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Evaluation of percutaneous ultrasound-guided biopsies of solid mass lesions of the pancreas: a center's 10-year experience

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ABSTRACT

Objective: To assess the efficacy and complication rates of percutaneous ultrasound (US)-guided pancreatic mass biopsy and to determine if location of the mass or method of biopsy affects efficacy.
Methods: Imaging, pathology, and clinical records of all patients undergoing percutaneous US-guided pancreatic mass sampling from January 2001 until November 2011 were reviewed. Of 88 pancreatic masses, 13 underwent fine needle aspiration (FNA) only, 60 underwent core needle biopsy only, and 15 underwent both. Diagnostic rate, sensitivity, specificity, accuracy, and positive predictive value and negative predictive value (NPV) based on location of the mass (head/neck vs. body/tail) and method of biopsy (core vs. FNA vs. combined) were determined. The final diagnosis was determined on the basis of follow-up imaging, clinical course, and/or surgical pathology. Complications were assessed by reviewing clinical notes and postprocedural imaging.
Results: The overall diagnostic rate, sensitivity, accuracy, and NPV of all 88 biopsies were 94%, 93%, 93%, and 57%, respectively. Five samples were nondiagnostic and considered false negatives. There were no false-positive biopsy results. No significant difference was observed in the diagnostic rate, sensitivity, accuracy, and NPV between core biopsies, FNAs, and combined core and FNA biopsies. Furthermore, no significant difference was found between head/neck and body/tail samplings. In 96.7% (85/88) of the cases, the procedure was uneventful. There were no major complications.
Conclusions: Percutaneous US-guided sampling of pancreatic mass is safe and effective irrespective of location of the mass and method of biopsy.

1. Introduction

Solid mass lesions of the pancreas frequently represent malignancy with primary adenocarcinoma being the most common type [1]. However, many other lesions, most notably focal chronic pancreatitis, can mimic malignant neoplasms. These lesions can be difficult to differentiate using imaging and laboratory tests [2,3]. Pancreatic biopsy is therefore often required for initial diagnosis of pancreatic masses. In those patients with clear imaging and biochemical evidence of malignancy, biopsy may still be needed to determine the histopathologic features of the neoplasm prior to the initiation of chemotherapy or radiotherapy [4,5]. Biopsy can be performed intraoperatively [6,7], endoscopically [8], or percutaneously with computed tomographic (CT) [9] or ultrasound (US) guidance [10,11]. Although percutaneous US-guided pancreatic biopsies provide a clear advantage over CT-guided biopsies through its lack of ionizing radiation, many centers continue to use primarily CT guidance.

Previous studies have demonstrated that percutaneous US-guided pancreatic core biopsy and fine needle aspiration (FNA) are both safe and effective methods for the diagnosis of pancreatic masses, with sensitivity as high as 93% for core biopsies [12–16] and 99% for FNA [16–21]. Complication rates for core and FNA biopsies ranged from 2.6% to 21% [14–16], and from 1.5% to 20% [16,17,20], respectively. However, no studies to date have directly compared the safety and efficacy of US-guided core biopsy vs. FNA or investigated whether the location of the lesion in the pancreas affects the diagnostic outcome of the biopsies.

The purpose of our study was to assess the effectiveness of percutaneous US-guided pancreatic mass biopsy and to determine whether the type of biopsy (core vs. FNA vs. combined core and FNA) or the location of the mass in the pancreas affects the diagnostic yield.

2. Materials and methods

2.1. Study population

A retrospective review was conducted on all percutaneous US-guided biopsies of solid mass lesions of the pancreas performed between January 1, 2001 and November 30, 2011 at our multisite,

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tertiary, academic medical center. Every patient had been evaluated with CT, magnetic resonance, US, or a combination of these modalities, prior to referral for biopsy. All patients were referred for a biopsy because a solid mass (±cystic/necrotic component) was discovered in their pancreas on imaging. US-guided biopsies were included regardless of patient age, gender, final diagnosis, or indication for the scan. CT-guided biopsies were excluded as were any biopsies of pancreas transplants. All biopsy procedures were performed by 1 of 14 fellowship-trained abdominal and interventional radiologists with at least 7 years of clinical experiencing performing US-guided procedures. The study was approved by the institutional research ethics board.

2.2. Biopsy technique

Percutaneous US-guided biopsies were performed with transducers ranging in frequency from 2.5 to 5.0 MHz (Aplio, Toshiba, Tokyo, Japan and iU22, Phillips Healthcare, Bothell, WA). Before sampling, the pancreatic lesion was routinely studied with grayscale and Doppler US and relation to the adjacent major blood vessels was assessed, prior to choosing a suitable route to biopsy the lesion. Coaxial or noncoaxial technique was used to perform the core biopsy. The coaxial technique constituted using a 17-gauge introducer needle and matching 18-gauge core biopsy needles (Bard, Tempe, AZ or Temno Biopsy System, Allegiance, McGaw Park, IL). The noncoaxial technique constituted just an 18-gauge core biopsy needle. For FNA, tissue sampling was performed using 22-gauge needle (Chiba, Cook Medical, Bloomington, IN) either directly or with coaxial technique through 17-gauge introducer needle. The number of cores obtained and aspirations performed was determined by the operating radiologist. When FNA was performed, the samples were assessed for adequacy on-site by a cytologist whenever possible at the time of the procedure. Biopsies were generally performed using an anterior approach with the patient in the supine position. Transhepatic, transgastric, and transenteric routes were used when a direct path to the lesion was not possible. The transcolonic route was avoided to minimize the risk of infection and peritonitis. Procedures were performed under local anesthesia and intravenous conscious sedation using fentanyl and midazolam. All patients underwent standard continuous hemodynamic monitoring during the procedure. Post-procedure, patients were monitored in the Medical Imaging Day Unit for 4 h, prior to discharge. After the biopsy, the samples were sent to the pathology/cytology department for assessment.

2.3. Data evaluation

Consecutive percutaneous US-guided pancreatic biopsies were identified by a search of the radiology information system. Cases involving biopsy of a transplanted pancreas were manually excluded. The procedural and imaging reports were then evaluated by one reviewer and the following information were extracted: patient demographics, study indication, location of the pancreatic mass, type of tissue obtained (core and/or FNA), complications, and results of follow-up imaging. The electronic patient record of these patients was reviewed to obtain their clinical course, pathology results, and any late complications from the biopsy.

The final diagnosis was determined on the basis of a combination of follow-up imaging, clinical course, and/or surgical pathology. A biopsy result was considered true positive if pathology was positive for or strongly suggestive of malignancy. A biopsy result was considered true negative if pathology was negative for malignancy without subsequent evidence (such as follow-up imaging or repeat pathology) suggestive of malignancy. A biopsy result was considered false negative if pathology was negative for malignancy but additional evidence suggested malignancy. Finally, a biopsy result was considered false positive if pathology was positive for or strongly suggestive of malignancy but further evidence resulted in an alternative diagnosis.

2.4. Statistical analysis

Data were entered and analyzed in a Microsoft Excel spreadsheet (Microsoft Corp., Redmond, CA). Diagnostic rate (proportion of procedures in which sufficient sample was obtained for a diagnosis to be made), sensitivity, specificity, accuracy, and positive predictive value (PPV) and negative predictive value (NPV) based on location of the mass (head/neck vs. body/tail) and method of biopsy (core vs. FNA vs. combined core and FNA) were determined. Differences between groups were compared using Fischer's exact test. All tests were two-sided and a P value of $<.05$ was considered statistically significant.

The diagnostic rate was defined as the proportion of procedures from which sufficient sample was obtained for pathology for a diagnosis to be made. The sensitivity was calculated as the ratio of [true positives]/[true positives+false negatives]. The specificity was calculated as the ratio of [true negatives]/[true negatives+false positives]. The accuracy of biopsies was defined as the ratio of [true positives]+[true negatives] divided by the total number of biopsy procedures. The NPV was calculated as the ratio of [true negatives]/[true negatives+false negatives]. The PPV was calculated as the ratio of [true positives]/[true positives+false positives].

3. Results

A total of 88 consecutive patients who underwent US-guided percutaneous pancreatic mass biopsy were included in this study (median age: 66 years; range: 29–87 years), 43 (49%) were men, and 45 (51%) were women. The distributions of biopsy type (core, FNA, or both) and location of the pancreatic mass are shown in Table 1. A summary of the biopsy results is shown in Table 2. Of 88 biopsy samples, 74 showed true-positive results for malignancy. Eight samples were true negatives for malignancy. One biopsy result was false negative, for which the final clinical diagnosis was neuroendocrine tumor. One biopsy specimen was incorrectly diagnosed as a pancreatic adenocarcinoma. The final diagnosis turned out to be a neuroendocrine tumor. This sample was not counted as false negative for any of the following analyses, given that both outcomes were malignancies. There were no false-positive biopsy results. The final diagnosis was confirmed by surgical pathology in 12 patients and follow-up imaging and clinical course in the remaining 76 patients.

The diagnostic performance of pancreatic biopsies was examined both with respect to the type of biopsy performed (Table 3) and the location of the mass from where the biopsy sample was retrieved (Table 4). Because there were no false-positive results, the specificity and PPV were both 100% for all groups and are thus not specifically mentioned in subsequent analyses. There were no significant differences in diagnostic performance related to lesion location or biopsy type.

When comparing the types of biopsy to each other (core vs. FNA vs. core+FNA; Table 3), sampling was nondiagnostic in 5.7% (5/88) of cases. Four of these five cases were core biopsies. The other case was an FNA, during which a cytologist was not present. For analysis

Table 1
Biopsy method and location of mass where biopsy was taken

	Pancreatic biopsy location			Total
	Head/neck	Body/tail	Unclear	
Biopsy type				
No. of Core	45	13	2	60
No. of FNA[a]	10	3	–	13
No. of core+FNA	9	5	1	15
Total	64	21	3	88

[a] FNA = Fine Needle Aspiration.