

Correlation of Preoperative Scoring System with Intraoperative Scoring System for Predicting Difficult Laparoscopic Cholecystectomy: A Research Protocol

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ABSTRACT

Introduction: Laparoscopic Cholecystectomy (LC) is the gold standard of care for benign gallbladder disease. The incidence of conversion from LC to open cholecystectomy is 14.3%. A high degree of anatomical variation exists in the cystic duct, cystic artery and gallbladder, making this surgery challenging at times, even in the hands of the most experienced surgeons.

Need of the study: Understanding the correlation between the preoperative score and the intraoperative score early in the disease course can facilitate timely conversion to open surgery, thereby reducing the risk of inadvertent injury. Additionally, this approach can improve the efficiency of operating room scheduling and ensure that a more skilled laparoscopic surgeon is available. Furthermore, it can assist surgeons in managing complications or legal issues that may arise postoperatively.

Aim: This study aims to assess the correlation between preoperative grading and an intraoperative scoring system to

forecast difficulties in LC and the potential for conversion to open cholecystectomy.

Materials and Methods: A prospective observational study will be conducted in the inpatient department of General Surgery at Acharya Vinoba Bhave Rural Hospital (AVBRH) in Sawangi, Wardha, Maharashtra, India, from March 2024 to February 2026. A total of 35 patients with cholelithiasis will be included in the study. Patients will be scored based on a preoperative scale (the Modified Randhawa scoring system) and counselled regarding the difficulty and possibility of conversion, which will then be correlated with an intraoperative score to assess their predictive value for the risk of conversion. The correlation between preoperative and intraoperative scores will be assessed using Pearson or Spearman correlation coefficients. For intergroup comparisons, the t-test or Mann-Whitney U test will be applied with a 5% significance level. Logistic regression models will be evaluated using the Hosmer-Lemeshow test and ROC curve analysis.

Keywords: Conversion, Cystic duct variation, Laparoscopic open cholecystectomy, Minimal invasive surgery

INTRODUCTION

Gallbladder surgery (LC) has become the procedure of choice for the management of symptomatic gallstone diseases because it is minimally invasive and associated with less postoperative pain and early recovery. A high degree of anatomical variation exists in the cystic duct, cystic artery and gallbladder, making this surgery difficult at times, even in the hands of the most experienced surgeons [1,2]. The incidence of conversion from LC to open cholecystectomy is 14.3% [3]. On rare occasions, conversion to open cholecystectomy may be necessary to manage bleeding, prevent damage to other organs, clarify unclear anatomical relationships, or address related problems. Factors such as extended hospital stays, pulmonary and surgical site infections and increased morbidity have all been found to lead to the conversion from laparoscopic to open cholecystectomy [4]. Predicting whether LC will be straightforward or complex before surgery is impossible. Consequently, it would be beneficial to assess the potential for forecasting the likelihood of a challenging LC. A more informed decision can be made by the patient if they are aware of the true risks of the procedure, as laparotomy is associated with higher morbidity and longer convalescence than laparoscopy [5]. Preoperative prediction aids in early decision-making by the surgeon if there is a need to convert to open cholecystectomy. This allows for more effective operating list scheduling and ensures the availability of a more skilled laparoscopic surgeon, which would be further advantageous.

There is no standard scoring method that can be used to predict the level of difficulty before surgery or link the intensity of difficulty with intraoperative scoring. Comparing the results or providing a consistent reference point for similar future research becomes more challenging. To forecast the difficulty of LC preoperatively, this study pertains to compare the intraoperative scoring system [2] with the preoperative scoring method, the Modified Randhawa and Pujahari score [6,7]. The validation and score used for preoperative scoring include the following factors: age, gender, duration of illness, history of previous Gallbladder (GB) disease, concurrent systemic illnesses, Body Mass Index (BMI) (obesity), abdominal scars (whether infraumbilical or supraumbilical), upper abdominal tenderness, palpable GB and sonographic findings—GB wall thickness, pericholecystic collection, size and number of calculi and anatomical anomalies [6]. The validation of the intraoperative scoring system was conducted by Gupta S et al., which includes five aspects: appearance and adhesion of GB, degree of distension or contraction of GB, ease of access, local or septic complications and time required for cystic artery and duct identification [8].

REVIEW OF LITERATURE

The LC is regarded as the gold standard treatment for symptomatic cholelithiasis. Predicting problematic LC before surgery helps the operating surgeon prepare for potential complications. LC has

displaced open cholecystectomy in the management of simple biliary lithiasis and is a safe and efficient technique [9].

Conversion to open cholecystectomy is occasionally necessary to avoid or repair injury, delineate confusing anatomical relationships, or treat associated conditions. Conversion to open cholecystectomy has been associated with increased overall morbidity, as well as surgical site and pulmonary infections and longer hospital stays [3,4]. The Modified Randhawa scoring system, developed by Phillip AM and Anjarbeedu RR, offers a holistic grading system to estimate the degree of difficulty of LC [7]. To predict the level of difficulty, this scoring system considers various factors, including demographics such as age and sex, hospitalisation history for acute cholecystitis, clinical factors such as BMI, the presence of an abdominal scar, gallbladder palpability and sonographic features such as wall thickness, pericholecystic collection and impacted stones.

Many times, a difficult LC presents a nerve-racking situation for surgeons. It endangers patients by causing potential injury to vital structures [10]. Bhandari TR et al., conducted a retrospective cross-sectional study involving a total of 338 patients (82 males) with a median age of 47 years. Surgical records were analysed to identify predictors of difficult LC, leading to the conclusion that male gender, a history of acute cholecystitis, gallbladder wall thickness (≥ 4 -5 mm), a fibrotic gallbladder and adhesions at Calot's triangle are significant predictors of difficult LC [9]. In a study by Raza M and Rajeev VM, it was observed that the present Modified Randhawa and Pujahari scoring system is valuable and appropriate for predicting operative outcomes in LC, which in turn facilitates better preparedness [11].

The intraoperative scoring system for LC plays a crucial role in evaluating surgical complexity in real time and assisting with decision-making. It helps surgeons predict procedural difficulty by assessing factors such as adhesions, gallbladder inflammation and anatomical variations, allowing them to anticipate challenges. This system improves patient safety by categorising cases into mild, moderate, severe, or extreme difficulty, enabling surgeons to adjust their approach and minimise complications. Additionally, it serves as a guide for determining the need for conversion to open cholecystectomy, thereby reducing operative risks when extreme difficulty is indicated. Beyond the operating room, standardised difficulty scores contribute to surgical education and research, offering trainees valuable insights into complex procedures and helping refine techniques for future cases [8].

An intraoperative scoring or grading system for the degree of difficulty during LC, developed by Sugrue M et al., is based on intraoperative findings such as the GB appearance including contraction/distension of GB and degree of adhesions; access to the peritoneal cavity; Calot's triangle dissection time; and any complications (septic/local). Based on scores, patients are graded into four categories [12]. Preoperative scoring systems assess patient-related factors such as gallbladder wall thickness, previous history of cholecystitis and imaging findings to estimate surgical complexity [6-8]. In contrast, intraoperative scoring systems evaluate real-time surgical challenges, including adhesions, GB distension and anatomical variations [12,13]. The correlation between preoperative and intraoperative scoring systems in predicting the difficulty of LC is a crucial aspect of surgical planning.

Therefore, this study aims to assess the correlation between preoperative grading and an intraoperative scoring system to forecast difficulties in LC and the need for conversion to open cholecystectomy.

Primary objectives:

- To score all patients preoperatively based on the Modified Randhawa and Pujahari scoring system to predict the difficulty of LC.
- To score the intraoperative difficulty level of LC in terms of operative time, bile/stone spillage and the need for conversion.

Secondary objectives:

- To correlate preoperative and intraoperative scores in terms of difficulty leading to conversion to open surgery, partial cholecystectomy, or cholecystostomy.

Null hypothesis: There will be no significant correlation between the preoperative and intraoperative scoring systems in predicting the conversion of LC to open cholecystectomy.

Alternative hypothesis: There will be a significant correlation between the preoperative and intraoperative scoring systems in predicting the conversion of LC to open cholecystectomy.

MATERIALS AND METHODS

A prospective observational study will be conducted in the inpatient department of General Surgery at Acharya Vinoba Bhave Rural Hospital (AVBRH) in Sawangi, Wardha, Maharashtra, India, from March 2024 to February 2026. The study protocol was approved by the Institutional Ethics Committee of Datta Meghe Institute of Higher Education and Research, Wardha, as per letter no: Ref no. DMIHER (DU/IEC/2024/178 dated 1st March 2024). Thirty-five patients with gallstone disease who fulfill the inclusion and exclusion criteria and provide informed written consent will be included in the study.

Inclusion criteria:

- Age >18 years and consenting to the study.
- All patients diagnosed with gallbladder stones, diagnosed with acute or chronic cholecystitis, or symptomatic cholelithiasis who are planned for LC.

Exclusion criteria:

- Unfit for laparoscopic surgery;
- Patients with retained Common Bile Duct (CBD) stones after Endoscopic Retrograde Cholangiopancreatography (ERCP).
- Patients with features of obstructive jaundice or concurrent pancreatitis.
- Previously operated (laparotomy/laparoscopy).
- Diagnosed with cirrhosis or portal hypertension.

Sample size calculation:

Formula:

$$n = \frac{(Z^2 P(1-P))}{d^2}$$

Z=1.96

P=Sensitivity of Preoperative Scoring System for Predicting Difficult LC=93.02% = 0.9302 [1]

d=Desired margin of error=10% = 0.10

$n = \{1.96^2 \times 0.9302 \times (1 - 0.9302)\} / 0.10^2 = 24.94$

which rounds up to 25 subjects needed in the study.

Considering the margin of error of 10%, the final sample size was determined to be 28. The study subjects total 35.

All patients scheduled for and undergoing LC, who consent to the study, will be operated on by a single laparoscopic surgeon at our institute with at least 8 years of experience.

Outcomes: Following the initial preoperative evaluation, each patient will receive a preoperative score (see [Table/Fig-1]) based on their medical history, clinical examination and sonographic results, according to the guidelines of the Modified Randhawa and Pujahari Score [7]. A score of up to five is defined as easy, 6-10 as difficult, and 11-15 as very difficult. Based on these findings, the surgical procedure will be predicted to be easy, difficult, or very difficult [7]. Based on this score, appropriate counselling of the patients will be performed for written informed consent.

Intraoperative scoring will be conducted based on parameters such as gallbladder adhesions, gallbladder distension/contraction, complications, and the time taken to identify the cystic duct and cystic artery [Table/Fig-2]. Intraoperatively, the surgical procedure

History	Findings (score)	Maximum score
Age (years)	<60 (0) >60 (1)	1
H/O previous attack of cholecystitis	No (0) Yes (2)	2
Post ERCP/ stenting	No (0) Yes (2)	2
BMI (Kg/m ²)	<25 (0) 25-27.5 (1) >27.5 (2)	2
Abdominal scar	No (0) Intraumbilical (1) Supraumbilical (2)	2
Palpable Gallbladder (GB)	No (0) Yes (2)	2
Wall thickness	<4 mm (0) >4 mm (2)	2
Pericholecystic collection	No (0) Yes (1)	1

[Table/Fig-1]: Modified Randhawa et al., preoperative score [6,7].

Gallbladder appearance	
No adhesions	1
Adhesions <50% of Gallbladder	3
Adhesions burying Gallbladder	3
Distention/contraction	
Distended/Contracted Gallbladder	1
Unable to grasp with traumatic forceps	1
Stone >1 cm Impacted in Hartman's pouch	1
Access	
BMI <30	1
Adhesions from previous surgery limiting access	1
Severe sepsis/complication	
Bile or Pus outside gallbladder	1
time to identify cystic artery and duct >90 min	1

[Table/Fig-2]: Intraoperative grading.

will be classified as easy (time <60 min, no spillage, no injury to duct/artery), difficult (time 60-120 min, bile/stone spillage, injury to duct, and no conversion) and very difficult (time >120 min, bile/stone spillage, injury to duct and conversion to open surgery) based on the time taken during the procedure, bile spillage and injury to surrounding tissues [2,12].

The two scores will be compared to assess their correlation in predicting conversion rates in difficult LC using statistical methods.

STATISTICAL ANALYSIS

All results will be calculated using R software version 4.3. Demographic characteristics of the study population will include mean, median

and standard deviation for continuous variables, as well as frequency distributions for categorical variables. After checking the normality of the data, correlation analysis will be performed between the variables of the preoperative grading system and the intraoperative scoring system by calculating Pearson correlation coefficients or Spearman's rank correlation coefficients, depending on the nature of the variables. Preoperative and intraoperative scores will be compared using statistical tests (e.g., t-test, Mann-Whitney U test) at a 5% level of significance. Model evaluation will be conducted to assist in determining the goodness-of-fit of logistic regression models using measures such as the Hosmer-Lemeshow test and Receiver Operating Characteristic (ROC) curve analysis.

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Extended Data: Hyperlink to consent and proforma.

https://acrobat.adobe.com/id/urn:aaid:sc:VA6C2:43d81bcf-8e1b-4f90-b8fe-2e967262b6a8

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