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## Single Port vs. Four Port Cholecystectomy – Randomized Trial on Quality of Life

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation;  
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### Abstract

**Background.** Classical laparoscopic cholecystectomy involves four ports while most novel ‘single port’ technique only requires one incision on the abdominal wall. This technique is thought to decrease surgical trauma and improve cosmesis although there are reports pointing out that classical laparoscopic cholecystectomy is also feasible in terms of cosmesis.

**Objectives.** In this study we tried to determine if there are certain advantages in quality of life after single port surgery which would justify its utilization instead of classical laparoscopic cholecystectomy.

**Material and Methods.** This is a prospective randomized study which enrolled 30 patients randomized either into classical laparoscopic cholecystectomy or single port surgery. The primary endpoint was patient satisfaction after surgery. This was assessed with short form 36 and gastrointestinal quality of life index (first preoperatively and then 3 months postoperatively) and a visual analogue scale on the first and seventh days.

**Results.** There was not a statistically significant difference between groups in the emotional role, social functions, mental health, vitality and general health subscales of short form 36. At the end of 12 weeks, both groups demonstrated increases in the gastrointestinal and social subscales of the gastrointestinal quality of life index. There was not a statistically significant difference between groups when the visual analogue scale scores on first and seventh days were compared.

**Conclusions.** The equal length of hospitalization, patient quality of life and pain perception and the longer operative times, high likelihood of incisional hernia and surgical site infection call into question the utilization of single port surgery, as it does not seem to confer an advantage over classical laparoscopic cholecystectomy (*Adv Clin Exp Med* 2015, 24, 3, 469–473).

**Key words:** single port surgery, laparoscopy, cholecystectomy, quality of life, randomized study.

The emergence of laparoscopic cholecystectomy in the mid 80’s opened a new era for minimal invasive abdominal surgery [1]. Classical laparoscopic cholecystectomy (CLC) involves 4 ports while the most novel ‘single port’ technique only requires 1 incision on the abdominal wall [2]. The latter technique is thought to decrease surgical trauma and improve cosmesis [3] although there are reports pointing out that CLC is also feasible in terms of cosmesis [4].

Single port surgery (SPS) requires additional training and special instruments over laparoscopic

surgery. Comparative studies assessing the differences between the 2 techniques are lacking. In this study, we tried to determine if there are certain advantages in quality of life after SPS which would justify its utilization instead of CLC.

### Material and Methods

This study was carried out between 2010 and 2012 in a university hospital. Randomization was done with computerized selection. All subjects

were included in the study after informed consent procedures. The study was approved by the hospital ethics committee, and followed the Helsinki Declaration.

This is a prospective randomized study which enrolled patients who had an indication for elective cholecystectomy. Patients were randomized into either a CLC group or a SPS group. Each group contained 30 patients.

The primary endpoint of our study was patient satisfaction after the surgery. This was assessed with short form 36 (SF-36) and the gastrointestinal quality of life index (GIQLI) (first preoperatively and then 3 months postoperatively) and the visual analogue scale (VAS) on the 1<sup>st</sup> and 7<sup>th</sup> days. The SF-36 is a generic health status questionnaire that has 36 questions to assess 8 domains (physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role and mental health) [5]. The GIQLI is a disease-specific health status measure. It includes specific questions on gastrointestinal symptoms, for both the upper and the lower gastrointestinal tract, as well as questions on physical, emotional and social capabilities. It is a mixed questionnaire that includes both generic and specific questions. Based on face validity, 5 subscales are distinguished in addition to a total score [6].

The secondary endpoint was to analyze the demographic data about the two groups. The data collected for this purpose was body mass index (BMI), American Society of Anesthesiologists (ASA) score, duration of surgery and hospitalization.

Exclusion criteria were pregnant women, coagulopathic patients, acute cholecystitis and patients who could not comply with a follow-up.

For CLC, the patients were placed supine, an infraumbilical incision was made for insufflation and 3 more ports were introduced for dissection. The gallbladder was taken out from the epigastric port. Port sizes were two 10 mm and two 5 mm.

For SPS, the patients were placed in the Lloyd Davies position, a transumbilical incision was made and a SILS<sup>®</sup> port (Covidien, Mansfield MA) was inserted. The gallbladder was taken out from the umbilical incision.

For both CLC and SPS, intra-abdominal pressure was maintained between 11–12 mm Hg. In both groups, the umbilical fascia was closed with a polyglycolic acid suture and the umbilical skin and extra-umbilical sites were approximated with interrupted 4–0 polypropylene sutures. Dressings were applied using a piece of gauze packed into the umbilicus covered with an occlusive dressing and a piece of gauze for extra-umbilical sites.

All patients received a preoperative dose of antibiotics prior to the operation and post-operative

antibiotics were not utilized. All patients were allowed a clear liquid diet upon returning the floor, and the diet was advanced as tolerated. Patients were discharged when tolerating a regular diet. Postoperative analgesia was maintained with meperidine 25 mg intravenously every 6 h and patients were allowed 25 mg of oral diclofenac every 4 h as needed for pain.

Statistical analysis was carried out with SPSS<sup>®</sup> 13.0 software (SPSS Inc, Chicago, Illinois). Significance was defined as *p* value of  $\leq 0.05$ . The descriptive data was presented as mean value and standard deviation, with non-parametric analyses being used to assess differences. The Mann-Whitney *U* test and  $\chi^2$  test were used to assess the differences where appropriate.

## Results

The mean follow up time was  $16 \pm 4.1$  months. The majority of patients in both groups were female. The differences in age, ASA score and gender were not statistically significant. The difference in duration of the surgery between the groups was statistically significant ( $p < 0.05$ ). The difference in length of hospital stay was not statistically significant ( $p > 0.05$ ). There was not a statistically significant difference in the mean BMI of the patients (Table 1).

Two patients in the CLC group and 4 patients in the SPS group had surgical site infections. Two patients in the SPS group had incisional hernia during follow-up.

The VAS scores in both groups decreased on postoperative day 7 when compared to postoperative

**Table 1.** Demographics and operative data of the patients enrolled in the study

	CLC (n = 30)	SPS (n = 30)	p-value
Age (years)	44.04 $\pm$ 11.3	48.53 $\pm$ 7.4	0.081
Male/female	12/18	9/21	0.134
BMI (kg/m <sup>2</sup> )	28.54 $\pm$ 5.5	30.3 $\pm$ 4.29	0.376
ASA score I/II/III	16/14/0	12/15/3	0.128
Duration of surgery (min)	65.8 $\pm$ 32.1	83 $\pm$ 40.4	< 0.005*
Hospitalization time (days)	1.56 $\pm$ 0.8	1.96 $\pm$ 1.0	0.295

CLC – classical laparoscopic cholecystectomy, SPS – single port surgery, ASA – American Society of Anesthesiologists score, BMI – body mass index.

\* statistically significant.

**Table 2.** Comparison of VAS scores of groups on 1<sup>st</sup> and 7<sup>th</sup> days

VAS score	CLC group	SPS group	p
1 <sup>st</sup> day	3.9 ± 1.1	4.1 ± 1.0	ns.
7 <sup>th</sup> day	1.9 ± 1.1	2.1 ± 1.1	ns.
<b>P</b>	< 0.05	< 0.05	

VAS – visual analogue scale, CLC – classical laparoscopic cholecystectomy, SPS – single port surgery, ns. – not significant.

day 1 (Table 2) ( $p < 0.05$ ). There was not a statistically significant difference between groups when the VAS scores on the 1<sup>st</sup> and 7<sup>th</sup> days were compared.

In terms of quality of life measurements of the patients in both groups, improvements were observed at 12 weeks inside each group in the physical function, physical role, general health, body pain and vitality subscales. Additionally, the CLC group showed improvement in the social function and emotional function subscales. Changes in the mental health subscale were insignificant in both groups. There was not a statistically significant difference between groups in any of the subscales of SF-36 (Table 3) at 12 weeks.

When the GIQLI scores were evaluated at the end of 12 weeks, both groups demonstrated increases in all subscales when compared to preoperative measurements. The CLC group also showed a statistically significant increase ( $p < 0.05$ ) in the physical function subscale (Table 4) when compared to the SPS group at the end of the 12<sup>th</sup> week.

## Discussion

Laparoscopic cholecystectomy is one of the most commonly applied procedures in general surgery [7]. A number of techniques have been devised since 1995 [8] and single incision transumbilical laparoscopic cholecystectomy was first published in 1999 [9]. SPS requires laparoscopic expertise and special laparoscopic instruments which raises the question whether this technique is superior to CLC, justifying its utilization.

In our study, we tried to eliminate biases by enrolling an adequate number of patients and excluding those with a possible confounding effect on outcomes. Randomization also improved the scientific value of our study.

Although SPS was performed by the same surgeons, the operative times in the SPS group was

**Table 3.** Comparison of SF-36 between classical laparoscopic cholecystectomy and single port laparoscopic cholecystectomy groups

SF-36		Preoperative	6 <sup>th</sup> week	12 <sup>th</sup> week	p-value (inside each group)	p-value (between groups)
PF	CLC	26.08 ± 36.4	27.44 ± 72.5	28.52 ± 82.1	< 0.05	0.259
	SPS	25.52 ± 53.1	25.41 ± 67.9	27.00 ± 67.9	< 0.05	
PR	CLC	6.44 ± 0.27	6.68 ± 0.87	8.23 ± 27.3	< 0.05	0.543
	SPS	6.52 ± 0.62	6.52 ± 0.45	7.08 ± 18.9	< 0.05	
GH	CLC	14.96 ± 58.3	15.48 ± 34.9	15.02 ± 56.2	< 0.05	0.342
	SPS	15.17 ± 47.9	15.47 ± 67.3	15.41 ± 63.5	< 0.05	
BP	CLC	6.28 ± 0.64	4.24 ± 0.57	3.56 ± 0.11	< 0.05	0.628
	SPS	6.23 ± 0.73	4.52 ± 0.74	3.61 ± 0.67	< 0.05	
SF	CLC	6.28 ± 0.67	6.32 ± 0.96	6.76 ± 0.93	< 0.05	0.451
	SPS	6.17 ± 0.59	6.41 ± 0.78	6.08 ± 0.89	> 0.05	
EF	CLC	4.52 ± 0.73	4.56 ± 0.73	4.76 ± 0.76	< 0.05	0.256
	SPS	5.05 ± 0.77	4.94 ± 0.82	4.66 ± 0.78	> 0.05	
V	CLC	14.00 ± 41.9	14.48 ± 54.7	14.28 ± 34.9	< 0.05	0.292
	SPS	13.76 ± 42.8	13.88 ± 45.9	14.25 ± 45.2	< 0.05	
MH	CLC	19.88 ± 36.8	20.20 ± 67.1	20.36 ± 67.3	> 0.05	0.634
	SPS	19.64 ± 41.2	20.29 ± 73.9	19.91 ± 64.8	> 0.05	

CLC – classical laparoscopic cholecystectomy, SPS – single port surgery, PF – physical function, PR – physical role, GH – general health, BP – body pain, SF – social function, EF – emotional function, V – vitality, MH – mental health.

**Table 4.** Comparison of GIQLI in classical laparoscopic cholecystectomy and single port surgery groups

GIQLI		Preoperative	6 <sup>th</sup> week	12 <sup>th</sup> week	p-value (inside each group)	p-value (between groups)
SF	CLC	19.52 ± 73.7	21.64 ± 55.7	22.40 ± 65.7	< 0.005	ns.
	SPS	17.11 ± 56.9	19.70 ± 75.4	21.88 ± 67.3		
EF	CLC	17.88 ± 64.3	21.56 ± 44.8	22.44 ± 56.9	< 0.005	ns.
	SPS	16.17 ± 77.1	18.52 ± 53.6	21.08 ± 73.7		
PF	CLC	11.40 ± 57.8	13.72 ± 66.1	14.80 ± 55.9	< 0.005	< 0.005
	SPS	11.00 ± 43.4	12.29 ± 33.7	11.58 ± 73.5		
GIS	CLC	53.12 ± 47.6	61.52 ± 74.3	62.68 ± 63.9	< 0.005	ns.
	SPS	49.58 ± 53.5	61.76 ± 69.8	64.16 ± 59.7		

SF – social function, EF – emotional function, PF – physical function, GIS – gastrointestinal system.

longer than in the CLC in our study. This could be related to the learning curve of the single port technique. The main factor adversely affecting the learning curve was instrument conflict which made dissection harder and unsafe.

In terms of length of hospitalization we did not find a significant difference between the two groups. The occurrence of surgical site infection was higher in the SPS group and more patients had incisional hernias than in the CLC group. This might increase secondary hospital admissions and longer total duration of hospitalizations for SPS. Additionally, SPS patients might need to be followed longer in order not to miss incisional hernias. This latter finding was also supported by another study on SPS [10].

The differences between the two groups in all subscales of SF-36 at 12 weeks were not statistically significant. This latter finding might be an implication that questions SPS's superiority over CLC in terms of patient quality of life. The lesser number of incisions might not always bring about more comfort. In the GIQLI assessment the physical function scale value in favor of CLC could be attributed to more infectious complications and more incisional hernias in the SPS group.

Although the SPS technique requires a bigger fascial defect than CLC and more pain was anticipated, the VAS score of our patients in both groups did not differ significantly on both the 1<sup>st</sup> and 7<sup>th</sup> days. This finding is in favor of SPS and could be supported by the equal length of primary hospitalization mentioned earlier.

The main drawback of our study was that we did not assess the cosmetic outcome of each technique so there is not any comment given per se. We also did not assess the hospital charges including the cost of the SILS™ port and instruments required along with it. This latter might make surgeons in developing countries stand against the SPS technique.

As for the conclusion, SPS is a novel technique which requires advanced laparoscopic skills and instruments. Surgeons reflect subjective difficulty in dissection with inverted instruments. The equal length of hospitalization, equal patient quality of life and pain perception, and the longer operative times, high likelihood of incisional hernia and surgical site infection questions the utilization of SPS, as it does not seem to confer an advantage over CLC.

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