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A Study on Various Pre–Operative Indicators for Difficult Laparoscopic Cholecystectomy in Saveetha Medical College and Hospital

Giridhar Aravind B.*, Gunasekar C., Kuppan C. T., Sanjana Chiramel
Department of General Surgery, Medical College and Hospital, Thandalam, Tamil Nadu, India

Abstract

Laparoscopic cholecystectomy (LC) is the preferred surgical approach for treating gallstone disease; however, there are cases that pose significant challenges, often leading to a switch to open surgery. This study aims to identify preoperative indicators that suggest a difficult laparoscopic cholecystectomy (LC), focusing on demographic factors, inflammatory markers, and intraoperative challenges. A prospective study was performed on patients diagnosed with acute or chronic cholecystitis, examining factors such as gender, age, diabetes mellitu), CRP, ESR, and TC. The findings revealed a strong association between male gender, older age, and diabetes mellitus with surgical complications (p = 0.001). CRP, ESR, and TLC were significantly linked to intraoperative challenges and the need for conversion to open surgery. The severity grade of the Tokyo Guidelines (TG-13) was substantially associated with surgical difficulty (p = 0.001). These findings points out the significance of preoperative evaluation in recognising high-risk patients, facilitating enhanced surgical planning and improved patient outcomes. Nevertheless, constraints such as a single-center design and retrospective data collecting require more multi-center prospective research to improve predictive accuracy and investigate sophisticated imaging and biochemical indicators for enhanced risk stratification.

Keywords: *Diabetes Mellitus, Laparoscopic Cholecystectomy, Preoperative Signs, Surgical Complications.*

Introduction

Gallstone disease is a prevalent condition impacting the digestive system. The incidence of gallstones is associated with age, sex, and ethnicity. The incidence of gallstones exhibits significant geographical variation. 20 million individuals in the US are thought to have gallstones, with around 1 million new cases of cholelithiasis occurring year. The estimated prevalence in India is approximately 4%. The shifting incidence in India is mostly ascribed to the westernisation of nutrition, alterations in the socioeconomic structure, and the accessibility of ultrasound for diagnostic purposes in both rural and urban regions [1]. Biliary colic often arises from a stone trapped in the cystic duct or common bile duct within the biliary system. Colic denotes intermittent pain, often occurring post-consumption of a substantial, fatty meal that induces gallbladder contraction. Nonetheless, the pain is typically persistent rather than intermittent. Surgery is the primary treatment for this condition, entailing the excision of the gallbladder, mostly performed by a laparoscopic approach. This medical ailment often does not necessitate hospitalization [2, 3]. LC has become the preferred method for addressing symptomatic gallstone disease. It is estimated that 2–15% of attempted LC will require conversion to open surgery due to various complications that may arise during the procedure. [4]. Recent studies

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****Corresponding Author: giridhararavind@gmail.com***

are aimed at developing and confirming pre-operative grading systems to predict the difficulties linked with LC. These evaluation systems take into account a variety of clinical, biochemical, and radiologic factors that can complicate surgical procedures. A research study developed a risk score through an objective grading system, indicating that elements such as male gender, increased BMI, and a background of acute cholecystitis are significant predictors of difficult cholecystectomy procedures. [5]. A previous hospitalisation due to acute cholecystitis is a significant indicator of potential challenges during surgery. Such patients would have widespread adhesions and anatomical distortion and are hard to operate upon. Ultrasonographic features, i.e., thickness of the gallbladder wall and ascites surrounding the gallbladder, have also been noted as good predictors for challenging laparoscopic cholecystectomy. They are signs of chronic inflammation and scarring that would render it difficult to recognize anatomical structures and dissect [6]. Biochemical markers, such as increased liver enzymes and bilirubin levels, together with predictive models, have enhanced in their accuracy. They are signs of underlying hepatobiliary disease, which is often present in more complex surgical cases. Employment of scoring systems that include such factors has proved to stratify patients effectively with respect to complicated laparoscopic cholecystectomy (LC) risk. Studies have confirmed that this grading system can indeed predict the degree of complexity involved in the procedure as well as the likelihood of having to switch to open surgery [7]. The current research investigates the relevance of preoperative markers like CRP, ESR, TC, and DM in determining the difficulty of laparoscopic cholecystectomy. This study will improve preoperative evaluation through studies on the association of surgical complexity with acalculous and calculous cholecystitis. Improved surgical planning and patient outcomes will be achieved through the findings.

Materials and Methods

This prospective analytical study was carried out at Saveetha Medical College and Hospital, located in Thandalam, Tamil Nadu, within the Department of General Surgery. The patients admitted in the Department of Surgery and Surgical Gastroenterology with the clinical diagnosis of acute or chronic cholecystitis with or without gallstones were included in this study. Institutional ethical clearance has been obtained from the Institution's Ethical Clearance Committee, and informed written consent were obtained from all the participants. The research work will be carried out from the months of October 2020 to October 2021 on patients.

The objective of this research is to determine the correlation between CRP, ESR, TC, and diabetes mellitus, in patients with acute calculous or acalculous cholecystitis and chronic cholecystitis. Patients who are eligible for inclusion will be subjected to routine preoperative investigations, and intraoperative findings will be correlated with these preoperative markers. The level of complexity of laparoscopic cholecystectomy will be determined based on the Tokyo Guidelines 13 (ANNEXURE 1 and 2). The study's inclusion criteria encompass individuals aged 18 and older, regardless of gender, diagnosed with acute calculous or acalculous cholecystitis, acute on chronic cholecystitis, or acute cholecystitis with complications including pyocele, mucocele, or perforation. The exclusion criteria encompass patients diagnosed with hepato-biliary malignancies, individuals with pre-existing conditions that independently elevate CRP, ESR, or TC levels (including cholangitis, inflammatory bowel disease, atherosclerosis, autoimmune disorders such as rheumatoid arthritis and systemic lupus erythematosus, cardiac conditions like pericarditis and coronary artery disease, acute

pancreatitis, or other organ injuries), as well as patients undergoing percutaneous cholecystostomy due to significant comorbidities or sepsis, and those with bleeding diathesis.

All participants will undergo a set of laboratory assessments upon admission. This encompasses standard blood tests, including CBC, Platelet Count, and Reticulocyte Count, as well as Liver Function Tests (LFTs), which comprise Total and Direct Bilirubin, SGPT, SGOT, and ALP. Furthermore, seropositivity assays for HbsAg, HCV, and HIV will be performed, in conjunction with urinalysis (routine and microscopic), blood typing, and coagulation assessment. The intraoperative observations, especially instances of gangrenous gallbladder, pyocele, mucocele, or mass formation, will be compared with the preoperative laboratory metrics to evaluate their prognostic significance for surgical complexity.

Sample Size

The sample size determination is based on the research by Stanisic et al. (2020), which found that 70% of patients who faced intraoperative complications had elevated CRP levels, compared to only 6% of those without complications. To achieve a 99% confidence interval and 90% power, the minimum required sample size for each group was set at 10 patients. To mitigate sampling error and enhance the study's robustness, a total of 100 patients (including both groups) will be included.

Statistical Analysis

Statistical analysis will be conducted using R programming and MS Excel. Frequency and percentage will represent categorical variables, while continuous variables will be expressed as mean and standard deviation. The association between two categorical variables will be analysed through the Chi-square test or Fisher's exact test, whereas variations among groups based on continuous variables will be assessed using the independent sample t-test. Pearson correlation was used to correlate predictors with complications. A significance level of 5% ($p < 0.05$) is considered statistically significant.

Results

Table 1 illustrates the correlation between demographic characteristics (gender, age, and diabetes mellitus) and the incidence of complications during laparoscopic cholecystectomy. In Sex and Complications, of the 73 patients without complications, 24 (32.9%) were male and 49 (67.1%) were female. Among the 27 patients that experienced problems, a notably greater number, 19 (70.4%), were male, whereas just 8 (29.6%) were female, with a p-value of 0.001, signifying a statistically significant correlation between male sex and an elevated risk of problems. The mean age of patients without complications was 48.12 ± 11.31 years, whereas the mean age of those who faced difficulties was 59.30 ± 11.39 years. The independent t-test yielded a value of -4.378 and a p-value of 0.001, demonstrating a notable age difference between the two groups. This suggests that elderly patients face an increased risk of problems after laparoscopic cholecystectomy. Diabetes mellitus (DM) was significantly correlated with surgical complications. Of the 73 individuals without problems, 51 (69.9%) were non-diabetic, whereas 22 (30.1%) were diabetic. Conversely, of the 27 individuals who experienced problems, only 3 (11.1%) were non-diabetic, while 24 (88.9%) had diabetes. The Chi-square statistic for this association is 27.389, accompanied by a p-value of 0.001, indicating a very significant link between diabetes and an elevated risk of complications.

Table 1. Association of Demographic Variables with Complications

Demographic Variables		Complication		Statistic	P-value
		No	Yes		
Sex					
Male	N	24	19	11.305	0.001**
	%	32.90%	70.40%		
Female	N	49	8		
	%	67.10%	29.60%		
Total	N	73	27		
	%	100.00%	100.00%		
Age		48.12±11.31	59.30±11.39	-4.378	0.001**
DM					
No	N	51	3	27.389	0.001**
	%	69.90%	11.10%		
Yes	N	22	24		
	%	30.10%	88.90%		
Total	N	73	27		
	%	100.00%	100.00%		

Table 2 demonstrates the relationship between preoperative inflammatory indicators (CRP, ESR, and total leukocyte count) and problems arising after laparoscopic cholecystectomy. The Fisher's exact p-value of 0.001 for all three measures underscores their robust predictive significance. In patients without problems, 50.7% exhibited normal CRP levels, 64.4% demonstrated normal ESR values, and 74% presented normal leukocyte counts. Conversely, all patients who experienced problems exhibited higher levels of all three markers, indicating a substantial correlation between inflammation and surgical challenges. Increased CRP, ESR, and total leukocyte counts are significant preoperative predictors of challenging laparoscopic cholecystectomy. Evaluating these markers can facilitate risk classification and enhance surgical planning.

Table 2. Association of Clinical Indicators with Complications

Indicators		Complication		Fisher's exact P-value
CRP levels		No	Yes	0.001**
Normal	N	37	0	
	%	50.70%	0.00%	
Elevated	N	36	27	
	%	49.30%	100.00%	
Total	N	73	2700.00%	
	%	100.00%	100.00%	
ESR levels				0.001**
Normal	N	47	0.00%	
	%	64.40%	0.00%	
Elevated	N	26	27	

	%	35.60%	100.00%	
Total	N	73	2700.00%	
	%	100.00%	100.00%	
Total count				0.001**
Normal	N	54	0.00%	
	%	74.00%	0.00%	
Elevated	N	19	27	
	%	26.00%	100.00%	
Total	N	73	27	
	%	100.00%	100.00%	

Table 3 illustrates the relationship between operation variables and complications after laparoscopic cholecystectomy, with statistically significant Fisher's exact p-values (<0.05) denoting a robust correlation. Intraoperative Difficulty shows that among patients without complications, 65.8% exhibited a normal degree of difficulty, but 66.7% of those with complications encountered moderate difficulty, and 33.3% faced severe difficulty (p = 0.001). Conversion to Open Procedure shows that a significant majority of cases (98.6% without issues and 81.5% with complications) were successfully finished laparoscopically; nevertheless, 18.5% of patients with complications necessitated conversion to open surgery (p = 0.005). Tokyo Guidelines (TG-13) Severity Grading found 83.6% of patients without complications were not categorised under the TG-13 grading system, while 74.1% of complicated cases were categorised as Grade 2 (moderate) and 14.8% as Grade 3 (severe) (p = 0.001). The intensity of intraoperative challenges, the necessity for conversion to open surgery, and TG-13 grading are substantially associated with surgical problems. Preoperative risk evaluation utilising these variables can enhance surgical planning and decision-making.

Table 3. Intraoperative Challenges and Surgical Outcomes

Operative Variables		**Complication**		**Fisher's exact P-value**
Intra operative Difficulty		No	Yes	
Normal	N	48	0	0.001**
	%	65.80%	0.00%	
Moderate	N	24	18	
	%	32.90%	66.70%	
Severe	N	1	9	
	%	1.40%	33.30%	
Total	N	73	27	
	%	100.00%	100.00%	
Conversion to open procedure				0.005*
No	N	72	22	
	%	98.60%	81.50%	
Yes	N	1	5	
	%	1.40%	18.50%	
Total	N	73	27	

	%	100.00%	100.00%	
TG - 13 GRADE				0.001**
NA	N	61	0	
	%	83.60%	0.00%	
G1	N	6	3	
	%	8.20%	11.10%	
G2	N	6	20	
	%	8.20%	74.10%	
G3	N	0	4	
	%	0.00%	14.80%	
Total	N	73	27	
	%	100.00%	100.00%	

Table 4 displays the correlation analysis among CRP, ESR, total count, diabetes mellitus (DM), and complications in laparoscopic cholecystectomy utilising Pearson/Spearman correlation coefficients. A statistically significant correlation ($p < 0.05$) is established among these factors. CRP exhibits a significant positive correlation with ESR ($r = 0.870$, $p = <0.0001$), total count ($r = 0.808$, $p = <0.0001$), diabetes mellitus ($r = 0.626$, $p = <0.0001$), and complications ($r = 0.568$, $p = <0.0001$), signifying that elevated CRP levels are linked to heightened inflammatory markers, diabetes, and an increased risk of surgical complications. Likewise, ESR exhibits a substantial correlation with total count ($r = 0.803$, $p = <0.0001$), diabetes mellitus ($r = 0.588$, $p = <0.0001$), and complications ($r = 0.591$, $p = <0.0001$), so affirming its function as an inflammatory marker indicative of surgical complexity. Moreover, the total count is significantly correlated with DM ($r = 0.508$, $p = <0.0001$) and complications ($r = 0.639$, $p = <0.0001$), underscoring its relevance in evaluating preoperative risks. Diabetes mellitus exhibits a significant link with complications ($r = 0.498$, $p = <0.0001$), indicating that diabetic patients have an elevated risk of surgical difficulties. These data underscore the substantial correlation between inflammatory markers, diabetes, and surgical problems, emphasising their importance as critical preoperative indicators for forecasting challenging laparoscopic cholecystectomy.

Table 4. Correlation between CRP, ESR, Total Count, DM and Complications

		CRP	**ESR**	**TOTAL COUNT**	**DM**	**COMPLICATION**
CRP	Pearson Correlation	1	.870**	.808**	.626**	.568**
	P-value		<0.0001	<0.0001	<0.0001	<0.0001
ESR	Pearson Correlation		1	.803**	.588**	.591**
	P-value			<0.001	<0.001	<0.0001
TC	Pearson Correlation			1	.508**	.639**
	P-value				<0.0001	<0.0001
DM	Pearson Correlation				1	.498**
	P-value					<0.0001

COMPLICATION	Pearson Correlation					1
	P-value					

Discussions

This research uncovers a substantial correlation between preoperative elevated inflammatory markers and increased intraoperative challenges, conversion to open surgery, and higher severity grading based on the Tokyo Guidelines (TG-13). This supports the purpose of our study, which evaluates these factors as markers of surgical complications for preoperative planning and risk assessment. In our study, we observed that males were more prone to complications. This finding aligns with previous studies identifying male sex and performing laparoscopic cholecystectomy (LC) more than 96 hours after symptom onset as independent risk factors for increased surgical difficulty [8]. also lists multiple predictors of complicated laparoscopic cholecystectomy, the majority of which are consistent with our results. Their study incorporates elevated inflammatory markers (WBC $>10 \times 10^9$ g/L) as the most significant predictive factor, similar to our results also showing that increasing leukocyte, CRP, and ESR are risk factors for complications in surgery. Their findings provide a significant association between diabetes and postoperative complications that corroborates with our findings, diabetes mellitus was found to be a good predictor of difficulty in surgery [9]. Other studies have examined preoperative predictors of conversion and their association with local inflammation in acute cholecystitis. Increased WBC count, CRP levels, and the degree of inflammation have been identified as significant risk factors for conversion to open surgery, findings that closely align with ours, as we found WBC, CRP, and ESR to be strong predictors of postoperative complications.

Previous research has identified age and male gender as conversion risk factors, similar to our findings, where both older age and male gender were strongly associated with postoperative complications [10]. Other studies concur with our results, particularly regarding CRP as a significant predictor of challenging LC. Elevated CRP is strongly associated with longer operating times, higher complication rates, and increased conversion rates to open surgery. As with our research, CRP, ESR, and WBC count have been identified as significant preoperative predictors of surgical difficulty, further reinforcing the role of inflammatory markers in predicting surgical complications.

These findings highlight the value of preoperative measurement of inflammatory markers in risk assessment. Surveillance of CRP can optimize surgical planning, patient selection, and overall management strategies to reduce complications and improve outcomes [11]. Other studies support our findings, referencing preoperative prognosis in challenging LC. Risk factors like male gender, advanced age, and inflammatory markers were core variables in our study. Extensive preoperative assessment to anticipate surgical difficulties has been suggested, which aligns with our findings of CRP, ESR, total leukocyte count, and diabetes mellitus as potential predictors of complications [12].

Additional research has shown that patients with elevated CRP levels have an increased likelihood of experiencing difficult LC or requiring conversion to open cholecystectomy [15]. Findings indicate that WBC count, in conjunction with CRP, serves as an indicator for conversion from LC to open surgery [13]. It has been demonstrated that individuals with CRP levels at or below 220 mg/L experienced a conversion rate of 3.2%, whereas those with CRP levels exceeding 220 mg/L showed a markedly elevated conversion rate of 61.9% (P

< 0.001). Furthermore, higher WBC counts and a history of ERCP were also indicative of conversion, with these predictors showing a slight advantage over CRP alone in forecasting conversion [14].

Several studies have enumerated risk factors for complicated LC, including male sex, advanced age, acute cholecystitis, obesity, and prior upper abdominal surgery. These studies emphasize preoperative recognition of such factors and recommend techniques like the fundus-first approach and subtotal cholecystectomy to reduce complications and conversion [15]. Other research findings align with our study, as multiple studies have identified male gender, advanced age, and higher inflammatory markers as predictors of challenging LC. High WBC counts and inflammatory markers have been shown to increase the complexity of surgery, consistent with our findings of a significant correlation between CRP, ESR, total leukocyte count, and complications ($p = 0.001$) [16]. Additional studies have observed that elevated WBC counts and CRP were strong predictors of acute cholecystitis, a post-laparoscopic surgical complication. Such findings reinforce our research, which incorporates these predictors into preoperative evaluations to anticipate potential surgery-related complications [17].

Research has identified preoperative gallbladder drainage and severe neck scarring of the gallbladder as significant risk factors for difficult three-port LC. Recommendations include ensuring adequate surgical assistance and considering conversion to subtotal or open cholecystectomy early in high-risk patients to prevent intraoperative complications [18]. Additional research emphasizes achieving the Critical View of Safety for accurate identification of biliary structures and recommends routine intraoperative cholangiography to detect anatomical variations. In difficult cases, recommendations include the application of subtotal cholecystectomy, with the technique of gallbladder removal left to the surgeon's discretion based on patient-specific considerations [19]. Other researchers have developed predictive models to identify patients at increased risk for difficult cholecystectomy (DC), facilitating improved surgical planning and patient counseling [20].

This study has some limitations. Its single-center design may restrict the generalizability of findings to other populations, and data collection may introduce potential biases. Additionally, variability in surgical expertise and institutional protocols could influence outcomes. Future research should focus on multi-center prospective studies with larger and more diverse populations to confirm these findings. Further investigations should explore the integration of innovative biomarkers and advanced imaging modalities to enhance preoperative risk evaluation and refine surgical decision-making.

Conclusion

The research underscores the significance of preoperative markers in forecasting the intricacy and possible complications of laparoscopic cholecystectomy. Male sex, advanced age, and diabetes mellitus were recognised as significant demographic risk factors, with diabetic patients demonstrating a greater prevalence of problems. Increased inflammatory indicators, such as CRP, ESR, and total leukocyte count, significantly linked with surgical challenges, hence enhancing their predictive utility in preoperative evaluation. Moreover, intraoperative variables, including procedural complexity, conversion to open surgery, and TG-13 severity classification, were substantially correlated with negative outcomes. Correlation research validated the interrelationship among inflammation, diabetes, and surgical complications, highlighting their significance in risk classification and surgical planning.

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Conflict of Interests

The authors declare that they have no conflicts of interest.

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