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Diagnostic Accuracy of Ultrasonography in Choledocholithiasis Taking Intraoperative Findings as Gold Standard

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ABSTRACT

INTRODUCTION: It is very important to find a a non invasive, less time consuming and relatively easy modality, non operator dependent and available even remote areas for the common bile duct stones (choledocolithiasis) in symptomatic patients. Instant diagnosis will lead to prompt decision making for treatment strategies that will ultimately decrease the morbidity.

OBJECTIVE: To determine the diagnostic accuracy of ultrasonography in detection of Choledocholithiasis in suspected patients taking intraoperative findings as gold standard.

STUDY DESIGN: Descriptive Cross sectional Study

SETTING: Department of Radiology, Jinnah postgraduate Medical Center, Karachi

DURATION: Six months study from Feb 2020 onwards.

SUBJECTS AND METHODS: All patients with age 30-60 years of either gender having clinically suspected with duration of symptoms of more than or equal to 7 days were enrolled. The ultrasound was performed and presence of CBD diameter of > 7 mm on US was taken as CBD stones. Presence of CBD stones intra operatively was noted.

RESULTS: Mean age of the patients was 51.29 ±7.03 years. There were 75 (62%) females and 46 (38%) males. Overall diagnostic accuracy of ultrasonography was found to be 89.25%. Sensitivity was found to be 80.48%, specificity 93.75%, PPV 86.84% and NPV 90.36%.

CONCLUSION: The diagnostic accuracy of ultrasonography was found satisfactory in detection of Choledocholithiasis in suspected patients taking intraoperative findings as gold standard.

KEYWORDS: Choledocholithiasis, ultrasonography, intraoperative findings

INTRODUCTION

Gallstone disease is responsible for about 1.8 million ambulatory care visits and more than 700,000 cholecystectomies yearly in the United States.[1-2]In Canada, adjusted annual rate of elective cholecystectomy was 260.8 per 100 000 population during the period 1992-2000.[3] Gallstones disease is the second most common reason for hospitalization (with an estimated of US$5.8 billion annually), although only 15% of people with gallstones have related symptoms.[4-7] One complication is the occurrence of stones stones in the common bile duct.[4–7]

Stones in the common bile duct (choledocholithiasis) most commonly result from the passage of gallstones through the cystic duct into the common bile duct.

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Less frequently, they may originate in the common bile duct itself. Choledocholithiasis can cause biliary obstruction, cholangitis, pancreatitis or secondary biliary cirrhosis in patients who have had the stones for a long time. More than 1 in 10 patients (10%-18%) undergoing cholecystectomy for gallstones have concomitant common bile duct stones,[7] and up to 3.8% have symptoms related to choledocholithiasis during the first year after cholecystectomy.[8]

Patients with asymptomatic bile duct stones exhibit typical signs, such as elevated liver function tests, dilated bile ducts on ultrasound, a history of jaundice, or pancreatitis. The magnitude of asymptomatic bile duct stones is about 10%, but up to 2% of patients show no signs of the disease.[9] In a study MRC or ERC was performed because of suspected choledocholithiasis and CBD stones were diagnosed in 45 (30.4%) of the 148 patients.[10]

The evaluation of common bile duct stones in patients with gallstone disease involves stratifying their probability of having a stone in the common bile duct to: low (<10%), intermediate (10%–50%) or high (> 50%).[11]

Many imaging modalities are available for investigating suspected stones in the common bile duct. These include include older techniques such as intravenous Cholangiography and endoscopic retrograde cholangiopancreatography (ERCP) and newer techniques such as magnetic resonance cholangiopancreatography and ultrasonography.

The sensitivity, specificity, positive and negative predictive value of ultrasonography in detecting CBD stones in a study was 65%, 60%, 76.47% and 46.15% respectively.[12]

The rationale of the study is to generate local data on this topic as no local data is available and to find a non invasive, less time consuming and relatively easy modality, non operator dependent and available even remote areas for the common bile duct stones (choledocolithiasis) in symptomatic patients. Instant diagnosis will lead to prompt decision making for treatment strategies that will ultimately decrease the morbidity.

LITERATURE REVIEW:

Choledocholithiasis is a medical condition that mandates surgical intervention. It may occur in 3% – 10% of patients with cholecystectomy,[13] and as high as 14.7% in some series. [14] Generally, the prevalence of asymptomatic bile duct stones is reported between 5.2% and 12%.[15]

There are several diagnostic approaches for common bile duct (CBD) stones. These include: laboratory analysis, ultrasonography (US), computed tomography scans (CT scan), magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasonography (EUS), and endoscopic retrograde cholangiopancreatography (ERCP). Intraoperative cholangiography (IOC) during cholecystectomy can be performed routinely or selectively to diagnose choledocholithiasis.[16,17]

Nowadays, 2 groups of interventions have a significant role in the management of patients with gallstone and CBD stones: pre- or post-cholecystectomy ERCP with endoscopic sphincterotomy (ES), which is a two-stage procedure, and surgical bile duct clearance and cholecystectomy by single open or laparoscopic surgery (one-stage procedure). Several randomized controlled trials have shown comparable effectiveness of these modalities.[18,19]

Other methods include electrohydraulic lithotripsy (EHL), extracorporeal shockwave lithotripsy (ESWL), laser lithotripsy and dissolving solutions that are advocated for special conditions.[20,21]

Although, ERCP and laparoscopic CBD exploration are preferred methods in most centers, open CBD exploration should never be abandoned. Some studies have proposed choledochotomy with primary laparoscopic closure of the CBD which eliminates the need for a T-tube, thus reducing surgical time and postoperative morbidity.[22]

However, open CBD exploration with T-tube insertion remains the standard procedure for most patients. The management of choledocholithiasis has always been challenging. Nowadays, ERCP has essentially replaced open surgery for safe and effective CBD stone extraction. Open CBD exploration is an important surgical procedure when ERCP fails and expertise for laparoscopic CBD exploration is not available. The optimal method for performing open CBD exploration is unclear.[23]

The routine use of IOC during laparoscopic cholecystectomy remains controversial.[24] Stuart et al. have performed IOC in 348 patients, of which it was abnormal in 17 (5%) cases. However, documented retained stones that existed in 5 patients were removed by CBD exploration or ERCP in that study.[25] Mir et al. did not perform IOC, and reported reductions in costs and hospital stay.[26]

Generally, ERCP is more feasible in this subgroup since postoperative T-tube cholangiography shows the anatomy of the biliary tree and large or impacted stones that have been extracted during surgery. In patients with sepsis due to cholangitis and accompanying diseases, it was necessary to shorten the time of surgery. In addition, biliary-enteric anastomosis increased the risk of complications. In such cases, the T-tube was inserted following CBD exploration. In cases with CBD diameters less than 12 mm, the T-tube was used because of the high risk for anastomotic

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stricture[27] and subsequent complications. Most authors have preferred insertion of T-tube for CBD drainage, but some centers have utilized transcystic tubes (C-tube) or antegrade stenting with choledochorrhaphy for CBD drainage.[28]

In patients with residual distal stone, ductal imaging in the postoperative period and provision of an access route for removal of residual CBD stones has been performed.[29] The most commonly used choledochoenterostomy is side-toside choledochoduodenostomy, usually in the setting of a dilated CBD.[30]

In cases where duodenal anastomosis was impossible, choledochojejunostomy was performed. Currently, many centers use laparoscopy for CBD surgeries. Ex-pert surgical teams have reported a CBD clearance rate of about 97%.[23] The morbidity rate has been reported to be 9.5% and retained stone rate of 2.7% for exploratory laparoscopic CBD.[24]

METHODOLOGY:

Sample Size:

Prevalence of choledocolithiasis[10]=30.4%
Confidence level=95%
Bond on error=10% for specificity and 13% for sensitivity
Sensitivity[12]=65%
Specificity[12]=60%
Sample size=121 symptomatic patients

Sampling Technique:

Non Probability Consecutive sampling

SAMPLE SELECTION

Inclusion Criteria

- Clinically suspected Patients diagnosed as defined in operational definition)
- Duration of symptoms of more than or equal to 7 days
- Age 30-60 years
- Either gender

Exclusion Criteria

Patients having following conditions were excluded from the study

- Carcinoma head of pancreas
- Periampullary carcinoma
- CBD strictures
- Cholangiocarcinoma

DATA COLLECTION

The study was conducted post approval of ethical review committee of the institute. Clinically suspected Patients diagnosed as defined in operational definition) meeting the inclusion criteria attending the out-patient department of JPMC, Karachi was enrolled in the study. The purpose and procedure of the study was explained, confidentiality was ensured and Informed consent was taken from the patient for inclusion in the study. The ultrasound was performed by the sonologist having more than five years of experience. Presence of CBD diameter of > 7 mm on US was taken as CBD stones. All patients will undergo surgery performed by a consultant having more than 5 years year of experience. Presence of CBD stones intra operatively was noted by the researcher. Demographics of the patients like age, gender, BMI along with US and intraoperative findings was entered in the proforma by the researcher.

DATA ANALYSIS

Data was entered and analyzed on SPSS version 20 for windows. Frequency and percentages was estimated for gender, US and intraoperative findings. Mean±SD was calculated for age, duration of symptoms and BMI of the patients. Sensitivity, specificity, PPV and NPV was calculated for US taking intra operative findings as gold standard. Stratification of age, gender and BMI was done to control effect modifiers.

RESULTS:

The age ≤45 and comparison of ultrasound findings with intraoperative findings is showed below:

n=40

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US Findings	Intraoperative Finding			p-value
	Yes	No	Total	
Yes	11	2	13	0.001
No	2	25	27	
Total	13	27	40	

Sensitivity = (11÷ 13) × 100 = 84.61%
Specificity = (25 ÷ 27) × 100 = 92.59%
Positive predictive value = (11÷ 13) × 100 = 84.61%
Negative predictive value = (25÷27) × 100 = 92.59%
Diagnostic Accuracy= (11+25÷ 11+2+2+25) = 90%

The age >45 and comparison of ultrasound findings with intraoperative findings is showed below:

n=81

US Findings	Intraoperative Finding			p-value
	Yes	No	Total	
Yes	22	3	25	0.001
No	6	50	56	
Total	28	53	81	

Sensitivity = (22÷ 28) × 100 = 78.57%
Specificity = (50 ÷ 53) × 100 = 94.33%
Positive predictive value = (22÷ 25) × 100 = 88%
Negative predictive value = (50÷56) × 100 = 89.28%
Diagnostic Accuracy= (22+50÷ 22+3+6+50) = 88.89%

Male gender and comparison of ultrasound findings with intraoperative findings is showed below:

n=46

US Findings	Intraoperative Finding			p-value
	Yes	No	Total	

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Yes	13	5	18	0.001
No	1	27	28	
Total	14	32	46	

Sensitivity = (13÷ 14) × 100 = 92.85%
Specificity = (27 ÷ 32) × 100 = 84.37%
Positive predictive value = (13÷ 18) × 100 = 72.22%
Negative predictive value = (27÷28) × 100 = 96.42%
Diagnostic Accuracy= (13+27÷ 13+5+1+27) = 86.95%

Female gender and comparison of ultrasound findings with intraoperative findings is showed below:

n=75

US Findings	**Intraoperative Finding**			**p-value**
	Yes	**No**	**Total**	
Yes	20	0	20	0.001
No	7	48	55	
Total	27	48	75	

Sensitivity = (20÷ 27) × 100 = 74.07%
Specificity = (48 ÷ 48) × 100 = 100%
Positive predictive value = (20÷ 20) × 100 = 100%
Negative predictive value = (48÷55) × 100 = 87.27%
Diagnostic Accuracy= (20+48÷ 20+48+0+7) = 90.66%

≤30 BMI and comparison of ultrasound findings with intraoperative findings is showed below:

n=38

US Findings	**Intraoperative Finding**			**p-value**
	Yes	**No**	**Total**	
Yes	10	1	11	0.001
No	1	26	27	

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Total	11	27	38	

Sensitivity = (10÷ 11) × 100 = 90.90%
Specificity = (26 ÷ 27) × 100 = 96.29%
Positive predictive value = (10÷ 11) × 100 = 90.90%
Negative predictive value = (26÷27) × 100 = 96.29%
Diagnostic Accuracy= (10+26÷26+10+1+1) = 94.73%

>30 BMI and comparison of ultrasound findings with intraoperative findings is showed below:

n=83

US Findings	**Intraoperative Finding**			**p-value**
	Yes	**No**	**Total**	
Yes	23	4	27	0.001
No	7	49	56	
Total	30	53	83	

Sensitivity = (23÷ 30) × 100 = 76.66%
Specificity = (49 ÷ 53) × 100 = 92.54%
Positive predictive value = (23÷ 27) × 100 = 85.18%
Negative predictive value = (49÷53) × 100 = 92.45%
Diagnostic Accuracy= (23+49÷ 23+49+4+7) = 86.74%

DISCUSSION

Choledocholithiasis can cause biliary obstruction, cholangitis, pancreatitis or secondary biliary cirrhosis in patients who have had the stones for a long time. More than 1 in 10 patients (10%-18%) undergoing cholecystectomy for gallstones have concomitant common bile duct stones,[7] and up to 3.8% have symptoms related to choledocholithiasis during the first year after cholecystectomy.[8]

Patients with asymptomatic bile duct stones exhibit typical signs, such as elevated liver function tests, dilated bile ducts on ultrasound, a history of jaundice, or pancreatitis. The magnitude of asymptomatic bile duct stones is about 10%, but up to 2% of patients show no signs of the disease.[9] In a study MRC or ERC was performed because of suspected choledocholithiasis and CBD stones were diagnosed in 45 (30.4%) of the 148 patients.[10]

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Many imaging modalities are available for investigating suspected stones in the common bile duct. These include include older techniques such as intravenous Cholangiography and endoscopic retrograde cholangiopancreatography (ERCP) and newer techniques such as magnetic resonance cholangiopancreatography and ultrasonography.

In our study, overall diagnostic accuracy of ultrasonography was found to be 89.25%. Sensitivity was found to be 80.48%, specificity 93.75%, PPV 86.84% and NPV 90.36%. The sensitivity, specificity, positive and negative

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predictive value of ultrasonography in detecting CBD stones in a study was 65%, 60%, 76.47% and 46.15% respectively.[12]

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CONCLUSION

The diagnostic accuracy of ultrasonography was found satisfactory in detection of Choledocholithiasis in suspected patients taking intraoperative findings as gold standard.

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