A COMPARATIVE STUDY OF EXTRA CORPOREAL KNOTTING VERSUS CLIPS FOR LIGATING CYSTIC DUCT IN LAPAROSCOPIC CHOLECYSTECTOMY

Submitted by

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P.G in General Surgery

DISSERTATION SUBMITTED TO

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In

GENERAL SURGERY

UNDER THE GUIDANCE OF

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LIST OF ABBREVIATIONS USED

CHD	Common Hepatic Duct
CBD	Common Bile Duct
LC	Laparoscopic Cholecystectomy
USG	Ultrasonography
GB	Gall Bladder
P value	Predictive value
CT	Computed Tomography
HIV	Human Immunodeficiency Virus
HbsAg	Hepatitis B Surface antigen
HCV	Hepatitis C Virus
ECG	Electrocardiogram
MRI	Magnetic Resonance Imaging
HS	Highly significant
NS	Not significant

ABSTRACT

AIMS AND OBJECTIVE OF STUDY

The aims of present study are as following: To compare extracorporeal knotting versus clips for ligating cystic duct in laparoscopic cholecystectomy in terms of:

Feasibility

Operative time (incision to closer) based on types of cholecystitis

Post-operative pain

Operative cost

Associated morbidities like Gall bladder perforation, Bile leak, Liver bed injury, Port site infection, Migration of clips, Slipping of knot.

MATERIALS AND METHODS

It is a randomized prospective study done in patients who undergo laparoscopic cholecystectomy in Department of Surgery, B.L.D.E. (DEEMED TO BE UNIVERSITY) SHRI B.M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE, VIJAYAPURA– 586103, KARNATAKA.

All the patients will be assigned by randomization into either of two groups:

Study Group: Patients in whom extracorporeal knotting will be done for ligation of cystic duct.

Control Group: Patients in whom clips will be used for clipping of cystic duct.

RESULTS

Out of 60 patients, In the study group there were no intraoperative complications noted among the 30 patients.

In the control group, 11 patients there were intraoperative complications, 7 patients had clip slippage and stone spilling in to the peritoneal cavity from the gall bladder, 3 patients had clip slippage and bile spillage in to the peritoneal cavity from the gall bladder and in 1 patient there was clip migration.

In the study group mean time taken for the operation was 67.37 minutes when compared to control group of 61.83 minutes.

The average cost of the Suture material used in study group is 302 rupees and the average cost of the Titanium clips used in control group is 500 rupees.

CONCLUSION

In laparoscopic cholecystectomy, extracorporeal knotting has the advantage over clipping of cystic duct in terms of operative cost and lesser intraoperative complications, with the only limitation being operative time.

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INTRODUCTION:

Cholecystectomy is the common operation of the biliary system[1].

In cholecystectomy cystic duct is ligated with the sutures or clips.

The conception of laparoscopy has revolutionized the art of surgery due to its advantages over open technique.

The lately innovated laparoscopic cholecystectomy has been drastically refined over the years by better exploration of ergonomics, new energy sources and endo suturing[2].

The conventional four ports access technique has been modified to three ports, two ports and single incision laparoscopic surgery.

Cystic duct ligation methods using metallic clips, harmonic scalpel, plasma kinetic, intracorporeal and extracorporeal suturing techniques have been tried with gratifying results[3-8].

Laparoscopic cholecystectomy has become the gold standard in the treatment of gallbladder pathology and is replacing open cholecystectomy. The rate of conversion from laparoscopic cholecystectomy to open cholecystectomy is 5 to 10%.

AIMS AND OBJECTIVE OF STUDY

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RESEARCH HYPOTHESIS

In laparoscopic cholecystectomy, extracorporeal knotting has the advantages over clipping of cystic duct in operative cost and lesser post-operative complications, with the only limitation being operative time.

REVIEW OF LITERATURE

HISTORICAL ASPECTS

The Roman Celsus mentioned the liver in his text De Medicina (translated by W.G. Spencer in 1935) & described its anatomical position in a precise form: "The liver, which starts from the actual partition under the precordia on the right side, is concave within (that is on the inferior surface) & convex without; its projecting part lightly rests on the stomach & it is divided into 4 lobes. The gallbladder adheres to it outside of its lower section"[9].

"A hemoperitoneum coming from an abscess which had eroded the portal vein was found by vesalius that he had. The gallbladder was yellow in color & contained eighteen calculi which was very light in weight & of triangular shapes having even surfaces & edges, green by color somewhat blackish. The spleen was exceptionally large"[9].

In 1769, morgagni published an analysis of disease under the title Seats & Causes of Disease, among which are those of the liver & biliary tract[9].

The papilla of the duodenum was first described by Vater (1684-1751)[9]. The term biliary colic was introduced by Petit[9].

1878: Cholecystostomy was performed by Kocher in two stages.

1971 Glenn. He packed the wound with gauze to the bottom of the gallbladder in the first stage, & eight days later the residual stones from the gallbladder was emptied by him.

1882: The first elective cholecystectomy was performed by Langenbuch.

1882: Cholecystenterostomy was developed by Von Winiwarter.

1885: The first cholecystostomy for gallbladder lithiasis was performed by Tait in one stage.

1895: Kocher wrote an article on internal choledochoduodenostomy to remove supra-ampullary choledochal calculi.

1897: Kehr placed a rubber tube in the common bile duct through the cystic duct; this was the first systematic use of biliary intubation.

1898: The first removal of a stone from the common bile duct was performed by Thornton.

1898: MacBurney published his experience with papillotomy & duodenostomy in subjects with impacted periampullary calculi.

1898: On plain x-rays, the biliary calculi had been observed by Buxbaum.

1912: T-tube was developed by Kehr.

1923: Choledochoscopy was developed by Bakes.

1924: The oral cholecystography was developed by Graham.

1932: Postoperative cholangiography was developed by Mirizzi.

1937: Intraoperative cholangiography was developed by Mirizzi.

1989: The first series of laparoscopic cholecystectomies was published by Dubois in Paris (Dubois et al)[9].

HISTORY OF LAPAROSCOPY AND LAPAROSCOPIC CHOLECYSTECTOMY

George killing of Dresden, Germany first performed Laparoscopy (In Greek, Laparo meaning the flank & Skopein meaning to examine), in 1901 using room air filtered through sterile cotton for pneumoperitoneum & a wide cystoscope to view the abdominal cavity of dog. For pneumoperitoneum, the carbon dioxide (CO_2) use was first recommended by Richard Zollikofer of Switzerland in 1924[10].

In 1938, Janos Veress of Hungary introduced the primary mode of insufflation which was the Veress needle[10].

The laparoscopic lysis of abdominal adhesions for the diagnosis of bowel obstructions was first reported by a German general surgeon, Feowers in 1933[10].

The new aspects of fiber optic were incorporated by Kurt Semm where automatic gas insufflator was used which allowed precise controlled intra-abdominal pressure[11].

The laparoscopic cholecystectomy for acute cholecystitis was described by Lukichev and colleagues in 1983[11].

The first laparoscopic assisted cholecystectomy was performed by Muhe of Boblinger, Germany in 1985[12].

The first video-laparoscopic cholecystectomy was performed by a French surgeon in Lyon, Phillipe Mouret in 1987.

Extracorporeal Knotting

In laparoscopy there is lack of direct manual contact with tissue, therefore the sense of feel of tissue is restricted, secondly the image is transmitted to a two-dimensional video screen & the laparoscope magnifies the image. This accentuates a person's natural tremor and a two-dimensional view eliminates true depth perception[1].

Extracorporeal knotting of cystic duct is done either by absorbable or non-absorbable suture material.

Using Maryland grasper suture is passed from the epigastric port, suture is wrapped around the cystic duct and is brought out from the epigastric port.

Different methods of Extracorporeal knotting are Roeder knot, Duncan loop, Nicky’s knot, Weston knot, Tayside1 knot, Meltzer knot, Tennessee slider knot, etc.,

Extracorporeal knotting is done using one of the above knotting techniques. Knot is pushed by using a knot-pusher, ligating and tightening of the cystic duct. The duct is ligated twice one at the cystic duct end near common bile duct and the second one at the specimen side towards the gall bladder. Knot is secured and cystic duct is cut in between the knots.

ANATOMY

The extra-hepatic biliary tree consists of common hepatic duct, right & left hepatic ducts, cystic duct & gallbladder & the common bile duct.

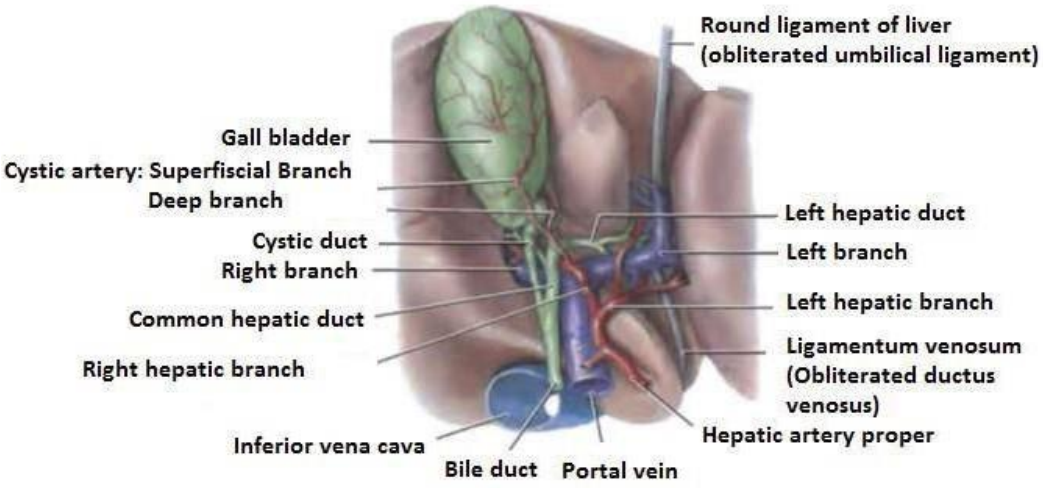


Figure 1: Inferior of Gall Bladder Anatomy[13]

Gall bladder is a flask-shaped, blind-end diverticulum where the cystic duct attaches to the common bile duct. It usually lies in a shallow fossa in the peritoneum-covered liver parenchyma continued from the surface of the liver. This attachment can be widely varied[13].

The gall bladder lies on a cystic or fibrous plate that forms part of the fibrous perihilar tissue system. At the anterior surface of right portal pedicle, the cystic plate directly attaches to it.

Within the cystic plate, the hepatic parenchyma lies deep inside where small bile ducts can penetrate to enter into the gallbladder. Between the

gallbladder's cystic plate & muscularis, a thin, areolar tissue layer slowly thickens downwards from the top of the gallbladder.

The posterior cystic artery surface & bile duct will be reached during the dissection of the gallbladder from the liver when the areolar tissue is left on the cystic plate. Dissection should be performed deep into the cystic plate because the surface to the right portal pedicle could be breached and can induce damage to the right portal pedicle structures and the right hepatic duct.

NECK

Neck lies near the porta hepatis at the medial end, & it has a short peritoneal cover which is attached to the liver (MESENTERY); this mesentery generally contains the cystic artery.

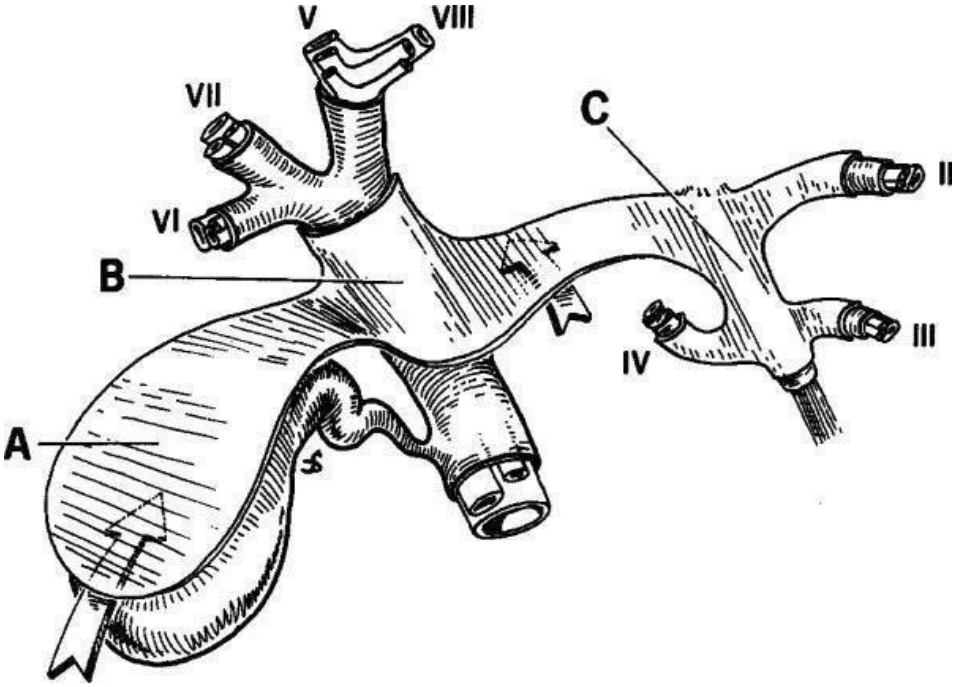


Figure 2: The anatomy of the plate system. cystic plate (A) above the gallbladder, the hilar plate (B) above the biliary confluence and at the base of the quadrate lobe, and the umbilical plate (C) above the umbilical portion of the portal vein[13].

BODY AND FUNDUS:

The gall bladder body normally lies in contact with surface of the liver. It lies anterior to the duodenum's second part & transverse colon's right end. The fundus lies at the body's lateral end and commonly projects to a variable length in the inferior border of the liver.

It also remains behind the nineth costal cartilage in contact with the anterior abdominal wall where the right rectus abdominis lateral edge crosses the costal margin. It is where gall bladder enlargement is best looked for on clinical review. Gall bladder fundus can be folded back to gall bladder body: PHRYGIAN CAP.

EXTRAHEPATIC BILIARY TREE CYSTIC DUCT

The length of cystic duct is about 3 to 4 cm, which passes posteriorly to the left from the gallbladder neck and attaches the common hepatic duct to form the common bile duct. It runs parallelly to it and adheres for a short distance to common hepatic duct before joining.

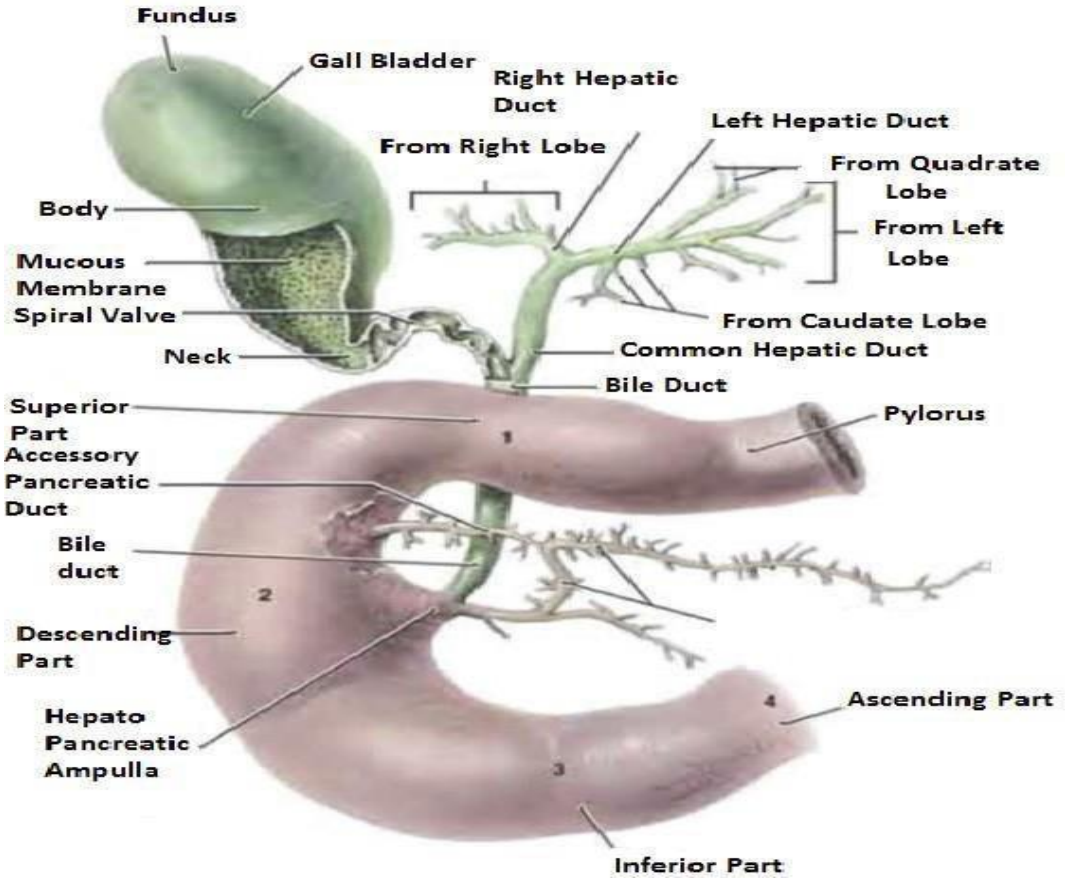


Figure 3: Anatomy of the gallbladder, biliary radicals, pancreatic duct and the hepato-pancreatic ampulla[14]

ANATOMICAL VARIATIONS OF CYSTIC DUCT

Occasionally, the cystic duct drains into the right hepatic duct, in which case it may be elongated, lying anterior or posterior to CHD & joining in the left border of right hepatic duct[13].

The cystic duct lies along the right edge of the lesser omentum, all the way down to the duodenum level before forming the junction. Here cystic ducts and common bile ducts usually adhere closely. The cystic duct may be double or absent in which case gall bladder drains directly into CBD.

Occasionally, one or more accessory hepatic ducts emerge from the liver's segment V and either join the right hepatic duct, the common hepatic duct, common bile duct, cystic duct, or the gall bladder.

In regular succession, they project obliquely, seeming to form a spiral valve when the longitudinal section of the duct is cut. The spaces between the folds dilate when the duct is distended, and outwardly it appears twisted like the gallbladder neck.

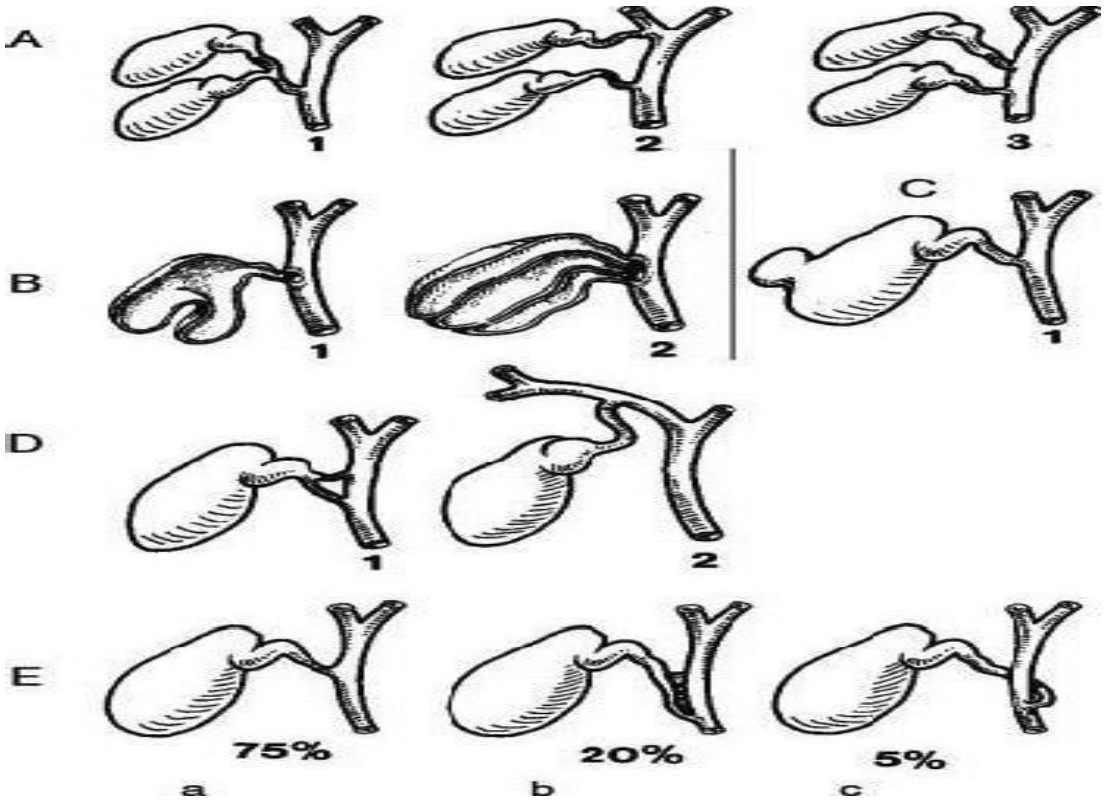


Figure 4: Variations in gallbladder and cystic duct anatomy: duplicated gallbladder (A), septum of the gallbladder (B), diverticulum of the gallbladder (C), variations in cystic ductal anatomy (D). Different types of union of the cystic duct and common hepatic duct (E)[15]

HEPATIC DUCTS

The main right and left hepatic ducts originated from the liver and unite as the common hepatic duct near the right end of the porta hepatis. Before joining cystic duct at an acute angle, this descends for about 3 cm to form common bile duct.

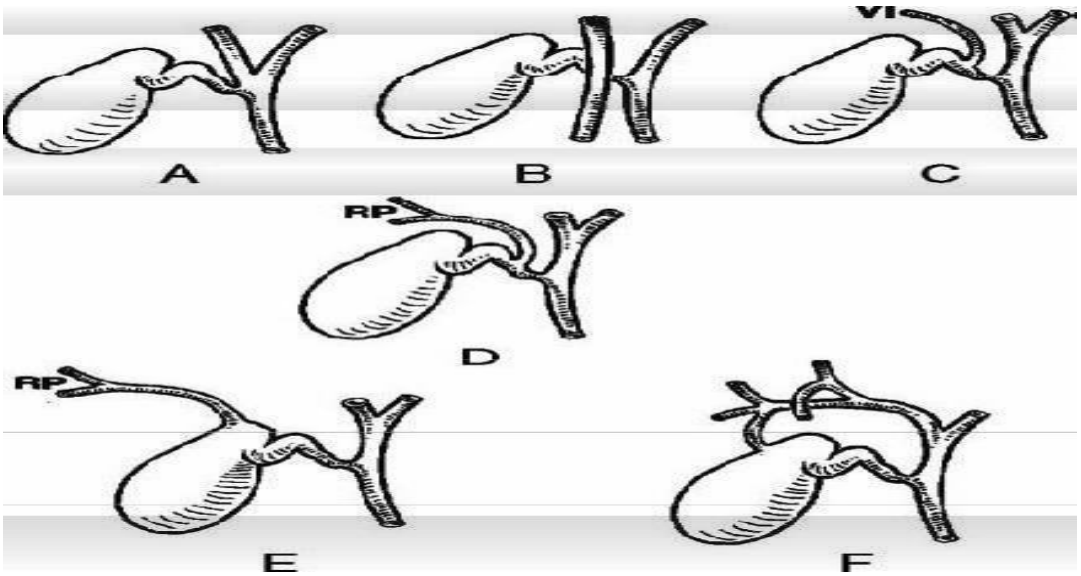


Figure 5: The variations of ectopic drainage of the intrahepatic ducts into the gallbladder and cystic duct. A, cystic duct into the biliary confluence. B, cystic duct into the left hepatic duct associated with no biliary confluence. C, segment VI duct into the cystic duct. D, right posterior sectorial duct into the cystic duct. E, distal part of the right posterior sectorial duct into the neck of the gallbladder. F, proximal part of the right posterior sectorial duct into the body of the gallbladder[15]

COMMON BILE DUCT

Common bile duct is formed at the junction of the cystic and common hepatic ducts, near the porta hepatis. In adults, it is usually length will be between 6 and 8 cm and diameter of about 6 mm. It descends posteriorly

and to the left, anterior to epiploic foramen, in the right border of lesser omentum. It is located at anterior and to the right of portal vein and to the right of the hepatic artery. The duct may present close to the medial wall of the duodenum's second part or as much as 2 cm from it.

HEPATOPANCREATIC AMPULLA (OF VATER)

Before entering the second part of the duodenum it is formed by the union of CBD and pancreatic duct. Circular muscles commonly surround by the CBD lower part (bile duct sphincter) and surround the main pancreatic duct terminal part (pancreatic duct sphincter) and the hepatopancreatic ampulla (sphincter of oddi).

CALOT'S TRIANGLE - CHOLECYSTOHEPATIC TRIANGLE

Calot's triangle is commonly referred to as the near triangular space formed between the cystic duct, common hepatic duct and the inferior surface of the liver's Segment V. It is enclosed by a double layer of peritoneum forming the short mesentery of the cystic duct, it may be better described as a pyramidal space with one apex lying at the junction of the gallbladder's cystic duct and fundus, one at the porta hepatis and two closer apices at GB 's attachment to the liver bed. The base of the triangle thus locates on the liver inferior surface[16].

CONTENTS OF THE CALOT'S TRIANGLE[16]

Cystic artery.

Cystic lymph node (Calot's node).

Lymphatics from the GB.

1 or 2 cystic veins.

Autonomic nerves to the GB.

Adipose tissue.

May contain any accessory ducts which drain into GB from liver.

VASCULAR SUPPLY AND LYMPHATIC DRAINAGE CYSTIC ARTERY

The cystic artery generally originates from the right hepatic artery. In order to reach the superior aspect of the gallbladder's neck, it usually passes posterior to the common hepatic duct and anterior to the cyst duct. It divides into superficial & deep branches, superficial branches ramify on the gallbladder's inferior aspect, the deep branches on the superior aspect. These arteries anastomose over the surface of the body and fundus. The cystic artery is an end artery & its occlusion are followed by the gangrene of the gall bladder.

ANATOMICAL VARIATIONS

May originate from common hepatic artery, or sometimes from left hepatic artery, or rarely from gastro-duodenal or superior mesenteric arteries. In this case the gallbladder can be reached by crossing anterior (or less commonly posterior) to CBD or CHD. An accessory artery may originate from the common or one of its branches of the hepatic artery. The cystic artery often splits near its origin, giving rise to 2 arteries that supply the gallbladder.

Multiple fine arterial branches may originate from the liver parenchyma (segment IV or V) and contribute to the body's supply especially when the GB is significantly intrahepatic. The cystic artery generates several fine branches that supply the common as well as lobar hepatic ducts and the upper part of the CBD.

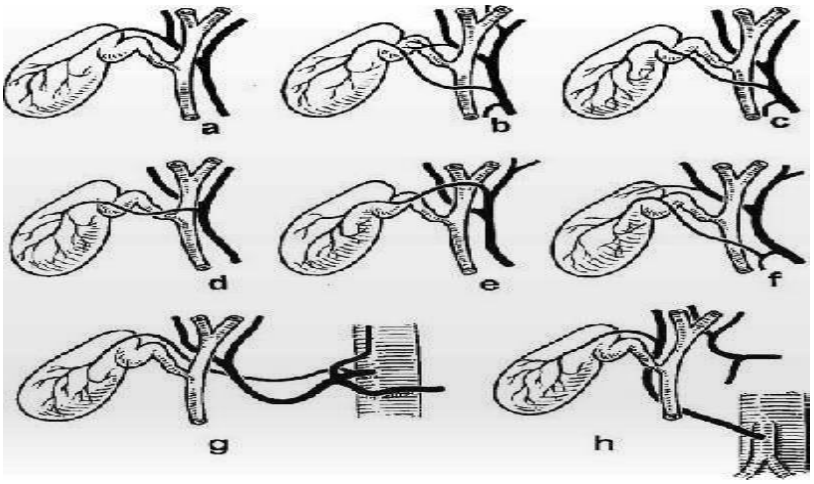


Figure 6: Variations of the cystic artery: typical course (a); double cystic artery (b); cystic artery crossing anterior to main bile duct (c); originating from the right branch of the hepatic artery and crossing the common hepatic duct anteriorly (d); originating from the left branch of the hepatic artery (e) originating from the gastro duodenal artery (f); arising from the celiac axis (g); originating from a replaced right hepatic artery (h)[15]

DUCTAL ARTERIES:

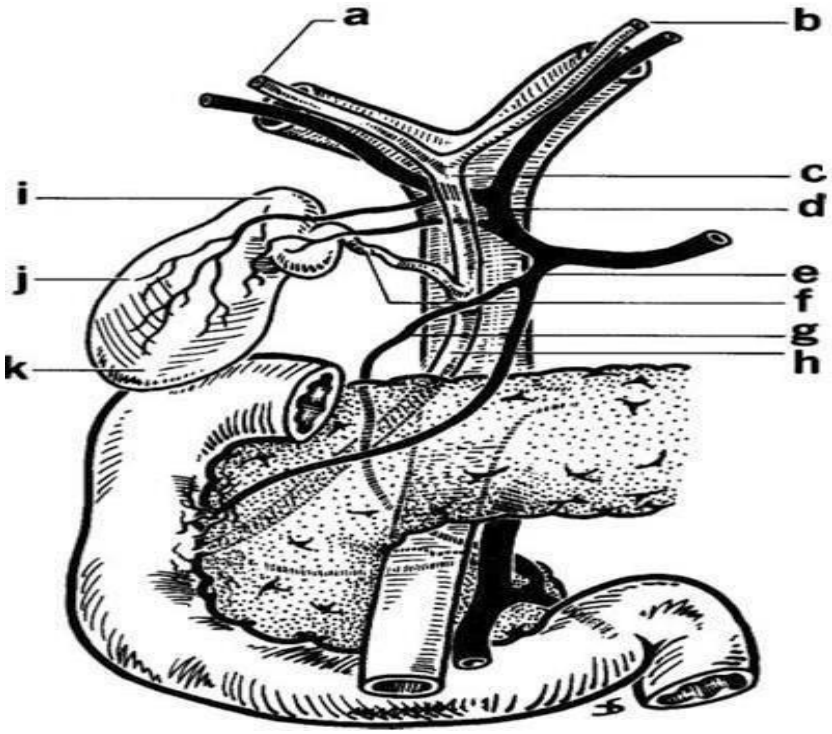


Figure 7: Bile duct blood supply. Note the axial arrangement of the vasculature of the supra duodenal portion of the main bile duct and the rich network enclosing the right and left hepatic ducts: right branch of the hepatic artery (a); 9 o'clock artery (b); retro duodenal artery (c); left branch of the hepatic artery (d); hepatic artery (e); 3 o'clock artery (f); common hepatic artery (g); gastroduodenal artery (h)[15]

A fine network of vessels supplies the common bile ducts & hepatic ducts, which lie in close vicinity to the ducts themselves. Network disruption during long-length surgical exposure of the bile ducts often causes chronic ischemia as well as stenosis.

Anterior to the CBD, from the retro duodenal branch of the gastro duodenal artery, 2 to 4 ascending vessels arise. As this vessel passes near the lower CHD, 3 to 4 descending branches of right hepatic and cystic arteries emerges. These descending & ascending arteries form long narrow anastomotic channels along the length of the duct called medial & lateral trunks. Posteriorly, a retro portal artery often emerges from the coeliac axis, superior mesenteric artery, or one of its main branches, near to its aorta origin. It contributes to the supplying arterial network of the supraduodenal part of the bile duct system. It runs upward on portal vein's posterior surface.

CYSTIC VEINS

Those originating from the body & neck's superior surface, lie in the areolar tissue between the gall bladder as well as the liver and enter parenchyma of liver to drain into the segmental portal veins.

LYMPHATICS

Various lymphatic vessels on all aspects of the gall bladder and cystic duct develop from the submucosal and subserosal plexuses. Those on the gallbladder's hepatic aspect connect with the intrahepatic lymphatics. The rest drain into the cystic node, which usually lies in the tissue of Calot's triangle above the cystic duct. This node, along with some lymphatic channels that bypass the cystic node, drain into a node located in the free edge of the lesser Omentum's anterior border.

INNERVATION

Branches from the hepatic plexuses innervate the gall bladder and the extrahepatic biliary branch. The retroduodenal section of the CBD also has contributions from the pyloric branches of the vagus, which also innervate the hepatopancreatic ampulla's smooth muscles.

REFERRED PAIN

Pain from the stretch of CBD or gallbladder is attributed to the central epigastrium, as with other structures of foregut origin. Overlying somatic peritoneum activity causes pain that is more localized to the right quadrant.

EMBRYOLOGY

The liver primordium appears at the distal end of the foregut in the mid of the third week as an outgrowth of the endodermal epithelium. This outgrowth, the hepatic diverticulum or the hepatic bud is made up of rapidly dividing cells that infiltrate the septum transversum, which is the mesodermal plate between the pericardial cavity and the yolk sac stalk. As the hepatic cells begin to enter the septum, the bile ducts forming the connection between the hepatic diverticulum and the foregut (duodenum) narrows.

On 26th day, a clear endodermal thickening develops on the ventral side of the duodenum just caudal to the base of the hepatic diverticulum and buds into ventral mesentery.[17] This cystic diverticulum forms both the GB and the cyst duct. Cells proliferate at the junction of the hepatic and cystic duct and form the CBD. In the 10th week, due the large number of sinusoids and large nests of proliferating cells, which contain red blood cells and white blood cells, the weight of the liver will be 10 percent of the total body weight. It lies between vessel's hepatic cells and wall. Somewhere around the 12th week of life, liver starts producing bile, which is dark green in color.

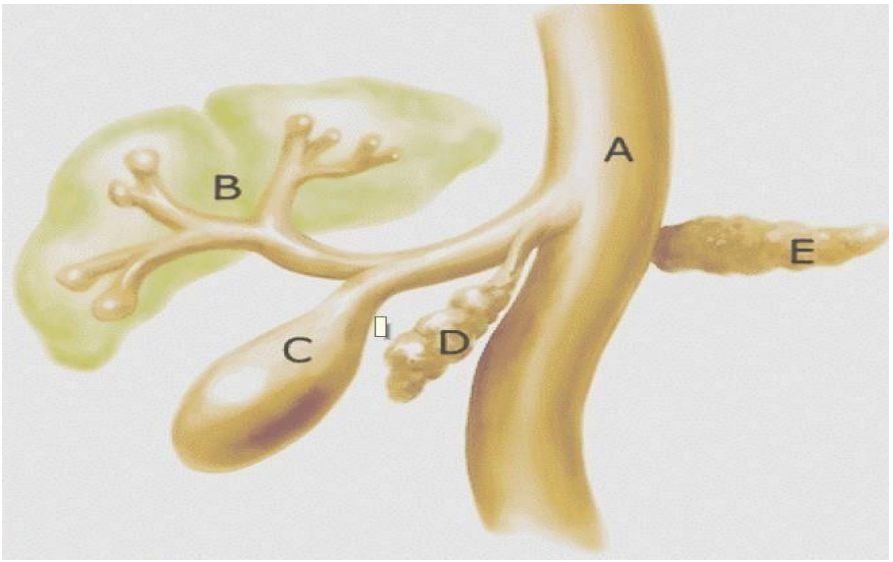


Figure 8: Illustrating the foregut (A), the cranial end of the hepatic diverticulum which represents Pars hepatica (B) and the Cystic diverticulum (C). The ventral (D) and dorsal (E) pancreas are also demonstrated[17]

HISTOLOGY GALLBLADDER

The mucosa is yellowish-brown with a honeycomb appearance and elevated into minute rugae. In section, mucosal projections into the lumen of the gallbladder resemble intestinal villi, but these are not fixed structures, and as the gallbladder fills with bile, the surface flattens.

The epithelium is a single-layered columnar epithelium with apical microvilli. Goblet cells are absent. Basally, it dilates the spaces between epithelial cells. Many capillaries lie under the basement membrane. Beneath

it is a thin fibromuscular layer comprised of fibrous tissue mixed with smooth muscles which are arranged loosely in longitudinal, circular & oblique bundles.

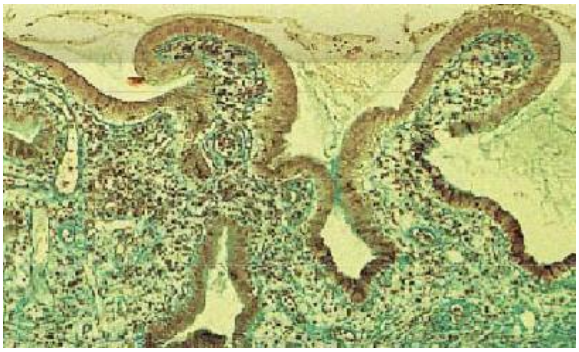


Figure 9: Microscopy of gall bladder wall

BILE DUCTS:

Majority of the biliary ducts have external fibrous and internal mucous layers. The former is fibrous connective tissue connective tissue containing variable amount of connective tissue containing variable amount of longitudinal, oblique and circular smooth muscles. The epithelial covering is columnar & includes several tubuloalveolar mucous glands.

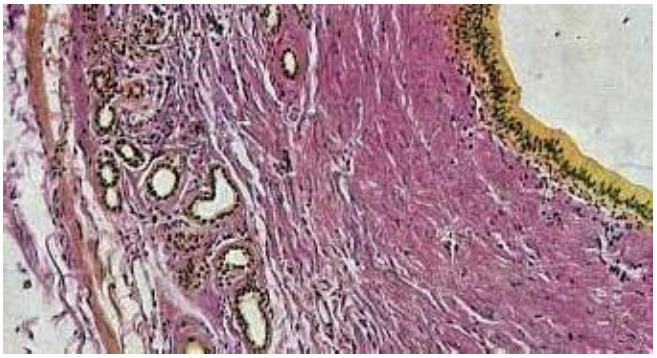


Figure 10: Microscopy of common bile duct

PATHOGENESIS:

In west, around 80 percent are cholesterol stones, containing more than 50 percent of crystalline cholesterol monohydrate. The remaining are composed mainly of bilirubin calcium salts & are called as pigment stones.

CHOLESTROL STONES

Cholesterol is rendered soluble in bile by aggregation with water soluble bile salts and water insoluble lecithin, both of which act as detergents. When cholesterol concentration, exceed the solubilizing capacity of bile (supersaturation).

Bile must be supersaturated with cholesterol: this tends to be a primary defect, caused by irregular regulation of hepatic mechanisms for delivering cholesterol to bile. The free excess free cholesterol is toxic to gallbladder,

entering the wall and exceeding mucosal ability to detoxify it by esterification. Gallbladder hypo motility ensues. Muscular stasis tends to arise from both intrinsic neuromuscular dysmotility and reduced neuromuscular response to CCK[18].

Gallbladder hypomotility promotes nucleation[18]. The nucleation of cholesterol in bile is accelerated: due to a change in the balance between antinucleating and prenucleating proteins and the presence of inorganic or organic calcium salts micro precipitates. Hypersecretion of mucus in the GB traps the crystals, allowing for their aggregation into stones.

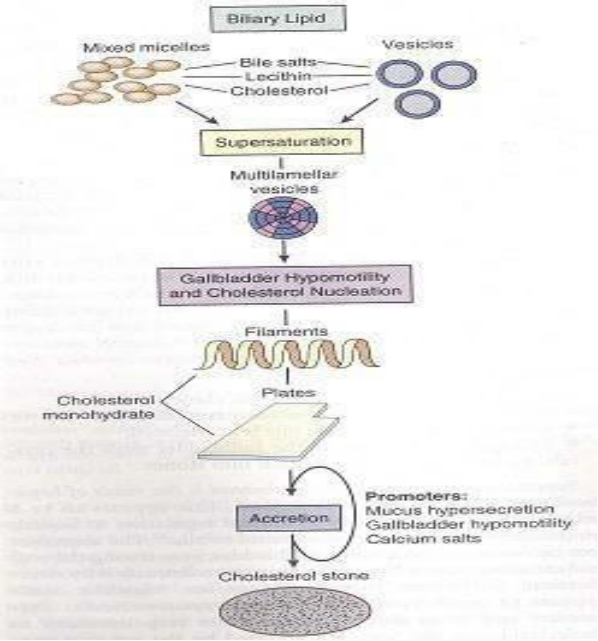


Figure 11: Schematic representation of four contributory factors for cholelithiasis: supersaturation, gallbladder hypomotility, crystal nucleation and accretion within the gallbladder mucous layer[18]

Table 1: Superimposed conditions that exacerbate defective GB emptying and cholesterol stone formation

Prolonged fasting	Total parenteral nutrition
Pregnancy	Spinal cord injury
Rapid weight loss	

PIGMENT STONES

Pigment stones are complex mixtures of unconjugated bilirubin's abnormal insoluble calcium salts along with inorganic calcium salts. Biliary tract infection with *E. coli* or *ascaris lumbricoids* or by the liver flukes *opisthorchis sinensis* leads to release of microbial β-glucuronidase, which hydrolyses bilirubin glucuronides to unconjugated bilirubin[18].

MORPHOLOGY CHOLESTEROL STONES

This occurs exclusively in GB and consists of 100 to 50 per cent cholesterol. Pure cholesterol stones are pale yellow, round to ovoid in shape and have a fine granular morphology with hard external surface which on transection reveals a glistening radiating crystalline palisade. With increasing proportions of calcium carbonate, phosphates and bilirubin, the stones exhibit discoloration and may be lamellated and gray white to black on transection[9,18].

Most often there are multiple stones that range in diameter up to several centimeters. Owing to tight apposition, surfaces of multiple stones may be rounded or faceted. Stones that are primarily composed of cholesterol are radiolucent; sufficiently calcium carbonate is present in 10 to 20 percent of cholesterol stone to make them radiopaque.

PIGMENT STONES

Pigment stones are classified as black stones and brown stones. Black pigment stones are found in sterile gallbladder bile, and brown in infected intrahepatic and extrahepatic ducts. Mucin glycoproteins in both cholesterol and pigment stones functions as binding proteins.

THE NATURAL HISTORY OF GALLSTONES

In 1992, it was estimated that 10 to 15 percent of the adult population in the United States had gallstones and about 1 million patients are newly diagnosed evert year. Gallstones are the most common digestive disease[19].

EPIDEMIOLOGY:

Gallstones are most common gastrointestinal condition with a prevalence of 11 to 36 percent in autopsy reports. Only first-degree relatives of gallstones patients and obesity (BMI >30 kg/m^2) have been observed as strong risk factors for the development of symptomatic gallstone disease[20].

Table 2: Risk factors for gallstones

Obesity	First degree relatives
Rapid weight loss	Drugs: Ceftriaxone, postmenopausal estrogens, total parenteral nutrition
Childbearing	Ethnicity: Native American (Pima Indian) , Scandinavian
Multiparity	Ileal disease, resection or bypass
Female sex	Increasing age

CLINICAL PRESENTATION

Despite their gallstones, most of the patients remain asymptomatic. While the mechanism is not clear evidenced, some patients experience symptomatic biliary colic gallstones induced by a stone obstructing the cystic duct. About 1 to 2 percent of asymptomatic patients with gallstones experience severe symptoms or complications related to their gallstones per year; thus, cholecystectomy is needed by just about 1 percent. Once symptomatic, patients are likely to get recurring symptoms, usually recurrent biliary colic episodes. In 10 to 30 per cent of patients, non-specific gastrointestinal symptoms develop and in 5 to 10 per cent of patients, develop with classic biliary symptoms.

BILIARY COLIC

Acute calculi obstruction of the gallbladder results in biliary colic, a common misnomer because the pain in the epigastrium or upper right quadrant is not colicky. Biliary colic is a persistent pain that builds up in intensity and can radiate to the back, interscapular region, or right shoulder. The pain is defined as band-like tightness in upper abdominal region which may be combined with nausea and vomiting[21]. This is due to a normal gallbladder that contracts against a luminal obstruction, such as a gallstone that impacts the gallbladder's neck, cystic duct, or CBD. The pain is most typically caused by fatty foods, but it can also be started or even spontaneously occur by other types of foods. In only 50 percent of patients there is a correlation with meal, and in these patients the pain also persists after eating more than 1 hour also.

INVESTIGATIONS

Patients will be referred for laboratory investigations Hemoglobin, Total count, Differential count, Erythrocyte sedimentation rate, Platelet count, bleeding time, clotting time and Biochemical routine including Blood Urea, Serum creatinine and urine analysis, Liver function tests, USG abdomen. Radiodiagnosis such as Chest X-ray and Electrocardiography.

LIVER FUNCTION TEST[21]

Biliary colic does not produce unusual laboratory values in the absence of gallbladder pathology or obstruction in the bile duct. Obstructive choledocholithiasis induced direct bilirubin and increased levels of alkaline phosphatase[21].

Leukocytosis predominantly neutrophils are present in a Cholecystitis and cholangitis. PT-INR: Prolonged PT is present in liver dysfunction which needs to be stabilized before surgery.

IMAGING STUDIES PLAIN RADIOGRAPHS

Only about 15 per cent of gallstones contain contains sufficient calcium to make them radiopaque and thus noticeable in plain abdominal films. The exclusion of perforated ulcer with free intraperitoneal air, bowel obstruction with dilated loops, or right lobe pneumonia is essential in plain films.

ULTRASONOGRAPHY

An ultrasound is the early investigation of any patient who is suspected with biliary tree disease. Abdominal ultrasound is a part of routine evaluation in patients with cholelithiasis and it has a sensitivity of greater than 98 percent and sensitivity of greater than 95 percent[23]. Along with detecting gallstones, ultrasound can also provide signs of cholecystitis such as gallbladder wall thickening, pericholecystic fluid, and impacted stone in the gallbladder neck.

Extrahepatic (> 10 mm) or intrahepatic (> 4 mm) dilation of the bile ducts suggest biliary obstruction[22].

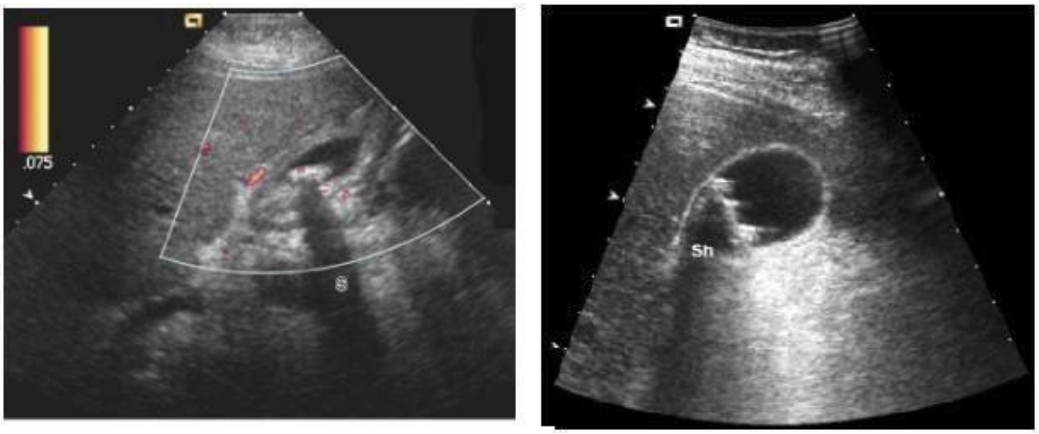


Figure 12: A, Echogenic foci in the gallbladder with acoustic shadowing (S) are characteristic of gallstones. In this patient, the gallbladder wall is thickened, but not hypervascular. Features suggest chronic cholecystitis. B, Multiple stones are layered in the dependent portion of the gallbladder, but the wall is not thickened[24]

ORAL CHOLECYSTOGRAPHY

Identifies filling flaws in a visualized, opacified gallbladder after oral administration of a radio-opaque compound that passes into the gallbladder[23]. In patients with vomiting, biliary obstruction, jaundice, or hepatic failure it is contraindicated.

COMPUTED TOMOGRAPHY

CT detects gallstones with a sensitivity of just around 55% to 65% inside the biliary tree and gallbladder. This is because both gallstone and bile are isodense, so stones are only detected if calcificated[25].

SCINTIGRAPHY

Scintigraphy is useful for visualizing the biliary structure and assessing the role of the liver and gallbladder. No visualization of the gallbladder is reliable evidence of cystic duct obstruction at 2 hours after injection. Biliary scintigraphy accompanied by CCK administration is beneficial when gallbladder contraction causes biliary track pain in patients with no evidence of stones (CCK hepatobiliary 2,6- dimethyl- iminodiacetic acid (HIDA))[26].

INTRAOPERATIVE CHOLANGIOGRAPHY

Micken had reported the first operative cholangiogram in 1936. The first cystic duct cholangiography was performed by Mirizzi in 1937 and this technique remains the most established method for performing (IOC) today[27].

COMPLICATIONS OF GALLSTONES[28]

Acute cholecystitis

Chronic calculus cholecystitis

Choledocholithiasis with or without cholangitis

Gallstone pancreatitis

Gallstone ileus

Gall bladder carcinoma.

MANAGEMENT OF CHOLELITHIASIS

Gall stones non-operational control has fascinated physicians. In 1782, Durande attracted early interest in the notion of dissolving gallstones. Makino documented dissolution of gall stone by administration of ursodeoxycholic acid in 1975.

EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY(ESWL)

Extracorporeal shock wave lithotripsy has been in use since 1986. It is used to fragment stones. Selection of patients is very critical for success and are chosen according to criteria.

The criteria are functioning of gall bladder and stone should be

Cholesterol stone

Less than 3 in number

Less than 3 cm.

Recurrence rate is 5-7% at 12 months and 15% at 24 months.

MEDICAL MANAGEMENT

Ursodiol (ursodeoxycholic acid) constitutes less than 5% of total bile salt pool[29].

CLINICAL USES

Dissolution of small cholesterol gallstones in patients with symptomatic gallstones who refuse cholecystectomy or who are poor candidates for surgery. Dissolution occurs in up to 50 per cent of patients with small (< 5-10 mm) uncalcified gallstones at a dosage of 10 mg/kg/day for 12 -24 m[30].

Prevention of gallstones in obese patients undergoing rapid weight loss therapy[30]. At a 13-15mg/kg/d dosage, it is helpful for patients with early stage primary biliary cirrhosis, reducing abnormalities in liver function and improving histology in the liver.

ADVERSE EFFECTS

Ursodiol has almost no significant side effects. Bile salt induced diarrhea is uncommon.

PREOPERATIVE PREPARATION

In prior cases, coagulation of the blood can be reduced by giving vitamin K (IM in 3 doses). A prophylactic antibiotic is given either with premedication or on induction of anesthesia. A second generation of cephalosporin is advisable[31]. Subcutaneous heparin or ant embolic stocking are used to prevent deep vein thrombosis.

OPEN CHOLECYSTECTOMY

Indications

Poor pulmonary or cardiac reserve

Suspected or known gallbladder cancer

Cirrhosis and portal hypertension.

Third-trimester pregnancy

Combined procedure

LAPAROSCOPIC CHOLECYSTECTOMY

Laparoscopic Cholecystectomy is one of the most commonly performed surgeries and has substituted open cholecystectomy. In 1992, a consensus development conference of the National Institute of Health (NIH)[32] narrated that laparoscopic cholecystectomy "provides safe and effective treatment for most patients with symptomatic gallstones[2].

INDICATIONS [33]

Symptomatic cholelithiasis

Biliary colic: Once the patient experiences symptoms, there is a chance that they will continue to have symptoms by greater than 80 per cent. There is also a finite risk of disease associated complications such as acute cholecystitis, gallstone pancreatitis and choledocholithiasis.

Acute cholecystitis.

Gallstone pancreatitis.

Asymptomatic cholelithiasis

Asymptomatic gallstone patients are less than 20% likely to develop symptoms and the risks associated with prophylactic operation outweigh the potential benefit of surgery in most of the patients[34]. Therefore, prophylactic cholecystectomy is suggested in:

Sickle cell disease[35]

Total parenteral nutrition

Chronic immunosuppression.

No immediate access to health care facilities (eg: missionaries, military personal, peace corps workers, relief workers).

Incidental cholecystectomy for patients undergoing procedures for other indications.

Acalculous cholecystitis or biliary dyskinesia

Gallbladder polyps >1 cm in diameter.

Porcelain gallbladder.

CONTRAINDICATION TO LAPAROSCOPIC CHOLECYSTECTOMY

ABSOLUTE

Unable to tolerate general anesthesia.

Refractory coagulopathy

Suspicion of carcinoma[35]

In porcelain gallbladder and potentially curable GB malignancy due to ongoing resection issues and port site metastasis reports associated with the use of minimally invasive surgical technique to treat intra-abdominal malignancies[35].

RELATIVE

Previous upper abdominal surgery[35]

Cholangitis

Diffuse peritonitis with hemodynamic compromise

Cirrhosis and /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.

Cholecystoenteric fistula.

Chronic obstructive pulmonary disease.

Pregnancy.

Due to unknown effect of CO_2 on fetus, it is avoided in first trimester. Open insertion of port or location of initial port in right upper quadrant to prevent uterine damage. To avoid fetal acidosis, maintenance of pneumoperitoneum up to <12 mm of hg and maternal hyperventilation with PCO_2 monitoring is needed[35].

APPROACH (NORTH AMERICAN)

The patient is kept in supine in anti-Trendelenburg position (15 degree head up tilt) with left lateral tilt (15-20 degree) this ensures that the bowel and Omentum falls down and medially, away from the operative site. The operating surgeon and camera surgeon stand on patient's left while the assistant surgeon stands on patient's right. Two monitors are placed at 10'O and 2'O clock position[36].

PORT PLACEMENT

Ports are positioned by screwing motion. Second hand is used to avoid unintentional plunge of the trocar. The assistant would provide counter traction on the abdominal wall while the first trocar was being mounted.

In the midline, 10 mm port will be placed[37], typically via umbilicus. Sub-umbilical position preferred in patients with cirrhosis due to the presence of dilated, tortuous anastomotic veins in the periumbilical region, visceroptic liver, hepatomegaly and in patients with pendulous abdomen.

If a previous abdominal surgery was done via a vertical midline incision, the abdomen is insufflated through a site adjacent to the umbilicus, and in the right upper quadrant, a primary 5 mm trocar is placed. The 10 mm trocar is then placed under direct vision, avoiding the adhesions from previous

operation, under direct vision through a 5 mm telescope passed through 5 mm port.

Pneumoperitoneum is created through Hasson technique if previous surgery prevents primary puncture through the umbilicus[38].

At the level of liver inferior edge and to the right of falciform ligament, another 10 mm port is placed in the epigastrium starting from the midline and angling towards the gallbladder.

If it is placed too high, segment IV of the liver will obstruct the ability to get to the gallbladder[38].

In the midclavicular line, a trocar of 5 mm is positioned 2 to 3 cm below the costal line. The fourth, a 5 mm trocar is normally positioned in the anterior axillary line several centimeters below the gallbladder 's fundus, but its position varies[38].

EXPOSURE OF PORTA HEPATIS

The gallbladder fundus is held with a ratchet grasper, and removed in a cranial direction by the assistant, which raises the liver's right lobe and reveals the liver's calots triangle and hilum. Adhesions to the underside of the liver and bladder are carefully taken down beginning near the fundus and proceeding down towards the neck[19].

DISSECTION OF THE CHOLECYSTOHEPATIC TRIANGLE (CALOTS TRIANGLE)

It can be decompressed in tensely distended GB in two forms- percutaneous veress needle aspiration or the midclavicular trocar is directly inserted into the gallbladder fundus and aspired content. To retain the infundibulum and retract it downwards and to the right, an atraumatic grasper is introduced through the left-hand working port. The peritoneum of the infundibulum is held and penetrated using small bursts of cautery current using the forceps of a Maryland which is inserted through the epigastric harbour. The anterior and posterior parts of peritoneum are taken off. The infundibular grasper moved infero-laterally and supero-medially by flag technique to support the dissection of the triangle of the calot's anterior and posterior surface[40].

IDENTIFICATION OF THE CYSTIC DUCT AND ARTERY

Methods for ductal identification in laparoscopic cholecystectomy

Infundibular or infundibular-cystic technique: This procedure is used to isolate the cystic duct by dissection on the front and back of the calot's triangle and once isolated it can be traced on to the gallbladder.

Critical view of the safety triangle: Procedure includes complete dissection of the cholecystohepatic triangle and separation of the base of the gallbladder infundibulum from the liver bed. Once this view is obtained, cystic duct and artery may only be the two structures that join the gallbladder. Not necessary that the common bile duct is needed to be seen.

Cystic duct is located at the gallbladder junction (SAFETY ZONE) and followed down for appropriate length for cholangiography. There is not necessary to identify and dissect Cystic duct junction CBD (DANGER ZONE)[41].

Cystic artery can be identified by blunt dissection along with its anterior and posterior branches[41]. Often, the cystic node overlays the cystic artery. There is a clipping on both the cystic duct and the artery, two clips on the side of the cystic duct and one on the side of the gallbladder. Before clipping, the cystic duct of the stones in the cystic duct is milked back to GB. Artery is divided before the duct but in some cases the duct is divided first to give artery visibility. The cystic duct is clipped at its junction with GB in the case of an impacted cystic duct stone, and a partial cut is made just distal to the clip, and the impacted stone is milked back and removed[41].

DETACHMENT OF GB FROM THE LIVER BED

The GB can be separated from the liver bed using a spatula with monopolar cautery, hook with monopolar cautery, scissors with monopolar cautery or harmonic scalpel. Care needs to be taken to keep away from the porta hepatis and the liver bed, and to avoid gallbladder perforation[42]. Dissection is supported by traction and counter traction. Any inadvertent spillage of bile or stones from the GB during the procedure must be managed instantly by attaching clips, pre-tied loops or reapplying the grasping clamp[41].

Spilled bile is immediately sucked, and stone extracted. The liver bed is checked for sufficient hemostasis or bile leak before complete detachment of the gallbladder. The remainder of the cystic duct and the stumps of the cystic artery are inspected. Minor oozing from the liver bed is regulated with cauterizing & continuous suction irrigation. When the complete hemostasis is achieved, GB is completely isolated[41].

EXTRACTION OF THE GB

Extraction of the GB can be done through umbilical or epigastric port. Epigastric port is preferred because:

No need to change camera port.

Facilitates thorough rinsing to avoid port tract infection

By extending skin incision, the fascial opening can be easily dilated, and majority of GB extracted

Fascial opening closed easily by cutaneous approach.

Better cosmetic appearance.

Gall bladder is extracted by introducing a claw shaped forceps and used to grasp the neck of the GB. If gall bladder is too distended, through the skin incision the neck is pulled out, small nick made, and bile suctioned, and stones crushed using sponge holder. Fascial incision is enlarged if the gall bladder is thick and it prevents the extraction procedure. To minimize the infection of port side, necrotic or GB with suspicion of carcinoma is placed inside a sterile bag before the extraction.

FINAL INSPECTION AND IRRIGATION

The epigastric port is replaced after GB is removed, and the surgical site is inspected for bleeding. The GB bed, Morrison's pouch, paracolic gutter, and perihepatic areas are given thorough wash with saline that is immediately suctioned.

Venous ooze is controlled from the liver bed by

Gelatin sponge soaked in hemostatic solution.

Use of harmonic ball application.

Rarely intracorporeal suturing.

Argon plasma coagulator.

DRAINGE AND CLOSURE

A 14F Redivac tube is placed via 5 mm trocar lateral most port if drain is required. Trocars are separated from Trocar site under direct vision to check for bleeding. Pneumoperitoneum evacuated and subcuticular stitch/skin clip/Dermabond.

METHODOLOGY

It is a randomized prospective study done in patients who underwent laparoscopic cholecystectomy in Department of Surgery, B.L.D.E. (DEEMED TO BE UNIVERSITY) SHRI B.M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE, VIJAYAPURA– 586103, KARNATAKA.

All the patients were assigned by randomization into either of two groups:

Study Group: Patients in whom extracorporeal knotting was done for ligation of cystic duct.

Control Group: Patients in whom clips were used for clipping of cystic duct.

Period of study was from November 2018 to June 2020.

SAMPLING: (Prospective, interventional study)

Based on a study done by Kuldeep Singh et al at Patiala in 2017[1], the anticipated mean ± SD of operating time by Extracorporeal knotting vs using clips was 60.50±14.93 and 47.83±14.77 respectively. The minimum sample size is 30 per group with 95% level of significance and 80% power.

Formula used is:

$$N = 2\left[\frac{\left(Z_{1-\propto/2} + z_{\beta}\right) * S}{d}\right]^2$$

$Z_{1-\propto/2}$ Level of significance=95%

$Z_{1-\beta}$--power of the study=80%

d=clinically significant difference between two parameters

SD= Common standard deviation

Statistical analysis:

Data will be represented using Mean ±SD, percentages and diagrams

Significant difference between quantitative data will be found using unpaired t test/ Wilcoxon signed rank test

Significant difference between Qualitative data will be found using Chi square or Fisher's Exact test

METHOD OF COLLECTION OF DATA:

Patients admitted for Cholecystectomy were included in the study and allocated to study and control group alternatively.

Detailed history was taken, thorough clinical examination and investigations were performed for all the patients in both the study and control groups.

A Proforma was used to collect all the relevant data from the patients pre, intra and post operatively.

All cases were followed up to discharge and subsequently for a follow up of three months.

Following evaluation, the patient was subjected to laparoscopic cholecystectomy and time taken, biliary / stone spillage, injury to duct/ artery & cost of clips/suture was noted. Post operatively cases were followed up for any complication.

INCLUSION CRITERIA

Patients with Cholecystitis – Calculous / Acalculous

Patients with cholelithiasis

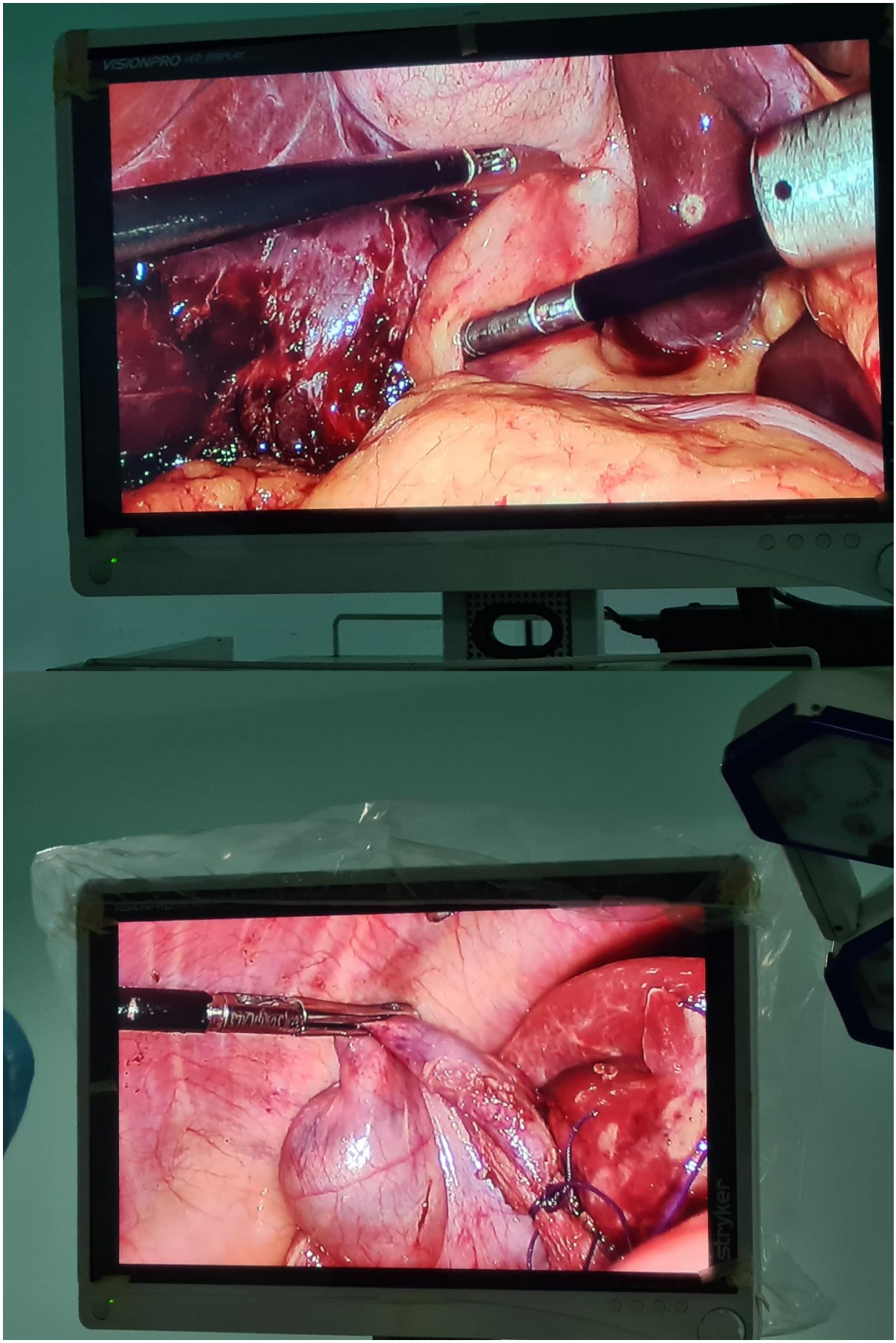
EXCLUSION CRITERIA

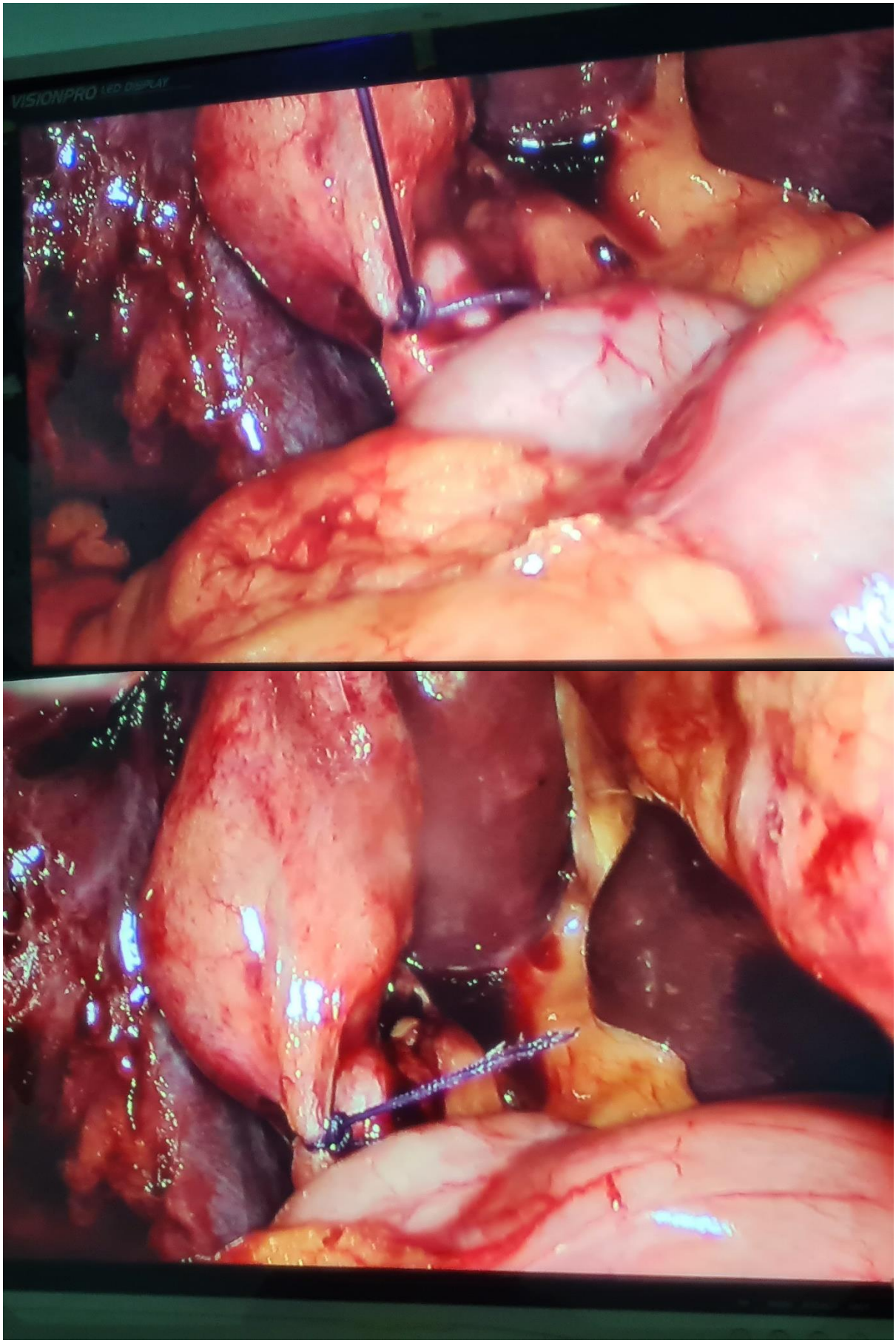
Cardiac disease

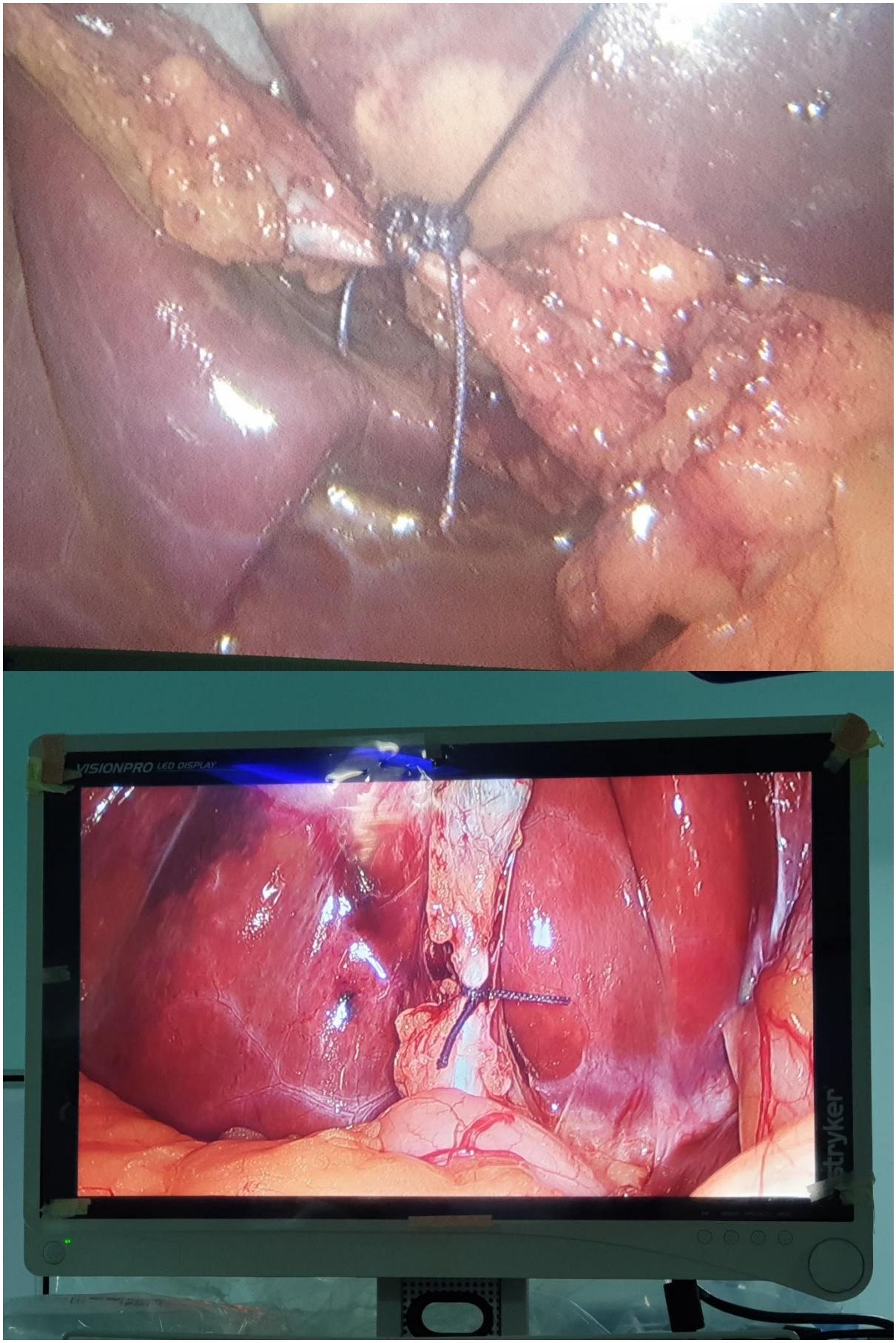
Pregnancy

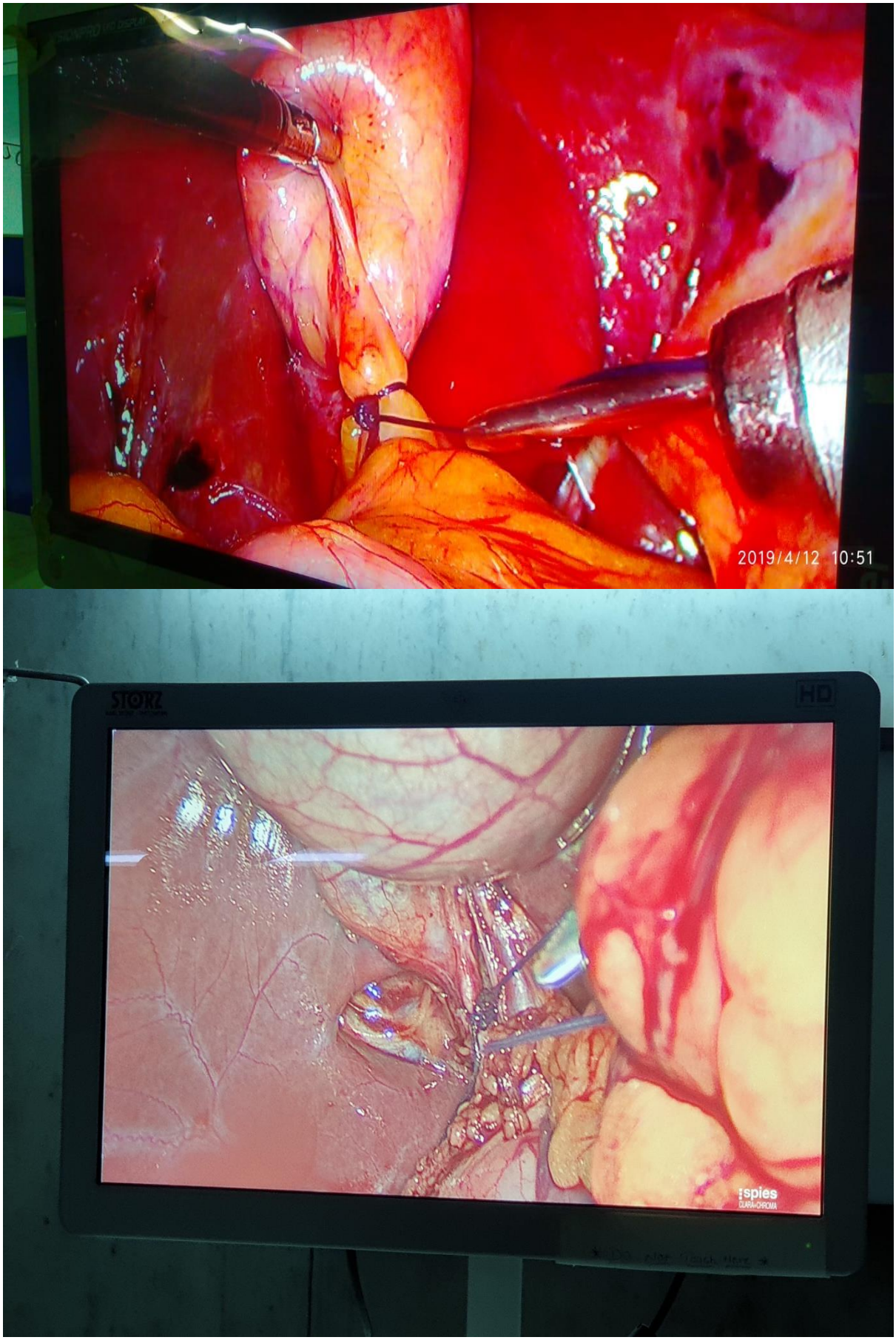
Unfit for general anesthesia

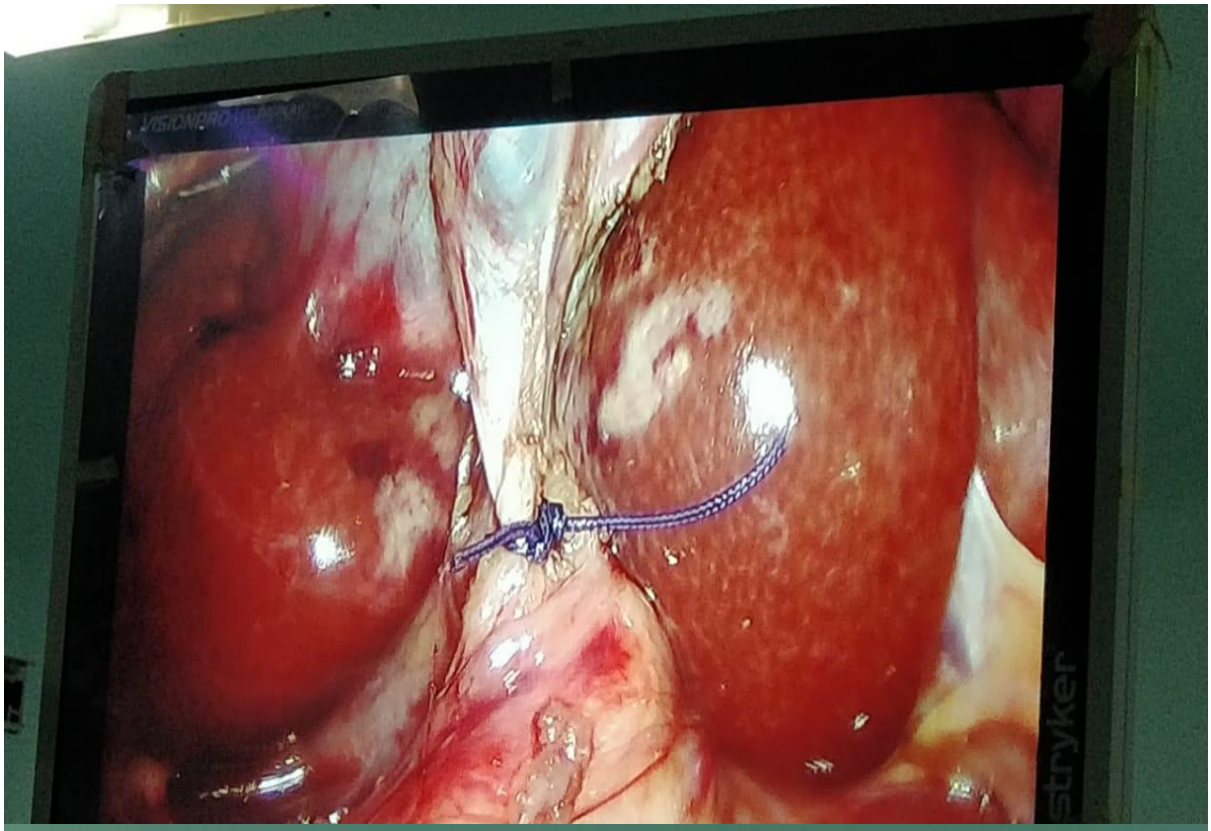
Patients with CBD stone

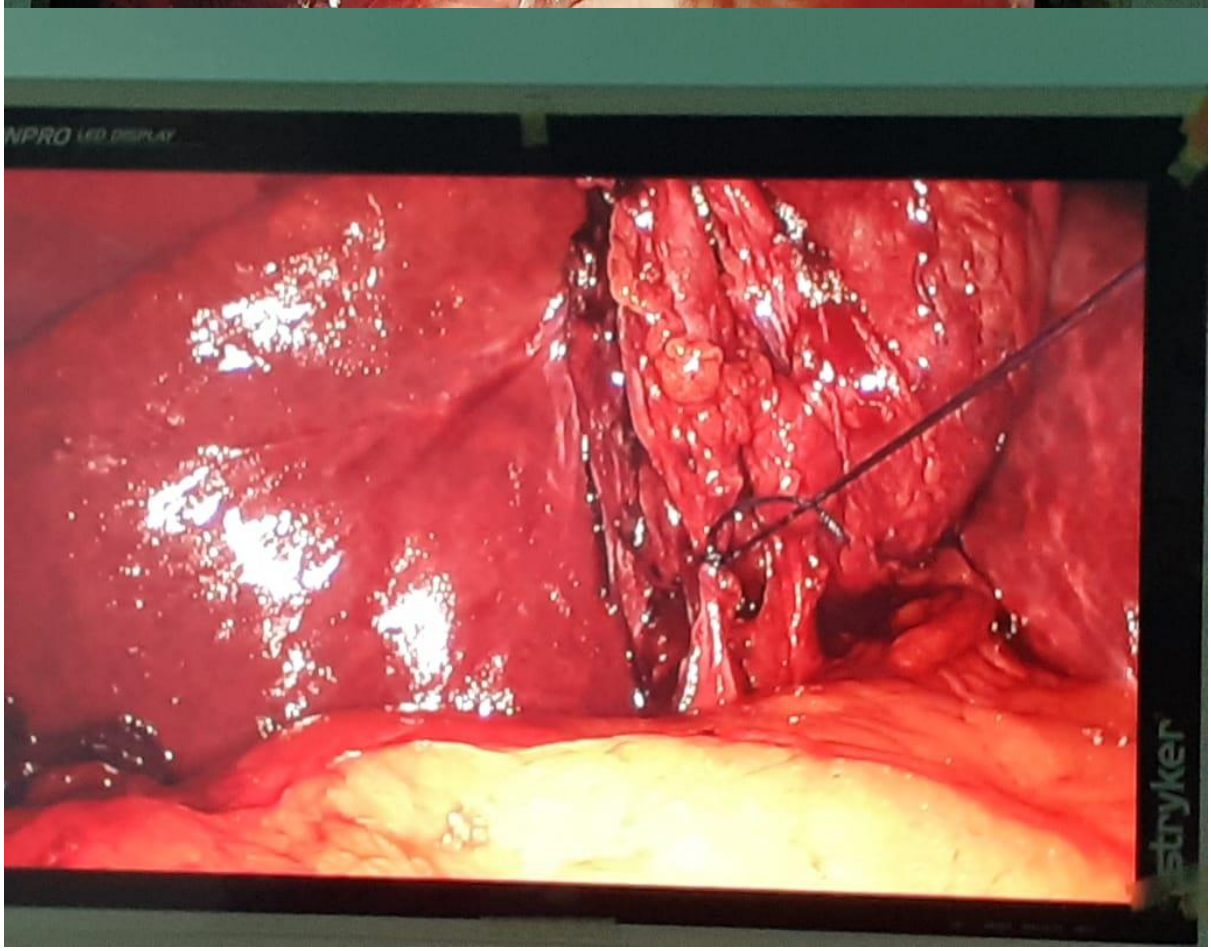












RESULTS

This study included 60 cases that were studied prospectively over a period of 20 months, from November 2018 to June 2020.

AGE DISTRIBUTION

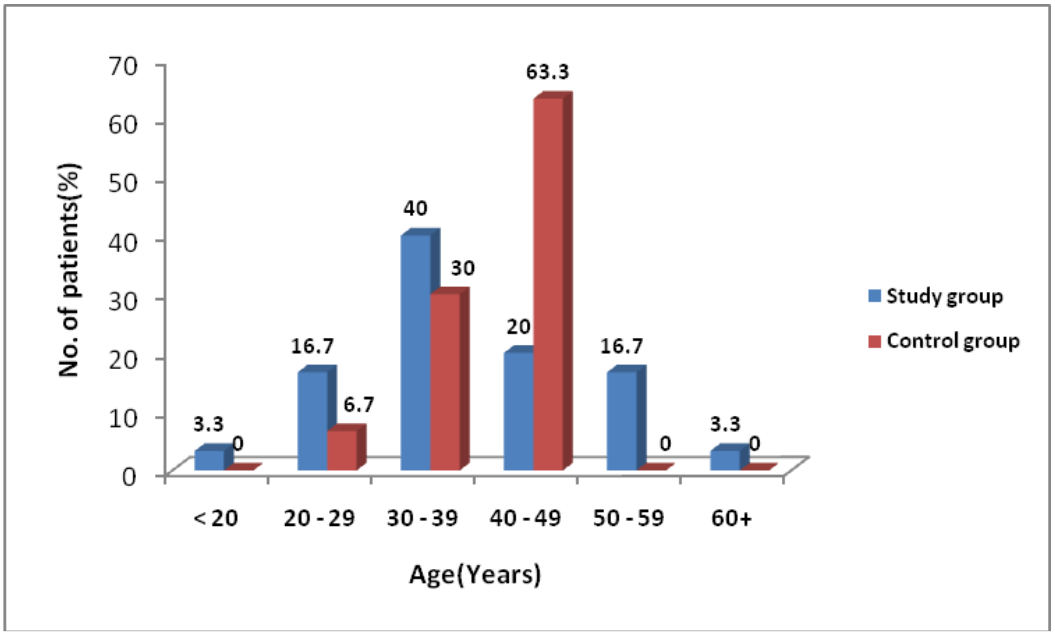
In the present study the youngest patient was 17 years of age and the oldest was 63 years of age. Majority of the patients in the present study were in the age group of 40-49 years of age.

Table 1: Distribution of subjects according to Age (Years)

Age (Years)	Study group		Control group	
	N	%	N	%
< 20	1	3.3	0	0
20 - 29	5	16.7	2	6.7
30 - 39	12	40.0	9	30.0
40 - 49	6	20.0	19	63.3
50 - 59	5	16.7	0	0
60+	1	3.3	0	0
Total	30	100.0	30	100.0

Table 2: Comparison of Age (Years) between Study and Control groups

Age (Years)	**Mean**	**± S.D.**	**Mann Whitney U test**	**P value**	**Remarks**
Study	40.83	10.161	U=386.000	P=0.3477	NS
Control	39.366	5.89			
NS: No significant					



In 30 of the study group patients below the age of 20 years is One and in 30 of the control group is None.

In the age group of 20-29 years, study group has 5 patients and control group has 2 patients.

In the age group of 30-39 years, study group has 12 patients and control group has 9 patients.

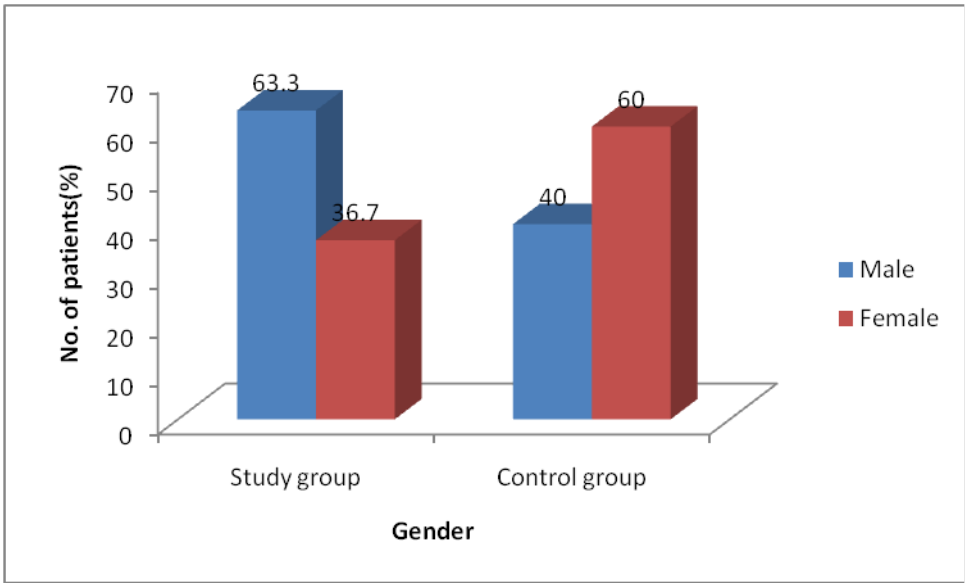
In the age group of 40-49 years, study group has 6 patients and control group has 19 patients.

In the age group of 50-59 years, study group has 5 patients and control group has no patients.

In the age group of 60 years and above there was one patient in study group and none in control group.

Table 3: Distribution of subjects according to Gender

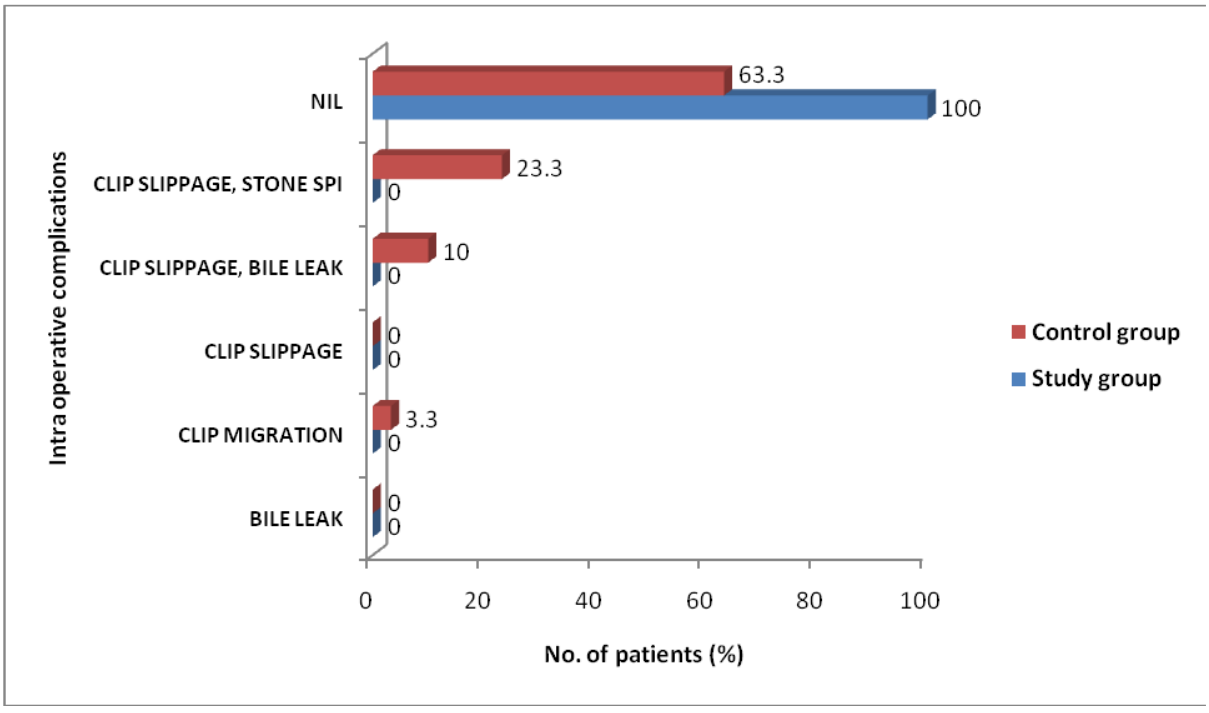
Gender	Study group		Control group		Chi square test	Remark
	N	%	N	%		
Male	19	63.3	12	40.0	$X^{2=}3.270$	P=0.0705 NS
Female	11	36.7	18	60.0		
Total	30	100.0	30	100.0		
NS: No significant						



As per gender, in the study group there are 19 males and 11 females, when compared to control group there are 12 males and 18 females.

Table 4: Distribution of subjects according to I**ntra operative complications**

Intra operative complications	Study group		Control group		Chi square test	Remark
	N	%	N	%		
BILE LEAK	0	0	0	o	X^2=13.469	P=0.0037*
CLIP MIGRATION	0	0	1	3.3		
CLIP SLIPPAGE, BILE LEAK	0	0	3	10		
CLIP SLIPPAGE, STONE SPILLAGE	0	0	7	23.3		
NIL	30	100	19	63.3		
Total	30	100.0	30	100.0		
*: Highly significant						



In the study group there were no intraoperative complications noted among the 30 patients.

In the control group, 11 patients there were intraoperative complications, 7 patients had clip slippage and stone spilling in to the peritoneal cavity from the gall bladder, 3 patients had clip slippage and bile spillage in to the peritoneal cavity from the gall bladder and in 1 patient there was clip migration.

Table 5: Comparison of Operation time (Minutes) between Study and Control groups

Operation time (Minutes)	**Mean**	**± S.D.**	**Difference in mean (%)**	**Unpaired t test**	**P value**	**Remarks**
Study	67.37	15.230	4.68 (6.94%)	t=1.636	P=0.107	NS
Control	61.83	10.55				
NS: Not significant						

In the study group mean time taken for the operation was 67.37 minutes when compared to control group of 61.83 minutes.

In the study group maximum time taken was 105 minutes and the minimum time taken was 35 minutes.

In the control group maximum time taken was 80 minutes and the minimum time taken was 38 minutes.

Table 6: Comparison of Cost of Suture/Clips (In Rupees) between Study and Control groups

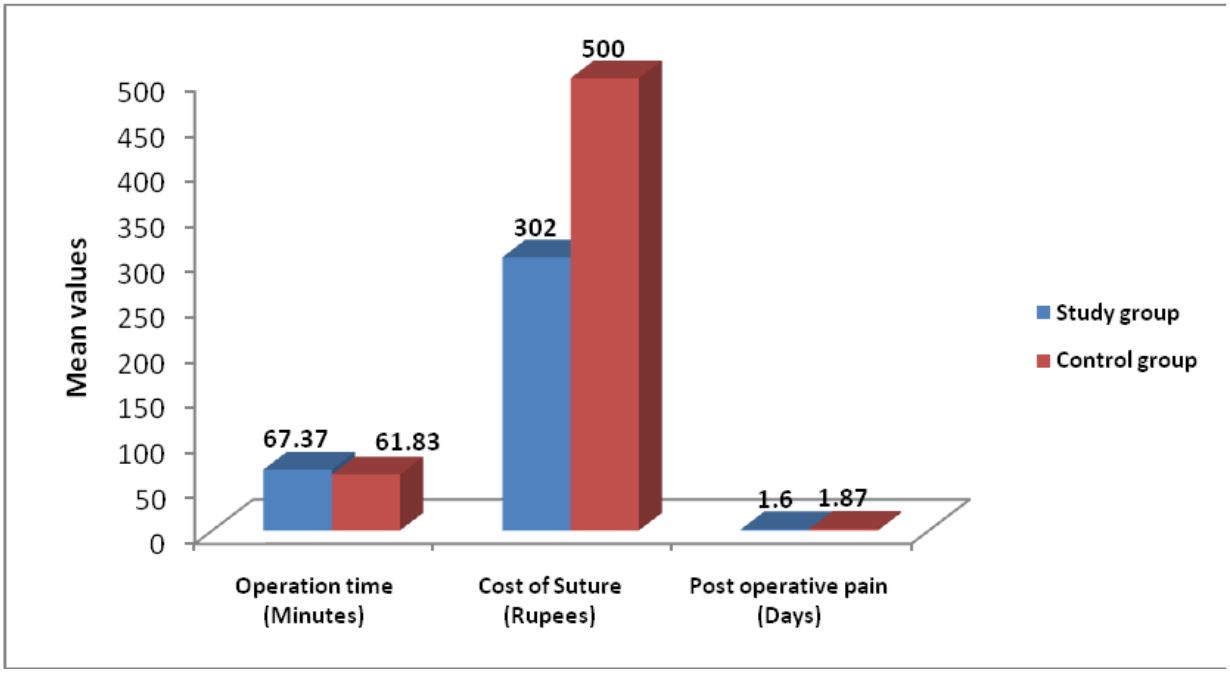
Cost of Suture/Clips (Rupees)	**Mean**	**± S.D.**	**Difference in mean (%)**	**Mann Whitney U test**	**P value**	**Remarks**
Study	302.00	.000	198 (39.6%)	NA		
Control	500.00	.000				
NA: Not applicable (SD=0)						

The average cost of the Suture material used in study group is 302 rupees and the average cost of the Titanium clips used in control group is 500 rupees.

Table 7: Comparison of Post-operative pain (Days) between Study and Control groups

Post-operative pain (Days)	Mean	± S.D.	Difference in mean (%)	Mann Whitney U test	P value	Remarks
Study	1.60	.498	0.27 (0.144%)	U=348.000	P=0.074	NS
Control	1.87	.571				
NS: Not significant						

Post-operative pain is almost similar in both the study and control groups which is statistically not significant.



FOLLOW UP

All patients were followed up for a period of 1 month and no significant complication was noted.

DISCUSSION

The mankind was affected with gall stones from centuries and the best treatment for the symptomatic gall stone disease is Cholecystectomy.

In elective cholecystectomy, laparoscopic cholecystectomy is considered best and feasible.

Laparoscopic cholecystectomy yields good results and better prognosis when compared to the open cholecystectomy in terms of early post-operative recovery, pain, shorter hospital stays and early getting back to routine life style.

In laparoscopic cholecystectomy, preferably titanium clips are used to clip the cystic duct. In recent times, different ways of suturing and knotting are used by either intracorporeal or extracorporeal technique.

However, there are only few prospective studies that compare the cystic duct occlusion with knotting and using titanium clips in laparoscopic cholecystectomy.

In the present study, the maximum percentage of patients who underwent laparoscopic cholecystectomy were under the age group of 30 to 49 years of age i.e. 77%, in another study done by Nidoni R et al in the year 2015 done a study on predicting difficult laparoscopic cholecystectomy based on clinicoradiological assessment in 180 patients also reported that 30 years to 50

years was the most common age group to undergo laparoscopic cholecystectomy[50].

In another study done by Kuldip Singh et al in the year 2017 done a study on Extracorporeal knotting with silk versus liga clips for ligating cystic duct in laparoscopic cholecystectomy in 60 patients reported that most common age group of presentation was between 30 years to 50 years[1].

In this study, the male to female ratio is almost 1:1, in a study done by Nidoni R et al in the year 2015 done a study on predicting difficult laparoscopic cholecystectomy based on clinicoradiological assessment in 180 patients reported that male to female ratio was 1:1.76 [50].

In another study done by Kuldip Singh et al in the year 2017 done a study on Extracorporeal knotting with silk versus liga clips for ligating cystic duct in laparoscopic cholecystectomy in 60 patients reported that there was a female predominance i.e. 90% [1].

In the present study, the mean operating time for group in which extracorporeal knotting done was 67.37 minutes when compared to control group using clips was 61.83 minutes. However, statistical analysis showed that the difference between the two groups was not significant.

Using clips will reduce the intraoperative time which has advantage over the extracorporeal knotting. But there are situations such as wide cystic duct where

clipping is difficult, in such cases using the extracorporeal knotting for occluding the cystic duct is best alternative.

However, the difference in the operating time between the two groups was mainly because surgeons do not commonly use the extracorporeal knotting when compared to the frequently used clips during laparoscopic cholecystectomy and also there are technical difficulties associated with extracorporeal knotting. But as experience increasing with extracorporeal knotting, we have observed that operating time was decreasing.

In the present study cost of the suture (Vicryl 1) used is 302 rupees when compared to titanium clips that cost 500 rupees.

In a study done by Kuldip Singh et al in the year 2017 done a study on Extracorporeal knotting with silk versus liga clips for ligating cystic duct in laparoscopic cholecystectomy in 60 patients concluded that though it takes more time for extracorporeal knotting of cystic duct when compared to liga clips it makes a significant difference with respect to cost without affecting the safety and efficacy in laparoscopic cholecystectomy[1].

In the present study using clips had some drawbacks with respect to the intraoperative complications, in 7 cases there was clip slippage and stone spillage seen during the dissection of gall bladder from the liver bed and during extraction. Finding and retrieving the spilled stones in the peritoneum is again a difficult task which also extends the operating time.

In 3 cases there was clip slippage at the specimen side and bile was spilled in to the peritoneal cavity, in all these cases peritoneal cavity was irrigated with normal saline.

In the present study, in one case there was clip migration seen during the final inspection, which needed clipping again.

In the present study, there was no case with cystic duct leak post-operatively in both the groups i.e. either with extracorporeal knotting or clipping of cystic duct, which indicates cystic duct is safely secured in both the groups.

CONCLUSION

- In laparoscopic cholecystectomy, extracorporeal knotting has the advantages over clipping of cystic duct in operative cost and lesser intraoperative complications with the only limitation being operative time.
- Extracorporeal knotting has more advantages over clips in cases of acute cystic duct inflammation where the duct is oedematous and thickened.

SUMMARY

This study was done to compare the efficacy and safety of extracorporeal knotting with clipping of cystic duct in patients undergoing laparoscopic cholecystectomy.

The study period was from November 2018 to June 2020 with follow-up period of 1 month, a total of 60 patients were included with 30 in each group i.e., extracorporeal knotting and clipping of cystic duct.

The results were evaluated and assessed, it was found that extracorporeal knotting was feasible and cost effective with lesser intraoperative complications as compared to clipping of cystic duct.

Follow-up period for both the groups were uneventful.

Hence it can be safely concluded that Extracorporeal knotting has the advantage over clipping of cystic duct in terms of operative cost and lesser intraoperative complications, with the only limitation being operative time.

Extracorporeal knotting has more advantages over clips in cases of acute cystic duct inflammation where the duct is oedematous and thickened.

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11. ANNEXURE I CERTIFICATE OF ETHICAL CLEARANCE

B.L.D.E (Deemed to be University)
SHRI.B.M.PATIL MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE
VIJAYAPUR – 586103

IEC/NO:286/2018
17-11-2018

INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 13-11-2018 at 03-15 PM scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has accorded Ethical Clearance.

Title : A comparative study of extra corporeal knotting versus clips for ligating cystic duct in Laparoscopic Cholecystectomy.

Name of P.G. Student : Dr H Vishnuteja Department of General Surgery

Name of Guide/Co-investigator: Dr Deepak R Chavan, Associate Professor of Surgery

DR RAGHAVENDRA KULKARNI
CHAIRMAN
Institutional Ethical Committee
BLDEU's Shri B.M. Patil
Medical College,BIJAPUR-586103.

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.

ANNEXURE II -PARTICIPANT CONSENT FORM

TITLE OF THE PROJECT:

"A COMPARATIVE STUDY OF EXTRA CORPOREAL KNOTTING VERSUS CLIPS FOR LIGATING CYSTIC DUCT IN LAPAROSCOPIC CHOLECYSTECTOMY"

NAME OF THE INVESTIGATOR: Dr. H VISHNU TEJA

NAME OF THE GUIDE: Dr. DEEPAK R CHAVAN

PROCEDURE: Laparoscopic cholecystectomy

CONFIDENTIALITY OF RECORDS:

I understand that medical information produced by this study will become a part of this hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical record, but will be stored in the investigation research file only by a code number. The code key connecting name to numbers will be kept in the medical records. If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time, Dr H VISHNU TEJA is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me and that a copy of this consent form will be given to me to keep it and for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary, I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that Dr. H VISHNU TEJA, will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to _____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date:

Dr. Deepak R Chavan **Dr. H Vishnu Teja**

(Guide) **(Investigator)**

Participant's name: **Address:**

TITLE OF THE PROJECT:

"A COMPARATIVE STUDY OF EXTRA CORPOREAL KNOTTING VERSUS CLIPS FOR LIGATING CYSTIC DUCT IN LAPAROSCOPIC CHOLECYSTECTOMY"

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the above study.

_____ _____

(Participant) (Date)

_____ _____

(Witness to signature) (Date)

_____ _____

(Investigator to signature) (Date)

ANNEXURE III - PROFORMA

Date:

Name:

Age:

Sex:

IP NO:

Occupation:

Address:

Mobile No.:

Chief complaints:

Brief history:

Pain abdomen-

Aggravating factors-

Relieving factors-

Fever-

Altered bowel habits-

Urinary complaints-

Past history:

Diabetes Mellitus-

Hypertrension-

Personal history:

Diet- Appetite-

Sleep- Bowel & bladder habits-

Habits-

General physical examination:

Vitals pallor/icterus/cyanosis/clubbing/lymphadenopathy/edema

Pulse Rate-

Blood pressure-

Temperature-

Systemic examination:

Per abdomen:

Inspection-

Palpation-

Percussion-

Auscultation-

Cardiovascular system:

Respiratory system:

Central nervous system:

Provisional diagnosis:

Management:

Investigations:

1. HEMOGRAM- HB , TC , DC , PLATELET COUNT
2. BLOOD SUGAR
3. BLOOD UREA , SERUM CREATININE
4. COAGULATION PROFILE,
5. HIV , HBSAG , HCV
6. ELECTROCARDIOGRAM
7. CHEST X-RAY PA VIEW
8. LIVER FUNCTION TEST
    - TOTAL BILIRUBIN
    - CONJUGATED BILIRUBIN
    - UNCONJUGATED BILIRUBIN
    - TOTAL PROTEIN
    - SERUM ALBUMIN
    - SGOT
    - SGPT
    - ALP
9. ULTRASOUND ABDOMEN
10. OTHER INVESTIGATION

Final diagnosis:

Treatment:

Cost of the procedure -

Duration of the procedure -

Comments (if any)

KEY TO MASTER CHART

SL NO – Serial number

IP NO – In patient number

G – Gender

M – Male

F – Female

CASES								
SL.NO	NAME	AGE	G	IP NO	OPERATING TIME (IN MINUTES)	COST OF SUTURE (IN RUPEES)	POST OPERATIVE PAIN (IN DAYS)	INTRA OP COMPLICATIONS
1	Tippanna	48	M	11060	105	302	2	NIL
2	Ashwini	26	F	7141	75	302	1	NIL
3	Anushaya	40	F	40437	82	302	1	NIL
4	Laxman	47	M	17167	72	302	1	NIL
5	Vinod	46	M	17160	76	302	2	NIL
6	Dhaneshwari	29	F	16939	66	302	2	NIL
7	Nisha prakash	17	F	18464	35	302	1	NIL
8	Basavaraj	38	M	20143	40	302	1	NIL
9	Dondiba	52	M	19238	70	302	2	NIL
10	Kashimbi	44	F	16738	38	302	2	NIL
11	Mamata	43	F	18684	60	302	2	NIL
12	Sunil	55	M	21740	68	302	2	NIL
13	Shoba	45	F	22738	48	302	2	NIL
14	Revati	42	F	20354	65	302	2	NIL
15	Mahantesh	39	M	21334	75	302	2	NIL
16	Ashama	28	F	20560	55	302	2	NIL
17	Lakshmi	42	F	33655	65	302	2	NIL
18	Kousalya	44	F	32078	75	302	2	NIL
19	Bharati	50	F	40815	68	302	1	NIL
20	Kaveri	36	F	41643	62	302	1	NIL
21	Rajeshwari	24	F	820	60	302	1	NIL
22	Revati	63	F	45	56	302	2	NIL
23	Neelakantayya	38	M	5044	72	302	1	NIL
24	Prabhu	29	M	8424	65	302	1	NIL
25	Yellawwa	46	F	8098	66	302	2	NIL
26	Suchita	36	F	9789	62	302	2	NIL
27	Janaki	36	F	9781	80	302	2	NIL
28	Savitri	55	F	14253	85	302	1	NIL
29	Mahiboob	50	M	14263	85	302	1	NIL
30	Praveen	37	M	16200	90	302	2	NIL

CONTROLS								
SL.NO	NAME	AGE	G	IP NO	OPERATING TIME (IN MINUTES)	COST OF CLIPS (IN RUPEES)	POST OPERATIVE PAIN (IN DAYS)	INTRA OP COMPLICATIONS
1	Sudhakar	35	M	5343	56	500	2	
2	Sayabanna	36	M	3167	68	500	3	
3	Basu	40	M	5446	60	500	2	CLIP SLIPPAGE, STONE SPILLAGE
4	Renukamma	38	F	8076	55	500	3	CLIP SLIPPAGE, BILE LEAK
5	Ambresh	44	M	7658	66	500	2	
6	Ramsingh	42	M	7026	42	500	1	CLIP SLIPPAGE, STONE SPILLAGE
7	Appashi	45	M	6549	65	500	1	CLIP MIGRATION
8	Laxmi	26	M	9378	80	500	2	
9	Sumangala	41	F	10044	80	500	2	
10	Shantabai	44	F	42008	76	500	1	
11	Irabasamma	42	F	39562	70	500	2	CLIP SLIPPAGE, STONE SPILLAGE
12	Bhimrao	43	M	42022	68	500	1	
13	Kalpana	36	F	14406	72	500	1	CLIP SLIPPAGE, STONE SPILLAGE
14	Neelamma	43	F	16026	65	500	2	
15	Lalitabai	40	F	17972	38	500	2	CLIP SLIPPAGE, BILE LEAK
16	Vittal	48	M	26739	50	500	1	
17	Shyanta	43	F	28283	60	500	2	
18	Rayappa	42	M	27607	60	500	1	
19	Mirabai	41	F	27692	68	500	1	
20	Jairabee	35	F	20612	62	500	1	CLIP SLIPPAGE, STONE SPILLAGE
21	Bheemabai	30	F	21457	52	500	1	
22	Shrushti hiremat	22	F	36507	75	500	2	
23	Subhas	40	M	8008	62	500	2	
24	Manjula	36	F	7142	68	500	2	CLIP SLIPPAGE, BILE LEAK
25	Uma kamalesh	36	F	4482	50	500	1	
26	Mamata	40	F	2724	45	500	1	
27	Girija	45	F	1807	60	500	1	CLIP SLIPPAGE, STONE SPILLAGE
28	Anita	42	F	884	65	500	2	
29	Rahul	37	M	43435	65	500	2	CLIP SLIPPAGE, STONE SPILLAGE
30	Kamalabai	49	F	9592	52	500	1	