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Original article

Comparison of Endoscopic Ultrasonography Evaluation of SuspectedPancreaticobiliary Malignancy in Patient with or without Biliary Decompression

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ABSTRACT

Background: Endoscopic ultrasound (EUS) is a modern modality aids in the diagnosis and treatment of pancreatic and biliary diseases. It also allows tissue sampling and staging. **AIM:** To compare the diagnostic accuracy of Endoscopic Ultrasonography (EUS) guided fine needle aspiration (FNA) before and after biliary decompression in suspected pancreaticobiliary malignancy. **Patients and Methods:** This prospective cross-sectional study was conducted in Tanta University (internal medicine department) and Benha University (hepatology, gastroenterology and infectious disease department) on (120) patients with suspected pancreaticobiliary malignancy referred for EUS evaluation with or without fine needle aspiration (FNA). And they classified into two groups based on the presence or absence of biliary stent. All patients included in this study subjected to: Complete history taking and thorough clinical examination, laboratory investigations (Complete blood picture, liver profile, CA19-9), imaging (Pelvi abdominal ultrasonography (US) and or, Abdominal triphasic CT scan and or, Magnetic Resonance Cholangiopancreatography (MRCP), endoscope (Endoscopic ultrasound (E.U.S). **Results:** Comparing between both groups using the univariate regression analysis, increasing the tumor size, increasing the number of passes and use of 22-guage needle were shown as predictors associated with accurate diagnosis by EUS. However, with application of multivariate regression analysis, increasing the tumor size and use of 22-guage needle were shown as independent predictors associated with accurate diagnosis by EUS. the presence of stent did not influence the accuracy of diagnosis.**Conclusion:**Pre-EUS stenting of biliary obstruction due to pancreaticobiliary malignancy didn't influence the rate of tissue diagnosis.

Keywords: Endoscopic Ultrasonography, Biliary Decompression, Pancreaticobiliary Malignancy.

Introduction:

Pancreaticobiliary malignancies arise from different areas within the pancreas and biliary tree. Among all pancreaticobiliary malignancies, pancreatic cancer is the most common. Cholangiocarcinoma is another important pancreaticobiliary malignancy, which accounts for about 3% of all gastrointestinal cancers [(1)]. Primary ampullary carcinomas are most rare, with an incidence of only 3–4 cases per million of population, with its incidence being increased among patients who have familial adenomatous polyposis or Lynch syndrome [(2)]. Endoscopic ultrasound (EUS) is a well-recognized diagnostic and therapeutic modality in the treatment of pancreaticobiliary diseases, and more specifically, pancreaticobiliary malignancies [(3)]. Endoscopic ultrasonography is essential in the diagnosis by obtaining tissue (FNA or fine needle biopsy (FNB)) and in the loco-regional staging of the disease. The advancement in EUS techniques has made this modality a critical adjunct in the management process of pancreatic cancer [(4)]. EUS-FNA has a diagnostic accuracy of 60% to 90%, depending on the site that is investigated [(5)]. Current society guidelines recommend that EUS should be performed before biliary stent placement in all patients with suspected pancreaticobiliary malignancy as well as a lack of benefit from pre-operative biliary decompression [(6)]. The acoustic reverberation and shadowing induced by biliary stents impairs the image quality, tumor visualization, and staging accuracy of EUS. [(7&8)] These limitations can be even more exaggerated in patients with indwelling self-expandable metallic stent (SEMS). This prospective cross-sectional study aimed to compare the diagnostic accuracy of EUS guided FNA before and after biliary drainage.

Patients and methods:

This prospective cross-sectional study was conducted on (120) patients with suspected pancreaticobiliary malignancy. Who referred to Hepatology, Gastroenterology and Infectious Diseases, Benha University Hospital, Benha University and Internal Medicine Department, Tanta University from February 2021 to April 2022.

The study protocol WAS approved by ethical committee of Benha university hospital, Benha University {study No M.D.8.12.2020}. All studied patients gave an informed written consent for participation in the study after explanation of the procedure and its possible hazards. The patients classified into two groups based on the presence or absence of biliary stent.

- **Patients with suspected pancreaticobiliary malignancy who enrolled in our study were classified into two groups based on the presence or absence of biliary stent.**

• **<u>Group I</u>:** patients with suspected pancreaticobiliary malignancy with obstructive jaundice underwent biliary decompression by stent insertion.

- **Group II**: patients with suspected pancreaticobiliary malignancy with obstructive jaundice with no stent insertion.

Inclusion criteria:

Patients with suspected pancreatic or biliary malignancy with suspicious based on (clinical data e.g obstructive jaundice - laboratory investigation e.g elevation of total and direct bilirubin , elevated alkaline phosphatase, elevated gamma glutamyl transeferase, elevated CA19-9 and or CEA - Imaging e.g hyper echoic regions, calcification, dilated common bile duct, increased intrahepatic biliary radical dilatation and or pancreatic duct dilatation) referred for EUS evaluation with or without fine needle aspiration (FNA).

Exclusion criteria: Patient refused the procedure, Patients with severe coagulopathy (INR ≥2.5**,** Thrombocytopenia platelet ≤100.00), Patients with massive ascites, Patients with severe cardiac (ejection fraction < 40% and or New York classification from II to IV and or recurrent arrythmia with or without respiratory decompensation.

All patients included in this study subjected to: Complete history taking and thorough clinical examination, Laboratory investigations (Complete blood picture, Liver profile, CA19-9), Imaging (Pelvi abdominal ultrasonography (US) and or, Abdominal triphasic CT scan and or, Magnetic Resonance Cholangiopancreatography (MRCP), Endoscope (Endoscopic ultrasound (E.U.S) (CT and MRCP were not obligatory in all patients).

Statistical methods:

All data were analyzed by the statistical package SPSS (Statistical Package for the Social Sciences) version 22 (IBM Corp., Armonk, NY, USA). Categorical data were presented as numbers and percentages, while numerical data were first tested for normality by the Shapiro-Wilk test and expressed as either mean ± standard deviation if they were normally distributed or median and interquartile range (25th-75th percentiles) if they were not normally distributed. The associations between categorical variables were tested by the Chi-Square or Fisher Exact tests as appropriate. For comparison of normally distributed numerical data between two groups, the independent T-test was applied, while the Mann-Whitney U test was performed if the data were not normally distributed. The diagnostic performance, including sensitivity, specificity, positive predictive value, negative predictive value, and accuracy, of FNA in comparison to the standard diagnosis with FNB in patients with an initial inconclusive diagnosis was calculated in each group. As well, the diagnostic performance of CT and MRCP investigations in comparison to the EUS findings was calculated. Furthermore, univariate regression analysis for the factors associated with accurate diagnosis (conclusive diagnosis) was performed. A P-value <0.05 was considered statistically significant.

Agreement analysis:

- Kappa agreement coefficient was used to represent the association between the two diagnostic techniques.

Diagnostic accuracy

The diagnostic performance of a test, or the accuracy of a test to discriminate diseased cases from non-diseased cases is evaluated.

Validity indices calculated according to the following equations

1-Sensitivity (Sn) =detection rate=TPR (TPF): ability of test to detect disease in those who are actually diseased

$$Sn = \frac{TP}{TP + FN} X100$$

2-Specificity (Sp) =TNR (TNF): ability of test to exclude disease in those who actually do not have it.

$$Sp = \frac{TN}{TN + FP} X100$$

3-Positive predictive rate (PPR): proportion of people with +ve test who are diseased

$$PPV = \frac{TP}{TP + FP} X100$$

4-Negative predictive rate (NPR): proportion of people with -ve test who are not diseased

$$NPV = \frac{TN}{TN + FN} X100$$

5-Accuracy:

$$Accuracy = \frac{TN+TP}{TP+TN+ FN +FN} X100$$

RESULTS:

This study included 120 patients with suspected pancreaticobiliary malignancy.

Patients were classified into two groups: group I (N=70) comprised patients with obstructive jaundice who underwent biliary decompression by stent insertion, and group II (N=50) included patients with obstructive jaundice with no stent or biliary drainage.

The majority of cases in in both groups were male (75 patients) versus female (45 patients) . The mean age in Group I was 58.1 while in group II was 55.1 with no significant differences as shown in (figure 1).

Regarding to method of biliary decompression in group I , ERCP was used in most cases (92.9%) while percutaneous trans hepatic drainage used only in 7.1% of cases.

A plastic stent was used in 60 patients while metallic stent was used in 10 patients.

As regard laboratory investigations done in both groups. The median ALT, direct bilirubin, GGT and alkaline phosphatase were significantly higher in group I than in group II. On the other hand median of total bilirubin and indirect bilirubin were significantly lower in group I compared to group II (table 1).

Regarding to image finding, the main concern in imaging report (either transabdominal US, CT and or MRCP), was the presence of a pancreatic or ampullary mass, double duct sign, and presence of biliary stricture) as shown in table (1)

Curvilinear EUS was done in all cases, with special emphasis on pancreaticobiliary examination, criteria of mass if present, relation to vessels, and presence of lymph nodes as shown in (table 2 and figures 2, 3 &4)

We did not find a pancreatic or ampullary lesion in 9 patients. Therefore, FNA was done in 111 patients only (64 in group I and 47 in group II) as shown in table 3 & figure 2.

After careful evaluation of the lesion by EUS, FNA was done and Rapid On-Site Evaluation (ROSE) was available in all cases. ROSE could differentiate benign cytology from malignant in 88.9 % of cases in group I and in 85.1 % of cases in group II while inconclusive results was in 11.1 % of cases in group I 14.9 % while in group II as shown in (figure 5&6).

For patients with inconclusive results, FNB was arranged in another session and same pathologist was asked to interpreter the tissue as shown in (table 4).

In group I, there were 5 patients with true negative diagnosis and 2 with false negative diagnosis. The calculated Sensitivity, Specificity, PPV, NPV, and accuracy were 72%, 71%, 71.29%, 71.72%, and 71.50%, respectively (table 4).

In group II, one patient showed a false negative diagnosis, while 6 patients showed a true negative diagnosis. The calculated sensitivity, specificity, PPV, NPV, and accuracy were 86 %.(table 4).

There was high degree of agreement in the detection of malignant lesions by EUS .The EUS showed 92.5% sensitivity, 90.9% specificity, 92.18% accuracy, 98% PPV and 71.4% NPV in detection of malignancy in group I with stent . As regard group II (without stent) there was high degree of agreement in the detection of malignant lesions by EUS, and this value showed high significant value (p <0.001) The EUS showed 100% sensitivity, 66.7% specificity, 93.6% accuracy, 92.7% PPV and 100% NPV in detection of malignancy as shown in table (5).

With using the univariate regression analysis, increasing the lesion size, increasing the number of passes and use of 22-guage needle were shown as predictors associated with accurate diagnosis by EUS. However, with application of multivariate regression analysis, increasing the lesion size and use of 22-guage needle were shown as independent predictors associated with accurate diagnosis by EUS as shown in table (6).

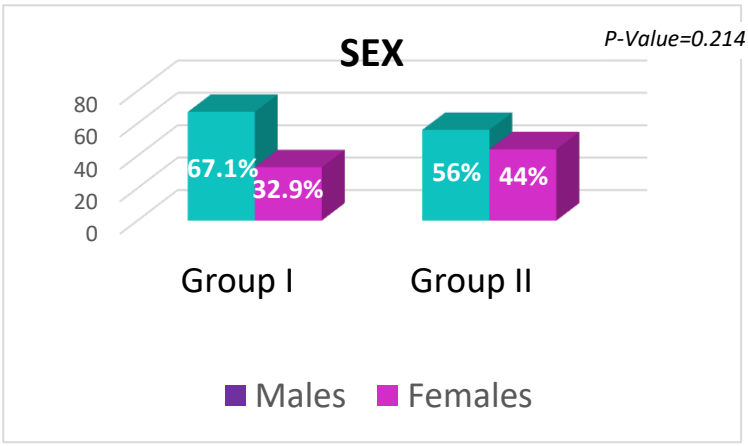

Figure (1): a-Distribution of sex in the studied groups

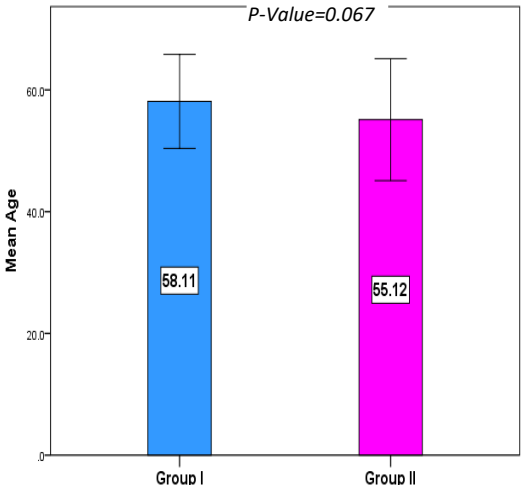

Figure (1): b-Comparison of the age in the studied groups

fig.(1) : Demographic criteria of study population

Table (1): Comparison between both groups regarding laboratory investigations and imaging (ultrasound, CT, and MRCP findings).

		Groups		Test statistic	P-Value
		Group I N=70	**Group II N=50**		
Hemoglobin (mg/dL)	Mean± SD	12.7±1.8	12.2±1.9	1.502	0.136 [a]
WBCs (U/L)	Median	4300.0	4300.0	1.188	0.235 [b]
	IQR	4100.0-5200.0	3900.0-5200.0		
Platelets count (U/L)	Mean± SD	167.4±23.5	177.9±56.7	1.389	0.168 [a]
ALT (IU/dL)	Median	127.5	93.0	2.638	**0.008*** [b]
	IQR	90.0-182.0	70.0-155.0		
AST (IU/dL)	Median	82.0	71.0	1.961	0.050 [b]
	IQR	65.0-115.0	55.0-102.0		
Total bilirubin (mg/dL)	Median	10.30	15.30	3.658	**<0.001*** [b]
	IQR	10.60-18.60	7.50-15.00		
Direct bilirubin (mg/dL)	Median	12.05	8.60	3.586	**<0.001*** [b]
	IQR	9.00-16.30	6.00-12.30		
Indirect bilirubin (mg/dL)	Median	2.1	2.3	2.043	**0.041*** [b]
	IQR	2.0-3.3	1.3-3.0		
Serum albumin (mg/dL)	Mean± SD	3.9±.5	4.0±.3	2.064	**0.041*** [a]
INR	Mean± SD	1.1±.1	1.1±.1	0.558	0.578 [a]
CA19-9 (U/mL)	Median	192.0	218.0	1.692	0.103 [b]
	IQR	89.0-340.0	125.0-380.0		
GGT(IU/L)	Median	183.0	100.0	4.372	**<0.001*** [b]
	IQR	65.0-160.0	145.0-200.0		
Alkaline phosphatase (U/L)	Median	204.0	67.0	8.762	**<0.001*** [b]
	IQR	175.0-300.0	43.0-100.0		
Serum creatinine (mg/dL)	Mean± SD	1.1±.1	1.1±.1	0.048	0.962 [a]

		Groups					
		Group I N=70		**Group II N=50**			
		N	**%**	**N**	**%**	**X^2**	**P-Value**
US	**Normal pancreas**	60	85.7%	35	70.0%	4.367	0.037*
	Bulky pancreas	10	14.3%	15	30.0%		
CT	**Heterogenous pancreas**	35	50.0%	25	52.0%	3.206	0.541
	Pancreatic lesion	29	41.4%	22	44.0%		
	ampullary lesions	0	0.0%	1	2.0%		
	Not done	3	4.3%	2	4.0%		
	No lesion	3	4.3%	0	0.0%		
	Intra - abdominal lymphadenopathy	45	64.3%	33	66.0%	0.038	0.846
MRCP	**Not done**	6	8.6%	24	48.0%		
	Both common and pancreatic duct dilation (double duct sign)	28	43.8%	16	32.0%	2.314	0.126
	Distal biliary stricture	36	51.4%	10	20.0%		

[a] Independent T-test, [b] Mann-Whitney test
SD: standard deviation, IQR: interquartile range

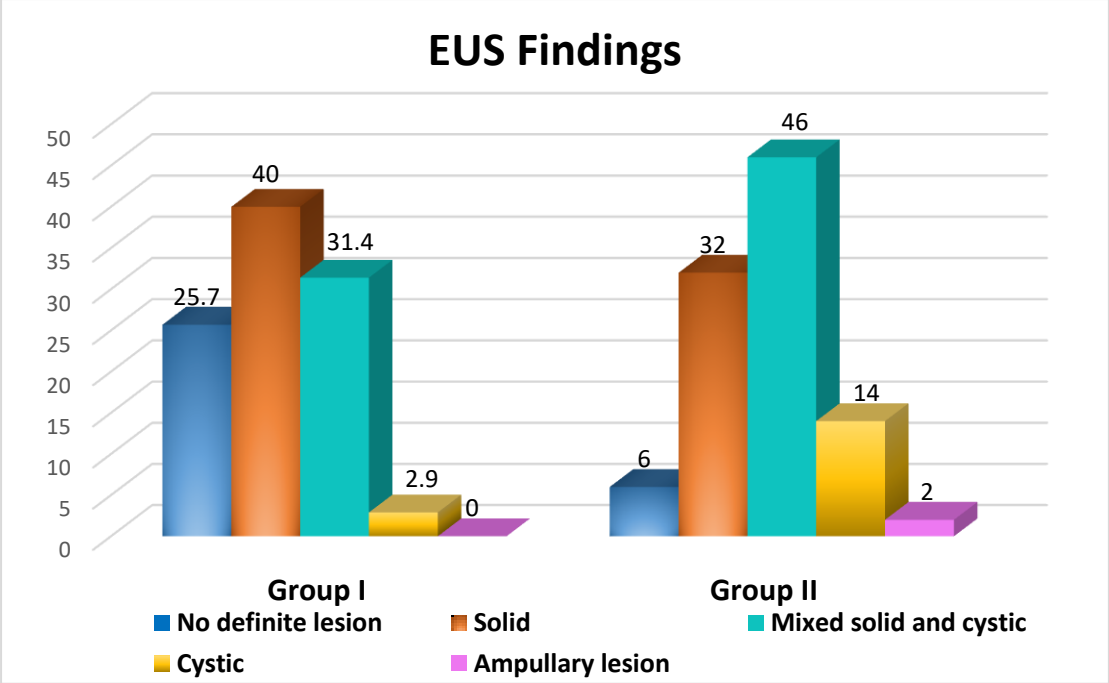

Fig.(2): characteristics of lesions by EUS

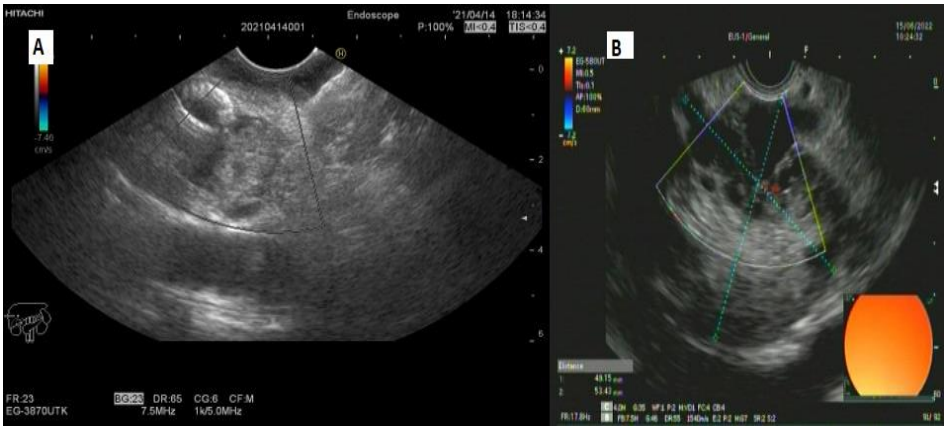

Figure (3): EUS findings (A): A pancreatic head solid mass with metallic stent seen in CBD. (B) Mixed solid and cystic lesion in pancreatic head without a stent in CBD

Table (2): The relation of the lesion to the blood vessels in the studied groups and the measurements of the detected lesions, lymph nodes, common bile duct and the main pancreatic duct in the studied groups.

		Groups					
		Group I		Group II			
The relation of the lesion to the blood vessels		**N=52**		**N=47**			
		N	%	N	%	**X^2**	**P-Value**
Away or no relation from a blood vessel		23	44.2%	20	42.5%	**0.783**	**0.998**
Abutment to superior mesenteric vein		12	23.1%	11	23.4%		
Encasement of superior mesenteric vein		8	15.4%	7	14.9%		
Abutment to portal vein		5	9.6%	4	8.5%		
Abutment to SMA		3	5.8%	3	6.4%		
Encasement of SMA		1	1.9%	2	4.3%		
measurements of the detected, lesions, lymph nodes, common bile duct and the main pancreatic duct in the studied groups			**Groups**			**Test statistic**	**P-value**
			Group 1		**Group2**		
Anteroposterior diameter of the lesion	**Minimum-Maximum**		4.4-67.9		4.6-83.0	**0.619**	**0.537** [a]
	Mean± SD		34.8±15.4		37.0±19.1		
Transverse diameter of the lesion	**Minimum-Maximum**		4.9-66.0		4.3-52.5	**0.891**	**0.376** [a]
	Mean± SD		24.9±13.6		27.5±13.7		
Anteroposterior diameter of LN	**Minimum-Maximum**		2.3-34.2		1.9-32.0	**1.255**	**0.210** [b]
	Median		10.5		7.8		
	IQR		7.2-15.0		5.6-12.0		
Transverse diameter of LN	**Minimum-Maximum**		.0-18.0		2.1-45.0	**0.521**	**0.602** [b]
	Median		8.0		5.8		
	IQR		3.6-11.6		3.4-11.1		
Common bile duct diameter (mm)	**Minimum-Maximum**		5.50-26.50		4.30-19.0	**2.618**	**0.009*** [b]
	Median		8.90		8.0		
	IQR		8.50-10.20		7.0-11.0		
Main pancreatic duct (mm)	**Minimum-Maximum**		2.70-11.10		2.70-8.40	**0.416**	**0.677** [b]
	Median		3.25		3.80		
	IQR		3.10-5.10		3.10-4.90		

[An] Independent T-test, [b] Mann-Whitney test
SD: standard deviation, IQR: interquartile range

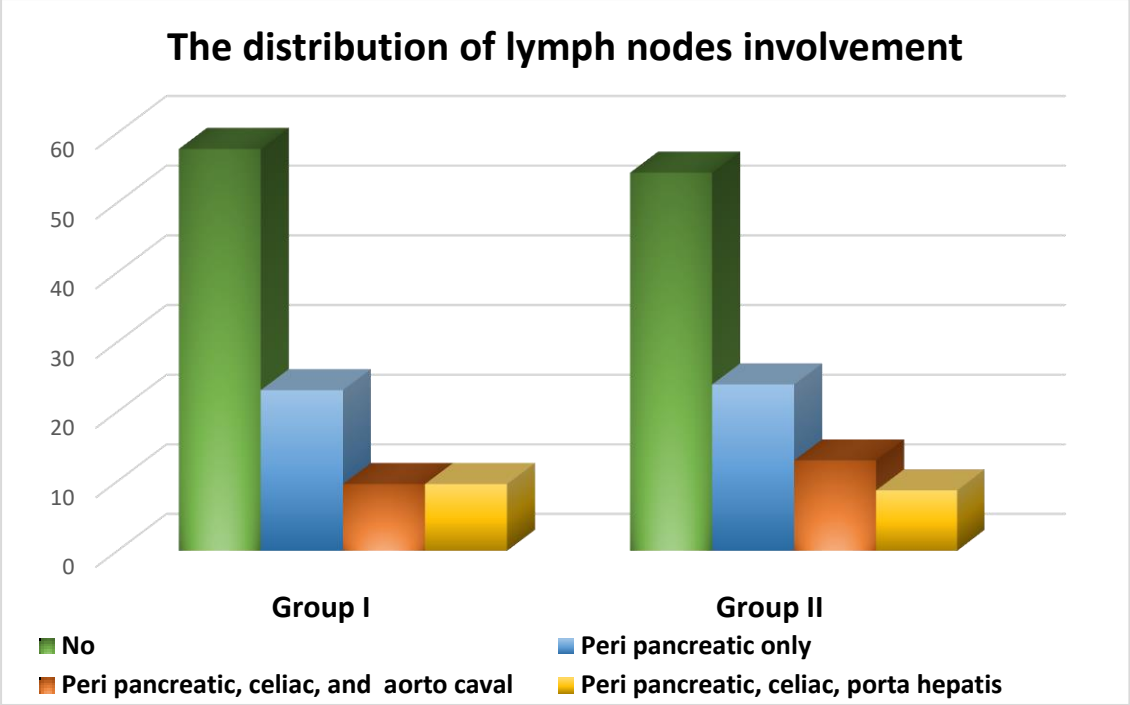

Figure (4): Distribution of lymph nodes involvement in 2 groups

Table (3) : Comparison between both groups as regard FNA was done or not , route of fine needle pass , number of passes.

		Groups					
		Group I N=64		Group II N=47			
		N	%	N	%	X2	P-Value
Need for FNA	**Done**	64	91.4%	47	94.0%	0.278	0.733
	No need for FNA(not done)	6	8.6%	3	6.0%		
Route of fine needle pass	**Trans duodenal**	42	65.6%	38	80.9%	3.375	0.175
	Tans gastric	21	32.8%	9	19.1%		
	Trans gastric and trans duodenal	1	1.6%	0	0.0%		
Number of passes	**2**	36	56.3%	35	74.5%	4.526	0.104
	3	22	34.4%	11	23.4%		
	1	6	9.4%	1	2.1%		

The size of the needle in all patients who underwent FNA was 22 gauge.

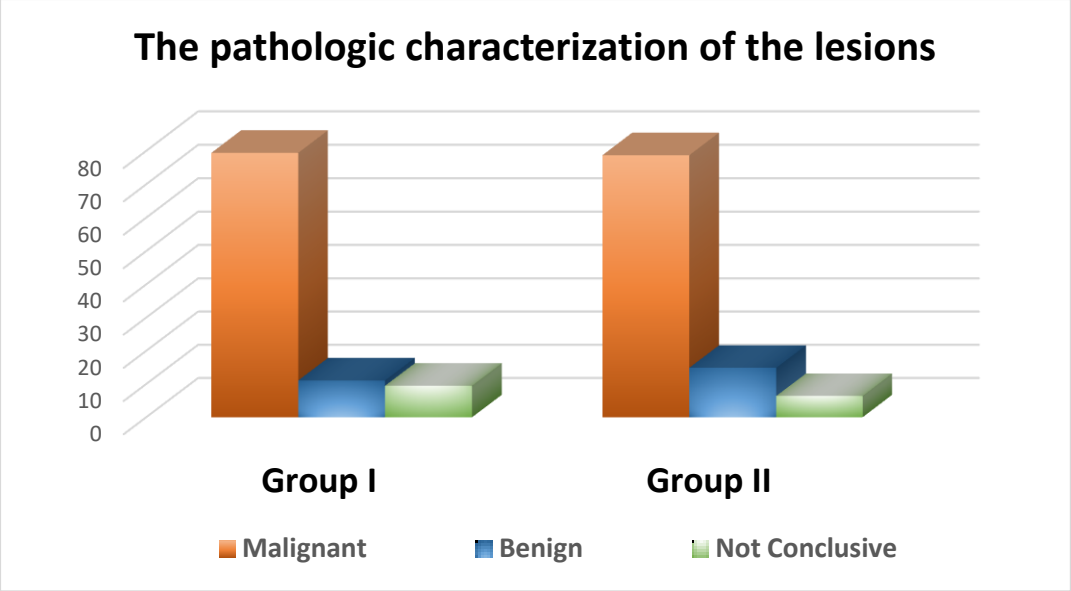

Figure (5) : ROSE interpretation of EUS –FNA

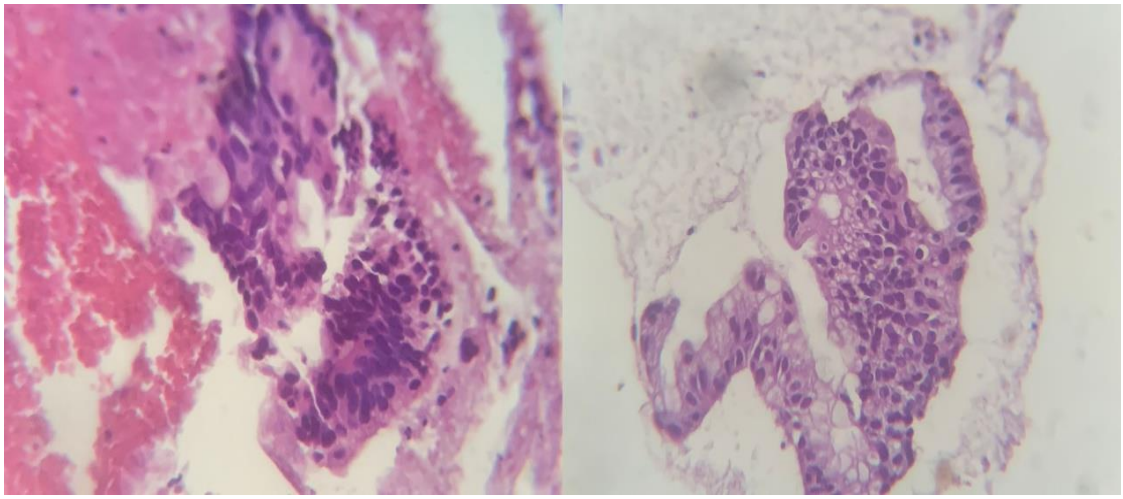

Figure (6): Pancreatic adenocarcinoma diagnosed by EUS-FNA

Table (4): Diagnostic performance of FNA in comparison to diagnosis with FNB in patients with an initial inconclusive diagnosis in group I and group II.

Not conclusive Group I	**FNA**	**FNB**	
1	extensive fibrosis and inflammatory infiltrate	chronic pancreatitis with fibrosis, no malignancy	**True Negative**
2	extensive fibrosis and inflammatory infiltrate	chronic pancreatitis with fibrosis, no malignancy	**True Negative**
3	extensive fibrosis and inflammatory infiltrate	chronic pancreatitis with fibrosis ,no malignancy	**True Negative**
4	extensive fibrosis and inflammatory infiltrate	moderately differentiated adeno carcinoma	**False Negative**
5	extensive fibrosis and inflammatory infiltrate	Chronic pancreatitis with fibrosis ,no malignancy	**True Negative**
6	extensive fibrosis and inflammatory infiltrate	Chronic pancreatitis with fibrosis ,no malignancy	**True Negative**
7	extensive fibrosis and inflammatory infiltrate	moderately differentiated adeno carcinoma	**False Negative**
Sensitivity	72% (95% CI: 62.13% to 80.52%)		
Specificity	71% (95% CI: 61.07 % to 79.64%)		
PPV	71.29 (95% CI: 64.09% to 77.55%)		
NPV	71.72 (95% CI: 64.39% to 78.05%)		
Accuracy	71.50 (95% CI: 64.71% to 77.64%)		
Not conclusive Group II	**FNA**	**FNB**	
1	Extensive fibrosis and inflammatory infiltrate	Chronic pancreatitis with fibrosis (no malignancy)	**True negative**
2	Extensive fibrosis and inflammatory infiltrate	Chronic pancreatitis with fibrosis (no malignancy)	**True negative**
3	Extensive fibrosis and inflammatory infiltrate	Chronic pancreatitis with fibrosis (no malignancy)	**True negative**
4	Extensive fibrosis and inflammatory infiltrate	Chronic pancreatitis with fibrosis (no malignancy)	**True negative**
5	Extensive fibrosis and inflammatory infiltrate	Chronic pancreatitis with fibrosis (no malignancy)	**True negative**
6	Extensive fibrosis and inflammatory infiltrate	Chronic pancreatitis with fibrosis (no malignancy)	**True negative**
7	Extensive fibrosis and inflammatory infiltrate	Moderately differentiated adenocarcinoma	**False Negative**
Sensitivity	86% (95% CI: 77.63% to 92.13%)		
Specificity	86% (95% CI: 77.63% to 92.13%)		
PPV	86% (95% CI: 78.97% to 90.95%)		
NPV	86% (95% CI: 78.97% to 90.95%)		
Accuracy	86% (95% CI: 80.41% to 90.49%)		

PPV: positive predictive value,
NPV: negative predictive value,
CI: confidence interval.

Table (5): EUS criteria of the lesion as compared to pathology in detection of malignancy in group I (n=64) & group II (n=47).

	EUS criteria of the lesion in group I (n=64)				**Test of significance**	**P value**
	Benign (n= 11)		**Malignant (n= 53)**			
	No	**%**	**No**	**%**		
EUS findings						
Suspected benign (N=14)	10 (TN)	90.9	4 (FN)	7.5	**κ= 0.752**	**<0.001***
Suspected malignant (N= 50)	1 (FP)	9.1	49 (TP)	92.5		
Sensitivity				92.5%		
Specificity				90.9%		
Accuracy				92.18%		
PPV				98%		
NPV				71.4%		
	EUS criteria of the lesion in group II (n=47)				Test of significance	P value
	Benign (n= 9)		Malignant (n= 38)			
	No	%	No	%		
EUS findings						
Suspected benign (N=14)	6 (TN)	66.7	0 (FN)	0	κ= 0.764	<0.001*
Suspected malignant (N= 50)	3 (FP)	33.3	38 (TP)	100		
Sensitivity				100%		
Specificity				66.7%		
Accuracy				93.6%		
PPV				92.7%		
NPV				100%		

K.Kappa agreement coefficient *: Statistically significant
PPV: Positive predictive value TN: true negative
NPV: Negative predictive value TP:true positive
FN: false negative FP: false positive

Table (6): Univariate and multivariate regression analysis for prediction of accurate diagnosis by EUS.

Predictors	**Univariate regression**				**Multivariate regression**			
		Odds ratio	95% C.I. for odds ratio			Odds ratio	95% C.I. for odds ratio	
	P value		Lower	Upper	P value	Lower		
Age	0.169	0.884	0.627	1.156				
Gender (male vs. female)	0.204	1.009	0.716	1.487				
Lesion size	**<0.001***	2.875	2.٢89	3.534	**0.001***	2.06	1.27	2.89
Number of passes	**0.00٥***	1.٤25	١.004	٢.123	0.122	1.599	0.736	1.763
Stent	0.238	0.733	0.541	1.276				
22-guage needle	**<0.001***	2.465	1.47	3.25	**0.001***	2.364	1.11	2.78

Discussion:

EUS-FNA provides a cytological diagnosis of malignancy may obviate the need to obtain cytology using ERCP, which has a disappointingly low sensitivity in most cases, especially for pancreatic carcinoma. This low sensitivity often results in additional procedures, including EUS-FNA, to make a cytological diagnosis of cancer. Nevertheless, it is not clear whether EUS-FNA should be performed before ERCP for the diagnosis of a pancreatic mass, especially there is no biliary stricture [(9)]

There is scarce evidence on the impact of biliary stents on endoscopic ultrasound (EUS) fine-needle biopsy (FNB) or fine-needle aspiration (FNA) of pancreaticobiliary lesions.

So, we aimed in this work is to compare the Endoscopic Ultrasonography (EUS) evaluation of suspected pancreaticobiliary malignancy before and after biliary decompression by stent insertion.

The present work revealed, the mean age of the included cases was 58.1±7.7 years and 55.1±10.0 years in group I and group II respectively. The highest percentages of the cases were males who represented 67.1% and 56% in group I and group II respectively.

Many studies had been conducted with the same aim and conducted the same result as a study during which they enrolled 123 patients with a better percentage of male patients (88 males (71.5%), 35 females (28%), and median age 61.3 years) [(10)]

This is also in agreement with a study that enrolled 234 patients 127 males (54.2 %), 107 females (45.8%), median age 64) [(11)]

As regards to sensitivity and specificity of EUS in detecting pancreatic and ampullary lesions, the results of EUS in detection of malignancy was relatively high in both groups. In group I, the EUS showed 92.5% sensitivity, 90.9% specificity, 92.18% accuracy, 98% PPV and 71.4% NPV in detection of malignancy. In group II, the EUS showed 100% sensitivity, 66.7% specificity, 93.6% accuracy, 92.7% PPV and 100% NPV in detection of malignancy, the values were in consistent with many studies which had been conducted with the same aim and conducted with the same result as study in which 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[(12)]. Another study compared CT and EUS. EUS had superior accuracy to CT for T staging (67% vs 41%) but similar accuracy to CT for N staging (44% vs 47%), detection of respectable tumors (88% vs 92%) and unrespectable tumors (68% vs 64%)[(13)]**.** Also there was a study showed that the sensitivity and specificity value for malignant stricture detected by EUS were 96.6% and 90.6%, respectively, with positive predictive value of 90.3%, negative predictive value of 96.7, and accuracy of 93.4% [(14)]**.**

Our results show that with using the univariate regression analysis, increasing the lesion size, increasing the number of

passes and use of 22-guage needle were shown as predictors associated with accurate diagnosis by EUS. However, with application of multivariate regression analysis, increasing the lesion size and use of 22-guage needle were shown as independent predictors associated with accurate diagnosis by EUS. This came in agreement with a study [that] evaluated the impact of metal and plastic stents on endoscopic ultrasound-guided aspiration cytology and core histology of head of pancreas masses. The study included 141 patients with self-expandable metal stents, 149 with plastic stents, and 341 with no stent, they showed that increasing lesion size, number of passes, and use of a fork-tip needle were independently associated with improved tissue sampling accuracy[(15)], additionally by using multivariate analysis, the increasing lesion size (OR: 1.05, 95% CI: 1.02–1.09, *P* = 0.01) and use of large bore needles (OR: 1.70, 95% CI: 1.09–2.66, *P* = 0.02) were independently associated with higher diagnostic accuracy[(16)]. And by using multivariable analysis. Also another study reported that increasing number of passes and use of a 22-gauge needle was associated with increased accuracy [(17)].

In our current study, the diagnostic performance of FNA in comparison to the standard diagnosis with FNB in patients with an initial inconclusive diagnosis in group I. The calculated Sensitivity, Specificity, PPV, NPV, and accuracy were 72%, 71%, 71.29%, 71.72%, and 71.50%, respectively. More over in group II. The calculated sensitivity, specificity, PPV, NPV, and accuracy were 86% each. This indicates that biliary stent insertion didn't affect the diagnostic performance of FNA. This were consistent with a study reported that in patients without stents, the rate of tissue diagnosis via EUS-FNA was 92.4% (157/170), compared with a rate of 88.5% (77/87) in those with stents placed >24 hours prior to EUS-FNA (p=0.36). Prior stenting of biliary obstruction due to pancreatic adenocarcinoma does not influence the rate of tissue diagnosis if performed more than 24 hours before EUS-FNA[(18)].

On contrast a randomized control trial analyzed 140 patients to compare EUS-FNA and EUS-FNB for diagnosing pancreatic masses. Although not statistically significant, the diagnostic yield for FNB was 91.7% compared to 78.4% for FNA[(19)].

The results of the current study showed no major difference between the diagnostic ability of EUS as compared to pathological findings. The agreement coefficient between the EUS and the pathology was 0.752 and 0.764 in group I and group II respectively. The diagnostic parameters were slightly higher in group II (without previous stenting) except for the specificity.

The current study came in accordance with the following three retrospective studies. One included 243 patients with pancreatic cancer who underwent ERCP and EUS with fine-needle aspiration or biopsy (FNA or FNB). The authors reported that out of the total number of patients, 68 were stented prior to EUS. They found that the EUS-FNA diagnostic yield is not influenced either by the presence of biliary stent, nor by the type of stent (plastic or metallic) [(20)]. Another found no negative effect of SEMS on

diagnostic accuracy in a study in which 577 patients with plastic stents (accuracy 99.8%) were compared with 100 patients with SEMS (accuracy 100%)[21].

The same conclusion by a study that found no difference in EUS-FNA accuracy between no stent and stent (93.7% vs. 95.3%) or between plastic stents and SEMS (95.2% vs. 95.5%) in a cohort of 214 patient, 150 of whom received stents (105 plastic, 45 SEMS); ROSE was available for all cases [22].

ON another hand the result of a recent meta-analysis reported that the presence of a metal stent negatively impacts on diagnostic yield of EUS tissue sampling for pancreatic head lesions, whereas no difference seems to be observed with plastic stents. Therefore, in jaundiced patients, EUS tissue sampling should precede ERCP, especially when metal stents are used [23].

Another study found that the diagnostic accuracy was only 63.6% (n = 11) when stents were placed less than 24 hours before EUS-FNA compared with 88.5% (n = 87) when stents were placed more than 24 hours before EUS. The authors postulated that inflammation resulting from recent bile duct instrumentation deleteriously affects the ability to image the pancreatic mass at EUS [8].

Furthermore, another study showed that among 631 individuals undergoing 698 procedures, 535 (84.8%) had a final diagnosis of malignancy, 141 had SEMS, 149 had plastic stents, and 341 had no stent. Using strict criteria, SEMS were associated with an increased occurrence of incorrect diagnosis of EUS tissue sampling, with an odds ratio (OR) of 1.96 (95% confidence interval [CI] 1.24–3.10) [15].

Limitation of this study:

Mainly the small sample size and very small number of patient who had metallic stent. Also, it didn't consider the time interval on the diagnostic accuracy of EUS.

Conclusion

Endoscopic ultrasound fine-needle aspiration is considered a highly accurate and reliable diagnostic technique for suspected pancreaticobiliary malignancy. Pre-EUS stenting of biliary obstruction due to pancreaticobiliary malignancy didn't influence the rate of tissue diagnosis.

References:

1. **Siegel, R. L., Miller, K. D., & Jemal, A.** Cancer statistics. CA: a cancer journal for clinicians 2018, 68(1), 7-30.
2. **Benhamiche, A. M., Jouve, J. L., Manfredi, S., Prost, P., Isambert, N., & Faivre, J.** Cancer of the ampulla of Vater: results of a 20-year population-based study. European journal of gastroenterology & hepatology 2000, 12(1), 75-79.
3. **Yusuf, T. E., & Bhutani, M. S.** Role of endoscopic ultrasonography in diseases of the extrahepatic biliary system. Journal of gastroenterology and hepatology 2004, 19(3), 243-250.
4. **Blackford A.L, Canto M.I, Klein A.P, Hruban R.H & Goggins, M.** Recent trends in the incidence and survival of stage 1A pancreatic cancer: a surveillance, epidemiology, and end results analysis. JNCI: Journal of the National Cancer Institute 2020, 112(11), pp.1162-1169.

5. **Dumonceau, J. M., Polkowski, M., Larghi, A., Vilmann, P., Giovannini, M., Frossard, J. L., et al.** Indications, results, and clinical impact of endoscopic ultrasound (EUS)-guided sampling in gastroenterology: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline. Endoscopy2011, 43(10), 897-912.
6. **Eloubeidi, M. A., Varadarajulu, S., Desai, S., Shirley, R., Heslin, M. J., Mehra, M., et al.** A prospective evaluation of an algorithm incorporating routine preoperative endoscopic ultrasound-guided fine needle aspiration in suspected pancreatic cancer. Journal of Gastrointestinal Surgery2007, 11, 813-819.
7. **Fusaroli, P., Manta, R., Fedeli, P., Maltoni, S., Grillo, A., Giovannini, E., et al.** The influence of endoscopic biliary stents on the accuracy of endoscopic ultrasound for pancreatic head cancer staging. Endoscopy 2007, 39(09), 813-817.
8. **Fisher J& Gordon SR.** The impact of prior biliary stenting on the accuracy and complication rate of endoscopic ultrasound fine-needle aspiration for diagnosing pancreatic adenocarcinoma. Pancreas. 2011; 40:21–24.
9. **Kawamura, R., Ishii, Y., Serikawa, M., Tsuboi, T., Tsushima, K., Nakamura, S., et al.** Optimal indication of endoscopic retrograde pancreatography-based cytology in the preoperative pathological diagnosis of pancreatic ductal adenocarcinoma. Pancreatology2022, 22(3), 414-420..
10. **Heinzow, H. S., Kammerer, S., Rammes, C., Wessling, J., Domagk, D., & Meister, T.** Comparative analysis of ERCP, IDUS, EUS and CT in predicting malignant bile duct strictures. World Journal of Gastroenterology: WJG 2014, 20(30), 10495.
11. **Makar, M., Zhao, E., & Tyberg, A.** Personalized Approach to the Role of Endoscopic Ultrasound in the Diagnosis and Management of Pancreaticobiliary Malignancies. Journal of Personalized Medicine2021, 11(3), 180.
12. **Abou Bakr, S., Elessawy, H., Ghaly, S., Elezz, M. A., Farahat, A., & Zaghloul, M. S.** Diagnostic accuracy of endoscopic ultrasound in evaluation of patients with obstructive jaundice: single-center experience. Egyptian Liver Journal 2022, 12(1), 16.
13. **DeWitt, J., Devereaux, B., Chriswell, M., McGreevy, K., Howard, T., Imperiale, T. F., et al.** Comparison of endoscopic ultrasonography and multidetector computed tomography for detecting and staging pancreatic cancer. Annals of internal medicine 2004, 141(10), 753-763.
14. **Maluf-Filho F, Sakai P, Cunha J, Garrido T, Rocha M, Machado M. C. C., et al.** Radial endoscopic ultrasound and spiral computed tomography in the diagnosis and staging of periampullary tumors. Pancreatology2004, 4(2), 122-128.
15. **Bekkali, N. L., Nayar, M. K., Leeds, J. S., Thornton, L., Johnson, S. J., Haugk, B., et al.** Impact of metal and plastic stents on endoscopic ultrasound-guided aspiration cytology and core histology of head of pancreas masses. Endoscopy2019, 51(11), 1044-1050.
16. **Crinò, S. F., Bellocchi, M. C. C., Antonini, F., Macarri, G., Carrara, S., Lamonaca, L., et al.** Impact of biliary

stents on the diagnostic accuracy of EUS-guided fine-needle biopsy of solid pancreatic head lesions: A multicenter study. Endoscopic Ultrasound 2021, 10(6), 440.

17. **Antonini, F., Fuccio, L., Giorgini, S., Fabbri, C., Frazzoni, L., Scarpelli, M., et al.** Biliary plastic stent does not influence the accuracy of endoscopic ultrasound-guided sampling of pancreatic head masses performed with core biopsy needles. Digestive and Liver Disease 2017, 49(8), 898-902.
18. **Fisher J. M, Gordon S. R. & Gardner T. B.** The impact of prior biliary stenting on the accuracy and complication rate of endoscopic ultrasound fine-needle aspiration for diagnosing pancreatic adenocarcinoma. Pancreas2011, 40(1), 21-24.
19. **Aadam A.A, Wani S, Amick A, Shah J.N, Bhat Y.M, Hamerski C.M, et al.** A randomized controlled cross-over trial and cost analysis comparing endoscopic ultrasound fine needle aspiration and fine needle biopsy. Endosc. Int 2016.Open 4, E497–E505.
20. **Constantinescu, A., Plotogea, O. M., StanIlie, M., Ciurea, T., Gheonea, D. I., Ungureanu, B. S., et al.** Impact of biliary stenting in endoscopic ultrasound-guided tissue acquisition among patients with pancreatic cancer. Journal of Clinical Ultrasound2022, 50(6), 844-849.
21. **Siddiqui, A. A., Fein, M., Kowalski, T. E., Loren, D. E., & Eloubeidi, M. A.** Comparison of the influence of plastic and fully covered metal biliary stents on the accuracy of EUS-FNA for the diagnosis of pancreatic cancer. Digestive diseases and sciences2012, 57, 2438-2445.
22. **Ranney, N., Phadnis, M., Trevino, J., Ramesh, J., Wilcox, C. M., & Varadarajulu, S.** Impact of biliary stents on EUS-guided FNA of pancreatic mass lesions. Gastrointestinal endoscopy2012, 76(1), 76-83.
23. **Ramai, D., Facciorusso, A., Gkolfakis, P., Chandan, S., Lisotti, A., Bellocchi, M. C., et al.** S1122 Impact of Biliary Stents on Diagnostic Yield of Endoscopic Ultrasound-Guided Tissue Acquisition of Solid Pancreatic Head Lesions: A Systematic Review and Meta-Analysis. Official journal of the American College of Gastroenterology ACG 2022, 117(10S), e817-e818.

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