

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 of 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 economic 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. The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. During the academic year, eight 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. Also, a listserv 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 40 articles and reviews that 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 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, four of the reviews are published in condensed versions in the *Canadian Journal of Surgery* and the other four are 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

Stapled Hemorrhoidopexy Compared with Conventional Hemorrhoidectomy: Systematic Review of Randomized Controlled Trials

Nisar PJ, Acheson AG, Neal KR, et al. *DCR* 2004;47(11):1837–1845.

Reviewed by

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ABSTRACT

Objective: To determine whether conventional hemorrhoidectomy (Cnv) or stapled hemorrhoidopexy (Stp) is superior for management of hemorrhoids.

Data Sources: MEDLINE, EMBASE and the Cochrane Library.

Study Selection: Randomized controlled trials comparing conventional hemorrhoidectomy with stapled hemorrhoidopexy.

Outcomes Measures: (1) Duration of procedure, (2) length of inpatient stay, (3) time taken to return to work or normal activity, (4) pain scores, (5) anal manometry, (6) satisfaction and quality of life scores, (7) incontinence score, (8) individual complications and (9) total complications.

Results: One thousand and seventy seven patients were included from 15 trials. Followup ranged from 6 weeks to 37 months. Qualitative analysis showed that stapled hemorrhoidopexy is less painful than hemor-

rhoidectomy. Stapled hemorrhoidectomy has a shorter inpatient stay (WMD -1.02 days; 95% CI, 1.47 to -0.57 ; $P = 0.0001$), operative time (WMD -12.82 mins; 95% CI, -22.61 to -3.04 ; $P = 0.01$), and return to normal activity (SMD, -4.03 days; 95% CI, -6.95 to -1.10 ; $P = 0.007$). Stapled hemorrhoidectomy has a higher recurrence rate (OR, 3.64 ; 95% CI, 1.40 – 9.47 ; $P = 0.008$) at a minimum followup of six months.

Conclusions: Although stapled hemorrhoidectomy is widely used, the data available on longterm outcomes is limited. Stapled hemorrhoidectomy has unique potential complications and is a less effective cure. Hemorrhoidectomy remains the “gold standard” of treatment.

Comment: This study was a systematic review of randomized trials comparing Cnv to Stp, with the goal of determining whether one was superior for the management of hemorrhoids with regards to 1) safety and 2) efficacy. Two reviewers independently searched and applied specific inclusion criteria to identify eligible studies reportedly following the methods of the Cochrane collaboration. The quality of the trials was subsequently assessed and a meta-analysis of results calculated if possible. The trial heterogeneity was estimated using the chi-squared test. Out of 18 eligible studies, 15 trials reporting on 1077 patients were analyzed.

There were a large number of outcomes reported and analyzed; these were combined using two methods. The authors performed a meta-analysis of the weighted results of the randomized controlled trials and pooling of the raw data. Unfortunately most of the trials failed to report the raw data so these latter analyses are limited. In the meta-analyses, there were no significant differences in overall complication rate, the transfusion rate, or the requirement for additional procedures for hemorrhage control, but immediate postoperative hemorrhage occurred significantly more often with Stp, OR 2.90 (CI 95% 1.18 , 7.08) and bleeding at one to two weeks after the procedure occurred more often with Cnv, OR 0.37 (CI 95% 0.22 , 0.62). Also, recurrent prolapse at a minimum six-month followup occurred more frequently after Stp, OR 3.64 (CI 95% 1.4 , 9.47). There were no significant differences in the other outcomes such as sphincter damage, thrombosed hemorrhoids, persistent wound discharge, anal stenosis, residual skin tags, anal fissures, and acute urinary retention. Stp did have the specific advantages of significantly reduced operative time, WMD -12.82 (CI 95% -22.61 , -3.04), re-

duced hospitalization, WMD -1.02 (CI 95% -1.47 , -0.57), quicker return to normal activity SMD -4.03 (95% CI -6.95 , -1.1) and reduced pain scores 24 hours after surgery, WMD -2.53 (95% CI -4.64 , -0.42).

Overall, this was a sensible and generally well done systematic review that reportedly followed the standard methods of the Cochrane collaboration. There are a number of points worth commenting upon though. The authors reported searching the MEDLINE, EMBASE, and Cochrane Library electronic records, and thereafter hand-searching identified trials for additional applicable trials. The ideal systematic review would also typically involve making personal contact with known content experts examining abstracts presented at relevant scientific meetings, and examining other less frequently used databases in order to recover studies never published in peer-reviewed journals. Because authors are more likely to submit, and peer reviewed journals are more likely to publish, positive studies, there can be a systematic overestimation of the treatment effect known as publication bias.

In deciding what studies to include in a systematic review it is crucial to select well-performed original studies free of systemic bias. In the current review we are told that two reviewers independently searched and applied specific inclusion criteria and performed the data extraction, but we are not informed about what criteria were used to both select the studies for inclusion nor were quality scores given for each trial. It is also not possible to determine the degree to which there was consensus between the reviewers. The authors performed a meta-analysis of the outcomes “if possible” but did not describe how they determined whether this was or was not feasible. The authors reported that they followed the methods of the Cochrane collaboration, but more specific information about the methods used would be helpful to judge the quality of the included trials and rigorosity of the systematic review and meta-analysis.

One of the strengths of a meta-analysis is to increase the likelihood of detecting an effect because studies are combined and thus the sample size is increased. But, this approach is valid only if the populations studied, procedures performed, and outcomes are similar enough to be reasonably grouped together in a meaningful way. There are three specific criteria to consider when deciding whether to combine the results: 1) how similar are the best estimates of the treatment effect (point estimates);

2) to what degree do the confidence intervals (CI) around the point estimate in each study overlap and 3) by testing for “homogeneity” or the extent to which the differences of the results among the individual studies are greater than would be expected by chance alone assuming that all compiled studies were measuring the same underlying effect. In this study, the authors estimated trial heterogeneity using the chi-squared statistic. The authors stated in the discussion that there was significant statistical heterogeneity between trials, meaning that chance was an unlikely explanation for the difference in outcomes in the included trials. This information, however, was not reported. Despite this, they performed meta-analyses, which question the validity of the results of the meta-analysis.

Stp is a “pexy” procedure which aims to restore the hemorrhoidal cushions to their normal position. It is therefore ineffective in treating external hemorrhoidal disease. Nevertheless, Stp has been used to treat grade 3 and 4 hemorrhoids and this meta-analysis attempts to further evaluate the efficacy of Stp compared to Cnv. Essentially this meta-analysis confirms that Stp produces dramatically less pain and disability compared with Cnv, but longterm gain is sacrificed with significantly higher recurrence rates (approximately three times higher) at a minimum of 6 months followup.

While Stp is not a difficult procedure, specific training is required. Improperly performed, the procedure can lead to poor results including pain, bleeding, sphincter injury and incontinence. Key technical issues all relate to the placement of the purse string suture that must be placed high in the anal canal and include only mucosa and submucosa. If not, some unique complications have been reported, including persistent pain, rectovaginal fistula and severe pelvic infection-although none of these was observed in this series of trials. It is suggested that a minimum of 12 cases should be observed before a surgeon starts performing this procedure. Another consideration is cost. The disposable stapler is expensive and the relatively small savings in operating room time (mean 13 minutes) does not offset the cost of it.

What is the role of Stp? It is important to point out that only a small percentage of patients with hemorrhoids require surgery. Stp does not have a role in the treatment of hemorrhoids that could be managed with simpler and less invasive techniques. Similarly, because it does not treat large external hemorrhoids or skin tags, some patients with grade 4 hemorrhoids will still require Cnv. Thus, a more relevant comparison might be rubber band ligation rather than Cnv. This meta-analysis provides convincing evidence that there is less pain and more rapid return to normal function after Stp compared with Cnv. On the other hand, recurrence is higher and the relative risk of severe complications is not well known. Further followup will be required before we really know the place of Stp in the treatment of this common disease. For now, the authors’ conclusion that Cnv remains the “gold standard” is probably correct.

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