

Single-access transumbilical laparoscopic appendectomy and cholecystectomy using new curved reusable instruments: a pilot feasibility study

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Abstract

Background The umbilicus can be considered as the embryological opening for single-access laparoscopic procedures. We report on single-access transumbilical laparoscopic appendectomy (SATLA) and cholecystectomy (SATLC), performed using new curved reusable instruments.

Patients and methods A retrospective review of a prospectively maintained database of 30 patients who underwent SATLA and 20 patients who underwent SATLC between May and November 2009 was undertaken. All procedures were performed with an 11-mm nondisposable trocar for the scope, and curved reusable instruments (Karl Storz—Endoskope, Tuttlingen, Germany) placed transumbilically without trocars. Outcome measures were conversion to standard laparoscopy, operative time, scar length, complications, hospital stay, and use of pain medication.

Results All SATLA patients had acute appendicitis, and SATLC patients had symptomatic gallstones (15), chronic cholecystitis (3), and acute cholecystitis (2). No extraumbilical trocars were necessary. Mean total operative times were 57.3 ± 15.9 min (SATLA) and 73.9 ± 20.1 min (SATLC). Mean laparoscopic times were 39 ± 13.1 min (SATLA) and 57.5 ± 18.9 min (SATLC). Mean scar lengths were 14.8 ± 2.2 mm (SATLA) and 15.8 ± 2.3 mm (SATLC). Five SATLA patients and one SATLC patient

developed postoperative complications. Mean hospital stay was 2.9 ± 1.3 days for SATLA patients and 1.8 ± 0.8 days for SATLC patients. Pain medication used was minimal. At the minimum follow-up of 3 months no late complications were registered.

Conclusions SATLA and SATLC can be performed safely using curved reusable instruments, which helps avoid the conflict between the surgeon's hands or between the instruments' tips and allows the surgeon to operate in an ergonomic position. The reusable instruments kept the cost similar to that of classic laparoscopy.

Keywords Single port · Single incision · Single access · Appendectomy · Cholecystectomy · Laparoscopy

With the advent of Natural Orifice Transluminal Endoscopic Surgery (NOTES), presently there is a strong development in laparoscopic surgery to avoid or reduce the number of the abdominal incisions. A bridge between NOTES and standard laparoscopy could be the option to perform the laparoscopic procedures through a single access. The umbilicus is a well-healing site for access to the peritoneal cavity. Moreover, the use of the umbilicus for accessing the peritoneum does not incur the problem of opening and closing viscera (stomach, vagina, colon) which is involved with NOTES procedures [1].

The first description of appendectomy by single-access laparoscopy (SAL) was reported by Kala et al. [2] in 1996, and of cholecystectomy by Navarra et al. [3] in 1997. Recently, this minimally invasive approach has received widespread interest and triggered the development of new laparoscopic instruments and different transabdominal port devices permitting realization of laparoscopic procedures through a single-access [4].

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One of the rules of laparoscopy is the alignment of the monitor, the operative field, and the surgeon's head [5]. Another rule is to keep the surgeon's two effectors at a right angle, with the optical system the bisector of this angle [6]. Hence, our objective was to participate in the development of new instruments that would allow the application of the latter rule in SAL. The classic straight laparoscopic instruments inserted through the same opening (e.g., umbilicus) do not allow this theorem (Fig. 1A). If the instruments' shafts are curved where they are outside of the access (Fig. 1B), the conflict between the surgeon's hands can be avoided. Adding curves to the area of the shaft that is inside the access (Fig. 1C) could permit a similar working triangulation closed to the viscera, avoiding the conflict between the instruments' tips and the scope. Accordingly, no additional trocars are needed to be inserted inside the abdomen to perform SAL. Another advantage of SAL realized with curved instruments is that the surgeon is able to work in a convenient ergonomic position with the arms flexed, similar to standard laparoscopy, because the handles can be kept at the distance of the scope.

The technique of single-access transumbilical laparoscopic appendectomy (SATLA) and cholecystectomy (SATLC) using new curved reusable instruments is described. The preliminary results of these procedures on the 30 patients who underwent SATLA and the 20 patients who underwent SATLC show that these procedures with the new instruments are feasible and safe.

Patients and methods

From May to November 2009, 30 patients (SATLA) and 20 patients (SATLC) were prospectively followed up after undergoing surgery. Informed consent was obtained from all patients. Data were collected prospectively in a dedicated database and reviewed retrospectively.

The purpose of our analysis was to get a preliminary assessment of the feasibility and safety of the procedure with new curved instruments. Our goal was to describe the

outcomes, and we used summary parameters to describe the distribution of continuous variables (mean for locating the distributions and standard deviation to report on their dispersion). The categorical variables were reported using frequency tabulations.

Outcome measures were conversion to standard laparoscopy, total and laparoscopic operative times, estimated blood loss, perioperative complications, umbilical scar length, postoperative complications, hospital stay, and use of pain medication. Total operative time was the time between skin incision and fascia closure. Laparoscopic time was the time between the beginning of pneumoperitoneum and the removal of the instruments and trocar. During SATLA, 2 g amoxicillin was given i.v. to all patients perioperatively and to selected patients postoperatively. During SATLC, 2 g cefazoline was administered i.v. to all patients perioperatively.

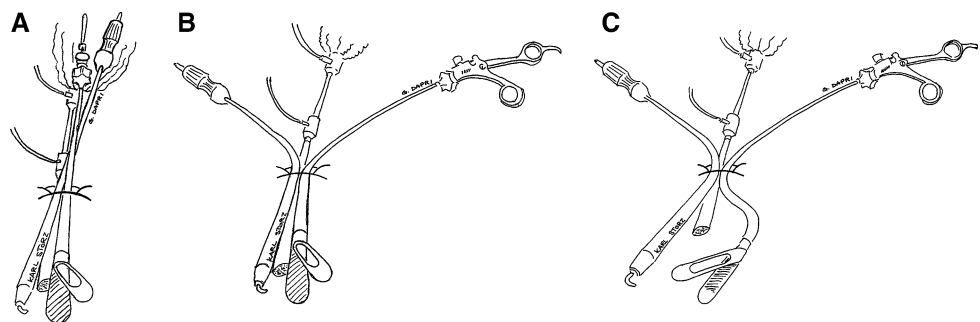
One gram paracetamol was given intravenously to all patients at the end of the surgical procedure. Postoperative analgesia was given following the WHO visual analog pain scale (VAS). In the recovery room the following scheme was followed: for VAS between 1 and 3, 1 g paracetamol i.v. was pushed; for VAS between 4 and 8, 100 mg tramadol i.v. was used; for VAS greater than 8, 1 mg piritamide i.v. was incremented. After the patient left the recovery room, pain was assessed every 6 h, with 1 g paracetamol administered i.v. if VAS was between 1 and 3, and 100 mg tramadol administered i.v. if VAS was between 4 and 8. Upon discharge, 1 g paracetamol perorally or 50 mg tramadol perorally were prescribed only if needed. Office visits were scheduled for 10 days and 1 and 3 months after the procedure.

Surgical technique

SATLA

General anesthesia was induced i.v. with 0.2 $\mu\text{g}/\text{kg}$ sufentanyl, 2 mg/kg propofol, and 0.6 mg/kg rocuronium. After tracheal intubation, anesthesia was maintained with 5–6%

Fig. 1 The concept of the curved instruments is based on the creation of the working triangulation both outside and inside the abdominal cavity



desflurane. In case of crush induction, 2 mg/kg etomidate and 1 mg/kg succinylcholine were used i.v., and after the intubation a 0.2 µg/kg sufentanyl and 0.1 mg/kg rocuronium were administered. The patient was placed in a supine position with the arms along side the body and the legs straight. The surgeon stood to the patient's left, in front of the umbilicus, and the camera assistant to the surgeon's right. The video monitor was placed in front of the surgeon. The umbilicus was incised, and using the Hasson technique the peritoneal cavity was entered. A purse-string suture using 1 polydioxane (PDS) was placed in the umbilical fascia at 2, 4, 6, 8, 10, 12 o'clock positions, and after the introduction of a nondisposable 11-mm trocar into the abdomen, pneumoperitoneum was established. A 10-mm, 30° angled, nonflexible, standard-length scope (Karl Storz—Endoskope, Tuttlingen, Germany) was used. Curved reusable instruments (Karl Storz—Endoskope, Tuttlingen, Germany) were inserted into the abdomen through the umbilicus without trocars. The curved grasping forceps I (Fig. 2A) was advanced through a separate opening, 5 mm outside the purse-string suture at 8 o'clock through the umbilical fascia. Other instruments such as the curved coagulating hook (Fig. 2B), curved scissors (Fig. 2C), curved suction device, and straight 5-mm endoloop device (Ethicon, Johnson & Johnson, Cincinnati, OH, USA) were introduced on the other side of the grasper, alongside the 11-mm trocar and inside the purse-string suture (Fig. 3). The suture was adjusted to maintain a tight seal around the 5-mm tools and the 11-mm trocar, and opened only when necessary. The abdominal cavity was checked for presence of free fluid and if found a bacteriological sample was obtained. The appendix was exposed using the curved grasping forceps I and the mesentery was controlled by the curved coagulating hook, from extremity to base. Because of the curves of the instruments there was no conflict between the instruments' tips inside the abdomen (Fig. 4A), or between the surgeon's hands outside the abdomen (Fig. 4B). Hence, SATLA appeared to be performed as standard laparoscopy. Two preformed knots (endoloops) were placed at the base of the appendix, which was sectioned between them. The appendix was placed into a plastic bag, inserted through the 11-mm trocar, and removed by a straight grasping forceps transumbilically. The umbilical fascia, including the separate opening for the grasper, was closed using absorbable sutures.

SATLC

The same general anesthesia used for SATLA was used for SATLC. The patient was placed in a supine position, with the arms along side the body and the legs abducted. The surgeon stood between the patient's legs, and the camera assistant to the patient's left. The video monitor was placed in front of the surgeon. The umbilicus was incised, and

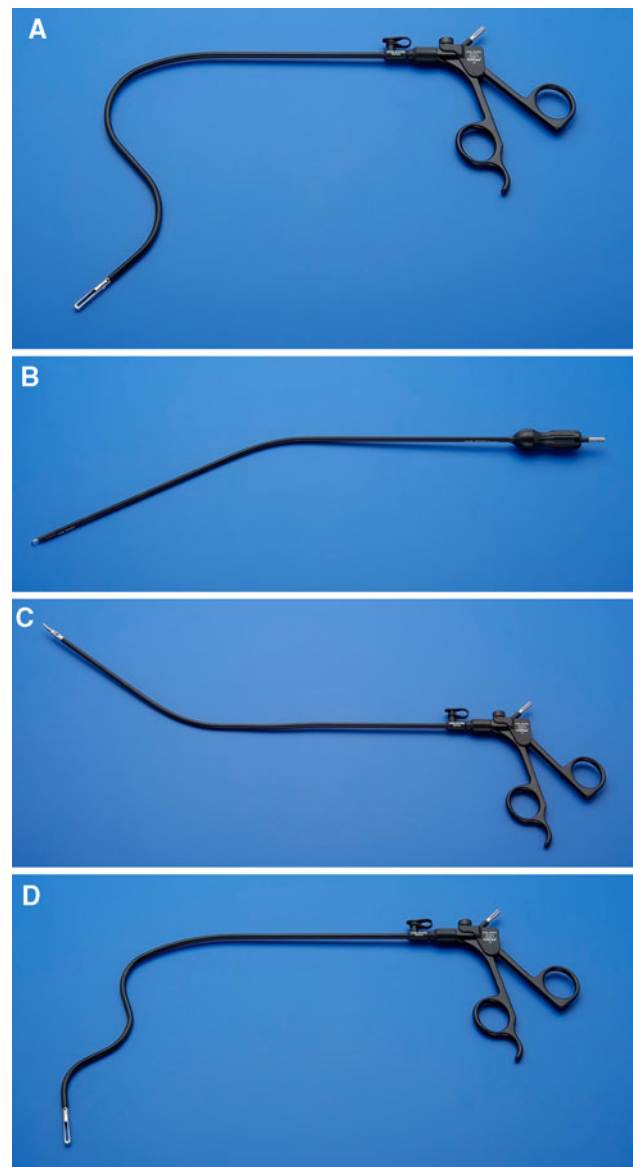


Fig. 2 Curved reusable instruments according to DAPRI: **A** grasping forceps I, **B** coagulating hook, **C** scissors, **D** grasping forceps II (courtesy of Karl Storz—Endoskope, Tuttlingen, Germany)

using the Hasson technique the peritoneal cavity was entered. A purse-string suture of 1 PDS was placed in the umbilical fascia at 2, 4, 6, 8, 10, 12 o'clock positions, and after introduction of a nondisposable 11-mm trocar into the abdomen, pneumoperitoneum was established. A 10-mm, 30° angled, nonflexible, standard-length scope was used. Curved reusable instruments were inserted into the abdomen through the umbilicus without trocars. The curved grasping forceps II (Fig. 2D) was inserted through a separate opening, 5 mm outside the purse-string suture at 10 o'clock through the umbilical fascia. Other instruments such as the curved coagulating hook (Fig. 2B), curved scissors (Fig. 2C), curved suction device, and straight

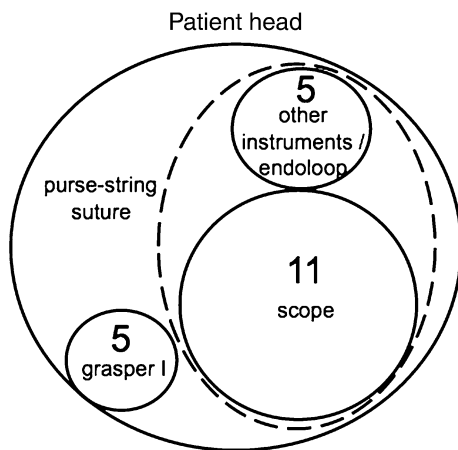


Fig. 3 SATLA: placement of the instruments, scope, and purse-string suture through the umbilicus

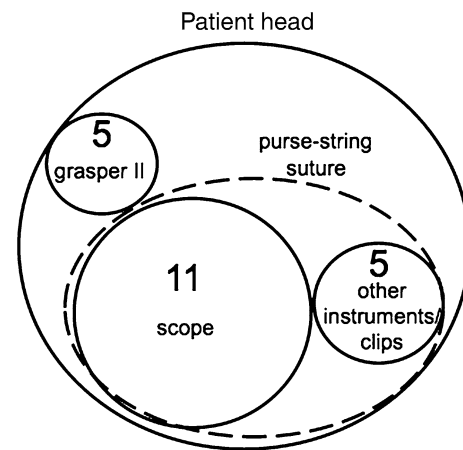


Fig. 5 SATLC: placement of the instruments, scope, and purse-string suture through the umbilicus

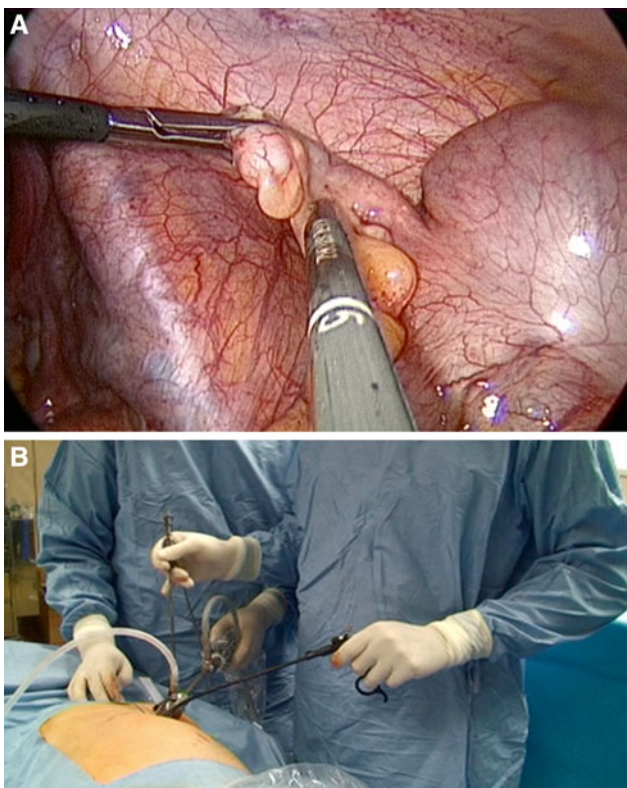


Fig. 4 SATLC: **A** absence of the conflict between the instruments' tips inside the abdomen and **B** between the surgeon's hands outside the abdomen

5-mm clip applicator (Weck Hem-o-lok, Teleflex Medical, Belgium) were introduced on the other side of the grasper, alongside the 11-mm trocar and inside the purse-string suture (Fig. 5). The suture was adjusted to maintain a tight seal around the 5-mm tools and the 11-mm trocar, and opened only when necessary. The gallbladder was retracted using the curved grasping forceps II. Because of the curves

of the instruments, the scope never appeared to conflict with the instruments' tips (Fig. 6A), and conflict between the surgeon's hands was avoided (Fig. 6B). Different tractions of the gallbladder permitted the exposure of Calot's triangle and the isolation of the cystic duct and artery. The cystic artery was coagulated or sectioned between clips, and the cystic duct was sectioned between clips as per routine. However, when good exposure of the operative field could not be achieved or complications like bleeding occurred, a millimetric wire (Veress needle) was placed under the right costal margin. The gallbladder was freed from the liver and placed in a plastic bag that was inserted into the abdomen through the 11-mm trocar. The gallbladder was removed transumbilically by a straight grasping forceps, and absorbable sutures closed the umbilical fascia, including the separate opening for the grasper.

Results

Between May and November 2009, 30 patients (19 males, 11 females) underwent SATLA and 20 patients (5 males, 15 females) underwent SATLC. Mean age was 31.5 ± 13.3 years (16–76) for SATLA patients and 39.8 ± 13.4 years (17–62) for SATLC patients. Mean body mass index was 24.1 ± 3.1 kg/m² (18–31.6) for SATLA patients and 26.7 ± 4.6 kg/m² (18.3–34.5) for SATLC patients (Table 1). All patients who underwent SATLA had acute appendicitis, and the patients who underwent SATLC had symptomatic gallstones (15), chronic cholecystitis (3), and acute cholecystitis (2). Four SATLA patients (2 caesarean sections, 1 total extraperitoneal inguinal hernia repair, and 1 urethral repair) and five SATLC patients (2 appendectomies, 2 caesarean sections,

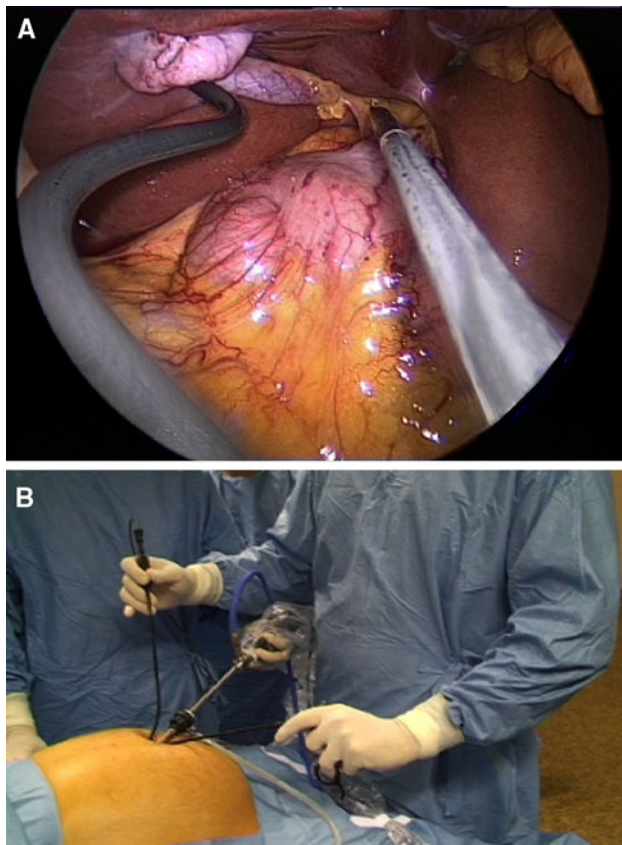


Fig. 6 SATLC: **A** the scope is not in conflict with the instruments' tips and **B** the conflict between the surgeon's hands is avoided

and 1 extrauterine pregnancy) had previously had abdominal surgery. Five SATLC patients had a previous endoscopic sphincterotomy.

No conversion to standard laparoscopy with an extraumbilical trocar was necessary. Mean total operative time for SATLA was 57.3 ± 15.9 min (31–100) and for SATLC it was 73.9 ± 20.1 min (35–110). Mean laparoscopic time was 39 ± 13.1 min (18–72) for SATLA and 57.5 ± 18.9 min (24–100) for SATLC. Mean estimated blood loss was 15 ± 32.5 ml (0–150) for SATLA and 35.7 ± 64.9 ml (0–300) for SATLC. Three patients of SATLA had perioperative bleeding from the mesentery, which was controlled perioperatively by electrocautery, but no hemotransfusion or reoperation was necessary postoperatively. In the SATLC group, four patients had a gallbladder perforation, two patients had bleeding from the cystic artery, and three patients a bleeding from the liver. There were no common bile duct injuries, bile leaks, or reoperations needed in this group. A millimetric wire (Veress needle) was inserted under the right costal margin in seven SATLC patients (35%) to improve exposure of Calot's triangle and in another one (5%) to control bleeding. Perioperatively, three SATLA patients benefited of a combined procedure (ovarian cystectomy, treatment of stage 1 pelvic endometriosis, and small bowel

adhesiolysis). Mean umbilicus scar length was 14.8 ± 2.2 mm (10–20) for SATLA and 15.8 ± 2.3 mm (12–24) for SATLC.

During the hospital stay, two SATLA patients (6.6%) developed postoperative ileus. The mean length of stay was 2.9 ± 1.3 days (2–8) for SATLA patients and 1.8 ± 0.8 days (1–4) for SATLC patients (Table 1).

In the SATLA group, a VAS between 4 and 8, requiring tramadol administered i.v., was recorded for the first 6, 12, 18, and 24 h in 11, 9, 7, and 7 patients, respectively. During the following 48 h, the same VAS was registered in 4, 3, 2, and 1 patient, respectively. Similarly, in the SATLC group, a VAS between 4 and 8, requiring tramadol administered i.v., was recorded for the first 6, 12, 18, and 24 h in 9, 6, 7, and 6 patients, respectively, and in the following 48 h in 1, 2, 3, and 0 patients, respectively. In both groups, upon discharge use of only paracetamol perorally was registered and it was stopped no later than 3 days after discharge.

All patients were followed up for a minimum of 3 months. At 8 days postoperatively, it was found that one SATLA patient (3.3%) had developed a mesenteric hematoma, necessitating rehospitalization for CT-scan guided drainage. At 10 days after discharge (first office visit), one SATLC patient (5%) had developed an umbilical abscess. Within the first month, two SATLA patients (6.6%) developed an umbilical abscess. No other complications were recorded in either group after the first and the third month postoperatively.

Discussion

SAL can be performed using standard straight instruments [7, 8], but working difficulties such as jamming because of

Table 1 Patients' characteristics and outcome measures

	SATLA	SATLC
Characteristics		
Gender (m/f)	19/11	5/15
Age (years)	31.5 ± 13.3	39.8 ± 13.4
Body mass index (kg/m ²)	24.1 ± 3.1	26.7 ± 4.6
Outcome measures		
Conversion rate (%)	0	0
Total operative time (min)	57.3 ± 15.9	73.9 ± 20.1
Laparoscopic time (min)	39 ± 13.1	57.5 ± 18.9
Blood loss (ml)	15 ± 32.5	35.7 ± 64.9
Peroperative complications (n)	3	9
Scar length (mm)	14.8 ± 2.2	15.8 ± 2.3
Postoperative complications (n)	5	1
Hospital stay (days)	2.9 ± 1.3	1.8 ± 0.8

Values are mean \pm SD

parallel directions and overall absence of working triangulation spurred the research and development of new instruments. Some companies such as Novare Surgical Systems, Inc. (Cupertino, CA, USA) and CambridgeEndo (Framingham, MA, USA) worked on the production of articulating instruments, which have flexible handles and flexible tips. Such instruments allow the surgeon to move the handles in specific directions, with corresponding movement of the instruments' tips. Thanks to this flexibility, the problem of working with parallel instruments can be avoided and an operative field similar to that obtained with standard laparoscopy could be created. Another option is to make the tip of the instrument articulate, as in the tools from Covidien, Inc. (Norwalk, CT, USA). However, both the latter and the former instruments have the disadvantage in that the surgeon needs to cross hands in order to obtain the correct working angle. Furthermore, these instruments are disposable, which consequently increases the cost of each SAL.

The idea of maintaining one of the rules of classic laparoscopy in SAL led us to develop the curved instruments discussed here in order to establish the working triangulation, both inside and outside of the abdominal cavity. Thanks to the absence of articulations, these curved instruments are reusable, and because only one non disposable trocar is used (introduction of the scope), disposable ports for SAL are not needed. Hence the cost of SAL is maintained similar to that of classic laparoscopy.

The curved instruments have to be inserted in different ways through the umbilicus. The reason for placing the grasper through a separate opening in the umbilical fascia is because this tool is held on the surgeon's nondominant hand (left) and is never changed during the procedure. The instruments held in the surgeon's dominant hand (right) change during the different steps of the operation, hence they're introduced alongside the 11-mm trocar and inside the purse-string suture. The purse-string is adjusted to maintain a tight seal during the procedure, avoiding loss of pneumoperitoneum, and is opened when the smoke created by the cautery has to be evacuated or when the instruments have to be changed.

The introduction of the curved instruments in the abdomen is realized following the shaft's curve, forming a 45° angle with the abdominal wall plane. In our experience no contact with the greater omentum or small bowel was registered during the introduction of the instruments into the cavity.

The grasping forceps I has the first angulation at the level of the umbilicus and the second near the instrument tip. The first curve avoids the conflict of the nondominant surgeon's hand with the scope, and the second curve allows triangulation with the other curved instruments inside the abdomen. The curved hook and curved scissors have just

one curve at the entrance in the abdomen, avoiding the external conflict between the surgeon's hand and the camera assistant's hand. The grasping forceps II has two additional curves besides the main curve at the umbilicus. One curve avoids the conflict with the scope inside the abdomen, and the other permits traction of the gallbladder at both the infundibulum and the fundus. At the beginning of the learning curve, the grasping forceps must be inserted and manipulated using both surgeon's hands in order to maintain a stability and safety of the movements.

We agree with other authors [9, 10] that patient selection at the beginning of the learning curve is important to avoid conversion to standard laparoscopy and to reduce operative time. Operative time is obviously dependent on the surgeon's learning curve [11, 12]. Tacchino et al. [13] reported a reduction in operating time for cholecystectomy from 3 h to approximately 50 min after the first five cases. This experience was also confirmed by Rivas et al. [14], where a drop in operative time from 73 to 45.1 min was achieved after the first 50 patients. During SATLA, we recorded a mean total operative time of 57.3 min, which is in the range of 20–87.5 min reported in the literature [12, 15–23]. Our SATLA total operative time appears high compared to that of other authors [15–17, 21], but in our technique the resection of the appendix is completely performed laparoscopically and not outside the umbilicus as reported. Furthermore, our data include the time to gain access to the abdomen and to close the umbilical fascia, which required a supplementary mean time of 18.3 min (difference between total and laparoscopic time). Total operative time can also be increased by combining procedures, as was the case in three of our SATLA patients, who had an ovarian cystectomy, treatment of stage 1 pelvic endometriosis, and small bowel adhesiolysis. During SATLC, we achieved a total operative time similar to that reported in the literature, ranging between 30 and 143 min [3, 8, 9, 12–14, 18, 24–30].

Despite perioperative bleeding that occurred in three SATLA patients and in five SATLC patients, we recorded negligible blood loss during SATLA, which is in accordance with the results of other authors during SATLC [14, 24, 27, 30]. Obviously, complicated situations will mean more bleeding or the necessity to place another trocar [27]. In four SATLC patients, the gallbladder was accidentally perforated while freeing it from the liver. This complication is not rare during cholecystectomy [9] and can be treated by simple lavage of the cavity and placement of the specimen in a plastic bag for wound protection during extraction.

SAL does bring up some questions. During SATLA, drains can be necessary in case of peritonitis, complicated appendicitis with appendiceal abscess, cecum perforation, and placement of trocars can be needed with retrocecal

appendix position or pregnant patients. Hong et al. [20] reported the need to convert to a conventional three-port appendectomy because of gangrene at the base of the appendix in 1 of 33 patients (3%), and the need to place a drain in another patient. Chouillard et al. [21] reported 13 patients (23.6%) converted to conventional laparoscopy because of difficulties exposing a complicated appendicitis. D'Alessio et al. [17] reported inserting an additional trocar in 6 of 150 patients treated (4%), and two additional trocars in other 22 patients (14.6%). Hence, placement of a second port during SATLA can always be contemplated, with an incidence reported in literature between 3.7 and 18.7% [16, 17, 19, 23, 31]. SATLC raises in own questions. The problem of the operative field exposure, overall of Calot's triangle, is a frequent aspect of conversion. Bresadola et al. [8] converted 7 of 28 patients (25%) during SATLC because of poor hilum exposure. One of the possible solutions is the use of suture traction, passed through the fundus or the infundibulum of the gallbladder [3, 8, 14, 27, 32, 33], but bile leakage due to the traction can be cumbersome. Another solution is to place a millimetric wire under the right costal margin which requires a second small skin incision [24, 26]. Eight of our SATLC patients needed to have a millimetric wire inserted, in 7 patients (35%) to gain better exposure of Calot's triangle and in 1 patient (5%) to control operative bleeding. We believe that in the noninflamed gallbladder, unlike cholecystitis, the floppiness of the wall impairs exposure of the elements of the hilum. The need for additional help in exposing the hilum is reported to be between 6.8 and 41.1% [24, 27]. Another option for better exposure is the use of intra-abdominal anchors applied at one end of the fundus of the gallbladder and at the opposite side to the parietal peritoneal sheet [33]. Anchors can also be maneuvered by external handheld magnets [34, 35]. The presence of adhesions between the gallbladder and the greater omentum or the duodenal stump or the transverse colon is often another cause of placing one or more additional ports [8]. It has been reported that intraoperative cholangiography is feasible by SAL [3, 8, 25, 28], but exploration of the common bile duct sometimes seems too tedious with this approach and requires insertion of an additional port [24].

In both of our groups the umbilical scar did not exceed 16 mm in length, except in one SATLA case (20 mm) and one SATLC case (24 mm). The latter was related to the presence of a 4-cm stone. Our scar length seems quite similar to those from standard laparoscopy and actually compares favorably with the 22 mm scar length reported in literature for SATLA [23].

Laparoscopic procedures performed through single umbilical access can have some umbilical complications

such as abscess, hematoma, and wound seroma [28]. During the hospital stay, in this small series of patients we encountered two SATLA patients with postoperative ileus, as reported in literature during SATLC [28]. Treatment was conservative and patients were discharged on the sixth and eighth postoperative day, respectively. At the first office consultation (10 days after discharge), one SATLC patient developed an umbilical abscess, retrospectively related to the perioperative contamination of the umbilical scar during the stone extraction. In the SATLA group, one patient presented with a mesenteric hematoma, probably related to perioperative bleeding, which was CT-scan drained. Within the first month, two SATLA patients developed an umbilical abscess.

Length of hospital stay for our series of SATLA patients was similar to that reported in literature [15, 16, 19–23, 36]. Martinez et al. [36] reported a significantly different length of hospital stay between SATLA and open appendectomy of 2.84 and 4.83 days, respectively. The hospital stay in our SATLC patients was similar to that reported in literature as well [3, 9, 25, 27, 28, 30] which did not differ from standard laparoscopic cholecystectomy.

For postoperative pain, we treated our patients with minimal pain therapy. Martinez et al. [36] reported a reduction of postoperative pain and less need for analgesia therapy after SATLA as compared to open appendectomy. Also after SATLC two randomized trial between single-access cholecystectomy and standard cholecystectomy showed a statistically significant reduction in VAS value and mean dose of analgesic therapy in favor of SATLC [8, 30]. Larger series of patients enrolled in randomized trials comparing SAL and standard laparoscopy will confirm this latter outcome measure.

Conclusions

SATLA and SATLC can be performed safely using curved reusable instruments. The curved shape deals with both the conflict between the surgeon's hands outside the abdomen and that between the instruments' tips inside the abdomen. The curves enable surgeon to operate in an ergonomic position quite similar to classic laparoscopy. Thanks to this approach, the umbilical scar length and the use of pain medication were kept to a minimum and there was no additional cost for disposable materials.

Disclosures Giovanni Dapri is a consultant for Karl Storz—Endoskope (Tuttlingen, Germany). Lorenzo Casali, Hélène Dumont, Laurens Van der Goot, Leila Herrandou, Els Pastijn, Maurice Sosnowski, Jacques Himpens, and Guy-Bernard Cadière have no conflicts of interest or financial ties to disclose.

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