

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. Generally, critical appraisal requires that the clinician have some knowledge of biostatistics, clinical epidemiology, decision analysis, and economics as well as clinical knowledge.

The Canadian Association of General Surgeons and the American College of Surgeons jointly sponsor a program entitled “Evidence Based Reviews in Surgery” (EBRS). The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. Evidence Based Reviews in Surgery 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 rel-

evant 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.csrscs.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, CSRCS, 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 *Diseases of the Colon & Rectum*. Evidence Based Reviews in Surgery is useful in improving your critical appraisal skills and in keeping abreast of new developments in colorectal surgery; and, most importantly, you are 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

Temple LK, Bacik J, Savatt SG, et al. The development of a validated instrument to evaluate bowel function after

sphincter-preserving surgery for rectal cancer. *Dis Colon Rectum*. 2005;48:1353–1365

OBJECTIVE: The aim of this study was to develop a validated instrument to evaluate bowel function after sphincter-preserving surgery.

METHODS: A 41-item bowel function survey was developed from a literature review, expert opinions, and 59 patient interviews. An additional 184 patients who underwent sphincter-preserving surgery between 1997 and 2001 were asked to complete the survey and quality-of-life instruments (Fecal Incontinence Quality of Life, European Organization for Research and Treatment of Cancer QLQ 30/Colorectal Cancer 38). A factor analysis of variance was performed. Test-retest reliability was evaluated, with 20 patients completing 2 surveys within a mean of 11 days. Validity testing was done with clinical variables (sex, age, radiation, length of time from surgery), surgical variables (procedure: local excision, low anterior resection, coloanal anastomosis), reconstruction (J-pouch, straight), anastomosis (handsewn, stapled), and quality-of-life instruments. **RESULTS:** The survey response rate was 70.1% (129/184). Among the 127 patients with usable data, 67% were male, the median age was 64 (range, 38–87) years, and the mean time for restoration of bowel continuity after sphincter-preserving surgery was 22.9 months. Patients had a median of 3.5 stools/day (range, 0–30), and 37% were dissatisfied with their bowel function. Patients experienced a median of 22 symptoms (range, 7–32), with 27% reported as severe, 37% reported as moderate, and 36% reported as mild. The 5 most common symptoms were incomplete evacuation (96.8%), clustering (94.4%), food affecting frequency (93.2%), unformed stool (92.8%), and gas incontinence (91.8%). The factor analysis identified 14 items that collapsed into 3 subscales: frequency ($\alpha = 0.75$), dietary ($\alpha = 0.78$), and soilage ($\alpha = 0.79$) with acceptable test-retest reliability for the 3 subscales and total score (0.62–0.87). The instrument detected differences between patients with preoperative radiation ($n = 67$) versus postoperative radiation ($n = 15$) versus no radiation ($n = 45$) ($p = 0.02$); local excisions ($n = 10$) versus low anterior resection ($n = 55$) versus coloanal anastomosis ($n = 62$) ($p = 0.002$); and handsewn ($n = 18$) versus stapled anastomosis ($n = 99$) ($p = 0.006$). The total score correlated with 4 of 4 Fecal Incontinence Quality of Life ($p < 0.01$) and 9 of 17 European Organization for Research and Treatment of Cancer subscales (all $p < 0.01$).

CONCLUSION: Patients undergoing sphincter-preserving surgery for rectal cancer have impaired bowel function, and those treated with radiation, coloanal anastomoses, or handsewn anastomoses have significantly worse function. This reliable and valid instrument should be used to prospectively evaluate bowel function after sphincter-preserving surgery in patients undergoing rectal cancer therapy.

COMMENTARY: Over the past 20 years, major advances in rectal cancer treatment—specifically preoperative radiation and the dissemination of total mesorectal excision—have led to substantially improved local recurrence and survival rates, as well as the preservation of GI continuity without colostomy. Currently, about 60% to 80% of the patients who have low rectal cancer undergo sphincter-preserving surgery (SPS).² Some authors have even suggested using SPS rates as a measure of the quality of surgical care.³ Unfortunately, however, SPS frequently is associated with poor functional outcomes that can vary from mild inconvenience to incapacitation.

Bowel dysfunction among patients who have rectal cancer largely depends on treatment factors such as preoperative (and postoperative) radiation, height of the anastomosis, type of reconstruction, and the presence of an anastomotic leak,^{4–7} implying that alterations in treatment may mitigate dysfunction. However, there has been little progress in the development of a coordinated approach to bowel dysfunction after SPS—or even a reliable mechanism for setting patient expectations. For the most part, studies focused on improving bowel function after SPS have assessed only the type of reconstruction. A Cochrane review, for example, examined the effect of coloplasty, straight anastomosis, and colonic J-pouch on bowel function.⁸ Comparison across studies was limited by the absence of a uniform outcome measure. In fact, the literature in general has lacked a sensitive, validated instrument specifically designed to measure bowel function among patients who have rectal cancer, and meaningful clinical progress in this population may depend on one.

To that purpose, Temple et al developed and validated the Memorial Sloan-Kettering Cancer Center (MSKCC) Bowel Function Index to assess bowel function specifically among patients who have undergone SPS for rectal cancer.⁹ The MSKCC Bowel Function Index measures function by using 18 questions grouped among the 3 domains of frequency of stool, soilage/urgency, and dietary modification, as well as single items to measure the ability to control gas, the ability to differentiate gas from stool, clustering (passage of stool within 15 minutes of a previous bowel movement), and the ability to totally empty the bowels. It was designed as a discriminative instrument to differentiate between patients with better and worse function—not changes within individual patients over time (an evaluative instrument).

The MSKCC Bowel Function Index was developed and tested with the use of rigorous methodology. Items were generated by using all relevant sources: a literature review, a focus group with 6 clinical content experts, and 3 pilot studies with patients that included a qualitative interview, a cognitive interview regarding survey items, and a subsequent survey pilot. Items were then reduced by using correlations and factor analysis of variance, with follow-up

to ascertain that no important items were lost. Construct validity was demonstrated by the high correlation between the MSKCC bowel function instrument and the Fecal Incontinence Quality of Life, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) C30 and EORTC QLQ-C38 (for colorectal cancer). Reliability was tested by asking participants to complete the survey again a mean time of 11 days after the first completion. Twenty patients participated, and the Pearson correlation coefficient was highly statistically significant for all subscales, indicating high reliability.

Every patient with rectal cancer who underwent SPS at MSKCC was invited to participate, thereby permitting a comparison of results based on modifiable treatment variables such as the use and timing of radiation and different surgical techniques. For this study, it was appropriate to measure only postoperative patients (cases) without “normal” controls, because the intervention was necessary among cases and would not be performed among noncancer patients (controls). The use of patients with rectal cancer who had undergone abdominoperineal resection (not SPS) as controls would have been appropriate for measurement of quality of life⁶ but not for defecatory function.

Temple et al found that the instrument was able to detect statistically significant differences in function based on radiation therapy (preoperative versus postoperative versus none), radicality of operation (local excision versus low anterior resection versus coloanal anastomosis), and method of anastomosis (stapled versus handsewn) anastomosis for both the frequency and soilage subscales.

The study also reported important clinical outcomes. The median number of daily bowel movements for patients undergoing restorative proctectomy for rectal cancer was 3.5 (range, 0–30). Patients experienced a median of 22 symptoms (range, 7–32); 27% had severe symptoms, 37% had moderate symptoms, and 36% had mild symptoms. The 5 most common symptoms were incomplete evacuation (96.8%), clustering (94.4%), food affecting frequency (93.2%), unformed stool (92.8%), and gas incontinence (91.8%). Only 50% of patients were satisfied with their bowel function, whereas 43% were distressed. Despite these findings, only 3% of patients reported that they would have preferred a permanent stoma “always or most of the time.”

This article introduces a useful research tool and also provides clinical insight into the degree of alteration in bowel function that follows restorative proctectomy for rectal cancer. Most existing bowel function questionnaires assess continence in patients with benign disease and are not designed to assess the other components of bowel function that may be unique to patients who have been treated for rectal cancer. These components include the effect of preoperative radiation, the extent of resection, method of reconstruction, and the height and method of anastomosis.

The study is necessarily limited by a focus on postoperative function, and therefore does not measure well-being, chronic pain, role function, sexual function, and other important aspects of health-related quality of life. Several studies have shown that bowel function deteriorates in almost every patient who has rectal cancer after treatment, but the effect on quality of life is variable.^{5–7,10} For a more comprehensive assessment, this instrument could be paired with a quality-of-life instrument such as the EORTC QLQ-C38 noted above. In addition, the Bowel Function Index has only been validated as a discriminatory instrument. Its evaluative properties, which would identify change within individual patients over time or after treatment, remain to be tested. It could potentially serve a valuable purpose in this regard to predict how bowel function may change over time or to assess interventions to improve bowel function among individuals. Finally, because the Bowel Function Index has been used in only 2 studies to date,^{11,12} it is not yet clear how it may be best deployed for clinical use.

In summary, understanding and improving postoperative bowel function is vital to patient-centered care in the setting of rectal cancer. Radiation may not provide a clinical benefit to every patient⁴ nor does restoration of intestinal continuity always result in improved quality of life.¹³ The complex risk:benefit decisions that patients and physicians must make and the evolving “individualized treatment approach” now advocated by many rectal cancer experts⁸ require that the impact of current treatment modalities on bowel function and quality of life be accurately measured by using a valid and reliable instrument. The MSKCC Bowel Function Index, applied consistently, would be highly valuable to rectal cancer surgeons and their patients, because it could provide the opportunity to integrate study results, enhance shared decision making in the choice of procedure, and permit the coordination of care around postoperative bowel function.

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