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EDITORIAL

Is It Time to Take a Pass on the Increased Number of Passes in EUS-FNA?

Shantel Hébert-Magee · Robert H. Hawes · Shyam Varadarajulu

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Despite the extensive use of endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA), there still exists a wide variation in the number of samples required to ensure acquisition of diagnostic material from pancreatic lesions. Although multiple passes can be performed during EUS-FNA, prolonging the procedure likely increases risk, decreases procedural efficiency, and increases the probability of samples being tainted with blood. It has been 21 years since EUS-FNA was used to obtain pancreatic tissue for cytologic analysis [1, 2], 16 years since the publication of the first reports evaluating the clinical impact and staging of pancreatic lesions sampled by EUS-FNA [3], and 14 years since the publication of the initial reports of the evaluation of the number of passes needed to obtain a diagnostic yield and the significance of on-site cytopathology during the procedure [4–7]. During this time, the focus has been on determining the necessity of on-site cytopathologic evaluation, the optimal number of needle passes, and the most effective needle type used for tissue acquisition. Despite numerous studies addressing these issues, many endoscopists are still perplexed about the nature of the best practices needed to ensure optimal results, in particular with regard to the need for on-site cytopathology for skilled and experienced endosonographers practicing at a high-volume center. To date, multiple meta-analyses have confirmed the diagnostic accuracy, cost-effectiveness, accuracy, and safety of EUS-FNA for solid pancreatic lesions [8–12]. Moreover, structured literature reviews have concluded that rapid on-site evaluation (ROSE) improves diagnostic accuracy [8, 9]. Notwithstanding these considerable successes, ongoing refinements to EUS-FNA continue to be explored.

Regardless of the likelihood that increasing numbers of passes raises the risk of needle failure, tissue injury, post-procedural complications, and medical expenses, the endosonographer is caught between the need to provide adequate tissue needed to optimize diagnostic yield weighed against the cost and risk of making additional passes. Failed EUS-FNA often engenders additional risk and expense due to the need to repeat EUS or to obtain tissue with radiologic or surgical guidance. Moreover, as treatment options for pancreatic cancer advance, rendering an onsite diagnosis alone may not be adequate, since additional tissue may be required to perform ancillary studies and molecular mapping. Nevertheless, ROSE may not be financially viable due to excess time commitment, limited resources, relatively low reimbursements, and acceptable adequacy rates achieved by more experienced endosonographers. In order to have a sustainable EUS practice with optimal clinical outcomes, it may be beneficial to provide some degree of ROSE training for endosonographers incorporating the "fanning" FNA technique combined with an algorithmic approach to needle selection [13–15].

In this issue of *Digestive Diseases and Sciences,* Schmidt et al. [16] examined current practices of lesion sampling, weighing diagnostic accuracy against the probability of adverse events in the presence and absence of ROSE. The authors provide empirical data regarding the diagnostic yield and performance characteristics of EUS-FNA of solid pancreatic lesions using mathematical modeling to determine the likelihood of adverse events with a fixed number of passes (no-ROSE) versus a variable number of passes (ROSE) while controlling for other variables. Schmidt and colleagues used a discrete-event simulation model to conclude that ROSE reduces the number of passes, thereby reducing the

S. Hébert-Magee · R. H. Hawes · S. Varadarajulu (✉)
Center for Interventional Endoscopy, Florida Hospital,
601 East Rollins Street, Orlando, FL 32803, USA
e-mail: svaradarajulu@yahoo.com

probability that adverse events will occur. The ability of these investigators to create a simulation model that adjusts for confounding variables (e.g., experience of the center, variability of patient characteristics, lesion size, and location) is quite convincing, even to those who inherently doubt the need for ROSE. Hence, the principal importance of the Schmidt et al. study is the use of unambiguous, unbiased, computational analysis in the formulation of the authors' conclusions.

As a pathologist and proponent of on-site evaluation (S.H.M.), I recognize the value of being present in the endoscopy suite during the procedure. Being on site enabled me to obtain clinical information that may not be available on the requisition form, evaluate the aspirated material, render a preliminary diagnosis when possible, triage the specimen appropriately, provide the endosonographer with procedure-altering information, and provide information that could expedite clinical management. In addition to the substantial time commitment, other objections to ROSE raised by pathologists may be due to a lack of specific training or experience with the specialized methods used. Unlike other EUS-FNA target tissues, the pancreas presents particular diagnostic challenges, especially for the inexperienced assessor, that can mostly be overcome with teams experienced with ROSE [17, 18].

The data presented by Schmidt et al. suggest that ROSE is mostly useful when the FNA procedure is being performed by a novice endosonographer, the lesion is technically challenging, or if the sampling technique is poor. These findings, combined with the published data, provide a compelling case to provide for ROSE universally in an effort to improve diagnostic accuracy while increasing patient safety.

While it may be impractical for onsite cytology assistance to be made available at every center, onsite evaluation of cytologic samples is definitely feasible, in light of the basic training in EUS-cytology increasingly provided to advanced endoscopy fellows [19] combined with the growing number of procedures being performed, the rising demand for EUS-FNA of solid pancreatic lesions, and the expectation of not only providing a diagnosis but also determining the need for ancillary studies and molecular characterization. In short, the independent endosonographer can no longer solely rely on a fixed number of passes to provide diagnostic sufficiency in many cases, but should have access to ROSE or be trained in EUS cytopathology in order to achieve optimal clinical outcomes.

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