CANADIAN ASSOCIATION OF GENERAL SURGEONS AND ACS, EVIDENCE-BASED REVIEWS IN SURGERY

The term "evidence-based medicine" was first coined by Sackett and colleagues1 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.

The Canadian Association of General Surgeons and the American College of Surgeons jointly sponsors 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 disease, natural 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. A listserve 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 50 articles and reviews which can be accessed at any time. Beginning in October, 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

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

SELECTED ARTICLE: Use of Colonic Stents in Emergent Malignant Left Colonic Obstruction: A Markov Chain Monte Carlo Decision Analysis

Govindarajan A, Naimark D, Coburn NG, et al. Dis Colon Rectum 2007;50:1811-1824

Reviewed by

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ABSTRACT

Question: Is colonic stenting cost effective as a bridge to surgery vs surgery alone in the management of emergent, malignant left colonic obstruction?

Base Case: Seventy year-old male with a complete emergent malignant left colonic obstruction secondary to a left-sided colon cancer with no evidence of metastatic disease.

Treatment Alternatives: Emergency surgery to relieve the obstruction and/or resect the cancer with temporary or permanent colostomy and emergency colonic stenting as a bridge to definitive surgery.

Outcomes Considered: Quality-adjusted life expectancy, cost, acute mortality, proportion of patients requiring a permanent stoma, and recurrence rate.

Sources of Estimates for Probabilities and Utili-

ties: Baseline probabilities were derived from systematic reviews of 54 studies comprising 1,198 patients. Utilities were used to quantify patient preferences and quality of life for health states, such as living with a colostomy and were obtained from a study in which the utilities of patients with colorectal adenomas were determined holistically by direct elicitation using the standard gamble method.

Results: Colonic stenting was more effective (9.2 quality-adjusted life months benefit) and less costly (CAD \$3,763; US \$3,135) than emergency surgery. Its benefits were sec-

ondary to reductions in acute mortality and in the likelihood of requiring a permanent colostomy. The results were only dependent on the rate of stenting complications (perforation, technical placement failure, and migration) and patients risk of surgical mortality with the greatest benefits among patients at high risk of operative mortality.

Conclusion: Colonic stenting as a bridge to surgery is more effective and less costly than surgery in the treatment of emergent, malignant left colonic obstruction.

Commentary: This month's Review is a decision analysis comparing the use of stents and emergency surgery in the management of patients presenting with left colon obstruction. The best way to compare these two treatment modalities would be a randomized clinical trial, but there are no published trials. As the authors state, "Decision analysis is a well-developed and valid methodology that is useful to explore complex surgical management decisions while explicitly accounting for short- and longterm risks and benefits, patient preferences, and costs. In a decision analysis, treatment strategies for a patient are modeled by using data derived from a complete review of the literature." Sensitivity analysis can then be used to vary important variables which might alter the results of the study. Readers must decide if all relevant treatment options are explored, if all relevant outcomes are considered, and if the rates of complications, treatment failures, and treatment successes are reasonable. Patient preferences should be considered, but may be difficult to obtain. Finally, readers must decide if all the relevant literature has been included and if there is any bias in the literature cited.

In this scenario, standard treatment for an obstructive cancer would be a Hartmann's procedure followed by elective reversal of the ostomy. In this model patients in the surgery group could have unresectable disease and receive a diverting colostomy, or be resectable and have a Hartmann's procedure or primary anastomosis. Placement of self-expanding metallic stents (SEMS) followed by elective surgery was the treatment alternative. The intent of treatment in both groups was curative. Outcomes assessed were: mortality, proportion of patients requiring colostomy, quality-adjusted life expectancy, and cost-effectiveness. Two base case scenarios were modeled. BASE-1 was a 70 year-old male patient without metastatic disease, who was obstipated, required nasogastric decompression, would not tolerate bowel preparation, and had an ASA score of 3. This base case was chosen to reflect the characteristics of an average patient presenting with malignant large bowel obstruction. BASE-2 was a patient with minimal impairment of physiologic status and no elevation of ASA score.

The study premise is highly relevant to surgical practice. Colorectal cancer affects 6% of North Americans and some patients present as acute LBO. Patients so presenting are often ill. Immediate surgical intervention is technically demanding, results in at least a temporary stoma in up to 80%, and leads to mortality in close to 30%. Placement of SEMS successfully relieves acute obstruction in 80% to 90% of patients. Successful placement converts the emergency to an elective procedure which increases the feasibility of optimizing the patient and performing definitive single-stage surgical intervention without an ostomy.

In Base Case Scenario 1 (BASE -1) colonic stenting as a bridge to surgery was the preferred strategy with a benefit of 9.2 quality-adjusted life months (QALMs) and decreased costs by CAD \$3,763. This was because of a reduction in acute mortality to 15% from 34% and reduction in the permanent stoma rate to 12% from 17%. In the BASE-2 scenario, there was less of a benefit, but colonic stenting was preferred with 1.4 QALMs. Sensitivity analysis varying the probabilities of the various outcomes in the two scenarios demonstrated that the advantage of stents diminished as stent-related complications increased and as perioperative mortality rates decreased after emergency surgical treatment.

The validity of a decision analysis depends on the quality of the available data. For this decision analysis, data were obtained from 78 studies, most of which were retrospective case series. Less than 5 were prospective studies. None of the data were derived from randomized controlled trials. The process used to identify and select relevant articles was not explicitly stated, so potentially the data may be biased. The results of this decision analysis are limited by both of these factors.

Several assumptions in this decision analysis are debatable. Only three stent outcomes were considered: successful placement, failed placement, and perforation. Successful placement may not lead to resolution of the obstruction in a small proportion of patients for other reasons. Second, the model assumes that an emergent operation to remove an obstructing cancer is carried out with the same degree of fastidiousness as an elective oncologic resection. Considering the potential for massively dilated proximal colon, incomplete staging, and under-optimized comorbidities, the survival and disease free statistics may be quite different. Finally, reporting institutions were viewed homogeneously. Yet, the relatively low annual mean patients per institution (n = 2.5-5 for 5 to 10 years), indicates that many reporting centers had limited experience with SEMS. Inexperience may contribute to lower rates of success and a higher incidence of perforation and migration. Centers with higher volumes would be expected to have better outcomes.

The authors found that colonic stenting resulted in an increase of 9.2 quality adjusted life months in the Base Case I scenario while the benefit was only 1.4 QALM in the Base Case II scenario. An increase of 9.2 months generally would be considered significant and is similar n magnitude to other procedures such as coronary revascularization. On the other hand, an increase of 1.4 QALM is not clinically significant. Thus, stenting would seem more appropriate in older individuals with comorbidities rather than more fit individuals. This is an important consideration because while the risk of perforation is low in experienced hands, perforation converts a potentially curable situation to a palliative situation. Without significant gain, there must be caution in recommending stenting in patients with potentially curative cancers.

Are the results generalizable? The practicality, feasibility, and generalizability of colonic stenting in patients presenting emergently with primary colon cancer depends on many factors including adequate facilities and physician expertise. From the cited literature, it seems that only 2.5 cases per year were accumulated. To safely implement SEMS insertion on a routine basis, each institution would have to achieve the same target rates of stent perforations (3.8%), migrations (11.3%) and placement failures (6.8%). If a center could not achieve these rates, better results are likely attained from emergency surgery. This emphasizes the importance of a surgeon's involvement in these cases so that stenting is offered to patients when there is accurate understanding of the surgical alternative.

In summary, in the setting of a lack of clinical trials, the decision analysis is a worthwhile aid in making complex surgical decisions. There are clearly more published data related to left colon surgery than to colonic stenting. Yet, there is a formidable body of published evidence that has found colonic stenting to be safe and successful in greater than 85% of patients with malignant LBO. The high mortality rate associated with emergency surgery encourages the acceptance of this analysis and the use of SEMS but

only in centers with appropriate resources, expertise, and support staff. In the right center, stent placement to relieve acute malignant left colon obstruction results in a better quality of life for these patients with an added benefit of cost savings from decreased mortality and decreased incidence of permanent colostomy. However, to mandate this approach as a standard for all hospitals, is premature and, in fact, could cause more harm than good. Whether or not an institution can perform emergency colonic stenting or chose to continue with emergency surgery, they need to be accountable to the morbidity and mortality rates that are described in these reports.

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