Randomized clinical trial

Randomized clinical trial of laparoendoscopic single-site *versus* conventional laparoscopic cholecystectomy

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Background: **Conventional laparoscopy with three or more ports remains the 'gold standard' for cholecystectomy, but a laparoendoscopic single-site (LESS) approach is emerging, designed to decrease parietal trauma and improve cosmesis. This study compared conventional laparoscopic (CL) with LESS cholecystectomy, with short-term clinical results as the main outcomes.**

Methods: **A randomized trial of CL and LESS cholecystectomies involving 150 patients was undertaken. Follow-up was for 1 month after surgery. The primary endpoint was body image results evaluated by means of validated scales. Secondary endpoints were: postoperative pain measured on a visual analogue scale, analgesia requirement, morbidity, quality of life (QoL) measured with Short Form 12, duration of operation, hospital stay, time to return to work and cost analysis.**

Results: **Operating times and complications were similar in the two groups. Two LESS procedures (3 per cent) were converted to two-port laparoscopy owing to difficulties with exposure, and one CL operation was achieved through a single port because extensive fibrous peritoneal adhesions prevented placement of other ports. There were three and four port-site seroma/haematomas in the LESS and CL groups respectively. Better pain profiles and lower analgesia requirements were recorded in the LESS group ($P < 0{\cdot}001$). QoL, body image and scar scale results were also better ($P < 0{\cdot}001$). Operative costs were higher for LESS procedures ($P < 0{\cdot}001$), although median time to return to work was shorter ($P = 0{\cdot}003$).**

Conclusion: **LESS is an alternative to CL cholecystectomy associated with better cosmesis, body image, QoL and an improved postoperative pain profile. Registration number: NCT00904865 (http://www.clinicaltrials.gov).**

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Introduction

Laparoscopic cholecystectomy using three or more ports is widely accepted as the standard operation for benign gallbladder disease[1,2]. The laparoendoscopic single-site (LESS) approach has emerged in an attempt to decrease parietal trauma and improve the cosmetic result[3–6].

Transumbilical single-incision cholecystectomy was first described in the 1990s[7], but has been reserved mainly for selected patients owing to technical difficulties[8–10]. With instrumentation developments, recent reports of LESS cholecystectomy have demonstrated its more general feasibility[3,6,11–15]. Criticisms of its potential advantages and safety have, however, been raised[16].

This randomized trial was undertaken to compare the short-term results of LESS compared with conventional laparoscopic (CL) cholecystectomy.

Methods

This randomized trial was undertaken from June 2009 to September 2010, in a state university hospital serving as primary centre. Inclusion criteria were: elective patients with symptomatic gallbladder stones, history of cholecystitis, history of common bile duct stone migration and/or biliary pancreatitis, and age over 18 years. Patients presenting as an emergency with acute gallbladder disease, contraindications to

pneumoperitoneum, cirrhosis or mental impairment were not eligible.

Patients were included after giving informed consent to the protocol previously accepted by the institutional ethics committee (ClinicalTrials.gov identifier: NCT00904865). During preoperative outpatient visits all patients received information about surgical technique; risks associated with cholecystectomy were explained, in particular that the complication rates of LESS cholecystectomy might be higher than those of the CL approach. Differences in surgical technique were referred to only as the performance of a single umbilical incision for LESS and four incisions for CL laparoscopy. No reference was made to postoperative pain.

Patients were allocated to LESS or CL cholecystectomy using a randomization table after their preoperative visit by the surgeon. Participating surgeons with individual experience of over 50 LESS and over 100 CL cholecystectomy operations conducted all LESS procedures and conducted or assisted senior trainees during all CL operations.

LESS cholecystectomy was performed using a surgical technique similar that for CL cholecystectomy, except that a single umbilical incision was used (*Fig. 1*). A multiport trocar (TriPort®; Advanced Surgical Concepts, Wicklow, Ireland) was used with a 1·5-cm transumbilical incision. Dissection of Calot's triangle was conducted as described by Gigot and colleagues[17,18]. Dissection of the cystic artery and duct involved 5-mm flexible LESS instrumentation (LESS instruments™; Olympus, Hamburg, Germany) and an intracorporeal grasper (EndoGrab™; Virtual Ports, Caesarea, Israel). A deflectable-tip endoscope was used (LTF Endo-Eye™; Olympus). Cystic artery and duct control were achieved using 5-mm laparoscopic clips (Ligamax™ EL5ML; Ethicon Endo-surgery, Spreitenbach, Switzerland). Intraoperative cholangiography was attempted in all patients by placement of a cholangiography catheter inside the proximal cystic duct (Cook, Limerick, Ireland). Gallbladder bed dissection was performed using a hook dissector. No specimen bag was used for LESS cholecystectomy in most patients, as the TriPort® already acted as a wound protector.

CL cholecystectomy was performed by a four-port approach with two 10-mm and two 5-mm ports. A 30° laparoscope was used. The first transumbilical port was placed via an open approach. Gallbladder extraction was done with a retrieval bag (MemoBag®; Laboratoire pharmaceutique Rüche, Betschdorf, France).

Cholangiography was attempted routinely, with recording of the critical view of safety. All patients had irrigation of the right upper quadrant with at least 0·5 litres of saline solution. The umbilical and 10-mm incisions were closed using PDS™ 2/0 (Ethicon, Johnson & Johnson, Somerville, New Jersey, USA). Separate wound dressings were applied to each wound.

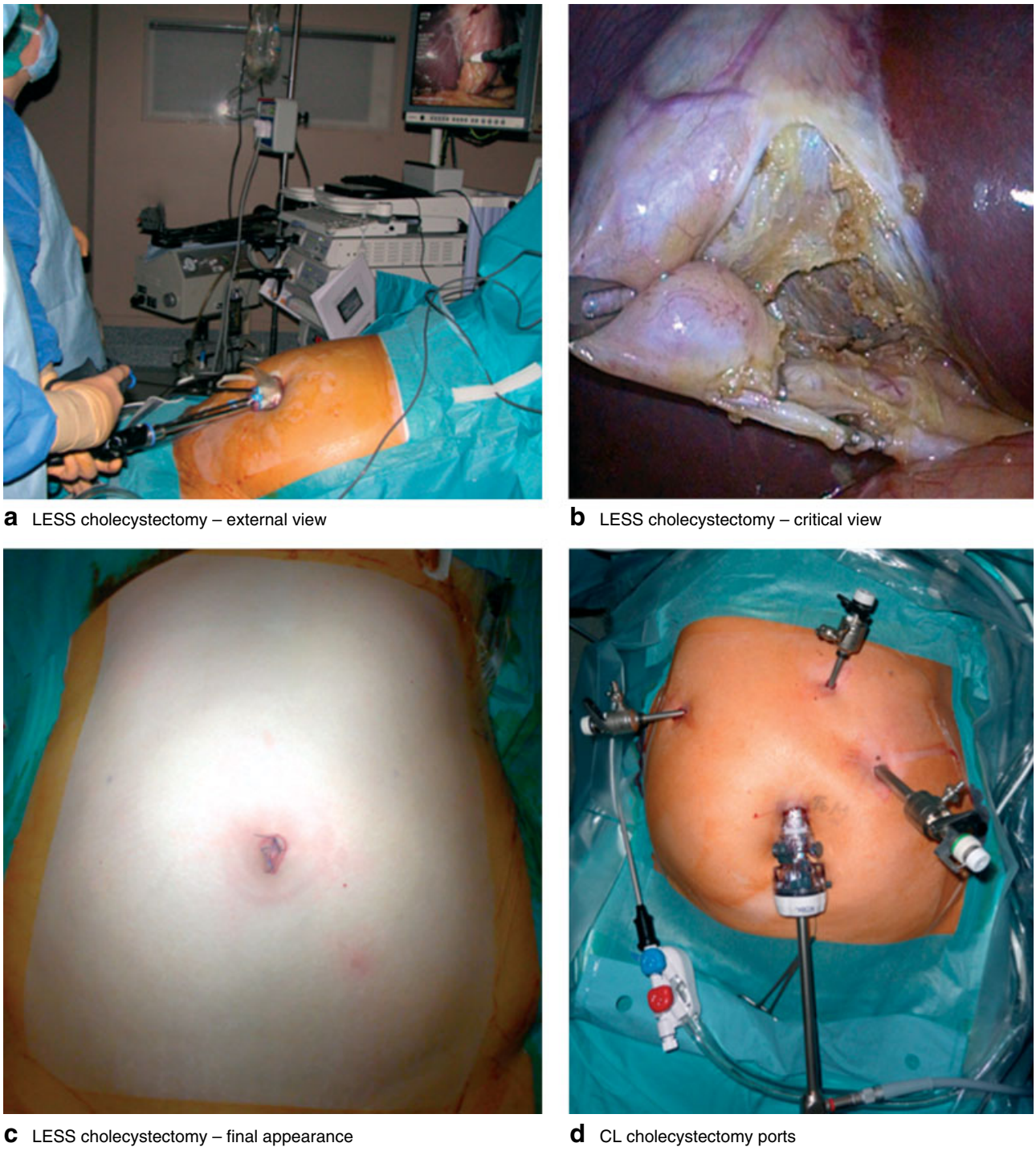
During the hospital stay all patients received the same postoperative analgesia prescription based on paracetamol (1 g three times daily) and ibuprofen (400 mg three times daily), with morphine on demand titrated until the pain score measured on a visual analogue scale (VAS, range 0–10) was less than 3. All patients received the same prescription of paracetamol and ibuprofen for analgesia as required after discharge. All patients received single-dose peroperative antibiotic prophylaxis (2 g intravenous ceftriaxone). No postoperative antibiotics were given.

Follow-up was for 1 month after surgery. The primary endpoint was the cosmetic result analysed using the body image scale described by Dunker and co-workers[19,20]. This five-item scale investigates the influence of scars on body image after surgery, with results ranging from 5 points (best results, least body image modification) to 20 points (most important body image modification). Other endpoints were: postoperative pain (VAS), analgesia requirement, rating on scar satisfaction scale[21], morbidity, duration of operation (time from skin incision to wound dressing), need for main port enlargement for specimen extraction, QoL assessed by means of the Short Form 12 questionnaire (SF12®; QualityMetric, Lincoln, Rhode Island, USA), hospital stay, time to return to work and operative costs. QoL questionnaires were completed before operation and 30 days after surgery. Body image and scar scales were completed at discharge, and at 10 and 30 days after surgery in the outpatient clinic. Operative costs were estimated according to disposables used and operating room charges (including salaries). Patients completed all questionnaires without supervision.

Statistical analysis

Data were collected in a specific institutional database and analysed on an intention-to-treat principle. The hypothesis was that LESS cholecystectomy might be associated with better cosmetic results (evaluated using a validated cosmetic scale) and cause less pain, measured by VAS score, than the CL procedure. Based on the results of a preliminary prospective trial (NCT00961506), to show a 1-point difference in score on the cosmetic scale between groups or a 1-point difference on the VAS, it was calculated that 66 patients would be required in each group with $\alpha = 0{\cdot}05$ and a power of 90 per cent. This study therefore planned to include 150 patients to allow for dropout.

The results for LESS and CL cholecystectomy groups were compared using Student's *t* test and χ^2 test or Fisher's



a LESS cholecystectomy – external view

b LESS cholecystectomy – critical view

c LESS cholecystectomy – final appearance

d CL cholecystectomy ports

Fig. 1 Operative views: **a** external view of laparoendoscopic single-site (LESS) cholecystectomy; **b** critical view during LESS cholecystectomy before cholangiography; **c** final appearance after LESS cholecystectomy; **d** port placement for conventional laparoscopic (CL) cholecystectomy

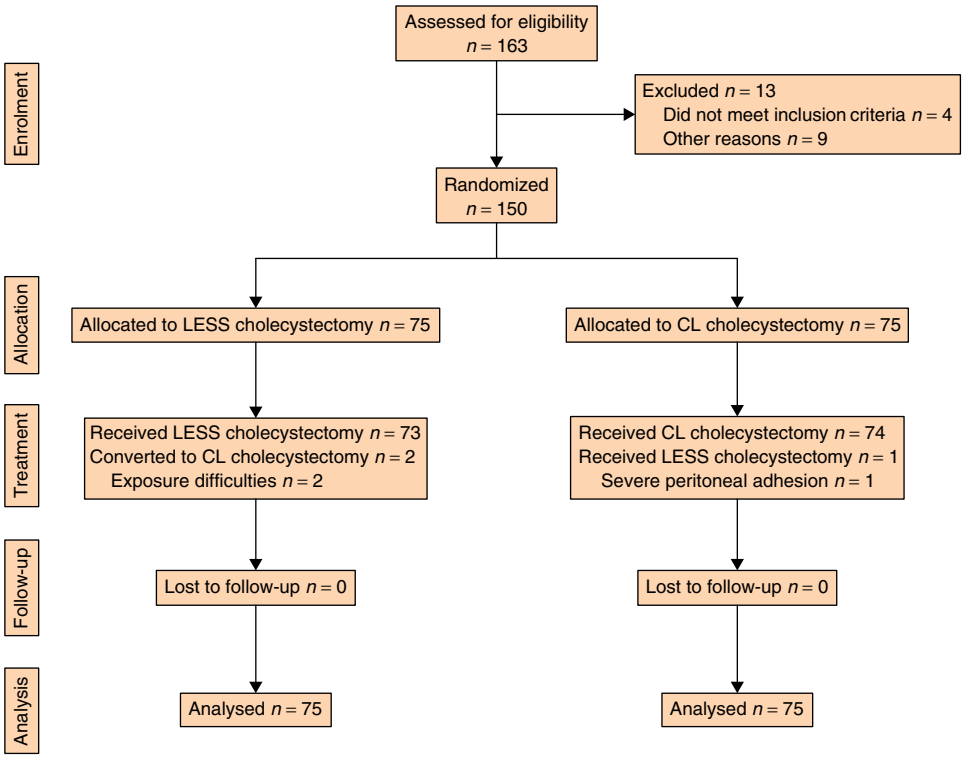


Fig. 2 CONSORT diagram for the trial. LESS, laparoendoscopic single-site; CL, conventional laparoscopic

exact test, as appropriate. $P < 0{\cdot}050$ was considered statistically significant. Statistical analyses were performed with GraphPad InStat® (GraphPad Software, San Diego, California, USA).

Results

Of the 163 patients considered for the study, 150 were randomized to undergo either LESS or CL cholecystectomy (*Fig. 2*). Four patients were ineligible. Of the other nine, six refused to participate, two had a concomitant groin hernia and one a hiatus hernia. All nine underwent CL cholecystectomy with hernia repair where applicable. The two groups were similar with respect to age, sex, body mass index, pathology, history of previous abdominal surgery and American Society of Anesthesiologists classification (*Table 1*).

Two morbidly obese patients undergoing LESS cholecystectomy had an additional 5-mm port placed in the epigastrium to improve visualization and facilitate dissection. One patient planned for CL cholecystectomy underwent a LESS procedure because dense and diffuse adhesions were discovered after placement of the first port; the surgeon opted for a LESS procedure rather than extensive adhesiolysis.

Operating times were similar in the two groups (*Table 2*). The critical view of safety was achieved in all patients. Cholangiography was attempted in all patients and performed successfully in 62 and 57 operations in the CL and LESS groups respectively ($P = 0{\cdot}420$). No common bile duct stones or leaks were identified by cholangiography, but two anatomical variants and a large choledochal cyst were found. Enlargement of the umbilical incision for specimen and/or stone extraction was needed in 25 per cent of operations in the CL group compared with 4 per cent in the LESS group ($P < 0{\cdot}001$). Operative costs were higher for LESS procedures, mainly owing to port and endograsper costs ($P < 0{\cdot}001$). This additional cost was estimated at US $400 per procedure. Intraoperative and postoperative complication rates were similar in the two groups (*Table 2*). No complication needed specific therapy (all Clavien class I).

According to VAS evaluation, the pain profile was significantly better in the LESS group from 6 h to 10 days after operation ($P < 0{\cdot}001$) (*Table* 3). This was associated with less requirement for analgesia. Time to resumption of work was shorter in the LESS group ($P = 0{\cdot}003$).

Postoperative cosmetic results were significantly in favour of LESS cholecystectomy (*Table 4*). Body image results were better in the LESS group at discharge

Table 1 Patient characteristics

	LESS cholecystectomy ($n = 75$)	CL cholecystectomy ($n = 75$)	P†
Age (years)*	42 (18–81)	44 (20–78)	0·399
BMI (kg/m^2)*	26 (22–35)	25 (19–34)	0·437
Previous abdominal surgery	29 (39)	27 (36)	0·866‡
Diagnosis			0·641‡
Symptomatic gallstones	25 (33)	30 (40)	
Acute or chronic cholecystitis	37 (49)	33 (44)	
Biliary pancreatitis	12 (16)	12 (16)	
Incidental cancer	1 (1)	0 (0)	
ASA score*	2 (1–3)	2 (1–3)	0·999
Preoperative QoL score (SF-12®)*	35 (27–41)	34 (28–40)	0·473

Values in parentheses are percentages unless indicated otherwise; *values are median (range). LESS, laparoendocopic single-site; CL, conventional laparoscopic; BMI, body mass index; ASA, American Society of Anesthesiologists; QoL, quality of life; SF-12®, Short Form 12. †Unpaired t test, except ‡Fisher's exact test.

Table 2 Operative results

	LESS cholecystectomy ($n = 75$)	CL cholecystectomy ($n = 75$)
Duration of operation (min)*	66 (32–109)	64 (38–117)
Cholangiography	57 (76)	62 (83)
Additional port added	2 (3)	—
Conversion to LESS procedure	—	1 (1)
Associated operation	9 (12)	6 (8)
Enlargement of umbilical incision for specimen extraction	3 (4)†	19 (25)
Perioperative complications		
Gallbladder perforation	9 (12)	6 (8)
Postoperative complications		
Haematoma/seroma at umbilical port	3 (4)	2 (3)
Haematoma/seroma at working ports	—	2 (3)
Umbilical hernia	0 (0)	0 (0)

Values in parentheses are percentages unless indicated otherwise; *values are median (range). LESS, laparoendocopic single-site; CL, conventional laparoscopic. †$P < 0·001$ *versus* CL cholecystectomy (χ^2 test).

Table 3 Postoperative results

	LESS cholecystectomy ($n = 75$)	CL cholecystectomy ($n = 75$)	P†
Pain profile (VAS score)*			
6 h	2 (0–4)	3 (2–7)	< 0·001
24 h	1 (0–4)	3 (2–5)	< 0·001
10 days	1(1–3)	2 (1–4)	< 0·001
Analgesia requirement			
Total morphine in 1st 24 h (mg)*	0 (0–7·5)	3 (0–12·5)	0·002
Patients taking analgesics on day 10	49 (65)	69 (92)	< 0·001‡
Patients taking analgesics on day 30	0 (0)	10 (13)	0·014‡
Hospital stay (days)*	0 (0–2)	1 (0–5)	0·014
Time to resume work (days)*	10 (5–14)	12 (11–15)	0·003

Values in parentheses are percentages unless indicated otherwise; *values are median (range). LESS, laparoendocopic single-site; CL, conventional laparoscopic; VAS, visual analogue scale. †Unpaired t test, except ‡χ^2 test.

Table 4 Postoperative cosmesis and quality of life

	LESS cholecystectomy ($n = 75$)	CL cholecystectomy ($n = 75$)	P§
Score on body image scale*			
At discharge	6 (5–7)	8 (7–11)	< 0·001
10 days	5 (5–7)	7 (6–9)	< 0·001
30 days	5 (5–6)	6 (5–7)	0·003
Score on scar scale†			
10 days	4 (3–5)	6 (4–9)	< 0·001
30 days	3 (3–4)	4 (3–6)	0·002
Postoperative QoL score (SF-12®)	40 (35–43)	35 (28–41)	0·028
Change in SF-12® score (preop. *versus* day 30 postop.)‡	5 (1–8)	2 (−3 to 4)	< 0·001

Values are median (range). *On scale from 5 (best result) to 20. †On scale from 3 (best result) to 15. ‡A positive result indicates improvement in quality of life (QoL). LESS, laparoendocopic single-site; CL, conventional laparoscopic; SF-12®, Short Form 12. §Unpaired t test.

($P < 0·001$). These may have been influenced by knowledge of the wound dressing, but remained in favour of LESS at 10 and 30 days after surgery ($P < 0·001$ and $P = 0·003$ respectively). QoL was better after surgery in the LESS group, as was the improvement in QoL compared with before cholecystectomy ($P < 0·001$).

Discussion

This randomized trial demonstrated that LESS cholecystectomy was associated with improved postoperative cosmesis and a more favourable postoperative pain profile, resulting in shorter recovery than CL cholecystectomy. LESS surgery had a smaller impact on body image and was associated with better QoL scores.

Recent progress in minimally invasive surgery may offer patients the opportunity of a potentially scarless approach associated with improved cosmesis and a better pain profile related to decreased parietal trauma[22–24]. Patients seem to favour scarless surgery over standard multiport laparoscopy[4,22,25–28]. The recent and rapid development of LESS surgery is thought to be driven mainly by cosmetic advantages, without struggling with technical barriers and potential access risks, as with natural-orifice transluminal endoscopic surgery[27].

In the present study, LESS was associated with better cosmetic results in terms of patients' satisfaction with scars and body image modification, which would seem to reflect the hidden single scar in the umbilicus and shorter total scar length. The common requirement to widen the umbilical incision during CL cholecystectomy to extract the gallbladder and/or stones may also account for body image modification. These cosmetic issues may have a favourable influence on QoL.

Many factors influence pain (scars, bile leakage, intraperitoneal pressure, use of local anaesthetics, peritoneal lavage and psychological factors)[29–32]. Only scar size and sites were different in the two groups in the present study, so the incisions were probably the variable most likely to be responsible for the better pain profile after LESS cholecystectomy.

Although the advantages of LESS cholecystectomy may be thought to be of low clinical impact compared with its potential risks and higher costs, emphasis on adverse events is warranted[16]. The critical view of safety[33,34] was achieved in all patients in the present study. This may be related to the LESS technique used, which reproduced 'four-port' cholecystectomy by the use of intracorporeal graspers, dedicated instrumentation and a telescope. The routine use of intraoperative cholangiography may also decrease the severity of any accidental injury to the biliary tract[17]. One specific criticism of LESS surgery is the higher risk of umbilical complications related to the larger incision. As shown here, this risk seems low provided that there is proper closure of the incision. No umbilical hernias were recorded, although follow-up was too short to reach a firm conclusion on this issue.

LESS cholecystectomy is associated with higher operative costs than the CL procedure. This cost difference is dependent on the materials used. Only reusable instrumentation was used for LESS cholecystectomy in the present study, except for the port, intracorporeal grasper and clip applier. Present costs reflect product development which cannot easily be compared with the cost of a routine procedure[35].

The authors recognize several limitations to this study. The results may have been influenced by operator bias. The same experienced surgeons performed all LESS operations, but not CL procedures where they assisted advanced trainees at some operations. It can be argued that the

patients were not blinded to the type of operation on the basis of their dressings and this may have influenced results. The results of LESS cholecystectomy may equally reflect instrumentation and technique used in the present study, where no transparietal sutures were used and multiple ports were not placed in a single incision.

Three smaller randomized trials on single-access cholecystectomy have shown similar improvement in cosmesis and/or pain profile compared with multiport laparoscopic cholecystectomy[32,36,37]. One of these showed an advantage for single-access cholecystectomy compared with minilaparoscopy in term of cosmesis[32], whereas mini-laparoscopy (needlescopic) has already been demonstrated to have advantages over conventional laparoscopy in terms of cosmesis and pain[38].

While surgeons develop techniques for reduced-port surgery, patient safety should remain a concern. Larger series are needed[24,39–41]. The present literature suggests that LESS cholecystectomy is as safe as a CL approach, although it is likely that publication bias may be creating a false sense of security[3,6]. It is recommended that this approach be offered to patients only in the context of approved research protocols, with reporting of all patients in large collaborative registries[22,41].

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