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## External Validation Of 10 Points Intraoperative Gallbladder Scoring System (G10) In Laparoscopic Cholecystectomy at RSUPN dr. Cipto Mangunkusumo

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## External Validation Of 10 Points Intraoperative Gallbladder Scoring System (G10) In Laparoscopic Cholecystectomy at RSUPN dr. Cipto Mangunkusumo

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### Abstract

**Introduction.** Laparoscopic cholecystectomy has become a standard treatment for symptomatic cholelithiasis in dr. Cipto Mangunkusumo Hospital (RSCM). This study aims as a preliminary study to externally validate the 10-point intraoperative gallbladder scoring system (G10), an assessment system of laparoscopic cholecystectomy's difficulty.

**Method.** A cross-sectional study was carried out. Enrolling subjects who underwent laparoscopic cholecystectomy from January 2019 to December 2019. Data of the subjects were collected from medical records. We assessed each of the subjects' G10 scores and operation techniques based on the intraoperative images and surgical reports. The surgical technique divided into two groups, those are the Critical View of Safety (CVS) technique and bailout procedure group, consisting of fundus-first cholecystectomy, subtotal cholecystectomy, and conversion. The correlation of G10 score between CVS and bailout was analysed using the Mann-Whitney nonparametric test. A Kendall's tau was performed to measure the correlation between the G10 score and the bailout procedure. Statistical power was calculated by G-power application. A ROC test was performed to calculate the sensitivity and specificity of the G10 scoring system to predict bailout procedure, then the cut-off value was determined.

**Results.** There was a significant and positive correlation between the G10 score with the bailout procedure ( $<0.001, +0.487$ ). Testing the G10 score on the validation set yielded an AUROC=0.865 ( $<0.001$ ), and the score  $>2$  indicate subjects at high risk of bailout procedure (72.2% vs. 20.98%).

**Conclusion:** This study showed that the G10 score has good accuracy in predicting a bailout procedure. The use of G10 scores intraoperatively is "essential" to provide valid and objective assessment in determining the difficulty of surgery. When the G10 score is 1 or 2, it's safe to perform the CVS technique. Whereas, if the G10 score is three or greater, surgeon should consider bailout procedure.

**Keywords:** G10, laparoscopic cholecystectomy, bailout, CVS.

### Introduction

Laparoscopic cholecystectomy has become a standard treatment for symptomatic cholelithiasis in dr. Cipto Mangunkusumo Hospital (RSCM). During 2008-2012, there were 217 cases of laparoscopic cholecystectomy recorded. Of these numbers, the biliary complication rate was 2.4%, and the conversion rate to open cholecystectomy was 3.9%.<sup>1</sup> In 2014, of 90 laparoscopic cholecystectomies, the biliary complication rate was 3.33%, and the conversion rate was 4.44%.<sup>2</sup> Usually, the biliary complication rate is higher than open surgery due to difficult gallbladder (DGB), where an inflamed gallbladder is hard to dissect and identify the cystic duct. Failure to identify the cystic duct may cause biliary injury. As the prevention, surgeons are advised to change the infundibular technique with Critical View of Safety (CVS).<sup>3</sup> There are some alternatives when surgeons have difficulty implementing CVS in a difficult gallbladder. They are bailout procedures, such as fundus-first cholecystectomy (FF), subtotal cholecystectomy (SC), open cholecystectomy conversion, and cholecystostomy.<sup>4</sup>

Surgeons have to prevent biliary injury that leading to morbidity. The first step is to be familiar with the surgery's difficulty level, then knowing how to handle it. For this purpose, an assessment of the difficulty level during laparoscopic cholecystectomy is required. With this simple and

objective intraoperative assessment, the surgeon's appropriate decision can prevent biliary injury. To date, various intraoperative gallbladder assessment system has been published, but none was widely accepted.

Publications show the correlation between the system used with the incidence rate of open cholecystectomy conversion to confirm the difficult gallbladder. Recently, Sugrue et al. proposed using a 10-point intraoperative gallbladder assessment system (G10) for laparoscopic cholecystectomy. The system uses a scoring system and assessment variables that easy to be remembered and evaluated. It assesses a gallbladder based on the extent of the gallbladder adhesion, distended or contracted gallbladder, inability to hold the gallbladder without decompressing/injuring, stones measuring of  $>1$  cm which have an impact on Hartmann's pouch, Body Mass Index (BMI) of  $>30$ , adhesions following previous surgery, bile or pus beyond gallbladder and the presence of fistula (Mirizzi type 2/3). The G10 scores are predictive of the conversion to open cholecystectomy.<sup>5</sup> The conversion of open cholecystectomy is not the only bailout procedure chosen by the surgeon to handle difficult gallbladder. For this reason, the G10 scoring can be used to predict all types of bailout procedures as well.

There is no intraoperative gallbladder assessment system implemented in RSCM. This study aimed to validate the G10 scoring system to the bailout procedures in RSCM

**Method**

We proceeded with a retrospective analytic study using a cross-sectional design. Data was taken from medical records, including intraoperative photos documented in the Department of Surgery, dr. Cipto Mangunkusumo Hospital (RSCM). The population was the subjects who had laparoscopic cholecystectomy from January 2019 to December 2019. Each subject observed for the points as follows: gallbladder adhesion, gallbladder distention or contraction, operator's inability to hold the gallbladder without decompressing or without injuring the gallbladder, impacted stones of >1 cm in Hartmann's pouch, body mass index >30, adhesions following previous surgery related to gallbladder exposure, presence of bilious fluid or pus beyond the gallbladder and presence of fistulas/Mirizzi type 2 or 3. The variable subjected to the score presented as follows:

Intraoperative assessment parameters	
Gallbladder adhesion:	
-	<50% (score 1)
-	≥50% (score 2)
-	Completely buried gallbladder (score 3)
Distended or contracted gallbladder (score 1)	
Inability to grasp without decompression (score 1)	
Stone >1 cm impacted in Hartmann's pouch (score 1)	
BMI >30 (score 1)	
Adhesion from previous surgery (score 1)	
Free bile or pus outside the gallbladder (score 1)	
Fistula (score 1)	
<b>G10 score</b> = Total score obtained (range 1–10)	

The surgical technique of laparoscopic cholecystectomy for each subject was noted and divided into two groups; those are the Critical View of Safety (CVS) technique group and bailout procedure group, consisting of Fundus First cholecystectomy (FF), Subtotal Cholecystectomy (SC), and open surgery conversion. The grouping of bailout procedures is based on The Delphi Consensus<sup>4</sup> and The 2018 Tokyo Guidelines. The Mann-Whitney nonparametric used to find the correlation of the G10 score to the CVS and the bailout procedure. A Kendall's tau was performed to measure the correlation between the G10 score and the bailout procedure. We calculated statistical power using the G-power application version 3.1.9.6. A ROC analysis was used to find the sensitivity and specificity of the G10 scoring system to predict bailout procedure, then an optimal cut-off value was determined. Socio-demographic data and perioperative factors were presented descriptively. The committee of ethics Faculty of Medicine, Universitas Indonesia approved the study.

**Results**

One hundred four subjects had laparoscopic cholecystectomy surgery from January 1, 2019, to December 31, 2019. Only 99 subjects fulfilled the inclusion criteria and were included as research subjects. Five subjects were excluded from the research subjects due to incomplete data (Figure 1)

The correlation between G10 score and bailout procedure  
The median of G10 score for subjects with the Critical View of Safety (CVS) was 1 (range 1-6). The median of the G10 score for subjects who had bailout procedure was 4 (range 2-8). An analysis using the Mann-

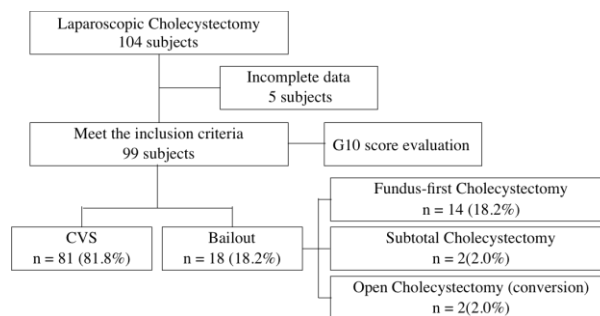


Fig.1. Flowcharts of subjects enrolled in the study

Table1. Subjects' characteristics

Characteristics	Mean±SD n (%)
Age in year	49.80±13.421
Gender (n, %)	
• Male	37 (37.4 %)
• Female	62 (62.6 %)
Body Mass Index (kg/m <sup>2</sup> )	25.26 ± 4.40
History of abdominal surgery (n, %)	
• No	80 (80.8 %)
• Yes	19 (19.2 %)
Main Complaints (n, %)	
• Pain with jaundice	62 (62.6 %)
• Jaundice/history of jaundice	37 (37.4 %)
History of intervention before surgery:	
• ERCP	37 (37.37 %)
• ESWL	5 (5.05 %)
Complaint Duration (n, %)	
• < 1 year	85 (85.9 %)
• ≥ 1 year	14 (14.1 %)
Diagnosis Support (n, %)	
• USG	87 (87.9 %)
• CT SCAN	10 (10.1 %)
• MRCP	28 (28.3 %)
• ERCP	37 (37.4 %)
Description of Imaging findings (n, %)	
• Stone in gallbladder	
• Sludge	91 (91.9 %)
• Hydrop in gallbladder	9 (9.1 %)
• Thickening gallbladder wall	3 (3.0 %)
• Fluid beyond gallbladder	11 (11.1 %)
• Fluid beyond gallbladder	2 (2.0 %)
Comorbidity (n, %)	
• Yes	54 (54.5 %)
• No	45 (45.5 %)
Types of Comorbidity:	
- Hypertension	27 (27.27 %)
- Diabetes melitus	13 (13.13 %)
- Hepatitis	7 (7.07 %)
- Coronary artery disease	4 (4.04 %)
- Cirrhosis	2 (2.02 %)
- Chronic kidney disease	2 (2.02 %)
- Hyperthyroid	2 (2.02 %)
- Tuberculosis	2 (2.02 %)
ASA (n, %)	
• 1	22 (22.2 %)
• 2	68 (68.7 %)
• 3	9 (9.1 %)
Diagnosis (n,%) based on ICD X	
• Acute Cholecystitis	4 (4.0 %)
• Chronic Cholecystitis	23 (23.2 %)
• Cholecystolithiasis without cholecystitis	68 (68.8 %)
• Acute cholangitis	4 (4.0 %)
Types of surgery (n, %)	
• Emergency (emergency operating theater)	1 (1.0 %)
• Urgent (1-2 weeks after admission)	7 (7.1 %)
• Elective surgery	91 (91.9 %)

Table 2. Distribution of G10 score

Intraoperative assessment parameters		CVS		Bailout	
1	Gallbladder adhesion:				
	- <50% (score 1)	65	80.2%	4	22.2%
	- ≥50% (score 2)	13	16.0%	8	44.4%
	- Completely buried gallbladder (score 3)	3	3.7%	6	33.3%
2	Distended or contracted gallbladder (score 1)	21	25.9%	13	72.2%
3	Inability to grasp without decompression (score 1)	3	3.7%	7	38.9%
4	Stone >1 cm impacted in Hartmann's pouch (score 1)	5	6.2%	4	22.2%
5	BMI >30 (score 1)	14	17.3%	2	11.1%
6	Adhesion from previous surgery (score 1)	1	1.2%	1	5.6%
7	Free bile or pus outside the gallbladder (score 1)	1	1.2%	2	11.1%
8	Fistula (score 1)	0	0.00%	1	5.6%
<b>G10 score = Total score obtained (range 1-10)</b>					

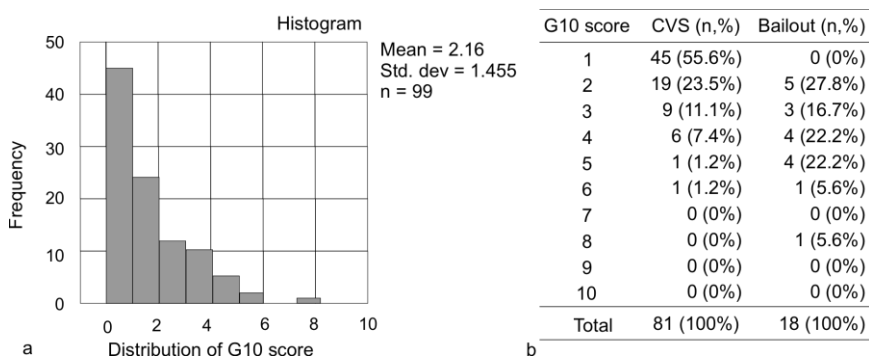


Fig. 2. a. Frequency diagram of the G10 score. b. Table of the G10 score distribution on subjects based on CVS and bailout procedures

Table 3. Distribution of G10 score in CVS and bailout procedure

No	Variables	CVS (n = 81)	Bailout Procedures		
			FF (n = 14)	SC (n = 2)	Conversion (n = 2)
1	G10 score (median, min-max)	1 (1-6)	3 (2-6)	5 (5-5)	6.5 (5-8)
2	Duration of operation in minutes (median, min-max)	150 (45-320)	210 (150-305)	285 (180-390)	250 (230-270)
3	Intraoperative bleeding in mL (median, min-max)	10 (5-100)	20 (5-300)	85 (20-150)	525 (350-700)
7	Pain on the first postoperative day in VAS (median, min-max)	2 (1-4)	2 (1-3)	2.5 (2-3)	4 (4-4)
8	Postoperative length of stay in days (median, min-max)	2 (1-7)	3.5 (1-9)	4.5 (2-7)	5.5 (5-6)
9	Complication				
	• Bleeding	1	0	0	0

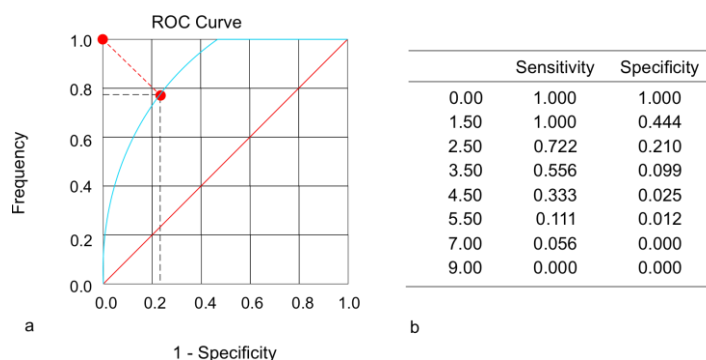


Figure 3. a. The ROC curve of G10 score to predict bailout procedure. b. Table of sensitivity and 1-specificity based on G10 score.

Whitney nonparametric test showed a significance value of  $p < 0.001$ . A Kendall's tau test showed a positive correlation with  $p < 0.001 + 0.474$ . G-power to Kendall's tau correlation 0.474 based on sample size 99 yields data with power 98.3%. Further, the accuracy of the G10 score assessed using the Receiver Operating Characteristic (ROC) curve and found that the G10 score had an AUC of 0.865 ( $p < 0.001$ ) and we found the cut-off of the G10 score of 2.5 ( $\chi^2$ ,  $p$  value = 0.000019). The G10

score > 2 identified subjects at high risk of bailout procedure (72.2% vs 20.98%).

### Discussion

The most common problem encountered on difficult gallbladder is adequate exposure. In this study, 19 subjects (19.2%) had a history of

abdominal surgery. However, only two subjects (2.02%) had difficulty in gallbladder exposure due to adhesion and required for adhesiolysis. Although impossible to accurately predict what surgery might lead to adhesions that may impact gallbladder's exposure, the scar may warn the surgeon to consider the first trocar insertion for camera port. The first port for camera is not always placed in infra-umbilical. Another site (right subcostal anterior axillary line) of non-scar area is considered. In our hospital, the first trocar placement using open technique (Hasson). Following camera insertion, an evaluation proceeded for the safe insertion the next trocar through the surgical scar. A history of multiple surgeries and/or surgery on liver, stomach and duodenum also has a greater risk of adhesion on gallbladder.

The most diagnosis was cholecystolithiasis without cholecystitis, followed by chronic cholecystitis and acute cholangitis. Meanwhile, the percentage of acute cholecystitis was only 4.0%. This finding showed a lower than other studies,<sup>6</sup> related to the government's referral health care system. Most of acute cholecystitis managed in the first hospital. Only complicated ones were referred to ours, which most of them were treated electively.

The median of G10 score among the groups was different. The Critical View of Safety (CVS) has the lowest median score, followed by Fundus First cholecystectomy (FF) and subtotal cholecystectomy (SC). The conversion has the greatest median score. In this study, most of the surgical techniques used were CVS (81.8%). The CVS had a shorter surgery duration, less intraoperative bleeding, less pain on first postoperative day and shorter postoperative length of stay than the others. In this study, the CVS had a lower median G10 score than the others. The findings associated with a less severe of gallbladder. The more severe or difficult gallbladder, the more bailout procedures carried out. Severity of gallbladder may impact surgery duration and intraoperative bleeding. Thus, we may not assume that the CVS technique is better than the others. There was a case with bleeding due to spontaneous release of hem-o-lock clip used for cystic artery ligation, thus reoperation had to be performed. There was no biliary trauma in the CVS group.

Fundus-first cholecystectomy (FF) is the common bailout technique used in RSCM (14.2%). With a technique, the triangle of safety may be exposed better in difficult case.<sup>7</sup> However, it used infrequently in non-difficult case. In this study, the FF used in a widening of cystic duct (five subjects), contracted gallbladder (four subjects), cystic plate adhesion (three subjects) and liver kyphosis (two subjects). Mahmud reported that FF reduced the potency of conversion from 5.2% to 1.2%.<sup>8</sup> Huang also reported that FF group showed a lower prevalence of conversion, a lower complication and a shorter length of postoperative treatment than the conventional group.<sup>9</sup> This study shows that subjects who proceeded with FF had longer duration of surgery than CVS, but shorter than other techniques. Intraoperative bleeding, first day postoperative pain, and length of stay were similar to CVS. Even though this technique is one of the bailout procedures, the surgeon must remember the risk of biliary injury due to an "error trap".<sup>10</sup> The surgeon must be alert and clearly understand the cystic plate anatomy. The dissection keeps close to the gallbladder. In this study, there was no biliary injury in FF technique.

Laparoscopic subtotal cholecystectomy (SC) was performed on 2.0% of subjects. The SC technique was used for severe adhesion on the safety triangle, where it was hard to identify and dissect the cystic structure. The technique rarely used in RSCM compared to FF technique. This finding differed to Manatakis's study showing a technique widely used by the surgeon than FF technique.<sup>11</sup> Iwashita found that the SC technique well-known and recommended by American surgeons, whereas Taiwanese and Korean surgeons frequently use the FF technique.<sup>4</sup> The risk of complication in SC technique is probably higher than FF technique;<sup>12</sup>

therefore most surgeons use FF technique for the first preference. In a non-succeeded case, the SC technique is considered.<sup>13</sup> SC technique required longer duration of surgery than CVS and FF. However, intraoperative bleeding, first day postoperative pain, and length of stay were similar to the CVS and FF techniques. In this study, no complication found in subject with SC technique.

There were 2.0% of conversion in the study because of adhesion to duodenum (one subject) and Mirizzi type 2 (one subject). This finding similar to other studies.<sup>11</sup> In this study, conversion purposes for an adequate exposure, using tactile sensation and making better manipulation to prevent iatrogenic injury. The open cholecystectomy rate recently decreased, because both patients and surgeon preference. Laparoscopic cholecystectomy is frequently used rather than open cholecystectomy. However, when dealing with difficult gallbladder, surgeons prefer the bailout procedures rather than open cholecystectomy conversion.<sup>5,14</sup>

In this study, the conversion places the greatest median score, the longest duration of surgery, intraoperative bleeding, first day postoperative pain, and the longest stay. Wolf reported a higher morbidity and mortality in male, elderly, and those with history abdominal surgery whose proceed with conversion than those continued in laparoscopic cholecystectomy. A conversion must be carefully considered for the benefit and adjusted with the readiness of the surgical team.<sup>15</sup> However, the conversion is not considered as a complication nor failure of laparoscopic cholecystectomy.

#### **G10 score as guidance on the bailout procedure for laparoscopic cholecystectomy**

The intraoperative gallbladder assessment system is an important tool in laparoscopic cholecystectomy. The assessment purposed to have a same perception to the gallbladder severity and become the guideline in decision an appropriate technique in preventing the risk of biliary injury. The selected G10 scoring system has advantages, such as practical scoring system, having assessment variables that easy to be remembered and evaluated, and statistically correlating with the conversion to open cholecystectomy.<sup>5</sup>

The Critical view of safety (CVS) has been used as the standard for laparoscopic cholecystectomy in our hospital. Surgeons found no problem with the implementation on noninflamed gallbladder; problem comes on difficult gallbladder. For this reason, surgeons can choose to use an alternative bailout procedure to handle difficult gallbladder, therefore they can complete the operation with lower risk.

In dealing with difficult gallbladder, surgeon may use intraoperative imaging (such as intraoperative cholangiography (IOC), intraoperative ultrasonography (IOUS) fluorescence cholangiography to explore a disconfigured biliary anatomy. Studies reveal the use of intraoperative imaging reduce the risk of biliary injury.<sup>16</sup> However such imaging techniques not widely distributed in health facilities in Indonesia. To date, IOC has only selectively used in RSCM due to limited resources. Of 99 subjects with laparoscopic cholecystectomy, none assessed using IOC. IOC assessment is difficult in dealing with difficult gallbladder; surgeon need to proceed good dissection and optimize alternative bailout procedures.

We found a significant difference ( $p < 0.001$ ) in G10 score between subjects with CVS (median 1, range 1-6) and bailout procedure (median 4, ranges 2-8). G10 score of bailout procedure showed a positive and significant correlation ( $p < 0.001$ ,  $+0.478$ ). A correlation shows that the greater G10 score indicates greater difficulty in gallbladder surgery in inflamed, fibrosis, or adhesions.<sup>16</sup> Consequently, the bailout procedure carried out frequently in difficult gallbladder surgery. Manatakis showed

that the use of proper bailout procedure may prevent biliary injury.<sup>11</sup> Thus, the CVS technique and various alternative bailout procedures may cover one another to prevent biliary injury.

Evaluation using the ROC curve showed the G10 score has a good accuracy to predict the bailout procedure (AUC 0.865), with the cut-off value for predicting bailout procedures is 2.5 (sensitivity 72.2%, specificity 79.0%). The G10 score of 1 and 2 referred to the safe margin for the CVS technique. Should the G10 score greater than 3, the surgeon may consider using a bailout procedure (72.2% sensitivity). However, this guidance subjected to the flexibility. The specificity of 79.0% shows that 21.0% of the CVS techniques were performed to subjects who score greater than 3. When the surgeons perform laparoscopic cholecystectomy frequently, their ability and expertise to maneuver laparoscopic surgery and apply the CVS technique in difficult gallbladder. Nonetheless, good surgeons always have to put their patient safety first on any decision being made.

In contrast to previous studies focused on the correlation between G10 score and the conversion, the present study investigated the correlation between G10 score and bailout procedure. The study's limitations were the small sized sample, which may limit the study to evaluate the correlation of the G10 score with each surgical technique (CVS, FF, SC and open surgery conversion), even though there was stratified difference of the G10 score median in each group. Studies may be carried out with a larger sample size to solve this problem in the future direction.

Although this study is preliminary study with limited sample size, it has good statistical power (98.3%). G10 score has good sensitivity and specificity to predict the bailout procedure. With this scoring system, surgeon may assess the difficult surgery objectively, and decide an appropriate treatment to prevent biliary injury

## Conclusion

This study showed that G10 score has good accuracy in predicting a bailout procedure, therefore the use of G10 score intraoperatively by surgeon performing laparoscopic cholecystectomy is "essential" to provide valid and objective assessment in determining the difficulty level of surgery. When the G10 score is 1 or 2, it's safe to perform the CVS technique. Whereas, if the G10 score is 3 or greater, the surgeon should consider performing bailout procedure

## Disclosure

Authors declared no conflict of interests

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