

EndoDrill® Model X Biopsy Instrument, The Advent of the First EUS Guided 17 Gauge Core Needle Biopsy

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PURPOSE / OBJECTIVES

Endoscopic ultrasonography (EUS) assisted fine-needle aspiration/biopsy (FNA/FNB) has been in clinical use for many years in order to diagnose gastrointestinal lesions. However, even if the fine-needle technique is well established in clinical practice, it bears diagnostic shortcomings since the samples tend to contain smallish amounts of cells or fragments. For optimal and more accurate diagnostics, it is crucial to collect representative core needle biopsies (CNB). We present clinical results from a pilot study using EndoDrill® Model X (BiBBInstruments AB, Lund, Sweden) – a new electromechanically driven, 17 gauge, EUS biopsy instrument enabling EUS-CNB.

MATERIAL & METHODS

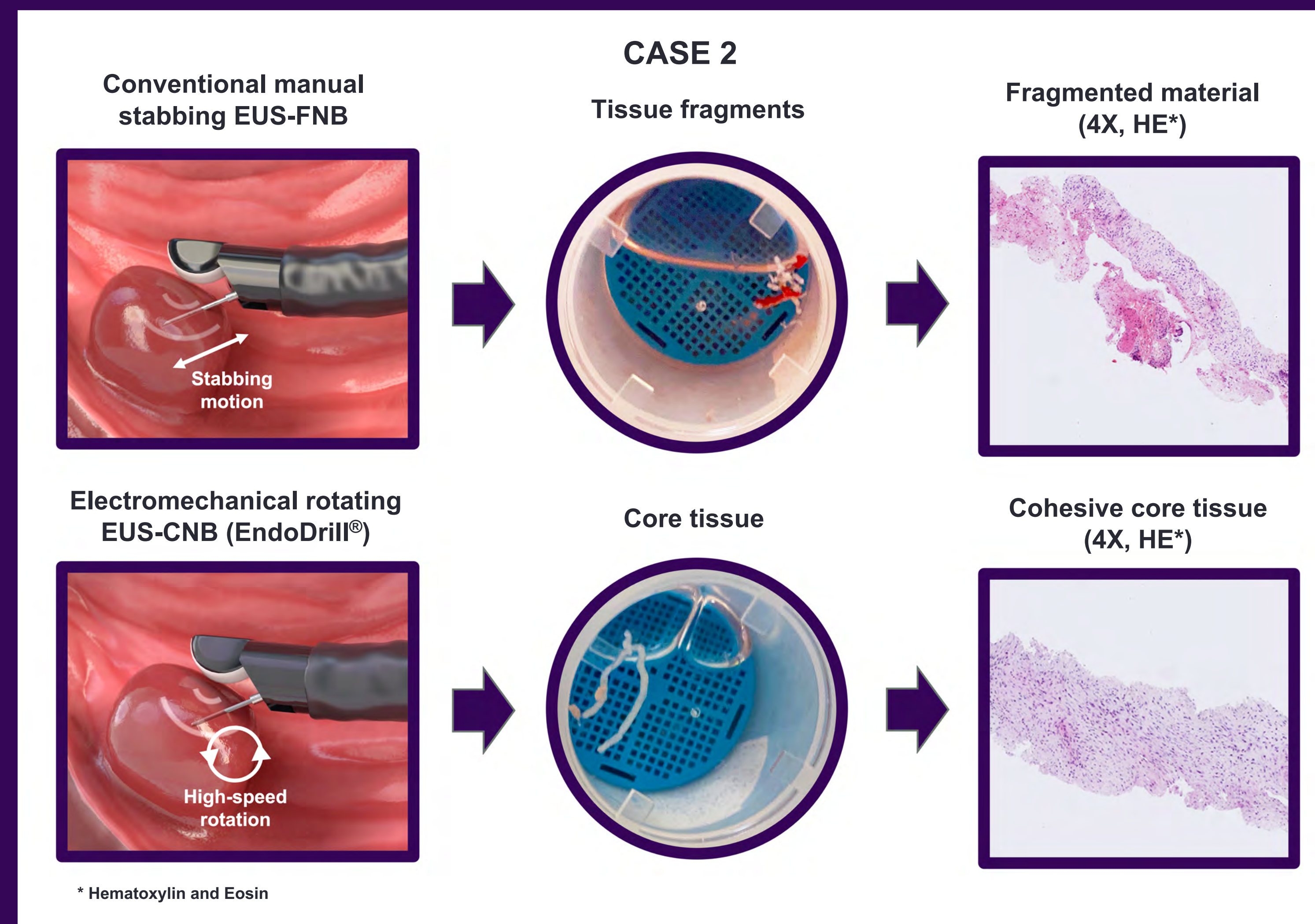
We conducted an investigator led prospective open label, intention to treat and safety control study, using EndoDrill® Model X biopsy vs. standard sampling with FNB. According to criteria of inclusion and informed consent, 7 patients (female n=4, median 71 y, range 28-75) with undetermined submucosal lesions (median size 30 mm, range 17-90) in the upper GI-tract (stomach n=6, duodenum n=1) were eligible and followed up 14 days after index procedure.

Seven investigations were completed with both techniques applied at the same time and according to protocol, the order of which instrument to start with was decided by randomization. FNB: 2 punctures with 4 fanning passes and CNB: 2 punctures with 3 fanning passes. Conscious sedation was used in 6 patients and general anaesthesia in 1 patient.

For more information about the novel EndoDrill® EUS-CNB instrument, please scan the QR code.

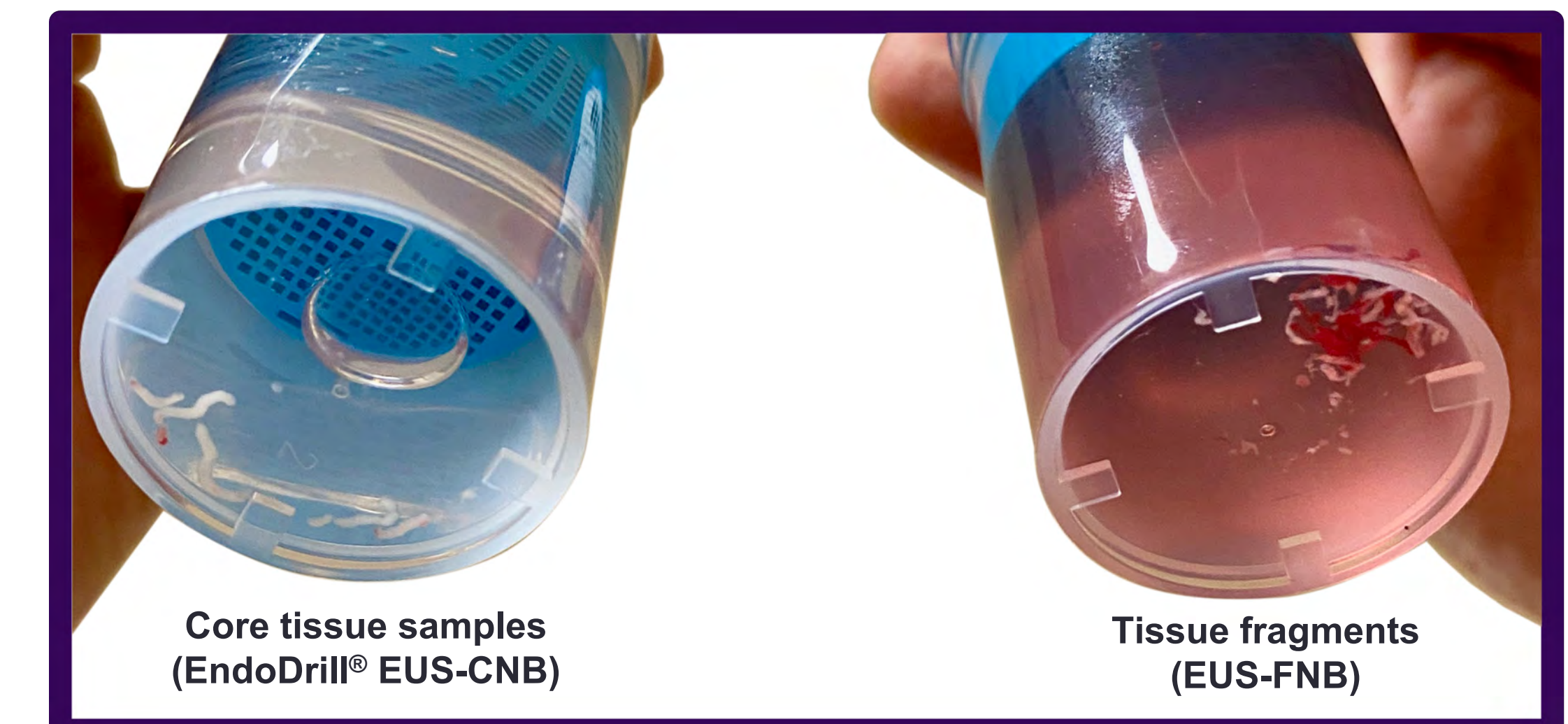
RESULTS

- Quality of the FNB and CNB samples were assessed as “visible pieces” (>5 mm): FNB (n=5/7) (fragmented/blood imbibed n=1, poor tissue quantity n=1) compared with CNB (n=7/7).
- Histological diagnosis could be obtained with CNB in all 7 patients. FNB technique reached correct diagnosis in six patients with one case (GIST) non-diagnostic due to no evaluable cell material.
- One transient mild bleeding was noticed at examination. No other adverse events noted. At 14-d follow-up 1 patient had experienced a transient nausea that could not be related to the procedure per se.



RESULTS

CASE 3



CASE 1 – 7

Case	Age (years)	Sex	Tumor localization	Tumor size	EndoDrill® histological diagnosis	EUS- FNB histological diagnosis
1	72	Female	Stomach	49 mm	GIST	No material
2	28	Female	Stomach	90 mm	Desmoid	Desmoid
3	75	Female	Stomach	30 mm	Adenocarcinoma	Adenocarcinoma
4	52	Female	Duodenum	30 mm	Neuroendocrine tumor	Neuroendocrine tumor
5	71	Male	Stomach	17 mm	Schwannoma	Schwannoma (artefacts)
6	55	Male	Stomach	25 mm	Leiomyoma	Leiomyoma
7	64	Male	Stomach	35 mm	Leiomyoma	Leiomyoma

SUMMARY / CONCLUSION

This is the first pilot study demonstrating a novel EUS-guided electromechanical core needle biopsy (EUS-CNB) instrument on seven patients with submucosal gastrointestinal lesions. The results show accurate and safe sampling which provides a true 17 gauge cylinder core from the area of interest. Compared with standard FNB samples, the EndoDrill® Model X can provide coherent histological specimens that can be handled and prepared in the same manner as standard core needle samples e.g. breast and prostate cancer.