

A COMPARATIVE CLINICAL EVALUATION OF LAPAROSCOPIC CHOLECYSTECTOMY WITH SINGLE AND MULTIPOINT ACCESS

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ABSTRACT: Single port laparoscopic cholecystectomy (SPLC) was introduced to minimize postoperative morbidity and improve cosmesis. We performed a comparative study to assess feasibility, safety and perceived benefits of SPLC. Two groups of patients (40 each) with comparable demographic characteristics were selected for SPLC and multiport laparoscopic cholecystectomy (MPLC) between November 2010 to October 2011. SPLC was performed using X-cone with 5 and 10 mm extra-long (50 cm) telescope and 3 ports for hand instruments. MPLC was performed with traditional 4 port technique. A large window was always created during dissection to obtain the critical view of safety. Data collection was prospective. The primary end points were postoperative pain and surgical complications. Secondary end points were patient assessed cosmesis and satisfaction with body image and operating time. The mean VAS scores for pain at rest in MPLC group were higher on day 0 (SPLC 3.38 versus MPLC 4.80, p0.0001). VAS on coughing/straining was also significantly higher in MPLC group on day 0 (SPLC 3.98 versus MPLC 6.48, p0.0001). VAS on post-operative day 1 was significantly higher in MPLC group (SPLC 2.25 versus MPLC 3.80, p0.000). Number and nature of surgical complications was statistically insignificant. Post-operative resumption of normal activity was earlier in SPLC group (SPLC 7.08, MPLC 10.83, p0.0001). Patient assessed cosmesis and satisfaction with body image scores on likert index (SPLC 5 in 100% versus MPLC 3 in 82.5% and 3 in 7.50%) indicating better cosmesis and greater patient satisfaction in SPLC. SPLC took longer to perform (87.63min versus 58 min in MPLC). Additional laparoscopic device (Alligator, 2.3 mm grasper) was used for retraction of gall bladder in 6 patients and 5mm right subcostal port in SPLC. SPLC appears to be feasible and safe with cosmetic benefits in selected patients. However, challenges remain to improve operative ergonomics. SPLC needs to be proven efficacious with a high safety profile to be accepted as standard laparoscopic technique.

KEYWORDS: Single port laparoscopic cholecystectomy, Single incision laparoscopic surgery, X cone, Patient assessed cosmesis, Patient satisfaction scores, Learning curve.

INTRODUCTION: Laparoscopic cholecystectomy is currently the standard for gall bladder removal with open technique being largely reserved for failure of laparoscopic resection [1]. In the quest for making MAS more-patient friendly in terms of fewer complications and better cosmesis, single-port laparoscopic cholecystectomy (SPLC) has emerged as a novel technique.

Having initially met with skepticism and uncertainty, traditional multiport laparoscopic cholecystectomy (MPLC) eventually has emerged as the most widely performed laparoscopic procedure. For any new technique to be adopted, it has to offer the safety and feasibility of the previously available techniques as well as has the potential to confer further benefits. To examine the feasibility, safety, and perceived benefits of SPLC, we conducted a prospective and comparative study between two groups of patients who underwent SPLC and MPLC.

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MATERIALS AND METHODS: The present study was conducted in the Postgraduate Department of Surgery, Government Medical College, Jammu for a period of one year from December, 2010 to November, 2011 on 80 patients suffering from cholelithiasis. The patients were randomly and equally divided into two groups of 40 patients each after matching parameters like age group, body mass index (BMI) and co-morbid conditions. The procedure was explained to the patients and a written consent was taken. Laparoscopic cholecystectomy in both techniques (SPLC and MPLC) was performed with a standardized operating protocol.

However 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.

Surgical Procedure: 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 20mm was made along the natural circumference of the umbilicus. A vertical facial incision measuring 15 to 20mm was made. Stay sutures was placed at cranial and caudal ends of the fascial incision. The X-cone was inserted and ports were utilized as shown in picture [Fig. 1 & 2].

Pneumoperitoneum was created through Leuer stop-cock using electronic CO₂ insufflator at the pressure of 12 to 14mmHg. 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 MPLC (Ethicon Endosurgery, USA). A monopolar diathermy/ultracission 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, and skin closed with 2 octyl cyanoacrylate glue. Multiple port laparoscopic cholecystectomy (MPLC) was performed using the traditional four-port technique.

The following data of all the patients were prospectively collected and maintained in a database: age, gender, weight, BMI, comorbid conditions, surgical approach (SPLC or MPLC), operative time, intra- and postoperative complications, length of hospital stay, pain assessment scores, patient-assessed cosmesis scores, and patient satisfaction scores. Primary and secondary end points of the study were identified and compared between the two groups. Postoperative pain and surgical complications were defined as primary end points. The secondary end points were patient assessed cosmesis scores, patient satisfaction scores, and operating time.

Post-operative pain was assessed by using visual analog scale (VAS) score on day 0 (at 6hrs postoperatively at rest and coughing/straining) and postoperative day 1 (At 24 h postoperatively) of surgery. As a routine pain management protocol, all patients received injection diclofenac 75mg alternately every 8hrs for the first 24hrs after surgery. VAS is a means of measuring subjective characteristics or attributes that cannot be directly measured. We used the VAS score in the form of questionnaires handed over to patients for scoring pain, cosmesis, and overall satisfaction with the surgical procedure. 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

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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. Complications were recorded as intraoperative and postoperative.

RESULTS: SPLC was performed in 40 selected patients between December 2010 and November 2011. Another group of 40 patients with comparable demographic characteristics who underwent traditional MPLC during the same period was selected for comparison. In the SPLC group, conversion was required in 1 of 40 patients. One patient required conversion to MPLC due to CBD injury. 6 patients required additional 2.3mm mini laparoscopic instrument (alligator forceps) through right subcostal margin for gall bladder retraction because of difficulty in exposing Callot's triangle and maintenance of critical angle of safety due to dense adhesions.

The mean VAS scores at rest for pain in MPLC group were higher on day 0 (SPLC 3.38 versus MPLC 4.80, $p=0.0001$) and VAS on coughing/straining was also significantly higher in MPLC group on day 0 (SPLC 3.98 versus MPLC 6.48, $p=0.0001$). VAS on post-operative day 1 was significantly higher in MPLC group (SPLC 2.25 versus MPLC 3.80, $p=0.000$). Post-operative resumption of normal activity was 7.08 days SPLC as compared to MPLC which was 10.83 days ($p=0.0001$).

Intra operative surgical complications were experienced by 9 patients (22.5%) in the SPLC group and by 10 patients (25.00 %) in the MPLC group ($P=0.792$). Post-operative complications were noted in 3(7.5) and 4(10) patients each in SPLC and MPLC respectively ($P=0.692$). The most common complications in the SPLC group gall bladder perforation and bile spillage (5 patients). In the MPLC group, rupture of gallbladder (5 patients) and trocar site bleeding (6 patients) were the most common complications. The perception of cosmetic outcome and satisfaction with body image was 4.78 in SPLC and 2.78 in MPLC group ($P=0.0001$), thereby indicating that patients in the SPLC group were more satisfied with their cosmetic results. The mean duration of hospital stay was 41.65 hours and 36.95 hours in SPLC and MPLC respectively ($P=0.49$). The mean operating time was significantly higher in the SPLC group—SPLC 87.62min, MPLC 58.00 min, ($P=0.001$).

DISCUSSION: Single-incision laparoscopic surgery (SILS) is among the most recent innovations in the field of MAS. The synergy between medical industry, technology, and surgical expertise is driving efforts to devise more patient-friendly approaches to surgery. The rationale of SILS is to reduce surgical trauma of access and provide scar less surgery as the wound of access is most often concealed within the natural umbilical scar. These include single-incision single-port surgery, single incision multiport surgery, and single-incision direct access surgery. The history of SILS dates back to 1997, when Navarra et al.^[2] described the transumbilical technique for cholecystectomy without the use of additional incisions. This was further described by Piskun and Rajpal.^[3] This was further refined and popularized by Podolsky et al.^[4] and published subsequently with their original technique of entry. In their techniques, a skin incision was made at the umbilicus, allowing a flap at the umbilicus to be raised. Further, three to four separate sheath incisions were made 2–3 cm apart in the classical "Mickey Mouse" configuration allowing insertion of three to four trocars.

We took up the study with an aim to compare single-port access laparoscopic cholecystectomy versus multi-port conventional laparoscopic cholecystectomy in relation to safety, efficacy and post-operative morbidity in these two groups of patients. In our study, 80 patients were randomly and equally divided into two groups of 40 patients each. In one group of patients, single-port access laparoscopic cholecystectomy was performed, whereas in the other group, multi-port

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conventional laparoscopic cholecystectomy was carried out. Similar parameters were observed in studies conducted by Mehmood Z, Subhan A, Ali N, et al. (2010);^[5] and Duron VP, Nicastrri GR and Gill PS (2011).^[6]

Regarding operating time which was taken from initial incision to closure of wound was 87.63 ± 26.44 minutes in single-port access group and 58.00 ± 5.96 minutes in multi-port laparoscopic cholecystectomy group [Fig. 2]. In first 14 cases in single-port access laparoscopic cholecystectomy group, mean operating time was 118.1 minutes, while in next 26 cases it became stabilized 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. Similar observations were made in studies comparing the operating time between single-port access and multi-port conventional laparoscopic cholecystectomy and found more prolonged time for single-port access group and the time decreased when the surgeon gained the experience. Solomon D, Bell RL, Duffy AJ, et al. (2010)^[7] in their study of 54 patients reported a significant reduction in operating time from 110 minutes to 65 minutes. 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, Roh YH, Choi HJ, et al. (2011),^[8] where the operating time was more in first 30 cases and less in next 40 cases. Mean operating time in first 30 cases was 91.83 minutes and in other 40 cases it 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 skill to prevent fighting of instruments and camera. Whereas study conducted by Song SC, Ho CY, Kim MJ, et al. (2011)^[9] 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 as 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, Roh YH, Choi HJ, et al. (2011),^[8] because in their first 30 cases when they used articulating instruments, surgeon was uncomfortable with large handle and clashing of instruments. Whereas, Rao PP, Bhagwat SM, Rane A, et al. (2008); Martins MVDC, Skinovsky J, Coelho DE, et al. (2009); and Dapri G, Casali L, Dumont H, et al. (2010)^[10-12] 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 a ergonomic position

We had six cases of adhesions at Calot's triangle required additional mini-laparoscopic devices (allegator, 2.3 mm grasper) for the retraction of gall bladder in order to visualize Calot's triangle [Fig. 3]. Similar 2 mm diameter mini-laparoscopic grasper was used by Song SC, Ho CY, Kim MJ, et al. (2011)^[9] 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.

Conversion to multi-port conventional laparoscopic cholecystectomy or open cholecystectomy should never be regarded as a complication or failure of surgeons but merely as a means of making the operation easier and safe for a successful outcome. This applies also to conversion from conventional laparoscopic cholecystectomy to open. We did not have any conversion from multi-port conventional laparoscopic cholecystectomy to open cholecystectomy. No conversion

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either to conventional or open cholecystectomy has been reported by Rao PP, Bhagwat SM, Rane A, et al. (2008)^[10] in their study of 20 patients.

As far as conversion from single SPLC to MPLC, we had one case in our study where anatomy of Calot's triangle could not be made out and was converted to conventional laparoscopic cholecystectomy. Whereas higher conversion rates has been reported from single incision to conventional laparoscopic cholecystectomy. Ma J, Cassera MA, Spaun GO, et al. (2011)^[13] 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 visualization of Calot's triangle.

In single-port access laparoscopic cholecystectomy group, we had one bile duct injury. It was about 1.5 mm linear tear which was sutured laparoscopically with 3-0 polyglactin 910 without any postoperative sequelae. This patient required two additional 5 mm trocars. Bile duct injuries have been reported in literature. Kravetz AJ, Iddings D, Basson MD, et al. (2009)^[14] 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 visualizing 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 both the groups within 5 cases each. Gall bladder perforation and bile spillage has also been reported by Song SC, Ho CY, Kim MJ, et al. (2011).^[9] They reported bile leakage in 6.2% cases in multiport group and 3.7% cases in single incision laparoscopic cholecystectomy group.

Mean VAS for single-port access laparoscopic cholecystectomy group was 3.3 (± 1.13), whereas in multi-port conventional laparoscopic cholecystectomy it was 4.80 (± 1.44) [Fig. 4]. Patel AG, Murgatroyd B, Carswell K, et al. (2011)^[15] 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, Tsimoyiannis, Konstantinos E, et al. (2010).^[16]

Cosmetic outcome and satisfaction with body image was assessed by using Likert scale. The perception of cosmetic outcome and satisfaction with body image was 4.78 in SPLC and 2.78 in MPLC group (P0.0001). Similarly, Marks J, Tacchino R, Roberts K, et al. (2011)^[17] observed that there was increase in body image satisfaction for single incision laparoscopic cholecystectomy at 3 months (2.4 versus 1.0, $p = 0.009$) as compared to four port laparoscopic cholecystectomy.

This study has shown that single-port access laparoscopic cholecystectomy is as safe and feasible as conventional multiport laparoscopic cholecystectomy. SPA laparoscopic cholecystectomy takes more operating time than, four port conventional cholecystectomy, but with experience it definitely decreases and marginally more than conventional laparoscopic cholecystectomy. It is a patient demanding procedure because of its excellent cosmetic and satisfaction with body image, decreased postoperative pain, early ambulation and return to normal activity as compared to conventional multiport laparoscopic cholecystectomy. It is alternative in the hands of experienced laparoscopic surgeon and can be performed in a safe manner.

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Technique of retraction, instrumentation and exposing Calot's triangle differ significantly as compared to conventional multiport laparoscopic cholecystectomy and it is technically more difficult because of loss of triangulation, clashing of instruments and visualizing Calot's triangle and has learning curve for even experienced laparoscopic surgeon but it is feasible and safe once the learning curve of 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, with confidence that visualization is the same as in multiport laparoscopic cholecystectomy. For safety, surgeon should have less threshold for additional devices wherever required, still retaining benefits of minimal access surgery.

Laparoscopic cholecystectomy has reached an important turning point, with development of single incision laparoscopic surgery. Further effects and research can add improvements wherever necessary.

CONCLUSIONS: The 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 a path, we have not yet realized, and 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. More randomized trials are needed to evaluate the technique for its safety and efficacy.

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Fig. 1: Instruments and telescope inserted through X-cone



Fig. 2: Instruments for single-port access laparoscopic cholecystectomy

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Fig. 3: Graph showing distribution of cases according to operative time in SPA and MPC Laparoscopic cholecystectomy groups.

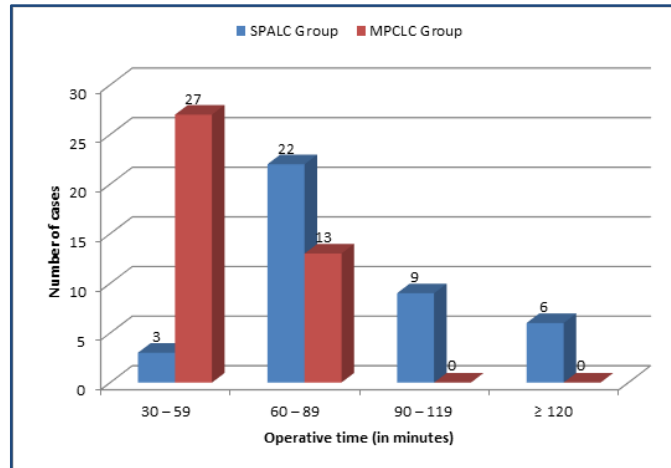


Fig. 3

Fig. 4: Mini-laparoscopic instrument Grasping the Hartman's pouch in difficult dissection.

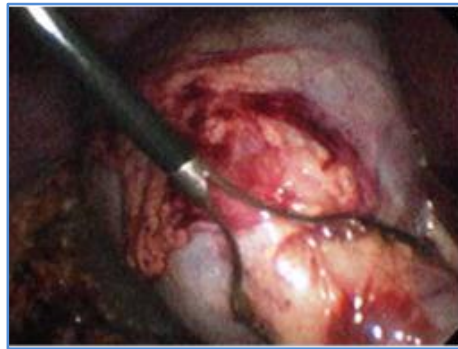


Fig. 4

Fig. 5: Graph showing distribution of cases according to pain on day of surgery at rest in SPA and MPC laparoscopic cholecystectomy groups.

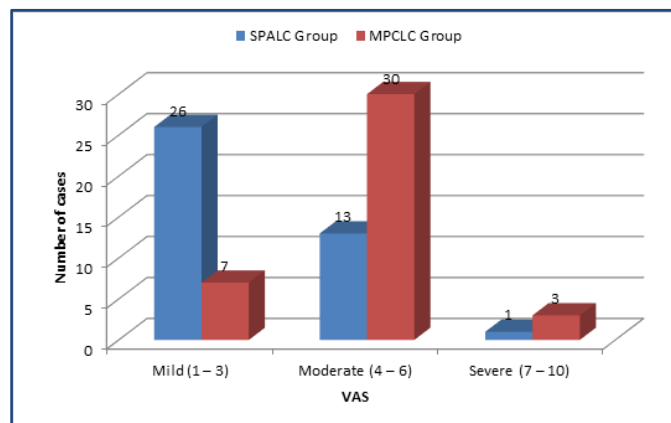


Fig. 5

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