A prospective study of various pre-operative factors and the development of a scoring system in predicting difficult laparoscopic cholecystectomy

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ABSTRACT

Background: Laparoscopic cholecystectomy (LC) is a common surgical procedure, the difficulty of which can vary significantly based on pre-operative factors. Identifying these factors can improve surgical planning, patient counseling, and outcomes. **Aims and Objectives:** To develop a predictive scoring system for assessing the difficulty of LC preoperatively based on individual patient parameters. To employ operative time and intra-operative events to validate the accuracy of the scoring system in reflecting the technical difficulty of LCs. **Materials and Methods:** This prospective study enrolled 104 patients scheduled for LC, assessing them with a pre-operative scoring system to predict operative difficulty. Patients were categorized into groups indicating expected levels of difficulty: Easy, difficult, and very difficult. Demographic information, clinical characteristics, and operative outcomes were analyzed to validate the scoring system's predictive accuracy. **Results:** Of the patients assessed, 68.3% were predicted to have an easy LC (scores 0–5), whereas 31.7% were anticipated to face a difficult LC (scores 6–10). Key predictors of operative difficulty included age, sex, history of previous hospitalization for acute cholecystitis, body mass index (BMI), the presence of an abdominal scar, palpable gallbladder (GB), thickened GB wall, pericholecystic collection, and impacted stone. The study found that operative outcomes closely aligned with pre-operative predictions, confirming the scoring system's moderate predictive accuracy (area under the curve of 0.798). **Conclusion:** The pre-operative scoring system demonstrated moderate effectiveness in predicting LC difficulty, with significant predictors including a history of hospitalization, BMI, palpable GB, and thickened GB wall. These findings can aid in pre-operative planning and optimizing patient outcomes.

Key words: Laparoscopic cholecystectomy; Pre-operative scoring; Operative difficulty; Predictive accuracy; Surgical outcomes

INTRODUCTION

Laparoscopic cholecystectomy (LC) is the standard surgical intervention for symptomatic gallstone disease and cholecystitis, heralded for its advantages over open cholecystectomy (OC), including reduced post-operative pain, shorter hospital stay, and faster recovery.[1] However, the difficulty of LC can vary significantly among patients due to various anatomical and pathological factors. This variability underscores the necessity for a reliable method to predict operative challenges preoperatively, thereby enhancing surgical planning, patient counseling, and managing expectations regarding potential complications and operative time.[2,3]

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The complexity of LC is influenced by multiple patient-related factors, including but not limited to, the history of previous abdominal surgeries, the patient's body mass index (BMI), the presence of acute or chronic inflammation, and specific gallbladder (GB) anatomical variations.[4] These factors can increase the risk of complications such as bile duct injury (BDI) or the need for conversion to OC, impacting the patient's recovery trajectory and overall outcome.[5]

Given this context, there has been significant interest in developing pre-operative scoring systems to categorize the anticipated difficulty of LC. Such systems aim to aggregate various predictive factors into a comprehensive score that reflects the potential for operative challenges, thereby guiding pre-operative decision-making.[6] By accurately predicting operative difficulty, surgeons can tailor their surgical approach, allocate appropriate resources, and better inform patients about the risks and expected recovery process.

This study contributes to the ongoing efforts to enhance LC outcomes by evaluating the predictive accuracy of a specific pre-operative scoring system. Through a prospective analysis of patients undergoing LC, this research seeks to validate the utility of pre-operative factors in forecasting operative difficulty, aiming to improve surgical efficiency, reduce complications, and optimize patient care.

Aims and objectives
Primary objectives
Develop a predictive scoring system for assessing the difficulty of LC preoperatively based on individual patient parameters.

Secondary objectives
1. Scoring system validation: Employ operative time and intra-operative events to validate the accuracy of the scoring system in reflecting the technical difficulty of LCs
2. Intra-operative events assessment: Investigate the intra-operative events contributing to LC difficulty within a specialized, low-mortality setting, performed by an experienced team of surgeons and anesthetists.

MATERIALS AND METHODS

Study setting and design
This prospective observational study was conducted at the Department of Surgical Gastroenterology, Sterling Hospitals, Ahmedabad, India, a single center with a specialized, low mortality rate. The study aimed to develop and validate a pre-operative scoring system for predicting the difficulty of LC based on individual patient parameters.

Inclusion criteria
All patients with symptomatic GB (GB disease) in whom LC was indicated.

Patients of age ≥18 years and both sexes, who have given informed consent, were included in the study.

Exclusion criteria
LC performed with other laparoscopic interventions in the same setting. Patients with carcinoma of GB, jaundice or abnormal liver function tests, cirrhosis, common bile duct stones, empyema GB, acute pancreatitis, history of more than two abdominal surgeries, portal hypertension, cholangitis, and pregnancy.

Absolute contraindications to LC such as cardiovascular or pulmonary disease, coagulopathies, and end-stage liver disease.

All cases of LC conversion to open procedure due to equipment failure or anesthetic complications.

Any emergency surgery (GB perforation with peritonitis, with acute pancreatitis/cholecystitis with hemodynamic instability).

Study duration and sample size
The study was carried out from April 2020 to September 2021. Based on the admission rate of gallstone patients in previous years and case records, a minimum sample size of 100 cases was projected. A total of 104 patients meeting the inclusion and exclusion criteria were enrolled through convenience sampling.

Data collection and study protocol
Participants' detailed procedural explanations were provided, covering associated complications and management strategies. Data on history, clinical examination, and sonological findings were collected using a patient information form. The scoring system was based on the most relevant three parameters from history, clinical factors, and ultrasonography findings, chosen to avoid complexity and ensure replicability. Variables included age, sex, history of hospitalization due to cholecystitis, BMI, abdominal scar, palpable GB, and specific ultrasonography findings. Biochemical parameters and diabetes status were collected but later excluded from the study to maintain scoring simplicity and due to financial constraints.[7]

Scoring system development
After a literature review and consultation, nine variables were selected for the scoring system, with a maximum score of 15. Variables included age, sex, history of hospitalization, BMI, abdominal scar, palpable GB, GB

wall thickness, presence of pericholecystic collection, and impacted stone, each assigned a specific score. Pre-operative scores were assigned based on history, clinical examination, and sonological findings 1 day before surgery.

Operative procedure

LC was performed by a single experienced surgeon with a consistent team. Standard procedures were followed, including pre-operative medications, patient positioning, creation of CO_2 pneumoperitoneum, dissection techniques, and post-operative care. Operative time, bile/stone spillage, BDI, and conversion to open surgery were carefully noted, alongside other intra-operative events affecting operative duration.

Ethical considerations

Ethical approval was obtained from the Institutional Ethical Committee, Sterling Hospital, Ahmedabad, India (SHEC/UN/DNB Thesis/184-2020) with written informed consent gathered from all study participants.

Statistical analysis

SPSS 21.0 software was utilized for data analysis, with Microsoft Word and Excel for generating graphs and tables. The area under the receiver operating characteristic (ROC) curve assessed the diagnostic and predictive value of the pre-operative score. The Chi-square test, Fisher's Exact test, and odds ratio analyses determined the significance of risk factors related to operative outcomes, with logistic regression for multivariate analysis. A significance level of 5% was set, where $P<0.05$ was considered significant.

RESULTS

In this prospective study, a total of 104 patients meeting the inclusion criteria were enrolled. These patients were preoperatively assessed using a scoring system designed to predict the level of operative difficulty for LC. The outcomes of this assessment are presented below, alongside operative outcomes and the predictive accuracy of the scoring system.

Estimation of operative difficulty

Based on the pre-operative scoring system, 71 patients (68.3%) were predicted to have an easy LC (score 0–5), whereas 33 patients (31.7%) were anticipated to face a difficult LC (score 6–10). Notably, no patients were scored above 10, which would have indicated a very difficult LC (Table 1).

Demographic and clinical characteristics

The participants ranged in age from 19 to 82 years, with a mean age of 46.3 years. A breakdown of the age distribution showed that among the patients aged ≤50 years, 76.4%

Table 1: Pre-operative scoring and difficulty level distribution

Level of Difficulty	Frequency	Percentage
Easy (0–5 score)	71	68.3
Difficult (>5 score)	33	31.7
Total	104	100

were expected to have an easy LC, compared to those older than 50 years, where the expected difficulty level was evenly split (Table 2).

The distribution of sex within the study showed that of the 34 male patients, 52.9% were expected to undergo an easy LC. Among the 70 female patients, a higher proportion (75.7%) was predicted to have an easy LC, suggesting sex as a factor in predicting LC difficulty (Table 3).

A history of previous hospitalization for acute cholecystitis emerged as a significant predictor, with all patients in this category (100%) anticipated to experience a difficult LC (Table 4 and Figure 1).

BMI and other pre-operative factors

BMI was another critical predictive factor. Patients with a normal BMI (<25 kg/m²) were predominantly expected to have an easy LC. In contrast, obese patients (BMI >27.5 kg/m²) showed a nearly even distribution between easy and difficult LC predictions (Table 5 and Figure 2).

Other pre-operative factors influencing the estimated level of operative difficulty included the presence of an abdominal scar, palpable GB, thickened GB wall, pericholecystic collection, and impacted stone. Each factor's distribution across the predicted levels of difficulty is detailed in Table 6.

Operative outcomes

The correlation between predicted and actual operative difficulties was substantiated through intra-operative outcomes, such as the duration of surgery, incidence of bile spillage, BDI, and the necessity for conversion to OC. The majority of surgeries classified as easy were completed in <60 min, with difficulties during surgery including challenges in creating pneumoperitoneum, managing frozen Calot's triangle, and unclear anatomy, among others.

Predictive accuracy of the pre-operative scoring system

The scoring system's predictive accuracy was further validated through sensitivity, specificity, and positive predictive values, with a ROC curve analysis yielding an area under the curve of 0.798. This outcome indicates a moderate predictive capability of the pre-operative scoring system in estimating the difficulty of LC.

Table 2: Distribution of age according to pre-operative score

Age Group	Easy (%)	Difficult (%)	Total (%)
≤50 years	55 (76.4)	17 (23.6)	72 (100)
>50 years	16 (50)	16 (50)	32 (100)
Total	71 (68.3)	33 (31.7)	104 (100)

Table 3: Distribution of sex according to pre-operative score

Sex	Easy (%)	Difficult (%)	Total (%)
Male	18 (52.9)	16 (47.1)	34 (100)
Female	53 (75.7)	17 (24.3)	70 (100)
Total	71 (68.3)	33 (31.7)	104 (100)

Table 4: Impact of previous hospitalization on operative difficulty

Previous Hospitalization	Easy	Difficult	Total
Yes (%)	0 (0)	22 (100)	22 (100)
No	71	11	82
Total	71	33	104

Table 5: Impact of BMI on operative difficulty

BMI Category	Easy (%)	Difficult (%)	Total (%)
<25 kg/m^2	38 (84.4)	7 (15.6)	45 (100)
25.1–27.5 kg/m^2	18 (64.3)	10 (35.7)	28 (100)
>27.5 kg/m^2	15 (48.4)	16 (51.6)	31 (100)

BMI: Body mass index

Table 6: Other significant predictive factors

Factor	Easy (%)	Difficult (%)	Total (%)
Abdominal scar present	11 (45.8)	13 (54.2)	24 (100)
Palpable GB	2 (13.3)	13 (86.7)	15 (100)
Thickened GB wall	0 (0)	9 (100)	9 (100)
Pericholecystic collection	1 (25)	3 (75)	4 (100)
Impacted stone	0 (0)	3 (100)	3 (100)

GB: Gallbladder

Univariate and multivariate analyses identified four variables – history of previous hospitalization, BMI >27.5 kg/m^2, palpable GB, and thickened GB wall – as statistically significant predictors of operative difficulty, underscoring the potential of the scoring system to facilitate pre-operative-planning-and patient counseling.

DISCUSSION

This analytical, hospital-based observational study was conducted on 104 individuals diagnosed with gallstones at a tertiary care center, encompassing both sexes and individuals aged ≥18 years. The aim was to devise a scoring system for predicting the pre-operative difficulty of LC,
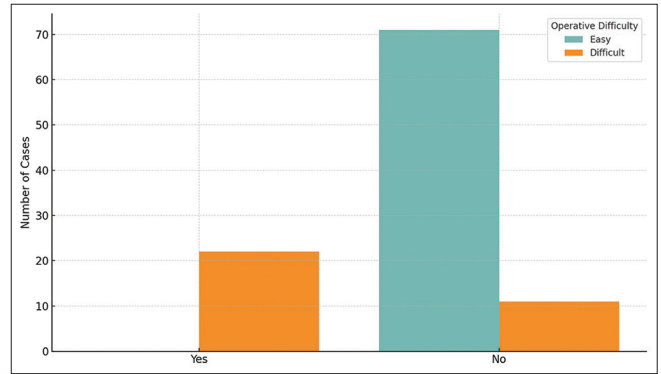

Figure 1: Impact of previous hospitalization on operative difficulty
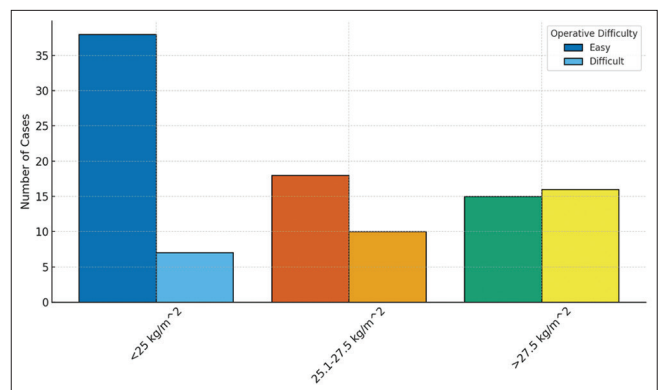

Figure 2: Impact of body mass index on operative difficulty

thereby aiding in reducing the morbidity and mortality associated with this common surgical procedure.

Burden of disease

Gallstones represent a significant health-care challenge, particularly in developed countries, with an adult prevalence rate of 10–15%, translating into 20–25 million affected individuals in the United States alone. The economic impact is substantial, with an estimated annual expenditure of approximately $6.2 billion. Despite the prevalence rate being lower in India at around 6%, the economic and health burdens are similarly impactful, although underreported due to the prevalence of daycare.[8] Since the advent of LC in 1989, cholecystectomy rates have surged, making it the most frequent elective abdominal surgery in the U.S. Despite a trend toward stabilization in the late 1990s, the procedure remains common, underscoring the importance of efficient pre-operative assessment.[9,10]

Mortality and morbidity

While the mortality rate associated with gallstone disease is relatively low (0.6%), the sheer volume of affected individuals results in significant mortality figures. Improvements in surgical techniques have contributed to a steady decline in case fatality rates, highlighting the potential benefits of optimizing pre-operative evaluation.[11]

Scoring systems for predicting LC difficulty

Previous efforts to predict LC difficulty have varied in complexity and efficacy. Bourgouin et al.,[12] developed a score based solely on operative time, whereas Vivek et al.,[13] more comprehensive approach included 22 variables. However, the latter's complexity renders it impractical for routine use. Our study proposes a scoring system that balances comprehensiveness with practicality, assigning points to nine critical factors.

Patient characteristics and predictive factors

The mean age of participants in our study was 46.3 years, reflecting the middle-aged predominance of symptomatic cholelithiasis. Analysis revealed no significant age-related risk for LC difficulty, aligning with some previous studies while contradicting others. Gender analysis indicated a higher incidence of gallstones in females, but no significant gender difference in LC difficulty, challenging some previous findings. History of hospitalization for acute cholecystitis emerged as a significant predictor of LC difficulty, corroborating other studies. BMI over 27.5 kg/m² also significantly predicted LC difficulty, echoing the findings of Gupta et al.,[14] and others. Contrary to some prior research, abdominal scars and palpable GB were significant predictors in our study, highlighting the importance of comprehensive pre-operative assessments.

Study limitations and strengths

The study's limitations include potential selection bias due to its tertiary hospital setting and observational nature. The exclusion of diabetes history and liver function tests could have omitted relevant predictive information. In addition, the study did not account for the post-operative course or the duration of gallstone presence. The surgeon's expertise may also influence the outcomes, potentially limiting the applicability of findings to settings with less experienced surgeons.

Despite these limitations, the study's strengths lie in its detailed analysis of difficult LC characteristics and the pre-operative assignment of scores. This approach provides an objective means to quantify LC difficulty, offering valuable insights for early and effective management of GB disease.

CONCLUSION

This study effectively formulated and validated a pre-operative scoring system to assess the difficulty of LC, showcasing high positive predictive values for distinguishing between easy and challenging procedures. The system highlights four significant predictors of LC difficulty: A history of previous hospitalization for cholecystitis, elevated BMI, the presence of a palpable GB,

and a thickened GB wall. These findings underscore the system's robustness and utility in guiding surgeons during pre-operative evaluations, enabling more accurate surgical planning and potentially reducing the risk of complications during LC.

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