Laparoscopy for Rectal Cancer: The Need for Randomized Trials

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ABSTRACT

The adoption of laparoscopic proctectomy for rectal cancer has been relatively slow, primarily because of the technical difficulty of the procedure. The wide surgeon-to-surgeon variability in disease-free survival and local pelvic recurrence noted after open proctectomy is probably due to differences in surgical technique, and these differences are likely to be magnified when the additional challenge of laparoscopy is added to the procedure. At present, oncologic and functional outcomes data are limited. Although the adoption of laparoscopic techniques to perform curative proctectomy is likely to expand as technical challenges are overcome and experience and training improve, the results of prospective multicenter trials are necessary to ensure that the procedures provide an oncologic and functional outcome equivalent to that of conventional surgery.

KEYWORDS: Laparoscopy, randomized trials, rectal cancer, proctectomy

Objectives: On completion of this article, the reader should be familiar with the published experience with laparoscopy for rectal cancer and appreciate the need for randomized prospective trials.

The technical aspects of proctectomy for adenocarcinoma of the rectum have received considerable attention in recent years because of wide surgeon-to-surgeon variability in both local pelvic recurrence and survival rates following curative resection.¹⁻⁸ The two most commonly identified surgeon-specific factors associated with good outcome have been specialty training and high case volume. The techniques of mesorectal mobilization and resection have been demonstrated to have prognostic significance, even when combined with neoadjuvant radiotherapy.¹ Likewise, data from the Dutch Colorectal Cancer Group rectal cancer trial indicate that the benefits of meticulous surgical technique and preoperative radiotherapy are additive, not compensatory.⁹

The technique of proctectomy is thus of critical importance, in terms of both disease-free survival and local pelvic recurrence. Although performing an oncologically sound proctectomy for an upper rectal cancer in a thin woman may be straightforward, proctectomy for a distal rectal tumor in an obese man with a narrow pelvis may be difficult. Adding the technical challenges of laparoscopy to such an operation has led some surgeons to express skepticism about the relative appropriateness of attempting laparoscopic proctectomy for rectal cancer. As is true of the evolution of many technically involved procedures, advances in instrumentation combined with greater experience and better training may allow surgeons to perform laparoscopic proctectomy for cancer and achieve excellent results. There is a need, however, for

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Laparoscopic Colorectal Surgery: Where Are We Now? Guest Editor, Peter W. Marcello, M.D.

Clin Colon Rectal Surg 2006;19:13-18. Copyright © 2006 by Thieme Medical Publishers, Inc., 333 Seventh Avenue, New York, NY 10001, USA. Tel: +1(212) 584-4662. DOI 10.1055/s-2006-939526. ISSN 1531-0043.

multicenter prospective randomized trials to ensure that the procedure can be performed safely and with outcomes equivalent to those of conventional surgery. A recent panel discussion of laparoscopic surgery for rectal cancer expressed the same concerns.¹⁰

TECHNICAL ASPECTS OF LAPAROSCOPIC PROCTECTOMY

In the past decade, there has been a rapid evolution of laparoscopic techniques to treat colorectal disease, as surgeons have sought to make laparoscopic colectomy and proctectomy more routine. In addition to advances in laparoscopic instrumentation and energy delivery, improvements in hand-assist technology have allowed surgeons to approach laparoscopic proctectomy armed with better tools.¹¹

The most appealing operation early in the laparoscopic proctectomy experience was abdominoperineal resection (APR).¹² APR does not require division of the distal rectum or mesorectum, nor does it require an abdominal extraction excision or anastomosis. Thus, the full benefits of the laparoscopic approach can theoretically be realized. Patients requiring APR typically have tumors abutting the anal sphincter complex, so dissection in the immediate vicinity of the tumor is performed primarily from a perineal approach, as one would during an open operation. Fears of tumor dissemination related to pneumoperitoneum were minimized because of the position of the tumor.

One of the concerns regarding laparoscopic proctectomy is the ability of the surgeon to mobilize the distal rectum and mesorectum, especially in the setting of a bulky rectal tumor. If retraction is difficult in the deep pelvis and visualization is limited, the surgeon may have a natural tendency to perform more of the dissection from the perineal approach. Although not intrinsically dangerous, the same pelvic morphology that would lead to lesser transabdominal mobilization may also make extensive perineal dissection more difficult. If complete resection of the tumor and mesorectum at risk for tumor spread is jeopardized by these technical issues, the surgeon has done a great disservice to his or her patient by performing APR by a laparoscopic approach. Alternatively, if the rectum and mesorectum can be mobilized in the same planes as during open APR, oncologic outcomes should be equivalent.

Laparoscopic anterior resection with colorectal or coloanal anastomosis differs from APR in several fundamental ways. Most surgeons utilize an abdominal incision to extract the specimen. In addition, an anastomosis is performed, and more extensive proximal mobilization of the colon is necessary to allow a tension-free anastomosis. The ability to mobilize the splenic flexure completely, divide the inferior mesenteric artery at the aorta, and divide the inferior mesenteric vein adjacent to

the ligament of Treitz without making a supraumbilical incision may prove to be the greatest benefit of laparoscopic proctectomy in the short term.

As with laparoscopic restorative proctocolectomy, some surgeons are performing what has been termed a "hybrid" technique, using laparoscopic techniques to mobilize the proximal colon and performing much of the pelvic dissection and anastomosis through a small Pfannenstiel or low vertical midline incision.¹³ Although semantic purists may argue that this is not truly a completely laparoscopic method, the benefits of laparoscopy may be preserved. Because an incision is necessary for anterior resection with anastomosis regardless of method, the debate over what is laparoscopic and what is not appears somewhat specious. Prospective trials will be necessary to determine whether there are any differences in postoperative immune suppression,¹⁴ pain, ileus, or other short-term outcomes between the various techniques of laparoscopic proctectomy.

LEARNING CURVE FOR LAPAROSCOPIC PROCTECTOMY

How long it will take a surgeon to master laparoscopic rectal resection for curable cancer remains unknown. To determine this, one needs to draw upon data regarding the learning curve of laparoscopic colectomy for colon cancer and data regarding the frequency with which surgeons perform rectal cancer surgery.

Recent publications on laparoscopic colectomy for colon cancer have suggested that the learning curve for laparoscopic colectomy is more than 20 cases. In a prospective randomized study of colon and rectal cancer in the United Kingdom, the CLASICC trial (Conventional versus Laparoscopic-assisted Surgery in Colorectal Cancer), surgeons had to perform at least 20 laparoscopic resections before they were allowed to enter the study.¹⁵ The study began in July 1996 and was completed in July 2002. Despite the surgeon's prior experience, the rate of conversion dropped from 38% to 16% over the course of the study, suggesting that a minimum of 20 cases may not be enough to reach the plateau of the learning curve. In the COLOR trial (Colon Cancer Laparoscopic or Open Resection) from Europe,¹⁶ another recent prospective randomized study for colon cancer that required a prerequisite experience in laparoscopic colon resection before surgeons could enter patients in to the study, surgeon and hospital volume were directly related to several operative and postoperative outcomes. The median operative time for high-volume (> 10 cases/year) hospitals was 188 minutes compared with 241 minutes for low-volume (< 5 cases/year) hospitals, and likewise conversion rates were 9% versus 24% for the two groups. High-volume groups also had more lymph nodes in the resected specimens, fewer complications, and

shortened hospital stay. These two recent studies suggest that the learning curve is clearly greater than 20 cases and that surgeons need to perform a minimum yearly number of procedures to maintain their skills.

The difficulty with the broad application of laparoscopic colectomy is that the vast majority of general surgeons perform fewer than 25 segmental colon resections per year. In a review of 2434 general surgeons who were taking the recertification examination for the American Board of Surgery, all of whom supplied their operative lists from the previous year, most surgeons performed fewer than 20 colon resections in 1 year.¹⁷ In fact, the mean number of colon resections performed by a surgeon was 11. Even at the 90th percentile, only 23 colectomies were performed by a surgeon in a single year. If the average surgeon performs 11 resections and only one half are eligible for a laparoscopic approach, assuming a learning curve of 40 cases, it would take a surgeon 8 years to feel comfortable performing laparoscopic colectomy.

The problems with case volume and acquisition of laparoscopic skills for colectomy are further magnified for proctectomy. Data from the American Board of Surgery suggest that the average general surgeon in the United States performs only one or two proctectomies per year for any reason.^{18,19} This paucity of practice experience is compounded by the relatively small number of patients with rectal cancer encountered during a general surgical residency. Data from the Residency Review Committee and the American Board of Surgery indicate that the average colorectal surgery resident performs more colectomies and APRs in a single year of training than the average general surgical resident performs in 5 years of residency.^{20,21} The number of laparoscopic proctectomies performed by both general and colorectal surgeons will undoubtedly be much less than their number of open proctectomies.

The only data about the learning curve for rectal cancer come from the CLASICC trial.¹⁵ In this trial, which included both colon and rectal resection, 242 laparoscopic rectal resections were performed. Experienced laparoscopic surgeons, who had done at least 20 laparoscopic colon resections before the trial began, performed the procedures. The conversion rate for colon resection was 25% and dropped over the course of the study. For rectal resection the rate of conversion was higher (34%) and the conversion rate remained higher throughout the course of the study. Tumor fixation and uncertainty of margins were the two most common reasons for conversion. This suggests that even in experienced hands, the procedure of laparoscopic proctectomy is more technically demanding. Therefore, the initial adoption of laparoscopic proctectomy as treatment for curable rectal cancer will be by well-trained surgeons, performing a high volume of both laparoscopic colectomy and open proctectomy for cancer, who are willing

to invest the time and effort to build a successful operative team.¹⁰

ONCOLOGIC ISSUES

R.J. Heald and others advocated a technique termed "total mesorectal excision" as a method to reduce local recurrence rates following proctectomy for rectal cancer.²² Total mesorectal excision has focused attention on two critical components of oncologic proctectomy: the lateral (radial) margin and the distal margin of mesorectal excision. Sharp dissection in the avascular plane surrounding the mesorectum so as to remove the mesorectum in its fascial envelope and achieve a wide lateral (radial) margin has been demonstrated to be essential in avoiding local recurrence of tumor in the pelvis.²³ Although this concept is not novel,²⁴ it has served to refocus attention on surgical technique during proctectomy, which is warranted given the widely divergent local recurrence rates reported in the literature. The second component of total mesorectal excision, as advocated initially by Heald et al, is the removal of the entire mesorectum distal to the tumor. However, the necessity of removing mesorectum more than 5 cm distal to a tumor in the proximal rectum is not supported by pathologic studies,²⁴ may have contributed to a high anastomotic leak rate in early series,²⁵ and has not been shown to be of benefit in other published reports. At present, many advocates of total mesorectal excision limit mesorectal resection to 5 cm distal to proximal rectal tumors,²² although some authors persist in referring to this technique as "total" mesorectal excision, which has caused continued confusion and controversy.

Our approach, and that of many others, has been to mobilize the mesorectum in its fascial envelope distal to the tumor and transect the mesorectum perpendicular to the rectum at the level of rectal transection, optimally 5 cm or more distal to the tumor. For tumors of the distal and middle rectum, this approach usually mandates complete removal of all mesorectal tissue, but for tumors of the upper rectum, the distal mesorectum and rectum is left in situ. The Mayo Clinic group has termed this technique "tumor-specific" mesorectal excision in an attempt to clarify the nomenclature issue.²⁶ Preservation of the vascular supply to the distal rectum in patients undergoing resection of proximal rectal tumors has not resulted in high local recurrence rates and possibly contributed to low anastomotic leak rates in published series.^{26,27}

Given the wide variability in oncologic outcomes following open proctectomy and the technical challenges of laparoscopic proctectomy, it is logical to assume that the differences in outcome between surgeons will only be magnified after laparoscopic proctectomy for rectal cancer. One of the major concerns regarding laparoscopic rectal resection is accidental tumor spillage caused by

grasping and manipulating the rectum and mesorectum in a narrow pelvis. The incidence of intraoperative tumor cell dissemination caused by iatrogenic tumor perforation or transection during laparoscopic APR has been reported to be as high as 5%.²⁸ Although large randomized, prospective trials of laparoscopic colectomy may show that experienced laparoscopists can achieve good outcomes for patients with curable intraperitoneal colon adenocarcinoma, these results cannot be immediately extrapolated to patients with rectal cancer. Thus, it will be critical to evaluate prospectively immediate pathologic and long-term oncologic results of laparoscopic proctectomy prior to recommending the technique for mass consumption.

At present, there are limited reports of the outcomes following laparoscopic proctectomy for rectal cancer.^{14,29-47} There have been only a handful of published series with more than 50 patients and greater than 3 years follow-up.^{36,44,45} Although the German and Austrian Laparoscopic Colorectal Surgery Study Group reported results from 380 patients undergoing laparoscopic proctectomy, follow-up was short (24 months). In addition to the problems of small numbers and short follow-up, some authors fail to perform time-to-event (actuarial, Kaplan-Meier) analysis of disease-free survival and local pelvic recurrence, making any conclusions regarding oncologic outcome difficult.⁴² Two of the more recent studies in single-institution reports have shown reasonable oncologic outcomes by experienced surgeons.^{44,45} Many series report results for selected patients with early stage tumors, which is reasonable given the technical issues of laparoscopic manipulation of tumor. However, such reports are not useful in making generalizations about the appropriateness of the technique for all patients with rectal cancer. In two series of patients undergoing laparoscopic proctectomy for more advanced tumors,^{32,39} local pelvic recurrence rates were relatively high (19% and 25%), although exactly matched by the local pelvic recurrence rate in the comparison groups of patients undergoing open proctectomy in each study.

There is limited information regarding the oncologic outcomes from the only prospective randomized trial of rectal cancer surgery, the CLASICC trial.¹⁵ In this United Kingdom study, the authors reported a very high rate of positive radial margins in patients undergoing anterior resection both in the open and laparoscopic group. The rate of positive radial margins in the pathologic specimen was 6% for the patients undergoing conventional surgery and 12% for laparoscopic procedures. Although this did not reach statistical significance ($p=0.19$), the results are very concerning. Pathologic results from other recent nonrandomized studies did not specifically report radial margins, and therefore no conclusions can be drawn from these selected single-institution studies.^{44,45} The

results of the CLASICC study¹⁵ need to be evaluated in a future prospective randomized study before one can say that laparoscopic rectal resection is safe.

PERIOPERATIVE OUTCOMES

Because of the relatively small numbers of patients undergoing laparoscopic proctectomy for rectal cancer reported in the literature and the paucity of randomized, prospective trials, true comparisons of functional outcomes and perioperative morbidity rates between laparoscopic and open proctectomy are lacking. The anastomotic leak rates in some series of laparoscopic anterior resection have been relatively high (9% to 20%),^{29,30} suggesting that surgeons are still on relatively steep portions of their learning curves. Alternatively, because many leaks are due to inadequate proximal blood supply and tension, it may suggest that surgeons are not enthusiastic about rigorous (and potentially time-consuming) mobilization of the splenic flexure and proximal mesentery when faced with the task of laparoscopic mobilization of the rectum and mesorectum. Results of a large single-institution study reported a leak rate for low pelvic anastomoses of 10%, which is consistent with the leak rate following conventional surgery.⁴⁵ Good technique by a good surgeon should yield equivalent results whether performed by open or laparoscopic means.

Other postoperative parameters following laparoscopic proctectomy, such as return of bowel function, tolerance of diet, pain scores, and length of stay, have shown similar results to laparoscopic colon resection.²⁹⁻⁴⁷ Most comparative studies report a shorter hospitalization and quicker return of intestinal function following a laparoscopic approach compared with open surgery.

Unique to pelvic surgery is the potential for urinary or sexual dysfunction that occurs following proctectomy. Few reports of laparoscopic proctectomy have addressed this specific issue. Several studies have demonstrated a higher rate of sexual dysfunction following a laparoscopic approach.^{46,47} In an earlier nonrandomized comparative study from Singapore, laparoscopic mesorectal excision in comparison with conventional surgery resulted in significant male sexual dysfunction.⁴⁶ Bladder function was not affected by surgery, nor was female sexual function. However, 7 of 15 sexually active males reported impotence or impaired ejaculation compared with only 1 of 22 patients having open surgery. Results of the CLASICC trial were similar.⁴⁷ In the 347 patients undergoing proctectomy in this trial, a response to urinary and sexual function queries was received in 247 (71%) patients. There was no difference in bladder function between open and laparoscopic procedures. More than 50% of men and women in this study were not sexually active following either open

or laparoscopic surgery. In sexually active males, sexual function was worse after a laparoscopic approach (41% versus 23%). However more patients in the laparoscopic group underwent a total mesorectal excision than in the open group, which may have affected the outcomes. Sexual dysfunction was no different among sexually active females. Dysfunction was reported in 28% of women following laparoscopic surgery and 18% following open surgery. While laparoscopy provides a magnified view into the pelvis, which would hopefully reduce the rate of nerve injury, the difficulty of remaining in the right planes may offset the better visualization offered by a laparoscopic approach. This also highlights the learning curve and complexity of the laparoscopic approach to rectal cancer surgery. Future randomized studies will need to verify not only postoperative outcomes and long-term oncologic outcomes but also urinary and sexual function after a laparoscopic resection of the rectum.

CONCLUSIONS

The adoption of laparoscopic techniques to perform curative proctectomy is likely to expand as technical challenges are overcome and experience and training improve. The results of prospective multicenter trials are necessary to ensure that the procedures provide oncologic and functional outcomes equivalent to those of conventional surgery.¹⁰ Prospective analysis of outcomes by expert laparoscopic proctectomists will be the first step toward determining whether patients should undergo laparoscopic proctectomy for rectal cancer.

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