"EFFICACY OF POWDER-FREE SURGICAL GLOVE BAG VS NO GLOVE BAG FOR RETRIEVAL OF THE GALLBLADDER DURING LAPAROSCOPIC CHOLECYSTECTOMY; A ONE YEAR RANDOMISED CONTROLLED STUDY"

BY

REGISTRATION NO: BH0116002

Dissertation

Submitted to
KLE UNIVERSITY, Belagavi, Karnataka

In partial fulfilment
of the requirements for the degree of

MASTER OF SURGERY
IN
GENERAL SURGERY

DEPARTMENT OF GENERAL SURGERY
JAWAHARLAL NEHRU MEDICAL COLLEGE
BELAGAVI- 590010.
KARNATAKA

APRIL 2019

KAHER, BELAGAVI, KARNATAKA

Endorsement by the HOD/ Principal/ Head of the Institution

This is to certify that the dissertation entitled **"EFFICACY OF POWDER-FREE SURGICAL GLOVE BAG VS NO GLOVE BAG FOR RETRIEVAL OF THE GALLBLADDER DURING LAPAROSCOPIC CHOLECYSTECTOMY; A ONE YEAR RANDOMISED CONTROLLED STUDY"** is a bonafide research work done by **REGISTRATION NO: BH0116002**

DR. A.S. GOGATE
MS (GENERAL SURGERY)
Professor and Head,
Department of General Surgery,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date :

Place : Belagavi

DR.(Mrs.) N.S. MAHANTSHETTI
M.D (PAEDIATRICS)
Principal,
J. N. Medical College,
Nehru Nagar, Belagavi – 10

Date :

Place : Belagavi

LIST OF ABBREVIATIONS

Glossary	Abbreviations
CI	confidence interval
CVS	a critical view of safety
GS	Gallstone
HCV	hepatitis C virus
LC	Laparoscopic cholecystectomy
MS	Metabolic Syndrome
NAFLD	Non-alcoholic fatty liver disease
NHANES III	National Health and Nutrition Examination Survey
NOTES	Natural Orifice Transluminal Endoscopic Surgery
RR	relative risk
SILS	Single Incision Laparoscopic Surgery

ABSTRACT

BACKGROUND:

Laparoscopic cholecystectomy (LC) is one of the commonly performed surgical procedures However there has been increasing report of infectious complications due to un-retrieved stones and spillage of bile. Economical sterile surgical gloves or sterile endobag can be used instead of expensive commercial ones to retrieve the gallbladder specimen and also intraabdominal spilt stones safely without complications. But the evidence available on the subject is still conflicting. The present study intended to ascertain the safety, ease of retrieval and septic complications of using powder-free surgical glove bag for retrieval of gallbladder specimens and the spilled gallstones during laparoscopic cholecystectomy.

OBJECTIVES:

1. To compare the duration of surgery with the use of powder-free glove bag versus without glove bag for extraction of gallbladder specimen.
2. To determine the ease, efficacy and complications associated with the use of glove bag versus without glove bag for extraction of gall bladder specimen.

MATERIALS AND METHODS:

This study was a randomized controlled trial, conducted in the Department of general surgery, Dr Prabhaker Kore hospital, KLE, Belgavi. All the patients who are admitted and undergoing laparoscopic cholecystectomy in the study setting were considered as the study population. The data collection for the study was done between 1st January 2017 to 31st January 2018 for one year. Patients with known latex allergy, Patients with deranged coagulopathy, Patients with significant other co-

morbidities, in whom ejection fraction is 20% or less, or with COPD and Patients diagnosed with peritonitis were excluded from the study.

Computer generated random numbers by SPSS programme were used to assign the type of intervention chosen for the patients that is, group A (use of powder-free glove bag for extraction of gallbladder specimen) and group B (without the use of glove bag for extraction of gallbladder specimen) The intra-op time taken for withdrawal of the specimen in both groups was measured and compared. Initial procedure of the conventional laparoscopic cholecystectomy is done. A powder-free glove bag is introduced into the peritoneal cavity through the umbilical port, with the help of the instruments, the specimen is carefully placed into the glove bag and retrieved through the umbilical port. Time taken for removal of the specimen (minutes), the median values were compared between study groups using the Mann-Whitney U test. (2 groups). The association between group and Gender, history of complaints, comorbidities, associated complications was assessed by cross-tabulation and comparison of percentages. Chi square test was used to test statistical significance.

RESULT

A total of 60 people were included in the analysis, with 30 participants each in study and control group. No statistically significant differences were observed between the study groups. The majority of 35.59% participants had Cholecystitis, followed by Cholelithiasis, Carcinoma of the gallbladder, gangrenous gallbladder, empyema gallbladder and gallbladder polyp was 20.33%, 6.76%, 5.08%, 5.08% and 3.38% respectively. Majority (86.44%) participants underwent laparoscopic cholecystectomy, followed by laparoscopic subtotal cholecystectomy with ERCP followed by laparoscopic cholecystectomy was 6.67% and 3.38% respectively.

Among the control group, the median time taken for removal specimen was 2.05 minutes, it was 4.25 minutes was a study group. The difference in the median time taken for removal specimen between the group was statistically significant (P value <0.001). Among the control, 13 (68.4%) participants had associated complications. Among the study group, 7 (31.8%) participants had associated complications. The difference in the proportion of associated complications between the group was statistically significant (P value 0.019). Among the control, 11 (57.9%) participants had extended incision. Among the study group, 2 (9.1%) participants had an extended incision. The difference in the proportion of extended incision between the group was statistically significant (P value 0.001). Among the control, 5 (26.3%) participants had an infection. Among the study group, 1 (4.5%) participants had infections. The difference in the proportion of infection between the group was statistically significant (P value 0.049). Among the control, 2 (10.5%) participants had intra op bile leak. Among the study group, 4 (18.2%) participants had intra op bile leak. The difference in the proportion of intra op bile leak between the group was statistically not significant (P value 0.489). Among the study group, only 1 (4.5%) participants had bile drained from GB in glove.

CONCLUSION:

The study has compared the postoperative outcomes between powder-free surgical glove bag and no bag groups, in patients undergoing gallbladder retrieval during laparoscopic cholecystectomy. The post-operative infective complications were significantly lower in the study group, as compared to controls. But the duration and the occurrence of intraoperative bile leak were higher among study group. Hence the choice procedure needs to made with caution, considering all the risks and benefits involved.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF PHOTOGRAPHS

INTRODUCTION

Laparoscopic cholecystectomy (LC) is considered worldwide the "gold standard" in the surgical treatment of symptomatic cholelithiasis and acute cholecystitis because it offers well-known and more definite advantages in comparison with open cholecystectomy.[1] LC, introduced in the late 1980s, has replaced the open technique, although the former is less invasive, requires shorter hospitalizations, and is associated with faster recovery than open cholecystectomy, gallbladder perforation and spillage are the common complications encountered during dissection and removal of gallbladder (25%).[2] However there has been increasing report of infectious complications due to un-retrieved stones and spillage of bile. Economical sterile surgical gloves or sterile endobag can be used instead of expensive commercial ones to retrieve the gallbladder specimen and also intraabdominal spilt stones safely without complications.[3]

LC was first described as a procedure requiring four ports: two 11-mm and two 5-mm trocars. With the advent of mini-instruments such as the 5-mm clip applier, a four-port technique using one 11-mm and three 5-mm trocars became possible. Later three- or two-port techniques were described for micro laparoscopy. With these techniques, removal of the gallbladder through the 11-mm umbilical port is mandatory.

In the developed world 90 % of cholecystectomies are completed laparoscopically. Since the introduction of laparoscopic surgery for gallbladder disease, different types of retrieval devices have been used to extract the gallbladder from the peritoneal cavity. These ranged from simple non-powdered gloves to several types of commercially produced bags.[4, 5] The use of retrieval devices have been advocated for several reasons, including prevention of wound infection and avoidance

of port site metastasis.[6-8] In LC, their use is thought to provide the further benefit of reducing the risk of stone spillage into the peritoneal cavity. However, the use of retrieval bags can make removal of the specimen more difficult, requiring enlargement of the port site incision and potential risk of abdominal organ damage during bag insertion and retrieval.[9, 10]

Intraperitoneal spillage of bile and gallstones and later implantation of gallstones, during dissection of the gallbladder off its liver bed and it is retrieval without endobag, are documented complications.[11, 12] In order to prevent above complications, gallbladder specimen and the spilt gallstones are retrieved in an endobag, usually through umbilical port. Distended gallbladders that are packed with stones always create a problem during their retrieval from the abdomen. Gallbladder removal in these cases required a needle decompression, stone fragmentation and stone removal from the gallbladder near the port site or enlargement of the one of the fascial incision to facilitate gallbladder retrieval, which causes more postoperative port site pain.

After laparoscopic cholecystectomy, extraction of the gallbladder is a time consuming and difficult job. So proper positioning of instruments (railroading) and orientation are required for retrieval of gallbladder specimen.[13] Although several techniques and methods are suggested to facilitate the retrieval of gallbladder 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, haematoma and infection as well as leaving a risky area for an incisional hernia.[14] The present study intended to ascertain the safety, ease of retrieval and septic complications of using powder-free surgical glove bag for retrieval of gallbladder specimens and the spilled gallstones during laparoscopic cholecystectomy.

AIMS AND OBJECTIVES

- To compare the duration of surgery with the use of powder-free glove bag versus without glove bag for extraction of gallbladder specimen.
- To determine the ease, efficacy and complication associated with the use of glove bag versus without glove bag for extraction of gallbladder specimen.

REVIEW OF LITERATURE

Laparoscopic cholecystectomy is a minimally invasive surgical procedure for removal of a diseased gallbladder. This technique essentially has replaced the open technique for routine cholecystectomies since the early 1990s. At this time, laparoscopic cholecystectomy is indicated for the treatment of cholecystitis (acute/chronic), symptomatic cholelithiasis, biliary dyskinesia, acalculous cholecystitis, gallstone pancreatitis, and gallbladder masses/polyps. These indications are the same for open cholecystectomy.

LC may be performed by single, two, three or four-port (3,5 and 10mm size) technique depending on the surgeon's choice. Endoscopes and long handle instruments are introduced into the body through an insertion port site. At the end of the procedure, proper positioning of instruments (railroading) and orientation are required for retrieval of gallbladder specimen.

The burden of Gallstone disease

Gallstones are formed in the biliary tract, mainly in the gallbladder. About 10-15% of gallstone patients have a simultaneous gallbladder and common bile duct stones, whereas intrahepatic stones occur less frequently. According to the chemical composition, there are three major types of stones: cholesterol, pigment (bilirubin), and mixed stones.

There is a marked geographic variation in gallstone prevalence. In developed countries, more than 85% of gallstones are cholesterol stones. About 20 million people in the USA (15% of the population) have gallstones[15] The Third National Health, and Nutrition Examination Survey (NHANES III) indicated a higher prevalence in Mexican-Americans than in non-Hispanic whites and a lower

prevalence in non-Hispanic blacks.[16] An extraordinarily high prevalence was found in American Indians (specifically, the Pima tribe from Arizona).

Overall, 10 to 15% of the affected US population had asymptomatic gallstones. Of these, 20% are symptomatic (biliary colic). Of the 20% who are symptomatic approximately 1% to 4% will manifest complications (acute cholecystitis, gallstone pancreatitis, choledocholithiasis, gallstone ileus). The incidence of gallstones increases with an increase in age, with females more likely to form gallstones than males. Age 50 to 65 approximately 20% of women and 5% of men have gallstones. Overall, 75% of gallstones are composed of cholesterol, and the other 25% are pigmented. Despite the composition of gallstones, the clinical signs and symptoms are the same.

In Europe, ultrasound studies revealed a prevalence of 9 - 21% and an incidence of 0.63/100 persons/year.[17] A trend for increasing gallstone prevalence has been identified in Europe and North America by necroptic[18] and ultrasound studies.[19] This trend has also been demonstrated in Japan. Here, a higher gallstone prevalence (10%) than that previously described as well as an increased proportion of cholesterol stones has been documented by the Japan Gallstone Study Group.[20] In South-Eastern Asia, the prevalence of gallstones (mostly brown pigment) is low. Gallstone prevalence rates are even lower in Africa.

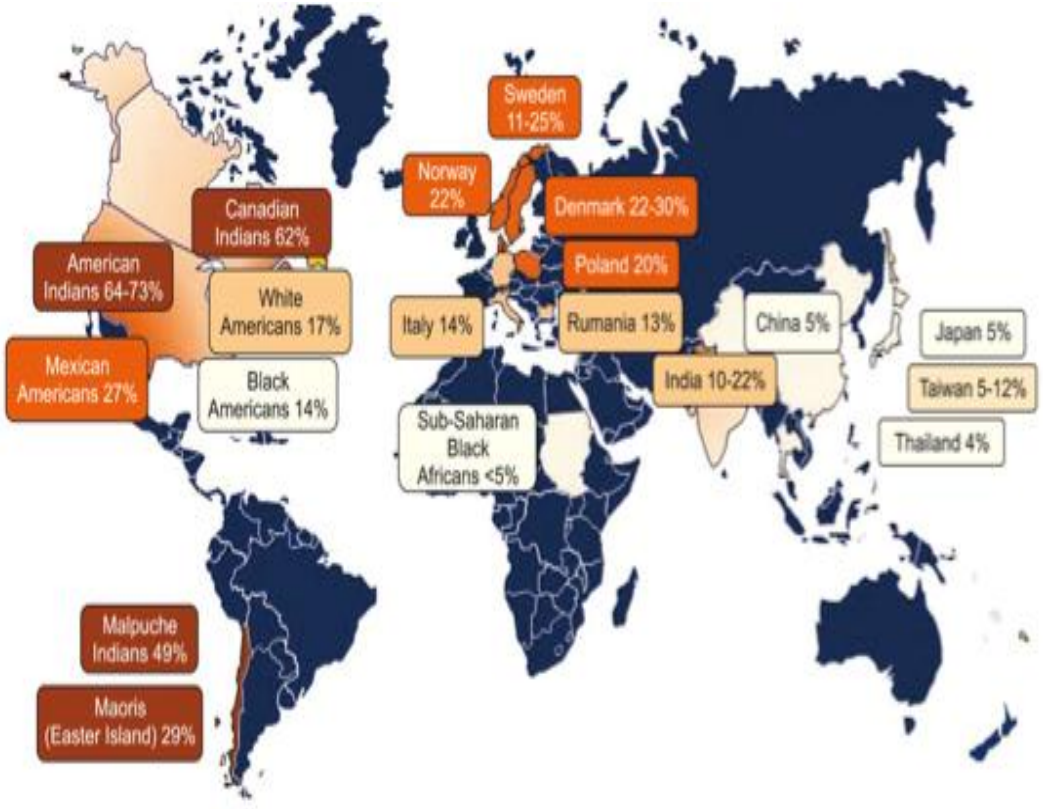


Figure 1: Worldwide prevalence of gallstones in females based on ultrasonographic surveys

Risk factors for gallstones

Cholesterol gallstones result from oversaturation of the bile with cholesterol, combined with accelerated nucleation of crystals and impaired gallbladder motility. Advanced age, gender and heredity are major risk factors for cholesterol lithogenesis. Cholesterol GD results from the interaction between genetic susceptibility and "lithogenic" environmental factors. Based on twin studies, genetic susceptibility has been estimated to contribute about 25% of the total gallstone risk.[21] Variants of the cholesterol transporter ABCG5/G8 may account for one-third of the genetic risk.[22]

Table 1: Risk factors for gallstone disease

Risk factors for cholesterol gallstones
Non-modifiable
• Advancing age
• Female Gender
• Ethnicity
Modifiable
• High calorie/high carbohydrate diet
• Low fiber diet
• Pregnancy and parity
• Reduced physical activity
• Obesity/metabolic syndrome
• Diabetes mellitus/hyperinsulinism
• Rapid weight loss/weight "cycling"
• Total parenteral nutrition
• Drugs: estrogen, progesterone, octreotide, ceftriaxone, thiazide diuretics
• Bariatric surgery/gastrectomy
• Chronic hepatitis C virus infection
Risk factors for pigment stones **Non-modifiable**
• Age
Modifiable
• Chronic hemolysis (black stones)
• Liver cirrhosis*
• Crohn's disease *
• Extensive ileal resection (black stones)
• Cystic fibrosis (black stones)
• Biliary infections/infestations (brown stones)
* both black pigment and cholesterol stones

Pigment gallstones form when bilirubin is excreted in excess into bile (black stones) or in association with bile duct infections (brown stones). The major risk factors for black stones are chronic hemolysis and liver cirrhosis, and patients with biliary infections or infestations are at risk for brown stones.

Risk factors contributing to the increasing prevalence of GD

The GD prevalence is rising in the industrialized countries in Europe and America due to the changes in lifestyle. A similar trend appears to be present in some developing countries. Apart from the ageing of the population, key risk factors accounting for the increasing GD prevalence are environmental.

Obesity

Obesity is a major risk factor for cholesterol GD, due to the increased hepatic cholesterol synthesis (via increased HMG-CoA reductase activity) and biliary cholesterol excretion. The risk is higher in women and very high in morbidly obese individuals. Multiple weight cycling and rapid weight loss (e.g. after bariatric surgery) enhance the gallstone risk.

An increase in the body mass index between 1980 and 2008 has been documented worldwide, with great variations in different countries. In 2008, an estimated 1.46 billion adults were overweight, and of these, 500 million were obese.[23] The most dramatic obesity epidemic has been observed in the United States: in 1990 no state had an obesity prevalence equal to or higher than 15%; while in 2010 obesity was present in more than 25% of the adult population in half of the country's states.[24]

Diabetes mellitus

Type 2 diabetes is associated with an increased risk for GD. An increased cholesterol secretion into bile and gallbladder stasis, due to neuropathy, may explain the higher proportion of gallstone carriers among people with diabetes. Due to

population growth, urbanization, ageing and the increasing frequency of obesity and sedentary lifestyle, diabetes will continue to be a major health problem in developed countries and a growing problem in developing countries.[25] At the global level, the number of people with diabetes increased from 153 million in 1980 to 347 million in 2008.[25] Accordingly, the age-standardized adult diabetes prevalence rate was significantly higher in 2008 (9.8% in men and 9.2% in women) than in 1980 (8.3% and 7.5%, respectively).

Metabolic Syndrome (MS)

The association between GD and obesity is now recognized as part of the MS, which includes central obesity, high triglyceride and low HDL-cholesterol levels, glucose intolerance, and hypertension. Hepatic insulin resistance stimulates cholesterol secretion into bile and impairs bile acid synthesis, favoring gallstone formation.[26] Hepatic insulin resistance is associated with GD even in non-diabetic, non-obese individuals.[27] The prevalence of MS is increasing up to epidemic proportions in many developed countries.

Non-alcoholic fatty liver disease (NAFLD)

NAFLD is the hepatic expression of the MS. Gallstones are more frequent in NAFLD patients than in the general population[28], as NAFLD and cholesterol GD share a common lifestyle and metabolic risk factors. The obesity epidemic will lead to an increased prevalence of NAFLD.

Dyslipidemia

Although there is no correlation between cholesterol gallstones and total cholesterol levels in the blood, GD is associated with low HDL-cholesterol and high triglyceride serum levels. Nearly all patients with hypertriglyceridemia have supersaturated bile, even if they are lean.[29]

"Western-type" diet

The change over time in gallstone prevalence suggests that there has been a similar change with respect to environmental risk factors. One of the main environmental exposures is nutrition. Chronic over nutrition with refined carbohydrates and reduced intake of dietary fiber might account for the increased cholesterol gallstone prevalence in Native Americans, European countries and urban centers in Eastern Asia (Japan). This increase is linked to obesity, slow intestinal transit, hypertriglyceridemia, and insulin resistance. Moderate alcohol consumption and coffee consumption seem to be protective factors for gallstone formation, or at least for the development of symptoms in gallstone carriers.

Decreased physical activity

Prospective studies have shown that sedentary behavior is associated with an increased risk of cholecystectomy, both in women and men.[30] On the contrary, regular exercise improves - alone or most pronounced in association with low-calorie diet - the metabolic profile associated with obesity and cholesterol gallstones, decreasing the lithogenic risk.

Liver cirrhosis and chronic hepatitis C virus (HCV) infection

The end-stage liver disease is a well-known risk factor for GD. About 25-30% of cirrhotic patients have gallstones. Pigment lithogenesis is favored by chronic hemolysis and changes of liver metabolism. Cholesterol gallstones are also frequent in liver cirrhosis, particularly in cirrhotic patients with chronic HCV infection or NAFLD. Chronic HCV infection was shown to be an independent risk factor for GD both in patients with liver cirrhosis[30] and in chronic hepatitis.[31] The prevalence of liver cirrhosis in HCV-infected patients has increased significantly over the past years.[32] It will continue to increase, given the fact that the spread of HCV infection in

the USA and Europe occurred mainly after the 1970s and long duration of infection are necessary for cirrhosis to develop cholesterol, combined with accelerated nucleation of crystals and impaired gallbladder motility. Advanced age, gender and heredity are major risk factors for cholesterol lithogenesis. Cholesterol GD results from the interaction between genetic susceptibility and "lithogenic" environmental factors. Based on twin studies, genetic susceptibility has been estimated to contribute about 25% of the total gallstone risk.[21] Variants of the cholesterol transporter ABCG5/G8 may account for one-third of the genetic risk.[22]

1. Jayanthi V et al.[33] (2016) compared the composition of GB bile from healthy liver donors and patients with GS from the north and south India. Gallbladder bile from healthy liver donors from the north (10) and south India (8) served as controls. Cases were patients from the north (21) and south India (17) who underwent cholecystectomy for GS disease. Gallbladder bile from both cases and controls was analyzed for cholesterol, lecithin (phospholipid), and bile salts. Gallstones were classified as cholesterol, mixed, and pigment based on morphology and biochemical analysis. The median cholesterol concentration in control bile from the north was significantly high compared to the south ($p<0.001$) with no difference in lecithin and bile salts (p NS). Except for one sample each from north and south, the cholesterol solubility of controls was within the critical micellar zone. Mixed GS were most frequent in north India (61.9 %) while pigment GS dominated in the south (61.9 %). The median cholesterol concentration in bile samples of cholecystectomy patients from north India was significantly high GS ($p < 0.00001$) with significant lowering of bile salts and lecithin ($p < 0.00001$). Gallbladder bile in controls and patients with GS from north India had

significantly high cholesterol concentration. In south India, patients with mixed GS had cholesterol-rich bile while pigment GS had higher concentrations of bile salts.

2. Chandran AP et al.[34] (2014) aimed to identify dietary factors and lifestyle patterns among southern Indian patients with gallstone (GS) disease. Seventy-one consecutive patients with GS disease were compared with age- and sex-matched controls. Results showed that the demographic and lifestyle variables were similar in both groups. The family history of GS disease and diabetes mellitus was higher among cases (16.9 %; p = 0.01; odds ratio (OR) 2.02; 95 % CI 1.58 to 2.58 for both). Vegetables consumed >/= 2 times per week (OR 0.09; 95 % CI 0.04 to 0.21), fruits (OR 0.45; 95 % CI 0.20 to 0.99), and sugar (OR 0.27; 95 % CI 0.07 to 0.95) consumed >/= 3 times per week were negatively associated with GS. Tea and coffee were taken less frequently by cases (2.5 vs 2.9 cups/day; ANOVA p < 0.01). Tamarind (OR 27.6; 95 % CI 9.5 to 84.4), spicy foods (OR 6.6; 95 % CI 2.8 to 16.3), and fried foods (OR 9.1; 95 % CI 2.8 to 33.2) when taken >/= 4 times per week and cooking oil >/= 300 mL per month (OR 62.0; p < 0.0000) increased the risk for GS. They opined that several dietary preferences were associated with GS disease in this southern Indian population.
3. Sodhi JS et al.[35] (2014) carried out a case-control study to determine the prevalence of gallstones (GS) in patients with T2D, risk factors, and the relative risk compared with subjects without diabetes, selected from the general population. Among 450 cases with T2D of a >/=2-year duration, 377 (88.8 %) participated. Cases and controls were matched for age, gender, and body mass index (BMI). Gallstones were seen in 67 (17.7 %) cases compared to 40 (5.8 %) in controls (p = 0.001). Prevalence increased with increasing age with peak in the

sixth decade (23.4 % in cases and 4.4 % in controls (p = 0.001) and was higher in women (27.9 %) in cases and (7.8 %) in controls, (p = 0.001). In univariate analysis, risk factors for GS included age, female sex, BMI, multiparity, family history of GS, and high triglycerides and cholesterol with low high-density lipoprotein cholesterol. In multivariate analysis, age, (relative risk [RR] 1.54, confidence interval [CI] 1.1-2.1), female sex (RR 1.6, CI 1.0-1.9), and BMI (RR 1.5, CI 1.3-2.5) were the independent risk factors in gallstone formation. Patients with T2D had a higher probability of having GS compared to the general population. Increasing age, female sex, and higher BMI were independently associated with gallstone disease.

4. Shaffer EA et al.[36](2006) extensively reviewed the epidemiology of gallstone disease. The literature revealed that gallstone disease is common: >700,000 cholecystectomies and costs of approximately 6.5 billion dollars annually in the U.S. The burden of disease is epidemic in American Indians (60-70%); a corresponding decrease occurs in Hispanics of mixed Indian origin. Ten to fifteen per cent of white adults in developed countries harbor gallstones. Frequency is further reduced in Black Americans, East Asia and sub-Saharan Africa. In developed countries, cholesterol gallstones predominate; 15% are black pigment. East Asians develop brown pigment stones in bile ducts, associated with biliary infection or parasites, or in intrahepatic ducts (hepatolithiasis). Certain risk factors for gallstones are immutable: female gender, increasing age and ethnicity/family (genetic traits). Others are modifiable: obesity, the metabolic syndrome, rapid weight loss, certain diseases (cirrhosis, Crohn's disease) and gallbladder stasis (from spinal cord injury or drugs like somatostatin). The only established dietary risk is high caloric intake. Protective factors include diets containing fiber,

vegetable protein, nuts, calcium, vitamin C, coffee and alcohol, plus physical activity.

5. Jayanthi V et al.[37] (2005) wanted to determine the association of dietary factors with mixed/pigment gallstones amongst southern Indian patients. Diet details were obtained from 346 patients (178 women) with gallstones and an equal number of healthy controls who were age- and sex-matched attendants of the patients, sharing similar socioeconomic and demographic characteristics, with normal abdominal ultrasonogram. There was no difference between cases and controls in consumption of non-vegetarian food, type of cereal, average oil and sugar consumption, and type of beverage consumed (tea/coffee/milk/combination). Individuals with BMI> 22 were at higher risk to develop gallstones (OR 1.49; 95% CI 1.09, 2.04; p=0.01). There was a significant risk of gallstone formation with the use of tamarind when consumed > 3 times a week (OR 1.76; 95% CI 1.05, 2.96; p=0.03). Higher BMI and tamarind use were significant risk factors even on multivariate logistic regression analysis (p=0.02). It was concluded that higher BMI and use of tamarind, a common ingredient of diet in southern India, are risk factors in the formation of gallstones in southern India.

LAPAROSCOPIC CHOLECYSTECTOMY: HISTORY AND EVOLUTION

Laparoscopic cholecystectomy is a minimally invasive surgical procedure for removal of a diseased gallbladder. This technique essentially has replaced the open technique for routine cholecystectomies since the early 1990s. At this time, laparoscopic cholecystectomy is indicated for the treatment of cholecystitis (acute/chronic), symptomatic cholelithiasis, biliary dyskinesia, acalculous cholecystitis, gallstone pancreatitis, and gallbladder masses/polyps. These indications

are the same for open cholecystectomy. Cases of gallbladder cancers are usually best treated with open cholecystectomy.

Surgery of the gallbladder has evolved tremendously over the past decades. Laparoscopic cholecystectomy is considered the gold standard for gallbladder removal and is the most common laparoscopic procedure worldwide.[38] The tendency of minimising surgical trauma encourages the use of new approaches in laparoscopic surgery. In recent times, the innovative techniques of Natural Orifice Transluminal Endoscopic Surgery (NOTES) and Single Incision Laparoscopic Surgery (SILS) have been applied in gallbladder removal as a step forward toward nearly scar less surgery. Navarra *et al*.[39] performed the first SILS cholecystectomy in 1997 using two trocars through one sub umbilical incision and three abdominal stay sutures to aid in gallbladder retraction.

After that, other early experiences with single incision laparoscopic cholecystectomy have been described. Although multiple groups have reported initial success with a single umbilical incision, no consensus exists concerning the optimum technique for this operation.[40]

The advantages of SILS are not yet clearly defined. It has been suggested that SILS has the potential advantages of reduced postoperative pain, faster return to work, reduced port-site complications and improved cosmesis.[41]

There are safety concerns regarding this technique due to the possible decreased visualisation or exposure, with a lack of triangulation and clashing of instruments. To date, no large safety and a feasibility study have been published. It would be not acceptable to trade increased patient comfort for a higher complication rate, particularly if this involves common bile duct injury.[42, 43]

1. Hassler KR et al.[44](2018) noted that approximately 20 million people in the United States have gallstones. Of these people, there are approximately 300,000 cholecystectomies performed annually. Ten per cent to 15% of the population has asymptomatic gallstones. Of these, 20% are symptomatic (biliary colic). Of the 20% who are symptomatic approximately 1% to 4% will manifest complications (acute cholecystitis, gallstone pancreatitis, choledocholithiasis, gallstone ileus). The incidence of gallstones increases with an increase in age, with females more likely to form gallstones than males. Age 50 to 65 approximately 20% of women and 5% of men have gallstones. Overall, 75% of gallstones are composed of cholesterol, and the other 25% are pigmented. Despite the composition of gallstones, the clinical signs and symptoms are the same.
2. Jones MW et al.[45] (2018) in their literature review observed that since the early 1990s, the gold standard for cholecystectomy has changed to a laparoscopic approach. This method showed a 30% increase in the overall performance of elective cholecystectomies. Today, 92% of all cholecystectomies are done laparoscopically. There are several indications in performing open cholecystectomies, and this procedure remains an important part of training for the general surgery resident. With the advent of laparoscopic cholecystectomies in the 1990s, CBD injuries increased by three to ten times. The injury rate dropped to 0.3% but has remained the same despite better training, preventative maneuvers, and equipment. Laparoscopic CBD injuries are typically more complex.
3. Hori T et al.[46] (2016) described the tips and pitfalls of LC in detail and discussed various technical considerations for laparoscopic cholecystectomy. They noted that though, Laparoscopic cholecystectomy (LC) does not require advanced techniques, the rate of biliary injuries has not decreased. The concept of the

critical view of safety (CVS) was first documented two decades ago. Unexpected injuries are principally due to misidentification of human factors. The surgeon's assumption is a major cause of misidentification, and a high level of experience alone is not sufficient for successful LC. They summarized the following mandatory protocol for safe LC: (1) consideration that a high level of experience alone is not enough; (2) recognition of the plateau involving the common hepatic duct and hepatic hilum; (3) blunt dissection until CVS exposure; (4) Calot's triangle clearance in the overhead view; (5) Calot's triangle clearance in the view from underneath; (6) dissection of the posterior right side of Calot's triangle; (7) removal of the gallbladder body; and (8) positive CVS exposure. We believe that adherence to this protocol will ensure successful and beneficial LC worldwide, even in patients with inflammatory changes and rare anatomies.

4. Jabbari NA et al.[47](2016) reviewed the literature on the diagnosis, prevention, consequences, and management of lost gallstones. All studies with a focus on lost gallstones or perforated gallbladder were analyzed to evaluate the postoperative complications. The authors observed that between 1991 and 2015, >250 cases of postoperative complications of spilled gallstones were reviewed in the surgical literature. The most common complications are intraperitoneal abscesses and fistulas. Confusing clinical pictures due to gallstones spreading in different locations makes diagnosis challenging. Even asymptomatic dropped gallstones may masquerade intraperitoneal neoplastic lesions. Every effort should be made to prevent gallbladder perforation; otherwise, they should be retrieved immediately during laparoscopy. In cases with multiple large spilled stones or infected bile, conversion to open surgery can be considered.

CONSEQUENCES OF LEFTOVER GALLSTONES:

Laparoscopic cholecystectomy has become the preferred surgical technique for symptomatic gallstone disease. The technique generally is safe. Probably one of the most common intra-operative complications is gallbladder perforation with stones spreading into the peritoneal cavity. LC entails the risk of gallbladder rupture and consequent loss of stones within the abdominal cavity, which is not an uncommon complication. The development of intraperitoneal abscesses due to the spilt gallstones is one of its major complications.

Although perforation of the gallbladder with spillage of gallstones during laparoscopic cholecystectomy often occurs, the incidence of major postoperative complications is low. However, in some cases reoperation is necessary. Removal of all spilled stones is therefore indicated to prevent complications.

1. Loffeld RJ et al.[48] (2006) reviewed the sequelae of lost gallstones after laparoscopic cholecystectomy and the diagnostic problems facing the clinician are reviewed. Abscesses and fistula formation in the abdominal wall occur. A long delay can be present between the initial operation and the complications of the lost stones. Although rupture of the gallbladder is usually noticed during preparation and retrieval, the surgeon may not be aware of losing stones. Due to the long delay, the occurrence of intra-abdominal abscesses and fistula is often not linked to the prior procedure.
2. Van dur Lugt JC et al.[49] (2005) presented a two case report in which, two women aged 79 and 69 years presented with abdominal pain at 15 and 38 months respectively after laparoscopic cholecystectomy. In both cases, perforation of the gallbladder had occurred with spillage of bile and gallstones. What a CT-scan

carried out at presentation showed signs of an abdominal abscess. The origin of the abscess was initially unknown. The first patient was operated on immediately. In the second patient, a drain was placed in the abscess under ultrasound guidance. During operation, gallstones were seen in the abscess cavity in both patients. Both patients recovered well. If abdominal symptoms persist after laparoscopic cholecystectomy, an abscess due to spilled gallstones should be considered. Ultrasound or CT is the most sensitive means for tracing spilled gallstones or abscesses.

3. Hashimoto M et al.[50] (2003) assessed reduction of the risk of unretrieved stones during laparoscopic cholecystectomy. They performed these procedures in 30 consecutive patients with gallbladder ruptured during operation. Dropped stones were noted in 5 patients and were retrieved successfully. Reduction of stone spillage and the retrieval of spilled stones were essential. It is advisable to retrieve as many gallstones as possible after gallbladder perforation during laparoscopic cholecystectomy.

TECHNIQUES OF RETRIEVAL OF GALLBLADDER:

The various options available for specimen retrieval include direct specimen retrieval, morcellation with specimen retrieval, and retrieval by bag extraction. Operative laparoscopic surgery has expanded its boundaries exponentially over the past two decades. In this regard, laparoscopic surgeons continue to face one persistent problem. This problem is the ability to safely and effectively remove a variety of laparoscopically resected tissues from the abdominal cavity. Of course, one solution to this problem is to enlarge one of the laparoscopic trocar incisions to remove the tissue specimen intact. This solution is, however, counterproductive to the concept of

minimally invasive surgery. Another solution is to morcellate the specimen with some morcellation device. Morcellation, however, is not acceptable in many surgical cases, because of the risk of dissemination of infection and/or malignant neoplasia. Also, morcellation may compromise adequate pathologic examination of the resected tissue specimen.

An ideal specimen retrieval system has to be easy to handle, open without requiring additional instrumentation and should allow the gallbladder to be opened inside the sac to release stones for easier crushing and extraction and provide good visibility of the surgical field while using a minimal number of ports, be resistant to manipulation. It should be of sufficient capacity to cope with the largest gallbladder and stone load. It should not be necessary to resort to enlargement of the trocar puncture. Furthermore, it should have a short learning curve and be cost-effective.[51]

HISTORY OF RETRIEVAL BAGS

In 1990, Clayman et al.[52] designed the first organ retrieval bag (LapSac, Cook Urological, Spencer, IN) specifically designed for laparoscopic nephrectomy. The first sacs to be tried were based on simple plastic bags. Various homemade specimen retrieval bags have been described in the literature, including condoms[53], zipper bags[54], the Nadiad bag, and more often surgical gloves tied in various ways.[4, 51] The use of drain packages has also been described.[55] 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).[56] Also some of these items (e.g. the Nadiad bag and various zipper bags) need to be made available at all times in the operating room, thus making it necessary to prepare and sterilize them prior to any operation.

Several commercially produced laparoscopic tissue retrieval sacs exist to facilitate removal of intact surgical tissue specimens (e.g., E-Sac, ENDO CATCH™, Pleatman Sac®, Endobag®) [4, 5] to simple non-powdered gloves.[4] The use of retrieval devices has been advocated for several reasons, including prevention of wound infection and avoidance of port site metastasis.[6, 7, 57] In laparoscopic cholecystectomy, their use is thought to provide the further benefit of reducing the risk of stone spillage into the peritoneal cavity. However, the use of retrieval bags can make removal of the specimen more difficult, requiring enlargement of the port site incision and potential risk of abdominal organ damage during bag insertion and retrieval.[9]

Though these sacs are very effective in isolating a surgical specimen from the peritoneal cavity and the abdominal incision, they all have one inherent disadvantage. This disadvantage is that they distend as the tissue inside of them is brought up to the interior aspect of the abdominal wall in preparation for removal from the abdominal cavity. The specimen becomes trapped in the abdominal cavity if the diameter of the distended sac becomes larger than the diameter of the incision. A variety of manoeuvres can be attempted using traditional surgical instrumentation to facilitate the removal of these laparoscopically resected tissue specimens with variable success. In many cases, a laparoscopic surgeon is frustrated by either rupturing the laparoscopic retrieval sac or enlarging an otherwise small incision.

Endobag[58]

Many surgeons who perform LC use an endobag if they foresee problems with retraction of the gallbladder. Four currently available systems could be selected for a description of the various functions described above:

i) The Clayman Lapsac - this represents the simple sac concept with two-piece construction with the inclusion of tabs on the mouth of the sac to facilitate

holding and a drawstring for closure and easy manipulation. The ripstop nylon material is stronger than simple plastic film sacs, but bulkier because of the polyurethane coating, so there is a penalty in size. The sac is not transparent.

ii) The Ethicon Endopouch - this device has a dedicated delivery system with an end loop snare in the mouth for closure and for retaining contact with the sac inside the abdomen. It is constructed from plastic film and requires instruments for opening and holding while the gallbladder is manipulated inside. Great care would be required in manipulating instruments within this sac because of its two-piece construction with the risk of tearing along the seam.

iii) The Autosuture Endocatch - this system attempts to offer a very comprehensive solution to all the problems of deployment and capture of the gallbladder. The delivery system incorporates an opening ring which both stabilises the mouth of the sac and opens it fully. The drawstring closure function is built in as well, but once again the construction is from plastic film. The deployment tube does not allow the use of any instrument while the sac remains open and still attached to the metal ring. The lack of strength in the sac construction requires the manufacturers to give the specific advice that unless the specimen fits easily through the incision, the incision should be enlarged before removal is attempted.

iv) The Espiner Retrieval System - this system combines the advantages of the ripstop nylon in its lightness and great strength with the thinness of a simple plastic film by reason of its special polyurethane coating; it is virtually transparent when wet. The sac is designed to have a large mouth for easy

capture of the gallbladder and along the large capacity body for easy manipulation of the gallbladder once inside. Its unique one-piece construction embodies an integral tail for retention to the outside so allowing 5 mm instrument access via its delivery tube or 10mm forceps into the sac through the main cannula. No drawstring is required; simple traction on the tail closes the mouth into the exit cannula to securely contain the contents upon withdrawal. The dedicated delivery system allows easy full deployment and the opening of the mouth while stabilising the whole structure.

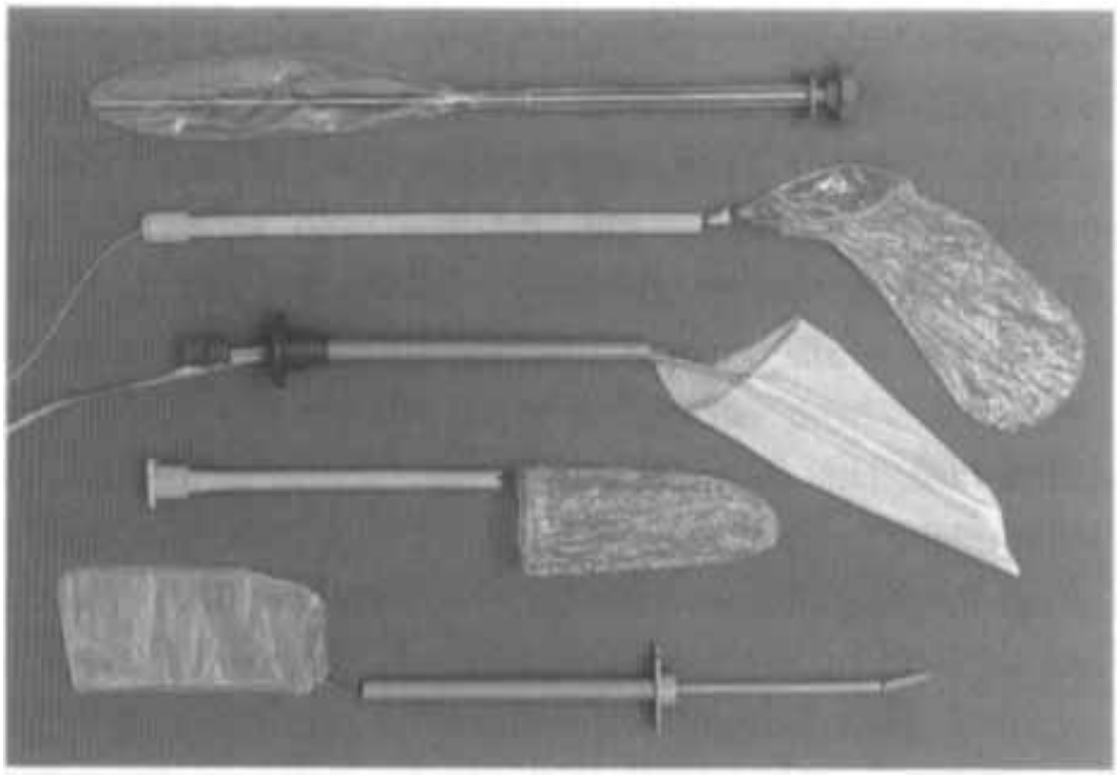


Figure 2.

From top down: (i)The Pleatman sac uses a straight pusher rod; (ii) The (prototype) Endomedix sac is deployed by using grasping forceps to push the spring-loaded mouth through the tube; (iii) The Espiner Retrieval System employs a flexible rod in a sleeve on the outside of the sac for deployment, opening and stabilizing the

mouth; (iv) The Dexide bag. This is presented backloaded into the tube: the projecting elastic ring incorporated in the mouth is grasped by forceps once in the abdomen; (v) The Ethicon Endosac uses a pusher rod which doubles as a retainer while loading the gallbladder and also controls the drawstring used inclosure.

Trocar

Hofferlin et al.[14] in 1993 developed a variation this instrument for quick and safe extraction of the stone-filled gallbladder. They called it "Bergetrokar", which is a trocar cannula with a trumpet valve and a cone-shaped tip which can be spread. When used among 180 cases, they observed no perforation of the gallbladder or loss of stones, which even reduced the extraction duration.

There are increasing reports of seeding of a tumour at the trocar sites following laparoscopic cholecystectomy in patients with unexpected or inapparent gallbladder carcinoma. Current literature suggests that tumour implantation occurring during laparoscopic cholecystectomy for inapparent carcinoma adversely affects prognosis, and, until the effect of laparoscopy on the spread of this tumour is better understood and controlled, the open operation should be performed when carcinoma of the gallbladder is suspected. When laparoscopic cholecystectomy is done for inapparent gallbladder cancer, surgical and adjuvant radiotherapy to the trocar sites appears to improve outcome in association with extended treatment to the gallbladder bed and adjacent areas.

Plastic bags

Some investigators have used plastic bags to retrieve specimens during LC. Stavrou et al.[57] (2015) used one such homemade retrieval bag made of plastic containing the catheter of a Redon drain system (Drenofast®, IHT- Iberhospitex S.A, Barcelona, Spain). The size of the plastic bag was10 × 5-cm, which was cut

approximately in half (7 × 5 cm) and then pleated longitudinally. They used this to retrieve the gallbladder among 85 patients undergoing laparoscopic cholecystectomy. The authors reported no incident of bile leak, rupture, or accidental opening of the bag during removal from the peritoneal cavity. There was maximum familiarity with the use of the bag after the first five operations. The common drawback of plastic bags was that if a large enough size was chosen and the plastic film was thin enough for delivery through an l0 mm puncture site, the material was too weak to withstand any force.

Another unique type of indigenously made, cost-effective, an innovative bag with the purpose of reducing the cost of laparoscopic surgery with effective specimen retrieval was developed by Ganpule et al.[56] in 2010, which is called the 'Nadiad bag'. The bag was prepared using a plastic roll (Sternberg, PCI, Kandivali, Mumbai, India), which can be cut into various sizes, ranging from 4 to 10 in. The sheet was closed at one end to prepare the retrieval bag; the seams of the bag were closed with an auto-seal device (Rainbow Manufacturers, Rajkot, India) to avoid leakage of the sac contents. A tunnel was created around the open end of the bag to thread the ureteral catheter with a nylon thread. The bag is prepared in 2 sizes, 5 4 in. Moreover, 5 7 in. The material used for the bag is low-density polyethene. The thickness of the polyethene is 200-300 gauge. The bag required an average of 9.6 5 minutes to prepare, provided the material to be readily available.

Simple non-powdered gloves

The risk of contamination caused by loss of the gallbladder, bile, or gallstones encouraged the development of endobags to prevent this. The routine use of commercial endobags is, however, expensive, and this has prompted us to use a surgical glove as a bag for removal of the gallbladder.[5, 59] The cost ratio of a surgical

glove plus suture to a disposable commercial bag is approximately 1:65, which speaks enormously in favour of the use of a glove.[60 61] Scattering of stones and specimen into the abdominal cavity can be avoided and may prevent serious infection. Spilled gallbladder stones have been reported to be recovered after two years of surgery, from supra umbilical port presented as a chronic discharging sinus, suggesting an endobag technique simple, safe and economical with fewer complications.

The procedure involves a simple bag being made from a surgical glove to collect specimens along the purse-string suture surrounds the opening or the base of the glove finger to secure material during retrieval. It is simple and convenient, and necessary construction material is readily available. When used the bag not only protected the specimen from contact with the wound but also cut short the operating time.[60, 62] Kao et al. [51] using one such bag reported no post-operative complications like wound infection, ileus, or intestinal adhesion. The homemade specimen retrieval bag was cost-effective and useful for the retrieval of intact specimens which was easy to make without any special equipment and safe to use.

Some investigators recommend the use of glove bag owing to many of its inherent advantages. First, it is not always possible to foresee problems with retraction of the gallbladder.[4] It will often be too late to use an endobag if, for example, the gallbladder ruptures during extraction through a small incision. Second, the glove bag is safe, easy to use, and inexpensive. The bag is easily introduced through the trocars and retracted through a small incision. Having retracted the ring of the glove bag, one has the opportunity to suck up bile, crush stones with a forceps, and divide a thick gallbladder, as reported by Kiriakidi.[63] Recently, Machado et al. [64] in a case report described a glove bag with a purse string suture to close the bag before extraction. However, Holme et al.[4] suggested that purse string suture was unnecessary thereby

excluding the above- mentioned possibilities of handling and extracting difficult stones and thick gallbladders.

It is easier to place the gallbladder and any spilled stones in the glove bag than in an ordinary endo-bag occupying a trocar. Additionally, the glove bag allows the surgeon to work with two hands because the bag lies free in the abdominal cavity and does not, like an ordinary endobag, occupy a trocar. Third, gallbladder cancers that are incidentally discovered after LC have the potential for tumor seedings at the port sites.[65] It has, therefore, become the standard practice in many institutions to excise laparoscopic port sites in these patients after the primary operation. Routine use of the glove bag is expected to prevent port site implantation of tumor cells.

Biogel glove used in some cases as glove bag is reported to be hypoallergenic and powder free but not latex free. Hence it is advised among patients with known or suspected latex allergy, a latex-free glove, together with other measures, should be used for the making of the glove bag.[66] Additionally, a wet glove, however, may collapse due to irrigation or contact with the peritoneal fluid, making it difficult to handle.[54] Finally, gloves carry a low resistance to traction and manipulation, making them prone to tearing.[54] In the case of surgical gloves, the talcum powder may promote adhesion formation[67], so it is necessary to rinse them with normal saline prior to being used.

Also, most bags are constructed by heat sealing two halves and the seam is at risk under pressure; direct puncture of the sheet by a sharp instrument leads to rapid migration of the tear, so any advantage of retrieval this way is immediately lost. The same applied to latex products, such as gloves and condoms; the latex film is thicker, thus further limiting the potential size of a sac and the material has no defence against forceps puncture with rapid loss of integrity with any force. Also, there are serious

risks with the inappropriate use of these items - condoms always contain some starch which can induce delayed hypersensitivity[68], and if the quality of the latex is not of the highest order, there is the potential of latex allergy as well. Much stronger sheet materials derived from polyurethane are now becoming available, and a number of retrieval sacs in the marketplace have used this technology. For all these materials the problem remains, however, that for any increase in strength there is a penalty of an increase in thickness and therefore bulk and consequent reduction in size.

Notwithstanding such shortcomings, researchers suggest the use of a powder-free glove bag as a safe and inexpensive method for retraction of the gallbladder and stones during LC, and further, it may preclude the use of expensive ready-for-use retrieval bags reducing operative costs.

In cases of elective laparoscopic cholecystectomy, there is rarely an ongoing inflammatory process which obviates the risk of wound infection during specimen retrieval. Furthermore, when the gallbladder is dissected free without spillage of its contents, there is no further benefit in placing it in a retrieval bag and fact further manipulation by trying to do so may lead to stone spillage.

1. Stavrou G et al.[57] (2015) developed a homemade specimen retrieval bag for laparoscopic cholecystectomy by polyethylene bag containing the catheter of a Redon drainage set. The bag was cut in half and pleated longitudinally; then, the gallbladder was placed in the bag and removed through the umbilicus with grasping forceps. From September 2011 to June 2012, they used the homemade bag on 85 patients undergoing laparoscopic cholecystectomy. No rupture, accidental opening, or bile leak was observed. The authors opined that their homemade specimen retrieval bag seems to be a safe, effective, and easy tool for tissue extraction.

2. Judge JM et al.[69] (2014) investigated the development and testing of a novel device for the safe, minimal enlargement of laparoscopic port sites to extract large, stone-filled gallbladders from the abdomen. The study device consists of a handle with a retraction tongue to shield the specimen and a guide for a scalpel to incise the fascia within the incision. Patients enrolled underwent laparoscopic cholecystectomy. Twenty (51 %) of 39 patients required the device. Average extraction time for the first eight patients was 120 s. After an interim analysis, an improved device was used in 12 patients and average extraction time was 24 s. There were no adverse events. Postoperative pain ratings and incision cosmesis were comparable between patients with and without the use of the device. The study device enabled safe and rapid extraction of impacted gallbladders through the abdominal wall.

3. Kao CC et al.[51] (2012) explored an easily produced and cost-effective specimen retrieval bag that can be used to reduce the cost of laparoscopic surgery among 135 patients. The retrieval bag was produced from a large sterile surgical glove, 2-0 nylon thread, and 1-0 RB-1 needle Vicryl thread. A purse-string suture at the opening of the bag was made using the nylon thread, and the bottom of the bag was double-tied using the tail of the Vicryl thread. The bag was introduced into the peritoneal cavity via a 12-mm port, and the specimen was enclosed with the use of two laparoscopic instruments. The bag was then extracted by extending the port incisional wound. They used a homemade retrieval bag to extract specimens from 110 patients who underwent robot-assisted laparoscopic radical prostatectomy and 25 patients who underwent laparoscopic adrenalectomy. The procedure was performed safely, and no bags were broken. No complications

were observed after the operations such as wound infection, ileus, or intestinal adhesion. The homemade specimen retrieval bag is cost-effective and useful for the retrieval of intact specimens. It is also easy to make and safe to use.

4. Ganpule AP.et al[56] (2010) described an innovative bag for effective specimen retrieval with the aim of reducing the cost of surgery. The components of the retrieval bag were a polyethylene roll, nylon thread, and a five ureteral catheter. The lower end was double-sewn with an autoseal device. The neck of the bag consisted of a folded edge of the polyethylene bag, which was single-sewn. The folded tunnel accommodated the 5F ureteral catheter and nylon thread. The introduction was performed through the 10-mm port with the help of an atraumatic grasper without any special introducer sheath. Two laparoscopic instruments were required to open, place the specimen within, and close the bag. The bag was extracted by extending the port incision if required. They concluded that the retrieval bag is inexpensive and easy to make and maintain, and effectively useful with good maneuverability
5. Holme JB et al.[4] (2005) tested the use of a simple and cheap powder-free glove bag to extract the gallbladder during laparoscopic cholecystectomy (LC). The medical records of 142 consecutive patients who had their gallbladder removed using a powder-free glove bag were reviewed. No complications in the form of bile or stone spillage during extraction were observed. The absence of complications and the low cost make routine use of the glove bag a wise option for extracting the gallbladder during LC. The use of the glove bag seemed to reduce the risk of contamination with bacteria, bile, and gallstones and may reduce contamination by malignant cells in case of unexpected gallbladder carcinoma.

6. Machado MA et al.[64] (2004) described an efficient, simple, and inexpensive technique is described that allows removal of the gallbladder through an 11-mm trocar without the need for a 5-mm telescope. It permitted removal of the specimen in acute suppurative or thick-wall cholecystitis independently of the technique used.
7. Harling R et al.[7] (2000) did a prospective, randomized trial of prophylactic antibiotics versus bag extraction in the prophylaxis of wound infection in laparoscopic cholecystectomy. A total of 76 patients undergoing laparoscopic cholecystectomy were randomized to either receive an antibiotic or to have their gallbladder removed from the abdomen in a plastic bag. Complicated cases were excluded. There was a total of 6 wound infections (7.9%), 3 in each of the study groups. All these were associated with skin commensals. Bacteriological studies grouped the organisms isolated from the bile and the wound as potential pathogens and likely commensals. A total of 10 potential pathogens were isolated, 9 of which were found in the group receiving antibiotics. They concluded that septic sequelae of uncomplicated laparoscopic cholecystectomy are uncommon, but not entirely prevented by antibiotic or mechanical prophylaxis.
8. Yao CC et al.[62] (2000) reported the use of a simple bag made from a surgical glove to collect specimens; a long purse-string suture surrounds the opening or the base of the glove finger to secure material during retrieval. The authors opined that their method found to be simple and convenient, and necessary construction material is readily available. The bag not only protected the specimen from contact with the wound but also cut short the operating time.
9. Kanehira E et al.[70] (1994) developed a new extraction bag that had a characteristic shape to arrange the stones or fragments in a linear order. To evaluate the efficacy

of the new bag, we conducted in vitro stone extraction experiments and compared the new bag technique with conventional stone removal techniques. Mean experiment time to extract 60 small stones in a conventional technique group was 710 seconds, whereas it was 316 seconds with the new bag technique ($p < 0.001$). With this technique, larger stones are also extracted without extending the parietal incision once they are fragmented in the bag. They suggested the new extraction bag as a simple and safe technique in minimally invasive stone extraction in laparoscopic cholecystectomy.

10. Hofferlin A et al.[14] (1993) described their newly developed instrument for quick and safe extraction of the stone-filled gallbladder. The instrument, called "Bergetrokar", is a trocar cannula with a trumpet valve and cone-shaped tip which can be spread. The application of this device is simple. After using the "Bergetrokar" in about 180 cases, we have not observed any perforation of the gallbladder or loss of stones. They observed that extraction times were reduced.

MATERIALS AND METHODS

Study site: This study was conducted in the Department of general surgery, Dr. Prabhaker Kore hospital, KLE, Belgavi

Study population: All the patients who are admitted and undergoing laparoscopic cholecystectomy in the department of general surgery at Dr. Prabhaker Kore hospital, KLE, Belgavi were considered as the study population

Study design: The current study was a randomised single blinded controlled trial.

Sample size: Based on the previous studies published on the subject the sample size was calculated assuming the expected proportion of post-operative infective complications in the study group to 7.9% as per study by Harling R et al.[7] To be able to detect 25% difference between the two study groups, with 80% power of study and 5% one sided alpha error, a total of 30 subjects are required in each group. The sample size was calculated using STATA IC software version 13, to detect difference in the proportion between two groups, using chi square test. To account for non-participation rate and loss to follow up of 10% another 3 subjects were additionally randomized. The final analysis included 30 people in each group.

Randomization: Randomization was done using computer generated random number sequence

Allocation concealment: Allocation concealment was done using Serially Numbered Opaque Sealed Envelope (SNOSE) method

Blinding: Participants were blinded to the intervention. Investigator blinding was not possible

Study duration: The data collection for the study was done between 1st January 2017 to 31st January 2018 for one year.

Inclusion Criteria:

Patients who were admitted and underwent laparoscopic cholecystectomy in the department of general surgery at Dr Prabhakar Kore hospital, KLE, Belgavi and those who have written and informed consent for participation in the study.

Exclusion criteria:

1. Patients with known latex allergy.
2. Patients with deranged coagulopathy
3. Patients with significant other co-morbidities, in whom ejection fraction is 20% or less, or with COPD
4. Patients diagnosed with peritonitis

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

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

Methodology: After obtaining the informed written consent, Computer generated random numbers by SPSS programme were used to assign the type of intervention chosen for the patients that is, group A (use of powder-free glove bag for extraction of gallbladder specimen) and group B (without the use of glove bag for extraction of gallbladder specimen) The intra-op time taken for withdrawal of the specimen in both groups was measured and compared.

Surgery: Initial procedure of the conventional laparoscopic cholecystectomy is done. A powder-free glove bag is introduced into the peritoneal cavity through the umbilical port, with the help of the instruments, the specimen is carefully placed into the glove bag and retrieved through the umbilical port.

Investigations:

- Routine blood investigations including coagulation profile, USG abdomen and pelvis, CT abdomen wherever applicable.

Intervention:

- Powder-free glove bag was used to retrieve the gallbladder specimen after laparoscopic cholecystectomy.

STATISTICAL METHODS:

Gender, history of complaints, comorbidities, diagnosis, were considered as primary outcome variables. Group was considered as a primary explanatory variable.

All Quantitative variables were checked for a normal distribution within each category of an explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro- wilk test was also conducted to assess normal distribution. Shapiro wilk test p-value of >0.05 was considered as a normal distribution.

For non-normally distributed time taken for removal of the specimen (minutes), the median values were compared between study groups using the Mann-Whitney U test. (2 groups).

The association between group and Gender, history of complaints, comorbidities, associated complications was assessed by cross-tabulation and comparison of percentages. Chi square test was used to test statistical significance.

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis. [71]

RESULTS

A total of 60 people were included in the analysis.

Table 2: Descriptive analysis of group in the study population (N=60)

Group	Frequency	Percentages
Control group	30	50.00%
Study group	30	50.00%

Among the study population, 30 (50%) participants were in control, and 30 (50%) were study group (cases). (Table 2)

Table 3: Comparison of the group with the gender of the study population (N=60)

Gender	Group		Chi square	P-value
	The control group(N=30)	Study group(N=30)		
Male	12 (40%)	12 (40%)	0.000	1.000
Female	18 (60%)	18 (60%)		

Among the control, 12 (40%) participants were male, and 18 (60%) participants were female. Among the study group, 12 (40%) participants were male, and 18 (60%) participants were female. The difference in the proportion of gender between study group was statistically not significant (P value 1.000). (Table 3)

Table 4: Comparison of the group with a history of complaints (N=60)

History of complaints	Group		Chi square	P-value
	Control group (N=30)	Study group (N=30)		
Pain in abdomen				
Yes	28 (93.3%)	30 (100%)	**	*
No	2 (6.7%)	0 (0%)		
Dyspepsia				
Yes	1 (3.3%)	0 (0%)	**	*
No	29 (96.7%)	30 (100%)		
Vomiting				
Yes	8 (26.7%)	7 (23.3%)	0.089	0.766
No	22 (73.3%)	23 (76.7%)		
Fever				
Yes	2 (6.7%)	5 (16.7%)	1.456	0.228
No	28 (93.3%)	25 (83.3%)		
Chills				
Yes	1 (3.3%)	1 (3.3%)	0.000	1.000
No	29 (96.7%)	29 (96.7%)		
Abdominal distension				
Yes	1 (3.3%)	0 (0%)	**	*
No	29 (96.7%)	30 (100%)		
Nausea				
Yes	3 (10%)	3 (10%)	0.000	1.000
No	27 (90%)	27 (90%)		

**Chi square test not applicable.

*No statistical test was applied- due to 0 subjects in the cells.

Among the control, 28 (93.3%) participants had abdomen pain. Among the study group, all of them 30 (100%) participants had abdomen pain. Among the control, 1 (3.3%) participants had dyspepsia. Among the control, 8 (26.7%) participants had vomiting. Among the study group, 7 (23.3%) participants had vomiting. The difference in the proportion of vomiting between the group was statistically not significant (P value 0.766). Among the control, 2 (6.7%) participants

had a fever. Among the study group, 5 (16.70%) participants had a fever. The difference in the proportion of fever between the group was statistically not significant (P value 0.228). Among the control, 1 (3.3%) participants had chills. Among the study group, 1 (3.3%) participants had chills. The difference in the proportion of chills between the group was statistically not significant (P value 1.000). Among the control, 1 (3.3%) participants had abdominal distension. Among the control, 3 (10%) participants had nausea. Among the study group, 3 (10%) participants had nausea. The difference in the proportion of nausea between study group was statistically not significant (P value 1.000). (Table 4)

Table 5: Comparison of the group with a past history of comorbidities (N=60)

Past history comorbidities	Group		Chi square	P-value
	The control group (N=30)	Study group (N=30)		
Hypertension				
Yes	13 (43.3%)	11 (36.7%)	0.278	0.598
No	17 (56.7%)	19 (63.3%)		
Diabetic mellitus				
Yes	7 (23.3%)	12 (40%)	1.926	0.165
No	23 (76.7%)	18 (60%)		
IHD				
Yes	1 (3.3%)	1 (3.3%)	0.000	1.000
No	29 (96.7%)	29 (96.7%)		
Epilepsy				
Yes	1 (3.3%)	0 (0%)	**	*
No	29 (96.7%)	30 (100%)		
Past history Asthma				
Yes	1 (3.3%)	0 (0%)	**	*
No	29 (96.7%)	30 (100%)		
Past history chronic smoker				
Yes	0 (0%)	1 (3.3%)	**	*
No	30 (100%)	29 (96.7%)		

**Chi square test not applicable.

*No statistical test was applied- due to 0 subjects in the cells.

Among the control, 13 (43.3%) participants had hypertension. Among the study group, 11 (36.7%) participants had hypertension. The difference in the proportion of hypertension between the group was statistically not significant (P value 598). Among the control, 7 (23.3%) participants had diabetic mellitus. Among the study group, 12 (40%) participants in diabetic mellitus. The difference in the proportion of diabetic mellitus between the group was statistically not significant (P value 0.165). Among the control, 1 (3.3%) participants had IHD. Among the study

group, 1 (3.3%) participants had IHD. The difference in the proportion of IHD between the group was statistically not significant (P value 1.000). Among the control, 1 (3.3%) participants had epilepsy. Among the control, 1 (3.3%) participants had asthma. Among the study group, 1 (3.3%) participants had a chronic smoker. (Table 5)

6: Descriptive analysis of diagnosis in the study population

Diagnosis	Frequency	Percentages
Cholecystitis	21	35.59%
Cholelithiasis	12	20.33%
Carcinoma of the gallbladder (incidental finding)	4	6.76%
Gangrenous Gallbladder	3	5.08%
Empyema gallbladder	3	5.08%
Gallbladder polyp	2	3.38%
Gallstone pancreatitis	1	1.69%
Mucocele of gallbladder	1	1.69%

The majority of 35.59% participants had Cholecystitis, followed by Cholelithiasis, Carcinoma of the gallbladder, gangrenous gallbladder, empyema gallbladder and gallbladder polyp was 20.33%, 6.76%, 5.08%, 5.08% and 3.38% respectively. (Table 6)

Table 7: Descriptive analysis of procedure done in the study population

Procedure did	Frequency	Per cent
laparoscopic cholecystectomy	51	86.44%
laparoscopic cholecystectomy subtotal cholecystectomy	4	6.67%
ERCP followed by laparoscopic cholecystectomy	2	3.38%
ERCP-Basketting of stone, CBD stent Laparoscopic cholecystectomy	1	1.69%
lap cholecystectomy with laparoscopic hernia repair, meshplasty	1	1.69%
Laparoscopic Cholecystectomy with anatomical repair of a paraumbilical hernia	1	1.69%
Laparoscopic cholecystectomy with adhesiolysis	1	1.69%
Laparoscopic cholecystectomy with biopsy of the liver nodule	1	1.69%
Laparoscopic cholecystectomy with Choledochotomy	1	1.69%
Laparoscopic cholecystectomy with tubectomy, mesh repair	1	1.69%

Majority (86.44%) participants underwent laparoscopic cholecystectomy, followed by laparoscopic subtotal cholecystectomy and ERCP followed by laparoscopic cholecystectomy was 6.67% and 3.38% respectively. (Table 7)

Table 8: Comparison of median time taken for removal specimen between the two groups (N=60)

Parameter	Group		Mann Whitney U Test (P value)
	The control group (N=30)	Study group (N=30)	
Time taken for removal specimen (minutes) **Median (IQR)**	2.05 (1.69, 3.56)	4.25 (3, 7.20)	<0.001

Among the control, the median time taken for removal specimen was 2.05 minutes, it was 4.25 minutes was a study group. The difference in the median time taken for removal specimen between the group was statistically significant (P value <0.001). (Table 8 & Figure 3)

Figure 3: Comparative box plots of Comparison of median time taken for removal specimen between the two groups (N=60)

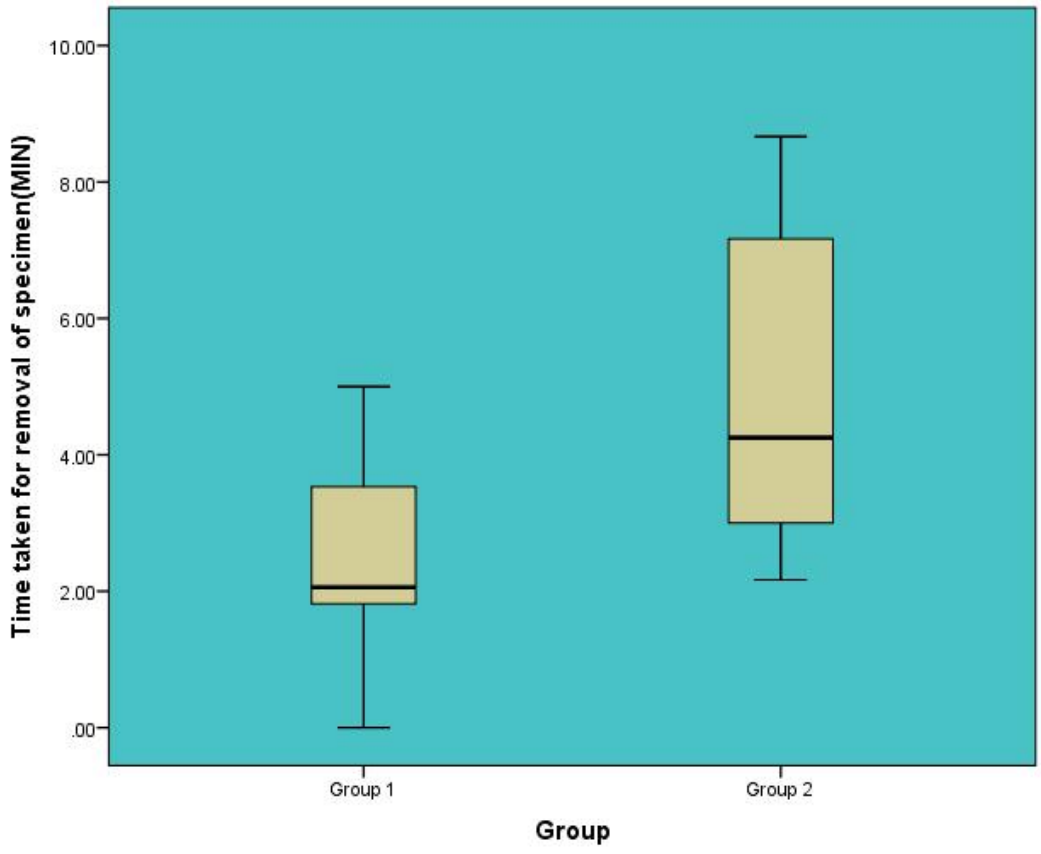


Table 9: Comparison of the group with associated complications (N=41)

Associated complications	Group		Chi square	P-value
	The control group (N=19)	Study group (N=22)		
Yes	13 (68.4%)	7 (31.8%)	5.467	**0.019**
No	6 (31.6%)	15 (68.2%)		

Among the control, 13 (68.4%) participants had associated complications. Among the study group, 7 (31.8%) participants had associated complications. The difference in the proportion of associated complications between the group was statistically significant (P value 0.019). (Table 9)

Table 10: Comparison of the group with associated types of complications (N=41)

Associated complications	Group		Chi square	P-value
	The control group (N=19)	Study group (N=22)		
Extended incision				
Yes	11 (57.9%)	2 (9.1%)	11.21	0.001
No	8 (42.1%)	20 (90.9%)		
Infection				
Yes	5 (26.3%)	1 (4.5%)	3.868	0.049
No	14 (73.7%)	21 (95.5%)		
Intra op bile leak				
Yes	2 (10.5%)	4 (18.2%)	0.478	0.489
No	17 (89.5%)	18 (81.8%)		
Bile drained from GB in glove				
Yes	0 (0%)	1 (4.5%)	**	*
No	19 (100%)	21 (95.5%)		

**Chi square test not applicable.

*No statistical test was applied- due to 0 subjects in the cells.

Among the control, 11 (57.9%) participants had extended incision. Among the study group, 2 (9.1%) participants had an extended incision. The difference in the proportion of extended incision between the group was statistically significant (P value 0.001). Among the control, 5 (26.3%) participants had an infection. Among the study group, 1 (4.5%) participants had infections. The difference in the proportion of infection between the group was statistically significant (P value 0.049). Among the control, 2 (10.5%) participants had intra op bile leak. Among the study group, 4 (18.2%) participants had intra op bile leak. The difference in the proportion of intra op bile leak between the group was statistically not significant (P value 0.489). Among the study group, only 1 (4.5%) participants had bile drained from GB in glove. (Table 10)

DISCUSSION

Gallstone disease is one of the commonly encountered diseases among the general population, and its prevalence is variable in different countries from 10-15%.[36] Surgery for gallbladder removal is the only treatment for gallbladder stones, and until 1986 this surgery was carried out only through open abdominal surgery Some of the complications of open gallbladder removal (open cholecystectomy) are due to the abdominal wall injury. To decrease such problems Flip, more performed the first Laparoscopic Cholecystectomy (LC) in 1987, which is now prevalent. Cholecystectomy is one of most common general elective surgeries.[72]

Laparoscopic cholecystectomy was introduced as the first surgical treatment for symptomatic diseases of gallbladder and its advantages against open cholecystectomy are well described.[73] Laparoscopic cholecystectomy has been established as the most preferred approach in the management of symptomatic gallbladder diseases due to short hospital stay, early recovery, less postoperative pain, good cosmetic results and early return to work. Spilled or implanted gallstones and spillage of infected bile in the peritoneal cavity are common events during LC without using endobag. Spillage of infected bile and gallstones in the peritoneal cavity and retrieval port site with implantation of the gallstones in the subcutaneous tissues of the abdominal wall causing discharging sinus or abscess are reported complications.[74]

The present study demonstrates an easy, safe and cheap method for removal of the gallbladder in LC, which is in agreement with a study by Yano et al.[60] and Holme et al.[4] Overall 60 subjects were included with equal proportion in the control group (50%) and study group (50%). In comparison, Sajid M et al.[75] had included 50 consecutive cases of acute cholecystitis, while a prospective study by AL-Dhahiry[76] carried out at an Iraqi teaching hospital had 306 patients with symptomatic

cholelithiasis. An Iranian retrospective study Amir D et al.[77] between 1999-2005 analysed 426 patients with cholecystitis.

Gender wise the Iraqi study[76] had most of its subjects being females (91.2%) with 8.8% males, so are those reported by Sajid M et al.[75] (females-92%: 8% males). Though the present had a relatively lesser proportion of female participants, still, a higher proportion of females (60%) was noted in relation to males (40%) both in control and study groups. These findings corroborate that the prevalence of cholelithiasis is more common among females.

Among the participants, cholecystitis (35.59%) was the commonest diagnostic condition followed by cholelithiasis (20.33%), gangrenous gallbladder (5.08%) and gallbladder polyp (3.38%). AL-Dhahiry[76] reported that chronic calculous cholecystitis (88.6%) as the most common condition among the subjects, followed by mucocele of the gallbladder (5.9%) and acute episode of chronic acalculous cholecystitis (3.9%).

Comparison of the group with a history of complaints

Among the control group, 93.3% participants had abdomen pain, while the study group, all of them (100%) had abdomen pain.

Dyspepsia was observed in more study participants (26.7%) than those in the control group (3.3%). Among the study group, 7 (23.3%) participants had vomiting. A higher proportion of study participants (16.7%) had fewer than those in controls (6.7%). Among the control, 1 (3.3%) participants had chills. Among the study group, 1 (3.3%) participants had chills. Among the control, 1 (3.3%) participants had abdominal distension. Nausea was reported by an equal proportion of participants in control (10%) and study groups (10%).

Cholelithiasis can be either asymptomatic or symptomatic. Symptoms can be specific including intermittent pains in the right upper quadrant of the abdomen or can be nonspecific as nausea and vomiting.[78]

Majority of participants (86.44%) underwent laparoscopic cholecystectomy, followed by laparoscopic subtotal cholecystectomy (6.67%) and ERCP followed by laparoscopic cholecystectomy (3.38%). Similar to our findings, Sajid M et al.[75] performed laparoscopic cholecystectomy in 92% of patients. Currently, more than 80% of cholecystectomies globally are laparoscopically performed.[79]

Regarding the complications during or after surgery, AL-Dhahiry[76] noted postoperative bile leak among 2% of their cases, while no port site infection, intraperitoneal infection was present in the patients. However, bleeding from the cystic artery was noted in 4.2% of patients, accidental spillage of the gallbladder with/without spillage of stones was seen in 3.6% patients, and perforation of condom endobag during the retrieval of specimens occurred in 3.8% cases. Sajid M et al.[75] noted postoperative bile leak in 2% patients which were due to the minor injury of CBD, which required re-exploration & suturing of the defect and 6% patients developed a wound infection.

Of the 41 participants having surgical complications, a significantly higher (P = 0.019) proportion of them were present in the control group (68.4%) in relation to the study group (31.8%).

A significantly higher (P = 0.001) proportion of controls (57.9%) had extended incision than the study group (9.1%) participants. Contrastingly Majid et al.[80] noted that among 9.7% (36) patients who required an extended incision, 75% (27) of them belonged those in whom retrieval bag was used.

Among the control, 26.3% participants had an infection while in the study group only one participant (4.5%) had an infection and the difference was statistically significant (P = 0.049). Concurring this is the findings from Majid et al.[80] who found that among those post LC surgery patients with superficial wound infections, 57% patients were in the group in whom retrieval bag was not used compared with those in whom retrieval bag was used (43%). Wound infections can be prevented by; appropriate administration of antibiotic prophylaxis, sterile techniques and the use of specimen endobags for specimen extraction.[81]

Bile leakage and biliary peritonitis after open cholecystectomy are rare, but its rate increases in Machado et al.[64] reported that nearly 50% of the cases with complications had bile leakage, while Amir D et al.[77] reported in 1.4% of patients. However, in our study, a higher proportion of bile leak was noted during the operation. This was more participants in the study group (18.2%) than the control group (10.5%).

Bile duct injuries are the most serious complication of LC. Although no significant difference has been reported in the rate of bile duct injury between open and laparoscopic cholecystectomy, injuries are more frequent in LC than open surgery, and this rate is variable from almost 1% in LC to 0.5% in open cholecystectomy. However, special attention must be paid to the high rate of bile duct injuries. For preventing these injuries knowledge on local anatomy during surgery is mandatory.[77]

Unlike primary reports that indicated an increase in the complications rate of LC in comparison to open surgery, recent data shows that LC accounts for less morbidity and mortality compared to open surgery. Mounting evidence suggests that laparoscopic cholecystectomy is an effective and safe technique of treating

symptomatic gallstones even in cases of acute cholecystitis because of accelerated recovery couple with less postoperative pain and short hospital stay.[64, 76, 77]

The study findings reveal that post-operative pain was not significantly different among patients of either group. Concurring with these findings Majid et al.[80] reported that the post-operative pain was not significantly different between the group undergoing LC using a retrieval bag and the group where no bag was used.

Use of endobags not only facilitates collection of operative specimens, spilled gallstones but also minimizes the chances of contamination of the abdominal cavity and the retrieval port site.[5, 81, 82] However, original disposable endobags prices range from 14 -15US$ (endosac, Zenithmedical), and14US$ for (Dexdelac).[83] Endopouch® is one of the commercial endo bags available in India that costs Rs. 3500 per set. In comparison, Gammex® non-powdered gloves cost Rs.80, that can justify their use in the developing country like India, especially in rural areas.

The mean time taken for specimen removal among the study group was significantly (P value <0.001) higher (4.25 minutes) than that of the control group (2.05 minutes). Kirshtein et al.[84] reported similar increase in overall operative time in the drain (endobag) group (42.5 minutes) than the non-drain group (37 minutes) It could be possibly due to delay in using the glove bag, which in turn influenced by the surgeon's inexperience in manoeuvring the glove bag, the need to crush the gallstones before retrieval, the need to drain bile before retrieval, the necessity to remove the specimens without increasing the incision size or combination of all these factors.

The cost of laparoscopic operations often exceeds the cost of the same operations performed in an open fashion due to the expensive disposable equipment used in the former. Bearing in mind that the cost is approximately one Euro for the surgical glove plus suture compared with approximately Euro 10-60 for a disposable commercial

bag, this speaks in favor of the glove and is a way to reduce the costs in connection with LC.[85] In a developing country like India, access and affordability to such high-cost materials can minimize its use, so use of powder-free surgical glove offers a more economical and easily available modality for retrieval of specimens.

Recently, Champault et al.[85] and Holme JB et al.[4] reported how the cost of LC could be reduced from V560 per operation to V330 per operation by not using the expensive disposable equipment. Among other things, in both the studies, a powder-free surgical glove was used for removal of the gallbladder instead of an endobag.

Many surgeons who perform LC use an endobag if they foresee problems with retraction of the gallbladder. They do not use an endobag on a routine basis due to the high cost. For several reasons, we recommend the use of the glove bag as presented in this study on a routine basis. First, it is not always possible to foresee problems with retraction of the gallbladder. It will often be too late to use an endobag if, for example, the gallbladder ruptures during extraction through a small incision. Second, the glove bag is safe, easy to use, and inexpensive. The bag is easily introduced through the trocars and retracted through a small incision. Having retracted the ring of the glove bag, one has the opportunity to suck up bile, crush stones with a forceps, and divide a thick gallbladder, as reported by Kiriakidi.[63] Recently, Machado et al.[64] in a case report described a glove bag with a purse-string suture to close the bag before extraction. It seems that this purse-string suture is unnecessary and excludes the above- mentioned possibilities of handling and extracting heavy stones and thick gallbladders.

It is easier to place the gallbladder and any spilled stones in the glove bag than in an ordinary endo-bag occupying a trocar. The glove bag allows the surgeon to work with two hands because the bag lies free in the abdominal cavity and does not, like an

ordinary endobag, occupy a trocar[2]. Third, gallbladder cancers that are incidentally discovered after LC have the potential for tumor seedings at the port sites.[65] It has, therefore, become the standard practice in many institutions to excise laparoscopic port sites in these patients after the primary operation. Routine use of the glove bag is expected to prevent port site implantation of tumor cells.

Biogel glove used in some studies is hypoallergenic and powder free but not latex free, which is similar to the one used in the present study. In patients with known or suspected latex allergy, a latex-free glove, together with other measures, should be used for the making of the glove bag.[66, 86]

CONCLUSION

- The study has compared the postoperative outcomes between powder-free surgical glove bag and no bag groups, in patients undergoing gallbladder retrieval during laparoscopic cholecystectomy.
- No statistically significant differences were found in any of the demographic and clinical parameters between the two study groups. The prevalence of co-morbidities like diabetes mellitus and hypertension was also comparable between the two groups.
- The most common etiology in the study was Cholecystitis, followed by Cholelithiasis. The other conditions were metastatic adenocarcinoma of gallbladder, gangrenous gallbladder and gallbladder polyp. Laparoscopic cholecystectomy was the most common surgical procedure. A minor portion had prior ERCP, and very few patients had undergone laparoscopic subtotal cholecystectomy. The etiology and surgical procedures were comparable between the two groups.
- The median time taken for removal among the control group was significantly shorter, compared to the intervention group.
- The incidence of complications was significantly lower in intervention groups, as compared to the control group (31.8% Vs 68.4%, P value = 0.019)
- The proportion of participants, which needed extended incision was quite higher among controls, as compared to cases (57.9%) Vs 9.1%, P value 0.001)
- The proportion of people with infection was significantly higher among controls as compared to cases (26.3% Vs 4.5%, P value 0.049)

- Intraoperative bile leak was higher among the intervention group, as compared to controls (18.2% vs 10.5%, P value 0.489). However, the difference was statistically not significant.
- Among the study group, only 1 (4.5%) participants had bile drained from GB in glove.

LIMITATIONS:

1. Investigator blinding was not possible due to the nature of the intervention. Hence the role of ascertainment bias cannot be ruled out from the study.
2. Generalizability of the study findings is limited as the study was conducted in a single center.

RECOMMENDATIONS:

1. There is a need for further large-scale studies on the subject to enhance the quality of available evidence on the subject.

SUMMARY

The study has compared the postoperative outcomes between powder-free surgical glove bag and no bag groups, in patients undergoing gallbladder retrieval during laparoscopic cholecystectomy. The study included 60 participants, who were randomly assigned to either of the treatment groups. No statistically significant differences were found in any of the demographic and clinical parameters between the two study groups. The prevalence of co-morbidities like diabetes mellitus and hypertension was also comparable between the two groups. The most common etiology in the study was Cholecystitis, followed by Cholelithiasis. The other conditions were metastatic adenocarcinoma of gallbladder, gangrenous gallbladder and gallbladder polyp. Laparoscopic cholecystectomy was the most common surgical procedure. A minor portion had prior ERCP, and very few patients had undergone laparoscopic subtotal cholecystectomy. The etiology and surgical procedures were comparable between the two groups. The median time taken for removal among the control group was significantly shorter, compared to the intervention group. The intervention group had longer removal time lower rate of complications and a lower rate of infection. Intraoperative bile leak was slightly higher among the intervention group, but the difference was statistically not significant. Only a minor portion of intervention group people had bile drained from GB in glove.

BIBLIOGRAPHY

1. Litwin DE, Cahan MA. Laparoscopic cholecystectomy, ix. Surg Clin North Am. 2008;88(6):1295-313.
2. Brockmann JG, Kocher T, Senninger NJ, Schurmann GM. Complications due to gallstones lost during laparoscopic cholecystectomy. Surg Endosc. 2002;16(8):1226-32.
3. Sathesh-Kumar T, Saklani AP, Vinayagam R, Blackett RL. Spilled gall stones during laparoscopic cholecystectomy: a review of the literature. Postgrad Med J. 2004;80(940):77-9.
4. Holme JB, Mortensen FV. A powder-free surgical glove bag for retraction of the gallbladder during laparoscopic cholecystectomy. Surg Laparosc Endosc Percutan Tech. 2005;15(4):209-11.
5. Patton JT, Jorgensen JO, Imrie CW. Specimen retrieval in laparoscopic cholecystectomy. Br J Surg. 1997;84(7):957.
6. Drouard F, Delamarre J, Capron JP. Cutaneous seeding of gallbladder cancer after laparoscopic cholecystectomy. N Engl J Med. 1991;325(18):1316.
7. Harling R, Moorjani N, Perry C, MacGowan AP, Thompson MH. A prospective, randomised trial of prophylactic antibiotics versus bag extraction in the prophylaxis of wound infection in laparoscopic cholecystectomy. Ann R Coll Surg Engl. 2000;82(6):408-10.
8. Samel S, Post S, Martell J, Becker H. Clostridial gas gangrene of the abdominal wall after laparoscopic cholecystectomy. J Laparoendosc Adv Surg Tech A. 1997;7(4):245-7.

9. Schellpfeffer MA. A novel laparoscopic tissue retrieval device. JSLS. 2011;15(4):527-32.
10. Upadhyaya M, Sundararajan LS, Woodward MN. Dangerous deliveries: lessons learned during retroperitoneal specimen retrieval. J Pediatr Surg. 2011;46(4):e13-5.
11. Syed Asad Ali, Faisal Ghani Siddiqui. Implanted Gallstones at Port site. World J Min Access Surg. 2013;2(2).
12. Diez J, Arozamena C, Gutierrez L, Bracco J, Mon A, Almeyra RS, et al. Lost stones during laparoscopic cholecystectomy. HPB Surg. 1998;11(2):105-8.
13. Kang KJ, Lim TJ. Tip for microlaparoscopic cholecystectomy: easy removal of the gallbladder after laparoscopic cholecystectomy using the three-port technique. Surg Laparosc Endosc Percutan Tech. 2003;13(2):118-20.
14. Höferlin A, Höhle KD. Our experience with a new instrument for laparoscopic gallbladder extraction, the “Bergetrokar”. Endosc Surg Allied Technol. 1993;1(5-6):320-1.
15. Everhart JE, Ruhl CE. Burden of digestive diseases in the United States Part III: Liver, biliary tract, and pancreas. Gastroenterology. 2009;136(4):1134-44.
16. Everhart JE, Khare M, Hill M, Maurer KR. Prevalence and ethnic differences in gallbladder disease in the United States. Gastroenterology. 1999;117(3):632-9.
17. Festi D, Dormi A, Capodicasa S, Staniscia T, Attili AF, Loria P, et al. Incidence of gallstone disease in Italy: Results from a multicenter, population-based Italian study (the MICOL project). World J Gastroenterol. 2008;14(34):5282-9.
18. Acalovschi M, Dumitrascu D, Caluser I, Ban A. Comparative prevalence of gallstone disease at 100-year interval in a large Romanian town, a necropsy study. Dig Dis Sci. 1987;32(4):354-7.

19. Aerts R, Penninckx F. The burden of gallstone disease in Europe. Aliment Pharmacol Ther. 2003;18 Suppl 3:49-53.
20. Tazuma S. Gallstone disease: Epidemiology, pathogenesis, and classification of biliary stones (common bile duct and intrahepatic). Best Pract Res Clin Gastroenterol. 2006;20(6):1075-83.
21. Nakeeb A, Comuzzie AG, Martin L, Sonnenberg GE, Swartz-Basile D, Kissebah AH, et al. Gallstones: genetics versus environment. Ann Surg. 2002;235(6):842-9.
22. Buch S, Schafmayer C, Volzke H, Becker C, Franke A, von Eller-Eberstein H, et al. A genome-wide association scan identifies the hepatic cholesterol transporter ABCG8 as a susceptibility factor for human gallstone disease. Nat Genet. 2007;39(8):995-9.
23. Finucane MM, Stevens GA, Cowan MJ, Danaei G, Lin JK, Paciorek CJ, et al. Global Burden of Metabolic Risk Factors of Chronic Diseases Collaborating Group (Body Mass Index). National, regional, and global trends in body-mass index since 1980: systematic analysis of health examination surveys and epidemiological studies with 960 country-years and 9.1 million participants. Lancet. 2011;377(9765):557-67.
24. Centers for Disease Control and Prevention (CDC). Vital signs: state-specific obesity prevalence among adults --- United States, 2009. MMWR Morb Mortal Wkly Rep. 2010;59(30):951-5.
25. Danaei G, Finucane MM, Lu Y, Singh GM, Cowan MJ, Paciorek CJ, et al. Global Burden of Metabolic Risk Factors of Chronic Diseases Collaborating Group (Blood Glucose). National, regional, and global trends in fasting plasma glucose and diabetes prevalence since 1980: systematic analysis of health

examination surveys and epidemiological studies with 370 country-years and 2.7 million participants. Lancet. 2011;378(9785):31-40.

26. Biddinger SB, Haas JT, Yu BB, Bezy O, Jing E, Zhang W, et al. Hepatic insulin resistance directly promotes formation of cholesterol gallstones. Nat Med. 2008;14(7):778-82.
27. Chang Y, Sung E, Ryu S, Park YW, Jang YM, Park M. Insulin resistance is associated with gallstones even in non-obese, non-diabetic Korean men. J Korean Med Sci. 2008;23(4):644-50.
28. Loria P, Lonardo A, Lombardini S, Carulli L, Verrone A, Ganazzi D, et al. Gallstone disease in non-alcoholic fatty liver: prevalence and associated factors. J Gastroenterol Hepatol. 2005;20(8):1176-84.
29. Ahlberg J. Serum lipid levels and hyperlipoproteinaemia in gallstone patients. Acta Chir Scand. 1979;145(6):373-7.
30. Leitzmann MF, Rimm EB, Willett WC, Spiegelman D, Grodstein F, Stampfer MJ, et al. Recreational physical activity and the risk of cholecystectomy in women. N Engl J Med. 1999;341(11):777-84.
31. Li X, Gao P. Hepatitis C Virus Infection Increases Risk of Gallstone Disease in Elderly Chinese Patients with Chronic Liver Disease. Sci Rep. 2018;8(1):4636.
32. Kanwal F, Hoang T, Kramer JR, Asch SM, Goetz MB, Zeringue A, et al. Increasing prevalence of HCC and cirrhosis in patients with chronic hepatitis C virus infection. Gastroenterology. 2011;140(4):1182 - 8.e1.
33. Jayanthi V, Sarika S, Varghese J, Vaithiswaran V, Sharma M, Reddy MS, et al. Composition of gallbladder bile in healthy individuals and patients with gallstone disease from north and South India. Indian J Gastroenterol. 2016;35(5):347-53.

34. Chandran AP, Sivarajan R, Srinivasan V, Srinivas M, Jayanthi V. Risk profile for gallstone disease in southern Indian population: is there anything new? Indian J Gastroenterol. 2014;33(3):254-7.
35. Sodhi JS, Zargar SA, Khateeb S, Showkat A, Javid G, Laway BA, et al. Prevalence of gallstone disease in patients with type 2 diabetes and the risk factors in North Indian population: a case control study. Indian J Gastroenterol. 2014;33(6):507-11.
36. Shaffer EA. Gallstone disease: epidemiology of gallbladder stone disease. Best Pract Res Clin Gastroenterol. 2006;20(6):981-96.
37. Jayanthi V, Anand L, Ashok L, Srinivasan V. Dietary factors in pathogenesis of gallstone disease in southern India--a hospital-based case-control study. Indian J Gastroenterol. 2005;24(3):97-9.
38. Chamberlain RS, Sakpal SV. A comprehensive review of single-incision laparoscopic surgery (SILS) and natural orifice transluminal endoscopic surgery (NOTES) techniques for cholecystectomy. J Gastrointest Surg. 2009;13(9):1733-40.
39. Navarra G, Pozza E, Occhionorelli S, Carcoforo P, Donini I. One-wound laparoscopic cholecystectomy. Br J Surg. 1997;84(5):695.
40. Chow A, Purkayastha S, Aziz O, Paraskeva P. Single-incision laparoscopic surgery for cholecystectomy: an evolving technique. Surg Endosc. 2010;24(3):709-14.
41. Edwards C, Bradshaw A, Ahearne P, Dematos P, Humble T, Johnson R, et al. Single-incision laparoscopic cholecystectomy is feasible: initial experience with 80 cases. Surg Endosc. 2010;24(9):2241-7.

42. Curcillo PG, 2nd, Wu AS, Podolsky ER, Graybeal C, Katkhouda N, Saenz A, et al. Single-port-access (SPA) cholecystectomy: a multi-institutional report of the first 297 cases. Surg Endosc. 2010;24(8):1854-60.
43. Schlager A, Khalaileh A, Shussman N, Elazary R, Keidar A, Pikarsky AJ, et al. Providing more through less: current methods of retraction in SIMIS and NOTES cholecystectomy. Surg Endosc. 2010;24(7):1542-6.
44. Hassler KR, Jones MW. Gallbladder, Cholecystectomy, Laparoscopic. StatPearls. Treasure Island (FL): StatPearls Publishing

StatPearls Publishing LLC.; 2018.

45. Jones MW, Deppen JG. Gallbladder, Cholecystectomy, Open. StatPearls. Treasure Island (FL): StatPearls Publishing

StatPearls Publishing LLC.; 2018.

46. Hori T, Oike F, Furuyama H, Machimoto T, Kadokawa Y, Hata T, et al. Protocol for laparoscopic cholecystectomy: Is it rocket science? World J Gastroenterol. 2016;22(47):10287-303.
47. Jabbari Nooghabi A, Hassanpour M, Jangjoo A. Consequences of Lost Gallstones During Laparoscopic Cholecystectomy: A Review Article. Surg Laparosc Endosc Percutan Tech. 2016;26(3):183-92.
48. Loffeld RJ. The consequences of lost gallstones during laparoscopic cholecystectomy. Neth J Med. 2006;64(10):364-6.
49. van der Lugt JC, de Graaf PW, Dallinga RJ, Stassen LP. [Abscess formation due to lost stones during laparoscopic cholecystectomy]. Ned Tijdschr Geneeskd. 2005;149(48):2683-6.

50. Hashimoto M, Matsuda M, Watanabe G. Reduction of the risk of unretrieved stones during laparoscopic cholecystectomy. Hepatogastroenterology. 2003;50(50):326-8.
51. Kao CC, Cha TL, Sun GH, Yu DS, Chen HI, Chang SY, et al. Cost-effective homemade specimen retrieval bag for use in laparoscopic surgery: experience at a single center. Asian J Surg. 2012;35(4):140-3.
52. Clayman RV, Kavoussi LR, Long SR, Dierks SM, Meretyk S, Soper NJ. Laparoscopic nephrectomy: initial report of pelviscopic organ ablation in the pig. J Endourol. 1990;4(3):247-52.
53. Chung S, Li M, Li A. Lost stone during laparoscopic cholecystectomy: retrieval using a condom. HPB Surg. 1993;7(1):67-8.
54. Weber A, Vázquez JA, Valencia S, Cueto J. Retrieval of specimens in laparoscopy using reclosable zipper-type plastic bags: a simple, cheap, and useful method. Surg Laparosc Endosc. 1998;8(6):457-9.
55. Turial S, Schier F. The use of a plastic bag from a drain package instead of an endobag in children: a safe, effective, and economical alternative. Surg Innov. 2010;17(3):269-72.
56. Ganpule AP, Gotov E, Mishra S, Muthu V, Sabnis R, Desai M. Novel cost-effective specimen retrieval bag in laparoscopy: Nadiad bag. Urology. 2010;75(5):1213-6.
57. Stavrou G, Fotiadis K, Panagiotou D, Faitatzidou A, Kotzampassi K. Homemade specimen retrieval bag for laparoscopic cholecystectomy: A solution in the time of fiscal crisis. Asian J Endosc Surg. 2015;8(2):223-5.
58. Espiner H. Endo-bags for gall bladder removal: An overview. Minim Invasive Ther Allied Technol. 1996;5(2):115-20.

59. Kent RB 3rd, Stahl R. Laparoscopic retrieval of spilled stones. Surg Laparosc Endosc 1992;2(2):152-3.
60. Yano H, Okada K, Kinuta M, Iwazawa T, Kanoh T, Monden T. Use of non-powder surgical glove for extraction of gallbladder in laparoscopic cholecystectomy. Dig Endosc. 2003;15(4):315-9.
61. Rolton DJ, Lovegrove RE, Dehn T. Use of a sterile glove as a retrieval bag in laparoscopic surgery. Ann R Coll Surg Engl. 2009;91(5):440.
62. Yao CC, Wong HH, Yang CC, Lin CS, Liu JC. Liberal use of a bag made from a surgical glove during laparoscopic surgery for specimens retrieval. Surg Laparosc Endosc Percutan Tech. 2000;10(4):261-3.
63. Kiriakidi S. Technique for removal of thick-walled gallbladder in laparoscopic cholecystectomy. Surg Endosc. 1999;13(8):828.
64. Machado MA, Herman P. A simple technique for removal of the gallbladder during microlaparoscopic cholecystectomy. Surg Endosc. 2004;18(8):1289-90.
65. Fong Y, Brennan MF, Turnbull A, Colt DG, Blumgart LH. Gallbladder cancer discovered during laparoscopic surgery. Potential for iatrogenic tumor dissemination. Arch Surg. 1993;128(9):1054-6.
66. Swartz J, Braude BM, Gilmour RF, Shandling B, Gold M. Intraoperative anaphylaxis to latex. Can J Anaesth. 1990;37(5):589-92.
67. Robertson D, Lefebvre G, Leyland N, Wolfman W, Allaire C, Awadalla A, et al. CLINICAL PRACTICE GYNAECOLOGY COMMITTEE. Adhesion prevention in gynaecological surgery. J Obstet Gynaecol Can 2010;32(6):598 - 602.
68. Grant J, Davies J, Jones J, Espiner H, Eltringham W. The immunogenicity of starch glove powder and talc. Br J Surg. 1976;63(11):864-6.

69. Judge JM, Stukenborg GJ, Johnston WF, Guilford WH, Slingluff CL, Jr., Hallowell PT. Design, development, and evaluation of a novel retraction device for gallbladder extraction during laparoscopic cholecystectomy. J Gastrointest Surg. 2014;18(2):334-9.
70. Kanehira E, Omura K, Kawai K, Ishikawa N, Watanabe Y. A new extraction bag to facilitate stone extraction in laparoscopic cholecystectomy: in vitro experiments. Endosc Surg Allied Technol. 1994;2(6):297-9.
71. IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.
72. Al-Ghnaniem R, Benjamin I. Long-term outcome of hepaticojejunostomy with routine access loop formation following iatrogenic bile duct injury. Br J Surg. 2002;89(9):1118-24.
73. Lo C-M, Liu C-L, Fan S-T, Lai EC, Wong J. Prospective randomized study of early versus delayed laparoscopic cholecystectomy for acute cholecystitis. Ann Surg. 1998;227(4):461-7.
74. Memon A, Ali S, Soomro A, k Sangrasi A, Siddiqui A. A safe and inexpensive technique of retrieval of gallbladder specimen after laparoscopy. Sci J Med Science. 2013;2(11):219-24.
75. Sajid M, Azim K, Rehman S, Saqib K. Early cholecystectomy; in acute cholecystitis: our experience. Professional Med J 2014;21(1):010-5.
76. AL-Dhahiry JKS. Laparoscopic Cholecystectomy: Retrieval of the Gallbladder Specimen and Spilled Gallstones, Inside a Sterile Male Condom as an Endobag, Reduces the Septic Complications. Iraqi Postgrad Med J. 2015;14(2):209-15.
77. Amir D, Amin N. Frequency of complications due to laparoscopic cholecystectomy in Hamedan Hospitals. J Pak Med Assoc. 2012;62(1):13.

78. Vogt DP. Gallbladder disease: an update on diagnosis and treatment. Cleve Clin J Med. 2002;69(12):977-84.

79. Murphy MM, Shah SA, Simons JP, Csikesz NG, McDade TP, Bodnari A, et al. Predicting major complications after laparoscopic cholecystectomy: a simple risk score. J Gastrointest Surg. 2009;13(11):1929-36.

80. Majid MH, Meshkat B, Kohar H, El Masry S. Specimen retrieval during elective laparoscopic cholecystectomy: is it safe not to use a retrieval bag? BMC Surg. 2016;16(1):64.

81. Sathesh-Kumar T, Saklani A, Vinayagam R, Blackett R. Spilled gall stones during laparoscopic cholecystectomy: a review of the literature. Postgrad Med J 2004;80(940):77-9.

82. Vracko J, Wiechel KL. Why is it necessary to retrieve small bile duct stones at cholecystectomy? Surg Laparosc Endosc Percutan Tech. 1999;9(2):119-23.

83. Bisgaard T, Klarskov B, Trap R, Kehlet H, Rosenberg J. Microlaparoscopic vs conventional laparoscopic cholecystectomy: a prospective randomized double-blind trial. Surg Endosc. 2002;16(3):458-64.

84. Kirshtein B, Bayme M, Bolotin A, Mizrahi S, Lantsberg L. Laparoscopic cholecystectomy for acute cholecystitis in the elderly: is it safe? Surg Laparosc Endosc Percutan Tech. 2008;18(4):334-9.

85. Champault A, Vons C, Dagher I, Amerlinck S, Franco D. Low-cost laparoscopic cholecystectomy. Br J Surg. 2002;89(12):1602-7.

86. Raj P, Katris F, Linderman C, ReMine S. An inexpensive laparoscopic specimen retrieval bag. Surg Endosc. 1998;12(1):83-.

INFORMED CONSENT

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. _____ we are requesting you to enrol yourself in study titled " EFFICACY OF POWDER-FREE SURGICAL GLOVE BAG VS WITHOUT GLOVE BAG FOR RETRIEVAL OF THE GALLBLADDER DURING LAPARASCOPIC CHOLECYSTECTOMY, A ONE YEAR RANDOMISED CONTROLLED STUDY " conducted by Dr. _____ , Post graduate in M.S General Surgery under the guidance of Dr. _____, Department of General Surgery, J.N Medical College, Belgavi under KLE University, Belgavi.

Respected Sir/ Madam, we request you to participate in our study as you are eligible to participating in the study. Your participation in the research is absolutely voluntary. Your decision to participate in the study or otherwise will not affect the relationship with KLE Hospital. If you decide not to participate, you are free to withdraw at any time. During the study your operative outcome will be accessed by some questions which will be answered by your operating surgeon.

PURPOSE OF THE STUDY:

Laparoscopic cholecystectomy, introduced in the late 1980s, has replaced the open technique. Although laparoscopic cholecystectomy is less invasive, requires shorter hospitalizations, and is associated with faster recovery than open cholecystectomy, gall bladder perforation and spillage are the common complications encountered during dissection and removal of gall bladder (25%). However there has been increasing report of infectious complications due to un-retrieved stones and

spillage of bile. Economical sterile surgical gloves or sterile endobag can be used instead of expensive commercial endobags to retrieve the gallbladder specimen and also intra-abdominal spilled stones safely without complications. After laparoscopic cholecystectomy gallbladder specimen is retrieved in an endobag (specimen pouch) usually through umbilical port. Distended gallbladder packed of stones always creates a problem during its retrieval from the abdomen. Gallbladder removal in these cases requires a needle decompression, stone fragmentation and stone removal from the gallbladder near the port site or enlargement of the one of the fascial incision to facilitate gallbladder retrieval, which causes more postoperative port site pain. Original disposable endobags prices range from Rupees 1000-3500 as majority of our patients belongs to low socio-economic status we cannot afford such a high cost. No previous studies have been done to study the ease and efficacy of glove bag in terms of the intra-op time taken. Hence, we wish to evaluate efficacy and cost effectiveness of technique of using sterile glove endobag to retrieve gallbladder along with any anticipated complications.

PROCEDURE INVOLVED:

If you agree to enrol yourself in my study, you will be asked your detailed history. Then you will be clinically examined in detail and routine investigations like HB, TC, DC, PLATELET COUNT, RBS, BLOOD UREA, SERUM CREATININE, BLOOD GROUPING, CHEST XRAY, USG ABDOMEN AND PELVIS, CT ABDOMEN (wherever applicable), ECG will be done accordingly. Computer generated random numbers are used to assign the type of surgery to the patients that is group A and group B.

Two techniques are used in the extraction of gall bladder after laparoscopic cholecystectomy viz. With the use of powder free glove bag (group A) and without the use of a glove bag (group B)

The intra-operative time taken for retrieval of the gall bladder specimen in both groups shall be measured and compared.

Risks and benefits:

There is no increased risk involved in becoming a part of this study and the complications are those that are normally anticipated. This study will help estimate the incidence of post-operative infection rate in the techniques described above. The results derived at the end of study will benefit all similar patients admitted in this hospital.

WITHDRAWAL/ REMOVAL FROM THE STUDY

The participant has freedom to withdraw from the study whenever he/ she wishes and with any prior notice. Even if you decline to participate, there will not be any change in the line of your management or the relationship with your doctor. You will be told about all the new information that affects your decision to participate in this study. The investigator may also exclude a participant from the study at any time.

PRIVACY AND CONFIDENTIALITY:

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

1. In emergency to protect your rights and welfare.

2. If required by law.

INSTITUTIONAL/ SPONSORS POLICY:

If any unforeseen complications or injury occurs during the period of study the participant will be given treatment within limitations of KLE'S Prabhakar Kore hospital general ward.

FINANCIAL INCENTIVES FOR PARTICIPATION:

The participant neither gets any financial incentives during the period of study nor will be asked to pay for the purpose of this study.

AUTHORISATION TO PUBLISH RESULTS:

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

CONTACT DETAILS:

The participant can contact me at any time during the study period for clarification of doubts or any questions. In case of any queries, you can contact the following:

DR. _____

Associate Professor,

Department of surgery,

J.N. Medical College,

KLE University, Belgavi

DR. _____

Post-graduate,

Department of surgery,

J.N Medical College,

KLE University, Belgavi

In case of queries regarding your right as participant you may contact: Chairperson, College ethical dissertation and research committee,

DR. GANGA PILLI,

Professor of pathology,

J.N. Medical College,

KLE University, Belgavi

Ph no: 9480275601

CONSENT STATEMENT:

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

Subject name:

Signature or the Left Thumb Print of subject:

Witness Name: Signature:

Investigators Name: Signature:

Date:

Place:

PROFORMA:

PROFORMA OF CLINICAL EXAMINATION OF INDIVIDUAL PATIENT

NAME:	AGE:
ADDRESS:	IP NO:
SEX:	RELIGION:
EDUCATION:	DATE OF ADMISSION:
OCCUPATION:	DATE OF DISCHARGE

HISTORY:

Onset, quality, duration, aggravating and relieving symptoms:

Associated features: vomiting, loose stools, fever

other complaints:

Past history:

Family history:

GENERAL PHYSICAL EXAMINATION:

Built and nourishment:

Weigh:

Pallor/ icterus/ cyanosis/ clubbing/ oedema/ lymphadenopathy

Vital signs:

P: RR:

BP: Temp:

SYSTEMIC EXAMINATION:

Per Abdomen:

Inspection:

size:

shape:

scars:

Palpation:

Consistency:

Tenderness:

PERCUSSION:

AUSCULTATION:

Respiratory system:

Central Nervous System:

Cardio-Vascular System:

DIAGNOSIS:

PROCEDURE DONE:

USG REPORT:

CT REPORT:

INTRA-OP FINDINGS:

TIME TAKEN FOR REMOVAL OF SPECIMEN:

ASSOCIATED COMPLICATIONS:

ANNEXURE III I- PHOTOGRAPH

Figure 1 A size 6 1/2 glove

Figure 2 Glove tied with free silk to create the bag.

Figure 3 **Glove bag created after the finger end of the glove has been cut off**

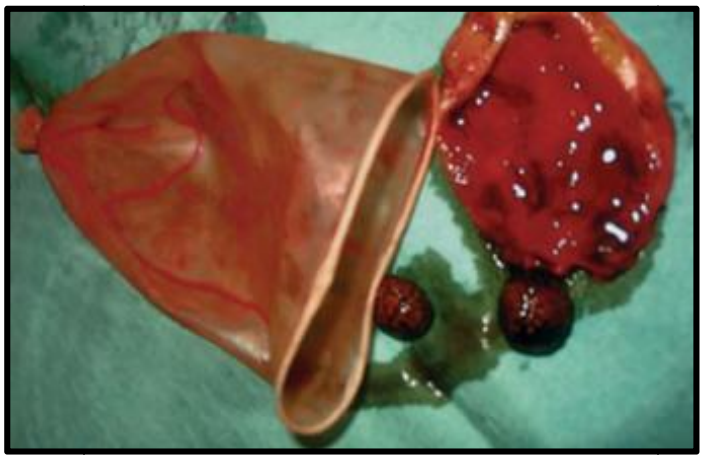
Figure 4 ***Glove bag depicting the rim which keeps the bag open which facilitates easy placement of the specimen***

Figure 5 Specimen retrieval Intra-op

Figure 6 Specimen being delivered through the umbilicus

Figure 7 Stones being crushed and extracted in cases with large stones

Figure 8 Glove bag with retrieved specimen



MASTER CHART

S. No	IP No	Group	Age (in years)	Gender	Religion	Education	Occupation	History of complaints							Past history comorbidities					
								vomiting	Fever	chills	Abdominal distension	Dyspepsia	Pain in abdomen	nausea	Hypertension	Diabetic mellitus	IHD	Epilepsy	Asthma	chronic smoker
1	7,47,221	Group 1	55	Male	Hindu	Higher secondary school	Business	Yes	No	No	No	No	Yes	No	Yes	Yes	No	No	No	No
2	7,49,879	Group 1	57	Female	Christian	Higher secondary school	Business	Yes	Yes	No	No	No	Yes	No	Yes	Yes	No	Yes	No	No
3	7,57,783	Group 1	54	Female	Hindu	NA	House wife	No	No	No	No	No	Yes	No	No	No	No	No	No	No
4	7,61,059	Group 1	26	Male	Hindu	School	House wife	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No
5	7,65,113	Group 1	61	Male	Hindu	Graduation	Business	Yes	No	No	Yes	No	Yes	No	Yes	No	No	No	No	No
6	7,70,508	Group 1	68	Female	Muslim	Graduation	Business	No	No	No	No	No	Yes	Yes	Yes	No	No	No	Yes	No
7	7,71,289	Group 1	34	Female	Hindu	Graduation	office manager	No	No	No	No	No	Yes	No	No	No	No	No	No	No
8	7,75,441	Group 1	42	Male	Hindu	Graduation	Engineer	Yes	No	No	No	No	Yes	No	Yes	No	No	No	No	No
9	7,77,332	Group 1	60	Male	Hindu	Higher secondary school	House wife	No	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No
10	7,83,811	Group 1	57	Female	Hindu	NA	House wife	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No
11	7,91,742	Group 1	56	Female	Hindu	NA	House wife	No	No	No	No	No	Yes	No	No	No	No	No	No	No
12	7,94,417	Group 1	38	Male	Hindu	Graduation	Business	No	No	No	No	No	Yes	No	No	No	No	No	No	No
13	7,95,826	Group 1	54	Male	Hindu	Graduation	Business	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No
14	7,96,937	Group 1	45	Female	Hindu	Higher secondary school	House wife	No	No	No	No	No	Yes	No	No	No	No	No	No	No
15	7,97,955	Group 1	75	Female	Hindu	NA	House wife	Yes	No	No	No	Yes	Yes	Yes	Yes	No	No	No	No	No
16	8,04,663	Group 1	62	Female	Hindu	NA	House wife	No	No	No	No	No	Yes	No	Yes	Yes	Yes	No	No	No
17	8,13,849	Group 1	57	Female	Hindu	NA	House wife	Yes	No	No	No	No	Yes	No	Yes	Yes	No	No	No	No
18	8,15,371	Group 1	47	Female	Muslim	Higher secondary school	NA	No	No	No	No	No	Yes	No	No	No	No	No	No	No
19	8,20,405	Group 1	75	Female	Hindu	NA	House wife	No	No	No	No	No	Yes	No	No	No	No	No	No	No
20	8,21,224	Group 1	39	Female	Hindu	Higher secondary school	House wife	No	No	No	No	No	Yes	No	No	No	No	No	No	No
21	8,21,340	Group 1	57	Male	Hindu	Master graduation	Business	No	Yes	Yes	No	No	Yes	No	No	Yes	No	No	No	No
22	8,23,403	Group 1	42	Male	Muslim	Graduation	Business	No	No	No	No	No	Yes	No	No	No	No	No	No	No
23	8,51,654	Group 1	29	Female	Hindu	Graduation	Teacher	No	No	No	No	No	No	No	No	No	No	No	No	No
24	8,55,612	Group 1	62	Male	Hindu	Graduation	Retired	No	No	No	No	No	Yes	No	Yes	Yes	No	No	No	No
25	7,46,592	Group 1	38	Female	Hindu	Graduation	House wife	No	No	No	No	No	Yes	No	No	No	No	No	No	No
26	7,57,626	Group 1	42	Female	Hindu	Graduation	House wife	No	No	No	No	No	Yes	No	No	No	No	No	No	No

27	7,57,126	Group 1	76	Male	Hindu	NA	Farmer	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No
28	7,56,145	Group 1	49	Male	Hindu	Graduation	Business	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No
29	7,48,513	Group 1	26	Female	Hindu	Graduation	Lab assistant	No	No	No	No	No	Yes	No	No	No	No	No	No	No
30	7,47,561	Group 1	32	Female	Hindu	Graduation	Teacher	No	No	No	No	No	Yes	No	No	No	No	No	No	No
31	7,44,329	Group 2	60	Female	Hindu	Higher secondary school	NA	No	No	No	No	No	Yes	No	Yes	Yes	No	No	No	No
32	7,45,854	Group 2	43	Female	Hindu	NA	House wife	No	No	No	No	No	Yes	No	No	No	No	No	No	No
33	7,48,537	Group 2	22	Male	Muslim	Higher secondary school	Student	No	No	No	No	No	Yes	No	No	No	No	No	No	No
34	7,55,484	Group 2	20	Female	Hindu	Higher secondary school	Student	No	No	No	No	No	Yes	No	No	No	No	No	No	No
35	7,77,778	Group 2	58	Male	Hindu	NA	Farmer	No	No	No	No	No	Yes	No	No	No	No	No	No	No
36	7,99,728	Group 2	55	Female	Hindu	NA	House wife	No	No	No	No	No	Yes	No	Yes	Yes	No	No	No	No
37	8,00,358	Group 2	68	Female	Hindu	NA	House wife	No	No	No	No	No	Yes	No	Yes	Yes	No	No	No	No
38	8,02,754	Group 2	61	Male	Muslim	NA	Farmer	Yes	Yes	No	No	No	Yes	No	Yes	Yes	Yes	No	No	No
39	8,05,960	Group 2	35	Female	Hindu	NA	House wife	Yes	No	No	No	No	Yes	Yes	No	No	No	No	No	No
40	8,11,868	Group 2	52	Male	Hindu	Graduation	Business	No	No	No	No	No	Yes	No	No	No	No	No	No	No
41	8,14,100	Group 2	20	Female	Hindu	Higher secondary school	Student	No	No	No	No	No	Yes	No	No	No	No	No	No	No
42	8,19,251	Group 2	62	Male	Hindu	Graduation	Business	Yes	Yes	No	No	No	Yes	No	Yes	No	No	No	No	Yes
43	8,19,487	Group 2	24	Female	Hindu	Graduation	Secretary	No	No	No	No	No	Yes	Yes	No	No	No	No	No	No
44	8,19,829	Group 2	58	Female	Hindu	Higher secondary school	House wife	No	Yes	No	No	No	Yes	No	Yes	Yes	No	No	No	No
45	8,22,003	Group 2	24	Male	Hindu	Graduation	Engineer	No	No	No	No	No	Yes	No	No	No	No	No	No	No
46	8,23,253	Group 2	57	Male	Hindu	Graduation	Engineer	Yes	No	No	No	No	Yes	No	No	Yes	No	No	No	No
47	8,23,599	Group 2	46	Male	Hindu	Higher secondary school	Business	No	No	No	No	No	Yes	Yes	Yes	No	No	No	No	No
48	8,23,802	Group 2	70	Female	Hindu	NA	House wife	Yes	No	No	No	No	Yes	No	Yes	Yes	No	No	No	No
49	8,24,395	Group 2	31	Female	Muslim	Higher secondary school	House wife	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No
50	8,24,415	Group 2	75	Female	Hindu	NA	House wife	No	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No
51	8,11,526	Group 2	65	Female	Hindu	NA	House wife	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No
52	8,55,117	Group 2	46	Female	Hindu	Graduation	House wife	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No
53	9,15,006	Group 2	29	Female	Muslim	Higher secondary school	House wife	No	No	No	No	No	Yes	No	No	No	No	No	No	No
54	8,11,300	Group 2	62	Female	Hindu	NA	House wife	Yes	No	No	No	No	Yes	No	Yes	Yes	No	No	No	No
55	8,25,277	Group 2	56	Male	Hindu	NA	Farmer	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No
56	8,25,412	Group 2	29	Male	Hindu	Graduation	Administrator	No	No	No	No	No	Yes	No	No	No	No	No	No	No
57	8,15,612	Group 2	56	Male	Hindu	NA	Farmer	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No
58	7,56,175	Group 2	30	Female	Hindu	Graduation	House wife	No	No	No	No	No	Yes	No	No	No	No	No	No	No
59	7,98,156	Group 2	38	Male	Hindu	NA	Farmer	No	No	No	No	No	Yes	No	No	No	No	No	No	No
60	7,47,113	Group 2	52	Female	Hindu	NA	House wife	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No

S. No	Procedure done	USG report	CT report	Time taken for removal of specimen (MIN)	Associated complications	Associated complications						Diagnosis							
						DM	HTN	Extended incision	infection	intra op bile leak	bile drained from GB in glove	Cholecystitis	Cholelithiasis	Carcinoma of gall bladder (incidental finding)	Gangrenous Gallbladder	Empyema gallbladder	Gallbladder polyp	Gall stone pancreatitis	Mucocele of gall bladder
1	laparoscopic cholecystectomy, anatomical repair of paraumbilical Hermia	Calculous cholecystitis, paraumbilical	NA	3.00	NA	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No
2	laparoscopic cholecystectomy & adhesiolysis	Incisional hernia & calculous cholecystitis	NA	4.12	NA	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No
3	lap cholecystectomy	Cholelithiasis	NA	3.53	Yes	No	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No
4	lap cholecystectomy	Cholelithiasis & annular pancreas	NA	2.12	NA	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No
5	lap cholecystectomy	Calculous cholecystitis	Perforated GB, empyema, Calculous cholecystitis	5.00	Yes	No	No	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No
6	lap cholecystectomy	Calculous cholecystitis	NA	4.00	Yes	No	Yes	Yes	No	Yes	No	Yes	No	No	No	No	No	No	No
7	laparoscopic cholecystectomy, tubectomy, mesh repair	calculous cholecystitis, incisional hernia	NA	2.33	NA	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No
8	lap cholecystectomy	cholecystitis	NA	0.67	NA	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No
9	lap cholecystectomy	cholecystitis	NA	1.00	NA	No	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No
10	lap cholecystectomy	Calculous cholecystitis	NA	2.00	Yes	No	Yes	Yes	No	No	No	Yes	No	No	No	No	No	No	No
11	lap cholecystectomy	Cholelithiasis	NA	0.67	NA	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No
12	lap cholecystectomy	Cholelithiasis	NA	1.00	NA	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No
13	laparoscopic cholecystectomy	Calculous cholecystitis	NA	4.00	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No
14	laparoscopic cholecystectomy	Calculous cholecystitis	NA	2.00	NA	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No
15	laparoscopic cholecystectomy	Chronic Calculous cholecystitis	Chronic Calculous cholecystitis, Distal CBD stricture, fatty liver	3.00	Yes	No	No	Yes	No	No	No	Yes	No	No	Yes	No	No	No	No
16	lap cholecystectomy	Calculous cholecystitis	NA	3.00	NA	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No
17	ERCP-Basketting of stone, CBD stent laparoscopic cholecystectomy	Dilated GB, Dilated CBD, CBD store noted	Gall stone induced pancreatitis, empyema gallbladder, CBD calculi	5.00	Yes	No	No	No	Yes	Yes	No	No	No	No	No	Yes	No	No	No
18	NA	NA	NA	0.00	NA	No	No	No	No	No	No	No	No	No	No	No	No	No	No
19	laparoscopic cholecystectomy	Gangrene of gall bladder, cholelithiasis	NA	3.33	Yes	No	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No

20	laparoscopic cholecystectomy	Cholelithiasis	NA	1.33	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
21	laparoscopic cholecystectomy, Therapeutic ERCP	Calculous cholecystitis, CBD calculi	NA	3.67	Yes	Yes	No	No	Yes	No	No	Yes	No	Yes	No	No	No	No	No
22	laparoscopic cholecystectomy	Cholelithiasis	NA	1.83	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No
23	laparoscopic cholecystectomy	Cholelithiasis	NA	2.00	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
24	laparoscopic cholecystectomy	Cholelithiasis	NA	2.00	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No
25	laparoscopic cholecystectomy	Cholelithiasis	NA	1.82	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
26	laparoscopic cholecystectomy	Cholelithiasis fatty liver	NA	2.00	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
27	ERCP followed by laparoscopic cholecystectomy	Cholelithiasis, CBD store & dilation	NA	5.00	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No
28	laparoscopic cholecystectomy	Cholelithiasis fatty liver	NA	2.00	Yes	No	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No
29	laparoscopic cholecystectomy	Cholelithiasis	NA	3.50	Yes	No	No	Yes	No	No	No	No	Yes	No	No	No	No	No	No
30	laparoscopic cholecystectomy	Cholelithiasis fatty liver	NA	0.00	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No
31	laparoscopic cholecystectomy	Cholelithiasis	NA	7.33	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No
32	laparoscopic cholecystectomy	empyema of gallbladder	NA	8.67	NA	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No
33	laparoscopic cholecystectomy	Cholelithiasis	NA	4.17	NA	No	No	No	No	No	No	Yes	No	No	No	No	No	Yes	No
34	laparoscopic cholecystectomy	Cholelithiasis single line fetus	NA	5.67	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No
35	laparoscopic cholecystectomy	Cholelithiasis fatty liver	NA	4.50	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No
36		Finger like projection noted in gall bladder	NA	5.17	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No
37	laparoscopic subtotal cholecystectomy	Cholelithiasis	NA	5.33	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No
38	laparoscopic subtotal cholecystectomy	Perforated gall bladder, Calculi	NA	7.50	Yes	No	No	No	No	Yes	No	Yes	No	No	No	Yes	No	No	No
39	laparoscopic cholecystectomy, choledochotomy	Acute Cholelithiasis, dilated CBD	NA	3.83	NA	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No
40	laparoscopic cholecystectomy	Fatty liver & Cholelithiasis	NA	4.33	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No
41	laparoscopic cholecystectomy	Cholelithiasis	NA	3.67	NA	No	No	No	No	No	No	No	No	No	No	No	No	No	No
42	laparoscopic cholecystectomy	Finger like projection noted in gall bladder	NA	6.33	NA	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No
43	laparoscopic cholecystectomy	Cholelithiasis	NA	2.17	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No
44	lap cholecystectomy with laparoscopic hernia repair, meshplasty	Incisional hernia, Cholelithiasis	NA	8.00	NA	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No
45	laparoscopic cholecystectomy	Cholelithiasis	NA	4.33	Yes	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No
46	laparoscopic cholecystectomy	Empyema Gall Bladder	NA	8.33	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No
47	laparoscopic cholecystectomy	Cholelithiasis	NA	3.17	NA	No	No	No	No	No	No	No	No	No	No	No	No	No	No
48	laparoscopic cholecystectomy subtotal cholecystectomy,	Gangrenous Gall bladder, multiple stores	NA	7.63	Yes	No	No	No	Yes	Yes	No	No	No	Yes	Yes	No	No	No	No

	biopsy of liver nodule																		
49	laparoscopic cholecystectomy	Dilated GB, stone	NA	8.17	Yes	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	Yes
50	Laparoscopic sub total cholecystectomy	Gangrenous Gall bladder	NA	7.17	NA	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No
51	laparoscopic cholecystectomy	Cholelithiasis	NA	3.00	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No
52	laparoscopic cholecystectomy	Cholelithiasis	NA	2.33	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No
53	laparoscopic cholecystectomy	Cholelithiasis	NA	3.00	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No
54	laparoscopic cholecystectomy	Cholelithiasis	NA	2.65	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No
55	laparoscopic cholecystectomy	Cholelithiasis	NA	2.98	No	Yes	No	No	No	No	No	No	Yes	No	No	No	No	No	No
56	laparoscopic cholecystectomy	Cholelithiasis	NA	3.00	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No
57	laparoscopic cholecystectomy	Cholelithiasis	NA	4.00	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No
58	laparoscopic cholecystectomy	Cholelithiasis	NA	2.33	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No
59	laparoscopic cholecystectomy	Cholelithiasis	NA	2.50	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No
60	laparoscopic cholecystectomy	Cholelithiasis	NA	4.17	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No