"TO VALIDATE A SCORING SYSTEM TO PREDICT DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY: A ONE-YEAR CROSS-SECTIONAL STUDY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC, BELAGAVI"

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This is to certify that the thesis **"TO VALIDATE A SCORING SYSTEM TO PREDICT DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY: A ONE-YEAR CROSS-SECTIONAL STUDY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC, BELAGAVI"** is a bonafide research work done by **REG NO:BH0116004.**

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LIST OF ABBREVIATIONS

List of Abbreviations	
BMI	Body mass index
ERCP	Endoscopic retrograde cholangiopancreatography
GBC	Gallbladder cancer
LC	Laparoscopic cholecystectomy
TLC	Total leucocyte count
USG	Ultrasonography
XGC	Xanthogranulomatous cholecystitis
GB	Gallbladder
CT	Computed tomography
CI	Confidence interval

ABSTRACT

BACKGROUND AND OBJECTIVES: Laparoscopic cholecystectomy is one of the most common surgical procedures performed in recent times in surgical practice. Various patient and disease related factors can be associated with difficult laparoscopic cholecystectomy. Identifying these patients in the preoperative period, may aid the surgeon in effective risk communication and preoperative preparation to deal with the situation. There are various structured scoring systems in use across the globe, but their utility on Indian subjects is yet to be studied extensively. The current study has attempted to validate a new scoring system, for its utility in risk stratification of people undergoing laparoscopic cholecystectomy.

MATERIALS & METHODS: The current prospective observational study was conducted in the department of General Surgery at KLES Dr. Prabhakar Kore Hospital and Medical Research centre, Jawaharlal Nehru Medical College, KAHER, Belagavi. All the eligible patients undergoing laparoscopic cholecystectomy between January 2017 to December 2017 were considered as study population. The study had excluded people with jaundice, cholangitis, raised alkaline phosphatase, dilated common bile duct, common bile duct stones, empyema of gall bladder, acalculous cholecystitis, LC done along with common bile duct exploration, LC with other intervention at the same setting, patients with anesthetic complications and patients with co-morbid diseases were excluded from the study.

The scoring system used has considered age, gender, history of hospitalization, BMI, abdominal scar, palpable gall bladder and three ultrasonographic features (thick gallbladder, pericholecystic collection and impacted stone) for risk stratification. Sensitivity, specificity and predictive values of the preoperative scoring system were

calculated. p value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

RESULTS: A total 50 people were included in the final analysis., with the mean age of 43.36 ± 9.84 years. Females constituted 82% of the study population. Among the study population 12(24%) people had difficult intraoperative outcome. The proportion of difficult intraoperative outcome was much higher among males, as compared to females. The other factors associated with intraoperative difficulty were prior hospitalization and impacted stone. Age of the person, presence of abdominal scar, palpable gall bladder, thick gallbladder, pericholecystic collection and BMI had no association with difficult intraoperative outcome in study population. Among the 36 people with preoperative score between 0 to 5, 3(8.3%) people had difficult intraoperative outcome. Among the 14 people with preoperative score between 6 to 10, 9(64.3%) people had difficult intraoperative outcome. The difference between preoperative score and intraoperative outcome was statistically significant, (p value<0.001). To predict Intra operative difficulty, pre operative score had sensitivity of 75.00% (95% CI 42.81% to 94.51%). The specificity was 86.84% (95 CI 71.91% to 95.59%), false positive rate was 13.16% (95 CI 4.41% to 28.09%), false negative rate was 25.00% (95 CI 5.49% to 57.19%), positive predictive value was 64.29% (95 CI 35.14% to 87.24%), negative predictive value was 91.67% (95 CI 77.53% to 98.25%), and the total diagnostic accuracy was 84.00% (95 CI 70.89% to 92.83%).

CONCLUSION: The current scoring system had a sensitivity of 75% and specificity of 86.84% in predicting difficult laparoscopic cholecystectomy, which makes it a reasonably good scoring system for preoperative risk stratification of subjects.

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INTRODUCTION

Gallstones constitute a significant health problem globally. About 10- 15% of the adult population globally are affected by gallstones in a year.[1, 2] Gallstones is one of the leading causes of morbidity due to gastrointestinal causes, which makes it the leading cause for gastrointestinal causes of hospital admission.[3] Gallstones per se increase the risk of development of cancer.[4, 5] Complications like gallstone related pancreatitis increases the morbidity and mortality burden caused due to gallstones.[6] The risk factors for the gallstone disease are categorized into modifiable and non-modifiable. Non-modifiable risk factors cannot be altered like family history of gallstone disease, genetic predilection, ethnic background, female sex and age. Modifiable factors are obesity, metabolic syndrome, diabetes mellitus, dyslipidemia, reduced physical activity, rapid weight loss, diet. These modifiable risk factors are mostly lifestyle oriented. In developing and developed countries, change in lifestyle of people poses a greater risk of gallstone disease. In India, as part of development, there is an increased lifestyle change among people thereby making them prone to the development of gallstones.

The number of surgical procedures for cholelithiasis has risen markedly in developed countries since 1950.[7] The introduction of laparoscopic cholecystectomy(LC) in 1989 further increased the cholecystectomy rate.[7-9] The change in practice emanated from the laparoscopic surgical approach, which represented a less invasive, more cosmetically acceptable operation while providing a lower surgical risk compared to the then conventional or “open” procedure. This likely resulted in more surgeries being done in patients previously thought to be too high a risk, or in those with minimal symptoms. Although there is undoubtedly an element of overuse,

cholecystectomy is now the most common elective abdominal surgery performed in the United states.

Laparoscopic cholecystectomy has become the procedure of choice for the treatment of symptomatic gallbladder disease.[10] It has been observed that surgeons encountered difficulty while doing LC when there were dense adhesions at Calot's triangle, fibrotic and contracted gallbladder, acutely inflamed or gangrenous gall bladder and cholecystoenteric fistula etc.[11] There are many risk factors which make laparoscopic surgery difficult like old age, male sex, attacks of acute cholecystitis with fever and leucocytosis, obesity, previous abdominal surgery, clinical signs of acute cholecystitis, and certain ultrasonographic findings i.e. thickened gall bladder wall, distended gall bladder, pericholecystic fluid collection, impacted stone etc.[12]

Laparoscopic cholecystectomy is the safe and effective treatment for patients with symptomatic gallstones and it is the treatment of choice for cholelithiasis. The advantages of laparoscopic cholecystectomy over open cholecystectomy are minimal post operative pain, shorter hospital stay, better cosmetic outcome and earlier recovery. In some cases, laparoscopic cholecystectomy may pose undue difficulties due to ductal and vascular anomalies or distorted anatomy following acute or chronic inflammation and these patients require conversion to open cholecystectomy. This conversion to open cholecystectomy is an attempt to avoid complications. A preoperative scoring system based on history, clinical examination and sonological findings can be used to predict the intraoperative difficulties. This scoring system helps in deciding the surgical approach, counseling the patient and thereby reducing the morbidity, complications, rate of conversion to open cholecystectomy and cost of the overall treatment.

Different scoring methodologies have been suggested from time to time using different criteria, further adding to the controversy. The following study was planned keeping in mind this basic knowledge of the uncertainties encountered on the operating table due to certain 'difficult' situations that arise during laparoscopic cholecystectomy. Even though studies were done for developing a scoring system, there is a lack of adequate number of studies on Indian population. There is a need for studies to validate a scoring system based on the Indian population and Indian hospital system. Hence, this study was undertaken to validate a scoring system to predict difficult laparoscopic cholecystectomy.

OBJECTIVE

- To validate a scoring system to predict difficult laparoscopic cholecystectomy.

REVIEW OF LITERATURE

ANATOMY OF GALLBLADDER AND BILIARY SYSTEM:

Gallbladder is situated beneath the liver where the bile is stored and concentrated before releasing into the small intestine.[13] It sits below the right lobe of the liver. It is grey blue in color. When fully distended, it measures approximately 7 to 10 centimeters (2.8 to 3.9 inches) in length and 4 centimeters (1.6 inches) in diameter.[14] The capacity of gallbladder is 50 milli-liters.[13] The pear shaped gallbladder's tip opens into the cystic duct.[15] Three parts of the gallbladder are the fundus, body and neck. The rounded base of gall bladder facing the abdominal wall is fundus. The part that lies in between fundus and neck is the body of the gallbladder. Its tapering neck is in continuation with the cystic duct and forms part of the biliary tree.[13] The gallbladder fossa, against which the fundus and body of the gallbladder lie, is found beneath the junction of hepatic segments IVB and V.[16] The cystic duct and common hepatic duct unite and form common bile duct. At the junction of the neck of the gallbladder and the cystic duct, there is an out-pouching of the gallbladder wall forming a mucosal fold known as 'Hartmann's pouch.'[13]

The gallbladder varies in size, shape and position between different people.[13] Rarely, two or even three gallbladders may coexist, either as separate bladders draining into the cystic duct, or sharing a common branch that drains into the cystic duct. Additionally, the gallbladder may fail to form at all. Gallbladders with two lobes separated by a septum may also exist. These abnormalities are not likely to affect function and are generally asymptomatic.[17] The location of the gallbladder in relation to the liver may also vary, with documented variants including gallbladders found within[18] above, on the left side of, behind, and detached or suspended from the liver.

Such variants are very rare, from 1886 to 1998, only 110 cases of left-lying liver, or less than one per year, were reported in scientific literature.[13, 19, 20] An anatomical variation can occur, known as a Phrygian cap, which is an innocuous fold in the fundus, named after its resemblance to the Phrygian cap.[21]

BILIARY TRACT:

The biliary tract is also called as biliary tree or biliary system. It refers to the liver, bile ducts and gallbladder. They function to produce, store and secrete bile. Bile consists of water, electrolytes, bile acids, cholesterol, phospholipids and conjugated bilirubin. Some components are synthesized by hepatocytes (liver cells), the rest are extracted from the blood by the liver. The biliary tract is the path the secreted bile must travel in order to reach the first part of the duodenum. A structure common to most members of the mammal family, the biliary tract is often referred to as a tree because it begins with many small branches which end in the common bile duct, sometimes referred to as the trunk of the biliary tree. The duct, the branches of the hepatic artery and portal vein form the central axis of portal triad. Bile flows in the direction opposite to that of the blood present in the other two channels.

The tract is as follows:

- Bile canaliculi >> Canals of Hering >> intrahepatic bile ductule (in portal tracts / triads) >> interlobular bile ducts >> left and right hepatic ducts.
- These merge to form the common hepatic duct.
- This exits the liver and joins with the cystic duct from gall bladder.
- Together, these form the common bile duct which joins the pancreatic duct.
- These pass through the ampulla of Vater and enter the duodenum.

PHYSIOLOGY OF BILIARY SYSTEM:

The main function of gallbladder is to store bile, which is needed for the digestion of fat rich foods. Produced by the liver, bile flows through small vessels into the larger hepatic ducts and ultimately through the cystic duct (parts of the biliary tree) into the gallbladder, where it is stored. At any one time, 30 to 60 milliliters of bile is stored within the gallbladder.[22] A fat rich meal in the gastrointestinal system stimulates enteroendocrine cells of duodenum and jejunum to secrete cholecystokinin. It acts on the gallbladder and contracts it rhythmically. This contraction makes it to release its content into the common bile duct. Eventually the bile drains into the duodenum through the ampulla of Vater. The emulsification of the fat in the duodenal content is done by bile. It also acts as a medium through which the metabolic end product of hemoglobin breakdown, the bilirubin is excreted out.[22] The bile that is secreted by liver and stored in the gallbladder is not the same as the bile that is secreted by the gallbladder. During gallbladder storage of bile, it is concentrated by removal of some water and electrolytes. This is through active transport of sodium ions across the epithelium of the gallbladder, which creates an osmotic pressure that also causes water and other electrolytes such as chloride to be reabsorbed.[22]

RISK FACTORS:

There are various diseases that are caused due to malfunctioning of gallbladder and the biliary system. A few of them are gallstones, cholecystitis, cholangitis, carcinoma of gallbladder. Various physiological and anatomical conditions predispose an individual to the development of these diseases. The factors that pose a higher risk of development of these diseases in an individual called as risk factors. The various risk factors for development of gall bladder diseases are being

female, being age 40 or older, being a native American, being a Mexican-American, being overweight or obese, being sedentary, being pregnant, eating a high-fat diet, eating a high-cholesterol diet, eating a low-fibre diet, having a family history of gallstones, having diabetes, losing weight very quickly, taking medications that contain oestrogen, such as oral contraceptives or hormone therapy drugs and having liver disease. A famous quote of the risk factors is "Fat Fertile Forty Female". These risk factors are mostly because of lifestyle. They are almost always modifiable and early identification of these risk factors gives a chance for correction and prevention of gallbladder diseases. The most common reason any disease in the biliary tract is caused, is due to obstruction of the biliary tree. The obstruction is always due to gallstones or stricture. So, any factor that predisposes to the risk of gallstones also indirectly increases the risk of other biliary pathologies. A large number of opportunistic organisms like anaerobic organisms such as Clorstridium and Bacteroides (especially in the elderly and those who have undergone previous surgery of the biliary system) can infect the obstructed path and cause cholangitis. Parasites, which may infect the liver and bile ducts, may cause cholangitis, these include roundworm and liver flukes.

Burden of Gall stone disease in India:

Gallstones are hardened deposit of bile that collects in the gallbladder. They vary in size and shape from as small as a grain of sand to as large as a golf ball.[23] Imbalance in chemical constituents of bile results in precipitation and stone formation. Gallstones have been known to humans since the time immemorial. Egyptian mummies dating back to 1000BC have been found with gallstones.[24, 25] Gallstones are common in all regions of the world. The incidence of the disease increases with age.[26]

About a quarter of women above the age of 60yrs develop the disease.[27] Even after diagnosis most patients don't develop any symptoms. Only 10% become symptomatic after five years and 20% after 20 years of diagnosis.[28, 29] Thus the average risk of developing symptomatic disease is low, and approaches 2.0-2.6%/year.[29] Composition of gallstones is mainly cholesterol, calcium salts and bilirubin with small quantity of protein and other substances.[30, 31] There are different types of gallstones. Pure cholesterol stones contain atleast 90% cholesterol, brown or black pigment stones contains 90% bilirubin and mixed stones contain varying proportions of cholesterol, bilirubin and other substances like calcium palmitate, calcium carbonate and phosphate.

Many risk factors for cholesterol gallstone formation are not modifiable such as ethnic background, increasing age, female gender and family history or genetics. Conversely, the modifiable risks for cholesterol gallstones are obesity, rapid weight loss and a sedentary lifestyle. The rising epidemic of obesity and the metabolic syndrome predicts an escalation of cholesterol gallstone frequency.

Gallstones constitute a significant health problem in developed societies, affecting 10% to 15% of the adult population. [1, 2, 32, 33] With an estimated 1.8 million ambulatory care visits each year, gallstone disease is a leading cause for hospital admissions related to gastrointestinal problems.[3]

The number of surgical procedures for cholelithiasis has risen markedly in the developed countries since 1950.[7] The introduction of laparoscopic cholecystectomy in 1989 further increased the cholecystectomy rate.[7, 9] The change in practice emanated from the laparoscopic surgical approach, which represented a less invasive, more cosmetically acceptable operation while providing a lower surgical risk compared to the then conventional or "open" procedure. This likely resulted in more surgeries

being done in patients previously thought to be too high a risk, or in those with minimal symptoms. Although there is undoubtedly an element of overuse, cholecystectomy is now the most common elective abdominal surgery performed.[34] There have been significant paradigm shifts in the treatment of acute cholecystitis and management of complex acute biliary problems in the past few years. These changes include earlier surgery and index admission cholecystectomy.[35-37] While laparoscopic cholecystectomy has become the approach of choice for elective cholecystectomy, 48.7% of acute cholecystitis are nowadays still operated with the open technique. Currently, most cholecystectomies are performed laparoscopically. The conversion from LC to open cholecystectomy results in a significant change in outcome for the patient because of the higher rate of postoperative complications and the longer hospital stay.[38] Conversion rate and complications associated with LC depend on the experience of the surgeon and the degree of difficulty faced during surgery, which can be affected by factors such as a history of previous abdominal surgery, recurrent attacks of cholecystitis, acute cholecystitis, advanced age of the patient, or male gender.[38-40] There are many studies in the literature concerning the conversion rate for LC and the reasons for conversion. According to published studies in recent years, the conversion rates vary widely (2.6% to 7.7%).[41-47]

In India till date, there are several reports describing North-South differences in the type of gallstones,[48-51] the North being predominantly of the cholesterol type and South of the pigment variety. While the characteristics of individuals with gallstones from the North have been identified, similar reports are not available from the South. Northern India has one of the highest reported incidence of gallbladder cancer (GBC) in the world.[52] The highest incidence rates of GBC in the world are

21.5/100 000 in females in Delhi, 13.8/100 000 in Karachi and 12.9 /100 000 in Quito.[52] Gallstones (GST) were said to play a major role.[53]

CHOLECYSTECTOMY INDICATIONS:

Cholecystectomy is the surgical removal of the gallbladder. Cholecystectomy is a common treatment of symptomatic gallstones and other gallbladder conditions. There are various indications for performing cholecystectomy.

Recurrent biliary colic:

It is also known as gallbladder attack or gallstone attack. Gallstone temporarily blocking the bile duct causes sudden colic pain. The pain is usually located in the right upper quadrant of the abdomen and might radiate to shoulders.[54] The pain usually lasts for a few hours and mostly occurs after a fat rich meal. Repeated attacks and night attacks are common. The risk factors for biliary colic is similar to risk factors for gallstones. Age, female sex, family history, race, pregnancy, parity, obesity, birth control, diabetes mellitus, cirrhosis, prolonged fasting, rapid weight loss, total parenteral nutrition, ileal disease and impaired gallbladder emptying are known risk factors.[55] Patients that have gallstones and biliary colic are at increased risk for complications, including cholecystitis.[56] Complications from gallstone disease are 0.3% per year and therefore prophylactic cholecystectomy is rarely indicated, except part of a special population that includes porcelain gallbladder, individuals eligible for organ transplant, diabetics and those with sickle cell anemia.[57]

Acute cholecystitis:

It is inflammation of the gallbladder. Symptoms include right upper abdominal pain, nausea, vomiting, and occasionally fever.[58] Biliary colic often precedes cholecystitis. The pain lasts longer in cholecystitis. Without adequate treatment, it tends to recur. Complications of acute cholecystitis include gallstone

pancreatitis, common bile duct stones, or inflammation of the common bile duct. Occasionally acute cholecystitis occurs as a result of vasculitis, chemotherapy, or during recovery from major trauma or burns.[59] Treatment is usually with laparoscopic gallbladder removal, within 24 hours if possible.[60]

Chronic cholecystitis:

Chronic cholecystitis occurs after repeated episodes of acute cholecystitis and is almost always due to gallstones.[61] Chronic cholecystitis may be asymptomatic, may present as a more severe case of acute cholecystitis, or may lead to a number of complications such as gangrene, perforation, or fistula formation.[61] Xanthogranulomatous cholecystitis (XGC) is a rare form of chronic cholecystitis which mimics gallbladder cancer although it is not cancerous.[62, 63]

Cholangitis:

Cholangitis also known as ascending cholangitis is the inflammation of the bile duct. It is usually caused by bacteria ascending from duodenum. It tends to occur if the bile duct is already partially obstructed by gallstones. It can be life threatening, hence regarded as a medical emergency. Characteristic symptoms include yellow discoloration of the skin or whites of the eyes, fever, abdominal pain, and in severe cases, low blood pressure and confusion. Most common cause of obstruction is gallstones. 10–30% of cases, however, are due to other causes such as benign stricturing (narrowing of the bile duct without an underlying tumor), postoperative damage or an altered structure of the bile ducts such as narrowing at the site of an anastomosis (surgical connection), various tumors (cancer of the bile duct, gallbladder cancer, cancer of the ampulla of Vater, pancreatic cancer, cancer of

the duodenum), anaerobic organisms such as Clostridium and Bacteroides (especially in the elderly and those who have undergone previous surgery of the biliary system).

Gall stone pancreatitis:

Gallstone pancreatitis is a type of pancreatitis resulting from the obstruction of pancreatic duct by gallstones. The patient presents with severe epigastric pain, nausea, vomiting, loss of appetite, chills, hemodynamic instability leading to shock. It most often resembles biliary colic.

Recurrent biliary colic in an individual is the most common reason for performing cholecystectomy. Interruption of normal flow of bile results in cholecystitis or inflammation of gallbladder which is also an indication for cholecystectomy.[64] Most of the cases of acute cholecystitis are caused by impacted gallstones leading to drainage block in gallbladder.[65] People with repeat episodes of acute cholecystitis can develop chronic cholecystitis from changes in the normal anatomy of the gallbladder.[65] This can also be an indication for cholecystectomy if the person has ongoing pain. Cholangitis and gallstone pancreatitis are rarer and more serious complications from gallstone disease. Both can occur if gallstones leave the gallbladder, pass through the cystic duct, and get stuck in the common bile duct. The common bile duct drains the liver and pancreas, and a blockage there can lead to inflammation and infection in both the pancreas and biliary system. While cholecystectomy is not usually the immediate treatment choice for either of these conditions, it is often recommended to prevent repeat episodes from additional by gallstones getting stuck.[64] Carcinoma of the gallbladder is a rare indication for cholecystectomy. In cases where cancer is suspected, the open technique for cholecystectomy is usually performed.

EVOLUTION OF CHOLECYSTECTOMY:

Carl Langenbuch performed the first successful cholecystectomy at the Lazarus hospital in Berlin on July 15, 1882.[66] Erich Mühe performed the first laparoscopic cholecystectomy on September 12, 1985 in Böblingen, Germany.[67] Mühe was inspired to develop a technique for laparoscopic cholecystectomy by the first laparoscopic appendectomy, performed by gynecologist Kurt Semm in 1980.[68] He subsequently designed an optical laparoscope with a working channel large enough to fit a distended gallbladder. Philippe Mouret performed laparoscopic cholecystectomy on March 17, 1987 in Lyon, France.[68] His technique was rapidly adopted and improved in France. It was subsequently introduced to the rest of the world over the next three years. Driven by popularity among patients, the laparoscopic technique became preferred over open surgery and noninvasive treatments for gallstones. By 2013, laparoscopic cholecystectomy had replaced open cholecystectomy as the first-choice of treatment for people with uncomplicated gallstones and acute cholecystitis.[69] By 2014 laparoscopic cholecystectomy had become the gold standard for the treatment of symptomatic gallstones.[70, 71]

Differences in primary outcomes like mortality and complication proportions (particularly bile duct injuries) are important reasons to choose one of the two operative techniques. When these primary outcomes show no significant difference, then secondary outcomes like non-severe complications, pulmonary outcomes, differences in health status related quality-of-life, hospital stay, and differences in cost-effectiveness analysis should help decide which technique is superior.

LAPAROSCOPIC CHOLECYSTECTOMY:

There are various methods available for cholecystectomy. The methods are conventional open cholecystectomy, single incision cholecystectomy, natural orifice transluminal cholecystectomy and laparoscopic cholecystectomy. The most commonly and widely used is laparoscopic cholecystectomy. The procedure of laparoscopic cholecystectomy starts with making incision for ports. 1.5 to 2 cm small incisions are made in the abdominal wall. Through these ports and laparoscope are inserted. Abdomen is entered, and carbon dioxide insufflation is done up to a maximum of 15mmhg. The patient is put on reverse trendelenburg position. The exploration is done and fundus of the gallbladder is identified. Triangle of Calot is identified. The cystic artery and duct are identified, clipped and transected. Clipping and division of cystic structures are done. Then the gallbladder is mobilized and removed. The gallbladder fossa should be finally inspected for any bleeders. The ports are removed, and abdominal closure should be done. At any point in this procedure there can be adhesion between the structures, aberrant blood vessels and various other factors that can make the laparoscopic procedure difficult. A difficult laparoscopic cholecystectomy must be converted to an open procedure.

Advantages and disadvantages of laparoscopic cholecystectomy:

The laparoscopic procedure has the advantage of shorter stay in hospital, faster recovery period, reduced post-operative recovery time, improved cosmetic outcome, minor pain and ileus, non-muscle splitting incision and less blood loss, low rate of wound complications. Very low operative mortality from laparoscopic cholecystectomy. A serious complication of laparoscopic cholecystectomy is biliary injury. Bile duct strictures and biliary leakages are severe complications after

cholecystectomy procedure. Biliary leakages are considered an early complication and biliary strictures are a late complication. It was observed that the rate of clinically-relevant bile leaks after conventional open cholecystectomy ranges was between 0.1% and 0.5%[72, 73]. Biliary leakages have increased after the development of laparoscopic cholecystectomy by up to 3%.[74-76]There is a report where the incidence of biliary tract injuries was found to be up to 0.6% for laparoscopic versus 0.1% for open cholecystectomy[77]. The injury can be identified intraoperatively and corrected, or they manifest in the early postoperative period. Laparoscopic procedure may not be available at all hospitals, hence poor accessibility. With high-tech instruments the procedure is quite expensive, and the patients may not be able to afford. Laparoscopy is technically demanding and need expertise with experience.

Difficult laparoscopic cholecystectomy:

Laparoscopic cholecystectomy is one of the most commonly performed surgeries world over and is undergoing regular amendments with growing technology in order to make it safer, cosmetically acceptable, and cost effective. Age is a risk factor for difficult gallbladder surgery.[38] In studies done worldwide, male sex has been described to be associated with difficult LC. Clinically palpable gallbladder was found to be predictor of difficult LC.[78] There is a linear correlation between previous history of hospitalization due to acute attacks of cholecystitis and the difficulty level of LC[79]. Each attack of cholecystitis increases the gallbladder wall thickness and the gallbladder becomes scarred and fibrosed. It further increases the adhesions at the Calot's triangle and between gallbladder and fossa. While performing LC, stone impacted at the neck of gallbladder poses some technical problems, because of distension of gallbladder, as is with thick gallbladder wall. It is difficult to grasp the

gallbladder neck to allow adequate retraction to perform dissection at the Calot's triangle.[80] Obese patients may have a difficult laparoscopic surgery due to various factors.[81] Port placement in obese patient takes longer time due to the thick abdominal wall. Dissection at the Calot's triangle is also technically difficult due to the obscure anatomy because of excessive intraperitoneal fat and difficulty in the manipulation of instruments through an excessively thick abdominal wall. Pericholecystic collection was found to be a predictor of difficult LC.[82] Upper abdominal scars (indicators of previous upper abdominal surgeries) may cause the formation of intraperitoneal adhesions that may lead to increased probability of injury and bleeding while placement of umbilical port.[83] Increased GB wall thickness is associated with difficult dissection of the gallbladder from its bed.[84] Presence of a thick gallbladder wall may make grasping and manipulation of gallbladder difficult. This makes the dissection at the Calot's triangle and the gallbladder bed to be difficult and limits the extent of anatomical definition. Adhesions are an important cause for difficulty encountered in LC and these cannot be assessed on routine ultrasonography (USG) done for cholelithiasis. One more factor is the presence of anatomical variation, making the identification of structures, a demanding task.[85]

PREDICTORS OF DIFFICULT LAPROSCOPIC CHOLECYSTECTOMY:

Lot of scoring systems have been developed in past to predict preoperatively, intraoperatively difficult LC and to predict conversion. Various parameters were considered for scoring, history, clinical and sonological findings, previous history of hospitalization, clinically palpable gallbladder, impacted gallbladder stone, pericholecystic collection, and abdominal scar due to previous abdominal surgery. Intraoperative factors are appearance and adhesion of gallbladder, distension or

contracture degree of gallbladder, ease in access, local or septic complications, and time required for cystic artery and duct identification. Age greater than 40 years and being diabetic were also the risk factors for conversion to open surgery. Factors contributing to conversion included male sex, age group between 31 to 40 years, over weight and history of biliary pain within last two to four months, ultrasonography findings of multiple calculi and gallbladder wall thickness of more than 3 mm. Intraoperative gallbladder perforation with spillage of its contents in abdominal cavity and dense adhesions with difficult anatomy resulted in higher conversion rates. Surgery performed by surgeons in learning phase of laparoscopic surgery was more prone to conversion.[86-90]

SCORING METHODS:

Lal et al[89] developed a scoring system to preoperatively predict the conversion from laparoscopic cholecystectomy to open. In this scoring system they considered four ultrasonographic parameters. On the day of surgery ultrasonography of abdomen was performed for all study participants(n=73). The parameters considered were, namely gallbladder wall thickness (more than 4-mm thick gallbladder wall thickness was predicted to be a difficult laparoscopic cholecystectomy); gallstone mobility (gallstone impacted at the neck of the gallbladder was taken to be a difficult laparoscopic cholecystectomy); gallbladder size, that is whether gallbladder is contracted or not (contracted gallbladder was predicted to be a difficult laparoscopic cholecystectomy); common bile duct diameter (CBD size more than 6 mm was predicted to be a difficult laparoscopic cholecystectomy).

Nidhoni et al[90] developed a scoring system to predict difficult laparoscopic cholecystectomy based on clinico-radiological assessments. Four parameters number

of attacks, total leucocyte count, gall bladder wall thickness and pericholecystic fluid collection on ultrasonography of each patient were recorded preoperatively and compared with intraoperative findings. Intraoperative findings were divided into easy laparoscopic cholecystectomy, difficult laparoscopic cholecystectomy and conversion to open cholecystectomy. Difficult laparoscopic cholecystectomy was judged based on presence of at least one of the following i.e. dense adhesions between gallbladder and surrounding, dense adhesions between gallbladder and liver bed and frozen Calot's triangle. 180 study participants were assessed with the above scoring system. The sensitivity, specificity, positive predictive value and negative predictive value of number of previous attacks of cholecystitis >2 in predicting difficult laparoscopic cholecystectomy are 38.88%, 96.82%, 84% and 78.70% respectively. It was found that patients with TLC >11000/cu mm had significant high rates of difficulty. It was found that patients with peri cholecystic collection had significant high rates of difficulty.

Ahmed et al[86] developed a new scoring system to identify intraoperative predictors of difficult LC. The scoring system included five aspects. Appearance and adhesion of gallbladder, distension or contracture degree of GB, ease in access, local or septic complications, and time required for cystic artery and duct identification. Each parameter was given a specific score. The specific intraoperative parameters considered were gallbladder appearance: No adhesions- 0, Adhesions < 50% of GB - 1, Adhesions burying GB- 3. Maximum score was 3. Distended gallbladder or contracted shrivelled GB was given score 1, Unable to grasp with atraumatic laparoscopic forceps-1, Stone ≥1 cm impacted in Hartmann's Pouch -1. BMI >30- 1, adhesions previous surgery limiting access- 1, bile or pus outside GB- 1, Time to identify cystic artery and duct >90 minutes -1. The scoring system ranges from 0 to

10, classified as score of less than 2 (easy), 2 to 4 (moderate), 5 to 7 (very difficult), and 8 to 10 (extreme).

Global studies:

Ahmed N et al [86] (2018) did a study to evaluate an intraoperative scoring system to predict difficult LC and conversion to open surgery. The study was done in Shalimar hospital with 120 patients belonging to the age of above 18 yrs. Intraoperatively they were evaluated using the new scoring system. The scoring system had five aspects of assessment: appearance and adhesion of gallbladder (GB), distension or contracture degree of GB, ease in access, local or septic complications, and time required for cystic artery and duct identification. Scoring ranged from 0 to 10 and classified as easy for less than 2 score, 2 to 4 as moderate, 5-7 as very difficult and 8-10 as extreme. In this study the conversion rate to open surgery was 6.7%. The overall mean intra-operative scores was 3.52 ± 2.23; however significant difference was seen in mean operative score of converted to open and those not converted to open (8.00 ± 0.92 Vs. 3.20 V 1.92; p-value = 0.001). Among eight cases converted to open, three (37.5%) were in very difficult category while five (62.5%) were in extreme category. Moreover, age greater than 40 years and being diabetic were also the risk factors for conversion to open surgery. The study concluded that a scoring system could help in predicting the conversion and help in patient's clinical outcome.

Atta et al [87] (2017) did a cohort study to analyse the preoperative and postoperative predictors of difficult LC performed by trainees against the experienced surgeons. A cohort of 180 patients who underwent LC for cholelithiasis was analysed. The statistics were done by regression analysis and rate of complications by Pearson's chi-square test. The result showed that patients with impacted stone in neck of the

gallbladder, with adhesions in the Calot's triangle, with gallbladder rupture were more likely to experience difficult LC. There was no difference between trainees and trained surgeons in the rate of cystic artery injury or GB rupture. However, operative time of LC's performed by trained surgeons was significantly shorter compared with the surgical trainee's operative time. The study concluded that, surgical trainees can perform difficult LC safely under supervision with no increase in complications albeit with mild increase in operative time.

Bat O et al [88] (2015) conducted a retrospective study to evaluate and score the patients those who underwent difficult LC. All patients who underwent LC in period of 2010 to 2015 were retrospectively reviewed for the study. They classified the difficult laparoscopic cholecystectomy based on intraoperative findings into Class I difficulty: Adhesion of omentum majus, transverse colon, duodenum to the fundus of the gallbladder. Class II difficulty: Adhesions in Calot's triangle and difficulty in dissection of cystic artery and cystic duct. Class III difficulty: Difficulty in dissection of gallbladder bed (scleroatrophic gallbladder, hemorrhage from liver during dissection of gallbladder, cirrhotic liver). Class IV difficulty: Difficulty in exploration of gallbladder due to intra-abdominal adhesions including technical problems. Out of 146 patients who underwent difficult LC, the most common difficulty was Class I. In 98 patients LC was converted to open surgery. The study showed a statistical significance between LC time and conversion to open surgery. LC with longer duration were more likely to be converted to open surgery. The operation time was found to be longest in Class II difficulty, hence needing more conversion rate in the class II. Hence Class II difficulty characterised by adhesions in Calot's triangle posed most serious problem among difficult laparoscopic cholecystectomy cases with longer operation time and high conversion rates.

Gabriel R et al [91] (2009) did a study to identify and evaluate the risk factors that may predict the conversion of LC to open surgery. The study was done at Kasturba Medical College during the period from January 2003 to July 2005. Total of 234 Laparoscopic cholecystectomies were attempted out of which 61 were converted to open surgery. A combination of both retrospective and prospective analysis was done based on patient factors, intraoperative factors and surgeon factors. 26.1% of LC required conversion to open surgery. Factors contributing to conversion included male sex, age group of 31-40 years, over weight and history of biliary pain within last two to four months, ultrasonography findings of multiple calculi and gallbladder wall thickness of more than 3 mm. Intraoperative gall bladder perforation with spillage of its contents in abdominal cavity and dense adhesions with difficult anatomy resulted in higher conversion rates. Surgery performed by surgeons in learning phase of laparoscopic surgery was more prone to conversion.

Giger U F et al [92] (2006) did a secondary data analysis from Swiss association of laparoscopic and thoracoscopic surgery database, to determine risk factors that predict perioperative complications in laparoscopic cholecystectomy. Analysis was done by stepwise logistic regression model. Total of 22,953 patients of age ranging from 17 to 89 underwent elective and emergency LC. Multivariate analysis showed that male gender, duration of intervention, body weight and surgeons experience were independently associated with increase intraoperative local complication rate. Higher incidence of postoperative complications was seen in males, those who underwent emergency surgery and in those with ASA score above III. The study concluded that the perioperative complications can be predicted by assessing the risk factors such as patient characteristics (gender, age, ASA score, body weight), clinical findings (acute versus chronic cholecystitis), and the surgeon's expertise in LC. So, in the likelihood

of a case being a "difficult cholecystectomy," an experienced surgeon should be involved both in the decision-making process and during the operation. If LC lasts longer than 2 hours, the cumulative risk for perioperative complications is four times higher compared with an intervention that lasts between 30 and 60 minutes, independent of the surgeon's personal skills with LC.

Gwinn E C et al [93] (2013) did a study to assess the role of laparoscopic ultrasound in permitting safe completion of difficult laparoscopic cholecystectomy. 44 patients were selected prospectively with severe cholecystitis. Laparoscopic ultrasound was considered critical in those patients to identify bile ducts intraoperatively. LC patients were compared, on an intention to treat basis, with 41 contemporaneous patients with severe cholecystitis who had planned open cholecystectomy. Laparoscopic ultrasound identified extra-hepatic bile ducts in all cases. 40% of those cases were completed laparoscopically. Patient who underwent open surgery had higher rates of acute cholecystitis and preoperative percutaneous cholecystostomy tubes. Blood loss and drains needed were minimal in patients who underwent Laparoscopic cholecystectomy. LC patients had fewer post-operative complications, significantly fewer ICU admissions. By allowing identification of the extrahepatic bile ducts during difficult cholecystectomy, Laparoscopic ultrasound results in a high rate of successful laparoscopic completions. Laparoscopic cholecystectomy is associated with better clinical outcomes.

Harilingam M et al[94] (2016) developed a technique of Laparoscopic modified subtotal cholecystectomy to replace LC in difficulty arising due to distorted anatomy in Calot's triangle. A retrospective analysis of 993 consecutive patients who underwent cholecystectomy was done. The data included patient's demographic profile, operative details, intraoperative and postoperative complications,

postoperative stay including follow-ups. 98.5% were listed for LC and 1.5% were listed for open cholecystectomy. 902 patients underwent LC and 64 underwent laparoscopic modified subtotal cholecystectomy (LMSC). The LMSC technique avoided conversion in 6.5% of patients.

Joshi M R et al [95] (2015) did a prospective study to develop and validate scoring system to predict difficult LC preoperatively. To develop a scoring system history, physical examination, abdominal ultrasound and biochemical parameters were considered preoperatively. 100 patients undergoing LC were included in the study. Preoperative assessment was done using the scoring system and postoperative comparison was done. The scoring system developed had a sensitivity of 53.8% and 89.2% specificity in identifying difficult LC preoperatively.

Kim M S et al [96] (2014) did a retrospective study to assess the role of computed tomography in predicting the preoperative indicators of difficult LC. The study also proposed a risk scoring model that can be used to predict conversion by integrating clinical, laboratory and CT parameters. 183 patients who underwent LC were retrospectively reviewed for clinical, laboratory, CT parameters. Univariate and multivariate regression analysis was done. 175 of the patient underwent conversion. Age older than 60 years, male gender and pericholecystic fluid were independent predictors of conversion. The risk score for conversion showed 83% sensitivity and 72% specificity. Pericholecystic fluid collection was the only CT parameter that had a preoperative prediction for conversion in this study.

In a study done by Nikhil Gupta et al[97] (2013), they found that history of hospitalization, palpable gall bladder, impacted stone and gall bladder wall thickness were statistically significant factors for prediction of difficult laparoscopic cholecystectomy. Conversion rate from laparoscopic to open cholecystectomy was

found to be 4.28%. The drawback of this study is that the small sample size may be an impediment in attaining complete statistical validity.

Partha Bhar et al [98] (2013) studied seven parameters such as age, sex, body mass index, ASA class, hypertension, diabetes and previous abdominal surgery to determine the factors that were associated with difficult laparoscopic cholecystectomy. In 22.32% patient's pre-operative difficulties were encountered and out of these 5.35% required conversion to open procedure. ASA class, hypertension and diabetes mellitus were found to be statistically significant predictor of difficult laparoscopic cholecystectomy. However, age, male sex, body mass index (BMI) and past abdominal surgery were not found to be statistically significant variables.

The risk factors such as age >50 years, male gender, body mass index (BMI) 25.1-27.5 and >27.5, previous surgery, prior hospitalization, palpable gall bladder, gallbladder wall thickening, impacted stone, and pericholecystic collection were evaluated by Prashant S. Dhanke et al[82]. Each risk factor was given a score preoperatively. The total score up to 5 predicted easy, 6-10 difficult and >10 very difficult. They found that BMI >27.5, history of prior hospitalization, palpable gallbladder, impacted stone and pericholecystic collection are significant predictors of difficult laparoscopic cholecystectomy. Limitation of this study is the defined age group. No patients above 60 years were included and the majority of the population in this study were young to middle aged group. Hence, this score does not predict difficult laparoscopic cholecystectomy for older age group.

The factors like BMI > 27.5, previous hospitalization, palpable gall bladder, ultrasound diagnosed thick walled gall bladder are found to be statistical significant in predicting difficult laparoscopic cholecystectomy by Jaskiran S. Randhawa et al.[78]

The drawback is that there was no correlation of score and conversion to open cholecystectomy.

In a study done by Ravindra Nidoni et al[90] (2015), 5.56% patients required conversion to open cholecystectomy. The total leucocyte count (TLC) >11000, more than two previous attacks of cholecystitis, gall bladder wall thickness of >3mm and pericholecystic collection were all statistically significant for predicting difficult laparoscopic cholecystectomy and its conversion.

Karam Kamal Younis et al[99] (2013) analyzed prospectively different preoperative data including patient's age, gender, weight, height, previous abdominal surgery and previous attack of acute cholecystitis. The dependent variables (outcomes) included the duration of operation, bleeding, difficult accessing, bile leak, difficult dissection of gall bladder, and conversion to open cholecystectomy and found that the factors contributing to difficult laparoscopic cholecystectomy were, male gender, previous upper abdominal surgery and BMI >35.

And then similar study done by U Jethwani et al[100] showed that male gender, single large stone, thick walled gallbladder, previous abdominal surgery and contracted gallbladder predict difficult laparoscopic cholecystectomy.

Indian Studies:

Gupta N et al [101] (2013) did a prospective study to analyze the risk factors and to predict degree of difficult LC preoperatively by using a scoring system. The scoring system developed by them considered the following parameters, old age, male sex, history of hospitalization, obesity, previous abdominal surgery scar, palpable gall bladder, wall thickness of gall bladder, pericholecystic collection and impacted stone. The study was conducted among 210 patients who has indications to undergo LC. The

scoring system was applied preoperatively, and results were compared with the surgical outcome. It was observed that history of hospitalization, palpable gall bladder, impacted stone and gall bladder wall thickness were statistically significant factors for prediction of difficult laparoscopic cholecystectomy. The preoperative scoring method developed by them had a sensitivity of 95.74% and specificity of 73.68%. the scoring system had a positive predictive value of 90% and 88% for easy and difficult cases respectively.

Randhawa J S et al [78] (2009) did a study to develop a scoring method to predict difficult LC preoperatively. The duration of study was for a period of two years. 228 cases were operated by a single experienced surgeon in those two years. The scoring system had inputs from history, clinical and sonological findings. The score ranges from 0 to 15. Less than 5 predict easy LC, 6-10 predict difficult and score more than 10 predict very difficult. The predictions of the scoring were correct 88.8% for easy and 92% for difficult cases. BMI, previous hospitalisation, palpable gallbladder and thick walled gallbladder all had significant role in predicting difficult LC. The scoring system developed had a sentivity of 75% and specificity of 90.24%.

Sharma S K et al [102] (2007) did a study to determine the role of preoperative ultrasonogram in predicting the risk of conversion in difficult LC. 200 patients planned to undergo LC were recruited into the study. The sonographic parameters included the size of gallbladder, wall thickness, distance between hepaticoduodenal ligament and Hartmann's pouch and the size of stones was also taken into consideration. The sonological parameters were statistically significant in predicting the preoperative risk of conversion. 8 out of 200 patients needed conversion in this study.

Lal P et al [89] (2002) conducted a prospective study with 73 patients who underwent elective LC for uncomplicated gallstone disease. It assessed the role of preoperative ultrasound in predicting difficult LC. Four parameters of the ultrasound were considered preoperatively namely, gallbladder wall thickness, contracted gallbladder, impaction of gallstones at the neck of the gallbladder, and common bile duct stones. Five operative parameters were considered 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. Out of 73 cases, 17 of the cases were converted to open surgery. The scoring predicted 21 cases to be difficult out of which 17 had technical difficulty and 13 were converted to open procedure. Of the 52 cases predicted to be easy on ultrasonography, only 7 cases needed difficult surgery, of which 4 were converted to open. The study concluded that the preoperative ultrasonography had a high predictive rate for identifying difficult LC.

Agarwal N et al[103] (2015) did a study to evaluate a scoring method to predict the difficult LC preoperatively. 20 cases operated by an experienced surgeon were taken as participants. There are total 15 score from history, clinical and sonological findings. Score up to 5 predicted easy, 6–10 difficult and >10 are very difficult. The factors like previous history of hospitalization, clinically palpable gallbladder, impacted gallbladder stone, pericholecystic collection, and abdominal scar due to previous abdominal surgery were found statistically significant in predicting difficult LC. The study concluded that the scoring system developed was 76.47% sensitive and 100% specific in predicting difficult LC preoperatively.

Chand P et al [104] (2015) did a study to know the role of preoperative ultrasonography in predicting difficult laparoscopic cholecystectomies. The study was

conducted in Patiala, 50 patients with cholelithiasis were selected from surgical out patient department. The patients were planned for elective laproscopic cholecystectomy. Preoperatively all the patients were subjected to ultrasonography with the same probe. The surgery was performed 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.

Mittalgodu Anantha Krishna Murthy Vivek et al [105] (2014) in their study found that elderly patients, males, recurrent cholecystitis, obese patients, previous surgery, patients who needed preoperative endoscopic retrograde cholangiopancreatography (ERCP), abnormal serum hepatic and pancreatic enzyme profiles, distended or contracted gall bladder, intraperitoneal adhesions, structural anomalies or distortions and the presence of a cirrhotic liver on ultrasonography (USG) were identified as predictors of difficult LC.

The key lacunae identified in the literature were lack of substantial evidence on utility of any one particular scoring system to predict difficult laparoscopic cholecystectomy. The parameters proposed in each of the scoring systems, even though had shown significant overlap, were also different in different studies. The operational definition used for difficult cholecystectomy is also sometimes had shown variation across studies. The studies assessing utility of any pre-operative scoring system are very limited on Indian population.

METHODOLOGY

Study site: This study was conducted in the Department of General Surgery at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Jawaharlal Nehru Medical College, KAHER, Belagavi.

Study population: All the eligible patients undergoing laparoscopic cholecystectomy in the department of General Surgery at KLES Dr. Prabhakar Kore Hospital and Medical Research centre, Jawaharlal Nehru Medical College, KAHER were considered as study population.

Study design: The current study was a cross sectional study.

Sample size: The sample size was calculated assuming the expected proportion of difficult laparoscopic cholecystectomy in the population, based on study by Gupta et al[101] as 27.1%. Considering 13% absolute precision and 95% confidence level. The sample size was calculated using the following formula.

$$n = \frac{Z^2 P(1-P)}{d^2}$$

Where n = Sample size

Z = Z statistic for a level of confidence) = 1.96

P = Expected prevalence of proportion

(If the expected prevalence is 20%, then P = 0.271), and

d = Precision (If the precision is 5%, then d=0.13).

The required sample size, as per the above mentioned calculation was 45 subjects. To account for a loss to follow up and non-participation rate of 5% each, it was decided to sample50 subjects into the study.

Sampling method: All the eligible subjects were recruited into the study consecutively by convenient sampling till the sample size is reached.

Study duration: The data collection for the study was done between January 2017 to December 2017 for a period of 1 year.

Inclusion Criteria:

All patients who require cholecystectomy for reasons like

- Acute calculous cholecystitis
- Chronic calculous cholecystitis

Exclusion criteria:

- Presence of jaundice
- Cholangitis
- Raised alkaline phosphatase
- Dilated common bile duct
- Common bile duct stones
- Empyema of gall bladder
- Acalculous cholecystitis
- LC done along with common bile duct exploration
- LC with other intervention at the same setting
- Patients with anesthetic complications
- Patients with co-morbid diseases
- Technical and equipment deficiency

Ethical considerations: Study was approved by institutional human ethics committee. Informed written consent was obtained from all the study participants and only those participants willing to sign the informed consent were included in the study. The risks and benefits involved in the study and voluntary nature of participation were explained to the participants before obtaining consent. Confidentiality of the study participants was maintained.

Data collection tools: All the relevant parameters were documented in a structured study proforma.

Methodology: After obtaining the informed written consent, all the patients were evaluated by thorough clinical history, physical examination. The following structured scoring system was used to categorize the patients preoperatively to easy, difficult and very difficult categories.

Table 1: Scoring factors used for grading the patient parameters

		SCORE	MAX SCORE
HISTORY			
AGE	≤50 YRS	0	1
	>50 YRS	1	
SEX	MALE	1	1
	FEMALE	0	
HISTORY OF HOSPITALIZATION FOR ACUTE CHOLECYSTITIS	YES	4	4
	NO	0	
CLINICAL PARAMETERS			
BMI	<25	0	2
	25-27.5	1	
	>27.5	2	
ABDOMINAL SCAR	NO	0	2
	INFRAUMBLICAL	1	
	SUPRAUMBLICAL	2	
PALPABLE GALLBLADDER	YES	1	1
	NO	0	
SONOGRAPY			
WALL THICKNESS	THIN <4 mm	0	2
	THICK≥ 4mm	2	
PERICHOLECYSTIC COLLECTION	NO	0	1
	YES	1	
IMPACTED STONE	NO	0	1
	YES	1	

Score 0-5 easy, 6-10 difficult, 11-15 very difficult.

Surgery was done using CO_2 pneumoperitoneum with 10 mmHg pressure and using standard two 5 mm and two 10 mm ports. Time was noted from first port-site insertion till last port closure. All intraoperative events like duration of surgery, bile/stone spillage, injury to duct/artery were recorded and surgery was labeled as easy/difficult/very difficult based on these findings.

Table 2: Intraoperative assessment

PARAMETERS	SCORE	GRADING
Time taken < 60 min & No bile spillage & No injury to duct	0-5	Easy
Time taken 60-120 min and/or Bile or stone spillage and/or Injury to duct	6-10	Difficult
Time taken > 120 min or conversion	11-15	Very difficult

The scores were compared in each patient to come to a conclusion whether preoperative predictive score was a useful method or not.

Investigation: Ultrasound - Abdomen

Intervention / Surgery: Laparoscopic cholecystectomy

Statistical methods:

Intraoperative outcome (difficulty) was considered as outcome variables

The preoperative risk group as classified by the structured scoring system was considered as primary explanatory variable.

Abdominal scar, impacted stone, thick gallbladder, palpable gallbladder, pericholecystic collection were considered as explanatory variables.

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

The association between intraoperative outcome and categorical abdominal scar, impacted stone, thick gallbladder, palpable gallbladder, pericholecystic collection was assessed by cross tabulation. Chi square test was used to test statistical significance.

The sensitivity, specificity and predictive values of preoperative score in predicting the intra operative outcome were calculated. p value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis. [106]

RESULTS

RESULTS:

A total 50 people were included in the final analysis

Table 3: Descriptive analysis of Age in study population (n=50)

Parameter	Mean ± SD	Median	Min	Max	95% C.I	
					Lower	Upper
Age	43.36 ± 9.84	42.50	27.00	64.00	40.56	46.16

The mean of age was 43.36 ± 9.84 years. Minimum age was 27 and maximum age was 64. (95% CI 40.56 to 46.16). (Table 3)

Table 4: Descriptive analysis of age group in the study population (n=50)

Age group	Frequency	Percentages
≤50 years	38	76.00%
51 years and above	12	24.00%

Among the study population 38(76%) people were aged up to 50 years and remaining 12(24%) people were age above 51 years. (Table 4 & figure 1)

Figure 1: Bar graph for age group distribution in study population (n=50)

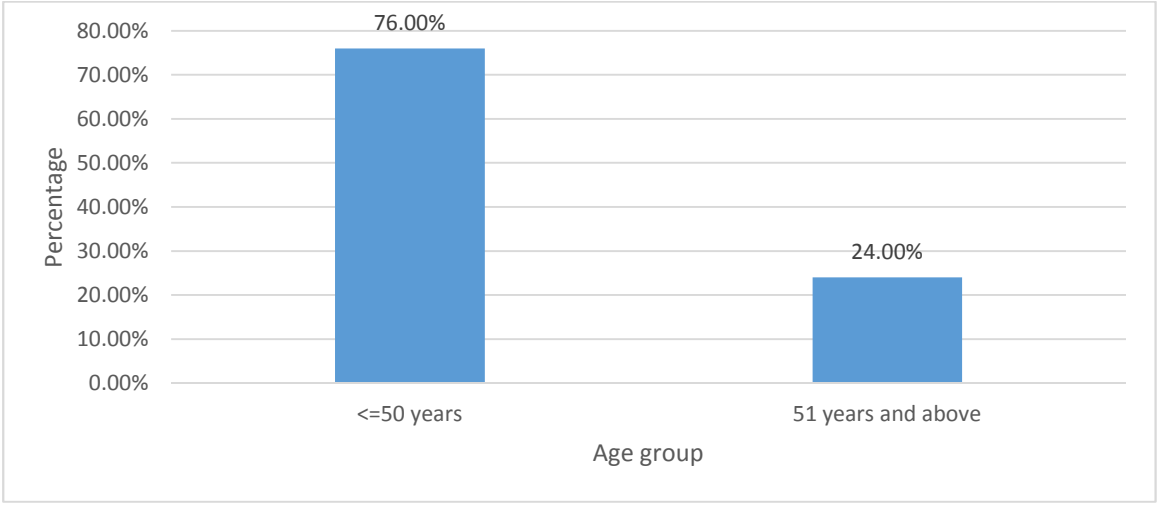

Table 5: Descriptive analysis of gender in the study population (n=50)

Gender	Frequency	Percentages
Male	9	18.00%
Female	41	82.00%

Among the study population 9(18%) people were males and remaining 41(82%) people were females. (Table 5 & figure 2)

Figure 2: Bar graph for gender distribution in study population (n=50)

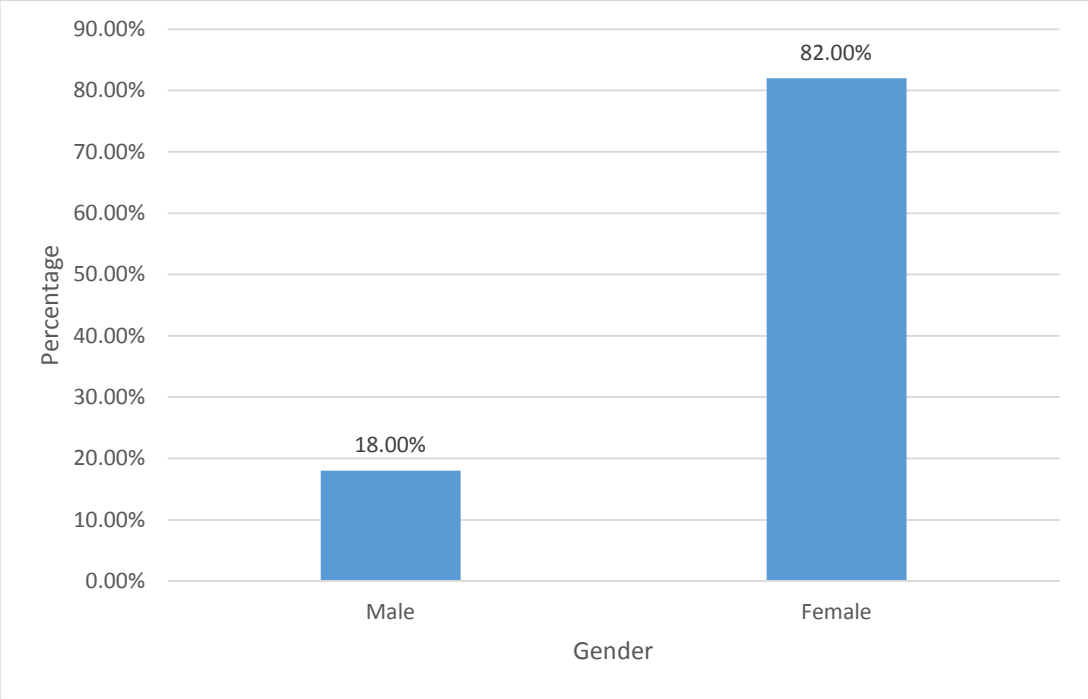

Table 6: Descriptive analysis of history of hospitalization in the study population (n=50)

History of hospitalization	Frequency	Percentages
Yes	14	28.00%
No	36	72.00%

Among the study population only 14(28%) people had history of prior hospitalization. (Table 6 & figure 3)

Figure 3: Bar graph for history of hospitalization distribution in study population (n=50)

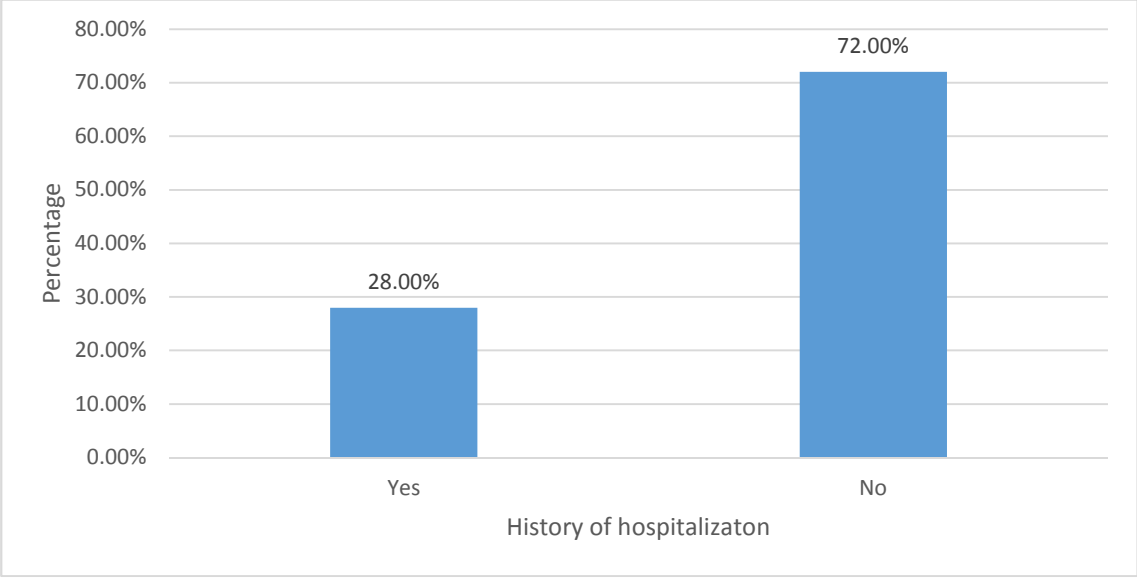

Table 7: Descriptive analysis of BMI in study population (n=50)

Parameter	Mean ± SD	Median	Min	Max	95% C.I	
					Lower	Upper
BMI	24.32 ± 2.32	23.85	21.00	28.30	23.66	24.98

The mean of BMI was 24.32 ± 2.32. Minimum level was 21 and maximum level was 28.30. (95% CI 23.66 to 24.98). (Table 7)

Table 8: Descriptive analysis of BMI category in the study population (n=50)

BMI category	Frequency	Percentages
≤25	36	72.00%
25.1 to 27.5	3	6.00%
27.6 and above	11	22.00%

Among the study population 36(72%) people had BMI up to 25, 3(6%) people had 25.1 to 27.5 and remaining 11(22%) people had BMI 27.6 and above. (Table 8 & figure 4)

Figure 4: Pie chart for BMI category distribution in study population (n=50)

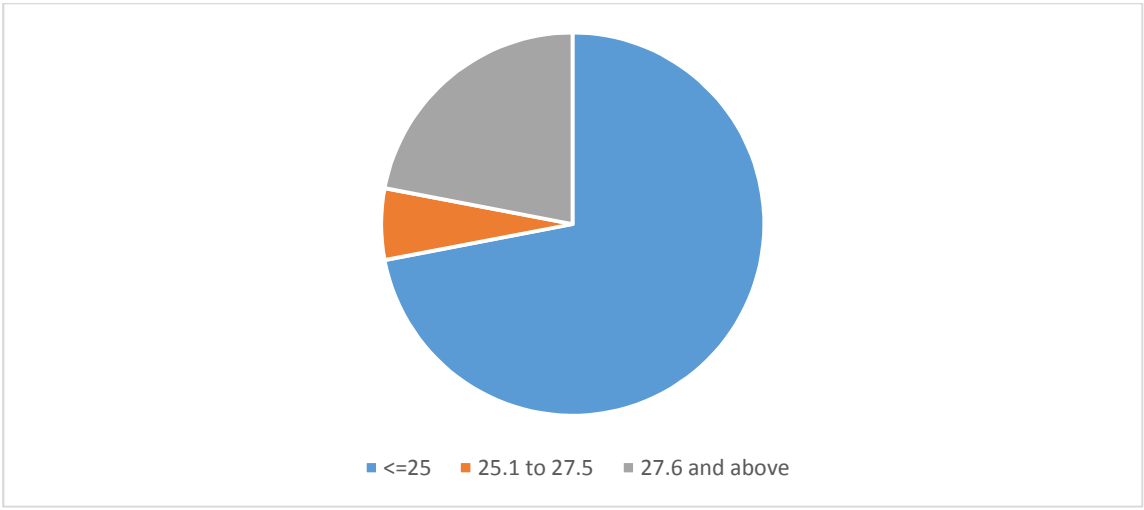

Table 9: Descriptive analysis of abdominal scar in the study population (n=50)

Abdominal scar	Frequency	Percentage
Yes	4	8.00%
No	46	92.00%

Among the study population 4(8%) people had abdominal scar. (Table 9 & figure 5)

Figure 5: Pie graph for abdominal scar distribution in study population (n=50)

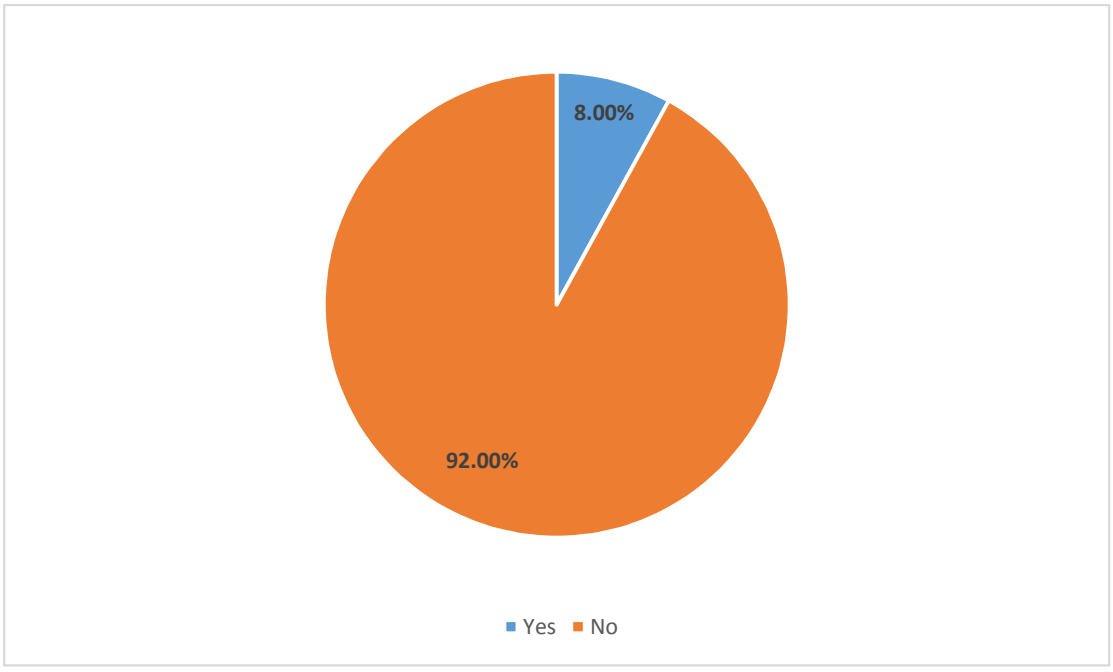

Table10: Descriptive analysis of palpable gallbladder in the study population (n=50)

Palpable gallbladder	Frequency	Percentages
Yes	4	8.00%
No	46	92.00%

Among the study population, 4(8%) people had palpable gallbladder. (Table 10 & figure 6)

Figure 6: Pie graph for palpable gallbladder distribution in study population (n=50)

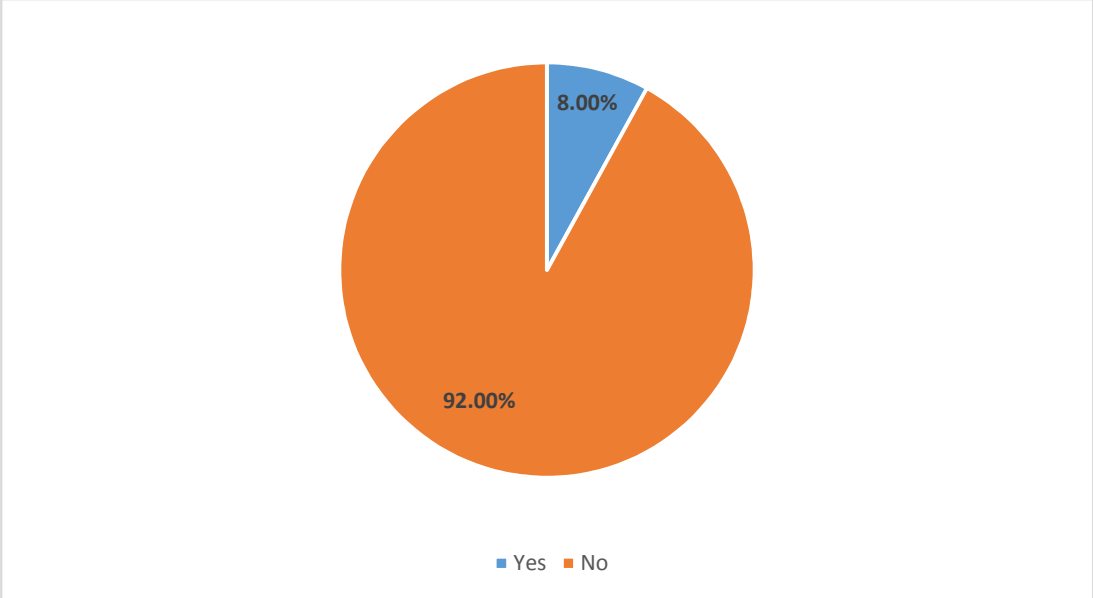

Table 11: Descriptive analysis of thick gallbladder in the study population (n=50)

Thick gallbladder	Frequency	Percent
Yes	13	26.00%
No	37	74.00%

Among the study population, 13(26.00%) people had thick gallbladder. (Table 11 & figure 7)

Figure 7: Pie graph for thick gallbladder distribution in study population (n=50)

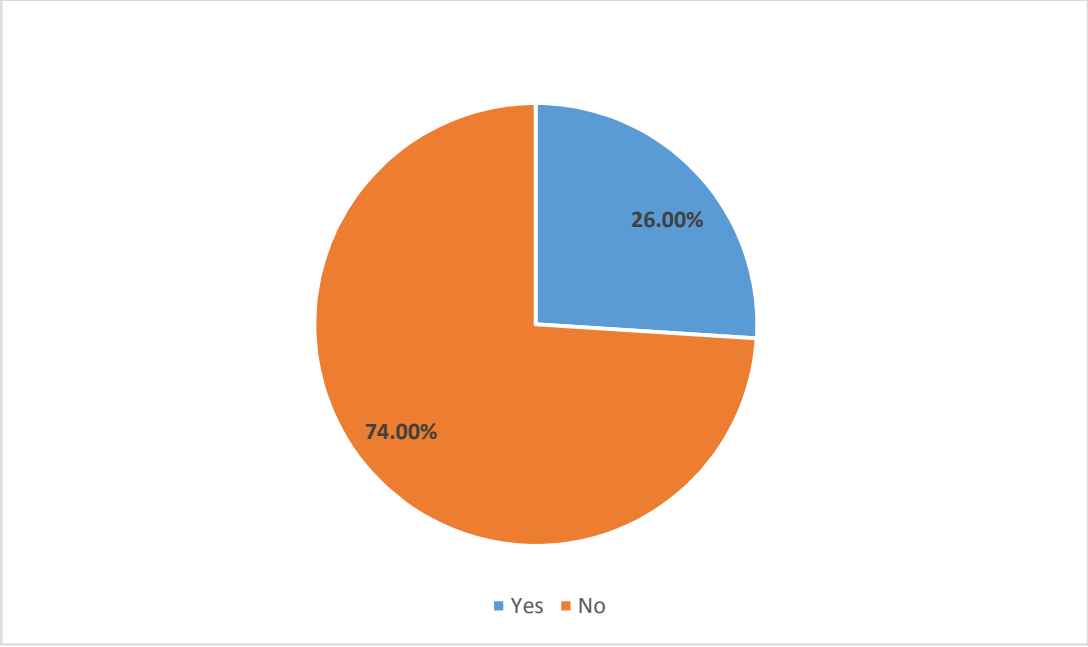

Table 12: Descriptive analysis of pericholecystic collection in the study population (n=50)

Pericholecystic collection	Frequency	Percentages
Yes	9	18.00%
No	41	82.00%

Among the study population, 9 (18%) people had pericholecystic collection. (Table 12 & figure 8)

Figure 8: Pie graph for pericholecystic collection distribution in study population (n=50)

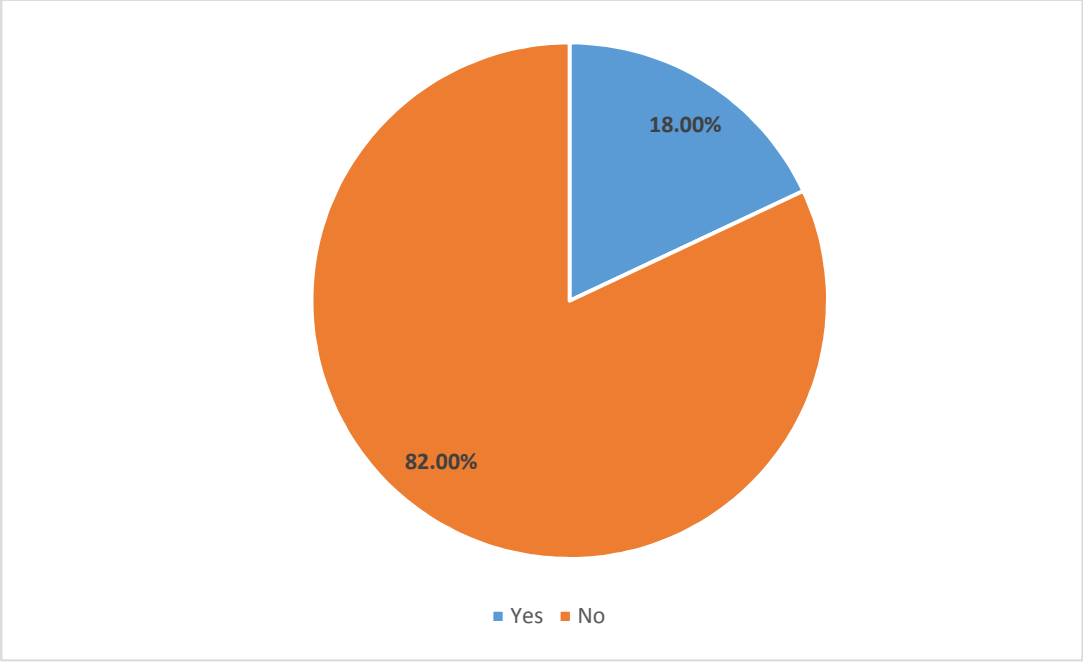

Table 13: Descriptive analysis of impacted stone in the study population (n=50)

Impacted Stone	Frequency	Percentages
Yes	5	10.00%
No	45	90.00%

Among the study population, 5 (10.00%) people had impacted stone. (Table 13 & figure 9)

Figure9: Pie graph for impacted stone distribution in study population (n=50)

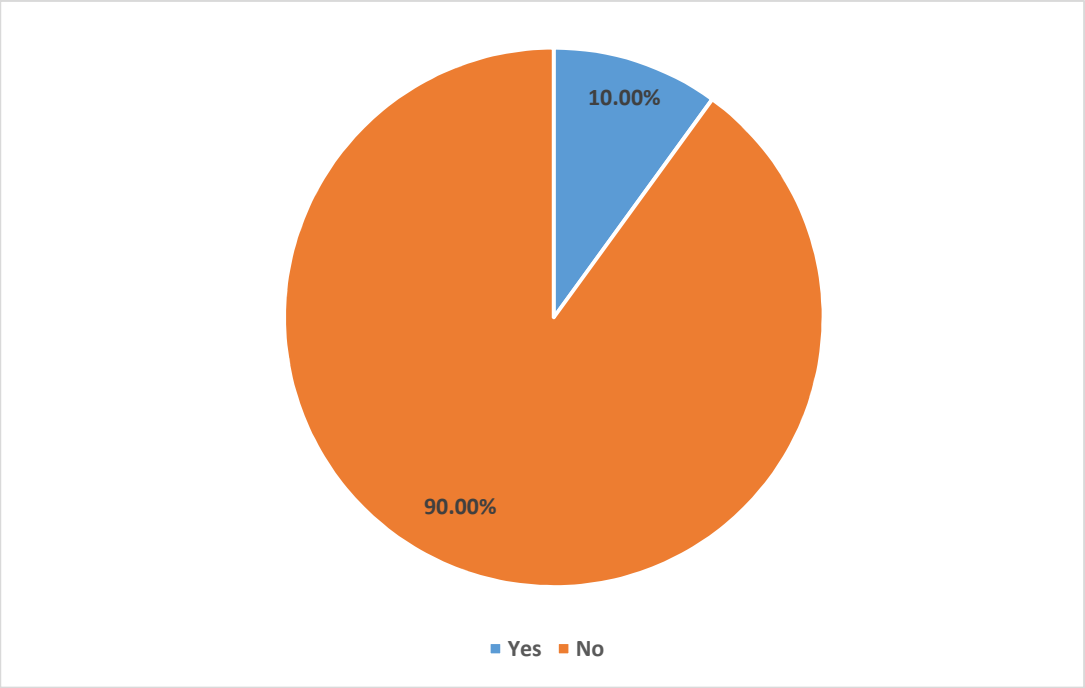

Table 14: Descriptive analysis of preoperative score in study population (n=50)

Parameter	Mean ± SD	Median	Min	Max	95% C.I	
					Lower	Upper
Preoperative score	3 ± 2.61	2.00	0.00	8.00	2.26	3.74

The mean of preoperative score was 3 ± 2.61. Minimum level was 0 and maximum level was 8. (95% CI 2.26 to 3.74). (Table 14)

Table 15: Descriptive analysis of preoperative score category in the study population (n=50)

Preoperative score category	Frequency	Percentages
0 to 5	36	72.00%
6 to 10	14	28.00%

Among the study population, 36(72%) people had preoperative score 0 to 5 and remaining 14(28%) people had preoperative score 6 to 10. (Table 15 & figure 10)

Figure10: Pie graph for preoperative score distribution in study population (n=50)

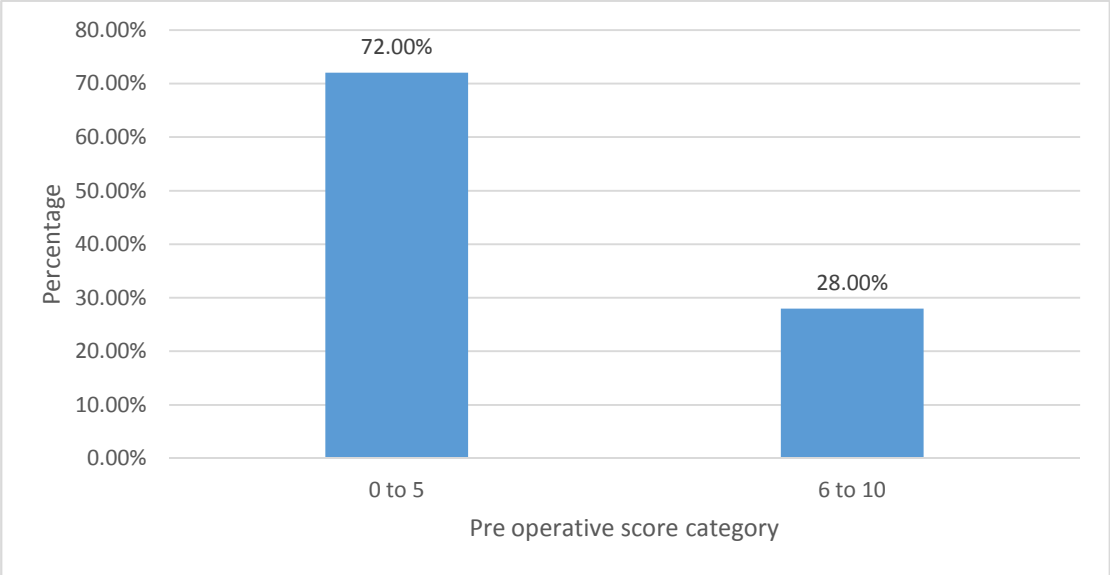

Table 16: Descriptive analysis of intraoperative outcome in the study population (n=50)

Intraoperative outcome	Frequency	Percentage
Difficult	12	24.00%
Easy	38	76.00%

Among the study population, 12(24%) people had difficult intraoperative outcome and 38(76%) people had easy intraoperative outcome. (Table16 & figure 11)

Figure11: Pie graph for intraoperative outcome distribution in study population (n=50)

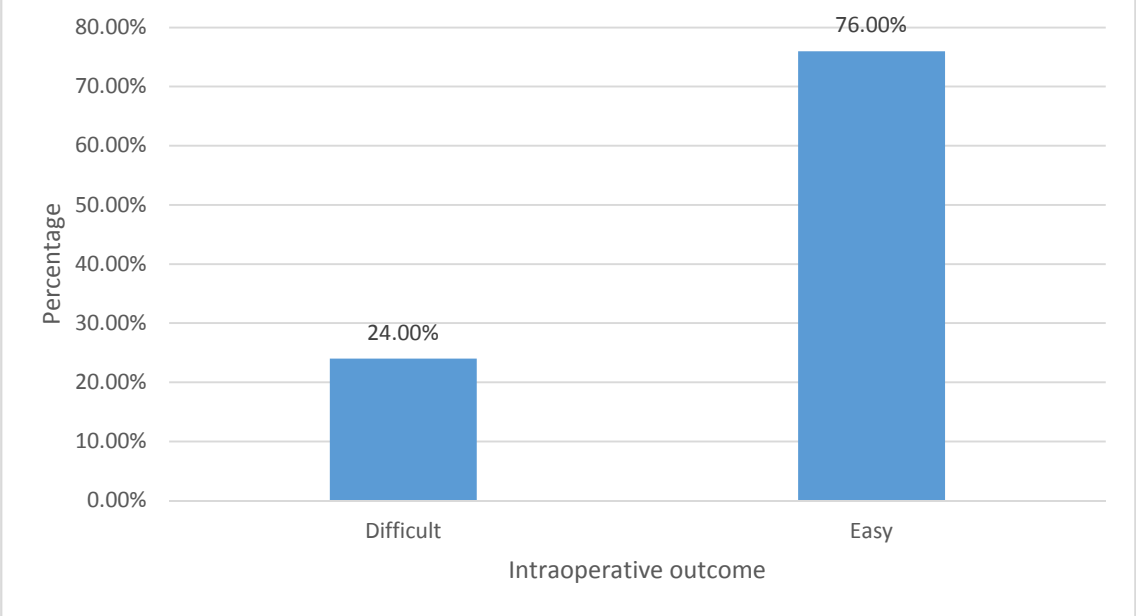

Table 17: Comparison of intraoperative outcome with gender (n=50)

Gender	Intraoperative outcome		Chi square	p-value
	Difficult	Easy		
Male(n=9)	8 (88.9%)	1 (11.1%)	25.33	<0.001
Female(n=41)	4 (9.8%)	37 (90.2%)		

Among the males, 8 (88.9%) people had difficult intraoperative outcome, only 1 (11.1%) person had easy intraoperative outcome. Among the females, 4 (9.8%) had difficult intraoperative outcome and 37 (90.2%) had easy intraoperative outcome. The difference between intraoperative outcome between male and female was statistically significant. (p value <0.001) (Table 17 & figure 12)

Figure12: Staked bar graph for comparison of intraoperative outcome with gender (n=50)

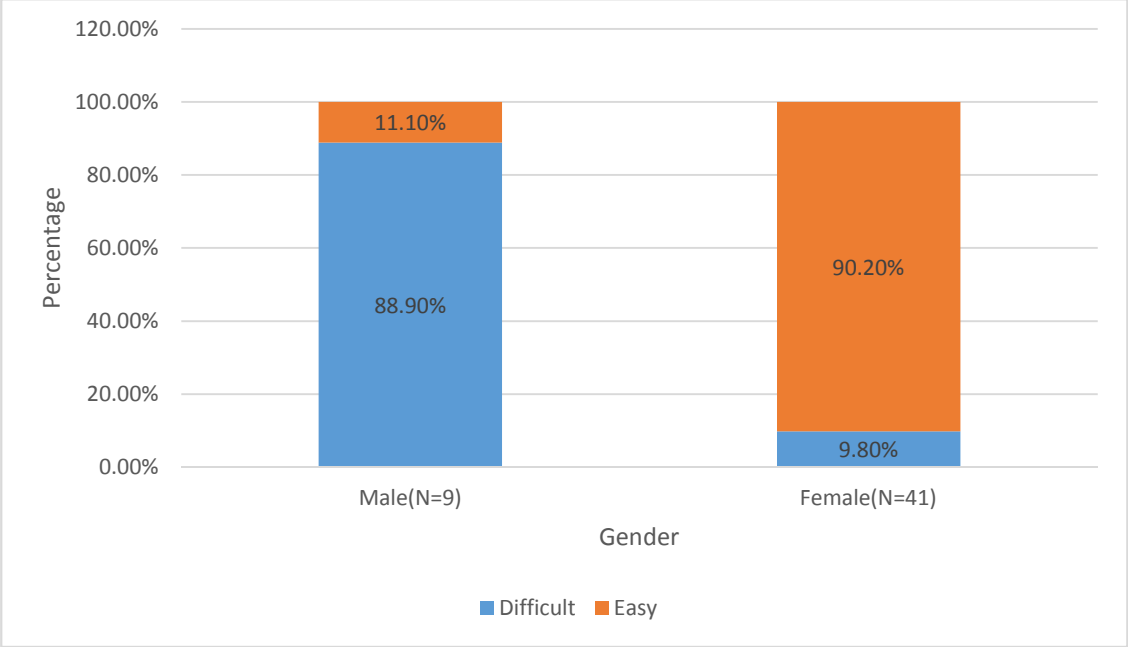

Table 18: Comparison of intraoperative outcome with history of hospitalization (n=50)

History of hospitalization	Intraoperative outcome		Chi square	p value
	Difficult	Easy		
Yes(n=14)	9 (64.3%)	5 (35.7%)	17.30	<0.001
No(n=36)	3 (8.3%)	33 (91.7%)		

Among the people with history of hospitalization, 9 (64.3%) people had difficult intraoperative outcome and only 3 (8.3%) of the 36 people without hospitalization had difficult intraoperative outcome. The difference between intraoperative outcome and history of hospitalization was statistically significant. (p value <0.001) (Table 18 & figure 13)

Figure 13: Staked bar graph for comparison of intraoperative outcome with history of hospitalization (n=50)

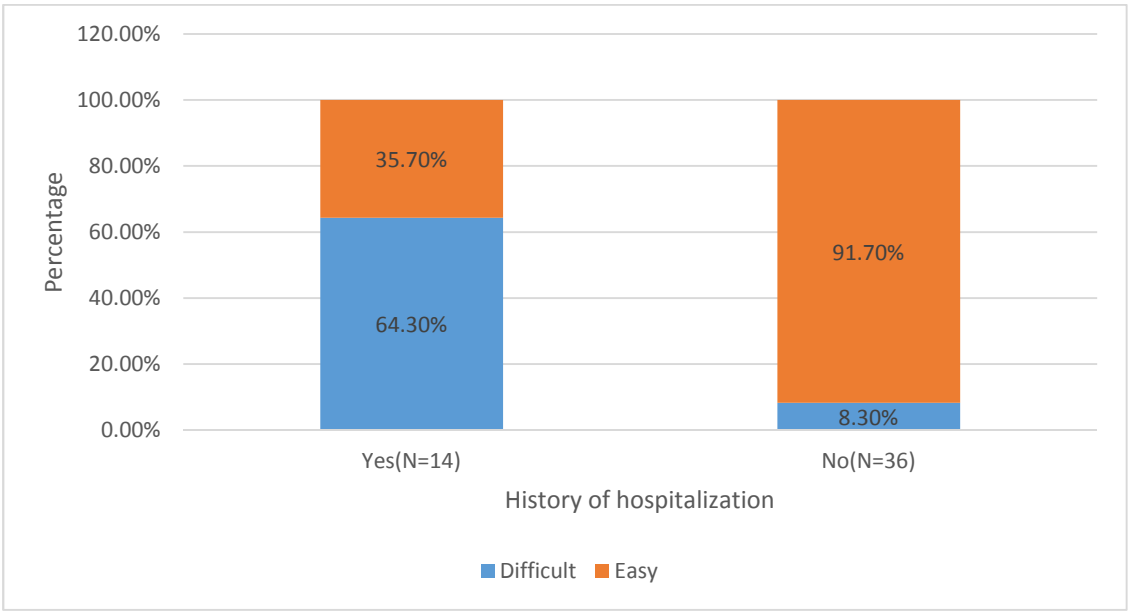

Table 19: Comparison of intraoperative outcome with abdominal scar (n=50)

Abdominal scar	Intraoperative outcome	
	Difficult	**Easy**
Yes(n=4)	0 (0%)	4 (100%)
No(n=46)	12 (26.1%)	34 (73.9%)

**No statistical test was done, as the data does not satisfy the assumptions of chi-square test/Fisher's exact test*

All the 4 people with abdominal scar had easy intraoperative outcome and 12 (26.1%) of the people without abdominal scar had difficult intraoperative outcome. The statistical association could not be tested for this. (Table 19 & figure 14)

Figure 14: Staked bar graph for comparison of intraoperative outcome with abdominal scar (n=50)

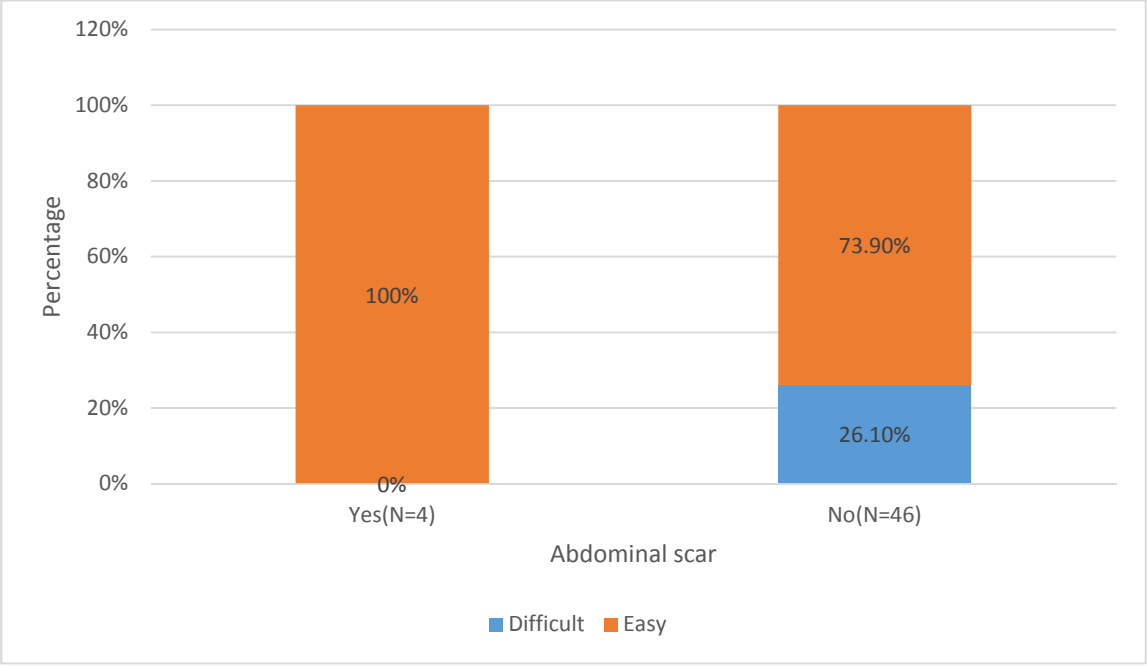

Table 20: Comparison of intraoperative outcome with palpable gallbladder (n=50)

Palpable gallbladder	Intraoperative outcome		Chi square	p-value
	Difficult	Easy		
Yes(n=4)	2 (50%)	2 (50%)	1.611	0.204
No(n=46)	10 (21.7%)	36 (78.3%)		

Among the 4 people with palpable gallbladder, 2 (50%) people had difficult intraoperative outcome and among 46 people without palpable gallbladder, 10 (21.7%) had difficult intraoperative outcome. The difference between intraoperative outcome among people with and without palpable gallbladder was statistically not significant. (p value 0.204). (Table 20 & figure 15)

Figure 15: Staked bar graph for comparison of intraoperative outcome with palpable gallbladder (n=50)

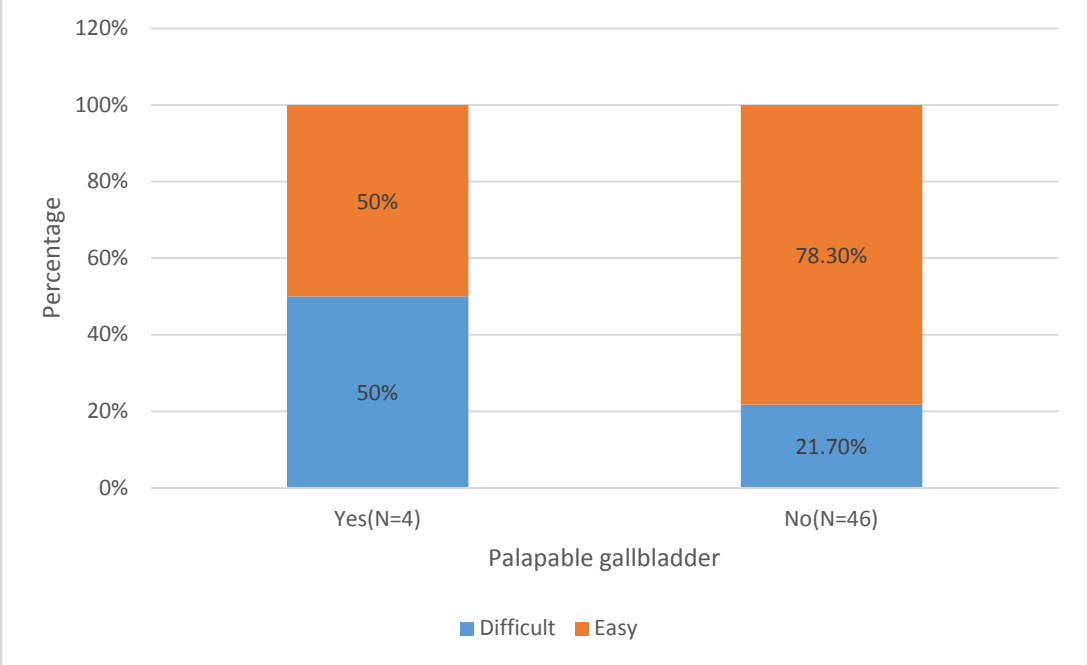

Table 21: Comparison of intraoperative outcome with thick gallbladder (n=50)

Thick gallbladder	Intraoperative outcome		Chi square	P-value
	Difficult	Easy		
Yes(n=13)	3 (23.1%)	10 (76.9%)	.008	0.928
No(n=37)	9 (24.3%)	28 (75.7%)		

No statistically significant association was found between thick gall bladder and intraoperative outcome (p value 0.928). (Table 21 & figure 16)

Figure 16: Staked bar graph for comparison of intraoperative outcome with thick gallbladder (n=50)

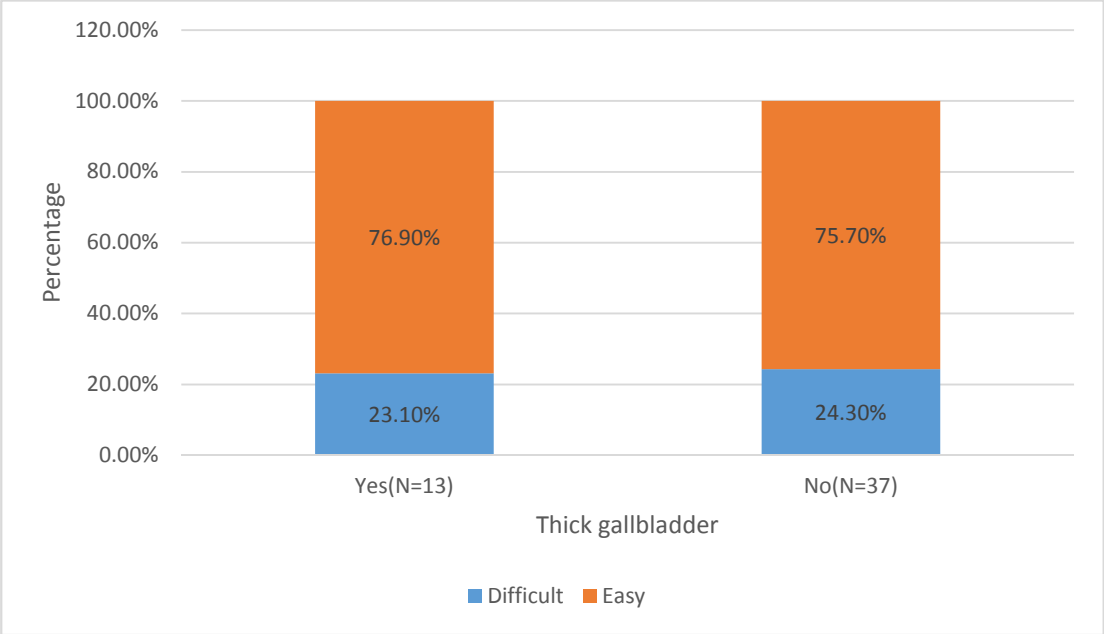

Table 22: Comparison of intraoperative outcome with pericholecystic collection (n=50)

Pericholecystic collection	Intraoperative outcome		Chi square	p-value
	Difficult	Easy		
Yes(n=9)	4 (44.4%)	5 (55.6%)	2.515	0.113
No(n=41)	8 (19.5%)	33 (80.5%)		

No statistically significant association was found between pericholecystic collection and intraoperative outcome (p value 0.113). (Table 22 & figure 17)

Figure 17: Staked bar graph for comparison of intraoperative outcome with pericholecystic collection (n=50)

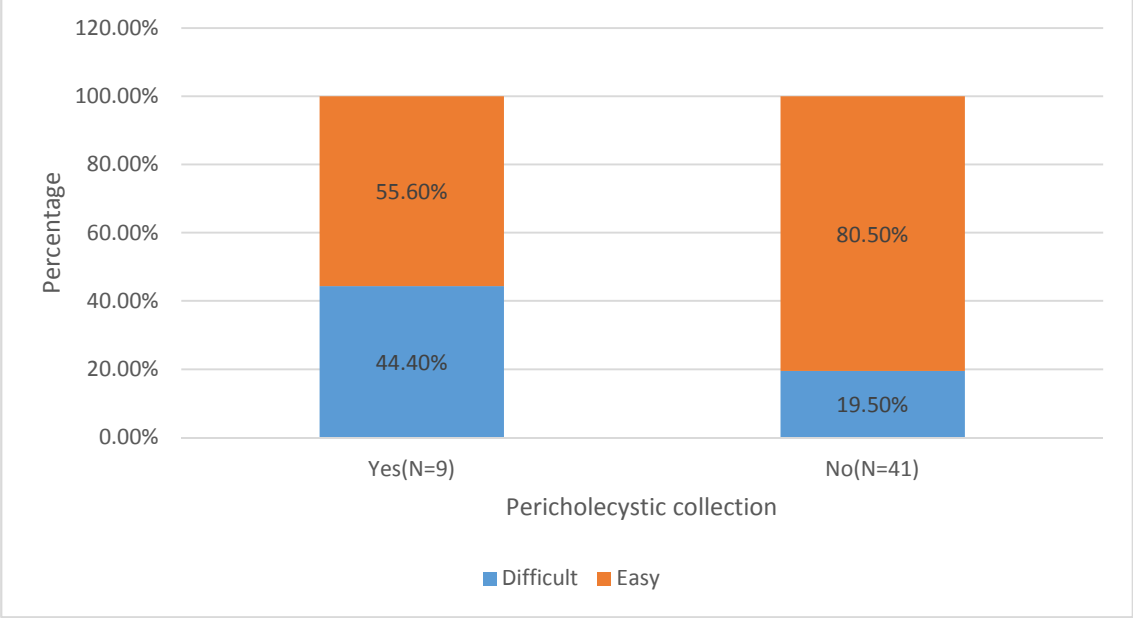

Table 23: Comparison of intraoperative outcome with impacted stone (n=50)

Impacted Stone	Intraoperative outcome		Chi square	p-value
	Difficult	Easy		
Yes(n=5)	3 (60%)	2 (40%)	3.947	0.047
No(n=45)	9 (20%)	36 (80%)		

Among the people with impacted Stone, 3 (60%) people had difficult intraoperative outcome and among 45 people with no impacted stone, 9 (20%) people had difficult intraoperative outcome. The difference was statistically significant. (p value 0.047). (Table 23 & figure 18)

Figure18: Staked bar graph for comparison of intraoperative outcome with impacted stone (n=50)

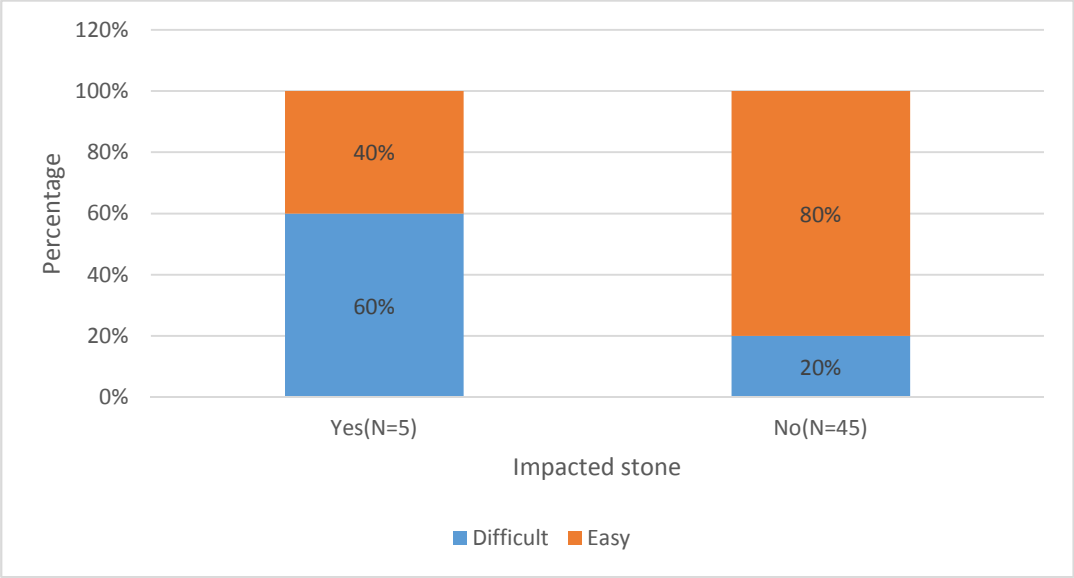

Table 24: Comparison of intraoperative outcome with age group (n=50)

Age group	Intraoperative outcome		Chi square	P-value
	Difficult	Easy		
≤50 years(n=38)	9 (23.7%)	29 (76.3%)	.009	0.926
51 years and above (n=12)	3 (25%)	9 (75%)		

No statistically significant difference was found between people ≤50 years and people with 51 years and above in proportion of difficult intraoperative outcome. (p value 0.926). (Table 24 & figure 19)

Figure 19: Staked bar graph for comparison of intraoperative outcome with age group (n=50)

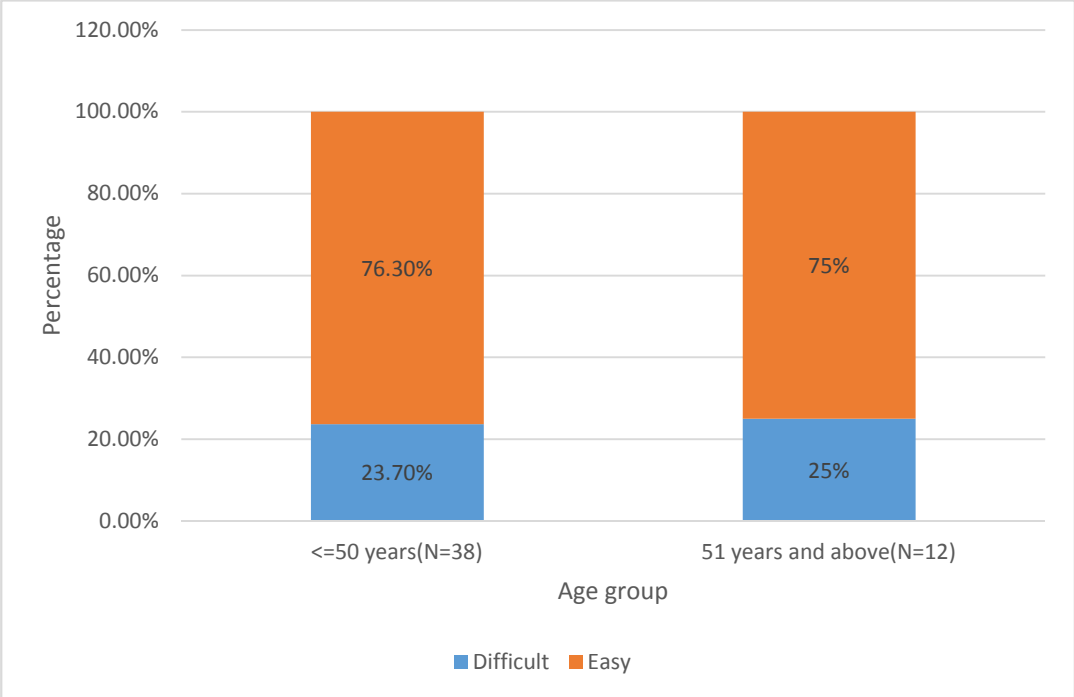

Table 25: Comparison of intraoperative outcome with BMI category (n=50)

BMI category	Intraoperative outcome	
	Difficult	**Easy**
≤25(n=36)	7 (19.4%)	29 (80.6%)
25.1 to 27.5(n=3)	0 (0%)	3 (100%)
27.6 and above(n=11)	5 (45.5%)	6 (54.5%)

**No statistical test was done, as the data does not satisfy the assumptions of chi-square test/Fisher's exact test*

Among the people with BMI up to 25, only 7(19.4%) people had difficult intraoperative outcome and among the people with BMI 27.6 and above, 5(45.5%) people had difficult intraoperative outcome. The statistical association could not be tested (Table 25 & figure 20)

Figure 20: Staked bar graph for comparison of intraoperative outcome with BMI category (n=50)

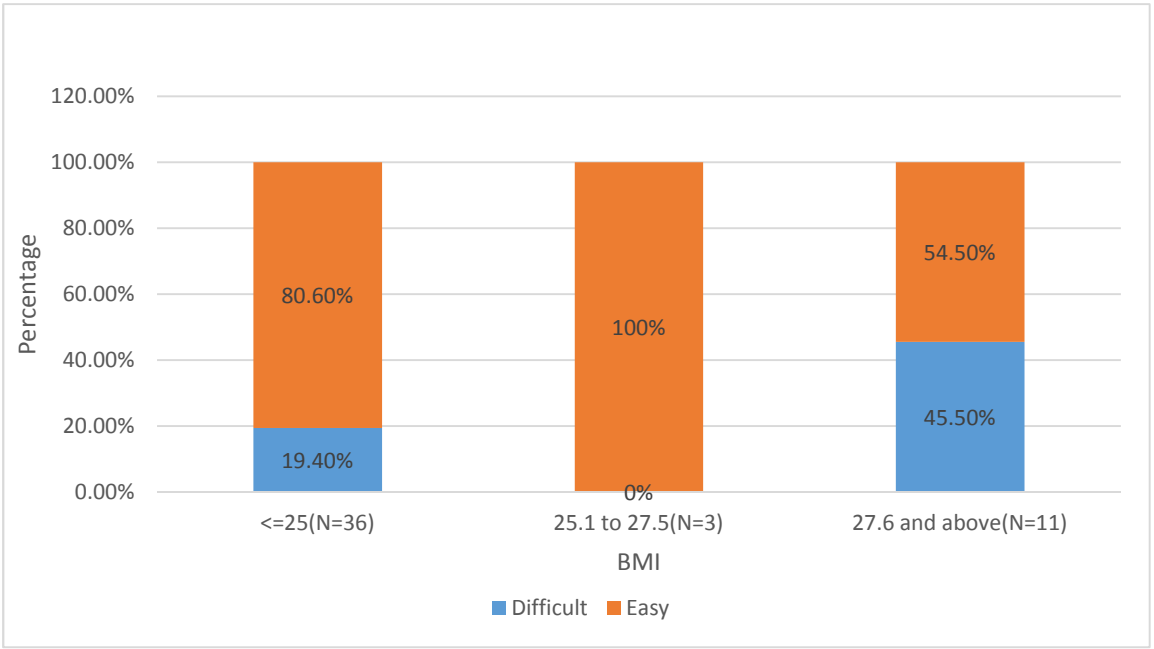

Table 26: Comparison of intraoperative outcome with preoperative score category (n= 50)

Preoperative score category	Intraoperative outcome		Chi square	p-value
	Difficult	Easy		
0 to 5 (n=36)	3 (8.3%)	33 (91.7%)	17.30	<0.001
6 to 10 (n=14)	9 (64.3%)	5 (35.7%)		

Among the 36 people with preoperative score between 0 to 5, 3(8.3%) people had difficult intraoperative outcome. Among the 14 people with preoperative score between 6 to 10, 9(64.3%) people had difficult intraoperative outcome. The difference between preoperative score and intraoperative outcome was statistically significant, (p value<0.001). (Table 26 & figure 21)

Figure 21: Staked bar graph for comparison of intraoperative outcome with preoperative score category (n= 50)

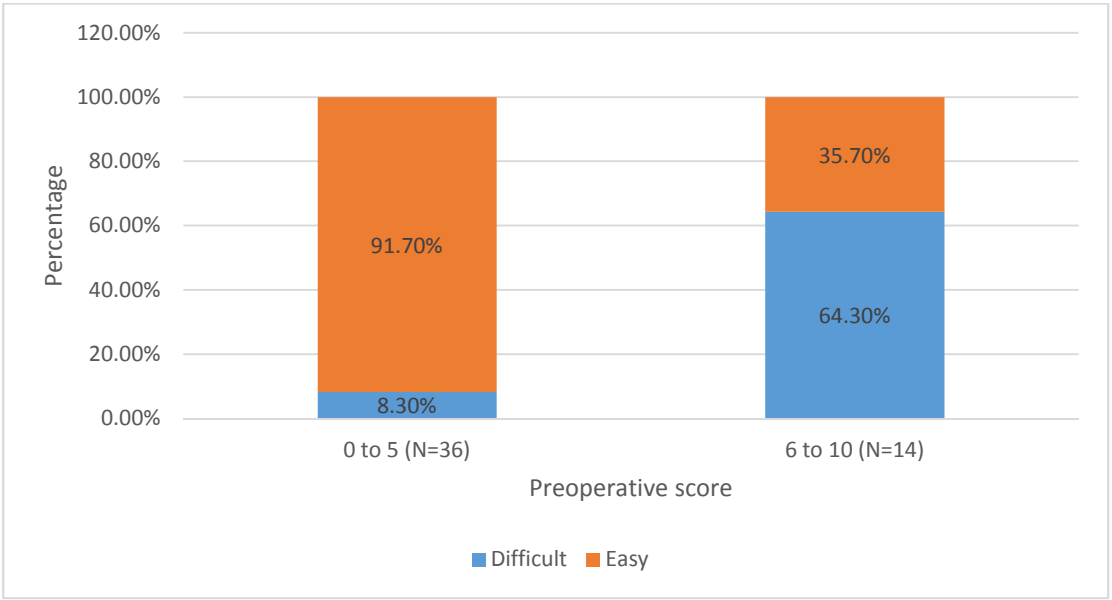

Table 27: Comparison of intraoperative outcome with preoperative score (n=50)

Preoperative score	Intraoperative outcome		Chi square	p value
	Difficult (n=12)	Easy (n=38)		
Difficult (6 To 10)	9 (75%)	5 (13.16%)	17.301	**<0.001**
Easy (0 To 5)	3 (25%)	33 (86.84%)		

Among 12 people with difficult intraoperative outcome, 9 (75%) had difficult (6 to 10) pre-operative score. Among the 38 people with easy intraoperative outcome, 5 (13.16%) had difficult (6 to 10) pre-operative score. The difference between the two methods was statistically significant (p value <0.001). (Table 27)

Table 28: Comparison of intraoperative outcome with preoperative score (n=50)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	75.00%	42.81%	94.51%
Specificity	86.84%	71.91%	95.59%
False positive rate	13.16%	4.41%	28.09%
False negative rate	25.00%	5.49%	57.19%
Positive predictive value	64.29%	35.14%	87.24%
Negative predictive value	91.67%	77.53%	98.25%
Diagnostic accuracy	84.00%	70.89%	92.83%
Positive likelihood ratio	5.70	1.02	15.306
Negative likelihood ratio	0.29	0.06	0.773

To predict intraoperative difficulty, pre operative score had sensitivity of 75.00% (95% CI 42.81% to 94.51%). The specificity was 86.84% (95 CI 71.91% to 95.59%), false positive rate was 13.16% (95 CI 4.41% to 28.09%), false negative rate was 25.00% (95 CI 5.49% to 57.19%), positive predictive value was 64.29% (95 CI 35.14% to 87.24%), negative predictive value was 91.67% (95 CI 77.53% to 98.25%), and the total diagnostic accuracy was 84.00% (95 CI 70.89% to 92.83%).(Table 28).

DISCUSSION

Laparoscopic cholecystectomy has become the gold standard management of gallbladder diseases, but it is technically more demanding than the open cholecystectomy. Greater chances of damage to the common bile duct and surrounding viscera exist. Initially, the complication rate with LC was high but with technological advancement and increase in the expertise, it has now reached a remarkably low level at 2.0- 6.0%.[107] Conversion rate of 7-35% has been reported in literature.[108]

In our study laparoscopic cholecystectomy was performed in 50 patients and different predictive risk factors for difficult laparoscopic cholecystectomy were analysed. Old age, male sex, history of hospitalization, obesity, previous abdominal surgery, palpable gall bladder, and ultrasonographic findings like gall bladder wall thickness, pericholecystic fluid collection, impacted stone were included as risk factors in this study.

The aim of our study was to evaluate a scoring system, which can reliably predict the chances of conversion to the open procedure and the complications during laparoscopic cholecystectomy. Also, it may benefit patients because they can be informed of the possibility of complications and conversion to the open procedure, so that the patient can be mentally prepared and can adjust his or her expectations accordingly. In addition, the surgeon can directly perform the classical open cholecystectomy in the patients with presumed difficult surgery, saving operating time and the conversion rate.

Many studies have attempted to form a scoring system to predict difficult LC, but most of them are complex, use large number of determining factors, and they are

difficult to use in day to day practice.[97, 105, 109, 110] And many of these scoring systems cannot be applied preoperatively.[97]

Male gender as an independent risk factor for difficult laparoscopic cholecystectomy is controversial. Few studies have shown that male sex is a risk factor for difficult LC.[84, 111-116] However, Liu et al., did not notice sex to be associated with considered study.[117] In this present study, male gender was a significant predictor of intraoperative difficult LC.

Age is a risk factor for difficult gallbladder surgery.[38] In our study, majority of the patients belonged to age group below 51years (38 patients) and only 12 belonged to above 51years age group. However, in our study we found no significant correlation between age and the difficult level of surgery. This could be because of the small sample size of the study population and also there was an unequal distribution of the patients into different age group with only 12 cases in >51 years age group with clustering of cases in ≤51 years age group.

Obese patients may have a difficult laparoscopic surgery due to various factors.[82] Port placement in obese patient takes longer time, due to thick abdominal wall. Dissection at the Calot's triangle is also technically difficult due to the obscure anatomy because of excessive intraperitoneal fat and difficulty in the manipulation of instruments through an excessively thick abdominal wall. In our study, we found no correlation between BMI and difficult level of surgery. Surgical expertise of the operating surgeon could be one of the reasons for this discrepancy; as such increased BMI is not a technical problem.

History of hospitalisation in the past was also a preoperative predictor of difficult LC. Among people with prior hospitalisation, 64.3% had difficult LC. Similar results has been concluded in other studies as well.[84, 115, 117, 118]

Abdominal wall scarring was not a predictor of difficult LC according to the data analysis of the present study. All people with abdominal wall scarring had in fact easy intraoperative outcome. No previous studies are available on abdominal wall scarring as a risk factor.

In the present study a palpable gallbladder was considered as a predictor. In contrast to the ideation, there was no statistical significance observed between palpable gallbladder and intraoperative difficult LC. In contrast to present study, Randhawa et al[78], in their study observed that palpable gallbladder was a predictor of difficult LC (p=0.022).

In previous studies, a thick gallbladder was considered as predictor of difficult LC. Schreck P et al[119] in their study had 4.3% conversion rate in people with thick gallbladder. Fried GM et al[84], in their study observed a 5.6% conversion rate. In contrast to above studies, present study's data analysis showed no statistical significance between thick gallbladder and difficult LC.

Previous studies have considered pericholecystic collection of fluid as a predictor of difficult LC.[82] In the present study, among the people with Pericholecystic collection, 55.5% of them had easy LC and 44.4% had difficult LC. It was found to be not statistically significant. Hence, based on the present study pericholecystic collection is not a preoperative predictor of difficult LC.

During LC, stone impacted at the neck of the gallbladder poses problems, because of distention of gallbladder, as is with thick walled gallbladder. It is difficult to grab the neck to perform retraction of the gallbladder to allow dissection at Calot's triangle. Impacted stone was found to be statistically significant in predicting difficult LC in our study. 60% of the people with impacted stones had difficult

intraoperative outcome in the present study. Not many studies are available on this aspect, making the present study unique.

The sensitivity of the scoring system developed in the present study is 75.00% (95% CI 42.81% to 94.51%) and specificity is 86.84% (95 CI 71.91% to 95.59%) Which is very similar to a study done by Jaskiran S et al [78] where the sensitivity and specificity of their scoring system were 75.00% and 90.24%, respectively. Scoring system developed by Nikhil Gupta et al [101] had a sensitivity of 95.74% and specificity of 73.68%.

In the present study, 36 people has preoperative score below 5 predicting easy LC. As predicted 91.7% of them has easy intraoperative outcome. 14 people had score above 6 predicting difficult LC. Of them 64.3% had difficult intraoperative outcome. Hence, this system can be utilised in preoperative period to predict and anticipate the upcoming difficulty and to plan the procedure accordingly.

With the help of accurate prediction, high risk patient may be informed beforehand regarding the probability of conversion and hence they may have a chance to make arrangements accordingly. On the other hand, surgeons also may have to schedule the time and team for the operation appropriately. Surgeons can also be aware about the possible complications that may arise in high risk patients.

Although sample size is small, but the predictors of difficult LC correlated well with previous studies. We may conclude that the scoring system evaluated in our study is a sturdy, reliable and useful benchmark to predict difficult cases. However, the small sample size may be an impediment in attaining complete statistical validity. We propose large scale, multicentric studies to validate the scoring methodology and establish its efficacy.

CONCLUSION

- The current study has been conducted on 50 people undergoing laparoscopic cholecystectomy to evaluate the predictive validity of a structured pre-operative scoring system to predict difficult laparoscopic cholecystectomy.
- The study had included people with an average age of 43.36 ± 9.84 years, with high female preponderance.
- The preoperative score has classified 72% of the study population as probable cases of easy laparoscopic cholecystectomy and 28% were categorized as probable cases of difficult laparoscopic cholecystectomy
- The proportion of people with difficult intraoperative outcome was 24 % among the study population. The proportion of difficult intraoperative outcome was much higher among males, as compared to females. The other factors associated with intraoperative difficulty were prior hospitalization and impacted stone.
- Age of the person, presence of abdominal scar, palpable gall bladder, thick gallbladder, pericholecystic collection and BMI had no association with difficult intraoperative outcome in study population.
- Among the people with preoperative score of 0 to 5, only 3(8.3%) people had difficult intraoperative outcome. Among the people with preoperative score between 6 to 10 only 9(64.3%) people had difficult intraoperative outcome. The difference between pre-operative score and intraoperative outcome was statistically significant, (p value<0.001).
- The current scoring system had a sensitivity of 75% and specificity of 86.84% in predicting difficult laparoscopic cholecystectomy, which makes it a reasonably good scoring system for preoperative risk stratification of subjects.

LIMITATIONS:

1. The sample size of the study was limited. Hence the probability of chance occurrence of many statistical associations was very high.
2. The study is only a descriptive study and no comparison was done with other scoring systems to document the relative performance of the current scoring system.
3. The generalizability of study findings is very limited, as the study was conducted people reporting to a single study center and hailing from limited geographical area. The key differences in the demographic factors and the health system related factors to be kept in mind, while generalizing the study findings.

RECOMMENDATIONS:

1. Further large scale prospective studies are needed to demonstrate the consistency of the performance of the predictive scoring systems in different sub groups of the population.
2. Also there is a need to conduct comparative studies on the same population groups, with the other scoring systems to identify the most efficient scoring system, which is simple, cost effective and with good diagnostic accuracy, especially useful for resource limited settings.

SUMMARY

Laparoscopic cholecystectomy is one of the most common surgical procedures performed in recent times in surgical practice. Various patient and disease related factors can be associated with difficult laparoscopic cholecystectomy. Identifying these patients in the preoperative period, may aid the surgeon in effective risk communication and preoperative preparation to deal with the situation. There are various structured scoring systems in use across the globe, but their utility on Indian subjects is yet to be studied extensively. The current study has attempted to validate a new scoring system, for its utility in risk stratification of people undergoing laparoscopic cholecystectomy. The proportion of people with difficult intraoperative outcome was 24% among the study population. The proportion of difficult intraoperative outcome was much higher among males, as compared to females. The other factors associated with intraoperative difficulty were prior hospitalization and impacted stone. Age of the person, presence of abdominal scar, palpable gall bladder, thick gallbladder, pericholecystic collection and BMI had no association with difficult intraoperative outcome in study population. Among the people with preoperative score of 0 to 5, only 3(8.3%) people had difficult intraoperative outcome. Among the people with preoperative score between 6 to 10, only 9(64.3%) people had difficult intraoperative outcome. The current scoring system had a sensitivity of 75% and specificity of 86.84% in predicting difficult laparoscopic cholecystectomy, which makes it a reasonably good scoring system for preoperative risk stratification of subjects.

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ANNEXURE I – CONSENT FORM

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in study titled **"**TO VALIDATE A SCORING SYSTEM TO PREDICT DIFFICULT LAPAROSCOPIC CHOLECYCTECTOMY: A ONE YEAR CROSS-SECTIONAL STUDY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC, BELAGAVI**"** conducted by Dr. _____, Post Graduate in M.S. General Surgery under the guidance of Dr. _____ M.S Professor, Department of General Surgery, J.N. Medical College, Belgaum under KLE university, Belgaum.

Respected Sir / Madam We request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge and co-operate for clinical examination.

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N.Medical College / Hospital. If you decide to participate you are free to withdraw at any time.

Purpose of the study: The purpose of the study is to validate a scoring system to predict difficult laparoscopic cholecystectomy based on history, clinical examination and sonological investigation.

Procedure Involved:

If you agree to enrol yourself in my study, you will be asked your detailed history. Then you will be clinically examined in detail and routine investigations like CBC, RBS, LFT, Chest X-ray, ECG, USG Abdomen will be done accordingly. Then Intra-operative findings will be noted. Preoperative imaging along with clinical

findings and operative difficulties were assessed and noted down for analyzing the factors predicting difficult laparoscopic cholecystectomy.

Risks:

No additional study related risks and side effects

Benefits:

Results will help the doctors to predict difficult laparoscopic cholecystectomy preoperatively and allow for a better treatment plan (counseling, conversion from laparoscopy to open method, duration of hospital stay and expenses)

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at K.L.E. hospital.

Alternatives:

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with your identity remaining confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation:

In the event of injury related to the study, treatment will be made available through KLES Hospital &MRC, Belgaum. There is no compensation or payment for such medical treatment by law. If you are injured you may contact Dr. Naresh Veeranki, Department of General Surgery, KLES Hospital& MRC, Belagavi -10, Ph. No: 07353972777.

Contact details:

In case you have any queries related to the study, in future or in case of study related injury or illness, you can contact

Dr. _____

Post graduate

Department of General Surgery

KLE Hospital and MRC, Belagavi -590010

Dr. _____

Associate Professor

Department of General Surgery

KLE Hospital and MRC, Belagavi - 590010

If you have any queries about your rights as a study subject, you may call

DR. GANGA PILLI M.D.

Professor,

Department of Pathology,

Chairman, J.N. Medical College Institutional Ethical Committee for Human Subjects Research J.N. Medical College, Belagavi. Ph : 9480275601.

CONSENT STATEMENT

I, Mr/Ms/Mrs. _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights. I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or the Left Thumb Print of Subject :_____

Date:

Witness Name : _____

Signature:_____

Investigators Name:

Signature:_____

Date:

Place : _____

PROFORMA

"TO VALIDATE A SCORING SYSTEM TO PREDICT DIFFICULT LAPAROSCOPIC CHOLECYSCTECTOMY: A ONE YEAR CROSS-SECTIONAL STUDY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC, BELAGAVI**"**

Case No. DOA: DOD:

IP. No.

Name: Age/Sex: Occupation:

Address with phone no. :

PRE PROCEDURE EVALUATION:

Chief Complaints:

History of presenting illness:

Past History:

Family History:

General Physical Examination:

Vitals:

Temperature: Weight:

Pallor

PR: Height:

Icterus

BP: BMI:

Cyanosis

RR:

Clubbing

Edema

Lymphadenopathy:

SYSTEMIC EXAMINATION:

Per Abdomen:

Cardiovascular System:

Respiratory System:

Central Nervous system:

Diagnosis:

INVESTIGATIONS:

CBC	**MR**	**LFT**
ECG:		
Hb%:	Urea:	T.bil:
PCV:	Creatinine:	D.bil:
TC:	Na:	SGOT:
DC:	K:	SGPT:
CXR:		
Platelet:	HCO3:	ALP:
ESR:	Cl:	T.Protein:
PT INR:		S.Alb:
PS:		A:G:

USG report:

Pre – operative score	Intra- op findings and score

PHOTOGRAPHS

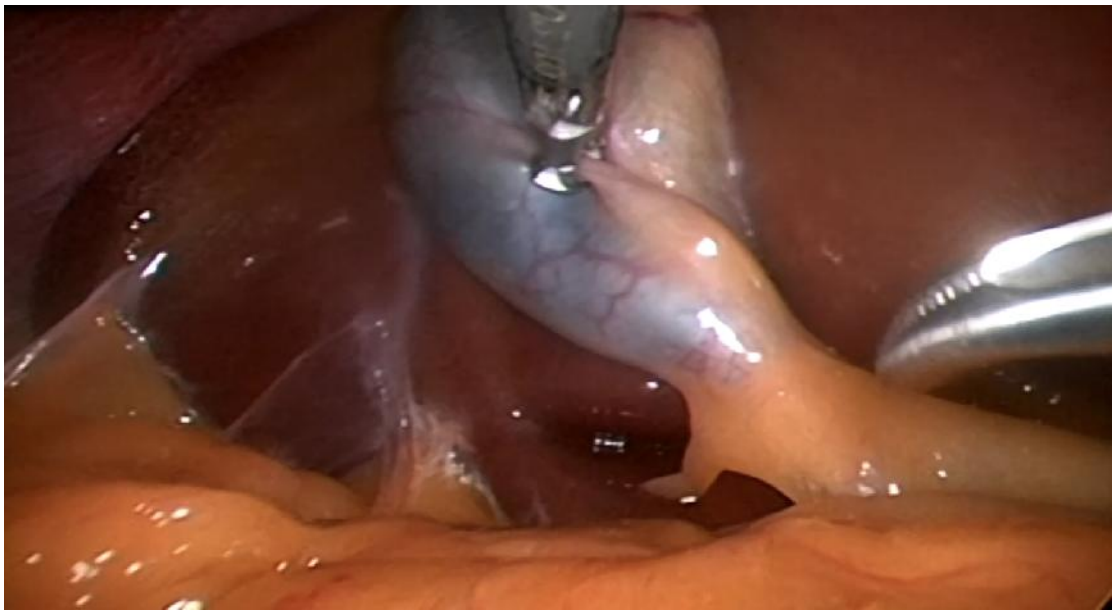

fig 1: thick gallbladder with multiple adhesions

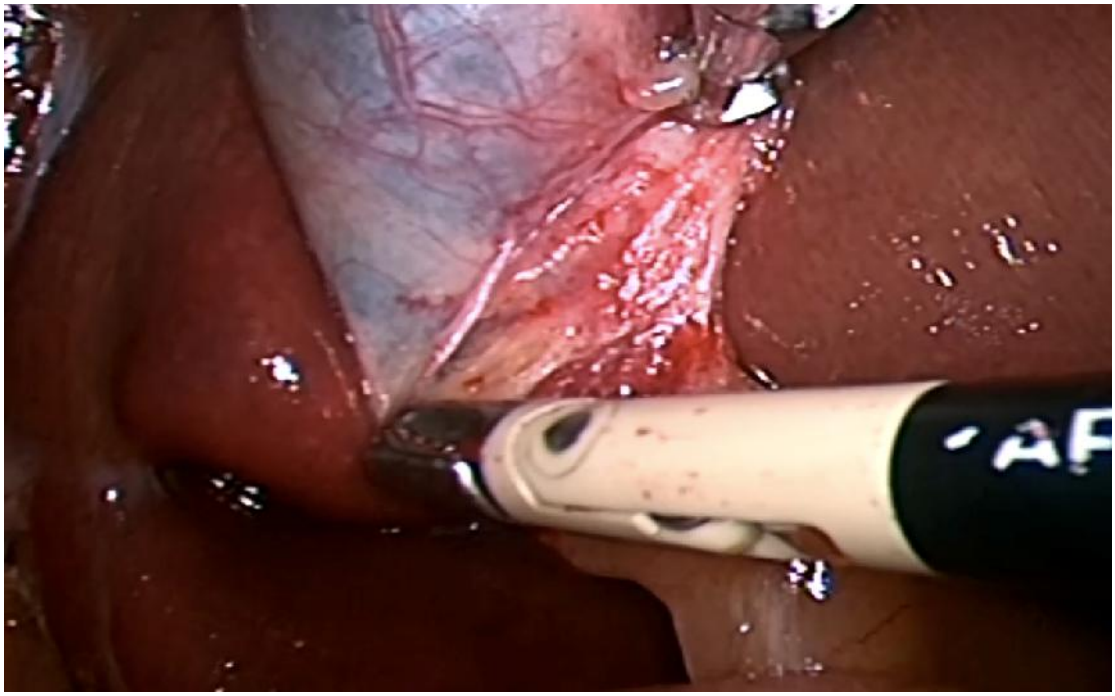

fig 2 : posterior dissection of gallbladder with multiple adhesions

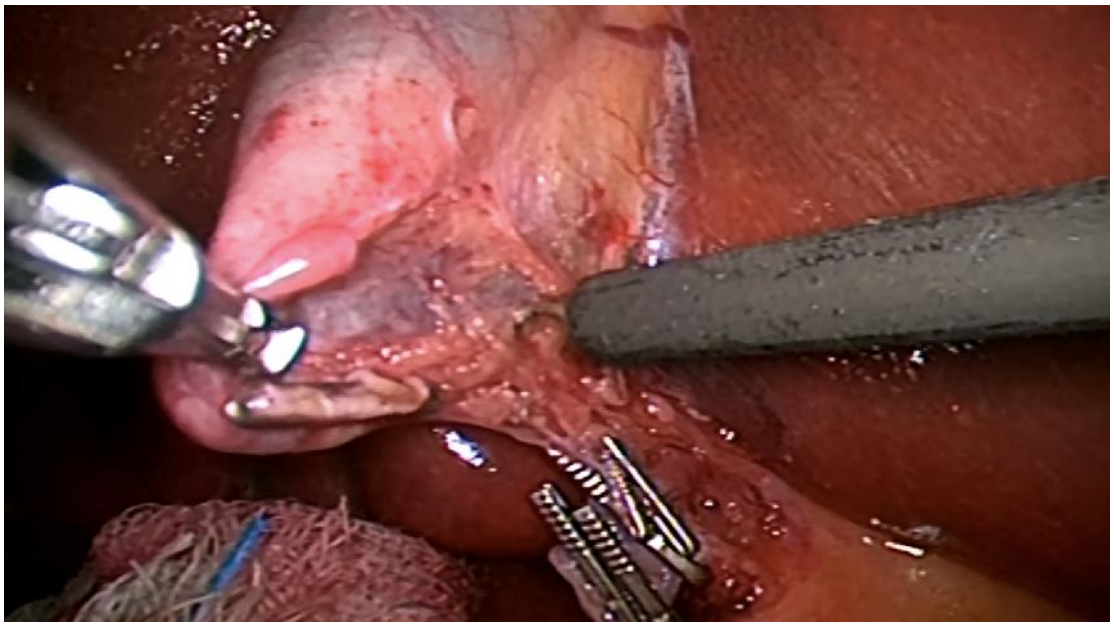

fig 3: dissection of gallbladder with multiple adhesions

SNO	I.P No.	Age	Sex	History of hospitalisation	BMI	Abdominal scar	Palpable gallbladder	Thick gallbladder	Pericholecystic collection	Impacted stone	*Preoperative score*	Intraoperative outcome	Age group	BMI category	Preoperative score
1	782124	55	Male	Yes	21.0	No	No	No	No	Yes	7	Difficult	51 years and above	≤25	Difficult(6 to 10)
2	787120	32	Male	Yes	24.3	No	No	No	Yes	No	6	Difficult	≤50 years	≤25	Difficult(6 to 10)
3	781297	41	Female	Yes	22.7	No	No	No	Yes	Yes	6	Easy	≤50 years	≤25	Difficult(6 to 10)
4	787862	46	Female	Yes	28.1	Yes	No	No	No	No	7	Easy	≤50 years	27.6	Difficult(6 to 10)
5	790125	39	Female	Yes	27.8	No	No	Yes	No	No	8	Difficult	≤50 years	27.6	Difficult(6 to 10)
6	792584	32	Male	No	28.3	No	No	No	No	No	3	Difficult	≤50 years	27.6	Easy(0 to 5)
7	793257	58	Female	No	28.2	No	No	No	No	No	3	Easy	51 years and above	27.6	Easy(0 to 5)
8	794101	31	Female	No	27.9	No	No	No	No	No	2	Easy	≤50 years	27.6	Easy(0 to 5)
9	792444	42	Female	No	22.7	No	No	Yes	No	No	2	Easy	≤50 years	≤25	Easy(0 to 5)
10	794321	39	Female	No	22.3	No	No	Yes	No	No	2	Easy	≤50 years	≤25	Easy(0 to 5)
11	796063	44	Female	No	24.1	No	No	Yes	No	No	2	Easy	≤50 years	≤25	Easy(0 to 5)
12	793128	36	Female	No	25.5	No	Yes	No	Yes	No	3	Easy	≤50 years	25.1 to 27.5	Easy(0 to 5)
13	797861	27	Female	No	24.3	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
14	797848	45	Female	No	22.4	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
15	800128	40	Female	No	24.0	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
16	816851	56	Female	No	22.0	No	No	No	No	No	1	Easy	51 years and above	≤25	Easy(0 to 5)
17	804440	35	Female	No	23.7	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
18	811551	62	Female	No	21.7	Yes	No	No	No	No	2	Easy	51 years and above	≤25	Easy(0 to 5)
19	813357	31	Female	No	23.1	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
20	814135	46	Female	No	24.8	No	No	Yes	No	No	2	Easy	≤50 years	≤25	Easy(0 to 5)
21	815576	30	Female	No	23.6	No	No	Yes	No	No	2	Easy	≤50 years	≤25	Easy(0 to 5)
22	815855	59	Female	No	21.5	No	No	Yes	No	No	3	Easy	51 years and above	≤25	Easy(0 to 5)
23	815902	49	Male	No	24.5	No	No	Yes	No	No	3	Difficult	≤50 years	≤25	Easy(0 to 5)
24	817912	45	Female	No	23.5	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
25	818638	60	Female	No	22.5	No	No	No	No	No	*1*	Easy	51 years and above	≤25	Easy(0 to 5)

SNO	I.P No.	Age	Sex	History of hospitalisation	BMI	Abdominal scar	Palpable gallbladder	Thick gallbladder	Pericholecystic collection	Impacted stone	Preoperative score	Intraoperative outcome	Age group	BMI category	Preoperative score
26	819221	42	Male	No	26.5	No	No	No	No	No	2	Easy	≤50 years	25.1 to 27.5	Easy(0 to 5)
27	821300	51	Female	Yes	23.0	No	Yes	No	Yes	No	7	Difficult	51 years and above	≤25	Difficult(6 to 10)
28	820033	64	Female	Yes	21.5	No	No	No	Yes	No	6	Easy	51 years and above	≤25	Difficult(6 to 10)
29	823177	47	Female	Yes	28.2	No	No	No	Yes	Yes	8	Difficult	≤50 years	27.6	Difficult(6 to 10)
30	823593	44	Male	Yes	23.2	No	Yes	No	No	No	6	Difficult	≤50 years	≤25	Difficult(6 to 10)
31	824107	54	Male	Yes	21.0	No	No	No	No	Yes	7	Difficult	51 years and above	≤25	Difficult(6 to 10)
32	821707	33	Male	Yes	24.3	No	No	No	Yes	No	6	Difficult	≤50 years	≤25	Difficult(6 to 10)
33	826188	39	Female	Yes	22.7	No	No	No	Yes	Yes	6	Easy	≤50 years	≤25	Difficult(6 to 10)
34	826717	48	Female	Yes	28.1	Yes	No	No	No	No	7	Easy	≤50 years	27.6	Difficult(6 to 10)
35	826928	40	Female	Yes	27.8	No	No	Yes	No	No	8	Difficult	≤50 years	27.6	Difficult(6 to 10)
36	898193	33	Male	No	28.3	No	No	No	No	No	3	Difficult	≤50 years	27.6	Easy(0 to 5)
37	829788	56	Female	No	28.2	No	No	No	No	No	3	Easy	51 years and above	27.6	Easy(0 to 5)
38	833016	33	Female	No	27.9	No	No	No	No	No	2	Easy	≤50 years	27.6	Easy(0 to 5)
39	833785	43	Female	No	22.7	No	No	Yes	No	No	2	Easy	≤50 years	≤25	Easy(0 to 5)
40	834719	40	Female	No	22.3	No	No	Yes	No	No	2	Easy	≤50 years	≤25	Easy(0 to 5)
41	835204	46	Female	No	24.1	No	No	Yes	No	No	2	Easy	≤50 years	≤25	Easy(0 to 5)
42	836317	34	Female	No	25.5	No	Yes	No	Yes	No	3	Easy	≤50 years	25.1 to 27.5	Easy(0 to 5)
43	837299	28	Female	No	24.3	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
44	838351	44	Female	No	22.4	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
45	838457	42	Female	No	24.0	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
46	838906	54	Female	No	22.0	No	No	No	No	No	1	Easy	51 years and above	≤25	Easy(0 to 5)
47	839231	36	Female	No	23.7	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
48	839297	60	Female	No	21.7	Yes	No	No	No	No	2	Easy	51 years and above	≤25	Easy(0 to 5)
49	840012	30	Female	No	23.1	No	No	No	No	No	0	Easy	≤50 years	≤25	Easy(0 to 5)
50	840101	47	Female	No	24.8	No	No	Yes	No	No	2	Easy	≤50 years	≤25	Easy(0 to 5)