The Implementation of a Standardized Approach to Laparoscopic Rectal Surgery

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ABSTRACT

Background and Objectives: The purpose of this study was to audit our results after implementation of a standardized operative approach to laparoscopic surgery for rectal cancer within a fast-track recovery program.

Methods: From January 2009 to February 2011, 100 consecutive patients underwent laparoscopic surgery on an intention-to-treat basis for rectal cancer. The results were retrospectively reviewed from a prospectively collected database. Operative steps and instrumentation for the procedure were standardized. A standard perioperative care plan was used.

Results: The following procedures were performed: low anterior resection (n=26), low anterior resection with loop-ileostomy (n=39), Hartmann's operation (n=14), and abdominoperineal resection (n=21). The median length of hospital stay was 7 days; 9 patients were readmitted. There were 9 cases of conversion to open surgery. The overall complication rate was 35%, including 6 cases (9%) of anastomotic leakages requiring reoperation. The 30-day mortality was 5%. The median number of harvested lymph nodes was 15 (range, 2 to 48). There were 6 cases of positive circumferential resection margins. The median follow-up was 9 (range, 1 to 27) months. One patient with disseminated cancer developed port-site metastasis.

Conclusions: The results confirm the safety of a standardized approach, and the oncological outcomes are comparable to those of similar studies.

Key Words: Laparoscopic colorectal surgery, Rectal cancer, Low anterior resection, Fast-track surgery.

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INTRODUCTION

Over the last 10 years, studies have shown the positive effect of fast-track (FT) rehabilitation programs on the results of surgical treatment.[1,2] The introduction of laparoscopic colorectal surgery (LCRS) and the implementation of FT programs have been focusing on shorter hospital stay and less morbidity and surgical stress.[3,4] Several large randomized trials[5-8] and Cochrane reviews[9,10] have concluded that LCRS has better short-term outcomes and that oncological outcomes were comparable to those of the conventional open approach. These trials comparing laparoscopic and open surgery have been performed in a traditional perioperative care setting. However, it remains controversial, whether the combination of LCRS and FT programs can produce a dramatic effect on perioperative outcomes in colorectal surgery.

The laparoscopic rectal procedures can be technically challenging and are associated with a steep learning curve, longer operative time, expensive equipment, and the risk of conversion, which can result in significant increases in cost and morbidity. The optimum laparoscopic resection of rectal cancer necessitates using a wide spectrum of efficient and safe operative approaches to ensure oncological clearance and good clinical outcomes, regarding medical and surgical complications. During the implementation of LCRS in our department, we have standardized our operative approach to laparoscopic rectal surgery and perioperative care of the patients. The purpose of this article is to audit the clinical, surgical, and oncological results during this standardization of the operative technique within a FT recovery setting.

MATERIALS AND METHODS

Patient Selection

From January 2009 to February 2011, 100 consecutive patients underwent laparoscopic surgery in our department on an intention-to-treat basis for rectal cancer. The clinical, operative, and pathological data of these patients were retrospectively reviewed from a prospectively collected database. Every patient who was operated on laparoscopically for rectal cancer in an elective setting in the period was included. There were no exclusion criteria.

Preoperative Workup

The preoperative workup included biopsy, endoscopy, computed tomography (CT), liver ultrasound, chest X-ray, and magnetic resonance imaging (MR). All patients were staged according to national guidelines. Each patient was reviewed at our multidisciplinary colorectal cancer (MDT) meetings before and after surgery. Patients with ≥T3 tumors and those with a threatened circumferential resection margin (CRM) underwent neoadjuvant chemoradiotherapy. Surgery was carried out 6 weeks to 8 weeks after completion of treatment. Patient characteristics, tumor size and location, as well as perioperative data, pathological results, morbidity, length of hospital stay (LOS), readmission rate, 30-day mortality, and follow-up were recorded prospectively. All procedures were performed by the same surgical team.

Tumors were considered rectal cancers if located below 15cm from the anal verge measured with a rigid rectoscope. Rectal cancer suitable for surgery was defined as a biopsy-proven adenocarcinoma. Patients were considered suitable for laparoscopic surgery if they had no serious health conditions precluding a laparoscopic procedure. Patients with CT or MR evidence of tumor infiltration of adjacent organs and T4 cancers were considered unsuitable for laparoscopic surgery. All patients were informed about possible risks and benefits of laparoscopic surgery, and informed written consent was obtained. A phosphate enema was given as bowel preparation prior to surgery. Stoma sites were marked preoperatively. All patients received epidural anesthesia (bupivacaine/fentanyl) or intravenous morphine as postoperative pain relief. Perioperative care was previously described and primarily developed for open colonic surgery in FT settings.[1,2,11] The FT settings included initiation of mobilization and full oral feeding (minimal oral intake of 1500mL of fluid but a full diet was allowed) on the evening of surgery, removal of epidural catheter and urinary or suprapubic catheter on the third day of surgery and planning of discharge as soon as possible hereafter. During the hospital stay, all patients received thromboembolic prophylaxis. Nasogastric tubes and drains were not used routinely.

Surgical Method

We used 5 port sites. The standardized operative steps for laparoscopic rectal resection are (1) open insertion of the umbilical port for establishment of pneumoperitoneum and peritoneal inspection. The patient was then placed in a steep Trendelenburg position and the operating table was rotated towards the right side. (2) Placement of 3 or 4 ports at variable sites: a 10-mm to 12-mm port is inserted into the right lower quadrant approximately 2cm to 3cm medial and superior to the anterior superior iliac spine. A 5-mm port is then inserted in the right upper quadrant at least a hand's breath superior to the lower quadrant port. A 5-mm left upper quadrant port is also inserted to aid the traction of rectosigmoid colon or splenic flexure mobilization. All of these ports are inserted lateral to the epigastric vessels. An optional 5-mm port can also be inserted at the suprapubic site, in which a Pfannenstiel incision is anticipated. (3) Mesocolic dissection and inferior mesenteric pedicle isolation was achieved with a medial approach, and the inferior mesenteric artery was ligated close to its origin with clips or Endo-GIA. The superior rectal artery was divided just below the inferior mesenteric artery after application of 5-mm clips in the cases of abdominoperineal resection (APR) and Hartmann's operation (HO). (4) The left ureter was recognized and subsequently, with the patient placed supine and rotated left side up, medial-to-lateral dissection was continued cranially up until the left colon was mobilized. (5) The patient was returned to the Trendelenburg position, and the small bowel was reflected cranially after the completion of mobilization of the left colon. A grasper was used to elevate the rectosigmoid colon out of the pelvis and away from the retroperitoneum and sacral promontory, to enable entry into the presacral space. (6) The posterior aspect of the mesorectum was easily identified, and the mesorectal plane dissected with Harmonic scalpel, preserving the hypogastric nerves. Dissection was continued down to the presacral space in this avascular plane toward the pelvic floor. (7) Dissection proceeded laterally on both sides of the rectum until circumferential mobilization of the lower rectum was accomplished. (8) Digital examination was performed to verify the distance between the inferior margin of the tumor and the line of resection, and the adequacy of the distal margin was marked with a clip. (9) An EndoGIA 45-mm Roticulator stapler (Covidien Ltd., Norwalk, CT, USA) was fired twice to divide the lower rectum safely. The abdomen was then deflated, and a suprapubic incision of 4cm to 6cm performed to extract the left colon and resect the specimen. A wound protector (Alexis OTM, Applied Medical Rancho Santo Margarita, CA) was placed at the incision. (10) Extracorporal preparation of the proximate colon was completed with placement of the anvil of a 29-mm circular stapler (Proximate ILS circular stapler, Ethicon, Endo-surgery, Cincinnati, OH, USA) in position to perform a side-to-end or end-to-end colorectal anastomosis in the cases of low anterior resection (LAR). Bowel anastomosis was performed intracorporeally by the double staple technique. The splenic flexure was not routinely mobilized. For tension-free anastomosis, full splenic flexure mobilization was performed in case of lack of redundancy of the sigmoid colon during surgery. The low pelvic dissection in APR was performed first posteriorly, then anteriorly, and finally with lateral dissection. The remainder of the deep pelvic dissection was performed through a perineal approach, including removal of the tip of os coccyx together with the specimen ad modum Holm.[12] In cases of HO and APR, a stoma was placed in the lower left quadrant according to the preoperatively marked stoma-site. A standardized perioperative care protocol was used. Conversion to an open procedure was defined as any abdominal incision larger than the above-mentioned to extract the specimen.

A protective loop ileostomy was performed for the patients needing anastomosis within 5cm of the anal verge. Intestinal continuity was re-established 3 months later or after completion of postoperative adjuvant therapy.

Follow-up

Postoperative complications were defined as any morbidity, including wound infection, in the postoperative period in the hospital or in the outpatient clinic within 30 days after the operation. Perioperative death was defined as death occurring within 30 days after surgery. Anastomotic leaks were defined as any dehiscence of the anastomosis observed by endoscopy, digital examination, CT-scan, or Gastrografin enema. All patients were referred for colonoscopy and CT-scan after the first and third year of surgery.

Pathologic Method

All specimens were examined by local pathologists with special attention to the number of harvested lymph nodes, circumferential resection margin (CRM), distal resection margin (DRM) and completeness of the mesorectal fascia (MRF).

Statistical Analysis

Data were collected in an SPSS worksheet (SPSS version 19; SPSS INC. Chicago, IL). All values are presented as median (range). When appropriate, Fisher's exact test (chi-square test) was used for nonparametric data. $P<.05$ was considered statistically significant.

RESULTS

Patient characteristics are summarized in **Table 1**, and perioperative data are shown in **Table 2**. Nine patients (9%) were readmitted for a median of 3 days (range, 1 to 13). There were 9 operations where conversion to open surgery were necessary. Indications for conversion included fixation of the tumor to the surrounding organs (n=6), dense adherences (n=1), tumor growth into the bladder (n=1), and progressive respiratory insufficiency related to establishment of pneumoperitoneum.

Intraoperative complications occurred in 3 cases. One bladder injury and one superficial laceration of the rectum occurred during laparoscopic resections. These injuries were repaired laparoscopically without conversion. Finally, one perforation of the anal canal occurred during perineal dissection in an APR-procedure.

In the postoperative period, we registered 11 cases of anastomotic leaks in accordance with our previously mentioned criteria among the 65 patients who underwent low anterior resection. Among those, 6 patients (9%) required reoperation. The remaining 5 patients (8%) were treated conservatively or with endoscopic vacuum-assisted closure. **Table 3** outlines all postoperative complications encountered. We found a 30-day mortality rate of 5% (5 patients). Mean follow-up was 9 months (range, 1 to 27).

The oncologic outcomes are shown in **Table 4**. Twenty-four patients underwent neoadjuvant treatment before the surgical procedure. Five of these (20.8%) had a complete pathological response with no residual tumor detectable in the resected specimen. The median length of the specimen was 17cm (range, 10 to 35), the median DRM was 30mm (range, 2.5 to 35), the median CRM was 10mm

Table 1.
Patient Demographics

Sex, m/f (n)	61/39
Age, median (years)	66 (range 30–88)
Body Mass Index, median (kg/m^2)	24 (range 17–40)
ASA-score, median*	2 (range 1–3)
Tumor location, median (cm from anal verge)	10 (range 2–15)
Previous intraabdominal surgery (n)	31
Preoperative chemo-radio-therapy	
None	76
Chemo- and radiotherapy	24

*ASA=American Society of Anesthesiologists.

(range, 0 to 55), and CRM was positive in 6 patients. The overall median number of harvested lymph nodes was 15 (range, 2 to 48). The median lymph node harvest in patients who underwent preoperative neoadjuvant treatments (n=24) was 12 (range, 4 to 35), and in patients who underwent primary resection without neoadjuvant treatment (n=76), the median lymph node harvest was 16 (range, 2 to 28). The MRF was complete or near complete in 84 cases and not complete in 14 cases. The MRF was not described in the histopathological reports in 2 cases. One patient with disseminated cancer developed port-site metastasis.

Table 2.
Perioperative Data

Surgical procedure	(n)
Low anterior resection	26
Low anterior resection with loop-ileostomy	39
Hartmann's operation	14
Abdominoperineal resection	21
Operative time, median (min)	250 (range, 51–397)
Low anterior resection	181 (range, 51–353)
Low anterior resection with loop-ileostomy	261 (range, 100–376)
Hartmann's operation	186 (range, 114–345)
Abdominoperineal resection	280 (range, 131–397)
Loss of blood, median (mL)	100 (range, 0–1145)
Hospital stay, median (days)	7 (range, 3–80)
Re-admission (n)	9

DISCUSSION

The increasing amount of available data on laparoscopic resection of the rectum suggests that the method is feasible and safe for select patients with favorable short- and mid-term outcomes.[13,14] Nonetheless, laparoscopic rectal surgery has been viewed with significant skepticism by the surgical community, and the majority of rectal resections continue to be carried out using the conventional open approach. Currently, several multicenter randomized controlled trials comparing laparoscopic and open surgery for rectal cancer are registered, and until these data become available, some surgeons believe that open total mesorectal excision is regarded as the gold standard treatment of rectal cancer. The limited access to experienced laparoscopic colorectal surgeons may also play a role in this turnover process. The resection of low rectal tumors is technically challenging, and the learning curve to achieve an adequate clearance margin is steep. Training in advanced colorectal workshops that utilize both animal and human cadaver models is extremely helpful to shorten this learning curve. Appropriate patient selection is also an essential component of surgical practice at the beginning of training and ideal cases to start on to help

Table 3.
Postoperative Complications

Complication	Number of patients (n)	Treatment
Urine tract infection	5	Antibiotics
Gastrointestinal bleeding	1	Self-resolved
Superficial wound infection	2	Drainage
Leakage of the rectal "stump"	3	Ultrasound-guided drainage
Compartment syndrome	2	Fasciotomy
Necrosis of the stoma	2	Stoma refashioned
Ileus (adhesions)	1	Lysis of the adherences
Early port-site hernia	1	Repaired
Peritonitis	2	Laparotomy
Parastomal hernia	2	Repaired
Presacral abscess	3	Ultrasound-guided drainage
Anastomotic leak	5	Conservative treatment/Endo-VAC[a]
Anastomotic leak	6	Reoperation
Total	35	

[a] Endo-VAC = Endoscopic vacuum-assisted closure.

Table 4.
Oncologic Results

Circumferential resection margin, median (mm)	10 (range 0–55)
Distal resection margin, median (mm)	30 (range 2,5–70)
Length of specimen, median (cm)	17 (range 10–35)
Harvested lymph-nodes, median (n)	15 (2–48)
Mesorectal fascia (n)	
Complete	68
Near complete	16
Incomplete	14
R0 resection	94

climb the learning curve. However, permanent supervision and training with experienced surgeons who routinely perform a significant number of laparoscopic rectal procedures, in our opinion, is the best way to acquire the required skills in this procedure, because there is less case selection with varying difficulty of the operations and the multitude of factors that effect the outcomes in laparoscopic rectal surgery in the later period of training. Lindsetmo and Delaney[15] described a standard, stepwise laparoscopic procedure for rectal resections. We have adapted this technique, which makes the operation predictable and reproducible for the whole surgical team. The process of adapting this standardized technique is probably one of the causes for the median operative time of 250 minutes, which is longer than time in comparable studies.[8,16] Other causes could be that a new surgical setting was implemented and that 2 new surgeons in our team were educated to perform laparoscopic rectal surgery during the study period. Furthermore there were a high number of patients with a history of previous abdominal surgeries in our series (31%).

There have been reports about increasing complication rates in patients converted from laparoscopic to open surgery.[17] Our rate of conversion was 9%, which is lower than that in other studies.[8,18] This may reflect some degree of bias, because our patients were selected candidates for laparoscopic surgery and not randomized to either open or laparoscopic surgery. Morbidity and length of hospital stay for converted patients were however similar to those completed laparoscopically. Our data therefore confirm that careful selection of patients for laparoscopic surgery makes the procedure practicable and the need to convert small. This study also confirms that our strategy to convert whenever there is failure to progress in the very difficult operative field is safe. At present, our approach is to initially plan the laparoscopic method for almost all patients, only exclusions being T4 tumors or local growth into neighboring organs.

A median postoperative hospital stay of only 7 days in this series is short compared to that in other studies with a median hospital stay of 8 days to 15 days.[8,16,19-22] This great variety of results is probably due to cultural and economic differences in health care systems between countries. In our department, there are very well-established routines in our fast-track surgery program that was originally developed for postoperative care after colon surgery.[1,2] It has over the years been adjusted for rectal surgery. Hence, all patients were already prepared for stoma self-care prior to surgery by one of the specialist nurses from our ward. Furthermore, all patients, if possible, received epidural analgesia up to 3 days after surgery, and all patients were encouraged to early oral feeding and mobilization as soon as possible after surgery, at the latest the first day after surgery, and drains and catheters were withdrawn the third postoperative day. Our readmission rate of 9% with a median secondary hospital stay of 3 days is comparable to that in similar studies where up to 23% of the patients were readmitted after fast-track rectal cancer surgery.[23]

Table 3 shows that the majority of complications were surgical. There is no difference in complication rates between the first and the last 50 patients in this series. Our overall complication rate of 35% matches results of other studies.[8,16,21] There is a small tendency towards increased risk of complications, if the patient had received preoperative radiotherapy, as 40.9% of the radiated patients experienced complications versus 35.9% of the nonradiated patients. The tendency is however not statistically significant ($P=.803$). Although a total of 15 reoperations seem to be a high figure, it is comparable to that in other reported series of laparoscopic rectal surgery.[24,25]

Much depends on the author's definition of anastomotic leakage when it comes to calculating leakage rates. We have used wide-spanning criteria for our definition of anastomotic leaks. Our rate of leakages that required reoperation (9%) is acceptable in comparison with that in other series.[8,16,22] Neither conversion nor neoadjuvant therapy resulted in higher risk of development of anastomotic leakage in this series. However, **Figure 1** shows that there is a decreasing tendency in the leakage rate in the latter part of the study period (study period B), where the standardized surgical approach had been fully implemented. The difference between these rates of leakages is however not significant ($P=.094$).

Our 30-day mortality was 5%, which is relatively high compared to that in other studies.[18,20] The postoperative

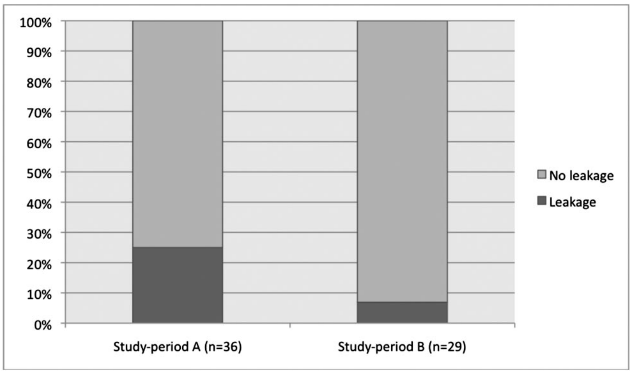

Figure 1. Anastomotic leakage rates. In study period A, patients no. 1–50 underwent surgery and 9 had anastomotic leak (25%). In study period B, patients no. 51–100 underwent surgery, and 2 had anastomotic leaks (6.9%) (P=.094).

morbidity and mortality in FT settings remain challenging and controversial due to mainly a nonselected, high-risk elderly population with coexisting illnesses.[26-28] In the present series, the 5 patients who died were 78 to 88 years of age at the time of the operation. They all suffered preoperatively from severe degrees of ischemic heart failure. Moreover, one of the patients suffered from severe chronic obstructive lung disease and non-insulin dependent diabetes mellitus, one patient suffered from renal failure and obesity (BMI=33), and one patient had recently been hospitalized due to lung embolia. After primary surgery, all 5 patients experienced surgical complications and underwent reoperations. In 2 patients, reoperation was needed because of fecal peritonitis (anastomotic leak and small bowel perforation), in 2 cases because of severe ischemia of the stoma, and in 1 case because of nonfecal peritonitis of unknown origin. All 5 patients died due to sepsis and failure of multiple organs.

Large randomized trials comparing laparoscopic versus open resection for colorectal cancer have shown an equivalent oncological outcome.[6,7] Adequate surgical margin clearance remains crucial for local recurrence rates. The results of the CLASICC trial with a trend towards increased rate of involved CRM (6% open vs. 12% laparoscopic) for anterior resection were initially alarming.[8] However, a recent metaanalysis suggests that there are no differences between laparoscopic and open surgery for rectal cancer in terms of number of harvested lymph nodes, involvement of CRM and local recurrence.[29] The rate of positive CRM was 6% in our study. All positive margins occurred in patients with T4 tumors or node positive (N2) disease. This rate is comparable to that in other reports.[8,16] The number of lymph nodes harvested from the mesorectum during surgery is also an important predictor of prognosis.[30] In our study, there was a median harvest of 15 lymph nodes, and 80% of the specimens contained 12 lymph nodes or more, which is equal to results of several studies.[14,16,18,20] The mesorectal fascia was not complete in 16% of our patients. Macroscopic evaluation of the mesorectal fasciae is considered an important quality measure in rectal cancer surgery. Tears and shallow breaks in the mesorectum, however, are difficult to avoid, particularly when dealing with large bulky tumors in LCRS. Other factors like a narrow pelvis and a fatty mesorectum increase the risk of damaging the mesorectal fascia with the laparoscopic instruments as well. For that reason, the grading of the mesorectal fasciae was characterized as only nearly complete in some cases, even though dissection was carried out in the correct plane.

Nagtegaal et al[30] have shown that a complete or nearly complete mesorectal fascia is prognostic for good long-term oncological outcomes, whereas an incomplete fascia is prognostic for unfortunate oncological long-term outcomes. Because of the short follow-up period, it is not possible to conclude whether our oncologic result influences the long-term oncologic outcome. Only one patient with disseminated cancer developed a port-site metastasis.

The main limitations of this study are furthermore that this retrospective series with prospectively registered data does not include a large number of patients. More data are needed from large randomized controlled trials regarding long-term oncological outcome.

CONCLUSION

Our data support the view that standardization of the operative steps in laparoscopic rectal surgery seems to limit the risk of anastomotic complications and provides clear indications for early and safe conversion to open surgery. This stepwise technique can be used to train colorectal surgeons in the future. Oncological outcomes are comparable to those of similar studies, but we need to optimize the short-term outcome further.

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