Surgical challenges in diverticular disease

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Chapter | 7

Laparoscopic versus open elective sigmoid resection in diverticular disease: six months follow-up of the randomized control Sigma-trial

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Abstract

Background

The short-term results of the Sigma-trial, comparing laparoscopic (LSR) versus open (OSR) elective sigmoid resection for diverticular disease, showed a 15.4% reduction in major complication rates, less pain, and shorter hospitalization at the cost of a longer operating time. Present data complements these results with six months follow-up.

Methods

This was a prospective, multi-center, double-blind, parallel-arm, randomized control trial, eligible patients were randomized to either LSR or OSR. Short-term results of the Sigma-trial have been published previously, methodological and operative details can be found in this original article. Patients attended the outpatient clinic six weeks and six months after surgery. Physical examination was carried out and the quality of life questionnaires were completed. In case of readmission, medical records were prospectively evaluated. Primary endpoints were mortality and late complications occurring between 30 days from surgery until six months postoperative.

Results

From 2002 to 2006, 104 patients were randomized in five centers. All patients underwent the allocated intervention. 52 LSR patients were comparable to 52 OSR patients for gender, age, BMI, ASA grade, comorbid conditions, previous abdominal surgery, and indication for surgery. Conversion rate was 19.2%. LSR was associated with short-term benefits like a 15.4% reduction in major complication rates, less pain, and shorter hospitalization at the cost of a longer operating time. At six months follow up no significant differences in morbidity and mortality rates were found. Two patients died of cardiac causes (overall mortality 3%). Late complications (LSR 7 vs. 12 OSR; $p = .205$) consist of three incisional hernias, five small bowel obstructions, four enterocutaneous fistulas, one intra-abdominal abscess, one retained gauze, two anastomotic strictures and three recurrent episodes of diverticulitis. Nine of these patients underwent additional surgical interventions. Only 30% of ten ostomies were reversed during the follow-up period. The Short Form-36 (SF-36) questionnaire showed significantly better quality of life for LSR at the six weeks follow-up, but at the six moths follow-up these differences were decreased.

Conclusions

No significant differences were found at six months follow-up between LSR and OSR in terms of complications, re-interventions, quality of life or ostomy reversal. When overall morbidity is considered, approaching patients with symptomatic diverticular disease laparoscopically could reduce major morbidity with 27%.

Introduction

Laparoscopic surgery in the treatment of diverticular disease has gained popularity over the last two decades. Particularly in an elective setting laparoscopic sigmoid resections have shown beneficial effects on postoperative outcomes.[1,2] Traditionally, elective open sigmoid resections have been associated with high postoperative complication rates and a mortality rate of two to five percent.[3] Furthermore, new insights in the natural history of diverticular disease showed that once treated conservatively for an uncomplicated episode, recurrent disease will follow a rather mild course.[4,5] Together these two aspects resulted in a more conservative policy in the treatment of diverticular disease.[6]

In contrast, the reported short-term morbidity and mortality rates from laparoscopic resections are substantially lower than the open approach.[1,2,7] Moreover, the incidence of diverticular disease is growing, mainly among younger people.[8] These findings led to revival of the discussion on elective resections for diverticular disease, a more aggressive approach has already been proposed again.[9] Data on late outcomes after laparoscopic versus open sigmoid resections are scarce, but could be of decisive value in this ongoing controversy.

In January 2009 the short-term results of the Sigma-trial were published, comparing laparoscopic (LSR) versus open (OSR) elective sigmoid resections.[10] This prospective, multi-center, randomized control trial has shown a significant 15.4% reduction in major complication rates, less pain, shorter hospitalisation, and improved quality of life at the cost of a longer operating time in the laparoscopic approach. Present data complements these results with outcomes of six months follow-up, in order to compare mid-term effects of LSR and OSR on patients with symptomatic diverticulitis.

Patients and methods

Short-term results of the Sigma-trial regarding perioperative parameters and postoperative recovery up to six weeks after surgery have been published previously. Methodological and operative details can be found in this original article and the earlier published protocol.[10,11]

The Sigma-trial was a prospective, multi-center, double-blind, parallel-arm, randomized control trial. 104 patients with symptomatic diverticulitis of the sigmoid colon were randomized for either open (OSR) or laparoscopic (LSR) sigmoid resection, patients and hospital staff were blinded to the allocation sequence during initial admission. The study was conducted in accordance to the principles of the Declaration of Helsinki and 'good clinical practice' guidelines. The study protocol was approved by the Institutional Review Boards of all participating institutions. Prior to randomization, written informed consent was obtained from all patients.

After discharge patients attended the outpatient clinic six weeks and six months after surgery. Physical examination was carried out and the quality of life questionnaires were completed. In case of readmission, medical records were prospectively evaluated.

Primary endpoints were: 1) mortality defined as death from whatever cause occurring between 30 days postoperative until six months postoperative; 2) late complications after 30 days from surgery until six months postoperative included: incisional hernias, small bowel obstruction, recurrent episodes of diverticulitis, fistula, anastomotic strictures, abscesses and re-operations.

Secondary outcome measures included: 1) quality of life assessment by the Short Form-36 (SF-36) questionnaire measured preoperatively, six weeks and six months after surgery[12]; and 2) restoration of bowel continuity after stoma formation.

Results

A total of 104 consecutive patients who underwent elective surgery for symptomatic diverticulitis of the sigmoid colon were randomized in five centers from February 2002 to December 2006. All patients underwent the allocated intervention. 52 LSR patients were comparable to 52 OSR patients for gender, age, BMI, ASA classification, prevalence

of comorbid conditions, previous abdominal surgery, preoperative workup, and indication for surgery.

Short-term results of the Sigma-trial have been published previously, in summary LSR was associated with a 15.4% reduction in major complication rates, less pain, shorter hospitalisation, and improved quality of life at the cost of a longer operating time.

Table 1 Indications for re-admissions 30 to 180 days

		LSR (n=52)	OSR (n=52)	P
Morbidity 30 to 180 days		7 (13.5%)	12 (23.1%)	.205
	Anastomotic stricture	1 (1.9%)	1 (1.9%)	1
	Enterocutaneous fistula*	2 (3.8%)	2 (3.8%)	1
	Incisional hernia	1 (1.9%)	2 (3.8%)	.558
	Intra-abdominal abscess	1 (1.9%)	0 (0%)	.315
	Recurrent diverticulitis†	1 (1.9%)	2 (3.8%)	.558
	Retained gauze	0 (0%)	1 (1.9%)	.315
	Small bowel obstruction‡	1 (1.9%)	4 (7.7%)	.169

Morbidity are reported per patient. * One OSR patient with enterocutaneous fistula recovered without surgery; † One patient in each arm with recurrent diverticulitis recovered without surgery; ‡ One OSR patients with small bowel obstruction required surgery. LSR = Laparoscopic Sigmoid Resection; OSR = Open Sigmoid Resection. The distribution of dichotomous data were given in percentages. Pearson Chi-square test was used for discrete variables.

There were no significant differences between LSR and OSR in terms of morbidity and mortality at six month postoperatively (see Table 1). Demographics of patients with adverse events during six months follow-up are shown in Table 2. Two patients died in the LSR group during the follow-up period (p = .153), leading to an overall mortality of 3%. Both cardiac deaths occurred in patients with no complications. A total of seven late complications were recorded in the LSR versus 12 in OSR (p = .205), nine of these patients (47%) were finally re-operated (LSR 4 versus OSR 5; p = .727) (see Table 3). All three incisional hernias were repaired, one of five patients with a small bowel obstruction underwent adhesiolysis. One patient with a recurrent episode of perforated diverticulitis

Table 2 Demographics of patients with adverse events postoperative day 30 to 180

		LSR (n=7/52*)	OSR (n=12/52*)	P
Gender Male		3 (42.9%)	3 (25.0%)	.419
Age, years		66 (35 – 75)	69 (41 – 80)	.571
BMI, kg/m^2		27.3 (24.1 – 31.7)	28.5 (23.0 – 39.0)	.409
ASA grade	I	4 (57.1%)	5 (41.7%)	.652
	II	3 (42.9%)	6 (50.0%)	
	III	0 (0.0%)	1 (8.3%)	
Comorbidity		3 (42.9%)	8 (66.7%)	.311
	Cardiac	1	4	
	Crohn's disease	1	0	
	Diabetes mellitus	1	1	
	Hypertension	0	3	
Previous abdominal surgery		5 (71.4%)	10 (83.3%)	.539
Indication for initial sigmoid resection				
	Recurrent diverticulitis	2 (28.6%)	10 (83.3%)	.017
	Sigmoid stricture	5 (71.4%)	2 (16.7%)	.017
Major complications within postoperative day 30		3 (42.9%)	2 (16.7%)	.211
	Anastomotic leakage	2	2	
	Intra-abdominal abscess	1	0	

*7 of 52 patients and 12 of 52 patients randomized to LSR and OSR, respectively. LSR = Laparoscopic Sigmoid Resection; OSR = Open Sigmoid Resection; BMI = Body Mass Index; ASA = American Society of Anesthesiologists. Values were expressed as median and range for continuous variables. The distributions of dichotomous data were given in percentages. Independent Samples T-test was used for continuous variables with normal distribution, otherwise Willcoxon W test was used. Pearson Chi-square test was used for discrete variables.

required a Hartmann's procedure. Three out of four enterocutaneous fistulas were taken down, two with a small bowel resection and one without. Another patient required a re-operation to remove a retained gauze (10 x 10 cm), four months after the initial surgery.

Table 3 Treatment for morbidity 30 to 180 days

		LSR (n=7/52*)	OSR (n=12/52*)	P
Re-operations		4 (57.1%)	5 (41.7%)	.727
	Adhesiolysis	0 (0.0%)	1 (1.9%)	.315
	Enterocutaneous fistula take down	2 (3.8%)	1 (1.9%)	.558
	Hartmann's procedure for perforated diverticulitis	1 (1.9%)	0 (0.0%)	.315
	Incisional hernia repair	1 (1.9%)	2 (3.8%)	.558
	Removal of retained gauze	0 (0.0%)	1 (1.9%)	.315
Endoscopic dilatation of anastomosis		1 (14.3%)	1 (8.3%)	.683
Percutaneous drainage of abscess		1 (14.3%)	0 (0%)	.315
Conservative management		1† (14.3%)	6 (50.0%)	.361

Re-interventions and complications are reported per patient. *7 of 52 patients and 12 of 52 patients who were originally randomized to LSR and OSR; † See footnote in Table 3 for details. LSR = laparoscopic sigmoid resection; OSR = open sigmoid resection. The distribution of dichotomous data were given in percentages. Pearson Chi-square test was used for discrete variables.

In eleven patients an ostomy was created (LSR 6 versus OSR 5; p = .750), three protective ileostomies were created at the initial operation and eight resulted from anastomotic leakages followed by Hartmann's procedure (see Table 4). One of the patients required a Hartmann's procedure despite the fact that a protective ileostomy was already created. In only three out of eleven patients (27%) with a temporary ostomy, bowel continuity was actually restored.

Short-term analysis demonstrated 18 patients with major complications, five of these patients (28%) also had a late complication versus 14 patients (16%) with an uncomplicated short-term course (p = .251). The occurrence of enterocutaneous fistulas was significantly associated with short-term anastomotic leakages or abscesses (17%; p = .002). When overall morbidity is considered (0 to180 days) a significant 27% reduction in major morbidity can be observed (LSR 9 versus OSR 23; p .003) (see Table 5).

SF-36 data are depicted in Figure 1, scale scores of physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy / fatigue,

Table 4 Creation and reversal of ostomies

		LSR (n=6/52*)	OSR (5/52*)	P
Total number of ostomies†		6 (11.5%)	5 (9.6%)	.750
	Hartmann's procedure	5 (9.6%)‡	4 (7.7%)	.727
	Protective loop ileostomy	2 (3.8%)	1 (1.9%)	.558
Reversal of ostomy		2 (33.3%)	1 (20.0%)	.558
	After Hartmann's procedure	1 (16.7%)	1 (20.0%)	1
	After loop ileostomy	1 (16.7%)	0 (0.0%)	.315

* 6 of 52 patients and 5 of 52 patients who were originally randomized to LSR and OSR; † Ten ostomies were created during the initial admission within 30 days after surgery; ‡ One patient with a protective loop ileostomy also required Hartmann's procedure. LSR = Laparoscopic Sigmoid Resection; OSR = Open Sigmoid Resection. The distribution of dichotomous data were given in percentages. Pearson Chi-square test was used for discrete variables.

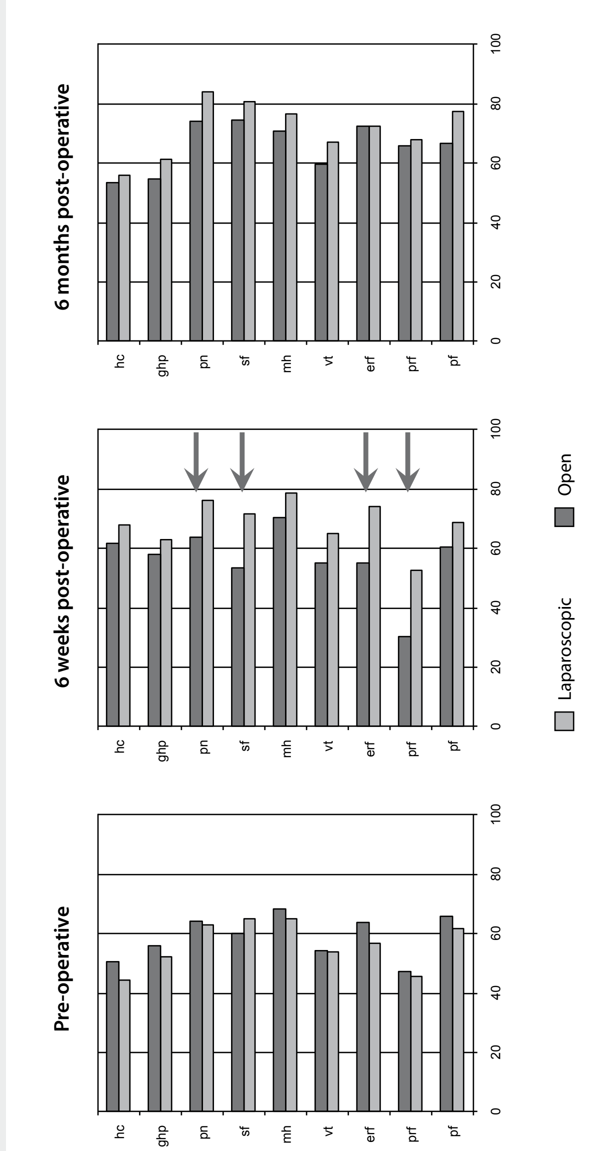
Table 5 Overall morbidity and mortality

	LSR (n=52)	OSR (n=52)	P
Morbidity 0 to 30 days	5 (9.6%)	13 (25.0%)	.038
Morbidity 30 to 180 days	7 (13.5%)	12 (23.1%)	.205
Morbidity 0 to 180 days*	9 (17.3%)	23 (44.2%)	.003
Mortality 0 to 30 days	0 (0.0%)	1 (1.9%)†	.558
Mortality 30 to 180 days	2 (3.8%)‡	0 (0.0%)	.153
Mortality 0 to 180 days	2 (3.8%)	1 (1.9%)	.558

Morbidity and mortality are reported per patient. * Three LSR patients and two OSR patients had more than one complication. † Short-term post-operative mortality caused by myocardial infarction; ‡ Both cardiac deaths occurred in patients with no complications. LSR = Laparoscopic Sigmoid Resection; OSR = Open Sigmoid Resection. The distribution of dichotomous data were given in percentages. Pearson Chi-square test was used for discrete variables.

emotional well-being, social functioning, pain, general health and health change were measured preoperatively, six weeks and six months postoperatively. There were no preoperative inter-group differences. Six weeks postoperative SF-36 data were significantly better in LSR patients for role limitations due to physical and emotional problems, social functioning and pain-level. At the six months follow-up these differences could no longer be demonstrated.

Figure 1 Results of SF-36 questionnaire



Mean scale scores of the SF-36 questionnaires. The arrows indicate significantly different data between LSR and OSR for PRF (p = .039), ERF (p = .024), SF (p = .015) and PN (p = .032). A higher score resembles a better outcome 12. PF = Physical functioning; PRF = Role limitations due to physical health; ERF = Role limitations due to emotional problems; VT = Energy / fatigue; MH = Emotional well-being; SF = Social functioning; PN = Pain; GHP = General health; HC = Health change.

Discussion

The published short-term data of the Sigma-trial has shown a reduction in major complication rates, less pain, shorter hospitalisation, and improved quality of life at the cost of a longer operating time after the laparoscopic approach.[10] Present data includes the six month follow-up for LSR and OSR patients. No differences were found in late complications, such as incisional hernias, anastomotic strictures, enterocutaneous fistulas, small bowel obstruction due to adhesions or recurrent episodes of diverticulitis, neither in their surgical treatment. The improved quality of life six weeks postoperative returned to baseline values six month after surgery.

These mid-term results describe a follow-up period of six months as stated in the Sigma-trial protocol.[11] Some complications and recurrent episodes of diverticulitis might occur later than six month postoperative, therefore a long-term evaluation will be performed at the proper time. Late complications yet to be expected, might be related to the approach (incisional hernias or intestinal obstruction), the operative technique (anastomotic stenosis) or the disease itself (recurrence). Retrospective data on these long-term outcomes are rare and no other randomized control trials on elective surgery for diverticular disease have been reported.

In this study ten ostomies were created, three as protective ileostomy at the initial operation and eight resulted from anastomotic leakage after Hartmann's procedure. One patient still had a clinically important anastomotic leakage, despite the fact that a protective ileostomy was created. Remarkably, only three (30%) of these temporary ostomies were closed. This number seems low compared to the 90% reversal after Hartmann's procedure presented by Oomen et al., other series present reversal rates of 31% to 85%.[13] The main difference is that the eight Hartmann's procedures in this study all follow anastomotic leakages and not a primary peritonitis in the case of Hinchey stage III and IV diverticulitis. It might be that such a severely complicated course makes the patients to be more apprehensive to undergo another elective procedure.

The quality of life assessment showed significant improved role limitations due to physical health, role limitations due to emotional problems, social functioning and pain at six weeks after surgery. When analysing this questionnaire at six months follow-up, no significant advantages of LSR are seen. This might be explained by the substantial drop in response rate, 27% of patients did not complete the six months questionnaire. The short-term improvements in several aspects of the quality of life assessment are in concordance with the reduced complication rate and shorter hospital stay. After six months these inconveniences seem to be dissolved, which might be linked to a similar long-term complication risk in both groups.

As demonstrated, patients having short-term complications do not have a higher risk on late complications, although enterocutaneous fistulas usually follow short-term abscesses or anastomotic leakages. On the other hand, pooling of short-term major morbidity and late complications result in a significant 27% reduction of major morbidity in favour of the laparoscopic approach.

In conclusion, the laparoscopic approach offers short-term advantages over the open approach for elective sigmoid resections for diverticular disease. Comparable outcomes were found at six months follow-up in terms of late complications, mortality and quality of life. LSR should be preferred over OSR for patients presenting with symptomatic diverticular disease of the sigmoid colon, because a 27% reduction in overall major morbidity could be achieved.

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