



## General Surgery

## IMPLEMENTATION OF A NEWLY DEvised SCORING SYSTEM TO DETECT RETAINED COMMON BILE DUCT STONES IN GALLSTONE PANCREATITIS

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**ABSTRACT** Gallstones pancreatitis is caused by gallstones, which migrate to and block the common bile duct (CBD). To detect retained CBD stones, a scoring system was devised with the parameters (with 1 point for each): CBD size  $\geq 9$  mm, Gamma glutamyl transferase (GGT)  $\geq 350$  U/L, Alkaline phosphatase (ALP)  $\geq 250$  U/L, Total bilirubin (TB)  $\geq 3$  mg/dL and Direct bilirubin (DB)  $\geq 2$  mg/dL. A prospective observational study was carried out at a large tertiary care urban healthcare center over a period of 2 years comprising of 43 patients. Using our scoring system, we propose the following for patients: those with 0 or 1 points undergo LC with follow up; 2 points undergo LC or MRCP, based on the values of AST/ALT; 3 or 4 points undergo MRCP; and 5 points should go directly to ERCP.

**KEYWORDS :** gallstone, pancreatitis, scoring, retained stones

### Introduction

Gallstones, produced in the gallbladder, can migrate to and block the common bile duct (CBD). This stops the pancreatic enzymes from travelling to the small intestine and forces them back into the pancreas, causing autodigestion of the pancreas, resulting in pancreatitis. Most stones in the CBD pass spontaneously; however, retained CBD stones cause persistent biliary obstruction, thereby increasing the morbidity, and are an important factor in the recurrence of pancreatitis and biliary complications.

A 2009 paper by Telem et al<sup>1</sup> used retrospective data and multivariate analysis to determine 5 quantitative variables and their cutoffs that have a positive predictive value (PPV) for CBD stones:

1. CBD size  $\geq 9$  mm
2. Gamma glutamyl transferase (GGT)  $\geq 350$  U/L
3. Alkaline phosphatase (ALP)  $\geq 250$  U/L
4. Total bilirubin (TB)  $\geq 3$  mg/dL
5. Direct bilirubin (DB)  $\geq 2$  mg/dL.

In a follow-up paper from the same institute by Sherman et al<sup>2</sup> a scoring system was suggested and validated for use in cases of gallstone induced acute pancreatitis to detect retained CBD stones. Under the proposed system, at the time of admission, the above 5 criteria were assessed and 1 point was given for the presence of each. Majority of the patients with scores 0-1 did not have CBD stones, whereas, patients with scores 4-5 had 92% risk of persistent CBD stones. The results of this study recommended that patients with a score of 0 undergo laparoscopic cholecystectomy with intraoperative cholangiogram (LCIOC), treatment of patients with scores of 1-3 were to be made on an individual basis, and those with scores of 4 and 5 were to undergo endoscopic retrograde cholangiopancreatography (ERCP) and necessary procedures such as sphincterotomy, stone extraction and stent insertion.

The Department of General Surgery at the study center admits numerous patients of gallstone pancreatitis over a period of one year. The devised scoring system would help in triaging these patients and deciding their management of choice. This would, in turn, prevent wastage of resources and unnecessary expensive investigations on the patients.

### Aim & Objectives

- To predict the incidence and management of retained CBD stones in gallstone pancreatitis.
- To test the feasibility of the recommended management protocol.

### Materials & Methods

A prospective observational study was carried out at a large tertiary care urban healthcare center over a period of 2 years from July 2015 to

October 2017 comprising of 43 patients who met the inclusion criteria, aged 12 years or more, with gallstone pancreatitis, admitted under the Department of General Surgery.

**CASE SELECTION:** To be done with respect to history, clinical examination and radiological examination.

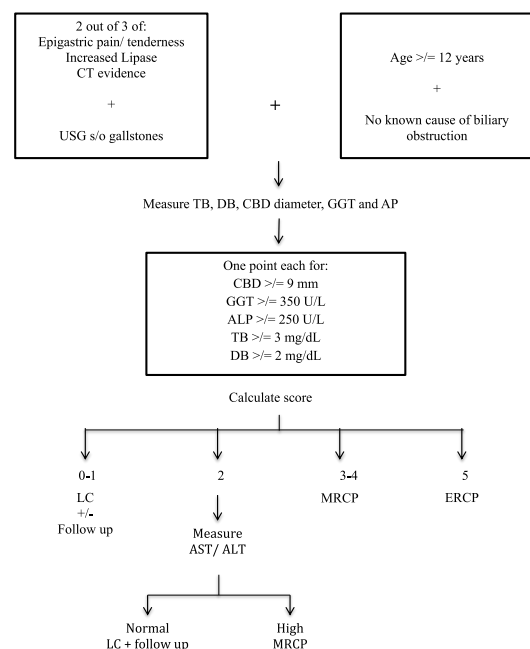
### Inclusion Criteria:

1. Clinical diagnosis of pancreatitis, suggested by the presence of any 2 out of the following 3 features:
  - Characteristic epigastric pain/tenderness
  - Elevated serum lipase/amylase
  - Computerized Tomography (CT) evidence of pancreatitis
2. Presence of gallstones on ultrasonography (USG)

### Exclusion Criteria:

1. Known biliary obstruction from other causes (e.g. stricture, malignancy, etc.)
2. CBD stone clearly identified on ultrasonography

**PROTOCOL:** Protocol for patients presenting with suspected biliary pancreatitis:



Approval for this study was obtained from the Institutional Ethics Committee. The study took place from July 2015 to October 2017. We used the same 5 quantitative variables and their cutoffs as determined by the original study to determine the score for each patient enrolled in the study. Patients were given 1 of 6 possible scores (0–5). Initial admission laboratory values and ultrasonography results were used. One point was assigned for each of the following: CBD size  $\geq$  9 mm, GGT  $\geq$  350 U/L, AP  $\geq$  250 U/L, TB  $\geq$  3 mg/dL, and DB  $\geq$  2 mg/dL. However, we modified the proposed treatment protocol slightly, which is described as follows:

- Score 0 – LC with follow up for 3 months
- Score 1 – LC with follow up for 6 months

As Intraoperative Cholangiogram was unavailable in our setup, patients with low suspicion of having retained CBD stones were closely followed up to look for recurrence of pancreatitis or biliary obstruction in case of any undetected retained distal CBD stones. If the patients did present with any of the features mentioned above and USG suggested obvious biliary obstruction, they were sent for ERCP straightaway. However, in case of no known cause of biliary obstruction, they were subjected to MRCP first.

- Score 2 – LC or MRCP

In the study by Sherman et al<sup>2</sup>, AST and ALT have been found to be significantly higher among patients with CBD stones. Keeping this in mind, patients with score of 2 were subjected to LC with follow up if AST/ ALT were found to be within normal limits, and MRCP if they were higher than the normal range.

- Score 3,4 – MRCP
- Score 5 – ERCP

All patients were offered a laparoscopic cholecystectomy as a definitive treatment if medically able.

Patient characteristics and laboratory values between the 2 groups were compared with Chi-square and independent sample t-tests to determine if any significant factors between the groups existed. Statistical analysis was done using statistical software package SPSS v22.0. Data is represented as mean  $\pm$  SD. Mean value of continuous variable was compared using t-test and nominal variables were compared using Chi-square test. ROC curve (Receiver Operating Characteristics) was plotted to determine the cut off value of the scoring system. P-value  $<$  0.05 was taken as significant.

**Observations and Results**

**Table 1: Prevalence of CBD stone presence in current study**

	CBD stone	
	Present	Absent
<b>Frequency (%)</b>	17 (39.6%)	26 (60.4%)

**Table 2: Frequency distribution of Score**

Score	Frequency	Percent
0	15	34.9
1	7	16.3
2	7	16.3
3	6	14.0
4	4	9.3
5	4	9.3
<b>Total</b>	<b>43</b>	<b>100.0</b>

**Table 3: Comparison of various parameters in subjects who had CBD stone and subjects who don't**

Parameter	Cut off value	CBD stone	N	Mean	Std. Deviation	p-value
Amylase (U/L)	-	N	26	1222.1	1221.8	0.238
		Y	17	2066.5	3281.2	
Lipase (U/L)	-	N	26	3564.1	4201.3	0.368
		Y	17	2479.4	3144.0	
CBD size (mm)	9	N	26	6.6	2.3	<b>&lt;0.001***</b>
		Y	17	9.6	2.2	
ALP (U/L)	250	N	26	140.8	64.1	<b>&lt;0.001***</b>
		Y	17	340.1	246.3	
GGT (U/L)	350	N	26	176.2	95.7	<b>&lt;0.001***</b>
		Y	17	371.2	233.4	

TB (mg/dL)	3	N	26	2.3	3.2	<b>0.001**</b>
		Y	17	6.1	3.8	
DB (mg/dL)	2	N	26	1.2	2.4	<b>0.001**</b>
		Y	17	4.3	3.4	
AST (U/L)	-	N	26	99.7	132.1	0.125
		Y	17	168.8	155.2	
ALT (U/L)	-	N	26	102.6	123.4	0.308
		Y	17	142.8	126.3	

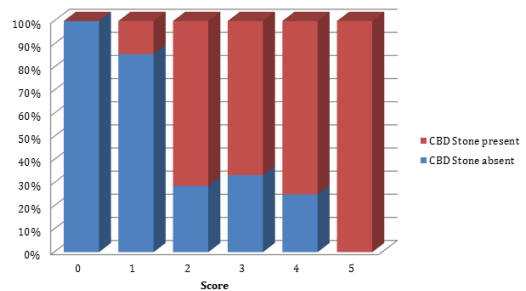
t-test analysis suggests that CBD size, ALP, GGT, TB and DB were significantly higher in subjects with CBD stone than in subjects without CBD stone. Rest of the parameters didn't have any statistically significant difference.

**Table 4: Correlation between Scores and CBD stone presence**

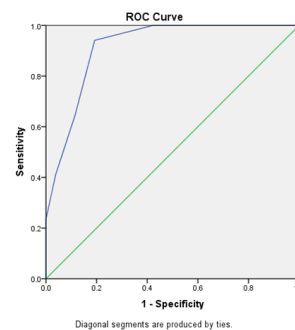
Score	CBD stone		Total	Chi square value	p-value
	N (%)	Y (%)			
0	15 (100)	0 (0)	15	24.723	<b>&lt;0.001***</b>
1	6 (85.7)	1 (14.3)	7		
2	2 (28.6)	5 (71.4)	7		
3	2 (33.3)	4 (66.7)	6		
4	1 (25)	3 (75)	4		
5	0 (0)	4 (100)	4		
<b>Total</b>	<b>26</b>	<b>17</b>	<b>43</b>		

Chi square analysis suggests that as the score increase chances of presence of CBD stone increases. The Chi square value was 24.723 and the p-value was  $<$  0.05.

**Graph 1: Bar diagram showing the frequency of presence and absence of CBD stones among subjects with various scores**



**Graph 2: ROC (Receiver operating characteristics) curve analysis to determine cut off value of score for prediction of presence of CBD stone**



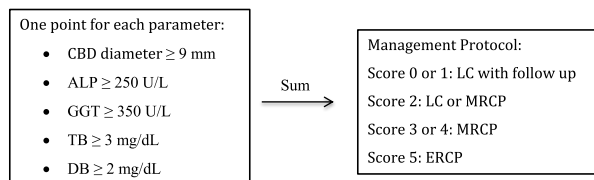
Area Under the Curve (AUC)				
Area	Std. Error	p-value	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
0.915	0.042	<b>&lt;0.001***</b>	0.833	0.997

The AUC is 91.5%, which indicates the diagnostic ability of overall scoring system, which is statistically significant (p  $<$  0.05).

**Discussion**

Our prospective data confirms that AP, GGT, TB, DB, and CBD size at the time of admission are 5 factors that can differentiate between those patients with and without CBD stones. Although AST and ALT were found to be higher among patients with CBD stones, the result was not significant in our study<sup>3,5</sup>.

Our data show that scores of 0 and 5 are very accurate in predicting the absence and presence of CBD stone, respectively. Scores of 1–4 should be used to determine the next step in diagnosing the presence of a CBD stone. Based on our prospective data, we propose the following revised protocol for the management of gallstone pancreatitis:



Patients with 0 or 1 point should proceed directly to laparoscopic cholecystectomy as an initial treatment, as they have a very low chance of having stones. These patients can then be followed up postoperatively to look for recurrence of pancreatitis or biliary obstruction in case of any undetected retained distal CBD stones.

Patients with score of 2 should undergo LC or MRCP based on their AST/ALT values. As AST/ALT have been proven to be higher in patients with CBD stones, the subjects with score 2 having high AST/ALT are subjected to MRCP to look for CBD stones and those with normal AST/ALT are taken up for LC with follow up.

Patients with a score of 3 or 4 are made to undergo MRCP to detect CBD stones, as these patients have a high probability to be having CBD stones but the same is not certain. Instead of subjecting the patients to an unnecessary ERCP, which is quite probable in such cases, it is better to evaluate the biliary tree using MRCP first<sup>6</sup>. If MRCP shows a stone, the patient can undergo stone removal either with ERCP or CBD exploration based on surgeon preference and their clinical picture.

Patients with a score of 5 should directly undergo ERCP; in our data, they have 100% chance of having a CBD stone and should have urgent decompression of the biliary system to prevent cholangitis.

The calculated accuracy shows that the scoring system is an accurate predictor of persistent gallstones, especially for patients with a score of 0 or 5. The accuracy falls slightly with the addition of patients who score in the middle of the scoring range. This decline in accuracy further supports the clinical implication of having the patient receive an MRCP. MRCP is highly accurate in diagnosing CBD stones (> 90%)<sup>7</sup>. Because ERCP is not without morbidity, MRCP is a good way to select patients for therapeutic ERCP instead of jumping to diagnostic ERCP. There were no negative ERCPs in our study. Every patient who underwent ERCP had a CBD stone. This reduction of negative ERCP rate is important, because ERCP is not without complications<sup>8</sup>. By reducing negative ERCPs, we eliminate the cost of the procedure itself and the cost of treating the complications of ERCP. ERCP along with sphincterotomy, stone extraction, and intraoperative CBD exploration are 2 ways to remove CBD stones. Both are equally effective in removing CBD stones, and intraoperative CBD exploration may have a lesser risk of morbidity, mortality, and recurrence of CBD stones. Performing intraoperative CBD exploration during cholecystectomy instead of a separate ERCP procedure for CBD stone reduces the number of total procedures and length of stay. The decision of choosing the modality for CBD stone removal depends on a combination of surgeons' comfort level with intraoperative CBD exploration and the availability of skilled advanced endoscopists at the institution.

## Conclusion

Our scoring system has a place in the management of gallstone pancreatitis. This scoring system can help to stratify the risk of having retained CBD stones based on a set of their admission laboratory values and initial ultrasonography findings. Furthermore, our scoring system and protocol helped to reduce the number of negative ERCPs in our institution.

Using our scoring system, we propose the following for patients: those with 0 or 1 points undergo LC with follow up to rule out biliary obstruction or recurrent pancreatitis post-operatively; 2 points undergo LC or MRCP, based on the values of AST/ALT; 3 or 4 points undergo MRCP; and 5 points should go directly to ERCP.

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