Adverse events of EUS-guided FNA of pancreatic cystic and solid lesions by using the lexicon proposed in an ASGE workshop: a prospective and comparative study

Antonio Rodríguez-D'Jesús, MD,[1] Gloria Fernández-Esparrach, MD, PhD,[1] Carlos Marra-Lopez, MD,[2] Aitor Orive-Calzada, MD,[2] Oriol Sendino, MD, PhD,[1] Isis K Araujo, MD,[1] Cristina Rodríguez de Miguel, RN,[1] Enrique Vázquez-Sequeiros, MD, PhD,[3] Henry Córdova, MD, PhD,[1] Cristina Sánchez-Montes, MD,[1] Begoña González-Suárez, MD, PhD,[1] Angels Ginès, MD, PhD[1]

Barcelona, Vitoria-Gasteiz, Madrid, Spain

Background and Aims: Pancreatic cysts and solid lesions are routinely examined by EUS-guided FNA (EUS-FNA). The aim of this study was to compare the incidence of adverse events (AEs) of this procedure by using the lexicon recommended by the American Society for Gastrointestinal Endoscopy (ASGE).

Methods: This was a prospective and comparative study of patients who underwent EUS-FNA in which a 22-gauge needle was used. In the pancreatic cystic lesions group (group I), complete fluid evacuation in a single needle pass was attempted, and ciprofloxacin was given during the procedure and for 3 days after. In the pancreatic solid lesions group (group II), the number of passes was determined by the on-site evaluation of the sample. AEs were defined and graded according to the lexicon recommended by the ASGE. Patients were followed for 48 hours, 1 week, and 1 month after the procedure.

Results: A total of 146 patients were included, 73 in group I and 73 in group II. Potential factors influencing the incidence of AEs (ie, access route for FNA) were similar in both groups. AEs occurred in 5 of 146 patients (3.4%; 95% confidence interval [CI], 1.3%-8%): 4 in group I (5.5%; 95% CI, 1.7%-13.7%) and 1 in group II (1.4%; 95% CI, −0.5% to 8.1%) ($P = .03$). Severity was mild in 1 of 5 patients (20%) and moderate in 3 of 5 patients (60%). One patient with a solid mass in the head of the pancreas had a duodenal perforation after EUS and died after surgery. All other AEs occurred in the first 48 hours and resolved with medical therapy. There were 3 incidents of transient hypoxia and self-limited abdominal pain in 1 and 2 patients, respectively. No patients were lost to follow-up.

Conclusion: EUS-FNA of pancreatic cysts has an AEs rate similar to that of solid pancreatic masses, which is small enough to consider this procedure a safe and effective method for managing patients with both types of lesions. AEs occurred early after EUS-FNA, and patients should be closely followed during the first 2 days after the procedure. (Gastrointest Endosc 2016;83:780-4.)

An increase in the availability of high-quality abdominal imaging has resulted in a high detection of incidental pancreatic cystic lesions (PCLs).[1] The prevalence of incidental PCLs detected on abdominal imaging ranges between 2.6% and 13.6%, and they are more prevalent in the elderly.[2,3] There is always the concern that these incidental lesions might be intraductal papillary mucinous neoplasms or mucinous cystadenomas because they have an

Abbreviations: AE, adverse event; ASGE, American Society for Gastrointestinal Endoscopy; CI, confidence interval; CTCAE, Common Technology Criteria for Adverse Events; EUS-FNA, EUS-guided FNA; PCL, pancreatic cystic lesion; PSL, pancreatic solid lesion; IPMN, Intraductal papillary mucinous neoplasm.

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Current affiliations: Endoscopy Unit, Gastroenterology Department, ICMDM, Hospital Clínic, IDIBAPS, CIBERehd, University of Barcelona, Barcelona (1), Hospital Universitario Araba, Vitoria-Gasteiz (2), Instituto Ramón y Cajal de Investigación, Madrid (3), Spain.

Reprint requests: Angels Ginès, MD, PhD, Endoscopy Unit, ICMDM, Hospital Clínic, Villarroel 170, 08036 Barcelona, Spain.

If you would like to chat with an author of this article, you may contact Dr Ginès at magines@clinic.ub.es.

increased risk of malignant transformation. Accurately identifying and diagnosing PCLs remain a challenge in clinical practice. Thus, appropriately differentiating neoplastic from nonneoplastic/low-risk PCLs is of key importance because this dictates management and has an impact on patient survival. Further confirmatory studies of incidental PCLs include magnetic resonance imaging and EUS with or without FNA. EUS is considered a better technique because it allows aspiration of cystic fluid for cytological and biochemical analysis.[4,5] EUS-guided FNA (EUS-FNA) has been shown to be the most accurate method for the cytological diagnosis of PCLs.[4,6] In contrast, solid pancreatic masses are almost always malignant and symptomatic at the time of diagnosis.

The reported rate of adverse events (AEs) after EUS-FNA of PCLs ranges from 2.2% to 14%.[7-9] The most common AE is pancreatitis (as high as 4.9%), followed by intracystic bleeding (as high as 1.3%), GI bleeding (0.6%), and fever (0.1%). This is in contrast to the reported rate of AEs after EUS-FNA of solid lesions where the incidence is less than 1%.[10] However, these numbers vary among studies due to the heterogeneity in study design and mainly because they do not use the same uniform nomenclature and definitions of AEs.[10] The need for a standardized nomenclature and agreement on definitions of AEs was addressed by the American Society for Gastrointestinal Endoscopy (ASGE) in a 2008 workshop.[11] There are no published prospective studies on the incidence of AEs in cystic and solid pancreatic lesions by using the ASGE lexicon for AEs. Thus, the aim of this study was to prospectively determine the incidence and outcome of AEs after EUS-FNA of PCLs and pancreatic solid lesions (PSLs) by using the ASGE lexicon for AEs.

METHODS

Patients

This was a prospective and comparative study performed at 2 referral centers for EUS in Spain: Hospital Clínic de Barcelona and Hospital Universitario de Araba, Vitoria-Gasteiz. All patients with PCLs (group I) and PSLs (group II) referred for EUS-FNA were eligible for inclusion in the study. Inclusion criteria were (1) age greater than 18 years (2) platelet count more than 50,000/mL and/or prothrombin time higher than 50%. Exclusion criteria were (1) aspirin within the previous 3 to 7 days (depending on aspirin dose and patient's thrombotic risk), (2) clopidogrel during the previous 7 days, (3) evidence of ongoing infection, (4) use of antibiotics for any reason at least 5 days before the procedure, (5) refusal to participate in the study, and (6) inability to contact by phone. The institutional review board of each participating center approved the study. Before the EUS procedures, all patients provided a signed informed consent.

Endosonography was performed at each institution by using radial and linear echoendoscopes for diagnostic EUS and EUS-FNA, respectively (Hospital Clinic: GF UM160 and GF UC140P; Hospital of Vitoria-Gasteiz: GF-UCT140 and GF-UE160-AL5; Olympus America Inc, Melville, NY). For EUS-FNA, a 22-gauge needle (Wilson-Cook Medical Inc, Winston-Salem, NC) was used in all patients. EUS and EUS-FNA were performed according to the standard techniques described elsewhere.[12] Patients were placed in the left lateral decubitus position, and conscious sedation with intravenous midazolam or fentanyl plus propofol was administered by an anesthesiologist in all patients.

Lesions in the head of the pancreas were approached transduodenally, whereas body and tail lesions were targeted via a transgastric approach. In PCLs, complete cystic fluid aspiration with a single needle pass was attempted in all cases, and fluid was sent for cytological and/or biochemical analysis. Due to the scarce cellularity of the fluid, on-site evaluation was not performed in PCLs, whereas in solid masses a cytotechnologist was always available at the bedside to examine the specimen. When a mural nodule, associated mass, or thickened wall were identified within the cyst, they were also sampled.

Patients with PCLs received 1 intravenous dose of antibiotic during the procedure (ciprofloxacin 200 mg) followed by a 3-day course of oral ciprofloxacin 500 mg twice a day. Variables were recorded in database templates. The database included demographic characteristics, medical and drug history, morphological features of the cysts on EUS, technical information about the EUS procedure, type of sedation, laboratory tests, AEs and measures for correcting them, and patient outcome.

Assessment of AEs

AE was defined according to the lexicon of the ASGE Workshop[11] as an event that prevents completion of the EUS-FNA and/or results in admission to hospital, prolongation of existing hospital stay, another procedure (requiring sedation/anesthesia), or subsequent medical consultation. AEs were assessed and recorded by a physician during and after the procedure and up to 24 hours later in those admitted for observation. At 48 hours, 1 week, and 30 days after the procedure, a telephone call was made to ask patients whether they had experienced any symptoms or required medical assistance. Telephone calls were made by an independent physician unaware of the results of the exploration to avoid a potential bias in collection and interpretation of patient's information. Responses were recorded and entered into a database.

Severity of AEs was graded as mild, moderate, severe, and fatal according to the ASGE classification. AEs were defined as mild or moderate if patients required fewer than 4 nights or between 4 and 10 nights of hospitalization, respectively. They were classified as severe if unplanned or prolonged hospitalization was required for more than