Advantages of Mini-laparoscopic vs Conventional Laparoscopic Cholecystectomy

Results of a Prospective Randomized Trial

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Hypothesis: The use of smaller instruments during laparoscopic cholecystectomy (LC) has been proposed to reduce postoperative pain and improve cosmesis. However, despite several recent trials, the effects of the use of miniaturized instruments for LC are not well established. We hypothesized that LC using miniports (M-LC) is safe and produces less incisional pain and better cosmetic results than LC performed conventionally (C-LC).

Design: A patient- and observer-blinded, randomized, prospective clinical trial.

Setting: A tertiary care, university-based hospital.

Patients: Seventy-nine patients scheduled for an elective LC who agreed to participate in this trial were randomized to undergo surgery using 1 of the 2 instrument sets. The criteria for exclusion were American Society of Anesthesiologists class III or IV, age older than 70 years, liver or coagulation disorders, previous major abdominal surgical procedures, and acute cholecystitis or acute cholelithiasis.

Intervention: Laparoscopic cholecystectomy performed with either conventional or miniaturized instruments.

Main Outcome Measures: Patients’ age, sex, operative time, operative blood loss, intraoperative complications, early and late postoperative incisional pain, and cosmetic results.

Results: Thirty-three C-LCs and 34 M-LCs were performed and analyzed. There were 8 conversions (24%) to the standard technique in the M-LC group. No intraoperative or major postoperative complications occurred in either group. The average incisional pain score on the first postoperative day was significantly less in the M-LC group (3.9 vs 4.9; \( P = .04 \)). No significant differences occurred in the mean scores for pain on postoperative days 3, 7, and 28. However, 90% of patients in the M-LC group and only 74% of patients in the C-LC group had no pain (visual analog scale score of 0) at 28 days postoperatively (\( P < .05 \)). Cosmetic results were superior in the M-LC group according to both the study nurse’s and the patients’ assessments (38.9 vs 28.9; \( P < .001 \), and 38.8 vs 33.4; \( P = .001 \), respectively).

Conclusions: Laparoscopic cholecystectomy can be safely performed using 10-mm umbilical, 5-mm epigastric, 2-mm subcostal, and 2-mm lateral ports. The use of mini-laparoscopic techniques resulted in decreased early postoperative incisional pain, avoided late incisional discomfort, and produced superior cosmetic results. Although improved instrument durability and better optics are needed for widespread use of miniport techniques, this approach can be routinely offered to many properly selected patients undergoing elective LC.

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The use of laparoscopy has gained widespread popularity in surgical approaches to abdominal wall hernias and intestinal and solid organ resection. However, no other operation has been as profoundly affected by the advent of laparoscopy as cholecystectomy. In fact, laparoscopic cholecystectomy (LC) has clearly become the procedure of choice for routine gallbladder removal. The advantages of this approach include decreased scarring, decreased incisional pain, shorter hospitalization, and faster functional recovery.\(^1\)\(^-\)\(^4\)

In recent years, many investigators have attempted to further improve on the established technique of LC. Generally, the goal has been to minimize the invasiveness of this procedure by reducing the number and, more commonly, the size of the operating ports and instruments.\(^5\)\(^-\)\(^7\) Although several recent trials from Europe and Asia\(^8\)\(^-\)\(^14\) provided level I data, the effects of the use of miniaturized instruments for LC are still not well established. In this article, we report the results of a prospective, randomized blinded trial that compared the safety, degree of postoperative pain, and cosmetic results of LC.
performed conventionally (C-LC) and using miniports (M-LC) (Figure 1).
Seventy-nine patients agreed to participate in this study and signed an informed consent document (Figure 2). Eight patients were excluded from the study after they were enrolled owing to an episode of acute cholecystitis (n = 6) and an intraoperative need for a common bile duct exploration (n = 2). Four additional patients (2 in each group) did not undergo an allocated treatment for logistical reasons. Thirty-three C-LCs and 34 M-LCs were performed; the patients in each group were of a similar age (41.8 ± 12.4 vs 46.7 ± 12.1 years, respectively; P = .16; t test) and sex (88% vs 76% women, respectively). The indications for surgery in both groups are summarized in Table 2. No significant difference occurred in the average operative time between C-LC and M-LC (54.9 ± 22.4 vs 50.5 ± 15.4 minutes; P = .33; t test). The average intraoperative blood loss was minimal (<30 mL) in both groups. An intraoperative cholangiogram was performed in 7 patients who had C-LC and 3 patients who had M-LC. There were 8 conversions (24%) to the standard technique in the M-LC group owing to inadequate grasping (n = 5), instrument bending (n = 1), large cystic duct (n = 1), and damage to the trocar (n = 1). These patients were excluded from the analysis of the degree of incisional pain and cosmesis. When the operative times between the groups were compared on an intent-to-treat basis (including patients who were converted to M-LC), there was still no significant difference (54.9 ± 22.4 vs 49.0 ± 17.3 minutes; P = .24; t test). Furthermore, as noted by the operating surgeons, M-LC instruments performed suboptimally in an additional 7 patients (20%). No intraoperative complications and no conversions to open cholecystectomy occurred in either group. One patient in the M-LC group was readmitted for vomiting and dehydration. Otherwise, there were no major postoperative complications in either group.

PAIN

The average pain scores in both groups are summarized in Table 3. Preoperative pain tolerance was equal between C-LC and M-LC groups (6.2 ± 2.3 vs 6.7 ± 1.9; P = .49; Wilcoxon rank sum test). The average pain score on the first postoperative day was significantly less in the M-LC group (3.9 ± 1.5 vs 4.9 ± 1.8; P = .04; Wilcoxon rank sum test). No significant differences occurred in the mean scores for postoperative incisional pain on postopera-

COSMESIS ASSESSMENT

Only 10-mm port sites were closed with absorbable subcuticular stitches. Steri-Strips (3M) were applied to all port sites. All incisions were covered by a small sterile dressing for 48 hours. The appearance of each incision was rated on a scale of 1 (worst) to 10 (best) at the 1-month follow-up visit by patients and by a study nurse blinded to the type of instruments used. The cosmesis score was the total of 4 incisions. Both (patient- and nurse-assigned) scores were recorded for each patient.

STATISTICAL ANALYSES

The data are expressed as mean ± SD unless specified otherwise. The sample size was calculated using the formulas de-

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tive day 3, 7, or 28. However, 90% of patients in the M-LC group and only 74% of patients in the C-LC group had no pain (VAS score of 0) at 28 days postoperatively (P = .05; Fisher exact test).

**COSMESIS**

Cosmetic results were superior in the M-LC group according to both the study nurse and the patients’ assessments. When assessed by a nurse, the mean scores were 38.9 ± 2.1 for the M-LC group and 28.9 ± 5.7 for the C-LC group (P < .001; Wilcoxon rank sum test). Similarly, when assessed by the patients, the mean cosmesis scores were 38.8 ± 1.7 and 33.4 ± 5.7, respectively (P = .001; Wilcoxon rank sum test).

<table>
<thead>
<tr>
<th>Pain</th>
<th>C-LC</th>
<th>M-LC</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain tolerance (preoperative)</td>
<td>6.2 ± 2.3</td>
<td>6.7 ± 1.9</td>
<td>.496</td>
</tr>
<tr>
<td>Postoperative day 1</td>
<td>4.9 ± 1.8</td>
<td>3.9 ± 1.5</td>
<td>.04</td>
</tr>
<tr>
<td>Postoperative day 3</td>
<td>2.8 ± 1.6</td>
<td>2.7 ± 2.0</td>
<td>.49</td>
</tr>
<tr>
<td>Postoperative day 7</td>
<td>1.8 ± 1.8</td>
<td>1.4 ± 1.7</td>
<td>.36</td>
</tr>
<tr>
<td>Postoperative day 28</td>
<td>0.6 ± 1.2</td>
<td>0.1 ± 0.3</td>
<td>.12</td>
</tr>
</tbody>
</table>

**COMMENT**

The main advantages of laparoscopic surgery include better cosmetic results, decreased postoperative pain, and faster functional recovery. Although it is unclear whether these benefits stem from a decreased need for retraction and dissection, lack of exposure of the viscera to room air, or smaller-access incisions, attempts to further improve surgical outcomes have resulted in a decrease of incision number and size. Modern technological advances have armed the surgeon with smaller-caliber laparoscopic instruments, better optics, and better light sources. Although successful use of the mini-laparoscopic technique for diagnostic purposes was reported as early as 1980, the smaller instruments have been used only recently in laparoscopic appendectomy, Nissen fundoplication, Heller myotomy, splenectomy, adrenalectomy, thoracic sympathectomy, and segmental colon resections.24-20

Most investigative trials evaluating mini-laparoscopic and standard laparoscopic techniques have used LC as their procedure for comparison. After the feasibility and potential benefits of M-LC were established in small series, several prospective randomized trials outside the United States produced mixed results (Table 4). In this first prospective, randomized blinded trial conducted in the United States, we evaluated the safety and outcomes of LC performed with smaller epigastric, substomal, and lateral ports.

Decreased incisional pain is a well-established benefit of laparoscopic surgery. However, the direct link between further reduction in the size of access incisions and decreased pain has not been confirmed, probably because of the multifactorial etiology of incisional pain. Nevertheless, several investigators demonstrated that using smaller incisions decreases postoperative pain. Cheah et al reported in a prospective randomized trial that using three 2-mm instead of three 5-mm trocars significantly reduced postoperative pain scores and analgesic requirements after LC. Similarly, Bisgaard et al found reduced incisional pain at smaller port sites 6 hours postoperatively. The authors also reported decreased total pain scores during the first postoperative week, but mean scores at 1 week were not significantly different. Our study found an early reduction in pain scores in the mini-laparoscopic group. Although we did not document analgesic requirements, VAS scores were significantly lower in the M-LC group on the first postoperative day. Statistically significant differences in pain scores were not seen at other time points in our trial. However, we discovered that a significantly larger proportion of patients in the M-LC group were completely free of incisional pain 1 month postoperatively. Almost a quarter of the patients in the C-LC group had some residual, albeit minor, incisional discomfort. The clinical significance of this late finding is not clear and may be of value to only a small group of patients.

The use of smaller-access incisions has also been suggested to result in minimal scarring and better cosmesis. However, the evaluation of postoperative cosmetic results is challenged by the absence of a reliable objective scale. The combination of multiple contributing factors, potential observer bias, and variations in patients’ expectations contributes to difficulties in assessing cosmetic results. To minimize bias in our assessment of cosmetic results, we used both patients and blinded observers to evaluate postoperative scars. The comparison between the groups was performed separately for both patient- and study nurse–derived scores. In our series, we observed that both patients and blinded observers scored mini-laparoscopic wounds significantly better with regard to cosmetic appearance. Similar cosmetic benefits were reported by other prospective trials. Although the clinical relevance of differential scarring after smaller incisions is debatable in the medical literature, a small cosmetic benefit may be psychologically important to some patients undergoing LC.

Prolonged surgical times often limit implementation of new technologies. Using small instruments in our study did not result in increased duration of the operations. Regardless of the port size, our patients experienced uncomplicated operations with minimal blood loss and same-day discharges. Similarly, other investigators reported no significant increase in operative times when mini-laparoscopic techniques were used. In contrast, Huang et al reported greater operative times in a prospective randomized trial of C-LC and M-LC techniques. However, this finding occurred only when they used a challenging setup with one 10-mm and three 2-mm ports. Prolonged operative times were not seen when a 5-mm port was substituted for the 2-mm port in the epigastrium. Overall, the preponderance of evidence establishes that M-LC techniques do not result in longer
operative times for routine LC. In addition, the use of smaller instruments did not prevent us from performing intraoperative cholangiograms in selected patients. Intraoperative conversions from M-LC to both C-LC and open cholecystectomy have been reported in as many as 23% to 38% of patients. The most common factor contributing to conversions is the presence of chronic cholecystitis with a markedly inflamed, thickened gallbladder and dense adhesions. Grasping and manipulating the gallbladder in this circumstance may be extremely difficult and may lead to damage of graspers and trocars. In addition, smaller-diameter laparoscopes remain inferior in resolution and clarity when compared with standard laparoscopes. Such “instrument failures” in our series occurred in 24% of patients. We discovered that in addition to a thick gallbladder wall, a thick abdominal wall may be a limiting factor as well. It is plausible that with the development of stronger, more durable instruments and better optics and light sources, fewer conversions from M-LC will be necessary. Nevertheless, a conversion from M-LC to C-LC is not a failure by any means. Since the mean operative time of both groups was similar when compared on both intent-to-treat and treatment-rendered bases, conversions from M-LC to C-LC did not prolong the operative times in our series. This may, however, be attributed to timely decisions by experienced laparoscopic surgeons to convert to C-LC in our trial, avoiding prolonged, futile, and possibly unsafe attempts to complete procedures with miniports. Thus, a planned M-LC should be abandoned either after identification of significant right upper quadrant inflammation or scarring on initial diagnostic exploration or when significant limiting factors in anatomical dissection are encountered. In the latter circumstance, the conversion would merely entail up sizing lateral trocars and should not be delayed.

In conclusion, LC can be safely performed using 10-mm umbilical, 5-mm epigastric, 2-mm subcostal, and 2-mm lateral ports. The use of mini-laparoscopic techniques resulted in decreased early postoperative incisional pain and was more likely to result in the absence of complications.

### Table 4. Results of Prospective Randomized Trials Comparing M-LC and C-LC

<table>
<thead>
<tr>
<th>Source</th>
<th>Country</th>
<th>No. of Patients</th>
<th>Ports, mm*</th>
<th>Operating Time</th>
<th>Pain in M-LC</th>
<th>Cosmesis in M-LC</th>
<th>Conversion From M-LC, No. (%)</th>
<th>Additional Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schwenk et al, 2000</td>
<td>Germany</td>
<td>M-LC: 25</td>
<td>5-5-2-2</td>
<td>Equal</td>
<td>No difference</td>
<td>Superior</td>
<td>1 (4)</td>
<td>No difference in pulmonary function, less pain with coughing</td>
</tr>
<tr>
<td>Cheah et al, 2001</td>
<td>Singapore</td>
<td>C-LC: 25</td>
<td>10-10-5-5</td>
<td>Equal</td>
<td>Decreased</td>
<td>NA</td>
<td>5 (14)</td>
<td>Similar oral analgesic requirements</td>
</tr>
<tr>
<td>Look et al, 2001</td>
<td>Singapore</td>
<td>C-LC: 38</td>
<td>10-5-5-5</td>
<td>NA</td>
<td>Decreased</td>
<td>NA</td>
<td>7 (25)</td>
<td>Similar functional recovery</td>
</tr>
<tr>
<td>Alponat et al, 2002</td>
<td>Turkey</td>
<td>C-LC: 36</td>
<td>10-5-5-5</td>
<td>Equal</td>
<td>No difference</td>
<td>Superior</td>
<td>5 (23)</td>
<td>Randomization after laparoscopic examination M-LC is a “feasible alternative”</td>
</tr>
<tr>
<td>Bisgaard et al, 2002</td>
<td>Denmark</td>
<td>M-LC: 25</td>
<td>10-10-5-5</td>
<td>Equal</td>
<td>No difference</td>
<td>Superior</td>
<td>4 (16)</td>
<td>M-LC is “feasible”</td>
</tr>
<tr>
<td>Sarli et al, 2003</td>
<td>Italy</td>
<td>M-LC: 67</td>
<td>3-3-3-3</td>
<td>Equal</td>
<td>Decreased</td>
<td>Superior</td>
<td>Not reported</td>
<td>M-LC enhances the advantages of laparoscopy</td>
</tr>
<tr>
<td>Ainslie et al, 2003</td>
<td>United Kingdom</td>
<td>C-LC: 68</td>
<td>10-5-5-12</td>
<td>Equal</td>
<td>No difference</td>
<td>NA</td>
<td>3 (14)</td>
<td>Reduced use of parenteral analgesia. No difference in immune response, pulmonary function, or quality of life</td>
</tr>
<tr>
<td>Huang et al, 2003</td>
<td>Hong Kong</td>
<td>C-LC: 19</td>
<td>10-10-5-5</td>
<td>Increased</td>
<td>Decreased</td>
<td>No difference</td>
<td>5 (17)</td>
<td>“No reason for M-LC to become universally accepted”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-LC: 25</td>
<td>10-2-2-2</td>
<td>Equal</td>
<td>No difference</td>
<td>Equal</td>
<td>1 (3)</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** C-LC, laparoscopic cholecystectomy performed conventionally; M-LC, laparoscopic cholecystectomy performed using miniports; NA, not applicable.

*Umbilical, epigastric, subcostal, and lateral ports.
†The 12-mm port is in the left upper quadrant.
of late incisional discomfort when compared with conventional LC. In addition, smaller-access incisions resulted in superior cosmetic results according to both patients and blinded observers in this trial. Although improved instrument durability and better optics are needed for widespread use of miniport techniques, this approach can be routinely offered to many properly selected patients undergoing elective LC.

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REFERENCES