CHAPTER

SINGLE-INCISION VERSUS CONVENTIONAL LAPAROSCOPIC CHOLECYSTECTOMY; A CASE CONTROL STUDY

P.B. van den Boezem, Ph.M. Kruyt, M.A. Cuesta, C. Sietses

ABSTRACT

Background
Single-incision laparoscopic surgery (SILS) is a minimally invasive technique, which can be used for treatment of gallbladder disease. To evaluate our initial experience, patients treated with SILS cholecystectomy were compared with a comparable group of patients treated with a conventional four trocart technique (LC).

Methods
Between May 2009 and April 2010, 60 SILS cholecystectomies were performed. These patients were matched by Body Mass Index (BMI) with 60 cases of conventional LC.

Results
The operative time was significantly longer in the SILS group 55 min (range, 25-126 min) compared to 49 min (range, 28-75 min) for the LC group. Excluding the first 15 SILS cases the operative time became comparable to the conventional technique, with a mean operative time of 51 min (range, 25-90 min). No patients were converted to open cholecystectomy. In the SILS group 3 patients developed a wound infection, in the conventional LC group 2.

Conclusion
SILS cholecystectomy seems to be a safe and feasible procedure when performed by an experienced laparoscopic surgeon. Complication rates are comparable to conventional LC. With a learning curve of around 10 to 15 procedures, operative times approach those of conventional LC.
INTRODUCTION
Currently laparoscopic techniques are the standard of care for most abdominal procedures. Patients benefit from the reduced surgical trauma and clinical advantages are well known. They include faster recovery, improved cosmesis and fewer wound related complications. Attempts to further minimize the impact of surgery stimulated the development of single-incision laparoscopic surgery (SILS). Using SILS, multiport laparoscopic procedures can be performed through one small incision, often hidden in the umbilicus. Various small series have demonstrated the feasibility of this technique for most laparoscopic procedures. Currently the only clear advantage is the cosmetic result.

The SILS technique was introduced in our clinic in May 2009. To evaluate our initial experience with SILS cholecystectomy we compared these data with a comparable group of patients who were treated with conventional laparoscopic cholecystectomy (LC).

Material and methods
Between May 2009 and April 2010, 60 patients were included for SILS cholecystectomy. Initially only patients with a body mass index (BMI) below 30 were selected, after experience increased all patients were included. All SILS procedures were performed by a single surgeon (CS). A comparative group of 60 patients, who underwent conventional LC during the same period, were selected with comparable BMI (table 1). All patients in this group were operated by 1 of three experienced and laparoscopically trained gastro-intestinal surgeons. The surgeon who performed all the SILS procedures is one of the three. All patients in this case control study underwent surgery for symptomatic cholelithiasis. Diagnosis of gallbladder stones was made by ultrasound and all patients were classified ASA grade I or II and had no prior abdominal surgery. No intraoperative cholangiography was performed in both groups. Operative time was calculated as “skin to skin”, i.e., from time of first incision to time of completion of skin closure. Patient demographic data as well as height, weight, BMI, operative time, length of hospital stay and peroperative complications were collected in our database. Informed consent was received from all patients. All patients were given the option to undergo either a SILS procedure or a standard multiport laparoscopic procedure. Approval of the local ethical committee was obtained before we started to perform the SILS procedure.

SILS Surgical technique
The patient is placed in the French position with the surgeon between the legs. The assistant is standing on the left side of the patient. After infiltrating the umbilicus with bupivacaine 0.25%, extra care was taken to clean and disinfect the umbilicus. The umbilicus is everted and opened longitudinally, after which the SILS port (Covidien, Mansfield, MA, USA) was introduced. Pneumoperitoneum is established and a 30° laparoscope is used to visualize the peritoneal cavity. The patient is positioned in a slightly anti-Trendelenburg position with some rotation to the left.

Two different techniques were used to retract and manipulate the gallbladder. Initially the technique described by Cuesta et al. was used. A Kirschner wire, introduced subcostally, is used to retracted
the gallbladder and visualize Callot’s triangle. Roticulator instruments (Roticulator Endograps 5mm, Roticulator Endo Dissect 5mm, AutoSuture) were used to visualize Callot’s triangle. Dissection of the cystic duct and artery were performed according to the critical view of safety rules. The cystic artery and duct were clipped using a 5mm Endoclip (Covidien, Mansfield, MA, USA).

After experience increased, the surgical technique was changed to a technique described by Paraskeva et al. Retraction and manipulation was achieved with Vicryl sutures as described in detail elsewhere. Normal straight laparoscopic instruments were used to dissect Callot’s triangle. In some patients the roticulator instruments were used for safe dissection.

In case no critical view of safety (CVS) could be reached additional trocars were introduced.

No antibiotic prophylaxes or wound protective measures were used. The umbilical fascia was closed using interrupted Vicryl (Ethicon, Cincinnati, Ohio, USA) sutures, the umbilicus was restored using Monocryl (Ethicon, Cincinnati, Ohio, USA) intracutaneous sutures.

Data were collected retrospectively. Statistical analysis was performed using SPSS version13.0 (SPSS, Chicago, Illinois, USA). Student’s t-test was used for continuous variables. $P < 0.050$ was considered statistically significant.

RESULTS

Patient characteristics are depicted in table 1. The two groups were comparable for age, gender and BMI. The operative time was significantly different between both groups in favor of the conventional LC group ($P = 0.0003$). The median operative time was 55 min (range, 25-126 min) for the SILS group and 49 min (range, 28-75 min) for the LC group. Excluding the first 15 SILS cases the operative time became comparable to the conventional technique, with a mean operative time of 51 min (range, 25-90 min).

<table>
<thead>
<tr>
<th>Table 1. Patient characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SILS</strong></td>
</tr>
<tr>
<td>Age (years) *</td>
</tr>
<tr>
<td>Sex ratio (F:M)</td>
</tr>
<tr>
<td>BMI*</td>
</tr>
</tbody>
</table>

* Values are median (range). BMI: body mass index. SILS: single incision laparoscopic surgery. LC: laparoscopic cholecystectomy.

No patients were converted to open cholecystectomy. In all operated patients critical view of safety (CVS) was reached. A total of 6 patients in the SILS group needed additional trocars to reach CVS. Three patients that needed additional trocars were among the first 15 patients who underwent SILS cholecystectomy.
Complications were comparable in both groups. In the SILS group 3 patients developed a wound infection compared to 2 in the LC group. One patient developed a minor postoperative bleeding which was treated conservatively. This patient was discharged after 2 days. All other patients were discharged on the first postoperative day. During a median follow up time of 25 months, one umbilical hernia was seen. The conventional group didn’t show a hernia with a median follow up time of 23 months.

DISCUSSION

Technical developments within the surgical field have reduced the surgical trauma, resulting in faster recovery, less complications and improved cosmetic results. SILS is the logical next step to further reduce surgical trauma. Although initially described in 1995, SILS cholecystectomy has developed rapidly in recent years. However, the introduction of SILS in the Netherlands is very slow due to questions about safety and possible increase of procedure related complications. The Dutch Endoscopic Association created guidelines for a safe introduction. Before SILS techniques could be introduced a SILS course should be followed and since it is a new technique every hospital should report to the local ethical committee. Due to these rules and concerns, the increased difficulty and costs of the procedure most Dutch surgeons are hesitant to introduce the SILS technique.

In this study we compare our initial experience with SILS cholecystectomy with patients operated during the same period with conventional laparoscopic cholecystectomy in order to address some of the abovementioned concerns.

One of the most important concerns was patient safety and fear for an increase in bile duct injuries, as seen after introduction of laparoscopic cholecystectomy 20 years ago. Concerns
about safety were brought forward by the expected increased complexity of the SILS technique. E.g., dissection with roticulator or bent instruments, crossing either inside or outside the patient and making it necessary to dissect with the non-dominant hand. In this series, the first 30 patients were operated with roticulator instruments crossing inside the patient. Dissection was performed with the left hand, while traction was given with the right hand. This is exactly opposite to conventional laparoscopy.

The additional costs of the roticulator instruments made us search for an alternative technique in which the available normal endoscopic instruments could be used. Paraskeva et al. described a technique in which sutures were used for retracting and manipulating the gallbladder10. Instead of bent instruments a suture is placed through Hartmann’s pouch and clips are placed on either side of the gallbladder. Dissection is performed with a straight instrument. Even though this technique is easier to learn the operative time remained comparable.

Critical view of safety, as described by Strasberg et al. was obtained in all cases13. However, in 6 patients additional trocars were needed for safe dissection. This is comparable with literature.10,13,15 Curcillo et al. reported a multi-institutional study of 297 patients and in 34 cases additional trocars were needed.15 Surgical principles for safe dissection should always be followed and additional trocars should be used if necessary. It is important therefore to notice that no procedure related complications were seen. The percentage of wound related complications, is comparable between SILS and conventional LC. To date, only one umbilical hernia was seen during a relatively short follow up (median 25 months).

Another important factor for the slow introduction is the perceived complexity of the procedure and the expected long learning curve. In our series the operative time declined rapidly to an average time comparable to conventional laparoscopic cholecystectomy. Operative times reported in literature are all relatively long, however, these are all from the introduction period of SILS. Tacchino et al. reported a short learning curve with average operative times stabilizing around 50 min16. More recently, Solomon et al. concluded that the learning curve for a trained laparoscopic surgeon is approximately 10 procedures17. Our results are similar, operative times stabilized to around 55 minutes after 10 to 15 procedures.

When evaluating our experience with SILS, we must address the additional costs brought forward by the new technique. Initially, we routinely used bend instruments, which are relatively expensive compared to conventional laparoscopic cholecystectomy (an additional 697 Euros on disposable instruments). In the current economic situation these additional costs can influence further implementation of this new technique, especially when the only apparent advantages are cosmetic result and patient satisfaction. After changing to the suture technique as described by Paraskeva et al. the additional costs were only 251 euro10.

The current study was not intended to demonstrate superiority of either technique, but rather as a feasibility study to demonstrate that SILS cholecystectomy is a safe procedure with results that are comparable to conventional laparoscopic cholecystectomy. It should be noted,
however, that this was a selected group of patients with low risks and low BMI. Whether SILS techniques are really less traumatic remains to be demonstrated, as well as possible clinical advantages. Until now the only perceived benefit is the cosmetic outcome. The first randomized clinical trial comparing single-incision laparoscopic cholecystectomy with mini laparoscopic cholecystectomy has recently been reported. The single-incision technique was found to be superior in terms of cosmetic outcome, but not in postoperative pain. This trial included 70 patients with a mean operative time of more than 70 minutes. Additional, larger randomized trials are needed to determine the potential benefits of the SILS cholecystectomy.

CONCLUSION

SILS cholecystectomy seems to be a safe and feasible procedure when performed by an experienced laparoscopic surgeon. Complication rates are comparable to conventional laparoscopic cholecystectomy. With a learning curve of around 10 to 15 procedures, operative times approach those of conventional laparoscopic cholecystectomy.
REFERENCES


