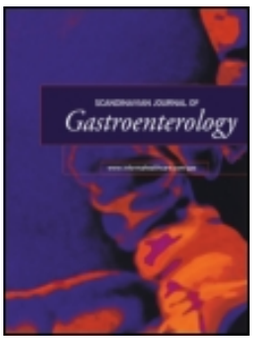

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Impact of the operator's experience on value of high-resolution transabdominal ultrasound in the diagnosis of choledocholithiasis: A prospective comparison using endoscopic retrograde cholangiography as the gold standard

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ORIGINAL ARTICLE

Impact of the operator's experience on value of high-resolution transabdominal ultrasound in the diagnosis of choledocholithiasis: A prospective comparison using endoscopic retrograde cholangiography as the gold standard

STEFFEN RICKES, GERHARD TREIBER, KLAUS MÖNKEMÜLLER, ULRICH PEITZ, ANTAL CSEPREGI, STEFAN KAHL, ANIKA VOPEL, KATHLEEN WOLLE, MATTHIAS P. A. EBERT, SABINE KLAUCK & PETER MALFERTHEINER

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Abstract

Objective. Transabdominal ultrasound (US) is the most frequently used imaging method for the diagnosis of choledocholithiasis. The aim of this prospective study was to evaluate the diagnostic accuracy of high-resolution US in the diagnosis of common bile duct stones depending on the operator's experience and in comparison with endoscopic retrograde cholangiography (ERC) as the gold standard. ***Material and methods***. From April 2003 through November 2004, 126 patients referred because of clinically and biochemically suspected common bile duct stones were included in the study. Two patients were excluded because they refused to undergo ERC. Consequently, the study comprised 124 patients (86 F, 38 M, mean age 63.2 years, range 21–91 years). High-resolution US was performed (2–5 MHz sector scanner; Siemens Elegra, Erlangen, Germany) by operators who were unaware of the results of other imaging procedures. The definitive diagnosis was established by means of ERC. ***Results***. Thirty-five out of 124 patients were investigated by experienced examiners. Twenty-seven of 35 patients (77%) were found to have stones at ERC. Bile duct stones were correctly found by US in 22 out of 27 patients (sensitivity 82%, 95% CI: 63–92). Of the 8 patients without stones at ERC, one false-positive diagnosis was made with US (specificity 88%, 95% CI: 53–98). Correct diagnoses were made in 29 out of 35 (accuracy 83%, 95% CI: 67–92) patients investigated by experienced examiners. Eighty-nine out of 124 patients were investigated by less-experienced examiners. Fifty-four of 89 patients (61%) were found to have stones at ERC. Choledocholithiasis was found correctly in only 25 out of 54 patients (sensitivity 46%, 95% CI: 34–59). Of the 35 patients without stones at ERC, three false-positive diagnoses were made with US (specificity 91%, 95% CI: 78–97). In conclusion, correct diagnoses were observed in 57 of 89 patients (accuracy 64%, 95% CI: 54–73) investigated by less-experienced examiners ($p < 0.05$ in comparison with the results of experienced examiners). ***Conclusions***. High-resolution US carried out by experienced examiners has a high diagnostic accuracy in the diagnosis of choledocholithiasis. Therefore, good training and continued experience are prerequisites for successful sonographic detection of bile duct stones using US. Under these conditions, further expensive and invasive methods such as ERC, magnetic resonance cholangiopancreatography and endoscopic ultrasonography may not be necessary in cases with a clear sonographic diagnosis.

Key Words: *Choledocholithiasis, high-resolution transabdominal ultrasound, endoscopic retrograde cholangiography*

Introduction

Choledocholithiasis is a common complication of gallbladder stones, occurring in 15–20% of patients [1]. Among patients who undergo cholecystectomy, 1–5% retain or have recurrent bile duct stones [1]. Although there are several useful clinical and biochemical abnormalities associated with this condition, they are neither accurate nor specific enough for diagnosis [1].

Endoscopic retrograde cholangiography (ERC) is considered to be the best diagnostic method for common bile duct stones [2]; however, this procedure is invasive. Transabdominal ultrasonography (US) is a quick and non-invasive method generally

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used for the initial evaluation of patients presenting with symptoms consistent with choledocholithiasis but its diagnostic yield is variable [3]. The reasons for such variability include the US equipment used, patient characteristics and, especially, the expertise of the operator.

The aim of this prospective study was to evaluate the diagnostic accuracy of high-resolution US in the diagnosis of choledocholithiasis in a homogeneous population depending on the operator's experience and in comparison with ERC as the gold standard technique.

Material and methods

Patients

From April 2003 through February 2005, patients were included in the study if they had clinical and/or biochemical signs of choledocholithiasis according to the following criteria: a combination of epigastric or right upper quadrant pain with fever or jaundice; one or two of the previous signs together with an elevated serum alkaline phosphatase level or an increase in serum g-glutamyl transpeptidase or transaminase level above the upper limit of normal; acute pancreatitis, defined as acute epigastric pain associated with an increased in serum amylase, lipase, or urinary amylase level of more than two times the upper limit of normal; and unexplained cholestasis defined by an elevated serum alkaline phosphatase level and an increase in serum g-glutamyl transpeptidase level of more than two times the upper limit of normal. Patients were excluded if long-term daily alcohol intake exceeded 80 g, if they were taking hepatotoxic drugs, if serum hepatitis B or C antibodies were present, or if they refused to undergo US and/or ERC. The study was conducted following the Good Clinical Practice Guidelines and according to the guidelines of the Helsinki Declaration.

Techniques

All patients underwent US and ERC. All examinations were performed by two different operators unaware of the results of the other investigation.

US

The patients were randomized to an experienced (more than 10,000 own investigations and more than 4 years' US experience) or a less-experienced investigator (less than 2000 own investigations and/or fewer than 4 years' US experience). Because there was a greater number of less-experienced than experienced examiners, more patients were investigated by less-experienced investigators. US was done with a dynamic 2–5 MHz sector scanner (Siemens Elegra). The diagnostic criterion for choledocholithiasis was a hyperechoic structure within the common bile duct sometimes associated with an acoustic shadow. The common hepatic duct was considered enlarged if the diameter was more than 7 mm (or more than 10 mm for patients who had undergone cholecystectomy).

ERC

All ERC procedures were performed within 24 h after US by experienced gastrointestinal endoscopists using a standard technique with an Olympus duodenoscope (TJF 140; Olympus, Hamburg, Germany). All patients gave written consent to the procedure. Retrograde cholangiograms were interpreted by the endoscopist who performed the procedure. An instrumental exploration of the common bile duct using Dormia baskets and/or retrieval balloon passage through the bile duct was performed in all cases after sphincterotomy. The presence of common bile duct stones was confirmed on their removal or if they were actually seen passing through the sectioned sphincter into the duodenal lumen.

Statistical analysis

The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of US in the diagnosis of choledocholithiasis were calculated with a 95% CI. The chi-square test was used to detect significant differences between the accuracies of experienced and less-experienced examiners; p-values of less than 0.05 were considered significant. Data analysis was done with SPSS, version 10.0 (SPSS Inc., Chicago, Ill., USA).

Results

From April 2003 through November 2004, 126 patients were enrolled in the study. Two patients were excluded because they refused to undergo ERC. Consequently, the study comprised 124 patients (86 F, 38 M, mean age 63.2 years, range 21–91 years). Forty-eight patients (39%) had gallbladder stones at the time of presentation. Results of US in the diagnosis of choledocholithiasis are summarized in Tables I, II and III.

Thirty-five of 124 patients were investigated by experienced examiners. Twenty-seven of 35 patients (77%) were found to have stones at ERC. Thirteen of these patients had a stone measuring 10 mm or more in diameter and 14 a stone of less than 10 mm in diameter. The common bile duct could be visualized entirely by US in 31 out of 35 patients

Table I. Results of US in the detection of common bile duct stones.

	No detection of stones at ERC	Detection of stones at ERC
Experienced US investigator		
No detection of stones ($n=12$)	7	5
Detection of stones ($n=23$)	1	22
Less-experienced US investigator		
No detection of stones ($n=61$)	32	29
Detection of stones ($n=28$)	3	25

Abbreviations: US = ultrasound; ERC = endoscopic retrograde cholangiography.

(89%). Bile duct stones were found correctly with US (Figures 1 and 2) in 22 of 27 patients (sensitivity 82%, 95% CI: 63–92). All five stones not diagnosed by US were smaller than 15 mm in diameter. Furthermore, in 4 of these 5 cases (80%) the common bile duct was not visible in its entirety because of bowel gas and/or increased adipose tissue. Of the 8 patients without stones at ERC, one false-positive diagnosis was made with US (specificity 88%, 95% CI: 53–98). In this case, the diameter of the stone was 5 mm as seen by US in a common bile duct with a normal diameter. This patient also had swelling of the papilla detected at ERC, in all likelihood caused by recent stone migration. Finally, correct diagnoses were observed in 29 out of 35 (accuracy 83%, 95% CI: 67–92) patients investigated by experienced examiners.

Eighty-nine of 124 patients were investigated by less-experienced examiners. Fifty-four of 89 patients (61%) were found to have stones at ERC. The common bile duct could be visualized entirely with ultrasound in 76 out of 89 patients (85%). Choledocholithiasis was found correctly in only 25 of 54 patients (sensitivity 46%, 95% CI: 34–59).

Table II. Detection of common bile duct enlargement at US. The common hepatic duct was considered enlarged if the diameter was more than 7 mm (or more than 10 mm for patients who had undergone cholecystectomy).

	Common bile duct	
	Enlarged at US	Not enlarged at US
Experienced investigator		
No detection of stones ($n=12$)	4	8
Detection of stones ($n=23$)	19	4
Less experienced investigator		
No detection of stones ($n=61$)	37	24
Detection of stones ($n=28$)	22	6

Abbreviation: US = ultrasound.

Table III. Overall results of US in the diagnosis of choledocholithiasis.

	Experienced investigator	95% CI	Less experienced investigator	95% CI
Sensitivity (%)	82	63–92	46	34–59
Specificity (%)	88	53–98	91	78–97
Positive predictive value (%)	96	79–99	89	73–96
Negative predictive value (%)	58	32–81	52	40–64
Accuracy (%)	83*	67–92	64*	54–73

Abbreviations: US = ultrasound; CI = confidence interval.
*$p<0.05$.

All stones not diagnosed with US were smaller than 15 mm in diameter, and in 11 of these 29 patients (38%) the common bile duct was not visible in its entirety because of bowel gas and/or increased adipose tissue. Of the 35 patients without stones at ERC, 3 false-positive diagnoses were made with US (specificity 91%, 95% CI: 78–97). In conclusion, correct diagnoses were observed in 57 of 89 patients (accuracy 64%, 95% CI: 54–73) investigated by less-experienced examiners ($p<0.05$ in comparison with the results of experienced examiners).

Discussion

Diagnostic imaging of the biliary ductal system typically begins with non-invasive modalities such as US and computed tomography (CT). US is the easiest, fastest and least expensive imaging procedure used for the diagnosis of choledocholithiasis. The diagnostic accuracy of this technique for extrahepatic jaundice is high, the sensitivity reaching 94% and the specificity 100% [4–6]. Although the level of biliary obstruction is identified more than 90% of the time, the cause can be determined in only 70% of patients. In cases resulting from stone obstruction, diagnostic failures are caused mainly by the location of the stones within the intrapancreatic portion of the bile duct and the frequent absence of bile duct dilatation. With the use of real-time and high-definition US, diagnostic sensitivity for choledocholithiasis is only about 55% [3,7–9].

The overall diagnostic accuracy of CT for extrahepatic cholestasis is 87–98% [10–12]. CT seems to be more accurate than US, especially in examinations of overweight patients and those with interposed digestive gas. CT has a sensitivity of 76% and a specificity of 98% for the diagnosis of choledocholithiasis [13]. For endoscopic ultrasonography

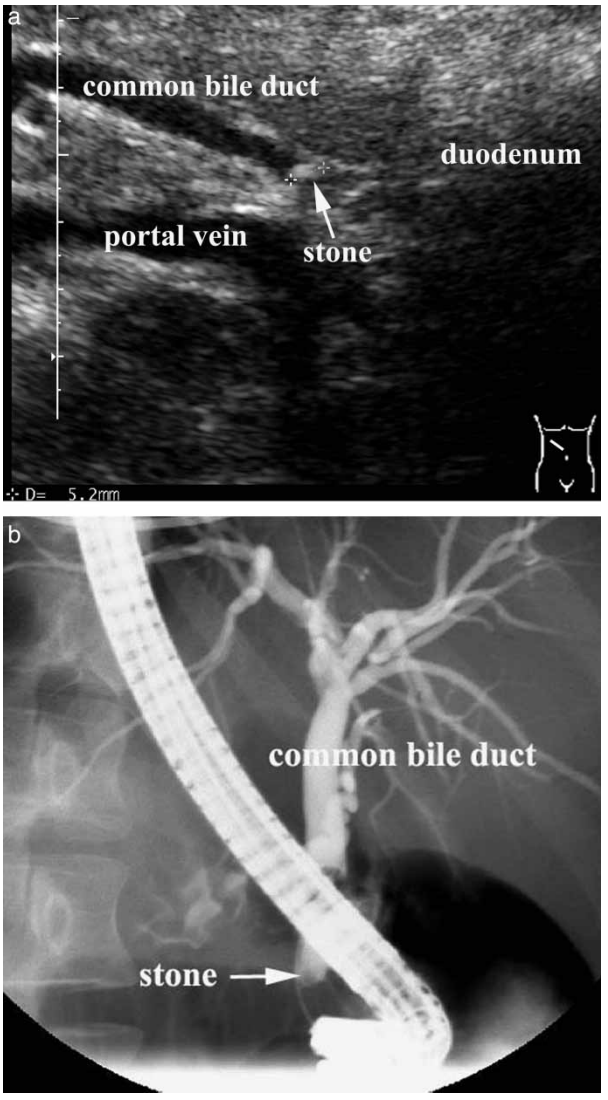

Figure 1. Small stone (diameter about 5 mm) at the distal common bile duct in ultrasound (US) (a) and endoscopic retrograde cholangiography (ERC) (b).

(EUS) and magnetic resonance cholangiopancreatography (MRCP), sensitivities of nearly 100% and specificities between 70% and 95% were observed in the diagnosis of choledocholithiasis [14–16]. However, these techniques are costly, and EUS is an invasive procedure.

One of the main problems in the diagnosis of choledocholithiasis with US is the high degree of operator dependency. Therefore, the aim of this prospective study was to evaluate the accuracy of US in the diagnosis of choledocholithiasis depending on the operator's experience and in comparison with the gold standard technique, ERC. The results demonstrate that experienced examiners reach a significantly higher diagnostic accuracy than less-experienced investigators (83% versus 64%, $p < 0.05$). The results of experienced US examiners are comparable with those of CT.

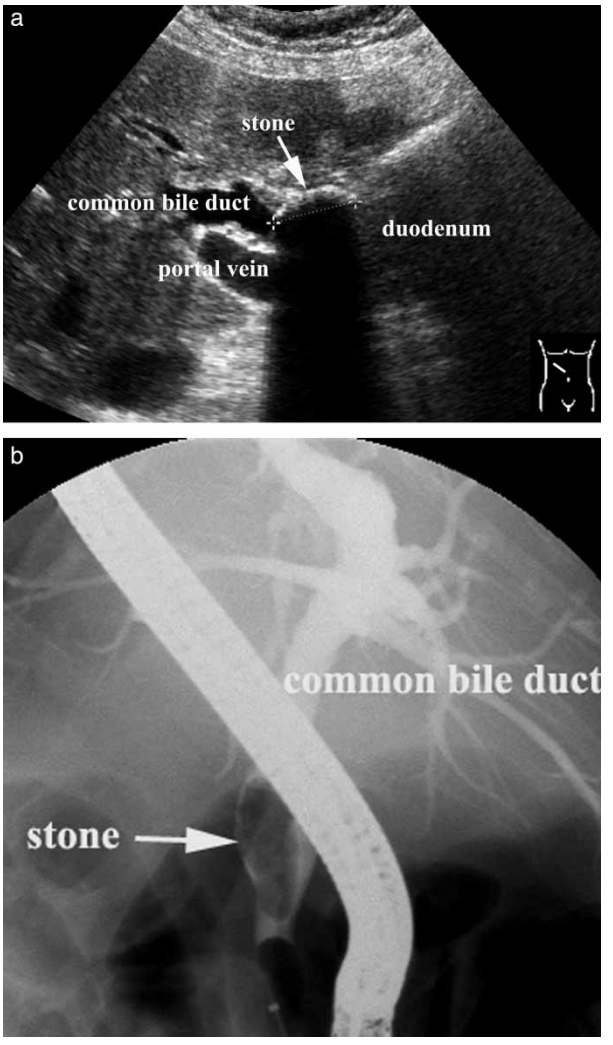

Figure 2. Large stone (diameter about 25 mm) at the common bile duct in ultrasound (US) (a) and endoscopic retrograde cholangiography (ERC) (b).

ERC and intraoperative cholangiography are considered to be the best imaging procedures for the diagnosis of choledocholithiasis. However, ERC is an invasive procedure and has a morbidity rate of 3–5% [17], which increases to 8–10% if sphincterotomy is performed [18]. In addition, the procedure-related mortality can reach 1% [19]. ERC and intraoperative cholangiography may not help detect small stones (<3 mm in diameter) in a dilated common bile duct [20]. There are no data on sensitivity, but the rate of false-negative results of intraoperative cholangiography has been estimated at 2–7% [21,22]. The sensitivity of ERC in the diagnosis of choledocholithiasis is 90% and the specificity 98% [16,23]. The advantages and disadvantages of ERC and US in the diagnosis of choledocholithiasis are compared in Table IV.

There are some possible explanations for the four false-positive findings of US in the diagnosis of

Table IV. Advantages and disadvantages of ERC and US in the diagnosis of choledocholithiasis [17].

	Advantages	Disadvantages
ERC	Direct visualization of the bile ducts with contrast medium	Invasive and associated with complications (morbidity rate of 3% to 5%)
	Gold standard in the diagnosis of bile duct stones	Expensive
	Intervention is possible	Possible side effects of the contrast medium
US	Non-invasive	High operator dependence
	Quick	Problems with bowel gas and/or increased adipose tissue
	Inexpensive	Problems in the diagnosis of small bile duct stones
		Purely diagnostic technique

Abbreviations: US = ultrasound; ERC = endoscopic retrograde cholangiography.

choledocholithiasis in our study. First, a false-positive result might be a false-negative diagnosis with ERC. Second, in 2 of the 4 instances of false-positive findings, swelling of the papilla found during ERC might indicate recent stone migration. Thus, our results concerning specificity and negative predictive value are probably underestimated. The stone diameter is a principal problem in the diagnosis of choledocholithiasis for experienced and less-experienced examiners. In the present study, all patients with false-negative results had stones with a diameter of less than 15 mm at ERC. In addition, in 44% of these patients the common bile duct could not be entirely evaluated because of bowel gas and/or increased adipose tissue.

The advantages of this study include its prospective design and evaluation of information, its homogeneous group of patients and availability of ERC as the gold standard in all cases. ERC was performed in all patients because of the high clinical and biochemical suspicion of choledocholithiasis. A potential disadvantage is the relatively small number of patients, but nonetheless, this represents one of the largest experiences comparing US with ERC as the gold standard. We are a reference centre and the equipment, population and examiners are likely different from those in a primary care setting. But our findings underline the hypothesis that experience in interpreting US is paramount for detecting bile duct stones. Because there was a greater number of less-experienced than experienced examiners, more patients were investigated by less-experienced investigators.

Optimal management of patients with choledocholithiasis needs timely coupling of diagnosis and therapy. In conclusion, the results of the present study demonstrate that high-resolution US done by experienced examiners has a high diagnostic accuracy in the diagnosis of common bile duct stones. Therefore, good training and continued experience are prerequisites for successful sonographic detection of bile duct stones with US. Under these conditions, further expensive and invasive methods such as ERC, MRCP and EUS may not be necessary in cases with a clear sonographic diagnosis.

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