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LONG-TERM OUTCOMES FOLLOWING LAPAROSCOPICALLY ASSISTED VERSUS OPEN ILEOCOLIC RESECTION FOR CROHN'S DISEASE

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Abstract

Background

Long-term results of laparoscopically assisted versus open ileocolic resection for Crohn's disease were evaluated in a randomized trial.

Methods

Sixty patients who underwent ileocolic resection between 1999 and 2003 were followed prospectively. Primary outcomes were reoperation, readmission and repeat resection rates for recurrent Crohn's disease. Secondary outcomes were quality of life, body image and cosmesis.

Results

Five patients were lost to follow-up. Median follow-up was 6.7 (interquartile range 5.7–7.9) years. Sixteen of 29 and 16 of 26 patients remained relapse free after ileocolic resection in the laparoscopic and open groups respectively (risk difference 6% (95% confidence interval −20 to 32)). Resection of recurrent Crohn's disease was necessary in two of 29 versus three of 26 patients (risk difference 5% (95% confidence interval −11 to 20)). Overall reoperation rates for recurrent Crohn's disease, incisional hernia and adhesion-related problems were two of 29 versus six of 26 (risk difference 16% (95% confidence interval −3 to 35)). QOL was similar, whereas body image and cosmesis scores were significantly higher after laparoscopy (p = 0.029 and p < 0.001 respectively).

Conclusions

Laparoscopically assisted ileocolic resection results in better body image and cosmesis, whereas open surgery is more likely to produce incisional hernia and obstruction.

6

INTRODUCTION

Crohn's disease (CD) is an idiopathic chronic inflammatory bowel disorder characterized by relapsing transmural inflammation of the gastrointestinal mucosa [1]. It can affect the entire gut from mouth to anus, but in half of patients disease activity is confined to the terminal ileum.

Disease activity located at the terminal ileum that is refractory to medical treatment is best treated by means of an ileocolic resection. This can be performed laparoscopically or by an open approach. Several studies, including two randomized trials [2,3] have compared these two approaches with regard to short-term outcomes. Four systematic reviews analysing all available publications describing the short-term results concluded that laparoscopic ileocolic resection is feasible and safe. It is associated with a shorter hospital stay, shorter duration of ileus and similar morbidity rates compared with an open approach, and conversion rates are acceptable [4-7]. It should be noted that all these comparative studies on the short-term differences were in the setting of traditional perioperative care pathways [8].

As CD is a chronic relapsing condition characterized by exacerbations and remissions, long-term results are probably of greater interest than short-term outcomes. Data on the long-term comparison of laparoscopic versus open ileocolic resection with regard to disease recurrence, readmission and reoperation rates, and quality of life (QOL) are scarce. Suggested long-term benefits after a laparoscopic approach are a lower incidence of incisional hernia and adhesive small bowel obstruction (SBO). Additionally, a higher level of satisfaction with the cosmetic result is also to be expected as a long-term benefit of the laparoscopic approach, especially as patients with CD are generally young.

The objective of the present study was to compare long-term clinical outcome and QOL in a randomized cohort of patients who underwent open or laparoscopically assisted ileocolic resection for CD.

PATIENTS AND METHODS

Patients

A series of 60 randomized patients with refractory CD who underwent an ileocolic resection in a previously randomized multicentre trial were evaluated prospectively [2]. Inclusion criteria were CD scheduled for an elective procedure and age above 16 years. Exclusion criteria were a fixed palpable inflammatory mass prior to surgery, prior median laparotomy, earlier bowel resection or pregnancy. Operations took place between September 1999 and November 2003. Short-term perioperative results and post-operative recovery up to 3 months after surgery have been reported previously [2]. Methodological and operative details can be found in the same article.

Follow-up procedure

Medical records of all 60 patients were evaluated prospectively, focusing on disease recurrence, incisional hernia and adhesive complaints requiring additional therapy from 3 months after surgery until the end of the study period. The end of this long-term study was set at September 15 2008. On this day, QOL, body image, and cosmesis were assessed by means of a postal survey. Patients received questionnaires at home accompanied

by a stamped addressed return envelope. After completing the postal survey, all patients were invited to the outpatient department to verify the findings from the medical files and to rule out any treatment in other hospitals. Physical examination was performed to exclude the presence of incisional hernia and to measure the length of the incisional scar. Patients who were unable to attend were contacted by telephone; they were asked to measure the length of the incisional scar and asked whether recorded findings were correct.

Only patients with complete follow-up were considered eligible for analysis of the clinical outcome parameters. Those who did not have up-to-date medical files at the end of the study period (last contact with the hospital between 15 March and 15 September 2008) and/or did not attend the outpatient visit or were not successfully contacted by telephone were considered lost to follow-up.

Direct post-operative care was similar in the two groups [2]. The type and frequency of follow-up was performed following the Dutch treatment consensus on CD and was therefore similar at all three study sites and between the treatment groups. This follow-up was not, however, described in the protocol.

Outcome parameters

Primary outcome measures were the number of patients with intestinal disease recurrence requiring reoperation, number of patients requiring reoperation for incisional hernia or SBO owing to adhesions, and number of patients requiring non-surgical treatment for recurrent CD. Diagnosis of disease recurrence was based on history, physical examination, laboratory tests, and endoscopic and radiologic findings. In patients who needed a repeat resection, disease recurrence was also confirmed by pathological examination. The decision to admit or treat a patient at the outpatient department was at the discretion of the attending gastroenterologist.

Secondary outcome measures were QOL assessed by means of the Short-Form 36 (SF-36®; Medical Outcomes Trust, Waltham, Massachusetts, USA) [9] and Gastrointestinal Quality of Life Index (GIQLI) [10], and body image and cosmesis as measured by the Body Image Questionnaire (BIQ) [11]. These are all validated questionnaires. SF-36® QOL data for all patients with CD were also compared with data from a Dutch healthy control database, matched in a 1:1 ratio for age and sex. The data in this database are subdivided in age decades.

The BIQ includes body image and cosmesis scales. The body image scale ranges from 5 (worst) to 25 (best) and is used to rate the patients' perception of, and satisfaction with, the appearance of their own body. The cosmetic scale (ranging from 3 to 24, with higher score indicating greater satisfaction) represents the satisfaction with the cosmetic result of the scar. To evaluate the degree of satisfaction, a Photoseries Questionnaire (PSQ) was also used. First, patients had to grade their own scars on a scale from 1 to 10 (higher score indicating greater satisfaction). Next, they had to grade two pictures of scars in patients who underwent the alternative approach. These images were the most representative of each approach, one of a male and one of a female abdomen for each approach. They were included in the postal survey in a sealed envelope, with instructions not to open the envelope until arrival at this question. After seeing the result of the alternative approach, patients were asked to grade their own incisional scars once more. Finally, they were asked which approach they would have preferred and whether they would be willing to spend extra money to receive a laparoscopic approach.

Statistical analysis

All patients were analysed according to the intention-to-treat principle. Sample size was calculated for the short-term outcomes and has been described previously[2]. To give a quantitative impression of the size of the treatment effect, the analysis of clinical outcomes (readmission, further resection and reoperation rates) was performed by calculating the risk difference with 95% confidence interval. Differences between questionnaire scores were analysed by means of the parametric Student's t-test or with the non-parametric Mann-Whitney U test, if data were skewed. To test for within-group differences, the non-parametric Wilcoxon's signed-rank test was used. The chi-squared test or Fisher's exact test was used to compare proportions. Kaplan-Meier curves were constructed for survival without repeat resection or reoperation, with differences analysed by means of the log rank test. To correct for multiple testing, the Bonferroni correction was used to adjust the QOL analyses; $p < 0.010$ was considered statistically significant for GIQLI data and $p < 0.005$ for SF-36® data. For all other tests, $p < 0.050$ indicated statistical significance. Statistical analysis was performed by using SPSS® software version 15.0 (SPSS, Chicago, Illinois, USA).

TABLE 1: CHARACTERISTICS OF 55 PATIENTS AVAILABLE FOR CLINICAL OUTCOME ANALYSIS

	Open (n=26)		Laparoscopic (n=29)	
Sex ratio (M:F)	9:17		12:17	
Age at time of follow-up (years)*	38.9	(29.4-46.6)	34.8	(29.0-41.2)
Length of follow-up (years)*	6.5	(5.8-7.9)	6.8	(5.6-7.8)
Body Mass Index (kg/m2)*	24.3	(22.0-26.4)	23.9	(22.8-26.6)
Smoker	9	(35%)	9	(31%)
Length of resected bowel (cm)*	23.0	(16.8-37.5)	28.3	(21.5-37.8)
Additional procedures at first resection†	9	(35%)	13	(45%)

Type of anastomosis
    Side-side
    Side-end or end-side
    End-end
	4
	20
	2
			8
			18
			3	

* Values are presented as median (interquartile range); †Fistula, adhesolysis, extra resection

RESULTS

Of the 60 patients who participated in the trial, five were lost to follow-up owing to an incomplete medical file or unknown current address. A total of 55 patients (92%) was therefore available for analysis of the primary outcome parameters. There were 21 men and 34 women with a median age of 35.2 (inter quartile range (IQR) 29.5 - 42.0) years and median follow-up of 6.7 (IQR 5.7 - 7.9) years. Fifty-three patients (88%), 20 men and 33 women, completed and returned the questionnaires on QOL, body image and cosmesis. Their median age was 35.2 (IQR 29.6 - 42.7) years and median length of follow-up was 6.7 (IQR 5.7 - 7.8) years.

Clinical outcome

Details on the short term outcomes up to 3 months post-operatively have been published previously [2]. Among 55 patients available for analysis of long-term clinical outcomes, baseline characteristics were similar after a laparoscopic or open approach (Table 1). Forty-one patients (75%) attended the outpatient department for verification of the findings of the medical files, 17 who had an open procedure and 24 a laparoscopic operation. The remaining 14 patients were contacted by telephone.

Thirty-two patients had no disease recurrence, of whom 23 were not receiving prophylactic therapy, six were taking azathioprine or methotrexate, two were on 5-aminosalycates and one was on prednisone for gestational herpes.

Crohn's symptoms recurred in the remaining 23 patients (Table 2). Three patients from the open group and two from the laparoscopic group needed a further resection at or near the anastomosis. A survival curve of the period free from further resection showed no difference between an open or laparoscopic operation (Figure 1a).

TABLE 2: INTESTINAL DISEASE RECURRENCE FOR 55 PATIENTS WITH COMPLETE FOLLOW-UP

	Open N=26 (%)	Laparoscopic N=29 (%)	Risk difference (95% C.I.)
No clinical recurrence	16 (62)	16 (55)	6.4% (-0.20 to 0.32)
Clinical recurrence	10 (38)	13 (45)	6.4% (-0.32 to 0.20)
Managed at outpatient department	6 (23)	8 (28)	4.5% (-0.18 to 0.28)
- anti-TNF	3	3	
- steroids (prednisone / budesonide)	2	3	
- trial medication	1	1	
- endoscopic balloon dilatation	0	1	
Managed during hospital readmission:			
No further resection	1 (4)	3 (10)	6.5% (-0.07 to 0.20)
- anti-TNF	0	2	
- prednisone	1	0	
- trial medication	0	1	
Resection of neoterminal ileum	3 (12)	2 (7)	4.6% (-0.11 to 0.20)

C.I. = confidence interval; TNF = tumor necrosis factor

TABLE 3: OVERALL REOPERATION RATE FOR 55 PATIENTS WITH COMPLETE FOLLOW-UP

	Open (n=26)	Laparoscopic (n=29)	Risk difference (95% C.I.)
Incisional hernia requiring surgery	2 (8)	0	7.7% (-0.026 to 0.18)
Adhesions requiring surgery	1 (4)	0	3.9% (-0.036 to 0.11)
Intestinal recurrence requiring resection	3 (12)	2 (7)	4.6% (-0.11 to 0.20)
Overall number reoperated	6 (23)	2 (7)	16% (-0.025 to 0.35)

C.I. = confidence interval

FIGURE 1A: RE-RESECTION-FREE SURVIVAL
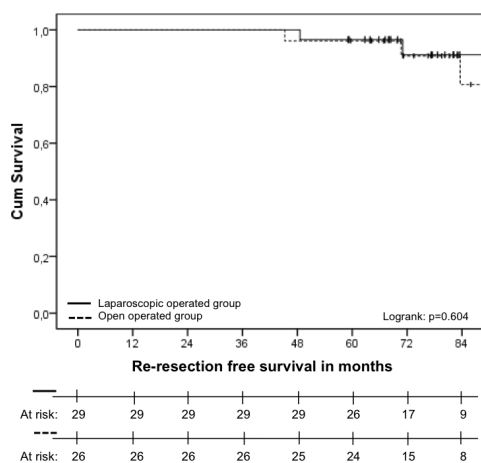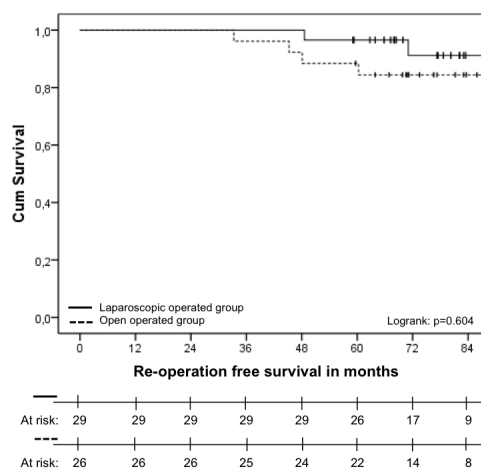

FIGURE 1B: RE-OPERATION-FREE SURVIVAL

There was no significant difference in the overall reoperation rate for disease recurrence, incisional hernia and adhesional obstruction after open and laparoscopic ileocolic resection (six of 26 versus two of 29 respectively) (Table 3). Figure 1b shows the survival curve for reoperation-free survival.

Quality of life, body image and cosmesis

QOL assessed by the SF-36® was similar in the two groups on all eight subscales and the physical and mental component scale (data not shown). To put the QOL of patients with CD into general perspective, the QOL scores of the two groups were combined and compared with data for healthy individuals matched by age and sex. The mental health score was significantly better in the patient group (p = 0.002), whereas scores for vitality and general health perception, and the physical component score were significantly better in the healthy control group (p = 0.004; p < 0.001 and p = 0.001 respectively). There were no significant differences in the remaining subscale scores between the groups. Results of the GIQLI, which measures intestine-specific QOL, did not differ after open or laparoscopically assisted operation (data not shown).

Body image and cosmesis scale scores of the BIQ were significantly higher in the laparoscopic group, reflecting a more positive perception and attitude of patients towards their bodily appearance and a higher satisfaction with the cosmetic result. Median (IQR) score on the body image scale was 18.0 (16.0-19.0) in the open group versus 19.0 (17.0-20.0) in the laparoscopic group (p = 0.029). Median scores on the cosmesis scale were 14.0 (9.5-19.0) and 22.0 (17.0 -24.0) respectively (p < 0.001). In the PSQ, patients in the laparoscopic group graded their scars significantly more favourably than those in the open group (Table 4). After seeing the alternative approach, the open group gave their own scars a significantly lower grade than before seeing the pictures of the laparoscopic approach. The laparoscopic approach would have been preferred by 64% of the open operated patients, whereas only one patient from the laparoscopic group would have preferred an open approach. Fifty-six % of the patients who answered this question would be willing to spend money to have a laparoscopic procedure.

TABLE 4: RESULTS OF THE PHOTOSERIES QUESTIONNAIRE

	Open (n=25)	Laparoscopic (n=28)	P*
Rating of own scars before seeing pictures			
Median (IQR)	6.0 (4.3 - 8.0)	9.0 (7.0 - 10.0)	< 0.001
Mean	5.8	8.5	
Rating of pictures of other approach			
Median (IQR)	8.3 (7.5 - 9.4)	5.1 (4.5 - 6.5)	< 0.001
Mean	8.3	5.3	
Rating of own scars after seeing pictures of other approach			
Median (IQR)	5.0 (2.0 - 7.0)	9.0 (8.0 - 10.0)	< 0.001
Mean	4.8	8.6	
Mean difference (after - before)	-1.0†	+0.1‡	
Preference for specific approach			
Open	2 (8)	1 (4)	
Laparoscopic	16 (64)	23 (82)	
No preference	6 (24)	2 (7)	
No response	1 (4)	2 (7)	
Would personally pay additional fee to undergo laparoscopy			
Nothing	15 (60)	7 (25)	
€0-1000	6 (24)	12 (43)	
> €1000	3 (12)	7 (25)	
No response	1 (4)	2 (7)	

* Mann-Whitney U test. † P = 0.005, ‡ P = 0.465 (Wilcoxon rank test)

6

DISCUSSION

There were no differences in rates of recurrence and repeat resection after an open or a laparoscopically assisted ileocolic resection for CD but, as the wide confidence intervals indicate, there may have been a type II error owing to the small sample size. The sample size of the trial was intended to compare short-term outcomes, and is likely to be insufficient for this study of the long-term effects.

Only one other randomized trial has investigated long-term follow-up after laparoscopic versus open ileocolic resection for CD, with a follow-up of 10 years [12]. One non-randomized patient series, with a follow-up of 8 years, has been published by our group [13]. These studies support the conclusions that rates of recurrence and repeat resection after a laparoscopically assisted ileocolic resection for CD are not different from those after open resection.

In the present study, 58% of all patients remained relapse free after a median follow-up of 6.7 years. This low relapse rate shows that ileocolic resection is an effective treatment for steroid-refractory CD located in the terminal ileum. In the two other available studies, the rate of further resection was higher, at 23% [13] and 29% [12]. However, those studies were conducted when infliximab and adalimumab were not available, and follow-up periods were longer.

Incisional hernia and SBO were uncommon and occurred only in the open group, in accordance with two other studies [12,13]. With regard to incisional hernia, both studies reported a higher reoperation rate for incisional hernia repair in the open groups, although these differences did not reach statistical significance. Duepree et al. [14] investigated the incidence of adhesive SBO and ventral hernia of 716 patients who underwent open or laparoscopic bowel resection for different conditions, including inflammatory bowel disease, and found a significantly higher incidence of post-operative hernia after an open approach. A large study on long-term advantages of the laparoscopic approach in rectal cancer also noted a significantly higher incidence of incisional hernia after an open total mesorectal excision than a laparoscopic procedure [15].

This study provided objective confirmation that a smaller scar leads to better body image and greater satisfaction with the cosmetic result from the patients' perspective. Laparoscopic surgery not only appears to lead to more satisfaction with the operative area, but also influenced the general perception of bodily appearance. Improvement or maintenance of body image and cosmesis are often mentioned only as additional benefits, of secondary importance to operative outcomes such as accelerated post-operative recovery and shorter hospital stay. For patients, however, these 'additional' advantages are long-lasting and important, and may be even more important than the commonly addressed short-term outcomes.

QOL was similar after a laparoscopic or open approach. However, it was significantly worse on three physical subscales in patients with CD than in a Dutch healthy control group matched for age and sex. Remarkably, patients with CD had better scores on the mental health subscale. The finding that patients with CD and healthy controls had similar QOL scores on several subscales is not in accordance with a previous retrospective study, in which QOL in those with CD was significantly poorer on all subscales [13]. The lower relapse rate among patients who participated in the present trial might have contributed to this discrepancy as having frequent relapses significantly impairs QOL [16].

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6