

# 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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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.”<sup>1</sup> 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, and clinical knowledge, as well.

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 Endo Surgery Inc and Ethicon Endo Surgery Canada. 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 Evidence Based Reviews in Surgery-Colorectal Surgery (EBRS-CRS) Web site. 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 Web site ([www.cags-accg.ca](http://www.cags-accg.ca)), the American College of Surgeons Web site ([www.facs.org/education/ebrs.html](http://www.facs.org/education/ebrs.html)), the Canadian Society of Colon and Rectal Surgeons (CSRCS) Web site ([www.cscr.ca](http://www.cscr.ca)), and the American Society of Colon and Rectal Surgeons (ASCRS) Web site ([www.fascrs.org](http://www.fascrs.org)). All journal articles and reviews are available electronically through the Web site. 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, CSRCS, and ASCRS Web sites or should email the administrative coordinator, Marg McKenzie at [mmckenzie@mtsinai.on.ca](mailto: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*. Evidence Based Reviews in Surgery is useful in improving your critical appraisal skills and keeping you 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](mailto:mmckenzie@mtsinai.on.ca)

## SELECTED ARTICLE

Karas JR, Uranues S, Altomare DR, et al. No rectopexy versus rectopexy following rectal mobilization for full-thickness

rectal prolapse: a randomized controlled trial. *Dis Colon Rectum* 2011;54:29–34.

**OBJECTIVE:** This study aimed to determine whether recurrence rates following no rectopexy are not inferior to those following rectopexy for full-thickness rectal prolapse (FTRP).

**DESIGN:** This was a randomized controlled trial.

**SETTING:** This study was conducted at 41 tertiary centers in 21 countries.

**PATIENTS:** Two hundred fifty-two patients who underwent elective surgery for FTRP were randomly assigned to rectopexy or no rectopexy and followed up for 5 years from the time of surgery.

**INTERVENTION:** The rectopexy arm was defined as abdominal surgery with mobilization and rectopexy, and the no-rectopexy arm was defined as abdominal surgery with mobilization only. Sigmoid resection was added in cases of preexisting documented constipation.

**OUTCOME MEASURES:** The primary outcome measured was recurrence rates.

**RESULTS:** There were 136 patients randomly assigned to the rectopexy group, and 116 were assigned to the no-rectopexy group. There were significantly fewer men in the no-rectopexy group (33.8% vs 17.1%,  $p = 0.013$ ), and the length of the external FTRP was significantly longer (8 vs 5 cm,  $p = 0.076$ ). There was no significant difference in intraoperative data in the 2 study arms. Sigmoid resection was performed significantly more frequently in the no-rectopexy arm (58.6% vs 18.3%,  $p \leq 0.001$ ). There was no significant difference in complication rates (11% vs 17.9%,  $p = 0.139$ ). The loss of patients to 5-year follow-up was 10.3%. Actuarial analysis demonstrated a significant difference in 5-year recurrence rates between study arms (8.6% vs 1.5% (log rank  $p = 0.003$ )).

**CONCLUSION:** Rectopexy is superior to no rectopexy for the containment of FTRP recurrence at 5-year follow-up.

**COMMENTARY:** Depending on the needs of their patients and their own preferences, modern surgeons can select from and tailor many established, but largely unproven, strategies to treat FTRP. The fact that so many therapeutic options are available suggests that our current understanding of rectal prolapse is insufficient to design a more universal operation, that both rectal prolapse and the specific needs of our patients are too heterogeneous for a single approach, or that there is currently insufficient evidence to establish the effectiveness of established procedures. These uncertainties have created a chaotic marketplace of surgical procedures and technical modifications, rather than evidence-based algorithms that can inform and standardize decisions, to ensure optimal care.

In North America, surgeons commonly select from (and modify) 3 operations for FTRP based on clinical presentation and experience, but without the benefit of high-quality evidence. A *sigmoid resection with rectopexy* consists

of a posterior mobilization of the rectum to the pelvic floor (tip of coccyx), anterior mobilization to the upper third of the vagina, and a lateral dissection that stops short of the pelvic floor. This lateral dissection preserves the “lateral ligaments.” There is some evidence, none that would survive close analysis, hinting that preservation of the lateral ligaments saves nerves and minimizes rectal evacuation problems. The mobilized rectum is retracted cephalad and posteriorly, and the fascia propria is sutured to the presacral fascia, off the midline, with a silk suture, one on each side, about 5 cm below the promontory. A sigmoid resection is usually added as the already redundant sigmoid is made even more prone to angulation or volvulus. With the sigmoid colon removed, the splenic flexure may help keep the rectum up, and there is some suggestion that sigmoid resection may address constipation in patients who have prolapse. Almost all of the features of this operation (extent of mobilization, rectopexy method, sigmoid resection, type of incision or laparoscopic approach), although intuitive, remain unsupported by high-quality evidence. The *Delorme procedure* is often performed in frail, elderly patients (or patients with significant comorbidities), with a “small” procidentia and some anal tone. This operation is extremely well tolerated. A perineal approach is also well tolerated by young patients with a small prolapse, who do not necessarily need an abdominal operation, which can be associated with anastomotic leaks, urinary tract injuries, retrograde ejaculation, small-bowel injuries, and rectal perforations. However, despite the appeal of the Delorme procedure, its effects on constipation, evacuation, and continence remain unknown. Finally, a *perineal proctosigmoidectomy with levatorplasty* can be considered for frail, elderly patients (or patients with significant comorbidities) who have a significant prolapse and a patulous anus, especially if fecal incontinence is a major part of the problem. A levatorplasty is added to address incontinence, although without extensive support from the literature. This is a common operation for an archetypal presentation of FTRP. This procedure, although also common and intuitive, is not supported by rigorous evidence.

Collecting high-quality evidence to support 1 procedure or another is fraught with complexity, and investigators must address a myriad of questions if they hope to reach meaningful conclusions. How should the condition be defined? What patient population should be studied, and which procedure or technique should be tested? What outcomes are most important? And, perhaps most importantly, how can the effects of bias toward a particular procedure or confounding by indication be addressed?

Karas and colleagues have entered the fray in an effort to resolve a key controversy in the management of rectal prolapse with a multicenter, randomized controlled trial spanning 21 countries and including 41 participating surgeons. Their principal challenge was to find a balance between internal validity and generalizability in the

study of a wildly variable surgical therapy. Although various (almost any) aspects of FTRP surgery could have been evaluated, the investigators chose to focus on the impact of rectopexy on 5-year recurrence of FTRP in patients said to be without preexisting pelvic floor descent. Aside from rectopexy, a considerable amount of variability in surgical technique was permitted (extent of rectal mobilization, rectopexy technique, and use of sigmoid resection).

Patients undergoing abdominal operations for FTRP formed the study population. It is notable that the proportion of males in this study (27%) is higher than that in the North American FTRP population, which may make the study results somewhat less generalizable to the more predominantly female North American FTRP population. Subjects were randomly assigned to 1 of 2 treatment arms (rectopexy or no rectopexy) before the operation. As the authors point out, randomization before the operation commenced, rather than just before the rectopexy step, may have introduced bias by permitting early operative variations between groups. Despite randomization and a relatively large sample size, the study groups were significantly different in mean length of prolapse, and, more importantly, the proportion of patients undergoing sigmoid resection. The addition of sigmoid resection, ostensibly reserved for patients with constipation, varied greatly between the study arms, with the no rectopexy group having many more resections than the rectopexy group (use of sigmoid resection: rectopexy 18.3%, no rectopexy 58.6%,  $p = 0.001$ ). This suggests that either the prevalence of constipation (and therefore straining) was truly much higher in the no-rectopexy group, or that surgeons preferentially added sigmoid resection to the no-rectopexy operation because of a perceived shortcoming with the no-rectopexy technique. A greater tendency toward constipation and straining in the no-rectopexy group may have predisposed this group to FTRP recurrence from the outset, regardless of the operative intervention. A greater tendency to use sigmoid resection in the no-rectopexy group also means that the study does not specifically compare rectopexy and no rectopexy, but rather rectopexy and *no rectopexy plus sigmoid resection*. The discrepancy in the performance of sigmoid resection could conceivably favor the no-rectopexy group (by allowing the splenic flexure to create a rectopexy of sorts) and therefore reduce the observed treatment effect. Unmeasured treatment differences may also have resulted from influences such as lack of blinding and practice variability between hospitals and countries.

Not all patients were accounted for: 26 of 252 patients (10.3%) were lost to follow-up, and no specific information is provided about their baseline or procedural characteristics, or whether these patients differed in some way from those patients who completed the study. However, it appears that available data on all patients were analyzed according to the intention-to-treat principle.

The main outcome (recurrent FTRP at 5 years) was meticulously documented and both statistically and clinically different between the no-rectopexy and rectopexy groups (8.6% vs 1.5% (log rank,  $p = 0.003$ )). The study concludes that rectopexy is superior to no rectopexy with respect to recurrence of FTRP at 5 years. The evidence supports the specific conclusion that the use of rectopexy diminishes the rate of prolapse recurrence. The 10% loss to follow-up raises some uncertainty about the size of the treatment effect. A suggestion of higher morbidity in the rectopexy group and the lack of quality-of-life data still leave some room for interpretation in the selection of procedures for FTRP.

Generalizability of the study findings to the North American context may be compromised by at least 2 additional design issues. First, patients with pelvic floor descent were excluded from this study. It is unclear how pelvic floor descent was defined, but, in the United States, pelvic floor descent is a common finding in patients with rectal prolapse. The definition of pelvic floor descent and why it was part of the exclusion criteria should have been explained and justified. The number of patients excluded based on this point may have been large enough to make the generalizability of the results questionable. Second, in a multicenter trial of a surgical treatment, the operation must be carefully standardized to ensure that comparisons are valid. Variability of surgical practice can decrease the ability to assess the effectiveness of the specific intervention being studied and can make it difficult for surgeons to interpret what was actually done. In a study as important as this, it is unfortunate that the degree of rectal mobilization was not standardized. The amount of mobilization was left to the surgeon's discretion and included 360 degrees to only posterior mobilization distally to the levator ani. Debate exists regarding the need for anterior mobilization and if division of the lateral ligaments influences recurrence. It is unclear if the degree of mobilization was recorded and analyzed. The authors also did not consider how the variable amount of mobilization might have influenced their results.

Despite its limitations, this study, with its randomized design and rigorous prospective data collection, provides some of the best evidence to date in support of the use of rectopexy in abdominal operations. It will serve as a benchmark for future high-quality studies seeking to clarify our options to deal with a difficult problem. But, in the meantime, will it change practices that have evolved and been refined over decades of surgical experience? Until sufficient studies accumulate to support evidence-based algorithms for FTRP, the practical wisdom of generations of surgical practice will likely remain in place. Many more questions remain in the management of FTRP, even regarding the most fundamental and intuitive strategies. Karas and colleagues are to be commended for taking a significant first step in this challenging journey.

## ACKNOWLEDGMENT

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## REFERENCE

1. Evidence Based Medicine Working Group. Evidence-based medicine: a new approach to teaching the practice of medicine. *JAMA* 1992;268:2420–2425.