

Laparoscopic versus open sigmoid resection for diverticulitis: long-term results of a prospective, randomized trial

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Received: 19 November 2010 / Accepted: 8 April 2011 / Published online: 10 May 2011
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Abstract

Background Elective laparoscopic sigmoid resection for diverticulitis has proven short-term benefits, but little data are available from prospective randomized trials regarding long-term outcome, quality of life, and functional results.

Methods Of 113 patients randomized to undergo laparoscopic (LAP) versus open (OP) sigmoid resection for diverticulitis, 105 (93%, LAP = 54, OP = 51) patients were examined and answered the Gastrointestinal Quality of Life Index (GIQLI) questionnaire, with a median follow-up of 30 (range, 9–63) months after surgery.

Results Incisional hernias were detected in five (9.8%) patients in the OP group versus seven (12.9%) in the LAP group, $P = 0.84$). Overall satisfaction with the operation on a scale of 0 (very poor) to 10 (excellent) was 9 (range, 2–10) in the OP group versus 9 (range, 2–10) in the LAP group ($P = 0.78$). Median GIQLI score was 115 (range, 57–144) in the OP group versus 110 (range, 61–134) in the LAP group ($P = 0.17$). Overall satisfaction with the cosmetic aspect of the scar on a scale of 0 (very poor) to 10 (excellent) was 8 (range, 1–10) in the OP group versus 9 (range, 0–10) in the LAP group ($P = 0.01$). Finally, median hospital cost (including reoperations for hernias)

was 11,606 (5,230–147,982) CHF in the LAP group versus 12,138 (6,098–39,786) CHF in the OP group ($P = 0.47$).

Conclusions Both open and laparoscopic approaches for sigmoid resection achieve good long-term results in terms of gastrointestinal function, quality of life, and patients' satisfaction. Significant long-term benefits of laparoscopic surgery are restricted to cosmetic (ClinicalTrials.gov protocol #NCT00453830).

Keywords Diverticulitis · Sigmoidectomy · Surgery · Laparoscopy · Randomized trial

During the past 10 years, several nonrandomized studies have demonstrated that laparoscopic resection is a good alternative to open surgery for sigmoid diverticulitis. Short-term benefits associated with a minimally invasive approach for sigmoidectomy include a reduction in post-operative complications, pain, ileus, and hospital stay [1–4]. By comparison, long-term benefits are poorly investigated and of lesser magnitude. A couple of studies reported better cosmetic results, less adhesions, and a reduced risk of incisional hernias [5–7]. However, none of these series have reported the long-term outcome of prospective, randomized trials comparing open and laparoscopic sigmoid resection for diverticulitis. In addition, it remains unclear whether a laparoscopic approach in these patients is associated with increased cost for the hospital and better quality of life for the patients [8, 9].

Therefore, unbiased evidence of long-term benefits is needed to provide additional support for the laparoscopic approach in this indication. We previously undertook a prospective, randomized study to compare outcome of laparoscopic versus open sigmoid resection for diverticulitis with the patient and the nursing staff blinded to the

Presented at the Annual Meeting of the European Society of Coloproctology, Sorrento, September 24, 2010.

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surgical approach [10]. The purpose of the present study was to assess the long-term outcome of these patients in terms of incisional hernias, gastrointestinal function, quality of life (QoL), and global satisfaction with the procedure.

Materials and methods

From January 1, 2005 to February 28, 2009, we conducted a single-center, randomized trial comparing laparoscopic versus conventional open sigmoid colectomy for diverticulitis. The patients and hospital staff were blinded to the procedure for 4 days after surgery to ensure that all patients would receive equivalent postoperative care and that the measurement of short-term clinical outcomes would be unbiased. The protocol was approved by the research ethics committee at Geneva University Hospitals and registered with the United States National Institutes of Health (ClinicalTrials.gov protocol #NCT00453830). Data were analyzed based on the intention-to-treat principle, i.e., patients in whom the procedure was converted from laparoscopic to open surgery were analyzed in the laparoscopic arm of the trial.

Patients and HRQOL assessment

A total of 113 patients who completed the initial protocol were invited by mail to participate in the current follow-up study. A clinical examination was conducted by one of the two surgeons (PG and II) who were involved in their initial operation. Careful assessment of the wounds was performed to detect incisional hernias, and when in doubt, further CT scan imaging was performed. Regarding episodes small bowel obstruction, we reviewed all subsequent admissions in our institution and determined their cause.

In addition all patients were asked to answer the Gastrointestinal Quality of Life Index (GIQLI), which was specifically validated to assess QoL of individuals with gastrointestinal diseases [11]. This is a 36-item questionnaire with five response categories, ranging in score from 0 (the worst) to 4 (the best). Final GIQLI score is calculated by the addition of scores for each question, the most desirable option scoring 4 points and the least desirable option scoring 0 point. Mean GIQLI score for normal individuals is 125 (95% confidence interval 121.5–127.5), and this value was our predefined endpoint for assessing quality of life following sigmoid colectomy [12].

Procedures

Surgical techniques have been previously described in detail [10]. Briefly, patients in both groups were operated by two surgeons who had performed more than 100

laparoscopic sigmoid resections each before operating on trial patients. In the laparoscopic group, a five-trocar technique was used with the operating 10-mm trocar located in the right iliac fossa, and specimen extraction through a suprapubic transverse 6- to 7-cm incision. Conversion was defined as the need to perform part of the procedure through a midline laparotomy, irrespective of the size of the latter. In the open colectomy group, peritoneal cavity was entered through a midline incision, which was extended above the umbilicus; complete mobilization of the splenic flexure was optional and left to the discretion of the surgeon, but was required in most cases to create a tension-free colorectal anastomosis. In both groups, a similar technique for reconstruction was used to perform a double-stapled anastomosis between the descending colon and the upper rectum with 29-mm circular stapler.

Outcome measures

Primary outcome variables of the study were:

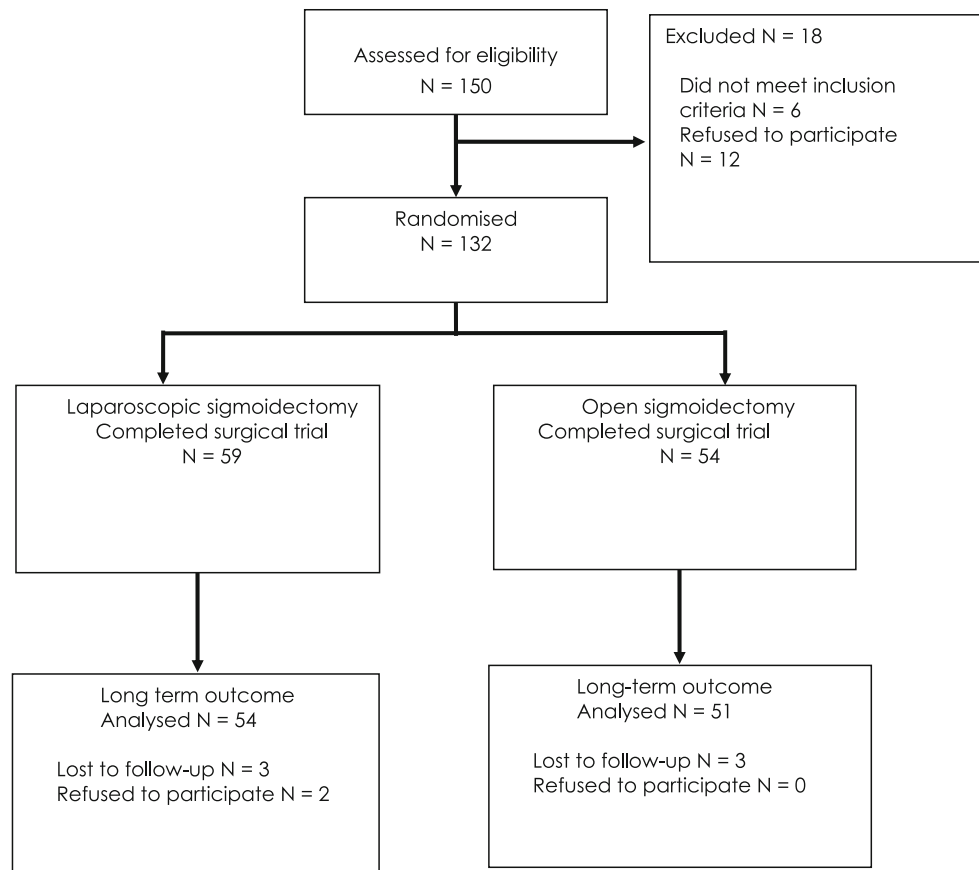
- 1) Overall satisfaction with the procedure, on a scale ranging from 0 (very unhappy) to 10 (completely satisfied).
- 2) Evaluation of the cosmetic result of the operation, on a scale ranging from 0 (very unhappy) to 10 (completely satisfied).
- 3) Functional result of the operation, assessed by the GIQLI questionnaire.

Secondary outcome variables were:

- 1) Reoperation rate for complications, such as bowel obstruction or incisional hernias.
- 2) Recurrent colonic diverticulitis rate.
- 3) Overall costs, including costs related to readmissions and reoperations.

Statistical analysis

To assess the comparability of the two groups, we examined the characteristics of the patients at baseline. To compare overall satisfaction scores and quality of life scores, we performed Mann–Whitney tests. To compare proportions of patients with events, we used cross-tabulation and Fisher exact tests. The analysis was performed on SPSS software, version 15. A *P* value inferior to 0.05 was considered statistically significant. The study was initially powered to detect difference in short-term endpoints, such as 1.0 units in 0–10 Visual Analog Pain Scores (VAS), and a delay of 24 h from surgery to the first passing of stool, with a power of >80% and a type 1 error probability of 5%. In similar patients at our hospital, the standard deviation of postoperative VAS assessments is between 1.5 and 2.0, and

Fig. 1 Flow chart diagram

the standard deviation of stool delay is 36–48 h; therefore, we sought to detect a mean difference of 0.6 standard deviations (effect size). We determined that 2×55 patients would provide the necessary power.

Results

Responders

Of 113 randomized patients, 105 (92.9%) agreed to participate in the follow-up study. There were 54 responders in the LAP group and 51 responders in the OP group. Of 54 patients initially randomized in the LAP group and who responded to the questionnaire, 5 (9.2%) had their sigmoid resection converted to an open procedure. The trial flow diagram is shown in Fig. 1, and patients' characteristics are summarized in Table 1.

Nonresponders

Six patients were lost to follow-up, and two patients refused to answer the questionnaire and to be interviewed, because they did not feel that this was important. Among

Table 1 Patients demographic and clinical characteristics

Variable	Laparoscopic group (n = 54)	Open group (n = 51)
Male/female ratio	24/30	21/30
Median age, year (range)	59 (29–82)	63 (38–84)
ASA grade		
1	9	13
2	41	36
3	4	2
BMI (kg/m ²)	27 (19–35)	26 (20–37)
Conversion to open surgery	5	
Median follow-up, mo (range)	30 (10–63)	29 (9–60)
Incision length, cm (median)	5 (4–30)	18.5 (13–27)
GIQLI score (median, range)	110 (61–134)	115 (57–144)

the eight patients who failed to participate in the follow-up study, seven had undergone uneventful surgery and were not readmitted after the index procedure. One patient had developed a postoperative complication (pneumonia in the OP group) and, therefore, was likely to have a relatively poor satisfaction score.

Readmissions (nonoperated)

Recurrent diverticulitis

Two patients (one in each group) developed recurrent diverticulitis: one in the transverse colon, one in the descending colon. Both episodes were of minor severity and responded quickly to intravenous antibiotics.

Small bowel obstruction

One patient (in the OP group) was readmitted for small bowel obstruction 3 months after surgery. This episode resolved quickly with bowel rest and gastric aspiration. Long-term complications in both groups are detailed in Table 2.

Reoperations

Incisional hernias

Incisional hernias were detected in five (9.8%) patients in the OP group versus seven (12.9%) in the LAP group, $P = 0.84$). Of seven incisional hernias in the LAP group, four occurred in patients who underwent a laparotomy (two for conversion and two for complications). Three hernias occurred in patients who underwent a true laparoscopic approach (including one on the suprapubic incision made

Table 2 Long-term complications

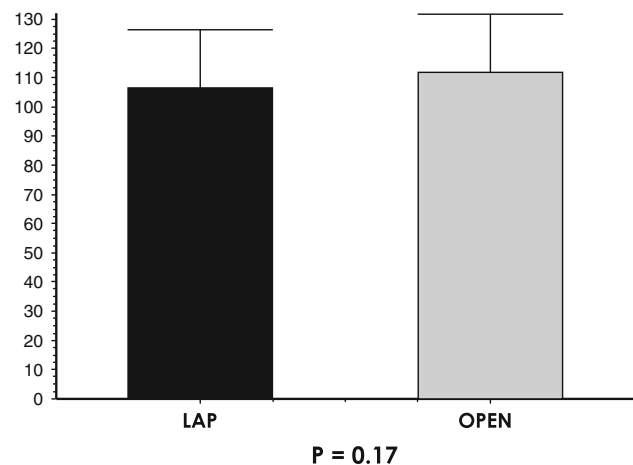
Event	Laparoscopic group ($n = 54$)	Open group ($n = 51$)	P
Recurrent diverticulitis	1	1	
Small bowel obstruction	0	1	
Incisional hernias	7	5	
Total	8 (14.8%)	7 (13.7%)	0.87

Table 3 Incisional hernias

Event	Laparoscopic group ($n = 7$)	Open group ($n = 5$)	P
Midline incision	4 ^a	5	
Suprapubic (specimen extraction)	1		
Supraumbilical trocar (camera)	1		
Right iliac fossa (10 mm)	1		
Total	7 (12.9%)	5 (9.8%)	0.84

^a Two patients underwent conversion to open surgery and two patients underwent explorative laparotomy (one for peritonitis due to small bowel perforation, and one for small bowel obstruction)

a GIQLI SCORES IN THE LAPAROSCOPIC (BLACK) AND OPEN (GREY) GROUPS



b COSMETIC RESULTS IN THE LAPAROSCOPIC (BLACK) AND OPEN (GREY) GROUPS

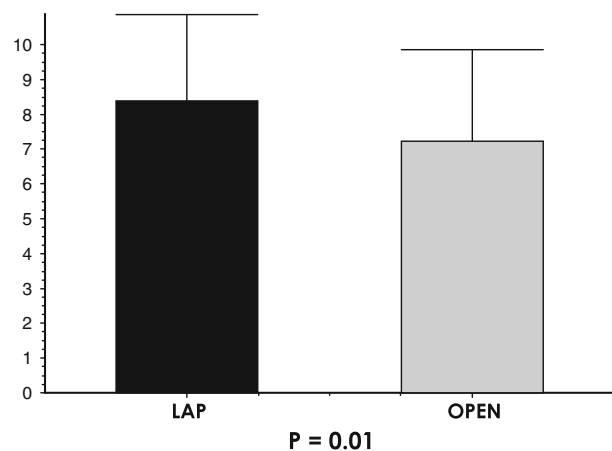


Fig. 2 Comparison of long-term outcomes between groups. **a** GIQLI scores in the laparoscopic (black) and open (grey) groups, **b** cosmetic results in the laparoscopic (black) and open (grey) groups

for specimen extraction). A detailed analysis of incisional hernias in both groups is presented in Table 3.

Long-term outcomes

Quality of life was similar in the two groups: GIQLI scores were 110 (range, 61–134) in the LAP group versus 115 (range, 57–144) in the OP group (Mann-Whitney test, $P = 0.17$). Overall satisfaction with the operation on a scale from 0 (very unhappy) to 10 (completely satisfied) was similar in the two groups (9 [range, 2–10] in the OP group versus 9 [range, 2–10] in the LAP group [$P = 0.78$]). Overall appreciation with the cosmetic aspect of the scar on a scale of 0–10 was 8 (range, 1–10) in the OP group versus 9 (range, 0–10) in the LAP group ($P = 0.012$). Finally, median hospital cost (including reoperations for hernias)

was 11,728 (5,230–147,982) CHF in the LAP group versus 12,537 (6,098–39,786) CHF in the OP group ($P = 0.47$; Fig. 2).

Discussion

We report the long-term outcome of laparoscopic versus open sigmoid colectomy for diverticulitis in a group of 105 patients initially enrolled into a single-site, prospective, randomized trial. In the current study, long-term assessment of outcome was performed according to the intention-to-treat principle and converted patients were analyzed in the laparoscopic group. Both laparoscopic and open approaches achieve similar long-term results in terms of hernias, complications, and quality of life. The benefits of laparoscopy are restricted to cosmetic, and it is fair to say that the magnitude of this benefit is smaller than anticipated.

For years, laparoscopic surgeons have claimed that minimally invasive surgery is associated with a significant reduction in both postoperative adhesions and incisional hernias. However, data from prospective, randomized trials on colorectal cancer [13], as well as systematic reviews from the Cochrane group [14], did not support this view. In the CLASICC trial, 9.2% of patients in the open group and 8.6% of patients in the laparoscopic group developed an incisional hernia. In our study, the relatively high incidence of hernias in the laparoscopic group is due to the high rate of incisional hernias in the converted group of patients (40%). This finding is in accordance with many studies that have shown that the outcome of converted patients is relatively poor [15]. Thus, in this aspect as in many others, the outcome of converted patients has a negative impact on the global results of laparoscopic colorectal surgery.

Most patients were satisfied with the overall results of the procedure and both approaches were associated with similar GIQLI scores: these findings are in accordance with recent series that addressed the functional results of laparoscopic versus open surgery for diverticulitis. Forgiione et al. reported GIQLI scores of 113 and 112 at 3 and 6 months respectively after laparoscopic sigmoid resection for diverticulitis [9]. Thus, overall QoL after this procedure is similar to the general population, and some authors have pointed out that potential improvement in QoL must be considered when discussing the indication for laparoscopic surgery in patients with diverticulitis [16].

Compared with open surgery, laparoscopic resection of the sigmoid colon is associated with better cosmetic results. Again, this finding is hardly surprising and has been repeatedly observed for a variety of colorectal procedures and conditions, such as colorectal cancer [17] and Crohn's disease [18]. Yet, the magnitude of this difference is

smaller than expected, probably because a majority of patients were old and/or overweight and did not consider cosmetic as a primary issue. In this respect, we noted with interest that four of five converted patients (who have, in addition of a midline laparotomy, three port-site incisions) had a score >8 when evaluating the cosmetic aspect of their scars!

Another controversial issue is related to costs; in a subset of Swedish patients enrolled in the COLOR trial, the costs of operation and the costs of first admission were higher in the laparoscopic group [19]. Another cost-benefit analysis from a randomized trial showed that laparoscopy was associated with additional costs related to higher operative room charges (1,100 Euros per patient randomized) [20]. It is interesting to note that total costs for the first admission were similar in Sweden and Switzerland (6,931 Euros and 11,606 Swiss Francs, respectively, in the laparoscopic group). In our series, 2.5 years after surgery, there was no difference in total costs to the institution incurred by laparoscopic and open sigmoid resection. It is possible that a large number of incisional hernias will eventually develop in the open group; in the meantime, however, we conclude that a laparoscopic approach for sigmoid resection has no a significant cost benefits.

We cannot exclude a type II error due to insufficient statistical power to detect long-term benefits of laparoscopic sigmoid resection. However, the fact that the same number of patients was large enough to demonstrate statistically significant short-term benefits of the laparoscopic approach indicates that the long-term advantages of laparoscopic approach (if they exist) are of lesser magnitude than the benefits observed for short-term endpoints, such as pain and resolution of postoperative ileus.

In conclusion, both open and laparoscopic techniques for sigmoid resection achieve excellent long-term results in terms of gastrointestinal function, quality of life, and patient satisfaction. Significant benefits of laparoscopic surgery are cosmetic only. Additional long-term benefits, including a reduction in incisional hernias, adhesions, and small bowel obstruction, are yet to be demonstrated in prospective, randomized trials, when the outcome of converted patients is considered according to the intention-to-treat principle. Beside proven short-term benefits (30% reduction in postoperative ileus), laparoscopic sigmoid colectomy for diverticulitis is associated with similar long-term outcome in terms of gastrointestinal function and quality of life. This approach should be considered the “gold standard” in this indication.

Disclosures Pascal Gervaz and Ihsan Inan have been employed since 2008 as consultants and have received honoraria from Covidien (formerly Tyco Healthcare) for a total sum of 4,000 Euros each per year. Béatrice Mugnier-Konrad, Philippe Morel, and Olivier Huber have no conflicts of interest or financial ties to disclose.

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