A Prospective Multicenter Single-blind Randomized Controlled Trial Comparing FNA and FNB in the Diagnosis of Solid Masses

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ABSTRACT:

Background and Aims: Endoscopic ultrasound (EUS) guided fine needle biopsy (FNB) with side fenestration on the needle was developed aiming to obtain both cytological aspirates and histological core samples. To reveal the diagnostic yield of FNB sampling solid mass compared to standard fine needle aspiration (FNA), we conducted a large-scale multicenter study in patients with pancreatic and non-pancreatic masses. We also aimed to establish optimal techniques in EUS tissue acquisition.

Methods: This was a prospective multicenter single-blind randomized controlled trial. Between December 2014 and January 2016, 408 patients were enrolled from five tertiary-care academic medical centers and randomized at a 1:1 ratio to receive either 22G FNA or 22G FNB. Two tissue acquisition (TA) techniques (1^{st} and 2^{nd} passes using slow pull vs. 3^{rd} and 4^{th} passes using suction methods) were performed on all EUS needles. The primary outcome was the diagnostic yield comparing FNA and FNB on all solid lesions, pancreatic and non-pancreatic masses, respectively. Secondary endpoints were the quality of the histologic specimen (quantity of cell, tissue integrity, and blood contamination).

Results: In all examined lesion, FNB group (n=190) provided superior histological diagnostic yield than FNA group (n=187) (91.44% vs. 80%; p = 0.0015). For pancreatic mass, FNB group (n=123) achieved better histological diagnostic yield compared to FNA group (n=126) (92.68% vs. 81.75%; p = 0.0099), and also higher cytological diagnostic yield (88.62% vs. 79.37%; p = 0.00468), respectively. For non-pancreatic mass, there was

no difference between FNB and FNA on diagnostic accuracy. Furthermore for pancreatic mass, when slow pull technique was applied in the first and second passes, FNB was superior to FNA on specimen quality and diagnostic yield.

Conclusions: The overall diagnostic yield using EUS-FNB was higher compared to EUS-FNA. For examining pancreatic mass when slow pull technique was applied in the first two passes, FNB also achieved better histological diagnostic yield and higher cytological diagnostic yield.

Trial registration: Clinical Trials.gov, NCT02327065.