Effect of a stylet on a histological specimen in EUS-guided fine-needle tissue acquisition by using 22-gauge needles: a multicenter, prospective, randomized, controlled trial

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Background: EUS-guided FNA (EUS-FNA) has become the most efficacious way to obtain specimens from a solid lesion adjacent to the GI tract. Previous reports regarding the use of a stylet during EUS-FNA were all based on cytological diagnosis and have showed no significant superiority in terms of diagnostic yield.

Objective: To clarify the noninferiority of EUS-FNA without a stylet (S−) compared with EUS-FNA with a stylet (S+) on histological assessment.

Design: A prospective, single-blind, randomized, controlled crossover study.

Setting: Five tertiary referral centers in Japan.

Patients: Patients referred for EUS-FNA of a solid lesion.

Intervention: EUS-FNA S+ and S− in a total of 4 alternate passes with randomization to S+ first or S− first.

Main Outcome Measurements: The primary endpoint was the acquisition rate of an appropriate and sufficient specimen for histological assessment. The secondary endpoints were cellularity, contamination, bloodiness, diagnostic ability, and diagnostic accuracy.

Results: We enrolled 107 patients (110 lesions) and analyzed 220 specimens each in the S+ and S− groups. The acquisition rate of appropriate and sufficient specimens in the S+ group was 121 of 220 (55.0%) and 122 of 220 (55.5%) in the S− group. The difference in the acquisition rate of the specimen (S− minus S+) based on the generalized estimating equation was 0.42% (95% confidence interval, −6.72% to 7.56%), which was less than 10% of the prespecified noninferiority margin of this study. With regard to cellularity, contamination, bloodiness score, diagnostic ability, and diagnostic accuracy, there were no significant differences between both groups. There were no dropouts in the study.

Limitations: A variety of target lesions, multiple pathologists, lack of an assessment of intraobserver and interobserver variability, and a single-blind study for the pathologists.

Conclusion: EUS-FNA S− is noninferior to EUS-FNA S+ on histological assessment. (Clinical trial registration number: UMIN000008695.) (Gastrointest Endosc 2015;82:837-44.)

Abbreviations: CI, confidence interval; EUS-FNA, EUS-guided FNA; H&E, hematoxylin and eosin; IHC, immunohistochemistry; ROSE, rapid on-site evaluation; S+, with a stylet; S−, without a stylet.

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Since EUS-guided FNA (EUS-FNA) was introduced into clinical practice in the early 1990s, it has met with widespread acceptance as one of the most useful methods for the diagnosis and staging of both GI and non-GI malignancies.[1,2] EUS-FNA has also become the easiest and most efficacious method with which to obtain samples from lesions in various organs adjacent to the GI tract.[3] Thus far, trials have studied the diameter of the FNA needle,[4-8] the number of punctures,[9,10] and negative pressure suction[11-13] in an effort to find the best method for obtaining high-quality samples during EUS-FNA.

Several reports have emphasized the need for a stylet during EUS-FNA,[2,14-19] but this remains controversial. Conventionally, EUS-FNA has been performed by using a stylet in the needle lumen to prevent blockage or contamination by the intestinal mucosa and allow more adequate aspiration of the target tissue. In a previous report, the use of a stylet did not demonstrate a statistically significant difference in the diagnostic accuracy of malignant lesions, but did decrease the amount of blood in the EUS-FNA specimen compared with that obtained without a stylet.[15] Moreover, a stylet is needed to maintain needle stiffness, allowing a puncture of a fibrotic lesion.[15] However, the use of a stylet can lead to increased procedure time and the risk of an unintentional needlestick injury,[2] especially when multiple passes are needed. One report indicated that use of a stylet did not improve the yield of EUS-FNA and lowered sample quality.[14]

Previous clinical studies[2,14-19] regarding stylet use were all based on cytological assessment alone, which is occasionally insufficient for the diagnosis of tumors of unknown origin or with a complex background. In many cases, a sufficient specimen is necessary to confirm the histological subtype of the tumor by immunostaining, especially in cases of unresectable tumors, for selecting a chemotherapy regimen.[20,21] Large-caliber cutting needles, such as side-port needles and core-biopsy needles, are generally used to obtain adequate specimens for histological assessment. However, these needles are difficult to use in some cases, such as when a puncture of the duodenum is needed to obtain a biopsy sample of a lesion in the head of the pancreas.[7] The thinner 22-gauge needles enable punctures of various sites and are usually used to obtain cytological specimens. Therefore, we attempted to clarify the effect of stylet use on the histological specimens obtained with a standard end-hole 22-gauge needle. This was a prospective, randomized, controlled trial involving more than 10 endoscopists at 5 tertiary referral centers.

METHODS

Study design

A multicenter prospective, single-blind, randomized, controlled trial was conducted at Hokkaido University Hospital, Sapporo Medical University Hospital, Gifu University Hospital, Gifu Municipal Hospital, and The University of Tokyo Hospital. This study was designed as a crossover investigation between EUS-FNA with and without the use of a stylet for each lesion and was approved by the institutional review board at each institution. All patients provided informed consent for the procedure, and the study was registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (no. 000008695).

Patients

Consecutive patients referred for EUS-FNA of a solid lesion in the pancreas, lymph node, left adrenal gland, upper GI tract, or mediastinum were prospectively enrolled in the study from August 2012 to January 2013. The inclusion criteria were (1) 20 years of age and older, (2) the ability to provide informed consent, and (3) the presence of a solid target lesion that was expected to be approached from the GI tract and confirmed by at least 1 other investigational modality such as CT, US, or EGD. The exclusion criteria were (1) an Eastern Cooperative Oncology Group performance status of 4, (2) American Society of Anesthesiologists Physical Status classification greater than 3, (3) inability to stop anticoagulation therapy, (4) pregnancy, (5) the inability to undergo an endoscopic approach, (6) already diagnosed through other investigations, (7) coagulopathy (prothrombin time/international normalized ratio >1.5), and (8) thrombocytopenia (platelet count $<$ 50,000/μL).

Procedure

EUS was performed with a curved linear array echoendoscope (GF-UC240P-AL5, GF-UCT240-AL5, or GF-UCT260; Olympus Medical Systems, Tokyo, Japan). The echoendoscope model was chosen by each endosonographer. All procedures were performed at the participating facility by an experienced endosonographer (>50 EUS-FNA procedures in the past year or >100 EUS-FNA procedures total). Procedures were performed with patients in the left lateral position under moderate conscious sedation with intravenous diazepam, midazolam, pethidine, or fentanyl.

For each lesion, 4 needle punctures were performed, 2 with a stylet (S+) and 2 without a stylet (S−). The order of these punctures was set in 1 of 2 patterns: (1) S+ puncture first: S+ → S− → S+ → S− and (2) S− puncture first: S− → S+ → S− → S+. The pattern used was randomized just before EUS-FNA by a computer-generated sequence. The endoscopist could not be blinded to the S+ or S− assignment of the passes.

The S+ puncture was performed as follows. The stylet was placed inside the needle leaving a few millimeters at the proximal side before puncture. The stylet was advanced and removed after puncture of the lesion. Needle strokes were performed without the stylet. Needles were changed between S+ and S− punctures;

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