Surg Endosc (2002) 16: 31–35
DOI: 10.1007/s00464-001-9035-4

SURGICAL ENDOSCOPY
and Other Interventional Techniques

Training period in laparoscopic colorectal surgery

A case-matched comparative study with open surgery

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Received: 14 February 2001/Accepted in final form: 19 April 2001/Online publication: 5 October 2001

Abstract
Background: Thorough training is essential to the success of colorectal laparoscopic surgery (LPS). The aim of this study was to evaluate the results of a 3-month training period in LPS.
Methods: Before beginning the study, the surgical team attended several courses of LPS and spent a long time working at a large animal facility to perfect laparoscopic techniques. Twenty-six consecutive patients underwent LPS in a 3-month training period. Controls ($n = 26$) who underwent open colorectal surgery (LPT) were selected to match the LPS patients for age, gender, primary disease, type of surgery, comorbidity, and nutritional status.
Results: Conversion to open surgery was necessary in one patient (3.8%). The operative time was 1 h longer for LPS than LPT ($p < 0.001$). The mean number of lymph nodes harvested was 17 in LPS and 18 in LPT ($p = 0.76$). The first flatus ($p < 0.02$) and bowel movement ($p < 0.002$) occurred earlier in the LPS group. The postoperative infection rate was 11.5% for LPS and 19.2% for LPT ($p = 0.33$). Two anastomotic leaks occurred in each group. The mean postoperative hospital stay was 9.6 days (standard deviation [SD], 2.6) for LPS and 11.0 days (SD, 5.2) for LPT ($p = 0.68$). Recovery of postoperative physical performance and social life occurred earlier in the LPS than the LPT group ($p < 0.001$). At 1-year follow-up, no difference was found in terms of cancer recurrence or long-term complications.
Conclusion: Oncologic results and postoperative morbidity were comparable for LPS and LPT. LPS allows a faster postoperative recovery.

Key words: Laparoscopy — Colorectal surgery — Training — Bowel function — Postoperative morbidity — Learning curve

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Laparoscopic surgery (LPS) is gaining acceptance as the optimal approach for patients with polyps, diverticular disease, and other benign colorectal diseases because it has a less marked immunosuppressive effect and allows for a more rapid recovery from surgery [6]. It is still somewhat controversial for cancer patients, however, due to the possibility for the spread of cancer to portsites; there is also some uncertainty about its adequacy for bowel resection and lymphatic dissection, as well as its effect on long-term survival [14, 17].

The need for specific training programs and the paucity of data demonstrating substantial cost savings have delayed the wide acceptance of colorectal LPS [3, 5, 16, 20, 21, 26]. A key difficulty is the length and type of training period needed to ensure the acquisition of the necessary surgical skills.

The aim of this study was to evaluate the results of a 3-month training period in colorectal LPS in terms of feasibility, safety, and short- and long-term morbidity.

Patients and methods

During a 3-month period (July 1999–September 1999), we scheduled for LPS all 34 patients with ages ranging between 18 and 80 years who were candidates for elective surgery to treat colorectal disease. Exclusion criteria were as follows: emergency surgery ($n = 2$), previous laparotomy ($n = 1$), cancer of the transverse colon ($n = 1$), cancer of the rectum < 6 cm from the anal verge ($n = 1$), cancer infiltrating an adjacent organ ($n = 2$), and severe cardiovascular dysfunction (New York Heart Association class > 3) or respiratory dysfunction (arterial $PO_2 < 70$ torr) ($n = 1$). The remaining 26 patients were deemed to be eligible for LPS.

Before beginning this study, the surgical team (M.B., W.Z., A.V.) was well experienced in both open colorectal surgery [23, 24] and other laparoscopic procedures (cholecystectomy and biliary tract surgery, appendectomy, splenectomy, and Nissen fundoplication) [11, 13]. Moreover, the surgical team had attended colorectal laparoscopic courses and spent several months working at a large animal facility to perfect their laparoscopic resectional techniques.

In all patients scheduled for laparoscopic surgery, demographics, nutritional status, and primary diagnosis were recorded. Undernutrition was defined as occurrence of >10% weight loss with respect to usual body weight in the 6-month period before admission. Presence of comorbidity factors was assessed at hospital admission according to the American Society of Anesthesiologists (ASA) score.

Since 1994, the demographics, operative variables, postoperative complications, and histopathology for >1200 patients operated on at our hospital for colorectal diseases have been recorded prospectively in a computerized database. The control patients, who underwent open surgery, were selected from this database starting from June 1999 and proceeding backward until we had identified one control subject for each case. The same exclusion criteria used for the LPS patients were applied to the control patient selection. The identification of control patients was made by a statistician who was unaware of the postoperative outcome. Controls were selected to match for primary disease, type of surgery, age (±3 years), gender, nutritional status, and ASA score.

In both LPS patients and controls, bowel preparation was done the day before the operation by intestinal washout with an iso-osmotic solution (3 L). As antibiotic prophylaxis, all patients received a single dose of cefotetan (2 g intravenously) during the induction of anesthesia. A second dose of the same antibiotic was administered intraoperatively if surgery lasted > 4 h. Deep vein thrombosis prophylaxis was carried out with low-molecular-weight heparin (3000 IU/day) in all patients. Postoperative infusion of fluids and electrolytes was given in all patients according to their clinical requirements.

The following details of the surgical procedure were recorded in all patients: duration of operation, operative blood loss, amount of homologous blood transfused, and type of surgical procedure performed, including details about intestinal anastomosis (manual/stapling, intra-extracorporeal). Tumor classification was by Dukes' stage. The number of lymph-nodes collected in the specimen was recorded in all patients.

Postoperative bowel function was evaluated with respect to the first flatus and bowel movement (days). In all patients, recovery of oral feeding began after first flatus. None of the patients were discharged before recovery of bowel movement.

The following postoperative infectious complications were recorded by members of the surgical staff who were not involved in the study: peritonitis, abdominal abscess, surgical wound infection, urinary tract infection, pneumonia, bacteremia, and sepsis, as previously defined [1]. Microbiological analysis and positive culture proved all infectious complications. Clinically evident anastomotic leak was also recorded.

Patients were followed up for infectious complications for 30 days after hospital discharge by office visits. Moreover, patients were followed up quarterly by office visits in the 1st postoperative year to record potential recurrence in cancer patients (including port site recurrences), long-term complications, and hospital readmission. Patients were also asked to fill out and return a questionnaire designed to assess their subjective evaluation of the time needed for the full recovery of physical performance and social life after operation.

Laparoscopic procedure

In all patients, a blended anesthesia (general plus thoracic epidural) was used. All patients were placed in the Lloyd-Davis position to facilitate both transanal stapled anastomosis, when appropriate, and access for either the first surgeon or the assistant. Pneumoperitoneum was induced using carbon dioxide (CO_2) by placement of an infraumbilical trocar via an open technique. The abdomen was insufflated to a pressure of 13 mmHg, which was mantained during the surgical procedure. After exploration of the abdominal cavity through the initial trocar, two to four additional trocars were inserted under laparoscopic guidance according to the procedure to be performed.

Identification and division of the lymphovascular pedicle and the associated mesentery and adequate mobilization of colonic segment were done in all patients using a harmonic scalpel. In patients undergoing rectum anterior resection, division of the rectum was performed with a linear stapler. In all patients, identification of vital structures such as the ureter and duodenum when appropriate (right hemicolectomy) was mandatory to continue the procedure. For patients undergoing right or left hemicolectomy, the intended margins of excision and the extent of colonic mobilization were comparable to open surgery. Once bowel mobilization and the division of the lymphovascular pedicle were completed, either a transverse abdominal (5–8-cm) or a Pfannenstiel incision was used to remove the specimen. A plastic bag was used to protect the surgical wound during specimen extraction. Once the colonic specimen was removed, the anastomosis was fashioned extracorporeally (right hemicolectomy) or intracorporeally with a circular stapler (colorectal anastomosis). Working ports were removed under direct vision at the end of the surgical procedure.

Table 1. Demographics, nutritional status, surgical procedure, and primary diagnosis

Variable	*Laparoscopic surgery* (n = 26)	*Open surgery* (n = 26)
Age (yr)	61.7 (9.4)	62.0 (8.9)
Male/female	11/15	11/15
ASA score (1–4)	2 (0.7)	2 (0.7)
Undernutrition (weight loss >10 %)	5	5
Surgical procedure and primary diagnosis		
Sigmoid resection		
Diverticular disease	4	4
Sigmoid polyp	1	1
Low anterior resection		
Rectal cancer	5	5
Right hemicolectomy		
Right colon cancer	8	8
Left hemicolectomy		
Sigmoid cancer	7	7
Megacolon	1	1

ASA, American Society of Anesthesiologists
Data reported as mean (SD) or number of patients

Statistical analysis

Descriptive data are shown as mean, standard deviation (SD), and median or as number of patients and percentage. Comparison between proportions was made with the chi-square test or Fisher's exact test when appropriate. Student's t -test and the nonparametric Mann-Whitney U test were used to compare between-groups differences of continuous variables. All 'p' values < 0.05 were considered to indicate statistical significance (two-tailed test).

Results

Laparoscopic resection was attempted in 26 patients by the same surgical team (M.B., W.Z., and A.V.). In one patient (3.8%), conversion to open surgery was necessary due to colonic perforation during splenic flexure mobilization. This patient was included in the laparoscopic resection group according to the intention-to-treat analysis.

To identify one matched control patient for each case, we had to check 192 patients by proceeding backward from June 1999 to July 1998. Demographics, nutritional status, surgical procedures, and diagnosis are reported in Table 1. The principal investigator (M.B.) performed 15 of the 26 open operations; the others were carried out by a senior surgeon (V.D.C.).

Table 2 lists the operative variables for the two groups of patients. The operating time was significantly longer in LPS patients than in those who underwent open surgery (p<0.001). None of the patients in the LPS group had an associated procedure, whereas a cholecystectomy was done in one of the conventional surgery patients. In six LPS patients three sigmoid cancer, two rectal cancer, one sigmoid polyp), an intraoperative proctoscopy was necessary to locate the lesion and identify the distal resection margin. There was less intraoperative blood loss in the LPS group, but the difference was not statistically significant (p = 0.14).

Table 2. Operative variables

Variable	Laparoscopic surgery ($n = 26$)	Open surgery ($n = 26$)	p value
Duration of surgery (min)	206 (50); 190	149 (48); 130	<0.001
Intraoperative blood loss (ml)	202 (165); 175	254 (203); 200	0.14
Patients transfused	3	5	0.59
Distance from the anal verge (cm)[a]	9.8 (4.1); 9.4	10.2 (3.2); 9.7	0.81
No. of lymph nodes collected[b]	17 (5); 16	18 (7); 18	0.76
Primary protective stoma	1	1	1.0

Data reported as mean (SD), median, or number of patients
[a] Only in patients with rectal cancer
[b] Only in cancer patients

In cancer patients, the mean number of lymph nodes identified by the pathologist in the resected specimen was 17 (range, nine to 27) in the laparoscopic group and 18 (range, nine to 39) in the open group ($p = 0.76$). Adequate tumor margin clearance was obtained in all cancer patients. The distribution of Dukes' staging in the 20 cancer patients who underwent laparoscopic surgery was A in six cases, B in eight, C in four, and D in two. In the conventional surgery patients, it was A in four patients, B in three, C in twelve, and D in two.

There were no deaths in the postoperative period. Details of the postoperative surgical complications are shown in Table 3. The overall postoperative infection rate was 11.5% in the LPS group and 19.2% in the open surgery group ($p = 0.33$). In both groups, there were two anastomotic dehiscenes, leading to one reoperation in the LPS group and two reoperations in the open surgery group.

LPS patients experienced a more rapid recovery of bowel function, as indicated by first flatus (mean [SD], 2.61 [0.69] vs 3.07 [0.68] days; $p = 0.02$) and first bowel movement (mean [SD]; 4.85 [0.97] vs 5.73 [1.00] days; $p = 0.002$).

The mean (SD) postoperative stay was 9.6 (2.6) days in the LPS group and 11.0 (5.2) days in patients who underwent open surgery ($p = 0.68$). The mean (SD) time needed to return to full physical and social activity after the operation was 34.4 (13.2) days in the LPS group and 76.1 (29.7) days in the open group ($p < 0.001$).

At 1-year follow-up, all patients were alive. Cancer recurrence was found in three LPS and four open patients. There were no port site metastases in the LPS group, and no wound recurrences in the open surgery group. Long-term complications occurred in two LPS patients (one intestinal obstruction, one incisional hernia) and three open patients (two intestinal obstructions, one incisional hernia). Hospital readmission was necessary in two LPS patients (one liver metastasis, one intestinal obstruction) and four open patients (two cancer recurrences, two intestinal obstructions). Reoperations were performed in one LPS patient (liver metastasis) and two open patients (one pelvic recurrence of rectal cancer, one intestinal obstruction).

Table 3. Postoperative surgical complications

	Laparoscopic surgery ($n = 26$)	Open surgery ($n = 26$)	p value
Surgery-related infections, *n*			
Abdominal abscess	0	1	
Surgical wound	2	1	
Nosocomial infections, *n*			
Pneumonia	1	2	
Urinary tract	0	1	
All infections, *n* (%)	3 (11.5%)	5 (19.2%)	0.33
Anastomotic leak, *n*	2	2	
Overall, *n* (%)	5 (19.2%)	7 (26.9%)	0.74
Reoperation, *n* (%)	1 (3.8%)	2 (7.7%)	0.99

Discussion

One of the key issues in colorectal LPS is the type of training program needed to ensure the progressive acquisition of the skills needed by the surgical team without compromising the safety of the operation. It is crucial to evaluate the methods and results of the training period for the following reasons: (a) Usually, the first cases are excluded from randomized trials because of possible biases linked to the limited skills of the surgical team; (b) it is mandatory that the appropriateness of both the training modality and the educational program be verified; (c) it is important to encourage new surgical teams—and especially young surgeons—to learn the basic principles so that colorectal LPS can be developed further.

There have already been a number of studies on the learning period for laparoscopic colorectal surgery [3, 5, 9, 10, 20, 21, 26]. All of them stressed the relationship between the surgeon's experience and patient outcome. High-volume surgeons (> 40 cases) had a lower conversion rate [20], a shorter operating time [20, 26], and fewer intrapostoperative complications [3] than low-volume surgeons. However, since the operating times and complication rates for the early and late cases were not compared, the existence of a learning curve was not demonstrated definitively. A significant reduction in operative time for surgeons with a case volume >15 was reported by Simons et al. [21]. Bruch et al. [5] studied the outcome of 300 colorectal procedures performed within a period to evaluate the impact of the learning curve on the incidence of morbidity. With increasing experience, the occurrence of major complications, the conversion rate, the operating time, and the postoperative length of hospital stay all declined; however, the effect appeared to be more pronounced after the first 100 cases.

Two important issues are seldom considered in the training program: the duration of the training period and the background of the surgical team in other laparoscopic operations and conventional open colorectal surgery. To foster an environment that would favor the acquisition of skills in LPS, we decided to submit all patients with colorectal disease admitted to our department in a 3-month period to the laparoscopic approach, so that a large number of patients would be treated within a short period of time. Because of our team's lack of specific experience with LPS, we applied strict exclusion criteria, such as emergency surgery, previous laparotomy, cancer infiltrating adjacent organs, and severe cardiorespiratory dysfunction.

Since this period was only the preliminary phase of our colorectal laparoscopic experience, we considered it ethically inappropriate to randomize patients before one dedicated surgical team could complete an adequate training period. The current trial was therefore designed as a matched and controlled study, a particularly useful design for small studies [4]. The data for the control patients, including postoperative complications and follow-up, had been recorded prospectively in a database. Control patients were matched for age, primary disease, type of operation, gender, nutritional status, and ASA score. A possible bias could arise from the different periods in which the cases (July–September 1999) and controls (July 1998–June 1999) were operated on. However, in the last 2 years, no substantial variation in perioperative management has occurred at our institution (preoperative mechanical bowel preparation, antibiotic and deep venous thrombosis prophylaxis, anesthesia technique, and postoperative pain control).

In the LPS group, there were no major intraoperative complications and the conversion rate to open surgery was 3.8% (one of 26); these results are consistent with other reports [3, 5, 12, 22, 25]. The low conversion rate may reflect the strict selection policy, which mandated the exclusion of patients with locally advanced disease. The mean operative blood loss was 202 ml, and the homologous blood transfusion rate was 11.5% (three of 26), less than our standard in open surgery [23]. The laparoscopic procedure took significantly longer than open surgery, as has been reported by other investigators [12, 22]. No difference was found in either the number of operative lymph nodes sampled or cancer recurrence at 1-year follow-up; thus, LPS could be considered to be as curative as open surgery, as has been reported previously [5, 7, 8, 15, 17–19]. In the present series, we did not find any port site metastases, probably because we routinely use a plastic bag to protect the wound.

In terms of postoperative complications and anastomotic dehiscence rate, there was no difference between LPS and open surgery. LPS allowed a faster recovery of both bowel function and tolerance to oral feeding. This translated to a shorter postoperative stay, confirming the results of other comparative studies [2, 12, 22]. Yet it is noteworthy that the LPS patients enjoyed a much faster return to normal physical and social activity. This rapid recovery of normal function could be expected to result in an earlier return to work and a subsequent reduction of social costs.

In conclusion, we would stress that before starting colorectal LPS the surgical team should be well experienced in both open colorectal and other laparoscopic procedures, as well as undergoing specific training at a large animal facility and/or by using training devices. New advances in laparoscopic technology, such as the introduction of the harmonic scalpel, and our ability to concentrate a large number of operations into a relatively short period of time probably allowed us to reduce the surgical volume necessary to acquire good technical skills.

Once the training period is completed, our next step will be to randomize patients in a large trial to evaluate whether laparoscopic surgery is cost-effective.

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