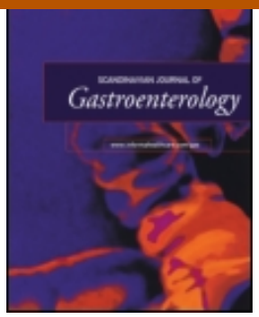

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ORIGINAL ARTICLE

A randomized multicenter study of minilaparotomy cholecystectomy versus laparoscopic cholecystectomy with ultrasonic dissection in both groups

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ABSTRACT

Objective: Ultrasonic dissection (UsD) has been used in laparoscopic cholecystectomy (LC), though it is not the golden standard technique. Applying UsD to cholecystectomy by minilaparotomy (MC) is less common and there are no prospective randomized trials comparing these two techniques. Therefore, we conducted the present study to investigate the use of the UsD in the MC versus the LC procedure. *Material and methods*: Initially 104 patients with non-complicated symptomatic gallstone disease were randomized into MC ($n = 53$) or LC ($n = 51$) groups, both groups using UsD, over a period of 2 years (2013–2015). The study groups were similar in terms of age and American Society of Anesthesiologists (ASA) physical status score. *Results:* The demographic variables and the surgical data were similar in the study groups. Similar low postoperative pain scores were reported in the two study groups during the first four hours after surgery. The incidence of nausea/vomiting was similar between the two study groups, 47% in the MC group versus 42% in the LC group. However, the patients in the MC group were treated more frequently with antiemetics, the incidence being 39% in the MC group versus 21% in the LC group ($p = 0.02$). The pain at rest at 24h after the surgery was similar in the two study groups, but the LC patients reported less pain at the normal activity, the mean of numerical rating scale (NRS) of 0–10 score being 3.9 in the MC group versus 2.9 in the LC group ($p = 0.05$), and the pain at the quick movement/coughing, the mean NRS being 4.9 in the MC group versus 3.2 in the LC group ($p = 0.005$). The length of sick leave was 17.4 days in the MC group and 14.4 days in the LC group ($p = 0.05$). *Conclusion:* Our results suggest that both MC and LC are feasible and safe options for mini-invasive cholecystectomy. A new finding with clinical relevance in the present work is a relatively similar short-term outcome in the MC and LC althought the LC patients reported significantly lower pain score 24 hours postoperatively and a shorter convalescence.

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Introduction

Laparoscopic cholecystectomy (LC) with dissection by monopolar electrosurgical energy (ME) is the gold-standard operative technique for the treatment of symptomatic gallstone disease. The ME technique is routinely used because of the ease of securing haemostasis and low costs. The ultrasonic dissection (UsD) has been used increasingly in endoscopic surgery [1–3] and the use of the UsD in the LC has been evaluated in some studies [4–12]. The results indicate that the UsD favours shorter recovery time [8,9,12] and fewer postoperative complications than the ME technique in the LC [5,7–10,12].

The laparoscopic technique is the golden standard of cholecystectomy although cholecystectomy by minilaparotomy (MC) has shown to lead to as good early recovery after surgery [13–26]. We have earlier done a study where we assessed the MC with UsD versus the LC with ME. Our results showed that the operated patients experienced less pain and had earlier recovery in the MC group compared to the LC group [27,28]. The different dissection technique between the study groups remained unclear whether the results were due to the minilaparotomy or laparoscopic technique or the dissection device. Therefore, we designed the present study to investigate the use of UsD in MC versus LC procedure in a prospective randomized setting. The hypothesis of our study was that no difference between the MC and the LC procedures would be detected when applying the UsD in both the MC and the LC groups.

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Subjects and methods

The study was approved by the Ethics Committee of Helsinki and Uusimaa University District, Helsinki, Finland (DNRO 120/13/02/02/2010, May 12, 2010), it was registered in the ClinicalTrials.gov database (ClinicalTrials.gov Identifier: NCT0172340, Consort diagram, Figure 1), and it was conducted in accordance with the Declaration of Helsinki. Participants gave written consent after receiving verbal and written information. Operations were carried out in two hospitals in Finland; Helsinki University Central Hospital, Helsinki ($n = 28$) and Kuopio University Hospital, Kuopio ($n = 76$) between March 2013 and May 2015. The flowchart of the study is presented in Figure 1. The study design was a prospective, randomized, multicenter clinical trial with two parallel groups. Altogether 104 patients with uncomplicated symptomatic cholelithiasis confirmed by ultrasound were randomized to undergo cholecystectomy with LC, 51 patients, or with MC, 53 patients. After patient enrolment, randomization was done with a sealed envelope method either to LC or MC groups. The operations were carried out by three consultant-level surgeons (JH, PJ, ME), and both techniques were familiar for each operator. Only elective patients suitable for day-case surgery with symptomatic gallstones confirmed by ultrasound were included in the study. The exclusion criteria specified American Society of Anesthesiologists Physical Status class of >3, earlier acute cholecystitis, jaundice, suspicion of stones in the common bile duct, previous upper abdominal operation and cirrhosis of the liver or suspicion of cancer. Two patients of the MC group were excluded after the surgery, one with failed anesthesia protocol and one with a suspicion of a liver tumor and the final number of the study patients was 51 patients in both groups (Figure 1).

The used surgical techniques were standardized in both groups [20,27]. The LC procedure was performed using the four-trocar technique (two 10 mm and two 5 mm trocars). An optical trocar was used to penetrate into the abdominal cavity and intra-abdominal pressure was set at 12 mmHg [20,27]. The ultrasonic scissors (Harmonic ACE®, Ethicon Endo-Surgery, Cincinnati, OH) were used both in the MC and LC procedure. The gallbladder was dissected from the liver with ultrasonic scissors. The cystic artery was sealed with ultrasonic scissor and two metal clips were inserted to the cystic duct. The rectus muscle was split, not cut in the MC technique. The cutting the rectus muscle or a skin incision longer than 7 cm in the MC group was considered to be a conversion to conventional open operation [20,24,27]. At the end of the operation, the wounds were infiltrated with local anaesthetic (20 ml ropivacaine 7.5 mg/ml) in both groups.

Endotracheal anaesthesia and postoperative care were standardized and similar in the two groups. Patients were given 60–120 mg etoricoxib one hour before the surgery per oral and 1 g i.v. paracetamol after the surgery. For rescue analgesia ,the patients were given oxycodone 3 mg i.v. at every 10 minutes if the pain was on an 11 point numeric rating scale (NRS; 0 = no pain; 10 = most pain) at rest, 3/10 or higher or during cough, and/or movement 5/10 or higher. After discharge, the patients were prescribed per oral paracetamol and ibuprofen as analgesics.

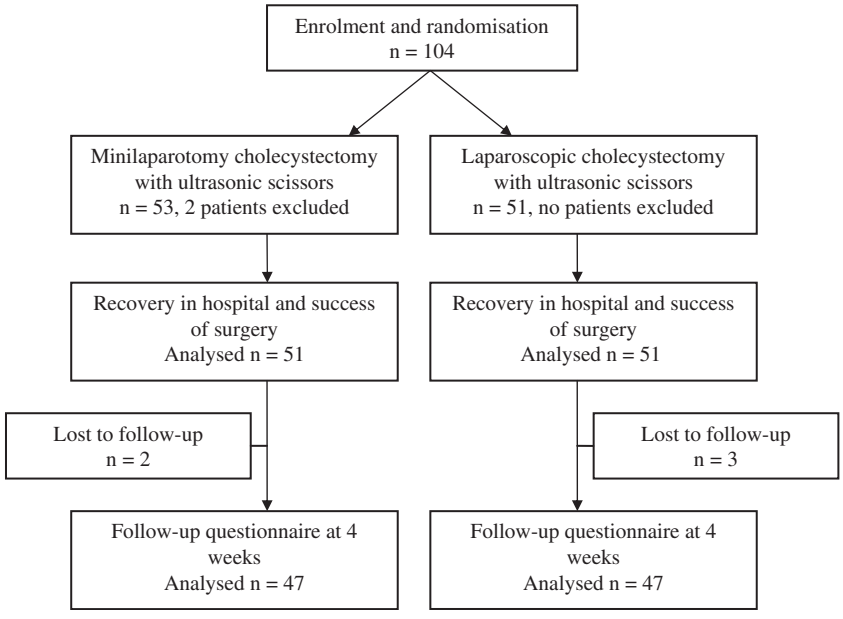

Figure 1. Flowchart of the study design.

The primary outcome measures were the success of the day case surgery, the postoperative pain at hospital (0–5 hours), pain at 24 hours, pain at 4 weeks and the convalescence time (length of sick leave after the operation in days). The secondary outcome measures were the operation time (minutes), length of the skin incision (cm), nausea and vomiting and other complications, and the need to contact the hospital or other health care providers after the discharge. The sample size calculation was based on the assumption that the convalescence should be 16 days (SD 4) in the LC group [20,24,27]. In order to show a 3-day difference in the convalescence between the two groups, 40 patients per group were required at a study power of 0.9 and two-sided alfa-level of $\leq$0.05 to show a statistically significant difference between the groups.

Each patient was interviewed by phone at 24 hours after surgery. Furthermore, the patients' recovery was assessed with a follow-up questionnaire to be filled and returned in a prepaid envelope at four weeks post-operatively, the non-responders were contacted by phone. The postoperative medical history for the first four postoperative weeks was checked also from the hospitals patient records.

The data were entered and analyzed with a statistical software program (IBM SPSS Statistics 21.0, IBM, Somers, IL). The results are presented as mean and standard deviation, median and minimum and maximum, or as the number of patients when appropriate. For non-normally distributed data, the Mann–Whitney test was used. The Pearson chi-square test was used to analyze the frequency data. A two-sided *p*-value of less than 0.05 was considered statistically significant.

Results

The two study groups were similar in terms of the demographic variables and the perioperative surgical data (Table I). Three cholecystectomies were converted to open laparotomy in the LC group; two with severe chronic cholecystitis and one with abnormal anatomy. One patient in the MC group with the incision longer than 7 cm was considered to be a conversion.

Recovery at hospital

There was no statistical significant difference between the two studies in the postoperative pain during the first four hours after surgery (Table II). There was no

Table II. Postoperative pain in the two study groups. Pain was assessed with an 11-point numeric rating scale (0 = no pain, 10 = most pain).

Variable	Minilaparotomy cholecystectomy $n = 51$	Laparoscopic cholecystectomy $n = 51$	*p*-Value
Pain at hospital			
At 1 hour	3.5 (2.2) 3 [0–9]	3.3 (2.4) 3 [0–10]	0.52
At 2 hours	2.3 (1.8) 2 [0–6]	2.4 (2.2) 2 [0–9]	0.91
At 3 hours	2.2 (1.7) 2 [0–7]	1.6 (2.1) 1 [0–7]	0.10
At 4 hours	1.7 (1.8) 1 [0–7]	1.5 (1.8) 1 [0–7]	0.54
Most pain at hospital	3.8 (2.0) 3 [0–9]	3.6 (2.2) 3 [0–10]	0.66
At discharge	1.1 (1.2) 0 [0–3]	0.6 (0.9) 0 [0–3]	0.28

Data are mean (standard deviation) and median [range].

Table I. Baseline demographic characteristics and surgical data for the two study groups.

Variable	Minilaparotomy cholecystectomy $n = 51$	Laparoscopic cholecystectomy $n = 51$	*p*-Value
Age (years)	49.4 (13.4) 49.0 [21–73]	52.0 (13.2) 52.5 [19–64]	0.34
Height (cm)	168 (7.7) 167 [154–185]	168 (8.9) 166 [146–187]	0.97
Weight (kg)	76.6 (14.0) 73.5 [50–90]	82.2 (17.2) 85.0 [50–90]	0.06
BMI (kg/m^2)	27.2 (4.3) 26.3 [18–35]	29.1 (5.6) 28.1 [17–35]	0.12
Gender male/female	11/40	16/35	0.39
ASA 1/2/3	27/19/5	18/21/12	0.95
Operative time (minutes)	67 (26) 60 [28–104]	68 (26) 59 [25–167]	0.81
Time at the operation theatre (minutes)	116 (26) 117 [70–140]	125 (37) 124 [74–213]	0.23
Bleeding (ml)	40 (63) 20 [0–300]	29 (37) 15 [0–150]	0.60
Length of the skin incisions (cm)	4.8 (1.0) 4.6 [2.9–8.5]	7.8 (2.5) 7.8 [3.7–20.0]	0.0001

BMI = body mass index; ASA = American Society of Anesthesiologists physical status score.
Data are mean (standard deviation), median [range] or number of cases.

Table III. Postoperative pain, number of analgesic doses and recovery during the first 24 hours after surgery in the two study groups.

Variable	Minilaparotomy cholecystectomy $n = 51$	Laparoscopic cholecystectomy $n = 51$	p-Value
Pain at 24 h			
Pain at rest	1.9 (2.0) 1.0 [0–7]	1.6 (2.2) 1.0 [0–7]	0.40
Pain while coughing or fast movement	4.9 (2.3) 5 [0–10]	3.2 (2.6) 3 [1–10]	0.005
Pain at normal activities	3.9 (2.3) 4 [0–9]	2.9 (2.4) 3 [0–9]	0.05
Number of analgesic doses during the first 24 h	5.1 (4.6) 4 [0–27]	4.4 (3.4) 4 [2–6]	0.42
Efficacy of analgesics	7.4 (2.1) 8 [0–10]	7.6 (2.6) 8 [0–10]	0.18
Total amount of oxycodone (mg)	19.0 (15.5) 15 [0–75]	16.6 (15.1) 13 [0–75]	0.29
Nausea (yes/no)	8/43	14/37	0.31
Grading of nausea (NRS)	0.7 (1.7) 0 [0–8]	1.0 (1.9) 0 [0–7]	0.30
Vomiting (yes/no)	8/43	5/46	0.30
Antiemetics received (yes/no)	20/31	11/40	0.02

Pain, nausea and analgesic efficacy was assessed with an 11-point numeric rating scale (0 = no pain/pain relief, 10 = most pain/total pain relief). Data are mean (standard deviation) and median [range].

difference in the need of rescue of analgesia, in the MC group all except one versus all except two in the LC group were given oxycodone in the recovery room. The incidence of nausea/vomiting (47% vs 42%) was similar in the two study groups, but the patients in the MC group were treated more frequently with antiemetics, the incidence being 39% in the MC group versus 21% in the LC group ($p = 0.02$). The success of day surgery was quite similar in the LC group (77%) compared to the MC group (65%) ($p = 0.31$). Postoperative nausea ($n = 13$), postoperative pain ($n = 11$) and difficulties to pass urine ($n = 3$) were the most common reasons for unplanned overnight admission.

Recovery after discharge

The pain at rest 24h after the surgery was quite similar in the two study groups (Table III). The LC patients reported significantly lower pain score at the normal activity ($p = 0.05$), and at quick movement/coughing ($p = 0.005$) and the LC patients received less antiemetics ($p = 0.02$) (Table III). Nevertheless, there was no difference in the number of analgesic doses during the first 24h, total amount of oxycodone or efficacy of analgesics between the two study groups (Table III). The length of sick leave days was longer in the MC group versus the LC group (17.4 versus 14.4 days, $p = 0.05$).

Twenty-one patients (41%) in the MC group and 15 patients (29%) in the LC group called or visited a health care professional after discharge ($p = 0.21$). There was one superficial infection in the MC group and one in a converted LC, both of which were treated with subcutaneous wound opening and per oral antibiotics. One patient in the MC group had a deep infection, wound opening and a long line of treatments and the patient wished to discontinue the study. One patient in the LC group developed a fever and stomach pain and was admitted back to the hospital on the 2nd postoperative day. In a second-look of the operation, a Luschka duct leak was found and treated successfully.

Discussion

The minilaparotomy cholecystectomy has shown to have a similar perioperative course than the LC and follow-up results on early postoperative recovery indicates that these two techniques share a similar short-term recovery [13–26]. We described earlier the accuracy of ME in the MC versus the LC [27,28] and our results suggest a relatively similar 5-year and 10-year outcome after the MC and the LC [29,30]. The short-term outcome after the LC with the UsD in several trials shows that it could be a feasible and safe technique for routine cholecystectomy [4–12]. The results indicate that the UsD leads to a shorter mean operation time [5–9,20] and shorter mean hospital stay [14–17,12], less intraoperative blood loss [8–10], fewer intraoperative conversions, gallbladder perforations [5–10,12] and fewer postoperative intra-abdominal fluid collections [8,9] and less bile leakage and postoperative abdominal pain and nausea [6,8,9,12].

Considering the positive effects of ultrasonic dissection in the LC, it seemed attractive to apply the UsD also in the MC procedure. In our previous report [27,28], we used the ultrasonic dissection in the MC and compared

this approach to the conventional LC using ME in a randomized setting. We found that the patients in the MC with the UsD group had less early postoperatively pain, less use of analgesic doses postoperatively, shorter sick-leave, better success rate for day surgery and faster return to work. Hereby, the hypothesis of our present study was that no difference between the MC and the LC procedures would be detected when applying the UsD in both the MC and the LC groups.

The results of this study show that there were no statistically significant differences between the two study groups regarding perioperative outcome. The proportion of conversions was higher in the LC patients ($n = 3$) versus MC patients ($n = 1$). There were no differences in the rescue analgesics consumption, analgesics doses, and nausea/vomiting.

In the pain reports, the LC patients had significantly lower pain score at normal activities and at fast movement/while coughing at 24 hours after surgery and the LC patients received significantly less antiemetics ($p = 0.02$). Nevertheless, no difference in the analgesics consumption was observed between the two study groups. There was no significant difference in convalescence, pain or analgesics use at four weeks after the surgery. For some reason, the patients in the MC group seemed to need a slightly longer sick leave. In conclusion of the early postoperative recovery, no major differences between the two study groups were observed. We suggest that the explanation for the fairly similar recovery is the use of the UsD in both study groups.

These results concerning early outcome after the MC vs. the LC with the UsD are in concordance compared to studies using traditional dissecting methods, suggesting that these techniques are comparable in safety and efficacy also when the UsD is applied [27–30]. The favourable effects of the UsD compared to the conventional ME on adjacent tissue damage, and its preciseness in cutting and dissecting makes this technique appealing to apply in the elective surgery of gallstone disease. As the competency of the ultrasonic dissection in the LC procedure has been well-established earlier, we have shown in the present study that the favourable effects of the UsD are also applicable in the MC procedure.

In conclusion, our results suggest that both MC and LC are feasible and safe options for mini-invasive cholecystectomy. A new finding with clinical relevance in the present work was a relatively similar short-term outcome in the MC and LC groups when applying the UsD in both groups, although the LC patients reported significantly lower pain score 24 hours postoperatively and a shorter convalescence.

Declaration of interest

Drs Aspinen, Harju, Kinnunen, Juvonen, Kokki and Eskelinen have no conflicts of interest or financial ties to disclose. The study was funded by the EVO-funding of the Helsinki University Hospital and the Kuopio University Hospital.

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