

Original Research Article

Outcome of spillage of gallbladder contents during laparoscopic cholecystectomy: a case control study

Ruhul Amin¹, Mir Rasekh Alam Ovi^{2*}, Shamima Nasrin³

¹Department of Plastic Surgery, DMCH, Dhaka, Bangladesh

²Department of Surgery, BSMMU, Bangladesh

³Department of Surgery, AKMMC, Bangladesh

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*Correspondence:

Dr. Mir Rasekh Alam Ovi,

E-mail: ovidmc@gmail.com

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ABSTRACT

Background: Bile leakage due to many causes are common during laparoscopic cholecystectomy (LC). We sought to determine prospectively the incidence of gallbladder perforation during LC and to ascertain whether or not spillage of gallbladder contents resulted in overt complications.

Methods: Between July 2013 to December 2013, 120 patients underwent LC participated in this study. All patient's pre-operative ultrasonogram reports were collected. Of the 120 patients, 53 patients had spillage of gallbladder contents due to intra operative perforation. Per operative data were collected. Bile sample of all the hundred twenty patients were sent for culture and sensitivity. All patients were followed-up for two weeks post operatively.

Results: Compared with those without GB perforation, there was a larger percentage of men (41.5%) in the spillage group. Spillage also common in patients having acute cholecystitis (32%), pigment stones (26 out of 38 pigment stone), multiple number of stones (77.3%), positive bile culture (30%). Most common complication was port site wound infections (3 in no. out of 53). There was no difference in post-operative amount or type of analgesia administered, duration of post-operative hospital stays in between two groups.

Conclusions: Perforation of gallbladder and intra peritoneal spillage of bile and stones during LC is still a common incident, but are not associated with undesirable events and are not indications for conversion. When spilled bile is properly aspirated by peritoneal irrigation the operative and post-operative courses are similar to those of patients without spillage of gallbladder contents.

Keyword: Bile spillage, LC, Bile culture, Port infection

INTRODUCTION

Gall stones are the most common abdominal reason for admission to hospital in developed countries and account for an important part of healthcare expenditure. Around 5.5 million people have gall stones in the United Kingdom and over 50,000 cholecystectomies are performed each year.¹ Removing of gallbladder using an upper abdominal incision has been the preferred therapy for gallstone disease since soon after its description in 1882.² The risk of death and major complications from

this operation are low, and cholecystectomy is regarded as the "gold standard" for patients with cholelithiasis.³ However, traditional cholecystectomy causes significant pain and post op disability and results in a cosmetically unappealing scar. From this point of view, LC is now becoming standard of care for surgical treatment of gallbladder disease. Here patient experience less post op pain, earlier hospital discharge and more rapid return to full activity with minimally invasive procedure than open cholecystectomy. In era of microsurgery, LC is the most widely used method for gall bladder disease since it was

introduced in 1987.⁴ Following its establishment as a strong contender of its open counterpart, several published series of laparoscopic cholecystectomies have found overall morbidity of about 5%.^{5,6}

In the performance of LC, the gallbladder itself is used as a retractor to elevate the right lobe of the liver and to gain visualization of porta hepatis. This is done by securing gallbladder with grasping forceps and pushing it in a cephalad direction. After dividing the cystic duct and artery, the gallbladder is removed from its hepatic bed using thermal energy, either laser or electrocautery.^{7,8} One complication that may be occurring more often with this technique is gallbladder perforation and spillage of bile and stones into the peritoneal cavity. Gallbladder perforation is reported in the range of 10%-40% in various series.^{5,6,9,10-12} Several clinical studies showed that necessary gallbladder traction and hepatic fossa dissection lead to these frequent episodes of perforation of gallbladder. Incidence is more common when operating on an acutely inflamed gallbladder in men, the elderly, obese person, in presence of adhesion, positive bile cultures and in those with pigment stones.^{9,10} Spillage of contents of gallbladder during cholecystectomy risks infection, intra-abdominal abscess formation/adhesion with subsequent intestinal obstruction. Intra-abdominal bile may cause peritonitis. These complications are said to occur in 0.08-0.3% of patients.¹³

The fate of iatrogenic gallbladder perforation has provoked several exciting experimental studies, mostly on rats. All of the studies were proceeded by implanting gall stones and bile (both sterile and infected) in the abdomen of rats. The study done by Cline et al suggested spillage of sterile stones should not cause increased morbidity during or after LC.¹⁴ The study done by Zorluoglu et al concluded that the combination of multiple stones and infected bile increased the incidence of adhesions and intra-abdominal abscesses.¹⁵ Another study conducted by Gurleyik et al came to conclusion that chemical composition of the stones has a significant influence on the fate of intra-abdominal gall stones specifically with bilirubinate stones as these stones often contain viable bacteria.^{16,17} The area of concern of these studies is to determine the risk factors and probable complications of intraoperative gallbladder perforation but does not give any clear idea about the effect over patient's outcome. We therefore sought to ascertain the incidence of gallbladder perforation during LC and to determine if spillage of gallbladder contents adversely influences the outcome of patients treated in this fashion.

LC was first reported in Germany (1985) and France (1987) more than two decades ago. Although not immediately universally adopted, LC has revolutionized general surgery. In the early 1990s, there was widespread initial skepticism regarding the benefits of LC, but the number of LCs increased dramatically during these early years driven by the patients demand and the perception that the surgery had lower risk, shorter recovery and less

postoperative pain. By 1992, a national institutes of health consensus statement in North America endorsed LC as a legitimate tool in the surgeon's armamentarium for the treatment of symptomatic cholelithiasis, and 10 years after introduction of LC, 80% of cholecystectomies was done laparoscopically. LC has become the new gold standard for the treatment of symptomatic cholelithiasis. Despite the tremendous impact of LC on the management of biliary pathology, however, surgeons continue to face challenges in the application of LC in daily practice. The above discussion about a general overview of LC has taken from an international paper done by dept' of surgery of university of Massachusetts medical school.¹⁸

A prospective study by dept' of surgery, Washington university school of medicine; the incidence of gall bladder perforation and to ascertain the effect of intraoperative bile leakage.¹⁹ The study revealed that bile leak occurred more in men ($p < 0.01$) and in overweight person ($p < 0.01$). The operating time was longer in patient with gallbladder perforation than in those without it ($p < 0.01$) but there was no difference in postoperative analgesia used, interval to return to full activity or the development of postoperative infections.

Another study by Memon et al, regarding iatrogenic gallbladder perforation during LC.²⁰ The authors of this study analyzed prospectively data from 1059 consecutive LC performed over a 3-year period. The iatrogenic gallbladder perforation was 29%. The factors associated with higher incidence of gallbladder perforation included male gender, increasing age, body weight and the presence of omental adhesions. The study demonstrated that spillage of gallbladder contents is associated with statistically significant incidence of fever and intra-abdominal abscess compared with intact LC. However, the overall risk of serious complications is very low. The authors emphasized the need for removal of as many calculi as possible laparoscopically.

Another recent study done by Kamran et al, predicting iatrogenic gallbladder perforation during LC.²¹ In the study, 17 independent risk factors were examined using multivariate logistic regression analysis on 856 patients undergoing LC by a single surgeon. The study found that the variables male sex, H/O acute cholecystitis and presence of a grossly inflamed gallbladder as seen by the surgeon intra operatively were individually significant ($p < 0.05$). Based on these findings, the study recommends that during the learning curve of LC, surgical trainees should be closely supervised when undertaking this procedure in male patients presenting with acute cholecystitis or having strong H/O of acute cholecystitis.

A study conducted by Hui et al, etiology and sequelae of iatrogenic gallbladder perforation during LC.²² The authors prospectively studied 1412 patients undergoing LC over a 6-year period. Study showed that the most common mechanisms of GB perforation laceration due to grasper traction (55%) and electrocautery dissection

(40%). No difference was observed in the rate of wound infections between spillage and non-spillage group (1.6% vs 1.8%). Study found no late intra-abdominal abscesses or complications attributable to retained gallstones after a long-term follow-up averaging 48 months.

Another recent study by Suk et al published regarding effects of iatrogenic gall bladder perforation on clinical outcomes of LC.²³ This study showed that the mean operative time and duration of hospital stay were longer in perforated group ($p=0.015$ and $p=0.001$). Complications such as ileus and trocar site infection developed more frequently in patients with a gall bladder perforation ($p=0.001$ and $p=0.004$). There was no significant factor related to gall bladder perforation except for male gender ($p=0.017$).

In a recent retrospective study by Schafer et al regarding spilled gallstones after LC.⁵ This study analyzed 10,174 LCs performed at 82 surgical institutions over a 3-year period, the incidence of iatrogenic gallbladder perforation was only 6%, and serious postoperative complications occurred very rarely (0.08%). The authors concluded that elderly patients who have acute cholecystitis with infected bile and spilled stones may experience an increased risk of intra-abdominal abscess formation. Therefore, perforation of the gallbladder should be prevented whenever possible.

The objective of the study was to determine the influence of intraoperative gallbladder contents spillage on the overall outcome of the patient after LC. Besides it helped to compare the presence of predicted risk factors of intraoperative gallbladder contents spillage in between the two groups and to sort out the occurrence of postoperative complications in between the two groups.

METHODS

It was a prospective, case control study conducted in the department of surgery of Dhaka medical college and hospital, Dhaka, Bangladesh in July 2013 to December 2013. Patients underwent LC for cholelithiasis was the study population. Total 284 patient underwent LC in that period. Among them 120 patients were included in study. Cholelithiasis with other biliary disease like carcinoma gallbladder or other site of biliary tract, patients having diabetes (as it increases the chance of infection), severe concomitant conditions like, immunocompromised state like HIV infection, on long steroid therapy, on chemotherapy, history of implant (cardiac stenting) or transplant (kidney, liver); these patients are more prone to develop infection was excluded from the study.

On the basis of per-operative GB perforation these 120 patients are divided into two groups. Group A (Case group): Those with intra-operative GB contents spillage during LC. Group B (Control group): Those without intra-operative GB contents spillage during LC.

Operative procedure

All operations were done under general anesthesia. An 'open' laparoscopic technique to access the peritoneal cavity, insert the primary sub umbilical cannula and establish a pneumoperitoneum. A 30° laparoscope is used for obtaining 'angled' views and for 'looking down' onto Calot's triangle. Standard four ports operation was done by monopolar diathermy. Metallic or plastic clips were used to secure bile duct. Specimens were extracted from the abdominal cavity through the epigastric port.

When spillage of gallbladder content occurred, operative field was irrigated until the aspirate was clear, and an attempted was made to retrieve and remove all gallstones that spilled into abdominal cavity as much as possible.

Data on all patients were obtained in prospective fashion. All patients' ultrasonographic findings were recorded preoperatively. The postoperative findings of the resected gallbladder and the nature of the stone were recorded. Bile was sent for culture and sensitivity. The duration of post-operative hospitalization, type and number of analgesic medications administered, and development of post-operative complications were recorded. Post operative ultrasonogram was done after 48hrs of operation. All patients were followed up post operatively for 2 weeks either by direct interviewing or by conversing over the telephone. Results in the two groups were compared using the Chi-square analysis, and significance was assumed to exist when $p<0.05$. Statistical analysis has been carried out using Statistical Package for Social Science (SPSS) for Windows version 18.0. Ethical clearance was taken from the hospital ethical committee of DMCH).

RESULTS

This study showing that, chance of spillage increases with increasing age ($p<0.05$). The age of patients ranged between 26-67 years in non-spillage group (Mean- 45 ± 3) and between 28-76 years in spillage group (Mean- 51 ± 2).

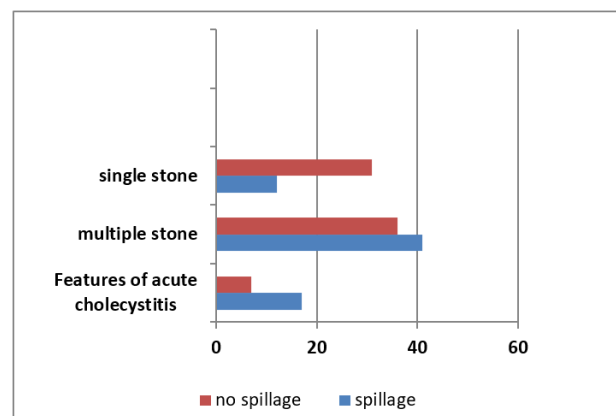


Figure 1: Preoperative sonographic findings.

Table 1: Age incidence of the patients, (n=120).

Age (In years)	Spillage group, n (%)	Non-spillage group, n (%)	Total, n (%)
21-30	2 (28.5)	5 (71.5)	7 (100)
31-40	10 (38.5)	16 (61.5)	26 (100)
41-50	12 (32.5)	25 (67.5)	37 (100)
51-60	19 (54.29)	16 (45.71)	35 (100)
61-70	8 (61.5)	5 (38.5)	13 (100)
71-80	2 (100)	0 (0)	2 (100)
Total	53 (44.16)	67 (55.84)	120 (100)

Comparative pre-operative sonological report analysis shows that, of spillage group:77.3% patients had multiple stone, 22.6% patients had single stone

Table 2: Relation with per-operative findings and spillage.

Variables	Spillage	No spillage
Adhesion	34	16
No adhesion	19	51
Total	53	67

Per-operative findings showed that, 50 patients had adhesion; among which 34 patients developed spillage as showed in Table 2. So, adhesion present more in spillage group (64%) than those of the non-spillage (24%) which is statistically significant ($p=0.002$, <0.05).

Table 3: Post operative macroscopic findings.

Characteristics of stone	Spillage	No spillage	Total
Cholesterol	27	55	82
Pigment	26	12	38
Total	53	67	120

Per operatively we found that 38 patients had pigment stones among those 26 had spillage of GB contents ($p<0.05$) which is clearly greater than those with cholesterol stones (27 spillage out of 82).

Table 4: Post operative evaluation.

Results	Spillage, n (%)	Non-spillage, n (%)
Positive bile culture(a)	16 (30)	7 (10)
Pyrexia	01	0
Wound infections	03 (6)	2 (3)
Postoperative hospital stay (days)	2 $\pm$ 0.03	2 $\pm$ 0.01

Bile cultures were positive in 30% of spillage group and in 10% of non-spillage group ($p=0.047$; <0.05). Post-operative pyrexia develops only one patient in spillage group. Superficial post-operative wound infections

developed in 5.6% of patients with spillage and in 3% of those without spillage of GB contents

DISCUSSION

Laparoscopy has become the procedure of choice for routine cholecystectomy due to its obvious benefits to the patients. It is now offering almost 100% success rate. This technique of minimum access surgery has gained wide acceptance because LC provides to the patients a quicker and comfortable recovery with rapid return to work by reducing the trauma of operative access. So, LC is now a therapeutic reality progressively expanding its horizon. The overall results were favorable, and in experienced hand it is a safe procedure with low morbidity or mortality. Due to its increasing acceptance by both the surgeons and the patients, this surgical procedure has been subjected to a great number of international studies for detailed analysis.

The increasing use of LC in the surgical world is undoubtedly accompanied by the emergence of its associated complications. The most common complication is the iatrogenic perforation of the gallbladder and spillage of bile and stones into the abdominal cavity, which have always been of concern to operating surgeons. Jones et al studying his first 225 elective laparoscopic cholecystectomies, reported an incidence of intraoperative gallbladder perforation of 33%.²⁹ Cuschieri et al summarized the experience of a number of European medical centers with 1236 elective laparoscopic cholecystectomies, and reported an incidence of perforation of 16%.²⁷ Deziel et al presented a survey of 77,604 LC, starting a high incidence of gallbladder perforation and consecutive intra-abdominal stone spillage.²⁸ In his study, six cases were reported in which the loss of stones caused complications, indicating an incidence of 1 out of 13,000. It is clear that LC results in a significant number of gallbladder perforations with contents of spillage. In our study about half (44%) of the gallbladder contents (53 out of 120) spillage occurred. It is my observation that when LC was done by junior surgeons the incidence of intra operative GB perforation was increased, though all were under supervision of an experienced surgeon. During this regard, a study conducted by Barrat et al showed that there was a clear correlation to the skill and experience of the surgeon ($p=0.01$) with the occurrence of intra operative GB perforation.²⁹

The age incidence of the patients divided in decades has been showed in Table 1 ranging between 21 and 80. This study showing that, chance of spillage increases with increasing age ($p<0.05$). The age of the patients ranged between 26-67 years in non-spillage group (Mean-45 $\pm$ 3) and between 28-76 years in spillage group (Mean-51 $\pm$ 2). Rice et al conducted a study on 1059 patients over a 3-year period and found that increasing age was statistically significant ($p<0.05$).¹⁰

Spillage of gallbladder contents can occur during dissection of gallbladder from the liver bed, tearing with the grasping forceps or during extraction of gallbladder through one of the port sites. Brockmann et al in a study found intra operative GB perforation during dissection is 73.5% and during GB removal through port site is 26.5%.³⁰ Another study conducted by Barrat et al showed that GB perforation mostly occurred during dissection (83.3%).²⁹ In our study among the 120 patients, 30 patients were overweight, of which 22 patients developed spillage of GB contents. Over weighted patients are found more in spillage group (41.5%) than in non-spillage group (12%). This study shows no significant relationship between overweight and spillage of GB contents ($p=0.250$, >0.05). Gallbladder content spillage occurred mostly during dissection (60%), while exit from port sites (13%), grasper traction (16%) and others (11%). In the view to find out the relationship between the size of the GB and spillage, we found that of the spillage group about 73.58% had normal sized GB which is smaller in percentage than those of non-spillage group (92.5%). On the other hand, of spillage group 17% had distended and 9% had fibrosed GB, which were greater than those of non-spillage group 4.4% and 4.2% respectively. This study found no significant relationship between the size of the GB with the spillage ($p=0.207$).

Several international studies have done to find out the predisposing factors for intra operative gallbladder perforations and the most common variables are: older age, male sex, presence of pericholecystic adhesion, acute cholecystitis, pigment stone, positive bile culture. We have also found out most of the above variables are predisposing GB perforation.

There were 43 male and 77 female patients included in our study population, among them 22 male patients and 31 female patients had experienced spillage. We found that, spillage of gallbladder contents is more common in male patients (41.5% vs 31.3%). Kamran et al examined seventeen independent risk factors regarding iatrogenic gallbladder perforation using multivariate logistic regression analysis and found that male sex is an independent risk factor for gallbladder perforation ($p<0.05$).²¹ As our study group is small, in which female patients are more. We found gallbladder perforation occurred frequently in male sex but not statistically significant.

Rice et al done a study on 1059 patients over a 3-year period and concluded that intra operative GB perforation occurred more in overweight patients ($p<0.001$; significant).¹⁰ In my study, 22(41.5%) out of 53 spilled patients were overweight ($BMI\geq 25$). As our study dealt with a comparatively small sample size, so we could not find any significant relationship between GB perforation and overweight.

Suk et al have showed that intra operative GB perforation occurred more in case of distended gallbladder

($p=0.001$).²³ In our study, we found that, normal sized GB found more in non-spillage group than in spillage group (92.5% vs 73.58%). On the other hand, perforation found more in distended GB (17% vs 4.4%). The same study also showed that, the number of stone did not predispose GB perforation. In our study, 77.3% patients had multiple stones in spillage group and 54% of those in non-spillage group ($p=\text{not significant}$).

Comparative pre-operative sonological report analysis shows that, of spillage group: 77.3% patients had multiple stone, 22.6% patients had single stone and 32% patients had signs of acute cholecystitis in comparison to those of non-spillage where they had the above variables in 54%, 46%, and 10% respectively. This study shows significant relationship of spillage of GB contents with patient's having features of acute cholecystitis ($p=0.036$).

The incidence of perforation may increase if the gallbladder is acutely inflamed because such a gallbladder is quite fragile and prone to tearing under the stress of traction.^{20,31} Bickel et al and Hutchinson et al have showed that as LC is the treatment of choice for acute cholecystitis in elderly and in male patients, the chance of iatrogenic gallbladder perforation has increased in those two groups.^{32,33} Similarly, our study also found acute cholecystitis as a significant predisposing factor for spillage of gallbladder contents. There were 24 patients having acute cholecystitis included in our study, among which 17 patients had intra operative gallbladder perforation (32%; $p<0.05$).

Per-operative findings showed that, 50 patients had adhesion; among which 34 patients developed spillage as showed in Table 2. So, adhesion present more in spillage group (64%) than those of the non-spillage (24%) which is statistically significant ($p=0.002$, <0.05). Suk et al on 198 patients, where they found that Pericholecystic adhesion was a significant risk factor for intra operative GB perforation ($p=0.025$; significant).²³

According to epidemiological studies, pigment stones are found less than 20% in patients of gallstone disease.³⁴ In pigment stones, bacterial contamination is present in 83% as compared to 33% in cholesterol stones.^{17,35} Again, pigment stones dissolved faster than cholesterol stones and thus might release bacteria faster. Thus, pigment stones appear to have a high potential for developing complications if spillage occur. Several studies showed that, pigment type of stone have been found almost 90% in case of gallbladder spillage. Gurleyik et al concluded that chemical composition of gallstones plays a major role regarding spillage.¹⁶ Another study done by Kimura et al where they found that, there was a significant correlation ship between pigment stone and GB perforation ($p<0.02$).¹² In the present study, per operatively we found that 38 patients had pigment stones among those 26 had spillage of GB contents ($p<0.05$) which is clearly greater than those with cholesterol stones (27 spillage out of 82).

Kimura et al showed that intraoperative gallbladder perforation was more frequent in patients with positive bile culture ($p < 0.02$).¹² In our study, 23 out of 120 patients had positive bile cultures, 30% in the spillage group and 10% in those without spillage of gallbladder contents ($p = 0.047$, < 0.05). Despite this finding, superficial wound infections (port sites) were infrequent, being apparent in only 5.6 % of the patients. These port sites infection was managed with local care as outpatients. Hui et al showed there was no difference in development of wound infections between intra operative gallbladder contents spillage and non-spillage (1.6% versus 1.8%).²² The incidence of wound infections was lower as all of our patients received per and post operative antibiotics irrespective of gallbladder contents spillage. Suk et al suggested that, trocar sites infection in GB perforated group could be lowered by using prophylactic peri-operative antibiotics.²³

In our study only one patient developed post operative pyrexia in spillage group. This pyrexia was developed on second post operative day, stayed only for 24 hours and remitted by using antipyretic drug. The use of peri-operative antibiotic as I mentioned above, may also played a vital role in reducing post operative pyrexia. Rice et al showed that post operatively pyrexia was more common in patients with spillage of gallbladder contents (18% vs. 9%; $p < 0.001$).¹⁰

Spillage of gallbladder contents did not cause any untoward early complications. Post operative pain (as measured by the amount and type of analgesics administered) and duration of post-operative hospital stay were virtually identical in the two groups. As spillage occurred intra operatively, the operating surgeons have made an effort to remove all spilled calculi, but small stones have undoubtedly been left in the abdominal cavity. But no significant post operative complications have been resulted during the short follow-up period, and no change found in sonological findings performed 48 hours following operation. A number of retrospective and prospective clinical studies have been undertaken to determine the potential consequence of spilled gallstones in the abdominal cavity. Soper and Dunnegan and Schafer et al who analyzed 10,174 laparoscopic cholecystectomies performed at 82 surgical institutions over a 3-year period and their findings showed that the mortality rate and the incidence of serious complications of retained gallstones are extremely low.^{5,36} Bile cultures were positive in 30% of spillage group and in 10% of non-spillage group ($p = 0.047$; < 0.05).

Post-operative pyrexia develops only one patient in spillage group. Superficial post-operative wound infections developed in 5.6% of patients with spillage and in 3% of those without spillage of GB contents. The duration of post-operative hospital stay was near identical in the two groups. Post-operative intra-abdominal infections did not occur in any of the 120 patients treated by LC.

Limitations

There were some limitations in this study, most important of them is the small study sample. As only patients with cholelithiasis were selected for this study excluding other biliary disease (choledocholithiasis, GB malignancy, patients with significant co-morbidity or infections); it significantly reduced my study sample. Also, it was conducted in a single institution within a six months period, the sample population was chosen to be minimum hundred twenty (120) patients. For this small sample size, some of the observations are likely to be affected, though they are statistically valid according to various international studies. Development of post operative wound infection has might been biased as all of the study population were under coverage of peri-operative prophylactic antibiotics. Late complications followed by spillage of gallbladder could not be evaluated as the period of follow-up was short (only 2 weeks). Studies with larger population with longer period of follow up is needed to evaluate the actual outcome of spillage of GB contents during LC.

CONCLUSION

LC has become the ideal treatment procedure for gallbladder disease. But the procedure is facing intra operative gallbladder perforation as its main technical complications; it needs to clarify the actual outcome of spillage of gallbladder contents and to find out the possible way to reduce it. We have prospectively studied 120 patients underwent LC and found a considerable number from this people experienced gallbladder perforation and spillage of its contents. The incidence was commonly found in older age, male sex, overweight patients, acute cholecystitis, multiple stones, pigment stone and presence of peri-cholecystic adhesion. Despite the large number of patients having spillage, serious post operative complications did not occur.

So, spillage of gallbladder contents during LC is not a serious problem that can make surgeons worried. If spillage occurs, retrieve of lost stones followed by irrigation of spilled bile is enough to reduce the chance of development of post operative complications.

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