

## TO PREDICT ACCURATELY THE PRESENCE OF COMMON BILE DUCT STONES (CBDS) AMONG THE CASES OF SYMPTOMATIC GALL STONE DISEASE BY COMBINED APPROACH USING EASILY AVAILABLE TOOLS LIKE CLINICAL ASSESSMENT, ABDOMINAL SONOGRAPHY AND LIVER FUNCTION TEST

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### Abstract

**Background:** The aim of the present study was to predict accurately the presence of common bile duct stones (CBDs) among the cases of symptomatic gall stone disease by combined approach using easily available tools like clinical assessment, abdominal sonography and liver function tests. **Materials and Methods:** The present study was conducted in the General Surgery Indoor (Victoria & Curzon Ward) & Outdoor registered patients, IPGMER & SSKM Hospital, Kolkata. All the patients visiting this hospital for treatment for gall stone disease under General Surgery Dept, IPGMER & SSKM Hospital, Kolkata (mostly from state West Bengal & allied area in eastern India) were included. 500 patients were included in the study. **Result:** 12.60% had choledocholithiasis whereas, 87.40% had cholelithiasis. Among the clinical history noted, history of Diabetes Mellitus was statistically significantly associated with diagnosis. The USG findings and diagnosis were statistically significant. Among choledocholithiasis participants, 11.1% had less than 4 mm CBD diameter, 50.8% had more than 6 mm CBD diameter. The mean and standard deviation of serum SGOT, SGPT, ALP and GGT were 58.8 ( $\pm$  39.7), 63.3 ( $\pm$  41.8), 307.1 ( $\pm$  206.2) and 183.9 ( $\pm$  113.2) respectively among participants with choledocholithiasis. Raised SGOT was present among 77.8% of choledocholithiasis, raised ALP among 52.4% of the participants with choledocholithiasis, raised GGT among 58.8% of the participants. **Conclusion:** Parameters for suspected CBDs stones with positive association among gall stone disease patients are raised ALP, SGOT, GGT, GB morphology-contracted, GB stone morphology- multiple small stones, CBD diameter >6mm, Multiple episodes of pain abdomen and raised bilirubin (more than 2.1 mg/dl).

## INTRODUCTION

Choledocholithiasis or common bile duct (CBD) stone is characterized by the presence of stones in the bile duct. The most common form is secondary CBD stone: stones originate in the gallbladder, then migrate to the bile duct.<sup>[1]</sup> Management usually includes cholecystectomy (gallbladder removal);<sup>[2]</sup> this procedure is currently performed using a laparoscopic approach. CBD stones are suspected in symptomatic gallstone patients on the basis of relevant clinical manifestations, abnormal liver function test (LFT) results, or abnormal relevant imaging parameters.<sup>[3]</sup> CBD stones can cause severe lethal complications;<sup>[4]</sup> the current recommendation

is that all detected stones should be treated.<sup>[5]</sup> However, it is challenging to select the optimal investigation approach from the available options. The endoscopic retrograde cholangiography (ERC) has therapeutic potential but can cause morbidity or (rarely) mortality.<sup>[6]</sup> In contrast, intraoperative cholangiography (IOC) enables single-stage management (i.e., exploration combined with cholecystectomy).<sup>[7]</sup> Nevertheless, experienced surgeons and more specialized equipment are required for the treatment of CBD stones, particularly in the laparoscopic era.<sup>8</sup> In this context, guidelines, recommendations, and scoring systems have been constructed,<sup>[5,9-13]</sup> however, such resources generally were not designed exclusively for patients with

suspected CBD stones,<sup>[5,9,13]</sup> and they have questionable relevance in high-prevalence populations.<sup>[14,15]</sup> Notably, published scoring systems are not widely used.<sup>[10-12]</sup>

Gallstone-related disease refers to cases that are due to the presence of asymptomatic and symptomatic stones in the gallbladder or CBD presented with similar symptoms and/or complications.<sup>[16]</sup> Although the mortality rate of this disease is low, its high rate of complications imposes a financial burden. According to the results of studies, 21%–34% of CBD stones move spontaneously, and these stones increase the risk of pancreatitis or cholangitis if the distal duct is blocked. Given that biliary pancreatitis and cholangitis may be life-threatening conditions, it is generally recommended to remove the CBD stones.<sup>[17,18]</sup>

The aim of the present study was to predict accurately the presence of common bile duct stones (CBDs) among the cases of symptomatic gall stone disease by combined approach using easily available tools like clinical assessment, abdominal sonography and liver function tests.

## MATERIALS AND METHODS

The present study was conducted in the General Surgery Indoor (Victoria & Curzon Ward) & Outdoor registered patients, IPGMER & SSKM Hospital, Kolkata. All the patients visiting this hospital for treatment for gall stone disease under General Surgery Dept, IPGMER & SSKM Hospital, Kolkata (mostly from state West Bengal & allied area in eastern India) were included. 500 patients were included in the study.

### Inclusion Criteria-

- USG confirmed Symptomatic gall stone disease patients aged >12 year having baseline investigations
- Willingness of the patients to participate and comply with the study protocol

### Exclusion Criteria-

- Any patients with Hepatitis & Liver Disease
- Any patients Cholelithiasis with known haemolytic disorders, long term TPN Therapy and resection of Terminal ileum
- Any patient with confirmed CBD stone previously
- Any seriously ill patient
- Previous history of biliary surgery (Cholecystectomy etc)
- Clinical Jaundice/ Cholangitis
- Previous history of ERCP/ CBD canulation
- Patients with acute/chronic Liver disease contributing to derangement of LFT
- Pregnancy
- HIV & other immunocompromised state
- Unwillingness of the patients to participate and comply with the study protocol

## Methods

1. Radiologically-Ultrasonography confirmed symptomatic Gall stone patients in Surgical IPD / Surgical OPD are selected.
2. Evaluation of the patient as per inclusion and exclusion criteria.
3. Interview: to Discuss about participation & Informed consent with the study subject
4. History of present Illness: gall stone related
5. Clinical Examination: all system especially Abdominal (hepatobiliary)
6. Radiological tests: USG Whole abdomen- (including Hepato-biliary system)
7. Blood tests -Biochemical: Liver function test (including GGT) & Routine tests
8. Confirmation of presence of CBD stone in suspected cases based on study parameters by ERCP/MRCP/Endo US/ Operative finding
9. follow up the study subject for final outcome within specified time limit mentioned for this study
10. Filling up the printed questionnaire
11. Input of data in the master table and statistical analysis to find out the significant relation of the various parameters.
12. To find out any relation/association & compare them with previously done studies & to reach out any conclusion.

### Study design:

All the patients at Surgical Out Patient Department and Inpatient General Surgical Department with diagnosis of Gallstone Disease will undergo through evaluation in the form of detailed history taking and meticulous clinical examination, radiological examination and Pathological tests. Patients, who will fulfil the inclusion criteria and give consent, will be included in the study. Written informed consent will be obtained from all the patients after they are given a full explanation of the procedure, and they agree to participate in regular follow-up assessments. In our institution All the patients of symptomatic gall stone disease are evaluated by clinical examination, baseline radiological examination like Trans Abdominal USG and Blood tests (pathological & Haematological) and pre-operative investigations suggested by Anaesthesiology; those results are used in this study. After full assessment according to study design the patient with probability of CBD stones are evaluated with MRCP/ERCP/EUS according to convenience & availability. Negative (for CBDs) cases undergo cholecystectomy (open/laparoscopic) procedure under general anaesthesia. Positive (for CBDs) cases are planned for stone clearance by ERCP & staged cholecystectomy after achieving CBD clearance or CBD exploration (in failed / inappropriate for ERCP) as standard treatment modality. All the patients were followed up clinically in the OPD up to at least 3 months postoperatively if within the specified time period of the study. After putting all the required data from “case record form” in a Microsoft Excel sheet (master chart), with the help of computer software IBM SSPS version 21

these tables/ analysis has been made & relevantly discussed for each variable.

## RESULTS

**Table 1: Distributions of participants as per final diagnosis.**

Final diagnosis	Number	Percentage
Cholelithiasis	437	87.40
Choledocholithiasis	63	12.60
Total	500	100.0

12.60% had choledocholithiasis whereas, 87.40% had cholelithiasis.

**Table 2: Distribution of participants as per diagnosis and clinical history**

Clinical history	Diagnosis			P-value
	Cholelithiasis (n=437)	Choledocholithiasis (n=63)	Total (n=500)	
Jaundice (last 2 months)	129 (29.5%)	24 (38.1%)	153 (30.6%)	0.167
Cholangitis	28 (6.4%)	5 (7.9%)	33 (6.6%)	0.648
Pain abdomen & tenderness in right hypochondrium	310 (70.9%)	51 (81.0%)	361 (72.2%)	0.097
Multiple episodes of pain abdomen	85 (19.5%)	12 (19.0%)	97 (19.4%)	0.940
<b>CO-MORBIDITIS</b>				
H/O Hypertension	84 (19.2%)	12 (19.0%)	96 (19.2%)	0.974
H/O Diabetes Mellitus	103 (23.6%)	22 (34.9%)	125 (25.0%)	0.048

Overall and also among those with choledocholithiasis history of pain upper abdomen & tenderness in right hypochondrium was most common clinical history (72.2% and 81.0% respectively). Multiple episodes of pain abdomen found in similar % in both study group & is statistically not significant. History of jaundice

within last 2 months was present among 38.1% of the choledocholithiasis patients. Diabetes Mellitus was present among 34.9% of the choledocholithiasis patients compared to 23.6% among cholelithiasis patients. Among the clinical history noted, history of Diabetes Mellitus was statistically significantly associated with diagnosis.

**Table 3: Distribution of participants as per USG findings and Diagnosis**

	Diagnosis			P-value
	Cholelithiasis (n=437)	Choledocholithiasis (n=63)	Total (n=500)	
Contracted GB	35 (8.0%)	11 (17.5%)	46 (9.2%)	0.015
Large stone	201 (46.0%)	23 (36.5%)	224 (44.8%)	0.157
Multiple small stones	174 (39.8%)	24 (38.1%)	198 (39.6%)	0.794
GB sludge	60 (13.7%)	7 (11.1%)	67 (13.4%)	0.568
Dilated intrahepatic biliary radicles	102 (23.3%)	30 (47.6%)	132 (26.4%)	<0.001

Dilated intrahepatic biliary radicles were present among 47.6% of the participants with choledocholithiasis. Contracted GB was found in among 17.5% of choledocholithiasis patients. The USG findings and diagnosis were statistically significant.

**Table 4: Distribution of participants as per Diagnosis and CBD diameter**

CBD diameter	Diagnosis			P-Value
	Cholelithiasis	Choledocholithiasis	Total	
<4	122 (27.9%)	7 (11.1%)	129 (25.8%)	<0.001
4 – 6	253 (57.9%)	24 (38.1%)	277 (55.4%)	
>6	62 (14.2%)	32 (50.8%)	94 (18.8%)	
Total	437 (100.0%)	63 (100.0%)	500 (100.0%)	

Among choledocolithiasis participants, 11.1% had less than 4 mm CBD diameter, 50.8% had more than 6 mm CBD diameter.

**Table 5: Comparison of biochemical profile of the participants according to diagnosis**

Biochemical profile	Diagnosis [Mean (± Standard Deviation)]		P-value
	Cholelithiasis	Choledocholithiasis	
Serum Bilirubin	1.2 (± 0.8)	1.2 (± 0.9)	0.492
Serum SGOT	40.6 (± 27.9)	58.8 (± 39.7)	<0.001
Serum SGPT	49.8 (± 45.7)	63.3 (± 41.8)	0.027
Serum ALP	130.1 (± 89.2)	307.1 (± 206.2)	<0.001
Serum GGT	58.9 (± 43.2)	183.9 (± 113.2)	<0.001

The mean and standard deviation of serum SGOT, SGPT, ALP and GGT were 58.8 ( $\pm$  39.7), 63.3 ( $\pm$  41.8), 307.1 ( $\pm$  206.2) and 183.9 ( $\pm$  113.2) respectively among participants with choledocholithiasis.

**Table 6: Distribution of participants as per diagnosis and biochemical profile of the study participants**

Biochemical profile	Diagnosis			P-value
	Cholelithiasis (n=437)	Choledocholithiasis (n=63)	Total (n=500)	
Raised Bilirubin level (Jaundice)	65 (14.9%)	12 (19.0%)	77 (15.4%)	0.391
Raised SGOT level	230 (52.6%)	49 (77.8%)	279 (55.8%)	<0.001
Raised SGPT level	191 (43.7%)	36 (57.1%)	227 (45.4%)	0.045
Raised ALP level	206 (47.1%)	56 (88.9%)	262 (52.4%)	<0.001
Raised GGT level	237 (54.2%)	57 (90.5%)	294 (58.8%)	<0.001

Raised SGOT was present among 77.8% of choledocholithiasis, raised ALP among 52.4% of the participants with choledocholithiasis, raised GGT among 58.8% of the participants.

**Table 7: Predictive values of deranged biochemical profile among the study participants for a diagnosis of Choledocholithiasis**

Biochemical profile	Positive Predictive Value	Negative Predictive Value
Raised Bilirubin level (Jaundice)	15.58%	87.94%
Raised SGOT level	17.56%	93.67%
Raised SGPT level	15.86%	90.11%
Raised ALP level	21.37%	97.06%
Raised GGT level	19.39%	97.09%

Raised level of ALP documented best PPV in the study sample (21.37%). NPV of raised ALP and raised GGT both were high, and were comparable (97.06% and 97.09% respectively). In terms of both PPV and NPV raised serum bilirubin had lower values in this study sample of 500 participants.

## DISCUSSION

Choledocholithiasis, also known as CBD stones, are primary or secondary according to stone origin. Primary stones are formed in the bile duct and these stones are mainly composed of bilirubin and are probably associated with biliary stasis and infection. Secondary stones form in the gallbladder that moves into the CBD. In such cases, the biochemical composition of the CBD stones is quite similar to that of gallstones, which are mainly composed of cholesterol.<sup>19,20</sup> CBD stones may be asymptomatic or symptomatic and may be associated with symptoms such as colic pain, obstructive jaundice, cholangitis, and gallstone-induced pancreatitis.<sup>[21,22]</sup> 12.60% had choledocholithiasis whereas, 87.40% had cholelithiasis. Overall and also among those with choledocholithiasis history of pain upper abdomen & tenderness in right hypochondrium was most common clinical history (72.2% and 81.0% respectively). Multiple episodes of pain abdomen found in similar % in both study group & is statistically not significant. History of jaundice within last 2 months was present among 38.1% of the choledocholithiasis patients. The history of asymptomatic gallstones suggests that a large number of affected individuals will remain asymptomatic throughout life, and 10%–25% will develop symptoms such as colic. The annual risk of pain is 2%–3% and for severe complications is 1%–2%.<sup>[23]</sup> Acute Choledocholithiasis is an inflammation of the gallbladder caused by gallbladder obstruction. The disease should be suspected in patients with fever,

RUQ pain, or Murphy signs. In a morphological examination to confirm acute choledocholithiasis, the examiner touches the patient's right rib deeply with the right hand and asks the patient to take a deep breath. The sudden cessation of inspiration due to pain characterizes a positive “Murphy sign.” Patients with gallstone pancreatitis due to obstruction at the level of the edema sphincter are usually associated with epigastric pain.<sup>[24]</sup>

Diabetes Mellitus was present among 34.9% of the choledocholithiasis patients compared to 23.6% among cholelithiasis patients. Among the clinical history noted, history of Diabetes Mellitus was statistically significantly associated with diagnosis. Dilated intrahepatic biliary radicles were present among 47.6% of the participants with choledocholithiasis. Contracted GB was found in among 17.5% of choledocholithiasis patients. The USG findings and diagnosis were statistically significant. Among choledocholithiasis participants, 11.1% had less than 4 mm CBD diameter, 50.8% had more than 6 mm CBD diameter. The mean and standard deviation of serum SGOT, SGPT, ALP and GGT were 58.8 ( $\pm$  39.7), 63.3 ( $\pm$  41.8), 307.1 ( $\pm$  206.2) and 183.9 ( $\pm$  113.2) respectively among participants with choledocholithiasis. Pancreatitis, inflammation of the pancreas, can cause amylase and lipase levels to increase up to 3 times normal. Elevated values of serum alanine aminotransferase level (ALT) indicate that the origin of pancreatitis may be gallstones. The amount of bilirubin and white blood cells can be normal or abnormal, depending on the location and severity of the blockage and the amount of infection. Leukocytosis is also common in acute choledocholithiasis where total bilirubin is usually normal or slightly elevated, unless in co-choledocholithiasis.<sup>[24]</sup>

However, when considering LFTs which had been examined within 7 days before the reference tests, a large number of CBD stone “absent” patients still had

LFTs abnormalities. LFTs may take several weeks to return to normal, especially among patients with prolonged and high degree of obstruction.<sup>[25]</sup> Raised SGOT was present among 77.8% of choledocholithiasis, raised ALP among 52.4% of the participants with choledocholithiasis, raised GGT among 58.8% of the participants. Raised level of ALP documented best PPV in the study sample (21.37%). NPV of raised ALP and raised GGT both were high, and were comparable (97.06% and 97.09% respectively). In terms of both PPV and NPV raised serum bilirubin had lower values in this study sample of 500 participants.

## CONCLUSION

Parameters for suspected CBDs stones with positive association among gall stone disease patients are raised ALP, SGOT, GGT, GB morphology-contracted, GB stone morphology- multiple small stones, CBD diameter >6mm, Multiple episodes of pain abdomen and raised bilirubin (more than 2.1 mg/dl). Parameter with good negative predictive value for CBD stones are Normal liver enzymes (SGOT, SGPT, ALP, GGT).

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