Mini-laparotomy Cholecystectomy Versus Laparoscopic Cholecystectomy: Which Way to Go?

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Purpose: The aim of this paper is to report the results of a prospective clinical trial investigating traditional laparoscopic cholecystectomy versus "mini-lap" cholecystectomy in a tertiary care University Hospital.

Materials and Methods: This is a prospective, randomized, single-center observational study. Forty-four patients were allocated in each group; patients in group L underwent laparoscopic cholecystectomy, whereas patients in group M had open "mini-lap" cholecystectomy with a small incision through the rectus abdominis muscle.

Results: The operation lasted significantly longer in group L compared with group M, whereas patients in group L had a shorter hospital stay. There was no difference between groups regarding postoperative day on which patients commenced eating. There was no significant difference between groups regarding doses of analgesics used during surgery or in the recovery room. However, patients in group M used significantly more opioids in the postoperative period. Time to resume normal activity was significantly shorter in group L. A very good aesthetic result was obtained in 97.7% of patients in group L and 77.3% of patients in group M.

Conclusions: Cholecystectomy through a mini-laparotomy incision is a lower-cost, versatile, and safer alternative to laparoscopic cholecystectomy.

Key Words: laparoscopic cholecystectomy, mini-laparotomy cholecystectomy

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Laparoscopic cholecystectomy (LC) was first described in 1989 and has now become the mainstream surgical therapy for gallbladder disease. LC is the most frequently performed laparoscopic procedure in modern hospitals of developed countries. It confers significant, proven benefits in terms of shortened hospitalization, reduced postoperative pain, shorter convalescence period, better cosmetic results and, in centers with experience, reduced intraoperative and postoperative complications. However, LC is an expensive operation with high start-up costs, because of the need for highly skilled surgeons and expensive equipment.

On the other hand, the advent of fine-caliber surgical instruments and minimally invasive paradigms has resulted in a gradual reduction in length of abdominal wall incisions for open cholecystectomy. An oblique subcostal incision less than 8 cm long is defined as mini-laparotomy, whereas an incision smaller than 4 cm is known as micro-laparotomy. "Mini-lap" cholecystectomy can be performed with conventional surgical tools available in any operating room and is slowly gaining acceptance as a versatile, low-cost alternative to LC. "Mini-lap" cholecystectomy may confer certain advantages, such as decreased postoperative morbidity and rapid return to normal life, which is similar to those of LC, while avoiding the increased rate of bile duct injury associated with LC. In addition, "mini-lap" cholecystectomy may be more cost-effective than LC, because it obviates the need for sophisticated equipment and specialized medical personnel.

The aim of this paper is to report the results of a prospective, randomized, observational clinical study comparing laparoscopic versus "mini-lap" cholecystectomy in a tertiary care University Hospital.

MATERIALS AND METHODS

This prospective, randomized, single-center observational study was approved by the Ethics Committee of the Hospital. Inclusion criteria included elective surgery for choledolithiasis or cholecdocholithiasis, diagnosed by clinical symptoms and confirmed by ultrasonography or computed tomography. Most patients who underwent cholecystectomy during the study period had intraoperative findings of chronic cholecystitis (possibly recurrent episodes of subclinical cholecystitis that resolved without medical intervention). As a result, in most cases we had intraoperative technical difficulties due to tissue scarring or adhesions. Patients over 80 years old, and those with neurologic dysfunction or impaired mental status were excluded. All patients were fully informed about the investigational nature of mini-laparotomy cholecystectomy and the advantages and limitations of each...
procedure and signed an informed consent document. Eighty-eight patients were allocated to 1 of the 2 groups (44 patients in each group) with a computerized randomization protocol (Graphpad Prism for Windows, version 4.00, GraphPad Software, Inc). Patients in group M underwent open mini-laparotomy cholecystectomy by an incision through the rectus abdominis muscle, whereas patients in group L underwent laparoscopic cholecystectomy (LC). Demographic data of the study population are summarized in (Table 1).

LC was performed with a standard 4-trocar technique with electrocautery dissection, as previously described in detail by other investigators. After the gallbladder was dissected, it was retracted from the abdomen through the umbilical incision, and a suction drain was electively placed in the abdominal cavity when needed.

Mini-laparotomy cholecystectomy was performed through an oblique, right subcostal incision (5 to 7 cm long) with partial dissection of the rectus abdominis muscle. Intercostal infiltration with 10 ml of 0.25% bupivacaine was performed for pain control during wound closure and no drains were used.

All procedures were performed by 1 of 2 surgeons: Konstantinos Vagenas (surgeon A) performed all LC procedures and Dionissios Karavias (surgeon B) performed all open “mini-lap” procedures. Early oral intake and mobilization were encouraged in both groups (Table 1).

Data collected included use of analgesic medications (opioids and NSAID) in the intraoperative period, recovery room, and postoperative period, duration of postoperative ileus, time to oral intake, length of hospital stay, and aesthetic outcome. Postoperative pain was not directly measured. Instead, pain was assessed indirectly by recording the amount of analgesics used postoperatively.

The perioperative analgesic regimen was not standardized, but was left to the discretion of the attending anesthesiologist. All doses of opioid medications administered were recorded and converted to equianalgesic doses of morphine sulfate (MS), so as to allow comparisons between groups. Meperidine doses were converted to morphine equianalgesic doses using the ratio of 10 mg of meperidine to 1 mg of morphine. Fentanyl doses were converted to morphine using the ratio 100 mcg fentanyl = 5 mg of morphine. NSAID doses were also recorded and compared between groups. The cosmetic result was evaluated after the patient was discharged from the hospital, with a 3-point questionnaire (very satisfied, satisfied, not at all satisfied).

The SPSS statistical software package (Version 12 for Windows, SPSS, Inc) was employed for statistical analysis. All statistical tests were 2-sided and the threshold of statistical significance was set at 5% ($P < 0.05$).

Kolmogorov normality test was used to determine whether continuous data should be treated as originating from normal distributions. Student $t$ test for independent samples was used to compare means for data that met the normality test, and the Mann-Whitney $U$ test was used to compare means for data that did not meet the normality test. Fisher exact test was used to compare proportions between groups.

RESULTS

There were no significant demographic differences between groups (Table 1). There were 15 men and 29 women in group L, versus 14 men and 30 women in group M. Patients were slightly older in group L, but the difference was not statistically significant ($54.34 \pm 2.15$ yr in group L vs. $50.82 \pm 2.43$ yr in group M; $P = 0.29$) (Table 2).

The operating room time in group L (101.30 ± 4.99 min) was significantly longer than in group M (64.32 ± 3.13 min; $P < 0.0001$), but hospital stay was significantly shorter in group L (2.28 ± 0.15 d in group L vs. 3.11 ± 0.37 d in group M; $P = 0.001$). There was no difference in duration of postoperative ileus (0.05 ± 0.04 d in group L vs. 0.07 ± 0.04 d in group M; $P = 0.32$). Time to oral intake was shorter in group L (0.91 ± 0.08 d in group L vs. 1.07 ± 0.04 d in group M; $P = 0.02$), but this difference, although statistically significant, is probably clinically irrelevant. There was no difference between groups in opioid use in the operating room (12.04 ± 0.8 mg MS in group L vs. 10.23 ± 0.84 mg MS in group M, $P = 0.24$), or in the recovery room (2.78 ± 0.45 mg MS in group L vs. 2.78 ± 0.48 mg MS in group M, $P = 0.89$).

| TABLE 2. Results | Group L | Group M | $P$ |
|------------------|---------|---------|--|--|
| OR time (min)    | 101.3 ± 4.99 | 64.32 ± 3.13 | <0.0001 |
| OR dose (mg MS)  | 12.04 ± 0.8 | 10.23 ± 0.84 | NS |
| PAR              | 2.78 ± 0.45 | 2.78 ± 0.48 | NS |
| Postop           | 3.41 ± 0.63 | 10.57 ± 0.73 | <0.0001 |
| NSAID dose (mg)  | 0.5 ± 0.1 | 0.46 ± 0.12 | NS |
| PAR              | 0.39 ± 0.07 | 0.39 ± 0.04 | 0.001 |
| Postop           | 0.11 ± 0.05 | 0.11 ± 0.05 | 0.02 |
| Time To oral intake | 0.91 ± 0.08 | 1.07 ± 0.04 | 0.02 |
| Hospital stay    | 2.28 ± 0.15 | 3.11 ± 0.37 | 0.001 |
| Return to normal activity | 10.68 ± 1.59 | 16.02 ± 2.23 | 0.05 |

Cosmetic result

| Very satisfied | 43 | 36 | 0.03 |
| Satisfied      | 1  | 5  | NS |
| Not satisfied  | 0  | 3  | NS |

Results are presented as Mean ± SEM.

NS indicates morphine sulfate; NS, no statistically significant difference; OR, operating room; PAR, postanesthesia recovery room.

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TABLE 3. Postoperative Complications

<table>
<thead>
<tr>
<th>Postoperative Complications</th>
<th>Group L</th>
<th>Group M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Ileus</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>0</td>
<td>1</td>
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<tr>
<td>Hernia</td>
<td>0</td>
<td>1</td>
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Postoperative opioid use was significantly higher in group M \((10.57 \pm 0.73\ mg\ MS\ in\ group\ M\ vs.\ 3.41 \pm 0.63\ mg\ MS\ in\ group\ L;\ P < 0.0001)\). NSAID use, however, displayed a different pattern: there was no difference in NSAID use in the operating room \((0.5 \pm 0.1\ doses\ in\ group\ L\ vs.\ 0.46 \pm 0.12\ doses\ in\ group\ M;\ P = 0.56)\), but NSAID use was greater in group L in the recovery room \((0.39 \pm 0.07\ doses\ in\ group\ L\ vs.\ 0.09 \pm 0.04\ doses\ in\ group\ M;\ P = 0.001)\). NSAID use was greater in group M in the postoperative period \((0.11 \pm 0.05\ doses\ in\ group\ L\ vs.\ 0.39 \pm 0.09\ doses\ in\ group\ M;\ P < 0.02)\), suggesting that the laparoscopic procedure may elicit greater visceral pain immediately after surgery, yet this pain quickly improves and subsequently postoperative pain is somewhat greater in the open procedure.

Time to return to normal activity was shorter in group L \((10.68 \pm 1.59\ d\ in\ group\ L\ vs.\ 16.02 \pm 2.23\ d\ in\ group\ M;\ P < 0.05)\). Postoperative complications were comparable between groups; there were 1 case of ileus, 1 case of fever, and 1 case of hernia in group L, versus 1 case of pneumonia and 2 cases of fever in group M. The aesthetic result differed somewhat between procedures, with higher patient satisfaction in group L: a very good aesthetic result was obtained in 43 of 44 patients \((97.7\%)\) in group L versus 36 of 44 patients \((81.8\%)\) in group M \((P < 0.03\ by\ Fisher\ exact\ test)\) (Table 3).

DISCUSSION

The rationale for performing open cholecystectomy through a mini abdominal wall incision is to achieve some of the benefits attributed to laparoscopic cholecystectomy (LC), such as reduced morbidity, less pain, and shorter convalescence period, while using the resources and tools of a standard operating room and the skills of general surgeons with conventional training. In this way, the need for highly specialized human resources and expensive high-technology equipment may be obviated and the cost-effectiveness of healthcare services may be optimized. A large-scale retrospective study by Syrakos et al.\(^\text{13}\) showed reduced perioperative morbidity and a 75% reduction of total hospital cost with mini-laparotomy, compared with LC. A randomized, blinded trial by Ros et al.\(^\text{14}\) comparing laparoscopic versus mini-laparotomy cholecystectomy reported a higher rate of minor surgical complications, such as gallbladder perforation or a stone left in the abdomen in the LC group, but showed no difference in bile duct injury.

Our study showed that perioperative morbidity and clinical outcomes were comparable between the 2 groups. Operating room time was 35% shorter for mini-laparotomy compared with laparoscopic cholecystectomy, and this finding is consistent with reports from other major randomized trials,\(^\text{4,15}\) as preparation and testing of laparoscopic instruments adds about 10 minutes to the length of the procedure.\(^\text{16}\)

One criticism for our study can be that our operating room times are long, and seem to be below United States benchmarks, as some US centers report mean and median operating room times of 30 minutes or less for elective LC. However, the benchmarks established from performing elective LC in the United States may not necessarily be applicable to our situation. Greek patients usually delay seeking medical attention until symptoms of gallbladder disease become unbearable, or a severe exacerbation forces them to seek care urgently. As a result, most patients in our study had intraoperative findings of chronic cholecystitis, and therefore the laparoscopic procedure was technically challenging owing to scarring and adhesions. However, despite the technical challenges, our operating times, although long by United States benchmarks, are within the range reported in other studies, and shorter compared with a recent study from Sweden.\(^\text{14}\)

Another limitation of our study is related to hospital length of stay: although elective LC is often carried out as an outpatient in the United States, LC patients in our study stayed in the hospital for slightly over 2 days. However, the longer hospitalization in our study is due to valid logistic and demographic factors, which prevent us from discharging patients to home before the morning of the second postoperative day; as our hospital is a referral center for a large geographic area, our patients come from far away. As a result, factors such as limited transportation, societal expectations, and absence of an adequate support system at home force us to keep patients in the hospital longer, even after they are "ready for discharge" by North American standards.

Consequently, although we acknowledge that our length of stay and other outcomes can be improved, a number of valid factors prevent us from doing so. However, as these factors apply equally to both groups, improvements would be expected in both groups when these outside factors are addressed. Therefore, we believe that, despite these limitations, our conclusions derived from comparisons between groups are still valid.

Hospital stay was shorter in the LC compared with the mini-laparotomy group in our study. This finding is consistent with findings from some studies, yet the length of hospital stay remains a controversial issue, as contradicting results have been published, and there is no consensus in the literature.\(^\text{13,15}\)

With regards to convalescence, patients in the LC group used significantly lower amounts of analgesics and returned to normal activity significantly earlier after surgery in our study, a finding consistent with data in the literature.\(^\text{17}\)

Overall, pain medication consumption was small in our study. As time to resume normal activity may depend
on advice given to patients and their use of painkillers, our study could be criticized in that a more liberal analgesic regimen might expedite return to normal activity, so that the differences observed between groups could be smaller. However, as pain medications were administered on a PRN basis in our study, the frequency of pain medication requests and the amount of medications administered are influenced by cultural factors and by the availability of nursing personnel. In our hospital, nursing shortage can be an issue, especially at night, and may have influenced the amount of pain medications administered. However, any such influence should have affected both groups equally, and therefore should not affect the validity of our findings.

Patient expectations and societal norms are important additional factors influencing the use of analgesic medications. Our patients come mostly from a rural, agricultural background. In this culture, patients are still (although this is gradually changing) coming to surgery expecting to experience some pain. In addition, fear and misconceptions among patients and their families regarding pain medications may explain why the number of pain medication requests and of doses administered in our study is lower than it would be in the United States or other Western societies. However, any cultural influence on medication consumption should have affected both groups equally. Therefore we believe that, despite these shortcomings, our findings are still valid.

As far as the aesthetic result, our data show better aesthetic result in the LC Group, confirming that (at least in the short term) punctures from fine-caliber laparoscopic instruments are superior to small surgical incisions. However, data show no significant long-term difference between groups regarding the aesthetic result. 10 We do not report data on long-term aesthetic results in this study, but in our anecdotal experience there is no significant aesthetic difference between groups at 6 to 12 months. The lack of long-term follow-up data is a significant shortcoming of this study. However, because of the demographic characteristics of our population, it is very difficult to convince patients to come for follow-up visits after their acute problem is resolved, and therefore it was not feasible to collect and report long-term data.

Today, 25% to 30% of all cholecystectomy operations are performed open, either because they were scheduled as such from the beginning, or because a procedure scheduled as LC had to be converted to open. 16,19 Patients having the open procedure are generally older and sicker than patients having LC, and therefore are more likely to benefit from the advantages of the small-incision open procedure.

In conclusion, our study shows that open cholecystectomy through a mini-laparotomy is a safe, low-cost alternative to LC. The major advantage of mini-laparotomy cholecystectomy is versatility. It can be performed without high-technology equipment by surgeons not trained in laparoscopic surgery, thus accomplishing a significant hospital cost reduction. More prospective clinical trials are needed, however, to better define the relative merits of the 2 procedures. Valid data from trials examining the impact of these procedures on morbidity, mortality, and quality of life will help us make better decisions when treating individual patients.

REFERENCES