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Impact of biliary-pancreatic double stents on EUS-guided tissue acquisition among patients with solid pancreatic lesions: A multicenter study

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ABSTRACT

Background and Objective: Although the impact of biliary stents on the accuracy of EUS-guided tissue acquisition (EUS-TA) is still controversial, the influence of biliary-pancreatic double stents on EUS-TA is even more inconclusive. The aim of the study was to determine whether the diagnostic yield of EUS-FNA in the diagnosis of solid pancreatic lesions will be affected after placement of biliary-pancreatic double stents.

Methods: A multicenter retrospective study including patients who underwent EUS-FNA with biliary duct obstruction was performed. Patients were divided into 2 groups according to whether there were biliary-pancreatic double stents before EUS-FNA. The patients' EUS-FNA report, histopathological results, and clinical case data were reviewed and compared.

Results: Ninety-two patients were included, 42 with biliary-pancreatic double stents and 50 without any stents. The puncture time taken by EUS-FNA was significantly longer in the stent group than the no-stent group (19 *vs.* 15 min, $P < 0.001$). No significant differences were observed in accuracy (90.5% *vs.* 94%), sensitivity (89.5% *vs.* 93.6%), specificity (100% *vs.* 100%), NPV (50% *vs.* 50%), PPV (100% *vs.* 100%), respectively, in both groups. Patients with larger lesions (OR = 1.600, 95% CI: 1.124–2.277) and those who required more passes had a higher diagnostic yield (OR = 9.376, 95% CI: 1.356–64.819) by multivariate analysis.

Conclusions: ERCP before EUS-FNA is feasible for the treatment of solid pancreatic lesions causing obstructive jaundice. It will not have a negative impact on the diagnostic accuracy and surgical complications, but the EUS-FNA operation time will be prolonged.

Key words: Endoscopic retrograde cholangiopancreatography; Obstructive jaundice; EUS-FNA; Biliary-pancreatic double stents

INTRODUCTION

With the increasing incidence and the low 5-year survival of pancreatic cancer, how to differentiate and diagnose pancreatic mass more accurately has become a popular topic. Painless obstructive jaundice is the most common clinical manifestation of solid pancreatic head lesions, suggesting a rare opportunity for primary surgical resection and long-term survival.[1] EUS is the primary and important mode of diagnostic evaluation for patients with solid pancreatic lesions.[2] Pancreatic specimens of the mass can be acquired by EUS-FNA and biopsy (EUS-FNB), called EUS sound–guided tissue acquisition (EUS-TA). The diagnostic yield of EUS-TA including accuracy, specificity, and sensitivity can be affected by several factors, such as location of the mass, lesion size, needle type, number of needle passes, technique of sampling, availability of rapid on-site evaluation, and experience of the operating endoscopist.[3]

ERCP is one of the treatment choices for patients with obstructive jaundice. In majority of the cases, bile stent is usually placed to solve the jaundice and acute inflammation. However, during the ERCP procedure, if the guidewire enters the pancreatic duct first, double guidewire or precut technique through the pancreatic duct will be used, and stents will be implanted in both the bile duct and pancreatic duct.[4] Double-stent drainage on biliary and pancreatic duct obstruction is mostly applied in benign and malignant tumors of ampulla, bile duct, and pancreatic head, as well as chronic inflammation.[5] In order to alleviate obstruction and to reduce the acute inflammation, which is more urgent, patients with severe obstruction often undergo ERCP as the initial examination and treatment but also due to the wider accessibility than EUS, despite concerns for adverse events.[6] Therefore, biliary-pancreatic double stenting usually precedes EUS-TA in some instances. The presence of the stents could hinder the observation of the lesion owing to the shadows or reverberation [Figure 1].

However, the impact of the presence of those stents on the diagnostic yield of EUS-TA remains unclear. There are a total of 7 studies about the impact of single biliary stent published with conflicting

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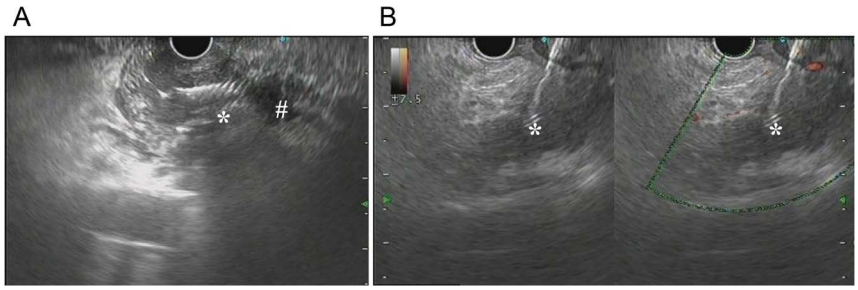

Figure 1. EUS-guided FNA of a pancreatic tumor with biliary-pancreatic double stents. A, A small pancreatic head tumor (#) is hidden by a biliary metal stent (*). B, The most marginal part of a pancreatic head solid lesion (#) is sampled beside a pancreatic stent (*).

results, among which 3 studies showed no difference in diagnostic yield of EUS-FNA and EUS-FNB, and the other 4 studies revealed the negative effects.[7–9] To date, the study on the impact of biliary-pancreatic double stenting is still lacking, although it is a common clinical condition.

We performed the research as a multicenter retrospective study, and the primary aim of our study is to compare the diagnostic yield of EUS-TA in patients with solid pancreatic lesions with or without biliary-pancreatic double stents, trying to provide ideas for determining the order of clinical selection on ERCP and EUS.

METHODS

Patients and study design

This study was a multicenter retrospective study including Wuhan Union Hospital and First Affiliated Hospital of Shihezi University. Consecutive patients with obstructive jaundice from a solid pancreatic head lesion who underwent EUS-FNA between January 2018 and December 2021 were identified using the internal endoscopy database. Pancreatic cystic lesions and lesions located in other pancreatic regions were excluded.

As for the indications of pancreatic duct stent placement, except for patients with pancreatitis or abdominal pain, prophylactic pancreatic stenting is recommended in selected patients at high risk of post-ERCP pancreatitis according to European Society of Gastrointestinal Endoscopy (ESGE) guideline, including inadvertent guidewire insertion more than once or difficult intubation.[10]

Demographic data including age and sex were obtained from each patient. The level of serum total bilirubin at first presentation of jaundice was recorded. To describe the pancreatic lesion, all radiographic examinations were reviewed including computed tomography, magnetic resonance imaging, and ultrasound. In order to obtain the needle type, the number of needle passes and the size of the lesions, and the presence of the stents, ERCP and EUS-FNA reports were searched and recorded. The final diagnosis is based on comprehensive evaluation, including imaging examinations, additional biopsy samples such as surgically resected specimen and other tissue acquisition from endoscopic or percutaneous modalities, or follow-up for at least 12 months. Positive biopsy results, disease progression, distant metastasis, or cancer-related death were defined as the evidence to prove malignance. If there is no significant change or enlargement of the masses, or no distant metastasis at least 12 months of follow-up, the masses are defined to be benign.

Tissue acquisition by EUS-FNA was done with the Echotip Ultra needles (Cook Endoscopy Inc., Limerick, ME), using linear echoendoscopes (GF-UCT 260; Olympus, Tokyo, Japan). All EUS-FNA procedures were performed by the same experienced endoscopist who has performed more than 1000 EUS procedures in his career and at least 50 EUS-FNA procedures per month. The stroke length was defined as the length of the mass measured by EUS. After the needle reached the target region, the stylet was removed, and suction was applied using a 5-mL syringe. Twenty to-and-fro movements and fanning method were employed for each puncture during the EUS-TA procedure. ROSE was not used to evaluate the results, and all pancreatic tissue samples were firstly fixed in formalin, then embedded into paraffin. Patients were given moderate sedation under the guidance of the endoscopist in GI center of the hospital.

The study was approved by the Medical Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology (ethical approval number: 2022-S218), and the Medical Ethics Committee of The First Affiliated Hospital of Shihezi University (ethical approval number: KJX2022-007-01).

Definitions

Biliary-pancreatic double stents were proved by presence at the time of EUS. Specimens obtained by EUS-FNA were classified as malignant, benign, and atypical. Pancreatic malignancy found by pathology includes adenocarcinoma, lymphoma, pancreatic neuroendocrine tumor, and metastatic lesions to the pancreas. The diagnostic accuracy of EUS-FNA was defined by the histologic results of the specimen obtained from the pancreatic head mass. Biliary stent was defined by presence of plastic or metal biliary stent at the time of the EUS-FNA.

Statistical analysis

Diagnostic yield of EUS-TA including accuracy, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) was calculated according to the pathologic results. Continuous variables were described as mean and standard deviation or median (range) values, and categorical values were expressed as frequency with 95% confidence intervals (CIs).

Accuracy was defined as ratio between sum of true positive and true negative values divided by the total number of lesions and was

calculated with 95% CI. Sensitivity and specificity of EUS-FNA for malignancy were calculated with 95% CI. For comparing outcomes of patients with or without biliary-pancreatic double stents, the chi-squared test or *t* test was used. Factors with a *P* value <0.2 on the univariate analyses were entered stepwise into a multivariate logistic regression model to derive their adjusted odds ratios (ORs) and 95% CI. A *P* value < 0.05 was considered statistically significant. Statistical analyses were performed with IBM SPSS version 23.0 and MedCalc.

RESULTS

Patient characteristics

The study consisted of 42 patients who underwent biliary and pancreatic double-stent placement and 50 patients who did not receive any stent placement. All patients were consecutive and with pancreatic lesions causing biliary duct obstruction. The overall patient population was 92, with a mean age of 60.3 ± 8.4 years, and all of them underwent EUS-TA (56.5% male). All pancreatic stents are plastic stents, whereas bile duct stents can be either plastic or metal stents. No stents were removed or replaced before EUS examination. As shown in Table 1, the mean lesion size was 32.4 ± 7.2 mm, demonstrating that there was no difference on the basis of lesion size. In terms of stents placement, the total bilirubin level in the stent group was significantly higher than the no-stent group (271.1 ± 107.6 *vs.* 160.1 ± 71.3 μmol/L, *P*<0.001). Overall, the needle size was used more frequently as the 22G (90.2%) owing to the distribution of the pancreatic lesion, followed by the 19G (9.8%), and a mean of 2 needle passes per patient was performed. There was no significant difference in the needle type and the number of needle passes between the 2 groups.

Findings at EUS-TA

The study found that the puncture time taken by EUS-TA was significantly longer in the stent group than the no-stent group (19 *vs.* 15 minutes, *P* < 0.001). Table 2 revealed diagnostic yield of EUS-TA in patients with double stents and without any stents. According to the pathologic results, the overall accuracy, sensitivity, specificity, PPV, and NPV were 92.4% (95% CI: 85%–96.9%), 91.8% (95% CI: 83.8%–96.6%), 100% (95% CI: 59%–100%), and 100% and 50% (95% CI: 33.0%–67.0%), respectively. No significant differences were observed in accuracy (90.5% *vs.* 94%), sensitivity (89.5% *vs.* 93.6%), specificity (100% *vs.* 100%), PPV (100% *vs.* 100%), and NPV (50% *vs.* 50%), respectively. Concerning the complications after EUS-TA, the overall incidence of complication rate was low (5.4%), with 2 cases of pancreatitis and 3 cases of bleeding, and there was no significant difference between the 2 groups. Both patients with pancreatitis were graded as mild, and the symptoms were relieved with 72 hours. The clinical manifestation of patients with bleeding included melena and decreasing level of hemoglobin, and all of them were self-limited with 48 hours.

The final diagnosis of the pancreatic lesions is shown in Table 1. The most common diagnosis was adenocarcinoma (81.5%), followed by autoimmune pancreatitis (6.5%), neuroendocrine carcinoma (1.1%), chronic pancreatitis (1.1%), metastatic cancer (1.1%), lymphoma (1.1%), and the other malignant diseases (7.6%).

Factors associated with diagnostic yield of EUS-TA

On multivariate logistic regression analysis shown in Table 3, the diagnostic yield was not influenced by the existence of the stents, sex, age, the level of serum total bilirubin, and the needle type in

Table 1

Baseline patients' characteristics

Patients' Characteristics	Stent (*n* = 42)	No Stent (*n* = 50)	Overall (*n* = 92)	*P*
Male sex, *n* (%)	23 (54.8)	29 (58)	52 (56.5)	0.755
Age, y (mean ± SD)	61.3 ± 6.9	59.5 ± 9.5	60.3 ± 8.4	0.301
Lesion size, mm (mean ± SD)	31.9 ± 7.2	32.8 ± 7.2	32.4 ± 7.2	0.547
Total bilirubin, μmol/L (mean ± SD)	271.1 ± 107.6	160.1 ± 71.3	210.8 ± 105.1	<0.001*
Needle type, *n* (%)				0.088
22G	38 (90.5)	45 (90)	83 (90.2)	
19G	4 (9.5)	5 (10)	9 (9.8)	
N. of passes median (IQR)	2 (2–2)	2 (2–2)	2 (2–2)	1
Puncture time, min median (IQR)	19 (17–22.3)	15 (13–18)	17 (14.5–20)	<0.001*
Type of biliary stent, *n* (%)				
Plastic	20 (47.6)			
Metallic	22 (52.4)			
Final diagnosis, *n* (%)				
Adenocarcinoma	33 (78.6)	42 (84)	75 (81.5)	
Neuroendocrine carcinoma	0	1 (2)	1 (1.1)	
Chronic pancreatitis	1 (2.4)	0	1 (1.1)	
Autoimmune pancreatitis	3 (7.1)	3 (6)	6 (6.5)	
Metastatic cancer	1 (2.4)	0	1 (1.1)	
Lymphoma	0	1 (2)	1 (1.1)	
Other malignant diseases	4 (9.5)	3 (6)	7 (7.6)	

Continuous data are expressed as mean ± SD or median and IQR. Categorical data are expressed as number (percentage).

*Statistical significance.

IQR: interquartile range; SD: standard deviation; Other malignant diseases

Table 2

Primary clinical outcomes

Characteristic	Stent (*n* = 42)	No Stent (*n* = 50)	Overall (*n* = 92)	*P*
Accuracy (95% CI)	90.5 (77.4–97.3)	94 (83.5–98.7)	92.4 (85–96.9)	0.81
Sensitivity (95% CI)	89.5 (75.2–97.1)	93.6 (82.5–98.7)	91.8 (83.8–96.6)	0.695
Specificity (95% CI)	100 (39.8–100)	100 (29.2–100)	100 (59–100)	
PPV, percentage (95% CI)	100	100	100	
NPV, percentage (95% CI)	50 (28.4–71.6)	50 (25.1–74.9)	50 (33–67)	
Complications, *n* (%)	3 (7.1)	2 (4.0)	5 (5.4)	0.841
Pancreatitis	1 (2.4)	1 (2)	2 (2.2)	
Bleeding (self-limited)	2 (4.8)	1 (2)	3 (3.3)	
Perforation	0 (0)	0 (0)	0 (0)	

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

patients with double stents or without stent. Patients with larger lesions (OR = 1.600, 95% CI: 1.124–2.277) and those who required more passes had a higher diagnostic yield (OR = 9.376, 95% CI: 1.356–64.819) in both groups.

DISCUSSION

The role and the sequence of EUS-TA and ERCP in the management of solid pancreatic head lesions are controversial.[11] It is acknowledged that pathological diagnosis and biliary drainage are essential for patients staged with unresectable or metastatic cancer before the further treatment such as chemoradiotherapy.[12] Although the Canadian Society for Endoscopic Ultrasound states that EUS-TA should precede ERCP,[13] stent placement is often performed earlier than EUS-TA considering that the depression of the biliary duct can be more urgent and the wider availability of ERCP. On the other hand, it is stated by the international consensus that ERCP for relieving the obstruction of distal biliary strictures has no influence on the outcomes of EUS-TA.[14]

Crinò et al. compared the diagnostic sensitivity and accuracy of EUS-FNB in patients with and without biliary stent and found that the sensitivity and accuracy were significantly higher in patients without biliary stent than in those with stent (91.9% and 92.1% *vs.* 85.9% and 86.4%, $P = 0.010$), demonstrating that a biliary stent negatively impacted the diagnostic accuracy of EUS-FNB, especially in the case of small tumors.[15] Meanwhile, the other 3 studies revealed that there was no significant difference in diagnostic yield of EUS-FNA and EUS-FNB for pancreatic head lesions in patients with a biliary plastic stent or self-expandable metal stents (SEMS).[16–18]

In contrary to those results, a study including 180 patients conducted by Kim et al. reported a lower accuracy of EUS-FNA in the existence of a biliary stent, regardless of its type.[19] In a study with a large sample of 631 individuals, the presence of SEMS was related to a higher rate of inconclusive procedures including either EUS-FNA or EUS-FNB.[8] Consistently, a recent meta-analysis demonstrated evidence of a greater impact of SEMSs on the diagnostic accuracy of EUS-TA, possibly owing to a larger caliber of SEMSs as well as the acoustic shadowing under ultrasound.[7]

To date, most studied on the diagnostic yield of EUS-FNA claimed no significant difference between patients with or without a biliary stent. However, it remains more controversial in whether biliary stents significantly reduced the diagnostic accuracy of EUS-FNB, probably caused by the already low accuracy of EUS-FNA.[8,20] Because the evidence on whether the presence of the biliary stents influences the diagnostic yield of EUS-TA is limited, there is much less on the biliary-pancreatic double stents. Placement of a pancreatic duct stent is widely used for management of various malignant and benign pancreatic diseases, relieving the pain of chronic pancreatitis, preventing post-ERCP pancreatitis and treating pancreatic cancer.[21] Considering another more stent placement than a single biliary stent, biliary-pancreatic double stents could have more impacts on the accuracy of EUS-TA in our hypothesis.

Aiming to access the diagnostic yield of EUS-TA in patients with solid pancreatic lesions with or without biliary-pancreatic double stents, we performed a multicenter retrospective study including 92 patients with obstructive jaundice causing by solid pancreatic head lesions and compare the outcomes of the stent and the no-stent groups. Also, multivariate analysis was performed to find

Table 3

Univariate and multivariate logistic regression analyses of factors associated with diagnostic accuracy in 92 patients who underwent EUS-guided fine-needle aspiration

	Univariate Analysis			Multivariate Analysis		
Study Variable	OR	95% CI	*P*	OR	95% CI	*P*
Stent	1.649	(0.348–7.823)	0.529			
Male sex	2.021	(0.371–11.005)	0.416			
Lesion size (mm)	1.559	(1.161–2.094)	0.003*	1.600	(1.124–2.277)	0.009*
Total bilirubin (μmol/L)	0.998	(0.991–1.004)	0.484			
Needle type (22G *vs.* 19G)	1.171	(0.555–2.469)	0.679			
Number of passes	15.802	(2.936–85.040)	0.001*	9.376	(1.356–64.819)	0.023*
Puncture time (min)	1.168	(0.938–1.454)	0.166			

*Statistical significance.

CI: confidence interval; OR: odds ratio.

the factors associated with diagnostic yield of EUS-TA except for the presence of stents. Our study is the first research on the impact of biliary-pancreatic double stents among those patients.

Comparing the diagnostic yield of EUS-TA among patients without biliary-pancreatic double stents, no significant difference was found between accuracy, sensitivity, specificity, PPV, and NPV, but the duration of puncture operation was found to be longer in the stent group. It may be explained by influence of the shadows or reverberation caused by the stents, taking the endoscopist longer time to recognize the masses. Also, the study reported that larger lesions and more number of passes were associated with higher diagnostic yield, which was consistent with previous studies on the factors related to the accuracy of EUA-TA.[22]

Our findings have several meaningful clinical implications. We demonstrated that the placement of biliary-pancreatic double stents could be performed by ERCP preceding EUS-TA, and there was no impairment on the accuracy and the specificity. For patients with solid pancreatic lesions, pancreatic duct obstruction always leads to poor pancreatic juice outflow, resulting in severe abdominal pain, acute pancreatitis, decreased quality of life, and shortened survival period.[23,24] In view of this, when simultaneous obstruction of the biliary and pancreatic ducts occurs, it is best to perform double-stent drainage of the biliary and pancreatic ducts to quickly reduce the pressure in both ducts and achieve ideal therapeutic results.[25] The study provided evidence on the sequence of EUS-TA and ERCP, stating less impact we need to concern about.

Our study has several limitations. First, considering the nonrandomized study design, there may be biases that affect histological accuracy between patients with or without biliary-pancreatic double stents prior to EUS examination. Second, this is a retrospective study based on collected database, so there may be deviations in data collection such as the size of the needle used. However, it should be noted that there were no significant differences between the 2 comparison groups in baseline characteristics of patients underwent EUS-TA.

CONCLUSION

To conclude, our study revealed that there is no impact on the diagnostic yield of EUS-TA, regardless of the sequence of EUS and stents placement. Additionally, we found no difference in the overall rate of EUS-TA–related complications. Therefore, EUS-TA does not necessarily need to be performed prior to the placement of biliary-pancreatic stents by ERCP.

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Ethical Approval

The study (EUSJ-23-027) was conducted according to the principles and the recommendations of the 2013 Declaration of Helsinki. The study was approved by the Medical Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology (ethical approval number: 2022-S218), and the Medical Ethics Committee of The First Affiliated Hospital of Shihezi University (ethical approval number: KJX2022-007-01). We ensured that the patients had not opposed the use of their medical records for research.

Conflicts of Interest

The authors declare no conflicts of interest for this article.

Author Contributions

Guochen Shang and Zhen Ding designed the study. Guochen Shang and Qi He collected medical records data, analyzed the data, and drafted the manuscript. Xianwen Guo and Chaoqun Han contributed to data collection. Zhen Ding, Weigang Chen, and Rong Lin supervised the study and revised the manuscript.

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