

What is the Preferred Surgery for Perforated Left-Sided Diverticulitis?

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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 (CAGS) and the American College of Surgeons (ACS) jointly sponsor a program titled, “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 listserv discussion is held in which 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. Each 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 multiple choice questions. Additional information about EBRS is on the ACS website or by email to 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*, 4 in the *Journal of the American College of Surgeons*, and 4 in *Diseases of Colon and Rectum* each year.

REFERENCE

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

SELECTED ARTICLE

Multicenter randomized clinical trial of primary anastomosis or Hartmann’s procedure for perforated left colonic diverticulitis with purulent or fecal peritonitis

Oberkoffer CE, Rickenbacker A, Raptis DA, et al. *Ann Surg* 2012;256:819–827

Question: What are the outcomes after a Hartmann’s procedure (HP) vs a primary anastomosis (PA) with a diverting ileostomy performed for perforated left-sided diverticulitis?

Study Design: Multicenter randomized controlled trial.

Patients: Patients with acute left-sided colonic perforation with purulent or fecal peritonitis (Hinchey III and IV).

Intervention: Hartmann’s procedure was defined as surgical resection of the sigmoid colon with closure of the rectal stump and creation of an end colostomy. Primary anastomosis was defined as surgical resection of the sigmoid colon with PA and diverting ileostomy followed by stoma reversal. Stoma reversal for both

procedures was to take place up to 3 months after the first operation. Colonic anastomoses were performed by transanal circular stapling.

Main Outcome: Overall postoperative complication rate, including those after the first (colon resection) and second (stoma reversal) operations.

Results: The overall complication rates were similar in both groups (80% after HP vs 84% after PA, $p = 0.813$). Although the outcomes after the initial colon resection did not show any significant differences (mortality 13% vs 9% and morbidity 67% vs 75% in HP and PA, respectively), the stoma reversal rate after PA with diverting ileostomy was higher (90% vs 57%, $p = 0.005$) and serious complications (Grades IIIb to IV 0% vs 20%, $p = 0.046$), operating time (73 minutes vs 183 minutes, $p < 0.001$), hospital stay (6 days vs 9 days, $p = 0.016$), and in-hospital costs (US \$16,717 vs US \$24,014) were significantly reduced in the PA group.

Conclusions: PA with diverting ileostomy is preferred over HP in patients with perforated diverticulitis.

Commentary: Perforated diverticulitis remains a common problem in North America. Current management of this condition remains controversial. Current practice parameters for the management of diverticulitis set forth by the American Society of Colon and Rectal Surgeons (ASCRS) state that in the setting of diffuse peritonitis, "...anastomosis might be performed, depending on the status of the patient and the severity of intra-abdominal contamination," although "a traditional Hartmann procedure is commonly performed..." Surgical dogma suggested that any resection and attempt at primary anastomosis in the setting of purulent or feculent peritonitis carried a prohibitive risk of anastomotic leak. For this reason, either proximal diversion alone or resection of the involved segment of colon along with stoma formation (Hartmann's procedure) has been considered the standard of care for this condition. There are multiple variables that may affect decision making including the degree of contamination, the physiologic derangement (and consequent physiologic reserve) of the patient, the burden of comorbid disease, training and skill-set of the surgeon, and local factors (health of tissue, blood supply of bowel, ability to fashion a tension-free anastomosis, body habitus of the patient). Studies from other areas like trauma (where primary repair of unprepared bowel injuries is accepted) have challenged this dogma and the possibility of a primary anastomosis in the setting of a sigmoid resection for perforated diverticulitis has been

revisited. The majority of the current literature is retrospective, prone to bias, and difficult to interpret.

The study by Oberkofler and colleagues examines the outcomes after Hartmann's procedure (HP) and primary anastomosis (PA) with diverting ileostomy for perforated left-sided diverticulitis. Patients from 4 participating hospitals were enrolled in the study at admission, but they were randomized (in a 1-to-1 ratio using an online computer-generated random allocation to HP or PA) at the time of anesthesia induction. Of 83 eligible patients, 62 were randomized (30 HP and 32 PA). The baseline characteristics of the 2 groups were similar. The a priori primary endpoint was overall complication rate. There was no statistically significant difference in complication rates (80% in the HP vs 84% in the PA groups, odds ratio 0.74 [95% CI, 0.2 to 2.74]). In the intention-to-treat analysis there were, however, significant differences in the stoma reversal rates (90% in the PA group vs 57% in the HP group, $p = 0.0005$) and there were other differences at the second operation including serious complications (0% vs 20%, $p = 0.046$), operating time (73 minutes vs 183 minutes, $p < 0.001$), hospital stay (6 days vs 9 days, $p = 0.016$), and hospital costs (US \$16,717 vs \$24,014) in the PA vs HP groups, respectively. The 95% confidence intervals around the odds ratios were, in general, wide and this is a consequence of the small sample size. The authors stated, "This is the first randomized clinical trial favoring PA with diverting ileostomy over HP in patients with perforated diverticulitis."

There are a number of reasons why this study may not change current care as significantly as the conclusion appears to imply. First of all, the study did not examine all clinically relevant outcomes. Examples of important outcomes not assessed include overall and gastrointestinal quality of life and rates of incisional hernia related to the laparotomy and stoma closure. It is significant that 10% of patients in the PA group did not receive a PA. Was this for technical reasons, patient factors such as comorbidities, or intraoperative issues? It is important to recognize that in some situations a PA will not be possible. Another area of concern is the premature interim analysis at 62 patients. Trials that are stopped early with small numbers are at risk for overestimating any observed treatment effect. There was no a priori definition of safety cut-offs for early termination and based on the secondary data points, there is limited rationale for termination on safety alone. The only significant outcome with respect to safety was complication severity after the second operation. It is hard to know how premature termination affected outcomes because it may have occurred at a time when the desired outcome was temporarily favored.

There is no mention of blinding of the adjudicators. This may bias the results, although it is probably not as

important in the assessment of major outcomes but may have been more important with assessing secondary outcomes, which do differ in the 2 groups, and may have led to the early stoppage of the trial. These issues do limit the strength of the conclusion. It is apparent that the major advantage of primary anastomosis and proximal diversion over the Hartmann's procedure is due to the fewer complications after the subsequent stoma reversal. We also know from previous work that the likelihood of colostomy reversal after HP is low. This was also found in this trial, in which only 58% of colostomies were reversed compared with 90% of ileostomies ($p < 0.012$).

This study confirms that perforated Hinchey III and IV diverticulitis is characterized by high morbidity regardless of the surgical approach. Based on the primary endpoint of total complications, this trial demonstrated no benefit of PA over HP. However a much larger randomized controlled trial with strict eligibility criteria and randomization will be required to answer this question. The ideal procedure would be broadly applicable across the spectrum of Hinchey III and IV cases, could be performed safely with low morbidity and mortality after both procedures, or would potentially avoid a stoma altogether. Alternatively, there is an evolving body of literature focusing on the potential role of laparoscopic lavage in this setting, which may be especially applicable for cases of purulent peritonitis, allowing either no further therapy or a delayed single stage operation without a stoma.

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