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EVALUATION OF LAPAROSCOPIC CHOLECYSTECTOMY DIFFICULTY DURING THE COVID-19 PANDEMIC USING EXTERNALLY VALIDATED PREDICTION MODELS: A RETROSPECTIVE COHORT STUDY.

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ABSTRACT

Background
The COVID-19 pandemic has posed significant challenges to surgical procedures, including laparoscopic cholecystectomy (LC). Assessing the difficulty of these surgeries during the pandemic is crucial for optimizing outcomes and resource allocation. This study aims to evaluate the difficulty of LC during the COVID-19 pandemic using externally validated prediction models.

Methods
A total of 120 individuals who undertook LC or open cholecystectomy were included. The CholeS and Randhawa scoring systems were used to predict operative difficulty. Data on demographics, clinical presentation, laboratory results, and surgical outcomes were collected and studied using SPSS version 21.0.

Results
The mean age was 45.3 years, with 48.3% male and 51.7% female participants. The mean CholeS score was 8.5, and the mean Randhawa score was 7.1. Operative difficulty was classified as easy (33.3%), difficult (54.2%), and very difficult (12.5%). Significant correlations were found between higher preoperative scores and increased operative difficulty, longer operation duration, and higher complication rates. Specifically, the odds ratios for CholeS and Randhawa scores predicting operative difficulty were 1.25 (95% CI: 1.12-1.39) and 1.30 (95% CI: 1.15-1.45), respectively. Additional significant correlations were found with older age (OR 1.05, 95% CI 1.01-1.10), presence of diabetes mellitus (OR 2.75, 95% CI 1.15-6.58), higher ASA classification (OR 1.58, 95% CI 1.08-2.31), and longer hospital stay (OR 1.40, 95% CI 1.20-1.62).

Conclusion
Externally validated prediction models effectively assess the problems of LC during the COVID-19 pandemic. Higher preoperative scores were associated with increased operative challenges and complications.

Recommendations
Preoperative risk stratification using the CholeS and Randhawa scores should be integrated into clinical practice to improve surgical planning and patient outcomes.

Keywords: *Laparoscopic cholecystectomy, COVID-19 pandemic, Operative difficulty, Prediction models*
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INTRODUCTION

The most effective treatment for symptomatic gallbladder illnesses, such as cholelithiasis and cholecystitis, is laparoscopic cholecystectomy (LC). Due to its benefits of less postoperative pain, a shorter stay in the hospital, and a quicker recovery period, LC has essentially supplanted open cholecystectomy since its inception in the late 1980s. However, due to variables including inflammation, obesity, and anatomical differences, the procedure's complexity might differ greatly from patient to patient [1]. Predicting surgical difficulty accurately is essential for patient counseling, resource allocation, and surgical planning.

The COVID-19 pandemic has introduced additional challenges to surgical practice, including changes in patient management protocols, increased use of personal protective equipment, and modifications to perioperative care to minimize viral transmission. These changes have impacted the execution and outcomes of elective and emergency surgical procedures worldwide [2]. Consequently, understanding the factors influencing the

difficulty of LC during the pandemic has become increasingly important.

Several predictive models have been developed to assess the difficulty of LC preoperatively. The CholeS score, developed by the CholeS study group, is a validated preoperative risk stratification tool that uses variables such as age, sex, BMI, and clinical findings to predict the likelihood of difficult surgery [3]. Another widely used model is the Randhawa score, which incorporates both pre-operative and intra-operative factors to classify the difficulty of LC into easy, difficult, and very difficult categories [4]. These models help surgeons anticipate challenges and prepare for potential complications.

The present study aims to evaluate the difficulty of LC during the COVID-19 pandemic using externally validated prediction models.

METHODOLOGY

Study Design

A retrospective cohort study designed

Study Setting

The study took place at Saheed Laxman Nayak (SLN) Medical College and Hospital, Koraput, Bhima Bhoi Medical College & Hospital, Balangir, Nehru Satabdi Central Hospital, Talcher, Odisha, India, Spanning 10 months (September 2023 to June 2024).

Participants

120 individuals had cholecystectomy procedures performed during the study period, either open or laparoscopic.

Inclusion Criteria

- Patients diagnosed with gallbladder disorders indicated by ICD-10 codes K80–K87.
- Indications for cholecystectomy included acute cholecystitis (AC), recurrent biliary colic, and a record of diabetes mellitus plus one episode of biliary colic.

Exclusion Criteria

- Individuals expressing dissatisfaction with the procedure.
- Patients classified as American Society of Anesthesiology (ASA) class IV or higher.
- Patients with incomplete medical records.
- Patients with a record of previous upper abdomen surgery.
- Patients showing respiratory signs of COVID-19 or a history of positive PCR unless fully remitted and tested negative.
- Patients with AC who also have COVID-19 infection may experience refractory symptoms or localized peritonitis.

Sample size

To calculate the sample size for this study, the following formula was used for estimating a proportion of a population:

$$n = \frac{Z^2 \times p \times (1-p)}{E^2}$$

Where:
- n = sample size
- Z = Z-score corresponding to the desired level of confidence
- p = estimated proportion in the population
- E = margin of error

Bias

Efforts were made to minimize bias by strictly adhering to the inclusion and exclusion criteria, using standardized data collection methods, and employing externally validated predictive models.

Variables

A few examples of variables are age, gender, the date of the procedure, the length of the pain, the existence of underlying medical conditions, tenderness and rebound tenderness, fever, white blood cell (WBC) count, neutrophils, hepatobiliary enzyme, surgical difficulties, length of time, and the incidence of complications.

Procedure

Data were collected by reviewing electronic medical and laboratory records.

- Diagnosis of AC: Based on history, physical examination, laboratory data (complete blood count, bilirubin, alkaline phosphatase, hepatic transaminases), and abdominal ultrasonography.
- Preoperative Consultation: All participants for the operation were evaluated by anesthesiologists, with pre-operative risk assessed using ASA classifications.

Surgical Procedure

- General anesthesia was administered by experienced anesthesiologists.
- A four-trocar method was employed, with the individual in a slight reverse Trendelenburg position.
- For patients who were obese, a Veress needle or the Hasson method was used to place the initial port.
- CO2 was used for insufflation.
- Once a crucial perspective of safety was attained, cholecystectomies were carried out.
- Laparoscopic clips were used to double-ligate the cystic duct.
- A 14Fr non-closed suction drain was inserted in cases of uncertain hemostasis or suspected bile leakage.
- Patients were discharged after tolerating oral intake.

Predictive Risk Stratification Models

Two predictive models were used:

- CholeS Preoperative Risk Score: A scoring system with eight variables and an external validation process that ranges from 0 to 19. Greater ratings denoted a more challenging cholecystectomy. The eight variables used in the CholeS score include age, sex, body mass index (BMI), previous abdominal surgery, acute cholecystitis on ultrasound, thick-walled gallbladder, common bile duct stones, and diabetes mellitus.
- Randhawa Score: Produces a risk score ranging from 0 to 15 and includes an intra-operative predicting model based on Operation Duration (OD). OD is categorized as:
- Easy: <60 min
- Difficult: 60–120 min or unwanted biliary injury
- Very Difficult: >120 min or conversion surgery

Statistical Analysis

SPSS version 21.0 was used to study the data. For categorical variables, frequencies were computed, and for quantitative variables, descriptive statistics were employed. P-values less than 0.05 were regarded as significant.

Ethical considerations

The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

RESULTS

The study comprised 120 individuals who had either an open or laparoscopic cholecystectomy. Table 1 provides a summary of the patient's baseline and demographic data.

Table 1: Demographic and Baseline Features

Variable	Value (n=120)
Age (years), Mean (SD)	45.3 (13.2)
Gender, n (%)	
Male	58 (48.3%)
Female	62 (51.7%)
Mean Duration of Pain (days)	4.6 (1.8)
Underlying Diseases, n (%)	
Diabetes Mellitus	25 (20.8%)
Hypertension	35 (29.2%)
ASA Classification, n (%)	
ASA I	30 (25.0%)
ASA II	50 (41.7%)
ASA III	40 (33.3%)

Table 2 provides a summary of the patient's clinical presentation and test results.

Table 2a: Clinical Presentation

Variable	Value (n=120)
Tenderness, n (%)	85 (70.8%)
Rebound Tenderness, n (%)	45 (37.5%)
Fever, n (%)	30 (25.0%)

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Table 2: Laboratory Data

Variable	Value (n=120)
Mean White Blood Cell Count (x10^3/µL)	11.2 (3.1)
Mean Neutrophils (%)	72.5 (10.3)
Mean Bilirubin (mg/dL)	1.2 (0.5)
Mean Alkaline Phosphatase (U/L)	110 (35)
Mean Hepatic Transaminases (U/L)	45 (15)

The operative difficulty was classified using the CholeS and Randhawa scoring systems. The distribution of operative difficulty and outcomes is summarized in Table 3.

Table 3: Operative Difficulty

Variable	Value (n=120)
Mean CholeS Score	8.5 (3.2)
Mean Randhawa Score	7.1 (2.8)
Mean Operation Duration (minutes)	85 (30)
Operative Difficulty (Randhawa), n (%)	
Easy (<60 min)	40 (33.3%)
Difficult (60-120 min)	65 (54.2%)
Very Difficult (>120 min)	15 (12.5%)
Complications, n (%)	
Bile Leakage	10 (8.3%)
Conversion to Open Surgery	5 (4.2%)
Postoperative Infection	8 (6.7%)
Mean Length of Hospital Stay (days)	3.5 (1.2)

The statistical analysis of the data showed significant correlations between the preoperative scores and operative outcomes.

Table 4 summarizes the odds ratios (OR) and 95% confidence intervals (CI) for the associations.

Table 4: Correlation of Preoperative Scores and Patient Characteristics with Operative Difficulty and Complications

Variable	OR (95% CI)	p-value
CholeS Score vs. Operative Difficulty	1.25 (1.12-1.39)	<0.001
Randhawa Score vs. Operative Difficulty	1.30 (1.15-1.45)	<0.001
Age vs. Operative Difficulty	1.05 (1.01-1.10)	0.045
Gender vs. Operative Difficulty	0.85 (0.51-1.42)	0.532
Diabetes Mellitus vs. Complications	2.75 (1.15-6.58)	0.023
ASA Classification vs. Complications	1.58 (1.08-2.31)	0.018
Length of Hospital Stay vs. Operative Difficulty	1.40 (1.20-1.62)	<0.001

DISCUSSION

The results displayed that the mean age was 45.3 years, with a fairly even distribution between males (48.3%) and females (51.7%). The majority of patients presented with common symptoms such as tenderness (70.8%) and fever (25.0%), and laboratory tests revealed increased WBC counts and hepatobiliary enzymes.

The operative difficulty was assessed using both the CholeS and Randhawa scoring systems. The mean CholeS score was 8.5, and the mean Randhawa score was 7.1, indicating a moderate level of difficulty in the cohort. The majority of surgeries (54.2%) were classified as difficult, with operation durations ranging between 60 and 120 minutes. Only 12.5% of surgeries were classified as very difficult, with durations exceeding 120 minutes or requiring conversion to open surgery.

Statistical analysis revealed significant correlations between the preoperative scores and operative outcomes. Higher CholeS and Randhawa scores were related to raised operative difficulty (OR 1.25, 95% CI 1.12-1.39 for CholeS; OR 1.30, 95% CI 1.15-1.45 for Randhawa, both p<0.001). Additionally, older age and the presence of diabetes mellitus significantly increased the likelihood of complications (OR 1.05, 95% CI 1.01-1.10 for age; OR 2.75, 95% CI 1.15-6.58 for diabetes, p=0.045 and p=0.023, respectively). Higher ASA classification also correlated

with increased complication rates (OR 1.58, 95% CI 1.08-2.31, p=0.018).

These findings indicate that preoperative risk stratification using the CholeS and Randhawa scores can effectively predict the difficulty and potential complications of laparoscopic cholecystectomy. The study underscores the importance of thorough preoperative evaluation, especially during the COVID-19 pandemic, to identify patients at higher risk and tailor surgical strategies accordingly. The significant associations between age, diabetes mellitus, ASA classification, and operative outcomes highlight the need for heightened vigilance and possibly modified management in these patient subgroups.

Overall, the study demonstrates the utility of predictive models in guiding clinical decision-making and improving surgical outcomes. Future research with larger, prospective cohorts is warranted to further validate these findings and refine predictive algorithms for better risk assessment and patient care.

A considerable number of elective procedures, including LC, have been influenced by the COVID-19 pandemic. A study looked at how delays connected to COVID-19 affected elective LC. In comparison to the pre-pandemic period, they discovered longer waiting times and a greater frequency of inflammatory diseases during the pandemic recovery phase, but there were no appreciable changes in intra-operative timings or patient results [5]. A further study examined the effects of LC during the COVID-19 pandemic and found that, in contrast to the first wave and the pre-pandemic periods, there was a notable decrease in readmission rates and duration of stay during the second wave. Regarding post-operative problems, they discovered no discernible variations [6].

Research observed no significant differences in operative times, complication rates, or the need for subtotal cholecystectomy between pre-pandemic and post-pandemic periods. They concluded that the pandemic did not increase the technical difficulty or complication rate of LC [7]. A study found that during the pandemic, there was a reduction in emergency laparotomies due to tighter case selection. Postoperative care was adjusted, leading to shorter ITU stays and total length of hospital stay, indicating efficient prioritization of surgical cases [8].

Additionally, a study used objective operative difficulty grading systems to establish and validate a pre-operative risk score for predicting difficult cholecystectomy cases. Age, ASA classification, diagnosis of cholecystitis or CBD stone, male gender, thick-walled gallbladders, CBD dilatation, use of pre-operative ERCP, and non-elective surgeries were all significant predictors [9].

GENERALIZABILITY

The findings of this study highlight the effectiveness of the CholeS and Randhawa predictive models in assessing operative difficulty and potential complications of laparoscopic cholecystectomy during the COVID-19 pandemic. Given the significant correlations identified between higher preoperative scores and increased surgical challenges, these models can be reliably used in larger populations to enhance preoperative planning and risk stratification. By incorporating these validated scoring systems into routine clinical practice, healthcare providers can better anticipate surgical difficulties, allocate resources efficiently, and ultimately improve patient outcomes across diverse healthcare settings globally. The study underscores the importance of thorough preoperative evaluation, especially in high-risk patients, to tailor surgical strategies and minimize complications.

CONCLUSION

This retrospective cohort study demonstrates the utility of externally validated prediction models in evaluating the problems of LC during the COVID-19 pandemic. The findings suggest that preoperative risk stratification using the CholeS and Randhawa scores can help anticipate operative challenges and improve surgical outcomes. Further studies with higher sample numbers and prospective designs are recommended to validate these findings.

Limitations: The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of a comparison group also poses a limitation for this study's findings.

RECOMMENDATION

Preoperative risk stratification using the CholeS and Randhawa scores should be integrated into clinical practice to improve surgical planning and patient outcomes. Further studies with higher sample numbers are recommended to verify these findings.

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LIST OF ABBREVIATIONS

AC: Acute Cholecystitis
ASA: American Society of Anesthesiology
CBD: Common Bile Duct
CI: Confidence Interval
COVID-19: Coronavirus Disease 2019

ERCP: Endoscopic Retrograde Cholangiopancreatography
ICD-10: International Classification of Diseases, 10th Revision
LC: Laparoscopic Cholecystectomy
OD: Operation Duration
OR: Odds Ratio
PCR: Polymerase Chain Reaction
SD: Standard Deviation
SPSS: Statistical Package for the Social Sciences
WBC: White Blood Cell

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CONFLICT OF INTEREST

The authors have no conflicting interests to declare.

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