



“STUDY OF PREDICTORS OF COMMON BILE DUCT STONES IN PATIENTS ADMITTED FOR CHOLECYSTECTOMY”

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“Abstract”

Risk scoring system based on the derangement in clinical, biochemical and radiological parameters helps significantly in predicting the chances of synchronous CBD stones which are not detected by ultrasonography alone, thus avoiding postoperative complications due to missed CBD stones.

Materials and Methods:

This prospective study was conducted in the Department of Surgery, Jaipur Golden Hospital, New Delhi, India from October 2007 to October 2009. All patients of upper abdominal pain admitted as routine or emergency cases underwent ultrasound study of the abdomen to rule out gallstone disease.

In a known case of gallstone disease, suspicion of CBD stone was based on (A) history and clinical features, (B) biochemical tests and (C) ultrasonographic findings. Those patients of gallstone disease with absent risk factors (i.e. clinical, biochemical or radiologic) and those with obvious CBD stones on the ultrasound were excluded from the study.

Results:

1. History of jaundice, raised serum levels of liver function tests (Serum bilirubin >1.5mg% and AST, ALT and Serum Alkaline phosphatase greater than upper limits of normal in combination) or individually Serum bilirubin >1.5mg%, ALT greater than three times the

upper limit of normal, Serum Alkaline phosphatase greater than three times the upper limit of normal and CBD size >7mm on ultrasound are the statistically significant predictors of CBD stones in patients of gallstone disease admitted for cholecystectomy.

Conclusions;

Patients with Risk score 1 and 2 should be subjected to MRCP to confirm CBD stones before cholecystectomy as it is noninvasive. Risk score 3 patients should be subjected to ERCP before cholecystectomy due to higher chances of CBD stones in these patients and to get the best out of the endoscopic management of CBD stones.

Key words:

AMY: Serum amylase, AST: Aspartate aminotransferase, ALT: Alanine aminotransferase, ALK PHOS: Serum alkaline phosphatase, BIL: Serum total bilirubin

Background:

CBD stones complicate the workup and management of cholelithiasis, necessitate additional diagnostic and therapeutic procedures and add to the morbidity and mortality of gallstone disease. Several diagnostic modalities are available and these are best divided into preoperative and intraoperative studies.

Obstruction of the CBD by gallstones leads to symptoms and complications that include pain, jaundice, cholangitis, pancreatitis and sepsis. Approximately 11% of patients with gallbladder stones have associated CBD stones at the time of cholecystectomy and the incidence may climb to 18% in older patients who have had gallstones for a longer period of time.² A single abnormal laboratory value does not confirm the diagnosis of CBD stones, rather a coherent set of laboratory and radiological studies leads to the correct diagnosis. WBC count elevations indicate the presence of infection or inflammation. Serum bilirubin level elevations indicate obstruction of the CBD: higher the bilirubin level greater is the predictive value. CBD stones are present in approximately 60% of patients with serum bilirubin levels greater than 3 mg/dl. Serum amylase and lipase values are

elevated in the presence of acute pancreatitis complicating choledocholithiasis. Serum Alkaline phosphatase and Gamma-glutamyl transpeptidase levels are elevated in patients with obstructive choledocholithiasis. Liver transaminases are elevated in patients with CBD stones complicated by cholangitis, pancreatitis or both.

Ultrasound is a noninvasive, inexpensive and readily available modality for assessment of the biliary tree. The detection of CBD stones by ultrasound may be impeded by the presence of gas in the duodenum, possible reflection and refraction of the sound beam by curvature of the duct and the location of the duct beyond the optimal focal point of the transducer. On the other hand CBD dilatation is identified accurately with up to 90% accuracy.

Direct coronal T2-weighted imaging readily available with MRI easily identifies common bile duct stones. MRCP provides excellent anatomic details of the biliary tract and has a sensitivity of 95% and a specificity of 98% in detecting CBD stones.³ MRCP however can miss CBD stones of less than 5mm in diameter. Cost, inconvenience and limitations (obesity, presence of metal objects e.g. pacemakers) are some of its disadvantages.

ERCP was introduced in the early 1970's and has become the diagnostic and therapeutic tool of choice in patients with CBD stones. The success rate of ERCP in cases of CBD stones is 85% to 92% in experienced hands⁵. In a systemic survey of prospective studies the complications of ERCP occurred in 6.85% of the cases. These included bleeding (1.34%), perforation (0.6%), infections (1.44%), pancreatitis (3.47%), and an overall mortality rate of 0.33%¹.

Operative cholangiography was introduced by Mirizzi in Argentina in 1932. Cholangiography remains the most reliable test for the diagnosis of CBD stones, but its invasive nature, associated morbidity and cost preclude it from being the screening test of choice. Routine Intraoperative Cholangiography (IOC) during a cholecystectomy is an area of much debate. Older patients have a higher incidence of CBD stones and thus it is particularly important to use Operative cholangiography routinely when operating upon elderly patients. IOC findings have a significant predictive value for the detection of CBD Stones. The procedure can fail due to (1) inability to cannulate the cystic duct; (2) leakage of contrast during the injection; (3) air bubbles mimicking stones; (4) contrast flowing too quickly into the duodenum preventing proper filling of the biliary tree and (5) spasm of the Sphincter of Oddi. It has the disadvantage that there is possibility of an allergic reaction to iodinated contrast and the hazard of radiation to the patient.

Recent times have thrown in a fair share of controversy in the management of CBD stones both due to technological innovations and cost-reduction pressures. Thus the aim in choledocholithiasis as in any benign disease is to discover a therapeutic algorithm with minimal morbidity, no mortality and should be

available at a reasonable cost.

Aim and objectives:

1. To define a simple and an accurate predictive model to detect synchronous common bile duct stones in patients admitted for cholecystectomy.
2. To assess the usefulness of MRCP in low risk group and that of ERCP in Moderate risk and High risk groups.

Data Collection Techniques and Tools:

Inclusion criteria:

1. Fifty patients of gallstone disease with suspected CBD stones were chosen for the study.
2. Eligible patients of all age groups and of either sex were subjected to the study.

Exclusion criteria:

1. Gallstone disease patients already diagnosed with CBD stones.
2. Post-cholecystectomy patients with retained CBD stones.

Assessment of risk score:

These patients admitted with gallstone disease were evaluated on the basis of the presence of any derangement in each of the above parameters i.e. clinical, biochemical and ultrasound findings. We would designate one point to each of the above criteria. Presence of more than one individual criterion under each parameter would still be considered as one point. Thus, Risk score 1 patient has 1 criterion (either of clinical, biochemical or ultrasonographic) present, Risk score 2 patient has 2 criteria present and Risk score 3 patient has all the 3 criteria present. MRCP was done on low risk patients, ERCP was done on moderate and high risk patients and Intraoperative

cholangiography (IOC) was done on patients with failed ERCP.

Definition of predictors:

- 1 .Age is evaluated as a dichotomous variable (>55years versus <55 years).
2. Jaundice is defined as yellowish discoloration of skin, conjunctiva and other mucous membranes caused by hyperbilirubinemia.
3. Pancreatitis is defined as inflammation of pancreas that is characterized by epigastric pain radiating to back and raised serum amylase and lipase greater than three times the normal.
4. Cholangitis is infective inflammation of common bile duct secondary to CBD stones and causes pain, fever and jaundice.
5. Bilirubin is raised if >1.5 mg% (Normal lab range up to 1.1)

6. Serum AST is raised if >37 U/L (Normal lab range 15 - 37)
7. Serum ALT is raised if >65 U/L (Normal lab range 30 - 65)
8. Serum ALP is raised if >136 U/L (Normal lab range 50 - 136)
9. Serum Amylase is raised if >230 U/L (Normal lab range 25-115)
10. Dilated CBD >7 mm in diameter on ultrasound.

Statistical Analysis:

Statistical analysis is performed using the Chi-square test and Fisher’s exact test as per the situations to determine the p- value of the predictors of common bile duct stones. All predictors were analyzed whether significant or not.

In this study the “Epi info SPSS” software of WHO was used for statistical analysis.

Observations:

Chart-I

Distribution according to the age groups of the patients

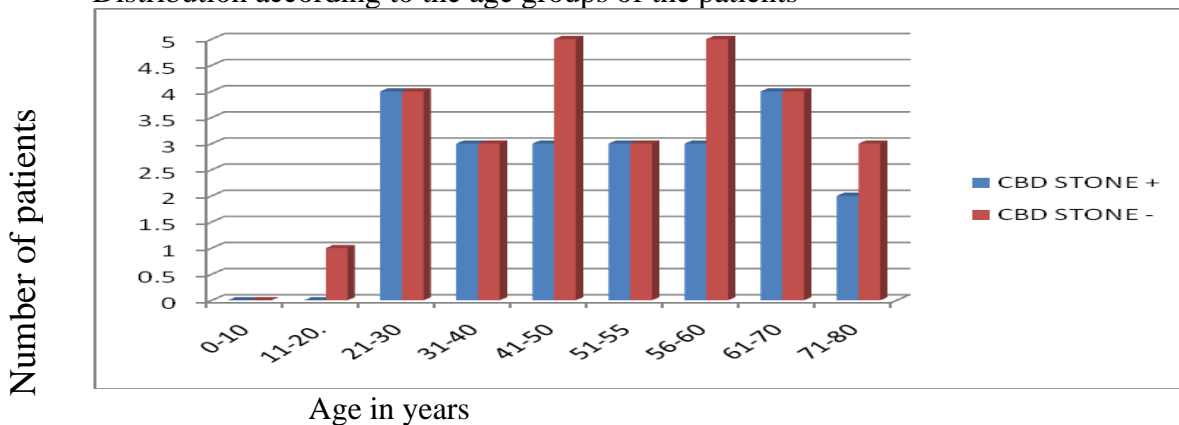
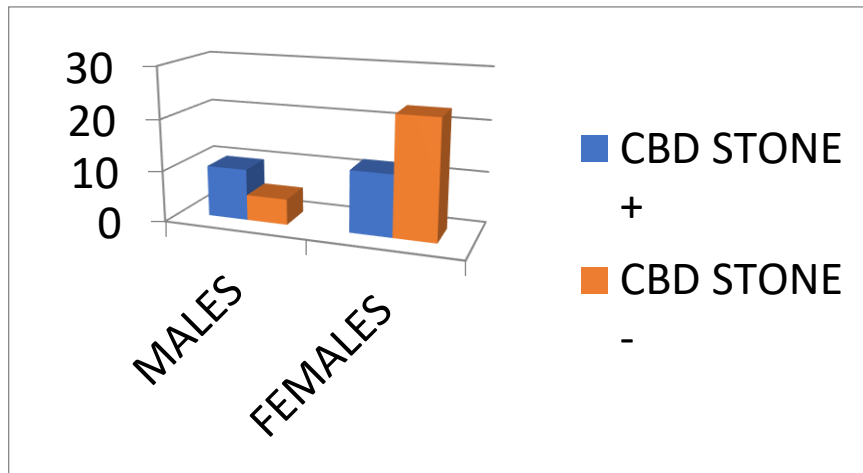


Chart-II

Distribution according to gender of the patients

Number of Patients

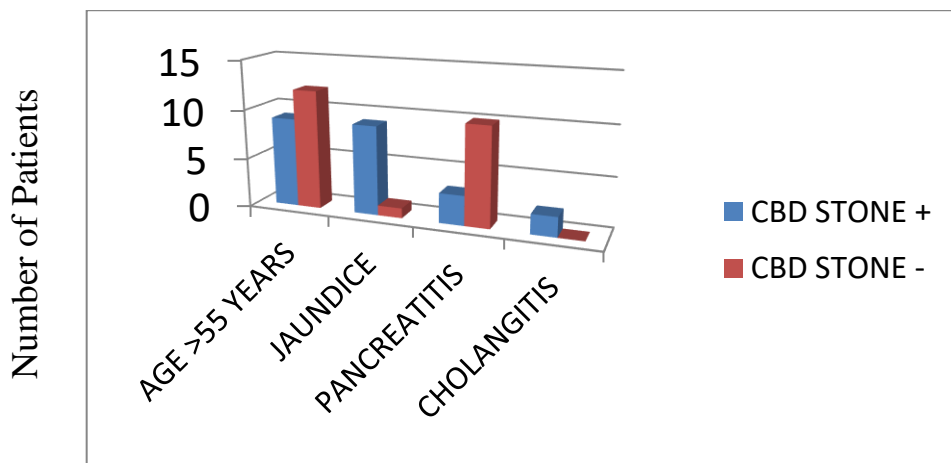


Gender of Patients

Out of the 50 cases 15 (30%) were males and 35 (70%) were females. CBD stone was present in 10 (66%) male patients and 12 (34%) female patients.

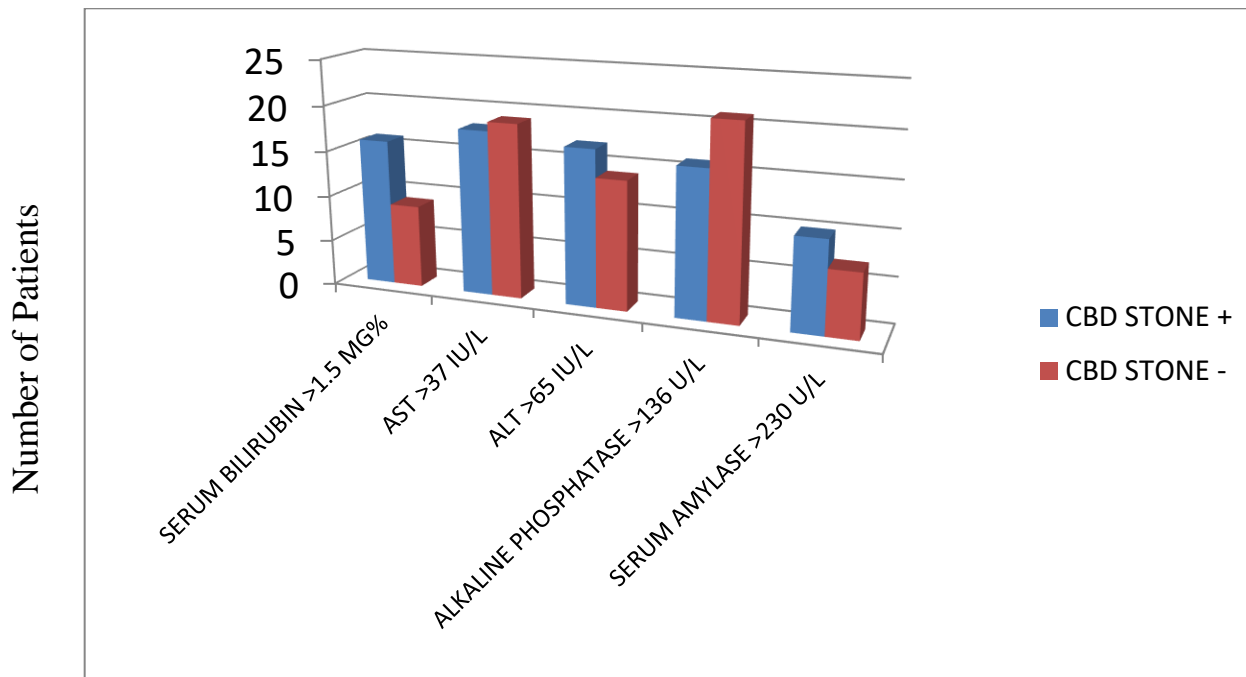
Chart-III

Distribution according to the clinical predictors



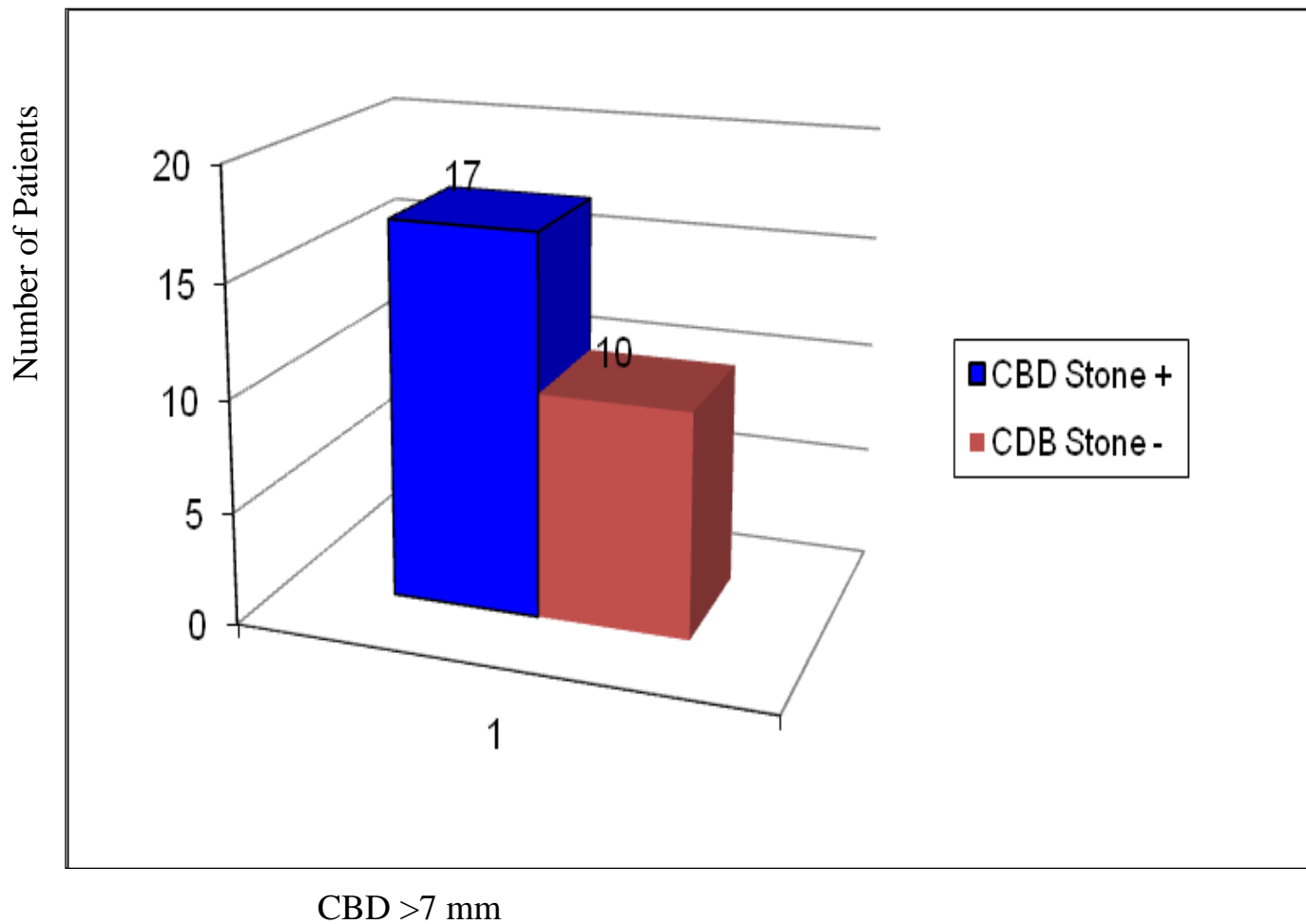
Clinical Predictors

Chart-IV
Distribution according to biochemical predictors



Biochemical Predictors

Chart-V
Distribution according to ultrasound finding of CBD >7mm



Results:

The maximum number of cases of CBD stone were present in the age group of 21-30 (8%) and 61-70 (8%), (Chart No.1). In our study, the mean age of patients with CBD stone was 50.04%. Age >55 years did not prove to be a statistically significant predictor in our study which may be due to the small study number.

Cholangitis was present in 2 patients and both of them (100%) had CBD stone (Chart No. III). The results of the clinical parameters in our study were comparable to the quoted studies, however individually only the history of jaundice proved to be a statistically significant predictor (p-value 0.001) in our study of 50 patients which may be due to small study number.

Liver function tests (S. Bilirubin, AST, ALT, Serum Alkaline Phosphatase) can be used to predict CBD stones. In our study serum bilirubin levels of more than 1.5mg% was present in 25(50%) patients and out of these 16 (64%) patients had CBD stone having the sensitivity of 68.2%, specificity of 67.9%, positive predictive value of 62.5% and a significant p value (0.011). AST more than 37 IU/L was present in 37 (74%) patients and out of these 18 (48.6%) patients had CBD stone leading to a sensitivity of 81.8%, specificity of 32.1% and positive predictive value of 48.6% for detecting CBD stones. ALT greater than 65 IU/L was present in 33 (66%) patients and out of these 17 (54.83%) patients had CBD stone leading to a sensitivity of 77.3%, specificity of 42.9% and positive predictive value of 51.5% for detecting CBD stone. Serum Alkaline Phosphatase greater than 136 U/L was present in 37 (74%) patients and out of these 16 (43.2%) patients had CBD stone leading to a sensitivity of 72.7% , specificity of 28.6% and positive predictive value of 44.4%. Serum amylase

level greater than 230 IU/ L was present in 17 (34%) patients with CBD stone in 10 (58.8%) having the sensitivity (45.5%), specificity (75%) and positive predictive value (58.8%) in detecting CBD stones. (Chart No. IV).

All the four components of LFT (S.Bilirubin, AST, ALT and S. ALP) were raised in 21 (42%) patients out of these 15 (71.42%) patients had CBD stones leading to a sensitivity of 68.2% and increase in specificity to 78.6% and positive predictive value to 71.4% and a significant p-value (0.002).

Thus the biochemical predictors which were statistically significant in our study are Serum Bilirubin >1.5 mg% (p- value 0.011) individually and raised LFT (S.Bilirubin >1.5 mg%, AST >37 IU/L, ALT >65 IU/L, S.ALP >136U/L) combined with p- value (0.002).

The predictive value of biochemical parameters in our study increased after raising the cut-off values. Thus, the predictive value of S. Bilirubin >2 times the upper limit of normal, AST >2 times the upper limit of normal, ALT >3 times the upper limit of normal and Serum Alkaline Phosphatase >3 times the upper limit of normal produced a positive predictive value of 73.3%, 51.6%, 60.9% and 81.8% respectively. The cumulative positive predictive value of all the four elevated liver function variables was 66.9%. Out of these ALT >3 times the upper limit of normal produced statistically significant p-value (0.027) and Serum Alkaline phosphatase >3 times the upper limit of normal also produced statistically significant p- value (0.004). Our observations were comparable with the quoted literature.

CBD size of greater than 7mm was present in 27 (54%) patients and out of these 17

(62.96%) patients had CBD stones. It had the sensitivity of 77.3%, specificity of 60.7% and a positive predictive value of 60.7% for detecting CBD stones (Chart No. V). In our study also CBD size >7mm is statistically significant for detecting CBD stones (p- value 0.007).

In our study MRCP was done in 7 patients of risk score 1. Only one patient from low risk category had evidence of CBD stone. However statistical significance of MRCP as the diagnostic test for CBD stones may not be reproduced in our study as we had only 7 patients in Risk score 1 who underwent MRCP. A larger study number may be required to confirm the accuracy of MRCP in detecting CBD stones. However considering the high efficacy of MRCP in detecting CBD stones as per the available literature and considering its noninvasive nature we recommend MRCP for detecting CBD stones in Risk Score 1 patients.

In our study ERCP was done in 41 (82%) patients and out of these CBD stone was retrieved in 20 (48.78%) patients. Out of the 28 (56%) patients of Risk score 2 ERCP was done in 28 patients and out of these CBD stones were confirmed in 11 patients which were successfully removed. Out of 15(30%) patients of the Risk score 3 ERCP was attempted in 14 patients and out of those 14 patients CBD could not be cannulated in 2 patients. In rest of the 12 patients ERCP was successfully completed and CBD stones were detected and were successfully removed in 8 patients. In those 2 patients in whom CBD could not be cannulated, intraoperative cholangiogram was done by cannulating cystic duct which detected CBD stone in both. CBD exploration was done in same sitting and stones were successfully removed. However the remaining one patient in high

risk category did not give consent for ERCP. This patient was subjected to intraoperative cholangiography which was not suggestive of any CBD stone. The main complications of ERCP i.e. clinical pancreatitis in about 2% and cholangitis in about 1% of patients were managed conservatively.

Considering the observations, we recommend MRCP in Risk score 2 patients to decrease the chances of complications associated with negative ERCP.

In Risk score 3 patients where the chance of CBD stones is considerably high ERCP is advised to get the best out of the endoscopic management of CBD stones.

In our study to confirm CBD stones, intraoperative cholangiogram was obtained in total of 3 (6%) patients. IOC helped in confirming the presence of CBD stones in 2 patients of high risk category in which ERCP failed and CBD stones were detected. One patient of high risk category had not given consent for ERCP and in this patient IOC did not detect any CBD stone.

To summarize, out of the 50 patients of suspected CBD stones in our study 7 (14%) patients were of Risk score 1 out of which CBD stone was present in only 1 (14.28%) patient, 28 (56%) patients were of Risk score 2 out of which CBD stones were detected in 11 (39.28%) patients and 15 (30%) patients were of Risk score 3 out of which 10 (66.66%) patients had CBD stones, (Table VI). Thus the chances of having synchronous CBD stones in gallstone disease patients are highest when all the three risk factors are present.

Our observation is in accordance to Chung chin et al¹⁷ in whose study CBD stones in the low risk group was 7%, that in the intermediate group was 36.4% and in the high risk group was 78.9%.

Also, Kim KH et al¹⁹ found the low risk group patients in which the CBD was not dilated and the prevalence of CBD stones was 1.5%, the moderate risk group patients in which there was a dilated CBD with normal liver function tests and a prevalence of stones of 48.8%, and the high risk group in which there was a dilated CBD and abnormal liver function tests and the prevalence of stones was 66.7%. A similar study with larger case number may be required to reproduce the efficacy of the predictors.

Conclusions:

1. History of jaundice with gallstone disease, deranged liver function tests and CBD size >7mm on ultrasound are the statistically significant predictors of CBD stones in our patients of gallstone disease.
2. Risk scoring system based on the derangement in clinical, biochemical and radiological parameters helps significantly in predicting the chances of synchronous CBD stones which are not detected by ultrasonography alone, thus avoiding postoperative complications due to missed CBD stones.
3. As there are minimal chances of having CBD stones in Risk score 1, such patients should be subjected to MRCP as it is noninvasive.
4. In Risk score 2 patients it is better to confirm CBD stones with MRCP as compared to ERCP to avoid the complications of negative ERCP.
5. In patients of high risk group where there is high chance of having CBD stone we should prefer ERCP as a combined diagnostic and therapeutic

modality to get the best out of endoscopic management of CBD stones prior to Cholecystectomy.

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