Optimal time for surgery in women with serous ovarian cancer

Comparative effectiveness and safety of gastric bypass, sleeve gastrectomy and adjustable gastric banding

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* Comparative clinical significance has not been established.

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Les lecteurs trouveront en direct le JCC à l’adresse canjsurg.ca.

Datum isn’t; data are

The views expressed in this editorial are those of the author and do not necessarily reflect the position of the publisher.

Selection of manuscripts for publication in a scientific journal is a subjective process. Safeguards, such as using multiple independent reviewers, review templates and conflict of interest guidelines, try to make the process fair. It is clear to editors that some reviewers’ judgments are guided by whether they just liked a manuscript or not. The editor’s job is to divine if the reasons for the opinion are valid. For some manuscripts, the description “poorly written” weighs heavily in the mind of the reviewer. Use of the term “data” as a singular noun is often seen as a marker of either scientific naïveté or poor writing. I suspect that failure to use “data” as a plural noun has, on occasion, resulted in dismissal of an otherwise acceptable manuscript. Hopefully not in CJS.

Acceptance of the singular form of the word “data” has increased in all fields except academic medicine. The justification cited in medicine is that the word “data,” the Latin plural of “datum,” refers to multiple facts or observations. In ordinary speech where use of the plural form of data can be cumbersome and pompous, the singular noun is much more acceptable. Journalists use only the singular form, regardless of whether their reports are written or spoken. Other branches of science, such as computing and engineering, have abandoned use of “data” as a plural noun. A search of Google Books shows that the use of plural form of “data,” which once outnumbered the singular form by a factor of 4, has been reduced to equality in the last 2 decades. However, a similar search of PubMed shows the plural form in academic medicine to have remained at 3 times the use of the singular form. Therefore, academic medicine, alone among all the sciences, has stuck firm to the requirement for the plural form of “data.” Curiously, the term “datum” is almost never used and appears to be replaced by compound nouns, such as “data point.” So, is the word “data” singular or plural, and does it matter?

We cannot ask the Romans because they did use not the words “datum” or “data” as we do in science. The past participle of the verb to give, the words may have been applied as adjectives meaning “given.” For example, “data” was written on a letter to signify that it was given to the recipient. However, “data” in this example is the feminine form of the word to agree with the word “epistola” rather than the plural. Interestingly, this use led to the modern word “date” and its use in letters. Since the seventeenth century logicians have applied the word “data” to elements of a premise upon which conclusions are deduced. Here, “given” implies that further proof is not required. Since the premise should consist of facts if a conclusion is to be sound, the origin of the modern scientific term “data” to mean facts or observations is explained. Many writers credit Pullen’ with the earliest use of the modern scientific meaning, but a quick perusal of his book, which is available online, reveals that he used “mathematical data” as the title to a chapter containing common trigonometry formulas, the equivalent to the logicians’ given premise. Others credit the Computation Laboratory at Harvard University for the first modern use of the term “data” when they described, in 1946, the cards used to feed the computer “with empirical or other data.” However, these writers, and subsequent computer scientists, used “data” to mean the functions programmed by the cards. The introduction of computers into science and medicine in the 1960s resulted in a gradual shift of this meaning to its modern form in science that describes the observations themselves rather than the methods used to analyze them.

Therefore, “data,” a very recently coined term in academic medicine, has evolved as required by writers for the purposes of clear communication. The belief that “data” must be treated as a plural noun is not part of that evolution. It is worth remembering the origin and fate of a similar word, “agenda.” It was also coined in the seventeenth century as a noun to describe a collection of items with no “singular form.” This time the word was derived from the Latin verb agere (to do) and had a theological meaning of things to do. Its use evolved in the Nineteenth century to mean items of business at a meeting. A collective noun, it is always treated with the singular tense. Like “datum,” its singular form, “agendum,” feels contrived.

There are many situations where “data” is meant as a collective noun to describe the body of observations of an experiment, and use of the singular tense is more natural. There are other situations where “data” describe multiple discrete observations and the plural feels more appropriate. This editor’s advice is to use the phrase that feels most like your spoken voice. Our promise is
that use of the singular or plural tense with the word “data” will have no impact on the evaluation of a manuscript for CJS.

Vivian C. McAlister, MD
Coeditor, Canadian Journal of Surgery

Acknowledgements: The idea for this editorial, for which the author is solely responsible, grew out of enlightening conversations with Prof. Paul Ridgway, Dublin, Ireland.

Competing interests: None declared.

DOI: 10.1503/cjs.009316

References


De l’usage du pluriel (ou non) du mot « data »

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

L’a sélection des manuscrits pour publication dans une revue scientifique est un processus subjectif. Des mesures sont prises pour assurer un certain contrôle et rendre la démarche aussi équitable que possible, notamment le recours à de multiples examinateurs indépendants, l’imposition de grilles d’examen et la mise en place de lignes directrices sur les conflits d’intérêts. Les rédacteurs voient bien que le jugement de certains examinateurs est guidé par leur sympathie (ou leur antipathie) pour un manuscrit. Le travail de l’éditeur consiste à discerner le bien-fondé des opinions. Dans certains cas, la description « mal écrit » pese lourd dans l’esprit de l’examinateur. L’utilisation (en anglais) du mot « data » comme nom commun singulier est souvent perçue comme signe soit de naïveté scientifique ou de faute de grammaire. Or, je soupçonne que le défaut d’attribution du pluriel au mot « data » a eu comme résultat, à l’occasion, le refus d’un manuscrit par ailleurs acceptable. Pas dans le JCC, espérons-le.

L’usage du mot « data » au singulier s’est étendu à tous les domaines, sauf aux milieux universitaires de la médecine. En médecine, on justifie ce refus par le fait que le mot « data », pluriel du latin « datum », renvoie à de multiples faits ou observations. Dans le langage ordinaire, où l’utilisation de la forme plurielle de « data » peut paraître lourde et pompeuse, le nom au singulier est beaucoup plus acceptable. Les journalistes utilisent uniquement la forme singulière, à l’écrit ou à l’oral. D’autres branches de la science, notamment l’informatique et le génie, ont abandonné l’usage de « data » comme nom pluriel. Une recherche dans Google Books révèle que « data » pluriel, autrefois 4 fois plus fréquent que « data » singulier, a évolué au cours des 2 dernières décennies jusqu’à atteindre une fréquence d’utilisation égale. Une recherche semblable dans PubMed révèle toutefois que, dans les écrits savants en médecine, la forme plurielle est 3 fois plus utilisée que la forme singulière. Ainsi, la médecine, seule parmi toutes les sciences, est demeurée ferme dans son utilisation de la forme plurielle de « data ». Curieusement, le mot « datum » n’est presque jamais utilisé et semble être remplacé par des expressions telles que « data point ». Alors, le mot « data » est-il singulier ou pluriel, et cela a-t-il de l’importance?

Nous ne pouvons pas consulter les Romains, puisqu’ils n’utilisaient pas les mots « datum » et « data » comme nous le faisons aujourd’hui en sciences. Pour le participe passé du verbe « to give » (donner), ils utilisaient peut-être des adjectifs signifiant « given » (donné), par exemple, le mot « data » écrit sur une lettre pour indiquer qu’elle était donnée au récipiendaire. On note toutefois que le mot « data » dans cet exemple est au féminin, car il doit s’accorder avec « epistola » plutôt qu’avec le pluriel. Il est intéressant de voir que cet usage a donné lieu au mot contemporain « date » et à son usage dans la correspondance. Depuis le dix-septième siècle, les logiciens ont appliqué le mot « data » aux éléments d’une prémisse de laquelle des conclusions sont déduites. Ici, le mot « given » sous-entend qu’aucune autre preuve n’est requise. Puisqu’une prémisse doit être constituée de faits pour que la conclusion soit valide, cela explique l’origine de l’acception scientifique moderne de « data », soit faits ou observations. Beau-coup d’auteurs attribuent à Pullen1 la première utilisation du mot dans sa signification scientifique moderne, mais un coup d’œil à ce livre, que l’on peut consulter en ligne, révèle qu’il a utilisé l’expression « mathematical data » comme titre d’un chapitre portant sur les
formules trigonométriques courantes, équivalent de la prémisse donnée du logicien. D’autres donnent le crédit de la première utilisation moderne au Laboratoire d’informatique de l’Université Harvard, qui qualifiait, en 1946, les cartes utilisées pour nourrir l’ordinateur d’« empirical or other data » (données empiriques ou autres). Ces auteurs, cependant, de même que les informaticiens qui les ont suivis, utilisaient « data » pour représenter les fonctions programmées par les cartes. L’avènement des ordinateurs en sciences et en médecine dans les années 1960 a entraîné un glissement graduel vers l’acception contemporaine de « data » (description des observations elles-mêmes plutôt que des méthodes utilisées pour les analyser).

Ainsi, « data », mot très récent dans le vocabulaire savant de la médecine, a évolué à mesure des besoins des auteurs aux fins de clarté de communication. La croyance selon laquelle le mot « data » doit être traité comme un nom pluriel ne fait pas partie de cette évolution. Il vaut la peine de rappeler l’origine de ce mot. Ce mot est lui aussi né au dix-septième siècle pour décrire une collection d’items « sans forme singulière ». Cette fois le mot était dérivé du latin « agere » (agir) et avait une signification théologique de choses à faire. Son usage a évolué jusqu’à ce qu’il signifie, au dix-neuvième siècle, « items à étudier au cours d’une réunion ». Il s’agit d’un nom collectif employé au singulier. Comme dans le cas de « datum », le singulier latin « agendum » n’est pas passé dans l’usage.

Il existe de nombreuses situations où le mot « data » est employé comme nom collectif pour décrire l’ensemble des observations découlant d’une expérience et alors, le singulier semble plus naturel. En revanche, il y a des cas où « data » s’emploie pour décrire une multitude d’observations distinctes et alors, le pluriel semble mieux convenir. Je conseille donc d’utiliser l’accord qui s’apparente le mieux à celui de votre langue parlée. Nous promettons que votre choix d’accord singulier ou pluriel du mot « data » n’aura aucune répercussion sur l’évaluation d’un manuscrit soumis pour publication au JCC.

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Remerciements : L’idée de cet éditorial, pour lequel l’auteur est le seul responsable, a germé de conversations éclairantes avec le Pr Paul Ridgway, de Dublin, en Irlande.

Intérêts concurrents : Aucun déclaré.

DOI: 10.1503/cjs.009816

Référence

Nous croyons au libre accès à la recherche

Afin de continuer à assurer le libre accès à tout le contenu du JCS, partout dans le monde, les articles présentés pour publication seront assujettis à compter du 1er janvier 2014 à des frais de soumission de 100 $ (dollars canadiens). Les auteurs correspondants affiliés aux commanditaires du JCS seront exonérés des frais de soumission. Les articles acceptés dans les sections Recherche, Revue et Formation médicale continue sont assujettis à des frais de publication de 700 $, dans les sections Commentaires et Discussions, à des frais de publication de 500 $, payables sur acceptation en dollars canadiens.

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The optimal time for surgery in women with serous ovarian cancer

Background: Advanced high-grade serous ovarian carcinoma (HGSC) is commonly treated with surgery and chemotherapy. We investigated the survival of patients treated with primary or interval surgery at different times following neoadjuvant chemotherapy. Their survival was compared with that of patients treated with primary cytoreductive surgery and adjuvant chemotherapy.

Methods: Patients with stage III or IV HGSC were included in this retrospective cohort study. Clinical data were obtained from patient records. Patients were divided into 2 groups based on treatment with neoadjuvant chemotherapy and interval cytoreductive surgery (NAC) or with primary cytoreductive surgery and adjuvant chemotherapy (PCS). Study groups were stratified by several clinical variables.

Results: We included 334 patients in our study: 156 in the NAC and 178 in the PCS groups. Survival of patients in the NAC group was independent of when they underwent interval cytoreductive surgery following initiation of neoadjuvant chemotherapy ($p < 0.001$). Optimal surgical cytoreduction had no impact on overall survival in the NAC group ($p < 0.001$). Optimal cytoreduction ($p < 0.001$) and platinum sensitivity ($p < 0.001$) were independent predictors of improved survival in the PCS but not in the NAC group. Patients in the NAC group had significantly worse overall survival than those in the PCS group (31.6 v. 61.3 mo, $p < 0.001$).

Conclusion: Women with advanced HGSC who underwent PCS had better survival than those who underwent interval NAC, regardless of the number of cycles of neoadjuvant therapy. Optimal cytoreduction did not provide a survival advantage in the NAC group.

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Accepted for publication Feb. 17, 2016

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DOI: 10.1503/cjs.014315
Conclusion: Les femmes atteintes d’un carcinome ovarien séreux bien différencié de haut grade ayant subi une chirurgie de réduction tumorale initiale et une chimiothérapie adjuvante (PCS) ont affiché un taux de survie plus élevé que les patientes ayant subi une chimiothérapie néoadjuvante et une chirurgie de réduction tumorale d’intervalle (NAC), peu importe le nombre de cycles de chimiothérapie néoadjuvante. La réduction tumorale optimale n’a pas été associée à un taux de survie plus élevé chez ces dernières.

Epithelial ovarian cancer is the most common cause of death from gynecologic malignancy.\(^1\) High-grade serous ovarian cancer (HGSC) is the most common type of epithelial ovarian cancer, representing 70% of all diagnosed tumours.\(^2\) Most ovarian cancers (70%) are diagnosed at an advanced stage of disease (Stage III/IV), and 80%-90% of these advanced-stage tumours are HGSC.\(^3\) As such, the 5-year overall survival rate for women with HGSC is approximately 44%.

The standard of care treatment for HGSC has essentially remained the same for the past 2 decades and includes a combination of surgical cytoreduction and platinum-/taxane-based adjuvant chemotherapy.\(^5,6\) However, despite aggressive surgery and chemotherapy, cure is rare for the majority of women with HGSC. Survival in these patients largely depends on the tumour sensitivity to platinum-based chemotherapy\(^6,7\) and the degree of surgical cytoreduction.\(^8,9\) Even extensive surgeries leaving more than 1 cm of residual tumour have limited impact on survival.\(^10-12\) Since the original publication by Griffiths,\(^9\) which suggested an association between the amount of residual disease and survival, the definition of “optimal” cytoreduction has been shifting from an initial definition of no single residual lesion measuring less than 2 cm in diameter to a definition of less than 1 cm and, most recently, to a definition of no macroscopic disease.\(^13-15\)

As optimal surgical cytoreduction is one of the strongest predictors of outcome for patients with HGSC, many studies have investigated the use of neoadjuvant chemotherapy as an alternative treatment strategy to reduce tumour burden before surgery.\(^16\) There are several putative advantages of the neoadjuvant treatment strategy, including less extensive surgery, reduced morbidity and increased optimal cytoreduction. Furthermore, it currently provides the only means to identify patients with platinum-resistant disease at presentation.\(^17\)

Many studies suggest equivalent survival in patients receiving adjuvant versus neoadjuvant chemotherapy.\(^18-28\) Notably, Vergote and colleagues\(^20\) reported the only phase III randomized controlled trial in which patients with advanced-stage HGSC were treated with either primary surgery and adjuvant platinum-based chemotherapy (PCS group) or neoadjuvant platinum-based chemotherapy followed by interval cytoreductive surgery and additional adjuvant chemotherapy (NAC group). Although patients in the NAC group had higher rates of optimal cytoreduction and fewer perioperative complications, this did not translate into improved survival. This trial was criticized by many for poor progression-free and overall survival rates in both study arms.\(^29-31\)

Importantly, several studies addressing the use of primary surgery versus neoadjuvant chemotherapy indicated that patients in the NAC group have inferior overall survival than patients in the PCS group.\(^32-34\) Bristow and Chi\(^16\) conducted a meta-analysis that suggested the number of neoadjuvant chemotherapy cycles before surgery was inversely proportional to the median overall survival. In addition, these authors demonstrated that although the difference in survival between the NAC and PCS groups did not reach statistical significance in previous studies, survival was often reduced by up to half in the NAC group.\(^19\)

Hence, controversy remains about the use of neoadjuvant chemotherapy as a first-line treatment in patients with HGSC. Surveys of members of the Society of Gynecologic Oncology\(^35\) and the European Society of Gynecologic Oncology\(^36\) suggest that 18% and 70% of gynecologic oncologists, respectively, routinely recommend neoadjuvant chemotherapy to their patients. Furthermore, the appropriate number of neoadjuvant chemotherapy cycles that should be administered before interval cytoreductive surgery is subject to debate. Hence, a deeper understanding of the effect of the treatment strategy, post-treatment tumour biology and survival outcomes are required.

In this study, we examine the progression-free and overall survival of patients in the NAC group as compared with patients in the PCS group. The objective of this work was to study surgical factors, including the timing of surgery, in relation to the number of preoperative neoadjuvant chemotherapy cycles and the rate of optimal cytoreduction in the NAC and PCS groups. We aimed to analyze the impact of these factors on survival in women with HGSC.

**METHODS**

**Patient selection and clinical data**

We included patients with Stage III or IV HGSC diagnosed between 2003 and 2011 in this retrospective cohort study. Clinical data were extracted from the patients’ health records and from a prospectively maintained institutional database. Inclusion criteria consisted of a diagnosis of advanced-stage HGSC of mullerian origin. Patients were triaged to undergo primary cytoreductive surgery followed by adjuvant chemotherapy (PCS group) or to receive neoadjuvant chemotherapy with interval cytoreductive surgery.
We used the Student t test to examine differences in the distributions of age and the number of cycles of primary platinum-based chemotherapy in the NAC and PCS groups. In addition, Fisher exact tests were used to compare rates of optimal cytoreduction and platinum sensitivity (defined as no disease recurrence or recurrence > 6 mo from last platinum-based treatment) between the 2 study groups. Log-rank (Mantel–Cox) tests were used to examine progression-free and overall survival, and Kaplan–Meier plots were generated. We performed all pairwise analyses using a Bonferroni multiple-comparisons correction. All analyses were performed using Graph Pad Prism 6 software. We performed a Cox proportional hazard regression analysis of overall survival. Treatment, age at diagnosis, debulking status, sensitivity to platinum-based chemotherapy and cycles of primary chemotherapy were included in univariate and multivariate analyses. We built the multivariable model using backward elimination, and only significant predictors were kept in the model. The selected multivariable model included treatment, debulking status, and sensitivity to platinum-based chemotherapy, which was included in the model as a stratification factor.

**RESULTS**

**Characteristics of patients with HGSC typically treated with neoadjuvant chemotherapy**

We included 398 patients with Stage III or IV HGSC in this study: 156 in the NAC group and 178 in the PCS group. Patients in the NAC group were treated with neoadjuvant chemotherapy and interval surgery, and those in the PSC group were treated with primary surgery followed by adjuvant chemotherapy. Comparison of patient characteristics between these groups revealed no difference in tumour stage (Fig. 1A). Patients in the NAC group were older than patients in the PCS group (median age 60 v. 56; p = 0.025; Fig. 1B). All patient characteristics are described in Table 1.

As the volume of residual disease after surgery and the sensitivity to first-line platinum-based chemotherapy are the strongest known predictors of outcome in HGSC, these variables were compared in the 2 study groups. Patients treated with neoadjuvant chemotherapy were significantly more likely to achieve optimal debulking to less than 1 cm of residual disease (80% in the NAC group v. 68% in the PCS group, p = 0.008; Fig. 1C). Notably, patients in the NAC group were significantly more likely to demonstrate resistance to first-line platinum-based chemotherapy (38% in the NAC group v. 20% in the PCS group, p < 0.001; Fig. 1D).

**Survival of patients with HGSC treated with neoadjuvant chemotherapy**

Overall survival of patients with HGSC in the NAC group was compared with that of patients in the PCS group. Patients in the NAC group had a significantly worse overall survival than patients in the PCS group (Fig. 2A), with a median overall survival of 33.4 and 69.5 months, respectively. This difference in survival was independent of the patients’ age (p < 0.001; Fig. 2B). Similarly, analysis of progression-free survival showed worse outcomes in the NAC group than the PCS group, independent of age (Fig. 2C and D). The survival difference between the treatment groups remained significant after adjusting for confounding factors, including age, debulking status and sensitivity to platinum-based chemotherapy (Table 2 and Table 3).

**Timing of surgery**

In the NAC group, no significant difference in overall or progression-free survival was noted based on the number of...
neoadjuvant chemotherapy cycles given before interval cytoreductive surgery. Patients who received up to 3 cycles, 4 cycles, or 5 or more cycles had a median overall survival of 34.1, 32.7 and 34.2 months, respectively, as compared with the adjuvant group ($p < 0.001$, Fig. 3A). The same trend was observed in the analysis of progression-free survival, with median progression-free survival of 14.1 (≤ 3 cycles), 13.7 (4 cycles) and 20.5 months (≥ 5 cycles; Fig. 3B).

**Effect of surgical cytoreduction**

As optimal cytoreduction was more commonly achieved in the NAC group (Fig. 1C), we examined the impact of optimal cytoreduction on survival. Optimal cytoreduction was an independent predictor of improved overall survival in the PCS group ($p < 0.001$, Fig. 4A), with a median survival of 92.9 months versus 36 months in the optimal and PCS suboptimal groups. In the NAC group, there was a trend toward improved survival if optimal cytoreduction was achieved; however, this didn’t reach statistical significance ($p = 0.07$). The median survival was 35.1 months in the NAC optimal group and 25.4 months in the NAC suboptimal group. When comparing all patients in the study who were optimally debulked, those who were pretreated with neoadjuvant chemotherapy had worse overall survival than patients who were chemotherapy-naive at the time of their surgery (35.1 mo v. 92.9 mo, $p < 0.001$). However, when comparing survival of study patients who underwent suboptimal cytoreduction, no significant difference was observed between the NAC and PCS groups (25.4 mo v. 36 mo, $p = 0.24$). The same trends were observed in the analysis of progression-free survival (Fig. 4B); however, all pairwise comparisons reached statistical significance.

**Sensitivity to platinum-based chemotherapy**

Notably, patients who were resistant to first-line platinum-based chemotherapy demonstrated significantly
worse overall survival than platinum-sensitive patients in both the PCS and NAC groups \( (p < 0.001, \text{Fig. 5A}) \). In addition, there was no difference in the survival of platinum-resistant patients in the PCS and NAC groups, with a median survival of 20.4 and 22.6 months, respectively. Among platinum-sensitive patients, those in the NAC group demonstrated a reduced overall survival compared with patients in the PCS group \( (p < 0.001) \), with a median survival of 45.2 versus 92.9 months, respectively. The same trends were observed when progression-free survival was assessed (Fig. 5B).

**Discussion**

The primary treatment of women with newly diagnosed ovarian HGSC commonly includes a combination of surgery and chemotherapy. The decision of whether to treat with upfront chemotherapy often rests with the treating physician. This study was conducted at the largest cancer centre in Canada. Given the open access health care system in Canada, all women with HGSC had access to care at our academic centre. While there are inherent biases in a retrospective study design, this study included all women with HGSC treated at our centre between 2003 and 2011. All clinical charts were analyzed, and those who met the inclusion criteria were included in the analyses. We performed univariate and multivariate analyses to control for potential confounders of survival.

To our knowledge, this study represents the largest retrospective analysis worldwide examining survival of patients with HGSC, the most common and most lethal form of ovarian carcinoma. In this large patient cohort, women in the NAC group had a significantly worse progression-free and overall survival than women in the PCS group. This finding was independent of the patients’ age at diagnosis.

The use of neoadjuvant chemotherapy as a treatment strategy for patients with HGSC was proposed as a means to reduce tumour burden before surgical cytoreduction, thereby increasing the ability to achieve optimal surgical cytoreduction with less extensive surgery and reduced morbidity.\(^\text{16}\) The only phase III randomized controlled trial that compared patients treated with NAC or PCS showed equal

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<tr>
<td>Cycles of primary chemotherapy</td>
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<td>( \geq 9 )</td>
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survival between the 2 groups.\textsuperscript{20} Interestingly, despite the increased rate of optimal surgical cytoreduction reported in the neoadjuvant group, no concomitant increase in survival was observed. Other retrospective analyses have reported similar findings.\textsuperscript{18–28} By contrast, several studies have shown that patients treated with neoadjuvant chemotherapy have a worse survival than those treated with primary surgery.\textsuperscript{12–34} Overall, controversy remains about the use of neoadjuvant chemotherapy as a first-line treatment strategy for women with newly diagnosed HGSC.

![Figure 2](image-url)

Fig. 2. Overall and progression-free survival of patients treated with neoadjuvant chemotherapy and interval cytoreductive surgery (NAC) compared with primary cytoreductive surgery and adjuvant chemotherapy (PCS). (A) Patients treated with neoadjuvant chemotherapy followed by surgery have a significantly worse overall survival than patients treated with primary surgery and adjuvant chemotherapy ($p < 0.001$). (B) The difference in overall survival was independent of the patients’ age at diagnosis ($p < 0.001$). (C) Patients treated with neoadjuvant chemotherapy had a significantly worse progression-free survival measured by radiologic imaging (i.e., clinical recurrence) ($p < 0.001$). (D) The significant difference in progression-free survival is independent of the age of the patient at diagnosis. All statistics were calculated with a log-rank (Mantel–Cox) test.

<table>
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<tr>
<th>Variable</th>
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<th>Multivariate</th>
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<td>2.56 (1.91–3.42)</td>
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</tr>
<tr>
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<td>1.52 (1.09–2.11)</td>
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<tr>
<td>Resistant to platinum-based chemotherapy</td>
<td>Sensitive</td>
<td>—</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Cycles of primary chemotherapy &gt; 6</td>
<td>≤ 6</td>
<td>1.92 (1.43–2.56)</td>
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</table>

CI = confidence interval, HR = hazard ratio; NAC = neoadjuvant chemotherapy and interval cytoreductive surgery; PCS = primary cytoreductive surgery and adjuvant chemotherapy.

*Log-rank test. Sensitivity to platinum-based chemotherapy has nonproportional hazard. It was included in the multivariate analysis as a stratification factor.
One of the major concerns when giving neoadjuvant chemotherapy is that the administration of an increasing number of neoadjuvant chemotherapy cycles could increase the likelihood of selection for platinum-resistant clones.\(^\text{13}\) This viewpoint was largely driven by the meta-analysis by Bristow and Chi,\(^\text{16}\) which suggested a negative association between overall survival and the number of neoadjuvant chemotherapy cycles administered. By contrast, in this cohort, the decreased survival of patients with HGSC in the NAC group was independent of the number of cycles administered before surgery. This discrepancy might be due to all patients in our study receiving platinum-based neoadjuvant chemotherapy, whereas the study by Bristow and Chi\(^\text{16}\) included 16 different treatment combinations, which may account for the variable survival rates. Notably, our data suggest that the putative selective effects of neoadjuvant chemotherapy are incurred early, with as few as 3 cycles of treatment. Women receiving 3 or fewer cycles of neoadjuvant chemotherapy before interval surgery had equivalent survival to women receiving 4 cycles and to women receiving 5 or more cycles. The early clonal emergence hypothesis is supported by the observation that the most dramatic alteration in tumour bulk (measured by serum CA125 levels) is typically observed early in the course of treatment.\(^\text{37–19}\)

Importantly, optimal surgical cytoreduction represents one of the strongest predictors of outcome in patients with HGSC treated with primary cytoreductive surgery.\(^\text{8,9}\) Although previous reports have suggested that neoadjuvant chemotherapy improves the rate of optimal surgical cytoreduction, none have demonstrated that this translates into improved survival.\(^\text{20–22,28,32}\) In our study, women in the NAC group had a significantly higher rate of optimal cytoreduction than chemotherapy-naïve patients undergoing primary cytoreduction. Yet, this did not confer a survival advantage. The lack of survival difference between optimally and suboptimally cytoreduced patients in the NAC group calls into question the accuracy of estimating the cytoreduction status after neoadjuvant chemotherapy. Notably, chemotherapy

<table>
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<th>Multivariate analysis</th>
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<td>0.96 (0.69–1.34) 0.82</td>
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CI = confidence interval, HR = hazard ratio; NAC = neoadjuvant chemotherapy and interval cytoreductive surgery; PCS = primary cytoreductive surgery and adjuvant chemotherapy.

*Sensitivity to platinum-based chemotherapy has nonproportional hazard. It was included in the multivariate analysis as a stratification factor.

**Fig. 3.** Overall and progression-free survival stratified by the time to interval cytoreductive surgery. (A) Survival in the neoadjuvant group (NAC) was independent of the timing of surgery with respect to the number of cycles of neoadjuvant chemotherapy. Patients treated with neoadjuvant chemotherapy had a worse overall survival (\(p<0.001\)), independent of whether they were treated with up to 3, 4, or 5 or more cycles before surgery (\(p = 0.92\)). (B) Patients treated with neoadjuvant chemotherapy had a significantly worse progression-free survival independent of the timing of interval cytoreductive surgery with respect to the number of cycles of neoadjuvant chemotherapy received (\(p<0.001\)). All statistics were calculated with a log-rank (Mantel–Cox) test. PCS = primary cytoreductive surgery and adjuvant chemotherapy.
can affect the gross morphologic appearance of tumour tissue and surgical planes, which could lead to anatomic variability and render the assessment of residual disease and optimal surgical excision challenging.40

Finally, when stratifying patients by platinum sensitivity, the negative impact of neoadjuvant chemotherapy on survival is noted. It is well known that patients with platinum-resistant disease have significantly worse survival.5,7 In this study, patients with platinum-sensitive disease had worse overall and progression-free survival when treated with neoadjuvant chemotherapy than with primary surgery. Importantly, these differences remained significant after adjusting for confounding factors, including age, debulking status and sensitivity to platinum-based chemotherapy.

**CONCLUSION**

Our data indicate that neoadjuvant chemotherapy is associated with inferior survival in patients with HGSC, independent of other prognostic factors. Women with advanced ovarian cancer who undergo neoadjuvant chemotherapy often undergo interval surgery at various points during their treatment. The variation in the timing of surgery depends on multiple factors, including patients’ medical conditions and surgical access. Importantly, this study demonstrates that surgical factors, including the timing of surgery and the rate of optimal cytoreduction, do not appear to add a survival advantage to women treated with neoadjuvant chemotherapy.

Our study raises important questions: Does early exposure to neoadjuvant chemotherapy provoke biologic and genetic changes in tumour cells that ultimately result in hastened platinum resistance? Is emergence of platinum resistance accelerated by the lack of true surgical cytoreduction in the neoadjuvant group? Given the increased adaptation of neoadjuvant chemotherapy in the management of women with advanced ovarian carcinoma, it is essential to examine the factors that influence treatment response and survival in this patient population. Studying the molecular alterations associated with neoadjuvant chemotherapy is essential.

**Fig. 4.** Overall and progression-free survival of patients treated with neoadjuvant chemotherapy and interval cytoreductive surgery (NAC) or primary cytoreductive surgery and adjuvant chemotherapy (PCS) stratified by surgical cytoreduction status. (A) Optimal surgical cytoreduction to less than 1 cm residual tumour had no significant impact on overall survival in the neoadjuvant group. In addition, within the suboptimally debulked group, neoadjuvant chemotherapy had no significant effect. However, within the optimal subgroup, the neoadjuvant patients had a worse overall outcome ($p < 0.001$). Within the adjuvant group, patients who were optimally debulked had a significantly improved survival ($p = 0.001$). (B) Optimal surgical cytoreduction resulted in better progression-free survival in patients treated with neoadjuvant chemotherapy or primary surgical cytoreduction ($p = 0.002$ and $p = 0.002$, respectively). However, in the optimally and suboptimally surgically debulked groups, the patients who received neoadjuvant chemotherapy had a significantly worse progression-free survival ($p < 0.001$ for both comparisons). All statistics were calculated with a log-rank (Mantel-Cox) test. Bonferroni corrections were applied for all multiple comparisons. N/S = nonsignificant.
imperative and may lead to greater understanding of the impact of early chemotherapy exposure on survival in women with ovarian HGSC.

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Competing interests: None declared.

Contributors: J. Stewart and T. May designed the study. J. Stewart, M. Bernardini, S. Ferguson, S. Laframboise, J. Murphy, B. Rosen and T. May acquired the data, which J. Stewart, A. Tone, H. Jiang and T. May analyzed. J. Stewart and T. May wrote the article, which all authors reviewed and approved for publication.

References
Comparative effectiveness and safety of gastric bypass, sleeve gastrectomy and adjustable gastric banding in a population-based bariatric program: prospective cohort study

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Accepted for publication Feb. 25, 2016

Background: Bariatric surgery in Canada is primarily delivered within publicly funded specialty clinics. Previous studies have demonstrated that bariatric surgery is superior to intensive medical management for reduction of weight and obesity-related comorbidities. Our objective was to compare the effectiveness and safety of laparoscopic Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (LSG) and adjustable gastric banding (LAGB) in a publicly funded, population-based bariatric treatment program.

Methods: We followed consecutive bariatric surgery patients for 2 years. The primary outcome was weight change (in kilograms). Between-group changes were analyzed using multivariable regression. Last-observation-carried-forward imputation was used for missing data.

Results: We included 150 consecutive patients (51 RYGB; 51 LSG; 48 LAGB) in our study. At baseline, mean age was 43.5 ± 9.5 years, 87.3% of patients were women, and preoperative body mass index (BMI) was 46.2 ± 7.4. Absolute and relative (% of baseline) weight loss at 2 years were 36.6 ± 19.5 kg (26.1 ± 12.2%) for RYGB, 21.4 ± 16.0 kg (16.4 ± 11.6%) for LSG and 7.0 ± 9.7 kg (5.8 ± 7.9%) for LAGB (p < 0.001). Change in BMI was greater for the RYGB (–13.0 ± 6.6) than both the LSG (–7.6 ± 5.7) and the LAGB (–2.6 ± 3.5) groups (p < 0.001). The reduction in diabetes, hypertension and dyslipidemia was greater after RYGB than after LAGB (all p < 0.05). There were no deaths. The anastomotic and staple leakage rate was 1.3%.

Conclusion: In a publicly funded, population-based bariatric surgery program, RYGB and LSG demonstrated greater weight loss than the LAGB procedure. Bypass resulted in the greatest reduction in obesity-related comorbidities. All procedures were safe.
The prevalence of obesity in Canada has increased 225% since 1985. In absolute terms, approximately 60% of Canadians are overweight and 24% are defined as clinically obese (body mass index [BMI] > 30). The majority of this increased prevalence is accounted for by increases in class II (BMI > 35) and class III (BMI > 40) obesity. Individuals with obesity demonstrate a 2- to 5-fold greater prevalence of type 2 diabetes, a 2- to 4-fold increased prevalence of cardiovascular risk factors (coronary artery disease, hypertension), and a reduction in life expectancy by 8 to 13 years compared with individuals with a healthy weight. Substantial increases in obesity-related morbidity and associated health care expenditures have been recognized.

The weight loss effectiveness of bariatric surgery compared with medical management of obesity is well documented. In a recent randomized controlled study in a private U.S. health care setting, Schauer and colleagues demonstrated increased weight loss and improvement in type 2 diabetes 36 months following bariatric surgery compared with intensive medical management. Similarly, a recent meta-analysis by Padwal and colleagues reported substantial weight loss following bariatric surgery with low overall complication rates.

Parallel to the growing evidence supporting surgery over medical management, the number of people undergoing bariatric surgery has doubled worldwide (up to 350,000 procedures/yr) since 2000. Accordingly, funding for bariatric surgical care in Canada has greatly increased. For instance, in 2009 the province of Ontario contributed $75 million in public funding toward a Bariatric Care Network, and the province of Quebec has doubled the number of bariatric procedures from 1000 to 2000 per year since 2005.

Bariatric surgical care in Canada is largely delivered within specialized multidisciplinary programs with central referral and triage. Compared with bariatric centres in the United States that are generally privately funded, the typical patient encountered in a public setting is likely to be of lower socioeconomic status, less highly selected and possibly more treatment-refractory. Therefore, outcomes in Canadian patients may differ from those of patients enrolled in studies from other countries. In Alberta, the Edmonton Adult Bariatric Specialty program is a publicly funded venture offering a tiered approach for centrally referred patients, who progress from a wait list to intensive medical management and ultimately to bariatric surgery (if indicated). In this clinic, there is no systematic process for choosing a specific type of bariatric surgery. Instead, a combination of empirical evidence, patient preference, institutional practice and surgeon advice is used.

At present, there is a lack of longitudinal studies that compare the effectiveness and safety of the common bariatric procedures on patients with obesity enrolled in a population-based, publicly funded system. Consequently, the objective of this prospective cohort analysis was to compare weight loss, safety and obesity-related outcomes of laparoscopic Roux-en-Y gastric bypass (RYGB), laparoscopic sleeve gastrectomy (LSG) and laparoscopic adjustable gastric banding (LAGB).

**Methods**

A detailed study protocol, approved by the University of Alberta Health Research Ethics Board, has been previously published. All participants provided written informed consent.

**Setting**

The Edmonton Adult Bariatric Specialty program serves nearly 1.6 million residents within the Edmonton zone of the Alberta Health Services (AHS) network and constitutes one of the largest health care delivery systems in Canada. The program itself is a centralized, single point of access referral system for patients with a BMI of 40 or higher, or with a BMI of 35 or higher as well as obesity-related comorbidities (e.g., type 2 diabetes, sleep apnea, hypertension, osteoarthritis). All patients are placed on a wait list (first come first serve), and upon enrolment patients undergo intensive multidisciplinary evaluation and care, including health behaviour management, psychological support for mental illness and prior abuse and, if indicated, bariatric surgery. Between November 2008 and November 2011, this program received 2598 new patient referrals who were wait listed for enrolment (average wait time of 2 yr); of those who continued in the program, 2116 were enrolled in medical management and 498 bariatric surgeries were performed. All procedures were performed by 1 of 3 bariatric surgeons at a large tertiary teaching hospital in Edmonton, Alta. The surgical procedures are described in Appendix 1, available at canjsurg.ca.

**Participants and study groups**

Between November 2008 and November 2011, consecutive, consenting surgical patients aged 18–60 years from the Adult Bariatric Specialty program were enrolled into the Alberta Population-based Prospective Evaluation of the Quality of Life Outcomes and Economic Impact of Bariatric Surgery (APPLES) study. The overall results of this cohort, including 2-year weight changes in wait-listed, medically treated and surgically treated patients has been previously detailed. The present study focuses on detailing the results and adverse effects of surgical subgroups. Inclusion criteria and BMI thresholds for surgery were the same as the inclusion criteria for the APPLES study. Absolute contraindications to surgery included pregnancy or nursing, uncontrolled psychiatric illness,
active smoking or substance abuse, active eating disorders, or a high-risk medicsurgical comorbidity (e.g., severe coronary artery disease) precluding an operation. All surgical patients underwent approximately 24–36 weeks of intensive, multidisciplinary management of obesity, obesity-related comorbidities and mental health screening before the decision to undergo surgery was made. Approval for surgery was a joint decision between the patient and a multidisciplinary team, taking into account the perceived likelihood of adherence to postoperative instructions and diet. Patients accepted for surgery continued on close medical monitoring while waiting for the procedure to be performed (10–14 mo).

For approved patients, the choice of RYGB versus LSG versus LAGB was made based on surgeon advice, patient preference and local patterns of practice.

Measurements and data collection

Detailed case report forms have been previously published. Baseline data were collected within 2 weeks before surgery and included age, sex, race, marital status, employment status, household income, general medical history and obesity-related comorbidities, smoking status (current, past, never), medications, weight, BMI, waist circumference, blood pressure, fasting lipid levels, fasting glucose level, hemoglobin A1c (HbA1c) insulin and C-reactive protein (CRP). Body weight was recorded to the nearest 0.1 kg using a calibrated, validated bariatric scale (Scale Tronix, serial numbers 6702–4440 and 6702–6229). Participants wore light indoor clothing with empty pockets, no shoes and had an empty bladder. Height was measured to the nearest 0.1 cm using a wall-mounted stadiometer. A single reading taken using an automated blood pressure monitor and appropriately sized blood pressure cuff was recorded after 5 min of seated rest.

Outcomes

The primary study outcome was weight change (in kilograms), measured every 6 months over the 2-year period. Both absolute and relative changes from baseline were analyzed. Ten percent weight reduction thresholds were subsequently examined. Secondary outcomes included hyperten-

sion, dyslipidemia and glycemic control. Hypertension was considered present if self-reported, if blood pressure levels were 140/90 mm Hg or more (≥ 130 mm Hg in patients with type 2 diabetes), or if patients were currently taking antihypertensive medications. Type 2 diabetes was considered present if self-reported, if HbA1c was ≥ 6.5% or greater, if fasting glucose level was 7.0 mmol/L or greater, or if patients were currently taking antidiabetic medications. Insulin resistance was assessed using the homeostatic model (HOMA-IR), as previously reported. Dyslipidemia was considered present if self-reported, if the patient was currently taking lipid lowering therapy or if any of the following biochemical parameters were present: total cholesterol of 6.2 mmol/L or greater, low-density lipoprotein (LDL) of 4.1 mmol/L or greater, high-density lipoprotein (HDL) less than 1.0 mmol/L, or triglycerides of 2.3 mmol/L or greater. Obesity-related comorbidities were considered present if any of the above-mentioned specific criteria were present. Comorbidity resolution was defined as the absence of all of the comorbidity-specific criteria listed above at any point during follow-up.

Adverse events

Adverse events were documented prospectively throughout follow-up appointments and classified according to a modified Clavien–Dindo surgical complications system, focusing on grades III or higher. Grade V complications were defined as death. Grade IV and grade III events included those requiring surgical, radiologic or endoscopic intervention. Major surgical adverse events, such as gastrointestinal/staple line leakage or bleeding, were confirmed intraoperatively. Anastomotic ulcers and strictures were confirmed endoscopically. Abscess or band slippage and hernia were confirmed with computed tomography if clinically suspected.

Statistical analysis

We performed descriptive analyses, including calculation of proportions, means, standard deviations, medians and interquartile ranges as appropriate. Within-group change scores were calculated and normality assumptions verified. Baseline variables were compared among study groups using 1-way analysis of variance (ANOVA) for continuous outcomes and χ² tests for dichotomous ones. Between-group change scores were compared using 2-way ANOVA plus Bonferroni post hoc or multivariable linear regression, adjusting for age, sex and baseline BMI with adjusted prediction and average marginal effects. We considered results to be significant at p < 0.05. Patients were censored if they became pregnant (n = 2) or underwent a second (different) bariatric surgical procedure within the program (n = 1). We used a last-observation-carried-forward (LOCF) analysis to account for censoring or missing data in the primary analysis. We then repeated this analysis using a more conservative baseline-observation-carried-forward (BOCF) analysis as well as a more liberal (completers) analysis, including only patients who reached the 2 years of follow-up. We did not perform multiple imputations because the data were not missing completely at random. All analyses were performed using SAS software version 9.3 and STATA software version 14.1.
**Results**

**Participants**

We enrolled 150 consecutive, consenting surgical patients in our study: 51 underwent RYGB, 51 underwent LSG and 48 underwent LAGB.

**Baseline characteristics**

Baseline characteristics of the study group are presented in Table 1. The mean age was 43.5 ± 9.5 years, and 87.3% of patients were women. On average, patients were in the severe obesity category with a mean BMI of 46.2 ± 7.4. There were statistically significant differences in the baseline BMI among participants undergoing different bariatric procedures, with BMI being lower in the LAGB group and larger in the RYGB group (Table 1). In terms of obesity-related comorbidities, there were no statistically significant differences among groups in blood pressure, lipid profile, HbA1c, fasting glucose, HOMA-IR index or plasma levels of CRP. Additionally, patients tended to come from varied socioeconomic backgrounds, including all levels of education, income ranges and family status. The percentage of patients who successfully completed the 2-year follow-up was 86.2% in the RYGB group, 84.6% in the LSG group and 87.5% in the LAGB group (Fig. 1).

**Overall weight changes**

In the primary LOCF analysis, absolute and relative (% of baseline) mean weight losses were 36.6 ± 19.5 kg (26.1 ± 12.2%) in the RYGB group, 21.4 ± 16.0 kg (16.4 ± 11.6%) in the LSG group, and 7.0 ± 9.7 kg (5.8 ± 7.9%) in the LAGB group (p < 0.001, ANOVA). Results of the BOCF and completers analyses were consistent with the primary analysis (Table 2). There was a significantly greater total weight loss and BMI reduction when comparing the RYGB group to the LSG and LAGB groups (both p < 0.05), as well as when comparing the LSG group to the RYGB group (all p < 0.05) at all time points (Fig. 2A and B). The proportion of 5% and 10% responders was significantly reduced in the RYGB group compared with other surgical groups at any time point (Fig. 2C and D).

**Obesity-related comorbidities**

At 2 years, the prevalence of type 2 diabetes, hypertension and dyslipidemia was reduced in all 3 surgical groups. For type 2 diabetes, the reduction in absolute prevalence was 33.3% for RYGB, 21.6% for LSG and 12.5% for LAGB. For hypertension, the reduction in absolute prevalence was 31.4% for RYGB, 11.8% for

### Table 1. Baseline characteristics of study participants

<table>
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<tr>
<th>Characteristic</th>
<th>RYGB (n = 51)</th>
<th>LSG (n = 51)</th>
<th>LAGB (n = 48)</th>
<th>p value*</th>
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<td>Age, yr</td>
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</tr>
<tr>
<td>Total cholesterol, mmol/L</td>
<td>4.2 ± 0.9</td>
<td>4.4 ± 0.9</td>
<td>4.6 ± 0.9</td>
<td>0.14</td>
</tr>
<tr>
<td>HDL cholesterol, mmol/L</td>
<td>1.2 ± 0.6</td>
<td>1.2 ± 0.3</td>
<td>1.2 ± 0.3</td>
<td>0.87</td>
</tr>
<tr>
<td>LDL cholesterol, mmol/L</td>
<td>2.4 ± 0.7</td>
<td>2.5 ± 0.7</td>
<td>2.7 ± 0.7</td>
<td>0.23</td>
</tr>
<tr>
<td>Triglycerides, mmol/L</td>
<td>1.5 ± 0.6</td>
<td>1.5 ± 0.6</td>
<td>1.6 ± 0.8</td>
<td>0.69</td>
</tr>
<tr>
<td>HbA1c, %</td>
<td>5.8 ± 0.5</td>
<td>5.8 ± 0.7</td>
<td>6.1 ± 1.0</td>
<td>0.2</td>
</tr>
<tr>
<td>Fasting glucose, mmol/L</td>
<td>5.5 ± 0.9</td>
<td>5.7 ± 1.6</td>
<td>6.0 ± 1.6</td>
<td>0.3</td>
</tr>
<tr>
<td>HOMA-IR</td>
<td>4.8 ± 3.4</td>
<td>4.7 ± 4.2</td>
<td>5.4 ± 5.1</td>
<td>0.7</td>
</tr>
<tr>
<td>CRP, mg/L</td>
<td>8.7 ± 6.7</td>
<td>10.2 ± 6.9</td>
<td>9.9 ± 7.9</td>
<td>0.6</td>
</tr>
</tbody>
</table>

BP = blood pressure; CRP = C-reactive protein; HbA1c = glycated hemoglobin A1c; HDL = high-density lipoprotein; HOMA-IR = (fasting glucose mmol/L × fasting insulin mU/L)/22.5; LAGB = laparoscopic adjustable gastric banding; LDL = low-density lipoprotein; LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric by-pass; SD = standard deviation.

* Using 1-way analysis of variance.
LSG and 8.3% for LAGB. For dyslipidemia, the reduction in absolute prevalence was 45.1% for RYGB, 31.3% for LSG and 18.8% for LAGB. While the change in absolute prevalence of type 2 diabetes, hypertension and dyslipidemia did not reach statistical significance between LSG and RYGB or between LSG and LAGB, there was a significantly greater change in prevalence after RYGB compared with LAGB at 2 years. Absolute and relative change in prevalence of comorbidities are presented in Figure 3. The 2-year changes in cardiovascular risk factors are shown in Table 3.

**Adverse events**

Adverse events were classified according to a modified Clavien–Dindo surgical complications system, focusing on grade III or higher.\textsuperscript{21,22} All reported adverse events required intervention, admission, or reoperation (Table 4). Total adverse event rates were 19.6% for RYGB, 9.8% for LSG and 14.6% for LAGB. There were no deaths in any group at 2-year follow-up. Surgical adverse events included 2 anastomotic/staple line leaks and 2 intraabdominal abscesses requiring radiologic drainage in the RYGB group.

**Table 2. Two-year changes in weight and body mass index**

<table>
<thead>
<tr>
<th>Analysis; outcome</th>
<th>Group; mean ± SD</th>
<th>p value*</th>
<th>RYGB – LSG</th>
<th>LSG – LAGB</th>
<th>RYGB – LAGB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RYGB</td>
<td>n = 51</td>
<td>LSG</td>
<td>n = 51</td>
<td>LAGB</td>
</tr>
<tr>
<td>Δ Weight, kg</td>
<td>–36.6 ± 19.5</td>
<td>–21.4 ± 16.0</td>
<td>–7.0 ± 9.7</td>
<td>&lt; 0.001</td>
<td>–11.8 (–17.5 to –6.2)</td>
</tr>
<tr>
<td>Δ Weight, %</td>
<td>–26.1 ± 12.2</td>
<td>–16.4 ± 11.6</td>
<td>–5.8 ± 7.9</td>
<td>&lt; 0.001</td>
<td>–8.4 (–12.6 to –4.2)</td>
</tr>
<tr>
<td>Δ BMI</td>
<td>–13.0 ± 6.6</td>
<td>–7.6 ± 5.7</td>
<td>–2.6 ± 3.5</td>
<td>&lt; 0.001</td>
<td>–4.3 (–6.3 to –2.3)</td>
</tr>
<tr>
<td></td>
<td>RYGB</td>
<td>n = 44</td>
<td>LSG</td>
<td>n = 43</td>
<td>LAGB</td>
</tr>
<tr>
<td>Δ Weight, kg</td>
<td>–31.0 ± 22.6</td>
<td>–17.9 ± 16.6</td>
<td>–6.4 ± 9.8</td>
<td>&lt; 0.001</td>
<td>–10.4 (–17 to –3.8)</td>
</tr>
<tr>
<td>Δ Weight, %</td>
<td>–22.3 ± 14.7</td>
<td>–14.0 ± 12.3</td>
<td>–5.2 ± 7.9</td>
<td>&lt; 0.001</td>
<td>–7.4 (–12.2 to –2.6)</td>
</tr>
<tr>
<td>Δ BMI</td>
<td>–11.0 ± 7.8</td>
<td>–6.5 ± 6.0</td>
<td>–2.3 ± 3.5</td>
<td>&lt; 0.001</td>
<td>–3.8 (–6.1 to –1.4)</td>
</tr>
</tbody>
</table>

BMI = body mass index; BOCF = baseline observation carried forward; CI = confidence interval; LAGB = laparoscopic adjustable gastric banding; LOCF = last observation carried forward; LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric bypass; SD = standard deviation.

* Using analysis of variance.

† p < 0.05 using a Wald test of simple and composite linear hypotheses, adjusted for age, sex and BMI at baseline using multiple linear regression plus adjusted prediction with marginal effects at representative values.
There were 4 internal hernias after 1 year in the RYGB group, all of which required reoperation, and 3 anastomotic ulcers that were treated medically. There was 1 anastomotic/staple line bleed in the LSG group that required urgent reoperation and 1 intra-abdominal abscess that required radiologic drainage. There were 6 reoperations for band removal in the LAGB group. Other serious adverse events included 1 non-ST elevation myocardial infarction and 1 cardiac arrhythmia that required chemical cardioversion and 1 pulmonary embolus that required anticoagulation in the LSG group. In total, there were 21 grade IIIa or IIIb complications, and 1 grade IV complication.

**DISCUSSION**

To our knowledge, this is the first study to compare the effectiveness and safety of 3 common bariatric surgical approaches in a population-based, publicly funded, centrally triaged bariatric program. In this cohort with class III (BMI > 40) obesity, RYGB and LSG were effective in producing clinically important weight loss over a 2-year follow-up period. The RYGB procedure tended to produce the largest reduction in weight loss, followed by LSG, with the LAGB demonstrating modest weight loss at best. Additionally, RYGB demonstrated superiority in

![Fig. 2: Weight change among surgical subgroups. Data presented as (A) absolute weight change, (B) relative weight change and proportion of participants achieving weight loss greater than (C) 5% and (D) 10% of baseline. The p values represent significance in overall differences among surgical subgroups using 2-way analysis of variance (ANOVA). *p < 0.05 compared to LAGB using a Bonferroni post hoc correction after 2-way ANOVA. LAGB = laparoscopic adjustable gastric banding; LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric bypass.](image-url)
reducing type 2 diabetes, hypertension and dyslipidemia as compared with LAGB. In terms of safety, there were no deaths in any group and low rates of major adverse effects. Both the RYGB and LSG groups had low rates of major early postoperative adverse effects, most importantly anastomotic/staple line leakage and gastrointestinal/staple line bleeding. The RYGB had the second highest rate of postoperative surgical intervention, with LAGB being the highest related to issues requiring removal of the band.

Comparison

Previous clinical trials have demonstrated the superiority of bariatric surgery combined with intensive medical treatment compared with medical treatment alone in obese individuals. A randomized controlled trial by O’Brien and colleagues reported significantly greater short-term and long-term (10-yr) weight reduction following LAGB compared with intensive medical weight loss in patients with a BMI of 30–35. Schauer and colleagues compared intensive medical treatment and RYGB or LSG versus intensive medical treatment alone and also demonstrated greater weight loss and type 2 diabetes remission in both surgical groups with class II obesity (BMI > 35). Comparatively, both the trials by O’Brien and colleagues and Schauer and colleagues included patients with lower average BMIs than our population-based cohort (BMI 30–37 v. BMI > 40).

Additionally, comparative trials for bariatric surgical procedures are sparse in the literature. A prospective trial comparing RYGB versus LAGB by Angrisani and colleagues randomized 51 patients with a mean BMI of 43.2. At 5-year follow up, the RYGB group had significantly greater weight reduction than the LAGB group.

Fig. 3: Absolute and relative change in prevalence of comorbidities 2 years after surgery. Data presented as (A) absolute and (B) relative reduction in the proportion of participants with diabetes, hypertension and dyslipidemia 2 years after bariatric surgery. *Represents a significant change in prevalence (p < 0.05) relative to baseline in the same surgical subgroup. †Represents a significant difference in the prevalence of each risk factor compared to the effect observed in the those receiving laparoscopic adjustable gastric banding (LAGB). LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric bypass.

Table 3. Two-year changes in cardiovascular risk factors*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group</th>
<th>mean ± SD</th>
<th>p value†</th>
<th>RYGB – LSG</th>
<th>LSG – LAGB</th>
<th>RYGB – LAGB</th>
</tr>
</thead>
<tbody>
<tr>
<td>∆ Systolic BP, mm Hg</td>
<td>RYGB</td>
<td>0 ± 16</td>
<td>0 ± 16</td>
<td>0.90</td>
<td>0 (–6 to 6)</td>
<td>0 (–7 to 6)</td>
</tr>
<tr>
<td></td>
<td>LAGB</td>
<td>0 ± 12</td>
<td>0 ± 16</td>
<td>0.50</td>
<td>–1 (–6 to 3)</td>
<td>–3 (–8 to 2)</td>
</tr>
<tr>
<td></td>
<td>LSG</td>
<td>0 ± 12</td>
<td>0 ± 16</td>
<td>0.05</td>
<td>0 (–6 to 3)</td>
<td>–3 (–8 to 2)</td>
</tr>
<tr>
<td>∆ Total cholesterol, mmol/L</td>
<td>RYGB</td>
<td>0 ± 0.8</td>
<td>0.2 ± 0.6</td>
<td>0.50</td>
<td>–0.2 (–0.5 to 0.1)</td>
<td>0 (–0.3 to 0.3)</td>
</tr>
<tr>
<td></td>
<td>LAGB</td>
<td>0.4 ± 0.3</td>
<td>0.2 ± 0.2</td>
<td>0.08</td>
<td>–0.1 (–0.3 to 0.1)</td>
<td>0 (–0.3 to 0.4)</td>
</tr>
<tr>
<td></td>
<td>LSG</td>
<td>0.4 ± 0.3</td>
<td>0.2 ± 0.2</td>
<td>0.08</td>
<td>–0.1 (–0.3 to 0.1)</td>
<td>0 (–0.3 to 0.4)</td>
</tr>
<tr>
<td>∆ LDL cholesterol, mmol/L</td>
<td>RYGB</td>
<td>–0.2 ± 0.6</td>
<td>–0.1 ± 0.7</td>
<td>0.10</td>
<td>–0.1 (–0.4 to 0.1)</td>
<td>–0.2 (–0.4 to 0.1)</td>
</tr>
<tr>
<td></td>
<td>LAGB</td>
<td>–0.2 ± 0.2</td>
<td>–0.2 ± 0.2</td>
<td>0.30</td>
<td>–0.2 (–0.4 to 0.1)</td>
<td>0.0 (–0.3 to 0.2)</td>
</tr>
<tr>
<td></td>
<td>LSG</td>
<td>–0.2 ± 0.2</td>
<td>–0.2 ± 0.2</td>
<td>0.30</td>
<td>–0.2 (–0.4 to 0.1)</td>
<td>0.0 (–0.3 to 0.2)</td>
</tr>
<tr>
<td>∆ Triglycerides, mmol/L</td>
<td>RYGB</td>
<td>–0.4 ± 0.5</td>
<td>–0.2 ± 0.7</td>
<td>0.04</td>
<td>–0.2 (–0.4 to –0.01)</td>
<td>0 (–0.2 to 0.2)</td>
</tr>
<tr>
<td></td>
<td>LAGB</td>
<td>–0.5 ± 0.6</td>
<td>–0.5 ± 0.8</td>
<td>0.50</td>
<td>–0.0 (–0.4 to 0.0)</td>
<td>0 (–0.3 to 0.4)</td>
</tr>
<tr>
<td></td>
<td>LSG</td>
<td>–0.5 ± 0.6</td>
<td>–0.5 ± 0.8</td>
<td>0.50</td>
<td>–0.0 (–0.4 to 0.0)</td>
<td>0 (–0.3 to 0.4)</td>
</tr>
<tr>
<td>∆ HbA1c, %</td>
<td>RYGB</td>
<td>–0.3 ± 0.5</td>
<td>–0.1 ± 0.5</td>
<td>0.04</td>
<td>–0.1 (–0.4 to –0.01)</td>
<td>0 (–0.2 to 0.2)</td>
</tr>
<tr>
<td></td>
<td>LAGB</td>
<td>–0.5 ± 0.9</td>
<td>–0.5 ± 1.0</td>
<td>0.04</td>
<td>–0.1 (–0.4 to –0.01)</td>
<td>0 (–0.2 to 0.2)</td>
</tr>
<tr>
<td></td>
<td>LSG</td>
<td>–0.5 ± 0.9</td>
<td>–0.5 ± 1.0</td>
<td>0.04</td>
<td>–0.1 (–0.4 to –0.01)</td>
<td>0 (–0.2 to 0.2)</td>
</tr>
<tr>
<td>∆ HOMA-IR</td>
<td>RYGB</td>
<td>–3.0 ± 4.3</td>
<td>–1.8 ± 4.2</td>
<td>0.30</td>
<td>–0.9 (–2.6 to 0.7)</td>
<td>0.7 (–1.0 to 2.5)</td>
</tr>
<tr>
<td></td>
<td>LAGB</td>
<td>–3.7 ± 17</td>
<td>–4.1 ± 5.2</td>
<td>0.50</td>
<td>–1.6 (–3.8 to 7.1)</td>
<td>–2.7 (–8.2 to 2.9)</td>
</tr>
</tbody>
</table>

BP = blood pressure; CI = confidence interval; CRP = C-reactive protein; HDL = high-density lipoprotein; HOMA-IR = fasting glucose mmol/L × fasting insulin mU/L/22.5; LAGB = laparoscopic adjustable gastric banding; LDL = low-density lipoprotein; LSG = laparoscopic sleeve gastrectomy; RYGB = laparoscopic Roux-en-Y gastric bypass; SD = standard deviation.

*Last observation carried forward imputation.
†Using 1-way analysis of variance.
‡p < 0.05 using a Wald tests of simple and composite linear hypotheses adjusted for age, sex and BMI at baseline using multiple lineal regression plus adjusted prediction with marginal effects at representative values.
(BMI 29.8 v. 34.9). The patients undergoing LAGB in their study had a change in BMI from 43.4 to 34.9, which was relatively greater than the modest ~2.6 change in BMI seen in our cohort at 2-year follow-up. Interestingly, Christou and colleagues\textsuperscript{26} retrospectively reviewed outcomes of RYGB versus LAGB in Canada with 5-year outcomes. Similar to our findings, they also reported significantly greater weight loss with RYGB than with LAGB. Sjöström and colleagues\textsuperscript{27} reported 15-year follow-up data comparing RYGB, LAGB and vertical-banded gastoplasty. Their study did not include LSG, as it is the newest of the 3 procedures. At 2-year follow-up, the weight loss was 32% for RYGB and 20% for LAGB compared with baseline. Interestingly, in our study weight loss after RYGB was comparable; however, weight loss after LAGB was considerably less. It remains difficult to define the factors responsible for the variability in weight loss seen with LAGB among studies. Differences may relate to variations in patient selection (inclusion and exclusion criteria), local patterns of practice, or study design. This variability is unlikely related to different gastric banding devices or techniques, as previous trials have demonstrated.\textsuperscript{28,29}

Our data not only demonstrate marginal absolute weight loss with LAGB, but also superior comparative weight loss with LSG and RYGB, and greater reduction in obesity-related comorbidities with RYGB. Accordingly, in a shared decision-making model, our study will inform patients and referring physicians of the relative lack of effectiveness of the band for weight loss and comorbidity resolution. Also, our findings will inform bariatric surgeons that LAGB should not be routinely offered to patients with severe obesity who are interested in substantial weight loss and improvement in type 2 diabetes, hypertension and dyslipidemia. Instead, the primary bariatric surgical approach for these patients should consist of RYGB or LSG.

Our data also suggest that all 3 bariatric surgical procedures are safe. This is similar to the systematic review by Chang and colleagues\textsuperscript{30} in which mortality was 0.08% in a population of 161,756 patients. Both RYGB and LSG had greater and more serious adverse event rates than LAGB, related to the anastomotic and staple line challenges. However, the complication rates were similar to those reported in previous studies.\textsuperscript{11,25} We acknowledge that given the relative infrequency of these adverse effects, this study is likely underpowered to detect true differences in adverse effects.

**Limitations**

The APPLES surgical cohort analysis is unique in that it provides prospective data with a relatively large study population to compare 3 common types of bariatric surgery with relatively modest loss to follow-up. The major limitation is the nonrandomized nature of the study. This resulted in baseline imbalances in weight, which we addressed using

<table>
<thead>
<tr>
<th>Table 4. Adverse events at 24 months of follow-up*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse event</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Death</td>
</tr>
<tr>
<td>Requiring hospitalization\textsuperscript{1}</td>
</tr>
<tr>
<td>Requiring surgical intervention</td>
</tr>
<tr>
<td>Requiring radiological/endoscopic intervention</td>
</tr>
<tr>
<td>Surgical adverse events</td>
</tr>
<tr>
<td>Gastrointestinal/staple line leak</td>
</tr>
<tr>
<td>Gastrointestinal/staple line bleed</td>
</tr>
<tr>
<td>Anastomotic ulcer</td>
</tr>
<tr>
<td>Stricture</td>
</tr>
<tr>
<td>Band slippage or removal</td>
</tr>
<tr>
<td>Intraabdominal abscess</td>
</tr>
<tr>
<td>Hernia</td>
</tr>
<tr>
<td>Other serious adverse events</td>
</tr>
<tr>
<td>Intravenous hydration for hypovolemia</td>
</tr>
<tr>
<td>Transfusion</td>
</tr>
<tr>
<td>Transient renal insufficiency</td>
</tr>
<tr>
<td>NSTEMI/STEMI/arrhythmia</td>
</tr>
<tr>
<td>Pulmonary embolus</td>
</tr>
<tr>
<td>Total adverse events</td>
</tr>
</tbody>
</table>

LAGB = laparoscopic adjustable gastric banding; LSG = laparoscopic sleeve gastrectomy; N/A = not applicable; NSTEMI = non-ST-segment elevation myocardial infarction; RYGB = laparoscopic Roux-en-Y gastric bypass; STEMI = ST-segment elevation myocardial infarction.

*Clavien–Dindo grade III or higher. Many patients had more than one event, or one complication leading to multiple adverse events. These events were not counted separately in the totals.

\textsuperscript{1}Either prolonged hospitalization (length of stay > 5 d) or rehospitalization.
regression techniques. In terms of generalizability, this study should be generalizable to publicly funded bariatric programs in Canada; however, generalizability beyond Canada should be made with caution. Additionally, with obesity being a chronic disease, our data provide only short-term follow up.

**CONCLUSION**

The RYGB and LSG procedures were substantially more effective for weight loss and resolution of obesity-related comorbid disease than LAGB in our population-based cohort. Although RYGB and LSG were associated with greater perioperative risk, these adverse effects were uncommon, and the weight loss efficacy of LAGB was relatively poor. Our findings will inform patients, primary physicians, multidisciplinary teams and surgeons in Canada regarding the effectiveness and safety of the 3 most common bariatric surgical procedures. Furthermore, our findings support the preferential use of RYGB and LSG in publicly funded bariatric surgical programs in Canada.

**Affiliations:** From the Centre for the Advancement of Minimally Invasive Surgery (CAMIS), Royal Alexandra Hospital, Edmonton, Alta. (Gill, Karmali); the Department of Medicine, University of Alberta, Edmonton, Alta. (Majumdar, Rueda-Clausen, Sharma, Klarenbach, Padwal); and the Department of Surgery, University of Alberta, Edmonton, Alta. (Apte).

**Competing interests:** D. Birch declares educational grants from Johnson & Johnson/Ethicon Endo-Surgery, Covidiem and Stryker. S. Karmali declares consultant fees and honoraria from Ethicon Endo-Surgery. No other competing interests declared.

**Contributors:** S. Majumdar, S. Karmali, A. Sharma and R. Padwal designed the study. R. Gill, S. Apte and R. Padwal acquired the data, which all authors analyzed. R. Gill, C. Rueda-Clausen, S. Apte, S. Karmali and R. Padwal wrote the article, which all authors reviewed and approved for publication.

**References**

Same-day discharge after unilateral parathyroidectomy is safe

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Adrienne L. Melck, MD, MPH

This work was presented in part at the British Columbia Surgical Society Spring Meeting, 2015.

Accepted for publication Mar. 22, 2016

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DOI: 10.1503/cjs.013715

Background: Minimally invasive parathyroidectomy (MIP) with intraoperative parathyroid hormone monitoring is the most common surgical approach among endocrine surgeons for primary hyperparathyroidism (PHPT). Overnight hospitalization after MIP represents a drain on resources and may be unnecessary. The aim of this study was to determine the safety of same-day discharge after MIP.

Methods: We performed a retrospective cohort study of patients treated for PHPT between August 2010 and July 2015. Patients were stratified by their length of stay in hospital and compared in terms of postoperative complications.

Results: During the study period 154 MIPs were performed. Of these, 101 patients were discharged on the day of their surgery (group 1) and the remaining 53 stayed 1 or more days (group 2). Three patients in group 2 required readmission within 30 days of discharge ($p = 0.039$). Seven patients in group 1 and 1 patient in group 2 visited the emergency department within 30 days of discharge ($p = 0.72$). Two patients in group 1 experienced persistent or recurrent PHPT ($p = 0.55$). Patients in group 2 were older than those in group 1 (69 v. 61 yr, $p < 0.001$) and had a higher mean American Society of Anesthesiologists classification of physical status (2.66 v. 2.24, $p < 0.001$).

Conclusion: Same-day discharge after MIP is a safe practice and saves the cost of an overnight stay in hospital. Same-day discharge should be considered for all patients undergoing MIP if there are no clear indications for overnight hospitalization.

Contexte : La parathyroïdectomie à effraction minimale avec surveillance peropératoire de la parathormone est la technique chirurgicale la plus employée par les chirurgiens endocrinien pour traiter l’hyperparathyroïdie primaire. L’hospitalisation d’une nuit suivant cette intervention, qui engloutit des ressources considérables, pourrait ne pas être nécessaire. La présente étude visait donc à déterminer la sécurité des chirurgies d’un jour dans ce contexte.

Méthodes : Nous avons mené une étude de cohorte rétrospective portant sur les patients qui avaient subi l’intervention entre août 2010 et juillet 2015. Après avoir stratifié les patients selon la durée de leur séjour à l’hôpital, nous avons comparé l’incidence de complications postopératoires.

Résultats : Au cours de la période visée, 154 parathyroïdectomies à effraction minimale ont été pratiquées. De ces 154 patients, 101 ont reçu leur congé le jour même (groupe 1), tandis que les 53 autres ont été hospitalisés 1 journée ou plus (groupe 2). Dans les 30 jours suivant leur congé, 3 patients du groupe 2 ont dû être réhospitalisés ($p = 0.039$), tandis que 7 patients du groupe 1 et 1 patient du groupe 2 se sont rendus à l’urgence ($p = 0.72$). Deux patients du groupe 1 ont continué de présenter une hyperparathyroïdie primaire persistante ou récurrente ($p = 0.55$). Les patients du groupe 2 étaient plus âgés que ceux du groupe 1 (69 ans contre 61 ans; $p < 0.001$) et appartenaient à une catégorie plus élevée du système de classification de la santé physique de l’American Society of Anesthesiologists (2.66 contre 2.24; $p < 0.001$).

Conclusion : Il est donc sécuritaire de donner leur congé le jour même aux patients qui subissent une parathyroïdectomie à effraction minimale. Cette pratique, qui permet d’éviter les coûts associés à une hospitalisation, devrait être envisagée pour tous les patients, sauf en cas d’indication claire d’hospitalisation.
Primary hyperparathyroidism (PHPT) is the most common cause of hypercalcemia in the outpatient setting, with an annual incidence of 0.2%. Approximately 85% of cases of PHPT are caused by a single parathyroid adenoma, while the remainder are caused by multigland disease or parathyroid carcinoma. While bilateral 4-gland exploration has historically been the gold standard surgical approach, most endocrine surgeons favor a minimally invasive parathyroidectomy (MIP), given the low frequency of multigland disease.

Traditionally, patients are monitored overnight following MIP, but a recent study from the United Kingdom has begun to explore the feasibility of same-day discharge after this operation. The safety of this practice has not been well studied in the Canadian context. The purpose of our study was to document the safety of a same-day discharge protocol following MIP at an urban Canadian centre.

**METHODS**

**Study cohort**

We retrospectively reviewed the charts of patients who received parathyroidectomies performed by a single endocrine surgeon between August 2010 and June 2015 at St. Paul’s Hospital, Vancouver, BC, and patients were stratified into 2 groups based on their length of stay (LOS). Patients in group 1 were discharged on the same day as the operation after 4 hours of observation, whereas patients in group 2 were hospitalized for at least 1 night after their MIP. Reasons that group 2 patients were admitted overnight included the following: the procedure was performed too late in the evening to allow for same-day discharge, there was an ongoing need for cardiorespiratory monitoring after general anesthetic, the procedure was performed on an inpatient basis, the patient was from a distant geographic location, and no ride home was available on the day of the procedure.

Only patients undergoing MIP were included in the data analysis. Patients undergoing reoperation or bilateral parathyroid exploration were excluded. In addition, patients undergoing concomitant procedures were also excluded, unless that operation was an ipsilateral cervical procedure, such as a thyroid lobectomy. The study protocol was approved by our institutional ethics review board.

**Minimally invasive parathyroidectomy**

As described by Chen and colleagues, MIP involves preoperative localization of the target adenoma using a sestamibi scan and ultrasound, directed exploration of the imaged gland through a 2 cm incision, and the use of intraoperative parathyroid hormone (ioPTH) measurement to confirm the absence of multigland disease. All patients stayed at least 4 hours postoperatively and were then examined for hematoma or other acute complications before discharge. There is no specific enhanced recovery after surgery (ERAS) pathway for MIP patients, nor an established protocol for area hospitals for hematoma management. However, each patient is counselled extensively by the attending surgeon before discharge, and an information pamphlet is provided upon discharge. Specifically, patients are counselled on wound care, signs of hematoma requiring urgent presentation to the nearest hospital, and symptoms of hypocalcemia necessitating institution of oral calcium supplementation and a phone call to the surgeon’s office. A more extensive information pamphlet that will be distributed to patients preoperatively is currently under development. All patients were seen in follow-up 2 weeks and 6 months after discharge.

**Statistical analysis**

Demographic information including patient age, sex, distance between home address and the hospital, and American Society of Anesthesiologists (ASA) physical status classification was recorded to identify potential confounding variables. Operative details, including location of adenoma and ioPTH levels were also recorded. We compared postoperative mortality and rates of the following complications between the 2 groups: hematoma, wound infection, permanent recurrent laryngeal nerve (RLN) paralysis, permanent hypoparathyroidism, persistent/recurrent PHPT, visits to the emergency department (ED) within 30 days of discharge, and rehospitalization within 30 days of discharge. Additionally, we recorded the duration of follow-up and serum calcium and PTH levels at or after 6 months postoperatively.

**RESULTS**

During the study period, 217 patients underwent cervical parathyroidectomy for treatment of PHPT. After excluding 48 patients who underwent bilateral explorations, 14 patients who underwent reoperative surgery and 1 patient who underwent a concomitant procedure not in the ipsilateral neck, 154 patients were left for analysis (Fig. 1). Stratification of these patients by LOS resulted in 101 patients who were discharged on the same day (group 1), and 53 patients who stayed 1 or more days in hospital (group 2). The mean duration of follow-up in each group was 7 months.

Demographic comparison of the study groups showed that group 2 patients were older (p < 0.001) and had higher...
ASA scores ($p < 0.001$) than patients in group 1. There was also a trend toward group 2 patients living farther away from the hospital than group 1 patients (Table 1).

There was 1 death in group 2 ($p = 0.34$). This patient had been admitted to hospital 6 weeks before the diagnosis of PHPT after a fall. The MIP occurred as an inpatient procedure and was tolerated well without complications. The patient succumbed to nosocomial *Clostridium difficile* infection on postoperative day 69.

There were no instances of hematoma, wound infection, permanent hypoparathyroidism or permanent RLN paralysis in either group (Table 2). Two patients from group 1 had persistent or recurrent disease ($p = 0.55$); 1 of them had disease recurrence secondary to parathyroid carcinoma and the other had persistently elevated PTH levels despite being normocalcemic and having an ioPTH reduction greater than 50%. Ultimately the latter of these patients went on to have another parathyroid exploration, and a double adenoma was found on the contralateral side.

Eight patients visited the ED within 30 days of their discharge: 7 from group 1 and 1 from group 2; however, this difference was not significant ($p = 0.72$). The majority of the 8 patients who visited the ED were seen for cardiorespiratory conditions not related to their recent operation. Three patients visited the ED with paresthesias, but all were found to have normal calcium levels. Table 3 outlines the reasons for the ED visits.

Interestingly, all 3 patients who were readmitted to hospital within 30 days of discharge belonged to group 2, and this was the only statistically significant difference in complication rates between the groups ($p = 0.039$). One patient was admitted for a dysrhythmia that pre-existed MIP, 1 patient was admitted for a mechanical back injury, and the third was a patient with parasthesias but normal calcium who was admitted overnight for anxiety.

**DISCUSSION**

The results of our study reveal no significant increase in complications with same-day discharge following MIP. Upon examination of the complications that did arise after surgery, many could be attributed to reasons other than the recent MIP. Most of our patients who were readmitted to hospital or who were seen in the ED within 30 days of their MIP presented for reasons unrelated to their parathyroid surgery with the exception of 3 patients who presented with paresthesias. However, all 3 of these patients were found to be normocalcemic, as one would expect given that only a unilateral parathyroid exploration was performed and only a single adenoma was resected. This suggests that there is no increased risk of postoperative complications with same-day discharge following MIP when compared with an overnight stay.

In group 1, 7 patients visited the ED postoperatively compared with only 1 patient in group 2. Though this was not a statistically significant difference, it may reflect the impact of geography on how patients access care postoperatively. The majority of these visits were cardiorespiratory.

![Fig. 1: Selection of patients for participation in the study. PHPT = primary hyperparathyroidism.](discharge-peel.indd)
issues that could have been investigated by a primary care physician outside of the ED. However, demographic analysis of our groups revealed a trend toward group 1 patients tending to live closer to the hospital than group 2 patients. Though not formally investigated by this study, we speculate that patients who live closer to the hospital choose to visit the ED rather than their primary care physicians postoperatively, whereas patients who live farther away prefer their primary care physicians. The time of presentation may also dictate where a patient chose to present (e.g., presenting with concerns to the ED at night when the primary care physician’s office is closed). There are multiple factors affecting access to care postoperatively, and this was beyond the scope of this study.

Demographic comparison of sample groups revealed a significant difference in age and ASA classification status. While these differences are not the result of randomization, they serve to demonstrate features of a population that required longer hospitalization after MIP at our center. Older patients, patients with greater comorbid disease burden, and patients undergoing bilateral excision may not benefit from same-day discharge as reliably. For this reason, we suggest same-day discharge be considered for all patients undergoing MIP, but acknowledge that overnight hospitalization may be required in certain populations for the reasons outlined above.

Currently, MIP is the preferred approach in the majority of cases of PHPT for its improved cost-effectiveness and cosmesis.\(^1\) Udelsman\(^7\) reported in 2002 that MIP without overnight hospitalization confers a 50% reduction in operating time and a savings of $USD 2693 per procedure, with a reduction in complications compared with bilateral explorations.\(^1\) To our knowledge, there is no Canadian study on the cost-effectiveness of MIP, and a cost analysis was beyond the scope of the present study; however, a similar trend would be expected.

Same-day discharge following parathyroidectomy has found support in recent literature. In the European context, same-day discharge has been explored following thyroid and parathyroid surgery with some success. Rajeev and colleagues\(^4\) found that parathyroidectomy with same-day discharge was suitable in select patient populations. The authors of that study reported no increased risk of hematoma or severe complications for patients discharged on the day of surgery. However, the authors did note a concern about hypocalcemia postoperatively, which was likely explained by the inclusion of patients undergoing bilateral parathyroid exploration in their study.\(^4\)

Flynn and colleagues\(^8\) recently reported that same-day discharge after parathyroidectomy is a safe option compared with overnight hospitalization. However, they found that outpatient parathyroidectomy tends to occur more frequently in patients with few comorbidities, whereas more complex patients tend to be kept overnight in hospital. These findings are useful in identifying a population that may benefit from same-day discharge and mirror our own results that patients requiring overnight stay tend to have more comorbidities and be older. In addition, Flynn and colleagues\(^8\) found that the majority of outpatient parathyroidectomies tended to be MIP procedures. They also observed no difference in driving distance from home to hospital in the American context, but our findings suggest that geography may indeed play a role in the surgeon’s decision to hospitalize patients following MIP in the Canadian context. Together, these findings suggest that same-day discharge after MIP may be a safe option, but their study design does not demonstrate this explicitly. Our findings more directly show that same-day discharge after MIP is safe, and, to our

| Table 1. Demographic and clinical characteristics of study participants |
|--------------------------|--------------------------|--------------------------|
| Characteristic           | Group 1 (n = 101)        | Group 2 (n = 53)         | p value |
| Mean age, yr             | 61                       | 69                       | < 0.001 |
| Mean ASA score           | 2.24                     | 2.66                     | < 0.001 |
| Female sex, %            | 76                       | 74                       | 0.85    |
| Mean driving distance from home to hospital, km | 77.3 | 114.3 | 0.44 |

ASA = American Society of Anesthesiologists.

| Table 2. Comparison of postoperative complications among study participants |
|--------------------------|--------------------------|--------------------------|
| Complication             | Group 1 (n = 101)        | Group 2 (n = 53)         | p value |
| Hematoma                 | 0                        | 0                        | N/A     |
| Wound infection          | 0                        | 0                        | N/A     |
| RLN palsy                | 0                        | 0                        | N/A     |
| Hypoparathyroidism       | 0                        | 0                        | N/A     |
| Persistent/recurrent PHPT| 2                        | 0                        | 0.55    |
| ED visit within 30 d     | 7                        | 1                        | 0.72    |
| Readmission within 30 d  | 0                        | 3                        | 0.039   |
| Death                    | 0                        | 1                        | 0.34    |
| All-cause complication    | 9                        | 5                        | > 0.99  |

ED = emergency department; N/A = not applicable; PHPT = primary hyperparathyroidism; RLN = recurrent laryngeal nerve.

| Table 3. Postoperative ED visits within 30 days |
|--------------------------|--------------------------|
| Patient Reason for ED Visit | Group |
| 1 Chest pain, workup negative, not admitted | 1 |
| 2 Palpitations workup negative, not admitted | 1 |
| 3 Dyspnea, workup negative, not admitted | 1 |
| 4 Dyspnea, workup negative, not admitted | 1 |
| 5 Renal colic, not admitted | 1 |
| 6 Paresthesias, Ca2+ normal, not admitted | 1 |
| 7 Paresthesias, Ca2+ normal, not admitted | 1 |
| 8 Paresthesias, Ca2+ normal, admitted for anxiety | 2 |

ED = emergency department.
knowledge, our study is the first to demonstrate this in the Canadian context.

Limitations

Despite strong evidence in favour of same-day discharge and MIP, no consensus guidelines or patient-care pathways have been produced at our centre or elsewhere to direct care. The results of our study may contribute to this mounting evidence, but we are limited in the data produced by retrospective analysis. Further limitations of our study include our relatively small sample size, limited generalizability given that our study reflects the practice of a single surgeon, and the potential for information bias given our retrospective study design. In addition, patients did not routinely undergo laryngoscopy postoperatively, so rates of permanent RLN injury may have been underestimated.

Conclusion

Our study has shown that same-day discharge has no increased risk of adverse events following MIP. This non-inferiority makes same-day discharge favourable, especially when considering the cost of an overnight stay in hospital. We recommend that same-day discharge be considered for all patients undergoing MIP, though older patients, patients with more significant comorbidities, or patients with geographic burdens should be considered for an overnight stay.

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Competing interests: None declared.

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

References

Accuracy of the modified Hardinge approach in acetabular positioning

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DOI: 10.1503/cjs.011415

Background: The surgical approach chosen for total hip arthroplasty (THA) may affect the positioning of the acetabular component. The purpose of this study was to examine the accuracy in orienting the acetabular component using the modified Hardinge approach.

Methods: We used our institutional arthroplasty database to identify patients with primary, press-fit, hemispherical acetabular components of a metal-on-polyethylene THA performed between 2003 and 2011. Patients with radiographs obtained 1–3 years after the index procedure were included for measurement of anteversion and inclination angles. Acceptable values of anteversion and abduction angles were defined as $15^\circ \pm 10^\circ$ and $40^\circ \pm 10^\circ$, respectively.

Results: We identified 1241 patients from the database, and the modified Hardinge approach was used in 1010 of the patients included in our analysis. The acetabular component was anteverted in the acceptable zone in 54.1% of patients. The abduction angle was within the defined range in 79.2% of patients. Combined anteversion and abduction angles within the defined zone were present in 43.6% of patients.

Conclusion: Consistent with studies examining accuracy from other approaches, our study reveals that the modified Hardinge approach was only moderately accurate in positioning the acetabular component in the acceptable zone.

Acetabular component positioning is paramount for successful total hip arthroplasty (THA). Poor cup positioning affects impingement,1–5 dislocation rates6–10 and edge loading11 and may lead to liner fractures.1 However, studies have shown that excess abduction angle is correlated with increased bearing surface wear rates in metal-on-polyethylene and metal-on-metal articulations.12–15 In metal-on-metal hip resurfacing, Hart and colleagues16 showed increased blood metal ion levels in patients with insufficient cup...
Surgical approach may influence dislocation rates, postoperative function, heterotopic ossification and the possibility of neurovascular damage. The selection of surgical approach is largely a matter of preference based on prior training of the surgeon. Callanan and colleagues identified surgical approach to be an independent risk factor in cup malpositioning. They identified a 68% incidence of cup malpositioning with the use of the direct lateral approach compared with 42.7% when using the posterolateral approach. Barrack and colleagues reported only 21% of the cups positioned outside their defined range using the anterolateral approach. Both studies, however, used different acceptable ranges for the cup position, with an emphasis on the posterolateral approach as the most popular surgical approach at their centres. Furthermore, the lateral approaches were being performed by low-volume surgeons in both studies, making it difficult to determine the generalizability of the results.

The modified Hardinge approach is the most common surgical approach used at our institution for total hip replacements. This approach offers good visualization of the acetabulum, facilitating optimal cup positioning as well as excellent stability of the total hip joint. The purpose of this study was to evaluate the accuracy of intraoperative acetabular component positioning with use of the modified Hardinge approach performed by high-volume surgeons at a tertiary centre.

**METHODS**

Ethics approval was obtained from our institutional review board. We used our institutional arthroplasty database to obtain information on patients who underwent THA between 2003 and 2011, including their age, sex, date of their procedure, laterality of the hip, implant information and surgical approach used for the procedure. All THAs were either executed under the guidance of or performed directly by fellowship-trained high-volume surgeons, each of whom perform more than 250 total joint replacements per year. Mean duration of employment of these surgeons was 23.3 ± 13.4 years.

The study cohort consisted of patients with a diagnosis of osteoarthritis who underwent a cementless THA with the use of the modified Hardinge approach. Patients were required to have digital postoperative radiographs collected prospectively, 24–36 months from their index procedure. We excluded patients for whom the surgical approach was not recorded in the database. We also excluded patients who had diagnoses of metastatic cancer, avascular necrosis, inflammatory arthritis, post-traumatic arthritis, acute fracture or developmental hip dysplasia; those who had metal-on-metal articulations or cemented acetabular components; and those who had undergone bipolar hemiarthroplasty, modular neck-stem implants and revision surgeries.

The acetabular components used in our cohort were all press fit, hemispherical shells, and included Reflection (Smith and Nephew), Duraloc (Depuy), R3 (Smith and Nephew), Pinnacle (Depuy) and Trident (Stryker) models.

The modified Hardinge approach has previously been detailed by Frndak and colleagues. Patients were positioned in a lateral decubitus position with supporting posts. A lateral skin incision centred over the greater trochanter was used. The access to the hip joint was gained through an abductor muscle split approach. The fibres of the gluteus medius were split longitudinally at the junction of the anterior third to posterior two-thirds of the muscle belly. The gluteus minimus and capsule were then divided vertically along the same incision parallel to the gluteus medius split. Surgeons were attentive to keep the vertical split within 5 cm proximal to the greater trochanter to avoid injury to the superior gluteal nerve. During preoperative templating and the implantation of the cup, surgeons aimed the operative inclination and anteversion angles of the acetabular component to be within the Lewinnek zone. A combination of anatomic landmarks and mechanical guides were used intraoperatively.

Anteroposterior (AP) and lateral radiographs were examined for the purposes of this study. Using the General Electric Centricity Picture Archiving and Communications System (PACS), we measured the radiographic inclination angle and anteversion. Radiographs were analyzed by 2 observers (P.G. and A.L.). A subset of 20 radiographs was measured by both observers to calculate the concordance correlation coefficient and confirm adequate interobserver reliability, which was consistently greater than 0.93. Differences were reconciled through mutual agreement. Anteverision was measured using the technique described by Tiberi and colleagues. Inclination angle was measured between the face of the acetabular component and the horizontal axis, drawn by connecting the ischial tuberosities.

**Statistical analysis**

We performed statistical analyses using SPSS statistics software version 20 (IBM). Frequency analysis and \( \chi^2 \) tests were performed to determine the accuracy of the modified Hardinge approach at our institution. We performed a univariate analysis with 5 factors: age, sex, body mass index (BMI), head size and outer acetabular component...
diameter. Multivariate analysis was performed using logistic regression with the same 5 variables. We considered results to be significant at $p < 0.05$.

**RESULTS**

A total of 1241 THAs were performed during the study period; of these 1010 patients met our selection criteria and were included in the study.

The mean anteversion was $21.8° \pm 11.8°$, and the mean inclination was $44.32° \pm 7.0°$. At the time of the procedure, the mean age of the study population was $71.5 \pm 9.6$ years. There were 595 women (59%) and 415 men (41%). The majority of the procedures ($543 [53.7\%]$) were performed on the right hip. The average BMI was $29.6 \pm 6.1$. Only 1 dislocation was identified in the entire cohort.

The accuracy of achieving the targeted cup position is reported in Table 1. Accuracy was best for inclination, with 79.2% of the hips meeting the target inclination angle. For anteversion, 54.1% of the hips had the cup in the intended range. Examining combined inclination and anteversion angles, 43.6% of the hips had the acetabular component within the target range. The position of acetabular components in all patients are graphically represented in Figure 1. We found that 47.5% of the hips were within 1 standard deviation of the mean of combined anteversion and inclination angle, while 90.5% were within 2 standard deviations of the mean (Table 2).

The results of the univariate analysis for age, sex, BMI, head size and outer acetabular component diameter are shown in Table 3. The BMI and sex of the patient had a significant effect on combined position of the acetabular component. Men were more likely than women to have a correctly oriented acetabular component ($p < 0.001$). Furthermore, patients with lower BMI were more likely to have an acetabular component with inaccurate anteversion and inclination angle ($p = 0.020$). When acetabular inclination angle was examined separately, sex ($p < 0.001$) and femoral head size ($p < 0.001$) had an effect on acetabular inclination. Women and patients with head sizes of 28 mm or smaller were more likely to have an inclination angle outside the target zone. Akin to the combined absolute cup position, anteversion was similarly affected by sex ($p = 0.009$) and BMI ($p = 0.002$). Figure 2 graphically illustrates a reduction in inclination angle over time (Spearman $\rho = -0.19$, $p < 0.001$).

Multivariate analysis demonstrated that patients with a BMI between 25 and 40 were more likely to be have correct combined acetabular component position than those with a BMI lower than 25 or higher than 40 (Table 4). Sex, age, head size and outer acetabular diameter were not independent risk factors to cup malpositioning.

**DISCUSSION**

Using Lewinnek’s “safe zone,” we found that 43.6% of the cups were within the combined inclination and anteversion target using the modified Hardinge approach. There is no consensus in the literature to suggest the ideal position of the acetabular component. Barrack and colleagues$^{26}$ used the wider ranges of $30°–55°$ and $5°–35°$ as their reference ranges for inclination angle and anteversion, respectively. A direct comparison with the study performed by Barrack and colleagues was not possible, as they did not perform any of their surgeries using the modified Hardinge approach.$^{26}$ Callanan and colleagues$^{25}$ obtained an accuracy of 32% using the direct lateral approach with a slightly narrower reference range consisting of $30°–45°$ of inclination and $5°–25°$ of anteversion.$^{25}$ Only low-volume surgeons used the direct lateral approach in their study,$^{21}$ potentially explaining the greater accuracy seen in our study, in which the surgeries were being performed only by high-volume surgeons. Furthermore, the direct lateral group made up only 2.6% of the entire cohort (50/1952) in the study by Callanan and colleagues; therefore, there is more potential for error in their reported results.

Among different studies, cup positioning accuracy varies between 32% and 88% depending on the approach and the target range.$^{21,26}$ As shown in Table 1, Barrack and colleagues$^{26}$ had combined accuracy of 79% and 88% mainly

<table>
<thead>
<tr>
<th>Study; approach</th>
<th>No. of hips</th>
<th>Optimal range of inclination angle</th>
<th>Optimal range of anteversion</th>
<th>Components within both ranges, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Callanan et al.$^{25}$</td>
<td>1952</td>
<td>$30°–45°$</td>
<td>$5°–25°$</td>
<td>32.0</td>
</tr>
<tr>
<td>Direct lateral</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterolateral</td>
<td>1170</td>
<td></td>
<td></td>
<td>57.3</td>
</tr>
<tr>
<td>Anterolateral</td>
<td>560</td>
<td></td>
<td></td>
<td>37.0</td>
</tr>
<tr>
<td>Barrack et al.$^{26}$</td>
<td>1549</td>
<td>$30°–55°$</td>
<td>$5°–35°$</td>
<td>88.0</td>
</tr>
<tr>
<td>Posterolateral</td>
<td>896</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterolateral</td>
<td>154</td>
<td></td>
<td></td>
<td>79.0</td>
</tr>
<tr>
<td>Present study</td>
<td>1010</td>
<td>$30°–50°$</td>
<td>$5°–25°$</td>
<td>43.6</td>
</tr>
<tr>
<td>Modified Hardinge</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
due to a wider reference range using the anterolateral and posterolateral approach, respectively. Callanan and colleagues\textsuperscript{25} used a reference range comparable to the range targeted at our centre. They reported moderate accuracy in attaining cup position in all groups regardless of the approach used, which is comparable to the accuracy we obtained using the modified Hardinge approach.

Our study suggests that women are at risk to have inaccurate anteversion and inclination of their acetabular components. However, we also found that women were more likely to have a lower BMI than men ($p < 0.001$). The multivariate analysis also highlights this confounding phenomenon, as the significance no longer meets the threshold value to establish sex as a risk factor for cup malpositioning. This suggests that differences in malpositioning seen with sex are confounded by BMI, a factor that was previously identified to affect placement of the cup\textsuperscript{25,26} and confirmed by our study. These studies demonstrated that patients with a higher BMI are more likely to have an incorrect position of the cup with their chosen reference range of anteversion and inclination. Our study, however, also shows patients who have lower BMI were at risk for acetabular component malpositioning. Potential reasons for cup malposition in these patients include the use of smaller incisions, the potential for patients with lower BMI to have different pelvic obliquity on the operating table and the relatively lower number of patients with low BMI. Analogous to minimally invasive approaches that use smaller incisions, we know that limited exposure is a risk factor for cup malpositioning.\textsuperscript{25}

![Scatter diagram summary of the orientation of the acetabular components in our cohort. Data highlighted within the black box indicate the cups within the Lewinnek’s “safe zone.”](image)

**Fig. 1:** Scatter diagram summary of the orientation of the acetabular components in our cohort. Data highlighted within the black box indicate the cups within the Lewinnek’s “safe zone.”

<table>
<thead>
<tr>
<th>Distribution</th>
<th>Inclination angle</th>
<th>Anteversion</th>
<th>No. (%) of components within both ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total range</td>
<td>20° to 70°</td>
<td>–19° to –59°</td>
<td>1010 (100)</td>
</tr>
<tr>
<td>Mean ± 1 SD</td>
<td>37.4° to 51.3°</td>
<td>10.1° to –33.6°</td>
<td>685 (67.8)</td>
</tr>
<tr>
<td>Mean ± 2 SD</td>
<td>30.4° to 58.2°</td>
<td>–1.7° to 45.4°</td>
<td>956 (94.9)</td>
</tr>
</tbody>
</table>

$SD = \text{standard deviation.}$

Table 2: Distribution of the hips within described ranges of anteversion and inclination
Table 3. Univariate analysis of various factors for combined acetabular cup position within the Lewinnek’s “safe zone”

<table>
<thead>
<tr>
<th>Factor</th>
<th>Total</th>
<th>Within Lewinnek’s zone</th>
<th>Outside Lewinnek’s zone</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr (n = 1010)</td>
<td>1010</td>
<td>440 (43.6)</td>
<td>570 (56.4)</td>
<td>0.33</td>
</tr>
<tr>
<td>&lt; 50</td>
<td>36</td>
<td>19 (52.8)</td>
<td>17 (47.2)</td>
<td></td>
</tr>
<tr>
<td>50–69</td>
<td>359</td>
<td>148 (41.2)</td>
<td>211 (58.8)</td>
<td></td>
</tr>
<tr>
<td>≥ 70</td>
<td>615</td>
<td>273 (44.4)</td>
<td>342 (55.6)</td>
<td></td>
</tr>
<tr>
<td>Sex (n = 1010)</td>
<td></td>
<td></td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Male</td>
<td>415</td>
<td>210 (50.6)</td>
<td>205 (49.4)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>595</td>
<td>230 (38.7)</td>
<td>365 (61.3)</td>
<td></td>
</tr>
<tr>
<td>Body mass index (n = 965)</td>
<td></td>
<td></td>
<td></td>
<td>0.020</td>
</tr>
<tr>
<td>≤ 24.99</td>
<td>214</td>
<td>71 (33.2)</td>
<td>143 (66.8)</td>
<td></td>
</tr>
<tr>
<td>25–29.99</td>
<td>343</td>
<td>165 (48.1)</td>
<td>178 (51.9)</td>
<td></td>
</tr>
<tr>
<td>30–34.99</td>
<td>247</td>
<td>111 (44.9)</td>
<td>136 (55.1)</td>
<td></td>
</tr>
<tr>
<td>35–39.99</td>
<td>101</td>
<td>50 (49.5)</td>
<td>51 (50.5)</td>
<td></td>
</tr>
<tr>
<td>≥ 40</td>
<td>60</td>
<td>20 (33.3)</td>
<td>40 (66.7)</td>
<td></td>
</tr>
<tr>
<td>Head size (n = 1009)</td>
<td></td>
<td></td>
<td></td>
<td>0.32</td>
</tr>
<tr>
<td>≤ 28 mm</td>
<td>291</td>
<td>118 (40.5)</td>
<td>173 (59.5)</td>
<td></td>
</tr>
<tr>
<td>32 mm</td>
<td>509</td>
<td>222 (43.6)</td>
<td>287 (56.4)</td>
<td></td>
</tr>
<tr>
<td>≥ 36 mm</td>
<td>209</td>
<td>99 (47.4)</td>
<td>110 (52.6)</td>
<td></td>
</tr>
<tr>
<td>Outer cup diameter (n = 1002)</td>
<td></td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
<tr>
<td>&lt; 52 mm</td>
<td>44</td>
<td>16 (36.4)</td>
<td>28 (63.6)</td>
<td></td>
</tr>
<tr>
<td>52–56 mm</td>
<td>639</td>
<td>266 (41.6)</td>
<td>373 (58.4)</td>
<td></td>
</tr>
<tr>
<td>&gt; 56 mm</td>
<td>319</td>
<td>156 (48.9)</td>
<td>163 (51.1)</td>
<td></td>
</tr>
</tbody>
</table>

*χ² test.

Fig. 2: A temporal view of inclination angles of all hips from 2003 to 2011. \(R^2 = 0.041, y = -0.0015x + 101.75\)
The size of the acetabular cup was not a significant factor in cup malpositioning, which is consistent with the current literature. However, femoral head size was found to be an independent factor affecting inaccuracies in inclination angle. Smaller head sizes were associated with increased inclination angle. However, with further analysis, a temporal factor was demonstrated. Over time, the arthroplasty community has demonstrated an increased tendency to use larger diameter head sizes. Concurrent with the trend to increased head size is an increased understanding and acceptance of the effect of inclination and wear, resulting in a tendency toward a decreased inclination angle (Fig. 2). Therefore, the association of smaller head sizes with increased cup inclination has time as a confounding factor.

Previous reports investigating acetabular positioning have relied on a variety of techniques to measure anteversion angles, including edge detection software, computed tomography (CT) and anteroposterior radiographs centred on the hip. We used the method outlined by Tiberi and colleagues, which is comparatively reliable to edge detection software. Overall, we found the mean inclination angle in our study to be comparable to studies in the literature. The mean anteversion angle of 21.82° found in our study, however, is the highest among these studies.

**Limitations**

Limitations of our study include the lack of a comparison group. A small proportion of total hip replacements were performed using other surgical approaches at our institution. However, these groups were too small to obtain any meaningful comparisons and could not be used (53 hips used a posterior approach, 7 used an anterior approach). The method used for anteversion measurements on routine radiographs is not standardized in literature. It is currently difficult to ascertain the accuracy of radiographic measurements compared with CT scans, as current reports in the literature use variable reference planes to determine anteversion and inclination angles. In order to be consistent, we assessed radiographic measurements using the radiographic coronal plane, which is a method currently used and understood by surgeons and is therefore practical. The number of hips operated by trainees was not known in our study. Since only 1 dislocation was identified in this study, an ideal position for the acetabular component could not be determined. The effect of various patient positioning devices on cup positioning could not be determined because all the surgeries were uniformly performed with the use of bolsters.

**Conclusion**

To our knowledge, our study is the largest to date that attempts to study the accuracy of cup positioning using the modified Hardinge approach performed by high-volume surgeons. Our sample size is comparable to those reported in the literature evaluating the posterolateral approach to establish the accuracy of cup positioning. Consistent with other studies examining other surgical approaches, we showed that a modified Hardinge approach is moderately successful in attaining accurate combined anteversion and inclination angle within a target range.

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Can J Surg, Vol. 59, No. 4, August 2016  253

References


Diverticulitis in immunosuppressed patients: A fatal outcome requiring a new approach?

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Accepted for publication Mar. 29, 2016

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DOI: 10.1503/cjs.012915

Background: Diagnosis and treatment of diverticulitis in immunosuppressed patients are more challenging than in immunocompetent patients, as maintenance immunosuppressive therapies may mask symptoms or impair the patient’s ability to counteract the local and systemic infective sequelae of diverticulitis. The purpose of this study was to compare the in-hospital mortality and morbidity due to diverticulitis in immunosuppressed and immunocompetent patients and identify risk factors for lethal outcomes.

Methods: This retrospective study included consecutive in-patients who received treatment for colonic diverticulitis at our institution between April 2008 and April 2014. Patients were divided into immunocompetent and immunosuppressed groups. Primary end points were mortality and morbidity during treatment. Risk factors for death were evaluated.

Results: Of the 227 patients included, 15 (6.6%) were on immunosuppressive therapy for solid organ transplantation, autoimmune disease, or cerebral metastasis. Thirteen of them experienced colonic perforation and showed higher morbidity (p = 0.039). Immunosuppressed patients showed longer stays in hospital (27.6 v. 14.5 d, p = 0.016) and in the intensive care unit (9.8 v. 1.1 d, p < 0.001), a higher rate of emergency operations (66% v. 29.2%, p = 0.004), and higher in-hospital mortality (20% v. 4.7%, p = 0.045). Age, perforated diverticulitis with diffuse peritonitis, emergency operation, C-reactive protein > 20 mg/dL, and immunosuppressive therapy were significant predictors of death. Age (hazard ratio [HR] 2.57, p = 0.008) and emergency operation (HR 3.03, p = 0.003) remained significant after multivariate analysis.

Conclusion: Morbidity and mortality due to sigmoid diverticulitis is significantly higher in immunosuppressed patients. Early diagnosis and treatment considering elective sigmoid resection for patients with former episodes of diverticulitis who are wait-listed for transplant is crucial to prevent death.

Contexte : Le diagnostic et le traitement des diverticulites sont plus délicats chez les patients immunosupprimés que chez les patients immunocompétents, étant donné que les thérapies immunosuppressives d’entretien peuvent masquer les symptômes ou réduire la capacité du patient à lutter contre les infections locales ou systémiques pouvant découler de la diverticulite. La présente étude avait pour but de comparer les taux de mortalité et de morbidité en milieu hospitalier associés à la diverticulite chez des patients immunosupprimés et immunocompétents et de cerner les facteurs de risque de décès.


Résultats : Parmi les 227 patients retenus, 15 (6,6 %) suivaient une thérapie immunosuppressive en raison d’une greffe d’organe plein, d’une maladie auto-immune ou de métastases cérébrales. Parmi eux, 13 ont subi une perforation du côlon et présentaient un taux de morbidité supérieur (p = 0,039). Les patients immunosupprimés sont restés plus longtemps à l’hôpital (27,6 j c. 14,5 j, p = 0,016) et à l’unité de soins intensifs (9,8 j c. 1,1 j, p < 0,001), et présentaient des taux supérieurs d’intervention d’urgence (66 % c. 29,2 %, p = 0,004) et de mortalité pendant l’hospitalisation (20 % c. 4,7 %, p = 0,045). L’âge, une diverticulite perforée avec péritonite diffuse, une opération d’urgence, un résultat de protéine C réactive > 20 mg/dL et une thérapie immunosuppressive étaient des prédicteurs de décès significatifs. L’âge (rapport de risque [RR] 2,57, p = 0,008) et une opération d’urgence (RR 3,03, p = 0,003) sont demeurés significatifs après l’exécution d’une analyse multivariée.
Sigmoid diverticulitis is a frequent disease in Western countries, and its incidence is rising. Treatment depends on the severity of the disease, which can vary from slightly symptomatic diverticulosis to perforated diverticulitis with fecal peritonitis.

Indications for solid organ and bone marrow transplantation continue to expand, and the number of patients receiving maintenance immunosuppressive therapy for this or other indications, such as autoimmune diseases or cancer, is increasing. Nonetheless, no specific clinical management indications for sigmoid diverticulitis in this subpopulation have yet been found nor have special treatment strategies for these patients been established. In our experience, diagnosis and treatment of diverticulitis in immunosuppressed (IS) patients are more challenging than in immunocompetent (IC) patients, as maintenance immunosuppressive therapies may on one hand mask symptoms and on the other impair the patient’s ability to counteract the local and systemic infective sequelae of diverticulitis. The incidence of free peritoneal perforation or complicated disease is increasing in IS patients compared with IC patients. Since a number of studies have shown high mortality associated with diverticulitis in IS patients, particularly in transplant recipients, clinicians have been inclined to offer elective surgery after a single episode of uncomplicated disease. A recently published study showed similar morbidity and mortality in elective surgery of the colon in kidney transplant recipients, which supports the idea of preventive elective surgery for this high-risk group.

The aim of our study was to investigate morbidity and mortality in IS patients and to evaluate potential risk factors for lethal disease in these patients.

**Methods**

We performed a retrospective study of consecutive patients who received inpatient treatment for colonic diverticulitis in our department between April 2008 and April 2014.

Demographic data, grade of diverticulitis (Hansen/Stock or Hinchey classification), diagnostic methods, antibiotic treatment, change of antibiotic treatment, intervention and operative treatment, maximum C-reactive protein (CRP), number of episodes, immunosuppressive therapy, immunosuppression at admission, reason for immunosuppression, days in the intensive care unit (ICU) and days in hospital, complications (surgical, pulmonary, gastrointestinal, cardiovascular, allergic, urinary tract infection, renal failure, neurologic) and death during hospital stay were assessed by retrospective chart analysis. Smoking habits and number of diverticulitis episodes were assessed at admission by the front-line clinician.

The study population was divided in 2 groups: IS patients undergoing immunosuppressive therapy and IC patients without immunosuppressive medication. Kidney transplant recipients with nonfunctioning grafts and who were not receiving immunosuppression were considered IC patients.

**Inclusion and exclusion criteria**

All adult patients who received inpatient treatment for diverticulitis of grade 1–3 (Hansen/Stock classification) of the sigmoid colon at our department were included. We excluded patients with asymptomatic diverticulosis and patients younger than 18 years.

**Diagnosis and treatment of diverticulitis**

The diagnosis of sigmoid diverticulitis was based on abdominopelvic computed tomography (CT) scan, ultrasound or contrast radiography. The indications for surgery in the emergency, early elective and elective surgery groups were consistent with established international guidelines. An emergency operation was defined as surgery immediately after admission, early elective surgery was defined as surgery within 1 week after admission, and elective surgery was defined as a scheduled admission with programmed surgical resection.

Patients who had diffuse peritonitis or who were deemed to have extensive intraoperative contamination underwent damage control procedures with resection of the perforated colonic segment, open abdomen treatment with insertion of an abdominal vacuum sponge system followed by a second look operation 48 hours later, depending on whether an anastomosis or a colostomy would be performed.

**Primary end point**

The primary end point was in-hospital mortality and morbidity during treatment. Furthermore, potential and known risk factors for death in all patients were analyzed.

**Statistical analysis**

We report categorical variables as frequencies (%) and quantitative variables as means ± standard deviation. We compared IC and IS patients with respect to categorical
variables using the Fisher exact test or the Pearson $\chi^2$ test, while comparisons with respect to quantitative variables were performed using the Wilcoxon rank sum test. We considered results to be significant at $p < 0.05$. Logistic regression analysis was performed using the forward conditional method to test for intervariable relations. Factors that yielded a $p < 0.05$ in univariate analysis were assessed in the logistic regression model using the forward method. Statistical analyses were performed using SPSS software version 22.0 (SPSS, IBM Corp.).

RESULTS

In total, 227 patients received inpatient treatment for diverticulitis during the observation period: 15 IS and 212 IC. The diagnosis of sigmoid diverticulitis was based on abdominopelvic CT scan in 80.6% of the patients, on ultrasound in 8.8%, and on contrast radiography in 9.2%. Fifteen (6.6%) patients were under immunosuppressive medication at the time of hospital admission or after solid organ transplantation. Five patients were treated by oral corticosteroids for vasculitis ($n = 2$), systemic lupus erythematosus ($n = 1$), myelitis of unknown origin ($n = 1$), or cerebral and hepatic metastasis of non–small cell lung cancer ($n = 1$).

All 10 of the transplant recipients were maintained on immunosuppressive therapy perioperatively. Immunosuppressive regimens varied to some degree according to the transplanted organ. Kidney transplant recipients received tacrolimus or cyclosporine, with or without mycophenolate mofetil and steroids. One liver transplant recipient was treated with maintenance tacrolimus only. Four lung transplant recipients received cyclosporin with or without mycophenolate mofetil or azathioprine with or without prednisone.

### Table 1. Patient demographics and parameters comparing immunosuppressed with immunocompetent patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group; no. (%) or mean ± SD</th>
<th>$p$ value</th>
<th>Characteristic</th>
<th>Group; no. (%) or mean ± SD</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>IS ($n = 15$) 10 (66.7)</td>
<td>0.18</td>
<td>Maximum CRP, mg/dL</td>
<td>IC ($n = 212$) 97 (45.8)</td>
<td>0.11</td>
</tr>
<tr>
<td>Age, yr</td>
<td>IS ($n = 15$) 63.4 ± 12.2</td>
<td>0.75</td>
<td>Therapy</td>
<td>IS ($n = 15$) 22.9 ± 10.6</td>
<td>0.11</td>
</tr>
<tr>
<td>Smoker</td>
<td>IS ($n = 15$) 1 (6.7)</td>
<td>0.12</td>
<td>Nonoperative</td>
<td>IC ($n = 212$) 55 (25.9)</td>
<td>0.12</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td>Intervenional (drain)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>IS ($n = 15$) 3 (20.0)</td>
<td>0.18</td>
<td>Operative</td>
<td>IC ($n = 212$) 12 (5.7)</td>
<td>0.18</td>
</tr>
<tr>
<td>COPD</td>
<td>IS ($n = 15$) 0</td>
<td>0.43</td>
<td>Elective</td>
<td>IC ($n = 212$) 90 (42.5)</td>
<td>0.34</td>
</tr>
<tr>
<td>Hypertension</td>
<td>IS ($n = 15$) 5 (33.3)</td>
<td>0.12</td>
<td>Emergency</td>
<td>IC ($n = 212$) 29 (13.7)</td>
<td>0.12</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>IS ($n = 15$) 3 (20.0)</td>
<td>0.19</td>
<td>Abdominal vacuum therapy</td>
<td>IC ($n = 212$) 20 (9.5)</td>
<td>0.19</td>
</tr>
<tr>
<td>Obesity</td>
<td>IS ($n = 15$) 2 (13.3)</td>
<td>0.49</td>
<td>Discharge with anus praeter</td>
<td>IC ($n = 212$) 22 (10.4)</td>
<td>0.49</td>
</tr>
<tr>
<td>Grade of diverticulitis (Hansen/Stock)</td>
<td>IS ($n = 15$)</td>
<td>0.039</td>
<td>Antibiotic switch</td>
<td>IC ($n = 212$)</td>
<td>0.75</td>
</tr>
<tr>
<td>I</td>
<td>IS ($n = 15$) 1 (6.7)</td>
<td>64 (30.2)</td>
<td></td>
<td></td>
<td>IC ($n = 212$) 1 (6.7)</td>
</tr>
<tr>
<td>IIa</td>
<td>IS ($n = 15$) 1 (6.7)</td>
<td>9 (4.2)</td>
<td>Surgical</td>
<td>IS ($n = 15$) 7 (46.7)</td>
<td>74 (34.9)</td>
</tr>
<tr>
<td>IIb</td>
<td>IS ($n = 15$) 1 (6.7)</td>
<td>4 (0.9)</td>
<td>Pulmonary</td>
<td>IS ($n = 15$) 24 (11.3)</td>
<td>0 (0.5)</td>
</tr>
<tr>
<td>IIc</td>
<td>IS ($n = 15$) 0</td>
<td>0 (0.0)</td>
<td>Cardiovascular</td>
<td>IS ($n = 15$) 0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>III</td>
<td>IS ($n = 15$) 0</td>
<td>0 (0.0)</td>
<td>Gastrointestinal</td>
<td>IS ($n = 15$) 0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Diagnostic tool</td>
<td></td>
<td>0.17</td>
<td>Complications*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiography</td>
<td>IS ($n = 15$) 1 (6.7)</td>
<td>2 (0.9)</td>
<td>Allergic</td>
<td>IS ($n = 15$) 1 (6.7)</td>
<td>24 (11.3)</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>IS ($n = 15$) 0</td>
<td>20 (9.4)</td>
<td>Urinary tract infection</td>
<td>IS ($n = 15$) 0</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>CT scan</td>
<td>IS ($n = 15$) 14 (93.3)</td>
<td>169 (79.7)</td>
<td>Renal failure</td>
<td>IS ($n = 15$) 0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Contrast radiography</td>
<td>IS ($n = 15$) 0</td>
<td>18 (8.5)</td>
<td>Neurologic</td>
<td>IS ($n = 15$) 0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>IS ($n = 15$) 0</td>
<td>2 (0.9)</td>
<td>Stay in ICU, d</td>
<td>IS ($n = 15$) 0</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>MRI scan</td>
<td>IS ($n = 15$) 0</td>
<td>1 (5.0)</td>
<td>Return to solid food, d</td>
<td>IS ($n = 15$) 0</td>
<td>1 (5.0)</td>
</tr>
<tr>
<td>No. of episodes</td>
<td></td>
<td>0.32</td>
<td>Discharge, d</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>IS ($n = 15$) 14 (93.3)</td>
<td>158 (76.7)</td>
<td>Death in hospital, no.</td>
<td>IS ($n = 15$) 3 (20.0)</td>
<td>10 (4.7)</td>
</tr>
<tr>
<td>2</td>
<td>IS ($n = 15$) 1 (6.7)</td>
<td>19 (9.2)</td>
<td></td>
<td></td>
<td>IS ($n = 15$) 0</td>
</tr>
<tr>
<td>3</td>
<td>IS ($n = 15$) 0</td>
<td>22 (10.7)</td>
<td></td>
<td></td>
<td>IS ($n = 15$) 0</td>
</tr>
<tr>
<td>4</td>
<td>IS ($n = 15$) 0</td>
<td>4 (1.9)</td>
<td></td>
<td></td>
<td>IS ($n = 15$) 0</td>
</tr>
<tr>
<td>5</td>
<td>IS ($n = 15$) 0</td>
<td>3 (1.5)</td>
<td></td>
<td></td>
<td>IS ($n = 15$) 0</td>
</tr>
</tbody>
</table>

CHD = congestive heart disease; COPD = chronic obstructive pulmonary disease; CRP = C-reactive protein; CT = computed tomography; IC = immunocompetent; ICU = intensive care unit; IS = immunosuppressed; MRI = magnetic resonance imaging; SD = standard deviation.

*Multiple complications possible per patient.
Patient, therapeutic, and diagnostic characteristics are shown in Table 1. Baseline patient characteristics and comorbidities did not differ between IS and IC patients.

**Morbidity and mortality**

A higher rate of complicated diverticulitis (i.e., Hansen/Stock ≥ 2b or Hinchey ≥ 2, \( p = 0.039 \)) and consequentially a higher rate of emergency operations (66.7% v. 29.2%, \( p = 0.004 \)) were observed in IS patients than in IC patients. This resulted in a dramatically longer stay in the ICU (9.8 ± 16.4 d v. 1.2 ± 4.2 d, \( p < 0.001 \)) and a significantly longer hospital stay (27.6 ± 23.5 d v. 14.5 ± 19.9 d, \( p = 0.016 \)). Examining the complication rate during the hospital stay, IS patients experienced pulmonary complications (33.3% v. 4.7%, \( p < 0.001 \)) and renal failure (13.3% v. 1.4%, \( p = 0.002 \)) more frequently than IC patients, whereas urinary tract infections (\( p = 0.55 \)) and surgical (\( p = 0.11 \)), cardiovascular (\( p = 0.05 \)), gastrointestinal (\( p = 0.22 \)), allergic (\( p = 0.71 \)) and neurologic (\( p = 0.64 \)) complications occurred equally in the groups. Four (26.7%) IS patients were discharged with an anus praeter compared with 25 (16.5%) patients in the IC group (\( p = 0.24 \)). Hospital mortality was increased in IS (20%) compared with IC patients (4.7%; \( p = 0.045 \)). A comparison of Hansen/Stock and Hinchey diverticulitis classifications is shown in Table 2.

**Risk factors**

Univariate analysis of potential risk factors associated with in-hospital mortality was statistically significant for age (\( p = 0.008 \)), perforated diverticulitis with diffuse peritonitis (\( p = 0.007 \)), emergency operation (\( p = 0.001 \)), CRP > 20 mg/dL (\( p = 0.049 \)) and immunosuppression (\( p = 0.049 \); Table 3).

Linear regression analysis revealed age (OR 2.57, \( p = 0.008 \)) and emergency operation (OR 3.03, \( p = 0.003 \)) as significant parameters.

**Outcome of IS patients**

Patient characteristics, therapy, and outcome of IS patients are shown in Table 4. Sigmoid perforation developed in 1 patient during the same hospital stay in which lung transplantation was carried out. He died of sepsis as a consequence of anastomotic leakage 2 weeks after transfer to a rehabilitation hospital. Two of the 3 IS patients who died in hospital died during their first episode of diverticulitis. Two of the 5 IS patients treated with anastomosis (40%) (\( p = 0.045 \)). A comparison of Hansen/Stock and Hinchey diverticulitis classifications is shown in Table 2.

### Table 2. Comparison between Hansen/Stock and Hinchey classification

<table>
<thead>
<tr>
<th>Hansen and Stock</th>
<th>Hinchey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diverticulosis</td>
<td>I</td>
</tr>
<tr>
<td>Acute uncomplicated diverticulitis</td>
<td>II</td>
</tr>
<tr>
<td>Acute complicated diverticulitis</td>
<td>III</td>
</tr>
<tr>
<td>Phlegmon, peridiverticulitis</td>
<td>IV</td>
</tr>
<tr>
<td>Abscess, sealed perforation</td>
<td>Pericolic abscess or phlegmon</td>
</tr>
<tr>
<td>Free perforation</td>
<td>Pelvic, intraabdominal or retroperitoneal abscess</td>
</tr>
<tr>
<td>Chronic recurrent diverticulitis</td>
<td>Generalized purulent peritonitis</td>
</tr>
</tbody>
</table>

### Table 3. Univariate and multivariate analysis of factors associated with death in hospital

<table>
<thead>
<tr>
<th>Factor</th>
<th>Univariate; no. (%) or mean ± SD</th>
<th>Multivariate</th>
<th>( p ) value</th>
<th>( OR (95% CI) )</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>62.2 ± 15.3 73.8 ± 10.5</td>
<td>0.008</td>
<td>2.57 (0.001 to 0.004)</td>
<td>0.008</td>
<td></td>
</tr>
<tr>
<td>Male sex</td>
<td>107 (47.1) 7 (6.5)</td>
<td>0.41</td>
<td>0.63 (0.042 to 0.081)</td>
<td>0.95</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>23 (10.1) 1 (4.3)</td>
<td>0.61</td>
<td>−0.45 (−0.123 to 0.077)</td>
<td>0.77</td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td>12 (5.3) 0</td>
<td>0.48</td>
<td>−0.87 (−0.189 to 0.073)</td>
<td>0.74</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>95 (41.9) 5 (3.9)</td>
<td>0.52</td>
<td>0.67 (−0.040 to 0.082)</td>
<td>0.92</td>
<td></td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>23 (10.2) 2 (8.7)</td>
<td>0.39</td>
<td>0.19 (−0.093 to 0.112)</td>
<td>0.74</td>
<td></td>
</tr>
<tr>
<td>CHD</td>
<td>29 (12.8) 1 (3.4)</td>
<td>0.48</td>
<td>−0.14 (−0.106 to 0.092)</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td>Obesity</td>
<td>24 (10.6) 1 (4.2)</td>
<td>0.59</td>
<td>−0.36 (−0.117 to 0.081)</td>
<td>0.49</td>
<td></td>
</tr>
<tr>
<td>Immunosuppression</td>
<td>15 (6.6) 3 (20.0)</td>
<td>0.045</td>
<td>1.85 (−0.007 to 0.232)</td>
<td>0.14</td>
<td></td>
</tr>
<tr>
<td>Solid organ transplant</td>
<td>10 (4.4) 2 (20.0)</td>
<td>0.11</td>
<td>−0.01 (−0.252 to 0.252)</td>
<td>0.95</td>
<td></td>
</tr>
<tr>
<td>Emergency operation</td>
<td>72 (31.7) 10 (13.9)</td>
<td>0.001</td>
<td>3.03 (0.035 to 0.163)</td>
<td>0.003</td>
<td></td>
</tr>
<tr>
<td>Hansen/Stock &gt; 2b</td>
<td>47 (20.7) 7 (14.9)</td>
<td>0.007</td>
<td>1.51 (−0.017 to 0.128)</td>
<td>0.18</td>
<td></td>
</tr>
<tr>
<td>CRP &gt; 20 mg/dL</td>
<td>95 (41.9) 9 (5.9)</td>
<td>0.049</td>
<td>−0.12 (−0.086 to 0.075)</td>
<td>0.88</td>
<td></td>
</tr>
</tbody>
</table>

CHD = congestive heart disease; CI = confidence interval; COPD = chronic obstructive pulmonary disease; CRP = C-reactive protein; OR = odds ratio; SD = standard deviation.
### Table 4. Descriptive data, therapy and outcome of immunosuppressed patients

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age, yr</th>
<th>Organ</th>
<th>Years after Tx</th>
<th>Hansen/Stock</th>
<th>Operative therapy</th>
<th>Damage control</th>
<th>No. episodes</th>
<th>IS therapy</th>
<th>Underlying disease</th>
<th>Complication</th>
<th>Days in ICU</th>
<th>Discharge day</th>
<th>Death in hospital</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>87</td>
<td>—</td>
<td>—</td>
<td>IIc</td>
<td>1) Sigmoid resection 2) Descendostomy</td>
<td>Yes</td>
<td>1</td>
<td>Methylprednisolone</td>
<td>Arteritis temporalis</td>
<td>Pneumonia</td>
<td>2</td>
<td>14</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>53</td>
<td>—</td>
<td>—</td>
<td>IIb</td>
<td>Hartmann procedure</td>
<td>No</td>
<td>1</td>
<td>Methylprednisolone</td>
<td>Myelitis unknown origin</td>
<td>Wound infection</td>
<td>0</td>
<td>42</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>42</td>
<td>—</td>
<td>—</td>
<td>IIb</td>
<td>1) Sigmoid resection 2) Colorectostomy</td>
<td>Yes</td>
<td>1</td>
<td>Methylprednisolone</td>
<td>SLE</td>
<td>—</td>
<td>0</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>79</td>
<td>—</td>
<td>—</td>
<td>IIb</td>
<td>1) Sigmoid resection 2) Colorectostomy</td>
<td>Yes</td>
<td>1</td>
<td>Methylprednisolone</td>
<td>Cerebral vasculitis</td>
<td>—</td>
<td>1</td>
<td>14</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>72</td>
<td>—</td>
<td>—</td>
<td>IIb</td>
<td>—</td>
<td>—</td>
<td>2</td>
<td>Dexamethasone</td>
<td>NSCLC cerebral, hepatic metastasis</td>
<td>—</td>
<td>0</td>
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</tr>
<tr>
<td>6</td>
<td>71</td>
<td>Kidney</td>
<td>4</td>
<td>IIb</td>
<td>1) Sigmoid resection 2) Colorectostomy, loop ileostomy</td>
<td>Yes</td>
<td>1</td>
<td>Tacrolimus, MMF, prednisolone</td>
<td>Kidney transplant</td>
<td>Sepsis, pleural effusion</td>
<td>4</td>
<td>87</td>
<td>Yes</td>
</tr>
<tr>
<td>7</td>
<td>47</td>
<td>Kidney</td>
<td>13–18</td>
<td>IIb</td>
<td>—</td>
<td>—</td>
<td>1</td>
<td>Tacrolimus, MMF, prednisolone</td>
<td>Kidney transplant</td>
<td>Acute renal failure</td>
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<td>7</td>
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</tr>
<tr>
<td>8</td>
<td>55</td>
<td>Kidney</td>
<td>9</td>
<td>IIb</td>
<td>Laparotomy, drainage</td>
<td>No</td>
<td>1</td>
<td>Cyclosporine, prednisolone</td>
<td>Kidney transplant</td>
<td>Forrest Ia bleeding stomach</td>
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<td>34</td>
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</tr>
<tr>
<td>9</td>
<td>76</td>
<td>Kidney</td>
<td>0.5</td>
<td>IIc</td>
<td>1) Lavage, suture 2) Sigmoid resection colorectostomy</td>
<td>Yes</td>
<td>1</td>
<td>Cyclosporine, MMF, prednisolone</td>
<td>Kidney transplant</td>
<td>—</td>
<td>35</td>
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<tr>
<td>10</td>
<td>55</td>
<td>Kidney</td>
<td>18</td>
<td>IIc</td>
<td>1) Sigmoid resection 2) Descendostomy</td>
<td>Yes</td>
<td>1</td>
<td>Hydrocortisone</td>
<td>Kidney transplant</td>
<td>Anastomotic leakage</td>
<td>39</td>
<td>57</td>
<td>No</td>
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<tr>
<td>11</td>
<td>58</td>
<td>Kidney</td>
<td>23–30</td>
<td>Ila</td>
<td>—</td>
<td>—</td>
<td>1</td>
<td>Cyclosporine, prednisolone</td>
<td>Kidney transplant</td>
<td>—</td>
<td>0</td>
<td>6</td>
<td>No</td>
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<tr>
<td>12</td>
<td>67</td>
<td>Liver</td>
<td>11</td>
<td>I</td>
<td>—</td>
<td>—</td>
<td>1</td>
<td>Tacrolimus</td>
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<td>13</td>
<td>62</td>
<td>Lung</td>
<td>2</td>
<td>IIb</td>
<td>Hartmann procedure</td>
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<td>1</td>
<td>Cyclosporin</td>
<td>Lung transplant</td>
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<tr>
<td>14</td>
<td>60</td>
<td>Lung</td>
<td>0.1</td>
<td>IIb</td>
<td>1) Sigmoid resection, descenderecostomy 2) Hartmann procedure</td>
<td>No</td>
<td>1</td>
<td>Cyclosporin, azathioprine, methylprednisolone</td>
<td>Lung transplant</td>
<td>Anastomotic leakage</td>
<td>1</td>
<td>38</td>
<td>No*</td>
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<tr>
<td>15</td>
<td>64</td>
<td>Lung</td>
<td>0.6</td>
<td>Ila</td>
<td>1) Sigmoid resection 2) Descendostomy</td>
<td>No</td>
<td>1</td>
<td>Cyclosporin, MMF</td>
<td>Lung transplant</td>
<td>Pneumonia</td>
<td>41</td>
<td>41</td>
<td>Yes</td>
</tr>
</tbody>
</table>

ICU = intensive care unit; IS = immunosuppression; MMF = mycophenolate mofetil; NSCLC = non–small cell lung cancer; SLE = systemic lupus erythematosus; Tx = transplant.

*Patient died 2 weeks after transfer to rehabilitation hospital.
experienced an anastomotic leakage after colorectostomy compared with 9 of 97 IC patients treated with anastomosis (9.3%, \( p = 0.031 \)) and were treated with colostomy.

**DISCUSSION**

Immunosuppressed patients show an increased incidence of diverticulitis (1%) compared with the general population (0.02%).\(^{13}\) Studies have shown that among patients with diverticulosis diagnosed before transplantation, about 16% of cases developed under immunosuppression.\(^{14}\)

We show that not only is the incidence of diverticulitis in these patients increased, the severity of the disease is also much higher than in the non-IS population, and the consequences are life threatening. Immunosuppression and steroid intake are known risk factors for perforated diverticulitis.\(^{15,16}\)

Given the fatal outcome of diverticulitis in IS patients, there is a need to reconsider a strategy to reduce mortality. First, it is crucial to establish the correct diagnosis as soon as possible. Most common symptoms, such as abdominal pain, abdominal tenderness and leukocytosis with or without fever, should immediately lead to a CT scan to distinguish complicated from uncomplicated diverticular disease. A CT scan is the tool that best directs treatment during the initial acute episode of diverticulitis and is less subject to operator interpretation than an ultrasound.\(^{17}\) Early diagnosis guides prompt therapy and is the most important variable at disease onset, particularly for IS patients.

Second, the question arises whether elective surgical resection of the sigmoid colon should be recommended in high-risk IS patients. Our findings are consistent with data published by others,\(^{1,18}\) thus we suggest that the guidelines and recent recommendations for the treatment of complicated diverticulosis\(^{11,19}\) should specify that recurrent and chronic diverticulitis be indications for elective sigmoid resection and should not be applied for patients under immunosuppression regimes.

In these patients, diverticulosis per se may be the indication for elective surgery, considering that emergency operations occur in 80%–90% at the first episode.\(^{20}\) This thesis is underlined by several other studies, which have shown that complicated diverticulitis most commonly occurred during the first episode rather than during recurrent episodes.\(^{21–23}\) Therefore, the aim in IS patients is to avoid diverticulitis. Smoking and obesity are known to increase the incidence of diverticulitis and complicated diverticulitis\(^{24–27}\); in contrast physical activity prevents diverticulitis and reduces the risk of complicated diverticulitis.\(^{28,29}\) The effects of nutrition habits on diverticulitis are controversial.\(^{30–32}\) In contrast to lifestyle changes, operative therapies for diverticulitis seem effective because they are independent of patients’ compliance. Several studies have shown that a “prophylactic” sigmoid resection can prevent future episodes of diverticulitis and emergency colostomy.\(^{7,13}\) However, no such data are available for IS patients. The question that remains unanswered is whether or not to perform a sigmoidectomy, given that the rate of recurrent hospitalizations for patients with diverticulitis after nonoperative management (4%–13%)\(^{34}\) is comparable to the rate in those who have had a colectomy (5%–11%).\(^{15}\) Certainly, the risk for anastomotic leakage must be counterbalanced by the benefits of lowering the risk of diverticulitis. Reshef and colleagues\(^{35}\) showed in a case-matched comparison that there was similar morbidity (29%) and mortality (0%) in IS kidney transplant recipients \((n = 14)\) and the IC control group. A 1%–3% risk of anastomotic failures requiring “rescue colostomy” persists in elective surgery.\(^{36,37}\) In contrast, in terms of comparable risks in elective surgery, Krysa and colleagues\(^{38}\) showed that emergency colorectal surgery in patients who received renal replacement therapy resulted in an 81% overall complication rate, mortality of 26% and a substantial anastomotic leakage rate of 71% for primary anastomosis. Our study confirms the increased anastomotic leakage rate after emergency operations and suggests performing a protective loop ileostomy in case of colorectostomy.

Thus, we suggest that elective surgery should be carried out before the development of diverticulitis and probably before immunosuppression; however, this may not be feasible in patients wait listed for liver transplantation, as cirrhosis and portal hypertension are associated with a higher risk (up to 53%) of anastomotic leakage and postoperative mortality mainly due to postoperative infections.\(^{39,40}\) There is a lack of data on liver transplant recipients and diverticulitis, which suggests that this condition is rare and could be explained by the relatively low and often steroid-free immunosuppression necessary in these patients compared with recipients of other solid organ transplants.

In patients wait listed for renal transplantation the perioperative risk in those undergoing colorectal surgery is elevated. Stewart and colleagues\(^{41}\) showed in a large nationwide in-patient sample database that kidney transplant recipients experienced significantly fewer complications and had lower morbidity and mortality after colorectal surgery than patients with end-stage renal disease. Interestingly, Halabi and colleagues\(^{42}\) showed that the risk of anastomotic leakage in kidney transplant recipients in elective colorectal surgery was equal to that of the general population, whereas acute renal failure, wound complications, and mortality were higher. Summing up published data, the best time point to carry out elective colorectal surgery is after kidney transplantation, but before diverticulitis.

For those patients wait listed for lung or heart transplantation, the perioperative risk should likewise be assessed carefully. The incidence of acute diverticulitis in heart transplant patients is described to be between 1.4% and 4.2%.\(^{1,2}\) A comparable, but slightly lower incidence of 0.7%–1.4% has been reported for lung transplant recipients.\(^{44}\) Diverticulitis in lung transplant recipients occurs
early, most likely in the first 2 years after transplantation, due to high levels of immunosuppression. These results could be confirmed by our study.

For patients requiring immunosuppression for non-transplant reasons, similarly, the best time point for elective resection should be determined depending on the intensity of immunosuppression.

Several authors have proposed screening for diverticular disease in patients as part of the pretransplant evaluation process, though McCune and colleagues showed that pretransplantation colonic screening of patients older than 50 years was ineffective in predicting post-transplantation colonic complications.

**Limitations**

Our study was limited by its retrospective design and by the small group of IS patients (n = 15) in a total of 227 patients. Thus, a multivariate analysis of potential risk factors for inhospital mortality in this small cohort was not conclusive. Furthermore, we were not able to draw a conclusion regarding the type and adjustment of immunosuppressive medication affecting morbidity and mortality due to diverticulitis in these patients given the small sample size.

Comparing the results of the multivariate analysis with the findings of previously published studies, we confirmed an independent risk factor for death. Emergency operation increases the risk of death by more than 3 times in patients with colonic resection and is performed in patients with perforated diverticulitis and peritonitis only.

**Conclusion**

Based on our findings and previously published results, it is difficult to make general recommendations on screening and treatment of diverticular disease in IS patients. Our study confirms the fatal outcome of diverticulitis in IS patients and underlines the importance of early diagnosis, including CT scan, and therapy given that in many cases the first episode of diverticulitis can be lethal.

Common guidelines for IC patients may not apply for IS patients, and the decision for elective sigmoid resection to prevent fatal outcomes due to sigmoid diverticulitis must be made individually based on additional risk factors and on an ideal time point for intervention.

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**Competing interests:** None declared.

**Contributors:** A. Brandl, R. Kafka-Ritsch, J. Pratschke and R. Ollinger designed the study. A. Brandl, T. Kratzer, A. Braunwarth, S. Weiss, M. Bielbl and F. Aignr analyzed the data, which A. Brandl, T. Kratzer, R. Kafka-Ritsch, C. Denecke, S. Weiss, G. Atanasov, R. Sucher, M. Bielbl and F. Aignr analyzed. A. Brandl wrote the article, which all authors reviewed and approved for publication.

**References**


Comparison of robotic and laparoscopic colorectal resections with respect to 30-day perioperative morbidity

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Ahmad Elnahas, MD, MSc
Shaheena Bashir, PhD
Michelle C. Cleghorn, MSc
Fayez A. Quereshy, MD, MBA

Background: Robotic surgery has emerged as a minimally invasive alternative to traditional laparoscopy. Robotic surgery addresses many of the technical and ergonomic limitations of laparoscopic surgery, but the literature regarding clinical outcomes in colorectal surgery is limited. We sought to compare robotic and laparoscopic colorectal resections with respect to 30-day perioperative outcomes.

Methods: The American College of Surgeons National Surgical Quality Improvement Program database was used to identify all patients who underwent robotic or laparoscopic colorectal surgery in 2013. We performed a logistic regression analysis to compare intraoperative variables and 30-day outcomes.

Results: There were 8392 patients who underwent laparoscopic colorectal surgery and 472 patients who underwent robotic colorectal surgery. The robotic cohort had a lower incidence of unplanned intraoperative conversion (9.5% v. 13.7%; \(p = 0.008\)). There were no significant differences between robotic and laparoscopic surgery with respect to other intraoperative and postoperative outcomes, such as operative duration, length of stay, postoperative ileus, anastomotic leak, venous thromboembolism, wound infection, cardiac complications and pulmonary complications. On multivariable analysis, robotic surgery was protective for unplanned conversion, while male sex, malignancy, Crohn disease and diverticular disease were all associated with open conversion.

Conclusion: Robotic colorectal surgery has comparable 30-day perioperative morbidity to laparoscopic surgery and may decrease the rate of intraoperative conversion in select patients.

Contexte : La chirurgie robotique est de plus en plus utilisée comme option de rechange peu effractive à la laparoscopie classique. La robotique permet de remédier à bon nombre des restrictions techniques et ergonomiques de la chirurgie laparoscopique, mais peu d’articles font état des résultats cliniques en chirurgie colorectale. Nous avons donc cherché à comparer les 2 techniques de résection colorectale en ce qui concerne les résultats peropératoires dans les 30 jours suivant l’intervention.

Méthodes : À l’aide de base de données du National Surgical Quality Improvement Program de l’American College of Surgeons, nous avons recensé tous les patients ayant subi une résection colorectale par chirurgie laparoscopique ou robotique en 2013. Nous avons ensuite mené une analyse de régression logistique pour comparer des variables peropératoires et les résultats après 30 jours.

Résultats : En tout, 8392 patients avaient subi une chirurgie colorectale par laparoscopie pendant la période visée, et 472 avaient subi une intervention par chirurgie robotique. Le second groupe avait une incidence plus faible de conversion peropératoire imprévue (9,5 % par rapport à 13,7 %; \(p = 0.008\)). On n’a relevé aucune différence significative entre les 2 types d’intervention quant aux autres résultats peropératoires et postopératoires, soit la durée de l’intervention, la durée du séjour à l’hôpital et la survenue d’un iléus, d’une fuite anastomotique, d’une thromboembolie veineuse, d’une infection de la plaie ou de complications cardiovasculaires ou pulmonaires. D’après l’analyse multivariables, la chirurgie robotique préviendrait les conversions imprévues, tandis que le sexe masculin, la présence d’une tumeur maligne, la maladie de Crohn et la diverticulose colique étaient associés à une conversion peropératoire.

Conclusion : Les taux de morbidité peropératoire après 30 jours pour une résection colorectale par chirurgie robotique et une intervention par chirurgie laparoscopique sont comparables. La chirurgie robotique pourrait de plus réduire le taux de conversion peropératoire chez certains patients.
The use of minimally invasive techniques in colorectal surgery is generally regarded as a safe and feasible modality with a shorter postoperative recovery time.1–4 However, laparoscopic procedures can be technically and physically challenging to perform, necessitating conversion to open approaches, particularly for rectal resections.5,7 Moreover, 2 recent randomized trials have not been able to establish that laparoscopic surgery is not inferior to open techniques.6,7 When the da Vinci Surgical System was approved for patient use in 2000, it helped address some of the ergonomic limitations of laparoscopic surgery.8 Many of the reported advantages of the robotic platform are linked to the increased instrument dexterity and degrees of articulation.9 However, it remains unclear whether these advantages translate into improved clinical outcomes.

The literature surrounding robotic colorectal surgery is limited and mostly consists of case series from individual institutions.10–12 Prior studies have demonstrated that robotic surgery is feasible and safe13,14,15,16,17,18 but may be associated with higher cost and longer operative duration, particularly for rectal resections.16,17 Given the single-centre reporting bias present in much of the literature, there is a need for research using multi-institutional data. The objective of our study was to compare robotic and laparoscopic colorectal resections with respect to perioperative clinical outcomes.

Methods

Data sources

We used the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) participant use files (PUF) to obtain information on all robotic and laparoscopic colorectal resections performed in 2013. The ACS-NSQIP database is a validated program that prospectively collects preoperative, intraoperative, and 30-day outcome data from participating hospitals across North America and abroad.22,23

We used the ACS-NSQIP colon-targeted file to identify all patients who underwent a robotic or laparoscopic colorectal resection based on the following Current Procedural Terminology (CPT) codes: 44204–12, 44140–7, 44150, 44155, 44157–8 and 44160. We excluded patients who underwent a combined approach that involved open techniques. Similarly, we excluded abdominal-perineal resections. We merged selected cases from the colon-targeted database with the general ACS-NSQIP main database using the unique CASEID to collect all relevant demographic, intraoperative, and postoperative information. We performed an additional subgroup analysis for rectal procedures to compare the 2 modalities in patients undergoing pelvic resections. We used the CPT codes 44145, 44146, 44147, 44207 and 44208 to classify rectal resections for the subgroup analysis. The study protocol was approved by the Research Ethics Board of The University Health Network, Toronto, Canada.

Outcome measures

Our outcomes of interest included intraoperative variables, such as operative duration, conversion rate, and transfusion requirements. Postoperative complications included ileus, anastomotic leak, pulmonary embolism, myocardial infarction, pneumonia, superficial site infection and urinary tract infection. We also analyzed overall length of stay, unplanned readmissions, reoperations and 30-day mortality.

Statistical analysis

We performed an exploratory series of univariate analyses to compare the 2 cohorts with respect to patient demographics and study outcomes. Converted cases were analyzed based on the initial approach (i.e., intention-to-treat analysis). We used a Student t test to test mean differences across groups for continuous variables and a χ² test or Fisher exact test where appropriate for categorical variables. We also conducted a subgroup analysis of rectal resections and performed a multivariable analysis for outcomes that were found to be significantly different in the univariate regression, to adjust for potential cofounders. Regardless of statistical significance, all factors that were likely to have clinical influence on the outcome of interest were included in the multivariable model. All data analyses were carried out using SAS software version 9.4 (SAS Institute).

Results

A total of 472 robotic and 8392 laparoscopic colorectal resections were identified from the ACS-NSQIP database. Demographic and surgical characteristics as well as 30-day outcomes for all patients who underwent either a colon or rectal resection are compared in Table 1. The groups were similar in terms of age, sex, body mass index (BMI), comorbidities and functional status. In the robotic group, more patients underwent surgery for a cancer diagnosis than for other indications (p < 0.001). There was no difference between the robotic and laparoscopic approach in operative duration (190 v. 187 min, p = 0.48) or requirement for blood transfusion (8.1% v. 7.4%, p = 0.59). Of note, there was a significantly lower incidence of unplanned conversion to an open procedure within the robotic group (9.5% v. 13.7%, p = 0.008). There were no significant differences in any of the postoperative outcomes studied. The incidences of ileus (9.4% v. 10.5%, p = 0.49), anastomotic leak (3.8% v. 3.1%, p = 0.34), venous thromboembolism (0.9% v. 1.1%, p = 0.82), wound infection (4.8% v. 5.8%, p = 0.47), cardiac complication (0.6% v. 0.4%, p = 0.45), and pulmonary complication (1.9% v. 1.0%, p = 0.06) were similar between the 2 groups.

We compared patients who underwent a rectal resection in a separate subgroup analysis (Table 2). There were
79 robotic rectal resections and 1370 laparoscopic rectal resections. There was no significant difference in any of the baseline patient characteristics. In terms of perioperative outcomes, no difference was observed in operative duration, requirement for blood transfusion, or rate of unplanned conversion. However, with respect to 30-day outcomes, robotic rectal resections had a lower incidence of ileus than laparoscopy (3.80% vs. 11.18%, \( p = 0.039 \)).

Given that unplanned conversion to an open approach was the only significant variable on univariate analysis, we developed a subsequent multivariable model to identify independent factors associated with conversion (Table 3). While male sex (odds ratio [OR] 1.143, \( p = 0.038 \)), colon cancer (OR 1.810, \( p < 0.001 \)), Crohn disease (2.194, \( p < 0.001 \)) and diverticular disease (OR 1.980, \( p < 0.001 \)) were all associated with an increased incidence of conversion on multivariable analysis, robotic surgery was found to be protective against unplanned conversion when compared with laparoscopic surgery (OR 0.713, \( p = 0.035 \)). Ulcerative colitis was not significantly associated with unplanned conversion. Similarly, age older than 60 years, BMI greater than 30, American Society of Anesthesiologists (ASA) classification greater than 3, intraoperative transfusion and operative duration did not appear to increase the risk of conversion. A Forest plot illustrates the results of the multivariable model (Fig. 1).

**Discussion**

Whether robotic surgery offers improved clinical outcomes over laparoscopic surgery remains controversial. In the present study, we found that robotic surgery was associated with a decreased incidence of conversion. We found no significant difference in operative duration between the robotic and laparoscopic approaches. Moreover, we found no difference in any 30-day postoperative complications between the 2 modalities. In the subgroup analysis of rectal resections, robotic surgery was associated with a decreased incidence of ileus.

Our results support the finding from a recent series that demonstrated robotic surgery had a lower incidence of unplanned conversion to open procedures than laparoscopic surgery.\(^{19}\) Given that our study was nonrandomized, potential selection bias between patients who received robotic surgery versus laparoscopic surgery may have influenced this finding. For this reason, we performed a multivariate analysis to further inform what factors were independently associated with conversions. Upon further analysis, we found that several factors were independently associated with unplanned conversions, including male sex, malignancy and most inflammatory diseases of the colon. In patients with these risk factors, the benefit of robotic surgery may be substantial. In our subgroup analysis of rectal resections, we did not observe a significant difference in the conversion rate. Given the sample size, this finding may reflect the low event rate rather than meaningful clinical differences in the operative approach. Other published series have supported the

<table>
<thead>
<tr>
<th>Table 1. Comparison of robotic versus laparoscopic colon and rectal resection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristic</td>
</tr>
<tr>
<td>-------------------------------</td>
</tr>
<tr>
<td>Indication for surgery</td>
</tr>
<tr>
<td>Diverticular disease</td>
</tr>
<tr>
<td>Crohn disease</td>
</tr>
<tr>
<td>Ulcerative colitis</td>
</tr>
<tr>
<td>Colon cancer</td>
</tr>
<tr>
<td>Nonmalignant polyp</td>
</tr>
<tr>
<td>Site of surgery</td>
</tr>
<tr>
<td>Colon</td>
</tr>
<tr>
<td>Rectal</td>
</tr>
<tr>
<td>Comorbidities</td>
</tr>
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<td>ASA class ≥ 3</td>
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<tr>
<td>Bleeding disorder</td>
</tr>
<tr>
<td>Renal failure</td>
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<tr>
<td>COPD</td>
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<tr>
<td>CHF</td>
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<td>Smoker</td>
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<td>Functional status</td>
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<td>Totally dependent</td>
</tr>
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</tr>
<tr>
<td>Intraoperative outcomes</td>
</tr>
<tr>
<td>Operative duration, min*</td>
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<tr>
<td>Conversion to open</td>
</tr>
<tr>
<td>Intraoperative transfusion</td>
</tr>
<tr>
<td>Postoperative complications</td>
</tr>
<tr>
<td>Ileus</td>
</tr>
<tr>
<td>Anastomotic leak</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
</tr>
<tr>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>Pneumonia</td>
</tr>
<tr>
<td>Superficial site infection</td>
</tr>
<tr>
<td>Urinary tract infection</td>
</tr>
<tr>
<td>LOS, d*</td>
</tr>
<tr>
<td>Unplanned readmission</td>
</tr>
<tr>
<td>Unplanned reoperation</td>
</tr>
<tr>
<td>30-d mortality</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; BMI = body mass index; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; LOS = length of stay; SD = standard deviation.

*Student t test.
benefit of robotic surgery in rectal resections with regards to conversion.\textsuperscript{25,26} Preliminary results of the Robotic Versus Laparoscopic Resection for Rectal Cancer (ROLARR) randomized control trial did not show a statistically significant difference in conversion rates between the 2 modalities overall.\textsuperscript{27} However, subgroup analysis supported a benefit with the robotic approach for male patients, obese patients, and those with lower tumours. It is difficult to assess whether the difference in conversion rate with robotic surgery warrants widespread adoption of this technique given the increased cost. Ramji and colleagues\textsuperscript{28} report on a Canadian series comparing robotic, laparoscopic and open rectal cancer resections. They found an incremental cost difference of approximately $6000 per case for robotic resections versus either laparoscopic or open resections. Robotic surgery may become less financially prohibitive in the future, as new platforms are expected to make costs more competitive.

In our study, we found no difference in operative durations, as has been reported in other recent publications.\textsuperscript{24,25} Earlier experiences with robotic resections reported significantly increased operative durations compared with laparoscopic surgery, representing a major limitation of the modality.\textsuperscript{29} The often reported longer duration associated with robotic surgery is likely explained by the port placement and robot docking. With increased use of robotic surgery, it is possible to overcome this learning curve and have comparable operative durations.

Bhama and colleagues\textsuperscript{30} recently published a report using the ACS-NSQIP database to compare all robotic and laparoscopic colorectal surgeries. That study compared aggregated results for a multitude of procedures, including formation of colostomy, rectopexy and other surgeries that did not involve resections. It is difficult to interpret results from this comparison of a wide variety of procedures. Our study was limited to colorectal resections without hybrid approaches in order to better characterize the effect of a robotic approach. Bhama and colleagues\textsuperscript{30} found that robotic surgery was associated with longer operating duration. Nonresectional surgery includes a variety of smaller procedures that may not

### Table 2. Comparison of robotic versus laparoscopic rectal resection

<table>
<thead>
<tr>
<th>Group; no. (%) or mean ± SD</th>
<th>Robotic ((n = 79))</th>
<th>Laparoscopic ((n = 1370))</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr* (\pm 15.8)</td>
<td>58.5 ± 15.8</td>
<td>59.1 ± 13.7</td>
<td>0.84</td>
</tr>
<tr>
<td>Male sex</td>
<td>33 (44.30)</td>
<td>613 (44.74)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>BMI* (\pm 7.27)</td>
<td>29.42 ± 7.27</td>
<td>28.73 ± 7.07</td>
<td>0.717</td>
</tr>
<tr>
<td>Indication for surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diverticular disease</td>
<td>24 (30.38)</td>
<td>341 (24.89)</td>
<td>0.10</td>
</tr>
<tr>
<td>Crohn disease</td>
<td>2 (2.53)</td>
<td>78 (5.69)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Ulcerative colitis</td>
<td>0</td>
<td>39 (2.85)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Colon cancer</td>
<td>37 (46.84)</td>
<td>536 (39.12)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Nonmalignant polyp</td>
<td>11 (13.92)</td>
<td>179 (13.07)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Other</td>
<td>5 (6.33)</td>
<td>197 (14.38)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA class &gt; 3</td>
<td>34 (44.74)</td>
<td>631 (46.98)</td>
<td>0.73</td>
</tr>
<tr>
<td>Bleeding disorder</td>
<td>2 (2.53)</td>
<td>33 (2.41)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Renal failure</td>
<td>0</td>
<td>2 (0.15)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>COPD</td>
<td>1 (1.27)</td>
<td>52 (3.80)</td>
<td>0.36</td>
</tr>
<tr>
<td>CHF</td>
<td>0</td>
<td>1 (0.07)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Hypertension</td>
<td>33 (41.77)</td>
<td>602 (43.94)</td>
<td>0.73</td>
</tr>
<tr>
<td>Diabetes</td>
<td>9 (11.39)</td>
<td>165 (12.04)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Smoker</td>
<td>13 (16.46)</td>
<td>288 (21.02)</td>
<td>0.39</td>
</tr>
<tr>
<td>Steroid use</td>
<td>5 (6.33)</td>
<td>108 (7.88)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Functional status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent</td>
<td>79 (100)</td>
<td>1350 (98.54)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Partially dependent</td>
<td>0</td>
<td>14 (1.02)</td>
<td></td>
</tr>
<tr>
<td>Totally dependent</td>
<td>0</td>
<td>2 (0.15)</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>4 (0.29)</td>
<td></td>
</tr>
</tbody>
</table>

### Table 3. Multivariable analysis for unplanned conversion in colon and rectal resection

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Referent</th>
<th>OR (95% CI)</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robotic approach</td>
<td>Laparoscopic approach</td>
<td>0.713 (0.521–0.977)</td>
<td>0.035</td>
</tr>
<tr>
<td>Male sex</td>
<td>Female sex</td>
<td>1.143 (1.008–1.296)</td>
<td>0.038</td>
</tr>
<tr>
<td>Age &gt; 60 yr</td>
<td>(\leq 60)</td>
<td>0.961 (0.843–1.094)</td>
<td>0.54</td>
</tr>
<tr>
<td>BMI &gt; 30</td>
<td>(\leq 30)</td>
<td>0.934 (0.817–1.068)</td>
<td>0.32</td>
</tr>
<tr>
<td>Colon cancer</td>
<td>Nonmalignant polyp</td>
<td>1.810 (1.424–2.300)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Crohn disease</td>
<td>Nonmalignant polyp</td>
<td>2.194 (1.585–3.037)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Diverticular disease</td>
<td>Nonmalignant polyp</td>
<td>1.980 (1.542–2.542)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Other</td>
<td>Nonmalignant polyp</td>
<td>2.865 (2.215–3.706)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Ulcerative colitis</td>
<td>Nonmalignant polyp</td>
<td>1.327 (0.822–2.141)</td>
<td>0.25</td>
</tr>
<tr>
<td>Intraoperative transfusion</td>
<td>None</td>
<td>1.093 (0.856–1.396)</td>
<td>0.47</td>
</tr>
<tr>
<td>Operative duration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA class &gt; 3</td>
<td>(\leq 3)</td>
<td>1.001 (1.000–1.001)</td>
<td>0.50</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; BMI = body mass index; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; LOS = length of stay; SD = standard deviation.

*Student t test.

ASA = American Society of Anesthesiologists; BMI = body mass index; CI = confidence interval; OR = odds ratio.
warrant a robotic approach. Comparison of operative durations over a multitude of procedures is problematic, given a selection bias for one modality over another, depending on the procedure. When we compared only the resections, we did not find a significant difference in operative durations. Furthermore, Bhama and colleagues\(^\text{30}\) reported a significantly shorter length of stay in patients who underwent robotic surgery. Again, this finding is difficult to interpret given that comparison was made over a broad range of procedures. In our analysis of colon and rectal resections, we did not find any difference in length of stay between the 2 groups. Both studies report a decreased rate of conversion with robotic surgery in select patients.

**Limitations**

There are several important limitations to consider in our study. As a retrospective nonrandomized analysis, our study cannot eliminate potential selection bias. Patients may be preferentially selected for either robotic or laparoscopic procedures based on the anticipated degree of difficulty with the resection. As robotic surgery has been proposed to address some of the ergonomic and anatomic difficulties encountered in laparoscopic surgery, challenging cases may be preferentially performed robotically. In other situations, the choice of surgical modality may be motivated by patient preference or financial considerations. We chose to use the ACS-NSQIP database as it includes a variety of demographic variables and pre-existing patient comorbidities. This enabled us to mitigate selection bias by adjusting for clinically relevant variables with a multivariable analysis. Moreover, the variables collected by ACS-NSQIP have standardized definitions but do not provide details for the individual cases. In particular, a standard definition of the operating procedure is not available. Possible variations in the operative approach may include open components or a combination of robotic and laparoscopic surgery. We attempted to minimize this effect by excluding all patients who underwent procedures with a planned open component, but there are likely more subtle differences in operative procedure that were not captured. Furthermore, ACS-NSQIP data do not enable identification of institutional characteristics or surgeon experience, both of which may influence patient outcomes. Surgeon experience has been highly correlated with rates of conversion to open procedures.\(^\text{30}\) It is possible that the group of surgeons performing robotic surgery are proportionally more proficient in minimally invasive surgery, influencing the finding that robotic surgery is associated with a lower rate of conversion.

**Conclusion**

We found that robotic colorectal resection has comparable 30-day perioperative morbidity relative to laparoscopic surgery. In certain patients, robotic resection may have a lower rate of unplanned conversion to an open procedure. Given that our study focused on short-term outcomes, it is possible differences between the 2 techniques may be related to long-term outcomes, such as sexual and urinary function. There is a need for a randomized control trial to definitively compare robotic and laparoscopic modalities in terms of both short-term perioperative outcomes and long-term results.

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**Competing interests:** None declared.

**Contributors:** A. Feinberg, M. Cleghorn and F. Quereshy designed the study. A. Feinberg and A. Elnahas acquired the data, which S. Bashir and F. Quereshy analyzed. A. Feinberg wrote the article, which all authors reviewed and approved for publication.

**References**


Attitudes and beliefs about the surgical safety checklist: Just another tick box?

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Accepted for publication Apr. 26, 2016

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DOI: 10.1503/cjs.002016

Background: Following a landmark study showing decreased morbidity and mortality after implementation of the surgical safety checklist (SSC), it has been widely adopted into perioperative policy. We explored the impact of attitudes and beliefs surrounding the SSC on its uptake in Calgary.

Methods: We used qualitative methodology to examine factors influencing SSC use. We performed semistructured interviews based on Rogers’ theory of diffusion of innovation. Purposive and snowball sampling were used to identify surgeons, anesthesiologists and operating room nurses from hospitals in Calgary. Data collection and analysis were based on grounded theory. Two individuals jointly analyzed data and achieved consensus on emerging themes.

Results: Generated themes included 1) the SSC has brought organization to previous informal perioperative checks, 2) the SSC is most helpful when it is simple, and 3) the 3 current components of the checklist are redundant. The briefing was considered the most important aspect and the debriefing the least important. Initially the SSC was difficult to implement owing to a shift in time management and perioperative culture; however, it has now assimilated into perioperative routine. Finally, though most participants agreed that the SSC might avoid some delays and complications, only a few believe there have been observable improvements to morbidity and mortality.

Conclusion: Although the SSC has been integrated into perioperative practice in Calgary, participants believe that previous informal checkpoints were able to circumvent most perioperative issues. Although the SSC may help with flow and equipment, participants believe it fails to show a subjective, clinically important improvement.

Contexte : Après une étude charnière ayant montré une baisse de la morbidité et de la mortalité après la mise en œuvre de la liste de contrôle de la sécurité chirurgicale, cette dernière a été largement intégrée aux politiques périopératoires. Nous avons examiné l’effet des attitudes et des croyances entourant la liste sur son adoption à Calgary.


Résultats : Voici les principales conclusions dégagées : 1) la liste a permis de structurer les contrôles périopératoires non officiels du passé, 2) la liste est surtout utile quand elle est simple et 3) les 3 composantes actuelles de la liste de contrôle sont redondantes. Le briefing était considéré comme étant l’aspect le plus important et le débriefage, le moins important. Au départ, la liste a été difficile à mettre en œuvre en raison des changements à apporter à la gestion du temps et à la culture périopératoire; cependant, elle est maintenant bien intégrée dans la routine périopératoire. Enfin, bien que la plupart des participants conviennent que la liste peut éviter des retards et des complications, seuls quelques-uns croient qu’il y a eu une amélioration observable de la morbidité et de la mortalité.

Conclusion : Si la liste de contrôle de la sécurité chirurgicale a été intégrée dans la pratique périopératoire à Calgary, les participants croient que les points de contrôle non officiels du passé pouvaient prévenir la plupart des problèmes périopératoires. La liste est utile pour ce qui est du processus et de l’équipement, mais les participants croient qu’elle n’apporte pas d’amélioration subjective importante d’un point de vue clinique.
Adverse events (AEs) are unintended injuries caused by medical management rather than disease processes. A Canadian audit revealed an incidence of 7.5 AEs per 100 hospital admissions, which is concordant with other national AE rates. Nearly half of these occur in surgical patients, and 36%-51% of them are retrospectively judged to be preventable. Additionally, a substantial portion of these AEs are “never events,” such as wrong site surgery and retained foreign objects. Often, the etiology of these AEs is attributed to a failure of communication.

The World Health Organization (WHO) Surgical Safety Checklist (SSC) was developed to improve communication in the perioperative care of patients. A landmark study published in 2009 illustrated that the implementation of the WHO SSC in varied socioeconomic settings worldwide was associated with marked improvements in surgical outcomes, including significant reductions in morbidity and mortality. Numerous studies published since then have shown similar results, and consequently the SSC has seen rapid and widespread adoption. Many of these studies have shown compliance to be the most important factor for improved mortality and morbidity.

A modified version of the WHO SSC has been adopted by Alberta Health Services (AHS), the single health authority for the province of Alberta, Canada. The AHS governs operations of institutional institutions within the province and often introduces policies for clinical practice. In 2009 a modified version of the SSC was formally implemented across Alberta. This checklist has 3 components, as outlined in Figure 1: a “briefing” before induction of anesthesia, a “time out” before skin incision and a “debriefing” before the patient leaves the operating room. All 3 components require the attending surgeon, anesthesiologist and an OR nurse to be present. Residents and other trainees are not permitted to perform any component of the SSC. A prior study from our institution, including hospitals associated with the University of Calgary, illustrated an overall 62.1% compliance across all 3 components. A growing body of literature illustrates there are a variety of objective and subjective barriers contributing to a lack of implementation and compliance. A common factor affecting compliance has been the attitudes of health care providers toward the SSC. Therefore, the objective of this qualitative study was to determine the attitudes of health care providers toward the SSC that may impact its adoption and compliance in Calgary, Canada.

**Methods**

**Theoretical framework**

We used an exploratory approach using qualitative methodology to examine the attitudes and beliefs regarding the SSC in Calgary, Canada. A framework based on Rogers’ theory of diffusion of innovation was used to guide the outline of the semistructured interviews. This theory describes how a new idea or technology, such as the SSC, is integrated into practice. This theoretical framework has previously been used to determine the adoption of clinical innovations and was selected to better understand how specific factors contribute to the overall implementation of the SSC. The specific factors influencing adoption are outlined in Table 1: awareness, relative advantage, compatibility, complexity, trialability and observability. Questions in the semistructured interviews were aimed at specifically addressing these factors. We obtained ethics approval from the Research Ethics Board of the University of Calgary.

**Data collection**

The theoretical basis of data collection was guided by grounded theory. A single interviewer (N.D.) conducted a single pilot interview in person. This interview was audio-recorded, transcribed verbatim and then discussed among the research team (N.D., M.L.Q.) to confirm that all topics of interest were addressed. The questions of the semistructured interview guide were subsequently adjusted to reflect the discussion. All subsequent interviews were conducted by a single interviewer (N.D.) in person, audio-recorded, and transcribed verbatim. We obtained informed consent from all interviewees before initiation of the interview. Interviewees were informed that interviews could be aborted at anytime and were reassured that responses were confidential and would not be attached to any identifying data.

**Sampling and recruitment**

We identified potential participants through a snowball sampling strategy, and they were purposively sampled to obtain a variety of perspectives. Initial health care providers were identified based on nominations from clinical leads or division heads. Using the snowball sampling approach, each interviewee was then asked to recommend additional health care providers who could participate in our study. We then approached the recommended providers in person for potential inclusion. Finally, each potential participant was asked to further recommend other potential participants.

Our goal was to interview a minimum of 10 surgeons, 10 anesthesiologists and 10 operating room nurses within Calgary or to interview participants until we reached the point of saturation (i.e., until no new information was obtained as per the snowball sampling approach). We selected 3 acute care hospitals to provide different perspectives, as surgical services are regionalized to various hospitals in Calgary. While all 3 hospitals are university-affiliated teaching centres, 1 is home to the only trauma and cancer centre, as well as vascular and cardiac surgery; 1 is a...
general hospital providing vascular surgery, and the 1 is a pediatric centre. The AHS implementation strategy was delivered to all sites at the same time.

Data analysis

The qualitative analysis of the interview transcripts was conducted with an inductive approach, which involved repeated reading of transcripts, development of a coding scheme to reflect unique ideas within interviews, application of the novel coding scheme to the transcript text, and grouping of coded text. These themes were then tabulated. To improve the reliability of the codes, 2 investigators (N.D., C.C.) analyzed the transcripts. Findings were then compared with discrepancies resolved through discussion.

Results

A total of 31 health care providers were interviewed between October 2012 and August 2013: 12 surgeons, 10 anesthesiologists and 9 operating room nurses; at this point, saturation was reached. As mentioned, these health care providers work at 3 main hospitals within Calgary: 2 adult acute care centres and 1 pediatric centre. All 3 institutions are tertiary-care, academic centres. All 3 hospitals were equally represented within the sample group. Despite a variety of hospital settings, we found that the themes were similar across health care providers and did not differ among the sites. As such, they are presented together.

Themes

Awareness of innovation

All participants were aware of the SSC. Surgeons and anesthesiologists were knowledgeable of the WHO study supporting the implementation and, thus, understood the goal of the SSC was to improve perioperative morbidity and mortality through improved communication. One major concern expressed by physicians regarding the implementation of the SSC was “the improvement in morbidity and mortality evidence appear to be more supportive in less resource-rich health care systems.” Nurses had become aware of the SSC through the AHS implementation process. One nurse noted,
We were told that this is what we were going to do, but were not informed of the evidence other than its potential role in perioperative patient safety. Instead, [AHS] told us [nurses] that it helps with patient safety.

Relative advantage
An informal checklist existed before the province-wide implementation of the SSC; however, most participants observed the AHS SSC to be more structured, formal and comprehensive. Health care providers “looking for history, consent, whether a side needed to be marked; so [the SSC] just took it a little bit further.” The formality of the SSC was found to translate into a consistent safety checkpoint and “hasn’t added much to what [health care providers] were already doing, but it has standardized it.” The participants noted that the endorsed implementation of the SSC led to improved patient perception of safety. For example, a surgeon noted, “my patients have told me of the SSC’s role in improving communication as an attempt to improve patient safety resonated with all health care providers, as they use it to communicate.

Compatibility
All participants believed that the intention of the SSC was to improve perioperative patient care in some capacity. As all interviewees were invested in patient safety, the SSC was consistent with their goals and ideals. An anesthesiologist commented, “even if we improve things a small amount, it’s worth it.” There was concern from several participants that the SSC was not necessarily functioning in the capacity intended. As items not included in the original WHO SSC, such as medical reconciliation of outpatient medications, were added, health care providers objected quite strongly. A participant noted, “you need to study whether the changes have had an unanticipated negative impact or makes no positive impact.” However, the SSC’s role in improving communication as an attempt to improve patient safety resonated with all health care providers, as they use it to communicate.

Complexity
The complexities of adoption were varied among the 3 groups interviewed. The main complexity of adopting the SSC from a nursing point of view was coordinating all 3 parties: nursing, anesthesiologists and surgeons. Nurses expressed their frustration as “sometimes it feels like we nurses spend a lot of time lassoing people to get them to participate.” Nurses often perceived they needed to ensure the completion of the SSC by organizing the surgeons and anesthesiologists, and they hoped “the physicians would take more responsibility for the process.”

The main complexity perceived by the surgeons was the additional burden of completing the SSC while managing their busy days in the operating room. Surgeons were used to having time between cases to take care of other tasks, such as ward issues, administrative work and teaching. The SSC can be viewed as “a hassle because [surgeons] don’t have as much time between cases for multitasking.” Completing all 3 portions of the SSC was found to be cumbersome, particularly for numerous, similar, repetitive procedures, such as tonsillectomies and lumpectomies. One surgeon noted the SSC is “harder during those quick little cases that [health care providers] do, and it would be nice if we could do an abbreviated version in those situations.”

For all parties, the briefing and time out aspects of the SSC were the easiest to use, whereas the debriefing was

<table>
<thead>
<tr>
<th>Table 1. Factors of Rogers’ theory of diffusion of innovation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor</td>
</tr>
<tr>
<td>Awareness</td>
</tr>
<tr>
<td>Relative advantage</td>
</tr>
<tr>
<td>Compatibility</td>
</tr>
<tr>
<td>Complexity</td>
</tr>
<tr>
<td>Trialability</td>
</tr>
<tr>
<td>Observability</td>
</tr>
</tbody>
</table>

AHS = Alberta Health Services; OR = operating room; SSC = surgical safety checklist.
most difficult to implement. There were many reasons postulated by the interviewees as to why the debriefing had such poor compliance. Nurses found that attending surgeons had “often left the room by the time [nurses] can do the debriefing because [surgeons] have an important responsibility to speak with the family of the patient postoperatively.”

From the surgeons’ perspective, briefing is less of an issue if the case has gone as planned, and when other health care providers “don’t have any concerns you sometimes just move on; sometimes it’s because the nurses are busy at the end of the case getting ready for the next case.”

Anesthesiologists found they were occupied with waking a patient at the end of a case when the debriefing is meant to be completed. This is an important component of perioperative care, and anesthesiologists “are very concerned with the emergence and are not really focused on the debrief because [they] have conflicting priorities at that time.” Most interviewees commented the debriefing was more likely to be completed for procedures that had an unexpected course and also for patients who were being transferred to the intensive care unit (ICU). Of note, the anesthesiologist and nursing staff usually carried out this debriefing with the ICU staff “because of carry through of care.”

**Trialability**

The SSC was overall feasible to trial within hospitals. There was no new equipment, training or expertise required. The most difficult aspect of trialing the SSC within Calgary operating rooms was to change the current framework of how health care providers manage their time between cases. As mentioned, surgeons often multitask between cases, and having to attend the 3 aspects of the SSC can interfere with their other clinical roles. As such, it was most difficult to ask surgeons to further divide their time by using the SSC, and their cooperation “was the biggest challenge in the process.” However, as the SSC continued to be used, most health care providers felt that it was integrated into routine perioperative care in Calgary.

**Observability**

Most health care providers were able to observe a change in perioperative culture with the implementation of the SSC. However, differences of opinion existed regarding the main changes observed with the SSC. Most interviewees found themselves more aware of patient and operating room issues and processes, particularly special equipment that may be required for the procedure and confirming the need for and availability of blood products. There also appeared to be an improved awareness of patient allergies among the entire team. The change in communication was noticed by all 3 subgroups of health care providers. Nurses were better informed about tasks that needed to be completed for upcoming procedures. Surgeons noted that the SSC provided an opportunity to confirm that all necessary equipment for a procedure would be present for the case before it started: “the SSC reduces the number of questions from the team because [the surgeons] state it up front and there is lots of clarity about equipment and how things will be done.” This was thought to improve operative efficiency; however, most health care providers subjectively did not notice a change in morbidity or mortality. One participant expressed, “I know it’s supposed to save lives and reduce morbidity; I’m not sure it does that. I think that it improves the efficiency of my OR.”

**DISCUSSION**

In this qualitative study, we found that the SSC has been successfully accepted and adopted; however, there are mixed attitudes regarding its utility in completing its purported objective of reducing perioperative morbidity and mortality. The adoption and subsequent barriers to adoption of the SSC can be described by factors defined by Rogers’ theory of diffusion of innovation. The utilization of the SSC in Calgary was enabled by ubiquitous awareness, perceived relative advantage and compatibility with existing ideals. The barriers of adoption, however, include complexity of integration into the current perioperative workflow, difficult trialability and lack of observability of the desired effect (i.e., decreased morbidity and mortality).

Our findings parallel those of previous studies that showed high levels of awareness of the SSC in institutions that had mandated its usage. For example, Abdel-Galil reported 100% awareness at his institution, and Hurtado and colleagues noted 93.8% awareness; both institutions had mandated the use of the SSC. Awareness of the SSC is integral in its successful adoption; however, it is not sufficient to stop there; it is important to explain the rationale for using the SSC as well as outlining the anticipated benefits. An explicit implementation strategy had been carried out in Calgary, including formal presentation at clinical rounds and web-based resources, which likely contributed to widespread awareness. A large driver of implementation was the introduction of its use via the nursing staff, who were less autonomous in their scope of practice and were mandated by their clinical managers to use the SSC.

Prior to the implementation of the SSC, an informal checklist or “time out” was in place. However, its use was inconsistent and was far from comprehensive. The health care providers who participated in our study noted that the modified WHO SSC had added value, likely owing to its structured and formal nature. Furthermore, the consistent and collaborative use of the SSC provided a platform for improved communication and patient safety. This opinion echoes the sentiment noted in another
study in which participants strongly disagreed with the statement “[the SCC] brings no added value to existing safety procedures.” The ability of the SSC to have benefits beyond improved morbidity and mortality has been established within the literature. Health care providers included in the qualitative study by Thomassen and colleagues evaluating nurses’ and physicians’ acceptance of the SSC felt that it was able to reveal insufficient equipment standardization and improve physician–nurse cooperation. They concluded that the checklist could further be used in situations for which it was not originally intended. In addition, we found subjective improvement in OR communication, which was also found by Papaconstantinou and colleagues. They administered a pre- and post-SSC implementation questionnaire and found that implementation of the SSC led to overall significant improvement in the perceptions of effective communication regarding equipment needs and availability, critical events or anticipated difficulties during the operation, and surgical team debriefing for patient recovery and postoperative management.

Most studies report an overall compliance with the SSC between 38% and 96% in developed countries. These rates are concordant with the qualitative experience in Calgary, as interviewees reported using some version of the SSC for almost all procedures. However, these rates fail to capture the adherence to the 3 components specifically. Our study found Calgary health care providers were least invested in the debriefing component of the SSC, with some providers commenting the debriefing is likely used for 15%–40% of cases. Levy and colleagues noted that despite 100% documentation of SSC completion, not all components of the SSC were completed as defined. Cullati and colleagues found similar results in university hospitals in Switzerland. The “briefing” and “time out” were completed 90% and 83% of the time, respectively; however the “debriefing” was completed only 47% of the time. Another study noted that poor compliance with “debriefing” may be because of ambiguity of the item or the need to dispel interdisciplinary tension that may arise from detection of errors. Our study, however, identified alternative barriers to compliance with the “debrief”: mainly health care providers are concerned about the utility and feasibility of carrying out another checklist item at the end of a procedure, particularly if the procedure went as planned. The SSC was viewed as being disruptive to previous perioperative workflow, which was considered a barrier to adoption from a complexity and trialability perspective. In the study by Thomassen and colleagues, health care providers in Norway found their version of the SSC disrupted their established workflow and, consequently, caused stress to both providers and patients. These disruptions dissipated over time as the SSC assimilated into the perioperative culture; this was reflected in the attitudes of the health care providers in our study as well. In a qualitative study by Gagliardi and colleagues evaluating factors that influence SSC adherence, health care providers commented that the quality of completion of the SSC was suboptimal. Even when operating room staff complied with the components of the SSC, other staff members were sometimes obstructive, inattentive and preoccupied with other tasks, which may reflect a lack of belief in the utility of the SSC.

One of the most striking results from our study was the belief of health care providers, particularly surgeons and anesthesiologists, that the SSC is unlikely to have a role in decreasing morbidity and mortality in their patient population. This perception is discordant with the findings of multiple studies showing a decrease in perioperative morbidity and mortality with the implementation of the WHO SSC. The reasons are likely multifactorial. A study by Haynes and colleagues showed improved rates of morbidity and mortality with specific modification of the WHO SSC. The AHS modified version of the SSC is very similar to the WHO SSC; however, it has not specifically been validated to have similar benefits. Second, the rates of AEs in Calgary may not be equal to reported rates elsewhere, as there was an informal checklist previously in place (preop “time out”). As such, the relative reduction in AE rates may be less significant, given that 1 of the 3 main components of the SSC had already been in place and operational before SSC implementation. Interestingly, a multicentre observational study carried out in Ontario, Canada, confirmed this lack of decreased morbidity and mortality with the implementation of the SSC in a similar Canadian population. The postulated reasons for this unexpected finding include a potential Hawthorne effect in studies showing an improvement, the lower likelihood of negative studies being published and poor rates of real-life compliance (despite high rates of documented compliance). The mismatch of documentation and actual compliance has been established in a study by Levy and colleagues. In this prospective observational study, despite 100% documented completion of the briefing phase of the SSC, they found that most tasks were not executed as designed or were not executed at all. This poor implementation fidelity may also be an issue in Calgary. A previous study by our group noted equal documented compliance to all components of the SSC, but this equal level of compliance was not reflected in this qualitative study, particularly for the debriefing section of the SSC. This may be a result of our documentation practice of checking a box on the operative record when each component of the checklist is complete; anecdotal reports of all 3 boxes being checked before the cases starting have been reported, and may account for the discrepancy between reported compliance and our findings.

This study also highlights similarities and differences in attitudes toward the SSC based on the category of health care providers. Each provider group felt at least somewhat
burdened by the task of completing the SSC. In particular, each provider group felt the SSC had the potential to distract from their own clinical duties. Furthermore, each provider group expected other groups to take more ownership of completing the SSC. The motivation for completing the SSC appeared to differ for nurses and physicians. The nurses interviewed emphasized the SSC was a mandated protocol and, thus, needed to be completed. The physicians were more concerned with the potential safety and communication benefits of the SSC. This may explain why nurses voiced they needed to “lasso” physicians into completing the SSC.

Strengths and limitations

There are multiple strengths of this study. Its qualitative nature allowed further depth into the attitudes and beliefs of health care providers in Calgary than a quantitative study would yield. The face-to-face semistructured interview process captured more information than a formally structured interview or survey method would have captured. The analysis of themes by 2 independent researchers provides additional validation of our results. There are also several limitations of this study. This study interviewed health care providers only in Calgary. This collective opinion may be reflective of other similar populations; however, these results may not be completely generalizable. The attitudes of health care providers may differ substantially owing to differing baseline perioperative procedures before implementation of the SSC and to low incidence of AEs. Owing to the face-to-face interview design, this study is susceptible to a social desirability bias. We attempted to circumvent this potential bias by assuring confidentiality of participants and by asking pointed questions prompting reporting of both positive and negative opinions.

Conclusion

This qualitative study shows there are both positive and negative attitudes and beliefs regarding the SSC as implemented and mandated by AHS. Health care providers are motivated to use the SSC owing to high rates of awareness, perceived improvement in communications and efficiency, and high stakes in improved patient care. The SSC has, however, caused disruptions in workflow, and the prevailing belief among health care providers challenges its efficacy in its original intent of improving perioperative morbidity and mortality. Irrespective of this failing, most believe it is a useful tool that improves the perioperative process. The WHO recommends the SSC be modified in order to suit the setting in which it will be used. This study highlights the usefulness of the SSC for improving communication. As the AHS SSC continues to evolve, it will be important to emphasize communication rather than create “another tick box.”

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Funding: This study received funding from the MSI Foundation.

Competing interests: None declared.

Contributors: All authors designed the study. N. Dharampal and M. Quan acquired and analyzed the data, which C. Cameron also analyzed. N. Dharampal and M. Quan wrote the article, which all authors reviewed and approved for publication.

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The enigma of neurogenic thoracic outlet syndrome following motor vehicle collisions

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Accepted for publication Apr. 28, 2016

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DOI: 10.1503/cjs.009814

Background: The concept of neurogenic thoracic outlet syndrome (N-TOS) including upper and lower plexus syndromes secondary to soft tissue neck injury after motor vehicle collisions (MVCs) has been contentious. We considered that analysis of objective data from this group of patients could provide insight into this controversial type of N-TOS.

Methods: During the 10-year period January 2001 through December 2010 we examined patients who had received a diagnosis of N-TOS following an MVC. We graded the principal diagnosis based on the objective data from our physical examination.

Results: In total 263 patients received a diagnosis of N-TOS during the study period. At the highest accuracy level of diagnosis there were 56 patients with ulnar entrapment syndrome (UES), 40 with carpal tunnel syndrome (CTS) and 55 with nonorganic disease (NOD), for a total of 151 (57.4%) cases in which the diagnosis of N-TOS was brought into question. The elevated arm stress test (EAST) reproduced the symptoms of UES in 33 of the 56 patients of UES (58.9%) and reproduced the symptoms of CTS in 18 of the 40 patients with CTS (45.0%).

Conclusion: There appears to be a high incidence of misdiagnosis of N-TOS following MVCs. The EAST is not a prime test for N-TOS.

Contexte : Il n’y a pas consensus sur le concept de syndrome du défilé thoraco-brachial (SDTB) neurogène comprenant des syndromes du plexus brachial inférieur et supérieur consécutifs à une blessure aux tissus mous du cou découlant d’une collision de véhicules motorisés. Nous avons pensé que l’analyse de données objectives sur les patients touchés pourrait aider à comprendre ce type controversé de SDTB neurogène.

Méthodes : Durant une période de 10 ans, soit de janvier 2001 à décembre 2010, nous avons examiné des patients ayant reçu un diagnostic de SDTB neurogène après une collision de véhicules motorisés. Nous avons coté le diagnostic principal selon les données objectives de notre examen physique.

Résultats : Au total, 263 patients ont reçu un diagnostic de SDTB neurogène durant la période à l’étude. Au degré le plus précis de diagnostic, 56 patients étaient atteints de syndrome canalaire du nerf cubital, 40, de syndrome du canal carpien et 55, de maladies non organiques, pour un total de 151 patients, ou 57,4 % des cas pour lesquels le diagnostic de SDTB neurogène avait été envisagé. La manœuvre du chandelier (test de Roos) a reproduit les symptômes du syndrome canalaire du nerf cubital chez 33 des 56 patients atteints (58,9 %) et ceux du syndrome du canal carpien chez 18 des 40 patients atteints (45,0 %).

Conclusion : Il semble y avoir une forte incidence de mauvais diagnostics de SDTB neurogène après des collisions de véhicules motorisés. Le test de Roos n’est pas un test de premier choix pour ce syndrome.
clinical term “thoracic outlet.” Today it is generally accepted that, although rare, N-TOS is due to pressure on the lower trunk of the brachial plexus, which carries the anterior primary rami of the eighth cervical spinal nerve (C8) and the first thoracic spinal nerve (T1), thus giving symptoms and signs in the dermatomes and myotomes of C8 and T1 in the upper limb.

In 1913, Wilson described cases with wasting of the muscles of the thenar eminence, especially the abductor pollicis and opponens pollicis, and with sensory change along the radial border of the hand and fingers in association with a cervical rib. He discussed treatment by excision of the rib. In retrospect he was probably describing carpal tunnel syndrome (CTS). Also in 1913, Marie and Foix described spontaneous compression of the median nerve in the carpal tunnel, including the autopsy findings, but this went unnoticed at the time. In 1938, Moersch also described spontaneous compression of the median nerve in the carpal tunnel and warned against an incorrect diagnosis of cervical rib. Following further studies by Woltman in 1941, Zachary in 1945, Brain and colleagues in 1947 and Kremer and colleagues in 1953, there was increasing recognition of CTS, and by 1959 a widely read textbook of surgery stated, “It is now becoming recognized that many of the symptoms which in the past were ascribed to the cervical rib and the ‘costoclavicular syndrome’ are in reality the result of compression of the median nerve in the wrist at the site of the carpal tunnel.”

However, in 1966 the concept of the upper plexus N-TOS was revived by Roos and Owens, later supported by Urschel and Razzuk in 1998 and by Sanders and colleagues in 2000. As a result, the hypotheses of upper plexus and lower plexus N-TOS have been used to explain a variety of neurologic symptoms in the upper limb following motor vehicle collisions (MVCs) and alleged to be due to soft tissue injury of the neck leading to hypothetical scalene muscle spasm and compression of the brachial plexus. The existence of this form of N-TOS has been very controversial, with little objective evidence but strong opinions resulting in claims that it is either underrated or overdiagnosed.

We have had the opportunity to carry out independent medical-legal examinations of patients with diagnoses of N-TOS secondary to an MVC. Analysis of the objective data from these examinations has provided some insight into this controversial form of N-TOS. To our knowledge, this type of objective data has not been available in the medical literature before.

**METHODS**

We analyzed the cases of all patients referred for an independent medical opinion concerning a diagnosis of N-TOS or following an MVC and seen between Jan. 1, 2001, and Dec. 31, 2010.

Document reviews without examination of the patient were excluded. Each patient had been referred by a lawyer or an insurance company representative. It should be noted that for residents of the province of British Columbia there is mandatory MVC coverage by a single insurance agency, the Insurance Corporation of BC.

We obtained a full history, carried out a physical examination with special attention to the upper extremities, reviewed the results of investigations and reviewed the medical records that had been sent to us. The results of the physical examination were recorded on a standardized form and included the range and strength of joint movement in the upper limbs; a detailed examination of the muscles involved in entrapment neuropathies of the upper limb (especially flexor digitorum profundus, abductor digitii minimi, abductor pollicis brevis and opponens pollicis); and the provocative tests reported to be indicative of N-TOS, including the hyperabduction test and the elevated arm stress test (EAST).

The hyperabduction test was carried out with the patient seated. The arm was passively abducted in the coronal plane while the radial pulse was monitored by the examiner. The angle of elevation was based on the line of the humerus in relation to vertical when the comfortable limit of abduction had been reached. The EAST was also carried out with the patient seated; the arms were abducted to 90° in the coronal plane with the forearms vertical and palms forward. After checking the radial pulse, the examiner asked the patient to clamp and unclamp the hands for up to 3 minutes. The distribution of any increased or reproduced neurologic symptoms was noted.

Neurological diagnosis was based on the neuroanatomy of the dermatomes and myotomes for TOS and for cervical radiculopathy versus the sensory and motor supplies of peripheral nerves in CTS and ulnar entrapment syndrome (UES). We also took into account pain or tenderness at the site of entrapment, radiation of pain or parathesias from the site of entrapment and the results of provocative tests, such as the Phalen test for CTS and the elbow flexion test for UES. We reviewed the results of nerve conduction studies (NCS) and electromyography (EMG) when they were available. Because we were giving an independent medical-legal opinion we were unable to ensure receipt of appropriate NCS and EMG results in all cases. We did not use the results of provocative tests for TOS for diagnosis because they have never been scientifically validated; however, we did analyze the results of these tests.

For any nerve entrapment syndrome there is a spectrum of diagnosis from possible to certain. Therefore, a method of grading the accuracy of our diagnosis was required. The grading system we used is laid out in Table 1 and can be applied to N-TOS, UES and CTS. There were many patients in whom symptoms were nonanatomic, nonphysiologic and associated with multiple disparities on physical examination (analogous to Waddell signs in low back
A grading system was devised for these cases of nonorganic disease (NOD) and is shown in Table 2. We made no attempt to diagnose the cause of the somatization or conversion disorder resulting in nonorganic disease.

**RESULTS**

A total of 263 patients who had received a diagnosis of N-TOS were seen during the study period; 58 were men and 205 were women. All had been in an MVC, including 1 pedestrian, 1 motorcyclist and 1 farm tractor driver. Neck injury had occurred in 219 patients and resulted in a whiplash-associated disorder grade 1 or 2.17 The remaining 44 (16.7%) patients, had no mention of a clinically important neck injury in the medical records early after the MVC. Therefore, injury of the scalenus anterior muscle secondary to a neck injury cannot be an essential factor in causation of N-TOS.

When seen by us, 260 patients had symptoms of tingling or numbness in 1 or both upper limbs, 1 patient reported tremors, 1 reported feelings of “electricity” and 1 had no neurologic symptoms but had received a diagnosis of TOS on the basis of a very easily occluded radial pulse. However, this was secondary to a Bankart operation for recurrent dislocation of the shoulder.

The principal diagnoses with the grading for diagnostic accuracy are given in Table 3. In no case was there tingling or numbness corresponding to the dermatomes of C8 and T1 or weakness corresponding to the myotomes of C8 and T1. Therefore, it is our view that no patient had recognizable TOS. We considered the possibility of the hypothetical “upper plexus” TOS, but the 2 patients with C6 and the 1 patient with C7 dermatome and myotome involvement were adequately explained on the basis of cervical radiculopathy with severe stenosis of the neural foramen on imaging studies. Because NOD, especially the more severe grades 3 and 4, may obscure the presence of organic disease, we cannot completely exclude the possibility of N-TOS obscured by NOD. The 14 patients whose cases were classified as miscellaneous are listed in Table 4.

Nerve conduction studies had been performed in certified laboratories, reported by certified specialists and were available for 196 patients. In a further 43 patients, the studies had been done but were never made available to us. For 24 patients no NCS were on record. For the grade 4 cases of CTS and UES the correlation of muscle weakness and positive nerve NCS is shown in Table 5. For grade 4 UES the high number of negative NCS, despite the presence of specific muscle weakness, was surprising. Analysis of the data sheets showed that inching studies were rarely performed and that the date of the NCS had preceded the date of our physical examination by 1–65 months (mean 22.5 mo). Furthermore, in 3 cases we could not find evidence that measurements had been taken across the elbow segment. In 1 patient the NCS had been done on the less affected side.

When seen by us, 24 patients had undergone surgery on 1 or both sides for N-TOS (23 had had first rib resections and 1 had had a scalenectomy), but most or all of their original symptoms had recurred. In our opinion, the correct diagnosis was UES in 9 patients, CTS in 4 patients and NOD in 11 patients, suggesting that the preoperative diagnosis had been incorrect.

Because the EAST has been reported to be the best of the tests for N-TOS,12 we analyzed the results of this test for the grade 4 cases of UES and CTS. The EAST reproduced or increased the symptoms of UES in 58.9% of the
grade 4 UES cases and reproduced the symptoms of CTS in 45.0% of the grade 4 CTS cases. Therefore, the EAST is not a reliable test for TOS.

In 59 patients there was significant disparity between the active and passive ranges of shoulder abduction on 1 or both sides associated with NOD. Therefore these cases were excluded from the analysis of the results of the hyperabduction test. Among the remaining 204 patients the hyperabduction test occluded the radial pulse on 1 or both sides in 59 cases (39%).

Among the 56 patients with grade 4 UES, 17 (30.4%) had a sensory deficit that included the ulnar 2 and a half digits compared with the normal expected incidence of 15%–20% for this variant. From review of the medical-legal reports, some physicians did not recognize this variant and appeared to use it to make a diagnosis of TOS, thus inflating the incidence to 30.4% in our series.

**Discussion**

Although the present series can be criticized for having been selected by lawyers and insurance company representatives, the original diagnosis had been made by a physician or surgeon.

Until now, to our knowledge, the only attempt to obtain objective data about N-TOS was a study by Cherington and Cherington that analyzed payment agencies and N-TOS surgery in Colorado, USA. The authors concluded that no surgery had been carried out in patients who could not pay. Among the 56 patients with grade 4 UES, 17 (30.4%) had a sensory deficit that included the ulnar 2 and a half digits compared with the normal expected incidence of 15%–20% for this variant. From review of the medical-legal reports, some physicians did not recognize this variant and appeared to use it to make a diagnosis of TOS, thus inflating the incidence to 30.4% in our series.

**Table 4. Miscellaneous diagnoses**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raynaud</td>
<td>4</td>
</tr>
<tr>
<td>Occupational neck and shoulder pain</td>
<td>4</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>2</td>
</tr>
<tr>
<td>Childhood head injury</td>
<td>1</td>
</tr>
<tr>
<td>Bicipital tendinitis</td>
<td>1</td>
</tr>
<tr>
<td>Bankart operation (for recurrent shoulder dislocation)</td>
<td>1</td>
</tr>
<tr>
<td>Lateral palmar digital nerve injury</td>
<td>1</td>
</tr>
</tbody>
</table>

**Table 5. Positive NCS and specific muscle weakness in grade 4 UES and CTS**

<table>
<thead>
<tr>
<th>Muscle weakness</th>
<th>NCS +</th>
<th>UES</th>
<th>CTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific muscle weakness absent</td>
<td>NCS +</td>
<td>14</td>
<td>29</td>
</tr>
<tr>
<td>Specific muscle weakness present</td>
<td>NCS +</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Bankart operation (for recurrent shoulder dislocation)</td>
<td>NCS –</td>
<td>26</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>NCS – or ND</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>56</td>
<td>40</td>
<td></td>
</tr>
</tbody>
</table>

**Discussion**

Eisen studied the use of electrophysiology in the early diagnosis of UES by examining healthy controls and patients with mild UES and severe UES. There were 34 patients with severe UES, all of whom had “clear-cut evidence of an ulnar nerve compression at the elbow” and muscle atrophy, weakness and appropriate sensory deficit specific for UES. These 34 cases approximate to, but were probably more severe than, our grade 4 cases because not all our cases had muscle atrophy. Using Eisen’s data, 21.2%– 61.6% of his NCS were normal in cases of severe UES. Thus, the presence of normal NCS may not exclude a grade 4 UES. This is in addition to the other factors contributing to normal NCS in patients with severe UES.

In our series there were 151 diagnoses of grade 4 UES, CTS and NOD. Therefore, it is probable that the diagnosis of N-TOS was incorrect in 57.4%, and it is probable that there were more cases of incorrect diagnosis among the remaining 42.6%. In our opinion, the cases of failed surgery were due to UES in 9 patients, CTS in 4 patients and NOD in 11 patients, giving further support to the suggestion that there is a high level of misdiagnosis. Our results also support MacKinnon’s comments in the discussion on the study by Urschel and Razzuk stating that her own group reserves surgical intervention for the unusual patient who cannot be treated for CTS or UES.

Reliance on the Roos elevated arm stress test or EAST as a specific test for N-TOS contributed to the misdiagnosis. Our results show that the EAST was positive for the peripheral neuropathy in about 45% of the grade 4 cases of UES and nearly 60% of the grade 4 cases of CTS. In 1985, Costigan and Wilbourne reported that the EAST produced symptoms in the fingers in 19% of patients with known CTS but none in the asymptomatic controls. The higher incidence in our group was probably due to reliance on the EAST as a specific test for N-TOS by the physician making the original diagnosis of N-TOS. The incidence of a positive EAST in patients with a primary diagnosis of UES is unknown but, like CTS, is probably less than the incidence in this series because of reliance on the EAST as a specific test for N-TOS before entering this study.

In 1941, Wright showed that the radial artery pulse can be occluded in more than 80% of the healthy population with the shoulder or shoulder girdle in more extreme positions and commented that “hyperabduction is today being widely but erroneously used as a test for the scalenus anticus syndrome.” Therefore, we disregarded vascular laboratory studies that reported N-TOS on the basis of arterial pulse occlusion. Our result for easy radial artery pulse occlusion was 39%, whereas Wright’s most easily occluded cases were 32%.

Other factors possibly contributing to misdiagnosis were lack of knowledge of the neuroanatomy of the upper limb and reliance on a diagnosis of “double crush syndrome” to explain any evidence of a peripheral neuropathy. These possibilities were not analyzed in the present study.
Finally, combining the diagnoses in Table 3, Table 4 gives our experience in the differential diagnosis of TOS during the 10 years analyzed.

CONCLUSION

Our results suggest that there is a high incidence of error in the diagnosis of N-TOS in patients presenting for medical-legal insurance examinations following MVCs. Recurrence of symptoms following first rib resection may be associated with an incorrect preoperative diagnosis. In our experience the EAST is not specific for TOS because it can be positive for CTS or UES. Our results should be confirmed by others.

Acknowledgements: The authors thank their teachers of anatomy at Western University, Ontario, and Kings College, London, without whom this paper would not have been possible, and Dr. W.R.E. Jamieson for helpful advice.

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Competing interests: None declared.

Contributors: Both authors designed the study, A.I. Munro acquired and analyzed the data and wrote the article, which both authors reviewed and approved for publication.

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Aging and orthopedics: how a lifespan development model can inform practice and research

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Orthopedic surgical care, like all health care today, is in flux owing to an aging population and to chronic medical conditions leading to an increased number of people with illnesses that need to be managed over the lifespan. The result is an ongoing shift from curing acute illnesses to the management and care of chronic illness and conditions. Theoretical models that provide a useful and feasible vision for the future of health care and health care research are needed. This review discusses how the lifespan development model used in some disciplines within the behavioral sciences can be seen as an extension of the biopsychosocial model. We posit that the lifespan development model provides useful perspectives for both orthopedic care and research. We present key concepts and recommendations, and we discuss how the lifespan development model can contribute to new and evolving perspectives on orthopedic outcomes and to new directions for research. We also offer practical guidelines on how to implement the model in orthopedic practice.

In 2015, it was estimated that people aged 65 and older represented 15% of the population in the United States, 16% in Canada, 20% in Sweden and 26% in Japan.1 This aging population is contributing to a health care landscape that is already in flux across the western world. New technologies, medications, treatments and procedures have greatly advanced medical knowledge, most notably in the last 50 years. As a result of these medical advancements, adults across the industrialized world are living longer, although many have chronic illnesses. Some of these chronic conditions are related to suboptimal lifestyle choices (e.g., diet and exercise), which are increasing the number of middle-aged and younger individuals coping with conditions that need to be managed, rather than cured, over a portion of the lifespan. This has particular relevance for clinicians and researchers in orthopedics, where the number of people seeking care will increase exponentially in the coming decades. It could be said that orthopedics is both a field of medicine that deals with trauma and injury and one that directly addresses issues of aging within the context of function and mobility.

In the present review, we propose that looking beyond some of the theoretical models that underlie the entire system of health care can contribute to a
useful and feasible vision for the future of health care that accommodates the needs of our aging population. Specifically, we propose that the lifespan development approach already being used in some disciplines within the behavioural sciences can play a role in setting the direction for a vision of orthopedic care and research.

**Biomedical and biopsychosocial models**

The biomedical model of illness has informed medical practice and health care for more than 2 centuries and still holds considerable prominence today. As the dominant explanatory model of illness and health, the biomedical model conceptualizes health and illness as physiologic processes. Illness and disease are explained as a disruption of these processes caused by injury, biochemical imbalances, or infection. The model's widespread appeal comes from its linear cause and effect explanation of illness as either a failure or breakdown of human physiology.

Although the biomedical model has led to many great achievements in health care and the cure of disease, it has been criticized for being overly reductionist; illness is viewed as a linear cause and effect process, with the body separate and distinct from psychological and social influences. Too often, what cannot be explained by cellular or molecular pathology is disregarded or downplayed. Under the biomedical model, the role of the patient was that of a submissive recipient of medical intervention, not a co­contributor to his or her own health outcomes. A shift in the valuation of the role of the patient is one of the hallmarks of the biopsychosocial (BPS) model. In his seminal 1977 paper, George Engel argued for a more holistic view of the patient, one that would “reverse the dehumanization of medicine and disempowerment of patients.” Thus, the BPS model expands on the biological explanation of illness to include psychological and social factors, which can differentially impact the outcomes of a number of well­known orthopedic interventions. For example, psychological factors, such as anxiety and depression, have been identified as mediating variables in pre­ and postoperative knee function and functional outcomes of total knee arthroplasty. In addition, social factors, such as race and socioeconomic status, have been implicated in functional outcomes of total knee arthroplasty and patient satisfaction. Clearly, biopsychosocial variables are important in determining patient outcomes. We propose that the lifespan development theory can be viewed not only as a logical extension of the biopsychosocial approach, but also may add particularly useful perspectives to orthopedics care and research.

**Lifespan development theory**

The lifespan development theory was originally viewed as part of developmental psychology and was focused on the study of human development from conception to death. Studied empirically since the 1960s and '70s, the lifespan development approach proposes an “integrative perspective on development as a multidimensional, multidirectional, context-specific and malleable phenomenon that goes beyond classic conceptions of a linear, unidirectional growth or differentiation.”

In 1987 Baltes identified and later adapted a number of key concepts that compose lifespan theory. We summarize these briefly here and propose some implications of these views that are particularly pertinent to orthopedics.

**Lifespan development is a lifelong process of changes in adaptive capacity**

Researchers and clinicians need to focus on how patients adapt throughout their lives and, in particular, must assume that change is ongoing and that adaptation is possible until the moment of death. For a patient experiencing accumulating losses in mobility, a clinician who takes into account the patient’s willingness and ability to adapt to change in circumstances may be particularly effective in offering optimal clinical care.

**Change is multidimensional and multidirectional**

It is important to be constantly aware that many or all aspects of a person’s life are affected by an illness or medical condition and that, at any point, there can be gains and losses in functioning and in adaptation that may co­occur. Development also comprises gains and losses throughout the lifespan rather than increasing gains until mid­adulthood followed by slow declines into old age. This challenges the views held by many that only improvements occur until maturation and that only losses occur after maturation is reached. We already see how orthopedic interventions contribute to gains in functioning even among the oldest and frailest patients. This focus on within­person modifiability implies 2 key issues. First, the end point of a disease or condition (at least in terms of some multidimensional outcomes) is not predetermined and can be influenced by interventions. Second, the effectiveness of such interventions is determined not only by the disease itself, but also by the life events and experiences of the individuals, thus emphasizing the individual nature of how patients will progress through their diseases and their treatments. The clinician cannot depend solely on the person’s age, or even on objective measures of joint performance, to determine which patients will benefit from interventions.

**All human development is embedded within a historical and cultural context**

As stated, the lifespan perspective emphasizes that the past experiences of the individual affect how he or she reacts to a situation. However, this does not discount the likelihood that individuals of the same culture, the same race and the same historical era experience relatively similar events and
influences on at least some levels. Thus, interventions, treatments and interpretations of individuals’ behaviours must take into account the person’s generation and culture. For example, while educated baby boomers may want and need to be equal partners in making decisions about their health, those from earlier generations, particularly if low literacy is present, may want and need to have their health care providers take the lead, or even make the decisions.

The lifespan development model identifies 3 types of influence to underline the biopsychosocial nature of change: influences linked to chronological age, influences associated with one’s cohort or generation and changes due to random biological and environmental events (e.g., accidents). Realizing that these influences constantly work together interactively to explain the developmental paths of individuals, generational cohorts and societal trends can help researchers and clinicians move between case studies, clinical research and epidemiological studies. For example, a number of epidemiological studies have reported that the onset of knee osteoarthritis (OA) is influenced not only by the biological processes of aging, but also by secular trends, such as the prevalence of sedentary work and middle-age obesity, and by traumatic injury, such as sport injury or a motor vehicle crash. Understanding all 3 types of contextual influences provides an alternate lens for examining different health outcomes within and across age cohorts and individuals.

The study of development is intrinsically multidisciplinary

The study of development encompasses a variety of perspectives, with each having the potential to influence and be influenced by the others. Thus, not only research teams, but also care teams will be more effective and more successful if the perspectives, knowledge and skills of people trained within different disciplines are used and respected.

Heckhausen and colleagues recently proposed the lines of defence model, which provides an example of an application of the lifespan model. Although empirical testing is still in progress, this model in particular offers a deeper exploration of how goal engagement and disengagement can change over the course of an illness and over the lifespan. The lines of defence model proposes that individuals use control strategies of goal engagement, disengagement and new goal re-engagement across 4 disease states: disease-free, subclinical disease, chronic disease and terminal illness.

The first line of defence is to engage in goals that will promote patients’ disease-free state until their genes, environment, or behaviour makes a disease-free state impossible. The second line of defence is subclinical, and the focus is avoiding chronic disease by engaging in goals that facilitate a return to a disease-free state or that delay progression to a chronic disease state. When this is no longer possible, the third line of defence is breached, and chronic disease becomes the health state. At this point, the goal is to maintain patients’ activities of daily living (e.g., eating, bathing, dressing, walking) and those activities that allow people to live independently. The control strategies used here show a shift from primary control strategies (action-oriented) to secondary control strategies (inner-directed) and include a gradual dependence on assistive devices and support from others. For example, a person with knee OA may use anti-inflammatory medications to accomplish activities of daily living, but when the condition progresses beyond what medication can ameliorate, a cane or walker is required to accomplish basic activities of daily living. The fourth line of defence is end of life, which involves one of the most challenging tasks in all of human development: disengaging from goals that cannot be achieved and focusing solely on “minimizing physical and psychological suffering, coming to terms with the end of life, minimizing burden on others, and shaping the legacy one leaves behind.”

From an orthopedic care perspective, the second and third lines of defence are central because orthopedic interventions are most often in response to trauma, pathology, or chronic conditions. For example, with a traumatic injury, the health goals at the second line of defence would include recovering to an injury-free state, and the control strategies to achieve those goals are engagement, disengagement, and re-engagement. For a patient with a meniscal tear sustained while playing soccer, for example, goal engagement would involve adhering to a postoperative physiotherapy regime in order to improve physical functioning and regain preinjury health status. Once injury-free status is attained, the patient may then re-engage in first line of defence control strategies to avoid similar injuries in the future (e.g., wearing a brace or playing a different sport).

In the third line of defence, a progressive and chronic disease state, such as OA, the health goals are returning to a subclinical state of the second line of defence through an orthopedic intervention, or to avoid or delay progression of the disease. Similar to the second line of defence, there are cycles of control strategies of engagement, disengagement and re-engagement, but here they span 5 sublevel functioning goals that reflect the progression of the disease from lesser to greater disability: regaining or maintaining physical abilities, such as undergoing physiotherapy or losing weight to slow the progression of OA; using assistive devices and making modifications to the living and working environments to maintain independence; obtaining assistance from others when assistive devices and environmental modifications are no longer effective; determining which activities of daily living are most important; and minimizing physical suffering, especially through the management of pain.

For orthopedic care providers (and researchers), understanding the lines of defence from the perspective of the patient means recognizing that every patient must navigate...
the lines of defence and that patients’ age and life experiences have an impact. How and when the lines of defence are navigated and the relative psychological resilience required for goal engagement, disengagement and re-engagement is very subjective. For example, an otherwise healthy 80-year-old with knee OA may not be ready to adopt assistive devices until she has disengaged from the goals of the second line of defence, and presenting such devices to her before she is ready (i.e., before she has disengaged from goals linked to returning to a disease-free state), may create frustration and even distrust of the care provider. Conversely, a comorbidly ill 55-year-old with knee OA may welcome and appreciate the suggestion of assistive devices, which would increase trust and rapport with the care provider.

In sum, the tenets of lifespan psychology propose that development is “a lifelong process of adaptation to physical, social and psychological changes as well as the active role of the individual.” This illustrates how lifespan development theory is the logical extension of the BPS model of health care. Not only does lifespan development theory provide a more comprehensive understanding of older persons, which is lacking in other health care models, but it can also lead to new avenues for research and ways of interpreting the findings for people of all ages and developmental stages. More importantly, it can provide valuable insights on what interventions are appropriate throughout the patient’s journey.

**Recommendations**

We propose that the lifespan development model provides a useful and fertile guide for patient-centred care, orthopedic research and clinical practice. While this model was developed with an individualistic focus, as would be expected for a psychological theory, we contend that this focus can easily be widened to include broader issues. In this section, we discuss recommendations and implications for how the lifespan development model can contribute to new and evolving perspectives on orthopedic outcomes and to new directions for research. We offer practical guidelines on how to implement the model in orthopedic practice.

*Lifespan development theory in the context of orthopedic research*

**Determining ideal outcomes**

Perhaps the biggest impact of using lifespan development theory as a guide to orthopedic care is the fact that it can identify new pathways of care that can emerge from using a multidimensional and multidirectional perspective. One issue of particular importance is the very basic notion of desired “outcomes.” In a traditional biomedical model, an ideal outcome occurs when the patient is cured and returns to a state of health. However, with aging and chronically ill populations, the interplay of psychological well-being and physical status becomes complex. For example, if a total knee replacement surgery was a success from the surgeon’s perspective but the patient still has ongoing pain, no significant change in range of motion, and regrets having the surgery, is the outcome positive? As younger patients undergo total knee replacement surgery, how can they prepare for the revision surgery that is likely to occur once, or maybe even twice in their lifetime? Thus, care pathways and research are needed to identify which patients will benefit from which treatments. This means not only providing the best care for each particular patient at a particular time, but also avoiding expensive interventions that will not lead to positive outcomes, however these are defined. This directly aligns with the concept of patient-centred care that is predominant in today’s health care environment.

**Functional age and optimal health care outcomes**

Anecdotal data abound on individual differences in function and mobility among middle-aged and older adults in need of orthopedic care. A common distinction in orthopedics is the young, active patient and the frail, older patient; each may require different interventions reflective of their adaptive capacity and resilience. As with any such classification, there are outliers who may not respond the same as those in their chronological age groups; there are healthy, active 80-year-olds who may have more optimal outcomes than other patients their age, and there are patients in their 50s who are sedentary and have chronic illnesses. Optimal care is more subjective than ever. In lifespan theory, “functional age” (i.e., time until death) is often found to be more useful than chronological age (i.e., time since birth), and there is recognition that life stage is an integral part in understanding how a person experiences an event. Such notions may be an important element in addressing core issues for health care in general, specifically in orthopedics.

*Lifespan development theory in the context of orthopedic research*

**Multifactorial approaches are needed**

By its very nature, lifespan development theory suggests that research designs simultaneously consider multiple variables, and the complex interactions among all of these variables, in order to truly understand a phenomenon. Thus, interacting factors from the biological, psychological and sociological domains need to be considered. From a practical standpoint, particularly when doing quantitative analyses, this may mean that regression approaches and multivariate approaches are most useful.

**Multidisciplinary approaches are needed**

As emphasized earlier, lifespan development theory is inherently multidisciplinary. Thus, the use of research
teams (and care teams) consisting of multiple members is encouraged, particularly when these team members come from different academic and clinical traditions.

**Mixed-methods research designs are optimal**
Quantitative research usually takes a nomothetic approach, whereby the goal is to describe the general characteristics of a group of people, and the individual is considered as an exemplar of his or her group. In quantitative research, the central aim is therefore generalizability of findings, which is achieved by using the criteria of validity, reliability and objectivity. In contrast, qualitative research usually takes an idiographic approach, with the aim of describing individuals' unique experiences and behaviours. Within qualitative research, the central aim is often described as trustworthiness, a quality that emerges when results are seen as credible, transferable and confirmable. Quantitative and qualitative approaches tend to address very different research questions and topics. Traditionally, health care research has made a greater use of quantitative research designs, but an increasing awareness of the important contribution of qualitative research to health research is evident. Mixed methods, where data from quantitative and qualitative methods are integrated, are increasingly being used across the social sciences. We propose that the adoption of the tenets of lifespan development theory, while not requiring mixed methods, does highlight the usefulness of this approach to truly recognize and appreciate the multidimensionality of human experience.

**Lifespan development theory in the context of orthopedic practice**

We propose that the first steps in integrating a lifespan development approach to orthopedic care involve enhancing patient–surgeon communication to ensure not only that patients are well informed about their care, but also that surgeons have the skills to elicit from each patient the information they require to develop appropriate and targeted care plans.

**Enhancing communication training**
Implementing lifespan development theory in orthopedic practice begins with introducing and integrating the tenets of the theory in the communication training of residents and in the continuing medical education of practising surgeons. Whether for residents or experienced orthopedic surgeons, “medical education should incorporate a lifespan perspective that emphasizes the physical, psychological and communication changes that occur throughout the aging process.” For residents, the CanMEDS Physician Competency Framework of the Royal College of Physicians and Surgeons of Canada is an ideal platform through which to introduce the theory. The 7 physician competencies of CanMEDS (medical expert, communicator, collaborator, manager, health advocate, scholar and professional) would benefit from the contribution of lifespan development theory not only because it provides a more nuanced understanding of patients, but also because it can be applied to patients of all ages and stages. For practising surgeons, continuing medical education programs could incorporate the model in future curriculum development. For example, the American Academy of Orthopaedic Surgeons (AAOS) in partnership with the Institute for Healthcare Communication offers the Communication Skills Mentoring Program, which uses a clinical model known as the “4Es”: engage, empathize, educate, enlist. The curriculum uses peer mentors and training videos to help clinicians better understand the “4Es” model and how to apply it in the office or clinic. The program could be enhanced with a lifespan development focus.

**Multidisciplinary care teams**
It is well established that emotional health can impact orthopedic surgical outcomes. Perioperative care pathways that recognize and include the role of psychology are likely to be very beneficial. While multidisciplinary care teams exist in a number of orthopedic care pathways, the focus most often remains on the physical rather than the psychological well-being of the patient. Yet, “successful postoperative care may require different care pathways with different levels of support, depending on the patient’s preoperative emotional health. Such pathways may involve teams of clinicians, including physical therapists, behavioural psychologists, and other support professionals.” A useful analogy for how best to integrate the lifespan model in orthopedic care is the professional sports team. While many sports teams now include psychologists as part of their organizations, this dimension is often missing in many orthopedic multidisciplinary care teams. More research is needed to define perioperative strategies that will simultaneously support the physical and emotional health of our patients to ensure optimal functional gain after technically successful surgery.

**Developing communication tools**
Although quality communication contributes significantly to patient satisfaction, it may be challenging to achieve in orthopedic clinics because of the expediency required in the fee for service structure of the medicare system in Canada. One possible solution is the use of checklists. Checklists are used in health care settings, such as surgical, intensive care and trauma units, and have been shown to decrease medical errors and improve overall standards of patient care. However, no research exists, to our knowledge, that uses a checklist to enhance orthopedic surgeon–patient communication. A communication tool that improves the quality of time-limited surgeon–patient interactions could optimize the surgeon’s role in helping patients set and manage postoperative expectations that are realistic and achievable, thus
increasing patient satisfaction with the surgery. We are currently developing and testing a checklist to be used as a postoperative communication tool for surgeons. Using a mixed methods approach that began with a qualitative exploration of patients’ experience with recovery from total knee replacement surgery, we applied the findings in the creation of a communication checklist that will be tested quantitatively to determine if it contributes to greater patient satisfaction 6 months after surgery. We hope the tool is efficient enough to meet the surgeons’ time constraints, but comprehensive enough to provide a forum for both patients and surgeons to exchange the information that will lead to optimal outcomes.

CONCLUSION

The aging of the population entails fundamental changes to the health care system in general and to orthopedics care and research in particular. We propose that the notions integral to the lifespan developmental approach may offer useful and generative pathways for exploring the future of health care in an aging world. Recognition of the multidirectionality and multidimensionality of change within and across individuals will enhance clinical orthopedic care and produce more far-reaching research, both of which will contribute to better patient outcomes overall.

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Competing interests: None declared.

Contributors: S. Gautreau and O. Gould designed the study. S. Gautreau acquired and analyzed the data, which M. Forsythe also analyzed. S. Gautreau and O. Gould wrote the article, which all authors reviewed and approved for publication.

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Impact of sex on the clinicopathological characteristics and prognosis of papillary thyroid cancer

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Accepted for publication Apr. 6, 2016

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DOI: 10.1503/cjs.003816

Papillary thyroid cancer (PTC) is the most common endocrine malignancy. Observed clinical and pathological differences between the sexes of PTC patients have been reported. There is currently no consensus regarding the impact of sex on PTC prognosis. We studied 566 PTC patients and observed that there was a higher PTC incidence in women, that PTC diagnosis was more challenging in women, and that men tended to present with larger cancers. However, once PTC is diagnosed, both sexes have a similar cancer prognosis, as evaluated using the MACIS (Metastasis, Age, Completeness of Resection, Invasion, Size) score. Our observations suggest that research efforts should be especially directed at improving the diagnostic yield of preoperative fine-needle aspiration biopsy in women who present with nodular thyroid disease.

SUMMARY

Papillary thyroid cancer (PTC) is the most common endocrine malignancy; it accounts for more than 85% of all thyroid cancer cases, and globally its incidence has been steadily rising. Despite the considerable progress that has been made in understanding the molecular pathways that underlie thyroid cancer development and progression, the influence of sex on PTC clinicopathological characteristics and prognosis is currently unclear. Some reports have suggested that mortality might be twice as high in men with PTC than in women. However, other groups have reported that the only clinically significant prognostic factors for PTC are histopathologic subgroup, American Joint Commission on Cancer Stage (determined by patient age, cancer size and the presence of nodal or distant metastases), and the completeness of surgical resection. Our objective was to characterize and compare the clinicopathological characteristics and prognosis of PTC between the sexes.

We studied 566 sequential patients with newly diagnosed primary PTC who presented to St. Paul’s Hospital, Vancouver, B.C., between January 2000 and December 2013. Preoperative fine needle aspiration biopsy (FNAB) cytology was characterized as being either cancer, benign, indeterminate or inadequate. At our institution, the extent of thyroid surgery is consistent with American Thyroid Association (ATA) guidelines for management of adult patients with thyroid nodules and differentiated thyroid cancer. The MACIS score (Metastasis, Age, Completeness of Resection, Invasion, Size) was calculated for each patient as an estimation of PTC prognosis.

The clinical and pathological characteristics of the study population are summarized in Table 1. Most (77.6%) of the PTC patients were women. The average PTC size was significantly larger in men than women (1.98 cm vs. 1.68 cm, \( p = 0.002 \)). There was also a statistically significant difference in the proportion of women compared with men who underwent a total thyroidectomy as their initial operation (30.9% vs. 20.9%, \( p = 0.001 \)). Interestingly, there was no significant difference in PTC prognosis, as determined by the MACIS score, when comparing men to women (4.70 vs. 4.58, \( p = 0.08 \)). Similarly, we did not observe any statistically significant differences between the sexes with respect to mean age at PTC presentation, presence of vascular invasion by cancer, presence of lymph node metastasis, presence of distant metastasis and completeness of cancer resection. In addition, the incidence of papillary microcarcinoma (PMC; PTC < 1 cm) was not
DISCUSSIONS EN CHIRURGIE

significantly different when comparing women and men (34.4% v. 33.9%, \( p = 0.91 \)).

Some groups have suggested that thyroid cancer is more aggressive when diagnosed in men, with reduced survival rates in men compared with women. Our research focused on PTC, and although we observed that the average PTC size was significantly larger in men, this did not lead to a significant difference in their cancer prognosis. Our observations also suggest that PTC presents a greater diagnostic challenge in women. Women with an underlying PTC diagnosis were more likely than men to have an indeterminate preoperative cytological diagnosis (15.0% v. 4.7%, \( p = 0.032 \)), which led to more fluctuations than men in their TSH levels, with women undergoing more diagnostic thyroid lobectomies than men. After a pathological PTC diagnosis, the vast majority of these women also later went on to undergo a second operation for removal of their remaining thyroid lobe.

The ATA guidelines recommend that in the absence of prior head and neck irradiation or a history of familial thyroid cancer, a thyroid lobectomy is sufficient for treatment of PMCs without evidence of extrathyroidal cancer extension and/or the presence of lymph node metastases. We found the incidence of PMCs to be similar in both sexes. Thus, PMC should have had little influence on the type of operation initially performed, or on cancer prognosis, in our male and female patient population.

Thyroid stimulating hormone (TSH) is a known promoter of hyperplasia and may therefore be involved in thyroid tumorigenesis and progression. Women have more fluctuations than men in their TSH levels, with higher levels of TSH occurring during parts of the menstrual cycle, during pregnancy, or when using oral contraceptives. Differences in the TSH levels of men and women have been suggested to contribute to differences in thyroid nodule incidence, size and pathology. Sex hormones may also contribute to the observed sex differences in PTC patients. Using a transgenic mouse model of follicular thyroid cancer, Zhang and colleagues found that testosterone appeared to promote thyroid cancer progression through suppression of immune surveillance against cancer cells and reduction of tumour suppressor gene expression.

Our research had several limitations. As our study was retrospective, the thyroid nodule cytology was not consistently reported using the diagnostic groups outlined in the Bethesda System for Reporting Thyroid Cytopathology (BSRTC). Thus, confirmation of our observations regarding the increased difficulty in preoperative PTC diagnoses in women, in a BSRTC-characterized population, would be important. In addition, the extent of thyroid surgery for PTC treatment in current ATA guidelines is based on patient and cancer characteristics, and so completion thyroid lobectomy may not be recommended as commonly now as in the past. Furthermore, study of PTC is challenging because it may recur over more than 20 years; therefore, we used a composite PTC prognosticator, the MACIS score, to determine patient prognosis.

Our observations suggest that once diagnosed the treatment of PTC in men and women should be similar. However, treating physicians should be aware that female patients with an indeterminate preoperative cytological diagnosis are more likely than male patients to have an underlying cancer diagnosis. While this difference does not impact their final cancer prognosis, it may influence preoperative patient counselling and the extent of the initial thyroid operation. We believe that research efforts should be especially directed at improving the diagnostic yield of preoperative FNAB in women who present with nodular thyroid disease. Thus, patient sex should be considered when formulating a plan for the management of thyroid nodules, with the ultimate goal of minimizing morbidity and improving outcomes.

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Competing interests: None declared.

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

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**Table 1. Clinical and pathological characteristics of the PTC study population stratified by sex**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patient sex, mean ± SD (range) or %</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>Women (n = 439) 46.1 ± 13.5 (15.0–95.0)</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>Men (n = 127) 47.6 ± 12.7 (21.0–78.0)</td>
<td></td>
</tr>
<tr>
<td>Cancer size, cm</td>
<td>1.68 ± 1.43 (0.03–13.0)</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>1.96 ± 1.74 (0.05–10.0)</td>
<td></td>
</tr>
<tr>
<td>MACIS score</td>
<td>4.58 ± 1.09 (3.13–9.44)</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>4.70 ± 1.21 (3.15–8.90)</td>
<td></td>
</tr>
<tr>
<td>PMC incidence, %</td>
<td>34.4</td>
<td>0.91</td>
</tr>
<tr>
<td></td>
<td>33.9</td>
<td></td>
</tr>
<tr>
<td>Presence of distant metastases, %</td>
<td>0</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Presence of VI, %</td>
<td>19.6</td>
<td>0.08</td>
</tr>
<tr>
<td>Presence of LN metastases, %</td>
<td>37.8</td>
<td>0.67</td>
</tr>
<tr>
<td>Proportion of incomplete resections, %</td>
<td>7.3</td>
<td>&gt; 0.99</td>
</tr>
</tbody>
</table>

LN = lymph nodes; PMC = papillary microcarcinoma; PTC = papillary thyroid cancer; SD = standard deviation; VI = vascular invasion.
LETTER TO THE EDITOR: RESPONSE TO “SURGEON UNEMPLOYMENT: WOULD PRACTICE SHARING BE A VIABLE SOLUTION?”

We read with great interest the article by Wakeam and Feinberg regarding a shared practice model whereby a surgeon who is winding down practice partners with a young surgeon. Does this type of practice model need only apply to a transition into and out of practice? Are there other forms of sharing a practice where efficient use of resources and mentoring can occur? Our shared practice model may represent an alternative.

Although our clinic, endoscopy and operative resources have not increased proportionally as we hire surgeons to our colorectal group, complete clinical integration has afforded us a work environment that is efficient, fun and, most importantly, provides great patient care. There is a 1-line system to “The Ottawa Colorectal Group,” whereby 1 surgeon in our group may provide the initial consultation and obtain consent for an operative procedure, which may be performed by any of the 3 surgeons (soon to be 4); our offices and administrative support are all in 1 area. At times, all 3 of us are in clinic together, but invariably there are extra operative days, endoscopy time, academic activities or vacation that usually lead to 2 surgeons working together in clinic. Consequently, a surgeon in our group may meet a patient for the first time on the day of an operation and therefore must rely on a partner to establish a therapeutic relationship. With an automatic second opinion available at the time of consult, or when we run the list of patients with their management plans (at the end of clinic with the entire team, including our administrative staff), patients are happy to know that multiple surgeons are involved in their care. This also extends to the operating room, where we are consistently in each other’s rooms. There is also “round the clock” coverage of patients in all clinical settings (i.e., clinic to operating room), as the schedule is set up to ensure that at least 1 surgeon is always available. Hence, resources are not wasted, and inpatients receive consistent care through a rotating weekly coverage schedule (which is really nice from a lifestyle perspective). As eluded to, we are able to capture extra resources that become available, and now, as we expand to a fourth surgeon, we are extending beyond the academic centre to work with a large community hospital where, as a group, we will have privileges and regular operative time. This new partnership will not only foster mentorship within our group but also provide a means to mentor community-based surgeons wishing to learn new techniques in colorectal surgery, thereby enhancing patient care throughout our region. The right people are crucial for this model to work, as it is built on trust — personalities, technical skills, judgment and core value systems need to be aligned. We also need to communicate regularly and frequently — a good electronic medical record would facilitate improvement.

As general surgeons, we see this concept in action on the acute care service, which is replacing the traditional emergency surgery model; our shared practice represents a similar evolution within the elective setting.

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DOI: 10.1503/cjs.006216

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AUTHOR RESPONSE

Dr. Moloo and colleagues of the Ottawa Colorectal Group have posed an interesting question about how we can redesign practice models to maximize mentoring. Shared practices need not be restricted to surgeons coming into and out of practice. They describe another method of shared practice that would be useful in ensuring better mentoring and quality patient care. General surgery is an intense medical specialty where the maxim of “one sick patient is the difference between being not busy enough and too busy” is lived every day. As we evolve, we need to look to different ways of practising. We suggested a “job-share” as a way of integrating new graduates into practice with senior mentors, and Dr. Mooloo’s group has taken this shared practice to the next level.

One important consideration, however, is that the model we propose is a response to a lack of permanent employment positions. Of course, the benefits of additional mentorship and more flexible work hours in the early stages of practice to accommodate family life are perks of this system that apply regardless of the job situation; the most ideal circumstance is one in which all new graduates would have permanent positions that meet their needs and those of their patients. If we understand the model being proposed by Dr. Moloo and colleagues, it will not decrease the employment pressures on new graduates, though it may have other benefits.

Whether this works for all surgeons and patients will depend on philosophy of care and culture (e.g., in our opinion it is not ideal to meet a patient for the first time at the doors to the operating room, but this is purely a matter of preference). For the Ottawa model to work, it requires excellent communication, patient education and a consistent approach to care.

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From the General Surgery Residency Program, University of Toronto, Toronto, Ont. (Wakeam); and the Division of General Surgery, North York General Hospital, University of Toronto, Toronto, Ont. (Feinberg).

DOI: 10.1503/cjs.009416
The Moncton Hospital is recruiting a full-time Thoracic Surgeon to begin practice immediately. The department at present consists of five and a half general surgeons, one thoracic and two vascular surgeons. Applicants must be eligible for licensure in New Brunswick and hold subspecialty certification in Thoracic Surgery. Applicants will be expected to participate in the call schedule and teaching of residents. We are NCIC affiliated and opportunities exist for research. The hospital has two state-of-the-art MIS suites as well as a new outpatient complex including an up-to-date GI/ endoscopy suite, clinics and minor OR suites.

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

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

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

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

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

Applicants are invited to forward their CV to:

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