### STUDY OF EFFICACY OF ENDOBAG IN LAPAROSCOPIC CHOLECYSTECTOMY TO REDUCE PORT SITE INFECTION"

By Dr. D VAIBHAVI



# DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA In partial fulfilment of the requirements for the degree of M.S. GENERAL SURGERY

**Under the Guidance of** 

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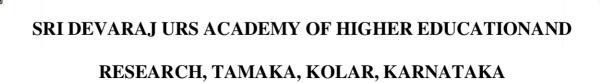
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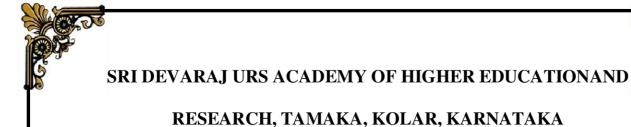
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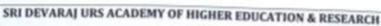
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My heartfelt gratitude to all my patients who submitted themselves most gracefully and wholeheartedly to participate in this study.

gracefully and wholeheartedly to participate in this study.

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STUDY OF EFFICACY OF ENDOBAG IN LAPAROSCOPIC CHOLECYSTECTOMY TO REDUCE PORT SITE INFECTION ABSTRACT : INTRODUCTION : Gallstone development due to cholesterol is the first phase to cholesterol crystal nucleation. Lack of proteins that inhibit nucleation, surplus pronucleating proteins, supersaturation of biliary cholesterol and gallbladder issues which includes hypomobility are few reasons that disrupts the process of crystallization. Laparoscopic cholecystectomy is essential in eradicating the need for open abdominal surgery and blockage in case of complications. The patient can leave the hospital in couple of days and recommence their routine activities in about a week post operation and face minimal pain as compared to earlier. used surgical methods. MATERIAL AND METHODS: All patients with suspected gallstone diseases were considered for the study. A complete detailed history and physical examination was done followed by relevant investigations after obtaining an informed consent. Patients were divided into using odd(A) and even(B) method each consisting of 30 patients. All patients were subjected to pre-anaesthetic evaluation to determine their fitness for surgery. Comorbidities if any were appropriately corrected pre-operatively. All the parameters to compare the two techniques was recorded and tabulated. RESULTS: A total of 60 patients were enrolled and were divided into two study groups. Patients in group A underwent laparoscopic cholecystectomy using endobag while patients in group B underwent laparoscopic cholecystectomy without endobag. Mean age of the patients of group A and group B was 50.6 years and 44.47 years respectively. Both the groups were comparable in terms age-wise distribution of patients. 20 percent of the patients of Group A and 13.33 percent of the patients of group B were males. Remaining all are females.

Both the groups were comparable in terms of gender-wise distribution. Mean BMI of the patients of the Group A and Group B was 25.75 Kg/m2 and 24.87 Kg/m2 respectively. Both the groups were comparable in terms of BMI. None of the gatients of Group A showed presence of SSI while 23.33 percent of the patients of Group B showed presence of SSI on postoperative day 3. On 5th 23.33 percent of the patients of order by seen in 20 percent of the patients of Group B while it was absent in Group A. On 7th postoperative day, SSI was seen in 13.33 percent of the patients of Group B while it was absent in Group A. In all the 7 patients of Group B exhibiting SSI, infection was superficial in nature. Gall bladder retrieval port among patients of both Group A and Group B was Epigastric port. Mean duration of surgery among patients of group A and group B was 1.11 hours and 1.06 hours respectively; on comparing the values, non-significant results were obtained None of patient showed perforation of Endobag. Intraabdominal spillage was seen among 10 percent of the patients of Group A and among 23.33 percent of the patients of Group B. Histopathological diagnosis among patients of group A was Calculous cholecystitis, Cholesterosis gallbladder, Chronic calculous cholecystitis, Chronic cholecystitis and Subacute chronic calculous cholecystitis found to be present in 3.33 percent, 10 percent, 70 percent, 13.33 percent and 3.33 percent of the patients respectively, Histopathological diagnosis among patients of Group B was Chronic calculous cholecystitis, Chronic acalculous cholecystitis, Chronic cholecystitis and Chronic cholecystitis with Cholesterosis was 73.33 percent, 3.33 percent, 20 percent, and 3.33 percent of patients respectively. CONCLUSION: During laparoscopic cholecystectomy, an endobag was found to be superior to a straight gall bladder extraction for gall bladder retrieval. INTRODUCTION: Gallstone disease is frequently regarded as a significant ailment in modern world. On the other hand, gallstones dates back to 1000BC as discovered in gallbladder of mummified bodies in Egypt depicting the fact that they were well known since ages. There is no predilection of age and

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### LIST OF ABBREVIATIONS



GLOSSARY	ABBREVATION
GB	Gallbladder
LC	Laparoscopic Cholecystectomy
CBD	Common Bile Duct
PSI	Port Site Infection
SSI	Surgical Site Infection
BMI	Body Mass Index
POD	Post Operative Day
MAS	Minimal Access Surgery
LS	Laparoscopic Surgery









#### **INTRODUCTION:**

Gallstone development due to cholesterol is the first phase to cholesterol crystal nucleation. Lack of proteins that inhibit nucleation, surplus pronucleating proteins, supersaturation of biliary cholesterol and gallbladder issues which includes hypomobility are few reasons that disrupts the process of crystallization. Laparoscopic cholecystectomy is essential in eradicating the need for open abdominal surgery and blockage in case of complications. The patient can leave the hospital in couple of days and recommence their routine activities in about a week post operation and face minimal pain as compared to earlier used surgical methods.

#### **MATERIAL AND METHODS:**

All patients with suspected gallstone diseases were considered for the study. A complete detailed history and physical examination was done followed by relevant investigations after obtaining an informed consent. Patients were divided into two groups using odd(A) and even(B) method each consisting of 30 patients. All patients were subjected to pre-anaesthetic evaluation to determine their fitness for surgery. Comorbidities if any were appropriately corrected pre-operatively. All the parameters to compare the two techniques was recorded and tabulated.

#### **RESULTS:**

A total of 60 patients were enrolled and were divided into two study groups. Patients in group A underwent laparoscopic cholecystectomy using endobag while patients in group B underwent laparoscopic cholecystectomy without endobag. Mean age of the patients of group A and group B was 50.6 years and 44.47 years respectively. Both the groups were comparable in terms agewise distribution of patients. 20 percent of the patients of Group A and 13.33 percent of the patients of group B were males. Remaining all are females. Both the groups were comparable in terms of gender-wise distribution. Mean BMI of the patients of the Group A and Group B was 25.75 Kg/m² and 24.87 Kg/m² respectively. Both the groups were comparable in terms of BMI. None of the patients of Group A showed presence of SSI while 23.33 percent of the patients of Group B showed presence of SSI on postoperative day 3. On 5<sup>th</sup> postoperative day, SSI was seen in 20 percent of the patients of Group B while it was absent in Group A. On 7<sup>th</sup>

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#### **CONCLUSION:**

During laparoscopic cholecystectomy, Gall bladder extraction through an endobag was found to be superior to direct extraction of gall bladder.









S. No	TITLE	Page No.
1	INTRODUCTION	1
2	AIMS AND OBJECTIVES	4
3	REVIEW OF LITERATURE	5
4	MATERIALS & METHODS	56
5	RESULTS	59
6	DISCUSSION	73
7	CONCLUSION	81
8	SUMMARY	82
9	BIBLIOGRAPHY	85
10	ANNEXURES	
	I. PROFORMA	
	II. PATIENT INFORMATION SHEET	92
	III. INFORMED CONSENT FORM	
	IV. MASTER CHART	
11	PHOTO GALLERY	97





### LIST OF TABLES

S.No	Table Description	Page No
1	Age wise distribution of patients	59
2	Gender wise distribution of patients	61
3	Distribution of patients based on BMI	62
4	Distribution of patients according to SSI on postoperative	63
	day 3	
5	Distribution of patients according to SSI on postoperative	64
	day 5	
6	Distribution of patients according to SSI on postoperative	65
	day 7	
7	Distribution of patients according to type of infection	66
8	Distribution of patients according to gall bladder retrieval	67
	port	
9	Distribution of patients according to duration	68
10	Distribution of patients according to perforation of	69
	Endobag	
11	Distribution of patients according to presence of intra	70
	abdominal spillage	
`12	Distribution of patients according to Histopathological	71
	diagnosis	
13	Comparison of age of the patients among the two groups	74
	across various studies to present study	
14	Comparison of gender of the patients among the two	75
	groups across various studies to present study	
15	Comparison of BMI of the patients among the two groups	75
	across various studies to present study	
16	Comparison of SSI in patients among the two groups	76

	•
across various studies to present study	
Comparison of duration of surgery among the two groups	77
	78
studies to present study	70
Comparison of intra abdominal spillage among the two	78
groups across various studies to present study	
	Comparison of duration of surgery among the two groups across various studies to present study  Comparison of perforation of endobags across various studies to present study  Comparison of intra abdominal spillage among the two





### LIST OF FIGURES

S.No	Figure Description	Page
		No
1	Gallstones and Anatomy of Gall Bladder, Cystic Duct and	7
	CBD	
2	The Gallbladder laid open with the Hepatic Duct, Cystic	7
	Duct, Spiral Valves and CBD	
3	Diagram of the Calots Triangle and Local Anatomy	9
4	Embryo of 36 days old showing Development of Gall	10
	Bladder and Pancreas	
5	Blood supply of the Biliary system	11
6	Blood supply of the Cystic duct and CBD	11
7	Blood supply of the Gall bladder	12
8	Nerve supply to the Biliary system	13
9	Variants of Cystic duct anatomy	14
10	Biliary anatomy Variations	21
11	Intraoperative image of Plastic Wound Protector	33
12	Alexis wound protector	35
13	Intraoperative image showing Ioban 2 Antimicrobial Incise	37
	Drape	
14	Silicone wound protector	39
15	Intraoperative image showing Ethicon Endopath Dexus	41
	wound protector	
16	Endocatch bag	42
17	Intraoperative image showing use of Condom Endobag	43
18	Glove Endobag	43
19	Intraoperative image showing use of Urobag as Endobag	44
20	Intraoperative image showing use of Drainage Bag as	44

		000
	Endobag	
21	Intraoperative image showing use of Glove Endobag	45
22	Polyethylene Endobag	45
23	Nylon Endobag	46
24	Polyvinyl Chloride (PVC) Endobag	47
25	Silicone Endobag	47
26	Bar chart depicting the age wise distribution of patients	60
27	Bar chart depicting the gender wise distribution of patients	61
28	Bar chart depicting the distribution of patients according to	62
	BMI	
29	Bar chart depicting distribution of patients according to SSI	63
	on post operative day 3	
30	Bar chart depicting distribution of patients according to SSI	64
	on post operative day 5	
31	Bar chart depicting distribution of patients according to SSI	65
	on post operative day 7	
32	Bar chart depicting distribution of patients according to the	66
	type of infection	
33	Bar chart depicting distribution of patients according to the	67
	gall bladder retrieval port	
34	Bar chart depicting the duration of surgeries	68
35	Bar chart depicting the perforations of Endobags	69
36	Bar chart based on intra abdominal spillage in patients	70
37	Bar chart depicting distribution of patients according to	71
	Histopathological diagnosis	





## INTRODUCTION

#### **INTRODUCTION**

Gallstone disease is frequently regarded as a significant ailment in modern world. On the other hand, gallstones dates back to 1000BC as discovered in gallbladder of mummified bodies in Egypt depicting the fact that they were well known since ages. There is no predilection of age and escalates with age. Gallstones cases are gradually rising and may vary based on topography. Data shows about one fourth females face the problems of gallstones. Post diagnosis, it is seen that in a time span of 5 to 20 years, ten to twenty percent cases show symptoms whereas most of them go unchecked due to no symptoms. Therefore, this disease shows approximately two and a half percent rise per year due to its little chances of becoming symptomatic.<sup>1</sup>

Gallstone development due to cholesterol is the first phase to cholesterol crystal nucleation. Lack of proteins that inhibit nucleation, surplus pronucleating proteins, supersaturation of biliary cholesterol and gallbladder issues which includes hypomobility are few reasons that disrupts the process of crystallization.<sup>2</sup>

Instigating pain is somewhat necessary to manage gallstones. The supreme sign to treat stones in the gallbladder is frequent events of upper abdominal pain. Laparoscopic Cholecystectomy was acknowledged as the benchmark to cure stones of gallbladder and was considered as the putative technique in 1992 by National Institute of Health Consensus (NIH) Development Conference. Bile is a fluid required for digestion, however, sometimes gets accumulated in the gallbladder resulting in gall stones. The accumulated fluid hardens and can be present in any shape or size from being as trivial as sand or can be big as a golf ball.<sup>1</sup>

When gall stones initiate showing symptoms, cholecystectomy is the best cure for the disease. Before the introduction of laparoscopy, open approach was used to treat gallstones also called as cholelithiasis. However, in the eighteenth century, the first cholecystectomy was executed. By late 1980s, with the innovation of Laparoscopic Cholecystectomy, open cholecystectomy made a breakthrough in the field of biliary surgery.<sup>3, 4</sup>

A surgeon has to assess the organs view 2D imaging which necessitates expertise and skillfulness during a laparoscopic cholecystectomy. An inverted video is seen on the monitor when camera is directed to the surgeon and requires good hand- eye coordination. A "learning

curve" has been well designated for laparoscopic cholecystectomy, with rates of difficult circumstances for an individual surgeon declining with operative practice.<sup>3-6</sup>

The voyage was not challenging as the surgeons were supposed to modify their technique. Psychosomatic pleasure of the patient was the main benefit of this transition from scalpel to use of scope and subside the intrusiveness of the surgery.<sup>5, 6</sup>

Laparoscopic cholecystectomy is essential in eradicating the need for open abdominal surgery and blockage in case of complications. The patient can leave the hospital in couple of days and recommence their routine activities in about a week post operation and face minimal pain as compared to earlier used surgical methods.<sup>4</sup>

One crucial aspect of quality, which encompasses various aspects such as pain levels and cosmetic results, in minimal access surgery is management of pain. Patient's comfort and well-being are now considered essential factors in determining the success of surgical procedure. The surgeons as well as the patient consider surgery without scars as the most essential aim. Advancements are still made in surgical methods to make the minimal invasion. The intricacy of procedures has risen markedly with the advancements in tools and equipment's.<sup>5,6</sup>

Routinely, 4 ports are made into the abdomen to operate. Each port is utilized to conduct a certain step in the procedure, for instance, one is used retract organs, one to use camera for imaging and remaining two for tissue handling.<sup>7</sup> To attain minimal access surgery, LC has undergone many innovations and advancements to bring down number and measurements of the port.<sup>8-11</sup>

Enhanced medical service and affordability are triumphed when the patient is able to quickly recover and has minimum pain after operation. With reduction in dimension and number of ports, patient experience minimal pain after surgery as seen in various studies.<sup>12, 13</sup>

With rise in popularity of laparoscopic cholecystectomies, wider array of obstacles came into existence. The foremost complication of ill health and death are vascular injuries following anaesthetic impediments. Published studies showed that LC contains biliary and non-biliary problems which includes intestinal injuries, diaphragm injuries, injuries to vessels and pneumothorax caused by physician whereas biliary problems comprise of lesions of right hepatic duct, common bile duct along with damage to the gallbladder due to stones.<sup>14</sup>

To attain the specimen of gallbladder, appropriate correct placement and alignment of surgical tools is required to conclude the surgical procedure. When conducting a laparoscopic cholecystectomy, there is a higher chance of stones from the gall-bladder spilling and getting embedded in the abdomen, as well as corruption of the port-site. Endobag is used to collect the specimen from gall bladder to avoid any mentioned impediments. Removing a gallbladder that is severely inflamed or expanded and filled with stones can be problematic. In these cases, one can either lengthen the incision site, disintegration of stones before removal or needle decompression which usually leads to severe pain at the operated site. <sup>15</sup>

Therefore, this current investigation was done to reduce the incidence of port site infections and evaluate the effectiveness of Endobag in laparoscopic cholecystectomy.

## AIMS AND OBJECTIVES

### AIMS AND OBJECTIVES

- 1. To evaluate the incidence of port site infection without the use of endobag.
- 2. To evaluate the incidence of port site infection with the use of endobag.
- 3. To compare the incidence of port site infection with and without the use of endobag.

## REVIEW OF LITERATURE

#### **REVIEW OF LITERATURE**

After the introduction of LC thirty years ago, the area of laparoscopic surgery was revolutionized. Based on clinical experience, without randomized trials, LC was immediately accepted by patients and surgeons in short period of time leading to the National Institutes of Health to pronounce LC as, "the treatment of choice for many patients with symptomatic cholelithiasis." In comparison to open cholecystectomy, retrospective data showed LC to be safe and effective and described it as "obvious and compelling."<sup>8-13</sup>

LC was responsible for the initial success and popularity for the laparoscopic revolution in general surgery. The general surgeons who had earlier neglected operative laparoscopy were forced to notice it due to the tremendous public interest. To perform more complex laparoscopic procedure, LC has served as the igniting spark in the laparoscopic surgery explosion among general surgeons.<sup>8, 14, 15</sup>

Laparoscopic cholecystectomy was first performed in Germany on September 12, 1985 by Prof Dr Med Erich Mühe of Böblingen. When the German Surgical Society got to know about Mühe in 1986 and his first laparoscopic cholecystectomy, they rejected it. On the flip side in 1992, German Surgical Society Anniversary Award which was German Surgical Society's highest award was presented to Mühe. 16, 17

On September 12, 1985, Mühe inaugurated Galloscope while planning cholecystectomy. By securing pneumoperitoneum with a Veress needle, he used Galloscope at the patient's umbilicus. To dissect the gallbladder, Weck-Reynolds pistol grip hemoclip applier and scissors were used in the lower abdomen area either through channels in the Galloscope or via small portholes. Mühe in April 1986, showed his experience at the Congress of the German Surgical Society (GSS). However, he was not well appreciated for his work and stated his procedure as "Mickey Mouse surgery" some called it as "small brain small incision." <sup>18-24</sup>

Using gynecological instruments, the first human video laparoscopic cholecystectomy was performed by Philippe Mouret in Lyons, France in March 1987.<sup>25</sup>

François Dubois of Paris used mini-laparotomy in the late 1980s to perform cholecystectomy. Minimal incision and no drainage made this method well liked in France leading to less time in hospitals compared to the earlier done cholecystectomy. When Dubois did his first "one-day cholecystectomy," sharing his passion with the new scrub nurse Claire Jeaupitre but she was not at all amazed by the incision size as she witnessed LC earlier which was performed by Mouret in Lyon. Dubious was furious when he got to know this and considered it impossible contacting Mouret to get more details on this. He finally believed it when Mouret showed him a video of his LC performed in December 1987 in Paris. On the contrary, Dubois's first LC was done in April 1988.<sup>26</sup>

In July 1988, Professor Jacques Perissat was fantasized by Dubois's speech on laparoscopic appendectomy which led to advancement of LC in Bordeaux. Perissat introduced ultrasonic lithotripter into the gallbladder by employing intracorporeal lithotripsy and found it appealing to use LC with own technique as an alternative or in synergy with it. He started using LC after performing his ultrasonic lithotripter on cholelithiasis cases in early 1989.<sup>26</sup>

Except Mühe, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Convention recognized Perissat, Berci, Cuschieri, Dubois, and Mouret for using early laparoscopic cholecystectomies in Atlanta in 1990. However, SAGES appreciated Mühe in 1999 for doing the first laparoscopic cholecystectomy being invited by the SAGES to present the Storz Lecture. Mühenarrated the first procedure in the presentation titled as "The First Laparoscopic Cholecystectomy," in San Antonio, Texas in the year 1999. This at last gave Mühe worldwide praise for his revolutionary work.<sup>22</sup>

#### ANATOMY OF THE GALLBLADDER AND BILIARY TREE

Small bile ducts arise from liver lobules constituting the liver parenchyma and blood vessels. The left and right hepatic bile ducts are formed by small branches of bile ducts in liver which further leads to the formation of common bile ducts in portahepatis. The length of common hepatic duct is 4 to 6 cm. Finally, it joins the common bile duct (CBD) passing through pancreas and in the major duodenal papilla, it terminates. Cystic duct links the biliary tree and the gallbladder. The gallbladder relaxes in the fossa of the liver joined via connective tissue. It is pear shaped and is 8 to 12 cm long bag. A spiral diaphragmatic fold of mucosa partially separates lumen of the neck of the gallbladder and its connection with the cystic

duct. Coeliac trunk gives off hepatic artery which fulfills gallbladder's blood supply via cystic artery. Although, while executing cholecystectomy, anatomy of the cystic duct and artery may show dissimilitude regardless of the fact that gallbladder and extra hepatic biliary tree are usually in perfect synchronization.<sup>27, 28</sup>

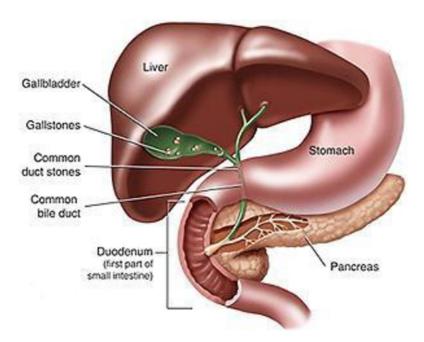


Figure 1: Gallstones and anatomy of gallbladder, cystic duct and CBD

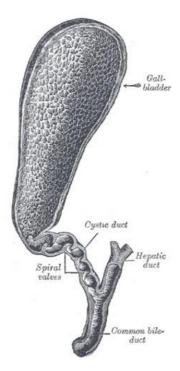


Figure 2: The Gallbladder and Bile Ducts Laid Open. The hepatic duct, cystic duct, spiral valves, and common bile duct.

Biliary duct is formed by combination of branches of bile ducts which secretes Bile that mainly participates in digestion. Hepatocyte is the functional unit of liver which at cellular level racks up bile from each lobule via intralobular duct. Canaliculi are responsible for the collection of bile which are described as narrow tubular channels. In between the lobules are interlobular ducts draining the intralobular ducts arranged in such a way that it forms the right hepatic duct and the left hepatic duct which are the two chief bile ducts of the liver. Outside the liver, the cystic duct comes in proximity to the common hepatic duct passing the hepatoduodenal ligament which originates forms due to unification of the right hepatic duct and the left hepatic duct. The fusion of the common hepatic and cystic duct makes the common bile duct. The bile reaches the second portion of duodenum through hepatopancreatic ampulla, which is spherical structure located at the site of the confluence of the common bile duct and pancreatic duct. It is also known as the hepatopancreatic duct or ampulla of Vater. The sphincter of Oddiacts as a barrier for the bile to enter into the small intestine which is overseen by the smooth muscle fibres and opens at the duodenal papilla.<sup>29,</sup>

#### Intrahepatic Ducts

Canaliculi: Equipped with microvilli to increase surface area

Intralobular ducts: the ducts are situated adjacent to hepatic artery and portal vein. These three entites collectively form what is known as the portal triads, which are encased within connective tissue layer called Glisson's capsule.

#### Interlobular ducts

Right hepatic duct: Responsible for draining the right lobe of liver especially segments V, VI, VII, and VIII.

Left hepatic duct: Handles drainage of left lobe of the liver encompassing segments II, III, IV

The caudate lobe of the liver, which is segment I, is drained by diminutive ducts emanating from both the right and left lobes.

#### Extrahepatic Ducts

These pertain to the portions of the right and left hepatic ducts that are outside the liver.

Common hepatic duct. Measures roughly 4 cm in length

Cystic duct: Serves as the exit pathway for the gallbladder, with a diameter of about 7 mm and is characterized by the presence of the valves of Heister.

Common bile duct: Typically, the width should not exceed 6 mm. The length of this duct ranges from 6.0 cm to 8.0 cm. <sup>30-33</sup>

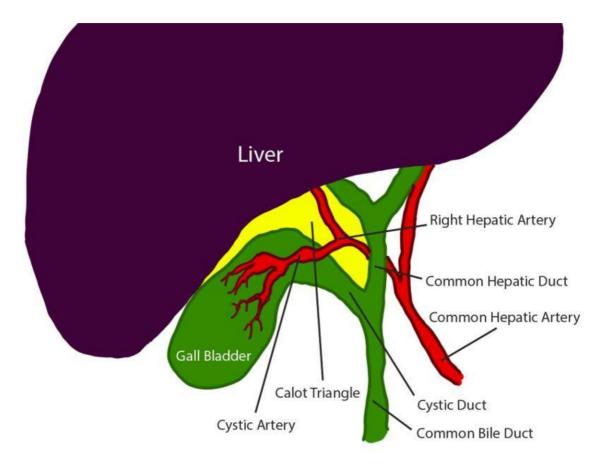


Figure 3: Diagram of the Calot Triangle and Local Anatomy.

#### **Function**

The primary role of biliary tract is to regulate and the transportation and secretion of bile. Gallbladder is essential as it hold and intensifies the concentration of bile. Bile plays a crucial role in digestion and absorption of fats as well as fat soluble vitamins and it also facilitates excretion of lipid soluble waste. The key constituents of bile include cholesterol, bile salts, and bilirubin. It is bilirubin that imparts the distinctive yellow-green hue to bile and contributes to the coloration of stool. <sup>30-33</sup>

#### **Embryology**

The bile ducts have their embryonic roots in the foregut. The endodermal epithelium of the ventral foregut gives rise to the hepatic diverticulum in the 4th week of development. The hepatic diverticulum serves as the precursor for the liver, extrahepatic ducts, gallbladder, and ventral pancreas. It is segmented into two distinct buds: the cranial bud that leads to the

formation of intrahepatic bile ducts while the caudal bud gives rise to extrahepatic biliary tree. A critical step in the process of recanalization of the hepatic diverticulum, which is necessary for duct formation. Hepatoblasts undergo stimulation to transform into cholangiocytes, which are the cells if the intrahepatic bile ducts. <sup>30-33</sup>

Congenital anomalies linked to the biliary tract encompass conditions such as biliary atresia, choledochal cysts, and congenital biliary ectasia. Biliary atresia arises from an unsuccessful recanalization process in the formation of bile ducts, leading to considerable health complications and frequently advancing to terminal liver failure. The condition is diagnosed and surgically addressed through the Kasai portoenterostomy procedure. <sup>30-33</sup>

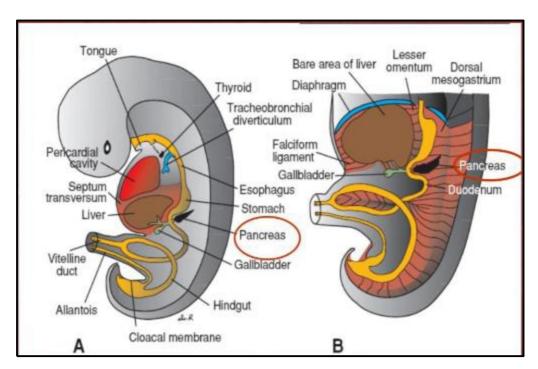


Figure 4: Embryo of 36 Days Old Showing Development of Gall Bladder and Pancreas

### **Blood Supply and Lymphatics**

#### **Arterial**

The biliary system's blood supply stems from the coeliac trunk, which branches off the abdominal aorta at T12 level. This trunk divides into the splenic artery, the common hepatic artery and and left gastric artery. The biliary tree primarily receives its blood from the common hepatic artery's offshoots, which include the proper hepatic, cystic, gastroduodenal and superior pancreaticoduodenal arteries. Additionally, the gallbladder's blood supply is provided by the cystic artery. <sup>30-33</sup>

The common hepatic artery originates from the celiac trunk and branches into hepatic artery, gastroduodenal artery, and right gastric artery.

The proper hepatic artery diverges into common hepatic artery and splits into left hepatic artery, right hepatic artery and cystic artery.

The gastroduodenal artery emerges from the common hepatic artery and gives rise to the right gastroepiploic artery and the superior pancreaticoduodenal artery. <sup>30-33</sup>

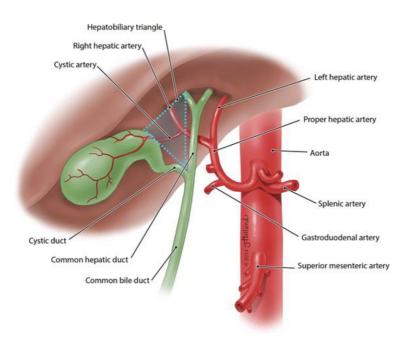


Figure 5: Blood supply

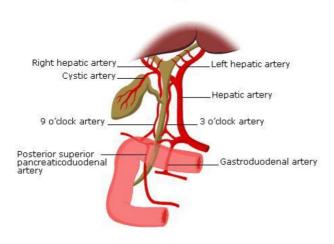


Figure 6: Blood supply of cystic duct and CBD

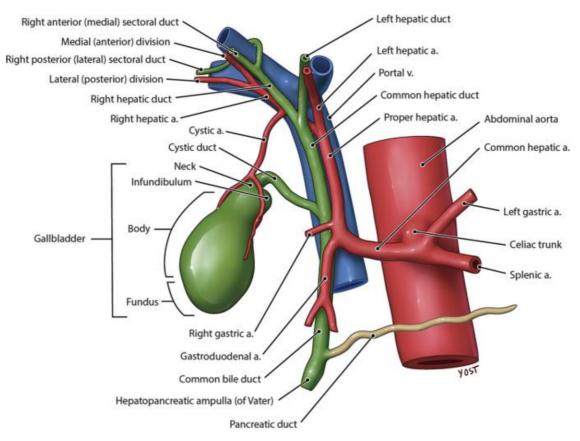


Figure 7: Blood supply of gallbladder

#### **Venous Drainage**

The extensive documentation of the venous drainage of the biliary ducts is lacking. Multiple small veins are responsible for draining both the liver and gallbladder. Ultimately, the primary vein of the gallbladder, known as the cystic vein, drains into the portal vein. <sup>30-33</sup>

#### Lymphatics

Indeed, the lymphatic drainage pattern of the gallbladder is more frequently detailed compared to that of the biliary ducts. The lymphatic fluid from the gallbladder typically passes through a series of nodes in a specific order:

It begins with the cystic nodes

Then moves to the hepatic nodes

And finally reaches the celiac nodes

This systematic flow is crucial for the proper functioning of the lymphatic system in relation to the gallbladder. <sup>30-33</sup>

#### **Nerve supply**

Both sympathetic and parasympathetic fibers from the celiac plexus innervate the biliary tree. Sympathetic fibers are transmitted through the splanchnic nerves, while parasympathetic fibers travel via the vagus nerve. Activation of the splanchnic nerve's visceral efferent fibers leads to gallbladder relaxation, facilitating the flow of bile into the gallbladder through the cystic duct for storage. <sup>30-33</sup>

On the other hand, the hormone cholecystokinin (CCK), secreted by the duodenum in response to the presence of food in the small intestine, primarily mediates gallbladder contraction and bile secretion. The parasympathetic fibers from the vagus nerve provide assistance to CCK in facilitating this physiological response. <sup>30-33</sup>

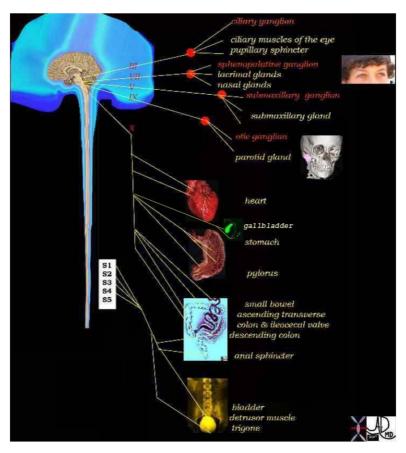


Figure 8: Nerve supply of biliary system

#### **Physiologic Variants**

A significant proportion, roughly 66%, of patients exhibit variant anatomical configurations of the biliary tree and its blood supply, which differ from the traditional description. It can be concluded that anomalies are more common than the norm, as only 30% of individuals possess the classic anatomy of the biliary tree. <sup>30-33</sup>

The cystic duct has a very wavering pattern ranging from joining the common hepatic duct situated high, almost at the biliary confluence, or running parallel to the common hepatic duct before entering the common bile duct almost at the level of the pancreas. <sup>30-33</sup>

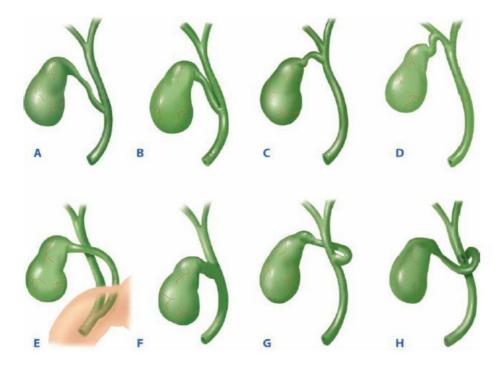


Figure 9: Variants of the cystic duct anatomy. A. Low junction between the cystic duct and common hepatic duct. B. Cystic duct adherent to the common hepatic duct. C. High junction between the cystic and the common hepatic duct. D. Cystic duct drains into right hepatic duct. E. Long cystic duct that joints common hepatic duct behind the duodenum. F. Absence of cystic duct. G. Cystic duct crosses posterior to common hepatic duct and joins it anteriorly. H. Cystic duct courses anterior to common hepatic duct and joins it posteriorly. 30-33

#### COMPLICATION OF GALLSTONES

# In the gall bladder

- Cholecystitis with abscess
- Perforation of gallbladder
- ➤ Gangrene of gallbladder
- Mucocele of gallbladder
- > Empyema of gallbladder
- ➤ Acute/ Chronic cholecystitis
- > Silent stones
- ➤ Mirizzi's syndrome
- Porcelain gallbladder
- > Hydrops gallbladder
- Carcinoma gallbladder

#### In the bile ducts:

- Obstructive jaundice
- Cholangitis
- ➤ Gallstone Pancreatitis<sup>30-33</sup>

#### In the intestine:

- > Acute Intestinal obstruction
- Cholecystoenteric fistula
- > Gallstone ileus

#### Laparoscopic cholecystectomy

In 1983, a German gynaecologist, Kurt Semm (1983), performed the first endoscopic appendectomy. It inspired another German surgeon, Erich Mühe (1986, 1990, Litynski GS 1998), to develop the endoscopic surgical technique, and in 1985 he performed the first endoscopic cholecystectomy with a special "Galloscope". A French surgeon, Mouret, continued to develop laparoscopic cholecystectomy and in 1987performed it in the same style as it is done today. Very rapidly after Mouret's discovery, laparoscopic cholecystectomy became popular without randomized trials, and in 1993 the National Institutes of Health made a consensus statement about laparoscopic cholecystectomy being the choice of treatment for most patients with symptomatic gallstones. The most common technique for laparoscopic

cholecystectomy is a four-trocar procedure. There are some studies which suggest that fewer trocars (two or three) might decrease the postoperative pain, but that the operation might be more difficult to perform. Traditionally, the favored method in laparoscopic cholecystectomy has been antegrade dissection, which means that the dissection of the gallbladder starts from the neck of the gallbladder. In difficult open cholecystectomy, a retrograde ("fundus first") dissection is often used to be sure about the cystic duct anatomy. If there are difficulties in identifying the 11 structures of Calot's triangle, a retrograde dissection can be used successfully also in laparoscopic cholecystectomy. The retrograde dissection might decrease the risk of conversion to the open cholecystectomy and common bile duct injuries. However, subtotal cholecystectomy or conversion must not be delayed if after the neck of the gallbladder is reached the anatomy is still unclear.<sup>34, 35</sup>

#### Port site infection (PSI)

Rapid growths in health care technology have given the surgeon the power of not only treating diseases surgically but also limiting surgical invasiveness. The greatest example is minimal access surgery (MAS) also commonly termed laparoscopic surgery (LS) or keyhole surgery, which has caused a paradigm shift in the approach to modern surgery, by limiting the access related morbidities. LS, however, has its package of unique complications. One such complication, which is preventable although, is the port site infection (PSI). PSI soon erodes the advantages of LS, with the patient becoming worried with the indolent and nagging infection and losing confidence on the operating surgeon. There occurs a significant increase in the morbidity, hospital stay and financial loss to the patient. The whole purpose of MAS to achieve utmost cosmesis is turned into an unsightly wound, and the quality of life of patients is seriously affected. 36-38

#### **Incidence of PSIs**

No surgical wound is completely immune to infections. Despite the advances in the fields of antimicrobial agents, sterilization techniques, surgical techniques, and operating room ventilation, PSIs still prevail. Incidence of SSI after elective laparoscopic cholecystectomy is less than that after open elective cholecystectomy due to shorter length of incision. The technique of primary port entry to the peritoneum does not show any difference in umbilical PSIs in patients undergoing laparoscopic cholecystectomy. The umbilical PSI rate in LS has been reported to be 8% with 89% of the infections occurring after laparoscopic cholecystectomy, whereas 11% after laparoscopic appendectomy. Francis et al studied the

factors predicting 30-d readmission after laparoscopic colorectal cancer surgery. Out of 268 patients in their study who underwent laparoscopic colorectal surgery, 48 (18%) were readmitted with surgical site infection (SSI). Several other authors have found that SSI rate is much higher in conventional surgical procedures than in MAS. The immune functions are less affected in LS as compared to open surgery. <sup>36-38</sup>

#### SSIs and PSIs

SSIs are infections consequent to the surgery that are present within a month of the operative procedure. Surveillance in surgeries, such as breast, cardiac, cranial, spinal and bone surgeries, with use of prosthetic material, extends to 90 d after surgery. PSI is a type of SSI but limited to LS. The same criteria for SSIs are applicable to PSIs, but the infections are limited to superficial and deep surgical sites only as detailed below.<sup>39, 40</sup>

According to the definitions developed by the United States Centre for Disease Control (CDC), SSIs were categorized into: (1) Superficial SSIs which involve skin and subcutaneous tissue; (2) Deep SSIs which involve fascia and muscle layers; and (3) Organ/Space SSIs. <sup>39, 40</sup>

Wounds are classified as (as per CDC criteria for SSI 2015): (1) Clean: A surgical wound that is neither exposed to any inflamed tissue nor has breached the gastrointestinal, respiratory, genital, or uninfected urinary tract; (2) Clean-Contaminated: Surgical wounds where there is controlled entry into the gastrointestinal, respiratory, genital, or uninfected urinary tract with minimal contamination; (3) Contaminated: Fresh wounds related to trauma, surgical wounds with major breach in sterile technique or gross contamination from the gastrointestinal tract, and incisions through non purulent inflammatory tissues; and (4) Dirty or Infected: Old wounds following trauma having devitalized tissue and surgical procedure performed in the presence of active infection or visceral perforation. <sup>39, 40</sup>

Most of the surgical procedures done by laparoscopy belong to Classes 1 and 2 wounds. The human body hosts a variety of microbes which can cause infections. When the host systemic immunity is suppressed due to any disease, medications or disruptions of the integrity of the skin or mucous membranes secondary to surgical insult, patients' own commensal microbial flora may cause infection. The PSIs in LS manifest in the form of seropurulent discharge from the port sites with surrounding skin inflammation or symptoms

related to the organ/space infection. The million-dollar question is why at all there occur PSIs in clean and clean contaminated wounds after LS. Is it because of the contamination from the endogenous source or through exogenous source? The endogenous source of infection cannot be avoided. But the incidence of PSIs after LS due to endogenous cause can be reduced by using sterile endobag for specimen retrieval. <sup>39, 40</sup>

#### INDICATIONS FOR LAPAROSCOPIC CHOLECYSTECTOMY

- Symptomatic cholelithiasis
- ➤ Biliary colic
- > Acute cholecystitis
- Choledocholithiasis
- ➤ Obstructive jaundice or cholangitis
- ➤ Gallstone pancreatitis
- Asymptomatic cholelithiasis
- > Sickle cell disease
- > Chronic immunosuppression
- > No immediate access to health care
- Incidental cholecystectomy for patients undergoing intra-abdominal operations for other reasons
- Acalculous cholecystitis
- Functional gallbladder disorder
- Gallbladder polyps >10 mm
- Porcelain gallbladder

#### CONTRAINDICATIONS TO LAPAROSCOPIC CHOLECYSTECTOMY

#### **Absolute**

- Unable to tolerate general anesthesia
- Refractory coagulopathy
- Gallbladder carcinoma

#### Relative

- Cholangitis
- Diffuse peritonitis
- Cirrhosis and/or portal hypertension
- Cholecystoenteric fistula

Relative contraindications are dictated primarily by the surgeon's philosophy and experience. These include previous upper abdominal surgery with extensive adhesions, cirrhosis, portal hypertension, severe cardiopulmonary disease, morbid obesity, and pregnancy. In most patients, little is lost by initiating a laparoscopic cholecystectomy with conversion to laparotomy if the laparoscopic approach is deemed too risky.

Pregnancy is a controversial relative contraindication to laparoscopic cholecystectomy because of the unknown effects of prolonged carbon dioxide (CO2) pneumoperitoneum on the fetus. Laparoscopic cholecystectomy can be performed safely during pregnancy but only with great care. The timing of cholecystectomy during pregnancy is a topic of controversy and was traditionally limited to the second trimester of gestation after organogenesis is complete and prior to the uterine fundus reaching a size and height that encroaches on the operative field. However, there are no data to suggest that laparoscopy during the first trimester is more dangerous, and current society recommendations are generally in favor of performing laparoscopic cholecystectomy at any point during pregnancy as soon as symptoms arise. Open insertion of the initial port in a supraumbilical or right upper quadrant position should be used to avoid injury to the gravid uterus, and the insufflation pressure should be limited to less than 12 mm Hg to avoid respiratory embarrassment and decreased vena caval return. Also, maternal hyperventilation with close monitoring of end-tidal CO2 should be undertaken to prevent fetal acidosis. When visualization of the biliary tree is required, laparoscopic ultrasound is used in place of cholangiography in order to limit fetal

radiation exposure. Finally, perioperative consultation with an experienced obstetrician is advisable, as is perioperative fetal heart monitoring.

Early experience suggested that acute cholecystitis was a relative contraindication to performing laparoscopic cholecystectomy. However, as general surgeons have gained more experience with laparoscopic cholecystectomy and laparoscopy in general, it has uniformly become the preferred initial approach to patients with cholecystitis. There is clearly a higher rate of conversion in the setting of acute cholecystitis. In particular, after 72 hours, the rate of conversion increases significantly. One should not hesitate to convert to an open cholecystectomy if significant adhesions or inflammation precludes safe dissection during laparoscopy.

# **OPERATIVE TECHNIQUE**

#### **Anatomy**

The classic anatomy of the biliary tree is present in only 30% of individuals, so it may be said that anomalies are the rule, not the exception. As with any procedure, the knowledge of normal anatomy and common variants is critical to the success of surgical intervention. The cystic duct may join the CBD at an acute angle, travel parallel to the common duct for several centimeters prior to insertion, insert into the right hepatic duct, or be congenitally absent.

The cystic artery usually arises from the right hepatic artery, but one must be absolutely sure that the cystic artery is visualized entering the gallbladder wall. Occasionally the right hepatic artery will loop up onto the surface of the gallbladder, and a very short cystic artery will arise. Furthermore, there can often be a posterior cystic artery, which can easily be injured if not recognized. The CBD begins at the junction of the cystic duct and the common hepatic duct and passes inferiorly to the ampulla of Vater. Its normal diameter is less than 6 mm, although it may be larger in elderly patients and those with biliary obstruction.

It is important to clearly identify the structures within the hepatocystic triangle, which is the ventral aspect of the area bounded by the gallbladder wall and cystic duct, the liver edge, and the common hepatic duct. Contained within the hepatocystic triangle is the eponymic Calot triangle: The boundaries of the Calot triangle include the cystic duct, cystic artery, and common hepatic duct. Aberrant anatomy is a well-recognized risk factor for biliary injury. An aberrant right hepatic duct is the most common anomaly causing problems during laparoscopic cholecystectomies. The most dangerous variant is when the cystic duct

joins a low-lying aberrant right sectoral duct. Injuries to these ducts are underreported since occlusion of an aberrant duct may be asymptomatic and even unrecognized.

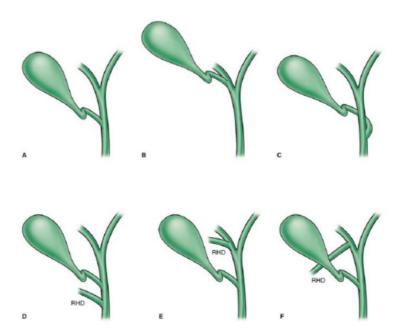


Figure 10: Biliary anatomy variations. A. Normal anatomy. B. Cystic duct insertion on right hepatic duct. C. Anterior or posterior spiral insertion of cystic duct. D, E, and F. Common variants of accessory right hepatic duct (RHD)

#### **Patient Preparation**

As with any abdominal operation, patients are fasted for a minimum of 8 hours prior to the operation. Patients without major comorbidities are generally scheduled as outpatient procedures. Prophylactic antibiotics are up to the surgeon's discretion; evidence suggests that most patients have a very low risk of perioperative infection, and perioperative antibiotics have not been shown to significantly decrease this risk. Antiembolic stockings and sequential compression devices are placed on both legs to avoid pooling of blood in the lower extremities by the reverse Trendelenburg position generally used during this operation. Patients at higher risk for lower extremity deep vein thrombosis (DVT) are additionally given prophylactic dose subcutaneous unfractionated or low-molecular-weight heparin. Following induction of general endotracheal anesthesia, an orogastric tube should be placed to decompress the stomach. The abdomen is shaved and prepared in standard sterile fashion with particular care taken to rid the umbilicus of all debris.

# LAPAROSCOPIC CHOLECYSTECTOMY

# **OPERATING ROOM SETUP**

Most surgeons use 2 video monitors, 1 on each side of the operating table above the patient's shoulders to facilitate visualization by both the surgeon and assistant. Using the American technique, the surgeon stands to the left of the patient and the first assistant stands to the patient's right. If a laparoscopic video camera operator is used, he or she stands to the left of the surgeon. In the French technique, the patient's legs are abducted and the surgeon stands between the legs.

#### **PNEUMOPERITONEUM**

A working space, provided by a pneumoperitoneum, is essential for the surgeon to see and to operate within the abdominal cavity. CO2 has the advantage of being noncombustible and rapidly absorbed from the peritoneal cavity. It may, however, lead to hypercarbia in patients with significant cardiopulmonary disease. The most common location for initial peritoneal entry is at the midline near the umbilicus. Supraumbilical or infraumbilical incisions may be made in vertical, horizontal, or curvilinear orientations based on surgeon's preference.

Pneumoperitoneum can be established by either a closed or an open technique. In the closed technique, CO2 is insufflated into the peritoneal cavity through a Veress needle, which is subsequently replaced with a laparoscopic port placed blindly into the abdominal cavity. In the open technique, a laparoscopic port is inserted under direct vision into the peritoneal cavity via a small incision; only after ensuring definitive and safe peritoneal entry is the pneumoperitoneum established. There are advantages and disadvantages to both techniques. Surgeons performing laparoscopic cholecystectomy should learn both and use them selectively based on the patient's body habitus and previous surgical history.

#### PORT PLACEMENT AND EXPOSURE

Depending on the surgeon's preference, a 5- or 10-mm laparoscope is inserted into the abdomen through the periumbilical port and the abdominal cavity is visually explored. It is generally advantageous to use an angled (30-or 45-degree) laparoscope rather than a 0-degree scope, because the angled scopes enable obtaining multiple views of the same operative field. The patient is then placed in a reverse Trendelenburg position of 30 degrees while rotating the table to the left by 15 degrees. This maneuver allows the colon and duodenum to fall away from the liver edge. The falciform ligament and both lobes of the liver are examined closely for abnormalities. The gallbladder can usually be seen protruding beyond the edge of

the liver, and the degree of inflammation surrounding the gallbladder can be gauged. Two small accessory subcostal ports are then placed under direct vision. The first 5-mm trocar is placed along the right anterior axillary line between the 12th rib and the iliac crest. This trocar should be at least 2 finger breadths inferior to the costal margin and as lateral as possible while remaining anterior to the ascending colon. A second 5-mm port is inserted in the right subcostal area in the midclavicular line. Grasping forceps are placed through these 2 ports to secure the gallbladder. The assistant manipulates the lateral grasping forceps, which are used to grasp the fundus and elevate the liver.

The fourth working port is then inserted through an incision in the midline of the epigastrium. This trocar is usually inserted approximately 5 cm below the xiphoid process, but the precise position and angle depend on the location of the gallbladder as well as the size of the medial segment of the left lobe of the liver. It should be placed so that the trocar enters the peritoneum to the right of the falciform ligament.

Dissecting forceps are then inserted and directed toward the gallbladder neck. One should note that the orientation of the laparoscope is generally parallel to that of the cystic duct when the fundus is elevated, whereas the instruments placed through the other 3 ports enter the abdomen at right angles to this plane. The surgeon uses a dissecting forceps to raise a serosal fold of the most dependent portion of the fundus. The assistant's heavy grasping forceps are then locked onto this fold using either a spring or ratchet device. With these axillary grasping forceps, the fundus of the gallbladder is then pushed in a lateral and cephalad direction, rolling the entire right lobe of the liver cranially.

This maneuver is complicated in patients with a fixed, cirrhotic liver or a heavy, friable liver because of fatty infiltration. In patients with few adhesions to the gallbladder, pushing the fundus cephalad exposes the entire gallbladder, cystic duct, and porta hepatis. Most patients, however, have adhesions between the gallbladder and the omentum, hepatic flexure, and/or duodenum. These adhesions are generally avascular and may be lysed bluntly by grasping them with dissecting forceps at their site of attachment to the gallbladder wall and gently stripping them down toward the infundibulum. Extreme caution should be taken to avoid damage to surrounding structures. Use of electrocautery may accidentally damage the unvisualized CBD or proximally located duodenum. After exposing the infundibulum, blunt grasping forceps held in the surgeon's left hand and placed through the midclavicular trocar

are used to grasp and place traction on the neck of the gallbladder.

#### DISSECTION

The infundibulum is grasped, placing traction on the gallbladder in a lateral direction to distract the cystic duct from the CBD. Fine-tipped dissecting forceps (Maryland) are used to dissect away the overlying fibroareolar structures from the infundibulum of the gallbladder. The dissection should begin from a known structure, for example, the gallbladder, rather than in an unknown area, to avoid damage to the underlying structures such as a bile duct or hepatic artery. The dissection initially commences 4 or 5 cm proximal to the neck of the gallbladder and proceeds distally, such that a modified "top-down" technique is employed. The objective of the initial dissection is to free the gallbladder from its bed such that there is a window beneath it through which the liver substance can be seen. This dissection is typically initiated on the lateral (ie, anatomic right) side of the gallbladder to avoid approaching the cystic duct and artery until the anatomy, including the true edge of the gallbladder, has been more clearly defined. During this portion of the dissection, the infundibulum should be retracted medially and superiorly. Blunt dissection is used to create a "window" in the lateral edge of the peritoneum overlying the gallbladder. Once this window has been opened, it is safe to use an L-shaped electrocautery hook to open the rest of the lateral peritoneal edge, heading toward the gallbladder fundus, away from the cystic duct and portal structures. When applying electrocautery, it is important to pull the instrument away from the gallbladder to avoid a perforation or other injury to underlying structures. We then retract the infundibulum laterally and inferiorly and repeat this process to open the medial peritoneal edge of the gallbladder.

After both peritoneal edges have been opened high up onto the gallbladder fundus, the hepatocystic triangle is maximally opened and converted into a trapezoid shape by retracting the infundibulum of the gallbladder inferiorly and laterally while maintaining the fundus under traction in a superior and medial direction. A lymph node usually lies on the surface of the cystic artery, and occasionally it is necessary to use a brief application of low wattage electrosurgical coagulation to obtain hemostasis as the lymph node is bluntly swept away. To expose the reverse of the Calot triangle, the infundibulum of the gallbladder is pulled in a superior and medial direction.

The use of an angled laparoscope facilitates viewing both sides of the hepatocystic triangle when used in combination with these retraction techniques. After clearing the structures from the apex of the triangle, the junction between the infundibulum and the origin

of the proximal cystic duct can be tentatively identified. The strands of peritoneal, lymphatic, and neurovascular tissue are stripped away from the cystic duct to clear a segment from the surrounding tissue. Curved dissecting forceps are helpful in creating a window around the posterior aspect of the cystic duct to skeletonize the duct itself. Alternatively, the tip of the hook cautery can be used to encircle and expose the duct. It is generally unnecessary and potentially harmful to dissect the cystic duct down to its junction with the CBD. The cystic artery is separated from the surrounding tissue by similar blunt dissection at this time. If the cystic artery crosses anterior to the duct, the artery may require dissection and division prior to approaching the cystic duct, although if at all possible, this should be avoided until all relevant anatomy has been clearly identified.

The neck of the gallbladder is thus dissected away from its liver bed, leaving a large window at its base through which the liver parenchyma is visualized. At least one-third of the cystic plate (ie, gallbladder bed) should be exposed in this manner. At this point, there should be 2, and only 2, structures (the cystic duct and artery) crossing this window—this is the "critical view of safety," which should be demonstrated prior to clipping or cutting any tubular structures. To reiterate, no structure should be divided until the cystic duct and cystic artery are unequivocally identified. Developing this critical view of safety is an essential step to minimize the chance of bile duct injury during laparoscopic cholecystectomy

#### COMPLETION OF CHOLECYSTECTOMY

The cystic duct is clipped using an endoscopic clip applier and divided using scissors. Two clips are placed distally on the cystic duct, and 1 clip is placed toward the gallbladder. For cystic ducts that are large or friable, a preformed endoloop is preferable for ligating the distal cystic duct. After the duct is divided, the cystic artery is dissected from the surrounding tissue for an adequate distance to permit placement of 3 clips. The surgeon must determine that the structure is indeed the cystic artery and not the right hepatic artery looping up onto the neck of the gallbladder or an accessory or replaced right hepatic artery. After an appropriate length of cystic artery has been dissected free, it is clipped proximally and distally prior to transection. Electrocautery should not be used for this division, as the current may be transmitted to the proximal clips, leading to subsequent necrosis and hemorrhage.

The ligated stumps of the cystic duct and the artery are then examined to ensure that there is no leakage of either bile or blood and that the clips are placed securely and compress the entire lumen of the structures without scissoring or impinging on adjacent tissues. A suction-irrigation catheter is used to remove any debris or blood that has accumulated during

the dissection. Separation of the gallbladder away from its hepatic bed is then initiated using an electrosurgical probe to coagulate small blood vessels and lymphatics. While maintaining cephalad traction on the fundus of the gallbladder with the axillary forceps, the midclavicular forceps pulls the neck of the gallbladder anterosuperiorly and then alternatively medially and laterally to expose and place the tissue connecting the gallbladder to its fossa under tension. An electrocautery spatula or hook is used to coagulate and divide the tissue. Intermittent blunt dissection will facilitate exposure of the proper plane.

Dissection of the gallbladder fossa continues from the infundibulum to the fundus, progressively moving the midclavicular grasping forceps cephalad to allow maximal countertraction. The dissection proceeds until the gallbladder is attached by only a thin bridge of tissue. At this point, prior to completely detaching the gallbladder, the hepatic fossa and porta hepatis are once again inspected for hemostasis and bile leakage. Small bleeding points are coagulated, and the right upper quadrant is liberally irrigated and then aspirated dry while checking for any residual bleeding or bile leakage. The final attachments of the gallbladder are divided, and the liver edge is again examined for hemostasis.

After the cholecystectomy has been performed, the gallbladder must be removed from the abdominal cavity. The gallbladder may be placed within an entrapment sac prior to extracting it through the abdominal wall. This is recommended particularly if the gallbladder has been perforated intraoperatively or if the specimen is large. If the stone burden is small, the gallbladder can be extracted at the subxiphoid port site. Usually, the gallbladder is most easily removed at the umbilical port site where there are no muscle layers anterior to the fascial plane. Also, if the fascial opening needs to be enlarged because of large or numerous stones, extension of the umbilical incision causes less postoperative pain and has better cosmesis than does enlarging the subxiphoid incision. The laparoscope is removed from the umbilical port and placed through the epigastric port. Large "claw" grasping forceps are introduced through the umbilical port to grasp the infundibulum of the gallbladder. The forceps, trocar, and gallbladder neck are then retracted as a unit through the umbilical incision. The neck of the gallbladder is thus exteriorized through the anterior abdominal wall with the fundus remaining within the abdominal cavity. If the gallbladder is not distended with bile or stones, it can be simply withdrawn with gentle traction. In many cases, a suction catheter introduced through an incision in the gallbladder neck is used to aspirate bile and small stones. Stone forceps can also be placed into the gallbladder to extract or crush calculi if necessary. Occasionally, the fascial incision must be extended to extract larger stones or thick-walled gallbladders.

Each incision is infiltrated with bupivacaine for postoperative analgesia. The fascia of the umbilical incision is closed with 1 or 2 large absorbable sutures in an interrupted or figure-of-8 fashion. Closure of the subxiphoid fascia is optional, as visceral herniation is unlikely to occur because of the oblique entry angle of the trocar into the abdominal cavity and its location anterior to the falciform ligament. The skin of the subxiphoid and umbilical incisions is closed with subcuticular absorbable sutures. The skin incisions at both 5-mm port sites can be closed with absorbable sutures, adhesive strips, or skin closure adhesives. The orogastric tube is removed in the operating room, and the patient is transferred to the post-anesthesia care unit. Patients are allowed out of bed as soon as they are fit enough to walk, and more than 90% of patients are discharged from the hospital within 24 hours. Fit patients who have been preoperatively selected may be safely discharged within 6 hours following surgery. Patients are evaluated 1 week following surgery. At this time, more than 95% of patients are back to a normal routine, and most return to work immediately following their clinic visit.

#### ADVANTAGES AND DISADVANTAGES

The advantages of laparoscopic cholecystectomy over other therapies for gallstone disease are multiple. Unlike non-resective techniques for gallstone ablation, laparoscopic cholecystectomy removes the diseased gallbladder along with its stones. Relative to traditional open cholecystectomy, postoperative pain and intestinal ileus are diminished with laparoscopic cholecystectomy. The small size of the fascial incisions allows rapid return to heavy physical activities. The small incisions are also cosmetically more appealing than is the large incision used during traditional cholecystectomy. The patient can usually be discharged from the hospital either on the same day or the day following operation and can return to full activity within a few days. These factors lead to overall decreased cost of laparoscopic cholecystectomy compared to its traditional open counterpart.

# ADVANTAGES AND DISADVANTAGES OF LAPAROSCOPIC CHOLECYSTECTOMY COMPARED WITH OPEN CHOLECYSTECTOMY

ADVANTAGES	DISADVANTAGES
Less pain	Lack of depth perception
Shorter hospitalization	Diffusedly in setting of dense
	adhesions/inflammation
Early return to full activity	More difficult to control hemorrhage
Decreased wound complications	Potential CO2 insufflation complications
(infection and hernia)	
Decreased total costs	Slight increase in bile duct injuries

There are, however, several potential disadvantages of laparoscopic cholecystectomy. As opposed to non-resective treatments for gallstones, patients must be acceptable candidates for general anesthesia and possible laparotomy. Three-dimensional depth perception is limited by the 2- dimensional monocular image of the videoscope. It is more difficult to control significant hemorrhage using laparoscopic technology than in an open surgical field. There is also less haptic discrimination of structures using laparoscopic instruments as opposed to direct digital palpation during open cholecystectomy. CO2 insufflation to create the pneumoperitoneum is associated with a number of potential risks, including reduction of vena caval flow and systemic hypercarbia with acidosis.

#### SPECIAL CONSIDERATIONS

#### **Conversion to Open Operation**

Surgeons performing laparoscopic cholecystectomy should not think of conversion to open operation as a complication, but rather a sound clinical judgment, and hence not hesitate to convert to a traditional open cholecystectomy if the anatomy is unclear, if complications arise, or if there is failure to make reasonable progress in a timely manner. Some complications requiring laparotomy are obvious, such as massive hemorrhage or major injury to the bile duct. Open laparotomy allows the additional tool of manual palpation and haptic sensation and should be performed when the anatomy cannot be delineated because of inflammation, adhesions, or anomalies. Fistulae between the biliary system and bowel are rare, but may require laparotomy for optimal management. The demonstration of potentially resectable gallbladder carcinoma also dictates an open exploration. Finally, CBD stones that

cannot be removed laparoscopically and are unlikely to be extracted endoscopically because of Billroth II anastomosis, previously failed ERCP, should be converted to open operation without hesitation.

### **Open Cholecystectomy**

The technical aspects of performing an open cholecystectomy have not changed significantly since Langenbuch's description of this procedure more than 100 years ago. Although this operation can be performed safely through a midline, paramedian, or right subcostal incision, most surgeons prefer the right subcostal (Kocher) incision. Adequate exposure of the gallbladder and the hepatoduodenal ligament is the key to performing a safe cholecystectomy.

Laparotomy sponges may be packed temporarily between the dome of the liver and the diaphragm, and appropriate self-retaining retractors should be inserted to optimize visualization of the hepatoduodenal ligament and its structures. The hepatic flexure of the colon is packed or retracted inferiorly, and the medial segment of the left liver lobe is retracted superiorly. When a large distended gallbladder is encountered, removal can be facilitated by decompressing the gallbladder. Adhesions of omentum or viscera adjacent to the gallbladder are divided with sharp dissection or electrocautery.

Meticulous dissection and positive identification of the cystic duct, its entry into the CBD, and the cystic artery are mandatory and significantly reduce the likelihood of bile duct injury. Most experienced surgeons prefer to identify these important structures before beginning dissection of the gallbladder from the hepatic bed. The fundus and infundibulum of the gallbladder are grasped with curved clamps. The fundus is retracted anteriorly and superiorly and the infundibulum inferiorly and laterally, exposing the structures of the Calot triangle. Caudal counter-retraction of the hepatoduodenal ligament stretches and exposes the porta hepatis, placing the peritoneum overlying the cystic duct and artery on tension. This maneuver may be accomplished with a retractor, although the left hand of the first assistant effectively retracts the duodenum. The surgeon introduces the left index finger into the foramen of Winslow and palpates for calculi in the CBD. Acute inflammation or chronic scarring may preclude approaching the infundibulum first; many surgeons prefer to dissect the fundus initially (ie, a fundus first or top-down technique), and the ductal and vascular structures subsequently, only after the organ has been separated from the liver. Careful ligation of the cystic duct is essential not only in preventing a biliary leak, but also in reducing the possibility of bile duct injury and stricture. Ligation of the cystic duct in close

proximity to its junction with the CBD has long been considered an essential component of open cholecystectomy. Experience with laparoscopic cholecystectomy suggests that the length of the cystic duct stump is not a critical factor and probably does not significantly contribute to post-cholecystectomy syndrome, a poorly defined clinical entity characterized by pain after gallbladder removal. Therefore, it is safer to divide the cystic duct closer to the gallbladder infundibulum once a "critical view of safety" has been obtained and to avoid dissection in proximity to the CBD altogether. The cystic artery should be dissected, secured, and divided near the surface of the gallbladder. This will reduce bleeding associated with division of the peritoneum investing the gallbladder and separation of areolar tissue between the gallbladder and the liver. Intraoperative cholangiography can be performed at the discretion of the surgeon.

Throughout the procedure, care should be exercised to minimize spillage of bile into the peritoneal cavity. Drains are not mandatory and are indicated only if the surgeon is concerned about identifying or controlling a possible bile leak. Common pitfalls are usually related to inadequate exposure, severe inflammation, bleeding, and anatomic variants, which can lead to injury of portal structures, including the CBD and the hepatic artery or its branches. With a short cystic artery, the right hepatic artery must be carefully identified.

Similarly with a short cystic duct, careful dissection and high ligation of the cystic duct near the gallbladder should be employed to avoid injury to the CBD. In fact, in the face of severe inflammation with obliteration of normal tissue planes, it may be safest to perform a subtotal cholecystectomy, leaving a portion of the infundibulum in situ (after removing all stones) and suture ligating the mucosal side of the cystic duct origin. If there is unintentional gallbladder puncture, a second clamp or purse string suture can be applied to prevent gallbladder bile and stone spillage. Before closing the abdominal incision, bleeding and bilious drainage must be controlled. Structures in the porta hepatis are reexamined, with special attention to the cystic duct stump. The subhepatic space is irrigated with warm saline and all irrigants are evacuated. The incision is usually closed in 1 or 2 layers. The skin can be closed with sutures or staples.<sup>41</sup>

# WOUND PROTECTORS<sup>42, 43</sup>

Wound protectors are devices used during surgery to protect the edges of a surgical incision and the underlying tissues. They help reduce the risk of infection and trauma. Types of wound protectors:

- 1. **Plastic Wound Protectors**: These are flexible, transparent plastic sheets that cover the wound edges. They help in isolating the incision site from potential contaminants.
- 2. **Ring-Based Wound Protectors:** These consist of an inner and outer ring connected by a cylindrical sleeve. The inner ring is placed inside the incision, and the outer ring remains outside, creating a barrier.
- 3. **Adhesive Wound Protectors:** These are adhesive films or drapes applied over the wound. They offer a sterile barrier and can also include antimicrobial properties.
- 4. **Silicone Wound Protectors:** Made of silicone, these protectors are soft and flexible, minimizing tissue trauma while maintaining a barrier.
- 5. **Disposable Wound Protectors:** Single-use protectors that ensure sterility for each surgical procedure and are discarded after use.

Each type of wound protector has its specific applications and benefits, depending on the surgical procedure and the surgeon's preference.

**PLASTIC WOUND PROTECTORS**:<sup>43, 44</sup> These are used during surgical procedures to protect the edges of the incision and the underlying tissues from contamination.

**Material:** They are typically made of transparent, flexible, and biocompatible plastic materials such as polyurethane or polyethylene.

**Design:** These protectors come in various shapes and sizes to accommodate different types of surgical incisions. Some may have adhesive edges to secure them in place around the incision site.

#### **Functions and Benefits:**

- Barrier Protection: Plastic wound protectors act as a physical barrier, isolating the incision site from potential contaminants, including bacteria and bodily fluids.
- Clear Visibility: The transparency of the plastic allows the surgical team to monitor the wound and the surrounding area without removing the protector.
- -Ease of Use: They are easy to apply and remove, and they can be cut to fit the specific dimensions of the incision.
- Sterility: Most plastic wound protectors are provided in sterile packaging to maintain a sterile environment during surgery. 43, 44

#### **Application and Usage:**

- Placement: The protector is placed over the wound after the incision is made, ensuring that it covers the wound edges adequately.
- Secure Fit: Adhesive versions ensure a secure fit, preventing displacement during the surgical procedure.
- Versatility: Suitable for various types of surgeries, including abdominal, thoracic, and orthopedic procedures. <sup>43, 44</sup>

# **Advantages**

- Reduced Infection Risk: By providing a sterile barrier, plastic wound protectors help reduce the risk of surgical site infections (SSI).
- Minimized Tissue Trauma: The soft, flexible nature of the plastic minimizes trauma to the wound edges, promoting better healing.
- Cost-Effective: They are generally cost-effective and widely available, making them a practical choice for many surgical settings. 43, 44

#### **Considerations**

- Single-Use: Most plastic wound protectors are designed for single use to ensure sterility and prevent cross-contamination.
- Compatibility: Compatibility with other surgical instruments and procedures being used should be checked
- Disposal: Proper disposal is necessary to adhere to medical waste management protocols.  $^{43}$ ,



Figure 11: Intraoperative image of Plastic wound protector

**RING-BASED WOUND PROTECTORS**: These are surgical devices designed to protect and retract the edges of an incision during surgery. They provide a sterile barrier and maintain the incision open, allowing better access and visibility for the surgical team.<sup>45</sup>

#### Structure:

- Inner and Outer Rings: These protectors consist of two rings – an inner ring placed inside the incision and an outer ring that stays outside. The rings are connected by a flexible, cylindrical sleeve.

Material: Typically made from biocompatible, flexible materials like silicone, latex, or polyurethane. The rings may be rigid or semi-rigid to maintain the shape and position. The connecting sleeve is usually transparent, allowing visibility into the wound, and is flexible to accommodate movement and manipulation. <sup>45</sup>

#### **Functions and Benefits:**

- Barrier Protection: Creates a physical barrier to protect the wound edges from contaminants and reduce the risk of infection.
- Retraction: Holds the wound edges apart, providing a clear view and access to the surgical site without additional retractors.
- Tissue Protection: The flexible sleeve minimizes trauma to the wound edges, promoting better healing and reducing postoperative pain and complications.
- Visibility and Access: The transparent sleeve and stable rings ensure that the surgical team has an unobstructed view and access to the operative field. 45

#### **Application and Usage:**

- Placement: The inner ring is inserted into the incision and then the outer ring is placed outside, adjusting the sleeve to fit the depth and width of the incision.
- Adjustment: The sleeve can be adjusted to accommodate different incision sizes, and some models allow tension adjustment to ensure a snug fit.
- Versatility: Suitable for various types of surgeries, including abdominal, thoracic, gynecological, and colorectal procedures.

# **Advantages:**

- Reduced Infection Risk: By maintaining a sterile barrier around the wound edges, ringbased wound protectors help lower the incidence of surgical site infections (SSI).
- Improved Healing: The device minimizes mechanical trauma and contamination, contributing to faster and better healing of the incision.
- Ease of Use: Simple to insert and adjust, reducing the need for multiple retractors and hands in the operative field.
- Single-Use: Many ring-based wound protectors are designed for single use, ensuring sterility for each procedure and eliminating the risk of cross-contamination. <sup>45</sup>

#### **Considerations:**

- Compatibility: Compatibility should be ensured with the specific surgical procedure and other instruments being used.
- Training: Proper training in the placement and adjustment of the device is essential for optimal performance and safety.
- Cost: The cost-effectiveness of single-use versus reusable options should be considered,
   taking into account the reduction in infection rates and improved outcomes.

#### **Examples:**

- Alexis Wound Protector/Retractor: A popular brand offering a variety of sizes and adjustable tension features.
- Mobius Wound Retractor: Known for its ease of use and effective retraction capabilities.

Ring-based wound protectors are valuable tools in modern surgery, providing enhanced protection, visibility, and access while promoting better healing and reducing infection risks.



Figure 12: Alexis wound protectors

**ADHESIVE WOUND PROTECTORS:**<sup>46</sup> They are used in surgical procedures to create a sterile barrier over the incision site. They help reduce the risk of contamination and infection while providing protection to the wound edges.

#### **Structure and Material:**

- Adhesive Film: Made from a thin, flexible, and transparent material, such as polyurethane or polyethylene, which adheres to the skin around the incision.
- Adhesive Layer: The underside of the film has an adhesive layer that securely attaches to the skin, creating a seal around the wound.
- Antimicrobial Properties: Some adhesive wound protectors are impregnated with antimicrobial agents to further reduce the risk of infection. <sup>46</sup>

#### **Functions and Benefits:**

- Barrier Protection: Provides a sterile barrier that isolates the incision site from potential contaminants, including bacteria, fluids, and other environmental factors.
- Secure Fit: The adhesive layer ensures that the protector stays in place during the procedure, maintaining a consistent protective barrier.
- Visibility: The transparent nature of the film allows the surgical team to monitor the wound and the surrounding area without removing the protector.
- Flexibility: The flexible material conforms to the contours of the body, providing protection without restricting movement or access to the surgical site. <sup>46</sup>

#### **Application and Usage:**

- Preparation: The skin around the incision site is cleaned and dried before applying the

adhesive wound protector to ensure optimal adhesion.

- Placement: The protector is carefully placed over the incision, with the adhesive layer securely attaching to the skin. It is smoothed out to eliminate any wrinkles or air bubbles.
- Removal: After the surgery, the adhesive wound protector can be gently peeled away from the skin, taking care not to disturb the wound. <sup>46</sup>

#### **Advantages:**

- Reduced Infection Risk: By providing a sterile barrier, adhesive wound protectors help reduce the risk of surgical site infections (SSI).
- Ease of Use: Simple to apply and remove, making them convenient for both the surgical team and the patient.
- Improved Healing: Protects the wound edges from contamination and trauma, promoting better healing and reducing postoperative complications.
- Cost-Effective: Generally cost-effective and widely available, making them a practical choice for various surgical settings. <sup>46</sup>

#### **Considerations:**

- Skin Sensitivity: Ensure the adhesive is compatible with the patient's skin to avoid allergic reactions or skin irritation.
- Proper Application: Correct application is crucial to maintain a sterile barrier and prevent gaps or wrinkles that could compromise protection.
- Single-Use: Most adhesive wound protectors are designed for single use to ensure sterility and prevent cross-contamination.
- Compatibility: Ensure compatibility with other surgical instruments and procedures being used.<sup>46</sup>

# Examples:<sup>47</sup>

- Ioban 2 Antimicrobial Incise Drape (3M): An adhesive drape with antimicrobial properties that helps reduce the risk of infection.
- OpSite Incise Drapes (Smith & Nephew): Transparent adhesive drapes that provide a sterile barrier and are easy to apply.
- Steri-Drape (3M): A range of adhesive surgical drapes designed to create a sterile field around the incision site. <sup>47</sup>



Figure 13: Intraoperative image showing Ioban 2 Antimicrobial Incise Drape (3M)

**SILICONE WOUND PROTECTORS**: They are used during surgical procedures to protect the edges of an incision and minimize trauma to the surrounding tissues. They are made from silicone, a material known for its flexibility, biocompatibility, and non-reactive properties.<sup>48</sup>

#### **Structure and Material:**

- Made from medical-grade silicone, which is soft, flexible, and durable. Silicone is chosen for its biocompatibility and minimal reactivity with bodily tissues.
- Typically consists of a flexible silicone ring or sleeve that fits around the edges of the incision. Some designs include additional features like a cylindrical sleeve or flanges for better stability and protection. <sup>48</sup>

#### **Functions and Benefits:**

- Tissue Protection: Silicone wound protectors provide a soft barrier that minimizes mechanical trauma to the wound edges during surgery. This helps in reducing inflammation and promoting better healing.
- Barrier Protection: They create a physical barrier that isolates the incision site from potential contaminants, reducing the risk of infection.
- Flexibility: The silicone material is highly flexible, allowing it to conform to the contours of the body and accommodate movement without losing its protective properties.
- Visibility: Silicone wound protectors are often transparent or semi-transparent, allowing the surgical team to monitor the wound and surrounding area without removing the protector. <sup>48</sup>

# **Application and Usage:**

- Placement: The silicone wound protector is placed over the incision site after the incision is made. It is gently positioned to cover the wound edges completely.
- Adjustment: The protector can be adjusted to ensure a snug fit around the incision, providing optimal protection without compressing the tissues.
- Versatility: Suitable for various types of surgeries, including abdominal, thoracic, gynecological, and orthopedic procedures.

# **Advantages:**

- Reduced Infection Risk: By maintaining a sterile barrier around the wound edges, silicone wound protectors help lower the incidence of surgical site infections (SSI).
- Improved Healing: The soft, flexible nature of silicone minimizes trauma to the wound edges, promoting better healing and reducing postoperative pain and complications.
- Ease of Use: Simple to apply and adjust, making them convenient for surgical teams.
- Reusability: Some silicone wound protectors are designed for multiple uses, making them a
  cost-effective option for many surgical practices. Proper sterilization between uses is
  essential. 48

#### **Considerations:**

- Proper Fit: The correct size and fit of the silicone wound protector is crucial for optimal performance and protection.
- Training: Proper training in the application and adjustment of the protector is essential to maximize its benefits and ensure patient safety.
- Sterilization: Reusable silicone wound protectors must be properly sterilized between uses to maintain sterility and prevent infection. <sup>48</sup>

#### **Examples:**

- Alexis O-Ring Wound Protector/Retractor: A popular brand offering a range of sizes and designs, known for its effective retraction and protection capabilities.
- Applied Medical Alexis Wound Retractor: Features a silicone ring and a flexible sleeve, providing excellent protection and retraction. 48

Silicone wound protectors play a vital role in modern surgery by protecting the wound edges, reducing infection risks, and promoting optimal healing conditions. Their flexibility,

biocompatibility, and ease of use make them a preferred choice in various surgical settings. 48



Figure 14: Silicon wound protector

**DISPOSABLE WOUND PROTECTORS:** These are single-use devices designed to protect surgical incisions from contamination and reduce the risk of infection during surgery. They provide a sterile barrier and are discarded after a single use, ensuring maximum sterility for each procedure.<sup>49</sup>

#### **Structure and Material:**

- These are typically made from medical-grade plastics or polymers, such as polyurethane or polyethylene, that are both flexible and durable.
- These protectors often feature an inner ring that is inserted into the incision and an outer ring that stays outside, connected by a cylindrical sleeve. Some may come with adhesive features to secure them in place.<sup>49</sup>

#### **Functions and Benefits**

- Sterile Barrier: Disposable wound protectors create a physical barrier around the wound edges, isolating the incision site from potential contaminants and reducing the risk of surgical site infections (SSI).
- Tissue Protection: They minimize mechanical trauma to the wound edges, promoting better healing and reducing postoperative pain and complications.
- Single Use: Designed for single use, which eliminates the risk of cross-contamination and ensures that each surgery starts with a completely sterile protector.

- Convenience: Being disposable, they simplify the surgical workflow by eliminating the need for sterilization and reprocessing. <sup>49</sup>

# **Application and Usage:**

- Placement: After making the incision, the inner ring is placed inside the incision, and the outer ring remains outside, with the sleeve providing a barrier. The protector is adjusted to fit the size and depth of the incision.
- Secure Fit: Some disposable wound protectors feature adhesive components or adjustable tension mechanisms to ensure a snug fit around the incision.
- Removal: After the surgery, the protector is carefully removed and discarded according to medical waste protocols. <sup>49</sup>

#### Advantages:

- Reduced Infection Risk: By providing a new, sterile barrier for each procedure, disposable wound protectors help significantly reduce the risk of SSIs.
- Improved Healing: They protect the wound edges from contamination and trauma, promoting better healing outcomes.
- Cost-Effective: Although they are single-use, the benefits of reduced infection rates and improved patient outcomes can make them a cost-effective choice in the long run.
- No Sterilization Needed: Eliminates the need for sterilization and reprocessing, saving time and resources in the surgical suite. 49

#### **Considerations:**

- Proper Fit and Size: The correct size and fit of the disposable wound protector is crucial for optimal performance.
- Environmental Impact: The use of disposable products contributes to medical waste. Proper disposal and consideration of environmentally friendly options are important.
- Training: Proper training in the application and removal of the protector is essential to maximize its benefits and ensure patient safety. 49

#### **Examples:**

- Alexis Wound Protector/Retractor (Applied Medical): A popular disposable wound protector known for its effective retraction and protection capabilities.
- Ethicon ENDOPATH Dextrus Wound Protector: Features a flexible sleeve and is designed

to provide reliable protection and ease of use. <sup>49</sup>

Disposable wound protectors are valuable tools in modern surgery, providing enhanced protection, reducing infection risks, and promoting better healing outcomes. Their single-use design ensures maximum sterility for each procedure, contributing to improved patient safety and surgical efficiency. <sup>49</sup>



Figure 15: Intraoperative image showing Ethicon ENDOPATH Dextrus Wound Protector

#### **TYPES OF ENDOBAGS:**

Various customized specimen retrieval bags have been described in the literature, including condoms, zipper bags, the Nadiad bag, and more often surgical gloves tied in various ways. The use of drain packages has also been described. Each of these bags bears the cost of materials needed to construct the specimen retrieval bag, including sterile gloves, sutures, and ureteral catheters (Nadiad bag). Each of this bags has advantages and disadvantages. In the case of surgical gloves, the talcum powder may promote adhesion formation, so it is necessary to rinse them with normal saline prior to being used. A wet glove however may collapse due to irrigation or contact with peritoneal fluid, making it difficult to handle. Finally, gloves carry a low resistance to traction and manipulation, making them prone to tearing. According to the manufacturer, the cover of the intravenous catheter is made of polyethylene. A number of bags and their alternatives have been used by surgeons to retrieve the specimens during laparoscopic surgery. 50-55

#### 1. Commercially used Endobags

Commercially available endobag is a specially designed bag to extract specimens during laparoscopic procedures. It consists of an introducer connected to a leak-proof bag with a radiopaque thread at one end, and a hand piece for the delivery and extraction of the bag at the other end. It is introduced through one of the port sites and the bag is opened with the hand piece followed by insertion of the specimen in the bag and subsequent removal of bag through the port. These commercially available endobags are frequently used in the developed world to avoid spillage of bile and stones and contamination of peritoneal cavity. Some examples of such bags include the Endobag, EndoCatch bag and Endopouch (Ethicon); Pleatman Sac (Abbot Medicals); and Ponsky Endosac (US Endoscopy). These commercially available endobags are easy to use, but the main disadvantage of these endobags is the huge cost, which limits their use in the developing countries. These bags are disposable and designed for single use only, which adds extra cost to the patient and the procedure. Sometimes it may also be difficult to handle the bags intra-corporeally due to limited space in the abdomen. The high cost of the commercially available bags adds to the financial burden on patients, especially in the developing world and in countries like Pakistan where patients generally have to pay the cost for surgery. 50-55



Figure 16: EndoCatch bag

#### 2. Inexpensive Alternatives

Several cost effective self-designed retrieval bags have been used in order to reduce the cost of commercially available bags. These include sterile male condoms, re-closeable zipper bags, Nadiad bags and surgical gloves. Several studies have shown the cost-effectiveness and safety of male condoms in reducing septic complications after gall bladder extraction in

laparoscopic cholecystectomies. Other inexpensive bag used for specimen extraction is the Nadiad bag used for urological procedures. It consists of a polyethylene bag, nylon thread and a 5F ureteral catheter. The neck of the bag is folded at the edge and sewn and the folded tunnel accommodates the ureteral catheter and nylon thread. It is introduced with an atraumatic grasper and specimen is placed in the bag and subsequently extracted through 10mm port. It is cheap, easy-to-make and easily deployable without the help of introducer sheath. The ureteral catheter is the key component to keep the bag open during entrapment. Another example of cheap extraction bag described in literature is sterile zipper bag which has been used for the extraction of various gynaecological and other laparoscopic specimens. 50-55



Figure 17: Intraoperative picture showing use of Condom endobag



Figure 18: Glove endobag



Figure 19: Uro-endobag

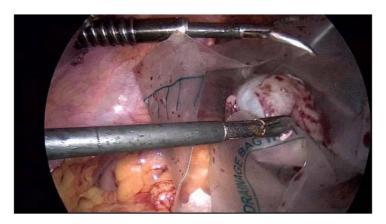


Figure 20: Intraoperative image showing use of drainage bag as endobag

#### 3. Glove Endobag

Most commonly used inexpensive retrieval bag for specimen extraction in laparoscopic cholecystectomy is the glove bag. A sterile glove is double-tied at the level of wrist with vicryl suture and fingers cut to shape it like a bag. The bag is lubricated or placed in saline and introduced into abdomen with a non-toothed grasper via epigastric port and placed on the superior surface of liver. Gall bladder along with spilled stones, if any, are placed in the glove, and the ends of glove are grasped with a toothed grasper via axillary port and removed through either umbilical or epigastric port depending on primary surgeon's preference. For large stones or distended gall bladders, stones can be crushed within the glove or gall bladders aspirated at the port sites with subsequent removal from port site. At times, port site incisions can be extended to facilitate easy delivery of the specimen, avoiding unnecessary spillage and contamination. An alternative way is to tie a purse-string suture at the opening of the glove to close the bag before extraction. Glove bag is inexpensive, easy to make and user-

friendly, and this has been consistently proven in literature from low-income countries.  $^{50-55}$ 



Figure 21: Intraoperative image showing use of glove endobag

Endobags are made from various materials that provide the necessary strength, flexibility, and biocompatibility for safely containing and removing specimens during minimally invasive surgeries. Different materials commonly used for endobags are: <sup>50-55</sup>

# 1. Polyethylene (PE):

- Properties: Lightweight, flexible, and resistant to chemicals.
- Advantages: Cost-effective, easy to manufacture, and provides good strength for smaller specimens.
  - Uses: Often used for standard endobags that handle less demanding retrieval tasks.



Figure 22: Polyethylene (PE) endobag

#### 2. Nylon:

- Properties: Strong, durable, and tear-resistant with excellent flexibility.
- Advantages: Provides high tensile strength, making it suitable for larger or heavier specimens. Resistant to tearing and punctures.
- Use Cases: Frequently used for self-opening and reinforced endobags designed for more challenging retrievals.



Figure 23: Nylon endobag

# 3. Polyurethane (PU):

- Properties: Highly flexible, transparent, and biocompatible.
- Advantages: Offers good elasticity and strength, allowing for clear visualization of the contents and easy manipulation.
- Uses: Commonly used in bags where transparency and flexibility are important, such as in standard and automatic closure endobags.

# 4. Polyvinyl Chloride (PVC):

- Properties: Flexible, durable, and chemically resistant.
- Advantages: Provides a good balance between flexibility and strength, making it suitable for various types of endobags.
- Uses: Used in both standard and more specialized endobags for a wide range of surgical applications.



Figure 24: Polyvinyl Chloride (PVC) endobag

# 5. Silicone:

- Properties: Soft, flexible, and highly biocompatible.
- Advantages: Non-reactive with tissues and fluids, making it ideal for applications where minimal reaction with the specimen is desired. Provides good elasticity and strength.
- Uses: Sometimes used in high-end endobags or specific medical applications requiring superior biocompatibility.



Figure 25: Silicone endobag

# Specialized Materials and Coatings: 50-55

#### 1. Reinforced Materials:

- Properties: Enhanced strength and durability with additional layers or embedded fibers.
- Advantages: Provides extra protection against tearing and punctures, especially for sharp or heavy specimens.
  - Uses: Used in reinforced endobags designed for particularly challenging retrievals.

# 2. Antimicrobial Coatings:

- Properties: Materials treated with antimicrobial agents to prevent bacterial growth.
- Advantages: Reduces the risk of infection by inhibiting the growth of bacteria on the bag's surface.
- Uses: Applied to endobags used in procedures with a high risk of contamination or infection.

#### 3. Low-Friction Coatings:

- Properties: Coatings that reduce friction to ease insertion and retrieval.
- Advantages: Facilitates smoother handling and reduces the risk of tissue damage during specimen removal.
  - Use Cases: Used in specialized endobags where easy deployment and retrieval are critical.

#### Considerations for Material Selection

- Strength and Durability: The material must be strong enough to contain the specimen without tearing or leaking.
- Flexibility and Elasticity: Flexibility is essential for maneuvering the bag within the body and ensuring it can conform to various specimen shapes.
- Biocompatibility: The material must be non-reactive with bodily tissues and fluids to prevent adverse reactions.
- Transparency: Clear materials allow for better visualization of the contents, which can be important for certain procedures.
- Cost-Effectiveness: Materials must be cost-effective, especially for disposable endobags, to ensure they are economically viable for widespread use. <sup>52, 56-59</sup>

By selecting the appropriate material, endobags can effectively and safely perform their

intended function in various surgical procedures, ensuring both patient safety and procedural efficiency. Comparison of incidence rates of port site infection and intra-abdominal spillage among various studies is shown below:

INCIDENCE OF PORT SITE INFECTION				
Author	Without endobag	With endobag		
Nida Mumtaz, et al (2023) <sup>57</sup>	6 percent	2 percent		
R, Jemin et al (2023) <sup>56</sup>	8 percent	0 percent		
Vergadia A et al (2020) <sup>50</sup>	8 percent	4 percent		
Narayanswamy T et al (2019) <sup>66</sup>	80 percent	7.2 percent		
Singh K et al (2018) <sup>52</sup>	8 percent	2 percent		
La Regina D et al (2018) <sup>53</sup>	5.9 percent	4.2 percent		
Comajuncosas J et al (2017) <sup>54</sup>	10 percent	9.21 percent		
A.I. Memon et al (2013) <sup>59</sup>	-	5 percent		

INCIDENCE OF INTRA-ABDOMINAL SPILLAGE					
Author	Without endobag	With endobag			
R, Jemin et al (2023) <sup>56</sup>	12 percent	0 percent			
Mohamed GQ et al (2021) <sup>58</sup> 16 percent 2 percent					
Vergadia, A et al (2020) <sup>50</sup>	6 percent	0 percent			
Singh K et al $(2018)^{52}$ 10 percent 2 percent					
Memon M et al (2014) <sup>59</sup>		0.88 percent			

In the study of Harling R et al (in the year 2000) evaluated two types of treatment to be given. One includes the use of cephalosporins class of antimicrobials and the other includes the removal of pouch of gall-bladder. In this study there were net seventy six individuals that were unevenly distributed into these two groups. The cases in which some other problems already existed have been not included in this study. Around six individuals reported with the infection, i.e., in both the groups three individuals were present. No individuals were reported with septicemia but every case comprises of dermal infective

microbes. He reported about the microbes present in the infective site and that are harmful. Ten microbes were reported. From which nine of them were present in the individuals taking cephalosporins drugs. So it came to an end that in the LC cases without any problems there are no chances of sepsis but antimicrobial druigs even don't treat them entirely.<sup>60</sup>

Goetze TO et al (2010) evaluated if puncturing the gall-bladder during surgery or removal of entire pouch of bladder will be harmful in cases with neoplasm that are spreading very fast. The individuals with puncturing the bladder during surgery revealed that they are harmful but the other group individual showed higher chances. But in cases of IGBC, if the puncturing has already took place than removal of pouch has no roles. <sup>61</sup>

Kao CC et al (2012) assessed about one hundred thirty five individuals with LC in cases where adrenal or prostatic gland is removed while artificial pouch is made. This pouch is made of huge disinfected gloves, with 2-0 nylon & vicryl thread along with RB-1 needle of 1-0 type. At the start of the pouch, nylon thread was used to make purse-string type of suturing type whereas at the end vicrly type of suture material was made for suturing it twice. This pouch was then put in the abdomen with twelve millimeters of port and it was covered by materials used for laproscopy. This pouch was removed later on expanding the site of injury. There were no postoperative problems seen. So it was concluded that this artificial pouch can be utilized by practitioners in their surgery to remove samples from the abdomen.

**Odabasi Met al (2014)** evaluated the efficiency as well as protection of combing tricky CD in the individuals with AC by Endo-GIA. With use of this approach around nineteen patients were affected. Everyone individual was effectively cured by this method. But the duration of being hospitalized is around three to four days. In four individuals, there was contamination of the umbilical region. The duration of regular check-up ranges from one month to fifty months. So to an end it was said that this approach is not harmful & even not difficult to perform in cases of expanded CD. Before joining, the cystic artery should be protected. To prevent the chances of hemorrhage, fibrin adhesives can be used only if protection and joining if artery is impossible. <sup>63</sup>

**Stavrou G et al (2015)** introduced an artificially made at home method of collecting sample in cases of LC. The catheter from Redon draining bag is collected along with polyethylene

pouch. This pouch is equally divided in two parts and folded & the bladder is put into this pouch and extracted by the use of forceps introduce in the umbilical region. They experimented this on eighty five individuals with LC. There were no chances of leakage, breakage or any chance of puncturing. This approach is quite protective, successful and simple to use for collecting the tissues. <sup>64</sup>

Majid MH et al (2016) examined the protective way to remove bladder by not using any removal tool. A total of three hundred seventy three patients underwent LC while this study. There was no pouch used in forty one percent individuals. The removable pouch was used in most of the individuals with aches and being hospitalized. There were reduced chances of contamination in those individuals who didn't use any pouch. In approximately ten percent cases deep cut is needed in the individuals where removable pouch is needed. After one year regular check-up, the development of hernia at the site of injury where no pouches are used is not seen but in the other group there were two cases seen with hernia. For individuals of LC without any problems radiographically it was established that use of pouch didn't proven to be beneficial. 65

Comajuncosas J et al (2017) assessed advantage of removing the bladder for avoiding contamination of injured site. For this study individuals with mild representation of biliary stones are considered & categorized in two parts. Eighty cases were with simple removal of bladder procedure but seventy six cases were where bladder pouch is not removed. For this study, the individuals with AC or cases where there is puncturing of the bladder by any chance are not included. But a comparison is made among this and very significant variation were reported. Among one hundred fifty six individuals, one hundred twenty one are females and thirty five are males. Also there was eighty individual as the control & seventy six taking part in the research. In the controlled category there were 7 cases of contamination & in the latter part there were around fifteen cases with contamination. Upon analysis, it was seen that both are similar. So it was said at the end that contamination of the bladder during LC is not because of the touch of microbes during the LC procedures. Hence, the need for removal of pouch is not mandatory. 66

**Taş et al (2017)** included cases where LC is performed in twenty individuals either by Endo pouch or simply performing it without the pouch. Every individual was examined properly and every history was taken from all the individuals. In the category where Endo-

pouch has been used comprise around fourteen men and six women with the average age of fifty six. Upon USG examination many small bony dark calculi was reported prior to surgery. If the site of injury gets contaminated it is examined and cleared by nurses. After regular check-up, there was no hernia after the surgery. The expense of surgery after the Endo-bag came into access has been raised till fifty Turkish Liras in about every individual with that of those who don't use them. The site of injury got contaminated along with the higher expenses with no puncturing was reported at the end in case of LC with the usage of endo-bag.<sup>67</sup>

**Begum S et al. (2019)** debated over the LC procedure which is the benchmark procedure globally for cases of biliary stones globally. Leakage of bile n abdomen as well as puncture in the bladder is the frequently seen problem intra-operatively. So to prevent these problems, bladder is removed along with the use of Endo-bag. Using made-made bag is effective in comparison to that of already made endo-bag.<sup>68</sup>

Narayanswamy T et al(2019) examined two hundred seventy individuals that are histopathologically confirmed AC cases. For the individuals of category A the use of pouch for removing bladder is not considered as compared to that of category B where the bag usage is necessary. In category A the rate of contamination is about 7.2 percent in around eighty percent individuals. It was seen that removal of bladder in the epigastric area by not using Endo-bag is more prevalent site for contamination of the injured site but if Endo-bag is utilized, this rate of contamination is lowered but with many drawbacks such as deeper cut and increased duration of surgery.<sup>55</sup>

Vergadia A et al (2020) researched that removal of GB specimen with the use of nativeendo-bag can stop infection at the port site in LC with or without using the bag. Out of 50 patients, only one patient was overweight with BMI of 32.38 mg/kg<sup>2</sup>.PSI occurred in about 4 percent patients who used bag during surgery while 8 percent in individuals who did not used bag. At 3<sup>rd</sup> day, a patient who had the surgery with the use of bag had PSI. More patients were reported to have infection at port site without endobag surgery as compared to removal with endobag.<sup>50</sup>

**Habib R et al (2020)** compared the occurrence of port site wound infection after extraction of gallbladder with or without using retrieval bag in LC. Average age of patients were  $40.77 \pm 10.95$  years. With 1:2.5 male to female ratio, 98 (38.58 percent) males and 156

(61.42 percent) females were examined making a total of 254 patients. Two groups were made, A and B respectively depicting 1 (0.4 percent) port site wound infections in group A and 14 (5.5 percent) patients in group B. To conclude, reduction in occurrence of infections was found when the gallbladder was extracted by using retrieval bags in LC. Various ages, genders and duration of cholelithiasis were all linked to port site wound infections.<sup>69</sup>

Qassem, Mohamed G et al (2021) estimated the need to use endobag for removal of gallbladder in comparison to direct removal. Two groups were made consisting of total 100 patients with one with extraction using endobag and other group had direct removal.8 (16 percent) patients showed leakage of bile in port site in the epigastric region in group B while group A only had 2 patients. Hospital stay of patients with endobag removal was only 23.68 h as compared to 27.08 h of direct extraction cases. Direct extraction depicted 6 patients (12 percent) with port site infection and none on the other group. Group A had 8 cases and group B had 11 cases with pain after 24 hours of surgery with mean visual analog scale score of 1.84±0.91 and 3.14±0.61 in groups A and B, respectively. In case of uncomplicated gallbladder stones, endobag usage is not necessary.<sup>58</sup>

In 2023, Mumtaz N et al assessed infection rate at port region with the use of endobag and not using endo bag during LC for extraction of gallbladder. With the use of blocked randomization, two groups were made of448 patients. Group A used endobag for removal of GB during LC whereas no endobag use was done in case of group B. After the procedure, standard triple antibiotics were given to all the patients along with analgesics and regular dressing of wounds maintaining all the necessary protocols. Endobag were used in Group A while they were not utilized in case of Group B. 44 years with SD ± 15.71 was the average age of Group A, on the flip side, 45 years with SD ± 14.39 was the average age of the other group. 87 patients were male (39 percent) whereas females were 137 (61 percent) in Group A. Group B presented 83 (37 percent) male patients and 141 (63 percent) female patients. About 4 (2 percent) patients showed infection in port region where 220 (98 percent) had no port site infection. In case of Group B, 211 (94 percent) did not showed port site infection while 13 (6 percent) showed port site infection. To summarize, no endobag for GB removal during LC were more as compared to extraction using endobag.<sup>57</sup>

In the year 2023, Ahmad M et al checked the difference in direct removal methods in case of SSI and removing the gallbladder via epigastric port in LC by the use of sterile

surgical gloves. Blocked randomization was used to divide the patients into 2 batches where Group A made use of sterile gloves for the removal while Group B did direct removal of the gallbladder. In group A, diabetes was seen in about 11 patients. On the other hand, 3 diabetic and 2 non diabetic patients faced PSI at the epigastric port, with p-value 0.031. In group B, diabetes was seen in 19 patients and PSI developed in 10 patients, as depicted on 7th day of follow up, 8 in diabetics were 8 in total and non-diabetics were 2 in number. No association was observed in PSI and diabetes mellitus. Though, PSI also was not linked among both groups. Also, port site infections in LC significantly reduced due to retrieval bag usage but the fraction was not enough to explain its influence on the time of operation.<sup>70</sup>

In 2023, Gómez F et al researched the effect of technique used for gallbladder retrieval in laparoscopic cholecystectomy on the likelihood of infections and its complications. 3 different groups were formed where home-made gallbladder retrieval bag (HMGRB) was used to perform LC, on the flip side, commercial gallbladder retrieval bag (CGRB) were used to do the LC. Abscess in the intra-abdominal region and infections on the superficial areas are the major complications. On 828 cases making about 92.41 percent, LC was done using CGRB while 68 patients undertook HMGRB which is about 7.58 percent. Patient groups were not affected due to negligible difference in sex distribution and infection before the operation. Variation in distribution in age among groups, surgical times, and length of stay were identified through utilization of a t-test. Also, variations in postoperative antibiotics usage, usage of drain and severity in Tokyo and Parkland Grading Scale was found by the use Chi square. However, SSI remained constant irrespectively. Increased time in surgery and more stay duration was observed in HMGRB and hazard of abscess in the abdomen after surgery or SSI were not linked with it when compared with CGRB.<sup>71</sup>

In the year 2023, Ali Wuheb et al assessed gallbladder removal using laparoscopic cholecystectomy and removing the gallbladder with the help of bag.970 direct extraction and 835 removal using endo-bag was examined making total 1805 cases in the review in about eight studies. All were observational studies except 4 randomized-controlled trials. Bag extractions had lesser SSI rates and bile leakage when compared with direct removal. On the other hand, endo-bag group had greater extension of fascial defect. Both the groups, port- site hernia and intra-abdominal collection showed relative results. With no influence on abdominal collection after operation, low SSI and bile leakage was observed with removal with the use of Endo-bag.<sup>72</sup>

In 2023, Mohamed HK et al examined difference in results of gallbladder removal using bag and removal via laparoscopic cholecystectomy (LC) method. The split of 1805 cases were done as follows: 835 patients were done by the endo bag procedure while 970 patients were subjected to direct extraction. In the direct extraction, discharge of bile and proportion of SSI were considerably greater. The two groups exhibited similar findings in terms of intra-abdominal collection with comparable findings. However, the endo-bag group batch has greater disruption in fascia and port-site hernia showed no alteration in the numbers. To summarize, the removal of gallbladder using endo-bags results in reduced incidence of surgical site infections and leakage of bile, while achieving comparable outcomes in terms of intra-abdominal collection after surgery.<sup>73</sup>

# MATERIALS & METHODS

# **MATERIALS AND METHODS**

#### **STUDY SITE:**

Patients undergoing laparoscopic cholecystectomy in R. L. JALAPPA HOSPITAL AND RESEARCH CENTRE, TAMAKA, KOLAR attached to SRI DEVARAJ URS MEDICAL COLLEGE Between SEPTEMBER 2022 TO FEBRUARY 2024.

**STUDY DESIGN:** The study was a Non-Randomized Control study.

**STUDY POPULATION:** 60 patients

#### **INCLUSION CRITERIA:**

- 1. Operable gallstone diseases
- 2. Fit for anesthesia.

#### **EXCLSUION CRITERIA:**

- 1. Immuno-compromised status
- 2. Common bile duct calculi
- 3. Chronic liver disease
- 4. Impaired liver function test
- 5. Perforated gall bladder
- 6. Proven malignancy
- 7. Local skin infections

#### **METHODOLOGY:**

- All patients who presented to R.L. Jalappa Hospital with suspected gallstone diseases were considered for the study.
- A complete detailed history and physical examination was done followed by relevant investigations after obtaining an informed consent.
- Patients were divided into two groups using odd(A) and even(B) method each consisting of 30 patients.
- All patients were subjected to pre-anaesthetic evaluation to determine their fitness for surgery.

• Comorbidities if any were appropriately corrected pre-operatively.

• Patients in group A underwent laparoscopic cholecystectomy using endobag.

• Patients in group B underwent laparoscopic cholecystectomy without endobag.

• All the parameters to compare the two techniques was recorded and tabulated.

STUDY PERIOD: From September 2022 to February 2024.

SAMPLE SIZE CALCULATION:

Bhagavan B C et al $^{60}$  has reported the mean VAS scores was 1.84±0.91 in the endobag extraction group and 3.14±0.61 in the direct extraction group respectively. Assuming alpha error of 5% (95% Confidence limit), Power of 80%, ratio of endobag: direct extraction group = 1:1

Presuming standard deviation of the VAS scores to be 1.5 in the endobag group and 2.0 in the direct extraction group,

The minimum required sample size to find the difference in mean VAS scores between the two-study group is calculated as 60 subjects (30 subjects in endobag group and 30 in direct extraction group)

The sample size was derived from the following formula:

Sample size (n) =;

Sample size (n) =  $\frac{2S_p^2[Z_{1-\frac{q}{2}} + Z_{1-\beta}]^2}{\mu_d^2}, \ S_p^2 = \frac{S_1^2 + S_2^2}{2}$ 

where,  $S_1$ : Standard deviation in the first group

S2: Standard deviation in the second group

μ<sub>d</sub>: Mean difference between the samples

a: Significance level

1-β: Power

**STATISTICAL ANALYSIS:** 

All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software. Chi-square test and student t test was used for evaluation of level of significance.

### **ETHICAL CONSIDERATIONS:**

The institution's human ethics committee authorized the study. All research participants provided written informed consent, and only those who were prepared to sign it were allowed to take part in the investigation. Before getting agreement, it was mentioned to the participants the risks and advantages of the study as well as the volunteer nature of their involvement. Participants in the research were kept in the strictest of confidence.

# RESULTS

# **RESULTS**

The present study was undertaken for assessing the efficacy of Endobag in laparoscopic cholecystectomy to reduce port site infection. A total of 60 patients were enrolled and were divided into two study groups. Patients in group A underwent laparoscopic cholecystectomy using endobag while patients in group B underwent laparoscopic cholecystectomy without endobag. Following results were obtained:

Table 1: Age-wise distribution of patients

Age group	Group A		Group B	
(years)	Number	Percentage	Number	Percentage
≤ <b>3</b> 0	3	10	5	16.67
31 to 40	3	10	7	23.33
41 to 50	11	36.67	7	23.33
51 to 60	4	13.33	9	30
61 to 70	7	23.33	2	6.67
More than 70	2	6.67	0	0
Total	30	100	30	100
Mean	50.6		44.47	
SD	14.59		12.09	
p-value	0.122		•	

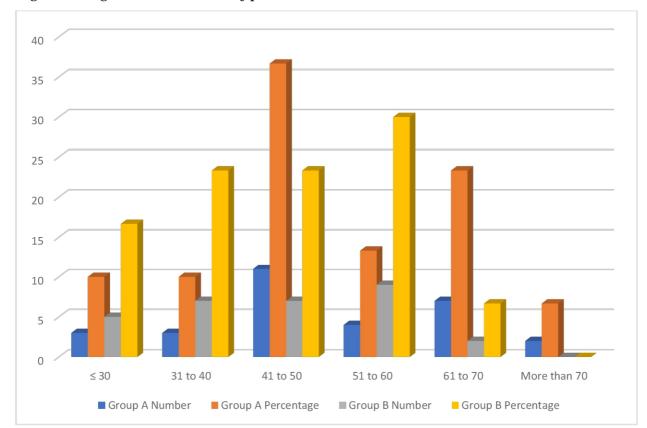


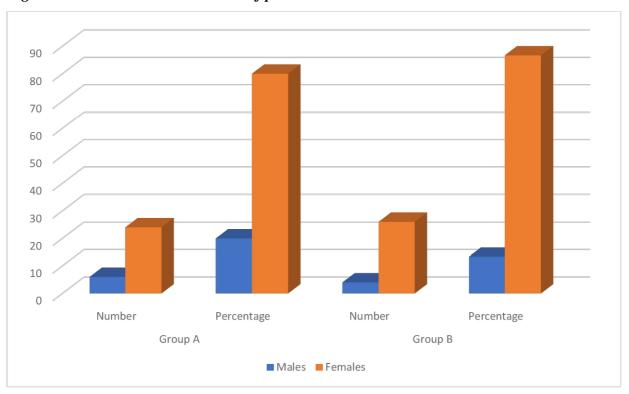
Figure 26: Age-wise distribution of patients

36.67, 23.33 and 13.33 percent of the patients of the group A belonged to the age group of 41 to 50 years, 61 to 70 years and 51 to 60 years respectively while 23.33, 6.67 and 30 percent of the patients of the group B belonged to the age group of 41 to 50 years, 61 to 70 years and 51 to 60 years respectively. 10 percent of the patients of the group A and 23.33 percent of the patients of group B belonged to the age group of 31 to 40 years respectively. Mean age of the patients of group A and group B was 50.6 years and 44.47 years respectively. Both the groups were comparable in terms age-wise distribution of patients.

Table 2: Gender-wise distribution of patients

Gender	Group A		Group B	
	Number	Percentage	Number	Percentage
Males	6	20	4	13.33
Females	24	80	26	86.67
Total	30	100	30	100
p-value	0.380			

Figure 27: Gender-wise distribution of patients

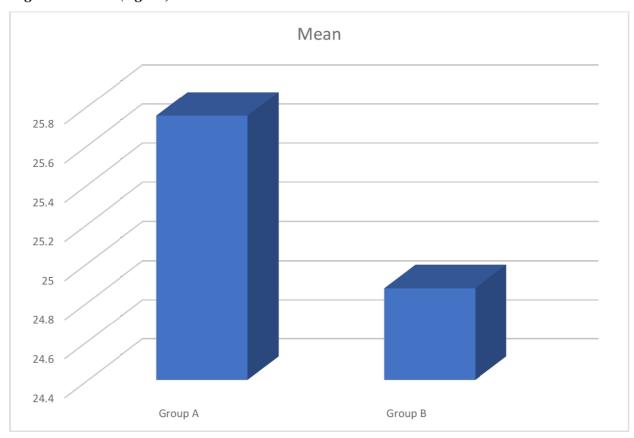


20 percent of the patients of Group A and 13.33 percent of the patients of group B were males. Remaining all are females. Both the groups were comparable in terms of gender-wise distribution.

Table 3:  $BMI(Kg/m^2)$ 

BMI (Kg/m <sup>2</sup> )	Group A	Group B
Mean	25.75	24.87
SD	1.84	1.93
p-value	0.64	

*Figure 28: BMI (Kg/m²)* 

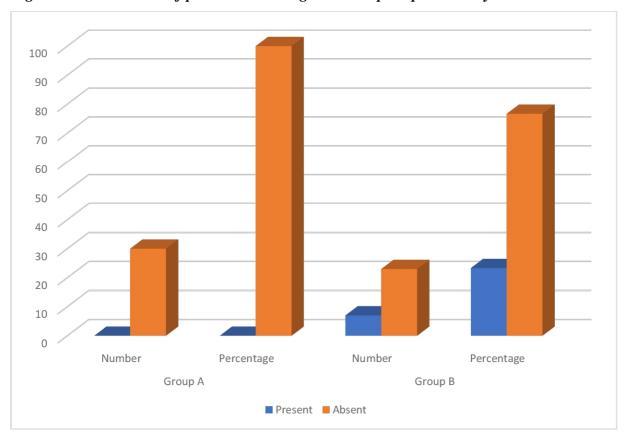


Mean BMI of the patients of the Group A and Group B was  $25.75~\text{Kg/m}^2$  and  $24.87~\text{Kg/m}^2$  respectively. Both the groups were comparable in terms of BMI.

Table 4: Distribution of patients according to SSI on postoperative day 3

SSI on	Group A		Group B	
Postoperative day 3	Number	Percentage	Number	Percentage
Present	0	0	7	23.33
Absent	30	100	23	76.67
Total	30	100	30	100
p-value	0.001 (Significant)			

Figure 29: Distribution of patients according to SSI on postoperative day 3

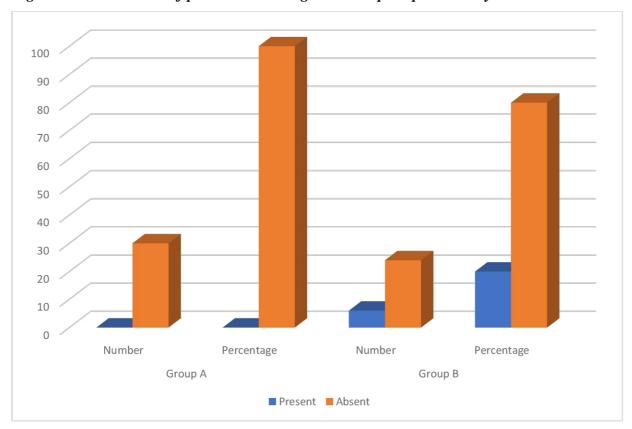


None of the patients of Group A showed presence of SSI while 23.33 percent of the patients of Group B showed presence of SSI on postoperative day 3. Incidence of SSI was significantly higher among patients of Group B.

Table 5: Distribution of patients according to SSI on postoperative day 5

SSI on	Group A		Group B	
Postoperative day 5	Number	Percentage	Number	Percentage
Present	0	0	6	20
Absent	30	100	24	80
Total	30	100	30	100
p-value	0.001 (Significant)			

Figure 30: Distribution of patients according to SSI on postoperative day 5

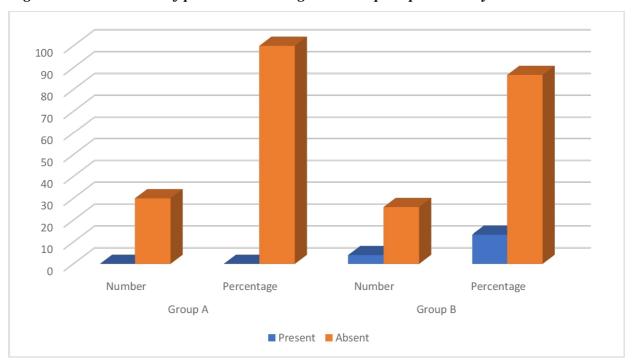


On 5<sup>th</sup> postoperative day, SSI was seen in 20 percent of the patients of Group B while it was absent in Group A. Incidence of SSI was significantly higher among patients of Group B on postoperative day 5.

Table 6: Distribution of patients according to SSI on postoperative day 7

SSI on	Group A		Group B	
Postoperative day 7	Number	Percentage	Number	Percentage
Present	0	0	4	13.33
Absent	30	100	26	86.67
Total	30	100	30	100
p-value	0.034 (Signific	ant)		

Figure 31: Distribution of patients according to SSI on postoperative day 7

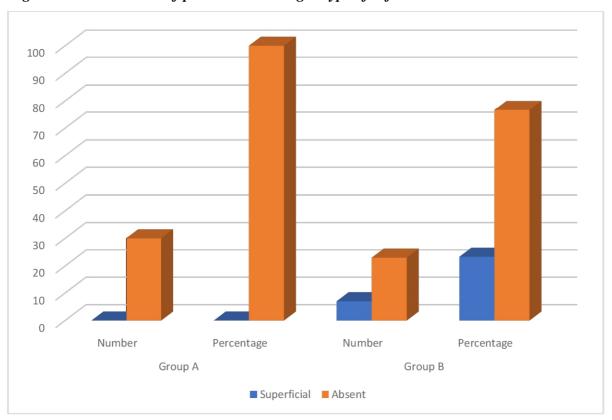


On 7<sup>th</sup> postoperative day, SSI was seen in 13.33 percent of the patients of Group B while it was absent in Group A. Incidence of SSI was significantly higher among patients of Group B on postoperative day 7.

Table 7: Distribution of patients according to type of infection

Type of infection	Group A		Group B	
	Number	Percentage	Number	Percentage
Superficial	0	0	7	23.33
Absent	30	100	23	76.67
Total	30	100	30	100
p-value	0.001 (Significant)			

Figure 32: Distribution of patients according to type of infection

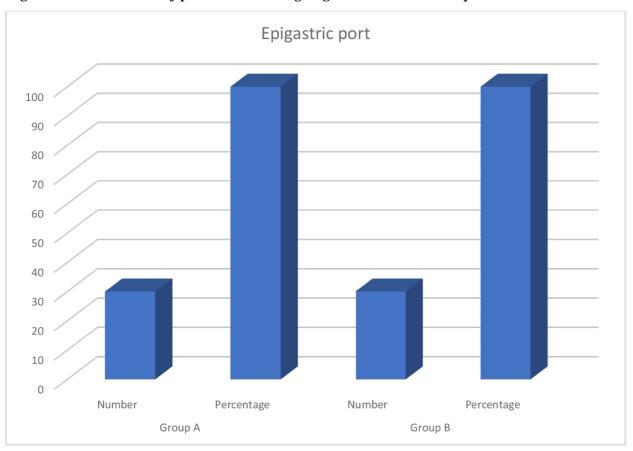


In all the 7 patients of Group B exhibiting SSI, infection was superficial in nature.

Table 8: Distribution of patients according to gall bladder retrieval port

Gall bladder	Group A		Group B	
retrieval port	Number	Percentage	Number	Percentage
Epigastric port	30	100	30	100
Total	30	100	30	100
p-value	1	•	•	

Figure 33: Distribution of patients according to gall bladder retrieval port

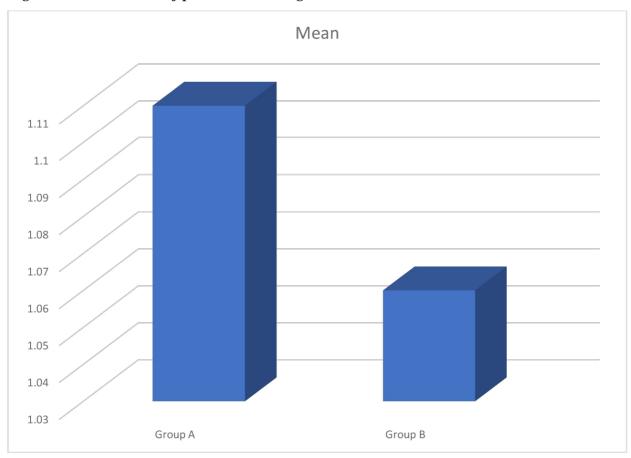


Gall bladder retrieval port among patients of both Group A and Group B was Epigastric port.

Table 9: Distribution of patients according to duration

Duration (hours)	Group A	Group B
Mean	1.11	1.06
SD	0.18	0.15
p-value	0.42	

Figure 34: Distribution of patients according to duration

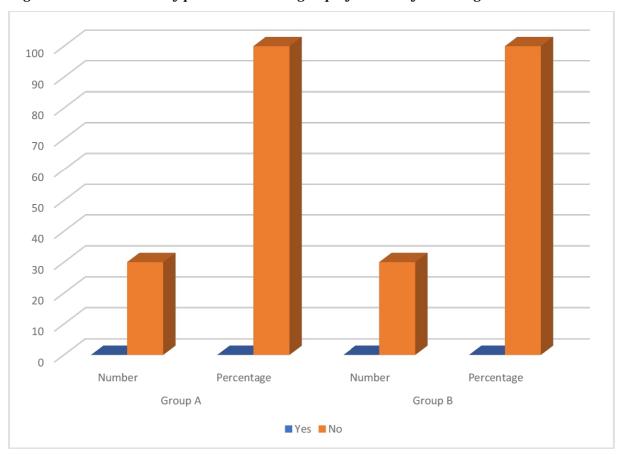


Mean duration of surgery among patients of group A and group B was 1.11 hours and 1.06 hours respectively; on comparing the values, non-significant results were obtained.

Table 10: Distribution of patients according to perforation of Endobag

Perforation of	Group A		Group B	
Endobag	Number	Percentage	Number	Percentage
Yes	0	0	0	0
No	30	100	30	100
Total	30	100	30	100
p-value	1			

Figure 35: Distribution of patients according to perforation of Endobag

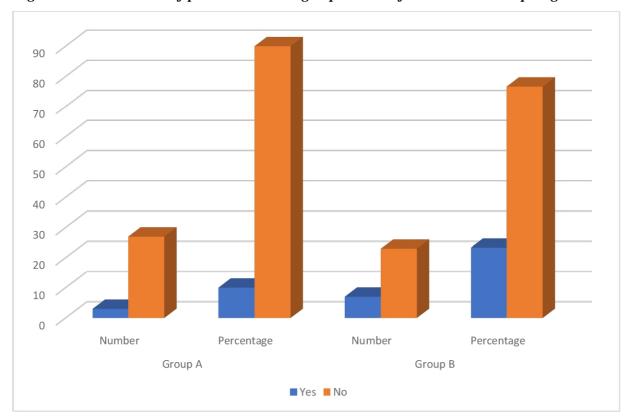


None of patient showed perforation of Endobag.

Table 11: Distribution of patients according to presence of intraabdominal spillage

Intrabdominal	Group A	Group A		Group B	
spillage	Number	Percentage	Number	Percentage	
Yes	3	10	7	23.33	
No	27	90	23	76.67	
Total	30	100	30	100	
p-value	0.165	-	1	,	

Figure 36: Distribution of patients according to presence of intraabdominal spillage

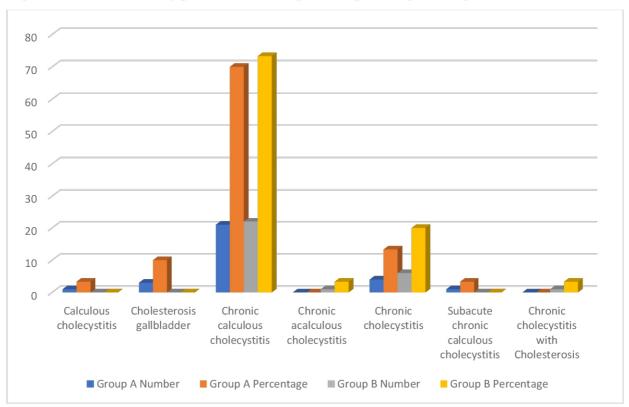


Intraabdominal spillage was seen among 10 percent of the patients of Group A and among 23.33 percent of the patients of Group B. On comparing the values; significant results were obtained.

Table 12: Distribution of patients according to histopathological diagnosis

Histopathological diagnosis	Group A	Group A		Group B	
	Number	Percentage	Number	Percentage	
Calculous cholecystitis	1	3.33	0	0	
Cholesterosis gallbladder	3	10	0	0	
Chronic calculous cholecystitis	21	70	22	73.33	
Chronic acalculous cholecystitis	0	0	1	3.33	
Chronic cholecystitis	4	13.33	6	20	
Subacute chronic calculous cholecystitis	1	3.33	0	0	
Chronic cholecystitis with Cholesterosis	0	0	1	3.33	
Total	30	100	30	100	
p-value	0.12	•			

Figure 37: Distribution of patients according to histopathological diagnosis



Histopathological diagnosis among patients of group A was Calculous cholecystitis, Cholesterosis gallbladder, Chronic calculous cholecystitis, Chronic cholecystitis and Subacute chronic calculous cholecystitis found to be present in 3.33 percent, 10 percent, 70 percent, 13.33 percent and 3.33 percent of the patients respectively, Histopathological diagnosis among patients of Group B was Chronic calculous cholecystitis, Chronic acalculous cholecystitis,

Chronic cholecystitis and Chronic cholecystitis with Cholesterosis was 73.33 percent, 3.33 percent, 20 percent, and 3.33 percent of patients respectively.

# DISCUSSION

# **DISCUSSION**

Because of swift advancements in medical technology, surgeons can now treat patients with surgery while minimizing surgical morbidity. The best example is minimal access surgery (MAS), also known as keyhole surgery or laparoscopic surgery (LS). By reducing access-related morbidities, MAS has fundamentally changed how modern surgery is approached.<sup>73-75</sup>

Reusable metallic or disposable plastic trocars are used in laparoscopic surgery (LS) and are inserted through tiny skin incisions or ports created on the skin away from the surgical site. These ports serve as the entrance for carrying out the surgical treatment using a telescope and specifically designed instruments. Better aesthetics, reduced pain, early ambulation, early hospital discharge with an early return to work, and a reduced financial burden on the patient have all contributed to its growing popularity. The technique has been used for many additional surgical operations, such as appendectomy, herniorrhaphy, colonic surgery, gastric surgery, urological, and gynecological surgery, since Philips Mouret originally described the first laparoscopic cholecystectomy in 1987. This is a result of how patients' growing acceptance of MAS and technological advancements working together to broaden the scope of LS. <sup>74-77</sup>

On the other hand, LS comes with a special set of complications. The port site infection (PSI) is one such consequence that can be avoided. The benefits of LS are quickly undermined by PSI, as the patient loses faith in the operating surgeon and grows anxious about the persistent infection. <sup>74-77</sup>

To avoid the aforementioned issues, the gallbladder specimen is removed using an endobag. A gallbladder that is severely inflamed or enlarged and filled with stones usually presents challenges when it comes to removal. with these situations, removing the gallbladder necessitates either extending one of the fascial incisions to aid with gallbladder extraction, which increases discomfort at the port site following surgery, or decompressing the needle and removing stones from the gallbladder close to the port site (Zehetner 2007).<sup>78</sup>

Hence; the present study was undertaken for assessing the efficacy of Endobag in laparoscopic cholecystectomy to reduce port site infection. A total of 60 patients were enrolled and were divided into two study groups. Patients in group A underwent laparoscopic cholecystectomy using endobag while patients in group B underwent laparoscopic cholecystectomy without endobag.

#### **AGE**

36.67, 23.33 and 13.33 percent of the patients of the group A belonged to the age group of 41 to 50 years, 61 to 70 years and 51 to 60 years respectively while 23.33, 6.67 and 30 percent of the patients of the group B belonged to the age group of 41 to 50 years, 61 to 70 years and 51 to 60 years respectively. Mean age of the patients of group A and group B was 50.6 years and 44.47 years respectively. Both the groups were comparable in terms age-wise distribution of patients. In a similar study conducted by Narayanswamy T et al, mean age of the patients with endobag group and without endobag group was 49.5 years and 42.6 years respectively. In a recent study conducted by Mumtaz N et al, mean age of the patients of the endobag group and non-endobag group was 44 years and 45 years respectively. Majid MH et al reported the mean age of the patients of the endobag group and non-endobag group was 52 years and 53 years respectively.

Studies	With endobag	Without endobag
Narayanswamy T et al (2009) <sup>55</sup>	49.5 years	42.6 years
Majid MH et al (2016) <sup>65</sup>	52 years	53 years
Comajuncosas J et al (2017) <sup>66</sup>	54.3 years	49.9 years
Qassem MG et al (2021) <sup>58</sup>	41.34 years	42.96 years
Mumtaz N et al (2023) <sup>57</sup>	44 years	45 years
Present study	50.6 years	44.47 years

### **GENDER**

20 percent of the patients of Group A and 13.33 percent of the patients of group B were males. Remaining all are females. Both the groups were comparable in terms of gender-wise distribution. In a study conducted by Narayanswamy T et al, 28.3 percent of the patients of endobag group and 26.8 percent of the patients of non-endobag group were males.<sup>55</sup> Our results were in concordance with the results obtained by previous authors who also reported female preponderance in their respective studies. In a study conducted by Mumtaz M et al, 39 percent of the patients of the endobag group and 37 percent of the patients of the non-endobag group were males.<sup>57</sup> Majid MH et al, reported that 24 percent of patients of endobag group and 23 percent of the patients of the non-endobag group respectively.<sup>65</sup>

Studies	With endobag	Without endobag
Narayanswamy T et al (2009) <sup>55</sup>	28.3 percent males;	26.8 percent males;
	71.7 percent females	73.2 percent females
Majid MH et al (2016) <sup>65</sup>	24 percent males;	23 percent males;
	76 percent females	77 percent females
Comajuncosas J et al (2017) <sup>66</sup>	17.5 percent males;	23.68 percent males;
	82.5 percent females	76.32 percent females
Qassem MG et al (2021) <sup>58</sup>	24 percent males;	22 percent males;
	76 percent females	78 percent females
Mumtaz N et al (2023) <sup>57</sup>	39 percent males;	37 percent males;
	61 percent females	63 percent females
Present study	20 percent males;	13.33 percent males;
	80 percent females	86.67 percent females

# BMI $(KG/M^2)$

Mean BMI of the patients of the Group A and Group B was 25.75 Kg/m<sup>2</sup> and 24.87 Kg/m<sup>2</sup> respectively. Both the groups were comparable in terms of BMI. In a similar study conducted by Mumtaz N et al, mean BMI among the patients of the endobag group and non-endobag group was 25 Kg/m<sup>2</sup> and 26 Kg/m<sup>2</sup> respectively.<sup>57</sup>

Studies	With endobag	Without endobag
Mumtaz N et al <sup>57</sup>	25 Kg/m <sup>2</sup>	26 Kg/m <sup>2</sup>
Present study	25.75 Kg/m <sup>2</sup>	24.87 Kg/m <sup>2</sup>

# SURGICAL SITE INFECTION

None of the patients of Group A showed presence of SSI while 23.33 percent of the patients of Group B showed presence of SSI on postoperative day 3. Incidence of SSI was significantly higher among patients of Group B. On 5<sup>th</sup> postoperative day, SSI was seen in 20 percent of the patients of Group B while it was absent in Group A. On 7<sup>th</sup> postoperative day, SSI was seen in 13.33 percent of the patients of Group B while it was absent in Group A. Incidence of SSI was significantly higher among patients of Group B on postoperative day 5 and day 7. In all the 7 patients of Group B exhibiting SSI, infection was superficial in nature. In a study conducted by Narayanswamy T et al, 1.47% of our patients of endobag group developed epigastric port

infection despite of using endobag, possibly due to contamination of the outer surface of endobag; and 5.96% of non-endobag group patients developed epigastric port site infections.<sup>55</sup> Memon et al. (2013) also reported 5% umbilical port sepsis in patients with acutely inflamed gall-bladder specimen despite of using endobag for its retrieval.<sup>79</sup> Another study reported port site wound infection 1.02% and port site hernia 1.38% (Sharma et al. 2013).<sup>14</sup> Ali & Siddiqui 2013 reported a rare complication of port-site infection due to implanted stones resulting in discharging sinus following laparoscopic cholecystectomy. All reasonable efforts should be made to remove spilled gall-stones; nevertheless, conversion to open surgery is not mandatory as the reported complication rate of lost stones is less than 1%.<sup>15,80</sup>

Studies	With endobag	Without endobag	p-value
Narayanswamy T et al (2009) <sup>55</sup>	1.47 percent	5.9 percent	Significant
Majid MH et al (2016) <sup>65</sup>	1.35	2.63 percent	Non-Significant
Comajuncosas J et al (2017) <sup>66</sup>	10 percent	9.21 percent	Non-Significant
Singh et al (2018) <sup>81</sup>	2 percent	10 percent	Significant
Vergadia A et al (2020) <sup>50</sup>	4 percent	8 percent	Significant
Taj MN et al (2012) <sup>82</sup>	0.20 percent	5.28 percent	Significant
Qassem MG et al (2021) <sup>58</sup>	0 percent	12 percent	Significant
Present study	0 percent	13.33 percent	Significant

The noted trend would raise the possibility that mare contact of the intact gall bladder may increase the risk of wound infection. Mumtaz N et al in a previous study, reported incidence of port site infection among 2 percent and 6 percent of the patients of endobag group and non-endobag group respectively.<sup>57</sup>

In a similar study conducted by Narayanswamy T et al, superficial infection was seen in 1.11 percent of the patients of the endobag group and 5.2 percent of the patients of the without endobag group.<sup>55</sup> In a study conducted by Vergadia A et al, 4 percent of patients with endobag had Superficial PSI whereas 8 percent of the patients without bag had Superficial PSI. None of the patients in any group had Deep PSI. That means patients who undergo laparoscopic cholecystectomy without endobag had a similar superficial infection in comparison to those where the bag was used.<sup>50</sup>

Ali SA et al and Helme et al stated that best way to avoid complications of spilled gallstones and port site contamination is to use endobag. Karthik S et al study had retrieval port site infection 1.8 %. Taj M N et al study showed that; port site infection was 5.28 % without using endoglove, whereas it was 0.20 % when using endoglove. Wound infections can be prevented by sterile techniques and the use of specimen endobags for specimen extraction. Endobag facilitates collection of operative specimens, spilled gallstones and minimizes the chances of contamination of the abdominal cavity and the retrieval port site. 14, 16, 83

#### GALL BLADDER RETRIEVAL PORT

Gall bladder retrieval port among patients of both Group A and Group B was Epigastric port. Similar to our study, Narayanswamy T et al reported that among patients of both with endobag group and without endo bag group, gall-bladder specimens were retrieved safely through 10mm epigastric port.<sup>55</sup>

#### **DURATION OF SURGERY**

Mean duration of surgery among patients of group A and group B was 1.11 hours and 1.06 hours respectively; on comparing the values, non-significant results were obtained. Our results were in concordance with the results obtained by previous authors who also reported similar findings. In a study conducted by Singh et al, mean duration of surgery among patients of endobag group and non-endobag was 1 hour and 1.3 hours respectively. Qassem MG et al reported mean duration of surgery among patients of the endobag group and non-endobag group was 38.22 minutes and 39.74 minutes respectively. Kirshtein B et al, in a previous study reported mean duration of surgery among patients of endobag group and non-endobag group to be 42.5 minutes and 37 minutes respectively.

Studies	With endobag	Without endobag	p-value
Singh et al (2018) <sup>81</sup>	1 hour	1.3 hours	Non-significant
Qassem MG et al (2021) <sup>58</sup>	38.22 minutes	39.74 minutes	Non-significant
Kirshtein et al (2008) <sup>84</sup>	42.5 minutes	37 minutes	Non-significant
Present study	1.11 hours	1.06 hours	Non-significant

#### PERFORATION OF ENDOBAG

None of patient showed perforation of Endobag. In a previous study conducted by Narayanswamy T et al, authors reported that the gall-bladder perforation was found in 1.48 percent in endobag group and 4.07 percent in without endobag group while spillage of stones/ port impaction in 1.11% in group-A and 0.36% in group-B patients.<sup>55</sup>

Studies	With endobag	Without endobag	p-value
Narayanswamy T et al (2009) <sup>55</sup>	1.48 percent	4.07 percent	Significant
Present study	0 percent	0 percent	-

### INTRAABDOMINAL SPILLAGE

Intraabdominal spillage was seen among 10 percent of the patients of Group A and among 23.33 percent of the patients of Group B. On comparing the values; significant results were obtained. In a previous study conducted by Narayanswamy T et al, authors reported that spillage of stones was seen in 0.36 percent of the patients of the endobag group and in 1.11 percent of the patients of the non-endobag group (p-value < 0.05). Singh et al, in a previous study, reported presence of intraabdominal spillage only in non-endobag group (8 percent of the patients). In another study conducted by Qassem MG et al, authors reported presence of intraabdominal spillage in 2 percent of the patients of the endobag group and in 10 percent of the patients of the non-endobag group.

Studies	With endobag	Without endobag	p-value
Narayanswamy T et al (2009) <sup>55</sup>	10 percent	23.33 percent	Significant
Singh et al (2018) <sup>81</sup>	0 percent	8 percent	Significant
Qassem MG et al (2021) <sup>58</sup>	2 percent	10 percent	Significant
Present study	0.36 percent	1.11 percent	Significant

However, a reported incidence of gall-bladder spillage varies from 6% to 30% (Kang 2003). Ali & Siddiqui (2013) and Helme et al (2009) stated that best way to avoid complication of spilled gall-stones and port site contamination is to use endobag. Golash in his series of 772 patients of Laparoscopic cholecystectomies retrieved the gall-bladder specimen through the umbilical port without using endobag, hence reported a high incidence of port site contamination and gall-stone spillage (Golash & Rahman, 2006). Qassem MG et al (2021)

showed that the use of endobag was directly associated with reduced incidence of port-site infection and port-site spillage, because endobag is supposed to contain the whole GB with its bile and stone contents, and act as a barrier against spillage. This undoubtedly aids in protecting the skin surface and subcutaneous tissues from unwanted contact with the potentially infected GB and its contents.<sup>58</sup>

#### HISTOPATHOLOGICAL DIAGNOSIS

Histopathological diagnosis among patients of group A was Calculous cholecystitis, Chronic cholecystitis and Subacute chronic calculous cholecystitis found to be present in 3.33 percent, 10 percent, 70 percent, 13.33 percent and 3.33 percent of the patients respectively, Histopathological diagnosis among patients of Group B was Chronic calculous cholecystitis, Chronic acalculous cholecystitis, Chronic cholecystitis and Chronic cholecystitis with Cholesterosis was 73.33 percent, 3.33 percent, 20 percent, and 3.33 percent of patients respectively. In a similar study conducted by Majid MH et al, all the 100 percent of the cases were of benign histology. Singh et al, in another study reported that among patients of endobag group and non-endobag group, chronic calculus cholecystitis was the most common diagnosis found to be present in 84 percent and 88 percent of the patients respectively.

After laparoscopic cholecystectomy, extraction of the gallbladder is a time consuming and difficult job. Although several techniques and methods are suggested to facilitate the retrieval of gall-bladder safely, problems occurring during retraction have not been completely remedied and generally widening of the port site is required. This increases the risk of bleeding, hematoma and infection as well as leaving a risky area for incisional hernia Sanz-Lopez et al. There is a lot of controversy regarding the retrieval of gall-bladder in an endobag or without endobag. A meta-analysis by Regina et al it's found that there is no statistically significant reduction in infection rate when the extraction of the gall bladder was done from the abdominal cavity with a retrieval bag. According to the "Guidelines for the Laparoscopic Application of Clinical Biliary Tract Surgery? of the Society of American Gastrointestinal and Endoscopic Surgeons(SAGES), the use of an endobag is left at the discretion of the operating surgeon. 87, 88

Similar results were observed in another study carried out by Regina DL et al in which wound infections were documented in 14 on 334 (4,2%) patients operated using a retrieval bag versus 16 on 271 (5,9%) patients operated without the use of a retrieval bag. The statistical analysis revealed a risk ratio (RR) of 0.82. Concerning sensitivity analysis the

estimated pooled RR ranged from 0.72 to 0.96, both not statistically significant. Harbord test did not reveal the occurrence of small-study effect (p = 0.892) and the funnel-plot showed no noteworthy pattern. Similar results were observed in another study carried out by Rehman H et al in which mean age of patients was  $40.77 \pm 10.95$  years. Out of 254 patients, 98 (38.58%) were males and 156 (61.42%) were females with male to female ratio of 1:2.5. Patients were divided in two groups A and B and the frequency of patients having port site wound infection in group A was 1(0.4%) whereas in group B was 14(5.5%). More over they had concluded that the use of retrieval bag to remove gallbladder in laparoscopic cholecystectomy resulted in decreased frequency of port site wound infection.

Depending on the choice of surgeon, a retrieval bag is used to extract the gallbladder through a trocar incision. Endobag should be used when gallbladder cancer is suspected, in order to minimize the risk of tumor cell dissemination and in case of acute cholecystitis to avoid spillage of infected bile, stones or pus. As a matter of fact, endoscopic bags are commonly used also in elective cholecystectomy despite increased costs and no sound evidence in their favor (Vergadia A et al).<sup>50</sup>

The infected specimen should be removed in an endobag in order to prevent wound infection and accidental spillage of contents or occult malignant cells. An improvised endobag can be prepared from a simple surgical glove which is easy to make, cheap, readily available and disposable (Taj et al).<sup>82</sup>

# CONCLUSION

#### **CONCLUSION**

Under the light of above obtained results, following conclusion can be withdrawn:

- An endobag for retrieval of gall bladder during laparoscopic cholecystectomy was found better than the direct extraction of the gall bladder.
- Hence endobag should be used for the extraction of gallbladder as it prevents spillage
  of stones and bile. It also reduces the incidence of port site infection, without taking
  any addition time during surgery. However; further studies are recommended for better
  exploration of results.

# SUMMARY

#### **SUMMARY**

The present study was undertaken for assessing the efficacy of Endobag in laparoscopic cholecystectomy to reduce port site infection. A total of 60 patients were enrolled and were divided into two study groups. Patients in group A underwent laparoscopic cholecystectomy using endobag while patients in group B underwent laparoscopic cholecystectomy without endobag. Following results were obtained:

- 36.67, 23.33 and 13.33 percent of the patients of the group A belonged to the age group of 41 to 50 years, 61 to 70 years and 51 to 60 years respectively while 23.33, 6.67 and 30 percent of the patients of the group B belonged to the age group of 41 to 50 years, 61 to 70 years and 51 to 60 years respectively. 10 percent of the patients of the group A and 23.33 percent of the patients of group B belonged to the age group of 31 to 40 years respectively. Mean age of the patients of group A and group B was 50.6 years and 44.47 years respectively. Both the groups were comparable in terms age-wise distribution of patients.
- 20 percent of the patients of Group A and 4 percent of the patients of group B were males. Remaining all are females. Both the groups were comparable in terms of genderwise distribution.
- Mean BMI of the patients of the Group A and Group B was 25.75 Kg/m2 and 24.87 Kg/m2 respectively. Both the groups were comparable in terms of BMI.
- None of the patients of Group A showed presence of SSI while 23.33 percent of the
  patients of Group B showed presence of SSI on postoperative day 3. Incidence of SSI
  was significantly higher among patients of Group B.
- On 5th postoperative day, SSI was seen in 20 percent of the patients of Group B while it was absent in Group A. Incidence of SSI was significantly higher among patients of Group B on postoperative day 5.
- On 7th postoperative day, SSI was seen in 13.33 percent of the patients of Group B
  while it was absent in Group A. Incidence of SSI was significantly higher among
  patients of Group B on postoperative day 7.
- In all the 7 patients of Group B exhibiting SSI, infection was superficial in nature.
- Gall bladder retrieval port among patients of both Group A and Group B was Epigastric port.

- Mean duration of surgery among patients of group A and group B was 1.11 and 1.06 respectively; on comparing the values, non-significant results were obtained.
- None of patient showed perforation of Endobag.
- Intraabdominal spillage was seen among 10 percent of the patients of Group A and among 23.33 percent of the patients of Group B. On comparing the values; significant results were obtained.
- Histopathological diagnosis among patients of group A was Calculous cholecystitis, Cholesterosis gallbladder, Chronic calculous cholecystitis, Chronic cholecystitis and Subacute chronic calculous cholecystitis found to be present in 3.33 percent, 10 percent, 70 percent, 13.33 percent and 3.33 percent of the patients respectively, Histopathological diagnosis among patients of Group B was Chronic calculous cholecystitis, Chronic acalculous cholecystitis, Chronic cholecystitis and Chronic cholecystitis with Cholesterosis was 73.33 percent, 3.33 percent, 20 percent, and 3.33 percent of patients respectively.

# LIMITATIONS AND RECOMMENDATIONS |

### LIMITATIONS AND RECOMMENDATIONS

- The results of this study are more likely to contain type-II statistical errors, so our findings need to be verified by carrying out a larger, multi-centric randomized trial.
- This study found acceptance as a viable alternative to the conventional method. There is still a need for more randomized trials with larger cohort populations.

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# ANNEXURES

# **ANNEXURES**

	PROFORMA	
Name:	DOA:	
Age:	DOD:	
Sex:	IP/OP NO:	
Sea.	n/or no.	
Religion:	Unit No:	
<b>Education:</b>	Date of surgery:	
Occupation:		
Address:		
1.Chief Complaints:		
Pain		
Vomiting/nausea		
Fever		
Diarrhea		
/constipation		
Yellowish discoloration of eyes		
Other complaints		
2.Vomiting		
Onset		
Duration		
Frequency		
Character of onset		
Amount		
Content		

# Past history Diabetes Hypertension

T.B

Asthma / previous allergy

Previous surgeries

Previous hospital admissions

#### **GENERAL PHYSICAL EXAMINATION:**

Appearance

Attitude

Level of consciousness

Built and nourishment

Dehydration

Pallor/Cyanosis/Icterus/Clubbing/edema/Generalized lymphadenopathy

#### **VITAL DATA:**

Pulse:

Temperature:

BP:

Respiration rate:

#### **Systemic examination**

Per Abdomen:

Respiratory system:

Cardiovascular system:

Central nervous system:

#### **PER ABDOMEN**

#### **Inspection:**

Shape of the abdomen-

Umbilicus-

Movement of all quadrants with respiration-

Any Mass, Scars, Sinuses, dilated veins. Visible pulsations-

External genitalia-

Hernial offices-

#### **Palpation:**

Local rise of temperature-

**Tenderness** 

Guarding and rigidity

Palpable mass

Hernial offices

Left supraclavicular and left axillary lymph node

**Percussion**: Free fluid

**Auscultation:** Bowel sounds

#### **Digital rectal examination:**

#### **Investigations:**

- Complete blood count
- Blood grouping and typing
- · Renal function test
- Liver function test
- Coagulation profile
- HIV and HBsAG
- USG abdomen pelvis

#### **Parameters:**

- 1. BMI
- 2. Operative time
- 3. Intra abdominal spillage
- 4. Endobag perforation
- 5. Gall bladder retrieval port
- 6. Signs of infection or inflammation at port sites
- 7. Histopathological report

# INFORMED CONSENT FORM

I Mr./Ms./Mrs have been explained in my own understandable	
language, that I will be included in a study which is "STUDY OF EFFICACY OF	
ENDOBAG IN LAPAROSCOPIC CHOLECYSTECTOMY TO REDUCE	
PORT SITE INFECTION"	
I have been explained that my clinical findings, investigations, postoperative findings will be	e
assessed and documented for study purpose.	
I have been explained my participation in this study is entirely voluntary and I can withdraw	7
from the study any time and this will not affect my relation with my doctor or the treatment	
for my ailment.	
I have been explained about the interventions needed, possible benefits and adversities due	
to interventions, in my own understandable language.	
I have understood that all my details found during the study are kept confidential and while	
publishing or sharing of the findings, my details will be masked.	
publishing of sharing of the fineings, my details will be masked.	
I have principal investigator mobile number for enquiries.	
I in my sound mind give full consent to be added in the part of this study.	
Signature of the patient:	
Name:	
Signature of the witness:	
Name:	
Relation to patient:	
Date:	
Place:	

#### **PATIENT INFORMATION SHEET**

- Study title: "ROLE OF ENDOBAG IN REDUCING PORT SITE INFECTION POST LAPAROSCOPIC CHOLECYSTECTOMY."
- GUIDE: DR. SREERAMULU.P. N
- STUDY CONDUCTED BY DR. D. VAIBHAVI
- Study location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.
- The purpose of the study is explained in detail to us and all information collected is
  for study purpose only. The data collected is submitted to the department of surgery,
  SDUMC, Kolar and confidentiality ensured .The merits and demerits explained
  briefly to us.
- All Patients diagnosed with cholelithiasis will be included in this study. Patients in
  this study will undergo routine investigations, CBC ,RFT, LFT, USG Abdomen pelvis
  . Patients planned for laparoscopic cholecystectomy and sent for biopsy.
- Please read the following information and discuss with your family members. You
  can ask any question regarding the study. If you agree to participate in the study, we
  will collect information (as per proforma) from you or a person responsible for you or
  both. Relevant history will be taken. This information collected will be used only for
  dissertation and publication.
- All information collected from you will be kept confidential and will not be disclosed
  to any outsider. Your identity will not be revealed. This study has been reviewed by
  the Institutional Ethics Committee and you are free to contact the member of the
  Institutional Ethics Committee.
- There is no compulsion to agree to this study. The care you will get willnot change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

For further information contact: Left thumb impression/signature of the patient

Dr. D. VAIBHAVI [Post Graduate]

Department of General Surgery

SDUMC, Kolar

Left thumb impression / signature of the witness

Phone number- 9790216254.

# PHOTO GALLERY

# **IMAGE GALLERY**

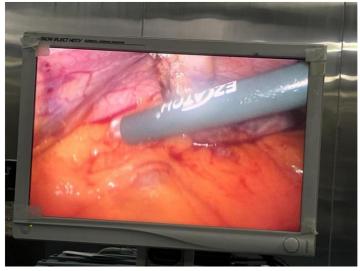
# **IMAGES OF ENDOBAG:**



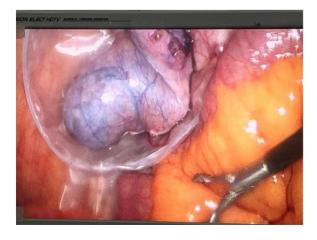




## **IMAGES OF CASES:**























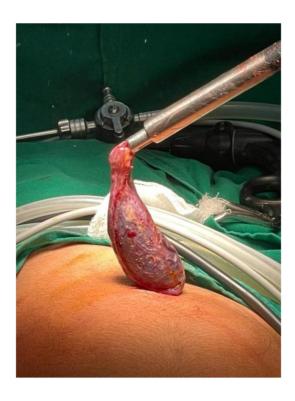
# IMAGES OF CONTROLS









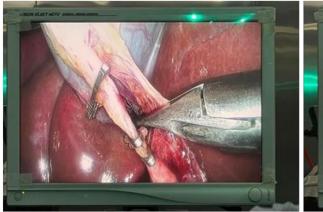


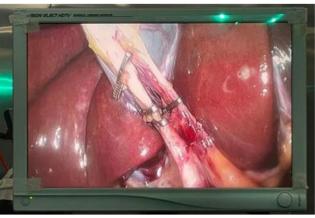
### IMAGE OF LAPAROSCOPIC INSTUMENT SET:



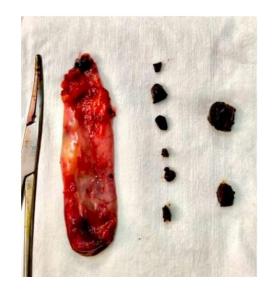
### IMAGES OF CALOTS TRIANGLE DISSECTION:





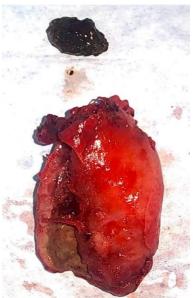


## **IMAGES OF GALL STONES:**





















## **KEY TO MASTER CHART:**

 $SSI-Surgical\ site\ infection$ 

BMI – Body mass index

HPE – Histopathological examination

M- Male

F-Female

N/A-Not applicable

# MASTER CHART

s.no	UHID NUMBER	AGE	SEX	вмі	ENDOBAG	SSI ON POD 3	SSI ON POD 5	SSI ON POD 7	TYPE OF INFECTION	GALL BLADDER RETRIVAL PORT	DURATION (HOURS)	PERFORATION OF ENDOBAG	INTRA ABDOMINAL SPILLAGE	НРЕ
1	161738	46	F	24	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.25	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
2	152605	28	F	24.4	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
3	127753	36	F	24.2	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
4	155723	67	M	25.9	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
5	268430	45	F	26.8	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
6	135812	43	F	24.1	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.5	NO	Yes	CHRONIC CHOLECYSTITIS
7	150085	63	F	25.7	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CALCULOUS CHOLECYSTITIS
8	125690	40	F	26.9	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC ACALCULOUS CHOLECYSTITIS
9	179450	28	M	23.9	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.25	NO	Yes	CHRONIC CALCULOUS CHOLECYSTITIS
10	194379	52	F	29.1	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
11	168592	61	M	26.7	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
12	178967	21	F	26.3	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	Yes	CHRONIC CALCULOUS CHOLECYSTITIS
13	179016	43	F	29	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.5	NO	No	CHOLESTEROSIS GALLBLADDER
14	199441	39	F	28	WITHOUT ENDOBAG	YES	YES	YES	SUPERFICIAL	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
15	196142	75	F	26.2	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
16	195740	45	F	24.5	WITHOUT ENDOBAG	YES	YES	YES	SUPERFICIAL	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
17	194132	65	F	28.9	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.25	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
18	147946	28	F	29.6	WITHOUT ENDOBAG	YES	YES	NO	SUPERFICIAL	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
19	186691	55	F	27.9	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHOLESTEROSIS GALLBLADDER
20	184082	35	F	24	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CHOLECYSTITIS
21	68002	56	M	26.1	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.5	NO	No	CHRONIC CHOLECYSTITIS
22	202030	59	F	24.1	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CHOLECYSTITIS WITH CHOLESTEROLOSIS
23	167963	68	M	27.8	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.5	NO	Yes	SUBACUTE CHRONIC CALCULOUS CHOLECYSTITIS
24	209730	49	F	25.6	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CHOLECYSTITIS
25	209236	45	F	24.3	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CHOLECYSTITIS
26	205460	56	F	23.8	WITHOUT ENDOBAG	YES	YES	YES	SUPERFICIAL	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
27	162206	27	F	24.4	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.15	NO	No	CHRONIC CHOLECYSTITIS
28	200835	54	M	26.6	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CHOLECYSTITIS
29	265133	65	M	29.5	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
30	255738	52	F	28.8	WITHOUT ENDOBAG	YES	YES	YES	SUPERFICIAL	EPIGASTRIC PORT	1.5	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
31	268168	80	F	29.4	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
32	258468	56	M	26	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	Yes	CHRONIC CHOLECYSTITIS
33	242329	60	F	23.9	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.15	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
34	248107	50	F	27.7	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	Yes	CHRONIC CALCULOUS CHOLECYSTITIS
35	254022	45	F	23.8	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.15	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS

S.NO	UHID NUMBER	AGE	SEX	ВМІ	ENDOBAG	SSI ON POD 3	SSI ON POD 5	SSI ON POD 7	TYPE OF INFECTION	GALL BLADDER RETRIVAL PORT	DURATION (HOURS)	PERFORATION OF ENDOBAG	INTRA ABDOMINAL SPILLAGE	НРЕ
36	261972	49	F	24.2	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
37	208320	41	F	24.8	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
38	246696	58	F	29.3	WITHOUT ENDOBAG	YES	YES	NO	SUPERFICIAL	EPIGASTRIC PORT	1	NO	No	CHRONIC CHOLECYSTITIS
39	244005	49	M	25.1	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
40	242298	36	F	23.7	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.15	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
41	86117	70	F	24.9	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
42	199416	40	F	24.7	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
43	381624	42	F	25.2	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
44	387282	56	F	25	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.15	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
45	371517	58	F	23.6	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
46	236055	28	F	23.5	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	Yes	CHRONIC CALCULOUS CHOLECYSTITIS
47	253966	46	F	23.7	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHOLESTEROSIS GALLBLADDER
48	225674	24	F	24.3	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.5	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
49	255779	45	F	24.4	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
50	150530	52	F	26.7	WITHOUT ENDOBAG	YES	NO	NO	SUPERFICIAL	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
51	260868	25	F	26.8	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CHOLECYSTITIS
52	222063	61	M	24.2	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
53	245120	66	F	24.3	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.5	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
54	265455	42	F	25.7	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	Yes	CHRONIC CALCULOUS CHOLECYSTITIS
55	265369	31	F	24.5	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
56	239583	32	F	23.9	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
57	268451	37	F	26.9	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1.15	NO	Yes	CHRONIC CALCULOUS CHOLECYSTITIS
58	217315	33	F	26.7	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
59	245741	45	F	25.8	WITH ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	No	CHRONIC CALCULOUS CHOLECYSTITIS
60	265613	49	F	28.9	WITHOUT ENDOBAG	NO	NO	NO	NA	EPIGASTRIC PORT	1	NO	Yes	CHRONIC CALCULOUS CHOLECYSTITIS