INTRA OPERATIVE GALLBLADDER SCORING PREDICTS CONVERSION OF LAPAROSCOPIC TO OPEN CHOLECYSTECTOMY: A PROSPECTIVE STUDY

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IN

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KARNATAKA 2020 DocuSign Envelope ID: CCA442E8-133C-4C74, BE77-BAAFC9243BC5 INTRA OPERATIVE GALLBLADDER

<u>SCORING PREDICTS CONVERSION OF LAPAROSCOPIC TO</u> <u>OPEN</u> <u>CHOLECYSTECTOMY: A PROSPECTIVE STUDY"</u>

MASTER OF SURGERY In GENERAL SURGERY

AININE XURE I

6.1.1 INTRODUCTION

• Laparoscopic cholecystectomy is the surgical resection of the gall bladder through laparoscopy. It is the most common method used and preferred by the majority in elective and emergency surgery. Its well-known advantages are smaller incisions, less pain, and early return to work, has made it popular as compared to open.

• Cholecystitis, both acute and chronic, has varying patients and sometimes difficult presentation. This is one of the commonest reasons for admission to hospital with considerable morbidity and mortality depending on the severity of gallbladder disease. quite often, Preoperative and intraoperative findings of the gallbladder are different.

• Hence in 2-15% of cases, conversion from laparoscopic to open cholecystectomy was necessary, which also proved safer.⁽²⁾

• The American association for the surgery of trauma (AAST) scoring system is valid and superior to the 2013 Tokyo classification as it included a greater number of grades of cholecystitis. ⁽³⁾

• Intraoperative G10 scoring system is a scoring system for intraoperative cholecystitis severity which has 10-point and can predict conversion of cholecystectomy from laparoscopic to open. ⁽⁴⁾

6.1.2 INTRAOPERATIVE GALLBLADDER SCORING TABLE

• SEVERITY OF CHOLECYSTITIS	Score	
• APPEARANCE		
• Adhesions < 50% of GB	1	
• Adhesions> 50%, but GB buried	2	
• Completely buried GB	3 (max)	
Distension/contraction		
• Distended GB or contracted shrilled GB	1	
• Inability to grasp without decompression	1	
• Stone > 1 cm impacted in Hartmann's pouch	1	
• Access		
• BMI > 30	1	
• Adhesions from previous surgery limiting surgery	1	
Sepsis and complications		
• Free bile or pus outside the gallbladder	1	
• Fistula	1	
Total possible	10	

cholecystectomy - easy < 2, moderate ($2 \le 4$), difficult ($5 \le 7$), extremely difficult ($8 \le 10$). completion of the procedure and conversion to open is predicted early intraoperatively.

ANNEXURE II

6.2 Need for Study

- Laparoscopic cholecystectomy, declared as the gold standard procedure by the National Institute of Health in 1992. It has many advantages over open, but there are a few other factors yet to be scrutinised, which lead to better surgical choices, performances and clinical outcomes in procedure approach and intraoperative findings, morbidity, duration of surgery and readmission to hospital. The Tokyo guidelines 2018 has extended the capacity of the scoring-grading system and has indicated a few, safe steps, but it is yet to be validated. ⁽⁵⁾
- cholecystectomy procedure cannot be completed in all patients through the laparoscope, and conversion to open is often required. The conversion rate for acute and chronic cholecystitis was reported in many series and ranged from 2 to 20%, with an average of 5%.⁽⁶⁾
- A number of publications have reported new scoring and grading systems ^{.(7)}
- Few of these scores are derived on preoperative clinical findings and imaging but focus only on actual operative findings restricting their use.^(8,9)
- Intraoperative cholecystitis scoring system is precise and quite reproducible in cholecystitis severity grading, and this scoring system is simple, easy to implement, and clinically and operatively relevant.

6.3 Aim and Objective of the study

• AIM:

Intra-operative gallbladder scoring predicts the conversion of laparoscopic to open cholecystectomy.

- **OBJECTIVE:** To Assess the ability of the intra-operative scoring system in terms of
- (1) Severity of cholecystitis
- (2) difficulty of the procedure.
- (3) Ability to estimate the necessity of the open cholecystectomy converting from laparoscopy.

EMBRYOLOGY

- Hepatic bud is an endodermal derivative which arises from the gut at the junction of the foregut and midgut.
 This gives rise to liver and biliary passages.
- \circ Liver primordium on the 25th day give rise to the hepatic diverticulum.
- \circ the bile duct is seen between the duodenum and the hepatic diverticulum.
- **Pars cystica**-bile dgives give rise to pars cystica which forms the gallbladder and cystic duct.
- Hepatic bud proximal to the pars cystica gives rise to the bile duct.
- On the ventral side of duodenum bile duct opens initially.
- Later, The differential growth of the duodenum a causes shift of the bile duct open dorsomedial side. ⁽¹⁰⁾



ANATOMY

- The gall bladder is a pear-shaped, and acts as reservoir of bile.
- located in the visceral undersurface of segment of the right lobe of the liver segments IVB and V.
- **cystic plate** -attached to the liver by connective tissue of liver Glissons capsule.
- It is partly intra peritoneal, with the peritoneum covering the nonhepatic surface and fundus
- Visceral surface is related to the transverse colon and the first and upper part of the second part of duodenum
- Floating gallbladder- gallbladder has its own mesentery; its absence makes it floating/roving and can cause torsion and infarction
- Length-7cm to 10cm
- Width-2.5cm to 3.5cm
- Wall thickness 3mm
- Capacity-can hold 30-60ml of bile as reservoir. ⁽¹¹⁾

Parts of gall bladder :

- 1) Fundus- round shape and projects beyond the liver edge. It is fully covered with peritoneum reflecting from the liver surface
- Body- is between fundus and infundibulum, situated between cystic fossa and transverse colon, duodenum
- 3) Infundibulum-narrowed part between body and neck
- Neck-it is funnel shaped which continues with cystic duct. It lies in the free border of the hepatoduodenal ligament

Hartmann's pouch-it's a normal variant due to dilatation of the infundibulum or neck.It can be acquired because of prolonged resistance to the emptying of the gall bladder.



The gallbladder is made up of 3 layers

- 1) Mucous membrane
- 2) Muscularis
- 3) Serosa

Mucus membrane-

- multiple rugae when in the resting phase.
- Columnar Epithelial cells- have a basal nucleus which lines mucosa. they have an absorptive and secretory functions.
- Lamina propria-made up of loose connective tissue, elastic fibers, mast cell and macrophages with lymphatics.
- Spiral valve of Heister-in neck mucosa is elevated in forms this spiral valve.
- Rokitansky- Aschoff sinuses -found in 40% of normal gallbladder and all inflamed gallbladder. Invagination of epithelium all layers.

Muscularis-

- there is absence of submucosa
- smooth muscles, collagenous tissue, elastic fibers, ganglia form the second layer.
- Ducts of Luschka-smallest bile ducts found in muscle layer in 10% of normal gallbladder.

Serosa/adventitia

• The visceral surface has well-forme serosa which is continuous peritoneum. It has blood vessels and lymphatics.⁽¹²⁾



• <u>Cystic duct</u>

- \circ Extends from the neck of the gall bladder to join common hepatic duct to form
- Common bile duct
- Length- 2cm-4cm (1cm to 6cm)
- Diameter- 1mm to 3mm
- Cystic duct variation courses normally or runs inferior-medially in the hepatic duodenal ligament for low union with a common hepatic duct. or can join the right hepatic duct ⁽¹³⁾



• HEPATOCYSTIC TRIANGLE/HEPATOBILIARY TRIANGLE-

- Superiorly inferior margin of right lobe liver
- Medially common hepatic duct Laterally- cystic duct



CALLOT'S triangle- Earlier JEAN FRANCOIS CALLOT described this as Medially-common hepatic duct,Laterally- cystic duct, Superiorly-cystic artery.

Later modified CALOTS TRIANGLE/HEPATOCYSTIC TRIANGLE contains The right hepatic artery, cystic artery, sometimes aberrant bile duct. All contents in this triangle must be clearly identified before clipping or ligation.⁽¹³⁾

HEPATIC DUCT

RIGHT and LEFT HEPATIC DUCT-

- right hepatic duct- average length 0.9cm. It is formed by the right anterior and posterior sectorial branches.
- left hepatic duct- average length 1.7cm, has longer extrahepatic course after formation, over a quadrate lobe of the liver
- common hepatic duct –
- anterior to the right branch of the portal vein both right and left unite to the common hepatic duct. This junction lies 0.25 to 2.5 cm from the surface of the liver.
- length -1.5cm to 3.5cm



• COMMON BILE DUCT

It's formed by the union of the cystic duct with the common hepatic duct

Length-5cm to 15cm (average 8cm)

Diameter -4mm to 9mm(mean 6mm)

1. Supra duodenal/Upper third - is situated in the free edge of the lesser omentum,

right to the hepatic artery proper and anterior to the portal vein.

- 2. Retroduodenal/middle third-posterior to first part of the duodenum, lateral to the portal vein and anterior to inferior vena cava.
- 3. Intrapancreatic/lower third- posterior to the pancreas in a groove or tunnel to enter 2 parts of the duodenum, where it is joined with the pancreatic duct. In duodenal wall it has oblique course to enter ampula of vater.

Pancreaticobiliary junction-this junction is variable.

Abnormal variations-

- Type 1-major pancreatic duct joins the side of the common bile duct
- Type2- major pancreatic duct is joined from the side by common bile duct the anatomic reason for pancreatitis

HILAR PLATE-it's a connective tissue that separates biliary confluence from liver

SPHINCTER OF ODDI- its terminal part of common bile duct and major pancreatic duct, made up of longitudinal and circular smooth muscle. Length-less than 1cm.⁽¹⁵⁾

o **Blood supply**⁽¹⁶⁾

Arterial supply – cystic artery

It arises as a single branch most commonly from the right hepatic artery. Its present in calots triangle runs parallel, medial and adjacent to cystic duct It can arise less commonly from common hepatic, left hepatic, superior mesenteric and gastroduodenal artery also. If it lies close to the hepatic duct, then the chances of injury to the hepatic duct may increase. It supplies cystic duct and gall bladder.

Venous supply

The Hepatic vein drains the superior surface of gall bladder

One or two cystic veins supply the remaining part of the gall bladder.

Lymphatic drainage

Cystic lymph node of Lund- lymphatics from gall bladder drain to this lymph node in calots triangle, later joins to lymph node of hiatus and posterior pancreatico-duodenal nodes.



FUNCTION OF BILE-

-excretion of bilirubin and cholesterol

-lipid and fat-soluble vitamins are absorbed in the presence of bile

COMPOSITION OF BILE

CHARACTERISTICS	HEPATIC	GALLBLADDER
NA	160	270
K	5	10
CL	90	15
HCO3	45	10
СА	4	25
MG	2	4
BILIRUBIN	1.5	15
PROTEINS	150	200
BILE ACIDS	50	150
PHOSPHOLIPIDS	8	40
CHOLESTEROL	4	18
TOTAL SOLIDS	-	125
PH	7.8	7.2

phospholipids like Lecithin forms 95%.

Cholesterol forms a major solute for bile.

Bile secretion by liver-1litre per day

Water and electrolytes are absorbed.

The gallbladder stores bile during starvation/fasting and releases during meal.

Gallbladder capacity-40-50ml

Gallbladder mucosa has highest absorptive capacity per unit of any other structure in the body.

Factors affecting bile flow

- Hormonal- hormones like secretin, gastrin, CCK, and glucagon increase water and electrolyte secretion.
- Neurogenic-vagal stimulation increases bile secretion and decreases with splanchnic stimulation
- Chemical-dietary fat

BILE –

- o secretion
 - Hepatocyte/liver cells secrete bile.
 - In the liver on a daily basis, bile salts cholic acid and deoxycholic acid are synthesized from cholesterol in the hepatic lobule are secreted to biliary canaliculi.
 - Daily production-500-600mg
 - 2 major pathways
 - 1) A classic pathway produces cholic acid
 - 2) Alternate pathway-synthesis of cheno deoxycholic acid.

Transport

Bile acids are bound to albumin and lipoproteins and circulate. Bile salt uptake into hepatocytes is through space of Disse through 2 mechanism

1)sodium-dependent/cotransport

2)sodium independent

• Secretion is limited by ATP-dependent active bile salt transport across a canalicular membrane.

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-In the intestinal terminal ileum lumen, most of the bile secreted is reabsorbed and transported back in albuminbound form through the portal vein which forms 95% of bile.

-Cycle occurs 6-10times a day.

-daily loss- in faeces 600mg

In the colon, bacterial flora converts cholic acid of chenodeoxy cholic acid into deoxycholate and lithocholate.

Disease involving the distal ileum leads to the loss of bile salt excessively and there is a compensatory increase in the production of bile.



- - Cholesterol is stored in micelles which are phospholipid-cholesterol complex.
 - Bile salts has two portions-outward hydrophilic and inward hydrophobic.
 - -Cholesterol is stored in the hydrophobic end.
 - -vesicles are bilaminar with phospholipids and cholesterol in which majority of cholesterol exists.
 - -crystal precipitation occurs when vesicle capacity gets saturated to transport.
 - -solubility depends on the concentration of cholesterol, bile salts, and phospholipids.

- Bilirubin is formed from heme.
- Majority of heme (80-85%) is derived from degraded RBC by reticuloendothelial cells.



• Gallbladder function :

- Storage and concentration of bile

- Absorption-

It is an active process via Na-Cl transport

Water is passively absorbed to the maximum.

Absorption of calcium is dependent on serum/hepatic bile calcium and bile salt concentration.

Phospholipids, cholesterol, and bilirubin are less absorbed.

Unconjugated bile salts are absorbed more than conjugated bile salt.

- Secretion

glycoprotein and hydrogen ions are secreted by epithelial cells. Mucin secretion -stimulated by prostaglandin. Hydrogen ion released maintains PH to 7.1-7.3.

- Motility

The ampulla is contracted to raise CBD pressure up to10-15 mm.

This facilitates gallbladder filling.

After a meal, CCK stimulates the gallbladder, which contacts and empties bile with simultaneous relaxation of the sphincter of ODDI.

In 30-40min, About 60% of emptying is done.

Refilling occurs in the next 60-90minutes.

o Gall bladder stones/cholelithiasis

- Very common in the western country 10-15% the of the population.
- In India, 15% of the population has gallstones.
- Asymptomatic in 80% of cases.1-2% of asymptomatic patients develop symptoms and need cholecystectomy.
- It's more common in the north (4.3%) compared to south India due to dietary and increased use of USG.
- Cholesterol stones are more in North India, whereas pigment stones are more in south India.
- Incidence-⁽²¹⁾
- Punjabi-7.4% Gujarathis-7.4% Bengali-4.4%
- South India 1.8%



TRIANGLE OF SOLUBILTY





The 3 major components of bile that decide the solubility and stability of cholesterol each can be quantified through molar percentage to show a ratio relative to the other two.

In pictures, only the small area shown in the left lower corner cholesterol is completely soluble, and micellar solution clearly exists below the closed circles .above this, where the area between the open and closed circles, stable though supersaturated cholesterol is seen, and hence only stasis induces crystallization.

Rest of area crystal formation occurs immediately as the cholesterol is supersaturated and unstable significantly $^{(22)}$

- 1) Cholesterol stones
- 2) Pigment stone
- 3) Mixed stone

CHOLESTEROL STONE:

cholesterol is insoluble in water.

Phospholipid vesicles/micelles are secreted by canalicular membrane keeping cholesterol thermodynamically stable.

Depending upon Concentration and which Type of Bile acid phospholipids leads to cholesterol stone.

PIGMENT STONES

contain <30% of cholesterol.

BLACK STONE: contain insoluble bilirubin pigment polymer mixed with calcium phosphate and calcium bicarbonate.

Over 20-30% are black stone. seen in haemolytic conditions like sickle cell disease, Hereditary spherocytosis, and cirrhosis. They are found in the gallbladder as exclusively because of the concentration of bilirubin.

BROWNSTONE: these are more common in the bile duct. Contain calcium bilirubinate, calcium palmitate, calcium stearate and cholesterol.

Cholesterol concentration is responsible for this colour. Bacterial infections and bile stasis biliary motility disorders leads to the formation of stone in the bile duct.Bacterial beta-glucuronidase deconjugates bilirubin diglucuronide, and insoluble unconjugated bilirubinate precipitates.

A Foreign body such as endoprosthesis/stents or parasites like ASCARIS LUMBRICOIDES and CLONORCHIS SINESIS.

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cholesterol stones



Black stone



Brown stone

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- Age more than 40years
- o Estrogens

The female sex a has 2-3times higher risk compared to men Pregnancy-risk increases with the number of pregnancies OCPs-rich in estrogen

- o Genetic/ethnic variation
- \circ High fat, low fiber diet
- o Obesity
- o Hyperlipidemia
- o Bile salt loss (ileal disease/resection/Crohn's disease)
- o Cystic fibrosis
- o Anti hyper lipidemic drugs
- o Impaired gallbladder emptying
 - Truncal vagotomy
 - Type 1 diabetes
 - Octreotide
 - TPN
 - Starvation or rapid voluntary weight loss
- o Pigment stone
 - Hemolytic disease Biliary stasis Biliary infection

- Asymptomatic in 80% cases
- o 1-2% of asymptomatic cases develop symptoms requiring cholecystectomy.
- Epigastric pain/right upper quadrant pain radiating to back, either Colicky or dull aching type present in 10-25%. pain may last for minutes to hours.
- o Dyspepsia
- o Flatulence
- \circ Food intolerance to fat
- Alteration in bowel frequency
- $\circ \quad \text{Jaundice if stone migrates to CBD}$
- Acute cholecystitis
- Chronic cholecystitis

- Biliary colic
- Acute calculous cholecystitis-calculous or gangrenous or empyema gallbladder, severe abdominal pain and tenderness in the right subcostal region- Murphy's sign- fever
- Chronic calculous cholecystitis- repeated episodes of pain right subcostal region with or without fever and vomiting.
- Empyema gallbladder-
- Mucocele-heaviness with the palpable gallbladder.
- Perforation of gallbladder-with localised collection abscess or septic peritonitis
- Biliary obstruction
- Acute cholangitis- Charcot's triad fever with chills/rigours, transient jaundice, and upper abdominal pain.
- Acute pancreatitis-gallstone-induced biliary pancreatitis
- Intestinal obstruction (gall stone ileus)
- Gallbladder carcinoma.⁽²⁴⁾

• INVESTIGATIONS :

Blood investigations

Complete haemogram, Liver function test, Renal function test with serum electrolytes Serum amylase and lipase. Coagulation parameters like prothrombin time (PT)/ aPTT.

- Xray abdomen plain-10% of stones are radio-opaque
- **USG abdomen and pelvis**⁽²¹⁾-high sensitive 96%, rapid and noninvasive method, detects stones larger than 1-2mm, can detect CBD stones and dilatation of ducts.

Findings are- gallstones or sludge.

Gallbladder wall thickening >2-4mm

Gallbladder distension (diameter >4cm, length >10cm)

Pericholecystic fluid

Air in gallbladder-from perforation

Sonographic Murphy sign (86-92% sensitivity,35% specific)-pain when probe pressed directly on the gallbladder.

In chronic calculous cholecystitis- Wall echo shadow (WES)/double arc sign-two echogenic arcs of WES complex represent adjacent gallbladder.

Wall, echogenic gallstones which are separated by thin layer of anechoic bile.

Computed tomography (CT) and MRI- considered if USG is unequivocal and in cases of stones in gallbladder neck/cystic duct/gangrenous type/perforation or abscess.

DocuSign Envelope ID: 0DF9F164-D13D-4AD	(moderate)	Grade III (severe)
 [•]No criteria for grade II or III Acute cholecystitis in a previously healthy patient with no organ dysfunction and with mild inflammation of the gallbladder 	Any of the following conditions: [•]Leukocytosis >18,000/mm3 • Palpable tumor in the right upper quadrant • Symptom duration > 72 h • Marked local inflammation (gangrenous cholecystitis, pericholecys- tic abscess, liver abscess, liver abscess, bile peritonitis, emphysema- tous cholecystitis)	 Any of the following organ dysfunctions: [•]Cardiovascular: Low blood pressure with need for 5 μg/kg/min of dopamine or norepinephrine Neurologic: decline in alertness. Respiratory: PaO2/FiO2 > 300 Kidney: oliguria or creatinine > 2.0 mg/dl Liver: INR > 1.5 Hematologic: platelets < 100,000/mm³

TOKYO CONSENSUS GUIDELINES FOR SEVERITY GRADING OF ACUTE CHOLECYSTITIS-2018⁽²⁵⁾

Indications

- 1) Symptomatic cholelithiasis causing
- -Biliary pain- repeated attacks
- -Mucocele
- -Choledocholithiasis with cholestasis
- -Biliary pancreatitis
- Gallstone ileus
- 2) Calculous cholecystitis-Acute/Chronic,
- Empyema, Perforation, Gangrene
- 3)Gallbladder polyp more than 10mm
- And in young more than 5mm.

CONTRAINDICATIONS

- The patient who are not eligible for general anaesthesia
- Portal hypertension
- Coagulopathy- sever
- o Gallbladder cancer

CONVERSION FROM LAPAROSCOPY TO OPEN CHOLECYSTECTOMY

- Previous history of multiple surgeries- difficulty in accessing peritoneal cavity
- Acute cholecystitis-severe grade inflammation leading to soft friable tissue, dense adhesions and oedema.
- o Acute pancreatitis-
- Abnormal anatomy
- Cirrhosis of the liver
- Pregnancy-3 trimester
- Morbid obesity
- Generalised peritonitis
- Septic shock due to cholangitis
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• General anaesthesia

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- Supine -Reverse Trendelenburg position (15degree head-up tilt) with left lateral tilt (15-20)
 Bowel and omentum will move inferior and medially out of the operative site
- Left of patient- Operating surgeon

camera surgeon

o Right of the patient-assistant surgeon



- A 10mm port in the infraumbilical region for the camera
- A 10mm port in midline in epigastrium

Right subcostal region ports

- o 5mm in in midclavicular line
- o 5mm in anterior axillary line

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- Created by open Hasson technique/closed Verses technique
- Open technique- 1cm transverse incision is made infraumbilically, subcutaneous fat retracted, midline fascia incision of 1cm taken and peritoneum identified and opened.
- o confirmed with the introduction of a finger which goes freely into the abdominal cavity
- o blunt Hasson trocar is introduced
- o laparoscope camera is introduced
- O co2 insufflation-12-14mm of h20

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Figure 7.5 The umbilical cicatrix is grasped with a tissue-grasping forceps (e.g. Littlewood's) and everted.



Figure 7.6 A curved subumblilical incision is made.



Figure 7.7 The skin is retracted to reveal the junction of the stalk and the linea alba.



Figure 7.8 A small vertical incision is made in the junction using an 11 bladed scalpel.



Figure 7.9 A blunt, long haemostat is used to enter the peritoneum and enlarge the incsion in the umbilical stalk.



Figure 7.10 A blunt primary trocar and cannula are inserted and their position is confirmed with the laparoscopic camera before insufflation.

The peritoneal cavity is inspected for

- 1) Detection of any unwanted or unexpected trauma that occurred during the insertion
- 2) Additional abdominal pathology like adhesion from previous surgery, other organ diseases which may
- or may not be detected preoperatively.
- 3) Assessment of the feasibility of the laparoscopic cholecystectomy

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In Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E Cholecystitis severity	
•	
Appearance	score
• Adhesions < 50% of GB	1
• Adhesions> 50% but GB buried	2
Completely buried GB	3
Distension/contraction	
• Distended GB or contracted shrilled GB	1
• Inability to grasp without decompression	1
• Stone > 1 cm impacted in Hartmann's pouch	1
• Access	
• BMI > 30	1
• Adhesions from previous surgery limiting surgery	1
Sepsis and complications	
• Free bile or pus outside the gallbladder	1
• Fistula	1
Total possible	10

Depending upon intra operative assessment of gallbladder grading of difficulty is 0 assessed.

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E O STEPS IN LAPAROSCOPIC CHOLECYSTECTOMY

- Fundus is first elevated and retracted in the cephalad direction and kept in the same.
- o Adhesions around the body/infundibulum/neck are peeled
- **Flag technique-** Infundibulum is grasped laterally and lifted to the right and inferior direction to show the anterior aspects of the calots triangle

anteromedially infundibulum is held and retracted to expose the posterior aspect of the calots triangle

• CALOT'S TRIANGLE DISSECTION

-dissection on the left side of the infundibulum done bluntly

-dissection around the neck with medial retraction of the Hartman pouch is carried

-cystic duct is isolated-always HUG THE GALLBLADDER- TO AVOID INJURY TO DUCT.

• Critical view of safety-described by STRASBERG

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E - The triangle of calors is dissected free of an ussue except

The cystic duct and cystic artery, and the base of the liver are exposed.

- o Cystic duct identified and clipped-2clips on cystic site and one gall bladder site and cut
- Cystic artery identified and 2 on gallbladder site and one on cystic site clipped and cut
- Resection of the gallbladder from the liver bed using a hook or scissors, bipolar cautery, or harmonic scalpel, the gallbladder is detached from the liver bed
- o complete hemostasis achieved
- \circ gallbladder extraction through a 10mm port at the epigastric region.
- \circ After extraction, final inspection and irrigation were done
- Trocars are removed only under the vision
- Ports are closed with vicryl 2.0.
- \circ Ryle's tube was placed in a 5mm port to drain any collection or bleeding⁽³⁰⁾

INSTITUTIONAL ETHICAL COMMITTEE(IEC) B.L.DE (DU) SHRI B.M PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, VIJAYAPUR.

Respected sir/madam

INTRA-OPERATIVE GALL BLADDER SCORING PREDICTS CONVERSION OF LAPAROSCOPIC TO OPEN CHOLECYSTECTOMY: A PROSPECTIVE STUDY.

I, Dr Krishna Prasad S V, P.G in general surgery, regarding the dissertation – INTRA OPERATIVE GALL BLADDER SCORING PREDICTS CONVERSION OF LAPAROSCOPIC TO OPEN CHOLECYSTECTOMY: A PROSPECTIVE STUDY, was asked about FINANCIAL DISCLOSURE SHEET. It is not applicable to my dissertation as this is an observational study, and there is no need for financial expenditure of any kind for this study.

Your sincerely

Dr Krishna Prasad S V,

P.G in general surgery

ANNEXURE V

6.4.1 RESEARCH DESIGN

• Design: Prospective Observational study

6.4.2 RESEARCH HYPOTHESIS

• Intra-operative gallbladder scoring can predict the conversion from laparoscopic cholecystectomy to open cholecystectomy.

6.5 DATA COLLECTION

- All cases planned for laparoscopic cholecystectomy in BLDE (DEEMED TO BE UNIVERSITY), SHRI B M PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, VIJAYAPUR.
- Period of study from JANUARY 2021 TO JULY 2022.
- Components of the G10 scoring system included: the appearance of gallbladder intraoperatively, whether shrilled or distended, access difficulty and intraperitoneal sepsis presence-pus or biliary peritonitis and/or a cholecysto-enteric fistula.
- The patients will be explained in detail about the procedure.
- Data collection will include -
 - 1. Elective or Emergency Laparoscopic cholecystectomy surgery.
 - 2. Age, sex, and socio-economic status.
 - 3. The operative time. 4. BMI.

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E 0.5.1 STUDY DESIGN

• Prospective Observational study

6.5.2 SAMPLE SIZE

With the anticipated Proportion of conversion occurring in patients with G10 scores of \geq 5 scores, 33% ^(ref), the study would require a sample size of 85 patients with a 95% confidence level and 10% absolute precision.

Formula used

$$n = \frac{z^2 p^* q}{d^2}$$

•

Where Z=Z statistic at α level of significance

 d^2 = Absolute error

P= Proportion rate

q= 100-p

STATISTICAL ANALYSIS

- The data obtained will be entered in a Microsoft Excel sheet, and statistical analysis will be performed using a statistical package for the social sciences (Verson20).
- Results will be presented as Mean (Median) ±SD, counts and percentages and diagrams. For normally distributed continuous variables between two groups will be compared using The Independent t-test for not normally distributed variables Mann Whitney U test will be used.

Pearson/Spearman's correlation will be used to find the relationship between the variables.

• ROC Curve will be performed to assess the precision of the G10 scoring system to predict laparoscopic cholecystectomy converting to open cholecystectomy.

7.2.3 INCLUSION CRITERIA-

All elective and emergency laparoscopic cholecystectomy surgery

7.2.4 EXCLUSION CRITERIA –

- Carcinoma gallbladder.
- Cholangiocarcinoma.
- Perihilar cholangiocarcinoma.



Mild degree <2 cholecystitis





Adhesion < 50%

well distended GB



GANGRENOUS GB WITH ADHESION>50%



STONE >1.5CM IN CYSTIC DUCT

RESULTS

AGE YEARS

	Frequency	Per cent
<= 27	19	21.3
28 - 34	17	19.1
35 - 45	21	23.6
46 - 58	15	16.9
59+	17	19.1
Total	89	100.0



Age 35-45 had the highest number of 21 cases with 23.6%, 18-27 years was seen in 119 cases at 21.3% and 46-58 years in 16.9%, 59+ was seen in 19.1% cases.

GENDER

	Frequency	Per cent
FEMALE	59	66.3
MALE	30	33.7
Total	89	100.0

Out of 89 cases- 59 cases were female seen in 66.33% and male cases 30 in 33.7%

SOCIOECONOMIC_GROUP

	Frequency	Per cent
LIG	44	49.4
MIG	44	49.4
UIG	1	1.1
Total	89	100.0

SURGEON

SUNGLON		
	Frequency	Per cent
Ι	10	11.2
II	13	14.6
III	12	13.5
IV	27	30.3
V	27	30.3
Total	89	100.0

LAPAROSCOPIC CHOLECYSTECTOMY

	Frequency	Per cent
YES	89	100.0

CONVERTED TO OPEN

	Frequency	Per cent
NO	86	96.6
YES	3	3.4
Total	89	100.0

ELECTIVE

	Frequency	Per cent
NO	0	0
YES	89	100.0
Total	89	100.0

EMERGENCY

	Frequency	Per cent
NO	89	100.0

All 89 were Elective cases

86 cases were completed laparoscopically with 96.6% an

3 cases were converted to open cholecystectomy with 3.4%

ADHESIONS<50%

Frequency Per cent

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E	yes	45	50.6
	no	44	49.4
	Total	89	100

ADHESIONS >50%

Т

	Frequency	Per cent
yes	44	49.4
no	45	50.6
Total	89	100

COMPLETELY BURIED GB

	Frequency	Per cent
no	81	91.1
Yes	8	8.9
Total	89	100

DISTENDED/SHRILLED GB

	Frequency	Per cent
yes	4	4.5
no	85	95.5
Total	89	100.0

INABILITY TO GRASP WITHOUT DECOMPRESSION

	Frequency	Per cent
no	61	68.5
yes	28	31.5
Total	89	100.0

STONE>1CM IN HARTMAN POUCH

	Frequency	Per cent
no	78	87.6
Yes	11	12.4
Total	89	100.0

BMI>30

Divit/50		
	Frequency	Per cent
Valid no	68	76.4
Yes	21	23.6
Tota	89	100.0

ADHESIONS FROM PREVIOUS SURGERY

	Frequency	Per cent
	70	78.7
	19	21.3
Total	89	100.0

SEPSIS_FREE BILE_PUS

	Frequency	Per cent
no	83	93.3
Yes	6	6.7
Total	89	100.0

FISTULA

Frequency	Per cent
89	100.0

TOTAL SCORE 10

	Frequency	Per cent
2	26	29.2
3	29	32.6

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E	4	18	20.2
	5	9	10.1
	6	3	3.4
	7	1	1.1
	8	2	2.2
	9	1	1.1
	Total	89	100.0

Mild <2

Mild <2		
	Frequency	Per cent
NO	59	66.3
YES	30	33.7
Total	89	100.0

Moderate 3-4

	Frequency	Per cent
NO	46	51.7
YES	43	48.3
Total	89	100.0

Difficult 5-7

	Frequency	Per cent
NO	75	84.3
YES	14	15.7
Total	89	100.0

Extreme difficult 8-10

Frequency Per cent

DecuSian Envolope ID: 0DE0E164 D13D 4AD6 853A 3A357A2E768E			1
	NO	86	96.6
	YES	3	3.4
	Total	89	100.0

- Mild < 2degree was seen in 30 cases with 33.7%,
- moderate degree 3-4 in 43 cases, 48.3%,
- difficult 5-7 seen in 14 cases 15.7%
- extreme difficulty 8-10seen in 3 cases 3.4%

OPERATIVE TIME/MIN

		Per
	Frequency	cent
<=	21	23.6
70		
71 -	20	22.5
80		
81 -	19	21.3
90		
91 -	16	18.0
105		
106+	13	14.6
Total	89	100.0

An operative time of 70min was seen in 21 cases with 23.6%.

71-80 min in 22.5%,81-90 min in 19cases with 21.3%.

90-105min in 16 cases 18.0% and 106+ min in 14.6% in 13 cases.

	Frequency	Per cent
<= 66	20	22.5
67 - 70	27	30.3
71 - 72	9	10.1
73 - 80	19	21.3
81+	14	15.7
Total	89	100.0

HEIGHT

	Per cent	
<= 156	23	25.8
157 - 158	17	19.1
159 - 162	21	23.6
163 - 165	12	13.5
166+	16	18.0
Total	89	100.0

BMI

	21111	
	Frequency	Per cent
<= 24.14	18	20.2
24.15 - 26.56	21	23.6
26.57 - 28.34	15	16.9
28.35 - 31.00	19	21.3
31.01+	16	18.0
Total	89	100.0

Association between DIAGNOSIS and BMI									
				BMI			Total		
				26.57	28.35				
		<=	24.15 -	-	-				
		24.14	26.56	28.34	31.00	31.01+			
DIAGNOSIS	ACUTE	1	1	1	2	2	7		
	CALCULOUS								
	CHOLECYSTITIS								
	CHOLELITHIASIS	12	17	11	14	10	64		
	CHRONIC	5	3	3	2	4	17		
	CALCULOUS								
	CHOLECYSTITIS								
	MIRIZZIS	0	0	0	1	0	1		
	SYNDROME							0.8	
Total		18	21	15	19	16	89		

BMI value was between 24.15-26.56 in 21 cases, 19 cases had 28.35-31, and 16 cases >31.01

	DIAGNOSIS *		OPERATIVE TIME in MIN						
			OPERATI	VE TIME i	n MIN		Total	P value	
					91 -				
		<= 70	71 - 80	81 - 90	105	106+			
NOSIS	ACUTE	2	0	1	2	2	7		
	CALCULOUS								
	CHOLECYSTITIS								
	CHOLELITHIASIS	17	19	13	12	3	64		
	CHRONIC	2	1	5	2		17		
	CALCULOUS					7			
	CHOLECYSTITIS								
	MIRIZZIS	0	0	0	0	1	1		
	SYNDROME							0.07	
		21	20	19	16	13	89		

s table, Chronic calculous cholecystitis requires more Operative time

acute calculous cholecystitis/cholelithiasis, which is statistically significant (p-value 0.007).

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0	Statistics

	AGE				OPERATIVE	TOTAL
	_YEARS	WEIGHT_KG	HEIGHT_CM	BMI	_TIME_MIN	SCORE_10
Ν	89	89	89	89	89	89
	0	0	0	0	0	0
Mean	41.69	71.61	159.26	26.9804	88.97	3.44
Std. Error	1.608	1.508	1.364	0.44184	2.345	0.157
of Mean						
Median	39.00	70.00	160.00	28.0000	85.00	3.00
Mode	60	70	158	26.56	80^{a}	3
Std.	15.173	14.230	12.867	4.16833	22.120	1.477
Deviation						
Variance	230.218	202.491	165.557	17.375	489.306	2.181
Skewness	0.473	2.978	-7.052	-0.443	0.930	1.499
Std. Error	0.255	0.255	0.255	0.255	0.255	0.255
of						
Skewness						
Kurtosis	-0.773	20.400	60.234	-0.314	0.849	2.729
Std. Error	0.506	0.506	0.506	0.506	0.506	0.506
of						
Kurtosis						
Range	62	120	122	17.60	105	7
Minimum	18	45	50	18.20	45	2
Maximum	80	165	172	35.80	150	9

ADHESIONS > 50 * CONVERTED			Р						
	TO_OPEN			value					
		CONVERTED							
		TO_O	PEN	Total					
		NO	YES						
ADHESION S <50	0	43	3	46					
	1	43	0	43					
Total		86	3	89	0.06	Not signific	cant		
		CONVEI	RTED_			Highly significant, Completely buried gallbladder has a high probability of			
		TO_OPEN		Total	0.001	converted t	to open		-
D	IAGN	NOSIS		CONVER	TED TO	O OPEN	-		
				CONVI	ERTED_	TO_OPEN	Total	Р	
				NO		YES		value	Significant
DIAGNOSIS	C CH	ACUTE CALCULO OLECYST	US TITIS	6	1		7		Yes chronic
	CH	OLELITHI	ASIS	64		0	64		cholecystitis
	C CH	CHRONIC CALCULO OLECYST	C US TITIS	15	2		17	0.03	Have a probability to covert
	S	MIRIZZIS SYNDROM	S 1E	1	0		1		to Open
Total				86		3	89		

	Iona IC			-8534-3435	74257685				
OPEN Crosstabulation									
		CONVE	RTED_						
		TO_C	OPEN	Total					
		NO	YES						
ADHESIONS	0	43	3	46					
<50									
	1	43	0	43					
Total		86	3	89	0.06	Not significant			
		CONVE	RTED_						
		TO_C	OPEN	Total					
		NO	YES						
OMPLETEL	0	81	0	81					
Y BURIED									
GB									
	3	5	3	8					
						Highly significant,			
Total		86	3	89		Completely buried gallbladder			
						has a high probability of			
					0.001	converted to open			

DocuSign Er	velope ID: 0DF9F164-D13D	-4AD6-	853A-3A35	7A2F768E		D	
			TO	OPEN	Total	r value	
			NO	YES		, and	
	DISTENDED/	0	4	0	4		
	SHRILLED GB						
		1	82	3	85		
	Total		86	3	89	0.8	Not significant
			CONV	ERTED			
			TO C	OPEN	Total		
			NO	YES			
	INABILITY TO	0	61	0	61		
	GRASP						
	WITHOUT						
	DECOMPRESSI						
	ON						Highly significant
		1	25	3	28		inability to grasp
	Total		86	3	89		without
						0.02	decompression

DocuSign En	velope ID: 0		AD6-853A-3A357A2F768	BE	P value	
		NO	YES		i varoo	Significant
NE >1CM ARTMAN OUCH	0	77	1	78		high chances of conversion if more than 1 cm
	1	9	2	11		in Hartman's
Total		86	3	89	0.03	pouch
		CONVER	FED_TO_OPEN	Total		
		NO	YES			
HESIONS	0	70	0	70		
FROM						significant
EVIOUS						high chances of
RGERY		_				conversion if
	1	16	3	19		adhesions from
Total		86	3	89	0.09	previous surgery

Regression Statistics					
Multiple R	0.98036294				
R Square	0.961111495				
Adjusted R Square	0.956125789				
Standard Error	0.309323029				
Observations	89				

ANOVA					
	df	SS	MS	F	Significance F
Regression	10	184.4470149	18.44470149	192.7734073	1.06471E-50
Residual	78	7.463097411	0.095680736		
Total	88	191.9101124			

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	ents	d Error	t Stat	value	95%	95%	95.0%	95.0%
	2.19385	0.20847	10.5232	1.2577	1.77881	2.60890	1.77881	2.60890
	7655	6714	7436	5E-16	2401	291	2401	291
	-		-		-	-	-	-
	0.90769	0.12519	7.25019	2.6226	1.15694	0.65845	1.15694	0.65845
NS less than 50	9186	6527	4634	9E-10	6324	2048	6324	2048
					-		-	
	0.06235	0.06188	1.00759	0.3167	0.06084	0.18555	0.06084	0.18555
NS more than 50	3915	365	9172	6251	6969	4798	6969	4798
	0.50260	0.06200	8.10528	5.8831	0.37915	0.62605	0.37915	0.62605
ELY_BURIED_GB	4405	945	7201	6E-12	3072	5738	3072	5738
	0.72476	0.16524	4.38589	3.5725	0.39578	1.05375	0.39578	1.05375
ED_SHRILLED_GB	8512	9766	7354	6E-05	15	5525	15	5525
Y_TO_GRASP_WITHOUT	0.73883	0.08126	9.09175	7.1632	0.57704	0.90061	0.57704	0.90061
RESSION	2436	4021	3376	9E-14	8198	6674	8198	6674
ore than 1CM IN	0.62188	0.11014	5.64588	2.5543	0.40259	0.84117	0.40259	0.84117
N POUCH	309	8063	3105	7E-07	5141	1039	5141	1039
	0.93675	0.08657	10.8198	3.4375	0.76439	1.10911	0.76439	1.10911
than 30	6381	7968	0094	9E-17	2887	9875	2887	9875
NS FROM PREVIOUS	0.95217	0.08643	11.0160	1.4630	0.78009	1.12425	0.78009	1.12425
	1694	5063	3522	6E-17	2703	0685	2703	0685
	0.99252	0.14832	6.69132	3.0276	0.69722	1.28782	0.69722	1.28782
REE BILE_PUS	1779	9707	1637	7E-09	0016	3541	0016	3541
				#NUM				
	0	0	65535	!	0	0	0	0

- The regression analysis displays a significant relationship between the independent variable and dependent variables.
- > In the present analysis, The gall bladder score is significantly affected by
 - Adhesions less 50(Beta coefficient =-0.90 p=<0.01),
 - Completely buried gall bladder GB (beta coefficient=0.5,p=<0.01),
 - ♦ Distended shrilled GB (Beta coefficient =0.7,p=<0.01),
 - ♦ Inability to grasp (beta cofficient=0.7,p=<0.01),
 - stone more than 1 cm (beta cofficient=0.6, p < 0.01),
 - BMI more than 30 (beta coefficient = 0.93, p=<0.01),
 - Adhesions from previous surgery (beta coefficient =0.95,p<0.01)
 - sepsis pus in bile (beat coefficient =0.9,p<0.01).

This concludes that the following factors affect the Total GB score.

Gallbladder disease has a mortality rate of 0.45% to 6%, and cholecystectomy is one of the most common procedures, which requires hospital admission. ⁽³¹⁾

It requires experienced surgeons and demands meticulous technique while performing surgery to achieve less complication rate. ⁽³²⁾

Longer duration of surgery with bile or stone spillage and conversion to open can make laparoscopic cholecystectomy a challenging procedure sometimes.

Preoperatively it's very difficult to predict. Currently, there is no standard, reliable scoring system to predict this difficulty. ⁽³³⁾

In our study, we found higher the severity of cholecystitis, the chances of difficulty in proceeding and conversion from laparoscopy to open increased, which often couldn't be predicted preoperatively as compared with a study conducted by Ewen Griffith et al. in the utilisation of an operative difficulty grading scale for laparoscopic cholecystectomy studied the Nassar scale. In this study, they found higher difficulty grades in surgery with a poor postoperative outcome, increased duration of stay with a median of 0-4 days, and 30 days complication rate7.6-24.4% as difficulty raised from grade I to IV. The conversion rate and 30-day mortality rate were high as severity increased. (34)

In a similar study conducted by Reshma Bharamgoudar et al., the development and validation of a scoring tool to predict the operative duration of elective laparoscopic cholecystectomy studied important factors that increased operative hours>90min, whereas, in our study, we found operative hours increased to > 88.97min.

Ten factors like ASA, age, previous surgical admissions, BMI, GB wall thickness, and CBD diameters were significant factors which independently affected operative time90.the risk score of these factors had AUROC 0.708(se=0.013, p<0001). The scoring tool was significantly predictive of the long duration of surgery, and our study had Completely buried GB - 5 cases(p < 0.001 very significant) Inability to grasp -25 cases(p< 0.02) Stone greater than 1cm in Hartman pouch in 9 cases (p< 0.03 highly significant).⁽³⁵⁾

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E vivex multify et an nau studieu 323 patients to assess unfficult laparoscopic cholecystectomy factors in a study A comprehensive predictive scoring method for difficult laparoscopic cholecystectomy analysed elderly patients, males, recurrent cholecystitis, obesity, previous surgery history, preop ERCP, abnormal liver function test and pancreatic function test, the appearance of gallbladder-like distended or shrilled, intra peritoneal adhesions, anatomical structure abnormality or distortions and cirrhosis.

AUCROC analysis of 0.956 with a difficulty level score above 9 had a sensitivity of 85% and specificity of 97.8%, concluded that predicting difficulty in laparoscopic cholecystectomy is possible with their scoring system.

As compared to the above study, In the present analysis, The gall bladder score is **significantly affected** by Adhesions < 50 (p=<0.01), Completely buried gall bladder GB (p=<0.01), Distended shrilled GB (p=<0.01), Inability to grasp (p=<0.01), stone more than 1 cm (p<0.01), BMI more than 30 (p=<0.01), Adhesions from previous surgery (p<0.01) sepsis pus in bile (beata coefficient =0.9,p<0.01). didn't include any preoperative ERCP.⁽³⁶⁾

As compared to Masamichi yoke et all, in their study TG13 diagnostic criteria and severity grading of acute cholecystitis, did a multicentre analysis of TG13 diagnostic criteria, suggesting a sensitivity of 91.2% and specificity of 96.9% are favourable and diagnostic capacity is almost the same as TG07. And set a new standard for diagnosis, severity grading, and management of acute cholecystitis.

our study was the single center and had comparable diagnostic capacity. This concludes that the following factors affect Total GB score ⁽³⁷⁾
- We studied 89 patients undergoing elective laparoscopic cholecystectomy for acute/chronic calculous cholecystitis/cholelithiasis. Aged between years18 to 27 was seen in 19patients, between28-34 years was seen in 17patients, age between 35to45years was seen in 21cases, Age between years 46 to 58 was seen in 21, Age between years 58+ was seen in 17cases.
- male patients were 30 and female 59,
- socioeconomic group LIG-44, MIG-44, UIG-1case
- laparoscopic cholecystectomy in 86cases with conversion in 3 cases
- adhesion <50% in 45cases(50.6%) and adhesion50% in 49cases (55.1%), Completely buried gall bladder GB 8(8.9%), gallbladder shrilled or distended was observed in4(4.5%), grasping is not possible without decompression 28(31.4%), stone more than 1cm was found in 11(12.3%), BMI 18 t0 2414 in 18(20.2%),24.15 to 26.56 in 21(23.6%)cases,26.57 to 28.34 in 15(16.9%)cases,28.35-31.00 in 19(21.3%)cases,31.01+ in 16(18.0%)cases,sepsis/pus in bile seen in 6(6.7%) cases.
- Mild < 2degree was seen in 30 cases with 33.7%,, moderate degree 3-4 in 43 cases, 48.3%, difficult 5-7 seen in 14 cases with 15.7%, and extreme difficulty 8-10seen in 3 cases3.4%
- An operative time of 70min was seen in 21 cases with 23.6%.71-80 min in 22.5%,81-90 min in 19 cases with 21.3%,90-105min in 16 cases with 18.0% and 106+ min in 14.6% in 13 cases.

In the present analysis, we summarise that the following factors affect total G10. The gall bladder score is

significantly affected by

- o Adhesions,
- Completely buried gall bladder GB,
- o gallbladder shrilled or distended,
- o grasping is not possible without decompression,
- o stone more than 1 cm,
- BMI more than 30,
- Adhesions from previous surgery,
- o sepsis/pus in bile.

CONCLUSION

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E grading, difficulty and need for conversion which are predicted early. It is simple, effective and easy to implement during laparoscopic cholecystectomy.

Laparoscopic cholecystectomy outcome depends significantly upon intraoperative appearance like adhesions, completely buried gallbladder, distended or shrilled gallbladder, unable to grasp without decompression, stone more than 1cm, BMI more than 30, sepsis/bile/peritonitis.

Intraoperative G10 scoring system can predict conversion of laparoscopic to open cholecystectomy.

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E ANNEXURE VII REFERENCES

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ANNEXURE VIII

SAMPLE INFORMED CONSENT FORM

B.L.D.E.(Deemed to be university) SHRI B.M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, VIJAYAPUR – 586103, KARNATAKA

TITLE OF THE PROJECT: Intra-operative gallbladder scoring predicts conversion of laparoscopic to open cholecystectomy: a prospective study

PRINCIPAL INVESTIGATOR:

DR KRISHNA PRASAD S V

POSTGRADUATE

DEPARTMENT OF GENERAL SURGERY

PGGUIDE

DR. RAMAKANTH BALOORKAR

M.S. (GENERAL SURGERY),

PROFESSOR

DEPARTMENT OF GENERAL SURGERY.

CONFIDENTIALITY:

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E REQUEST FOR MORE INFORMATION:

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

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me.

And that a copy of this consent form will be given to me to keep it and for careful reading.

REFUSAL OR WITHDRAWL OF PARTICIPATION:

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

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

INJURY STATEMENT:

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights. I have explained to _______ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date: DR. RAMAKANTH BALOORKAR

DR. KRISHNA PRASAD SV (Guide)

(Investigator)

STUDY SUBJECT CONSENT STATEMENT:

DocuSign Envelope ID: 0DF9F164-D13D-4AD6-853A-3A357A2F768E recommendation of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore, I agree to give my consent to participate as a subject in this research project.

(Participant)

Date

PROFORMA

SL NO	
NAME	PHONE NO
AGE	IP NO
SEX	UNIT
RELIGION	DOA
OCCUPATION	WARD

ADDRESS

DOD

SOCIO-ECONOMIC STATUS	MIG	LIG	UIG

SURGEON NAME-

Operative time-

PROVISIONAL DIAGNOSIS-

FINAL DIAGNOSIS-

OPERATIVE PROCEDURE –

FINAL OPERATIVE PROCEDURE-

CONVERTED TO OPEN CHOLECYSTECTOMY- YES/NO

REASON FOR CONVERSION-

CHIEF COMPLAINTS:

HISTORY OF PRESENT ILLNESS

PAST HISTORY:H/O previous abdominal surgery.

PERSONAL HISTORY:

GENERAL PHYSICAL EXAMINATION

BUILT: WELL/MODERATE/POOR

NOURISHMENT: WELL/MO	DERATE/POOR	HEIGHT:	WEIGHT:	BMI:
]				
PALLOR	ICTERUS		CYANOSIS	
CLUBBING	PEDAL EDEMA			GENERAL
LYMPHADENOPATHY				

VITAL DATA:

TEMPERATURE:	PULSE	RESPIRATORY RATE
BLOOD PRESSURE:		

SYSTEMIC EXAMINATION

PER ABDOMEN:

RESPIRATORY SYSTEM

CARDIOVASCULAR SYSTEM

CENTRAL NERVOUS SYSTEM

CLINICAL DIAGNOSIS:

INVESTIGATIONS

CBC

HB%

TOTAL COUNT

DIFFERENTIAL COUNT

N/L/E/B/M

LIVER FUNCTION TEST

TOTAL BILIRUBIN

DIRECT BILRUBIN

INDIRECT BILIRUBIN

SERUM ALBUMIN

SGOT

SGPT

ALKALINE PHOSPHATASE

HIV

HBsAG

HCV

RENAL FUNCTION TEST

BLOOD UREA

SERUM CREATININE

SERUM SODIUM

POTASSIUM

CHLORIDE

CHEST X RAY

USG ABDOMEN

CT ABDOMEN (IF DONE)

SYSTEMIC ANTIBIOTICS USED

DEFINITIVE PROCEDURE:

Cholecystitis severity scoring G10

Cholecystitis severity	Score
Appearance Adhesions < 50% of GB	1
Adhesions> 50% but GB buried	2
Completely buried GB	3 (max)
Distension/contraction	
Distended GB or contracted shrilled GB	1
Inability to grasp without decompression	1
Stone > 1 cm impacted in Hartmann's pouch	1
ACCESS	
BMI > 30	1
Adhesions from previous surgery limiting surgery	1
Sepsis and complications Free bile or pus outside the gallbladder	1
FISTULA	1
TOTAL POSSIBLE SCORE	10

SCORE BASED ON INTROP FINDINGS-

KEY TO MASTER CHART

Age-in years Sex Secg-Socioeconomic group Wt-weight in kg Ht-height in cm BMI diagnosis-chole-cholelithiasis acc-acute calculous cholecystitis ccc-chronic calculous cholecystitis optim- operating time unit lap-laparoscopic cholecystectomy con.op- converted to open ele-elective eme-emergency <50%-adhesion<50%, >50%- adhesion>50% cbg-completely buried d/sgb-distended/shrilled gallbladder, ingrde- inability to grasp without decompression st>1-stone>1cm in Hartmann pouch ,BMI>30 adpr-adhesion from previous surgery, sp/bl- sepsis/free bile/pus, fit- fistula, scre-totalscore10, mil-mild<2 mod-moderate3-4, sev-severly difficult 5-7, extr-extreme difficult 8-10

Age sex se	ecg w	/t ht k	omi dia	agnosis	unit	optin	n lap	con.	op ele	e eme	? <50%	50%	cbg d	/sgbI	ngrd	e st>1	bmi>	>30 a	dpr sp)/bl fi	t scre	e mil r	mod s	sev ex	ktr
29 FEMALE MIG	70	156	28	chole	П	60	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
70 MALE MIG	70	168	20.00	Ссс	v	120	YES	NO	YES	NO	0	2	0	0	1	0	0	1	0	0	4	NO	YES	NO	NO
58 MALE MIG	82	170	31.00	ссс	IV	150	YES	YES	YES	NO	0	0	3	1	1	1	1	1	1	0	9	NO	NO	NO	YES
36 FEMALE MIG	70	158	28.00	ссс	II	90	YES	NO	YES	NO	0	2	0	1	0	0	0	1	0	0	4	NO	YES	NO	NO
56 MALE MIG	82	170	26.00	ссс	IV	120	YES	NO	YES	NO	0	2	0	1	0	0	0	0	0	0	3	NO	YES	NO	NO
58 MALE MIG	78	156	32.00	ссс	IV	90	YES	NO	YES	NO	0	0	3	1	0	0	1	0	0	0	5	NO	NO	YES	NO
32 FEMALE MIG	54	150	22.00	ссс	I	82	YES	NO	YES	NO	0	2	0	1	0	0	0	0	0	0	3	NO	YES	NO	NO
27 FEMALE LIG	57	156	23.40	chole	V	90	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
26 FEMALE LIG	74	150	32.90	ссс	IV	120	YES	YES	YES	NO	0	0	3	1	1	0	1	1	1	0	8	NO	NO	NO	YES
33 FEMALE UIG	76	154	32.00	асс	IV	120	YES	YES	YES	NO	0	0	3	1	1	1	1	1	0	0	8	NO	NO	NO	YES
45 FEMALE LIG	50	155	21.00	chole	IV	80	YES	NO	YES	NO	0	2	0	1	0	0	0	0	0	0	3	NO	YES	NO	NO
60 FEMALE LIG	68	160	26.56	асс	V	150	YES	NO	YES	NO	0	2	0	1	1	0	0	0	1	0	5	NO	NO	YES	NO
57 FEMALE LIG	68	168	20.00	Ссс	V	75	YES	NO	YES	NO	1	0	0	1	0	0	0	1	0	0	3	NO	YES	NO	NO
23 FEMALE LIG	56	154	18.20	chole	IV	150	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
50 FEMALE LIG	48	165	18.20	Ссс	IV	150	YES	NO	YES	NO	1	0	0	1	0	0	0	0	1	0	3	NO	YES	NO	NO
40 FEMALE LIG	50	165	19.20	Ссс	IV	120	YES	NO	YES	NO	0	2	0	1	0	0	0	1	0	0	4	NO	YES	NO	NO
36 FEMALE LIG	70	158	28.04	chole	III	90	YES	NO	YES	NO	0	2	0	1	0	1	0	0	0	0	4	NO	YES	NO	NO
27 FEMALE LIG	72	164	26.02	chole	II	105	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
60 FEMALE LIG	70	156	28.20	Ccc	IV	85	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
80 FEMALE LIG	72	165	26.40	chole	III	80	YES	NO	YES	NO	0	2	0	1	0	0	0	0	0	0	3	NO	YES	NO	NO
30 FEMALE LIG	78	162	29.72	chole	I	95	YES	NO	YES	NO	1	0	0	1	0	0	0	1	0	0	3	NO	YES	NO	NO
27 FEMALE LIG	72	158	28.83	mirizizs	V	120	YES	NO	YES	NO	0	0	3	1	1	1	0	0	1	0	7	NO	NO	YES	NO
30 FEMALE LIG	84	168	31.23	chole	Ш	100	YES	NO	YES	NO	0	2	0	1	1	0	0	1	0	0	5	NO	NO	YES	NO

27	MALE	LIG	70	162	21.20	асс	IV	90	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
35	FEMALE	LIG	76	172	25.68	Ссс	IV	60	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
60	FEMALE	MIG	56	152	20.00	chole	IV	120	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
30	FEMALE	LIG	68	160	26.56	chole	V	80	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
50	FEMALE	LIG	66	152	28.56	chole	V	85	YES	NO	YES	NO	0	2	0	1	0	0	0	0	0	0	3	NO	YES	NO	NO
19	FEMALE	LIG	68	154	28.67	асс	IV	100	YES	NO	YES	NO	0	2	0	1	0	0	1	0	0	0	4	NO	YES	NO	NO
39	FEMALE	MIG	45	156	19.00	chole	IV	60	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
60	FEMALE	MIG	76	162	28.95	chole	IV	60	YES	NO	YES	NO	0	2	0	1	0	0	0	0	0	0	3	NO	YES	NO	NO
30	FEMALE	MIG	70	165	28.28	ссс	II	120	YES	NO	YES	NO	1	0	0	1	0	1	0	0	0	0	3	NO	YES	NO	NO
32	FEMALE	LIG	58	155	24.14	chole	IV	90	YES	NO	YES	NO	0	2	0	1	1	0	0	1	0	0	5	NO	NO	YES	NO
60	FEMALE	MIG	70	168	24.80	chole	V	90	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
45	FEMALE	MIG	50	166	19.00	chole	V	70	YES	NO	YES	NO	0	2	0	1	1	0	0	0	0	0	4	NO	YES	NO	NO
46	FEMALE	MIG	92	162	35.80	chole	V	105	YES	NO	YES	NO	1	0	0	1	0	0	1	0	0	0	3	NO	YES	NO	NO
31	FEMALE	LIG	68	158	27.23	chole	Ш	80	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
70	MALE	MIG	76	172	25.68	ссс	IV	105	YES	NO	YES	NO	0	0	0	1	0	0	0	0	0	0	3	NO	YES	NO	NO
49	MALE	MIG	72	170	24.91	chole	IV	90	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
22	MALE	LIG	68	160	26.56	chole	II	80	YES	NO	YES	NO	1	2	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
24	FEMALE	MIG	70	158	28.81	chole	II	75	YES	NO	YES	NO	1	0	0	1	1	1	0	0	0	0	3	NO	YES	YES	NO
60	FEMALE	MIG	72	158	28.04	асс	I	105	YES	NO	YES	NO	0	2	0	1	1	0	0	0	0	0	3	NO	YES	NO	NO
58	MALE	MIG	80	168	28.34	chole	V	130	YES	NO	YES	NO	1	0	0	1	1	0	0	0	0	0	3	NO	NO	NO	NO
27	' FEMALE	MIG	66	158	26.61	chole	V	70	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
60) FEMALE	LIG	62	160	23.62	chole	V	105	YES	NO	YES	NO	0	2	0	1	0	0	0	0	0	0	3	YES	NO	NO	NO
37	' FEMALE	MIG	78	158	30.60	chole	П	70	YES	NO	YES	NO	0	2	0	1	0	0	1	0	0	0	4	NO	YES	NO	NO

65	FEMAL	e lig	60	156	24.65	chole	V	90	YES	NO	NO	NO	1	0	0	0	0	1	0	0	0	0	2	YES	NO	NO	NO
36	FEMAL	e lig	70	158	28.04	chole	Ш	90	YES	NO	YES	NO	0	2	0	1	0	1	0	0	0	0	4	NO	YES	NO	NO
31	FEMAL	e Mig	68	160	26.56	chole	V	105	YES	NO	YES	NO	1	2	0	0	1	0	0	0	0	0	2	YES	NO	NO	NO
45	MALE	MIG	80	168	28.34	chole	IV	105	YES	NO	YES	NO	0	2	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
33	FEMAL	e Mig	46	152	18.50	chole	П	100	YES	NO	YES	NO	1	0	0	1	0	0	0	0	0	0	2	YES	NO	NO	NO
37	FEMAL	e Mig	82	162	31.26	Ссс	IV	85	YES	NO	YES	NO	0	2	0	1	1	0	1	1	0	0	6	NO	NO	YES	NO
62	MALE	LIG	82	162	31.24	асс	Ш	60	YES	NO	YES	NO	0	0	0	0	1	0	0	0	0	0	3	NO	YES	NO	NO
49	MALE	LIG	78	152	33.76	chole	I	75	YES	NO	YES	NO	1	0	0	1	0	0	1	0	0	0	3	NO	YES	NO	NO
23	FEMAL	e Mig	79	158	31.70	chole	V	95	YES	NO	YES	NO	0	2	0	1	0	0	1	0	0	0	4	NO	YES	NO	NO
40	MALE	MIG	60	156	24.65	chole	IV	69	YES	NO	YES	NO	0	2	0	1	1	0	0	0	0	0	4	NO	YES	NO	NO

ELD.E. (DEEMED TO BE UNIVERSITY) Declared vide notification No. F.9-37/2007-U.3 (A) Dated. 29-2-2008 of the MHRD, Government of India under Section 3 of the UGC Act, 1956) The Constituent College SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Institutional ethical committee of this college met on 11-01-2021 at 11-00 am to scrutinize the synopsis of Postgraduate students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has been accorded Ethical Clearance

Title: Intra –operative gall bladder scoring predicts conversion to laparoscopic to open

Name of PG student: Dr Krishna Prasad S V, Department of Surgery

Name of Guide/Co-investigator: Dr Ramakant S Baloorkar Associate Professor Department of Surgery

CHAIRMAN, IEC Institutional Ethical Committee L D E (Deemed to be University) Inri B.M. Patil Medical College, VIJAYAPUR-536103 (Karnataka)

Following documents were placed before Ethical Committee for Scrutinization:

1. Copy of Synopsis / Research project 2. Copy of informed consent form



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