ORIGINAL RESEARCH ARTICLE

An Observational Study of Pre-Operative Predictors of Difficult Laparoscopic Cholecystectomy using Clinical, Haematological, Radiological Parameters

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ABSTRACT

Introduction: Laparoscopic Cholecystectomy (LC) is the gold standard for most gallbladder ailments. However, under certain circumstances during surgery, an LC needs to be converted to Open Cholecystectomy (OC). Conversion to OC is determined by several intrinsic and extrinsic factors; some of these can be detected during the preoperative period using clinical examination and routine investigations. Aim: This prospective study aimed at determining if selected preoperative factors can determine the conversion of LC to OC.

Material and methods: This was a single centre, hospital-based, closed, prospective study involving sixty participants. Data on demographic variables, clinical history, haematological, and radiological parameters were collected preoperatively, and a predictive score was calculated to determine the conversion of LC to OC.

Results: Overall, for assorted reasons, about 8.3% of participants needed conversion to open cholecystectomy for completion of the procedure. Further, based on preoperative predictive score, four out of five participants (80%) required conversion to OC. On multivariable analysis, the strongest predictor of 'difficult' LC was the thickness of the Gallbladder. Gallbladder thickness of more than 3 millimetres increased the odds of a difficult LC by 17 times (95%CI = 4.3-93.7). Further, male gender, being overweight (BMI >27.5), history of the previous hospitalization, identification of pericholecystic collection and impacted GB stone on USG increased also increased the odds of difficult LC. Age of participants and total leukocyte count were not associated with increased odds of conversion to OC.

Conclusion: Despite, utmost precautions, the conversion of LC to OC in some cases is inevitable. However, some preoperative factors can accurately predict the conversion of Laparoscopic cholecystectomy to open cholecystectomy.

Keywords: Pre-Operative Predictors, Difficult Laparoscopic Cholecystectomy, Haematological Parameters, Radiological Parameters

INTRODUCTION

Within a decade since the first case was conducted in the year 1989, Laparoscopy Cholecystectomy had become the gold standard for managing many ailments of the gallbladder.[1,2] Further, ever since its introduction, LC's technique has undergone several drastic changes reflecting the needs of the patients, concerns of the surgeons, and advancements in the technology.[3] The most advanced, and least invasive development had been the introduction of single incision laparoscopic surgery (SILS).[4,5] However, the standard technique of performing LC uses four ports. Given its minimally invasive approach, Laparoscopic cholecystectomy is associated with less postoperative pain, reduced need for postoperative analgesia, shortened hospital stay (24-48 hours) and quicker return to full activity (within 1 week) in comparison to open cholecystectomy.[6–8]

Laparoscopy, despite its wide acceptance, increasing popularity and cost-effectiveness, has challenges of its own. In addition to the systemic risks of anaesthetic and surgery, common complications associated with laparoscopic cholecystectomy include bleeding, visceral injury, diarrhoea, retained gallstones, and injury to the bile ducts.[9–11] Most of the technical disadvantages associated with LC directly or indirectly result from the creation of pneumoperitoneum.[12–14] Anaesthetic management of a laparoscopic procedure is complicated by the following factors:

i Increased intra-abdominal pressure, secondary to the creation of pneumoperitoneum.[15]
ii Metabolic changes, secondary to absorption of carbon dioxide into the bloodstream.[16]
iii Patient's altered position.[13]

Over the decades, both surgeons and anaesthesiologists have evaluated a variety of techniques and guidelines to make the laparoscopy procedure safer and more comfortable. The most fundamental approach is to perform a thorough check-up of

the patients to detect an undiagnosed illness.[17,18] A complete physical and laboratory examination can inform the physician if the patient can tolerate the physio-pathological changes of laparoscopy. Although, absolute contraindications for GA and laparoscopy are rare, nevertheless, there are many conditions and diseases which makes LC challenging for the surgeon.[19] In many instances, the procedure needs to be converted into open cholecystectomy or the number of ports (in case of 3 or fewer ports) needs to be increased.[20,21]

With the advancement in radiography -, ultrasonography- and pathology, it has become possible to minimize the incidence of complications.[22] It may not be possible to accurately predict a 'difficult' LC for every patient, however, the occurrence of complications and other unfortunate events can be predicted with a fair degree of accuracy at least in some patients. Therefore, it is of utmost importance to identify all factors before the surgery that can assist a surgeon (and their team) to prepare in advance to minimize injury or limit the extent of complication(s) during LC. Thus, this study was conducted to investigate and identify clinical, haematological, and radiological factors that determine/predicts 'difficult' laparoscopy cholecystectomy among patients suffering from cholecystitis and cholelithiasis.

MATERIAL AND METHODS

Study design: This was a hospital-based, single-centre, prospective, observational study.

Study settings: The present study was conducted at the Department of General Surgery, LN Medical College, Bhopal. It is a tertiary care institute.

Study duration: The total duration of the study was 18 months; from December 2019 till May 2021

Study outcomes: Primary outcome parameters were the proportion of patients having difficult LC and to identify the determinants of difficult LC. In addition, the secondary outcome of the study was to determine the positive predictive value of a scoring system developed for this study. This scoring was developed after the review of the literature and taking into consideration the other scoring system recommended by several researchers.[23–25] The scoring system, categorisation of patients, and ease of LC are given in Tables 1, 2, and 3, respectively.

Sample size calculation: Using the prescribed formula for incidence/proportion the minimum required sample size for this study was calculated as 60. Sample size is calculated using following formula: n = [DEFF*Np(1-p)]/ [(d^2/$Z^2_{1-\alpha/2}$*(N-1) +p*(1-p)] (***https://www.openepi.com/SampleSize/SSPropor.htm); p- expected prevalence; p= 4.0% ((24)) ; $Z^2_{1-\alpha/2-}$ - Standard Normal Deviation; Confidence Interval =95%; d- desired precision = 0.05 for 95% CI; DEFF-Design Effect= 1; n- Minimum required sample size= 60.

Case definition: A patient presenting with acute or chronic cholecystitis with or without cholelithiasis undergoing laparoscopic cholecystectomy and fulfilling the below-mentioned selection criteria.

Inclusion Criteria

- Patients presenting with acute cholecystitis or chronic cholecystitis with or without cholelithiasis
- Patient advised/scheduled for laparoscopic cholecystectomy for their ailment(s).
- Patients aged more than 18 years of age.
- Patients giving written informed consent to participate in the study.

Exclusion Criteria

- Patients with Common bile duct calculi, dilated CBD, cholangitis, (conditions mandating CBD exploration).
- Patients with symptoms of obstructive jaundice.
- Patients with known Carcinoma of the gall bladder.
- Patients not willing for laparoscopic cholecystectomy or having absolute contraindication for laparoscopic surgeries.
- Patient's refusal to participate in the study.

Informed consent

A bi-lingual (Hindi & English) consent form was drafted following the prescribed guidelines for research on human participants. The consent form was sent to the ethical committee for approval. The consent form was given to all the participants to read. Thereafter, the contents of the consent form were explained to all the prospective participants. All the questions from participants about the study, procedure, follow-up, and data privacy were answered. The participants were informed and explained that they have the right to withdraw from the study at any point in time. Thereafter, willing participants were asked to sign the consent form. One signed copy of the consent form was retained by the principal investigators and one copy was given to participants.

Data collection: The data were collected in a paper-based proforma. The proforma had four parts as follows: (i) Demographics and Clinical details. (ii) Pathological and Radiological findings (iii) Pre- and Intra-operative details. (iv) Postoperative details.

Source of data: There were two sources of data. First was the interview with the participants containing details about the demographic details, clinical history, symptoms, and previous treatments (if any). The second source of the data were reports containing details about clinical examination, laboratory & radiographic findings.

PLAN and PROCEDURE

i **Clinical Examination:** Few days before the surgery, a detailed clinical examination of every patient was completed, this was followed by appropriate laboratory and radiological investigations.

ii **Pre-operative check-up:** A Day before the surgery, a team of anaesthesiologists completed the pre-anaesthetic check-up. After obtaining the consent from the participants, relevant data were collected from the participants clinical, laboratory, and radiological records.

iii **Operation Theatre:** On arrival in the operating room, the identity of the participant and the consent was verified again; the preoperative assessment was reviewed and updated.

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iv **Procedure:** All patients were operated on using a Standard Laparoscopy procedure.

v **Intraoperative Period:**
- a The vital parameters were recorded at the prescribed time points during the operative period.
- b The pathological characteristics of the gallbladder and the surrounding structures were noted.
- c Any instance of complication including injury, bile spillage, stone spillage, perforation etc., were recorded.
- d Total time for the surgery (skin incision to skin suturing) was noted.

vi **Postoperative period:** Predetermined clinical parameters were monitored during the postoperative period until discharge from the hospital.

Endpoint of study:
The study was terminated if: (i) A participant decided to withdraw from the study, (ii) if for any reason the surgery was postponed for more than 14 days, (iii) After the discharge from the hospital.

Statistical analysis plan: The primary outcome was the incidence of a difficult laparoscopy cholecystectomy procedure. We aimed to identify from the collected data the preoperative factors either clinical, pathological, or radiological that determined or predicted a difficult laparoscopic procedure. The coded data were imported into Stata 16.1 version for analysis. For the interval and ratio data types, the author calculated the mean, median, mode, and standard deviation.[26] For the nominal and ordinal data, the author calculated the frequency, percentage, and proportion. The interval and the ratio data variables were analysed using a student's t-test test. Categorical variables were analysed using chi-square (χ^2) tests.[27] A univariate and stepwise forward multi-variable logistic regression was conducted to identify the predictors of 'difficult' LC.[26] A *P*-value < 0.05 was considered statistically significant.

RESULTS

The mean and median age of participants in the present study was 48.6 and 48.5 years, respectively. The mean age of the participants for whom the LC was categorised as easy, difficult, and very difficult was 48.5, 51.6, and 46 years, respectively. Overall, there were more than twice as many female (70%) participants in comparison to male participants (30%).

The mean Total Leucocyte Count (TLC) among the participants in the easy, difficult, and very difficult groups were 8,173, 8120, and 13520, respectively. The difference in the mean TLC between the participants who had 'easy & difficult' and 'easy & very difficult' was statistically significant ($p<0.05$). None of the participants in our study was underweight (BMI < 18.5 Kg/sq. metres). The distribution of BMI i.e., normal, overweight, and obesity among the participants in the 3 groups was statistically significant ($p= 0.0172$). The mean BMI of the participants in easy, difficult, and very-difficult LC groups were 26.1, 29.1, and 28.7 Kg/sq. meters, respectively. The difference in the mean BMI among the participants in the three groups was statistically significant ($p<0.05$).

None of the participants who had an 'easy' LC had a pericholecystic collection on USG in comparison to 60% and 100% of participants who had a difficult and very-difficult LC. The proportion of participants who had an impacted Gallstone visible on USG among the easy, difficult, and very-difficult LC group was 6%, 20%, and 60%, respectively. The difference in the occurrence of both pericholecystic collection and impacted gallstone among the participants in the three groups was statistically significant ($p<0.05$). None of the participants in any of the three groups had adhesions visible on USG. The mean thickness of the gallbladder among the participants who had an easy, difficult, and very-difficult laparoscopic cholecystectomy was 3.12 mm, 4.0mm, and 4.7mm, respectively. The T-test value suggests that the difference in the mean thickness of the gallbladder among the participants in the three groups was highly significant (t

Scoring Factors	Minimum Score		Maximum Score		Total
	Variable	Score	Variable	Score	
Clinical					
Age	<50	0	>50	1	1
Sex	F	0	M	1	1
History of the previous hospitalization	No	0	Yes	3	3
BMI	<25	0	>27.5	2	2
Abdominal Scar	No	0	Yes	1	1
Palpable Gall bladder	No	0	Yes	1	1
Haematological					
TLC	<11000	0	>11000	1	1
USG					
Gall bladder wall thickness	<4 mm	0	>4 mm	2	2
Gall bladder adhesions	No	0	Yes	1	1
Pericholecystic fluid collection	No	0	Yes	1	1
Impacted Stone	No	0	Yes	1	1
Total Maximum Score = 15					

Table-1: Clinical Preoperative Scoring System

Difficulty	Score
Easy	0-5
Difficult	6-10
Very difficult	11-15

Table-2: Categorization of the patient based on the preoperative scoring system

Difficulty level	Criteria
Easy	• Operative Time <60 min • No bile spillage • No injury to duct or artery
Difficult	• Operative Time 60 - 120 min • Bile or stone spillage • Injury to duct or artery • No conversion to open
Very difficult	• Operative Time >120 min • Conversion to OC

Table-3: Criteria to categorize LC procedure

Category of LC	n	%
Easy	50	83.3
Difficult	5	8.3
Very Difficult	5	8.3
Total	60	100.0

Table-4: Distribution of participants based on the ease of Laparoscopic Cholecystectomy (LC) (n=60)

Total Score	Group		
	Easy (n, %)	Difficult (n, %)	V. Difficult (n, %)
Number			
0-5	50 (100.0)	0 (0.0)	1 (20.0)
6-10	0 (0.0)	5 (100.0)	0 (0.0)
11-15	0 (0.0)	0 (0.0)	4 (80.0)
TOTAL	50	5	5
Total Score			
Mean (SD)	2.5 (1.31)	6.4 (0.54)	10.4 (3.04)
Median (IQR)	4	6	11
Range	0 5	6 7	5 12

Table-5: Distribution of participants based on Total Predictive Score (n=60)

test= 5.72, p-value <0.0001).

Table 4 show the distribution of the included participants based on the categorization of laparoscopic cholecystectomy. Overall, for various reasons, about 8.3% of participants needed conversion to open cholecystectomy for completion of the procedure.

Table 5 shows the distribution of the total predictive score among the participants who were classified to have an easy, difficult, and very difficult LC using the pre-defined criteria. Only 1 participant who had a predictive score between 0-5 had a very difficult LC. There was an injury to CBD requiring conversion to OC, which led to the categorization of this participant as a very difficult LC.

Based on the preoperative predictive scoring system, 4 participants were demined to have a very difficult LC. However, by the end of the surgery, a total of 5 participants had a conversion to OC. Thus, the sensitivity of the predictive scoring system was 80%. The positive predictive value of the scoring system was 100%. Based on the preoperative predictive score, a total of 51 participants had a preoperative predictive score of 'easy' LC (0-5), however, by the end of LC, 1 among these had a conversion to OC and the rest 50 had an uneventful LC. Thus, the specificity (true negative =50/ total negative =50) was 100%. Further, the negative predictive value of the predictive score was 98% (true negative=50/all negative51). None of the participants who were classified as a 'difficult' LC required conversion to OC.

Table 6 shows the results of stepwise multivariable logistics regression analysis. The variables age and TLC count were not found significant on univariate analysis, hence were dropped from the multivariable analysis.

The strongest predictor of 'difficult' LC was the thickness of the Gallbladder. One millimetre increase in the thickness of GB on USG increased the odds of a difficult LC by 17 times. However, the 95% Confidence Interval was wide for (4-117) GB thickness. Nevertheless, even the lower limit of the 95% CI increased the odds of encountering a 'difficult' LC by at least 4 times. The GB thickness of more than 4 mm increased the odds of difficult LC by more than 17 times (OR= 17.5 95% CI = 3.26 -148.47, p-value = 0.002). A history of the previous hospitalization increased the odds of difficult LC by about 16 times. Identification of pericholecystic collection and impacted GB on USG increased the odds of difficult LC by approximately 7 and 9 times, respectively.

Variable	Factor	Odd's Ratio	95% CI	P value
Gender	Male	1.75	0.84 - 5.81	0.072
	Female	1		
Hospitalization	Yes	16.2	4.11 - 42.38	0.006
	No	1		
GB Impacted	Yes	7.31	2.86 - 45.80	0.08
	No	1		
Peri-Cholecystic Collection	Yes	8.89	3.62 – 25.78	0.042
	No	1		
Scar	Yes	5.07	2.80 - 11.28	0.013
	No	1		
BMI	Per unit	1.92	1.26- 2.85	0.028
GB Thickness	Per millimetre	17.58	4.70-117.73	0.002

Table-6: Multi-variable logistics regression for predictors of Laparoscopic Cholecystectomy

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DISCUSSION

Laparoscopic cholecystectomy is the gold standard procedure used worldwide for treating symptomatic gallbladder disease.[3] It has replaced open cholecystectomy as the treatment of choice for gallbladder disease.[1,2] But sometimes laparoscopic cholecystectomy poses difficulties: during the creation of the pneumoperitoneum, adhesions around the gallbladder, previous scars etc. Some of these circumstances need conversion of LC to OC. Preoperative prediction of the risk of conversion is an important aspect of planning laparoscopic surgery. Therefore, we conducted an observational cross-sectional study to assess preoperative predictors of difficult laparoscopic cholecystectomy using clinical, haematological, and radiological parameters at our tertiary care centre by enrolling a total of 60 participants. Among the total 60 cases enrolled in the present study, the preoperative scoring system was able to correctly predict the outcome for 59 participants (98.3%). Similarly, Randhawa JS et al. were able to predict the outcome in about 90% of cases, and Dhanke PS et al. were able to predict the outcome in 97% of participants.[24,25] In the present study, the predictive score was incorrect only one case. The patient had an injury to CBD requiring conversion to OC for the repair.

With the advancement in the field of medical imaging techniques, all patients are universally examined through ultrasonography to get the most accurate assessment of the clinicopathological condition of the patient.[22] In this regard, the detailed information about the anatomy of the gallbladder and the surrounding structure can be weighed more than gold for any surgeon. Laparotomy findings from several studies have confirmed that cases that required conversion from LC to OC had distended gallbladder with the thickened wall.[28,29] These two features of the GB can be easily identified on USG.[22]

In the present study, the mean thickness of the gallbladder among the participants who had an easy, difficult, and very-difficult laparoscopic cholecystectomy was 3.12 mm, 4.0mm, and 4.7mm, respectively (t test= 5.72, p-value <0.0001). On multivariable analysis, one of the strongest predictors of 'difficult' LC was the thickness of the Gallbladder. The empirical data from our study suggests that a one-millimetre increase in the thickness of GB on USG increased the odds of a difficult LC by 17 times. Further, the GB thickness of more than 3 mm also increased the odds of difficult LC several times (OR= 17.5 95% CI = 3.26 -148.47). Rothman et al. conducted a meta-analysis of factors that predicted a difficult LC.[23] The authors concluded that a gallbladder wall thicker than 4–5 mm on preoperative ultrasound was a risk factor for conversion to OC (OR = 8.17 (95% CI 5.38–12.40). Further, of the 11 studies included in their meta-analysis, the thickness of the gallbladder wall as a risk factor for conversion was evaluated in all 11 studies and 9 of these studies concluded that thickness of the gallbladder wall strongly predicted a difficult LC needing conversion to OC.[23] Similarly, Ishizaki et al. analysed the data of 1339 patients undergoing LC, they concluded that a thickened GB increased the odds of conversion to OC by more than 9 times.[30] Hutchinson et al. analysed the data of more than 500 patients undergoing LC and the authors reported that a thickened GB increased the odds of conversion to OC by about 6 times.[31] Randhawa et al. analysed the data of 228 patients undergoing LC all operated by a single surgeon at their centre and they reported that a thickened GB increased the odds of conversion to OC by 4.8 times.[24] Among all these studies, a GB wall thickness of more than 3-4 millimetres was associated with several times higher odds of a difficult LC needing conversion to OC.

In our study out of a total of 60 patients, 8 patients showed the presence of pericholecystic fluid collection on USG: 3 patients were in a difficult group and 5 patients were in a very difficult group (p-value =0.042). Suryawanshi PR et al reported that 6.5 % of cases who had peri gallbladder collection had difficult lap cholecystectomy.[32] Lipman et al reported that of the 19.6 % of patients who required conversion from lap to open had fluid collection around the gallbladder, which was statistically significant.[33]

Among obese individuals, the excess fat is predominantly deposited in the abdomen. The excess fat around gastrointestinal organs makes the approach and exploration during laparoscopy difficult. The mean body mass index among the participants in easy, difficult, and very-difficult LC was 26.1, 29.1, and 28.7 Kg/sq. meters, respectively (p<0.05). On multivariable analysis, each unit increase in BMI was associated with about 2 times higher odds of having a difficult LC (OR= 1.92, 95%CI = 1.26- 2.85). Rothman et al. conducted a meta-analysis involving 6 studies and concluded that high weight/BMI increased the odds of conversion to OC by 1.85 times (95% CI 0.92–3.75).[23] Similarly, Hutchinson et al. in their analysis of data from 587 LC concluded that a high BMI increased the odds of difficult LC requiring conversion to OC. Randhawa et al. reported that being obese increased the odds of conversion to OC by 3.6 times.[24] Fuks et al. reported that being obese increased the odds of conversion to OC by 2.7 times.[34] Among most of these studies, a BMI of more than 27 Kg/ sq. meter was associated with several times higher odds of a difficult LC needing conversion to OC.

On multivariable analysis, the presence of a scar on the abdomen increased the odds of encountering a difficult LC leading to OC by more than 5 times (OR = 5.07, 95%CI= 2.80-11.28). Rothman et al. reported that previous abdominal surgery was significantly associated with OC.[23] Several other studies also reported that the presence of abdominal scar as a significant risk factor for conversion to OC (OR ranged from 1.9 to 3.56).[35–37]

In our study, one of the strongest predictors of 'difficult' LC was the previous history of hospitalization (OR =16.2 [95%CI 4.11 - 42.38]). Wiebke et al. reported that a history of cholecystitis is a risk factor in the conversion of LC to OC.[38] In a study conducted by Nachnani J et al., the history of cholecystitis was the most common reason for conversion from LC to OC due to the inability to delineate the anatomy.[39] Lipman JM et al. reported that a history of cholecystitis was seen among about half of the total patients who need conversion of LC to OC (p-value < 0.001).[33]

CONCLUSION

Although laparoscopic cholecystectomy is the gold standard for many gallbladder diseases, the conversion of LC to OC is inevitable in some cases. Moreover, the conversion cannot always be predicted with absolute certainty in every case. Nevertheless, several preoperative factors when assessed collectively can predict a difficult LC including, the need for conversion to OC with reasonable accuracy in most cases. Patients who are likely to have a difficult LC should be offered preoperative counselling about the likelihood of a successful outcome. Lastly, preoperative prediction of the risk of conversion to OC should be thoroughly performed in every case. Thorough clinical examination and ultrasonography can predict difficult LC requiring conversion to OC will a high degree of accuracy. Hence, every surgeon should be trained in both laparoscopic and open cholecystectomy in case the need arises during the intraoperative period.

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