

Original Research Article

Comparison of pre-operative ultrasonography and magnetic resonance cholangiopancreatography with intra-operative surgical findings among patients suspicious to choledocholithiasis

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ABSTRACT

Background: Choledocholithiasis with cholelithiasis is a common problem in the middle and older age group people. Aim of this study is to assess the usefulness of ultrasonography in the diagnosis of choledocholithiasis in resource poor set up.

Methods: After matching the inclusion and exclusion criteria, all cases of diagnosed choledocholithiasis were taken for this prospective, single center, observational study.

Results: Out of total 130 subjects, 41 were male and 89 were female. Increased incidence of choledocholithiasis was found in females (M:F=1:2.08). The mean age of presentation was 49.27 ± 10.60 years. Ultrasonography was able to diagnose common bile duct (CBD) stones in 57 patients (43.84%) and ductal dilatation in 89 (68.46%). Whereas, magnetic resonance cholangiopancreatography (MRCP) detected CBD stones in 112 (86.15%). Cholelithiasis was associated with choledocholithiasis in 108 patients (83.07%).

Conclusions: In the evaluation of choledocholithiasis, in our study particularly trans-abdominal ultrasonography (USG) seemed to have a lower yield than expected for accuracy in determining choledocholithiasis when compared to MRCP and Intra-operative findings. So, a negative USG in a particular may not exclude choledocholithiasis. So, MRCP is the 'investigation of choice' among the suspicious patients for CBD stone disease. That is why prior to cholecystectomy in symptomatic patients with deranged liver function test, MRCP always to be done, to detect the missed stone in CBD.

Keywords: Choledocholithiasis, Ultrasonography, MRCP, Obstructive jaundice

INTRODUCTION

Choledocholithiasis with cholelithiasis is a common problem in middle and older age group of our society both in rural and urban areas. The occurrence of choledocholithiasis in patients with cholelithiasis varies from 5% to 15%, among only them 5% are symptomless.^{1,2} Though biliary calculus formation is seen in all age groups, but it is the 'fat, flatulent, fertile, female of fifty' who are commonly affected. Number of

documented cases of choledocholithiasis is continuously increasing in the developing countries owing partly to the availability of improved imaging facilities.³ The majority of common bile duct stones is formed within the gallbladder and then migrates down through the cystic duct to common bile duct.⁴ According to the site of formation of common bile duct stones, it is of two types; primary stones (found rarely) which is formed in bile duct and secondary common bile duct (CBD) stones, which passes into the common bile duct through cystic

duct. Studies have shown that the biliary tract stones were complicated by concomitant gallstones in 15-20% of patients.⁵ It was estimated that 3-33% of all patients with symptomatic cholelithiasis harbor concomitant CBD stones and in 4% to 20% subjects, CBD stones are detected incidentally during cholecystectomy.⁴ The incidence of choledocholithiasis in patients with cholelithiasis increases with age. Cholelithiasis is also more common in those with high serum lipid levels. Obese patients, subjects with low physical activity, patients with recent weight loss are found to have cholesterol stones. Black pigment stones are mainly seen in subjects with cirrhosis of liver, total parental nutrition recipients, and in patients with ileal resection. Brown pigment primary common bile duct calculus has nucleating factors, such as bacteria, as their source.⁶

Usually patients may complain of colicky pain, intermittent jaundice, pruritus, vomiting and dyspepsia. But these choledocholithiasis patients may develop some serious complications like cholangitis and acute pancreatitis and are associated with high morbidity and mortality. So, early detection and management of choledocholithiasis are essential. The detection of choledocholithiasis is usually done in clinically suspected patient by biochemical analysis (raised conjugated bilirubin, alkaline phosphatase (ALP) and gamma-glutamyl transpeptidase level) and with the help of certain imaging modalities. Diagnostic imaging tests for choledo-choolithiasis include trans-abdominal ultrasonography (USG), magnetic resonance cholangiopancreatography (MRCP), multi detector computed tomography (MDCT), cholangiography, endoscopic ultrasonography (EUS) and endoscopic retrograde cholangiopancreatography (ERCP).

Trans-abdominal USG is the most commonly used primary imaging modality. It is non-invasive, widely available, low cost, non-ionizing radiation imaging technique. Specificity of USG to detect common bile duct stone is up to 95%.⁷ But it is operator dependent, and it has a limitation in patients those with large amount of bowel gas and obesity. Trans-abdominal ultrasonography scans and liver function tests fail to accurately identify common bile duct calculus. MRCP is the next imaging modality in case of any uncertainty with USG. MRCP was introduced by Wallner et al.⁸ They used the rapid sequence gradient echo acquisition with three-dimensional post processing technique to evaluate the biliary system. MRCP has providing high resolution images of biliary tree non-invasively and does not require any contrast media.⁹ Presently, MRCP is being considered as more accurate and convenient imaging method for the diagnosis of choledocholithiasis.¹⁰

After confirming the diagnosis of choledocholithiasis, the prime modalities of treatment of common bile duct stones are ERCP extraction (in selected cases) or exploration of common bile duct by laparoscopic or open surgical approach. When endoscopic technique failed or not

feasible for the patient, choledochotomy is the best mode of treatment either by open approach or laparoscopic method. Many factors that have determined the optimal approach include variables such as disease status, unavailability of radiological facility and endoscopic and surgical expertise, patient's demographic and health care economics.

The aim of the present study is to compare the diagnostic efficacy between USG, MRCP with intra-operative findings in detection and characterization in patients with choledocholithiasis. So that, USG can be effectively used in resource poor setting where intra-operative cholangiogram or ERCP facilities are not available. In this study, the common hepatic duct and the common bile duct were considered as one structure, the common duct. The common duct is dilated when the caliber is 8 mm and more. The diagnosis of choledocholithiasis was made when an intraluminal echogenic focus with acoustic shadowing was demonstrated.¹¹

In this study, intra-operative demonstration of CBD stones and duct diameter was considered the "gold standard". In this study evaluation of the results of USG and MRCP and their correlation with surgical findings of choledocholithiasis were assessed. The sensitivity, specificity and predictive values of USG and MRCP as preoperative investigation were also evaluated.

METHODS

This is an institution based (single center) prospective, observational hospital based, comparative, cross sectional study. The study included 130 patients, who attended OPD from March 2018 to August 2019 in general surgery department of BSMCH Medical College. They were suspected of having choledocholithiasis (on the basis of any of the following parameters such as pain at right hypochondrium and epigastric area, intermittent jaundice status of post biliary pancreatitis, total bilirubin >1.2 mg/dl and ALP >220 IU/l, CBD stone suspected or diagnosed at sonography, CBD diameter at sonography >7 mm, CBD diameter at MRCP >7 mm or CBD stone suspect/ diagnosed at MRCP).

All cases of obstructive jaundice where the cause proved to be other than CBD stones were excluded from the study.

Inclusion criteria for this study were as both male and female individuals of age more than 11 years, who themselves or their legal guardians consented for surgery and do not like to undergo ERCP.

Subjects should be fit to receive general anaesthesia.

Exclusion criteria were patients less than 11 years, who are willing to undergo ERCP and unfit for general anaesthesia. Patients with contraindication to perform MRI were also excluded.

Study procedure

All the patients presented with pain at right hypochondrium and epigastric region, intermittent jaundice with or without fever, history of previous biliary pancreatitis were subjected to blood tests. Liver function test and trans-abdominal USG were done. Those with no positive finding suggestive of choledocholithiasis were excluded from the study. The subjects with dilated CBD (>7 mm) with or without CBD calculus, with increased total bilirubin level and increased ALP level were considered for the study. All of them were evaluated with MRCP study. Those with choledocholithiasis on MRCP were directly taken for CBD exploration.

All those who were negative for CBD calculus on MRCP were taken for open cholecystectomy and CBD palpation was done intraoperatively. Subjects having CBD calculus on palpation got their CBD explored. The subjects who were negative for CBD calculus both on MRCP and palpation were subjected to cholecystectomy only. Parameters such as age, Gender, severity of obstructive jaundice, Characteristics of the CBD stones (present or absent), position of stones (proximal or distal or ampullary), number of stones (single or multiple) and dilatation of CBD (<7 mm or ≥7 mm), size of stones were also studied.

Questionnaire for interview or proforma or checklist for clinical examination to collect baseline data, biochemical reports, and reports of ultrasonography and MRCP study were used as study tools.

The statistical analysis was carried out using available standard statistical software (SPSS-23). Odds ratio with 95% confidence interval (CI) and multivariate analysis has used establish the interrelationships between pre-operative and intra operative findings. All statistical tests have two tailed and p value <0.05 has taken as significant.

RESULTS

Patients' demographics

The study comprised 130 patients with suspected to choledocholithiasis who underwent Liver function test, Trans-abdominal USG and MRCP. Age distribution in the present study was found to be from 25 yrs to 71 yrs, the mean age of patients was 49.27±10.60 years, out of 130 patients, 89 patients were female and 41 patients were male, the ratio of male: female was 1:2.08.

Table 1 shows common bile duct stones are more common in female than male and male:female ratio is 1:2.08. This table reveals age specific distribution of choledocholithiasis among study participants, female were more than male in each group of age and the disease is common in 41-50 age group. The mean age is 49.27±10.60 yrs (range 25-71 yrs).

Table 1: Distribution of participants according to gender and present of CBD stone (n=130).

Characteristics	N (%)	N (%)	N (%)
Sex	CBD stone found (+)	CBD stone not found (-)	Total
Male	37 (28.46)	04 (3.08)	41 (31.54)
Female	77 (59.23)	12 (9.23)	89 (68.46)
Total	114 (87.69)	16 (12.31)	130 (100)
Age group (in years)	Male	Female	Total
21-30	03 (02.30)	09 (06.92)	12 (09.0)
31-40	04 (03.08)	10 (07.69)	14 (11.0)
41-50	16 (12.30)	35 (26.92)	51 (38.9)
51-60	10 (07.70)	21 (16.16)	31 (24.0)
>60	08 (06.16)	14 (10.77)	22 (17.1)
Total	41 (31.54)	89 (68.46)	130 (100)

Table 2 shows mean total bilirubin level is 3.50±1.36 mg/dl (range 1.02-7.04). Serum total bilirubin level was raised above 1.21 mg/dl except one case bilirubin is 1.02 mg/dl. Mean ALP level is 381.56±219.684 IU/l (range 156.04 -1304.15) in this study. 96 out of 130 serum alkaline phosphatase level were >235 IU/l.

Table 3 shows trans-abdominal USG detected only 43.85% CBS stones. 112 out of 130 (86.15%) CBD stones detected by MRCP. 114 out of 130 (87.69%) CBD stones detected during Intra-operative period.

Table 4 shows, choledocholithiasis CBD were dilated due to obstruction. Distal CBD stones are most common and Ampullary stones detection by MRCP is significant.

Table 5 shows, CBD stones detection by MRCP (84.61%) was very high almost near to gold standard (87.69%) but by USG it was low only 43.08%.

Table 6 shows, that results of the test i.e., USG significantly differ from the truth i.e., intra-operative findings. It means that the test USG didn't seem to be suitable for diagnosing the disease in question.

The sensitivity of USG was 49.12%, specificity was 93.75%, positive predictive value was 98.25% and negative predictive value was 20.55%.

The sensitivity of the test USG reflected that the test seemed to be weak in detecting the disease in question ie, too many false negative would be produced by the test. For an emergency surgical problem like choledocholithiasis it couldn't be the 'investigation of choice'. As there is very effective treatment is available for choledocholithiasis we are not ready to tolerate so much false negativity of the diagnostic which missed so many cases.

Table 2: Distribution of participants as per total bilirubin level and CBD stones findings.

Age group (in years)	Gender	N (%)	N (%)	N (%)	N (%)	N (%)
		<2.41 mg/dl	2.41-4.6 mg/dl	>4.6 mg/dl	Total	CBD stone found
21-30	Male	1 (0.77)	3 (2.31)	1 (0.77)	5 (3.85)	3 (2.63)
	Female	5 (3.84)	-	4 (3.08)	9 (6.92)	7 (6.14)
31-40	Male	2 (1.54)	-	-	2 (1.54)	3 (2.63)
	Female	4 (3.08)	8 (6.15)	2 (1.54)	14 (10.77)	10 (8.77)
41-50	Male	3 (2.31)	8 (6.15)	7 (5.38)	18 (13.84)	16 (14.04)
	Female	8 (6.15)	18 (13.85)	4 (3.08)	30 (23.08)	29 (25.44)
51-60	Male	-	6 (4.62)	4 (3.08)	10 (7.70)	8 (7.02)
	Female	5 (3.85)	7 (5.38)	8 (6.15)	20 (15.38)	19 (16.67)
>60	Male	-	1 (0.77)	5 (3.64)	6 (4.61)	6 (5.26)
	Female	2 (1.54)	3 (2.31)	11 (8.46)	16 (12.31)	13 (11.40)
Total		30 (23.08)	54 (41.54)	46 (35.58)	130 (100)	114 (100)

Distribution of participants as per serum ALP level with CBD stone findings.						
		<235 IU/l	≥235 IU/l	Total	CBD stone found	
		N (%)	N (%)	N (%)	N (%)	
21-30	Male	2 (1.54)	1 (0.77)	3 (2.31)	3 (2.63)	
	Female	3 (2.31)	6 (4.62)	9 (6.92)	7 (6.14)	
31-40	Male	2 (1.54)	5 (3.85)	7 (5.39)	3 (2.63)	
	Female	2 (1.54)	9 (6.92)	11 (8.46)	10 (8.77)	
41-50	Male	3 (2.31)	8 (6.15)	11 (8.46)	16 (14.04)	
	Female	12 (9.23)	24 (18.46)	36 (27.69)	29 (25.44)	
51-60	Male	2 (1.54)	8 (6.15)	10 (7.69)	8 (7.02)	
	Female	5 (3.84)	16 (12.31)	21 (16.16)	19 (16.67)	
>60	Male	2 (1.54)	6 (4.62)	8 (6.15)	6 (5.26)	
	Female	1 (0.76)	13 (10.00)	14 (10.77)	13 (11.40)	
Total		34 (26.15)	96 (73.85)	130 (100)	114 (100)	

Table 3: Distribution of participants as per CBD stones detected by USG (transabdominal), MRCP and CBD stones detected during intra-operative period.

Variables	USG		Total
	Stone detected in CBD	Stone not detected in CBD	
Sex	N (%)	N (%)	N (%)
Male	18 (13.85)	23 (17.69)	41 (31.54)
Female	39 (30.00)	50 (38.15)	89 (68.46)
Total	57 (43.85)	73 (56.15)	130 (100)
Gender	MRCP		Total
	CBD stone present	CBD stone absent	
Male	36 (27.69)	5 (3.85)	41 (31.54)
Female	76 (58.46)	13 (10.00)	89 (68.46)
Total	112 (86.15)	18 (13.85)	130 (100)
Gender	Intra-operative		Total
	CBD stone present	CBD stone absent	
Male	36 (27.69)	05 (3.85)	41 (31.54)
Female	78 (60.00)	11 (8.46)	89 (68.46)
Total	114 (87.69)	16 (12.31)	130 (100)

Table 7 shows that result of the test i.e., MRCP not significantly differ from the truth i.e., intra-operative findings. It means that the test MRCP seemed to be suitable for diagnosing the disease.

The sensitivity of MRCP was $(110/114) \times 100 = 96.491\%$, specificity was $(14/16) \times 100 = 87.500\%$, positive

predictive value was $(110/112) \times 100 = 98.214\%$, and negative predictive value was $(14/18) \times 100 = 77.777\%$.

The sensitivity of the test MRCP reflected that the test seemed to be strong in detecting the disease ie, very low false negative would be produced by the test. For an emergency surgical problem like choledocholithiasis it should be the 'investigation of choice'.

Table 4: Distribution of participants as per CBD diameter and as per position of CBD stones in different stages of evaluation (n=130).

Different stages of evaluation	CBD diameter		Total N (%)	
	<7 mm N (%)	≥7 mm N (%)		
CBD diameter on USG	41 (31.54)	89 (68.46)	130 (100)	
CBD diameter on MRCP	6 (4.61)	124 (95.39)	130 (100)	
CBD diameter intra-operative	7 (5.39)	123 (94.61)	130 (100)	
Findings at different stages	Overall (n=130) Number of patient stone (+) N (%)	Subgroups		
		Proximal CBD N (%)	Distal CBD N (%)	Ampullary N (%)
Position of stone at CBD in USG	57 (43.85)	2 (1.54)	55 (42.31)	-
Position of stone at CBD in MRCP	112 (86.15)	3 (2.31)	98 (75.38)	11 (8.46)
Position of stone at CBD in intra-operative.	114 (87.69)	2 (1.54)	100 (76.92)	12 (9.23)

Table 5: USG (trans-abdominal) & MRCP vs intra-operative (standard).

Imaging tests of choledocholithiasis		Intraoperative findings of choledocholithiasis		
		Present N (%)	Absent N (%)	Total N (%)
USG	Present	56 (43.08)	1 (0.77)	57 (43.85)
	Absent	58 (44.61)	15 (11.54)	73 (56.15)
	Total	114 (87.69)	16 (12.31)	130 (100)
MRCP	Present	110 (84.61)	2 (1.54)	112 (86.15)
	Absent	4 (3.08)	14 (10.77)	18 (13.85)
	Total	114 (87.69)	16 (12.31)	130 (100)

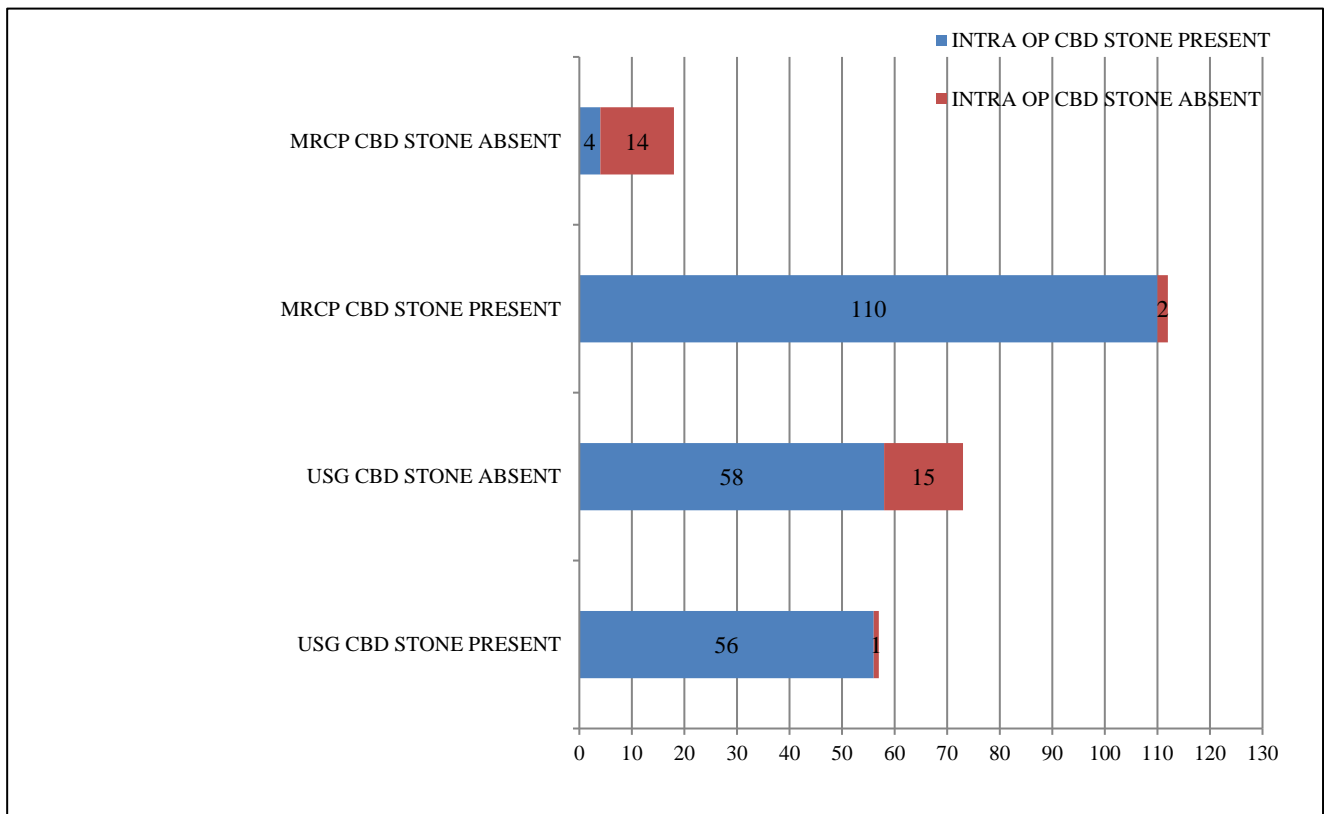


Figure 5: USG and MRCP vs intra-operative finding.

Table 6: Distribution of study population according to different operative procedures (n=130).

Operative procedures		Number of cases		
Lap GB + CBD exploration		22		
Open GB + CBD exploration		82		
CBD exploration		6		
Open GB+CBD palpation + exploration		4		
Open GB+CBD Palpation		16		
Distribution of participants as per trans-abdominal USG (test) vs intra-operative findings (gold standard= truth)				
USG findings	Intra-operative		Total	X ² , df, p value
	CBD stone present	CBD stone absent		
	N (%)	N (%)	N (%)	
Stone present	56 (43.08)	1 (0.77)	57 (43.85)	10.47, 1, 0.001
Stone absent	58 (44.61)	15 (11.54)	73 (56.15)	
Total	114 (87.69)	16 (12.31)	130 (100)	

Table 7: MRCP VS intra-operative (standard).

MRCP findings	Intra-operative findings		Total	X ² , df, p value
	Stone present	Stone absent		
	N (%)	N (%)	N (%)	
Stone present	110 (84.61)	2 (1.54)	112 (86.15)	0.6666, 1, 0.0001
Stone absent	4 (3.08)	14 (10.77)	18 (13.85)	
Total	114 (87.69)	16 (12.31)	130 (100)	-

Table 8: Distribution of participants as per USG test vs MRCP test (n=130).

USG report regarding CBD stones	MRCP report regarding CBD stones		Total	McNemar X ² , df, p value
	Positive (+)	Negative (-)		
	N (%)	N (%)	N (%)	
Positive (+)	56 (98.25)	01 (1.75)	57 (100)	53.070, 1, >0.05
Negative (-)	56 (76.71)	17 (23.29)	73 (100)	
Total	112 (86.15)	18 (13.85)	130 (100)	-

McNemar's Chi-Square Test (paired) X² = 53.070; DF=1, p value >0.05.

Table 8 shows for comparison of diagnostic accuracy of the test McNemar also called paired Chi-Square test was carried out considering the discordant values of cell b (false positive) and c (false negative).

McNemar $\chi^2 = (b-c)^2 / (b+c)$. It was revealed that the accuracy of the two test wasn't comparable rather they showed a statistically significant difference. It mean that the test with lower accuracy, shouldn't be the 'investigation of choice'.

Though, the MRCP is costly and complex in terms of applicability, but it should be the 'investigation of choice' unless otherwise indicated.

DISCUSSION

Cholelithiasis is most important complication of gall bladder stone disease which appears during the natural course of this disease.

Demographics

Incidence of cholelithiasis has been found to be slightly higher in females compared with males in our study (2.08:1). In our study, the most common age group affected is between 41 to 50 years. The mean age of the patients is 49.27±10.6028 years. The incidence and prevalence of cholelithiasis tends to increase with age. So, the disease is essentially of the middle and elderly.

Serum bilirubin level

Bilirubin level was raised in all patients except one, above 1.21 mg/dl. The mean total bilirubin level was found to be 3.50±1.36 mg/dl (range 1.02 to 7.04 mg/dl).

Impacted CBD stone was found intra-operatively in patients having bilirubin level more than 4.60 mg/dl in present study. Although jaundice can occur in the absence of stones, the degree of hyperbilirubinemia correlates well with stones.

Serum ALP level

Among the biochemical parameters studied, serum ALP has the highest sensitivity (65%) in the diagnosis of choledocholithiasis.¹²

In present study, mean serum ALP value was 381.56±219.68 IU/l (range 156.04-1304.15 IU/l) and all patients showed more than normal level (20-135 IU/l).

Role of USG in detecting CBD stone

Ultrasound was used as first investigation in all the patients suspecting of choledocholithiasis on the basis of laboratory findings. 68.2% of the patients have biliary dilatation in the USG. The sensitivity of ultrasonography for detecting biliary dilatation and choledocholithiasis as reported in various studies varies from 55 to 91%.¹³

The role of ultrasonography in detection of common duct stones is less certain. The sensitivity deteriorates as one goes from the proximal to distal duct. The absence of surrounding bile makes the stone difficult to differentiate from the periductal structures.¹⁴ However, the sensitivity of ultrasonography in detecting ductal dilatation which is an indirect evidence of CBD stones is very high. Hunt et al have showed that the probability of CBD stones increases as the duct size becomes larger.¹⁵ Laing et al while evaluating 53 patients with obstructive jaundice got a sensitivity of 29%, specificity of 91% and an accuracy of 55%.¹⁶

The accuracy of USG in detecting CBD stone is reported as ranging from 20-80% in many studies.¹⁷

In present study different parameters for USG was like the sensitivity of USG was 49.12%, specificity was 93.75%, positive predictive value was 98.25% and negative predictive value was 20.55%.

The sensitivity of the test (USG) reflected that it seemed to be weak in detecting CBD stone so many false negatives may be produced by the test. So, it could not be the investigation of choice.

Role of MRCP in detecting CBD stone

MRCP was used for the confirmation of diagnosis in all the patients. In the present study accuracy of MRCP found out to be 95.38%. Most of the large studies have reported that MRCP has sensitivity ranged from 81-100% and accuracy ranged from 89-100% for the diagnosis of choledocholithiasis.¹⁸

The sensitivity of MRCP was 96.491%, specificity was 87.500%, positive predictive value was 98.214% and negative predictive value was 77.777%.

Surgical technique

In the present study type of surgery has been selected on the basis of number, size of CBD stones and diameter of the CBD. Majority of the patients have undergone open choledocholithotomy (n=82, 63.08%). Laparoscopic choledocholithotomy was done in (n=22, 16.92%) patients. In 6 previously cholecystectomized patients only CBD exploration was done. 4 out of rest 20 patients during open cholecystectomy operation CBD stone was found by palpation and CBD exploration was done.

Rest 16 patients no CBD stone was found and only cholecystectomy was done.

So, CBD stone was found in 114 patients out of total study population of 130, i.e. 87.69%.

In this present study intra-operative finding was considered as 'gold standard'.

There were some limitations in this study.

The incidence and prevalence rate of choledocholithiasis among these populations was not studied previously. So, this study may not reflect exact size of the disease in this particular Demographic area and also the national and international level.

Some of CBD stones may pass during or before surgery, so exact figure may be missed.

The investigation reports may be operator dependant. Some expert operator may give good quality of reports. So, USG reports to some extent depends on operators.

CONCLUSION

The role of ultrasonography in detection of common duct stones is less certain. The sensitivity deteriorates as one goes from the proximal to distal duct. The absence of surrounding bile makes the stone difficult to differentiate from the periductal structures. However, the sensitivity of ultrasonography in detecting ductal dilatation which is an indirect evidence of CBD stones is very high. The sensitivity of the test (USG) reflected that it seemed to be weak in detecting CBD stone so many false negatives may be produced by the test. So, it could not be the investigation of choice. The sensitivity of the test (MRCP) reflected that the test seemed to be strong in detecting the disease ie, very low false negative would be produced by the test. For an emergency surgical problem like choledocholithiasis it should be the 'investigation of choice'.

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Ethical approval: The study was approved by the Institutional Ethics Committee, BSMCH, Bankura, West Bengal, India

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