

Single-port-access (SPA™) cholecystectomy: a multi-institutional report of the first 297 cases

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Abstract

Background An important aspect of a new surgical technique is whether it can be performed by other surgeons in other institutions. The authors report the first 297 cases in a multi-institutional and multinational review of laparoscopic cholecystectomy performed via a single portal of entry.

Methods Data were collected retrospectively for the initial patients undergoing single-port cholecystectomy by 13 surgeons who performed these procedures in their institutions after training by the authors. The review included operative time, blood loss, incision length, length of

hospital stay (LOS), necessary additional trocars, and other parameters important to cholecystectomy. A database of all the single-port-access (SPA) surgeries performed by the surgeons included demographic and procedural details, LOS, complications, and initial follow-up data.

Results To date, 297 single-port cholecystectomies have been performed for a variety of diagnoses, primarily cholelithiasis. The average operative time was 71 min, and the average LOS was 1–2 days. The average blood loss was minimal. The use of additional port sites outside the umbilicus occurred in 34 of the cases. Of the 35 intraoperative cholangiograms performed, 34 were successful. No significant complications occurred except for seromas and minor postoperative wound infections. These results are comparable with those for standard multiport cholecystectomy. In addition, no access site hernias (ASH) occurred.

SPA™ is a Trademark of Drexel University College of Medicine.

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Conclusions The findings demonstrate that SPA surgery is an alternative to multiport laparoscopy with fewer scars and better cosmesis. One factor affecting the rate for adoption of SPA surgery among other surgeons is the reproducibility of this new procedure. Although this study had insufficient data to determine fully the benefits of SPA surgery, the feasibility of this procedure with safe, acceptable results was demonstrated in this initial large series across multinational institutions.

Keywords Cholecystectomy · Laparoscopic cholecystectomy · Multi-institutional · Reduced-port surgery · Single-port access · SPA cholecystectomy · Single incision laparoscopic cholecystectomy

At the beginning of the last century, laparoscopic surgery was introduced by Dimitri Ott, Georg Kelling, and Hans Christian Jacobaeus. Erich Muhe performed the first minimally invasive cholecystectomy in 1985, paving the way for the advancement of laparoscopy within the field of general surgery [1]. Standardization of the technique, enabling its reproducibility in all types of medical facilities and centers, has resulted in laparoscopic cholecystectomy becoming the gold standard for the treatment of gallbladder disease throughout the world. We have observed faster recovery times, improved cosmetic results, and reduced postoperative pain with this approach [2].

The past 15 years have seen an increased interest in the performance of laparoscopic surgery with fewer incisions and trocars. In 1995, surgeons from France successfully performed 715 laparoscopic cholecystectomies with three trocars [3], and in 1997, Navarra et al. [4] performed a one-wound laparoscopic cholecystectomy with transabdominal sutures. Then in 2001, 70 laparoscopic cholecystectomies were performed with two trocars [5].

In 2004, Kalloo et al. [6] performed the first natural orifice transluminal endoscopic surgery (NOTES). In NOTES, natural orifices serve as the entry point to the abdomen (i.e., intraabdominal organs are accessed by passing an endoscope into the peritoneal space via a transvaginal or transgastric approach) [2].

In 2005, studies demonstrated successful transgastric cholecystectomies in pigs [7]. To date, however, no dominant technique has been developed, so the practice of reduced-port surgery has not become prevalent.

In April 2007, using a novel approach, laparoscopic cholecystectomy was performed successfully through a single portal of entry [8]. Since its inception, single-port-access (SPA) surgery has been applied to a number of minimal access surgical procedures using the umbilicus as the only portal of entry [9]. However, we maintain that for

a new surgical approach to be universally beneficial and ultimately applied by many surgeons to large series of patients, it must be easily learned and reproducible.

Since September 2007, our institution has provided training for surgical colleagues interested in SPA techniques with a specific focus on SPA cholecystectomy. A day-long training course has been offered, consisting of lectures and practice with the access technique, concluding with discussion. In conjunction with the Drexel University College of Medicine, University Laboratory Animal Resources (ULAR), we have established and provided a novel training symposium at Drexel University College of Medicine, teaching the techniques of SPA surgery in a porcine model. This method has been validated as an acceptable method for learning the skills of a new technique before its adequate and safe application in actual patient cases [10].

After one full year of training programs with follow-up data from fellow surgical colleagues, we report the outcomes of the first 297 SPA cholecystectomies in a multi-institutional and multinational review examining the first 2 years of the technique's practice.

Methods

We retrospectively collected, under institutional review board approval, data on the initial patients undergoing SPA cholecystectomies by 13 surgeons who have begun to perform this new technique. All the surgeons were board-certified general surgeons who work at academic university hospitals, community hospitals, or medical centers, nationally and internationally. Some of these surgeons have had additional fellowship training in laparoscopy, and all have attended an SPA training lecture or symposium. These surgeons became proficient and comfortable enough with this technique to incorporate it into their clinical surgical practice and thus were some of the first to adopt this new procedure and philosophy. We have recorded the SPA cholecystectomies they have performed in a common database. All data were self-reported by the surgeon or resident surgeon participating in each respective case.

A standard data collection spreadsheet was used by all the surgeons. The preoperative information collected included basic patient characteristics such as sex, age, and preoperative diagnosis. The intraoperative information included the procedure performed, operative time, estimated blood loss, and details of the SPA technique such as length of incision, additional trocars, and instruments used. The postoperative information included the final postoperative diagnosis, hospital length of stay (LOS), complications, and outpatient follow-up evaluation.

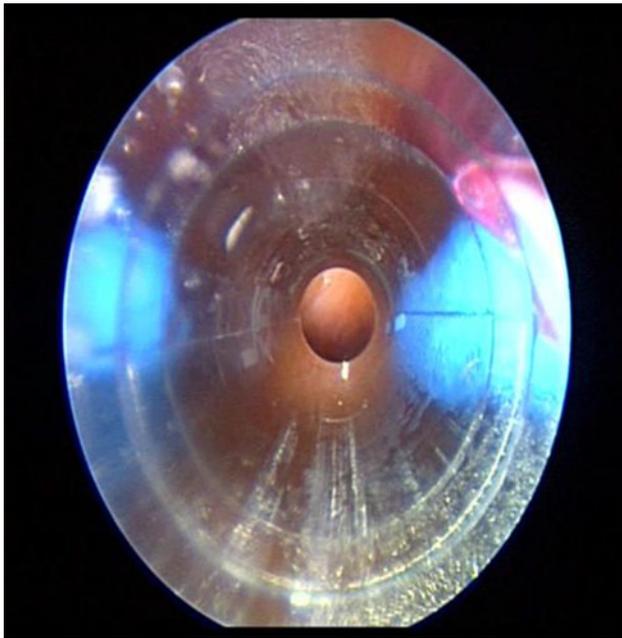


Fig. 1 Camera port visualizing entry of lateral trocars (*lateral*)

Surgical technique

Single-port-access cholecystectomy is performed through a single umbilical incision within the umbilicus measuring 14–20 mm in length [11]. An initial clear 5-mm trocar is inserted via open technique through an umbilical incision followed by insufflation of the abdominal cavity with carbon dioxide. Skin and soft tissue flaps are raised off the fascia through blunt dissection lateral to the initial trocar in both directions for approximately 2 cm within the same skin incision. A 5-mm 30° laparoscope then is inserted into the initial trocar and angled to the right and left of the trocar to enable visualization for insertion of two very-low-profile 5-mm trocars positioned 0.5–2 cm lateral and superior to the central trocar (Figs. 1 and 2). This arrangement allows each instrument independence of movement during the dissection [9] (Fig. 3). An optional additional fascial incision is made 5 mm inferior to the initial trocar to allow insertion of a single grasping instrument without a trocar to obtain fundal retraction, enabling performance of a three-instrument procedure (Fig. 4). This technique ensures fundal retraction above the liver toward the right shoulder.

An additional alternative is Navarra's technique of transabdominal suture retraction [4]. With this technique, the camera is placed through the central trocar, and the lateral trocars are used for the two dissecting instruments, clip applier, and electrocautery dissection instrument. Although rigid instrumentation generally is used, articulating instrumentation usually is available to the surgeons. The gallbladder is dissected in the standard fashion for a multiport

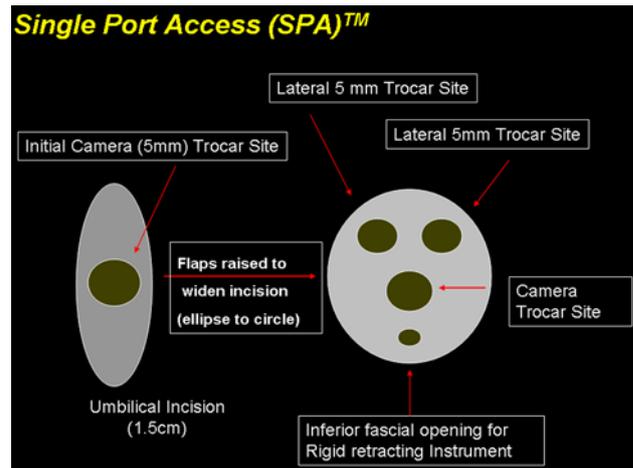


Fig. 2 Schematic of the single-port-access technique (incision and placement of trocars)



Fig. 3 External view of the placement of trocars

cholecystectomy, and gallbladder retrieval is through the umbilical incision.

Results

To date, 297 SPA cholecystectomies (for 240 women and 57 men) have been performed by the 13 surgeons mentioned above. The average patient age was 46 years (range, 16–87 years). Of these 297 patients, 35 (12%) underwent an intraoperative cholangiogram. For a significant majority of these patients, the indication for surgery was cholelithiasis, followed less frequently by acalculous cholecystitis, acute cholecystitis, chronic cholecystitis, biliary dyskinesia, and gallstone pancreatitis.

A simultaneous SPA appendectomy was performed in two of the cases. Similarly, one simultaneous SPA ventral

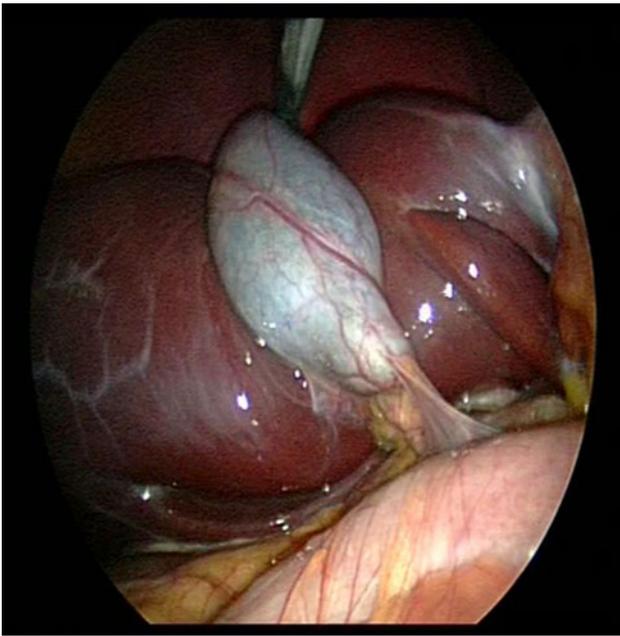


Fig. 4 Single-port access fundal retraction

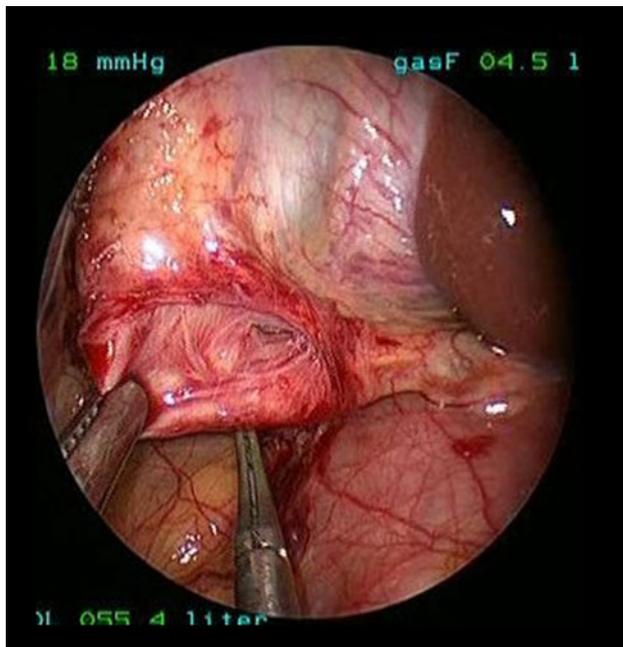


Fig. 5 Obtaining the “critical view” via single-port access

hernia repair and one right inguinal hernia repair were performed.

The overall average operative time was 71 min, and a subset analysis of patients with intraoperative cholangiograms yielded an average operative time of 74 min. Of the 35 cholangiograms, 34 were successfully performed. No significant bleeding was reported, with minimal estimated blood loss described in all cases.

All 297 cases were successfully managed. Four cases (1.3%) were converted to an open procedure due to difficult dissection. The length of the single umbilical incision in the cases managed with the SPA technique ranged from 14 to 20 mm. The average LOS was 1.5 days, and only 13 patients were discharged from the hospital after 48 h. Most of the patients were discharged as same-day surgery patients. No significant postoperative complications occurred.

Complications were experienced by 26 patients, including 9 wound seromas, 5 intraoperative bile or bag spillage, 3 umbilical abscesses, 2 umbilical hematomas, 2 cases of ileus, 1 case of retained stone requiring endoscopic retrograde cholangiopancreatography (ERCP), 1 biliary stricture at 1 year requiring successful ERCP, 1 laceration to the falciform ligament, 1 wound infection, 1 acute renal failure, and 1 iatrogenic skin laceration to the wound. To date, the follow-up assessment of patients 1–24 months after surgery has yielded no additional complications, no abdominal hernias, and no wound infections.

Discussion

One current goal of reduced-port laparoscopic procedures is to perform multiport laparoscopic procedures successfully and safely though fewer skin incisions, often hidden. Our study did not aim to prove that SPA cholecystectomy is better than standard multiport laparoscopic cholecystectomy, but we aimed to show that it is feasible and safe and thus may be used as an alternative technique.

A universal goal of any new technique should be its reproducibility by other surgeons. This will enhance its applicability by large numbers of surgeons and to large numbers of patients requiring cholecystectomy.

Other techniques have emerged in the literature in the form of small case series [12–15]. As this new platform develops, variations in technique will emerge. In some cases, a specially designed access port may be used.

Our technique uses the umbilicus as the single portal of entry into the abdominal cavity. This umbilical port accommodates multiple trocars, each with their own fascial insertion sites. This is the first report of a multi-institutional large series of patients demonstrating the success of this technique.

Our initial concerns in the early development of SPA cholecystectomy were the increased difficulty, costs, and concerns of safety [8]. We then enhanced the technique to address each of these concerns [17]. One such concern is the ability to maintain safe dissection and attention to safe aspects of laparoscopy while attaining “the critical view” [16]. It is important to emphasize that the principles of gallbladder dissection remain the same regardless whether

Fig. 6 Postoperative incision 1 month (*left*) and 12 months (*right*) after surgery for a patient who underwent a single-port-access (SPA) cholecystectomy



the procedure is performed via the SPA approach or through conventional multiport laparoscopy. Single-port-access cholecystectomy is performed via a different portal of entry but still successfully maintains this critical view (Fig. 5) [17]. The introduction of two retracting instruments allows for independent fundal retraction and infundibular manipulation, something we often take for granted in multiport cholecystectomy.

Another concern is the operative time for an SPA cholecystectomy compared with the standard multiport cholecystectomy. Extra time is required to perform SPA cholecystectomy due to the learning curve of a new technique. Our average operative time was 71 min. Naturally, operation times do improve with experience. However, we should not gauge the success of SPA cholecystectomy by the absolute time it takes to perform the procedure. Safety should always come first and never be sacrificed to do the procedure “quickly”. We report the time required for procedures simply to demonstrate that times are not increased such that they may prohibit adoption of the procedure.

When discussing overall time, we must address the role of intraoperative cholangiograms with SPA cholecystectomy in terms of their added performance time and technical difficulty. Although cholangiograms are not routinely performed for every patient undergoing a laparoscopic cholecystectomy, they are an integral part of the procedure and need to be possible with a new technique. Surgeons often perform an intraoperative cholangiogram either for a particular surgical disease or for better delineation of the biliary anatomy.

In SPA cholecystectomy, a cholangiogram catheter may be placed using one of the trocars within the umbilical incision or through a separate stab wound in the right upper quadrant. A separate trocar is not needed. As reported, 3 of the 13 surgeons in this study performed 35 SPA cholangiograms, 34 of which were successful. The average operative time for these patients was 74 min compared to an overall average operative time of 71 min for all 297

patients. However, a better estimate of the difference in times is accomplished by comparing the average operative time for SPA cholangiograms performed with the overall time only for those surgeons who performed the 35 cholangiograms. These three surgeons collectively performed operations for 111 patients in an overall average time of 55 min. Thus, for these patients, an additional 19 min was required for an intraoperative cholangiogram in an SPA cholecystectomy. Because recent literature reports an average additional time of 14 min to perform a cholangiogram [18], these extra 19 min for a cholangiogram in our collective data are acceptable. Surgeons who liberally perform an intraoperative cholangiogram in their patient population may do so comfortably without significantly increased operative times should they choose to proceed with the SPA method.

Laparoscopic cholecystectomy performed safely in an ambulatory setting has become widely popular and accepted [19, 20]. Our LOS was primarily 1–2 days, with more than half of the patients discharged in the ambulatory setting. Only 13 patients were discharged after a LOS exceeding 48 h. Because the technique is novel, with the allure of enhanced cosmesis, some patients traveled a distance to undergo the procedure. These patients were encouraged to stay at least overnight. For the patients with postoperative complications (e.g., hematoma), the hospital stay was lengthened for observation. Also, prolonged postoperative ileus required an extended hospital stay.

Most reported complications were minor. Our data collection was designed to note all complications including occurrences of seroma, incisional drainage, and hematoma, although these may not always be reported in multiport procedures. These complications did not require further intervention, but reporting these events, however, is important with regard to long-term follow-up evaluation. If umbilical hernias do occur, it is important to note their association, if any, to these events.

To date, no patient has presented with umbilical hernias. However, the postoperative time for some patients was

only 1 month at the time of data collection, so further follow-up assessment is necessary. The only long term complication was a biliary stricture which was treated with dilation via ERCP, with resolution and normalization of liver function tests. We must keep in mind that because a majority of these SPA procedures were performed primarily within the preceding 10 months, we are unable to report a large number of long term outcomes for patients followed up in the clinic 1 year or more since their surgery.

Drawbacks to our study were primarily in patient selection and long-term follow-up assessment. To become proficient, the surgeons may have tended toward careful selection of lower-risk or healthier patients in need of a cholecystectomy to undergo the SPA procedure. Thus we did not have a matched group of standard laparoscopic cholecystectomies performed for the morbidly obese or patients with multiple reoperations. This high selectivity is entirely appropriate and encouraged when a new technique is used. Hence, the positive outcomes for these patients may be slightly overestimated.

In addition, although this is the first large series of SPA procedures presented, the numbers do not provide the statistical power for adequate assessment of outcomes such as pain, recovery, and return to work compared with standard multiport procedures. Provided there is no increase in the umbilical hernia rate, the cosmetic results from a procedure performed through an incision smaller than 20 mm, at this point, is the primary benefit that may drive this procedure (Fig. 6).

Although all surgeons were shown the basic SPA technique, some variations did exist. Variability in surgeon

technique is present in any procedural task regardless whether it is performed via the standard multiport approach or via SPA. We minimized this variability by having all patient data come from surgeons who participated in the development of SPA surgery so that all knew and performed the SPA in a similar fashion.

The differences in technique stemmed primarily from surgeon preference for particular laparoscopic instruments, with some preferring straight instruments and some choosing articulating instruments. One surgeon switched the positioning of the camera, placing it in one of the lateral trocars instead of the central trocar, simply because of preference and comfort, after establishing the single access in our standard technique (Fig. 7).

For 34 of the patients, additional incisions and ports were placed to aid in the dissection. Of the 34 patients, 20 required one extra port, 11 required two extra ports, 2 required three extra ports, and 1 required four extra ports. The addition of extra ports is not only acceptable but also recommended to maintain safety in aiding the surgeon with the dissection. This applies also to conversion from laparoscopic to open cholecystectomies. It is reported in the literature that the rate of conversion to open cholecystectomy ranges from 5 to 10% [21]. In our case series, we report only four such events (1.3%). The concept of SPA “rescue” (i.e., placing additional ports) should never be regarded as a complication or a failure of the surgeon but merely as a means of making the operation easier and safer for a successful outcome.

Conclusion

As laparoscopic surgery has revolutionized the field of general surgery within the past two decades, other techniques such as SPA surgery and NOTES have built upon the principles of minimal access surgery. Single-port-access surgery offers a new technique that may be performed successfully in laparoscopic abdominal procedures while offering the patient a single “hidden” incision within the umbilicus. We recommend that surgeons interested in learning the SPA technique do so through an educational training model that serves as a bridge toward achieving proficiency in performing SPA surgery in human patients.

With the collection of results for nearly 300 SPA cholecystectomies performed by surgeons who learned this technique, we have demonstrated that the technique is safe and practical and may serve as an alternative to multiport therapy with fewer scars and better cosmesis. The strength of a new procedure is its reproducibility, and the results and outcomes for the first 297 cases of SPA cholecystectomy in this multi-institutional and multinational review are indicative of its technical feasibility and success. As the



Fig. 7 Placement of the camera in the patient’s right lateral trocar and dissecting instruments in the central and left trocars

database expands, larger series of cases will be followed up for the long term to determine the potential benefits of SPA cholecystectomy.

Disclosures Andrew S. Wu, Erica R. Podolsky, Namir Katkhouda, Alex Saenz, Robert Dunham, Marc Neff, Chad Copper, and Rodney Mason have no conflicts of interest or financial ties to disclose. Paul G. Curcillo speaks about single-port-access surgery for Storz Endoscopy, Ethicon Inc., Olympus, Inc., and Microline. Casey Graybeal provides educational and instructional assistance to Ethicon by virtue of telesurgery, which is covered by a “consulting” agreement, and has a consulting agreement with Carefusion (previously Cardinal Health) to serve on their Surgical Advisory Board. Marc Bessler receives fellowship support from Covidien and Ethicon and does consulting for these institutions and Olympus as well. Andrew A. Gumbs is a consultant for Ethicon, a proctor and course instructor for Covidien, a proctor for Novare Surgical and course instructor and lecturer for Applied Medical. Michael Norton is a stockholder in Access Instruments Inc. Dr Iannelli is a consultant for Covidien Inc. for single-port laparoscopic surgery. Ashkan Moazzez, Larry Cohen, Angela Mouhlas, and Alex Poor have no conflicts of interest or financial ties to disclose.

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