The outcomes of SILS cholecystectomy in comparison with classic four-trocar laparoscopic cholecystectomy

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Abstract

Introduction: *General approval of laparoscopy as well as persistent urge to minimize operative trauma with still existing difficulties in putting natural orifice transluminal endoscopic surgery (NOTES) into practice have contributed to the introduction of laparoscopic operations through one incision in the umbilicus named single incision laparoscopic surgery (SILS).*

Aim: *The main aim of this study was to assess the benefits to patients of applying SILS cholecystectomy as a method of gallbladder removal based on the comparison with classic four-port laparoscopic cholecystectomy.*

Material and methods: *Between 18.03.2009 and 09.12.2009, 100 patients were included in the study and they underwent elective gallbladder removal by applying the laparoscopic technique. All patients were divided into two equal groups: qualified for SILS cholecystectomy (group I) and qualified for classic four-trocar laparoscopic cholecystectomy (group II), whose ASA physical status was I and II. BMI was limited to 35 kg/m^2. Outcome measures included operative time, intensity of postoperative pain and consumption of painkillers, hospital stay, need for conversion, complications, and cosmetic effects.*

Results: *Mean operating time in group I was 66 min and in group II 47.2 min. Intensity of pain evaluated by using the visual analogue scale (VAS) 6 h after the operation in group I was 3.49 and in group II 4.53, whereas 24 h after the operation in group I it was 1.18 and in group II 1.55. The painkiller requirement in group I was smaller than in group II. Mean hospital stay after the operation in group I was 1.33 days and in group II 1.96 days. There were 4 conversions in group I and one conversion in group II. Among the complications in group I there were noted 2 cases of right pneumothorax, 1 case of choleperitonitis and 4 complications connected with wound healing. There was one injury of the duodenum and one wound infection in group II.*

Conclusions: *Single-incision laparoscopic surgery cholecystectomy can be an alternative to classic laparoscopic cholecystectomy, especially with reference to young people with body mass index less than 35 kg/m^2, without serious systemic diseases, operated on electively due to benign gallbladder diseases.*

Key words: *single-incision laparoscopic surgery, laparoscopy, cholecystectomy.*

Introduction

The turn of the 1980s and '90s was a time when a historical change in surgical technique happened through the introduction and fast spread of laparoscopy. These minimally invasive procedures gained broad acceptance and prospects for future development thanks to the significantly reduced operative

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trauma with the same therapeutic effect as with previously used 'open' procedures. Continuously increasing awareness that the size of the surgical incision determines the pace of return to good health after properly performed surgery as well as pursuit of the best cosmetic effect stimulated efforts towards broader implementation of the idea of natural orifice transluminal endoscopic surgery (NOTES) from 2005 [1]. However, the next 3 years showed that the use of NOTES in humans encountered various barriers resulting mainly from the shortcomings of the available equipment, as described in the White Book of Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) [2].

Awareness of all the difficulties associated with natural orifice surgery, mainly the lack of adequate, reasonably priced instruments as well as the need for highly sophisticated skills both in laparoscopy and endoscopy inspired further search for transitional solutions. These solutions were expected to bring similar benefits as NOTES and on the other hand they should allow the use of well-known laparoscopic technique. The answer to all these requirements was single incision laparoscopic surgery (SILS). The mainstay of SILS is that one can perform a procedure in the abdominal cavity by introducing all of the necessary instruments (including optics) through one small incision in the natural scar of the human body that is the umbilicus. It was not an entirely new idea, as the first person to use this technique (in 1995) was Navarra, who published the results of 30 SILS cholecystectomies in 1997 [3].

Material and methods

In our study we included 100 patients who underwent elective laparoscopic cholecystectomy in the period between 18.03.2009 and 09.12.2009. There were 81 female and 19 male patients with a score of I and II according to the American Society of Anesthesiologists (ASA) score. Maximum body mass index (BMI) was restricted to 35 kg/m^2. Patients with previous surgery in the upper abdomen (scar above the umbilicus) were excluded. Patients were assigned to two groups to achieve equal allocation of gender, age and BMI. Group I consisted of patients qualified to undergo SILS cholecystectomy and group II consisted of patients planned for classic multiport laparoscopic cholecystectomy.

Single-incision laparoscopic surgery cholecystectomy technique

The patient was placed in the supine position. The bottom of the umbilicus was grasped with Kocher forceps and averted. A horizontal incision of about 25 mm was made. After the skin was incised the umbilical scar was dissected from the fascia and that manoeuvre allowed more freedom during the ports' introduction. Pneumoperitoneum of 12 mm Hg CO_2 was achieved with a Veress needle. Then three 5 mm ports were inserted: the first was 100 mm in length (Genicon Europe Ltd) and was placed in the midline, in the location of the dissected umbilical scar, and then two ports, the first being 65 mm and the latter being 80 mm in length (Covidien), were placed on the sides of the first one in a way to keep tissue bridges of about 5 mm between ports. Ports were placed along one horizontal line in a fashion that would assure proper alignment of the trocar heads, preventing their collision during the use of the instruments. The head of the 100 mm long optical trocar was placed in the highest position. At this stage all patients were placed in the anti-Trendelenburg position with the table tilted by around 20° to the left side. Then, the fundus and in some cases also the neck of the gallbladder were suspended to the abdominal wall using a transabdominal 2-0 Monosof suture (on the straight needle) (Tyco). The first transabdominal suture was placed at the intersection of the right midclavicular line and the 7th intercostal space. Placement of the second suture depended on the anatomical situation and the size of the gallbladder. After pulling the sutures up and exposing Calot's triangle, the cystic duct and artery were separated using standard straight laparoscopic instruments and in some cases instruments with roticulation (Roticulator Endodissect and Roticulator Endograsp; AutoSuture).

Each structure was secured with 3 metal clips (Endoclip III 5 mm AutoSuture) and dissected to leave one or two clips on the stumps of the cystic artery and cystic duct. The gallbladder was dissected using a standard approach from the neck to the fundus using monopolar electrocautery. Just before freeing the fundus of the gallbladder, haemostasis was carefully checked and peritoneal lavage was done. We decided to do the lavage because we could frequently observe some small bile leakage along the punctures of the suspension suture. Only in 2 cases was

active drainage left in the abdomen and it was let out through the umbilical wound. The gallbladder was removed via the umbilical wound after the dissection of the tissue bridges between two or three trocars depending on the size of the gallstones. After fascial closure we recreated an umbilicus with 1-3 engraved absorbable sutures (Polysorb 3.0). We did not suture the skin.

Assessed factors

In this study we assessed the conversion rate, duration of operation, degree of postoperative pain, use of analgesics, hospitalization time (in particular after surgery), complications, and finally cosmetic effect.

In group I (SILS) we assessed the percentage of conversions to classic multiport laparoscopic cholecystectomy, as well as insertion of additional trocars. In both groups we assessed the rate of conversion to open surgery. Operation time was measured in full minutes starting with the first skin incision and ending with the last suture. Severity of postoperative pain was assessed 6 h and 24 h after surgery using the visual analogue scale (VAS).

All patients had a unified postoperative pain control scheme: pethidine 50-100 mg *i.m.* directly after the surgery (depending on patient's body mass and age) followed by metamizole sodium 4 ml *i.v.* as required. In cases when pethidine was contraindicated patients received tramadol 100 mg *i.m.* Patients with poor tolerance or allergy to metamizole received ketoprofen 100 mg in 100 ml of 0.9% saline in *i.v.* infusion. Analgesic requirement was assessed by adding all doses of analgesics during the postoperative period.

Hospitalization time was counted in full days, though the admission and discharge day were counted as one full day.

Assessment of cosmetic effect was based on subjective visual assessment performed by the surgeon and patient. It was scored by both the surgeon and the patient using a four-point scale: very good, good, satisfactory, and bad. The two scores were then added to obtain a final score.

Table I. Basic characteristics

Variable	Group I (n = 50)	Group II (n = 50)	Value of p
Female/male	43/7	38/12	
Age (mean/SD) [years]	45.5/12.11	50.18/11.79	< 0.05 (0.0265)
BMI (mean/SD) [kg/m^2]	25.86/3.54	26.44/2.96	> 0.05 (0.187)
ASA I/ASA II	33/17	30/20	> 0.05 (0.2672)
Length of the disease (mean/SD)	34.84/44.82	35.56/41.18	> 0.05 (0.4668)
Previous laparotomies (yes/no)	19/31	17/33	> 0.05 (0.3385)

Statistical analysis

In statistical analysis numerical data are presented as numbers, range of arithmetic means, standard deviations, results of analysis of probability distribution and hazard ratios. The Mann-Whitney *U* test for data with normal distribution, Student's *t*-test and χ^2 test were used to assess significance of differences in distributions of observations. We assumed *p*-values < 0.05 to be statistically significant. Statistical analysis was performed using the computer software Statistica 7.1 and Excel 2007.

Results

Characteristics of both groups with regards to age, gender, BMI, ASA, length of the disease and the number of previous laparotomies are shown in Table I.

There were 4 (8%) conversions in group I. In 1 patient (2%) introduction of an additional 5 mm trocar in the right subcostal area was necessary. It was a result of abnormal anatomy of the hepato-duodenal ligament and consequent difficulties to identify structures of Calot's triangle. In 3 patients (6%) conversion to multiport laparoscopic cholecystectomy was necessary due to extensive peritoneal adhesions. In none of the patients in this group was conversion to open surgery necessary.

There was 1 (2%) conversion to open surgery in group II. It was due to duodenal injury during the dissection of pericystic adhesions.

Five patients initially allocated to group I were excluded due to surgical technique modification that no longer fulfilled the inclusion criteria (conversion – 4 patients; laparotomy on the 4th postoperative day

Table II. Outcomes

Variables	Group I (n = 45)	Group II (n = 49)	Value of p
Total operative time (mean/SD) [min]	66/13.96	47.2/11.86	< 0.05 (< 0.001)
Pain 6 h after surgery (mean/SD) (range: 0-10)	3.49/1.60	4.53/1.49	< 0.05 (0.00096)
Pain 24 h after surgery (mean/SD) (range: 0-10)	1.18/0.83	1.55/0.84	< 0.05 (0.0187)
Number of doses of analgesics after surgery (mean/SD)	1.09/0.92	1.37/0.88	> 0.05 (0.0737)
Post-operative hospitalization time (mean/SD) [days]	1.33/0.48	1.96/0.54	< 0.05 (< 0.001)

Table III. Post-operative complications

Type of complication	Group I (n = 50)		Group II (n = 50)			
	1-25 procedures	Percentage	26-50 procedures	Percentage	1-50 procedures	Percentage
Complications as a result of the course of the operation						
Pneumothorax	2	4				
Choleperitonitis	1	2				
Duodenal injury					1	2
Complications as a result of the wound healing						
Marginal skin necrosis	1	2				
Granuloma in the umbilical wound	1	2				
Seroma in the umbilical wound	1	2				
Wound infection			1	2	1	2
Total	6	12	1	2	2	4

due to bile leak – 1 patient). Similarly, 1 patient was excluded from group II due to conversion to an open cholecystectomy. Table II shows a comparison of outcomes in groups I and II after the exclusions described above.

Postoperative complications were divided into two groups: complications that occurred as a consequence of the surgery and complications associated with wound healing. All complications with the time of occurrence are shown in Table III.

Follow-up examination at 3 months after surgery showed a significantly better cosmetic effect after single incision surgery than after multiport cholecystectomy. Forty-three patients (95.55%) from the SILS group rated the cosmetic effect as "very good". Two patients (4.45%) who had some infective wound complications said that the cosmetic effect was "good". None of the patients gave a "satisfactory" or "bad" mark. The final assessment of the cosmetic outcome in both groups was based on investigators' valuation only. This was because most of the patients in the group receiving classic multiport cholecystectomy showed generally high satisfaction levels that were due to comparison of the cosmetic effect of multiport versus open cholecystectomy; thus their opinions could not be taken into account as a valuable source of information on outcomes.

Discussion

During the year 2009, there were 58 SILS cholecystectomies performed in the Department of General and Minimally Invasive Surgery, University Hospital and Clinics in Olsztyn, Poland. The first 8 SILS cholecystectomies were not included in the study because surgical technique varied significantly in this

initial period. During that time the team searched for the best operative technique and tried to eliminate difficulties due to the lack of experience in using SILS and imperfection of the equipment and laparoscopic instruments used. As we became more proficient in using SILS, during a relatively short period of time we managed to work out our own surgical technique and could start the planned study. All centres that introduce novel operative techniques initially qualify patients with the lowest risk potential for the occurrence of technical difficulties. This is mainly because we are all aware of the difficulties associated with gaining the necessary experience during the first few applications of a new technique. A surgeon's conviction towards a new technique frequently depends on the outcomes of these first cases. The wrong choice of the first patients leads to higher complication rates and increased frequency of conversions to classic multiport laparoscopy. Bearing this in mind, we decided to qualify patients with a low anaesthetic risk, that is, patients with their health state assessed according to the American Society of Anesthesiologists (ASA) with a score of I and II. The upper BMI limit of 35 kg/m^2 was due to concerns that there might be more technical difficulties due to the thicker abdominal wall and excess of fat tissue around the gallbladder. We were also concerned about previous abdominal surgery, as it is well known that intra-abdominal adhesions are one of the basic factors that increase conversion rates [4-6]. Due to the above concerns, we decided not to qualify patients who had undergone previous abdominal surgery with a scar above the umbilicus. Patients with acute cholecystitis were also excluded because of a potentially increased risk of complications due to the inflammatory effusion, oedema and necrosis that might have impacted the anatomical situation [7].

One of the very important factors assessed during the comparative analysis of surgical techniques is total operative time. In the present study the mean operative time of SILS cholecystectomy was 66 min (range: 35-110 min). It was very close to the results of Solomon *et al.* [8]. When they excluded the first 10 cases (mean operative time of 80 min) and performed a sub-analysis of operative times for consecutive groups consisting of 10-11 patients, they could see that the mean operative time shortened successively, being 73, 71, 58 and 65 min in the consecutive groups. These results were similar to other published series [9-15]. It significantly differed from the mean operative time of 47 min for multiport cholecystectomy. This difference would be much greater if we compared our results with the best achieved operative times for laparoscopic cholecystectomy published by Stephenson *et al.* In his group of patients the mean operative time was 39 min (range: 25-60 min) [16]. Certainly, the significantly longer operative time of SILS cholecystectomy in comparison to multiport laparoscopy is a weakness of the technique. However, one should remember that this technique is novel. Historically, operative times of the first 100 laparoscopic cholecystectomies published by great laparoscopic surgeons were 98 min (Zucker *et al.*) and 85 min (Peters *et al.*) [17, 18]. These operative times are still longer when one compares these results with our and some other authors' initial outcomes of SILS cholecystectomy. One can expect that this scenario will be repeated soon with significantly improved published outcomes.

The post-operative pain is the next key parameter allowing a comparative analysis of both techniques. Post-operative pain is particularly important from the patient's point of view. It is a subjective measure of suffering that influences the post-operative quality of life. It is unquestionable that the post-operative pain after laparoscopic procedures lasts significantly shorter and its intensity is reduced when compared to open techniques [19-22]. The introduction of SILS and further reduction of operative trauma allows us to expect further improvement of post-operative pain. The main difference between multiport and SILS cholecystectomy is the number of abdominal wall incisions; thus one would expect a reduction of pain mainly in the abdominal wall and not in its cavity. The specific time intervals for pain measurement were at 6 h and 24 h post-operatively, when the patient passed urine for the first time and was fully mobilized. The intensity of post-operative pain 6 h after surgery was significantly smaller after SILS cholecystectomy, with a mean VAS score of 3.49, when compared to multiport surgery, with a mean VAS score of 4.53 (p = 0.00096). Similar results were published by Tsimoyiannis *et al.* [23]. Importantly, in their study most of the patients also declared that they were ready to leave the hospital 6 h after surgery. Similar results were published by Bresadola *et al.* with assessment performed at 4 h and 8 h after surgery [24]. Similarly, a significant but smaller difference in VAS scores was seen at 24 h, with VAS = 1.18 and 1.55 (p = 0.0187) for SILS and multiport cholecys-

tectomy respectively. Reduction of the difference in VAS score, seen also by Tsimoyiannis *et al.* [23], is a result of the fact that the main difference between the two techniques is the cumulative length of surgical incision. The remaining factors such as the mode of creation of pneumoperitoneum, intra-abdominal pressure, temperature and type of gases used during both techniques were identical. The larger the wound, the greater is the extent of operative trauma. Therefore, the difference in the VAS scores in favour of the SILS procedure was most clearly visible during the first 24 h after surgery. Reduced pain severity after SILS cholecystectomy was reflected in a decreased analgesic requirement during the post-operative period. Although the statistical analysis showed that the difference in analgesic requirement between groups was not significant, the *p* value of 0.0737 was very close to the significance level. Similar results were published by Bresadola *et al.* [24].

Hospitalization time might be measured in several ways. We decided to measure only the time that the patient stayed in the hospital after surgery, as the pre-operative period varies significantly depending on the activities required to prepare the patient for surgery in Polish hospital settings. The mean post-operative hospitalization time in group I was 1.33 days (range: 1-2 days) and in group II was 1.96 days (range: 1-3 days) ($p < 0.001$). Therefore, in terms of post-operative hospitalization time SILS cholecystectomy is more beneficial. Similar conclusions come from most of the cited publications, although direct comparisons are difficult to make as we assessed only post-operative hospitalization time, not the total hospitalization time as did other authors [10, 11, 13, 25-27].

Since the introduction of laparoscopy, one of the major factors allowing assessment of its value and usefulness has been the rate of conversions. It is obvious that SILS cholecystectomy, like all previous laparoscopic procedures, had to be assessed against this parameter. In the present study there were 4 conversions (8%) in group I. Our conversion rate seems to be good when compared with previously published reports, especially since the number of patients in our group is not that small. Most of the studies with conversion rates of 0 reported on outcomes in groups of 10 to 20 patients [13, 14, 27-31]. Studies with a similar or greater number of patients than our study reported similar conversion rates [8, 10-12, 25, 32]. Edwards *et al.* reported the necessity to introduce an additional 5 mm trocar in 6 cases and in 3 cases they had to convert to classic 4-port cholecystectomy in a study group of 76 patients [12].

Only three studies reported on single cases that required conversion to an open procedure [8, 11, 25]. All of these conversions were due to solid adhesions or inflammatory infiltration that was not amenable to laparoscopic manoeuvres. There was only 1 (2%) conversion to an open procedure in group II, which is in favour of SILS cholecystectomy that did not require such conversions. Nevertheless, one should not draw conclusions from this result as the assessment of conversions should be performed on significantly larger groups of patients.

Despite being minimally invasive, laparoscopic techniques are not free of post-operative complications. As SILS cholecystectomy is a very specific procedure, we decided to divide the complications into two groups. The first group was composed of complications that were a direct result of the course of operation and the second group was composed of complications of wound healing. There were 2 cases of right pneumothorax that occurred directly after putting the suspension suture into the gallbladder fundus via the 7th intercostal space (7th and 16th operations). In these cases we decided to reduce the pneumoperitoneum to 9-10 mm Hg and we pulled the gallbladder towards the abdominal wall with more strength. At the same time the anaesthesiologist increased the O_2 concentration in the inhaled gases to 50% and corrected the ventilation to keep $EtCO_2$ between 30% and 35%. In both cases the undertaken measures were sufficient and allowed the procedure to be finished as planned. Neither of these 2 patients required any thoracic drainage as the control bed-side chest X-ray showed no pneumothorax at the end of the procedure. Only one study has reported such a complication so far [33], although it seems it might be more frequent than reported. When we planned the procedure with the use of a transabdominal suspension suture we based it on the experience of Endo *et al.*, who placed such a suture in the intersection of the 7th intercostal space and midclavicular line with no pneumothorax in his group of 132 patients [34]. Based on our experience of pneumothorax in these 2 patients, in all further patients we decided to place the suspension suture in the 8th intercostal space and slightly lateral to the midclavicular line.

Another complication seen in our set of patients was the omission of the opened Luschka duct with

subsequent choleperitonitis. In our opinion the bile leak was due to the gallbladder punctures caused by the suspension suture and our relatively small experience in this type of procedure (17 operations). That misled the surgeon about the origin of the bile leak and prevented the search for the leakage. Similar problems were encountered by the teams of Solomon *et al.* and Edwards *et al.* [8, 12], but in their cases endoscopic exploration, bile duct stenting and percutaneous drainage of the peritoneal cavity was sufficient. We did not encounter such a complication in group II. Available literature shows that the rate of bile leaks after classic multiport cholecystectomy varies between 1% and 3% [35-41]; thus our 2% leak rate after SILS cholecystectomy is comparable with other centres.

We observed 4 cases (8%) of wound complications in group I. The first patient with a wound complication had marginal necrosis of the umbilical skin (4th patient). On the 7th postoperative day the patient had a necrectomy done and the wound was left to heal via granulation. Two other patients had seroma formations in the umbilical wounds. In 1 patient, drainage on the 4th postoperative day was sufficient to heal the wound. In the other case, the exudate was present for 3 weeks after drainage and formed a granuloma the size of a pea. It was later excised together with one of the fascial sutures under local anaesthesia with good results. One patient had a wound infection that required opening of the wound and delayed healing via granulation.

In group II there was 1 (2%) umbilical wound infection, which corresponds to the rates published by other authors [42]. Subanalysis of wound complications showed that although the complication rate in group I was 8%, which seemed much higher than 2% for group II, it was only true for the first subset of patients (n = 25 in each group). In the remaining half of study patients the frequencies of wound complications were equal (Table III). We think that this phenomenon was caused by the effect of the learning curve associated with the SILS technique, wound closure and recreation of the umbilicus. Most studies did not report on wound complications after SILS cholecystectomy [8, 10-15, 26, 27, 30, 43]. Just a few authors had no complications [29, 44, 45] and only Tacchino *et al.* reported a single case of periumbilical haematoma that was evacuated on the 7th postoperative day, which allowed for wound healing [28].

Nowadays, laparoscopic cholecystectomy is the gold standard in the treatment of gallbladder disorders. It is also one of the most frequently performed surgical procedures worldwide. Although it is a minimally invasive procedure, it leaves a few small scars on the abdominal surface. Single-incision laparoscopic surgery is a novel laparoscopic method that potentially allows for the removal of the gallbladder without leaving any new abdominal scars. Another benefit of this technique is the avoidance of typical complications of trocar sites such as trocar site hernias and trocar site bleeding into the abdominal cavity that frequently requires reoperation. Undoubtedly, SILS cholecystectomy is more difficult than the classic multiport procedure, which is reflected by longer operative times. This technique requires perfect team cooperation and dexterity in laparoscopic procedures. However, the constantly increasing number of publications on SILS procedures suggests that the SILS technique will gain wide acceptance soon and it will become a standard procedure especially in young patients with BMI up to 35 kg/m^2 with no active inflammation and no serious co-morbidities. We also hope that the interest and high activity of manufacturers of laparoscopic equipment will support the progress of surgery via a single incision in the umbilicus and eliminate difficulties encountered during the implementation of this technique.

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