“A CROSS SECTIONAL STUDY TO DETERMINE PREDICTIVE FACTORS FOR DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY USING ULTRASONOGRAPHIC CRITERIA”

By
REG No BH0115005

Dissertation

Submitted to the
KLE University, Belagavi, Karnataka

In Partial Fulfillment
of the requirements for the degree of

MASTER OF SURGERY (M.S.)
in
GENERAL SURGERY

DEPARTMENT OF SURGERY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELAGAVI, KARNATAKA

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ENDORSEMENT

This is to certify that the dissertation entitled **"A CROSS SECTIONAL STUDY TO DETERMINE PREDICTIVE FACTORS FOR DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY USING ULTRASONOGRAPHIC CRITERIA"** is a bonafide research work done by **CANDIDATE REG No. BH0115005**.

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LIST OF ABBREVIATIONS USED

ACR	-	American College of Radiology
ALP	-	Alkaline phosphatase
ALT	-	Alanine aminotransferase
AST	-	Aspartate aminotransferase
CBD	-	Common bile duct
CI	-	Confidence intervals
cm	-	Centimeter
CO_2	-	Carbon dioxide
CT	-	Computed tomography
DIDA	-	Diisopropyl iminodiacetic acid
ERCP	-	Endoscopic retrograde cholangiopancretography
ESWL	-	Extracorporeal Shock Wave Lithotripsy
EUS	-	Endoscopic Ultrasound
GB	-	Gallbladder
HBS	-	Hepatobiliary scintigraphy
HbSAg	-	Hepatitis B surface antigen
HIDA	-	Hepatobiliary iminodiacetic acid
HIV	-	Human immuno deficiency virus
ICU	-	Intensive care unit
LC	-	Laparoscopic cholecystectomy
mg	-	Milligrams
mm	-	Millimeter
MRCP	-	Magnetic resonance cholangiopancretography
MRI	-	Magnetic resonance imaging

n	-	Total number
NIH	-	National Institute of Health
OC	-	Open cholecystectomy
OPD	-	Out patient department
OR	-	Odds Ratio
p	-	Probability value
TPN	-	Total parenteral nutrition
US	-	Ultrasound
USA	-	United States of America
USG	-	Ultrasonography
VIP	-	Vasoactive intestinal polypeptide
VN	-	Veress needle
WBC	-	White blood cell count

ABSTRACT

Background and objectives

Ultrasonography is highly helpful characterizing the gallbladder appearance. The present study was undertaken to determine the role of ultrasonography in predicting difficult laparoscopic cholecystectomy and to correlate preoperative factors with intraoperative findings of laparoscopic cholecystectomy.

Methodology

This hospital based prospective study was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2016 to December 2016. A total of 60 patients presenting with right hypochondriac pain and diagnosed to have cholecystitis or cholelithiasis undergoing laparoscopic cholecystectomy were studied

Results

The male female ratio was 1.06:1 and 51.67% of the patients were males. The mean age was 47.62±10.35 years. Ultrasound findings showed 68.83% of the patients with multiple numbers of stones, 38.33% with stone size of ≥10 mm and 31.67% had gallbladder thickness of ≥4 mm. The gall bladder volume was contracted in 21.67% of the patients. Intra operative findings revealed difficult gall bladder extraction in 30.77% of the patients followed by stone spillage in 23.08% of the patients, bleeding in 15.38% of the patients, difficult Calot's triangle dissection and gall bladder perforation in 11.54% each. Based on these observations, 43.33% of the patients had difficult laparoscopic cholecystectomy.

Conversion from laparoscopic cholecystectomy to open cholecystectomy was noted in 11.67% of the patients. Significantly higher number of patients with difficult laparoscopy (26.92%) required conversion to open laparoscopic cholecystectomy (p=0.002). Also significantly higher number of patients with largest stone size of ≥10 mm (26.09%; p=0.010), gall bladder wall thickness of ≥4 mm (31.58%; p=0.003) and contracted gall bladder (38.46%; p=0.008) required conversion to open cholecystectomy.

Conclusion and interpretation

Hence, it may be concluded that, ultrasonographic finding namely, multiple numbers of stones, stone size of ≥ 10 mm, gall bladder thickness of ≥ 4 mm and contracted gall bladder volume help in predicting difficult laparoscopy.

Key words

Cholecystitis; Cholelithiasis; Difficult Laparoscopic cholecystectomy; Laparoscopic cholecystectomy; Open laparoscopic cholecystectomy;

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INTRODUCTION

Gallstone disease is one of the most common problems affecting the digestive tract.[1] Cholecystitis is defined as inflammation of the gall bladder that occurs most commonly because of an obstruction of the cystic duct due to cholelithiasis.[2,3] The prevalence of Gallstone disease in general population is 3% - 20% of the total population worldwide.[2,4] The prevalence of gallstones is related to factors like age, gender, and ethnic background. It is estimated that approximately 20 million people in the United States have gallstones and that approximately 1 million new cases of cholelithiasis develop each year. In India the prevalence is estimated to be around 4%,[1,5] and 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.[1]

Physical examination may reveal fever, tachycardia and tenderness in the right upper quadrant or epigastric region, often with guarding or rebound tenderness and sometime jaundice may be noted. It was only in the 1800s that surgical intervention for gallstone disease was initiated with creation of "*permanent cholecystectomy*". Later in the century, Carl Johann August Langenbuch developed the technique of cholecystectomy which has become the gold standard for symptomatic cholelithiasis and remained so far over a century, until the introduction of laparoscopic cholecystectomy in the 1980s.[2,3]

Minimal invasive surgery brings a revolutionary change in the treatment of patients with gallbladder stones. Mouret introduced laparoscopic cholecystectomy in 1987,[6] which brought a radical change in the treatment of patients with gallstones.

Laparoscopic cholecystectomy (LC) is now the standard procedure for the treatment of symptomatic gallstones.[1,2,7-10]

At present, laparoscopic cholecystectomy (LC) is considered the treatment of choice for symptomatic cholelithiasis. It has many advantages over open cholecystectomy in terms of minimal postoperative pain, shorter hospital stay, better cosmetics and early recovery. As the experience with LC is increasing throughout the world, selection criteria have become more liberal. Most of the factors like morbid obesity or previous upper abdominal surgery which were considered as contraindication for attempting LC have no longer remained as absolute contraindications. The number of contraindications have come down significantly over time. Attempts can be made in all cases of gall stone diseases with laparoscopic procedure except for patients with bleeding diathesis, carcinoma gallbladder and patients who are not fit for general anaesthesia.[11] The results of laparoscopic cholecystectomy are greatly influenced by the skill and experience of the surgeon performing the procedure. It reflect acquisition of appropriate technical skills. However, of all Laparoscopic cholecystectomies, 1-13% requires conversion to an open procedure for various reasons.[1,12]

Open cholecystectomy remains a safe and effective procedure for the treatment of patients with symptomatic gallstones and is the gold-standard with which all other procedures must be compared.[1,2,7-10] The conversion of laparoscopic to open cholecystectomy usually reflects a sound surgical judgment, and it should be considered as such, rather than a complication of the procedure.

Ultrasonography is the most commonly performed noninvasive, safe, and highly accurate screening test for cholecystitis or cholelithiasis. It can also help the surgeon to get an idea of potential difficulty to be faced during surgery in a particular patient.[13] On the basis of ultrasound findings, surgeons can select the cases appropriate for their skills aiming at reducing operative complications and minimizing the waste of operative time.[14] Based on ultrasonographic findings, certain preoperative factors can reliably predict the chances of conversion to the open procedure and the danger of certain complications, making the surgeon and the patient both mentally prepared.[15]

Thus, for surgeons it would be helpful to establish a 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.

Preoperative information of possible intra-operative complications such as uncontrollable bleeding or unclear anatomy, conversion to open surgery will give an extra benefits. It can be helpful to raise level of cautiousness and establish a criteria that could assess the risks for conversion preoperatively. It would be helpful to accurately identify an individual patient's risk for conversion based on preoperative information and can result in more meaningful and accurate preoperative counseling, improved operating room scheduling and efficiency, stratification of risk for technical difficulty, and appropriate assignment of resident assistance, also it may improve patient safety by minimizing time to conversion, and better mental preparation of surgeons and patients.

OBJECTIVES

The objectives of this study were;

- To determine the role of ultrasonography for predicting difficulty in laparoscopic cholecystectomy.

- To correlate preoperative factors with intraoperative findings of laparoscopic cholecystectomy.

REVIEW OF LITERATURE

Historical aspects

Archeological excavations have proven the presence of gall stones in young Egyptian women, which shows that humans have suffered from cholelithiasis for more than 2000 years.[16]

Greek physician Alexander Trallianus first described gallstones as calculi within the bile ducts. In the 16th century, Vesailius and Fallopius described gallstones found in the gall bladder of the dissected human bodies.[17] The first interaction of gallstones and surgeons occured in 1687. Stal Pert Von Der Wiel while operating a patient with peritonitis accidentally found gallstones.[18]

Jean-Louis Petit is known as the founder of gall bladder surgery. He described the removal of gallstone and drainage of the gall bladder by creating fistula in patients with empyema gallbladder in 1733.[19] In 1859, J. L. W Thudichum introduced elective cholecystostomy in two stages.[20,21] In the first stage, sewing the inflamed gall bladder to the anterior abdominal wall was done by making a small incision, which was used as a route for the removal of gall stone later. Dr John Stough Bobbs from Indianopolis, Indiana during operating on a patient with ovarian cyst on July 15, 1867, found an inflamed and adherent sac filled with "several solid ordinary rifle bullet" like structures. After opening the sac, it was incidentally found to be the gall bladder packed with multiple gallstones. He removed the gallstones, closed the defect in the gall bladder and left the gall bladder in situ (cholecystostomy).[22]

Marion Simms was credited for designing, perfecting and performing the first cholecystostomy on a 45-year-old woman with obstructive jaundice in 1878.[23] It paved the way for Theodor Kocher for performing the first successful cholecystostomy in June 1878.[15-17] Carl Johann August Langenbuch[17] described these measures to be only temporary and not a definite solution for gallstones. In those years, Zambecarri in 1630 and Teckoff in 1667 from two animal experiments explained that the gall bladder was not essential to life.[23] Also, physicians had a opinion that the gall bladder itself is responsible for formation of stones. Langenbuch practised the technique of cholecystectomy by cadeveric dissections. On July 15, 1882 he successfully performed cholecystectomy in a 43-year-old man who was suffering from the disease for 16 years.[23]

An audit performed in 1886 showed 39 cholecystostomy with a mortality of 27% against 8 cholecystectomies with a mortality of 12%. By the turn of the century it was established that cholecystectomy could provide permanent relief from pain as compared to cholecystostomy which gave a permanent fistula and did not relieve pain.[23]

In the late 19th century, before the modern era of cholecystectomy, Langenbuch explained gall stone pathology and performed the first successful cholecyctectomy.[24] On June 9, 1901 Langenbuch died because of complicated appendicitis but he showed the path for further advanced and modified biliary surgeries.[23]

Surgical Anatomy

The gallbladder is pyriform in shape and is located in the gallbladder fossa on the inferior surface of right lobe of liver. It projects from the right end of the porta hepatis to the inferior border of liver.[25] Gallbladder is attached to the liver by the connective tissue, ranging from being completely covered by the peritoneum to being connected to the liver by a short mesentry.

It is 7 to 10 cm long, 3 cm broad at its widest and have 30-50 ml capacity. It is divided as fundus, body and neck. The fundus, extends down, forwards and to the right. It is visible below the inferior border of liver and comes in contact with the anterior abdominal wall at the junction of the ninth right costal cartilage and the lateral edge of the right rectus abdominis muscle. Posteriorly it is related to transverse colon. The body is directed medially, towards the right end of the porta hepatis and it is continuous with neck. It is related above to the liver, below to the transverse colon and further back to the first and upper end of second part of the duodenum.

The neck is narrow, directed upwards and forwards and then abruptly backwards and downwards, and joins the cystic duct. Thin areolar tissue containing cystic artery connects the neck to the liver. The mucosa of the neck shows a spiral valve which gives its surface a spiral groove when the neck is distended. Hartmann's pouch (originally described by Broca) is a small recess going down and backwards.

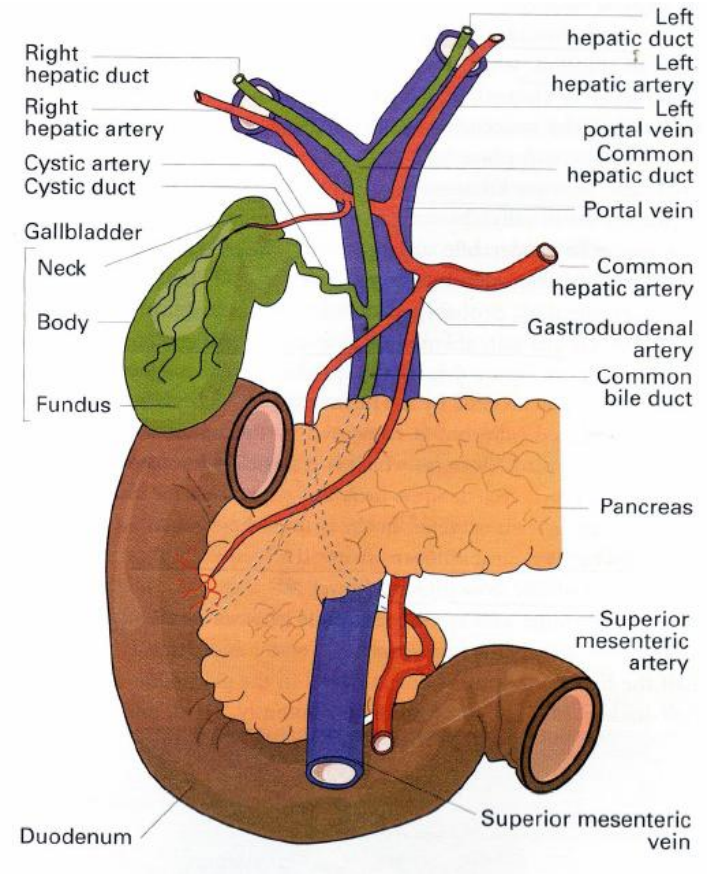


Figure 1. Surgical anatomy of biliary tract[26]

The cystic duct is 3 to 4 cm long; projecting backwards, downwards and medially. It begins from the neck of the gallbladder and joins the common hepatic duct to form the common bile duct. The junction is located just below the porta hepatis. But it may occur at a lower level, where the cystic duct lies along the right edge of lesser omentum. Its mucosa shows 5-10 concentric folds projecting obliquely in regular succession, like a spiral valve, referred as the "valve of Heister".[28-28]

Arterial Supply of the Gallbladder:[25]

Cystic artery, a branch of right hepatic artery is the major blood supply of the gall bladder. The gall bladder also receives many small vessels from hepatic bed. The cystic artery cross the posterior surface of common hepatic and cystic ducts and comes to lie on the neck of the gall bladder, after which it runs downward and forwards and divides into superficial and deep branches. The cystic artery gives branches to the hepatic ducts and to the upper part of the common bile duct. The lower part of the bile duct is supplied by several branches from the posterior superior pancreatico-duodenal artery. The right hepatic artery supplies branches to the bile duct.

Variations in the cystic artery's origin are of surgical interest. In 800 specimens, Anson (1963) observed the following incidences, origin from the right hepatic artery 63.9%, the hepatic trunk 26.9%, left hepatic 5.5% gastroduodenl 2.6%, superior pancreaticoduodenal 0.3%, right gastric 0.1%, coelic trunk 0.3%, and superior mesenteric 0.8%. Accessory cystic artery if present, may be the branch of the common hepatic or one of its branches while the cystic artery supplies the hepatic ducts and the upper part of common bile duct. The cystic artery is an end artery and its occlusion leads to the gangrene of the gall bladder.[29]

Venous Drainage of the Gallbladder:[25]

The venous drainage of the gall bladder may vary considerably. Those from its upper surface run directly into the liver through the fossa of the gallbladder to join the hepatic veins. Those from the rest of the gall bladder join to form one or

more cystic veins on its neck. Rarely a single or double cystic vein drains directly into the right branch of the portal vein. They do not accompany the cystic artery.

Lymphatic Drainage[25]

The lymphatic drainage the gall bladder is of significant importance in both inflammatory and malignant disease of gall bladder. The lymphatic channels from the subserosal and submucosal plexus drain into cystic lymph node of Lund, the sentinel lymph node , lies at the junction of cystic and common hepatic ducts. Efferent vessels from the nodes pass in the free edge of the lesser omentum and drain into the celiac group of preaortic nodes.

The sentinel node may attain a considerable size and may distort the normal anatomy in patients with acute cholecystitis or gallbladder carcinoma. The subserosal lymphatic vessels of the gall bladder also drain into the subcapsular lymphatic channels of liver, which is responsible for the frequent spread of carcinoma of gallbladder to the liver.

Nerve Supply[25]

The wall of the gall bladder is richly innervated with both sympathetic and parasympathetic nerve fibers, accompanying the hepatic artery and its branches. Parasympathetic fibers originate from the hepatic branch of anterior vagal trunk. They stimulate contraction of the gall bladder and relax the ampullary sphincter. Sympathetic fibers originate from the cell bodies in the celiac ganglia, with the pre-ganglionic cells in the lateral horn of the spinal cord segments, T7-T9 and they inhibit contraction. Autonomic plexus is situated in the muscular and submucous layers. Fibers from the right phrenic nerve communicate with celiac plexus and

reach the gallbladder via hepatic plexus. It explains the "referred pain at the right shoulder" in the gall bladder diseases. The biliary tract pain usually starts in the right hypochondrium or epigastrium and may radiate to the back in the infrascapular region, in the area of distribution of spinal nerve T7-T9.

Triangles of cholecystectomy

Jean – Francois Calot's defined a triangular anatomical area formed by the common hepatic duct medially, the cystic duct inferiorly and the cystic artery superiorly in 1891. The previous concept of the Calot's triangle has its upper limit not the cystic artery but the inferior surface of the liver which is now known as hepatocystic triangle.[23] This triangle is of considerable surgical importance because of important structures passing through it. Therefore it should be identified by the surgeons to prevent the damage to extrahepatic biliary system.[30]

Common anomalies and variations

1. Absent gall bladder –which is extremely rare, autopsy incidence of 0.03% have been reported.[25]

2. Variation in size and shape of gall bladder.
    a. Bilobed gall bladder.
    b. Fundal divertculum.
    c. Phrygian cap.
    d. Hour glass gall bladder.

3. Variation in position - left sided gall bladder, or floating gall bladder.

4. Double gall bladder, duplication of gall bladder - two separate cavities and two separate cystic ducts with an incidence of approximately 1 in 4000. In a pathological process such as cholelithiasis and cholecystitis one organ may get involved while the other is spared.[31]

5. Other anomalies related to gall bladder
    a. Intra-hepatic gall bladder
    b. Diverticulum of body or neck of gall bladder
    c. Accessory peritoneal fold due to congenital adhesions.

Floating gall bladder is seen when there is increase in the peritoneal attachment; seen in 5% of patients and susceptible for torsion, resulting in gangrene or perforation of the gallbladder.[25]

Rarely cystic duct may be absent. Two or more cystic ducts may combine. The junction of the cystic duct and common hepatic ducts may vary in its level from the porta hepatis to behind or even below the duodenum's first part. In the low insertion of the duct, these two may be connected by fibrous tissue. Accessory hepatic ducts may arise, most frequently from the right lobe of liver and join the main hepatic duct and rarely may drain in the cystic duct itself.[21]

Physiology of gall bladder[26,28,30]

The primary function of gall bladder is to concentrate the bile by absorption of water and sodium so that it acquires greater digestive power. The gallbladder and bile duct walls are well adapted for the function of storing and secreting bile into the duodenum during the process of digestion. The flow of bile in and out of the gallbladder is determined by contraction and relaxation of the sphincter of Oddi.

The normal gallbladder is rarely static. Continuous cycles of partial emptying and refilling is regulated by the intestinal migratory myoelectric complex in the fasting state. During refilling, it intermittently contracts and secretes pulses of bile into the duodenum. This constant fluctuation in the bile stasis and flow prevents stone formation.

Gallbladder tone is governed by both vagus and circulating peptides. During cephalic phase of digestion vagal stimulation causes gallbladder contraction. During interdigestive period, vagal neurons and circulating polypeptides mediate the contraction. Vasoactive intestinal polypeptide [VIP] released by vagal neurons inhibits gallbladder contraction and causes post prandial gallbladder filling. Gallbladder motility is inhibited by truncal vagotomy and by chronic fasting.

The gallbladder exhibits;

1. Tonic contractions
2. Rhythmic contractions

Constitution of bile

Bile at the point when it leaves the liver is composed of 97% of water, 1 to 2% of bile salts and 1% of bile pigments, cholesterol and fatty acids. The understanding of the constituents of bile is necessary as they have a great impact in the etiology of cholelithiasis.

Bile acids and bile salts:

The bile acids in the human bile are glycocholic and taurocholic acids which are conjugated products of amino acids - glycine and cystine with cholic acid respectively. Bile acids are present in bile in the form of bile salts - Sodium glycocholate and sodium taurocholate. Approximately human bile consists of 70 to 75% glycocholate and 25% of taurocholate.

Bile pigments

The bile pigments are bilirubin and biliverdin. Bilirubin is the chief pigment of the human bile and biliverdin is the exudative product of bilirubin and is present in small quantity. The pigment forms about 15 to 20% of total solids in the bile. They are derived mainly from hemoglobin and a small amount from chromoprotiens.

Lipids

The normal bile contains cholesterol, fatty acids and phospholipids. Cholesterol content of the bile is normally 0.04 to 0.16%. It is present in the free state and its concentration is more in gall bladder bile. Normally the cholesterol and bile salts ratio varies between 1:20 to 1:30.

Mucin

Its main constituent is mucealbumin and it increases in obstructive and inflammatory conditions of the biliary tract. It acts as cementing substance in gall stones. The functions of bile are brought about by the bile acids and are digestion and absorption of fats and fat soluble vitamins, mild laxative effects on the intestine

and also an antiputrefactive effect by their bacteriostatic property on intestinal flora. Bile salts are the best cholerectics.

Entero Hepatic Circulation

Following normal fatty meals, pancreatic lipase causes emulsification of the cleavage products from triglyceride hydrolysis results in the incorporation of fat into micelles. Absorption of fat occurs primarily in the upper intestine, whereas little absorption occurs in the lower third of the small intestine. In the ileum there are specific high affinity binding sites which are responsible for the active absorption of bile acids. Due to the efficiency of this absorptive process, less than 5% of the daily excreted bile reaches the colon. After absorption, bile acids enter the portal vein and are returned to liver. The efficiency of the hepatic removal of bile acids accounts for the extremely low peripheral blood levels normally found. The 95% return rate of bile acids to the liver has two consequences. First, most of the bile acids excreted in bile are actively recycled than being newly synthesized. Second bile acids exert a feedback inhibition that regulates estrogens, cholesterol and fat soluble vitamins.

Laparoscopic anatomy

The advent and popularity of Laparoscopic cholecystectomy has changed the look and understanding of the gallbladder anatomy mainly of the Calot's triangle. The term ‘laparoscopic anatomy’ is now described in anatomy texts. The different anatomical ‘laparoscopic view’ of the gallbladder and the structures around it, mainly the Calot's triangle after retraction intra-operatively leads to the distortion of anatomy. The Calot's triangle gets flattened in real instead of opening.[32] The

posterior dissection of the Calot's triangle during a laparoscopic cholecystectomy changes the view of biliary anatomy and adds to its distortion.[32]

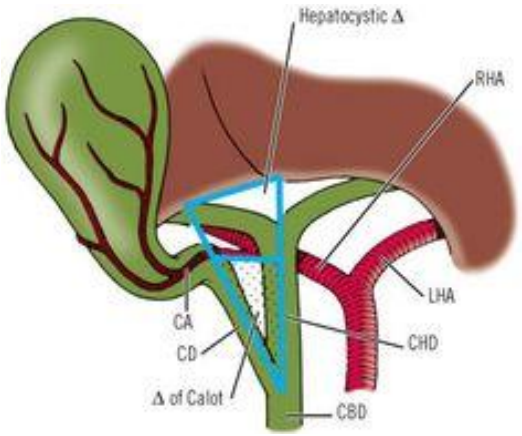


Figure 2. Calot's triangle

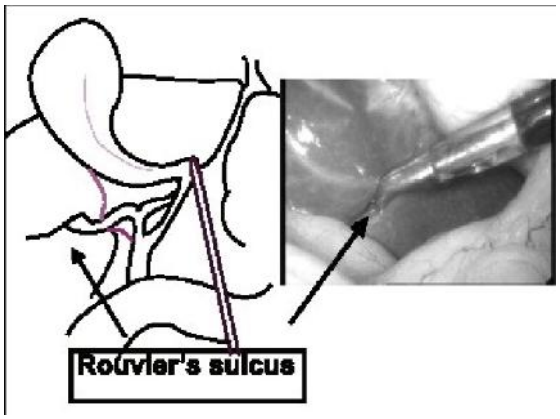


Figure 3. Rouviere's sulcus[32]

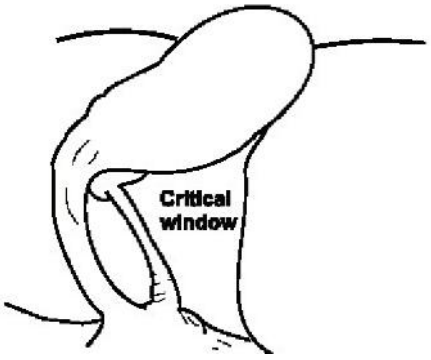


Figure 4. The critical view of safety window[32]

The Rouviere's sulcus is a narrow linear depression on the liver and is located at the level of the porta hepatis near the entry of right pedicle into the liver. It is clearly seen during the posterior dissection. The guidelines describe the safe dissection at the level anterior to this sulcus in order to prevent bile duct injury. Moreover, it is an 'extrabiliary' reference point so is unaffected due to bilary pathology. Similarly, a clear delineation of the point where cystic duct emerges from the gallbladder as well as the clear dissection in the space between the liver and the gallbladder (safety window or critical view) is an important measure in preventing intraoperative injury to the bile duct.[32]

Epidemiology

Cholecystitis is defined as the inflammation of the gallbladder. Ninety percent of cases occur due to stones in the gallbladder known as calculous cholecystitis, while remaining 10% cases represents acalculous cholecystitis.[33]

Gallstones cause significant morbidity in developed countries, affecting 10% to 15% of the adult population. 20 to 25 million Americans have gallstones or might develop at the later age.[34,35] With around 1.8 million reported cases every year, gallstone disease is a leading cause for hospital admissions due to gastrointestinal diseases.[34]

Gallstone disease also has inherent risks. Trials have shown an increased overall mortality from gallstone diseases, especially in Americans and Pima Indians.[35-37]

Due to the increase in the incidence of gallstone disease, a concomitant increase is seen in gallstones related complications.[38]

Age distribution

The incidence of cholecystitis rises with increasing age. At least 10% of adults have gallstones. The prevalence varies with age, sex, and ethnic group. There is an increasing prevalence with the age, after the age of 60 about 10 to 15% of men and 20 to 40% of women have gallstones.[17]

Sex predilection

Gallstones are seen two to three times more commonly in female population. Increased levels of progesterone during pregnancy may lead to biliary stasis, responsible for increased incidences of gallbladder disease in pregnant females. Acalculous cholecystitis is more commonly seen in elderly men.[39]

Race and ethnicity

Cholelithiasis is the major risk factor for cholecystitis. Scandinavian descent, Pima Indians, and Hispanic populations show an increased prevalence of cholelithiasis, while it shows decreased incidence in sub-Saharan African and Asian population. In the United States, white people suffer from gallstones more commonly than black people.[40,41]

The prevalence of gallstones is especially high in the Scandinavian countries and Chile. Among Native Americans, Mexican Americans and American Indians, especially the Pima tribe, have an increased predisposition to gallstone formation.[40]

Gallstone disease in India

Although well documented by authors in India, the data has not received much attention in the West. In literature of Medicine and Gastroenterology published from the West, India is included along with the countries which have low incidence of gallstones. The prevalence of gallstone disease varies in different parts of India.[42] Malhotra in 1966 conducted an epidemiological study in Indian Railway employees and it showed that North Indians had seven times higher prevalence of gallstones as compared to South Indian employees. In northern states including Kashmir where good epidemiological studies have been performed, a very high and increasing prevalence were reported.[43-47] Khuroo[46] from Kashmir reported a prevalence of 6.12% (men 3.07% and women 9.6%). The prevalence increases progressively to reach a peak in the sixth decade. The prevalence rate is significantly higher in multiparous women.[48] There was no correlation noted with diet, obesity or socioeconomic status.[44]

A different picture arises from data available from south India. Jayanthi et al[48] reported that mixed and pigment stones were more common compared to cholesterol stones in Tamilnadu. They found no correlation with demographic features or social customs. An interesting observation that needs confirmation is an association with high consumption of tamarind. There is no scientific explanation for this observation. The overall prevalence of gallstones in Tamilnadu appears to be lower than in the North. However cholecystectomy once an extremely uncommon surgery in south India has become very frequent reflecting either a real increase in the prevalence of the disease, better diagnosis because of ease of diagnosing stones by abdominal ultrasound or the availability of Laparoscopic cholecystectomy.[42]

Clinical aspects of gallstone disease

Asymptomatic/Silent gallstones

Gallstones are very common. 10% to 20% of Americans suffer from stones in their lifetime.[41] Most of them will remain asymptomatic. Upto 80% of the population will never develop biliary pain or complications due to gallstones such as acute cholecystitis, cholangitis, or pancreatitis.[50] Thus, most gallstones are clinically "silent," and are found incidentally during abdominal ultrasonography done due to other reasons. Asymptomatic patients, may eventually develop symptoms like biliary pain requiring treatment, but the risk is very low, around 2% to 3% every year, 10% by 5 years.[35,51,52] 1% to 2% every year may develop complications due to gallstones.[35,49] Hence, expectant management is an appropriate choice for silent gallstones. The exception is the population with high risk for developing biliary complications:[35]

Large gallstones (>3 cm) or gallbladder filled with stones carry a high risk for development of carcinoma gallbladder. It is an indication for prophylactic cholecystectomy.

Patients suffering from Sickle cell disease are at high risk for developing pigment gallstones. Prophylactic cholecystectomy should be considered because complications due to gallstones are difficult to distinguish from the clinical picture of a sickle cell crisis. When performed early, in an elective setting, cholecystectomy reduces the surgical risks, but still shows a mortality rate at 1% [53]

Patients receiving solid organ transplantation like heart, lung, kidney or pancreas- stem cell (bone marrow) transplantation has its own risk for cholelithiasis

and biliary sludge formation, more problematic are the consequences of solid organ transplantation in which gallstones develop frequently and lead to symptoms and complications like cholecystitis, more commonly in the first 2 years of life.[46] Liver transplantation is an exception as cholecystectomy is performed at the time of hepatectomy.

Abdominal surgery, being done for other pathology may benefit from cholecystectomy at the same setting, for patients with high risk for formation of gallstone and its complications. Prophylactic cholecystectomy is being considered in morbidly obese patients undergoing bariatric surgery.[54]

Symptomatic gallstone disease

Most gallstones are asymptomatic, hence it is necessary to define symptoms of gallstone disease like biliary pain and associated complications. Also nonspecific abdominal symptoms like dyspepsia and bloating. Biliary pain shows a particular pattern.[28] The established criteria defines biliary pain to be episodic, severe pain located in the upper abdomen which lasts more than 30 minutes and the associated features such as nocturnal onset; nausea and vomiting; radiating to the back. Avoiding an unnecessary cholecystectomy has becomes critically relevant with increasing rates of surgery.[35]

Acalculous (functional) gallbladder disease

The etiology of biliary pain is an increased intraluminal pressure due to the contraction of gallbladder against the outlet obstruction. In calculous cholecystitis, the obstruction is caused by a stone in the cystic duct while in acalculous cholecystitis (functional gallbladder disease, gallbladder dyskinesia), the pain may

be either due to obstruction in the cystic duct or because of lack of co-ordination between gallbladder contraction and sphincter of Oddi relaxation. An impaired gallbladder emptying can be reliably diagnosed by cholecystokinin-cholescintigraphy.[55]

The frequency and management of acalculous gallbladder disease is still unclear. Even though the exact frequency of functional gallbladder disease is unknown, increase in the rates of cholecystectomy for such cases definitely would affect the surgical rates. Thus, there is lack of evidence to support the role for cholecystectomy in functional gallbladder disease at present.[18,35]

Etiology

Risk factors for calculous cholecystitis are the same for cholelithiasis and include the following:[56]

- Female sex
- Certain ethnic groups
- Obesity or rapid weight loss
- Drugs (especially hormonal therapy in women)
- Pregnancy
- Increasing age

Acalculous cholecystitis is seen in pathologies leading to biliary stasis, and include the following:[57]

- Critical illness
- Major surgery or severe trauma/burns

- Sepsis
- Long-term total parenteral nutrition (TPN)
- Prolonged fasting

Other pathologies leading to acalculous cholecystitis such as:

- Cardiac diseases like myocardial infarction
- Sickle cell disease
- *Salmonella* infections
- Diabetes mellitus
- HIV positive patients with associated cytomegalovirus, cryptosporidiosis infection

Immuno-compromised patients have a higher risk of developing cholecystitis from various infectious sources.

Risk factors

Obesity

Incidence of gallstones is higher in markedly obese people and in those who lose weight rapidly. There is little agreement about the effect of dietary components on the risk of gallstones. Fasting is normally associated with increased biliary cholesterol saturation and this phenomenon persists or even become more accentuated in case of obesity. A clinical study showed an increased risk for gallstones formation associated with being even moderately overweight. Obesity also reduces gallbladder emptying.[39]

Estrogen and cholesterol lowering agents

Elevated estrogen levels in pregnancy, in patients receiving hormone replacement therapy and oral contraceptive pills are associated with raised cholesterol levels in bile and reduced gallbladder motility, both of which can lead to gallstones. Drugs that lower cholesterol levels in the blood lead to an increase in the cholesterol levels secreted in bile. This in turn can increase the risk of cholesterol gallstones. Clofibrate increases the biliary cholesterol and results in formation of the gall stone. Patients who are taking clofibrates are at an increase risk for cholecystectomy. During rapid weight loss, the metabolism of fat is accelerated, which increases the secretion of biliary cholesterol from liver, hence causing gallstones.[58]

Diabetes mellitus

Gallbladder atony added to autonomic neuropathy may favour stone formation in super saturated bile.[24] It has been stated that the diabetes patients have higher incidence of gallstone disease and are particularly prone to complications from there gallstones. There is an increased incidence of complications in case of other co-morbidities like cardiovascular disease and renal insufficiency.[59]

Fasting

Fasting decreases gallbladder motility leading to bile overconcentration with cholesterol, which can lead to gallstones formation. No clear relationship has been proved between diet and gallstone formation. However, low-fibre, high-cholesterol diets, and diets high in starchy foods may also contribute to gallstone formation. Wayne et al have concluded from their study that a dietary soluble fibre psyllium

inhibits cholesterol stone formation by reducing the biliary cholesterol saturation index. Gallstones are more frequent in type 4 hyperlipidaemia.[60]

Cirrhosis of the liver

Patients with cirrhosis have 3 times greater risk for gallstones than the normal population. The stones are usually of pigment type and probably results from the chronic haemolysis. Cholecystectomy when performed in cirrhotic patients is associated with increased morbidity and mortality.[16]

Vagotomy

Early clinical studies suggested that truncal vagotomy was associated with two fold increase in the incidence of gallstones, other studies have failed to confirmed this hypothesis. While ultrasonography suggested that truncal vagotomy is associated with dilated gallbladder. Nerve fibres from both vagal nerves merge to form the hepatic plexus which supplies parasympathetic motor nerves to the extra hepatic biliary system. A number of studies have investigated the effect of vagal stimulation and vagotomy on gallbladder contractability, but the results are generally inconclusive.[17]

Total parenteral nutrition and gallstone formation

A number of large clinical studies have confirmed the etiological relationship between TPN and gallstone formation in both children and adult. Symptomatic gallstone disease forms in approximately 45% of patients who are maintained on long term TPN. Ultrsonographic studies have helped to identify the scientific basis for gallstone formation and have our attention on the relationship between alter

gallbladder motor activity, decrease stimulation for gallbladder contraction and the formation of sludge and ultimately biliary lithiasis.[35]

Inflammatory bowel disease

Patients with ileal dysfunction which is more saturated with cholesterol and patients with jejuno-ileal operation are associated with increased risk of gallstone formation. When the ileum is diseased or removed, absorption of bile salts is impaired and a significant loss of bile salts will occur. Hence there will be relative increase in cholesterol leading to the gall stone formation.[61]

Miscellaneous

The prevalence of gallstones in thalassaemia is about 10%, in sickle cell disease is 10% to 40%, and in hereditary spherocytosis is 43% to 66%. Pigment gallstones are reported in 58% of patients with homozygous sickle disease and in 17% of the patients with heterozygous type.[62] Hormonal changes during pregnancy and alteration of gallbladder motility by progesterone are thought to be responsible for the development of gallstones in women.[63]

Children with cystic fibrosis have increased risk of gallbladder disease. There is a controversy over an association between the gallstone, colorectal cancer and gastric cancer.[64] Over 70% of patients who develop gallbladder carcinoma have gallstones. Large gallstones (>3mm) are associated with increased incidence of carcinoma gallbladder.[65]

Diagnosis

Diagnostic tests[42]

- Abdominal Ultrasonography: Single most useful test to evaluate gallstones, CBD size and stones.
- Endoscopic Ultrasound (EUS): Excellent to evaluate CBD stone, size. Expensive. Not easily available.
- ERCP: Has lost its diagnostic value.
- HIDA, DIDA, Radioisotope Scans: Accurate identification of cystic duct obstruction. Diagnosis of acute cholecystitis.
- CT Abdomen: Not ideal. Radiation. Not indicated in pregnancy
- MRI/MRCP: MRCP does not require contrast. It can be safely used in 2nd/3rd trimester of pregnancy. Reduces the number of invasive ERCPs.

Delay in the diagnosing acute cholecystitis is related to increased morbidity and mortality, especially in patients in intensive care unit (ICU) who develop acalculous cholecystitis. Early diagnosis and investigations helps in avoiding poor outcomes.[29]

Differential diagnosis[26,29]

- Cholelithiasis
- Choledocholithiasis
- Biliary Colic
- Biliary Disease
- Cholangitis

- Gallbladder Cancer
- Gallbladder Tumors
- Gastric Ulcers
- Acute gastritis
- Cholangiocarcinoma
- Appendicitis
- Acute Mesenteric Ischemia
- Abdominal Aortic Aneurysm

Approach

The workup for cholecystitis/ cholelithiasis includes laboratory investigations, radiograms, ultrasonography abdomen, computed tomography (CT), magnetic resonance imaging (MRI), hepatobiliary scintigraphy (HBS), and endoscopy.

Laboratory investigations[66]

Laboratory investigations are not reliable in diagnosing cholecystitis or cholelithiasis, but the following findings may be useful in the diagnosis:

- Increased leukocyte count may be associated with cholecystitis.
- Increased bilirubin and alkaline phosphatase levels are indicative of common bile duct obstruction.
- Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels are raised in case of hepatitis, cholecystitis or obstruction in the common bile duct.
- Rise in alkaline phosphatase levels is seen in 25% cases of cholecystitis.

Imaging

The 2010 American College of Radiology (ACR) Criteria offer states the imaging recommendations as follows:[67]

- Ultrasonography is the initial investigation of choice for the diagnosis of cholelithiasis, acute cholecystitis.
- CT is a secondary investigation which can rule out extrabiliary pathologies and complications of cholecystitis i.e. gangrene, perforation, empyema.
- MRI with intravenous gadolinium-based contrast is also secondary imaging test which confirms the presence of acute cholecystitis.
- Plain MRI eliminates the risk of radiation exposure and is indicated in pregnant women with failure of ultrasonography to diagnose the pathology.

Radiography

Gallstones may be visualized in plain X-ray abdomen only in 10-15% patients.

Ultrasonography

Ultrasonography has 90-95% sensitivity in diagnosing cholecystitis/ cholelithiasis and specificity of 78-80%. It has more than 95% sensitivity and specificity in diagnosing gallstones larger than 2 mm.[68,69]

Ultrasonography in acute cholecystitis may show the following findings: pericholecystic collection, gallbladder wall thickness more than 4 mm, and ultrasonographic Murphy's sign.[70]

Ultrasonography shows the best results when performed after fasting for at least 4 hours as the gallbladder is distended and bile-filled allowing clear visaulization of gallstones.[71]

Computed tomography and magnetic resonance imaging

Computed tomography and magnetic resonance imaging have greater than 95% sensitivity and specificity in the diagnosis of acute cholecystitis.[65] CT scan and MRI (unlike ERCP) are noninvasive, but they do not have any therapeutic value.

Findings which suggest the presence of cholecystitis are wall thickening (>4 mm), pericholecystic collection, subserosal oedema, presence of intramural gas, and breach in the mucosa.

Hepatobiliary scintigraphy (HBS)[66]

HBS has around 95% accuracy in detecting acute cholecystitis. It shows 90-100% sensitivity and 85-95% specificity. In the scintigraphy, the biliary tree with gallbladder is visualized within 30-45 minutes.

Endoscopic retrograde cholangiopancreatography

ERCP delineates the biliary anatomy in patients with common bile duct obstruction. Sahai et al mentioned in their study that ERCP was more useful than endoscopic ultrasonography (EUS) and intraoperative cholangiography in patients with high risk of formation of stone in the common bile duct who underwent laparoscopic cholecystectomy.[72]

Disadvantages of ERCP are high cost and it requires a trained operator. It is also associated with complications like pancreatitis, in 3-5% patients.

Histological findings

Early changes are the presence of edema and venous congestion. Findings specific for chronic cholecystitis are mucosal fibrosis or flattening and appearance of chronic inflammatory cells. Rokitansky-Aschoff sinuses are seen in 56% of the cases and are result of increased hydrostatic pressure. Focal necrosis along with neutrophils may also be present. Complicated cases may show gangrene or perforation of the gallbladder.[27]

Complications of Gallstone Disease

- Pancreatitis
- Cholecysto-enteric fistula, gallbladder perforation
- Gallstone ileus
- Mirizzi Syndrome
- Emphysematous cholecystitis
- Gangrene of the gallbladder
- Choledocholithiasis, cholangitis
- Porcelain gallbladder-intra mucosal calcification of gallbladder wall can occur with or without gallstones

Management

Non-surgical

Drug dissolution therapy

The efficacy of ursodeoxycholic acid in preventing gallstone formation is proved. A prospective study showed the rate of gallstone formation in 152 patients who underwent bariatric surgery (which is a known risk factor for gallstone formation). The daily intake of 500 mg of ursodeoxycholic acid versus placebo, for six months. The researchers found that gallstone formation occurred significantly lesser after intake of ursodeoxycholic acid compared to placebo at 12 months (3% *v* 22%) and at 24 months (8% *v* 30%).[73,74]

However, ursodeoxycholic acid is not useful after the formation of stones. A prospective randomized placebo controlled double blind study done in the Netherlands studied 177 patients with gallstones planned for cholecystectomy and it was found that ursodeoxycholic acid was not helpful in resolution of the biliary symptoms.[75]

Percutaneous drainage

Percutaneous cholecystostomy is efficacious as a treatment for biliary sepsis in patients who are unfit for surgery. In a retrospective study of 55 patients, percutaneous transhepatic cholecystostomy was successful in 98%; 95% of them recovered well and discharged.[76]

Surgical

Open cholecystectomy pioneered by Langenbuch had remained the gold standard for symptomatic gallstones for over a century. The only major change occurred in the surgery when Mirizzi introduced the technique of intra-operative cholangiography for the detection of common bile duct stone over 60 years ago.[22]

The term trocar was introduced in 1706. It was thought to be derived from the word "trocarter troise-quarts", which means a three-faced perforator enclosed in a metal canula. A German gynaecologist, Dimitri OH, in 1901 performed the first endoscopic examination (ventroscopy). Bernheim from the United States was the first surgeon who published his experience in laparoscopy named as "organoscopy" in the Annals Of Surgery,1911.[22]

Laparoscopy (from the Greek laparo, meaning the flank, and skopein, meaning to view) is the technique of accessing the abdomen endoscopically to diagnose and treat abdominal disease. The first laparoscopy was performed in 1901 when a cystoscope was inserted into the abdomen, allowing visual examination through a tiny incision of the external surfaces of the abdominal organs.[77] Before therapeutic operations could be performed, new technologies were needed to overcome ensuing obstacles. One obstacle was the lack of space in which to operate. In 1938, a spring-loaded needle was used to insufflate the abdominal cavity with carbon dioxide and establish a pneumoperitoneum.[78] Access to the coelomic cavity could then be attained with accessory ports, which were designed to allow introduction of modified surgical instruments without gas leakage. These modified instruments, developed for grasping, cutting, and cauterization, made simple

therapeutic procedures possible. Ultimately, a miniature television camera was attached to the laparoscope's eyepiece. It permitted the entire operating team to watch the procedure from the same perspective and freed the surgeon's hands to do more difficult operations. The first laparoscopic cholecystectomy was performed in France in 1987[79] the first in the United States was in 1988.[80,81]

Kelling in 1923 presented before the German surgical society his experience of diagnostic laparoscopy. That was the beginning of the era of minimally invasive surgery.[22,77]

Kalk, known as the "father of modern laparoscopy" refined the technique of laparoscopy by introducing the faroblique (135 degrees) lens system along with a separate pneumoperitoneum needle in 1929.[22,82] Veress in 1938 developed a needle which had a spring-loaded obturator allowing its safe and atraumatic insertion followed by peritoneal insufflation.[78] Kurt Semm, in 1966 was the first one to perform omental adhesiolysis, tumour biopsy, bowel suturing and incidental appendicectomy.[22,83]

Hasson introduced the technique of trocar placement under direct vision in 1978. It cleared much of the doubts among general surgeons regarding laparoscopic surgery.[84]

Mouret from France[6] was the first surgeon to perform the first human laparoscopic cholecystectomy. In March 1987 when he was performing a gynaecologic laparoscopy for a woman who was also suffering from gallstones, he examined the subhepatic area. He found a relatively free and supple gall bladder and decided to remove it laparoscopically rather than doing an open procedure for it. He

removed the gallbladder successfully using laparoscopic technique and the recovery of the patient was uneventful.[6]

In the USA, the procedure was being welcomed and adopted within two years and also there was an increased demand for it among the patients. In September 1992, laparoscopic cholecystectomy was declared as the treatment of choice for cholelithiasis in a NIH consensus conference held in Bethesda .[85]

With the advent of laparoscopic cholecystectomy the scenario of surgical management of cholelithiasis has changed drastically.[86] It has opened new horizons in the management of gallstones. Theoretical benefits of laparoscopic approach include reduced hospitalization and cost, decreased pain, avoidance of large incision with improved cosmetic and reduced post-operative recovery time with an early return to work. Although it showed early promising results, recent trials show an increase in the incidence of operative complications, especially common bile duct injury.[87] Expensive instruments, specialized training and long learning curve also limit the use of laparoscopy. This has led to a lot of soul searching and numerous attempts at comparing the merits and demerits of laparoscopic vis-a-vis open cholecystectomy. Recent upsurge in practice of laparoscopic surgery and other form of minimal access surgery has ushered a new era of surgical treatment which is having profound effect on surgical management. Minimal access surgery has touched every field of surgical specialty.[88] The non-operative methods for the treatment of cholelithiasis in the form oral bile acid (Chenodexycholic acid and Ursodexycholic acid) and Extracorporeal Shock Wave Lithotripsy (ESWL) have not shown promising results.[89-91]

Laparoscopic versus open surgery

A Cochrane review in which laparoscopic cholecystectomy was compared with open cholecystectomy showed no differences in view of mortality, intra-operative complications or operative time. However, patients undergoing laparoscopic cholecystectomy had a significantly shorter hospital stay (difference, −3 days (95% confidence interval −3.9 days to −2.3 days)) and quicker convalescence (−22.5 days (−36.9 days to −8.1 days)). These results were in favor of laparoscopic cholecystectomy than open cholecystectomy.[73]

Another study by Manger T. et al.[92] in 1999 reported that, of 1006 laparoscopic cholecystectomies performed, 42 were done for acute cholecystitis. Conversion to an open procedure was necessary in only one patient because of severe inflammatory changes. The overall mortality was zero. The average age was 45.9 years for all patients and 50.4 years for those with acute cholecystitis. The average operating time in patients with acute cholecystitis was 81 minutes compared to 62 minutes in patients who underwent elective laparoscopic cholecystectomy. The complication rate and the average hospitalization time did not differ significantly between the two groups. The study indicated that laparoscopic cholecystectomy is superior to the open procedure in the treatment of acute cholecystitis. Prerequisite is that the operation is performed less than 72 hours after the onset of the symptoms by an experienced operating team and the readiness to convert to open procedure if necessary. Under those circumstances laparoscopic cholecystectomy seems to be the treatment of choice for acute cholecystitis.

Laparoscopic cholecystectomy in high risk patients

High risk patients undergoing laparoscopic cholecystectomy differ from the patients with no existing comorbidities. To assess the safety of laparoscopic cholecystectomy, different high risk patients who were the candidates for laparoscopic cholecystectomy were studied. These studies included the patients having diabetes mellitus, cardiopulmonary diseases, renal diseases, sickle cell diseases, liver cirrhosis, pregnancy and the elderly. The results showed that laparoscopic cholecystectomy is a safe procedure and is recommended as the procedure of choice, provided that it is done cautiously and skilfully in case of high risk patients.[93]

Laparoscopic cholecystectomy has become the gold standard for the treatment of symptomatic gallstones with numerous advantages including reduced hospitalization, decreased morbidity, short recovery time, and better cosmesis,[6,7,14,94,95] On the other hand, the procedure is technically more demanding than the classical open cholecystectomy. Greater chances of damage to the common bile duct and surrounding viscera exist. Also laparoscopic cholecystectomy has increased risk of injury to common bile duct (CBD), duodenum, bowel, iliac vessels, and so on; high conversion rate in acute cholecystitis, and difficulty in management of simultaneous CBD stones.[13,96,97]

However, on the basis of radiological findings, surgeons can select the cases appropriate for their skills aiming at reducing operative complications and minimizing the waste of operating time available. Patients with long-standing disease and previous bouts of cholecystitis or pancreatitis are at higher risk of

experiencing a difficult procedure or conversion and may be at increased risk of bile duct injury or injury to the adjoining viscera. Preoperative information of possible intra-operative complications such as uncontrollable bleeding or unclear anatomy, conversion to open surgery will give extra benefits. It can be helpful to raise level of cautiousness and establish a criterion that could assess the risk for conversion preoperatively. It would be helpful to accurately identify an individual patient's risk for conversion based on preoperative information can result in more meaningful and accurate preoperative counseling, improved operating room scheduling and efficiency, stratification of risk for technical difficulty, and appropriate assignment of resident assistance, may improve patient safety by minimizing time to conversion, and better mental preparation of surgeons and patients also.[10]

Detection of gallstones on basis of ultrasonography, has been able to reach reliably in greater than 90% of symptomatic patients. Measurement of the thickness of the gallbladder wall by ultrasound is accurate to within 1 mm in 93% of patients.[10,98-101] Gallbladder wall thickness greater than 3mm is suggestive of cholecystitis in some, but not all literature reports.[102-104] There are several clinical reports in the literature where relationship between preoperative ultrasound gallbladder wall thickness and the technical difficulty of a LC is well established.[10,105-108]

Parmeggiani D et al.[109] reported that, conversion to laparotomy, in difficult cases involving inflammatory changes, aberrant anatomy or excessive bleeding, is not to be considered as a failure but rather as good surgical decision in order to ensure the patient's safety.

Ultrasonography is the most common noninvasive, safe, and highly accurate screening test for cholecystitis and cholelithiasis. It can also help surgeons to get an idea of potential difficulty to be faced during surgery in that particular patient.[13] On the basis of ultrasound findings, surgeons can select the cases appropriate for their skills aiming at reducing operative complications and minimizing the waste of operative time.[14] Based on ultrasonographic findings, certain preoperative factors can reliably predict the chances of conversion to the open procedure and the danger of certain complications so that the surgeon and the patient are mentally prepared.[15]

On the basis of ultrasound findings, surgeons can select the cases appropriate for their skills aiming at reducing operative complications and minimizing the waste of operating time available.[14] Patients with long-standing disease and previous bouts of cholecystitis or pancreatitis are at higher risk of experiencing a difficult procedure or conversion and may be at increased risk of bile duct injury or injury to the adjoining viscera.[96] It would be useful to have some reliable predictive factors for conversion or complications in laparoscopic cholecystectomy.[13]

Earlier, Jensen S. et al.[110] reported that, it is particularly important to identify preoperative factors that may predict conversion to open cholecystectomy (OC) at LC, with its concomitantly prolonged hospital recovery. In this series of 738 patients, the ultrasound features of stone size, gallbladder wall thickness, diameter of the common bile duct, number of stones, and the appearance of a contracted gallbladder were assessed preoperatively in all patients. The overall conversion rate was 3.5% (26 of 738). By logistic regression analysis, factors found to increase significantly the risk of conversion were patient age > 70 years ($p < 0.01$), a stone at least 20 mm in diameter ($p < 0.05$), a gallbladder wall thicker than 4 mm ($p < 0.05$),

a common bile duct wider than 6 mm ($p < 0.05$), and contracted gallbladder on ultrasound ($p < 0.02$). The number of stones in the gallbladder was not significant. Using these risk factors, it was possible to divide patients into high- and low-risk groups. The 118 patients in the high-risk group had 18 of the 26 conversions, for a conversion rate of 15.3%. The 620 patients in the low-risk group had eight of the 26 conversions, for a conversion rate of 1.3%. This low-risk subgroup represented 84% of the series of 738 LC procedures and may have been suitable for outpatient LC. Using preoperative ultrasound, it is possible to predict patients who are at low risk of conversion and are suitable for ambulatory surgery.

On the other hand, Carmody E. et al.[111] in 1994 performed a prospective study to assess the role of preoperative ultrasonography in predicting failed or difficult laparoscopic cholecystectomy. Fifty patients underwent detailed preoperative ultrasound examinations. The number and size of calculi, evidence of acute or chronic cholecystitis, gallbladder morphology, and the presence or absence of aberrant anatomy were documented. A comparison was made of the surgical outcome and the ultrasound findings in each patient. Six patients were converted to open cholecystectomy because of inflammatory changes in the gallbladder. The preoperative ultrasound studies in 5 of these patients demonstrated evidence of cholecystitis and cholelithiasis. Gallbladder wall thickening and contraction were also seen. Five gallbladder resections had intra-operative difficulties; preoperative ultrasonography demonstrated a thickened gallbladder wall in 2. Of 31 uneventful cases, 7 had evidence of gallbladder wall thickening and/or contraction. There were no ultrasound features that identified between the unsuccessful, difficult, or uneventful laparoscopic cholecystectomies. Authors concluded that detailed

preoperative ultrasound evaluation of the gallbladder in patients destined for laparoscopic cholecystectomy is of little value in screening for difficult or unsuitable cases.

On the other hand, Santambrogio R. et al.[112] reported a study in 1996 where the authors evaluated ultrasound findings as predictors of potential operative difficulties and complications during laparoscopic cholecystectomy during the period from October 1993 to June 1995 on a total of 143 patients with symptomatic cholelithiasis (50 males, 93 females, mean age 49.5 ± 15 years) were evaluated by ultrasound (US) the day before LC. The US examination assessed six parameters: gallbladder (GB) volume, GB wall thickness, GB neck position, GB stone mobility, stone maximum size, and GB adhesions. On the basis of these US findings, a predictive judgment of technical difficulties was expressed by degree: easy, difficult, and very difficult. Altogether 101 patients presented with uncomplicated symptomatic cholelithiasis, and 42 had acute cholecystitis. The operation was predicted to be easy in 38% of cases, difficult in 49%, and very difficult in 13% with a good correlation with the surgeon's intraoperative judgment (r 5 0.66). A significant association was found between stone mobility (r 5 0.37), presence of adhesions (r 5 0.36), and the difficulty of the procedure. The predictive US evaluation was significantly correlated with some intraoperative technical steps [dissection of Calot's triangle (r 5 0.41), dissection of the gallbladder bed (r 5 0.41)], and intraoperative bleeding (r 5 0.27). Our results suggest that preoperative US is a useful screening test for patients undergoing LC, and it can help predict technical difficulties. On the other hand, a relevant number of cases still exist wherein the concordance between the preoperative US classification and the surgical findings is

unsatisfactory. In this group the surgeon cannot safely rely on the US examination alone.

A prospective study was conducted by Lal P. et al.[13] from March 1999 to April 2000 that included 73 patients who underwent elective laparoscopic cholecystectomy for uncomplicated gallstone disease. The study was conducted at one surgical unit in the Department of Surgery and Department of Radio-diagnosis and one surgical unit in the Department of Surgery, Maulana Azad Medical College and the associated Lok Nayak Hospital, which is the largest referral hospital in northern India and is located in the capital of India. A preoperative ultrasound was performed just prior to surgery, and 4 ultrasonographic parameters were analyzed, namely gallbladder wall thickness, contracted gallbladder, impaction of gallstones at the neck of the gallbladder, and common bile duct stones. The surgical findings were objectively graded as difficult or easy laparoscopic cholecystectomy according to 5 operative parameters, namely total time taken for the surgery, time taken to dissect gallbladder bed, spillage of stones, tear of gallbladder during dissection, and conversion to the open procedure. Of the 73 cases, 17 (23.3%) were conversions to the open procedure. Of the 21 (28.76%) cases predicted to be difficult, 17 (23.3%) were technically difficult, of which 13 (17.8%) were converted to the open procedure. Of the 52 (71.23%) cases predicted to be easy on ultrasonography, only 7 (9.38%) were found to be difficult on surgery, of which only 4 (5.48%) had to be converted to the open procedure. Based on our results, we conclude that preoperative ultrasonography is of great value in selecting patients preoperatively for laparoscopic cholecystectomy and minimizing complications and conversion to the open procedure.

Sharma SK et al.[12] (2007) conducted a study to determine whether the preoperative USG finding can predict the risk of conversion or difficulty during the laparoscopic cholecystectomy. 200 patients undergoing Laparoscopic cholecystectomy at Kathmandu Medical College Teaching Hospital were included. Sonographic parameters like size of gall bladder, wall thickness, distance between hepaticoduodenal ligament and Hartmann's pouch and the size of stone were taken into consideration and difficulties in terms of adhesions around gall bladder, anatomy of calot's triangle and difficulty in peeling off gall bladder from the bed and retrieval were analyzed. In 8 of 200 patients (4%), LC was converted to open procedure. In univariate analysis all the sonographic parameters we had included in this study were statically significant (p value <0.05). Authors commented that, preoperative sonographic signs can predict the difficulty in laparoscopic cholecystectomy.

Oleary DP et al.[113] examined the importance of ultrasonic gallbladder characteristics on laparoscopic cholecystectomy conversion rates and then sought to devise a pre-operative predictive score for conversion. A retrospective analysis of patients undergoing a laparoscopic cholecystectomy was performed between January 2000 and December 2006. Patient demographic data and pre-operative imaging results from abdominal ultrasounds were analysed. We then devised a pre-operative predictive score for conversion based on independent variables derived from multivariate analysis. A total of 1061 patients underwent a laparoscopic cholecystectomy. Conversion to an open procedure was required in 58 cases. The overall conversion rate was 5.4%. Univariate analysis revealed male gender ($p < 0.0001$), gallbladder wall thickness >4 mm ($p = 0.0024$), a contracted

gallbladder ($p = 0.005$) and a dilated CBD ($p = 0.0416$) as being significantly associated with conversion. These variables were then evaluated using multivariate analysis and three variables, namely, male gender, a contracted gallbladder and a thickened gallbladder wall were identified as independent predictors. A pre-operative predictive score for conversion was devised from a training cohort ($n = 761$) and tested on a sub-cohort ($n = 300$). Patients with a score of 2 or more had a 19.2% risk of conversion ($p < 0.001$). The study concluded that, conversion to an open cholecystectomy shows a strong associated with gallbladder ultrasonographic characteristics which are available pre-operatively. The likelihood of conversion can be accurately predicted using a pre-operative scoring system.

Chand P. et al.[114] in 2015 conducted a study to see whether preoperative ultrasonography can be used as a predictor of difficult laparoscopic cholecystectomy or not. 50 patients of cholelithiasis, selected from surgical OPD of Rajindra Hospital Patiala, who fulfilled all inclusion and exclusion criteria for the study underwent elective cholecystectomy. Ultrasonography was done pre-operatively on all cases in the same setup and with same probe and patients underwent laparoscopic cholecystectomy in same setup. A significant prediction was found between ultrasonographic parameters and conversion of the procedure to open cholecystectomy which proved that pre-operative ultrasonography is a good predictor of difficulty in laparoscopic cholecystectomy in majority of the cases and should be used as a screening procedure. Authors concluded that, Preoperative ultrasonography should be used as a screening procedure as it is a good predictor of difficulty in laparoscopic cholecystectomy in majority of the cases. It can help surgeon to get an idea of potential difficulty that he can face in the particular patient.

Ali Rizvi SA et al.[10] in 2012 reported a prospective study that included 298 patients who underwent elective laparoscopic cholecystectomy for uncomplicated gallstone disease to forecast a difficult operation which may help the surgeon as well as the patient to prepare better for any intra-operative risk and its effective management. The entire series consisted of 298 patients, in whom 270 patients were operated laparoscopically, with 28 patients converted to open cholecystectomy. In 28 of 298 patients (9.4%), LC was converted to OC. In the univariate analysis, contracted gallbladder (< 5cm; Odds Ratio [OR] 0.776 95% confidence intervals [CI] 0.25 – 2.44), stone impaction (OR 2.6: 95% CI 1.12 – 5.1), thickened gall bladder wall (OR 3.81: 95% CI 1.11 – 13.11), and cholecystitis (OR 4.4: 95% CI 1.2 – 15.9) were able to predict pre-operatively the need for conversion. Logistic regression analysis defined only the sonographic sign of gall bladder thickness greater than 3 mm as a predictor of conversion. Ninety eight, out of total 298 patients, had gallbladder wall thickness of greater than 3 mm by preoperative ultrasonography and of these 46 (46.9%) had difficulty in dissection per-operatively and 20 (20.4%) underwent conversion to an open cholecystectomy. A preoperative ultrasonographic evaluation for symptomatic cholelithiasis, which shows a thick gallbladder wall (≥3 mm) with calculi, is a sign of caution clinically for likely a difficult laparoscopic cholecystectomy procedure which may require conversion to an open cholecystectomy procedure. These results revealed that conversion to open cholecystectomy can be predicted preoperatively. Laparoscopic conversion to open cholecystectomy also depends upon multiple factors like who have acute cholecystitis, multiple adhesions; however, the correlation between its clinical and pathologic diagnosis is poor. Radiological excellence in ability to determine the risk for conversion have paramount importance and implications in surgical care.

METHODOLOGY

The present study was conducted under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2016 to December 2016.

Study design

The study design was hospital based prospective study.

Study period and duration

This one year study was done from January 2016 to December 2016.

Place

This study was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi a tertiary care teaching hospital attached to KLE University's Jawaharlal Nehru Medical College, Belagavi.

Source of Data

Patients presenting with right hypochondriac pain and diagnosed to have cholecystitis and cholelithiasis undergoing laparoscopic cholecystectomy in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi during the study period were included in the study.

Sample size

A total of 60 patients were included in the study.

Sampling procedure

A large study by Unisa et al.[115] from India based on ultrasonography findings reported prevalence rate of gallbladder diseases as 6.20%. The sample size required for the present study was calculated using the formula as below.

$$n= 4 \times p \times q /d^2$$

where,

p = prevalence (6.20% from a study by Unisa et al)

q = 100 – p = 100-6.20 = 93.8

d = standard error = 8%

Therefore,

$$n = 4 \times 6.2 \times 93.8 / 8^2$$

$$n = 2326.24/64 = 36.34 \approx 37$$

Hence the minimum effect size required for the study was 37. However, 60 patients fulfilled selection criteria hence were enrolled.

Selection criteria

Inclusion

- Patients aged between 20 to 60 years.

- Patients with symptoms and signs of cholelithiasis / cholecystitis and diagnosed by ultrasonography of abdomen.

Exclusion

- Patients below 20 years of age.
- Patients with CBD calculus, raised ALP, dilated CBD where CBD exploration is needed.
- Patients with features of obstructive jaundice.
- Suspected malignant gall bladder disease.
- Patient medically unfit for laparoscopic surgery

Ethical clearance

Prior to the commencement, the study was approved from the Institutional Ethical Committee, Jawaharlal Nehru Medical College, Belagavi.

Informed Consent

The patients fulfilling selection criteria were informed about the procedure and explained about the nature of the study and a written informed consent was obtained (Annexure I).

Method of collection of data

Patients willing to participate in the study were interviewed. The demographic data and medical history including age, gender, past medical surgical history along with presenting complaints. Symptoms like, fever, pain in abdomen and vomiting were recorded. The patients were subjected to clinical examination and

vitals including pulse rate, temperature, blood pressure, and other clinical signs were noted. These findings were recorded on a predesigned and pretested proforma (Annexure II).

Investigations

The selected patients underwent following investigations.

- Complete blood count
- Mini renal profile
- Liver function test
- HIV
- HbSAg
- Random blood sugar
- International normalized ratio
- Serum creatinine
- Radiological investigations.
    - Chest X-ray
    - Ultrasound abdomen

Procedure

After the evaluation of pre-operative investigations and fitness for surgery the selected patients were subjected to ultrasonography and evaluated for gallbladder wall thickness (more than 4 mm thick gallbladder wall was predicted to be a difficult LC); whether gallbladder is contracted (≤3 cms) or distended or normal; presence of pericholecystic fluid or GB wall edema, size of calculi, impacted stone, perforated or

gangrenous gallbladder, anatomical variation. Following the evaluation, patient was subjected to laparoscopic cholecystectomy. Experienced surgeons performed the LC. LC was performed in a completely standardized technique. The patient was placed supine in American position. The surgeon was at the left patient's side, one assistant at opposite and one at the same side of the surgeon, and the monitor at the right side of patient‘s shoulder. The pneumoperitoneum was established using a Veress needle (VN) or open Hasson technique, CO_2 gas at 14 mm Hg after a supraumbilical incision and elevation of the fascia. In our setting we routinely perform a waterproof and the double click test. The umbilical trocar (10 mm) was inserted followed by the camera (Storz, Germany). Another 10 mm port (epigastric) and 5 mm ports were placed at the right upper quadrant. In case of previous abdominal surgery, the first trocar was inserted in an open Hasson technique. Therefore, the lower third of the gallbladder is dissected before the typical structures (cystic duct and cystic artery) were clipped and divided. After retrograde dissection, the gallbladder was extracted via the epigastric incision by use of an endobag. During the surgery following parameters were noted.

- Time taken for surgery - Duration of surgery included the time from the insertion of the Veress' needle to closure of the trocar site [5] and was evaluated as a dichotomous variable (≤90 minutes versus ≥90 minutes).
- Biliary/stone spillage.
- Bleeding during surgery.
- Difficult Calots triangle dissection.
- Gall bladder bed dissection.
- Anatomical variation.

- Injury to duct/artery.
- Difficult extraction of gall bladder.
- Extension of incision.
- Need for conversion.

Based on these findings by the operating surgeon the laparoscopic cholecystectomy was graded as either easy or difficult.

Outcome variables

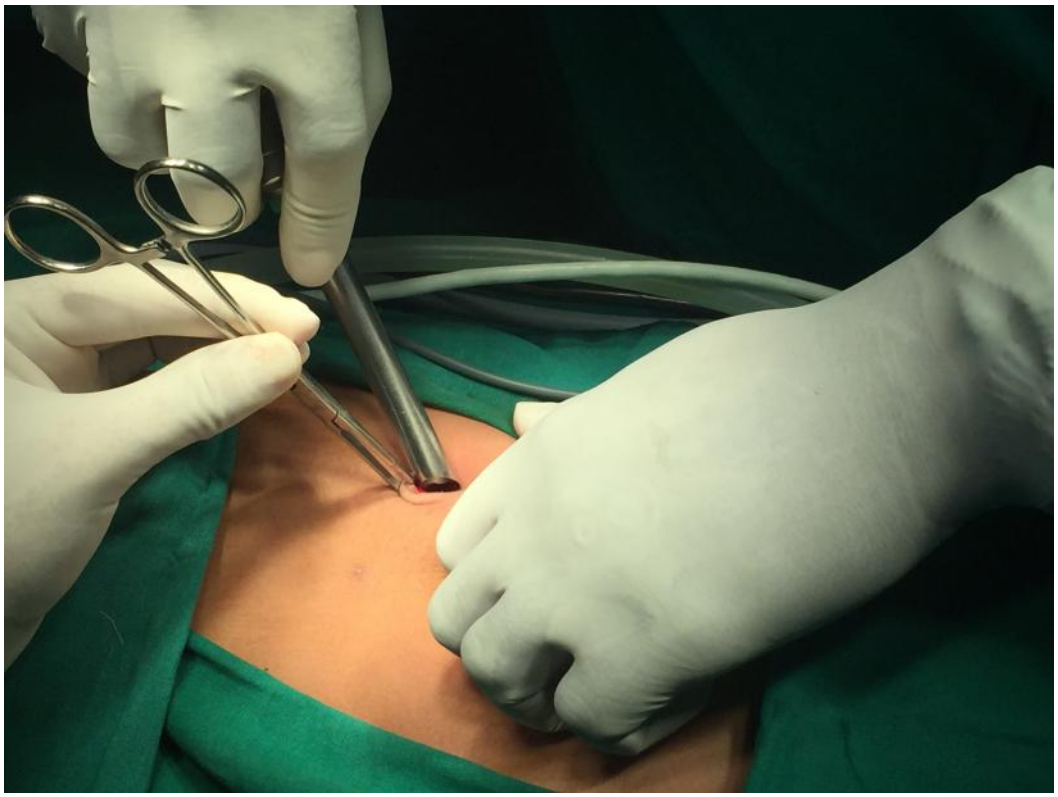
The role of ultrasonography for predicting difficult laparoscopic cholecystectomy was assessed finding relationship between ultrasonographic findings and intraoperative findings during laparoscopic cholecystectomy especially with easy and difficult laparoscopic cholecystectomy

Statistical analysis

The data obtained was coded and entered in Microsoft Excel Spreadsheet. The categorical data was expressed as rates, ratios and percentages. Continuous data was expressed as mean±standard deviation. The relationship between ultrasonographic findings and intraoperative findings during laparoscopic cholecystectomy was ascertained by either chi-square test or Fishers exact test. A probability value ('p' value) ≤0.05 at 95% confidence interval was considered as statistically significant.

Photograph 1. Laparoscopic instruments for cholecystectomy

Photograph 2. Laparoscopic monitor



Photograph 3. Insertion of supraumbilical trocar.

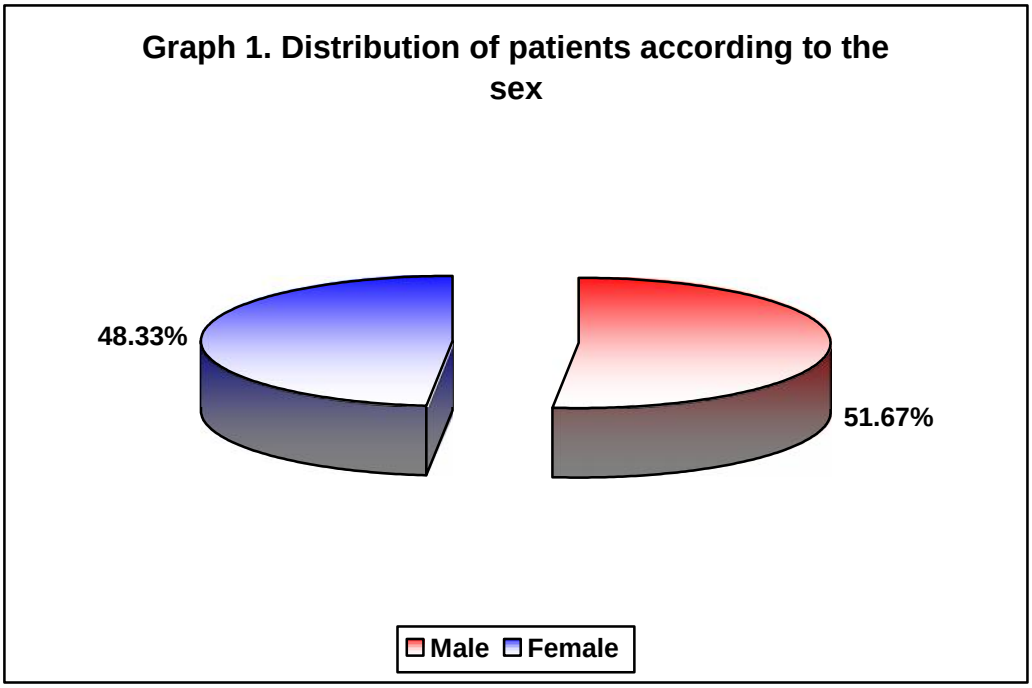
RESULTS

This hospital based prospective study was conducted under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2016 to December 2016. A total of 60 patients presenting with right hypochondriac pain and diagnosed to have cholecystitis undergoing laparoscopic cholecystectomy were studied.

The data obtained was analysed and the final results were tabulated and interpreted as below.

Table 1. Distribution of patients according to the sex

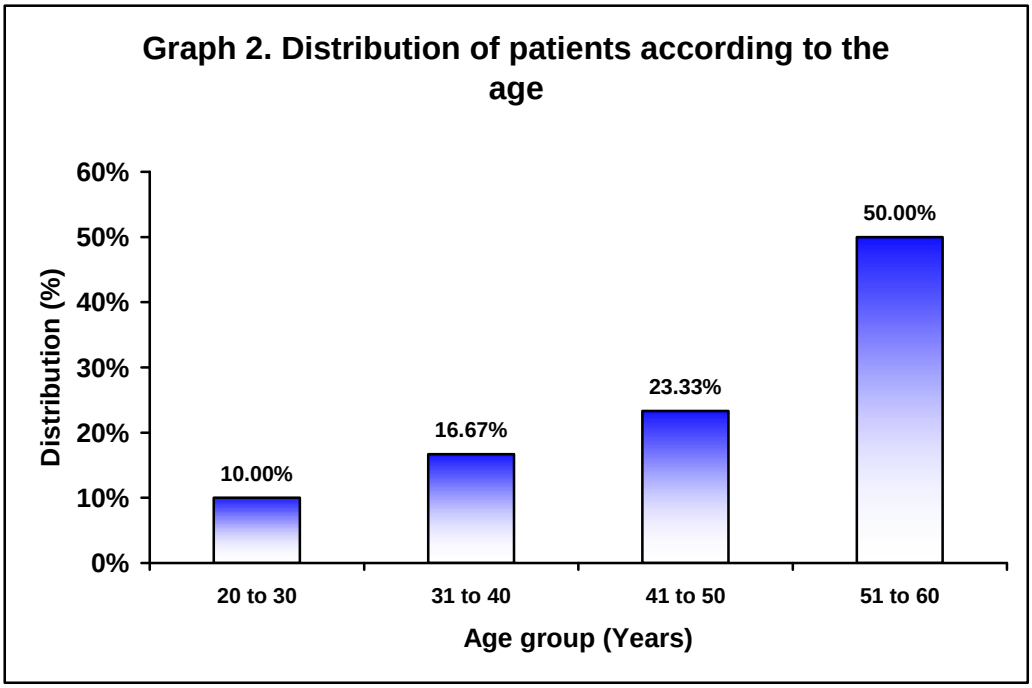
Sex	Distribution (n=60)	
	Number	**Percentage**
Male	31	51.67
Female	29	48.33
Total	**60**	**100.00**



In the present study 51.67% of the patients were males and 48.33% of the patients were females. The male to female ratio was 1.06:1.

Table 2. Distribution of patients according to the age

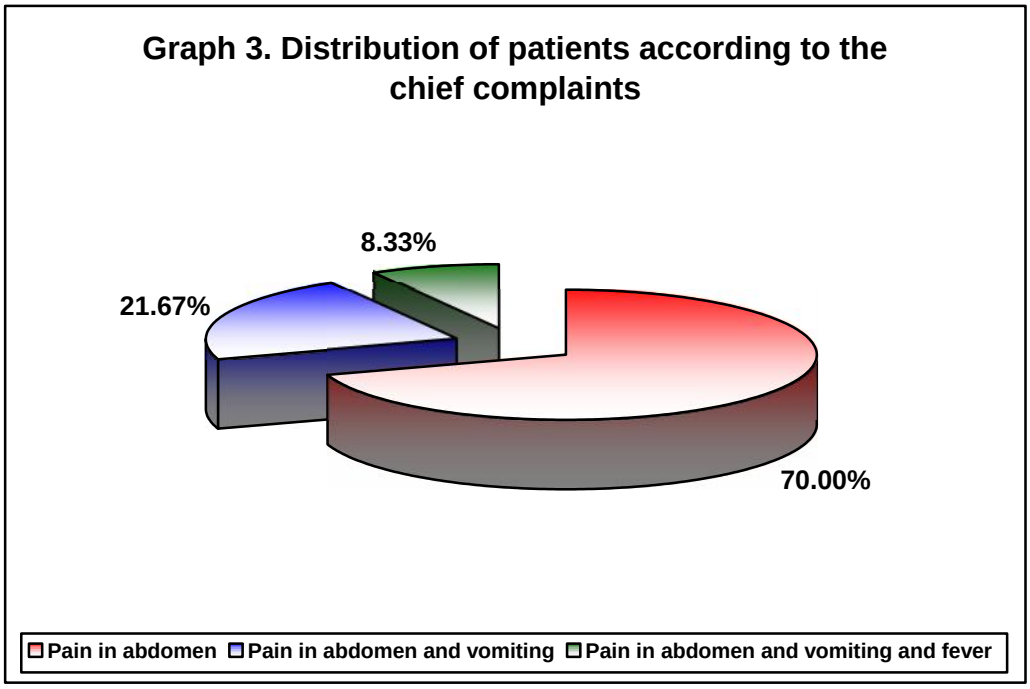
Age group (Years)	Distribution (n=60)	
	Number	**Percentage**
20 to 30	6	10.00
31 to 40	10	16.67
41 to 50	14	23.33
51 to 60	30	50.00
Total	**60**	**100.00**



In this study most of the patients (50%) were aged between 51 to 60 years. The mean age was 47.62±10.35 years. The median age was noted as 50 years and ranged between 20 to 60 years.

Table 3. Distribution of patients according to the chief complaints

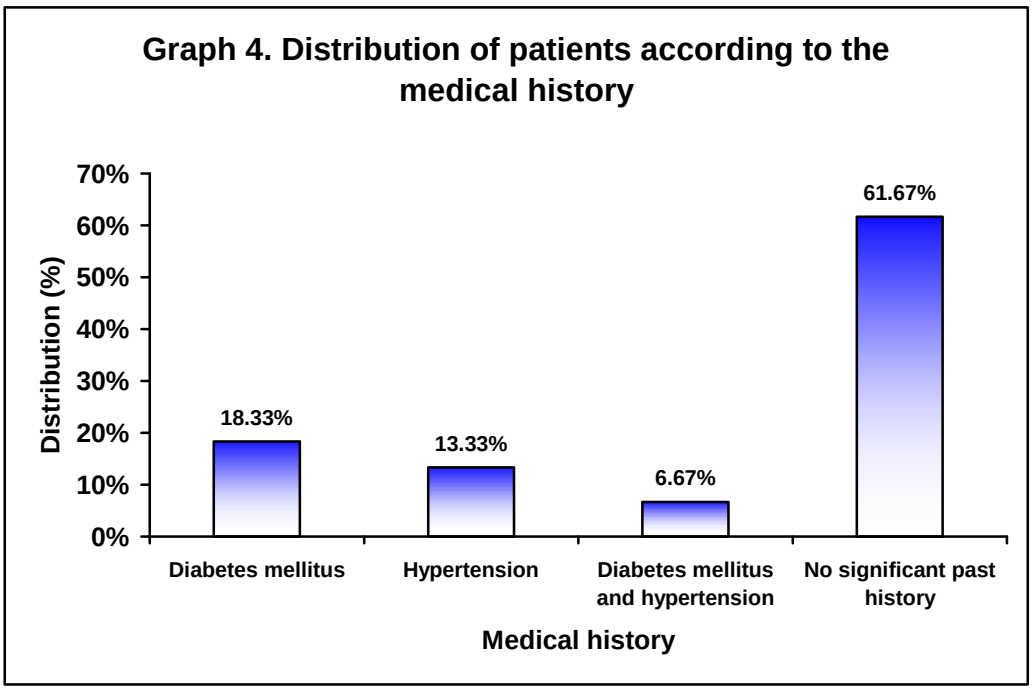
Chief complaints	Distribution (n=60)	
	Number	**Percentage**
Pain in abdomen	42	70.00
Pain in abdomen and vomiting	13	21.67
Pain in abdomen and vomiting and fever	5	8.33
Total	**60**	**100.00**



In the present study most of the patients had complaints of pain in abdomen (70%) followed by pain in abdomen with vomiting (21.67%) and pain in abdomen and vomiting and fever (8.33%).

Table 4. Distribution of patients according to the medical history

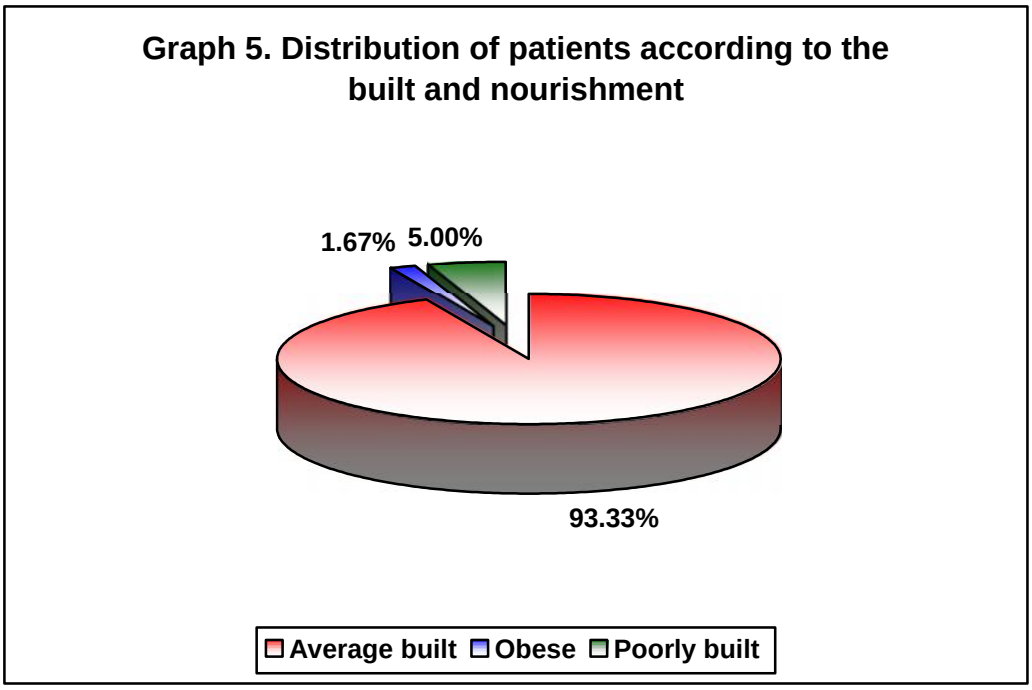
Medical history	Distribution (n=60)	
	Number	**Percentage**
Diabetes mellitus	11	18.33
Hypertension	8	13.33
Diabetes mellitus and hypertension	4	6.67
No significant past history	37	61.67
Total	**60**	**100.00**



In this study 18.33% of the patients had history of diabetes mellitus and 13.33% of the patients had hypertension while history of both diabetes mellitus with hypertension was noted in 6.67% of the patients. However, 61.67% of the patients did not had any significant history.

Table 5. Distribution of patients according to the built and nourishment

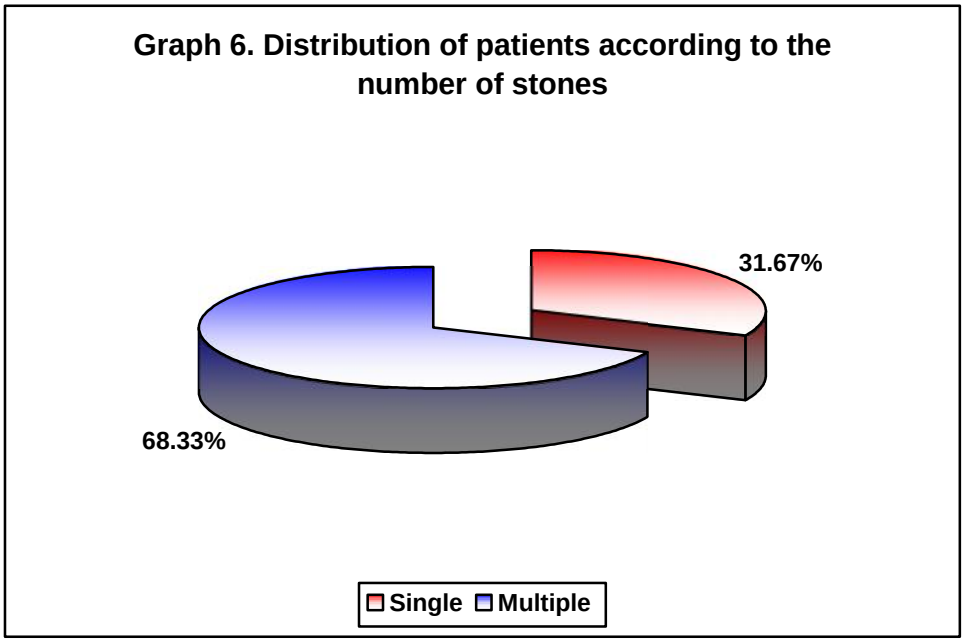
Built and nourishment	Distribution (n=60)	
	Number	**Percentage**
Average built	56	93.33
Obese	1	1.67
Poorly built	3	5.00
Total	**60**	**100.00**



In the present study the majority of the patients (93.33%) were average built and nourished, while 5% of the patients were poorly built and 1.67% of the patients were obese.

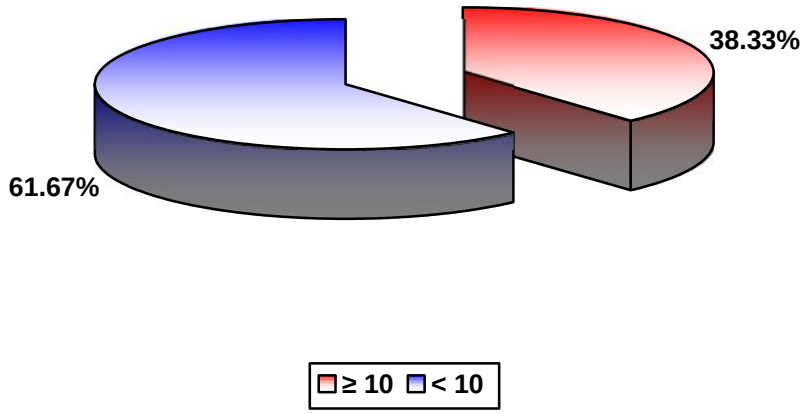
Table 6. Distribution of patients according to the ultrasound findings

Variables	Findings	Distribution (n=60)	
		Number	**Percentage**
No. of stones	Single	19	31.67
	Multiple	41	68.33
	Total	**60**	**100.00**
Size of largest stone (mm)	< 10	37	61.67
	≥ 10	23	38.33
	Total	**60**	**100.00**
Gall bladder wall thickness (mm)	< 4	41	68.33
	≥ 4	19	31.67
	Total	**60**	**100.00**
Gall bladder volume	Contracted	13	21.67
	Distended	4	6.67
	Normal	43	71.67
	Total	**60**	**100.00**



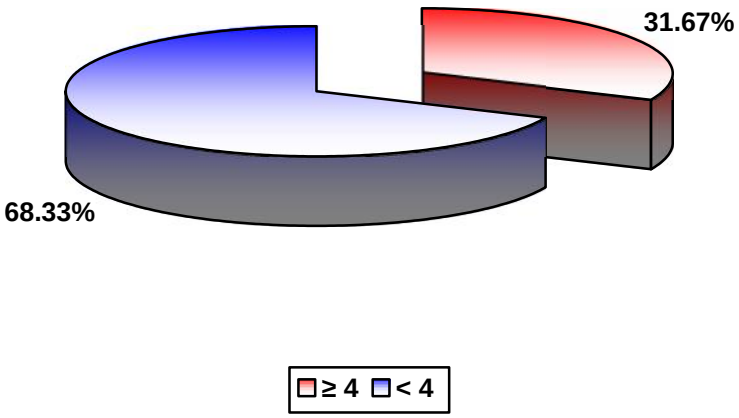
In this study ultrasound findings showed 68.33% of the patients with multiple numbers of stones.

Graph 7. Distribution of patients according to the size of largest stone

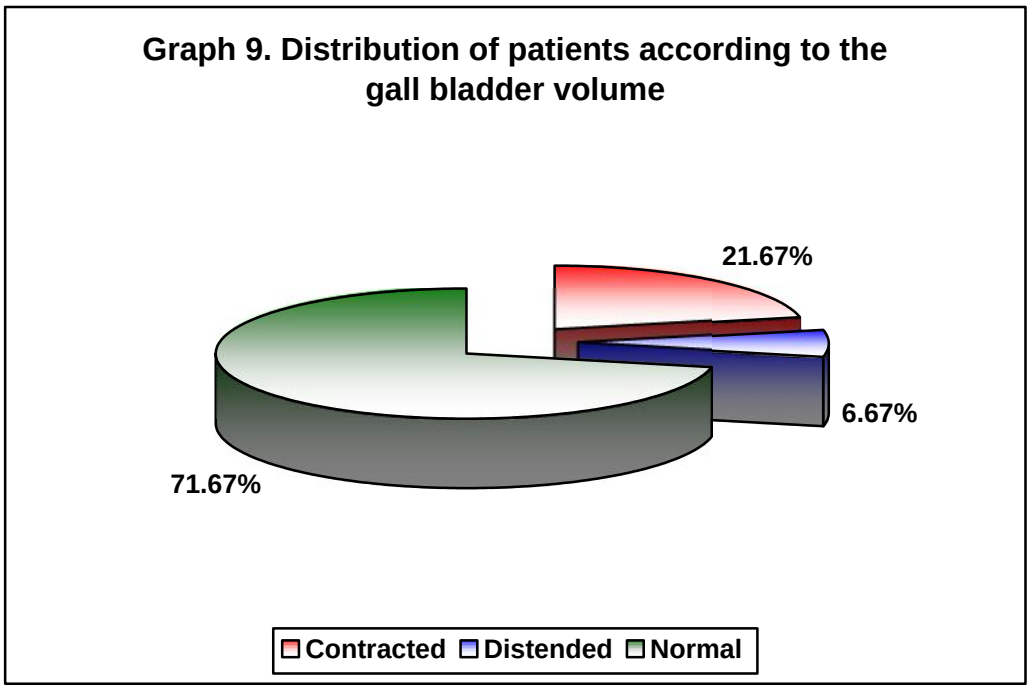


In the present study 38.33% of the patients had stone size of ≥10 mm.

Graph 8. Distribution of patients according to the gall bladder wall thickness



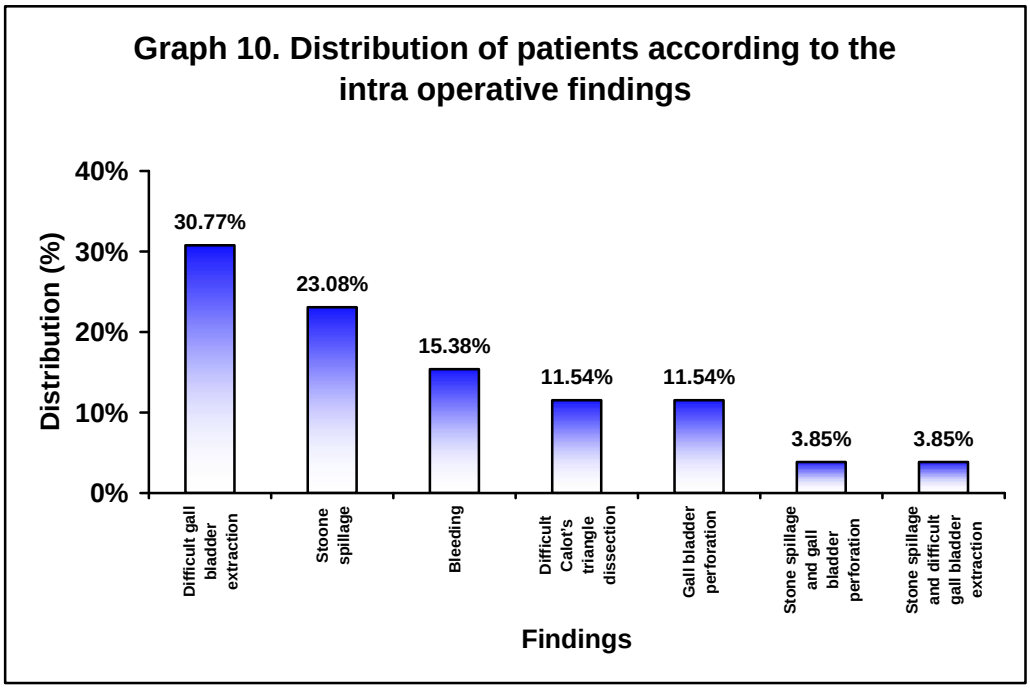
In the present study 31.67% of the patients had gallbladder thickness of ≥4 mm.



In the present study the gall bladder volume was normal among 71.67% of the patients, while contracted in 21.67% of the patients and distended in 6.67% of the patients.

Table 7. Distribution of patients according to the intra operative findings

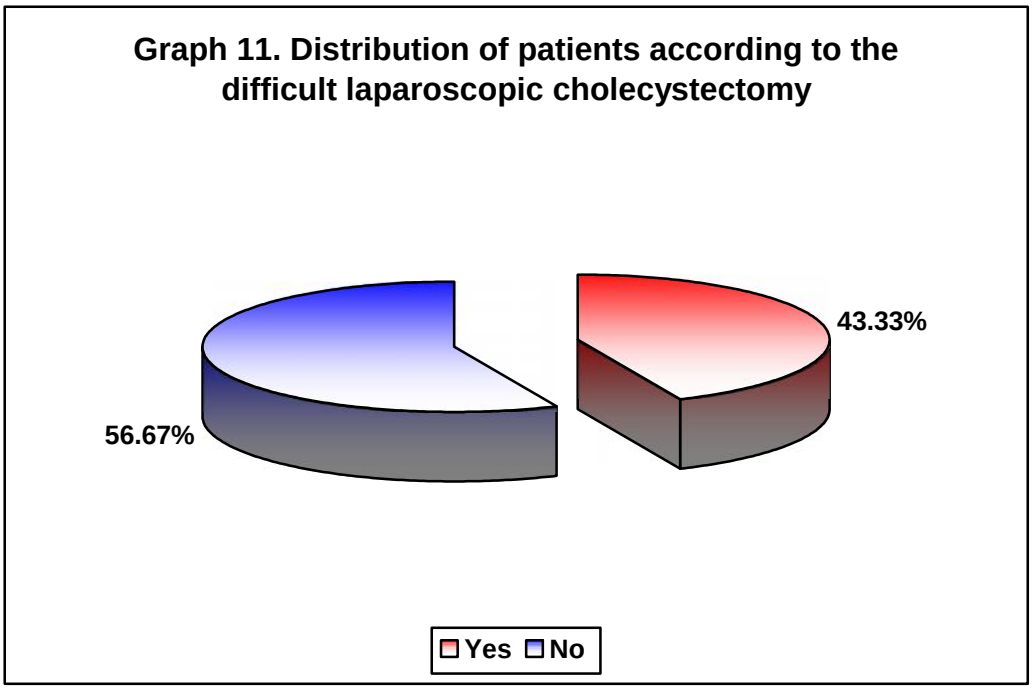
Findings	Distribution (n=26)	
	Number	**Percentage**
Difficult gall bladder extraction	8	30.77
Stone spillage	6	23.08
Bleeding	4	15.38
Difficult Calot's triangle dissection	3	11.54
Gall bladder perforation	3	11.54
Stone spillage and gall bladder perforation	1	3.85
Stone spillage and difficult gall bladder extraction	1	3.85
Total	**26**	**100.00**



In this study intra operative findings revealed difficult gall bladder extraction in 30.77% of the patients followed by stone spillage in 23.08% of the patients, bleeding in 15.38% of the patients, difficult Calot's triangle dissection and gall bladder perforation in 11.54% of the patients each.

Table 8. Distribution of patients according to the difficult laparoscopic cholecystectomy

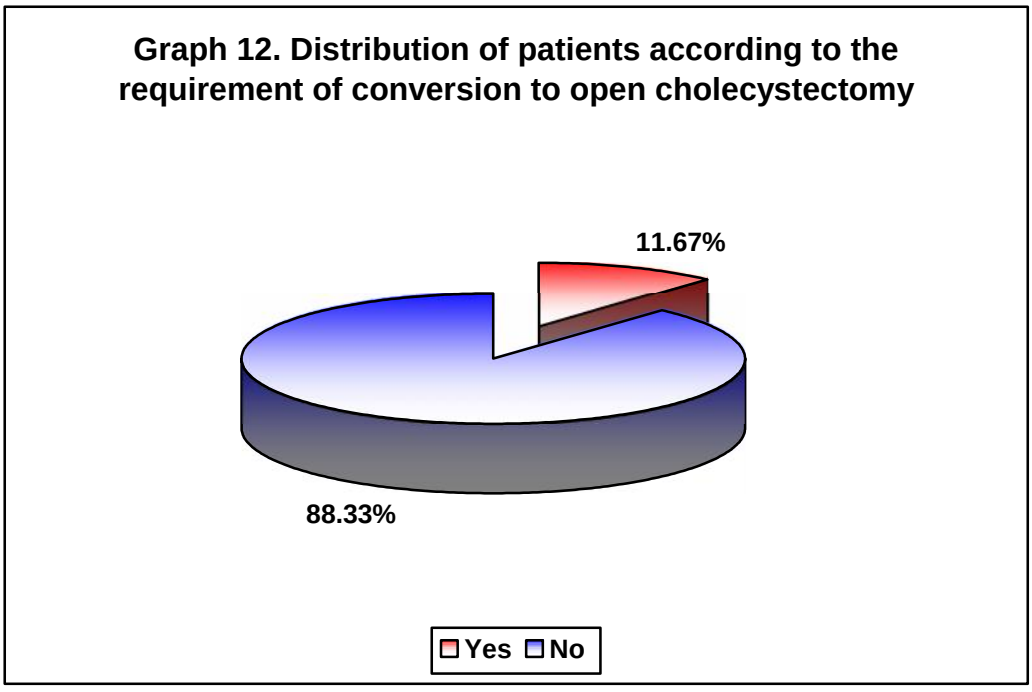
Difficult laparoscopic cholecystectomy	Distribution (n=60)	
	Number	**Percentage**
Yes	26	43.33
No	34	56.67
Total	**60**	**100.00**



In this study based on intraoperative findings, 43.33% of the patients had difficult laparoscopic cholecystectomy.

Table 9. Distribution of patients according to the requirement of conversion to open cholecystectomy

Conversion to open cholecystectomy	Distribution (n=60)	
	Number	Percentage
Yes	7	11.67
No	53	88.33
Total	**60**	**100.00**



In the present study 11.67% of the patients required conversion from laparoscopic cholecystectomy to open cholecystectomy.

Table 10. Association of conversion with difficult laparoscopic cholecystectomy

Difficult laparoscopic cholecystectomy	Conversion to open laparoscopic cholecystectomy				Total	
	Yes		No			
	No.	%	No.	%	No.	%
Yes	7	26.92	19	73.08	26	100.00
No	0	0.00	34	100.00	34	100.00
Total	**7**	**11.67**	**53**	**88.33**	**60**	**100.00**

p = 0.002

In the present study significantly higher number of patients with difficult laparoscopy (26.92%) required conversion to open laparoscopy (p=0.002).

Table 11. Association of conversion with number of stones

Number of stones	Conversion to open cholecystectomy				Total	
	Yes		No			
	No.	%	No.	%	No.	%
Single	0	0.00	19	100.00	19	100.00
Multiple	7	17.07	34	82.93	41	100.00
Total	**7**	**11.67**	**53**	**88.33**	**60**	**100.00**

p = 0.058

In this study 17.07% of the patients with multiple number of stones required conversion to open cholecystectomy compared to none of the patient with single stone (0%). However, this difference was statistically not significant (p=0.058).

Table 12. Association of conversion with size of largest stone

Size of largest stone (mm)	Conversion to open cholecystectomy				Total	
	Yes		No			
	No.	%	No.	%	No.	%
< 10	1	2.70	36	97.30	37	100.00
≥ 10	6	26.09	17	73.91	23	100.00
Total	**7**	**11.67**	**53**	**88.33**	**60**	**100.00**

p = 0.010

In the present study significantly higher number of patients (26.09%) with largest stone size of ≥10 mm required conversion to open cholecystectomy (p=0.010).

Table 13. Association of conversion with gall bladder wall thickness

Gall bladder wall thickness (mm)	Conversion to open cholecystectomy				Total	
	Yes		No			
	No	%	No	%	No	%
< 4	1	2.44	40	97.56	41	100.00
≥ 4	6	31.58	13	68.42	19	100.00
Total	**7**	**11.67**	**53**	**88.33**	**60**	**100.00**

p = 0.003

In this study significantly higher number of patients (31.58%) with gall bladder wall thickness of ≥4 mm required conversion to open cholecystectomy (p=0.003).

Table 14. Association of conversion with gall bladder volume

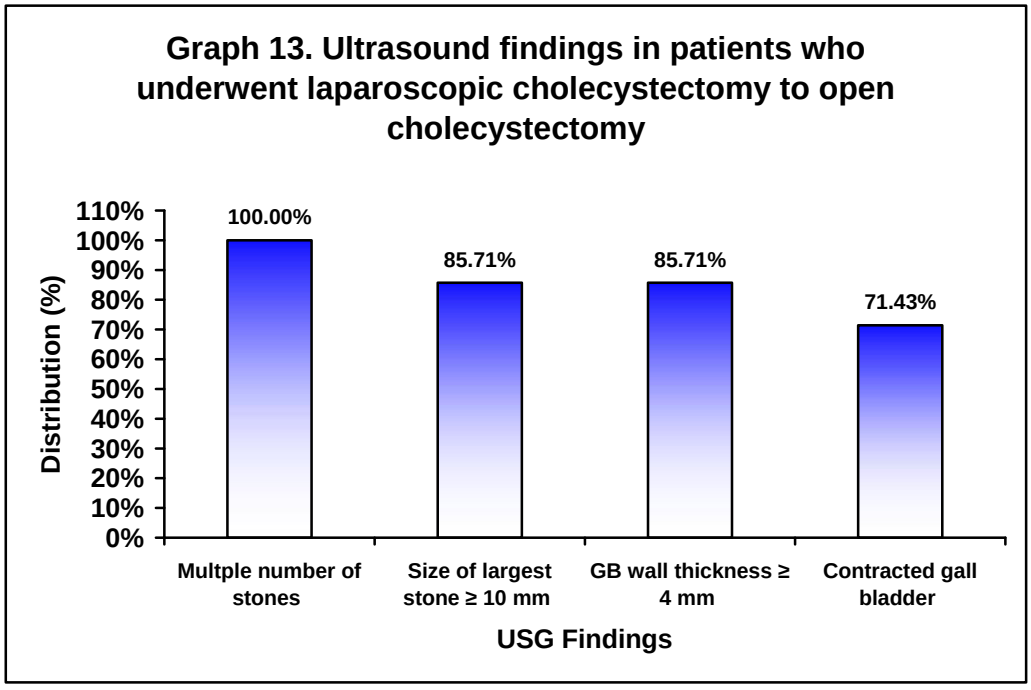
Gall bladder volume	Conversion to open cholecystectomy				Total	
	Yes		No			
	No.	%	No.	%	No.	%
Contracted	5	38.46	8	61.54	13	100.00
Distended	0	0.00	4	100.00	4	100.00
Normal	2	4.65	41	95.35	43	100.00
Total	**7**	**11.67**	**53**	**88.33**	**60**	**100.00**

p = 0.008

In the present study significantly higher number of patients with contracted gall bladder (38.46%) required conversion to open cholecystectomy (p=0.008).

Table 15. Ultrasound findings in patients who underwent laparoscopic cholecystectomy to open cholecystectomy

USG findings	Distribution (n=7)	
	Number	Percentage
Multiple number of stones	7	100.00
Size of largest stone ≥ 10 mm	6	85.71
GB wall thickness ≥ 4 mm	6	85.71
Contracted gall bladder	5	71.43



In this study all the patients who underwent conversion (100%) had multiple number of stones, and majority of the patients had size of largest stone ≥10 mm (85.71%), GB wall thickness ≥4mm (85.71%) and contracted gall bladder (71.43%).

Table 16. Association of intra operative findings with number of stones

Intra operative findings	Number of stones				Total	
	Multiple		Single			
	No.	%	No.	%	No.	%
Bleeding	4	100.00	0	0.00	4	100.00
Difficult Calot's triangle dissection	2	66.67	1	33.33	3	100.00
Difficult gall bladder extraction	4	50.00	4	50.00	8	100.00
Stone spillage	5	83.33	1	16.67	6	100.00
Stone spillage and gall bladder perforation	1	100.00	0	0.00	1	100.00
Stone spillage and difficult gall bladder extraction	1	100.00	0	0.00	1	100.00
Gall bladder perforation	3	100.00	0	0.00	3	100.00
No significant finding	21	61.76	13	38.24	34	100.00
Total	**41**	**68.33**	**19**	**31.67**	**60**	**100.00**

p = 0.574

In this study intraoperative findings revealed bleeding, stone spillage gall bladder perforation, stone spillage and gall bladder extraction and gall bladder perforation in all the patients (100%). However, no statistically significant difference was noted between intraoperative findings and number of stones (p=0.574).

Table 17. Association of intra operative findings with size of largest stone

Intra operative findings	Size of largest stone (mm)				Total	
	< 10		≥ 10			
	No.	**%**	**No..**	**%**	**No.**	**%**
Bleeding	0	0.00	4	100.00	4	100.00
Difficult Calot's triangle dissection	0	0.00	3	100.00	3	100.00
Difficult gall bladder extraction	0	0.00	8	100.00	8	100.00
Stone spillage	3	50.00	3	50.00	6	100.00
Stone spillage and gall bladder perforation	0	0.00	1	100.00	1	100.00
Stone spillage and difficult gall bladder extraction	1	100.00	0	0.00	1	100.00
Gall bladder perforation	3	100.00	0	0.00	3	100.00
Normal finding	30	88.24	4	11.76	34	100.00
Total	**37**	**61.67**	**23**	**38.33**	**60**	**100.00**

$p < 0.001$

In this study significantly higher number of patients with largest stone size of ≥ 10 mm had bleeding (100%), difficult Calot's triangle dissection (100%), difficult gall bladder extraction (100%), stone spillage with gall bladder perforation (100%) ($p<0.001$).

Table 18. Association of intra operative findings with gall bladder wall thickness

Intra operative findings	Gall bladder wall thickness (mm)				Total	
	< 4		≥ 4			
	No.	%	No.	%	No.	%
Bleeding	0	0.00	4	100.00	4	100.00
Difficult Calot's triangle dissection	1	33.33	2	66.67	3	100.00
Difficult gall bladder extraction	4	50.00	4	50.00	8	100.00
Stone spillage	3	50.00	3	50.00	6	100.00
Stone spillage and gall bladder perforation	0	0.00	1	100.00	1	100.00
Stone spillage and difficult gall bladder extraction	0	0.00	1	100.00	1	100.00
Gall bladder perforation	0	0.00	3	100.00	3	100.00
Normal finding	33	97.06	1	2.94	34	100.00
Total	**41**	**68.33**	**19**	**31.67**	**60**	**100.00**

p < 0.001

In the present study significantly higher number of patients with gall bladder wall thickness ≥ 4 mm had bleeding (100%), difficult Calot's triangle dissection (66.67%), difficult gall bladder extraction (50%), stone spillage and gall bladder perforation (100%), stone spillage and gall bladder extraction (100%) and gall bladder perforation (100%) ($p<0.001$).

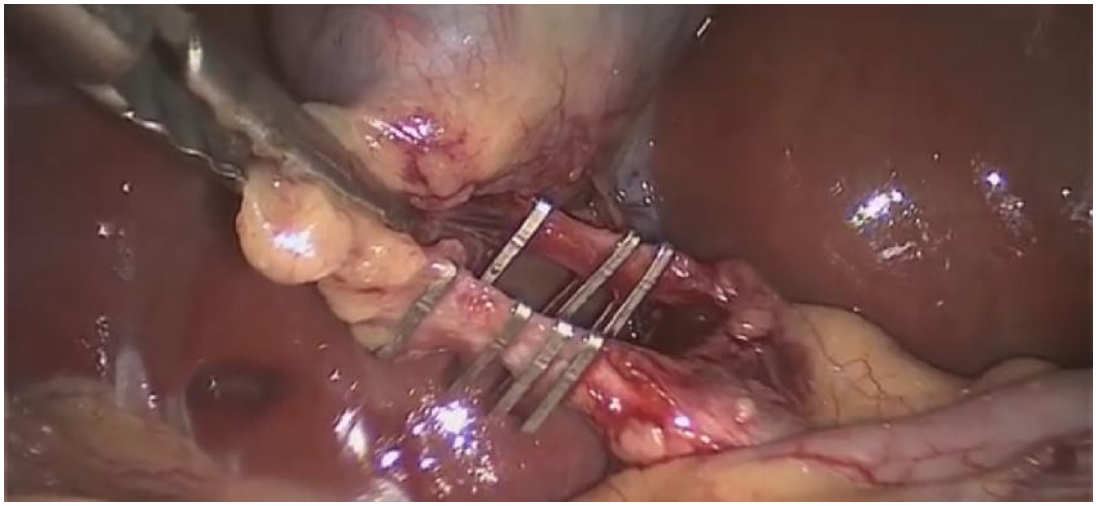
Table 19. Association of intra operative findings with gall bladder volume

Intra operative findings	Gall bladder volume						Total	
	Contracted		Distracted		Normal			
	No.	%	No.	%	No.	%	No.	%
Bleeding	3	75.00	1	25.00	0	0.00	4	100.00
Difficult Calot's triangle dissection	2	66.67	0	0.00	1	33.33	3	100.00
Gall bladder extraction	1	12.50	3	37.50	4	50.00	8	100.00
Stone spillage	3	50.00	0	0.00	3	50.00	6	100.00
Stone spillage and gall bladder perforation	0	0.00	0	0.00	1	100.00	1	100.00
Stone spillage and difficult gall bladder extraction	1	100.00	0	0.00	0	0.00	1	100.00
Gall bladder perforation	1	2.94	0	0.00	33	97.06	34	100.00
Normal finding	2	66.67	0	0.00	1	33.33	3	100.00
Total	**13**	**21.67**	**4**	**6.67**	**43**	**71.67**	**60**	**100.00**

$p < 0.001$

In this study significantly higher number of patients with contracted gall bladder volume had bleeding (75%), difficult Calot's triangle dissection (66.67%), stone spillage and difficult gall bladder extraction (100%) ($p<0.001$).

Photograph 4. Calot's triagle dissection with cystic duct and cystic artery



Photograph 5. Clip applied to cystic duct and cystic artery

DISCUSSION

The worldwide prevalence of gallstone disease in general population ranges between 3% to 20%. Minimal invasive surgery has brought revolutionary changes in the treatment of patients with gallbladder stones. Mouret[6] introduced laparoscopic cholecystectomy in 1987, since then minimal invasive surgery still evolving. It has rapidly replaced open cholecystectomy as the standard treatment. There are several definitive advantages of laparoscopic cholecystectomy includes reduced hospitalization, decreased morbidity, short recovery time, and better cosmesis.[6,7,14,94,95] Now-a-days Laparoscopic cholecystectomy (LC) is the standard procedure for the treatment of symptomatic gallbladder stones. Although few require conversion to open cholecystectomy.[7,10,14]

Patients with long-standing disease and previous bouts of cholecystitis or pancreatitis are at higher risk of experiencing a difficult procedure or conversion and may be at increased risk of bile duct injury or injury to the adjoining viscera. Gallbladder wall thickness greater than 3 mm is suggestive of cholecystitis in some, but not all literature reports.[13,96]

The present study was aimed to determine the role of ultrasonography in predicting difficult laparoscopic cholecystectomy. It would also correlate preoperative factors with intraoperative findings of laparoscopic cholecystectomy which may help in predicting difficult laparoscopy. In studies by Rizvi SAA et al., Cooperberg PL et al., Hardy KJ, et al, Leander P, et al. found ultrasonographic measurement of GB wall thickness is accurate to within 1 mm in 93% of patients.[10,98-101]

This hospital based prospective study was performed in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2016 to December 2016. A total of 60 patients presenting with right hypochondriac pain and diagnosed to have cholecystitis undergoing laparoscopic cholecystectomy were studied.

In the present study almost equal number of patients were males (51.67%) and females (48.33%) with the male to female ratio of 1.06:1. In contrast to these observations, Nidoni R. et al.[1] in their study reported maximum females with male to female ratio of 1:1.76 while a study by Prakash V. et al.[2] reported male preponderance (68%). Age ranged between 20 to 60 years. Nearly Half of the study population (50%) was aged between 51 to 60 years. The mean age was 47.62±10.35 years suggesting mostly middle age individuals. However, Nidoni R et al.[1] in their study reported most common age group as 40 to 50 years. A similar study by Santambrogio R. et al.[112] reported mean age of 49.5 ± 15.0 years which was consistent with the present study.

In this study, most of the patients presented with clinical features of pain in abdomen (70%) followed by pain in abdomen with vomiting (21.67%), with associated of history of fever in few (8.33%). With regard to medial history 18.33% of the patients had history of diabetes mellitus and 13.33% of the patients had hypertension while history of both diabetes mellitus with hypertension was noted in 6.67% of the patients. However, 61.67% of the patients did not report significant history. On examination, majority of the patients (93.33%) were average built and nourished, while 5% of the patients were poorly built and 1.67% of the patients were obese.

Gallstone size, gallbladder wall thickness, gallbladder volume, number of stones, common duct size, and stone impaction in the neck of gallbladder are various parameters that help predicting difficult laparoscopic cholecystectomy.[14] Impacted stones at the neck of GB, a distended GB pose some technical problems during LC, as seen with thick GB wall. It is difficult to grasp the GB neck to allow adequate retraction to perform dissection at the Calot's triangle.[96] Adhesions are the important cause for difficulty encountered in LC and these cannot be assessed on routine ultrasonography (USG) done for cholelithiasis.[114]

In this study the most common abnormality noted on ultrasound was multiple numbers of stones (68.33%), stone size of ≥ 10 mm (38.33%) and gall bladder thickness of ≥ 4 mm (31.67%). The gall bladder volume was contracted in (21.67%) and distended in 6.67% of the patients. Furthermore, based on intra operative findings including time taken for surgery, biliary/stone spillage, bleeding during surgery, difficult Calot's triangle dissection, gall bladder bed dissection, injury to duct/artery, difficult extraction of gall bladder, extension of incision and need for conversion were the determinants of difficult surgery.

In this study, the most common intra operative findings was difficult gall bladder extraction (30.77%) followed by stone spillage (23.08%), bleeding (15.38%), difficult Calot's triangle dissection and gall bladder perforation (11.54% each). Based on these findings, 43.33% of the patients had difficult laparoscopic cholecystectomy. Based on the intra operative observations, 43.33% of the surgeries were labeled as difficult surgeries. Making it slightly high compared to the other studies reported in the literature. For example, Prakash V et al.[2] predicted difficult laparoscopy in 65 out of 100 patients based on sonographic findings, the pre-op

assessment which was high compared to the present study. Another study by Santambrogio R. et al. operation was predicted to be easy in 38% of cases, difficult in 49%, and very difficult in 13%. Though the difficult laparoscopic cholecystectomy predicted by Santambrogio R. et al was in agreement with the present study they form three groups viz. easy, difficult and very difficult. One more study by Singh and Ohri[116] identified 1518 patients (21.5%) as difficult cases out of 6147 cases. These differences can be attributed to varied criteria in defining difficult laparoscopy and varied sample size of the study.

Sharma SK et al.[12] reported that of all Laparoscopic cholecystectomies, 1-13% requires conversion to an open for various reasons that includes age, WBC count, Gall bladder wall thickness and presence or absence of Pericholecystic collection. In this study the rate of conversion from laparoscopic cholecystectomy to open cholecystectomy was 11.67% making it consistent with the previous literature. The rate of conversion noted in the present study was comparable to a study by Rizvi SAA et al. who reported conversion rate of 9.4% among 298 patients. However, a recent study by Nidoni R. et al.[1] reported rate conversion to an open as 6% which was low compared to the present study. Tiwari KS. et al.[117] conducted a study which included 536 patients who underwent laparoscopic cholecystectomy. The Overall conversion rate in their study was 7.81%. Sharma SK et al.,[12] conducted a study on 200 patients undergoing laparoscopic cholecystectomy at Kathmandu medical college and reported the rate of conversion as low as was 4%. The conversion rate in their study was 4%. Yetkin et al.[118] studied that out in 108 patients, 19 (17.33%) needed conversion to open cholecystectomy. The higher rate

of conversion observed in the present study may be attributed to the smaller sample size of the study population.

In the present study significantly higher number of patients with difficult laparoscopy (26.92%) required conversion to open cholecystectomy (p=0.002). Hence these findings prove that ultrasonography is a reliable and accurate diagnostic examination for biliary tract disease and helps in predicting difficult laparoscopy based on multiple numbers of stones, stone size of ≥ 10 mm and gall bladder thickness of ≥ 4 mm (31.67%) and the gall bladder volume. These findings were consistent with a study by Nidoni R. et al.[1] who concluded that, the difficult laparoscopic cholecystectomy and conversion to open surgery can be predicted preoperatively based on number of previous attacks of cholecystitis, WBC count, Gall bladder wall thickness and presence or absence of Pericholecystic collection. However, the present study did not considered WBC count. In contrast to these observations a study was conducted by Kulbhushan H et al.[119] to determine whether the preoperative USG finding can predict the difficulty during the laparoscopic cholecystectomy and its conversion. Of the 400 cases, 24 (6.0%) were converted to open procedure. Of the 144 (36%) cases predicted to be difficult, 116 (29%) were technically difficult, of which 18 (4.5%) were converted to open procedure. Of the 256 (64%) cases predicted to be easy on ultrasonography, 19 (4.75%) were found to be difficult on surgery, of which only 6 (1.5%) had to be converted to open procedure.

Agarwal D et al.[120] reported that, multiple stone which are smaller in size have more chance of difficulty in laparoscopic Cholecystectomy because these patients have more repeated attacks of cholecystitis silently or clinically detected

previously. However, in the present study significantly higher number of patients with largest stone size of ≥ 10 mm had bleeding (100%), difficult Calot's triangle dissection (100%), difficult gall bladder extraction (100%), stone spillage with gall bladder perforation (100%) ($p<0.001$) suggesting higher frequency of a difficult procedure. Furthermore, significantly higher number of patients that is, 26.09% of the patients with largest stone size of ≥10 mm required conversion to open cholecystectomy ($p=0.010$). Thus suggesting, largest stone size of ≥10 is not only significantly associated with high rate of conversion but also associated with several difficulties like bleeding, difficult Calot's triangle dissection, difficult gall bladder extraction and stone spillage with gall bladder perforation during the laparoscopic cholecystectomy. Nachnani & Supe[121] (2005) also concluded that difficulty in extraction was associated with a calculus of size more than 1 cm. However due to lack limited number of studies in the literature and smaller sample size of this study, these finding need further validation.

Studies have found a good correlation between gallbladder wall thickness with conversion to the open procedure.[10] Though gall bladder wall thickness has been identified as a risk factor for conversion in almost all the studies, the thickness of gall bladder associated with conversion varies from study to study. It was 3 mm in some studies[99,121] and 4 mm in some other study.[110] In our study the critical gall bladder wall thickness was 4 mm. In the present study significantly higher number of patients with Gall bladder wall thickness ≥ 4 mm had bleeding (100%), difficult Calot's triangle dissection (66.67%), difficult gall bladder extraction (50%), stone spillage and gall bladder perforation (100%), stone spillage and difficult gall bladder extraction (100%) and gall bladder perforation (100%) ($p<0.001$). Also significantly

higher number of patients (31.58%) with gall bladder wall thickness of ≥4 mm required conversion to open cholecystectomy (p=0.003). Again these finding suggest that, Gall bladder wall thickness ≥ 4 mm is strongly associated with conversion to open procedure and likely to result in several complications which is in agreement with a study by Rizvi SAA et al.,[10] who reported a good correlation between gallbladder wall thickness with conversion to the open procedure where all the 28 patients in the series who required conversion to an OC, 20 patients (71.4%) had a preoperative ultrasound gallbladder thickness of 3 mm and more. In contrast to these observations, Santambrogio R. et al.[112] reported GB wall thickening was not confirmed to be a positive predictive factor as described in other studies.[107,122] Several other studies have reported oppositely that a thickened GB wall thickness was of little or no benefit in predicting operative technical difficulty or conversion to an OC.[107,122] Gadacz TR et al.[15] reported sensitivity, specificity, positive predictive value and accuracy of wall thickening as an indicator of technical difficulties were 66.7%, 94.1%, 84.2%, and 85.3% respectively.[116]

Increased GB wall thickness is associated with difficult dissection of the GB from its bed[99] making grasping and manipulation of GB difficult. Along with difficulties arising in Calot's triangle dissection hence limiting the extent of anatomical definition. In our study, we found significant correlation between the GB wall thickness and the difficulty level of surgery. Better randomization of the patients into the two groups and a larger sample size would have allowed us to extrapolate the results into the general population.

The contracted gallbladder is another important predictive factor for difficult laparoscopic cholecystectomy. In the present study significantly higher number of

patients with contracted gall bladder (38.46%) required to conversion to open cholecystectomy (p=0.008). Also significantly higher number of patients had bleeding (75%), difficult Calot's triangle dissection (66.67%), stone spillage and difficult gall bladder extraction (100%) (p<0.001). These findings were in agreement with a study by Chand P. et al.[114] where there were five cases with contracted gallbladder and all were difficult on surgery, but, none was converted to open. On the other hand Oleary DP et el.[113] reported that, conversion to an open cholecystectomy was a strongly associated with a contracted gallbladder (p = 0.005).

In this study, 17.07% of the patients with multiple numbers of stones required conversion to open cholecystectomy compared to none of the patient with single stone (0%). However, this difference was statistically not significant (p=0.058). Furthermore, intraoperative findings revealed bleeding, stone spillage Gall bladder perforation, Stone spillage and difficult gall bladder extraction and gall bladder perforation in all the patients (100%). However, no statistically significant difference was noted between intraoperative findings and number of stones (p=0.574). Nachnani & Supe[121] (2005) also concluded that difficulty in extraction was not associated with number of stones. However, these findings need to interpreted cautiously due to limited data in the literature.

Overall the present study showed that, ultrasonographic parameters that is, multiple numbers of stones, stone size of ≥ 10 mm, gall bladder thickness of ≥ 4 mm and contracted gall bladder help in predicting difficult laparoscopy and further prompt need for conversion to open procedure to the evaluating surgeon. However these finding needs to be interpreted cautiously due to the potential limitations. One of the main limitations of the study is the defined age group. The present study was

comprised of relatively small sample from a single tertiary care centre. No patients above 60 years were taken. Also the majority of the population in this study was young to middle aged group. Hence, it does not prove factors efficacy or co-relation for older age group. Hence further multicentric studies involving large samples covering all the age groups are warranted to enlighten the precise role of ultrasonography in predicting difficult laparoscopic cholecystectomy.

CONCLUSION

Based on the findings of this study it may be concluded that, ultrasonographic finding namely, multiple numbers of stones, stone size of ≥ 10 mm, gall bladder thickness of ≥ 4 mm and contracted gall bladder volume help in predicting difficult laparoscopy thereby prompting the likelihood of conversion to open procedure.

Furthermore, largest stone size of ≥ 10 mm, gall bladder thickness of ≥ 4 mm and contracted gall bladder volume are significantly associated with intra operative bleeding, difficult Calot's triangle dissection, difficult gall bladder extraction, stone spillage, stone spillage with gall bladder perforation, stone spillage with gall bladder extraction and gall bladder perforation.

SUMMARY

Although, laparoscopic cholecystectomy is the standard procedure for the treatment of symptomatic gallbladder stones, few requires conversion to open cholecystectomy. Ultrasonography is highly helpful characterizing the gallbladder appearance. The present study was undertaken to determine the role of ultrasonography in predicting difficult laparoscopic cholecystectomy and to correlate preoperative factors with intraoperative findings of laparoscopic cholecystectomy which may be helpful in predicting difficult laparoscopy.

This hospital based prospective study was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2016 to December 2016. A total of 60 patients presenting with right hypochondriac pain and diagnosed to have calculus cholecystitis or cholelithiasis undergoing laparoscopic cholecystectomy were studied. The most important findings are as summarized below.

- 51.67% of the patients were males and the male female ratio was 1.06:1.
- Most of the patients (50%) were aged between 51 to 60 years and the mean age was 47.62±10.35 years.
- Majority of the patients had presented with complaints of pain in abdomen (70%) and were average built and nourished (93.33%), while 5% of the patients were poorly built and 1.67% of the patients were obese.

- 18.33% of the patients had history of diabetes mellitus and 13.33% of the patients had hypertension.

- Ultrasound findings showed 68.83% of the patients with multiple numbers of stones, 38.33% of the patients with stone size of ≥10 mm and 31.67% of the patients had gallbladder thickness of ≥ 4 mm. The gall bladder volume was contracted in 21.67% of the patients and distended in 6.67% of the patients.

- Intra operative findings revealed difficult gall bladder extraction in 30.77% of the patients followed by stone spillage in 23.08% of the patients, bleeding in 15.38% of the patients, difficult Calot's triangle dissection and gall bladder perforation in 11.54% each.

- 43.33% of the patients had difficult laparoscopic cholecystectomy.

- 11.67% of the patients required conversion from laparoscopic cholecystectomy to open cholecystectomy.

- Significantly higher number of patients with difficult laparoscopy (26.92%) required conversion to open cholecystectomy (p=0.002).

- 17.07% of the patients with multiple numbers of stones required conversion to open cholecystectomy compared to none of the patient with single stone (0%) (p=0.058). Intraoperative findings viz. bleeding, stone spillage Gall bladder perforation, Stone spillage and difficult gall bladder extraction and Gall bladder perforation were not associated with number of stones (p=0.574).

- Significantly higher number of patients with largest stone size of ≥10 mm (26.09%; p=0.010), gall bladder wall thickness of ≥4 mm (31.58%; p=0.003) and contracted gall bladder (38.46%; p=0.008) required conversion to open cholecystectomy.

- Intraoperative findings viz. bleeding, stone spillage Gall bladder perforation, Stone spillage and Gall bladder extraction and Gall bladder perforation were associated with largest stone size of ≥10 mm (p<0.001), Gall bladder wall thickness ≥ 4 mm (p<0.001) and contracted Gall bladder volume (p<0.001).

Hence, it may be concluded that, ultrasonographic finding namely, multiple numbers of stones, stone size of ≥ 10 mm, gall bladder thickness of ≥ 4 mm and contracted gall bladder volume help in predicting difficult laparoscopy thereby prompting the likelihood of conversion to open procedure. Also these ultrasonographic findings are associated with intra operative findings viz. bleeding, difficult Calot's triangle dissection, difficult gall bladder extraction, stone spillage, stone spillage with gall bladder perforation, stone spillage with difficult gall bladder extraction and gall bladder wall perforation.

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ANNEXURE I – CONSENT FORM

Title of Research Study

"A CROSS SECTIONAL STUDY TO DETERMINE PREDICTIVE FACTORS FOR DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY USING ULTRASONOGRAPHIC CRITERIA"

Principal Investigator

DR. * **** *****
Department of General Surgery,
Jawaharlal Nehru Medical College,
Belagavi – 590 005

Co-investigators

DR. ** ***** ,**
Department of General Surgery,
Jawaharlal Nehru Medical College,
Belagavi – 590 005

Introduction and purpose

You are requested to participate in a study that is predicting factors for difficult laparoscopic cholecystectomy using ultrasonographic criteria.

The ability to accurately identify an individual patient's risk for conversion based on preoperative information can result in more meaningful and accurate preoperative counseling, improved operating room scheduling and efficiency, stratification of risk for technical difficulty, and appropriate assignment of resident assistance, may improve patient safety by minimizing time to conversion, and helps to identify patients in whom a planned open cholecystectomy is indicated.

Since the conversion rate from laparoscopic cholecystectomy to open cholecystectomy is 1.5 to 19%, there is need to evaluate various factors responsible for difficult laparoscopic cholecystectomy.

This study will be conducted by Dr. ***** ***** , Post Graduate in Department of Surgery, under the direct supervision and guidance of

**** ******* , Professor, Department of Surgery, Jawaharlal Nehru Medical College, Belagavi.

You need to be eligible, meeting all the selection criteria to participate in this study. You should be willing to provide information about yourself.

Procedure

If you agree to participate in this study, you will be evaluated as per criteria explained and laparoscopic cholecystectomy will be done.

Benefits

This technique causes less blood loss, decrease postop pain, reduce hospital stay reduce the chances of infection.

Risk Involved

The side effects of this technique will be minimal.

Compensation

Taking part in the study will not affect the cost of treatment i.e. it will be similar to the cost of standard procedure. In the event that you become injured as a result of taking part in this study, treatment will be offered to you or you will be given information about where to receive medical care. But you/your insurance company will be responsible for the costs. However, no reimbursement, compensation or free medical care will be given.

Confidentiality

Every effort will be made to protect the confidentiality of the information you provide. Only Dr. **** ***** Dr. ******** ***** and will have access to the information collected. Results of this study may be published but your name will not be revealed.

Voluntary participation / withdrawal

Taking part in this study is voluntary; you may choose not to enroll in this study. Your decision will not change the present or future health care services offered to you at K.L.E.S Dr. Prabhakar Hospital Belagavi. The alternative that you have is to undergo the traditional procedure that is carried out in K.L.E.S Hospital.

I you have any queries about the study, you may contact Dr. ***** ****** (Mobile No. ***** ******,); or Dr. **** ***** ***** (Mobile No. **** *****); If you need any further information regarding your rights as a study participant, you may also contact Dr. **** ****** (Mobile No. ***** *****), Chairman of Institutional Ethics Committee, Jawaharlal Nehru Medical College and Belagavi.

CONSENT TO PARTICIPATE IN THE STUDY

I Mr. /Ms. _____ have been explained about the research study, the need of the study, the intervention, their risks, benefits and alternatives available in my own vernacular language.

I voluntarily agree to participate in this study by signing up this form below. I understand that I may withdraw at any time from this study. I have been given adequate time to clarify my doubts about the study and my rights as a study participant.

My signature / thumb impression below indicates that I have read or information in the consent been read to me including the risks and benefits and have cleared my doubts.

Name of participant: Signature/LTI:

Name of legally authorized Representative (if applicable): Signature/LTI:

Relationship with participant:

Name of witness: Signature:

Date: Place:

ANNEXURE II – PROFORMA

The proposed proforma / questionnaire to be used for data collection for the study titled **"**A **CROSS SECTIONAL STUDY TO DETERMINE PREDICTIVE FACTORS FOR DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY USING ULTRASONAGRAPHIC CRITERIA."**

Patient Identification Data

Group: Ward:

Name: In patient number:

Age: Sex: Date of admission:

Address: Date of surgery:

Date of discharge:

Education:

Religion: Marital Status:

Occupation: Socio-Economic Status:

Chief complaints

History of presenting complaints

Past history:

Personal history:

Family history:

General physical examination

Built and Nourishment: Weight:

Pallor: Icterus:

Cyanosis: Clubbing:

Edema: Lymphadenopathy:

Vital Signs

PR: / min; Blood Pressure: mmHg;

Respiratory rate : /min ; Température :

Local Examination

Systemic Examination

Abdomen:

Central nervous system:

Cardiovascular system:

Respiratory system:

Clinical impression

Investigations

Operation details

Date of surgery:

Name of surgery:

Anaesthesia: _____ Anaesthesia

Any complications after surgery

ANNEXURE III – KEY TO MASTER CHART

-	-	Absent
A	-	Average built and nourished
BP	-	Blood pressure
C	-	Contracted
d	-	Difficult laparoscopic cholecysectomy
D	-	Distended
d/BD	-	Difficult laparoscopic cholecysectomy due to bleeding
d/CD	-	Difficult laparoscopic cholecysectomy due to difficult Calot's triangle dissection
d/GE	-	Difficult laparoscopic cholecysectomy due to difficult gallbladder extraction
d/SS	-	Difficult laparoscopic cholecysectomy due to stone spillage
DM	-	Diabetes mellitus
E	-	Easy
F	-	Female
g/GP	-	Difficult laparoscopic cholecysectomy due to gallbladder perforation
GA	-	General anaesthesia
GB	-	Gall bladder
HTN	-	Hypertension
Kgs	-	Kilograms
L - O	-	Laparoscopic cholecystectomy to open cholecystectomy
LC	-	Laparoscopic cholecystectomy

M	-	Male
m	-	Multiple
min	-	Minute
mm	-	Milimeter
mmHg	-	Milimeter of mercury
N	-	Normal
NR	-	No relevant history
P	-	Pain in abdomen
P&V	-	Pain in abdominal pain and vomiting
P&V&F	-	Pain in abdominal pain and vomiting and fever
PR	-	Pulse rate
RR	-	Respiratory rate
s	-	Single
T	-	Tenderness
US	-	Ultrasound
USG	-	Ultrasonography

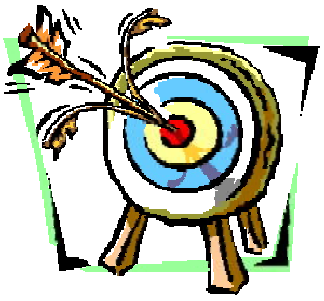
ANNEXURE III - MASTER CHART

Serial number	In patient number	Demographic data				Chief complaints	History				General physical examination																	USG abdomen					Clinical impression	Investigations	Operation details			Intra operative findings	Duration of surgery (minutes)
																		Vital signs																						
																			BP (mmHg)																				
		Age (Years)	Sex	Date of admission	Date of discharge		Present history	Past history	Personal history	Family history	Built and Nourishment	Weight (Kgs)	Pallor	Icterus	Cynasos	Clubbing	Edema	Lymphadenopathy	PR (min)	Systolic	Diastolic	RR (min)	Temperature	Abdomen	Central nervous system	Cardiovascular system	Respiratory system	Number of stones	Size of the largest stone (mm)	GB wall thickness (mm)	GB Volume (stage of GB)				Date of surgery	Name of surgery	Anaesthesia		
1	711958	60	F	05.01.16	09.01.16	P	P	NR	NR	NR	A	54	-	-	-	-	-	-	76	120	70	18	N	T	N	S1S2P	N	m	≥10	≥4	D	d	US	07.01.16	LC	GA	d/GE	>90
2	719318	53	F	16.01.16	02.02.16	P	P	DM	NR	NR	A	55	-	-	-	-	-	-	77	130	80	18	N	T	N	S1S2P	N	m	≥10	≥4	D	d	US	29.01.16	LC	GA	d/BD	>90
3	717129	35	M	03.02.16	07.02.16	P	P	NR	NR	NR	A	60	-	-	-	-	-	-	78	120	80	16	N	T	N	S1S2P	N	m	<10	<4	N	E	US	03.02.16	LC	GA	E	<90
4	717907	49	M	08.02.16	19.02.16	P	P	NR	NR	NR	A	66	-	-	-	-	-	-	80	130	70	18	N	T	N	S1S2P	N	m	<10	<4	N	E	US	10.02.16	LC	GA	E	<90
5	718031	40	F	08.02.16	20.02.16	P	P	DM	NR	NR	A	70	-	-	-	-	-	-	82	130	70	16	N	T	N	S1S2P	N	S	<10	<4	N	E	US	11.02.16	LC	GA	E	<90
6	718133	57	F	18.02.16	24.02.16	P	P	NR	NR	NR	A	65	-	-	-	-	-	-	84	120	70	16	N	T	N	S1S2P	N	m	<10	<4	N	E	US	20.02.16	LC	GA	E	<90
7	718332	50	M	22.02.16	30.02.16	P	P	NR	NR	NR	A	60	-	-	-	-	-	-	82	130	80	14	N	T	N	S1S2P	N	m	<10	<4	N	E	US	25.02.16	LC	GA	E	<90
8	724545	55	F	14.03.16	30.03.16	P	P	NR	NR	NR	A	66	-	-	-	-	-	-	72	120	70	16	N	T	N	S1S2P	N	m	<10	<4	N	E	US	16.03.16	LC	GA	E	<90
9	732467	33	F	05.04.16	03.05.16	P	P	NR	NR	NR	A	58	-	-	-	-	-	-	76	120	80	18	N	T	N	S1S2P	N	S	<10	<4	N	E	US	27.04.16	LC	GA	E	<90
10	734118	60	F	03.05.16	08.05.16	P	P	HTN	NR	NR	A	55	-	-	-	-	-	-	66	140	90	22	N	T	N	S1S2P	N	m	≥10	≥4	C	d	US	05.05.16	LC	GA	d/SS	>90
11	733881	47	F	02.05.16	11.05.16	P	P	NR	NR	NR	A	66	-	-	-	-	-	-	76	130	70	20	N	T	N	S1S2P	N	m	<10	<4	N	E	US	06.05.16	LC	GA	E	<90
12	735113	45	M	09.05.16	13.05.16	P	P	NR	NR	NR	A	70	-	-	-	-	-	-	80	120	70	20	N	T	N	S1S2P	N	S	<10	<4	N	E	US	11.05.16	LC	GA	E	<90
13	735933	60	F	10.05.16	16.05.16	P&V	P&V	DM	NR	NR	A	65	-	-	-	-	-	-	86	130	70	18	N	T	N	S1S2P	N	m	≥10	≥4	C	d	US	13.05.16	LC	GA	d/CD	>90
14	736424	55	M	17.05.16	25.05.16	P&V	P&V	HTN	NR	NR	A	65	-	-	-	-	-	-	82	120	70	20	N	T	N	S1S2P	N	m	≥10	≥4	C	d	US	18.05.16	L-O	GA	d/GE	>90
15	730801	55	M	18.06.16	28.06.16	P	P	DM	NR	NR	P	55	-	-	-	-	-	-	66	130	80	18	N	T	N	S1S2P	N	m	≥10	≥4	C	d	US	19.06.16	L-O	GA	d/BD	>90
16	730804	44	M	17.04.16	27.04.16	P	P	NR	NR	NR	A	60	-	-	-	-	-	-	72	120	70	16	N	T	N	S1S2P	N	S	<10	<4	N	E	US	18.04.16	LC	GA	E	<90
17	735113	59	M	11.05.16	13.05.16	P	P	NR	NR	NR	P	56	-	-	-	-	-	-	76	130	70	18	N	T	N	S1S2P	N	m	<10	<4	N	E	US	17.05.16	LC	GA	E	<90
18	748830	50	M	20.06.16	25.06.16	P	P	HTN	NR	NR	A	60	-	-	-	-	-	-	74	120	80	20	N	T	N	S1S2P	N	S	≥10	<4	N	E	US	22.06.16	LC	GA	E	<90
19	743555	50	F	20.06.16	25.06.16	P&V	P&V	NR	NR	NR	A	62	-	-	-	-	-	-	72	130	80	18	N	T	N	S1S2P	N	m	<10	<4	N	E	US	23.06.16	LC	GA	E	<90
20	745183	55	M	27.06.16	01.07.16	P	P	DM&HTN	NR	NR	A	66	-	-	-	-	-	-	76	120	70	20	N	T	N	S1S2P	N	S	≥10	≥4	C	d	US	25.06.16	LC	GA	d/CD	>90
21	745774	54	M	27.06.16	09.07.16	P	P	NR	NR	NR	A	55	-	-	-	-	-	-	68	130	80	18	N	T	N	S1S2P	N	m	<10	<4	N	d	US	29.06.16	LC	GA	d/SS	>90
22	745645	50	M	29.06.16	12.07.16	P&V	P&V	NR	NR	NR	P	50	-	-	-	-	-	-	66	120	70	20	N	T	N	S1S2P	N	S	≥10	<4	N	d	US	30.06.16	LC	GA	d/GE	>90
23	740522	50	M	01.07.16	08.07.16	P	P	NR	NR	NR	A	66	-	-	-	-	-	-	70	130	70	16	N	T	N	S1S2P	N	S	≥10	<4	N	E	US	05.07.16	LC	GA	E	<90
24	751546	51	F	20.01.16	13.08.16	P	P	NR	NR	NR	A	69	-	-	-	-	-	-	88	130	70	18	N	T	N	S1S2P	N	m	<10	<4	N	E	US	05.01.16	LC	GA	E	<90
25	755562	56	M	30.07.16	03.08.16	P	P	DM&HTN	NR	NR	A	75	-	-	-	-	-	-	56	140	80	22	N	T	N	S1S2P	N	m	≥10	≥4	D	d	US	01.01.16	LC	GA	d/GE	>90
26	755329	49	F	17.08.16	21.08.16	P&V	P&V	DM	NR	NR	A	59	-	-	-	-	-	-	84	130	80	18	N	T	N	S1S2P	N	m	≥10	<4	N	d	US	18.08.16	LC	GA	d/SS	>90
27	756319	48	M	22.08.16	27.08.16	P	P	HTN	NR	NR	A	66	-	-	-	-	-	-	80	140	90	20	N	T	N	S1S2P	N	S	≥10	≥4	D	d	US	24.08.16	LC	GA	d/GE	>90
28	757639	60	M	29.08.16	01.09.16	P&V	P&V&F	NR	NR	NR	A	75	-	-	-	-	-	-	96	130	70	22	N	T	N	S1S2P	N	m	<10	≥4	C	d	US	31.08.16	L-O	GA	d/SS&GE	>90
29	761723	60	F	19.09.16	24.09.16	P&V	P&V	NR	NR	NR	A	65	-	-	-	-	-	-	74	120	80	18	N	T	N	S1S2P	N	m	<10	<4	N	E	US	21.09.16	LC	GA	E	<90
30	762285	30	F	21.09.16	23.09.16	P&V	P&V	NR	NR	NR	A	52	-	-	-	-	-	-	82	130	70	20	N	T	N	S1S2P	N	S	≥10	<4	N	d	US	22.09.16	LC	GA	d/GE	>90
31	763267	28	F	22.09.16	25.09.16	P	P	NR	NR	NR	A	50	-	-	-	-	-	-	84	120	80	22	N	T	N	S1S2P	N	m	<10	<4	N	E	US	13.09.16	LC	GA	E	<90
32	763991	30	F	29.09.16	04.10.16	P&V	P&V	NR	NR	NR	A	46	-	-	-	-	-	-	76	120	80	16	N	T	N	S1S2P	N	m	<10	<4	N	E	US	29.09.16	LC	GA	E	<90
33	763995	60	F	18.09.16	05.10.16	P	P	DM	NR	NR	O	80	-	-	-	-	-	-	68	140	90	18	N	T	N	S1S2P	N	m	≥10	≥4	C	d	US	30.09.16	L-O	GA	d/BD	>90
34	781297	52	F	30.09.16	06.10.16	P&V	P&V	DM&HTN	NR	NR	A	66	-	-	-	-	-	-	78	130	70	20	N	T	N	S1S2P	N	m	≥10	<4	N	d	US	01.10.16	LC	GA	d/CD	>90

ANNEXURE III - MASTER CHART

Serial number	In patient number	Demographic data				Chief complaints	History				General physical examination																	USG abdomen				Clinical impression	Investigations	Operation details			Intra operative findings	Duration of surgery (minutes)
																		Vital signs																					
																			BP (mmHg)																			
		Age (Years)	Sex	Date of admission	Date of discharge		Present history	Past history	Personal history	Family history	Built and Nourishment	Weight (Kgs)	Pallor	Icterus	Cynasos	Clubbing	Edema	Lymphadenopathy	PR (min)	Systolic	Diastolic	RR (min)	Temperature	Abdomen	Central nervous system	Cardiovascular system	Respiratory system	Number of stones	Size of the largest stone (mm)	GB wall thickness (mm)	GB Volume (stage of GB)			Date of surgery	Name of surgery	Anaesthesia		
35	787562	30	F	09.02.16	15.02.16	P	P	NR	NR	NR	A	45	-	-	-	-	-	-	66	120	70	16	N	T	N	S1S2P	N	S	≥10	<4	N	d	US	12.02.16	LC	GA	d/GE	>90
36	756820	43	M	24.08.16	29.08.16	P&V	P&V	HTN	NR	NR	A	55	-	-	-	-	-	-	76	130	80	20	N	T	N	S1S2P	N	m	<10	≥4	N	d	US	25.08.16	LC	GA	g/GP	>90
37	782124	56	M	26.08.16	29.08.16	P	P	DM	NR	NR	A	80	-	-	-	-	-	-	88	140	70	28	N	T	N	S1S2P	N	S	≥10	<4	N	d	US	27.08.16	LC	GA	d/SS	>90
38	787130	32	M	06.02.16	10.02.16	P&V	P&V	NR	NR	NR	A	68	-	-	-	-	-	-	76	130	80	20	N	T	N	S1S2P	N	m	<10	<4	N	E	US	09.08.16	LC	GA	E	<90
39	787260	55	M	29.08.06	01.10.16	P	P	NR	NR	NR	A	66	-	-	-	-	-	-	82	140	90	16	N	T	N	S1S2P	N	S	<10	<4	N	E	US	30.08.16	LC	GA	E	<90
40	788121	35	F	01.09.16	05.09.16	P	P	NR	NR	NR	A	50	-	-	-	-	-	-	86	130	70	18	N	T	N	S1S2P	N	m	<10	≥4	C	d	US	02.09.16	LC	GA	g/GP	>90
41	711571	53	F	04.01.16	18.01.16	P	P	NR	NR	NR	A	65	-	-	-	-	-	-	74	120	80	20	N	T	N	S1S2P	N	m	<10	≥4	C	d	US	08.01.16	LC	GA	g/GP	>90
42	717830	39	F	07.02.16	11.07.16	P&V	P	NR	NR	NR	A	60	-	-	-	-	-	-	72	130	80	16	N	T	N	S1S2P	N	S	<10	<4	N	E	US	08.02.16	LC	GA	E	<90
43	718367	48	M	10.02.16	18.02.16	P	P	DM	NR	NR	A	65	-	-	-	-	-	-	76	120	70	18	N	T	N	S1S2P	N	m	<10	<4	N	E	US	15.02.16	LC	GA	E	<90
44	719277	56	F	16.02.16	27.02.16	P&V	P	HTN	NR	NR	A	70	-	-	-	-	-	-	80	130	80	20	N	T	N	S1S2P	N	m	<10	<4	N	E	US	19.02.16	LC	GA	E	<90
45	723605	38	M	09.03.16	19.03.16	P	P	NR	NR	NR	A	72	-	-	-	-	-	-	82	120	70	18	N	T	N	S1S2P	N	m	<10	<4	N	E	US	11.03.16	LC	GA	E	<90
46	724969	20	F	16.03.16	02.04.16	P	P	NR	NR	NR	A	76	-	-	-	-	-	-	86	130	80	20	N	T	N	S1S2P	N	S	<10	<4	N	E	US	25.03.16	LC	GA	E	<90
47	734082	56	M	03.05.16	14.05.16	P	P	DM	NR	NR	A	65	-	-	-	-	-	-	76	120	80	16	N	T	N	S1S2P	N	m	≥10	<4	N	d	US	05.05.16	L-O	GA	d/GE	>90
48	737195	44	F	18.05.16	02.06.16	P	P	HTN	NR	NR	A	68	-	-	-	-	-	-	66	130	70	14	N	T	N	S1S2P	N	m	<10	<4	N	E	US	23.05.16	LC	GA	E	<90
49	737205	35	M	21.06.16	27.06.16	P&V	P&V	NR	NR	NR	A	55	-	-	-	-	-	-	72	130	80	18	N	T	N	S1S2P	N	S	<10	<4	N	E	US	23.06.16	LC	GA	E	<90
50	745720	55	M	30.06.16	03.07.16	P	P	DM	NR	NR	A	60	-	-	-	-	-	-	76	140	90	20	N	T	N	S1S2P	N	m	≥10	≥4	C	d	US	01.07.16	L-O	GA	d/BD	>90
51	746902	55	F	22.06.16	28.06.16	P	P	DM&HTN	NR	NR	A	60	-	-	-	-	-	-	82	130	70	20	N	T	NR	S1S2P	NR	S	<10	<4	N	E	US	25.06.16	LC	GA	E	<90
52	756932	24	M	25.08.16	29.08.16	P	P	NR	NR	NR	A	64	-	-	-	-	-	-	86	140	90	18	N	T	NR	S1S2P	NR	m	<10	<4	N	E	US	26.08.16	LC	GA	E	<90
53	767179	58	F	17.10.16	20.10.16	P	P	NR	NR	NR	A	66	-	-	-	-	-	-	84	130	70	20	N	T	NR	S1S2P	NR	m	≥10	≥4	C	E	US	18.10.16	LC	GA	E	<90
54	773852	39	M	22.11.16	26.11.16	P	P	NR	NR	NR	A	60	-	-	-	-	-	-	82	120	80	22	N	T	NR	S1S2P	NR	m	<10	≥4	C	d	US	24.11.16	LC	GA	d/SS	>90
55	775766	52	M	03.12.16	09.12.16	P	P	HTN	NR	NR	A	65	-	-	-	-	-	-	86	130	86	16	N	T	NR	S1S2P	NR	S	≥10	<4	N	E	US	05.12.16	LC	GA	E	<90
56	776667	43	F	08.12.16	10.12.16	P	P	NR	NR	NR	A	60	-	-	-	-	-	-	84	120	70	22	N	T	NR	S1S2P	NR	m	<10	<4	N	E	US	09.12.16	LC	GA	E	<90
57	776812	45	F	09.12.16	15.12.16	P	P	NR	NR	NR	A	56	-	-	-	-	-	-	70	140	80	20	N	T	NR	S1S2P	NR	m	<10	≥4	C	d	US	12.02.16	LC	GA	d/SS	>90
58	777002	60	M	11.12.16	18.12.16	P&V	P&V	DM	NR	NR	A	66	-	-	-	-	-	-	76	130	70	18	N	T	NR	S1S2P	NR	m	≥10	≥4	N	d	US	12.12.16	L-O	GA	d/SS/GP	>90
59	778112	56	M	11.12.16	14.12.16	P	P	NR	NR	NR	A	60	-	-	-	-	-	-	72	120	80	16	N	T	NR	S1S2P	NR	m	<10	<4	N	E	US	13.12.16	LC	GA	E	<90
60	783112	40	M	12.12.16	16.12.16	P	P	NR	NR	NR	A	60	-	-	-	-	-	-	76	130	70	18	N	T	NR	S1S2P	NR	S	<10	<4	N	E	US	14.12.16	LC	GA	E	<90

Introduction



Objectives

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Bibliography

Annexure-I

Annexure-II

Annexure-III

Annexure-IV