

The term "evidence-based medicine" was first coined by Sackett and colleagues as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." 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 it is impossible for an individual clinician to read all the medical literature. For clinicians to practice evidence-based medicine, they must have the skills to read and interpret the medical literature so that they can determine the validity, reliability, credibility and utility of individual articles. These skills are known as 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.

In October 2005 the American College of Surgeons joined with the Canadian Association of General Surgeons to sponsor a program entitled "Evidence Based Reviews in Surgery (EBRS)," supported by an educational grant from Ethicon Inc. and Ethicon Endo Surgery Inc. The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. During the academic year, 8 clinical articles are chosen for review and discussion. They are selected not only for their clinical relevance to general surgeons but also because they cover a spectrum of issues important to surgeons; for example, causation or risk factors for dis-

ease, naturally history or prognosis of disease, how to quantify disease (measurement issues), diagnostic tests and the diagnosis of disease, and the effectiveness of treatment. Both methodologic and clinical reviews of the article are performed by experts in the relevant areas and posted on the EBRS website. As well, a listserv discussion is held where participants can discuss the monthly article. Fellows and candidates of the College can access Evidence Based Reviews in Surgery through the American College of Surgeons website (www.facs.org). All journal articles and reviews are available electronically through the website. Currently we have a library of 40 articles and reviews that are accessible at any time.

A new set of articles will be available each month until May. Surgeons who participate in the current (modules) packages can receive CME credits by completing a series of MCQ. For further information about EBRS the reader is directed to the ACS website or should email the administrator, Marg McKenzie at mmckenzie@mtsinai.on.ca.

In addition to making the reviews available through the ACS and CAGS websites, 4 of the reviews are published in condensed versions in the *Canadian Journal of Surgery* and the other four will be published in the *Journal of the American College of Surgeons* each year.

REFERENCE

Evidence Based Medicine Working Group. Evidence-based medicine. *JAMA* 1992;268:2420–2425.

SELECTED ARTICLE

Short-term Quality-of-Life Outcomes Following Laparoscopic-Assisted Colectomy vs. Open Colectomy for Colon Cancer. A Randomized Trial
Weeks JC, Nelson H, Gelber S, Sargent D, Schroeder G, for the Clinical Outcomes of Surgical Therapy (COST) Study Group *JAMA* 2002;287:321–328.

Reviewed by

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ABSTRACT

Objective: To compare short-term QOL (quality of life) outcomes after LAC (laparoscopic assisted colectomy) vs. open colectomy for colon cancer.

Patients: Four hundred and forty nine consecutive patients who were entered into the COST trial between September 1994 and February 1999.

Methods: All patients completed QOL instruments pre-operatively, 2 days, 2 weeks and 2 months post-operatively. These included the Symptoms Distress Scale (SDS), a 5-item QOL index which measures QOL in 5 domains (activity, daily living, health, support and outlook) and a global rating scale. The SDS measures both symptom frequency and distress in the domains of nausea, appetite, insomnia, pain, fatigue, bowel, concentration, breathing, outlook and cough. Both the frequency of symptoms and degree of distress are measured.

Results: Four hundred and twenty eight patients completed the QOL Index, the global rating scale score,

the SDS pain intensity and the SDS summary at each time point. The only statistically significant difference observed between the LAC and open colectomy groups was the global rating scale at 2 weeks post-operatively. The mean (median) scores for LAC was 76.9(80) vs. 74.5(75) for open colectomy. ($p = .009$).

Conclusions: Minimal short-term quality of life benefits were found with LAC for colon cancer.

Commentary: Documentation of an improvement in quality of life in the setting of cancer treatment is important. If cancer outcomes are not equivalent, quality of life must be markedly improved in order to justify an alternative treatment, in this case laparoscopic colectomy. Alternatively, if the improvement in quality of life is marginal, then the cancer outcomes must be equivalent or better in order to justify the new approach.

This randomized controlled trial is extremely relevant as the number of colectomies being done laparoscopically continues to rise over time. Most of the advantages touted for minimally invasive surgery (MIS) are based on quality of life issues including reduced pain, reduced length of stay and earlier return to work. In this trial, quality of life, need for analgesia and length of stay were assessed in addition to cancer survival outcomes.

An appropriate quality of life instrument is extremely important. The instrument(s) must measure aspects of patients' lives that patients themselves consider important, and aspects of quality of life that might reasonably be affected by the treatments studied. The Symptoms Distress Scale (SDS) was chosen because it measures both symptom frequency and distress in the domains of nausea, appetite, insomnia, pain, fatigue, bowel, concentration, breathing, outlook, and cough. This has the benefit over a simple symptom checklist because it allows the patient to determine the degree of importance assigned to that symptom. All of these symptoms reasonably might be expected to be affected by an operation and subsequent recovery period. Quality of life was measured with the Quality of Life Index (QLI) and a global rating scale. The Quality of Life Index measures quality of life in 5 domains—activity, daily living, health, support, and outlook. It is not clear whether all of these domains are important to patients during the first 2 months postoperatively. The global rating scale asks patients to evaluate their state of health during the last 2 weeks on a scale from 0 to 100. The relevance of this scale, particularly at 2 days and 2 weeks postoperatively,

might be questioned. The amount of parenteral analgesia required was also used as an outcome. This is likely irrelevant to patients. The relevant domain for patients is pain that was measured by the Symptoms Distress Scale. Length of stay was also an outcome. Again, it is likely irrelevant to both the clinical question and the patient. The decision to measure these various outcomes at 2 days, 2 weeks, and 2 months, is interesting. If there were differences in any measures at only 2 days, or 2 weeks, would that really be of either interest or importance to patients given they are undergoing a cancer operation? Cosmesis and the return to work, often cited as benefits of minimally invasive approaches, were not assessed by any of the HRQL measures chosen. Ability to increase activity early after a laparoscopic approach is not also well assessed by the chosen instruments.

In addition to these characteristics the instruments must be able to detect small but clinically significant differences (i.e. responsive/sensitive to change). There was no difference in the Symptom Distress Scale summary scores of the two groups at any time point, nor was there a difference in the Quality of Life Index scores at any time point. These two measures also did not change significantly post-operatively from the mean preoperative values. Two weeks postoperatively, there was a 5- point difference in the mean global rating scale score between groups. More importantly, at this time point the laparoscopic group had the same mean score as the preoperative score while the open group had a mean score 15 points lower than their preoperative score! Although the difference in the mean global rating scores of the 2 groups was statistically significant, the clinical significance is unclear, particularly as the other measures of quality of life did not differ from preoperative values. It also raises some concerns about the construct validity of the global rating scale. Furthermore, the only objective measure, use of analgesia, did not correlate with the pain score in the SDS.

In the study, at two weeks quality of life scores had returned to baseline. It is unusual that patients "feel" back to baseline 2 weeks postoperatively suggesting that the instruments were not sufficiently sensitive to detect either differences from baseline or differences between the laparoscopic and open groups. Although the chosen scales have been validated, the use of scales validated in populations with chronic disease but used to detect differences in acute treatments (in this case, surgical technique) is fraught with problems, the primary one being

lack of responsiveness. This is not to criticize the authors for choice of the outcome measures; quality of life instruments that specifically address surgical disease are sorely lacking. Those that are designed for cancer patients primarily address the underlying cancer rather than the specific surgical treatment of the disease.

Seldom does a single trial change practice patterns. This trial, however, has helped to dramatically increase the number of colectomies for cancer done laparoscopically. It is unlikely that a minimal quality of life benefit at a single point in time is responsible for such a dramatic increase. Of greater importance than the minimal, and perhaps insignificant, effect on quality of life is the fact that the cancer outcomes (reported subsequently in another article [Nelson H, Sargent DJ, Wieand S, et al; A comparison of laparoscopically assisted and open colectomy for colon cancer. *NEJM* 2004;350:2050–2059]) were equivalent and that experience and comfort with laparoscopic surgery continues to grow. There are some important exclusion criteria that limit the ability to generalize the results of this study. Patients with transverse colon cancer, obstructing cancers and those with known metastatic disease, scars, adhesions, or advanced local disease were excluded, as were patients with an ASA class of IV or V. These patients may not have the same results with respect to cancer recurrence or quality of life. As the quality of life benefits are small and these benefits are actually negated in patients who require conversion to an open procedure late in an

operation, rigorous patient selection and early conversion if necessary is appropriate. As well, these results also provide justification for continuing with standard open surgery, confident that quality of life for these patients is not harmed.

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