www.jcimcr.org

JCIMCR OPEN ACCESS Journal of Clinical Images and Medical Case Reports

ISSN 2766-7820

Research Article

Open Access, Volume 5

Role of endoscopic ultrasound in diagnosis of unexplained distal common bile duct structure

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Received: Jan 17, 2024

Accepted: Feb 01, 2024

Published: Feb 08, 2024

Archived: www.jcimcr.org

DOI: www.doi.org/10.52768/2766-7820/2847

Abstract

Purpose: Determining the etiology of a distal biliary stricture without an identifiable mass on imaging is crucial to the provision of appropriate therapy. This study aims to assess the ability of Endoscopic Ultrasound (EUS) to diagnose distal biliary strictures for which cross-sectional imaging modalities such as Computed Tomography (CT) scan and Magnetic Resonance Imaging (MRI) could not detect a causative mass or bile duct thickening.

Methods: Prospective study on 80 patients with unexplained distal biliary stricture diagnosed by Magnetic Resonance Cholangiopancreatography (MRCP), Endoscopic Retrograde Cholangiopancreatography (ERCP), CT or MRI underwent EUS.

Results: 80 patients (50 male; mean age 57.9±9.8 years) were studied. Based on EUS findings; 51 patients were diagnosed with malignant strictures 63.75% (21 distal cholangiocarcinoma, 17 pancreatic head mass, 11 ampullary mass lesion and 2 intraductal papillary mucinous neoplasm) and rest of patients were diagnosed with benign strictures 36.25%. ROC analysis between malignant and benign strictures for distal CBD wall thickness has shown a cutoff value >3.2 (Sensitivity 80.39%, Specificity 89.66%, Positive Predictive Value (PPV) 93.2, Negative Predictive Value (NPV) 72.2 and accuracy 85.7%).

Conclusion: EUS is a useful investigational modality for patients with unexplained distal CBD stricture and can be predictive of the nature of the stricture.

Keywords: Endoscopic ultrasound; Distal biliary structure; Common bile duct.

Abbreviations: EUS: Endoscopic Ultrasound; CT: Computed Tomography; MRI: Magnetic Resonance Imaging; MRCP: Magnetic Resonance Cholangiopancreatography; ERCP: Endoscopic Retrograde Cholangiopancreatography; CBD: Common Bile Duct; CA19-9: Carbohydrate Antigen 19-9; IHBRD: Intrahepatic Biliary Radicle Dilatation; EUS-FNA: EUS Fine Needle Aspiration; SPSS: Statistical Package For Social Science; SD: Standard Deviation; ROC: Receiver Operating Characteristic; HB: Hemoglobin; WBCs: White Blood Cells; GGT: Gammaglutamyl Transferase; CEA: Carcinoembryonic Antigen; MPD: Main Pancreatic Duct; IPMN: Intraductal Papillary Mucinous Neoplasm; LN: Lymph Nodes; ALT: Alanine Aminotransferase; AST: Aspartate Aminotransferase; ALP: Alkaline Phosphatase.

Introduction

Since its development, EUS became an established irreplaceable diagnostic modality, allowing visualization of previously inaccessible anatomical regions with the capability to obtain tissue for diagnosis [1]. Diagnostic EUS has progressed in the last decade by advances in imaging techniques and introducing novel methods of tissue characterization based on the vascular structure and tissue stiffness [2]. EUS has emerged as an important tool for evaluation of biliary disease. Apart from providing important diagnostic information concerning the biliary anatomy, it offers an opportunity to sample the tissue/lesion thereby providing a histologic diagnosis. It also helps determine invasion and local staging of any malignant lesion [3]. In patients presenting with a cholestatic clinical profile, intrahepatic and/or extrahepatic biliary strictures frequently present a diagnostic challenge to determine their benign or malignant nature. Appropriate diagnosis is essential to avoid missing malignancy in benign-appearing strictures, or unnecessary surgical exploration for benign disease mimicking malignancy [4]. Endoscopic ultrasound has become the imaging test of choice in patients with distal biliary obstruction, having high sensitivity and accuracy for malignant etiology [5]. Multiple studies have reported a sensitivity ranging from 40-90%, with most of these showing a sensitivity of more than 70% [6]. This study aims to assess the ability of EUS to diagnose distal biliary strictures for which cross- sectional imaging modalities such as CT and MRI could not detect a causative mass or bile duct thickning.

Methods

A prospective study conducted on 80 patients who underwent EUS at National Liver Institute, Menofia University for evaluation of distal biliary strictures. The study started after its approval by the ethical and scientific board of the National Liver institute. A written and informed consent had been taken from each patient before inclusion in this study. Patients with distal biliary stricture diagnosed by other imaging modalities such as MRCP, ERCP, CT or MRI were included in the study. Patients under 18 years old, unfit for EUS due to other severe comorbidities, refusing to be involved in this study, with identifiable mass lesions causing biliary strictures, patients with proximal bile duct strictures were excluded from the study. Patients were studied regarding full history taking, physical examination, laboratory and imaging investigations.

EUS was done for the patients to evaluate the prescence of masses that can cause extrinsic compression at the site of stricture and disruption of the normal 2-3 layers of the CBD [7]. EUS procedure was performed in the same fashion as standard endoscopic examinations. The majority of cases were performed on an outpatient basis and intravenous sedation [8]. EUS was performed using a 7.5-MHz US probe (UM-200; Olympus, Tokyo, Japan) connected to a standard EUS processor (EU-30; Olympus). This probe provides radial scanning perpendicular to its axis. For the aim of this study, EUS images were reviewed to identify extrinsic compression at the stricture site without knowledge of the final diagnosis. Evaluation points were:

(1) Presence of a mass that could create extrinsic compression at the site of the stricture;

(2) Disruption of the normal 2 or 3 sonographic layers of the bile duct wall [9]; and

(3) Continuation of a mass into adjacent structures [10].

Data was collected and entered to the computer using SPSS (Statistical Package for Social Science) program for statistical analysis, (version 13; Inc., Chicago. IL). Two types of statistics was done; Descriptive statistics including quantitative data shown as mean, SD, and range while qualitative data expressed as frequency and percent. Analytical statistics including Chi-square test, Student t-test, the ROC (Receiver Operating Characteristic) curve, Sensitivity, specificity, +ve and –ve predictive values, and diagnostic accuracy was calculated. P-value will be considered statistically significant when it is less than 0.05.

Results

Demographic and laboratory findings

This study involved 80 patients, at inclusion the mean age was (57.96±9.84 years), Most of the enrolled patients were males (n=50; 62.50%), urban (n=51; 63.75%), nonsmokers (n=72; 90%). Most comorbidities in the order were diabetes mellitus (n=53; 66.25%), hypertension (n=27; 33.75%), ischemic heart disease (n=15; 18.75%), Chronic liver disease (n=12; 15%) and Decompensated liver cirrhosis (n=6; 7.5%). The main complain in most patients was abdominal pain (n=66; 82.5%), jaundice (n=60; 75%), fatigue (n=45; 56.25%), itching (n=37; 46.25%), fever (n=35; 43.75%) and weight loss (n=19; 23.75%). (Table 1).

As regards laboratory investigations, Mean ALT was 84.55±90.13 IU/L while mean AST was 101.37±157.92 IU/L. Mean Alkaline phosphatase was 311±230.47 IU/L while mean GGT was 362.17±350.81 IU/L. Regarding tumor markers, mean CEA was 3.56±2.85 IU/L, mean CA19-9 was 2626.48±6619.53 IU/L while mean Alphafetoprotein was 9.31±8 IU/L (Table 1).

Imaging findings

Ultrasound of the studied patients before performing ERCP for biliary drainage showed dilated CBD and IHBRD was minimal (n=48; 60%), mild (n=11; 13.75%), moderate (n=16; 20%) and marked (n=4; 5%) while only one patient (1.25%) had NO IHBRD. Ultrasound detected enlarged different abdominal lymph nodes only in 7 patients (8.75%).

Endoscopic findings (ERCP and EUS)

Regarding ERCP finding; IHBR was dilated (n=68; 85%), dilated with stenotic segments (n=2; 2.5%) and there was NO IHBRD in 10 patients (12.5%). CBD was dilated proximally with distal stricture; so plastic stent was inserted (n=72; 90%) while there was distal smooth tapering (n=5; 6.25%) and abrupt distal narrowing (n=2; 2.5%) and also plastic stent was inserted in both, only 1 patient (1.25%) had normal CBD proximally with distal stricture.

Cholangiogram showed dilated main pancreatic duct only in 1 patient (1.25%) and rest of the patients had normal MPD. Number of patients needed to apply intervention to the papilla due to difficult cannulation (n=24; 30%) e.g Precut, Papillotomy or Sphincterotomy. Most patients done 1 trial of ERCP (n=61; 76.25%) while some needed 2 trials for biliary drainage (n=16; 20%) and few patients needed 3 trials (n=2; 2.5%) while only 1

patient (1.25%) had failed two trials of ERCP.

As regard EUS findings, diagnosis was established into Distal cholangicarcinoma (n=21; 26.25%), Pancreatic head mass (n=17; 21.25%), Ampullary mass lesions (n=11; 13.75%), Main branch IPMN intraductal papillary mucinous neoplasm (n=2; 2.5%), Inflammatory strictures (n=25; 31.25%), Primary sclerosing cholangitis (n=2; 2.5%) and Hydatidosis (n=2; 2.5%). Patients were classified into malignant strictures (n=51; 63.75%) and benign strictures (n=29; 36.25%). Mean distal CBD wall thickness was 3.9±1.43 mm, it was regular (n=50; 62.5%) and irregular (n=30; 37.5%). Main pancreatic duct was found dilated (n=28; 35%) and mean pancreatic duct dilatation was 8±4.37 mm. As regard lymph nodes detected on EUS, malignant looking LN was found (n=28; 35%) and likely reactive LN (n=9; 11.25%) while No LN were detected in rest of the patients (n=43; 53.75%) (Table 2).

Comparison between laboratory data of benign and malignant strictures

Mean total bilirubin of patients with benign strictures was 4.59±4.39 mg/dl and mean direct bilirubin was 3.33±3.54 mg/dl, while in patients with malignant strictures it was higher (mean total bilirubin 11.88±10.11 and mean direct bilirubin 8.45±7 mg/dl) with high statistical significant difference (P-value<0.001).

Mean CEA in patients with benign strictures was 2.31±1.11 while it was higher in patients with malignant strictures with mean 4.27±3.27 with high statistical significant difference (P-value<0.001). Mean CA19-9 in patients with benign strictures was 98.85±209.77 while it was higher in patients with malignant strictures 4063.76±7962.13 with high statistical significant difference (P-value<0.001) (Table 3).

Comparison of EUS finding between benign and malignant strictures

Mean distal CBD wall thickness in patients with benign strictures was (2.87±0.76) mm while it was higher in patients with malignant strictures (4.49±1.4) mm with high statistical significant difference (P-value<0.001). Regarding preservation of normal CBD layers; only 1 out of 29 patients (3.45%) with benign strictures have irregular wall thickness, while most patients with malignant strictures have irregular wall thickness (29 out of 51) (56.86%) with high statistical significant difference (P-value<0.001). Main pancreatic duct was found dilated (n=7; 24.14%) in patients with benign strictures while (n=21; 41.18%) in patients with malignant strictures with mean pancreatic duct dilatation (5.07±2.07) mm in benign strictures and (8.98±4.52) mm in malignant strictures with statistical significant difference (P-value<0.05). Regarding lymph nodes detected by EUS; in patients with benign strictures, likely reactive LN were detected in (n=7; 24.14%) while malignant looking LN were detected in (n=26; 50.98%) patients with malignant strictures with high statistical significant difference (P-value<0.001) (Table 4).

ROC analysis between malignant and benign strictures for distal CBD wall thickness has shown a cutoff value >3.2 (Sensitivity 80.39%, Specificity 89.66%, Positive Predictive Value (PPV) 93.2, Negative Predictive Value (NPV) 72.2 and accuracy 85.7%) (Table 5 and Figure 1).

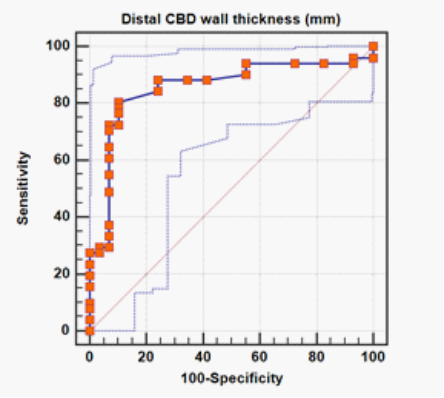

Figure 1: Diagnosis established by EUS features was compared to results obtained from EUS-FNA as shown (Table 6).

Discussion

EUS since its development became an established irreplaceable diagnostic modality, allowing visualization of previously inaccessible anatomical regions with the capability to obtain tissue for diagnosis [1]. In our study; the main complain in most patients was abdominal pain (n=66; 82.5%), jaundice (n=60; 75%), fatigue (n=45; 56.25%), itching (n=37; 46.25%), fever (n=35; 43.75%) and weight loss (n=19; 23.75%). A study done by M. Sousa et al. conducted on 56 patients underwent EUS from 2010 to 2017 due to unexplained dilated CBD detected by transabdominal ultrasonography TUS (CBD≥7 mm) or (CT) (CBD≥10 mm). Most patients were asymptomatic (n=28; 50%), abdominal pain was the most common presenting symptom in symptomatic patients (n=20; 36%), while jaundice (n=5; 9%) , weight loss (n=2; 4%) and itching (n=1; 2%) [11]. In the present study; mean total bilirubin 9.24±9.17 mg/dl while direct bilirubin was 6.59±6.48 mg/dl. Mean Alkaline phosphatase was 311±230.47 IU/L while mean GGT was 362.17±350.81 IU/L. As regards tumor markers; mean CEA in patients with benign strictures was 2.31±1.11 while it was higher in patients with malignant strictures with mean 4.27±3.27 with high statistical significant difference (P-value <0.001). Mean CA19-9 in patients with benign strictures was 98.85±209.77 while it was higher in patients with malignant strictures 4063.76±7962.13 with high statistical significant difference (P-value<0.001).

A study by Saifuku Y et al. conducted on 34 patients who underwent EUS at Dokkyo Medical School Hospital from December 2005 to December 2008 for evaluation of unexplained strictures in the biliary tract that were detected by ERCP or MRCP; jaundice (total bilirubin>2 mg/dL) was evident at presentation in 13 patients. In the 21 patients without jaundice, abnormal liver blood tests were found in 8 patients. Tumor markers were measured in 34 patients, and correctly identified malignancy in 13 of 17 malignant strictures and correctly identified a benign disease in 12 of 17 benign strictures. In terms of the proportion of correct diagnosis, no significant difference was seen between patients with malignant and benign lesions (76.5% vs 70.6%, P>0.05) [12].

In our study; as regard findings detected by EUS, diagnosis was established into Distal cholangicarcinoma (n=21; 26.25%), Pancreatic head mass (n=17; 21.25%), Ampullary mass lesions (n=11; 13.75%), Main branch IPMN intraductal papillary mucinous neoplasm (n=2; 2.5%), Inflammatory strictures (n=25; 31.25%), Primary sclerosing cholangitis (n=2; 2.5%) and Hydatidosis (n=2; 2.5%). Patients were classified into malignant strictures (n=51; 63.75%) and benign strictures (n=29; 36.25%).

Table 1: Demographic and laboratory data of the studied group.

Total					
Age	Range	29	-	80	
	Mean ±SD	57.963	±	9.846	
		N		**%**	
Sex	Male	50		62.50	
	Female	30		37.50	
Residence	Urban	51		63.75	
	Rural	29		36.25	
Special habits of medical importance	No	32		40.00	
	Smoker	8		10.00	
	Canal water contact	40		50.00	
Complaint	Abdominal pain	66		82.50	
	Weight loss	19		23.75	
	Jaundice	60		75.00	
	Fever	35		43.75	
	Fatigue	45		56.25	
	Itching	37		46.25	
Comorbidities	DM	53		66.25	
	HTN	27		33.75	
	IHD	15		18.75	
	Chronic liver disease	12		15.00	
	Decompensated liver cirrhosis	6		7.50	
HB	Range	8.7	-	15.6	
	Mean ±SD	11.978	±	1.766	
WBC	Range	2.1	-	19	
	Mean ±SD	8.000	±	3.409	
PLT	Range	60	-	447	
	Mean ±SD	242.513	±	97.847	
Total Bilirubin	Range	0.37	-	35.5	
	Mean ±SD	9.242	±	9.170	
Direct Bilirubin	Range	0.09	-	33.2	
	Mean ±SD	6.596	±	6.481	
ALT	Range	8	-	436	
	Mean ±SD	84.550	±	90.138	
AST	Range	18	-	846	
	Mean ±SD	101.375	±	157.924	
ALP	Range	54	-	1030	
	Mean ±SD	311.050	±	230.471	
GGT	Range	43	-	1344	
	Mean ±SD	362.175	±	350.814	
CEA	Range	0.2	-	12.3	
	Mean ±SD	3.561	±	2.851	
CA19-9	Range	1.13	-	39922	
	Mean ±SD	2626.486	±	6619.538	
Alpha-fetoprotein	Range	1.04	-	32	
	Mean ±SD	9.310	±	8.075	

In the study by Saifuku Y et al. there were 17 malignant strictures, 11 benign strictures and 6 normal cases. Among 8 cases of peripancreatic cancer, the diagnosis was confirmed as pancreatic cancer by pathological examinations using surgical specimens in 6 cases and 2 lesions were considered malignant based on clinical follow-up and died of liver failure 4 mo after EUS examination, accompanied by CA19-9 elevation. Among 7 cases of biliary cancer, the diagnosis was confirmed by pathological examination using surgical specimens in 5 cases and 2 lesions considered malignant on clinical follow-up were located in the middle duct. One patient was diagnosed with carcinoma of the papilla of Vater by pathological examination using surgical specimens [12].

The study by M. Sousa et al, where 56 pancreatico-biliary EUS procedures were performed during the study period due to an indication of dilated CBD. The majority of patients (n=39) had normal findings on EUS. Abnormal EUS findings were found in 30% (n=17) of patients. These included choledocholithiasis (n=6), ampuloma (n=3), choledochal cyst (n=2), benign CBD stenosis (n=2), cyst of the head of the pancreas (n=1), cholangio-

Table 2: Endoscopic ultrasound findings of the studied group.

Total				
		N		%
Diagnosis	Distal cholangiocarcinoma	21		26.25
	Inflammatory stricture	25		31.25
	Pancreatic head mass	17		21.25
	Ampullary mass lesion	11		13.75
	Main branch IPMN(intraductal papillary mucinous neoplasm	2		2.50
	Primary sclerosing cholangitis	2		2.50
	Hydatidosis	2		2.50
Benign or malignant	Benign	29		36.25
	Malignant	51		63.75
Distal CBD wall thickness (mm)	Range	2	-	7.5
	Mean ±SD	3.906	±	1.437
Regular or irregular wall thickness of distal CBD	Regular	50		62.50
	Irregular	30		37.50
Pancreatic duct dilatation	Not dilated	52		65.00
	Dilated	28		35.00
Pancreatic duct dilatation (mm)	Range	2	-	18
	Mean ±SD	8.004	±	4.370
Lymph nodes	No LN	43		53.75
	Malignant looking	28		35.00
	Likely reactive	9		11.25

Table 3: Comparison of laboratory data between patients with benign and malignant strictures.

		Benign or malignant						T-Test	
		Benign			Malignant			t	P-value
Total Bilirubin	Range	0.37	-	17.7	0.89	-	35.5	-3.677	<0.001*
	Mean ±SD	4.598	±	4.399	11.883	±	10.119		
Direct Bilirubin	Range	0.09	-	13.12	0.2	-	33.2	-3.652	<0.001*
	Mean ±SD	3.331	±	3.549	8.452	±	7.045		
CEA	Range	0.2	-	4.5	0.77	-	12.3	-3.105	0.003*
	Mean ±SD	2.315	±	1.111	4.270	±	3.277		
CA19-9	Range	1.13	-	840	2.5	-	39922	-2.674	0.009*
	Mean ±SD	98.853	±	209.778	4063.767	±	7962.134		
Alpha-fetoprotein	Range	1.7	-	22	1.04	-	32	-0.501	0.617
	Mean ±SD	8.706	±	6.920	9.653	±	8.711		

Table 4: Comparison of EUS findings between patients diagnosed with benign and malignant structures.

		Benign or malignant				Chi-Square	
		Benign		Malignant			
		N	%	N	%	X^2	P-value
Diagnosis	Distal cholangiocarcinoma	0	0.00	21	41.17	80.000	<0.001*
	Inflammatory stricture	25	86.20	0	0.00		
	Pancreatic head mass	0	0.00	17	33.33		
	Ampullary mass lesion	0	0.00	11	21.56		
	Main branch IPMN(intraductal papillary mucinous neoplasm	0	0.00	2	3.92		
	Primary sclerosing cholangitis	2	6.89	0	0.00		
	Hydatidosis	2	6.89	0	0.00		
T-Test						t	P-value
Distal CBD wall thickness (mm)	Range	2.1 - 5.4		2 - 7.5		-5.730	<0.001*
	Mean ±SD	2.876 ± 0.767		4.492 ± 1.402			
Chi-Square		N	%	N	%	X^2	P-value
Regular or irregular wall thickness of distal CBD	Regular	28	96.55	22	43.14	22.505	<0.001*
	Irregular	1	3.45	29	56.86		

Pancreatic duct dilatation	Not dilated	22		75.86	30		58.82	2.359	0.125
	Dilated	7		24.14	21		41.18		
T-Test								t	P-value
Pancreatic duct dilatation (mm)	Range	3.3	-	8	2	-	18	-2.189	0.038*
	Mean ±SD	5.071	±	2.050	8.981	±	4.528		

Table 5: ROC analysis between benign and malignant strictures regarding distal CBD wall thickness.

ROC curve between Malignant and Benign						
	Cutoff	Sens.	Spec.	PPV	NPV	Accuracy
Distal CBD wall thickness (mm)	>3.2	80.39	89.66	93.2	72.2	85.7%

Table 6: Results of EUS-FNA in patients diagnosed with benign and malignant structures.

Result of EUS-FNA	Benign or malignant						Chi-Square	
	Benign		Malignant		Total			
	N	%	N	%	N	%	X^2	P-value
No FNA	11	37.93	0	0.00	11	13.75	80.000	<0.001*
Distal cholangiocarcinoma	0	0.00	23	45.10	23	28.75		
Inflammatory stricture	15	51.72	0	0.00	15	18.75		
Pancreatic head mass (Adenocarcinoma)	0	0.00	8	15.69	8	10.00		
Pancreatic head mass (Mucinous cystadenocarcinoma)	0	0.00	5	9.80	5	6.25		
Pancreatic head mass (Neuroendocrine tumor)	0	0.00	3	5.88	3	3.75		
Papillary adenoma (benign)	1	3.45	0	0.00	1	1.25		
Main branch IPMN(intraductal papillary mucinous neoplasm	0	0.00	2	3.92	2	2.50		
Ampullary mass lesion (Ampullary carcinoma)	0	0.00	10	19.61	10	12.50		
Primary sclerosing cholangitis (Onion skin apperance)	2	6.90	0	0.00	2	2.50		
Total	29	100.00	51	100.00	80	100.00		

carcinoma (n=1), chronic pancreatitis (n=1) and CBD compression due to adenomegaly (n=1) [11].

Limitation of the study: Small sample size of the study, more data is needed to confirm the diagnosis of unexplained distal CBD stricture, Not all patients had done EUS-FNA.

Conclusion

EUS is a useful investigational modality for patients with unexplained distal CBD stricture. Distal CBD wall thickness and preservation of normal CBD layers can be predictive of the nature of the structure.

Competing interests: The authors have no relevant financial or non-financial interests to disclose.

Statements and declarations: The authors declare that no funds, grants or other support were received during the preparation of this manuscript.

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