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Cholecystectomy by single incision laparoscopic surgery (SILS): early experience and technique standardization

F. CECI, C. DI GRAZIA, B. CIPRIANI, S. NICODEMI, S. CORELLI, M. PECCHIA, A. MARTELLUCCI, A. COSTANTINO, F. STEFANELLI, C. SALVADORI, A. NAPOLEONI, M. PARISELLA, E. SPAZIANI, F. STAGNITTI

SUMMARY: **Cholecystectomy by single incision laparoscopic surgery (SILS): early experience and technique standardization.**

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Single Incision Laparoscopic Surgery (SILS) is a recent surgical technique, first described in the 1990s. Its aim is to optimize the esthetic result offered by laparoscopy by minimizing the number of abdominal incisions. Various preliminary studies have been carried out on the application of SILS, especially in cholecystectomy and appendectomy.

This study evaluates the preliminary results of cholecystectomy by SILS (SILS™ Port) conducted between October 2009 and February 2011 on 21 patients (4 men and 17 women) with a mean age of 49.9 years and a mean Body Mass Index (BMI) of 22.8. All patients were treated by the same team, which had previously undergone six months' simulator training. There were two main selection criteria, both evaluated intraoperatively: absence of adhesions and of significant inflammatory sequelae from previous cholecystitis; and suitable distance between gallbladder and SILS access port.

Conversion to traditional laparoscopy was necessary in just two cases, while an accessory trocar was introduced in another two cases. Conversion to open surgery was not necessary in any case. One case of SILS cholecystectomy was complicated by postoperative bile leakage, which was treated conservatively, as the fistula had a low output. The mean duration of hospitalization was 3.6 days.

This preliminary experience led us to conclude that SILS is safe and highly satisfactory in the postoperative phase, thanks to the reduced need for painkillers and the improved esthetic result.

RIASSUNTO: **Colecistectomia laparoscopica con tecnica SILS *(single incision laparoscopic surgery):* esperienza preliminare e standardizzazione della tecnica.**

F. CECI, C. DI GRAZIA, B. CIPRIANI, S. NICODEMI, S. CORELLI, M. PECCHIA, A. MARTELLUCCI, A. COSTANTINO, F. STEFANELLI, C. SALVADORI, A. NAPOLEONI, M. PARISELLA, E. SPAZIANI, F. STAGNITTI

La Single Incision Laparoscopic Surgery (SILS) è una recente tecnica chirurgica, descritta per la prima volta negli anni Novanta, nata dalla necessità di ottimizzare il risultato estetico, riducendo al minimo il numero delle incisioni chirurgiche addominali proprie della laparoscopia tradizionale. Vari studi preliminari sono stati effettuati sull'applicazione della tecnica SILS, soprattutto nelle colecistectomie e nelle appendicectomie.

Nello studio presentato vengono valutati i risultati preliminari della colecistectomia SILS (dispositivo SILS™ Port) in 21 pazienti (4 maschi e 17 femmine), giunti alla nostra osservazione da ottobre 2009 a febbraio 2011, con età media di 49,9 anni e BMI (Body Mass Index) medio di 22,8. Tutti i pazienti sono stati trattati dalla stessa équipe, precedentemente addestrata tramite training di 6 mesi con simulatore. I criteri di selezione dei pazienti sono stati principalmente due, entrambi valutati intraoperatoriamente: l'assenza di aderenze e di importanti esiti di flogosi da pregresse colecistiti; un'adeguata distanza tra accesso SILS e posizione della colecisti.

Solo in 2 casi è stata necessaria la conversione in laparoscopia tradizionale, in altri 2 è stato introdotto un trocar accessorio ed in nessun caso è stata effettuata conversione in open. Un solo caso di colecistectomia con SILS è stato complicato nel post-operatorio da leakage biliare, peraltro trattato in maniera conservativa, poiché la fistola era a bassa portata. La durata media della degenza è stata di 3,6 giorni.

Al termine della nostra esperienza preliminare, la tecnica SILS si è dimostrata sicura e molto soddisfacente nel postoperatorio, grazie alla ridotta necessità di terapia farmacologica antidolorifica e al miglior risultato estetico.

KEY WORDS: Cholecystectomy - Laparoscopy - SILS.
Colecistectomia - Laparoscopia - SILS.

"Sapienza" University of Rome, Italy
"A. Fiorini" Hospital, Terracina (LT), Italy
Department of General and Emergency Surgery
(Director: F. Stagnitti)

Introduction

Laparoscopy is considered the gold standard for gallbladder surgery. Single Incision Laparoscopy Surgery (SILS), developed with the aim of reducing the number of abdominal incisions with respect to traditional laparoscopy, was first described at the end of the 1990s (1). This area of abdominal surgery is under constant evolution and SILS is a further development in the search for minimally invasive techniques. The SILS devices currently available enable cholecystectomy to be carried out through a single 2-3 cm incision in the navel, thus using a natural scar.

Numerous studies have demonstrated that the reduction in the number and length of incisions significantly reduces the postoperative pain (2,3). Reduced pain is not the only benefit of SILS: it also minimizes duration of hospitalization and complications, and improves the final esthetic result. Its potential benefits over traditional laparoscopy consist of a lower use of narcotics in the postoperative period, faster discharge, faster return to work, and, given the improved esthetic result, increased patient satisfaction.

In contrast with transluminal endoscopy (through natural orifices), single incision laparoscopy does not need any particular instruments and so does not lead to any substantial increase in costs, making the new technique easily acceptable. Furthermore, the easy conversion of single port surgery to conventional multiport laparoscopy if necessary is a guarantee of safety.

The single port technique has so far been described for cholecystectomy (4,5), appendectomy (6-9), and bariatric procedures such as gastric banding and sleeve gastrectomy (10-12). There are also numerous reports of its use in colorectal, gynecological and urological surgery. In this international perspective, we present our initial experience of cholecystectomy carried out using a single incision in the navel.

Patients and methods

Between October 2009 and February 2011, 21 patients (17 women and 4 men) underwent single port laparoscopic cholecystectomy (Table 1). BMI and age were not included among the exclusion criteria. The procedure was in all cases carried out by the same surgeon, an expert in traditional laparoscopic cholecystectomy. Before beginning treatment of patients, the entire surgical team underwent six months' simulator training. In addition, during this learning period were carried out with just 3 access ports and two closely positioned operative trocars (T1 and T2), to gain familiarity with the reduced instrument triangulation. During simulator training the team members swapped around between the various positions, to better understand the difficulties related to coordinated instrument maneuvers.

All patients underwent routine preoperative examinations (cardiological examination, chest x-ray, abdominal ultrasound and blood chemical tests) and provided their specific informed consent to the operation. A SILS™ Port (Covidien™, Inc., Norwalk, CT, USA) was used in all cases.

Surgical technique

Pneumoperitoneum was induced through the umbilical port with a multiuse Hasson trocar to explore the abdominal cavity and evaluate whether or not to carry out the cholecystectomy through a single access port. The criteria used were the absence of adhesions and inflammatory sequelae from previous cholecystitis and the distance between gallbladder and navel: a distant gallbladder would make it much more difficult to complete the operation from a single access port.

Patients underwent general anesthesia and orotracheal intubation and were placed in the lithotomy and reverse Trendelenburg position (30°) rotated 15° to the left, with legs apart (French position). The operating surgeon stood between the patient's legs, with the assistant surgeon, handling the laparoscope, on his right, and the scrub nurse on his left.

During the initial experience, we used traditional laparoscopy instruments. We then familiarized ourselves with the use of articulated instruments, with the routine introduction of the Endo Grasp Roticulator™ (Autosuture™, Covidien™, Mansfield, MA, USA), to enable work with hands uncrossed and "unaligned", through use of a longer instrument. If exposure of the hepatobiliary triangle was inadequate with the use of the Roticulator™ alone, the gallbladder was suspended with a transparietal thread to keep its base up and to the side, while the Roticulator™ helped expose the elements of the hilum.

Hilum preparation and the cholecystectomy were carried out using an UltraCision® Harmonic Scalpel in the surgeon's right hand. The cystic artery duct were sectioned using the UltraCision® Harmonic Scalpel after clamping with metal clips. The gallbladder was removed by Endobag® (Ethicon Endo-Surgery™, Ethicon™, Cincinnati, OH, USA) at the same time as the SILS™ Port, at the end of the operation.

The duration of the operation was timed from the skin incision to insertion of the last surgical suture. In one case, a 5 mm accessory trocar was used in the right flank to control bleeding from the gallbladder bed. In another two cases, an accessory trocar was needed to place a subhepatic drain, following bleeding from the gallbladder bed and bile leakage. In another case, a subhepatic drain was placed using a transparietal technique, without inserting an accessory trocar.

All patients were permitted liquids from the evening of the day of the operation and a free diet from the day after, and encouraged to move around from the evening of the day of the operation. An abdominal ultrasound was conducted on postoperative day 7 to exclude any subhepatic effusion.

Results

The mean age of our patients was 49.9 years (range 23-76), and the mean BMI was 22.8 (range 18-29). Thirty-eight percent (8/21) presented medical comorbidities, and 19% (4/21) had already undergone abdominal surgery: appendectomy (1 case) and Cesarean section (3 cases) (Table 1).

The distance between the gallbladder and navel was highly important, while, at least in this preliminary experience, inflammatory sequelae were not an insur-

TABLE 1 - PATIENT STRATIFICATION.

Sex, n	4 M;17 F
Age, years	min. 23, max. 76 (mean 49.4)
Comorbidity, n/total	8/21 (38%)
Previous abdominal surgery, n/total	4/21 (19%)
BMI	min. 18, max. 29 (mean 22.8)
Hospitalization, days	min. 1, max. 25 (mean 3.6)
Chronic cholecystitis, n/total	13/21 (62%)

TABLE 2 - SURGICAL DATA.

	Patients, n/total
Duration (minutes), min-max (mean)	40-180 (75.2)
Accessory trocar	2/21 (9.5%)
Gallbladder suspension	9/21 (42.8%)
Use of Roticulator™	15/21 (71%)
Drain	4/21 (19%)
Conversion to traditional laparoscopy	2/21 (9.5 %)

mountable obstacle to the success of the procedure. The single port trans-umbilical procedure was completed in 19 patients (90.5%). In the other two, conversion to standard laparoscopy was necessary: in one case due to difficulty in visceral recognition and therefore to make an intraoperative cholangiography; and in the other due to excessive difficulty in articulating the instruments. A subhepatic drain was positioned in both these cases. A 5 mm accessory right subcostal trocar was used in another two cases (9.5%) to control bleeding from the gallbladder bed and insert a subhepatic drain. In one patient (4.7%) a right subcostal subhepatic drain was introduced via the transparietal route without using an accessory trocar. In one case (4.7%) an umbilical hernia was treated contemporaneously, with a Ventralex™ (Davil Bard Inc., Warwick, RI, USA) patch implant. The mean operation duration was 75.2 minutes (range 40-180) (Table 2).

There was only one postoperative complication following cholecystectomy with SILS™ Port. This consisted of bile leakage, which was treated conservatively, as the fistula had a low output. There were no cases of infection of the surgical wound (Table 3). No conversion to open cholecystectomy was necessary and mortality was 0%. The mean postoperative hospitalization was 3.6 days (range 1-25) (Table 4).

TABLE 3 - MORBIDITY AND MORTALITY.

	Patients, n/total	**Medical, n/total**	**Surgical, n/total**
Morbidity	1/21 (4.7%)	0/21	1/21 (bile leakage)
Mortality	0 (0%)		

Discussion

In this preliminary experience with SILS™ Port, we wanted to focus on the feasibility and safety of using a single access port to perform cholecystectomy and on the standardization of the technique. This procedure can be carried out even in patients with a high BMI and sequelae of cholecystitis. Postoperative histological examination in fact demonstrated chronic cholecystitis in 13 of the 21 patients (Table 1).

Just one case (4.7%) was complicated by bile leakage, prolonging hospitalization to 25 days. The low percentage of complications suggests that this procedure is safe, although there are no randomized or prospective studies to confirm this in the literature.

Duration of hospitalization and postoperative pain were not primary outcomes for the study, but the fact that no painkillers were needed in any of the 19 cases of cholecystectomy carried out with the SILS™ Port is very promising. The duration of postoperative hospitalization in these cases cannot be considered significant as, given that this was our preliminary experience, we adopted a cautious approach to discharging patients, especially in the first cases. The data reported in Table 4 do however reveal the effects of the progressive improvement in the team's manual skills and increased experience, with progressive standardization of the technique. By stratifying the 21 patients in groups of 7 by chronological order (Table 4), it can be seen that the mean duration of the operation dropped from 80 minutes in the first group to 56 in the third, by which time use of the Endo Grasp Roticulator™ had become more familiar (100% of cases) and gallbladder suspension very frequent (57%).

Conclusions

Our next objective will be the statistical evaluation of postoperative pain and patient satisfaction. In any case, these patients were very enthusiastic about the single incision and the consequent good esthetic result. Despite the small caseload, we can assert that SILS cholecystectomy is a safe technique, even in patients with a high BMI. However, larger studies are necessary for a fuller and more objective evaluation of the benefits of this procedure.

TABLE 4 - DIACHRONIC ANALYSIS (2009-2011) BY SUBGROUPS OF SURGERY DURATION (S) AND POSTOPERATIVE HOSPITALIZATION (H) RESPECT TO GALLBLADDER SUSPENSION AND USE OF ROTICULATOR™.

	Patient	H (days)	Mean H (days)	S (minutes)	Mean S (minutes)	Roticulator™	n/total, %	Gallbladder suspension	n/total, %
Group 1	**1**	4	**3**	180	**80**	yes	**3/7, 42%**	no	**3/7, 42%**
	2	2		60		yes		yes	
	3	2		60		no		no	
	4	2		60		no		no	
	5	2		80		no		no	
	6	7		50		no		yes	
	7	2		70		yes		yes	
Group 2	**8**	2	**5.5**	60	**72**	yes	**5/7, 71%**	yes	**2/7, 28%**
	9	2		60		yes		no	
	10	2		65		yes		no	
	11	3		75		no		yes	
	12	25		140		yes		no	
	13	2		50		yes		no	
	14	3		60		no		no	
Group 3	**15**	3	**2.2**	75	**56**	yes	**7/7, 100%**	no	**4/7, 57%**
	16	2		60		yes		no	
	17	2		45		yes		yes	
	18	2		40		yes		yes	
	19	4		70		yes		yes	
	20	2		60		yes		yes	
	21	1		45		yes		no	

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