DDW2025
Digestive Disease Week®

MAY 3–6, 2025 | SAN DIEGO, CA

Evaluation of a Novel Motorized EUS-Guided Fine-needle Biopsy Device and Pathology Quality Parameters Comparison to Standard Fine-needle Biopsy: A Prospective Pilot Study

Carlos Robles-Medranda, MD[1], FASGE; Jorge Baquerizo-Burgos, MD[1]; Maria Egas-Izquierdo, MD[2]; Miguel Puga-Tejada, MD[1]; Juan Murillo, MD[1]; Cristina Elias-Berrezueta, MD[1]; Martha Arevalo-Mora, MD[1,2]; Juan Alcívar-Vásquez, MD[1]; Domenica Cunto, MD[1]; Daniela Tabacelia, MD[3,4]

Affiliations: 1. Instituto Ecuatoriano de Enfermedades Digestivas (IECED), Guayaquil, Ecuador. 2. Larkin Community Hospital Inc., South Miami, FL, United States. 3. Elias Emergency University Hospital, Bucharest Romania. 4. University of Medicine and Pharmacy Carol Davila, Bucharest, Romania.

INTRODUCTION & AIM

The actual efficacy of endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) in practice depends on the site, size, target tissue characteristics, as well as the availability of a cytopathologist for on-site diagnosis (1,2). Fine-needles designed to obtain biopsy (FNB) specimens allow core samples to be collected. Precision-GI (Limaca Medical, Israel) is a novel motorized EUS-FNB (mFNB) which enables increased yield, bigger sample size retrieval with improved quality and fewer needle passes, providing tissue with preserved architecture and less blood contamination, enabling better histological analysis.

We aim to evaluate the safety, efficacy and comfortability of the mFNB and compare its performance to a standard FNB (sFNB).

METHOD

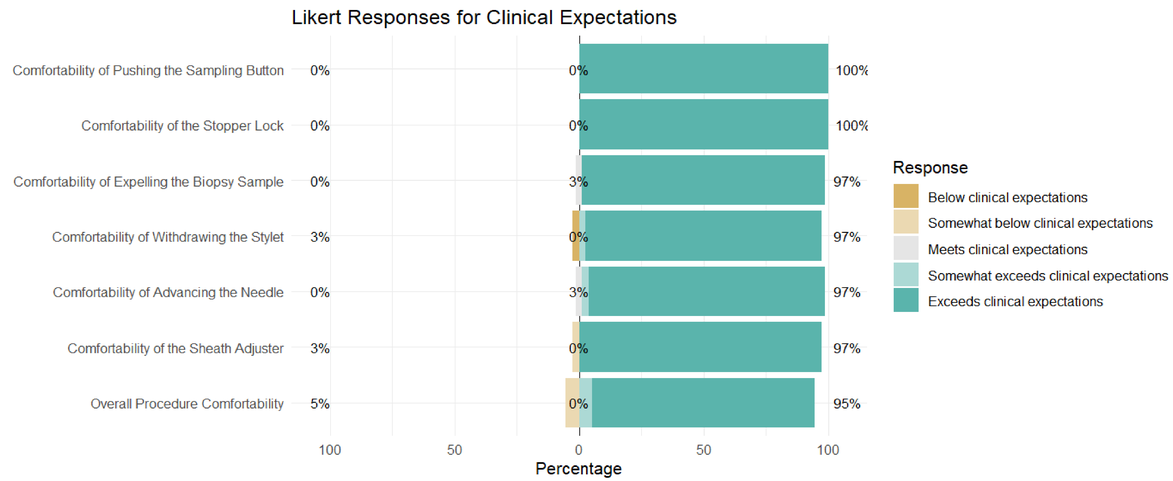
A single-center, prospective, pilot study performed in patients who were at least 18 years old, requiring EUS-FNB due pathologies such as submucosal lesions, mediastinal and pancreatic lesions, lymph nodes and intraperitoneal masses, from September 2023 to November 2024 at the Instituto Ecuatoriano de Enfermedades Digestivas, Guayaquil, Ecuador.

RESULTS

Forty participants were included, mean age was 65,0 (57.8 - 69.2) and 57.5% were female. Most biopsies were hepatic (55%), mean number of stabs was 4 (±2). A mild adverse event (gastric mucosal laceration) was reported with mFNB (2.5%). The mFNB obtained a 97.5% technical success. Biopsy was definitive in 95% with 2 cases reporting inadequate samples.

When comparing mFNB vs sFNB performance: mFNB blood contamination was reported as lower than 25% in 95% of cases, while 65% of sFNB samples had low contamination. Both FNB samples had adequate fragments (arquitecturally intact tissue) of 97.5%. 67.5% of mFNB samples were multiple fragments with at least one >5 mm in length and 30% at least one fragment >10mm; 82.5% of sFNB samples were >5 mm in length (15% had one fragment >10mm). A median number of portal triads observed 6 (4-8) with mFNB, and 2 (0.5-2.75) with sFNB.

Comfortability of the mFNB was evaluated using a 5-Point Likert Scale, considering: determining a preferred sheath length by adjusting the sliding sheath adjuster, comfortable to adjust the stopper lock position, comfortable to advance the needle into the lesion, comfortable to withdraw the stylet, comfortable to sample tissue by pushing the sampling button, comfortable to expel the biopsy sample. All parameters obtained a high agreement (>95%).



CONCLUSIONS

mFNB is safe and efficient to perform during EUS-FNB, with low adverse event rates and high technical success. Operators indicated high clinical expectations and comfortability regarding the different components of the needle. mFNB obtained larger tissue samples with less blood contamination compared to sFNB.

REFERENCES

1. Endoscopic ultrasound fine-needle aspiration vs. fine-needle biopsy: tissue is always the issue Endosc Int Open. 2016 May; 4(5): E506–E507. Eduardo Rodrigues-Pinto,, Ian S. Grimm, and Todd H. Baron

2. Current status of diagnostic endoscopic ultrasonography in the evaluation of pancreatic mass lesions. Dig Endosc. 2011;23 01:17–21 Itoi T, Sofuni A, Itokawa F. et al

ACKNOWLEDGEMENTS

None.