

SINGLE-USE ULTRASOUND ENDOSCOPE ATTACHED TO A STANDARD SCOPE: FIRST HUMAN CASES AND RESULTS OF A PROSPECTIVE PILOT STUDY

Robles-Medranda, Carlos¹; Arevalo-Mora, Martha¹; Puga-Tejada, Miguel¹; Alcívar-Vásquez, Juan M.¹; Del Valle, Raquel S.¹; Cohn, Josh²; Corbett, Scott²; Steinberg, Stephen²

¹ Endoscopy, Instituto Ecuatoriano de Enfermedades Digestivas, Guayaquil, Guayas, Ecuador

² EndoSound, Portland, OR, United States

BACKGROUND

Endoscopic ultrasound (EUS) allow real-time assessment, diagnosis, and endoscopic treatment of the gastrointestinal (GI) tract and its surrounding structures with high-resolution imaging. Current costly and very sophisticated EUS systems are required to perform EUS-guided interventions. Recently, a new, portable, low-cost concept of EUS device system has been developed to fasten onto any standard gastroscope.

AIMS

We aim to determine the feasibility, effectiveness, and safety of a new, single-use, EUS device system for visualization of GI anatomic structures and the performance of endoscopic procedures.

METHODS

We reported a prospective pilot study using this new, add-on, EUS device system, of the first five human cases referred for EUS-guided evaluation and/or intervention, between October and November 2021. Patients aged > 18 years were included and tendered to two consecutive procedures: first, a standard EUS (S-EUS) intervention using a therapeutic linear echoendoscope (Pentax EG38-J10UT; Pentax Medical, Hamburg, Germany), Pentax video processing (EPK-I7010), attached to an ultrasound console (Arietta 850 Hitachi, Tokyo, Japan). For the second intervention, a new adaptable EUS (N-EUS) was performed using a therapeutic linear endoscope (EG-2990I10, Pentax Medical, Hamburg, Germany) attached to a dedicated compact ultrasound beamformer (EndoSound Vision System (EVS), EndoSound, Portland - Oregon, USA) following manufacturer's instructions for use. The institutional review board approved the study protocol, and the study was conducted according to the Declaration of Helsinki and Strobe Statement. All patients provided written informed consent prior to any procedure.

RESULTS

Enrolled patients were evaluated by S-EUS and N-EUS using linear therapeutic scopes. Optimal endoscopic procedure performance and high-quality visualization of all anatomical structures was achieved with N-EUS. 1/5 patients required EUS-guided fine needle biopsy (EUS-FNB) due to a pancreatic head lesion. EUS-FNB was performed with S-EUS and N-EUS; pancreatic adenocarcinoma was confirmed in both samples. No immediate post-procedural complications were reported in any participant.

CONCLUSIONS

This new EUS system may be a feasible, effective, and safe alternative for accurately diagnosing GI pathologies and for enabling therapeutic endoscopic procedures with precise localization and high-quality imaging. Large case series and prospective cohorts are required to evaluate this device in clinical practice.

DISCLOSURES

Carlos Robles-Medranda is a consultant for Pentax Medical, Boston Scientific, Steris, Medtronic, Motus, Micro-tech, G-Tech Medical Supply, CREO Medical, and Mdconsgroup. The other authors declare no conflicts of interest.

