

Članki

Articles

Single-incision laparoscopic cholecystectomy – Have the promises come true?

Laparoskopska odstranitev žolčnika skozi eno incizijo – so se obeti uresničili?

Reinhold Függer, Odo Gangl

Dept. of Surgery, Krankenhaus der Elisabethinen

Avtor za dopisovanje (*Correspondence to*):

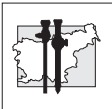
Prof. Reinhold Függer, M.D., Dept. of Surgery, Krankenhaus der Elisabethinen, Fadingerstrasse 1, 4020 Linz, Austria; e-mail: reinhold.fuegger@elisabethinen.or.at

Abstract

This review summarizes the recent development in the single- incision laparoscopic cholecystectomy (SILC).Based on the hypothesis that SILC is a step forward towards further minimizing the perioperative trauma, we analysed the feasibility, safety and possible benefits for the patient on the basis of published randomized controlled trials and matched-pair comparisons.

In conclusion, SILC has been found to be a feasible operative approach. In terms of safety, the incidence of major complications associated with SILC does not seem to be higher than that following a standard laparoscopic cholecystectomy. However, definitive proof of its benefits for the patient is still lacking.

Key words. *SILC, learning curve, laparoscopic cholecystectomy.*



Povzetek

Ta pregledni članek povzema najnovejši razvoj laparoskopske odstranitve žolčnika skozi eno samo incizijo. Izhajajoč iz predpostavke, da predstavlja ta poseg korak naprej k nadaljnjemu zmanjševanju pooperativne travme, smo na osnovi objavljenih randomiziranih kontroliranih študij in analize primerljivih skupin preučili izvedljivost, varnost in možne prednosti tega posega za pacienta.

Zaključujemo, da je ta operativni poseg izvedljiv in da pogostnost zapletov ne presega pogostnosti pri standardni laparoskopski odstranitvi žolčnika. Dokončnih dokazov o prednostih tega posega za pacienta pa zaenkrat še nimamo.

Ključne besede. SILC, učna krivulja, laparoskopska holecistektomija.

Reducing the surgical trauma seems to be the dominant motive of the development of new surgical methods and strategies over the past decades. The most prominent example was the introduction of minimally invasive surgery more than twenty years ago. Laparoscopic cholecystectomy (LC) marks the beginning of this surgical revolution (1,2). In properly selected patients, laparoscopic approach can now be used in nearly all abdominal operations, including the most demanding procedures, such as oesophagectomy, pancreatic resection and living donor nephrectomy. Further improvements in reducing the surgical trauma were achieved by using new perioperative strategies, including fast-track surgery, effective pain management, postoperative mobilisation and early enteral nutrition (3). However, no breakthrough comparable to the introduction of laparoscopy has occurred in the surgical technique proper. During the past two decades, some technical developments, such as gasless and hand-assisted laparoscopy, did not prove successful and failed to gain wide acceptance.

Recently, reducing the number or length of incisions has become a key technical consideration. Innovative techniques using natural orifices as entrance points of the endoscope (e.g. NOTES), the use of 3-mm ports in minilaparoscopy or a single-incision for all ports have been introduced (4,5). Their common goal was to reduce the operative trauma and contribute to further development of minimally invasive surgery. Not surprisingly, cholecystectomy has received the most attention from the beginning. Since 2008, the feasibility of

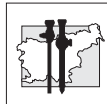
a single-incision access has been highlighted at many symposia and in a rapidly increasing number of published reports (6, 7). Many procedures using a single-incision access have been described so far, yet cholecystectomy remains the most frequently performed and reported procedure in single-incision surgery. Based on the status of single-incision laparoscopic cholecystectomy (SILC) in 2011, this review paper analyses all relevant publications on this topic in order to find out whether the expectations associated with SILC have been fulfilled.

Data

While the introduction of traditional laparoscopic cholecystectomy was not based on any accompanying scientific assessment except on a case series from the beginning of the 1990's, the current situation is much different. Although the surgical technique of SILC has not yet been standardised, several randomized controlled trials (RCT) and matched pair studies provided comparative data at the level II evidence. Furthermore, several reviews have summarised the published studies and evaluated the new technique (8, 9). In conclusion, this considerable amount of data and critical reviews allows surgeons to form their own opinion about SILC on an objective basis.

Patient selection

Most articles describe SILC in a selected patient population. Acute cholecystitis, prior surgery of the upper abdomen and elevated BMI represent



the most frequently cited contraindications. However, as in the case of standard laparoscopy, these limitations can be overcome with increasing surgeon experience. At the beginning we restricted the use of SILC to patients without evidence of acute cholecystitis and with no previous major abdominal surgery. After using the technique in the initial series of 20 patients, restrictions on the use of SILC were gradually loosened and no contraindication was defined. The decision of patient selection for SILC was thus made by the responsible surgeon on an individual basis, the only criterion being whether the surgeon felt that SILC was feasible in the individual patient. Using this selection process, at this department 29.1% of all cholecystectomies were performed by a single-incision approach during the study period of ten months (10). As for elevated BMI, some series suggest that SILC may be carried out also in patients with a BMI of more than 30kg/m² (7,11).

Safety

In comparison to LC, the review by Allemann et al. reports a higher overall complication rate (5.4%) and a biliary complication rate of 0.7% following SILC (8). However, elevated complication rates for SILC were reported by none of the RCTs or matched-pair studies, and the reader gets the impression that severe complications are very rare. According to all studies on SILC the procedure is feasible and safe. This appraisal is based on the subjective impression of the authors and is not an objective assessment. The number of patients included in comparative studies of SILC seems to be too small to allow definitive judgement. Considering a 0.2 – 0.3% incidence of iatrogenic bile duct injuries in LC, some thousands of patients undergoing SILC are needed to allow valuable comparisons.

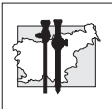
Feasibility and learning curve

Today there is no doubt that SILC is feasible. Completion rates vary and depend on the patient selection and surgeons' experience. While in one of the first published studies, Philipp reported that 48% of the procedures could be finished

using the intended single-incision technique, later studies by Curcillo and Rawlings reported completion rates of 88.6% and 88.9% for SILC without the use of additional trocars (12, 13). In our series, 85.1% of intended SILC procedures were completed successfully, and conversion to open cholecystectomy was required in only one (1.5%) of the 67 patients (10). Furthermore, we showed that completion rates of pure SILC increased with increase in the number of procedures performed, i.e. from 80% in operations 1 – 30 to 89.2% in numbers 31 – 67. Although this improvement was not statistically significant, we interpreted it as part of our learning curve. Similar observations were reported by Hernandez et al (14). They conducted the most accurate study on the learning curve, comparing cohorts of 25 patients operated consecutively by three surgeons. They did not find a decrease in operative time in any of the successive 25-patient cohorts. Complications were infrequent and remained unchanged during the study period; the rate was estimated to be within the range reported for LC. Other studies defined a learning curve after a cut-off at five or ten operations (6, 15). Although the learning curve is influenced by differences in the surgical technique, it seems to be short for surgeons experienced in laparoscopic surgery.

Reduction of the perioperative trauma

In addition to safety, which is a prerequisite for introducing a new technique, reducing the operative trauma is probably the most important element in the evaluation of SILC. Improved patient comfort, although not proved by scientific evidence at that time, was the driving power behind the successful introduction of LC more than twenty years ago. For SILC, data on postoperative pain, prescription of pain medication and length of postoperative hospital stay are presented in three RCTs and in some of the matched-pair studies. An overview of the studies is given in Table 1. Of the three RCTs only the Greek study claimed that SILC had the advantage of reducing postoperative pain: abdominal pain was



reported to decrease 12 hours postoperatively and shoulder pain at 6 hours after surgery. However, no differences between SILC and LC were found after 24 and 48 hours. In addition to the question whether a single difference in abdominal pain scores at 12 hours postoperatively is of clinical relevance, there may be some other bias in this trial. The group comprised only 18 and 19 patients, which seems to be an inadequate size for a profound statistical analysis. Moreover, two patients in the SILC group and one in the standard LC series developed a postoperative bile leak, the rate being too high. All other comparative studies, except the matched-pair analysis published by Khambaty, did not find any decrease in postoperative pain following SILC (17). One early study even described a higher VAS following

SILC (7). In our series, there was no difference between SILC and LC either in postoperative VAS at 24 and 48 hours or in the need for postoperative pain medication. Similar results have been obtained for the length of postoperative hospital stay. Lee et al. found a reduction of hospital stay from 2.9 days with minilaparoscopic cholecystectomy to 2.4 days with SILC (18). In all other studies there was no difference in the length of hospital stay between the two procedures. Unlike all other studies, our study addressed the issue of time needed to return to work or full daily activity. No difference was found between the two procedures, with a median of 7 days (min 1, max 40) for SILC and 9 days (min 1, max 40) for LC.

Table 1
SILC – Overview of RCTs and matched pair studies

Author	Design	n	Compl.	Pain	LOS	Cosmetic results	OP-time
Tsimoyiannis et al Surg Endosc 2010	RCT SILC - LC	40	=	SILC +	=	0	SILC -
Lee et al Br J Surg 2010	RCT SILC – MLC	70	=	=	SILC +	SILC +	SILC -
Marks et al Am J Surg 2011	RCT SILC – LC	83	=	=	0	SILC +	SILC -
Zornig et al Surg Endosc 2011	Matched NOTES – LC	200	=	=	=	NOTES +	NOTES -
Gangl et al Langenbecks Arch 2011	Matched SILC-LC	134	=	=	=	=	SILC -
Khambaty et al World J Surg 2011	Matched SILC-LC	107	0	SILC+	0	0	SILC -

Abbreviations:

SILC – Single-incision laparoscopic cholecystectomy

LC – standard laparoscopic cholecystectomy

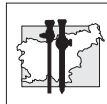
MLC – minilaparoscopic cholecystectomy

= no difference in results

+ better results

- worse results

0 not analysed



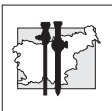
Some studies also address cosmesis, an advantage awaited in SILC. However, while Lee and Marks reported that SILC yielded better cosmetic results than minilaparoscopic or standard LC, patients in our study judged the cosmetic result to be similar (18,19). On a scale from 1 (best) to 5 (worst), mean cosmetic scores were 1.23 for SILC and 1.54 for the standard procedure. Although the scores were better for SILC, the difference was not significant. The main reason may be that most patients are satisfied with the cosmetic result of the traditional four-port cholecystectomy.

Conclusion and future perspectives

In summary, no convincing advantage of SILC over LC has been confirmed. The hypothesis that SILC constitutes the next step forward in further reducing perioperative trauma in minimally invasive surgery has not yet been proven true. Also, some other problems need to be solved. There is a lack of technical standardisation, and the need for determining the incidence of biliary complications in SILC and for publishing the data on cost. Irrespective of the longer operative time associated with SILC, this procedure is more expensive than the standard LC because of the use of commercial ports and special instruments that are not mandatory, but convenient for the surgeon. As a consequence, all patients undergoing SILC should be documented in databases or registries and included in large scale trials in order to provide more valid data. However, judging by the scientific programmes of meetings and recently published papers, the hype of SILC seems to be coming down and it is not clear whether the above questions will ever be answered.

References

1. Mouret P. Celioscopic surgery. Evolution or revolution? *Chirurgie* 1990; 116: 829-32
2. Reddick EJ, Olsen DO. Laparoscopic laser cholecystectomy. A comparison with mini-lap cholecystectomy. *Surg Endosc* 1989; 3: 131-3
3. Kehlet H., Wilmore DW. Evidence-based surgical care and the evolution of fast-track surgery. *Ann Surg* (2008); 248: 189-98
4. Marescaux J, Dallemagne B, Perretta S, Wattiez A, Mutter D, Coummaros D. Surgery without scars: a report of transluminal cholecystectomy in a human being. *Arch Surg* 2007; 142: 823-6
5. Zornig C, Mofid H, Emmermann A, Alm M, von Waldenfels HA, Felixmüller C. Scarless cholecystectomy with combined transvaginal and transumbilical approach in a series of 20 patients. *Surg Endosc* 2008; 22: 1427-9
6. Hodgett ST, Hernandez JM, Morton CA, Ross SB, Albrink M, Rosemurgy AS. Laparoendoscopic single site (LESS) cholecystectomy. *J Gastrointest Surg* 2009; 13: 188-92
7. Philipp SR, Miedema BW, Thaler K. Single-incision laparoscopic cholecystectomy using conventional instruments: early experience in comparison with the gold standard. *J Am Coll Surg* 2009; 209: 632-7
8. Allemann P, Schafer M, Demartines N. Critical appraisal of single port access cholecystectomy. *Br J Surg* 2010; 97: 1476-80
9. Antoniou SA, Pointner R, Granderath FA. Single-incision laparoscopic cholecystectomy: a systematic review. *Surg Endosc* 2011; 25(2): 367-77
10. Gangl O, Hofer W, Tomaselli F, Sautner TH, Függer R. Single incision laparoscopic cholecystectomy (SILC) versus laparoscopic cholecystectomy (LC) – a matched pair analysis. *Langenbecks Arch Surg* 2011; 396: 819-24
11. Rivas H, Varela E, Scott D. Single-incision laparoscopic cholecystectomy: initial evaluation of a large series of patients. *Surg Endosc* 2009; 24:1403-1412
12. Curcillo II PG, Wu AS, Podolsky ER, Graybeal C, Katkhouda N, Saenz A, Dunham R, Fendley St, Neff M, Copper Ch, Bessler M, Gumbs AA, Norton M, Iannelli A, Mason R, Moazzez A, Cohen L, Mouhlas A, Poor A. Single-port-access (SPA™) cholecystectomy: a multi-institutional report of the first 297 cases. *Surg Endosc* 2010; 24: 1854-60



13. Rawlings A, Hodgett StE, Matthews BD, Strasberg StM, Quasebarth M, Brunt LM. Single-Incision Laparoscopic Cholecystectomy: Initial Experience with Critical View of Safety Dissection and Routine Intraoperative Cholangiography. *J Am Coll Surg* 2010; 1-7
14. Hernandez J, Ross S, Morton C, McFarlin K, Dahal S, Golkar F, Albrink M, Rosemurgy A. The learning curve of laparoendoscopic single-site (LESS) cholecystectomy: definable, short and safe. *J Am Coll Surg* 2010; 211(5): 652-7
15. Erbella J Jr, Bunch GM. Single-incision laparoscopic cholecystectomy: the first 100 outpatients. *Surg Endosc* 2010; 24: 1958-61
16. Tsimoyiannis EC, Tsimoyiannis KE, Pappas-Gogos G, Farantos C, Benetatos N, Mavridou P, Manataki A. Different pain scores in single transumbilical incision laparoscopic cholecystectomy versus classic laparoscopic cholecystectomy: a randomized controlled trial. *Surg Endosc* 2010; 24(8): 1842-8
17. Khambaty F, Brody F, Vaziri K, Edwards C. Laparoscopic versus single-incision cholecystectomy. *World J Surg* 2011; 35(5): 967-72
18. 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(7): 1007-12
19. Marks J, Tacchino R, Roberts K, Onders R, Denoto G, Paraskeva P, Rivas H, Soper N, Rosemurgy A, Shah S. Prospective randomized controlled trial of traditional laparoscopic cholecystectomy versus single-incision laparoscopic cholecystectomy: report of preliminary data. *Am J Surg* 2011; 201(3): 369-73