OUR EXPERIENCE WITH SINGLE-INCISION LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

BACKGROUND

As we progressed from operations involving multiple ports to single access through umbilicus, there is empirical evidence that postoperative pain can be reduced as a result of single incision, in addition to accomplishing the laparoscopic procedure effectively and safely. This study was conducted to evaluate safety, efficacy and postoperative morbidity with this method.

MATERIALS AND METHODS

This case series was conducted on forty patients suffering from cholelithiasis, who met the inclusion criteria were selected for single port laparoscopic cholecystectomy (SPLC) over a period of one year. SPLC was performed using X-cone device in twenty patients and multiport through a single periumbilical incision in twenty patients.

RESULTS

The perception of pain was very less in immediate postoperative period and no patient required analgesics beyond one week. Early ambulation and early return to normal activity was observed.

CONCLUSION

SPLC is going to develop a platform of its own or lead us down the path we have not yet realised and will certainly become apparent over the next decade. It has become patient-demanding procedure, because of excellent cosmetics and satisfaction with body image with decreased postoperative pain, early ambulation and return to day-to-day activity. Whichever direction we go in, the driving force needs to be patient's safety and patient care about which we have concluded in our study.

KEY WORDS

Single Port Laparoscopic Cholecystectomy, Single Incision Laparoscopic Surgery, X-Cone, Single-Incision Cosmesis.

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BACKGROUND

The journey from conventional "open" operations to truly "minimally invasive" operations naturally includes progression from operations involving multiple trocars and multiple incisions to operations involving access through the umbilicus alone.^[1] The recent exposure of reduced port surgical techniques what we call as single port access laparoscopy surely has not only found us pushing further, but is also serving to test important aspects of any new development in surgery. More recently, single incision laparoscopic procedure has been used to accomplish many procedures. Initial experience suggests that it is equally safe and feasible. It has been questioned whether or not single-port laparoscopic cholecystectomy (SPLC) is associated with significant improvement in postoperative pain, and what other benefits can be acquired as compared to conventional laparoscopic cholecystectomy. Although, this procedure has been successfully performed, the technical challenges and the learning curve have restricted its wide spread use. Keeping in view the above-mentioned advantages, study was conducted to evaluate safety, efficacy and postoperative morbidity.

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MATERIALS AND METHODS

This case series was conducted over a period of one year on 40 patients suffering from cholelithiasis. The patients who met the inclusion criteria were taken for SPLC. Patients in paediatric age group, acute cholecystitis, previous abdominal and/ or surgery around umbilicus, suspected bile duct stones, suspected biliary malignancy, bleeding disorders and patients not fit for general anaesthesia were excluded from study. The procedure was explained to the patients and a written consent was taken. The patients were examined and investigated for co-morbid conditions. SPLC was performed with a standardised operating protocol.

Figure 1. Instruments for Single-Port Access Laparoscopic Cholecystectomy

Surgical Procedure

Single Port Laparoscopic Cholecystectomy (SPLC) was performed by the single-incision, single-port technique using X-cone (Karl Storz, Tuttlingen, Germany). X-cone is a reusable single-port device that allows insertion of three hand instruments and an optic through the same port. A periumbilical incision from 12 noon to 6 pm, measuring 15 to 20 mm was made along the natural circumference of the umbilicus. A vertical fascial incision measuring 15 to 20 mm was made. Stay sutures were placed at cranial and caudal ends of the fascial incision. The X-cone was inserted, and it was positioned with insufflation stop-cock at 12 o'clock. Telescope forward-oblique, 30°, 50 cm length, 5 mm in diameter was placed on far-right insertion access, holding instrument on far left and working instrument in the middle. Pneumoperitoneum was created through Leuer stop-cock using electronic CO₂ insufflator at the pressure of 12 to 14 mmHg. Diagnostic laparoscopy was performed to confirm feasibility of performing SPLC. The posterior peritoneum over the gallbladder was incised and posterior dissection was performed to identify the cystic duct and artery. A large window was always created to obtain the critical view of safety. The cystic duct and artery were clipped with traditional 10 mm clip applicators used in multi-port Laparoscopic Cholecystectomy (Ethicon Endosurgery, USA). A monopolar diathermy/ultracision dissection was performed to remove the gallbladder from its bed. The gallbladder was extracted through the same incision. The fascial incision was identified and meticulously closed with Vicryl sutures. The skin was closed with a subcuticular Ethilon suture or with 2 octyl cyanoacrylate glue.

Figure 2. Instruments and Telescope Inserted through X-Cone

The following data of all the patients were prospectively collected and maintained in a database: age, gender, weight, BMI, comorbid conditions, surgical approach, operative time, intra- and post-operative complications, length of hospital stay, pain assessment scores, patient-assessed cosmesis scores and patient satisfaction scores. Postoperative pain and surgical complications were defined as primary end points.

The secondary end points were patient assessed cosmesis scores, patient satisfaction scores and postoperative pain was assessed by using visual analog scale (VAS) score on Day 0 (at 6 hrs. postoperatively at rest and coughing/straining) and postoperative Day 1 (at 24 hrs. postoperatively) of surgery. As a routine pain management protocol, all patients received injection diclofenac 75 mg alternately every 8 hrs for the first 24 hrs. after surgery. Pain was assessed by visual analogue scale (VAS). Cosmetic outcome and satisfaction with body image was assessed using Likert index, in which a postoperative photograph was shown to the patient and was asked to score from 1 to 5 his/ her subjective perception of cosmetic outcome following surgery (1= Very poor, 2= Poor, 3= Satisfactory, 4= Good, 5= Very good) at their first follow-up when dressing was removed on postoperative Day 7 and subsequently upto 6 months following surgery. Complications were recorded as intraoperative and postoperative.

Analysis was conducted with the help of SPSS software 21. Variables were presented as mean and standard deviation for quantitative and percentages for qualitative or as deemed appropriate.

RESULTS

SPLC was performed on 40 selected patients over a period of one year. Mean age in our study was 37.35 ± 8.68 years with female predominance of 92.5%. The mean body mass index (BMI) of the patients was 23.35 ± 2.96 kg/m². 7 patients (17.50%) suffered from comorbidities including 1 patient (2.5%) from diabetes mellitus and 4 patients (10%) from hypertension.

The mean operating time in our study which was taken from initial incision to closure of wound was 87.63 ± 26.44 minutes. In first 14 cases, mean operating time was 118.1 minutes, while in next 26 cases it became stabilised to 70.1 minutes.

Intraoperative surgical complications were experienced by 9 patients (22.5%). One patient (2.5%) had fall in oxygen saturation due to pneumoperitoneum, which was managed. We had one case (2.5%) of trocar site bleeding, which was controlled by pressure on trocar site. There was one (2.5%) bile duct injury. It was about 1.5 mm linear tear, which was sutured laparoscopically with 3-0 polyglactin 910 with the help of two 5 mm ports inserted below right and left costal

margins without any postoperative sequelae. The most common complications were gall bladder perforation and bile spillage seen in 5 patients (12.50%). There was also one case (2.5%), in which stone spillage occurred during extraction.

One patient required conversion to multiport laparoscopic cholecystectomy conversion due to dense adhesions at Calot's triangle and in this patient fundus-first laparoscopic cholecystectomy was carried out. There was no conversion to open cholecystectomy observed in our study. There were 6 patients in which additional 2.3 mm mini laparoscopic instrument (alligator forceps) was used through right subcostal margin for gall bladder retraction, because of difficulty in exposing Calot's triangle and maintenance of critical angle of safety due to dense adhesions. In 2 patients of empyema gall bladder, one 5 mm port was used below right costal margin in mid-clavicular line for visualising Calot's triangle.

Peritoneal drain was kept in sub-hepatic space (Morrison's pouch) in 23 (57.50%) patients. "0" number polyglactin 910 for closing the port. Skin was closed with skin staplers in 4 cases (10%) and 2-octyl cyanoacrylate glue in 36 cases (90%).

Postoperatively, the mean VAS score for pain was 3.38 ± 1.13 at rest on day of surgery. Injectable diclofenac was used in first 24 hours in all cases followed by oral analgesics. Pain was found to be moderate at 6 hours and 12 hours following surgery. At 24 hours assessment of pain, it was observed to be mild in 26 (65%) cases and moderate in 13 (32.5%) cases and severe in 1 (2.5%) case.

At the end of first week, it was found mild in 31 cases and moderate in 9 cases. Beyond 1 week, no patient required analgesics. VAS of pain assessed on coughing/ straining was found to be mild in 19 (47.50%), moderate in 20 (50%) and severe in 1 (2.50%) case. 22 patients (55%) were made ambulatory on day of surgery and 16 patients (40%) on first postoperative day. The mean postoperative stay was 41.65 ± 48.85 hours.

The mean duration of our follow-up was 27.18 ± 2.87 weeks. On follow-up at 1 week we observed 1 (2.50%) port site infection, 1 (2.50%) wound dehiscence and 1 umbilical infection (2.50%). The average postoperative period for resumption of normal activity was 7.08 ± 2.63 days in SPLC.

Resumption of Normal Activity (In Days)	Number of Patients (n= 40) No. (%)
≤5	10 (25.00)
6-10	27 (67.50)
≥11	3 (7.50)
Total	40 (100.00)

Table 1. Distribution of Cases according to Resumption of Normal Activity among Patients

At 3 weeks follow-up, the mean VAS was 1.05 ± 0.32 (mild). There was one port site hernia noted during follow-up at 3 months. The perception of cosmetic outcome and satisfaction with body image was 5 on Likert scale in all the patients, thereby indicating that patients were very satisfied with their cosmetic results at 2 months following surgery.

Likert Scale	Number of Patients (n= 40) No. (%)
2	-
3	-
4	-
5	40 (100.00)
Total	40 (100.00)

Table 2. Distribution of Cases according to Cosmetic Outcome and Satisfaction with Body Image (Likert Scale)

DISCUSSION

Many surgeons have attempted to reduce the number and size of the ports in laparoscopic surgery to decrease abdominal trauma and related complications, in addition to improving the cosmetic results. So far, many studies are available which favour single port access over multiport conventional laparoscopic surgery with inherited benefits of cosmetics, less postoperative pain without any major postoperative complications.^[1,2]

We took up the study with an aim to assess the outcome of single port access laparoscopic cholecystectomy in relation to safety, efficacy and postoperative morbidity. In our study, 40 patients were randomly taken for SPLC.

Several different port access systems have been used in SILS. It has also been performed with multiple individual trocars through separate incisions within the umbilicus. We performed SPLC using X-cone single port access system, whereas there are authors who have used different types of access ports in their studies like Triport,^[3,4] R-Port,^[5] Glove port,^[6,7] Covideon.^[8]

The mean operating time in our study, which was taken from initial incision to closure of wound was 87.63 ± 26.44 minutes. In first 14 cases mean operating time was 118.1 minutes, while in next 26 cases it became stabilised to 70.1

minutes. This could be justified that when surgeon acquires new surgical skill in spite of his/ her experience in laparoscopic surgery, there is initial learning curve. According to authors, the learning curve for SPLC for a surgeon who is experienced in conventional laparoscopic cholecystectomy is 10 cases. Similar findings were noticed by Youn SH et al,^[6] where the mean operating time was 91.83 minutes in first 30 cases and less in next 40 cases which was 75.25 minutes.

According to authors, the most important factor that influenced operating time was not the instrument whether straight or articulating or combination of both, but the surgeon's skill to prevent fighting of instruments and camera. Whereas study conducted by Song SC et al^[7] showed that mean operating time was found less using articulating instruments with flexible laparoscope, which helped in reducing the learning curve. According to them long operating time was also due to severe inflammation of gall bladder has also been observed in two of our cases of empyema gall bladder.

In our study, we used straight instruments except for grasping forceps which was 42 cm long and curved at the distal end. Similarly, straight instruments were used by Youn SH et al,^[6] because in their first 30 cases when they used articulating instruments surgeon was uncomfortable with large handle and clashing of instruments. Whereas Rao PP et al,^[5] Martins MVDC et al^[9] and Dapri G et al,^[10] in their respective studies used curved reusable instruments to avoid clash between the surgeon's hands or between the instruments which allowed the surgeon to operate in better ergonomic position.

We had six cases of adhesions at Calot's triangle required additional mini-laparoscopic devices (alligator, 2.3 mm grasper) for the retraction of gall bladder in order to visualise Calot's triangle. Similar 2 mm diameter mini-laparoscopic grasper was used by Song SC et al,^[7] in their 5 patients of single incision laparoscopic cholecystectomy, inserted through right sub-costal margin or through the inferior portion of umbilicus for retraction of gall bladder in order to ensure safe single incision laparoscopic cholecystectomy. We strongly recommend this device for retraction of gall bladder to make dissection of Calot's triangle easier and safer.

Figure 3. Mini-Laparoscopic Instrument Grasping the Hartmann's Pouch in difficult Dissection

In two obese cases (BMI ≥ 30 kg/m²) associated with empyema of gall bladder, we used additional 5 mm extra-umbilical trocar in right hypochondrium to make the dissection easy.

Conversion to multi-port conventional laparoscopic cholecystectomy or open cholecystectomy should never be regarded as a complication or failure of surgeons, but merely as means of making the operation easier and safe for a successful outcome. We had one case of conversion from SPLC to conventional laparoscopic cholecystectomy where Calot's triangle could not be made out and no conversion to open cholecystectomy was needed. Whereas higher conversion rates have been reported from single incision to conventional laparoscopic cholecystectomy in a study conducted by Ma J et al,^[11] who reported that in their 21 patients of single port laparoscopic cholecystectomy 10 were converted to conventional laparoscopic cholecystectomy due to high level of inflammation and difficulty in visualisation of Calot's triangle. No conversion either to conventional or open cholecystectomy has been reported by Rao PP et al^[5] in their study of 20 patients, similar to our study where we did not convert any case to open cholecystectomy.

One of our patients had port site bleeding, which was managed similar to study conducted by Ma J et al^[11] where also 1 case of port site bleed was reported among 21 patients undergoing SILS.

We had one bile duct injury, which was sutured without any postoperative sequelae. Bile duct injuries have been reported in literature. Kravetz AJ et al^[3] had one postoperative biloma formation following bile duct injury in single incision laparoscopic cholecystectomy group of 20 patients, which was managed by percutaneous drainage followed by endoscopic retrograde cholangiopancreatography with stent placement.

We believe that laparoscopic bile duct injuries originate from visual perception illusion and not from error in skill, knowledge and judgment. It becomes necessary to take the help of additional devices for visualising the Calot's triangle to maintain the critical view of safety to reduce such biliary tract injuries whenever there are difficult situations and keeping an open mind for conversion to conventional laparoscopic or open cholecystectomy.

We had gall bladder perforations and spillage of bile in 5 cases. Gall bladder perforation and bile spillage has also been reported by Song SC et al,^[7] who reported bile leakage in 3.7% cases in single incision laparoscopic cholecystectomy patients. We did not have any complication of bleeding or injury to viscera.

Gall bladder extraction in our study was found easy even if gallbladder was loaded with multiple stones with extra time being spent on it during the procedure.

Perception of pain in postoperative period was assessed by visual analogue scale (VAS). It was found to be moderate at 6 hours and 12 hours following surgery. At 24 hours, it was observed to be mild in 26 (65%) cases and moderate in 13 (32.5%) cases and severe in only one case (2.5%). Mean VAS for single-port access laparoscopic cholecystectomy was 3.38 (± 1.13). Patel AG et al,^[4] in their study of 20 patients of fundus-first SILS port observed that perception of postoperative pain measured by VAS was 2.5 (range, 0 - 5) at 12 hours following surgery. Similar observations have been made by Evangelos et al,^[12] beyond 1 week pain was non-existent in all the patients.

Mean postoperative hospital stay was 41.65 $\pm$ 48.85 hours. Whereas, Martins MVDC et al^[9] discharged all patients between 24 - 35 hours postoperatively. The average

postoperative period for resumption of normal activity was 7.08 ± 2.63 days. In the follow-up period while assessing the wound related complications we found one port site infection, one wound dehiscence and one umbilical infection but no haematoma or seroma. Similarly, in a study conducted by Martins MVDC et al,^[9] 3 of their 81 patients developed wound infections and 8 cases developed small seromas managed conservatively.

One of our patients at 3 months follow-up developed umbilical hernia. Umbilical hernia has also been reported by various authors in their respective studies.^[13,11] In our study we used polyglactin 910 for approximating fascial defect created by access device, though we recommend polydioxanone 1-0 (delayed absorbable) suture material for closing the defect which may help in avoiding hernia at port site, but its use and incidence of hernia formation needs further follow-up.

Cosmetic outcome and satisfaction with body image was assessed by using Likert scale. All 40 patients (100%) were satisfied and Likert scale was very good. Similarly, Marks J et al^[14] in their study observed that there was increase in body image satisfaction for single incision laparoscopic cholecystectomy at 3 months.

This study has proved that single-port access laparoscopic cholecystectomy is safe and feasible. SPA laparoscopic cholecystectomy takes more operating time, but with experience it definitely decreases and is marginally more than conventional laparoscopic cholecystectomy. Laparoscopic cholecystectomy has reached an important turning point with the development of single incision laparoscopic surgery. Further effects and research can add improvements wherever possible.

CONCLUSION

Single-port laparoscopic cholecystectomy is safe and feasible alternative for experienced laparoscopic surgeon and can be performed in a safe manner. It is a better procedure because of its excellent cosmetic characteristics, satisfaction with body image post surgery, decreased postoperative pain, early ambulation and return to normal activity. Though SPLC is technically more difficult because of loss of triangulation, clashing of instruments and visualising Calot's triangle and has learning curve for even experienced laparoscopic surgeon, it is feasible and safe once the learning curve for even 10 to 14 patients is achieved. We strongly believe that when performing single-port-access laparoscopic cholecystectomy, the surgeon must have the same level of confidence and comfort, as with conventional multiport laparoscopic cholecystectomy. The critical view of safety must be achieved using adequate retraction. For safety, surgeon should have less threshold for additional devices which is using additional ports liberally wherever required, especially earlier in the learning curve and in patients with higher BMI or in difficult situations and still retaining benefits of minimal access surgery.

The main advantages of SPLC are improved cosmesis and greater patient satisfaction. Whether single-port access laparoscopic cholecystectomy surgery is going to develop a platform of its own or lead us down the path we have not yet realized, it will certainly become apparent over next few years. Whichever direction we go in, the driving force needs to be patient's safety and patient care. Keeping an open mind

for conversion to conventional laparoscopic cholecystectomy and assigning priority to the safety of the patients over cosmetics will help avoid serious complications when surgeon encounters difficulties during this type of surgery. More randomised trials are needed to evaluate the technique for its safety and efficacy.

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