SPECIAL ARTICLE

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

Larissa K. Temple, M.D. • W. Donald Buie, M.D. • C. Neal Ellis, M.D.
Christopher M. Schlachta, M.D., 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. 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 (CSRCS) 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 administrative coordinator, Marg McKenzie at mmckenzie@mtsinai.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@mtsinai.on.ca.

Dis Colon Rectum 2011; 54: 1202–1204
DOI: 10.1097/DCR.0b013e318226fba7
©The ASCRS 2011

Copyright © The American Society of Colon & Rectal Surgeons, Inc. Unauthorized reproduction of this article is prohibited.

SELECTED ARTICLE

Serra-Accil X, Bobardo-Junca J, Moreno-Matias J, et al; Randomized, controlled trial of the use of a mesh to prevent parastomal hernia. *Ann Surg*. 2009;249:583–587.

QUESTION: Does insertion of a lightweight mesh in the sublay position at the time of colostomy creation decrease the risk of parastomal hernia?

DESIGN: This study reports a randomized controlled trial.

SETTING: This study was conducted at a single center in Spain.

PATIENTS: Included were 55 patients who were scheduled for surgery for permanent sigmoid end colostomy to treat cancer of the rectum. One patient in the mesh group was excluded from the final analysis.

INTERVENTION: Patients in both groups had a total mesorectal excision and the creation of colostomy completed by 1 of 5 colorectal surgeons. Patients randomly assigned to the mesh group had mesh placed in the sublay position. Patients were examined and had a CT scan at 1 month and every 6 months.

MAIN OUTCOME MEASURE: The primary outcome measure was parastomal hernia observed clinically or on CT scan.

RESULTS: Surgical time and postoperative morbidity were not significantly different. Peristomal infection was observed in 1 patient (3.7%) in each group. Necrosis of the colostomy was observed in 1 patient (3.7%) in each group. After a median follow-up of 29 months (range, 13–49), hernias were observed in 11 of 27 (40.7%) patients in the control group compared with 4 of 27 (14.8%) patients in the study group ($P = .03$). CT of the abdomen identified hernias in 14 of 27 (44.4%) patients in the control group compared with 6 of 27 (22.2%) patients in the study group ($P = .08$).

CONCLUSION: Parastomal placement of a mesh at the time of colostomy construction reduces the risk of parastomal hernia.

COMMENTARY: Parastomal hernias are common following colostomy construction. For patients who have previously had to deal with a permanent stoma, the addition of a parastomal hernia can further negatively affect their quality of life and body self-image. Although several nonoperative strategies exist for coping with a parastomal hernia, studies report that at least 15% to 20% of patients eventually require surgical revision. Identifying the methods to prevent the development of parastomal hernias would have significant benefit for patients and health care systems.

Serra-Aracil et al randomly assigned 55 patients with rectal cancer who had a permanent colostomy to either "no mesh" or lightweight mesh in the operating room. At a median of 29 months, the authors reported that clinical hernia rates were significantly higher in the no-mesh group (40.7% vs 14.8%, $P = .03$), whereas the difference in radiological hernia rates was not statistically significant (44.4% vs 22.2%, $P = .08$). The authors concluded that the placement of a parastomal mesh reduces the occurrence of parastomal hernias, and is safe and effective. However, there are many problematic areas within the study that challenge these conclusions.

The Serra-Aracil et al study illustrates many of the difficulties that arise in conducting randomized controlled trials in surgery. Randomization often occurs in the operating room. In this study, patients were randomly assigned by opening sealed envelopes in the operating room. Although this method is an appealing option for real-time randomization, it is an imperfect method because envelopes can be opened in the incorrect sequence either intentionally or unintentionally, leading to bias.

Controlling for surgical technique and/or quality may also be problematic. Although only 5 surgeons participated in this study, it is unclear whether all had similar experience and/or operated on a similar number of cases in each of the 2 arms. Finally, blinding is always difficult in surgical trials. In this study, clinical assessment of parastomal hernia rates may be subject to bias. Assessment was performed by an independent assessor, but it is unclear whether he/she was blinded. In the event that blinding is not possible, a secondary assessment by someone not involved in clinical care might be a viable method for limiting the bias associated with nonblinding.

In addition to the methodological concerns, the Serra-Araci et al study is also problematic in that the primary outcome is unclear. One may argue that radiographic evidence of a parastomal hernia is more objective, but a clinician is generally more interested in the clinical rate of parastomal hernias and/or the frequency of reoperation to repair a hernia. In this study, the authors do not state whether the primary outcome was the frequency of radiographic or clinical parastomal hernia rates. A statistically significant difference was seen in the rates of clinical parastomal hernias but not in the rates of the more objective outcome of radiological parastomal hernias. Thus, if the primary outcome was CT-detected parastomal hernia, the study would have been an underpowered but negative trial. Furthermore, as stated previously, many parastomal hernias are asymptomatic, and those that are symptomatic and require reoperation may be the most clinically relevant. In this small trial with short follow-up, there were insufficient patients to assess this outcome (ie, 2/11 vs 0/4). Finally, the authors report parastomal hernia rates at a median follow-up of 29 months. This time interval may be too short, and differences between recurrence rates may have become more evident or even less evident over time as the number of parastomal hernias observed increased. It is of interest that the CT rates of parastomal hernia are almost identical for the first 15 to 20 months and only diverge after

Copyright © The American Society of Colon & Rectal Surgeons, Inc. Unauthorized reproduction of this article is prohibited.

that when the sample size is much smaller, and one can therefore be less certain of the results.

The authors reported secondary outcomes, including morbidity and mortality, suggesting that the mesh was safe. However, it would have been helpful to report 2 other important secondary outcomes: 1) cost, and 2) the number of patients who could avoid a hernia operation if mesh was used as standard therapy. These secondary outcomes might have helped answer the clinical question of whether prophylactic mesh is worth the potential morbidity and cost.

Although the authors described planning an intention-to-treat analysis, the 1 patient randomly assigned to mesh who did not receive the mesh was excluded from the primary analysis. Although this probably did not affect the findings, the exclusion of patients from the analysis may cause bias. During the study period, the authors state that 206 patients with rectal cancer were treated. It is unclear why 151 were not included in the study, and a CONSORT diagram would have been helpful to delineate the reasons for exclusion. The eligibility criteria for this study were quite strict and excluded several patients who might have been more likely to develop parastomal hernias. Including a high-risk group may have increased the prevalence of hernia and the complications of mesh placement, and increased the generalizability of the results, as well.

There is one other reported trial. Janes et al[2] reported the results of a well-designed randomized controlled trial of 47 patients randomly assigned to either placement of a polypropylene mesh underlay at the time of stoma creation or standard stoma formation without the prosthetic. After a median follow-up of 14 months, a hernia had developed in 13 of 26 patients (50%) who did not have a mesh placed in comparison with only 1 of 21 patients (4.7%) who had a mesh placed. At 5 years follow-up a parastomal hernia was present in 17 of 21 (81%) surviving patients without a prosthesis and 2 of 15 (13%) surviving patients who had a prosthesis.[3]

The trial by Serra-Aracil et al does not definitively answer the question of whether a mesh inserted at the time of colostomy construction decreases the risks of parastomal hernias. This was a single-center randomized controlled trial that attempted to address an important clinical issue, but several questions remain. First, it was a relatively small trial and may have been underpowered to truly detect meaningful differences in hernia and/or complication rates between the 2 groups. Second, the follow-up may have been too short. Finally, important issues such as cost, as well as the number of hernia operations prevented if everyone received mesh, were not discussed.

Although these data could be combined with data from the other small randomized controlled trial, the methodological concerns of the trial limit the value of these results and would not provide a definitive answer. Thus, the data from this trial should be used to help guide a larger multicenter study to address this issue.

ACKNOWLEDGMENTS

Members of the Evidence Based Reviews in Surgery Steering Committee: Nancy N. Baxter, M.D., Toronto, Ontario, Canada; Karen J. Brasel, M.D., Milwaukee, Wisconsin; Carl J. Brown, M.D., Vancouver, British Columbia, Canada; Prosanto K. Chaudhury, M.D., Montreal, Quebec, Canada; C. Suzanne Cutter, M.D., Los Angeles, California; Celia M. Divino, M.D., New York, New York; Elijah Dixon, M.D., Calgary, Alberta, Canada; Luc Dubois, M.D., London, Ontario, Canada; G. William N. Fitzgerald, M.D., St. Anthony, Newfoundland, Canada; Harry J. Henteleff, M.D., Halifax, Nova Scotia, Canada; Andrew W. Kirkpatrick, M.D., Calgary, Alberta, Canada; Steven Latosinsky, M.D., London, Ontario, Canada; Tara M. Mastracci, M.D., Cleveland, Ohio; Anthony R. MacLean, M.D., Calgary, Alberta, Canada; Robin S. McLeod, M.D., Toronto, Ontario, Canada; Arden M. Morris, M.D., Ann Arbor, Michigan; Leigh A. Neumayer, M.D., Salt Lake City, Utah; Larissa K. Temple, M.D., New York, New York; Marg McKenzie, R.N., Toronto, Ontario, Canada.

REFERENCES

1. Evidence-Based Medicine Working Group. Evidence-based medicine: a new approach to teaching the practice of medicine. *JAMA*. 1992;268:2420–2425.
2. Janes A, Cengiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh. *Arch Surg*. 2004;139:1356–1358.
3. Janes A, Cnegiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh: a 5-year follow-up of a randomized study. *World J Surg*. 2009;33:118–123.

Copyright © The American Society of Colon & Rectal Surgeons, Inc. Unauthorized reproduction of this article is prohibited.