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**Original Research Article**

# Analysis of the risk factors, acute presentation, management and outcome associated with post cholecystectomy bile duct injury

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## ABSTRACT

**Background:** Cholecystectomy is one of the most common surgeries in the world. However, its complication has dangerous effects on the patient's health and economic status. It also increases the patient's morbidity and mortality. Objective was to investigate the risk factors, acute presentation, treatment, and outcome of bile duct injury after cholecystectomy.
**Methods:** This prospective observational study included a total of 70 patients aged 18 years who underwent surgery for benign gallbladder disease. Malignancies of the gallbladder system, injury to the bile duct due to trauma, age >18 years or >70 years were excluded from the study. Various risk factors were queried preoperatively, intraoperatively, and postoperatively from patients and surgeons, and a conclusion was drawn.
**Results:** Most patients were in the age group 31-50, namely 45 (64.28%). Of the total 70 patients, 20 (28.58%) were male and 50 (71.42%) were female. Total 06 (75%) patients have severe adhesion and 02 (25%) patients have mild adhesion. Of the total 70 patients, only 08 patients have the CALOTS triangle. Total 06 (8.57%) patients had no drainage and 64 (91.42%) patients had drainage. Total 52 (74.28%) most patients had pigtail drainage and 02 (2.85%) least patients had portal vein repair. Most patients were discharged after 54 (71.42%), 09 (12.85%) after discharge on patient request (DOPR), and the fewest patients, 02 (2.85%), were not discharged.
**Conclusions:** In most cases, bile duct injury occurs after surgery for uncomplicated gallstone disease. Bile duct injury is associated with a variety of surgical complications and can be fatal. Bile duct injury is more common in women because gallstone disease is more common in women.

**Keywords:** Cholecystectomy, Bile duct injury, Gallstone

## INTRODUCTION

Cholecystectomy is a common treatment in gastrointestinal surgery, and the laparoscopic method has become the gold standard for symptomatic cholecystolithiasis and chronic and acute cholecystitis.[1] Apart from the advantages of a much faster recovery time and better cosmetic outcome, the laparoscopic approach carries a greater risk of iatrogenic bile duct injury (IBDI) and hepatic (right) artery injury. Bile duct injury (BDI) is one of the most frightening sequelae of cholecystectomy, associated with significant perioperative morbidity and mortality, decreased long-term survival and quality of life, and a high rate of subsequent lawsuits.[2-4] Despite increasing experience and advances in surgeons' laparoscopic skills, the incidence of IBDI remains elevated

compared with open cholecystectomy. After standard open cholecystectomy, the clinically significant bile leak rate ranges from 0.1 to 0.5 percent. In contrast, bile leak rates have increased by up to 3% in the era of laparoscopic cholecystectomy.[5]

Of note, only about 11% to 23% of BDI are discovered during the initial procedure. In the remaining cases, the majority of injuries are not detected during the initial hospitalization.[6] Since LC has become the "gold standard" for the treatment of symptomatic cholelithiasis, the incidence of iatrogenic BDI has increased significantly. In 71-97% of all cases of BDI, the primary cause has been shown to be an incorrect understanding of the architecture of the biliary tract.[7]

Over the years, numerous types of biliary injuries have been presented, as well as various approaches to prevent iatrogenic biliary injuries. Early recognition of BDI is critical. The ideal course of treatment is determined by the timing of damage detection, the extent of BDI, the clinical condition of the patient, and the availability of qualified surgeons. There are numerous categorization methods for BDI, with the Strasberg classification with bismuth modification being the most widely recognized. Although type A injuries are often categorized as "minor," they can result in significant morbidity due to chronic bile leakage and biliary sepsis. Short-term morbidity rates of up to 40-50% and death rates of 2-4% have been documented for severe injuries. Late complications such as biliary strictures, anastomotic strictures, recurrent cholangitis, and biliary cirrhosis further burden the patient.[7-9]

BDI can result in numerous hospitalizations and may require additional endoscopic, percutaneous, or surgical interventions depending on the extent and location of the injury. A multidisciplinary strategy involving hepato-, pancreato-, and biliary surgeons, gastroenterologists, and interventional radiologists is required to achieve the best outcomes. Ideally, the patient should be referred to a BDI-trained clinic.[6-12] Endoscopic therapies such as sphincterotomy, balloon dilatation, and biliary stent implantation have become more common as experience with this problem has increased.[13] To minimize subsequent difficulties and damage to the hepatoduodenal ligament, surgical procedures should be performed in collaboration with experienced hepatobiliary surgeons, interventional radiologists, and gastroenterologists at a tertiary referral hospital. Percutaneous transhepatic cholangiography with biliary drainage is a conservative technique to lower intrahepatic biliary pressure and promote healing of a BDI in some cases. BDI is an unanticipated and potentially fatal consequence of elective cholecystectomy. It is associated with a high morbidity and mortality rate and requires invasive treatment in most cases. In addition, people with BDI have a reduced quality of life (QoL) even years after cholecystectomy. A BDI not only has a significant impact on the individual patient, but is also associated with increased health care needs and costs, as well as legal claims.[14,15]

Therefore, the aim of this study was to investigate the risk factors, acute presentation, treatment, and outcome of bile duct injury after cholecystectomy.

## METHODS

This was a prospective observational study conducted in the Department of General Surgery, King George's Medical University, Lucknow, over a period of one year. The study was approved by the institutional ethics committee of King Georges Medical University, Lucknow. All patients admitted to the Department of General Surgery with a diagnosis of BDI.

A total of 70 cases were included in this study. The sample size was calculated based on the prevalence of the disease by using the equation given.

$$X = (Z\alpha/2)^2 \times p \times (1-p)/(MOE)^2$$

Where X is the calculated sample size; Zα/2 is the critical value of the normal distribution at α/2; MOE is the margin of error=0.01, patients willing to follow up, age=18 years, patients operated for benign gallbladder disease were included in the study. Malignancies of the gallbladder system, injury to the bile duct from trauma, age >18 years, or >70 years were excluded from the study.

Various risk factors were queried preoperatively, intraoperatively, and postoperatively from patients and surgeons, and a conclusion was drawn. Statistical analysis was performed using statistical package for social sciences (SPSS) version 21.0 software. The values were presented in "number (%) and percentages".

## RESULTS

Most patients were in the age group 31-50, namely 45 (64.28%). This was followed by 15 (21.4%) patients from the over 50 age group, and finally only 10 (14.28%) patients belonged to the 18-30 age group. Of the total 70 patients, 20 (28.58%) were male and 50 (71.42%) were female. Most patients (48, 68.57%) colicky pain and least patients (02, 2.85%) had jaundice and pancreatitis. Total 54 (77.14%) patients were not informed about the type of injury and in 16 (22.85%) patients the type of injury was explained. 49 (70%) patients did not know the name of their surgeon. however, 21 (30%) patients knew the names of their surgeons. The phone numbers of only 8 surgeons are available. We obtain intraoperative information from only 8 BDI cases. Only 08 patients have the same information. Of these, 06 (75%) patients have severe adhesion and 02 (25%) patients have mild adhesion. Of the total 70 patients, only 08 patients have the CALOTS triangle. Of these, 06 (75%) patients were not identified and 02 (25%) patients were identified. Only 08 patients have the CBD. Of these, 06 (75%) patients had it identified and 02 (25%) patients did not have it identified (Table 1).

Total 68 (97.14%) patients had no transfusion at all and 02 (2.85%) patients were identified with transfusion. Most patients, namely 49 (70%), had open procedures and least, namely 04 (5.71%), had LAP procedures open. Most patients, namely 28 (40.00%), were referred within 6-20 days and least, namely 10 (14.25%), were referred within >20 days. Most patients, namely 35 (50%), underwent surgery in the evening hours (5-10 pm). The fewest patients, namely 01 (1.4%), were operated on in the early morning hours (Table 2).

**Table 1: Baseline characteristics of patients.**

| Variables | N | % |
|---|---|---|
| **Age (years)** | | |
| 18-30 | 10 | 14.28 |
| 31-50 | 45 | 64.28 |
| >50 | 15 | 21.4 |
| **Gender** | | |
| Female | 50 | 71.42 |
| Male | 20 | 28.58 |
| **Pre-operative symptoms** | | |
| Colicky pain | 48 | 68.57 |
| Recurrent pain | 15 | 21.48 |
| Change in character of pain | 3 | 4.28 |
| Jaundice | 2 | 2.85 |
| Pancreatitis | 2 | 2.85 |
| **Nature of injury** | | |
| Explained to patient | 16 | 22.85 |
| Not explained | 54 | 77.14 |
| **Patients know about operating surgeon** | | |
| Know | 21 | 30.00 |
| Not know | 49 | 70.00 |
| **Telephonic conversation with surgeon possible** | | |
| Yes | 8 | 11.43 |
| No | 62 | 88.57 |
| **Pericholecystic adhesions** | | |
| Minimal | 0 | 0 |
| Mild | 2 | 25 |
| Severe | 6 | 75 |
| **CALOTS triangle** | | |
| Identified | 2 | 25 |
| Not identified | 6 | 75 |
| **CBD** | | |
| Not seen | 2 | 25 |
| Seen | 6 | 75 |

Of the total 70 patients, 06 (8.57%) patients had no drainage and 64 (91.42%) patients had drainage. Of the total 70 patients, 52 (74.28%) most patients had pigtail drainage and 02 (2.85%) least patients had portal vein repair (Table 3).

Most patients were discharged after 54 (71.42%), 09 (12.85%) after discharge on patient request (DOPR), and the fewest patients, 02 (2.85%), were not discharged (Table 4).

**Table 2: Details of blood transfusion, nature of procedure, post-operative hospital stays in index center and timing of surgery.**

| Variables | N | % |
|---|---|---|
| **Blood transfusion** | | |
| No | 68 | 97.14 |
| Yes | 02 | 2.85 |
| **Nature of procedure** | | |
| LAP | 17 | 24.28 |
| Open | 49 | 70 |
| LAP converted to open | 4 | 5.71 |
| **Post op hospital stay in index center (days)** | | |
| 1-5 | 14 | 20.00 |
| 6-10 | 28 | 40.00 |
| 11-20 | 18 | 25.27 |
| >20 | 10 | 14.28 |
| **Timing of surgery** | | |
| Early morning (before 8 am) | 1 | 1.40 |
| Morning (8-12) | 8 | 11.42 |
| Afternoon (12-5) | 18 | 25.71 |
| Evening (5-10) | 35 | 50.0 |
| Night (after 10 pm) | 8 | 11.42 |

**Table 3: Drain place and management at our center.**

| Variables | N | % |
|---|---|---|
| **Drain place** | | |
| No | 6 | 8.57 |
| Yes | 64 | 91.42 |
| **Management at our center** | | |
| Pig tail drainage | 52 | 74.28 |
| Laprotomy | 6 | 8.57 |
| HJ | 6 | 8.57 |
| CBD stenting and exploration | 4 | 5.7 |
| Portal vein repair | 2 | 2.85 |

**Table 4: Details of outcome.**

| Outcome | N | % |
|---|---|---|
| **Discharge** | 54 | 71.42 |
| **DOPR** | 9 | 2.85 |
| **Expired** | 5 | 7.14 |
| **Not discharged** | 2 | 2.85 |

## DISCUSSION

In our study, the majority of patients were between 31 and 50 years old, 45 (64.28%) with a mean age of 37.52±11.62 years, which is comparable to other study groups.[16,17] Mishra et al noted a mean age of 38 years (12-80 years) in their study at GB Pant Hospital.[18] The Indian study included 256 women and 44 men with a mean age of 36 years.[16,19] The mean age of participants in the John Hopkins Institute study was 45.5 years.[19] The results of our study were consistent with those of previous studies.

Of the total 70 patients, 49 (70%) did not know who their surgeon was. Twenty-one patients knew their surgeon. The telephone numbers of only eight surgeons could be reached. We obtained intraoperative data from only eight BDI patients. Fifty-four (77.14%) patients were not informed of the nature of the injury, whereas 16 (22.85%) were. The main cause of this ignorance and mismanagement is the lack of a national registration strategy, an adequate referral system, and a mechanism for evaluating complicated cholecystectomies. Sharma et al claim that surgeon experience does not protect against BDI at LC.[20] While 60% of BDIs occurred in the first five years of laparoscopic surgical practise, up to 15% of our respondents reported experiencing their first BDI after 10 years of practise. Approximately 40% of respondents reported that they had performed more than 100 laparoscopic procedures prior to their first BDI. However, the current study shows that the vast majority (70%) of BDI patients do not know the identity of their treating surgeon. These results suggest that BDI patients are uninformed. However, at this time, we cannot draw any conclusions about the relationship between BDI patients and the experience of the treating surgeon. Inadequate training, inexperience, overconfidence, and disregard for basic surgical concepts and methods of cholecystectomy account for the vast majority of cholecystectomy BDIs.[21] Cholecystectomy was most commonly performed for symptomatic uncomplicated gallstone disease, followed by symptomatic complex gallstone disease (e.g., cholecystitis, pancreatitis, and cholangitis). Of the total 70 patients, 48 (68.57 percent) reported colic-like symptoms. Thirty of the forty-eight patients had pain within ten days before surgery. Cholecystectomy is challenging in acute situations due to edema and hypervascularization. This may be one of the reasons for the increased bile duct injury associated with colicky pain. In the Western literature, 70% of patients with BDI underwent LC.[22] OC in contrast, in Indian research, the majority of patients underwent index surgery.[22]

In our study, 49 patients sustained injuries during open cholecystectomy, 17 patients sustained injuries during laparoscopic cholecystectomy, and four patients sustained injuries after laparoscopic conversion to open cholecystectomy. This suggests that injuries are more common during open cholecystectomy than during laparoscopic procedures. However, the incidence could not be calculated because the denominators were missing. The increased incidence of bile duct injury during open cholecystectomy in our study could be explained by the fact that our treatment facility serves a larger rural and suburban population with low socioeconomic and educational levels. In these areas, laparoscopic options are not available. This reverse trend has been observed in a number of studies conducted in India. A total of 88 patients were injured during open cholecystectomy, while 49 patients were injured during laparoscopic cholecystectomy.[18] In the Western literature, the rates of intraoperative identification of BDI are higher. Intraoperative identification of BDI occurred in five patients (3.64 percent); in our analysis, it occurred in three of seventy patients (4.3 percent).[18] This may be due to the lack of an effective referral system in rural and suburban health facilities. The surgeon's instinctive response to bleeding during laparoscopic cholecystectomy is to make an ill-considered attempt to contain it with a cautery or clamp. When the blood transfusion history was evaluated, it was found that the majority of the 68 patients (97.14 percent) had not received any transfusion at all, while 02 patients (2.85 percent) had received a transfusion.

In our study, most of the 35 patients (50 percent) were operated in the evening (5-10 pm). Yadav et al showed that the bile duct was misidentified as a cystic duct, which was assumed to be the mechanism of injury in both open and laparoscopic procedures.

In our study, most patients (55, 78.57 percent) arrived at the centre within five days after surgery. The length of postoperative hospital stay at the index centre is measured from the day of surgery to the day of admission. The majority of patients (40.00 percent) required a hospital stay of 6-10 days after surgery, followed by 11-20 days. Twenty-two patients (31.42 percent) issued a referral, while 48 patients (68.57 percent) did not issue a referral. They were not treated correctly in our centre. The majority of the patients presented to our institution with dyselectroemia, bilioma and other complications. The likely explanation for this is a lack of facilities and information on the management of bile duct damage after cholecystectomy. This information is particularly important because patients with BDI complications need appropriate therapy at the right time. Delay in this process is associated with an increase in mortality and morbidity, both of which have a negative outcome.

Most patients were diagnosed with bilioma (n=33, 47.14 percent), followed by external biliary fistula (n=12) and biliary stricture (n=5). Cholangitis is a very real possibility that can lead to sepsis, renal failure, and sudden cardiac arrest. Septic shock, renal failure, or other organ failure was documented in n=04 (5.71%) BDI patients in our study. Most patients were mismanaged and developed dyselectremia and sepsis as a result of delay in diagnosis and referral of BDI. Overall, 06 (8.57%) patients did not have drains placed, whereas 91.42% patients had drains placed. Only 2.5% of respondents reported benign biliary stenosis (BBS), followed by biliary injury (BDI). According to Kapoor et al, in 214 patients with acute BDI, external biliary fistula was found in 99 cases, biloma in 85 cases, biliary peritonitis in 19 cases, and biliary dropsy in 11 cases.[21] The largest number of patients who underwent open surgery was 49 (70 percent). Mishra et al found that the majority of patients (66.42 percent) had biloma with external biliary fistula (29.9 percent).[18] Five individuals were found to have BDI intra-operatively (3.64 percent). Pottakkat et al found that 42.2 percent of patients had biliary fistula and 53.8 percent had biliary stricture.[22] According to a study conducted by John Hopkins, the majority of patients who arrived within one month of

injury had signs of biliary fistula, biloma, or peritonitis, while those who arrived after one month had features of biliary stricture. Our results are comparable to those from previous studies.

In 2002, portal vein repair was reported in the fewest patients (2.85 percent). Most patients had biliomas and external biliary fistulas leading to cholangitis, sepsis, dyselektronemia, and malnutrition, which ultimately increased the likelihood of anastomotic leak in the early phase of definitive surgery. The majority of patients (74.28 percent) were treated conservatively by placing an image-guided drain. According to a John Hopkins study, most patients had biliary fistula, biloma, or peritonitis in the early phase (within 1 month) after injury. 32.4% of patients had intraoperative BDI, and most were treated with drainage.[19] In cases of moderate or incomplete injury, such as injury to the lateral bile ducts, ERCP is often useful both diagnostically and therapeutically. Peritonitis has been diagnosed in a few cases. Exploratory lavage with drainage was performed to treat the sepsis. Most patients improved and were scheduled for definitive treatment. According to the available studies and experience, a well-performed HJ seems to be the most appropriate treatment.[23,24]

Perera et al and Stewart et al studied the consequences of early versus late repair and found that the outcome of delayed repair was equivalent.[25,26] Sicklick et al advocated late definitive repair with a median time of 10.3 weeks.[19] According to Mishra et al, the time delay between index and definitive surgery had a statistically significant effect on treatment outcomes.[21] We waited approximately 6-8 weeks to treat the biliary leak and sepsis according to our protocol. In our study, the difference between index and final surgery had a significant impact on treatment outcomes. Portal vein repair was reported in 02 (2.85 percent) BDI patients. Vascular problems are a significant complication of cholecystectomy. They can occur later in life as a result of aneurysm bleeding or ligation/clip displacement. Mishra et al report that uncontrolled bleeding occurs in 2% of all bleeds at LC. Most of these bleeds often go unreported.[27] Six subjects suffered bowel damage requiring bile duct repair. To optimise outcome, intestinal and vascular damage associated with bile duct injury must be treated.

The highest number of patients discharged was 50 (71.42%), 02 (2.85%) DOPR-2 patients were not discharged proportionately. 5 (7.14%) patients died as a result of cholangitis, which can lead to sepsis, renal failure, and sudden cardiac arrest. Mishra et al reported a postoperative mortality rate of 2.8% in 107 individuals.[21] In addition, there is a lack of appropriately experienced surgeons and facilities in our country. The ignorance of some operating physicians may lead to late recognition of the risk. However, a limitation of the study was the small sample size and unilateral focus. Further multicenter studies with a large sample size are needed to validate and generalise the results.

## CONCLUSION

In most cases, bile duct injury occurs after surgery for uncomplicated gallstone disease. Bile duct injury is associated with a variety of surgical complications and can be fatal. Bile duct injury is more common in women because gallstone disease is more common in women. Most patients are not educated about the injury, leading to a delay in the treatment of bile duct injury and increased morbidity and mortality. When it comes to long-term outcomes after definitive surgery, postoperative biliary leak is the most important factor. Cholecystectomy is one of the most common surgeries in the world. However, its complication has dangerous effects on the patient's health and economic status. It also increases the patient's morbidity and mortality. Therefore, a national registration policy for cholecystectomy is needed for the prevention of BDI and its acute treatment at the right time, as well as for the analysis of various risk factors.

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