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Dr. Naheed Dosani
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CMA member
Closer to private health care options?

The lawsuit that was supposed to settle whether Canadian citizens have the right to timely health care has been delayed. Brian Day, former president of the Canadian Medical Association, had initially brought a lawsuit in 2009 to allow his private clinic to exist. A small group of his patients joined him in 2012. The hearing was supposed to commence in September 2014. Since 2012, lawyers on both sides have swelled the process, with dozens of witnesses expected. The lawsuit is expected to take several months to play out. Apparently both sides wanted the delay in order to attempt settling some of the issues out of court. The complexity of the overall case has become overwhelming; however, the initial events that led to the patient portion of the lawsuit seem to be plainly simple. The care of 2 patients with cancer and 2 others with musculoskeletal ailments removing them from normal daily activities were being held up by long wait times. The patients just wanted to get on with a normal life or live what little time they had left off of a wait list. The British Colombia government did not agree with that.

Other attempts in Canada to find an alternative pathway are not being accepted by all those involved. A proposed class action suit in Quebec has seen a private citizen bringing a suit against physicians allegedly charging unreasonable amounts for local anesthesia or eye drops. This suit should never have been necessary. Doctors trying to deliver care outside the constrictive envelope of the current health care structure may be charging large amounts for medications or actions that are not on the formulary. Physicians trying to pay the overhead for their clinic space may just be attempting to find ways to stay afloat in the face of government opposition to any outside care options despite the Chaoulli judgment of 2005. Forcing the physicians into this position is unfair to everyone — patients and doctors alike.

It has become painfully obvious that the health care system is broken. Rising demand and increasingly expensive incremental medical and technological advances are pushing the boundary of affordability and safety in our current health care programs. We as a people no longer have access to timely health care, particularly in surgery. Period. Certainly smaller and smaller pockets of surgeons still have an ability to treat patients — but this is no longer the rule. More and more studies show that timely care is cost-efficient — and not just for conditions associated with high mortality. Operating on the walking wounded promptly takes away the wounded adjective and allows a return to normal life. The BC lawsuit judgment will hopefully determine whether we can have an alternative pathway without prosecuting physicians or patients trying to speed up patient care. It will not mean the end of the current social health care system. I think we need to have options. The current amount of money being spent on health care by our governments is unsustainable. If we do not propose options now, we will not have a recognizable health care system much longer. It would be nice if there was a timely judgment on the Brian Day case, but it seems mired in bureaucracy — as much bureaucracy as the health care system it is examining.

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References

Se rapprocherait-on de modèles de soins de santé privés?


Au Canada, d’autres tentatives visant à trouver des solutions de rechange ne sont pas bien reçues par tout le monde. Au Québec, un recours collectif a été proposé par un citoyen contre des médecins en pratique privée qui facturaient des honoraires déraisonnables pour une anesthésie locale ou l’application de gouttes ophtalmiques. Un tel recours n’aurait jamais dû être nécessaire. Certains médecins qui tentent de fournir des services en dehors du cadre contraignant du régime de soins de santé actuel facturent peut-être des honoraires élevés pour une anesthésie locale, mais sans poursuivre les médecins ou les patients qui essaient d’accélérer le traitement des malades. Cela ne marquera pas la fin de notre système public de santé actuel. Mais, à mon avis, il faut avoir des choix. Il n’est plus viable pour nos gouvernements de continuer à assumer les coûts actuels des soins de santé. Si des solutions ne sont pas trouvées dès maintenant, notre système de santé deviendra rapidement méconnaissable. Souhaitons que l’affaire Brian Day ne tarde pas à se conclure, espérons-le, de savoir si une voie de rechange est possible, sans poursuivre les médecins ou les patients qui essaient d’accélérer le traitement des malades. Cela ne marquera pas la fin de notre système public de santé actuel. Mais, à mon avis, il faut avoir des choix. Il n’est plus viable pour nos gouvernements de continuer à assumer les coûts actuels des soins de santé. Si des solutions ne sont pas trouvées dès maintenant, notre système de santé deviendra rapidement méconnaissable. Souhaitons que l’affaire Brian Day ne tarde pas à se conclure, espérons-le, de savoir si une voie de rechange est possible, sans poursuivre les médecins ou les patients qui essaient d’accélérer le traitement des malades. Cela ne marquera pas la fin de notre système public de santé actuel. Mais, à mon avis, il faut avoir des choix. 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Références
C. Barber Mueller: Appreciation

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SUMMARY

This commentary was written in memory of C. Barber Mueller, who died at age 97 on Feb. 13, 2014. He was coeditor in chief of CJS from 1972 to 1992.

Barb was marked for a significant career from the time of his entry, on scholarship, to Medicine at Washington University in St. Louis, Mo; his membership in the Alpha Omega Alpha fraternity; his role as the last chief resident of Evarts Graham; and his role as an initial Markle Scholar with numerous publications in basic science journals. In medical school, his first paper was with Evarts Graham as his coauthor. Following internship, Barb served with distinction in the Pacific Theatre with the 4th U.S. Marine Division, participating in landings on 4 islands, including Iwo Jima, and winning the Bronze Star for meritorious service while being wounded twice. After finishing his residency in 1951, Barb joined the faculty at Washington University School of Medicine. At age 39, he became professor and chair of surgery at the State University of New York in Syracuse. In 1967, he moved to McMaster University and was integral to the planning and development of the novel “problem-based curriculum” as well as the planning and design of the medical centre.

Education was Barb’s passion. Indeed, he viewed himself “an educator by profession and a surgeon by trade.” Those who had the pleasure of being his guest as visiting professors also discovered, occasionally to their chagrin, that Barb had an uncanny ability to ask the key question that tested their presented research. I experienced his puckish sense of humour, clinical acumen and insight as he honed in on any weakness in my Grand Round or his evening case discussions with the students. Working with Barb was an educational experience for everyone. Five years after he retired, the students at McMaster awarded him the Student Teaching Excellence Award — a clear reflection of his devotion to them and his ongoing involvement after retirement from official positions. He brought that same educational drive to CJS.
Retirement simply brought a reorientation of his interests — almost a lateral arabesque — as he founded The Friends of the Health Sciences Library and personally made significant contributions to the McMaster library. His contribution was so great that the university has created an elegant space within the library, The C. Barber Mueller History of Health and Medicine Room. The university has honoured him with an Emeritus Professorship, inducted him into the Faculty of Heath Sciences Community of Distinction and given him an honorary degree (his third).

Most of us would have been tired out at this point, but Barb, remembering his chief, Evarts Graham, finished his biography, *Evarts A. Graham: The Life and Times of the Surgical Spirit of St. Louis*, in 2002. The title is an interesting reflection on Lindbergh’s airplane and Graham’s independent and innovative leadership in surgery. At age 94, Barb completed another work, *Excalibur: the Sword of Science that Reshaped the World*, which was published in 2012.

On a personal note, I have many fond memories of my meetings with Barb. The most memorable was one in which I was a visitor to his teaching exercises with the students. Barb was a great role model, and I left feeling better than when I arrived. In preparing this commentary, I was delighted to find that Barb had contributed a chapter to my grandfather’s text, *Practice of Medicine*, on the electron microscopy of the kidney. Barb and I met at least twice a year at the American Surgical and the American College meetings. I always left our visits feeling good about things; he had that way about him. He was always most interested in who he was talking with and with his lively sense of humour, bringing out the best in all those around him.

**Competing interests:** None declared.

**CORRECTION**

The article entitled “Low-intensity pulsed ultrasonography versus electrical stimulation for fracture healing: a systematic review and network meta-analysis,” published in June 2014 (Can J Surg 2014;57(3):E105-18), contained errors in references 35 and 39. The correct references are


An innovative paradigm for surgical education programs in resource-limited settings

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SUMMARY

The burden of surgical disease in low-income countries remains significant, in part owing to continued surgical workforce shortages. We describe a successful paradigm to expand Rwandan surgical capacity through the implementation of a surgical education partnership between the National University of Rwanda and the Centre for Global Surgery at the McGill University Health Centre. Key considerations for such a program are highlighted.

In recent years, there has been an important shift in the practice of global surgery. The traditional paradigm, which once consisted in large part of service-provision missions involving temporary transfers of resources, has been supplemented, and in many instances replaced, by building long-term partnerships meant to augment local capacity. The latter is seen as the superior approach for tackling the substantial surgical disease burden and workforce needs of low- and middle-income countries (LMICs).1,2

In a combined effort to tackle these challenges, a partnership was created in 2010 between the National University of Rwanda (NUR) and the Centre for Global Surgery at the McGill University Health Centre (CGS-MUHC). Its aim is to augment Rwanda’s surgical workforce, which in 2010 stood at 12 general surgeons for a population of 11 million, by expanding the academic component of the country’s only existing and mostly service-based general surgery program.3

Following a joint needs assessment, an original system-based curriculum was created. The curriculum is centred on 2-week modules covering locally relevant general surgery topics, with Canadian surgeons who have relevant expertise functioning as moderators for the modules. Each module contains 6 hours of didactic lectures, 2 hours of case presentation, 2 hours of morbidity and mortality rounds and 1 hour of module evaluations, with operative teaching provided on elective operating room (OR) days and emergency cases. From program implementation in January 2011 to January 2014, 21 modules have been completed.

At the core of this project lie the concepts of local accountability and initiative. Importantly, this partnership stems from an invitation from Rwandan surgical leaders, allowing for a targeted intervention based on local needs rather than Western models and expectations. This principle extends beyond the program’s initial conception, as its core, day-to-day operations are also under local governance. For this reason, Canadian surgeons have clearly defined responsibilities as moderators and educators, are responsible for only 2 of the 6 didactic lectures scheduled and are never asked to perform the clinical or academic responsibilities of local faculty or trainees, who remain jointly responsible for each module. In addition, their role is meant to be progressively effaced as current residents graduate and become educators, leading to gradual independence from foreign presence and strengthened local surgical capacity. This trend can already be seen in the continued implementation of academic activities during periods without Canadian presence.
Another prime concern for both partner organizations was to conduct early, context-appropriate and longitudinal assessments of the new project. As highlighted in a recent *Lancet* editorial, within the spectrum of activities conducted as part of global health initiatives, program evaluation is often “only an afterthought.” As a result, the relevance and outcomes of international interventions run the risk of being presumed rather than proven, and valuable input from local partners remains uncollected and unimplemented. To avoid this development, an evaluation process was implemented at program onset. Initial evaluation consisted of an 8-item questionnaire distributed to Rwandan residents after every module. On review of their feedback, the questionnaire was replaced with a more critical 31-item survey. Further expansion led to the creation of a 36-item questionnaire addressed to participating Canadian surgeons. The issues surveyed range from curricular relevance, skill appropriateness and project logistics to cooperation between partners, operating experience and research collaboration. By involving local and international partners as both developers and participants of this evaluation process, we hope to not only encourage changes favourable to all parties, but also to secure partnership sustainability by fostering shared ownership of and responsibility for the project.

An important component of our approach to creating relevant, setting-specific evaluation instruments is that they be constructed alongside the program and subsequently adjusted and expanded as the program evolves. For this purpose, the initial resident questionnaire was limited in scope, serving mainly to confirm residents’ acceptance of the curriculum and to provide qualitative feedback that would help identify shortcomings and issues important to participants. This information was used both to increase program quality and to expand and fine-tune existing evaluation tools, leading to the creation of a larger and more relevant questionnaire, whose quantitative items now addressed newly recognized themes. In this manner, the frequent inability of residents to attend teaching activities owing to large clinical workload was identified and consequently addressed by instituting dedicated academic days; this adaptation resulted in an average 31% increase in attendance. Similarly, on learning that 65% of Rwandan residents desired increased operative teaching, this curricular component was expanded; this process was based largely on recommendations subsequently submitted in Canadian faculty questionnaires. A feedback loop was thus created in which program assessment serves to both improve the partnership and the evaluation tools themselves.

In addition to improving the learning experience of Rwandan residents, this program addresses one of the major obstacles to health care provision in LMICs: workforce retention. On completion of their studies, up to 22% of graduates from sub-Saharan medical schools migrate outside the continent, most commonly owing to financial considerations and to lack of postgraduate training in nations of origin. Mature, in-country postgraduate training programs are more likely to reduce the need for foreign training while also generating locally relevant skill sets, augmenting the social accountability of trainees and providing potential hiring opportunities in education. The increase in the number of residents from 15 in 2010 to 21 in 2012 is encouraging in this respect.

Finally, this partnership further discounts previous cost-related misconceptions regarding global surgery that may have contributed to the prolonged lack of support for surgical interventions in sub-Saharan Africa. Efficient use of funds concentrates resources on Rwandan output rather than on donor administrative costs and income replacement, maintaining high educational benefits for the relatively low cost of Can$2140.24 per module, with the NUR covering housing costs and the CGS-MUHC covering travelling costs.

Successful capacity-building paradigms are essential to tackle the burden of disease arising from injury and surgical illnesses in LMICs. Educational programs targeting local health care professionals at early stages of their careers are the cornerstone of such success. Our experience in building a surgical education partnership suggests that such a paradigm can enhance the success, vitality and longevity of like-minded capacity-building endeavours.

**Competing interests**: D. Deckelbaum, G. Ntakiyiruta and P. Kyamanywa have received travel support from McGill University Health Centre. S. Liberman has received payment from Covidien for service on speakers’ bureaux. T. Razek is a board member (unpaid) for the Canadian Network for International Surgery.

**Contributors**: All authors have, at various stages, participated in the creation, implementation and evaluation of the surgical training program described in this commentary. Each author has also contributed to the design, drafting or editing of this commentary.

**References**

Decreased heart rate variability in surgeons during night shifts

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Background: Heart rate variability (HRV) has been used as a measure of stress and mental strain in surgeons. Low HRV has been associated with death and increased risk of cardiac events in the general population. The aim of this study was to clarify the effect of a 17-hour night shift on surgeons' HRV.

Methods: Surgeons were monitored prospectively with an ambulatory electrocardiography device for 48 consecutive hours, beginning on a precall day and continuing through an on-call (17-h shift) day. We measured HRV by frequency domain parameters.

Results: We included 29 surgeons in our analysis. The median pulse rate was decreased precall (median 64, interquartile range [IQR] 56–70 beats per minute [bpm]) compared with on call (median 81, IQR 70–91 bpm, p < 0.001). Increased high-frequency (HF) activity was found precall (median 199, IQR 75–365 ms²) compared with on call (median 99, IQR 48–177 ms², p < 0.001). The low-frequency:high-frequency (LF:HF) ratio was lower precall (median 2.7, IQR 1.9–3.9) than on call (median 4.9, IQR 3.7–6.5, p < 0.001). We found no correlation between the LF:HF ratio and performance in laparoscopic simulation.

Conclusion: Surgeons working night shifts had a significant decrease in HRV and a significant increase in pulse rate, representing sympathetic dominance in the autonomic nervous system.

Trial registration: NCT01623674 (www.clinicaltrials.gov).

Contexte : La variabilité de la fréquence cardiaque (VFC) a été utilisée comme mesure du stress et de l’effort mental chez les chirurgiens. On a établi un lien entre une faible VFC et la mort et le risque accru d’événement cardiaque dans la population générale. Cette étude visait à clarifier l’effet d’un quart de nuit de 17 heures sur la VFC des chirurgiens.

Méthodes : On a surveillé prospectivement des chirurgiens au moyen d’un appareil d’électrocardiographie ambulatoire pendant 48 heures consécutives en commençant la veille de la période de garde et durant toute la journée de garde (quart de 17 heures). Nous avons mesuré la VFC au moyen de paramètres du domaine fréquentiel.

Résultats : Notre analyse a porté sur 29 chirurgiens. Le pouls médian a diminué avant la période de garde (médiane de 64, plage interquartile [PIQ] de 56 à 70 battements/minute [b/m]) comparativement à la période de garde (médiane de 81, PIQ de 70 à 91 b/m, p < 0.001). On a constaté une activité de haute fréquence (HF) accrue avant la période de garde (médiane de 199, PIQ de 75 à 365 ms²) comparativement à la période de garde (médiane de 99, PIQ de 48 à 177 ms², p < 0.001). Le ratio basses fréquences/hautes fréquences (BF:HF) était moins élevé avant (médiane de 2,7, PIQ de 1,9 à 3,9) que pendant la période de garde (médiane de 4,9, PIQ de 3,7 à 6,5, p < 0.001). Nous n’avons constaté aucun lien entre le ratio BF:HF et le rendement au cours d’une simulation de laparoscopie.

Conclusion : Les chirurgiens qui faisaient des quarts de nuit présentaient une diminution importante de la VFC et une augmentation importante du pouls, ce qui représente une domination sympathique du système nerveux autonome.

hifting work hours, sleep deprivation and stress have been shown to affect surgeon performance.1–3 At the same time, there is a negative effect on the health of surgeons themselves.4 The negative effects are burnout and poor mental health.5–7 This stress induces changes in the autonomic nervous system that can be recorded noninvasively by an ambulatory electrocardiography (ECG) device with subsequent statistical analysis of heart rate variability (HRV). Heart rate variability has been used as a measure of mental strain in surgeons performing laparoscopic versus conventional surgery8 and in surgeons performing laparoscopic surgery in modern operating rooms compared with standard ones.9 Furthermore, HRV has been used as a measure of stress in surgeons before, during and after night shifts with a standardized resting period of 10 minutes.10 The HRV correlated with perceived stress, showing decreased stress levels during the night shift. A study by Nishi and colleagues11 stated that the lifespan of surgeons and obstetrician/gynecologists was shorter than that of physicians in basic medical sciences and internal medicine; the authors suggested that one of the reasons for this shorter lifespan was the degree of stress from work conditions. Furthermore, a systematic review and meta-analysis of 34 studies found that shift work was associated with increased risk of myocardial infarction and ischemic stroke.12 However, no increased mortality was associated with shift work.

Low HRV has a prognostic value in patients with myocardial infarction as a predictor of death and as a tool for risk stratification after myocardial infarctions.13 In the general population, low HRV has been associated with death and increased risk of cardiac events.14,15 To our knowledge, no previous study has investigated the development of HRV during an entire night shift among medical personnel. Our aim was to clarify the effect of a 17-hour night shift on surgeons’ HRV.

**METHODS**

**Design**

Surgeons were monitored prospectively with an ambulatory ECG device for 48 consecutive hours. The monitoring period started at 8 am on the morning of the call day, and recording continued through the second day, on which the surgeons worked a 17-hour night shift from 3:30 pm to 8:30 am. The ECG monitoring was discontinued at 8 am on the morning postcall. Overall, the surgeons were monitored for psychomotor performance, cognition, circadian rhythm, sleep and fatigue over a period of 4 consecutive days. Data on psychomotor performance, cognition and sleep have been published separately.16

**Participants**

We included male and female interns, residents and attending surgeons from an academic surgical department in a prospective monitoring study. The participants did not work night shifts in the 72 hours preceding the study in order to avoid pre-existing sleep deprivation. They were instructed to get their habitual amount of nighttime sleep during this period. Furthermore, individuals receiving medical treatment for known endocrine, autoimmune or heart conditions were excluded, as were those with a previously diagnosed sleep disorder. Pregnant or breastfeeding women were not included. Consumption of alcohol or stimulants in the 24 hours preceding the study and during the study was not allowed. As we wished to monitor the surgeons in the habitual state, we did not restrict their intake of liquids containing caffeine.

**HRV recording**

We started a 48-hour ECG recording on the morning of the call day, and recording continued through the on-call day. The ECG recording was discontinued on the morning postcall. We performed HRV monitoring using the Medilog AR12 recorder (Oxford Instruments Tubney Woods) with a 3-channel, 5-lead recording. We analyzed the HRV parameters using Medilog Darwin software (Huntleigh Healthcare). Mean values of short-term 5-minute recordings were manually viewed and excluded for noise, ectopy and missing beats; only normal-to-normal R waves were included to obtain reliable data. The normal-to-normal R waves are known as the NN interval. Only intervals with more than 90% valid data were included.

The parasympathetic (vagal) and sympathetic activity constantly interact. The vagal afferent stimulation leads to excitation of vagal efferent activity and, by reflex, inhibits sympathetic efferent activity.17 The opposite effects are mediated by the stimulation of sympathetic activity. The efferent vagal activity is a major contributor of high-frequency (HF) power. However, the interpretation of the low-frequency (LF) power is more controversial; some believe it represents sympathetic activity, whereas others argue it represents a parameter that includes both sympathetic and parasympathetic activity.17 In the present study, an increase of the LF power was used as a measure of sympathetic and parasympathetic activity.18,19 and HF power was used as a measure of increase in parasympathetic activity.17,20 The LF:HF ratio was used as an index of the sympathovagal balance.19,21,22 An increase in this ratio represented a larger sympathetic influence on the HRV, and a decrease represented a larger vagal influence.

**Data analysis**

Analysis was performed according to the guidelines of the HRV task force.17 The HRV power spectra were calculated using fast Fourier transformation.17 Two main spectral components were distinguished: an LF component of 0.04–0.15 Hz and an HF component of 0.15–0.4 Hz. The power and frequency of each spectral component were calculated as
absolute units (milliseconds squared). We measured heart rate from the mean NN values. The medians of the 5-minute intervals were determined for every hour. Then we determined the medians of the hourly intervals from 4 pm to 8 am precall and on call for every participant.

**Ethics and permissions**

Our trial fully complied with the Helsinki declaration on biomedical research. The Danish Regional Committee on Biomedical Research Ethics evaluated and approved the trial (H-4–2011–095). The Danish Data Protection Agency approved the collection, analysis and storage of data (2011–41–6384). All participants gave their informed consent before inclusion in the study. Participation in the study was voluntary; all participants received 500 Danish kroner (equivalent to $90 USD) at the end of the study. The trial was registered at www.clinicaltrials.gov (NCT01623674).

**Statistical analysis**

We used SPSS software version 19.0 for data entry and statistical analysis. Group values are presented as medians and interquartile ranges (IQRs). We used the Wilcoxon test for paired intragroup comparisons and the Friedman test for repeated intragroup comparisons. We considered results to be significant at \( p < 0.05 \).

**Results**

Thirty surgeons participated in the study; however, we included the data for only 29 participants in our analyses. One surgeon was excluded because she received a diagnosis of myxoedema 8 weeks after her participation in the study. Thus, the results are based on data from 9 interns, 11 residents and 9 attending surgeons. The median work experience was 5 (IQR 1–9) years. Participant characteristics are presented in Table 1.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
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<td>13</td>
</tr>
<tr>
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<td>37 (31–40)</td>
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<td>Weight, kg</td>
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<td>64 (56–69)</td>
</tr>
<tr>
<td>Height, cm</td>
<td>183 (180–187)</td>
<td>168 (165–171)</td>
</tr>
</tbody>
</table>

IQR = interquartile range.

![Image](image_url)

**Fig. 1.** The development of high-frequency (HF) power from 4 pm to 8 am (16:00–08:00) for the precall and on-call days. Squares represent precall values with a \( p < 0.001 \). Circles represent on-call values with a \( p < 0.001 \). The \( p \) values were determined using the Friedman test. The decrease in HF power from 10 pm to 7 am (22:00–07:00) on call represents a decrease in vagal activity.
**Discussion**

Our results showed a change in the autonomic nervous system activity, with sympathetic dominance in the nighttime on-call values compared with precall values. The HF values were significantly increased on the precall night compared with the on-call night, demonstrating a higher vagal influence (Figs. 1 and 2A). The surgeons had a significantly higher pulse rate (Fig. 2A) during the 17 hours they worked on a night shift, which supported the findings of sympathetic dominance of the autonomic nervous system activity while on call. The decrease in LF:HF ratio supported a larger vagal influence on the sympathetic balance precall, and the increase in LF:HF ratio on call demonstrated a sympathetic dominance (Fig. 2C). However, the LF values did not differ significantly when precall values were compared with on-call values (Fig. 2D), possibly owing to LF values representing both vagal and sympathetic influence on the HRV. The overall findings may be explained solely by surgeons being awake overnight; still, the findings demonstrate physiologic stress regardless of surgeons’ training levels.

Our study also showed that surgeons had decreased HRV during on-call hours, as the vagal activity was significantly reduced. A previous study examined anesthesiologists, pediatricians and otolaryngologists and compared their HRVs from 9 pm to 10 pm after daytime work, on a night shift and on the day after a night shift. A previous study examined anesthesiologists, pediatricians and otolaryngologists and compared their HRVs from 9 pm to 10 pm after daytime work, on a night shift and on the day after a night shift. The authors selected a random sample of 900 patients without prevalent coronary heart disease at baseline. The patients with low HRV determined from a 2-minute rhythm strip had an adverse cardiovascular risk profile and elevated risk of death from all causes, including cancer. This may imply that the night shifts causing a reduced HRV and higher pulse rate in surgeons may have a negative impact on their general health in the long run and may cause increased mortality.

Surgeons’ stress and ways to reduce or cope with stress have been described previously. A study used an anonymous self-report questionnaire and a randomized response technique (RRT), with a high degree of anonymity, to assess the use of prescribed or illicit drugs solely with the purpose of cognitive or mood enhancement among surgeons. According to the questionnaire, 8.9% of surgeons reported that they had used drugs at least once, merely for cognitive enhancement; however, the RRT revealed a prevalence of 19.9%. For mood enhancement, 2.4% of the surgeons stated on the questionnaire that they had used antidepressants;
again, the RRT revealed a higher prevalence (15.1%). The use of drugs is hardly recommended as a coping strategy for stress in surgeons. A study found that scheduled intraoperative breaks reduced surgeons’ cortisol levels by 22%, without prolonging the operation.26 A systematic review looking at residents’ health found 2 studies on protected sleep time to reduce residents’ fatigue.27 Further studies on scheduled breaks and protected sleep time with a focus on how surgeons’ stress can be reduced are needed.

The strengths of the present study were that HRV monitoring and analysis were performed continuously for the 17-hour periods of evening and nighttime both precall and on call, providing solid insight on the sympathovagal balance of the entire recording period. Unfortunately, we did not perform postcall HRV monitoring. This would have strengthened the study further, as it would have shown when a normalization of the sympathovagal balance took place.

CONCLUSION

Our study showed a significant decrease in HRV and a significant increase in pulse rate in surgeons working night shifts compared with nighttime hours off call. Future studies could investigate methods to reduce sympathetic dominance during night shifts, as the decreased HRV may be harmful to surgeons’ health.

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Competing interests: None declared.

Contributors: I. Amirian, J. Rosenberg and I. Gögenur designed the study. I. Amirian and L. Andersen acquired the data, which all authors analyzed. I. Amirian and I. Gogenur wrote the article, which all authors reviewed and approved for publication.

References

Inconsistencies between navigation data and radiographs in total knee arthroplasty are system-dependent and affect coronal alignment

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Background: Few studies have compared the effect of different computer navigation systems on postoperative alignment in patients who have had total knee arthroplasty (TKA). We examined 2 computed tomography (CT)–free computer navigation systems by comparing the accuracy of intraoperative measurements to postoperative alignment.

Methods: Patients underwent unilateral TKA performed by a single surgeon using 1 of 2 CT-free navigation systems. We compared final intraoperative tibial and femoral coronal angles and mechanical axis with the same angles measured on standing postoperative radiographs.

Results: Groups of 31 and 50 patients underwent TKA with the 2 systems, respectively. We noted a significant difference in the coronal tibial implant angle (1.29º ± 1.35º) and in the mechanical axis (1.59º ± 2.36º) for one navigation system (both p < 0.001), while only the coronal tibial implant angle showed a significant difference (1.17º ± 1.65º, p < 0.001) for the second system. The number of radiographic outliers also significantly differed. A significantly higher proportion (32%; p < 0.01) of patients in the second cohort exhibited unacceptable malalignment compared with the first cohort (24%).

Conclusion: Navigation systems for TKA continue to increase in sophistication and popularity. Owing to the significant difference in the proportion of alignment outliers in the 2 navigation systems tested in this study, orthopedic surgeons should not consider all TKA navigation systems equivalent. Additional investigations are needed to compare the accuracy of a variety of CT-free and CT-based navigation systems and to confirm our finding that accuracy is system-dependent.

Contexte : Il existe peu d'études ayant comparé divers systèmes informatiques de navigation de guidage servant à vérifier l'alignement postopératoire de l'articulation chez des patients ayant subi une arthroplastie totale du genou (ATG). On a évalué 2 systèmes de navigation de guidage sans base tomodensitométrique en comparant l'exactitude des mesures d'alignement intra-opératoires et celles des mesures postopératoires.

Méthodes : Des patients ont subi une ATG unilatérale, qui a été pratiquée par un seul chirurgien à l'aide de l'un des 2 systèmes de navigation de guidage sans base tomodensitométrique. On a comparé les mesures intra-opératoires et postopératoires de l'articulation tibiofémorale et de l'axe mécanique du genou aux angles mesurés sur les radiographies postopératoires en station debout.

Résultats : Un groupe de 31 patients et un groupe de 50 ont subi une ATG réalisée à l'aide des 2 systèmes respectivement. On a observé un écart significatif des mesures de l'angle frontal de l'implant tibial de la prothèse (1.29º ± 1.35º) et des mesures de l'axe mécanique du genou (1.59º ± 2.36º) avec l'un des systèmes de navigation (avec les deux, p < 0.001), tandis qu'avec l'autre, on a observé seulement une différence appréciable des mesures de l'angle frontal de l'implant tibial (1.17º ± 1.65º, p < 0.001). On a aussi observé une grande variation du nombre d'aberrations radiographiques. Dans la deuxième cohorte, on a observé une proportion significativement plus importante (32 %; p < 0.01) de patients présentant un défaut d'alignement inacceptable que dans la première (24 %).

Conclusion : Les systèmes de navigation de guidage servant à réaliser les ATG ne cessent de se perfectionner et d'être de plus en plus prisés. Cependant, en raison de l'écart significatif de la proportion des défauts d'alignement dépités entre les 2 systèmes de navigation testés au cours de cette étude, le chirurgien orthopédiste ne devrait pas croire que tous les systèmes sont équivalents. Il faudrait mener d'autres études pour comparer la précision de divers systèmes de navigation de guidage sans base tomodensitométrique à celle de systèmes à base tomodensitométrique pour corroborer notre constatation, c'est-à-dire que la précision dépend du système utilisé.
Computer-assisted orthopedic surgery (CAOS) for total knee arthroplasty (TKA) is generally considered to lead to component positioning that is more accurate and reproducible than conventional techniques. Additional advantages for the use of COAS in TKA include decreased perioperative blood loss owing to the avoidance of intramedullary instrumentation, fewer postoperative thromboembolic events and fewer systemic emboli. Hoffart and colleagues also demonstrated that CAOS provides better clinical outcomes at 5 years than conventional TKA. Furthermore, recent meta-analyses by Cheng and colleagues and Bauwens and colleagues demonstrated that using COAS for TKA significantly reduced the relative risk of excessive implant misalignment by 25% compared with conventional TKA. Another recent meta-analysis by Hetaimish and colleagues showed that CAOS produced better implant alignment in the coronal plane for both the tibial and femoral components as well as femoral and tibial slope than the conventional technique.

Although these investigations have demonstrated the improvement of component alignment with CAOS, they did not take into account a critical component of the operative procedure: the type of computer navigation system used. The only comparisons of alignment among different computer navigation systems have come from 2 studies that each compared a computed tomography (CT)-based system to a CT-free system. Given that studies used in the meta-analysis by Cheng and colleagues used a total of 6 different CT-free navigation systems and 2 CT-based systems while those used in the analysis by Bauwens and colleagues included 5 CT-free systems and 3 CT-based systems, further investigations are required to confirm that computer navigation systems are equivalently accurate in measuring TKA alignment. Such investigations are especially needed in CT-free CAOS systems, whose differences in hardware and software design have been previously identified as a potential source of inaccuracy.

The current gold standard for assessing the mechanical alignment of the lower extremity following TKA is the standing full lower extremity radiograph. Therefore, the ideal CAOS navigation system, when properly used, should provide intraoperative measurements for femoral and tibial cuts that match the final implant position and limb alignment as measured on postoperative radiographs. Using this logic, it is possible to compare CAOS navigation systems with one another by assessing the difference between intraoperative alignment measurements by the CAOS system to actual postoperative radiographic alignment values. Thus, it can be said that the smaller the difference between intraoperative and postoperative measurements, the more accurate the CAOS navigation system. The more accurate a CAOS navigation system is, the more confident the surgeon can be that measurements taken intraoperatively reflect the actual postoperative alignment. We have shown in previous work that angular measurements attained by a single CT-free CAOS navigation system intraoperatively can differ significantly from postoperative measurements taken from full length lower extremity radiographs. The present study compares this initial system to a second CT-free CAOS navigation system in order to determine if one is more accurate overall and produces fewer alignment outliers (≥3° of varus/valgus alignment).

We hypothesized that the variation between final intraoperative CAOS bony cut measurements and postoperative implant and extremity alignment would be different between the 2 CT-free navigation systems. We also hypothesized that the number of postoperative mechanical outliers (≥3° of varus/valgus) would be decreased for the navigation system that had more similar intraoperative and postoperative measures.

Methods

Patient selection

We retrospectively reviewed the medical records and radiographs for all consecutive patients who underwent CAOS-TKA at a single orthopedic institution in 2 time periods (November 2007–February 2008 and March 2009–December 2010). For the first cohort, all operations were performed with the assistance of the ORTHOsoft Knee 2.1 Universal system. For the second cohort, all operations were performed with the assistance of the Brainlab AG Ci Knee essential 2.1.1 system. All procedures were performed by a single arthroplasty surgeon (D.J.Z.) who received formal training for each navigation system. The specific time periods were selected for study evaluation as they represented the time by which the surgeon had surpassed the accepted threshold for the learning curve (30–50 cases) of each CAOS-TKA system. Consecutive patient inclusion was performed to minimize selection bias.

Operative procedure and perioperative data collection

All procedures were performed under spinal anesthesia, and the surgeon used a medial parapatellar approach. On exposure of the knee joint, articular landmarks and important bone areas were recorded using a pointer-like device, and external optical tracking devices were placed on the tibia and femur to template bony cuts. The 2 imaging systems used similar static landmarks, including the femoral condylar surfaces, centre of the talus, femoral intercondylar notch, borders of the tibial plateau and tibial spine, as well as dynamic motions to determine the centre of the femoral head. The main difference in landmark identification was the need to trace out (or “paint”) the entirety of the distal femoral and proximal tibial articular surfaces with the Brainlab system compared with several single point landmarks on the ORTHOsoft system. Apart from these differences and slight instrument sizing differences, the 2 navigation systems
similarly use optical trackers that provide data regarding knee position to an infrared receiver, which then displays real-time positional information on a digital display. Following navigation-assisted femoral and tibial cuts, trial components and a fitting spacer were placed, and knee range of motion was assessed. Following cement application and component placement, a final alignment assessment could be performed in both the Brainlab and ORTHOsoft systems to allow any further alignment correction due to the cement mantle. Knee range of motion and mechanical axis were then clinically assessed, and the subcutaneous tissue and skin was closed with a Jones bandage.

Data were collected intraoperatively through each CT-free navigation system. For both systems, the following parameters were recorded after insertion of final components: the coronal angle of the tibial cut, the coronal angle of the femoral cut and the final mechanical axis of the lower extremity.

**Postoperative data collection**

As per standard protocol at our institution, all patients underwent a full weight-bearing long axis radiograph of the lower extremities 6 weeks after surgery. Standing radiographs were obtained using a long film cassette with a radiography tube distance of 305 cm to capture the hips, knees and ankles. Although use of a long cassette is not universal and is subject to errors due to knee flexion and lower extremity rotation,

Data were collected intraoperatively through each CT-free navigation system. For both systems, the following parameters were recorded after insertion of final components: the coronal angle of the tibial cut, the coronal angle of the femoral cut and the final mechanical axis of the lower extremity.

**Statistical analysis**

We assessed interrater reliability for radiographic measurements by calculating the intraclass correlation coefficient using SPSS statistical software version 19, using a 2-way random-effects model assuming a single measurement and absolute agreement. An intraclass correlation coefficient of 1 represents perfect reliability, and any value greater than 0.8 indicates excellent reliability.

We compared intraoperative navigation and postoperative radiographs using paired t tests, with the level of significance set at \( p < 0.05 \). The proportions of postoperative complications and radiographic outliers were recorded for each system and compared using a \( \chi^2 \) test. A radiographic outlier was defined as a postoperative measurement of 3º of varus/valgus or greater.

**RESULTS**

Our study included 81 patients: 31 in the ORTHOsoft group and 50 in the Brainlab group. All patients successfully underwent unilateral TKA with no significant intraoperative complications. Patient demographics were similar in both groups. The mean patient age was 70.12 ± 10.66 years in the ORTHOsoft group and 74.27 ± 7.60 years in the Brainlab group. All patients began weight bearing by the second postoperative day and yielded similar rates of postoperative transfusions (\( \chi^2 = 1.547, p = 0.21 \)) and deep vein thrombosis (\( \chi^2 = 2.46, p = 0.11 \)). No major complications, including deep wound infection, myocardial infarction and pulmonary embolus, were noted in either group during the first 6 weeks. The mean Knee Society score at 6 weeks was comparable between the groups (mean 67.77 ± 14.15 in the ORTHOsoft group v. 67.09 ± 12.32 in the Brainlab group). Overall, interrater reliability for postoperative radiograph measurements was excellent, with intraclass correlation coefficients of 0.834 for the coronal angle of the tibial component (\( p < 0.001 \)), 0.842 for the coronal angle of the femoral component (\( p < 0.001 \)) and 0.962 for the mechanical axis (\( p < 0.001 \)).

We noted significant differences between intraoperative navigation measurements and postoperative radiograph measurements in each navigation group (Table 1). However, such differences were not observed in the same measurements. In the ORTHOsoft group, we noted a significant difference in the coronal tibial implant angle (1.29º ± 1.35º, \( p < 0.001 \)) and in the mechanical axis (1.59º ± 2.36º, \( p < 0.001 \)). In the Brainlab group, only the coronal tibial implant angle showed a significant difference (1.17º ± 1.65º, \( p < 0.001 \)); no difference was observed in the mechanical axis (0.75º ± 2.67º, \( p = 0.05 \)). In both groups, the coronal angle of the femur showed no significant change from intraoperative data to postoperative radiographs (0.30 ± 1.74, \( p = 0.33 \) in the ORTHOsoft group v. 0.22 ± 1.94, \( p = 0.49 \) in the Brainlab group).

The number of radiographic outliers also differed in each navigation system. The overall percentage of patients with at least 1 radiographic parameter more than 3º was 32% (10 of 31) in the ORTHOsoft group and 24% (12 of 50) in the Brainlab group (\( \chi^2 = 19.121, p < 0.01 \)). The percentage of outliers was higher in the ORTHOsoft group for both the mechanical axis (29% v. 22%; Fig. 1) and the coronal angle of the femoral component (6.4% v. 6%; Fig. 2). The Brainlab group had a higher percentage of coronal tibial angle outliers (12% v. 9.6%; Fig. 3).
DISCUSSION

Interest in comparing computer navigation systems in orthopedics is steadily emerging. Although not relevant to TKA, a study by Honl and colleagues compared acetabular orientation in 5 computer-assisted navigation systems for total hip arthroplasty and found variations among the systems. Specific to TKA, Harvie and colleagues prospectively followed

<table>
<thead>
<tr>
<th>Measure</th>
<th>Navigation system values</th>
<th>Radiograph values</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>p value</th>
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<td>Brainlab, n = 50</td>
<td></td>
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<tr>
<td>Coronal plane of femoral implant</td>
<td>0.14 ± 0.95</td>
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<td>0.21 ± 0.75</td>
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<td>Coronal plane of tibial implant</td>
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<td>HKA angle</td>
<td>0.02 ± 0.70</td>
<td>-0.73 ± 2.69</td>
<td>0.75 ± 1.99</td>
<td>-1.51 to 0.01</td>
<td>0.05</td>
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<td>ORTHOsoft, n = 31</td>
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<tr>
<td>Coronal plane of femoral implant</td>
<td>0.17 ± 0.63</td>
<td>0.48 ± 1.65</td>
<td>0.30 ± 1.74</td>
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<tr>
<td>Coronal plane of tibial implant</td>
<td>-0.66 ± 1.10</td>
<td>0.62 ± 1.78</td>
<td>1.29 ± 1.35</td>
<td>0.79 to 1.78</td>
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<tr>
<td>HKA angle</td>
<td>0.45 ± 1.20</td>
<td>2.04 ± 2.13</td>
<td>1.59 ± 2.36</td>
<td>0.73 to 2.46</td>
<td>&lt; 0.001</td>
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</tbody>
</table>

CI = confidence interval; HKA = hip-knee-ankle; SD = standard deviation.

*Positive measurements represent valgus orientation; negative measurements represent varus orientation. Comparison was made using a paired t test, with significance set at p < 0.05.

Fig. 1. Comparison of intraoperative measurements of the mechanical axis measured by Brainlab and ORTHOsoft navigation systems and postoperative measurements on standing radiographs. Intraoperative navigation measurements are organized from the most valgus to most varus.
40 patients who underwent the procedure using either an imageless full navigation system or an articular surface-mounted navigation system. They found no significant difference between the 2 systems with regard to the postoperative implant position verified. A comparison among imageless navigation systems has not been reported despite the general preference for CT-free over CT-dependent systems.

To our knowledge, the present study is the first to compare deviations between intraoperative navigation data and postoperative radiograph measurements of 2 CT-free navigation systems. It is also, to our knowledge, the first to propose that this form of intraoperative and postoperative comparison be used as a manner to measure accuracy for CAOS systems. Our results confirm our initial hypothesis that the greater the difference between intraoperative navigation system measurements and postoperative radiograph measurements, the greater the incidence of coronal misalignment in patients who have undergone TKA. It should be specifically emphasized that the differences between the 2 systems, although significant, were small and within 2° of each other. However, such small differences were enough to significantly change the overall proportion of radiographic outliers between systems, which is a pertinent finding given that one of the driving purposes of computer navigation in TKA was to eliminate knee malalignment. Since the difference between intraoperative and postoperative measurements was not the same for the 2 navigation systems studied, our results indicate that different CT-free navigation systems are not necessarily equivalent in predicting postoperative alignment during TKA.

Computed tomography–free navigation systems have been previously shown to decrease the prevalence of radiographic outliers to 10%.31–34 In our study, neither navigation system met this threshold. The navigation system that provided intraoperative measurements that better matched postoperative alignment (Brainlab) had fewer mechanical outliers (24%) than its less accurate counterpart (ORTHOsoft). This latter system produced

**Fig. 2.** Comparison of intraoperative measurements of the coronal orientation of the femoral implant measured by Brainlab and ORTHOsoft navigation systems and postoperative measurements on standing radiographs. Intraoperative navigation measurements are organized from the most valgus to most varus.
an incidence of mechanical outliers that surpassed the 30% rate seen with conventional instrumentation.\textsuperscript{15,16}

Controversy exists in the literature regarding the clinical relevance of the improved coronal alignment attained through CAOS-TKA. Khan and colleagues\textsuperscript{37} found that patients who underwent computer-assisted TKA with a mechanical axis alignment of 3° or more from neutral had lower Western Ontario and McMaster Universities Arthritis Index scores, indicating increased difficulty with daily activities. Furthermore, Lützner and colleagues\textsuperscript{38} randomly assigned 80 patients to receive either conventional or navigated TKA and found that patients who underwent navigated TKA were less likely to have mechanical axis malalignment postoperatively and had significantly improved Knee Society scores. However, a follow-up study involving the same cohort revealed no difference between the groups 5 years after surgery.\textsuperscript{39} A similar result was found at a 2-year follow-up of 71 patients who were also randomized to conventional or navigated TKA.\textsuperscript{40}

In addition to findings of equivalent outcome scores despite improved alignment, concerns for higher revision rates after navigated TKA have been raised. Gotheson and colleagues\textsuperscript{41} presented data from the Norwegian registry regarding 10 000 TKAs and found significantly higher revisions rates for navigation versus conventional (3.6% v. 2.1%) procedures. However, this finding is offset by findings of equivalent revision rates in a comparison study of 100 navigated and conventional TKAs\textsuperscript{42} as well as a retrospective evaluation of 1121 TKAs that yielded a significantly lower revision rate for navigated TKAs.\textsuperscript{43} Although these conflicting findings in the literature raise valid concerns regarding the long-term benefits of navigated TKA, it remains generally accepted that establishing a normal mechanical axis is a fundamental technical objective in TKA and that CAOS-TKA more reliably accomplishes this objective than conventional methods.\textsuperscript{44} However, findings from the present study indicate that some CAOS-TKA systems may not be as reliable in providing intraoperative

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![Fig. 3. Comparison of intraoperative measurements of the coronal orientation of the tibial implant measured by Brainlab and ORTHOsoft navigation systems and postoperative measurements on standing radiographs. Intraoperative navigation measurements are organized from the most valgus to most varus.](image)
alignment information that adequately correlates with the postoperative mechanical axis. Ultimately, additional studies comparing multiple CAOS-TKA systems and how their respective divergences between intraoperative and postoperative alignment variables affect long-term clinical outcome must be performed to evaluate the relevance of the present findings.

**Limitations**

This study has limitations. Although the navigation data and postoperative radiograph measurements were taken prospectively, patients were not randomized to a specific navigation system. Preoperative alignment and range of motion data were not compared between the 2 groups, a notable limitation given that a previous study reported greater divergence between intraoperative and postoperative alignment indices in patients with more severe preoperative alignment deformities. The study also does not provide short-term patient outcome information after the 6-week postoperative mark, making it difficult to determine the clinical importance of the observed discrepancies between intraoperative and postoperative alignment. Although patients in both groups were included only after the learning curve for each CAOS system had been surpassed, we acknowledge that the treating surgeon was more experienced in CAOS-TKA when performing surgeries on the Brainlab cohort and that this may have improved his intraoperative alignment technique for this group. Postoperative radiograph measurements, although recorded by the 2 blinded observers with excellent inter-rater reliability, are inherently susceptible to errors due to patient positioning as well as knee flexion and external rotation. In addition, as remarked by Choi and colleagues, intraoperative and postoperative measurements are performed under considerably different circumstances. Intraoperative measurements are taken before complete soft tissue closure in full extension and without weight bearing, whereas postoperative measurements are taken with full weight bearing and cannot control for soft tissue contractures elsewhere in the lower extremity.

Despite such differing circumstances, our inclusion of only a single surgeon performing the surgical procedures should minimize intersurgeon variation in how the intraoperative data were collected, making it less difficult to compare against postoperative radiographs. Furthermore, our choice to use long-cassette radiographs as the gold standard is justified, as this modality is considered an acceptable reference for alignment and sufficient for routine postoperative assessment. Another consideration is the cement mantle, which if applied unevenly can cause the final implant position to be different from the bony cut. Both systems used in the present study permit intraoperative alignment after cement and components are inserted, permitting the surgeon to apply coronal stresses or impact implants further before cement curing. This feature of final component alignment surveillance is not universal among CAOS-TKA systems and, along with various cementing techniques, could theoretically affect final component alignment. We are interested in evaluating the effect of cementing technique and CAOS final alignment capability, and we plan to perform a prospective evaluation at our centre. The slight difference in the way surface landmarks between the 2 systems were made is also of interest, but the effect this difference would have on alignment is unknown and should also be recorded in future system comparisons. Finally, long-term data were not included, making it difficult to conclude if such variability in discrepancy between navigation data and radiograph measurements impacted clinical outcome.

**Conclusion**

Computer-assisted orthopedic surgery for TKA continues to increase in sophistication and popularity, with new computerized systems attempting to incorporate aspects of both full navigation and conventional TKA. Although a sizeable amount of literature exists advocating the advantages in alignment that accompanies the use of CAOS, results from the present study suggest that orthopedic surgeons should not consider all TKA navigation systems to be the same. Additional investigations are needed to compare the accuracy of a variety of CT-free and CT-based navigation systems and to confirm our finding that accuracy is system-dependent, with greater accuracy leading to fewer mechanical outliers. This finding should be taken into account when reviewing conflicting data obtained from pooled results involving different systems, and should also be considered when switching to different systems in clinical practice.

Competing interests: None declared

Contributors: A. Carli, A. Aoude, A. Reuven, J. Antoniou and D. Zukor designed the study and acquired the data. A. Carli, B. Matache, J. Antoniou and D. Zukor analyzed the data. A. Carli, A. Aoude, A. Reuven, J. Antoniou and D. Zukor wrote the article, which A. Carli, B. Matache, J. Antoniou and D. Zukor reviewed. All authors approved the final version for publication.

**References**


Management of the open abdomen using combination therapy with ABRA and ABThera systems

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Background: The open abdomen is an increasingly used technique that is applied in a wide variety of clinical situations. The ABThera Open Abdomen Negative Pressure Therapy System is one of the most common and successful temporary closure systems, but it has limited ability to close the fascia in approximately 30% of patients. The abdominal reapproximation anchor system (ABRA) is a dynamic closure system that seems ideal to manage patients who may not achieve primary fascial closure with ABThera alone. We report on the use of the ABRA in conjunction with the ABThera in patients with an open abdomen.

Methods: We retrospectively analyzed patients with an open abdomen managed with the ABThera and ABRA between January 2007 and December 2012 at the Halifax Infirmary, QEII Health Science Centre, Halifax, Nova Scotia.

Results: Sixteen patients had combination therapy using the ABRA and ABThera systems for treatment of the open abdomen. After removing patients who died prior to closure, primary fascial closure was achieved in 12 of 13 patients (92%).

Conclusion: We observed a high rate of primary fascial closure in patients with an open abdomen managed with the ABThera system in conjunction with the ABRA. Applying mechanical traction in addition to the ABThera should be considered in patients predicted to be at high risk for failure to achieve primary fascial closure.

Management of the open abdomen is an increasingly used technique that is applied in a wide variety of clinical situations, including treatment and prevention of abdominal compartment syndrome, damage control laparotomy and severe intra-abdominal sepsis. Once the abdominal fascia has been opened, the viscera must be contained by a temporary abdominal closure (TAC). The goals of TAC include protection of the viscera, prevention of adhesions of the
viscera to the abdominal wall, removal of intra-abdominal fluid and prevention of fascial retraction. A variety of different techniques for TAC have been used in the past, including the Bagota bag, mesh, Wittmann patch and Barker vacuum pack. A systematic review and prospective observational trial have demonstrated that the ABThera Open Abdomen Negative Pressure Therapy System (KCI USA) may be the most effective TAC method.

Although the ABThera system achieves all the goals of TAC, progressive loss of abdominal domain may still occur because of the ABThera’s limited ability to stabilize the fascia in some patients (Fig. 1). The ABThera, when used alone, fails to reapproximate the fascia in about 30% of patients with an open abdomen. Failure to close the fascia primarily results in an increased risk of enterocutaneous fistula, requirement for skin grafting of the visceral mass and a large ventral hernia. Furthermore, early primary closure of the open abdomen has been associated with improved patient survival.

The use of mechanical traction with sequential suturing and mesh imbrication in conjunction with the ABThera have been shown to significantly increase primary fascial closure rates to approximately 90%. The abdominal re-approximation anchor system (ABRA; Canica Design Inc.) is a dynamic closure system that uses elastomers through the full thickness of the abdominal wall that slowly pull the fascia together under continuous variable tension. It is easier to manage than mesh imbrication or sequential suturing and allows for the abdominal wall to oscillate with patient movement and breathing. Four case series have previously demonstrated the ABRA’s efficacy in achieving fascial closure in the open abdomen. Although combined therapy using the ABThera and the ABRA seems ideal to manage patients who may not achieve primary fascial closure with ABThera alone, this has not been previously described.

We report on the use of the ABRA in conjunction of the ABThera in patients with an open abdomen.

**METHODS**

We conducted an institution review board–approved, single-institution, retrospective analysis of patients with an open abdomen who were managed with the ABThera and ABRA systems between January 2007 and December 2012. Patients were identified from the Acute Care Surgery Surgical Log, which recorded all emergency surgery cases performed at the Halifax Infirmary, QEII Health Science Centre, Halifax, Nova Scotia, Canada. During this time period there was no protocol for the management of the open abdomen. The decision to use the open abdomen was at the discretion of the attending surgeon, as was the use and timing of the ABThera and ABRA.

The usual practice at our institution was to use an ABThera for TAC during the first operation in which an open abdomen technique was employed. ABThera installation involved placing the fenestrated plastic dressing with the incorporated polyurethane sponge over the viscera, under the fascia, down to the retroperitoneum posteriorly, the diaphragm superiorly and pelvis inferiorly. This prevented adherence of the viscera to the abdominal wall and allowed for mobilization of the fascia while preventing injury to the viscera. A granufoam sponge was then placed over the plastic sheet and the abdomen was sealed with an adherent plastic sheet to the skin. The ABThera was then placed to −125 mm Hg continuous suction. The ABThera dressing was changed every 3–5 days in the operating room.

The ABRA was added to the ABThera at the surgeon’s discretion. Typically, this was done when significant fascial retraction was observed, or when the fascia was failing to mediolize over time. Installation of the ABRA involved placing elastomeres 5 cm from the fascial edge and 90° to the fascia through the skin and full thickness of the abdominal wall. The elastomeres were placed as close together as the skin anchor buttons would permit, approximately 3 cm apart. The elastomeres were placed over the ABThera fenestrated sheet and below the sponge (Fig. 2). If the fenestrated silicone sheet included with the ABRA kit was used, it was placed over the ABThera fenestrated sheet and below the granufoam sponges. An adhesive button tail was placed to the skin anchor buttons to prevent displacement and tilting. The ABRA elastomeres were tightened daily to 1.5 times their tension-free length along with manual mediolization of the fascia until primary closure was achieved. Primary closure was performed in the operating room when the fascia could be brought together under reasonable tension without causing physiologic compromise due to intra-abdominal hypertension. In some cases, intra-abdominal pressure was measured during closure. Fascial closure was performed using a running 1 polydioxanone suture.

**RESULTS**

During the study period, 78 patients underwent procedures using an open abdomen. Overall mortality was 24% (19 of 78). We identified 16 patients who had combination therapy using the ABRA and ABThera for treatment of the open abdomen (Table 1). The mean age of patients...
**Fig. 2.** Installation of the ABRA system to the ABThera.

### Table 1. Patients with an open abdomen managed with both the ABThera and ABRA

<table>
<thead>
<tr>
<th>Group; age, yr</th>
<th>Sex</th>
<th>L1 to ABRA</th>
<th>Treatment</th>
<th>LOS ICU</th>
<th>LOS HOSP</th>
<th>Ostomy</th>
<th>Anastomosis</th>
<th>Diagnosis</th>
<th>Outcome</th>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49 M</td>
<td>12</td>
<td>11</td>
<td>43</td>
<td>58</td>
<td>N</td>
<td>N</td>
<td>Pancreatitis</td>
<td>Primary closure</td>
<td>47</td>
<td>1A</td>
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<td>1A</td>
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<td>16</td>
<td>16</td>
<td>N</td>
<td>N</td>
<td>Ruptured AAA</td>
<td>Death from sepsis</td>
<td>58</td>
<td>1B</td>
<td></td>
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<td>Y</td>
<td>Post gastric sleeve</td>
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<td>1B</td>
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<td>12</td>
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<td>Primary closure</td>
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<td>46</td>
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<td>Primary closure</td>
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<td>52 F</td>
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<td>3</td>
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<td>40</td>
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<td>Y</td>
<td>Damage control</td>
<td>Primary closure</td>
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<td>1B</td>
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<td>58 M</td>
<td>7</td>
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<td>31</td>
<td>40</td>
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<td>Y</td>
<td>Damage control</td>
<td>Closure with vicryl mesh</td>
<td>39</td>
<td>1B</td>
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<td>5</td>
<td>27</td>
<td>Y</td>
<td>Y</td>
<td>Damage control</td>
<td>Primary closure</td>
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</tr>
<tr>
<td>62 M</td>
<td>3</td>
<td>4</td>
<td>29</td>
<td>46</td>
<td>Y</td>
<td>N</td>
<td>Intraabdominal sepsis</td>
<td>Primary closure</td>
<td>60</td>
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<td></td>
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<tr>
<td>54 M</td>
<td>19</td>
<td>6</td>
<td>29</td>
<td>122</td>
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<td>Intraabdominal sepsis</td>
<td>Primary closure</td>
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<td>146</td>
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<td>Intraabdominal sepsis</td>
<td>Primary closure</td>
<td>79</td>
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<tr>
<td>38 F</td>
<td>15</td>
<td>3</td>
<td>15</td>
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<td>N</td>
<td>N</td>
<td>Intraabdominal sepsis</td>
<td>Primary closure</td>
<td>97</td>
<td>1A</td>
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<td>65 F</td>
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<td>N/A</td>
<td>31</td>
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<td>N</td>
<td>Intraabdominal sepsis</td>
<td>Death from sepsis</td>
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<td>66 F</td>
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<td>N/A</td>
<td>36</td>
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<td>Y</td>
<td>Intraabdominal sepsis</td>
<td>Death from sepsis</td>
<td>58</td>
<td>1A</td>
<td></td>
</tr>
</tbody>
</table>

AAA = abdominal aortic aneurysm; ACS = abdominal compartment syndrome; F = female; GI = gastrointestinal; HOSP = hospital; ICU = intensive care unit; LOS = length of stay; M = male; N = no; N/A = not applicable; SAPS II = Simplified Acute Physiology Score; Y = yes.
was 52.5 (range 33–66) years, and 10 patients (63%) were men. In patients managed without an ABRA, mortality was 26% (16 of 62), and primary closure failed in 13 of the remaining 46 patients (28%). Of those in whom primary closure failed, 8 were bridged with mesh and 5 were managed with a planned ventral hernia.

In patients managed with an ABRA and ABThera, the most common reason for using an open abdomen was for the management of abdominal compartment syndrome (38%) and severe intra-abdominal sepsis (38%). Severe pancreatitis accounted for the majority of abdominal compartment syndrome cases. Damage control surgery, in the setting of trauma, accounted for 25% of cases.

An anastomosis was present in 9 of 16 (56%) and an ostomy (i.e., colostomy, ileostomy, diverting ileostomy/colostomy) was present in 6 (38%) patients. Four (25%) patients had both an anastomosis and an ostomy. There were no reported stoma complications related to the addition of the ABRA. None of the patients had a history of radiation treatment.

After the ABThera was installed, the addition of the ABRA system occurred at a median of 7 (range 0–19) days. Most patients had the ABRA system applied on the first or second ABThera dressing change. There was significant variability observed in the timing of ABRA installation, as it was at the discretion of the surgeon. The patient who had the ABRA placed on day 0 had a decompressive laparotomy for abdominal compartment syndrome. In this case, the elastomers were placed but not loaded under tension in an attempt to prevent fascial retraction in excess of what was required to relieve intra-abdominal hypertension.

All patients in whom the ABRA was used had a Björch Open Abdomen Classification System grade of 1A or 1B.14 After removing patients who died prior to closure, primary fascial closure was achieved in 12 of 13 patients (92%). The number of days required for fascial closure after the addition of the ABRA was a median of 17 (range 3–31) days. Fascial closure was not achieved in the remaining patient because the surgeon elected to remove the ABRA and bridge the fascial gap with a Vicryl mesh after 31 days with an open abdomen and 24 days of treatment with the ABRA and ABThera.

Skin breakdown at the ABRA button site was observed in 1 (6%) patient. Recurrent abdominal compartment syndrome was noted in 1 patient who was subsequently treated in the intensive care unit by decreasing the tension of the ABRA elastomers.

Overall survival in patients with an ABRA and ABThera was 75%, with 3 of the 4 deaths occurring before primary fascial closure was achieved. Sepsis and multisystem organ failure was the cause of death in all cases, including 1 patient who died from an anastomotic leak and ensuing sepsis after primary closure. The average Simplified Acute Physiology II Score (SAPS II) was 54 (range 41–97). The length of stay in the intensive care unit was a median of 30 (range 5–47) days. Excluding the 4 patients who died, the length of stay in hospital was a median of 43.5 (range 27–146) days.

**Discussion**

The use of the open abdomen, although a lifesaving technique, presents a clinical challenge that is associated with significant morbidity and mortality. Once the physiologic crisis necessitating the open abdomen has resolved, rapid primary closure of the fascia is required to prevent complications, such as fistula and loss of fluid, protein, heat and electrolytes. Failure to close the fascia results in a giant ventral hernia that requires a complex repair and has significant associated morbidity.5 Furthermore, delay in closure of the fascia is associated with increased mortality.

The ABThera open abdomen negative pressure therapy protects the viscera from adhering to the abdominal wall and effectively removes fluid from the entire abdominal cavity. This facilitates the safe mobilization of the native fascia and, compared with other types of TAC, improves the rate of primary fascial closure.13,15,16 However, the ABThera still fails to achieve primary closure in approximately 30% of patients with an open abdomen. In our experience as well as other authors’, it is usually apparent 4–7 days after placement of the ABThera that the fascia retracts further and will likely not close with the ABThera alone.10,17 Although the reason for using an ABRA in addition to the ABThera was not recorded in our series, surgeons typically choose to use the ABRA in patients in whom they feel the fascia is unlikely to close with the ABThera alone. Consequently, we hypothesize that if the ABThera had been used without the ABRA, a primary fascial closure rate of less than 70% would have been observed in these patients. In spite of this, the addition of the ABRA to the ABThera was associated with a successful primary fascial closure in 92% of patients in our study. In the 1 patient in whom primary fascial closure failed, the surgeon removed the ABRA and placed a vicryl mesh after 24 days of treatment with the ABRA. It is possible that primary fascial closure may have been possible in this patient as well if more time had been given with the ABRA, as successful closure has been reported at up to 31 days in our study and 62 days in other studies involving the ABRA.10–12 Achieving primary fascial closure avoids the morbidity of a ventral hernia and a second operation to repair it. However, the prolonged use of the ABRA to achieve primary closure comes at the cost of ongoing ABThera changes and increased length of stay in hospital. A cost analysis to determine the length of time after which attempting primary closure with the ABRA is no longer cost-effective could be a direction for future study.

The high rate of primary fascial closure observed in our series is consistent with that in other studies that have used the addition of mechanical traction to the ABThera system. Rasilainen and colleagues5 reported a primary fascial closure rate of less than 70% would have been observed in these patients. In spite of this, the addition of the ABRA to the ABThera was associated with a successful primary fascial closure in 92% of patients in our study. In the 1 patient in whom primary fascial closure failed, the surgeon removed the ABRA and placed a vicryl mesh after 24 days of treatment with the ABRA. It is possible that primary fascial closure may have been possible in this patient as well if more time had been given with the ABRA, as successful closure has been reported at up to 31 days in our study and 62 days in other studies involving the ABRA.10–12 Achieving primary fascial closure avoids the morbidity of a ventral hernia and a second operation to repair it. However, the prolonged use of the ABRA to achieve primary closure comes at the cost of ongoing ABThera changes and increased length of stay in hospital. A cost analysis to determine the length of time after which attempting primary closure with the ABRA is no longer cost-effective could be a direction for future study.
closure rate of 53% using the intra-abdominal vacuum-assisted closure (VAC) system alone, which increased to 93% primary closure when a mesh was sequentially imbricated over top. Similarly, sequential fascial suturing over the intra-abdominal VAC has increased rates of primary fascial closure to approximately 90%. Specific to the ABRA system, Verdam and colleagues reported primary fascial closure in 14 of 16 patients (88%), Salman and colleagues reported primary closure in 7 of 7 patients with an open abdomen, and Haddock and colleagues reported primary closure in 30 of 36 (83%) patients.

We speculate that early application of the ABRA may be important in achieving successful primary fascial closure. Early application prevents fascial retraction and can start pulling the fascia together while the tissues are relatively more dynamic. Preventing adhesions of the viscera to the abdominal wall is also important to allow for safe and unimpeded medialization of the fascia. This is highlighted in the study by Reimer and colleagues in which the ABRA was placed relatively later (average of 18 d) and in which primary closure was achieved in only 14 of 23 patients (61%). Success of primary fascial closure was associated with earlier application of the ABRA and having the fascia free of adhesions to the abdominal wall. Similar to us, Haddock and colleagues reported fascial closure in 83% of patients with an average time from first laparotomy to ABRA placement of 11.9 days. However, in their study, there appeared to be a longer median time from the first laparotomy to the placement of the ABRA in patients achieving primary fascial closure. They hypothesized that patients who had a more thorough decontamination of the abdomen with a longer duration of an open abdomen would be more amenable to closure. In our cohort, the ABRA was placed earlier in the trauma subgroup of patients relative to the gastrointestinal sepsis subgroup, highlighting the desire to create as clean an abdominal cavity as possible before placing the ABRA.

In previous studies, trauma patients had a higher rate of primary closure than those with septic abdomens. In our series, we observed an equally high rate of closure in patients with nontraumatic etiologies, possibly because we used the ABThera system, which allowed for suctioning of the pelvis, paracolic gutters and subdiaphragmatic spaces. The previous studies used a VAC system, which may not have been able to decontaminate the abdomen as readily and thereby prevented successful primary closure.

Our study demonstrates the severity of illness associated with patients managed with an open abdomen. The observed mortality of 25% is consistent with that of other cohorts of patients managed with an open abdomen. No deaths in our study were directly attributable to the ABRA device. Pressure sores related to the ABRA buttons have been reported as a complication of the ABRA, with the study by Verdam and colleagues reporting its occurrence in 12 of 18 patients. In our study, skin breakdown was observed in only 1 patient. The reason for this may be secondary to our practice of placing the ABRA buttons over the ABThera adherent dressing, which may have provided additional protection to the skin.

**Limitations**

This study has several weaknesses. First, it is uncontrolled and describes outcomes of a cohort of patients managed entirely at the surgeon’s discretion, with no protocol to guide therapy. The reasons the surgeon decided to add the ABRA were not specifically recorded for all patients. Second, as the study was not prospective, many pertinent data points, such as body mass index, were not available for all patients. This makes the generalization of our observations difficult.

Based on the experience gained from this cohort, and in context of other studies using the ABThera, we have proposed a treatment algorithm of the open abdomen that recommends early use of mechanical traction in addition to the ABThera (Fig. 3). This recommendation has been made by other authors as well. The ABThera is essential for removing fluid and contamination from the abdomen and prevents adhesions between the visceral mass and the abdominal wall. If the fascia is failing to medialize by the first dressing change on day 3–5, we suggest the addition of mechanical traction to the fascia in order to increase the rate of primary fascial closure.

![Proposal for management of the open abdomen.](image-url)

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**Fig. 3. Proposal for management of the open abdomen.**
fascia, progressive imbrication of mesh sutured to the fascia and the ABRA system. We prefer the ABRA system, as in our experience it takes less time to manage than mesh imbrication or sequential suturing, and tightening can be done daily at the bedside without disrupting the ABThera. Although not specifically recorded, a typical time to install the ABRA is about 10 minutes. The ABRA does not impede the changing of the ABThera, as the elastomers are easily loosened and retracted. The only extra time added to the ABThera change is the time required to tighten the elastomers, which typically takes less than 5 minutes. The ABRA system also leaves the edges of the native fascia undisturbed, which is an attractive advantage at the time of definitive closure.

**CONCLUSION**

We observed a high rate of primary fascial closure in patients with an open abdomen managed with the ABThera in conjunction with the ABRA. Consideration should be given to applying mechanical traction in addition to the ABThera change to achieve primary fascial closure.

**Competing interests:** S. Minor has received an honorarium from KCI to provide an educational talk on temporary abdominal closure. This occurred 3 times over the past 3 years. Each honorarium was approximately $1000. The talk was not specific to the ABThera product, but it did discuss its use. None declared for A. Mukhi.

**Contributors:** Both authors designed the study, acquired and analyzed the data, wrote and reviewed the article, and approved the final version for publication.

**References**

Surgical management of symptomatic hydatid liver disease: experience from a Western centre

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Background: Hydatid liver cysts are rare in North America. The objective of this study was to determine the optimal surgical management for hydatid liver cysts treated outside endemic areas.

Methods: We reviewed the cases of consecutive patients who underwent management of hydatid liver cysts. Radical liver resections were compared with other types of procedures. Clinical presentation, investigations, perioperative outcomes and long-term follow-up were evaluated. We evaluated disease recurrence using the Kaplan–Meier method.

Results: Forty patients underwent surgery for hydatid liver cysts. Most patients had single (68%) right-sided (46%) cysts with a median size of 10 cm. Most (83%) underwent liver resection with or without drainage/marsupialization. Radical liver resection was carried out in 60% (19 major, 5 minor). Additional procedures were required in 50% (biliary fistulization 30%, diaphragmatic fistulization 20% or paracaval location/fusion 8%). Postoperative complications occurred in 48%. The median follow-up was 39 months. The 3-year recurrence-free survival was significantly different between patients who had radical resection and those who had other procedures (100% v. 71%, $p = 0.002$).

Conclusion: The surgical management of hydatid liver cysts in North America remains rare and challenging and is frequently associated with fistulizing complications. Excellent long-term outcomes are best achieved using principles of radical liver resection that are familiar to North American surgeons.

Contexte : L’hydatidose (kyste hydatique du foie) est une affection rare en Amérique du Nord. Cette étude visait à déterminer quelle était la meilleure façon de prendre en charge cette maladie à l’extérieur de zones où elle est endémique.

Méthodes : On a revu les cas de patients consécutifs traités pour des kystes hydatiques du foie. L’ablation radicale du foie a été comparée à d’autres types d’intervention. Le tableau clinique, les examens exploratoires, les résultats périopératoires et le suivi de longue durée ont été évalués. On a aussi évalué la récurrence de la maladie en utilisant la méthode Kaplan–Meier.

Résultats : Quarante patients avaient été opérés pour des kystes hydatiques du foie. La plupart présentaient des kystes simples (68 %) dans le foie droit (46 %), qui mesuraient en moyenne 10 cm de diamètre. La plupart (83 %) avaient subi une résection hépatique avec ou sans drainage ou marsupialisation. Une résection radicale a été pratiquée chez 60 % des patients (19 cas majeurs, 5 cas mineurs). D’autres interventions se sont avérées nécessaires dans 50 % des cas (fistulisation dans les voies biliaires 30 %, fistulisation dans le diaphragme 20 %, localisation paracave ou fusion 8 %). Des complications postopératoires sont survenues dans 48 % des cas. La durée moyenne du suivi a été de 39 mois. On a observé une différence significative entre le taux de survie sans récidive sur 3 ans entre les patients ayant subi une résection radicale et ceux ayant subi une autre intervention (100 % c. 71 %, $p = 0.002$).

Conclusion : En Amérique du Nord, le traitement chirurgical de l’hydatidose reste rare, difficile et souvent compliqué par une fistulisation. La résection hépatique radicale, que les chirurgiens nord-américains maîtrisent bien, est l’intervention permettant d’obtenir les meilleurs résultats à long terme.
H ydatid disease is an important parasitic ailment that affects primarily the liver in 75% of cases. Most cases in humans are caused by *Echinococcus granulosus* or *Echinococcus multilocularis*, which account for cystic and alveolar echinococcosis, respectively. The worldwide annual incidence of cystic echinococcosis is 1–200 per 100 000. Dogs and other canids are the definitive hosts for the adult tapeworm, whereas ungulates (typically sheep) act as intermediate hosts by ingesting shed eggs. Humans living in proximity to definitive and intermediate hosts can become accidental intermediate hosts by the same mechanism. Hydatid disease is endemic in many sheep- and cattle-raising parts of the world, namely Mediterranean countries, the Middle East, Eastern Europe and South America.

The management of hydatid cysts of the liver is controversial. Therapeutic options can be broadly divided into 3 categories: medical treatment, conservative surgery and radical surgery. Medical therapy, using the antihelminthic agents albendazole or mebendazole, has been recommended for asymptomatic and uncomplicated cysts smaller than 5 cm. Conservative surgical options include external drainage and unroofing procedures in addition to various types of residual cavity management strategies. Radical surgical options include formal liver resection and complete pericystectomy.

The surgical management of hydatid liver cysts is most common in endemic regions of the world. Not surprisingly, surgeons in these areas have accumulated extensive experience and reported large series of patients, documenting recurrence rates of 7.7%–30% and morbidity of 21%–80% with conservative surgical therapies. In contrast, liver surgeons working in Western centres — particularly North American hospitals — can be expected to treat only a handful of such patients over the course of their careers. In this context, it becomes particularly important to define surgical treatment strategies that are specific to the expertise of Western liver surgeons, which is lacking in the literature. We sought to review a single North American tertiary care centre’s experience with patients who underwent liver surgery for hydatid cysts of the liver.

**METHODS**

This work was a retrospective review of our institutional experience with hydatid disease of the liver. All consecutive patients who underwent inpatient management or day procedures for hydatid liver cysts at our provincial referral hepatobiliary academic unit were included (1988–2012). The Centre Hospitalier de l’Université de Montréal Research Center Ethics Committee approved our study protocol.

In order to identify study patients, we searched discharge abstracts for diagnoses of hydatid disease based on the International Classification of Diseases (ICD)-10 (codes 122.8, 122.9) and ICD-9 (codes B67.8, B67.9). All other patients treated with albendazole were identified through the pharmacy database, as this drug is not approved for routine use in Canada and is thus dispensed on an individual patient basis after approval by Health Canada. Individual surgeon records were also mined for any missing cases. Cases of hydatid liver cysts were defined on the basis of characteristic imaging findings, echinococcal serology, microscopic identification of scolices within cyst fluid and pathological examination of resected specimens. We retrieved the medical records of potential study patients and checked them manually for inclusion. Relevant data pertaining to each study patient were extracted from the medical records and entered into a computerized data set. Data points of interest included patient demographics, preoperative features (serology, imaging, medical therapy), operative features (type of surgery, precautions specific to hydatid disease, cholangiography, complications, blood loss, duration) and postoperative features (length of stay, complications, pathology, recurrence, serology). No imaging classification of hydatid liver cysts was used at our centre during the study period, as such cysts are too infrequent in North America.

Indications for surgical treatment were based on World Health Organization recommendations. Briefly, surgery was indicated for large liver cysts; symptomatic cysts; cysts at risk of rupture; infected cysts; and cysts demonstrating or at risk for fistulization into the biliary tree, diaphragm/pleural cavity or other vital organs. Completely calcified cysts were not routinely treated. In general, complete surgical resection was the preferred treatment option at our institution. Pericystectomy was not performed owing to our lack of experience with this procedure. Combinations of resection and marsupialization/drainage were used when the entire burden of hepatic cysts could not be safely resected owing to anatomic location or concerns regarding the volume of the future liver remnant. Associated surgical procedures were performed based on the anatomic location of individual cysts and evidence of fistulizing disease on preoperative imaging. Diaphragmatic resection and primary repair was carried out whenever the cyst appeared to have invaded or be adherent to the diaphragm. Percutaneous puncture-aspiration-injection-reinjection (PAIR) was not performed at our institution except in patients who were deemed not to be surgical candidates.

Based on the Brisbane 2000 terminology, formal liver resection was defined as the complete surgical excision of all hydatid cysts within the liver. In practice, this approach involved resective principles similar to those used in oncologic liver surgery, with resection of the entire cyst, including at a minimum its laminated membrane and typically including the pericyst into healthy parenchyma to achieve a negative resection margin. When the cyst was initially too bulky to allow for safe liver resection, the cyst was incised and drained using a large-bore gynecologic suction aspirator. The cyst cavity was then filled with hypertonic...
saline and allowed to sit undisturbed for 10–15 minutes. In all cases, we took precautions, including isolating the liver with laparotomy pads soaked in hypertonic saline and suturing a plastic sterile drape to the apex of any cyst before suction aspiration, to avoid intra-abdominal spillage of cyst contents. Marsupialization involved the drainage of the cyst contents, unroofing of the cyst wall as much as possible and oversewing of the remaining wall circumference to avoid its reaccumulation. Operative drainage consisted of evacuation of the cyst contents in a manner analogous to PAIR.

Preoperative or postoperative antiparasitic agents were routinely administered after consultation with an infectious diseases specialist. All postoperative complications were recorded and graded according to the Clavien–Dindo classification. Follow-up after surgery was at the surgeon’s discretion and was typically carried out in conjunction with the infectious diseases consultant. Disease recurrence was defined on the basis of evidence of 1 or more novel hydatid cyst on high-quality imaging, as interpreted by experienced abdominal radiologists.

**Table 1. Demographic and clinical characteristics of study participants**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group; no. (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole cohort, n = 40</td>
</tr>
<tr>
<td></td>
<td>1988–2002, n = 20</td>
</tr>
<tr>
<td></td>
<td>2003–2012, n = 20</td>
</tr>
<tr>
<td>Sex, male/female</td>
<td>24 (60)/16 (40)</td>
</tr>
<tr>
<td></td>
<td>10 (50)/10 (50)</td>
</tr>
<tr>
<td></td>
<td>14 (70)/6 (30)</td>
</tr>
<tr>
<td>Age, median (IQR) yr</td>
<td>40.5 (32.5–55.5)</td>
</tr>
<tr>
<td></td>
<td>43 (31–57.5)</td>
</tr>
<tr>
<td></td>
<td>39.5 (33.5–50.5)</td>
</tr>
<tr>
<td>Country of birth†</td>
<td></td>
</tr>
<tr>
<td>Canada‡</td>
<td>9 (23)</td>
</tr>
<tr>
<td>Algeria</td>
<td>9 (23)</td>
</tr>
<tr>
<td>Lebanon</td>
<td>5 (13)</td>
</tr>
<tr>
<td>Morocco</td>
<td>4 (10)</td>
</tr>
<tr>
<td>Italy</td>
<td>3 (8)</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Greece</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Other§</td>
<td>5 (13)</td>
</tr>
<tr>
<td>Presenting symptoms/signs</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>28 (70)</td>
</tr>
<tr>
<td>No symptoms/incidental</td>
<td>11 (28)</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>6 (15)</td>
</tr>
<tr>
<td>Palpable mass</td>
<td>3 (8)</td>
</tr>
<tr>
<td>Jaundice and/or fever</td>
<td>3 (8)</td>
</tr>
<tr>
<td>Echinococcal serology†</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>25 (68)</td>
</tr>
<tr>
<td>Negative</td>
<td>12 (32)</td>
</tr>
<tr>
<td>Imaging modalities</td>
<td></td>
</tr>
<tr>
<td>Ultrasonography</td>
<td>35 (88)</td>
</tr>
<tr>
<td>CT, abdomen</td>
<td>38 (95)</td>
</tr>
<tr>
<td>CT, chest</td>
<td>6 (15)</td>
</tr>
<tr>
<td>MRI</td>
<td>20 (50)</td>
</tr>
<tr>
<td>CT = computed tomography, IQR = interquartile range; MRI = magnetic resonance imaging.</td>
<td></td>
</tr>
</tbody>
</table>
*Unless otherwise indicated. |
†Data missing for some patients. |
‡Four of the 9 Canadian patients were from the First Nations. |
§Afghanistan, Armenia, Romania, Spain, Turkey, each with n = 1. |
¶p = 0.06. |

**Statistical analysis**

We compared patients treated between 2003 and 2012 with those treated between 1988 and 2002. We generated summary statistics as proportions for categorical variables and as medians with interquartile ranges for continuous variables. Cyst recurrence was examined using the Kaplan–Meier and actuarial life tables methods, using the time from definitive surgery to recurrence in months. Dichotomous outcomes were compared using the Fisher exact test, and time-to-event data were compared using the log-rank test. All statistical analyses were performed using SAS software version 9.2 (SAS Institute Inc.).

**RESULTS**

Forty patients with hydatid liver cysts underwent surgery, 20 of which took place in the last 10 years (Table 1). Most patients were men and were of Mediterranean, Middle-Eastern and Canadian origin. Most patients presented with nondifferentiated abdominal pain and underwent a combination of ultrasonography and computed tomography of
the abdomen to make the diagnosis of hydatid liver cyst. Preoperative echinococcal serology was available for 37 patients and was positive in 68%.

The characteristics of all hydatid cysts are presented in Table 2. The majority of patients had a single hydatid cyst, whereas 10% had 4 or more concomitant cysts. Bilobar disease was found in 11 (28%) patients, 73% of whom had 2 or more cysts.

In total, 95% of patients underwent medical therapy: 67% (n = 26) in the preoperative phase, 87% (n = 34) in the postoperative phase and 60% (n = 24) in both the pre- and postoperative phases. All but 1 patient were treated with albendazole (1 patient was treated with mebendazole). The 3 patients who did not receive medical therapy were treated before 1992.

All patients included in this series underwent surgical therapy (Table 3): 33 (83%) patients underwent liver resection with or without marsupialization/drainage. Conservative therapy (drainage or marsupialization) was carried out as the sole procedure in 7 (18%) patients. Radical liver resection was the sole form of surgical therapy in 60% of patients. Of the 24 patients who underwent radical liver resections, 19 had major and 5 had minor hepatectomies. The 9 patients who underwent combination liver resection

<table>
<thead>
<tr>
<th>Table 2. Hydatid cyst features</th>
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<tbody>
<tr>
<td>Liver location†</td>
</tr>
<tr>
<td>Right hemiliver</td>
</tr>
<tr>
<td>Left hemiliver</td>
</tr>
<tr>
<td>Bilobar</td>
</tr>
<tr>
<td>Number of cysts</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>≥ 4</td>
</tr>
<tr>
<td>Maximal cyst diameter‡</td>
</tr>
<tr>
<td>All cysts, median (IQR), cm</td>
</tr>
<tr>
<td>Per patient, median (IQR), cm</td>
</tr>
</tbody>
</table>

IQR = interquartile range.
*Unless otherwise indicated.
†Data missing for some patients.
‡Fifty-three cysts in 37 patients.

<table>
<thead>
<tr>
<th>Table 3. Medical and surgical therapies of hydatid liver cysts</th>
</tr>
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<tbody>
<tr>
<td>Main procedures</td>
</tr>
<tr>
<td>Radical liver resection</td>
</tr>
<tr>
<td>Liver resection + marsupialization</td>
</tr>
<tr>
<td>Marsupialization</td>
</tr>
<tr>
<td>Liver resection + drainage</td>
</tr>
<tr>
<td>Drainage</td>
</tr>
<tr>
<td>Associated procedures</td>
</tr>
<tr>
<td>Intraoperative ultrasonography</td>
</tr>
<tr>
<td>Diaphragmatic resection/repair</td>
</tr>
<tr>
<td>Cholangiography</td>
</tr>
<tr>
<td>Closure of cyst-biliary fistula</td>
</tr>
<tr>
<td>CBD exploration</td>
</tr>
<tr>
<td>IVC resection/repair</td>
</tr>
<tr>
<td>Right adrenalectomy</td>
</tr>
<tr>
<td>Intra-abdominal abscess drainage</td>
</tr>
<tr>
<td>Other*</td>
</tr>
</tbody>
</table>

CBD = common bile duct; ERCP = endoscopic retrograde cholangiopancreatography; IVC = inferior vena cava.
*Gastric lesser curve resection, percutaneous resection, splenectomy, thoracotomy, ERCP, pelvic hydatid cysts excision, bilateral lung hydatid cysts excision (wedges at second operation 2 months later).
†p < 0.05.
and marsupialization/drainage had an additional 3 major and 6 minor liver resections. All but 1 patient who underwent resection and marsupialization had bilobar disease. Hypertonic saline was administered in 32 (80%) patients.

In 20 (50%) patients, an additional 34 procedures (excluding intraoperative ultrasonography) were performed during the same anesthetic (Table 3). These procedures were uniformly associated with anatomic or technical challenges associated with individual cysts, including fusion with the diaphragm (n = 8, 20%), paracaval/posterior location (n = 3, 8%) and concern over possible biliary fistulization (n = 12, 30%). The median duration of surgery was 295 (IQR 245–375, range 165–515) minutes. Intraoperative complications occurred in 7 (18%) patients; complications included hemorrhage (n = 2), minimal leakage of cyst contents controlled with hypertonic saline-soaked sponges (n = 3), hypotension suspected of being related to anaphylaxis (n = 2) and anesthesia-induced hypotension (n = 1). There was no difference in duration of surgery (p = 0.69) or operative complications (p = 0.63) between the study periods.

The median length of stay in hospital was 9.5 (IQR 6–16.5, range 4–93) days. Postoperative stay was 15 (IQR 10–22) days in 1988–2002 and 7 (IQR 6–8.5) days in 2003–2012 (p = 0.023). A total of 29 postoperative complications were identified among 19 (48%) patients. Based on the Clavien–Dindo classification, all postoperative complications were at most grade 3a in severity (Table 4). Of the complications directly related to the liver surgery, wound infection was the most common, followed by bile leakage. One patient underwent percutaneous drainage of an infected liver bed collection that was attributable to a bile leak (grade 3a) and also experienced delirium following right hepatectomy (grade 1). Four other patients had bile leaks identified within closed suction drains. Of these, 1 patient was managed conservatively (grade 1), 1 required the addition of antibiotics (grade 2) and 2 required endoscopic retrograde cholangiopancreatography for definitive control (grade 3a). Finally, 1 patient required percutaneous drainage of a residual liver abscess (grade 3a) and another had a delayed percutaneous drainage of a large pleural effusion at 3 weeks (grade 3a). There was no significant difference in overall postoperative complications between radical and other liver procedures (54% vs. 38%, p = 0.30). There was no significant difference in overall postoperative complication rates between study periods (50% vs. 45%, p = 0.75) except for postoperative bile leakage (25% vs. 0%, p = 0.047).

The preoperative diagnosis of hydatid liver cysts was confirmed at pathology and microscopic examination of cyst contents in all patients. The median follow-up after surgery was 39 (IQR 10–105, range 0.2–234) months. The Kaplan–Meier curve for recurrence-free survival is presented in Figure 1, comparing radical resection and other procedures (log-rank test p = 0.002). The 3-year recurrence-free survival was 89% for the whole cohort, 100% for radical resection and 71% for other procedure types. Four (10%) patients experienced hydatid cyst recurrence at 4, 12, 24 and 71 months, respectively, after undergoing simple drainage (n = 1), liver resection/drainage (n = 1), and liver resection/marsupialization (n = 2). No case of recurrence occurred in patients who underwent radical resection (25% vs. 0%, p = 0.020). There was no significant difference in the crude recurrence rate at maximal follow-up (p = 0.61) or in disease-free recurrence between the study time periods (p = 0.11).

**DISCUSSION**

This study has addressed the surgical management of hydatid liver cysts in the context of a Western tertiary hepatobiliary referral centre. This work has documented the relative rarity of liver surgery for echinococcal disease in North America and has also documented a high proportion of complicated cysts. Importantly, we have shown

| Table 4. Postoperative complications, by Clavien–Dindo classification |
|-----------------------------|----------------|----------------|---------------- Budget |----------------|
| Complications | Grade 1 | Grade 2 | Grade 3a | Total Budget |
| Wound infection | 6 | 1 | 7 | (18) |
| Bile leak | 1 | 1 | 3 | 5 (13) |
| Gastroparesis/ileus | 2 | 2 | 4 | 10 |
| Pleural effusion | 2 | 1 | 3 | 8 |
| Clostridium difficile colitis | 2 | 2 | 5 |
| Pneumonia | 2 | 5 |
| Residual abscess | 1 | 1 | 3 |
| Pulmonary edema | 1 | 1 | 3 |
| Urinary tract infection | 1 | 1 | 3 |
| Vocal cord trauma | 1 | 1 | 3 |
| Deltirum | 1 | 1 | 3 |
| Pancreatitis | 1 | 1 | 3 |
| Total, % of complications | 11 (38) | 11 (38) | 7 (24) | 29 |

**Fig. 1.** Kaplan–Meier curve for recurrence-free survival following hydatid cyst surgery, comparing radical resections (dashed line) and other procedures (solid line), log-rank test p = 0.002.
that long-term successful management of hydatid liver cysts can be achieved with radical liver surgery, demonstrating an acceptably low level of major postoperative morbidities and a low recurrence rate.

The literature on hydatid liver disease is intensely driven by investigators from Mediterranean centres as a consequence of their extensive experience with this pathology. Over the years, a few contributions from Western centres have appeared, originating mostly in Europe. In contrast, the North American experience with hydatid disease remains extremely limited owing to the rarity of this pathology and is restricted to rare series and occasional case reports. To our knowledge, the present series represents the largest combined surgical experience with hydatid disease of the liver in North America. Although the sample size presented in this work is small in comparison to large series from endemic areas, it is nevertheless highly important, as it portrays the work of trained liver surgeons with a wealth of experience in resective oncologic liver surgery but with limited experience with liver infestations. Moreover, the present series is unique in that it depicts a province-wide tertiary referral pattern within a city with steady immigration from Mediterranean and North African countries.

Despite the rarity of hydatid liver disease in nonendemic areas as well as the complexity of the procedures performed in this series, an acceptable rate of postoperative morbidity was achieved. Other series of liver surgery for hydatid disease have reported postoperative complication rates of 20%–49%. While the overall complication rate identified in this study (48%) was on the higher end of the previously published range, we argue that this is an acceptable morbidity rate. All recorded complications were classified as Clavien–Dindo grade 3a or less, with 76% of complications classified as grade 1 or 2. All surgical and medical complications were accounted for in our series in contrast to other studies that sometimes included only surgical or cyst cavity–related complications. In our series, the most notable complications were postoperative bile leaks in 5 patients, gastroparesis and/or ileus in 4 patients and wound infections in 7 patients — findings that are likely to be related to the complicated nature of cysts treated in this cohort.

Roughly half the patients included in this series required additional operative procedures related to complicated hydatidosis. Additional procedures associated with complicated cysts were broadly classified as biliary fistulization (30%), diaphragmatic fistulization (20%) and paracaval fusion (8%). Biliary fistulization is a well-known complication of hydatid disease that is thought to occur in 6.6%–26% of patients. The presence of a biliary fistula is independently associated with deep abdominal complications following hydatid surgery (odds ratio 2.27, 95% confidence interval 1.38–3.72). Our results are consistent with those of other series. For instance, Secchi and colleagues reported carrying out additional biliary procedures among 146 of 268 (54%) patients with complicated hydatid cysts, including bile duct exploration (52%), endoscopic therapy (17%) and enterobiliary anastomoses (31%). Kilic and colleagues also reported a direct association between maximal cyst size and the likelihood of biliary–cyst communication, with 7.5 cm being the cutoff with the best predictive value (sensitivity 79%, specificity 73%). Chautems and colleagues’ further reported that 71% of patients with complicated cysts were found at surgery to have a cyst–biliary fistula, as defined by the visualization of an open bile duct following removal of a cyst. Furthermore, this group also identified daughter cysts within the common bile duct in 50% of patients, who were treated by choledochotomy, clearance and T-tube placement. Diaphragmatic invasion was reported in 14% of complicated cysts within this same study. Findings from the present study, as well as comparison to the literature, lend further support to the use of radical surgery, particularly formal liver resection, as a primary mode of therapy for complicated hydatid cysts. When this approach is deemed technically feasible and safe by experienced liver surgeons, it allows for the resection of both the cystic cavity and any area of fistulization.

This work has documented an excellent recurrence-free survival rate among patients treated with radical surgery as well as among those treated with a combination of surgery and drainage procedures. These data compare favourably with those reported by Tagliaozzo and colleagues, who reviewed their experience with the surgical management of 454 patients with hepatic hydatosis. This group compared conservative (drainage, marsupialization, omentoplasty; n = 214) and radical surgery (resection, pericystectomy; n = 240), documenting recurrence rates of 30.4% and 1.2% (p < 0.001), respectively. Radical surgery was also associated with a much lower rate of postoperative morbidity (79.9% vs. 16.2%, p < 0.001) and comparable mortality (6.5% vs. 9.2%, p = 0.30). In another study, Chautems and colleagues reported on the surgical management of 35 patients with complicated cysts, achieving complete cyst removal in 69% of patients via hepatectomy (n = 12) or pericystectomy (n = 12). This strategy was comparable to our own, although it relied less heavily on formal hepatectomy, and achieved a 0% recurrence rate at a median of 103 months. More recently, Birnbaum and colleagues reported on 97 patients with hydatid disease, 85 of whom underwent radical surgical surgery (52 liver resections). While this group presented data in favour of radical resection, the median follow-up among those undergoing resection was only 1.5 months, thus limiting their conclusions on cyst recurrence. In contrast to these studies, other groups have documented variable but generally higher recurrence rates with conservative surgical procedures (11%–30%), highlighting the superiority of radical surgery in preventing recurrence of liver hydatosis. It should be noted that at least 1 group did not find any difference in recurrence rates between conservative and radical surgery after 10 years in a large cohort of 672 patients who underwent primarily conservative surgery (80%).
Limitations

This study has several limitations. First, it was a retrospective review of medical charts and surgeon records. As with all retrospective series, there is a risk of bias related to the information quality available in medical records as well as its extraction. Second, length of follow-up was unequal, with a small number of patients having follow-up at secondary institutions and being lost early to follow-up. Although it is possible that additional cases of disease recurrence may have occurred among these patients, we argue that this is unlikely given the specialized nature of therapy for echinococcal disease and the likelihood that these patients would have been referred back to our centre had recurrence occurred.

Conclusion

The surgical management of hydatid liver cysts in North America remains rare and challenging. Associated complications of hydatid liver cysts, such as biliary fistulization, diaphragmatic fistulization, or vascular abutment, are relatively common and must be anticipated. In the North American context, it is recommended that complicated hydatid cysts of the liver be managed whenever possible using principles of radical liver resection by experienced hepatic surgeons.

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Contributors: All authors designed the study and acquired the data, which G. Martel, A. Bégin and R. Lapointe analyzed. G. Martel wrote the article, which all authors reviewed and approved for publication.

References

Comparison of stable and unstable pertrochanteric femur fractures managed with 2- and 4-hole side plates

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Background: Sliding hip screw (SHS) fixation traditionally involves the use of 4-hole side plates; however, 4-hole plates have disadvantages, including longer surgery and greater postoperative pain, and there is little evidence that they provide increased stability. We compared 2- and 4-hole side plates in stable and unstable pertrochanteric fractures.

Methods: We prospectively enrolled consecutive patients with pertrochanteric femoral fractures treated between Jan. 1, 2004, and Apr. 30, 2009, with a 135° SHS using either a 2- or 4-hole side plate, based on surgeon preference.

Results: A total of 327 patients were managed with an SHS device (252 women, 75 men). There were 208 stable fracture patterns (AO/OTA 31 A1, A2.1) and 119 unstable (AO/OTA 31 A2.2, A2.3, A3). We managed 172 patients with 2-hole plates and 155 with 4-hole plates. The average duration of surgery (30.44 v. 51.45 min), blood loss (26.0 v. 31.3 g/L) and transfusion requirements (43% v. 31.60% transfusion) were significantly lower with the 2-hole than the 4-hole plate. There was no significant difference in length of stay (19 v. 16 d). With stable fractures there was no significant difference in failure rate (6.3% v. 4.9%). In unstable fractures there was a significantly higher rate of failure using 2-hole side plates (24.4% v. 10.8%).

Conclusion: In stable fractures, use of an SHS with a 2-hole side plate results in shorter surgery and less blood loss/transfusion than a 4-hole side plate, with equivalent survival. In unstable fractures, there is a greater than 2-fold rate of failure when a 2-hole side plate is used.

Contexte : La vis coulissante pour hanche (SHS) implique habituellement la pose de plaques latérales à 4 perforations; toutefois, ce type de plaque comporte des inconvénients, notamment une durée de chirurgie plus longue et des douleurs postopératoires plus persistantes, et il n’a pas été démontré qu’elle confère plus de stabilité. Nous avons comparé les plaques à 2 et à 4 perforations dans des fractures pertrochantériennes stables et instables.

Méthodes : Nous avons inscrit de manière prospective des patients consécutifs ayant des fractures pertrochantériennes du fémur et traités entre le 1er janvier 2004 et le 30 avril 2009 au moyen d’une SHS de 135° et d’une plaque latérale à 2 ou à 4 perforations, selon la préférence du chirurgien.

Résultats : En tout, 327 patients ont été traités de la sorte (252 femmes, 75 hommes). Nous comptons 208 fractures stables (AO/OTA 31 A1, A2.1) et 119 fractures instables (AO/OTA 31 A2.2, A2.3, A3). Nous avons traité 172 patients au moyen de plaques à 2 perforations, et 155 au moyen de plaques à 4 perforations. La durée moyenne de la chirurgie (30,44 c. 51,45 min), les pertes sanguines (26,0 c. 31,3 g/L) et les besoins transfusionnels (43 % c. 31,60 % transfusés) ont été significativement moindres avec les plaques à 2 perforations qu’avec les plaques à 4 perforations. On n’a noté aucune différence significative pour ce qui est de la durée du séjour hospitalier (19 c. 16 jours). En ce qui concerne les fractures stables, il n’y a pas eu de différence significative au plan du taux d’échec thérapeutique (6,3 % c. 4,9 %). En ce qui concerne les fractures instables, on a noté un taux significativement plus élevé d’échecs avec les plaques à 2 perforations (24,4 % c. 10,8 %).

Conclusion : Dans les fractures stables, l’utilisation d’une SHS et d’une plaque latérale à 2 perforations permet une chirurgie plus brève et cause moins de pertes sanguines et de transfusions que la plaque à 4 perforations, sans différence au plan de la survie. Dans les fractures instables, on observe un taux 2 fois plus élevé d’échecs lorsqu’on utilise une plaque latérale à 2 perforations.
The use of a sliding hip screw (SHS) and plate for the management of pertrochanteric femoral fractures introduced by Clawson in 1964 is well established as the gold standard of treatment. There is general consensus in the literature on the need to achieve medial and posterior cortical contact with the fracture reduction to improve physiologic distribution of force and on the positioning of the lag screw within the femoral head. Controversy remains, however, on the length of the plate used.

By convention a 4-hole plate has been traditionally used and allows for immediate weight bearing postoperatively. The reported disadvantages of a 4-hole plate, over a shorter side plate, include a longer incision and greater dissection, longer duration of surgery, more blood loss and greater postoperative pain. The evidence, however, of any increased stability conferred from the use of a 4-hole plate has been lacking.

In a biomechanical study conducted by Reich and colleagues, the optimal length of side plate was evaluated; they concluded that no more than 4 screws were necessary. Another cadaveric study was performed using a 3-hole side plate, which was found to provide adequate fixation. In that study, however, the specimens were not physiologically loaded, and the lag screw was prevented from telescoping. A comparison was performed by McLoughlin and colleagues between 2- and 4-hole side plates in cadaveric specimens with unstable 3-part fractures. They found that the 2-hole plate was as biomechanically stable as a 4-hole plate under the conditions tested.

Clinical studies using a 2-hole plate have also been published, demonstrating satisfactory outcomes and minimal complications. A study by Laohapoonrungsee and colleagues also found satisfactory results using a 2-hole plate with only 2 of 70 cases of side plate failure in unstable fractures. However, more than 80% of the cases resulting in moderate or severe collapse, using the method published by Bendo and colleagues, were in patients with an unstable fracture pattern.

Determining an outcome measure for these clinical studies is difficult, as mechanical failure of SHS is rare and these patients represent a group with multiple medical comorbidities and poor function preinjury. Objectively, however, Steinberg and colleagues found an increased rate of failure with more than 15 mm of telescoping of the lag screw. This excessive sliding has also been shown to be associated with greater postoperative pain.

It may be, therefore, that while a 2-hole plate is adequate for fixation of stable 2-part fractures, there may be an increased rate of failure with its use in patients with unstable fracture patterns.

The present study is a review of prospectively collected data for both stable and unstable pertrochanteric fractures treated at our institution with 2- or 4-hole side plates. We hypothesized that there would be a higher rate of failure associated with the use of 2-hole side plates in the management of unstable fractures.

### METHODS

All patients presenting to our level 1 trauma institution have prospective data collected in a database. This database includes demographic information; fracture type; duration of surgery; blood loss; length of stay in hospital; and follow-up data, including complications and reoperation. This study included all patients with stable and unstable pertrochanteric fractures treated between Jan. 1, 2004, and Apr. 30, 2009. Stable fractures were defined as AO/OTA type A1 and A2.1, and unstable fractures were defined as AO/OTA type A2.2, A2.3 and A3.

All surgeries were performed in a single institution by 1 of 5 staff surgeons, all of whom were subspecialty orthopedic trauma surgeons. Resident and fellow trainees were also involved in all cases; however, surgeries were performed under the direct supervision of the senior staff surgeon, who was present in the operating room at all times. All fractures were treated with 135° sliding hip screw (SHS; Synthes USA). The decision to use either a 2- or 4-hole side plate was based on surgeon preference in each case. At the time of the study, the preference was to use minimally invasive surgical techniques, favouring the 2-hole plate. However, there were no common criteria, and the decision was left entirely up to the surgeon. The plates were secured with 4.5 mm cortical screws.

Follow-up was attempted at intervals of 6 weeks until such time as fracture healing was determined both clinically and radiographically.

Failure of management was defined as the need for reoperation, implant failure, failure of fixation and nonunion. Excessive shortening was not used, as we did not have the ability to correlate this with follow-up data.

### RESULTS

We identified a total of 369 cases of pertrochanteric femur fractures treated during the study period. Nineteen patients died and were lost to follow-up, and 23 were excluded as they were not managed with a 2- or 4-hole side plate. There were therefore 320 patients with 327 pertrochanteric femoral fractures available for analysis (252 women, 75 men, mean age 85.5 yr, mean American Society of Anesthesiologists score 3.07; Table 1). There were 208 stable and 119 unstable fractures.

#### Table 1. Patient demographics in the 4 treatment arms

<table>
<thead>
<tr>
<th>Plate; fracture type</th>
<th>Fractures, no.</th>
<th>Average age, yr</th>
<th>Average ASA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2 hole</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable</td>
<td>127</td>
<td>83.6</td>
<td>2.98</td>
</tr>
<tr>
<td>Unstable</td>
<td>45</td>
<td>85.1</td>
<td>3.18</td>
</tr>
<tr>
<td><strong>4 hole</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable</td>
<td>81</td>
<td>87.1</td>
<td>3.08</td>
</tr>
<tr>
<td>Unstable</td>
<td>74</td>
<td>86.3</td>
<td>3.03</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists score.
The average duration of surgery was 38.44 minutes for procedures using a 2-hole side plate, which was significantly shorter than surgeries performed with a 4-hole plate (average duration 51.45 min, \( p < 0.001 \)).

The average change in hemoglobin pre- to postoperatively for cases involving a 2-hole plate was 26 g/L, with a transfusion rate of 43%. This was significantly less than that in cases using a 4-hole plate, which had an average change in hemoglobin of 31.3 g/L \( (p = 0.004) \) and a transfusion rate of 60%.

The average length of stay in hospital for patients treated with a 2-hole side plate was 19 days, whereas that for patients treated with a 4-hole plate was 16 days \( (p = 0.10) \).

There were 3 deep infections, 2 of which occurred in patients initially managed with a 2-hole side plate. One of these infections was successfully treated with irrigation, débridement and temporary antibiotic beads. The other required serial débridements and eventual conversion to a total hip arthroplasty. The third infection occurred in a patient treated with a 4-hole plate who was also managed successfully with irrigation, débridement and temporary antibiotic beads.

Fracture management with a 2-hole side plate failed in 19 of 172 (11%) patients. Seven failures were due to implant failure (plate pull-out and/or screw breakage). Seven were due to a loss of fixation, with lag screw cut-out from the femoral head. There were 3 cases of nonunion and 2 cases of deep infection requiring reoperation.

Fracture management with a 4-hole side-plate failed in 12 of 155 (7.7%) patients. There was 1 case of implant failure. Six cases were due to loss of fixation. Nonunion was diagnosed in 3 patients. There was 1 deep infection and 1 case of intraoperative fracture requiring revision.

The failure rate for stable fractures managed with a 2-hole plate was 8 of 127 (6.3%), and that for unstable fractures was 11 of 45 (24.4%). For stable fractures managed with a 4-hole side plate the failure rate was 4 of 81 (4.9%), and that for unstable fractures was 8 of 74 (10.8%; Table 2). There was no significant difference in failure rate between 2- and 4-hole fixation in patients with a stable fracture pattern \( (p = 0.68) \). There was a significantly higher rate of failure in those with unstable fractures when treated with a 2-hole side plate \( (p = 0.048) \).

**Discussion**

Consistent with previous studies, we found that the less invasive procedure of using a 2-hole side plate resulted in reduced duration of surgery, blood loss and need for transfusion compared with the 4-hole plate. There was no difference, however, in the overall length of stay in hospital between the 2 groups. This is likely a reflection of the premorbid function and medical comorbidities of these patients and the resulting difficulties in returning them to their previous level of independence postoperatively.

Overall, there was a relatively low rate of failure using both 2- and 4-hole side plates. This finding is also consistent with the results of published biomechanical and clinical studies.3–8,11–12 The previously reported clinical series, however, either compared the plates in the management of stable fractures specifically or had small samples of unstable fractures.

When we examined the failure rate allowing for fracture stability, there was a significantly higher rate of failure in patients with an unstable fracture pattern who were treated with a 2-hole side plate. This was in a much larger sample of patients with unstable fractures than previously reported.

The exact reason why 2-hole plates failed when used in patients with unstable fracture patterns is unclear, but it is interesting to note that there were 7 cases of implant failure with a 2-hole plate compared with only 1 implant failure with a 4-hole plate. It has been shown previously that most mechanical failures using SHS implants result in varus at the fracture site, which thereby increases tension at the screw-bone interface of the side plate.17 A longer plate with more screws may cope better with such forces.

Stable 2-part fracture patterns have minimal varus load with full weight bearing when adequately reduced. This is not the case, however, with comminuted unstable fractures that have lost their medial support, resulting in greater varus stress.3 These cases therefore have greater reliance on the fixation of the side plate to compensate for these increased forces.

**Conclusion**

We believe, based on our experience, that stable intertrochanteric fractures (AO/OTA 31A1 and A2.1) should be stabilized with a 2-hole side plate SHS because of shorter duration of surgery and less need for blood transfusion. For unstable patterns (AO/OTA A2.2, A2.3, A3), however, a 4-hole side plate is necessary to reduce the risk of mechanical failure.

**Competing interests:** P.J. O’Brien has received speaker fees from Zimmer, and his department receives academic funding from Depuy/Synthes. No other competing interests declared.
Contributors: All authors designed the study, acquired and analyzed the data. D. Cruickshank and R. Baird wrote the article, which all authors reviewed and approved for publication.

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Laparoscopic right hemicolecction with complete mesocolic excision provides acceptable perioperative outcomes but is lengthy — analysis of learning curves for a novice minimally invasive surgeon

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The data presented in this study have been presented as a podium presentation during the Canadian Association of General Surgeons annual conference in Calgary, Alta., Sept. 13–16, 2012.

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Background: Associated with reduced trauma, laparoscopic colon surgery is an alternative to open surgery. Furthermore, complete mesocolic excision (CME) has been shown to provide superior nodal yield and offers the prospect of better oncological outcomes.

Methods: All oncologic laparoscopic right colon resections with CME performed by a single surgeon since the beginning of his surgical practice were retrospectively analyzed for operative duration and perioperative outcomes.

Results: The study included 81 patients. The average duration of surgery was 220.0 (range 206–233) minutes. The initial durations of about 250 minutes gradually decreased to less than 200 minutes in an inverse linear relationship ($y = -0.58x + 248$). The major complication rate was 3.6% ± 4.2% and the average nodal yield was 31.3 ± 4.1. Cumulative Sum analysis showed acceptable complication rates and oncological results from the beginning of surgeon’s laparoscopic career.

Conclusion: Developing laparoscopic skills can provide acceptable outcomes in advanced right hemicolectomy for a surgeon who primarily trained in open colorectal surgery. Operative duration is nearly triple that reported for conventional laparoscopic right hemicolectomy. The slow operative duration learning curve without a plateau reflects complex anatomy and the need for careful dissection around critical structures. Should one wish to adopt this strategy either based on some available evidence of superiority or with intention to participate in research, one has to change the view of right hemicolectomy being a rather simple case to being a complex, lengthy laparoscopic surgery.

Contexte : La chirurgie du côlon par laparoscopie, qui réduit les traumatismes, est une solution de rechange à la chirurgie ouverte. De plus, il a été démontré que l’excision mésocolique complète (EMC) optimise le curage ganglionnaire et offre la perspective de meilleurs résultats oncologiques.

Méthodes : On a examiné rétrospectivement la durée de l’opération et les résultats périopératoires de toutes les résections du côlon droit réalisées par laparoscopie avec EMC pratiquées par un seul chirurgien depuis le début de sa carrière.

Résultats : L’étude a été menée auprès de 81 patients. La durée moyenne de l’intervention chirurgicale était de 220 minutes (intervalle de 206 à 233 minutes). Au début, l’intervention durait environ 250 minutes; avec le temps, sa durée a progressivement diminué de sorte qu’à la fin, elle était de moins de 200 minutes, d’après une relation linéaire négative ($y = -0.58x + 248$). Le taux de complications graves s’est établi à 3,6 % ± 4,2 % et le nombre moyen de nœuds lymphatiques excisés a été de 31,3 ± 4,1. En utilisant la méthode d’analyse des sommes cumulées, on a observé un taux de complications et des résultats oncologiques acceptables depuis le début de la carrière du chirurgien en laparoscopie.

Conclusion : En perfectionnant sa technique laparoscopique, un chirurgien formé principalement en chirurgie colorectale ouverte peut produire des résultats acceptables dans les cas d’hémicolectomie droite avancée. La durée de l’intervention chirurgicale est presque le triple de celle d’une hémicolectomie droite laparoscopique classique. La courbe d’apprentissage lente sans plateau montre bien la complexité des structures anatomiques et la nécessité de faire preuve de prudence lors de la résection autour de structures vitales. Quiconque souhaite adopter cette méthode, soit en raison de données démontrant sa supériorité ou dans le but de participer à une recherche, doit adopter une nouvelle perspective, c’est-à-dire que l’hémicolectomie droite laparoscopique n’est pas une intervention simple, mais une chirurgie complexe qui prend beaucoup de temps.
Laparoscopic colon surgery has been shown to offer clear evidence of benefit when compared to open surgery. These benefits include reduced length of hospital stay, earlier return of bowel function as well as reduced blood loss and pain without compromising quality of oncological resection and nodal yield.\textsuperscript{1-4} Furthermore, complete mesocolic excision (CME) has been demonstrated to provide superior nodal yield\textsuperscript{5} and offers prospects of better oncological outcomes than non-CME surgery.\textsuperscript{6} The purpose of this study is 2-fold: first, to analyze laparoscopic CME right hemicolecctiony with respect to operative durations and perioperative outcomes for a novice minimally invasive colorectal surgeon, and second, to draw conclusions with respect to the feasibility of adopting advanced laparoscopic right hemicolecctiony by a surgeon who primarily trained in open colon surgery.

**Methods**

From 2008–2011, prospective data on consecutive laparoscopic right hemicolectomies with CME for colon cancer were entered into a database and were later extracted for retrospective analysis. The surgical approach was approved by departmental committee, and patients provided informed consent.

All surgeries were performed by a single colorectal surgeon (B.S.M.) who was primarily trained in open colorectal surgery with general minimally invasive surgery (MIS) training in laparoscopic appendectomy and cholecystectomy. The surgeon had completed formal laparoscopic and robotic courses and had support from established MIS colorectal staff at his institution. Furthermore, the surgeon’s prior training involved open CME. The present series covers the beginning of his MIS colorectal practice.

**Statistical analysis**

Patient-specific data and outcome measures were analyzed using standard statistics. CumulativeSum (CUSUM) plots were used to track major complications and failures to harvest at least 12 lymph nodes. The CUSUM plots are commonly used to assess learning progress and proficiency in the medical field across many specialties, including colorectal surgery.\textsuperscript{7-9} They can be a valuable tool to rapidly depict unfavourable trends. The CUSUM plots are a visual representation of cumulative failures and successes; the plot starts at zero and goes down with success or up with failure. In its simplest form, as used in this study, the plot will decrease by a fraction consistent with established acceptable failure rate and up by a fraction consistent with a success rate. For example, if an acceptable rate of major complication is 10%, the graph will go down only by 0.1 units with a success and up by 0.9 units with a failure. Failure is therefore depicted more dramatically than success. While a plot centred on the zero line indicates a rate consistent with an established acceptable failure rate, upward and downward sloping plots indicate less and more favourable rates, respectively. A V-mask is an overlay shape in the form of a V on its side that is superimposed on the graph of the CUSUM in order to determine an out of control process. Minitab 15 statistical software was used to generate the CUSUM plots with the V-mask centred on the last case using standard settings, which assume Montgomery approximation.\textsuperscript{10} In the present study, for the purpose of generating a CUSUM plot, conversion to open surgery, perioperative death, hemorrhage, need for reoperation within 1 month and any leak or any type of intra-abdominal abscess were tracked and were considered operative failures. Conversion to open surgery was added to this category in order to simplify tracking operative failures for the CUSUM plots. Although, rates of these complications vary greatly, we chose an acceptable failure rate of 5%, as this rate would pass the bar set by all large trials.\textsuperscript{11-13} The American Joint Committee on Cancer (AJCC) recommends assessment of 12 or more nodes for accurate staging.\textsuperscript{14} Despite available reports on average yields of various right hemicolecctiony procedures, to our knowledge no studies report the rate of failure to retrieve at least 12 nodes in right hemicolecctiony. In their study of learning curves in laparoscopic sigmoidectomy, Choi and colleagues\textsuperscript{15} suggested a 10% lymph node retrieval failure rate for creating CUSUM plots.\textsuperscript{15} We set the failure rate to retrieve at least 12 lymph nodes at 10%, with the caveat that our actual rate could serve as the first reported benchmark for this parameter.

**CME laparoscopic right hemicolecctiony**

Although some adjustments were made during the initial period of about 15 cases, the following is a general description of the surgical technique used.

A 10 mm transumbilical camera port is placed through a 1 cm midline incision. This incision is later extended supra- and infraumbically for specimen extraction. The surgeon works mostly between the patient’s legs, using bilateral lower abdominal ports. An assistant applies traction as needed through a left upper quadrant (LUQ) port.

The root of the small bowel mesentery is lifted and the ileocecal junction is displayed. Adhesions and the peritoneum lateral to the ascending colon are incised past the hepatic flexure, staying between the embryological planes just anterior to the Gerota fascia, duodenum and ureter. The lateral mobilization proceeds carefully over the duodenum and pancreas with the landmark for the completion of lateral mobilization being the superior mesenteric vein.

The medial dissection begins by incising the base of the mesentery. The assistant’s grasper is used on the bloodless fold of Treves at the ileocecal junction to stretch up the mesentery toward the right lower quadrant port, lifting up the vessels from the retroperitoneum. This brings out a sulcus between the medial side of the ileocolic pedicle and
the retroperitoneum. An advanced energy device can eventually be used to further open the peritoneal opening and to isolate the vessels.

The preferred dissecting and sealing device is the curved EnSeal device with cutting blade (Ethicon Endo-Surgery). This is mostly for its ergonomics and ability to retain control over the length of a burn, allowing for faster work with avascular tissue.

When completely dissected, the ileocolic vessels are clipped at the root and transected. Having left a piece of gauze over the duodenum and pancreas from the lateral side at the conclusion of lateral dissection helps guide the depth of dissection and further assists in maintaining the correct dissection plane. The mesenteric dissection line is then extended further cephalad up to the origin of the right colic artery, if present, and toward the middle colic artery, which is always present.

The middle colic artery is always dissected to its origin from the superior mesenteric artery for maximal nodal yield. In limited resections involving very proximal lesions, dissection is often carried out further along the middle colic artery up to its bifurcation and only the right branch of the middle colic artery is transected. Lateral to the middle colic artery, the right colic vein, coursing anteriorly from the Henle trunk, can usually be identified and transected. All the central nodal tissue is then swept with the specimen.

With traction on the colon, the lesser sac is entered and the gastrocolic tissue is divided. The progress is continued along the mobilization plane, drawing the hepatic flexure inferiorly and medially. Generous distal resection margin is transected through the LUQ port using an endostapler. The remaining mesentery can then be transected using an advanced energy-based device, and the terminal ileum can be transected intracorporeally using an endostapler.

The specimen is put into an endo-bag, which is closed tight and parked over the liver for later retrieval through a 3 cm midline transumbilical incision. An intracorporeal anastomosis is performed, eliminating problems with extracorporeal delivery and unnecessary traction on the mesentery. The terminal ileum and transverse colon are aligned in side-to-side isoperistaltic fashion, and enterotomies are made for the insertion of an endostapler. Firing an endostapler through these enterotomies creates the crotch of the final anastomosis. The resulting common enterotomy is then put under tension using 3 traction sutures, and the enterotomy is closed with another load of endostapler completing the side-to-side, functional end-to-end anastomosis. Figure 1 shows an intracorporeal view of dissection extent, and Figure 2 shows a typical retrieved specimen.

RESULTS

The study included 81 patients. Data summarizing preoperative parameters and operative outcomes are shown in Table 1. Outcome results feature a major complication rate of 3.6%, which includes conversions, leaks/intra-abdominal abscesses and a need for reoperation for an early trocar hernia. The average nodal yield was 31.3. The average duration of surgery was 220.0 minutes. The duration of surgery curve (Fig. 3), shows that the initial duration of surgery of about 250 minutes gradually decreased to less than 200 minutes by the 81st case in an inverse linear relationship with successive cases \((y = -0.58 \times 248)\).

Finally, CUSUM plots (Fig. 4 and Fig. 5) indicate acceptable nodal yields and complication rates from the beginning of surgeon’s laparoscopic practice.

DISCUSSION

While adoption of total mesorectal excision in the management of rectal cancer has led to significant improvement in survival, the survival rates for colon cancer have
improved only slightly in the last 2 decades; disease-free survival rates for rectal cancer have even surpassed those for colon cancer in some studies.\textsuperscript{16–20} The reported survival rates for colon cancer vary widely among centres but seem higher in centres that routinely perform standardized, extensive colonic resections\textsuperscript{6,21,22}—a fact that may be subject to selection bias. Some of the most intriguing results come from Erlangen, Germany, reporting an 18% improvement in 5-year survival following the standardization of colonic resection to include CME.\textsuperscript{23} This result seems to be mostly attributable to surgery, as their data originate from a period before instigating adjuvant chemotherapy.\textsuperscript{23,24} Although most of these results are based only on regional, non-comparative studies and a multitude of other contributing factors, such as patient characteristics, regional diet and type of adjuvant care received, play a role, the published outcomes suggest probable room for optimizing surgical management. To our knowledge, no readily available studies have been published that specifically address laparoscopic colectomies with CME in the context of long-term survival.

Future research is necessary to quantify the effect CME has on survival rates for right-sided colon cancer.

### Table 1. Preoperative parameters and perioperative outcomes ($n = 81$)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Mean (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative parameters</strong></td>
<td></td>
</tr>
<tr>
<td>Age, yr</td>
<td>63.7 (60.7–66.76)</td>
</tr>
<tr>
<td>Sex, % male</td>
<td>58.0 (47.3–68.8)</td>
</tr>
<tr>
<td>BMI</td>
<td>23.3 (22.60–23.92)</td>
</tr>
<tr>
<td>Stage, %</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1.2 (0.0–3.6)</td>
</tr>
<tr>
<td>I</td>
<td>25.9 (16.4–35.5)</td>
</tr>
<tr>
<td>II</td>
<td>33.3 (23.1–43.6)</td>
</tr>
<tr>
<td>III</td>
<td>35.8 (25.4–46.2)</td>
</tr>
<tr>
<td>IV</td>
<td>3.7 (0.0–7.8)</td>
</tr>
<tr>
<td>Anesthesia ASA score, median (min–max)</td>
<td>2 (1–3)</td>
</tr>
<tr>
<td><strong>Operative outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>OR time, min</td>
<td>220 (206–233)</td>
</tr>
<tr>
<td>EBL, mL</td>
<td>116 (83–148)</td>
</tr>
<tr>
<td>No. of lymph nodes harvested</td>
<td>31.3 (27.2–35.4)</td>
</tr>
<tr>
<td>Lymph node yield &lt; 12, %</td>
<td>7.4 (1.7–13.10)</td>
</tr>
<tr>
<td>Major complications, %</td>
<td>3.7 (0.0–7.8)</td>
</tr>
<tr>
<td>Conversion to open†</td>
<td>0.0</td>
</tr>
<tr>
<td>Death/hemorrhage</td>
<td>0.0</td>
</tr>
<tr>
<td>Leak or any intra-abdominal abscess</td>
<td>2.6 (0.0–5.9)</td>
</tr>
<tr>
<td>Need for reoperation within 1 mo (incarcerated trochar site hernia)</td>
<td>1.2 (0.0–3.6)</td>
</tr>
<tr>
<td>Positive resection margin</td>
<td>0.0</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; BMI = body mass index; CUSUM = CumulativeSum; CI = confidence interval; EBL = estimated blood loss; OR = operating room.

*Conversion to open was added to this category in order to track operative failures, as defined for the CUSUM plots.

**Fig. 3.** Total duration of surgery. Ten-case moving average with best fit curve. OR = operating room.

**Fig. 4.** Outcome CumulativeSum curve with V-mask tracking failure to harvest at least 12 nodes, assuming an acceptable failure rate of 10%.

**Fig. 5.** Outcome CumulativeSum (CUSUM) curve with V-mask tracking major complications, as featured in Table 1, assuming an acceptable failure rate of 5%.
However, this was not the purpose of the present study. The intent of this study was to provide guidance to surgeons wishing to adopt this strategy based on the previously published evidence by showing that laparoscopic CME is possible with acceptable perioperative outcomes and outstanding nodal yields when adhering to good surgical principles. The results presented in this report suggest that a laparoscopic right-sided hemicolectomy with CME can be performed safely by a colorectal surgeon who primarily trained in open colorectal surgery in a setting where the surgeon attended a formal laparoscopic course and where adequate laparoscopic prototyping is available. This finding is demonstrated by CUSUM curves showing that perioperative safety and nodal yields were not compromised even early in the surgeon’s practice.

The average nodal yield of 31.3 is consistent with previously published reports of 30 lymph nodes with right hemicolectomy and CME and is superior to average yields of fewer than 20 lymph nodes with conventional surgery. We report a failure rate to retrieve at least 12 lymph nodes of 7.4% to serve as, to our knowledge, a first reported reference rate for this type of surgery. Although our results offer insight into the adoption of MIS among surgeons trained primarily in open surgery, they serve only as a guide because they are not necessarily generalizable as they originate from a single surgeon’s experience operating on a specific patient population.

A lateral to medial approach was used in our study. Not only is such an approach familiar from open surgery, it also helps ensure a correct dissection plane, which is often lost when performing CME from a medial approach. To surgeons who prefer high ligation of the ileocolic vessels early during the operation for further theoretical oncological reasons, we recommend simple ligation of the vessels using the medial approach followed by lateral mobilization to ensure a correct dissection plane before completing the medial dissection.

Duration of surgery remains one of the largest obstacles for laparoscopic CME. The operative duration learning curve reveals initial durations of about 250 minutes, which is more than double the durations reported for conventional laparoscopic right hemicolectomy performed by experienced laparoscopic surgeons. However, the duration decreased to below 200 minutes by the end of the study. Reflecting complex anatomy and the need for careful dissection around critical anatomic structures, especially during central vessel ligation, the operative duration learning curve reveals a rather slow linear inverse relationship between duration of surgery and successive operative cases. This relationship continues being linear without reaching a plateau, even at the end of the study, indicating potential for further improvement beyond the initial 81 cases.

**Conclusion**

In the current knowledge milieu where laparoscopic colon surgery provides superior perioperative outcomes and CME further offers prospects of better oncological outcomes, this data set offers encouragement in terms of feasibility to surgeons primarily trained in open colon surgery who wish to expand their skill set and can justify the additional time required. The question remaining is whether surgeons in North America should first adopt open CME or whether it is feasible to learn laparoscopic CME directly.

**Competing interests:** None declared.

**Contributors:** G. Melich, H. Hur, S.H. Baik, J. Faria, N.K. Kim and B.S. Min designed the study. D.H. Jeong and B.S. Min acquired the data, which G. Melich, D.H. Jeong, J. Faria and B.S. Min analyzed. G. Melich and B.S. Min wrote the article, which all authors reviewed and approved for publication.

**References**


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We hope to hear from you!
The clinical importance of different localizations of the papilla associated with juxtapapillary duodenal diverticula

Background: Previous studies have evaluated the presence of juxtapapillary duodenal diverticula (JPDD) and the association with pancreatobiliary disease, but not the association of the papilla with an existing JPDD. We investigated the association of different localizations of the papilla with JPDD.

Methods: We studied patients in whom JPDD was detected during endoscopic retrograde cholangiopancreatography. Patients were classified into 3 groups: 1) papilla located inside the diverticulum, 2) papilla located at the edge of the diverticulum and 3) papilla located closer than 3 cm to the diverticulum. The patients were examined with respect to localization of papilla-diverticula and to the association of the localization with pancreatobiliary disease.

Results: We enrolled 274 patients in our study. Biliary stone disease more frequently existed in group 3. The number of patients presenting with obstructive jaundice was higher in groups 2 (83.6%) and 3 (83.3%) than group 1 (66%). Cholangitis was more common in group 1 (21.3%) than in groups 2 (6.7%) and 3 (2.3%). The presence of biliary stone disease among patients presenting with pancreatitis was significantly different between groups 1 and 3 (p = 0.013) and between groups 2 and 3 (p = 0.017). The common bile duct more frequently contained stones or sludge in group 3 than in groups 1 and 2.

Conclusion: When the papilla is located close to the JPDD, the incidence of biliary stone disease decreases, and pancreatobiliary diseases are caused mostly in the absence of biliary stone disease.
Joddenal diverticula (DD) are classified as primary (true) or secondary (false) diverticula. Primary diverticula are mostly solitary and can be observed in the second part of the duodenum, in the ampulla vateri region (periampullary diverticula). They are also called juxtapapillary duodenal diverticula (JPDD). The clinical importance of JPDD originates from its association with the papilla and pancreaticobiliary disease. Several studies have suggested that JPDD are the reason for biliary stone disease. However, the association of the papilla with the diverticula and the effect of different positions of the papilla on biliary stone disease have not been investigated. To our knowledge, this association was first investigated in an earlier study conducted in our clinic. The present paper presents further results of this investigation.

Methods

This study was designed in a retrospective manner. We reviewed the cases of patients admitted to the Endoscopy Unit of the Department of General Surgery, Ataturk University School of Medicine, between May 1999 and December 2007 for endoscopic retrograde cholangiopancreatography (ERCP), and we enrolled those in whom JPDD were detected during ERCP. We noted the age and sex of the patients, indications for ERCP and endoscopic sphincterotomy (ES), the association of the JPDD with the papilla, laboratory values, cannulation success of the biliary tract and the diameter and contents of the common bile duct (CBD). We examined the localization of the papilla–diverticula and the association of the localization with pancreaticobiliary disease. The indications for ERCP were obstructive jaundice, cholangitis and pancreatitis. Patients who had gallbladder stones (including patients who previously underwent cholecystectomy for known gallbladder stones and patients who had a gallbladder stone and were not operated on at the time when the study was conducted), CBD stones, or both were considered to have biliary stone disease. Obstructive jaundice was defined as hyperbilirubinemia caused by mechanical obstruction of the biliary tract; cholangitis was defined as hyperbilirubinemia accompanied by fever and leucocytosis; and pancreatitis was defined as strongly suggestive evidence for pancreaticitis of biliary origin (radiological and laboratory findings). Patients with known hepatocellular diseases, such as viral or toxic hepatitis, cirrhosis, hepatic or biliary malignancies, or hepatic or biliary benign masses, patients using medication influencing the hepatocellular functions, and patients who were operated on previously for a biliary tract disease (not cholecystectomy) were excluded from the study. Patients were classified according to the location of the papilla and diverticula into 3 groups, as done by Yildirgan and colleagues: 1) papilla located inside the diverticulum, 2) papilla located at the edge of the diverticulum and 3) papilla located closer than 3 cm to the diverticulum. Patients with a papilla far away from the diverticulum were excluded. The patients were followed for at least 18 (range 18–24) months.

Statistical analysis

We conducted our analyses using SPSS software version 12.0 for Windows. Data were compared among the 3 groups. In addition, the association between indications for ERCP and biliary stone disease were investigated within groups. We conducted Student t tests for continuous variables and the χ2 test or Fisher exact test for categorical variables. We considered results to be significant at p < 0.05.

Results

A total of 2327 patients underwent ERCP in our endoscopy unit during our study period. Of these, 274 (11.7%) had JPDD. Twenty-five patients did not meet the inclusion criteria and were excluded. From the remaining 249 patients with JPDD, 103 (41.3%) were in group 1, 104 (41.7%) were in group 2, and 42 (17%) were in group 3.

The mean age; sex; indications; mean levels and activities of serum total bilirubin, conjugated bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), γ-glutamyl transferase (GGT) and alkaline phosphatase (ALP); deep cannulation success of the CBD; and mean diameter of the CBD are shown in Tables 1–4.

In group 1 (n = 103), 38 (36.9%) patients had biliary stones. Twelve (31.6%) of them had only gallbladder stones, 17 (44.7%) had both CBD and gallbladder stones, and 9 (23.7%) had only CBD stones.

In group 2 (n = 104), 35 (33.6%) patients had biliary stones. Six (17.1%) of them had only gallbladder stones, 19 (54.3%) had both CBD and gallbladder stones, and 10 (28.6%) had only CBD stones.

In group 3 (n = 42), 33 (78.6%) patients had biliary stones. Eight (23.2%) of them had only gallbladder stones, 19 (57.6%) had both CBD and gallbladder stones, and 6 (18.2%) had only CBD stones.

The number of patients presenting with obstructive jaundice was higher in groups 2 (83.6%) and 3 (83.3%) than in group 1 (66%; both p = 0.016). When the presence of biliary stone disease was compared among patients presenting with obstructive jaundice, patients in group 3 had a higher incidence of biliary stone disease than patients in the other 2 groups (both p = 0.001), and there was no difference between groups 1 and 2.

The number of patients who presented with cholangitis was significantly higher in group 1 (21.3%) than in groups 2 (6.7%, p = 0.011) and 3 (2.3%, p = 0.001). Among patients with cholangitis, 22.7% in group 1, 57.1% in group 2 and 100% in group 3 had biliary stone disease. There was a significant difference between groups 1 and 2 (p = 0.013), 1 and 3 (p = 0.001), and 2 and 3 (p = 0.014).
There was no difference among the groups in the presence of pancreatitis. The presence of biliary stone disease among patients presenting with pancreatitis was significantly different between groups 1 (38.4%) and 3 (83.3%, \( p = 0.013 \)) and between groups 2 (50%) and 3 (83.3%, \( p = 0.017 \); Table 1).

The CBD more frequently contained stones or sludge in group 3 than in the other groups (both \( p = 0.016 \)).

### Table 1. Shows age, sex, cannulation success and CBD diameter

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group 1, ( n = 103 )</th>
<th>Group 2, ( n = 104 )</th>
<th>Group 3, ( n = 42 )</th>
<th>Total, ( n = 249 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (IQR), yr</td>
<td>63.1 (31–80)</td>
<td>66.8 (34–85)</td>
<td>64.1 (29–76)</td>
<td>64.7 (29–85)</td>
</tr>
<tr>
<td>Sex, male/female</td>
<td>36:67</td>
<td>41:63</td>
<td>16:24</td>
<td>93:154</td>
</tr>
<tr>
<td>Cannulation success on first attempt, no. (%)</td>
<td>88 (85.4)</td>
<td>92 (88.4)</td>
<td>38 (90.4)</td>
<td>218 (87.5)</td>
</tr>
<tr>
<td>CBD diameter, mean, mm</td>
<td>14.6</td>
<td>14.3</td>
<td>15.2</td>
<td>14.7</td>
</tr>
</tbody>
</table>

CBD = common bile duct; IQR = interquartile range.

### Table 2. Indications for intervention

<table>
<thead>
<tr>
<th>Indication</th>
<th>Group 1, ( n = 103 )</th>
<th>Group 2, ( n = 104 )</th>
<th>Group 3, ( n = 42 )</th>
<th>Total, ( n = 249 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstructive jaundice</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>68 (66)</td>
<td>87 (83.6)</td>
<td>35 (83.3)</td>
<td>190 (76.3)</td>
</tr>
<tr>
<td>BSD</td>
<td>28 (41.1)</td>
<td>26 (29.8)</td>
<td>27 (77.1)</td>
<td>81 (42.6)</td>
</tr>
<tr>
<td>Cholangitis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>22 (21.3)</td>
<td>7 (6.7)</td>
<td>1 (2.3)</td>
<td>30 (12)</td>
</tr>
<tr>
<td>BSD</td>
<td>5 (22.7)</td>
<td>4 (17.1)</td>
<td>1 (100)</td>
<td>10 (33.3)</td>
</tr>
<tr>
<td>Biliary pancreatitis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>13 (12.6)</td>
<td>10 (9.6)</td>
<td>6 (14.2)</td>
<td>29 (11.6)</td>
</tr>
<tr>
<td>BSD</td>
<td>5 (38.4)</td>
<td>5 (50)</td>
<td>5 (83.3)</td>
<td>15 (51.7)</td>
</tr>
</tbody>
</table>

BSD = biliary stone disease.

### Table 3. Patient laboratory data

<table>
<thead>
<tr>
<th>Laboratory data</th>
<th>Group 1, ( n = 103 )</th>
<th>Group 2, ( n = 104 )</th>
<th>Group 3, ( n = 42 )</th>
<th>Total, ( n = 249 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>75.60</td>
<td>71.49</td>
<td>68.07</td>
<td>68.59</td>
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<tr>
<td>Conjugated</td>
<td>28.56</td>
<td>33.35</td>
<td>28.05</td>
<td>30.44</td>
</tr>
<tr>
<td>AST, ( \mu \text{kat/L} )</td>
<td>1.15</td>
<td>1.29</td>
<td>0.94</td>
<td>1.09</td>
</tr>
<tr>
<td>ALT, ( \mu \text{kat/L} )</td>
<td>1.30</td>
<td>1.46</td>
<td>1.19</td>
<td>1.29</td>
</tr>
<tr>
<td>GGT, ( \mu \text{kat/L} )</td>
<td>5.68</td>
<td>5.32</td>
<td>4.03</td>
<td>4.65</td>
</tr>
<tr>
<td>ALP, ( \mu \text{kat/L} )</td>
<td>5.88</td>
<td>6.20</td>
<td>5.69</td>
<td>5.60</td>
</tr>
</tbody>
</table>

ALT = alanine amino transferase; ALP = alkaline phosphatase; AST = aspartate amino transferase; GGT = \( \gamma \)-glutamyl transferase.

### Table 4. Common bile duct content and biliary stone presence

<table>
<thead>
<tr>
<th>Presence</th>
<th>Group 1, ( n = 103 )</th>
<th>Group 2, ( n = 104 )</th>
<th>Group 3, ( n = 42 )</th>
<th>Total, ( n = 249 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBD content</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>77 (74.7)</td>
<td>75 (72.1)</td>
<td>17 (40.4)</td>
<td>169 (67.8)</td>
</tr>
<tr>
<td>Stone or sludge</td>
<td>26 (25.3)</td>
<td>29 (27.9)</td>
<td>25 (59.6)</td>
<td>80 (32.7)</td>
</tr>
<tr>
<td>Biliary stone</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gallbladder stone only</td>
<td>12 (11.6)</td>
<td>6 (5.7)</td>
<td>8 (19)</td>
<td>26 (10.4)</td>
</tr>
<tr>
<td>CBD stone only</td>
<td>9 (8.7)</td>
<td>10 (9.6)</td>
<td>6 (14.2)</td>
<td>25 (10)</td>
</tr>
<tr>
<td>Gallbladder and CBD stone</td>
<td>17 (16.5)</td>
<td>19 (18.2)</td>
<td>19 (45.2)</td>
<td>55 (22)</td>
</tr>
<tr>
<td>Total BSD</td>
<td>38 (36.8)</td>
<td>35 (33.6)</td>
<td>33 (78.5)</td>
<td>106 (42.5)</td>
</tr>
</tbody>
</table>

BSD = biliary stone disease; CBD = common bile duct.
Biliary stone disease (including gallbladder stone, CBD stone, or both) more frequently existed in group 3 than in the other 2 groups (both \( p = 0.014 \)). The biochemical values of bilirubin (total and conjugated), AST, ALT, GGT and ALP did not differ significantly among the groups. The CBD diameters and cannulation success of the CBD were also similar among the groups.

The median follow-up period was 61 (range 6–71) months. A total of 19 patients (7 in group 1, 9 patients in group 2, and 3 patients in group 3) were readmitted to the clinic because of different reports of pancreatobiliary origin. Only 6 patients underwent re-evaluation with ERCP (2 in group 1, 3 in group 2, and 1 in group 3). There was no recurrent stone disease in readmitted patients.

**Discussion**

Several studies on the association between JPDD and biliary stone disease have been performed. Most of these studies state that biliary stone disease is associated with JPDD. The pathological mechanism of this association is explained by several hypotheses. The mechanical pressure of the diverticulum to the distal end of the biliary tract is commonly discussed. Another simple explanation is the dysfunction of the sphincter of Oddi (SO), which is believed to be caused by the accumulation of food in the diverticulum, putting pressure on the end of the bile duct and SO and leading to structure of the sphincter. The dysfunction of the SO causes obstruction and stasis of bile juice. Additional reflux caused by contractional malfunction of the sphincter leads to the reflux of gastrointestinal juice into the bile duct, bacterial infection of the bile duct and formation of pigment bile duct stones.\(^2\)\(^-\)\(^6\) The dysfunction of the SO (decrease of the pressure) has been demonstrated in manometric studies.\(^3\)\(^,\)\(^10\) The clinical result of the dysfunction of SO is the formation of CBD stones, infection (cholangitis) or pancreatic disease.

We sought to investigate the clinical effect of different localizations of the papilla associated with JPDD and management. We investigated whether the localization of the papilla was associated with JPDD, if this was important in the clinical presentation of JPDD, and what the therapeutic approach should be.

The reported incidence of biliary stone formation in patients with JPDD varies between 10% and 32%.\(^1\)\(^,\)\(^11\)\(^-\)\(^15\) In our series the incidence was 11.7%. Our patients had a median of age of 64.7 (range 29–85) years. It has been reported that DD is a disease of advanced age; the mean age of patients is reported to be 70–79 years in some series. It has been reported that the association with advanced age suggests a degenerative process involving local supporting structures as an additional factor in the pathogenesis of JPDD.\(^4\)\(^,\)\(^11\)\(^,\)\(^13\) We found no age difference among the groups.

The clinical presentation of JPDD is associated with biliary symptoms, including cholangitis, obstructive jaundice and pancreatitis.\(^3\)\(^,\)\(^16\)\(^-\)\(^22\)

The clinical presentation of our patients was mostly associated with elevated bilirubin and other liver enzymes, including AST, ALT, GGT and ALP, with or without abdominal pain, fever and leukocytosis (obstructive jaundice or cholangitis). It has been reported that patients with JPDD had less abdominal pain and more symptoms of biliary obstruction than patients without JPDD.\(^3\)\(^,\)\(^16\)\(^-\)\(^22\) The values of bilirubin (total and conjugated), AST, ALT, GGT and ALP did not differ among the groups. Patients in groups 2 and 3 were more likely to be admitted with symptoms of obstructive jaundice. But, the existence of biliary stone disease among patients with obstructive jaundice was different among the groups. Patients in group 3 had biliary stones more frequently than those in other groups.

Cholangitis was commonly seen in group 1. Zoepf and colleagues\(^3\) reported that supplicative cholangitis was more frequent in patients with JPDD than in control patients, but that this difference was not significant.\(^3\) They also claimed that the higher cholangitis rate associated with JPDD in their series was based only on the bile duct obstruction resulting from bile duct stones rather than on specific mechanisms associated with JPDD (e.g., ascending bacteria).\(^3\) In our series, however, cholangitis was more frequent in group 1, and these patients had biliary stone disease less frequently than those in the other groups. In contrast to Zoepf and colleagues,\(^3\) we thought that the high cholangitis rate in group 1 should be associated with specific mechanisms associated with JPDD rather than bile duct obstruction resulting from bile duct stones. Furthermore, obstructive jaundice was more commonly associated with biliary stone disease in group 3 patients. These 2 findings lead us to speculate that cholangitis and obstructive jaundice resulting from biliary obstruction were more commonly associated with stones in group 3 patients. Moreover, when the papilla is located closer to the JPDD, and even when the papilla is located inside it, cholangitis and obstructive jaundice become less frequently associated with the biliary stones.

There are some different reports about the development of pancreatitis in JPDD. Some investigators have suggested that pancreatitis is not associated with JPDD.\(^1\)\(^,\)\(^2\)\(^1\) Others reported that patients with DD have a higher rate of acute pancreatitis.\(^2\)\(^4\)\(^-\)\(^6\) The mechanism of pancreatitis in these patients is believed to be mainly of biliary origin. However, other investigators have suggested that JPDD is associated with acute idiopathic pancreatitis and have postulated that DD is a risk factor for acute idiopathic pancreatitis, especially in elderly patients.\(^2\)\(^6\) In our series, pancreatitis existed in 29 (11.6%) patients. We are not able to discuss the association with pancreatitis because we did not include control patients in the study. However, when the existing patients were evaluated, the distribution was homogeneous among
groups and there was no significant difference among the groups. We determined that the presence of biliary stone disease among patients presenting with pancreatitis differed significantly between groups 1 and 3 (p = 0.013) and groups 2 and 3 (p = 0.017). We think that this finding suggests that JPDD is associated with acute idiopathic pancreatitis and that DD is a risk factor for acute idio‑
pathic pancreatitis, especially when the papilla is located close to the JPDD. We also think that pan‑creatitis is caused by specific mechanisms, as mentioned previously.

Boix and colleagues11 have proposed a classification of the localization of the papilla according to the JPDD. They reported that JPDD do not significantly increase the difficulty of deep cannulation. We had an overall cannulation success rate of 87.5% at the first occurrence of ERCP. All patients were cannulated during the study for the first or second time. There was no statistical difference in cannulation success among the groups. We found that cannulation success did not depend on the localization of the papilla.

All of our patients underwent sphincterotomy. In our earlier paper, we stated that ES should be performed in the presence of biliary stone disease in group 3 patients.4 The present findings lead us to the same conclusion. Our findings showed that the biliopancreatic presentation of the JPDD depends on the existence of biliary stone disease in group 3 patients, and is partially independent from biliary stone disease in groups 1 and 2. Thus, we suggest ES in groups 1 and 2 even if there is no existing biliary stone disease. In group 3, ES should be performed according to the guidelines for biliary stone disease independently from JPDD.

CONCLUSION

When the papilla is located close to the JPDD, the incidence of biliary stone disease decreases, and pancreatobiliary diseases are caused mostly in the absence of biliary stone disease.

Competing interests: None declared.

Contributors: B. Ozogul, G. Ozturk, B. Aydinli and S.S. Atamanalp designed the study. B. Ozogul, A. Kisaoglu and M. Yildirgan acquired the data, which B. Ozogul, G. Ozturk and A. Kisaoglu analyzed. B. Ozogul, G. Ozturk, A. Kisaoglu, B. Aydinli and S.S. Atamanalp wrote the article, which B. Ozogul and M. Yildirgan reviewed. All authors approved the final version for publication.

References

Factors affecting transfusion requirement after hip fracture: Can we reduce the need for blood?

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Background: Hip fractures are common injuries that result in blood loss and frequently require the transfusion of blood products. We sought to identify risk factors leading to increased blood transfusion in patients presenting with hip fractures, especially those factors that are modifiable.

Methods: We retrospectively reviewed the cases of all patients who had fixation of their hip fractures between October 2005 and February 2010. The need for transfusion was correlated with potential risk factors, including age, sex, preoperative hemoglobin, fracture type, fixation method and more.

Results: A total of 835 patients had fixation of their hip fractures during the study period; 631 met the inclusion criteria and 249 of them (39.5%) were transfused. We found an association between need for blood transfusion and female sex (p = 0.018), lower preoperative hemoglobin (p < 0.001), fracture type (p < 0.001) and fixation method (p < 0.001). Compared with femoral neck fractures, there was a 2.37 times greater risk of blood transfusion in patients with intertrochanteric fractures (p < 0.001) and a 4.03 times greater risk in those with subtrochanteric fractures (p < 0.001). Dynamic hip screw (DHS) fixation decreased the risk of transfusion by about half compared with intramedullary nail or hemiarthroplasty. We found no association with age, delay to operation (p = 0.17) or duration of surgery (p = 0.30).

Conclusion: The only modifiable risk factor identified was fixation method. When considering blood transfusion requirements in isolation, we suggest a potential benefit in using a DHS for intertrochanteric and femoral neck fractures amenable to DHS fixation.
Hip fractures are among the most common fractures treated by orthopedic surgeons. With increasing life expectancy, it is estimated that the number of people aged 65 and older will increase from the recent estimate of 323 million to 1555 million by the year 2050. As a result, it is estimated that the number of hip fractures occurring worldwide will increase from 1.66 million in 1990 to 6.26 million in 2050.1

Hip fractures result in blood loss and frequently require the transfusion of blood products. While blood transfusions are potentially life-saving interventions, they can also cause patient morbidity. Blood transfusions are correlated with an increased risk of bacterial infections2–7 and possibly increased mortality.8,9 There are also substantial costs involved in the collection, preparation, transport and administration of blood.

In the United States, more than 15 million units of blood are transfused annually.10 Many of these transfusions are given to surgical patients, including elderly patients with hip fractures. We sought to determine whether any modifiable risk factors for transfusion exist. The purpose of this study, therefore, was to assess risk factors for blood transfusion requirements in patients presenting with hip fractures. We performed a retrospective study at a single level I trauma centre from 2005 to 2010. Blood transfusion requirements were correlated with patient variables, such as age, sex, delay to surgery, duration of surgery, preoperative hemoglobin, fracture type and fixation method.

METHODS

All patients undergoing surgical fixation of their hip fractures in a single academic trauma centre between October 2005 and February 2010 were included in this retrospective study. The fracture patterns included were femoral neck, intertrochanteric and subtrochanteric fractures. Fixation methods used included hemiarthroplasty, dynamic hip screw (DHS), cannulated screws and cephalomedullary nails. The study was approved by our institution’s review board. All patient information, including laboratory values and operative notes, were collected from our institution’s electronic patient database, Powerchart (Cerner Corporation). Blood transfusion information was collected from our institution’s blood transfusion laboratory.

The type of hip fracture was documented based on review of patients’ preoperative and postoperative radiographs. These included femoral neck fractures (AO-OTA 31-B1–4), intertrochanteric fractures (AO-OTA 31-A1–3) and subtrochanteric fractures (AO-OTA 32A,1–3 32-B[1–3] and 32-C[1–3]). Surgical fixation was documented based on review of patients’ preoperative and postoperative radiographs. The DHS used was from Synthes. All hemiarthroplasties were performed with the Conquest system (Smith & Nephew) through a standard Hardinge approach. The intramedullary nails were either Trigen or Intertan (both from Smith & Nephew). The cannulated screws were 7.3-mm screws (Synthes Inc). The following measures were recorded from the patients’ electronic charts: sex; age; American Society of Anesthesiologist (ASA) score; duration of surgery; and need for preoperative, intraoperative and postoperative blood transfusion. Time from admission to operation was also documented and was defined as the time from admission to our institution’s emergency department to the start of the operation. Criteria for administration of blood transfusion were a hemoglobin value less than 70 g/L or less than 80 g/L with signs/symptoms of anemia.

Patients were excluded from this study if they were younger than 60 years; had a known cancer in the region of the fracture; had a hemorrhagic complication in another anatomic site, such as a gastrointestinal bleed, pre- or postoperatively; were admitted to hospital for other clinically important comorbidities, such as sepsis or polytrauma; were undergoing revision surgery; had an intraoperative complication, such as a trochanteric fracture; were therapeutically anticoagulated or had documented hematologic disease before surgery; or had a delay in diagnosis of their fracture longer than 1 week.

Notably, all patients received thromboembolic prophylaxis with 5000 units of low molecular-weight heparin (dalteparin sodium, Pfizer Canada). This therapy was started on admission, withheld on the day of surgery and restarted on the first postoperative day.

Statistical analysis

We performed our statistical analyses using SPSS software. We conducted a univariate analysis of all independent variables (i.e., age, sex, duration of surgery, preoperative hemoglobin level, fracture type, fixation method) to establish an association with blood transfusion requirement. Variables that were found to have a significant association were then included in a multivariate analysis. We considered results to be significant at $p < 0.05$.

RESULTS

A total of 835 patients had fixation of their hip fractures during the study period; 631 patients met the inclusion criteria (Fig. 1). Forty-one patients were excluded because of multiple injuries, 73 patients were anticoagulated, 32 had pathologic or pending pathologic fractures, 23 had a significant hemorrhagic complication unrelated to their hip fracture, 16 underwent revision surgery, 9 experienced an intraoperative complication, 4 were excluded because of poor documentation and 6 were delayed to surgery because the fracture diagnosis was delayed longer than 1 week (Fig. 1).

The mean age was 81.6 (range 60–100) years. The sample comprised 455 women (72.1%, mean age 82.4 yr) and 176 men (27.9%, mean age 79.3 yr; Table 1). The mean delay from admission to surgery was 48.9 hours. Of the 631 patients in the study, 249 patients were transfused (39.5%). This group included 26% of patients with femoral...
Table 1. Characteristics of study participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)</th>
<th>n = 618</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD yr</td>
<td>81.6 ± 8.7</td>
<td></td>
</tr>
<tr>
<td>Sex, female</td>
<td>444 (71.8)</td>
<td></td>
</tr>
<tr>
<td>Delay to OR in h mean ± SD</td>
<td>48.9 ± 33.4</td>
<td></td>
</tr>
<tr>
<td>Delay to OR in h median (IQR)</td>
<td>43.3 (26.1–63.2)</td>
<td></td>
</tr>
<tr>
<td>Duration of surgery, mean ± SD min</td>
<td>63.3 ± 23.8</td>
<td></td>
</tr>
<tr>
<td>Preoperative hemoglobin, mean ± SD</td>
<td>118.8 ± 16.0</td>
<td></td>
</tr>
<tr>
<td>Fracture type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Femoral neck</td>
<td>318 (51.5)</td>
<td></td>
</tr>
<tr>
<td>Intertrochanteric</td>
<td>254 (41.1)</td>
<td></td>
</tr>
<tr>
<td>Subtrochanteric</td>
<td>44 (7.1)</td>
<td></td>
</tr>
<tr>
<td>Fixation type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemiarthroplasty</td>
<td>262 (42.4)</td>
<td></td>
</tr>
<tr>
<td>DHS</td>
<td>246 (39.8)</td>
<td></td>
</tr>
<tr>
<td>IM nail</td>
<td>108 (17.5)</td>
<td></td>
</tr>
<tr>
<td>Fracture by fixation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Femoral neck — hemiarthroplasty</td>
<td>262 (42.5)</td>
<td></td>
</tr>
<tr>
<td>Femoral neck — DHS</td>
<td>56 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Intertrochanteric — DHS</td>
<td>190 (30.8)</td>
<td></td>
</tr>
<tr>
<td>Intertrochanteric — IM nail</td>
<td>64 (10.4)</td>
<td></td>
</tr>
<tr>
<td>Subtrochanteric — IM nail</td>
<td>44 (7.1)</td>
<td></td>
</tr>
</tbody>
</table>

DHS = dynamic hip screw; IM = intramedullary; IQR = interquartile range; OR = operating room; SD = standard deviation.

*Unless otherwise indicated.

Fig. 1. Patients meeting inclusion criteria. Cann screws = cannulated screws; DHS = dynamic hip screw; hemi = hemiarthroplasty; intertroch = intertrochanteric fracture; nail = intramedullary nail; subtroch = subtrochanteric fracture.
neck fractures, 52% with intertrochanteric fractures and 71% with subtrochanteric fractures. The majority of blood transfusions were administered on postoperative day 1, 2 or 3 (Fig. 2).

The results of the univariate analysis are presented in Table 2. The 13 patients with femoral neck fractures treated with cannulated screws were removed from the analysis because of the small number of patients. The univariate analysis demonstrated an association between need for blood transfusion and increased age ($p = 0.004$), female sex ($p = 0.018$), lower preoperative hemoglobin level ($p < 0.001$), fracture type ($p < 0.001$) and fixation method ($p < 0.001$). Patients requiring a blood transfusion had an average ASA score of 3.4, whereas patients not receiving a transfusion had an average score of 3.3 ($p < 0.001$). We found no association with delay to operation ($p = 0.17$) or duration of surgery ($p = 0.30$).

Multivariate analysis demonstrated an association between blood transfusion requirement and 3 variables (Table 3). Men were at half the risk of women ($1.54$ odds ratio [OR], $95\%$ confidence interval [CI] $1.002–2.36$, $p = 0.049$), lower preoperative hemoglobin level ($p < 0.001$), fracture type ($p < 0.001$) and fixation method ($p < 0.001$). Patients requiring a blood transfusion had an average ASA score of 3.4, whereas patients not receiving a transfusion had an average score of 3.3 ($p < 0.001$). We found no association with delay to operation ($p = 0.17$) or duration of surgery ($p = 0.30$).

![Fig. 2. Number of patients receiving blood transfusions preoperatively, intraoperatively and postoperatively. Most transfusions were performed on postoperative day 1, 2 or 3. OR = intraoperative transfusion; preop 0 = preoperative transfusion day of surgery; postop 0 = postoperative transfusion day of surgery.]

**Table 2. Univariate logistic regression analyses to predict transfusion, $n = 618$**

<table>
<thead>
<tr>
<th>Potential predictor</th>
<th>OR (95% CI)</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, 5-yr increase</td>
<td>1.16 (1.05–1.28)</td>
<td>0.004</td>
</tr>
<tr>
<td>Sex, women v. men</td>
<td>1.61 (1.08–2.38)</td>
<td>0.018</td>
</tr>
<tr>
<td>Delay to operating room, 8-h increase</td>
<td>0.97 (0.93–1.01)</td>
<td>0.17</td>
</tr>
<tr>
<td>Duration of surgery, 5-min increase</td>
<td>0.98 (0.95–1.02)</td>
<td>0.30</td>
</tr>
<tr>
<td>Preoperative hemoglobin, 10-point increase</td>
<td>0.65 (0.58–0.73)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Fracture type</td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Intertrochanteric v. femoral neck</td>
<td>2.37 (1.65–3.39)</td>
<td></td>
</tr>
<tr>
<td>Subtrochanteric v. femoral neck</td>
<td>4.03 (2.11–7.70)</td>
<td></td>
</tr>
<tr>
<td>Fracture by fixation</td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Femoral neck, DHS v. hemiarthroplasty</td>
<td>0.51 (0.23–1.12)</td>
<td></td>
</tr>
<tr>
<td>Intertrochanteric, DHS v. intramedullary nail</td>
<td>0.57 (0.32–1.02)</td>
<td></td>
</tr>
</tbody>
</table>

CI = confidence interval; DHS = dynamic hip screw; OR = odds ratio.

**Table 3. Multivariable analyses to predict transfusion. Logistic regression with only those variables that were significant at $p = 0.05$ in univariate analyses, $n = 618$**

<table>
<thead>
<tr>
<th>Potential predictor</th>
<th>Adjusted OR (95% CI)</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, 5-yr increase</td>
<td>1.06 (0.95–1.19)</td>
<td>0.27</td>
</tr>
<tr>
<td>Sex, women v. men</td>
<td>1.54 (1.002–2.36)</td>
<td>0.049</td>
</tr>
<tr>
<td>Preoperative hemoglobin, 10-point increase</td>
<td>0.69 (0.61–0.78)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Fracture, fixation</td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Femoral neck, DHS v. hemiarthroplasty</td>
<td>0.49 (0.21–1.12)</td>
<td></td>
</tr>
<tr>
<td>Intertrochanteric, DHS v. intramedullary nail</td>
<td>0.52 (0.29–0.96)</td>
<td></td>
</tr>
</tbody>
</table>

CI = confidence interval; DHS = dynamic hip screw; OR = odds ratio.
p = 0.049). For every 10 g/L increase in preoperative hemoglobin, the risk of transfusion decreased by about 30% (OR 0.69, 95% CI 0.61–0.78, p < 0.001). Femoral neck fractures treated with DHS reduced the risk of transfusion by half compared with hemiarthroplasty (OR 0.49, 95% CI 0.61–0.78), and intertrochanteric fractures treated with DHS reduced the risk of transfusion by half compared with intramedullary nail (OR 0.52, 95% CI 0.29–0.95). This indicates that DHS fixation in either femoral neck fractures or intertrochanteric fractures decreases the risk of transfusion by about half compared with treatment with an intramedullary nail or hemiarthroplasty.

**Discussion**

We found a correlation between blood transfusion requirement and sex, preoperative hemoglobin, ASA score, fracture type and fixation method. No correlation was found with age, duration of surgery or delay from admission to operation.

Low preoperative hemoglobin is an independent risk factor for the need for blood transfusion. In the present study, preoperative hemoglobin was 112.0 ± 14.3 g/L in transfused patients and 122.1 ± 15.8 g/L in those not transfused (p < 0.001). Multivariate analysis showed that for every 10 g/L decrease in hemoglobin, patients had a 30% increased risk of blood transfusion (p < 0.001). This is consistent with a study by Adunsky and colleagues, who studied blood transfusion patterns in 302 patients with hip fractures. They found that a hemoglobin value less than 12 g/dL (120 g/L) increased transfusion risk 5-fold. They suggested that patients with a hemoglobin greater than 12 g/dL (120 g/L) did not require crossmatching preoperatively. Other studies have also identified low preoperative hemoglobin as a risk factor for transfusion.

Our univariate analysis showed that older patients were more likely to receive a blood transfusion, but age was not important in our multivariate analysis, which suggests that other factors explain the same variability in need for transfusion as age but were even more predictive. The average age of patients in our study who received a blood transfusion was 83.1 ± 7.9 years compared with 80.9 ± 9.0 years in patients who did not (p < 0.003). Swain and colleagues studied the transfusion requirements for 249 patients with femoral neck fractures and found that patients aged 80 years and older were transfused significantly more than those aged younger than 80 years. Similarly, Dillon and colleagues found that patients older than 75 years were at higher risk of receiving blood transfusion.

Patients receiving a blood transfusion had an average ASA score of 3.4 compared with 3.3 in patients who did not receive a transfusion (p < 0.001). This result was significant; however, it is difficult to determine the clinical significance with such a minor difference between scores (0.1). Previous studies examining ASA scores and transfusion requirements did not find any association.

Delay from admission to operation in elderly patients with hip fractures carries significant morbidity and mortality. Delay from admission to operation has been shown to increase mortality, postoperative infections and length of stay in hospital. However, the present study did not find a correlation with delay to operation and transfusion requirements. One would assume that while a patient is awaiting surgery, continued blood loss would be present at the fracture site, leading to greater blood loss and greater risk of transfusion. The equivocal risk of transfusion found in our study may be related to the formation of hematoma around the fracture site. The delay to surgery may have allowed the fracture hematoma to fully stabilize, minimizing the active bleeding before surgery. Intraoperatively, this may have resulted in less surgical blood loss and a lower rate of blood transfusion.

When comparing fracture types, patients with intertrochanteric or subtrochanteric fractures were at an increased risk of requiring a blood transfusion. When compared with femoral neck fractures, there was a 2.37 times greater risk of blood transfusion in patients with an intertrochanteric fracture (p < 0.001) and a 4.03 times greater risk in patients with a subtrochanteric fracture (p < 0.001). These results are consistent with those of Adunsky and colleagues, who found that patients with pertrochanteric fractures were transfused significantly more than patients with subcapital fractures. Swain and colleagues also found an increased transfusion requirement in patients with intertrochanteric fractures compared with those with intracapsular fractures, and Dillon and colleagues reported an increased risk for blood transfusion in patients with pertrochanteric fractures.

When comparing fixation methods for the different fracture types, we found a significant difference in blood transfusion requirements. In patients with femoral neck fractures, 24.8% treated with hemiarthroplasty were transfused compared with 14.3% of patients treated with DHS (p < 0.001). This may be partially related to severity of injury, as the more displaced fractures were likely treated with hemiarthroplasty. This finding is consistent with those of a meta-analysis performed by Wang and colleagues, who compared the outcomes of patients who underwent arthroplasty with those of patients who underwent internal fixation for displaced femoral neck fractures. They found greater operative blood loss and increased transfusion requirement in the hemiarthroplasty group. Similarly, Parker and colleagues found lower operative blood loss and lower transfusion requirements with internal fixation (using cannulated screws) than with hemiarthroplasty in patients with displaced femoral neck fractures. Similar to femoral neck fractures, intertrochanteric fractures treated with a DHS had a lower risk of transfusion than those treated with an intramedullary device. In our study, 37.9% of intertrochanteric fractures treated with a DHS were transfused compared with 51.6%
treated with an intramedullary device ($p < 0.001$). The literature comparing blood loss in intertrochanteric hip fractures treated with intramedullary nail or DHS is inconclusive. Authors have reported reduced blood loss,$^{25-27}$ increased blood loss$^{28}$ and no difference$^{29,30}$ in patients with intertrochanteric fractures treated with an intramedullary nail. The variability among studies may be related to differences in fracture severity, as patients with more displaced fractures are generally more likely to be treated with an intramedullary device.

**Limitations**

There are limitations to this study that should be considered. First, there may be inherent differences in medical comorbidities between the transfused and nontransfused patient samples that were not discerned by this retrospective, observational study. As mentioned, we attempted to stratify by ASA score, but it is difficult to determine if such a small difference in ASA score between groups has any clinical importance. Second, patients were generally given a transfusion based on the criteria of hemoglobin less than 70 g/L or less than 80 g/L with signs/symptoms of anemia. This threshold is consistent with the restrictive strategy group in a study by Carson and colleagues,$^{11}$ who compared restricted and liberal transfusion thresholds. Similar to Carson and colleagues,$^{11}$ we attempted to make the decision to transfuse as uniform as possible; however, there are difficulties with this. Determining signs/symptoms of anemia is subjective, and a lack of uniformity inherently exists among treating physicians. This may have resulted in some inconsistencies in decision to transfuse. Finally, we did not separately analyze patients with stable and unstable intertrochanteric fractures. One would assume that 3- and 4-part intertrochanteric fractures are most likely to cause greater blood loss and more likely to be treated with an intramedullary device. This would potentially affect the results of transfusion requirements between the intramedullary nail and DHS groups. However, previously published literature has failed to find convincing evidence of greater blood loss in patients with unstable fracture patterns.$^{12,13}$

**CONCLUSION**

We found a correlation with blood transfusion requirement and sex, preoperative hemoglobin, fracture type and fixation method. The only modifiable risk factor found in the present study was fixation method. Further studies would be beneficial to determine other potential modifiable risk factors. Based on our findings, when considering blood transfusion requirements in isolation, we suggest a potential benefit in using a DHS for intertrochanteric and femoral neck fractures amenable to DHS fixation.

**Competing interests:** None declared.

**Contributors:** S. Desai, D. Bryant, A. Laweny and D.W. Sanders designed the study. S. Desai, K.S. Wood and H. Abdo acquired the data, which S. Desai, J. Marsh, D. Bryant and A. Laweny analyzed. S. Desai wrote the article, which all authors reviewed and approved for publication.

**References**

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Emergency surgery for colorectal cancer does not result in nodal understaging compared with elective surgery

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DOI: 10.1503/cjs.019313

Background: It has been suggested that inadequate lymph node harvest may result in pathologically understaged or indeterminate staging of patients with colorectal cancer (CRC). We compared the adequacy of nodal staging in patients undergoing emergency surgery compared with elective surgery for CRC.

Methods: Using a prospectively collected CRC surgery database at a tertiary care centre, we performed a cohort study. The mean number of lymph nodes harvested and the proportion of patients who had inadequate staging (<12 nodes harvested) were compared between emergency and elective surgery cohorts. Our analysis was adjusted for tumour site, type of resection, surgical training and pathologic stage.

Results: A total of 1279 of 1356 (94%) enrolled patients had nodal data available for analysis; 161 (13%) patients had emergency surgery and 1118 (87%) had elective surgery. The mean number of nodes removed was higher in the emergency surgery group (mean difference +2.8, 95% confidence interval [CI] 0.6–5.1, p = 0.012). The proportion of patients with inadequate nodal staging did not differ between groups (emergency 16%, elective 17%, p = 0.79). The odds of adequate nodal staging, adjusting for site, type of resection, training and stage was no different between groups (OR 0.80, 95% CI 0.47–1.35, p = 0.41).

Conclusion: The evidence does not support the common belief that emergency surgery is more commonly understaged in CRC. Our data suggest emergency surgery resulted in a significant increase in the average number of nodes harvested, with no difference in inadequate nodal staging.

Contexte : Il semble qu’une méthode erronée de prélèvement de lymphonœuds pour- rait expliquer pourquoi le stade d’évolution du cancer colorectal (CCR) est sous-évalué ou qu’il est impossible de le déterminer chez certains patients. On a comparé la méthode de détermination de l’atteinte des lymphonœuds chez des patients atteints d’un CCR devant subir une chirurgie d’urgence à celle utilisée chez des patients devant subir une chirurgie non urgente.

Méthodes : En utilisant une base de données prospectives sur des chirurgies du côlon pratiquées dans un établissement de soins tertiaires, on a comparé le nombre moyen de prélèvements de lymphonœuds et la proportion de patients pour lesquels le stade d’évolution était erroné (prélèvement de <12 lymphonœuds) entre la cohorte de patients ayant subi une chirurgie d’urgence et celle ayant subi une chirurgie non urgente. Les résultats de notre analyse ont été ajustés en fonction du siège des tumeurs, du type de résection, de la formation chirurgicale et du stade pathologique.

Résultats : Pour 1279 (94 %) des 1356 patients recrutés, on disposait des données sur les lymphonœuds; 161 patients (13 %) avaient subi une chirurgie d’urgence et 1118 (87 %), une chirurgie non urgente. Le nombre moyen de lymphonœuds prélévés était plus élevé pour le groupe de patients ayant subi une chirurgie d’urgence (écart moyen +2,8, intervalle de confiance [IC] à 95 % 0,6–5,1, p = 0,012). Mais la proportion de patients pour lesquels le stade d’évolution de la maladie était erroné ne différait pas entre les groupes (intervention d’urgence 16 %, intervention non urgente 17 %, p = 0,79). La probabilité que le stade d’évolution soit exact, l’ajustement en fonction du siège des tumeurs, du type de résection, de la formation chirurgicale et du stade d’évolution ne différaient pas entre les groupes (RR 0,80, IC à 95 % 0,47–1,35, p = 0,41).

Conclusion : Les résultats de notre étude ne confirment pas la croyance répandue selon laquelle le stade d’évolution du CCR est plus souvent sous-évalué chez des patients ayant subi une chirurgie d’urgence. En effet, nos données semblent indiquer que les chirurgies d’urgence étaient associées à un nombre plus élevé de lymphonœuds prélévés, mais qu’il n’y avait aucune différence pour ce qui est des erreurs de détermination du degré d’atteinte des lymphonœuds.
C olorectal cancer (CRC) is the fourth most common cancer in Canada and accounts for the second most cancer-related deaths. An estimated 23 300 Canadians received diagnoses of CRC in 2012, with 9200 succumbing to the disease.1 The accepted management of CRC is complete resection, surgical dissection of the associated lymph node basin and removal of any contiguous organs involved. The common occurrence of CRC and the emphasis of early surgical intervention indicates that management of this disease is, and will remain, a significant part of general surgical practice.

Adjuvant chemotherapy has shown clear improvement in survival and lower recurrence rates in node-positive or stage III disease.2 Adjuvant chemotherapy with fluorouracil plus leucovorin or capecitabine-based regimes is now the standard of care for treatment of stage III disease.3,4 Although some advocate for adjuvant therapy in stage II disease, the evidence is less clear.5 A significant improvement in survival with adjuvant chemotherapy in stage II disease has been elusive, although there may be some benefit in high-risk populations.6

Pathological examination of the resected specimen is an essential step in determining node positivity, cancer stage, indication for the use of adjuvant chemotherapy and patient prognosis. The greater the number of nodes examined, the more confidence can be placed in the reported nodal status of the patient.7 The American Joint Commission on Cancer and the College of American Pathologists recommend examination of a minimum of 12 lymph nodes to accurately diagnose stage II disease.8 This has now become a measure of surgical resection adequacy in stage I–III CRC.

Patients presenting with obstructing or perforated cancers requiring emergent surgery represent a high-risk population with poor outcomes compared to those with nonemergently resected cancers. The cause for decreased survival in this high-risk population has been poorly evaluated in the literature.9 It has been suggested that owing to technical difficulty or instability of the patient, inadequate lymph node harvest may occur, resulting in pathologically understaged or indeterminate staging of the patient. Consequently these patients may not receive the survival benefits of adjuvant chemotherapy, or they may be subjected to unnecessary side effects of chemotherapeutic drugs.10,11

The objective of our study was to compare the adequacy of nodal staging in patients undergoing emergency surgery with those undergoing elective surgery for CRC in a high volume tertiary referral Canadian hospital.

METHODS

Database

Patient information was entered prospectively into a database from January 2008 to December 2013. Patient information was entered prospectively into a data-base and entered manually. Surgical nature (elective v. emergent) was determined from the operative notes and International Classification of Diseases (ICD)-10 codes during individual patient data entry. The indication for emergent surgery was not included in the original data set. Quarterly quality assessment data runs and random chart audits were completed to assure accuracy of the data set. We obtained information on pathologic staging and lymph node count from the synoptic pathology reports.

Exposure and outcomes

The primary exposure was the nature of surgery (emergency v. elective surgery). The primary outcome was adequacy of lymph node harvest, with 12 or more nodes considered adequate. In addition, we compared the mean number of nodes harvested between groups.

We explored several factors to determine if they modified the effect of nature of surgery on nodal harvest. These included surgeon subspecialty training (colorectal, surgical oncology, general surgery), tumour site (right, transverse, left, rectum, multiple), type of resection (right hemicolectomy, left hemicolectomy, sigmoid resection, segmental resection, abdominoperineal resection (APR), Hartmann, low anterior resection, subtotal colectomy) and pathologic stage. Owing to location and the expected difference in use between elective and emergent surgery, we grouped low anterior resections, APR and Hartmann procedure together for analysis.

Statistical analysis

We performed all statistical analyses using STATA software version 12.0 (Statacorp).

The crude association between nature of surgery and adequacy of lymph node harvest was determined using a Pearson χ² test. The difference in means was calculated using analysis of variance between groups. We completed a Mantel–Haenszel analysis to assess the effect of surgeon training, tumour site, type of resection and pathologic stage on the adequacy of lymph node harvest between groups.

We then performed logistic regression analysis to assess the association between adequacy of lymph node harvest and nature of surgery, adjusting for surgeon training, tumour site, type of surgery and pathologic stage. Significance testing was completed using the likelihood ratio test.

RESULTS

Of the 1356 patients enrolled in the database, 1279 patients (94%) had complete pathologic information and were
included in this study. Of these, 12.6% required an emergency operation. Patient characteristics can be found in Table 1. Overall, the most common tumour sites were right-sided (29.4%), left-sided or sigmoid (28.9%) or rectal (30.5%). The surgeons’ subspecialties included colorectal training (35.0%), surgical oncology (9.8%) and general surgery (54.9%).

The mean number of nodes harvested and proportion of adequate lymph node sampling can be found in Table 2. The emergency group on average had more lymph nodes sampled than the elective group (mean difference +2.8, 95% confidence interval [CI] 0.6–5.1, \( p = 0.012 \)). There was no difference in the proportion of adequate harvests between the emergency and elective groups (risk ratio 1.01, 95% CI 0.94–1.09, \( p = 0.79 \)). Furthermore, no trends were identified in the inadequate node harvest data set. The proportion of cases with fewer than 5 nodes and 5–9 nodes harvested were comparable in both emergent and elective groups.

We completed stratified analyses to assess the effect of surgeon training, tumour site, type of resection, pathologic stage and age on the association between adequacy of lymph node harvest and surgical nature (Table 3). The Mantel–Haenszel analysis revealed that the association between adequacy of lymph node harvest and surgical nature was not influenced by surgical training (test of homogeneity, \( p = 0.31 \)), tumour site (\( p = 0.31 \)) type of resection (\( p = 0.96 \)), pathologic stage (\( p = 0.45 \)) or age (\( p = 0.46; \) Table 4). A logistic analysis was completed assessing the association between lymph node adequacy and surgical nature, adjusting for surgeon training, tumour site, type of resection, pathologic stage and age. We found no evidence of an association between surgical nature and lymph node harvest, after adjusted analysis. The odds ratio of an adequate resection in the emergency group compared with the elective group was 0.77 (95% CI 0.45–1.31, \( p = 0.35; \) Table 4).

**DISCUSSION**

Our results showed that there was no evidence of a difference in the adequacy of lymph node harvest between elective and emergency surgery. This was true, even after adjusting for age, tumour site, type of resection, surgeon training and pathologic stage.

**Strengths and limitations**

This study used information from a prospectively collected database of patients with CRC. We had complete nodal information on more than 90% of patients who were included in the study. The accuracy of the pathology reports have been assured and maintained with routine audits. In addition, we had complete information on age, type of resection, tumour site, full pathologic staging and surgeon training. This allowed us to analyze the independent effects of the nature of surgery after adjusting for these potential confounders.

**Table 1. Characteristics of study participants**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total</th>
<th>Elective surgery</th>
<th>Emergency surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature of surgery</td>
<td>1342 (100)</td>
<td>1181 (87.4)</td>
<td>161 (12.6)</td>
</tr>
<tr>
<td>Age, yr</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 50</td>
<td>91 (7.1)</td>
<td>75 (6.7)</td>
<td>16 (9.9)</td>
</tr>
<tr>
<td>50–59</td>
<td>204 (15.0)</td>
<td>190 (17.0)</td>
<td>14 (8.7)</td>
</tr>
<tr>
<td>60–69</td>
<td>343 (26.0)</td>
<td>297 (26.6)</td>
<td>46 (28.6)</td>
</tr>
<tr>
<td>70–79</td>
<td>373 (29.2)</td>
<td>334 (29.2)</td>
<td>39 (24.2)</td>
</tr>
<tr>
<td>≥ 80</td>
<td>268 (20.0)</td>
<td>222 (19.1)</td>
<td>46 (28.6)</td>
</tr>
<tr>
<td>Tumour site</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right colon</td>
<td>376 (29.3)</td>
<td>325 (29.1)</td>
<td>51 (31.7)</td>
</tr>
<tr>
<td>Transverse colon</td>
<td>123 (9.6)</td>
<td>95 (8.5)</td>
<td>29 (17.4)</td>
</tr>
<tr>
<td>Left or sigmoid colon</td>
<td>370 (28.9)</td>
<td>307 (27.5)</td>
<td>63 (39.1)</td>
</tr>
<tr>
<td>Rectum</td>
<td>390 (30.5)</td>
<td>378 (33.8)</td>
<td>12 (7.5)</td>
</tr>
<tr>
<td>Multiple</td>
<td>10 (0.8)</td>
<td>6 (0.5)</td>
<td>4 (2.5)</td>
</tr>
<tr>
<td>Other</td>
<td>10 (0.8)</td>
<td>7 (0.6)</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td>Surgery type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right colectomy</td>
<td>433 (33.9)</td>
<td>367 (32.8)</td>
<td>66 (41.0)</td>
</tr>
<tr>
<td>Left colectomy</td>
<td>138 (10.8)</td>
<td>124 (11.1)</td>
<td>14 (8.7)</td>
</tr>
<tr>
<td>LAR</td>
<td>406 (31.7)</td>
<td>384 (34.4)</td>
<td>22 (13.7)</td>
</tr>
<tr>
<td>APR</td>
<td>129 (10.1)</td>
<td>128 (11.5)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Hartmann</td>
<td>31 (2.4)</td>
<td>14 (1.3)</td>
<td>17 (10.6)</td>
</tr>
<tr>
<td>Subtotal colectomy</td>
<td>76 (5.9)</td>
<td>45 (4.0)</td>
<td>31 (19.3)</td>
</tr>
<tr>
<td>Segmental colectomy</td>
<td>40 (3.1)</td>
<td>30 (2.7)</td>
<td>10 (6.2)</td>
</tr>
<tr>
<td>Other</td>
<td>13 (1.0)</td>
<td>13 (1.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Surgeon training</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorectal</td>
<td>448 (35.0)</td>
<td>417 (37.3)</td>
<td>31 (19.3)</td>
</tr>
<tr>
<td>Surgical oncology</td>
<td>125 (9.8)</td>
<td>109 (9.8)</td>
<td>16 (9.9)</td>
</tr>
<tr>
<td>General surgery</td>
<td>702 (54.9)</td>
<td>589 (52.7)</td>
<td>113 (70.2)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (0.3)</td>
<td>3 (0.3)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Pathologic stage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 0</td>
<td>50 (3.9)</td>
<td>50 (4.5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Stage I</td>
<td>226 (17.7)</td>
<td>224 (20.0)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Stage II</td>
<td>402 (31.4)</td>
<td>354 (31.5)</td>
<td>48 (28.8)</td>
</tr>
<tr>
<td>Stage III</td>
<td>465 (36.4)</td>
<td>404 (36.1)</td>
<td>61 (37.9)</td>
</tr>
<tr>
<td>Stage IV</td>
<td>135 (10.6)</td>
<td>85 (7.6)</td>
<td>50 (31.1)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (0.1)</td>
<td>1 (0.1)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

APR = abdominoperineal resection; LAR = low anterior resection.

**Table 2. Mean number of lymph nodes removed and proportion of adequate lymph node harvest, by surgical nature**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Elective surgery</th>
<th>Emergency surgery</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of nodes</td>
<td>19.1 (13.3)</td>
<td>22.0 (13.8)</td>
<td>0.012</td>
</tr>
<tr>
<td>Adequacy of lymph node harvest</td>
<td></td>
<td></td>
<td>0.79</td>
</tr>
<tr>
<td>Adequate, ≥ 12 nodes</td>
<td>928 (83.0)</td>
<td>135 (83.9)</td>
<td></td>
</tr>
<tr>
<td>Inadequate, &lt; 12 nodes</td>
<td>190 (17.0)</td>
<td>26 (16.1)</td>
<td></td>
</tr>
</tbody>
</table>

SD = standard deviation.
Limitations of the study may include misclassification of the nature of surgery. We extracted the nature of surgery from operative notes. We were unable to further validate the nature of surgery. In addition, the database did not capture the indication for surgery in the emergency group. It is possible that operating for bleeding, obstruction or perforation could affect the adequacy of the lymph node harvest differently. The database included patients who were treated at an academic institution by surgeons with varying levels of training. The results of this study may not translate to the community hospital experience, where training may be similar but volumes and case complexity may be variable. An additional limitation is that adequacy of lymph node harvest can be affected by the reporting pathologist. Our database did not distinguish among reporting pathologists, and adequacy of nodal harvest by pathologist was not available.

### Strengths and limitations in comparison to previous publications

A previous study by Lewis and colleagues examined 296 patients operated for colon cancer, 15% of whom had an emergency operation. Comparing the results from our study and theirs, we found a similar proportion of patients requiring emergency surgery (15% vs. 12.6%). The study by Lewis and colleagues did not include patients with rectal cancers. In addition, there was a smaller proportion of inadequate harvest in the elective group in their study (11.9% vs. 17.0%), but there was no difference in the proportion of inadequate harvest in the emergency group (14.0% vs. 16.1%). Univariate analysis in the study by Lewis and colleagues found no association between nature of surgery and adequacy of lymph node harvest ($p = 0.70$). They did not attempt to adjust for the effects of surgeon training, tumour site, resection type or pathologic stage.

Previous studies have found that specialty training may result in differences in adequacy of node harvest. In addition, tumour site has previously been found to affect adequacy of nodal harvest. Our study stratified and then adjusted for these 2 factors as well as resection type and pathologic stage. Even after adjusting for these important factors, we found no difference in the adequacy of nodal harvest.

### Table 3. Stratified analysis of adequacy of lymph node harvest, by surgical nature

<table>
<thead>
<tr>
<th>Factor</th>
<th>Elective surgery</th>
<th>Emergency surgery</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon training</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorectal</td>
<td>417 (17.3)</td>
<td>31 (9.7)</td>
<td>0.28</td>
</tr>
<tr>
<td>Surgical oncology</td>
<td>109 (18.4)</td>
<td>16 (6.3)</td>
<td>0.23</td>
</tr>
<tr>
<td>General surgery</td>
<td>589 (16.5)</td>
<td>113 (19.5)</td>
<td>0.44</td>
</tr>
<tr>
<td>Other</td>
<td>3 (33.3)</td>
<td>1 (0.0)</td>
<td>0.51</td>
</tr>
<tr>
<td>Tumour site</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right colon</td>
<td>325 (7.4)</td>
<td>51 (9.8)</td>
<td>0.55</td>
</tr>
<tr>
<td>Transverse colon</td>
<td>96 (9.5)</td>
<td>28 (3.6)</td>
<td>0.32</td>
</tr>
<tr>
<td>Left or sigmoid colon</td>
<td>307 (20.5)</td>
<td>63 (22.2)</td>
<td>0.76</td>
</tr>
<tr>
<td>Rектum</td>
<td>378 (24.3)</td>
<td>12 (25.0)</td>
<td>0.96</td>
</tr>
<tr>
<td>Multiple</td>
<td>6 (0.0)</td>
<td>4 (0.0)</td>
<td>N/A</td>
</tr>
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<td>Other</td>
<td>7 (28.6)</td>
<td>3 (100.0)</td>
<td>0.038</td>
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<tr>
<td>Right colectomy</td>
<td>367 (7.4)</td>
<td>66 (9.1)</td>
<td>0.63</td>
</tr>
<tr>
<td>Left colectomy</td>
<td>124 (18.6)</td>
<td>14 (14.3)</td>
<td>0.70</td>
</tr>
<tr>
<td>LAR/APR/Hartmann</td>
<td>539 (20.8)</td>
<td>40 (27.5)</td>
<td>0.32</td>
</tr>
<tr>
<td>Subtotal colectomy</td>
<td>46 (8.9)</td>
<td>31 (9.7)</td>
<td>0.91</td>
</tr>
<tr>
<td>Segmental colectomy*</td>
<td>30 (36.7)</td>
<td>10 (40.0)</td>
<td>0.85</td>
</tr>
<tr>
<td>Other</td>
<td>13 (100.0)</td>
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<td>Pathologic stage</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Stage 0</td>
<td>50 (36.0)</td>
<td>0 N/A</td>
<td></td>
</tr>
<tr>
<td>Stage I</td>
<td>224 (23.6)</td>
<td>2 (50.0)</td>
<td>0.39</td>
</tr>
<tr>
<td>Stage II</td>
<td>354 (15.0)</td>
<td>48 (16.7)</td>
<td>0.76</td>
</tr>
<tr>
<td>Stage III</td>
<td>404 (11.6)</td>
<td>61 (6.6)</td>
<td>0.24</td>
</tr>
<tr>
<td>Stage IV</td>
<td>85 (21.2)</td>
<td>50 (26.0)</td>
<td>0.52</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (100.0)</td>
<td>0 N/A</td>
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<tr>
<td>Age, yr</td>
<td></td>
<td></td>
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<tr>
<td>&lt; 50</td>
<td>75 (12.0)</td>
<td>16 (12.5)</td>
<td>0.96</td>
</tr>
<tr>
<td>50–59</td>
<td>190 (16.8)</td>
<td>14 (28.6)</td>
<td>0.27</td>
</tr>
<tr>
<td>60–69</td>
<td>297 (17.2)</td>
<td>46 (8.7)</td>
<td>0.15</td>
</tr>
<tr>
<td>70–79</td>
<td>334 (20.4)</td>
<td>39 (23.1)</td>
<td>0.69</td>
</tr>
<tr>
<td>≥ 80</td>
<td>222 (13.5)</td>
<td>46 (15.2)</td>
<td>0.76</td>
</tr>
</tbody>
</table>

*Nonformal resection (e.g., cecectomy, segment of sigmoid).

### Table 4. Mantel–Haenszel and logistic regression analysis

<table>
<thead>
<tr>
<th>Type of analysis</th>
<th>OR (95% CI)</th>
<th>Significance testing</th>
<th>Test of homogeneity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mantel-Haenszel odds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjusted for training</td>
<td>1.06 (0.68–1.68)</td>
<td>$p = 0.77$</td>
<td>$p = 0.31$</td>
</tr>
<tr>
<td>Adjusted for site</td>
<td>0.87 (0.54–1.41)</td>
<td>$p = 0.57$</td>
<td>$p = 0.31$</td>
</tr>
<tr>
<td>Adjusted for type of resection</td>
<td>0.82 (0.50–1.31)</td>
<td>$p = 0.40$</td>
<td>$p = 0.96$</td>
</tr>
<tr>
<td>Adjusted for pathologic stage</td>
<td>0.99 (0.61–1.63)</td>
<td>$p = 0.99$</td>
<td>$p = 0.45$</td>
</tr>
<tr>
<td>Adjusted for age group</td>
<td>1.01 (0.64–1.58)</td>
<td>$p = 0.97$</td>
<td>$p = 0.46$</td>
</tr>
<tr>
<td>Logistic regression</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Adjusted for training, site, type of resection, stage and age group</td>
<td>0.77 (0.45–1.31)</td>
<td>$p = 0.35$</td>
<td>N/A</td>
</tr>
</tbody>
</table>

CI = confidence interval; N/A = not applicable; OR = odds ratio.
Population-based studies have identified age as a statistically significant variable affecting adequacy of lymph node resection.\textsuperscript{18,19} Baxter and colleagues\textsuperscript{19} studied more than 100,000 patients with invasive colon and rectal cancer. Our results show a similar trend with decreasing rates of adequate lymph node resection with increasing age. The rates of adequate resection are improved compared with these previous findings of Baxter and colleagues in patients younger than 50 (12\% v. 45\%) and older than 71 years of age (16.9\% v. 65\%).\textsuperscript{18} Our stratified analysis assessing the effect of age on adequacy of lymph node resection was not significant when comparing the emergent and elective groups.

**Conclusion**

Patients undergoing emergency surgery had no difference in the adequacy of nodal staging compared with their elective counterparts. The commonly held belief that inadequate staging occurs more frequently in the emergency group was not supported by our patient population and analysis.

**Competing interests:** None declared.

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

**References**

Trauma Non-Technical Training (TNT-2): the development, piloting and multilevel assessment of a simulation-based, interprofessional curriculum for team-based trauma resuscitation

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Effective trauma resuscitation requires the coordinated effort of an interdisciplinary team. Medical error is common during trauma resuscitations, occurring even in well-resourced settings with experienced practitioners. The majority of errors are non-technical in nature, stemming from ineffective team leadership, nonstandardized communication among team members, lack of global situational awareness, poor use of resources and inappropriate triage and prioritization. Lessons from high-hazard, high-reliability industries have therefore informed the development of medical and surgical crisis resource management (CRM) principles and team training applications to address local and domain-specific needs. There is currently no formally derived or systematically evaluated non-technical skills curriculum for Canadian surgical trainees. Simulation-based CRM training provides an opportunity for focused instruction, deliberate practice, feedback and assessment on the communicator, collaborator and manager roles espoused by the CanMEDS framework in a manner that is consistent and reproducible and poses no threat to patients. We describe the development, piloting and multilevel evaluation of a novel, interprofessional, simulation-based trauma team training curriculum for Canadian surgical trainees: Trauma Non-Technical Training (TNT-2).

The TNT-2 curriculum was piloted as a prospective, 2-phase, single blinded education study and was informed by a Best Evidence Medical Education systematic review and a focused literature review by the authors. The strength of the TNT-2 study stems from the multilevel curriculum assessment, with objective assessment of team performance as the primary study outcome.

The course was held at the Allen Waters Family Simulation Centre at St. Michael’s Hospital in Toronto, Ont., and used SimMan (Laerdal), an operator-controlled, full-sized human patient simulator. The “health” of SimMan can be interactively manipulated on the basis of management decisions. The simulation theatre was set up to resemble a trauma room, and teams had access to equipment and diagnostic test results in real time. Two confederates were trained to respond in a standardized fashion according to scenario scripts. A single experienced operator controlled all scenarios, and teams were video-recorded for subsequent blinded evaluation.

Summary

Medical error is common during trauma resuscitations. Most errors are non-technical, stemming from ineffective team leadership, nonstandardized communication among team members, lack of global situational awareness, poor use of resources and inappropriate triage and prioritization. We developed an interprofessional, simulation-based trauma team training curriculum for Canadian surgical trainees. Here we discuss its piloting and evaluation.
All second-year trainees from the General Surgery program at the University of Toronto were invited to participate. In addition, 4 experienced trauma nurses were recruited to participate. Nineteen individuals participated in the first phase, and 9 (6 trainees and 3 nurses) elected to participate in the follow-up phase.

On the training day, participants were randomly divided into teams comprising 3 trainees, 2 nurses and a facilitator with extensive trauma and education experience. Teams received a standard orientation to the simulator environment, followed by a 20-minute prebriefing course, which included a question and answer period with the facilitator and a viewing of a segment of the film The Deadliest Plane Crash about the Tenerife aviation catastrophe.

Teams participated in 3 peer-reviewed standardized trauma resuscitation scenarios lasting 15 minutes each that were designed to highlight 1 or 2 nontechnical, team-based challenges known to encumber effective trauma team performance. The manner in which participants responded to and negotiated these nontechnical challenges then formed the basis for subsequent debriefings. Debriefings consisted of 30 minutes of feedback by the facilitators and focused on scenario-specific learning objectives, such as managing authority gradients, recognizing and avoiding fixation errors, resource utilization, problem solving and team communication skills.

Six months after their initial training, participants voluntarily returned to the simulation centre to participate in the second phase using new scenarios with similar training goals, objectives and levels of difficulty. Participants were rerandomized into teams and facilitated through 3 scenario–debriefing couples in a manner similar to the first phase.

The impact of TNT-2 was evaluated on multiple levels. Our primary outcome, team performance, was assessed using the Mayo High Performance Team Scale (MHPTS), which rates team performance based on the consistency of 16 different criteria and is designed to evaluate global team performance. We used the Ottawa Global Rating Scale (OGRS) to evaluate the performance of the team leader; the scale consists of 5 nontechnical criteria and a global assessment score.

The OGRS and MHPTS were completed by the team facilitator immediately after each scenario and before the debriefing. Two trained blinded reviewers subsequently analyzed recorded data and rated performance on the MHPTS and OGRS scales.

To measure attitudinal shifts occurring as a result of training, participants completed the Human Factors Attitudes Survey (HFAS) before and after each scenario on each training day. Positive changes in HFAS scores reflect improved attitudes toward team-based behaviours.

We quantified participants’ perceptions of training using the Participant Evaluation of Training Quality (PETQ) tool. The PETQ questionnaire measures the face validity of the simulation environment, the perceptions on the usefulness of the intervention and perceived personal benefit. The HFAS and PETQ scores were secondary study outcomes.

From our preliminary analysis, the TNT-2 curriculum was feasible and well received, and it provided a strategy for teaching and evaluating key nontechnical behaviours pertinent to team-based trauma resuscitation. The MHPTS and OGRS scores improved but did not reach statistical significance. Considering the small number of participants, this result was not surprising. Decay in CRM skills by trainees did not occur, and the 6-month interval between phases 1 and 2 is the longest reported to date for this type of training, suggesting that biannual instruction may be sufficient for nontechnical skill maintenance. Moreover, to our knowledge, TNT-2 is the first resident study to use team performance, as evaluated by a validated behavioural rating scale, as the primary outcome.

Significant, positive changes in HFAS scores suggest that an important attitudinal shift regarding team-based behaviours occurred as a result of TNT-2 training. Several observations on the PETQ, including scenario realism and satisfaction with high-fidelity simulation training, averaged greater than 5 on a 6-point Likert scale. In addition, there was no change in PETQ scores across all scenarios in both phases, which suggests that standardized, realistic trauma team training can be created and maintained even after initial training and exposure.

Finally, there was excellent agreement between the 2 blinded reviewers and between blinded assessment and unblinded, real-time raters (facilitators) using the MHPTS and the OGRS. This result informs the argument that behavioural rating scales may be reliable for real-time assessment and feedback.

Competing interests: This work was supported in part by funds from a University of Toronto Education Development Fund grant (N. Ahmed and C.M. Hicks.), a St. Michael’s Hospital Keenan Research Centre Scholarship and a Queen’s University Research Studentship (A.G. Doumouras).

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References
Percutaneous drainage of Morel-Lavallée lesions when the diagnosis is delayed

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Morel-Lavallée lesions are a closed internal degloving that occurs most commonly over the greater trochanter region, but can also occur in other regions, such as the knee.1 The injury is typically caused by a vertical shearing force over soft tissue that abruptly separates skin and subcutaneous tissue from the underlying fascia, thus creating a dead space that becomes filled with hematoma and necrotic fat.1 The condition generally takes several days to develop, and delayed diagnosis has been reported to occur in one-third of cases or more.1 The condition is typically treated with open débridement of the degloved areas and complete removal of hematoma and necrotic tissue.2,3 However, the vertical blood vessel branches from the underlying muscle and deep fascia have been separated from the degloved skin by the injury, and open débridement may jeopardize the subdermal arterial plexus, the only remaining blood supply to the skin in the area of the lesion.

We performed percutaneous drainage to treat 3 men and 5 women with a delayed diagnosis of Morel-Lavallée lesions and found the procedure to be effective; it was associated with minimal morbidity as well as preservation of the remaining blood supply to the skin. The mean age of our 8 patients was 41.9 years, and the mean time from injury to diagnosis was 11.9 (range 8–17) days. The criteria for diagnosis were a local fluctuant area with skin mobility and systemic symptoms, such as fever and hyperleukocytosis (Fig. 1A), and imaging evidence on ultrasound (Fig. 1B) or computed tomography scan. All patients were treated within 1 day after diagnosis.

Ultrasonography was performed to detect the location and area of the lesion and to determine the location of the operative incisions. Several 2-cm incisions were made and suction tips inserted through the incisions into the lesion (Fig. 1C). Suction was then applied to remove hemorrhagic fluid and necrotic and liquefied tissue. In some patients, necrotic fascia were scraped out through the incision using a plastic brush. A planer tool used in arthroscopy was also used and effectively removed necrotic adipose tissue. After fluid and necrotic tissue were removed, extensive irrigation was performed. Finally, abdominal double-lumen catheters were placed subcutaneously, and continuous suction was applied (Fig. 1D).

We administered cefuroxime intravenously each day until bacterial culture results were available. If the catheters became obstructed, another operation was performed for percutaneous drainage, débridement and catheter replacement. When the drainage was under 30 mL for a 24-hour period, all catheters were removed, the incisions were sutured, and elastic bandages were used to apply...
pressure to the degloved skin. Healing of the lesion was defined as disappearance of the fluctuant lesion and loss of excessive skin mobility upon manual examination (Fig. 1E).

Percutaneous drainage was performed successfully without complications in all patients, and systemic inflammatory response syndrome scores all decreased to 0 by the third postoperative day. Because of catheter obstruction, 6 patients received a second débridement, and 2 received a third procedure. Complete healing of the soft tissue and skin occurred in 6 patients. Skin necrosis occurred in 2 patients and was treated by skin grafting. The mean soft tissue healing time was 3.25 weeks. There were no reoccurrences of the lesions and no deep infections or other complications during the 1-year follow-up period.

While Harma and colleagues advocated that Morel-Lavallée lesions in the pelvic and gluteal regions can be managed conservatively when the overlying skin is intact and the fluid accumulation is not excessive, open débridement is generally recommended to evacuate any hematoma and remove necrotic tissue once an injury is identified because neglected lesions can become infected. Nonetheless, open débridement may violate the blood supply of the injured skin and introduces a risk of infection.

Percutaneous management of Morel-Lavallée lesions was introduced by Tseng and Tornetta in order to preserve the subdermal arterial plexus. In their series of 19 patients, percutaneous drainage with débridement, irrigation and suction drainage was performed through 2 small incisions in the skin, and all patients achieved soft tissue healing without recurrence or infection. There are some differences between our method and theirs. First, we made more incisions for complete débridement and to enable insertion of double-lumen catheters to provide circulation for postoperative drainage. Second, we used continuous suction.

Percutaneous drainage is an effective treatment for patients with a delayed diagnosis of Morel-Lavallée lesions. The procedure is associated with minimal morbidity and preserves the remaining blood supply to the skin. Percutaneous treatment may be more complex and last longer than open surgery, but the benefits outweigh these factors.

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Contributors: All authors contributed substantially to writing and revising and to the conception and design of the manuscript and approved the final version submitted for publication.

References


Fig. 1: (A) A 53-year-old man with a femoral shaft fracture treated with closed intramedullary nailing. Local swelling appeared with gradual development of fluctuation and skin hypermobility. (B) Ultrasound showing a fluid collection in the subcutaneous tissue adjacent to the fascia lata, confirming a Morel-Lavalle lesion. (C) Percutaneous drainage was performed through a 2-cm incision with suction tips. (D) Several incisions were made for débridement, and double-lumen catheters were placed for suction drainage. (E) Three months postoperatively the soft tissue had healed without complications.
Is early transfusion of plasma and platelets in higher ratios associated with decreased in-hospital mortality in bleeding patients?

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

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

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

Reference


SELECTED ARTICLE

Key points about the article

Question: Is early transfusion of plasma:red blood cell (RBC) and platelet:RBC in higher ratios associated with decreased in-hospital mortality in bleeding patients?

Design: Prospective cohort study. Setting: Ten level 1 U.S. trauma centres. Patients: Adult trauma patients surviving for 30 minutes after admission who received a transfusion of at least 1 unit of RBCs within 6 hours of admission and at least 3 total units of RBCs, plasma or platelets within 24 hours. Main outcome: In-hospital mortality. Results: Of a total of 34,632 patients, 905 (2.6%) met the inclusion criteria. Plasma:RBC and platelet:RBC ratios were not constant during the first 24 hours (both \(p<0.001\)). In a multivariable time-independent Cox model, increased plasma:RBC ratios (adjusted hazard ratio [HR] 0.31, 95% confidence interval [CI] 0.16–0.58) and platelet:RBC ratios (adjusted HR 0.55, 95% CI 0.31–0.98) were independently associated with decreased 6-hour mortality when hemorrhagic death predominated. In the first 6 hours, patients with ratios less than 1:2 were 3 to 4 times more likely to die than patients with ratios of 1:1 or higher. After 24 hours, plasma and platelet ratios were not associated with mortality.

Conclusion: Higher plasma:RBC and platelet:RBC ratios early in resuscitation were associated with decreased mortality in patients who received transfusions of at least 3 units of blood products during the first 24 hours after admission. Further assessment with a randomized controlled trial is required.

Commentary

The term damage control resuscitation (DCR) describes a therapeutic approach to critically injured patients with ongoing hemorrhage. It involves simultaneous therapies to arrest persistent bleeding (prehospital, surgical and/or percutaneous techniques) and resuscitate with a more rapid, balanced and aggressive transfusion of blood components that theoretically approximate whole blood (plasma, platelets, RBCs). In an ideal setting, DCR approaches at least a 1:2 ratio of plasma:RBC and often a 1:1:1 ratio of plasma:platelet:RBC. This technique also possesses the added benefit of minimizing crystalloid administration and, therefore, seems to reduce coagulopathy, acidosis, hypothermia, endothelial permeability and the total time to definitive closure of the patient’s abdominal wall.

The classical approach to massive hemorrhage management promulgated by older guidelines consisted of providing blood components as per laboratory-based triggers; for example, plasma transfusion was indicated to keep an international normalized ratio higher than 1.5 in a bleeding patient. In 2007, however, a report by Borgman and colleagues challenged this approach by proposing early transfusion at higher plasma:RBC ratios. This retrospective work was supported by biologic plausibility and basic clinical science revealing that coagulopathy develops early in about 25% of injured patients and is associated with worse clinical outcomes. This approach seemed to be associated with remarkable clinical outcomes. Thus, the approach was quickly popularized and many more observational studies followed, many of which were criticized for poor methodological quality and survival bias.

The PROMMTT study, therefore, constituted an important multicentre effort to address these questions in the most rigorous fashion short of a large multicentre randomized controlled trial. Many if not most of the previous studies were threatened by either survival bias (patients living long enough to receive the treatment appear to do better than those who die too early to receive it) or the competing mortality bias (causes of death other than hemorrhage begin to dominate trauma patient hospital course after the first 24 hours). However, the PROMMTT study carefully recorded the blood-component ratios at various times through the critical phases of care. Research assistants were available at all hours to screen and enroll patients and record the exact times of fluid infusion and blood-component transfusion as well as patient outcomes during direct observation. Direct bedside observation began at trauma team activation and continued until active resuscitation ended (defined as the time the centre transfusion protocol was discontinued, death occurred, or 2 hours elapsed since the last blood product transfusion, whichever came first). The study is unique in collecting these critical data with great precision. The investigators also avoided using the traditional definition of massive transfusion to determine eligibility, and the statistical analytic approaches attempted to minimize the effect of survival bias.

There were 34,362 trauma admissions in the 10 centres over an average of 58 weeks. Data collection was initiated for 12,560 (36.6%) patients, and of these 12,455 (3.6%) met all PROMMTT study eligibility criteria. A total of 905 (2.6%) adult trauma patients who survived at least 30 minutes after admission and received at least 1 unit of RBCs within 6 hours of admission and at least 3 units of RBCs within 24 hours at 10 U.S. level 1 trauma centres were enrolled in the study. A distinct attribute of the study was the fact that the authors included patients who experienced major trauma rather than only those who were massively bleeding. In contrast, previous studies have included patients who required at least 10 units of RBCs in 24 hours.

Using a time-dependent model, researchers assessed the association of increased plasma and platelet ratios on in-hospital mortality. Within the first 6 hours, patients with ratios of less than 1:2 were found to be 3 to 4 times more likely to die than patients with ratios of 1:1. During the
The results of the PROMMTT study support the beliefs that in-hospital mortality remains high (21%) in patients who require any RBC transfusions within the first 6 hours, that earlier and higher ratios of plasma and platelets are associated with lower mortality within 6–24 hours after arrival and that this benefit is not observed among survivors beyond 24 hours. Because of its detailed, time-based analysis, the PROMMTT study provides the strongest evidence to date to support this treatment regimen. Despite the limitations, the study showed an apparent survival benefit with close resuscitation ratios of plasma:RBC and platelet:RBC in patients with severe hemorrhage. It is important to recognize some limitations of this prospective study. First, the vast majority of trauma patients had blunt trauma and not penetrating trauma. Second, only 35% had the abdominal cavity as a source of hemorrhage, with only 24% of the study group undergoing damage control surgery, whereas 26% had compressible limb injuries. Third, the mean quantity of RBC transfusion in the cohort analyzed was greater than 3 units over 24 hours, but it was evident that most of the patients analyzed did not receive more than 10 units of RBCs over 24 hours nor in the first 6 hours. In other words, how sick were these patients? Fourth, patients who died within the first 30 minutes were excluded from the analysis owing to predefined exclusion criteria. This last one raised the concern of survivor bias. Did this group receive any RBCs or plasma? If so, why were they excluded? Finally, no data on coagulation parameters, hemoglobin or platelet counts during resuscitation were provided. Therefore, it is not clear whether the strategy was effective in addressing hemostatic derangements. No information was provided on the use of tranexamic acid, an antifibrinolytic agent, which has been shown to decrease mortality in trauma patients by a recent randomized controlled trial (CRASH-2 investigators). The rate of transfusion-related complications (e.g., volume overload, acute lung injury) were not reported. These complications tend to occur later in the resuscitation (> 6 h later) and may significantly contribute to patient morbidity and mortality. It would have been interesting to see how many of the surviving patients who received 1:1 resuscitation experienced such complications and to learn more about these patients. The potential benefit and safety of the high ratio approach may differ among populations. For example, previous studies have shown that women, patients with blunt (v. penetrating) injuries and those with traumatic brain injuries benefited less from high plasma:RBC ratio transfusion. 

While the PROMMTT study adds further evidence to support transfusions with higher plasma:RBC transfusions, further studies are needed, especially regarding how to efficiently identify the patients who will benefit from early administration of the therapy. Future studies looking at the infusion rate of each component on mortality will also help clarify this question further. Clinicians cannot be confident, however, that by administering enhanced ratios of plasma and platelets that they will influence the mortality of their seriously injured patients, and a randomized controlled trial is still urgently required. The Pragmatic, Randomized, Optimal Platelet and Plasma Ratios (PROPRR) is a Phase III trial designed to evaluate the difference in 24-hour and 30-day mortality among patients predicted to receive massive transfusion (defined as receiving 10 or more units of RBCs within the first 24 h) has been completed, and the results are imminently expected; they may greatly advance this critical area of practice.

Competing interests: None declared.
Moola and colleagues\(^1\) have done a lot of work on attempting primary closure for all open fractures, and they have found that primary closure for all open fractures is a safe and efficient practice. However, we have some concerns regarding the paper and wish to share them.

First, there was an obvious mistake in the design of the study. As we know, the timing of wound closure in the management of open fractures is very clear both in the orthopedic traumatology textbook and literature. The open fracture, from Gustilo type I to Gustilo type IIIa, should be treated with primary wound closure. Delayed wound closure is mainly performed in patients with Gustilo types IIIb and IIIc wounds, which always require second-look débridement to assess gross contamination. Such complicated open fractures no doubt have higher rates of infection and nonunion.\(^2\)\(^,\)\(^3\) However, in this study the authors analyzed the following patients with open fractures: 152 type I (51.2%), 73 type II (24.6%), 46 type IIIa (15.5%), 13 type IIIb (4.4%) and 13 type IIIc (4.4%) injuries. Of these, types I, II and IIIa accounted for 91.3% of all open fractures. This means that most open fractures for the study should have been treated with primary wound closure. Therefore, the results comparing Gustilo type I, II and IIIa and Anderson type I and II, determining that they had the highest rates of definitive immediate closure, was meaningless, repetitive work. We suggest the authors analyze the attempting of primary closure for type IIIb and IIIc open fractures, which remains somewhat controversial in orthopedic traumatology.

Second, certain types of open fracture wound closure need to be treated with delayed wound closure, which are not subject to Gustilo type restrictions (e.g., wounds with delayed presentation (>12 h) or high-risk of anaerobic contamination). Even in the study by DeLong and colleagues\(^2\) there were still some Gustilo I and II wounds treated with delayed closure.

Third, the authors claimed that the only published prospective study evaluating wound closure protocol for open fractures is by Rajasekaran and colleagues.\(^3\) However, we are aware of at least 2 published prospective articles in the literature.\(^6\)\(^,\)\(^7\)

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Author Response

We are happy to address your concerns with our paper.

You have the following 3 concerns:

1. Timing is still controversial. We felt that there was enough evidence in the literature to start an institutional protocol. Reviewers still feel that we are too radical with our protocol. On average this is not a design flaw, but rather an attempt to answer a real question in North America: “Can you close open fractures?”. The inclusion of all grades is a review of a system protocol change, not a case-by-case dictation of whether to close or not. The paper is as much a review of a protocol implementation — whether it was successful and whether all surgeons followed — as it is a review of what happens with these patients.

2. Contaminated wounds and old wounds underwent the same protocol; excision of all contaminated areas converted the wound to a clean wound. The protocol did not forbid second looks, and patients were allowed to be taken back to the operating room for débridement. As long as the skin was closed initially, they fell in the primary closure group.

3. At the time of the initiation of the protocol, the quoted paper by Benson and colleagues\(^1\) was the only prospective paper addressing this subject matter. This is the paper we quote in our design consideration.

Thank you so much for your letter; it is always great to have people read your work so keenly.

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Regarding the height and weight of players, the data for height and weight were obtained for the season itself. We used this data for 2 reasons: (1) the players are in the NHL because of their current fitness and physical attributes, not the attributes they were drafted with, and (2) this information was most readily available and verified.

Regarding other jurisdictions, although this information is not readily available, other jurisdictions probably do not have the same narrow and restrictive draft conditions that cause an RAE. We discuss in the article why the RAE happens in some sports and not others worldwide. Pavel Datsuk has stated publicly that if he had been in the Canadian system as a youth he would never have been drafted. That would have been a real loss!

Thank you for your questions. I hope this response answers your concerns.

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MEDICAL STUDENT–RUN EDUCATION: THE NEXT STEPS

The recently published paper by Li and colleagues1 offers interesting insights into the potential for medical student–run medical education. The medical student–run provision was popular and the researchers were able to show significantly more interest statistically in surgical careers in the intervention group. However, the researchers are also correct that further qualitative analysis of their data should prove useful. The limited qualitative data that they have provided are tantalizing. The learners felt that the senior medical students were good role models and clearly felt more empowered to ask them questions. Conversely, the teaching staff was perceived as being more cut- edge, albeit limited by staff time constraints. It would likely prove fruitful if further qualitative research could delve into these thoughts and reflections. Such qualitative research is unlikely to find that one form of education is better than another, but it might tease out the exact outcomes that are most effectively and efficiently achieved with student- delivered and staff-delivered learning. A learning package could then be put together, taking the best features of both forms of delivery. This package could then be evaluated.

Another point of note is that the researchers understandably concentrated on the learner outcomes; however, it would be interesting also to hear the feedback of the student educators. It would be interesting to know whether they felt positive about the experience, whether they consolidated their own knowledge and skills by teaching others, and whether they developed teaching skills themselves. This would be a secondary but still worthwhile outcome. As soon as students graduate and become doctors, they are automatically expected to begin teaching juniors, so any experience that they can obtain as undergraduates would likely prove useful. Many of the teaching skills that they develop are also transferable skills (e.g., communication and presentation skills). These are yet more reasons to encourage the involvement of students in the teaching process.

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Reference

A NOT-SO-SYSTEMATIC REVIEW

In evaluating Ebrahim and colleagues’ meta-analysis,1 which compared low-
intensity pulsed ultrasound (LIPUS) to electrical stimulation for fracture healing, we were disappointed to find several glaring errors and omissions.

Fracture nonunion was improperly defined. Nonunion was defined to include both “possible unions (bridging at 3 cortices) and nonunion (bridging at 2 ≤ cortices),”1 yet bridging at 3 cortices defined a healed fracture in 3 of the 7 LIPUS studies evaluated (references 32, 37 and 39).2–4 Fractures that had been defined as healed in these 3 LIPUS studies were therefore arbitrarily reclassified by Ebrahim and colleagues5 as treatment failures.

Reduced time to radiographic union was considered a “surrogate end point,” yet a survey of 335 orthopedic surgeons concluded that “radiographic outcomes were more important than functional outcomes” in designing clinical trials.6 Overall, 88.1% of surgeons accepted that nonunion is defined by radiographic and clinical criteria; whereas “return to function” was seen as important by just 29.9%.5

Seminal LIPUS papers were omitted. It is possible that simple error accounts for omission of the first randomized clinical trial (RCT) to evaluate LIPUS. The Heckman study6 evaluated in preference to the RCT7 is actually an econometric evaluation of tibial fracture. Simple error might also account for why a registry study8 was analyzed instead of an RCT published by the same author in the same year.8 Finally, the only RCT in which LIPUS was used to evaluate delayed union9 was omitted for unspecified reasons.

The selection of studies for analysis was biased. Figure 2 in the meta-analysis1 identified 6 biased studies (≥5 of 8 categories at high risk of bias). There were 3 biased LIPUS studies and 3 biased ESTIM studies, and these 6 studies should have been excluded. Yet the meta-analysis included all 3 biased LIPUS studies (references 37, 39 and 41),10–12 while excluding all 3 biased ESTIM studies (references 46, 51 and 55).11–13 A contrast is therefore drawn between the weakest LIPUS papers and the strongest ESTIM papers, whereas meta-analyses usually strive to avoid such imbalances.

Whether fractures were fresh or nonunion prior to treatment was ignored. Fresh fractures treated with LIPUS were evaluated, as compared to nonunion fractures treated with ESTIM. Of the LIPUS papers evaluated, 6 of 7 were about fresh fracture; of the ESTIM papers evaluated, 5 of 8 were about nonunions. Normal healing is expected in fresh fractures; no spontaneous healing at all is expected in nonunions. Thus, any impact of LIPUS would be hard to document, whereas even a minor impact of eStim should be quite obvious.

We believe these problems invalidate the effort of Ebrahim and colleagues to produce a clinically useful meta-analysis.

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References
Dr. Heeckt and colleagues have raised a number of potential issues with our systematic review and network meta-analysis on low-intensity pulsed ultrasound (LIPUS) versus electrical stimulation for fracture healing.1

Their first concern was that “fracture nonunion was improperly defined,” specifically with respect to our definition of fracture union only including bridging at 4 cortices, and our decision to merge possible union (bridging at 3 cortices) and nonunion (bridging at ≤ 2 cortices) into 1 category (nonunion). To facilitate our standard meta-analyses and network meta-analysis, we dichotomized the outcome of fracture union to create a common outcome measure across trials. Our decision to merge possible union and nonunion into 1 category was informed by an experienced orthopedic surgeon who was blinded to the eligible studies in our review. This description was provided in the “Synthesis of results” subsection in the Methods section of our review.

Their second concern was that “reduced time to radiographic union was considered a surrogate end point.” Dr. Heeckt and colleagues cited a survey,2 led by one of us (M.B.), that found orthopedic surgeons consider radiographic outcomes to be more important than functional outcomes when designing clinical trials. Our systematic review specifically considered patient-important outcomes (Table 4, Question C in the systematic review). Return to functioning is a patient-important outcome, whereas radiographic outcomes are an indirect measure of functional recovery. This is an important distinction for readers, as improvements in surrogate outcomes may not translate to commensurate improvements in function. A systematic review by Busse and colleagues3 on the effectiveness of LIPUS for fracture healing found that although there was low-quality evidence from 6 trials to suggest that LIPUS was effective in reducing time to radiographic healing, only 4 trials directly assessed functional recovery, with 3 showing no effect.

Their third concern was that “seminal LIPUS papers were omitted.” Our extraction and analysis did include data from the trials they cited as being omitted,4,5 but the cited references were incorrect. Thank you for bringing this to our attention; we have now provided the correct references to CJFS.

Their fourth concern was that “the selection of studies for analysis was biased” and that studies with high risk of bias should have been excluded. Although these studies suffer from high risk of bias in multiple components on the Cochrane Risk of Bias tool, this does not warrant exclusion of the studies simply on the basis of risk of bias. It is inappropriate to exclude studies from meta-analyses based on arbitrary thresholds for study quality without first conducting subgroup analyses to explore whether or not treatment effect estimates differ among trials with low risk of bias and trials with high risk of bias.6 We planned to perform such subgroup analyses to explore components of risk of bias as a factor to explain heterogeneity in treatment effect estimates, and we included this in our review as follows:

We generated the following a priori hypothesis to explain variability between studies: studies with greater risk of bias will have larger effects than studies with lower risk of bias. This subgroup analysis was completed only on a risk of bias component × component basis if there was considerable variability within the risk of bias component. On consulting with a methodologist, we performed subgroup analyses only when there were at least 5 studies to avoid high risk of spurious subgroup findings.7

Given that each of our analyses consisted of fewer than 5 trials, we were underpowered to perform subgroup analyses to explore risk of bias as a factor to explain heterogeneity in effect estimates. To provide transparency to readers, we provided a risk of bias summary and a GRADE summary of findings table (Table 2 and 3 in the systematic review). Additionally, the ESTIM studies (with multiple components of high risk of bias) were not excluded from our review because of risk of bias, but because they did not report the outcome of interest (union rates) for our analysis. This was described in our Results section as follows:

Eight trials evaluating LIPUS (7 fresh fracture and 1 nonunion populations), and 7 trials evaluating ESTIM (3 fresh fracture and 5 nonunion populations), reported union rates as one of their outcomes and were used in the network meta-analyses.1

Their final concern was the claim that “whether fractures were fresh or nonunion prior to treatment was ignored.” This distinction was not ignored in our review and we separated these 2 types of fractures in our analyses. This was stated in our objectives as follows:

(...) to systematically review the LIPUS and ESTIM literature and perform a network meta-analysis of these 2 treatments for accelerating fracture healing in both fresh fracture and nonunion populations.

We also provided the results separately for these 2 populations — we found that in patients with a fresh fracture, there was a nonsignificant benefit of LIPUS versus standard care and ESTIM on union rates at 6 months, and in patients with an existing nonunion or delayed union, we found a nonsignificant benefit of ESTIM over standard care on union rates at 3 months.

We thank Dr. Heeckt and colleagues for their interest in our paper and continue to believe our findings represent a careful and systematic review and analysis of the literature. Ultimately, the goal of our review was to shed light on knowledge gaps and we stand by our recommendation for large head-to-head trials with safeguards against bias that assess patient-important outcomes to confirm or refute the role of bone stimulation devices for fracture healing in either fresh fracture or nonunion populations.

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