Original Article

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Pre-Operative Score Development: Predicting Difficulty in Elective Laparoscopic Cholecystectomy

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Abstract:

Objective: To develop and internally validate a pre-operative scoring system to predict difficulty in elective laparoscopic cholecystectomy (LC).

Material and Methods: A retrospective diagnostic prediction study was conducted. Patients undergoing elective LC; from September 2016 to January 2023, at Hatyai Hospital in Southern Thailand were included. Patients were categorized by difficultly of LC according to the Nassar scale (grades 1-2 as non-difficult LC and grades 3-4 as difficult LC). Pre-operative data were compared between both groups; utilizing multivariable logistic regression. Internal validation was performed via the bootstrapping procedure.

Results: In total, three hundred and eighteen patients were categorized into either; difficult LC 121 patients or non-difficult LC 197 patients. From this, 7 variables obtained from the multivariable logistic reduced model (male, cirrhosis, history of ERCP, ASA III, gallbladder wall ≥4 mm, dilated gallbladder, contracted gallbladder) were developed as a pre-operative score. The scoring (range: 0.0-16.6) was classified into 3 groups for clinical practicability. The positive predictive values (PPV) were 18.1 for low-risk, 38.0 for moderate-risk, and 76.0 for high-risk. Internal validation, via bootstrap technique, showed a C-statistic value of 0.76, and bootstrap shrinkage was 0.995. The prediction ability (AuROC) of the pre-operative score was 0.76.

Conclusion: The developed of a pre-operative score had a good predictive performance, with fewer predictors for prediction difficulty of elective LC that can assist surgeons in surgical management selection.

Keywords: difficult laparoscopic cholecystectomy, predictive scoring, pre-operative score

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Introduction

Currently, the laparoscopic approach is the mainstay treatment for cholecystectomy, as it causes less postoperative pain, shortened hospital stay and faster recovery, compared with an open approach. When difficult laparoscopic cholecystectomy (LC) occurs, the risk of bile duct injury increases by up to 10 times, having a high conversion rate, more postoperative complications as well as longer operative time[1]. Longer surgical time can cause the following scheduled operations to be postponed or canceled. The conversion to open cholecystectomy causes longer abdominal incision, more pain, higher hospital cost, longer stay in the hospital and increases risk of complications. Hence, pre-operative score development for prediction of difficult LC can may help new surgeons to effectively plan their surgical schedule, choose appropriate surgeons and optimize trained surgeons according to their level of training[2,3].

Different criteria have been used to create pre-operative scoring systems to predict whether an LC would or would not be difficult. However, many studies created preoperative prediction models by using long operative times[4-6], conversion[7] or both[5,8-9] as a label to predict difficult LC. However, the duration of surgery, also depends on the surgeon's expertise and equipment availability. Likewise, the decision to convert to open cholecystectomy depends on the judgment and experience of surgeons. As previously reported by the CholeS study group[2], the threshold for conversion is likely to vary between surgeons and can be related to several factors; such as patient-related factors, surgeon's experience, and procedural difficulty. Therefore, these criteria are not widely accepted and used. The thickened gallbladder (GB) and dense adhesion at the Calot's triangle make it truly difficult to perform LC. This results in longer operation times as well as higher morbidity according to the Nassar study[2].

In this study, the intraoperative difficulty assessment from GB characteristics and adhesion according to the Nassar scale[2] was chosen to generate a pre-operative score. This study aimed to create a pre-operative score that can predict difficulty in an elective LC.

Material and Methods

This retrospective diagnostic prediction research was conducted at Hatyai Hospital, a referral center in Southern Thailand, using data from September 2016 to January 2023. Patients aged over 13 years old, scheduled for elective LC and having had recorded intraoperative videos were included. Emergency or early LC, after gangrenous cholecystitis, empyema cholecystitis, Mirizzi syndrome, choledochoenteric fistula and LC including other additional operations in the same setting were excluded. In case of missing data, no imputation was used.

The study was designed to evaluate the performance of a pre-operative score for predicting difficult LC according to the Nassar scale (Table 1). The grading system was designed to incorporate the worst factor found in the individual aspect of either the: 'Gallbladder', 'Cystic Pedicle', or 'Adhesions' to define the final overall grade. The large or short cystic duct, gangrenous cholecystitis and empyema GB in the Nassar scale were not included in this study. The patients were categorized into 2 groups according to the Nassar scale, based on review of the operative video by experienced surgeons who did not know about the patient's characteristics or surgical information. It labelled the Nassar scales 1-2 as the non-difficult LC group, and the Nassar scales 3-4 as the difficult LC group. The surgical trainee who collected patient data would not know about group of patients to avoid possible bias. The selected logistic coefficients were transformed into a risk-based scoring system. Internal validation was done with the bootstrapping procedure.

Table 1 Assessment of difficulty; according to the Nassar scale

Grade	Gallbladder	Cystic pedicle	Adhesions
1	Floppy, non-adherent	Thin and clear	Simple up to the neck/ Hartmann's pouch
2	Mucocele, Packed with stones	Fat laden	Simple up to the body
3	Deep fossa, Acute Cholecystitis, Contracted, Fibrosis, Hartmann's adherent to CBD, Impaction	Abnormal anatomy or cystic duct short, dilated or obscured	Dense up to fundus; Involving hepatic flexure or duodenum
4	Completely obscured, Empyema, Gangrene, Mass	Impossible to clarify	Dense, fibrosis, wrapping the gallbladder, Duodenum or hepatic flexure difficult to separate

CBD=common bile duct

Model development and validation

The pre-operative variables: including age, gender, diabetes, cirrhosis, body mass index, ASA classification, pre-operative white blood cell count, history of endoscopic retrograde cholangiopancreatography (ERCP); history of cholangitis, history of right upper quadrant abdominal pain, image (ultrasound, computer tomography, magnetic resonance imaging) findings of the thickened GB (GB wall thickness ≥4 mm), impact stone at the cystic duct, contracted GB, dilated GB (10 centimeters in length and >5 centimeters in width); and pericholecystic collection, were extracted from medical records. Exploratory analysis of significant predictors were analyzed by using univariable logistic regression. The predictive significance of each predictor was justified by the diagnostic odds ratio along with its p-value. The area under the receiver operating characteristics (AuROC) was also quantified for each of the univariable logistic regression models. All predictive variables were chosen for the multivariable logistic regression, reduced model derivation (backward elimination) of the study; with the binary outcome for model development. Continuous predictors e.g., ASA classification were transformed into binary attributes.

The diagnostic accuracy of the reduced multivariable model was evaluated in terms of calibration and discrimination. Measure of the calibration was performed with Hosmer-Lemeshow goodness of fit statistics. A calibration plot comparing the agreement between the disease probabilities estimated, via the model versus the observed disease data, was also presented. Test of discriminative power was tested, visualized by a distribution plot, and reported with AuROC. Internal validation was executed using the bootstrapping procedure (100 replicates) by STATA version 15 (StataCorp, College Station, TX, USA).

Simplified risk score transformation

Each item was assigned, to a specific score derived from the logistic regression coefficients of the multivariable model. The regression coefficient of each item was divided by the lowest coefficient, then rounded to one decimal place. The total score was then categorized into 3 risk groups (low, moderate, and high risk) for applicability in clinical practice. Due to the population-analog approach, PPV was calculated to present predictive performance separately for each risk category. The measurement of calibration and discrimination was also performed via a score-based multivariable logistic regression model.

Sample size calculation

Forty patients were randomly assigned to calculate the number of patients to study. Calculations were conducted for all potential predictors. The number of samples needed to achieve 90 percent statistical power and a two-sided alpha error of 0.05 was calculated from age, requiring 195 for the non-difficult LC group and 117 for the difficult LC group. In our study, all retrievable data were used to maximize the power and generalizability of the model derived. All data were analyzed by the STATA program. This research was written in accordance with to the TRIPOD statement.

Ethical consideration

The study and statistical analysis were approved by: "The Human Research Ethics Committee, Hatyai Hospital of Songkhla Province: document ID number HYH EC 015-66-01.

Results

In total 318 patients were categorized according to non-difficult LC group (197 patients) and difficult LC group (121 patients). A total of 307 patients with completed information were included in the analysis and pre-operative score development. Eleven patients with incomplete imaging results were not included in the pre-operative score development. When comparing patients between both groups, univariable analysis found that the patients in the difficult LC group significantly had higher age (52.1 vs 47.7 years, p-value 0.014), of male gender (38.8% vs 25.9%, p-value 0.018), ASA class III (34.7% vs 19.8%, p-value 0.014), and a higher proportion of image findings, which were comprised of thickened GB (54.7% vs 18.2%, p-value<0.001), dilated GB (8.5% vs 0.5%, p-value<0.001), and pericholecystic collection (5.1% vs 0%, p-value 0.003). Among all clinical predictors, the thickened GB had the highest predictive ability measured by AuROC (0.68). The difficult LC group significantly had longer operative time, more estimate blood loss, higher length of hospital stays and increased frequency of intestinal injury. There was no statistically significant difference in conversion to open surgery and risk of common bile duct (CBD) injury between the two groups (Table 2).

Model development and validation

All predictors were combined in the multivariable reduced logistic model (backward elimination) for the derivation of the scoring system. Predictors were selected based on clinical significance in combination with statistical significance to generate the model with the highest predictive power. The seven significant predictors were: male, cirrhosis, ASA III, history of ERCP, and GB imaging characteristics (thickened GB, dilated GB, contracted GB).

Calibration of the pre-operative score with Hosmer-Lemeshow goodness of fit test and Pmcalplot was tested. The Pmcalplot is a model to compare whether predicted difficult LC by pre-operative scores (expected diff LC) was either similar or not similar to difficult LC patients in this study (observed diff LC) (Figure 2). The line through the expected difficult LC did align with the reference line (dash line); indicating, that the pre-operative score can predict the risk of difficult LC close to difficult LC in this study (slope=1.000). The AuROC in the final model was 0.77 (95% confidence interval (CI) 0.71-0.82) (Figure 1), and the p-value of Hosmer-Lemeshow goodness of fit test was 0.166. This indicated that the predicted pre-operative score was not overfitting. Internal validation via the method of bootstrapping gave a C-Statistic of 0.75, slope=1.00, and bootstrap shrinkage=0.99. Higher pre-operative score was directly associated with higher risk of difficult LC (Figure 3).

Score transformation

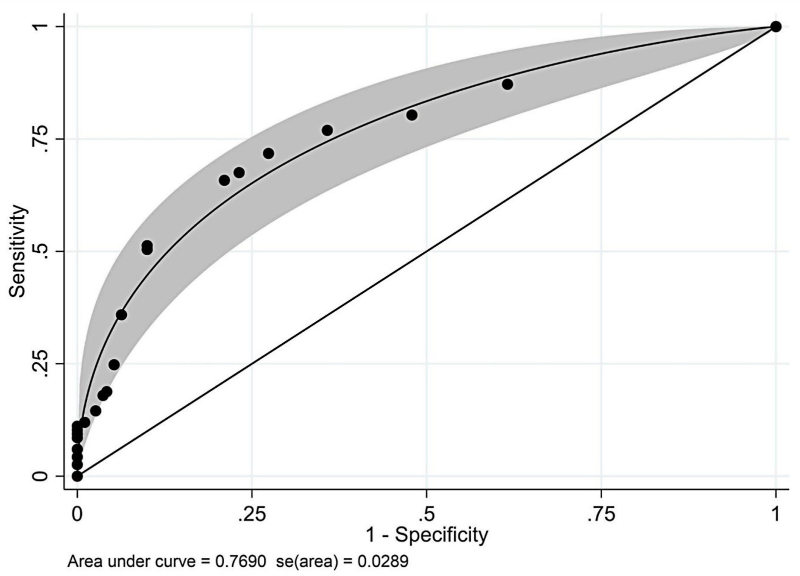
Each potential predictor in the multivariable model was assigned with a specific score derived from the logistic regression coefficient (Table 3). The scoring scheme, with a total score ranging from 0 to 16.6, was then further categorized into 3 risk subcategories for clinical applicability (Table 4). This categorization is based on the calibration plot between the probability of having difficult LC and score distribution (low-risk group score 0-1.5, moderate risk group score 1.6-3.0 and high-risk group score 3.1-16.6). The mean total score was significantly different between both groups (3.5±0.2 vs 1.4±0.1, p-value<0.001). The PPV was: 18.1 for low risk, 38.0 for moderate risk, and 76.0 for high risk. For discriminative ability, AuROC of the score-based logistic regression model was 0.76 (95%CI 0.71-0.82).

The pre-operative score was intended to predict the difficulty of elective LC before surgery. Treatment in the difficulty of LC (pre-operative) is surgical supervision by an experienced surgeon to prevent CBD or bowel injury. The benefit of using preoperative scores to predict difficult LC is shown in the decision curve analysis (Figure 4). 'Treat none' (black line) means no treatment in all elective LC, whether difficult, they are or not. Therefore, the net benefit of treat none is zero. Treat-all (dot line) means surgical supervision by an experienced surgeon in all elective LC. The dashed line (benefit of using a pre-operative score) above these 2 lines at the threshold probability is more than 0.18, this means, using a pre-operative score has more benefits than 2 in these treatments; when the prevalence of difficult LC is more than 18%.

Table 2 Patient characteristics and operative outcomes

Clinical characteristics and operative outcomes	Difficult LC (n=121)		Non-difficult LC (n=197)		Odds ratio	p-value	AuROC
	n	%	n	%			
Age (years) (mean ± S.D.)	52.1	(15.3)	47.7	(15.2)	1.02	0.014	0.58
Male	47	38.8	51	25.9	1.82	0.018	0.56
NIDDM	22	18.2	28	14.2	1.34	0.346	0.52
Cirrhosis	6	5	2	1	5.09	0.057	0.52
BMI (kg/mm^3)(mean ± S.D.)	26.0	(5.0)	26.4	(5.3)	0.98	0.463	0.52
ASA classification					1.57	0.014	0.57
Class I	16	13.2	31	15.7			
Class II	63	52.1	127	64.5			
Class III	42	34.7	39	19.8			
WBC (cell/mm^3)(mean)	7,653		7,751		1.00	0.686	0.52
Right upper quadrant pain	99	81.8	152	77.2	1.33	0.396	0.52
Cholangitis	11	9.1	10	5.1	1.87	0.170	0.52
ERCP	18	14.9	17	8.6	1.85	0.098	0.53
Imaging finding*							
Gallbladder wall ≥4 mm	64	54.7	35	18.2	5.35	<0.001	0.68
Impacted stone at cystic duct	2	1.7	0	-	1.00	0.144	0.51
Contracted gallbladder	12	10.3	12	6.3	1.70	0.274	0.52
Dilated gallbladder	10	8.5	1	0.5	17.66	<0.001	0.54
Pericholecystic collection	6	5.1	0	-	1.00	0.003	0.52
Operative time (min)(median, IQR)	120	90, 155	70	55, 90		<0.001	
LOS (day)(median, IQR)	3	2, 4	2	2, 3		<0.001	
Conversion to open	2	1.6	0	-		0.144	
Bile duct injury	1	0.83	0	-		0.381	
EBL (ml) (median, IQR)	100	50, 150	10	10, 20		<0.001	
Bowel injury	4	100	0	-		0.020	
Pathology						0.001	
Acute cholecystitis	16	13.2	6	3.1			
Chronic cholecystitis	105	86.8	191	96.9			

(LC=laparoscopic cholecystectomy, AuROC=area under the receiver operating characteristics, S.D.=standard deviation, BMI=body mass index, WBC=white blood cell count, LOS=length of hospital stay, EBL=estimated blood loss)
*Imaging finding (non-difficult LC: n=190, difficult LC: n=117)



AuROC=area under the receiver operating characteristics

Figure 1 Performance of the pre-operative score, AuROC and 95% confidence band

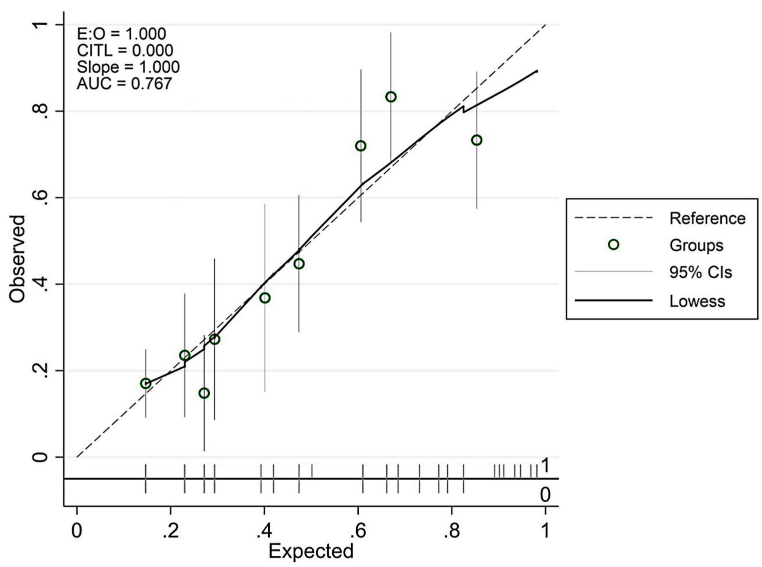


Figure 2 Pmcalplot of observed vs expected difficult laparoscopic cholecystectomy

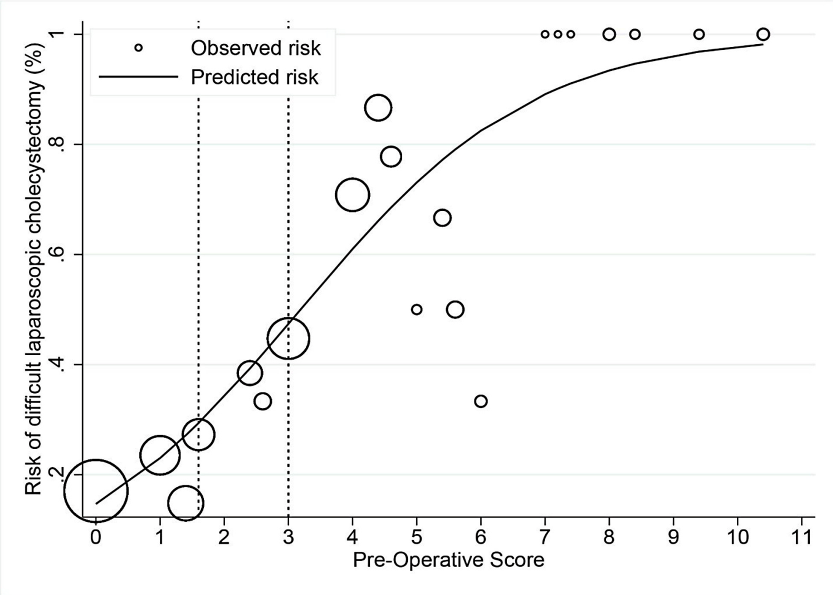
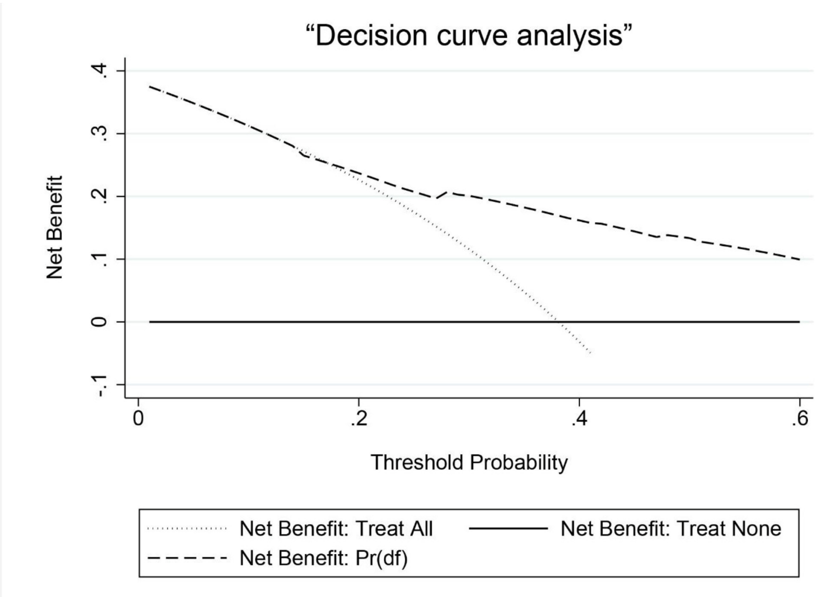


Figure 3 Risk of difficult laparoscopic cholecystectomy vs pre-operative score



Pr(df)=using pre-operative score

Figure 4 Decision curve analysis of using the pre-operative score

Table 3 Pre-operative score derivation using multivariable logistic regression coefficients

Potential predictors	Odds ratio	95% Confidence interval	p-value	Coefficients	Score
Gender					
Female		reference	-	-	0
Male	1.74	1.00-3.05	0.051	0.555880	1
Cirrhosis					
Absence		reference	-	-	0
Presence	5.44	0.93-31.76	0.060	1.694414	3
ASA Classification					
ASA I, II		reference	-	-	0
ASA III	2.16	1.20-3.89	0.010	0.770395	1.4
History of ERCP					
Absence		reference	-	-	0
Presence	2.37	1.08-5.20	0.010	0.864603	1.6
GB wall ≥4 mm					
Absence		reference	-	-	0
Presence	5.20	3.00-9.04	<0.001	1.649312	3
Contracted GB					
Absence		reference	-	-	0
Presence	2.45	0.96-6.27	0.061	0.897740	1.6
Dilated GB					
Absence		reference	-	-	0
Presence	16.33	1.83-145.96	0.012	2.793340	5

GB=Gallbladder, ASA=The American Society of Anesthesiologists physical status classification, ERCP=endoscopic retrograde Cholangiopancreatography

Table 4 Pre-operative score to predict difficult LC and outcomes

Pre-operative score (score)	Difficult LC(n=117)		Non-difficultLC (n=190)		PPV (95%CI)	Operative time (minute)	LOS (day)	EBL (ml)
	n	%	n	%				
Low (<1.6)	27	18.1	122	81.9	18.1* (12.3-25.2)	78*	2.4	34*
Moderate (1.6-3.0)	30	38.0	49	62.0	38.0** (27.3-49.6)	103*	2.7	66*
High (>3.0)	60	76.0	19	24.0	76.0* (65.0-84.8)	118*	3.6	102*
Mean±SE	3.5	0.2	1.4	0.1				

LC=Laparoscopic cholecystectomy, PPV=Positive predictive value, SE=standard error, LOS=length of hospital stay, EBL=estimate blood loss, ml=milliliter
*=p-value<0.001, **=not significant p-value

Discussion

Predicting the difficult LC via the utilization of a large number of patients requiring LC can help with effective surgical planning improvement (optimized surgeons, equipment and surgical schedules), pre-operative counseling (risk of complication and any unfavorable events), prediction of conversion or complications; such as bile duct injury, intestinal injury, bleeding, among others; in addition to predicting conversion to open cholecystectomy[10]. Surgery under the supervision of experienced surgeons may be necessary for difficult LC. In surgical training hospitals, trainee surgeons may be permitted to perform LC in those who are predicted to be at low risk of difficulty.

Patients with significant inflammation or fibrosis in the Calot's triangle area, causing an inability of the identification of anatomical landmarks or the critical view of safety, may prove difficult or impossible to use the laparoscopic approach. In this scenario, the surgery should be changed to either; using an intra-operative cholangiogram or conversion to open cholecystectomy, In patients in whom the critical view of safety cannot even be obtained on open surgery, dissection in this region should be avoided and subtotal cholecystectomy should be performed.

Several studies have shown that males have a higher chance of conversion to open cholecystectomy, or have a high risk of difficult LC[7,11]. This is because males tend to endure or ignore repeated abdominal pain, and visit the hospital when symptoms become unbearable, more so than females. Repeated inflammation results in thickening of the GB and severe adhesion at the Calot's triangle. Male gender was a statistically significant predictor in the pre-operative prediction score, which is consistent with the Nassar study[2] in which the Nassar scale was used to assess difficulty in LC.

Although, ASA classification was assessor-dependent and moderately reliable, after careful examination it was found to be a good indicator of the patient's health status before surgery[4]. Other studies have shown that an ASA classification was correlated with difficult LC[2,7], and risk of conversion to open cholecystectomy[4,9]. This study shows a significant correlation between ASA classification and difficult LC in both univariable analysis and multivariable analysis.

Thickened GB, contracted GB, dilated GB and impacted stone at the neck of GB made grasping by laparoscopic instruments much more difficult. Fibrotic changes make grasping of fundus by grasper, positioning of GB, and identification of the cystic artery and cystic duct more difficult, so to GB dissection from the liver tissue; due to the absence of an avascular dissection area between the GB and liver tissue. Moreover, these findings were also frequently associated with severe adhesion caused by previous severe inflammation. The forceps, with large jaws, must be used to grasp or suture the GB wall to extract or cut off a part of the GB wall, and then firmly pull it. Thickened GB is a risk factor for difficult LC[2,18] and conversion to open cholecystectomy[7-8,12-13]. The thickened GB had the highest predictive value in predicting the difficulty of LC; additionally, it was a significant predictor in the prediction model. A contracted GB can increase the predictive power in multivariable analysis; thus, taken as a part of the predictive model; although there was no statistical difference. The pericholecystic fluid collection and impacted stone at the cystic duct did not increase the predictive power, because data on these conditions were relatively limited in the patients within this study. Hence, they were excluded from the prediction model.

Gallstones are more common in cirrhosis, because of decreased bile salts production, GB motility and bile excretion[14]. LC in cirrhosis patients shows relatively more rapid recovery and increases tolerance for surgery. It is also safe for the surgical team as there is less contact with the patient's blood and internal organs. In addition, laparoscopic techniques cause less abdominal wall and blood vessel injury. Furthermore, they decrease ascites leakage from surgical wounds and infection[15]. In this study, there was no significant difference in both the univariable analysis (p-value 0.057) and the multivariable analysis (p-value 0.060) probably due to the small number of patients. However, cirrhosis as a predictor could increase the prediction ability of pre-operative core.

Pre-operative ERCP can increase the risk of cholangitis and pancreatitis, resulting in inflammation and fibrosis around the Carot's Triangle; leading to significantly longer operative times and high conversion rates[17]. There are studies that designate ERCP as a significant predictor of difficult LC[6,16-17]. Pre-operative ERCP was found to be a significant predictor for predicting difficult LC in this study.

In previous predictive score development for difficult LC; the duration of surgery or conversion to open cholecystectomy or both, were used as criteria to determine as to whether LC was difficult or not. Both criteria depends on the surgical expertise as well as the surgeon's judgment. There are no widely accepted criteria and it is not applicable to all patients. Intraoperative assessment, according to the Nassar scale, was used to create the pre-operative score because of its clear assessment level of difficulty. There are two studies that used the Nassar scale as criterion for predicting difficult LC[2,18]. Admission type (emergency, elective, delay LC) was a significant factor in predicting the difficulty of LC. Patients that underwent emergency or early LC have active inflammation of GB. However, the severity of inflammation depends on the onset of symptoms, and whilst some patients have symptoms for the same duration the inflammation may not be the same. Abnormal structural features; such as short or large cystic ducts, were not used for the prediction model development because pre-operative prediction scores could not predict abnormal structures. This study aimed to determine the criteria for trainee surgeons to begin practicing elective laparoscopic cholecystectomy (elective or delayed LC), and choose patients for day-case surgery.

Similar to previous studies, four predictors (male, history of ERCP, ASA III and thickened GB) were found as significant predictors[2,18]. However, this study's pre-operative score for predicting difficult LC 7 variables. The predictive power determined by AuROC was high at 76 percent. The pre-operative score was separated by the risk of difficult LC into 3 groups. For low-risk difficult LC, surgery can be performed by less experienced or trainee surgeons and as criteria for day-case surgery. High-risk for difficult LC should be performed LC under the supervision of experienced surgeons; managed with an appropriate operative time schedule and counsel for the patients before surgery in regards to the risk of complication or conversion to open cholecystectomy. Surgery depends on the surgeons's expertise and the availability of equipment at moderate risk of difficult LC. Comparing pre-operative scores and outcomes of LC in both groups, the high risk score had significant differences in longer operation times, more estimated blood loss, and longer hospital stays. There was no statistically significant difference in conversion to open surgery and risk of CBD or bowel injury between the two groups. The prediction model should be externally validated and used in patients in other hospitals before actual use.

The limitation of this study is that all data were collected retrospectively. Prospective studies could improve the reliability and completeness of the data. Although, internal validation was conducted in this study, the reproducibility of risk scoring is still not known. Therefore, external validation studies using data set form other hospitals should be performed. Further studies should develop predictive scores in case of emergency LC.

Conclusion

The pre-operative score had good performance for prediction difficulty of elective LC, which can help surgeons for decision making in surgical approach.

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None.

Conflict of interest

The authors declare no conflicts of interest.

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