No benefit to surgical fixation of flail chest injuries compared with modern comprehensive management

Conservative versus operative management in stable patients with penetrating abdominal trauma

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Physician and government disconnect is becoming a chasm

It seems like it is getting harder to practise medicine in Canada. It seems more difficult every month, and that should not be the case. Normally Canadian physicians have been fairly trusting of government oversight and involvement in the management of health care. In fact, our system depends on it. We have relied on 2-way communication to make the system work. So why is there an increasing gap between physician needs for patient care and the rationing of health care dollars from the health departments?

Communication has definitely broken down in Ontario. You would think that having a physician as a health minister would help communication, but this did not seem to be the case in that province. The lack of leadership in the Ontario Medical Association (OMA) has allowed the Ontario government to circumvent physician input in order to put forward a plan that will only hurt patients. The ruling was headed off at the last minute by a group of doctors, the Coalition of Ontario Doctors, acting as the OMA executive should have been acting: ensuring future care for patients. The Health Minister, Eric Hoskins, who is 1 of 3 provincial health ministers who are doctors, had planned to freeze the envelope for health care in the face of an aging populace, a growing population and the need for more services. He was expecting the system, which is already not functioning adequately to care for the current patient population, to continue without any provision for expanded care. This is not exactly the kind of forward-thinking vision we need in Canada right now, and I am not sure whether this is the battle that the health ministry of Ontario wants to undertake. While physicians are worried about patient care, the government has focused on a health system envelope freeze in order to keep the budget on track. The current Ontario government has shown its inability to handle infrastructure, electricity, economic growth and the Ontario pension plan. The CancerCare Ontario scandal, the Ontario Health Premium and eHealth problems give us little hope that the government can do better in the health field.

Is the problem localized to Ontario? Probably not. The truth is more than one-third of Canadian doctors practise in Ontario; what happens in Ontario affects all of us. The realization that 80% of physicians in Nova Scotia voted in favour of an agreement that probably will not even cover cost of living increases is yet another example of the increasing mistrust that doctors have in the negotiation process.

Oversight and meddling from the federal government is not going to help the process or patient care. Health care, for better or worse, is a provincial mandate. The federal government should not be allowed to try making political gains by earmarking specific programs, such as home care. Rumors of the federal government threatening withdrawal of transfer payments if private health care continues to expand are extremely disconcerting. It is obvious to anyone who wants to save health care that privatization of certain services is necessary to save the public system. Provincial decisions need to be made with foresight and intimate knowledge of local health care conditions — they should not be determined by the “head in the clouds” federal government decades removed from the nuts and bolts of patient care. I also await the long-delayed (by government) Brian Day case in British Colombia. A seemingly easy legal decision of endangerment of patient health by the current rules should open the door to reconfiguring the health care systems to meet today’s realities.

Overall there are certainly signs that the health care system is not in good health. The physicians who provide care have been marginalized with unilateral decisions at all levels of government. The population has recently become more critical of the doctors, seeming to blame doctors for poor access to health care despite high wages. The Ontario physicians at least have an active subgroup attempting to effect positive change in health care decision-making, but all across the country there should be concern over heavy-handed administrative decisions. It is time for physicians at large to recoup their rightful place alongside the government in decision-making for health care delivery in this country.

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Competing interests: E.J. Harvey is the Chief Medical Officer of Greybox Healthcare (Montreal) and Chairman of the Board of NXT-Sens Inc. (Montreal).

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

Ils semble être de plus en plus difficile de pratiquer la médecine au Canada. On dirait que la difficulté s’accentue chaque mois, et ce n’est pas normal. Généralement, les médecins canadiens se sont montrés plutôt confiants à l’égard de la surveillance et du rôle exercés par le gouvernement dans la gestion des soins de santé. En fait, notre système en dépend; c’est pourquoi nous avons misé sur la communication bidirectionnelle pour en assurer le fonctionnement. Dans ce cas, pourquoi l’écart s’élargit-il entre les besoins des médecins en matière de soins aux patients et les budgets prévus par les ministères de la Santé?

La communication s’est indéniablement détériorée en Ontario. On pourrait croire qu’avoir un médecin comme ministre de la Santé faciliterait les échanges, mais il semble que ce n’ait pas été le cas ici. Le manque de leadership de l’Association médicale de l’Ontario (AMO) a permis au gouvernement d’ignorer les commentaires des médecins pour mettre de l’avant un plan qui ne ferait que nuire aux patients. La décision a été annulée à la dernière minute grâce à un groupe de médecins, la Coalition of Ontario Doctors, qui a fait ce que la direction de l’AMO aurait dû faire : garantir la prestation de soins aux patients. Eric Hoskins, ministre de la Santé de l’Ontario — l’une des 3 provinces où cette fonction est assurée par un médecin —, avait prévu geler le budget alloué à la santé malgré le vieillissement de la population, la croissance démographique et l’accroissement des besoins. Il s’attendait à ce que le système, déjà incapable de fournir des soins adéquats à la population actuelle, poursuive ses activités sans aucun financement supplémentaire. Ce modèle ne correspond pas vraiment à la vision proactive dont le pays a besoin en ce moment, et je doute que ce jeu en vaille la chandelle. Tandis que les médecins se préoccupent des soins aux patients, le gouvernement ne pense qu’à geler les dépenses en santé pour équilibrer son budget. En outre, le gouvernement en place est montré incapable de gérer les dossiers des infrastructures, de l’électricité, de la croissance économique et du régime de retraite de l’Ontario. Et n’oublions pas le scandale d’Action Cancer Ontario, la Contribution-santé et les problèmes chez cyberSanté, qui nous donnent peu d’espoir de voir le gouvernement faire mieux en matière de santé.

L’Ontario est-il seul dans sa situation? Probablement pas. Mais comme plus du tiers des médecins canadiens exercent dans cette province, nous sommes tous touchés par ce qui s’y passe. Le fait que 80 % des médecins de la Nouvelle-Écosse aient voté pour une entente qui sera probablement insuffisante pour compenser l’augmentation du coût de la vie est un autre exemple de la méfiance accrue des médecins à l’égard du processus de négociations.

La surveillance et l’ingérence de la part du gouvernement fédéral n’amélioreront ni ce processus ni les soins aux patients. La santé est une compétence provinciale, pour le meilleur et pour le pire; le fédéral ne devrait donc pas avoir le champ libre s’il tente d’augmenter ses appuis politiques en s’appropriant des programmes particuliers, comme les soins à domicile. Je trouve extrêmement troublantes les rumeurs selon lesquelles Ottawa menacerait de ne plus verser de paiements de transfert si le secteur privé venait à s’étendre davantage. Il est évident, pour quiconque défend les soins de santé, que la privatisation de certains services est essentielle à la survie du système public. Les provinces doivent prendre leurs décisions en faisant preuve de prévoyance et en ayant une connaissance approfondie des réalités locales des soins de santé. Ces décisions ne devraient pas être influencées par un gouvernement fédéral déconnecté, qui ne connaît plus le contexte clinique depuis des dizaines d’années. À ce sujet, j’ai hâte que soit entendue l’affaire Brian Day en Colombie-Britannique, qui est constamment repoussée (par le gouvernement). Dans cette affaire, la reconnaissance juridique apparemment évidente du danger des règles en vigueur pour la santé des patients devrait ouvrir la porte à une reconfiguration des systèmes de santé visant à les adapter à la situation actuelle.

De façon générale, les signes que le système de santé n’est pas en santé lui-même ne manquent pas. Les médecins qui donnent des soins ont été mis de côté par la prise de décisions unilatérales à tous les paliers de gouvernement. De plus, la population est récemment devenue plus critique à l’endroit des médecins : elle semble les blâmer d’offrir un piétre accès aux soins malgré leurs salaires élevés. Les médecins ontariens peuvent au moins compter sur un sous-groupe actif qui travaille à améliorer le processus décisionnel dans le domaine des soins; toutefois, c’est l’ensemble du pays qui devrait s’inquiéter des décisions administratives répressives. Il est maintenant temps pour la profession médicale de rependre la place qui lui revient, aux côtés du gouvernement, dans la prise de décisions en matière de soins au pays.

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A review of the literature and discussion: establishing a consensus for the definition of post-mastectomy pain syndrome to provide a standardized clinical and research approach

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See the related review article by Waltho and Rockwell on p. 342.

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SUMMARY

Chronic pain presents a management challenge for physicians and patients alike, and post-mastectomy pain is no exception. In this issue, Waltho and Rockwell present a review of post-mastectomy pain syndrome (PMPS) and propose a standard definition that should allow future studies to be comparable. The proposed definition of “post–breast surgery pain syndrome” includes pain after any type of breast surgery that is of at least moderate intensity and comprises neuropathic qualities, that is present in the ipsilateral breast/chest/arm, that lasts longer than 6 months and is present at least half the time. Further work is needed to clarify whether this pain syndrome is in fact driven by neuralgia resulting from the axillary dissection component of breast cancer surgery.

Chronic pain presents a management challenge for physicians and patients alike, and post-mastectomy pain is no exception. In this issue, Waltho and Rockwell present a review of post-mastectomy pain syndrome (PMPS) and propose a standard definition that should allow future studies to be comparable. The proposed definition of “post–breast surgery pain syndrome” includes pain after any type of breast surgery that is of at least moderate intensity and comprises neuropathic qualities, that is present in the ipsilateral breast/chest/arm, that lasts longer than 6 months and is present at least half the time. Further work is needed to clarify whether this pain syndrome is in fact driven by neuralgia resulting from the axillary dissection component of breast cancer surgery.

Post-mastectomy pain syndrome (PMPS) has typically been defined based on location and proximity to recent breast surgery, affecting the anterior thorax, axilla and medial aspect of the upper arm, and 87% of the studies reviewed by Waltho and Rockwell included this anatomic restriction in their definitions of PMPS. The authors propose that the clinical picture that occurs depends on which nerves are damaged during surgery, namely the intercostobrachial, medial pectoral, lateral pectoral, thoracodorsal or long thoracic nerves. Since the neuropathic pain quality is critical to the definition of PMPS, injury to 1 or more of these nerves is presumed to be the etiological factor in its development.

Breast surgery is most commonly performed to diagnose or treat breast cancer, and therefore typically involves axillary lymph node surgery for staging (limited or complete axillary lymphadenectomy). Unfortunately, the authors were not able to differentiate whether the studies included in their review included patients who had concomitant axillary surgery versus breast surgery alone, which is a common limitation of many such publications on PMPS to date. While chronic pain has been reported after breast surgery alone without concomitant axillary surgery, that study found that higher pain scores after the original breast and axillary surgery did in fact predict post-reconstruction pain, meaning the patients' pain syndrome can be attributed at least in part to their original axillary surgery.

It would appear that the axillary surgery may be predominantly responsible for PMPS. The nerves listed by these authors are all located within the axilla, although damage to them could also occur in the setting of breast reconstruction when elevating or transecting pectoral muscle. Historically, a complete axillary lymphadenectomy for staging was a standard part of breast cancer surgery, where intercostobrachial nerves are commonly divided in order to more readily access the lateral axillary lymph nodes (level I), while
Resection of the medial lymph nodes (level II) involve medial retraction and potentially injury to the median pectoral nerve. Injury to either, or to the long thoracic and thoracodorsal nerves, is much less likely with the more recent use of sentinel node biopsy (selective axillary lymph node sampling) for the majority of breast cancer surgeries. Sentinel lymph node biopsy became a standard part of breast cancer surgery worldwide in the early 2000s and has therefore not been included in most publications in the literature regarding PMPS, although there is some emerging work demonstrating that the sentinel node axillary sampling procedure is a significant protective factor for the development of PMPS.5

In order to move forward in better understanding and quantifying PMPS among breast cancer patients, the syndrome does need a unifying definition; however, further prospective work is needed in order to understand PMPS more as an axillary pain syndrome. The prevalence of PMPS has likely already diminished substantially with the use of sentinel node biopsy for axillary staging in patients with breast cancer and may become less of an issue as clinical trials continue to expand the indications for sentinel node biopsy among patients with positive clinical lymph nodes after neoadjuvant chemotherapy.

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**Competing interests:** None declared.

**References**


**Correction**

There was an error in Figure 2 of the article by Stewart and colleagues1 published in the August 2016 issue of *CJS*. The graphs were mislabelled in panels A to D. A corrected version of the article is available on our website at canjsurg.ca. We apologize for the error.

**Reference**

Five things they don’t teach you in medical school

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SUMMARY
You graduate from medical school with dreams of beginning your residency, during which you will study and train within the specialty you love more than any other. While you may be book-smart at this point in your career, medical school does not teach you everything you need to know. During residency you will learn the didactic and technical requirements for your future staff job, but medical school won't explicitly address many of the crucial “dos and don’ts” of a successful 2- to 5-year postgraduate training voyage. Here we discuss a few of the important things about residency that you’ll need to know that they don’t teach you in medical school.

1. RESIDENCY IS A 5-YEAR JOB INTERVIEW

Medical school does not teach you everything you need to know for your residency. During residency you will learn the didactic and technical requirements for your future staff job, but medical school won’t explicitly address many of the crucial “dos and don’ts” of a successful 2- to 5-year postgraduate training voyage. The following are 5 things you should know about residency that they don’t teach you in medical school.

While residency may well be the richest learning environment of your career, it is also a 5-year job interview. Although perhaps an intimidating thought, this reality can be framed as an opportunity. Residents should be encouraged to take advantage of every possible learning juncture, because the reality is that once your residency is over, the density of your learning moments and your opportunity for supervised teaching in an open and rich environment decreases dramatically. In other words, the commonly stated 10 000 hours required to become an “expert” at a given task represent only the beginning of mastering the art of surgery.1 It is clear that this time stamp substantially underestimates the required commitment.

Beyond the clinical opportunities to shine, it is also critical that trainees present themselves in a professional manner during residency. Specifically, arrive on time (or even early!) for every meeting and event, dress appropriately for clinical situations (remember that sick patients and faculty outside of your age demographic may not view your attire in the same way that you do), and treat the people around you (nurses, administrative assistants, housekeeping staff, porters, telephone operators, and other hospital staff) with kindness and respect. Engaging the operating room team via preparation for surgery by studying the relevant anatomy, procedural steps, preoperative imaging, and patient-specific variables relevant to the case at hand is critical for demonstrating a commitment to patient care and learning. Meeting the patient before the operation itself, for example, generates a bond that will not only help your postoperative relationship, but also make clear to the faculty that you understand the value of fostering good doctor–patient relationships. Remember that, in general, all of these people are working for
either the betterment of your patients and/or to enhance your personal education. The pillars of professionalism within your 5-year job interview are altruism, integrity, responsibility and respect. By remembering these principles, you will represent yourself well at all times and help develop your distinctive brand as a marketable and employable entity. At the end of the day, it does not take much more effort to stand out — when given an opportunity to do so, run with it! There will always be jobs, even in the toughest supply/demand cycles, for the cream of the crop surgical graduates.

2. Successful leadership and teamwork is about relationships: learn to play well in the sandbox

Collaborating effectively in a clinical, academic and administrative context is crucial to your success as a resident. You will need to interact in a professional manner with staff in other specialties for the betterment of your patients; engage in research projects to push your specialty forward (in addition to allowing you to stand out!); and work collaboratively with colleagues on a variety of tasks that maintain a practice, such as creating call schedules for you and your colleagues. Each of these endeavours is made easier and more pleasant if performed with mutual respect among colleagues. You will see some of the best examples of collaboration among your surgical faculty, as well as some of the worst. Learn from both the good and the bad, and apply what you’ve learned into your daily practice. Also remember that being a leader and ensuring strong relationships requires effort when you’re tired, honesty when it’s uncomfortable, and especially integrity when it’s difficult. Learning how to function and collaborate in a team is an absolute requirement in modern medicine. The days of Han Solo are long gone, so engage your teammates with enthusiasm and a “can do” attitude. Remember that surgery (of all types) is a “can do” business. Do your best to include and refocus team members who focus on negative thoughts, obstacles and reasons why things can’t be achieved. You have the equivalent of a doctorate in pragmatic solutions and problem solving as a surgeon; let your skill set shine through in both the clinical and nonclinical arenas. This must be balanced, however, with knowing when others cannot be refocused. In these instances, you may need to move past them with minimal drama and focus on accomplishing your goals.

3. Start thinking about the future now

While it feels like you’re just starting the voyage from an education standpoint, your residency will pass you by in what seems like a flash. Months seem like days, and then you’re done and it’s off to a fellowship or practice.

While you don’t have to commit to a specialty just yet, frame each rotation with that possibility in mind. Seek out rotations and elective time that allow you to explore specialty areas that might interest you. Go where the best training is — always! Taking advantage of moving around for rotations and/or electives in other centres (i.e., to different cities and programs) provides you with a lifelong improved understanding of things that can be successful and what leads to failure. This remains true in both a clinical and structural context. In every learning environment, surround yourself with mentors who are driven to change the world. These hyper-performers tend to cluster together like moths to a light, so follow the light! In general, faculty surgeons want to help you land in a career choice that you love, so take advantage of their insight, expertise and experience. The surgical world is small, so connections and first-hand testimonials are incredibly important when applying for your fellowship or first job.

4. Controlled ambition and drive is a good thing

Most successful surgical residents (and faculty) are ambitious and want to please others. These are generally great character traits as long as they are harnessed in a productive and nonobtrusive manner. Enthusiasm (i.e., that “can do” attitude) and effort for the purposes of self-advancement are among the most important characteristics of all successful residents. While the dominant and immediate goal of each and every training day must be providing high-quality detailed care to our patients, the educational and relationship benefits we can obtain from these goals are nearly endless. Wanting to impress your bosses, move forward in your careers and generally shine is natural and a large part of what has brought you this far. As with so many other concepts, your faculty want you to succeed and are willing to invest considerable time and energy in you. The key concept here, however, is “controlled” drive. Take a breath, think before you speak, come prepared, communicate with a professional and nonpressured style, and use faculty to your academic and clinical benefit. Medicine is full of smart and connected people with long memories. They are paying attention and quietly identify those surgical residents who reflect on both their errors and successes, invest in patient care, soak up feedback (regardless of its form), and clearly want to do well.

5. Remember to have fun and enjoy yourself

The truth is that we are all incredibly lucky to work as surgeons in any capacity. It is a true honour and privilege to have the opportunity to engage in such a special and intimate relationship with sick patients. Whether achieving a cure or saving a life is the goal, you will often...
represent the last bastion of hope for a sick patient. We
are also permitted to engage in a surgical relationship
that would constitute aggravated assault (at best) outside
of the operating theatre environment. Treat every
patient like he or she is the most important person on
earth at that instant. It is a privilege to cut, to cure, and
to lead. Surgery is in fact one of the very few occupations
that allow an individual to achieve “flow” where time
seems to slow down and all of our distractions fade
away. Although residency is tough and full of daily chal-
lenges, we should meet each hurdle with an inner smile
and a sense of optimism. Squeeze every bit of life and
enjoyment out of each day.

In summary, medical school teaches us a lot, but it
does not teach us everything. By following the advice
outlined above and gravitating to those faculty members
who are hyper-performers, you have the opportunity to
start a surgical career that will engage you, challenge you,
and fulfill you with a lifetime of clinical, academic, and
friendship opportunities.

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Contributors: All authors contributed substantially to the conception,
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publication.

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Canadian Surgery Forum

The Canadian Surgery Forum will hold its annual meeting Sept. 14–17, 2017, in Victoria, BC. This interdisci-
plinary meeting provides an opportunity for surgeons across Canada with shared interests in clinical prac-
tice, continuing professional development, research and medical education to meet in a collegial fashion. The
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students.

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- The Canadian Society of Surgical Oncology
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Other participating societies include the Canadian Association of University Surgeons, the Canadian Associa-
tion of Bariatric Physicians and Surgeons, the Canadian Hernia Society, the James IV Association of Canada,
the Ontario Association of General Surgeons and the Trauma Association of Canada.

For more information visit www.canadiansurgeryforum.com/
No benefit to surgical fixation of flail chest injuries compared with modern comprehensive management: results of a retrospective cohort study

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Background: Chest wall trauma is a common cause of morbidity and mortality. Recent technological advances and scientific publications have created a renewed interest in surgical fixation of flail chest. However, definitive data supporting surgical fixation are lacking, and its virtues have not been evaluated against modern, comprehensive management protocols.

Methods: Consecutive patients undergoing rib fracture fixation with rib-specific locking plates at 2 regional trauma centres between July 2010 and August 2012 were matched to historical controls with similar injury patterns and severity who were managed nonoperatively with modern, multidisciplinary protocols. We compared short- and long-term outcomes between these cohorts.

Results: Our patient cohorts were well matched for age, sex, injury severity scores and abbreviated injury scores. The nonoperatively managed group had significantly better outcomes than the surgical group in terms of ventilator days (3.1 v. 6.1, \( p = 0.012 \)), length of stay in the intensive care unit (3.7 v. 7.4 d, \( p = 0.009 \)), total hospital length of stay (16.0 v. 21.9 d, \( p = 0.044 \)) and rates of pneumonia (22% v. 63%, \( p = 0.004 \)). There were no significant differences in long-term outcomes, such as chest pain or dyspnea.

Conclusion: Although considerable enthusiasm surrounds surgical fixation of flail chest injuries, our analysis does not immediately validate its universal implementation, but rather encourages the use of modern, multidisciplinary, nonoperative strategies. The role of rib fracture fixation in the modern era of chest wall trauma management should ultimately be defined by prospective, randomized trials.

Contexte : Les traumatismes à la paroi thoracique sont une cause courante de morbidité et de mortalité. Dernièrement, des avancées technologiques et des articles scientifiques ont ravivé l’intérêt à l’égard du traitement chirurgical du volet costal. Les données fiables appuyant la fixation chirurgicale sont toutefois rares, et les avantages de cette technique n’ont pas été comparés à ceux de protocoles de prise en charge complets et modernes.

Méthodes : Nous avons jumelé des patients consécutifs admis dans 2 centres régionaux de traumatologie entre juillet 2010 et août 2012 pour une fixation d’une fracture des côtes à l’aide de plaques verrouillées avec un groupe témoin rétrospectif présentant des blessures de type et de gravité semblables, toutefois pris en charge selon des protocoles multidisciplinaires modernes ne nécessitant aucune intervention chirurgicale. Nous avons ensuite comparé les issues à court et à long terme dans ces cohortes.

Résultats : Les cohortes étaient bien appariées sur le plan de l’âge, du sexe et des indices de gravité des blessures. Les résultats des patients n’ayant pas subi d’intervention chirurgicale étaient significativement meilleurs que ceux de l’autre groupe en ce qui concerne le nombre de jours sous ventilation assistée (3,1 c. 6,1; \( p = 0,012 \)), la durée du séjour aux soins intensifs (3,7 c. 7,4 jours; \( p = 0,009 \)), la durée totale du séjour à l'hôpital (16,0 c. 21,9 jours; \( p = 0,044 \)) et le taux de pneumonie (22% c. 63%; \( p = 0,004 \)). Aucune différence significative n’a été observée en ce qui concerne les répercussions à long terme telles que les douleurs thoraciques ou la dyspnée.

Conclusion : Si la fixation chirurgicale des blessures au volet costal suscite un grand enthousiasme, les résultats de notre analyse n’appuient pas le recours systématique à cette intervention, mais encouragent plutôt l’utilisation de stratégies modernes multidisciplinaires sans intervention chirurgicale. En conclusion, le rôle de la fixation des fractures des côtes dans la prise en charge moderne des traumatismes à la paroi thoracique devrait être défini dans le cadre d’études prospectives randomisées.
Flail chest, which often signifies a combination of significant mechanical instability of the chest wall and underlying pulmonary parenchymal injury, is among the most severe and complex forms of chest trauma, with associated mortality of up to 33%. Associated injuries include hemopneumothorax and pulmonary contusion, and common complications are pneumonia and respiratory failure requiring mechanical ventilation. Management of flail chest remains an area of active interest and debate, as morbidity and mortality have not declined substantially over the years. There has been no substantial improvement in the outcomes of flail chest injuries since the 1970s, when Trinkle and colleagues demonstrated the benefits of optimizing lung function using comprehensive multidisciplinary care rather than reducing chest wall instability using mandatory invasive mechanical ventilation.

Continued advances in critical care medicine have supported a long era of nonoperative management as the standard of care for flail chest. The Eastern Association for the Surgery of Trauma (EAST) guidelines recommend optimal analgesia, particularly with epidural anesthesia, aggressive chest physical therapy and pulmonary toilet, supplemental oxygenation, and positive pressure ventilation as needed for respiratory failure.

Recently, promising studies of surgical fixation of flail chest injuries have prompted many centers to reconsider the added importance of reducing the instability of the chest wall in patients with flail chest. Three small, randomized controlled trials (RCTs) and a meta-analysis of 11 comparative studies have demonstrated improved short- and long-term outcomes following surgical stabilization of flail chest. However, these small studies have not yet triggered a universal change in the nonoperative status quo. In this study, we evaluated a new program of surgical fixation of flail chest by comparing the outcomes of operative and nonoperative management in the modern era of comprehensive, multidisciplinary, nonoperative care.

Methods

We conducted this retrospective matched cohort study at 2 major trauma hospitals in Vancouver, Canada. All patients with a flail chest injury who presented to either the Vancouver General Hospital or the Royal Columbian Hospital between July 2010 and August 2012 were considered for surgical fixation with the Synthes MatrixRIB fixation system. Criteria for flail chest fixation required that the patient have 3 or more adjacent, displaced, segmental rib fractures with evidence of respiratory compromise (functional vital capacity < 20 mL/kg or need for noninvasive or invasive mechanical ventilation), despite adequate analgesia. We included in this study patients aged 19 years or older who underwent operative repair of their flail chest (as per the above criteria) and in whom 3 or more fractured ribs were repaired with the MatrixRIB system.

The MatrixRIB fixation system was chosen as a standard approach to operative repair. This system, with its low profile, lightweight, precontoured plates and locking screws, was found to be relatively straightforward to use and to provide a stable and secure repair in most instances.

Patients who underwent surgical repair were independently matched to historical controls from 2008–2011 for same abbreviated injury score (AIS) and age within 5 years using the British Columbia Trauma Registry. Attempts were also made to match for AIS codes from other body regions and for presence of pulmonary contusion. The diagnosis of pulmonary contusion was made by reviewing patient charts and imaging reports for the diagnosis made at the time of injury.

All patients were subjected to the same rigorous medical management practices, in accordance with EAST guidelines. The same multimodal analgesia strategies were used in both groups and included epidural anesthesia; aggressive chest therapy and pulmonary toiletting were performed regularly in all patients, and ventilatory support with positive pressure ventilation was applied as needed.

Our primary end point was total ventilator days, and our secondary outcomes were length of stay (LOS) in the intensive care unit (ICU), total hospital LOS, rate of pneumonia, mortality and long-term quality of life measures. End points, such as LOS, death and rate of pneumonia, were gathered through the BC Trauma Registry. Quality of life surveys were done either in person or over the phone and involved the EQ-5D-5L survey as well as visual analogue scales, dyspnea scales and employment screening questions.

Statistical analysis

We used the Fisher exact test and Wilcoxon rank-sum test as appropriate for our statistical analysis, considering our small sample size.

Results

Nineteen surgical patients qualified for this study (14 from Vancouver General Hospital and 5 from Royal Columbian Hospital), and they were successfully matched to 36 nonoperative control patients. Patient demographic characteristics are outlined in Table 1. The surgical group was made up of 11 men (79%) and had an average age of 53 years. Patients in both groups had significant trauma burden, with average ISS of 31 and 29 in our case and control groups, respectively. Chest injury contributed significantly to injury severity, as the chest region had the highest AIS (4.3 in the case group and 4.1 in the control group). There was no significant difference between the case and control groups for any AIS. Twenty percent of the patients in each group were intubated on arrival to the
emergency department; 79% of surgical patients and 36% of control patients eventually required intubation.

Presence of pulmonary contusion was not well matched between the groups; all 19 of the patients in the fixation group had some degree of pulmonary contusion, whereas only 21 of the control patients had documented pulmonary contusions. Interestingly, all control patients with documented pulmonary contusions were from a single site.

In-hospital outcomes are shown in Table 2. Our primary outcome, invasive mechanical ventilation days, showed that nonoperatively managed patients required a mean of 3.1 ± 5.5 days on a ventilator, which is significantly less than the case group, which required a mean of 6.1 ± 5.9 days of ventilation (p = 0.012). Our secondary outcomes also favoured nonoperative management. Length of stay in the ICU (3.7 v. 7.4 d, p = 0.009), hospital LOS (16.0 v. 21.9 d, p = 0.044) and rate of pneumonia (22% v. 63%, p = 0.004) all showed significantly better outcomes in our control group, whereas mortality was not significantly different. The average time to surgery was 6.3 ± 3.6 days.

Long-term outcomes are shown in Table 3. Response rates were 47% for the control group and 85% for the case group, which are excellent for a follow-up questionnaire. Results from the EQ-5D-5L were not significantly different between groups for mobility, self-care, usual activities or anxiety/depression, but scores were significantly lower in the control group for pain/discomfort (2.0 v. 3.4). This did not seem to be the result of their thoracic trauma, however, as when specifically assessing chest pain, no difference was found between groups. Total health visual analogue scale scores were almost identical, and dyspnea classes were not significantly different between the groups. Additionally, while there was a trend toward improved return to work in the surgical group, this did not reach statistical significance.

**DISCUSSION**

Modern interest in flail chest fixation is the result of new studies and new technologies that favour improved outcomes with surgical fixation. Three RCTs have been published in the last dozen years that demonstrate significant improvements following surgical management of a flail chest when compared with nonoperative management. A salient RCT by Tanaka and colleagues demonstrated not only improved in-hospital data, such as length of mechanical ventilation, days in the ICU and rate of pneumonia, but also significant improvements in long-term outcomes, such as chest pain, chest tightness, dyspnea, time to return to work, and EQ-5D-5L scores.

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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cases n = 19</th>
<th>Controls n = 36</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>53.1 ± 14.3</td>
<td>56.5 ± 15.9</td>
<td>0.42</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td>0.54</td>
</tr>
<tr>
<td>Male</td>
<td>15 (79)</td>
<td>25 (69)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>4 (21)</td>
<td>11 (31)</td>
<td></td>
</tr>
<tr>
<td>ISS</td>
<td>31.4 ± 9.6</td>
<td>29.3 ± 8.1</td>
<td>0.48</td>
</tr>
<tr>
<td>Intubated on arrival to ED</td>
<td>Yes 4 (21)</td>
<td>7 (19)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Pulmonary contusion</td>
<td>Present 19 (100)</td>
<td>21 (58)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Face</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chest</td>
<td>2.8 ± 1.0</td>
<td>3.21 ± 0.97</td>
<td>0.37</td>
</tr>
<tr>
<td>Abdomen and pelvic contents</td>
<td>2.5 ± 0.71</td>
<td>2.5 ± 0.79</td>
<td>0.93</td>
</tr>
<tr>
<td>Extremities and pelvic girdle</td>
<td>2.7 ± 0.60</td>
<td>2.4 ± 0.63</td>
<td>0.16</td>
</tr>
<tr>
<td>External</td>
<td>1.0 ± 0.0</td>
<td>1.0 ± 0.22</td>
<td>0.53</td>
</tr>
<tr>
<td>AIS = abbreviated injury scale; ED = emergency department; ISS = injury severity score; SD = standard deviation.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 2. In-hospital outcomes**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Cases n = 19</th>
<th>Controls n = 36</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilator days</td>
<td>6.1 ± 5.9</td>
<td>3.1 ± 5.5</td>
<td>0.012</td>
</tr>
<tr>
<td>ICU LOS, d</td>
<td>7.4 ± 6.7</td>
<td>3.7 ± 6.0</td>
<td>0.009</td>
</tr>
<tr>
<td>SCU LOS, d</td>
<td>5.4 ± 5.6</td>
<td>3.7 ± 3.7</td>
<td>0.26</td>
</tr>
<tr>
<td>ICU + SCU LOS, d</td>
<td>12.8 ± 9.5</td>
<td>7.3 ± 6.5</td>
<td>0.002</td>
</tr>
<tr>
<td>Hospital LOS, d</td>
<td>21.9 ± 13.2</td>
<td>16.0 ± 12.1</td>
<td>0.044</td>
</tr>
<tr>
<td>Pneumonia</td>
<td></td>
<td></td>
<td>0.004</td>
</tr>
<tr>
<td>Present</td>
<td>12 (83)</td>
<td>8 (22)</td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>7 (37)</td>
<td>29 (78)</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td></td>
<td></td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Yes</td>
<td>1 (5)</td>
<td>1 (4)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>18 (95)</td>
<td>35 (96)</td>
<td></td>
</tr>
<tr>
<td>ICU = intensive care unit; LOS = length of stay; SCU = special care unit; SD = standard deviation.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 3. Long-term outcomes**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Cases n = 11</th>
<th>Controls n = 18</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>2.1 (1.3–2.9)</td>
<td>1.8 (1.3–2.3)</td>
<td></td>
</tr>
<tr>
<td>Self-care</td>
<td>1.6 (1.2–2.1)</td>
<td>1.3 (0.9–1.7)</td>
<td></td>
</tr>
<tr>
<td>Usual activities</td>
<td>2.4 (1.7–3.1)</td>
<td>2.2 (1.6–2.9)</td>
<td></td>
</tr>
<tr>
<td>Pain/discomfort</td>
<td>3.4 (2.6–4.1)</td>
<td>2.0 (1.7–2.3)*</td>
<td></td>
</tr>
<tr>
<td>Anxiety/depression</td>
<td>2.3 (1.5–3.1)</td>
<td>1.6 (1.2–2.1)</td>
<td></td>
</tr>
<tr>
<td>VAS score</td>
<td>65 (45.7–84.2)</td>
<td>67.2 (56.3–78.0)</td>
<td></td>
</tr>
<tr>
<td>VAS chest pain</td>
<td>1.9 (0.6–3.3)</td>
<td>0.8 (0.1–1.5)</td>
<td></td>
</tr>
<tr>
<td>Dyspnea class</td>
<td>1.0</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Return to employment, %</td>
<td>36</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>CI = confidence interval; VAS = visual analogue scale. *Unless indicated otherwise.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
were not randomized until 5 days postinjury and were nonoperative patients. When compared with the outcomes, what is more astounding, however, is how our conservatively managed patients than our surgical tal LOS, and rate of pneumonia were all significantly lower. The postoperative outcomes of our study are very similar to previously published postoperative outcomes. Where our study differs from others, however, is in our nonoperative outcomes. Days on a ventilator, ICU LOS and hospital LOS, and rate of pneumonia were all significantly lower in our conservatively managed patients than our surgical patients. What is more astounding, however, is how our outcomes compare with previously published outcomes in nonoperative patients. When compared with the RCT by Marasco and colleagues, days on a ventilator in our study were less than half of theirs, ICU LOS in our study was more than 11 days shorter, and hospital LOS was 9 days shorter, while their pneumonia rates were 3 times higher than ours. Despite our retrospective matched cohort design, our study raises some interesting questions for future examination, especially considering that the only other North American study on this topic also found no significant improvements in LOS or ventilator days with flail chest fixation. Perhaps it is a reflection of the North American critical care practices, or that critical care has universally improved since some of these studies were done (e.g., patients in the study by Tanaka and colleagues were randomized between 1992 and 1998).

Limitations

Our study does have its limitations. It is a small study, with only 19 cases of surgically managed patients. This is a recurring problem: the sum of cases in all 3 RCTs (which have profoundly influenced discourse in this area) is only 61.4–10 Our study is also limited by its retrospective nature and the practices of the time as patients who were selected for flail chest fixation were not improving despite excellent medical care, leading to a selection bias that would favour outcomes for nonoperatively managed (control) patients. Similarly, time to surgery was almost a week in our study, and earlier operative intervention may have resulted in better outcomes as atelectasis, myopathy and infection would not have had time to advance. However, patients in the study by Tanaka and colleagues were not randomized until 5 days postinjury and were operated at 8 days, while those in the study by Marasco and colleagues were randomized at 2.5 days and operated over 2 days later. Despite these delays, both groups found significant improvements with surgery. Therefore, while our delay seemed substantial, it was not expected to affect outcomes.

A confounding factor was our inability to match for presence of pulmonary contusion. While matched for age, sex, ISS and AIS, 100% of the fixation group had some degree of pulmonary contusion, whereas only 58% of the control group did. The remarkable difference in rates may have come primarily from differences in detection and reporting of this injury at 1 of the 2 study sites. All 9 control patients from 1 study site had no recorded pulmonary contusions. It is possible that this injury was not properly documented or coded in the registry at this hospital, as there are no good ways to determine or measure pulmonary contusion on radiographs, so the interpretation of what should have been included in the registry may have differed between hospitals. However, severity of injury, as reflected by the ISS and chest AIS scores, did not differ between hospitals or between patient groups, and all other covariates were well matched. Based on the even distribution of all other markers of injury severity between cases and controls, we believe that the patient groups were well matched and that the true difference in pulmonary contusion rates may be less than what we reported.

Conclusion

Current multidisciplinary care practices for the management of flail chest injuries produce excellent results for both short- and long-term outcome measures. The days on a ventilator, ICU LOS, total LOS and rate of pneumonia for operative patients in our study are very similar to previously published results, while our control patients had substantially better outcomes than those published previously. This supports the notion that surgical fixation of flail chest is not required for all patients.

For a common, life-threatening problem such as flail chest, the assessment of new therapeutic technologies has tremendous implications in terms of both clinical outcomes and cost. While existing trials have produced an exciting signal that favours the broader use of rib fracture fixation for flail chest, these trials, with all their methodological and temporal limitations, have not yet dispelled equipoise regarding the role and indications for surgical fixation in chest wall trauma. Large RCTs are needed to help define management strategies in this complex area and to guide the thoughtful implementation of a promising strategy in thoracic trauma. Until then, individual therapeutic decisions must account for patient-specific benefits and risks, recognize and account for limitations in the literature, and acknowledge uncertainty in this rapidly evolving area.
Affiliations: From the Section of Trauma and Acute Care Surgery Department of Surgery, University of British Columbia, Vancouver, BC (Farquhar, Slobogean, Garraway, Simons, Hameed); Surgery Department, King Abdulaziz University, Jeddah, Saudi Arabia (Almahrabi); and the Division of Orthopedic Trauma Department of Orthopedics, University of British Columbia, Vancouver, BC (Slobogean).

Competing interests: None declared.

Contributors: Y. Almahrabi, G. Slobogean, N. Garraway, R. Simons and M. Hameed designed the study. J. Farquhar, Y. Almahrabi and M. Hameed acquired and analyzed the data, which G. Slobogean, B. Slobogean and R. Simons also analyzed. J. Farquhar, Y. Almahrabi and M. Hameed wrote the article, which all authors reviewed and approved for publication.

References

Trends in revision hip and knee arthroplasty observations after implementation of a regional joint replacement registry

Background: National joint replacement registries outside North America have been effective in reducing revision risk. However, there is little information on the role of smaller regional registries similar to those found in Canada or the United States. We sought to understand trends in total hip (THA) and knee (TKA) arthroplasty revision patterns after implementation of a regional registry.

Methods: We reviewed our regional joint replacement registry containing all 30,252 cases of primary and revision THA and TKA performed between Jan. 1, 2005, and Dec. 31, 2013. Each revision case was stratified into early (< 2 yr), mid (2–10 yr) or late (> 10 yr), and we determined the primary reason for revision.

Results: The early revision rate for TKA dropped from 3.0% in 2005 to 1.3% in 2011 ($R^2 = 0.84$, $p = 0.003$). Similarly, the early revision rate for THA dropped from 4.2% to 2.1% ($R^2 = 0.78$, $p = 0.008$). Despite primary TKA and THA volumes increasing by 35.5% and 39.5%, respectively, there was no concomitant rise in revision volumes. The leading reasons for TKA revision were infection, instability, aseptic loosening and stiffness. The leading reasons for THA revision were infection, instability, aseptic loosening and periprosthetic fracture. There were no discernable trends over time in reasons for early, mid-term or late revision for either TKA or THA.

Conclusion: After implementation of a regional joint replacement registry we observed a significant reduction in early revision rates. Further work investigating the mechanism by which registry reporting reduces early revision risk is warranted.

Contexte: Ailleurs qu’en Amérique du Nord, les registres nationaux des remplacements articulaires ont été efficaces pour réduire le risque de révision. Cependant, il y a peu d’information sur le rôle des plus petits registres régionaux comme ceux qu’on trouve au Canada et aux États-Unis. Nous avons donc cherché à comprendre les tendances en matière de révision des arthroplasties totales de la hanche (ATH) et du genou (ATG) après la création d’un registre régional.

Méthodes : Nous avons passé en revue notre registre régional des remplacements articulaires, qui contient les 30,252 ATH et ATG primaires et de révision effectuées entre le 1er janvier 2005 et le 31 décembre 2013. Chaque cas de révision a été classé précoce (< 2 ans), moyen (de 2 à 10 ans) ou tardif (> 10 ans), et nous avons déterminé la raison principale de la révision.

Résultats : Le taux de révision précoce pour l’ATG a diminué de 3,0 % en 2005 à 1,3 % en 2011 ($R^2 = 0,84, p = 0,003$). De même, le taux de révision précoce pour l’ATH a diminué de 4,2 % à 2,1 % ($R^2 = 0,78, p = 0,008$). Malgré une augmentation des nombres d’ATG et d’ATH primaires de 35,5 % et de 39,5 %, respectivement, il n’y a pas eu de hausse concomitante du nombre de révisions. Les principaux motifs de révision de l’ATG étaient l’infection, l’instabilité, le descellement aseptique et la raideur. Les principaux motifs de révision de l’ATH étaient l’infection, l’instabilité, le descellement aseptique et les fractures périprothétiques. Aucune tendance n’a été décelée au fil du temps dans les motifs de révision précoce, moyenne et tardive pour l’une ou l’autre des interventions.

Conclusion : Nous avons observé une baisse significative des taux de révision précoce après la mise en œuvre d’un registre régional des remplacements articulaires. Il serait pertinent d’étudier plus en profondeur le mécanisme par lequel le signalement dans un registre réduit le risque de révision précoce.
It is generally accepted that lower extremity joint replacement registries are effective at reducing revision risk following elective primary total knee (TKA) and total hip arthroplasty (THA) by providing outcome information to surgeons, hospitals, and administrators. For example, recent reports from both the Swedish hip and knee arthroplasty registries document decreasing revision risk with each passing decade over the past 40 years. The reasons for the reduction in revision rate are no doubt multifactorial, and likely include such elements as patient and implant selection, surgical technique, and postoperative care. The Australian joint replacement registry has implemented a method to facilitate prompt identification of “outlier” prostheses, thus facilitating abandoning implants that have higher than expected early revision risk. The most recent Swedish hip arthroplasty registry has demonstrated a reduced early THA revision risk attributable to a decrease in revisions for instability; this may be explained by the increased use of large head sizes, which has also been reported in the National Joint Registry (NJR) of England and Wales. Based on findings from previous registry reports demonstrating revision risks associated with patellar component use, Swedish surgeons now resurface the patella in less than 3% of their patients.

While robust joint replacement registries have been in place for decades outside North America, there is little evidence of their effectiveness in a North American context, since there are no registries in either Canada or the United States that have capture rates above 90% or that routinely report on revision risk. This leaves North American surgeons dependent upon international registry reports, making it unclear whether registry reporting in Canada or the United States would be associated with the same positive effect on revision rates seen in other countries. Accordingly, we decided to examine patterns of THA and TKA revisions after implementation of a regional joint replacement registry in a Canadian health authority. Specifically, we sought to determine trends in THA and TKA revision caseload, early (< 2 yr) revision rate and reasons for revisions since implementation of our registry.

**Methods**

The Winnipeg Regional Health Authority (WRHA) is Manitoba’s largest health authority, serving a large proportion of Manitoba’s 1.2 million residents with 2 tertiary and 4 community hospitals. The province has a single-payer health care system that provides all necessary hospital, medical and surgical services, and private purchasing of joint replacement surgery is not allowed; this characteristic, along with Winnipeg’s relative geographic isolation, allows for nearly complete capture of all primary and revision TKAs and THAs. Currently, the region performs approximately 3000 primary and revision joint replacements per year among 19 surgeons.

**Description of the registry**

In partnership with the Manitoba Orthopaedic Society, the WRHA regional joint replacement registry was initiated in 2004 with partial coverage and expanded to full mandatory coverage in 2005. The registry collects patient demographic data; disease-specific and generic health related quality-of-life data both preoperatively and 1 year postoperatively; intraoperative information related to diagnosis, surgical technique and implant details; and 1-year self-reported complications and satisfaction. Funding for the registry is provided by the WRHA surgery program. Preoperative data capture occurs in the premission clinic under the guidance of the clinic nurse. Operating room nurses are responsible for ensuring that operative details are captured on the registry form. Postoperative data are collected via mail out, which is conducted by registry staff. Data entry is undertaken by both the hospital medical records department for hospital stay characteristics, and by the registry staff for patient-reported outcome measures. Surgical volumes are tracked through operative slate reconciliation with the regional orthopedic wait list database. Data from these 3 sources (hospital medical records, orthopedic wait list and patient-reported outcome measures) are combined to generate reports on a yearly basis for each surgeon performing TKA or THA and for each hospital site. All reports are reviewed by the WRHA Orthopaedic Standards and Quality Committee, while surgeons with outcomes inferior to regional averages for 2 or more years meet with the committee for review.

**Study sample**

This study received ethical approval from our university research ethics board. All patients who underwent either primary or revision TKA or THA within the WRHA between Jan. 1, 2005, and Dec. 31, 2013, were included in the study. When determining the 2-year revision rate, only primary joints inserted between Jan. 1, 2005, and Dec. 31, 2011, were included, as they all had a minimum of 2 years of follow-up at the time of analysis (January 2014). For revision cases, the reason for revision and date of the primary joint replacement were extracted from the registry; this was supplemented with data from the medical chart if the reason for revision was missing, or if the joint being revised was inserted before initiation of the registry. The primary reason for revision was coded using the same diagnostic codes as the Canadian Joint Replacement Registry.

**Statistical analysis**

Primary and revision volumes were plotted year over year to look for trends. We calculated the 2-year revision rate as the proportion of THAs or TKAs revised within...
2 years of the index procedure. Multiple revisions of the same joint were counted only once. We performed linear regression to assess the association between revision rate and year of surgery. For revision cases, the time to revision was stratified as early (< 2 yr), mid (2–10 yr) or late (> 10 yr). We then graphically plotted the top 4 reasons for revision as proportions, stratified by time frame and procedure, to examine trends.

RESULTS

We identified 10 920 primary and 1811 revision THAs and 16 202 primary and 1501 revision TKAs in the registry. After exclusion of repeat revisions and cases for which there was no information on either the date of the primary procedure or the reason for revision, 930 revision THAs and 734 revision TKAs were available for inclusion in our reason for revision analysis.

The average ages of primary and revision TKA patients were 67.1 and 66.9 years, respectively; 61.6% of the primary and 56.5% of the revision TKA patients, respectively, were women. The average ages of primary and revision THA patients were 67.5 and 68.7 years, respectively; 55.7% of the primary and 54.6% of the revision THA patients, respectively, were women. The average body mass index (BMI) of primary TKA and THA patients was 32.6 and 29.2, respectively.

Despite the yearly primary TKA volumes increasing by 35.5% from 1412 procedures in 2005 to 1913 procedures in 2013, the yearly revision TKA volumes stayed fairly constant at an average of 166 procedures per year (Fig. 1). As a proportion of total procedures, revision TKA dropped from 9.7% (151 of 1563) in 2005 to 6.0% (123 of 1401) in 2013.

The early (< 2 yr) revision rate for TKA improved nearly every year, dropping from 3.0% (42 of 1412) in 2005 to 1.3% (24 of 1895) in 2011; this downward trend was significant ($R^2 = 0.84, p = 0.003$). Similarly, the early revision rate for THA dropped nearly every year, from a high of 4.2% (37 of 884) in 2005 to 2.1% (32 of 1504) in 2013 ($R^2 = 0.78, p = 0.008$, Fig. 3).

The top 4 reasons for early (< 2 yr) TKA revision were infection (39%), instability (22%), stiffness (12%) and patella mal-tracking or instability (7%). There was no discernible change to this distribution of reasons from 2005 to 2013 (Fig. 4). Figure 5 illustrates how the reasons for TKA revision changed with the revision period (early, mid, late). As the time to revision increased from early to mid to late, infection dropped from 39% to 19% to 7%, instability increased from 22% to 25% to 27%, stiffness dropped from 12% to 10% to 1%, and aseptic loosening increased from 7% to 18% to 41%. The top 4 reasons for early (< 2 yr) THA revision were infection (32%), aseptic loosening (21%), instability (25%) and periprosthetic fracture (18%). There was no discernible change to this distribution of reasons from 2005 to 2013 (Fig. 6). Figure 7 illustrates how the reasons for THA revision changed with the revision period. As the time to revision increased from early to mid to late, infection dropped from 32% to 15% to 3%, aseptic loosening increased from 21% to 55% to 71%, instability decreased from 25% to 15% to 9%, and periprosthetic fracture decreased from 18% to 8% to 1%.

![Fig. 1: Primary and revision total knee arthroplasty (TKA) volumes throughout the study period.](image-url)
DISCUSSION

Since implementation of the registry, there has been a drop in the early (< 2 yr) revision rate for both TKA and THA. This finding is consistent with results reported by others on the effects of implementation of a registry. For example, Sweden’s 2-year revision rate for primary TKA dropped from approximately 5% for the decade 1976–1986 to approximately 2% for the decade 1986–1995. Examining more recent data, the Swedes have seen a drop in early THA revision risk from approximately 2.5% for the decade 1993–2002 to 2.0% for the decade 2003–2012. Our early revision rates of 1.3% for TKA and 2.1% for THA are similar to those found in the Australian registry of approximately 2.0% for TKA and 2.1% for THA.

Despite a significant increase in primary TKA and THA volumes over the time period examined (35.5% and 39.5%, respectively), there was no concurrent increase in the volume of revision procedures. This occurred because the falling early revision rate prevented an increase in early revision burden that would have been expected from the increased primary joint replacement volumes. This finding differs significantly from the rest of Canada; during this period revision TKA volumes increased nationally by 50.0%, and revision THA volumes increased nationally by 38.5%. Our revision hip replacement burden of 11.9% is slightly higher than the Canadian average of 11.1% (excluding partial hip replacements), but our knee revision burden of 6.0% compares favourably to the Canadian national average of 6.8%. The revision burden in the United States may be higher. Using data from 1990 to

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Fig. 2: Primary and revision total hip arthroplasty (THA) volumes throughout the study period.

Fig. 3: Early revision rates for total hip and total knee arthroplasty.
2002, Kurtz and colleagues\textsuperscript{10} found that 8.2\% of knee replacements and 17.5\% of hip replacements were revision procedures.

We found that the leading reasons for early TKA revision were infection, instability, stiffness and patella maltracking or instability. Owing to differences in coding and reporting time frame, it is difficult to compare these findings to those of studies examining other registries. However, these reasons are similar to those found in both the Australian Registry\textsuperscript{7} and the NJR\textsuperscript{4} (Table 1). The top 4 reasons for early THA revision in our registry were infection, aseptic loosening, instability and periprosthetic fracture; again, these are similar to those found in both the Australian Registry\textsuperscript{7} and the NJR\textsuperscript{4} (Table 2). The reasons for revision reported in the Swedish\textsuperscript{1,2} and Canadian\textsuperscript{5} Joint Replacement Registries could not be stratified into those associated with early, mid, or late time frames because the time frames were not reported.

The reasons for revision changed as the interval from the primary procedure increased. Revision for infection dropped for both knees and hips; this was expected as the early infections were likely related to the surgical procedure and the later ones to hematogenous spread. As the time frame increased, revision for aseptic...
loosening increased for both TKA and THA, which again we expected as a result of implant wear and osteolysis.

Limitations

Our study has a number of limitations. First, we were unable to include all of the revision procedures in our analysis of reasons for revision, as we were missing either the date of the primary procedure or the reason for revision in 33.8% (508 of 1501) of the revision TKAs and 36.7% (664 of 1811) of the revision THAs. The date of the primary procedure was incomplete because either the index procedure occurred before the registry was established, occurred outside of our health region, and/or the original operative report was unavailable. Data on the reason for revision were occasionally unavailable if they were not contained in either the registry (incomplete registry form completion) or in the revision procedure operation details in the medical chart. This limitation would affect primarily the late term revisions, and to a lesser extent the midterm revisions. Importantly, this limitation does not affect the early revision rate, as this was calculated using only primary procedures recorded in the registry.

Fig. 6: Reasons for early revision of total hip arthroplasty during the study period.

Fig. 7: Reasons for total hip arthroplasty revision changed depending on the revision period (early, mid, late).
Second, we did not look at the possible confounding effect of patient, surgical or implant characteristics on revision rates. However, in a separate analysis of the same data set, we found that patient characteristics and disease severity have not changed over the time period examined (data not shown), and we feel that motivating surgeons to improve both surgical technique and implant selection is an intended effect of the registry.

Third, since this is an observational study and not an experimental one, it is not possible for us to definitively conclude that our findings of decreased revision rates were a direct result of initiating the registry; they may in fact reflect pre-existing trends or other care improvement initiatives. However, the knowledge gained from registry reporting is broadly acknowledged to facilitate improvement in care, and a recent Cochrane review found support for the effectiveness of audit and feedback at driving improvement.11

CONCLUSION

Initiation of a regional joint replacement registry that incorporates individual surgeon performance review and feedback appears to be associated with a reduction in early revision rates. In our region, this allowed for a significant increase in primary TKA and THA procedures without an associated increase in revision volumes. Further work investigating the mechanism by which registry reporting reduces early revision risk is warranted.

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Competing interests: L. Louks was employed as a researcher with the Concordia Joint Replacement Group during the conduct of the study. No other competing interests declared.

Contributors: All authors designed the study. J. Singh, A. Politis, L. Louks and E. Bohm acquired and analyzed the data and wrote the article, which all authors reviewed and approved for publication.

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Plain film measurement error in acute displaced midshaft clavicle fractures

Background: Clavicle fractures are common and optimal treatment remains controversial. Recent literature suggests operative fixation of acute displaced mid-shaft clavicle fractures (DMCFs) shortened more than 2 cm improves outcomes. We aimed to identify correlation between plain film and computed tomography (CT) measurement of displacement and the inter- and intraobserver reliability of repeated radiographic measurements.

Methods: We obtained radiographs and CT scans of patients with acute DMCFs. Three orthopedic staff and 3 residents measured radiographic displacement at time zero and 2 weeks later. The CT measurements identified absolute shortening in 3 dimensions (by subtracting the length of the fractured from the intact clavicle). We then compared shortening measured on radiographs and shortening measured in 3 dimensions on CT. Interobserver and intraobserver reliability were calculated.

Results: We reviewed the fractures of 22 patients. Bland–Altman repeatability coefficient calculations indicated that radiograph and CT measurements of shortening could not be correlated owing to an unacceptable amount of measurement error (6 cm). Interobserver reliability for plain radiograph measurements was excellent (Cronbach $\alpha = 0.90$). Likewise, intraobserver reliabilities for plain radiograph measurements as calculated with paired t tests indicated excellent correlation ($p > 0.05$ in all but 1 observer [$p = 0.04$]).

Conclusion: To establish shortening as an indication for DMCF fixation, reliable measurement tools are required. The low correlation between plain film and CT measurements we observed suggests further research is necessary to establish what imaging modality reliably predicts shortening. Our results indicate weak correlation between radiograph and CT measurement of acute DMCF shortening.

Contexte : Les fractures de la clavicule sont fréquentes, et le choix du traitement optimal ne fait pas l’unanimité. Selon la littérature récente, la fixation chirurgicale des fractures du tiers médial déplacées (FTMD) aiguës raccourcissent de plus de 2 cm donnerait de meilleurs résultats. Nous avons voulu établir une corrélation entre la mesure du déplacement obtenue par radiographie simple et par tomodensitométrie (TDM) et la fiabilité inter- et intra-observateur des mesures radiographiques répétées.

Méthodes : Nous avons obtenu les radiographies et les TDM de patients ayant subi une FTMD aiguë. Trois orthopédistes et 3 résidents ont mesuré le déplacement radiographique au temps zéro et semaines plus tard. Les mesures par TDM ont permis d’identifier un raccourcissement absolu en 3 dimensions (en soustrayant de la longueur de la clavicule intacte celle de la clavicule brisée). Nous avons ensuite comparé le raccourcissement mesuré par radiographie au raccourcissement en 3 dimensions mesuré par TDM. La fiabilité inter- et intra-observateur a ensuite été calculée.

Résultats : Nous avons ainsi analysé les fractures de 22 patients. Les calculs du coefficient de répétabilité de Bland et Altman ont indiqué qu’il était impossible d’établir des corrélations entre les mesures obtenues par radiographie et par TDM compte tenu de l’ampleur inacceptable de l’erreur de mesure (6 cm). La fiabilité inter-observateur a été excellente pour les mesures radiographiques (coefficient $\alpha$ de Cronbach = 0,90). De même, la fiabilité intra-observateur pour les mesures radiographiques calculée par test t pour échantillons appariés a indiqué une excellente corrélation ($p > 0,05$ chez tous les observateurs, sauf 1 [$p = 0,04$]).

Conclusion : Pour que le raccourcissement devienne une indication de la FTMD, il faut disposer d’outils de mesure fiables. La faible corrélation que nous avons observée entre les mesures obtenues par radiographie et par TDM montre qu’il faut approfondir la recherche afin de déterminer quelle modalité permet de prédire de manière fiable le raccourcissement. Nos résultats démontrent une faible corrélation entre les mesures du raccourcissement obtenues par radiographie et par TDM dans la FTMD aiguë.
Clavicule fractures account for nearly 10% of all fractures evaluated by clinicians. Treatment of these fractures has evolved from primarily conservative methods to select indications for open reduction internal fixation (ORIF).

Data presented in recent literature suggest that nonoperative treatment of displaced midshaft clavicle fractures (DMCFs) leads to a higher incidence of nonunion than previously reported as well as reduced shoulder strength and endurance. Poor functional outcome has been associated with nonoperatively treated fractures that result in an overall clavicle length 15–20 mm shorter than the contralateral (unfractured) clavicle. Consequently, 20 mm of shortening has evolved as a relative indication for operative therapy.

The literature that has established 20 mm of shortening as a relative indication for surgical management of DMCF is the product of multiple studies that use different measurement modalities. These measurement modalities include clinical estimates with tape measure, radiological estimates made on uncalibrated plain films and computed tomography (CT) measurements in both the acute fracture and chronic malunion settings. In a recent study of healed clavicle fractures, Smekal and colleagues established that neither clinical nor plain film measures of clavicle shortening correlate with those obtained by CT (used as a reference measure). Additionally, of the 3 radiographs investigated (15° up-tilted panorama and 15° standardized tilted views) only the posteroanterior (PA) thorax radiograph that demonstrated the contralateral unfractured clavicle for comparison correlated with CT measurements of clavicle shortening. A PA thorax radiograph that includes the injured and normal clavicle is not routinely part of the diagnostic radiograph series for suspected clavicle fracture, and as such clinicians may not currently have access to the necessary imaging required to identify patients who meet shortening criteria for operative intervention.

To our knowledge, no reports to date have compared clavicle shortening measured on plain film to that measured on CT in the acute fracture setting. The purpose of this study was to define the correlation of plain film measurements with CT measurements of shortening in DMCF and assess the interobserver and intraobserver reliabilities associated with radiographic measurements of displacement.

**Methods**

Institutional ethics approval was obtained. We identified clavicle radiographs with corresponding CT scans obtained from skeletally mature patients at our institution between Nov. 20, 2003, and Aug. 31, 2012. The images had been obtained as part of either a routine trauma assessment or in the work-up of a pathologic fracture. We excluded studies from the analysis if a pathologic fracture was confirmed. Patients with a unilateral midshaft clavicle fracture who had dedicated plain film radiographs of the injured clavicle as well as a high-quality chest CT scan that completely visualized both clavicles were selected for analysis. Imaging studies (radiograph and CT) were anonymized and exported into a medical imaging software DICOM viewer (Osirix, Pixmeo). Studies were excluded if more than 3 days had elapsed between the radiograph and CT scan of the acute fracture to minimize the risk that an actual change in clavicle length occurred secondary to positioning changes.

This study is based on the assumption that clavicle length is symmetric as confirmed recently by Cunningham and colleagues. For the purposes of the present study, the unfractured clavicle was considered to represent a patient’s normal clavicle length. Clavicle length was measured in 3 dimensions on axial CT scan cuts using Osirix by an author (L.A.A.) who did not serve as an observer in the plain film analysis of shortening. A point (with x, y and z coordinates) was placed at the most medial and most lateral ends of both the intact and fractured clavicles (Fig. 1). We calculated clavicle length in 3 dimensions based on the x, y, z coordinates. Absolute clavicular shortening was then calculated by subtracting the fractured clavicle length from the length of the intact clavicle for each patient.

Three orthopedic staff and 3 orthopedic residents were provided with the series of plain films loaded on Osirix for review and oriented to the use of the DICOM viewer interface. Each plain film contained a full-length view of the fractured clavicle. The reviewers were asked to estimate the extent of shortening on the plain film using the standard computerized measurement caliper. Participants were not instructed on what specific points within the fracture should be measured to estimate shortening. After a 2-week washout period, the same participants repeated shortening estimates on the provided films.

![Fig. 1: To measure clavicle length, a point (with x, y, z coordinates) was placed at the most medial and most lateral ends of both the intact and fractured clavicles. Clavicle length was calculated in 3 dimensions based on the x, y, z coordinates.](image-url)
Statistical analysis

We used SPSS software version 12.0 for statistical analyses. Correlation between plain film and CT measurements of shortening was investigated using the Bland–Altman reliability coefficient. We compared clavicle shortening measured on plain radiographs at each time point by each observer with clavicle shortening measured in 3 dimensions on CT. Limits of agreement were then calculated using the standard deviation (SD) obtained for each observer (± 2 SD). Interobserver reliability was evaluated using the Cronbach α coefficient. Intraobserver reliability was calculated using paired t tests for each observer.

RESULTS

Twenty-two patients with appropriate radiographic studies were identified: 7 female and 15 male patients with a mean age of 48 (range 19–84) years. Eighteen patients sustained their injury secondary to high-energy trauma, whereas the remaining 4 patients had minimal trauma.

Two Bland–Altman repeatability coefficient analyses were performed for each observer using the 2 data sets (time zero and 2 weeks). The results of the analysis showed that measurements obtained by 5 of 6 observers did not correlate with CT measurements at both points owing to unacceptable measurement error (Table 1). The limits of agreement calculated with this statistical method revealed a mean of ± 3.48 cm. Therefore, the error inherent in plain film measurements in this study is 6.96 cm (Table 2). Interobserver reliability calculated with Cronbach α identified excellent correlation (0.90). Likewise, intraobserver reliabilities calculated with paired t tests demonstrated excellent correlation (p > 0.05 in all but 1 observer [p = 0.04]; Table 2). It should be noted that the outlying observer was a staff orthopedic surgeon with specialty training in traumatology.

Table 1. Bland–Altman repeatability coefficient used to identify confidence intervals (correlation of radiograph with computed tomography measurements) and the limits of agreement (amount of error accepted)

<table>
<thead>
<tr>
<th>Observer</th>
<th>Time point</th>
<th>Correlation</th>
<th>Bias</th>
<th>95% CI</th>
<th>Limit of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Time zero</td>
<td>0.27</td>
<td>–0.21</td>
<td>–0.96 to 0.54</td>
<td>± 3.38</td>
</tr>
<tr>
<td></td>
<td>2 weeks</td>
<td>–0.05</td>
<td>–0.24</td>
<td>–1.15 to 0.67</td>
<td>± 4.10</td>
</tr>
<tr>
<td>2</td>
<td>Time zero</td>
<td>0.26</td>
<td>–0.07</td>
<td>–0.74 to 0.60</td>
<td>± 3.02</td>
</tr>
<tr>
<td></td>
<td>2 weeks</td>
<td>0.32</td>
<td>–0.03</td>
<td>–0.73 to 0.66</td>
<td>± 3.15</td>
</tr>
<tr>
<td>3</td>
<td>Time zero</td>
<td>0.27</td>
<td>–0.29</td>
<td>–1.02 to 0.44</td>
<td>± 3.30</td>
</tr>
<tr>
<td></td>
<td>2 weeks</td>
<td>0.05</td>
<td>–0.40</td>
<td>–1.25 to 0.44</td>
<td>± 3.80</td>
</tr>
<tr>
<td>4</td>
<td>Time zero</td>
<td>0.34</td>
<td>–0.04</td>
<td>–0.73 to 0.65</td>
<td>± 3.12</td>
</tr>
<tr>
<td></td>
<td>2 weeks</td>
<td>0.22</td>
<td>–0.21</td>
<td>–0.98 to 0.55</td>
<td>± 3.44</td>
</tr>
<tr>
<td>5</td>
<td>Time zero</td>
<td>0.36</td>
<td>–0.12</td>
<td>–0.80 to 0.57</td>
<td>± 3.08</td>
</tr>
<tr>
<td></td>
<td>2 weeks</td>
<td>0.11</td>
<td>–0.15</td>
<td>–0.96 to 0.67</td>
<td>± 3.68</td>
</tr>
<tr>
<td>6</td>
<td>Time zero</td>
<td>0.09</td>
<td>–1.05</td>
<td>–1.90 to –0.20</td>
<td>± 3.84</td>
</tr>
<tr>
<td></td>
<td>2 weeks</td>
<td>–0.02</td>
<td>–0.89</td>
<td>–1.76 to –0.03</td>
<td>± 3.90</td>
</tr>
</tbody>
</table>

CI = confidence interval.

DISCUSSION

Approximately 20 of every 100 000 individuals sustain a DMCF each year. Traditionally, acute DMCFs were managed nonoperatively. Early attempts at ORIF of clavicle fractures produced high rates of nonunion and discouraged operative treatment of these injuries. However, emerging evidence suggests that the risks of surgical treatment may be outweighed by functional and financial benefits for patients with midshaft clavicle fractures shortened 20 mm or more.

In the 1960s, Rowe and colleagues and Neer and colleagues conducted large clinical series (566 patients and 2235 patients, respectively) documenting outcomes of patients with clavicle fractures treated nonoperatively. These studies independently reported nonunion rates less than 1% and failed to identify functional compromise with nonoperative treatment. Neer and colleagues included 18 cases of nonunion in their series and attributed 10 of these failures to operative intervention. Similarly, Rowe and colleagues reported a nonunion rate associated with operative intervention more than 4 times that of nonoperative management (3.7% v. 0.8%).

Data published recently challenge the uniform treatment of acute DMCF conservatively, citing the incidence of nonunion and shoulder dysfunction as unacceptably high with nonoperative therapy. Current literature suggests that nonunion may occur in up to 30% of conservatively treated DMCFs with shortening of 20 mm or more on initial injury films. In their prospective series of 208 patients followed up to 10 years, Nowak and colleagues determined that lack of cortical contact between fragments and displacement of the fracture fragments on initial injury films were predictors of poorer long-term outcomes. Wick and colleagues demonstrated an increase in the incidence of nonunion with initial shortening...
greater than 20 mm through the prospective treatment of 39 delayed or malunited midshaft clavicle fractures. Robinson and colleagues performed a prospective cohort analysis of 868 patients with clavicle fractures and identified lack of cortical apposition as being predictive of nonunion. Furthermore, a recent study by Murray and colleagues identified lack of cortical contact between fracture fragments in acute DMCFs as a risk factor for nonunion. Finally, Hill and colleagues identified initial shortening of 20 mm or greater to be significantly correlated with risk of nonunion through their cross-sectional study of 242 patients with clavicle fractures.

Global loss of shoulder strength and endurance has been associated with symptomatic malunion resulting from nonoperative treatment of an acute DMCF shortened in the medial-lateral plane. As early as 1986, Eskola and colleagues identified increased incidence of pain and weakness associated with radiographic clavicle shortening greater than 15 mm after fracture in a population of 89 patients treated nonoperatively. In a cross-sectional study of 30 patients with DMCF treated conservatively, McKee and colleagues noted a trend toward increased shoulder disability with shortening of 20 mm or greater (mean DASH score of 24.6 and mean Constant score of 71). Another cross-sectional study of 16 patients documented statistically significant loss of abduction, internal rotation and extension strength in shoulders with clavicle malunions (defined as shortening ≥ 15 mm as compared with the normal side measured on CT scan). In the same study, the authors demonstrated abnormal static anatomic relationships of the sternoclavicular joint and increased scapular anteversion with clavicle malunions, citing these anomalies as potential explanations for functional differences. A biomechanical study of 12 cadaveric shoulders recently demonstrated decreased posterior tilt and external rotation of the scapula during shoulder motion with more than 10% shortening of the clavicle. Matsumura and colleagues state that such anomalous biomechanics may explain shoulder dysfunction after clavicle shortening. Recently, Risteviski and colleagues quantified the degree of scapular deviation from normal positioning associated with clavicular malunion and identified scapular winging as a possible complication of scapular malposition. Lending the strongest clinical support for improved outcomes with ORIF of acute DMCF, a randomized control trial by Altamimi and McKee demonstrated significantly superior outcomes when operative therapy was selected for acute DMCF (10-point improvement in both mean DASH and mean Constant scores for operatively treated patients). Substantial additional literature supports accepting 20 mm or more of shortening in an acute DMCF as a relative, and potentially absolute, indication for ORIF.

Despite evidence to suggest clavicle shortening causes shoulder dysfunction, controversy remains. Nordqvist and colleagues failed to demonstrate an association between shortening and functional shoulder outcome in a review of 71 patients with clavicle fractures. Similarly, Oroko and colleagues found that shortening of the clavicle had no functional impact in 41 patients studied 3 or more months after clavicle fracture. Most recently, Robinson and colleagues failed to demonstrate an improvement in shoulder function associated with ORIF of DMCF compared with fractures treated nonoperatively in the absence of nonunion, suggesting that the benefit to ORIF lies in the decreased incidence of nonunion and not prevention of malunion.

Clavicle shortening has been estimated by several methods, including direct clinical measurement with tape measure, radiographic measurement from plain radiographs or calculation from CT data. Measurement from plain film is associated with significant error, highlighting the potential drawback of using this modality as a screening tool to identify operative candidates. Several pitfalls inherent in plain radiography potentially compromise the use of this modality as a reliable measuring tool for clavicle fractures. First, the complex s-shaped morphology of the clavicle prevents the bone from being positioned truly perpendicular to the radiograph cassette, and second, true orthogonal imaging of the clavicle is not easily obtained. Figure 2 illustrates the limitations of radiographic assessment of clavicle fractures and displays the same clavicle fracture in 3 projections (cephalad projection angle changed by 25° each time). Additionally, patient positioning (supine vs. upright) and distance of the patient from the radiograph cassette may contribute to error in measurement of clavicle shortening on plain films. In the present study, 18 patients sustained clavicle fractures as a result of high-energy trauma. As a result, not all patients could sit upright for clavicle films; however, each CT scan was obtained with the patient supine. Based on the study by Backus and colleagues, it is likely that a degree of measurement error was introduced by the inconsistent positioning of patients in this study during plain film radiography.

Open reduction and internal fixation of acute clavicle fractures exposes patients to risks, such as infection, symptomatic hardware, refracture after hardware removal and damage to adjacent neurologic and vascular structures. Justification of these risks requires appropriate patient
selection. If clavicle shortening of greater than 20 mm is to be used as an indication for surgery, reliable methods of measurement are required to accurately identify patients who will benefit from operative therapy. Although interobserver and intraobserver reliability were high in our study, comparison of measurements generated on plain film to those obtained in 3 dimensions using CT demonstrate correlation only if a large amount of error (6 cm) is accepted. Given the established indication of improved outcome for patients presenting with 20 mm of shortening, 6 cm of error is not acceptable. Of note, recent studies suggest that lack of cortical apposition may be an adequate surrogate measure for shortening when deciding which patients with acute DMCF would benefit from ORIF. Use of surrogate measures for shortening may enable appropriate patient selection in the absence of a reliable radiographic measuring tool.

Limitations

Limitations of this study include the inability to control for patient positioning for radiograph and CT scans, which could at least in part account for the measurement error observed in this study. Intraobserver reliability reported in this study may have been biased secondary to participant recall of the clavicle plain films (and measurements) between time points. However, the high intraobserver and interobserver reliability in this study suggests that individual recall of images was unlikely to be a significant source of error. Heterogeneity in the experience levels of participants reviewing the radiographs could be viewed as a shortcoming of this study. Orthopedic residents at various levels of training as well as orthopedic specialists with and without fellowship hand and upper limb training formed the observer group. Residents were in either their second, fourth or fifth years. In clinical practice, however, orthopedic surgeons with diverse backgrounds treat these fractures and, as such, the heterogeneity in the observer group may actually be representative of the real-world scenario.

Conclusion

Plain film measurements of acute DMCF do not reliably predict shortening. Computed tomography is an additional tool orthopedic surgeons can use to improve the accuracy of patient selection for surgery if it is available as part of a routine trauma work-up. However, when a CT scan is not a part of a patient’s routine trauma work-up, additional cost, time and radiation exposure are consequences of
obtaining further imaging. Therefore, further study to determine which plain film projection most closely approxi-
mates CT measurements of clavicular shortening in acute
DMCFs would be beneficial. Alternatively, surrogate
measures of shortening on plain films, such as lack of cotti-
cal contact between clavicle fracture fragments (on at least
1 of 2 radiographic views), may prove to be more appropri-
te selection criteria for determining which patients with
acute DMCF would benefit from treatment with operative
fixation.

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Competing interests: None declared.

Contributors: S. Hunt and A. Furey designed the study. L. Archer,
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data, which L. Archer, C. Stone and A. Furey analyzed. L. Archer and
S. Hunt wrote the article, which all authors reviewed and approved for
publication.

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Conservative versus operative management in stable patients with penetrating abdominal trauma: the experience of a Canadian level 1 trauma centre

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Background: The goal of conservative management (CM) of penetrating abdominal trauma is to avoid nontherapeutic laparotomies while identifying injuries early. Factors that may predict CM failure are not well established, and the experience of CM has not been well described in the Canadian context.

Methods: We searched a Canadian level 1 trauma centre database for all penetrating abdominal traumas treated between 2004 and 2014. Hemodynamically stable patients without peritonitis and without clear indications for immediate surgery were considered potential candidates for CM, and were included in the study. We compared those who were managed with CM with those who underwent immediate operative management (OM). Outcomes included mortality and length of stay (LOS). Further analysis was performed to identify predictors of CM failure.

Results: A total of 72 patients with penetrating abdominal trauma were classified as potential candidates for CM. Ten patients were managed with OM, and 62 with CM, with 9 (14.5%) ultimately failing CM and requiring laparotomy. The OM and CM groups were similar in terms of age, sex, injury severity, mechanism and number of injuries. There were no deaths in either group. The LOS in the intensive care (ICU)/trauma unit was 4.8 ± 3.2 days in the OM group and 2.9 ± 2.6 days in the CM group ($p = 0.039$). The only predictor for CM failure was intra-abdominal fluid on computed tomography (CT) scan (odds ratio 5.3, 95% confidence interval 1.01–28.19).

Conclusion: In select patients with penetrating abdominal trauma, CM is safe and results in a reduced LOS in the ICU/trauma unit of 1.9 days. Fluid on CT scan is a predictor for failure.
mandatory laparotomy for all penetrating abdominal trauma was considered the standard of care for the majority of the first half of the 20th century. In the absence of findings to suggest intra-abdominal injuries, laparotomy was performed primarily to rule out or intervene upon potential catastrophic injuries early. In hemodynamically stable, asymptomatic patients, laparotomy has been found to be nontherapeutic in up to 70% of cases, leading to clinically significant complication rates. Increasingly, conservative management (CM) of select patients with penetrating abdominal trauma is being used by trauma surgeons. A fairly common modern practice for stab wounds, CM has even recently been adopted for select patients with gunshot wounds to the abdomen. Conservative management consists of a thorough trauma assessment to rule out contraindications, computed tomography (CT) to assess intra-abdominal pathology, close hemodynamic monitoring, serial physical examinations and serial labwork. Contraindications to CM include hemodynamic instability, peritonitis on clinical examination and concomitant head injury or other condition precluding reliable serial examinations. Evisceration is largely considered to be a relative contraindication to CM. The majority of the literature pertains to adult patients; however, CM has also been shown to be safe in children.

A 2012 Cochrane review identified only 1 randomized controlled trial (RCT) comparing operative to nonoperative management for any type of abdominal trauma in hemodynamically asymptomatic patients. That 1996 RCT by Leppäniemi and Haapiainen randomized 51 stable, asymptomatic patients without evisceration to either mandatory laparotomy or observation. They found a 55% non-therapeutic laparotomy rate, with CM failing in 17% of the observed patients, ultimately requiring laparotomy. There was no difference between the groups in mortality or morbidity, and hospital stay in the observation group was 3 days shorter.

The primary objective of the present study was to compare the clinical outcomes of initial operative management (OM) with CM in hemodynamically stable, asymptomatic patients. A secondary objective was to identify predictive factors for patients in whom CM ultimately fails, leading to laparotomy. With relatively low volumes of penetrating trauma occurring in Canadian trauma centres compared with many centres in the United States or internationally, the role of CM has not been well studied in the Canadian context. The present study aims to describe the role and outcomes of CM in a Canadian level 1 trauma centre.

**Methods**

We performed a retrospective analysis of a prospectively collected trauma database to identify all patients who received a diagnosis of penetrating abdominal trauma between 2004 and 2014 at The Ottawa Hospital (TOH), a Canadian level 1 trauma centre. The database captures all patients with an injury severity score (ISS) of 12 or greater or for whom a trauma team activation was initiated. At TOH, all penetrating abdominal injuries initiate a trauma team activation. We reviewed the charts of all patients with a diagnosis of penetrating abdominal trauma to identify those who were considered to be candidates for CM. Candidates for CM included patients aged 18 years or older with evidence of peritoneal penetration who were hemodynamically stable throughout the trauma team assessment, who were found not to have peritonitis on examination, and in whom there was no absolute indication for operative management (e.g., retained foreign body, CT evidence of bowel injury, other severe intra-abdominal injury). Hemodynamic stability and peritonitis were determined based on the recorded interpretation of the treating surgeon. The CT images were obtained using intravenous contrast, but without oral or rectal contrast. Patients who were treated with CM were admitted to either the intensive care unit (ICU) or trauma unit, with 1:2 nursing and continuous monitoring. They were managed with serial examinations by the on-call trauma surgeon or resident every 2–3 h and repeat bloodwork every 6–8 h.

**Statistical analysis**

We collected descriptive demographic data on the included patients. We compared patients based on initial management (operative v. CM) using $\chi^2$ or Student $t$ tests. Outcomes of interest were in-hospital mortality, hospital length of stay (LOS), combined LOS in the trauma unit/ICU, non-therapeutic laparotomy rate, and rate of failed CM requiring laparotomy. Analysis was performed among patients treated with initial CM to identify predictive factors for failure of CM; this was done using frequency tables and the Fisher exact test for categorical variables and the Student $t$ test for continuous variables. We performed the statistical analyses using SAS software version 9.3 (SAS Institute Inc.).

**Results**

A total of 167 patients were identified as having penetrating abdominal trauma between 2004 and 2014 (Fig. 1). Of these, 95 were excluded. Common reasons for exclusion were no evidence of peritoneal penetration on either physical exam or CT ($n = 33$), CT findings requiring operative management ($n = 21$) and hemodynamic instability ($n = 20$). Other reasons included retained foreign bodies requiring retrieval, and transfer from an outside centre after emergency laparotomy. Therefore, 72 patients were identified as having penetrating abdominal trauma with peritoneal violation and were considered candidates for CM. Injury locations included 29 anterior, 18 flank, 15 thoracoabdominal and 3 back, and 7 patients had injuries in more than 1 anatomic location. Among these
patients, 10 were managed operatively while 62 were initially managed conservatively. Of those managed conservatively, CM ultimately failed in 9 (14.5%), requiring laparotomy. Table 1 displays the demographic characteristics and main presenting features of all 3 groups (OM, successful CM, and failed CM). No significant differences between the groups were found in terms of age, sex, ISS, mechanism and number of injuries, or vital signs. The mean age of included patients was 30.1 ± 14.3 years, and there was only 1 female patient.

Among the 10 patients managed operatively, 3 underwent laparoscopy and 7 underwent laparotomy. There was no surgical repair required in 6 patients, repair of abdominal wall bleeding in 2, repair of gastric laceration in 1, and placement of a Jackson-Pratt (JP) drain for a liver laceration in 1. The 6 cases resulting in no surgical repair were evenly split between laparotomy and laparoscopy, resulting in a negative laparotomy rate of 42.9% (or 57.1% if including the JP drain placement). In the failed CM group, the mean time to the operating room (OR) was 27.15 ± 11.25 h; however, this was affected by 1 significant outlier (124.9 h) who had persistent pain due to hemoperitoneum. Removing this outlier, the mean time to the OR was 14.9 ± 11.25 h, which approaches the median time to the OR of 15.3 h. Reasons to operate on a CM patient included development of peritonitis on examination (n = 3), reports of worsening pain (n = 3), hemodynamic changes (n = 2) and dropping hemoglobin value (n = 1). The operative findings in the failed CM group included 2 small bowel injuries requiring repair, 1 gallbladder injury requiring cholecystectomy, 3 abdominal wall bleeding vessels requiring repair, 1 liver laceration requiring suture repair, and 2 operative explorations without repair. Only 1 patient in the entire cohort underwent a procedure by interventional radiology; this was a hepatic artery embolization of a patient successfully treated by CM.

There were no deaths or major septic complications in either the OM or CM groups. The combined LOS in the trauma unit/ICU was 2.9 ± 2.6 days in the CM group and 4.8 ± 3.2 days in the OM group (p = 0.039). The patients in the CM group who did not require an operation had an LOS in the trauma unit/ICU of 2.79 days, whereas the 9 patients in whom CM failed had a stay of 3.56 days. The overall hospital LOS was 4.4 ± 4.1 days in the CM group and 16.4 ± 18.5 days in the OM group (p < 0.001); however, this result was confounded by an increased proportion of self-inflicted injuries among the OM group, resulting in longer stays under the psychiatric service.

Using frequency tables and t tests, multiple factors were evaluated as possible predictors for the failure of CM. Factors found to be nonpredictive were age (p = 0.77), initial heart rate on presentation in the emergency department (ED; p = 0.18), serum ethanol level (p = 0.44) and single versus multiple abdominal injuries (p = 0.23). There was a nonsignificant trend toward successful CM in patients who were assaulted compared with those who were self-harmed (odds ratio 0.21, 95% confidence interval [CI] 0.04–1.1). The only factor found to be predictive of CM failure was the presence of free

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**Fig. 1. Study patients with penetrating abdominal trauma identified from the trauma database.**

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167 patients with penetrating abdominal trauma

- Included n = 72
  - Conservative management n = 62
    - Managed successfully n = 53
    - Failed conservative management n = 9
  - Operative management n = 10
    - Laparotomy n = 7
    - Laparoscopy n = 3

Excluded n = 95
intra-abdominal fluid on the initial CT scan (odds ratio 5.3, 95% CI 1.01–28.19). In other words, CM eventually failed in 7 of 28 (25%) patients with free fluid on CT, requiring laparotomy. Comparatively, CM failed in 2 of 34 (5.9%) patients without free fluid on CT. Hence, free intra-abdominal fluid on CT demonstrates a sensitivity of 77.8%, a specificity of 60.4%, a positive predictive value of 25%, and a negative predictive value of 94.1% for requiring laparotomy.

**DISCUSSION**

The selective use of conservative management for penetrating abdominal trauma has become a well-established and accepted approach over the past few decades. As can be seen in the present study, 86% of patients identified as stable and asymptomatic between 2004 and 2014 at TOH were initially managed nonoperatively. Furthermore, this study demonstrates that CM can result in equally low rates of short-term mortality and morbidity as OM, while avoiding a negative laparotomy rate of 42.9% and reducing the LOS in the trauma unit/ICU by approximately 2 days. Both this negative laparotomy rate and reduction of LOS are comparable to results of other studies.9,10 We also highlight the importance of close clinical monitoring of patients treated with CM, as 14.5% ultimately required laparotomy. Similar failure rates can be seen in the literature.11,12 Peritonitis alone, in the absence of hemodynamic changes, was found in 1 study to have positive intra-abdominal injuries in 97% of cases.13 Therefore, these patients need repeated clinical exams, not just simple reassurance of normal vital signs. The presence of intra-abdominal free fluid on CT scan was an independent predictive factor for failure of CM, with 25% of these patients requiring laparotomy. This finding should increase a clinician’s suspicion of failure and could be a relative indication for diagnostic laparoscopy. While laparoscopy can certainly be a useful diagnostic and therapeutic tool in patients with penetrating abdominal injuries, it cannot entirely rule out intra-abdominal pathology. In particular, laparoscopy has been found to have a sensitivity of only 18% for gastrointestinal injuries.14 It can, however, be of great value for evaluating diaphragmatic injury in patients with thoracoabdominal injuries, which are not well assessed with CT scan.14 To increase sensitivity for diagnosing intestinal injury, the addition of oral and rectal contrast material before CT scan (triple-contrast CT) is used in some centres and has shown high accuracy in identifying the need for laparotomy.15,16 The technique performed in our centre for patients with penetrating abdominal trauma is intravenous contrast alone, which has also been shown to be effective.17 No comparisons between the techniques could be found in the literature.

To the best of our knowledge, the correlation between free fluid on CT and CM failure is unique in the literature. Free fluid in the peritoneal cavity can be blood, bile, or fluid secondary to peritoneal irritation. It has often been considered to be a concerning finding,1 but has been shown in the present study to have an odds ratio of 5.3 for failure of CM. Identifying free intra-abdominal fluid as a poor prognostic factor for patients receiving CM should help guide clinical decision-making and increase a clinician’s suspicion for intra-abdominal injury.

Another important strength of this study is the robustness of the prospectively collected database. A dedicated database manager records extensive clinical data on all trauma team activations and patients presenting to the ED with an ISS of 12 or greater. These data span the entire course of the patient’s hospital admission, from initial presentation to discharge. The breadth of data helps to ensure that the OM and CM groups in this study are comparable on many important factors. Furthermore, demonstrating the safety and potential benefit of CM in a Canadian trauma centre is important. While safe monitoring for CM patients requires an experienced trauma team, the present

| Table 1. Demographic characteristics and presenting features of all patients |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Category        | OM (n = 10)     | Successful CM (n = 53) | Failed CM (n = 9) | p value         |
| Age, yr         | 38.4 ± 22.8     | 28.6 ± 12.5      | 29.9 ± 10.5      | 0.14            |
| Male sex, %     | 100             | 98.1            | 100             | 0.83            |
| ISS             | 6.5 ± 6.9       | 10.9 ± 7.2      | 7.9 ± 5.2       | 0.13            |
| Mechanism of injury | 0.62         | 0.62            | 0.62            | 0.19            |
| Stab wound      | 9               | 48              | 9               |                 |
| Gunshot wound   | 1               | 5               | 0               |                 |
| No. of external injuries | 0.19        | 0.19            | 0.19            |                 |
| Single          | 5               | 36              | 8               |                 |
| Multiple        | 5               | 17              | 1               |                 |
| Initial heart rate, bpm | 108 ± 20   | 98 ± 20        | 88 ± 22         | 0.11            |
| Initial systolic BP, mm HG | 142 ± 30 | 132 ± 23       | 130 ± 16        | 0.35            |

BP = blood pressure; CM = conservative management; ISS = injury severity score; OM = operative management; SD = standard deviation.
*Unless indicated otherwise.
study has demonstrated its feasibility in a centre with a relatively low volume of penetrating trauma.

Limitations

The present study is limited by its retrospective nature. Reviewing charts and databases, no matter how robust, does not capture many of the clinical decisions made in the assessment of a trauma patient. There may have been evidence of more concerning injuries in the OM group that wasn’t recorded in the clinical notes or diagnostic imaging reports. The sample size, particularly in the OM group, was small but representative of the volume of penetrating trauma in the majority of Canadian trauma centres. The small sample size may have prevented the identification of other predictive factors for the failure of CM, such as mechanism or number of injuries. The sample size also contributed to decreased precision in the statistical analysis, as can be seen by the wide CIs of the odds ratios.

The duration of close clinical monitoring in patients receiving CM has been considered in previous studies, many of which concluded that if peritoneal signs are not present on examination after 12 h of observation, there is very low likelihood of intraperitoneal injury.\(^\text{18,19}\) In a series of 68 patients ultimately requiring laparotomy during CM, Alzamel and Cohn\(^\text{19}\) found that none occurred after the 12-h mark. In the present study, however, 5 of the 9 laparotomies in the CM group occurred after the initial 12-h window. Two of these laparotomies revealed only hemothorax with no repair performed, but 1 required ligation of a vessel. The wide CIs of the odds ratios of other predictive factors such as mechanism or number of injuries. The sample size also contributed to decreased precision in the statistical analysis, as can be seen by the wide CIs of the odds ratios.

CONCLUSION

Our study has demonstrated that, when compared with routine OM, CM is safe for well-selected patients with penetrating abdominal trauma in a Canadian level 1 trauma centre. Conservative management avoids negative laparotomies, the rate of which in the present series was found to be greater than 40%, and can result in a 2-day decreased hospital LOS. Patients who have findings of free intra-abdominal fluid on initial CT scan have an increased risk of CM failing and could be considered for OM (either laparotomy or diagnostic laparoscopy) or at least an increased suspicion for intra-abdominal injury. For patients treated with CM, we recommend an observation period of 24 h, after which they can be safely discharged if there is no evidence of deterioration.

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Competing interests: None declared.

Contributors: S. Bennett and J. Lampron designed the study. All authors acquired the data, which S. Bennett, A. Amath and J. Lampron analyzed. S. Bennett wrote the article, which all authors reviewed and approved for publication.

References

The impact of blood transfusion on perioperative outcomes following gastric cancer resection: an analysis of the American College of Surgeons National Surgical Quality Improvement Program database

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Background: Red blood cell transfusions (RBCT) carry risk of transfusion-related immunodulation that may impact postoperative recovery. This study examined the association between perioperative RBCT and short-term postoperative outcomes following gastrectomy for gastric cancer.

Methods: Using the American College of Surgeons National Surgical Quality Improvement Program database, we compared outcomes of patients (transfused v. non-transfused) undergoing elective gastrectomy for gastric cancer (2007–2012). Outcomes were 30-day major morbidity, mortality and length of stay. The association between perioperative RBCT and outcomes was estimated using modified Poisson, logistic, or negative binomial regression.

Results: Of the 3243 patients in the entire cohort, we included 2884 patients with nonmissing data, of whom 535 (18.6%) received RBCT. Overall 30-day major morbidity and mortality were 20% and 3.5%, respectively. After adjustment for baseline and clinical characteristics, RBCT was independently associated with increased 30-day mortality (relative risk [RR] 3.1, 95% confidence interval [CI] 1.9–5.0), major morbidity (RR 1.4, 95% CI 1.2–1.8), length of stay (RR 1.2, 95% CI 1.1–1.2), infections (RR 1.4, 95% CI 1.1–1.6), cardiac complications (RR 1.8, 95% CI 1.0–3.2) and respiratory failure (RR 2.3, 95% CI 1.6–3.3).

Conclusion: Red blood cell transfusions are associated with worse postoperative short-term outcomes in patients with gastric cancer. Blood management strategies are needed to reduce the use of RBCT after gastrectomy for gastric cancer.


Résultats : Parmi 3243 gastrectomies, 2884 patients avec des données complètes furent inclus, dont 535 (18,6 %) furent transfusés. La morbidité globale à 30 jours était 20 % et la mortalité 3,5 %. Après avoir contrôlé pour les caractéristiques démographiques et cliniques pertinentes, les TGR démontraient une association indépendante avec une morbidité majeure (risque relatif [RR] 3,1; intervalle de confiance [IC] à 95 % 1,9–5,0), une mortalité (RR 1,4; IC à 95 % 1,2–1,8), et une durée d’hospitalisation (RR 1,2; IC à 95 % 1,1–1,2) accrues. Les TGR étaient aussi associées aux complications infectieuses (RR 1,4; IC à 95 % 1,1–1,6), cardiaques (RR 1,8; IC à 95 % 1,0–3,2), et respiratoires (RR 2,3; IC à 95 % 1,6–3,3).

Conclusion : Les TGR sont associées à une détérioration de l’issue post-opératoire après gastrectomie pour CG, dont la morbidité majeure, la mortalité, et la durée d’hospitalisation. Des stratégies multidisciplinaires de gestion du risque transfusionnel sont nécessaires afin de limiter l’utilisation des TGRs après gastrectomie pour CG.
A s the second leading cause of cancer-related death worldwide, gastric cancer poses a substantial health care and societal burden.1 While advances in perioperative chemotherapy and targeted therapy contribute to improving long-term outcomes for gastric cancer,2,3 surgery remains the cornerstone of multimodal gastric cancer treatment, with survival contingent on complete resection.4 Advances in surgical technique and perioperative care have led to 5% perioperative mortality in high-volume centres.5 Further reduction of surgical sample sizes from individual hospitals.10–13

tric cancer surgery is restricted to studies with small current literature looking at the impact of RBCT on gas-
nancy are at particular risk for needing RBCT.8,9 The

The majority of the missing data pertained to patients (</uni00A0 1%), hematocrit (</uni00A0 7%) and cardiac history (10%).

Anesthesiologists (ASA) class, preoperative hematocrit values for the following variables: ASA class (</uni00A01%), sex
level, and baseline cardiovascular comorbidities (cardiac
heart failure, myocardial infarction, angina, hyperten-
sion). Albeit infrequent, there were sometimes missing
variables for the following variables: ASA class (</uni00A01%), sex
(</uni00A01%), hematocrit (</uni00A07%) and cardiac history (10%).

The majority of the missing data pertained to patients
treated in more recent years (2011–2012). Very few
patients treated between 2007 and 2010 were missing
data. To understand how this increasing level of missing data over time impacted the results, we completed a sen-
sitivity analysis restricted to patients who were operated during the timeframe with complete data (2007–2010).

The purpose of the present study was to estimate the effect of RBCT on 30-day postoperative outcomes follow-
ing elective gastrectomy for gastric cancer using the large
multi-institutional American College of Surgeons National
Surgical Quality Improvement Program (ACS-NSQIP) data set.

METHODS

Study design and population

We conducted a retrospective study using a cohort of patients entered in the ACS-NSQIP registry between Jan. 1, 2007, and Dec. 31, 2012, who underwent a gas-
trectomy, defined by Current Procedural Terminology (CPT) codes, and had a postoperative diagnosis of gastric cancer (ICD-9 code 151.x). We excluded patients who were undergoing an emergent operation, who were younger than 18 years, or for whom we were missing data on the following key variables: sex, American Society of Anesthesiologists (ASA) class, preoperative hematocrit level, and baseline cardiovascular comorbidities (cardiac heart failure, myocardial infarction, angina, hypertension). Albeit infrequent, there were sometimes missing values for the following variables: ASA class (</uni00A01%), sex (</uni00A01%), hematocrit (</uni00A07%) and cardiac history (10%).

Data sources

The ACS-NSQIP database is a multicity prospective registry designed to evaluate risk-adjusted outcomes of surgical patients. A total of 525 institutions, including both teaching and nonteaching hospitals, participate and are representative of various regions in North America. Variables collected include demographic characteristics, preoperative risk factors, procedural indication and details, and 30-day detailed postoperative morbidity and mortality. Data are collected by trained abstractors and validated for accuracy.14 The ACS-NSQIP data collection and auditing methods are presented elsewhere.15–18

Patients’ demographic and clinical characteristics and their treatment details were collected from the gastrec-
tomy admission records in the ACS-NSQIP database. The extent of surgery was defined according to CPT codes, and procedures were subdivided into total gastrectomy (CPT 43620, 43621 and 43622), subtotal gastrectomy (CPT 43631, 43632, 43633 and 43634) and multivisceral resec-
tion (CPT 38120, 38102 and 38129 for splenectomy; 44140, 44141 and 44160 for colectomy; 48146, 48145 and 48140 for pancreatectomy; 44121, 44120 and 44125 for enterectomy; 47100, 47120 and 47122 for hepatectomy; and 43124, 43117, 43118, 43101, 43121, 43122 and 43123 for esophagectomy). Cardiac comorbidities were defined as a history of congestive heart failure (in the 30 d before sur-
gery), myocardial infarction (in the 6 mo before surgery), angina (in the 30 d before surgery), or hypertension requiring antihypertensive medication (in the 30 d before surgery). We used the World Health Organization defini-
tion of anemia: hematocrit less than 40%.19 Perioperative RBCT was defined as receiving packed red blood cells (PRBC) intraoperatively or within 72 h postoperatively.14

A dichotomous transfusion variable was created. None of the patients were missing data on this variable.

Outcomes

Primary outcomes were 30-day mortality and major mor-
bidity. Major morbidity was defined as the occurrence of deep or organ-space surgical site infection (SSI), wound dehiscence, pneumonia, pulmonary embolism, prolonged mechanical ventilation beyond 48 h, unplanned re-intubation, renal failure, sepsis, myocardial infarction, cardiac arrest, or stroke. Postoperative mortality was defined as death within 30 days of the operation.

Secondary outcomes included system-specific 30-day morbidity grouped into infectious events (SSI, pneumonia, urinary tract infection, sepsis, septic shock), cardiac events (myocardial infarction, cardiac arrest), respiratory failure (prolonged mechanical ventilation > 48 h, unplanned re-intubation), venous thromboembolic events (pulmonary embolism, deep vein thrombosis), unplanned reoperation as well as hospital length of stay.14
**Statistical analysis**

Comparative statistics between the transfused and non-transfused patients were assessed with independent samples t tests (normally distributed) and Wilcoxon rank sum tests (skewed) for continuous data, and \( \chi^2 \) tests for categorical data. Categorical data are reported as absolute numbers (\( n \)) and proportions (%), and continuous data are reported as means with interquartile ranges (IQR). “Unknown” categories were created for missing data.

We used a modified Poisson regression analysis to examine the association between RBCT and common dichotomous outcomes (> 10%), while logistic regression was used for uncommon dichotomous outcomes (≤ 10%). Length of stay values were treated as count data, but since the data were skewed and violated the assumptions of Poisson regression, negative binomial regression was used to measure the association between transfusion and length of stay. We selected covariates a priori based on timing (known preoperatively), clinical relevance (considered when assessing a patient for risk of adverse perioperative events) and existing literature (established relationship with worse surgical outcomes). Variables on the causal pathway were excluded from the multivariate regression in order to estimate the total effect of blood transfusions on worse surgical outcomes. The most parsimonious model was selected to maintain adequate study power. Multivariate analyses were adjusted for the following variables: age, body mass index (BMI; < 20, 20–29, 30–39, ≥ 40, unknown), race, ASA class, preoperative hematocrit values, cardiac comorbidities (a composite variable of hypertension, history of congestive heart failure, angina or myocardial infarction), bleeding disorder, preoperative international normalized ratio (INR; normal, abnormal, unknown), preoperative bilirubin (normal, abnormal, unknown), extent of gastrectomy and surgical procedure (total gastrectomy v. subtotal gastrectomy, and whether or not a multivisceral resection was performed), the year of the operation and operative duration. Results are reported as relative risks (RR) with 95% confidence intervals (CI). All statistical analyses were done using SAS version 9.3 for Windows (SAS Institute Inc.). We considered results to be significant at \( p < 0.05 \).

**RESULTS**

We identified 3243 patients in the cohort, 2884 of whom satisfied inclusion criteria (Fig. 1). Of those, 535 (18.6%) received RBCT. Demographic and clinical characteristics are presented in Table 1. Transfused patients were older \( (p < 0.001) \), had a higher ASA class \( (p < 0.001) \) and were more likely to have diabetes \( (p = 0.003) \), chronic obstructive pulmonary disease \( (p < 0.001) \), or a bleeding disorder \( (p < 0.001) \) than the nontransfused patients. Transfused patients were also more likely to have a total gastrectomy that included a multivisceral resection (Table 2). The mean operative duration was 30 minutes longer for transfused patients \( (p < 0.001) \). The 30-day postoperative outcomes are detailed in Figure 2. Patients receiving RBCT were more likely to experience 30-day major morbidity (33.8% v. 17.4%, \( p < 0.001 \)) and had higher mortality (8.4% v. 2.3%, \( p < 0.001 \)) than patients who did not receive RBCT.

Results of the multivariate analysis are presented in Table 3. Transfusion was independently associated with
increased 30-day mortality (RR 3.1, 95% CI 1.9–5.0) and major morbidity (RR 1.4, 95% CI 1.2–1.8), after adjusting for baseline and clinical characteristics. Postoperative infections (RR 1.4, 95% CI 1.1–1.6), cardiac events (RR 1.8, 95% CI 1.0–3.2) and respiratory failure (RR 2.3, 95% CI 1.6–3.3) were increased with RBCT, whereas no association was observed for venous thromboembolic events (RR 1.1, 95% CI 0.6–2.1). Patients receiving RBCT were significantly more likely to undergo an unplanned reoperation (RR 1.6, 95% CI 1.1–2.3). After adjustment, patients receiving RBCT had a longer hospital length of stay (RR 1.2, 95% CI 1.1–1.2).

The conclusions of the analyses did not change when the cohort was restricted to the calendar years with the most complete data (2007–2010).

DISCUSSION

Using the ACS-NSQIP data, we present the impact of RBCT on short-term outcomes following resections for gastric cancer. After adjusting for potential confounders, transfusion was associated with a 3-fold increase in the risk of death, and a 1.5-fold increase in the risk of major morbidity. Transfused patients also had a prolonged hospital stay compared with their nontransfused counterparts.

A large proportion of patients undergoing gastrectomy for gastric cancer are anemic from either intraoperative blood loss or low-rate tumour bleeding. Thus, transfusions are common in this patient group, and the effect of transfusion on surgical outcomes is an important issue. Studies of other gastrointestinal surgeries have highlighted the increased morbidity and delayed recovery associated with RBCT, some using the ACS-NSQIP. However, these analyses included a variety of surgical procedures with equally variable transfusion risk and morbidity profiles. Owing to the nature of the disease, patients receiving RBCT were significantly more likely to undergo an unplanned reoperation (RR 1.6, 95% CI 1.1–2.3). After adjustment, patients receiving RBCT had a longer hospital length of stay (RR 1.2, 95% CI 1.1–1.2).

The conclusions of the analyses did not change when the cohort was restricted to the calendar years with the most complete data (2007–2010).

#### Table 1. Demographic and clinical characteristics of the included patients based on transfusion status

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Transfused (n = 535)</th>
<th>Nontransfused (n = 2349)</th>
<th>p value</th>
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</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td></td>
<td></td>
<td>&lt; 0.001</td>
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<tr>
<td>&lt; 40</td>
<td>10 (1.9)</td>
<td>77 (3.3)</td>
<td></td>
</tr>
<tr>
<td>40–64</td>
<td>142 (26.5)</td>
<td>862 (36.7)</td>
<td></td>
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<tr>
<td>65–74</td>
<td>168 (31.4)</td>
<td>683 (29.0)</td>
<td></td>
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<tr>
<td>≥ 75</td>
<td>215 (40.2)</td>
<td>727 (31.0)</td>
<td></td>
</tr>
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<td>Male sex</td>
<td>320 (59.8)</td>
<td>1366 (58.1)</td>
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<tr>
<td>White</td>
<td>255 (47.7)</td>
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<tr>
<td>Black</td>
<td>83 (15.5)</td>
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<tr>
<td>Other</td>
<td>46 (8.6)</td>
<td>293 (12.5)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>151 (28.2)</td>
<td>601 (25.6)</td>
<td></td>
</tr>
<tr>
<td>ASA Score</td>
<td></td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>I</td>
<td>3 (0.56)</td>
<td>30 (1.3)</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>99 (18.5)</td>
<td>761 (32.4)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>363 (67.9)</td>
<td>1434 (61.1)</td>
<td></td>
</tr>
<tr>
<td>IV/V</td>
<td>70 (13.1)</td>
<td>124 (5.3)</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
<td>0.13</td>
</tr>
<tr>
<td>&lt; 20</td>
<td>56 (10.5)</td>
<td>203 (8.6)</td>
<td></td>
</tr>
<tr>
<td>20–29</td>
<td>352 (65.8)</td>
<td>1576 (67.0)</td>
<td></td>
</tr>
<tr>
<td>30–40</td>
<td>99 (18.5)</td>
<td>476 (20.3)</td>
<td></td>
</tr>
<tr>
<td>≥ 40</td>
<td>23 (4.3)</td>
<td>62 (2.6)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>5 (0.93)</td>
<td>32 (1.4)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>134 (22.8)</td>
<td>453 (19.3)</td>
<td>0.003</td>
</tr>
<tr>
<td>Active smoker</td>
<td>80 (15.7)</td>
<td>431 (18.4)</td>
<td>0.06</td>
</tr>
<tr>
<td>COPD</td>
<td>47 (8.8)</td>
<td>113 (4.8)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Dyspnea</td>
<td></td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>At rest</td>
<td>13 (2.4)</td>
<td>12 (0.51)</td>
<td></td>
</tr>
<tr>
<td>With moderate exertion</td>
<td>91 (17.0)</td>
<td>235 (10.0)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>353 (66.0)</td>
<td>1417 (60.3)</td>
<td>0.015</td>
</tr>
<tr>
<td>Cardiac comorbidity</td>
<td>535 (97.1)</td>
<td>1422 (60.6)</td>
<td>0.005</td>
</tr>
<tr>
<td>Bleeding disorder</td>
<td>38 (7.1)</td>
<td>74 (3.2)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Corticosteroid use</td>
<td>11 (2.1)</td>
<td>40 (1.7)</td>
<td>0.58</td>
</tr>
<tr>
<td>Weight loss &gt; 10%</td>
<td>112 (20.9)</td>
<td>326 (13.9)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Preoperative albumin &lt; 3g/dL</td>
<td>358 (66.9)</td>
<td>1710 (72.8)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Preoperative serum albumin (g/dL)</td>
<td>3.4 (3.0–3.9)</td>
<td>3.8 (3.5–4.2)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Preoperative hematocrit (%)</td>
<td>31.7 (28.4–37.7)</td>
<td>36.9 (33.7–40.4)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Preoperative INR (%)</td>
<td>1.1 (1.0–4.4)</td>
<td>1.0 (1.0–3.6)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Preoperative chemotherapy (within 30 d of surgery)</td>
<td>29 (5.4)</td>
<td>159 (6.8)</td>
<td>0.47</td>
</tr>
<tr>
<td>Preoperative radiation therapy (within 30 d of surgery)</td>
<td>10 (1.9)</td>
<td>54 (2.3)</td>
<td>0.79</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; BMI = body mass index; COPD = chronic pulmonary obstructive disease; INR = international normalized ratio; IQR = interquartile range.

#### Table 2. Operative characteristics for the included patients, based on transfusion status

<table>
<thead>
<tr>
<th>Variable</th>
<th>Transfused</th>
<th>Nontransfused</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative duration, min</td>
<td>253 (180–305)</td>
<td>223 (150–274)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Operative year</td>
<td>0.09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>89 (16.6)</td>
<td>369 (15.7)</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>90 (16.8)</td>
<td>415 (17.7)</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>109 (20.4)</td>
<td>446 (19.0)</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>81 (15.4)</td>
<td>470 (20.0)</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>92 (17.2)</td>
<td>328 (14.0)</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>74 (13.8)</td>
<td>321 (13.7)</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td></td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Total gastrectomy</td>
<td>243 (45.4)</td>
<td>841 (35.8)</td>
<td></td>
</tr>
<tr>
<td>Subtotal gastrectomy</td>
<td>292 (54.6)</td>
<td>1508 (64.2)</td>
<td></td>
</tr>
<tr>
<td>Multivisceral resection</td>
<td>84 (15.7)</td>
<td>205 (8.7)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Colectomy</td>
<td>25 (4.7)</td>
<td>37 (1.6)</td>
<td></td>
</tr>
<tr>
<td>Pancreatectomy</td>
<td>28 (5.2)</td>
<td>32 (1.4)</td>
<td></td>
</tr>
<tr>
<td>Enterectomy</td>
<td>14 (2.6)</td>
<td>41 (1.8)</td>
<td></td>
</tr>
<tr>
<td>Hepatectomy</td>
<td>28 (5.2)</td>
<td>96 (4.1)</td>
<td></td>
</tr>
<tr>
<td>Esophagectomy</td>
<td>7 (1.3)</td>
<td>16 (0.7)</td>
<td></td>
</tr>
<tr>
<td>Splenectomy</td>
<td>29 (5.4)</td>
<td>40 (1.7)</td>
<td></td>
</tr>
</tbody>
</table>

IQR = interquartile range.
high frequency of preoperative anemia and requirement for extensive lymph node dissection, patients with gastric cancer present a specific risk for perioperative transfusion requirement. The evidence regarding RBCT and its impact on gastric cancer surgery specifically remains limited. Most studies to date have focused on the effects of RBCT on long-term oncologic outcomes, reporting worse survival and recurrence patterns for transfused patients. Only 1 study investigated short-term outcomes, reporting an increased overall 30-day morbidity with RBCT (60% v. 14.2%, \( p = 0.024 \)) for a sample of 588 patients at a single institution. No morbidity details were presented, such that one cannot decipher the type of complications associated with RBCT. Our large multi-institutional sample size provides strong evidence of the detrimental effects of RBCT on postoperative outcomes for gastric cancer, for both local and systemic complications. Unplanned reoperations were also associated with RBCT, but this could have been due to postoperative bleeding requiring both RBCT and re-interventions.

It is believed that RBCT-induced healing impairment results from transfusion-related immune modulation, which can exacerbate the stress-induced postoperative immunosuppressive state. While the exact underlying mechanism of transfusion-related immune modulation is unclear, several hypotheses have been proposed, such as leukocyte-mediated immunosuppression in allogeneic blood, a transfusion-induced reduction in natural killer cells and interleukin-2, and the infusion of incompatible major histocompatibility complex antigens between donor

Fig. 2. Postoperative outcomes for patients undergoing gastrectomy for gastric cancer based on transfusion status.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Unadjusted</th>
<th>Adjusted*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RR (95% CI)</td>
<td>p value</td>
</tr>
<tr>
<td>Major morbidity</td>
<td>1.95 (1.69–2.26)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mortality</td>
<td>3.83 (2.55–5.75)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Postoperative infections</td>
<td>1.81 (1.55–2.12)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Cardiac events</td>
<td>2.41 (1.44–4.03)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>3.02 (2.23–4.08)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Venous thromboembolic events</td>
<td>1.63 (0.94–2.83)</td>
<td>0.08</td>
</tr>
<tr>
<td>Reoperation</td>
<td>1.91 (1.40–2.62)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Length of stay</td>
<td>1.36 (1.28–1.44)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

CI = confidence interval; RBCT = red blood cell transfusion; RR = relative risk.

*Adjusted for: age, sex, race, body mass index, American Society of Anesthesiologists class, hematocrit, bilirubin, international normalized ratio, cardiac comorbidities, bleeding disorder, primary operation, multivisceral resection and operative duration.
and recipient. In the early postoperative course following gastric cancer resection, the increased infectious and cardiopulmonary complications observed in transfused patients may not be solely related to transfusion-related immune modulation; transfusion-associated circulatory overload, allergic reactions, transfusion-related acute lung injury, hemolytic reactions and graft-versus-host disease also have to be considered. However, the occurrence of these adverse events is well documented and rare enough that they cannot account for all the morbidity excess associated with RBCT that we observed. Therefore, there is a potential for impact of RBCT on postoperative morbidity beyond that of traditional direct transfusion-related adverse reactions.

Postoperative morbidity carries repercussions beyond the immediate surgical recovery period. In addition to prolonging it, the increased complication rate seen following transfusions may hinder the delivery of adjuvant cancer therapy. Evidence from breast, colorectal and pancreatic cancer has shown that delays in receipt of adjuvant therapy negatively impacts disease-free survival, disease-specific survival and overall survival. Given the importance of systemic therapy in gastric cancer survival, minimizing postoperative morbidity in order to get patients, in a timely manner, to their intended oncologic therapy is paramount. We identified RBCT as being associated with increased postoperative morbidity and thus as a potentially modifiable factor that can be addressed to improve gastric cancer outcomes.

Despite evidence and clinical guidelines supporting restrictive strategies for blood transfusions, practices still vary significantly, such that RBCT is still considered an overused treatment. When such gaps between practice and guidelines exist, the most effective strategy to ensure successful changes requires practice-specific data on which to base tailored approaches to knowledge translation. This study provides procedure-specific evidence to do so. Comprehensive transfusion reduction initiatives involving blood conservation consultants, institutional guidelines and the use of alternative transfusion strategies have successfully been implemented. Similar strategies for patients with gastric cancer could be adopted and could also include medical interventions like the use of iron supplementation (alone or in combination with erythropoietin for anemic patients) and antifibrinolytic agents to reduce the need for RBCT.

Further research is required to determine whether blood-conserving tactics (with potential ensuing reduction in transfusion rates) would actually translate into improved outcomes in gastric cancer surgery. While some large retrospective databases risk containing information bias, the ACS-NSQIP registry has repeatedly been shown to provide accurate and valid data. The ACS-NSQIP database lacks cancer-specific variables, which may result in uncontrolled confounding, and this could in turn result in an over- or underestimate of the effect of blood transfusions on perioperative morbidity. For example, staging data are not collected. Operations in patients with more advanced disease can be technically challenging, potentially increasing the risk for transfusion and postoperative morbidity. While we used and corrected for extent of gastric resection (total v. subtotal gastrectomy, and multivisceral resection) and operative duration as surrogate markers for technical complexity, those variables do not fully account for the potential influence of cancer stage on receipt of RBCT. Reﬁnement of the timing of RBCT into intra- or postoperative could not be obtained with the data available within ACS-NSQIP. While the impact of RBCT on outcomes is unlikely to differ whether it was administered intra- or postoperatively, such information could be useful in tailoring knowledge-translation efforts to improve adherence to restrictive transfusion guidelines to operating room or postoperative care teams. Finally, potential institutional-level variation in practice and outcomes could not be accounted for in this analysis, since institution and physician information is not available in ACS-NSQIP owing to privacy policies.

Moreover, we acknowledge the challenge of establishing causality in retrospective studies. Ascertaining whether transfusions are the cause of major morbidity directly or whether they are a response to surgical complications is difficult. However, the ACS-NSQIP deﬁnes the receipt of perioperative RBCT as occurring within the first 72 h following gastric resection or intraoperatively, thus RBCT administration is likely to have preceded complications.

Clinical variables, including hemoglobin level before transfusion, dictating the indication for RBCT were not available. Many factors play a role in the decision to transfuse a patient, and some may contribute to increased morbidity independently of RBCT. Therefore, this analysis could not decipher the indication for individual patients' transfusions and identify the subgroup of patients in which RBCT could have been avoided. Transfused and nontransfused patients differed significantly at baseline, as evidenced in Table 2, with transfused patients appearing less healthy and therefore at higher risk of postoperative morbidity. To mitigate selection and confounding biases inherent to retrospective studies, we corrected for all known variables associated with RBCT in our robust regression models. In particular, age was included in the multivariate model as a continuous variable in an attempt to account for the increased frequency of transfusion with older age. However, we acknowledge that this does not account for unknown confounders or for residual confounding that may result from potential imperfect measure of comorbidities.

Nevertheless, this study provides results with high external validity, given it is, to our knowledge, the largest and ﬁrst multi-institutional appraisal of its kind. It provides procedure-speciﬁc evidence to raise awareness about the need to minimize use of RBCT when it can be safely avoided for elective gastric cancer resection. Stronger procedure-specific evidence to support change in practice could be
obtained with a randomized study design aimed at comparing the impact of a comprehensive blood management strategy focused on restrictive transfusion guidelines compared with traditional practice on postpancreatectomy outcomes.

CONCLUSION

Perioperative RBCT was associated with increased 30-day mortality, major morbidity and hospital length of stay following elective gastrectomies for gastric cancer. This information further the rationale to minimize the use of RBCT in surgical patients when it can be safely avoided. Blood conservation strategies to reduce unnecessary transfusions and their detrimental effects on gastric cancer postoperative outcomes are needed and could be examined in future studies.

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Disclaimer: The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) and the hospitals participating in the ACS-NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

Competing interests: None declared.

Contributors: M. Elmi, N. Coburn and J. Hallet designed the study. All authors analyzed the data. M. Elmi, A. Mahar, D. Kagedan and J. Hallet wrote the article, which all authors reviewed and approved for publication.

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Efficacy of intraoperative cell salvage in decreasing perioperative blood transfusion rates in first-time cardiac surgery patients: a retrospective study

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Background: Evidence regarding the safety and efficacy of intraoperative cell salvage (ICS) in transfusion reduction during cardiac surgery remains conflicting. We sought to evaluate the impact of routine ICS on outcomes following cardiac surgery.

Methods: We conducted a retrospective analysis of patients who underwent nonemergent, first-time cardiac surgery 18 months before and 18 months after the implementation of routine ICS. Perioperative transfusion rates, postoperative bleeding, clinical and hematological outcomes, and overall cost were examined. We used multivariable logistic regression modelling to determine the risk-adjusted effect of ICS on likelihood of perioperative transfusion.

Results: A total of 389 patients formed the final study population (186 undergoing ICS and 203 controls). Patients undergoing ICS had significantly lower perioperative transfusion rates of packed red blood cells (pRBCs; 33.9% vs. 45.3%, \( p = 0.021 \)), coagulation products (16.7% vs. 32.5%, \( p < 0.001 \)) and any blood product (38.2% vs. 52.7%, \( p = 0.004 \)). Patients receiving ICS had decreased mediastinal drainage at 12 h (mean 320 [range 230–550] mL vs. mean 400 [range 260–690] mL, \( p = 0.011 \)) and increased postoperative hemoglobin (mean 104.7 ± 13.2 g/L vs. 95.0 ± 11.9 g/L, \( p < 0.001 \)). Following adjustment for other baseline and intraoperative covariates, ICS emerged as an independent predictor of lower perioperative transfusion rates of pRBCs (odds ratio [OR] 0.32, 95% confidence interval [CI] 0.31–0.87), coagulation products (OR 0.41, 95% CI 0.24–0.71) and any blood product (OR 0.47, 95% CI 0.29–0.77). Additionally, ICS was associated with a cost benefit of $116 per patient.

Conclusion: Intraoperative cell salvage could represent a clinically cost-effective way of reducing transfusion rates in patients undergoing cardiac surgery. Further research on systematic ICS is required before recommending it for routine use.


Résultats : L’échantillon à l’étude était composé de 389 patients (186 dans le groupe ATPO et 203 dans le groupe témoin). Par rapport au groupe témoin, les patients ayant reçu une ATPO ont eu besoin significativement moins souvent d’une transfusion de concentrés de globules rouges (33.9% c. 45.3%; \( p = 0.021 \)), de produits coagulants (16.7% c. 32.5%; \( p < 0.001 \)) et de produits sanguins, tous types confondus (38.2% c. 52.7%; \( p = 0.004 \)). Chez les patients ayant reçu une ATPO, on a constaté un volume de drainage médiastinal après 12 h plus faible (moyenne : 320 mL [étendue de 230–550] c. 400 mL [étendue de 260–690]; \( p = 0.011 \)) et une hémoglobine postopératoire plus élevée (moyenne : 104,7 ± 13,2 g/L c. 95,0 ± 11,9 g/L; \( p < 0.001 \)). Après des ajustements pour tenir compte d’autres covariables des mesures de base et peropératoires, nous avons conclu que le recours à l’ATPO était un facteur prédicteur indépendant de taux de transfusion périopératoire plus faibles de concentrés de globules rouges (rapport de cotes [RC] : 0.52; intervalle de confiance [IC] à 95% : 0.31–0.87), de produits coagulants (RC : 0.41; IC à 95% : 0.24–0.71) et de produits sanguins, tous types confondus (RC : 0.47; IC à 95% : 0.29–0.77). De plus, l’ATPO a été associée à des économies de 116 $ par patient.

Conclusion : L’autotransfusion peropératoire pourrait constituer un moyen cliniquement efficace en fonction des coûts de réduire les taux de transfusion des patients subissant une chirurgie cardiaque. D’autres recherches sur le recours systématique à l’ATPO devront être menées avant qu’on puisse recommander son utilisation de routine.
Patients undergoing cardiac surgery often experience blood loss and coagulopathy requiring the administration of blood products to alleviate anemia, achieve hemodynamic stability and/or reduce the risk of ongoing bleeding. Despite this, blood transfusions have repeatedly been shown to be associated with increased morbidity and mortality. For this reason, strategies have been devised to reduce rates of transfusion in this population.

One such strategy is intraoperative cell salvage (ICS), the act of collecting shed blood throughout a surgical procedure, processing it via a cell saver device and reinfusing it into the patient during and/or at the end of the surgery. Direct transfusion of shed blood has been shown to be associated with a systemic inflammatory response, and the act of processing shed blood via filtration and centrifugation is felt to reduce the blood’s inflammatory potential and alter the need for transfusion. Despite these theoretical benefits, evidence as to whether ICS is safe and effective has been conflicting.

Several studies have shown ICS to reduce exposure to allogeneic blood products with no changes in clinical outcomes or cost, while others have suggested that reinfusion with washed cell salvaged blood results in increased postoperative bleeding and heightened transfusion.

The purpose of this study was to determine the effect of ICS on outcomes following cardiac surgery.

Methods

Study design

We retrospectively analyzed the cases of all patients who underwent nonemergent, first-time, on-pump cardiac surgery performed by a single surgeon 18 months before and 18 months after the implementation of ICS. Patients who refused blood products were excluded. The study was approved by the Horizon Health Research Ethics Board. Written informed consent to be included in the New Brunswick Health Centre registry was obtained from all patients. Following separation from CPB, heparin was reversed with protamine (1 mg protamine/100 units of heparin). Modified ultrafiltration during CPB was not used.

Cell salvage procedure

We performed cell salvage in the ICS group using the Autolog autotransfusion system (Medtronic). The cell saver device processed blood collected from the surgical site to produce washed red blood cells (RBCs) for return to the patient during and/or at the end of the surgery. Cell salvage was used from the time of skin incision up until skin closure. Only when the patient was fully heparinized and on CPB were CPB suction catheters used preferentially where potentially large volumes of blood could be returned immediately to the CPB circuit. After the CPB, the patient received blood from the CPB circuit via the aortic cannula until hemodynamic stability was achieved. Cell salvage was resumed after administration of protamine. Once protamine had been administered and the aortic and venous cannulae were removed, all remaining pump contents were added to the cell saver reservoir and washed before being returned to the patient. At all times, cell saver blood was administered to the patient through a Lipiguard Filter (Terumo CVS), a 40 μm polyester screen-type lipid filter. A leukocyte-depleting filter was not used in this study.

By contrast, patients in the control group had shed mediastinal blood captured using a combination of CPB and wall suction catheters. Blood collected via CPB suction catheters was returned directly to the CPB circuit, while blood collected via wall suction catheters was discarded. At the end of the procedure, residual contents of the CPB circuit were directly reinfused into the patient following administration of protamine and upon transfer to the intensive care unit (ICU). Residual heparin in pump blood was reversed with additional protamine on admission to ICU.

Transfusion protocol

With respect to packed RBCs (pRBCs), an actual or anticipated hemoglobin level less than 70 g/L was treated with 1 or more units of pRBCs to maintain a hemoglobin level of 70 g/L or greater. No coagulation product transfusion protocol was used during the study. Coagulation products were administered in response to actual bleeding, perceived bleeding and/or a measured
coagulopathy (e.g., elevated ACT, elevated international normalized ratio/partial thromboplastin time [INR/PTT] level or decreased platelet count). At no time were platelet function testing, fibrinogen assays and thromboelastography used to guide transfusion of coagulation products.

Data collection

Data were obtained from the New Brunswick Heart Centre Cardiac Surgery Database, a detailed observational clinical registry based on the core variables and data definitions contained within the Society of Thoracic Surgeons Adult Cardiac Surgery Database version 2.35. This registry prospectively collects pre-, intra- and postoperative data on all patients undergoing cardiac surgery at the Saint John Regional Hospital. Where lacking, additional data were collected through detailed chart review.

We collected data regarding the following baseline characteristics: age, sex, body mass index, smoking history, diabetes, dyslipidemia, renal failure (creatinine > 176 μmol/L), hypertension, chronic obstructive pulmonary disease (COPD), peripheral vascular disease, cerebrovascular disease, recent myocardial infarction (MI; ≤21 d), congestive heart failure, stable and unstable angina, atrial fibrillation, preoperative medications (ASA, angiotensin converting enzyme [ACE] inhibitors, β blockers and cholesterol-lowering agents), New York Heart Association (NYHA) class (IV v. I/II/III), ejection fraction (EF) lower than 40% and urgency status (elective v. urgent). In addition, we obtained data regarding the following intraoperative variables: type of surgical procedure, duration of CPB, aortic cross clamp time (AXC), administration of inotropes upon transfer to the ICU, and placement of intra-aortic balloon pump (IABP).

Primary outcomes

The primary outcome of interest was perioperative blood products. Perioperative blood product transfusion was defined as the administration of pRBCs and/or coagulation products, including fresh frozen plasma (FFP), platelets, cryoprecipitate, and factor eight inhibitor bypassing activity (FEIBA), either intraoperatively or within the first 24 hours after surgery. Both the percentage of patients receiving any of the aforementioned blood products and the volume of blood products administered per patient were considered. Volume of pRBCs, platelets and cryoprecipitate were measured in units. The approximate volumes per unit were as follows: pRBC 300 mL, platelet 200 mL and cryoprecipitate 10 mL. Fresh frozen plasma was measured in milliliters. We did not consider FEIBA volume owing to variability in dose per reconstituted vial.

Secondary outcomes

Secondary outcomes of interest included volume of chest tube drainage in the first 12 h postoperatively; rates of postoperative adverse outcomes (in-hospital mortality, re-operation for hemorrhage, infection, atrial fibrillation, renal failure, stroke, prolonged ventilation > 24 h and hospital length of stay [LOS]); pre- and postoperative hematological variables, including hemoglobin, INR/PTT and platelet count; and cost-effectiveness.

We estimated cost-effectiveness based on the reduction in volume of blood products administered among patients in the ICS group compared with controls after taking into account the expense associated with the use of the cell saver device. The cost, in Canadian dollars, of blood products was estimated as follows: pRBCs $425 per unit, FFP $716 per litre, platelets $603 per unit, cryoprecipitate $136 per unit, and FEIBA $1.46 per unit. Meanwhile, the cost of ICS was estimated at $202 per patient. The volume of blood products used per patient was multiplied by the cost per product. The total cost of blood products was then calculated for the ICS and control groups and then divided by the number of patients in each group to give an average cost of blood product use per patient. After factoring in the cost of the cell saver device among ICS patients, we then derived the average difference in cost between ICS and control patients to determine cost-effectiveness.

Statistical analysis

We made unadjusted comparisons between the ICS and control groups using the χ² test or Fisher exact test for categorical variables. Continuous variables that followed a normal distribution were compared using t tests, whereas non-normally distributed continuous variables were compared using the Kruskal–Wallis test. We used multivariable logistic regression modelling techniques to adjust for other prognostically relevant baseline characteristics and intraoperative variables. Backward elimination was applied to 200 bootstrap subsamples to derive a parsimonious model for each outcome, including covariates retained in at least 50% of the subsamples. Bootstrapping also allowed for the estimation of the 95% confidence interval (CI) around the c-statistic from the 2.5th and 97.5th percentiles of the bootstrap distribution. We considered results to be significant at p < 0.05. All statistical analyses were performed using the SAS statistical software package, version 9.3.

RESULTS

A total of 389 patients formed the final study population: 186 in the ICS group and 203 in the control group; 158 (40.6%) patients were 70 years of age or older, and 96 (24.7%) were women. Baseline characteristics were similar
between the 2 groups, with the exception that those in the ICS group were more likely to present with unstable angina, NYHA class IV symptoms and an urgent status (Table 1). There were no differences in procedure type or the use of inotropes or IABP between the 2 groups; however, patients in the ICS group had shorter CPB and AXC (Table 2).

In the ICS group, the median amount of blood suctioned into the cell saver reservoir was 500 mL (interquartile range [IQR] 257.5–1000 mL), and the median amount of blood left over in the CPB circuit that was processed by the cell saver was 1000 mL (IQR 800–1200 mL), resulting in a median of 426 mL (IQR 317.75–600 mL) of concentrated RBCs to be transfused into the patient.

**Primary outcomes**

Concerning the primary outcome of interest, patients in the ICS group were less likely than controls to be exposed to pRBCs, coagulation products or any blood products in the perioperative period (Table 3). In addition, patients in the ICS group received a significantly lower volume of pRBCs (mean 0.75 ± 1.50 units v. 1.15 ± 1.79 units, p = 0.017) and FFP (mean 155 ± 433 mL v. 281 ± 450 mL, p < 0.001). The volume of platelets received by patients in the ICS group was also lower (mean 0.26 ± 0.66 units v. 0.36 ± 0.62 units, p = 0.10), but this difference did not reach statistical significance.

**Secondary outcomes**

Regarding the secondary outcomes of interest, patients in the ICS group had less postoperative chest tube drainage in the first hour after surgery than those in the control group (50 v. 70 mL, p < 0.001), and this difference persisted over the first 12 h (median 320 mL [IQR 230–550 mL] v. median 400 mL [IQR 260–690 mL], p = 0.011; Fig. 1). No significant differences were noted in rates of postoperative adverse outcomes between the 2 groups (Table 4). Finally, despite having had similar hemoglobin, platelet and INR levels preoperatively, the ICS group had higher mean hemoglobin levels and lower median INR and platelet levels upon admission to the ICU than the control group (Table 5).

---

**Table 1. Baseline patient characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group; no. (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 70 yr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICS, n = 186</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control, n = 203</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI &lt; 25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25–29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 30</td>
<td></td>
<td></td>
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<tr>
<td>Smoking history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
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<tr>
<td>Dyslipidemia</td>
<td></td>
<td></td>
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<tr>
<td>Renal failure</td>
<td></td>
<td></td>
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<tr>
<td>Hypertension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI ≤ 21 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angina</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unstable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation</td>
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<tr>
<td>Medications</td>
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<tr>
<td>ASA</td>
<td></td>
<td></td>
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<tr>
<td>ACE inhibitors</td>
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<td></td>
</tr>
<tr>
<td>β blockers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol-lowering agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NYHA IV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EF &lt; 40%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operative status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elective</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urgent</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 2. Intraoperative variables**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group; no. (%) or median [IQR]</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure</td>
<td></td>
<td>0.53</td>
</tr>
<tr>
<td>Isolated CABG</td>
<td>117 (62.9)</td>
<td></td>
</tr>
<tr>
<td>Isolated valve</td>
<td>21 (11.3)</td>
<td></td>
</tr>
<tr>
<td>CABG + valve</td>
<td>29 (15.6)</td>
<td></td>
</tr>
<tr>
<td>Other + CABG + valve</td>
<td>19 (10.2)</td>
<td></td>
</tr>
<tr>
<td>CPB duration, min</td>
<td>89.5 [72–116]</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>AXC, min</td>
<td>66.5 [51–84]</td>
<td>0.001</td>
</tr>
<tr>
<td>Inotropes</td>
<td>45 (24.2)</td>
<td>0.59</td>
</tr>
<tr>
<td>IABP insertion</td>
<td>0 (0)</td>
<td>&gt; 0.99</td>
</tr>
</tbody>
</table>

**Table 3. Perioperative exposure to blood products**

<table>
<thead>
<tr>
<th>Blood product</th>
<th>Group; no. (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any blood transfusion</td>
<td></td>
<td>0.004</td>
</tr>
<tr>
<td>pRBC</td>
<td>63 (33.9)</td>
<td>0.021</td>
</tr>
<tr>
<td>Coagulation products</td>
<td>31 (16.7)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>FFP</td>
<td>30 (16.1)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Platelets</td>
<td>29 (15.6)</td>
<td>0.002</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>14 (7.5)</td>
<td>0.90</td>
</tr>
<tr>
<td>FEIBA</td>
<td>14 (7.5)</td>
<td>0.42</td>
</tr>
</tbody>
</table>

---

ACE = angiotensin-converting-enzyme; ASA = acetylsalicylic acid; BMI = body mass index; COPD = chronic obstructive pulmonary disease; EF = ejection fraction; ICS = intraoperative cell salvage; MI = myocardial infarction; NYHA = New York Heart Association.
Following adjustment for baseline and intraoperative covariate risk factors, including prolonged duration of CPB, ICS emerged as an independent predictor of lower rates of perioperative RBC transfusion (odds ratio [OR] 0.52, 95% CI 0.31–0.87), coagulation product transfusion (OR 0.41, 95% CI 0.24–0.71) and transfusion with any blood product (OR 0.47, 95% CI 0.29–0.77). Full regression models are presented in Appendix 1, Table S1, available at canjsurg.ca. The median c-statistic for each of these 3 models derived using bootstrapping methods was 0.86 (95% CI 0.82–0.89) for pRBC transfusion, 0.79 (95% CI 0.73–0.84) for coagulation product transfusion and 0.84 (95% CI 0.80–0.88) for overall transfusion.

With respect to cost, the average cost of blood products per patient was significantly lower in the ICS group than in the control group ($604 ± $1194 v. $922 ± $1259, p = 0.011). After factoring in the cost of the cell saver device, an average savings of $116 was noted per patient when ICS was used.

**DISCUSSION**

Intraoperative cell salvage was associated with decreased blood product transfusion, decreased postoperative bleeding, no differences in rates of postoperative adverse outcomes, and higher postoperative hemoglobin levels. Following adjustment for differences in baseline characteristics and intraoperative variables, ICS was independently associated with lower perioperative blood product transfusion rates. This decrease in blood product utilization translated into a significant cost savings per patient.

The decreased risk of perioperative pRBC transfusions found in patients who received ICS in our study compared favourably to findings from certain previously published studies8,12,14–16,19,22 but differed from others where either no change7,9,13,18 or an increase in perioperative pRBC transfusion rates17 was noted with the use of ICS. With respect to coagulation product transfusion, to our knowledge, the present study is the first to have shown a decrease in coagulation product transfusion with the use of ICS. This may reflect the relatively high transfusion rate of FFP (31.5%) and platelets (29.1%) in the control group, which may limit the applicability of these findings to other patient populations. Though this study did not demonstrate an overall reduction in morbidity associated with ICS, blood transfusions have been associated with poorer long-term outcomes, suggesting the reduction observed in this study is of clinical importance.1–3

Previous studies that have looked at ICS and the use of coagulation products have concluded that the removal of essential platelets and coagulation factors through cell salvage led to increased bleeding17 and greater coagulation product transfusion.8,17 While ICS was associated with lower postoperative platelet levels in this study, the absence of any deleterious effect of reduced postoperative platelet counts on chest tube drainage and blood product transfusion suggests that this hematological finding is of little clinical consequence.

The significant variation seen across studies in the effects of ICS on perioperative blood product transfusion and postoperative hematological parameters may reflect heterogeneity in how the cell saver was used in each study.

**Table 5. Hematological variables**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group; mean ± SD or median [IQR]</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin (g/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>130.9 ± 15.6</td>
<td>0.31</td>
</tr>
<tr>
<td>Postoperative</td>
<td>104.7 ± 13.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>INR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>1.0 [0.9–1.0]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Postoperative</td>
<td>1.2 [1.2–1.3]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Platelets (× 10^9/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>212 [176–251]</td>
<td>0.65</td>
</tr>
<tr>
<td>Postoperative</td>
<td>128 [100–161]</td>
<td>0.013</td>
</tr>
</tbody>
</table>

ICS = intraoperative cell salvage; SD = standard deviation.
In our study, the cell saver was used from the first incision until the end of the surgery, including the processing of residual contents from the CPB circuit after administration of protamine. Few ICS studies explicitly stated whether or not residual CPB contents were processed through the cell saver. Of those that did, it appears that the processing of residual CPB contents was associated with a significant decrease in pRBC transfusion\(^{12,14,15,19,22}\) and a decrease in postoperative chest tube drainage.\(^{19}\) The beneficial effect of ICS seen when processing residual CPB contents may result, in part, from the removal of excess heparin\(^{23}\) or an accumulation of inflammatory mediators commonly associated with CPB.\(^{24}\)

We demonstrated an average cost savings of $116 per patient for whom ICS was used. This is in contrast to the results of Klein and colleagues,\(^{12}\) who found no cost advantage to using ICS. Varying methods of cost analysis as well as differences in the extent to which transfusion rates and volumes were reduced could have accounted for discrepancies in findings. Additionally, a minimum volume of blood processed has been shown to be necessary in order for ICS to be cost-effective.\(^{25}\) Studies in which residual CPB contents were not processed may not have observed the cost benefit that was appreciated in the present study owing to insufficient volume of blood processed. Regardless, the significant cost savings that we observed indicates that ICS is cost-effective.

**Limitations**

This study is not without its limitations. First, the retrospective nature of the study did not allow for complete elimination of confounding or bias in our analysis. Second, in the absence of strict coagulation product transfusion protocols at our institution, subjective differences in coagulation product transfusion practices over time may have played a role in the administration of blood products. By restricting our analysis to a single surgeon, we anticipate that some of this interpractitioner variability may have been eliminated. Third, as this study represents a pre- and postintervention analysis, it is possible that lower rates of transfusion following the institution of ICS was the result of increased experience and improved surgical technique on the part of the participating surgeon, as outcomes tend to improve as one gains experience.\(^{26}\) While we adjusted for the duration of CPB in the risk-adjusted analysis, adjusting for “evolution” in overall ability is statistically challenging and remains a limitation. Despite these limitations, the overall 18% reduction in blood products and, more specifically, the large 49% reduction in coagulation products are unlikely to be explained by change in surgeon experience or ability alone. Finally, the sample size of the study did not allow for risk stratification or examination of efficacy and cost-effectiveness of ICS in special high-risk groups. Undoubtedly, there may be increased cost savings in higher-risk surgical populations. However, the objective of this study was to examine the efficacy and cost-effectiveness of routine ICS in the general cardiac surgery population, and we were still able to demonstrate a benefit with ICS in this setting.

**CONCLUSION**

This study suggests ICS is a clinically and cost-effective method of reducing perioperative blood product transfusion in patients undergoing first-time cardiac surgery. These findings support the use of ICS as an agent of blood conservation in routine cardiac surgery. However, a prospective randomized multi-institutional controlled trial with evaluation of coagulation status and a strict transfusion algorithm is necessary to determine the true benefit of ICS.

**Affiliations:** From Dalhousie Medicine, New Brunswick, Saint John, NB (Côté); Cardiovascular Research, New Brunswick Heart Center, Saint John Regional Hospital, Saint John, NB (Yip, MacLeod, Forgie, Pelletier, Hassan); Clinical Perfusion Services, Saint John Regional Hospital, Saint John, NB (O’Reilly); the Cardiovascular Data Management Centre, Hospital for Sick Children, University of Toronto, Toronto, Ont. (Murray); and the Toronto General Hospital, Toronto, Ont. (Ouzounian).

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**Competing interests:** None declared.

**Contributors:** C. Côté, M. Ouzounian, C. Brown, R. Forgrie and A. Hassan designed the study. C. Côté, J. MacLeod, B. O’Reilly and A. Hassan acquired the data, which C. Côté, A. Yip, J. Murray, M. Pelletier and A. Hassan analyzed. C. Côté and A. Hassan wrote the article, which all authors reviewed and approved for publication.

**References**


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**Forum canadien de chirurgie**

La réunion annuelle du Forum canadien de chirurgie aura lieu du 14 au 17 septembre 2017 à Victoria (C.-B.). Cette réunion interdisciplinaire permet aux chirurgiens de toutes les régions du Canada qui s’intéressent à la pratique clinique, au perfectionnement professionnel continu, à la recherche et à l’éducation médicale d’échanger dans un climat de collégialité. Un programme scientifique intéressera les chirurgiens universitaires et communautaires, les résidents en formation et les étudiants.

Les principales organisations qui parrainent cette réunion sont les suivantes :

- L’Association canadienne des chirurgiens généraux
- La Société canadienne des chirurgiens du côlon et du rectum
- La Société canadienne de chirurgie thoracique
- La Société canadienne d’oncologie chirurgicale
- L’Association canadienne hépato-pancréato-biliaire


Pour vous plus de renseignements, veuillez consulter le site www.canadiansurgeryforum.com/
Length of stay, wait time to surgery and 30-day mortality for patients with hip fractures after the opening of a dedicated orthopedic weekend trauma room

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Background: In September 2011, Kingston General Hospital (KGH) opened a dedicated orthopedic weekend trauma room. Previously, 1 weekend operating room (OR) was used by all surgical services. We assessed the impact this dedicated weekend trauma room had on hospital length of stay (LOS), time to surgery and 30-day mortality for patients with hip fractures.

Methods: Patients admitted between Oct. 1, 2009, and Sept. 30, 2012, were identified through our trauma registry, representing the 2 years before and 1 year after the opening of the orthopedic weekend trauma room. We documented type of fracture, mode of fixation, age, sex, American Society of Anesthesiologists (ASA) score, time to OR, LOS, discharge disposition and 30-day mortality. We excluded patients with multiple fractures, open fractures and those requiring trauma team activation.

Results: Our study included 609 patients (405 pre- and 204 post–trauma room opening). Mean LOS decreased from 11.6 to 9.4 days ($p = 0.005$) and there was a decreasing trend in mean time to OR from 31.5 to 28.5 hours ($p = 0.16$). There was no difference in 30-day mortality ($p = 0.24$). The LOS decreased by an average of 2 days following opening of the weekend trauma room ($p = 0.031$) and by an average of 2.2 additional days if the patient was admitted on the weekend versus during the week ($p = 0.024$).

Conclusion: The weekend trauma OR at KGH significantly decreased the LOS and appears to have decreased wait times to surgery. Further analysis is needed to assess the cost-effectiveness of the current strategy, the long-term outcome of this patient population and the impact the additional orthopedic weekend trauma room has had on other surgical services (i.e., general surgery) and their patients.

Contexte : En septembre 2011, l'Hôpital général de Kingston (HGK) a rendu disponible la fin de semaine une salle d'opération consacrée exclusivement aux traumatismes orthopédiques. Auparavant, une seule salle d'opération était ouverte la fin de semaine, et tous les services de chirurgie se la partageaient. Nous avons évalué l'incidence de la disponibilité de cette nouvelle salle sur la durée de séjour, la durée de l'intervention et le taux de mortalité dans les 30 premiers jours des patients ayant une fracture de la hanche.

Méthodes : Nous avons recensé dans nos registres de traumatismes les patients hospitalisés entre le 1er octobre 2009 et le 30 septembre 2012, ce qui correspond à 2 années avant et 1 année après l'ouverture de la salle de fin de semaine. Nous avons noté le type de fracture, le mode de fixation, l'âge, le sexe, le score ASA (de l'American Society of Anesthesiologists), le délai avant l'entrée en salle d'opération, la durée de séjour, l'état à la sortie et le taux de mortalité dans les 30 premiers jours. Nous avons exclu les patients ayant subi de multiples fractures ou des fractures ouvertes et ceux ayant nécessité l'activation de l'équipe de trauma.

Résultats : L'étude portait sur 609 patients (405 avant et 204 après l'ouverture de la salle). La durée de séjour moyenne a diminué après l'ouverture, passant de 11,6 à 9,4 jours ($p = 0,005$), tout comme le délai moyen avant l'entrée en salle d'opération, qui est passé de 31,5 à 28,5 heures ($p = 0,16$). Aucune différence n'a été relevée pour ce qui est du taux de mortalité dans les 30 premiers jours ($p = 0,24$). La diminution moyenne de la durée de séjour après l'ouverture de la salle était de 2 jours ($p = 0,031$), et de 2,2 jours additionnels si le patient avait été hospitalisé durant la fin de semaine ($p = 0,024$).
Hip fractures are a relatively common occurrence in the elderly population and pose a substantial financial burden on the health care system. Low-energy mechanical falls are the most common mechanism, and osteoporosis is the underlying cause in the vast majority of cases. The incidence of hip fractures increases exponentially after the age of 50 years, approximately doubling every 5 years thereafter. In Ontario, the hip fracture rate is approximately 3.3 per 1000 persons (1.7 men v. 4.6 women), which is comparable to other locations around the world. One-year mortality has been estimated to be 12%–37%, and 4%–12% of patients will die during their initial admission. Approximately 11% of patients who survive to be discharged home or transferred to another facility will be readmitted within 2 years secondary to another fracture, and 5.6% of patients will experience a second hip fracture in their lifetime. The mean length of stay (LOS) in hospital following a hip fracture is approximately 21 days. Wiktorowicz and colleagues examined the health care burden of hip fractures in Canada and found that the yearly cost was approximately $26 000 per patient and that the initial hospitalization of community-dwelling patients accounted for 58% of this cost. The annual economic impact of hip fractures in Canada at the turn of the century was approximately $650 million, and this is projected to increase to approximately $2 billion by the year 2041. With the aging patient population and with limited and diminishing resources, it will be up to hospitals to find more efficient ways of providing high-quality health care to patients with hip fractures.

In September 2011, Kingston General Hospital (KGH), a tertiary care centre affiliated with Queen’s University with approximately 200 inpatient surgical beds, opened a dedicated orthopedic surgical trauma room on Saturdays and Sundays. Prior to the addition of the weekend trauma time, hip fractures were already given a higher priority than other orthopedic surgical conditions, with a target time to surgery within 48 hours of admission. However, on weekends only 1 operating room (OR) was used by all surgical services. The aim of this study was to assess the impact the dedicated weekend orthopedic surgical trauma room had on LOS, wait time to surgery and 30-day mortality for patients admitted with hip fractures.

**Methods**

Ethics approval was obtained following Research Ethics Board review. All patients admitted to KGH with a diagnosis of hip fracture between Oct. 1, 2009, and Sept. 30, 2012, were identified through our trauma registry, representing the 2 years before and 1 year after the opening of the weekend orthopedic trauma room. Nine staff surgeons performed surgical fixation depending on the trauma call schedule.

We reviewed patient charts and collected data, including type of fracture, mode of fixation, age, sex, American Society of Anesthesiologists (ASA) score, time from admission to fixation, LOS, discharge disposition and 30-day mortality. Thirty-day mortality was determined through follow-up records and by contacting family physicians, patients, families and permanent residences. All the patients included in the study were accounted for.

We included patients with a diagnosis of subcapital fracture, femoral neck fracture, basivertebral fracture, intertrochanteric fracture or subtrochanteric extension fracture. We excluded patients for whom no diagnosis was available, those who died before surgical fixation, those who underwent nonoperative management, those who had open fractures or additional fractures/injuries and those who required trauma team activation.

**Statistical analysis**

Data were entered into an Excel spreadsheet and imported into SPSS version 22.0 for Windows (IBM) for statistical analysis. Data were initially analyzed descriptively, including frequencies and percentages for categorical data and means and standard deviations for continuous data. We graphed LOS and time to OR to assess their underlying distribution. We compared the pre- and post-trauma room groups using \( \chi^2 \) tests for categorical data, independent samples \( t \) tests for continuous data and the Mann–Whitney \( U \) test for LOS. Additional analyses included Pearson and Spearman correlations to assess the associations between continuous variables, such as age, with ASA, LOS and time to OR. Variables with a potential association (e.g., \( p < 0.15 \)) with the outcomes on the bivariate analyses were entered into multivariable linear regression models to identify predictors of LOS and time to OR. For LOS, outliers (defined as the mean ± 3 standard deviations) were removed to normalize the data. This
was considered preferable to log-transformation as the original unit of measure (days) is retained and it was the intent to assess the associations for typical patients rather than the very few outliers who were awaiting placement for long-term care.

**RESULTS**

We included 609 patients in the analysis: 423 women (69.5%) and 186 men (30.5%). The mean age at diagnosis was 79.5 ± 12.6 (range 17–105) years, the mean time from admission to operative fixation was 30 ± 24.1 h, and the mean operative duration was 61 ± 22.6 min. The median LOS was 7.7 days, with the 25th and 75th percentiles being 5.0 and 12.7 days, respectively. The most frequent admitting diagnoses were intertrochanteric fracture (40.8%) and femoral neck fracture (36.9%). More than half (58.8%) of patients had an ASA classification of 3, and 24.6% had an ASA classification of 4. Thirty-two patients (5.3%) died within 30 days of their admission, 272 (44.7%) were discharged to long-term care facilities, and 237 patients (38.8%) were discharged to their homes with support services. The most frequent modes of surgical fixation were bipolar hemiarthroplasties (28.8%), cephalomedullary nails (28%) and dynamic hip screw constructs (23.8%). Twelve patients were considered LOS outliers and were removed to normalize the distribution, although they were retained in all other analyses. Of these, 10 of 405 (2.5%) were from the pre–trauma room group and 2 of 204 were from the post–trauma room group (p = 0.35).

We performed Student t tests on the continuous outcome data (LOS, duration of surgery, time to OR) and found no association between these data and sex or operative side, but the patients admitted over the weekend (Friday to Sunday) were found to have shorter LOS than patients admitted during the week (p = 0.017). Time to OR was longer for admissions occurring between Friday and Sunday (p = 0.036).

The pre and post–trauma room periods are compared in Table 1. Correlation between continuous data points were analyzed using the Pearson correlation test. Older patients had higher ASA classification scores (p < 0.001), shorter duration of surgery (p = 0.003), and longer time to OR (p < 0.001); using the Spearman rho correlation test, older patients had longer LOS (p < 0.002).

Multivariable linear regression (Table 2) was performed after controlling for age, ASA class and weekend/weekday admission. The LOS was decreased by an average of 2 days following opening of the weekend trauma room (p = 0.031) and by an average of 2.2 additional days if the patient was admitted on the weekend versus during the week (p = 0.024). In addition, each 1-point increase in ASA level was associated with an average of 2.9 additional days (p < 0.001), while age was not significant (p = 0.64). The multivariable model for time to OR indicated an average decrease of 2.4 h following the implementation of the weekend trauma room, although the results fell short of statistical significance (p = 0.25) with other stronger variables in the model. Of note, every 1-point increase in ASA class resulted in an average of 10.7 additional hours of surgical delay (p < 0.001).

**DISCUSSION**

It may be intuitively obvious that adding extra dedicated orthopedic trauma room time on the weekend would...
decrease time to surgery and LOS. However, in a climate of resource constraints it is important to evaluate the effectiveness of policy decisions objectively. We chose to evaluate a fracture type that was already given priority over less urgent cases to better gauge whether this policy change would have a substantial impact. One could argue that routine outpatient fracture fixation (e.g., wrist fractures) performed 2 days earlier may not have major long-term outcome benefits. By contrast, hip fractures are associated with lengthy hospital stays, they have a substantial impact on the functional status of patients and they carry high mortality. It should be noted that there was already a policy in place to complete hip fracture surgery within 24–48 h once the patient was deemed medically stable. The completion of these cases competes with other urgent cases, both orthopedic and nonorthopedic. There were no identified additional policy changes or formal initiatives undertaken during the study period that would confound the results.

Our results are of interest for several reasons. After controlling for appropriate variables, LOS was decreased by 2 days overall and by an additional 2 days for patients admitted on the weekend. The daily cost of keeping a senior patient in hospital is approximately $900 per day (excluding investigations), and although a complete cost analysis was beyond the scope of this study, a decrease of 2–4 days is economically substantial. Moreover, time to OR decreased by 2.4 h overall, and while not significant in the multivariable model, this decrease was significant in univariate analysis when looking at the subset of patients who underwent weekend surgery, where there was an average decrease of 6.9 h. The 30-day mortality in our study (5.3%) was similar to or better than previously reported North American and European rates. Our mortality rate was not adversely affected by the opening of the dedicated weekend orthopedic trauma room, which suggests that patients were not harmed by earlier discharges. Efforts to improve outcomes, including mortality, continue, and the province of Ontario has recently set a benchmark for hip fracture surgery and hip fracture surgery within 48 h of admission.

The mean time from admission to OR was 30 h, which is comparable to other published times and under the current guidelines. Twenty-five percent of our patients were in the OR within 16 h, and 75% within 40 h. Like at most centres, time to OR is often delayed for patients requiring preoperative optimization (dialysis, echocardiograms, stabilization in the intensive care unit [ICU]). The LOS in the present study is below published standards, and 75% of our patients are going home, to rehabilitation or to extended care facilities within 13 days. It should be noted that LOS data were badly skewed, and outliers needed to be excluded in order to provide representative data and analysis. This underlines the complex issue of postoperative patient disposition and the continued lack of long-term extended care beds. Given an aging population and diminishing resources, this is an area of care that all hospitals will need to pursue aggressively.

The additional resources allocated to increasing dedicated orthopedic daytime trauma room time from 5 to 7 days per week would seem to be justified based on these results. The benefits extend beyond just patients admitted on the weekend (Friday–Sunday). The timely completion of urgent orthopedic cases on the weekend helped to avoid the typical backlog of cases encountered at the beginning of the week, thus indirectly benefitting patients admitted on weekdays as well.

**CONCLUSION**

Hip fractures are and will continue to be a major focus in orthopedic surgery. They are associated with high mortality and decreased independence and are among the most expensive fractures to treat when patient, hospital and societal costs are taken into account. At KGH, the addition of a dedicated orthopedic weekend trauma room has had a positive impact on LOS and time to surgery without negatively affecting mortality. These types of time and resource allocation strategies are and will continue to be important parts of health care delivery in Canada. It is hoped that this study may support the increased availability of dedicated orthopedic trauma time at other centres.

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**Competing interests:** None declared.

**Contributors:** M. Taylor and J. Yach designed the study and acquired and analyzed the data, which W. Hopman also analyzed. M. Taylor and J. Yach wrote the article which all authors reviewed and approved for publication.

**References**


Background: Post-mastectomy pain syndrome (PMPS) is a frequent complication of breast surgery. There is currently no standard definition for this chronic pain syndrome. The purpose of this review was to establish a consensus for defining PMPS by identifying the various elements included in the definitions and how they vary across the literature, determining how these definitions affect the methodological components therein, and proposing a definition that appropriately encompasses all of the appropriate elements.

Methods: We searched PubMed to retrieve all studies and case reports on PMPS, and we analyzed definitions of PMPS, inclusion/exclusion criteria, and methods of measuring PMPS.

Results: Twenty-three studies were included in this review. We identified 7 independent domains for defining PMPS: surgical breast procedure, neuropathic nature, pain of at least moderate intensity, protracted duration, frequent symptoms, appropriate location of the symptoms and exacerbation with movement. These domains were used with varying frequency. Inclusion/exclusion criteria and methods for assessing PMPS also varied markedly.

Conclusion: To prevent future discrepancies in both the clinical and research settings, we propose a new and complete definition based on the results of our review: PMPS is pain that occurs after any breast surgery; is of at least moderate severity; possesses neuropathic qualities; is located in the ipsilateral breast/chest wall, axilla, and/or arm; lasts at least 6 months; occurs at least 50% of the time; and may be exacerbated by movements of the shoulder girdle.
Pain plays an important role in human survival, aiding in prompt withdrawal from sources of damage and preventing further exposure to painful elements. Pain after injury further serves to promote the protection of vulnerable area(s) of the body. Thus, pain typically exists in a transitory state, which remits once painful stimuli are removed and tissue damage is healed. However, in some cases, pain can become chronic, lasting well beyond its useful period and becoming pathological. Chronic pain can be extremely burdensome, reducing the quality of life and overall functional ability of the patient. In many cases, typical analgesic methods do not provide effective relief and/or present with their own consequences in the form of side effects. Unfortunately, chronic pain syndromes are common, occurring in up to 64% of North Americans and 55% of people worldwide. For these reasons, it has been a prominent topic of study in many areas of medicine.

Breast cancer is very common, second only to lung cancer in both developed and developing countries. The mastectomy procedure is the foremost curative treatment of breast cancer. As with any surgical procedure, acute and/or delayed complications can occur.

One such complication is chronic pain, which may last months to years after surgery. Persistent pain following mastectomy was reported as early as 1978. Since then, this phenomenon has been named post-mastectomy pain syndrome (PMPS). This syndrome has emerged as a ubiquitous complication of breast surgery, with a reported frequency of 4%–100%. There is currently no standard definition of what constitutes PMPS. The International Association for the Study of Pain (IASP) defines PMPS as persistent pain soon after mastectomy/lumpectomy affecting the anterior thorax, axilla, and/or medial upper arm. The IASP has been often misquoted as defining a duration of more than 3 months for PMPS, when in reality no explicit duration is stated. In general, the IASP claims that 3 months is a convenient point from which pain may be considered chronic; however, they go on to state that 6 months is often preferred for research purposes. Indeed, 3 months may not be the most appropriate time point. Despite its name, the term PMPS may also be used when discussing patients who underwent breast-conserving surgery.

The ambiguity surrounding the definition of PMPS has resulted in a well-studied topic that has not been well defined, wherein several definitions have been used in the literature. For instance, a study by Vilholm and colleagues defined PMPS as pain of a neuropathic nature with intensity greater than 4 on a 10-point numeric scale, located at the surgical site or ipsilateral arm, and lasting longer than 6 months following surgery. However, Couceiro and colleagues defined PMPS as any type of pain located in the anterior surface of the chest axilla, shoulder or upper half of the arm, and persisting for longer than 3 months. In this example, we are effectively dealing with 2 different conditions. The variety of definitions used for PMPS has likely translated into a difference in methodology, namely inclusion/exclusion criteria and outcome measures. Ultimately, the epidemiology and potential etiology and treatments surrounding PMPS are not applicable to one another.

The purpose of this study was to review the literature to identify all operational definitions currently being used for PMPS; identify corollaries among the domains of each definition; identify variation in the methodological properties for diagnosing, measuring and assessing PMPS; and, if need be, propose a standard definition taking into account the results of the literature review and make recommendations for methodology. In doing so, we intend to make future study of PMPS analogous, both in terms of research and clinical diagnosis.

**METHODS**

**Search strategy**

We searched all records in the PubMed database from creation (1946) to June 5, 2015, using both medical subject heading (MESH) terms and text words “(post mastectomy OR postmastectomy) pain syndrome.”

**Inclusion and exclusion criteria**

The review included all study designs, including randomized trials, nonrandomized studies and case reports/series. For inclusion in this review, studies needed to include the term “post-mastectomy pain syndrome” in the abstract, methods and/or results of the article. Non–English language articles were excluded from the study.

**Data extraction**

Following the search, we reviewed the full text of articles and extracted the following data: definition(s) of PMPS, inclusion/exclusion criteria used germane to PMPS, case descriptions (if applicable), measurement methods for pain and any other symptoms germane to PMPS, and duration of the study.

**RESULTS**

**Search**

Our search of the literature retrieved 67 articles. After excluding articles that did not specifically address PMPS and articles published in languages other than English, we selected 23 studies specifically exploring PMPS for full-text review. Of these studies, 4 were case reports. All reviewed articles were published between 1988 and 2015 and are analyzed hereafter.
Definition of PMPS

We identified a total of 7 domains among all definitions of PMPS: surgical breast procedure, neuropathic nature, pain of at least moderate intensity, protracted duration, frequent symptoms, appropriate location of the symptoms and exacerbation with movement. The contents of PMPS definitions in each of the reviewed articles is summarized in Table 1, Table 2, Table 3, Table 4, Table 5, Table 6 and Table 7.

Corollaries of these domains across the literature are summarized in Table 8. None of the articles’ definitions included all 7 domains, and 17% of the articles’ definitions included 6 of the 7 domains. One of the articles did not explicitly define PMPS.33

Surgical breast procedure: all breast surgery versus mastectomy alone

Thirty per cent of articles restricted the definition of PMPS to only mastectomy procedures, whereas the remaining two-thirds used a broader definition, including lumpectomy (13%), quadrantectomy (9%), any breast cancer surgery (22%), and any breast surgery (17%).

Neuropathic nature

Eighty-three per cent of studies included neuropathic nature to define the quality of the pain, and of those studies, 79% elaborated on specific qualities that render the pain neuropathic (i.e., altered sensation, such as dysesthesia, hypo/hyperesthesia and allodynia; or particular qualities of dysesthesia, such as pins and needles, shock-like, burning, dull, aching, and stabbing/lancinating pain in the painful area).

Pain of at least moderate intensity

Pain intensity was included in the definition of PMPS in 22% of the reviewed studies and was based on either numerical or analogue scales (e.g., 10-point scale), or descriptive terms (e.g., moderate or severe pain).

Protracted duration

Sixty-five per cent of included studies identified a protracted duration of symptoms as a requisite for PMPS. Of these, 67% of studies required symptom duration to be 3 months or longer for consideration of a PMPS.

Frequent symptoms

Continuity of symptoms was defined as either “continuous” or “intermittent” or in terms of hours per day or days per week. Nine per cent of studies required pain for 12 hours per day, 9% required pain for 4 days a week, and 13% of studies included either continuous and/or intermittent pain.

Appropriate location of the symptoms

Appropriate location of symptoms (i.e., surgical site, axilla, arm, shoulder, and/or chest wall) was the most consistent domain of the PMPS definition across the literature; it was included in 87% of studies.

Table 1. Operational definitions of post-mastectomy pain syndrome, surgical procedure domain

<table>
<thead>
<tr>
<th>Study</th>
<th>Measure(s) fulfilling definition</th>
<th>Quantification(s)/qualification(s) fulfilling definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shahbazi et al14</td>
<td>Mastectomy</td>
<td>—</td>
</tr>
<tr>
<td>Ebaid and El-Sodany15</td>
<td>Mastectomy, lumpectomy</td>
<td>—</td>
</tr>
<tr>
<td>Kojima et al16</td>
<td>Breast cancer surgery</td>
<td>—</td>
</tr>
<tr>
<td>Maione et al17</td>
<td>Mastectomy, lumpectomy</td>
<td>—</td>
</tr>
<tr>
<td>Dessay et al19</td>
<td>Mastectomy</td>
<td>—</td>
</tr>
<tr>
<td>Meijuan et al18</td>
<td>Mastectomy, quadrantectomy</td>
<td>—</td>
</tr>
<tr>
<td>Bauml et al20</td>
<td>Mastectomy</td>
<td>—</td>
</tr>
<tr>
<td>Alves Nogueira Fabro et al21</td>
<td>Breast cancer surgery</td>
<td>—</td>
</tr>
<tr>
<td>Cavigiolli et al22</td>
<td>Mastectomy, quadrantectomy</td>
<td>—</td>
</tr>
<tr>
<td>Vilholm et al8</td>
<td>Breast cancer surgery</td>
<td>—</td>
</tr>
<tr>
<td>Vilholm et al23</td>
<td>Breast cancer surgery</td>
<td>—</td>
</tr>
<tr>
<td>Eisenberg et al24</td>
<td>Breast surgery</td>
<td>—</td>
</tr>
<tr>
<td>Macdonald et al25</td>
<td>Breast surgery</td>
<td>—</td>
</tr>
<tr>
<td>Blunt and Schmede26</td>
<td>Mastectomy, lumpectomy</td>
<td>—</td>
</tr>
<tr>
<td>Reuben et al8</td>
<td>Breast surgery</td>
<td>—</td>
</tr>
<tr>
<td>Miguel et al27</td>
<td>Breast cancer surgery</td>
<td>—</td>
</tr>
<tr>
<td>Smith et al28</td>
<td>Mastectomy</td>
<td>—</td>
</tr>
<tr>
<td>Stevens et al32</td>
<td>Breast surgery</td>
<td>—</td>
</tr>
<tr>
<td>Dini et al30</td>
<td>Mastectomy</td>
<td>—</td>
</tr>
<tr>
<td>Watson and Evans31</td>
<td>Mastectomy</td>
<td>—</td>
</tr>
<tr>
<td>Watson et al32</td>
<td>Mastectomy</td>
<td>—</td>
</tr>
</tbody>
</table>
Exacerbation with movement
Thirteen per cent of studies included exacerbation of pain with movement when defining PMPS.

Methodological factors
Inclusion and exclusion criteria
For 7 (30%) of the articles, PMPS was not an initial inclusion criterion (i.e., studies assessed the prevalence of PMPS), and thus other than a history of breast surgery, a PMPS definition did not factor into the study.

Of the other 12 non–case report studies, 6 (50%) listed PMPS as a criterion for inclusion, while 4 (33%) articles specifically outlined neuropathic pain or neuropathic symptoms in their criteria. Five (42%) of these studies outlined specific locations (i.e., chest/breast, arm/shoulder and/or axilla) for which symptoms were needed. Half of the studies also required symptoms to persist for more than 3 months. Intensity of pain was a criterion in 2 (17%) of the 12 studies, and at least moderate severity was required in both.

Assessing PMPS
The visual analogue scale (VAS) was the most common method of assessing pain used to identify PMPS; this method was used in 7 (30%) of the 23 studies. A verbal intensity scale (VIS) accompanied the VAS in 2 (9%) of these studies. A numeric pain scale out of 10 was an

### Table 2. Operational definitions of post-mastectomy pain syndrome, protracted duration domain

<table>
<thead>
<tr>
<th>Study</th>
<th>Measure(s) fulfilling definition</th>
<th>Quantification(s)/qualification(s) fulfilling definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shahbazi et al(^{14})</td>
<td>Post Mastectomy Pain Syndrome questionnaire (designed by cancer research centre, Shohada Hospital, Tajrish, Tehran, Iran)</td>
<td>&gt; 3 mo</td>
</tr>
<tr>
<td>Kojima et al(^{16})</td>
<td>Not included in methodology</td>
<td></td>
</tr>
<tr>
<td>Maione et al(^{17})</td>
<td>Unclear</td>
<td>&gt; 3 mo</td>
</tr>
<tr>
<td>Couceiro et al(^{9})</td>
<td>Not included in methodology</td>
<td></td>
</tr>
<tr>
<td>Dessy et al(^{18})</td>
<td>Follow-up time points</td>
<td>3 mo</td>
</tr>
<tr>
<td>Meijuan et al(^{19})</td>
<td>Unclear</td>
<td>&gt; 3 mo</td>
</tr>
<tr>
<td>Alves Nogueira Fabro et al(^{21})</td>
<td>Physiotherapeutic assessments</td>
<td>6 mo</td>
</tr>
<tr>
<td>Cavigiolli et al(^{22})</td>
<td>Follow-up time points</td>
<td>&gt; 3 mo (12–15 mo follow-up)</td>
</tr>
<tr>
<td>Vilholm et al(^{23})</td>
<td>Unclear</td>
<td>&gt; 3 mo</td>
</tr>
<tr>
<td>Macdonald et al(^{25})</td>
<td>Follow-up time points</td>
<td>7–12 yr</td>
</tr>
<tr>
<td>Blunt an Schmiedel(^{26})</td>
<td>Follow-up time points</td>
<td>“Long lasting” (4–11 mo follow-up)</td>
</tr>
<tr>
<td>Smith et al(^{27})</td>
<td>Follow-up time points</td>
<td>&gt; 3 mo (6 yr follow-up)</td>
</tr>
<tr>
<td>Dini et al(^{30})</td>
<td>Follow-up time points</td>
<td>&gt; 3 mo (5 mo follow-up)</td>
</tr>
<tr>
<td>Watson and Evans(^{31})</td>
<td>Follow-up time points</td>
<td>&gt; 3 mo (10–30 mo follow-up)</td>
</tr>
<tr>
<td>Watson et al(^{32})</td>
<td>Follow-up time points</td>
<td>&gt; 3 mo (7 mo–20 yr follow-up)</td>
</tr>
</tbody>
</table>

### Table 3. Operational definitions of post-mastectomy pain syndrome, pain of moderate intensity or greater domain

<table>
<thead>
<tr>
<th>Study</th>
<th>Measure(s) fulfilling definition</th>
<th>Quantification(s)/qualification(s) fulfilling definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vilholm et al(^{23})</td>
<td>Numerical rating scale (0–10)</td>
<td>≥ 4 out of 10</td>
</tr>
<tr>
<td>Vilholmet et al(^{28})</td>
<td>Numerical rating scale (0–10)</td>
<td>≥ 3 out of 10</td>
</tr>
<tr>
<td>Dini et al(^{30})</td>
<td>VAS At least moderate (middle third of scale), severe (final third of scale)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>VIS At least moderate (middle third of scale), severe (final third of scale)</td>
<td></td>
</tr>
<tr>
<td>Watson and Evans(^{31})</td>
<td>VAS At least moderate (middle third of scale), severe (final third of scale)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>VIS At least moderate (middle third of scale), severe (final third of scale)</td>
<td></td>
</tr>
</tbody>
</table>

VAS = visual analogue scale; VIS = verbal intensity scale.
alternative pain assessment tool in 4 (17%) studies. Questionnaires, including the McGill Pain Questionnaire (MPQ) and short-form MPQ (used in 26% of studies) and the UCSF Pain Service Questionnaire (used in 13% of studies) were also used to identify PMPS. Physical examination was used to identify sensory changes in 5 (22%) studies. Four studies also incorporated analgesia requirement into the assessment. In addition to pain assessment, quality of life questionnaires, namely the Short Form 36, were included in some methodologies. Finally, 4 studies used patients’ report for assessment of PMPS symptoms.

**DISCUSSION**

Post-mastectomy pain syndrome is a chronic pain syndrome that incorporates a number of different clinical pictures, depending on the particular nerve or nerves that are damaged.\(^{34}\) Variation exists across the literature as to how PMPS is defined, wherein inclusion of any number of these domains and the details therein is heterogeneous. Though pain has been an obvious corollary across studies, there are notable differences in how the nature, intensity, frequency, location and triggers of that pain is described with respect to the definition of PMPS.

In this review, all studies using the term “post-mastectomy pain syndrome”\(^{29}\) were assessed to identify the operational definitions being used and their respective influence on inclusion and exclusion criteria as well as assessment of pain symptoms. Seven independent domains were identified for defining PMPS within the included studies. Thus, we cannot be confident of the true prevalence of PMPS or optimal management based on the research to date, since different results have been reported based on different inclusion criteria and assessment of PMPS.

<table>
<thead>
<tr>
<th>Table 4. Operational definitions of post-mastectomy pain syndrome, frequent symptoms domain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study</strong></td>
</tr>
<tr>
<td>Shahbazi et al(^{14})</td>
</tr>
<tr>
<td>Meijuan et al(^{19})</td>
</tr>
<tr>
<td>Cavigiolli et al(^{22})</td>
</tr>
<tr>
<td>Vilholm et al(^{22})</td>
</tr>
<tr>
<td>Vilholm et al(^{24})</td>
</tr>
<tr>
<td>Macdonald et al(^{25})</td>
</tr>
<tr>
<td>Blunt and Schmiedel(^{26})</td>
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<tr>
<td>Watson and Evans(^{27})</td>
</tr>
<tr>
<td>Watson et al(^{29})</td>
</tr>
</tbody>
</table>

MPQ = McGill Pain Questionnaire.

<table>
<thead>
<tr>
<th>Table 5. Operational definitions of post-mastectomy pain syndrome, neuropathic pain domain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study</strong></td>
</tr>
<tr>
<td>Shahbazi et al(^{14})</td>
</tr>
<tr>
<td>Ebid and El-Sodany(^{20})</td>
</tr>
<tr>
<td>Maione et al(^{27})</td>
</tr>
<tr>
<td>Dessy et al(^{28})</td>
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<tr>
<td>Meijuan et al(^{19})</td>
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<td>Bauml et al(^{29})</td>
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<td>Cavigiolli et al(^{22})</td>
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<td>Vilholm et al(^{22})</td>
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<td>Eisenberg et al(^{24})</td>
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<td>Macdonald et al(^{25})</td>
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<tr>
<td>Blunt and Schmiedel(^{26})</td>
</tr>
<tr>
<td>Reuben et al(^{26})</td>
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</table>

MPQ = McGill Pain Questionnaire.
As such, the parameters surrounding inclusion and exclusion of patients with PMPS and the assessment of PMPS was heterogeneous across studies. In order to identify PMPS, the reviewed studies used a variety of methods for assessing the respective operational definitions, including questionnaires, scales, sensory examination and non-questionnaire, patient-reported symptoms. The latter 2 methods have inherent biases and inconsistencies in the setting of research. Of the questionnaires that were used, the MPQ, was a frequent basis for PMPS assessment. The MPQ is effective in identifying neuropathic pain based on identifying words as well as pain intensity, frequency and location. Thus, the MPQ covers 4 of the essential 6 operational definitions for PMPS, the other 2 being accurately and easily retrieved from patient history or medical record. The VAS and VIS were also commonly used in select studies to quantify pain intensity. Another notable questionnaire is the Post-Mastectomy Pain Syndrome Questionnaire recently developed by Shahbazi and colleagues; however, we were unable to obtain a copy.

Incorporation of the key operational definitions identified in our review offers a comprehensive characterization of PMPS while accommodating for the spectrum of potential clinical findings. In reviewing the literature, we were able to identify important domains that address the syndrome from many facets.
Breast surgery

Despite the nomenclature, the mechanism for causing pathological postoperative pain in PMPS is likely not limited to mastectomy procedures. Any other surgical procedure involving breast parenchyma or underlying muscle is prone to the same outcome.9

Given the broader purview of surgical procedures to which PMPS applies, we propose that post-breast surgery pain syndrome (PBSPS) is a more clinically appropriate term. The term is used henceforth in this discussion.

Neuropathic nature

A neuropathic quality of pain within the PBSPS definition is crucial for identifying the pathological pain process that makes it a true chronic pain syndrome. Persistent postoperative pain beyond physiologic healing has been attributed to nerve damage or traction incurred during the procedure, in particular to the intercosto-brachial, medial pectoral, lateral pectoral, thoracodorsal or long thoracic nerve.34 Neuropathy can be measured subjectively through clinical assessment or questionnaires to determine the presence of any neuropathic qualities (e.g., dysesthesia, burning), or it can be measured objectively using quantitative sensory testing (QST). A reliable account of neuropathic pain is required for a diagnosis of PBSPS.

Pain of at least moderate intensity

In order to identify a clinical pain problem, there should be evidence that the symptoms are of clinical importance. It has been reported that pain intensity significantly correlates with quality of life.10 Pain of at least moderate intensity (i.e., within the middle third of a pain scale) is classically considered for sensitivity in a pain trial.11

Protracted duration

The duration of pain should be beyond the expected time for normal healing after breast surgery. The 2 most commonly used markers for duration to be considered chronic pain versus acute pain are 3 and 6 months.12 The IASP has stated that 3 months is considered a normal healing time, but that 6 months is preferred for research purposes.6 By extending the definition of PBSPS to encompass a 6-month duration of symptoms postoperatively, one can be certain that each case is truly a pathological pain syndrome rather than normal postoperative healing.

Frequent symptoms

In line with pain intensity, in a clinically important chronic pain syndrome the pain should occur frequently. The definition of PBSPS should be based on symptoms

Table 8. Distribution of domains defining post-mastectomy pain syndrome across articles

<table>
<thead>
<tr>
<th>Author</th>
<th>Surgical breast procedure</th>
<th>Neuropathic nature</th>
<th>Pain of at least moderate intensity</th>
<th>Protracted duration</th>
<th>Frequent symptoms</th>
<th>Appropriate location of the symptoms</th>
<th>Exacerbation with movement</th>
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</thead>
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<tr>
<td>Shahbazi et al14</td>
<td>✓</td>
<td>✓</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Ebid and El-Sodany15</td>
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<td>✓</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<td>Blunt and Schmiedel24</td>
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<td>Watson and Evans31</td>
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<tr>
<td>Rogers et al33</td>
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</table>
that are present for a clinically important amount of time: at least 4 days per week for more than 12 hours per day.

Appropriate location of symptoms

Symptoms local to the surgical site and surrounding structures indicate a procedure-related cause, reducing the likelihood of other processes or events (perioperative or otherwise) being the source of PBSPS symptoms. The breast, chest wall, axilla, or arm of the affected side represent the site of direct trauma to these structures. Presence of symptoms in at least 1 of these sites is thus essential to diagnosing PBSPS.

Exacerbation with movement

What triggers or intensifies pain is important when classifying it clinically. Though pain exacerbation with shoulder movement is not necessarily a requisite when defining or diagnosing PBSPS, it is likely to be closely associated with the syndrome owing to proximity to the surgical site.

CONCLUSION

The purpose of this review was to identify the domains for defining PBSPS, their variation across the current literature and subsequent methodological discrepancies. We found substantial variation therein, bringing to light a need for a standard definition of PBSPS. All 7 of the identified domains have been shown to be important for appropriately and comprehensively defining PBSPS. We conclude that a complete definition of PBSPS is pain that occurs after any breast surgery; is of at least moderate severity; possesses neuropathic qualities; is located in the ipsilateral breast/chest wall, axilla, and/or arm; lasts at least 6 months; occurs at least 50% of the time; and may be exacerbated by movements of the shoulder girdle. It is our hope that a consensus can be drawn regarding the inclusion of patients and appropriate assessment of PBSPS in subsequent research and to help guide surgeons and physicians when they encounter these cases.

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Competing interests: None declared.

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

References


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Users’ guide to the surgical literature: how to assess an article about harm in surgery

Surgery often walk a proverbial tightrope, balancing the benefits and harms of surgical care. At all times, they must strive to ensure that the benefits of surgery outweigh any potential harm. For example, does the benefit of repairing minimally symptomatic inguinal hernia outweigh the risks in a patient with severe asthma and coronary heart disease? Indeed, patient safety is the cornerstone of good surgical practice.

The need for an evidence-based approach to harm reduction is imperative. In addition to surgical skills, we must possess the skills and confidence to identify and appraise the available evidence.

The patient in our clinical scenario wants to know if there is potential harm associated with breast reconstruction using silicone breast implants, particularly an increased risk of ALCL developing in the breast(s). Naturally, the surgeon must communicate to the patient all risks and benefits and how they compare such that the patient and surgeon can arrive at a decision together. However, it is the surgeon’s responsibility to seek out the relevant and most up-to-date information to ensure the patient is adequately informed. There are a multitude of harms associated with various surgical specialties, procedures within specialties, surgical environments and technical skills of surgeons. Unfortunately these cannot be covered in a single article. For example, the choice of new techniques/technologies has been addressed in a recent article entitled “Methodological guide to adopting new aesthetic surgical innovations.”

The focus of the present article was to provide a global guide to appraise surgical articles that deal with the issue of harm.

In line with our tenets of EBS, we must consult the best evidence for resolving issues about harm. Ideally, one would hope to acquire preappraised literature on the topic, providing expert review on primary literature and offering opinions for surgical management. However, with an emerging
topic, such as that in our clinical scenario, we should not be surprised if primary literature is the only available resource. Ideally, the answer should be found in a well-designed, large randomized controlled trial (RCT) or, if available, a meta-analysis of RCTs. Primarily, RCTs are designed to evaluate the efficacy of a new treatment in improving patients’ outcomes, and secondarily they are intended to measure complications or harms related to the new treatment compared with the conventional treatment or no treatment. Ethically we cannot randomize patients to a harmful intervention. As some harmful effects take a long time to occur postexposure, we should be searching for a longitudinal cohort study, preferably a prospective cohort study. Furthermore, many of the harmful effects of therapy are too rare to be detected by RCT. For example, the rule of thumb for detectable adverse events in an RCT is roughly a 1% event rate.7 In the absence of prospective cohort studies, a retrospective, historical cohort study or a case–control study may be the most appropriate evidence. It was, after all, a case–control study that identified the association of phocomelia and thalidomide in the 1960s.8 Case–control studies may be more suitable if the harmful outcome under study is either rare or requires a long time to occur. For example, it is not feasible to follow patients in an RCT comparing breast implant versus autogenous tissue breast reconstruction after mastectomy for 20 years to see if some patients will experience an uncommon form of cancer like ALCL. The key strengths and limitations of the above study designs are summarized in Table 1.

**FINDING THE EVIDENCE**

To identify the best evidence and inform the patient in our clinical scenario, we performed a literature search according to the Users’ Guide for Surgical Literature: How to perform a high-quality literature search.2 Deconstructing our research question using the PICOT (population, intervention, comparison, outcome, time horizon) format allowed us to choose important keywords for our search.9

- **Population:** female mastectomy patients
- **Intervention:** silicone gel breast implants
- **Comparison:** no intervention
- **Outcome:** ALCL
- **Time horizon:** any period of time after breast implant

Searching PubMed Clinical Queries using the search terms “anaplastic large cell lymphoma” AND “breast” AND (implant OR prosth*), we identified 13 articles, including 1 case–control study, 1 retrospective historical cohort study and 3 systematic reviews that were relevant. With the above search strategy, the multiple case reports associated with this topic were eliminated. No RCTs were identified that dealt with ALCL in patients with breast implants. A systematic review represents an ideal source to answer our question, and we identified 3 studies of this type.10–12 Systematic reviews are, in general, of a higher level of evidence than a single study owing to the greater power of their pooled results. However, one must also take

| Table 1. Description of the primary study designs, adapted from Levine et al7 |
|---------------------------------|-----------------|-----------------|-----------------|
| Characteristic                  | Randomized controlled trial | Prospective cohort study | Case–control study |
| Starting point                  | Intervention status | Intervention/exposure status | Event/outcome status |
| Group allocation                | Randomization; groups are balanced for known and unknown confounding factors | Groups are selected to intervention or exposure; groups may not be balanced | Groups are selected to intervention or exposure; groups may not be balanced |
| Outcome measures                | Incidence of disease | Incidence of disease | Prevalence of disease |
| Measure of risk                 | Relative risk; odds ratio; risk difference | Relative risk; odds ratio; risk difference | Odds ratio |
| Temporal relationship between exposure and disease | Easier to establish | Easier to establish | Harder to establish |
| Strength                        | Bias controlled | Bias uncontrolled | Bias uncontrolled |
| Validity (if well-designed)     | Level I evidence | Level II evidence | Level III evidence |

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Box 1: Framework for critical appraisal of an article that deals with harm

I – Are the results valid?

- **Cohort studies:** apart from the exposure of interest did the exposed and control groups start and finish with the same risk for the outcomes?
- **Were patients similar in terms of prognostic factors that are known to be associated with the outcome (or was statistical adjustment necessary)?**
- **Were the circumstances and methods for determining exposure similar for cases and controls?**
- **Was the correct temporal relationship demonstrated?**
- **Was there a dose–response relationship?**

II – What are the results?

- **How strong is the association between exposure and outcome?**
- **How precise was the estimate of the risk?**

III – How can I apply the result my patient or clinical practice?

- **Were the patients in the appraised study similar to the patient in my practice?**
- **Was follow-up sufficiently long?**
- **Is the exposure similar to what might occur in my patient?**
- **What is the magnitude of the risk?**
- **Are there any benefits that are known to be associated with exposure?**

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J can chir, Vol. 59, N° 5, octobre 2016
into account that a systematic review is only as strong as the articles included in its results; thus, it is important to ensure that the review has reported sufficiently appraised studies and appraised the methodology used for each of them. None of the systematic reviews retrieved using our search strategy offered a comprehensive critical appraisal of the included studies. Moreover, systematic reviews may include case reports and case series that are inherent to bias.

The cohort study identified in our literature search was excluded because no ALCL was identified. Thus, we selected the article by de Jong and colleagues because it represented the best available evidence addressing our clinical scenario. It was a case–control study that included all cases of patients with lymphoma in the breast from the entire population of the Netherlands in a 16-year span. In the absence of any RCTs, we believe this study design to be the most appropriate for measuring causation in the case of a rare harmful outcome, such as ALCL. The key methodological characteristics of the study by de Jong and colleagues are summarized in Box 2.

**CRITICAL APPRAISAL OF THE ARTICLE**

The 2 most common designs dealing with harm are the cohort and case–control designs. Box 1 includes questions that need be answered for the appraisal of either a cohort or case–control study. As the article by de Jong and colleagues uses a case–control design, our appraisal questions will pertain to this study.

**Are the results valid?**

Did the patients and controls have the same risk (chance) for being exposed in the past? Valid results are essential to making a clinical or surgical decision. Without adequate confidence that the results represent what they are intending to represent, there is insufficient evidence from which to draw conclusions.

**Were patients and controls similar with respect to the indication or circumstances that would lead to exposure?**

To assess possible causation in a case–control study, patients and controls with similar baseline characteristics are essential to minimize selection bias. This criterion outlines 1 area where randomized groups may be optimal; however, it is important for the surgeon to anticipate an absence of randomization and pay careful attention to how the groups were balanced. The study by de Jong and colleagues identified 389 women from a Dutch national database with histological evidence for lymphoma for the period 1990–2006; 11 women in total received diagnoses of ALCL. A standardized questionnaire was sent to the treating physicians for acquisition of medical information of each patient and control, including previous malignancies, staging results, presence of a breast prosthesis and mammographic results. Balancing of comparison groups was achieved to an extent by matching each patient with 3–7 controls for age (within 5 years) and year of diagnosis (within 2 years), all of whom were nested in the same cohort of female patients with primary breast lymphoma. Baseline prognostic factors were presented in Tables 1 and 2 of their article and included age at diagnosis, year of diagnosis, stage of the lymphoma, breast involvement and lymph involvement, year of placement of the prosthesis, and removal and the type of prosthesis (not provided in all cases). Based on the presented information, the comparison groups had similar baseline prognostic factors except for breast implant(s).

When assessing if the patient and control groups are comparable at baseline, it is important to ensure that all documented risk factors are addressed. Of course we cannot be absolutely certain of all the risk factors. Is the size of the breast, for example, a risk factor for ALCL? We presume that women who had breast implants had smaller breasts than controls, but we cannot be absolutely certain. It would be important in the appraisal of the study to be confident that those risks on their own could not account for the high ACLC rate. Based on the methods used, we were satisfied that patients and controls in the study by de Jong and colleagues were comparable at baseline.

**Were the circumstances and methods for determining exposure similar for patients and controls?**

There are certain biases that should be considered in a case–control study. The methods of diagnosing the outcome and assessing the exposure are particularly important to avoid case-ascertainment and misclassification bias. Ascertainment bias refers to the error associated with selecting patients and controls based on their exposure

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**Box 2: Key methodological features of the matched case–control**

<table>
<thead>
<tr>
<th>Source of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands population-based database: Pathologisch Anatomisch Landelijk Geautomatiseerd Archief (PALGA)</td>
</tr>
<tr>
<td>429 (389 women and 40 men) histologically proven cases of lymphoma of the breast</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Source of controls</th>
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<tbody>
<tr>
<td>Controls with non-ALCL breast lymphoma from PALGA database</td>
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</table>

<table>
<thead>
<tr>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 11</td>
</tr>
<tr>
<td>All female patients with ALCL</td>
</tr>
<tr>
<td>2 of 11 patients recently diagnosed by the authors</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of controls</th>
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<tr>
<td>n = 35, matched for age and year of diagnosis with a ratio of 3–7 controls to 1 case</td>
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<table>
<thead>
<tr>
<th>Analysis</th>
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</thead>
<tbody>
<tr>
<td>Individually matched cases</td>
</tr>
<tr>
<td>Conditional logistic regression estimated the odds ratio of ALCL associated with breast prosthesis</td>
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</tbody>
</table>

ALCL = anaplastic large T-cell lymphoma.
status, such that they do not have an equal chance of inclusion in the study. Misclassification bias refers to the error associated with the misidentification of an exposure status or disease such that the participant is assigned to the incorrect group. To confirm diagnosis of ALCL (outcome) in the study by de Jong and colleagues, all the histological material and medical records were retrieved, and additional immunohistochemical analysis and molecular studies were performed. To determine presence of breast implant, standardized questionnaires were disseminated to the treating physician; these questionnaires included patient history, such as previous breast malignancies, staging results and presence of prosthesis. Information was similarly collected for both patients and controls.

Surveillance bias may also occur in case–control studies; patients may receive extra attention for ascertaining exposure. In the study by de Jong and colleagues, we are not convinced that any surveillance bias was present, as the exposed and unexposed groups alike were extracted from a database of patients with diagnoses of lymphoma, and the same questionnaire was used to ascertain exposure. We are satisfied that the outcomes and exposures were measured comparably in both patients and controls. The authors, however, did not provide information regarding the placement or removal and type of implants used in 5 of 11 patients with ALCL.

Was the correct temporal relationship demonstrated?
To determine true causation, it is necessary to confirm that the surgical management preceded the harmful outcome (introduction of breast prostheses preceded the development of the ALCL). Case–control studies begin by identifying the outcome first and working back toward the exposure, which is why the issue of temporal relationship is so critical to this study design. The study attempts to elucidate the temporal relationship by providing data on time of prosthesis insertion and time of diagnosis of ALCL, which is presented in Table 1 of the article by de Jong and colleagues. However, their information appears to be limited to only 5 of the 11 cases reported. In each of these patients, the implantation of the prosthesis preceded the diagnosis of ALCL. Thus, we cannot be certain of the temporal relationship between exposure and outcome with all patients, leading to uncertainty in the appraisal of the study’s validity.

Was there a dose–response relationship?
Identification of a dose–response phenomenon between exposure and a harmful outcome is yet another measure to justify true causation. A classic example of a dose–response gradient germane to the harm topic is demonstrated in a study by Doll and Hill, wherein cigarette smoking (measured in pack years) showed a dose–response relationship to lung cancer. In our clinical example, we would be more confident in attributing ALCL development to breast implant exposure if we could demonstrate that greater exposure (i.e., greater silicone volume and longer-duration implants) increases the likelihood of ALCL. However, dose–response data may not be a realistic expectation when dealing with surgical studies in general, since the exposure often cannot be titrated to specific doses, as in medication studies.

What are the results?
How strong is the association between exposure and the outcome?
Statistical analysis for measuring effect in a case–control study is typically done using an odds ratio (OR). An OR measures how strong of an association there is between an exposure (breast implant) and disease (ALCL). It is different from other measures of effect, such as relative risk (RR) used in RCT and cohort study designs, and can be more difficult to interpret. The RR cannot be used with a case–control study design since incidence of the disease is unknown; however, the RR and OR approach similar values in the case of rare disease. In a case–control study, the data are classically represented in a 2 × 2 table (Table 2). Patients and controls are classified as exposed and unexposed. Table 2 presents a simple 2 × 2 table for the calculation of an OR, defined as the odds of an event in the exposed group (A + B) divided by the odds of an event in the unexposed group (C + D). An OR greater than 1 indicates that the risk of disease is higher when exposed to the risk factor in question, whereas an OR equal to 1 indicates no risk/association. In the study by de Jong and colleagues, this representation does not hold true since patients and controls were matched; instead a matched analysis method was used to calculate OR. Matching is essential to statistically analyze the results of the study owing to loss of independence between the 2 groups. In this case, conditional logistic regression analysis using the software program EGRET is used to more appropriately estimate the OR of ALCL associated with breast prosthesis while adjusting for between-group differences with respect to other risk factors. The study reported an OR of 18.2 (95% confidence interval [CI] 2.1–156.8) for ALCL in patients who received a breast prosthesis placed for cosmetic reasons, which means that the odds of ALCL developing in those exposed to breast implants is 18.2 times greater than in those with ALCL who have not had breast implants. This can be interpreted as 18 times greater odds for the

### Table 2. Calculating odds ratios

<table>
<thead>
<tr>
<th>Harmful outcome</th>
<th>ALCL</th>
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<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Yes</td>
<td>a</td>
</tr>
<tr>
<td>No</td>
<td>c</td>
</tr>
</tbody>
</table>

\[
OR = \frac{a \times d}{b \times c} = \frac{(5 \times 34)}{(1 \times 6)} = 28.3
\]

ALCL = anaplastic large T-cell lymphoma; OR = odds ratio.
development of ALCL in those with implants than in those without implants; note that the simple calculation included in Table 2 yields an OR of 28.3. de Jong and colleagues\textsuperscript{13} did not perform any subsequent analysis on missing data, instead excluding 1 patient in whom ALCL could not be confirmed.

The sample size in the study by de Jong and colleagues\textsuperscript{13} is too small to draw a valid conclusion. The article appropriately suggests that the findings are preliminary and recommends further confirmation of the association between ALCL and breast prosthesis.

**How precise was the estimate of the risk?**
Although the authors report an OR of 18.2 (95% CI 2.1–156.8), one must not make any swift conclusions when interpreting this value and take into account the characteristics of the specific harmful outcome. In our scenario, ALCL is a rare form of lymphoma, and thus its absolute risk remains very low; absolute risk refers to the probability of a cause-specific event occurring in a specific interval of time in the population, regardless of risk factors.\textsuperscript{17} The estimated incidence at all sites reported by de Jong and colleagues\textsuperscript{13} was 0.1/100 000 per year, which implies an exceedingly low overall risk of the disease developing. The authors estimated that the magnitude of risk for ALCL developing in the breast would be between 0.1 and 0.3/100 000 in women with breast prosthesis per year, based on 11 cases being identified in the Netherlands, with a population of 8 million women, during this period. Therefore the absolute risk of breast cancer developing in a breast containing a prosthesis is much higher than the risk of ALCL as reported in their study.

**How can I apply the result in my patient or clinical practice?**
As discussed earlier, the risk of ALCL with breast prosthesis is small. However, the CI was inclusive to a large odds ratio. It is in fact more likely that the patient in our clinical scenario will have breast cancer during her lifetime regardless of breast implant use because she is a carrier of the BRCA gene (11.7% in Canada) than our calculated risk of ALCL attributable to breast implant.\textsuperscript{18} Thus, ALCL need not be a primary concern despite the speculations in the patient’s magazine.

**Were the patients in the appraised study similar to the patient in my practice?**
The age of patients in the study by de Jong and colleagues\textsuperscript{13} ranged from 24–68 years (though they state a median age of 40), and the population (the Netherlands) is comparable to that of North America. Our patient is 35 years old, falling within their reported age range. The risk of ALCL may be slightly different for our patient in 2015. Our patient is interested in breast reconstruction, and she would most likely have a newer-generation implant with a cohesive silicone gel. The implants made today are different from those used in Dutch women in 1990–2006. Presently there is no evidence that the new implants have a risk profile identical to those of patients in the study by de Jong and colleagues.\textsuperscript{11}

**Was follow-up sufficiently long?**
Adequate follow-up and measurement of the outcomes are important issues to consider in prospective RCTs and cohort studies. We are assessing a case–control study, the event has taken place previously and follow-up for diagnosis of ALCL was not a factor in the study per se. The investigators reported the study time period, which was 1990–2006. This period, extending to 16 years, may be insufficient for the identification of ALCL in controls, as the time from surgery to development of ALCL has been reported to be up to 32 years; however, the mean is 11 years.\textsuperscript{12}

The importance of follow-up should not be understated when appraising a harm article that involves a prospective study design. Whereas some harmful effects may occur early on in a patient’s follow-up, many harmful outcomes can manifest years after surgery. A prospective study with an insufficient follow-up period can mask the association of harm with a surgical procedure. Such was the case with Poly Implant Prothèse breast implants that were later found to be composed of improper quality materials leading to complications, including high rates of rupture.\textsuperscript{19} We are satisfied with the length of follow-up in the study by de Jong and colleagues.\textsuperscript{13}

**Is the exposure similar to what might occur in my patient?**
The age of patients in the study by de Jong and colleagues\textsuperscript{13} ranged from 24–68 years (though they state a median age of 40), and the population (the Netherlands) is comparable to that of North America; our patient is 35 years old, falling within their reported age range. The risk of ALCL may be slightly different for our patient in 2015. Our patient is interested in breast reconstruction, and she would most likely have a newer-generation implant with a cohesive silicone gel. The implants made today are different from those used in Dutch women in 1990–2006. Presently there is no evidence that the new implants have a risk profile identical to those of patients in the study by de Jong and colleagues.\textsuperscript{11}

**What is the magnitude of the risk?**
The OR does not tell us how frequently ALCL occurs. It tells us only that this harmful outcome occurs more often in the exposed group than in the unexposed group. To determine the clinical importance of the results, it is advisable to calculate the number of patients who would need to be exposed to breast implants to result in 1 additional harmful event; this value is known as the number needed to harm (NNH).

The NNH is conceptually and mathematically simple in studies where there are distinct exposed and unexposed groups (RCTs or cohort studies); however, the NNH becomes more complex when we attempt to calculate it based on OR values, as is typically the case with a case–control
study. With case–control results, we also need to know the expected event rate for ALCL in the unexposed population, known as the patient-expect event rate (PEER) or control event rate (CER). The NNH is calculated as follows: \[ \text{NNH} = \frac{\text{PEER} \times (\text{OR} - 1) + 1}{\text{PEER} \times (\text{OR} - 1) \times (1 - \text{PEER})} \]

For PEER we can use an appropriate value of incidence for ALCL from the literature. In our case, we can apply the estimated incidence of ALCL found in the discussion of the study by de Jong and colleagues,\(^13\) which is 0.1/100 000 (0.000001) per year. Note that this is an estimated incidence, and thus our final NNH will also be an estimate. Our calculation was as follows: \[ \text{NNH} = \frac{[0.000001 \times (18.2 - 1)] + 1}{0.000001 \times (18.2 - 1) \times (1 - 0.000001)} \]

The calculation produces an NNH of just over 58 140, meaning that more than 58 000 patients would need to be treated with breast implants per year to result in 1 case of ALCL. The NNH provides both you and the patient with an easy-to-understand representation of the risk of harm.

Are there any benefits known to be associated with exposure?

After assessing the evidence that an exposure is causing harm and the results are applicable to our patient, we are faced with the difficult task of determining what the adverse effects are of not exposing our patient to the potentially harmful breast implants. There is ample evidence that breast implants in postmastectomy reconstruction have a beneficial effect for the patient that is both clinically important and statistically significant. The beneficial effects that must be considered in lieu of ALCL include improved well-being and long-term health in breast cancer survivors.\(^21,22\) In our clinical scenario where the magnitude of the risk is so small in contrast to the well-studied benefits of implant-based reconstruction, the decision moving forward may be much easier to make. To add context for future appraisals we recommend that one should know the risks. Basically one should ask if the benefits are worth the risks.

**Conclusion**

For a surgeon counselling a patient on surgical care, informed consent is integral. A well-informed decision should involve communicating all known risks based on evidence that is not only up to date, but also stands up to the rigours of a well-conducted critical appraisal by the surgeon or other expert in the field. If upon reviewing the literature, there is sufficient concern regarding harm associated with surgical management, the surgeon should discuss the findings with the patient. The discussion should take into account the patient’s desires for a given technique/procedure, availability of resources, the surgeon’s own comfort with the procedures and the potential for undesirable results.

**Resolution of the clinical scenario**

By applying the 3 steps in Box 1, we concluded that the study by de Jong and colleagues\(^13\) holds up to methodological standards of the case–control study, demonstrating no important bias between groups that could render the results unreliable. We observed a significantly positive association (OR 18.2, 95% CI 2.1–156.8) between breast implants and ALCL. However, taking into account that the risk of ALCL developing is very low overall, we concluded that the risk of ALCL in our patient is very small (in this case, the NNH is 58 140). Having learned this information, our patient decided to proceed with breast reconstruction using the technique of tissue expansion and silicone gel implants.

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Predicting which patients actually receive radiation following breast conserving therapy in Canadian populations

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SUMMARY

Canadian women with breast cancer may choose breast conserving therapy as their course of treatment, requiring both breast conserving surgery and adjuvant radiation therapy. However, more than 15% of Canadian women fail to receive the appropriate radiation therapy, putting them at increased risk for recurrence. Age, distance from their radiation therapy centre and stage of disease affect patients’ likelihood of receiving prescribed radiation therapy. We propose a nomogram that allows physicians to predict which patients will and will not receive radiation. This nomogram, once validated, could be used to guide decision making when choosing between breast conserving therapy and mastectomy as the treatment course and thereby change the practice of breast cancer management.

Breast conserving therapy (BCT) is a mainstay of treatment for early stage breast cancer, consisting of breast conserving surgery (BCS) followed by adjuvant radiotherapy (RT). Breast conserving therapy carries equivalent survival for 20 years after surgery when compared with mastectomy; however, this success requires receipt of both the BCS and RT components of therapy.1 Receiving BCS alone is associated with an increased risk of tumour recurrence (5-fold increased risk of distant disease) and the need for additional treatments, such as reoperation and chemotherapy.2 This causes an increased financial burden on the health care system and patient. Yet, RT rates after BCS vary widely, with large U.S. studies reporting rates of approximately 85%.3 This phenomenon remains understudied in Canadian populations.

The decision between mastectomy and BCT for the management of early breast cancer carries important consequences for patient health and for the health care system. In an effort to understand the barriers to RT receipt, U.S. studies have identified factors associated with RT nonreceipt: increased age, medical comorbidity, increased distance from RT centre, high stage/grade, large tumour size, positive lymph node status, negative estrogen receptor status, in situ disease, and more. Insurance status has been identified as an important factor in receipt of RT in these studies; therefore, assessment of RT receipt in a universal health care system may help translate this knowledge into a Canadian context.4,5

We used data collected from 2006 to 2013 in the prospective breast cancer patient database in London, Ont., to create a cohort of all 1722 consecutive patients who received BCS for treatment of breast cancer. Variables included age at diagnosis, patient forward sortation area (FSA; the first 3 digits of the postal code), estrogen receptor (ER) status, progesterone receptor (PR) status, Her2Neu status, pathological stage, whether the tumour was invasive or in situ, and whether or not RT was delivered. Geographic access to treatment was calculated using the FSA and was defined as the time necessary to drive from the patient’s home to the nearest cancer centre offering RT, with cancer centres geocoded using ArcGIS 10.3. Time from each FSA to the nearest cancer centre was calculated using a road network based on route speed limits without traffic.
The cohort was divided into 2 groups: those who received RT, and those who did not. To determine the effect of case variables on whether or not a patient received RT, we performed logistic regression with backward elimination using R: a language and environment for statistical computing. We considered results to be significant at \( p < 0.05 \).

Of the 1722 patients who received BCS, 1455 received RT, while 267 did not. This produces a radiation receipt rate of 84.5%, meaning that 15.5% of patients fail to receive RT.

Time and age were significant covariates negatively associated with RT receipt (i.e., as age and time to RT centre increased, rate of RT receipt decreased). Disease stage had a variable association with RT receipt; compared with patients with in situ disease, those with early and metastatic disease (stage I, IIA, and IV) were less likely to receive RT and those with advanced non-metastatic disease (stage IIB and III) were more likely to receive RT.

We used the logistic regression data to produce a formula that calculates the likelihood \( (p) \) that a patient will receive RT following BCS:

\[
p = \frac{1}{1 + e^{-\text{linear predictor}}}
\]

\( \text{linear predictor} = 7.6768 - (0.00961 \times t) - (0.0251 \times a) - (2.2854 \times S_i) - (1.8696 \times S_{in}) + (2.0277 \times S_{ia}) + (2.2449 \times S_{ib}) - (4.0593 \times S_{II}) - (1.8696 \times S_{III}) + (2.0277 \times S_{IV}) \), where \( t \) = driving time from patient’s home to RT centre (min), \( a \) = patient’s age (yr), \( S_i = 1 \) if stage I disease present (0 if not), \( S_{in} = 1 \) if stage Ila disease present (0 if not), \( S_{ia} = 1 \) if stage Iib disease present (0 if not), \( S_{III} = 1 \) if stage III disease present (0 if not), and \( S_{IV} = 1 \) if stage IV disease present (0 if not).

The magnitude of each covariate’s effect was used to produce a nomogram by rescaling variables to numbers between 0 and 100 (Fig. 1). Because the log (odds) of receiving radiation is additive regarding these covariates, their respective contributions are represented in the nomogram, and the sum is taken to determine a log (odds) and subsequently the odds of radiation receipt (Table 1). This nomogram predicts a given patient’s likelihood of receiving RT, which is valuable for clinicians, highlighting patients for whom extra encouragement, counselling and education on the importance of RT as an adjuvant therapy is warranted.

This tool may make clinicians aware of the existing barriers faced by their patients, as clinicians and patients themselves may not be cognizant of the importance of these barriers at the initial consult. For instance, a clinician may not consider how specific distances, measured in minutes, from the cancer centre impact the chance of patients failing to receive complete treatment.

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<th>Age</th>
<th>Points</th>
<th>Stage</th>
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</table>

*RT = adjuvant radiotherapy.

\*To use this reference table, 1) determine the patient’s variables for time, age, and stage; 2) obtain the corresponding point values; 3) add these 3 values to find the total points value; and 4) obtain the corresponding probability value.

†Time from patient’s home to the nearest cancer centre.
A more intriguing application of this tool is its use for patient selection. If a clinician determines preoperatively that a patient is unlikely to receive RT, the clinician might consult with radiation oncology before selecting BCT as a course of treatment or may recommend against BCT entirely, offering mastectomy instead. Such a tool makes the decision between BCT and mastectomy — a decision made by 1 in 9 women — evidence-based, rather than based on patient choice, especially when the patient has no pragmatic understanding of the treatment course. Finally, the tool may be used by investigators or granting agencies to guide patient selection for research, or by governments/payers to determine appropriate patients for BCT.

To our knowledge, this study is the first in Canada to highlight the unappreciated fact that 15% of patients undergoing BCS for breast cancer do not receive standard of care treatment, which includes radiation. This nomogram tool — the first of its kind — has the potential to change the practice of breast cancer management in Canada, and in so doing, improve the health of Canadian women and the health care system. The nomogram developed here should be externally validated in large administrative databases, at which point management recommendations could be developed for guidelines describing at what threshold to recommend BCT or advise against it, based on a patient’s likelihood of receiving RT.

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