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TRANSUMBILICAL LAPAROSCOPIC CHOLECYSTECTOMY VERSUS STANDARD 4-PORT LAPAROSCOPIC CHOLECYSTECTOMY – RESULTS FROM PROSPECTIVE RANDOMIZED TRIAL AND 7 YEARS OF FOLLOW-UP

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ABSTRACT

PURPOSE: Laparoscopic cholecystectomy is a standard of care for patients with benign gallbladder disease. Recently single-incision techniques gained popularity in order to decrease surgical trauma and to improve cosmetic results and patient satisfaction. The aim of this study is to compare the results of our own modification of transumbilical cholecystectomy versus standard 4-port cholecystectomy in patients with uncomplicated gallstone disease.

METHODS: 80 patients (14 male, 66 female) at a mean age of 35±2,5 years (range 18-80) were randomly assigned to either standard 4-port cholecystectomy (n=40) or transumbilical cholecystectomy (n=40). Operative times, intraoperative complications, conversion rate, postoperative complications, pain, vomiting and cosmetic results were compared between two groups.

RESULTS: The total mean operative time in the SILC group was 43.63 ± 7.49 min., while in the SLC group it was 37.95 ±8.06 min., (p=0.002). Intraoperative complications and conversions were not recorded in this series. The mean postoperative pain assessed by VAS was: at 6th hour 3.35 (2-5) vs. 3.53 (2-6) (p=0.439), at 24th hour 2.58 (1-4) vs. 2.2 (1-5) (p=0.04), at 48th hour 1.63 (1-3) vs. 1.78 (1-5) (p=0.544). The mean 10-point pain scores for SILC patients at 6 hours was 5.78 (3-9) vs. 6.33 (1-10) in SLC (p=0.161), at 24 hours 4.05 (1-7) vs. 3.58 (1-5) (p=0.122), at 48 hour 2.83 (1-5) vs. 2.4 (1-5) (p=0.093). Postoperative vomiting was observed in 2 (5%) of patients with SILC and 3 (7.5%) of those with SLC by the end of the second hour after surgery. In the early postoperative period up to 72h, no complications were reported. In the late postoperative period up to 7 years 1 (2.5%) operative wound surgery in the area of umbilical incision was reported in the SLC group and the presence of an umbilical hernia in 2 (5%) of patients with SILC. Results of the cosmetic result evaluation at the end of the first month - Body Image Score - mean score of 10.35 ± 1.48 (min. 7, max. 12) for SILC and 10.38 ± 1.41 (min. 6, max. 13) for SLC (p = 0.776). Cosmetic score - mean of the sum of points 20 ± 1,87 (min.17-max. 24) for SILC and 19.08 ± 2,1 (min. 14-max. 23) for SLC (p = 0,577). On a scale of 1 to 10, where 1 is "very ugly" and 10 is "almost imperceptible" (question N8), the mean for patients in the SILC group is 8.3 ± 0.79 (min. 7-max. 10) and at SLC 7.93 ± 0.73 (min. 6-max. 9) (p = 0.125).

CONCLUSION: The results of this study demonstrated that both transumbilical cholecystectomy and standard 4-port cholecystectomy are equally safe and effective in the treatment of uncomplicated gallstone disease.

Key words: transumbilical laparoscopic cholecystectomy, standard laparoscopic cholecystectomy.

INTRODUCTION

More than 20 years ago, laparoscopic cholecystectomy (LC) replaced open cholecystectomy as a procedure of choice for the treatment of benign gallbladder diseases.

The aim of this Randomised Controlled Trial (RCT) is to compare our own modified technique of SILC (1) versus the standard 4-port laparoscopic cholecystectomy (SLC) with respect to the operative time, intraoperative complications, conversion rate, postoperative complications, pain, vomiting and cosmetic results.

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PATIENTS AND METHODS:

The criteria for inclusion in the study are: age over 18 years and the presence of uncomplicated gallstone disease, indicated for elective cholecystectomy.

Exclusion criteria: contraindications for general anesthesia, previous operations in the upper-right quadrant, pregnancy, clinical signs for acute cholecystitis.

Patients

The study includes 80 patients, aged 18 to 80 years (mean 35 ± 2,5). They were operated by the same team during the period 2012 to 2015.

The patients were divided into two groups by randomization at the operating theatre, and were allocated to either standard LC or transumbilical LC. Closed envelopes method was used for the randomization of the patients.

Randomization

The admitted patients were randomized into 2 groups (SILC group and standard 4-port LC) using sealed opaque envelopes.

The randomization was performed just before surgery, after the induction of anesthesia. The flow chart of the study is presented at **Figure 1**.

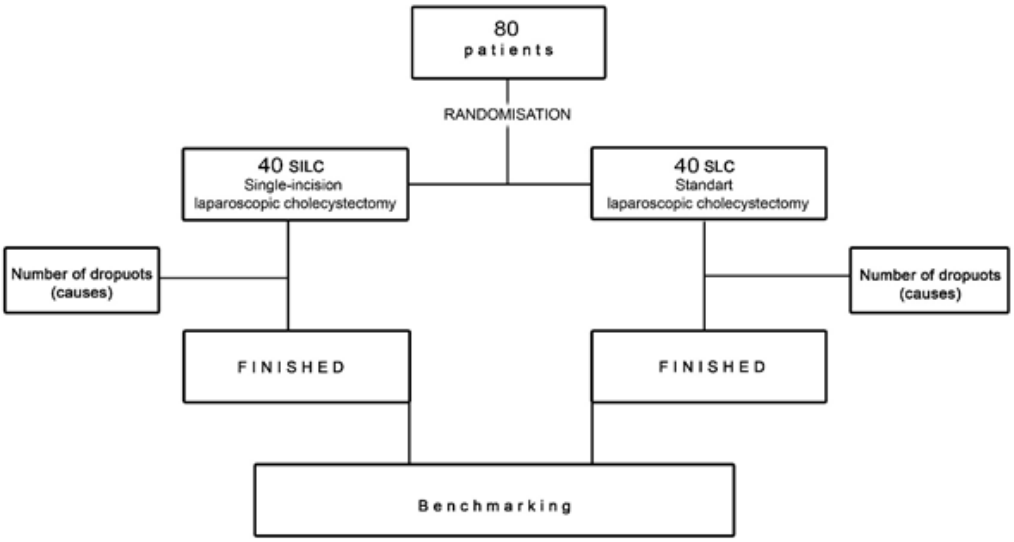

Figure 1. Randomisation of the patients.

Preoperative evaluation of patients

Preoperatively, all patients were examined for BCC, coagulation profile, biochemical studies to evaluate the functional status of the liver and kidney, chest radiography, abdominal ultrasound and ECG, consultation with a cardiologist, anesthesiologist and other specialists as needed.

Position of the patient and the team

All patients underwent general anesthesia in the supine position on the operating table with the legs folded. The position of the operator was to the left of the patient, and of the assistant and the operating nurse - to the right. The monitor was placed on the right side of the patient, at an angle comfortable for the operator and the entire team. In two monitors, one was on the right side of the patient-facing the operator and the other on the left side of the patient facing the assistant and the surgery nurse.

Operative techniques

Our SILC technique has been previously described elsewhere (1). In brief, we use a single continuous incision within the umbilical folds, 2 ports placed through the incision (one 10 mm and one 5 mm) and a single 10-mm 30° camera. The concept of retracting sutures through the abdominal wall was applied to achieve a good exposure of the gallbladder and triangulation. We transfixed the infundibulum of the gallbladder with 2 or 3 bites in a figure-of-eight fashion, with one end of the suture passed through the abdominal wall at the midline and the other at the anterior axillary line. This allows retracting the gallbladder in the desired lateral direction by maneuvering different ends of the suture, thus greatly facilitating the exposure. When necessary, more retracting sutures can be passed in a similar way. This technique helps overcoming difficulties in exposure when adhesions or inflammation are present. The other steps of

the procedure are similar to the standard LC. In cases of large stones, we cut the fascial bridge between ports to remove the gallbladder and always close the fascia with sutures.

Post-operative period and follow-up of patients:

For all patients, the surgical post-operative period expired in a surgical department. Standard therapy in the first 24 hours includes 1000ml 10% glucose solution with 12E Insulin, 500ml Ringer, parenteral Dexketoprofen twice a dose of 50mg. i.v. and Pethidine hydrochloride twice a dose of 50mg. In the presence of co-morbidity, the appropriate drug therapy is included.

Verticalization and feeding of the patients begin within the first 6-8 hours after surgery.

The follow-up of patients in both groups includes:

1. Early postoperative period - the following are reported:

1.1. The degree of pain on several visual-analogue scales at 6, 24 and 48 hours, respectively, and the needs for additional analgesia.

1.2. Passage recovery time - from the end of the operation until the first flatulation.

1.3. Post-operative nausea and vomiting - how many times and at what hour of surgery;

1.4. Postoperative complications;

1.5. The hospital stay.

Statistical analysis

For statistical analysis of the results, we used the SPSS program for Windows version 10.0 (SPSS, Chicago, IL, United States).

Descriptive statistics. Tests and graphs for normality of distribution.

Variational analysis. Student's t-test was used to compare groups of independent variables.

Alternative analysis. Test $\chi 2$ and Fisher test. These tests were used to assess intragroup and intergroup differences.

For all analyzes used, statistically significant differences were assumed at a significance level of $p < 0.05$ and a guarantee probability level of 0.95.

RESULTS

Table 1. *Destribution of the patients by Sex, BMI, Age, ASA*

	SILC	SLC
Female / Male	32 (80%) / 8 (20%)	34 (85%) / 6 (15%)
BMI	27,2 (20,8-37,5)	29,8 (19,2-41,1)
Age	53,64 (18-80)	57,26 (20-79)
ASA	2 (1-4)	2 (1-4)

The total mean operative time in the SILC group was 43.63 ± 7.49 min., while in the SLC group it was 37.95 ± 8.06 min., with a statistically significant difference (p = 0.002). **(Table 2)**

Table 2. *Operative times*

	SILC	SLC	p
Total mean operative time	43,63 (32-72)	37,95 (25-56)	**p=0,002**
From skin incision to trocars / sutures placement	6,85 (3-15)	6,3 (2-12)	P=0,307
A. et d. cysticus transection	16,03 (5-34)	13,5 (6-25)	**P=0,033**
Gallbadder extraction	13,3 (5-25)	11,2 (4-24)	**P=0,031**
Ports closure	7,9 (3-16)	7,27 (5-13)	P=0,173

In 7 (17.5%) of the patients in the SILC group and in 9 (22.5%) of the SLC group, intraoperative pericholecystic adhesions were found. Intra-abdominal adhesions throughout the upper right quadrant were observed in 2 (5%) patients in the SLC group and in 1 (2.5%) patient with SILC.

No significant differences were found in the two groups according to the presence and severity of adhesions.

Intraoperative complications and conversions were not recorded in this series.

An additional dose of analgesics was needed in the SILC group of 5 (12.5%) patients versus 3 (7.5%) in SLC.

Table 3. *Pain*

VAS	SILC	SLC	p
6h	3.35 (2-5)	3.53 (2-6)	P=0,439
24h	2.58 (1-4)	2.2 (1-5)	**P=0,04**
48h	1.63 (1-3)	1.78 (1-5)	P=0,544
10 point scale			
6h	5.78 (3-9)	6.33 (3-9)	P=0,161
24h	4.05 (1-7)	3.58 (1-5)	P=0,122
48h	2.83 (1-5)	2.4 (1-5)	**P=0,093**

Postoperative vomiting was observed in 2 (5%) of patients with SILC and 3 (7.5%) of those with SLC by the end of the second hour after surgery.

Intestinal passage recovery occurred in patients in the SILC group on average 16.9 (7-24) hours after surgery and in the SLC group 17.3 (10-24) hours.

The average hospital stay in patients with SILC was 2.7 (1-5) days, with their subjective assessment of their condition ready for hospitalization on 2.1 (1-5) postoperative day. In the SLC group, 3.2 (1-9) day and 2.4 (1-5) day, respectively.

In the early postoperative period, up to 72h., no complications were reported. In the late postoperative period, up to 7 years, 1 (2.5%) operative wound surgery in the area of umbilical incision was reported in the SLC group and the presence of umbilical hernia in 2 (5%) of the patients with SILC.

Results of the cosmetic result evaluation at the end of the first month:

Table 4. *Cosmetic results*

	SILC	SLC	p
Body Image Score	10.35	10.38	p = 0.776
Cosmetic Score	20	19.08	p = 0,577
10 point scale	8,3	7,93	p = 0.125

DISCUSSION

Similar to the results of other studies, operative time was longer in the SILC group compared to the SLC group (43.63 minutes versus 37.95 minutes). The mean operative time at SILC was 5.68 minutes longer than that for SLC, this making our results comparable to those of Aprea et al. (41.03 ± 12 / 35.6 ± 5.6 min.), and Tsimoyiannis et al. (49.65 ± 9 / 37.3 ± 9.2 min.)(14,15). SILC is slower in dissection in the Calot's triangle and in the dissection of the gallbladder from the gallbladder's bed compared to the SLC. Notwithstanding these results, it should be noted that the length of time that the SILC is longer is shorter of the SD for both operations, thus operating time cannot be regarded as an important factor in the choice of technique. The difficulties associated with SILC are mainly related to the parallel position of the trocars, causing space deficit, poor triangulation of the instruments, and the conflict at their proximal ends. The weak possibilities for triangulation between the instruments are successfully compensated by our modified method of gallbladder traction with two transparietal sutures. This allows the technique to be mastered relatively quickly by a team experienced in laparoscopic surgery and successfully applied to all candidates to laparoscopic cholecystectomy.

The advantage of our modification of the SILC technique is that it can performed with conventional laparoscopic instruments, which does not complicate the procedure. In contrast, most SILC techniques currently available use a variety of multichannel ports and specially designed instruments, which usually increases the cost of the procedure. On the other hand, our technique uses two trocars and two

graspers less than SLC, which makes it more cost effective than standard (2).

No significant differences were found in the two groups according to the presence and severity of adhesions. Intraoperative complications and conversions were not recorded in this series.

A number of studies show different results in respect of postoperative pain in SILC and SLC groups. Bresadola et al. reported that postoperative pain is significantly lower for the SILC group (3). Increased postoperative pain in the SILC group was reported by Philipp et al. (4). The results of this study show that VAS pain scores at 48 hours, where statistical significance was found. It is stronger at SILC compared to SLC. Similar results are shown by a study of Lirici MM at al., whichis probably due to the higher pressure on the tissues around the umbilical port and the greater tissue trauma in the area (5).

Like other studies, this also shows there is no statistically significant difference in the two groups in terms of postoperative nausea and vomiting, recovery of the intestinal passage, average hospital stay (6, 7).

Postoperative complications in laparoscopic cholecystectomy are divided into surgical and non-surgical. The surgical ones can be divided into complications obtained in the early or late postoperative period. Most often these are:
1. Wound complications - bleeding, supra surgery, scar necrosis;
2. Intra-abdominal hemorrhage;
3. Biliragia;
4. Residual choledocholithiasis;
5. Biliary strictures;
6. Postoperative hernia.

A meta-analysis of Milas et al. ncluding 30 randomized controlled trials (SILC N = 1209, MLC N = 1202) reported a rate of postoperative complications of 5.35% in the SILC group, versus 3.79% in SLC (8). A similar study by Garg et al. reported an overall incidence of postoperative complications of 16% for SILC and 12.3% for SLC (9). Both meta-analyzes lack a statistically significant difference between the two methods. In our study, the overall incidence of postoperative complications was 5% for SILC and 2.5% for SLC. According to the literature, the highest incidence is complications of the wound. A meta-analysis by Garg et al. indicated 4.6% wound complications with SILC and 2.6% with SLC, with no statistically significant difference for the two methods (9). In the same study, the incidence of post-operative hernias at the incision site was reported to be 1.43% with SILC and 0.32% SLC, also with no statistically significant difference. Pisanu et al. reported for incisional hernia 1.3% in SILC vs. 0.2% in SLC, again statistically insignificant (10). In our study, we had one superophylaxis in the area of the umbilical incision (2.5%) in a patient in the SLC group and two (5%) postoperative hernias in the SILC group over a 6-month period onaverage.

Marks et al. in randomized controlled trials comparing SILC with SLC showed that SILC is superior to SLC in terms of cosmetic outcomes (11). Using a ten-point scale, 3 weeks postoperatively, Ma et al. reported a 9.3 score in the SILC group vs. 8.9 in the SLC group (12). In our series, when performing a correlation analysis with respect to the sex distribution, all three cosmetic test did not show statistically significant differences.

When dividing the SILC and SLC group by performing the BIS, CS, 1-10 tests, we found that in the first group in the 1-10 test, 62.5% of men identified their cicatrix as very good, while this percentage in women was 90, 6% ($x2 = 3.97$; $p = 0.046$). Using the other two tests, there is such a trend, but with no statistically significant difference. There is no statistically significant difference between patients in the SILC group and those with SLC in terms of the cosmetic effect after surgery.

CONCLUSION

Both procedures are comparable with respect to intraoperative difficulties and complications, postoperative nausea and vomiting, time to recover from the bowel passage, hospital stay, postoperative complications and cosmetic effect.

The data in the literature on cosmetic effects are quite contradictory. Given the lack of statistically significant difference between the two methodologies in our study, the cosmetic effect should be a factor for the patient's choice of methodology.

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