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and Other Interventional Techniques

Minilaparotomy cholecystectomy versus laparoscopic cholecystectomy

A randomized study with special reference to obesity

J. Harju, P. Juvonen, M. Eskelinen, P. Miettinen, M. Pääkkönen

Department of Surgery, Kuopio University Hospital, Post Office Box 1777, 70211 Kuopio, Finland

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Abstract
Background: Minilaparotomy cholecystectomy (MC) has recently challenged the role of the laparoscopic approach (LC) for cholecystectomies. However, the situation is far from clear when operating times and recovery are evaluated.
Methods: Altogether 157 patients with uncomplicated symptomatic gallstones were randomized into MC (n = 85) and LC (n = 72) groups. Both groups were similar in terms of age, body mass index, American Society of Anesthesiology (ASA) physical fitness classification, and operating surgeon.
Results: The mean operating time was 55 ± 19.5 min in the MC group and 79 ± 27.0 min in the LC group ($p <$ 0.0001). The postoperative hospital stay and length of sick leave did not differ between the two groups. There were no significant differences in postoperative pain, analgesic consumption, or postoperative pulmonary function between the groups. The body mass index did not influence operating time or patient recovery in either group. No major complications occurred in either groups.
Conclusion: The MC procedure seems to be a faster technique than the LC approach for noncomplicated gallstone disease, with no difference in recovery times. The MC procedure also seems to be suitable for the obese patient.

Key words: Cholecystectomy — Gallstone disease — Laparoscopy — Minilaparotomy

Laparoscopic cholecystectomy (LC) has become a widely accepted operating method during the past 15 years in elective biliary surgery. Several clinical studies have shown cholecystectomy using a minilaparotomy (MC) incision to be a comparable or better procedure than laparoscopic surgery in [1, 2, 8, 12, 14, 15]. On the other hand, some trials have shown LC to have an advantage over MC [3, 4, 6, 8, 9, 13].

There is great variation in the division of the rectus abdominis muscle as well as in the length and location of the incision used in MC. Consequently, the exact role of MC in elective cholecystectomies has been difficult to establish. Tyagi et al. [15] described a new technique for minimally invasive cholecystectomy. With this technique, a small transverse incision was made at the so-called "minimal stress triangle", and the rectus muscle was left intact. Patient recovery in the MC group was comparable with that after LC in their study. Schmitz et al. [11] found that a short-incision (5–8 cm) subcostal cholecystectomy and a conventional cholecystectomy (incision length, 11–17 cm), did not differ in terms of postoperative pain. This confirms the idea that incision technique may have a major role, as Tyagi et al. [15] described in their study.

Obesity has previously been contraindication for LC, but recent clinical studies have shown that LC can be performed for obese patients also [7, 10]. There are only limited data on the use of MC with the obese patient. It may be expected that morbid obesity may cause technical problems when the MC procedure is performed.

Postoperative pulmonary function is reported to be better after LC than after MC [7], but the situation is far from clear [12]. With respect to postoperative pain, two studies [6, 12] have reported less pain after LC.

The aim of this study was to establish the role of MC using Tyagi's technique with respect to operation and recovery times, pulmonary function, and postoperative pain for nonobese and obese patients.

Patients and methods

The study, approved by the Joint Ethics Committee of the University of Kuopio and Kuopio University Hospital, was concluded in accor-

Correspondence to: J. Harju

Table 1. Demographic characteristics of the study groups

	Minilaparotomy	Laparoscopy	Total	Significance
No. of patients (females)	85 (65)	72 (60)	157 (125)	NS
Age (yr): mean (range)	49.54 (17–78)	48.78 (17–76)	49.19 (17–78)	NS
BMI: mean (range)	27.7 ± 5.4 (18.3–48.4)	27.1 ± 3.8 (18.6–35.9)	27.4 ± 4.7 (18.3–48.4)	NS
ASA 1–2/3–4	79/6	65/7	144/13	NS

N, non-significant; BMI, body mass index (kg/m^2); ASA, American Association of Anesthesiologists' physical fitness classification

Table 2. Details of time in the operating theater and operating and recovery times

	Minilaparotomy mean (range)	Laparoscopy mean (range)	***p*** Value
Overall time at the operating theatre (min)	102 ± 22.1 (65–101)	127 ± 31.6 (75–228)	< 0.0001
Operating time (min)	55 ± 19.5 (20–125)	79 ± 27.0 (35–170)	< 0.0001
Hospital stay (days)	2.12 (1–7)	2.06 (1–20)	NS
Sick leave (days)	17.2 (8–38)	15.7 (8–38)	NS

NS, nonsignificant

dance with the Declaration of Helsinki. Participation was based on written consent after verbal and written information. All operations were performed in the Department of Surgery at the Kuopio University Hospital.

The study was prospective and randomized in design, but not blinded. Randomization was performed in the surgery ward 1 day before the operation. The study subjects were not managed consecutively. Altogether, 157 patients were randomized with sealed envelopes either to MC (n = 85) or LC (n = 72) groups from February 3, 1998, to April 26, 2004. There were no significant differences between the two groups in terms of gender, age, body mass index (BMI), or American Association of Anesthesiologist' (ASA) physical fitness classification (Table 1). A BMI of 30 kg/m^2 or more characterized 27 patients (32%) and 16 patients (22%) in the LC group.

Only elective patients with symptomatic gallstones confirmed by ultrasound and suitable for surgery were included in the study. The exclusion criteria specified earlier jaundice, suspicion of stones in a common bile duct (serum elevated alkaline phosphate or bilirubin or a wide common bile duct on ultrasound), previous upper abdominal operation (relative exclusion criteria), and cirrhosis of the liver or suspicion of cancer. The patients were asked to come for a control visit 1 month after their operation in the outpatient department.

The operations were performed by 18 operators, 11 of whom were trainees, and 7 consultants. Trainees were the main operators in 23 MC and 21 LC operations. Groups were statistically similar concerning experience of the operating surgeon (trainee or consultant). The LC technique was familiar to all surgeons, but the MC procedure was new for all. During the randomization period, the total number of cholecystectomies was 1,955.The number of open cholecystectomy procedures, including minilaparotomies, was 1,264 (64.6%) and the number of laparoscopic cholecystectomies was 691 (35.5%), performed by the same group of surgeons who were performed operations in this study. Acute cholecystetectomies were often performed in the evenings by junior surgeons using conventional open procedure.

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. [15] in their article, but the study protocol did not mention which technique should be used for dissection of the gallbladder ("fundus first" or retrograde). The cystic artery and duct were ligated with clips. No cholangiogram was performed, and no local anesthetic was given in either group.

All the patients received diazepam 0.2 mg/kg orally 1 h before surgery. Induction of anesthesia was started with midazolam 30 μg/kg, fentanyl 2 μg/kg, and propofol 2 mg/kg. At the time of intubation, patients were given atracurium 0.5 mg/kg. Anesthesia was maintained with air/oxygen/isofluran gas. For analgesia, additional fentanyl 1 to 2 μg/kg was given when necessary, and to maintain relaxation, atracur 0.1 mg/kg was given. At the end of anesthesia relaxation was abated with glycopyrrolate or neostigmine. For the treatment of postoperative pain, ibuprofen 400 to 800 mg × 3 was administered orally or rectally. If there was a contraindication for nonsteroidal antiinflammatory drugs (NSAIDs), parasetamol 1.0 g × 3 orally or rectally. Oxycodone was administered intramusoulary at a dose of 0.8 mg/kg for more severe pain. In the recovery room, 3-mg doses of intravenous oxycodone was used when necessary. Pain was assessed for the patients using the visual analogue scale (VAS). Pulmonary function (forced vital capacity [FVC], forced expiratory volume in 1 s [FEV_1] and peak expiratory flow rate [PEFR]) was measured preoperatively and on the first postoperative day. Measurements were made by portable spirometry (Escort, Buckingham, England). Both pre- and postoperative pulmonary functions were obtained from 47 patients in the LC group and 46 in the MC group.

In the statistical analyses, the Mann–Whitney U-test, repeated measures analysis of variance and (ANOVA) were used. Statistical significance was defined as a p value less than 0.05.

Results

The overall time in the operating theater and the operating time were significantly shorter in the MC group. There were no statistically significant differences in the postoperative hospital stay and the length of sick leave (Table 2). The operating surgeon (trainee or consultant) did not have any significant influence on the operating time. Higher BMI had no statistically significant influence on either the operating time or the recovery in either group (Table 3). Postoperatively, pulmonary function was significantly decreased in both groups (p < 0.0001), but there was no statistically significant difference between the MC and LC groups (Table 4).

On the average oral food was intake started on postoperative day 1, without a statistically significant difference between the two groups. Postoperative nausea, vomiting, pain, and the use of analgesics did not differ between the MC and LC groups.

Four (5.9%) conversions to open laparotomy occurred in the LC group, and two (2.4%) in the MC group. The difference was not significant. Both cases in the MC group, involved an intrahepatic gallbladder and chronic cholecystitis. The reasons for conversions in the

Table 3. Details of operating time, time in the operating theater, and recovery time for obesity cases

	LC BMI ≥ 30 (n = 16) mean ± SD (range)	LC BMI < 30 (n = 56) mean ± SD (range)	MC BMI ≥ 30 (n = 27) mean ± SD (range)	MC BMI < 30 (n = 58) mean ± SD (range)
Operating time (min)	81.56 ± 24.6 (35–130)	78.07 ± 27.8 (35–170)	64.56 ± 22.3 (37–125)	50.24 ± 16.3 (20–115)
Overall time in the operating theater (min)	136.88 ± 32.9 (95–228)	123.55 ± 30.9 (75–215)	110.41 ± 26.2 (65–161)	98.19 ± 18.9 (70–157)
Hospital stay (days)	2.00 ± 0.6 (1–3)	2.07 ± 2.6 (1–20)	1.93 ± 1.2 (1–7)	2.21 ± 1.2 (1–7)
Sick leave (days)	15.75 ± 6.1 (8–29)	15.64 ± 3.9 (9–30)	19.53 ± 6.8 (13–38)	16.09 ± 4.0 (12–30)

LC, laparoscopic chlecystectomy; MC, minilaprotomy chlecystectomy; SD, standard deviation

Table 4. Pre- and postoperative pulmonary functions

	LC preoperative mean ± SD (range)	LC postoperative mean ± SD (range)	MC preoperative mean ± SD (range)	MC postoperative mean ± SD (range)	Significance between LC and MC
FVC	3.40 ± 1.0 (1.67–6.89)	2.82 ± 1.0 (0.80–6.40)	3.41 ± 0.8 (1.08–5.03)	2.71 ± 0.7 (1.11–3.97)	NS
FEV1	2.93 ± 0.8 (1.62–6.24)	2.42 ± 0.9 (0.72–5.80)	2.86 ± 0.8 (1.05–4.71)	2.32 ± 0.6 (0.87–3.62)	NS
PERF	402 ± 116 (135–736)	325 ± 109 (171–637)	422 ± 150 (97–767)	314 ± 125 (90–725)	NS

LC, laparoscopic chlecystectomy; MC, minilaprotomy chlecystectomy; SD, standard deviation; FVC, forced vital capacity; NS, nonsignificant; FEV, forced expiratory volume in 1 s; PERF, peak expiratory flow rate

LC group were adhesions in one case, adhesions and chronic cholecystitis in one case, and difficult anatomy in two cases.

One cystic stump leak occurred in the LC group. The MC group, had one deep and two superficial wound infections, one pneumonia, and three urinary tract infections. However, the difference between the groups was not statistically significant.

Discussion

During the past 15 years, LC has been established as a dominant cholecystectomy procedure despite studies [1, 2, 8, 12, 14, 15] showing MC to be very comparable. There may be several reasons that favor laparoscopy without firm scientific evidence. Companies that sell laparoscopic instruments, also may influence surgeons' attitudes. Both patients and surgeons often have the attitude that laparoscopy is a modern and more advanced technique than open surgery, which may influence patient recovery. Our study was not blinded, which may have had some effect on patient recovery.

In earlier studies comparing LC and MC operations, there was great variation in the MC technique, especially concerning whether the rectus muscle was cut or not and the maximum size of an incision. We believe that the incision technique plays a major role in the MC procedure. In our opinion, cutting the rectus muscle means conversion to conventional laparotomy. The variation in incision technique might explain the differences in results between MC and LC studies.

In several earlier studies, the operating time was shorter for the MC group than for the LC group [2, 4, 5, 9, 14], which also was seen in our study. The operating time for the LC group was rather long, and there is no good explanation for that. The study was not consecutive, and not all surgeons were enthusiastic about taking patients to the study. The waiting time for elective cholecystectomy was quite long in our hospital because of the economic situation, and then there was a risk that the technique for the elective operations would be more difficult. The postoperative hospital stay was slightly shorter for the LC group in some studies [3–5, 9], but some studies showed no difference in the postoperative hospital stay between MC and LC [2, 8, 14, 15]. In our study, the postoperative hospital stay did not differ between the groups. This is an important result for health care administrators because of limitations in health care resources.

McMahon et al. [6] found better postoperative pulmonary function and less postoperative pain in the LC group, but they used a subcostal 5- to 10-cm incision in the MC group. We did not find any statistically significant difference in postoperative pulmonary function or pain between the LC and MC groups. The difference between our study and that of McMahon et al. [6] may reflect the different incision technique.

Before we started our study, we hypothesized that obesity may cause problems, especially in the MC group. The influence of obesity either has not been mentioned in most studies comparing MC and LC or obese patients have been excluded from the studies. We did not find any association between obesity and a less favorable outcome in MC group, as compared with the LC group, using ANVOA, indicating that MC is an acceptable method for obese patients as well.

The instrumentation for the MC procedure is rather easy. No disposable instruments are needed, whereas for the LC procedure, disposable instruments often are used. The cheaper instrumentation and the shorter operating time combined with a similar recovery implies a cost advantage for MC.

The MC technique was a new procedure compared with LC. However, it seems that there is no remarkable learning curve for the MC procedure. The operating surgeon (trainee or consultant) did not have any significant influence on the results, although the number of trainees participating was high. This indicates that MC is a rather elementary operation to learn.

The number of complications and the conversion rate both were rather low in both groups, with no difference between the groups. There were three wound infections in the MC group as compared with none in the LC group. Although the difference was not statistically significant, this finding suggests that antibiotic prophylaxis may benefit the MC group.

For the operative treatment of noncomplicated gallstone disease, the MC procedure seems to be very attractive. In the future, detailed analyses of costeffectiveness and patient compliance are needed for making the choice of the right operating techniques.

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