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Diagnostic accuracy of endoscopic ultrasound in evaluation of patients with obstructive jaundice: single-center experience

Shereen Abou Bakr¹, Hagar Elessawy¹, Sameh Ghaly¹, Muhammed Abo Elezz², Ahmed Farahat² and Mariam Salah Zaghoul^{3*}

Abstract

Background/aims: We prospectively evaluated the role of endoscopic ultrasound (EUS) in detecting the cause of common bile duct (CBD) dilatation in patients in whom trans-abdominal ultrasound (TUS) could not demonstrate the cause of dilation as a proper second step in the diagnostic workup of patients with obstructive jaundice compared to magnetic resonance cholangiopancreatography (MRCP).

Methods: This study was conducted on patients with obstructive jaundice admitted to the inpatient ward or the outpatient endoscopy unit of Theodor Bilharz Research Institute (TBRI) during the period between January 2019 and August 2019. A patient with obstructive jaundice and TUS showed CBD dilatation with internal diameter ≥ 7 mm and biliary stricture.

Results: During the period between January 2019 and August 2019, 136 were recruited; 8 patients who were pregnant and 3 patients who had gastric bypass surgery were excluded. Sixty-five patients were diagnosed confidently by TUS as biliary stones and were excluded from the analysis. Sixty patients with obstructive jaundice and indefinite etiology on TUS were included in the final analysis. The final diagnosis of patients was 38 patients (63.33%) of malignant etiology [26 pancreatic cancer (43.33%), 4 cholangiocarcinoma (6.66%), and 8 with ampullary cancer (13.33%)] and 22 patients (36.67%) of benign etiology [10 calcular obstruction (16.66%), 8 benign stricture (13.33%), and 4 pancreatitis (6.66%)]. The sensitivity and specificity values for malignant stricture detected by EUS were 100% and 86.36%, respectively, with positive predictive value of 92.68%, negative predictive value of 100%, and accuracy of 95%, while MRI showed 82.14% sensitivity and 25% specificity with positive predictive value of 79.31 and accuracy of 69.4%. EUS supported correct diagnosis in 57 patients (95%: CI 86.08 to 98.96%) while MRI did it in 36 patients (69.44%: CI 51.89% to 83.65%). Only 43 (71.7%) patients needed endoscopic retrograde cholangiopancreatography (ERCP) for management of obstructive jaundice, sparing 17 patients (28.3%) unnecessary invasive procedures.

Conclusions: EUS is a minimally invasive method with low incidence of complications with high diagnostic accuracy in patients with dilated CBD and normal MRCP.

*Correspondence: mariam_zaghoul@med.kfs.edu.eg

³ Hepatology, Gastroenterology and Infectious Diseases Department, Faculty of Medicine, Kafrelsheikh University, Kafrelsheikh, Egypt
Full list of author information is available at the end of the article

Highlights

Dilatation of the common bile duct (CBD) can be caused by diverse etiologies either benign or malignant. Trans-abdominal ultrasound (TUS), in skilled hands, can correctly identify biliary obstruction and its underlying etiology. However, it has high interobserver variability with poor sensitivity for the detection of pancreatic neoplasms compared with other imaging techniques. There is heterogeneity in the literature regarding the competencies of endoscopic ultrasound (EUS) and magnetic resonance cholangiopancreatography (MRCP) in the evaluation of pancreaticobiliary disorders. We showed our real-life experience that suggests that EUS is a minimally invasive method with low incidence of complications with high diagnostic accuracy in patients with dilated CBD and even with unremarkable MRCP.

Keywords: Abdominal ultrasound, Endoscopic ultrasound, Obstructive jaundice, Magnetic resonance cholangiopancreatography

Introduction

Obstructive jaundice is a common daily practice problem that indicates blockage in the pathway between the intrahepatic conjugation site of bile and its entry site into the duodenum through the ampulla of Vater [1]. The obstruction could be intrahepatic, at the biochemical, cellular, or canalicular level, or extrahepatic in the bile ducts. Surgical jaundice refers to the extrahepatic causes of obstructions. While laboratory tests confirm the presence of cholestasis, the imaging studies of the biliary tree are pivotal in determining the site of obstruction and its cause [1].

The conventional trans-abdominal ultrasound (TAU) is the first step in the diagnostic workup of patients with obstructive jaundice. Ultrasound could detect dilatation of the intrahepatic or extrahepatic biliary tree in 85–95% of patients with proven obstruction, although the definitive etiology could be achieved in only about one third of patients [2].

Meanwhile, other cross-sectional imaging like multi-detector computed tomography MDCT [3] and magnetic resonance cholangiopancreatography MRCP [4] contributed to accurate classification of patients with obstructive jaundice. Although non-invasive, CT involves exposure to radiation and contrast and has low sensitivity in detecting biliary diseases. Moreover, MRCP mandates the use of contrast and incapable of providing a histological diagnosis [5].

Endoscopic ultrasound has proven high sensitivities of up to 97% in the detection of CBD stones [6]. EUS is also accurate in diagnosing the cause of obstruction [7] in cases of stricture, neoplasm, and other extra-ductal causes of obstruction relating to the ampulla and head of pancreas. EUS is considered a safe and useful technique for selecting patients for therapeutic ERCP, allowing many patients to avoid the potential complications of ERCP of doubtful indication [8].

Despite advances in MRCP technology that improved the diagnosis of biliary abnormalities, it is not uncommon

to face cases with dilated common bile duct (CBD) without obvious cause on MRCP [5, 9]. Therefore, we prospectively evaluated the role of EUS in detecting the cause of CBD dilatation in patients in whom TUS could not demonstrate the cause of dilation as a proper second step in the diagnostic workup of patients with obstructive jaundice compared to MRCP.

Patients and methods

Study design

This is a prospective observational study.

Patients

This study was conducted on patients with obstructive jaundice admitted to the inpatient ward or the outpatient endoscopy unit of Theodor Bilharz Research Institute (TBRI) during the period between January 2019 and August 2019.

Inclusion criteria

Patients with obstructive jaundice and abdominal US showed CBD dilatation with internal diameter ≥ 7 mm and biliary stricture.

Exclusion criteria

The exclusion criteria are patients with history of surgery with gastroenteric anastomosis (Roux-en-Y gastrojejunostomy or Whipple's procedure), which might interfere with a successful EUS and ERCP procedure, pregnant female, patients with coagulopathy, or those who failed to sign the informed consent were excluded from the study.

All patients underwent abdominal US, MRI, and EUS, with ERCP and/or EUS-FNA for identification of the final diagnosis of obstructive jaundice.

All patients were subjected to full history taking, clinical examination, and laboratory investigations before endoscopic procedure including complete blood count by (Quintus five parts differential, Sweden), coagulation profile (prothrombin time (PT), international normalization

ratio (INR), partial thromboplastin time (PTT) by Stago STA compact max, France, liver function tests (LFTs) by Cobas 8000 auto-analysis, Japan, and kidney function tests and electrolytes [blood urea nitrogen (BUN), serum creatinine, sodium (Na), potassium (K), and CRP (C-reactive protein)].

- Abdominal ultrasound (HITASHI Avius, Curvilinear probe 2–5 MHZ, Japan) to measure diameter of CBD and detect IHBRDs, EHBRDs, gall bladder, and pancreas if visualized and detection of the cause if seen
- MRCP (Siemens, Germany) to confirm biliary obstruction and detect the cause and to compare with EUS performance
- EUS was performed with Linear EUS EG-3870UTK Ultrasound video Endoscopy, PENTAX (3.8), Japan, sedated with propofol. Operators were blinded to the MRCP results
- ERCP for relief of biliary obstruction (Pentax ED 3485 T)
- Tissue diagnosis was done using EUS-fine needle aspiration (FNA) (EUS FNA19, 22, Gauge, USA) and biopsy core in case of suspected malignancies of pancreatic head, ampulla of Vater, and distal biliary duct lesions to prove the final diagnosis.

Statistical analysis

Statistical analysis was performed with the SPSS® software package (IBM® SPSS® Statistics release 25.0, USA). For nonparametric data, median and IQR were used for a better description. Wilcoxon test was used for paired ordinal data, and diagnostic performance test was done for used modalities to get each sensitivity and specificity percentage.

Ethical considerations

The study protocol was approved by the Hospital Ethics Committee. All patients gave a written informed consent for participating in the study and for performing all relevant interventions. The study protocol was adherent to practice guidelines and Declaration of Helsinki.

Results

During the period between January 2019 and August 2019, 136 were recruited; 8 who were pregnant and 3 patients who had gastric bypass surgery were excluded. Sixty-five patients were diagnosed confidently by TAU as biliary stones and were excluded from the analysis. Sixty patients with obstructive jaundice and indefinite etiology on TUS were included in the final analysis.

Table 1 The baseline demographic data and laboratory investigations of patients

Variable	Patients (n = 60)
Age years, mean (SD)	58.01 (11.44)
Sex, male/female n (%)	38/22 (63.3%: 36.7%)
T. bilirubin mg/dL, median (IQR)	9.00 (6–12)
D. bilirubin mg/dL, median (IQR)	5.50 (3.23–7.30)
ALP U/l, median (IQR)	301.00 (246.25–452.25)
AST IU/L, median (IQR)	46.50 (39.25–84.00)
ALT IU/L, median (IQR)	53.00 (35.00–102.50)
INR, median (IQR)	1.10 (1.00–1.19)

Table 2 Final diagnosis of patients in the study sample

		N	%	
Malignant	Pancreatic cancer	26	43.33	38 (63.33%)
	Cholangiocarcinoma	4	6.67	
	Ampullary adenocarcinoma	8	13.33	
Benign	Benign obstruction	8	13.33	22 (36.67%)
	Biliary stone obstruction	10	16.67	
	Pancreatitis	4	6.67	

The mean age of the patients was 58 years old with a total number of males being 38 patients (63.3%) and the total number of females being 22 (36.7%).

The baseline demographic data and laboratory investigations of patients are demonstrated in Table 1.

The final diagnosis of patients was 38 patients (63.33%) of malignant etiology [26 cases with pancreatic cancer (43.33%), 4 cases with cholangiocarcinoma (6.66%), and 8 cases with ampullary cancer (13.33%)] and 22 patients (36.67%) of benign etiology [10 cases with calculous obstruction (16.66%), 8 cases with benign stricture (13.33%), and 4 cases with pancreatitis (6.66%)] (Table 2).

As regards patients with malignant OJ, the total number of enlarged pancreas showed by US was 32 (84.2%), while by EUS, it was 9 (28.1%) (most cases were shown by US as enlarged pancreas and were shown to be mass by EUS). The total number of pancreatic mass showed by EUS was 29 (73.7%).

Comparative data of EUS diagnosis and final diagnosis

The total number of the patients with malignant obstruction detected by EUS was 41 patients (63.8%), while in the final diagnosis of malignant obstruction, it was 38 patients (63.3%) (three cases were shown by EUS to be malignant obstruction, but pathology showed them benign; one case was ampullary adenocarcinoma by EUS; pathology revealed adenoma; 2 cases were shown as

pancreatic cancer, and pathology revealed chronic pancreatitis). EUS successfully detected all patients with pancreatitis, cholelithiasis, and benign strictures.

The sensitivity and specificity values for malignant stricture detected by EUS were 100% and 86.36%, respectively, with positive predictive value of 92.68%, negative predictive value of 100%, and accuracy of 95%, while it showed 100% sensitivity, specificity, and accuracy in benign etiologies (Table 3).

Comparative data of MRI diagnosis and final diagnosis

The total number of malignant obstructions showed by MRI was 29 patients (48.33%), while in the final diagnosis of malignant obstructions, it was 38 patients (63.3%). The total number of pancreatitis showed by MRI was 1 patient (1.6%), while in the final diagnosis, it was 4 patients (6.66%). The total number of calcular obstruction showed by MRI was 2 patients (3.33%), while in the final diagnosis, it was 10 patients (16.66%); the total number of benign obstructions was 4 patients (6.66%), while in the final diagnosis, it was 8 (13.33%).

The sensitivity and specificity values for malignant stricture detected by MRI were 82.14% and 25% respectively with positive predictive value of 79.31 and accuracy of 69.4%. On the other hand, for benign etiologies, MRI showed 33.33% sensitivity and 96.97% specificity with positive predictive value of 50% and accuracy of 91.67% (Table 3).

In our study, EUS supports correct diagnosis in 57 patients (95%: CI 86.08% to 98.96%), while MRI did it in 36 patients (69.44%: CI 51.89% to 83.65%).

Only 43 (71.7%) patients needed ERCP for management of obstructive jaundice, sparing 17 patients (28.3%) unnecessary invasive procedures.

Discussion

Dilatation of CBD can be caused by diverse etiologies either benign like choledocholithiasis, CBD stricture, and papillary stenosis or malignant like cholangiocarcinoma and pancreatic head mass [10]. TUS, in skilled hands, can diagnose biliary obstruction via demonstration of biliary dilation. TUS may potentially identify the pancreatic mass or hepatic metastases as well as allowing needle biopsy of these lesions [11]. However, it has a

relatively poor sensitivity for the detection of pancreatic neoplasms compared with other techniques [12].

Both EUS and MRCP are excellent modalities with comparative accuracy for evaluation of pancreaticobiliary disorders. Multiple studies have shown high diagnostic performance of them with no significant difference in the diagnostic yield [13, 14]. On the other hand, some demonstrated that the diagnostic yield of MRCP decreases in the presence of dilated CBD and small CBD stones [15]. Therefore, in these situations, EUS has a favorable diagnostic yield. So, we prospectively evaluated the role of EUS in patients with dilated CBD and inconclusive TUS.

In the present study, TUS successfully identified patients with cholelithiasis but failed to diagnose 60 patients with dilated CBD. Moreover, most of patients with bulky pancreas on TUS revealed to be definite pancreatic mass on further EUS evaluation.

This was in accordance with Songür et al. [16] who investigated 90 patients with dilated CBD of unexplained cause on US with EUS, and correct diagnosis was achieved in 92% cases with EUS.

Surinder et al. [17] retrospectively analyzed 40 patients with dilated CBD on MRCP without obvious etiology referred for further evaluation by EUS. The EUS diagnosis was CBD stones in 15 (37.5%), with largest size of CBD stone being 9mm, mass in CBD in 2 (5%), benign biliary stricture in 2 (5%), and biliary stricture with underlying chronic pancreatitis in 1 (2.5%) patient respectively. EUS examination revealed normal CBD in 20 (50%) patients, and two of these patients had periampullary diverticulum.

In our study, the sensitivity and specificity value for malignant obstruction detected by EUS was 100% and 86.36%, respectively, with positive predictive value of 92.68%, negative predictive value of 100%, and overall accuracy of 95%. This was in agreement with Chen et al. study, in which the sensitivity and specificity value for malignant obstruction detected by EUS was 97.5% and 97.6%, respectively, with positive predictive value of 95.1%, negative predictive value of 98.8%, and overall accuracy of 92.9% [18].

Also, Maluf-Filho et al. [19] showed that the sensitivity and specificity value for malignant stricture detected by EUS were 96.6% and 90.6%, respectively, with positive

Table 3 Comparative data regarding sensitivity, specificity of MRI and EUS diagnosis for malignant, inflammatory, benign, and calcular obstruction

	Malignant stricture		Inflammatory process		Benign stricture		Calcular obstruction	
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
MRI diagnosis	82.14%	25%	0.00%	96.90%	0.00%	0.00%	33.30%	96.90%
EUS diagnosis	100%	86.30%	85.71%	100%	50%	100%	100%	100%

predictive value of 90.3%, negative predictive value of 96.7, and accuracy of 93.4%, while Thomas Rösch et al. [20] showed that the sensitivity and specificity for diagnosis of malignancy in the 50 patients were as follows: 85%/75% for ERCP/PTC, 85%/71% for MRCP, 77%/63% for CT, and 79%/62% for EUS.

Moreover, in Hauke et al. [21] who compared different diagnostic tools for detecting bile duct malignancy, it has accuracy rates of 91% (ERCP/IDUS), 59% (ETP), 92% (IDUS + ETP), 74% (EUS), and 73% (CT), respectively.

In our study, the sensitivity and specificity values for benign strictures detected by EUS were 100% and 98.4%, respectively, with positive predictive value of 90%, negative predictive value of 100%, and accuracy of 98.33%. This was in agreement with Chen et al. [18] who found that the sensitivity and specificity value for calculi obstruction detected by EUS was 92.9% and 97.7%, respectively, with positive predictive value of 92.9% and negative predictive value of 97.9% and overall accuracy of 92.9%. Also, the overall accuracy of EUS was 100% for benign obstruction.

Alhawarey et al. [22] demonstrated that EUS, as diagnostic tool, has sensitivity, specificity, PPV, NPV, and accuracy of 100%, 92.8%, 93.7%, 100%, and 96.5% respectively.

Also, in Meeralam et al. [23] meta-analysis of the diagnostic accuracy of EUS compared with MRCP in detecting choledocholithiasis, the overall diagnostic odds ratio of EUS was significantly higher than the one with MRCP (162.5 vs. 79.0, respectively; $P = .008$).

In our study, the sensitivity and specificity values for malignant stricture detected by MRI were 82.14% and 25% respectively with positive predictive value 7 of 9.31 and accuracy of 69.4%. On the other hand, for benign etiologies, MRI showed 33.33% sensitivity and 96.97% specificity with positive predictive value of 50% and accuracy of 91.67%. EUS supported correct diagnosis in 57 patients (95%: CI 86.08% to 98.96%), while MRI did it in 36 patients (69.44%: CI 51.89% to 83.65%). This was in line with Songür et al. [16] who investigated 90 patients with dilated CBD of unexplained cause on US by EUS, and correct diagnosis was achieved in 83 cases with EUS. Maluf-Filho et al. [19] EUS supported correct diagnostic hypothesis for pancreatobiliary malignancy in 40:46 patients (87.0%; CI 77.2–96.7), while CT did in 31:36 patients (67.4%; CI 53.8–80.9).

In our cohort, only 43 (71.7%) patients needed ERCP for management of obstructive jaundice, sparing 17 patients (28.3%) unnecessary invasive procedures. This was in line with Patel et al. [24] study where EUS ruled out choledocholithiasis in 38 patients (48.7%). Two of them were found to have

choledocholithiasis on follow-up. The sensitivity, specificity, and positive and negative predictive value of EUS for detecting choledocholithiasis were 93.9%, 97.3%, 96.9%, and 94.7%, respectively. Unnecessary ERCP was avoided in 57.7% of the patients by using the EUS-first approach.

Our study has its own limitations. This is a single-center experience, but it has the privilege of prospective evaluation of patients. So, multicenter studies with cost effective analysis are recommended. We believe that the malignant life-threatening etiologies of biliary obstruction should not be missed; it is of utmost importance that those who do not have a pathologic cause of biliary dilatation are not subjected to unnecessary invasive/semi-invasive evaluation.

In conclusion, EUS is a minimally invasive method with low incidence of complications with high diagnostic accuracy in patients with dilated CBD and normal MRCP.

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Current knowledge

1- Dilated common bile duct (CBD) without obvious cause is a not uncommon finding on TU.

2- Endoscopic ultrasound (EUS) provides important diagnostic tool concerning the biliary anatomy and also provides an opportunity to sample the tissue/lesion thereby providing a histological diagnosis.

New

EUS is an important diagnostic modality that can help establish the diagnosis in patients with dilated CBD and inconclusive MRCP.

Authors' contributions

All authors equally contributed to this research work. All authors have read and approved the manuscript.

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None

Availability of data and materials

The data that support the findings of this study are available from the corresponding author, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request.

Declarations

Ethics approval and consent to participate

All patients who participated in the present study signed an informed consent form. The study protocol was approved by the Ethics Committee of the Faculty of Medicine, Ain-Shams University, Egypt, and is in accordance with the Helsinki Declaration of 1975.

Consent for publication

Written informed consents were obtained from patients. Patients involved in this study agree for publication of data.

Competing interests

The authors declare that they have no competing interests.

Author details

¹Internal Medicine Department, Gastroenterology and Hepatology Unit, Ain Shams, Cairo, Egypt. ²Theodor Bilharz Research Institute, Giza, Egypt. ³Hepatology, Gastroenterology and Infectious Diseases Department, Faculty of Medicine, Kafrelsheikh University, Kafrelsheikh, Egypt.

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