, British Columbia. The American College of Surgeons National Surgical Quality Improvement Program (NSQIP) was introduced at our hospital in 2011. We used NSQIP data to identify all patients who underwent colorectal procedures at our site from Apr. 1, 2011, through Dec. 31, 2015. The NSQIP methodology was applied by 2 surgical-clinical reviewers to rigorously collect demographic information, clinical variables and 30-day outcomes for all patients who underwent colorectal resection during the study period. Custom fields were created within the NSQIP workstation to track compliance rates for the perioperative processes within both the ERAS and the SSIB protocol.
We categorized patients into 1 of 3 groups based on the implementation dates of the SSIB and ERAS interventions as follows: pre-ERAS/pre-SSIB (control group) (Apr. 1, 2011, to June 16, 2013), pre-ERAS/post-SSIB (June 17, 2013, to May 20, 2014) and post-ERAS/post-SSIB (May 21, 2014, to Dec. 31, 2015).

Outcome measures

The primary outcome measures included hospital length of stay and wound complications. Secondary outcome measures included death within 30 days, readmission within 30 days, unplanned return to the operating room and various complications captured in the NSQIP database.

Statistical analysis

We compared baseline demographic characteristics, patient characteristics and 30-day postoperative outcome variables between groups using the nonparametric Kruskal–Wallis test for continuous variables (age, body mass index) since the data did not follow a normal distribution, and the χ² or Fisher exact test, as appropriate, for categorical variables. We used a propensity score approach to account for baseline differences between groups owing to the nonrandomized design of the study. The propensity score model was developed through a careful approach selecting variables thought to be related to the outcomes. Covariates included age, body mass index, sex, American Society of Anesthesiologists classification, wound classification, laparoscopic procedure, diabetes status and smoking status. We examined the balance of the propensity score across treatment and comparison groups in quintiles using t tests and reported standardized differences remaining in the baseline covariates after reweighting, along with adjusted covariate variances. To estimate the average treatment effect of the SSIB and ERAS interventions, we used inverse proportional weighting with weighted comparisons between pre-ERAS/pre-SSIB v. post-ERAS/pre-SSIB, post-ERAS/pre-SSIB v. post-ERAS/post-SSIB, and pre-ERAS/pre-SSIB v. post-ERAS/post-SSIB. The level of significance for all statistical tests was set at p < 0.05. All analyses were conducted in Stata/SE version 15 (StataCorp).

RESULTS

Patient characteristics

There were 368 patients in this study, 94 in the control group, 95 in the post-SSIB/pre-ERAS group and 179 in the post-SSIB/post-ERAS group. The cohorts were balanced for sex, body mass index, American Society of Anesthesiologists classification, diabetes, chronic obstructive pulmonary disease, smoking status, functional status and preoperative chemotherapy (Table 1). However, statistically significant differences were observed for median age (control group 73 yr, post-SSIB/pre-ERAS group 68 yr, post-SSIB/post-ERAS group 70 yr, p = 0.049), laparoscopic procedure (80.9%, 91.6% and 93.3%, respectively, p = 0.007) and clean/contaminated wound classification (67.0%, 84.2% and 84.4%, respectively, p = 0.008).

After application of inverse proportional weighting, all baseline patient characteristics used in the propensity score model were balanced in all groups (Table 2).

Postoperative outcomes

Significant decreases were observed in the unadjusted values for mean length of stay (control group 9.0 d, post-SSIB/pre-ERAS group 6.4 d and post-SSIB/post-ERAS group 5.2 d, p = 0.01) and median length of stay (5 d, 3 d and 3 d, respectively, p < 0.001). There were also significant decreases in the overall rates of wound infection (16.0%, 9.5% and 5.0%, respectively, p = 0.01), superficial surgical site infection (8.5%, 4.2% and 0.6%, respectively, p = 0.001) and urinary tract infection (4.3%, 0.0% and 0.6%, respectively, p = 0.02) (Table 3).

After application of inverse proportional weighting, decreases in length of stay and rates of wound complications including superficial and organ space infections and urinary tract infections were observed after implementation of the SSIB pathway; however, only the change in the urinary tract infection rate was statistically significant (p = 0.04) (Table 4). Introduction of the ERAS pathway continued to demonstrate similar clinically relevant trends, without statistical significance. Comparison between the control group and the post-SSIB/post-ERAS group showed significant decreases in mean length of stay (7.6 d v. 5.5 d, p = 0.04) and the rate of overall wound complications (14.7% v. 6.5%, p = 0.049) and superficial surgical site infections (8.2% v. 1.8%, p = 0.047). Although not statistically significant, a trend of decreasing organ space surgical site infection was also observed (7.3% v. 4.7%, p = 0.4).

Perioperative pathway compliance

Target rates of compliance of at least 80% were achieved for 9 of the 18 components of the SSIB, although analysis of trends over time illustrated consistent improvement in compliance. Target rates of compliance were achieved for 11 of the 18 ERAS components (Table 5).

DISCUSSION

Evidence-based quality-improvement pathways were implemented sequentially in a community hospital to evaluate the impact on outcomes in patients undergoing colorectal surgery. When introduced effectively, these types of quality-improvement initiatives can lead to improvements in patient outcomes.3–5,7,10 In the unadjusted analyses, the sequential implementation of the ERAS and SSIB
initiatives had a significant cumulative impact on overall length of stay and wound complication rates. These findings are consistent with those of the only other study we are aware of in which similar objectives were investigated.3

In the adjusted analyses, the implementation of SSIB resulted in marginal, nonsignificant reductions in a number of outcomes, including length of stay, superficial surgical site infections, organ space surgical site infections and urinary tract infections. Subsequent implementation of ERAS appears to have supplemented the improvements in the same outcomes shown in the SSIB-alone cohort, with the added benefit of reduced rates of septic shock. Comparison of the pre- and postintervention groups showed that patient length of stay was significantly reduced, and overall wound complication rates were significantly lower. Subgroup analysis showed that the lower wound complication rates were mainly due to reduction of the rates of superficial surgical site infections. Although there was a trend only toward lower urinary tract infection rates, the control group had low rates of this complication, which may have been secondary to previous quality-improvement efforts at our site to address this specific outcome. Similarly, there were no cases of postoperative deep venous thrombosis or pulmonary embolism, and high levels of adherence to

Table 1. Characteristics of patients who underwent colorectal procedures stratified by implementation date of the surgical site infection bundle and enhanced recovery after surgery care pathways

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group; no. (%) of patients*</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-SSIB/pre-ERAS n = 94</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post-SSIB/pre-ERAS n = 95</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post-SSIB/post-ERAS n = 179</td>
<td></td>
</tr>
<tr>
<td>Age, yr, median (Q1, Q3)</td>
<td>73 (64, 80)</td>
<td>0.049</td>
</tr>
<tr>
<td>Body mass index, median (Q1, Q3)†</td>
<td>28 (24, 31)</td>
<td>0.9</td>
</tr>
<tr>
<td>Age, yr, mean ± SD</td>
<td>71.2 ± 11.7</td>
<td>0.04</td>
</tr>
<tr>
<td>Sex</td>
<td>Male 38 (40.4)</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>Female 56 (59.6)</td>
<td></td>
</tr>
<tr>
<td>American Society of Anesthesiologists class</td>
<td>0.09</td>
<td></td>
</tr>
<tr>
<td>1–2</td>
<td>33 (35.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>46 (48.4)</td>
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<tr>
<td>3–4</td>
<td>61 (64.9)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>49 (51.6)</td>
<td></td>
</tr>
<tr>
<td>Wound classification</td>
<td>63 (67.0)</td>
<td>0.008</td>
</tr>
<tr>
<td></td>
<td>80 (84.2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>151 (84.4)</td>
<td></td>
</tr>
<tr>
<td>Laparoscopic procedure</td>
<td>12 (12.8)</td>
<td>0.007</td>
</tr>
<tr>
<td></td>
<td>5 (5.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 (4.5)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>Yes 76 (80.8)</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>87 (91.6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>167 (93.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No 18 (19.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 (8.4)</td>
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<tr>
<td></td>
<td>12 (6.7)</td>
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ERAS = enhanced recovery after surgery; Q1, Q3 = quartile 1, quartile 3; SD = standard deviation; SSIB = surgical site infection bundle.

*Except where noted otherwise.
†Data missing for 7 patients.
prophylaxis, which may have been because of preexisting initiatives to improve compliance with the introduction of order sets for venous thromboembolism prevention. Prolonged postoperative deep vein thrombosis prophylaxis was not routinely used for any of the patient groups.

Based on the adjusted outcomes, it appears that the addition of a second standardized protocol, ERAS, provided the most benefit to patients undergoing colorectal surgery. However, there was no cohort in which ERAS was the only quality-improvement initiative implemented. In the only other study that investigated the same initiatives implemented sequentially, ERAS was introduced before SSIB.3 Results in that study mirror the trend observed in the current study of larger improvements after the introduction of a second quality-improvement initiative. It may be that sustained evidence-based quality-improvement efforts, rather than multiple protocols, lead to greater improvements in patient outcomes. However, our study cannot comment on the effectiveness of either protocol separately.

Although both standardized quality-improvement initiatives in the present study largely relied on existing quality-improvement infrastructure within our hospital, we recognize that the opportunity cost of implementing these protocols is potentially high. Implementing each protocol consumes finite resources. Future research may help teams decide which quality-improvement initiative to choose to implement to most improve outcomes.

Establishing sustainable quality-improvement projects can be challenging. These multicomponent programs are complex initiatives, and the development of strategies by key stakeholders to address the challenges with each pathway component is crucial. Our community site was able to achieve sustainability by hosting frequent meetings with key stakeholders to reinforce program objectives and

### Table 2. Cohort characteristics after inverse proportional weighting

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ERAS = enhanced recovery after surgery; SD = standard deviation; SSIB = surgical site infection bundle; std. Δ = standard difference.
*Except where noted otherwise.
†Values less than 20% indicate negligible differences between groups for a particular covariate.
### Table 3. Thirty-day postoperative outcomes

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<th>p value</th>
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ERAS = enhanced recovery after surgery; SSIB = surgical site infection bundle.

*Except where noted otherwise.

### Table 4. Thirty-day postoperative outcomes after inverse proportional weighting

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ERAS = enhanced recovery after surgery; SSIB = surgical site infection bundle.

*Unless indicated otherwise.
identify areas for improvement. Information was disseminated by widely sharing quarterly reports, displaying posters in visible areas to motivate front-line providers and providing direct, real-time feedback to these providers. Appropriate system changes at each stage of the perioperative journey were introduced to improve compliance and knowledge translation. Finally, the patient must not be forgotten as a vital stakeholder. Engaging patients in their own care leads to greater effectiveness of project implementation. Our site developed initiatives including patient booklets and websites to help patients contribute to the sustainability and success of the quality-improvement initiative.

**Limitations**

There are several limitations to our study. Although the data were collected prospectively, the retrospective nature of the analysis may have introduced biases and may have led to the inability to collect missing data. The adjusted analyses, in which patient characteristics from the NSQIP database were used, attempted to account for differences in patient characteristics between the cohorts, as was found for wound classification and laparoscopic procedure. We did not expect inherent differences in these characteristics between these successive cohorts. The differences may have been due to the quality-improvement initiatives themselves. With the introduction of SSIB, there was a focus on several variables that may have affected wound classification, including use of a wound protector, isolation technique, efforts to minimize spillage during creation of the anastomosis, standardized use of bowel preparation with oral antibiotic therapy and education to help nurses/surgeons properly determine wound class. Similarly, increasing rates of laparoscopic surgery between the successive cohorts is in keeping with compliance with the 2 protocols’ processes. The adjusted outcomes may therefore underestimate the effectiveness of the interventions, and the unadjusted outcomes may be a more useful measure of their effectiveness. However, we acknowledge that there may have been unmeasured confounding variables or other real differences between the cohorts that may have affected our results. Delivery of multicomponent quality-improvement programs has a learning curve. Therefore, sequentially introducing different programs may have led to better compliance with the second intervention as the stakeholders had an implementation strategy developed and the staff were accustomed to delivering complex care plans. Also, as greater attention is paid to relevant processes, documentation may become more accurate over time. This could cause the appearance of differences between cohorts that are not real. Finally, the sample size may have been too small for improvements in some outcomes to reach statistical significance.
CONCLUSION

Our findings show that sequential implementation of perioperative care pathways in colorectal surgery can lead to a cumulative improvement in patient outcomes. The absolute benefit attributable to either protocol separately is difficult to define. Unadjusted outcomes improved with sequential implementation of the quality-improvement protocols. Significant improvement in the adjusted primary outcomes of length of stay and wound complication rates was realized after implementation of ERAS. Our results show that community hospitals are able to effectively and successfully implement multiple complex perioperative quality-improvement pathways, with results comparable to those in large academic centres. Integrating these pathways can be resource and time intensive but can lead to substantial benefit for patients in terms of shorter length of stay and decreased morbidity rates.

Acknowledgements: The authors acknowledge the dedication and hard work of the National Surgical Quality Improvement Program team and front-line providers at Royal Inland Hospital, and Jodi Siever for her assistance and guidance with statistical analysis and creation of the tables.

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Competing interests: None declared.

Contributors: T. Wallace designed the study. J. Wootton acquired the data, which K. D’Souza, J.-I. Choi and T. Wallace analyzed. K. D’Souza, J.-I. Choi and T. Wallace wrote the article, which all authors reviewed and approved for publication.

References

Incidence and predictors of postoperative delirium in the older acute care surgery population: a prospective study

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Background: Among older inpatients, the highest incidence of delirium is within the surgical population. Limited data are available regarding postoperative delirium risk in the acute care surgical population. The purpose of our study was to establish the incidence of and risk factors for delirium in an older acute care surgery population.

Methods: Patients aged 65 years or more who had undergone acute care surgery between April 2014 and September 2015 at 2 university-affiliated hospitals in Alberta were followed prospectively and screened for delirium by means of a validated chart review method. Delirium duration was recorded. We used separate multivariable logistic regression models to identify independent predictors for overall delirium and longer episodes of delirium (duration ≥ 48 h).

Results: Of the 322 patients included, 73 (22.7%) were identified as having experienced delirium, with 49 (15.2%) experiencing longer episodes of delirium. Postoperative delirium risk factors included Foley catheter use, intestinal surgery, gallbladder surgery, appendix surgery, intensive care unit (ICU) admission and mild to moderate frailty. Risk factors for prolonged postoperative delirium included Foley catheter use and mild to moderate frailty. Surgical approach (open v. laparoscopic) and overall operative time were not found to be significant.

Conclusion: In keeping with the literature, our study identified Foley catheter use, frailty and ICU admission as risk factors for delirium in older acute care surgical patients. We also identified an association between delirium risk and the specific surgical procedure performed. Understanding these risk factors can assist in prevention and directed interventions for this high-risk population.

Contexte: Parmi les patients âgés, l’incidence la plus élevée d’épisodes de délire s’observe chez les patients opérés. On dispose de données limitées au sujet du risque de délire postopératoire chez ces patients soumis à une chirurgie d’urgence. Le but de notre étude était de connaître l’incidence des épisodes de délire et les facteurs de risque chez la population âgée soumise à une chirurgie d’urgence.

Méthodes: Nous avons suivi de façon prospective les patients de 65 ans ou plus soumis à une chirurgie d’urgence entre avril 2014 et septembre 2015 dans 2 centres hospitaliers universitaires de l’Alberta et nous avons recensé les épisodes de délire au moyen d’une méthode validée d’analyse des dossiers. La durée des épisodes de délire a été notée. Nous avons utilisé des modèles séparés d’analyse de régression logistique multivariée pour dégager les prédicteurs indépendants des épisodes globaux de délire et des épisodes plus longs (durée ≥ 48 h).

Résultats: Parmi les 322 patients inclus, 73 (22,7 %) ont manifesté un épisode de délire, dont 49 (15,2 %) un épisode plus long. Les facteurs de risque à l’égard des épisodes de délire postopératoire ont inclus : l’emploi d’une sonde Foley, la chirurgie intestinale, la chirurgie de la vessie bilaire, l’appendicectomie, un séjour à l’unité de soins intensifs (USI) et un état de fragilité léger ou modéré. Les facteurs de risque à l’égard d’un épisode de délire postopératoire prolongé ont inclus : l’emploi d’une sonde Foley et un état de fragilité léger ou modéré. L’approche chirurgicale (ouverte c. laparoscopique) et la durée globale de l’intervention n’ont pas joué un rôle significatif.

Conclusion: Faisant écho à la littérature publiée, notre étude a identifié l’emploi de la sonde Foley, l’état de fragilité et le séjour à l’USI comme des facteurs de risque de délire chez les patients âgés soumis à une chirurgie d’urgence. Nous avons aussi observé un lien entre le risque de délire et certains types d’interventions chirurgicales. En comprenant mieux ces facteurs, il sera possible de prévenir ces épisodes et d’orienter les interventions chez cette population à risque élevé.
Delirium is characterized by acute, fluctuating alteration in mental function and disturbance in attention. The duration of delirium can be prolonged, and cognitive impairment can last up to a year. The cause of delirium is believed to be multifactorial. Previously identified risk factors include both nonmodifiable predisposing factors (such as illness severity, surgery and admission to the intensive care unit [ICU]) and modifiable precipitating risk factors (such as immobility and presence of invasive tubes). Older surgical patients (≥65 yr) are particularly vulnerable to delirium owing to advanced age and greater rates of frailty.

The incidence of delirium has been noted to be as high as 60% in all inpatients and 7%–35% within the general surgery population. The consequences of delirium result in substantial health care expenditure owing to a prolonged hospital stay and increased disability, necessitating escalated levels of care at discharge. Delirium is also associated with increased mortality rates during the hospital stay and substantially increased overall 6-month and 1-year mortality rates.

The vast majority of the literature on delirium in the surgery population is based on orthopedic and cardiovascular populations, with a limited literature base evaluating the general surgical population. Almost all of the general surgery literature pertains to the elective population, with few published papers evaluating the incidence and risk factors for delirium in the acute care surgery (emergency nontrauma general surgery) population. The limited data available suggest that the older acute care surgery population has a higher rate of postoperative delirium than the overall acute care surgery population, ranging from 18% to 55%. Given that older people represent the most rapidly increasing segment of the population and that a third of inpatient operations are being performed in older patients, it is vital to determine the risk factors for delirium in this population, particularly since delirium is preventable in 30%–40% of cases. By identifying risk factors, targeted preventive measures can be implemented.

The purpose of our study was to determine the incidence of postoperative delirium and of longer episodes of delirium, and examine the association of delirium with pre- and perioperative risk factors in an older acute care surgery population.

Methods

Setting and participants

The study cohort comprised patients recruited from the Elder-friendly Approaches to the Surgical Environment (EASE) study; details of the EASE study, including design and analytic plan, have been previously described. In brief, this prospective concurrently controlled paired study was designed to assess the impact of an elder-friendly surgical unit on clinical, humanistic and economic outcomes. The participants included in the current analysis were all patients within the pre-EASE-initiative cohorts at the University of Alberta Hospital, Edmonton, and the Foothills Medical Centre, Calgary, who had been recruited between April 2014 and September 2015. Patients were included if they were 65 years of age or more, were admitted directly to the acute care surgery service and underwent acute abdominal surgery. Patients who underwent elective, palliative or trauma surgery, were not residents of Alberta, or were dependent in 3 or more activities of daily living were excluded. Ethics approval was obtained from both the University of Alberta Research Ethics Board and the University of Calgary Conjoint Research Ethics Board.

Measurements

Data were collected via chart review and patient interview and included age, sex, race, body mass index, marital status, smoking status, previous comorbidities, living situation before admission and Clinical Frailty Scale score. Frailty scores were further condensed into 3 categories: very fit/well, managing well/vulnerable, and mildly or moderately frail. In all patients, a Charlson Comorbidity Index score was calculated at admission. Preoperative hemoglobin concentration, length of time in the operating room, pre- or intraoperative Foley catheter placement, American Society of Anesthesiologists physical status classification score and postsurgery admission to the ICU were also captured. The patients’ operative procedure was classified based on the “surgery area” and included appendix (open or laparoscopic appendectomy), gallbladder and biliary tract (open or laparoscopic cholecystectomy), hernia (nonelective hernia repair) or other gastrointestinal (lysis of adhesions, small bowel resection, hemi- or total colectomy, colostomy/ileostomy creation or revision, or other gastrointestinal surgery confirmed by the study team).

Delirium measure

The Inouye chart review method was used to screen for delirium. This validated chart-based instrument has a sensitivity of 74% and a specificity of 83% compared with the gold-standard Confusion Assessment Method. Abstractors reviewed the full charts (including progress, nursing and consultant notes) for key terms indicating acute mental status change. If the result was positive for an acute confusional state, further information regarding the information source, onset and duration of the episode, and evidence of reversibility were collected.

Statistical analysis

We calculated descriptive statistics. We built separate multivariable logistic regressions to identify covariate-adjusted
independent predictors of delirium and of longer episodes of delirium (acute confusional state lasting ≥ 48 h). Covariates assessed in the regression included age, smoking status, comorbidities on admission, living situation before admission, Clinical Frailty Scale score, American Society of Anesthesiologists classification score, operative procedure, operative technique (open or laparoscopic), duration of surgical procedure, Foley catheter use and postoperative admission to the ICU. We added covariates to each model only if the covariate was found to be statistically significant (p < 0.05) on univariate analysis, was deemed important based on the literature and expert opinion, or was associated with confounding based on a 10% or greater change in the β coefficient within the model irrespective of statistical significance. No variables forced into the models. The p value for statistical significance for all comparisons was < 0.05. We did not perform any adjustments for multiple testing, as the analysis was intended to be exploratory. We selected the most efficient models (in which all variables had a p value < 0.05) and judged them for fit using the Hosmer–Lemeshow goodness-of-fit test; we determined accuracy using receiver operating characteristic curves. We used Stata/SE-13 (StataCorp) for all analyses.

RESULTS

The baseline characteristics of the 322 patients included in this analysis are shown in Table 1. The overall mean age for this cohort was 76.1 (standard deviation [SD] 7.66) years, with 146 patients (45.3%) being women, 238 (73.9%) being white, 232 (72.0%) living at home without support, and 78 (24.2%) having mild to moderate frailty. The most common operation was intestinal (142 patients [44.1%]), with gallbladder and biliary tract being second most common (75 patients [23.3%]). The overall mean length of stay was 13.7 (SD 17.0) days (range 1−105 d).

The incidence of delirium in our study population was 22.7% (73/322). The mean duration of delirium was 1.75 (SD 0.60) days, with the initial report of delirium usually occurring within the first 48 hours after surgery (53 patients [73%]). Compared to patients without delirium, delirious patients were frailer (p < 0.001) and more likely to have cardiovascular disease (p = 0.04), dyslipidemia (p = 0.02), previous cognitive impairment (p = 0.004) and respiratory problems (p = 0.04). Delirious patients were taking significantly more medications than patients who did not experience delirium (mean 5.85 [SD 3.80] v. 4.57 [3.44], p = 0.003), had longer operation times (127 [SD 60.7] min v. 106 [SD 54.8] min, p = 0.001) and were more likely to have had a Foley catheter inserted before or during surgery (64 [87.7%] v. 153 [61.4%], p < 0.001) (Table 1).

Significant independent risk factors for delirium included Foley catheter use (odds ratio [OR] 3.37, 95% confidence interval [CI] 1.36–8.35), intestinal surgery (OR 4.74, 95% CI 1.86–12.08), gallbladder or biliary tract surgery (OR 4.48, 95% CI 1.41–14.17), appendix surgery (OR 5.26, 95% CI 1.40–19.75), ICU admission postoperatively (OR 1.37, 95% CI 1.06−1.78) and mild to moderate frailty (OR 4.50, 95% CI 1.76–11.50).

Longer episodes of delirium occurred in 49 patients (15.2% of the overall cohort and 67% of those with delirium). There were no statistically significant differences in patient characteristics between patients with short delirium episodes and those with longer episodes. Foley catheter use (OR 4.48, 95% CI 1.76–11.50) and mild to moderate frailty (OR 7.77, 95% CI 2.18–27.65) were statistically significant independent risk factors for longer episodes of delirium (Table 2).

DISCUSSION

There are limited studies investigating delirium in the acute care surgery population, and, to our knowledge, no studies that specifically assess type of emergency surgery performed as a risk factor. Consequently, the current study provides necessary assessment of this surgical population. We found that Foley catheter use, ICU admission, frailty, and biliary tract surgery, intestinal surgery and appendectomy were significant independent risk factors for postoperative delirium in the acute care surgery population. In patients with longer episodes of delirium, only Clinical Frailty Scale score and Foley catheter use were found to be significant.

The overall incidence of delirium in our study was 23%, which is consistent with the literature. Studies in elective (nonacute) general surgery populations document delirium rates of 7%–35%, with a mode of 16% or less. In acute care surgical populations, rates of delirium of 18%−55% have been reported, with a mode over 20%. Studies in elective general surgical populations document delirium rates of 18%−55%. This wide range of delirium incidence in the literature is likely due to variations in patient populations, most notably the inclusion of patients with baseline cognitive deficits and neuropsychiatric disorders owing to different inclusion and exclusion criteria. Nonetheless, our data show a consistent trend of a higher incidence of delirium in the acute care surgical population than in the elective general surgical population. The difference may be related to differences in the patient population, as elective patients undergo preoperative screening and medical optimization. This high rate of delirium may also in part explain the higher incidence of illness and death among older people who undergo acute care surgery. Our results indicate that surgery for appendiceal and biliary disease in addition to bowel resection is a risk factor for postoperative delirium. In comparison, procedures such as hernia repair, both inguinal and abdominal, were not associated with an increased rate of postoperative delirium. We postulate that this association may be related to the fact that the underlying disease in these cases is mostly infectious and inflammatory. This conclusion is consistent with the finding that higher rates of postoperative delirium
were seen in populations with elevated leukocyte count and C-reactive protein level at admission.11,18

Interestingly, our univariate analysis suggested an association between the overall duration of surgery and postoperative delirium, although this did not reach statistical significance (p = 0.9). There was also no evidence that the type of surgical approach (open v. laparoscopic) had an effect on the development of delirium (p > 0.05). Finally, we did not find an association between the type of surgery or operating time and postoperative delirium (p > 0.2).

A well-established modifiable risk factor for delirium is catheter use in both the surgical and nonsurgical population.11,13,32 Consistent with our findings, a pooled analysis showed that urinary catheterization was among the most common risk factors associated with the development of delirium, with an OR of 3.16.33

<table>
<thead>
<tr>
<th>Table 1. Baseline characteristics of older (age ≥ 65 yr) acute care surgical patients according to delirium status</th>
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<td><strong>Total no. of medications, mean ± SD</strong></td>
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<td>Hernia repair</td>
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<td>Other</td>
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<td><strong>Time in operating room, min, mean ± SD</strong></td>
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<td><strong>Intensive care unit admission</strong></td>
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<td><strong>Foley catheter use</strong></td>
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<td><strong>Length of stay, d, median (interquartile range)</strong></td>
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SD = standard deviation.
*Except where noted otherwise.
†Acute confusional state for 48 hours or more.
‡p < 0.05 compared to no delirium.
emphasizes that early removal of catheters and lines should be the goal in this high-risk population.

Admission to the ICU is an established risk factor for delirium in the nonsurgical population and has been associated with delirium in the surgical population. A recent systematic review of patients undergoing vascular surgery also showed that ICU admission was a strong independent risk factor for postoperative delirium. 

There is limited literature assessing the ability of the Clinical Frailty Scale to predict specific clinical outcomes such as delirium. However, the scale does take into consideration, both directly and indirectly, components that have been established as independent risk factors for delirium, including functional status, comorbid disease burden and cognitive impairment. Baseline cognitive impairment has been identified as a significant risk factor for delirium in several studies evaluating general surgery populations. As such, it seems apparent that frailty assessment at admission could help identify patients at risk for delirium. Despite the consequences of frailty, there is a lack of knowledge of frailty among health care professionals, and, as a consequence, frailty assessments are not frequently used in patient care and prevention.

Although the identified risk factors of ICU admission, frailty status and surgery type are nonmodifiable, early identification of these patients can allow for potential targeted interventions to reduce the incidence and impact of delirium. Proactive interventions to target patients with nonmodifiable risk factors could include comprehensive geriatric assessment and early geriatrician consultation in surgical settings. This has been examined in trauma and elective surgery populations, with improved outcomes, including decreased delirium rates. Further research in the acute care surgery population is necessary and is currently underway.

The fact that 73% of our patients who experienced delirium did so within the first 48 hours postoperatively suggests a key window for targeted prevention and intervention. This trend was shown in other studies evaluating the general surgery population, with the majority of cases of delirium (up to 80%) occurring within 48–72 hours postoperatively.

### CONCLUSION

Overall, our findings show that older patients undergoing nonelective surgery are at significant risk for delirium. Patients at high risk in this population include those who are frail, have Foley catheters, are admitted to the ICU, and have surgery for appendiceal or biliary disease in addition to those requiring bowel resection. Further research is necessary around preventive and targeted interventions in these patients, especially within the first 48–72 hours of surgery.

### Acknowledgements

The authors thank the Acute Care Emergency surgical teams (Edmonton and Calgary) for their support, Ms. Ashley Wanamaker and Ms. Carrie Le for their assistance in study coordination and Ms. Hanhui Huynh for assistance in data collection.

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### Funding

The Elder-friendly Approaches to the Surgical Environment (EASE) study is funded by grant 201300465 from Alberta Innovates Health Solutions Partnership for Research and Innovation in the Health System. This project was also funded by the Alberta Health Services Seniors Health and Surgery Strategic Clinical Networks.

### Competing interests

None declared.

### Contributors

B. Saravana-Bawan, L. Warkentin and R. Khadaroo designed the study. L. Warkentin acquired the data, which all authors analyzed. B. Saravana-Bawan, L. Warkentin, D. Rucker, F. Carr and R. Khadaroo wrote the article, which all authors reviewed and approved for publication.

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Quantifying recall bias in surgical safety: a need for a modern approach to morbidity and mortality reviews

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Accepted Apr. 17, 2018; Published online Dec. 1, 2018

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DOI: 10.1503/cjs.017317

**Background:** Despite recent investments into reducing errors and adverse events in health care, methods for quality improvement in surgery are outdated and ineffective. Most current efforts in this field are centred around morbidity and mortality conferences (MMCs), which have remained unchanged for over 100 years. The present study aimed to quantify the recall bias associated with details from surgical cases.

**Methods:** We gathered immediate postoperative questionnaires from 1 surgeon, 1 fellow and 11 trainees following 25 routine surgical cases. Information elicited included their perceived level of concentration, mental preparedness and assessment of whether the procedure deviated from its expected course, including any intraoperative adverse events. We readministered the questionnaire 7-9 days later to assess participants’ ability to recall important aspects of the procedure.

**Results:** After 1 week, members of the surgical team were universally inaccurate in their recollection of even major details from the operating room. Although most participants felt mentally prepared and perceived no issues with concentration during the case, all participants misclassified operations as having been performed with or without adverse events in almost every included case.

**Conclusion:** Our findings show that recall bias regarding surgical safety events is exceedingly common. This likely has a major impact on the integrity of data presented at MMCs.

**Contexte** : Malgré les récents investissements visant à réduire les erreurs et les effets indésirables en santé, les méthodes d’amélioration de la qualité en chirurgie sont dépassées et inefficaces. Les efforts les plus récents dans ce domaine sont axés sur les conférences portant sur la morbidité et la mortalité (CMM), qui sont les mêmes depuis une centaine d’années. La présente étude souhaitait quantifier les biais de rappel relatifs aux détails des cas de chirurgie.

**Méthodes** : Nous avons recueilli les questionnaires postopératoires immédiats d’un chirurgien, d’un moniteur clinique et de 11 stagiaires après 25 chirurgies de routine. L’information recueillie incluait leur degré perçu de concentration, leur état de préparation mentale et leur évaluation du déroulement de l’intervention par rapport au plan prévu, y compris tout effet indésirable périopératoire. Nous avons réadministré le questionnaire 7 à 9 jours plus tard pour évaluer la capacité des participants à se rappeler les aspects importants des interventions.

**Résultats** : Après 1 semaine, les souvenirs des membres de l’équipe chirurgicale étaient tous imprécis en ce qui concerne même certains éléments majeurs des interventions. Même si la plupart des participants se sentaient mentalement prêts et qu’ils n’ont perçu aucun problème de concentration au cours des interventions, ils ont tous commis des erreurs de classification des opérations effectuées, avec ou sans effets indésirables, dans près de la totalité des cas inclus.

**Conclusion** : Nos observations montrent que les biais de rappel au sujet des enjeux de sécurité en cours d’intervention sont extrêmement fréquents. Cela exerce sûrement un impact de taille sur l’intégrité des données présentées lors des CMM.
It has long been understood by physicians that the morbidity and mortality conference (MMC) serves primarily as an opportunity to learn from each other’s mistakes. Since its introduction in the early 1900s by Codman, the MMC has compelled the health care team to carefully dissect adverse medical events or outcomes in order to identify strategies to prevent future errors leading to patient harm. The MMC is a universal tool to evaluate and improve health care quality and safety, and surgeons have long been innovators in this endeavour.

In 2002, the Canadian government budgeted $50 million over 5 years for the creation of the Canadian Patient Safety Institute, and many health care organizations have subsequently initiated efforts to improve patient safety. The most widely adopted strategy for quality assessment in academic surgical programs is the departmental MMC, which uses case-finding methods to identify opportunities for improvement in patient outcomes.

Although historically the MMC has held an important educational role, it is known that case-finding strategies for safety and quality assessment have several limitations, including a focus on individual performance rather than organizational processes and attention to individual events rather than patterns of outcomes. In addition, it has been established that self-reporting behaviour is subject to recall bias. Gaskell and colleagues suggested 4 types of recall error: forgotten details or entire events (omission), recall of events that did not occur (commission), reporting that an event happened earlier than it actually did (backward telescoping) and reporting that an event happened more recently than it did (forward telescoping). It has also been recognized that the longer the recall period, the less accurate the reporting becomes. However, although the likelihood of recall error increases with longer recall periods, so does the amount of information available, so there is a potential trade-off between recall error and information gathering.

To better understand these issues of recall bias and knowledge gathering around adverse events in surgery, we questioned members of the surgical team about organizational, situational, communication and team dynamics as well as any perceived deviations from the expected course of the operation, and repeated this questionnaire 1 week postoperatively. Substantial discrepancy in case recall lends justification to the adoption of alternative documentation strategies for surgical safety improvement, such as surgical video integration into the MMC, as means of improving education, patient safety and health care delivery.

METHODS

Study design

This survey study was conducted at an academic tertiary care centre with a high volume of laparoscopic surgery. The survey was administered at the end of an operative case and was completed by 3 members of the surgical team: the surgeon, the fellow and the medical trainee (resident or medical student). The questionnaire was then readministered 7–9 days postoperatively to test for recall bias. All abdominal and pelvic laparoscopic operative cases were included, ranging from simple procedures such as cholecystectomy and laparoscopic hernia repair to complex upper gastrointestinal procedures such as laparoscopic gastrectomy for cancer, fundoplication and bariatric surgery. Both elective and emergency cases were included. Patient identifiable data were removed.

Survey

The questionnaire was designed to assess multiple factors that could affect the recall of the operative case (Appendix 1, available at canjsurg.ca/017317-a1). After basic participant demographic information was collected, the surgical team member was asked in a closed-ended way whether the case deviated from the standard operative course. If the response was “Yes,” the participant was given the opportunity to provide a brief description of the deviation, classify it as minor or major, and state whether the team discussed it at the time. Participants were also asked to rank their mental preparedness/readiness for the procedure, as well as the level of interpersonal communication, on Likert-type scales of 1–4. This was done to ensure the absence of factors that could limit the participants’ ability to recall details of the case. Finally, the questionnaire inquired whether the case was scheduled as planned and whether participants felt they were able to adequately concentrate during the procedure.

Seven to 9 days postoperatively, participants were asked whether they could remember the details of the case, and, if they did, the questionnaire was repeated.

Participants provided consent to participate and to provide anonymous survey responses. Owing to the deidentified nature of the study, patients were not asked to provide consent.

RESULTS

Twenty-five surgical cases were included in the final analysis. All physicians approached to participate in the study agreed. Twenty-five questionnaires were collected from a single staff surgeon and from 1 fellow, and 20 questionnaires were collected from 11 different trainees (6 PGY-1, 7 PGY-4 and 7 PGY-5).

In the immediate postoperative period, the staff surgeon felt that he was able to concentrate adequately and that the procedure had been scheduled as planned in all included study cases. He felt that communication in the operating
room team was optimal in 22 cases (88%) and that he was mentally prepared for the operation in all cases (Fig. 1). In 13 cases (52%), the surgeon reported a deviation from the normal course of the operation, major in 8 cases and minor in 5. Interestingly, at 1 week postoperatively, the surgeon could not recall details from 15 cases (60%), misclassified 4 cases (16%) as having minor deviations and incorrectly recalled 5 cases (20%) as being performed without any deviation (Table 1).

A similar phenomenon was observed with the fellow. Again, in all included cases, the fellow felt that there were no limitations on his ability to concentrate and that the case was appropriately scheduled as planned. He felt mentally prepared for the operation in 23 cases (92%) and rated the communication in the operating room as optimal in 24 cases (96%) (Fig. 1). There was strong agreement between the faculty surgeon and the fellow in the immediate postoperative period regarding whether a deviation from the planned operative course occurred (22/25 [88%]). The fellow felt that 16 cases (64%) contained deviations in operative course, of which 6 were major and 10 were minor. However, when asked 1 week later, he was unable to recall 18 cases (72%), and he incorrectly classified 3 cases (12%) as involving deviations and 4 (16%) as having occurred without any intraoperative events (Table 1).

Medical trainees felt mentally prepared in 18/20 cases (90%) and felt that communication was optimal in all cases (Fig. 1). They did not readily agree with the faculty surgeon regarding whether a deviation from the planned operative course occurred (7/20 [35%]). Trainees felt that 7 cases (35%) contained deviations in operative course. At the time of follow-up 1 week later, they were unable to recall the details of 13 cases (65%) and misclassified 3 cases (15%) as deviating from the standard procedural course. However, they were able to correctly recall 4 cases (20%) as having no events intraoperatively (Table 1).

**Discussion**

We used a survey instrument to quantify the effect of time delay in recalling events regarding patient safety in surgical procedures. This gap in memory has the potential to negatively affect the quality of data presented at

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**Table 1. Participant responses regarding whether the case deviated from the standard operative course postoperatively and 7−9 days later**

<table>
<thead>
<tr>
<th>Participant</th>
<th>Immediately postoperatively, no. (%) of cases</th>
<th>7−9 d postoperatively, no. (%) of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Surgeon</td>
<td>13 (52) (8 major, 5 minor)</td>
<td>12 (48)</td>
</tr>
<tr>
<td>Fellow</td>
<td>16 (64) (6 major, 10 minor)</td>
<td>9 (36)</td>
</tr>
<tr>
<td>Medical trainees</td>
<td>7 (35) (4 major, 3 minor)</td>
<td>13 (65)</td>
</tr>
</tbody>
</table>
the MMC, which may have adverse consequences for education, quality improvement and patient safety. We found that the number of operative cases incorrectly classified as following the expected operative course was high among all members of surgical team; errors included those of omission as well as commission. Although the MMC remains a gold standard for surgical quality improvement and surgical education, there remains a lack of quantitative data on the accuracy of the data presented at these conferences. Efforts to improve the educational value of surgical MMCs remain limited, and previous efforts to assess the MMC have been largely qualitative, with findings inherently difficult to reproduce. Other groups have published tools to improve the educational experience of the MMC, generally consisting of rubrics to enhance situational awareness or to provide structured methods of analysis and presentation of data only.

There has been limited investigation surrounding the phenomenon of recall bias as it pertains to patient safety. Our data conclusively show that the surgeon and the fellow were unable to remember pertinent details from operations as few as 7 days earlier, despite reporting immediately postoperatively being mentally prepared and being allowed to adequately concentrate during the operation. Interestingly, the most accurate recall was among the medical trainee cohort. This may suggest that increasing exposure to a given surgical procedure leads to a decreased ability to discriminate between recent cases, further adding to the list of limitations of the MMC.

One possible solution to overcoming recall bias regarding intraoperative safety events is the inclusion of operative video capture as routine practice or incorporation of video data into the medical record. The routine use of prospective media capture in the operating room is currently being investigated as a means of improving the ability to assess surgical safety and to implement quality-improvement strategies in surgery. In a study by Bonrath and colleagues, analysis of intracorporeal video captured during 38 laparoscopic surgical procedures identified 66 human errors, and in 25 operations they identified an adverse event that required additional rectification by the surgeon. Wauben and colleagues showed that, although surgeons performing laparoscopic cholecystectomy recorded having achieved the “critical view of safety” in the medical record in 100% of cases, objective video review of these cases showed that this was done in only 43% of cases. Combined with our findings, these reports suggest that objective analysis of operative video would increase both the accuracy and the educational yield of the MMC, providing specific and detailed examples not only of human errors but also of latent safety threats that could be mitigated through targeted intervention.

Limitations

There are limitations to our study that must be mentioned. First and most notably, a single staff surgeon and a single fellow were surveyed, which may limit the generalizability of the findings. Therefore, it is important that these initial findings be validated with a larger and more heterogeneous surgeon cohort. Second, the absence of video capture from the included cases means that a detailed analysis of the mechanism of error in these cases was impossible. Third, our sample was not large enough to warrant any inferential statistical analysis. However, we feel that our findings are hypothesis-generating and should spur future investigation into the phenomenon of recall bias in surgery and its effects on patient safety and quality improvement. Finally, there was substantial disagreement between medical trainees and the staff surgeon postoperatively regarding whether the case went as planned. However, we feel that this finding adds to the argument that subjective recall of intraoperative events is unreliable and that even greater variability may exist among trainees, who are often tasked with gathering the data and presenting the MMC. We plan to evaluate changes in patient outcomes following the implementation of a formal video capture program and subsequent curricula development and data-enhanced MMC.

Conclusion

A surgeon, a fellow and medical trainees were unable to accurately recall simple details from surgical cases that were performed only 7–9 days previously. Without improved technology-supported methods of data capture in surgery, crucial information that can benefit both the training of future surgeons and patients’ well-being will continue to be lost.

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Competing interests: None declared.

Contributors: H. Alsubaie and T. Grantcharov designed the study. H. Alsubaie acquired the data, which all authors analyzed. M. Goldenberg and T. Grantcharov wrote the article, which all authors reviewed and approved for publication.

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Can we reduce ischemic cholangiopathy rates in donation after cardiac death liver transplantation after 10 years of practice? Canadian single-centre experience

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DOI: 10.1503/cjs.012017

Background: Outcomes in liver transplantation with organs obtained via donation after cardiocirculatory death (DCD) have been suboptimal compared to donation after brain death, attributed mainly to the high incidence of ischemic cholangiopathy (IC). We evaluated the effect of a 10-year learning curve on IC rates among DCD liver graft recipients at a single centre.

Methods: We analyzed all DCD liver transplantation procedures from July 2006 to July 2016. Patients were grouped into early (July 2006 to June 2011) and late (July 2011 to July 2016) eras. Those with less than 6 months of follow-up were excluded. Primary outcomes were IC incidence and IC-free survival rate.

Results: Among the 73 DCD liver transplantation procedures performed, 70 recipients fulfilled the selection criteria, 32 in the early era and 38 in the late era. Biliary complications were diagnosed in 19 recipients (27%). Ischemic cholangiopathy was observed in 8 patients (25%) in the early era and 1 patient (3%) in the late era ($p = 0.005$). The IC-free survival rate was higher in the late era than the early era (98% v. 79%, $p = 0.01$). The warm ischemia time (27 v. 24 min, $p = 0.049$) and functional warm ischemia time (21 v. 17 min, $p = 0.002$) were significantly lower in the late era than the early era.

Conclusion: We found a significant reduction in IC rates and improvement in IC-free survival among DCD liver transplantation recipients after a learning curve period that was marked by more judicious donor selection with shorter procurement times.

Contexte: L’issue des greffes de foie suite à un don d’organe après décès cardiocirculatoire (DDC) a été sous-optimale comparativement aux dons suivant la mort cérébrale. Cela serait surtout attribuable à une forte incidence de cholangiopathie ischémique (CI). Nous avons évalué l’effet d’une courbe d’apprentissage échelonnée sur 10 ans sur les taux de CI chez des receveurs de greffe de foie après DDC dans un seul centre.


Résultats: Parmi les 73 greffes de foie par suite de DDC, 70 receveurs répondaient aux critères de sélection, 32 pour la première époque et 38 pour la seconde époque. Des complications biliaires ont été diagnostiquées chez 19 receveurs (27%). La cholangiopathie ischémique a été observée chez 8 patients (25%) de la première époque et 1 patient (3%) de la seconde ($p = 0,005$). Le taux de survie sans CI a été plus élevé pendant la seconde époque que pendant la première (98% c. 79%, $p = 0,01$). Le temps d’ischémie chaude (27 minutes c. 24, $p = 0,049$) et le temps d’ischémie chaude fonctionnelle (21 minutes c. 17, $p = 0,002$) ont été significativement plus courts durant la seconde époque que durant la première.

Conclusion: Nous avons observé une réduction significative des taux de CI et une amélioration de la survie sans CI chez les receveurs de greffes de foie par DDC après une courbe d’apprentissage qui a été marquée par une sélection plus judicieuse des donneurs et des délais d’obtention plus courts.
Recommended strategies to expand the donor pool in liver transplantation and decrease waiting list mortality include using extended-criteria donors and living donation. Encompassed among extended-criteria donors is donation after cardiocirculatory death (DCD), the process of organ retrieval that follows irreversible cessation of cardiopulmonary function. Donation after cardiocirculatory death has been widely questioned because of its higher rate of biliary complications. Compared to organs from donation after brain death (DBD), organs from DCD are exposed to severe ischemia reperfusion injuries due to prolonged warm ischemia time (WIT), resulting in cytokine storms, circulatory dysfunction and circulatory arrest and, therefore, a higher risk of negative outcomes. Among the most feared complications encountered with DCD are ischemic cholangiopathy (IC) and primary non-function. Despite the higher rate of complications, the number of centres performing DCD liver transplantation has increased more than 5 times over the last 7 years owing to organ scarcity and high waiting list mortality.

Donation after cardiocirculatory death is defined according to the situation of the cardiac arrest: uncontrolled (patient is declared dead on arrival or after resuscitation failure, occurring inside or outside the hospital) or controlled, in which the treating team and family are "awaiting cardiac arrest." The first successful human liver transplantation was performed in 1963 with uncontrolled DCD; however, this practice stopped during the mid-1970s owing to the poor outcomes and establishment of brain death criteria. In 1995, the University of Pittsburgh and the University of Wisconsin published their experiences with the introduction of controlled DCD, and their results encouraged other programs to further pursue this innovative practice. During the following years, DCD was considered an ethical practice by the US Institute of Medicine and gained more popularity, with a steady rise in the number of DCD transplantation procedures for more than 10 years. Nonetheless, the journey was not free of challenges, and this growth levelled out in 2005. Some centres began publishing major complications and inferior survival rates among recipients of DCD organs. The wide discrepancy in IC rates between centres (1.4%–50%) prompted the transplantation community to reassess protocols and investigate donor and recipient risk factors. Foley and colleagues and de Vera and colleagues reported an increased risk of biliary complications in donors older than 40 and 60 years, respectively, but Taner and colleagues and Firl and colleagues did not find age to be a risk factor for IC. Other characteristics associated with higher IC rates are increased donor weight, prolonged cold ischemia time (CIT) and prolonged WIT.

The journey toward the use of DCD organs in Canada started in 2005. After 3 days of extensive examination and more than 100 experts’ opinions, the Canadian Council for Donation and Transplantation sanctioned the use of DCD organs. Consequently, the London Health Sciences Centre, London, Ontario, did its first DCD liver retrieval and transplantation in July 2006. Over the next decade, transplantation surgeon expertise, institutional volume and multidisciplinary team experience accumulated, resulting in growth along the DCD learning curve. Expected outcomes of a transplantation centre’s learning curve include reduced operative time, reduced number of complications, including IC, fewer unplanned interventions and improved recipient survival. This study aimed to assess the learning curve of the pioneer Canadian DCD liver transplantation program in London, focusing on IC.

METHODS

Design and setting

We conducted a cohort study using a prospectively maintained database of all patients who underwent orthotopic liver transplantation at a single transplantation centre in Ontario. We performed a retrospective analysis using data collected from patients who received organs procured via DCD between July 2006 and July 2016. The cohort was divided into early (July 2006 to June 2011) and late (July 2011 to July 2016) eras. We compared donor and recipient characteristics, and transplantation outcomes between eras to assess the effect of the learning curve of our DCD liver transplantation program. Ethics approval was obtained from the Western University Office of Research Ethics.

Population

Patients with end-stage liver disease were evaluated and listed for liver transplantation by a multidisciplinary team. The Model for End-Stage Liver Disease was used for graft allocation. Candidates for DCD grafts were generally similar to candidates for DBD grafts; however, patients with a history of extensive abdominal surgery or portomesenteric vein thrombosis were listed for DBD only. In general, DCD donor age was limited to 60 years, with a preferred WIT of less than 30 minutes; however, cases were considered on an individual basis, and some donor grafts with longer WIT were used. Furthermore, the graft pattern appearance after cold perfusion was assessed subjectively for organ selection.

Only controlled DCD grafts were procured, according to the technique described in the literature. In brief, withdrawal of life support occurred in the intensive care unit or the operating room according to the donor centre’s policy. Administration of heparin before death was fully disclosed during the consent discussion based on ethics and institutional policies. In our practice, all donors receive heparin (400 units/kg given intravenously) 5 minutes before withdrawal of life support if allowed by the donor hospital institutional policies. If not allowed, heparin is added to...
the preservation fluid. In the current series, all donors received heparin before withdrawal of life support. Death certification was performed by a physician independent from the transplantation team. After a 5-minute standstill period, as is Canada’s standard, the donor transferred to the operating room for rapid organ procurement, during which the inferior vena cava was cannulated first to drain the static blood from the liver, followed by aortic and superior mesenteric vein cannulation for flushing of the preservation solution (histidine–tryptophan–ketoglutarate [HTK]). Ice was placed in the abdominal cavity, the bile duct was divided, and bile was drained from the gallbladder and bile duct by flushing with cold saline solution in situ and with HTK preservation solution ex situ.

Static cold storage is the most commonly used preservation technique. It is not only the low temperatures that help preservation; preservation fluids also provide homeostasis and delay cell metabolism and cell damage. University of Wisconsin solution, HTK solution, Celsior solution (Waters Medical Systems) and IGL-1 solution are commonly used. In a 2013 meta-analysis, Lema Zuluaga and colleagues19 found no difference between type of solution in early allograft dysfunction, 1-year patient survival or biliary complications, whereas 2 trials showed inferior outcomes with HTK.19,20 As a method of preservation, static cold storage has been shown to cause injury to bile duct epithelium in 88% of cases.19,20

In our centre, HTK preservation solution is used as the standard in our DCD protocol owing to its low viscosity, which allows a better flow rate and distribution (3 times faster than University of Wisconsin solution) into the liver bed, resulting in quicker organ cooling. Moreover, in contrast to University of Wisconsin solution, the low K+ concentration (9 mmol/L) of HTK solution means that it can be released safely into the circulation, minimizing the risk of hyperkalemic cardiac arrest.16

Data collection

We calculated 4 procurement times: WIT, skin cut to flush time, skin cut to liver out and CIT. We defined WIT as the time elapsed from withdrawal of life support until aortic cold perfusion flush, and CIT as the time from cold perfusion in the donor to reperfusion at implantation in the recipient. We compared donor characteristics, recipient characteristics and outcomes between eras to assess the effect of the learning curve for our DCD liver transplantation program. The primary outcomes were IC incidence and IC-free survival time. Secondary outcomes were graft survival and need for any intervention.

Ischemic cholangiopathy is defined as a complex pathological entity characterized by multiple intrahepatic strictures in the absence of hepatic artery thrombosis or stenosis.21 Biliary tree assessment with imaging modalities was performed only in patients who had biochemical or clinical evidence of biliary obstruction. The diagnosis of IC was made based on cholangiography studies (endoscopic retrograde cholangiopancreatography [ERCP], percutaneous transhepatic cholangiography or magnetic resonance cholangiopancreatography). Ischemic cholangiopathy was considered present if imaging showed 2 or more nonanastomotic intrahepatic biliary strictures in the context of a patent hepatic artery. Internal or external biliary drainage treatment was applied with ERCP or percutaneous transhepatic cholangiography in symptomatic patients (hyperbilirubinemia or cholangitis).

Initially, posttransplantation follow-up was performed twice a week, assessing clinical and biochemical parameters (liver enzyme, bilirubin, alkaline phosphatase and immunosuppression levels). Subsequently, follow-up was done 1 month, 3 months and 6 months after transplantation, based on the patient’s clinical progression. The minimal length of follow-up was 6 months and the maximal length, 9 years (median 3 yr). In most cases, IC manifests by 6 months after transplantation.4 We defined primary nonfunction as early (within the first 72 h) graft failure in the absence of detectable technical, immunological or infectious problems, with alterations in and progressive elevation of transaminase levels, coagulopathy, changes in mental status and metabolic acidosis.5,22–24

Statistical analysis

We tested the distribution of continuous variables for normality using the Shapiro–Wilk test. Continuous variables with normal distributions were expressed as mean and standard deviation and were compared by means of the independent sample t test. Variables with nonnormal distributions were expressed as median and interquartile range (IQR) and were compared by means of the Mann–Whitney test. We computed categorical variables using the Fisher exact test. We computed survival curves using the Kaplan–Meier method and compared them using log-rank tests. All statistical analysis was performed with IBM SPSS Statistics 23 (IBM Corp.).

RESULTS

From July 2006 to July 2016, 73 consecutive DCD liver grafts were transplanted at University Hospital, of which 70 (96%) met our study criteria. Of the 70 procedures, 32 were performed in the early era and 38 in the late era.

Donor characteristics

The donor characteristics are summarized in Table 1. The median Donor Risk Index score was significantly lower in the late era than in the early era (2.1 v. 2.5) (p = 0.02). Late-era donors were younger than early-era donors, although not significantly so, and were more likely to be
male (28 [74%] v. 16 [50%]) \((p = 0.04)\). Anoxia was more common as the cause of death in the late-era group than in the early-era group (16 [42%] v. 6 [19%]) \((p = 0.049)\), and local donor allocation was significantly higher in the late era than in the early era (27 [71%] v. 15 [47%]) \((p = 0.04)\).

**Procurement times**

The median time from cut to cannulation and flush in the early era was 6 minutes (IQR 2–12 min) versus 4 minutes (IQR 2–8 minutes) in the late era \((p = 0.02)\) (Table 1). The WIT was 27 minutes (IQR 18–121 min) versus 24 minutes (IQR 16–48 min), respectively \((p = 0.049)\), and the CIT was 5.56 hours (IQR 4.45–6.45 h) versus 5.10 hours (IQR 4.46–6.37 h), respectively \((p = 0.4)\).

**Recipient characteristics**

Recipient characteristics including age and sex in the 2 eras were comparable. The Model for End-Stage Liver Disease score was similar between the 2 groups \((p = 0.7)\); however, recipients had a significantly higher incidence of hepatocellular carcinoma in the late era than in the early era (15 [39%] v. 8 [25%]) \((p = 0.003)\) (Table 1).

### Table 1. Study population characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Early era (n = 32)</th>
<th>Late era (n = 38)</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Donors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographic</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Age, yr, median (IQR)</td>
<td>44 (18–62)</td>
<td>38 (12–59)</td>
<td>0.1</td>
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<tr>
<td>Male sex</td>
<td>16 (50)</td>
<td>28 (74)</td>
<td>0.04</td>
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<tr>
<td>Height, cm, median (IQR)</td>
<td>169 (150–193)</td>
<td>175 (152–188)</td>
<td>0.1</td>
</tr>
<tr>
<td>Weight, kg, mean ± SD</td>
<td>76 ± 5.6</td>
<td>75 ± 14.6</td>
<td>0.49</td>
</tr>
<tr>
<td>Body mass index, median (IQR)</td>
<td>25 (17–46)</td>
<td>24 (17–35)</td>
<td>0.2</td>
</tr>
<tr>
<td>Donor Risk Index score, median (IQR)</td>
<td>2.46 (1.7–3.2)</td>
<td>2.1 (1.6–3.4)</td>
<td>0.02</td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
<td>0.04</td>
</tr>
<tr>
<td>Local</td>
<td>15 (47)</td>
<td>27 (71)</td>
<td></td>
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<tr>
<td>Regional</td>
<td>17 (53)</td>
<td>11 (29)</td>
<td></td>
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<tr>
<td>Cause of death</td>
<td></td>
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<td>0.049</td>
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<tr>
<td>Trauma</td>
<td>13 (41)</td>
<td>15 (39)</td>
<td></td>
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<tr>
<td>Anoxia</td>
<td>6 (19)</td>
<td>16 (42)</td>
<td></td>
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<tr>
<td>Cerebrovascular accident</td>
<td>13 (41)</td>
<td>7 (18)</td>
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<tr>
<td><strong>Procurement times</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Warm ischemia time, min, median (IQR)</td>
<td>27 (18–121)</td>
<td>24 (16–48)</td>
<td>0.049</td>
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<tr>
<td>Cut–cannulation–flush, min, median (IQR)</td>
<td>6 (2–12)</td>
<td>4 (2–8)</td>
<td>0.02</td>
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<tr>
<td>Skin cut to liver out, min, median (IQR)</td>
<td>56 (21–97)</td>
<td>52 (28–121)</td>
<td>0.2</td>
</tr>
<tr>
<td>Cold ischemia time, h, median (IQR)</td>
<td>5.56 (4.45–6.45)</td>
<td>5.10 (4.46–6.37)</td>
<td>0.4</td>
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<tr>
<td><strong>Recipients</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, yr, median (IQR)</td>
<td>54 (26–69)</td>
<td>57 (36–66)</td>
<td>0.3</td>
</tr>
<tr>
<td>Male sex</td>
<td>26 (81)</td>
<td>26 (68)</td>
<td>0.2</td>
</tr>
<tr>
<td>MELD score, median (IQR)</td>
<td>15 (8–40)</td>
<td>17 (3–35)</td>
<td>0.7</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td>0.003</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>12 (38)</td>
<td>4 (10)</td>
<td></td>
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<tr>
<td>Hepatocellular carcinoma</td>
<td>8 (25)</td>
<td>15 (39)</td>
<td></td>
</tr>
<tr>
<td>Alcoholic liver disease</td>
<td>5 (16)</td>
<td>2 (5)</td>
<td></td>
</tr>
<tr>
<td>Autoimmune</td>
<td>3 (9)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Nonalcoholic steatohepatitis</td>
<td>0 (0)</td>
<td>5 (13)</td>
<td></td>
</tr>
<tr>
<td>Primary biliary cirrhosis</td>
<td>0 (0)</td>
<td>3 (8)</td>
<td></td>
</tr>
<tr>
<td>Primary sclerosing cholangitis</td>
<td>0 (0)</td>
<td>3 (8)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4 (12)</td>
<td>6 (16)</td>
<td></td>
</tr>
</tbody>
</table>

IQR = interquartile range; MELD = Model for End-Stage Liver Disease; SD = standard deviation.

*Except where noted otherwise.
Transplantation outcomes

Biliary complications

The overall incidence of biliary complications during the follow-up period was 27% (19/70). There was a trend toward a higher proportion of biliary complications in the early era than in the late era (12 [38%] v. 7 [18%]) (p = 0.07) (Table 2).

Overall, IC (9 [13%]) and anastomotic stricture (7 [10%]) represented the most common type of biliary complication. The incidence of IC was significantly higher in the early era (8 [25%]) than in the late era (1 [3%]) (p = 0.005), whereas the incidence of anastomotic stricture was similar between the 2 eras (p = 0.9). The IC-free survival rate at 1 and 2 years was 79% in the early era and 98% in the late era (p = 0.01).

All cases of IC occurred within the first 6 months after transplantation (Fig. 1). Retransplantation due to IC was performed in 1 patient in the early-era cohort and no patients in the late-era cohort. The remaining 8 patients with IC were treated successfully with ERCP or percutaneous transhepatic cholangiography. At the time of writing, 6 of the 8 were still alive, and 2 had died due to metastatic hepatocellular carcinoma.

Endoscopic (ERCP) intervention was the most common therapeutic approach for patients with biliary complications (19 [27%]). A greater proportion of patients in the early era than the late era required ERCP (13 [41%] v. 6 [16%]) (p = 0.02). Furthermore, the total number of ERCP procedures was higher in the early era (52, range per patient 1–16) than in the late era (7, range per patient 1–2) (p = 0.008). The total number of stents per patient was significantly higher in the early era (20, range of stent per patient 1–4) than in the late era (6, range of stent per patient 1–2) (p = 0.05).

Graft and patient survival

No significant differences between eras were found in graft or patient survival (Table 2). The median length of follow-up for graft failure was 88 months in the early era and 22 months in the late era. Primary nonfunction developed in 4 grafts (6%) during the study period, with no significant difference between eras (p = 0.9). Of the 4 patients, only 1 underwent retransplantation; the remaining 3 died while waiting for a liver graft. A total of 12 grafts (17%) failed, with a significantly higher proportion of failures in the early era than in the late era (9 [28%] v. 3 [8%])

Table 2. Transplantation outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%) of recipients*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Early era</td>
</tr>
<tr>
<td>Biliary complications</td>
<td>12 (38)</td>
</tr>
<tr>
<td>Ischemic cholangiopathy</td>
<td>8 (25)</td>
</tr>
<tr>
<td>Anastomotic stricture</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Bile leak</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Choledocholithiasis</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Management of biliary complications</td>
<td></td>
</tr>
<tr>
<td>ERCP</td>
<td>13 (41)</td>
</tr>
<tr>
<td>Total no. of ERCP procedures</td>
<td>52 (1–16)</td>
</tr>
<tr>
<td>No. of patients with stent</td>
<td>9 (28)</td>
</tr>
<tr>
<td>Total no. of stents (range per patient)</td>
<td>20 (1–4)</td>
</tr>
<tr>
<td>Length of stay, d, median (IQR)</td>
<td>12 (8–161)</td>
</tr>
<tr>
<td>Graft function</td>
<td></td>
</tr>
<tr>
<td>Primary nonfunction</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Graft failure</td>
<td>9 (28)</td>
</tr>
<tr>
<td>Survival</td>
<td></td>
</tr>
<tr>
<td>Graft survival, d, mean ± SD</td>
<td>2778 ± 266</td>
</tr>
<tr>
<td>90 d</td>
<td>29 (91)</td>
</tr>
<tr>
<td>1 yr</td>
<td>27 (84)</td>
</tr>
<tr>
<td>3 yr</td>
<td>24 (75)</td>
</tr>
<tr>
<td>Retransplantation</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Patient survival, d, mean ± SD</td>
<td>3016 ± 251</td>
</tr>
<tr>
<td>90 d</td>
<td>29 (91)</td>
</tr>
<tr>
<td>1 yr</td>
<td>28 (88)</td>
</tr>
<tr>
<td>3 yr</td>
<td>25 (76)</td>
</tr>
<tr>
<td>Death</td>
<td>8 (25)</td>
</tr>
</tbody>
</table>

* Except where noted otherwise.

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(p = 0.02). Four patients (6%) underwent retransplantation, without a significant difference between eras (p = 0.2): there were 3 cases (9%) (1 case each of primary nonfunction, IC and hepatitis C recurrence) in the early era and 1 case (3%) (hepatitis C recurrence) in the late era (Table 2). Of the 5 remaining patients who did not undergo retransplantation, 2 had sepsis with subsequent multisystem organ failure, and metastatic hepatocellular carcinoma developed in 3.

**DISCUSSION**

In this study we assessed the learning curve of the pioneer Canadian DCD liver transplantation program in London. Donor and recipient selection characteristics in the late era were significantly more favourable than those in the early era. Consequently, the incidence of IC and overall biliary complications, and the need for ERCP and stenting were significantly reduced in the late era, and the IC-free survival time was significantly improved. These findings suggest that IC rates at centres introducing the DCD technique may be decreased with judicious donor selection and accrual of multidisciplinary transplantation team experience.

DCD liver transplantation has been associated with a higher complication rate than DBD liver transplantation. Reported rates of biliary complications have ranged from 13% to 50%.2,11,25 According to different reports, the incidence of IC can vary from 4.5% to 16%.9,11,12,14,26,27 Therefore, multiple strategies have been implemented to improve outcomes and reduce biliary complication rates. These strategies include using thrombolytic therapy based on the hypothesis that thrombolysis will break down the microthrombi forming in the peribiliary vascular capillary plexus during DCD procurement. Although different groups have shown promising results with this practice,28,29 recent evidence from a group in the Netherlands shows no reduction in nonanastomotic biliary strictures from the use of urokinase before liver transplantation.30 We believe that the low rates of IC attributed to thrombolytic therapy are actually due to the multifactorial effect of accumulating experience with DCD liver transplantation (i.e., proper donor/recipient selection and shorter ischemic times). In our DCD liver transplantation protocol, we do not use thrombolytic therapy.

Endoscopic interventions are the most common therapeutic strategy for biliary complications, and the need for repeated interventions in patients with severe complications, such as IC, are associated with increased cost, prolonged hospital stays, and hospital readmission for diagnostic and therapeutic measures.11,25,31,32

We have previously hypothesized that judicious donor selection and cumulative transplantation team experience would have a positive impact on IC rates.17 Limited investigation has not shown a correlation between experience and improved outcomes for DCD liver transplantation.11 However, we believed that improvements in procurement and implantation times would mitigate ischemic injury and prevent development of complications such as IC. To assess the learning curve of our DCD liver transplantation
program, we used donor and recipient selection and procurement times as proxy measures for evidence of learning, which is supported by other studies.\textsuperscript{4,11,14,25,26,32,33}

Assessment of graft survival and biliary complications in DCD liver transplantation has shown that donor age, donor WIT greater than 30 minutes and CIT greater than 10 hours are highly predictive of poor graft outcomes compared to DBD liver transplantation.\textsuperscript{3,11,14,25,30} In our present series, compared to patients in the early era, those in the late era had a significantly shorter time to cannulation and flush, lower WIT and a trend toward decreased CIT. These improvements likely explain the significant reductions in biliary complication rates achieved in the late era.

Devising preventive strategies is crucial to encourage greater use of DCD grafts. The American Society of Transplant Surgeons published its support toward procurement and transplantation of DCD organs, recommending different strategies and protocols to improve the use of these grafts.\textsuperscript{14} In our experience, adequate resources, improved knowledge, understanding of the DCD surgical technique and proper multidisciplinary team organization were fundamental for our achievements.

A learning curve can be defined as an improvement in performance over time or with increasing experience or training.\textsuperscript{35} Outcome measures used to depict learning curves are mostly proxy measures and include time to completion of a task, increasing experience by volume of procedures, decreasing rate of complications and proportion of satisfactory results.\textsuperscript{35} The proportion of biliary complications decreased after we reached 30 DCD liver transplantation procedures. This might represent the beginning of the expertise point of the learning curve in DCD liver transplantation owing to improvement in the donor procurement technique (faster cannulation) but also to better donor and recipient selection criteria for DCD organs.

The lower rate of IC observed in the late era of our study was associated with significantly decreased use of ERCP and therapeutic stents. Reducing the number of preventable interventions and hospital readmissions, and minimizing the risk of intervention-related patient complications shows how improvements in specific outcomes following DCD liver transplantation may have an impact on hospital resources and cost.

Although our graft and patient survival rates were not as high as with DBD grafts, our results were acceptable. Moreover, waiting list mortality decreased, proving the use of DCD grafts as an option for liver transplantation.

Important recommendations arise from this study. During the development of a DCD liver transplantation program, a learning curve can account for early inferior results. However, as experience accumulates, shorter procurement ischemia times, improved organ procurement technique, and meticulous donor and recipient selection may enable superior transplantation outcomes and wider acceptance of DCD liver transplantation. Thus, recruitment of staff with prior experience in DCD organ procurement may benefit new DCD programs with the goal of minimizing initially poorer transplantation outcomes. In the current series, fewer cases of IC and biliary complications occurred in the late era, in which significantly more local donors were procured. Therefore, avoiding external factors that can prolong WIT and CIT is important. In addition, through meticulous donor and recipient selection, refinements in the DCD procurement technique may yield better transplantation outcomes. In our practice, contrary to the traditional DCD liver transplantation procurement technique, we ensure drainage of the inferior vena cava to remove static blood from the liver and then flush the aorta, divide the bile duct and irrigate the gallbladder in the initial stage of procurement. This is aimed at rapidly flushing out toxins to reduce toxic hepatic effects. Thus, making improvements in factors that can be controlled by the transplantation team, including donor and recipient selection, surgical technique and minimization of ischemic times, may result in better DCD outcomes and an overall reduction in adverse outcomes.

Advancements of the near future will likely involve developing and improving present technology and pharmacological innovations that can reduce, restore or revert the consequences of ischemic reperfusion. Ongoing research is focused on the development and use of perfusion machines, not only in restoring hepatobiliary function and mitochondrial oxygenation but also in reducing or repairing a pre-existing hepatobiliary injury sustained during procurement. Moreover, the information provided by machine perfusion provides the opportunity of identifying and testing DCD livers at risk for failure or future complications.

Limitations

Some limitations arise as a result of the study design. The retrospective nature and the sample size limited the analysis. Furthermore, although the observed results are attributed to the transplantation team’s progression along a learning curve, other, unmeasured factors may have played a role.

Conclusion

Experience with DCD liver transplantation over a 10-year period at our institution has resulted in lower rates of IC, associated with better donor selection and improvement in procurement ischemia times in the late era. This suggests that a learning curve exists for DCD liver transplantation.

Acknowledgement: The authors thank Corinne Weernink for her assistance in database acquisition and study data administration.

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Alejandro wrote the article, which all authors reviewed and approved for publication. M. Tun-Abraham, M. Levstik acquired the data, which M. Tun-Abraham, H. Sharma, I. Al-Hasan and R. Hernandez-Alejandro designed the study. M. Tun-Abraham, K. Wanis, C. Garcia-Ochoa, H. Sharma, I. Al-Hasan and R. Hernandez-Alejandro wrote the article, which all authors reviewed and approved for publication.

References


Clinical outcomes of single-incision robotic cholecystectomy versus conventional 3-port laparoscopic cholecystectomy

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Accepted May 11, 2018

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Background: Few studies have compared the surgical results of single-incision robotic cholecystectomy (SIRC) with those of conventional laparoscopic cholecystectomy (CLC). The purpose of this study was to evaluate the relative clinical efficacy of SIRC by comparing the number of postoperative days, pain level and complications between the 2 surgical methods.

Methods: We retrospectively collected demographic, perioperative and postoperative data for all patients who underwent SIRC or CLC performed by a single surgeon from June 2016 to May 2017. Operative time was recorded, divided into anesthesia time, docking time, console time and total operation time. Postoperative pain was measured with the Numerical Pain Rating Scale.

Results: A total of 121 patients underwent cholecystectomy during the study period, of whom 61 had SIRC and 60 had CLC. The mean total operation time of SIRC and CLC was 93.52 (SD 20.27) minutes and 37.67 (SD 19.73) minutes, respectively (p < 0.001). The total operation time excluding console time of SIRC was significantly longer than that of CLC (82.77 [SD 18.27] min v. 37.67 [SD 19.73] min) (p < 0.001). The mean Numerical Pain Rating Scale score was 4.73 (SD 1.25) (SIRC: 4.75 [SD 1.24]; CLC: 4.70 [SD 1.22]) (p = 0.8) within 1 hour after the operation; scores after 6 hours and 1 day decreased in a similar manner in the 2 groups (p = 0.1).

Conclusion: Postoperative pain, use of an additional port, complication rates, operation time and cost of SIRC were similar to or greater than those of CLC. Large randomized controlled trials are needed to examine the true benefits of SIRC.

Contexte: Peu d'études ont comparé les résultats chirurgicaux de la cholécystectomie robotique par incision unique (CRIU) à ceux de la cholécystectomie laparoscopique classique (CLC). Le but de la présente étude était d'évaluer l'efficacité clinique relative de la CRIU en comparant le nombre de jours postopératoires, l'intensité de la douleur et les complications avec les 2 méthodes chirurgicales.

Méthodes : Nous avons recueilli de manière rétrospective les données démographiques, périopératoires et postopératoires de tous les patients soumis à une CRIU ou à une CLC effectuée par un seul chirurgien entre juin 2016 et mai 2017. Le temps opératoire a été enregistré, subdivisé entre anesthésie, temps d'installation, temps à la console et durée totale de l'intervention. La douleur postopératoire a été mesurée au moyen d'une échelle numérique d'évaluation de la douleur.

Résultats : En tout, 121 patients ont subi une cholécystectomie durant la période de l'étude, dont 61, une CRIU et 60, une CLC. La durée opératoire totale moyenne des CRIU et des CLC a été de 93.52 (É.-T. 20.27) minutes et de 37.67 (É.-T. 19.73) minutes, respectivement (p < 0.001). La durée opératoire totale excluant le temps à la console a été significativement plus longue avec la CRIU qu'avec la CLC (82.77 [É.-T. 18.27] minutes c. 37.67 [É.-T. 19.73] minutes) (p < 0.001). Le score moyen à l'échelle numérique d'évaluation de la douleur a été de 4,73 (É.-T. 1,25) (CRIU: 4,75 [É.-T. 1,24]; CLC: 4,70 [É.-T. 1,22]) (p = 0,8) 1 heure suivant l'intervention; après 6 heures et après 1 jour, les scores avaient diminué de façon similaire dans les 2 groupes (p = 0,1).

Conclusion : La douleur postopératoire, l'utilisation d'un port additionnel, les taux de complication, le temps opératoire et le coût de la CRIU ont été similaires ou supérieurs à ceux de la CLC. Il faudra réaliser de plus grands essais randomisés et contrôlés pour analyser les bénéfices réels de la CRIU.
Gallbladder disease is one of the most common diseases requiring surgical treatment. In the United States, more than 500,000 people are reported to undergo gallbladder surgery annually. Since laparoscopic cholecystectomy was first introduced as a viable replacement for open cholecystectomy, in 1985, it has been widely used and has become the gold standard method for the treatment of gallbladder disease. Surgeons’ efforts to reduce invasiveness have led to the development of single-incision laparoscopic cholecystectomy (SILC), which has been reported to be safe and to have good clinical outcomes. However, although the cosmetic results obtained with SILC are good, this technique has several limitations related to proper triangulation, instrument collisions, the surgeon’s unstable ergonomic posture and damage to surrounding tissues.

The da Vinci Single-Site robotic system (Intuitive Surgical) was developed to overcome these problems. This system allows the robot arm to electronically manipulate the inverse surgeon’s hand movements. The instrument inserted through the 2- to 3-cm umbilical incision is operated through an electrical reverse, minimizing interference between surgical instruments during operation. To adapt to this system, all surgeons learn the technique through animal and cadaver training before the first operation. Good results, including quick healing time, less pain, reduced blood loss and good cosmetic results, have been reported with single-incision robotic cholecystectomy (SIRC). The ability to obtain a good cosmetic effect with fewer port sites is an important advantage that cannot be refuted. However, SIRC is much more expensive than conventional 3-port laparoscopic cholecystectomy (CLC), even when considering only the disposable devices required for SIRC and not the base cost of the robot system. In addition, few studies have directly compared SIRC with CLC. We performed a study to evaluate the relative efficacy of SIRC by comparing clinical results such as length of hospital stay, pain level and complications between SIRC and CLC.

**Methods**

The study was approved by the ethics review board of our hospital. We retrospectively collected clinical features and surgical outcomes for all patients who underwent SIRC or CLC performed by a single surgeon at our institute from June 2016 to May 2017 via review of the medical record. Both surgical methods were explained to patients, who decided which method was used. Patients aged 18–80 years with cholelithiasis, gallbladder polyps or chronic cholecystitis were included in this study. Patients with acute cholecystitis and associated inflammation of other organs such as cholangitis or pancreatitis were excluded.

**Surgical procedure**

For CLC, the patient was placed on the operating table in a supine position. Pneumoperitoneum was created through an anterior approach at the umbilicus, and an 11-mm trocar was inserted. Two 5-mm trocars were then inserted in the right subcostal region at the midclavicular line and subxiphoid under endoscopic view (Fig. 1). Cholecystectomy was performed by means of a routine method. The gallbladder was pulled out through the incision, which was closed with a 2–0 Vicryl suture.

For SIRC, the patient was prepared in the same way as for CLC. A 2- to 3-cm incision was made in the umbilicus, and the main port was inserted through the incision. At the main port, a camera, 2 robot arms and an assist trocar were inserted, and the patient was placed in a reverse Trendelenburg position. The operation cart was located for

![Fig. 1. Conventional laparoscopic cholecystectomy. (A): Standard 3-port insertion state. (B): Wound after skin closure of all 3 ports.](image-url)
docking, and the camera was inserted through the port. The cannula was then located near the gallbladder, and the grasper and dissector were inserted through the cannula (Fig. 2). Cholecystectomy was performed by means of a routine method. The gallbladder was pulled out through the incision, which was closed with a 2–0 Vicryl suture.

**Clinical features and surgical outcomes**

Blood tests, ultrasonography and computed tomography were performed in all patients, and magnetic resonance cholangiopancreatography was performed when clinically necessary. Operative time was recorded, divided into anesthesia time (from induction to recovery), docking time (from port insertion until the start of intraperitoneal surgery), console time (time during which actual cholecystectomy was performed in the abdominal cavity) and total operation time (from incision to wound closure). We estimated the amount of blood loss by analyzing the anesthesia records of irrigation and suction volumes. Postoperative pain was measured with the Numerical Pain Rating Scale. Nonsteroidal anti-inflammatory agents were routinely used to control the patients’ pain.

**Statistical analysis**

We performed all statistical analyses with Stata version 14.0 (Stata Corp). A p value < 0.05 was considered statistically significant.

**RESULTS**

A total of 121 cholecystectomy procedures were performed between June 2016 and May 2017, of which 61 (50.4%) were SIRC and 60 (49.6%) were CLC (Table 1). Body mass index, body surface area, American Society of Anesthesiologists Scale score and number of patients with symptomatic gallbladder were not significantly different between the SIRC and CLC groups. Patient age ranged from 28 to 79 years (mean 46.48 [standard deviation (SD) 11.64] yr). Patients in the SIRC group were significantly younger than those in the CLC group (mean age 42.69 [SD 8.95] yr v. 50.33 [SD 12.82] yr, p < 0.001). None of the patients had a previous history of upper abdominal surgery. However, 3 patients (5%) in the SIRC group and 5 patients (8%) in the CLC group had a history of lower abdominal surgery.

The most common indication for cholecystectomy was cholelithiasis (23 patients [38%] in the SIRC group and 46 [77%] in the CLC group). The incidence of cholelithiasis was significantly different between the 2 groups (p < 0.001). Some patients had medical comorbidity such as diabetes, hypertension and thyroid disease, but the incidence of these diseases was not significantly different between the 2 groups (p > 0.05). There was no difference in the American Society of Anesthesiologists Scale score between the 2 groups (p = 0.05).

The intraoperative and postoperative outcomes are summarized in Table 2. The mean docking time was 10.75 (SD 4.33) minutes (range 4–30 min), and the mean console time was 44.84 (SD 13.83) minutes (range 15–90 min). The mean total operation time for SIRC and CLC was 93.52 (SD 20.27) minutes and 37.67 (SD 19.73) minutes, respectively (p < 0.001). The total operation time excluding docking time for SIRC was significantly greater than that for CLC (82.77 [SD 18.27] v. 37.67 [SD 19.73]) (p < 0.001).

None of the patients had altered operative procedures or additional ports inserted because of bleeding or adhesion. The mean number of in-hospital postoperative days was 2.35 (SD 1.38) (SIRC: 2.26 [SD 0.92] d; CLC: 2.43 [SD 1.73] d) (p = 0.5). There were no intraoperative complications such as massive bleeding or common bile duct injury. There were also no postoperative complications such as incisional hernia, wound infection, complicated fluid collection, postoperative ileus, or postoperative bile leakage.

**Fig. 2. Single-incision robotic cholecystectomy.** (A) Single port insertion state. (B) Multichannel single port with an assistant port in the middle.
The mean pain score at 1 hour after the operation was 4.73 (SD 1.23) (SIRC: 4.75 [SD 1.24]; CLC: 4.70 [SD 1.22]) ($p = 0.8$); scores at 6 hours and 1 day decreased in a similar pattern in the 2 groups ($p = 0.1$).

**Discussion**

In this retrospective study, we found that postoperative pain, use of an additional port, complication rates, operation time and cost of SIRC were similar to or greater than those of CLC. During SIRC, through the electrical inverse signal, the movement of the surgeon became ergonomic, and there was little collision between the instruments. This resulted in almost no damage to surrounding tissues and no delay of operation time.

In the study of Morel and colleagues, the average total operation time for SIRC was 91.1 minutes, the mean console time was 50.9 minutes, and the mean docking time was 6.6 minutes. The corresponding values in the present study were 93.52 minutes, 44.84 minutes and 10.75 minutes.
However, SIRC required a significantly longer total operation time than CLC (p < 0.001), even when the operation time was compared without the docking time (p < 0.001).

Similar pain scores for SILC and CLC were reported in 2 previous studies. Luna and colleagues showed that the inflammatory reaction to surgery, as measured by interleukin 6 and C-reactive protein levels, was similar after SILC and CLC. The reason for this is that many manipulations in SILC have been reported, and pain may be reduced through decreased manipulation. Based on these studies, it appears that SIRC may be less painful than CLC. However, we found no significant difference in pain scores between SIRC and CLC. Although there are few incision sites in SIRC, the length of the incision is long, many instruments are inserted into a single incision, and the operation time is relatively long. This may have contributed to the lack of difference in the degree of pain between the 2 groups.

Konstantinidis and colleagues reported a mean of 23.84 (SD 10.27) postoperative hours with SIRC. Morel and colleagues reported a mean of 2.4 postoperative days. In the current study, we noted a mean of 2.35 (SD 1.38) postoperative days for the overall group of patients (2.26 [SD 0.92] d for the SIRC group and 2.43 [SD 1.73] d for the CLC group). The length of the hospital stay after surgery was not significantly different between the 2 groups. The higher number of postoperative days after CLC was not due to complications but, rather, to the national insurance system, which has low admission charges. In addition, no patients required use of an additional port, there was no conversion to laparotomy or laparoscopy, and there were no postoperative complications. Overall, the perioperative and postoperative results were not significantly different between the 2 groups.

Limitations

This study had several limitations, including short-term analysis, a single hospital setting and its retrospective nature. Therefore, large randomized controlled trials are needed to examine the true benefits of SIRC.

CONCLUSION

Although the cosmetic outcomes of SIRC are excellent, postoperative pain, use of an additional port, complication rates, operation time and cost were similar to or greater than those of CLC.

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Competing interests: None declared.

Contributors: All authors designed the study. S. Lee acquired the data, which all authors analyzed. S. Lee wrote the article, which all authors reviewed and approved for publication.

References

Understanding the patellofemoral joint in total knee arthroplasty

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DOI: 10.1503/cjs.001617

Total knee arthroplasty (TKA) is one of the most successful procedures in orthopedic surgery. Nevertheless, postoperative patellofemoral complications remain a challenging problem, affecting a substantial proportion of patients. Complications involving the patellofemoral joint (PFJ) can occur in both resurfaced and nonresurfaced patellae. Types of PFJ complications include anterior knee pain, maltracking, fracture, avascular necrosis and patellar clunk. The causes of patellofemoral complications can be categorized into patient-, surgeon- and implant-related factors. Patient characteristics such as female sex, young age, depression and increased body mass index have been linked with increased complications. Important technical considerations to avoid complications include achieving appropriate rotational alignment of the femoral and tibial components, maintaining joint line height, medializing the patellar button and avoiding “overstuffing” the PFJ. Component design features such as conformity, shape and depth of the femoral trochlea have also been shown to be important. Although the cause of patellofemoral complications after TKA may sometimes be unknown, it remains important to minimize errors that can lead to these complications.

La prothèse totale du genou (PTG) est l’une des interventions qui réussit le mieux en chirurgie orthopédique. Les complications fémoro-patellaires postopératoires n’en restent pas moins un problème complexe qui affecte une proportion substantielle de patients. Les complications affectant l’articulation fémoro-patellaire (AFP) peuvent survenir en présence de rotules resurfacées ou non. Les types de complications de l’AFP incluent, douleur au devant du genou, défaut d’alignement, fracture, nécrose avasculaire et accrochage rotulien. Les causes des complications fémoro-patellaires peuvent appartenir à diverses catégories selon qu’elles sont liées au patient, au chirurgien ou à la prothèse elle-même. Des caractéristiques liées aux patients, comme le fait d’être de sexe féminin, le jeune âge, la dépression et un indice de masse corporelle élevé, sont associées à une hausse des complications. Les enjeux techniques importants pour éviter les complications incluent : obtenir un alignement rotationnel approprié des éléments fémoraux et tibiaux, maintenir la hauteur de la ligne articulaire, médialiser le bouton patellaire et éviter d’encombrer l’AFP. Les caractéristiques de la modélisation des éléments, comme la conformité, la forme et la profondeur de la trochlée fémorale se sont aussi révélées importantes. Même si la cause des complications fémoro-patellaires post-PTG est parfois inconnue, il est important de prévenir les erreurs susceptibles de mener à de telles complications.

Patellofemoral complications historically have contributed up to 50% of revision surgery.1 With modern design refinements and improved techniques, the burden of revision from patellofemoral complications is less than it was previously; however, these complications remain some of the most challenging problems in knee arthroplasty.

Complications involving the patellofemoral joint (PFJ) can occur with both resurfaced and nonresurfaced patellae. In resurfaced patellae, complications include patellar maltracking, fracture, avascular necrosis, clunk and anterior knee pain. In knees with nonresurfaced patellae, some of the same complications can take place, such as maltracking, clunk,
avascular necrosis and anterior knee pain, in addition to a possibly higher rate of reoperation.

In this evidence-based review, we discuss basic anatomic and kinematic features of the PFJ and review the types, mechanisms and causes of patellofemoral complications in total knee arthroplasty (TKA). The role of patient factors, implant design features and surgical techniques are reviewed.

BIOMECHANICS OF PATELLOFEMORAL JOINT

The most important function of the patellofemoral articulation is to increase the efficacy of the quadriceps muscle, facilitating knee extension. Studies have shown that the patella increases the extension force by as much as 50%.\(^2\) As a result, the PFJ experiences substantial forces. In the native knee, biomechanical modelling has shown that PFJ reactive forces during activities of daily living can range from 2.5 to 7.6 times the body weight.\(^3\) Aside from increasing quadriceps torque, the patella serves to increase the surface area of force distribution and aids in centralizing the extensor mechanism forces.\(^2\)

Although there are similarities in patellofemoral kinematics between native and prosthetic knees, differences exist with respect to the patellar translation, areas and magnitude of contact forces, and patellar tilt (Fig. 1). The native patella exhibits medial translation in early flexion, followed by progressively increased lateral translation with increased flexion.\(^4\) Similar to the native patella, the prosthetic patella experiences most of the contact distally in low amounts of flexion. The point of contact migrates more proximally with increasing flexion, reaching the superior pole in 60°–90° of flexion.\(^5\) Although the cause is likely multifactorial, it may be partially explained by reduced, or occasionally reversed, femoral rollback following TKA.\(^6\) Patellar tilt appears to increase with increasing flexion in both native and prosthetic knees; however, the increase appears to be more substantial after TKA.\(^4\)

Finally, prosthetic knees lose the normal 5° external rotation of the tibia on the femur (“screw-home mechanism”).\(^4\)

IMPLANT FEATURES

Femoral component

The morphological features of femoral and patellar components have substantial effects on patellofemoral kinematics. Among the various features of the femoral component, the anatomic features that affect patellofemoral kinematics design include the asymmetry of the trochlea, the depth of the trochlear groove and the proximal extension of the trochlea (Fig. 2).\(^7\)–\(^9\)

Fig. 1. Summary of native (top row) and prosthetic (bottom row) patellofemoral kinematics. (A) Patellar tracking between 0° and 90°. The native patella translates medially in early flexion and translates laterally in further flexion. The patella tracks more medially following total knee arthroplasty (TKA). (B) Frequency-of-contact map showing patellofemoral contact between 0° and 90°. The distal patella initiates contact and, with increasing flexion, the contact area migrates more proximally (adapted and redrawn from reference 5 with permission of Elsevier). (C) Patellar tilt before and after TKA. The patellar tilt appears to be increased following TKA, particularly between 10° and 45° (reproduced from reference 4 with permission of Springer). L = lateral; M = medial; P = proximal.
Extending the trochlea proximally allows the patella to enter the trochlear groove properly. In femoral components where the trochlear surface is terminated at the proximal extent of the femoral cartilage, the patella is not engaged in the trochlear groove properly. In an early cadaveric study, Yoshii and colleagues performed an in vitro comparison of various trochlear designs and found that a deepened trochlear groove and a raised lateral flange allowed the patellar button to be constrained in the groove and minimized tracking abnormalities. Similar findings were reported by Petersilge and colleagues in a cadaveric study and by Theiss and colleagues in a retrospective clinical study. Although design elements are important for facilitating tracking, surgical technique, particularly avoiding the internal rotation of the femoral and tibial components, is critical. In other words, if the femoral component is malrotated and the design of the femoral component forces the patella to enter the groove, this will likely result in a stiff and, potentially, snapping patella.

Over time, manufacturers included improvements in femoral component design to create “patella-friendly” designs. In general, these designs incorporate features such as proximal extension of the trochlea, raised lateral flange, lateralized groove and deepened trochlea. L = lateral; M = medial.

The orientation of the trochlear groove in the coronal plane is another factor previously considered in implant design. In modern implants, the groove is typically in 5°–7° valgus in order to reduce lateral shear forces by approximating the anatomic axis of the femur and the direction of the extensor mechanism. In a finite element model, D’Lima and colleagues showed that valgus alignment of the prosthetic trochlea reduced shear forces in low flexion angles up to 90°. They postulated that, in higher flexion angles, the patella articulates against the distal trochlea and the femoral condyles, where the valgus orientation would not apply.

**Patellar component**

Over the years, various prosthetic patella designs have been proposed (all-polyethylene, dome-shaped, modified dome, anatomic, metal-backed and mobile-bearing). Metal-backed components were introduced in the 1980s and quickly fell out of favour owing to numerous complications. To accommodate the metal baseplate, these components featured a thin polyethylene surface, which was susceptible to accelerated wear, particularly in the high-load-bearing or unsupported areas. This subsequently led to fracture and loosening of the component.

Currently, the all-polyethylene dome-shaped patella is most commonly used. Although these components are still susceptible to wear owing to the substantial forces experienced at the PFJ, reports of catastrophic wear are rare, potentially owing to increased polyethylene thickness as well as femoral component designs that facilitate proper patellofemoral kinematics. Furthermore, the relative ease of application, reduced risk of malalignment and excellent track record make the all-polyethylene dome-shaped patella a popular choice.

Although failure of the all-polyethylene patellar components is rare, identified risk factors for failure are increased body weight, high preoperative flexion, retinacular release, weakness of the pegs of the component and avascular necrosis of the patella.

**Tibial component**

Tibial component alignment has been found to affect patellofemoral kinematics. To decrease the effect of tibial component positioning, a rotating-bearing design was proposed. From a conceptual standpoint, the advantage of a rotating platform design is the ability of the femoral–tibial articulation to align itself. In an intraoperative study, Sawaguchi and colleagues compared fixed and mobile bearings and showed that rotating platform inserts in TKA significantly improved patellar tracking and decreased patellofemoral contact stress. This is based on the assumption that the
mobile-bearing insert is continuously moving after implantation. However, multiple other clinical studies failed to show an advantage of the mobile bearing. Pagnano and colleagues, in a randomized study, found that rotating tibial platforms did not decrease the prevalence of lateral release or patellar tilt, or improve stair-climbing ability. In a 2015 Cochrane review, no significant differences were found between mobile- and fixed-bearing designs in knee pain, or clinical or functional scores. Although the mobile-bearing design is conceptually appealing, the lack of a difference between a mobile and a fixed bearing raises the possibility that a mobile-bearing insert acts more like a fixed bearing in vivo.

**Complications Related to Patellofemoral Joint**

Although component design has evolved substantially, PFJ complications still occur following TKA. Anterior knee pain is most prevalent, affecting up to 23% of patients with knee replacements, and its cause is multifactorial. Less common (<1%) complications are maltracking, fracture, avascular necrosis, patellar clunk and component loosening, each of which can be debilitating and can contribute to anterior knee pain and dysfunction.

**Anterior knee pain**

Anterior knee pain can occur from a variety of sources. A large number of free nerve endings and fibres exist, particularly in the quadriceps muscles, retinacula, patellar tendon and synovium. Anterior knee pain can result from any one of these sources, and clinicians typically have difficulty identifying the exact source. Previous studies showed that the state of the cartilage is not the only consideration. S.F. Dye asked a colleague to perform knee arthroscopy on him using local anesthetic. His findings were instructive: he did not feel any pain in the PFJ, whereas the capsule and prepatellar fat pad were exceptionally painful.

Another study showed that radiographic changes of patellofemoral osteoarthritis do not correlate with patellofemoral symptoms. Indeed, addressing degenerative articular surface by resurfacing the patella has not universally resolved patellofemoral symptoms.

Although in many cases we cannot identify the specific cause, pain after TKA has been shown to be associated with certain patient factors. Bourne and colleagues identified female sex, young age, depression and increased body mass index to be risk factors for more anterior knee pain after TKA.

“Overstuffing” the PFJ has traditionally been implicated to be a potential contributory factor to patellofemoral pain. When using the measured-resection technique, the combined thickness of the prosthesis should match the combined thickness of the femoral and patellar bone cuts; otherwise, the PFJ will be overstuffed (Fig. 3). Theoretically, overstuffing the PFJ could lead to increased patellofemoral forces, decreased range of motion and anterior knee pain.

![Fig. 3. “Overstuffing” may be a factor contributing to anterior knee pain. It can occur when the size of the femoral or patellar component is greater than the amount of bone that was resected. AP = anteroposterior.](image-url)
Biomechanical data suggest that overstuffing can adversely affect patellofemoral contact forces, knee range of motion and patellar tilt.\textsuperscript{31} Computer-based modelling combined with cadaveric knee experimentation showed that knee flexion decreased with increasing patellar thickness.\textsuperscript{31} In particular, Abolghasemian and colleagues\textsuperscript{31} found that, for every 1 mm of increased patellar thickness, knee flexion decreased by 1.08°. They recommended restoring preoperative patellar thickness in order to maximize postoperative knee flexion. An in vitro study showed that a thicker patella or femoral components larger than the anterior condyle resected may have an adverse effect on contact forces, lead to increased shear forces and contribute to abnormal patellofemoral motion.\textsuperscript{12} Although increases in the size of the femoral component can lead to overstuffing in posterior-referenced systems, decreasing component size can lead to understuffing and femoral notching. Some investigators suggested that femoral notching can heighten the risk of fracture following TKA,\textsuperscript{33,34} but other authors have questioned this link.\textsuperscript{35} Although not shown in the literature, theoretically, understuffing may lead to quadriiceps insufficiency, weakness and knee instability.

Previous clinical studies have not shown adverse effects of overstuffing on patient outcomes.\textsuperscript{36,37} Pierson and colleagues\textsuperscript{37} conducted a retrospective clinical study examining the effect of overstuffing the PFJ in resurfaced knees with 2 different knee designs and found no adverse effects associated with overstuffing. Beldman and colleagues\textsuperscript{36} evaluated the effect of overstuffing the PFJ on clinical outcomes or anterior knee pain in TKA without patellar resurfacing. They found no association between overstuffing and anterior knee pain or patient-reported outcomes.

In our practice, erring toward downsizing is preferred, accepting the risk of notching to avoid overstuffing. It is likely that improvements in implant fit are possible by increasing the availability of femoral components of various sizes and shapes.

Based on the presence of many terminal nerve branches around the patella, electrocautery around this structure has been proposed as a technique to reduce the incidence of anterior knee pain.\textsuperscript{38} This technique involves removing the osteophytes around the patella and then performing electrocautery around the patellar rim to a depth of about 1 mm, while avoiding damage to the patellar cartilage. Despite the theoretical benefits, however, Kwon and colleagues\textsuperscript{39} found no benefit in a randomized trial with 5 years of follow-up. More encouraging findings were reported by Fan and colleagues\textsuperscript{18} in a systematic review of the topic. They concluded that, although rates of anterior knee pain remained similar, evidence pointed to improved functional scores with electrocautery patellar denervation.

Currently, one of the main downsides of the literature is the absence of a specific, widely used, standardized patellofemoral rating system to study outcomes. Such a system might help refine outcome measures and identify the factors involved in anterior knee pain.

**Patellar maltracking**

Patellofemoral complications can be affected by surgical technique and decision-making. Malrotation of the femoral and tibial components and its effect on patellar maltracking is one of the most discussed variables in the literature. The substantial influence of femoral component rotation on quadriiceps forces, collateral ligament forces and varus/valgus kinematics was demonstrated by computer modelling.\textsuperscript{40} Previous retrospective radiographic studies showed that poor rotational alignment of the femoral component can lead to patellar maltracking and adverse patient outcomes.\textsuperscript{18} Barrack and colleagues\textsuperscript{18} identified that component malrotation is a contributing factor to anterior knee pain, but it is clearly not the only factor involved, as some patients with evidence of malrotation were symptom-free, which points to the multifactorial nature of anterior knee pain. The ideal rotation of the femoral component varies based on the alignment strategy used, mechanical (classic) or anatomic. For mechanically aligned TKA, the amount of external rotation that clinically matters seems to vary, but most studies suggest that 2°–5° of external rotation relative to the articular surface of the posterior femoral condyles leads to optimal outcomes (Fig. 4).\textsuperscript{41}

Malrotation of the tibial component appears to affect outcomes as well. In an analysis of postoperative computed tomography scans, Bédard and colleagues\textsuperscript{42} found that internal rotation of the tibial component may contribute to knee stiffness after TKA. Nicoll and Rowley\textsuperscript{18} reported that tibial component internal rotation is associated with medial and anterior knee pain. The ideal amount of rotation has not been identified, and anatomic references have been proposed, such as the central third
of the tibial tubercle or the middle of the talus (Fig. 5),
but most investigators agree that any amount of internal
rotation, either of the femur or the tibia individually or a
combination of both, is undesirable.18

When resurfacing the patella, the location of patellar
component placement plays a role in knee kinematics. In
a laboratory study, Yoshii and colleagues8 found that
deedening the patellar groove and positioning the patellar
button medially led to a decreased Q angle and improved
patellar tracking. Placing the patellar button in a medial-
ized position may decrease patellar tracking problems and
reduce the need for a lateral retinacular release pro-
cedure. D'Lima and colleagues13 used finite-element mod-
elling to show that a medialized patellar button position
(Fig. 6) leads to a substantial reduction in patellofemoral
lateral shear forces. Nevertheless, the decision to place
the patellar component in an eccentric position needs to
be balanced against theoretical concerns, such as a
decreased quadriceps lever arm, rotational torque on the
femoral component and difficulty with fixation of the
patellar component.

A lateral retinacular release procedure is one of the
commonly described methods to manage maltracking, to
potentially improve patellar tracking. Reported rates of
the procedure vary substantially, between 3% and 45%.44
Some of the concerns with this technique have been
patellar avascular necrosis and fracture.44 Bone scans
showed a “cold patella” rate of 56% after lateral release,45
but the clinical significance of this finding is unclear.
Furthermore, although some authors historically associated
lateral release with patellar pain, more recent evidence,
including a 2014 comparative study,46 does not support
this association. An alternative technique to deal with
patellar maltracking is lateral facetectomy, which has
been reported as useful in enhancing patellar tracking and
potentially decreasing anterior knee pain.47 Although this
procedure may occasionally be a useful tool, it will not
compensate for other factors that may lead to maltrack-
ing, such as internal rotation of the femoral or tibial
component.

Other complications

Other patellofemoral complications occur rarely (< 1%)
but can be quite disabling and challenging to manage. The
most common of these complications are patellar fracture,
avascular necrosis and clunk.

Patellar fracture after TKA is quite rare, with a
reported rate of 0.12%–3.9%.48 Nonoperative manage-
ment is recommended for nondisplaced fractures. These
fractures can have a longitudinal or transverse orientation
and a stable patellar implant, and occasionally can be
completely asymptomatic. Displaced longitudinal frac-
tures with an intact extensor mechanism and stable patel-
lar component are also suitable for treatment in a knee
brace locked in extension. The results following a period
of immobilization are satisfactory overall, with a low
complication rate (9%).49 Displaced transverse fractures
through the middle third of the patella may require oper-
ative intervention, particularly if the patellar component

![Fig. 5. Alignment of the tibial component. The tibial component is placed in external rotation; various landmarks, such as the tibial tubercle or ankle joint, can be used. The centre of the ankle corresponds to the medial and middle thirds of the space between the malleoli.](image)

![Fig. 6. Centred (A) and medialized (B) patellar button placement. The latter may allow a reduction in lateral patellar shear forces.](image)
is loose or the extensor mechanism is disrupted. Operative management of this complication, particularly the use of tension band wiring, leads to disappointing results\textsuperscript{49,50} and is associated with high rates of complications (50\%), reoperation (42\%) and persistent symptoms (57\%).\textsuperscript{49} Occasionally, displaced fractures are best addressed with removal of the patellar component or partial patellectomy, and, in cases in which repair fails, allograft reconstruction of the extensor mechanism remains an option.\textsuperscript{51}

A serious complication following TKA is avascular necrosis of the patella.\textsuperscript{50} The prevalence is quite low, at 0.05\%–2\%.\textsuperscript{50} The risk for avascular necrosis may be increased with a lateral retinacular release procedure.\textsuperscript{52} Median parapatellar and subvastus approaches to the knee result in similar changes in patellar vascularity.\textsuperscript{50} Overall, it remains unclear whether intraosseous patellar blood flow correlates with anterior knee pain after TKA.

Patellar clunk occurs in up to 14\% of patients following TKA.\textsuperscript{53} It is thought to be secondary to entrapment of proliferative fibrous tissue at the junction of the superior pole of the patella and the distal quadriceps tendon (Fig. 7).\textsuperscript{53} This tissue gets trapped within the intercondylar box and limits patellar excursion until it lets go with a “clunk.” Classically, this complication was more common in posterior-stabilized designs owing to a high, abrupt transition zone from the trochlear groove to the intercondylar box. The length of the intercondylar box compared to the anteroposterior length of the femoral component, termed the intercondylar box ratio, affects the incidence of patellar clunk (Fig. 8).\textsuperscript{54} Newer posterior-stabilized designs accommodated for this by increasing the anteroposterior size of the femoral component compared to the length of the trochlea, effectively lowering the transition point and decreasing the intercondylar box ratio. This led to substantially decreased rates of patellar clunk. Other factors found to be associated with patellar clunk are patella baja, use of a small patellar component and increased posterior condylar offset.\textsuperscript{53}

**CONCLUSION**

There is increasing evidence that patellofemoral complications following TKA can be minimized through patella-friendly component design and appropriate surgical techniques. To decrease the chance of patellofemoral complications, patellar resurfacing should be used in designs known to be challenging for the PFJ, whereas nonresurfacing is acceptable in friendlier designs. When resurfacing, the all-polyethylene dome-shaped patellar component has become the default choice owing to positive outcomes and ease of application. Patellofemoral complications can be avoided through meticulous technique, with particular attention to setting appropriate component rotation, avoiding gross overstuffing, performing circumferential patellar denervation and placing the patellar button in a medialized position (Table 1). Some complications, including patellar fracture and avascular necrosis of the patella, are best managed with anatomically shaped cementless resurfacing components.
necrosis, continue to challenge surgeons. Controversies still exist regarding practices such as patellar resurfacing, rotational alignment targets and thresholds for over- and understuffing, leaving room for additional evidence-based research.


Competing interests: J. Matz declares no competing interests. B. Lanting declares ownership of IdealFit Spacer Solutions, paid consultancies with Intellijoint Surgical, Stryker and DePuy Synthes, and research grants from Stryker, DePuy Synthes and Smith & Nephew. J. Howard declares ownership of PersaFix Technologies, paid consultancies with DePuy Synthes, Stryker, Smith & Nephew and Intellijoint Surgical, and institutional research support from DePuy Synthes, Smith & Nephew, Stryker, Zimmer Biomet and MicroPort.

Contributors: All authors designed the study. J. Matz acquired the data, which all authors analyzed. All authors wrote the article and approved the final version for publication.

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Table 1. Summary of techniques to avoid patellofemoral complications after total knee arthroplasty

<table>
<thead>
<tr>
<th>Complication</th>
<th>Technique for avoidance</th>
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<tr>
<td>Patellar maltracking or instability</td>
<td>Femoral component design: extended and deepened trochlear groove</td>
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<td></td>
<td>Femoral component rotation (3° external rotation compared to posterior condylar axis)</td>
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<tr>
<td></td>
<td>Tibial component rotation (central third of tibial tubercle)</td>
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<td></td>
<td>Place patellar button in medialized position</td>
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<td></td>
<td>Lateral patellar facetectomy</td>
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<tr>
<td>Patellar clunk</td>
<td>Use femoral component with low intercondylar box ratio</td>
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<tr>
<td></td>
<td>Avoid substantial changes in joint line height, decreased patellar thickness or use of small patellar button</td>
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<tr>
<td></td>
<td>Maintain posterior femoral condylar offset</td>
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<tr>
<td>Patellar avascular necrosis</td>
<td>Avoid unnecessary lateral retinacular release</td>
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<td></td>
<td>Avoid excessive patellar reaming</td>
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<tr>
<td>Patellar fracture</td>
<td>Use all-polyethylene patellar component</td>
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<td></td>
<td>Avoid excessive patellar resection when resurfacing</td>
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<tr>
<td>Anterior knee pain</td>
<td>Attempt to minimize any of the above issues</td>
</tr>
<tr>
<td></td>
<td>Select appropriately sized femoral and patellar components, preoperative templating to avoid patellofemoral offset changes</td>
</tr>
<tr>
<td></td>
<td>Circumferential patellar deretration</td>
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Utility of the Vascular Quality Initiative in improving quality of care in Canadian patients undergoing vascular surgery

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Accepted Apr. 16, 2018; Published online Dec. 1, 2018

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DOI: 10.1503/cjs.002218

The Vascular Quality Initiative (VQI) is a national cooperative quality-improvement initiative designed to evaluate processes of care and outcomes in vascular surgery. The purpose of this report is to show the utility of such a database to provide insight into the standard of care provided, to highlight areas of local quality improvement, to benchmark our data against local, regional and national trends, and to ultimately improve safety in Canadian patients undergoing vascular surgery. We present the history of the database, its spread in the Canadian health care system and examples of quality improvements achieved from analyses of data recorded and retrieved from the VQI. Using the VQI, our institution was able to decrease the length of stay after endovascular aneurysm repair, decrease the contrast volume in endovascular aneurysm repair, save on costs, and provide medium-term outcome data on peripheral vascular interventions and smoking cessation strategies. The VQI is a powerful tool to improve patient safety and quality in vascular surgery. Its ability to create local regional improvement groups fosters a quality-focused culture and is important for Canadian patients.

In the age of advanced surgical procedures for complex diseases, patient safety and quality improvement are at the forefront of effective patient-centred care. In the United States and Canada, 2 independently maintained quality-improvement databases have emerged as the primary vascular surgery quality-measurement tools with the purpose of evaluating perioperative outcomes and assessing hospital and physician quality: the Society for Vascular Surgery Vascular Quality Initiative (VQI) and the American College of Surgeons National Surgical Quality Improvement Program (NSQIP). The former is a national cooperative quality-improvement initiative designed to evaluate processes of care and outcomes in vascular surgery. It has 100% capture for 11 major vascular surgery procedures. Additional follow-up data are collected 1 year after the procedure. The NSQIP is a national database to collect data from the preoperative period through to 30 days postoperatively. Surgical cases are sampled on the basis of institution program options, with a minimal requirement of cases analyzed annually.
The VQI has grown rapidly in the US since its inception, with more than 400 participating centres. Currently, there are 5 centres in Canada registered with the VQI — Grey Nuns Community Hospital, Edmonton; Thunder Bay Regional Health Sciences Centre, Thunder Bay; Toronto General Hospital and St. Michael’s Hospital, Toronto; and the Centre intégré de santé et de services sociaux de l’Outaouais, Gatineau, Que.) — with more in the process of joining (Nova Scotia Health Authority and Centre hospitalier de l’Université de Montréal). The Department of Vascular Surgery at the Toronto General Hospital has employed the VQI since August 2010.

**History**

The Vascular Study Group of New England was founded in 2001 as a voluntary cooperative group of clinicians and hospital administrators whose aim was to continuously improve the quality, safety, effectiveness and cost of caring for patients with vascular disease. The group used aggregated data to recognize patterns of outcomes and their associated causes. Through regular meetings, the group defined processes that affect outcome improvement in numerous areas in vascular surgery and allow individual hospitals and physicians to understand their results in the context of regional benchmarks.1 Within a decade after the inception of the group, numerous similar regional quality initiatives had been developed as part of what is now a national and international movement sponsored by the Society of Vascular Surgery as the VQI. The VQI continues to expand nationally and internationally. Today there are over 430 participating centres in 46 US states and Canada with more than 3200 physicians of varying specialties. There are 18 regional quality groups, including Canada, which hold semiannual meetings focused on quality improvement.

Currently, the VQI collects data on a variety of vascular procedures ranging from aortic aneurysm repair (open and endovascular), arterial bypass and peripheral vascular interventions for aneurysmal and inclusive disease, lower extremity amputations and cerebrovascular disease, to arterial venous access, varicose vein surgery and inferior vena cava filter removal. The size and power of the database have enabled it to work on postmarket device evaluation in partnership with the US Food and Drug Administration. There are several active projects, 1 of which involves the use of thoracic endografts following type B aortic dissection.4

**How has our institution used the Vascular Quality Initiative?**

Our institution has been recording data on several commonly performed vascular procedures in the VQI since 2010. These data have been used in our local institution to identify, review and resolve quality issues.

The VQI has developed powerful tools for quality improvement. Two examples are the Center Opportunity Profile for Improvement reports and the Analytics and Reporting Engine. The former, which are prepared by the Society for Vascular Surgery Patient Safety Organization, focus on a specific procedure and present an analysis of variables according to centre, region and VQI as a whole. Centres are presented with tables identifying where the opportunities lie (Appendix 1, available at canjsurg.ca/002218-a1). Other tools include a free app and online clinical risk calculators (https://www.qxmd.com/calculate-online/vascular-surgery). The Analytics and Reporting Engine allows the individual user to generate custom reports in real time for a single procedure or across procedures, depending on the variables selected. Filters can be applied to narrow the population of interest, and reports are produced that can incorporate benchmarking for the centre, region and/or the rest of the VQI. An example of this type of report incorporating all of the VQI is provided in Appendix 1.

We highlight a few procedures studied at our institution and how we leveraged data from the VQI to improve patient safety and quality of services.

**Shortening length of stay after endovascular aneurysm repair**

The VQI provides risk-adjusted benchmarking expectations. Early on in our institution’s experience, a Center Opportunity Profile for Improvement report identified that our group had a longer than expected length of stay following elective endovascular aneurysm repair. Following analysis, we instituted some changes including reduction in opioid and catheter use, early mobilization, and management of patient and family expectations. Within 6 months, our risk-adjusted length of stay had reversed and become statistically significantly shorter than expected. We repeated the study 2 years later and found that, not only had we sustained the change in practice, we were able to save 34 hospital days in the second cohort. The unadjusted average costs declined from $27 191 to $26 275, a decrease of 3.4%. These data are easily accessible in real time, unlike most hospital administrative databases, and offer the potential for cost savings.1

**Reducing iodinated contrast volume in endovascular aneurysm repair**

A query of the Analytics and Reporting Engine identified that, on average, our iodinated contrast volume per endovascular aneurysm repair case was higher than for other VQI sites. We reduced contrast volume by diluting it while maintaining the same image quality. This enabled us to match nationally benchmarked contrast volumes.
Predicting outcomes and assessing risk of peripheral vascular interventions

In addition to using analytic functions built into the VQI, users can download raw data from the VQI, combine them and run additional statistics. We wanted to analyze the population undergoing percutaneous transluminal angioplasty to assess risk and identify characteristics that significantly affect outcome. We found that consistent predictors of worse patency outcome were female sex, high Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) classification, prior major amputation, younger age and cigarette smoking. Our outcomes were comparable to those reported in the literature.

Smoking cessation rates among patients undergoing vascular surgery

Smoking is associated with both the development and the progression of occlusive peripheral arterial disease and aneurysmal disease. Although smoking cessation is a key priority in vascular surgical practice, there has been substantial variability in the efficacy of cessation treatment among patients at our institution. The framework of the VQI allows institutions to track the success or failure of targeted interventions. We performed a study to determine the prevalence of smoking and cessation rates among patients undergoing vascular surgery using VQI data. We found a smoking prevalence of 33.5% and a 1-year cessation rate of 41.6%.

DISCUSSION

The VQI has been shown to be an important tool in quality improvement in the United States and now in Canada. It allows real-time benchmarking of individual physicians and centres against local, regional and national trends. The VQI is a powerful tool for vascular surgeons as it was engineered specifically for vascular surgery. It uses self-reported data to capture a continuous data sample on all vascular procedures, since all eligible procedures are entered.

In contrast to the VQI, the NSQIP employs nurse abstractors to record samples of procedures instead of all procedures. Because of the different data collection methods, the 2 registries capture different patient outcomes. When this factor is eliminated by using identical collection periods, differences in variable definition and variable collection result in discordance in postoperative variables and outcomes. The unique continuous data-collection method employed by the VQI and the 1-year follow-up data allow for a more complete review of procedural and long-term–outcome activity at each institution.

A key question for any clinical registry is how to translate information into system change to improve quality. Many registries gather clinical data and produce comparative reports for distribution among its members. The VQI is unique because it allows the collaboration of centres in regional quality groups. It offers the opportunity of comparing processes and learning from the ideas, successes and techniques of others. There is now a Canada-specific regional quality group meeting twice a year, which allows the comparison of Canadian data, as these can vary substantially from US data and hospital practices.

Institutions participating in the VQI have more patients using appropriate preoperative risk-factor–modifying medications and have better long-term outcomes. Centres registered with the VQI are encouraged to participate in regional quality groups to tackle focused small or large projects. One such group in southern California was able to significantly increase both preoperative statin and anti-platelet use and discharge statin and antiplatelet use in patients with peripheral arterial disease over 3 years.

Involvement in the VQI and its regional quality groups increases accountability and, in turn, positively affects patient outcomes. An added benefit of VQI-based quality improvement is the cost savings for institutions, as shown in our experience with length of stay after endovascular aneurysm repair.

Importantly, with the advent of Quality-Based Procedures, using a quality database can assist in identifying centres that use best practices for quality improvement. In Ontario, the Ministry of Health and Long-Term Care has implemented several Quality-Based Procedures programs, with more in development. The VQI has given us the tools to examine and improve quality of care and show this to our local hospital and provincial counterparts. It is expected that future funding will be based on quality results, and VQI will allow centres to focus on quality and show their positive outcomes.

CONCLUSION

The VQI is a powerful tool to improve patient safety and quality in vascular surgery. It highlights opportunities for quality improvement and allows institutions to deliver patient-centred care while also being economically advantageous. In each of the 4 examples highlighted in this report, we were able to study and improve the quality of vascular procedures performed at our institution by analyzing self-reported VQI data. Identifying shortcomings is an important first step to achieving long-term sustained quality improvement. Understanding the patient population receiving procedures and predictors of outcome is important in preoperative prevention and risk stratification, and in patient selection for procedures. Reflecting on current practices improves future care and surveillance. By participating in the VQI, our institution increases its accountability, develops better practices and improves patient outcomes.
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Competing interests: None declared.

Contributors: E. Liao, N. Eisenberg, J. Montbriand, K.-T. Tan and G. Roche-Nagle designed the study. E. Liao, N. Eisenberg, A. Kaushal and G. Roche-Nagle acquired the data, which E. Liao, N. Eisenberg, J. Montbriand and G. Roche-Nagle analyzed. E. Liao, N. Eisenberg, J. Montbriand and G. Roche-Nagle wrote the article, which all authors reviewed and approved for publication.

References

A high-quality scientific journal could not be produced without the anonymous, unpaid and often inadequately appreciated work of its reviewers. The editors and staff of the *Canadian Journal of Surgery* thank the following people, who reviewed submissions to the journal in 2018.

MaryAnn Aarts  
*Toronto, Canada*

Najma Ahmed  
*Toronto, Canada*

Murad Aljiffry  
*Jeddah, Saudi Arabia*

Nawar Alkhamesi  
*London, Canada*

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I would like to respond to the commentary “Oncoplastic and reconstructive breast surgery in Canada: breaking new ground in general surgical training” by Peiris and colleagues. First, I completely agree with the notion that breast reconstruction is beneficial for many women undergoing mastectomy or significant volume loss with breast-conserving surgery. The corollary of this is that all women facing this type of surgery must be informed of all treatment options. Both Alberta and Ontario (using evidence-based approaches with multi-disciplinary panels that included breast oncologists and plastic surgeons) have recommended standardized information about breast reconstruction early in the decision-making process, encompassing all types of breast reconstruction, including implant-based, autologous flap, and combination reconstructions (i.e., autologous with implant).

In Canada, the only surgeons trained to discuss and provide all of these options are Royal College-certified plastic surgeons. This expertise is currently embedded in the Royal College’s objectives of training in plastic surgery and will be a key part of competency by design at all levels of training after transition to discipline. While volume-replacement breast reconstruction is part of the surgical practice of some oncologic breast surgeons in Europe, this is not the case in Canada. In fact, there are many aspects of surgical care that are different between the jurisdictions. One obvious example is the role of a trauma surgeon in Europe which involves treating extremity, abdominal, thoracic and central nervous system trauma. In Canada, this spectrum of expertise rests in multi-disciplinary teams, and there appears to be no reason to change.

The same holds true for breast cancer surgery and breast reconstruction. Peiris and colleagues state “a lack of plastic surgeons specializing in breast reconstruction is often cited as the main reason for low rates of immediate breast reconstruction in Canada. It therefore stands to reason that increasing the number of surgeons performing immediate breast reconstruction will increase rates.” This statement is erroneous in multiple aspects. Although all plastic surgeons in Canada are trained in breast reconstruction, Platt found that there was a strong correlation between rates of breast reconstruction and the presence of a plastic surgeon in the hospital where the mastectomy was done; that is, the issue is not that plastic surgeons lack breast reconstruction skills but rather the lack of plastic surgeons. However, there are equally important factors limiting the rates of breast reconstruction, including a persistent and erroneous belief among ablative surgeons and medical and radiation oncologists that reconstruction will delay adjuvant therapies or “hide” tumour recurrence. Finally, a lack of dedicated operative resources for breast reconstruction is a significant impediment because it requires complex coordination among general surgeons and reconstructive surgeons, and there is a legitimate concern on the part of general surgeons that their already scarce operative time will be taken up with potentially long reconstructive procedures after they have completed a mastectomy. In our institution, dedicated ablative/reconstructive operating time allows both plastic surgeons and general surgeons to run concurrent clinics and surgical lists once they have completed their portion of the breast procedure.

Our position papers6,7 argue for general surgeons, plastic surgeons, radiologists, medical oncologists, radiation oncologists and dedicated nursing staff to work in a multi-disciplinary team. We agree that the general surgeon trained in breast repositioning techniques should complete level I and level II surgery and that this represents a significant advancement in breast-conserving surgery. However, we strongly endorse that volume replacement (e.g., implants, autogenous tissue) and significant volume reduction (e.g., breast reduction) only be done by a combined general surgery and plastic surgery team. This supports the concept of the right surgeon doing the right procedure at the right time, ensures that women will be informed of all of their reconstructive options, takes advantage of the expertise of all team members and provides the best outcomes for patients.

An optimal future for patients does not rest with physicians “breaking new ground” outside the scope of their training, but instead in modifying the health delivery system to foster integrated, multi-disciplinary teams in which shared learning, innovation and expertise become routine. For instance, to address the regional variation in rates of breast reconstruction, we are investigating care pathways that would allow mastectomies to be done in community hospitals followed by expedited assessment for so-called “delayed immediate reconstruction.” The care of patients with breast cancer is a “team game,” and we encourage all surgeons caring for these patients to become involved in the formation of a team in their community and region.

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Competing interests: None declared.
DOI: 10.1503/cjs.1962101
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Author response to “Breast reconstruction: no need to break new ground”

We thank Douglas Ross for his letter in response to our recent commentary in which we compare breast surgical training and practice in Canada to that in the United Kingdom.

We knew that this would be a controversial — and perhaps emotive — topic, and it is this very reason that we firmly believe a line of dialogue should be opened addressing this issue. Most of the opposition to the notion of general/breast surgeons performing immediate breast reconstruction (IBR) will, understandably, come from members of the plastic surgery community.

First, a case of misunderstanding. In our paper, we suggested that “a lack of plastic surgeons specializing in breast reconstruction” is one of the main reasons for comparatively lower rates of IBR in Canada. Dr. Ross suggests that in fact “a lack of plastic surgeons” in the hospital where the mastectomy is being performed is the main contributory factor, citing Platt and colleagues’ paper published in the World Journal of Surgery. We would argue that this is surely the same thing. Zhong and colleagues reported barriers to breast reconstruction in Ontario. As would be expected, when there are no reconstructive breast surgeons in a hospital performing mastectomy surgery, the IBR rate is 0%; when 1 reconstructive breast surgeon is present, the IBR rate is 10.5%; and when 2 or more reconstructive surgeons are present, the IBR rate almost doubles to 19%. If Dr. Ross, and the breast cancer-treating community, agree that IBR is a positive and constructive cancer-treating community, agree

Second, a case of misunderstanding. We referred to the “legitimate concern on the part of surgeons” with cross-specialty training of performing mastectomy surgery, the IBR rate is 0%; when 1 reconstructive breast surgeon is present, the IBR rate is 10.5%; and when 2 or more reconstructive surgeons are present, the IBR rate almost doubles to 19%. If Dr. Ross, and the breast cancer-treating community, agree that IBR is a positive and constructive step, then surely improving access to, and rates of, these procedures should be welcomed. As long as the surgeons performing these procedures have appropriate training at a high-volume centre, a body of experience reflecting expertise in these procedures and evidence to confirm low rates of complications, then their surgical background and route of training should not be relevant.

The UK Intercollegiate Surgical Curriculum Project (ISCP) publishes and updates the training curriculum and learning objectives for the various surgical specialties in the United Kingdom and is overseen by the Joint Committee on Surgical Training. The ISCP syllabus for general surgical trainees in the UK wishing to pursue a career in breast surgery lists both immediate and delayed implant-only breast reconstruction and implant-assisted pedicled-lattissimus dorsi breast reconstruction as procedures that qualifying trainees should be “competent to perform without assistance and deal with the complications that arise.” All qualifying British general surgeons wishing to perform breast surgical oncology should therefore have this skill set as a minimum requirement.

Dr Ross’s second point relates to a persistent and erroneous belief amongst ablative surgeons and medical and radiation oncologists that reconstruction will delay adjuvant therapies or ‘hide’ tumour recurrence. In making this point, he incorrectly cites Khayat and colleagues’ paper published in the Canadian Journal of Surgery. We believe he meant to cite Coroneos and colleagues’ paper published in Breast in 2017. This paper summarizes a survey sent to general surgeons, surgical oncologists, plastic surgeons and medical/radiation oncologists regarding beliefs and practice patterns among physicians treating breast cancer. The study describes significant variation in reconstructive practices and advice given by the various specialties involved – some of which contradict national and international guidelines. We would suggest, however, that rather than restricting the scope of practice of oncoplastic/reconstructive breast surgeons, this would surely be an argument for creating “total breast surgeons” with cross-specialty training in all aspects of breast cancer care – both ablative and restorative.

Dr Ross’s final point seems to be the most confusing. He comments on the “legitimate concern on the part of general surgeons that their already scarce operative time will be taken up with potentially long reconstructive procedures after they have completed the mastectomy.” We feel this comment does not seem relevant to the main message of our paper: the concept of expanding the Canadian...
general surgery training curriculum to allow general surgery residents who wish to become breast surgeons to gain training in oncoplastic and reconstructive breast surgery. If anything, this model seems to solve the problem of an antiquated, disjointed approach to reconstructive breast surgery requiring the coordination of 2 busy services to be available for 1 operation.

This is not to say that 1 surgeon can truly offer all options. The microvascular skill set that comes with plastic surgery training lends itself to free-flap reconstruction and it is difficult to see how, with the current training curriculum, general/breast surgeons will ever offer this form of surgery. Data from both the breast surgeons will ever offer this itself to free-flap reconstruction and with plastic surgery training lends microvascular skill set that comes can truly offer all options. The 1 operation.

approach to reconstructive breast problem of an antiquated, disjointed thing, this model seems to solve the reconstructive breast surgery. If any-
to gain training in oncoplastic and general surgery training curriculum institutions. In the era of shared curency, took part in an online poll at the time of registration asking “Should breast surgeons be trained to perform immediate breast reconstruction?” Of the 23 attendees, only 1 answered “no.” A similar question was asked of UK general surgical trainees with an interest in breast surgery in 1996, of which 84% said that they wished to acquire technical skills in breast reconstruction.10 The longterm result is a UK Training Interface Group (T1G) Fellowship that accepts applicants from both general and plastic surgery backgrounds; the end point is a breast surgeon who is trained in both the oncological as well as the reconstructive elements of breast cancer treatment. The UK scheme has trained more than 100 new consultants with cross-specialty skills, coinciding with a doubling in breast reconstruction rates right across the country.11

Furthermore, it would stand to reason that if we are proposing an improved access to IBR by training breast surgeons in these techniques then, by the same rationale, we should be training plastic surgical residents who wish to perform breast surgery in the concepts and surgical skills required to perform breast surgical oncology.

We therefore challenge Dr Ross’s contention that “an optimal future for patients does not rest with physicians “breaking new ground” outside the scope of their training.” We believe that reconstructive breast surgery should be within the scope of training of breast surgeons. Furthermore, we would suggest that appropriately trained surgeons from both general surgery and plastic surgery disciplines can and should be trained in both the science of breast surgical oncology and the art of restorative breast surgery in order to create a new breed of “total breast surgeons.”

Once again, we thank Dr. Ross for his comments.

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DOI: 10.1503/cjs.1962102

References
Can we improve the efficiency of care in patients with colorectal cancer from the time of their initial referral for colonoscopy to surgical resection?

More than 25,000 Canadians receive diagnoses of colorectal cancer each year. It is clear that when colorectal cancer is identified at an earlier stage, patients have high disease-specific survival. Although complete pathological responses following systemic therapy occur, it is generally accepted that surgical resection is the dominant potentially curative treatment modality. As a result, individuals with suspected colorectal cancer require prompt referral to a surgeon for consideration of resection.

Preoperative tests should be limited to those with the ability to influence subsequent clinical decisions. The gold standard diagnostic test for colorectal cancer remains a colonoscopy with synchronous biopsy. Staging is then completed via computed tomography (CT) of the chest, abdomen and pelvis. Additional tests, such as positron emission tomography, anorectal ultrasonography, pelvic magnetic resonance imaging (MRI), and contrast-enhanced ultrasonography and/or MRI of the liver may be required on an ad hoc basis depending on the tumour location on the CT scan.

The time interval between the index colonoscopy and subsequent operative resection is a quality metric in many health systems. Although unlikely to alter the resectability of a given colonic lesion, potential delays in meeting the ultimate decision-maker (i.e., the surgeon) as well as the wait time for surgical resection represent significant psychological challenges for most patients.

We identified all adult patients who underwent a resection for colorectal cancer in Southern Alberta over a 1-year period. Specific time points for analysis included the dates of the initial family practitioner referral for colonoscopy, the index colonoscopy and the surgical resection. We excluded patients who presented to the emergency department and received a colonoscopy without a formal outpatient referral, including those with colonic obstruction and/or perforation ($n = 66$); required neoadjuvant therapy for either rectal cancer (chemotherapy and radiation) or other scenarios, such as synchronous colorectal liver metastases ($n = 54$); underwent colonic resections, but whose primary cancers were not colorectal cancer ($n = 28$); and patients whose clinical course deviated from the typical pattern (e.g., diagnostic colonoscopy performed in another country, large polypectomies found to have adenocarcinoma) ($n = 48$). Patients

### SUMMARY

Delays in the diagnosis and treatment of colon adenocarcinoma are distressing to patients and clinicians alike. Of 224 patients with resected colon cancer identified via a province-wide administrative database, 170 (76%) received their colonoscopy from a gastroenterologist (GI). Patients waited significantly longer between their colonoscopy and surgical resection when the colonoscopy was performed by a GI within an urban city ($43 \pm 27$ d; $p = 0.02$). The total time from family practice referral to colonoscopy to surgical resection was shorter when a surgeon performed colonoscopy within an urban setting ($105 \pm 114$ d; $p = 0.03$). In community settings, there were no significant differences in any interval, regardless of which service performed the colonoscopy.
whose initial referral dates were not attainable were also excluded ($n = 31$). Ethics approval was obtained via the University of Calgary.

Of the 224 patients across southern Alberta who had a colorectal cancer resected, 170 (76%) received their preceding colonoscopy by a gastroenterologist (GI) and 54 (24%) by a general or colorectal surgeon. Patient characteristics were similar, irrespective of who performed the colonoscopy. Gastroenterologists performed 86% and 23% of the colonoscopies within and outside of metropolitan Calgary (i.e., community setting), respectively; surgeons completed 14% and 77%, respectively.

The specific results for wait times within the city of Calgary are presented in Table 1. Although patients within metropolitan Calgary underwent colonoscopies slightly faster when they were performed by a surgeon than when they were performed by a GI (41 v. 50 d), a statistically significant difference was not identified ($p = 0.19$). Patients waited significantly longer for surgical resection when a GI performed their colonoscopy (27 v. 43 d; $p = 0.02$). The overall time between family practitioner referral for colonoscopy and surgical resection was also shorter when a surgeon performed the colonoscopy (83 v. 105 d; $p = 0.03$).

Although most colonoscopies within Calgary were performed by GI (86%), most colonoscopies conducted within the community settings of southern Alberta (outside of metropolitan Calgary) were completed by surgeons (77%). Within this community practice there were no significant differences in any interval wait times, regardless of which service performed the colonoscopy (Table 2). This pattern was also present when analyzing all patients within southern Alberta (i.e., both within and outside of metropolitan Calgary; Table 3).

When the specific indications for the index colonoscopy referral were evaluated (i.e., screening v. diagnostic), there were no alterations in the findings described previously. Only patients who underwent a colonoscopy performed by a surgeon in metropolitan Calgary had shorter times between

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### Table 1. Wait times for patients in metropolitan Calgary

<table>
<thead>
<tr>
<th>Interval</th>
<th>Group, median</th>
<th>General surgeon as colonoscopist ($n = 27$)</th>
<th>Difference in medians</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time between family physician referral and colonoscopy, d</td>
<td>50</td>
<td>41</td>
<td>9</td>
<td>0.193</td>
</tr>
<tr>
<td>Time between colonoscopy and surgery, d</td>
<td>43</td>
<td>27</td>
<td>16</td>
<td>0.018</td>
</tr>
<tr>
<td>Total time between family physician referral and surgery, d</td>
<td>105</td>
<td>83</td>
<td>22</td>
<td>0.03</td>
</tr>
</tbody>
</table>

GI = gastroenterologist.

### Table 2. Wait times for patients outside of metropolitan Calgary, but within southern Alberta

<table>
<thead>
<tr>
<th>Interval</th>
<th>Group, median</th>
<th>General surgeon as colonoscopist ($n = 27$)</th>
<th>Difference in medians</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time between family physician referral and colonoscopy, d</td>
<td>45</td>
<td>48</td>
<td>3</td>
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<tr>
<td>Time between colonoscopy and surgery, d</td>
<td>41</td>
<td>57</td>
<td>16</td>
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<tr>
<td>Total time between family physician referral and surgery, d</td>
<td>96</td>
<td>105</td>
<td>9</td>
<td>0.479</td>
</tr>
</tbody>
</table>

GI = gastroenterologist.

### Table 3. Wait times for patients both inside and outside of metropolitan Calgary, and within southern Alberta

<table>
<thead>
<tr>
<th>Interval</th>
<th>Group, median</th>
<th>General surgeon as colonoscopist ($n = 54$)</th>
<th>Difference in medians</th>
<th>$p$ value</th>
</tr>
</thead>
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<tr>
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<td>48</td>
<td>2</td>
<td>0.196</td>
</tr>
<tr>
<td>Time between colonoscopy and surgery, d</td>
<td>43</td>
<td>36</td>
<td>7</td>
<td>0.57</td>
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<tr>
<td>Total time between family physician referral and surgery, d</td>
<td>103</td>
<td>98</td>
<td>5</td>
<td>0.123</td>
</tr>
</tbody>
</table>

GI = gastroenterologist.
the colonoscopy itself and the subsequent surgical resection. The median wait time between the referral request and date of colonoscopy was longer for patients whose colonoscopies were for screening than those whose colonoscopies were diagnostic ($p = 0.02$). Wait times for a GI varied from 1 to 726 days. This compared with 6 to 327 days for surgeons.

Although the specific challenges in achieving expedited cancer care vary among types of cancer, there is a broad understanding among clinicians of the required diagnostic and management pathway for colorectal cancer (accurate identification of patients at risk for colorectal cancer, expedient colonoscopy, urgent referral to a surgeon for consideration of potential resection versus neoadjuvant/palliative).

It is evident that patients who underwent a colonoscopy by a surgeon in an academic centre had an overall faster time from referral for colonoscopy to subsequent surgical resection. Although there was a trend toward shorter wait times from initial referral to the time of colonoscopy, the dominant reason for an overall shorter pathway was a significantly more rapid movement from the date of colonoscopy to surgical resection among surgeons. It was interesting to note that this did not vary based on whether or not the same surgeon was responsible for both the colonoscopy and the resection.

We suspect that there are multiple underlying reasons for the delay in referral between urban GIs and surgeons, including waiting for final pathology confirmation and/or staging CT studies before referral to a surgeon, failing to obtain preoperative staging CT imaging at the time of the index colonoscopy/diagnosis, and a more intimate setting between clinicians in nonurban community settings. This efficient and rapid care among our rural and community patients is both reassuring and encouraging.

**Conclusion**

Patients who were referred by their family practitioners for colonoscopy and subsequent surgical resection within a large metropolitan area received more efficient and timely care by surgeons. Targeted improvements should focus on improving communication strategies between urban GIs and surgical colleagues.

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**Competing interests:** None declared.

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

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How well do we do what we do, and how do we know it? The importance of patient-reported experience measures in assessing our patients’ experience of care

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Accepted July 27, 2018

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DOI: 10.1503/cjs.006618

Feedback, according to my wife, is the reason that I am still married after 20 years. Her feedback often leads me to the Home Depot, where after each purchase I am asked by the friendly cashier to rate their service online. Do we do that in medicine? How well do we do what we do, and how do we know it?

The godfather of the National Surgical Quality Improvement Program (NSQIP), Ernest Codman, at the turn of the 20th century, pioneered the idea that all hospitals must analyze their results, compare them with those of other hospitals and publicly report their successes and failures. This was considered heresy at the time. Have things changed 100 years later?

As specialists affiliated with the Royal College of Physicians and Surgeons of Canada, we’re mandated to complete 400 hours of continuing medical education per 5-year cycle, but we are not trained in customer service, the patient experience, or health care communication skills. We are trained to focus on outcomes and on patient care.

What is a good patient experience, and why is it important?

What is the patient experience? The Beryl Institute defines it as “the sum of all interactions, shaped by an organization’s culture, that influence patient perceptions across the continuum of care.” It encompasses physicians’ manner, timely compassionate nursing care, clean surroundings and respectful and courteous treatment.

In his seminal book, Service Fanatics, Dr. James Merlino detailed the journey of the Cleveland Clinic from the lowest ranks in patient experience scores as determined by the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey to the 92nd percentile in 5 years. The Center
for Medicare, understanding the importance of patient satisfaction, withholds $1.8 billion per year as part of their value-based purchasing program; how hospitals do on their HCAPS scores determines the payment of huge resources.

**FUNCTION VERSUS PURPOSE**

As caregivers and staff in a hospital, we need to understand the difference between our function and our purpose. We all have different functions, such as administration, computer support, nursing care and provision of surgical services, but we need to understand that we all have the same purpose — the reason why our job exists — in our hospitals. At Oakville Trafalgar Memorial Hospital, our vision is “exemplary patient experiences always,” and that is our collective purpose. These 4 simple words have a profound meaning in modern health care. At times, caregivers forget their purpose and perform only their function. Why should surgeons, who are traditionally taught to focus only on outcomes, care about patients’ attitudes, expectations, or experiences? Because it is clearly demonstrated that patient attitude affects patient outcomes. The COST trial, which looked at open versus laparoscopic colon resections, surprisingly identified the fact that a low quality of life score before surgery predicted surgical complications.

**EXPECTATIONS AND OUTCOMES**

Many studies are now showing that patients’ expectations affect their outcomes after surgery. What’s more important: the patient’s care or the patient’s experience of care? Is it better to receive optimal care or to believe that you did? Most patients, for example, will never see an elegant bowel anastomosis or the care with which their surgeons close the abdominal wall. They may not understand some of the complexities of modern surgical care, but they do know respect, courtesy, caring, emotional connection and listening, and we have to understand that, to them, these are proxies for quality of care.

Despite what we were taught in medical school, physicians need to connect with patients and show empathy and compassion. Why is paying attention to the patient experience important? Because it’s the right thing to do; it’s how we would want to be treated, it’s how patients perceive quality, and it’s the basis of the patient-centred care model.

Maya Angelou said, “At the end of the day people won’t remember what you said or did, they will remember how you made them feel.” After completing a colonic resection for cancer several weeks ago, several days after the surgery the patient told me, “Doctor, I honestly don’t remember everything you told me in the office, but I do remember I felt I could trust you.”

Patients are concerned about a lack of respect. They want to be treated as individuals and want a personal connection so that they get better health care. They want health care providers to communicate with each other; they don’t want nursing staff asking patients, “What did the doctor tell you?”.

**ASSESSING PATIENT EXPERIENCES USING SURVEYMONKEY**

Our surgical program has started to use a readily available Internet-based survey tool, SurveyMonkey, and we endeavour to assess every single patient encounter in every single division, including surgical day care, ambulatory care, and the inpatient units, every single day. We use this information to guide training in great patient customer service. We participated in the development of the Ontario Hospital Associations Ontario Day Surgery Experience Survey. A group composed of the chief of surgery, surgical program director, patient care manager for the OR/PACU, and all surgical division leads excerpted a portion of the questions for our hospital. We have already started surveying patients coming through our surgical day care unit (Fig. 1, Fig. 2, and Appendix 1, available at canjsurg.ca/006618-a1). The survey is completely anonymous and we
do not, at this point, identify the surgeons involved in the patients’ care.

Bias is always a concern with an anonymous survey such as ours. The survey is also open to manipulation owing to its anonymous Web-based access. As such, we are not looking for statistical significance; rather, we are looking for trends to follow and address. This technique provides a very cost-effective way for smaller institutions to assess patient care experience.

Our early results point to a number of issues for us to consider: postoperative nausea and pain control, varying wait times and lack of communication throughout the surgical experience, and inadequate information provided to patients about their surgical procedure. As a result, we have tasked our pain control service to address postoperative nausea and vomiting, and we have started implementing a multimodal day surgery pain protocol for hospital and discharge. An upgrade to our operating room booking and patient information system is underway to streamline care and provide real-time information to patients and their families through short message service (SMS) and a Web portal. To address communication about patient surgical procedures, we are developing a postoperative day one program modelled on suggestions from a colleague to improve patient satisfaction, where the attending surgeon calls or has a video visit with patients the day after surgery. Our surgeons discuss the anonymous survey data at our departmental meetings to provide us with further insight on how we can improve.

We can measure staff satisfaction in the same way, because numerous insights will come from our front-line employees. Our caregivers want to be heard, to contribute, to be appreciated and to be on the winning team.

Dr. Codman’s original statement, “If you can’t measure it, you can’t improve it,” has now evolved; in the words of Professor James D. Perkins from the University of Washington, “If you don’t show it, it doesn’t matter.” We need to post all of our quality-improvement survey results, regardless of whether they are positive or negative, on our hospital’s website in order to control the narrative and give people a voice.

All caregivers who have contact with patients need training in great customer service and need to be engaged and believe in their purpose. A focus on improved patient experience has been shown to reduce medicolegal costs and to improve the efficiency of health care delivery. We need to have a purpose-driven relationship mindset, not a functional task mindset. Patients need and want to be a part of their health care experience.

Once surveys of patient experience have produced results, how can we act on the results and create meaningful change? There are many organizations dedicated to improving the patient experience, including the Beryl Institute, the Association for Patient Experience and the Institute for Healthcare Improvement. We need to be a part of the evolution of patient experience to the forefront of care and use data to improve what we do.

CONCLUSION

As physicians move into leadership positions, the importance of measuring performance and value becomes increasingly clear. We must understand that the loss of autonomy leads to the strengthening of team performance, and the importance of measuring this performance and using these metrics will become increasingly clear and will lead to more cost-effective and efficient care. Our patients want to be a part of their health care teams, and as we organize their care around them, they will inevitably, and rightly, become the centre of what we do.

Acknowledgements: The author thanks Julie McBrien, program director of surgery at Halton Healthcare Services, who has been an invaluable colleague in the development and implementation of our feedback strategies. Without her support we would not have been able to sustain the pace or success of our initiatives.

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References

Evaluation of common suturing techniques to secure implantable cardiac electronic device leads: Which strategy best reduces the lead dislodgement risk?

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Accepted May 11, 2018

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Summary

Implantable cardiac electronic device lead dislodgement is a relatively common complication and carries significant comorbidities. A potential cause of lead dislodgement includes inadequate anchoring along the lead suture sleeve at the venous insertion site. We assessed which of the 3 commonly applied knot-tying techniques results in the most effective anchoring of a pacing lead along its suture sleeve, which could be associated with minimized lead motion post-implant. Following controlled traction force measurements, the anchor knot technique offered the greatest amount of lead stability when compared with the simple knot and the looping knot techniques.

During implantation of cardiac electronic devices, such as pacemakers and defibrillators, leads are commonly inserted transvenously along upper-extremity veins, such as the axillary, cephalic, or subclavian veins. After their fixation in the desired cardiac chambers, the leads are secured along their sleeves to subcutaneous tissue at the venous insertion site with sutures to minimize lead motion and the risk of dislodgement. Lead dislodgement is a common complication, occurring in around 2% of patients. It is a problematic complication owing to the resultant device malfunction and the increased risk of device infection associated with reoperation for lead repositioning.

There is no universally accepted suturing technique to secure leads along their sleeves at the venous insertion site. The type of suturing technique applied depends entirely on the surgeon’s preference; techniques include the simple knot (Fig. 1), the looping knot (Fig. 2) and the anchor knot (Fig. 3). We compared these 3 suturing techniques to determine which technique provides the most stable and sturdy approach.

Evaluation of Suture Techniques

Standard pacing leads with suture sleeves were used in addition to 2–0 Ethibond sutures. A Spectranetics lead locking stylet was connected to the proximal end of the pacing lead to allow attachment of a manual weight scale used to apply longitudinal traction on the lead (Fig. 4). The lead was subsequently sutured along its suture sleeve with the various knot-tying techniques onto a silicon suture block. Manual longitudinal force was then applied on the weight scale handle and the registered weight recorded (in pounds) at the time of lead dislodgement; lead dislodgement was defined as any movement of the lead at the suture sleeve site during application of longitudinal force. This process was repeated 3 times for each suturing technique. The anchor knot appeared to provide the most stability, as the greatest amount of force was required to...
induce lead dislodgement; the simple knot provided the least anchoring stability (Fig. 5).

**Discussion**

The use of cardiac implantable devices, such as pacemakers and defibrillators, has been on the rise over the years as clinical indications continue to be validated. Lead dislodgement remains a common concern, and strategies to minimize this risk are lacking. Many lead-tying techniques can be considered to secure leads along their suture sleeves during implantation; however, to date there is no consensus as to which technique conveys the greatest lead stability. Based on our evaluation of the 3 most commonly applied suturing techniques, the anchor knot appears to provide the greatest stability, and the simple knot the least; the anchor knot tolerated 3.9 ± 0.1 lbs ($p = 0.0001$) of weight before lead dislodgement compared with 2.7 ± 0.1 lbs ($p = 0.0008$) for the looping knot and 1.1 ± 0.1 lbs ($p = 0.0008$) for the simple knot (Fig. 5). These observations suggest that using the anchor knot to secure leads along suture sleeves could potentially reduce the risk of lead dislodgement due to increased lead anchoring stability.

The anchoring knot likely offers the greatest lead stability compared with the other techniques, because the suture material gets wrapped around the suture sleeve directly without encompassing any extraneous
material in between that could lead to weakening of knot tension and lead slippage. In this case, the extraneous material refers to the suturing pad material, and when in vivo would refer to soft tissue near the venous insertion site where the lead is being implanted. On the other hand, the simple knot grasps the greatest amount of extraneous material between the suture and lead sleeve, rendering the knot tension the least stable.

Our evaluation of lead anchoring stability of the various suturing techniques is limited by the fact that testing was performed in vitro. Nonetheless, it is reasonable to assume similar performance of the various knot-tying types in vivo because the same principle of knot tension stability based on the degree of encompassed extraneous material within the knot would still apply. Furthermore, the described anchor knot is not

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**Figure 3.** Anchor knot technique to secure the pacemaker lead along its suture sleeve. Before stabilizing the lead, an anchor knot is placed underneath the sleeve.

**Figure 4.** (A) Lead locking stylet connected to the pacing lead to allow attachment of the manual electronic weight scale. (B) Manual weight scale attached to the back of the lead locking stylet.

**Figure 5.** Average weight measurements (in pounds) at the time of lead dislodgement for the 3 common suture techniques.
very technically challenging, is already a common technique and carries no extra risk to the patient than the other knot-tying techniques.

**CONCLUSION**

Based on our evaluation, applying the anchor knot technique to secure leads along their sleeves during implantation may best reduce the risk of lead dislodgement until in vivo assessment of the various suturing techniques is undertaken.

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**Competing interests:** None declared.

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

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The importance of costing perspective: an example evaluating the cost-effectiveness of a locking versus nonlocking plate in medial opening wedge high tibial osteotomy

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DOI: 10.1503/cjs.018317

High tibial osteotomy (HTO) fixation can be achieved using various plate designs. Compared with nonlocking plates, the stability of locking plates allows patients to return to weight-bearing and work sooner and may also decrease postoperative complications, introducing the potential for overall cost savings. However, material costs for locking plates are higher, and the plate bulkiness may lead to additional surgery to remove the plate. We conducted a retrospective study to evaluate the cost-effectiveness of a locking versus a nonlocking plate in HTO from both the health care payer and societal perspectives up to 12 months postoperative. We observed that from a health care payer perspective, the locking plate was not cost-effective. However, the locking plate was cost-effective from the societal perspective (addition of indirect costs, such as time off work). These findings highlight the importance of considering costing perspective in economic evaluations for chronic conditions, particularly in publicly funded health care systems.
To test this hypothesis, we retrospectively reviewed the cases of patients who underwent a medial opening wedge HTO with a locking plate versus a nonlocking plate and evaluated the cost-effectiveness from the health care payer (Ontario Ministry of Health and Long-Term Care) and societal perspectives at 12 months following surgery. A description of our methods and results are reported in Appendix 1, available at canjsurg.ca/018317-a1.

Our cost-effectiveness analysis showed that from the health care payer perspective, the use of a locking plate in HTO is unlikely to be cost-effective. The health care payer perspective includes any direct costs (e.g., surgery, staffing, imaging) to the public payer. However, from a societal perspective, the locking plate is highly likely to be cost-effective, highlighting the importance of costing perspective in economic evaluations. The societal perspective includes both direct and indirect costs (e.g., time off work).

Although patient-reported outcomes (Knee injury and Osteoarthritis Outcome Scores [KOOS]) slightly favoured the locking plate, the difference was not statistically significant, suggesting that the cost-effectiveness is highly driven by cost differences. We found that the surgical and postoperative complication costs were similar between groups. Therefore, the difference in direct cost between interventions (+$665 for the locking plate) is reflected in the difference in plate and screw costs.

The incremental cost-effectiveness ratio (ICER) value for the health care payer perspective was +$399.41 per 1 additional point improvement in the KOOS total change score, suggesting that the public payer must be willing to pay $4000 more per patient to achieve a clinically important improvement in KOOS (i.e., 10-point improvement) to use the locking plate. This was further supported by net benefit regression (NBR) and cost-effectiveness

![Fig. 1](image-url)

**Fig. 1.** (A) From the health care payer perspective, the probability that the locking plate is cost-effective did not exceed 55% at a willingness to pay (WTP) of $1000 or greater. (B) From the societal perspective, the locking plate was cost-effective with 99% certainty, regardless of WTP.
acceptability curve (CEAC) results, which showed the probability that the locking plate is cost-effective does not exceed 55% at a willingness to pay (WTP) of $1000 (Fig. 1A). Therefore, from a health care payer perspective, which looks strictly at direct costs to the public payer, the locking plate is likely not cost-effective.

Alternatively, we found that by incorporating indirect costs (e.g., time off work) to evaluate from a societal perspective, the locking plate is cost-effective. The difference in societal costs between treatment groups favoured the locking plate, with $6228.21 cost savings at 12 months following HTO. Additionally, the NBR and CEAC indicated that the locking plate was cost-effective with 99% certainty, regardless of WTP (Fig. 1B). The cost difference is largely attributable to a sooner return to work and activities for patients receiving the locking plate.

An institutional decision-maker examining our results may opt to use the nonlocking plate owing to lower system costs; however, considering solely the direct costs could substantially undermine the true societal benefit of using the locking plate. The rehabilitation period after HTO involves altered weight-bearing (i.e., crutch ambulation) that can continue several weeks after surgery. Consequently, most patients are required to take time off work and are limited in daily activities for extended periods of time, which can generate large losses in productivity for society, particularly for young patients (around 45 years of age) who are members of the working population. These are vital aspects to consider when assessing cost-effectiveness in this population.

In economic analyses for OA, much attention is given to the direct health care costs. Indeed, these costs are important to consider when comparing surgical interventions. However, this paper emphasizes that inclusion of indirect costs is arguably more important. An estimated 80% of the overall annual costs for OA result from time lost from work and leisure by both participants and unpaid caregivers.1 In Canada, 1 in 8 workers has OA, and this number is projected to grow to 1 in 3 workers over the next few years.1 Similar trends are seen in other chronic MSK conditions (e.g., rheumatoid arthritis) that lead to disability and for interventions, such as elective orthopedic interventions, that involve an extended recovery period that limits patient activity. As the rate of MSK diseases continues to increase along with its economic burden, it is essential to identify interventions that are cost-effective. Importantly, our results show that the conclusions regarding the value of interventions are likely to change depending on the perspective of the analysis. These findings highlight the importance for consideration of costing perspective in economic evaluations for chronic conditions, particularly in publicly funded health care systems.

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Competing interests: None declared.

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

References
Expanding the trauma code to other causes of hemorrhagic shock — ruptured abdominal aortic aneurysms

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Accepted July 27, 2018

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DOI: 10.1503/cjs.018717

Ruptured abdominal aortic aneurysms (RAAAs) represent a surgical emergency with high mortality. New strategies for optimizing prompt delivery of care for RAAA are an important goal. In trauma surgery, implementation of a trauma code has been successful at streamlining diagnosis and treatment. The trauma code notifies all members of the team via overhead page and places the computed tomography (CT) scanner and operating room (OR) on standby. The goal is to clarify each team member’s role and prioritize the care of the trauma patient in the emergency department (ED). Elsewhere, code protocols have been implemented to address other medical emergencies, such as ST-elevation myocardial infarction (STEMI), stroke and fetal distress, with a reported reduction in times to treatment. As coordinated, high-level care provided to trauma patients is facilitated by activating a trauma code protocol, it follows that this framework should be extended to conditions of similar acuity, such as RAAAs.

At our institution, trauma is managed using a code protocol, but RAAAs are not. Our centre is the regional vascular surgery referral centre for all eastern Ontario. Coordination of care for a suspected or known diagnosis of RAAA is managed with the standard ED triage model. In contrast, when a trauma code is called, the entire trauma team is notified by overhead page, and the CT scanner, OR and blood bank are placed on standby, often before patient arrival. When an RAAA presents, assessment, and thus definitive management, may be delayed because of the wait for an unreserved CT scanner or administrative delays in the ED. We believe a code protocol should be in place for conditions that have time-sensitive outcomes and for which management depends on the mobilization of multiple hospital resources; RAAA is a condition that satisfies these criteria. RAAA is an important differential diagnosis of abdominal pain in unstable patients and can be rapidly ruled out with point-of-care ultrasound. We also know that time to the OR is critical in ensuring survival of patients with RAAA based on clinical principles and retrospective data. Finally, the management of RAAA requires mobilization of a

**Summary**

Expediting life-saving care for hemorrhagic shock through multi-disciplinary code protocols is a potential method to improve outcomes. Trauma codes have become standard of care at most tertiary care centres; however, it is unclear if similar protocols can improve delivery of care for other forms of hemorrhagic shock. We examined the feasibility of a code protocol for ruptured abdominal aortic aneurysms (RAAAs) by reviewing the literature and comparing patient outcomes for RAAA and trauma patients at our institution, where the latter have a well-established trauma code protocol. We show that, despite being similarly unstable, patients with RAAA experienced delays to care milestones compared with trauma patients, even when accounting for diagnostic delays. Combining these data with present understanding of factors implicated in RAAA survival, we propose that a “CodeAAA” protocol may fill an important gap in RAAA care and that further prospective studies examining the utility of such a code are warranted.
large multidisciplinary team, including a vascular surgeon, anesthesiologist, the blood bank, radiologist and interventional radiologist, fluoroscopy technicians, the intensive care unit and OR personnel. This is particularly true in the endovascular era.

We examined the feasibility of a “CodeAAA” protocol at our institution by conducting a retrospective review of all trauma codes and RAAAs over a period of 2.5 years.¹ We showed that patients with traumas and RAAAs had similar hemodynamic vital signs and Canadian Triage and Acuity Scale (CTAS) scores, suggesting that both populations share similar acuity. However, patients with RAAAs overall experienced significant delays to physician assessment, even when accepted in transfer with a known diagnosis. Interestingly, the median time to OR for transferred patients with RAAAs was less than that for trauma patients; 97% of patients with RAAAs required urgent transfer to the OR compared with 20% of trauma patients. Thirty-day mortality was also higher for RAAAs, but the difference was not statistically significant. We believe these data highlight a potential shortcoming in the delivery of care for patients with RAAA that could be addressed by a “CodeAAA,” especially considering that both patient populations appear to be equally hemodynamically unstable. The shorter time to OR for patients with RAAAs is likely because RAAAs require less preoperative resuscitation than traumas.

A “CodeAAA” protocol would allow for activation by an emergency physician, or vascular surgeon/senior trainee who has high suspicion of an RAAA either clinically or radiographically (including bedside ultrasound). An overhead page would notify vascular surgery, radiology and OR personnel. The CT scanner in the ED would be placed on standby, and the OR would be prepared for either open or endovascular AAA repair. To our knowledge, no studies published to date have directly examined the impact of a “CodeAAA”; however, there are data supporting its potential utility. A retrospective study reported an association between delays to the OR and poorer survival in patients with RAAA.² In addition, improved outcomes have been reported for RAAAs managed at academic centres, possibly because these institutions are more likely to have protocols for hemorrhagic shock in place.³ Finally, another retrospective study reported a low mortality associated with RAAA after implementation of a multi-disciplinary endovascular aneurysm repair protocol.⁴

The main shortcomings of a “CodeAAA” are that it may not improve the timing of RAAA diagnosis and that there is potential for over-calling codes (“false-calls”). Indeed, RAAA can present subtly with normal vital signs; there is a reported misdiagnosis rate as high as 40%.⁵ In our data set, the largest delay was from arrival to physician assessment in patients with RAAA without an admitting diagnosis. Despite this, we believe that a code protocol could expedite the diagnosis of RAAA by maintaining awareness among staff. The potential for RAAA false-calls can be accurately assessed only using a prospective study and will depend on each institution’s criteria. Nonetheless, false-calls are an inherent feature we see with STEMIs and strokes, especially the latter, which carries a misdiagnosis rate above 25%.⁶ Over time, the detection of RAAA will improve with the uptake of point of care ultrasound in the ED, and the rate of false-calls would be expected to decrease accordingly.

**CONCLUSION**

Taken together, the decision to adopt a code protocol for any cause of hemorrhagic shock rests on a critical appraisal of each institution’s unique dynamics and patient populations. Here, we approached the possible considerations for RAAA from the perspective of a tertiary care centre. Our data document care delays for RAAAs and establish similar acuity to trauma code patients. A code protocol should be extended to RAAAs to prioritize care, mobilize an interdisciplinary team, minimize delays and maintain staff education, much as it has for trauma codes. Future prospective studies will be required to determine the effectiveness of a code protocol in improving outcomes of patients with RAAA. Given the importance of rapid diagnosis and prompt mobilization of a multidisciplinary team for definitive management of RAAA, the benefits afforded to trauma patients through the implementation of a code protocol should be shared with equally hemodynamically unstable surgical emergencies like RAAA.

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Phyllodes tumour of the breast and margins: How much is enough?

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Accepted July 27, 2018

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DOI: 10.1503/cjs.005718

Phyllodes breast tumours are fairly uncommon, and they can be benign, borderline or malignant. General surgeons usually encounter them following the surgical excision of a breast lump that had the appearance of a fibroepithelial lesion. The surgeon is then faced with the question of what to do to establish an acceptable treatment margin. In this discussion, we recommend a plan for the management of Phyllodes tumours based on a review of the recent literature, confirmed by a retrospective review of the results from our centre. A negative margin is acceptable treatment following a lumpectomy for Phyllodes tumours. Only patients with a positive margin should undergo a revision.

SUMMARY

Phyllodes breast tumours are fairly uncommon, and they can be benign, borderline or malignant. General surgeons usually encounter them following the surgical excision of a breast lump that had the appearance of a fibroepithelial lesion. The surgeon is then faced with the question of what to do to establish an acceptable treatment margin. In this discussion, we recommend a plan for the management of Phyllodes tumours based on a review of the recent literature, confirmed by a retrospective review of the results from our centre. A negative margin is acceptable treatment following a lumpectomy for Phyllodes tumours. Only patients with a positive margin should undergo a revision.

What does the literature tell us?

The data available in literature on Phyllodes tumours include retrospective reviews and large, single-centre studies.5–9 The following points summarize what these studies tell us about the management of Phyllodes tumours:

- Prognosis is excellent for Phyllodes tumours following surgical excision, with no requirement for adjuvant therapy.5,6
- As long as the microscopic surgical margins are free of disease, the extent of surgery does not correlate with disease-free survival or local recurrence.7,8
- Distant recurrences are more frequent in patients with malignant tumours.5
- The upgrade rate of fibroepithelial lesions to Phyllodes tumours following a period of observation is low.9

We performed a retrospective review at our single tertiary referral centre of all patients who had undergone surgical therapy for Phyllodes
tumours between May 2009 and June 2015 (Appendix 1, available at canjsurg.ca/005718-a1). The largest subgroup of patients available for analysis was the group with benign Phyllodes tumours (n = 52; Appendix 1). In this group, 21 (40%) patients had close, negative margins, and 20 (38%) had positive margins on the initial surgical excision. One-third of the patients with positive margins (n = 7) underwent a margin re-excision and the rest (n = 13) opted to undergo a wait and watch policy with close observation. All patients with malignant Phyllodes tumours (n = 4) and a positive margin (n = 1) were offered further surgery to clear the margin.

The local recurrence rate for the whole cohort of patients was 1.9% (n = 1); this patient had a benign Phyllodes tumour with a positive margin and opted for a wait and watch policy with close surveillance.

**WHAT SHOULD SURGEONS DO FOR NOW?**

The setting in which most general surgeons encounter Phyllodes tumours of the breast is in the context of a core biopsy from a breast lump or a fibroepithelial lesion that is surgically excised. Based on the data available in literature, as well as the findings from our investigation, we propose an algorithm for the management of suspected and unsuspected Phyllodes tumours of the breast (Fig. 1) and suggest the following:

- The NCCN guidelines advocating a 1 cm margin for surgical therapy for Phyllodes tumours is overtreatment.
- Surgeons should request that pathologists classify the Phyllodes tumours as benign, borderline or malignant breast tumours in their reports.
Patients with a microscopically negative margin following a lumpectomy for Phyllodes tumours require no adjuvant therapy and can be followed up with annual surveillance.

Patients with a positive margin can be treated with margin re-excision or close surveillance if they have benign or borderline histology.

Patients with a positive margin and malignant histology should undergo further surgery to obtain clear margins.

Acknowledgements: The authors thank Dr. Jesse McLean, research manager at the Royal Victoria regional hospital, for his help with the data presentation and manuscript preparation. They also thank Miss Emma Hawkes for her help with collecting and charting the data used for the study.

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Competing interests: None declared.

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

References
Applications are invited for the position of Head of the Department of Surgery, in the Faculty of Health Sciences at Queen's University and its affiliated teaching hospitals. We are searching for an outstanding academic physician with proven administrative experience and strong leadership skills who, as Head, will draw on strong interpersonal and organizational skills to develop and manage teams that will foster excellence in teaching, patient care and research within the Department. The qualified applicant must be eligible for licensure with the College of Physicians and Surgeons of Ontario.

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