Evidence-Based Guidelines?

To the Editor—In a recent issue of Diseases of the Colon & Rectum, The Standards Practice Task Force of The American Society of Colon and Rectal Surgeons published the Practice Parameters for dealing with colorectal cancer. They were claimed to be based on the best-available evidence—even grading the level of evidence and the strength of the different recommendations.

The use of prophylaxis of thromboembolism is recommendation, but it is stated, “Whether there is an additive effect by the use of more than one mode is yet to be determined.” I would like to draw the readers’ attention to The Cochrane Review on thromboembolism in colorectal surgery, which has been in the Cochrane Library for two years and the primary evidence has been available for more than ten years.

Another issue is the discussion on preoperative bowel cleansing. In the Task Force paper it is stated that five randomized trials have failed in proving any efficacy of preoperative mechanical bowel cleansing. They even cite a six-year-old meta-analysis coming to the same conclusion. Also in this matter the evidence presented is outdated. A Cochrane Review on the topic was first published in January 2003 followed by a paper version of this review in the Journal in 2003. The conclusion in this review is that preoperative bowel cleansing leads to more anastomotic dehiscence and perhaps more wound infections.

Evidence-based guidelines based on systematic appraisal of the evidence are thought to enhance the quality of daily practice, but this demands that the evidence is regularly updated and the search for the evidence is systematic. This seems not to have been the fact in the Task Force work.

REFERENCES


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The Authors Reply

To the Editor—We appreciate the opportunity to respond to the letter by Dr. Wille-Jorgensen. His major criticisms are that the Cochrane Reviews on venous thromboembolism prophylaxis (which he authored) and bowel preparation (which he also coauthored) were not cited in the Practice Parameters for Colon Cancer. These are valid criticisms and relate to a variety of factors that caused this particular practice parameter to have an excessively long life cycle.

First, Cochrane Reviews are now routinely used in our practice parameters and typically featured prominently where applicable. Furthermore, great efforts have been undertaken to shorten the time from literature review to publication of the practice parameters.
However, despite their clear value in promoting evidence-based medicine, the Cochrane Reviews have drawbacks. For example, the Cochrane Review on thromboprophylaxis concludes that the combination of graduated compression stockings and low-dose unfractionated heparin is the “optimal prophylaxis.” However, there is little evidence, and in fact it seems doubtful, that graduated compression stockings are superior to intermittent pneumatic compression boots for deep venous thrombosis prophylaxis. There is virtually no literature comparing these two modalities as well as many of the key issues that pertain to prophylaxis. As such, the seventh ACCP (American College of Chest Physicians) guidelines consider combined heparin with graded compression stockings or intermittent pneumatic compression boots for colorectal cancer as a Grade “C” recommendation. We should not pretend that we know the definitive answer with respect to the ideal deep venous thrombosis prophylaxis for colon cancer patients, because critical gaps remain in the comparative literature.

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REFERENCES

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The Authors Reply

To the Editor—I note the letter by Desmond Winter, M.D., F.R.C.S.I., in response to our article. Please note that the failure to acknowledge publications from 2003 was not a deliberate omission but the result of the fact that we submitted our article for publication in September 2002. I apologize if it seemed otherwise.

Fundamentally, I agree that vacuum-assisted closure therapy is a welcome addition to the options available for the treatment of pilonidal disease especially in cases of recurrent or refractory disease states.

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The Dark Side of Double-Stapled Transanal Rectal Resection

To the Editor—We read with interest the article by Boccasanta et al. that was recently published in the Journal. According to their experience, 96 percent of the patients who underwent double-stapled transanal rectal resection (STARR) for obstructed defecation had good results after one year. The authors did not report any case of pelvic sepsis and rectovaginal fistula. Unfortunately, such complications requiring diverting stoma, and a much higher recurrence rate of constipation, have been reported by others. Excruciating anal pain, fecal incontinence, and massive bleeding also have been described; depression, anxiety, and anismus, i.e., nonrelaxing puborectalis on straining, are the most frequent causes of recurrent constipation.1,2

Boccasanta and coworkers report only 2.2 percent of fecal urgency and incontinence in their article; however, urgency and soiling after the same procedure occurred in more than 20 percent of the cases operated on by the same author and published in another study.3 Incontinence is likely to be caused by the large size of the stapling device inserted through deficient sphincters of multiparous females, which may cause a fragmentation of the internal sphincter, previously reported after stapled hemorrhoidopexy.4

Obstructed defecation is an “iceberg syndrome,” a multifactorial entity, mostly related to occult pathologies, which may not require a surgical intervention, but are better cured with pelvic floor rehabilitation, high-fiber diet, or colonic irrigation.5 A double rectal resection seems rather invasive for a functional disease.

Postoperative bleeding occurred in 15 percent of 37 patients who had the STARR procedure performed in our Units between 2000 and 2004. Eleven percent of the patients had new-onset fecal incontinence. Constipation and rectocele recurred in 33 percent of them after one year, more than the 4 percent reported by Boccasanta and coworkers, and were still on laxatives postoperatively. As far as the intervention rate, they operated on one-half of their constipated patients compared with one-third of those operated on by Herriot et al., at a rate of 13 patients per center per year, much higher than the 5 patients per year of the British authors. Therefore, we agree with Robin Phillips who raises the criticism that “a surprising number of patients have been recruited in an impressively short time.”1 According to Bassotti, who also reports the Mayo Clinic experience, only 5 percent of constipated patients may benefit from surgical treatment.6

In their reply to Professor Phillips, the authors invite him for a demonstration of the STARR technique on behalf of their Society. At these live demonstrations, sponsored by the manufacturing company, general surgeons, who often are unaware of anismus in neurotics, pelvic floor weakness in multiparous females, and hidden enteroceles in hysterectomized patients, are encouraged to perform this novel procedure. This may explain the increasing number of patients with postoperative complications referred to our Units.1,2

The STARR operation has some potential benefits, because it is aimed at correcting both rectocele and rectal intussusception, but it may have severe complications and its use should be restricted to experienced colorectal surgeons. Before adopted by the surgical community, its superiority over costless and effective standard procedures needs to be clearly demonstrated by randomized, controlled trials performed in specialized centers without conflict of interest.

REFERENCES
The Authors Reply

To the Editor—Comments by Dr. Mario Pescatori, who is one of the pioneers of coloproctology in Italy, are always appreciated. Even if we agree with the conclusions of the letter to the editor, a point-by-point reply to criticisms is necessary to avoid any misunderstanding.

We did not observe pelvic sepsis or rectovaginal fistula in our series; however, this does not mean that the risk of such serious complications after double-stapled transanal rectal resection (STARR) should be excluded. Moreover, even standard procedures can be complicated by pelvic and retroperitoneal sepsis, with one reported case of Miles operation after traditional hemorrhoidectomy.

We clearly stated that patients with anismus must be excluded from surgery, as well as patients with mental disorders, pudendal neuropathy, and sphincter defect. It is, therefore, mandatory to carefully study patients before operating on them. The job of a good coloproctologist must be to recognize the occult diseases in the iceberg syndrome of obstructed defecation and only operate on patients who really need to be operated on. If it is not possible to perform all the necessary preoperative evaluations, it is preferable to submit patients to pelvic floor rehabilitation, diet, and colonic irrigation (or psychologic support), and only operate on the nonresponders.

In conclusion, our opinion, which is clearly expressed in the reply to Professor Phillips, is that very strict selection criteria must be used.

The exact rates for fecal urgency and incontinence at one month were 17.8 and 8.9 percent respectively (see Table 5 in article): these results were similar (16 percent fecal urgency and 8 percent incontinence to flatus) to those reported in our randomized study.

Questions about incontinence, anal dilator, and size of stapling device have been clearly discussed in our article. Please remember that standard procedures can damage anal sphincters the same, or more than, the stapler can. In the work by Ho et al. mentioned in the letter, the reported rates of internal sphincter fragmentation after stapled and diathermic hemorrhoidectomy were 3.1 and 6.5 percent, respectively.

The main problem for patients with obstructed defecation is to solve their complaints, rather than know whether their disease is functional or organic. Rectal intussusception and rectocele should be considered cause of mechanical, and not functional, obstruction.

There was a misreading of the study, concerning the rate of constipated patients operated on: not all constipated patients observed in our units were recruited, but only those, in whom a combination of intussusception and rectocele had been found at clinical examination. The reason for the “surprisingly large number of patients recruited during an impressively short time” is that our trial was multicentric: ten patients per ten months for each unit is not unreasonable.

We cannot exclude that STARR operations with wrong indications were performed by inexperienced surgeons during live demonstrations, sponsored by manufacturing companies; however, we were not responsible for this.

Finally, we encourage the authors of the letter to perform randomized trials, rather than retrospectively report complications of inexperienced or unlucky surgeons, or have or raise doubts about conflicts of interest (please read the acknowledgments of our article).

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Avoiding Overtreatment With Day-Case Hemorrhoidopexy

To the Editor—We read with interest the article by Esser and colleagues1 concerning stapled hemorrhoidopexy under local anesthesia. Patients were discharged within two hours. The idea is plausible; however, we missed some more data about used supplemental intravenous sedation. Only one surgeon routinely prescribed metronidazole. Did this group of patients have less pain or sepsis? Life-threatening pelvic sepsis after stapled hemorrhoidopexy has been reported,2 and it seems wise to consider antibiotic prophylaxis with metronidazole.

The follow-up of two months seems to be too short, because anal stenosis in 2 percent of cases has been reported three to five months after the operation.3,4 If detected early, anal stenosis can be treated easily without another operation. In such cases, we pinch off the scar on three places and recommend anal dilators.5 It might be interesting to know what degree of hemorrhoids had patients complaining of some anal seepage and urgency after the operation. After having operated on more than 200 cases in day hospital, we are more cautious in opting for stapled hemorrhoidopexy in second-degree hemorrhoids, because two of five patients with urgent defecation in our group had second-degree hemorrhoids, and another three of five had small third-degree piles. Stapled hemorrhoidopexy might have been an overtreatment in these cases. Hemorrhoidal tissue has been described as possibly functioning as the corpus cavernosus of the anus,6 and it might be that interruption of the terminal branches of the superior hemorrhoidal arteries diminished its maintenance, so that they could not contribute sufficiently to the continence.

We missed some more data about patient selection for day surgical procedures. Our experience, shared with other authors,6 is that proctologic outpatient surgery is possible, safe, and has a low complication rate. However, patient selection is mandatory; the criteria have been clearly reported.7

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The Authors Reply

To the Editor—I thank Drs. Mlakar and Košorok for their valuable comments and solicitation for clarification and shall address all of the issues raised by them.

1. The patients were discharged no longer than two hours before checking into the ambulatory facility. Indeed, some of the patients went home within one hour. No patient was hospitalized.
2. Supplemental intravenous sedation often was Midazolam (Baxter Healthcare Corp., Deerfield, IL) 2 to 4 mm. Some patients required Diprivan 1 percent (AstraZeneca Pharmaceuticals LP, Wilmington, DE) at the time of insertion of the instrument.
3. Metronidazole was used in approximately 20 patients and since has been abandoned, because it had no influence on the degree of pain or local reaction to the staples. We had no incidence of overall sepsis.
4. We did make it a point in our article that a follow-up of two months is indeed short. I have no doubt that some side effects will emerge in the future.
5. All of the patients whom we operated on had third-degree and fourth-degree hemorrhoids. We did not notice any difference between the subset of the two, in terms of anal seepage or urgency after the operations. We strongly believe, just as the comment is given, that this operation is ill advised for second-degree hemorrhoids.
6. We support the theory that hemorrhoidal tissue functions as corpora cavernosa and its elimination would impair continence. However, that should be more of a factor during conventional excision hemorrhoidectomy than some shrinkage of the tissue by interruption of the terminal branches of the superior hemorrhoidal artery.
7. We had no selection criteria, and if the patients had third-degree or fourth-degree hemorrhoids, we offered the procedure to all patients regardless of their age, gender, or other systemic disorders. The Department of Anesthesia screened all patients preoperatively, and although our routine workup is minimal, appropriate pulmonary and cardiac workup was performed by the anesthesia department to make the operation safe.

Again, we appreciate the comments by Drs. Mlakar and Košorok.

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