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ORIGINAL ARTICLE

Diagnostic accuracy of ultrasonography-guided percutaneous core needle biopsies of pancreatic lesions

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Abstract

Objective: This study evaluates the diagnostic accuracy and complications of ultrasound-guided percutaneous core needle biopsies for solid pancreatic masses.

Methods: Between January 2009 and June 2013 A total of 60 biopsy procedures were performed in 53 patients (30 males, 23 females) and 11 specimens were benign and 45 specimens were malignant according to histopathologic results.

Results: Sensitivity was 84.9%, specificity was 100% and diagnostic accuracy was 85.7%. No complications were observed during or after biopsy procedures

Conclusion: This study shows that ultrasound-guided biopsy is a reliable, time- and cost-saving method with a very low complication rate, high diagnostic accuracy and sensitivity, but benign biopsy findings should not be used to exclude the presence of pancreatic malignancy and biopsy should be repeated if there is a high clinical suspicion of malignancy.

Keywords: US; pancreatic solid mass; core needle biopsy

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Introduction

Pancreatic cancers are more common in men than in women and the incidence is gradually increasing. The annual incidence in our country is 4.1/100.000 in men and 3.5/100.000 in women [1, 2, 3]. Pancreatic cancers constitute approximately 20% of all gastrointestinal cancers and the most common type is solid infiltrative pancreatic ductal adenocarcinoma [2, 4].

Untreated pancreatic cancer has a 5-year survival rate of only 6%. [5]. Interventional techniques used in conjunction with imaging methods for the diagnosis and treatment of lesions are successfully applied today. Core needle biopsies were first performed by Parker et al. in 1993 [6]. In addition to the benign-malignant differentiation, the histopathological analysis of tissue samples obtained by core needle biopsy methods can determine the tumor type and tumor subtype, histological grade, hormone receptor status that can guide oncological treatment. Compared to other interventional diagnostic methods, percutaneous biopsies are more reliable and more easily tolerated by patients. It can be performed under ultrasonography (USG), Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) guidance. The choice of guidance method usually depends on the localization of the lesion, its size, its relationship with adjacent organs and vascular structures, and the personal preference of the radiologist [4,7,8]. In patients with pancreatic masses, histopathologic confirmation is usually required in patients with inoperable tumors or in patients who are medically unsuitable for surgery. The National Comprehensive Cancer Network (NCCN) strongly recommends that all patients with resectable pancreatic masses should have confirmation of the histopathologic diagnosis prior to medical therapy or at least one repeat biopsy in patients with benign biopsy results [8].

The aim of this study was to evaluate the results and complications of US-guided percutaneous core needle biopsy of solid mass lesions of the pancreas performed at our university hospital between January 2009 and June 2013.

Material and Methods

Patients

We retrospectively evaluated the results and complications of US-guided percutaneous cutting organ biopsy of solid mass lesions of the pancreas between January 2009 and June 2013 in our university hospital. A total of 53 patients, 30 males and 23 females with a mean age of 66 years, were included in the evaluation. Patients who did not have adequate clinical and radiologic follow-up, whose definitive clinical diagnosis could not be determined, whose biopsy did not provide sufficient information for histopathologic diagnosis, and who did not undergo repeat biopsy were excluded.

Imaging protocol and Biopsy Procedure

All patients underwent at least one of CT and MRI examinations before biopsy. The location of the mass lesions in the pancreas (head, body, tail) and their dimensions in the longest and shortest axis were evaluated with CT and/or MRI images.

All biopsy procedures were performed by an interventional radiologist with 15 years of experience using a General Electric Logiq 5 Pro (Milwaukee WI, USA), 3.5 MHz probe and 20G fully automatic cutting biopsy needles. Complete blood count and bleeding parameters (INR, PTZ, aPTT) were checked in all patients before biopsy. All patients were informed about the biopsy method, possible complications and treatment methods and informed consent was obtained.

Before biopsy, the appearance characteristics of the lesion (solid-cystic), its relationship with adjacent structures, especially with vascular structures using color Doppler technique were routinely evaluated with US in all patients. Biopsy procedures were performed in the supine position, avoiding the transverse colon, small intestines, liver, spleen and vascular structures, especially by determining the shortest distance to reach the lesion and usually using the trans-gastric approach with the “free hand technique”.

The sizes of the tissue samples taken after biopsy were measured by the pathology department, these measurements were obtained from the pathology reports, and the sample sizes were divided into two groups as below 1 cm and 1 cm and above, and the results and their relationship with the final clinical diagnoses were analyzed. In each biopsy procedure, the number of needle insertions in the same session was divided into two groups as 1 and 2 times, and the results, complications and the relationship with the final clinical diagnoses were also evaluated.

After biopsy procedure, clinical follow-up information (examination findings, laboratory results and imaging techniques) of all patients were checked for early and late possible complications and no biopsy-related complication was found in any patient.

Statistical Analysis

Results were evaluated by Student's t-test, Chi-square test with Yates correction and Fisher's exact Chi-square test. Sensitivity was calculated using the formulas TP/TP+FN, specificity TN/TN+FP, positive predictive value TP/TP+FP, negative predictive value TN/TN+FN (TP; true positive, FP; false positive, TN; true negative, FN; false negative). $P<0.05$ was considered statistically significant. Statistical procedures were performed using SPSS PC program.

Results

Histopathologic analysis revealed that 29 of 30 male patients were malignant and 1 benign, while 22 of 23 female patients were malignant and 1 benign. Malignancy rate was 96.7% in males and 95.6% in females and benignity rate was 3.3% in males and 4.4% in females. When benign and malignant final clinical diagnoses were compared with the gender of the patients, no statistically significant difference was found between benign and malignant results between males and females (p: 0.698).

When the distribution of the final clinical diagnoses according to the age of the cases was analyzed, chronic pancreatitis was seen in two cases with ages 66 and 36 pancreatic adenocarcinoma was seen in 48 cases with ages ranging between 45 and 87, Pancreatic non-adenocarcinoma tumors were seen in a total of 3 patients, 1 female and 2 male, and the diagnosis of these three patients was malignant neuroendocrine tumor and the ages were 50, 65, 65, respectively. When the age distribution of the final clinical diagnoses was analyzed, no statistically significant correlation was found between the age distribution of the cases and the final clinical diagnoses (p: 0.750).

The mass lesions were divided according to the location of the pancreatic head, body and tail. 26 of the 53 masses were located only in the pancreatic head (49.1%), 13 were located only in the pancreatic body (4.5%) and 1 was located only in the tail (1.9%). 13 masses (4.5%) were localized in two regions, body-tail and body-head, of which 7 were localized in body-tail and 6 were localized in body-head. 3 (60.4%) of the masses were located in the head, 6 (49.1%) in the body and 8 (15.1%) in the tail. Pancreatic adenocarcinomas were most commonly localized in the head of the pancreas in our patients. In 3 patients diagnosed with malignant neuroendocrine tumors, 1 of the masses was located in the body and tail, 1 in the head and 1 in the body. One of the chronic pancreatitis cases was located in the pancreatic head and the other in the body.

Patients Who Underwent Core Needle Biopsy Twice	Histopathological results of the 1st biopsy			Histopathological results of the 2nd biopsy			Definitive Clinical Diagnosis	
	Insufficient	Benign	Malign	Insufficient	Benign	Malign	Benign	Malign
1	+	-	-	-	-	+	-	+
2	-	+	-	-	+	-	+	-
3	-	+	-	-	-		-	+
4	-	+	-	-	-	+	-	+
5	+	-	-	+	-	-	-	+
6	+	-	-	-	+	-	-	+
7	-	+	-	-	-	+	-	+
Total(n)	3	4	0	1	2	4	1	6

Table 1: Comparison of histopathological results with definitive clinical diagnoses in patients who underwent a total of 2 percutaneous core needle biopsies.

Definitive Diagnosis	Results of 60 core needle biopsies performed once or twice							
	TP	TN	FP	FN	PPV	Sensitivity	Specificity	Diagnostic accuracy
Chronic Pancreatitis (Benign)	3 (5.3%)	45 (80.3%)	8 (14.4%)	0	27.3%	100%	84.9%	85.7%
Adenocarcinoma	43 (81.1%)	3 (5.7%)	0	7 (13.2%)	100%	86%	100%	86.8%
Neuroendocrine Tumor	2 (66.6%)	0	0	1 (33.4%)	100%	66.6%	100%	66.6%
Malign (Total)	45	3	0	8	100%	84.9%	100%	85.7%

Table 2: Distribution of TP, FP, TN and FN results when comparing the results of 60 percutaneous needle biopsies performed once and twice with the definitive clinical diagnoses.

Biopsy Specimen Size	Biopsy Result					
	Insufficient	True Positive	True Negative	False Negative	Sensitivity	Diagnostic Accuracy
Under 1 cm	4 (18.2%)	11 (50%)	2 (9.1%)	5 (22.7%)	68.7%	72.2%
Over 1 cm	0	34 (89.5%)	1 (2.6%)	3 (7.9%)	91.9%	92.1%
Total (n=60)	4 (6.7%)	45 (75%)	3 (5%)	8 (13.3%)	84.9%	85.7%

Table 3: Comparison of biopsy results with definitive clinical diagnoses in US-guided percutaneous core needle biopsies with a fragment size of under 1 cm and 1 cm or more.

Biopsy Count (n)	Sensitivity (%)	Specificity (%)	Diagnostic Accuracy (%)	Guide Method	Needle Size (G)	Researchers
212	86	100	86	US	21	Matsubara et al. (2008)
142	90.9	-	92.6	US	-	Jennings et al. (1989)
100	90	-	-	US	-	Karlson et al. (1996)
92	92.5	100	93.3	US	18	Paulsen et al. (2006)
50	90.4	-	92	US	-	Elvin et al. (1990)
60	84.9	100	85.7	US	20	Our Study (2013)

Table 4: Percutaneous core needle biopsies of pancreatic masses, sensitivity, specificity, diagnostic accuracy, guide method, needle size, researchers.

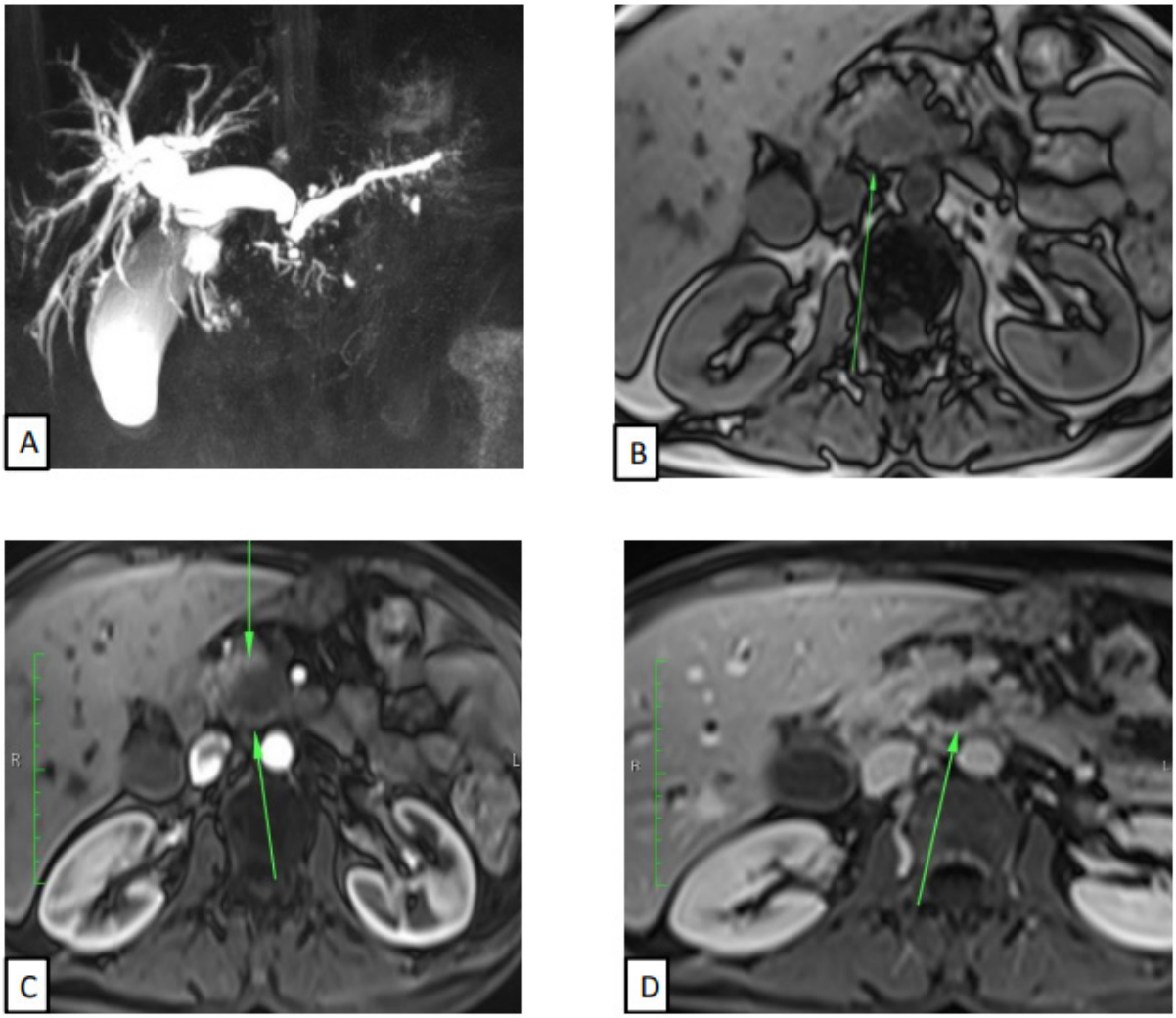

Figure: 61-year-old male patient. On MRI examination, MRCP series (A) showed dilatation of the biliary tract and pancreatic duct, which terminated abruptly at the level of the pancreatic head, and T1-weighted out-of-phase in the area corresponding to this localisation. There is a mass lesion (arrows) which is hypointense compared to the muscles in the images (B), doesn't show a significant contrast enhancement in the arterial phase images after IVCM (C), but in the late phase images (D), there is a circumferentially contrasted mass lesion (arrows) except for the central non-contrasting necrotic area. Intraoperative biopsy was performed and the result was evaluated as chronic pancreatitis. Afterwards, USG-guided core needle biopsy was performed and resulted as adenocarcinoma. As a result of the follow-up clinical findings and imaging examinations, progression was detected in the findings accompanied by liver metastasis. The clinical diagnosis of the patient is pancreatic adenocarcinoma.

Seven patients underwent biopsy twice. The comparison of the results of the 1st and 2nd biopsies performed in these patients is summarized in **table 1.**

In our study, repeat biopsies were performed in 20 patients with inconclusive histopathologic results or with histopathologic results, imaging and clinical discrepancies, such as cases with benign biopsy results but clinical and imaging findings strongly suggestive of malignancy, using percutaneous Fine Needle Aspiration (FNA) biopsy and core needle biopsy, intraoperative biopsy and 1 case of metastatic liver mass core needle biopsy. The results of the 1st percutaneous core needle biopsy were 4 inadequate, 7 true positive, 8 false negative, 1 true negative, and the results of repeat biopsy were 1 inadequate, 14 true positive, 4 false negative, 1 true negative.

In cases with repeat biopsy, the histopathologic result of the first biopsy was inadequate in 4 cases (20%), false

negative in 8 cases (40%), inadequate in 1 case (5%), false negative in 4 cases (20%) with repeat biopsies, and the sensitivity increased from 46.7% to 77.8% and the diagnostic accuracy rate increased from 50% to 78.9%.

In a total of 46 patients who underwent percutaneous core needle biopsy once, histopathologic evaluations resulted as true negative in 1 case, false negative in 4 cases and true positive in 41 cases. False positive results were not obtained in any case.

In 53 patients, the total number of percutaneous core needle biopsy procedures was 60, including those performed once and twice in 7 patients. In these 60 biopsy procedures, the sensitivity, specificity, positive predictive value, positive predictive value and diagnostic accuracy of US-guided percutaneous core needle biopsy were 84.9%, 100%, 100% and 85.7%, respectively **(Table 2).**

In our study, the sizes of tissue samples obtained after core needle biopsy were measured by the pathology department and these measurements were obtained from the pathology reports. In a total of 60 US-guided percutaneous core needle biopsies, 4 (18.2%) of the procedures with fragment size less than 1 cm resulted in insufficient specimens and the false negative rate was 5 (22.7%). None of the 38 biopsy procedures with a fragment size of 1 cm or more resulted in insufficient specimens and the false negative rate was 3 (7.9%). In addition, the sensitivity and diagnostic accuracy of percutaneous core needle biopsies with a fragment size of 1 cm or more were higher than those with a fragment size of less than 1 cm, with a statistically significant difference ($p<0.05$) **(Table 3).**

Discussion

In the histocytopathologic diagnosis of pancreatic masses, methods such as US or CT-guided percutaneous FNAB or core needle biopsy, EUS-guided FNAB or core needle biopsy, and intraoperative biopsy are used. Intraoperative FNAB has been used in pancreatic masses since the 1960s [9] and core needle biopsy since the 1970s [10]. Later, US, CT, MRI and endoscopic ultrasonography (EUS) imaging techniques were used to evaluate and characterize pancreatic masses. Most importantly, the use of all these methods as a guide to needle biopsies has been shown to prevent the morbidity, mortality and high cost of surgical procedures performed only for tissue sampling for cytohistopathologic diagnosis [11]. Compared to other interventional diagnostic methods, percutaneous biopsies have become more reliable and easier for patients to tolerate. Among these guidance methods, the advantages of US are that it can be applied rapidly, it is inexpensive and practical, the needle can be visualized simultaneously and can be advanced in the desired direction [4,7,8]. In previous studies on percutaneous biopsies of the pancreas, it has been shown that the stomach, spleen, colon and small intestine can be crossed to reach the target lesion during the procedure without any complications, and as a general approach, it has been accepted to perform the biopsy procedure using the shortest route to reach the target lesion as far away from vascular structures as possible [7,8]. The current practice for core needle biopsies of the pancreas is to be performed in patients with radiologically detected metastatic disease thought to originate from the pancreas or in patients with an resectable pancreatic mass. Thus, biopsy procedures can prevent unnecessary laparotomies, identify malignancies other than primary pancreatic tumors or different subtypes of pancreatic tumors, obtain benign results mimicking malignancy and, as a result of all these, decide on the most appropriate treatment method for the patient. Moreover, due to the relatively advanced tumor burden, unrecognized neuroendocrine tumors can be diagnosed, especially in patients with poor systematic evidence of malignancy. Pancreatic neuroendocrine tumors can be biopsied even in the absence of known metastases. The prognosis for survival in the presence of metastases in these tumors is promising and long-term treatment outcomes can be monitored with repeat core needle biopsies. Furthermore, samples from these biopsies can be used to determine individualized treatment modalities, including both conventional cytotoxic regimens and biotherapy [7].

The results of US-guided percutaneous needle biopsy in patients with pancreatic masses by different researchers and our study are shown in Table 4. In our study, the sensitivity and diagnostic accuracy of US-guided percutaneous needle biopsies performed 60 times in 53 patients were 84.9% and 85.7%, respectively, and our results were generally consistent with the results reported in the literatüre. False negative results are associated with inadequate sampling of the target tissue, misplacement of the needle, which is more frequently seen in small masses, and hard desmoplastic reaction around pancreatic adenocarcinoma, and its clinical effect is best demonstrated by negative prediktif value (NPV) [13].

In the study by Stasi et al., US-guided needle biopsy results led to a diagnosis in 86% of cases, with false negative results in 14% of cases including inadequate sampling. The reason for these results was thought to be the presence of fibrotic or necrotic areas around or within the tumor, small target lesion size, and misdiagnosis in well-differentiated forms. It is generally agreed that false negative results can be reduced by more aggressive methods (repeat biopsies) which may increase the risk of complications and that negative needle biopsy results should be carefully evaluated [7,14].

In the study by Paulsen et al. the NPV was 60%, which is considered unacceptably low to safely exclude pancreatic malignancies. Paulsen et al., along with other investigators, agreed that in cases where FNA or core needle biopsies are negative, these results should be carefully reviewed together with follow-up clinical and imaging findings [13].. The false negative results we obtained in our study and the change of these results in favor of malignancy with repeat biopsies or follow-up clinical and imaging findings support this view.

In their study, Stasi et al. obtained excellent results in the differentiation of cases including pancreatic metastasis, non-Hodgkin lymphoma and abscesses when they considered the effectiveness of US-guided percutaneous biopsy methods in the differential diagnosis of different pancreatic pathologies (100%). In their study, they prevented unnecessary surgical applications by providing histopathological diagnoses in chronic pancreatitis with mass appearance, anresectable pancreatic cancers, normal pancreatic tissue with pseudo-mass appearance and metastatic tumors of the pancreas diagnosed by US-guided needle biopsy for the first time [14].

There is no data in the literature regarding the size of fragments obtained after US-guided core needle biopsy procedures performed on solid mass lesions of the pancreas and the study results. As summarized in Table 3 in our study, there was a significant difference in terms of intervals and diagnostic accuracy rate in distinguishing benign and malignant lesions in percutaneous core needle biopsies performed on solid mass lesions of the pancreas under USG guidance, higher performance and capacity in procedures with fragment sizes of 1 cm and above compared to procedures with fragment sizes of less than 1 cm ($p<0.05$)

Major complications of pancreatic biopsies include hemorrhage, tumor seeding along the needle tract and pancreatitis, while minor complications include transient fever, nausea-vomiting and vaso-vagal reaction after biopsy. Although acute pancreatitis after biopsy is extremely rare, when it occurs, it can be quite serious and sometimes fatal, and this can be seen as the main reason why biopsy procedures are not widely used. Studies have shown that the rate of acute pancreatitis after biopsy varies between 0-1.7% [8,15].

In patients with anresectable pancreatic cancer, the tumor is usually large in size and located just below the surface of the pancreas. In these cases, a piece of the tumor can be removed percutaneously without penetrating the normal pancreatic tissue, which explains the idea that the development of biopsy-related acute pancreatitis is unlikely in such lesions [16]. Biopsy of normal pancreatic tissue increases the risk of developing acute pancreatitis, and 5 of 7 patients who underwent similar biopsy in the literature died after biopsy [14,16]. In the study by Matsubara et al. no clinical or microscopic cases of infection were detected in relation to biopsy; however, transient fever (4.4%) was observed in 1 case after biopsy, they also checked serum amylase levels in these cases, and amylase levels were found above the upper limit in two cases. Therefore, it was thought that transient fever after biopsy may be the initial sign of acute pancreatitis that may develop due to a potentially life-threatening biopsy procedure [8].

Although the frequency of peritoneal tumor dissemination associated with pancreatic biopsies is unknown, it is not thought to have any impact on the invariably poor prognosis of resectable pancreatic cancers. On the other hand, the practice of preoperative percutaneous pancreatic biopsy in patients with resectable pancreatic cancer is controversial because some studies suggest a high incidence (16.3-75%) of peritoneal tumor dissemination associated with percutaneous biopsy procedures [8,17]. The NCCN has reported that malignancy does not need to be proven by biopsy before surgical resection and that non-diagnostic sampling should not be allowed to cause delays in surgery, which is the only curative treatment for pancreatic cancer [8,18]. In the literature, tumor invasion along the needle tract was reported in 8 cases after CT or US guided percutaneous needle biopsy [14,19]. Studies by Civardi et al. and Fornari et al. showed that the risk of tumor invasion may be related to the number of needle accesses, with a higher number of needle accesses associated with a higher risk of tumor invasion [20,21].

Our study had some limitations. The most important limitation is the non-randomized retrospective design of our study. The second limitation is the inadequate laparotomy and autopsy practices regarding the accuracy

of definitive clinical diagnoses, which are considered the gold standard. Finally, the histopathologic examination of the biopsy materials was evaluated by pathologists with different experience.

Considering the previous studies on US-guided percutaneous needle biopsies of pancreatic masses, the sensitivity in exocrine tumors of the pancreas and peripancreatic tumors was found to be around 91%, while in our study, our sensitivity rate was slightly lower at 86%. No false positive results were obtained in the studies including our study. All these results support the feasibility and reliability of US-guided percutaneous core needle biopsy for the evaluation of pancreatic malignancies. It has been reported that if a benign lesion is detected in tissue sampling, these results should be regarded with suspicion, should never be used to exclude malignant or metastatic pancreatic lesions, and the biopsy should be repeated [7]. In the literature, the rate of malignancy detection in repeated biopsies due to non-specific or benign findings varies between 35-45% [14,22].

Conclusion

In patients with inoperable solid pancreatic mass lesions, if visualization of the lesion is sufficient, the use of percutaneous core needle biopsies under US guidance is a sensitive, safe, and highly accurate biopsy method. Benign biopsy findings should not be used to exclude the presence of pancreatic malignancy, and if there is a high clinical suspicion of malignancy, the biopsy should be repeated. Since it increases the sensitivity and diagnostic accuracy in distinguishing between malignancy and benign and reduces the rate of inadequate sampling, care should be taken to ensure that the sample size is 1 cm or larger, and a repeat biopsy should be performed in the same session, whenever possible, to save time and money and to prevent delays in diagnosis and treatment.

Conflict of interest

The authors declare no competing interests. The authors declare they have no financial interests.

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