Performance characteristics of EUS for locoregional evaluation of ampullary lesions (CME)

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Background: The accuracy of EUS in the locoregional assessment of ampullary lesions is unclear.

Objectives: To compare EUS with ERCP and surgical pathology for the evaluation of intraductal extension and local staging of ampullary lesions.

Design: Retrospective cohort study.

Setting: Tertiary-care referral center.

Patients: All patients who underwent EUS primarily for the evaluation of an ampullary lesion between 1998 and 2012.

Intervention: EUS.

Main Outcome Measurements: Comparison of EUS sensitivity/specificity for intraductal and local extension with ERCP and surgical pathology by using the area under the receiver-operating characteristic (AUROC) curves and outcomes of the subgroup referred for endoscopic papillectomy.

Results: We identified 119 patients who underwent EUS for an ampullary lesion, of whom 99 (83%) had an adenoma or adenocarcinoma. Compared with ERCP (n = 90), the sensitivity/specificity of EUS for any intraductal extension was 56%/97% (AUROC = 0.77; 95% confidence interval [CI], 0.64-0.89). However, when using surgical pathology as the reference (n = 102), the sensitivity/specificity of EUS (80%/93%; AUROC = 0.87; 95% CI, 0.76-0.97) and ERCP (83%/93%; AUROC = 0.88; 95% CI, 0.77-0.99) were comparable. The overall accuracy of EUS for local staging was 90%. Of 58 patients referred for endoscopic papillectomy, complete resection was achieved in 53 (91%); in those having intraductal extension by EUS or ERCP, complete resection was achieved in 4 of 5 (80%) and 4 of 7 (57%), respectively.

Limitation: Retrospective design.

Conclusions: EUS and ERCP perform similarly in evaluating intraductal extension of ampullary adenomas. Additionally, EUS is accurate in T-staging ampullary adenocarcinomas. Future prospective studies should evaluate whether EUS can identify characteristics of ampullary lesions that appropriately direct patients to endoscopic or surgical resection. (Gastrointest Endosc 2015;81:380-8.)

Abbreviations: AUROC, area under the receiver-operating characteristic; BD, bile duct; CI, confidence interval; LN, lymph node; PD, pancreatic duct.

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The diagnostic approach to suspected ampullary tumors remains controversial. For ampullary adenomas, endoscopic resection is preferred over surgery given its lower morbidity.[1] However, some patients will undergo incomplete endoscopic resection in the setting of occult adenocarcinoma, often caused by invasion of the duodenum, pancreas/pancreatic duct (PD), or bile duct (BD).[2-4] A previous prospective study of 106 patients with a benign tumor of the major or minor papilla treated endoscopically reported intraductal extension significantly reduced the likelihood of complete endoscopic resection from 83% to 46% ($P < .001$).[3] In our recent cohort study of individuals undergoing endoscopic papillectomy, patients with incomplete resection had a significantly higher rate of intraductal extension (as defined by ERCP) than those with complete resection (31.3% vs 9.0%; $P = .0002$).[2] EUS is a less-invasive alternative to ERCP for the local staging of ampullary lesions. Although intraductal extension is not an absolute contraindication to endoscopic resection, EUS findings of intraductal extension or duodenal/pancreas invasion may triage patients to nonendoscopic treatment modalities and minimize the likelihood of incomplete endoscopic resection.[5-9]

Because of a paucity of evidence, the American Society for Gastrointestinal Endoscopy guideline recommends using EUS on a case-by-case basis in the workup of ampullary lesions.[9] In a prospective trial of patients with ampullary lesions (n = 40), surgical resection was avoided in 10 patients (25%) who underwent EUS and intraductal US.[5] Of those referred for endoscopic papillectomy (n = 10), all (7 with adenoma and 3 with adenocarcinoma limited to the mucosal layer) underwent successful endoscopic resection. Although several studies showed the reliability of EUS for T staging of ampullary neoplasms, these were limited by small sample size, heterogeneity of study design (combining both duodenal and ampullary lesions), or limited comparative analysis of intraductal extension with ERCP and surgical pathology.[5,8,10]

Our primary objective was to compare EUS with ERCP and surgical pathology for the locoregional evaluation of ampullary lesions. Specifically, we measured the rates of intraductal extension and local tissue invasion by using surgical pathology as the reference standard. The secondary objectives were to describe the impact of intraductal extension (defined by EUS, ERCP, or both) on endoscopic resectability and the performance characteristics of EUS-FNA in this setting. Although there are subtle histopathological differences between a lesion arising from the duodenal aspect of the major papilla and one arising from within the ampulla, we use the terms ampulla and papilla interchangeably and papillectomy to describe the endoscopic resection technique.

METHODS

Study population

By using an endoscopy database (ProVationMD; Wolters Kluwer Health, Philadelphia, Pa), we identified all patients who were referred for EUS to evaluate a known or suspected ampullary lesion (a previous biopsy suggesting adenoma/adenocarcinoma) between January 1998 and December 2012. Patients who had a previous ERCP with or without biliary stent placement were excluded from the study. Lesions were categorized as adenomatous (ranging from adenoma to adenocarcinoma) and nonadenomatous. We abstracted medical records for relevant demographic and clinical data, including the following lesion characteristics: intraductal (BD or PD) extension, local tissue (duodenum, pancreas, other) invasion, and size (by endoscopy, EUS, and surgical pathology). We describe each patient's management after EUS, including endoscopic or surgical resection and medical treatment. The accuracy of tumor staging, intraductal extension, and histological features were evaluated by using surgical pathology as the reference standard. Our local institutional review board approved the study protocol before the collection of data.

EUS examination

All EUS examinations were performed before deciding to proceed with endoscopic or surgical resection (or neither). All patients underwent EUS with the absence of an overlying biliary stent. The indications for EUS included characterizing the tumor, locoregional staging (the assessment of intraductal extension and local tissue invasion), and/or obtaining a tissue diagnosis. All EUS procedures were performed by 1 of 6 experienced endosonographers (J.L., S.S., J.D., M.A., L.M., or G.C.) and ERCP by 1 of 6 experienced providers in ERCP (S.S., E.F., L.M., G.C., J.W., or G.L.), 3 of whom also performed EUS. During the examination, EUS was routinely completed to assess (1) tumor depth, (2) invasion into local structures (duodenum and/or pancreas), (3) intraductal extension (BD, PD, or both), and (4) involvement of regional lymph nodes (LNs). The decisions to perform CT or magnetic resonance imaging before EUS or to perform FNA during the procedure were left to the discretion of the treating physician. EUS was performed by using radial echoendoscopes (GF-UM20, GF-UM130, or GF-UM160; Olympus America, Inc, Center Valley, Pa) and/or linear echoendoscopes (32UA or 32 UX; Pentax Medical Co, Montvale, NJ or GF-UC30P or GF-UC140P; Olympus America, Inc). In some cases, FNA was performed by using a 19- or 22-gauge needle (Cook Endoscopy, Winston-Salem, NC) with the presence of on-site cytopathology.

Post-EUS management

After EUS, a therapeutic decision to proceed with endoscopic or surgical resection or to refer to medical oncology was made by the treating physician/endosonographer. Pre-resection sampling histopathology (mucosal biopsies) was performed at the discretion of the referring physician/endoscopist. Indications influencing the decision to proceed with ERCP included 1 or more of the following: