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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he 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." 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. 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 sponsor a program entitled "Evidence Based Reviews in Surgery" (EBRS). The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. Evidence Based Reviews in Surgery has 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 EBRS-Colorectal Surgery (EBRS-CRS) website. In addition,

a listsery 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.cagsaccg.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 monthly packages can receive 6 CME and/or maintenance of certification credits by completing an evaluation and a series of multiple choice questions each month. 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 *Diseases of the Colon & Rectum*. Evidence-Based Reviews in Surgery is useful in improving your critical appraisal skills, keeping abreast of new developments in colorectal surgery, and, most importantly, you are able to obtain 6 CME credits each month from anywhere that you have access to a computer. Comments about EBRS may be directed to mmckenzie@ mtsinai.on.ca

SELECTED ARTICLE

Kwon, S, Morris A, Billingham R, et al. Routine leak testing in colorectal surgery in the surgical care and outcomes assessment program. *Arch Surg.* 2012;147:345–351

OBJECTIVE: The aim of this study was to evaluate the effect of routine anastomotic leak testing (performed

Dis Colon Rectum 2014; 57: 1149–1151 DOI: 10.1097/DCR.0000000000000189 © The ASCRS 2014 1150 Brasel et al: Evidence Based Reviews

to identify leaks) vs selective testing (performed to identify a suspected leak in higher-risk or technically difficult anastomosis) on outcomes in colorectal surgery and to determine whether testing can be used as a quality improvement metric.

DESIGN: This was an observational, prospective cohort study.

DATA SOURCE: Data from Washington State's Surgical Care and Outcomes Assessment Program (SCOAP) were used.

RESULTS: Among the 3449 patients, the composite adverse event (CAE) rate was 5.5%. Provocative leak testing increased (from 56% in the starting quarter to 76% in quarter 16), and overall rates of CAE decreased (from 7.0% in the starting quarter to 4.6% in quarter 16; both $p \le 0.01$) over time. Among patients at hospitals that performed routine leak testing, there was a relative reduction of more than 75% in the adjusted risk of CAEs (OR, 0.23; 95% CI, 1.05– 0.99)

CONCLUSION: Routine leak testing of left-sided colon and rectal anastomosis appears to be associated with a reduced rate of CAEs at hospitals in SCOAP and meets many of the criteria of a worthwhile quality improvement metric.

COMMENTARY: After restoring GI continuity following colorectal resections, surgeons sit with fingers crossed, stressed about their patients' anastomoses. An anastomotic leak can be a truly devastating complication that results in significantly increased morbidity and mortality, a dramatic increase in hospital length of stay, and costs to the health care system and, more importantly, to the patient. Much research and time has been spent assessing factors that affect the healing of colorectal anastomoses, and most would agree these could be characterized as patient factors (poor nutrition, chronic obstructive pulmonary disease, smoking, steroids), location of anastomosis (right sided, left sided, coloanal), and surgeon or technical factors (length, type of anastomosis, vascular supply). It is this last group, the surgeon/technical factors, that many attempt to improve on with provocative testing of the anastomosis.

Provocative leak testing is usually performed by placing the anastomosis under water or saline, obstructing the proximal bowel, and then either instilling fluid or insufflating with air with the use of a proctoscope. If a leak is identified with "bubbles," it is addressed with primary repair of the defect or complete revision of the anastomosis, with or without proximal diversion. The efficacy of this approach has been studied with mixed results. Early case series by Gilbert and Trapnell² indicated that provocative testing was a reliable way of determining leaks due to technical factors. More recently, Ricciardi et al³ performed a large cohort study on 998 patients undergoing left-sided colonic surgery. They noted a significantly higher rate of clinical leaks in patients with untested anastomoses versus those who had intraoperative testing.

In the current study, Kwon and colleagues compared selective (<90%) with routine (>90%) anastomotic leak testing in a cohort of patients undergoing left-sided colonic and rectal resections between 2005 and 2009.⁴ Data were collected from Washington State's SCOAP. The question being addressed was whether provocative testing affects the number of CAEs.

This is a prospective observational cohort study, comparing broad outcomes from hospitals where surgeons used a leak test routinely with hospitals in which it was used more selectively in high-risk patients or anastomoses. This design does not evaluate the efficacy of a leak test on reducing clinically relevant leak rates. A randomized controlled trial where patients are randomly assigned to a leak test or no leak test and all other variables and interventions are standardized would be required to answer a question of efficacy. The authors suggest that this design evaluates the effectiveness, rather than the efficacy, of a leak test more broadly applied to the entire population of patients undergoing leftsided colon and rectal resections. However, owing to the use of the hospital as the level of evaluation rather than the patient, evaluation of true effectiveness is not possible because of multiple potential confounders. Furthermore, because of the nonexperimental design of the study, one can only conclude that there is an association and not a cause or effect.

Even in the selective group, there was a 71% use of leak testing; the decision to use 90% as the cutoff to define routine versus selective was clearly arbitrary. The CAE rate in patients in whom a leak test was performed was 5.8% vs 11.1% in those in whom a leak test was not performed (p = 0.18) at hospitals that routinely performed a leak test. After adjustment for relevant patient and clinical factors, the overall OR for CAE in patients at hospitals performing routine leak testing, compared with patients in hospitals that were more selective, was 0.23. The 95% CI was 0.05 to 0.99, suggesting a relatively large and imprecise difference. Although this adjustment accounted for patient factors, the authors do not present the characteristics of the hospitals in the 2 groups (routine testing vs selective testing). Because hospital use of testing is the unit that is being studied, this information would be very useful, including the volume of colorectal procedures performed and the number and training of surgeons. Obviously, the surgeons at all hospitals were different, which could also be a significant confounder. Not enough procedures were performed in each group by individual surgeons to do a comparison by surgeon.

The most interesting findings are the temporal trends. In Donabedian terms, quality of health care can be measured by assessing structure, processes, and outcomes. ^{5,6} The SCO-AP group had these objectives in mind. The authors discuss benchmarking and education programs to improve rates of intraoperative leak testing. In many ways, a process measure such as leak testing has distinct advantages. First, by measuring the process or action taken, there is a lack of stigma that

often is associated with an outcome measure such as mortality from a leak. Second, there is most likely a reduction in case-mix bias and less risk adjustment required. Moreover, process measures result in a larger effect because they promote everyone to improve, not just those performing poorly.

Although the authors attribute the improved outcomes to an increase in the percentage of patients having a leak test, there may be other changes that occurred over time, because SCOAP is a broad quality initiative, and there probably were other quality measures adopted by hospitals over the same time. In addition, simply providing performance data back to hospitals may have led to improvement in outcomes. Although we cannot assume that this decrease in CAE is attributable to leak testing, it seems that the process measure used by the SCOAP hospitals works. This makes provocative leak testing a reasonable quality improvement metric. Finally, and importantly, leak testing does not prevent leaks from occurring, and the performance of leak testing is not the panacea for decreasing CAE. Ricciardi et al³ found that there was a 3.8% leak rate even in tested anastomoses. Even if all surgeons in all hospitals leak-tested their anastomoses, CAE would still occur.

ACKNOWLEDGMENT

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REFERENCES

- 1. Evidence Based Medicine Working Group. Evidence-based medicine: a new approach to teaching the practice of medicine. *JAMA*. 1992;2420–2425.
- Gilbert JM, Trapnell JE. Intraoperative testing of the integrity of left-sided colorectal anastomoses: a technique of value to the surgeon in training. *Ann R Coll Surg Engl.* 1988;70:158–160.
- 3. Ricciardi R, Roberts PL, Marcello PW, Hall JF, Read TE, Schoetz DJ. Anastomotic leak testing after colorectal resection: what are the data? *Arch Surg.* 2009;144:407–411.
- Kwon S, Morris A, Billingham R, et al. Surgical Care and Outcomes Assessment Program (SCOAP) Collaborative. Routine leak testing in colorectal surgery in the Surgical Care and Outcomes Assessment Program. *Arch Surg.* 2012;147:345–351.
- 5. Rubin HR, Pronovost P, Diette GB. The advantages and disadvantages of process-based measures of health care quality. *Int J Qual Health Care*. 2001;13:469–474.
- 6. Lilford RJ, Brown CA, Nicholl J. Use of process measures to monitor the quality of clinical practice. *BMJ*. 2007;335:648–650.

RETRACTION

LigaSure Hemorrhoidectomy Versus Stapled Hemorrhoidopexy: A Prospective, Randomized Clinical Trial: Retraction

This article has been retracted in full due to duplicate publication in the June 2010 issue of *Minerva Chirurgica* as follows.

Sakr MF, Moussa MM, Elserafy M. Ligasure hemorrhoidectomy versus Stapled hemorrhoidopexy: a prospective randomized clinical trial. *Minvera Chir.* 2010;65:251–258.

Robert D. Madoff, M.D. *Editor-in-Chief*

REFERENCE

1. Sakr M, Moussa MM, Elserafy M. LigaSure hemorrhoidectomy versus stapled hemorrhoidopexy: a prospective, randomized clinical trial. *Dis Colon Rectum.* 2010;53:1161–1167.