

Effectiveness and Safety of Minilaparoscopic Cholecystectomy

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1. Abstract

1.1. Background: Minilaparoscopy instruments emerged as an alternative to conventional laparoscopic cholecystectomy trying to obtain a faster recuperation, however there are not randomized clinical trials conducted to establish its usefulness compared to conventional 3 ports laparoscopic cholecystectomy where it seems to have advantages because reduce ports size seems to reduce postoperative pain.

1.2. Aim: To compare post operative evolution from patients submitted to cholecystectomy with two different techniques: 1) Standard laparoscopic three ports approach and 2) Use of minilaparoscopic instruments.

1.3. Method: We conducted a comparative, prospective, longitudinal and experimental study with P.O. pain as the main outcome in a general open population hospital with two randomized groups: 1) Laparoscopic cholecystectomy with the standard 3 ports access: 10 mm umbilical, 5 mm subxiphoid and 5 mm right subcostal, and 2) Minilaparoscopic cholecystectomy with 3 ports 10 mm umbilical, 5 mm subxiphoid and 2.3 mm right subcostal. We assessed postoperative pain with a visual analogous scale at the surgery recuperation bed and after 4, 24 hrs, 5° and 8-days, we compare results with Student t test for dimensional variables and chi square test for nominal variables.

1.4. Results: Forty-four patients were recruited and, by simply random process, assigned to standard 3 ports laparoscopic cholecystectomy (LC3P) group or minilaparoscopic cholecystectomy (MLC) group; there were not differences in age, gender, body mass index, surgical time, hemorrhage, surgical findings, trans operative or post operative complications or length of stay. The evaluation of the post operative pain shows a significant difference in recovery ($p=0.025$), but there was no difference at 4 hrs ($p=0.885$), the difference was significant at 24 hrs ($p=0.038$) and then at the 5° day ($p=0.043$). At in 8° day there was not significance but the p value was marginal ($p=0.186$). The need for analgesics was less frequent each 8hrs for the MLC group ($p=0.04$).

1.5. Conclusion: Minilaparoscopic cholecystectomy is a safe and effective technique in symptomatic biliary lithiasis patients, their results are similar to conventional laparoscopic cholecystectomy, but pain reduction is a major advantage in this technique.

2. Keywords: Minilaparoscopy; Cholecistectomy; Pain Reduction

3. Introduction

Since the adoption of the laparoscopic cholecystectomy as the gold standard in the treatment of the symptomatic biliary lithiasis[1] many technique modifications have been made in order to reduce the postoperative pain, reduction of time for recovery, to reduce wound complications and obtain less inability. Such modifications are: decrease the ports number [2], use of low diameter instruments [3], even single port surgery or the use of natural orifices [4]. Another well recognized advantage of the laparoscopic surgery was the improvement in cosmesis.

Some of the disadvantages of the single port and natural orifice techniques are the need to learn a new technique and, of course, its learning curve. Advantage of the minilaparoscopy over other techniques is the use of the same technique used in conventional laparoscopy, bimanual dexterity, instruments triangulation and a well learned technique allows the learning curve to be reached more quickly.

Minilaparoscopy is defined as the use of 3 mm instruments or less diameter, and also has been referred as “needlescopy” [5]; one limitation of the minilaparoscopy cholecystectomy is the size of the final wound to extract the gallbladder, especially with large calculi, so modifications to the technique must be made to obtain a good final result. Industry advances was evolved to develop more and better instruments, better optics and instruments sets with all the forceps needed to perform different surgeries as cholecystectomy, Nissen fundoplication [6], appendectomy [7], inguinal plasties[8], and other procedures, a lot of studies have been published and the results show very good results with the technique; some disadvantages of those instruments are strength and limited durability [9, 10], the availability of 5 mm optics and a 5 mm clip applier.

Recently a new generation of disposable mini instruments has been developed and they don't need a trocar to be inserted in the abdomen (Figure 1). The tip has point have a needle form and can be inserted direct across the abdominal wall and diameter is 2.4 mm (Minilap™,

Teleflex Medical, Research Triangle Park, NC, USA), the objective of this study is to compare the performance of laparoscopic cholecystectomy with the habitual 3 ports technique against the laparoscopic cholecystectomy perform with mini instruments (Minilaparoscopic Cholecystectomy).

4. Patients and Methods

Study was designed to include patients with symptomatic cholelithiasis to whom laparoscopic cholecystectomy (LC) were offered. They were prospectively randomized by a simple card draw from a box with sealed envelopes in the moment when surgical procedure was schuled to each group: group 1 included patients to be operated with the traditional 3 ports technique (LC3P) and group 2 included patients to be operated with the minilaparoscopy technique (MLC). Informed consent was obtained from all patients, all procedures were performed by the same surgeons group in an open population general hospital. Inclusion criteria were: 1) Consecutive patients who were scheduled for elective LC due to gallstones, 2) American Society of Anesthesiology grade I or II classification, 3) Normal liver function tests and 4) No jaundice or pancreatitis antecedents. The only exclusion criterion was refusal to participate in the study. Elimination criteria were: choledocolitiasis diagnosed at the moment of surgery, conversion to open surgery, and the need to insert an additional trocar.

In all the included patients pain was measured using a standard visual analog scale with faces, numbers and pain intensity descriptions; pain was recorded in the recovery room, and at 4 hours, 24 hours, day 5 and day 8, the observer was blinded to the LC group. Daily total analgesic dose and the use of rescue therapy were also documented.

As secondary outcomes we registered demographic variables, intra or postoperative complications, time of operation, hemorrhage, length of stay, body mass index 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 a 7.5% solution of ropivacaine. All patients were managed on an ambulatory bases when possible. In the 10-12 mm ports the fascia was

routinely closed with polyglactin and skin wounds 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 were used as a rescue therapy.

4.1. Surgical technique

A standard high-definition laparoscopic module was used (Karl Storz, Tuttlingen, Germany) in both groups. An urinary catheter was inserted for the duration of the surgery, no routine gastric decompression was used, pneumoperitoneum was created with the Verres needle, keeping intra-abdominal pressure under 12 mmHg in all cases. Patients were placed in a reverse Trendelenburg position, with slight rotation to the left side. The surgical procedure was performed under balanced general anesthesia with the same protocol for all patients. Patients arrived to the operating room with an i.v. catheter inserted, and were monitored by pulse oximetry, noninvasive blood pressure, capnography, electrocardiography and esophageal temperature. Patients were induced with propofol 2 mg/kg and

fentanyl 2 µg/kg; after administration of 0.6 mg/Kg of rocuronium bromide, the trachea was intubated and the position of the tube was confirmed with capnography. All patients were managed with mechanical ventilation using intermittent mandatory ventilation to preserve normocapnia. Anesthesia was maintained with a mixture of air/O₂/desflurane and fentanyl as required. In all cases the skin incisions were infiltrated with 7.5% Ropivacaine before the wounds were made.

4.2. LC3P

One 10-12 mm umbilical port, one 10-12 mm subxiphoid port and one 5 mm right subcostal area of the midclavicular line were installed, the standard 10 mm 0° optics and standard straight instruments were used; gallbladder was pulled to expose the Calot's triangle and the dissection of the hepatoduodenal ligament was made to obtain a critical view, the cyst duct and the artery were ligated with titanium clips, and the gallbladder dissection of the hepatic bed was performed with an electro-surgical hook.

4.3. MLC

One 10-12 mm umbilical port, one 5 mm subxiphoid port and one 2.4 mm right subcostal area of the midclavicular line were installed, a 5 mm 30° optics was used; gallbladder was pulled with the 2.4 mm transcutaneous grasper (Minilap™, Teleflex Medical, Research Triangle Park, NC, USA), the dissection was made with standard straight instruments; gallbladder was pulled to expose the Calot's triangle and the dissection of the hepatoduodenal ligament was made to obtain a critical view, the cyst duct and the artery were ligated using polymer security clips (Hem-o-lock, Teleflex Medical, Research Triangle Park, NC, USA), with a 5 mm clip applier.

5. Statistical Analysis

Using postoperative pain score as the main outcome a sample size of 22 patients (n=44) per group was calculated; $\alpha=0.05$, $\beta=0.1$ (power=0.9) and allocation rate of 1; using a previous study [2], a minimum pain score was 2 points and a maximum of 4.2 points with 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 v3.0.1, IBM Corp, Armonk, New York, USA). The statistical analysis was performed by a blind investigator using Student's t test for the pain comparison analysis and other dimensional variables and the chi square test for the nonparametric analysis; calculations were made with the Statistical Package for Social Sciences software (SPSS V.20 IBM Corp, Armonk, New York, USA); statistical significance level was fixed at 0.05.

6. Results

Between May and October 2018 (6 months), 45 consecutive patients agreed to be enrolled and randomized in two groups 23 in group 1 (LC3P) and 22 in group 2 (MLC), one patient was eliminated due to conversion to open cholecystectomy due to an equipment failure (**Figure 2**); there were no differences between groups in age, gender, body mass index, operation time, hemorrhage, complications or length of stay (Table 1); no drains were used in both groups.

Pain scores showed differences during the recovery time, with less pain in MLC group ($p=0.025$) but at 4 hours there was no difference ($p=0.885$), at 24 hours and day 5 patients from MLC group showed less pain ($p=0.038$)

and 0.043), at 8 days no difference was observed with a marginal value ($p=0.186$) (**Figure 3** and **Table 2**). Total analgesic dose was similar in both groups, there were difference only in the MLC group with a less frequent dosage at 8hrs ($p=0.04$), there were no need for rescue therapy in any group; There were no major complications nor mortality. Results are shown in **Table 2**.

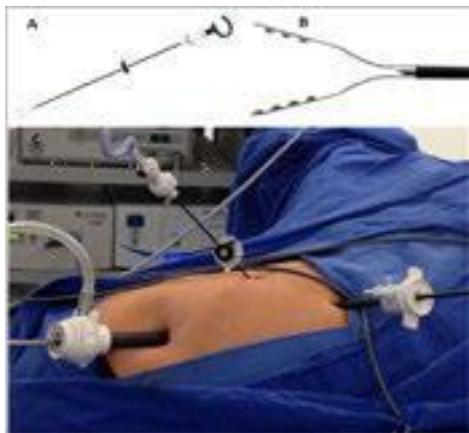


Figure 1. Minilap instruments: A) Grasper, B) Tip of the grasper, C) Trocars and needle positioning.

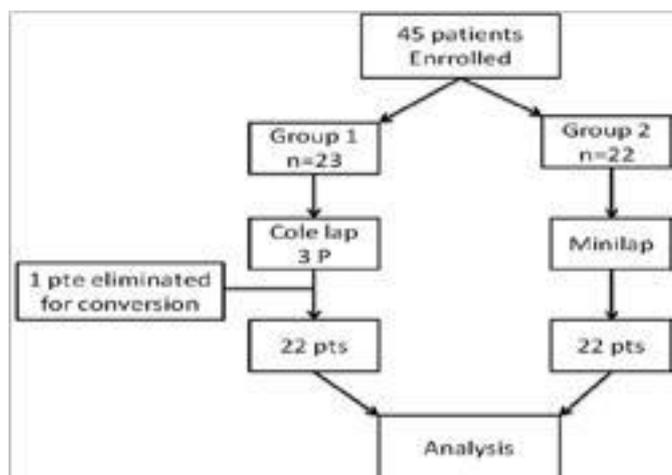


Figure 2. Patient's flowchart.

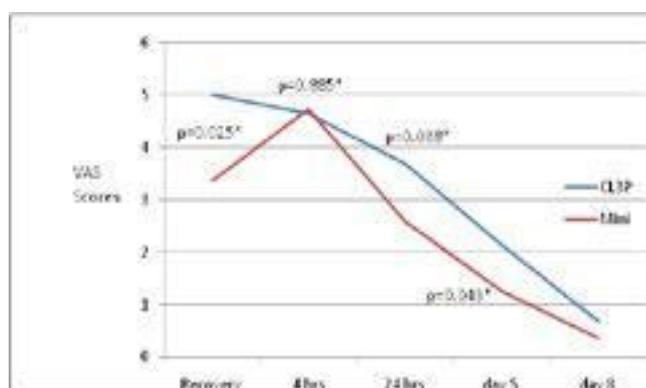


Figure 3. Pain scores.
*Student's t test

Table 1. Patient's demographic and surgery characteristics.

	LC3P N=22	Minilap N=22	p
Age (years X±SD)	42.7±18.9	42.5±19.6	0.969*
Women N (%)	18(81.8)	19(86.4)	0.746**
BMI (Kg/m2) X±SD	26.6±3.6	26.8±5.95	0.887*
Duration of surgery Minutes (X±SD)	54.5±17.2	52.3±14.1	0.641*
Hemorrhage (ml±SD)	30.2±22.9	20.8±26.8	0.857*
Intraoperative findings	1 Cirrhosis 1 Acute Cholecystitis	NO	-----
Intraoperative complications	NO	Capsule Tear	-----
Postoperative complications	NO	NO	-----
Ambulatory N (%)	6 (27.3)	5 (27.8)	-----
Added procedures	1 umbilical plasty	NO	-----

*Student t test
**Chi Square test

Table 2. Comparison from pain scores between groups (All data show Visual Analogue Scale scores, mean and standard deviation).

	LC3P N=22	Minilap N=22	p
Recovery	5.00±2.43	3.36±2.24	0.025*
At 4 hrs	4.64±2.38	4.73±1.72	0.885*
At 24 hrs	3.68±1.96	2.59±1.37	0.038*
At 5 days	2.14±1.55	1.27±1.16	0.043*
At 8 days	0.68±0.84	0.36±0.73	0.186*

*Student t test

7. Discussion

Basic concept in laparoscopy is to reduce postoperative pain in order to obtain a shorter recuperation time, moreover, a shorter inability time; thus, the intention to reduce number or ports diameter carries the same concept; DrCarvalho and coworkers in 2011 [11] developed an interesting theory about how to calculate the tissue damage volume from a laparoscopic wound assuming that the volume of tissue damage is equivalent to pain, so smaller instruments mean less pain. In a previous paper we proved that diminishing number of ports reduces postoperative pain [2]; in this study we reduced the ports diameter hypothesizing that reducing size reduces pain, assuming a 31.85 mm abdominal wall thickness, the tissue damage diminishing from 5,628 mm³ to 3,271 mm³ means a 42% less tissue damage and, this seems to reduce postoperative pain and improves a not studied but well observed cosmetic result.

We need to remember that P.O. pain in Laparoscopic Cholecystectomy has 3 main components: Visceral pain, wall pain and shoulder pain [12]. By reducing the ports diameter only wall pain is diminished, so the 42% reduction in tissue damage was obtained because only wall pain component is affected, then in spite we can observe a pain reduction that was statically significant at P.O. day 1 and P.O. day 5; at day 8 the significance no was obtained, but the median pain scores in both groups were less than 1 point.

Other authors proposed single port approach for cholecystectomy, however only few studies proved a real benefit in pain reduction, increasing technical difficulty [13] and learning a new technique is required, increasing intra operative complications until the learning curve is raised, even more operative complications [14] in our study surgical times and all others regarding surgery variables studied show be equals in the two techniques proposed.

One of the most important things to practice MLC is to have access to all the necessary instruments and optical devices, in our environment, the access to this equipment is often difficult, such as 5 mm 30° lens, a 5 mm clip applier and proper mini instruments are indispensable. Other studies [9] suggest the use of the Minilap™ grasper instead of the 5 mm subcostal trocar using two additional 10 mm trocars; we believe that the benefit of the Minilap™ grasper is powered by reducing the size of the subxyphoid trocar.

8. Conclusion

We conclude that MLC seems to have at least the same results that conventional Laparoscopic Cholecystectomy and even with less pain, with a no necessary learning curve, it is a safe and effective procedure in the treatment of the symptomatic biliary lithiasis, however more studies must to be done to confirm this and probably consider the mini laparoscopic cholecystectomy as the new gold standard.

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