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Ten-year outcome after minilaparotomy versus laparoscopic cholecystectomy: a prospective randomised trial

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Abstract
Background Laparoscopic cholecystectomy (LC) and minilaparotomy cholecystectomy (MC) are the two most commonly performed mini-invasive surgical techniques for the treatment of symptomatic gallstone disease, but the long-term outcome after these two procedures has not been compared in prospective clinical trials. We therefore investigated the outcome after LC and MC in 127 patients operated at Kuopio University Hospital.
Patients and methods Initially 157 patients with uncomplicated symptomatic gallstones were randomised to MC ($n = 85$) or LC ($n = 72$) over a 5-year period (1998–2004), and 127 of them (81 %), 69/85 with MC and 58/72 with LC, were reached for a follow-up interview 10.5 (7.3–13.6) years after the surgery.
Results Baseline and surgical parameters were similar in the two groups; 3/69 MCs and 2/58 LCs were converted to open laparotomy. The prevalence of chronic post-surgical pain 10 years after procedure was similar in the two groups: 5/69 (7 %) in the MC group and 1/58 (2 %) in the LC group ($p = 0.14$). Residual abdominal symptoms were common, but less frequent in the MC group (14/69; 20 %) than in the LC group (21/58 patients; 36 %) ($p = 0.039$). In the MC group 63/69 (91 %) and 57/58 (98 %) in the LC group ($p = 0.059$) were satisfied with the cosmetic outcome.
Conclusion Our results suggest a relatively similar long-term outcome after MC and LC.

Keywords Cholecystectomy · Laparoscopy · Minilaparotomy · Treatment outcome · Postcholecystectomy syndrome · Randomised controlled trial

Laparoscopic cholecystectomy (LC) was introduced in 1985, when Mühe performed the first cholecystectomy by laparoscope [1]. Since then LC has become the gold standard for surgical treatment of non-complicated cholelithiasis and replaced open cholecystectomy (OC) during the past 15 years in elective biliary surgery [2]. Tyagi et al. [3] introduced in 1994 a minimally invasive technique for OC, and this minilaparotomy cholecystectomy (MC) has recently challenged the role of LC [4–8].

The short-term outcome after LC and MC procedures in several trials [8–13] indicates that both could be feasible techniques for elective cholecystectomy. However, the long-term outcome, residual abdominal pain and cosmetic satisfaction after MC have not been reported. We therefore conducted the present study with the aim of investigating the long-term outcome after LC and MC in 127 patients operated at Kuopio University Hospital.

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Patients and methods

The study was approved by the Research Ethics Committee of the Hospital District of Northern Savo, Kuopio, Finland and was conducted in accordance with the Declaration of Helsinki. Participants gave written consent after receiving verbal and written information. All operations were carried out in the Department of Surgery at Kuopio University Hospital.

The study design was an open, prospective, randomised clinical trial with two parallel groups [5]. In the original study, altogether 157 patients with uncomplicated symptomatic cholelithiasis confirmed by ultrasound were randomised to undergo cholecystectomy with LC (72 patients) or with MC (85 patients). The operations were performed between 3 February 1998 and 26 April 2004.

Standardised surgical techniques were used in both groups. The LC procedure was performed using the four-trocar technique (two 10-mm and two 5-mm trocars). A 12-mmHg pneumoperitoneum (CO_2) was created using a Veress needle. For the MC procedure, the incision was made as described by Tyagi et al. [3]. No cholangiography was performed in either group. Endotracheal anaesthesia and postoperative care were standardised and similar in the two groups. There were five converted procedures: three in the LC group and two in the MC group.

A telephone interview with a questionnaire with closed-ended questions was conducted between August and October 2011. The author (S.A.) who carried out all interviews had not participated in the primary operation or treatment of any of the study patients and was blinded to the operative technique used in cholecystectomy. Altogether 69/85 patients (81 %) in the MC group and 61/72 patients (85 %) in the LC group were reached by telephone. One patient in the LC group declined the telephone interview, and two patients in the LC group had severe Alzheimer disease and were unable to answer the questions. Three patients in each group had died for disease unrelated to gallstones or the operation during the follow-up period. The flowchart of the study is presented in Fig. 1.

In a structured interview the patients were asked whether they have similar abdominal symptoms, or right upper quadrant pain, as they had before cholecystectomy, whether they have diarrhoea, loose stools or reflux symptoms, whether they had to avoid fatty or fried food, or whether they had pain or other symptoms in the incision area/port sites. Regarding satisfaction with the surgery, the patients were asked whether the operation had had any impact on their quality of life (QoL), if they were satisfied with the cosmetic outcome and the satisfaction with the surgery in general. The patients were asked to answer the question on a five-point Likert scale.

Statistics

Data were entered and analyzed using a statistical software program (IBM SPSS Statistics 19; IBM, Somers, USA). The results are presented as median, minimum and maximum, mean and standard deviation, or as the number of patients when appropriate. Because the data were not

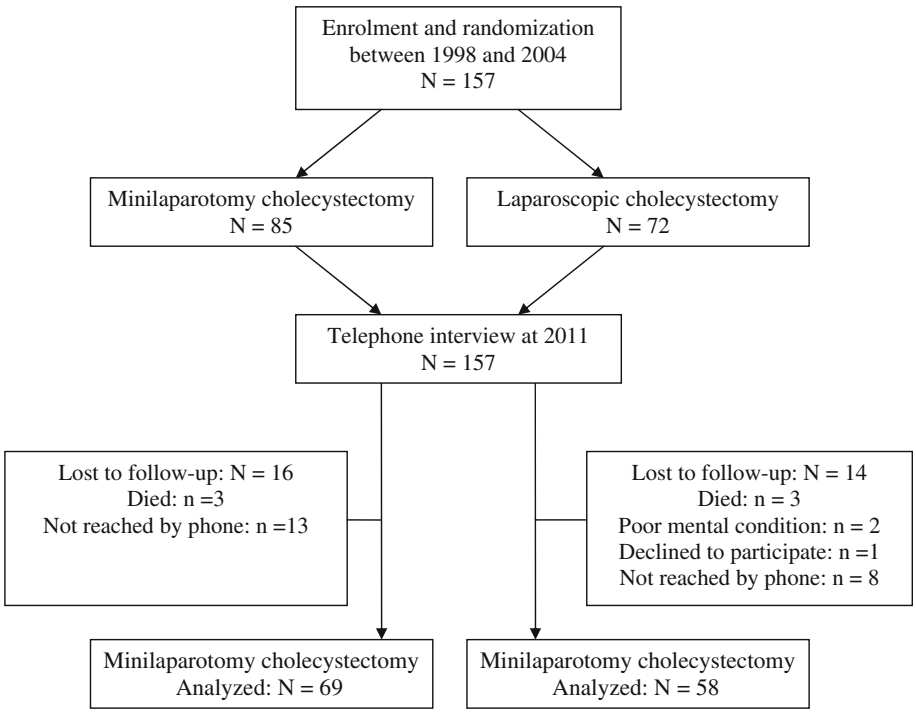

Fig. 1 Flowchart

normally distributed, the Mann–Whitney *U*-test was used to compare ordinal and continuous data. For categorical data, the chi-square test was applied to compare the outcome after the two surgical techniques. For the main outcome results, 95 % confidence intervals (CI) were calculated. A two-sided *p*-value less than 0.05 was considered statistically significant.

Results

Altogether data from 69/85 patients (81 %) in the MC group and 58/72 patients (81 %) in the LC group were analyzed. The demographic characteristics and the follow-up time were similar in the two groups (Table 1).

The outcomes of the patients are presented in Table 2. At the follow-up interview, the patients in the LC group reported significantly more residual abdominal symptoms, similar to those which were considered to be caused by gallstones preoperatively (21/58 patients, 36 %), than the patients in the MC group (residual abdominal symptoms, 14/69, 20 %) (difference 16; 96 % CI for difference: 0–32 %; $p = 0.039$). Twelve patients in both groups reported to still have right upper abdominal pain attacks ($p = 0.57$). One woman in the LC group and five women in the MC group reported pain at the operation sites ($p = 0.14$). Most had just mild pain, but one woman in the MC group had moderate chronic post-surgical pain (CPSP). A post hoc analysis showed that neither patient characteristics (age, weight, height) nor early postoperative pain or need for analgesics during the early recovery at hospital had impact on the risk of developing CPSP. None of the 25 male patients versus 6 out of the 102 women had CPSP ($p = 0.21$). The mean of most pain after surgery had been 5 (range 3–6) in the patients with CPSP versus 5 (0–10) ($p = 0.66$) in those with no residual pain, and the need for oxycodone for rescue analgesia during the first 24 h after surgery had also been similar: 14 (0–25) mg versus 15 (0–56) mg ($p = 0.68$), respectively. Four women with CPSP versus 87 with no residual pain ($p = 0.78$) were obese, i.e., had body mass index (BMI) higher than 30 kg/m^2.

Most patients were satisfied with the cosmetic results; only three patients in the MC group were dissatisfied ($p = 0.19$). All five patients (three in the LC group, two in the MC group) for whom the operation was converted to conventional open surgery were satisfied with the cosmetic results. One patient in the MC group developed a postoperative 'scar hernia' and underwent herniotomy, but she also was satisfied with the cosmetic result.

Most patients in the LC group (56/58) would recommend the operation for others, whereas 7 out of 69 in the MC group patients were unsure, and two would not recommend the operation for others ($p = 0.13$).

Fifty-five patients (95 %) with LC and 62 patients (90 %) with MC reported improved QoL after the surgery; the two patients with worse self-rated QoL were in the LC group ($p = 0.05$).

Table 1 Baseline demographic characteristics of the study groups at the time when operations were done

Variable	Minilaparotomy $n = 69$	Laparoscopy $n = 58$	p value
Sex: male/female	16/53	9/49	0.28
Age (years)	48 (17–78)	50 (17–76)	0.75
Weight (kg)	75 (51–127)	72 (44–105)	0.39
Height (m)	165 (154–187)	165 (151–192)	0.17
BMI (kg/m^2)	27.0 (18.3–48.4)	26.4 (18.6–35.9)	0.84
ASA 1/2/3	35/29/5	32/20/6	0.63

Data are median (range) or number of cases

BMI body mass index, *ASA* American Society of Anaesthesiologists score

Table 2 The main outcome measures in the two study groups

Variable	Minilaparotomy $n = 69$	Laparoscopy $n = 58$	p value
Residual abdominal symptoms: yes/no/could not say	14/55/–	21/36/1	0.039
Right upper quadrant pain attacks: yes/no/could not say	12/57/–	12/44/2	0.57
Chronic post-surgical pain: yes/no	5/64	1/57	0.14
Reflux symptoms: less/not changed/more	34/31/4	23/29/6	0.44
Diarrhoea or loose stools: less/not changed/more	6/56/7	7/44/7	0.57
Avoid fatty/fried food: yes/no/could not say	29/40/–	30/27/1	0.24
Satisfaction with cosmetic outcome: satisfied/dissatisfied/could not say	63/3/3	57/–/1	0.19
Overall satisfaction with the procedure: satisfied/dissatisfied	67/2	56/2	0.86
Quality of life: better/not changed/worse	62/7/–	55/1/2	0.05
Would you recommend the procedure to others: yes/no/could not say	60/2/7	56/1/1	0.13

Data are number of cases

In the LC group 23 patients (40 %) and in the MC group 34 patients (49 %) reported less reflux symptoms, but 6 patients in the LC group and four patients in the MC group reported more reflux symptoms than they had before the operation ($p = 0.44$).

Seven patients in both groups had more, and seven patients in the LC group and six in the MC group had less diarrhoea than before the surgery ($p = 0.57$).

In order to control the symptoms, 23 patients (40 %) in the LC group and 24 patients (35 %) in the MC group had avoided fatty and fried food after the surgery ($p = 0.24$).

Most patients were very satisfied with the operation, but two patients in both groups were unsatisfied ($p = 0.86$).

Discussion

Only a few studies have reported the long-term prevalence of chronic post-surgical pain (CPSP). In the present 10-year follow-up study, there were six patients (5 %, 6/121) with CPSP. The correct diagnosis of cholecystolithiasis and indication for cholecystectomy are highly important. Our results indicate, in accordance with some previous studies, that residual abdominal symptoms are common even 10 years after cholecystectomy.

Purkayastha et al. [7] reviewed randomised trials published between 1992 and 2005, and nine studies cited in the literature of elective LC versus MC for symptomatic gallstone disease were included. The major limitation of the report lies in the accurate definition of 'MC' used by the studies in the meta-analysis. Lengths of the MC incision varied from 3 to 10 cm. We have earlier highlighted this problem, suggesting that incisions that require some degree of division of the rectus muscle should be considered conversion to 'conventional laparotomy' [5].

The issue of cosmetic satisfaction and QoL has been relatively poorly addressed by earlier studies. Purkayastha et al. [7] did not include cosmetic satisfaction and the QoL outcomes in their meta-analysis, due to inconsistencies in the way that these outcomes were reported. Barkun et al. [9] in 1992 and McMahon et al. [10] in 1994 found that QoL following LC and MC procedures is equal, although in the LC group post-operative recovery is slightly more rapid than in the MC group. One year after operation in 1995, McMahon et al. [13] found in a randomised controlled trial of 299 patients that the only statistically significant difference was a higher rate of 'heartburn' in the MC group. In another 1-year follow-up study, Ros et al. [12] found no significant difference in cosmetic satisfaction and QoL between the LC and MC groups after 1-year follow-up.

In our earlier report, there was no statistically significant difference between the LC and MC groups in general health perceptions, physical functioning, emotional well-being, social functioning, energy, bodily pain and role functioning/emotional scores as assessed by the RAND-36 questionnaire. The role functioning/emotional score was the only statistically different variable, being higher in the LC group [14].

Evidence-based guidelines advise the use of the disease-specific gastrointestinal QoL index (GIQLI) and the short form (SF-36) for evaluating health status in patients undergoing cholecystectomy, because these questionnaires appear to be valid for evaluating patients' functional recovery after cholecystectomy [15]. Keus et al. [8] used SF-36 and GIQLI questionnaires and found no statistically significant difference between the LC ($n = 120$) and the MC groups ($n = 137$) 12 weeks postoperatively.

In earlier reports, the issue of symptom relief after cholecystectomy has been relatively poorly addressed. Gui et al. [16] evaluated 92 patients followed up after cholecystectomy for a mean of 31.1 months and found that abdominal pain continued to be present, or arose de novo in 28/92 (30 %) patients. Abdominal bloating, dyspepsia, heartburn, fat intolerance, nausea and vomiting were significantly improved after cholecystectomy, but diarrhoea, constipation and excessive flatus were not. In our study, at the follow-up interview, the patients in the LC group reported significantly more residual abdominal pain than the patients in the MC group. This is surprising, because it seems logical that no recurrences of pain and symptoms of gallbladder colic are to be expected when the gallbladder is removed. Especially when LC and MC procedures are compared, no differences in symptom relief are to be expected. Data from our study suggest that, in 38 % of patients in the LC group and in 20 % of the patients in the MC group, symptoms recur after cholecystectomy. The explanation for the high figure of residual symptoms after the LC procedure remains unknown, and it indicates how difficult it is to determine 'gallstone-specific' symptoms preoperatively. Therefore, symptom relief should become the focus of therapy with the correct diagnosis of symptomatic cholelithiasis and the right indication for cholecystectomy.

Most of the patients in both groups were satisfied with the operation overall, but for some reason the patients in the LC group were more often ready to recommend the operation for others. It is interesting that the converted patients were satisfied with the overall result and with the cosmetic results also. However, the small number of converted patients in our study makes statistical analysis difficult.

In conclusion, our results suggest a quite similar long-term outcome in the MC and LC groups. However, the patients in the MC group had fewer residual abdominal symptoms, but also a trend for dissatisfaction with the cosmetic results.

Disclosures

Jukka Harju, Samuli Aspinen, Petri Juvonen, Hannu Kokki and Matti Eskelinen have no conflicts of interest or financial ties to disclose.

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