Clinical Science

Laparo-endoscopic single site cholecystectomy versus standard laparoscopic cholecystectomy: results of a pilot randomized trial

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Abstract

BACKGROUND: In recent years, new devices providing multiple channels have made the performance of laparoscopic cholecystectomy through a single access site not only feasible but much easier. The potential benefits of laparoendoscopic single-site (LESS) cholecystectomy may include scarless surgery, reduced postoperative pain, reduced postoperative length of stay, and improved postoperative quality of life. There are no comparative data between LESS cholecystectomy and standard laparoscopic cholecystectomy (LC) available at present with which to quantify these benefits.

METHODS: This study was a prospective, randomized, dual-institutional pilot trial comparing LESS cholecystectomy with standard LC. The primary end point was postoperative quality of life, measured as length of hospital stay, postoperative pain, cosmetic results, and SF-36 questionnaire scores. Secondary end points included operative time, conversion to standard LC, difficulty of exposure, difficulty of dissection, and complication rate.

RESULTS: No significant differences in postoperative lengths of stay were found in the two groups. Postoperative pain evaluation using a visual analogue scale showed significantly better outcomes in the standard LC arm on the same day of surgery ($P = 0.041$). No differences in postoperative pain were found at the next visual analogue scale evaluation or in the postoperative administration of pain-relieving medications. Cosmetic satisfaction was significantly higher in the LESS group at 1-month follow-up (mean, 94.5 ± 9.4% vs 86 ± 22.3%; median, 100% vs 90%; $P = .025$). Among the 8 scales of the SF-36 assessing patients’ physical and mental health, scores on the Role Emotional scale were significantly better in the LESS group (mean, 80.05 ± 29.42 vs 68.33 ± 25.31; median, 100 vs 66.67; $P < .0001$).

CONCLUSIONS: In this pilot trial, LESS cholecystectomy resulted in similar lengths of stay and improved cosmetic results and SF-36 Role Emotional scores but performed less well on pain immediately after surgery. A larger multicenter trial is needed to confirm and further investigate these results.

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KEYWORDS:
Laparoendoscopic single-site surgery; LESS; Single-incision laparoscopic cholecystectomy; Laparoscopic cholecystectomy; Single-port access cholecystectomy; SPA

Currently, the 4-port approach to laparoscopic cholecystectomy (LC) is the gold-standard treatment for gallstones. Recently, laparoendoscopic single-site (LESS) cholecystectomy was demonstrated to be feasible.$^{1-19}$ Its potential benefits may include improved cosmetic results, reduced post-
operative pain, reduced postoperative lengths of stay (LoS), and improved postoperative quality of life (QoL). On the other hand, there are concerns regarding whether the LESS approach is safe, how much the quality of exposure and dissection might be impaired with this approach, and whether there are differences in operating time and conversion rate. There are no comparative data between LESS cholecystectomy and standard LC available with which to quantify these benefits and concerns. A pilot trial was conducted to detect any difference between LESS cholecystectomy and standard LC, obtaining information on the power and sample size needed for a planned multicenter randomized controlled trial (RCT).

Methods

Study design

This study was a prospective, randomized, dual-institution pilot trial comparing 20 LESS cholecystectomy with 20 standard LC procedures. The ethics committee of both institutions approved the study protocol. Participation in this study was offered to all patients fitting the selection criteria reported in Table 1, undergoing LC at the departments of surgery of Bianchi Melacrin Morelli Hospital in Reggio Calabria and Monaldi Hospital in Naples, from April 2009 to June 2009. The study was concluded 1 month after the last cholecystectomy was performed (1-month follow-up) to assess postoperative QoL.

Randomization was performed preoperatively, and stratification was performed intraoperatively, after visualization of the operative field. Patients were randomized to 1 of 2 groups: LESS cholecystectomy or standard LC. Patients were stratified into 3 groups, Nassar grades I, II, and III, according to the grade of difficulty of cholecystectomy (Nassar score) assessed at the initial inspection of the operating field (Table 2).

Patients did not know the treatment received until their discharge. A large drape was used to cover the abdomen after surgery, thus hiding the surgical wounds.

All operations were performed by 2 highly skilled laparoscopic surgeons (1 at each institution) with >15 years of experience in advanced laparoscopic surgery and Transanal Endoscopic Microsurgery (TEM).

Difficulty (impaired) of exposure and difficulty of dissection were assessed subjectively by the operating surgeon and scored from 1 (“no difficulties”) to 4 (“most difficult,” with need for conversion).

Perioperative care was similar in all patients and at both institutions. An independent physician assessed the patient postoperatively. Postoperative pain was evaluated using a visual analogue scale (VAS) ranging from 1 (“least pain”) to 10 (“most pain”) on the day of surgery, on postoperative days 1 and 2 (discharge), and at 1-month follow-up. Pain was also deduced from the consumption of pain-relieving medications. Patients received pain medications only on demand, and these were administered in incremental strength beginning with peripheral analgesics as nonsteroidal antirheumatic agents.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Inclusion and exclusion criteria for entry into the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion</td>
<td>Inclusion</td>
</tr>
<tr>
<td>Age (y)</td>
<td>18–75</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>≤30</td>
</tr>
</tbody>
</table>

Previous surgery/adhesions: No surgery, lower GI surgery, pelvic surgery.

Clinical US findings: Gallstones, acute cholecystitis, bile duct stones, pancreatitis.

ASA score: I–III, >III

Nassar grade: I–III, IV

ASA = American Society of Anesthesiologists; BMI = body mass index; GI = gastrointestinal.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Difficulty grading for laparoscopic cholecystectomy, Nassar classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nassar grade</td>
<td>Gallbladder</td>
</tr>
<tr>
<td>Grade I</td>
<td>Floppy, nonadherent</td>
</tr>
<tr>
<td>Grade II</td>
<td>Mucocele</td>
</tr>
<tr>
<td>Grade III</td>
<td>Deep fossa, Acute cholecystitis</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Contracted, Fibrous Hartman’s pouch adherent to common bile duct or with stone impaction</td>
</tr>
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<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

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Individual satisfaction for cosmetic results was evaluated using a VAS ranging from 0% (“the worst result”) to 100% (“the best result”). Cosmetic results were also evaluated by measuring the length of umbilical incision at the end of the operation in both study groups. The incision length was measured after gallbladder removal (during standard LC, the incision may be enlarged to allow the passage of thick gallbladder or bigger stones).

QoL was further assessed at postoperative month 1 using the SF-36 questionnaire.

Objectives and end points

The objectives of the study were the assessment of possible differences between LESS cholecystectomy and standard LC and the definition of an optimal sample size for a multicenter RCT.

Postoperative QoL was the primary end point and was assessed analyzing as LoS, postoperative pain, cosmetic results, and SF-36 questionnaire scores.

Secondary end points included operative time, conversion to standard LC, difficulty of exposure, difficulty of dissection, and complication rate.

Data collection

The following data were collected in a database:

- Demographics: age, gender, American Society of Anesthesiologists score, and body mass index
- Indication
- Nassar grade (I–III; grade III was included when there was no sign of acute cholecystitis)
- Procedure: operation (LC or LESS cholecystectomy), operating time, intraoperative complications, difficulty of exposure, difficulty of dissection, conversion to open or standard LC (yes or no), reason for conversion, and length of skin incision
- Postoperative results: LoS; postoperative pain VAS I, II, or III; pain-relieving medication I, II, or III (yes or no); postoperative complications; and cosmetic result VAS I
- 30-day follow-up: postoperative pain VAS IV, cosmetics VAS II, and SF-36 score

Technique

Standard LC. The patient lies in a supine position, with the surgeon standing between the legs (the French position). A 12-mm cannula is inserted under direct view (“open laparoscopic” technique) through an umbilical incision. The operative field is inspected, and the grade of difficulty of cholecystectomy is assessed according to the Nassar scoring system. Three more cannulas are introduced: one 12 mm (upper left quadrant) and two 5 mm (right flank on the midline and below the xiphoid). LC is performed, according to surgeon’s preference, with either high-frequency or ultrasonic energized dissection, standard or fundus-first gallbladder dissection, closure of the artery by ligature or clip or ultrasonically, and closure of the cystic duct by ligature or clip. The gallbladder is removed with a retrieval bag. Removal of a gallbladder containing larger stones required the enlargement of the umbilical incision; smaller stones were extracted one by one before gallbladder withdrawal in order not to widen the skin incision.

LESS cholecystectomy. The TriPort (Olympus America, Center Valley, PA) is a sterile, disposable endoscopic multi-instrument access port that allows abdominal incision retraction, maintaining pneumoperitoneum, and specimen removal. It consists of a polymeric film retractor sleeve and a removable boot section with 3 legs (one 12 mm and two 5 mm), each containing a gel valve. An introducer is used to deploy the TriPort device (Fig. 1).

The TriPort device is inserted at the navel site through an approximately 20 mm skin and fascia incision. The device is delivered into the peritoneal cavity by the introducer with an open laparoscopic technique.

The procedures were carried out with the chip-on-the-tip 5-mm EndoEYE video endoscope connected to a high-definition imaging system (Olympus America). After exploration, the difficulty of the endoscopic procedure is scored according to Nassar grade.

Two working instruments (a grasper and an energized device) are used. The placement of a further cannula to enhance exposure or dissection was considered a conversion to standard laparoscopy. The use of 1 needleseoscopic grasper (1.8–3 mm in diameter) to provide a clearer view of the operating field (instead of a transfixed stay suture for gallbladder traction by fixing its fundus to the abdominal wall) was not considered a conversion.

Gallbladder dissection is accomplished either after preparation of the cystic duct and artery (Strasberg critical view) or with a fundus-first technique, by high-frequency hook/scissors or ultrasonic shears. The cystic artery is either divided between clips or closed or divided by ultrasound. The duct is always secured with a titanium or absorbable clip.

The gallbladder was removed with or without a retrieval bag. In the case of smaller stones, the gallbladder was removed through the TriPort sleeve, avoiding abdominal wall contamination.

Randomization

Randomization was performed preparing 2 sets of 20 numbered, opaque, sealed envelopes, with the envelopes of each set containing indications for 10 LESS cholecystectomy procedures and 10 standard LC procedures. One set of envelopes was kept at Bianchi Melacrinco Morelli Hospital and the other at Monaldi Hospital. The envelopes were opened in numeric order for each patient by an assistant not involved in the surgical operations, right before surgery.
The surgeons performed standard LC or LESS cholecystectomy as indicated on the sheet inside the envelope.

Sample size

The primary end point was QoL, measured as a combination of LoS, postoperative pain, cosmetic results, and SF-36 questionnaire results. The hypothesis was that LESS cholecystectomy improves QoL and cosmetic results and reduces postoperative pain and LoS. Results for VAS pain, VAS cosmetics, incision length, LoS, and SF-36 scores were compared; therefore, the standardized difference could vary. Altman nomograms were used to calculate the presumed sample size of an actual RCT, arbitrarily assuming a most likely small standardized difference (.3). With a significance criterion set at .05, using a 2-tailed test, the number of patients per group required for 90% power was about 500. Therefore, it was decided to carry on this pilot trial, enrolling 40 patients (20 each group), to assess differences in any of the end points and tailoring the sample size of the scheduled larger multicenter RCT accordingly.

Data analyses

Data were analyzed using XLSTAT version 2009/5/1 (Addinsoft, New York, NY). An “intent-to-treat” analysis was performed.

Patient demographics across treatment groups were compared using $\chi^2$ tests for categorical measures and $t$ tests for continuous data. Mann-Whitney $U$ tests were used to compare LoS, postoperative pain VAS, cosmetics VAS, length of skin incision, 8 parameters of the SF-36 questionnaire, operating time, difficulty of exposure, and difficulty of dissection in the 2 arms. Chi-square tests were used to compare conversion rate and the administration of pain medication, which was dichotomized as yes or no, in the 2 arms. All variable were significant at $P < .05$. Logistic model results are reported as odds ratios, 2-sided 95% confidence intervals, and $P$ values.

Results

Patient population

Overall, 40 patients were recruited for entry into this pilot trial at the 2 institutions. During the period of study, a further 53 patients entered the departments of surgery of the 2 institutions to undergo cholecystectomy but were not recruited because they did not meet the selection criteria (Table 1). The 2 leading surgeons at the 2 institutions performed all operations. A total of 20 patients were en-
rolled in the LESS cholecystectomy arm and 20 patients in the standard LC arm.

Demographic and intraoperative data

Table 3 shows the patients’ data in each arm. Patient demographics, including age, gender, American Society of Anesthesiologists score, and body mass index were comparable between groups. The only intraoperative parameter considered in this study, the Nassar score for grading the difficulty of LC, was not statistically different between groups. According to this scoring system, 5 of 20 patients in the LC group and 6 of 20 patients in the LESS cholecystectomy group were scored grade III for the presence of adhesions or unclear anatomy. No cases enrolled in this study were scored as Nassar grade IV and therefore excluded.

Table 3  Demographics and intraoperative data for the patients enrolled in the study

<table>
<thead>
<tr>
<th>Variable</th>
<th>LC</th>
<th>LESS cholecystectomy</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>50 (24–67)</td>
<td>45 (26–63)</td>
<td>NS</td>
</tr>
<tr>
<td>Men/women</td>
<td>6/14</td>
<td>6/14</td>
<td>NS</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27 (18–30)</td>
<td>25 (18–29)</td>
<td>NS</td>
</tr>
<tr>
<td>ASA score I/II/III</td>
<td>4/12/4</td>
<td>5/14/1</td>
<td>NS</td>
</tr>
<tr>
<td>Nassar grade*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>4</td>
<td>3</td>
<td>NS</td>
</tr>
<tr>
<td>II</td>
<td>11</td>
<td>11</td>
<td>NS</td>
</tr>
<tr>
<td>III</td>
<td>5</td>
<td>6</td>
<td>NS</td>
</tr>
</tbody>
</table>

Data are expressed as median (range) or as numbers. ASA = American Society of Anesthesiologists; BMI = body mass index.

*Grade of difficulty in performing cholecystectomy, according to the Nassar scoring system.

Table 4  Primary end points and results

<table>
<thead>
<tr>
<th>End point</th>
<th>LC</th>
<th>LESS cholecystectomy</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>LoS (d)</td>
<td>2.65, 2 (2–9)</td>
<td>2.5, 2 (2–7)</td>
<td>NS</td>
</tr>
<tr>
<td>Postoperative pain (VAS score)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I*</td>
<td>3.15, 2.5 (0–9)</td>
<td>3.75, 3.5 (1–9)</td>
<td>.041</td>
</tr>
<tr>
<td>II†</td>
<td>2.25, 2 (0–9)</td>
<td>2.55, 2 (0–8)</td>
<td>NS</td>
</tr>
<tr>
<td>III‡</td>
<td>.1, 0 (0–7)</td>
<td>1.35, .5 (0–7)</td>
<td>NS</td>
</tr>
<tr>
<td>IV§</td>
<td>.3, 0 (0–5)</td>
<td>.6, 0 (0–8)</td>
<td>NS</td>
</tr>
<tr>
<td>Pain-relieving medications (yes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I*</td>
<td>16</td>
<td>17</td>
<td>NS</td>
</tr>
<tr>
<td>II†</td>
<td>4</td>
<td>5</td>
<td>NS</td>
</tr>
<tr>
<td>Cosmetic results (VAS score)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I*</td>
<td>75%, 80% (0%–100%)</td>
<td>83.5%, 85% (60%–100%)</td>
<td>NS</td>
</tr>
<tr>
<td>II‡</td>
<td>86%, 90% (0%–100%)</td>
<td>95.5%, 100% (70%–100%)</td>
<td>.025</td>
</tr>
<tr>
<td>Skin incision (mm)*</td>
<td>14.31, 14 (10–23)</td>
<td>18.8, 19 (13–25)</td>
<td>.002</td>
</tr>
</tbody>
</table>

Data are expressed as mean, median (range).

*Day of surgery.
†Postoperative day 1.
‡Postoperative day 2.
§At 1-month follow-up.
| Skin incision (mm)*         | 14.31, 14 (10–23) | 18.8, 19 (13–25)   | .002|
| QoL (SF-36 score)           |               |                       |     |
| Physical Activity           | 89.75, 92.5 (60–100) | 89.25, 87.5 (75–100) | NS  |
| Role Physical               | 66.25, 75 (0–100)  | 70.5, 75 (0–100)     | NS  |
| Physical Pain               | 72.85, 74 (31–100)  | 75.4, 74 (31–100)    | NS  |
| General Health              | 79.2, 82 (25–100)  | 84.3, 92 (42–100)    | NS  |
| Vitality                    | 69.25, 75 (40–85)   | 70.75, 65 (45–100)   | NS  |
| Social Activities           | 77.5, 75 (50–100)  | 77.5, 75 (25–100)    | NS  |
| Role Emotional              | 68.33, 66.67 (0–100) | 80.05, 100 (0–100)  | .001|
| Mental Health               | 78, 80 (44–96)     | 81, 80 (64–100)      | NS  |

LoS

No differences were found in the 2 groups; a patient undergoing standard LC converted to laparotomy and a patient undergoing LESS cholecystectomy with postoperative blood collection in the infrahepatic space were discharged on postoperative days 9 and 7, respectively. LoS ranged in all other patients from 1 to 4 days (Table 4).

Postoperative pain

Pain evaluation by VAS showed a significant better outcome in the standard LC arm on the same day of surgery (P = .041). Nevertheless, the number of patients in the 2 arms who required pain-relieving medications did not differ: the increased pain in the LESS cholecystectomy arm did not influence perioperative management (Table 4).
Cosmetic results

Cosmetic satisfaction was significantly higher in the LESS cholecystectomy group at 1-month follow-up. In contrast, the umbilical incisions were significantly shorter in the LC group. Differences in navel incision length were found when analyzing the data from the 2 participating institutions, being longer in patients operated on at Monaldi Hospital (average, 21.1 ± 2.55 vs 16.5 ± 2.67 mm). No differences were found in the VAS evaluation results at the 2 institutions (Table 4).

QoL

There were no differences in the 4 physical health scales of the SF-36 questionnaire at 30-day follow-up. Among the 4 scales assessing patients’ mental health, the Role Emotional scale scores were significantly better in the LESS cholecystectomy group (P < .0001; Table 4).

Secondary end points

Results for secondary end points are shown in Table 5. A significant difference (in favor of standard LC) was found in operating time between the 2 groups (P < .0001). The operating time was shorter for the operations performed at Monaldi Hospital (average, 59 ± 12.4 vs 94.5 ± 16.7 minutes). Exposure was significantly more difficult in the LESS cholecystectomy group (P = .004), while no statistically significant differences were found for difficulty of dissection. No conversion happened in the LESS cholecystectomy group, but the insertion of a needlescopic grasper was requested in 2 patients to enhance the exposure. One conversion to open surgery was necessary in a patient in the standard LC group. No significant difference in complication rate (intraoperative and postoperative) was found between the 2 groups. A blood collection occurred in a patient in the LESS cholecystectomy group and was treated conservatively with a longer LoS (7 days). Intraoperative complications in the LC arm occurred in 3 patients: 2 bleedings from the epigastric trocar site and 1 partial avulsion of a short cystic duct from the common bile duct, the first controlled intraoperatively and the latter requiring conversion to open surgery for a safe repair. The postoperative course in this case was uneventful, but the LoS was longer than the average (9 days). No wound infection or healing complication of laparoscopic or single-site incisions was seen at follow-up.

Comments

No RCT has been reported comparing LESS cholecystectomy with standard LC. Observational and retrospective studies have indicated that a LESS approach may improve the outcomes of LC by affecting postoperative pain, cosmetic results, and overall postoperative QoL.15,16,19,22

The hypothesis of this study was that LESS cholecystectomy is not only a feasible procedure but would have better QoL outcomes compared with standard LC.

Among the primary end points, we found differences, somewhat controversial, in postoperative pain, cosmetic results, and the Role Emotional scale of the SF-36 instrument. We were unable to prove that postoperative pain was diminished in the LESS cholecystectomy group; in fact, this randomized trial demonstrated that pain on the day of surgery was higher in this group of patients (mean, 3.80 ± 1.85 vs 3.15 ± 1.9; median, 3.5 vs 2.5; P = .041). In contrast, even though the umbilical skin incisions were significantly longer in LESS cholecystectomy patients (mean, 18.8 ± 3.47 vs 14.31 ± 4.14 mm; median, 19 vs 14 mm; P = .002), cosmetic satisfaction was higher among these patients (mean, 94.5 ± 9.4% vs 86 ± 22.3%; median, 100% vs 90%; P = .025).

No differences were seen on SF-36 scales except for the Role Emotional scale, which had significantly better scores in the LESS cholecystectomy arm (mean, 80.05 ± 29.42 vs 68.33 ± 25.31; median, 100 vs 66.67; P < .0001).

There is a trend to replace LC with procedures that may further minimize its invasiveness. Prerequisites are similar safety while achieving better postoperative QoL.

The natural orifice transluminal endoscopic surgical approach to cholecystectomy seems to reduce postoperative pain but requires access through internal viscera or structures that have no direct relations to the targeted organ, thus posing ethical issues and criticisms. Furthermore, almost no “pure” natural orifice transluminal endoscopic surgical cholecystectomy procedures have been reported in human beings, with most of these procedures being hybrid operations.

Table 5  Secondary end points and results

<table>
<thead>
<tr>
<th>End point</th>
<th>LC</th>
<th>LESS cholecystectomy</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty of exposure*</td>
<td>1.5, 1 (1–4)</td>
<td>2.2, 2 (1–3)</td>
<td>.004</td>
</tr>
<tr>
<td>Difficulty of dissection*</td>
<td>1.55, 1 (1–4)</td>
<td>2, 2 (1–3)</td>
<td>NS</td>
</tr>
<tr>
<td>Operating time (min)</td>
<td>48.25, 35 (15–280)</td>
<td>76.75, 75 (45–115)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Conversion rate</td>
<td>1/20</td>
<td>None</td>
<td>NS</td>
</tr>
</tbody>
</table>

Data are expressed as mean, median (range).
*Subjective surgeon’s evaluation scoring system (increasingly higher difficulty from 1 to 4).
accomplished by placing 1 or 2 trocars through the abdominal wall to enhance exposure or surgical maneuvers.\textsuperscript{23,24}

The umbilicus is an existing scar on the abdominal wall and may be an optimal route to the peritoneal cavity for a LESS access device. This results in a nearly invisible scar shortly after the patient’s discharge.\textsuperscript{3,13,20} In contrast to natural orifice transluminal endoscopic surgery, LESS procedures can be easily converted to standard laparoscopy if deemed necessary, without the need to repair internal viscera or other access pathways.\textsuperscript{25,26}

Most likely, postoperative pain, which was higher in the LESS cholecystectomy group on the day of surgery, is strictly related to the length of the umbilical incision and seems not to be influenced by the other smaller incisions of the standard laparoscopic approach. The correlation between the length of the umbilical incision and postoperative pain was further investigated by comparing VAS results in patients with \( \geq 20 \)-mm incisions with those in patients with \(<20\)-mm incisions. In 10 of 20 LESS cholecystectomy patients, the incisions were \( \geq 20 \) mm, and the mean postoperative pain on day of surgery was 4.3, compared with 2.6 in LESS cholecystectomy patients with \(<20\)-mm incisions. In the LC group, in which only 4 patients had umbilical incisions \( \geq 20 \) mm, the mean VAS result of postoperative pain on the day of surgery was 3.15. Notwithstanding the results of VAS evaluation on day of surgery, the number of patients requiring pain-relieving medications did not differ between the 2 groups. The explanation for this is that the level of pain was considered relatively low by almost all patients in both groups.

Even though the umbilical incisions were longer in the LESS arm, cosmetic satisfaction was significantly higher among these patients. This may be because at 1-month follow-up, the umbilical scar is nearly invisible, and the presence of 3 more scars in the standard LC group affected the final cosmetic results.

The SF-36 instrument for QoL assessment includes scales dealing with physical and mental health. At 1-month follow-up, physical health was similar in the 2 groups. Only 1 scale showed a significant difference: the Role Emotional component of mental health. This parameter measures the extent to which emotional problems interfere with work or other daily activities, including decreased time spent on activities, accomplishing less, and not working as carefully as usual. It could only hypothesized that this finding is related to the patient perception of his health status after surgery. It is likely that when there are no visible scars, patients’ emotions interfere less with work or daily activities. Patients were not aware of the treatment received until their discharge. Knowledge of having been enrolled in a new experimental group with expected better results could have influenced the improved satisfaction and QoL only after discharge. Larger studies may clarify whether this was a true bias or not.

In this study, a baseline SF-36 questionnaire was not completed before surgery. One may consider this point as a study weakness. Nevertheless, we believe that a baseline assessment is strongly required when the effectiveness of a given treatment is studied. In this study a new approach (LESS cholecystectomy) was evaluated, not the treatment itself, by comparing it with the standard LC approach. Our results show that demographics were similar in both study groups: it is unlikely that significant differences in QoL were present in the 2 arms before surgery.

A true bias in this study was the evaluation and comparison of operating time between the 2 study groups. Surgeons performing the operations at both participating institutions were highly experienced in standard laparoscopy but were still in the LESS learning-curve phase. Operating time dropped from an average 94 minutes in the first 5 procedures to 75 minutes in the last 5 procedures, showing a progressive decrease over time and the number of procedures performed.

There was a correlation between operating time and the length of the umbilical incision: the wider the incision, the less the operating time. This is explained by the features of the access device used in this study. The TriPort consists in a soft polymeric sleeve that adapts itself to both the thickness of the abdominal wall and the width of the parietal incision. The wider the incision, the more the freedom in instrument handling. This is particularly true when straight instruments are used to accomplish the operation. This correlation may explain the differences of data between the 2 participating institutions: at Monaldi Hospital, there were wider umbilical incisions and decreased operating time, and at Bianchi Melacrinio Morelli Hospital, there were shorter umbilical incisions and longer operating time.

The LESS working environment is challenging and makes the overall ergonomics of cholecystectomy fair, caused by physical constraints and lack of triangulation.\textsuperscript{27,28} New deflectable or preshaped curved instruments, spring technology, and new alloys\textsuperscript{29} will enhance LESS ergonomics by providing effective gallbladder and liver traction. This study was carried out using standard straight laparoscopic instruments, because at that time, no preshaped curved instrument was available at the 2 participating institutions.

This study showed that exposure of the operating field in the LESS arm was significantly impaired compared with the LC arm \((P = .004)\).

In the future, especially dedicated platforms and the combination with robotic technology could enhance the overall ergonomics of LESS, providing a clearer view of the operating field and more degrees of freedom of surgical instruments.\textsuperscript{30–33}

With a morbidity rate not different from that of standard LC, LESS cholecystectomy was safe in this study. Our results show that LESS cholecystectomy QoL data are controversial: cosmetic results and SF-36 Role Emotional scores improved, no differences were found for LoS, and early postoperative pain was higher, but no impact on the need for pain-relieving medications was found. There might
be concerns regarding the learning curve for LESS cholecystectomy. These data are preliminary, and further investigation with larger studies is needed.

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References