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One, Two, or Three Ports in Laparoscopic Cholecystectomy?

Jaime Manuel Justo-Janeiro[1,2], Gustavo Theurel Vincent[1], Fernando Vázquez de Lara[2], René de la Rosa Paredes[1], Eduardo Prado Orozco[1], Luis G. Vázquez de Lara[2]

[1]*Department of Surgery, General Hospital of Puebla "Dr. Eduardo Vázquez Navarro," Puebla, Mexico*

[2]*Faculty of Medicine, Benemérita Universidad Autónoma de Puebla, Puebla, Mexico*

Single-port laparoscopic cholecystectomy (LC) has been compared with 3- or 4-port LC. To our knowledge, there are no studies comparing the 3-, 2-, and 1-port techniques. Patients were randomized into 3 groups: LC 1-port using SILS, LC 2-port using a laparoscope with a working channel, and LC 3-port using the standard ports. Pain was evaluated at recovery, 4 hours, 24 hours, day 5, and day 8, using an analog visual scale. Homogenous groups in their demographic characteristics; all confirmed gallbladder lithiasis. At recovery, there was less pain in group 1 ($P = 0.002$); at 4 hours pain was similar in all groups ($P = 0.899$); at 24 hours there was less pain in groups 2 and 3 ($P = 0.031$); and at days 5 and 8 there was marginal ($P = 0.053$) and significant ($P = 0.003$) relevance. In terms of pain perception, LC performed through 1 port does not offer advantages when compared with 2 or 3 ports. More clinical trials are needed to confirm these data.

Key words: Laparoscopic cholecystectomy – Single-port laparoscopic cholecystectomy – Pain in laparoscopic cholecystectomy

In 1989, laparoscopic cholecystectomy (LC) emerged as a new approach in the treatment of symptomatic biliary lithiasis[1,2]; it was then quickly adopted around the world, and in 1992 soon after it became the new gold standard.[3] The benefits were assessed very soon afterward: less postoperative pain, shortened hospital stay, rapid recovery, and better cosmetic results. As the technique became a routine procedure, modifications were made in order to make it less invasive. Initially, a 3-port (LC3P) instead of the initial 4-port (LC4P) approach was preferred when the anatomy was clearly visualized at the time of the initial laparoscopic evaluation and no technical difficulties were anticipated. Later, technical advances introduced the 5-mm laparoscope and the 5-mm clip appliers, thus

Reprint requests: Jaime M. Justo-Janeiro, Calle Kepler 2143, Office 940-B, R. T. Atlixcáyotl Puebla, Puebla 72190, Mexico. Tel.: +52 222 303 83 91; E-mail: jaime_justo@hotmail.com

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decreasing the port size, and later the newer 2- or 3-mm instruments allowed the surgeons to make smaller incisions. The use of a working channel laparoscope made it possible to use only 2 ports (LC2P), along with transdermal sutures and needles, for an easier manipulation of the gallbladder. More recently, the development of devices that made the introduction of the laparoscope and different instruments through the same incision feasible gave rise to 1-port LC (LC1P).[4] Another new approach, not yet clinically available, is the natural orifice transluminal endoscopic surgery technique.

In order to elucidate which of these approaches is the best procedure, many studies have been designed.[5–8]

Comparisons have always been made between LC1P and LC3P or LC4P[9]; therefore, we believe that LC1P must be compared with the technique for LC2P and LC3P.

To our knowledge, there are no studies that compare the technique between 3-, 2-, or 1-port approaches; therefore, we aimed to compare the pain perception in 3 groups of patients: LC performed with 3 ports, 2 ports, and 1 port in an open population from The General Hospital of the city of Puebla, Mexico.

Patients and Methods

Patients were prospectively randomized to each group by simple card draw from a box with sealed envelopes at the moment the surgical procedure was scheduled. In group 1, patients were assigned to LC1P; in group 2, patients were assigned to LC2P; and in group 3, patients were assigned to LC3P. Informed consent was obtained for all patients, and surgical procedures were performed by the same group of surgeons in an open-population general hospital. Inclusion criteria were as follows: (1) consecutive patients who were scheduled for elective LC due to gallstones, with (2) American Society of Anesthesiology grade I or II classification and (3) normal liver function tests. The only exclusion criterion was refusal to participate in the study. Elimination criteria were choledocholithiasis diagnosed at the time of surgery, conversion to open surgery, and the need to insert an additional trocar.

In all of the included patients, pain was measured using a standard visual analog scale with faces, numbers, and pain description; pain was recorded in the recovery room, and at 4 hours, 24 hours, day 5, and day 8, and the observer was blinded to the LC type. The total daily analgesic dose and the use of rescue therapy with 125 mg of lysine clonixinate tablets were also documented.

As secondary outcomes we registered demographic variables, intraoperative or postoperative complications, time of operation, hemorrhage, length of hospital stay, and additional procedures.

The same general anesthesia protocol was used in all patients. At the beginning of the surgery, all port sites were infiltrated with 0.5% bupivacaine. All patients were managed on an ambulatory basis when possible. When 10- to 12-mm ports were used, the fascia was routinely closed with polyglactin, and skin ports with polypropylene. The postoperative analgesic protocol consisted of 10 mg of oral ketorolac tablets, allowing the patients to decide the number of doses up to 4 times a day. If necessary, 125 mg of lysine clonixinate tablets up to 3 times a day was used as rescue therapy.

Surgical technique

In all groups a standard high-definition laparoscopic module was used (Karl Storz, Tuttlingen, Germany), a urinary catheter was inserted for the duration of surgery, no routine gastric cannulation was used, and pneumoperitoneum was created with the Veress needle, keeping intra-abdominal pressure below 12 mmHg in all cases. Patients were placed in a reverse Trendelenburg position, with slight rotation to their left side.

LC3P

One 10-mm umbilical port, one 10-mm subxiphoid port, and a 5-mm port in the right subcostal area of the midclavicular line were installed, the standard rigid 10-mm 0° optics and standard straight instruments were used, the gallbladder was pulled to expose Calot's triangle and the dissection made to obtain a critical view,[10] the cyst duct and the artery were ligated with titanium clips, and the gallbladder dissection of the hepatic bed was performed with an electrosurgical hook.

LC2P

One umbilical 12-mm port and a 10-mm port in the right flank midaxillary line were installed, a rigid 12-mm 30° laparoscope with a working channel was introduced through the umbilical port, the right flank port was used with the auxiliary standard instruments to pull and fix the gallbladder, the clip applier was used to ligate the cyst duct and the artery,

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dissection was made with instruments introduced through the working channel and a 65-cm Maryland dissector, and hook and scissors were used. In this technique the patient was placed in lithotomy position, with the surgeon standing between the legs. The gallbladder was extracted via the umbilical port.

LC1P

One umbilical 20-mm wound was used to enter the peritoneal cavity; digital inspection was used to discard any adhesions close to the wound. The SILS device was installed (Covidien, Mansfield, Massachusetts), and through their 5-mm ports, a rigid 5-mm 30° laparoscope and standard straight instruments were introduced.[11] The cyst duct and the artery were ligated with a polymer clip (Hem-o-lock, Teleflex Medical, Research Triangle Park, NC) because it is the only 5-mm clip applier available at our hospital. Surgical positioning was the same as for LC2P.

In all cases the intraoperative goal was to obtain the critical view of the Calot's triangle[10,12] before any clip was applied or any cut was made.

A sample size of 17 patients in each group was calculated (n = 51) using the pain score from previous studies as the main variable[5]; $\alpha = 0.05$, $\beta = 0.2$ (power = 0.8) with an allocation rate of 1; a minimum pain score of 2 points and a maximum of 4.2 points; and a standard deviation score of 2, which makes a 1.2-point difference with a size effect (f) of 0.45, using Sample Power software (IBM SPSS Sample Power v.3.0.1, IBM Corp, Armonk, New York). The statistical analysis was performed by a blind observer, using 1-way analysis of variance (ANOVA) with Bonferroni post hoc test for the pain analysis, and other dimensional variables and the χ^2 test for the nonparametric analysis; calculations were made with the Statistical Package for Social Sciences software (SPSS v.18, IBM). The statistical significance level was fixed at 0.05.

Results

Between January and November 2011, 55 consecutive patients agreed to be enrolled and randomized to 1 of 3 groups: 18 in group 1, 18 in group 2, and 19 in group 3; 4 of the patients were eliminated, 1 in group 1 because of technical reasons, 1 in group 2 because of a dilated cyst duct and the need for another 2 ports, and 2 in group 3 because of choledocholithiasis and the need for postoperative ERCP (Endoscopic Retrograde Cholangiopancreatography)(Fig. 1), no drains were used in all groups.

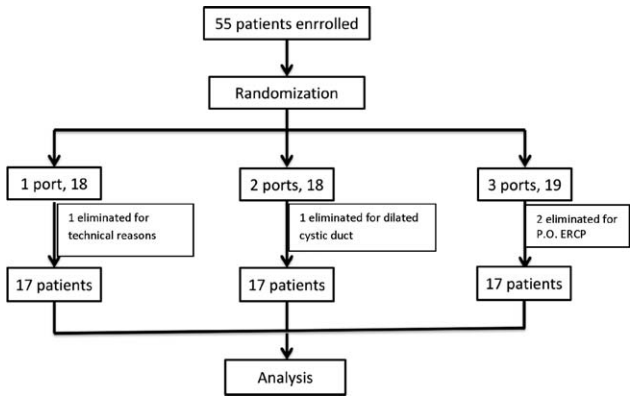

Fig. 1 Patients' flowchart.

The 3 groups were homogeneous in composition; demographics are shown in Table 1.

Among the variables studied, only mean operative time was statistically significant, with the LC1P technique showing a longer duration of the surgical procedure ($P = 0.007$; Fig. 2), an observation made by other authors.[4] Complications and discharge were similar between groups, as was the need for another procedure or the need to make a transcystic cholangiography.

Pain scores showed differences during the recovery time, with less pain in the LC1P, but at 4 and 24 hours there were no differences. At 5 and 8 days, patients from the LC1P reported more pain than the LC2P or LC3P groups (Table 2 and Fig. 3). Total analgesic dose and the need for rescue therapy were similar among groups. There were no conversions, major complications, or mortality.

Discussion

Since its introduction in the last century, laparoscopy has substantially modified the basic concepts and goals of modern surgery, shifting the focus toward reducing operative trauma and recovery time, and improving cosmetic results. These new goals have become particularly desirable in the most common surgical procedures done worldwide, such as appendectomy and cholecystectomy. Today, LC currently stands as the gold standard in the treatment of symptomatic biliary lithiasis because of its clear advantages over open cholecystectomy in reducing recovery time and postoperative pain, shortening hospital stay, and allowing patients an earlier return to everyday living.[3]

Because of the success that has been obtained with traditional LC, surgeons are now striving to be even

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Table 1 Patients, operation, and postoperative characteristics

	Group 1, LC1P	Group 2, LC2P	Group 3, LC3P	*P*
No. of patients enrolled	18	18	19	
No. of eliminations	1[a]	1[b]	2[c]	
Women, No. (%)	16 (88.8)	16 (88.8)	13 (68.4)	0.204*
Age, y, mean ± SD (min–max)	42.75 ± 15.8 (24–76)	35.4 ± 13.4 (16–62)	44.12 ± 17.5 (13–81)	0.297**
BMI, kg/m^2, mean ± SD (min–max)	28.17 ± 3.1 (22.9–32.4)	27.94 ± 6.7 (18.3–35.7)	27.60 ± 4.7 (15–33)	0.888**
ASA I, No.	7	11	8	0.889*
Operation time, min, mean ± SD (min–max)	67 ± 21.9 (35–120)	54.7 ± 13.5 (30–90)	48.9 ± 17.8 (12–80)	0.007***
Hemorrhage, mL, mean ± SD (min–max)	23.4 ± 14.4 (0–50)	26.4 ± 15.8 (0–50)	29.7 ± 19.9 (0–75)	0.674**
Acute cholecystitis				
Gallbladder empyema, No.	1	0	1	
Gallbladder hydrops, No.	1	0	0	
T.O. complications				
Gallbladder perforation, No.	1	1	0	
Postoperative complications, No.	0	0	0	
Discharge, No. (%)				
Ambulatory	9 (52.9)	11 (64.7)	13 (76.5)	
24 h	7 (41.2)	6 (35.3)	3 (17.6)	0.315*
48 h	1 (5.9)	0	1 (5.9)	
Other procedures, No.				
Umbilical plasty	2	0	0	
Transoperative cholangiography	1	3	2	

ASA, American Society of Anesthesiology; BMI, body mass index.

*Chi-square test.

**One-way ANOVA.

***One-way ANOVA, significantly different.

[a]Eliminated for technical reasons.

[b]Eliminated for dilated cystic duct.

[c]Eliminated for postoperative Endoscopic Retrograde Cholangiopancreatography (ERCP).

less invasive by reducing the size of the ports or their number.[13] The surgeon's interest in LC1P is very recent; notably, since 2008 there has been a substantial increase in the number of publications about this technique.[6] Theoretically, if surgical trauma is reduced to a minimum it will lead to improved outcomes in pain management, patient comfort, postoperative complications, and shortened hospital stay. In our opinion, the added benefit of improving cosmesis is a natural consequence of the less invasive techniques but should not be a goal by itself.[9] Lee *et al*[14] demonstrated that there is no difference between LC3P versus LC1P regarding pain as the most important variable. Pain after LC has been differentiated into 3 components: visceral, abdominal wall, and that referring to the shoulder.[15] We did not characterize the pain in this manner, but we could speculate that visceral pain could be worse in the LC1P group because of the fact that it was a more time-consuming procedure[16]; accordingly, we observed more pain that was statistically significant in the LC1P group at 24 hours and 5 days (Table 2). However, we believe that the difference in visual analog scale units was minimal

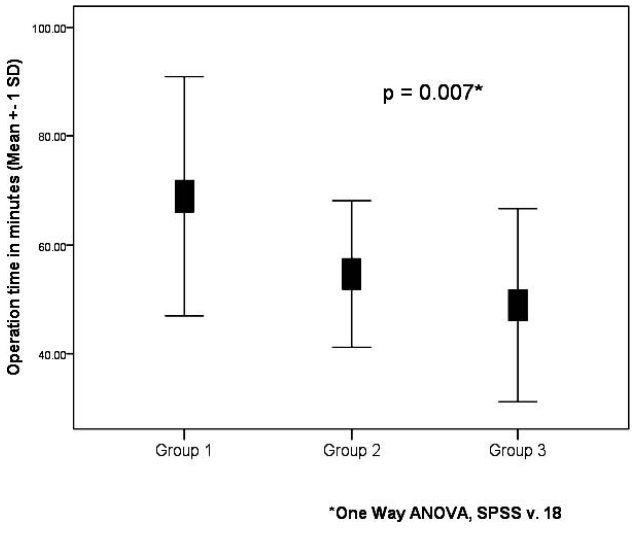

Fig. 2 Operation time. The bars show mean time in minutes ± SD. Group 1, LC1P; Group 2, LC2P; and Group 3, LC3P. p represents statistical significance between groups.

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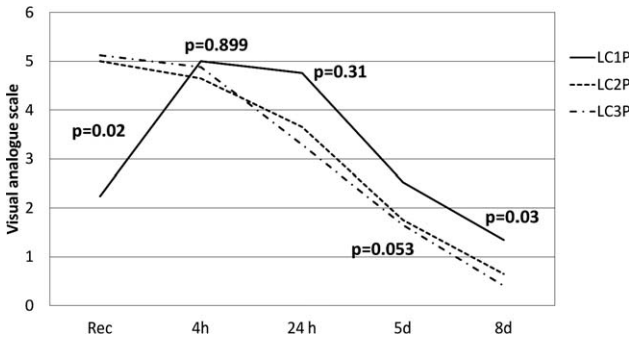

Fig. 3 Postoperative pain.

and clinically irrelevant, because overall analgesic needs were the same in all groups.

Some studies have used low body mass index as an inclusion criterion,[17] excluding obese patients. In order to avoid this potential bias, we enrolled consecutive patients, even those with a body mass index of 35.7 kg/m^2. Previous studies have focused on evaluating single-port LC versus the traditional approach; nevertheless, we believe that the hypothetical advantages of using fewer ports cannot be demonstrated reliably by solely comparing 1 versus 4 ports because of the significant technical differences between these two approaches.[18–20] Furthermore, we should not forget that before LC1P was introduced, other techniques were used and their advantages had been demonstrated; these include the 3-port technique with standard ports, the 2-port technique using a laparoscope with a working channel, and the use of percutaneous sutures or needles to manipulate the gallbladder as well as the use of mini-instruments. Thus there was a need to compare the 1-port technique with other alternatives, such as the 2- and 3-port approaches.

The adoption of any new technique is generally accompanied by technical difficulties at the time of its implementation, requiring the development of new skills by the surgeon. Accordingly, this leads to increased operative times compared with traditional techniques,[21] even when the learning curve is reached. In our study the operative time was the only variable that had a significant difference between groups ($P = 0.007$), which is consistent with what is reported in the literature.[4,5]

A not studied but well-observed effect in our study was that the 1-port technique allows for an easier extraction of the gallbladder even when larger calculi are involved. In addition, if an umbilicus repair is needed, having a sole incision allows for an easier repair of the defect because of the 20-mm incision versus the 10-mm incision.

We believe that the improved cosmetic effect should not be assessed as a primary outcome because it is only a natural consequence of reducing the port number and does not justify increasing the risk of intraoperative or postoperative complications. This is based on previous works reporting higher bile duct injury and higher hernia rates in single-incision LC.[8] Some authors have used cosmetic result as a main outcome; however, there is evidence to support that the inherent risks of this surgery are potentially increased by the technical difficulty posed by the 1-port technique.[23]

In summary, our study does not support 1-port technique for LC in terms of reducing pain, hospital stay, or recovery time. More studies, including those on alternatives to traditional 4-port LC and single-port LC, such as minilaparoscopy or microlaparoscopy,[24] are needed to corroborate our findings.

Conclusions

Laparoscopic cholecystectomy performed with 1 port in does not seem to offer any advantage over

Table 2 Postoperative pain and analgesic needs

	Group 1, LC1P	Group 2, LC2P	Group 3, LC3P	*P**
Pain at recovery, mean ± SD	2.24 ± 1.35	5 ± 3.02	5.12 ± 2.71	0.002**
4 h pain, mean ± SD	5 ± 2.18	4.65 ± 2.32	4.88 ± 2.32	0.899
24 h pain, mean ± SD	4.76 ± 1.99	3.65 ± 1.69	3.29 ± 1.1	0.031**
Day 5 pain, mean ± SD	2.53 ± 1.55	1.76 ± 0.75	1.65 ± 1.06	0.053
Day 8 pain, mean ± SD	1.35 ± 1.06	0.65 ± 0.61	0.41 ± 0.62	0.03**
Need for analgesic (10 mg of oral ketorolac)				
Days with every 6 h, mean ± SD (minimum–maximum)	2.88 ± 1.49 (0–5)	2.06 ± 1.75 (0–5)	2.13 ± 1.66 (0–5)	0.407
Days with every 8 h, mean ± SD (minimum–maximum)	2.63 ± 1.49 (1–7)	2.53 ± 1.55 (0–5)	2.5 ± 2.34 (0–8)	0.422
Days with every 12 h, mean ± SD (minimum–maximum)	0.25 ± 0.56 (0–2)	0.47 ± 0.80 (0–2)	0.5 ± 0.72 (0–2)	0.438
Oral lysine clonixinate, No. (%)	1 (5.9)	1 (5.9)	2 (11.8)	

*One-way ANOVA test for all *P* values.

**Significance.

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the 2- or 3-port approach, and between these, the latter seems to produce similar pain perception with less surgical time. More clinical trials are needed to confirm these data.

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