Endoscopic ultrasonography-guided fine needle aspiration: Relatively low sensitivity in the endosonographer population

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Abstract

AIM: To assess the characteristics and quality of endoscopic ultrasonography-guided fine needle aspiration (EUS-FNA) in a large panel of endosonographers.

METHODS: A survey was conducted during the 13th annual live course of endoscopic ultrasonography (EUS) held in Amsterdam, Netherlands. A 2-page questionnaire was developed for the study. Content validity of the questionnaire was determined based on input by experts in the field and a review of the relevant literature. It contained 30 questions that pertained to demographics and the current practice for EUS-FNA of responders, including sampling technique, sample processing, cytopathological diagnosis and sensitivity of EUS-FNA for the diagnosis of solid mass lesions. One hundred and sixty-one endosonographers who attended the course were asked to answer the survey. This allowed assessing the current practice of EUS-FNA as well as the self-reported sensitivity of EUS-FNA for the diagnosis of solid mass lesions. We also examined which factors were associated with a self-reported sensitivity of EUS-FNA for the diagnosis of solid mass lesions > 80%.

RESULTS: Completed surveys were collected from 92 (57.1%) of 161 endosonographers who attended the conference. The endosonographers had been practicing endoscopy and EUS for 12.5 ± 7.8 years and 4.8 ± 4.1 years, respectively; one third of them worked in a hospital with an annual caseload > 100 EUS-FNA. Endoscopy practices were located in 29 countries, including 13 countries in Western Europe that totaled 75.3% of the responses. Only one third of endosonographers reported a sensitivity for the diagnosis of solid mass lesions > 80% (interquartile range of sensitivities, 25.0%-75.0%). Factors independently associated with a sensitivity > 80% were (1) > 7 needle passes for pancreatic lesions or rapid on-site cytopathological evaluation (ROSE) (P < 0.0001), (2) a high annual hospital caseload (P = 0.024) and (3) routine isolation of microcores from EUS-FNA samples (P = 0.042). ROSE was routinely available to 27.9% of respondents. For lymph nodes and pancreatic masses, a maximum of three needle passes was performed by approximately two thirds of those who did not have ROSE. Microcores were routinely harvested from EUS-FNA samples by approximately one third (37.2%) of survey respondents.

CONCLUSION: EUS-FNA sensitivity was considerably lower than reported in the literature. Low EUS-FNA sensitivity was associated with unavailability of ROSE, few needle passes, absence of microcore isolation and low hospital caseload.

Key words: Caseload; Community surveys; Cytopathological evaluation (ROSE)
INTRODUCTION

Endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) has become widely available in a variety of endoscopy settings. Due to its high diagnostic accuracy, EUS-FNA plays an important role in the management of masses located in or close to the gastrointestinal tract. For example, median sensitivity of EUS-FNA to differentiate between benign and malignant masses of the pancreas (technically the most difficult location) is reported to be greater than 80%.[6] Such a high sensitivity for malignancy diagnosis has allowed EUS-FNA to significantly impact patient management in various clinical situations, including pancreatic cancer,[3, 7, 8] mediastinal lesions,[6, 8] lung cancer,[4, 5] and solid liver lesions.[7, 8]

Excellent results of EUS-FNA such as those cited above have mostly been reported by dedicated endoscopists, many of them working in academic centers. The quality of EUS-FNA in the endosonographer population is poorly known, despite the fact that the quality of endoscopic procedures has become a central concern for the American and European Societies of Gastrointestinal Endoscopy.[6, 11]

To characterize the situation of EUS-FNA in the community, we performed a survey in a large audience of endosonographers to assess (1) current modalities of EUS-FNA; (2) self-reported sensitivity of EUS-FNA for the diagnosis of solid masses; and (3) factors associated with a diagnostic yield similar to that reported in the literature.

MATERIALS AND METHODS

Survey design and administration

A 2-page, 30-item, questionnaire (Appendix 1) was developed for the study. Content validity of the survey was determined based on input by experts in the field and a review of the relevant literature. Participants were asked to answer questions pertaining to demographics (6 items), their own current practice for EUS-FNA (16 items), sample processing (3 items), cytopathological diagnosis (3 items) and sensitivity of EUS-FNA for the diagnosis of solid mass lesions.

The survey was conducted during the 13th annual live EUS course held in Amsterdam, Netherlands, June 3rd and 4th 2010, as previously described.[12, 13] Briefly, questionnaires were placed in bags distributed to course participants, and attendees were asked to deposit completed surveys in a dedicated box at the registration desk. Consent to participate in this study was inferred from voluntary completion of the survey. Efforts to increase response rates included reminders by the course director and moderators, projection of a reminder slide during breaks, and collection of surveys by staff members. No gift or financial incentive was granted to attendees.

Statistical analysis

Results are expressed as mean ± SD or as a percentage. Answers for each individual question were obtained from all survey respondents except when otherwise stated (each response was included in the analysis, regardless of the completeness of the survey); therefore, the number of respondents for each individual question (i.e., the denominator for percentage calculations) is indicated.

Comparisons between groups were performed with the Pearson χ² test or Fisher’s exact test (Freeman-Halton extension where applicable) for categorical data and the Wilcoxon signed rank test for continuous variables. We also examined, by using multiple logistic regression analysis, which factors-including years of EUS practice, EUS-FNA annual hospital caseload, availability of rapid onsite cytopathological evaluation (ROSE) of EUS-FNA samples, number of needle passes > 7 or based on ROSE for three lesion types (lymph node, pancreas mass < 25 mm, pancreas mass > 25 mm) – method of EUS-FNA sample preservation and routine isolation of microcores from EUS-FNA samples—were associated with a sensitivity of EUS-FNA for the diagnosis of solid mass lesions > 80%. All tests were 2-sided and P values < 0.05 were considered statistically significant. All analyses were performed with JMP software (version 9.0.0; SAS, Cary, NC, United States).

RESULTS

Study population

Completed surveys were collected from 92 (57.1%) of 161 endosonographers who attended the conference (excluding international faculty members, local faculty, fellows, and industry delegates). Survey respondents had been practicing endoscopy and EUS for 12.5 ± 7.8 years and 4.8 ± 4.1 years, respectively; 38 (42%) of them had been performing EUS for more than 5 years (Table 1). Approximately one third of respondents were practicing in a center with an annual caseload > 100 EUS-FNA. Endoscopy practices were located in 29 countries, including 13 countries in Western Europe (Austria, Belgium, Denmark, Germany, France, Greece, Italy, Netherlands, Portugal, Spain, Sweden, Switzerland and the United Kingdom) that totaled 75.3% (67 out of 89) of the responses. Most (77.1%) survey respondents were performing FNA or drainage in fewer than 40% of EUS procedures. For patients subjected to both endoscopic biliary drainage
and EUS-FNA, only 27% of survey respondents were performing both procedures during a single endoscopy session. Staging of pulmonary cancer was performed by approximately one third of survey respondents (27 of 86; 31.4%).

**Practice of EUS-FNA**

A 22G needle was used for all lesion types by the majority of endosonographers; a 25G needle was used by 19.8% of survey respondents for EUS-FNA of the pancreas head (as compared to 6.8% for esophagogastric lesions; \( P = 0.009 \)) (Table 2). ROSE of EUS-FNA samples was available to less than half of survey respondents, routinely (27.9% of answers) or in selected cases (15.1% of answers). Most endosonographers who had ROSE routinely available used it to determine the number of needle passes during EUS-FNA, while a maximum of three needle passes was performed by approximately two thirds of those who did not have ROSE routinely available. Samples were prepared using liquid-based methods plus smearing by approximately half of survey respondents (46.5%); microcores were routinely harvested from EUS-FNA samples by approximately one third (37.2%) of survey respondents. Paraffin-embedded blocks were prepared for histopathological examination of EUS-FNA samples in the laboratory of approximately half of survey respondents (55.8%). Forty-five (52.9%) of 85 survey respondents had regular meetings with the pathologist examining EUS-FNA samples.

If EUS-FNA was repeated after a first inconclusive procedure, survey respondents repeated an identical procedure or referred the patient to another endosonographer in 35.3% and 8.2% of cases, respectively. Those who modified the procedure performed more needle passes, used a larger needle and, in 25% of cases, added ROSE of the EUS-FNA sample. The vast majority of survey respondents performed Doppler examination before EUS-FNA (79 of 88 responses; 89.7%) and administered antibiotic prophylaxis before EUS-FNA of pancreatic fluid collections (82 of 86 responses; 95.3%); antibiotic prophylaxis was less consistently administered in other indications of EUS-FNA (perirectal lesions, 43 (58.1%) of 74 responses; pancreatic solid lesions, 10 (11.6%) of 86 responses). For sampling of pancreatic cysts, EUS-guided cyst wall brushing was rarely used (5 of 86 responses, 5.8%).
DISCUSSION

The main finding of our survey is that the sensitivity of EUS-FNA for the diagnosis of solid mass lesions was strikingly lower than that reported in the literature. Only one third of endosonographers reported a sensitivity > 80% and one fourth of them reported a sensitivity < 60%. For comparison, a median sensitivity of 83% was reported in a large review of 28 studies that reported the performance of EUS-FNA to differentiate benign vs malignant pancreatic masses, technically the most difficult location; only one of these 28 studies reported a sensitivity < 60%.[14] The relatively poor performance of EUS-FNA reported by endosonographers in this survey is unlikely to be due to reporting bias as respondents would likely have over-, not under-, estimated their sensitivity for the diagnosis of solid mass lesions.

Quality has become a central concern in endoscopy. The large variability in sensitivities reported by endosonographers (interquartile range of 25%-75%) suggests that there is much more room for quality improvement in EUS-FNA compared to other procedures that have long been scrutinized such as colonoscopy and endoscopic retrograde cholangio-pancreatography (ERCP). For comparison, (1) in the case of ERCP for instance, deep cannulation of the desired duct was validated as a measure of quality; it was achieved in 83.6% of 3210 patients undergoing their first ever ERCP in an audit of 76 endoscopy units[15]; and (2) regarding colonoscopy, cecal intubation rates ranged between 88% and 97% for 9 of 10 endoscopists investigated over a 6-year period.[16] No quality indicator has been recommended by the Societies of Gastrointestinal Endoscopy to assess the diagnostic accuracy of EUS-FNA[17]. Recently, the overall yield of malignancy for pancreatic masses was proposed as a benchmark for EUS-FNA[18].
Factors independently associated with a high sensitivity of EUS-FNA in our study included (1) the usage of ROSE to determine the number of needle passes or, if no ROSE was available, > 7 passes; (2) a high annual hospital caseload of EUS-FNA; and (3) routine isolation of microcores from EUS-FNA samples. The number of needle passes reported by approximately half of endosonographers was ≤ 3 for lymph nodes as well as for pancreatic masses, although a minimum of 5 or even 7 passes have been recommended for the pancreas when ROSE is not available (for lymph nodes, three needle passes are sufficient)[18-20]. In a study of pancreas EUS-FNA, sensitivity for malignant diagnoses increased from 16.7% with one needle pass to 86.7% if more than 7 passes were performed and another study showed that tumor differentiation was the single factor associated with the number of needle passes required to make a diagnosis[18,19]. The low number of needle passes performed by many endosonographers in the pancreas could be related to procedure duration (approximately five minutes are required per needle pass). To shorten procedure duration, Möller et al[21] have proposed to perform only two needle passes for solid pancreatic masses, to harvest microcores for histopathological examination and to subject the residual sample to cytopathological examination. Using this technique, they obtained a sensitivity of 82.9% in a multicenter retrospective study that included 192 patients. A new EUS-FNA needle could also facilitate acquisition of samples adequate for histopathological evaluation[22].

Of note, routine isolation of microcores was another independent factor associated with a high sensitivity in our survey. Microcores adequate for histopathological evaluation can be obtained in 83.9%-90.9% of EUS-FNA of pancreatic masses performed using a standard 22G needle (the model used by most of our survey respondents)[23,24]. Several nonrandomized studies have suggested that microcores are useful: (1) in the study by Möller et al[21], combined cytopathological and histopathological examination was more sensitive than cytopathological or histopathological examination alone for discriminating malignant vs benign pancreatic lesions using two needle passes (82.9% vs 68.1% vs 60.0%, respectively; P < 0.01); and (2) in a prospective series of 50 patients with lymphoma, a diagnostic accuracy of 96% was reached by examining microcores obtained using a 19G needle as compared with 57% in another series when cytopathological examination alone was considered[25,26]. Paraffin-embedded cell blocks might represent an alternative to microcore isolation, however, cell blocks are made in the laboratory, not in the endoscopy room, and thus out of the control of the endosonographer (one third of survey respondents did not know if cell blocks were made with the samples that they provided to the laboratory); furthermore cell blocks have not been as well studied as microcores.

ROSE was routinely available to 28% of endosonographers only, compared to 90% in a study performed among 21 centers in the United States, of which 81% were academic[27]. Anecdotal evidence suggests that low ROSE availability in EUS-FNA facilities may be related to logistical issues, lack of perceived benefit and cost even though ROSE has been shown to be cost-effective during EUS- and percutaneous-guided FNA in some settings[28-29]. Studies about the usefulness of ROSE to reach a high diagnostic yield are contradictory. A retrospective comparison of EUS-FNA performed by a single endosonographer in two university hospitals, one with ROSE available and the other without ROSE, is traditionally cited to support the usefulness of ROSE, but differences in patient populations and indications for EUS-FNA between the two hospitals preclude definitive conclusion[18]. In another, more recent, retrospective study of EUS-FNA for pancreatic masses with ROSE available for 43.8% of 520 procedures, ROSE was associated with a higher diagnostic yield in multivariate analysis (odds ratio, 3.1; P = 0.0001)[19]. Nevertheless, in a multicenter prospective study that evaluated 409 patients with 474 lesions[30], a similarly high diagnostic accuracy was achieved in centers regardless of ROSE availability and, in a prospective series of 108 consecutive EUS-FNAs performed without ROSE by a single endosonographer[29], diagnostic accuracy of EUS-FNA for pancreatic lesions was 97%. The authors of the latest study attributed their results to higher diagnostic accuracy and good endosonographer and cytopathology. Our finding that a high sensitivity of EUS-FNA was independently associated with ROSE and the annual hospital caseload supports that view.

A significant relationship between hospital caseload and quality has been demonstrated for few endoscopy procedures. For ERCP, a large administrative study showed that procedural failure rates were lower for inpatients undergoing ERCP at high- compared to low-volume US hospitals but the difference, albeit statistically significant because of the large sample size (> 2500 hospitals), was small (4.7% vs 6.0% in hospitals with an annual caseload ≥ 200 EUS-FNAs, respectively vs 6.0% in hospitals with an annual caseload ≥ 200 EUS-FNAs, respectively[31]). The difference in sensitivities reported by endosonographers in our study was much larger, with 15.0% vs 60.0% of endosonographers reporting a sensitivity greater than 80% depending if they worked in a hospital with an annual caseload < 50 vs > 200 EUS-FNAs, respectively (P = 0.024), as illustrated in Figure 2. This supports the view that centralization should be discussed for at least some of the EUS-FNA procedures, as has recently been proposed for ERCP[32]. Such a change would be important as only 8.2% of our survey respondents were referring patients to another endosonographer after a first inconclusive EUS-FNA.

Limitations of our survey include selection and recall bias: (1) surveyed endosonographers were working mostly in Western Europe and our findings may not apply to other locations; and (2) self-reported data are exposed to recall and goodwill biases because surveyed professionals tend to give the expected answer more than the real one, which indeed strengthens our main conclusion that the performance of EUS-FNA is significantly lower than...
assumed from published studies. In particular, sensitivity for the diagnosis of solid mass lesions was reported by 61 (37.8%) of 161 participants in the EUS course. Because of these limitations (recruitment of participants from a course, response rate), our conclusion that sensitivity for the diagnosis of solid mass lesions is strikingly lower in the community than reported in the literature should be confirmed by larger studies.

In conclusion, the quality of EUS-FNA, as assessed in this survey by its most crucial result, i.e., sensitivity for cancer diagnosis, was relatively low. Low quality was associated with unavailability of ROSE, low number of needle passes for pancreatic EUS-FNA, absence of routine microcore isolation and low annual hospital caseload. Efforts should be made to improve the quality of EUS-FNA amongst endosonographers; we suggest that endoscopists review their sensitivity for cancer diagnosis and, if this is < 80%, then they should modify their practice taking into account the factors cited above. These recommendations may be particularly valuable for endoscopists working in hospitals with a low annual caseload of EUS-FNA.

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