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Gallbladder Perforation during Elective Laparoscopic Cholecystectomy: Incidence, Risk Factors, and Short-term Outcomes in Sana'a City, Yemen

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Abstract:

Background: Gallbladder perforation (GP), which has been documented to occur with a high incidence after cholecystectomy, is a common intraoperative complication.

Objectives:

The research aimed to determine the incidence, risk factors, and short-term outcomes of gallbladder perforation (GP) after elective laparoscopic cholecystectomy.

Methods: This prospective observational study was conducted at Kuwait University Hospital and 48 Model Hospital in Sana'a, Yemen, from January to December 2022. A structured online questionnaire was used to gather the data. The presence of gallbladder perforation led to the division of patients into two groups. SPSS version 26 was used to analyze incidence, potential risk factors, and short-term outcomes.

Results: This study included 130 cases, with a mean age of 43.42 ± 12.724. Compared to men, women made up the majority of cases (84.6% vs. 15.4%). The GP was noticed in 34 of 130 cases, with a 26.2% incidence rate. Significant risk factors for GP were mean age > 43 years (P = 0.000), obesity (BMI > 30 kg/m2) (P = 0.02), and ASA grades (P = 0.000). Comorbidities, including IHD, HTN, and DM, were associated with an increased incidence of GP (P = 0.05). A significant risk was also linked to previous hospitalizations for acute cholecystitis, elevated alkaline phosphate levels, and leukocytosis (P = 0.009). The presence of adhesions and a difficult dissection as described by the Cushier scale (P = 0.02), as well as ultrasound findings of a distended gallbladder, the presence of sludge, and multiple gallbladder stones, were all significantly linked with GP (P = 0.000). Comparing the perforated group to the non-perforated group regarding the short-term outcomes, in the perforated group there was a significant increase in operative time (P = 0.000), length of hospital stay (P = 0.00), duration of post-operative ileus (P = 0.000), and the rate of postoperative complications.

Conclusions: According to this study, the incidence rate of GP was high and comparable to the reported incidence worldwide. Multiple risk factors can influence the GP during elective laparoscopic cholecystectomy. Gallbladder perforation can adversely affect the outcome and increase the complication rate of the operation. Multiple studies performed in different high- and low-volume centers shared similar results about some risk factors for GP but differed in the results of other risk factors, as revealed by our study. This may indicate that the volume of procedures performed is critical for achieving better outcomes in future studies. We believe that additional prospective randomized controlled studies on controllable surgery-related factors and long-term outcome can be performed using a complementary study design.

Keywords: elective laparoscopic cholecystectomy, gallbladder perforation, incidence, risk factors, short-term outcomes.

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Introduction

Cholecystectomy is the second-most frequent abdominal procedure in general surgery [1, 2]. In comparison to the traditional procedure, laparoscopic cholecystectomy provides some benefits, such as better cosmetic outcomes, less postoperative pain, a shorter hospital stay, and an earlier return to normal activities [3]. Additionally, cholecystectomy is not without danger and may result in serious side effects such as pancreatitis, hemorrhage, abscess, and bile duct injury. A high incidence of 10%–33% gallbladder perforation (GP), a frequent risk factor, and intraoperative complications following cholecystectomy have been documented [4–9].

According to some research, the risk of GP is increased by male sex, a history of acute cholecystitis or prior laparotomies, a distended gallbladder, an inflammatory or non-visualized gallbladder, and a difficult surgery [5–7]. Additionally, it has only occasionally been documented that bile and stone leakage cause serious issues [10–15]. However, it has been noted that lost stones following GP may sporadically result in secondary complications, such as pain, fever, or intra-abdominal abscesses; because they are a potential source of infection and bile spillage may result in chemical peritonitis [4, 10–16].

However, GPs do not worsen the outcome of the procedure, according to some literature [10–15]. Most of the information in that literature may be false because it is largely based on retrospective data, and it is likely that GPs were not noted in the operation documents because they are typically thought to be harmless and have no negative effects.

There have been no recent studies conducted locally in our country assessing the incidence, risk factors, and outcomes of GPs during elective laparoscopic cholecystectomy. Therefore, we embarked on this study. Conducting this study is important in several ways. First, the study will provide insights into the incidence of gallbladder perforation during elective laparoscopic cholecystectomy among the Yemeni population. This is particularly important given that gallstones have a high prevalence worldwide, with limited research on gallbladder perforation in third world-countries. Second, the study will provide information on risk factors that may increase the possibility of gallbladder perforation during elective LC. It can also help the clinician avoid or correct these risk factors before an operation. Third, the study will identify the relationship between gallbladder perforation and postoperative complications and outcomes. The study findings will help to make informed clinical decisions and contribute to the development of evidence-based guidelines for the management of gallbladder perforation in our practice hospitals in Yemen.

Patients and Methods

This is a prospective observational study conducted at Kuwait University Hospital and 48 Model Hospital in Sana'a, Yemen, from January to December 2022. All male and female patients who underwent elective laparoscopic cholecystectomy due to symptomatic gallstone disease and agreed to participate in the study were recruited. Patients with confirmed choledocholithiasis, patients with previous upper abdominal surgeries, pregnant patients, and patients planned for an emergency laparoscopic cholecystectomy, or patients converted to open cholecystectomy were excluded. A total of 137 potential eligible cases were collected during our study, all of whom met the inclusion criteria. However, only 130 cases were confirmed eligible and included in our study. Seven patients were excluded because they were converted to the open technique, and the reasons for convergence were recorded as follows: four patients due to instrument failure, two patients due to severe adhesions, and one patient due to severe bleeding.

Data Collection

Data from 130 patients who met the inclusion criteria were collected directly during pre- and postoperative hospital stay periods using a pre-prepared questionnaire based on previous studies [17, 18].

The following data were collected:

- Demographic characteristics (sex, age)
- Preoperative clinical data (body mass index, American society of anesthesiology grades, hypertension, diabetes mellitus, chronic obstructive lung disease, chronic liver disease, ischemic heart disease, previous hospitalization or treatment for acute cholecystitis, indication of LC, laboratory findings, and radiological findings)
- Intraoperative clinical data (surgical approach, gallbladder perforation, timing of gallbladder perforation, experience of the operator, and the difficulty of the surgery)
- Postoperative data (operative time, drain placement, hospitalization period/day, the duration of postoperative ileus/day, and complications)

The degree of difficulty was calculated according to Cuschieri's scale, which defines the complexity of the procedure in four grades [19]. Grade 1 refers to an easy cholecystectomy without any further problems. Grade 2 refers to the presence of light pericholecystitis or adherences or fatty tissue masking the cystic pedicle or mucocele. According to this scale, grade 3 defines severely difficult cholecystectomies in patients with gangrenous cholecystitis; shrunken fibrotic gallbladder; intense pericholecystitis; sub

hepatic abscesses; or advanced hepatic diseases, such as cirrhosis or portal hypertension. In those patients, the dissections of the cystic pedicle or the body gallbladder from the hepatic bed are hard or sometimes impossible because of the accompanying problem or adherence of Hartman's pouch over the common bile duct. Patients with grade 4 difficulties were excluded because it refers to conversion to open surgery [19]. The timing of perforation was noted as follows: during traction of the gallbladder, during the dissection of adhesions and bands, during the dissection of Callot's triangle prior to cystic duct clipsing, during the further dissection of Callot's triangle after cystic duct clipsing, during the dissection of the gallbladder from the hepatic fossa, and during the extraction of the gallbladder from the abdominal cavity.

Outcome measures

The primary outcome measures were the incidence rate of gallbladder perforation and the perioperative risk factors that may increase the possibility of gallbladder perforation during elective laparoscopic cholecystectomy. Secondary outcome measures were the relationship between gallbladder perforation and postoperative short-term outcomes.

Operative procedure

The procedures were carried out with a four-trocar approach, as reported [20], and were either carried out or overseen by one of our departments. The management in the event of GP during the procedure was typically the same: free bile was aspirated, the soiled areas were irrigated with physiological saline until clear, and dropped stones were recovered whenever it was practical. Most of the time, these patients received oral and intravenous antibiotics for one week. The operating surgeon decided to convert to open surgery and implant a drain. The patients were typically released from the hospital the next day, but occasionally a prolonged hospital stay was required.

Statistical analysis

IBM SPSS Statistics, version 26.0 (IBM Corp., Armonk, NY), was used to conduct the statistical analyses. The Kolmogorov-Smirnov test was used to determine the normality of continuous variables. The median with a data range (minimum to maximum) was used for non-normally distributed data, while means with a standard deviation (SD) were used for normally distributed data. The chi-squared test was used to calculate the rates and proportions of discrete variables; if any of the expected values were less than 5, Fisher's exact test was applied instead. For normally distributed data, the independent T test was used, and for nonparametric groups, the Mann-Whitney U test. A two-sided P-value of less than 0.05 was used to define statistical significance.

Ethical aspect

For this investigation, approval from the 48 Model Hospital and Kuwait University Hospital administrations was obtained. Before surgery, a consent document was signed by each patient. Additionally, we adhered to the principles of the Helsinki Declaration when conducting this study.

Results

Demographic characteristics

Gender

The study included 130 cases, with a mean age of 43±12.7. In comparison to men (n=20, 15.4%), women (n=110, 84.6%) made up the majority **(Figure 1)**. No significant risk was found between sex distribution and gallbladder perforation (P = 0.5).

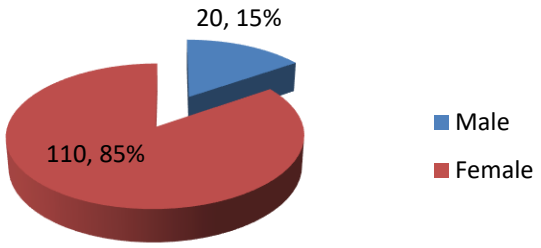

Figure 1: Sample distribution by gender

Age

The mean age for perforated group was (49.88 ±12.96) while the mean age of non-perforated group was (41.13 ±11.881). Significant risk was found between age and gallbladder perforation (P=0.000).

The incidence rate of GP during elective LC

Thirty-four of 130 patients developed gallbladder perforation intraoperatively, representing a 26.2% incidence rate **(Figure 2)**. GPs most commonly occurred during dissection of the GP from its bed (n = 26, 76.5%) and then during extraction of the GP from the abdominal cavity (n = 6, 17.6%).

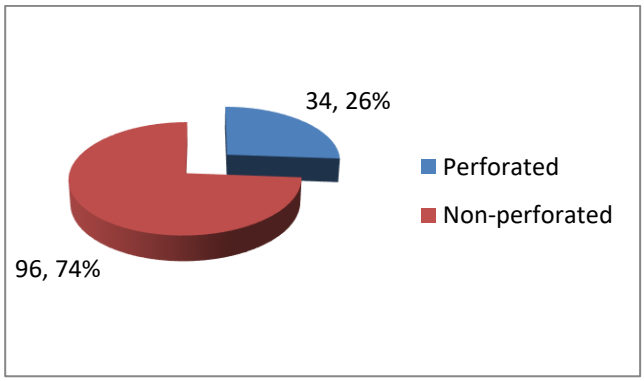

Figure 2: The incidence of GP

The risk factors for GP during elective LC:

Preoperative risk factors

The mean age of the perforated group was 49.88 ± 12.96, compared to 41.13 ± 11.881 for the non-perforated group. A significant difference was found between both groups regarding age and GP (P = 0.000). Study results revealed that obesity (n = 48, 36.9%), with the distribution between perforated and non-perforated groups (n = 20, 41.7% vs. n = 28, 58.3%, respectively), showed a significant difference between both groups regarding BMI and GP (P = 0.002) **(Table 1)**. Regarding ASA grades, a significant difference was found between both groups regarding ASA grades and GP (P = 0.00) **(Table 1)**. The most frequent comorbidities were hypertension, followed by diabetes mellitus, ischemic heart disease, and liver cirrhosis caused by the hepatitis B virus **(Table 1)**. No patients were identified to be smokers or to have heart failure, chronic obstructive pulmonary disease, asthma, or renal failure. A significant difference was found between both groups regarding HTN, DM, and IHD (P = 0.000, 0.024, and 0.001, respectively) and GP, while there was no significant difference in relation to other comorbidities. A prior history of acute cholecystitis was observed to show a significant difference in gallbladder perforation (P = 0.009) **(Table 1)**. Regarding indications for cholecystectomy, no significant difference was found between both groups and GP (P = 0.18) **(Table 1)**. In terms of the laboratory findings, only elevated levels of leukocytes and alkaline phosphates (ALP) were significantly linked with an increased risk of gallbladder perforation (P = 0.000 and P = 0.00, respectively) **(Table 1)**. Regarding the ultrasound findings, a distended gallbladder, multiple GB stones, and the presence of sludge were significantly related to GP (P = 0.02, P = 0.005, and P = 0.000, respectively) **(Table 1)**.

Table 1. The preoperative risk factors for GPs during elective LC

Risk factors	Perforated N=34, (26.2%)	Non-perforated N=96, (73.8%)	P
Age	49.88 ± 12.96	41.13 ± 11.88	0.00*
Gender			
Female	4 (3.1%)	16 (12.3%)	0.5
Male	30 (23.1%)	80 (61.5%)	
BMI			
>30 kg/m2	20 (41.7%)	28 (58.3%)	0.02*
<30kg/m2	14 (17.1%)	68 (82.9%)	
ASA grades			
I	10 (12.2%)	72 (87.8%)	0.000*
II	22 (47.8%)	24 (52.2%)	
III	2 (100%)	0 (0.0%)	
Comorbidities			
DM	10 (45.5%)	12 (54.5%)	0.02*
CLD	0 (0%)	4 (100%)	0.2
HTN	16 (50%)	16 (50%)	0.00*
IHD	6 (75%)	2 (25%)	0.00*
Previous hospitalization	12(9.2%)	14(10.8%)	0.00*
Indications for LC			
Symptomatic GBS	18(13.8%)	72(55.4%)	0. 18
Acute cholecystitis	10(7.7%)	6(4.6%)	
Chronic cholecystitis	6(4.6%)	18(13.8%)	
Laboratory results			
Elevated ALP	12(75%)	4(25%)	0.00*
Elevated WBC	8(100%)	0	0.00*
Elevated total bilirubin	2(33.3%)	4(66.7%)	0.6
Elevated GGT	8(44.4%)	10(55.4%)	0.058
Low Hb	0(0%)	2(100%)	0.4
Low Albumin	0(0%)	2(100%)	0.4
Ultrasound Findings			
Size of GB			
normal	6 (17.6%)	46 (47.9%)	0.00*
distended	28(82.4%)	36(37.5%)	
contracted	0(0%)	14 (14.5%)	
Number of stones			
single	8(23.5%)	52(54.2%)	0.02*
multiple	26(76.5%)	44(45.8%)	
Presence of sludge	8(23.5%)	6(6.3%)	0.00*

Data are presented as either median [range] or mean ± standard deviation. Information in the parentheses indicates the percentages.* significant p-value

The intraoperative risk factors:

In terms of the experience of surgeons, no statistically significant difference was found in both groups related to GP (P = 0.872) **(Table 2)**.According to the Cushier scale, grades II and III showed a significant association with gallbladder perforation (P = 0.000) **(Table 2)**.

Table 2. The intra-operative risk factors for GPs

Risk factors	Perforated N=34, (26.2%)	Non-perforated N=96, (73.8%)	P
Surgeon experience			
Consultant	20(26.5%)	58(74.4%)	0.8
Specialist	14(26.9%)	38(73.1%)	
The degree of difficulty of the operation			
Grade I	14(13.7%)	88(86.3%)	0.000*
Grade II	18(69.2%)	8(30.8%)	
Grade III	2(100%)	0(0%)	

Data are presented as frequency and Information.
in the parentheses indicates the percentages. * Significant p- value

Short-term outcomes of gallbladder perforation after elective LC:

In patients with GP, there was a significant increase in the rate of complications (18.4%) compared with patients without GP (7.7%). Wound infection (10.8%), bile and stone spillage (9.2%), and pulmonary complications (4.6%) were the most common complications. However, GP showed a significant association only with bile and stone spillage and pulmonary complications (P = 0.00) **(Table 3)**.

Regarding postoperative outcomes, the median operative time was 54 minutes (40–109). Operative time significantly increased in the perforated group (60.47 min, 64–109) compared with the non-perforated group (49.50 min, 40–105) (P = 0.000) **(Table 3)**.

The drain was used in 122 patients (93.9%). Since the drain was used in most patients postoperatively regardless of whether GP occurred or not, we couldn't assess the relationship between GP and drain use **(Table 3)**.

The median hospitalization period was 2–8 days for the perforated group and 1–4 days for the non-perforated group, revealing a significant increase in the hospital stay in patients with GP (P = 0.00) **(Table 3)**.

The mean postoperative ileus (1.76 ± 0.819) in the perforated group and (1.02 ± 0.250) in the non-perforated group revealed a significant increase in postoperative ileus in patients with GP (P = 0.00) **(Table 3)**.

Discussion

130 patients who underwent elective LC were included in our study. Mean age: 43. The incidence of GP was 26.2 percent.

Table 3. The postoperative short-term outcomes and complications of GPs

Outcomes	Perforated N=34, (26.2%)	Non-perforated N=96, (73.8%)	P
Operation time(min)	60.47 (64-109)	49.50(40-105)	0.000*
Drain used	34 (26.2%)	88(67.7%)	0.08
Hospitalization period / days	2 (2-8) days	1(1-4)	0.00*
postoperative ileus / day	1.76 ± 0.819	1.02±0.250	0.000*
Bile and stone spillage	12(100%)	0(0%)	0.000*
pulmonary complications	6 (100%)	0(0%)	0.00*
Wound infection	6 (42.9%)	8 (57.1%)	0.132
Re-hospitalization	0	2(100%)	0.4

Data are presented as either median [range] or mean ± standard deviation. Information in the parentheses indicates the percentages.* significant p-value

The most patients were female (84.6%). The majority of GP occurred after the dissection of the gallbladder from its bed (n = 26, 76.5%). Symptomatic GBS was the most frequent cause of elective LC, followed by chronic calicular cholecystitis. Seven individuals (5.1%) were excluded because their procedure was changed to an open procedure. These seven patients, however, were not included in our study. Convergence was most frequently attributed to instrument failure, significant adhesions, and extreme bleeding.

These variables were consistent with the variables of multiple large- and low-volume studies [17, 18, 21, 22, 23] **(Table 4)**. After analyzing the quantitative and qualitative variables of the patients in relation to GP, we found that some of these variables were correlated with the occurrence of GP and others were not.

In our study, age (*P* = 0.000), obesity (BMI > 30 kg/m2, *P = 0.02*), and ASA grade II or III (*P = 0.000*) were all significant risk factors for gallbladder perforation. Comorbidities, including ischemic heart disease, hypertension, and diabetes mellitus, increased the incidence of gallbladder perforation (P = 0.05). A significant risk of gallbladder perforation was linked to previous hospitalization for acute cholecystitis prior to surgery, high alkaline phosphate levels, and elevated leukocytes (P = 0.009). Cushier scale grades II and III (P = 0.02), as well as ultrasound findings of a distended gallbladder, the presence of sludge, and the number of stones, were also significantly linked with risk for GP (P = 0.000). Other risk factors for gallbladder perforation, including gender, other comorbidities, common bile duct size, existence of polyps, indications for the procedure, and experience of the surgeon who performed the operation, showed no significance.

Table 4. Comparison between our study and other studies

Study	Number of patients	Mean age	Gender	The incidence of GP	Timing of GP	
Altuntaş (2017) [17]	664	49 y	(78.9%) F	36.1%	82.1%	dissecting GB from its bed
Sankpal (2016) [18]	440	44.71 y	(64%) F	33%	-	-
Barrat (2004) [21]	121	56.4 y	(75%) F	20%	83.3%	dissecting GB from its bed
Choudhury (2017) [22]	150	48 y	(61%) F	18.6%	22%	dissecting GB from its bed
Paleti (2006) [23]	2587	56 y	71% M	29%,	47%	dissecting GB from its bed
Present study	130	49	(84.6%) F	26.2%	76.5%	dissecting GB from its bed

The following studies performed in different high- and low-volume centers shared the same result about some risk factors for GP but differed in the results of other risk factors shown by our study. This may point out that the volume of procedures performed is critical for achieving better outcomes.

According to the **Altuntaş (2017)** study, the only significant risk factor for GP was a preoperatively elevated alanine transaminase level (*P = 0.005*), which we did not examine during our research because patients with elevated liver enzymes were not subjected to elective LC in our hospital [17].

Preoperative ultrasonography results of gall bladder wall thickness greater than 3 mm were linked to a higher incidence of GP, according to the **Sankpal (2016)** study. Acute cholecystitis and obesity (BMI > 30 kg/m2) were also linked to an elevated risk of GP [18]. That outcome is similar to ours.

Gallbladder perforation was clearly associated with the ability and experience of the surgeon, according to the **Barrat (2004)** study, while acute cholecystitis was associated with a higher rate of perforations (though not significantly higher rates) [21].

Age, obesity, and male gender were found to be risk factors for gallbladder perforation in the **Paleti (2006)** study (*P = 0.001*) [23]. There is no link between prior abdominal surgery and a higher risk of gallbladder perforation during surgery. A higher risk of gallbladder perforation was associated with adhesions between the gallbladder and the omentum (*P = 0.001*). Although there was a marginally greater incidence of acute cholecystitis among individuals in the perforated group compared with the intact group (11% vs. 8.5%), this difference was not statistically significant.

In terms of complications, our study showed a significant increase in the complication rate in the perforated group, with an overall complication rate of 18.4%. The most common complication was bile and stone spillage, followed by pulmonary complications and wound infection, compared with the non-perforated group, which had an overall complication rate of 7.7%, with wound infection being the most common and re-hospitalization. No mortality was recorded in our study.

The complication rates for laparoscopic and open cholecystectomy in the **Sankpal (2016)** study were 8.18% and 10.9%, respectively. As a result, there was little variation in the frequency of problems. Gallstone spillage was the most frequent complication of laparoscopic cholecystectomy, followed by gall bladder perforation during surgery and biliary duct damage. The most frequent complications following open cholecystectomy were postoperative wound infection and postoperative bile leakage. The rate of problems was comparable across the two study groups; however, laparoscopic cholecystectomy had increased intraoperative morbidity and severity of complications [18]. Gallbladder perforation is associated with a higher (but non-significant) postoperative morbidity in the **Barrat (2004)** study, which is connected to older patients and more severe cholecystitis in this group [21]. In the **Choudhury (2017)** study, although all visible spilled stones were retrieved during surgery, a complication rate of 0.66% was observed [22].

In terms of outcomes for GP during elective LC, our study shows a significant increase in operative time in the perforated group compared with the non-perforated group. Drain was used in most patients postoperatively regardless of whether GP occurred or not, so no significant relation was found between GP and increased drain use. The hospitalization period was significantly increased for the perforated group compared with the non-perforated group (*P = 0.00*), as was the duration of post-operative pain (*P = 0.00*) and the duration of postoperative ileus.

The two groups in the **Altuntaş (2017)** study exhibited comparable results, although the GP group's operation time (*P = 0.000*) and incidence of drain use (*P = 0.000*) increased [17]. The mean operating time increased in instances that required difficult intraoperative surgery, according to **a Sankpal (2016)** study [18]. The operating time for patients in the perforated group was somewhat longer (*P = 0.01*) but of little clinical importance in the study by **Paleti (2006)** [23]. In both patient groups, surgical residents conducted a comparable number of laparoscopic cholecystectomy procedures (*P* = 0.573). The median hospital stay in the perforated group was longer.

Unfortunately, data concerning the outcome of GP in elective LC in Yemen is lacking, making comparison of our results with those of tertiary centers in the country difficult. Furthermore, comparing our initial experience, which is of low volume, with that reported from larger-volume western units, is unjustifiable. Hence, this study can be used as a baseline to evaluate the incidence of GP, risk factors, and short-term outcomes during elective LC. Whether there is room for further improvement and to

analyze the factors that may influence GP during elective LC.

Conclusions: According to our study, the incidence rate of gallbladder perforation was high and comparable to the reported incidence worldwide. Multiple risk factors can influence the GP during elective laparoscopic cholecystectomy. Gallbladder perforation can adversely affect the outcome and increase the complication rate of the operation. Multiple studies performed in different high- and low-volume centers shared similar results about some risk factors for GP but differed in the results of other risk factors, as revealed by our study. This may indicate that the volume of procedures performed is critical for achieving better outcomes in future studies.

Recommendation

The most important recommendation are that informed consent from the patient and family should be obtained preoperatively, that every effort should be made to retrieve the gallstones, that the peritoneum should be irrigated with copious saline, that there is no need for converting the laparoscopic procedure to a laparotomy for gall bladder perforation, that the surgeon should have long term follow up of these patients, and that the surgeon should alert to rule out possible complications due to gall bladder perforation and spillage.

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