Validation of CLOC Score in Predicting the Risk of Conversion from Laparoscopic to Open Cholecystectomy in Dr Cipto Mangunkusumo Hospital

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Abstract

Introduction: Laparoscopic cholecystectomy is the gold standard for treatment of symptomatic cholelithiasis. Although relatively safe and effective, laparoscopic cholecystectomy is a difficult procedure. The rate of conversion to open cholecystectomy is estimated to be 1–15%. A preoperative predictive model may be helpful in determining whether open cholecystectomy is preferred over laparoscopic cholecystectomy to prevent morbidity and mortality associated with conversion. Conversion from laparoscopic to open cholecystectomy (CLOC) score can potentially predict the risk of conversion based on preoperative parameters. The purpose of this study is to validate the application of CLOC score in Dr Cipto Mangunkusumo Hospital's patient population.

Materials and methods: This was a retrospective study of patients undergoing laparoscopic cholecystectomy from January 2018 to December 2019 in Dr Cipto Mangunkusumo Hospital. Patient data were obtained from medical records. Descriptive analysis, Chi-square test, logistic regression analysis, and score validation using receiver-operating characteristic (ROC) curve by calculating the area under curve (AUC), sensitivity, and specificity were conducted. Based on the CLOC Score, the patients were stratified into two groups: low-risk (<6) and high-risk (>6).

Results: There were 163 subjects with a mean age of 51.06 ± 13.3 years. The rate of conversion was 3.1% ($n = 5$). Most of the subjects were 40–69 years of age (111 subjects, 68.1%). Of all 163 subjects, 103 (63.2%) were female. The indications for surgery were colicky pain (symptomatic gallstone disease) in 144 subjects (88.3%). Based on the logistic regression analysis, common bile duct dilation was found to be the only statistically significant variable [odds ratio (OR) = 10.97; 95% confidence interval (CI): 1.72–69.95]. The AUC approached 78.8% (fair) (95% CI: 58.2–99.4%; $p = 0.029$) for a cut-off value of 6.5 (sensitivity = 80.0%; specificity = 79.1%). The median duration of procedure in the low-risk group vs the high-risk group was 120 minutes (30–330) vs 180 minutes (45–405) ($p = 0.001$), respectively.

Conclusion: Common bile duct dilation was the only risk factor found to be significantly associated with conversion of laparoscopic cholecystectomy to open surgery. Other factors, such as age, sex, indication for surgery, gallbladder wall thickness, and ASA score were not found to be statistically significant risk factors. Conversion from laparoscopic to open cholecystectomy score was considered valid and useful in predicting the risk of conversion. A CLOC score of 7 or more was associated with a higher risk of conversion to open surgery.

Keywords: Cholecystectomy, CLOC score, Conversion, Laparoscopy.

World Journal of Laparoscopic Surgery (2022): 10.5005/jp-journals-10033-1531

Introduction

Currently, laparoscopic cholecystectomy is deemed the gold standard in the treatment of symptomatic cholelithiasis. Although considered to be safe and effective, laparoscopic cholecystectomy is a difficult surgical procedure, indicated by the relatively high rate of conversion to open cholecystectomy of approximately 1–15%. Conversion to open cholecystectomy usually increases perioperative time and complication rate in addition to overall healthcare costs. Open conversion is also associated with various complications, including injury to the biliary system, bile leak, hemorrhage, reoperation, need for blood transfusion, and even death.[1–3]

Predicting the risk of conversion from laparoscopic to open cholecystectomy preoperatively is an important aspect of preoperative planning. With the more accurate prediction tool, surgeons can prepare and plan the procedure better to reduce perioperative morbidity and mortality. Patients will also benefit from more accurate information with regards to the procedure so that they may make informed medical decisions better suited to their expectations. Preoperative prediction tools can also improve the assessment and the decision-making in choosing for the more

appropriate initial approach whether open should be preferred over laparoscopic cholecystectomy in order to avoid morbidity and mortality associated with conversion.[2–4]

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The various predictive preoperative scoring systems of conversion from laparoscopic to open cholecystectomy have been proposed. However, the clinical benefits are limited due to small sample sizes and/or lack of validation. Sutcliffe et al. has proposed the CLOC risk score according to the CholeS prospective study involving 8820 subjects. The results were patients with a CLOC score of >6 had a higher risk of conversion to open surgery, specifically six times higher risk compared with those with a CLOC score of ≤6. This score had a sensitivity of 77.1% and a specificity of 65.4%; thus, this score may be utilized in the clinical settings to accurately predict the risk of conversion.[4] Other important issue in laparoscopic cholecystectomy is prolonged operative time. Prolonged duration of surgery according to Sutcliffe et al.[4] is an important determinant of overall complication rate, including bile leak, injury to biliary duct, and longer length-of-stay. Among the proposed risk scoring systems, CLOC risk score is the preoperative predictive score that has been developed according to prospective data with a large sample size and has been widely validated. On the other hand, in Indonesia, there has been no data and preoperative conversion risk scoring system. The CLOC risk score may be utilized to reduce the risks of morbidity and mortality associated with conversion to open procedure.

Previously, G10 scoring system for predicting bailout procedure has been validated in Dr Cipto Mangunkusumo Hospital (RSCM). However, this scoring system uses intraoperative parameters and is not specific for predicting conversion to open cholecystectomy. The CLOC scoring system has the advantage of utilizing preoperative parameters. This system can specifically predict the risk of conversion and thus may be utilized for risk estimation and preparation for open cholecystectomy if the patient is considered high-risk. However, in order for this scoring system to be applied in RSCM, it need to be validated accordingly. RSCM will be the first hospital to validate this scoring system outside of the center where this score was developed.

MATERIALS AND METHODS

Population

This study is a retrospective study of patients who underwent laparoscopic cholecystectomy procedures in RSCM from January 2018 to December 2019 period. Patients with incomplete medical records were excluded. Data according to CLOC score variables, including age, sex, indication for surgery, ASA class, gallbladder wall, and common biliary duct diameter were collected.

Data Analysis

Data were analyzed using IBM Statistical Package for the Social Sciences (SPSS) version 20. Data analysis conducted included both descriptive and inferential statistics. Descriptive statistics were provided in the form of table. The Kolmogorov–Smirnov test was opted because the number of subjects for this study was >50 patients. Afterwards, bivariate and multivariate statistical analyses were conducted. Bivariate analysis was conducted using a Chi-square (χ^2) test. Alternatives for Chi-square test were Fisher test or Mann–Whitney test. Multivariate analysis was conducted along with logistic regression test to identify the cause-and-effect relationship among all the parameters/components of the CLOC scoring system and the rate of conversion. Calculation of the sensitivity and specificity of the CLOC scoring system for patients in RSCM were conducted using the ROC curve.

RESULTS

Baseline Characteristics

A total of 163 subjects were included in this study, with a mean age of 51.06 ± 13.3 years. Data on subjects' age were distributed normally. There was no statistically significant difference with regards to subjects' age ($p = 0.483$), with an average age of 55.20 ± 17.2 years among those who underwent conversion to open cholecystectomy and an average age of 50.93 ± 13.3 years among those who did not. Based on age-groups, most of the subjects were 40–69 years and only 11 subjects who were <30 years. Most of the subjects were female (103 subjects, 63.2%).

The indication for laparoscopic cholecystectomy in this study was almost exclusively colicky pain (symptomatic gallstones), which comprised of 144 cases (88.3%). A total of 146 subjects (89.0%) in this study also had normal gallbladder wall thickness (<4 mm), and a total of 141 subjects (86.5%) did not have dilated common biliary duct diameter. Based on the ASA classification, a total of 123 subjects (75.5%) were ASA class 2. The only variable found to have statistically significant difference in proportion was dilation of common biliary duct ($p = 0.010$). This result was obtained through Fisher test.

The median duration of surgery in this study was 135 (30–105) minutes, with an interquartile range of 70. Data with regards to duration of surgery were expressed in the form of median and interquartile range due to abnormal distribution. There was a statistically significant difference between the duration of surgery and rate of conversion ($p < 0.001$). The median duration of surgery in the conversion group was 270 (230–300) minutes, compared with 130 (30–405) minutes in the control group. Detailed information on subjects' characteristics was shown in Table 1.

Association between the CLOC Score and the Rate of Conversion to Open Cholecystectomy

Because the data obtained in this study did not fulfill the criteria for Chi-square test, Fisher's exact test were conducted to obtain the proportion of low-risk (≤6) and high-risk (>6) CLOC score for conversion. Among subjects with low-risk CLOC score, 1 (0.8%) underwent conversion, while the remaining 33 subjects (99.2%) had straightforward laparoscopic cholecystectomy.

There was a statistically significant difference in the rate of conversion between subjects who had a low-risk CLOC score and subjects who did not ($p = 0.010$). The difference in the rate of conversion to open cholecystectomy between those with low-risk score and those with high-risk score was 10.0%. Because the difference in proportion was less than 20%, clinically there was no difference between low-risk and high-risk CLOC score in terms of the rate of conversion in RSCM patients. The slight difference in proportion may be due to the small sample size. The difference in proportion was shown in Table 2.

Logistic Regression Analysis

Based on the bivariate analysis in Table 1, the variables age, age-group, dilation of common biliary duct diameter, and ASA class had p-values of ≤0.25 and thus may be further included in logistic regression analysis. On the other hand, the variables sex, indication for surgery, and gallbladder wall thickness all had p-values of >0.25 and thus were not included in logistic regression analysis. However, all parameters included in CLOC score theoretically were considered important. Logistic regression analysis was performed with backward methods until the regression model was obtained

Table 1: Baseline characteristics of the subjects

		Conversion to open		
Variables	Subjects (n = 163)	Yes (n = 5)	No (n = 158)	p
Age[a], year	51.06 ± 13.3	55.20 ± 17.2	50.93 ± 13.3	0.483
Age-group[b]				0.683
<30	11 (6.7%)	0 (0%)	11 (100.0%)	
30–39	23 (14.1%)	2 (8.7%)	21 (91.3%)	
40–69	111 (68.1%)	1 (0.9%)	110 (99.1%)	
≥70	18 (11.0%)	2 (3.1%)	16 (88.9%)	
Sex[c]				0.261
Female	103 (63.2%)	2 (1.9%)	101 (98.1%)	
Male	60 (36.8%)	3 (5.0%)	57 (95.0%)	
Indication for surgical intervention[c]				0.466
Colicky pain (symptomatic gallstones)	144 (88.3%)	4 (2.8%)	140 (97.2%)	
Cholecystitis	19 (11.7%)	1 (5.3%)	18 (94.7%)	
CBD stones	0 (0%)	0 (0%)	0 (0%)	
Gallbladder wall thickness[c]				0.447
Normal (<4 mm)	145 (89.0%)	4 (2.8%)	141 (97.2%)	
Increased (≥4 mm)	18 (11.0%)	1 (5.6%)	17 (94.4%)	
Common biliary duct diameter[c]				0.018*
Normal	141 (86.5%)	2 (1.4%)	139 (98.6%)	
Dilated	22 (13.5%)	3 (13.6%)	19 (86.4%)	
ASA classification[b]				0.054
ASA = 1	22 (13.5%)	0 (0%)	22 (100%)	
ASA = 2	123 (75. 5%)	3 (2.4%)	120 (97.6%)	
ASA ≥ 3	18 (11.0%)	2 (11.1%)	16 (88.9%)	
Duration of surgery[b], minutes	135.0 (70.0)	270.0 (62.5)	130.0 (70.0)	<0.001*

[a]Unpaired t-test; [b]Mann–Whitney test; [c]Fisher's test
*Statistically significant difference (p <0.05)
SD, standard deviation; IQR, interquartile range; data with normal distribution were expressed in mean ± SD; data with abnormal distribution were expressed in median (IQR)

Table 2: Difference in proportion between CLOC risk score and rate of conversion

	Conversion				
CLOC score	Yes	%	No	%	p
Low-risk (≤6)	1	0.8	125	99.2	0.010*
High-risk (>6)	4	10.8	33	89.2	
Total	5	3.1	158	96.9	

Fisher's exact test
*Statistically significant result (p <0.05)

after the sixth step, and the other five variables were eliminated. The results of logistic regression analysis were shown in Table 3.

Based on the logistic regression model in Table 3, the p value of diameter coefficient was less than 0.05 and the confidence interval of the odds ratio did not cross the number 1. It was, therefore, concluded that the diameter variable was significantly associated with the risk of conversion in RSCM patients. In addition, this result was considered clinically significant; with an OR of 10.974, patients with common

biliary duct dilation who had laparoscopic cholecystectomy had 10.97 times higher risk for conversion to open cholecystectomy.

ROC Curve Analysis

Analysis using ROC curve was performed to obtain the optimal cut-off score that may accurately predict the risk of conversion in RSCM patients. The cut-off score obtained was a CLOC score of 6.5, with a sensitivity of 80.0% and a specificity of 79.1%.

The AUC was 78.8% (95% CI: 58.2–99.4%; p = 0.029). Statistically, the CLOC score had a significant difference compared with the reference line due to a p value of <0.05 and the confidence interval values which did not cross 50%. Clinically, an AUC of 78.8% was considered fairly significant because researcher aimed for the minimal AUC value of 70%. Therefore, it was concluded that there was a significant association between CLOC score with the rate of conversion, both statistically and clinically (Fig. 1).

CLOC Score and Duration of Surgery

The results of nonparametric Mann–Whitney test showed that the median duration of surgery in the low-risk group was significantly

Table 3: Logistic regression model

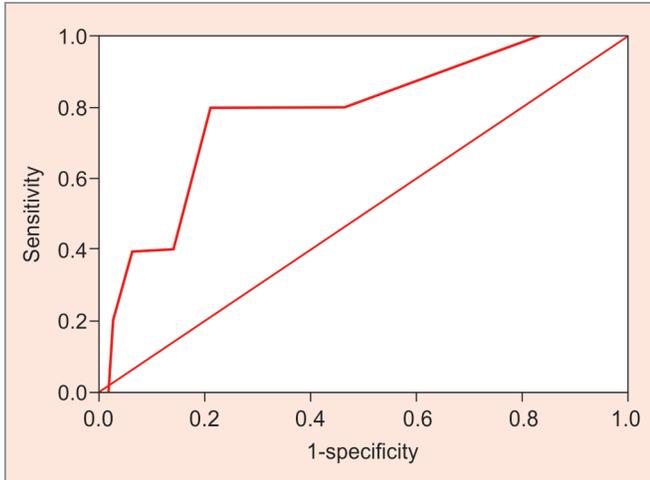|		Coefficient	df	OR	95% CI Lower	95% CI Upper	p
6th step	Diameter (1)	2.396	1	10.974	1.721	69.952	0.011
	Constant	−4.241	1	0.014			0.000

Fig. 1: ROC curve of CLOC score and the rate of conversion. Area under the curve (AUC) = 78.8% (95% CI: 58.2–100.0%; p = 0.029)

Table 4: Comparison between CLOC risk score and duration of surgery

Skor CLOC	n	Duration of surgery (minutes) Median	IQR	p
Low-risk (≤6)	126	120.0	50.0	0.001*
High-risk (>6)	37	180.0	100.0	
Total	163	135.0	70.0	

Mann–Whitney test
*Statistically significant difference (p <0.05)
IQR, interquartile range

different with the median duration of surgery in the high-risk group [120 (30–330) vs 180 (45–405) minutes; p = 0.001]. Results of the comparison were shown in Table 4.

DISCUSSION

Subject Characteristics

The rate of conversion to open cholecystectomy in this study was relatively small. However, this number was similar to the study by Sutcliffe et al.,[4] which was 3.3%, and lower than both the study by Tayeb et al.[5] in Pakistan, which was 8.4%, and the study by Amin et al.,[6] which was 7.8%. The indication for conversion was the inability to locate Calot's triangle during laparoscopic approach.[5,6]

Risk Factors for Conversion

According to the study by Sutcliffe et al.,[4] there were six variables associated with the rate of conversion: age, sex, ASA class, indication for surgery, gallbladder wall thickness, and dilation of common biliary duct above normal diameter.

In this study, the average age of subjects who needed conversion to open surgery was similar with those who did not

(55.20 ± 17.2 vs 50.93 ± 13.3; p = 0.483). According to the age-group, the largest difference of proportion is among the age-group 30–39 years, who had an 8.7% higher risk for conversion compared with subjects in the age-group <30 years. Other risk factors not found to be significantly associated with the rate of conversion in this study are sex, indication for surgery, gallbladder wall thickness, and ASA classification. Dilation of the common biliary duct above the normal diameter was found to be significantly associated with the risk of conversion. The group with dilation of the common biliary duct had a 12.2% higher risk for conversion to open procedure compared with those with normal diameter with a p-value of 0.018.

The most common surgical indication associated with conversion was mostly colicky pain (symptomatic gallstones), which was found in four subjects (2.8%). This finding was different with the study by Sutcliffe et al.,[4] which reported that the most common indication of conversion to open surgery was CBD calculi (9.1%), in stark contrast with colicky pain (1.2%).

After logistic regression multivariate analysis, only dilation of common biliary duct variable was found to be statistically significant, with an OR of 10.974 (95% CI: 1.271–69.952; p = 0.011). RSCM patients with dilation of common biliary duct had a 10.97 times higher risk of conversion to open procedure compared with patients without common biliary duct dilation. Thus, although other factors were found to be not statistically significant, if RSCM patients had the risk factor of dilated common biliary duct above the normal diameter, they had a significantly higher probability of undergoing later conversion. The accuracy of this parameter was up to 74% (95% CI: 47.9–100.0%; p = 0.068). Although it was found not statistically significant, clinically this value was important. The association between dilation of common biliary duct and rate of conversion was also reported by several authors.[7–9] In the study by Sutcliffe et al.,[4] the OR was lower, which was 1.70. Dilation of common biliary duct above normal diameter and increased gallbladder wall thickness indicate chronic inflammation due to recurrent cholecystitis. Both of these conditions in various reports are associated with an increased risk of conversion.[10–12]

Validation of CLOC Score in Predicting Conversion to Open Cholecystectomy

In this study, CLOC score was significantly associated with the rate of conversion (p = 0.010). Clinically, the difference in proportion of conversion in the high-risk group and the low-risk group was only 10%; however, this finding may be explained by the low-risk of conversion in our center. Validation of CLOC score was performed by ROC curve analysis, and it was found that CLOC score had a diagnostic accuracy of 78.8% (95% CI: 58.2–99.4%; p = 0.029), which were both statistically and clinically significant. The optimal cut-off value was 6.5, with a sensitivity of 80.0% and a specificity of 79.1%. These results mean that 80.0% patients with a CLOC score of >6 (high-risk) were more likely to undergo conversion and approximately 79.1% patients with a CLOC score of ≤6 (low-risk) were more likely to not require conversion; however, about 20.9% patients with a low-risk score were still at-risk for conversion.

The sensitivity and specificity values of CLOC score found in this study were considered decent for screening tool. In addition, the optimal cut-off value found in this study was similar to the original study, which was lower risk for conversion in patients with a CLOC score of ≤6 and higher risk of conversion in patients with a CLOC score of >6.[4] Thus, CLOC score may be reliably applied as a predictive tool for conversion to open procedure in patients who will undergo laparoscopic cholecystectomy in RSCM hospital.

The Association between CLOC Score and Duration of Surgery

The median duration of surgery in the conversion group in this study was significantly different with the median duration in the control group. Patients who underwent conversion had longer median duration of surgery compared with those who did not undergo conversion [270 (230–300) vs 130 (30–405) minutes]. In the study by Sutcliffe et al.,[4] the median duration of laparoscopic surgery was 60 minutes, while the median duration of conversion to open surgery was 120 minutes ($p < 0.001$). The longer duration of laparoscopic surgery in RSCM was possibly related to its status as an academic hospital and thus procedures were more likely to be performed by inexperienced residents or fellows. Longer duration of surgery according to Sutcliffe et al.[4] may be one factor associated with increased rate of overall complications, bile leak, biliary duct injury, and longer length of stay.

In accordance with those findings, CLOC was also found to be associated with the median length of surgery with a $p = 0.001$. In the low-risk CLOC score group, the median duration of surgery was 180 (45–405) minutes, which was 60 minutes longer compared with the high-risk CLOC score group, which was 120 (30–330) minutes. This finding supports the reasoning that care of high-risk patients is more complex and thus prolongs their duration of surgery.

An English study by Tafazal et al.[13] reported the difference between mean duration of laparoscopic cholecystectomy procedure between consultant surgeons (52.5 minutes) and trainees (51.4 minutes); however, this difference was not found to be statistically significant. When adjusted and stratified for case complexity, surgeries performed by consultant surgeons were 5 minutes faster compared with operations by trainees. On the other hand, a study by Subhas et al.[14] in Michigan, the duration of laparoscopic cholecystectomy ranged from 3 hours to 6 hours 40 minutes. Average duration of surgery was 3 hours 37 minutes. Causes of prolonged surgery were a previous history of abdominal surgery and bowel adhesion, with an OR of 6.7; obesity (OR 3.1); gallstones measured >2.5 cm and educational participation of residents during surgery were also found to increase the duration of cholecystectomy.[15,16]

Study Limitations

The calculation of sample size for this study used the formula for single sample proportion. In that formula, no component of statistical power was calculated, although there was the component of precision or study accuracy (d). At the beginning of calculation, the author had set a precision value of 5%. If re-calculated with such proportion number, a value of 0.03 and a sample size of 163 subjects were obtained. The sample size used in this study exceeded the targeted minimum sample size, which was 50 subjects. The statistical power of this study was 80%, and thus, the findings were not considered preliminary and can be applied widely in various populations.

However, this study did have several limitations. This study did not have any subjects with CBD gallstones; thus, this study cannot yet include CBD gallstones as a risk factor for conversion to open cholecystectomy in RSCM. Subsequent multicenter study encompassing more variable indication for surgery is required. Alternatively, an isolated study identifying patients indicated for cholecystectomy due to CBD gallstones might also be conducted.

Conclusion

Conversion from laparoscopic to open cholecystectomy risk score is deemed valid and applicable for predicting the risk of conversion from laparoscopic to open cholecystectomy in RSCM. A cut-off value of a high-risk score (>6) was associated with the rate of conversion, and a low-risk score (≤6) was not associated with conversion. Other significant risk factors were dilation of the common biliary duct above normal diameter. Risk factors not found to be significantly associated with conversion were age, sex, indication for surgery, gallbladder wall thickness, and ASA classification. The median duration of laparoscopic cholecystectomy surgery and conversion in RSCM was longer compared with most other studies. The finding of this study suggested that the CLOC risk score may be employed in preoperative assessment of patients planned to undergo cholecystectomy to predict the risk of conversion and prevent the mortality and morbidity risks associated with conversion. During laparoscopic cholecystectomy, procedure may also be prolonged, especially in patients with high-risk CLOC score.

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Acknowledgments

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