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A retrospective assessment of the complications and associated risk factors of laparoscopic cholecystectomy

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Abstract
Aim: The aim of the present study to assess the risk factors and complications of Laparoscopic Cholecystectomy.
Material and Methods: This was a retrospectively analysed study conducted in the Department of General Surgery, Shri Shankaracharya Institute of Medical Sciences, Bhilai, Chhattisgarh, India, from December 2018 to November 2019. 100 patients who were diagnosed with cholelithiasis and had laparoscopic cholecystectomy were included in this study. We analysed the type and frequency of intraoperative and postoperative complications, as well as factors that increase the risk for development of complications. We noted causes and incidence of conversions and the way they resolved. We noted gender, age, body mass index (BMI), white blood cell count, and level of C-reactive protein (CRP), preoperative ultrasonographic findings, Patho histological findings of the surgically removed gallbladder, as well as their correlation with the occurrence of complications.
Results: Out of the 100 patients in the study, 68 were female (68%), and 32 were male (32%). The most common complications noted were: iatrogenic perforations of the gallbladder- 5 (5%), bleeding from the tissues adjacent to the gallbladder 3 (3%), gallstones spilt into the peritoneal cavity 2 (2%). Intraoperative bleeding from the cystic artery occurred in 1 (1%), bleeding from the port in 1 (1%) and bleeding from the ligaments of the liver in 1 patients (1%). The transection of the common bile duct, a major complication, occurred in only one patient (1%). The most common postoperative complications were: bleeding from the abdominal cavity more than 100 ml/24h (in 3 patients or 3%), bile leaks through the drain > 50-100 ml/24h (2 patients, or 2%). In addition, the ultrasonographic findings of empyema, gangrene of the gallbladder wall, and increased gallbladder wall thickness > 3 mm (group II) is a significant predictor of complications and conversion (OR = 4.92, 95% CI 1.61-18.13, $p< 0.001$). Patho histologic analysis of the surgically extracted gallbladder with the diagnosis of acute cholecystitis was also the significant predictor for complications and conversion (OR 1.82, 95% CI 2.52-16.66, $P< 0.001$).
Conclusion: the laparoscopic cholecystectomy as a new technique for treatment of cholelithiasis, introduced a new spectrum of complications. Major biliary and vascular complications are life threatening, while minor complications cause patient discomfort and prolongation of the hospital stay.

Keywords: Laparoscopic cholecystectomy, risk factors, complications

Introduction
Gallstone disease is common biliary pathology [1]. Approximately 1-2% of patients develop symptoms requiring surgical intervention. Cholelithiasis has peak in 5th and 6th decade and women are more affected than men in ration of 4:1.1 Cholecystectomy is a very common operation performed throughout the world. There are certain advantages of laparoscopic cholecystectomy over open cholecystectomy such as earlier return of bowel functions, less postoperative pain, better cosmoses and short hospital stay, earlier return of function and less cost [1]. In addition the rate of surgical site infection is also less. Laparoscopic cholecystectomy (LC) is gold standard procedure in the treatment of symptomatic gallstones [2, 3]. Efficiency and safety of LC depends on the experience and expertise of the surgeon and on the underlying pathology. In the hospitals where there is smaller number of experienced surgeons, prevention of injuries of the bile ducts and vascular structures during LC is extremely important because very often there are no conditions for their definite successful treatment [3]. It is accepted that the rapid adoption of laparoscopy as the technique of choice for cholecystectomy has been attributed to shorter hospital length of stay, decreased patient morbidity, faster return to routine activity, and improved overall patient satisfaction [4].

It is currently estimated that more than 700,000 laparoscopic cholecystectomies (LCs) are performed annually in the United States which is approximately 90% of all cholecystectomies [5]. Similarly, tend of use of LCs has dramatically increased in developing countries including Nepal but the data are lacking. The rate of conversion from LC to open cholecystectomy (OC) is consistently reported to range between 2% and 15% [6, 7]. Various other studies have been done to find out possible factors responsible for conversion that include age; sex; obesity; diabetes mellitus; body mass index; duration of symptoms; total leucocyte count; LFT; ultrasound; acute cholecystitis; history of biliary diseases such as jaundice, cholangitis, etc.; history of pancreatitis and preoperative endoscopic retrograde cholangiopancreatography [8, 9]. Several preoperative risk factors have been associated with a higher rate of conversion from LC to OC, including older age, male gender, cardiovascular disease, gangrenous cholecystitis, and acute cholecystitis associated with elevated leukocyte count [10]. On the other hand, during operation, the need for conversion is usually due to difficulty in dissection at Calot's triangle, instrument failure or a complication [11]. Recent study explored that the most common reason for conversion was inadequate visualization of elements of Calot's triangle and unclear anatomy, bleeding from the GB lodges and lost stones, perforation of the GB with lost stones and injury of common bile duct at one patient with Mirizzi syndrome and empyema of the GB [12]. The current rates of OC or conversion to OC within different setting are variable. Moreover, it is unclear whether a higher rate of OC at a specific hospital or group of hospitals is due to a patient population with different characteristics, or to particular surgeons' technical expertise with laparoscopy. 6 Preoperative knowledge of risk factors that indicate the occurrence of difficulties that can occur in different phases of the operation are of great importance not only for the safety of patients but also explore assessment of the competence of the surgical team for the performance LC [12]. Preoperative identification of operative difficulties predictors is particularly important in non-referential LC centers and in the hospitals where open cholecystectomy (OC) became a rarity as a primary prevention in intra operative injuries of the bile ducts and vascular structures.6 When the likelihood of conversion is high, proceeding to OC will help prevent initial laparoscopy with its associated risks of prolonged and dangerous dissections and its higher costs [13]. When the factors leading to conversion can be addressed preoperatively, their elimination can result in higher rates of successful LC. In addition, the potential identification of non–patientrelated predictors of a higher OC rates can provide insights leading to system-level improvements in the surgical care of patients with gallbladder disease [4].

Material and Methods: This was a retrospectively analysed conducted in the Department of General Surgery, Shri Shankaracharya Institute of Medical Sciences, Bhilai, Chhattisgarh, India, from December 2018 to November 2019, after taking the approval of the protocol review committee and institutional ethics committee.

Methodology: 100 patients who were diagnosed with cholelithiasis and had laparoscopic cholecystectomy were included in this study. The analysis included operative protocols, Anesthesiology records, the medical history which included the history of the disease, documented laboratory findings and imaging results. We analysed the type and frequency of intraoperative and postoperative complications, as well as factors that increase the risk for development of complications. We noted causes and incidence of conversions and the way they resolved.

We noted gender, age, body mass index (BMI), white blood cell count, and level of C-reactive protein (CRP), preoperative ultrasonographic findings, Pathohistological findings of the surgically removed gallbladder, as well as their correlation with the occurrence of complications. The patients were divided into groups according to their age (older than 55, and younger than 55), gender (male, and female), BMI (greater than 25 kg/m^2, and less than 25 kg/m^2), white blood cell count (greater than 10 x 109 /l, and less than 10 x 109 /l), and CRP level (greater than 5 ml/l, and less than 5 ml/l). Subsequently, the correlation between these factors and type/frequency of intraoperative and postoperative complications were analysed.

All surgically extracted gallbladders were examined by pathophysiologists in order to confirm the diagnosis of acute cholecystitis, chronic cholecystitis or presence of malignancy. Subsequently, correlations between these pathohistological findings and type/frequency of intraoperative and postoperative complications were analysed. An ultrasonographic exam was performed 24 hours before each surgery. In order to simplify the analysis of the correlation between ultrasonographic findings and possible complications, all ultrasonographic findings were grouped into three groups: group I- chronic cholecystitis, group II- acute cholecystitis, gallbladder empyema, increased gallbladder wall thickness > 3 mm, and group III- gallbladder with fibrous changes and a calculus with >2 cm in diameter. We used a standard four-port technique in all surgical interventions.

Results

Out of the 100 patients in the study, 68 were female (68%), and 32 were male (32%). The median age was 50 years, including participants that were 18 to 89 year old. There were 17 patients (17%) with intraoperative complications (IOC) (Table 1).

The most common complications noted were: iatrogenic perforations of the gallbladder- 5 (5%), bleeding from the tissues adjacent to the gallbladder 3 (3%), gallstones spilt into the peritoneal cavity 2 (2%). Intraoperative bleeding from the cystic artery occurred in 1 (1%), bleeding from the port in 1 (1%) and bleeding from the ligaments of the liver in 1 patients (1%). The transection of the common bile duct, a major complication, occurred in in only one patient (1%) This complication caused conversion to open procedure and was resolved by hepatopathy with a T-drain. IOC was more frequent in males (12 males, or 12%) compared to females (5 females, or 5%).

Table 1: Intraoperative complications

Intra-operative complications	IOC=17	Percentage
IOC – types		
Bleeding from tissues adjacent to gallbladder	3	3
Bleeding from cystic artery	1	1
Iatrogenic perforations of the gallbladder	5	5
Injuries to the common bile duct	1	1
Bleeding from the abdominal wall (port)	1	1
Spilled gallstones	2	2
Bleeding from the ligaments of the liver	1	1
Lesions of the omentum	3	3

There were 13 patients (13%) with postoperative complications (POC) (Table 2). The most common postoperative complications were: bleeding from the abdominal cavity more than 100 ml/24h (in 3 patients or 3%), bile leaks through the drain > 50-100 ml/24h (2 patients, or 2%). Less frequent complications were surgical wound infection (1 patients, or 1%),

incisional hernia at the place of port (1 patients, or 1%), and intra- abdominal abscess caused by residual calculus in the abdominal cavity (1 patients, or 1%). In the postoperative period, one case of subhepatic collection and 1 cases of abscess formed around retained calculi were treated by laparotomy and they subsequently resolved. Hematoma of the abdominal wall around the working port was noted in 1 patients (1%). Choledocholithiasis was noted in 1 patients (1%), and this was resolved by endoscopic papillotomy. Carcinoma of the gallbladder was confirmed by pathohistological analysis in 1 patients (1%). POC was more frequent in males (10 patients, or 10%) compared to females (3 patients, or 3%).

Table 2: Postoperative complications (POC)

Postoperative complications	POC=13	Percentage
Bleeding from abdominal cavity >100 ml/24h	3	3
Bile leaks >50-100 ml/24h	2	2
Subhepatic collection	1	1
Surgical wound infection	1	1
Incisional hernia	1	1
Hematoma of the abdominal wall	1	1
Gallbladder carcinoma	1	1
Retained calculus in choledochal duct	1	1
Lost gallstones (abscess)	1	1
Choleperitoneum	1	1

Both IOC and POC were more common in males compared to females, and this difference was χstatistically significant (2 = 0.577, $p< 0.01$).

There were 9 conversions (9%), and they were more common in males (7 males, 7%) compared to females (2 females, or 2%). This difference was χalso statistically significant (2 = 6.683, $p<0.05$). The causes for conversions are shown in Table 3. Table 4 shows analysed variables and their correlations with an occurrence of POC and IOC. In addition, it shows the correlation between the noted risk factors and the need for a conversion. The multivariate regression analysis showed the most important predictive factors for the occurrence of IOC, POC, and conversions with the confidence interval of 95%.

Table 3: Causes of conversions

Causes of conversions	Number	Percentage
Conversions- causes	9	9
Difficult access to Calot's triangle. Identification of anatomical structures	2	2
Bleeding from the tissues adjacent to gallbladder	1	1
Spilled gallstones	1	1
Gallbladder empyema	1	1
Mirizzi II	1	1
Bleeding from the vascular supply	1	1
Transection of the common bile duct	1	1
Impacted calculus	1	1

Table 4: Correlation between examined variables and incidence of complications

Variable	N/%	IOC=17	POC=13	CONV=9	p-value
Age <55	76 (76%)	7 (7%)	4 (4%)	2 (2%)	<0.05
>55	24 (24%)	10 (10%)	9 (9%)	7 (7%)	
Gender Male	32 (32%)	12 (12%)	10 (10%)	7 (7%)	<0.001
Female	68 (68%)	5 (5%)	3 (3%)	2 (2%)	
BMI <25	40 (40%)	4 (4%)	3 (3%)	2 (2%)	<0.001
>25	60 (60%)	13 (13%)	10 (10%)	7 (7%)	
White blood cell count <10X10^9/l	62 (62%)	5 (5%)	4 (4%)	1 (1%)	<0.01
>10X10^9/l	38 (38%)	12 (12%)	9 (9%)	8 (8%)	
CRP <5	51 (51%)	5 (5%)	3 (3%)	1 (1%)	0.0001
>5	49 (49%)	12 (12%)	10 (10%)	8 (8%)	
Pathohist report: Acute cholecystitis	25 (25%)	15 (13%)	12 (12%)	8 (8%)	<0.001
Chronic cholecystitis	75 (75%)	2 (2%)	1 (1%)	1 (1%)	

Ultrasound findings					
Group I (chronic cholecystitis)	58 (58%)	3 (3%)	1 (1%)	1 (1%)	<0.001
Group II (empyema, gangrene, wall thickness >3mm)	30 (30%)	10 (10%)	8 (8%)	7 (7%)	
Group III (gallbladder wall fibrosis, calculus >2cm)	12 (12%)	4 (4%)	4 (4%)	1 (1%)	

In addition, the ultrasonographic findings of empyema, gangrene of the gallbladder wall, and increased gallbladder wall thickness > 3 mm (group II) is a significant predictor of complications and conversion (OR = 4.92, 95% CI 1.61-18.13, $p< 0.001$). Pathohistologic analysis of the surgically extracted gallbladder with the diagnosis of acute cholecystitis was also the significant predictor for complications and conversion (OR 1.82, 95% CI 2.52-16.66, $P< 0.001$).

Table 5: Analysis of risk factors

Risk factors	**Level**	**Number**	**Percentage**
Age (years)	≤55	76	76
	>55	24	24
Sex	Female	32	32
	Male	68	68
BMI wt(kg)/ht(m^2)	<25	40	40
	>25	60	60
Previous Surg.	Nil	77	77
	Yes	23	23
GB palpable	Nil	74	74
	Yes	26	26
USG- wall thick	Nil	70	70
	Yes	30	30
Adhesions	Nil	74	74
	Yes	26	26

Discussion

Laparoscopic cholecystectomy became the preferred method for the treatment of symptomatic cholelithiasis. Laparoscopic cholecystectomy has many advantages over the standard open cholecystectomy: minimal trauma, decreased pain, shorter hospital stay, satisfactory cosmetic outcome, quick recovery, and return to work. However, numerous studies have shown this that laparoscopic cholecystectomy is associated with a higher frequency of complications compared to the standard open cholecystectomy including lesions to the common bile duct, injury to the vascular and visceral structures during the application of a Veress needle, and a trocar with fatal outcomes [14]. Review of recent literature shows that the incidence of injuries to the common bile duct is 0.1- 0.6% [15, 17]. Nuzzo *et al.* [17] analysed complications of laparoscopic cholecystectomies done in 184 hospitals in Italy in the time period from 1998 to 2000 and reported 235 (or 0.41%) injuries of the common bile duct. In the presented study, we report one case of the common bile duct transection (1%) that was corrected by choledochoeneteroanastomosis with the Roux-en-Y loop. Although recent publications lead to the conclusion that injuries of the common bile duct are more commonly encountered with the laparoscopic procedure, the controversy related to this issue is still present [81-20]. Tanitia *et al.* [19] analysed data from 13,305 laparoscopic cholecystectomies that were done over a period of 13 years and found that 52 (0.32%) cases had a transection of the common bile duct.

As laparoscopic cholecystectomies gained wider acceptance, the spectrum of complications associated with this procedure also became wider. Vascular injuries are the most common ones, and after the complications of anaesthesia, they are the second leading cause of mortality and morbidity in laparoscopic surgery [21-23]. in this study the most common complications noted were: iatrogenic perforations of the gallbladder- 5 (5%), bleeding from the tissues adjacent to the gallbladder 3 (3%), gallstones spilt into the peritoneal cavity 2 (2%). Intraoperative bleeding from the cystic artery occurred in 1 (1%), bleeding from the port in 1 (1%) and bleeding from the ligaments of the liver in 1 patients (1%). The transection of the common bile duct, a major complication, occurred in in only one patient (1%).

Both biliary and nonbiliary complications take an important place in the published studies. The most common biliary complications described are lesions of the common bile duct, lesions of the right hepatic duct, and perforation of the gallbladder with spilt calculi. Vascular injuries, injuries to the intestine, diaphragm, and iatrogenic pneumothorax represent the most important non-biliary complications.

In our study, there were 2 patients with the bile leak > 50-100 ml/24 h in the postoperative period. Other studies have shown that the injuries that are most commonly seen are minor injuries to the gallbladder, and ducts of Luschka with bile leaks, smaller bleeds with hematomas of the abdominal wall at the place of port, or in the tissues adjacent to the gallbladder. Although major injuries to the great blood vessels like the aorta, inferior vena cava, or iliac artery are rare, they are associated with high mortality rate [21-24]. A study by Kaushik R [24] reports that complications with bleeding occur at a rate at up to 10%. In this study, he analysed 10,320 publications in English, and showed results from seven medical centers by seven authors with more than 1,000 laparoscopic cholecystectomies each. Khan reported 2 complications with bleeding (0.04%) out of 4,975 laparoscopic surgeries. Marakis G *et al.* [23] reported 15 (1.22%) out of 1,225, and Kaushik R, 6 (0.49%) out of 1,233 laparoscopic cholecystectomies [24]. Intraoperative bleeding can be caused by insertion of the trocar, dissection of the gallbladder and the structures of the Calot's triangle. Postoperative bleeding can be caused by the removal of clips or ligatures and due to necrosis of the wall caused by effects of term cauterization.

The experience of the surgical team with the operative technique and equipment are important factors in preventing the complications. Surgeons who performed less than 100 laparoscopic cholecystectomies had more complications compared to surgeons with the greater number of surgeries [25, 26]. Contrary to that, there are other studies that show that surgeons with the greater number of laparoscopic surgeries have more complications [27]. Perforation of a gallbladder with gallstones spilt into the peritoneal cavity is a frequent complication, especially when associated with acute cholecystitis and larger gallstones [28, 20, 29]. Z'graggen K *et al.* [20] published a prospective study on 10,174 patients and showed that 1.4% complications were due to spilt gallstones. The estimated rate of gallbladder perforation is 10-30%. Duca *et al.* [30] reported that the incidence of iatrogenic perforation of the gallbladder was 1,517 (15.9%) out of 9,542 patients who underwent laparoscopic cholecystectomy. In our study, we report 5 (5%) iatrogenic perforations of the gallbladder. Out of that, 2 cases (2%) were associated with spilt gallstones, which is

in accordance with studies published by others Studies show that the most common complications after spilt and retained calculi in the abdominal cavity are: intra-abdominal abscesses, fistulas, and tumefactions of the abdominal wall [31, 33]. Dasari BVM *et al*. [32] reported spilt calculi in 19.8% laparoscopic cholecystectomies in their study. In our study, we report abscess collections during the postoperative period in 1 cases (1%). They required laparotomy and evacuation. In addition, we report that spilt gallstones during surgery were a cause for conversion to open procedure in 1 cases (11.11% out of all conversions).

In recent publications, the incidence of injuries to the intestine varies between 0.07 to 0.7%. Intestinal injuries are usually caused by insertion of the trocar, dissection of adhesions from previous surgeries, or from the present inflammation. Frequently, they are not recognised intraoperatively [14]. Some authors report intestinal ischemia, as well as an evisceration of the section of intestine through a port [34, 35]. None of the cases from our study had intestinal injuries.

Surgical wound infection is a complication that occurs with higher frequency in open cholecystectomy compared to laparoscopic cholecystectomy [36, 37]. In our prospective study, we report 1 (1%) patients with the operative wound infection. one patients (1%) had the incisional hernia, which agrees with studies published by other researchers. Boni *et al*. [36] reported that incisional complications were less commonly encountered in laparoscopic cholecystectomies compared to open cholecystectomies (mean 1.1% vs. 4.0%).

Hernias at the port insertion site have been reported in many papers with the incidence between 0.14% and 22%. Bunting DM [38] analysed 7 studies published in English, that were completed in the time period between 1995 and 2010, and that included 5984 patients who had laparoscopic cholecystectomies. This analysis reports 99 (on average 1.7%) cases of a hernia at the port insertion site as a postoperative complication. In the 7 studies that were included in this analysis, the incidence of this postoperative complication varies from 0.3% to 5.4%. The most common causes for the development of an incisional hernia were increased BMI, a diameter of the trocar duration of the surgery, a presence of a preexisting hernia, severity of inflammation, widening of the port for extraction of a gallbladder, and the age of the patient [38, 39]. In modern laparoscopic surgery, conversion is not considered to be a complication, but instead a way for the surgeon to safely finish the surgery. Therefore, the surgeon should have a low threshold for conversion [28, 32, 33]. In our study, we report 9 conversions (9%). Conversions were more frequent in males (7%) compared to females (2%), which agrees with studies published by others. Marakis G. *et al*. [23] published results of a 12- year study that included 1,225 patient who had laparoscopic cholecystectomies. This study reports 19 (1.5%) major complications, and 7.4% conversions. A meta-analysis on 14,545 laparoscopic cholecystectomies by Yang TF *et al*. reports 940 (6.41%) conversions [40]. This analysis shows that older age, male gender, acute cholecystitis, a gallbladder wall thickness > 3 mm and history of previous surgeries is all predictive factors for conversion. The rate of conversion reported in today's literature are 2-15% [41]. In cases with acute inflammatory process reported rates of conversion increase up to 35% [42].

Conclusion

We concluded that the laparoscopic cholecystectomy as a new technique for treatment of cholelithiasis, introduced a new spectrum of complications. Major biliary and vascular complications are life threatening, while minor complications cause patient discomfort and prolongation of the hospital stay. It is important recognising IOC complications during the surgery so they are taken care of in a timely manner during the surgical intervention.

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