



Preoperative scoring system validation and analysis of associated risk factors in predicting difficult laparoscopic cholecystectomy in patients with acute calculous cholecystitis: A prospective observational study

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ABSTRACT

Objective: Today laparoscopic cholecystectomy (LC) is the treatment of choice for acute cholecystitis. However, the presence of severe inflammation makes it challenging for the surgeons to accurately recognize the Calot's triangle which increases the risk of intraoperative complications. The aim of this study was to explore the validity of a scoring system used to predict difficult LC and to analyse the risk factors associated with difficult cholecystectomy in the setting of acute calculous cholecystitis.

Material and Methods: An observational study was conducted between December 2018 and December 2020 among 132 patients diagnosed with acute cholecystitis, who underwent laparoscopic cholecystectomy. A scoring system by Randhawa et al. was used preoperatively for all of these patients to predict difficult LC, which was correlated to intraoperative difficulties in actual surgery. Data were analysed using the SPSS version 26.0.

Results: Mean age was 43.63 ± 13.37 , with almost equal representation from both sexes. History of previous attacks of cholecystitis, impacted stone, thickness of GB wall were statistically significant in calculating preoperative difficulty of laparoscopic cholecystectomy. The scoring system had a sensitivity and specificity of 82.6% and 63.5%, respectively. The conversion rate to open cholecystectomy was 6.9%.

Conclusion: Analysing the significant risk factors before operating in the presence of an inflamed gallbladder can reduce the overall mortality and morbidity. An accurate preoperative scoring system will enable the operating surgeon to be well prepared with adequate resources and time. The patient attenders can also be counselled regarding the risk involved beforehand.

Keywords: Laparoscopy, cholecystectomy, risk factors, cholecystitis

INTRODUCTION

Gallstones are hardened deposits of the bile that is formed within the gallbladder and varies in size and shape (1). When an imbalance in the chemical constituents of the bile occurs, it leads to the precipitation of one or more of the components resulting in the formation of gallstones. Gallstones are becoming common and are seen in all age groups, with incidence gradually increasing with age and about a quarter of women developing it above the age of 60. In most cases, they are asymptomatic, and only about 10% will show symptoms within five years of diagnosis. Hence, the risk of developing symptomatic cholelithiasis is close to 2.0-2.6%/year, which is quite low (2). Acute calculous cholecystitis (ACC) constitutes around one-third of all surgical emergencies at the hospital. According to the study conducted by World Society of Emergency Surgery (WSES), ACC is the second most common source of complicated intra-abdominal infection (18.5%). The main cause, biliary stones, is seen in about 6.5% and 10.5% of men and women, respectively (3).

After its implementation in 1987 by P. Mouret, laparoscopic cholecystectomy (LC) has become the treatment of choice in managing symptomatic gallstone diseases. The advantages of LC are well defined relative to open cholecystectomy and includes less postoperative pain, shorter ileus, earlier diet and sooner discharge from hospital (4-9). However, LC remains a highly demanding technical procedure which can lead to dramatic complications, especially when the surgeon is faced with serious inflammation that obscures the calot's triangle during emergency LC in the setting of acute cholecystitis which causes increased operative time, high con-

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version rate and common bile duct injuries with other postoperative complications. Many factors can make a laparoscopic cholecystectomy complicated, which includes old age, male sex, fever and previous symptomatic episodes, obesity, prior gastro-intestinal surgery, prior symptomatic cholecystitis and some ultrasonographic findings, such as distended gallbladder (GB) with a thick wall, collection around the gallbladder fossa and an impacted stone (10). The difference between emergency and scheduled LC, however, is not adequate to accurately predict operational problems, which improves the risk of surgery and encourages dissolution of the staff and the operating theatre (11).

In order to classify high risk treatments, a preoperative predictive statistical score for operating complexity is significant and may be effective in enhancing patient and attenders counselling, maximizing pre-operative preparation, and recognizing high risk patients and training them beforehand. A significant feature of the preparation of laparoscopic surgery is the preoperative estimation of the possibility of conversion or operating difficulties. High Risk patients can be notified beforehand with aid of detailed prediction, and the operating team will have a chance to be cautious. Surgeons will also get an insight about the procedure so that they can properly ready the team for surgery. Prolonged hospitalization with intensive postoperative care should be scheduled for patients with a high-risk score. From time to time, numerous ranking methodologies have been proposed using various standards adding to the debate. Due to some difficult conditions that exist during laparoscopic cholecystectomy in acute cholecystitis, the following study is designed to consider the challenges faced in the operating room and determine the risk factors of a difficult laparoscopic cholecystectomy in the picture of acute cholecystitis using a scoring system devised previously.

MATERIAL and METHODS

Study Design and Participants

A prospective observational study was conducted between the period of December 2018 and December 2020 for all patients who were diagnosed with acute cholecystitis on the basis of clinical, laboratory and ultrasound findings and presented to the surgery out-patient department or to the emergency department and underwent laparoscopic cholecystectomy during the study period of two years. Patients with bile duct stones, pregnant/pediatric patients, patients in cholangitis, patients in cardiac failure and patients in whom laparoscopic cholecystectomy was performed with other laparoscopic intervention in the same setting; were excluded from this study. The sample size for our study was calculated based on a study by Brodsky A et al. in which the reported proportion of patients having complications (infection, adhesion, bleed, bile duct injury) in laparoscopic cholecystectomy in the background of acute cholecystitis is 17%

(12). Using this as an estimated proportion of patients with complications in acute cholecystitis at a relative precision of 6.5% and at 95% confidence level, we estimated that the minimum sample size required for our study would be 130 patients.

Study Tools and Data Collection

The recruited patients were categorized into mild, moderate, and severe cholecystitis based on Tokyo guidelines 2018 (TG 2018) (13). TG 2018 diagnostic criteria for acute cholecystitis includes: 1. Local signs of inflammation; right upper quadrant mass/pain/tenderness (Murphy's sign), 2. Systemic signs of inflammation; fever, elevated CRP, elevated white blood cell (WBC) count and 3. Ultrasound findings; thick gallbladder wall (>4 mm), gallbladder size, debris echo, ultrasound murphy's sign, pericholecystic fluid (13). Based on these TG 2018 criteria, patients were divided into:

1. Grade I (Mild) cholecystitis; Grade I can be defined as acute cholecystitis in healthy patients. These patients present without organ dysfunction and mild inflammatory changes in the gallbladder.
2. Grade II (Moderate) cholecystitis; can include any one among- elevated WBC counts (>18.000), positive Murphy's sign, prolonged duration of symptom onset (>72 hrs), marked local signs of inflammation (gangrenous cholecystitis, pericholecystic abscess, hepatic abscess, biliary peritonitis, emphysematous cholecystitis)
3. Grade III (Severe) cholecystitis; cardiac failure (hypotension requiring inotropic supports), neurological dysfunction, pulmonary dysfunction ($\text{PaO}_2/\text{FiO}_2$ ratio > 300), kidney injury (oliguria and creatinine > 2 mg/dL), hepatic failure (PT-inr > 1.5), thrombocytopenia < 100.000.

Data were collected as per the designed case record form (CRF). A patient information sheet containing the study rationale, noting strict voluntary participation was provided. After providing consent, the participant was interviewed for the study. The following data were collected in the structured case record form.

1. Socio-Demographic Characteristics: Patient initials, age, sex.
2. Patient Clinical Characteristics: BMI, previous episodes of cholecystitis, presence of abdominal scar, palpable gallbladder, wall thickness, collection, impacted stone, conversion of operative procedure.

All patients diagnosed with acute calculous cholecystitis who were admitted were kept Nil per oral until the surgery and started on Injection Cefuroxime 1.5 gm iv Q12H with adequate analgesia every sixth hourly. Their pulse rate, blood pressure and saturation were monitored at regular intervals and progress noted. All routine blood investigations like total count, differential count, renal function test and liver function tests were sent. Clotting parameters were also noted. The patients were also

given detailed information regarding their condition, plan of surgery, duration of hospital stay for approximate number of days. They were also informed regarding their participation in the study, and informed consent was taken. The complications of laparoscopic cholecystectomy such as bleeding, risk of bile duct injury causing bile leak, iatrogenic bowel injury, need for drain placement, possibility of conversion to an open cholecystectomy procedure were also explained to the patient and the attenders in a language understood by them. A scoring system employed by Randhawa et al. was used for all the patients admitted after due permissions were obtained (Table 1) (14). The patients were given a score at the time of admission based on the history, clinical findings and the ultrasonographic findings. The patients were then divided into easy, difficult, and very difficult based on their scores pre-operatively (Table 2). The patients were given a pre-operative score based on the above table with a total score of 15.

All surgeons in the hospital were involved in the surgery. All of the patients were operated on within seven days of presentation of the symptoms. Surgery was performed using carbon

dioxide pneumoperitoneum with a pressure of 12 mmHg and with two 5 mm, two 10 mm standard ports. The surgery was started after the induction of anaesthesia. The pre-operative checklist protocol was strictly followed. The time taken from first port incision until the last port closure was documented. All intraoperative events including the duration of surgery, gall bladder appearance, bile leakage, spilled gallstones, common bile duct injury, conversion and the number of blood transfusions were also noted in case of haemorrhage. Based upon the events intra-operatively, surgery was also classified into easy, difficult, and very difficult grades. Intraoperative assessment was then compared with the preoperative predictive score to determine the usefulness of the preoperative predictive score: 1) Easy was where the time taken was less than sixty minutes, 2) Difficult was where the time taken was between sixty to one hundred and twenty minutes or with bile spillage or with common bile duct injury, 3) Very difficult was where the time taken was more than one hundred and twenty minutes or the surgical procedure was converted to open cholecystectomy (Table 3).

Table 1. Preoperative score parameters-total maximum score 15

Parameters			Maximum Score
Age	<50 years (0)	>50 years (1)	1
Sex	Female (0)	Male (1)	1
Previous attacks of cholecystitis	No (0)	Yes (4)	4
BMI	<25 (0)	25-27.5 (1) > 27.5 (2)	2
Abdominal scar	No (0)	Infra-umbilical (1)	
supra-umbilical (2)	2		
Palpable gallbladder	No (0)	Yes (1)	1
GB wall thickness	Thin (0)	Thick > 4 mm (2)	2
Pericholecystic collection	No (0)	Yes (1)	1
Impacted stone	No (0)	Yes (1)	1

Table 2. Preoperative prediction of difficulty levels according to the scoring system

Scores	Preoperative difficulty level
0-5	Easy
6-10	Difficult
11-15	Very difficult

Table 3. Intraoperative difficulty level classification of the patients

Intraoperative Difficulty Level	Basis
Easy	Easy was where the time taken is less than sixty minutes.
Difficult	Difficult was where the time taken was between sixty to one twenty minutes or with bile spillage or with common bile duct injury.
Very difficult	Very difficult was where the time taken was more than one twenty minutes or the surgical procedure was converted to an open cholecystectomy.

Statistical Analysis

The collected data were extracted into Microsoft Excel 2020 and coded for analysing using SPSS 26.0. Proportions, mean, and standard deviation were calculated to describe the data. Univariate analyses were performed to study the association between demographic factors and outcome variables, using chi-square test, ANOVA test and independent sample t test, as appropriate. Significant variables from univariate analysis were put into the multivariate model and analysed via multivariate logistic regression. A p-value of less than or equal to 0.05 was considered significant for all purposes.

Ethics Consideration

Ethics approval for the study was obtained from the institutional ethics committee of the hospital to which the researchers are affiliated (IEC no: 390/2018). Informed consent was obtained from each participant prior to participation in the study.

RESULTS

Mean age of 132 patients included in this study was 43.63 ± 13.37 years. There was almost equal representation from both sexes in this study, with males (48.1) and females (51.9). According to Tokyo Guidelines, 102 patients belonged to Grade 1, 24 patients to Grade 2 and six patients belonged to Grade 3.

Clinical parameters used to calculate the preoperative score are depicted in Table 4. Most patients did not report previous attacks of cholecystitis (60.3), had normal BMI (67.2), had no abdominal scar (64.1). In the setting of acute cholecystitis, a palpable gallbladder was found only in 5.3% of the patients in this study. Ultrasonographic study findings showed most of the patients had thick GB walls (57.3), without any collection (88.5) and without the presence of any stone (82.3). The conversion rate from laparoscopic cholecystectomy to open cholecystectomy was 6.9%. Out of the nine converted patients, five patients had dense adhesions, one patient had suspected CBD injury, two patients had suspected bowel injury and one patient had gangrenous cholecystitis.

On scoring the surgeries preoperatively, 47.3% cases were evaluated to be easy while 52.7% were difficult/very difficult surgeries. On intraoperative assessment of the surgery, 64.9% of the surgeries were easy while 35.1% were difficult. Based on comparison of pre-operative outcome, the sensitivity of intra-operative outcome was 82.6% and specificity was 63.5% (Table 5).

Multivariate analysis comparing intraoperative difficulty with associated risk factors depicted that only three variables (previous attacks of cholecystitis, thick GB wall and an impacted stone) were statistically significant in predicting preoperative difficulty (Table 6).

Table 4. Patient parameters for preoperative score assessment

Patient parameter (n= 132)	Summary statistics n (%)
Age	
≤50	93 (70.2)
>50	39 (29.8)
Sex	
Female	69 (51.9)
Male	63 (48.1)
Previous attacks of cholecystitis	
No	80 (60.3)
Yes	52 (39.7)
BMI	
<25	89 (67.4)
25-27.5	30(22.9)
>27.5	13 (9.8)
Abdominal scar	
No	85 (64.1)
Infraumbilical	42 (32.1)
Supraumbilical	5 (6.6)
Palpable gallbladder	
No	124 (94.7)
Yes	8 (5.3)
Wall thickness	
Thin (<4 mm)	57 (42.7)
Thick (≥4 mm)	75 (57.3)
Pericholecystic collection	
No	116 (88.5)
Yes	16 (11.5)
Impacted stone	
No	108 (82.3)
Yes	23 (17.7)
Conversion	
No	123 (93.1)
Yes	9 (6.9)

DISCUSSION

Cholecystectomy is the procedure to remove the gallbladder as a result of stone or inflammation. Today, laparoscopic cholecystectomy has become the gold standard for the management of acute cholecystitis (15). It provides many advantages over open surgery, such as minimal postoperative pain, good cosmesis, short hospital stays and fast recovery. However, 2-15 % of the patients undergoing LC are converted to open cholecystectomy

Table 5. Comparison between preoperative and intraoperative difficulty assessment

	No of cases easy on surgery n (%)	No of cases difficult/very difficult on surgery n (%)	χ^2	p
No of cases easy on preoperative evaluation	55 (41.2)	8 (6.1)	25.49	<0.001
No of cases difficult/very difficult on preoperative evaluation	31 (23.7)	38 (29.0)		

Table 6. Univariate and multivariate analyses of intraoperative outcome with risk factors

Risk factors	Intraoperative outcome n (%)		Unadjusted odds ratio (95% CI)	p	Adjusted odds ratio (95% CI)	p
	Easy (n= 86)	Difficult/very difficult (n= 46)				
Age (years)						
≤50	64 (74.4)	29 (63.0)	Reference	0.09	Reference	0.16
>50	22 (25.5)	17 (37.0)	1.96 (0.91, 4.23)		2.04 (0.76, 5.51)	
Sex						
Female	45 (52.3)	24 (52.1)	Reference	0.75	Reference	0.81
Male	41 (47.7)	22 (47.9)	1.13 (0.55, 2.31)		0.90 (0.37, 2.16)	
Previous attacks of cholecystitis						
No	64 (74.4)	16 (34.7)	Reference	<0.001	Reference	0.01
Yes	22 (25.6)	30 (65.3)	6.30 (2.86, 13.87)		3.34 (1.33, 8.35)	
BMI						
<25	56 (65.1)	33 (71.7)	Reference		Reference	
25-27.5	18 (20.9)	12 (26.0)	1.34 (0.58, 3.12)	0.50	1.65 (0.57, 4.78)	0.36
>27.5	12 (13.9)	1 (0.3)	0.15 (0.02, 1.17)	0.07	0.39 (0.04, 3.68)	0.41
Abdominal scar						
No	56 (65.1)	29 (63)	Reference		Reference	
Infraumbilical	25 (29.0)	17 (37.0)	1.36 (0.63, 2.92)	0.57	1.15 (0.43, 3.05)	0.60
Supraumbilical	5 (5.8)	0 (0)	0.50 (0.05, 4.69)	0.43	0.19 (0.01, 5.76)	0.78
Palpable gallbladder						
No	83 (96.5)	41 (89.1)	Reference	0.06	Reference	0.16
Yes	3 (3.5)	5 (10.9)	5.06 (0.94, 27.21)		4.93 (0.54, 44.79)	
Wall thickness						
Thin (<4 mm)	50 (58.1)	7 (15.2)	Reference	<0.001	Reference	0.002
Thick (≥4 mm)	36 (41.8)	39 (84.7)	9.52 (3.64, 24.89)		6.15 (1.99, 19.04)	
Impacted stone						
No	84 (97.6)	24 (52.1)	Reference	0.001	Reference	0.04
Yes	2 (2.3)	22 (47.9)	12.91 (2.88, 57.82)		7.52 (1.13, 50.03)	
Collection						
No	79 (91.8)	37 (80.4)	Reference	0.04	Reference	0.76
Yes	7 (8.2)	9 (19.6)	3.20 (1.06, 9.66)		1.26 (0.30, 5.24)	

due to various difficulties encountered during the procedure (15). The difficulty in cholecystitis is due to adhesions present around at the Calot's triangle, history of upper abdominal surgery, acutely inflamed and gangrenous gallbladder, gallbladder

empyema, Mirizzi's syndrome, previous cholecystostomy, and cholecystogastric/duodenal fistula (16).

The complications of laparoscopic cholecystectomy are haemorrhage, gallbladder perforation causing biliary leakage, bile

duct injury, subhepatic collection, biliary fistula, surgical site infection, hematoma formation (17). Preoperative and intraoperative factors, such as male sex, old age, body mass index (BMI), history of abdominal surgery, leucocytosis and ultrasonographical findings like distension of the gallbladder, thick gallbladder lining, impacted stone, and pericholecystic fluid collection are the risk factors that make laparoscopic cholecystectomy technically difficult and time consuming (18). The controversy surrounding the timing of laparoscopic cholecystectomy continues all over the world. In this study, patients were operated within three days of presentation, which is in accordance with Tokyo guidelines 2018. In our study, we compared the perioperative and intraoperative risk factors which predict a difficult cholecystectomy in the setting of acute cholecystitis. In this study, laparoscopic surgery was conducted in 132 patients, and the risk factors of a difficult gallbladder were analysed.

Old age is considered as a significant risk factor to predict difficult laparoscopic cholecystectomy in various studies (18). In this study, age was not a significant risk factor. This is probably because of the low sample size of our study. Sex is known to be an important risk factor for difficult surgery (18). However, in this study, sex did not play any major role in the surgery. Patients with history of previous episodes of cholecystitis have been previously reported to have difficult laparoscopic cholecystectomy (19). In this study, similarly, patients with past cholecystitis attack history had difficult LC. This can be probably explained by the presence of dense adhesions at the Calot's triangle and gallbladder fossa due to repeated episodes of inflammation. Clinical findings such as BMI, abdominal scar, and palpable gallbladder have been shown to be significant risk factors in the prediction of operative difficulties (19). However, in this study, palpable gallbladder was not a significant risk factor for a difficult LC. Body mass index (BMI) and abdominal scar in this study were not associated with difficulty at surgery which was in similarity with other studies (15). Increased gallbladder thickness was another significant risk factor which helps to predict difficult laparoscopic cholecystectomy because it limits the extent of anatomical definition and makes dissection difficult from the gallbladder bed and due to distorted Calot's triangle. In this study, gallbladder wall thickness ≥ 4 mm was also a risk factor making LC difficult intra-operatively. Stone impacted at the neck of the gallbladder is an important risk factor. Impacted stone causes distension of the gallbladder making it difficult to grasp and making dissection difficult similar to the thickened gallbladder (15). This risk factor was also significant in our study.

CONCLUSION

Our study concluded that gallbladder wall thickness, impacted stone and previous attacks of cholecystitis were significant risk factors in predicting difficult laparoscopic cholecystectomy in the setting of acute calculous cholecystitis. Hence, by analysing

these risk factors, overall mortality and morbidity while operating in the presence of inflamed gallbladder can be reduced. Preoperative scoring system also helps the operating surgeon and team to be well prepared with adequate resources and time and the patient attenders along with patient can also be counselled regarding the risk involved beforehand.

Limitations of the Study

One of the limitations of this study was its sample size. A small sample size may have influenced non-significant relationship between few variables. Second, the participation of surgeons with different levels of expertise in this study may have indirectly placed a bias on measuring intraoperative difficulty in surgery. Even with few limitations, this study is among a few novel studies to successfully explore the validity of a preoperative scoring system to predict difficult laparoscopic cholecystectomy in the setting of acute cholecystitis. However, a prospective study with larger sample size may help us to better assess and validate this scoring system.

Ethics Committee Approval: This study was approved by the Institutional Ethics Committee of St. Johns Medical College and Hospital, and informed consent was obtained from all the participants prior to participation in the study (IEC 390/2018).

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ORJİNAL ÇALIŞMA-ÖZET

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Akut taşlı kolesistitli hastalarda zor laparoskopik kolesistektomiye öngörmede ilişkili risk faktörlerinin analizi ve preoperatif skorum sistemi validasyonu: Prospektif gözlemsel bir çalışma

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ÖZET

Giriş ve Amaç: Günümüzde laparoskopik kolesistektomi (LK), akut kolesistit için tercih edilen tedavi yöntemidir. Ancak, şiddetli enflamasyonun varlığı, cerrahların intraoperatif komplikasyon riskini artıran Calot üçgenini doğru bir şekilde tanımasını zorlaştırır. Çalışmamızın amacı, zor LK'yi tahmin etmek için kullanılan bir puanlama sisteminin geçerliliğini araştırmak ve akut taşlı kolesistit ortamında zor kolesistektomi ile ilişkili risk faktörlerini analiz etmektir.

Gereç ve Yöntem: Aralık 2018 ile Aralık 2020 arasında akut kolesistit tanısı alan ve laparoskopik kolesistektomi yapılan 132 hasta üzerinde gözlemsel bir çalışma yapılmıştır. Gerçek cerrahideki intraoperatif zorluklarla ilişkili olan zor LK'yi tahmin etmek için tüm bu hastalara preoperatif olarak Randhawa ve arkadaşları tarafından geliştirilen bir skorum sistemi kullanıldı. Veriler SPSS versiyon 26.0 kullanılarak analiz edildi.

Bulgular: Ortalama yaş 43,63 ± 13,37 idi ve her iki cinsiyet neredeyse eşitti. Laparoskopik kolesistektominin preoperatif zorluğunun hesaplanmasında önceki kolesistit ataklarının öyküsü, gömülü taş, safra kesesi duvar kalınlığı istatistiksel olarak anlamlıydı. Puanlama sistemi sırasıyla %82,6 ve %63,5 duyarlılık ve özgüllüğe sahipti. Açık kolesistektomiye geçiş oranı %6,9 idi.

Sonuç: İltihaplı bir safra kesesi varlığında ameliyattan önce önemli risk faktörlerinin analiz edilmesi genel mortalite ve morbiditeyi azaltabilir. Doğru bir preoperatif skorum sistemi, ameliyatı yapan cerrahın yeterli kaynak ve zaman ile iyi hazırlanmasını sağlayacaktır. Hasta refakatçileriyle önceden ilgili risk konusunda da istişare edilebilir.

Anahtar Kelimeler: Laparoskopik, kolesistektomi, risk faktörleri, kolesistik

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