SPECIAL ARTICLE

Canadian Association of General Surgeons and the American College of Surgeons

Arden Morris, M.D. • Randolph Bailey, M.D. • Ken Woolfson, M.D.
for the Members of the Evidence Based Reviews in Surgery Group

The term evidence-based medicine was first coined by the Evidence Based Medicine Working Group 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). Generally, critical appraisal requires that the clinician has some knowledge of biostatistics, clinical epidemiology, decision analysis, and economics and 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 and Ethicon Endo Surgery Inc and Ethicon Endo Surgery. The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. Beginning 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 EBRS–Colorectal Surgery (CRS) Web site. In addition, a listserv discussion is held during which participants may discuss the monthly article. Members of the Canadian Association of General Surgeons (CAGS) and the American College of Surgeons (ACS) can access Evidence Based Reviews in Surgery–Colorectal through the Canadian Association of General Surgeons Web site (http://www.cags-accg.ca), the American College of Surgeons Web site (http://www.facs.org), the Canadian Society of Colon and Rectal Surgeons (CSCRS) Web site (http://www.cscrs.ca), and the American Society of Colon and Rectal Surgeons (ASCRS) Web site (http://www.fascrs.org). All journal articles and reviews are available electronically through the Web site. Surgeons who participate in the current (modules) packages can receive Continuing Medical Education 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 Web sites or may e-mail the administrator, Marg McKenzie, at mmckenzie@mtsinai.on.ca.

In addition to making the reviews available through the CAGS and the ACS Web sites, a condensed version of the reviews will be published in the *Diseases of the Colon & Rectum*. We are hopeful readers will find EBRS useful both in improving their critical appraisal skills and in keeping abreast of new developments in general surgery. Comments about EBRS may be directed to mmckenzie@mtsinai.on.ca.

SELECTED ARTICLE

Wang JY, Tsai HL, Chen FM, et al. Prospective, randomized controlled trial of Starion vs Ligasure hemorrhoidectomy for prolapsed hemorrhoids. *Dis Colon Rectum*. 2007; 50:1146–1151.

QUESTION: Is Starion hemorrhoidectomy with submucosal dissection as effective and safe as Ligasure hemorrhoidectomy?

DESIGN: Randomized controlled trial.

SETTING: Single center: Medical University Hospital in Taiwan.

PATIENTS: Sixty-four patients with grades III and IV hemorrhoids.

INTERVENTION: Patients were randomly allocated to either Starion or Ligasure hemorrhoidectomy.

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RESULTS: The mean blood loss, operating time, duration of hospital stay, and time off from work or normal activity were not significantly different between the 2 methods. The mean pain score was significantly lower in the Starion group (4.2 ± 0.1 vs 5.1 ± 0.2, $P = .032$). In addition, patients in this group required parenteral analgesic injections (6 vs 11, $P < .001$). There were no differences in early and delayed postoperative complications. Two patients in the Ligasure group developed symptomatic anal stenosis requiring treatment.

CONCLUSIONS: Starion hemorrhoidectomy results in less pain and reduced parenteral analgesic in the short term. In addition, there was no significant difference in postoperative complications overall and a significant decrease in the rate of symptomatic anal stenosis in the Starion group.

COMMENTARY: Hemorrhoidectomy is a common operation for a common condition. Symptomatic hemorrhoids are estimated to affect approximately 4% of the US population,[2] ultimately resulting in 32,000 operations per year.[3] Although an excisional hemorrhoidectomy may be considered a "minor" operative procedure, postoperative complications can be substantial. Patients tend to experience severe postoperative pain and disability lasting for weeks after the procedure has been performed. Patients may also experience bleeding, urinary retention, constipation, and other complications for weeks after the procedure. To decrease postoperative pain and complications, various changes in operative technique have been used, including using other energy sources.

Thus, the present study is a randomized controlled trial comparing the efficacy and outcome of 2 vessel sealing systems (Starion thermal welding system (Starion Instruments Corp, Sunnyvale, CA) and Ligasure sealing device (ValleyLab, Inc, Boulder, CO)) for sutureless hemorrhoidectomy. After recruitment, patients were randomly allocated to the 2 groups; the patient group was revealed in the operating room by opening a sealed envelope. This method is not optimal because concealment cannot be guaranteed. Furthermore, if the envelopes are not drawn in order, the randomization scheme (not described by the authors) may be altered. The groups did appear closely matched with respect to sex, age, symptom duration, and grade of the hemorrhoids. Operative techniques were identical except for the energy source. Follow-up assessment of an array of outcome measures was completed for all patients at 3 months postoperatively. To the credit of the investigators, outcomes were assessed by an independent provider. However, it is unclear whether the assessor was blinded to the treatment assignment.

The study results revealed no surprise results but raised several questions. First, the authors state that 64 patients were randomly assigned and the data suggest that 64 patients completed the trial. An explicit statement that all patients completed the trial would be reassuring given that a drop-out rate of 10% is considered low in most randomized controlled trials even for a relatively short study. Most journals now require that reports of randomized controlled trials include a Consolidated Standards of Reporting Trials (CONSORT) diagram, which was absent from this article. A CONSORT diagram is a flow chart that indicates the number of patients screened for inclusion in the trial, the number who fit the inclusion criteria, the number who actually participated in the trial and were randomized, and the number who completed the trial and what happened to those who did not.

Second, the primary outcome measures ("efficacy and safety of the 2 procedures") were not clearly stated. There were multiple outcomes measured, including mean blood loss, operating time, pain score, hospital stay, and return to work; the proportion who suffered from constipation, urinary retention, hemorrhage, poor wound healing at 4 weeks, and anal stenosis at 12 weeks; and use of parenteral analgesics. Only mean pain score and the proportion of patients requiring parenteral analgesics were statistically significantly different between the groups, with advantage to the Starion group. Notably, the mean operative time, blood loss, and pain scores and the standard deviations for Ligasure were exactly the same as in the authors' previous randomized controlled trial.

Third, the long-term outcomes were not well defined ("poor wound healing" and "symptomatic anal stenosis") and were poorly measured. Because the indication for hemorrhoidectomy is usually pain and bleeding, a patient-centered outcome assessment would have been valuable—such as a composite score permitting patients to assess whether their symptoms disappeared and their satisfaction.

Finally, because this was an underpowered study, it is not possible to state with confidence that there is no difference among most of the outcome measures reported. For the outcome of pain, the mean difference between groups of 0.9 on a 0 to 10 pain scale was statistically significantly different but likely is not clinically significant. There was a nonsignificant trend to an increased risk of anal stenosis in the Ligasure group, which is clinically concerning but most clinicians would likely be cautious in making statements about the risk of anal stenosis after these 2 different operations.

In summary, this randomized controlled trial does not establish superiority of either of the sutureless hemorrhoidectomy methods. A sufficiently powered study with blinded assessment of more clearly defined outcome measures, including incremental cost, is still needed to identify a preferred strategy for operative hemorrhoidectomy. Furthermore, a more fundamental question may be whether either technique is better than the traditional excisional hemorrhoidectomy.

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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 Chaudhury, M.D., Montreal, Quebec, Canada; Thomas H. Cogbill, M.D., LaCrosse, Wisconsin; C. Suzanne Cutter, M.D., Los Angeles, California; Elijah Dixon, M.D., Calgary, Alberta, Canada; G. William N. Fitzgerald, M.D., St. Anthony, Newfoundland, Canada; Harry Henteleff, M.D., Halifax, Nova Scotia, Canada; Andrew W. Kirkpatrick, M.D., Calgary, Alberta, Canada; Steven Latosinsky, M.D., London, Ontario, Canada; Anthony MacLean, M.D., Calgary, Alberta, Canada; Tara M. Mastracci, M.D., Cleveland, Ohio; 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. Morin N. Hemorrhoids & Fissure-in-Ano. http://www.fascrs.org/physicians/education/core_subjects/2008/hemorrhoids_fissure_in_ano. Accessed November 19, 2009.
3. Russo CA, Owens P, Steiner C, Josephsen J. Ambulatory Surgery in U.S. Hospitals, 2003. Rockville, MD: Agency for Healthcare Research and Quality; 2007. HCUP Fact Book No. 9. AHRQ Publication No. 07-0007. ISBN 1-58763-228-4.