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DEVELOPMENT AND VALIDATION OF A PREOPERATIVE SCORING SYSTEM TO PREDICT THE DIFFICULTY OF LAPAROSCOPIC CHOLECYSTECTOMY: A PROSPECTIVE OBSERVATIONAL STUDY

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Abstract

Background: Laparoscopic cholecystectomy is considered the gold standard treatment for any gall bladder pathology. Laparoscopic cholecystectomy has grown challenging at times. When there are extensive adhesions and bile/stone spillage, it takes longer and sometimes requires an open cholecystectomy. Anticipating the level of difficulty before surgery is a challenging task. By determining the variables that may indicate difficulty during a laparoscopic cholecystectomy, problems can be avoided.

Aim: To develop and validate a preoperative scoring system to predict the difficulty of laparoscopic cholecystectomy.

Methods: The study was conducted from August 2022 to June 2024, involving 115 patients undergoing LC. The following parameters were assessed to predict the difficult LC, demographic data, BMI, Number of attacks of pain, past history of acute cholecystitis, Tenderness in the right hypochondrium, CBC, LFT, U.S.G. abdomen (Gallbladder (normal/contracted/distended), Gb wall thickness, No. Of stones, Pericholecystic fluid collection. The scoring system used categorised scores into easy (0-5), difficult (6-10), and very difficult (11-15). The scores were then correlated with intraoperative findings. Data was analysed using SPSS (version 20) software.

Results: Age (p-value-0.047), BMI(p-value-<0.001), previous history of acute cholecystitis (p-value-0.024), total leucocyte count(p-value-<0.001), gallbladder wall thickness (p-value-<0.001) and a number of stones (p-value-0.014) is a significant risk factor in predicting difficulty. The prediction was true in 82.60 % of easy cases and 78.26% of difficult cases. The sensitivity of the scoring system is 100%, and specificity is 79.3%. The positive predictive value is 82.6%, and the negative predictive ***value is 100%.***

Conclusion: The preoperative scoring system is an effective and reliable tool for predicting the difficulty of laparoscopic cholecystectomy. This can improve surgical planning, minimize complications, and potentially reduce the need for conversion to open cholecystectomy.

Keywords: Laparoscopic cholecystectomy, preoperative predictive scoring, gallstones, surgical difficulty.

Introduction

Cholelithiasis disease is the most common biliary condition, affecting 10-15% of the total population[1], though 80% of those affected are asymptomatic [2]. The prevalence of gallstones varies significantly across different regions globally, with an estimated 4-5% occurrence in India [3]. Research among railroad workers indicated that North Indians are seven times more likely to develop gallstones compared to South Indians.

In the United States, it is estimated that over 20 million population have gallstones, with around 1 million new patients diagnosed each year [4]. Factors contributing to the change in the incidence in India include increased access to ultrasonography in both urban and rural areas, changes in socioeconomic structures, and westernisation. Gallstones primarily form due to bile concentration and stasis in the gallbladder.

The incidence of cholelithiasis is low in the first 2 decades of life but increases steadily after age 21, peaking in the fifth and sixth decades. Women are four times more likely than men to be affected. Each year, one in two asymptomatic individuals will develop symptoms that necessitate surgical intervention, making laparoscopic cholecystectomy (LC) a common procedure for general surgeons [5].

Laparoscopic cholecystectomy is a gold standard method for treating gallbladder diseases because it has several advantages over open cholecystectomy. These include a quicker return to normal activities, shorter duration of hospital stays, lesser postoperative pain, good cosmetic results, and faster recovery of bowel function. However, laparoscopic cholecystectomy can be challenging, especially when there are extensive adhesions or bile/stone spillage, which can prolong surgery or necessitate conversion to open cholecystectomy.

This study aims to develop and validate a scoring system by assessing the clinical, radiological, haematological and biochemical parameters for predicting the difficult laparoscopic cholecystectomy and correlate it with intraoperative difficulty.

Materials and Methods

This study was conducted from August 2022 to June 2024. The study included 115 cases of cholelithiasis aged between 18-60 years who underwent laparoscopic cholecystectomy across various surgical units. Patients with icterus, cholangitis, a dilated common bile duct, and bleeding disorders were excluded from the study.

Patients with symptoms such as pain in the abdomen, dyspepsia, nausea, fever, and vomiting were screened. Patients were scored based on demography, clinical, radiological, biochemical and haematological findings before surgery. The scoring system used categorised scores into easy (0-5), difficult (6-10), and very difficult (11-15).

Table 1: Preoperative Predictive Scoring System

Clinical Findings	Scoring Factor		Maximum Score
Age	<50y (0)	>50y(1)	1
Gender	Women (0)	Man(1)	1
BMI	<25(0)	25-27.5(1),>27.5(2)	2
Number of attacks of pain	<3(0)	>3-6(1),>6(2)	2
Past History of acute cholecystitis	No(0)	Yes(1)	1
Tenderness in the right hypochondrium	No(0)	Yes(1)	1
Biochemical findings			
Deranged LFT	No(0)	Yes(1)	1
Haematological findings			
TLC	4000-11000(0)	>11000(1)	1
Radiological findings			
Gall bladder wall thickness	<4mm(0)	>4mm(1)	1
Peri-cholecystic collection	No(0)	Yes(1)	1
Impacted stone in the cystic duct	No(0)	Yes(1)	1
Number of stones	0(0)	>1(1)	1
Gall bladder	Normal (0)	Contracted/ Distended(1)	1

BMI: body mass index
LFT: liver function test
TLC: total leucocyte count

Intra Operative Criteria:

Intra Operative Criteria	Time Taken	Complications/Challenges
Easy	< 60 minutes	No thick adhesions, no bile leakage. There is no damage to the duct or artery, and Calot's triangle is not frozen.
Difficult	60-120 minutes	Stone or bile leakage; duct injury; dense adhesions; frozen Calot's triangle; and refusal to open surgery
Very Difficult	> 120 minutes	Conversion to open surgery

Following preoperative scoring, all patients underwent laparoscopic cholecystectomy by creating Carbon dioxide penumoperitoneum with 14mmhg pressure with two, 10mm ports and two,5 mm ports. The timings were noted from first port site incision till the last port site closure. All the intraoperative events were observed. The preoperative predictive scores were then correlated with intraoperative difficulty levels. Post-operative periods were uneventful.

Statistical analysis:

With α balancing on both sides, the exact proportion difference from constant (binomial test, one sample case) was utilised for sampling, and the required sample size was determined using an a priori analysis. It was discovered that a sample size of 115 could detect a 95% power difference in the proportion of pericholecystic conversion collection, which was 33.33%. The software they were using was G*Power 3.1.9.4. Data were entered into Microsoft Excel sheet and then analysed using SPSS (Version 20). At a p-value of less than 0.05, all two-tailed statistical tests were considered statistically significant

Results

Table 2: Demographic and Clinical Characteristics

Characteristic	**Count (N=115)**	**Percentage(%)**
Age in Years		
10-20	5	4.35%
21-30	17	14.78%
31-40	19	16.52%
41-50	22	19.13%
51-60	52	45.22%
Gender		
Male	50	43.48%
Female	65	56.52%
Obesity (BMI Category)		
Normal	82	71.30%
Overweight	30	26.09%
Obese	3	2.61%
BMI: body mass index		

The study showed that 45.22% of patients were in the 51-60 age group, followed by 41-50, suggesting the change in the trend of preponderance in the age group of 40-50 indicates that focus on issues pertinent to the older age group, with females, comprising 56.52% of the study population suggests that gallstones are more common in females.

Overweight was noted in 26.09% of patients and is common; 2.61% of patients are obese and less prevalent, and 71.30% of the population had normal weight, which also suggests a change in the incidence of gallstone disease in obese. The demographic data shows gallstones are common in old age, more in females and normal-weight people.

Table 3: Clinical History and Laboratory Findings

Characteristic	Count (N=115)	Percentage(%)
Past History (Number of Attacks)		
1	2	1.74%
2	7	6.09%
3	13	11.30%
4	31	26.96%
5	1	0.87%
No	59	51.30%
Several	2	1.74%
Previous History of Acute Cholecystitis		
No	111	96.52%
Yes	4	3.48%
Deranged Liver Function Test		
No	100	86.96%
Yes	15	13.04%
Total Leucocyte Count		
Increased	33	28.70%
Normal	82	71.30%

The majority of individuals (51.30%) had no history of attacks of pain, and a significant number (26.96%) had experienced 4 episodes of attack of pain. Most of the individuals had no previous history of acute cholecystitis. A majority of individuals (86.96%) had normal liver function tests, and only 13.04% had deranged liver function tests in that only alkaline phosphatase was mildly raised. 71.03% of individuals had a normal total leucocyte count, and around 28.70% of individuals had an increased total leucocyte count indicative of underlying cholecystitis.

Table 4: Radiological Findings and Gallbladder Condition

Characteristic	Count (N=115)	Percentage(%)
USG Findings of Abdomen and Pelvis		
Normal	96	83.48%
Thickened	20	16.52%
Impacted Stone in Cystic Duct	0	0%
Pericholecystic Collection	0	0%
Number of Stones		
Multiple	86	74.78%
Single	29	25.22%
Gall Bladder Condition		
Contracted	3	2.61%
Distended	110	95.65%

Characteristic	Count (N=115)	Percentage(%)
Normal	2	1.74%
USG: ultrasonography		

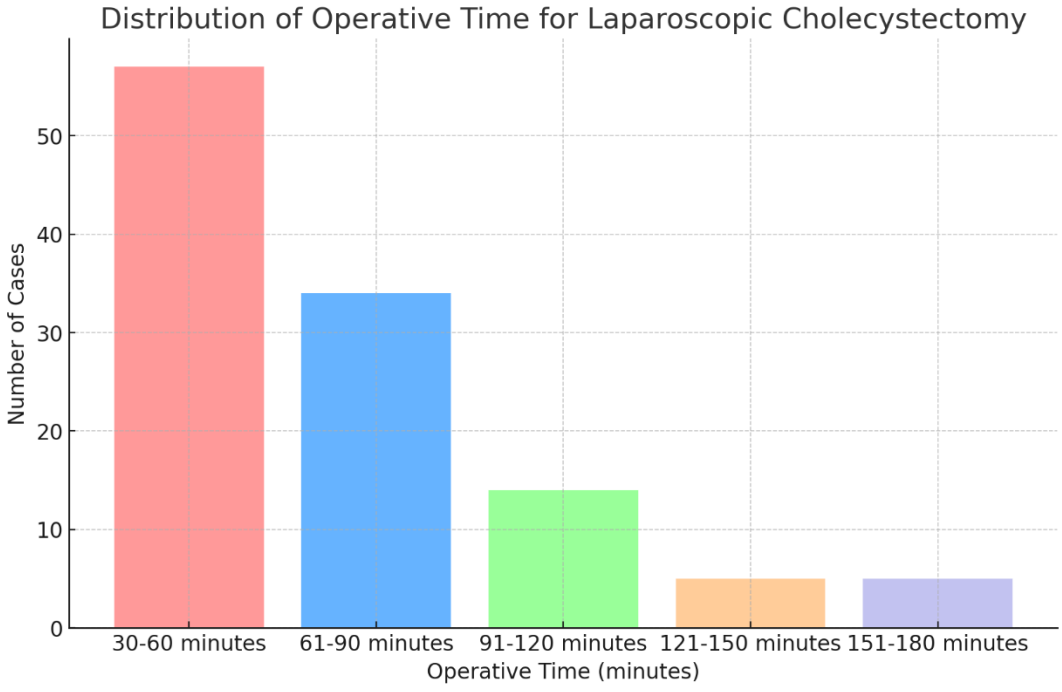
Ultrasonography findings showed that 16.52% of individuals had thickened gall bladder walls suggestive of inflammation. 74.78% of patients had multiple stones, 25.22% of patients had single stones,95.65% of patients had distended gallbladders due to multiple stones or mucocele or empyema gallbladder suspected 2.61% had contracted gallbladder suggestive of gallstones or cholecystitis.

Table 5: Preoperative Score Distribution

Preoperative Score	Count (N=115)	Percentage (%)
0 to 5	69	60%
6 to 10	46	40%
11 to 15	0	0%

This indicates the majority of the patients had an easy/difficult level preoperatively, and none of them had a very difficult level of preoperative concern.

Figure 1: Operative Time Distribution



The operative times varied significantly depending on the difficulty level. 57 Easy cases took between 35 to 60 minutes, 48 difficult cases between 62 to 120 minutes, ten very difficult cases between 135 to 180 minutes, and 4 cases requiring Conversion took approximately 180 minutes. Overall, the majority of the cases were completed within 60-90 minutes, indicating that these are the typical operative times for this procedure.

Table 6: Intraoperative Findings

Intraoperative Findings	Count (N=115)	Percentage (%)
Accessory Cystic Duct	1	0.87
Adhesion Between Anterior Abdominal Wall, Omentum, and Liver Bed	1	0.87
Bile Spillage	2	1.74
Cystic Duct Could not Be Visualized	1	0.87
Cystic Duct Perforation	1	0.87
Empyema Gallbladder	2	1.74
Gangrenous Gallbladder	2	1.74
GB Adhered to the Right Liver Lobe	1	0.87
Less Than 50% Adhesion Between GB and Omentum	1	0.87
Less Than 50% Adhesion Between Omentum, liver and GB	18	15.65
More Than 50% Adhesion Between GB and Omentum	15	13.04
More Than 50% Adhesion Between GB, Liver, and Omentum	14	12.17
More Than 50% Adhesion with Multiple Hemorrhages on Small Bowel and Peritoneum	1	0.87
Mucocele	3	2.61
Mucocele, More Than 50% Adhesions Between Omentum	3	2.61
Cholelithiasis	45	39.13
Perforated Gallbladder with Bile Spillage	1	0.87
Ruptured Mucocele, More Than 50% Adhesion Between Omentum and GB	1	0.87
GB: gallbladder		

During the operations, various intraoperative findings were noted. Out of 115 patients, 51 had adhesions around the gall bladder, three had mucocele, and one patient each had a perforated gall bladder with bile/bile stone spillage, an accessory duct, a gangrenous gall bladder, a cystic duct perforation, a frozen Clot's triangle, and empyema of the gall bladder. The most frequent finding during the surgeries was cholelithiasis, as suggested by ultrasound findings, followed by various types and extents of adhesions. Each finding provides insight into the complexities that can arise during laparoscopic cholecystectomy

Table 7 Analysis of Preoperative Score:

Characteristic	**Difficult**, N = 46	**Easy**, N = 69	P-value
Age			
Less than 50	20 (43.48%)	43 (62.32%)	0.047
More than 50	26 (56.52%)	26 (37.68%)	
Gender			
Female	24 (52.17%)	41 (59.42%)	0.4
Male	22 (47.83%)	28 (40.58%)	
BMI			
Normal	22 (47.83%)	56 (81.16%)	<0.001
Obese	5 (10.87%)	1 (1.45%)	
Overweight	19 (41.30%)	12 (17.39%)	

Characteristic	**Difficult**, N = 46	**Easy**, N = 69	**P-value**
Number of attacks of pain			
1	1 (2.17%)	1 (1.45%)	0.11
2	3 (6.52%)	4 (5.80%)	
3	4 (8.70%)	9 (13.04%)	
4	18 (39.13%)	13 (18.84%)	
5	1 (2.17%)	0 (0.00%)	
No	18 (39.13%)	41 (59.42%)	
Several	1 (2.17%)	1 (1.45%)	
Past history of acute cholecystitis	4 (8.70%)	0 (0.00%)	0.024
Tenderness in the right hypochondrium			
Yes	46 (100.00%)	69 (100.00%)	N/A
Deranged LFT	8(17.39%0	7(10.14%)	0.3
TLC			
Increased	26 (56.52%)	7 (10.14%)	<0.001
Normal	20 (43.48%)	62 (89.86%)	
Gb wall thickness			
Normal	30 (65.22%)	66 (95.65%)	<0.001
Thickened	16 (34.78%)	3 (4.35%)	
Pericholecystic collection			
No	46 (100.00%)	69 (100.00%)	N/A
No. Of stones			
Multiple	40 (86.96%)	46 (66.67%)	0.014
Single	6 (13.04%)	23 (33.33%)	
Gall bladder			
Contracted	1 (2.17%)	2 (2.90%)	0.8
Distended	45 (97.83%)	65 (94.20%)	
Normal	0 (0.00%)	2 (2.90%)	
Impacted stone in CBD			N/A

Characteristic	Difficult, N = 46	Easy, N = 69	P-value
No	46 (100.00%)	69 (100.00%)	

BMI: body mass index
TLC: total leucocyte count
LFT: liver function test
GB: gallbladder
CBD: common bile duct

Characteristics with low p-value, age, BMI, total leucocyte count, gall bladder wall thickness, and number of stones are significant risk factors for the difficulty of laparoscopic cholecystectomy.

Table 8: Comparison Between Preoperative Predictive Score and Outcome

Preoperative Score	Easy	Difficult	Very Difficult	Conversion
Easy(69)	57	12	0	0
Difficult(46)	0	36	6	4

A preoperative score of 0-5(easy) with most patients (57) had easy procedure intraoperatively,12 were difficult, and none of them had a very difficult conversion procedure. A preoperative score of 6-10(difficult), with most of the patients (36) having a difficult procedure,6 being very difficult, and 4 were converted into open. It highlights the correlation between the preoperative assessment and the actual difficulty encountered during surgery. This indicates that the higher preoperative scores are associated with increased procedural difficulty and a higher likelihood of conversion to an alternative approach. Cases were assessed as difficult /very difficult preoperatively; none of these cases were found to be very easy during surgery, suggesting that preoperative evaluation is a good predictor of intraoperative difficulty in these instances. However, some cases assessed as easy preoperatively may turn out to be more challenging during surgery, indicating that preoperative assessment is not always perfectly accurate; the preoperative predictive scoring method is 100% sensitive and 79.3% specific, with a positive predictive value of 82.6% and a negative predictive value of 100%.

Table 10: Detailed Analysis of Preoperative Score with Intraoperative finding

Characteristic	Conversion, N = 4	Difficult, N = 48	Easy, N = 57	Very difficult, N = 6	P-value
Pre-op score					**<0.001**
Difficult	**4 (100.00%)**	**36 (75.00%)**	**0 (0.00%)**	**6 (100.00%)**	
Easy	**0 (0.00%)**	**12 (25.00%)**	**57 (100.00%)**	**0 (0.00%)**	
Operative time	**170.00 (143.8, 180.00)**	**75.00 (68.0, 100.00)**	**55.00 (50.0, 58.00)**	**143.00 (135.3, 172.50)**	**<0.001**

From our study, it is clear that our preoperative score and intraoperative findings correlate with a significant p-value (<0.001), and operative time is also statistically significant with a p-value (<0.001).

Discussion

The most prevalent biliary disease is cholelithiasis, which affects 10-15% of the general population, and 80% of patients have no symptoms. The gold standard procedure in this period is laparoscopic cholecystectomy. Sometimes, the surgeries convert to open as the surgeon cannot assess the risk. Therefore, a preoperative method for anticipating a difficult LC is a must. For the safe removal of the gall bladder, conversion to an open cholecystectomy may be needed in 5–10% of laparoscopic cases. The results of this study indicate several significant findings related to the predictors of difficult laparoscopic cholecystectomy. The demographic analysis showed that the majority were aged between 51 and 60 years, which is higher compared to other studies where the peak incidence was observed in younger age groups [6]. Higher conversion rates and mortality in males over 50 and

females under 50 suggest that age, combined with other factors, is a significant risk factor for a predictor of difficulty in laparoscopic cholecystectomy [7].
In our study, Females constituted 56.52% of the patients, and males were 43.48%. Females have a higher prevalence of cholelithiasis [9]. Obesity was identified as a significant (<0.001) risk factor, with 30 patients being overweight and three being obese [10,11]. One author found that obesity with a previous history of acute cholecystitis is the most important risk factor for conservation [10]. Challenges posed by obesity include the presence of a thick abdominal wall, difficulty in creating a pneumoperitoneum, a fat-filled omentum and a falciform ligament.
Fifty-six patients had a history of prior attacks of pain. Those who experienced repeated episodes of pain were more likely to undergo difficulties during laparoscopic cholecystectomy [12]. This shows that recurrent inflammation results in dense adhesions between the gallbladder and the omentum. A history of recurrent cholecystitis may be a predictor of surgical difficulty. Four patients had a previous history of acute cholecystitis, which was a significant risk factor [13,14]. Previous episodes of acute cholecystitis can lead to dense adhesions at the calots triangle and gall bladder fossa. These cases require more time for dissection of the calots triangle and gall bladder from the liver bed. There are reports that acute cholecystitis can lead to a higher chance of bleeding, ductal injuries and subsequent conversion.

Deranged liver function tests (LFTs) were present in 15 patients and were not significantly associated with difficult laparoscopic cholecystectomy [6]. An increased total leucocyte count (TLC) was observed in 33 patients, which was a significant risk factor in facing difficult laparoscopic cholecystectomy [12]. This can probably be attributed to persisting acute inflammation with edema of the gallbladder-making the surgery difficult.
Ultrasonography assessment showed that the gallbladder wall was thickened in 20 patients, which is a strong predictor of conversion [8,14]. This study did not find any significance of impacted stones and pericholecystic collections, but these factors should still be taken into consideration. Impacted stones have been shown to distend the gallbladder and make the dissection difficult, the same as in thickened gallbladder.86 patients had multiple stones, which suggests a higher risk of difficulty because it can be difficult to grasp and manipulate a distended gall bladder, as it is a unique feature of our study. 110 patients had a distended gall bladder, which was related to a difficult laparoscopic cholecystectomy. Fewer studies have shown that contracted and distended gallbladder is a significant risk factor for difficulty [6].
A study by Randhawa et al. found that BMI over 25, palpable gallbladders, gallbladder wall thickness on ultrasonography, and a history of hospitalization were associated with difficult laparoscopic cholecystectomy [11]. Another study found that higher difficulties and conversion rates after laparoscopic cholecystectomy were related to advanced age, male gender, obesity, and past episodes of acute cholecystitis [15]. Our study found that advanced age, obesity, previous history of acute cholecystitis, elevated leucocyte count, thickened gall bladder wall, and multiple stones are significant risk factors for predicting difficulties. Our scoring method has a sensitivity of 100%, specificity of 79.3%, positive predictive value of 82.6% and negative predictive value of 100% comparable to those reported in other studies [11], indicating that the method can reliably predict the difficulty.
Limitation of the study:
While this study provides valuable insights into the predictors of difficult laparoscopic cholecystectomy, it is not without limitations. The sample size, although sufficient for preliminary analysis, may not be large enough to generalise the findings to the broader population. Additionally, the study was conducted in a single institution, which may limit the applicability of the results to other settings with different patient demographics and surgical practices. Further multicentric studies with larger sample sizes are recommended to validate these findings and develop a standardised scoring system for predicting difficult laparoscopic cholecystectomy

Conclusion:

The preoperative scoring system is an effective and reliable tool for predicting the difficulty of laparoscopic cholecystectomy. This can improve surgical planning, minimize complications, and potentially reduce the need for conversion to open cholecystectomy.

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