# D0005 (S8) Pilot Trial of Endoscopic Ultrasound-Guided Fiducial Marker Placement to Facilitate Intraoperative Management of Pancreas Tumors

Patrick W. Chang, MD, Jonathan Sadik, MD, Wissam Kiwan, MD, Ravi J. Kankotia, MD,
Christopher Ko, MD, Jessica Serna, MS, Alex Rodriguez, BS, Helen Lee, ANPC, Mohd Raashid Sheikh, MD, Ara B. Sahakian, MD, James L. Buxbaum, MD MS

## Problem

- Small neuroendocrine tumors and selected adenocarcinoma may be amenable to minimally invasive pancreatic surgery. However, lesions may be difficult to localize intraoperatively.
- Currently, Endoscopic Ultrasound (EUS) is used to place fiducial coils to guide stereotactic radiation therapy of pancreatic tumors.
- This trial studies fiducials placed into tumors at the time of tissue sampling with the specific intent to guide pancreatic surgery.

## Methods

- This is a prospective trial of 20 patients with pancreas masses that underwent EUS with fine needle biopsy (EUS-FNB) with rapid-on-site evaluation (ROSE) followed by EUS with fiducial marker placement (EUS-FMP) using the same multi-purpose delivery system (NCT02863783).
- The main outcomes included the technical success of EUS-FMP and ease of detection of tumor during subsequent pancreatic surgery.
- Secondary outcomes include post-EUS-FMP complications including pancreatitis, abdominal pain, infection and bleeding up to 3 months following placement.
- At intervention, the surgeon's real time impression of tumor detection by intraoperative ultrasound and palpation was record by a dedicated research coordinator.
- A Single Sample *t* was calculated for the difference between the rated ease of fiducial detection (10 most facile, 0 most challenging) and the predetermined comparator of 5 for surgery for an equivalent lesion without fiducial placement.

## Sponsorships

- This study was sponsored by Medtronic. We appreciate their support of patient care and the advancement of pancreaticobiliary research.

**Figure 1. Screening, enrollment and patient outcomes for 20 of 96 patients**

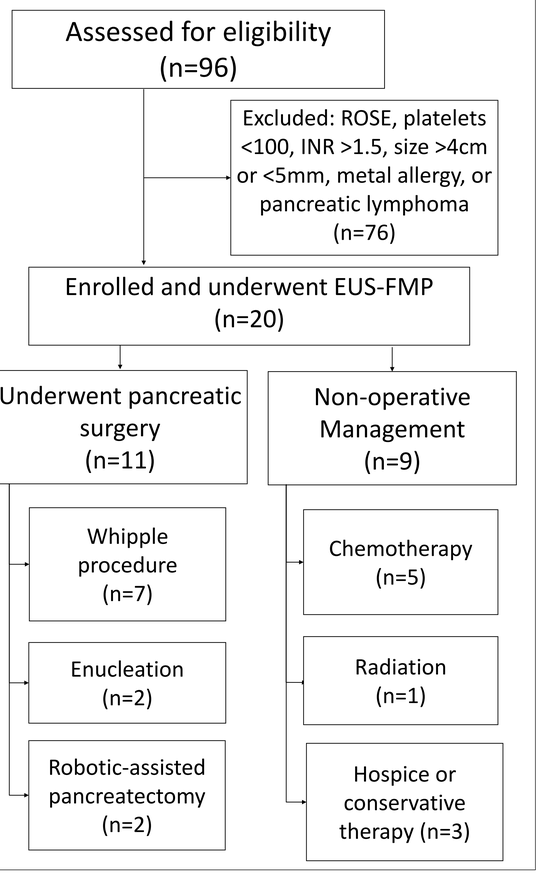



**Table 1: EUS features of patients undergoing EUS-FMP**

| Patient characteristics | |
|---|---|
| **mean (SD)** | |
| *Age (y)* | 58 (14) |
| *Body Mass Index* | 25 (4) |
| *Reported Weight Loss (lb)* | 16 (16) |
| **N (%)** | |
| *Female Gender* | 12 (60) |
| *Hispanic Ethnicity* | 11 (55) |
| *Diabetes* | 6 (30) |
| *Prior Pancreatitis* | 2(10) |
| **EUS features** | |
| **mean (SD)** | |
| *Pancreatic duct (mm)* | 3.7 (1.6) |
| *Bile duct diameter (mm)* | 9.8 (6.2) |
| *Biopsy needle passes* | 4(3) |
| *Fiducials placed* | 2 |
| ***Sonographic findings*** | |
| **N (%)** | |
| *Hypoechoic* | 10 (50) |
| *Heterogenous* | 9 (45) |
| *Hyperechoic* | 1 (5) |
| **Rapid-on-Site Cytology Results** | |
| *Adenocarcinoma* | 13 (65) |
| *Neuroendocrine* | 6 (30) |
| *Solid pseudopapillary tumor* | 1 (5) |

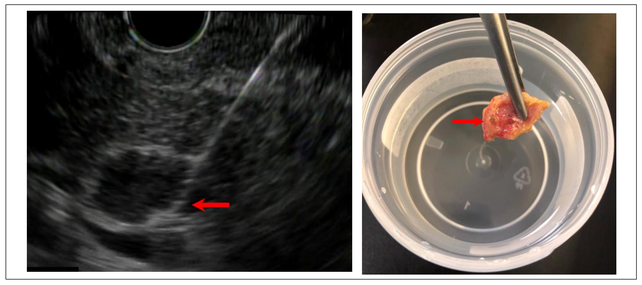
**Table 2. Outcomes of endoscopy and surgery of patients undergoing EUS-FMP**

| Procedure | N | | | |
|---|---|---|---|---|
| **Endoscopy** | | **Technical Success N(%)** | **Reported Ease of Placement (1-10 +/- SD)** | **Adverse Events** |
| **Any EUS - FMP** | **20** | **20 (100%)** | **9.1 +/- 1.3** | **1(5%)** |
| *EUS FMP and EUS FNB* | 10 | | | |
| *EUS FMP, EUS FNB and ERCP* | 10 | | | |
| **Surgery** | | **Tumor size Mean +/-SD** | **Reported Ease of Detection (1-10 +/- SD)** | **p-value*** |
| **Pancreatic resection** | **11** | **1.7 +/- 0.9** | **7.8 +/- 2.2** | **0.011** |
| *Surgery for pancreatic adenocarcinoma* | 7 | | | |
| *Surgery for pancreatic neuroendocrine tumor* | 4 | | | |

## Results

- Between January 2017 and March 2022, twenty patients had successful EUS-FMP following tissue sampling using a multi-purpose delivery system.
- On final pathology, a total of thirteen patients had pancreatic adenocarcinoma, six had neuroendocrine tumors, and one patient had a solid pseudopapillary neoplasm.
- Ultimately, eleven patients underwent surgery, and all had negative surgical margins on final pathology. For patients that underwent surgical excision, the mean tumor size on EUS was 1.7+/- 0.9 cm (range: 0.5-3.6 cm).
- Real-time assessment indicated that fiducials improved tumor detection (7.8+/-2.2, p=0.011).
- One of twenty patients developed post-EUS pancreatitis.

**Figure 2a-b. EUS Guided FMP; Fiducial in surgical pathology**



## Conclusion

- EUS-guided fiducial placement is a feasible and safe technique that may facilitate pancreatic surgery.
- Multipurpose platforms which combine biopsy with fiducial placement enable tumors to be simultaneously sampled and precisely marked for resection.

## References

- Bockhorn M, Uzunoglu FG, Adham M, et al. Borderline resectable pancreatic cancer: A consensus statement by the International Study Group of Pancreatic Surgery (ISGPS). Surgery. 2014;155(6):977-988.
- Park WG, Yan BM, Schellenberg D, et al. EUS-guided gold fiducial insertion for image-guided radiation therapy of pancreatic cancer: 50 successful cases without fluoroscopy. Gastrointest Endosc. 2010;71(3):513-518.
- BeaconTM FNA Exchange System | Medtronic. Accessed June 2, 2022