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Laparoscopic Single-Port Versus Traditional Multi-Port Laparoscopic Cholecystectomy

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ABSTRACT

Background and Objectives: Safety, efficacy, and costs are still debated issues in single-port laparoscopy. The aim of the study was to compare clinical outcomes and hospital costs for conventional 4-port laparoscopic cholecystectomy (4PLC) and single-port laparoscopic cholecystectomy (SPLC) performed at a single institution.

Methods: A series of 40 SPLC patients operated on from October 2016 to May 2017 were compared to a hystorical series of 40 4PLC patients. Primary endpoints were the operative time, blood loss, postoperative pain, analgesia requirement, length of stay, and morbidity. Secondary endpoints were the operative costs and total hospital costs.

Results: No patient required surgical conversion in both groups. Duration of surgery was significantly longer in the SPLC group. Length of hospitalization was shorter for patients operated on by SPLC (1.9 ± 0.9 vs 2.3 ± 1.2 days; P = .104). According to visual analogue scale evaluation, the pain profile was similar. Minor postoperative complications were present in 12.5% of the SPLC group and 2.5% in 4PLC group (P = .200). The total hospitalization costs associated with SPLC procedure were lower compared to standard 4PLC procedure. As regards the disposable operating room equipment costs, a statistically significant difference in favor of SPLC technique was found.

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Conclusion: SPLC has shown relevant procedure and postoperative outcomes when compared to traditional 4PLC. The technique has proved to be promising even in cases of acute cholecystitis considered to date a relative contraindication. Further studies are needed to confirm its safety and feasibility in this setting. In contrast with the current evidence of increased costs for the single-port technique, a reduction of material and hospitalization costs was experienced in our study.

Key Words: Cholecystectomy, Laparoscopic, Treatment Outcome, Health Care Costs.

INTRODUCTION

In order to minimize the number of skin incisions and ports required and to enhance the benefit of the laparoscopic approach, in recent years surgeons have developed the use of single-incision laparoscopic surgery. Single-incision laparoscopic cholecystectomy was first described in 1995 by Navarra and colleagues¹ in a report of 30 patients with favorable outcomes. This approach has also been used for appendectomy, sleeve gastrectomy, splenectomy, and colectomy.^{2–5}

Retrospective reports of laparoscopic cholecystectomy through a single access show this approach to be feasible and associated with outcomes similar to standard 4-port laparoscopic cholecystectomy (4PLC).⁶ The proposed benefits of decreased pain, improved cosmesis, and increased satisfaction were cited in numerous retrospective series, even if sometimes results are controversial.^{7,8}

Specially designed equipment has been developed for single-incision procedures including purpose-built optics and instruments, such as ports, roticulating devices, and fixation instruments.

A recognized issue related to these new instruments, mostly disposable, is cost. The use of single-use instruments generally increases instrumental costs also for laparoscopic cholecystectomy.

Recent studies seem to penalize single-port technique as, with the exception of a few studies, the majority show

higher operational costs for single-port laparoscopic cholecystectomy (SPLC) compared to conventional 4PLC when disposable material is used.^{9,10} Since the Unimax disposable single-port device has become routinely used at our institution, we aimed at evaluating how it influenced the clinical outcomes and the operative and total hospital costs when compared to 4PLC.

METHODS

SPLC was introduced at our department in October 2016. Since then, all the laparoscopic cholecystectomies (n = 40) performed until October 2017 were SPLCs and registered consecutively in a prospective database. Patients characteristics included patient age, sex, body mass index, previous abdominal surgery, and associated comorbidities. All the SPLC and 4PLC procedures were performed by the same surgeon (MC), experienced in laparoscopic procedures.

Forty 4PLC patients operated on before the advent of single-port were selected to serve as matching controls. All the patients with symptomatic gallbladder stones were included. Acute cholecystitis (AC) and chronic cholecystitis (CC) were not considered a contraindication to SPLC and therefore included in the study. The outcome of the procedures was defined by the following parameters: duration of operation (time from skin incision to wound dressing), blood loss, associated operations, surgical conversion, need of additional trocars, abdominal drain positioning, postoperative pain measured by visual analogue scale, analgesia requirement, length of hospital stay, and postoperative morbidity (according to Clavien-Dindo Classification).

Detailed costs of the two techniques were evaluated. The total operating room (OR) costs (actual cost to the hospital for equipment, and time of OR occupation) and postoperative period hospital costs were examined to have the complete total hospitalization costs. OR personnel salaries were excluded from OR costs since they were similar and changeless for both procedures.

The operative costs included only the use of disposable material employed, namely the single-port or the trocars, a sterile bag (only in 4PLC patients), an Endo-clip applier charger and a suction/irrigation device. The procedure time costs were calculated on a forfait basis of 500 euros/ hour and costs related to the in-hospital stay calculated on 450 euros/day.

SPLC technique

The four-channel single-port system (Single port, Unimax Medical Systems Inc., Taipei, Taiwan) (**Figure 1**) is inserted through a 2-cm fascial incision in the umbilicus. After creation of pneumoperitoneum, a 5-mm 30° -angle telescope is introduced. One transabdominal stay suture is passed in the fundus and used for transcutaneous retraction of the gallbladder. In case of a really long gallbladder, an additional suture is passed in the infundibulum. This suture allows a "puppeteering technique" for mobilization of the infundibulum, enabling complete visualization of Calot's triangle by suture traction.¹¹

Dissection is conducted with a reusable 5-mm laparoscopic hook and a 5-mm reusable prebent grasper (Olympus Medical Systems, Hamburg, Germany). The cystic artery and duct are isolated following the "critical view of safety" principles, closed with clips (10-mm Endoclip, Microfrance, Saint Aubin le Monial, France) and divided by reusable scissors.

No specimen retrieval bag is used as the Unimax device already acts as a wound protector.

4PLC Technique

We performed standard laparoscopic cholecystectomy (LC) in according to the American technique.¹²

The pneumoperitoneum is achieved through the umbilicus via an open technique; a 10-mm trocar is inserted to accomodate a 30°-angle telescope. Another 10-mm trocar is inserted in the epigastrium, which is the main right



Figure 1. Intra-operative view. The four-channel Unimax singleport positioned at the umbilicus for a laparoscopic procedure.

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working port for the surgeon. One 5-mm trocar in the right lumbar region is used for gallbladder fundus traction and another 5-mm trocar in the right midclavicular line, below the costal margin for the surgeon's grasper. All the instruments are reusable like in the SPLC. After following surgical steps identical to SPLC, the gallbladder is placed in a disposable sterile bag and extracted from the umbilical port.

Statistical Analysis

Correlations were assessed by the Spearman rank correlation coefficient. Comparisons between groups were carried out by the nonparametric Mann Whitney *U*-test for continuous variables and by the χ^2 test for binary variables. A *P* value < .05 was considered statistically significant.

A logistic regression model was used to identify variables affecting the probability of a conversion and of postoperative complications in univariate analysis. All parameters with a P value < .05 at univariate analysis were included in a multivariate model through a backward selection procedure to evaluate potential independent predictors for conversion and postoperative complications. Statistical analysis was performed using the software package SPSS Version 13.0 (SPSS Inc, Chicago, Illinois, USA).

RESULTS

SPLC and 4PLC patients did not differ significantly regarding age, sex, body mass index, and comorbidity (**Table 1**). Preoperative endoscopic treatment for suspected choledocholithiasis was performed in 3 SPLC and one 4PLC patients. Previous abdominal surgery in the upper quadrants was not experienced in both groups. No patient required conversion to an "open" approach for technical difficulties in both groups. One trocar was added in a SPLC patient due to a bleeding from a hepatic vein branch of the liver bed. In this case, an abdominal drain was left in place at the end of surgery. Blood loss < 50 mL was showed in 5 SPLC and 2 4PLC patients, respectively, and it was absent in the remnant.

Table 1. Characteristics of Patients and Postoperative Results Crouped for Laparoscopic Procedure				
Characteristic	$\frac{1}{\text{SPLC (n = 40)}}$	$\frac{4PLC (n = 40)}{4PLC (n = 40)}$	<i>P</i> -Value	
Sex, F/M	21/19	18/22	.502	
Age, years	55.7 (13)	59.9 (15)	.199	
BMI, kg/m ²	27.2 (5)	27 (5.3)	.846	
Associated co-morbidities, patients (%)	23 (57.5)	30 (75)	.097	
Duration of surgery, minutes	86.8 (32.9)	64.5 (22.2)	<.001	
Trocar addition, n	1	0	.999	
Surgery conversion, n	0	0	_	
Associated operation, n	2	1	.999	
Abdominal drain positioning	1	10	.003	
VAS at 4 hours	1.69 (1.8)	1.68 (1.8)	.967	
VAS at 24 hours	1.59 (2.1)	1.23 (1.8)	.413	
Pain medications, patients (%)	35 (87.5)	32 (80)	.227	
Paracetamol, g/d,	2.5 (1.7)	2.1 (1.5)	.265	
Ketorolac, mg/d,	11.6 (24.4)	7.5 (18.9)	.405	
Hospital stay	1.9 (0.9)	2.3 (1.2)	.101	
Morbidity, patients (%)	5 (12.5)	1 (2.5)	.200	
Hystological Diagnosis (1/2/3)*	6/9/25	2/2/36	.019	

4PLC, 4-port laparoscopic cholecystectomy; BMI, body-mass index; SPLC, single-port laparoscopic cholecystectomy; VAS, visual analogue scale.

Values are meant as median (SD) unless indicated otherwise.

*Diagnosis, 1) symptomatic gallbladder stones, 2) acute cholecystitis, 3) chronic cholecystitis.

Duration of surgery was significantly longer in SPLC group (86.8 \pm 32.9 minutes vs 64.5 \pm 22.2 minutes; *P* < .001). An appendectomy was associated to cholecystectomy in 2 SPLC patients and in one 4PLC patient.

While in the 4PLC group the duration of surgery did not change significantly in relation to the diagnosis, in the SPLC group it depended on the inflammatory state of the gallbladder. In particular, mean length of surgery increased from symptomatic gallbladder stones (80 min), to CC (87.5 minutes) and to AC (105 minutes). AC and symptomatic gallbladder stones conditions differed considerably but without reaching a statistical significance (P = .092).

CC was the predominant histological diagnosis in both groups. However, significant differences were found between pathological categories. In fact, symptomatic gallbladder stones, AC, and CC accounted respectively for 15/ 22.5/62.5% in the SPLC group and 5/5/90% in the 4PLC group (P = .019).

Other clinical parameters able to influence the operative time such as gender, age, body mass index, associated comorbidities, and previous surgery, were analyzed in both groups but no significant correlation was found. A significant difference was found in abdominal drain positioning, since 10 4PLC patients experienced it vs 1 SPLC patient (P = .003).

According to visual analogue scale evaluation, the pain profile was similar, but SPLC group was associated with more analgesics requirement. Length of hospitalization was shorter for patients operated on by SPLC when compared to the 4PLC group (P = .104), reaching a statistically significant advantage of the former when a binary analysis is performed (P = .04). Other clinical factors influencing the hospital stay in the whole group were analyzed and a positive correlation with the age of the patients (P = .049) was found. Postoperative complication rates were 12.5% in SPLC group and 2.5% in 4PLC group (P = .2).

In both groups mostly minor complications such as fever as only symptom (4 SPLC and 1 4PLC patients) and one prolonged abdominal pain were experienced. All complications except for one SPLC patient were classified as Clavien class I and managed conservatively. In this case, the patient needed reoperation through a laparotomy to manage a bile leak from the liver bed. As regards costs, evaluation per single procedure and hospitalization are showed in **Table 2**.

The disposable OR equipment costs are significantly in favor of SPLC technique. In fact, the cost of the Unimax single-port device is 122 euro compared to 268.40 euro that is the cost of 4 standard disposable trocars. Furthermore, a sterile bag for gallbladder retrieval has been routinely used in the 4PLC group. In SPLC technique this device is unnecessary since the Unimax single-port is already equipped with a wound protector. Since duration of surgery is longer in SPLC group than in 4PLC group, the total OR costs, taking into account OR occupation time and material costs, become equivalent (929 vs 916.52 euros, respectively; P = .807). Merely postoperative period care costs are again in favor of SPLC technique, thanks to a shorter hospital stay (P = .104).

The total hospitalization costs associated with SPLC procedure are lower than standard 4PLC procedure, without reaching a statistically significance (1811.76 vs 1989.87 euros; P = .204).

The saving obtained by each hospitalization for a SPLC procedure when compared to 4PLC technique is 178 euros. Thus, for the 40 SPLC procedures examined in the present study, a saving of 7120 euros was obtained.

Table 2. Costs Evaluation per Single Procedure and Hospitalization				
Characteristic	SPLC $(n = 40)$	4PLC ($n = 40$)	P-Value	
Disposable OR equipment costs, euro	212.17 (10.9)	380.25 (0)	<.001	
Total OR costs (equipment, time), euro	929 (265)	916.52 (184)	.807	
PO care costs, euro	888.75 (426.1)	1068.75 (545.8)	.104	
TH costs, euro	1811.76 (562.1)	1989.87 (677.7)	.204	

Values are expressed as mean (SD).

4PLC, 4-port laparoscopic cholecystectomy; OR, operating room; PO, post-operative; SPLC, single-port laparoscopic cholecystectomy; TH, total hospitalization.

DISCUSSION

In the present study, the preliminary results of a prospective study regarding costs, feasibility and safety of SPLC compared to the traditional laparoscopic cholecystectomy have been represented. Some studies testify a greater technical difficulty of the single-port procedure when compared to the traditional technique.^{6,8} In the multicentre, randomized controlled trial conducted on 600 patients (MUSIC trial) by Arezzo et al.⁷ a 5% conversion rate and a 6% rate of additional trocar added was reported.

In our study, no surgical conversions and one case (2.5%) of trocar addition were reported in SPLC group. Furthermore, an abdominal drain was positioned in only one case and blood loss was absent in 34 (85%) patients. These facts testify the possibility of overcoming the difficulties related to the technique. The reason behind the longer operative times are related to the use of limited instruments and difficult ergonomics associated with the single-port technique. Another factor affecting the operative time is related to the initial learning curve. In fact, in our series we observed a 10-minute average decrease in operative time in the last 15 cases of SPLC.

SPLC can be hazardous in patients with AC because of the increased risk of bleeding and biliary lesions. This pathological condition is considered a contraindication in most the current experiences described in literature.^{8,9} In our series, AC did not represent an exclusion criterion. In SPLC group, however, time of surgery was related with histological diagnosis. In fact, AC cases showed longer operative times, consistent with the experience reported by Beninato et al.¹³ Notwithstanding, this condition didn't seem to affect the postoperative course and hospital stay, thus confirming the reliability of the single-port approach also in case of AC. SPLC technique, for its less invasive nature, should theoretically produce less postoperative pain and less analgesics requirement compared to the traditional 4PLC technique. Postoperative pain assessment is consistently included as a primary or secondary outcome in recent studies. However, the outcome remains uncertain as there are reports showing equivalent,6,14 higher,^{15,16} and lower^{8,17} pain perception in single-port technique compared to the traditional 4PLC.

In our study, according to visual analogue scale evaluation, the pain profile was similar but SPLC group was associated with more analgesics requirement. However, this occurrence has not prevented the SPLC patients from having a shorter hospital stay if compared to the 4PLC group. This represents a promising result and in line with the results of the literature.⁷ Postoperative complications in both groups were similar and all classified as Clavien Dindo I. Only one SPLC patient had a bile leak managed operatively, not directly due to a failure of the technique. A morbidity rate of 12.5% in SPLC group is aligned with the latest results described in literature.^{6,7,18–20}

The outcomes in minimal-access surgery are not only judged by patient's safety but also by a better quality of care in terms of pain, cosmesis, and costs. Until today, SPLC was considered uneconomical for application in everyday surgical practice.9,10,21 The cost of specially designed equipment like purpose-built optics, disposable roticulating or prebended instruments, multichannel ports and fixation instruments significantly exceed costs of traditional cholecystectomy. In our experience, disposable OR equipment costs for SPLC group was almost half the cost of the 4PLC group equipment. The four-channel single-port system produced by Unimax Medical Systems is the first device with an advantageous cost compared to a set of 4 disposable trocars produced by companies that are most frequently found on the market. Besides this, only a reusable prebended grasper was necessary for the SPLC procedure. While most authors agree that OR costs are higher for the single-port, total hospitalization cost results are not univocal.^{22,23} In our study, postoperative period care costs and total hospitalization costs are again in favor of SPLC, thanks to a reduced hospital stay.

CONCLUSION

Despite longer operative times partly due to the "learning curve" and to the greater number of AC treated, SPLC has shown relevant procedure and postoperative outcomes when compared to traditional laparoscopic cholecystectomy.

Our results therefore appear aligned with those of the literature and show that this technique is safe and effective in experienced hands and represents a valid alternative to traditional 4PLC for the treatment of symptomatic cholelithiasis. Our study has also included cases of AC considered to date a relative contraindication. The experience has proved to be promising even if further studies are needed to confirm its safety and feasibility before its widespread adoption. Contrary to what is described to date in literature, economic advantages related to the SPLC technique are evident not only for the instrumentation but also for the overall hospital costs. In fact, single-port technique has shown to be more cost-effective than standard 4PLC when the use of disposable instruments is limited and when the length of hospitalization is shorter.

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