SPECIAL ARTICLE

Canadian Association of General Surgeons, the American College of Surgeons, the Canadian Society of Colorectal Surgeons, and the American Society of Colorectal Surgeons Evidence Based Reviews in Surgery – Colorectal Surgery

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The term "evidence-based medicine" was first coined by Sackett and colleagues as "the conscientious, explicit and judicious use of the current best evidence in making decisions about the care of individual patients."[1] The key to practicing evidence-based medicine is applying the best current knowledge to decisions in individual patients. Medical knowledge is continually and rapidly expanding and reading all of the medical literature is impossible for an individual clinician. For clinicians to practice evidence-based medicine, they must have the skills to read and interpret the medical literature so they can determine the validity, reliability, credibility and utility of individual articles, ie, critical appraisal skills. In general, critical appraisal requires that the clinician have some knowledge of biostatistics, clinical epidemiology, decision analysis, and economics, and clinical knowledge, as well.

The Canadian Association of General Surgeons and the American College of Surgeons jointly sponsor a program entitled "Evidence Based Reviews in Surgery" (EBRS), supported by an educational grant from Ethicon Endo Surgery Inc and Ethicon Endo Surgery Canada. The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. EBRS has a module covering topics in colorectal surgery. Each academic year, 6 clinical articles are chosen for review and discussion. The articles are selected not only for their clinical relevance to colorectal surgery, but also to cover a spectrum of methodological issues important to surgeons; for example, causation or risk factors for disease, natural history, or prognosis of disease, quantifying disease (measurement issues), diagnostic tests and the diagnosis of disease, and the effectiveness of treatment. Both methodological and clinical reviews of the article are performed by experts in the relevant areas and posted on the Evidence Based Reviews in Surgery-Colorectal Surgery (EBRS-CRS) Web site. In addition, a listserv discussion is held where participants can discuss the monthly article. Members of the Canadian Association of General Surgeons (CAGS) and the American College of Surgeons (ACS) can access EBRS-CRS through the Canadian Association of General Surgeons Web site (www.cags-accg.ca), the American College of Surgeons Web site (www.facs.org/education/ebrs.html), the Canadian Society of Colon and Rectal Surgeons (CSRCS) Web site (www.cscrs.ca), and the American Society of Colon and Rectal Surgeons (ASCRS) Web site (www.fascrs.org), All journal articles and reviews are available electronically through the Web site. Surgeons who participate in the monthly packages can receive 6 CME and/or Maintenance of Certification credits by completing an evaluation and a series of multiple-choice questions each month. For further information about EBRS-CRS, readers are directed to the CAGS, ACS, CSCRS, and ASCRS Web sites or should email the administrative coordinator, Marg McKenzie at mmckenzie@mtsinai.on.ca

In addition to making the reviews available through the CAGS and the ACS Web sites, a condensed version of the reviews will be published in the *Diseases of the Colon & Rectum*. EBRS is useful in improving your critical appraisal skills, in keeping abreast of new developments in colorectal surgery, and, most importantly, in being able to obtain 6 CME credits each month from anywhere that you have access to a computer. Comments about EBRS may be directed to mmckenzie@mtsinai.on.ca

SELECTED ARTICLE

Simunovic M, Coates A, Goldsmith CH, et al. The cluster-randomized quality initiative in rectal cancer trial:

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evaluating a quality-improvement strategy in surgery. *CMAJ*. 2010;182:1301–1306.

QUESTION: Does a quality improvement strategy in rectal cancer surgery improve outcomes?

DESIGN: This article is based on a cluster-randomized controlled trial.

SETTING: This study was conducted at 16 hospitals with an annual volume of 15 or more major resections for rectal cancer.

SUBJECTS: One hundred five surgeons, 56 surgeons (n = 558 patients) in the intervention arm and 49 surgeons (n = 457 patients) in the control arm, were eligible if they performed major rectal surgery (ie, partial or complete segmental resection of rectum with or without an anastomosis) for a diagnosis of primary rectal cancer from May 2002 to December 2004.

INTERVENTIONS: Surgeons in the intervention arm attended workshops, used opinion leaders, invited a study team surgeon to demonstrate optimal techniques of total mesorectal excision, completed postoperative questionnaires, and received audits and feedbacks. Surgeons in the control arm received no intervention.

MAIN OUTCOMES: The primary outcomes measured were the hospital rates of permanent colostomy and local recurrence of cancer.

RESULTS: The median follow-up of patients was 3.6 years. In the intervention arm, 70% of surgeons participated in workshops, 70% participated in intraoperative demonstrations, and 71% participated in postoperative questionnaires. Surgeons who had an intraoperative demonstration provided care to 86% of the patients in the intervention arm. The rates of permanent colostomy were 39% in the intervention arm and 41% in the control arm (OR 0.97, 95% CI 0.63–1.48). The rates of local recurrence were 7% in the intervention arm and 6% in the control arm (OR 1.06, 95% CI 0.68–1.64).

CONCLUSION: Despite good participation by surgeons, the resource-intense quality-improvement strategy did not reduce hospital rates of permanent colostomy or local recurrence in comparison with usual practice.

COMMENTARY: Simunovic and colleagues[2] performed a randomized controlled trial designed to determine whether an intensive education program consisting of education workshops, intraoperative demonstrations by expert surgeons, and audit and feedback would improve surgical techniques of total mesorectal excision (TME) and lead to decreased permanent colostomy rates and local recurrence following rectal cancer surgery. Surgeons at 16 hospitals in Ontario were cluster randomly assigned to the intervention group or a control group (where they performed surgery according to their normal practice and had no additional TME education). In total, 56 surgeons who operated on 558 patients were included in the intervention group and 49 surgeons who operated on 457 patients were included in the control group. Of surgeons in the intervention hospitals, approximately 70% attended a TME workshop, had 1 or more intraoperative demonstrations, and completed at least 1 postoperative questionnaire. The baseline characteristics of the patients in the 2 groups were similar, although patients in the intervention arm were slightly more likely to have preoperative radiation (15.6% vs 9.6%). After a median follow-up of 3.6 years, the authors found there were no significant differences in the rates of permanent colostomy (39% in the intervention and 41% in the control group) or in the local recurrence rates (7% in the intervention and 6% in the control group).

Although there were no significant differences in the primary outcomes, there were several interesting findings in the study: more than 91% of surgeons who worked at the study hospitals participated in the trial. Surgeons in the intervention arm uniformly reported that the trial strategy led to improvements in the quality of their rectal surgery. Finally, it is noteworthy that surgeons were more likely to request an intraoperative demonstration in patients with low tumors.

Although the trial failed to show differences in outcomes, the local recurrence rates of 6% and 7% are similar to those reported in other population-based studies, and in large randomized controlled trials, as well. In both the Dutch and UK studies,[3,4] rectal cancer excision with the use of TME techniques was the standard. In the control groups of these studies, the local recurrence rates were 8.2% in the Dutch and 11% in the UK trials, although lower rates were observed in the groups that received neoadjuvant radiation (2.4% in the Dutch and 4% in the UK trials), likely because neoadjuvant radiation was given to only 15% of patients in the intervention and 9% of the patients in the control groups. Although circumferential radial margin positivity was not a primary objective, the circumferential radial positivity rates of 7.3% in the intervention and 9.6% in the control arms compare favorably with those observed in the Dutch and UK trials: circumferential radial margins were histologically positive in 17% of T3 and 25% of T4 cancers in the Dutch trial and 10% in the UK trial.

Permanent colostomy rates in this study were also similar to those observed in both the Dutch and UK trials. In the United States, the reported permanent colostomy rates are about 50%, with great variation among geographic counties (less than 20%–100%) with higher rates in more rural areas where there are lower volumes of rectal cancer operations.[5] Subspecialty high-volume rectal cancer centers report permanent colostomy rates of less than 20% while maintaining local recurrence rates of less than 5%.

In this study, the quality of TME was not assessed, because the authors stated that there were no validated

methods for assessing the quality of TME when the trial was started. Subsequently, Quirke and colleagues[6] have proposed a method for objectively assessing the quality of surgical excision. With the use of this method, the plane of surgical dissection was good (mesorectal) in 52%, intermediate (intramesorectal) in 34%, and poor (muscularis propria plane) in 13%. The corresponding local recurrence rates were 4%, 7%, and 13%. The Dutch study reported the surgical dissection plane in a subset of abdominoperineal resection patients as mesorectal in 9.8%, intramesorectal in 57.1%, and muscularis in 33.1%.

So how does one interpret the results of this trial? One interpretation is that this trial may have been performed "too late," because TME surgery was introduced and adopted in the 1990s in many countries. Thus, most Canadian surgeons would have been aware of the appropriate surgical technique, and the preexisting operative skills of surgeons in both the intervention and control arms were likely equivalent, so there was little impact from the addition of an education program. Another possibility is that rectal cancer surgery techniques are so topical, and there may have been medical education events held concurrently that changed the practice of those in the control group. Finally, there may have been a Hawthorne effect. Hawthorne effect is the improvement in performance that results from subjects being aware that a study is being performed to improve outcome rather than from the experimental intervention itself. Unfortunately, because outcome data were not collected at baseline in patients who had surgery performed by the surgeons who participated in the trial, one can only speculate on the reason. However, by 2002, results from other countries had been published and had shown improved outcomes after the introduction of TME surgery. The Swedish training program resulted in a decrease in local recurrence from 19% to 8%, and reduced end colostomy rates from 55% to 27%, with a 10% increase in survival.[7] Wibe and colleagues[8] reported similar results in a Norwegian project. Thus, it is likely that similar changes in technique and outcome had also occurred in Canada.

Although the researchers hoped to show a difference in the colostomy rates, it may be that the colostomy rate has nothing to do with surgical skill, but is related more to good surgical judgement. There are so many different considerations that affect the stoma rate that it would be more-or-less impossible to observe a difference between the groups. Furthermore, after a very low anterior resection or an intersphincteric resection, at least 20% of patients will become completely incontinent. It can be questioned, therefore, if sphincter preservation is a good and valid end point in rectal cancer surgery, even when quality of life is considered.

What does this study tell us about the value of quality improvement initiatives? Workshops have been used in Sweden, the Netherlands, Norway, and the United Kingdom to teach TME techniques, and publications have shown a consistent improvement in outcomes in patients having surgery for rectal cancer.[9]

The results of this study should not change the practice of using workshops, conferences, and demonstrations for continuing medical education. With the introduction of new surgical techniques (another example is laparoscopic colectomy), such education interventions are necessary to keep practicing surgeons up-to-date with new technologies. However, further research is required to determine whether such education interventions are effective in improving clinical outcomes in patients and to assess the effectiveness of an educational strategy. Education interventions are costly, but are necessary for clinicians to keep up with medical advances if they are effective.

As an alternative to interventions such as this, audit and feedback may be equally effective and less expensive. The experience from the Scandinavian countries is that auditing can change outcome dramatically. Important end points such as lymph node retrieval and the effect of tumor boards have been evaluated. Initially, outcomes were far from perfect, but within 3 years the lymph node retrieval rate in Sweden reached acceptable levels and that was the same experience with discussions of patients in tumour boards.

Finally, the results of this study should not be taken to mean that there is no room for further improvement. Recent publications have reported 1% local recurrence rates suggesting that outcome can be improved further. This may require more training or improvements in other disciplines such as radiation oncology, pathology, and imaging.

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ERRATUM

The Uses of Surgical History: Erratum

In the Editorial appearing in the August 2012 issue, the inaugural article in the Historical Perspectives section was mistakenly attributed to Rodrigo O. Perez. The first author of the Historical Perspectives article is Fábio Guilherme Campos.

Therefore, the correct sentence in the final paragraph of the Editorial should read as follows:

> The inaugural article by Fábio Guilherme Campos et al., "Abdominal Excision: Evolution of a Centenary Operation" is an outstanding review of the evolution of surgery for rectal cancer.[8]

In addition, reference 8 in this Editorial contains an incorrect author listing. The correct reference 8 is as follows.

Campos FG, Habr-Gama A, Nahas SC, Perez RO. Abdominal excision: evolution of a centenary operation. *Dis Colon Rectum*. 2012;55:844–853.

We apologize for this error and any inconvenience that has resulted.

REFERENCE

1. Madoff RD. The uses of surgical history. *Dis Colon Rectum*. 2012;55:829–830.