## Single-port laparoscopic cholecystectomy vs standard laparoscopic cholecystectomy

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**Abstract: Background:** Single-incision laparoscopic cholecystectomy (SILC) is a newer approach that may be a safe alternative to traditional laparoscopic cholecystectomy (TLC) based on retrospective and small prospective studies. As the demand for single-incision surgery may bedriven by patient perceptions of benefits, we designed a retrospective study to compare Single port laparoscopic cholecystectomy and the traditional 4 port laparoscopic cholecystectomy. **Methods:** patients having symptomatic Cholelithiasis. All cases were selected after fulfilling the criteria of inclusion into the study. Preoperative characteristics and operative data were recorded, including length of stay, Pain scores in recovery and for 48 h and satisfaction with wound appearance at 2 and 4 weeks were reported by patients. **Results:** The median Total Operative Time was statistically significantly shorter in the TLC group compared to the SPLC group (52 Vs 71 minutes). Only 2 patient (4%) in the SPLC group developed a port-site hernia 6 months after surgery that was treated by mesh repair. **Conclusions:** SILC is a longer operation but has the potential to be a safe technique with a low complication rate, short in-hospital stay. Recovery and pain scores are not significantly different. There may be an improvement inpatient satisfaction with wound appearance. Both procedures are valid approaches to cholecystectomy.

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#### 1. Introduction:

Gallstone disease is one of the most common problems affecting the digestive tract. Autopsy reports have shown a prevalence of gallstones from 11-36 percent. Obesity, pregnancy, dietary factors, Crohn's disease, terminal ileal resection, gastric surgery, hereditary spherocytosis, sickle cell disease and thalassemia all are associated with an increased risk of developing gallstones. Women are three times more likely to develop gallstones than men.<sup>(1)</sup>

Laparoscopic cholecystectomy is the standard operative procedure for patients with symptomatic cholelithiasis. Introduced in 1985, laparoscopic cholecystectomy, has been an important development in general surgery. Its introduction resulted in surgical procedures with reduced blood loss, enhanced recovery and less major wound complications.<sup>(2)</sup>

Single incision laparoscopic surgery techniques were introduced in the 1990s. When performing this particular type of laparoscopic surgery only one incision is made, usually through the umbilicus. In general, smaller and fewer incisions result in less pain, accelerate postoperative recovery and improve cosmetic result.<sup>(3)</sup>

The current standard approach to laparoscopic cholecystectomy [conventional laparoscopic cholecystectomy (CLC)] involves a 10-mm incision on the umbilicus, a 5- or 10-mm incision in the

Epigastric or subxyphoid region, and one or two 5-mm incisions in the right upper quadrant.<sup>(3)</sup>

In Single-incision laparoscopic cholecystectomy, a single 15–25 mm incision is made around the umbilicus and a single port is passed through the fascia. The cosmetic outcome of SILC is, therefore, expected to be better because the surgical wound is hidden within the umbilicus, leaving no visible abdominal scars, hence it is called "scar less" surgery.<sup>(4)</sup>

Single-port laparoscopic cholecystectomy has the potential to be a safe technique with a low complication rate, short in-hospital stay and comparable operating time. Single-port cholecystectomy provides the patient an almost non-visible scar while preserving optimal quality of surgery.<sup>(5)</sup>

Single incision laparoscopic cholecystectomy was a technically more challenging but safe procedure compared with conventional laparoscopic cholecystectomy because of the close proximity of the working instruments with limited triangulation; limited range of motion of the laparoscope and instruments, and decreased number of ports all contributed toward increased difficulty. The operating time is long initially, but it reduces as surgeons become more experienced.<sup>(6)</sup>

## 2. Patients and Methods:

This retrospective study was conducted on 100 patients having symptomatic Cholelithiasis. All cases were selected after fulfilling the criteria of inclusion into the study.

## **Inclusion criteria**

The patients are considered appropriate candidates for the present study if they are willing to provide consent and comply with the evaluation and treatment method. Inclusion criteria are patients less than 60 years with symptomatic cholecystolithiasis confirmed by ultrasound.

#### **Exclusion criteria**

exclusion included The criteria acute cholecystitis (diagnosedpreoperatively by clinical examination and confirmed by ultrasound), patients over 60 years, choledocholithiasis (icterus and/or high bilirubin higher than the normal range), cholangitis, patients with a single large stone more than 2 cm in size (as it may lead to widening of the port site to remove it), known pregnancy, moderate to severe systemic disease (ASA III or more), known liver cirrhosis, coagulopathy, and patients with severe chronic obstructive pulmonary disease, history of abdominal malignancy, morbidly obese patients (BMI>35 kg/m 2), and calcified gall bladder.

#### Patients were divided to 2 groups

Group A: (50 patients) with single port laparoscopic cholecystectomy.

Group B: (50 patients) with Traditional laparoscopic cholecystectomy.

After full preoperative evaluation, patients were randomly assigned to either one of two groups using the closed envelope technique:

1) The single-port laparoscopic cholecystectomy (SPLC) group.

#### 2) The traditional 4 ports laparoscopic cholecystectomy (TLC) group.

# **Operative technique**

All patients received perioperative prophylactic antibiotics as well as general anesthesia with endotracheal intubation.

The incision extended the whole length of the umbilicus taking great care not to extend beyond it and usually ranged between 2-3 centimeters in length. After accessing the peritoneal cavity, the SILS<sup>™</sup> Port was introduced.

#### Single-port Laparoscopic cholecystectomy:<sup>(7)</sup> Instruments

Standard straight instruments were used including scissor, non-toothed grasper, needle holder, Maryland, hook, spatula, clip applier 10 mm, 30° 10mm camera and /or 5 mm 0 angle camera and suction aspirator. The Harmonic ACE<sup>TM</sup> (Ethicon Endo-Surgery, Cincinnati, OH, USA) was also used for division/ closure of the cystic duct and artery. The SILS<sup>™</sup> Port (Single Incision Laparoscopic Surgery) with multiple access channels (Covidien, Mansfield, MA, USA) was the port used in the present study.

# Positions

Patients were placed in a supine position with the operating surgeon standing between the patient's legs and the assistant (camera man) on the left side of the patient.

#### Procedure

A Single vertical intra-umbilical incision was made by pulling out the umbilicus. Patients were placed in a supine position with the operating surgeon standing between the patient's legs and the assistant (camera man) on the left side of the patient. Three trocars were introduced through the SILS<sup>™</sup> Port three working channels; one for the camera, a second for the dissecting instrument and a third for the non-toothed grasper used to hold the neck of gall bladder. Within the SILS<sup>™</sup> Port, the camera was placed inferiorly and the two working ports at 2 and 10 o'clock. Pneumoperitoneum was next created to a pressure of the 15 mm/Hg. An additional 2/0 polypropylene suture on straight needle was introduced through the abdominal wall at the right hypochondrial region and passed through the gallbladder fundus and back through the abdominal wall to retract the fundus of gall bladder upwards and laterally. At this point the patient was place in a reverse Trendelenburg position with the right shoulder elevated. After appropriate exposure of Calot's triangle, the steps and principles of the operative procedure were the same as in conventional four-port laparoscopic cholecystectomy i.e., dissection of the cystic duct, the cystic artery and the gallbladder from its liver bed. A critical view of safety was attempted in all patients. This was followed by transection of the cystic duct and cystic artery and removal of the gall bladder. For closure/division of the cystic duct and artery, clips and scissors were used.

#### Statistical analysis of the data

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. Significance of the obtained results was judged at the 5% level.

# 3. Results:

The present study included hundred patients admitted to Alexandria Main University Hospital with ultrasonographically-proven diagnosis an of symptomatic uncomplicated gallstone disease.

They were 98 females (98%) and a two male (2%).

Their age ranged from 19-65 years with a median of 34 years.

Following preoperative evaluation and preparation for surgery, patients were randomly assigned using the closed envelope technique into either one of two groups: the Single Port Laparoscopic Cholecystectomy (SPLC) group= 50 patients and the Traditional Laparoscopic Cholecystectomy (TLC) group=50 patients.

There was no statistically significant difference between both study groups as regards age and sex distribution, Body mass index (Kg/m<sup>2</sup>), associated comorbodities and the incidence of patients who had prior lower abdominal surgeries as shown in Table 1.

	SPLC gr	oup	TLC gr	oup		
	(n = 50)		(n = 50)		р	
	No.	%	No. %			
Age (years)						
Range	19.0 - 51	.0	23.0 - 6	5.0		
Mean $\pm$ SD.	$31.96 \pm 9$	.22	$36.56 \pm$	9.79	0.017	
Median	30.0		34.0			
Sex						
Male	2	4.0	0	0.0	<sup>FE</sup> p=	
Female	48	96.0	50	100.0	0.495	
BMI (kg/m <sup>2</sup> )						
<25	16	32.0	6	12.0		
25 - 29	8	16.0	14	28.0	0.039	
>30	26	52.0	30	60.0		
Range	18.50 - 4	18.50 - 41.50		33.0		
Mean $\pm$ SD.	$28.49 \pm 5.30$		$29.40 \pm 3.30$		0.305	
Median	29.20		30.50			
Associated co-morbidities						
Diabetes Mellitus	0	0.0	6	12.0	FEp = 0.027	
Hypertension	0	0.0	6	12.0	FEp = 0.027	
Asthma	4	8.0	6	12.0	$^{FE}p = 0.741$	
Previous lower abdominal surgery						
Appendectomy	4	8.0	2	4.0	<sup>FE</sup> p=0.678	
Caesarian section	18	36.0	22	44.0	0.541	

Table (	(1)	: Com	parison	between	both s	study	group	s as re	gards	their	demogra	phic da	ata
									<b>-</b>				

FE: Fisher Exact test- t: Student t-test \*: Statistically significant at  $p \le 0.05$ 

Data regarding the operative time, the need for an extra trocar, conversion to either conventional laparoscopic or open cholecystectomy are illustrated in Table 2.

All procedures were completed laparoscopically and there were no conversions to neither conventional four port nor open cholecystectomy. Furthermore, the addition of an extra trocar was not resorted to in any patient in SPLC patients.

The median *Total Operative Time* was statistically significantly shorter in the TLC group compared to the SPLC group.

The median *Abdominal Wall Time* (referring to the time consumed in accessing the abdominal cavity plus the time consumed in closure of abdominal incisions) constituted 43.5% of the total operative time in the SPLC group compared to 9.9% in the TLC group with this difference being statistically significant ( (Figures 1 & 2).

In the SPLC group the Harmonic  $ACE^{TM}$  was used for both closure/division of the cystic duct and artery as well as dissection of the gallbladder from its liver bed in 20 patients (80%). In the TLC group, the Harmonic  $ACE^{TM}$  was used in 8 patients (32%).

Intra-operative complications encountered in both study groups are illustrated in Table 3. The incidence of gallbladder perforation with bile spillage was significantly higher in the SPLC group.

However the difference in the incidence of stone spillage into the peritoneal cavity was statistically insignificant between both study groups. Neither bile leaks nor common bile duct injuries were encountered in the present study.

	SPLC grou	p (n = 50)	TLC grou	n	
	No.	%	No.	%	р
Total operation time (min)					
Range	50.0 - 97.0		40 - 65		
Mean $\pm$ SD.	$71.32 \pm 13.4$	12	$51.4 \pm 7.97$		< 0.0001
Median	71.0		52.0		
Dissection time (min)					
Range	16.0 - 72.0		30.0 - 60.0		
Mean $\pm$ SD.	$41.44 \pm 16.1$	9	$46 \pm 6.74$		0.069
Median	44.0		45.0		
Abdominal wall time (min)					
Range	15.0 - 52.0		4.0 - 10.0		
Mean $\pm$ SD.	$29.88 \pm 8.50$	)	$5.72 \pm 1.74$		< 0.001
Median	28.0		5.0		
The need for an extra trocar					
No	50	100.0	50	100.0	-
Yes	0	0.0	0	0.0	
Conversion to conventional LC					
No	50	100.0	50	100.0	-
Yes	0	0.0	0	0.0	
Conversion to open LC					
No	50	100.0	50	100.0	
Yes	0	0.0	0	0.0	-

Table (2): Comparison between both study groups as regards the op	perative time, the need for an extra trocar
and the conversion to either conventional or open LC.	



Figure (1): Distribution of studied sample according to Dissection time (in minutes) and abdominal wall time (in minutes) in SPLC group.



Figure (2): Distribution of studied sample according to Dissection time (in minutes) and abdominal wall time (in minutes) in the TLC group.

	SPLC group	(n = 50)	TLC group	(n = 50)					
	No.	%	No.	%	р				
Intra operative complications									
GB perforation	24	48.0	10	20.0	0.0031				
Stone spillage	4	8.0	2	4.0	1.000				
CBD injury	0	0.0	0	0.0	-				
Bowel injury	0	0.0	0	0.0	-				
Bleeding	0	0.0	0	0.0	-				

Table (3): Intra-operative complications encountered in both study groups

FE: Fisher Exact test- t: Student t-test \*: Statistically significant at  $p \le 0.05$ 

The postoperative course and complications are illustrated in Table 4. No statistically significant difference was detected between the incidence of postoperative nausea and vomiting (PONV) in both study groups. Liquid diet was started in all patients six hours postoperatively and was well tolerated.

All patients in the present study were discharged on the morning of postoperative day one. Readmission was required in one patient (2%) in the TLC group who presented on the tenth postoperative day with right leg deep vein thrombosis that was treated by anti-coagulants on an inpatient basis for one week before discharge.

Only 2 patient (4%) in the SPLC group developed a port-site hernia 6 months after surgery that was treated by mesh repair.

	SPLC group	(n = 50)	TLC group		
	No.	%	No.	%	р
Nausea and vomiting					
No	48	96.0	46	92.0	$FE_{p} = 0.678$
Yes	2	4.0	4	8.0	p= 0.078
Post-operative complications					
Bile leakage	0	0.0	0	0.0	-
Bleeding	0	0.0	0	0.0	-
Jaundice	0	0.0	0	0.0	-
Wound infection	0	0.0	0	0.0	-
Port site hernia	2	4.0	0	0.0	<sup>FE</sup> p= 0.495
Need for readmission					
No	50	100.0	49	98.0	$FE_{n-} > 0.05$
Yes	0	0.0	1	2.0	p->0.05
Cause of readmission					
DVT	0	0.0	1	2.0	$FE_{p} = >0.05$

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FE: Fisher Exact test

The overall 24-hour postoperative median pain score in the SPLC group ranged from 0-5 with a median of 3. In the TLC group, the overall 24-hour postoperative median pain score ranged from 0-6 with a median of 4. The difference in the overall 24-hour postoperative median pain score between both study groups was statistically insignificant as shown in figure3.



Figure (3): The overall 24-hour postoperative median pain score in both study groups.

There was no statistically significant difference between both study group as regards the number of patients whose VAS was more than 4 at 6, 12 and 24 hours postoperatively and therefore received one analgesic ampoule accordingly as shown in Table 5.

Table (5): The number (percentage) of patients who received one analgesic ampoule at 6, 12 and 24 hours postoperatively in both study groups

	SPLC group (n =	= 50)	TLC group (n =	n		
	No.	%	No.	%	Р	
Pain score (>4)						
6 hours	36	72.0	34	68.0	0.663	
12 hours	14	28.0	24	48.0	0.039	
24 hours	12	24.0	12	24.0	1.000	

In the SPLC group, the median patient satisfaction score was 10 in all patients (100%) while in the TLC group it ranged from 9-10 with a median of

9. The difference in the median patient satisfaction score between both study groups was statistically significant as shown in Figure 4.



Figure (4): The median patient satisfaction score in both study groups.

Follow up was done at the end of the first and second postoperative weeks, patients underwent physical assessment and abdominal ultrasonography.

At the end of the third and sixth postoperative months, physical assessment was repeated. In addition, blood was sampled for bilirubin, aminotransferase, alkaline phosphatase, and gamma-glutamiltransferase levels.

No significant abnormailities were encountered.

#### 4. Discussion:

During recent years, laparoscopic surgery has developed rapidly. With great technical progress, the visualization and handling of the instruments has been improved enormously. For that reason many surgical diseases can be treated laparoscopically ensuring the same safety standard as conventional surgery. Applying laparoscopic techniques, operations are less traumatic; thus, the incidence of wound infections and incisional hernias, of which especially overweight patients are affected, has decreased. Furthermore, there is less postoperative bowel paralysis, allowing a faster postoperative feeding progress.<sup>(8)</sup>

After laparoscopic procedures, cosmetic results are much better compared with traditional operations. Postoperative pain is reduced, which results in faster mobilization and a lower number of immobilization-associated complications, such as venous thrombosis and pulmonary embolism.<sup>(9,10)</sup>

Furthermore less pneumonia, less use of analgesics, and shorter hospital stay characterize laparoscopic procedures. Summarized, the benefit for the patient is faster recovery and better cosmetic result. Even in oncological surgery, laparoscopic procedures have an outcome comparable with open surgery.

In the present study, SILS was attempted in 50 patients. The technique of SILS has not been standardized universally and the optimum technique remains to be defined. Consequently, different surgeons have attempted SILS in different ways all over the world. For gallbladder elevation to expose Calot's triangle, various techniques have been reported including the use of trans-abdominal sutures, Kirschner wires and loop retractors.<sup>(11)</sup>

In the present study, a transabdominal suture placed through the right hypochondrium was used to achieve elevation of the gallbladder upward and laterally while a non-toothed grasping forceps was used to retract the Hartmann's pouch laterally. Furthermore, different manipulative instruments were used for dissection namely straight and reticulating instruments. In the present study, the SILS<sup>TM</sup> PORT was used with straight instruments. Reticulating instruments have been reported to offer significant advantages and sometimes have been reported as indispensable for SILS.<sup>(12)</sup>

However, such instruments were not available at our institution at the time of the present study. In the present study, SILS was completed successfully in 50 patients (100%) using straight instruments. In addition, there was no need for either extra port insertion or conversion to the conventional four ports LC. Similar findings were reported by others who did not resort to the insertion of extra ports in SILS. <sup>(13,14)</sup>

The lack of need for either extra port insertion or conversion to the conventional four port LC in the present study can be attributed to the highly selective policy of patients adopted in the present study. All patients included had uncomplicated symptomatic gall stone disease and patients with complicated cholecystitis were excluded. Evidence to this conclusion come from the work of Kimberly et al and Chuang et al who reported their need to insert an extra port to in patients with severely inflamed gall bladder and/or in presence of dense pericholecystic fibrosis.<sup>(15)</sup> Other reported reasons for conversion to conventional four port LC in patients with uncomplicated gall stone disease which included obscure anatomy of Calot's triangle, inability to maintain pneumoperitoneum and inadequate exposure of Calot's triangle.<sup>(16)</sup>

In the Bucher et al study, the operative time ranged from 40-77min with a median of 52 minutes while in the study of that of ROA et al it ranged from 19-100 minutes with a median of 40 minutes. <sup>(17,18)</sup>

On the other hand, Hong et al reported an operative time that ranged from 35-165 min with a mean of 79 minutes. <sup>(14)</sup>

The median operative time for SILC in the present study was 71 minutes. The slightly longer operative time in the present study is related to the fact that this was an initial experience with this operative technique that would therefore represent a learning curve.

The duration of postoperative hospital stay for patients of SILC in the present study was one day for all patients. The reason for the overnight stay in the present study was the measurement of the pain scores and analgesic requirements during the first 24 hours postoperatively and there was no contraindication for day case surgery.

In the present study, TLC was attempted in 50 patients, the basic technique of TLC, initial peritoneal access was achieved at the umbilicus with either the open Hasson technique or with a Veress needle followed by placement of an 11-mm optical trocar under direct vision. A 5-mm, 30 laparoscope was inserted. Under direct vision, three additional 5-mm trocars were inserted in the epigastrium, right subcostal at the anterior axillary line, and right subcostal at the midclavicular line. The fundus was elevated cephalad and the cystic duct and artery were dissected free, ligated with a 5-mm clip applier, and divided with endo-shears. The gallbladder was dissected off of the liver bed with cautery and placed into an endocatch bag, which was retrieved through the umbilical incision. The umbilical incision was closed with a figure-of-8 0-Vicryl suture. The lateral 5-mm trocar incisions were not closed at the fascial level.

In the present study the median operative time was 52 minutes which is in accordance with that reported for the technique by others.

Similarly, the duration of postoperative hospital stay for patients of TLC in the present study was one day for all patients. The reason for the overnight stay in the present study was the measurement of the pain scores and analgesic requirements during the first 24 hours postoperatively and there was no contraindication for day case surgery. The present study has examined the differences between single-incision laparoscopic and traditional laparoscopic techniques for cholecystectomy on a variety of important outcomes, including the failure of surgical technique, adverse events, mortality, length of operative procedure, postoperative pain score and analgesic requirements, length of hospital stay and the patient satisfaction with the final cosmetic outcome.

The median Total Operative Time was statistically significantly shorter in the TLC group compared to the SPLC group.

When the *total Operative Time* was subdivided into the *dissection Time* and the *abdominal wall time* (representing the time consumed in entering the abdomen plus the time consumed in closure of the abdominal incision).

The *abdominal wall time* (representing the time consumed in entering the abdomen plus the time consumed in closure of the abdominal incision) was statistically significantly longer in the SPLC. This difference is attributed mainly to the time consumed in thorough closure of the wider fascial defect in the single incision approach which constituted 43.5% of the *total operative time* for this group. It is worthy to note that the conventional four port approach no fascial defects are closed.

It is worthy to note that there was no statistically significant difference between both study groups as regards the incidence of stone spillage in the peritoneal cavity.

Readmission was required in one patient (2%) in the TLC group because of deep vein thrombosis. No patient was readmitted in the present study for the management of a complication of the operative technique itself.

Port site hernia (PSH) was encountered in two patient (4%) in the SPLC group. Tonouchi et al recognized the first report in the literature of a port-site hernia (PSH) by Fear in the context of gynecological surgery (1968).<sup>(19,20)</sup>

The first publication of a PSH following LC was in 1991 by Maio et al.<sup>(21)</sup>

Whilst this complication has long since been recognized, its significance is becoming more important with the increasing number of patients being treated in this way. The incidence of PSH in a range of laparoscopic procedures has been described as between 0.14%- 22%.<sup>(22,23)</sup>

In addition to pain, PSH can lead to severe complications including bowel obstruction, strangulation, and perforation.<sup>(24,25)</sup>

The factors predisposing to PSH can be divided into patient factors and operative factors. Patient predisposing factors include obesity, large diameter gall stones, diabetes mellitus, chronic obstructive pulmonary disease and renal failure.<sup>(26,27)</sup> Operative or surgical factors include: increased duration of surgery, wound infection, extension of the port incision, the use of drain and poor closure technique.<sup>(28,29)</sup>

In the present study, there was no statistically significant difference between the median pain score at 6, 12 or 24 hours postoperatively between both study groups. The difference in the overall 24-hour postoperative median pain score between both study groups was also statistically insignificant. Finally, the number of analgesic ampoules required by patients whose VAS was more than 4 at 6, 12 and 24 hours postoperatively were statistically insignificant. In the present study we have not found the single incision approach to be less painful than the traditional approach for laparoscopic cholecystectomy.

#### Conclusion

Single-port laparoscopic cholecystectomy is a longer operation but has the potential to be a safe technique with a low complication rate, short inhospital stay. Recovery and pain scores are not significantly different. There may be an improvement in patient satisfaction with wound appearance, Both procedures are valid approaches to cholecystectomy.

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