

Efficacy and Safety of Single Port Laparoscopic Cholecystectomy: A Single Institute Experience

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ABSTRACT

Background: Over the past 5 years, minimal access surgery has been moved toward a new less invasive single port access surgery. Like any new technique, there is a need to ensure that basic tenets of safety and efficacy are maintained. In this study, we demonstrate the efficacy and safety of single port laparoscopic surgery for cholecystectomy in 22 consecutive cases in single institution.

Materials and methods: It is a case series of 22 patients (20 females/2 males) who underwent single port laparoscopic cholecystectomy (SPLC) a single laparoscopic surgeon at Barts and the Royal London NHS Trust performed all surgeries using straight conventional instruments from July 2009 to May 2011.

Results: In our series, the operations were performed by SPLC successful in 21 patients. In one case an extra-port was added due to inadequate exposure. The mean age was 37.27 years (24-70). The mean BMI was 25.25 kg/m² (21.1-35). The mean operative time was 69.21 minutes (30-90). Gallbladder perforations were recorded in three cases. Minor bleeding was found in one case. The mean hospital stay was <24 (10.05) hours. Visual analog scale was used to record pain severity and the mean was less than one. All patients had uneventful recovery.

Conclusion: The results from current series show SPLC to be a promising technique. We established in this series that SPLC is a safe, efficacious and feasible technique, but it took longer to perform than standard surgery. It can be performed using straight instruments. However, routine application of this novel technique requires evaluation of its safety and effectiveness in large randomized studies.

Abbreviation: SILS: Single incision laparoscopic surgery; SIMPLS: Single incision multiport laparoscopic surgery; OPUS: One port umbilical surgery; TUES: Transumbilical endoscopic surgery; SPAS: Single port access surgery, are acronyms of LESS: Laparoendoscopic single site surgery.

Keywords: Single incision laparoscopic, Cholecystectomy, Single port access surgery, Laparoendoscopic single sit.

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INTRODUCTION

Gallbladder surgery has developed from most invasive open surgery with extensive tissue trauma; prolonged recovery period and high morbidity to minimal invasive surgery.

Minimal invasive surgery has very limited tissue trauma and potentially less pain and wound complications, short hospital stay and faster return to work, no or minimum pain postoperatively and excellent cosmeses.¹⁻⁵ It also costs less. Therefore, it has crossed all traditional boundaries to specialties and disciplines.

On the other hand there are limitations of minimal access surgery, it has no tactile feedback, and surgeons depend on two-dimension images instead of three and lack of depth perceptions. Furthermore, in laparoscopic procedure surgeon might find it difficult to control bleeding and more chance to injure nearby structure due to hand eye in coordination or loss of triangulation. Moreover, longer operating time due to instruments crashing and crowding and training requirements might cause conversion to open surgery.⁵

With more experiences gained and further developments in surgical innovation and instrumentation, surgeons over the last few years made an effort to further minimize tissue invasiveness and access trauma and therefore results in less pain, quick recovery and better cosmeses results.⁶⁻⁹ In this new approach one skin incision is to be made almost always in the umbilicus and then either single or multiple facial incisions are made through which one multichannel port inserted. The Transumbilical technique for cholecystectomy, without additional incisions, was described first by Navarre et al in 1997 and later by Piskun et al in 1999, but failed to gain popularity due to lack of proper instrumentation.^{10,11}

According to some surgeons, single port laparoscopic cholecystectomy (SPLC) should only be offered to those with favorable anatomy and pathology similar to other indication of standard laparoscopic cholecystectomy.

The aim of single port is to minimize the access trauma, better cosmeses, less postoperative pain and at the same time maintain the dissection principles and safety issue and get the same outcome of standard laparoscopic cholecystectomy.

In SPLC, special skills are needed to be mastered to overcome some difficulties like working in limited spaces with few instrument, loss of triangulation and poor visibility due to instrument camera interface, there is little doubt that this procedure lacks clear evidence about patient's eligibility and common techniques and instruments to make it the standard way of laparoscopic cholecystectomy.

Like any other procedure, techniques, SPLC procedure requires proof to support the claim and the safety and efficacy offered in this approach in addition to its feasibility and its cost effectiveness. Another issue that needs to be addressed is how the patient feels about it and if it meets the patients' expectations, because what seems good and satisfactory is not necessarily shared by patients and social situations.

Safety and efficacy can be evaluated by carefully and continuously monitoring the results of the published studies. By following the principle of evidence base medicine, evidence should be obtained from large clinical trials in multiple centers in addition to series studies. This evidence can be then presented as proof of safety and efficacy of the approach. Maintaining continuous medical education and transparent communication to patients about their experience, outcomes and potential risks is an addition measure to support application of this procedure.

Our aim is to demonstrate the safety and efficacy of SPLC by presenting the outcomes of our initial experience.

MATERIALS AND METHODS

Inclusion Criteria

A group of 22 nonselected cases with symptomatic gallbladder diseases underwent single incision laparoscopic cholecystectomy at Brats and Royal London NHS Trust between July 2009 and May 2011, 21 patients had a completed successful procedure and one case had extra-port added to be completed. There were 20 female patients and two males. Data was collected from both clinical case notes and electronic database of the hospitals and reviewed retrospectively.

There were no restrictions on age, pathology and associated comorbidity. This study presents our institute's initial experience of SPLC. It obtained the necessary approval from the health authority of the trust. All operations were performed by one experienced laparoscopic surgeon (BP). One case was excluded due to extensive intra-abdominal adhesion. Only conventional straight instruments were used in this study including 5 mm 30° laparoscope. Preoperative blood tests and abdominal ultrasound were routinely examined for all patients who were to have the operation.

Exclusion Criteria

Two criterias were considered as exclusion from our study. One is patient with previous upper abdominal surgery and another is BMI more than 40 kg/m².

No acute cholecystitis cases were involved in this series however, there was no intention to exclude these cases.

DATA COLLECTION

The data was extracted from patient's electronic health records and operative notes. We used NICE audit support guidelines of SPLC in addition to the defined outcomes of laparoscopic cholecystectomy. Both demographic and operative characteristics were collected.

The defined outcomes were recorded based on previous systematic reviews and published papers. Patients were informed in great detail about the operative strategy of having single incision in the umbilicus with possibility of several more incisions or a conversion to an open technique prior to the surgery. Operative time is defined as the time from incision to time of closure. Pre- and postoperative outcomes (operative time, complications, hospital stay, estimated blood loss, conversion and pain score) were recorded.

Patient satisfaction and postoperative complications were also recorded by answering questionnaire on telephone conversation directly with the patients or their relatives in non-English speaker patients.

SINGLE INCISION LAPAROSCOPIC CHOLECYSTECTOMY TECHNIQUE

Single incision in length of 12 to 15 mm was made through umbilicus down to the midline fascia. A stay suture was placed on each side of the facial incision. The peritoneum was tented up and opened under direct vision. Then multichannel port (Covidien SILS, Triport or Gelport) was introduced into the abdominal cavity (open method access). Stay sutures were tightened around the port to ensure effective pneumoperitoneum. Carbon dioxide (CO₂) was insufflating at high flow rate to less than 12 mm Hg pressure. Two to three 5 mm trocars were put through the port along with 5 mm 30° laparoscopy. Straight conventional instruments were used in all procedures.

An endoloop was introduced in the right hypochondrium to retract gallbladder for good exposure of Calot triangle and cystic artery, duct and identify biliary anatomy. Critical view of safety was achieved by demonstrating both structure entering the gallbladder and the cystic—common bile duct relationship underneath liver in all cases. We do not usually carry out intraoperative cholangiogram as routine practice in our hospitals. After good exposure and dissection, cystic duct and artery were clipped separately. Division of both structures were performed by endo scissors.

Gallbladder was then dissected away from liver bed by monopolar electrocautery. Meticulous hemostasis was performed and saline washout before retrieving the gallbladder from abdominal cavity by endo-bag through umbilical incision. 0 Vicryl stitches was used to close

facial defect and 3/0 Vicryl stitches was used to close the umbilical skin.

RESULTS

Most of patients were female (F/M = 20/2) with average age 37.27 (24 to 70) years. All patients have symptomatic cholelithiasis with no emergency cases included. The mean BMI was 25.25 kg/m². General health state of all patients were assessed using American Society of Anesthologist (ASA) scoring system 1 and 2.

The mean operative time for 19 patients was 69.21 minutes (30-90). No records of operative time were found in three cases due to missing data. All cases underwent laparoscopic cholecystectomy using single port through umbilicus except one patient who had an extra-port for inadequate exposure. All patients had cholelithiasis. Straight conventional laparoscopic instruments including 5 mm 30° laparoscopes were used.

There was no conversion to conventional laparoscopic or open cholecystectomy. Some of the missing data was extracted either from electronic record of the patients or from the operating surgeon notebook.

There were five minor complications in this series (Table 1). We had three gallbladder perforations by electrocautery. One case had bleeding intraoperatively which was controlled easily by diathermy. One patient was readmitted for abdominal pain which got controlled conservatively. Operative time appear to decline significantly after the first 18 cases and was around 30 minutes in the last four procedures (Table 2). All patients discharged

on the same day except two patients. One patient was discharged on the second day. The other one stayed for 48 hours for social issue. The average blood loss during procedures was minimal and there was no need for blood transfusion.

No vascular or bowel injuries were seen on entering the peritoneal cavity. No intraoperative complications were found. No extension of primary incision was performed. Surgical principle of exposure and dissections were followed. Critical view of safety was demonstrated in all cases. There was no need for routine intraoperative cholangiogram as this is not the trust policy. Postoperative pain was assessed using visual analog scale and the mean was less than one. Patients were given simple oral analgesia which succeeded to control their mild-to-moderate postoperative pain. Most patients said that there was no need to take regular analgesia after being discharged from

Table 1: Operative outcomes of SPLC

Operative time (min)	69.21 (30-90)
Complication	All minors: Total 5 (22.7%) <ul style="list-style-type: none"> • 3 gallbladder perforations (13.6%) • 1 bleeding: No transfusion needed • 1 readmission for pain control
Critical view of safety	Demonstrated in all cases
Conversion	None
Hospital stays (hours)	<24 hours (the mean 10.05 hours)
Pain score (VAS)	<1
Blood loss	Minimum
Patient satisfaction	Satisfied 100% (14 patients surveyed)
Success rate	95.45%

Table 2: Summary of perioperative outcomes of SPLC

Patients	Operative time	Cri v safety	Complication	Pain	Hosp stay	Conversion
1	90	Yes	No	0	Same day	No
2	85	Yes	No	0	Same day	No
3	90	Yes	No	0	Same day	No
4	50	Yes	No	0	Same day	No
5	90	Yes	No	0	Same day	No
6	65	Yes	No	0	24 hours	No
7	80	yes	Bleeding	2	readmission	No
8	50	Yes	No	0	Same day	No
9	75	Yes	No	0	Same day	No
10	60	Yes	No	0	Same day	No
11	90	Yes	No	2	Same day	No
12	90	Yes	GB perforation	0	48 hours	No
13	70	Yes	No	0	Same day	No
14	Missing	Yes	No	NR	NR	One extra-port
15	90	Yes	GB perforation	0	Same day	No
16	Missing	Yes	No	NR	NR	No
17	Missing	Yes	No	NR	NR	No
18	80	Yes	GB perforation	0	Same day	No
19	45	Yes	No	0	Same day	No
20	35	Yes	No	0	Same day	No
21	30	Yes	Pain	2	Same day	No
22	50	Yes	No	0	Same day	No

Cri v safety: Critical view of safety; GB: Gallbladder; NR: Not recorded

hospital. Patients were surveyed between 1 month and 2 years postoperatively (Table 3). Fourteen patients were surveyed by telephonic conversations (63.63%) about pain, readmission and lumps in site of surgery, after being discharged from hospital or whether or not they sought help from general practitioner or emergency medical help. All 14 patients were satisfied with the results (100%). No contact details were found in three cases. There was no reply in five cases. The mean time for analgesia usage was 4.14 days, simple analgesia was taken on need only.

DISCUSSION

The same surgical principles and instruments of standard laparoscopic cholecystectomy were used in SPLC.

Although, the operative time was longer than the average standard approach but it has reduced significantly after the first 18 cases. The learning curve reduced from 90 minutes to become less than 50 minutes in the last four cases. We have used a multichannel port to complete all procedures.

No significant morbidity was reported and there was no mortality or conversion to standard or open surgery. One patient had one extra-port to complete the procedure due to inadequate exposure. No bowel, vascular or biliary injuries were encountered. By reviewing our series results, we have noticed that the majority of our patients were safely sent home on the same day of the surgery, the level of the pain on the lower margin of the scale and consequently less analgesia were taken, and all has shown a quick recovery.

Patients who underwent this approach in hospitals have expressed their satisfaction with the results months after being discharged from the hospital by answering some questions about the need for analgesia and development of complications and hospital readmission and finally the overall satisfactions with results of this approach.

All these benefits of the reduced port surgery, in addition to the fact that minimal scar and excellent patient's satisfaction, has encouraged us to carry on performing more cases. The limitations of this series are small number involved, single institute and all cases were performed by one surgeon and it is a retrospective study for single pathology. It would be of great benefit if we compare its results to that of conventional laparoscopic cholecystectomy to see how different it is in term of operative and postoperative outcomes in relatively similar groups, demographically and pathologically. In case of limited enrolment number, the chance of developing the morbidity is narrowed and the statistical significance is reduced. Therefore, larger numbers of multicenters and wider range of pathology and techniques are needed to determine long-term safety and continued monitoring of these parameters will only make us confident in adopting this approach worldwide.

This series demonstrated clearly that laparoscopic cholecystectomy by single port access is safe, feasible and reproducible procedure with few complications. The hospital stay and need for analgesia was minimal. The patient satisfaction is very good with no single negative response about this type of surgery.

CONCLUSION

The high success rates (95.45%) with no mortality or morbidity make us conclude that this technique is safe and efficacious in patients with symptomatic cholelithiasis. The patients were satisfied with the final results with no short- or long-term morbidity. The operative time was longer than but comparable to that of conventional laparoscopic cholecystectomy. The learning curve reduced after the first 18 operations. The same surgical principles of conventional

Table 3: Postoperative survey of 14 patients who underwent SPLC

Patients	How long did you use painkiller for regular and what type did you use?	Have you sought any medical help for your pain? NHS directs, GP or hospital A&E?	Have you noticed any swelling or lump at site of operation?	Have you been readmitted due to an issue with your operation?	Are you satisfied with the results of your operation
1	N	N	N	N	Y
2	N	N	N	N	Y
3	N	N	N	N	Y
4	7D/simple/PRN	N	N	N	Y
5	N	N	N	N	Y
6	14/simple/PRN	GP	N	N	Y
7	N	N	N	N	Y
8	14D/simple/PRN	A&E	N	N	Y
9	N	N	N	N	Y
10	N	GP	N	N	Y
11	N	N	N	N	Y
12	4D/simple/PRN	N	N	N	Y
13	5D/simple/PRN	N	N	N	Y
14	14D/simple/PRN	N	N	N	Y

N: No; D: Day; Y: Yes; PRN: As required; Simple: Simple Nonopoid analgesia

four-port laparoscopic cholecystectomy were applied in all cases and there was no need for conversion to open surgery or standard surgery. The majority of patients left the hospital on the same day. Just simple analgesia was taken for the first few hours after the surgery.

Despite the potential benefits of the SILS, like minimizing the tissue trauma, postoperative pain and hospital stay and great cosmetic advantages, its application on a wide range of patients and wide spectrum of intra-abdominal surgeries need convincing clear evidence about the safety and efficacy of this approach by conducting large randomized trials in different centers in future.

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