

TO EVALUATE THE DIAGNOSTIC ABILITY OF THE SCORING SYSTEM BASED ON TOTAL BILIRUBIN, ALKALINE PHOSPHATASE AND DILATED CBD IN PREDICTING CHOLEDOCHOLITHIASIS.

General Surgery

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ABSTRACT

Expensive and invasive methods like MRCP and diagnostic ERCP are used to predict and diagnose choledocholithiasis in this paper it is our attempt to assess a scoring system based on total bilirubin, alkaline phosphatase and dilated CBD in predicting choledocholithiasis in a patient with cholelithiasis. There are some situations in which CBD stone is identified intraoperatively which leads to increase in morbidity of the patient as a more invasive procedure has to be performed to remove such stone instead of ERCP. ERCP has transformed removal of stones from bile duct into a minimally invasive procedure. But there are significant number of risk factors associated with ERCP. Hence it is an attempt through this study to identify predicting ability of this score so that expensive scans like MRCP are omitted, misdiagnosis is avoided which leads to increased morbidity and correct patients are identified who are in actual need for ERCP. A score of >5 is suggestive to undergo ERCP with excellent diagnostic accuracy, sensitivity and specificity.

KEYWORDS

CBD stone, choledocholithiasis, ERCP, MRCP, Total bilirubin, Alkaline Phosphatase.

INTRODUCTION:

Cholelithiasis is stone in gall bladder which is most prevalent and clinically significant condition globally. 15% of Americans have gall stone disease. Cholelithiasis also has high incidence in developing countries like 10% in Asia and 5% in Africa (1). Prevalence of gall stones in India is 4.15% with a higher prevalence in northern India (2). Cholelithiasis is predominantly seen in females who are >40 and are obese (3).

Choledocholithiasis is stone in common bile duct. Normal CBD diameter is 6-8 mm. 10- 15% Of patients with cholelithiasis have choledocholithiasis (4). This incidence increases with age. CBD stones occurs either by migrating downstream from gall bladder (secondary stones) or originating in the CBD (primary stone). The features of choledocholithiasis includes wide range from obstructive jaundice to critical conditions like pancreatitis and ascending cholangitis.

Endoscopic retrograde cholangiopancreatography (ERCP) was introduced in the year 1968 as diagnostic aid. Within 5 years endoscopic sphincterotomy was developed that transformed ERCP into a therapeutic modality. It has been considered as a standard reference to diagnose CBD stone since a long time. With the evolution and improvements in radiological techniques, ERCP has improved as well (4). Along with its ability to diagnose, ERCP has the benefit of providing therapeutic benefit, that is after identification stone in the CBD, endoscopic sphincterotomy along with stone extraction can be performed during the same setting using balloon extractor or dormia basket. It has a success rate of 80- 90% using above mentioned methods (5). Cholecystectomy is recommended after clearance of bile duct from stones to reduce risk of cholecystitis and biliary colic in the near future. However, certain short-term complications of ERCP are post- ERCP pancreatitis, post-endoscopic sphincterotomy bleeding, cholangitis and perforation that can prolong morbidity and can also result in significant financial burden for the patient (6).

Magnetic resonance cholangiopancreatography (MRCP) is a non-invasive modality for better visualization of gall bladder and biliary system demonstrating ductal obstruction, strictures or other intraductal abnormalities. These can be achieved non-invasively without the potential complications like that of ERCP (7).

Expensive and invasive methods like MRCP and diagnostic ERCP are used to predict and diagnose choledocholithiasis in this paper it is our attempt to assess bats score in predicting choledocholithiasis in a

patient with cholelithiasis. There are some situations in which CBD stone is identified intraoperatively which leads to increase in morbidity of the patient as a more invasive procedure has to be performed to remove such stone instead of ERCP. ERCP has transformed removal of stones from bile duct into a minimally invasive procedure. But there are significant number of risk factors associated with ERCP. Hence it is an attempt through this study to identify predicting ability of the scoring system based on total bilirubin, alkaline phosphatase and dilated CBD so that expensive scans like MRCP are omitted, misdiagnosis is avoided which leads to increased morbidity and correct patients are identified who are in actual need for ERCP.

AIM:

To evaluate the diagnostic ability of the scoring system based on total bilirubin, alkaline phosphatase and dilated CBD in predicting choledocholithiasis.

OBJECTIVES:

- 1) To find diagnostic accuracy of the scoring system based on total bilirubin, alkaline phosphatase and dilated CBD in predicting choledocholithiasis.
- 2) To find sensitivity and specificity of the scoring system based on total bilirubin, alkaline phosphatase and dilated CBD in predicting choledocholithiasis.

MATERIAL AND METHODS:

A prospective study was performed in 80 individuals presenting to Mahatma Gandhi Mission hospital with complains of pain in abdomen, symptomatically presented as gall stones, biliary pancreatitis, obstructive jaundice and cholangitis with transabdominal ultrasonography done suggestive of gall bladder stones.

Patients were included in the study with strict inclusion and exclusion criteria (table 1). Patients' demographic data, history, blood investigations (particularly liver function test) were sent and data was collected, followed by transabdominal ultrasonography was done. Using all the above-mentioned data the patients were scored. The scoring is such that, total bilirubin >2mg/dl – 2 points, alkaline phosphatase >200iu – 2 points, dilated CBD on transabdominal ultrasonography-3 points, with a total score of 7 points.

Based on the scoring system (table 2) patient underwent ERCP, laposcopic cholecystectomy or MRCP, also keeping in mind patients' risk and morbidity. ERP and intraoperative findings were used for confirmation of choledocholithiasis.

Table 1 Inclusion And Exclusion Criteria

Inclusion criteria	Exclusion criteria
Admitted in hospital for symptomatic cholelithiasis,	No evidence of cholelithiasis in transabdominal USG,
Both males and females belonging to age group >18 yrs,	Malignancy
Patients that are fit for ERCP	Patients unfit for ERCP
All patients giving consent to take part in the study	Patients not giving consent to take part in the study

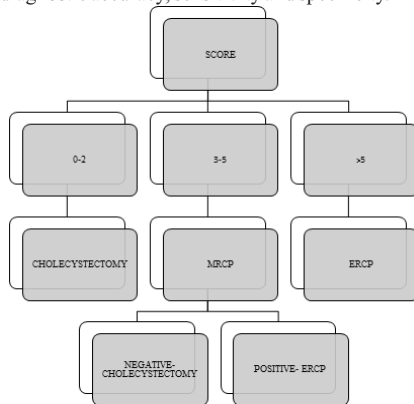
ERCP- endoscopic retrograde cholangiopancreatography.

Table 2- Scoring System

Criteria	Score (total- 7)
Bilirubin >.2mg/dl	2 points
Alkaline phosphatase >200iu	2 points
Dilated CBD on transabdominal ultrasonography	3 points

The sensitivity, specificity, positive predictive value and negative predictive value and diagnostic accuracy were obtained for the scoring system.

A score of >5 is suggestive that the patient should undergo ERCP, 3-5 - should undergo MRCP if findings are positive of CBD calculi therapeutic ERCP followed by or not cholecystectomy was performed, if MRCP findings are negative cholecystectomy should be done. Score of 0-2 indicates no stone in CBD and the patient was treated according to the management of cholelithiasis that is laproscopic cholecystectomy was performed. This scoring system has shown excellent diagnostic accuracy, sensitivity and specificity.

**Figure 1- Treatment Protocol Based On Score.**

Statistical Analysis:

Quantitative variables like age, T. Bilirubin, D. Bilirubin, Score are represented with Mean SD or Median, IQR. Qualitative variables like Cholelithiasis of the patients, gender, are presented with frequency and percentage. Association of cholelithiasis and age, gender, Cholelithiasis and age, , bilirubin ,ALP and Score levels was assessed by Chi Square test and. Fishers exact test wherever applicable. Mean Comparison of presence and absence of cholelithiasis and age, ,serum bilirubin levels, ALP and Score levels are assessed by unpaired T Test. Receiver Operating Characteristic (ROC) analysis was used to assess predictive performance. The Area Under the Curve (AUC) of the ROC was calculated to gauge the predictive accuracy of the Scoring system to predict Cholelithiasis. Statistical significance was established at a p-value less than 0.05. The statistical analyses were conducted using SPSS version 23.0 (IBM Corporation in the USA).

RESULT:

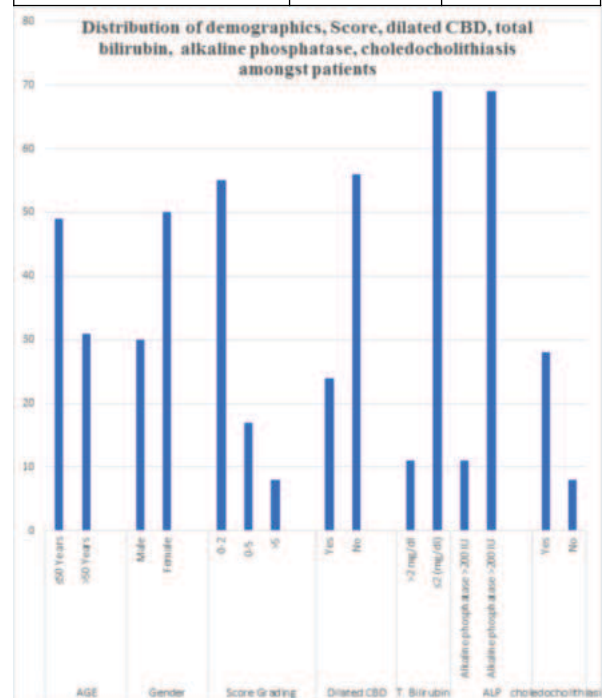
In this study this scoring system has shown an 89.3% sensitivity and 100% specificity. Distribution of demographics, Score, dilated CBD, total bilirubin, alkaline phosphatase, cholelithiasis amongst patients as shown in table 3 is suggestive that out of 80 patients 50 were female and 30 were males. According to age 49 were <50 years of age and 31 belonged to >50 years of age group. 24 had dilated CBD on transabdominal ultrasonography which was 30% of the study population. 86.3% study population had normal liver function test.

Out of 80 patients that were included in the study 36 had cholelithiasis and the score was able to identify 28 patients (true

positive) with 8 patients were later identified as having CBD stones during intraoperative findings (false negative).

Table 3: Distribution Of Demographics, Score, Dilated CBD, Total Bilirubin, Alkaline Phosphatase, Cholelithiasis Amongst Patients

Age		
	Frequency	Percentage
≤50 Years	49	61.3%
>50 Years	31	38.8%
Gender		
Male	30	37.5%
Female	50	62.5%
Score Grading		
0-2	55	68.8%
3-5	17	21.3%
>5	8	10.0%
Dilated CBD		
Yes	24	30.0%
No	56	70.0%
Total Bilirubin		
>2 mg/dl	11	13.8%
≤2 (mg/dl)	69	86.3%
Alkaline phosphatase >200 IU		
Alkaline phosphatase > 200 IU	11	13.8%
Alkaline phosphatase ≤200 IU	69	86.3%
cholelithiasis (N=44)		
Yes	28	77.8%
No	8	22.2%
Total	36	100.0%

**Figure 2- Distribution of demographics, , Score, dilated CBD, total bilirubin, alkaline phosphatase, cholelithiasis amongst patients.****Table 4: Association of cholelithiasis and age, gender, Cholelithiasis and age, , bilirubin ,ALP and BATS Score levels**

		cholelithiasis		Total	P value
		Yes	No		
Gender	Male	10	4	14	0.683
		71.4%	28.6%	100.0%	
	Female	18	4	22	100.0%
		81.8%	18.2%	100.0%	
Age Groups	≤50 Years	12	3	15	1.000
		80.0%	20.0%	100.0%	
	>50 Years	16	5	21	100.0%
		76.2%	23.8%	100.0%	

Dilated CBD	Yes	24	0	24	<0.001
		100.0%	0.0%	100.0%	
	No	4	8	12	
		33.3%	66.7%	100.0%	
Score Grading	<2	3	8	11	<0.001
		27.3%	72.7%	100.0%	
	2--5	17	0	17	
		100.0%	0.0%	100.0%	
	>5	8	0	8	
		100.0%	0.0%	100.0%	
Bilirubin	>2 mg/dl	11	0	11	0.076
		100.0%	0.0%	100.0%	
	≤2 (mg/dl)	17	8	25	
		68.0%	32.0%	100.0%	
Alkaline phosphatase	Alkaline phosphatase >200 IU	10	0	10	0.076
		100.0%	0.0%	100.0%	
	Alkaline phosphatase ≤200 IU	18	8	26	
		69.2%	30.8%	100.0%	

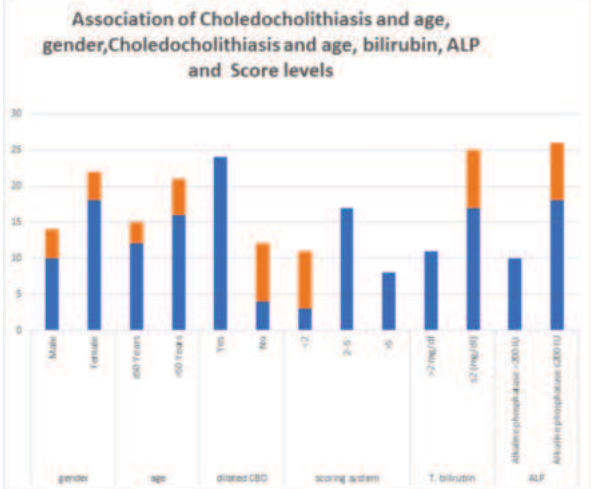


Figure 3- Association of Choledocholithiasis and age, gender, Choledocholithiasis and age, bilirubin, ALP and Score levels.

Association of those 36 patients diagnosed with choledocholithiasis with age, gender, bilirubin, ALP and Score levels showed that the false negative 8 patients had normal total bilirubin, alkaline phosphatase and normal CBD size on ultrasonography. (table- 4)

Table 5: Comparison of choledocholithiasis and age, bilirubin, ALP and Score levels					
	choledocholithiasis (Yes)		choledocholithiasis (No)		P value
	Mean	SD	Mean	SD	
AGE	51.8	17.5	52.9	13.5	0.853
T.BILI	3.3	4.9	0.7	0.3	0.009
D. BILI	1.4	2.5	0.3	0.2	0.202
ALP	224.5	182.5	92.0	15.8	0.001
SCORE	4.3	2.2	0.0	0.0	0.001

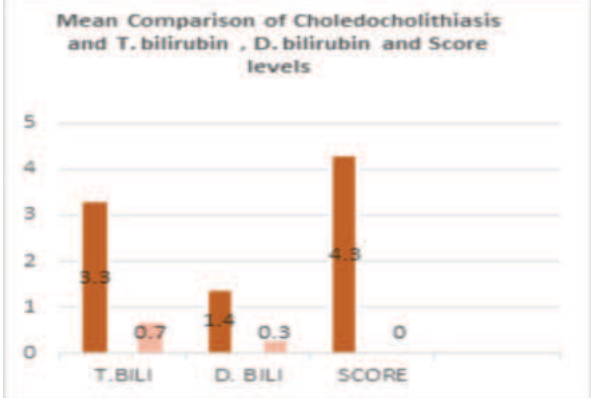


Figure 4- Mean Comparison Of Choledocholithiasis And T. bilirubin, D. Bilirubin And Score Levels.

Table 6: The receiver operating curves (ROC) of SCORE (Area Under the Curve)						
Test Result Variable (s)	Area	Std. Error	P value	95% Confidence Interval	Sensitivity	Specificity
Score	0.946	0.037	<0.001	(0.874-1.000)	89.3%	100.0%

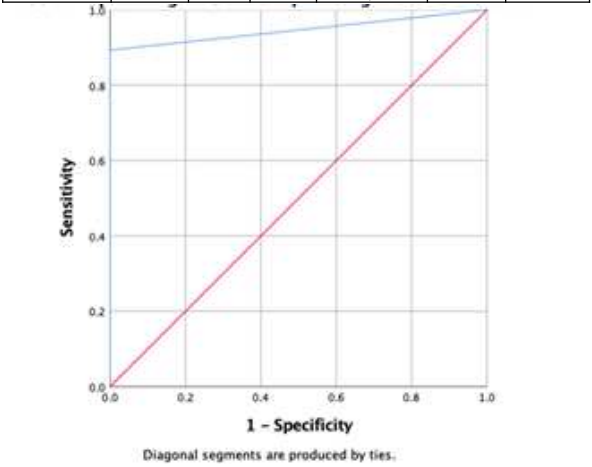


Figure 5: ROC Curve Predicting The Scoring System In Predicting Choledocholithiasis.

DISCUSSION:
This Scoring system has shown good sensitivity and specificity of 89.3% and 100% respectively, with diagnostic accuracy of 90%.

There was previous study done to determine a scoring system for predicting choledocholithiasis using biochemical, imaging methods and there combinations. Khan et al (8), in his study they used ALP, GGT and total bilirubin individually in predicting choledocholithiasis, they used endoscopic ultrasonography for confirmation choledocholithiasis. Diagnostic accuracy of their score was 87.3. There is still no adequate data available in confirming utility of that scoring system in that study.

Ali et al (9), did a study that included 131 patients of cholelithiasis developed a scoring system using a multivariate analysis, high serum bilirubin (>2 mg/dL) and alkaline phosphatase (200 IU) and dilated CBD (>6 mm) on transabdominal sonography, which had an area under the receiver operating curve (AUROC) of 0.98 in predicting the presence of CBD stone with a sensitivity of 93.18%, a specificity of 76.74%, and a diagnostic accuracy of 87.79. BATS score study has been done previously to assess its sensitivity, specificity, diagnostic accuracy and it has shown good results.

Al-Jiffry et al (10), aimed to develop and validate a clinical scoring system for predicting choledocholithiasis suggested that a score > 8 had a positive predictive of 91.7% and the scoring system had an area under the curve was 0.896 while in our study AUROC was 0.946.

American Society for Gastrointestinal Endoscopy (ASGE) proposed a scoring system in 2010 which has recently been modified in 2019 for risk categorisation of patients with CBD stones. Similarly, Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and European Society of Gastrointestinal Endoscopy (ESGE) have proposed their own scoring systems for predicting likelihood of choledocholithiasis before proceeding for ERCP. These Scores are based on presence of jaundice, dilated common bile duct on ultrasound, visible stone in CBD on imaging and presence of ascending cholangitis to classify patients into different categories. While our study did not use ascending cholangitis as a criterion for prediction of cholelithiasis (11)

CONCLUSION:
The scoring system based on total bilirubin, alkaline phosphatase and dilated CBD has shown good sensitivity and specificity but the result is inadequate due to a smaller number of sample size and need to be evaluated further in large number of population size.

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