Apples and oranges

In the February 2016 issue of the *CJS*, Malik and colleagues[1] present data comparing recurrence rates for inguinal hernia repairs done in Ontario general hospitals to those done at the Shouldice Hospital. The Ontario Association of General Surgeons has several concerns about this paper, especially about the issue of selection bias and fair up-to-date comparison.

The Shouldice Hospital is a controversial entity among Ontario general surgeons, who generally consider them to be "cherry picking" the easiest hernias. Malik and colleagues acknowledged the potential for selection bias and that their databases lacked detailed clinical information on smoking; obesity; and hernia characteristics, such as size, which would allow for fair comparison. The authors attempted to measure selection bias indirectly by comparing outcomes of a small subgroup of patients who had a consultation at the Shouldice Hospital between 2004 and 2006 and then had their surgeries elsewhere.

The recurrence rate in this group was 3%, which the authors felt was insufficient to explain the large difference in recurrence rate. We, however, beg to differ and would argue that the presented data suggest a large selection bias. Since this study ended in 2007, the subgroup had an average of only 2 years of follow-up, and their 3% early recurrence rate is approximately double the 2-year recurrence rate when data from all years is considered (see Fig. 1 of their study). If one adjusted for secular trends, where the recurrence risk for hernias done from 2003–2007 was half that of the reference range of 1993–1997 (see Table 3 of their study), it would make the recurrence rate in those rejected several times above the concurrent provincial average and in the range where selection bias could account for a significant portion of the results.

The authors' estimate of a 10% rejection rate based on consultation rates is also highly contentious.

Shouldice promotes itself as not requiring a referral (only one-third of their patients in 2004–2006 had a referral and consultation), so a huge proportion of their selection and rejection process would be completely invisible to the databases used by these researchers. The selection process at Shouldice has a significant emphasis on ideal body weight, and many patients are rejected owing to failure to achieve weight loss goals that are not imposed by most other surgeons. When one considers that 72% of middle-aged men in Ontario are obese or overweight,[2] a large proportion of these patients would be ineligible for surgery at the Shouldice Hospital despite its publicly funded status. This is a level of discrimination not seen at other Ontario hospitals.

We would also point out that there have been at least 16 randomized controlled trials of the Shouldice repair wherein selection bias is implicitly eliminated by randomization. A meta-analysis[3] and Cochrane review[4] of these trials clearly shows a strong advantage for mesh repairs, essentially showing the exact opposite of what Malik and colleagues reported, with mesh-based repairs being 4 times less likely to recur. In short, Malik and colleagues report an effect that is 16 times better than what the randomized literature shows. We also criticize the study for focusing on hospital volume rather than surgeon volume or technique, both of which were tracked in the databases used. The impact of hospital volume would be expected to influence only cases requiring complex hospital care and, indeed, this study found no trend between high- and low-volume general hospitals. Surgical technique, particularly the use of mesh, has been shown in multiple studies to have a significant impact,[3,4] yet it was not adjusted for.

We also criticize the study for presenting aggregate data that clearly span a transitional period in hernia repair, where most surgeons made an appropriate evidence-based shift away from tension-based tissue repairs to tension-free mesh repairs.[3] The overall 50% reduction in recurrence rate over the course of this study is hidden in the fine print and is probably due to technique. A comparison with an old technique that is largely abandoned only magnifies the difference in recurrence rates and doesn't inform about current practice.

The study does raise the interesting question as to whether extremely high surgeon volume can impact results. A population-based study from Sweden[5] found very little impact of surgeon volume, with recurrence rates generally plateauing at an annual rate of only 10 per year and, though volumes did not approach those of the Shouldice hospital, there was no trend toward better outcomes with higher volumes.

Finally, we point out that the fee code for recurrence is essentially a self-reported variable that is unvalidated in the setting of a private company with a marketing strategy that is based on low recurrence rates.

We feel that this paper gives a misleading picture of the current status of inguinal hernia surgery in Ontario and would caution health care planners that selection bias rather than process issues are by far the most likely explanation of the results presented. We do acknowledge that its publication will hopefully stimulate an important debate about the quality of hernia surgery in Ontario and the importance of measuring adjusted outcomes, of which recurrence is but one.

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References

1. Malik A, Bell CM, Stukel TA, et al. Recurrence of inguinal hernias repaired in a large hernia surgical specialty hospital and general hospitals in Ontario, Canada. *Can J Surg* 2016;59:19-25.
2. Statistics Canada. Table 105-0501 - Health indicator profile, annual estimates, by age group and sex, Canada, provinces, territories, health regions (2013 boundaries) and peer groups. CANSIM (database) (accessed 2016, Feb. 12).
3. EU Hernia Trialists Collaboration. Repair of groin hernia with synthetic mesh: meta-analysis of randomized controlled trials. *Ann Surg* 2002;235:322-32.
4. Amato B, Moja L, Panico S, et al. Shouldice technique versus other open techniques for inguinal hernia repair. *Cochrane Database Syst Rev* 2012;4:CD001543.
5. Nordin P, van der Linden W. Volume of procedures and risk of recurrence after repair of groin hernia: national register study. *BMJ* 2008;336:934-7.

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Author response

We don't know exactly why people who had an inguinal hernia repair at the Shouldice Hospital had a much lower rate of surgery for recurrence than those who had hernias repaired elsewhere in Ontario. Ultimately, there are only 3 possible explanations: patient selection, surgical technique, or perioperative care. Most likely, it is some combination of these factors.

Dr. Vinden suggests that patient selection largely explains the difference, and he may be correct. However, for selection alone to account for the extraordinary difference in surgical recurrences we observed, the influence of selection must be enormous. Even assuming that 30% of all patients seen at the Shouldice Hospital are rejected for surgery and have their hernia repairs done elsewhere, the recurrence rate among those patients would have to be nearly 14% to mask a "true" risk of recurrence that is equivalent to the surgical recurrence risk in general hospitals.

It is true that randomized trials do not support the use of the Shouldice technique for inguinal hernia repair, especially when compared to modern, tension-free repairs. Like Dr. Vinden, we do not believe that general surgeons should stop performing their usual technique of hernia repair — with which they are most skilled and confident — in favour of a repair that is notoriously difficult to perform well in typical practice settings. We also agree that it is neither advisable nor feasible to regionalize a procedure as common as inguinal hernia repair to specialty hospitals.

On the other hand, it appears that much may be learned about inguinal hernia repair from large specialty hospitals — even if those lessons relate to issues such as how patient selection and preparation influence outcomes, and the value of focused expertise even in a relatively minor surgical procedure.

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Letter to the Editor

We are writing to respond to Drs. Vinden and Ott's commentary, "GPs with enhanced surgical skills: a questionable solution for remote services." We commend the authors for appealing to research data to inform the discussion of the need for a standardized curriculum by considering the efficacy of family physicians with enhanced surgical skills (FPESS) in meeting the health care needs of rural Canadians. However, we feel some of the data referenced has been misconstrued and would like to contribute to this discussion, focusing primarily on data regarding maternity services and operative delivery.

Regarding the volume-to-outcomes data cited,[1] the context of the data was analysis of outcomes from 3 major hospital systems in the United States who committed to a volume threshold for 10 high-complexity surgeries. The author explains why volume is traditionally used instead of outcomes in the evaluation of surgical competence (to account for the procedure selection bias of surgeons and ease of data access) but concludes that "the mechanism underlying volume–outcomes relationships remain unknown." Further, he argues that if the underlying mechanism is one of increased practice leading to better outcomes, support for best practice models and quality improvement — not volume thresholds — is the most appropriate response.[1] As the author notes,

> if, on the other hand, outcomes improve because hospitals and surgeons gain expertise with incremental experience through a "practice makes perfect" mechanism, then the focus should be on dissemination of best practices and quality improvement.[1]

Additionally — and more pertinent to the current discussion — an earlier study by Urbach and colleagues[2] comparing volume studies from Canada and the United States found:

> (…)that volume–outcome associations are much less common in Canada than in the United States, perhaps because different models of health care financing and delivery affect patterns of procedure volumes and volume–outcome associations. Market-based models promote competition between hospitals and providers, which may exacerbate existing variations in quality of care. The extent to which models of health care financing and organization cause variation in health outcomes across hospitals, and contribute to volume–outcome associations, has not been fully appreciated or examined.