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Comparison between Transabdominal Ultrasound and Endoscopic Retrograde Cholangiopancreatography in the Detection of the Common Bile Duct Stone

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Abstract: ***The common bile duct stone (CBDS) is a common clinical problem that can cause serious complications, such as acute cholangitis and pancreatitis. It is important to have an accurate, safe and reliable method for the definitive diagnosis of CBDS before proceeding to therapeutic endoscopic retrograde cholangiopancreatography (ERCP). This study aimed to compare the accuracy of trans-abdominal ultrasound (TAUS) as a diagnostic tool at Al-Kindi teaching hospital in Baghdad/Iraq with invasive tool like ERCP in the diagnosis of bile duct stones, using specificity, sensitivity and positive and negative predictive values. After obtaining ethical committee approval & informed consent from every patient. This prospective study was conducted on 50 patients (15 male patients and 35females patients) whose ages ranged between (5-80) years and suspected to have CBDS depending on history, clinical suspicion and blood tests. Both TAUS and ERCP were performed. Final diagnosis was confirmed depending on ERCP as it served as a diagnostic standard in the diagnosis of CBDS. Among the50 patients suspected to have CBDS by TAUS, only 33 (66%) patients had stone and 38 (76%) patients had stone by ERCP. Our result also showed that sensitivity, specificity, positive predictive values and negative predictive values for TAUS were 79%, 75%, 91% and 53% respectively. TAUS can play an important role as an initial screening procedure for CBDS detection because of itsdifferent advantages like easy availability, cost effectiveness, no requirement of contrast material and lack of ionizing radiation but should be done with other imaging modality to avoid serious complications of ERCP.***

Keywords: TAUS, ERCP, CBDS

1. Introduction

Common bile duct stone (CBDS) or choledocholithiasis is a common clinical problem that can cause serious complications, such as acute cholangitis and pancreatitis [1]. Therefore, accurately diagnosing CBDS is important for clinical decision making [2]. CBDS could be primary or secondary; primary stones (10%): arising within the bile duct [3]. The primary stones are associated with biliary stasis and infection and are more commonly seen in Asian populations. The causes of biliary stasis that leads to the development of primary stones include biliary stricture, papillary stenosis, tumors and choledochal cyst [4] [5]. Secondary stones (retain or recurrent) (90%) [3], secondary CBDS, are the most common type [6] [7]. The vast majority of duct stones in western countries are formed within the gallbladder [4] [5]. The prevalence of gallbladder stones in the general population is up to 20% [8], which is twice as common in women as in men, and becomes more prevalent with increasing age [9] [10]; up to 20% of these patients have synchronous CBDS [11]. As many as 35% of patients with gallstones will ultimately become symptomatic and require cholecystectomy [12], while approximately (3-10%) of patients undergoing cholecystectomy will have (CBDS) [13]. These data mean that up to 2% of the general population may have CBDS during their life-span [2] [14]-[17]. The secondary CBDS forms within the gallbladder and then migrates into the CBD, following gallbladder contractions [18]. Once in the CBD, stones may reach the duodenum following the bile flow or due to the smaller diameter of the distal CBD at the Vater papilla; they may remain in the choledochus. In the latter case, gallstones may be fluctuant; thus may be asymptomatic [18], (about 5%) [19], or cause a variety of bile flow problems, including complete obstruction and jaundice [18]. The symptom of choledocholithiasis consists of right upper abdominal colicky pain, radiating to the right shoulder with jaundice accompanied by pale stools and dark urine [20]. Scholastically, Charcot's triad [21] (jaundice associated with biliary colicky pain, fever and chills), indicates acute cholangitis; as choledocholithiasis is the most frequent etiology of such a clinical picture, it should prompt immediate diagnostic confirmation and CBD drainage [16], whereas cutaneous itching is rarely present [22]. Patient with CBDS also may present as acute pancreatitis, showing with transversal abdominal pain potentially radiating to the back and associated with an increase of serum level of amylase/lipase. In the presence of gallstones, the prior cause will be being of biliary origin [16]. Hepatic abscess may also be a rarer infectious complication of CBDS whereas chronic CBD obstruction may also cause biliary cirrhosis [16]. Murphy's sign is commonly negative on physical examination in CBDS, helping to distinguish it from cholecystitis [23].

Diagnosis of choledocholithiasis is not always straightforward and clinical evaluation and biochemical tests are often not sufficiently accurate to establish a firm diagnosis [24]-[26]. Usually, the diagnosis of choledocholithiasis is based on a combination of clinical

suspicion, bio-chemical analysis and imaging findings. Unfortunately, all of these individually have varying diagnostic accuracies and none is a completely reliable method for identifying CBDS [27].

Liver function tests (LFT) can be used to predict CBDS, Traditionally, an elevated (direct bilirubin, gamma-glutamil-transpherase, alkaline phosphatase) was considered as potentially due to CBDS [25] [26].

Elevated serum bilirubin and alkaline phosphatase typically reflect biliary obstruction but these are neither highly sensitive nor specific for CBDS [26]. Jaundice and raised GGT level has been suggested to be the most sensitive and specific indicator of CBDS. A value of greater than 90 U/L has been proposed to indicate a high risk of choledocholithiasis [28], (normal value is about 0-30 IU/L) [25]. However, the biochemical predictive models may be affected by inflammatory gallstone disease due to abnormally elevated predictor levels secondary to acute transient hepatocellular injury [28]. Various imaging tests are used to confirm the diagnosis [24]-[26]. TAUS, endoscopic ultrasonography (EUS), magnetic resonance cholangiopancreatography (MRCP), endoscopicretrograde cholangiopancreatography (ERCP), and intraoperative fluorocholangiography (IOC) are available imaging modalities for the detection of CBDS. The optimal method for investigating suspected CBDS has not been determined [29].

Transabdominal Ultrasound (TAUS) represents the first line, non-expensive, non-invasive imaging examination and widely available [2] [19] [24] [30], for assessing the status of the biliary system, and has beenshown to be of value in the differentiation between obstructive and non-obstructive jaundice [31].

Endoscopic retrograde cholangiopancreaticography (ERCP) is the standard therapy for of biliary obstruction. However, the success rate is not 100%, depending on various patient and physician related factors [32]. Successful cholangiography by an experienced endoscopist is achieved in greater than 90% of patients. ERCP can have a failure rate of 5% to 10% even in experienced hands [33]. The main advantage of these techniques, is the ability to sample tissue and perform therapeutic maneuvers, such as biliary drainage, stenting or stone removal [34].

1.1 Patients and Methods

This prospective study was conducted on 50 patients (15 male patients and 35females patients) whose ages ranged between (5-80) years and suspected to have CBDS depending on history, clinical suspicion and blood tests. Both TAUS and ERCP were performed. Final diagnosis was confirmed depending on ERCP as it served as a diagnostic standard in the diagnosis of CBDS.Patients with obstructive jaundice, deranged liver function tests (raised total, direct bilirubin and alkaline phosphate and ALT) were included in the study. For the purposes of this study the hard copy images of ERCP and ultrasound examinations of each patient were collected and the patient details masked. The patients were fasted overnight (by gastroenterologist because they were prepared for ERCP) and ultrasound examination was done by experience ultrasonologist, in the supine and Left posterior oblique to optimally visualize the biliary ducts. Ultrasound study was performed transabdominally using axial, subcostal and intercostal approach. All ultrasound examinations were performed by using a General Electronic Model Voluson E6 ultrasound unit with (3.5-5) MHz curvilinear probe. The liver parenchyma was scanned to rule out parenchymal pathology and to detect any dilated biliary radicals. Gall bladder was examined to check for Lithiasis, distension, wall thickening, growth or soft tissue lesions.

Pancreas was examined to exclude pancreatic head mass or pathology that causes biliary obstruction. For the purpose of this study, the common hepatic duct and the common bile duct were considered as one structure, the common duct. This is because of the uncertain site at which the cystic duct joins the common hepatic duct to form the common bile duct. The common duct is arbitrarily divided into two parts: the proximal and the distal parts. The proximal part of the common duct is that segment from the porta down to the first part of the duodenum, whereas the distal part include that segment behind the duodenum and the intrapancreatic portion. Careful scanning of the entire course and caliber of the duct system whenever possible was done from portahepatis to pancreatic head to trace the extent of the duct dilatation and to localize the level of obstruction. CBD was identified using color Doppler us to differentiate from nearby vessels (portal vein and hepatic artery). The diagnosis of choledocholithiasis was made when intraluminal echogenic focus with or without acoustic shadowing was demonstrated. The final diagnosis was based on ERCP. The ERCP examination was performed by one experienced gastroenterologist.

ERCP was done in all patients after regular preparation i.e. overnight fasting, slow IV sedation and precaution of asepsis. Endoscopy was performed using side viewing Endoscope (OLYMPUS EXERA CLV-160) and Videoscope Monitor (Trinitron OEV203). In semiprone position using endoscopy they enter through the mouth until reaching the duodenum and face papilla then using sphicntrotome for biliary cannulation trial done a guide wire passed to bile duct then contrast will be injected to visualize the biliary tree with precautions taking to avoid injecting air. Endoscopicsphinctreotomy done and stone will be extracted using extraction balloon or basket, in case of tumor; plastic or metallic biliary stent will be deployed. A total dose of Buscopan injection (20 mg) was administered toparalyze the duodenum & to relieve the spasm if there is papillary spasm. Vital signs were monitored continuously throughout the procedure and till I hour after the ERCP.

The following conditions were excluded from our study: Heavy daily alcohol intake > 80 g, Hepatotoxic drug intake, Serologic findings of acute viral hepatitis A, C or B and Pancreatic head mass while the following conditions were included in our study: Patients with clinical signs and symptoms of jaundice, Patients with elevated liver function tests (elevated TBS, direct bilirubin, ALT, serum alkaline phosphate) and Patients with dilated CBD by US with or without obvious CBDS.

1.2 Statistical Analysis

Statistical Package for Social Sciences (SPSS) version 21 was used for data analysis. Descriptive statistics, and up-to-date statistical methods were used in the evaluations. P-values ≤ 0.05 were considered statistically significant.

2. Results

In this study, 50 patients have been screened with TAUS and ERCP, the mean age of the participants was 52.3 years, with a range from 5 to 80 years (table 1). The number and percentage of males was15 (30%) and females was35 (70%) patients. All had different presenting signs and symptoms. Generally, 30 (64%) of patients had jaundice, and the number and percentage of patients with other sign & symptoms such as: fever, RUQ pain, vomiting were: 26 (52%), 48 (96%), and 13 (26%) respectively. Although only RUQ pain was the dominant characteristic among the patients with a high incidence (96%), but patients could be grouped on diagnostic characteristics of Charcot triad (jaundice, fever, RUQ pain), patients with Charcot triad were 20 (40%) patients out of the total number (table 1).

In regard to blood tests, we found that 11 (22.0%) of the patients had a normal reading for serum Alkaline phosphatase, and 39 (78.0%) had abnormal or above normal results. The figures for Alanine aminotransferase (ALT) for normal and above normal results were, 20 (40.0%), and 30 (60.0%) of the patients respectively. Nine (18.0%) of the patients had normal readings for TSB, and 41 (82.0%) had above normal results (table 2).

Table 1: Age and sex distribution of patientswith signs and symptoms

Characteristic	Values
Age:	
(Mean ± SD)	52.3 ± 17.1
Range	5-80 years
Males	15 (30%)
Females	35 (70%)
Male/female ratio	~1/2
Sign & symptoms:	
Charcot triad	20 (40%)
Jaundice	30 (64%)
Fever	26 (52%)
RUQ pain	48 (96%)
Vomiting	13 (26%)
Total number of patients	50

Table 2: Frequency and percentage of patients with normal and above normal results for 3 liver function tests (Serum Alkaline Phosphatase, ALT, and TSB)

Variable		Frequency	%
Alkaline phosphatase	Normal	11	22.0%
	Above normal	39	78.0%
Alanine transferase	Normal	20	40.0%
	Above normal	30	60.0%
TSB	Normal	9	18.0%
	Above normal	41	82.0%

Table(3**)** explains the detection rates of CBD dilatation and CBD stone by each of TAUS and ERCP as diagnostic tools. TAUS revealed 37 (74%) cases out of 50 with CBD dilatation and ERCP revealed 43 (86%) cases with the same condition. In detection of CBD stones, the frequencies and percentages of detections for each of TAUS and ERCP were: 33 (66%), and 38 (76%) respectively (figure 6).

Table 3: Detection rates of TAUS and ERCP for CBD dilatation and CBD stones

Diagnostic characteristics	Frequency	Percentage of total
CBD dilatation		
Ultrasonography	37	74%
ERCP	43	86%
CBD stone		
Ultrasonography	33	66%
ERCP	38	76%
Total number	50	100%

It has come to our attention that there are gender differences in the abnormalities that we detected both in TAUS and ERCP. In TAUS, females had higher incidence rates in having dilated CBD and CBD stone, and the incidences were 77% and 71% respectively, and male/female risk ratios were 0.87 and 0.75 respectively, these ratios confirm that females have higher numbers of CBD stones and dilated CBDs (table 4). Although ERCP confirmed higher detection rates of abnormalities for both males and females compared to those of TAUS, but incidence of dilated CBD and CBD stones are still higher in females and were: 89%, and 80% respectively, while these incidences in males were; 80%, 67% respectively (table 4).

Table 4: Male/female differences and risk ratios, as well as diagnostic capability of both TAUS and ERCP in terms of gender differences

Type of test and diagnosis	Incidence in males n=15	Incidence in females n=35	Male/female risk ratio	P-value
Ultrasonography:				
CBD dilatation	10 (67%)	27 (77%)	0.87	0.70
CBD stone	8 (53%)	25 (71%)	0.75	0.37
ERCP				
CBD dilatation	12 (80%)	31 (89%)	0.90	0.69
CBD stone	10 (67%)	28 (80%)	0.84	0.53

We have decided to find the diagnostic characteristics of TAUS in detecting CBD stones. Sensitivity, specificity, positive and negative predictive values, positive and negative likelihood ratios were all calculated for TAUS, with 95% CIs, by using the findings at ERCP as the reference standard or the gold standard. True positive and true negative results were considered when the results for both tests were similar in detection of CBD stones. A finding was defined as false-positive when TAUS depicted a CBD stone but ERCP setting did not depict the same CBD stone. A false negative finding was considered to be present when a CBD stone was detected in ERCP but the same stone was not detected at TAUS. We could not find any CBD stones in 9 patients in both TAUS and ERCP. The number of true positives were 30 patients, three patients had false positive US results and 8 patients had false negative US results (table 5).

Table 5: True positive, true negative, false positive, and false negative results of CBDS by TAUS (considering ERCP as the gold standard)

		ERCP CBD stone		
		Yes	No	Total
CBD stone by TAUS	Yes	30	3	33
	No	8	9	17
	Total	38	12	50

In diagnosing CBDS, the sensitivity of TAUS, or the ability of the test to correctly identify patients with the same CBDS as ERCP, was 79% (95% CI: 62% to 90%) (Table 6). Specificity or the ability of TAUS to correctly identify those patients without any CBDS was 75% (95% CI: 43% to 93%). Positive predictive value, or the probability that a CBDS is present when TAUS test is positive for DBDS, was 91% (95% CI: 75% to 98%). Negative predictive value, or the probability that a CBDS is not present in a patient when TAUS test is negative, was 53% (95% CI: 29% to 76%) **(Table 6).** And finally, validity (Accuracy) of the test US was 78% (95% CI: 64% to 88%).

Table 6: Diagnostic characteristics of TAUS in detecting CBD stones as compared to ERCP

Statistic	Value	95% CI
Sensitivity	79%	[62% to 90%]
Specificity	75%	[43% to 93%]
Positive predictive value	91%	[75% to 98%]
Negative predictive value	53%	[29% to 76%]
Accuracy	78%	[64% to 88%]

And finally, from the table (Table 7)below, we have tried to explain the associationbetween diagnosed CBD dilatation on ultrasonography and presence of stones in the same patients on ERCP. We have 31 patients who had CBD dilatation on TAUS and tested positive on ERCP, 6 patients had CBD dilatation on TAUS and no stones on ERCP. Seven patients had no CBD dilatation on TAUS but ERCP tested positive for CBD stone, and 6 patients tested negative on both tests. It has come to our attention that the patients who had a dilated CBD on TAUS had 4 times higher probability of having a positive result for CBD stone on ERCP than having a positive result for CBD stone on ERCP when TAUS shows no CBD dilatation in the same patients (95% CI: 1.06 to 17.9, P-value = 0.039).

Table 7: Relation between dilated CBD and CBS

		ERCP CBD stone		
		Yes	No	Total
CBD dilated by TAUS	Yes	31	6	37
	No	7	6	13
	Total	38	12	50

3. Discussion

When evaluating a case of obstructive jaundice, the aim of the radiologist is to confirm the cause and site of obstruction. The success rate in diagnosing specific cause has continued to improve with advancing high resolution equipment, scanning technique and interpretive skills. With the availability of TAUS, MRI including MRCP, ERCP and PTC, diagnostic approach in a patient with biliary tract pathology has been completely revolutionized with accuracy of radiological diagnosis approaching 98% when combined with clinical data [4].

TAUS has always been used as the initial screening procedure because of the various advantages like easy availability, cost effectiveness, no requirement of contrast material and lack of ionizing radiation. It is well suited to visualize the Common Hepatic Duct (CHD) and proximal CBD [5] [35], also ultrasound enables sonologist to detect disease outside the biliary tree [36] [37].

The sex distribution of our sample shows female predominant, this could be explained by the fact that GS are twice common in female as in male [36] [37] and 90% of CBDS are secondary [3] [38] [39].

Our study showed that nearly all ages are at risk for CBDS. The mean age of patient was (52.3) years. Regarding the gallstones 13cases of our study had history of cholecystectomy and 37 case no history of cholycystectomy in these 37 cases 7 cases had no gallstone and 30 cases had gall stones.

Absence of stones wascorrectly detected by US in 9 of 17 cases, specificity 75% whichagreed with [40], [41], [42] and [38].
Our study had accuracy 78% and it was in agreement with [40], [39] and [43].

Regarding diagnostic errors in our have 3 false positive cases, two of these cases by US there was dilated duct and multiple small stones, by ERCP there was dilated CBD and no stones, these may be because ERCP could have false-negative results because of small stones located within dilated CBD, whereas fewer false-negative results were recorded consisted mostly of stones located in the upper common hepatic duct or lying within intrahepatic ducts [44], or may due stone passage to duodenum with bile flow [13].

Third case of the 3 false positive cases by US was suspecting CBDS but by ERCP diagnosed as distal CBD tumor proved by biopsy taken from the mass, these may be due to one of major limitations of US which are assessment of the distal CBD and pancreas, which are often obscured by overlying bowel gas in about 30% - 50% of the patients [5] [45]. The stone detection rate is also influenced by patient factors such as the number, size and site of stones, patient body habitus [31].

TAUS remain a highly operator-dependent and the results are always influenced by the skill of the examiner [46].

We had 9 true negative cases which had no stone by TAUS and ERCP, 6 of them had normal CBD by TAUS and ERCP, one of them had normal CBD by TAUS and dilated CBD by ERCP,2 of them had dilated CBD by TAUS and ERCP. From true negative; 6 of 9 have no abnormally detected by ERCP, 2 of them had sludge, and 1 distal CBD stricture. The true negative cases also included 2 passed CBD stones, in which the clinical course of the disease strongly suggested a choledochal stone. Endoscopic signs of a passed stone may include an open, reddish, and edemic papilla, but these signs may disappear in a few days.

The study design of our investigation offers an explanation for these false-negative results, as ERCPwas delayed several days compared to TAUS. If ERCP had been performed immediately after admission to hospital, the detection rate of stones would probably have improved. So, our study show NPV was 53% for CBDS by us so that CBDS not reliably excluded by negative TAUS examination.

4. Conclusions

It can be concluded from this study that TAUS can play an important role as an initial screening procedure for CBDS detection because of its different advantages like easy availability, cost effectiveness, no requirement of contrast material and lack of ionizing radiation but should be done with other imaging modality to avoid serious complications of ERCP

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