EUS-FNA is superior to ERCP-based tissue sampling in suspected malignant biliary obstruction: results of a prospective, single-blind, comparative study

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Background: Both EUS and ERCP sampling techniques may provide tissue diagnoses in suspected malignant biliary obstruction. However, there are scant data comparing these 2 methods.

Objective: To compare EUS-guided FNA (EUS-FNA) and ERCP tissue sampling for the diagnosis of malignant biliary obstruction.

Design: Prospective, comparative, single-blind study.

Setting: Tertiary center.

Patients: Fifty-one patients undergoing same-session EUS and ERCP for the evaluation of malignant biliary obstruction over a 1-year period.

Interventions: EUS-FNA and ERCP tissue sampling with biliary brush cytology and intraductal forceps biopsies.

Main Outcome Measurements: Diagnostic sensitivity and accuracy of each sampling method compared with final diagnoses.

Results: EUS-FNA was more sensitive and accurate than ERCP tissue sampling ($P < .0001$) in 51 patients with pancreatic cancers (n = 34), bile duct cancers (n = 14), and benign biliary strictures (n = 3). The overall sensitivity and accuracy were 94% and 94% for EUS-FNA, and 50% and 53% for ERCP sampling, respectively. EUS-FNA was superior to ERCP tissue sampling for pancreatic masses (sensitivity, 100% vs 38%; $P < .0001$) and seemed comparable for biliary masses (79% sensitivity for both) and indeterminate strictures (sensitivity, 80% vs 67%).

Limitations: Single-center study.

Conclusion: EUS-FNA is superior to ERCP tissue sampling in evaluating suspected malignant biliary obstruction, particularly for pancreatic masses. EUS-FNA appears similar to ERCP sampling for biliary tumors and indeterminate strictures. Given the superior performance characteristics of EUS-FNA and the higher incidence of pancreatic cancer compared with cholangiocarcinoma, EUS-FNA should be performed before ERCP in all patients with suspected malignant biliary obstruction. (Clinical trial registration number: NCT01356030.) (Gastrointest Endosc 2014;80:97-104.)

Abbreviation: EUS-FNA, EUS-guided FNA.

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Establishing a tissue diagnosis of malignancy before surgical or oncologic therapy is an important step in evaluating patients with suspected malignant biliary obstruction. The 2 most commonly used methods for tissue sampling are ERCP-based techniques and EUS-guided FNA (EUS-FNA). ERCP-based methods, most commonly performed using cytology brushes and/or intraductal forceps, predate the availability of EUS. In numerous studies, the diagnostic yield of ERCP-based tissue sampling has ranged from 35% to 70%, with higher yields usually found when both brushing and biopsies were performed.[1-6]

EUS-FNA, although a relatively newer modality compared with ERCP-based tissue sampling, now has a well-established sensitivity, ranging from 85% to 93% in recent studies.[7-11] This high yield is even achievable in the absence of an identifiable mass on previous imaging[12] and in the setting of suspected cholangiocarcinoma (sensitivity, 73%-89%).[19-22] EUS-FNA is also preferred over percutaneous tissue biopsy because of a better yield and lower risk of tumor seeding.[13,14]

Despite the widespread pervasiveness of ERCP and increasing availability of EUS at many centers, there are scant data that directly compare the 2 modalities in terms of tissue sampling. The aim of this study was to directly compare the diagnostic yield of same-session EUS-FNA and ERCP-based tissue sampling in a prospective series of consecutive patients with suspected malignant biliary obstruction.

Take-home Message

- EUS-guided FNA is superior to ERCP tissue sampling in evaluating suspected malignant biliary obstruction, particularly for pancreatic masses, but also appears to be comparable for biliary masses/strictures.
- Single-session EUS-FNA and ERCP may maximize diagnostic and therapeutic benefits.

METHODS

At our center, same-session EUS and ERCP are routinely offered for all patients with suspected pancreaticobiliary pathology. All patients with suspected malignant biliary obstruction based on clinical presentation of painless jaundice with elevated levels on liver tests in a cholestatic pattern and evidence of biliary obstruction, stricture, or pancreatic/biliary mass on preprocedure imaging (contrast CT or magnetic resonance imaging) were invited to participate in the study. Patients with pancreaticobiliary disease without clinical concern for underlying malignancy (eg, postoperative biliary stricture, chronic pancreatitis without suspected neoplasm) were not recruited to participate.

Participants underwent EUS first using a curvilinear echoendoscope (GF-UC140 or GF-UCT140; Olympus America, Center Valley, Pa). Any pancreatic masses, focal bile duct masses, or strictures (Fig. 1), lymph nodes, and/or liver lesions were targeted for EUS-FNA with a 22- or 25-gauge needle (Echotip; Cook Medical, Bloomington, Ind). Lesions that would confer a higher stage were targeted before the primary mass. All FNA procedures were performed with the presence of on-site, cytopathologic assessment. The specimen was expressed onto 1 to 2 slides for rapid evaluation by air-dried and/or alcohol-fixed review. Air-dried smears were prepared with Diff-Quik stain (Siemens, Newark, Del); alcohol-fixed smears were prepared with toluidine blue followed by Papanicolaou staining. Additional material was placed in a 30-mL 10% formalin container for subsequent cell-block analysis. Additional FNA passes were made based on the cytopathologist's assessment of specimen adequacy. EUS-FNA confirmation of metastasis to regional lymph nodes or the liver was considered acceptable for the primary tumor diagnosis without necessary FNA targeting of the primary tumor site.

ERCP was then performed, if clinically indicated, by a second endoscopist blinded to EUS and FNA results. Patients who provided study consent but did not require an ERCP were not enrolled in the study. During ERCP, initial cannulation and cholangiography was performed to determine the level of the bile duct obstruction. ERCP-based tissue sampling was then performed by using the following 2 devices in sequential order (Fig. 2): a conventional, over-the-guidewire cytology brush (Fusion Cytology Brush; Cook Medical) and intrabiliary forceps (FB-40Q-1; Olympus America or Radial Jaw 4 Pediatric Forceps; Boston Scientific, Natick, Mass). Strictures were not dilated before tissue sampling. Cytology brushings were obtained using 10 to-and-fro brushing strokes across the biliary stricture. The brush was then smeared on 2 glass slides that were air-dried and placed in a 95% ethyl alcohol fixative container. The tip of the brush was cut and submitted in a 10% formalin container for analysis. The intraductal biliary forceps were then introduced to the level of the stricture under fluoroscopy; 2 to 3 intraductal biopsy specimens were obtained. These were placed in a separate 10% formalin container and submitted for histopathologic analysis.

All EUS and ERCP procedures were performed at a single session under monitored anesthesia sedation. Two separate endoscopists of 3 experienced interventionalists (J.S., Y.B., K.B.; each performing >500 EUS and >400 ERCP procedures annually) performed the EUS and ERCP procedures.

Pathologists evaluating EUS-FNA and ERCP samples were not blinded to the clinical findings or the results of the alternative sampling technique. Tissue samples obtained at EUS-FNA and ERCP were routinely classified into 1 of the following categories: (1) malignant; (2) atypical, suspect malignant; (3) atypical, favor reactive/benign; (4) benign; and (5) nondiagnostic, insufficient material. Any sample labeled by the pathologist as "malignant" or