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Diagnostic yield of endoscopic ultrasound in dilated common bile duct with non-diagnostic cross-sectional imaging

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Abstract

Background Biliary dilatation without obvious etiology on cross sectional imaging warrants further investigation. This study aimed to assess yield of endoscopic ultrasound in providing etiologic diagnosis in such situation.

Methods Prospective cohort of consecutive patients with biliary dilatation & non diagnostic computed tomography (CT) and /or magnetic resonance imaging (MRI) underwent endoscopic ultrasound (EUS) with/without fine needle aspiration cytology (FNAC) and were followed clinically, biochemically with/without radiology for up to six months. The findings of EUS were corroborated with histopathology of surgical specimens and endoscopic retrograde cholangiography (ERCP) findings in relevant cases.

Results Median age of 121 patients completing follow up was 55 years. 98.2% patients were symptomatic and median common bile duct (CBD) diameter was 13 mm. EUS was able to identify lesions attributable for biliary dilatation in (67 out of 121) 55.4% cases with ampullary neoplasm being the commonest (29 out of 67 i.e. 43%). Multivariate logistic regression analysis identified jaundice as the predictor of positive diagnosis on EUS, of finding ampullary lesion and pancreatic lesion on EUS. EUS had sensitivity, specificity, positive predictive value and diagnostic accuracy of 95.65%, 94.23%, 95.65% and 95.04% respectively in providing etiologic diagnosis. Threshold value for baseline bilirubin of 10 mg%, for baseline CA 19.9 of 225 u/L and for largest CBD diameter of 16 mm were determined to have specificity of 98%, 95%, 92.5% respectively of finding a positive diagnosis on EUS.

Conclusion EUS provides considerable diagnostic yield with high accuracy in biliary dilatation when cross sectional imaging fails to provide etiologic diagnosis.

Keywords Common bile duct, Computed tomography, Choledochal cyst, Choledocholithiasis, Endosonography, Jaundice, Logistic models, Magnetic resonance cholangiopancreatography, Pancreatic neoplasms, Prospective studies

Introduction

Dilated common bile duct (CBD) with or without symptoms is a situation that is encountered by gastroenterologists in their daily practice. Magnetic resonance imaging (MRI) or computed tomography (CT) scan is usually employed for etiological evaluation of biliary obstruction after detection of dilated biliary tree on transabdominal ultrasound (USG). However, USG, CT and MRI all have their limitations in identifying the etiology of biliary obstruction. Transabdominal ultrasound has wide range of sensitivity in determining

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level (27 to 95%) and etiology (23 to 81%) of obstruction [1, 2]. The accuracy of CT scan in identifying the level of and etiology of obstruction is close to 90% [3, 4]. Magnetic resonance cholangiopancreatography (MRCP) also has high sensitivity and specificity for detection of benign and neoplastic biliary obstruction [5]. However, in 5 to 10% of cases the etiology of obstruction eludes CT & MRCP [3–5]. Endosonography or endoscopic ultrasound (EUS) is a helpful modality in this scenario to detect lesions producing biliary obstruction specially those located in the periampullary region [6, 7]. We undertook this single centre prospective observational study to assess the role of EUS in detecting lesions producing biliary obstructions when cross sectional imaging such as CT or MRI is unable to detect the same.

Methods

Patients

One hundred forty-one consecutive patients attending Gastroenterology outpatient department (OPD) or admitted in Gastroenterology department of Institute of Post Graduate Medical Education & Research, Kolkata with dilated common bile duct as initially detected by USG and subsequently evaluated with MRI (1.5 Tesla or higher) or CT scan (16 slices or higher) or both but without etiological diagnosis, were planned to undergo EUS. Most of the patients were referred from different centres for evaluation in our tertiary referral centre with CT scan and/or MRCP. CT scans were of 16 slices or higher and MRI were of 1.5 Tesla or higher. Clinical history, biochemical profile such as liver function test (LFT), carbohydrate antigen (CA 19.9) and radiology work up (USG, CT, MRI) were recorded at baseline. Study enrolment was conducted from August 2020 to June 2021.

Inclusions criteria: Patients referred for evaluation of biliary ductal dilatation (defined as CBD diameter > 6 mm on USG [8, 9], > 8 mm on CT abdomen [10] and > 6 mm on MRCP, in those with GB in-situ); and > 10 mm in post-cholecystectomy patients [11] with no definite etiology of CBD dilatation on cross sectional imaging.

Exclusion criteria: a) The patients who are not willing to give written consent b) patient with altered anatomy due to previous surgery c) pregnant females d) patients with age less than 18 years e) unfit for sedation required for EUS examination.

Study protocol

EUS

EUS was performed in 139 patients after getting proper consent. EUS examinations were performed by two gastroenterologists with experience of more than 1000 EUS procedures. All EUS procedures were performed by "Pentax" linear echoendoscope with patients in left lateral position. It was performed under conscious sedation using intravenous medications such as midazolam and propofol. In appropriate situation fine needle aspiration cytology (FNAC) was also done. After the procedure was done, all the patients were kept in day care for next four hours & were discharged on the same day. EUS examination could not be completed in two patients due to gastric outlet obstruction.

CT scan

Patients were kept nothing per oral for 4 h before the procedure and were asked to drink 1 L water within 30 min before CT images were taken. 1.5 ml / kg body weight of intravenous contrast (iohexol) was administered. 1.5 mm slice thickness with no interslice gap was used with multiplanar reconstruction (axial, coronal and sagittal planes).

MRI

Patients were kept nothing per oral for 4 h before the procedure. Heavily T2 weighted images with reconstructed MRCP view, 3 mm slice thickness axial cut, proton density image and volumetric 3 D images were obtained.

Follow up protocol

All the patients were followed up at first month, third month & sixth month from the day of the procedure. The data was collected on regular OPD visits & regular phone conversations with the patients & family members regarding the symptoms, general condition & surgical (including ERCP and histopathology) follow up of the patients. At the end of 6 months, the patients with negative findings on EUS at the initial procedure, underwent MRCP scan or clinical follow up with LFT. After end of six month follow up, assessment was made to note for any change of diagnosis as determined by EUS. 16 patients were lost to follow up and analysis was done for 121 patients.

Definitions used

Positive diagnosis on EUS

Finding of a lesion that can be attributed as etiology of biliary dilatation.

Negative diagnosis on EUS

No lesion found that can be attributed as etiology of biliary dilatation or presence of normal bile duct diameter on EUS.

True positive

The etiologic lesion found on EUS was confirmed by later therapeutic or diagnostic procedure.

False Positive

The etiologic lesion found on EUS was changed by later therapeutic or diagnostic procedure.

True negative

The absence of any etiologic lesion as noted on EUS, remained the same at the end of follow up period.

False negative

Etiologic lesion was not found on EUS but subsequently lesion was found on follow up imaging or ERCP as treatment of cholangitis.

Largest CBD diameter: patients with both MRCP and CECT abdomen reports showing biliary dilatation, the greater diameter of CBD among the images were taken as maximum CBD diameter.

All enrolled patients provided informed consent for participating in the study and also for the publication of study findings. The study protocol was approved by institutional ethical committee (IPGME & R Research Oversight Committee, Institute of Post Graduate Medical Education & Research, Kolkata; IRB No: IPGME&R/IEC/2020/552) and the study was done in compliance with Helsinki guidelines.

Statistical analysis

Categorical and continuous variables are presented as number (percentage) and median (range), respectively. Comparison between the groups was done with Mann–Whitney U test. Binary logistic regression was done to find the predictive factors for a positive diagnosis on EUS and also separately for pancreatic, bile duct and ampullary mass lesions. Receiver operating characteristic (ROC) curves were plotted for serum bilirubin, serum CA 19.9 and maximum CBD diameter to see their performance for a positive diagnosis on EUS, and cut-off value of these variables were selected to have a high specificity (> 90%) of a positive diagnosis on EUS. Area Under ROC curve (AUROC) with 95% confidence interval, standard error and *p*-values are provided. Sensitivity (Sn), positive predictive value (PPV), negative predictive value (NPV), likelihood ratios for positive (LR +) and negative (LR-) tests, pre-test and post-test odds were calculated for the cut-off values selected for the said variables [12]. All *p* values were two-sided and value < 0.05 was taken as statistically significant.

Statistical analysis was done using SPSS software (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp).

Results

Baseline characteristics

Complete follow up data of 121 patients were available for analysis. 51.2% of patients were male with median age of the cohort being 55 years. Most of the patients were symptomatic with abdominal pain (51.2%), jaundice (41.3%) and significant weight loss (25.8%) being the common presenting symptoms. Baseline characteristics are shown in Table 1.

Outcome of EUS examination

EUS was able to find out lesions responsible for biliary dilatation in more than half of the cases (67 out of 121 or 55.4%). Ampullary neoplasm, pancreatic mass lesion and bile duct calculus or worm were the common pathologies detected by EUS. In 54 (44.6%) patients, EUS did not find out any lesion attributable to biliary dilatation. Choledochal cyst was the commonest benign lesion. Outcome of EUS shown in Table 1. We performed EUS-FNAC in total ten (10) patients. Three patients of < 50 years of age with pancreatic SOL where diagnoses other than adenocarcinoma were considered. Two (2) patients with CCP and mass formation and five (5) patients with lymph nodes underwent EUS-FNAC.

Median (range) dimension of maximum & minimum diameter of the lesions picked up by EUS were 19 (10–27) and 15 (9–20) mm respectively (Table 2).

EUS findings with normal side view endoscopy examination

Twenty-nine (29) of the patients out of 121 with complete follow up data was noted to have normal finding on side view endoscopy. Among them eight & four patients were diagnosed with ampullary and pancreatic neoplasm. At the end of follow up, EUS diagnosis was confirmed (with surgical biopsy) in six of the patients with ampullary neoplasm and all those i.e. four with pancreatic neoplasm. Thus, EUS detected neoplastic condition in almost one third (10 out of 29 or 34.5%) of subjects with normal side view endoscopy examination. The other notable diagnoses of patients with normal side view examination were choledochal cyst (10 out of 29 or 34.5%), choledocholithiasis & chronic pancreatitis (two each out of 29 or 7%).

Table 1 Characteristics of the patients and outcome of endoscopic ultrasound examination

Variables	
Male/Total; n (%)	62/121 (51.2)
Age (years); Median (IQR)	55 (40–61)
Clinical presentation; n (%)	
a) Symptomatic patients	119 (98.3)
b) Abdominal pain	62 (51.2)
c) Jaundice	50 (41.3)
d) Cholangitis (Charcot's triad)	8 (6.6)
e) Abdominal lump	3 (2.6)
f) Significant weight loss	31 (25.8)
g) Anorexia	29 (24.2)
Subjects with Comorbidity; n (%)	66 (54.5)
Type of Comorbidity; n (%)	
a) Diabetes	25 (20.6)
b) Hypertension	26 (21.4)
c) CAD	6 (4.9)
d) Dyslipidemia	2 (1.6)
e) COPD	1 (0.8)
f) Others	2 (1.6)
g) Multiple	4 (3.2)
History of surgery; n (%)	23 (19%)
Bilirubin (Total) (mg/dL); Median (IQR)	1.7 (1.1–8.2)
AST (IU/L) categories; n (%)	
a) Normal	49 (40.5)
b) < 2X ULN	33 (27.3)
c) > 2XULN	39 (32.2)
ALT (IU/L) categories; n (%)	
a) Normal	49 (40.5)
b) < 2X ULN	33 (27.3)
c) > 2XULN	39 (32.2)
ALP (IU/L) categories; n (%)	
a) Normal	41 (33.9)
b) < 2X ULN	15 (12.4)
c) > 2XULN	65 (53.7)
CA 19.9 (U/L); Median (IQR)	23 (3–267)
CA 19.9 categories; n (%)	
a) Normal	52 (42.9)
b) < 2X ULN	7 (5.7)
c) > 2X ULN	27 (22.3)
d) Not available	35 (28.9)
Outcome; n (%)	
a) Normal CBD	16 (13.2)
b) Idiopathic dilated CBD /Choledochal cyst	38 (31.4)
c) Ampullary neoplasm	29 (24)
d) Pancreatic mass	14 (11.6)
e) CBD calculus / worm	8 (6.6)
f) CBD/GB mass	7 (5.8)
g) Lymph node	5 (4.1)
h) Chronic pancreatitis	4 (3.3)

Table 1 (continued)

Abbreviations: *IQR* Interquartile range represented as 25th and 75th percentile values, *CAD* Coronary artery disease, *COPD* Chronic obstructive pulmonary disease, *AST* Aspartate aminotransferase, *ULN* Upper limit of normal, *ALT* Alanine aminotransferase, *ALP* Alkaline phosphatase, *CA 19.9* Carbohydrate antigen 19.9, *CBD* Common bile duct, *GB* Gall bladder

Table 2 Dimensions of the lesions detected on EUS as the etiology of biliary obstruction

	Median (Range)
	Overall
Maximum dimension in mm	19 (10–27)
Minimum dimension in mm	15 (9–20)
	Ampullary lesion
Maximum dimension in mm	17 (10–24)
Minimum dimension in mm	14 (9–20)
	Pancreatic lesion
Maximum dimension in mm	20.5 (17–27)
Minimum dimension in mm	16 (10–20)
	Bile duct lesion
Maximum dimension in mm	20 (12–23)
Minimum dimension in mm	12 (10–16)
	Bile duct calculus
Maximum dimension in mm	4 (3.4–5.2)

Abbreviation: *EUS* Endoscopic ultrasound

Comparison between groups with positive or negative diagnosis on EUS

Among the clinico epidemiological factors, male sex and proportion of patients with jaundice, anorexia and significant weight loss at presentation were significantly higher in the group with a positive diagnosis on EUS. Median value of serum total bilirubin, serum CA 19.9 along with median diameter of common bile duct on imaging (trans abdominal ultrasound, MRCP, CECT abdomen or the highest diameter of either CT or MRCP) were significantly higher in the group with positive diagnosis on EUS (Table 3).

Predictors for positive diagnosis on EUS

Multivariate regression analysis identified jaundice at presentation being the sole predictive factor for positive diagnosis on EUS and also for detecting ampullary and pancreatic lesion (Table 4). Anorexia and significant weight loss at presentation were also the predictors for detecting mass lesion in ampulla and common bile duct respectively.

Threshold value for variables with high specificity for positive diagnosis on EUS:

Threshold value for baseline bilirubin of 10 mg%, for baseline CA 19.9 of 225 u/L and for largest CBD diameter of 16 mm were determined to have specificity of 98%,

Table 3 Comparison between groups with or without etiological diagnosis after endoscopic ultrasonography

	Findings on EUS		*P* value
	Negative	Positive	
	N = 54	*N* = 67	
Age in years; median (IQR)	55 (38–61)	54 (40–62)	0.93
Male; n (%)	16 (29.6)	46 (68.7)	< 0.001
Presence of comorbid illness n (%)	28 (51.9)	38 (56.7)	0.53
Past surgical history n (%)	13 (24.1)	9 (13.4)	0.14
Abdominal pain n (%)	27 (50.0)	29 (43.3)	0.44
Fever n (%)	6 (11.1)	16 (23.9)	0.07
Jaundice n (%)	8 (14.8)	48 (71.6)	< 0.001
Significant weight loss n (%)	0	30 (44.7)	< 0.001
Anorexia n (%)	2 (3.7)	26 (38.8)	< 0.001
Baseline abnormal LFT n (%)	9 (16.7)	34 (50.7)	< 0.001
Baseline total bilirubin in mg%; median (IQR)	1.2 (0.9–1.5)	6.0 (1.8–12.5)	< 0.001
Baseline CA 19.9 in U/L; median (IQR)	10.5 (3–31)	97 (12.5–455.5)	< 0.001
CBD diameter in USG in mm: mean ± SD	9 ± 2	12 ± 5	0.001
CBD diameter in Cross sectional image in mm: mean ± SD	12 ± 3	15 ± 5	< 0.0001
CBD diameter in MRCP in mm: mean ± SD	11 ± 3	14 ± 5	< 0.001
CBD diameter in CT in mm: mean ± SD	11 ± 3	15 ± 5	< 0.001

Abbreviations: *EUS* Endosonography, *IQR* Interquartile range, *LFT* Liver function test, *CA 19.9* Carbohydrate antigen 19.9, *CBD* Common bile duct, *USG* Ultrasonography, *SD* Standard deviation, *MRCP* Magnetic resonance cholangiopancreatography, *CT* Computed tomography

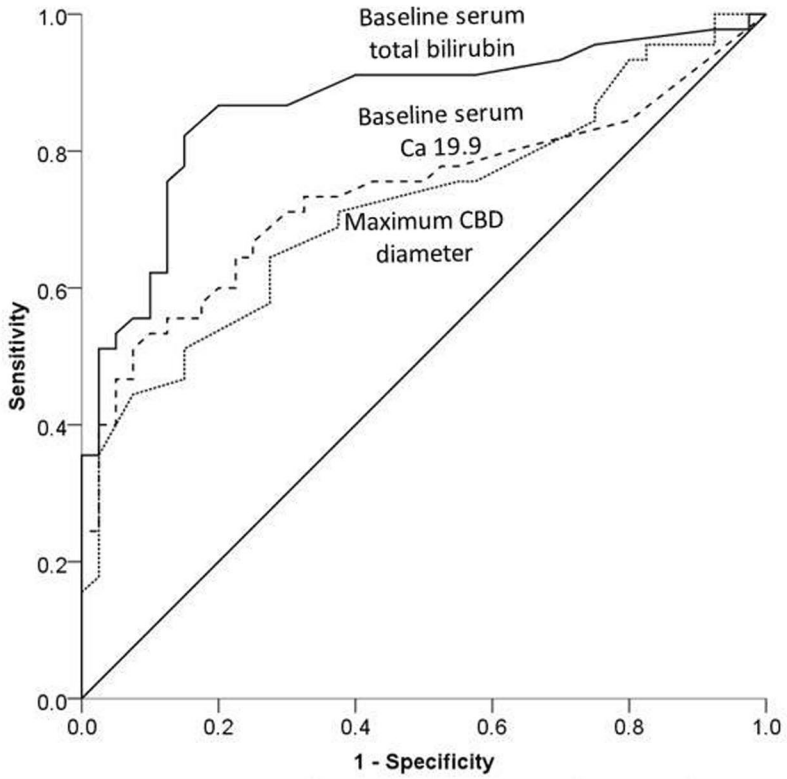
Table 4 Multivariate analysis for predictor of i) etiological diagnosis on endoscopic ultrasound ii) ampullary mass lesion iii) pancreatic mass lesion iv) common bile duct mass lesion

	Coefficient of regression	Standrad error	Odds ratio	95% Confidence interval	*P* value
Etiological diagnosis on EUS (all etiologies combined)					
Jaundice	2.47	0.67	11.89	3.19–44.30	< 0.0001
Ampullary mass lesion					
Jaundice	1.58	0.67	4.87	1.32–18.0	0.01
Anorexia	2.21	0.90	9.15	1.54–54.37	0.01
Pancreatic mass lesion					
Jaundice	1.59	0.69	4.93	1.26–19.29	0.02
CBD mass lesion					
Weight loss	2.72	1.21	15.25	1.42–163.69	0.02

95%, 92.5% respectively of finding a positive diagnosis on EUS (Fig. 1).

Comparison between patients with or without jaundice at presentation

Fifty patients had jaundice as compared to 71 patients who were anicteric at presentation. In subgroup analysis, we noted that patients with jaundice at presentation also had higher proportion of patients with anorexia and significant weight loss at presentation compared to anicteric group (38% & 44% in icteric group compared to 14.3% & 12.9% respectively; $p < 0.001$ in both). The mean baseline level of CA 19.9 and mean diameter of CBD at baseline were also higher in former group (mean CA 19.9 level 171 U/l in icteric vs 13 U/l in anicteric group; mean CBD diameter 16 mm in icteric vs 11 mm in anicteric group; $p < 0.001$ in both). In terms of outcome, icteric group had significantly higher positive diagnosis compared to anicteric patients (90% in icteric vs 31% in anicteric group; $p < 0.001$) with ampullary or pancreatic mass being the common pathology in the former (ampullary mass in 44% and pancreatic mass in 22% of icteric patients) and ampullary mass and choledocholithiasis being the common



Variables	AUC (95%CI)	SE	P value
Baseline serum total bilirubin	0.867 (0787-0.947)	0.41	<0.0001
Baseline serum Ca 19.9	0.737 (0.628-0.845)	0.55	<0.0001
Maximum CBD diameter	0.719 (0.611-0.828)	0.55	0.001

Fig. 1 Receiver operating characteristic curve for positive diagnosis on EUS for serum bilirubin, serum CA 19.9 and maximum CBD diameter

finding in latter group (ampullary mass in 9.8% & choledocholithiasis in 8.4% of anicteric patients).

Diagnostic performance of EUS

Overall, EUS was found to have sensitivity, specificity and accuracy of 95.65, 94.23% and 95.04% respectively in providing etiologic diagnosis of dilated biliary tree. In subgroup analysis, it was noted that EUS had higher sensitivity and diagnostic accuracy in those presenting with jaundice compared to those without. Specificity of EUS was higher in those without jaundice compared to those with jaundice (Table 5).

Adverse events

No adverse events were reported in any of the patients undergoing the endoscopic ultrasound with or without FNA.

Table 5 Diagnostic performance of endoscopic ultrasound in etiological diagnosis of dilated extrahepatic bile duct

	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Positive likelihood ratio	Negative likelihood ratio	Accuracy
Overall	95.65	94.23	95.65	94.23	16.58	0.04	95.04
Patients with jaundice	97.72	66.67	95.5	80	2.93	0.03	94
Patients without jaundice	92	83.33	95.83	71.42	5.52	0.09	90.32

Discussion

Biliary dilatation as detected by transabdominal ultrasound often requires further evaluation with cross sectional imaging such as CT scan or MRI or both. All the above three modalities have their limitations in detecting etiological diagnosis in the given setting. Endoscopic ultrasound, despite being invasive in nature, has the advantage of being in close proximity to distal bile duct and pancreas to detect lesions which might be missed by cross sectional imaging. Thereby, EUS have close to 100% specificity in detecting benign lesions and greater than 90% sensitivity and accuracy in detecting pancreatic neoplasms [13, 14]. Few studies have looked into role of EUS for evaluation of dilated bile duct as detected by transabdominal ultrasound without subjecting the patients to cross sectional imaging [15, 16]. However, in most of the institutions, as of today, patients undergo cross sectional imaging in attempt to detect etiology for biliary dilatation and EUS is usually employed after non-contributory cross-sectional imaging. Multiple studies have analysed role of EUS in detecting etiology of biliary dilatation after non-contributory CT [17, 18] or MRCP [19, 20] or both in retrospective [17–21] and prospective [22] fashion.

Current study attempted to find the diagnostic role of EUS in this real-world scenario in prospective fashion. In this cohort, most of the patients were symptomatic as was noted in another prospective study [22]. In more than half of the cases (54%), EUS was able to detect lesion responsible for biliary dilatation in our cohort with ampullary neoplasm being the commonest detected pathology. Similarly, EUS was noted to establish a positive diagnosis in other studies with outcome in favour of either neoplastic [16, 22] or benign [15] etiologies.

This study identified clinical jaundice at presentation as a predictor for a positive diagnosis on EUS as well as for finding ampullary mass or pancreatic mass on EUS. Male sex, altered LFT, elevated pancreatic enzymes and dilated MPD with CBD were noted to be predictors in the retrospective study by Carriere et al. [17]. However, the later study employed bivariate analysis for the same instead of multivariate analysis as was done in present study. Pausawasdi et al. [23], noted that intrahepatic biliary dilatation, in addition to male sex and elevated aminotransferase and alkaline phosphatase were predictive of pathological obstruction. However, in contrast to the present study, it was retrospective in nature.

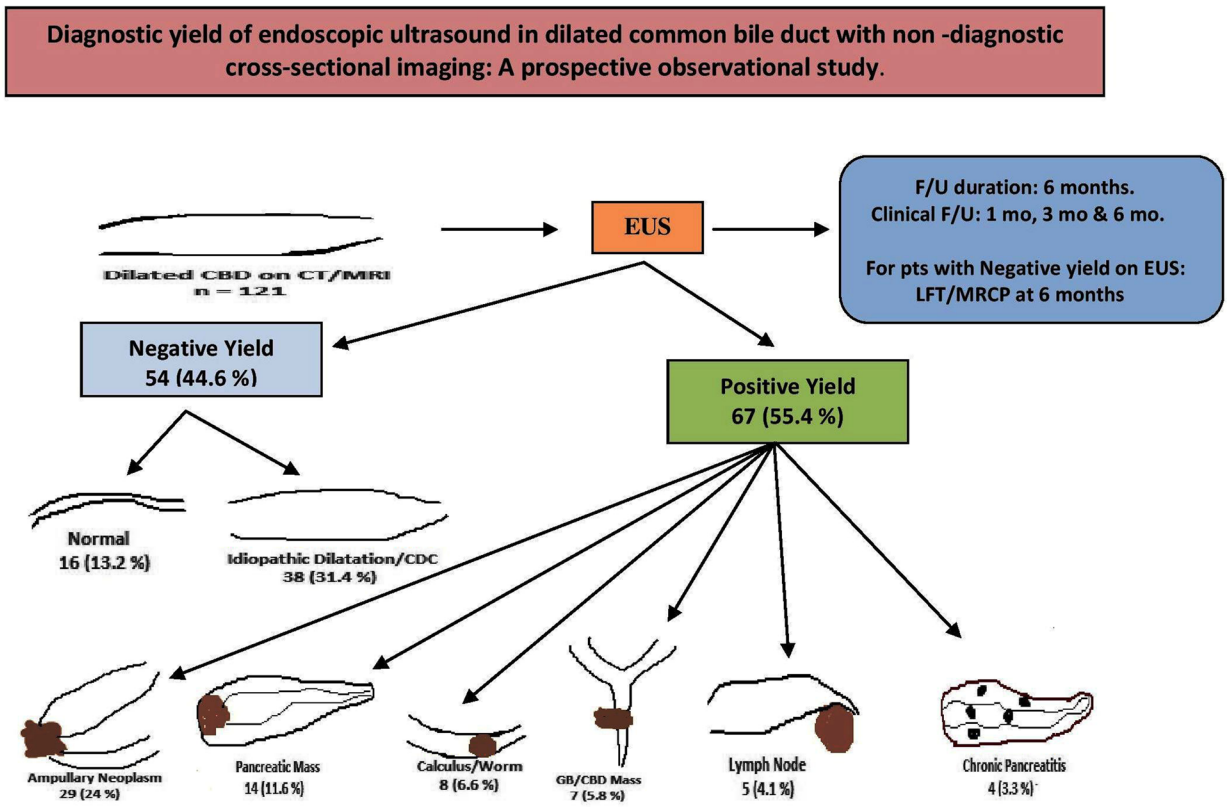
On the other hand, we found 31% patients without jaundice at presentation had a pathologic biliary obstruction. Ampullary mass and CBD calculus were the common pathologies detected in this subgroup. Similar observation was reported by Malik et al. [20], where periampullary diverticulum and choledocholithiasis were found to be the common reasons for biliary dilatation in anicteric patients. This study also noted that almost one third of patients with normal side view endoscopy examination had pathologic obstruction detected by EUS.

Our study identified a threshold for serum bilirubin, CA 19.9 and CBD diameter to have a high specificity (98, 95, 92.5% respectively) of positive diagnosis on EUS. The sensitivity of EUS at those threshold values go down below 50%. However, EUS being an invasive test which is done at a later part of diagnostic algorithm, threshold for high specificity was chosen at the cost of low sensitivity.

In this study, EUS was noted to have high sensitivity, specificity, positive predictive value and diagnostic accuracy (~95%, 94%, 95%, 95% respectively) in etiological diagnosis of dilated biliary tree. In the meta-analysis done by Garrow D et al. [6], pooled sensitivity and specificity of EUS were noted to be 88% and 90% respectively with higher sensitivity and specificity noted for benign conditions compared to neoplastic ones. A recent prospective study by Atalla et al. [22] also revealed sensitivity, specificity and diagnostic accuracy of EUS was more than 98%. These figures corroborate with the findings in our study.

This study addresses the role of endoscopic ultrasound as a diagnostic modality in a common clinical scenario where the conventional and often used imaging techniques fail to provide an etiologic answer. The study identifies clinical predictors of finding any positive diagnosis on endoscopic ultrasound and also separately the same for pancreatic, bile duct or ampullary lesions. Threshold for biochemical and imaging parameters were ascertained with high specificity of etiological diagnosis established by EUS. Detection of pathologic lesions by EUS in almost one-third of patients with normal side view endoscopy examination also affirms role of EUS in diagnostic algorithm. The study being prospective in nature, it circumvents the drawbacks of cross-sectional observational studies and helps us to corroborate the findings of endoscopic ultrasonography during the follow up duration of the patients. Thus, diagnostic performance of endoscopic ultrasound in this context was ascertained.

Single centre observation with short duration of follow up (six months) for patients without any positive diagnosis on EUS are the drawbacks of the study. We did not perform any cholangioscopy or brush cytology for dilated CBD without obvious mass lesion, and therefore there was a chance of missing slow growing malignant stricture of bile duct which might not be clinically apparent in a follow up duration of six months. Most of the patients also came with the CT/MRI reports from outside as they were referred to our institute as it is a



Diagnostic performance of EUS in etiological diagnosis

	Sn	Sp	PPV	NPV	Accuracy
Overall	95.6	94.2	95.6	94.2	95.04
Pts with Jaundice	97.7	66.6	95.5	80	94
Pts without jaundice	92	83.3	95.8	71.4	90.3

Predictors for positive EUS finding on multivariate analysis

	Predictive Factor	Odds Ratio (CI)
Positive EUS Yield (Overall)	Jaundice	11.89 (3.19-44.30)
Ampulllary Mass	Jaundice	4.87 (1.32 – 18.00)
	Anorexia	9.15 (1.54 – 54.37)
Pancreatic Mass	Jaundice	4.93 (1.26 – 19.2)
CBD Mass	Weight loss	15.25 (1.42 – 163.6)

Comparison of parameters of patients with positive and negative yield on EUS (only statistically significant parameters)

	Positive yield on EUS (n=67)	Negative yield on EUS (n=54)
Jaundice n(%)	48 (71.6)	8 (14.8)
Significant weight loss n (%)	30 (44.7)	0
Anorexia n (%)	26 (38.8)	2 (3.7)
Baseline abnormal LFT n (%)	34 (50.7)	9 (16.7)
Baseline total Bil in mg% (median)	6	1.2
Baseline CA 19-9 in U/L (median)	97	10.5
CBD diamter in cross sectional imaging in mm (mean +/-SD)	15 +/- 5	12 +/- 3

Fig. 2 Sensitivity, positive predictive value & accuracy of endoscopic ultrasound are close to 95% for establishing diagnosis in patients with dilated biliary tree and non diagnostic cross sectional imaging

tertiary referral centre. Many of the CT scans were also not of pancreatic protocol. The possible interobserver variability along with technical difference of image acquisition at baseline cross sectional imaging studies (as they were from different centres and interpreted by different radiologists) can be cited as a drawback of this study. The study also did not seek to evaluate role of elastography or contrast EUS as the modalities were not available at the place of study.

In conclusion, EUS provides considerable diagnostic yield with high accuracy in patients with dilated biliary tree and non-diagnostic cross-sectional imaging (Fig. 2). Therefore, EUS should be included in diagnostic algorithm of dilated biliary tree, even with normal side view endoscopy examination and especially in symptomatic patients with bilirubin > 10 mg% and CBD diameter of more than 16 mm.

Abbreviations

CT	Computed tomography
MRI	Magnetic resonance imaging
EUS	Endoscopic ultrasound
FNAC	Fine needle aspiration cytology
ERCP	Endoscopic retrograde cholangiopancreatography
CBD	Common bile duct
USG	Transabdominal ultrasound
MRCP	Magnetic resonance cholangiopancreatography
LFT	Liver function test
CA 19.9	Carbohydrate antigen 19.9
OPD	Out patient department
ROC	Receiver operating characteristic
AUROC	Area under ROC curve
Sn	Sensitivity
PPV	Positive predictive value
NPV	Negative predictive value
LR+	Positive likelihood ratios
LR	Negative likelihood ratios

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Ethical statement
All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and later versions.

Authors' contributions
AM, KD, DM, GKD contributed to the study conception and design. Material preparation, data collection and analysis were performed by AM, K, K D, D M, K D. The first draft of the manuscript was written by DM and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
Study protocol was approved by institutional ethical committee (IPGME & R Research Oversight Committee, Institute of Post Graduate Medical Education & Research, Kolkata; IRB No: IPGME&R/IEC/2020/552, dated 10/08/2020). Informed consent for it was obtained from all patients for being included in the study.

Consent for publications
Consent for it was obtained from all patients for publication of the result of the study.

Competing interests
The authors declare no competing interests.

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