

Single-incision vs three-port laparoscopic cholecystectomy: Prospective randomized study

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Abstract

AIM: To compare the clinical outcome of single-incision laparoscopic cholecystectomy (SILC) with three-port laparoscopic cholecystectomy (TPLC).

METHODS: Between 2009 and 2011, one hundred and two patients with symptomatic benign gallbladder diseases were randomized to SILC ($n = 49$) or TPLC ($n = 53$). The primary end point was post operative pain score (at 6 h and 7 d). Secondary end points were blood loss, operation duration, overall complications, postoperative analgesic requirements, length of hospital stay, cosmetic result and total cost. Surgical techniques were standardized and all operations were performed by one experienced surgeon, who had performed more than 500 laparoscopic cholecystectomies.

RESULTS: One patient in the SILC group required conversion to two-port LC. There were no open conversions or major complications in either treatment

groups. There were no differences in terms of estimated blood loss (mean \pm SD, 14 ± 6.0 mL vs 15 ± 4.0 mL), operation duration (mean \pm SD, 41.8 ± 17.0 min vs 38.5 ± 22.0 min), port-site complications (contusion at incision: 5 cases vs 4 cases and hematoma at incision: 2 cases vs 1 case), total cost (mean \pm SD, $12\,075 \pm 1047$ RMB vs $11\,982 \pm 1153$ RMB) and hospital stay (mean \pm SD, 1.0 ± 0.5 d vs 1.0 ± 0.2 d), respectively. TPLC had a significantly worse visual analogue pain score at 8 h after surgery (mean \pm SD, 3.5 ± 1.6 vs 2.0 ± 1.5), however, the scores were similar on day 7 (mean \pm SD, 2.5 ± 1.4 vs 2.0 ± 1.3). Cosmetic satisfaction, as determined by a survey at 2 mo follow-up favored SILC (mean \pm SD, 8 ± 0.4 vs 6 ± 0.2).

CONCLUSION: SILC is a safe and feasible approach in selected patients. The main advantages are a better cosmetic result and less pain.

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Key words: Cholecystectomy; Laparoscopic; Single-incision; Randomized; Laparoscopic cholecystectomy

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INTRODUCTION

Laparoscopic cholecystectomy (LC) has become one of the most effective procedures for the treatment of benign gallbladder pathology since its introduction in 1985^[1]. However, surgical standards of practice continue to evolve toward less invasive approaches, therefore many researchers have

attempted to minimize the invasiveness by reducing the number and size of the ports. In this context, single-port laparoscopic cholecystectomy (SILC) emerged in 1997^[2]. The proposed advantages of SILC include fewer port sites with the potential for decreased pain, cosmetic benefit and faster recovery^[3-10]. Some investigators have predicted that it may become a standard approach to LC^[11,12]. However, it has also been suggested that SILC has many disadvantages, such as the technique is difficult to handle, prolonged operative time, cost of special instruments and increased risk of per-operative complications^[9,13]. It is difficult to make an unbiased comparison between SILC and multi-port LC because of lack of prospective, randomized controlled trials (RCT). Therefore, we designed and conducted this RCT to evaluate the advantages and disadvantages of SILC and three-port laparoscopic cholecystectomy (TPLC).

MATERIALS AND METHODS

Inclusion criteria were as follows: (1) patients aged between 18 and 70 years; (2) body mass index less than 40 kg/m²; (3) preoperative diagnosis of symptomatic gallstones or gallbladder polyps, and (4) willing to comply with the protocol requirements and signed written informed consent.

Exclusion criteria were as follows: (1) American Society of Anesthesiologists class IV and V; (2) Patients with contraindication to laparoscopy; (3) Patients with suspected Mirizzi syndrome, common duct stones or malignancy; (4) Patients with previous upper abdominal surgery; (5) Patients on long-term anticoagulant treatment; (6) Acute cholecystitis or choledocholithiasis; and (7) Gallstones > 3 cm in diameter.

Eligible patients were randomized into two groups (SILC and TPLC) using sealed opaque envelopes which contained a computer-generated random number. Before the trial, all patients underwent basic investigations such as blood tests, electrocardiogram, ultrasonography of the abdomen and radiologic imaging such as chest radiograph. All operations were performed by one experienced surgeon, who had performed more than 500 laparoscopic cholecystectomies.

Operative techniques

Surgical techniques were standardized. SILC was performed with the help of 2 slings of sutures, which included four steps: (1) Under general anesthesia, a 20 mm (approximately) bracket-shaped skin incision was made through the inner margin of the umbilicus and a pneumoperitoneum was set at 13 mmHg. One 10 mm trocar (Kanger, Tong Lu, China) to allow the insertion of a 30 degree laparoscope (Olympus, Tokyo, Japan) was inserted through the abdomen at the left side of the incision and a 5 mm trocar (Kanger, Tong Lu, China) was inserted at the right side for the harmonic scalpel. The tissues between the trocars were preserved to prevent air leakage; (2) The first suture using a straight needle was inserted



Figure 1 A sketch of the suspension procedure.

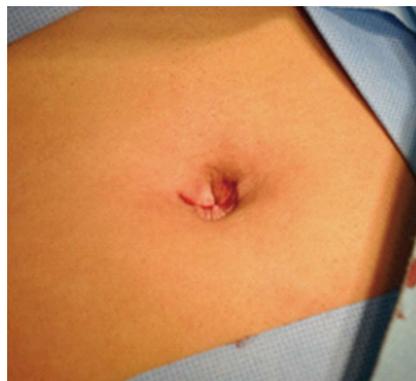


Figure 2 The incision is reconstructed after single-incision laparoscopic cholecystectomy.

through the right 7th intercostal space in the anterior axillary line, and the seromuscular layer of the gallbladder fundus was punctured and retracted toward the anterior abdominal wall. Hartmann's pouch was punctured and retracted using the second suture to expose Calot's triangle (Figure 1); (3) The harmonic scalpel (Ethicon Endo-Surgery, Cincinnati, OH, United States) was used to dissect Calot's triangle. Once the cystic artery and duct have been exposed, the cystic artery was cut using the harmonic scalpel, and the cystic duct was triple clipped and divided; and (4) The harmonic scalpel was used to dissect the gallbladder from the gallbladder fossa. When the gallbladder was free, the 5 mm trocar was exchanged for a 10 mm one, and through the 10 mm port, a specimen bag was inserted and the gallbladder was extracted after removal of the suspending sutures from the abdominal wall. The umbilical incision was closed and restored and no drainage tube was left in place (Figure 2).

In TPLC, a sub-umbilical incision, sub-xiphoid incision and right sub-costal incision were made. A 10 mm trocar placed in the sub-umbilical incision allowed the introduction of laparoscope and the other two trocars, a 10 mm and a 5 mm, respectively, were placed for the grasp and harmonic scalpel. The operation was performed following the routine TPLC procedure^[14], however, the cystic artery was divided and cut using the harmonic scalpel instead of being clipped and divided. The primary end-point of the

Table 1 Patients data and outcome

	SILC (<i>n</i> = 49)	TPLC (<i>n</i> = 53)	<i>P</i> value
Age (yr)	43.8 ± 14.0	45.2 ± 11.0	0.5493
Female	26	31	0.5810
WI (kg/m ²)	24.3 ± 6.0	25.1 ± 5.0	0.4649
ASA	1.5 ± 0.2	1.6 ± 0.3	0.0676
Clinical diagnosis			0.7790
Cholecystolithiasis	32	36	
Cystic polyps	17	17	
Operation duration (min)	41.8 ± 17.0	38.5 ± 22.0	0.4222
EBL (mL)	14 ± 6.0	15 ± 4.0	0.2643
VAS (1-10)			
8 h after surgery	2.0 ± 1.5	3.5 ± 1.6	0.0000
Day 7 after surgery	2.0 ± 1.3	2.5 ± 1.4	0.0651
Complications			
Contusion at incision	5	4	0.7350
Hematoma at incision	2	1	0.6070
Hospital stay (d)	1.0 ± 0.5	1.0 ± 0.2	1.0000
Cosmetic score	8 ± 0.4	6 ± 0.2	0.0000
Total cost (RMB)	12 075 ± 1047	11 982 ± 1153	0.6715

ASA: American Society of Anesthesiology; SILC: Single-incision laparoscopic cholecystectomy; TPLC: Three-port laparoscopic cholecystectomy; WI: Weight index; EBL: Estimated blood loss; VAS: Visual analog score; RMB: Renminbi yuan/Chinese yuan.

study was the postoperative pain score (at 6 h and 7 d). Secondary end-points included blood loss, operation duration, overall complications (intra- and post-operative complications), postoperative analgesic requirements, length of hospital stay, cosmetic result and total cost. A standard visual analog scale [range, 0 (no pain) to 10 (maximum pain)] was used for assessments at 8 h after surgery and on postoperative day 7. Cosmetic satisfaction of the surgical scar was rated on a scale [range, 0 (worst) to 10 (best)], and was evaluated at the 2-mo follow-up visit.

Statistical analysis

Statistical analysis was accomplished using the SPSS program for Windows 12.0 (SPSS, Chicago, IL, United States). The χ^2 test or the *t* test was used as indicated. All data were presented as mean ± SD. All *P* values were 2-sided. A *P* value of 0.05 was considered statistically significant.

RESULTS

From January 2009 to March 2011, 108 eligible patients were randomized to SILC (*n* = 51) or TPLC (*n* = 57). Two patients in the TPLC group and four patients in the SILC group refused to participate before surgery. In total, 102 patients (SILC, *n* = 49; TPLC, *n* = 53) were analyzed. Demographic variables in the two groups were similar (Table 1). All patients in the TPLC group successfully underwent three-port laparoscopic cholecystectomy without conversion to open surgery. Of 49 patients in the SILC group, one patient was converted to two-port LC due to anatomical difficulties and the operator felt it was unsafe to proceed with SILC. Overall, No major intra- or post-operative complications, such as biliary injury, abscess, bleeding, biliary collection or port-site hernia were

observed in the two treatment groups. Several patients experienced port-site complications such as contusion and hematoma, however, all recovered a few days after surgery. There were no significant differences in estimated blood loss (14 ± 6.0 mL *vs* 15 ± 4.0 mL; *P* = 0.2643), operation duration (41.8 ± 17.0 min *vs* 38.5 ± 22.0 min; *P* = 0.4222), port-site complications (contusion at incision: 5 cases *vs* 4 cases; *P* = 0.7350 and hematoma at incision: 2 *vs* 1; *P* = 0.6070), hospital stay (1.0 ± 0.5 d *vs* 1.0 ± 0.2 d; *P* = 1.0000) and total cost (12 075 ± 1047 RMB *vs* 11 982 ± 1153 RMB; *P* = 0.6715) between the SILC and TPLC groups. However, the TPLC group had a significantly worse visual analogue pain score at 8 h after surgery (3.5 ± 1.6 *vs* 2.0 ± 1.5; *P* = 0.0000), but the score was similar on day 7 (2.5 ± 1.4 *vs* 2.0 ± 1.3; *P* = 0.0651). Cosmetic satisfaction as shown by the cosmetic score was significantly higher in the SILC group than in the TPLC group (8 ± 0.4 *vs* 6 ± 0.2; *P* = 0.0000) (Table 1).

DISCUSSION

SILC has attracted wide attention because of its potential cosmetic results. It may even be possible for this approach to become a gold standard for cholecystectomy^[11,12]. However, there is still a long way to go before this approach is a gold standard, as standardization, safety, and the cosmetic results of SILC require validation^[15]. Although recent reports have focused on comparisons between SILC and multi-port LC, the safety, better cosmetic results and faster recovery following SILC have been agreed, however, SILC has not been standardized and there is much technical variation. On the one hand, different surgeons have attempted SILC in different ways. For example, in exposing Calot's triangle, trials using sutures, Kirschner wires and loop retractors have been reported, in addition to different manipulative instruments, such as straight instruments and reticulating instruments^[7]. On the other hand, devices used to prevent air leakage vary from one surgeon to another: some use common trocars^[8], some tend to use SILS multi-port^[7] and others favor self-designed devices such as sterile gloves^[16]. In our center, we have tried many approaches in the initial stage. For example, to prevent air leakage, we have tried tri-port and gel-port, but due to their high cost in special ports and larger lesions of about 3 cm requiring a trans-umbilical incision these devices are no longer used. We decided to select routine trocars in our practice because they were sufficient to prevent air leakage and were more economical. With regard to the selection of surgical instruments, we use the suture suspension method in SILC, which requires only a 30 degree laparoscope and a manipulative instrument, eliminating the need for more instruments intra-operatively.

In practice, we focus on improving the auxiliary procedure with suspension sutures. To achieve ideal exposure of Calot's triangle, we select the puncture spot at the superior chest wall along the costal margin so that the suspension suture can draw the liver up a bit more than in other

places, different to Piskun *et al*^[17] that the puncture spot should be selected at the inferior costal margin. In addition, the harmonic scalpel is effective for occluding 3 mm blood vessels and dissecting tissues^[18]. In our experience, cystic arteries in the trial were cut using the harmonic scalpel, indicating the safety of this scalpel. Intra-operative management of the gallbladder is critical for the safety in SILC. Initially, we were perplexed as to how to handle intra-operative bile leakage. First, we placed the suspension sutures into the seromuscular layer to avoid perforation of the cyst wall, but this was inevitable sometimes. Subsequently, we found that this technique was useful as long as evacuating and repeated rinsing were conducted.

There have been a few comparisons between SILC and conventional multi-port LC^[19,22]. These studies concluded that SILC is superior to multi-port LC in terms of cosmetic outcome, but not in terms of total cost, surgical time and postoperative pain. A similar cosmetic outcome in both treatment groups was observed in our study. However, there was no significant difference in the total cost between SILC and traditional LC when standard materials were selected. In addition, we found that SILC resulted in less postoperative pain than TPLC, and no significant difference in operation duration was observed between the two techniques. The higher pain score may be explained by the fact that there are more incisions in TPLC and the size of the incisions is larger than those in SILC. The different outcome of surgical time could be explained by difference in experience of the surgeon in SILC.

In conclusion, the results of this prospective trial demonstrate that SILC is a safe procedure when conducted by experienced surgeons, with some outcomes similar to that of TPLC, however, SILC was superior in terms of cosmetic outcome and postoperative pain. In the future, more high-powered randomized studies comparing SILC with conventional LC will be needed to validate its objective benefits and clinical role during the follow-up.

COMMENTS

Background

Laparoscopic cholecystectomy (LC) has been regarded as the "gold standard" for the management of benign gallbladder diseases since its introduction in 1985. However, surgical standards of practice continue to evolve toward less invasive approaches, therefore many researchers have attempted to minimize the invasiveness by reducing the number and size of the ports. In this context, single-incision laparoscopic cholecystectomy (SILC) emerged as a complement to standard LC. The proposed advantages of SILC include fewer port sites with the potential for decreased pain, cosmetic benefit and faster recovery. Some investigators have predicted that it may become a standard approach in LC. However, it has also been suggested that SILC has many disadvantages, such as the technique is difficult to handle, prolonged operative time, cost of special instruments and increased risk of per-operative complications. Therefore, it is difficult to make an unbiased comparison between SILC and multi-port LC due to the lack of prospective, randomized controlled trials.

Research frontiers

SILC has attracted wide attention because of its potential cosmetic results. However, it is unknown whether SILC could become a new standard procedure, and therefore it is necessary to compare the clinical outcome of SILC and multiple-port laparoscopic cholecystectomy.

Innovations and breakthroughs

This prospective randomized study was performed to explore the safety and

feasibility of SILC for the treatment of benign gallbladder diseases, and to compare the clinical outcomes with three-port laparoscopic cholecystectomy (TPLC).

Applications

In selected patients with benign gallbladder diseases, single-incision laparoscopic cholecystectomy is safe and feasible. The main advantages are that SILC result in a better cosmetic outcome and less pain compared with TPLC.

Terminology

SILC is a minimally invasive surgical procedure in which cholecystectomy is accomplished exclusively through a single 15-25 mm incision in the patient's navel. It is complementary to standard LC and an alternative to natural orifice transluminal endoscopic surgery. Unlike the traditional multi-port laparoscopic approach, SILC leaves only a single small scar in the navel.

Peer review

The authors have compared the clinical outcomes of SILC with TPLC and have concluded that SILC is a safe and feasible approach in selected patients. The main advantage is its better cosmetic result and less pain. The study is well organized and the content is adequately written, patient number is good and the authors have used good technique (harmonic for cystic artery).

REFERENCES

- 1 **Solomon D**, Bell RL, Duffy AJ, Roberts KE. Single-port cholecystectomy: small scar, short learning curve. *Surg Endosc* 2010; **24**: 2954-2957 [PMID: 20401494 DOI: 10.1007/s00464-010-1070-6]
- 2 **Navarra G**, Pozza E, Occhionorelli S, Carcoforo P, Donini I. One-wound laparoscopic cholecystectomy. *Br J Surg* 1997; **84**: 695 [PMID: 9171771 DOI: 10.1046/j.1365-2168.1997.02586.x]
- 3 **Barbaros U**, Sümer A, Tunca F, Gözkün O, Demirel T, Bilge O, Randazzo V, Dinççağ A, Seven R, Mercan S, Budak D. Our early experiences with single-incision laparoscopic surgery: the first 32 patients. *Surg Laparosc Endosc Percutan Tech* 2010; **20**: 306-311 [PMID: 20975500 DOI: 10.1097/SLE.0b013e3181f20cf6]
- 4 **Yu WB**, Zhang GY, Li F, Yang QY, Hu SY. Transumbilical single port laparoscopic cholecystectomy with a simple technique: initial experience of 33 cases. *Minim Invasive Ther Allied Technol* 2010; **19**: 340-344 [PMID: 20964560 DOI: 10.3109/13645706.2010.527772]
- 5 **Gajda Z**. 3 attempts at isolating lectures on dentistry at the Jagellonian University in the 1st half of the 19th century. *Czas Stomatol* 1979; **32**: 199-202 [PMID: 0374010 DOI: 10.1089/lap.2009.0395]
- 6 **Hirano Y**, Watanabe T, Uchida T, Yoshida S, Tawaraya K, Kato H, Hosokawa O. Single-incision laparoscopic cholecystectomy: single institution experience and literature review. *World J Gastroenterol* 2010; **16**: 270-274 [PMID: 20066749 DOI: 10.3748/wjg.v16.i2.270]
- 7 **Ponsky TA**. Single port laparoscopic cholecystectomy in adults and children: tools and techniques. *J Am Coll Surg* 2009; **209**: e1-e6 [PMID: 19854392 DOI: 10.1016/j.jamcollsurg]
- 8 **Kirschniak A**, Bollmann S, Pointner R, Granderrath FA. Transumbilical single-incision laparoscopic cholecystectomy: preliminary experiences. *Surg Laparosc Endosc Percutan Tech* 2009; **19**: 436-438 [PMID: 20027084 DOI: 10.1097/SLE.0b013e3181c3f12b]
- 9 **Edwards C**, Bradshaw A, Ahearne P, Dematos P, Humble T, Johnson R, Mauterer D, Soosaar P. Single-incision laparoscopic cholecystectomy is feasible: initial experience with 80 cases. *Surg Endosc* 2010; **24**: 2241-2247 [PMID: 20198490 DOI: 10.1007/s00464-010-0943-z]
- 10 **Rivas H**, Varela E, Scott D. Single-incision laparoscopic cholecystectomy: initial evaluation of a large series of patients. *Surg Endosc* 2010; **24**: 1403-1412 [PMID: 20035355 DOI: 10.1007/s00464-009-0786-7]
- 11 **Emami CN**, Garrett D, Anselmo D, Torres M, Nguyen NX. Single-incision laparoscopic cholecystectomy in children: a feasible alternative to the standard laparoscopic approach. *J Pediatr Surg* 2011; **46**: 1909-1912 [PMID: 22008326 DOI: 10.1007/s00464-010-0943-z]

- 10.1016/j.jpedsurg.2011.03.066]
- 12 **Jacob DA**, Raakow R. Single-port transumbilical endoscopic cholecystectomy: a new standard?. *Dtsch Med Wochenschr* 2010; **135**: 1363-1367 [PMID: 20589582 DOI: 10.1055/s-0030-1262419]
 - 13 **Elsey JK**, Feliciano DV. Initial experience with single-incision laparoscopic cholecystectomy. *J Am Coll Surg* 2010; **210**: 620-624, 624-626 [PMID: 20421017]
 - 14 **Trichak S**. Three-port vs standard four-port laparoscopic cholecystectomy. *Surg Endosc* 2003; **17**: 1434-1436 [PMID: 12799892 DOI: 10.1007/s00464-002-8713-1]
 - 15 **Allemann P**, Schafer M, Demartines N. Critical appraisal of single port access cholecystectomy. *Br J Surg* 2010; **97**: 1476-1480 [PMID: 20641051 DOI: 10.1002/bjs.7189]
 - 16 **Song SC**, Ho CY, Kim MJ, Kim WS, You DD, Choi DW, Choi SH, Heo JS. Clinical Analysis of Single-Port Laparoscopic Cholecystectomies: Early Experience. *J Korean Surg Soc* 2011; **80**: 43- 50 [DOI: 10.4174/jkss.2011.80.1.43]
 - 17 **Piskun G**, Rajpal S. Transumbilical laparoscopic cholecystectomy utilizes no incisions outside the umbilicus. *J Laparoendosc Adv Surg Tech A* 1999; **9**: 361-364 [PMID: 10488834 DOI: 10.1089/lap.1999.9.361]
 - 18 **Bessa SS**, Al-Fayoumi TA, Katri KM, Awad AT. Clipless laparoscopic cholecystectomy by ultrasonic dissection. *J Laparoendosc Adv Surg Tech A* 2008; **18**: 593-598 [PMID: 18721011 DOI: 10.1016/j.coolsurfa.2005.04.039]
 - 19 **Leung D**, Yetasook AK, Carbray J, Butt Z, Hoeger Y, Denham W, Barrera E, Ujiki MB. Single-incision surgery has higher cost with equivalent pain and quality-of-life scores compared with multiple-incision laparoscopic cholecystectomy: a prospective randomized blinded comparison. *J Am Coll Surg* 2012; **215**: 702-708 [PMID: 22819642 DOI: 10.1016/j.jbbr.2011.03.031]
 - 20 **Lee PC**, Lo C, Lai PS, Chang JJ, Huang SJ, Lin MT, Lee PH. Randomized clinical trial of single-incision laparoscopic cholecystectomy versus minilaparoscopic cholecystectomy. *Br J Surg* 2010; **97**: 1007-1012 [PMID: 20632264 DOI: 10.1002/bjs.7087]
 - 21 **Lai EC**, Yang GP, Tang CN, Yih PC, Chan OC, Li MK. Prospective randomized comparative study of single incision laparoscopic cholecystectomy versus conventional four-port laparoscopic cholecystectomy. *Am J Surg* 2011; **202**: 254-258 [PMID: 21871979]
 - 22 **Gangl O**, Hofer W, Tomaselli F, Sautner T, Függer R. Single incision laparoscopic cholecystectomy (SILC) versus laparoscopic cholecystectomy (LC)-a matched pair analysis. *Langenbecks Arch Surg* 2011; **396**: 819-824 [PMID: 21695591 DOI: 10.1007/s00423-011-0817-4]

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