# "A RANDOMISED CONTROL TRIAL TO COMPARE DRAIN VS NO DRAIN IN ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY"

REG NO. BH0112007

## Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

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

**DEPARTMENT OF SURGERY,**
**JAWAHARLAL NEHRU MEDICAL COLLEGE,**
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# ENDORSEMENT

This is to certify that the dissertation entitled **"A RANDOMISED CONTROL TRIAL TO COMPARE DRAIN VS NO DRAIN IN ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY"** is a bonafide research work done by **CANDIDATE REGISTER NO. BH0112007.**


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# LIST OF ABBREVIATIONS USED

| | | |
|---|---|---|
| ACR | - | American College of Radiology |
| APC | - | Argon plasma coagulator |
| BDI | - | Bile duct injuries |
| BP | - | Blood pressure |
| CBD | - | Common bile duct |
| CCK-DISIDA | - | Cholecystokinin–diisopropyl iminodiacetic acid |
| CI | - | Confidence interval |
| cm | - | Centimeter |
| CT | - | Computed tomography |
| ERCP | - | Endoscopic retrograde cholangiopancreatography |
| ESWL | - | Extracorporeal shock wave |
| g/dL | - | Gram per deciliter |
| HIDA | - | Hepatobiliary iminodiacetic acid |
| LC | - | Laparoscopic cholecystectomy |
| mL | - | Milligram |
| ml | - | Milliliter |
| mm Hg | - | Millimeters of mercury |
| n | - | Total number |
| NIH | - | National Institutes of Health |
| OC | - | Open cholecystectomy |
| p | - | Probability |
| PR | - | Pulse rate |
| RR | - | Respiratory rate |
| RYGB | - | Routine prophylactic LC prior to gastric bypass |

| | | |
|---|---|---|
| SAGES | - | Society of American Gastrointestinal Surgeons |
| SD | - | Standard deviation |
| Temp | - | Temperature |
| USG | - | Ultrasound |
| VAS | - | Visual analogue score |

# ABSTRACT


**Background and objectives**

Laparoscopic cholecystectomy is a safe and effective treatment for patients with gallstones. However, the routine use of drain after laparoscopic cholecystectomy is controversial. The present study was designed to compare drain versus no drain in elective laparoscopic cholecystectomy in terms of morbidity and post operative pain.

**Methodology**

The present one year randomized controlled trial was done from January 2013 to December 2013. A total of 60 patients undergoing elective cholecystectomy under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum were studied. Based on closed envelope method patients were randomized into two groups of 30 each that is, Group D (with drain) and Group ND (without drain). Assessment of pain was done based on VAS scores.

**Results**

In group D and group ND, 50% and 40% of the patients were females with male to female ratio of 1:1 and 1:1.5 respectively (p=0.436). The mean age in group D was 43.90 ± 14.06 years compared to 43.30 ± 15.85 years in group ND (p=0.181). The drain volume was found to be 3.06 ± 2.94 mL in a total of 25 numbers of patients. In group D, higher number of patients (83.33%) had collection in either drain or on USG compared to group ND (26.67%) (p<0.001). The mean post operative collection on ultrasound was comparable in both the

groups (4.20 ± 1.90 mL vs 4.50 ± 1.92 mL; $p=0.181$). The mean pain scores were high in group D (6.40 ± 1.83) compared group ND (2.50 ± 1.31) ($p<0.001$). In group D, mean total collection including drain collection and USG collection was significantly high (10.23 ± 5.40 mL) compared to mean collection on USG in group ND (4.50 ± 1.92 mL) ($p<0.001$).

**Conclusion and interpretation**

Placement of drain in peritoneal cavity following elective laparoscopic cholecystectomy did not have any advantages. Adversely it caused increase in severity of post operative pain.

**Keywords**

Drain; Laparoscopic cholecystectomy; Pain;

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# INTRODUCTION

Cholecystitis is the inflammation of the gallbladder that occurs most commonly because of an obstruction of the cystic duct from cholelithiasis. Ninety percent of cases involve stones in the cystic duct (that is, calculous cholecystitis), with the other 10% of cases representing acalculous cholecystitis.[1]

About 10% to 15% of the adult western population has gallstones. Between 1% and 4% become symptomatic in a year.[1] More than half a million cholecystectomies are performed per year in the United States alone. Regional differences exist in the cholecystectomy rates.[2]

Risk factors for cholecystitis mirror those for cholelithiasis and include increasing age, female sex, certain ethnic groups, obesity or rapid weight loss, drugs, and pregnancy.[3]

The symptoms include pain related to the gallbladder (biliary colic), inflammation of the gallbladder (cholecystitis), obstruction to the flow of bile from the liver and gallbladder into the small bowel resulting in jaundice (yellowish discolourisation of the body usually most prominently noticed in the white of the eye, which turns yellow), bile infection (cholangitis), and inflammation of the pancreas, an organ which secretes digestive juices and harbours the insulin secreting cells which maintain blood sugar level (pancreatitis).

The liver produces bile which has many functions, including elimination of waste processed by the liver and digestion of fat. The bile is temporarily stored in

the gallbladder (an organ situated underneath the liver) before it reaches the small bowel. Concretions in the gallbladder are called gallstones.

Removal of the gallbladder (cholecystectomy) is currently considered the best treatment option for patients with symptomatic gallstones. This is generally performed by key-hole surgery (laparoscopic cholecystectomy). Laparoscopic cholecystectomy provides a safe and effective treatment for patients with gallstones as it reduces post-operative pain with almost inadvisable scar, short hospital stay and earlier return to work.[4]

Drain is a tube that is left inside the abdomen to allow drainage of fluids to outside the abdomen. Some surgeons have routinely drained the peritoneal cavity after laparoscopic cholecystectomy because of the fear of collection of bile or blood requiring re-operation. As the name indicates, the drain may drain out these collections to the exterior, thereby avoiding open surgery. However, routine use of drains may necessitate the patient to stay overnight or require drain removal after discharge both of which increase resource utilisation in this era of day surgery (where patients are admitted and discharged on the same day of surgery).[5]

Peritoneal drainage after cholecystectomy has long remained an essential component of procedure, since its introduction by Langenbach in 1882.[6] The benefits of drains derive from the notion that they allow the egress of bile leaking from the gallbladder bed, cystic duct or damaged bile duct, as well the blood or exudates resulting from surgical trauma. Even if they do not drain these fluids completely, they do warn the surgeons of such leakage and prompt for early and necessary steps to deal with complications. On the contrary it is true that small

amounts of fluids are effectively absorbed by the peritoneum, while leakage of large amounts, sufficient to be of any clinical significance is uncommon, and if happens the drain sometime found ineffective as this often get blocked by omental plug or blood clot. Furthermore, the drains have been incriminated for a number of complications; converting a sterile collection into an infected one, secretion of serous fluid, and even at times the intestinal fistula formation.[7]

Despite the fact that, back in 1919, cholecystectomy without drainage referred to as “the ideal cholecystectomy” was introduced in Germany,[8] with a view of easier convalescence, shortened hospital stay and lower complication rate, vast majority of surgeons still continued the routine practice of placing a drain after simple, elective cholecystectomy. During the era of open cholecystectomy there have been many contradictory reports regarding the usefulness of drains. Though many of the randomized trials contradict their benefits, some of these showed that the use of drains might be harmful rather than beneficial.[9,10] In the early years of laparoscopic cholecystectomy most of the surgeons routinely retained a drain in the subhepatic space, but with gradual acceptance of the technique and increasing experience, many of the surgeons tailored the results of randomized trials in open cholecystectomy to laparoscopic one, and omitted draining the area routinely. Generally speaking opinion and practice of laparoscopic surgeons vary from routine drainage after cholecystectomy, drainage in selected cases to no drain at all.[11]

There is currently no evidence to support the routine use of drain after laparoscopic cholecystectomy. Hence, this study was intended to compare the drain versus no drain in elective laparoscopic cholecystectomy in terms of morbidity and post operative pain.

# OBJECTIVES

The objective of the study was to compare drain versus no drain in elective laparoscopic cholecystectomy.

# REVIEW OF LITERATURE

## GALL STONE DISEASE

Gallstones occur commonly in the western world.1-6 Most are asymptomatic, but still, gallstone disease contributes substantially to health care costs, and its complications are sometimes life threatening.

### Surgical Anatomy

### Anatomy

The gallbladder is a slate blue, piriform sac partly sunk in a fossa in the right hepatic lobe’s inferior surface. It extends forward from a point near the right end of the porta hepatic to the inferior hepatic border.[15] Its upper surface is attached to the liver by the connective tissue, elsewhere it is completely covered by the peritoneum and even connected to the liver by a short mesentry.

It is 7 to 10 cm long, 3 cm broad at its widest and 30-50ml in capacity. It is described as having a fundus, body and neck.

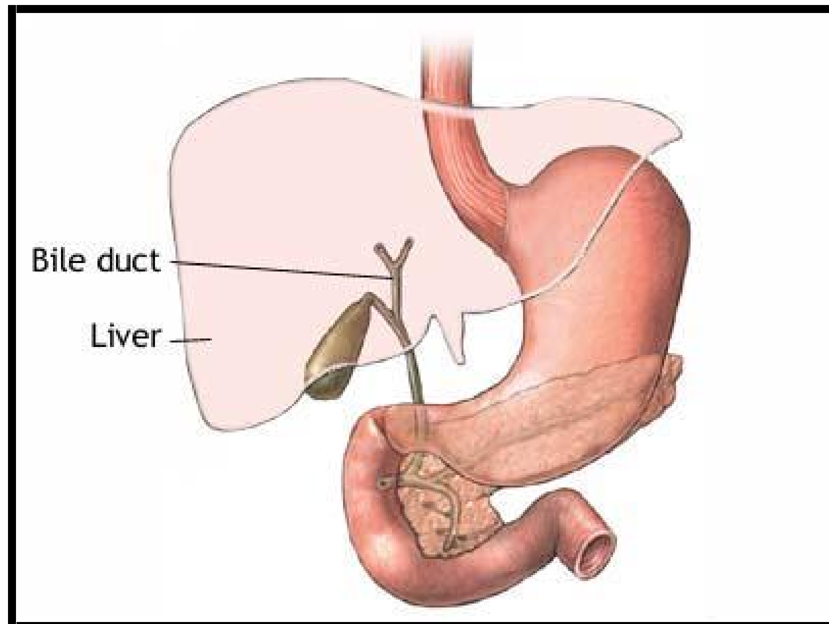



**Figure. 1. Anatomy of gall bladder**[12]

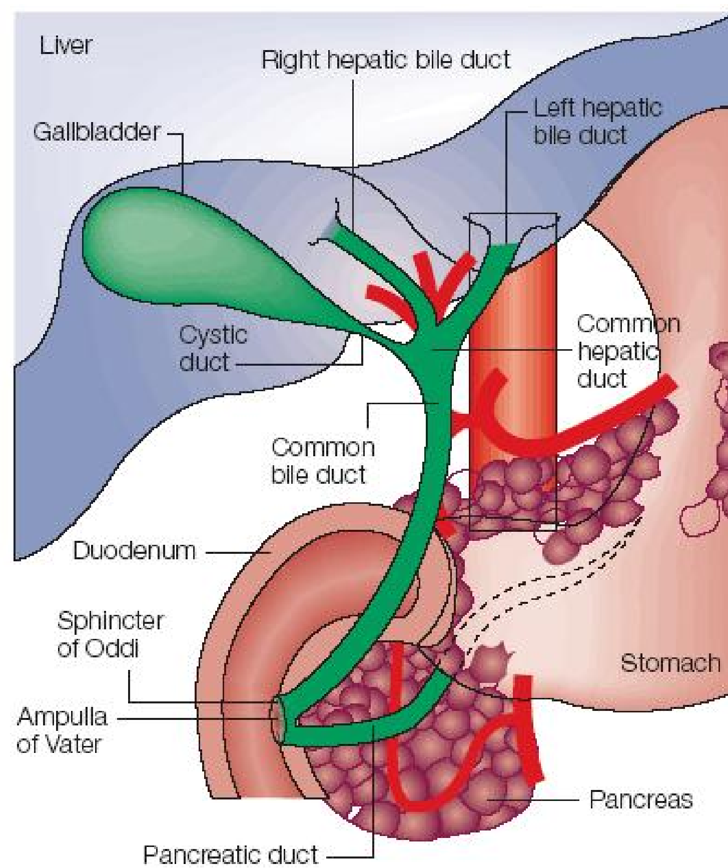



**Figure 2. Biliary tree**[12]

The fundus, the expanded end projects down, forwards and to the right, extending beyond the inferior border to contact the anterior abdominal wall behind the ninth right costal cartilage, where the lateral edge of the right rectus abdominus muscle crosses the costal margin. Posteriorly it is related to transverse colon, near its commencement. The body is directed back and to the left, near the right end of the porta it is continuous with neck. It is related above to the liver, below to the transverse colon and further back to the first and upper end of second segment of duodenum.

The neck is narrow, curving up and forwards and then abruptly backwards and downwards, to become the cystic duct, at which transition there is a constriction. The neck is attached to the liver by the areolar tissue containing the cystic artery. The mucosa of the neck is obliquely rigid forming a spiral valve, when the neck is distended this gives its surface a spiral grove.

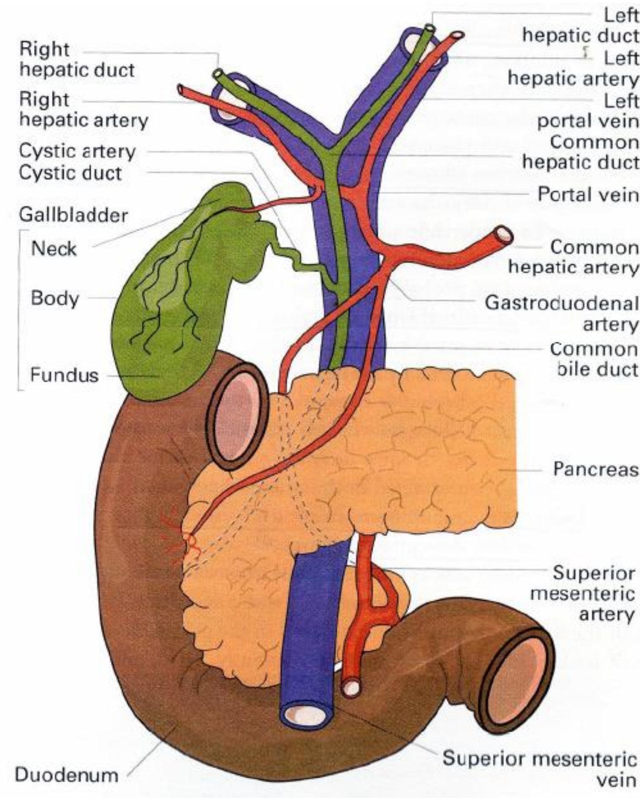



**Figure 3. Surgical anatomy of biliary tract**[12]

From the right side of the neck a small recess may project down and back towards the duodenum, often termed Hartmann's pouch (but originally described by Broca). It has been regarded as the constant feature but Davis and Harding (1942) have shown that it is always a sequelae of pathological states especially when dilated.

The cystic duct is 3 to 4 cm long, it passes back, down and to the left from the neck of the gall bladder, joining the common hepatic duct to form the bile duct. It is adherent to the common hepatic duct for a short distance before joining it. Which usually near the porta hepatis but sometimes lower, in which case the cystic duct lies along the lesser omentum's right edge. Its mucosa bears 5-10 concentric folds, they project obliquely in regular succession, like a spiral valve, which some times referred as the "valve of Heister".[13-16]

Arterial Supply of the Gallbladder:[13]

The major blood supply of the gall bladder is through the cystic artery, which is typically a branch of right hepatic artery. The gall bladder also receives many small vessels from its hepatic bed. The cystic artery usually passes behind the common hepatic and cystic ducts to the upper surface of the neck of the gall bladder, on which it runs downward forwards before dividing into superficial and deep branches. The former ramifies on the serosal surface and later on the hepatic surface of the gallbladder. The two branches must be secured during cholecystectomy. The cystic artery supplies branches to the hepatic ducts and to the upper part of the common bile duct. The lower part of the bile duct receives several branches from the posterior superior pancreatico-duodenal artery. The right hepatic artery gives branches to the middle part of the bile duct.

Variations in the artery's origin are of surgical interest. In 800 specimens Anson (1963) observed the following incidences, origin from the right hepatic artery 63.9%, the hepatic trunk 26.9%, left hepatic 5.5% gastroduodenl 2.6%, superior pancreaticoduodenal 0.3%, right gastric 0.1%, coelic trunk 0.3%, and superior mesenteric 0.8%. An accessory cystic artery may arise from the common hepatic or one of its branches. The cystic artery is an end artery and its occlusion is followed by the gangrene of the gall bladder.[17]

Venous Drainage of the Gallbladder:[13]

The veins draining the gall bladder vary considerably. Those from its upper surface lies in the areolar tissue between the gallbladder and liver and usually run directly into the liver through the fossa of the gallbladder to join the hepatic veins.

Those from the rest of the gall bladder join to form one or more cystic veins on its neck, and these commonly enter liver, either directly or after joining with the veins draining the hepatic ducts and upper part of the bile duct. Only rarely does a single or double cystic vein drain directly in to right branch of the portal vein. They do not accompany the cystic artery.

Lymphatic Drainage[13]

The lymphatics draining the gall bladder tend to be of considerable importance for both inflammatory and malignant disease of gall bladder. The lymphatic channels from the subserosal and sub mucosal plexus drain into cystic lymph node of Lund, the sentinel lymph node, which lies in the fork created by the junction of cystic and common hepatic ducts and to a node situated at the anterior border of epiploic foramen. Efferent vessels from the nodes pass in the free edge of the lesser omentum to the celiac group of preaortic nodes.

The sentinel node can be of considerable size and may distort the normal anatomy in patients with acute cholecystitis or carcinoma. The subserosal lymphatic vessels of the gall bladder also have connection with the subcapsular lymphatic channels of liver, and accounts for the frequent spread of carcinoma of gallbladder to the liver.

Nerve Supply[13]

The wall of the gall bladder is richly innervated with both sympathetic and parasympathetic nerve fibers, which pass along the hepatic artery and its branches. Parasympathetic fibers, mainly from the hepatic branch of anterior vagal trunk, stimulate contraction of the gall bladder and relax the ampullary sphincter.

Sympathetic fibers from the cell bodies in the celiac ganglia, with the preganglionic cells in the lateral horn of the spinal cord segments, T7-T9 inhibits contraction. Autonomic plexus of the nerve exists in the muscular and sub mucous layers. Fibers from the right phrenic nerve, through communication between phrenic and celiac plexus, appear to reach the gallbladder via hepatic plexus explaining referred “shoulder pain” in the gall bladder pathology. The biliary tract pain is usually felt in the right hypochondrium and epigastrium and may radiate round to the back in the inferior angle of scapula.

Triangle of cholecystectomy

Calots defined a triangle of anatomical area formed by the common hepatic duct medially, the cystic duct laterally and the cystic artery superiorly in 1891. The present concept is of the triangle of cholecystectomy has for its upper limit not the cystic artery but the inferior surface of the liver[20]. This triangle is of surgical importance because a number of important structures pass through it. Therefore during cholecystectomy it is a need to identify all structure within the triangle to prevent complications.[18]

**Cholecystectomy**

Laparoscopic cholecystectomy is the standard of care for the surgical treatment of cholecystitis. Studies have indicated that early laparoscopic cholecystectomy resulted in shorter total hospital stays with no significant difference in conversion rates or complications.[19-21] The ACR 2010 criteria state that laparoscopic cholecystectomy is the primary mode of treatment for cholecystitis.[22]

**Open cholecystectomy**

Open cholecystectomy (OC) was the method of choice for gallbladder surgery for almost a century.[23] However OC results in a significant change in outcome for the patient because of the higher rate of postoperative complications and the longer hospital stay.[24] The common indications for OC is difficulty during surgery, which can be affected by factors such as a history of previous abdominal surgery, recurrent attacks of cholecystitis, AC, advanced age of the patient, or male gender.[25]

It appears that previous history and/or new inflammation (i.e., AC) are two of the most frequent situations indicative of open cholecystectomy. Pericholecystitis makes laparoscopy challenging, changes the local anatomy, and increases the difficulty of identifying the Calot's triangle and common bile duct. Pericholecystitis can also predispose the patient to hemorrhage more easily from the gallbladder bed or cystic artery, and it causes an increased risk of gallbladder perforation and, thus, spillage of gallstones into the peritoneal cavity during dissection of the gallbladder. Other situations associated with increased difficulty of cholecystectomy are adhesions caused by previous operations, cirrhosis, obesity, cholecystoduodenal fistula, stones in the common bile duct, buried gallbladder, and a thickened gallbladder wall.[25]

Previous abdominal operations, even in the upper abdomen, are not a contraindication to a safe LC. However, previous upper abdominal surgery is associated with an increased need for adhesiolysis and a higher open conversion rate.[26] Ercan et al.[27] investigated the effects of previous abdominal surgery on the

conversion rate in a series of 2963 attempted LCs. They found a 4% conversion rate; among patients with conversion to OC, 37.2% had a history of previous abdominal operation.

It is postulated that, male gender is a significant factor for conversion to OC.[25] This association may be due to the increased severity of gallstone disease in men.[28] A study revealed that the conversion rate was 2.5-fold higher in men than in women (5.6% vs. 2.2%, respectively; p=0.001). When gender difference in comorbid diseases was investigated along with the high conversion rate in males, comorbid disease was found in 20.23% of males and 24.05% of females, respectively (p = 0.558). When the gender distribution according to AC rates was investigated, 17 (20.24%) male patients and 9 (11.39%) female patients were determined to have AC (p = 0.123). Increased disease activity (adhesions and fibrosis of Calot's triangle) occurred in 69 (82.14%) male patients and 40 (50.63%) female patients (p,0.001). These data may explain the cause of the significant differences between gender distributions and conversion rates.[25]

**Laparoscopic cholecystectomy**

Laparoscopy is the process of inspecting the abdominal cavity through an endoscope. Initially, gynecologists used these instruments to diagnose pelvic pain, holding the rigid telescope in one hand and looking through it with the naked eye, it was possible to manipulate a second instrument in the abdominal cavity to move abdominal structures, aspirate cysts, and apply clips to fallopian tubes for sterilization. As small video cameras became available in the 1980s, the surgeon was

able to use both hands to position surgical instruments, while one or more assistants could contribute to the procedure by sharing the same view as the surgeon.[29]

No other operation has been so profoundly affected by the advent of laparoscopy as cholecystectomy. In fact, the converse may be more accurate; laparoscopic cholecystectomy (LC) has been instrumental in ushering in the laparoscopic era. Laparoscopic cholecystectomy has rapidly become the procedure of choice for routine gallbladder removal and has become the most common major abdominal procedure performed in Western countries.[30]

The initial driving force behind the rapid development of LC was patient demand. Prospective randomized trials were late and largely irrelevant because advantages were clear. Hence, LC was introduced and gained acceptance not through organized and carefully conceived clinical trials but by acclamation.

LC decreases postoperative pain, decreases need for postoperative analgesia, shortens hospital stay from 1 week to less than 24 hours, and returns the patient to full activity within 1 week compared to 1 month after open cholecystectomy (OC).[31] LC also provides improved cosmesis and improved patient satisfaction as compared to OC.

Although the direct operating room and recovery room costs are higher for LC, the shortened length of hospital stay and rapid return to normal activity results in reduced cost.[32] In fact, with the higher rate of cholecystectomy in the laparoscopic era, the costs in the United States of treating gallstone disease may actually have increased. Recent trials show that LC patients in both outpatient and inpatient groups

recover equally well, indicating that a greater proportion of patients should be offered the outpatient modality. No differences were seen between the groups.[6]

**Historical note 1**

In 1882, Carl Langenbuch performed the first successful open cholecystectomy (OC) for gallstone disease; for over 100 years, it was the standard treatment for symptomatic cholelithiasis and acute and chronic cholecystitis.[34]

Dr. Med Erich Mühe of Böblingen, Germany, performed the first laparoscopic cholecystectomy (LC) on September 12, 1985.[34] The German Surgical Society rejected Mühe in 1986 after he reported that he had performed the first LC. In 1990, in Atlanta, at the Society of American Gastrointestinal Surgeons (SAGES) Convention, Perissat, Berci, Cuschieri, Dubois, and Mouret were recognized by SAGES for performing early LC, but Mühe was not. However, in 1999 he was recognized by SAGES for having performed the first LC.[34]

In 1987, Philippe Mouret introduced LC in France and quickly revolutionized the treatment of gallstones.[35] LC was popularized in Europe by Dubois and associates and Perissat and colleagues; in the United States, it was popularized by Reddick and Oslen.[34]

LC also more or less ended attempts at noninvasive management of gallstones, such as extracorporeal shock wave (ESWL) and bile salt therapy.

A National Institutes of Health (NIH) consensus statement in 1992 stated that LC provides a safe and effective treatment for most patients with symptomatic gallstones and has become the treatment of choice for many patients.[36]

LC has received nearly universal acceptance and is currently considered the criterion standard for the treatment of symptomatic cholelithiasis.[37] Many centers have special "short-stay" units or "23-hour admissions" for postoperative observation following this procedure.[38]

**Indications**

The general indications for laparoscopic cholecystectomy (LC) are the same as for the open procedure. Although LC was originally reserved for patients who are young and thin, LC is also offered today to patients who are elderly and obese; patients in the latter categories may, in fact, benefit even more from surgery through small incisions.

Asymptomatic patients

Cholecystectomy is not indicated in most patients with asymptomatic stones because only 2-3% of these patients go on to become symptomatic per year. To properly determine the indications for elective cholecystectomy, the risk of the operation (taking into account the age and comorbid factors of the individual patient) must be weighed against the risk of complications and death without operation.[39]

The widespread use of diagnostic abdominal ultrasonography has led to the increasing detection of clinically unsuspected gallstones. This, in turn, has given rise to a great deal of controversy regarding the optimal management of asymptomatic (silent) gallstones.[40]

Patients who are immunocompromised, are awaiting organ allotransplantation, or have sickle cell disease are at higher risk of developing complications and should be treated irrespective of the presence or absence of symptoms.

Additional reasons to consider prophylactic LC include calculi >3 cm in diameter, particularly in individuals in geographical regions with a high prevalence of gallbladder cancer; chronically obliterated cystic duct; nonfunctioning gallbladder; calcified (porcelain) gallbladder;[41] gallbladder polyp >10 mm or showing rapid increase in size;[42] gallbladder trauma;[40] and anomalous junction of the pancreatic and biliary ducts.

Morbid obesity is associated with a high prevalence of cholecystopathy, and the risk of developing cholelithiasis is increased during rapid weight loss. Routine prophylactic LC prior to gastric bypass (RYGB) is controversial, but LC should clearly precede or be performed at the time of RYGB in patients with a history of gallbladder pathology.[43]

Symptomatic gallstone disease

Biliary colic with sonographically identifiable stones is the most common indication for elective LC.[44]

Acute cholecystitis, when diagnosed within 72 hours from the onset of symptoms, can and usually should be treated laparoscopically. Once 72 hours pass after the onset of symptoms, inflammatory changes in the surrounding tissues are widely believed to render dissection planes more difficult. This may, in turn, increase the likelihood of conversion to an open procedure to 25%. Randomized

control trials have not borne out this 72-h cutoff and have shown no difference in morbidity. Interval LC after 4-6 weeks or percutaneous cholecystostomy are other options.[45]

Biliary dyskinesia should be considered in patients who present with biliary colic in the absence of gallstones, and a cholecystokinin–diisopropyl iminodiacetic acid (CCK-DISIDA) scanning should be obtained. The finding of a gallbladder ejection fraction < 35% at 20 minutes is considered abnormal and constitutes another indication for LC.[45]

**Contraindications**

Absolute contraindications include an inability to tolerate general anesthesia and uncontrolled coagulopathy. Patients with severe obstructive pulmonary disease or congestive heart failure (eg, cardiac ejection fraction < 20%) may not tolerate carbon dioxide pneumoperitoneum and may be better served with open cholecystectomy (OC) if cholecystectomy is absolutely necessary.

Gallbladder cancer must be considered a contraindication for laparoscopic cholecystectomy (LC). If gallbladder cancer is diagnosed intraoperatively, the operation must be converted to an open procedure. Theoretically, an open procedure allows a more controlled performance, with less chance of spillage; also, lymph nodes can be sampled intraoperatively to stage the disease.[46]

The conditions once felt to be contraindications to LC (eg, gangrenous gallbladder, empyema of the gallbladder, bilio-enteric fistulae, obesity, pregnancy, ventriculoperitoneal shunt, previous upper abdominal procedures, cirrhosis, coagulopathy) are no longer contraindications to the laparoscopic approach but

require special care and preparation of the patient by the surgeon and a careful evaluation of risk versus benefit. As surgeons have accumulated extensive experience with the laparoscopic technique, these contraindications have been discounted, and reports abound of successfully performed cases.[47,48]

**Complications**

Laparoscopic cholecystectomy (LC) remains an extremely safe procedure with a mortality rate of 0.22-0.4%. Major morbidity occurs in approximately 5% of patients.[49] Complications include the following:

<u>Trocar/Veress needle injury</u>

Intestinal injury may occur during establishment of abdominal access, adhesiolysis, or dissection of the gallbladder off of the duodenum or colon. An injury to the bowel should be repaired with careful 1- or 2-layer suture closure. The incidence of injury to viscera or vessels from a Hasson trocar or Veress needle is similar (in the range of 0.2%).[12]

<u>Hemorrhage</u>

Large-vessel vascular injury usually occurs at the time of initial abdominal access. These may be lethal complications. Development of a retroperitoneal hematoma or hypotension should be treated immediately by conversion to laparotomy.[12]

Excessive bleeding in the region of the triangle of Calot should *not* be treated laparoscopically. Attempts at blind clipping or cauterizing significant bleeding usually leads to worsening hemorrhage or hepatic artery injury. If, and only if, a

bleeding site can be *definitely* identified *and* the locations of both the hepatic artery and common bile duct (CBD) are known, bleeding may be controlled with electrocautery or clips.[12]

Bleeding in the gallbladder bed can usually be controlled by fulguration of the bleeding site. The authors prefer using a spatulated electrocautery wand for this purpose. If a larger intrahepatic sinus has been entered, hemostatic agents (eg, microfibrillar collagen) can be placed laparoscopically in the liver bed, and pressure can be held with a clamp. The argon plasma coagulator (APC) can be an excellent tool for severe gallbladder fossa oozing that is not responsive to simple electrocautery.[12]

Postcholecystectomy syndrome

This refers to a set of abdominal symptoms that occur with a frequency of up to 40% after cholecystectomy. Symptoms are often vague and include dyspepsia, flatulence, bloating, right upper quadrant pain, and epigastric pain. The most common causes of this syndrome are dietary indiscretion, retained CBD stones, inflammation of the cystic duct remnant, and sphincter of Oddi dysfunction.[50]

CBD injury or stricture

The most dreaded complication of LC is injury to the common bile or common hepatic duct. The estimated incidence of bile duct injury in cholecystectomies performed laparoscopically varies from 0.3-2.7%. In contrast, biliary tract injuries were noted to occur in 0.25-0.5% of open cholecystectomies. A major risk factor for bile duct injury is the experience of the surgeon.[51] Other risk

factors are the presence of aberrant biliary tree anatomy and the presence of local acute or chronic inflammation.[12]

Bile duct (common or hepatic) injury may manifest as bile leak (due to partial or complete bile duct transection leading to bile leakage into the peritoneum) or as biliary obstruction (which may be partial or complete and secondary to acute ductal ligation or chronic stricture formation).[12]

Bile duct injury may present as intraoperative: Injury is identified during index procedure; delayed presentation: Patients can present 3-7 days after surgery with fever, abdominal pain, anorexia, ileus, ascites, nausea, or jaundice; late-onset stricture may present months later with abdominal pain and jaundice.

The management of bile duct injury depends on degree of injury and the timing of identification.[12]

Intraoperatively: The injured duct should be repaired immediately. Depending on degree of injury, most CBD injuries can be primarily repaired over a T-tube.[52] Repair may require transfer to a specialized center

Postoperatively: Perform a CT scan to look for collections or ductal dilatation. Biliary scintigraphy using $^{99m}$ Tc-IDA or hepatobiliary iminodiacetic acid (HIDA) scan can be used to diagnose and sometimes localize the source of bile leakage. ERCP can be used both diagnostically and therapeutically.[12]

The treatment of bile duct injury can be summarized as CT-guided drainage of biloma followed by ERCP with sphincterotomy and stent placement is the treatment of choice for less severe lesions, such as minor lacerations of the common

bile duct, duct of Luschka leak, or displaced cystic duct clips. Lesions in the proximal biliary tree may be more amenable to percutaneous transhepatic approaches. Surgical biliary reconstruction may be necessary in cases of severe bile duct injury.[12]

Other complications include wound infection or abscess; ileus; gallstone spillage; deep vein thrombosis

Litigation

Litigation is much more common after LC than OC, for 2 apparent reasons. First, bile duct injuries (BDI) are more common with LC; second, missed intraoperative injuries may be more common in LC cases.[12]

The prevention of BDI include early conversion of LC to OC and the use of the critical view technique.

**Drain use in elective laparoscopic cholecystectomy**

Overall laparoscopic cholecystectomy provides a safe and effective treatment for patients with gallstones as it reduces post-operative pain with almost inadvisable scar, short hospital stay and earlier return to work.[4]

On the other side, many patients complain of abdominal pain, shoulder tip pain, and nausea/vomiting post-operatively. High pressure pneumoperitoneum using carbon dioxide gas was accused for those complications. The value of surgical drainage in open cholecystectomy is an issue that is not resolved till now. The same in laparoscopic cholecystectomy, where the lack of evidence on usefulness of drain is present. Again surgeons keep being divided among those placing a drain

selectively, and those who never place a drain, based on their personal experience, beliefs, or bias.[4]

Causes of collection

Many surgeons still continue drainage for reasons based on traditional teaching and anecdotal complications and not on reliable facts and figures. The major reason for drainage is the fear of bile leakage that may lead to bile peritonitis; this is usually due to an aberrant bile duct and not slippage of the cystic duct ligature. Slippage of cystic duct ligature is usually seen in cases of short cystic duct. Fear of blood collection requiring intervention is another reason for routine drainage after LC. Drainage also allows CO2 insufflation during laparoscopy to escape via the drain site, thereby decreasing the shoulder pain. Prevention of intra-abdominal collections after LC is the main reason of drainage. Situations where increased serous fluid may occur include extensive dissection from the bowel and omentum (which causes increased exudation) and excessive use of cautery.[53]

Fate of collection

The peritoneal cavity usually absorbs serous fluids rapidly, but blood and bile are absorbed more slowly. Postcholecystectomy collections in the subhepatic space are on the whole small, rapidly reabsorbed, and essentially similar in size and number whether a drain is used or not.[53]

Intraperitoneal collection of blood may cause postoperative pyrexia, prolong the hospital stay, and increase the incidence of wound infection, while the presence of bile in the peritoneal cavity produces peritoneal irritation. However, only some clinically significant abdominal collections may need intervention, while other

abdominal collections may not be clinically significant. An enlarging collection associated with persistent fever or worsening pain will suggest an abscess.[53]

Advantages

Traditionally, drains were used for the early detection of bile leaks and any unsuspected hemorrhage and to evacuate abdominal fluid collections without the need for more invasive procedures. When Lamgenebuch performed the first cholecystectomy in 1882, he placed a peritoneal drain as a part of the procedure. The routine placement of drains becomes a part of operation for a long period of time. However, controversy has surrounded this practice in elective conventional cholecystectomies, with most surgeons departing from this approach. Surgeons have routinely drained after laparoscopic cholecystectomy because of the fear of collection of bile or blood requiring open procedures.[54] Another reason for draining is to allow $CO_2$ insufflated during laparoscopy to escape via the drain site, thereby decreasing the shoulder pain. However, a Cochrane Database Systematic Review found no evidence to support the use of drains in laparoscopic cholecystectomy.[2]

Disadvantages

The disadvantages of drain include; ineffectiveness as they often get blocked; convert sterile collection to infected one; cause secretion of serous discharge; sometimes form intestinal fistula; cause more pain and drain fever syndrome a complication described by Myers in 1962 in which fever and pain appear in the right upper quadrant for atleast 48 hours after surgery, has been attributed to manipulation of the drain, the clinical manifestations of the syndrome subside after its removal.[55]

The drain may also give false sense of security as it may get blocked and the patient continue to bleed internally and later presenting with signs of shock, as reported in one study.[56] A study reported laparotomy for postcholecystectomy bile peritonitis in patients who had drains placed, suggesting that drain placement does not guarantee prevention of this complication.[57]

It is assumed that the use of a drain might be helpful for early detection of postoperative bleeding. However, significant bleeding can also be easily detected by clinical and ultrasonographic signs of intra-abdominal hemorrhage in the event that there is no drain.[57]

If there is doubt as to the significance of the collection, the ultrasonographic study can be repeated in a few days. An enlarging collection associated with persistent fever or worsening pain will suggest an abscess.[58]

However, one cannot eliminate the possibility that the drain, acting as a foreign body, stimulates the formation of this fluid. Whatever the mechanism, the result is a fluid accumulation, most probably serous, adjacent to a drain.[58]

The drain may prove dangerous after simple cholecystectomy as infection introduced along a drain may render an otherwise harmless collection of bile a cause of peritonitis.[53]

Also drain may rapidly becomes walled off, and then merely provokes an exudate in response to its own presence.[59] Even if complications do occur in non-drain cases, minimally invasive interventions such as percutanenous and/or endoscopic techniques can be applied to solve the problem according to minimally invasive principles.[58] It would be reasonable, however, to leave a drain if there is a

worry about an unsolved or potential bile leak, that is, imperfect closure of the cystic duct or bile staining in the lavage fluid or gallbladder bed, suggesting the possibility that an accessory duct has been missed. In these cases, a drain can be selectively used, bearing in mind that drain placement, although sometimes providing a false sense of security, guarantees neither prevention nor treatment of postoperative bile or blood collections.[58]

The advantages of not inserting a drain are reduction of hospital stay, patient comfort, and lower incidence of postoperative complications.[53]

Gurusamy et al.[5] reported lower wound infection rate in the no drain group than in the drain group, maybe because of the presence of a foreign body.

Johansson et al.[60] safely performed day-case LC with low rates of re-admissions. However, the insertion of drain can delay the discharge and, thus, decrease any saving in costs of day-case LC.

Further, drain-related pain may negate one of the most important advantages of the laparoscopic approach, that is, less pain.[58] Postoperative pain and postoperative nausea/ vomiting are important problems after a procedure that is designed for minimal discomfort. In fact, these are the most common cause of delayed discharge after laparoscopic procedures.[61]

Carbonic acid that results from CO2 insufflations and gas that separates the liver fromthe diaphragmcausing the stretch of the attachments of the liver result in the postoperative pain, especially shoulder tip pain.[62]

Nursal et al.[61] found subdiaphragmatic drain effective in reducing the incidence and the amount of subdiaphragmatic gas bubble. Another study in which residual gas was removed by active aspiration through the trocars rather than drains documented a decrease in opioid use, but not in VAS scores.[63] Another study used irrigation with relatively large amounts of saline, which presumably replaced the subdiaphragmatic gas and finally absorbed, and this proved effective in reducing pain.[64]

In a study, subdiaphragmatic gas volume was significantly lower in group A patients than in group B and C patients. Both active aspiration of CO2 through the trocar as well as saline lavage and suction had been used more efficiently during phase II, resulting in lesser subdiaphragmatic gas volume. This greatly reduces postoperative nausea/vomiting and shoulder tip pain from 18.99% (group A) and 17.11% (group B) to 5.96% in group C. Gurusamy et al.[5] in a metaanalysis reported decreased early postoperative shoulder pain in the drain group, that was not significant and reversed in the later postoperative period. This would not suggest that drainage of residual CO2 or peritoneal fluid is of value in reducing the pain of LC [16]. They also noted lower nausea rate in the drain group compared with the no drain group.[2]

Gurusamy et al.[5] noted that drain use after open or LC increases the wound infection, but chest complications occurred only in open cholecystectomy.[2]

One study of open cholecystectomy reported wound infection at 1.6% for non-drained cases and 8.4% for drained cases, with chest infection in 31% of cases

and the great majority of these were in the group that had been drained (21 of the 22 cases).[65]

A similar study showed wound infection was comparable in both groups occurring in 1.27% cases in drained group and 1.36% in non-drained groups, but chest infection occurred in 3.80% in drained group and 1.02% in non-drained groups. It would seem that the presence of the drain and the extra pain resulting cause a splintage of the lower right chest and predispose to atelectasis and chest infection. They also reported reoperation for collections more common after drainage, as well as the drain fever on removing or manipulating a drain that has been in situ for more than 48 h.[65]

Finally, the timing of randomization is important in evaluation of these studies. If the randomization was performed toward the end of the surgery (after the gallbladder dissection and hemostasis is complete), the dropouts and crossovers can be kept to a minimum. For example, a surgeon may obtain meticulous hemostasis if he knew that the patient was randomized to the 'no drain' group.[2]

# METHODOLOGY

This study was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period one year from January 2013 to December 2013.

**Study design**

The study design was a randomized controlled trial.

**Study period and duration**

This study was a one year randomized controlled trial was carried out from January 2013 to December 2013.

**Place**

The present study was done in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum a tertiacy care teaching hospital attached to KLE University's Jawaharlal Nehru Medical College, Belgaum.

**Source of Data**

Patients scheduled for elective cholecystectomy under the Department of General Surgery were studied.

**Sample size**

A total of 60 patients divided into two groups of 30 each were included.

**Sampling procedure**

As the effect size was not available, the sample size was considered as 60 with 30 in each group.

**Selection criteria**

Inclusion

- Patients scheduled for elective cholecystectomy.

Exclusion

- Patients with acute cholecystitis, cholingitis, pancreatitis.
- Patients requiring CBD exploration or any other procedure.
- Difficult laparoscopic cholecystectomy.

**Ethical clearance**

Prior to the commencement, the study was approved from the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belgaum.

**Informed Consent**

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

**Randomization**

Based on closed envelope method, the patients were randomly allocated into two groups. Patients were asked to pick an opaque brown concealed envelop which

furnished the information regarding the choice of drain. Based on the option picked up, the patients were divided into two groups of 30 each as below;

- Group D: Patients who selected drain formed group D.
- Group ND: Those patients who selected no drain formed group ND.

**Method of collection of data**

Demographic data such as age, sex and presenting complaints were recorded. These findings were noted on a predesigned and pretested proforma (Annexure II).

**Procedure**

Under general anesthesia, the abdomen was insufflated with CO2 after the introduction of the first 10 mm trocar with the Hasson technique through an infraumbilical incision. The other 10-mm and two 5-mm trocars were inserted through appropriate sub-xiphoid, subcostal midclavicular, and subcostal anterior axillary incisions. The pneumoperitoneum pressure was set at 12 mm Hg. A standard cholecystectomy with isolation and section between 10-mm clips of cystic duct and artery was always performed. The gallbladder was retrieved through the umbilical port. The duration of the operation (from infraumbilical skin incision to pulling off the trocars), bile spillage, and additional complications also were recorded.

After gallbladder removal, among the patients with group D, drain was inserted and in patients with group ND drain was not inserted. A 14 number suction drain was inserted from most lateral 5-mm trocar. In group D, after the surgeon inserted the drain and it was fixed to the skin with suture.

The surgeries were performed by surgeons of similar experience and expertise. Same analgesics were used for all patients for the first 24 hours.

**Outcome variables**

Presence of collection and bleeding

An abdominal ultrasonography was routinely performed on the first postoperative day with the goal to detect any fluid collection. If present, the volume of subhepatic collection was calculated. The drain was removed 24 h after surgery, unless there was bile (any amount) or 100 mL of blood in the drain. In case the drain had to stay in place for bile leak, it was not removed, unless the leak had completely ceased. In case the drain had to stay in place for bleeding, it was removed when the amount was less than 100 mL/24 h and the patient was hemodynamically stable with stable hemoglobin (no decrease[1 g/dL).

Outcome variables

Pain was assessed based on Visual Analogue Score ranging from 0 to 10 considering 0 as no pain and 10 as maximum pain taken 24 hours after surgery.

**Statistical analysis**

The data obtained was coded and entered in Microsoft Excel Spreadsheet. The categorical data was expressed as rates, ratios and percentages and comparison was done using chi-square test. Continuous data was expressed as mean ± standard deviation and the comparison was done using independent sample t test. A ‘p’ value of less than or equal to 0.05 at 95% CI was considered as statistically significant.

# RESULTS

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2013 to December 2013.

A total of 60 patients scheduled for elective cholecystectomy were studied. These patients were further randomized into two groups of 30 each as below;

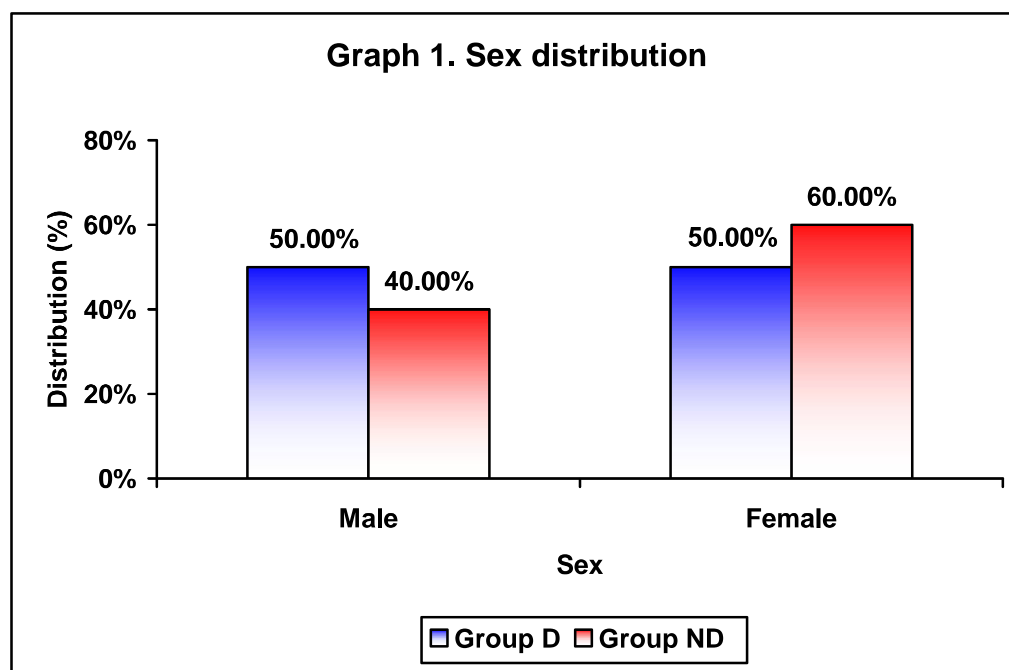
- Group D (n=30): Patients underwent cholecystectomy with drain.
- Group ND (n=30): Patients underwent cholecystectomy without drain.

The data obtained was coded and entered in Microsoft Excel Spreadsheet. Categorical data was expressed as rates, ratios and percentages and comparison was done using chi-square test. Continuous data was expressed as mean ± standard deviation and the comparison was done using independent sample t test. A ‘p’ value of less than or equal to 0.05 at 95% CI was considered as statistically significant. The data was analysed and the observations were tabulated as below.

**Table 1. Sex distribution**

| Groups | Group D (n=30) | | Group ND (n=30) | |
|---|---|---|---|---|
| | Number | Percentage | Number | Percentage |
| Male | 15 | 50.00 | 12 | 40.00 |
| Female | 15 | 50.00 | 18 | 60.00 |
| **Total** | **30** | **100.00** | **30** | **100.00** |

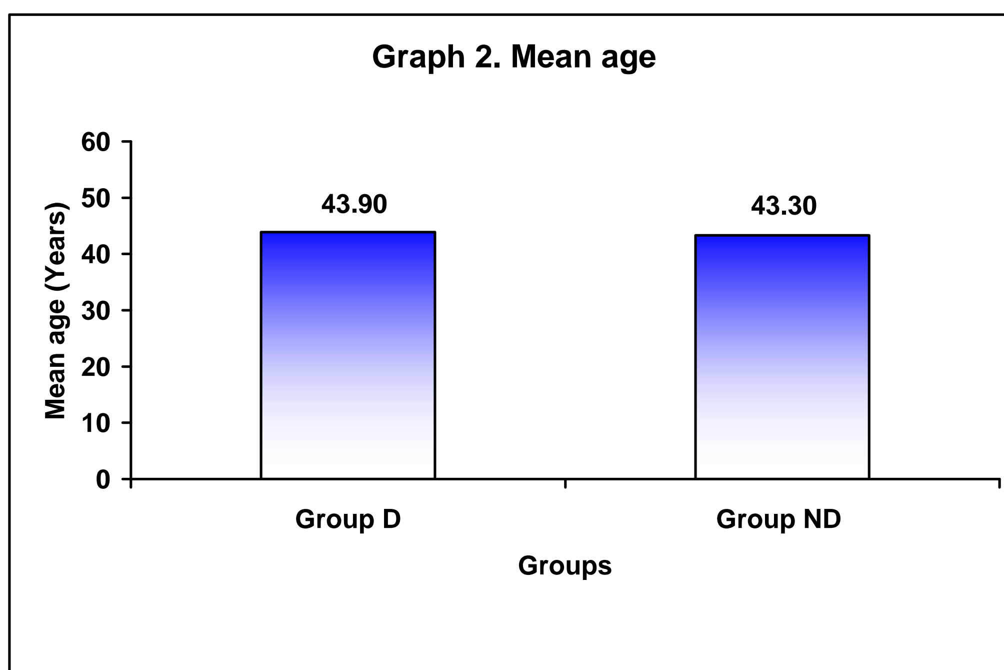
**p=0.436**




In the present study 50% of patients in group D and 40% of the patients in group ND were females. The male to female ratio in group D was 1:1 and in group ND it was 1:1.5. However the sex distribution in group D and ND was comparable (p=0.436)

**Table 2. Mean age**

| Variables | Group D (n=30) | | Group ND (n=30) | | p value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| Age (Years) | 43.9 | 14.06 | 43.3 | 15.85 | 0.181 |



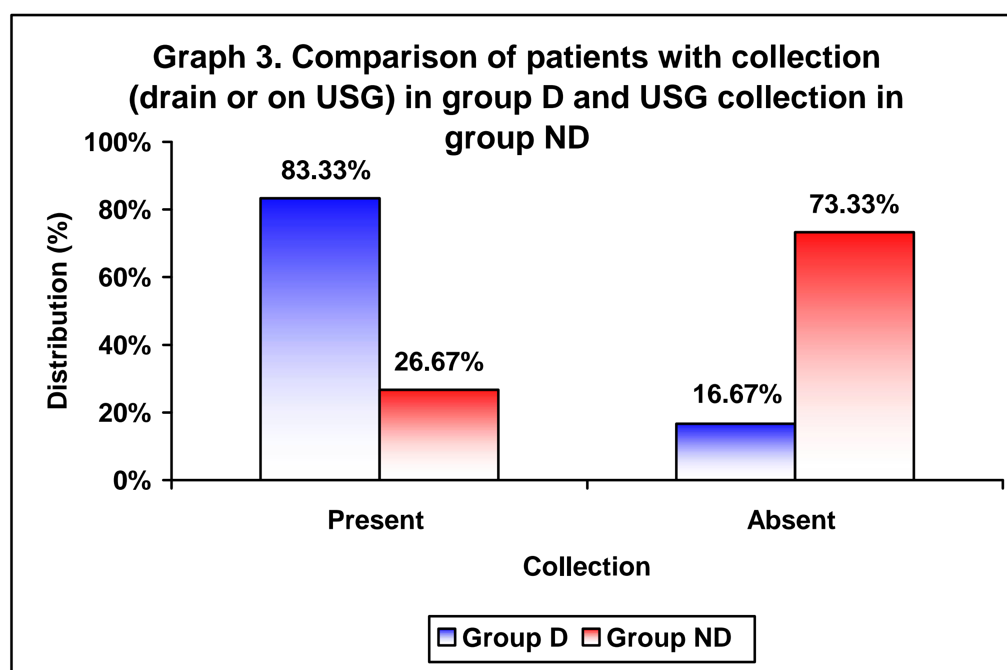

In the present study, the mean age in group D was 43.90 ± 14.06 years compared to 43.30 ± 15.85 years in group ND. However the difference was statistically not significant (p=0.181).

In this study the drain volume was found to be 3.06 ± 2.94 mL in a total of 25 numbers of patients.

**Table 3. Comparison of patients with collection (drain or on USG) in group D and USG collection in group ND**

| Collection | Group D (n=30) | | Group ND (n=30) | |
|---|---|---|---|---|
| | Number | Percentage | Number | Percentage |
| Present | 25 | 83.33 | 8 | 26.67 |
| Absent | 5 | 16.67 | 22 | 73.33 |
| **Total** | **30** | **100.00** | **30** | **100.00** |

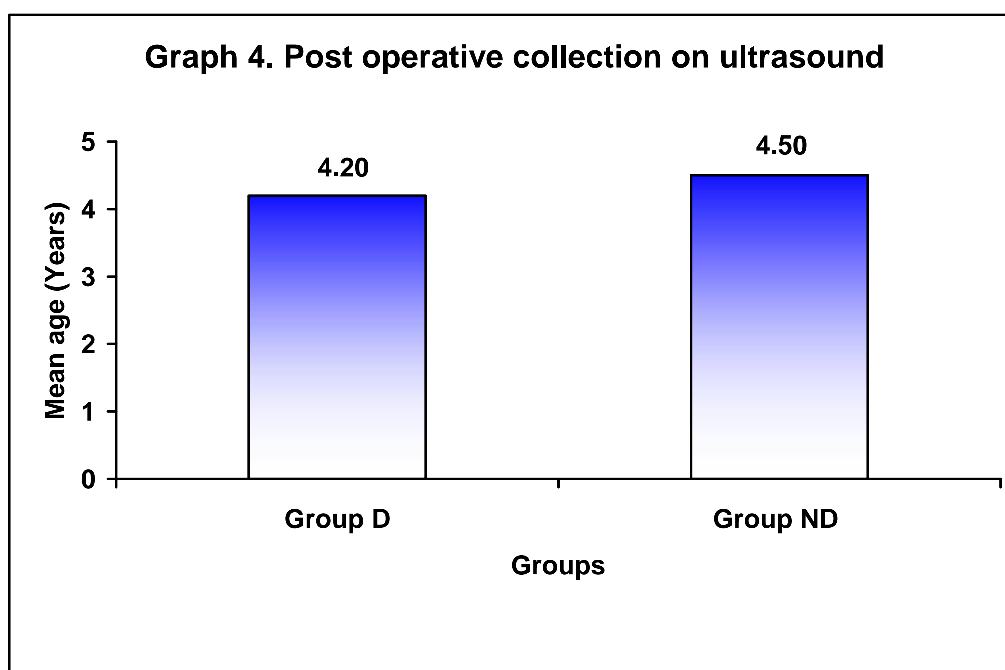
**p<0.001**




In the present study significantly higher number of patients had collection in either drain or on USG in group D (83.33%) compared to group ND that is collection on USG (26.67%) (p<0.001)

**Table 4. Post operative collection on ultrasound**

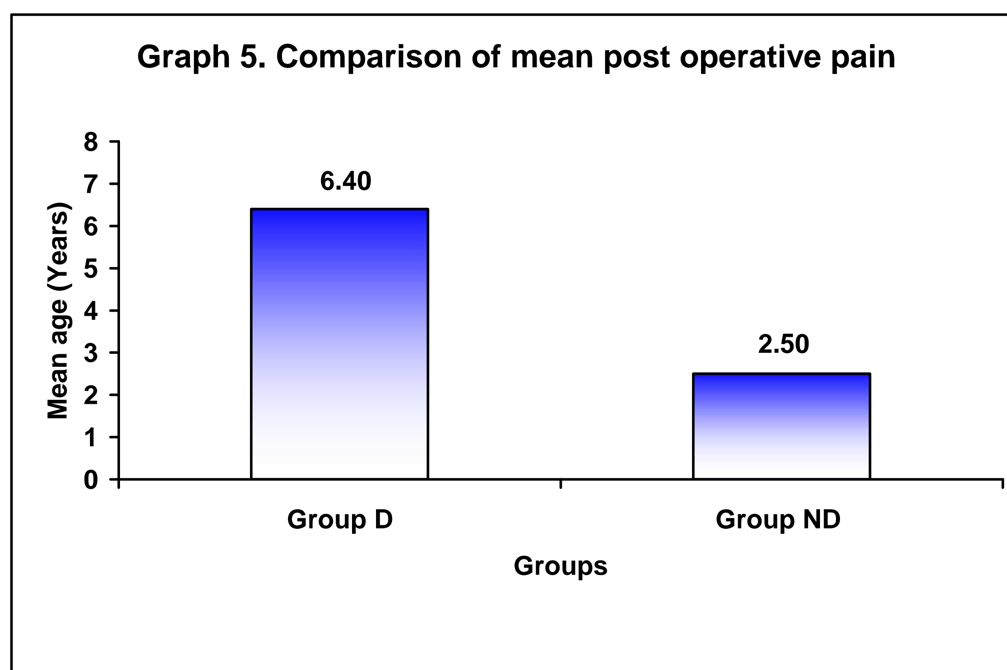
| Variables | Group D (n=15) | | Group ND (n=8) | | p value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| Collection | 4.20 | 1.90 | 4.50 | 1.92 | 0.783 |




In the present study, the mean post operative collection on ultrasound was comparable in both the groups (4.20 ± 1.90 mL vs 4.50 ± 1.92 mL; p=0.181).

**Table 5. Comparison of mean post operative pain**

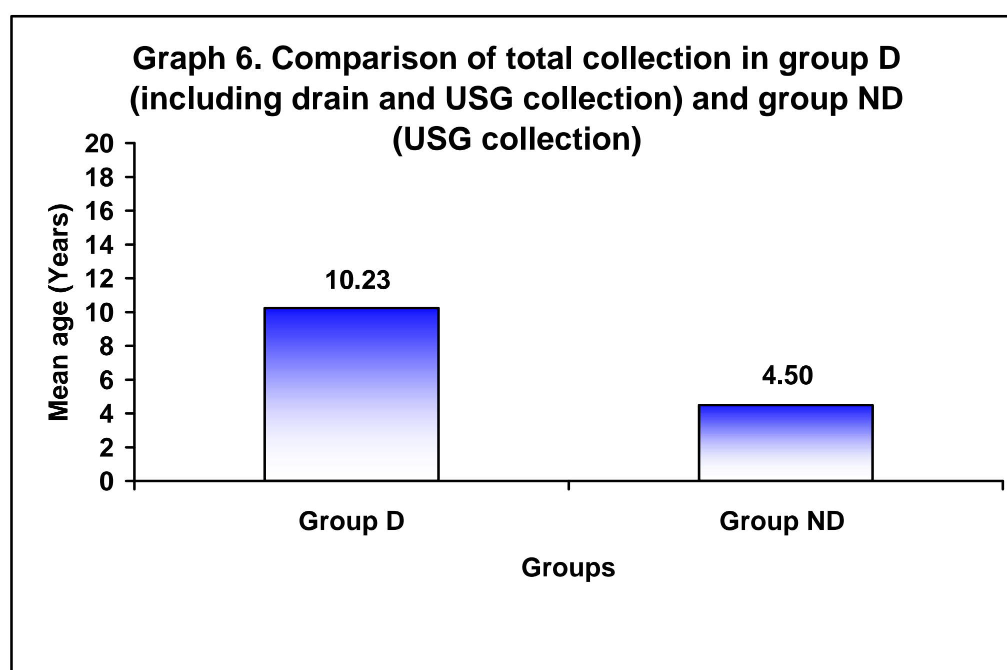
| Variables | Group D (n=15) | | Group ND (n=8) | | p value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| Pain | 6.40 | 1.83 | 2.50 | 1.31 | <0.001 |



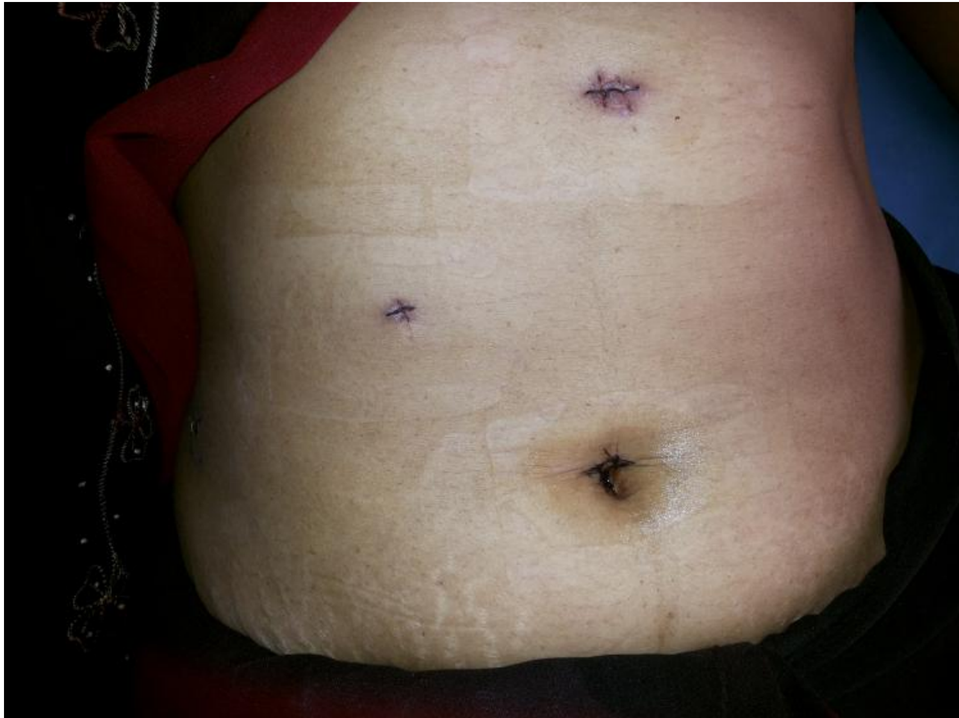

In the present study, the mean post pain score were significantly high in group D (6.40 ± 1.83) compared group ND (2.50 ± 1.31) ($p<0.001$).

**Table 6. Comparison of mean total collection in group D (including drain and USG collection) and group ND (USG collection)**

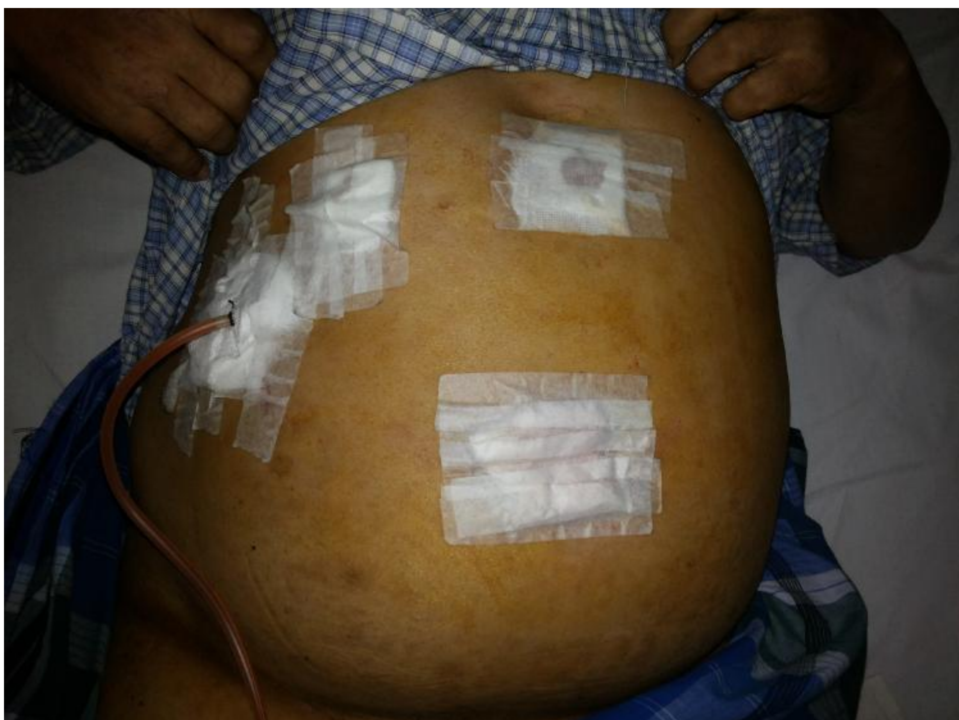
| Variables | Group D (n=25) | | Group ND (n=8) | | p value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| Collection (mL) | 10.23 | 5.40 | 4.50 | 1.92 | <0.001 |



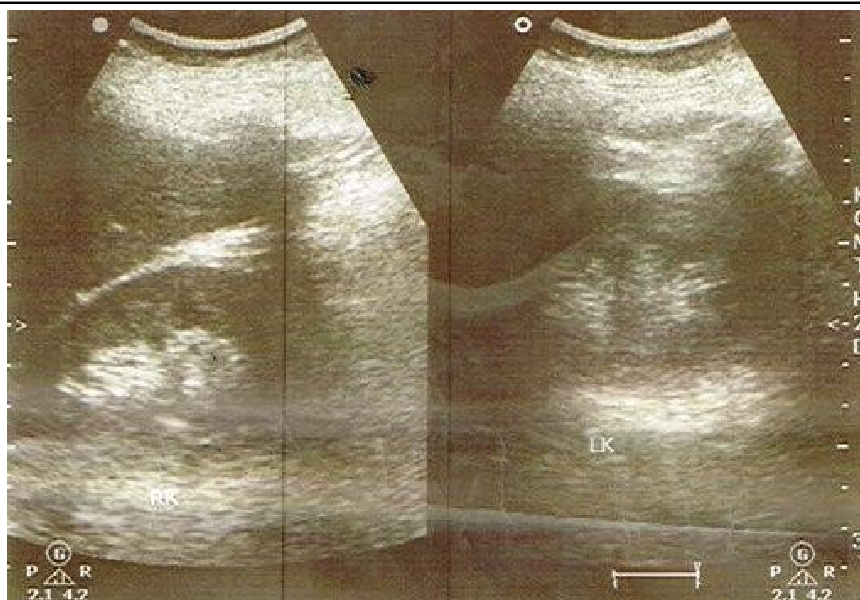

In the present study, the mean total collection in group D including drain collection and USG collection was significantly high (10.23 ± 5.40 mL) compared to mean collection on USG in group ND (4.50 ± 1.92 mL) ($p<0.001$).



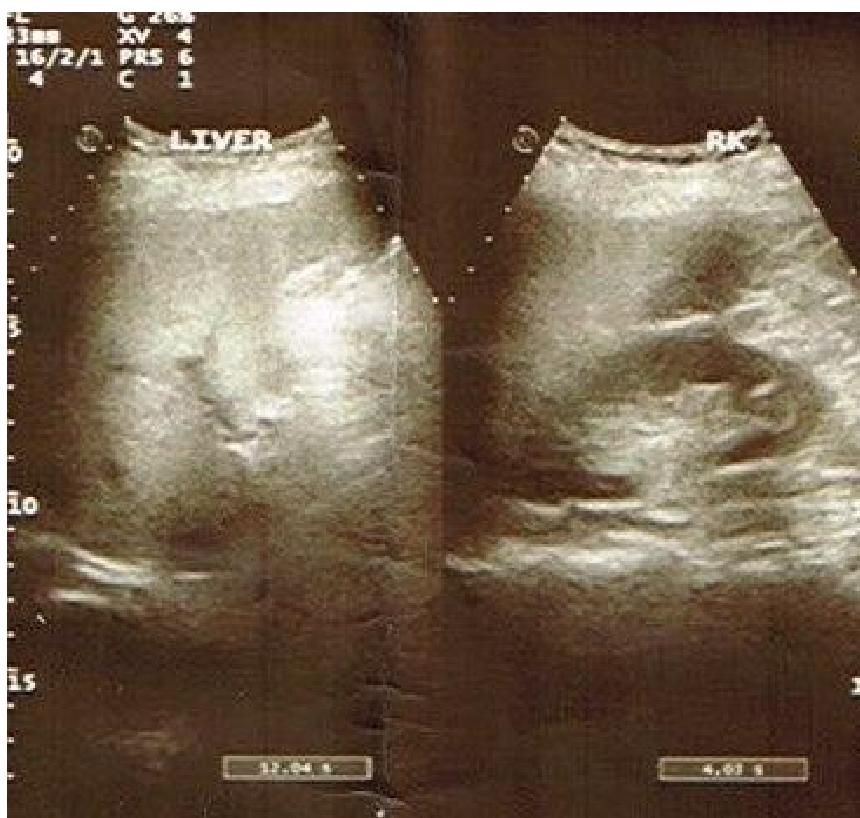
**Photograph 1. Post operative photograph showing patient of no drain group**



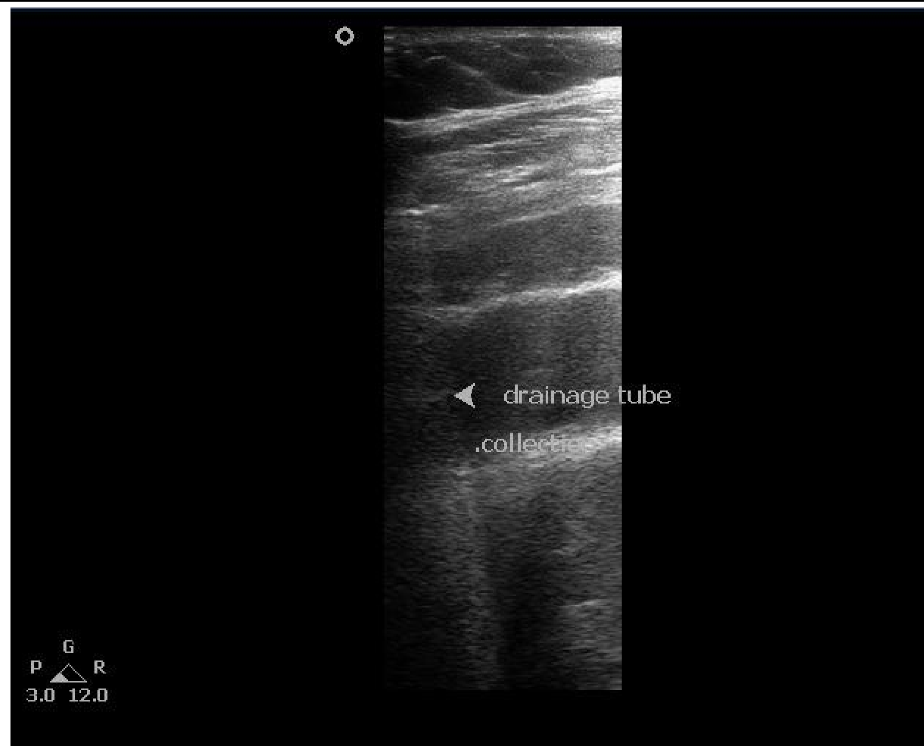
**Photograph 2. Post operative photograph showing patient of drain group**



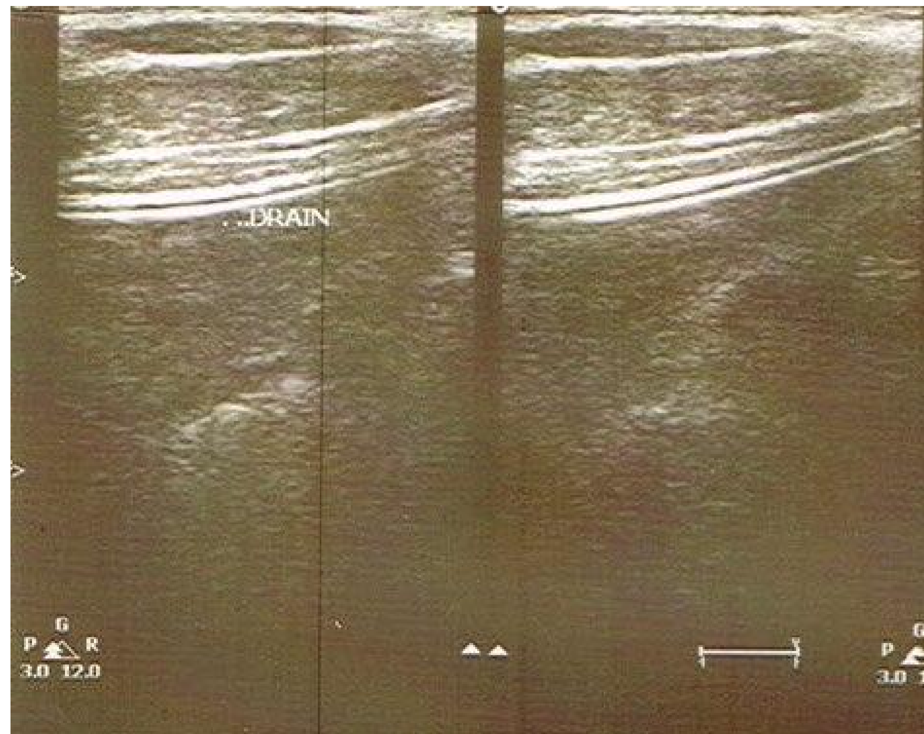

**Photograph 3. USG showing no collection in no drain group**




**Photograph 4. USG showing collection in no drain group**




**Photograph 5. USG showing drain in situ with collection**




**Photograph 6. USG showing drain with no collection**

# DISCUSSION

Today, laparoscopic cholecystectomy is the method of choice for the management of symptomatic gall stones.[30] Laparoscopic cholecystectomy has replaced open surgery in the treatment of cholelithiasis. However, peritoneal drainage after cholecystectomy has long remained an essential component of procedure, since its introduction in 1821.[6]

The benefits of drains derive from the notion that they allow the egress of bile leaking from the gallbladder bed, cystic duct or damaged bile duct, as well the blood or exudates resulting from surgical trauma. Even if they do not drain these fluids completely, they do warn the surgeons of such leakage and prompt for early and necessary steps to deal with complications. Another reason for draining is to allow Co2 insufflated during laproscopy to escape via the drain site, thereby decreasing the shoulder pain.[7]

On the contrary it is true that small amounts of fluids are effectively absorbed by the peritoneum, while leakage of large amounts, sufficient to be of any clinical significance is uncommon, and if it happens, the drain is sometimes found ineffective as it often gets blocked by an omental plug or a blood clot. Furthermore, the drain converts a sterile collection into an infected one, cause secretion of serous fluid, and at times leads to an intestinal fistula.[7]

In the early years of laparoscopic cholecystectomy most of the surgeons routinely retained a drain in the subhepatic space, but with gradual acceptance of the technique and increasing experience, many of the surgeons tailored the results of

randomized trials in open cholecystectomy to laparoscopic one, and omitted draining the area routinely.[11]

Still, surgeons are divided on the routine use of drains. Some place a drain selectively, some place a drain routinely and others never place a drain, based on personal experience, belief or bias. Hence the present study was an attempt to compare the drain versus no drain in elective laparoscopic cholecystectomy in terms of effectiveness and post operative pain.

This one year randomized controlled trial was carried out on a total of 60 patients scheduled for elective cholecystectomy under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2013 to December 2013. Based on closed envelope method patients were further randomized into two groups of 30 each that is, Group D (n=30) where patients underwent cholecystectomy with drain and Group ND (n=30) in which patients underwent cholecystectomy without drain.

In the present study among the patients with group D, equal proportion of patients were males and females that is, 50% each with male to female ratio of 1:1 while in group ND, 40% of the patients were males compared to 60% females with male to female ratio of 1:1.5. Despite this, sex distribution in group D and ND was comparable (p=0.436). In contrast a similar study from North India reported male to female ratio of 1:3.5 in drain and 1:4 in no drain group.[66] Several other studies have reported the male to female ratio of 1:3.[11]

In this study, the mean age in group D and ND was comparable that is, 43.90 ± 14.06 versus 43.30 ± 15.85 years respectively (p=0.181). A similar study by

Picchio M et al also reported the mean age as 48.6 years in patients with drain and 47.1 years in patients without drain. In contrast, a study from North India reported the average age of 36.25 years in drain and 37.90 in no drain group.

The sex distribution pattern and mean age of the patients in group D and ND suggest that both the groups were comparable in terms of demographic characteristics.

In the present study 83.33% of the patient in group D had collection in either drain or on USG or both whereas in group ND collection on USG was noted in 26.67% of the patients. This difference was statistically significant ($p<0.001$). This is probably due to fact that the drain, acts as a foreign body and stimulates the formation of fluid. Whatever the mechanism, the result is a fluid accumulation, mostly serous, adjacent to the drain.[58]

In this study, among the patients with drain, fluid was found in the drain among 25 patients and the mean volume was found to be 3.06±2.94 mL. The mean post operative collection on ultrasound in group D was 4.20 ± 1.90 mL (seen in 15 patients) and in group ND it was 4.50 ± 1.92 mL (Seen in 8 patients). However this difference was statistically not significant ($p=0.181$). The maximum fluid present in patient with drain was 15 mL and maximum collection seen on USG was 18 mL (incidentally it was seen in the same patient) in group D. The maximum collection seen in group ND was 8 mL and minimum collection was 2 mL.

Further, the mean collection in the drain in group D was 3.06 ± 2.89 mL and post operative collection on USG was found to be 4.26 ± 1.90 mL with a mean

difference of 1.20 ± 3.05 mL. This showed incomplete drainage despite using drain in after elective cholecystectomy (p=0.150).

In this study, among the patients in group D, the mean total collection including drain and on USG was significantly high compared to mean collection on USG in group ND (10.23 ± 5.40 mL vs 4.50 ± 1.92 mL; p<0.001).

Prophylactic drainage of peritoneal cavity after different operations has been a routine practice for years, based on traditions and habits, rather than any scientific evidence, with a view to watch postoperative bleeding, anastomotic, biliary or pancreatic leakage. However, recent reports have not only disputed their benefit after a range of intra-abdominal operations, but have also claimed the drains to be associated with a number of complications, including intra-abdominal and wound infection, increased abdominal pain, decreased pulmonary function, and prolonged hospital stay.[68-70]

Likewise, subhepatic space has been drained conventionally after cholecystectomy, with its efficacy been rarely evaluated in trials11. When the gallbladder bed can be obliterated completely, the use of drain in the absence of any suppurative process or bleeding seems to be unnecessary. The studies conducted in this regard in open cholecystectomy have shown that the routine drainage is not only unnecessary but It also associated with increased morbidity and prolonged hospital stay.[71,72]

The drain itself may cause minimal pain at drain site and more pain during its removal. If drainage is minimal it can be removed next day and patient discharged. However if the drainage is more than usual and is blood or bile, then the

drain has to be retained. If there is no drain and there is clinical picture of intra abdominal collection and the patient will not be discharged. The placing of drain itself does not cause prolonged stay. Its placement is prophylactic and for early recognition of complication.[11]

In this study none of the cases presented with fever (drain fever syndrome) which may be attributed to early removal of drain.

In 1913, 31 years after Langenbuch performed the first cholecystectomy, Spivak introduced the technique of un-drained ideal cholecystectomy. Since then many investigators have advocated omission of drainage after cholecystectomy. These reports describe a lower incidence of postoperative morbidity, decreased hospital stay, easier convalescence and less discomfort.[72] Most surgeons routinely place drain at sub-hepatic space after open cholecystectomy which is not scientifically proved. Mostly drains are advocated in empyema and gangrene of gall bladder, CBD exploration, incomplete haemostasis, anticipated biliary leak, abscess formation, and difficult cholecystectomy.[73]

The major reason for drained cholecystectomy is the fear of bile leakage leading to sub hepatic collection/abscess, peritonitis, intra-abdominal haemorrhage and Watmann Walter's Syndrome. Many cases have been reported where surgical drains failed to prevent these complications.[74]

The belief that surgical drains serve as an early warning of bile leakage, impending bile peritonitis, or intraabdominal haemorrhage is also disputed. Many cases have been reported where bile peritonitis has occurred weeks after open

cholecystectomies with drainage. Hence truly stated by Frederick Coller 'bile is not educated to climb drains.[75]

In this study, the mean post operative pain scores were significantly high in group D (6.40 ± 1.83) compared group ND (2.50 ± 1.31) ($p<0.001$). The effect of subhepatic drain on postoperative pain is controversial. Significant reduction of postoperative pain in patient without drain insertion with respect to those with subhepatic drains was reported in the trial of Tzovaras et al.[57] Uchiyama et al,[76] also found that the mean VAS scores were significantly greater in drain group than in non drain group at 24 and 48 h especially in women. On the contrary, the study of Hawasli et al.[54] failed to find any difference. Jorgensen et al.[77] showed that the use of a suction drain in LC decreases shoulder pain by allowing carbon dioxide gas to escape with respect to passive drain. Tzovaras et al.,[57] suggested that the routine use of a drain in elective laparoscopic cholecystectomy has nothing to offer and it is associated with increased pain. More recently a study from Pakistan also was unable to prove that suction drain has any effect on either abdominal or shoulder tip pain after LC.[53]

Hawasli and Brown[54] found that there were minor but not statistically significant differences between drain group and non drain group in terms of postoperative severity and duration of the abdominal pain and shoulder pain. However, Uchiayama et al.[76] found that the mean VAS scores were significantly greater in drain group than in non drain group at 24 and 48 h especially in women. On the contrary, Tzovaras et al[57] suggested that the routine use of a drain in elective laparoscopic cholecystectomy has nothing to offer and it is associated with increased pain.

Overall, based on these results the use of drain may not be favourable considering the increase of post operative pain and also no statistically significant difference in terms of post-operative subhepatic fluid collection. Surprisingly the drain itself may be a source of collection.

Ashraf and colleagues conducted a study on 75 patients who were studied ultrasonographically for post cholecystectomy fluid collection.[78] Drain was not used in 47 (62.6 percent) patient where gall bladder bed was dry, no spillage of gall bladder content occurred, and where there were no excessive adhesions. In 28 patients who did not fulfill this criteria a passive closed tube drain was put. Ultrasonography was done after 24 hours in each patient to find out the collection of fluid. Out of 75 patients, 41 (54.6%) had minimal or no collection of fluid (without drain 59.5 percent and with drain 46.4%). 44% patients had less than 10ml collection (without drain 40.4 percent and with drain 53.5%). Only one patient of drained group had 14ml collection (3.5%). From this study they concluded that drain should not be used routinely and at the same time it should not be withheld if the surgeon feels it necessary.

In conclusion, the present study was unable to prove that the drain was useful in elective, uncomplicated LC without acute cholecystitis, cholangitis, or pancreatitis and no significant intraoperative morbidity.

# CONCLUSION

Based on the findings of this study it may be concluded that there is no statistically significant difference in post operative sub hepatic collection with and without drain. Further, use drain significantly increases post operative pain. Hence placing of drain as routine after elective cholecystectomy has no advantage, therefore it should be avoided.

# SUMMARY

Laparoscopic cholecystectomy is a safe and effective treatment for patients with gallstones. However, the routine use of drain after laparoscopic cholecystectomy is controversial. The present study was designed to compare drain versus no drain in elective laparoscopic cholecystectomy in terms of morbidity and post operative pain.

The present one year randomized controlled trial was done from January 2013 to December 2013. A total of 60 patients undergoing elective cholecystectomy under the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum were studied. Based on closed envelope method patients were randomized into two groups of 30 each that is, Group D (with drain) and Group ND (without drain). Assessment of pain was done based on VAS scores.

In group D and group ND, 50% and 40% of the patients were females with male to female ratio of 1:1 and 1:1.5 respectively ($p=0.436$). The mean age in group D was $43.90 \pm 14.06$ years compared to $43.30 \pm 15.85$ years in group ND ($p=0.181$). The drain volume was found to be $3.06 \pm 2.94$ mL in a total of 25 numbers of patients. In group D, higher number of patients (83.33%) had collection in either drain or on USG compared to group ND (26.67%) ($p<0.001$). The mean post operative collection on ultrasound was comparable in both the groups ($4.20 \pm 1.90$ mL vs $4.50 \pm 1.92$ mL; $p=0.181$). The mean pain scores were high in group D ($6.40 \pm 1.83$) compared group ND ($2.50 \pm 1.31$) ($p<0.001$). In group D, mean total collection including drain collection and USG collection was significantly high

(10.23 ± 5.40 mL) compared to mean collection on USG in group ND (4.50 ± 1.92 mL) ($p<0.001$).

Placement of drain in peritoneal cavity following elective laparoscopic cholecystectomy did not have any advantages. Adversely it caused increase in severity of post operative pain.

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# ANNEXURE I – CONSENT FORM

**Title of research study: A randomized control trial to compare drain vs no drain in elective laparoscopic cholecystectomy.**

Principal Investigator
Dr **** ******
PROFESSOR AND HEAD
DEPARTMENT OF GENERAL SURGERY
JNMC, BELGAUM

Co investigator
DR ****** **********
PG STUDENT
DEPARTMENT OF
GENERAL SURGERY,
JNMC, BELGAUM

**INTRODUCTION AND PURPOSE**: You are requested to participate in a study that is an attempt to compare the role of drain vs no drain in elective laparoscopic cholecystectomy.

This study will be conducted by Dr. ***** *******, Post graduate in department of General surgery, under the direct supervision and guidance of Dr ***, ****** Professor and Head, Department of Surgery, JNMC, Belgaum.

You need to be eligible, meeting all the selection criteria to participate in this study. You should be willing to provide information about yourself. 60 subjects will be enrolled in this study who will then be randomized in either of 2 groups (details below).The randomization will be according to closed envelope method.

**PROCEDURE**: Depending on your group, either a drain will be inserted intra operatively or no drain will be inserted. On the 1$^{st}$ post operative day, an Ultrasound of the Abdomen will be done (of all subjects of both groups) to look for any collection. Also the post operative pain will be assessed of all subjects (of both groups) using the visual analogue scale on the 1$^{st}$ post operative day.

**BENEFITS**: The study will help us to compare the efficacy of drain in patients under going elective cholecystectomy to that of no drain at all. The results derived at the end of the study will benefit all similar patients admitted in this hospital. The benefits may be better drainage of abdominal fluid.

**RISK INVOLVED:** There is no increased risk involved in becoming a part of the study and the complications are those which are normally anticipated**.** The risks involved are infection, pain.

**VOLUNTARY PARTICIPATION/WITHDRAWAL:** Taking part in this study is voluntary; you may choose not to enroll in this study. Your decision will not change the present or future health care services offered to you at KLES Dr. Prabhakar Hospital, Belgaum. The alternative that you have is to undergo the traditional procedure that is carried out in KLES Hospital.

**COMPENSATION**: In the event that you become injured as a result of taking part in this study, treatment will be offered to you or you will be given information about where to receive medical care: but you/your insurance company will be responsible for the costs. No reimbursement, compensation or free medical care will be given.

**CONFIDENTIALITY:** Every effort will be made to protect the confidentiality of the information you provide. This means that the researchers will not let anyone, not a part of the study, see the information you provide. Only Dr. **** ******** and Dr. ****** ******* will have access to the information collected. Results of this study may be published but your name will not be revealed.

In case of any queries, you can contact the following

**Dr.** ***** ********
Post graduate student,
Department of General Surgery
J. N. Medical College,
KLE University, Belgaum
(Mobile NO-***** *****)

**Dr.** ****** ******
Professor and Head,
Department of General surgery,
J. N. Medical College,
KLE University, Belgaum
Mobile-***** *******

**Dr** ****** ******
Chairman, College Ethical Dissertation and Research Committee,
J. N. Medical College
KLE University, Belgaum
Mobile-**** *******

**CONSENT TO PARTICIPATE IN THE STUDY**

I voluntarily agree to participate in this study by signing up this form below. I may withdraw at any time from this study. I am not giving any of my legal rights by signing up this form. My signature / thumb impression below indicates that I have read or information in the consent been read to me including the risks and benefits and have cleared my doubts. I will be given a copy of this consent form.

Signature of the study patient:

Name of the study patient:

Signature of the legally authorized representative:

Relationship to the patient:

Signature of the witness:

Signature of the investigator:

Date:

# ANNEXURE II – PROFORMA

**Title: A randomized control trial to compare drain vs no drain in elective laparoscopic cholecystectomy**

| | | |
|---|---|---|
| Name and Address | : | Age : |
| Sex | : | IP No. : |
| Education | : | Religion: |
| Marital Status | : | Occupation: |

Socio-Economic Status:

**<u>HISTORY</u>**

CHIEF COMPLAINTS

1.

2.

3.

**<u>GENERAL PHYSICAL EXAMINATION</u>**:

Built and Nourishment:

Weight:

Pallor / Icterus / Cyanosis / Clubbing / Edema / Lymphadenopathy:

Vital Signs: PR: BP: RR: Temp:

**<u>SYSTEMIC EXAMINATION</u>**:

Per Abdomen:

Respiratory System:

Central Nervous System:

Cardio-Vascular System:

**INVESTIGATIONS:**

**OPERATIVE PROCEDURE**

**INTRA OPERATIVE FINDINGS**

**POST OPERATIVE ASSESMENT**

**1) USG ABDOMEN AND PELVIS 1$^{ST}$ POST OPERATIVE DAY FINDINGS (AND AMOUNT OF ABDOMINAL COLLECTION)**

**2) EVALUATION OF PAIN 24 HOURS AFTER SURGERY**

Pain will be assessed by visual analogue score (VAS) using a 10cm line labelled at “0” with “no pain” and “10” with “worst pain”

# ANNEXURE III – KEY TO MASTER CHART

| | | |
|---|---|---|
| - | - | Absent |
| + | - | Present |
| f | - | Female |
| m | - | Male |
| mL | - | Milliliter |
| Post op | - | Post operative |
| USG | - | Ultrasound |

## ANNEXURE III - MASTER CHART - GROUP D

| Serial Number | In patient number | Sex | Age (Years) | Chief complaints | | Drain | | Post op USG findings | | Post operative pain |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Upper abdominal pain | Dyspepsia | Drain | Quantity drained (mL) | Collection | Quantity | |
| 1 | 510438 | m | 42 | + | + | + | 15 | + | 18 | 8 |
| 2 | 518301 | m | 17 | - | + | + | 5 | + | 2 | 6 |
| 3 | 520080 | f | 27 | - | + | + | 8 | + | 5 | 7 |
| 4 | 552229 | f | 40 | + | + | + | 14 | + | 4 | 8 |
| 5 | 553564 | m | 22 | - | + | + | 0 | - | - | 7 |
| 6 | 566401 | m | 70 | - | + | + | 10 | - | - | 6 |
| 7 | 546939 | f | 37 | + | + | + | 4 | + | 5 | 2 |
| 8 | 554168 | f | 44 | - | + | + | 12 | - | - | 7 |
| 9 | 556807 | f | 62 | - | + | + | 5 | - | - | 8 |
| 10 | 568326 | m | 67 | - | + | + | 3 | + | 5 | 7 |
| 11 | 568424 | f | 52 | + | + | + | 10 | - | - | 5 |
| 12 | 569383 | m | 25 | - | + | + | 7 | + | 5 | 7 |
| 13 | 568177 | m | 60 | - | + | + | 8 | - | - | 8 |
| 14 | 566815 | m | 65 | - | + | + | 10 | - | - | 9 |
| 15 | 563779 | m | 40 | + | + | + | 5 | - | - | 3 |
| 16 | 562685 | f | 35 | - | + | + | 10 | + | 4 | 5 |
| 17 | 516229 | f | 50 | - | + | + | 0 | - | - | 6 |
| 18 | 521188 | m | 35 | + | + | + | 0 | + | 8 | 6 |
| 19 | 525420 | f | 30 | - | + | + | 0 | + | 5 | 4 |
| 20 | 528986 | f | 32 | - | + | + | 5 | + | 6 | 3 |
| 21 | 529520 | m | 60 | + | + | + | 8 | - | - | 8 |
| 22 | 534908 | f | 25 | - | + | + | 8 | + | 6 | 9 |
| 23 | 563221 | m | 48 | - | + | + | 10 | + | 3.6 | 6 |
| 24 | 558682 | m | 54 | + | + | + | 0 | - | - | 9 |
| 25 | 527420 | f | 45 | - | + | + | 8 | - | - | 6 |
| 26 | 542336 | f | 44 | - | + | + | 20 | - | - | 8 |
| 27 | 562053 | f | 41 | + | + | + | 5 | - | - | 4 |
| 28 | 547393 | m | 43 | - | + | + | 10 | + | 1 | 7 |
| 29 | 529439 | f | 58 | - | + | + | 10 | + | 4 | 7 |
| 30 | 530993 | m | 49 | + | + | + | 10 | - | - | 7 |

## ANNEXURE III - MASTER CHART - GROUP ND

| Serial Number | In patient number | Sex | Age (Years) | Chief complaints | | Drain | | Post op USG findings | | Post operative pain |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Upper abdominal pain | Dyspepsia | Drain | Quantity drained (mL) | Collection | Quantity | |
| 1 | 508875 | f | 32 | + | + | - | - | - | - | 4 |
| 2 | 519353 | m | 50 | - | + | - | - | - | - | 3 |
| 3 | 528716 | f | 55 | - | + | - | - | + | 4 | 5 |
| 4 | 532761 | f | 25 | + | + | - | - | - | - | 1 |
| 5 | 534732 | f | 46 | - | + | - | - | - | - | 4 |
| 6 | 539544 | m | 25 | - | + | - | - | + | 8 | 5 |
| 7 | 540788 | m | 65 | + | + | - | - | - | - | 1 |
| 8 | 554926 | m | 38 | - | + | - | - | - | - | 1 |
| 9 | 567680 | f | 55 | - | + | - | - | + | 2 | 3 |
| 10 | 522715 | m | 72 | + | + | - | - | + | 5 | 4 |
| 11 | 530333 | f | 37 | - | + | - | - | + | 3 | 2 |
| 12 | 535551 | f | 60 | - | + | - | - | - | - | 1 |
| 13 | 543229 | m | 55 | + | + | - | - | - | - | 1 |
| 14 | 545983 | f | 30 | - | + | - | - | - | - | 3 |
| 15 | 548209 | f | 40 | - | + | - | - | - | - | 1 |
| 16 | 563107 | m | 45 | + | + | - | - | + | 3 | 3 |
| 17 | 515482 | f | 35 | - | + | - | - | - | - | 3 |
| 18 | 520677 | f | 35 | + | + | - | - | + | 6 | 2 |
| 19 | 522949 | m | 18 | - | + | - | - | - | - | 2 |
| 20 | 526214 | m | 35 | + | + | - | - | - | - | 1 |
| 21 | 533518 | f | 14 | - | + | - | - | - | - | 4 |
| 22 | 558808 | f | 37 | - | + | - | - | + | 5 | 2 |
| 23 | 552825 | f | 80 | + | + | - | - | - | - | 4 |
| 24 | 513253 | f | 55 | - | + | - | - | - | - | 3 |
| 25 | 552521 | f | 44 | - | + | - | - | - | - | 2 |
| 26 | 541074 | m | 24 | + | + | - | - | - | - | 3 |
| 27 | 543487 | f | 33 | - | + | - | - | - | - | 2 |
| 28 | 513253 | m | 41 | - | + | - | - | - | - | 0 |
| 29 | 546074 | f | 55 | - | + | - | - | - | - | 3 |
| 30 | 516481 | m | 62 | - | + | - | - | - | - | 2 |

# *Introduction*

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# *Annexure-I*

# *Annexure-II*

# *Annexure-III*