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Robot-assisted versus laparoscopic single-incision cholecystectomy: results of a randomized controlled trial

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Abstract

Background Although single-port laparoscopic cholecystectomy (SILC) is safe and effective, inherent surgeons' discomfort has prevented a large-scale adaptation of this technique. Recent advances in robotic technology suggest that da Vinci Single-Site™ cholecystectomy (dVSSC) may overcome this issue by reducing the stress load of the surgeon compared to SILC. However, evidence to objectively assess differences between the two approaches is lacking.

Methods 60 patients [36 women, 24 men (mean age 52 years)] with benign gallbladder disease were randomly assigned to dVSSC ($n=30$) or SILC ($n=30$) in this single-centre, single-blinded controlled trial. The primary endpoint was surgeon's stress load. Secondary endpoints included operating time, conversion rates, additional trocar placement, blood loss, length of hospital stay, procedure costs, health-related quality of life, cosmesis and complications. Data were collected preoperatively, during the hospital stay, and at 1 and 12 months' follow-up.

Results The dVSSC group showed a significant reduction of mental stress load of the surgeon compared to SILC [Subjective Mental Effort Questionnaire (SMEQ) score: median 25.0 (range 8–89) vs. 42.5 (range 13–110) points; $p=0.002$] and a trend towards reduced physical stress load [Local Experienced Discomfort (LED) score: median 8 (range 2–27) vs. 12 (range 0–64) points; $p=0.088$]. The length of hospital stay was longer in the SILC group [mean 3.06 (median 2; range 1–26) vs. 1.9 (median 2; range 1–4) days, $p=0.034$] but overall hospital costs were higher for dVSSC [median 9734 (range 5775–16729) vs. 6900 (range 4156–99977) CHF; $p=0.001$]. There were no differences in the rate of postoperative complications that required re-intervention (Dindo–Clavien grade ≥ IIIa; SILC $n=2$ vs. dVSSC $n=0$, $p=0.492$) or other secondary endpoints.

Conclusions Da Vinci Single-Site™ cholecystectomy provides significant benefits over Single-Port Laparoscopic Cholecystectomy in terms of surgeon's stress load, matches the standards of the laparoscopic single-incision approach with regard to patients' outcomes but increases expenses. Clinicaltrials.gov registration-No.: NCT02485392.

Keywords Robot-assisted single-site · Laparoscopic single-incision · Cholecystectomy · Benign gallbladder disease · Randomized controlled trial

The surgical removal of the gallbladder can be done safely and effectively using the single-port technique through one small periumbilical incision, which results in reduced postoperative pain, less scarring and better cosmetic outcomes [1–6]. Despite those benefits, many surgeons do not feel comfortable with the single-port technology due to an increased personal discomfort experienced while conducting such a conventional single-incision laparoscopic cholecystectomy (SILC) [6]. In order to overcome this issue, the da Vinci Single-Site™ platform has introduced several potentially advantageous technological innovations, such as the utilization of ergonomic, curved robot-assisted devices that preserve triangulation within the operative field, the reassignment of the crossing instruments to the opposite side, motion scaling and a stable 3D view of the operating field [2]. These features are thought to reduce eye strain, improve the ergonomic outcomes for surgeons and minimize both the

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mental and the physical workload associated with single-incision laparoscopy [7]. As a result, they have the potential to refine both surgical performance and work satisfaction, as well as eventually impact beneficially on patient outcome [3, 7–14].

Indeed, preliminary evidence from case reports and case–control studies suggests that the utilization of the da Vinci Single-Site™ technology for cholecystectomy is safe, feasible and results in a shorter learning curve compared to conventional single-incision laparoscopic cholecystectomy [1–4]. In addition, the computer-aided technique has been shown to significantly reduce the cognitive and physical stress in a simulated experimental setup [7]. However, the described observations and putative advantages of the robotic technology are based solely on case series, case reports and experimental data, as high-quality clinical trials have not yet been performed. Therefore, the present study assesses in a randomized setting whether dVSSC provides a benefit compared with SILC in terms of surgeon's stress load, while matching the standards of the conventional single-incision approach with regard to peri- and postoperative outcomes.

Materials and methods

Trial design

This single-centre, single-blinded randomized clinical trial was conducted to compare dVSSC with SILC in patients with benign gallbladder disease. The study was conducted according to the principles of the Declaration of Helsinki and is reported on the basis of the CONSORT statement [15]. The protocol of the trial was approved by the local ethics committee, registered at clinicaltrials.gov (NCT02485392) and published previously [13].

Study endpoints

The primary endpoint of the study was the surgeon's physical and mental stress load at the time of surgery and was assessed by two validated visual analogue scales, the modified Local Experienced Discomfort (LED; Supplementary Figure S1) and Subjective Mental Effort Questionnaire (SMEQ; Supplementary Figure S2) [7, 13, 16]. Secondary endpoints included intraoperative blood loss, operating time, intraoperative conversion rate and additional trocar placement, complications, length of hospital stay, costs of procedure, Health-Related Quality of Life (HRQoL) and cosmesis. HRQoL and cosmesis were assessed using the validated Gastrointestinal Quality of Life Index (GIQLI) and a modified Body Image Questionnaires (BIQ), respectively [13, 17, 18]. Costs generated in the operating theatre included the costs for consumables specifically needed for the dVSSC and SILS procedures (recorded for each patient), non-procedure-specific surgical and anaesthesiologic consumables (calculated as costs per minute), the amortization of the equipment and staff salaries (calculated as costs per minute). On the ward, costs were divided into medical (such as radiographic imaging, gastroenterologic interventions, histopathologic assessments, laboratory exams) and non-medical expenses (such as nursing costs, ergo-/physiotherapy) and calculated as overheads per minute.

Sample-size calculations

Sample-size calculations utilized an estimated effect size of 0.8 as reported previously [7] at a power of 0.8, an alpha-error level of 0.05 and considered a potential additional error margin of 10–15% (G-Power 3.1 software, Heinrich-Heine University Duesseldorf/Germany). This resulted in a number of 30 randomized patients per arm (60 patients in total).

Participants

Eligible participants were adults with benign gallbladder disease, admitted for elective cholecystectomy at the Cantonal Hospital of Winterthur in Switzerland. The detailed inclusion and exclusion criteria have been described previously [13]. In brief, pregnant or breastfeeding women, patients with significant systemic disease, mental or organic disorders which could interfere with giving informed consent or receiving treatments, suspicion of malignant disease, previous extensive upper abdominal surgery, emergency cholecystectomy, obesity II°–III° (BMI > 35.0 kg/m^2), lack of patient compliance or geographic proximity were excluded (Fig. 1, CONSORT study flowsheet). The operation was performed according to the group assignment by three senior surgeons, who had received a formal training and gained extensive experience in both surgical techniques (dVSSC and SILC) prior to commencement of the study. All surgeons were aware that they were subject of a study and of its endpoints and agreed to participate in the trail.

Data collection and statistical methods

Informed consent and patient enrolment was carried out in the outpatient clinic. Data included in the patient report forms were stored on secuTrial®, an internet-based secure and encrypted data management platform (http://www.secutrial.com). The LED and SMEQ questionnaires were answered by the operating surgeon immediately after the completion of the surgery. The GIQLI questionnaire was answered by the patient preoperatively and, together with the BIQ and a clinical examination performed by a surgeon at the outpatient clinic, at the 1-month and the 1-year follow-up

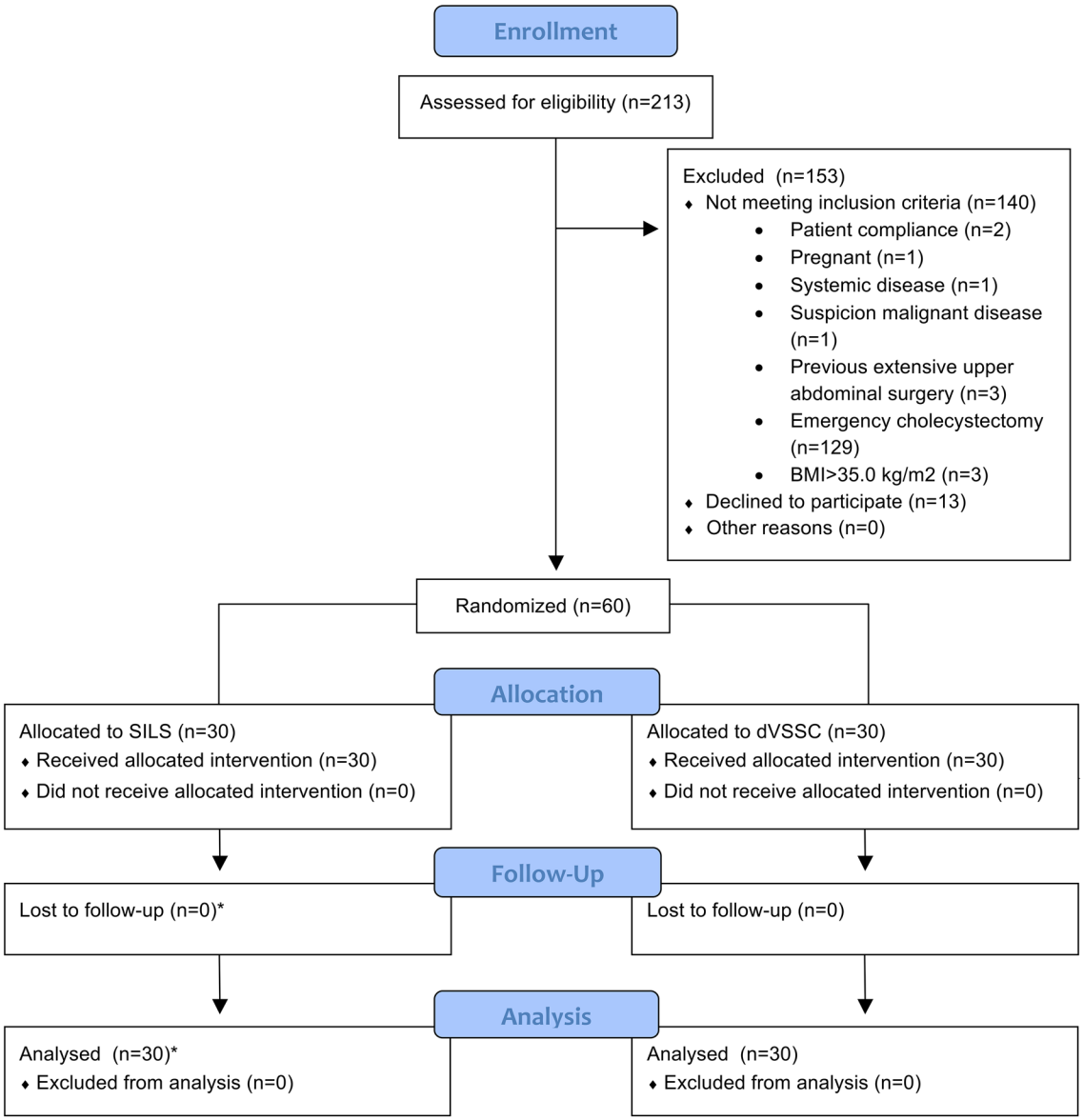

Fig. 1 CONSORT study flow diagram. *SILC* single-incision laparoscopic cholecystectomy, *dVSSC* da Vinci Single-Site Cholecystectomy. Asterisk represents the three patients who did not return the HRQoL and BIC questionnaires in the SILC group at 1-year follow-up and were therefore excluded from the HRQoL and BIC analyses at this time point

visits [13]. Patient data were analysed in the groups to which they were originally randomly assigned (intention-to-treat analysis). The Fisher's Exact Test was used to analyse contingency tables. Data distribution was assessed using the Kolmogorov–Smirnov Test. A two-tailed Mann–Whitney and a two-sided Student's *t* (unpaired) was applied to compare the data distributions in the two groups in data that deviate from normal distribution and in normally distributed data, respectively. All statistical analyses were performed using SPSS (Version 24.0). *P* values below 0.05 were considered significant. No interim analyses were planned or performed for the study.

Randomization and blinding

Non-stratified block randomization (random block sizes 2 and 4) on the secuTrial® platform was used to achieve balance in the allocation of participants to both treatment arms and prevent a premature decoding of the randomization scheme. Hereby, the patient and the ward staff were not informed about the group assignment until the last outpatient follow-up and only after the patient has completed and returned all study questionnaires.

Surgical technique

The surgical techniques have been described previously in greater detail [13]. In brief, the single-site robot-assisted cholecystectomy was performed using the da Vinci Si platform (Intuitive Surgical, Sunnyvale, CA, USA). Hereby, the cholecystectomy was performed in a standard fashion through a multiple-lumen Single-Site Port (one 8.5 mm da Vinci Endoscope Port, two 4-mm Single-Site Instrument Arm Ports and one 5-mm Accessory Port) which was placed through a 2.0–2.5-cm midline intra-umbilical incision. This technique utilizes ergonomic, curved robot-assisted laparoscopic devices. The robotic software independently reassigns the control of the crossing instruments to the opposite side.

The single-incision laparoscopic cholecystectomy was performed as previously described with slight modifications [5]. For patients undergoing SILC, a 12-mm atraumatic multiple-lumen access device (GelPOINT Mini Advanced Access Platform; Applied Medical, Rancho Santa Margarita, CA, USA) was placed through a 2.0–2.5-cm midline intra-umbilical incision. Exposure of the triangle of Calot and lateral retraction of the gallbladder infundibulum was performed using a bending grasper (Endograsp roticulator™, Covidien Inc., Norwalk, CT).

Results

Study flow

Figure 1 illustrates the patient flow according to the CONSORT guidelines [15]. Of the 213 patients assessed for eligibility, 60 were randomized. The most frequent reason for exclusion were cholecystectomies that were performed in an emergency setting ($n=129$) and therefore did not meet the inclusion criteria, followed by obesity II°–III° ($n=3$), previous upper abdominal surgery ($n=3$) and other less frequent reasons (Fig. 1). Thirty ($n=30$) patients were randomized to SILC and thirty ($n=30$) to dVSSC. All patients received the allocated intervention. 3 patients in the SILC group did not revisit the outpatient clinic at one postoperative year despite reminder letters and direct phone calls to the patients.

Baseline patient characteristics

Sixty patients [36 women, 24 men; mean age 52 (range 26–82) years] were included in the study. The patients' characteristics are listed in Table 1. Age, gender, body mass index, underlying conditions and comorbidities were equally distributed in both groups.

Table 1 Patient characteristics

	SILC	dVSSC	*p* Value*
Age (years), mean (range)	51.5 (30–78)	52.4 (26–82)	0.817**
Gender, female/male, *n*	16/14	20/10	0.430
BMI (kg/m^2), mean (SD)	27.3 (4.2)	27.3 (3.9)	0.997**
Condition, yes/no, *n* (%)			
Cholecystolithiasis	29 (96.7%)	29 (96.7%)	1.000
Gallbladder polyps	1 (3.3%)	1 (3.3%)	1.000
Comorbidities			
Any comorbidity, yes/no, *n* (%)	5 (16.7%)	2 (6.6%)	0.424
Cardiovascular	1 (3.3%)	0 (0%)	1.000
Respiratory	2 (6.6%)	2 (6.6%)	1.000
Renal	1 (3.3%)	0 (0%)	1.000
Endocrine	1 (3.3%)	0 (0%)	1.000

BMI body mass index, *SILC* single-incision laparoscopic cholecystectomy, *dVSSC* da Vinci Single-Site Cholecystectomy, *SD* standard deviation, *y* years

*Fisher's Exact Test (unless otherwise stated)

**Student *t* Test

Perioperative Characteristics

The perioperative characteristics are listed in Table 2. The operation duration did not differ significantly between the dVSSC and the SILC group [median 85.5 (range 48–148) vs. 74 (range 31–135) min]. Two patients were converted to a conventional 4-port laparoscopic cholecystectomy in the dVSSC and three patients in the SILC group, but the differences were not significant. Similarly, no significant differences were found between the number of operations which required an additional trocar placement, whereby extra trocars were used in four patients with SILC and none were required in the dVSSC group. Lastly, there were no conversions to open cholecystectomy and no differences in minor intraoperative complications (EAES I° and II°), and no major intraoperative complications (EAES ≥ III°) were noted [19].

Comfort of surgeon

The dVSSC group showed a significant reduction of mental stress load of the surgeon compared to SILC [SMEQ score: median 25.0 (range 8–89) vs. 42.5 (range 13–110) points; $p=0.002$, Table 2]. In addition, a non-significant trend towards reduced physical stress load was observed in the dVSSC group [LED score: median 8 (range 2–27) vs. 12 (range 0–64) points; $p=0.088$, Table 2].

Table 2 Comfort of surgeon and operative characteristics

	SILC	dVSSC	*p* Value*
Operation duration (min), median (range)			
Total	74 (31–135)	85.5 (48–148)	0.620
Time at console (dVSSC)	–	35.0 (21–107)	–
Conversion to conventional laparoscopy, yes/no, *n* (%)	3 (10%)	2 (6.7%)	1.000**
Conversion to open cholecystectomy, yes/no, *n* (%)	0 (0%)	0 (0%)	–
Additional trocar, yes/no, *n* (%)	4 (13.3%)	0 (0%)	0.112**
EAES intraoperative complication grade, *n* (%)			
No complications	16 (53.3%)	18 (60.0%)	0.795**
Grade I	11 (36.7%)	8 (26.6%)	0.580**
Grade II	3 (10.0%)	4 (13.3%)	1.000**
Grade III	0 (0%)	0 (0%)	–
Grade IV	0 (0%)	0 (0%)	–
Grade V	0 (0%)	0 (0%)	–
Type of complication, *n* (%)			
Peritoneal tear (EAES I°)	11 (36.7%)	8 (26.6%)	0.580**
Minor bleeding (EAES II°)	3 (10.0%)	4 (13.3%)	1.000**
Major bleeding (EAES > 11°)	0 (0%)	0 (0%)	–
Bile duct injury	0 (0%)	0 (0%)	–
Blood loss (ml), median (range)	3.5 (0–300)	5.0 (0–150)	0.598
Comfort of surgeon			
LED, median (range)	12 (0–64)	8 (2–27)	0.088
SMEQ, median (range)	42.5 (13–110)	25.0 (8–89)	0.002

LED local experienced discomfort, *SMEQ* subjective mental effort questionnaire, *SILC* single-incision laparoscopic cholecystectomy, *dVSSC* da Vinci single-site cholecystectomy

*Mann–Whitney Test (unless otherwise stated)

**Fisher's Exact Test

Postoperative surgical complications

With 13.3% overall complications that occurred within 30 days after dVSSC (Dindo–Clavien, I–V) [20] and 23.3% after SILC, postoperative complication rates were not different between the groups (Table 3). Grade I and II complications included superficial wound infections, periumbilical hematoma, one self-limiting fever episode, bowel paralysis, slight renal function impairment, urinary retention and nausea. There were two higher-grade complications in total (Dindo–Clavien ≥ IIIa) that required re-intervention. One IIIa complication occurred after SILC (stones in common bile duct that were successfully treated with an ERCP). The most serious complication (grade IVb) was noted in a 77-year-old male patient, who was randomized to the SILC group but underwent early conversion to conventional laparoscopic cholecystectomy due to an unexpected intraoperative finding of a chronic gallbladder empyema. During the postoperative course, the patient developed a cystic stump insufficiency with consecutive biliary peritonitis that required ERCP treatment with extraction of remnant bile duct stones and a stent placement in the common hepatic duct. In addition, a placement of two percutaneous peritoneal drainages was performed and the patient was treated with antibiotics. Concomitantly, he developed a sepsis with multi-organ dysfunction with hemodynamic and respiratory instability as well as renal function impairment, which required a transfer to our intensive care unit (ICU). He was discharged from the hospital 26 days after the surgery and later recovered well. 2 periumbilical incisional hernias were noted in each group within 1 year after cholecystectomy (Table 3).

Length of hospital stay

The length of hospital stay was significantly longer in the SILC group [median 2 days, mean 3.06 (range 1–26) days] than in the dVSSC group [median 2 days, mean 1.9 (range 1–4) days] ($p = 0.034$, Mann–Whitney Test; Table 3).

Health-related quality of life and cosmesis

Health-related Quality of Life as assessed by the GIQLI questionnaire improved significantly in both study groups after 1 month and 1 year compared to the preoperative assessment. Specifically, in the SILS group, the median

Table 3 Postoperative characteristics and study outcomes

	SILC	dVSSC	*p* Value*
Complications (within 30 postoperative days)			
Any complication, yes/no, *n* (%)	7 (23.3%)	4 (13.3%)	0.506**
Dindo–Clavien complication grade, *n* (%)			
No complications	23 (76.7%)	25 (83.3%)	–
Grade I	4 (13.3%)	2 (6.7%)	–
Grade II	1 (3.3%)	2 (6.7%)	–
Grade IIIa	1 (3.3%)	0 (0%)	–
Grade IIIb	0 (0%)	0 (0%)	–
Grade IVa	0 (0%)	0 (0%)	–
Grade IVb	1 (3.3%)	0 (0%)	–
Grade V	0 (0%)	0 (0%)	–
Type of complication, *n* (%)			1.000**
Superficial wound infection	1 (3.3%)	2 (3.3%)	–
Periumbilical hematoma	0 (0%)	1 (3.3%)	–
Self-limiting fever episode	1 (3.3%)	0 (0%)	–
Bowel paralysis	1 (3.3%)	0 (0%)	–
Renal function impairment	1 (3.3%)	0 (0%)	–
Urinary retention	0 (0%)	1 (3.3%)	–
Nausea	1 (3.3%)	0 (0%)	–
Common bile duct stones	1 (3.3%)	0 (0%)	–
Multi-organ failure	1 (3.3%)	0 (0%)	–
Incisional hernia (within 1 postoperative year)	2 (6.7%)	2 (6.7%)	1.000
Length of hospital stay (days), median (range)	2 (1–26)	2 (1–4)	0.034
Total cost of procedure (CHF), median (mean; SD)	6900 (10,466; 17,070)	9734 (9781; 2301)	0.001
Operating theatre			
Consumables	882 (1130; 1623)	2921 (2991; 563)	< 0.001
Amortization	493 (402; 287)	932 (763; 557)	0.020
Anaesthesiology***	1229 (1237; 1077)	1229 (1055; 485)	0.865
Surgery***	1555 (1645; 690)	1933 (2007; 614)	0.017
Ward***			
Medical (radiology, gastroenterology, laboratory, pathology, other)	872 (2002; 4443)	844 (1024; 534)	0.731
Non-medical (nursing, physio-/ergotherapy, other)	1110 (1621; 1897)	1238 (1278; 439)	0.665
Other costs	791 (2429; 7941)	317 (662; 1059)	0.312
HRQoL, median (range)			
Preoperative	109.5 (39–131)	107 (62–135)	0.965
1 month postoperative	120 (55–142)	123 (83–140)	0.666
12 months postoperative	128 (94–143)	123 (105–141)	0.286
Body image, median (range)			
1 month postoperative	38 (19–40)	37 (24–40)	0.404
12 months postoperative	39 (22–40)	35.5 (20–40)	0.055

CHF Swiss Francs, *LED* local experienced discomfort, *SMEQ* subjective mental effort questionnaire, *GIQLI* Gastrointestinal Quality of Life Index, *SILC* single-incision laparoscopic cholecystectomy, *dVSSC* da Vinci single-site cholecystectomy, *SD* standard deviation

*Mann–Whitney Test (unless otherwise stated)

**Fisher's Exact Test

***Overheads per minute

preoperative GIQLI score was 109.5 points (range 39–131), at 1 month postoperatively 120 (range 55–142) and 128 points (range 94–143) ($p < 0.001$, Mann–Whitney Test). Likewise, the median preoperative GIQLI score was 107 points (range 62–135) in the dVSSC groups, and improved at 1 month and 1 year postoperatively to 123 (range 83–140)

and 123 points (range 105–141), respectively ($p < 0.001$, Mann–Whitney Test). As shown in Table 3, there were no differences between the two groups at 1-month or 1-year follow-up. Correspondingly, no significant differences in the body image scores were observed between the two groups at any point after the cholecystectomy (Table 3).

Costs of procedure

Overall hospital costs were significantly higher for robotic-assisted cholecystectomy [median 9734 (range 5775–16,729) CHF] than in the SILC group [median 6900 (range 4156–99,977) CHF; $p = 0.001$, Mann–Whitney Test, Table 3]. Specifically, the costs accrued in the operating theatre including consumables [median 2921 (SD 563) CHF vs. median 882 (SD 1623) CHF], amortization [median 932 (SD 557) CHF vs. median 493 (SD 287) CHF] and surgical overheads per minute [median 1933 (SD 614) CHF vs. median 1555 (SD 690) CHF] costs were significantly higher in the dVSSC arm than in the SILC group (Table 3). All other costs, including anaesthesia (overheads per minute) and ward expenditures (overheads per minute) did not differ between the two groups (Table 3).

Conclusions

The study is the first randomized controlled trial that compares the da Vinci Single-Site™ platform (dVSSC) in minimally invasive cholecystectomy to the conventional single-incision laparoscopic approach (SILC). It demonstrates that the robotic technique significantly reduces the surgeon's mental stress load and shows a corresponding trend towards reduced physical stress load. Moreover, it suggests that it at least matches the standards of SILC with regard to postoperative outcomes. These data, together with the low rates of conversion and additional trocar placements observed in this study, provide evidence that the development of the robotic platform has led to a further optimization and facilitation of the minimally invasive, single-incision cholecystectomy technique. As demonstrated in a recent randomized controlled trial performed at our institution, the removal of the gallbladder through a single periumbilical incision with the SILC technique results in superior cosmetic outcomes, an improved body image, reduced postoperative pain and better quality of life than the standard 4-port laparoscopic cholecystectomy [6]. However, despite those advantages, SILC has been widely criticized by the surgical community for its ergonomic problems and the resulting reduction of the comfort of the surgeon. For example, our recent trial has shown that surgeons complained about discomfort in 25% of the SILC cases, which was significantly higher than in standard 4-port laparoscopic cholecystectomy (2% of cases) [6]. The present study suggests that these shortcomings of SILC can be successfully overcome with the robot-assisted system and may provide an important advantage to professionals who complain of fatigue and discomfort when conducting a minimally invasive single-incision cholecystectomy [8–12]. Importantly, this improvement has the potential to not only have a beneficial effect on the stress load of a surgeon, but also to improve patient outcomes. This is due to the fact that a surgeon's degree of burnout resulting from such fatigue and discomfort experienced at his or her workplace is strongly correlated with major medical errors, which in turn carry a great risk of affecting the patient's well-being and safety [12, 14, 21]. It will be important to show in future studies that the improvement of surgeon's comfort translates into better patients' outcomes.

In this study, the length of hospital stay was significantly shorter in the dVSSC than in the SILC group. However, the differences were only small (identical median of 2 days in both groups; in line with the average length of hospital stay in Switzerland, where elective cholecystectomy is not a day-care procedure). They were possibly due to the somewhat higher, albeit non-significant, rate of complications in the SILC arm of this study that required a hospitalization beyond the second postoperative day in a few cases, such as common bile duct stones, urinary retention and bowel paralysis. These are more likely to be coincidental than to reflect a true advantage of the robotic platform. In terms of cosmesis (body image), a trend towards higher body image scores in the SILC group at 1 year postoperatively was observed. However, these results did not reach significance at this time point ($p = 0.055$). In addition, this was in contrast to the nearly identical median body image scores at 1 month postoperatively, and the similar wound infection rates at the final visit, suggesting that this non-significant trend does not reflect true differences between the two study arms. Possibly, it may rather be attributable to the higher rate of drop-outs in the SILC group (one patient who did not return the body image questionnaire at 1 year achieved a score of 19 points, the lowest of all sixty patients at 1 postoperative month), which may have skewed the results in favour of SILC at 1-year follow-up. Lastly, overall hospital costs were significantly higher for dVSSC compared to the SILC approach. In addition to the high acquisition costs of the da Vinci Surgical System, the materials provided by Intuitive for the single-site approach, such as the single-port system devised for single use and the curved instruments with their (by design) very limited life span, are required for this procedure, which increase economic consumption. The higher expenses incurred by dVSSC do raise important issues related to cost-effectiveness, currently a key concern across a wide range of health-care systems worldwide. Ultimately,

those health-care organizations will have to individually and critically assess whether the perceived benefits of the robotic technique justify the higher costs of the procedure.

This trial has some important limitations that need to be addressed. First, the sample size has been calculated based on the expected effect size of the primary endpoint of the study and may be too small to detect differences in secondary endpoints, such as complications, conversion rates, Health-Related Quality of Life and cosmesis. In order to more accurately assess differences between the two approaches with regard to those endpoints, larger prospective trials and/or registry-based analyses need to be conducted in the future. A second limitation is the involvement of several surgeons who performed the operations, as this may increase the variability of the subjective assessments of the primary endpoint and also influence patient outcomes. However, this variability has been accounted for in the power calculation of this study. In addition, this design reduces the risk of bias due to the individual preference of a surgeon towards either technique and thus better reflects the diversity between surgeons who perform gallbladder surgery in daily clinical practice.

Taken together, dVSSC provides significant benefits over SILC in terms of a reduction of a surgeon's stress load and at least matches the standards of the laparoscopic single-incision approach with regard to patients' outcomes after minimally invasive cholecystectomy, one of the most frequently performed operations in general surgery. However, despite the fact that it overcomes the main limitation of the SILC approach, it increases the expenses of the procedure. This cost increase, together with the limited availability of the da Vinci robot system, may at present restrict the implementation of this surgical approach on a wider scale. However, the already apparent clinical benefits of robot-assisted surgery provide a clear direction for the future development of modern surgical techniques. With new and heavy-weight industrial players such as Verb Surgical just about to enter the market, further refinements of the robotic single-incision approach have the potential to further enhance the surgeon's ability to perform both basic laparoscopic procedures as well as assist in more complex ones.

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Compliance with ethical standards

Disclosures Lukasz Filip Grochola, Christopher Soll, Adrian Zehnder, Roland Wyss, Pascal Herzog and Stefan Breitenstein have no conflict of interest or financial ties to disclose.

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