

**COMPARATIVE STUDY BETWEEN SINGLE PORT
LAPAROSCOPIC CHOLECYSTECTOMY VERSUS
CONVENTIONAL LAPAROSCOPIC CHOLECYSTECTOMY**

By

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Dissertation submitted to BLDE UNIVERSITY VIJAYPUR



In partial fulfillment of the requirements for the degree of

MASTER OF SURGERY

In

GENERAL SURGERY

Under the guidance of

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I would like to dedicate this dissertation to my respected teachers of surgery without whom I could not have come this far.

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ABBREVIATIONS

SILS	–	SINGLE INCISION LAPAROSCOPIC SURGERY
CCK	–	CHOLECYSTOKININ
F	–	FEVER
CTD	–	CALOTS TRIANGLE DISSECTION
OA	–	OMENTAL ADHESIONS
AF	–	ADHESIONS AT FUNDUS
GBI	–	GALL BLADDER INJURY
FOUP	–	FOLLOW UP
AD	–	ADHESIONS
CBDI	–	COMMON BILE DUCT INJURY
BL	–	BILIARY LEAK
DOA	–	DATE OF ADMISSION
DOO	–	DATE OF OPERATION
DOD	–	DATE OF DISCHARGE
IOC	–	INTRA OPERATIVE COMPLICATION
PODC	–	POST OPERATIVE DAY COMPLICATION
LOHS	–	LENGTH OF HOSPITAL STAY

ABSTRACT

Background and objectives

Single incision laparoscopic cholecystectomy has gained popularity due to its advantages over conventional laparoscopic cholecystectomy. It is superior to conventional laparoscopic cholecystectomy in minimizing the operative scar. In this study we compared SILS with conventional laparoscopic cholecystectomy (LC).

Materials and methods

A prospective comparative study of 65 patients was done during the period of Oct 2013 – July 2015 who presented to hospital with Acute cholecystitis, Chronic cholecystitis, Cholelithiasis i.e. in conventional laparoscopic cholecystectomy (n = 45) and in Single Incision Laparoscopic Cholecystectomy (n = 20).

Results and Observations

Sixty five patients that were studied prospectively presenting with Calculous and Acalculous cholecystitis and divided in two groups 45 cases in conventional four port and 20 cases in SILS. In conventional four port group total male patients were 51.1% (n=23) and females 48.9% (n=22) in single port 60.0% (n=12) and females 40% (n=8) and time taken for surgery in single port is 129.0 min with standard deviation of 40.2 min and in conventional four port is 64.4 min with standard deviation of 28.8 and length of hospital stay was more in SILS 7.1 days compared with four port and complications were more in single port 35.0% (n=7) than in conventional four port is 15.6% (n=7). Intra operative complications like difficulty in dissecting Calot's triangle, iatrogenic injury to gallbladder, difficulty in dissecting dense

adhesions, injury to CBD which was short and Conversion rate was more in SILS compared with conventional four port.

Conclusion

From this study we conclude that Single Incision Laparoscopic Cholecystectomy (SILS) are an emerging technique and has better cosmesis however owing to its difficult technique and time consuming procedure when away from midline and high conversion rate, needs expertised hands and lot of learning curve when compared to Conventional Laparoscopic Cholecystectomy.

Key Words: SILS, Cholecystectomy, cosmesis, conversion rate, learning curve, Conventional laparoscopy.

TABLE OF CONTENTS

Sl. No.	Contents	Page No.
1.	INTRODUCTION	1
2.	AIMS AND OBJECTIVES	10
3.	REVIEW OF LITERATURE	11
4.	MATERIALS AND METHODS	34
5.	RESULTS AND ANALYSIS	36
6.	DISCUSSION	51
7.	SUMMARY	55
8.	CONCLUSION	57
9.	BIBLIOGRAPHY	58
10.	ANNEXURE ETHICAL CLEARANCE CONSENT FORM PROFORMA KEY TO MASTER CHART MASTER CHART	63

LIST OF TABLES

Sl. No	TABLES	Page No.
1.	Percent distribution of Age among total patients	36
2.	Percent distribution of Gender among total patients	37
3	Distribution of Ports	39
4	Association of Age by cases and controls	40
5	Association of Gender by cases and controls	41
6	Mean Duration by cases and controls	42
7	Mean LOHS by cases and controls	43
8	Association of Duration (min) by cases and controls	44
9	Association of Complications by cases and controls	45
10	Association of Complications by cases and controls	46
11	Association of Conversions by cases and controls	47
12	Association of IOC by cases and controls	48
13	Association of PODC by cases and controls	49
14	Association of LOHS (days) by cases and controls	50

LIST OF GRAPHS

SI No	Contents	Page No.
1.	Percent distribution of Age among total patients	36
2.	Distribution of Gender among total patients	37
3.	Percent distribution of Gender among total patients	38
4.	Distribution of Ports	39
5	Association of Age by cases and controls	40
6	Association of Gender by cases and controls	41
7	Mean Duration by cases and controls	42
8	Mean LOHS by cases and controls	43
9	Association of Duration (min) by cases and controls	44
10	Association of Complications by cases and controls	45
11	Association of Complications by cases and controls	46
12	Association of Conversions by cases and controls	47
13	Association of IOC by cases and controls	48
14	Association of PODC by cases and controls	49
15	Association of LOHS (days) by cases and controls	50

LIST OF FIGURES

Sl No	Contents	Page No.
1.	Calots Triangle	4
2.	Anamolies of Gall Bladder and Cystic Duct	5
3.	Pigment Stones	6
4.	Cholesterol Stones	6
5	Instruments for conventional laparoscopy	27
6	Showing port placement for Four Port	27
7	Showing Calots Triangle	28
8	Showing clipping of Cystic Duct and Cystic artery	28
9	Showing division of Cystic Duct and Cystic artery	29
10	Showing detachment of Gallbladder from Liver Bed	29
11	Showing extraction of Gallbladder	30
12	Showing sutured wound for Four port	30
13	Instruments for SILS	32
14	Showing incision for single port	32
15	Showing EK Glove Port	33
16	Showing sutured wound for single port	33

INTRODUCTION

Gallstone disease is one of the most common problems affecting the digestive tract. Autopsy reports have shown a prevalence of gallstones from 11 to 36%¹. The prevalence of gallstones is related to many factors, including age, gender, and ethnic background. The prevalence of gallstone varies widely in different parts of the world. It is estimated that at least 20 million people in the United States have gallstones and that approximately 1 million new cases of cholelithiasis develop each year. In India it is estimated to be around 4%. An epidemiological study restricted to rail road workers showed that north Indians have 7 times higher occurrence of gallstones as compared to south Indians². Changing incidence in India is mainly attributed to westernization of diet, change in socioeconomic structure and availability of ultrasound as investigation in both rural and urban areas. As Carl Langenbuch so aptly stated “The gallbladder should be removed not because it contains stones, but because it forms them”.

Surgical removal of gall bladder has been the gold standard for treatment of gall stones since it was described in 1882 by Carl Langenbuch. Open surgery, laparoscopic cholecystectomy and now single incision laparoscopic surgery for cholecystectomy has become routine approach³.

Laparoscopy laid the milestones and various open surgeries were done by laparoscopy. Furthermore, in order to keep the incision to minimum number of ports for laparoscopy, which gives way to Single Incision access surgery⁴.

Soon after introduction of laparoscopic surgery the idea of no scar surgery gripped the surgeons all over the world. Various natural orifices like umbilicus, vagina are being used as portals for surgery. Termed as single port access

surgery(SPA), also known as single incision laparoscopic surgery (SILS) or one port umbilical surgery (OPUS) or single port incisionless conventional equipment-utilizing surgery (SPICES) or natural orifice transumbilical surgery (NOTUS) is a novel technique which promises all advantages of reduced postoperative morbidity and almost invisible scar ⁵.

e-NOTES (Embryonic Natural Orifice Transumbilical Endoscopic Surgery) is a technique in which incision is made directly through the umbilicus, which is defined as natural embryonic scar. Therefore, the procedure is called e-NOTES (Embryonic Natural Orifice Transumbilical Endoscopic Surgery). In most cases , the scar is not visible after 2 weeks , especially in patients with deep umbilicus. It has more and more important for patients to undergo surgery with no scar or at least very small ones⁶.

SILS can be performed using (a) One of the many commercially available multichannel single-port devices: R-port (Advanced Surgical Concepts, Dublin, Ireland), XCONE (Karl Storz, Tuttlingen, Germany), SILS port (Covidien), and SPIDER (Trans Enterix, Durham, NC, USA); (b) Passing three 5mm trocars side by side through the fascia via a single umbilical incision; (c) Using an extra-small wound retractor (ALEXIS wound retractor XS, Applied Medical) and a surgical glove as the “single port” through the umbilical incision⁴.

Anatomy :

The gallbladder is a biliary reservoir which lies against the inferior surface of segments IV and V of the liver, which makes an impression against it and peritoneal layer covers most of the gallbladder except for the portion adherent to the liver. The gallbladder is adherent to the liver, in a layer of fibroconnective tissue known as the cystic plate, which is an extension of the hilar plate¹³. It is pear-shaped which measures about 7.5-12 cm long with capacity of about 25-30 ml and is divided into three parts fundus, body and neck that terminates in a narrow infundibulum and mucous membrane contains indentations of the mucosa that sink into the muscle coat known as crypts of Luschka¹⁴. The fundus usually projects slightly beyond the liver edge anteriorly and folded on itself known as a Phrygian cap. The body of the gallbladder is usually in close proximity to the second portion of the duodenum and the transverse colon. The infundibulum (or Hartmann's pouch) hangs forward along the free edge of the lesser omentum and can fold in front of the cystic duct. The portion of gallbladder between the infundibulum and the cystic duct is the neck of the gallbladder⁷.

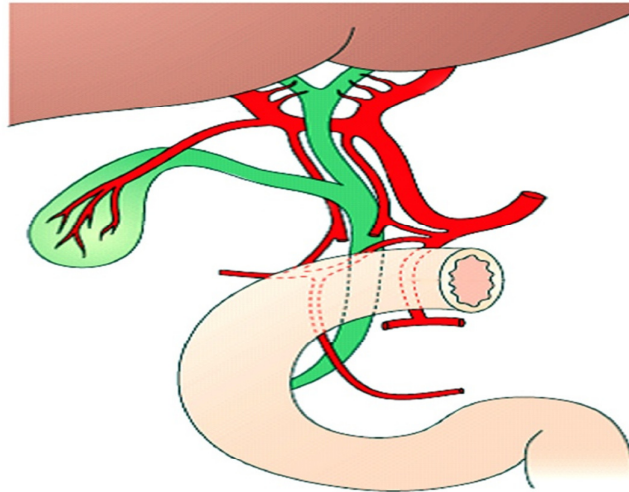


Figure 1 : Calots Triangle

The intrahepatic bile ducts are terminal branches of the right and left hepatic ductal branches that invaginate Glisson's capsule at the hilum along with corresponding portal vein and hepatic artery branches, forming the peritoneal covered portal triads. The main right hepatic duct bifurcates just above the right portal vein. The short right hepatic duct meets the longer left hepatic duct, forming the confluence anterior to the right portal vein, constituting the common hepatic duct.

The common hepatic duct drains inferiorly, and below the takeoff of the cystic duct is referred to as the common bile duct. The cystic duct is variable in its length and its insertion into the main biliary tree and measures about 3 cm in length and 1-3 mm in diameter. The first portion of the cystic duct is usually tortuous and contains mucosal duplications, referred to as the fold of Heister, that regulate the filling and emptying of the gallbladder and the cystic duct joins the hepatic duct to form the common bile duct which measures about 10-15 cm long and 6mm in diameter⁷.

Anamolies of Gall Bladder and Cystic Duct⁷:

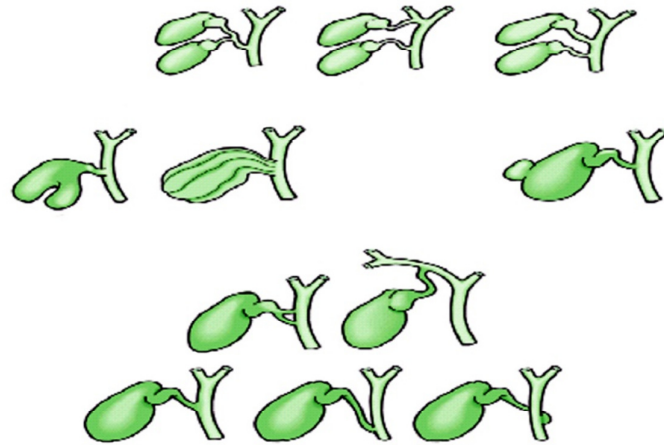


Figure 2 : Anamolies of Gall Bladder and Cystic Duct

- Anamolies of gallbladder are rare
 - Agenesis of gallbladder, bilobar gallbladder with two ducts or single ducts, sepetations
 - Congenital diverticulum of gallbladder
- The position and entry of cystic duct into main ductal system is variable
 - Double cystic duct drainig unilocular gallbladder and drainage into hepatic duct branches.
 - Cystic duct joins common hepatic duct at an angle, but can run parallel and enter more distally.
 - Cystic duct can fuse to hepatic duct along its parallel course by connective tissue.
- Cystic duct can run a spiral course anteriorly or posteriorly and enter the left side of common hepatic duct.
- Cystic duct can be short or absent.

Cholelithiasis:

Gallstones are the most common biliary pathology. It is estimated that gallstones are present in 10–15% of the adult population in the USA. They are asymptomatic in the majority (> 80%). In the UK, the prevalence of gallstones at the time of death is estimated to be 17% and may be increasing. Approximately 1–2% of asymptomatic patients will develop symptoms requiring cholecystectomy per year. To become symptomatic the gallstones must obstruct a visceral structure such as cystic duct, tends to occur at meal, in which secretion of CCK leads to gallbladder contraction. Gallstones can be divided into three main types: cholesterol, pigment (brown/black) or mixed stones⁸.

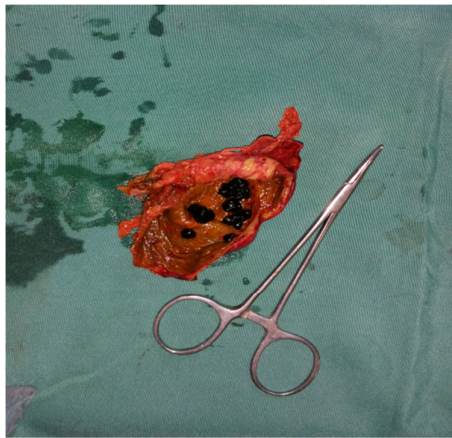


Figure 3 : Pigment Stones

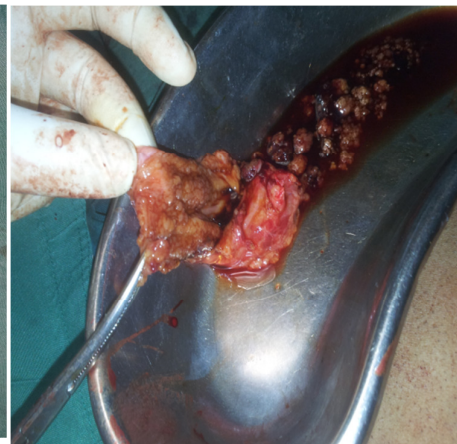


Figure 4 : Cholesterol Stones

Most patients will remain asymptomatic from their gallstones throughout life. Certain conditions predispose to the development of gallstones like obesity, pregnancy, dietary factors, Crohn's disease, terminal ileal resection, gastric surgery, hereditary spherocytosis, sickle cell disease, and thalassemia are all associated with an increased risk of developing gallstones. Women are three times more likely to

develop gallstones than men, and first-degree relatives of patients with gallstones have a two-fold greater prevalence¹.

For unknown reasons some patients progress to a symptomatic stage, with biliary colic caused by a stone obstructing the cystic duct. Symptomatic gallstone disease may progress to complications related to the gallstones. These include acute cholecystitis, choledocholithiasis with or without cholangitis, gallstone pancreatitis, cholecystocholedochal fistula, cholecystoduodenal fistula, cholecystoenteric fistula leading to gallstone ileus, and gallbladder carcinoma. Rarely, complication of gallstones is the presenting picture.

Gallstones in patients without biliary symptoms are commonly diagnosed incidentally on ultrasonography, Computed Tomography scans, abdominal radiography, or at laparotomy. Several studies have examined the likelihood of developing biliary colic or developing significant complications of gallstone disease. Approximately 3% of asymptomatic individuals become symptomatic per year (i.e., develop biliary colic)¹. Once symptomatic, patients tend to have recurring bouts of biliary colic. Complicated gallstone disease develops in 3 to 5% of symptomatic patients per year¹.

In the era of laparoscopic cholecystectomy inadvertent opening of gall bladder with spillage of stones is not infrequent, occurring in 20 to 40% of cholecystectomies. Risk factors for intraoperative perforation of gallbladder include cholecystitis, presence of pigment stones, number of stones (>15) and can lead to complications like abscess in the abdominal wall, broncholithiasis, stone expectoration, cellulites, fat necrosis posterior to the rectus muscle, fistula formation, gallstone granuloma, granulomatous peritonitis mimicking endometriosis, ileus, intestinal obstruction, liver

abscess mimicking malignancy, middle colic artery thrombosis, port site stones, port site abscess, recurrent staphylococcal bacteremia, trans diaphragmatic abscess. Careful dissection should be done making sure not to cause gallbladder perforation, Suctioning out gallbladder content prior to starting dissection in a fully distended turgid gallbladder, use of appropriate instruments such as nontoothed graspers, diligent application of clips to close the cystic duct wall, liberal use of irrigation and endobags to avoid port-site complications to avoid spillage of stones and treatment should include extensive irrigation, significant attempt to retrieve lost stones, a course of antibiotics^{15,18,19,20,21}. Over a 20-year period, about two thirds of asymptomatic patients with gallstones remain symptom free¹.

Now laparoscopic cholecystectomy (LC) is considered the treatment of choice for cholelithiasis. It has advantages over traditional open cholecystectomy in terms of minimal post operative pain, shorter hospital stay, better cosmetics and early recovery⁹.

Single-incision laparoscopic surgery (SILS) is an area of current investigation for laparoscopic surgery¹. A number of advantages of single-incision laparoscopic cholecystectomy (SILC) have been proposed, such as cosmesis (scarless cholecystectomy) and ability to convert to standard four-port laparoscopic surgery when needed¹⁰. A few different methods have been described for trocar access to perform SILC, including transumbilical single-port access.

With growing experience and overcoming the learning curve, selection criteria have become more liberal. Most of the previous contraindications such as morbid obesity and previous upper abdominal surgery are no longer absolute contraindications. Attempts can be made in all cases of gall stone diseases with

laparoscopic procedure except for patients with bleeding diathesis, carcinoma gallbladder and patients not fit for general anaesthesia.

However, of all Laparoscopic cholecystectomies, 1-13% requires conversion to an open for various reasons². Thus, for surgeons it would be helpful to establish criteria that would assess the risk of conversion preoperatively. This would be useful for informing patients and a more experienced surgical team could be assembled when risk for conversion appears significant .

AIMS AND OBJECTIVES OF THE STUDY

To compare outcome between single incision laparoscopic cholecystectomy and conventional laparoscopic cholecystectomy in terms of

- Duration of surgery
- Duration of requirement of post-operative analgesia.
- Duration of post-operative hospital stay.
- Intra-operative complications.
- Post-operative complications.
- Cosmesis.
- Convalescence period.

REVIEW OF LITERATURE

- Brittney L. Culp, Veronica E. Cedillo¹¹ and others conducted a retrospective study between Single-incision laparoscopic cholecystectomy versus traditional four-port cholecystectomy who underwent laparoscopic cholecystectomy from April 2008 to August 2011 in the Department of Surgery, Baylor University Medical Center at Dallas concluded that single-incision transumbilical laparoscopic cholecystectomy can be an effective alternative to traditional four-port laparoscopic cholecystectomy, with the added benefit of minimized scarring and a shorter length of stay. A longer operative time may be needed initially to adjust for a learning curve.
- Pankaj Garg, Jai Deep Thakur, Mahak Garg¹² and others conducted a study in Single-Incision Laparoscopic Cholecystectomy vs Conventional Laparoscopic Cholecystectomy: A Meta-analysis of Randomized Controlled Trials and data collected from Pubmed, Ovid, Embase, SCI database, Cochrane, and Google Scholar were searched in August 2012 concluded that Single-incision laparoscopic cholecystectomy does not confer any benefit in postoperative pain (6 and 24 h) and hospital stay as compared to conventional laparoscopic cholecystectomy while having significantly better cosmetic results at the same time. Postoperative complications, though higher in SILC, were statistically similar in both the groups.
- Eric C. H. Lai, George P, C Yang, Chung Ngai Tang¹³ and others conducted a prospective randomized comparative study of single incision laparoscopic cholecystectomy versus conventional four-port laparoscopic cholecystectomy from November 2009 to August 2010, 51 patients with symptomatic gallstone

or gallbladder polyps concluded that SILC was feasible and safe for properly selected patients in experienced hands.

- Stephen Kin Yong Chang ,Yi Liang Wang Liang Shen¹⁴ and others conducted a study on , A Randomized Controlled Trial Comparing Post-operative Pain in Single-Incision Laparoscopic Cholecystectomy Versus Conventional Laparoscopic Cholecystectomy from October 2010 and March 2012 concluded that SILC has improved short-term pain outcomes compared to LC and is not inferior in both short-term and long-term pain outcomes. The operating time is longer, but remains feasible in routine surgical practice.
- Liangyuan Geng, Changhua Sun¹⁵ and others conducted a study Single Incision versus Conventional Laparoscopic Cholecystectomy Outcomes: A Meta-Analysis of Randomized Controlled Trials from January 1997 to February 2013, SILC was the preferred procedure for the treatment of uncomplicated gallbladder stones and polyps, as it was associated with a better cosmetic result and less postoperative pain. There was not enough data to support SILC as the standard of care as it was associated with longer operating time and more frequently required additional instruments. A large prospective double-blind randomized controlled trial comparing SILC and CLC is needed to identify the best procedure. The presence of a learning curve for the surgeons needs to be accounted for.
- Culp BL, Cedillo VE, Arnold DT¹⁶ conducted a study Single-incision laparoscopic cholecystectomy versus traditional four-port cholecystectomy from April 2008 to August 2011 concluded that single-incision transumbilical laparoscopic cholecystectomy can be an effective alternative to traditional four-incision cholecystectomy, with the added benefit of minimized

scarring and a shorter length of stay and longer operative time may be needed initially to adjust for a learning curve.

- Zahid Mehmood, Anissubhan, Nasirali¹⁷ and others conducted a study Four Port versus Single Incision Laparoscopic Cholecystectomy from October 2009 to March 2010 concluded that SILS is a promising alternate method to conventional four port laparoscopic surgery. The major advantage of this was cosmesis but in this series, more pain, prolonged hospital stay and wound infection were major limitations.
- Muhammad S. Sajid, Nikhil Ladwa, Lorain Kalra¹⁸ and others conducted a study Single-Incision Laparoscopic Cholecystectomy Versus Conventional Laparoscopic Cholecystectomy: Meta-analysis and Systematic Review of Randomized Controlled Trials from November 2011 concluded that SILC does not offer any advantage over CLC for treating benign gallbladder disorders. CLC may be used assiduously for this purpose.
- A Prasad, K A Mukherjee¹⁹ and others conducted a study Postoperative pain after cholecystectomy: Conventional laparoscopy versus single-incision laparoscopic surgery from 1 September 2009 to 30 May 2010 concluded that there was no significant difference in the overall postoperative pain as operative time decreases with surgeon's experience in single incision laparoscopic cholecystectomy, postoperative pain at 8 hours appears to favour this method over conventional laparoscopic cholecystectomy.
- Osuagwu CC²⁰ conducted a study Review of Randomized Controlled Trials comparing Single Port Laparoscopic Cholecystectomy with Conventional Laparoscopic Cholecystectomy from 1st January 2009 to 20th February 2013 concluded that randomized controlled trial that were available were relatively

few, and the sample sizes were small, this may explain the failure to detect statistically significant differences in many of the safety criteria evaluated. However, improved cosmesis is the most consistent benefit derived from the trials, it is also noteworthy that bile duct leaks were low and no mortality was reported. These remarkably good outcomes may be spurious considering the meticulous criteria adopted in selecting the patients that participated in this study. Large scale multicenter trials are needed to challenge the findings in this review.

- Sigi Joseph, B. Todd Moore, G. Brent Sorensen²¹ conducted a study Single-incision laparoscopic cholecystectomy: A comparison with the gold standard from January 2008 to May 2009 concluded that Single-incision LC is safe, significantly reduces the hospital stay, and is an acceptable alternative to traditional LC. Although further study is warranted, initial results indicate that SILC may offer the most benefit for outpatient procedures.
- Muhammad Umer Ahmed, Azib Aftab, Haseeb Munaf Seriwala²² and others conducted a study Can Single Incision Laproscopic Cholecystectomy Replace the Traditional Four Port Laproscopic Approach: A Review from May 22, 2014, concluded that this minimally invasive procedure has been compared more and more to the normal method of 4PLC. While the cosmetic result of SILC is appreciated over that of 4PLC, SILC has yet to become the gold-standard procedure for surgical removal of gallbladder. It is non conclusive as to whether SILC is faster or slower in operative time as compared to 4PLC, due to the reported decrease in mean operative time as experience is gained , whereas others reported higher mean operative times. Also, due to the lack of a large number of randomized trials the complications associated with this

surgical method cannot be fully comprehended. Patient safety hasn't been confirmed in SILC nor has there been a clear indication of less post-operative pain after SILC because of the difficulty in measuring pain. Standardization and further randomized trials are required for surgeons around the world to verify whether or not SILC can substitute 4PLC. The increased reports will help in arriving to a verdict about certain areas which are currently inconclusive. Hence, SILC is a procedure still in the progress of being established in the surgical field of minimally invasive surgery.

- Renato A, Luna, Daniel B. Nogueira²³ and others conducted a study A prospective, randomized comparison of pain, inflammatory response, and short-term outcomes between single port and laparoscopic cholecystectomy from January 2010 to December 2010 Single-incision laparoscopic surgery does not significantly reduce systemic inflammatory response, postoperative pain, or analgesic use compared with conventional laparoscopic cholecystectomy.
- Fatima Khambaty, Fred Brody, Khashayar Vaziri²⁴ and others conducted a study Laparoscopic Versus Single-Incision Cholecystectomy from August 2008 to March 2010 concluded patients that undergo a successful single-incision laparoscopic cholecystectomy require fewer narcotics postoperatively and have a shorter LOS. Although this data is intriguing, the overall utility of single-incision procedures requires more analysis and potentially randomized trials.
- Markus J, Wagner, Hans Kern, Alexander Hapfelmeier²⁵ conducted a study Single-Port Cholecystectomy Versus Multi-Port Cholecystectomy: A Prospective Cohort Study with 222 Patients from June 2009 and December

2011 concluded that SPA (single port access) cholecystectomy is safe, although the operation is significantly longer. No differences in terms of major complications or the incidence of incisional hernia were seen after 1 year. Quality of life was significantly better in patients operated on with the SPA technique.

- Melissa S. Phillips, Jeffrey M. Marks, Kurt Roberts²⁶ and others conducted a study Intermediate results of a prospective randomized controlled trial of traditional four-port laparoscopic cholecystectomy versus single-incision laparoscopic cholecystectomy from May 2011 concluded that randomized controlled trial of SILC versus 4PLC, SILC appears to be safe with a similar biliary complication profile. Pain scores and wound complication rates are higher for SILC, however cosmesis scores favored SILC. For patients preferring a better cosmetic outcome and willing to accept possible increased postoperative pain, SILC offers a safe alternative to the standard 4PLC. Further follow-up is needed to detail the long-term risk of wound morbidities, including hernia recurrence.
- A. Sharma, V. Soni, M. Baijal²⁷ and others conducted a study Single Port Versus Multiple Port Laparoscopic Cholecystectomy—A Comparative Study from May 2010 to March 2011 concluded that advantages of SPLC are improved cosmesis and greater patient satisfaction. However, since SPLC is an emerging technique, it needs to be proved efficacious with a high safety profile to be considered a standard laparoscopic technique. More randomized trials are needed to evaluate the technique for its safety and efficacy.
- Daniel J. Ostlie, Obinna O, Adibe David Juang, Corey W. Iqbal²⁸ and others conducted a study Single incision versus standard 4-port laparoscopic

cholecystectomy: A prospective randomized trial from August 2009 to July 2011 concluded that Single site laparoscopic cholecystectomy produces longer operative times with a greater degree of difficulty as assessed by the surgeon. There was a trend toward more doses of post-operative analgesics and greater hospital charges with the single site approach.

- Elbert Khiangte, IheuleNewme, Karabi Patowary²⁹ and others conducted a study Single-Port Laparoscopic Cholecystectomy using the Innovative E. K. Glove Port: Our Experience from September 2009 to December 2011 concluded that SPLC appears to be cosmetically superior to standard laparoscopic cholecystectomy. We utilize the body's natural scar, the umbilicus to create a scar. SPLC technique with the innovative E. K. glove port is simple, reusable, costeffective, safe, reproducible, and a reliable gadget for single port cholecystectomy. It may be an alternative to the costly, commercially available single-port system, especially in a developing country like India. The operating time was reasonable and can be lessened with experience. The SPLC procedure using the E. K. port is becoming the standard of care for most of the authors' elective patients with gallbladder diseases.
- Homero Rivas, Esteban Varela, Daniel Scott³⁰ conducted a study Single-incision laparoscopic cholecystectomy: Initial evaluation of a large series of patients from January 2008 to March 2009 concluded that SILC technique with a two-trocar technique is safe, feasible, and reproducible. The operating times are reasonable and can be lessened with experience. Even complex cases can be managed with this technique.
- Maryam N Saïdy, Michele Tessier³¹ and others conducted a study Single-Incision Laparoscopic Surgery—Hype or Reality: A Historical Control Study

from March 2009 to February 2010 concluded that the most important factor for success with SILS is likely in judicious patient selection criteria.

- Tomohiko Adachi, Tatsuya Okamoto, Shinichiro Ono³² and others conducted a study Technical Progress in Single-Incision Laparoscopic Cholecystectomy in Our Initial Experience from January 2011 concluded that LC has reached an important turning point with the development of single-incision laparoscopic surgery. Further efforts and research will bring about improvements in SILC; however, it is crucial that we are able to assure that the procedure is as safe as 4-port LC. Also, especially in the early use of this procedure, we have to adopt strict criteria and select ideal patients.
- Pratibha Vemulapalli, Emmanuel Atta Agaba, Diego Camacho³³ conducted a study Single incision laparoscopic cholecystectomy: A single center experience from May 2008 to June 2010 concluded that SILS is technically challenging with a steep learning curve. Once mastered, operative time is comparable with conventional 4-port laparoscopic cholecystectomy. Early results indicate that it is cosmetically acceptable to patients and has high satisfactory index.
- Ramon Vilallonga, UmutBarbaros, Aziz Sumer³⁴ and others conducted a study Single-port transumbilical laparoscopic cholecystectomy: A prospective randomised comparison of clinical results of 140 cases from July 2009 and March 2010 concluded that Single-port transumbilical laparoscopic cholecystectomy can be feasible and safe. When technical difficulties arise, early conversion to a standard laparoscopic technique is advised to avoid serious complications. The SPA approach can be undertaken without the expense of additional operative time and provides patients with minimal

scarring. The cosmetic results and the degree of satisfaction appear to be significant for the SPA approach.

- Daniel Solomon, Robert L. Bell, Andrew J. Duffy³⁵ conducted a study Single-port cholecystectomy: small scar, short learning curve from November 2007 and August 2009 concluded that significant improvement in operative times after the first quintile followed by consistent results without subsequent variability suggests that the learning curve for the single-port cholecystectomy, in the hands of a fellowship-trained laparoscopic surgeon, is approximately ten cases.

HISTORICAL VIEW³:

- Gall stones have troubled humanity since ancient times. The earliest known gallstones date back to twenty first Egyptian dynasty (1085 – 945 B.C.) They were found in a mummy of a priestess of Amen.
- Alexander Trallianus (525 – 605 AD) a Greek physician was the first person to describe stones in the gall bladder and bile duct.
- Jean Ferri (1558 A.D.) provided a description of the physical characteristics of gall stones and noted that a calculus from gallbladder does not sink in water as that which is voided from the kidney or the urinary bladder.
- The first systematic data about the disease was published as “De Medical Historic Mirabilis” by Marcellus Donatus in 1596.
- Zambecari in 1636 performed cholecystectomy in a dog.
- Joenisius (1676 A.D.) first extracted gall stones through a biliary fistula that had formed from spontaneous drainage of an abdominal wall abscess.
- Power, Jean Louis Petit (1674 – 1760) observed that a gallbladder could become adherent to the abdominal wall and suggested that in such a condition it could be punctured through the abdominal wall by a trocar. Through the trocar a sound could be passed and if it gave the feeling of stones, the wound could be enlarged with a knife and the stones removed through the trocar and canula.
- Albrecht Von Haller (1708 - 1777) gave an accurate description of gall stones found at autopsy, describing the condition of the gall bladder, the bile ducts and the different kinds of bile associated with stones.

- The first cholecystectomy is credited to John Strong Bobbs on June 15, 1867.
- Kocher (1878 A.D.) performed a successful cholecystectomy for empyema gall bladder.

HISTORY OF LAPAROSCOPY AND LAPAROSCOPICCHOLECYSTECTOMY (LC):^{3,36}

- Karl Langenbuch of Berlin performed first planned cholecystectomy on July 15, 1882 using the aseptic technique of Joseph Lister.
- Laparoscopy took its origin in 1901 when George Kelling examined the abdominal cavity with an endoscope and named the procedure as celioscopy. He used air through a puncture needle to produce pneumoperitoneum.
- In 1929, Kalk introduced purpose designed instruments and was the first to advocate dual trocar technique which opened the way for diagnostic and therapeutic laparoscopy.
- In 1933, Fervers reviewed his experience with 50 patients and recommended changing from room air to oxygen or carbon dioxide as an insufflating agent.
- In 1938, Janos Veress Developed his spring loaded needle, the instrument of choice for creating pneumoperitoneum which remains almost unchanged to the present day.
- In 1960, Professor Kurt Semm in Germany developed an automatic insufflation device that monitored abdominal pressure and gas flow. He also developed a number of endoscopic instruments including thermo coagulation, angled lens, hook scissors, uterus vacuum mobiliser and endo-loop applicator. He developed irrigation - aspiration apparatus with modification to prevent

tube clogging and also popularized many laparoscopic procedures. He also facilitated laparoscopic training by creating the pelvi-trainer designed to demonstrate techniques required for operative laparoscopy.

- The first laparoscopic cholecystectomy was by Prof Dr Med Erich Muhe of Boblingen, Germany in 1985, this procedure overtook open cholecystectomy as the treatment of choice in cholelithiasis³⁷.

The 3 most important, basic instruments used in the first laparoscopic cholecystectomy were the laparoscope, hemoclip and pistol grip scissors. The laparoscope had been used by gynecologists for many years for diagnostic purposes before the general surgeon Muhe initiated laparoscopic cholecystectomy³⁸.

- In 1991, Tehemton Udwardia performed the first laparoscopic cholecystectomy in India.
- In 1992, The National Institute of Health (NIH) consensus development conference stated that laparoscopic cholecystectomy “provides a safe and effective treatment for most patients with symptomatic gallstones”¹⁰.
- In 1997, Navarra et al. first described one-wound laparoscopic cholecystectomy, and in 1999, Piskun and Rajpal performed SILS by inserting two trocars through the umbilical incision and putting additional stay sutures to retract and stabilize the gallbladder.
- Elbert Khiangte, Iheule Newme and others conducted a study of Single-Port Laparoscopic Cholecystectomy using the innovative E. K. Glove Port²⁹.

LAPAROSCOPIC CHOLECYSTECTOMY³⁹

LC is one of the most common surgeries performed and has replaced open cholecystectomy. Since the introduction of laparoscopic cholecystectomy, the number of cholecystectomy performed in the United States has increased from 5 lakh per year to 7 lakh per year²⁰.

INDICATIONS OF LAPAROSCOPIC CHOLECYSTECTOMY³⁶

a) Symptomatic cholelithiasis

- i. Biliary colic: Once the patient experiences symptoms, there is a greater than 80% chance that they will continue to have symptoms. There is also a finite risk of disease-related complications such as acute cholecystitis, gallstone pancreatitis and choledocholithiasis.
- ii. Acute cholecystitis.
- iii. Gallstone pancreatitis.

b) Asymptomatic cholelithiasis

Patients with asymptomatic gallstones have less than 20% chance of ever developing symptoms, and the risks associated with prophylactic operation outweigh the potential benefit of surgery in most patients⁷. Therefore prophylactic cholecystectomy is recommended in

- i. Sickle cell disease: Patients with sickle cell disease often have hepatic and vaso-occlusive crisis that can be difficult to differentiate from acute cholecystitis⁹.
- ii. Patients on total parenteral nutrition.

- iii. Chronic immunosuppression: In transplant patients, there is a concern that immunosuppression may mask the signs and symptoms of inflammation until overwhelming infection occurred³⁹.
 - iv. No immediate access to health care facilities (eg: missionaries, military personnel, peace corps workers, relief workers)
 - v. Incidental cholecystectomy for patients undergoing procedures for other indications.
- c) Acalculous cholecystitis or biliary dyskinesia
- d) Gallbladder polyps >1 cm in diameter.
- e) Porcelain gallbladder.

CONTRAINDICATIONS TO LAPAROSCOPIC CHOLECYSTECTOMY³⁶

ABSOLUTE

- 1) Unable to tolerate general anesthesia.
- 2) Refractory coagulopathy.
- 3) Suspicion of carcinoma

RELATIVE

- 1) Previous upper abdominal surgery
- 2) Cholangitis
- 3) Diffuse peritonitis with hemodynamic compromise
- 4) Cirrhosis or Portal hypertension

Brittle, friable liver that may be difficult to retract in cephalad direction, associated coagulopathy and due to abnormal portosystemic venous shunts in portal hypertension.

- 5) Cholecystoenteric fistula
- 6) Morbid obesity is a contraindication due short trocar length and sheath designs making institution of pneumoperitoneum problematic.
- 7) Chronic obstructive pulmonary disease .
- 8) Pregnancy.

Due to unknown effect of carbon dioxide on foetus-therefore avoided in first trimester. Open insertion of port or location of initial port in right upper quadrant to avoid damage to uterus. Maintenance of pneumoperitoneum to <12 mm of Hg and maternal hyperventilation with monitoring of PCO₂ is needed to avoid fetal acidosis.

PROCEDURE FOR CONVENTIONAL FOUR PORT LAPAROSCOPY TECHNIQUE

The abdominal cavity is entered under direct vision and once the peritoneal cavity is entered, the initial trocar is inserted and its position is secured . The abdominal cavity can then be insufflated with carbon dioxide gas of 10 to 12mm Hg.

Equipment

- a) High-quality 30 degree videoscope 10 mm with a 300 w light source coupled to high-resolution monitor.
- b) High-flow carbon dioxide insufflator.
- c) Four trocars: 10 mm trocars - 2 and 5 mm trocars - 2.

d) Hand instruments: Monopolar electrode, c-hook, suction and irrigation, a fine tipped dissector, two gallbladder grasper, a pair of scissors and a medium to large hemoclip applicator.

Procedure:

Incision is made in supraumbilical region measuring about 3cm for insertion of primary trocar i.e 10mm and trocar placed in screwing motion and pneumoperitoneum of about 12mm Hg is created and 30 degree scope is inserted through primary trocar.

Epigastric port i.e 10mm is inserted below the costal margin and next trocar inserted in right midclavicular line i.e 5mm below the costal margin and the last port placed in anterior axillary line 5 to 6 cm below the costal margin under vision.

Fundus of the gall bladder is held with ratcheted grasper and retracted in cranial direction which lifts the right lobe of the liver and expose the calot's triangle.

Using Maryland's forceps, dissection begins at the infundibulum of gallbladder and the cystic duct and the artery are identified and clipped and two clips applied on cystic duct side and one clip on gallbladder side.

Detachment of gallbladder from liver bed using hook with monopolar cautery. After complete detachment from liver bed, gallbladder is extracted through epigastric port and gallbladder fossa is inspected for bleeding and thorough wash given.

All the ports are removed and it's important to close the rectus sheath of primary port to avoid incisional hernia, its closed with vicryl 2-0 and skin closed with ethilon 2-0.



Figure 5 Instruments for conventional laparoscopy



**Figure 6 Showing port placement for Four Port
Case No:25**

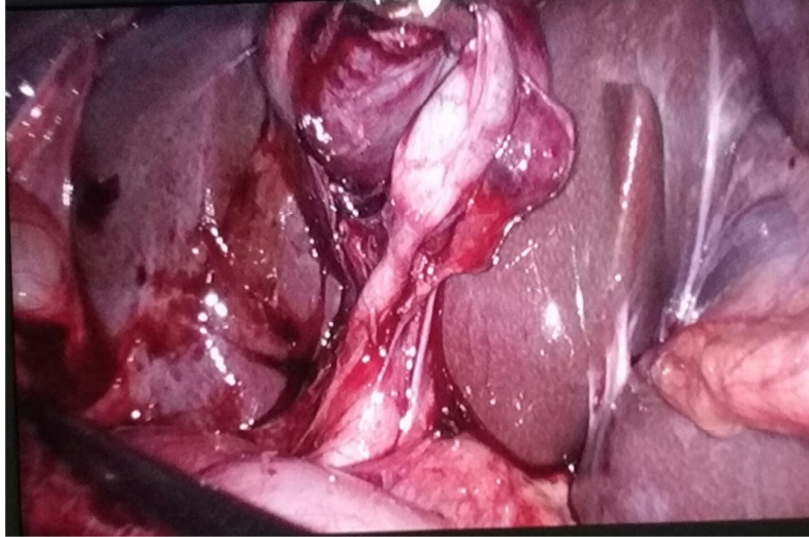


Figure 7 Showing Calots Triangle

Case No:25

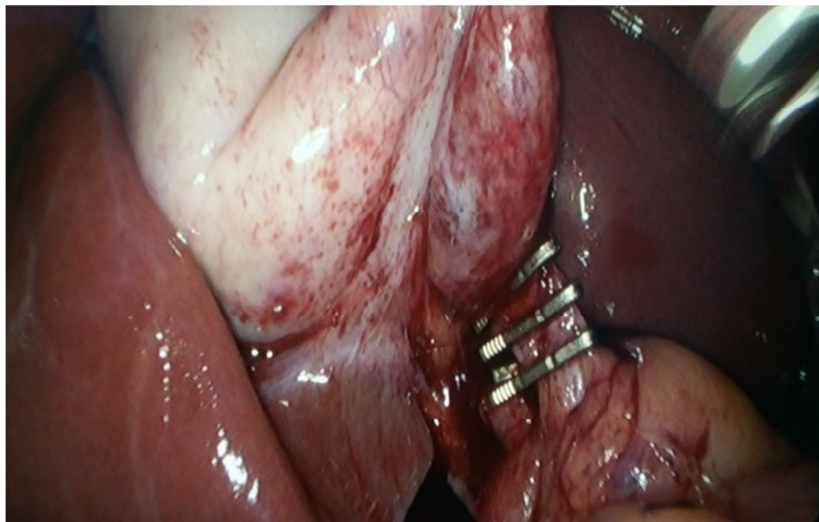
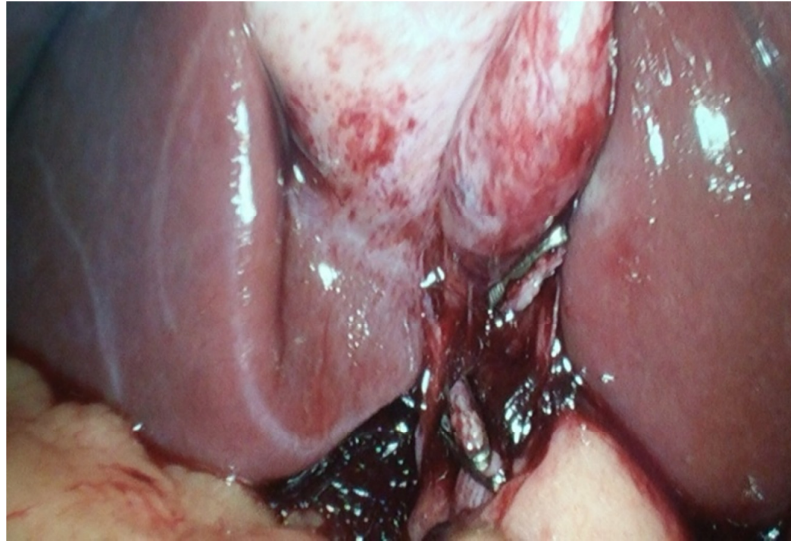
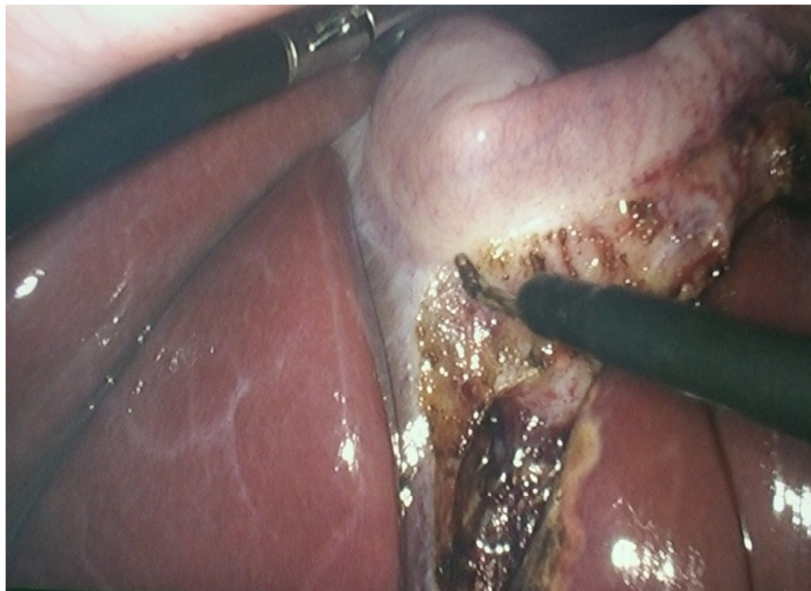


Figure 8 Showing clipping of Cystic Duct and Cystic artery

Case No:25



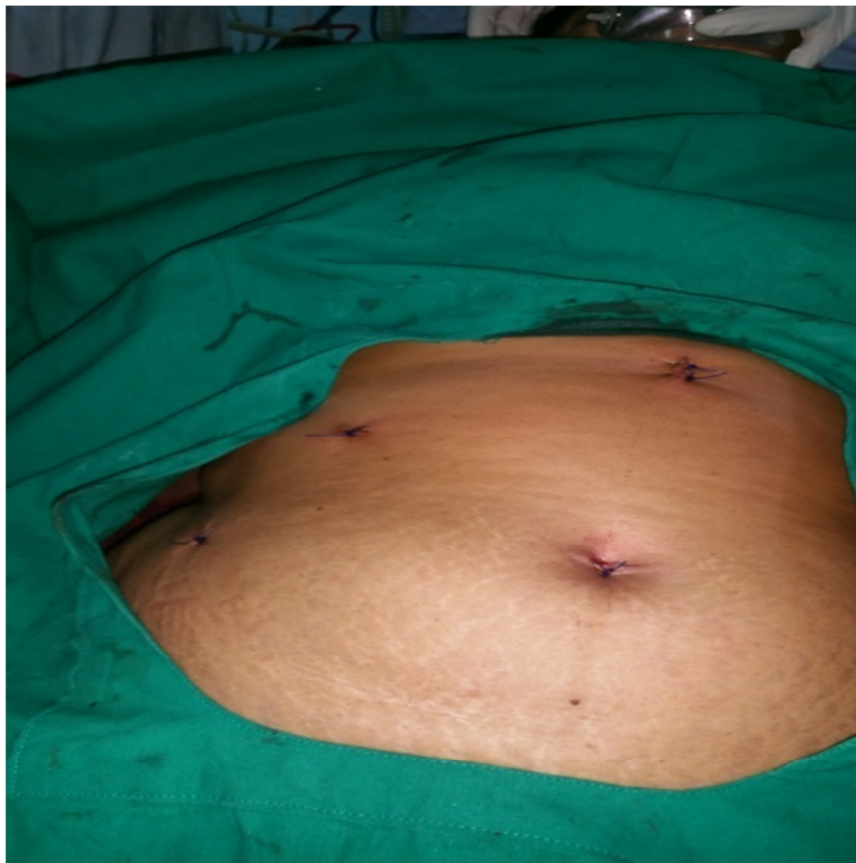
**Figure 9 Showing division of Cystic Duct and Cystic artery
Case No:25**



**Figure 10 Showing detachment of Gallbladder from Liver Bed
Case No:25**



**Figure 11 Showing extraction of Gallbladder
Case no:25**



**Figure 12 Showing sutured wound for Four port
Case No:25**

PROCEDURE FOR SILS TECHNIQUE

Equipment

- a) A pair of surgical gloves.
- b) Outer ring measuring 8*8 cm
- c) Inner ring measuring 5*5cm
- d) High-quality 30 degree videoscope 10 mm with a 300 W light source coupled to high-resolution monitor.
- e) High-flow carbon dioxide insufflator.
- f) Three trocars: 10 mm trocars - 1 and 5 mm trocars - 2.
- g) Hand instruments: Monopolar electrode, c-hook, suction and irrigation, a fine tipped dissector, two gallbladder grasper,a pair of scissors and large hemoclip applicator.

Glove port is prepared by using surgical glove and fingers of the gloves are cut into thin rings which can be used as rubber bands and fingers of the gloves which are cut can be used for placement of the trocars and fitted with rubber bands made earlier. Two 5 mm trocars and one 10 mm trocar is used . 10 mm trocar for videoscope and two 5 mm trocars for hand held instruments. Open end of the glove was passed through the inner ring and turned over the ring so that the inner ring is between the two layers of the glove and outer ring is placed over the glove .

Incision measuring 3 cm is made intraumbilical without extending the incision beyond the umbilical fold and incision was deepened and rectus sheath was cut along the line of incision. Previously prepared glove port fitted with inner ring introduced into the abdomen and outer ring placed over the glove .



Figure 13 Instruments for SILS



Figure 14 Showing incision for single port

Case No:1

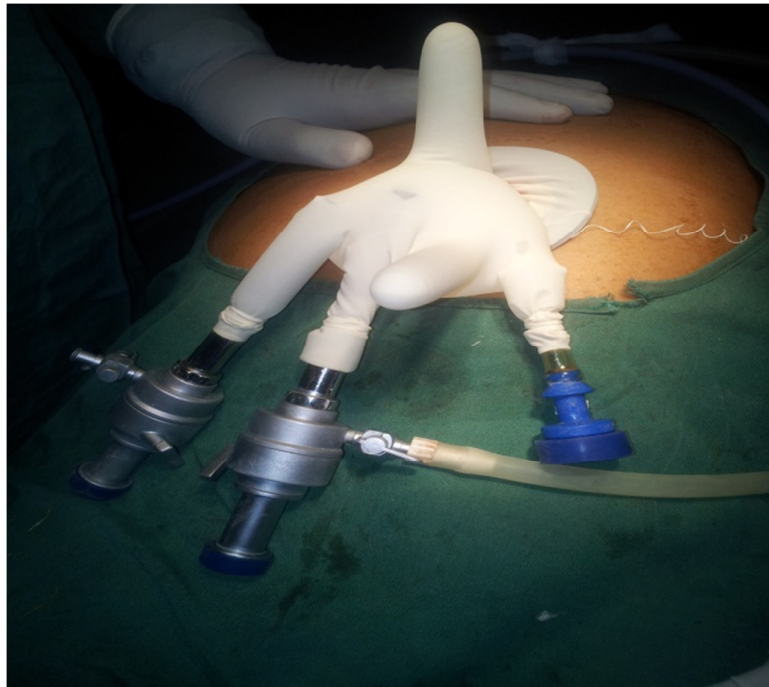


Figure 15 Showing EK Glove Port



Figure 16 Showing sutured wound for single port

Case No:1

MATERIALS AND METHODS

SOURCE OF DATA:

The patients admitted in B.L.D.E.U's Shri. B. M. Patil Medical College, Hospital and Research Centre Vijaypur admitted in surgery department who undergo Laparoscopic cholecystectomy.

RESEARCH HYPOTHESIS:

Single Port laparoscopic cholecystectomy has better cosmesis and less morbidity compared to conventional laparoscopic cholecystectomy.

METHOD OF COLLECTION OF DATA:

The patients admitted in B.L.D.E.U's Shri. B. M. Patil Medical College, Hospital and Research Centre Vijaypur admitted in surgery department undergo Laparoscopic cholecystectomy during period of Oct 2013 – July 2015.

Details of cases are recorded including history, clinical examination, and investigations done. Following parameters of each patient will be recorded preoperatively and compared with intraoperative findings. And post-surgical outcome will be studied for each SILS and Conventional laparoscopic cholecystectomy.

INTRAOPERATIVE FINDINGS

1. Duration of Surgery
2. Difficulties during the procedure
3. Rate of Conversion to conventional laparoscopy/Open Cholecystectomy.
4. Intra operative complications.

POST OPERATIVE FINDINGS

1. Post-operative Pain
2. Post-operative Complications.
3. Post-operative Hospital stay.
4. Convalescence period.
5. Cosmesis.

INCLUSION CRITERIA

All patients who require cholecystectomy for reasons like

- Acute cholecystitis
- Chronic cholecystitis.
- Cholelithiasis.

EXCLUSION CRITERIA

- Empyema of gall bladder.
- Perforated gallbladder.
- Cholangitis.
- Obstructive jaundice.
- Suspicious of gallbladder malignancy.
- Abnormal liver function.
- Morbid Obesity.
- Patient who is not fit for general anaesthesia.

RESULTS AND ANALYSIS

This study included 65 cases that were studied prospectively over a period of 21 months, from October 2013 – July 2015. The statistical analysis was as follows.

Table1: Percent distribution of Age among total patients

In our study the youngest patient was 16 yrs of age female and the oldest was 70 yrs of age female. Majority of the patients in our study were in the age group of 31- 45 yrs of age. The distribution is as follows.

Age (years)	N	Percent
15-30	17	26.2
31-45	27	41.5
46-55	10	15.4
>55	11	16.9
Total	65	100

Chart 1: Percent distribution of Age among total patients

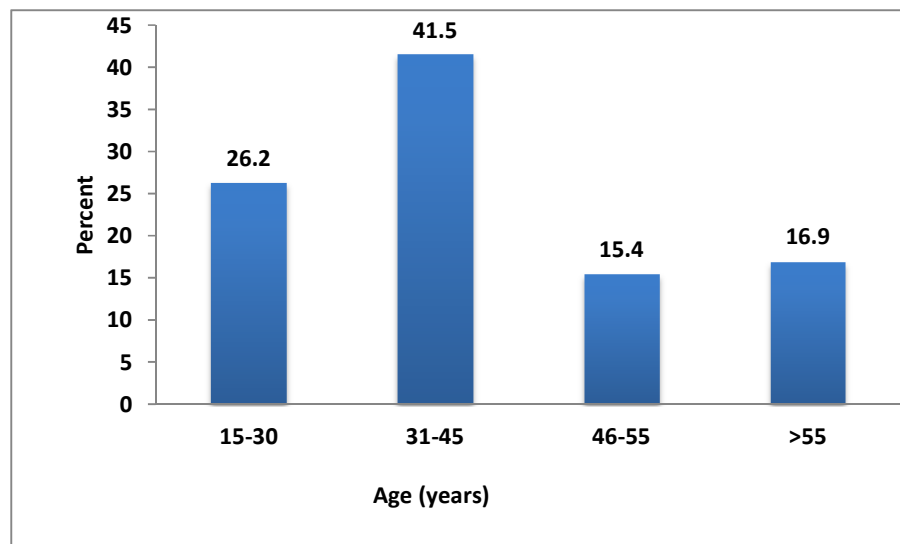


Table2: Percent distribution of Gender among total patients

Out of 65 patients 35 (53.8%) were males and 30 (46.2%) were females.

Gender	N	Percent
Male	35	53.8
Female	30	46.2
Total	65	100

Chart 2: Distribution of Gender among total patients

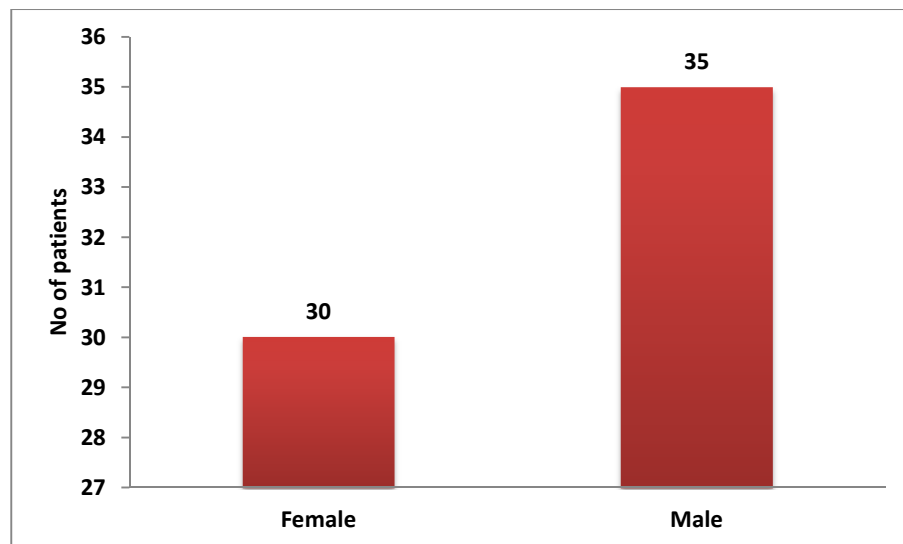


Chart 3: Percent distribution of Gender among total patients

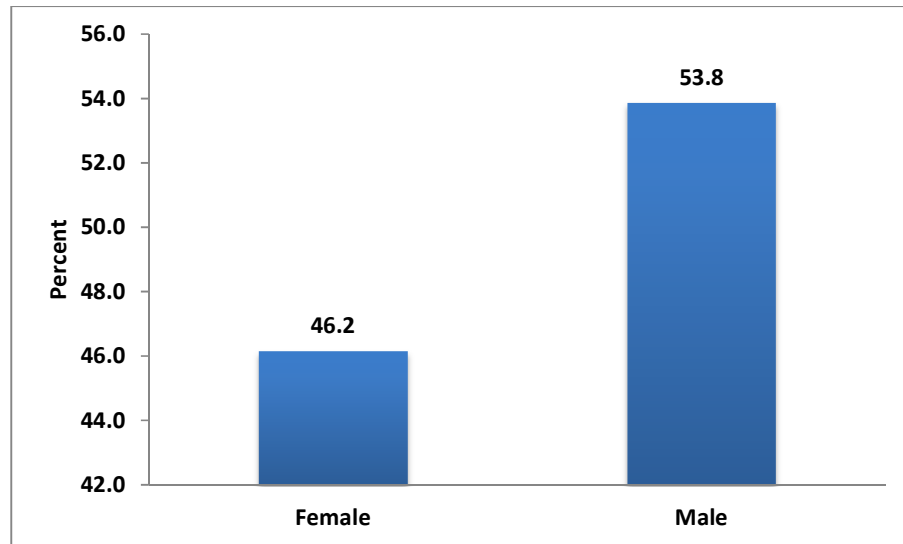


Table 3: Distribution of Ports

In our study out of 65 patients conventional four ports were 45 and single port were 20.

Types of ports	N
4 Ports	45
Single Ports	20

Chart 4: Distribution of Ports

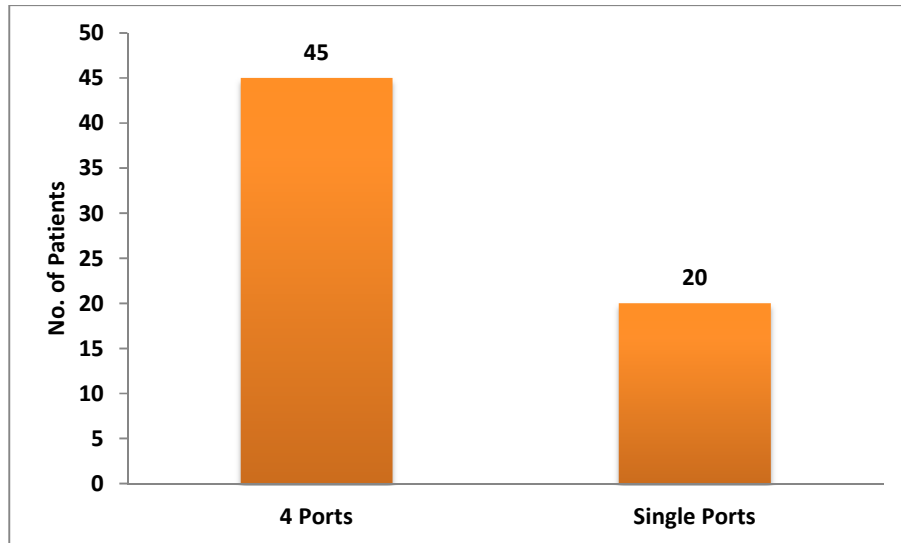


Table4: Association of Age by cases and controls

Age	4Port		Single Port		Total	p value
	N	Percent	N	Percent		
15-30	14	31.1	3	15.0	17	0.565
31-45	17	37.8	10	50.0	27	
46-55	7	15.6	3	15.0	10	
>55	7	15.6	4	20.0	11	

4 port patients are majorly from 31-45 years age group and single port patients are also mainly from same age group. Age is not significantly associated with ports (p =0.565)

Chart 5: Association of Age by cases and controls

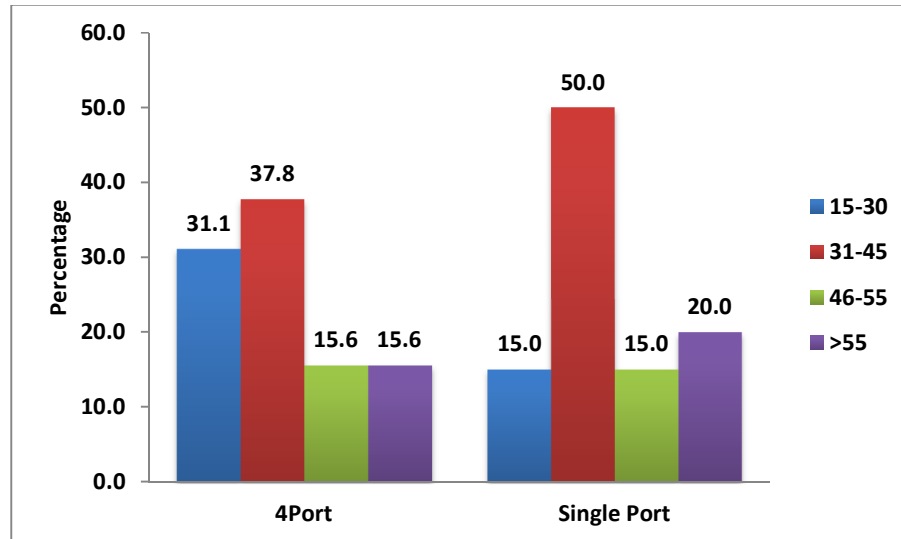


Table5: Association of Gender by cases and controls

In our study in conventional four port group total male patients were 51.1% (n=23) and females 48.9% (n=22) . In single port 60.0%(n=12) were males and females 40% (n=8)and gender is not significantly associated with ports (0.507).

Gender	4Port		Single Port		p value
	N	Percent	N	Percent	
Male	23	51.1	12	60.0	0.507
Female	22	48.9	8	40.0	
Total	45	100.0	20	100.0	

Chart 6: Association of Gender by cases and controls

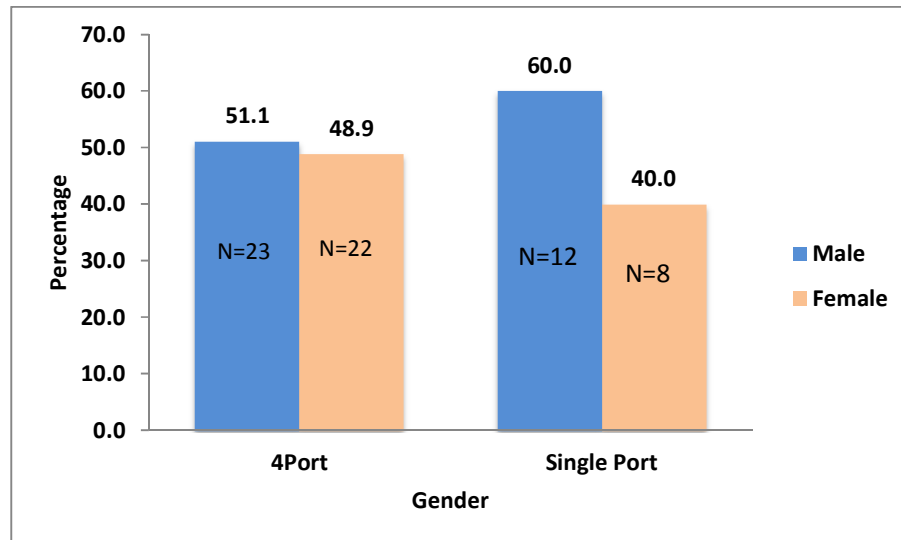


Table6: Mean Duration by cases and controls

Parameters	Groups	N	Mean(min)	SD	p value
Duration (Min)	4 Ports	45	64.4	28.8	0.000*
	Single Ports	20	129.0	40.2	

*significant with $p < 0.05$

Above table states that time taken for surgery was more in single port i.e 129.0 min with standard deviation of 40.2 compared with conventional four port is 64.4 min with standard deviation of 28.8.

Chart 7: Mean Duration by cases and controls

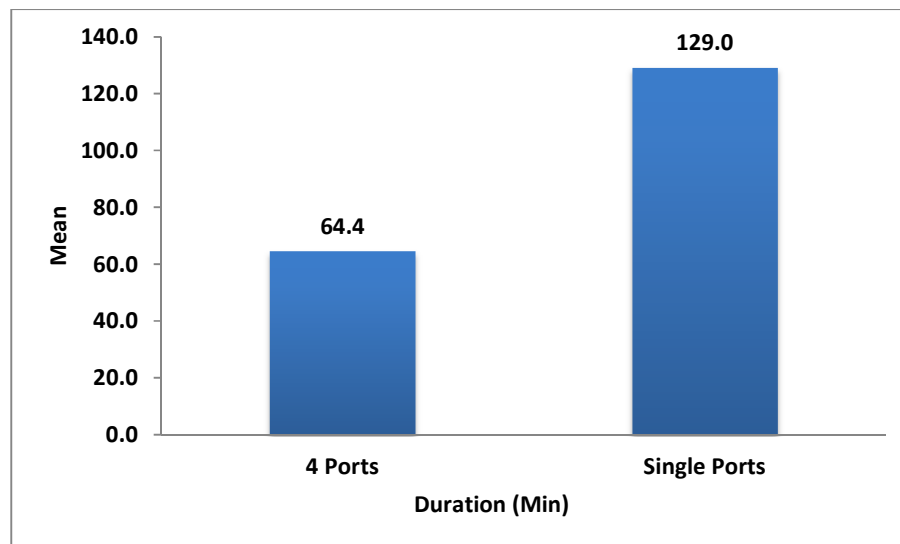


Table7: Mean LOHS by cases and controls

Parameters	Groups	N	Mean	SD	p value
LOHS (days)	4 Ports	45	4.2	1.9	0.001*
	Single Ports	20	7.1	4.9	

*significant with $p < 0.05$

Above table states that mean length of hospital stay in conventional four port is 4.2 days with standard deviation of 1.9 and in single port is 7.1 days with standard deviation of 4.9 days and number of ports is significantly associated with length of hospital stay.

Chart 8: Mean LOHS by cases and controls

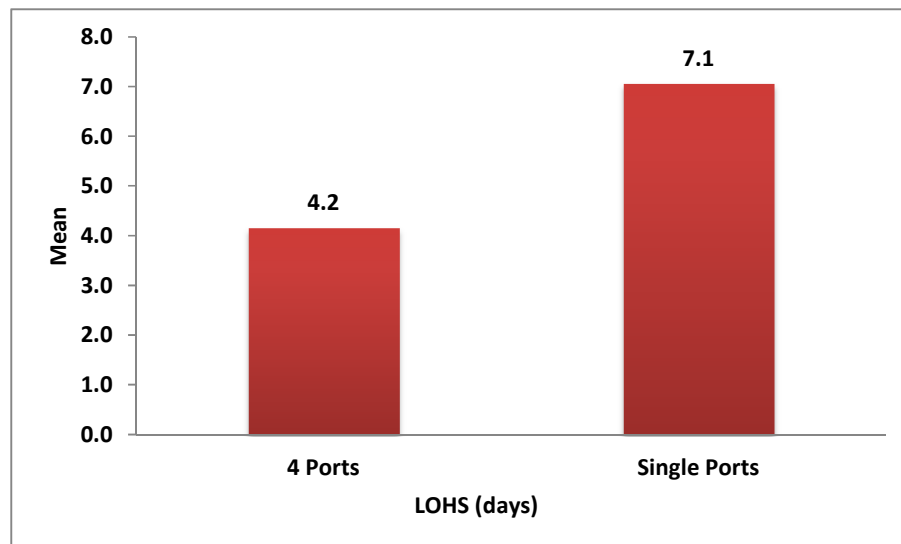


Table8: Association of Duration (min) by cases and controls

Duration (Min)	4 Ports		Single Ports		Total		p value
	N	Percent	N	Percent	N	Percent	
0-45	9	20.0	0	0.0	9	13.8	0.000*
46-60	30	66.7	0	0.0	30	46.2	
61-120	4	8.9	14	70.0	18	27.7	
>120	2	4.4	6	30.0	8	12.3	
Total	45	100.0	20	100.0	65	100.0	

*significant with $p < 0.05$

Above table states that average time taken in conventional four port is between 46 to 60 min (66.7%) and in single port is 61 to 120 min (70.0%) and number of ports is significantly associated with duration of surgery.

Chart 9: Association of Duration (min) by cases and controls

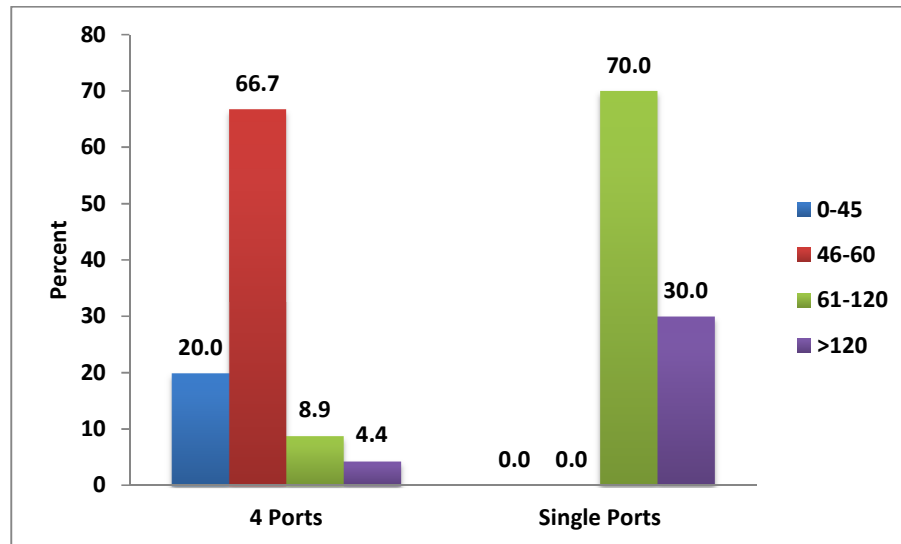


Table9: Association of Complications by cases and controls

Complications	4 Ports		Single Ports		Total		p value
	N	Percent	N	Percent	N	Percent	
NONE	38	84.4	13	65.0	51	78.5	0.000*
Seen	7	15.6	7	35.0	14	21.5	
Total	45	100.0	20	100.0	65	100.0	

*significant with $p < 0.05$

Above table states that complications was more in single port 35.0% (n=7) than in conventional four port 15.6% (n=7) and number of ports is significantly associated with complication.

Chart 10: Association of Complications by cases and controls

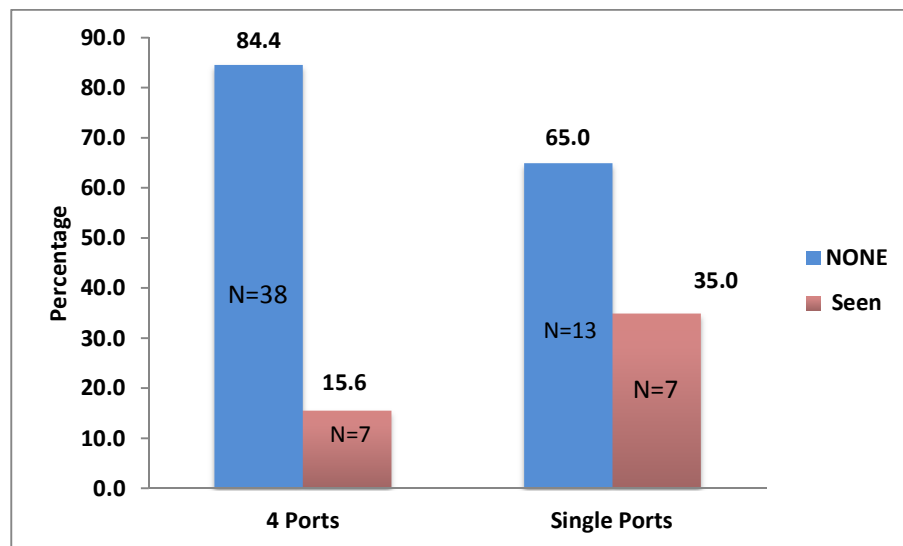


Table10: Association of Conversions by cases and controls

Conversion	4 Ports		Single Ports		Total		p value
	N	Percent	N	Percent	N	Percent	
4PORT	0	0.0	4	20.0	4	6.2	0.000*
NONE	37	82.2	13	65.0	50	76.9	
Open	8	17.8	3	15.0	11	16.9	
Total	45	100.0	20	100.0	65	100.0	

*significant with $p < 0.05$

Above table states that conversion rate in conventional four portis (n=8) 17.8% and in single port is (n=3) 15.0% and number of ports is significantly associated with conversion rate.

Chart 11: Association of Conversions by cases and controls

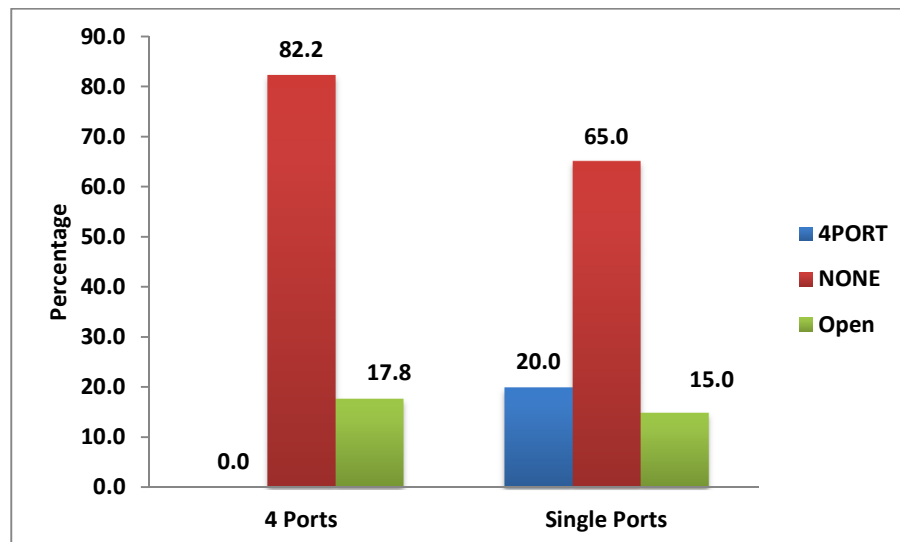


Table11: Association of IOC by cases and controls

IOC	4 Ports		Single Ports		Total		p value
	N	Percent	N	Percent	N	Percent	
ADS	2	4.4	3	15.0	5	7.7	0.211
CBDI	0	0.0	1	5.0	1	1.5	
CTD	4	8.9	3	15.0	7	10.8	
GBI	1	2.2	0	0.0	1	1.5	
NONE	38	84.4	13	65.0	51	78.5	
AF	1	2.2	0	0.0	1	1.5	
OA	1	2.2	2	10.0	3	4.6	

As per the results, intra operative complications seen in conventional four port were adhesions (n=2, 4.4%), difficulty in calots triangle dissection (n=4, 8.9%), injury to gall bladder (n=1, 2.2%), adhesions at the fundus of gall bladder (n=1, 2.2%), omental adhesions (n=1, 2.2%). In single port adhesions (n=3, 15.0%), common bile duct injury (n=1, 5.0%), difficulty in calots triangle dissection (n=3, 15.0%) and number of ports is not significantly associated with intraoperative complication.

Chart 12: Association of IOC by cases and controls

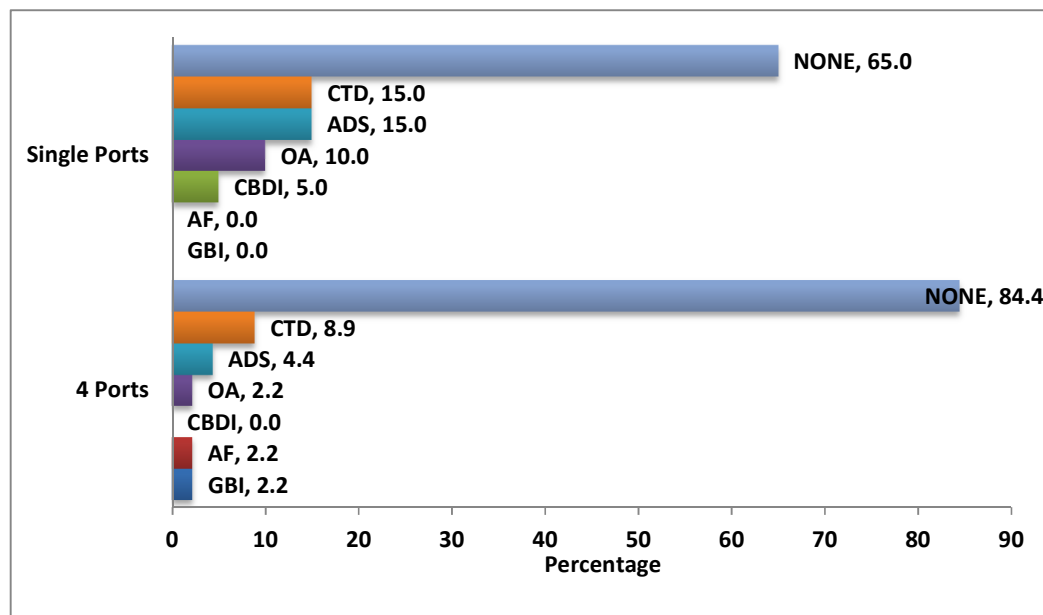


Table12: Association of PODC by cases and controls

PODC	4 Ports		Single Ports		Total		p value
	N	Percent	N	Percent	N	Percent	
BL	0	0.0	1	5.0	1	1.5	0.279
Fever	2	4.4	3	15.0	5	7.7	
None	38	84.4	14	70.0	52	80.0	
Pain	4	8.9	2	10.0	6	9.2	
Pain and Fever	1	2.2	0	0.0	1	1.5	
Total	45	100.0	20	100.0	65	100.0	

Above table states that post operative complication seen in conventional four port were fever (n=2, 4.4%), pain (n=4, 8.9%), pain and fever (n=1,2.2%) and in single port were fever (n=3, 15.0%), pain (n=2,10.0%), biliary leak (n=1,5.0%) and number of ports is not significantly associated with post operative complication.

Chart 13: Association of PODC by cases and controls

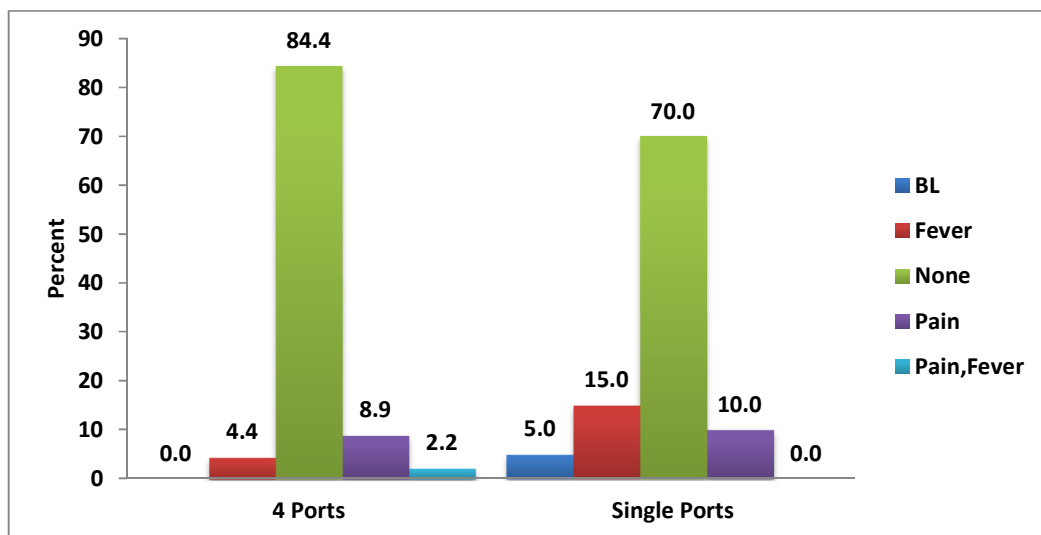


Table13: Association of LOHS (days) by cases and controls

LOHS (Days)	4 Ports		Single Ports		Total		p value
	N	Percent	N	Percent	N	Percent	
0-5	35	77.8	9	45.0	44	67.7	0.010*
6-10	10	22.2	9	45.0	19	29.2	
>10	0	0.0	2	10.0	2	3.1	
Total	45	100.0	20	100.0	65	100.0	

*significant with $p < 0.05$

Above table states that length of hospital stay in conventional four port seen is between 6 to 10 days i.e 22.2% and in single port is between 0 to 5 days and 6 to 10 days i.e 45.0% and number of ports is significantly associated with length of hospital stay.

Chart 14: Association of LOHS (days) by cases and controls in percentage

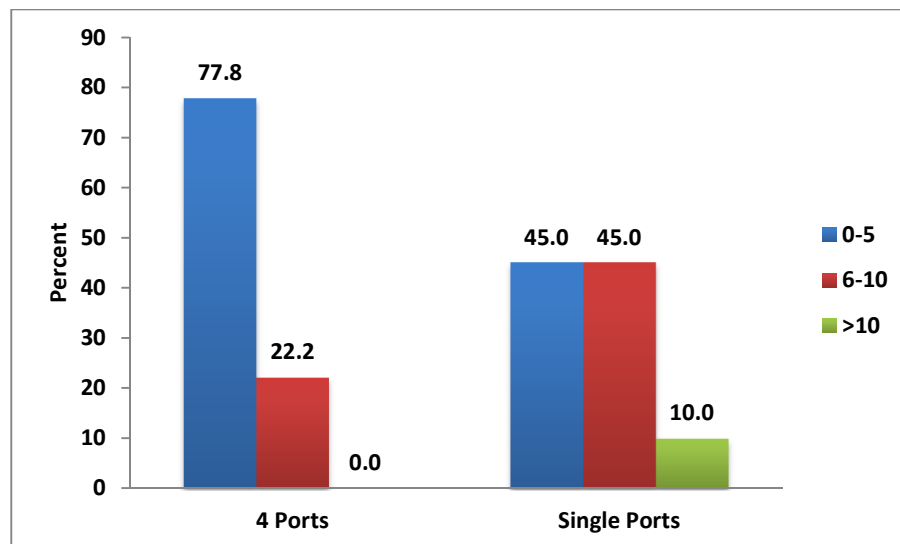


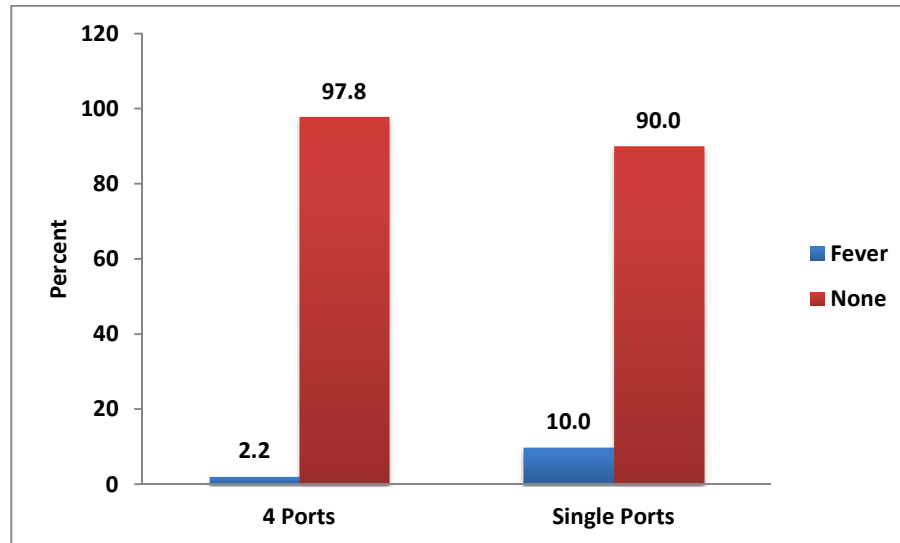
Table14: Association of Follow up by cases and controls

Followup after 3 weeks	4 Ports		Single Ports		Total		p value
	N	Percent	N	Percent	N	Percent	
Fever	1	2.2	2	10.0	3	4.6	0.000*
None	44	97.8	18	90.0	62	95.4	
Total	45	100.0	20	100.0	65	100.0	

*significant with $p < 0.05$

As per results, on follow up after 3 weeks fever was seen in one patient (n=1, 2.2%) in conventional four port and two patients (n=2, 10.0%) in single port and number of ports is significantly associated with follow up after 3 weeks.

Chart 15: Association of Follow up by cases and controls



DISCUSSION

Male to female ratio

	MALE CLC	FEMALE CLC	MALE SILS	FEMALE SILS
Chang SKY ¹⁴ et al(n=100)	20 (40 %)	30 (60 %)	19 (38 %)	31 (62 %)
Joseph S ²¹ et al (n=285)	56 (31.6%)	121 (68.4%)	22 (20.4%)	86 (79.6%)
Mehmood Z ¹⁷ et al (n=60)	4 (13.3%)	2 (6.7%)	26 (86.7%)	28(93.3%)
Our study	23(51.1%)	22(48.9%)	12(60.0%)	8(40.0%)

- Chang SKY¹⁴ et al study shows that number of patients in conventional laparoscopic cholecystectomy group were more in females i.e30 (60 %) compared with male patients 20 (40 %) and number of patients in single port group were more in females i.e31 (62 %) compared with male patients 19 (38 %).
- Joseph S²¹ et al study shows that number of patients in conventional laparoscopic cholecystectomy group were more in females i.e 121 (68.4%) compared with male patients 56 (31.6%) and number of patients in single port group were more in females i.e86 (79.6%) compared with male patients 22 (20.4%).
- Mehmood Z¹⁷ et al study shows that number of patients in conventional laparoscopic cholecystectomy group were more in males i.e 4 (13.3%) compared with female patients 2 (6.7%) and number of patients in single port group were more in females i.e 28 (93.3%) compared with male patients 12 (60.0%).

- In our study the number of patients in conventional laparoscopic cholecystectomy group were more in males i.e 23 (51.1%) compared with female patients 22 (48.9%) and number of patients in single port group were more in males i.e 12 (60.0%) compared with female patients 8 (40.0%).

Duration of surgery

	CLC	SILS	P VALUE
Ostlie DJ ³⁴ et al	56.1 ± 22.1min	68.6 ± 22.1min	0.03
Lai ECH ¹³ et al	46.5 ± 20.1 min	43.5 ± 15.4 min	0.716
Khambaty F ²⁴ et al	69.1 ± 21 min	81.5 ± 28 min	0.004
Our study	64.4 ± 28.8 min	129.0 ± 40.2 min	0.000

- Ostlie DJ³⁴ et al study shows that time taken for surgery in single port i.e 68.6 ± 22.1 min is more compared to conventional laparoscopic cholecystectomy i.e 56.1 ± 22.1 min.
- Lai ECH¹³ et al concluded that time taken for surgery in single port i.e 43.5 ± 15.4 min is less compared to conventional laparoscopic cholecystectomy i.e 46.5 ± 20.1 min.
- Khambaty F²⁴ et al concluded that time taken for surgery in single port i.e 81.5 ± 28 min is more compared to conventional laparoscopic cholecystectomy i.e 69.1 ± 21 min.
- In our study time taken for surgery in single port i.e 129.0 ± 40.2 min is more compared to conventional laparoscopic cholecystectomy i.e 64.4 ± 28.8 min.

Conversion Rate

	CLC	SILS
Khambaty F ²⁴ et al	0	26 (24%)
Chang SKY ¹⁴ et al	0	4(6 %)
Sharma A ²⁷ et al	0	5(5%)
Our study	8(17%)	7(35%)

- Khambaty F²⁴ et al study showed that conversion rate was more in SILS 26 (24%) and no conversion in conventional laparoscopic cholecystectomy .
- Chang SKY¹⁴ et al study showed that conversion rate was more in SILS 4 (6 %) and no conversion in conventional laparoscopic cholecystectomy.
- Sharma A²⁷ et al study showed that conversion rate was more in SILS 5 (5%) and no conversion in conventional laparoscopic cholecystectomy.
- In our study conversion rate was more in SILS 7 (35%) compared with conventional laparoscopic cholecystectomy i.e 8 (17%).

Complications

	CLC	SILS
Chang SKY ¹⁴ et al	4 (8 %)	4 (8 %)
Sharma A ²⁷ et al	22(21.2 %)	18(17.3 %)
Our study	7 (15.6%)	4(20.0%)

- Chang SKY¹⁴ et al study showed that complications were equal in both i.e single port 4 (8 %) compared with conventional laparoscopic cholecystectomy 4 (8 %).
- Sharma A²⁷ et al study showed that complications were more in conventional laparoscopic cholecystectomy i.e 22 (21.2 %) compared with single port 18 (17.3 %).
- In our study complications were more in conventional laparoscopic cholecystectomy i.e 7 (15.6%) compared with single port 4 (20.0%).

Length of hospital stay

	CLC	SILS
Culp BL ¹¹ et al	0.98	0.34
Mehmood Z ¹⁷ et al	1.70	1.00
Our study	4.2	7.1

- Culp BL¹¹ et al study showed that length of hospital stay in conventional laparoscopic cholecystectomy was more i.e 0.98 days compared with Single port 0.34 days.
- Mehmood Z¹⁸ et al showed that length of hospital stay in conventional laparoscopic cholecystectomy was more i.e 1.70 days compared with Single port 1.00 days.
- In our study length of hospital stay in single port was more i.e 7.1 days compared with conventional laparoscopic cholecystectomy 4.2 days.

SUMMARY

The present study include a total of 65 patients who were planned to undergo laparoscopic cholecystectomy.

This study include a total of 65 patients who were planned to undergo laparoscopic cholecystectomy out of which 45 patients were in conventional four port and 20 patients in single port.

In this study, out of 65 patients, 35 (53.8%) were males and 30 (46.2%) were females and the youngest patient was 16 yrs old female and the oldest was 70 yrs old female. Majority of the patients in our study were in the age group of 31- 45 yrs of age ($p=0.565$) and our study shows that age is not significantly associated with ports.

In our study in conventional four port group total male patients were 23(51.1%) and females 22 (48.9%) in single port 12(60.0%) and females 8 (40%) and gender is not significantly associated with ports (0.507).

In our study time taken for surgery was more in single port i.e 129.0 minutes with standard deviation of 40.2 minutes compared with conventional four port is 64.4 minutes with standard deviation of 28.8 .

In our study, complications were more in single port i.e 20.0% than conventional four port i.e 15.6% and number of ports is significantly associated with complications. Rate of conversion in conventional four port is (n=8) 17.8% and in single port is (n=3) 15.0% and number of ports is significantly associated with conversion rate and the reasons for conversion were difficulty in Calots triangle dissection, adhesions, injury to gallbladder and bile leak with spillage of gall stones ,

during the release of adhesions between GB wall and liver bed there was profuse bleeding from liver bed which could not be controlled by cauterisation. One patient had short cystic duct and CBD transection was done with electro cautery which was confused for cystic duct and persistent leakage of golden yellow bile and air bubblehenceconverted to open and CBD exploration was done along with end to end choledocho-choledochostomy along with infantfeeding tube acting as a stent and brought outside through separate incision. duodenotomy and post operative complication seen in conventional four port were fever (n=2, 4.4%), pain (n=4, 8.9%), pain and fever (n=1,2.2%) and in single port were fever (n=3, 15.0%), pain (n=2,10.0%), biliary leak (n=1,5.0%) and number of ports is not significantly associated with post operative complication.

In our study, mean length of hospital stay in conventinal four port is 4.2 days with standard deviation of 1.9 and in single port is 7.1 days with standard deviation of 4.9 and number of ports is significantly associated with length of hospital stay .

CONCLUSION

From this study we conclude that Single Incision Laparoscopic Cholecystectomy (SILS) are an emerging technique and has better cosmesis however owing to its difficult technique and time consuming procedure when away from midline and high conversion rate , needs expertised hands and lot of learning curve when compared to Conventional Laparoscopic Cholecystectomy.

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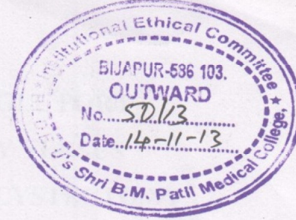
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ANNEXURES

ETHICAL CLEARANCE CERTIFICATE



B.L.D.E. UNIVERSITY'S
SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR-586 103
INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 13-11-2013 at 3-30pm to scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected & revised version synopsis of the Thesis has been accorded Ethical Clearance.

Title "Comparative Study between Single port Laparoscopic cholecystectomy versus conventional Laparoscopic cholecystectomy"

Name of P.G. student Dr Rohit Devani
Department of Surgery

Name of Guide/Co-investigator Dr B.B. Metan
professor of Surgery

DR. TEJASWINI VALLABHA
CHAIRMAN
INSTITUTIONAL ETHICAL COMMITTEE
BLDEU'S, SHRI.B.M.PATIL
MEDICAL COLLEGE, BIJAPUR.

Following documents were placed before E.C. for Scrutinization

- 1) Copy of Synopsis/Research project.
- 2) Copy of informed consent form
- 3) Any other relevant documents.

SAMPLE INFORMED CONSENT FORM

TITLE OF THE PROJECT : COMPARATIVE STUDY BETWEEN SINGLE
PORT LAPAROSCOPIC
CHOLECYSTECTOMY VERSUS
CONVENTIONAL LAPAROSCOPIC
CHOLECYSTECTOMY

GUIDE : DR. B. B. METAN
M.S. (GENERAL SURGERY)
PROFESSOR OF SURGERY
DEPARTMENT OF SURGERY

P.G. STUDENT : DR. ROHIT R. DEVANI

PURPOSE OF RESEARCH:

I have been informed that this study is conducted to compare Single incision laparoscopy surgery versus conventional laparoscopic cholecystectomy. I have also been given free choice of participation in this study.

PROCEDURE:

I am aware that in addition to routine care received I will be asked series of questions by the investigator. I have been asked to undergo the necessary investigations and treatment, which will help the investigator in this study.

RISK AND DISCOMFORTS:

I understand that I may experience some pain and discomforts during the examination or during my treatment. This is mainly the result of my condition and the procedures of this study are not expected to exaggerate these feelings which are associated with the usual course of treatment.

BENEFITS:

I understand that my participation in the study will help to conduct comparison between Single incision laparoscopic surgery versus conventional laparoscopic cholecystectomy .

CONFIDENTIALITY:

I understand that the medical information produced by this study will become a part of hospital records and will be subject to the confidentiality. Information of sensitive personal nature will not be part of the medical record, but will be stored in the investigations research file.

If the data are used for publication in the medical literature or for teaching purpose, no name will be used and other identifiers such as photographs will be used only with special written permission. I understand that I may see the photograph before giving the permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at anytime Dr.Rohit Devani at the department of surgery who will be available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of the study, which might influence my continued participation. A copy of this consent form will be given to me to keep for careful reading.

REFUSAL FOR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and that I may refuse to participate or may withdraw consent and discontinue participation in the study at any

time without prejudice. I also understand that DR.Rohit Devani may terminate my participation in the study after he has explained the reasons for doing so.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me resulting directly from my participation in this study, if such injury were reported promptly, the appropriate treatment would be available to me. But, no further compensation would be provided by the hospital. I understand that by my agreements to participate in this study and not waiving any of my legal rights.

I have explained to _____ the purpose of the research, the procedures required and the possible risks to the best of my ability.

Dr. RohitDevani
(Investigator)

Date

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. Rohit Devani has explained to me the purpose of research, the study procedure, that I will undergo and the possible discomforts as well as benefits that I may experience in my own language. I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give consent to participate as a subject in this research project.

(Participant)

Date

(Witness to signature)

Date

PROFORMA FOR CASE TAKING

SL NO

Name

Age

IP NO

Sex

UNIT

Religion

DOA

Occupation

DOO

DOD

Address :

Mobile No:

Clinical diagnosis-

Final diagnosis-

HISTORY OF PRESENT ILLNESS

History of Vomiting:-

History of Fever

History of Jaundice

PAST HISTORY

Diabetes Mellitus

Hypertension

PERSONAL HISTORY: Smoking

Alcoholic

Family History

GENERAL PHYSICAL EXAMINATION:

Built: Well/Moderate/Poor

Nourishment: Well/Moderate/Poor

Temperature

Pulse

B.P

Respiratory Rate

Pallor

Clubbing

Icterus

cyanosis

Pedal edema

Generalised Lymphadenopathy

SYSTEMIC EXAMINATION:

PER ABDOMEN:

Respiratory System

Cardio VascularSystem

Central Nervous System

CLINICAL/PROVISIONAL DIAGNOSIS

LABORATORY TESTS

Haemoglobin%

Total Count

Differential Count

Neutrophil :

Lymphocytes :

Eosinophils :

Basophils :

Monocytes :

Serum Creatinine :

Liver Function Test :

Serum Albumin :

Serum Glutamic-Pyruvic Transaminase(SGPT):

Serum Glutamic Oxaloacetic Transaminase(SGOT):

Alkaline Phosphatase:

HIV :

HBsAg :

Chest X Ray :

Electro Cardio Gram :

Ultrasonography of Abdomen :

OTHERS :

FINAL DIAGNOSIS:

OPERATIVE PROCEDURE:

Duration of Procedure:

Intra Operative Complications:

Post-Operative Analgesic Requirements:

Length of Stay in Hospital after Procedure:

POST OPERATIVE COMPLICATIONS:

1. Obstructive Jaundice
2. Post Operative Surgical Site Infection
3. Others

Convalescence Period

Follow up :

MASTER CHART OF SILS

SI No	NAME	AGE	SEX	IP NO	DOA	DOO	DOD	DURATION
1	IRANNA	46	M	1454	1/15/2014	1/17/2014	1/23/2014	3HRS
2	KHAJESAB	40	M	4812	2/18/2014	2/20/2014	2/24/2014	2HRS
3	BHARTI	32	F	9846	4/7/2014	4/11/2014	4/14/2014	3HRS
4	NARSAWWA	70	F	17609	6/17/2014	6/20/2014	6/25/2014	2.5HRS
5	PRATHIBA	30	F	22295	7/30/2014	8/1/2014	8/26/2014	4HRS
6	YASHODA	47	F	38190	12/17/2014	12/19/2014	12/24/2014	1.5HRS
7	VEERESH	44	M	38873	12/23/2014	12/24/2014	12/28/2014	2HRS
8	SAMSAD	40	M	13614	4/29/2015	5/2/2015	5/9/2015	1.5HRS
9	NAGVENI	45	F	13615	4/29/2025	5/1/2015	5/6/2015	2.5HRS
10	BHIMASHANKAR	40	M	14060	5/3/2015	5/3/2015	5/16/2015	3HRS
11	MALAMMA	65	F	14059	5/3/2015	5/5/2015	5/9/2015	2HRS
12	REVASAB	32	M	14061	5/3/2015	5/6/2015	5/11/2015	1.5HRS
13	HEMREDDY	40	M	14339	5/6/2015	5/8/2015	5/18/2015	2HRS
14	SAKKUBAI	34	F	17633	6/3/2015	6/3/2015	6/10/2015	1.5HRS
15	MOHAMMAD	62	M	17666	6/3/2015	6/4/2015	6/12/2015	1.5HRS
16	KALLANGOUDA	42	M	17667	6/3/2015	6/5/2015	6/14/2015	2HRS
17	VIJAYLAXMI	25	F	17661	6/3/2015	6/8/2015	6/16/2015	2HRS

18	KALAPPA	50	M	18418	6/10/2015	6/12/2015	6/16/2015	2HRS
19	HANUMANTH	26	M	21797	7/8/2015	7/10/2015	7/18/2015	2HRS
20	KALAWWA	60	M	22666	7/15/2015	7/17/2015	7/24/2015	1.5HRS

CONVERSION	COMPLICATION	IOC	PODC	LOHS	FOUP3WK
4PORT	seen	ADS	F	10DAYS	N
NONE	NONE	NONE	NONE	4DAYS	N
OPEN	seen	ADS	PAIN	6DAYS	N
NONE	NONE	NONE	NONE	4DAYS	N
OPEN	seen	CBDI	BL	25DAYS	N
NONE	NONE	NONE	NONE	5DAYS	N
NONE	NONE	NONE	NONE	4DAYS	N
NONE	NONE	NONE	NONE	6DAYS	N
NONE	NONE	NONE	NONE	6DAYS	N
OPEN	seen	CTD,OA	F	13DAYS	N
NONE	NONE	NONE	NONE	4DAYS	N
NONE	NONE	NONE	NONE	3DAYS	F
4PORT	seen	ADS	F	8DAYS	N
NONE	NONE	NONE	NONE	5DAYS	N
NONE	NONE	NONE	NONE	6DAYS	N
4PORT	seen	CTD	PAIN	9DAYS	N
NONE	NONE	NONE	NONE	5DAYS	N

4PORT	seen	CTD,OA	NONE	8DAYS	F
NONE	NONE	NONE	NONE	4DAYS	N
NONE	NONE	NONE	NONE	6DAYS	N

MASTER CHART OF CONVENTIONAL LAPAROSCOPIC C

SI No	Name	Age	Sex	I.P NO	DOA	DOO	DOD	Duration
1	FATIMA	45	F	26637	9/23/2013	10/2/2013	10/5/2013	1HR
2	SNEHLATA	24	F	1402	11/18/2013	11/25/2013	11/29/2013	50MIN
3	JAYALAXMI	65	F	4344	12/18/2013	12/19/2013	12/21/2013	45MIN
4	BHAGIRATI	38	F	5384	12/30/2013	1/1/2014	1/8/2014	40MIN
5	RAVI	45	M	5421	2/25/2014	2/26/2014	2/28/2014	1HR
6	SADIQU	30	M	7496	3/17/2014	3/18/2014	3/22/2014	50MIN
7	LALITHA	45	F	9289	4/2/2014	4/11/2014	4/14/2014	1HR
8	PRAKASH.P	35	M	10215	4/10/2014	4/12/2014	4/15/2014	1HR
9	ANIL	30	M	12646	5/2/2014	5/5/2014	5/12/2014	45MIN
10	CHANNAPPA	60	M	13337	5/7/2014	5/9/2014	5/13/2014	1HR
11	ROOPA	26	F	13669	5/9/2014	5/12/2014	5/16/2014	50MIN
12	PUSPHA	40	F	16907	6/10/2014	6/11/2014	6/12/2014	1HR
13	PRAKASH	42	M	22938	8/4/2014	8/14/2014	8/19/2014	40MIN
14	AMEENA	55	F	23764	8/12/2014	8/13/2014	8/16/2014	1HR
15	SUPRIYA	16	F	26789	9/8/2014	9/10/2014	9/13/2014	50MIN
16	IRANNA	45	M	26795	9/8/2014	9/17/2014	9/17/2014	1hr
17	MUTAWWA	70	F	34352	11/13/2014	11/22/2014	11/28/2014	2HRS
18	BABU	24	M	35033	11/19/2014	11/21/2014	11/24/2014	1HR
19	MAHADEV	40	M	3729	12/9/2014	12/11/2014	12/15/2014	1HR

SI No	Name	Age	Sex	I.P NO	DOA	DOO	DOD	Duration
20	SHIVAPPA	45	M	38370	12/18/2014	12/20/2014	12/25/2014	1HR
21	VEERESH	44	M	38873	12/23/2014	12/24/2014	12/26/2014	1HR
22	MUTAWWA	27	F	38858	12/23/2014	12/24/2014	12/26/2014	50MIN
23	DEVIKA	22	F	38789	12/23/2014	12/25/2014	1/10/2015	45MIN
24	MEGHANA	28	F	39058	12/25/2014	12/27/2014	12/31/2014	1.5HRS
25	MD.ABDUL	26	M	3037	1/28/2015	1/30/2015	2/3/2015	40MIN
26	ASHOK	39	M	3649	1/29/2015	1/31/2015	2/3/2015	1HE
27	BHAGVANT	63	M	3706	2/3/2015	2/7/2015	2/10/2015	2.5HRS
28	MAMATA	34	F	5089	2/16/2015	2/17/2015	2/19/2015	1HR
29	NAGANNA	53	M	63610	3/5/2015	3/7/2015	3/14/2015	50MIN
30	REVANSIDAPPA	54	M	11464	4/11/2015	4/12/2015	4/17/2015	1HR
31	ASTIRANJAN	60	M	11484	4/12/2015	4/17/2015	4/29/2015	3HRS
32	SHRIKANTH	53	M	14863	5/11/2015	5/13/2015	5/16/2015	1HRS
33	KEERTI	20	F	15139	5/13/2015	5/14/2015	5/16/2015	1HRS
34	SHIVAYOGI	32	M	15326	5/14/2015	5/18/2015	5/22/2015	45MIN
35	BASU	54	M	15428	5/15/2015	5/16/2015	5/21/2015	1HR
36	VEENA	39	F	17998	6/6/2015	6/9/2015	6/13/2015	2HRS
37	SHAMLABAI	48	F	18183	6/8/2015	6/10/2015	6/19/2015	2HRS
38	SHRUTI	28	F	20603	6/29/2015	7/1/2015	7/8/2015	1HR
39	SUNITA	20	F	21587	7/6/2015	7/8/2015	7/15/2015	45MIN
40	HANUMANTH	19	M	21797	7/8/2015	7/10/2015	7/14/2015	1HR

SI No	Name	Age	Sex	I.P NO	DOA	DOO	DOD	Duration
41	SONABAI	62	F	24326	7/29/2015	8/7/2015	8/17/2015	1HR
42	SHANTABAI	62	F	24411	8/15/2015	8/21/2015	8/21/2015	1HR
43	SHIVANAN	35	M	25531	8/16/2015	8/17/2015	8/24/2015	45MIN
44	SHIVATI	53	F	26980	8/18/2015	8/20/2015	8/27/2015	1HR
45	ASHOK	34	M	26870	8/22/2015	8/24/2015	8/31/2015	50MIN

CHOLECYSTECTOMY

COMPLICATION	CONVERSION	IOC	PODC	LOHS	FOUP3WK
NONE	NONE	NONE	F	3DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE
NONE	NONE	NONE	NONE	2DAYS	NONE
NONE	NONE	NONE	NONE	5DAYS	NONE
NONE	NONE	NONE	NONE	3DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	F
NONE	NONE	NONE	NONE	3DAYS	NONE
NONE	NONE	NONE	NONE	2DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE
NONE	NONE	NONE	NONE	3DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE
NONE	NONE	NONE	NONE	3DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE
NONE	NONE	NONE	NONE	6DAYS	NONE
NONE	NONE	NONE	NONE	3DAYS	NONE
NONE	NONE	NONE	NONE	1DAY	NONE
Seen	OPEN	ADS	NONE	6DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE

COMPLICATION	CONVERSION	IOC	PODC	LOHS	FOUP3WK
NONE	NONE	NONE	F	5DAYS	NONE
NONE	NONE	NONE	NONE	2DAYS	NONE
NONE	NONE	NONE	NONE	2DAYS	NONE
NONE	NONE	NONE	NONE	6DAYS	NONE
Seen	OPEN	CTD	PAIN	6DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE
Seen	OPEN	ADS	NONE	6DAYS	NONE
NONE	NONE	NONE	NONE	2DAYS	NONE
NONE	NONE	NONE	NONE	3DAYS	NONE
NONE	NONE	NONE	NONE	5DAYS	NONE
Seen	OPEN	GBI	PAIN,F	8DAYS	NONE
NONE	NONE	NONE	NONE	3DAYS	NONE
NONE	NONE	NONE	NONE	2DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE
NONE	NONE	NONE	NONE	3DAYS	NONE
Seen	OPEN	CTD	NONE	6DAYS	NONE
Seen	OPEN	CTD,OA	PAIN	9DAYS	NONE
NONE	NONE	NONE	NONE	5DAYS	NONE
NONE	NONE	NONE	NONE	3DAYS	NONE
NONE	NONE	NONE	NONE	5DAYS	NONE

COMPLICATION	CONVERSION	IOC	PODC	LOHS	FOUP3WK
Seen	OPEN	CTD,AF	PAIN	10DAYS	NONE
NONE	NONE	NONE	NONE	4DAYS	NONE
NONE	NONE	NONE	NONE	3DAYS	NONE
NONE	NONE	NONE	PAIN	7DAYS	NONE
NONE	NONE	NONE	NONE	2DAYS	NONE