

## 2016 Laparoscopic Surgery: Global view

**Single-incision laparoscopic surgery for biliary tract disease**

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**Abstract**

Single-incision laparoscopic surgery (SILS), or laparoendoscopic single-site surgery, has been employed in various fields to minimize traumatic effects over the last two decades. Single-incision laparoscopic cholecystectomy (SILC) has been the most frequently studied SILS to date. Hundreds of studies on SILC have failed to present conclusive results. Most randomized controlled trials (RCTs) have been small in scale and have been conducted under ideal operative conditions. The role of SILC in complicated scenarios remains uncertain. As common bile duct exploration (CBDE) methods have been used for more than one hundred years, laparoscopic CBDE (LCBDE) has emerged as an effective, demanding, and infrequent technique employed during the laparoscopic era. Likewise, laparoscopic biliary-enteric anastomosis is difficult to carry out, with only a few studies have been published on the approach. The application of SILS to CBDE and biliary-enteric anastomosis is extremely rare, and such innovative procedures are only carried out by a number of specialized groups across the globe. Herein we present a thorough and detailed analysis of SILC in terms of operative techniques, training and learning curves, safety and efficacy levels, recovery trends, and costs by reviewing RCTs conducted over the past three years and two recently updated meta-analyses. All existing literature on single-incision LCBDE and single-incision laparoscopic hepaticojejunostomy has been reviewed to describe these two demanding techniques.

**Key words:** Laparoendoscopic single-site surgery; Laparoscopic cholecystectomy; Laparoscopic common bile duct exploration; Laparoscopic hepaticojejunostomy; Single-incision laparoscopic surgery

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**Core tip:** Single-incision laparoscopic surgery (SILS) has been employed in various fields to minimize traumatic effects. Single-incision laparoscopic cholecystectomy (SILC) has been the most widely studied SILS approach to date. Hundreds of studies on SILC have failed to present conclusive results. Only a small number of studies on single-incision laparoscopic common bile duct exploration (SILCBDE) and single-incision laparoscopic hepaticojejunostomy (SILH) have been published. This paper serves as an updated review of SILC approaches and as the only existing review on SILCBDE and SILH. Our findings underscore the safety and efficacy of SILC, SILCBDE, and SILH and potential benefits and disadvantages of these methods in relation to conventional multi-incision laparoscopic surgery approaches.

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## INTRODUCTION

Single-incision laparoscopic surgery (SILS), also known as laparoendoscopic single-site (LESS) surgery, is a minimally invasive surgical procedure whereby a surgeon operates through a small incision. In addition to well-known cosmetic advantages of the approach, SILS methods can result in lower postoperative pain levels and shorter recovery periods. Various techniques for performing this novel procedure have been presented<sup>[1]</sup>. Accordingly, SILS serves more as a slightly surgical approach rather than as a specific operative technique.

Laparoscopic cholecystectomy (LC), which was first introduced in the 1980s, is currently the preferred procedure used to treat most benign gallbladder diseases<sup>[2,3]</sup>. It presents multiple advantages [*e.g.*, lower postoperative pain levels, faster recovery times<sup>[4]</sup>, and superior cosmetic outcomes relative to open cholecystectomy (OC) results]. As LC has become one of the most commonly used laparoscopic surgical methods, the application of SILS to cholecystectomy and single-incision laparoscopic cholecystectomy (SILC) has grown more popular worldwide. SILC is the most prevalent SILS<sup>[5-7]</sup>, and hundreds of studies related to this approach have been published to date. By contrast, documentation of SILS in relation to complicated biliary procedures (*e.g.*, common bile duct exploration (CBDE)<sup>[8-10]</sup> and *biliary-enteric anastomosis*<sup>[11]</sup>) is limited to a small number of series.

Herein we review SILC, single-incision laparoscopic common bile duct exploration (SILCBDE), and single-incision laparoscopic hepaticojejunostomy (SILH) methods in terms of operative techniques, training and

learning curves, safety and efficacy levels, recovery trends, and costs based on the most recent literature.

## SINGLE-INCISION LAPAROSCOPIC CHOLECYSTECTOMY

### *Operative technique*

While SILC outcomes largely depend on a surgeon's level of skill<sup>[1,12]</sup>, the variety of surgical techniques used in SILC must be discussed in detail. A recent systematic review of SILC methodologies and outcomes presented by Yamazaki *et al.*<sup>[1]</sup> demonstrated that specific technical factors are significantly correlated with corresponding complications. An analysis of uniform operative procedures is needed in order to establish the best operative procedures for SILC.

**Skin incision:** The most common skin incision site is the intraumbilical site. This thinnest part of the abdominal wall contains little fat and serves as an ideal access point into the peritoneal cavity. In addition, hiding the operative incision into the natural navel scar provides the best cosmetic outcome. However, several drawbacks have been reported. The deep umbilicus is not easy to repair and is susceptible to local wound complications<sup>[13-17]</sup>, especially in obese patients<sup>[18]</sup>. Higher rates of wound seroma, hematoma, wound infection, and incisional hernia have been observed following the execution of intraumbilical incisions for SILC in two recent meta-analyses, although the actual incidence rate is low<sup>[12,19]</sup>. Paraumbilical incisions are easier to close and serve as the main type of incision used for the optical port in a conventional multi-incision laparoscopic cholecystectomy (MILC) operation. The approach can also maintain cosmetic appearances if the incision is limited to the navel rim. Since we first began to employ SILC in 2010, we have routinely performed paraumbilical incisions. In our retrospective series of 200 consecutive SILC cases, the wound complication rate was found to be very low, and no incisional hernias were identified<sup>[20]</sup>. Any incision positioned outside of the umbilicus would inevitably leave an apparent scar that obviates the method's cosmetic advantages, and thus few reports on SILC use for the execution of extraumbilical incisions have been published<sup>[21]</sup>. However, the approach may provide excellent access in certain procedures (*e.g.*, a left subcostal incision in a SILS splenectomy<sup>[22,23]</sup>).

**Fascial incision:** There are two main ways to introduce a laparoendoscope and multiple working instruments into the peritoneal cavity during SILC. One involves creating a 2-3 cm fasciotomy to fit a multi-channel port that is either commercial<sup>[24]</sup> or homemade<sup>[25]</sup>. However, large fascial incisions are known to be correlated with higher incisional hernia rates relative to smaller ones made in conventional MILC procedures<sup>[12,13,19,26]</sup>. In a randomized controlled

study conducted by Pappas-Gogos *et al.*<sup>[27]</sup>, levels of 8-isoprostane (8-epiPGF2 $\alpha$ ), a biomarker of lipid peroxidation, were found to be significantly higher in a SILC group compared to a MILC group at six and 24 h postoperatively. 8-epiPGF2 $\alpha$  levels showed significant changes over time in the MILC group but not in the SILC group. Levels of uric acid, a marker of antioxidant status, were found to be significantly higher in the MILC group than that in the SILC group 24 h postoperatively. In another randomized controlled study conducted by Tsimogiannis *et al.*<sup>[28]</sup>, the value of  $\alpha$ -defensins, organism antimicrobial peptides and mediators in response to trauma were found to be statistically significantly higher in 24-h samples for their SILC group. The authors conclude that higher levels of tension resulting from the placement of a large multi-channel port on fascial tissue may cause higher inflammatory reactions in SILC conditions. Another approach involves inserting multiple conventional ports through small punctures on the fascia<sup>[29,30]</sup>. A "Swiss cheese" effect may theoretically weaken the fascia and result in an incisional hernia<sup>[31]</sup>, though this is inconsistent with our findings<sup>[20]</sup>. While umbilical incision enlargement at the skin and fascia levels for specimen retraction is frequently necessary in standard LC operations<sup>[32]</sup>, the comparable fasciotomy size (2 cm) measured during late stages of our single-incision multiple-port longitudinal-array (SIMPLY) technique may explain the zero incisional hernia rate found in our study<sup>[20]</sup>. However, several close fasciotomies may join together and cause significant air leakage during instrument manipulation. In our experience, this can be easily managed by positioning ointment gauze packing around ports.

**Working instruments:** Parallel (in and out) and fulcrum movements serve as major manipulation approaches, and rotational movements enable precise dissection<sup>[33]</sup> during laparoscopic surgery. In SILC, parallel movements in the same direction result in severe instrument clashing (sword-fighting). On the other hand, single-fulcrum movements allow instruments to diverge from the target area of the operative field. A chopstick effect causes a switch between right and left sides in the visual field. Though cross-hand techniques have been recommended as a means of addressing this "switch" problem, they are difficult to perform and are not ergonomic<sup>[34]</sup>. Curved or articulated instruments that restore triangulation during SILC without the use of cross-hand techniques have been developed<sup>[28,35-37]</sup>. However, curves and joints limit the movement range and may cause inadvertent damage to other organs positioned outside of the visual field. This elastic feature hinders the manipulation of firm fibrotic tissues. Furthermore, employing these new instruments requires additional training and costs. Other authors prefer conventional straight instruments, as they are more familiar and durable<sup>[29,30,34]</sup>. The longitudinal arrangement of ports

in our SIMPLY technique offers excellent gallbladder retraction and a clear critical view of safety<sup>[38]</sup> for SILC operation, even for the treatment of complex gallbladder diseases<sup>[39]</sup>.

**Laparoendoscope:** Flexible-tip laparoscopes and flexible endoscopes have been proven to be very useful when employed during SILC operations, as they are effective at inspection and prevent collisions with other instruments<sup>[25,40]</sup>. However, this delicate instrument is expensive and more fragile than a rigid laparoscope. Specialized training on this instrument is also required. Generally speaking, a 30-degree laparoscope is sufficient for SILC procedures, though the use of an extra-long bariatric laparoscope that can greatly reduce collisions between light cables and instrument handles is recommended when conducting complicated single-incision biliary tract surgical procedures<sup>[10,11]</sup>.

**Additional gallbladder traction:** Transparietal sutures created for gallbladder anchorage and Calot's triangle exposure (puppeteer technique) were first introduced by Navarra *et al.*<sup>[41]</sup>, who presented the first SILC series in 1997. This technique grew popular gradually and has been employed in numerous studies<sup>[29,42-44]</sup>. However, sutures in the gallbladder wall inevitably cause some bile leakage and may be responsible for higher bile spillage rates associated with SILC procedures<sup>[45]</sup>. Intraoperative bile spillage has been identified as a risk factor that influences wound infections following LC procedures<sup>[46]</sup> and that may violate oncologic safety levels<sup>[47]</sup>, as incidental gallbladder cancer has been found in 0.5%-1% of laparoscopic procedures<sup>[48,49]</sup>. Various gallbladder traction devices without gallbladder punctures (*e.g.*, endoloop<sup>[50]</sup>, endo-retractor<sup>[35]</sup>, and magnet grasper<sup>[51]</sup>) have been introduced, while other studies have shown that conventional straight instruments are sufficient for gallbladder traction<sup>[30,52]</sup>.

**Robotics:** In 2011, a novel Single-Site<sup>®</sup> robotic platform was developed as an addition to the da Vinci Si Robotic System<sup>®</sup> for the performance of SILS. Numerous studies on robotic single-site cholecystectomy (RSSC) have been published since, and the results have been promising<sup>[53-61]</sup>. The Single-Site<sup>®</sup> robotic platform serves as an excellent solution to technical difficulties associated with SILC (*e.g.*, instrument collisions and obscured laparoscopic views), and it therefore may help improve patient safety levels. RSSC is easier to learn compared to SILC, and the learning curve is very short for expert robotic surgeons<sup>[59,60]</sup>. Though RSSC has been shown to be as safe and efficacious as SILC, high costs of robotic surgery constitute a major barrier. In a study addressing the efficiency and costs of RSSC, costs were found to be comparable to those of SILC provided that the initial purchase price or cost of yearly da Vinci Si Robotic System<sup>®</sup> maintenance was excluded<sup>[57]</sup>. In

institutes with da Vinci Si Robotic Systems®, RSSC methods serve as a viable and reasonable alternative to SILC.

### **Training and learning curve**

**Training:** SILC adoption in fellowship or resident training programs has been found to be as safe and efficacious as the adoption of traditional MILC<sup>[62-64]</sup>. Dedicated SILC training appears to develop competencies in both SILC and MILC<sup>[65]</sup>. We have presented a step-by-step training program from MILC to SILC in a previous study<sup>[30]</sup>. Modifying a standardized procedure in a stepwise manner for the development of a new technique is reasonable from the standpoint of patient safety. A detailed and specialized training program is vital to education on SILC.

**Learning curve:** Existing studies on the learning curve towards SILC procedure competency have presented inconsistent results. Case numbers needed to pass through the learning phase have been reported as 0 to 40<sup>[17,20,66-69]</sup>. As the operative time is a commonly used parameter to define the learning curve, the same effect has also been observed with respect to procedure conversions and complications<sup>[14,70]</sup>. However, this result should be interpreted with caution. Case selection is very common during the SILC learning phase. As indication becomes broader during the experienced phase, complications can happen. Based on our retrospective study, the conversion and complication rates show no significant differences between the learning and experienced phases provided that a low threshold of conversion is maintained<sup>[20]</sup>. Procedure conversion should be treated as a means of patient safety rather than as a measure of surgical failure.

### **Safety and efficacy**

**Operative time:** SILC, an innovative but demanding procedure, would theoretically take more time to complete than MILC. Most randomized controlled trials (RCT) published since 2012 (Table 1) present the same result<sup>[13,71-80]</sup>, though equivalent operative times for both SILC and MILC have also been reported in other RCTs<sup>[27,37,40,42,44,81-83]</sup>. This inconsistency may be due to varying operative techniques, surgeon experiences and patient selection methods and due to small numbers of cases examined. According to two updated meta-analyses, the operative time of SILC is somewhat longer than that of MILC, but this minor difference (12.4-15 min) has limited clinical implications<sup>[12,19]</sup>. Moreover, SILC is a still evolving procedure. Techniques and technological advancements may further shorten the operative duration<sup>[84,85]</sup>. It seems too early to arrive at a conclusion at the present time.

**Intraoperative blood loss:** All recent RCTs (Table 1) that provide such data show equal levels of

intraoperative blood loss in SILC and MILC<sup>[13,42,44,73,75-77]</sup>. However, the difference may be too small to be detected in small-scale studies. The updated meta-analysis reported by Milas *et al.*<sup>[12]</sup> revealed more blood loss for SILC. Although the separate analysis of experimental and observational studies conducted by Tamini *et al.*<sup>[19]</sup> failed to draw the same conclusion (blood loss from SILC was reduced in non-RCTs but increased in RCTs), we believe the result of the latter to be more convincing. RCTs provide a significant higher level of evidence in evidence-based medicine (EBM). Therefore, we can conclude that intraoperative blood loss through SILC is a little more than that caused through MILC according to presently available evidence. However, once again, the minor difference (1.29 mL) is not clinically significant<sup>[12]</sup>.

**Procedure conversion:** The SILC conversion rate varies greatly (0%-28.3%) between RCTs<sup>[13,27,37,40,42-44,71-73,75-83]</sup> of the past three years (Table 1). The two updated meta-analyses show that procedure failure rates are clearly higher for SILC than for MILC<sup>[12,19]</sup>, but open conversion rates are similar. As SILC is a more demanding technique, some level of procedural failure may be inherent to it<sup>[12]</sup>. Furthermore, this comparison was limited to nearly ideal operative circumstances with the most difficult cases excluded<sup>[19]</sup>. Procedure conversions should be more frequent in SILC for complicated scenarios. In our most recent observational study, the conversion rate of SILC for all benign gallbladder diseases during the routine stage was found to be 12.6%<sup>[20]</sup>, which is twice as high as the value (6%) found *via* one updated meta-analysis<sup>[12]</sup>. However, we stress that a low threshold of procedure conversion for SILC should be always maintained for safety reasons. As the conversion almost exclusively involves the addition of a trocar<sup>[12]</sup>, this may have little impact on the clinical outcome.

**Complications:** Most of recent RCTs<sup>[37,40,42,44,71,73,75,76,79,81,83]</sup> show equivalent complication rates between SILC and MILC procedures, with the exception of two studies (Table 1). Marks *et al.*<sup>[13]</sup> reported higher incisional hernia rates (8.4%) following SILC, and Saad *et al.*<sup>[82]</sup> found SILC to be related to a higher number of complications (22.9%). No complications were found in the other three studies<sup>[27,78,80]</sup>. The two updated meta-analyses show the incisional hernia rate to be somewhat higher for SILC, while the overall complication rate was found to be similar for both procedures<sup>[12,19]</sup>.

In a systemic review of SILC methodologies and outcomes, wound infection and intra-abdominal abscess rates were found to be significantly higher for single fascia incisions created with an access port than those for single skin incisions made *via* multiple trocar insertion<sup>[1]</sup>. Port-site hernias were also found to be more common following single fascia



**Table 1 English prospective randomized control trials of single-incision laparoscopic cholecystectomy vs multi-incision laparoscopic cholecystectomy retrieved online via PubMed from Jan 2012 to Feb 2015 n (%)**

Ref.	Journal (Year)	SILC, n	SILC for AC			
Chang <i>et al</i> <sup>[71]</sup>	<i>World J Surg</i> (2015)	50	0			
<sup>1</sup> Pappas-Gogos <i>et al</i> <sup>[27]</sup>	<i>J Surg Res</i> (2015)	20	N/A			
Khorgami <i>et al</i> <sup>[72]</sup>	<i>J Invest Surg</i> (2014)	30	6 (20)			
Jørgensen <i>et al</i> <sup>[73]</sup>	<i>Br J Surg</i> (2014)	60	1 (1.7)			
Devenci <i>et al</i> <sup>[75]</sup>	<i>J Korean Surg Soc</i> (2013)	50	6 (12)			
Noguera <i>et al</i> <sup>[40]</sup>	<i>Surg Endosc</i> (2013)	40 (20 SILC, 20 flexible SILC)	0			
Yilmaz <i>et al</i> <sup>[81]</sup>	<i>J Korean Surg Soc</i> (2013)	43	0			
Zapf <i>et al</i> <sup>[76]</sup>	<i>Surgery</i> (2013)	49	7 (14.3)			
Brown <i>et al</i> <sup>[77]</sup>	<i>Surg Endosc</i> (2013)	40	0			
<sup>1</sup> Madureira <i>et al</i> <sup>[37]</sup>	<i>Surg Innov</i> (2013)	28	0			
Hu <i>et al</i> <sup>[78]</sup>	<i>J Laparoendosc Adv Surg Tech A</i> (2013)	30	0			
Marks <i>et al</i> <sup>[13]</sup>	<i>J Am Coll Surg</i> (2013)	119	0			
Ostlie <i>et al</i> <sup>[96]</sup>	<i>J Laparoendosc Adv Surg Tech A</i> (2013)	17	N/A			
Abd Ellatif <i>et al</i> <sup>[44]</sup>	<i>Surg Endosc</i> (2013)	125	0			
Luna <i>et al</i> <sup>[79]</sup>	<i>Surg Endosc</i> (2013)	20	0			
<sup>1</sup> Madureira <i>et al</i> <sup>[43]</sup>	<i>Surg Endosc</i> (2013)	28	0			
Saad <i>et al</i> <sup>[82]</sup>	<i>Br J Surg</i> (2013)	35	0			
Pan <i>et al</i> <sup>[42]</sup>	<i>World J Gastroenterol</i> (2013)	49	0			
Ostlie <i>et al</i> <sup>[80]</sup>	<i>J Pediatr Surg</i> (2013)	30	0			
Vilallonga <i>et al</i> <sup>[83]</sup>	<i>J Minim Access Surg</i> (2012)	69	14 (20.3)			
<sup>1</sup> Tsimogiannis <i>et al</i> <sup>[28]</sup>	<i>Surg Endosc</i> (2012)	20	N/A			
MILC, n	(Para)umbilical fasciotomy	Working instrument	GB suspension	IOC		
50	1 large	Articulated	Suture	Nil		
20	1 large + 1 small	Curved	Nil	Nil		
30 3ILC + 30 4ILC	3 small	Straight	Nil	N/A		
60	1 large	Roticular	Suture	1 (1.7)		
50	1 large	Articulated	Suture: 17 (34)	Nil		
20	SILC: 1 large; flexible SILC: 3 small	SILC: articulated; flexible SILC: straight	Nil	Nil		
40	1 large	N/A	Nil	Nil		
51	3 small	Articulated	Suture: 2 (4.1)	5 (10.2)		
39	3 small	Straight	Suture: partial	Nil		
29	1 large	Curved	Suture	Nil		
30	1 large	N/A	N/A	N/A		
81	1 large	Articulated (curved)	Nil	Partial		
24	N/A	N/A	N/A	N/A		
125	2 small	Straight	Suture	Nil		
20	1 large	Articulated	Suture: 2 (10)	Nil		
29	1 large	Curved	Suture	Nil		
35 mini-4ILC + 35 4ILC	1 large	Straight	K wire: 6 (17.1)	Nil		
53	2 small	Straight	Suture	Nil		
30	1 large	Straight	Nil	Nil		
71	1 large	Straight (roticular)	Nil	Nil		
20	1 large	Curved	Nil	Nil		
MILC incision and size (mm):	Learning curve	Operative time	EBL	Successful	Open conversion	Mortality
Paraumbilical, subxiphoid, right subcostal, right flank						
4ILC: 10, 5, 5, 5	N/A	S > M	N/A	47 (94)	0	0
4ILC: 10, 10, 5, 5	N/A	S = M	N/A	20 (100) <sup>2</sup>	0	0
3ILC: 10, 5, 5; 4ILC: 10, 5, 5, 5	N/A	S > 3ILC = 4ILC	N/A	27 (90)	0	0
4ILC: 12, 12, 5, 5	N/A	S > M	S = M	43 (71.7)	0	0
3ILC: 10, 10, 5	10 for op time	S > M	S = M	44 (88)	4 (8)	0
3ILC: 10, 5, 5	N/A	S = flexible S = M	N/A	40 (100)	0	0
4ILC: 10, 10, 10, 10	N/A	S = M	N/A	43 (100)	0 <sup>3</sup>	0
4ILC: 12, 5, 5, 5	40 for op time	S > M	S = M	44 (89.8)	0	0
4ILC: 10, 5, 5, 5	N/A	S > M	S = M	39 (97.5)	0	0
4ILC: 10, 5 (10), 5, 5	N/A	S = M	N/A	28 (100)	0	0
Mini-3ILC: 10+5, 2, 2	N/A	S > Mini-3ILC	N/A	28 (93.3)	0	0
4ILC: 10 (12), 5 (10) (12), 5, 5	N/A	S > M	S = M	118 (99.2)	0	0
N/A	N/A	N/A	N/A	N/A	N/A	N/A
4ILC: 10, 10, 5, 5	25 for op time	S = M	S = M	121 (96.8)	0	0
4ILC: 10, 10, 5, 5	N/A	S > M	N/A	18 (90)	0	0
4ILC: 10, 5 (10), 5, 5	20 for method standardization	S = M	N/A	28 (100)	0	0

Mini-4ILC: 10, 3, 3, 3; 4ILC: 10, 10, 5, 5	N/A	S = Mini-4ILC > 4ILC	N/A	34 (97.1)	0	0
3ILC: 10, 10, 5	N/A	S = M	S = M	48 (98.0)	0	0
4ILC: 10, 5, 5, 5	Nil	S > M	N/A	30 (100)	0	0
3ILC (4ILC): 10, 11, 5 (10, 11, 5, 5)	N/A	S = M	N/A	68 (98.6)	0	0
4ILC: 10, 10, 5, 5	N/A	S = M	N/A	20 (100) <sup>2</sup>	0	0
Overall complication	BDI	Incisional hernia	Pain	LOS		
S: 4 (8) = M	0	S: 1 (2) = M	S < M	S = M		
0	0	0	N/A	N/A		
0	0	0	S < M (3ILC or 4ILC)	S = M (3ILC or 4ILC)		
S: 2 (3.3) = M	S: 1 (1.7) → BL	S: 1 (1.7) = M	S = M	S = M		
S: 2 (4) = M	0	0	S > M (POD 1)	S = M		
S: 0 = flexible S: 1 (5) = M	0	0	S = flexible S = M	Flexible S = M		
S: 1 (2.3) = M	0	0	S > M (POm 30)	S = M		
S: 1 (2.04) = M	0	0	S = M	S = M		
N/A	0	N/A	S = M	S = M		
S: 3 (10.8) = M (wound complication)	0	0	S < M (POH 24)	N/A		
0	0	0	S = Mini-3ILC	S = Mini-3ILC		
S: 53 (45) = M	0	S: 10 (8.4) > M	S > M	N/A		
N/A	N/A	N/A	N/A	N/A		
S: 5 (4) = M	0	0	S < M (early to POW 1)	S = M		
S: 1 (5) = M	0	0	S = M	N/A		
S: 3 (10.8) = M (wound complication)	0	0	S < M (POH 24)	S: < 24 h = M		
S: 8 (22.9) > Mini-4ILC: 0 = 4ILC	0	S: 1 (2.9)	S = Mini-4ILC = 4ILC	S = Mini-4ILC = 4ILC		
S = M (port-site complication)	0	0	S < M (POH 8)	S = M		
0	0	0	S = M	S = M		
S: 3 (4.3) = M	0	S: 1 (1.4)	S < M (POH 12)	S > M		
0	0	0	S < M	S = M		
Cosmesis	Satisfaction	Cost	Follow-up			
S = M	S = M	N/A	6 mo			
N/A	N/A	N/A	N/A			
S = M (3ILC or 4ILC, late)	S = M (3ILC or 4ILC)	N/A	12 mo			
S > M	N/A	N/A	12 mo			
S > M	N/A	N/A	24 mo			
N/A	N/A	N/A	> 1 yr			
N/A	N/A	N/A	7 d			
S = M	S = M	S > M	16.4 mo			
S > M (POW2)	N/A	S = M	2-4 wk			
N/A	N/A	N/A	N/A			
S < Mini-3ILC	N/A	N/A	1 mo			
S > M	N/A	N/A	< 12 mo			
S > M (POM 16-38)	N/A	N/A	Early: 6-12 wk; Late: 16-38 mo			
S > M (POM 1,6)	N/A	N/A	6 mo			
N/A	N/A	N/A	1 mo			
N/A	N/A	N/A	5.92 mo			
S = Mini-4ILC > 4ILC (POM 6)	N/A	N/A	12 mo			
S > M (POM 2)	N/A	S = M	2 mo			
N/A	N/A	S = M	6 wk			
S > M	S > M	N/A	7.3 mo			
N/A	N/A	N/A	N/A			

<sup>1</sup>The same populations examined with different end points; <sup>2</sup>One case with a procedure converted to 2ILC was excluded; <sup>3</sup>Two cases with open conversion were excluded. SILC or S: Single-incision laparoscopic cholecystectomy; flexible SILC or S: Single-incision laparoscopic cholecystectomy using a flexible endoscope; AC: Acute cholecystitis; N/A: Not available; MILC or M: Multi-incision laparoscopic cholecystectomy; GB: Gallbladder; K wire: Kirschner wire; IOC: Intraoperative cholangiography; 4ILC: Four-incision laparoscopic cholecystectomy; 3ILC: Three-incision laparoscopic cholecystectomy; EBL: Estimated blood loss; BDI: Bile duct injury; BL: Bile leak from cystic duct stump; POD: Postoperative day; POm: Postoperative minute; POH: Postoperative hour; POW: Postoperative week; LOS: Length of hospital stay; POM: Postoperative month; large fasciotomy: ≥ 20 mm; small fasciotomy: ≤ 10 mm.

incisions, though the difference was not found to be statistically significant. Interestingly, all recent RCTs involving incisional hernia development following SILC

administration have involved single fascia incisions rather than multiple trocar insertions<sup>[13,71,73,82,83]</sup>. This implies that the majority of local wound complications

are related to adopted surgical techniques, and single fascia incision approaches may have a negative effect.

Bile duct injuries (BDI) are a rare but catastrophic complication of biliary tract surgery. Although two updated meta-analyses reported equivalent BDI rates between SILC and MILC<sup>[12,19]</sup>, this result should be reviewed carefully. To reveal a significant difference in the occurrence of this rare complication, it is necessary to assign a very large number of patients to SILC and MILC groups. Before a definitive conclusion can be made, related studies must continue to be conducted. Moreover, most SILC studies have been conducted under ideal operative conditions. Only five of the recent RCTs included patients with acute cholecystitis in small proportions (1.7%-20.3%)<sup>[72,73,75,76,83]</sup>. The use of SILC techniques on patients with gallbladder complications, obesity, or a history of abdominal operations should be carried out with caution, as an obscured operative view may result in inadvertent BDI.

A higher BDI rate of 0.72% for SILC was shown in a previous review of both RCTs and non-RCTs by Joseph *et al.*<sup>[86]</sup>, while Hall *et al.*<sup>[87]</sup> and Yamazaki *et al.*<sup>[1]</sup> reported lower rates (0.39% and 0.36%, respectively). In a recent review on biliary complications, the incidence of BDI for SILC was found to be 0.4% in 11 RCTs that involved 898 patients and 0.7% in 60 non-RCTs that involved 3599 patients<sup>[88]</sup>. This implies that the BDI rate for SILC appears to be slightly higher than historical data levels (0.5%) for standard MILC<sup>[89,90]</sup>. Qualified SILS surgeons must make every effort to prevent the development of this major complication through a strong focus on critical view of safety<sup>[38]</sup> and intraoperative cholangiography (IOC)<sup>[8,29,91-93]</sup>. When patient safety is in jeopardy, the procedure must be converted without hesitation.

### Recovery

**Postoperative pain:** When SILC is mainly recognized for causing less pain, the results of recent RCTs on this issue remain inconclusive (Table 1). SILC have been reported to cause more<sup>[13,75,81]</sup>, equal<sup>[40,73,74,76-80,82]</sup>, or less<sup>[28,37,42,44,71,72,83]</sup> postoperative pain than MILC at various times. While an updated meta-analysis conducted by Tamini *et al.*<sup>[19]</sup> reports less pain following SILC in both RCTs and non-RCTs, Milas *et al.*<sup>[12]</sup> find similar postoperative pain levels for SILC and MILC. Pain is a subjective feeling that can be influenced by other emotional factors (*e.g.*, satisfaction). Various surgical techniques and pain measurement methods may also be responsible for inconsistencies in the results. Nevertheless, all of the RCTs that reported higher pain levels for SILC involved the use of single fascia incisions *via* a multi-channel port<sup>[13,75,81]</sup>. Greater tension from a large port positioned on the fascial tissue may be related to stronger inflammatory reactions in SILC<sup>[27,28]</sup>. From the standpoint of postoperative pain levels through SILC, the multi-port puncture approach appears to be preferable to the

single fascia incision technique.

**Postoperative length of hospital stay:** SILC procedures may also result in shorter recovery periods. This measure includes postoperative length of hospital stay (LOS) and return-to-work intervals, though the latter data are rarely provided. With a focus on postoperative LOS periods, all recent RCTs<sup>[28,40,42-44,71-73,75-78,80-82]</sup> have reported an equivalent duration between SILC and MILC procedures with the exception of one RCT<sup>[82]</sup>, which shows a longer LOS period following SILC (Table 1). The two updated meta-analyses also present inconsistent results. While Milas *et al.*<sup>[12]</sup> present a similar postoperative LOS, Tamini *et al.*<sup>[19]</sup> report an earlier hospital discharge time for SILC in both RCTs and non-RCTs (only a marginal advantage). LOS periods largely depend on hospital discharge policies and health insurance systems when complications do not occur. It is nearly impossible to detect LOS differences on day-care basis<sup>[94,95]</sup>, and such policies are prohibited in some countries (*e.g.*, Taiwanese National Health Insurance). Though comparing postoperative LOS periods for SILC and MILC is sometimes impractical or liable to discharge policies, slightly shorter LOS periods typically follow after SILC procedures<sup>[19]</sup>.

**Cosmesis:** High cosmesis levels constitute a well-known advantage of SILC, as operative incisions made are hidden within the natural naval scar. This major advantage has been confirmed in most recent RCTs (Table 1)<sup>[13,42,44,73,75,77,82,83,96]</sup> and in two recent meta-analyses<sup>[12,19]</sup>, but it has not been identified in some studies<sup>[71,72,76,78]</sup>. Cosmesis is a mental feeling subject to patient perceptions. Symptom resolution, complication risks, and postoperative pain levels were found to be more important than cosmesis levels according to patient perspectives on SILC provided through two questionnaire-based studies<sup>[97,98]</sup>. In a recent RCT conducted by Zapf *et al.*<sup>[76]</sup>, the authors found it difficult to recruit subjects. Patients who had been attracted to SILC for cosmetic reasons did not want to risk being randomized to the MILC group. The equal cosmesis scores generated from a biased population of patients who did not care about this cosmetic factor should be interpreted carefully. In summary, SILC offers superior cosmetic outcomes than MILC<sup>[12,19]</sup>, at least objectively. However, this benefit may attenuate or be forgotten with time<sup>[99]</sup>.

### Costs

Of four recent RCTs that provide cost information (Table 1), three report equal costs for SILC and MILC<sup>[42,77,80]</sup>. The remaining show SILC to be more expensive<sup>[76]</sup>. No existing meta-analyses present such information. This cost difference may be attributable to surgical instruments, operative time periods (operative room charges and anesthesia fees), postoperative pain

levels (analgesic use), complications, and LOS factors (ward charges). Considering small differences for most of these parameters between SILC and MILC, novel surgical devices dedicated to SILS should play a major role in cost increases. In a large scale retrospective study<sup>[100]</sup>, Cheng *et al.*<sup>[100]</sup> showed that differences in operative time periods and total costs between SILC and MILC can be minimized by improving surgical skills provided that only conventional instruments are used. No significant differences in operative time periods and total costs were found when the last 100 cases in the two groups were compared. In brief, costs largely depend on surgical instruments and on a surgeon's skills rather than on procedures.

## SINGLE-INCISION LAPAROSCOPIC COMMON BILE DUCT EXPLORATION

### **Operative technique, training, and learning curve**

Only three published series, including our previous study, focus on SILS or LESS CBDE to date. All are retrospective studies, and case numbers of SILCBDE used in Yeo *et al.*<sup>[8]</sup>, Shibao *et al.*<sup>[9]</sup>, and in our series are four, 13, and 17, respectively. While Yeo *et al.*<sup>[8]</sup> and Shibao *et al.*<sup>[9]</sup> created a single fascia incision with a multi-channel port or multiple trocars insertion through an intraumbilical incision, we created a paraumbilical incision followed by multiple trocar punctures. Paraumbilical incisions were made within the naval rim to provide for excellent cosmetic outcomes. A roticulated grasper (Roticulator Endograsp; Covidien) was used in some cases in Yeo D's series with the assistance of transperitoneal gallbladder suturing (puppeteer technique). In Shibao K's series, an atraumatic forceps (the fourth port) was inserted into the peritoneal cavity just below the optic port to provide gallbladder traction. The Radius Surgical System (Tübingen Scientific Medical, Tübingen, Germany), a flexible manual manipulator, was used in some cases to facilitate both intracorporeal suturing and ligation. In our series, three 5-mm and one 3-mm ports were introduced into a longitudinal array, and only conventional straight instruments were used. A flexible laparoscope was used only in Shibao K's series. Yeo *et al.*<sup>[8]</sup> used a 10-mm 30-degree rigid laparoscope, and we adopted a 50-cm-long 5-mm 30-degree rigid laparoscope. The bile duct was explored using transcystic and choledochotomy approaches in Yeo D and our series, while Shibao *et al.*<sup>[9]</sup> only performed choledochotomy operations. Primary bile duct closures were created for choledochotomy procedures in all three studies, but biliary drainage methods were only adopted in Yeo D and Shibao K's series with the use of a transcystic tube or T-tube. A routine subhepatic drain was present in the (para)umbilical incisions created in Yeo D's series and our series, while the drain was moved from the right quadrant region for the last seven cases in Shibao K's series.

The number of cases is too small to show a learning curve for all three studies<sup>[8-10]</sup>. No training strategies are mentioned.

### **Safety, efficacy, recovery, and cost**

In our retrospective series, which serves as the only existing comparative study on SILCBDE and on standard multi-incision LCBDE, we recruited 17 patients for each group<sup>[10]</sup>. There was no significant difference between the two groups in terms of operative time periods, estimated blood loss levels, pethidine doses (postoperative pain), postoperative LOS periods, procedure conversions, and complications. One procedure (5.9%) was converted to a standard four-incision LCBDE, and one complication (5.9%) involving a minor bile leak and self-limited duodenal ulcer hemorrhaging occurred in the SILCBDE group. Although a cosmetic comparison was absent, all patients who underwent a successful SILCBDE procedure were very satisfied with the hidden scar. We did not conduct a cost analysis. However, because all parameters were similar in both groups and only conventional instruments were used, the total cost can be assumed to be equal. Owing to the limitations of small-scale retrospective inquiry, we conclude that SILCBDE serves as safe and efficacious LCBDE approach only when carried out by experienced surgeons.

## SINGLE-INCISION LAPAROSCOPIC HEPATICOJEJUNOSTOMY

### **Operative technique, training, and learning curve**

Only five series on SILH have been published to date, and all were conducted by the same research team<sup>[11,101-104]</sup> for children and neonates. One 5-mm and two 3-mm trocars were inserted into the peritoneal cavity of a horizontal array *via* a vertical intraumbilical skin incision<sup>[11]</sup>. Only conventional straight instruments were used with the assistance of two or three transabdominal suspension sutures of the gallbladder, the proximal common hepatic duct, or of the anterior wall of a large choledochal cyst. An extra-long 5-mm 30-degree laparoscope was used for visualization purposes. Ductoplasties were performed in cases where stenoses were detected. A retrocolic end-to-side hepaticojejunostomy was accomplished intracorporeally without biliary drainage. A suction drain was placed through the 3-mm umbilical working port as needed.

The learning curve for this approach is steep<sup>[104]</sup>. After four cases, the operative time of SILH is equal to that of conventional laparoscopic hepaticojejunostomy (CLH). No training strategy was mentioned.

### **Safety, efficacy, recovery, and cost**

The only existing large-scale case-control study, which



involved the recruitment of 75 patients into SILH and CLH groups, found operative blood loss levels to be minimal for each group<sup>[11]</sup>. No procedure conversion was conducted. One patient (1.3%) developed a bile leak and was managed conservatively in the SILH group. Overall complication rates, postoperative LOS periods, and periods required for full diet resumption did not differ significantly between the two groups. No data on postoperative pain or analgesic doses were presented. No noticeable scars were observed in the SILH group one month postoperatively, and child patient parents were satisfied with the cosmetic results. Though a cost analysis was not evaluated, no specially designed instruments were required in this series. SILH procedures did not increase hospital costs accordingly. The authors conclude that SILH, when carried out by experienced surgeons, is feasible and safe to perform on children with choledochal cysts and that the outcomes are comparable to those of CLH. The superior cosmetic outcome of SILH is preferable.

## CONCLUSION

SILC is as safe and efficacious as traditional MILC and has marginal advantages (*i.e.*, lower postoperative pain levels and shorter postoperative LOS periods). Longer operative time periods and higher degrees of intraoperative blood loss observed in SILC cases serve as minor and clinically insignificant differences. The incidence rate of local wound complications (*e.g.*, incisional hernia) is higher following SILC procedures, especially when the single fascia incision technique is employed. The BDI rate for SILC appears to be slightly higher than the historical data for the standard MILC, though this rate may improve with skill improvement, experience accumulation, and technological advancement. A low threshold of procedure conversion should always be maintained in the interest of patient safety. Well-established cosmetic benefits of SILC may be significantly influenced by patient perceptions.

SILCBDE and SILH are feasible, safe, and effective methods when carried out by experienced surgeons. With the exception of their well-known cosmetic advantages, other potential benefit or disadvantages of such approaches must be verified *via* large-scale RCTs.

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