

Pancreatobiliary Diseases Management by Endoscopic Ultrasonography/Endoscopic Retrograde Cholangiopancreatography Interface in Kurdistan Centre for Gastroenterology & Hepatology

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Abstract: *Background:* Pancreatobiliary diseases (PBD) comprises diseases of both biliary system and pancreas and their diagnosis depends on appropriate clinical evaluation and investigations including imaging modalities like transabdominal ultrasound (TAUS), Magnetic resonance cholangiopancreatography (MRCP) and computed tomography (CT); Endoscopic ultrasound (EUS) have been found to be more sensitive than other imaging modality for detecting PBD, and less invasive than endoscopic retrograde cholangiopancreatography (ERCP). *Aim of study:* To compare the sensitivity and specificity of EUS with other imaging studies like ERCP, TAUS, CT scan, and MRCP/MRI for diagnosing PBD. *Patients & Methods:* This study conducted in Kurdistan Centre for Gastroenterology and Hepatology (KCGH) from December 2013 through December 2014, after approval of institutional board ethical committee and taking written informed consents from all patients. A total number of 100 patients were enrolled in the study. We calculated the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of EUS, MRCP, and TAUS for PBD (benign & malignant). ERCP was used as a reference standard for comparison. *Results:* 60% were females and 40% were males; the main presenting symptoms were combined abdominal pain and obstructive jaundice. The sensitivity, specificity, PPV, NPV, and accuracy of EUS for detecting benign biliary diseases like (bile duct stone and its complications) were 96.1%, 65.2%, 86%, 83.3%, and 89%, respectively; and for detecting pancreatobiliary tumors (PBT) were 84.6%, 97.7%, 84.6%, 97.7%, and 96%, respectively. The sensitivity of TAUS, MRCP for diagnosing biliary diseases were 58%, and 60%, respectively; and their sensitivity for detecting PBT were 37.5%, and 50%, respectively. The comparison between CT scan and ERCP was not feasible statistically. *Conclusion:* EUS has a higher sensitivity in comparison to other imaging modalities in detecting PBD; we can depend on it in selecting patients for therapeutic ERCP, in order to avoid unnecessary ERCP and its complications. The sensitivity and specificity of EUS in KCGH is comparable to other studies elsewhere.

Keywords: PBD, EUS, ERCP, MRCP, KCGH (Kurdistan Centre for Gastroenterology & Hepatology), Sulaimani

1. Introduction

Pancreatobiliary diseases (PBD) comprises diseases of the biliary system and pancreas. Management of PBD depends on proper clinical evaluation (with history & proper physical examination), laboratory investigations, imaging, and endoscopic evaluation like endoscopic ultrasonography (EUS) and endoscopic retrograde cholangiopancreatography (ERCP). Patients with PBD might be asymptomatic identified incidentally or symptomatic, those who are

symptomatic might have jaundice (obstructive) or abdominal pain or other symptoms like nausea, pruritus etc ^[1]. Imaging plays an important role in differentiating medical from surgical causes of PB, latter (surgical PBD) usually needs intervention either endoscopically or surgically ^[1].

Invention of TAUS (gray scale) and ERCP in the mid 1970s boosted the management of PBD ^[2], however ERCP was invasive procedure with significant morbidity and mortality and TAUS neither highly sensitive nor specific for diagnosing PBD. With introduction of MRCP and EUS new

armamentarium were added to already available imaging for management of pancreatobiliary diseases [2].

Transabdominal ultrasound (TAUS) can detect only 50-75% of CBD stones [3], and nearly 75% of dilated common bile duct (CBD) [4].

Computed tomography (CT scan), can be used for detecting complications of gallstones such as abscess, perforation of CBD or Gallbladder, and pancreatitis [5]. MRCP has a sensitivity (93%) and specificity (94%) in comparison with ERCP, and it provide good information for more distal extra hepatic portion of the bile duct [6]. Endoscopic ultrasonography can be used for CBD stone diagnosis and has been found to be superior to MRCP [1].

Gastrointestinal endosonography introduced in the mid-1970s, and began to be used practically in the mid-1980s [7]. Endoscopes of EUS generally of two types, radial (or sector) and linear (or convex array). The linear echo-endoscope is beneficial for both diagnostic and therapeutic applications [8]. As a diagnostic modality, EUS has been used to evaluate diseases or lesions involving the Pancreatobiliary tree, the esophagus, the stomach, the rectum, the left adrenal gland, the liver (especially left lobe), and the posterior mediastinum [9]. As a therapeutic modality the two most important indications are in celiac plexus neurolysis and celiac plexus block among others [10].

Magnetic Resonance Cholangiopancreatography is a special type of MRI, used to study biliary and pancreatic ducts; it is largely replacing diagnostic role of ERCP, as it does not need contrast enhancement in the ductal system, thus, the morbidity associated with endoscopic procedures and contrast materials is avoided. But it cannot be used for intervention yet [11]. The addition of MRI to MRCP can be used for differentiating benign and malignant strictures of biliary system and assessing resectability of pancreatobiliary tumors [12].

Aim of study: To compare the sensitivity and specificity of EUS with other imaging studies like ERCP, TAUS, CT scan, and MRCP/MRI for diagnosing PBD.

2. Patients and Methods

2.1. Study Design and Setting

A prospective case-series study was carried out in KCGH-Sulaimani city, which serves as a tertiary referral center for the Sulaimani governorate, in addition to referrals from other governorates of Iraqi Kurdistan region and Iraq.

2.2. Selection of Cases

This study was carried out from December 2013 through December 2014, one hundred patients were included (60 females and 40 males); we included patients referred for ERCP and had performed EUS to evaluate pancreatobiliary diseases. Patients with already diagnosed & managed PBD and those with a known malignancy anywhere in the body were excluded. The interval between EUS and MRCP was 3-7 days.

2.3. Data Collection and Information

Our study commenced after approval from Institutional Board for medical studies. A written informed consents were taken from all patients, data collected from patients through interviewing by questionnaire.

2.4. Interpretation of Results

Demographic data were collected. Total serum bilirubin (TSB) of more than 1.5mg/dl regarded as abnormal. direct hyperbilirubinemia was considered obstructive after confirmation by elevated Alkaline phosphatase (ALP) of more than 3.5-fold of upper normal, and elevated aspartate and alanine aminotransferases (AST and ALT) means more than 19U/L in female and more than 30 U/L in male. Viral screen was performed for all patients; two patients have had inactive chronic carrier state of hepatitis B virus and only one patient with low titre hepatitis c virus (HCV) by polymerase chain reaction. Dilated common bile duct was defined by more than 6 mm in TAUS and EUS (> 7mm in cholecystectomized patients), more than 8 mm in CT scan and MRI/MRCP, and more than 9mm in ERCP [13,14,15].

2.5. Endoscopic Intervention and Type of Machine Used

Endoscopic ultrasound and ERCP were performed by certified gastroenterologists at KCGH, The diagnosis of choledocholithiasis was confirmed only if stones, stone fragment or sludge could be extracted out of the ampulla during ERCP. The machine which had been used for ERCP examination was (Olympus EXERA-I) with a video processor (CV-160), the machine used for EUS examination was (Olympus LUCERA) with a video processor (CV-260), ultrasound processor (EU-ME-1), and a linear probe of a version (GF-UCT260-AL5).

2.6. Statistical Analysis

All patients' data analyzed using computerized statistical software; Statistical Package for Social Sciences (SPSS) version 17. Descriptive statistics presented as (mean \pm standard deviation), frequencies and percentages. Multiple contingency tables conducted and appropriate statistical tests performed. Analysis of variance (ANOVA) was used to demonstrate the difference between different means. Validity of different tests was calculated by 2x2 tables. Level of significance (p value) set at ≤ 0.05 and the results presented as tables and or graphs.

2.7. Statistical Definition [16]

Sensitivity is the ability of a test to correctly classify an individual as 'diseased' (Probability of being test positive when disease present). Sensitivity = (true positive) / (true positive + false negative). Specificity is the ability of a test to correctly classify an individual as disease free (Probability of being test negative when disease absent). Specificity = (true negative) / (true negative + false positive). Positive predictive value is the percentage of patients with a positive test who

actually have the disease. $PPV = (\text{true positive}) / (\text{true positive} + \text{false positive})$. Negative predictive value is the percentage of patients with a negative test who do not have the disease. $NPV = (\text{true negative}) / (\text{false negative} + \text{true negative})$. Accuracy is how close a measured value is to the actual (true) value.

3. Results

A Total of one hundred patients were enrolled in present study with a mean age of 55 ± 19 years, patients with age ≥ 70 years were more prevalent. Females (60%) were more than males (40%). As demonstrated in table (1).

Table 1: Demographic characteristics of studied patients.

demographic data		(No.)	Total (%)
Gender	Female	60	100
	male	40	
Age (years)	< 30	10	100
	30-39	16	
	40-49	15	
	50-59	14	
	60-69	15	
	≥ 70	30	
thnicity	Kurdish	77	100
	Arabic	21	
	Turkmen	2	

Most of patients presented with combined abdominal pain and jaundice (43%), followed by abdominal pain (40%) and obstructive jaundice (17%) as illustrated in table (2).

Table 2: Initial presenting symptoms of studied patients.

Presenting symptoms	Number and percentage	Total
Jaundice and abdominal pain	43	100
Abdominal pain	40	
Jaundice	17	

Table 3 demonstrates that 66% of patients had past history of surgery.

Table 3: Past surgical history of studied patients.

Past history	No.	%
Past surgical history		
No	66	66.0
Cholecystectomy	18	18.0
Gastroduodenal surgery	2	2.0
Pancreatic surgery	2	2.0
Bile duct surgery	1	1.0
Extra-abdominal surgery	11	11.0
Total	100	100.0

Results of Oesophago-Gastro-Duodenoscopy (OGD) were abnormal among 15 patients (antral gastritis in 8 patients, non complicated duodenal ulcer in 3 patients and

gastroesophageal reflux in 4 patients). Detailed diagnosis of Biliary diseases by ERCP revealed that 50 patients had CBD stone, and the others as illustrated in table 4. Among 10 patients with PB tumor diagnosed by ERCP, seven patients had pancreatic tumor, two patients with liver cancer and one patient with cholangiocarcinoma, as illustrated in table 4.

Table 4: Findings of different diagnostic tools in studied patients.

Diagnostic tool	No.	%
Oesophagogastro-duodenoscopy		
Normal	85	85.0
Abnormal	15	15.0
Total	100	100.0
Transabdominal ultrasound		
Normal	13	34.2
Dilated common bile duct	20	52.6
Suspected PB Tumor	5	13.2
Total	38	100.0
Computed tomography scan		
Normal	3	27.3
Dilated common bile duct	7	63.6
Suspected PB tumor	1	9.1
Total	11	100.0
Magnetic resonance cholangio-pancreatography		
Normal	2	14.3
Dilated common bile duct	10	71.4
Suspected PB tumor	2	14.3
Total	14	100.0
Endoscopic ultrasonography		
Normal	10	10.0
Dilated common bile duct and stone	79	79.0
Suspected PB tumor	11	11.0
Total	100	100.0
Endoscopic retrograde cholangiopancreatography		
Normal	17	17.0
Dilated common bile duct and stone	73	73.0
Suspected PB Tumor	10	10.0
Total	100	100.0

PB = Pancreatobiliary

ANOVA analysis revealed no significant differences in age and pain severity between normal, biliary diseases and pancreatobiliary tumor patients, on other hand, jaundice duration mean was significantly higher among tumor patients (P value=0.01), as illustrated in table 5.

Table 5: Analysis of age, jaundice duration and severity of pain means according to final diagnosis by ERCP.

Final Diagnosis by ERCP	Age	Jaundice duration (weeks)	Pain Severity (Pain scale)
	Mean \pm SD	Mean \pm SD	Mean \pm SD
Normal	52 ± 19.9	3.6 ± 2.6	5.9 ± 1
Biliary diseases	55.5 ± 20	2.7 ± 2.05	5.7 ± 1
Pancreatobiliary tumors	55.7 ± 15.3	5.3 ± 5	4.5 ± 1
ANOVA (P value)	0.8	0.01	0.1

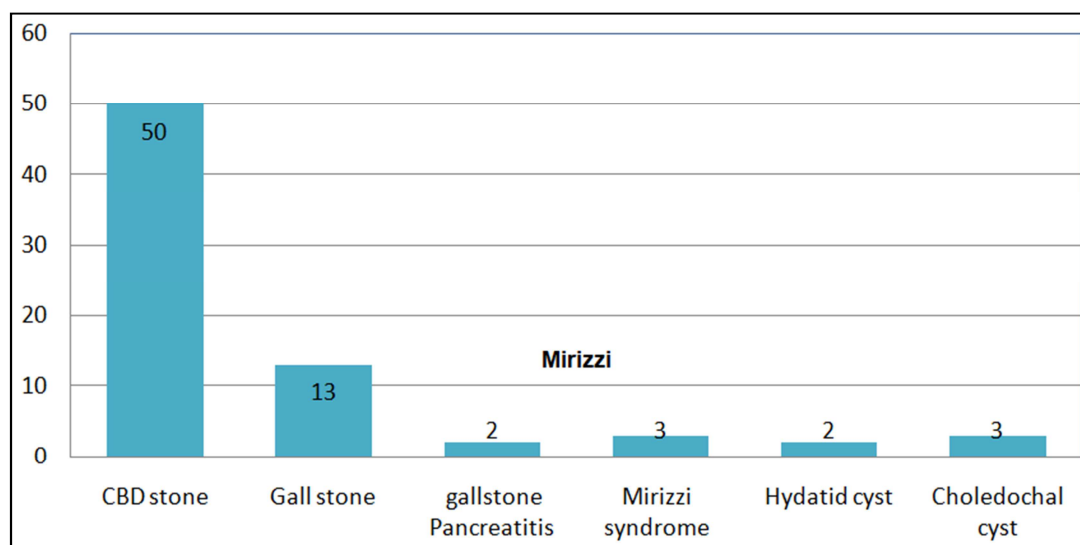


Figure 1: Categories of diseases under the title of Biliary disease patients by ERCP(N=100); (CBD= common bile duct).

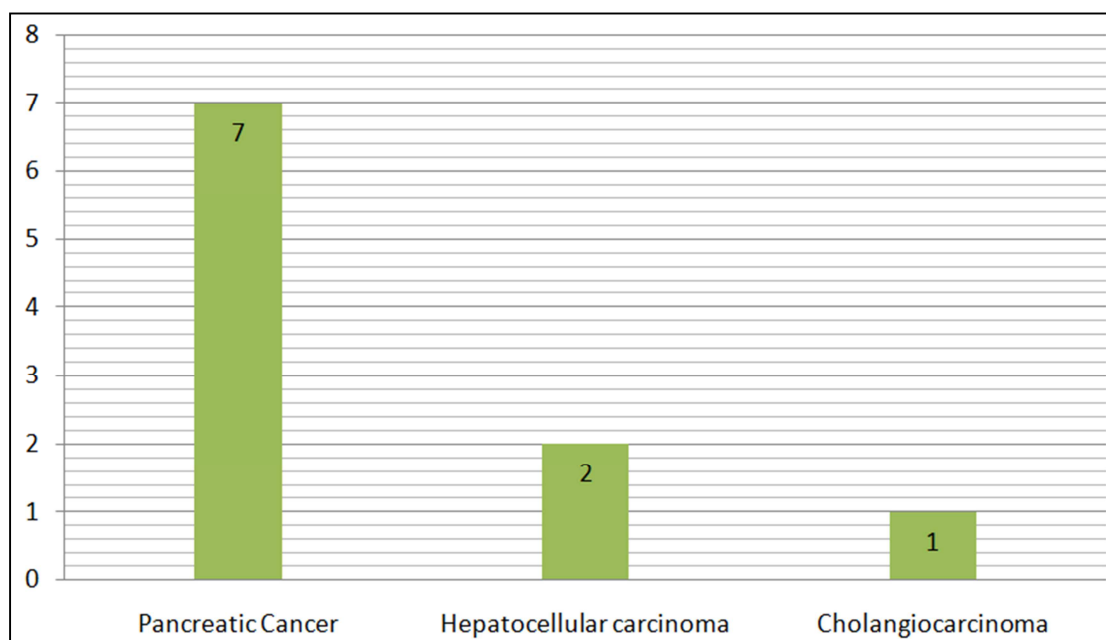


Figure 2: An ERCP spectrum of pancreatobiliary tumors.

Sensitivity of EUS in diagnosing biliary diseases was 96.1%, specificity 65.2% and accuracy was 89%, as illustrated in table 6.

Table 6: Validity of EUS vs. ERCP in diagnosing biliary diseases.

		ERCP		Total
		Positive	Negative	
EUS	Positive	74	8	82
	Negative	3	15	18
	Total	77	23	100
	Sensitivity 96.1%			
	Specificity 65.2%			
	Accuracy 89%			
	Positive predictive value 86%			
	Negative predictive value 83.3%			

Sensitivity of Transabdominal ultrasound (TAUS) in diagnosing biliary diseases was 58%, specificity 42.8% and accuracy was 55.2%, as illustrated in table 7.

Table 7: Validity of TAUS vs. ERCP in diagnosing biliary diseases.

		ERCP		Total
		Positive	Negative	
TAUS	Positive	18	4	22
	Negative	13	3	16
	Total	31	7	38
	Sensitivity 58%			
	Specificity 42.8%			
	Accuracy 55.2%			
	Positive predictive value 90.2%			
	Negative predictive value 42.8%			

Sensitivity of MRCP/MRI in diagnosing biliary diseases was 60%, specificity 50% and accuracy was 57.1%, as illustrated in table 8.

Table 8: Validity of MRCP/MRI vs. ERCP in diagnosing biliary diseases.

		ERCP		
		Positive	Negative	Total
MRCP /MRI	Positive	6	2	8
	Negative	4	2	6
	Total	10	4	14
	Sensitivity 60%			
	Specificity 50%			
	Accuracy 57.1%			
		Positive predictive value 75%		
		Negative predictive value 33.3%		

Sensitivity of EUS in diagnosing suspected PB tumors was 84.6%, specificity 97.7% and accuracy was 96%, as illustrated in table 9.

Table 9: Validity of EUS vs. ERCP in diagnosing pancreatobiliary tumors.

		ERCP		
		Positive	Negative	Total
EUS	Positive	11	2	13
	Negative	2	85	87
	Total	13	87	100
	Sensitivity 84.6%			
	Specificity 97.7%			
	Accuracy 96%			
		Positive predictive value 84.6%		
		Negative predictive value 97.7%		

Table 10 reveals sensitivity of TAUS was 37, 5% in detecting PB tumors with specificity of 93,9%.

Table 10: Validity of TAUS vs. ERCP in diagnosing Pancreatobiliary tumors.

		ERCP		
		Positive	Negative	Total
TAUS	Positive	3	2	5
	Negative	5	28	33
	Total	8	30	38
	Sensitivity 37.5%			
	Specificity 93.3%			
	Accuracy 93.9%			
		Positive predictive value 60%		
		Negative predictive value 84.8%		

Sensitivity of MRCP/MRI in diagnosing PB tumors was 50%, specificity 91.6% and accuracy was 85.7%, as illustrated in table 11.

Table 11: Validity of MRCP/MRI vs. ERCP in Pancreatobiliary tumors.

		ERCP		
		Positive	Negative	Total
MRCP/MRI	Positive	1	1	2
	Negative	1	11	12
	Total	2	12	14
	Sensitivity 50%			
	Specificity 91.6%			
	Accuracy 85.7%			
		Positive predictive value 50%		
		Negative predictive value 91.6%		

4. Discussions

Various invasive and non-invasive diagnostic modalities are available for PBD, thus we need to be careful in selecting an appropriate modality in order to reduce complications of unnecessary invasive procedures and saving time and cost.

In this study number of patients who underwent non-invasive diagnostic procedures were 38, 14, and 11 for TAUS, MRCP/MRI, and CT scan respectively; which made their comparison to EUS prone to inaccuracy; and basically we could not compare CT scan with ERCP (assuming that ERCP result used as a definite diagnosis), as their number were too little to do a statistical analysis.

Biliarypancreatic diseases were found in 73 cases (ERCP result) include CBD stone, gallstones, gallstone pancreatitis, Mirizzi syndrome, hydatid cysts (2 cases were found, one of them in the liver compressing CBD and another one was intrabiliary rupture), and bile duct cysts; while suspected tumor were found in 10 cases and include suspected pancreatic and periampullary tumor, hepatocellular cancer, and cholangiocarcinoma, as shown in detail in the figures (1& 2).

Three percent of patients found to have Mirizzi syndrome during ERCP, which is high in comparison to a study done by Yonetci et al^[17], in which the incidence of Mirizzi syndrome was 1.07% in patients undergoing ERCP; this difference may be related to their (retrospective) study or a large sample size (656 cases) in comparison to our smaller study.

In this study jaundice duration was significantly longer among suspected tumor patients (P value = 0.01), which is comparable to a study done by Giuseppe Garcea et al^[18].

In this study the sensitivity of TAUS, MRCP/MRI, and EUS for detecting biliary diseases were 58%, 60%, and 96.1%, respectively, which is comparable to a study done by Prachayakul et al^[19], in which the sensitivity of TAUS, MRCP, and EUS for detecting choledocholithiasis were 25-58%, 91% (33-100%), and 95%, respectively.

The difference in the results may be related to many facts. First our study was broad included both benign & malignant PBD that mean other pathologies which are included in the subset of biliary disease may have an impact on the result. Second in their study they depend on the likelihood (intermediate and high) for performing diagnostic modalities. Third in their study they declared a wide range of sensitivity of MRCP/MRI in detecting choledocholithiasis, which related to the size of CBD stone, which may be a factor in our study too. Finally MRCP/MRI were done and reported by different radiologists in this study.

In this study, The specificity of TAUS, MRCP/MRI, and EUS for detecting biliary diseases were 42.8%, 50%, and 65.2%, respectively; in comparison to Prachayakul et al⁽¹⁹⁾ in which specificity of TAUS and EUS were 68-91%, and 98%, respectively; and the difference may also be related to the same factors mentioned earlier.

In one study done by H.E. Adamek et al^[20], the specificity of MRCP was 81%. In another study done by De Ledingham et al^[21] the sensitivity, specificity, positive predictive value

(PPV), and negative predictive value (NPV) for suspected cholidocholithiasis (in 43 patients) were 100%, 95.4%, 90.9% and 100% for EUS, respectively; and 100%, 72.7%, 62.5%, and 100% for MRCP, respectively. In another study done by Chak A. et al ^[22], the PPV and NPV of EUS for diagnosing choledocholithiasis (in 36 patients) were 100% and 97%, respectively.

In the current study; in addition to the aforementioned data the PPV and NPV of EUS for diagnosing biliary diseases were 86% and 83.3%, respectively; and for MRCP were 75% and 33.3%, respectively.

By comparing our study to the above mentioned studies we can estimate a wide variability in the accuracy of different diagnostic modalities especially EUS and MRCP for diagnosing biliary diseases, and this may indicate multiple factors contributing to such difference, including level of expertise in performing EUS, Un availability of specific guidelines for a better patient stratification and a time lapse between different studies, in addition to the sample size as mentioned before. One of the important factor which should be taken in to consideration is a spontaneous passage of gallstones in a period between performing EUS and ERCP, this is supported by a study done by Frossard et al ^[23], which reported that spontaneous passage of stones occurred at a rate of 20% per a week, especially if a stone very small (<5 mm) ^[24].

In this study the sensitivity, and specificity of TAUS for identifying pancreato-biliary tumor were 37.5%, and 93.3%; this is comparable to a study done by Chen et al ^[25], in which a sensitivity of TAUS for detecting peri- ampullary tumor was 24%. In another study done by Karlson et al ^[26], the sensitivity and specificity of TAUS in the detection of all tumors in the pancreatic area were 88.6%, and 98.8%, respectively. This means TAUS is mostly operator dependent, and it needs a good expertise, but with comparable specificity to our study (because 7 out of 10 patients were diagnosed as pancreatic cancer).

The sensitivity, specificity, and accuracy of MRCP/MRI for diagnosing pancreatobiliary tumors in this study were 50%, 91.6%, and 85.7%, respectively, in comparison to a study done by Verma et al ^[27], in which results were 86%, 92%, and 98%, respectively; this indicate that sensitivity of MRCP/MRI were under question in both biliary diseases and pancreatobiliary tumors, and may be related in part to the poor technique of doing MRI/MRCP, as evidenced in an article written by Nayree Griffin et al ^[28], in which factors behind a poor techniques declared in details like: (1) artefacts related to technique and reconstruction; (2) normal variants mimicking pathology; (3) intra-ductal factors; (4) extra-ductal factors.

In the current study the sensitivity, specificity, PPV, and NPV of EUS for identifying pancreatobiliary tumors were 84.6%, 97.7%, 84.6%, and 97.7%, respectively, which in comparable to a study done by Shoup M. et al ^[29], in which the results of EUS for detecting peri-ampullary tumors were 97%, 33%, 94%, and 50%, respectively. In an article written by Gonzalo et al ^[30] the sensitivity of EUS for detecting

pancreatic tumor was 99% which is higher than in our study due to better experience in their study.

5. Conclusion

EUS is a valuable technique in both (benign & malignant) pancreatobiliary diseases diagnosis & evaluation before proceeding to further management by more invasive techniques like ERCP or surgery.

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