

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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for the members of the Evidence Based Reviews in Surgery Group

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, 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), supported by an educational grant from Ethicon Inc., Ethicon Endo Surgery, Inc., and Ethicon Endo Surgery. The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. Beginning in 2007, EBRS also included 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) website. 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 website (www.cags-accg.ca), the American College of Surgeons website (www.facs.org/education/ebrs.html), the Canadian Society of Colon and Rectal Surgeons (CSCRS) website (www.cscrs.ca), and the American Society of Colon and Rectal Surgeons (ASCRS) website (www.fascrs.org). All journal articles and reviews are available electronically through the website. Surgeons who participate in the current (modules) packages can receive CME and/or Maintenance of Certification credits by completing an evaluation and a series of multiple-choice questions. For further information about EBRS-CRS, readers are directed to the CAGS, ACS, CSCRS, and ASCRS websites or should email the administrator, Marg McKenzie at mmckenzie@mtsinaio.on.ca

In addition to making the reviews available through the CAGS and the ACS websites, a condensed version of the reviews will be published in the *Diseases of the Colon & Rectum*. We hope readers will find EBRS useful in improving their critical appraisal skills and also in keeping abreast of new developments in general surgery. Comments about EBRS may be directed to mmckenzie@mtsinaio.on.ca.

SELECTED ARTICLE

Cornish JA, Henry ST, Heriot AG, Lavery IC, Fazio VW, Tekkis PP. Meta-analysis of quality of life for abdominoperineal excision of rectum versus anterior resection for rectal cancer. *Ann Surg Oncol*. 2007;14:2056–2068.

PURPOSE: This article aimed to compare the quality of life in patients with rectal cancer who undergo an abdominoperineal resection (APR) vs an anterior resection (AR).

DATA SOURCES: A literature search of MEDLINE, Embase, PubMed, and Cochrane databases was conducted to identify studies between 1966 and 2006 reporting comparisons of quality of life between APR and AR.

STUDY SELECTION: Selected studies were included for analysis if they compared APR and AR, and if they used validated tools for quality-of-life measurement.

OUTCOME MEASURES: The SF-36 and QLQ C30/CR38 were used. Both instruments measure the quality of life within a range of domains as well as provide an overall indication of quality of life.

RESULTS: Outcomes for 1,443 patients from 11 studies, of whom 486 (33%) underwent APR, were included and quality-of-life assessments were made at periods of up to 2 years after surgery. There was no significant difference in global health scores between APR and AR. Vitality (weighted mean difference (WMD) -9.82 ; 95% CI $-27.01, -2.04$, $P = .01$) and sexual function (WMD -2.73 ; 95% CI $-4.93, -0.64$, $P = .01$) were significantly better in AR patients. Patients with low AR had improved physical function scores in comparison with APR patients (WMD -4.67 ; 95% CI $-9.10, -0.23$; $P = .004$). Cognitive (WMD 3.57 ; 95% CI $1.41, 5.73$; $P < .001$), and emotional function scores (WMD 3.51 ; 95% CI $1.40, 5.62$; $P < .001$) were higher for APR patients.

CONCLUSION: There was no difference in general quality of life in patients who had APR and AR. Vitality and sexual function were better in patients having AR, whereas cognitive and emotional function were higher in patients having APR.

COMMENTARY: When faced with the diagnosis of rectal cancer, one of the patient's greatest concerns is whether he or she will require a permanent stoma. The issue of a stoma is complex. On the one hand, our stoma rates are probably too high nationally, and many authors use sphincter preservation as a marker for quality. On the other hand, the impact of an ultralow anastomosis on a patient's overall quality of life (QOL) is largely unknown, yet it is likely more significant than clinicians or patients appreciate. Understanding the impact of a stoma on overall QOL after rectal cancer treatment is important clinically, because it enables surgeons to provide patients with meaningful information to better inform their decision-making process. This systematic review by Cornish et al is an important paper that remains highly topical in 2011.

Meta-analysis is a very powerful tool in medicine.² Combining data from randomized controlled trials can often result in clarifying findings from small discrepant trials. By combining small trials, one can argue that the results from a meta-analysis are valid because patients from the individual trials were randomly selected, so that there should be no systematic bias. In fact, some argue that the

results constitute a higher level of evidence than a randomized controlled trial. However, there is no perfect method to control for the fact that the results come from several trials rather than one large randomized controlled trial. It is also important to note that this systematic review includes data from retrospective rather than prospective studies to compare the quality of life in patients with and without permanent stomas. Although it is not as powerful as a meta-analysis that includes randomized controlled trials or even prospective observational trials, it still uses data from retrospective studies in a methodologically sound way.

Cornish et al set explicit inclusion and exclusion criteria. Therefore, the reader may make his or her own decisions about whether the results from the meta-analysis are clinically meaningful. In addition, Cornish used appropriate statistical techniques to derive summary scores by weighing the data from each study (using its sample size and standard deviations) to derive the results. Thus, larger studies and/or studies with less variation are more heavily weighted, because they are presumably methodologically stronger.

When reviewing the results of a meta-analysis, one of the major concerns is whether combining the results of various studies is even appropriate. It is particularly true in this meta-analysis, because it is likely that many important variables such as radiation, timing of radiation, level of tumor, time from surgery, and patient demographics are not balanced between the 2 groups. In addition, given that the criteria for performing an APR vs sphincter preservation differ between centers, it is likely that the sphincter preservation groups are overpopulated with patients treated for upper rectal cancer, who typically have better functional outcomes. The authors attempted to ensure that the combined data are similar enough to make comparisons using specific statistical tools (tests for heterogeneity, fixed effects vs random effects). Unlike studies with primary data, multivariate analyses are not really possible in meta-analyses. For important variables (clinical or methodological), sensitivity analyses can be performed to ensure that the inclusion or exclusion of certain studies (based on a priori features) does not change the results of the meta-analysis. In this study, the authors attempted to control for clinical features by excluding patients with high tumors, and performed sensitivity analyses comparing the outcomes of patients with low tumors (<8 cm from anal verge) who underwent low anterior resection with the outcomes of patients with APR. Regardless of statistical tests and/or sensitivity analyses, including the demographics of patients of the 2 groups and APR groups would have helped us formulate a better understanding of the similarities and/or differences in the 2 groups.

The data included in this meta-analysis were retrospective, and its quality was probably variable. The authors tried to control for this by "grading" the study quality and then performing sensitivity analyses based on quality

“grade.” However, this probably did not address many issues that are present in measuring QOL. There was no discussion about differences in the response rates and/or the completeness of data for a given subscale. This is an important limitation, because data from studies with low response rates and/or incomplete data for any subscale introduce significant bias into a study. For example, it may be that patients with lower quality of life were less willing to complete the survey, or more likely to skip important questions related to body image and/or sexual function. Thus, without a clear description of the data quality within this meta-analysis, it is possible that the data do not represent the population of patients who have undergone surgery for rectal cancer.

There were some differences in the subscales between the 2 groups; for instance, cognitive and emotional function and future perspective favored APR, and role function and sexual function favored anterior resection. Although it is possible that these differences are simply due to multiple comparisons, they are clinically sensible. However, these differences are not that striking, and it may be that currently available QOL instruments do not focus on the most important aspects of QOL that distinguish outcomes between patients with and without a stoma.

It is also important to note that, even though comparisons were made between APR and AR, it is the location of the tumor that dictates the surgical approach. Therefore, the outcomes may represent the role of response shifts and adaptation after treatment of rectal cancer, and results, in an equilibration of QOL between the 2 groups. This report clearly provides important data regarding postoperative QOL, but further studies are required to better understand the outcomes in these 2 groups.

Quality-of-life measurement can be quite difficult, and Cornish et al did an excellent job in synthesizing the available data. Although the study has some limitations, the inclusion of studies using validated instruments made it possible for the authors to compare outcomes between

patients with APR vs AR. The most interesting finding in this meta-analysis is that the differences between patients with and without a permanent stoma are quite small. Although there is increasing pressure to provide sphincter preservation and avoid a permanent stoma for all patients with rectal cancer, these data suggest that QOL does not differ significantly between the two. Developing methods to individualize the delivery of rectal cancer therapy is required and incorporating patient-centered outcomes into the decision-making process is paramount.

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