

CORE

Centro Oncologico ed Ematologico Reggio Emilia



# *Gli aghi per biopsia EUS guidata*

**PERUGIA 2-3 Febbraio 2022**
**Sala U. Mercati**
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aigo

Associazione Italiana Gastroenterologi
& Endoscopisti Digestivi Ospedalieri

EUS aigo Academy

# Endosonographically-Guided Fine Needle Aspiration Biopsy of Malignant Lesions in the Upper Gastrointestinal Tract

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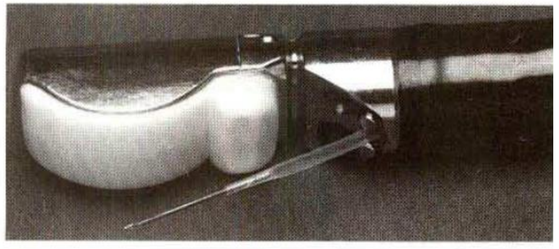


**Figure 1:** Tip of the ultrasonic endoscope with a prototype 1 needle. The needle is introduced into the biopsy channel which ends close to the optic lens. The curved array ultrasonic transducer is mounted at the tip of the endoscope enabling the needle to be introduced into a sector shaped sound field. The needle can therefore be visualized through the optics as well as on the ultrasound image.




**Table 2** Results in the diagnosis of malignant and benign lesions by means of EUS guided fine needle aspiration biopsy.

| Needle prototype | Malignant lesions: Diagnosis | Number | Site | | Benign lesions: Diagnosis | Number | Lesion type | |
|---|---|---|---|---|---|---|---|---|
| Prototype 1 | conclusive | 3 | esophagus | 2 | | | | |
| | | | pancreatic body | 1 | conclusive | 5 | gastritis | 4 |
| | | | | | | | pancreatic cystadenoma | 1 |
| | inconclusive or negative | 8 | stomach | 4 | | | | |
| | | | pancreas | 1 | inconclusive or negative | 6 | gastric lipoma | 1 |
| | | | common bile duct | 1 | | | gastric leiomyoma | 1 |
| | | | mediastinal mesothelium | 1 | | | gastritis | 2 |
| | | | abdominal lymph nodes | 1 | | | chronic pancreatitis | 2 |
| Prototype 2 | conclusive | 4 | pancreas | 1 | | | | |
| | | | colon | 1 | | | | |
| | | | stomach | 1 | | | | |
| | | | lymph node | 1 | inconclusive or negative | 1 | esophageal leiomyoma | 1 |
| | inconclusive or negative | 4 | esophagus | 2 | | | | |
| | | | stomach | 2 | | | | |
| Prototype 3 | conclusive | 7 | esophagus/cardia | 3 | | | | |
| | | | stomach | 1 | | | | |
| | | | pancreas | 1 | | | | |
| | | | common bile duct | 1 | | | | |
| | | | lymph node | 1 | | | | |
| | inconclusive or negative | 1 | stomach | 1 | | | | |

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Review

# Preoperative tissue diagnosis for tumours of the pancreas

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**Results:** The analysis included 53 studies, mostly of a retrospective nature. Despite acceptable rates for sensitivity and specificity, the negative predictive value of percutaneous and endoscopic ultrasonography-guided biopsies was 60–70 per cent. Biopsy results were considered to be essential for directing non-surgical therapy in advanced disease. However, they were of limited value in planning the treatment of resectable solid or cystic tumours, or focal lesions in the setting of chronic pancreatitis.
**Conclusions:** Biopsy of suspected pancreatic malignancies with systemic spread or local irresectability is indicated for planning palliative or neoadjuvant therapy. Preoperative biopsy of potentially resectable pancreatic tumours is not generally advisable, as malignancy cannot be ruled out with adequate reliability.

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Published online 17 November 2008 in Wiley InterScience (www.bjs.co.uk). **DOI:** 10.1002/bjs.6407

**Table 2** Sensitivity, specificity, negative predictive value and accuracy of endoscopic ultrasonography-guided fine-needle aspiration of pancreatic masses: results of studies published since 1997

| Reference | Year | No. of patients | Sensitivity (%) | Specificity (%) | NPV (%) | Accuracy (%) |
|---|---|---|---|---|---|---|
| Ross *et al.*[51] | 2008 | 87 | 85 | 100 | 63 | 88 |
| Maluf-Filho *et al.*[52] | 2007 | 74 | 83 | 91 | 48 | 84 |
| Rocca *et al.*[53] | 2007 | 205* | 83 | 89 | 69 | 84 |
| Ardengh *et al.*[54] | 2007 | 611 | 78 | 99 | 77 | 87 |
| Eloubeidi *et al.*[55] | 2007 | 547 | 95 | 92 | 80 | 94 |
| Iglesias-Garcia *et al.*[56] | 2007 | 56† | 84 | 100 | 92 | 90 |
| Mitsuhashi *et al.*[57] | 2006 | 267 | 95 | 100 | 82 | 96 |
| Horwhat *et al.*[34] | 2006 | 41 | 84 | 100 | 73 | 89 |
| Wittmann *et al.*[58] | 2006 | 83 | 60 | n.r. | 65 | 77 |
| Wakatsuki *et al.*[59] | 2005 | 53 | 93 | 100 | 79 | 94 |
| Ryozawa *et al.*[60] | 2005 | 52† | 82 | 100 | 79 | 89 |
| Volmar *et al.*[36] | 2005 | 489 | 80 | 99 | 73 | 87 |
| Agarwal *et al.*[61] | 2004 | 81 | 89 | 100 | 56 | 90 |
| Raut *et al.*[62] | 2003 | 233 | 91 | 100 | 44 | 92 |
| Afify *et al.*[63] | 2003 | 69 | 80 | 82 | 45 | 80 |
| Fritscher-Ravens *et al.*[64] | 2002 | 130‡ | 89 | 100 | 71 | 92 |
| | | 70§ | 54 | 100 | 91 | 91 |
| Mallery *et al.*[37] | 2002 | 68 | 74 | 100 | 27 | 76 |
| Harewood *et al.*[65] | 2002 | 185 | 94 | 71 | n.r. | 92 |
| Ylagan *et al.*[66] | 2002 | 80 | 78 | 100 | 78 | n.r. |
| Brandwein *et al.*[67] | 2001 | 43*† | 60 | 100 | 29 | 65 |
| Voss *et al.*[68] | 2000 | 90 | 75 | 88 | 26 | 74 |
| Williams *et al.*[69] | 1999 | 144 | 72 | 100 | 38 | 76 |
| Wiersema *et al.*[70] | 1997 | 164 | 83 | 90 | 80 | 85 |
| Baron *et al.*[71] | 1997 | 47¶ | 86 | 100 | 40 | n.r. |
| Chang *et al.*[72] | 1997 | 47 | 83 | 80 | 86 | 88 |
| Bhutani *et al.*[73] | 1997 | 47 | 64 | 100 | 16 | n.r. |
| Gress *et al.*[74] | 1997 | 121 | 80 | 100 | 91 | 85 |
| Faigel *et al.*[75] | 1997 | 41† | 94 | 100 | 82 | n.r. |
| Median (range) | | 81 (41–611) | 83 (54–95) | 100 (71–100) | 72 (16–92) | 88 (65–96) |

# EUS-guided FNA for diagnosis of solid pancreatic neoplasms: a meta-analysis

Volume 75, No. 2 : 2012 GASTROINTESTINAL ENDOSCOPY

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London, United Kingdom

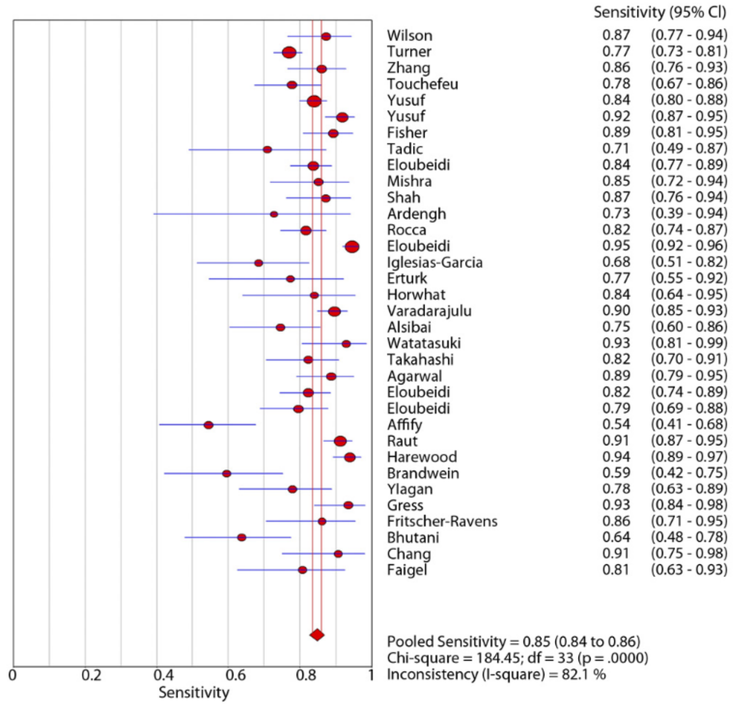



**Figure 2.** Forrest plot of sensitivity where malignant cytology alone was the determinant of a positive result (classification 1). CI, confidence interval; df, degrees of freedom.

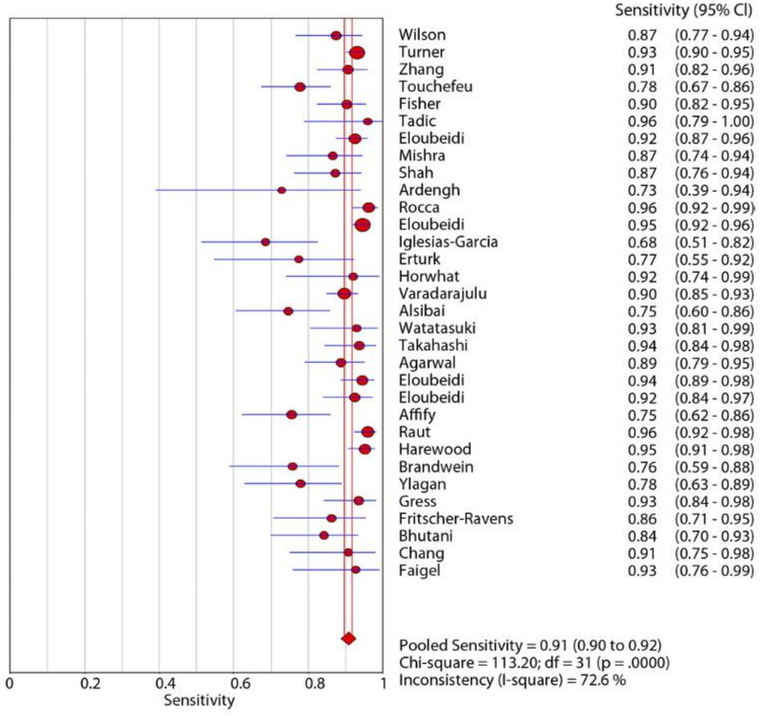



**Figure 5.** Forrest plot of sensitivity where atypical, suspicious, and malignant cytology was the determinant of a positive result (classification 2). CI, confidence interval; df, degrees of freedom.

**Results:** Thirty-three studies published between 1997 and 2009 were included, with a total number of 4984 patients. The pooled sensitivity for malignant cytology was 85% (95% confidence interval [CI], 84-86), and pooled specificity was 98% (95% CI, 0.97-0.99). If atypical and suspicious cytology results were included to determine true neoplasms, the sensitivity increased to 91% (95% CI, 90-92); however, the specificity was reduced to 94% (95% CI, 93-96). The diagnostic accuracy of EUS-FNA was enhanced in prospective, multicenter studies.

# False positive endoscopic ultrasound fine needle aspiration cytology: incidence and risk factors

Ferga C Gleeson,[1] Benjamin R Kipp,[2] Jill L Caudill,[2] Jonathan E Clain,[1] Amy C Clayton,[2] Kevin C Halling,[2] Michael R Henry,[2] Elizabeth Rajan,[1] Mark D Topazian,[1] Kenneth K Wang,[1] Maurits J Wiersema,[1] Jun Zhang,[2] Michael J Levy[1]

**Results** FNA was performed in 5667/18 066 (31.4%) patients undergoing EUS, of whom 2547 had cytology results interpreted as 'positive' or 'suspicious' or 'atypical' for malignancy or neoplasm. Subsequent surgical resection without prior neoadjuvant therapy was performed in 377 patients with positive or suspicious cytology. The FP rate was 20/377 (5.3%) and increased to 27/377 (7.2%) when FS cases were included. The incidence of discordance was consistent over time (1996—2002: 10/118 (8.6%) vs 2003—2008: 17/259 (6.6%); p=0.5) and was higher in non-pancreatic FNA (15%) than pancreatic FNA (2.2%; p=0.0001). Two-thirds of the non-pancreatic FP cases involved sampling of perioesophageal or perirectal nodes in patients with luminal neoplasms or Barrett's oesophagus.

*Gut* 2010;**59**:586—594. doi:10.1136/gut.2009.187765

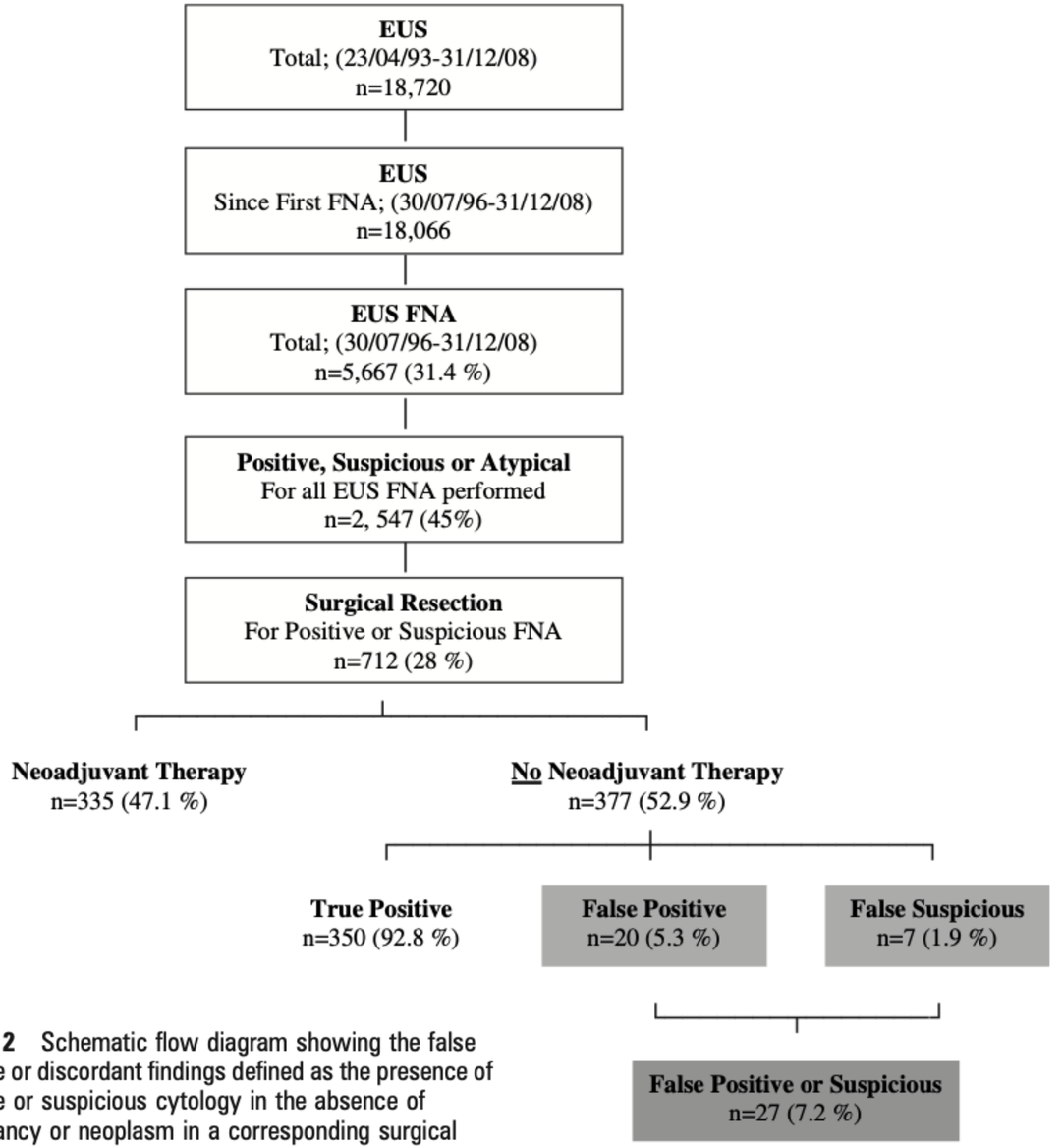



**Figure 2** Schematic flow diagram showing the false positive or discordant findings defined as the presence of positive or suspicious cytology in the absence of malignancy or neoplasm in a corresponding surgical pathology specimen. EUS, endoscopic ultrasound; FNA, fine needle aspiration.

Open Access

# Introduction; Value of Endoscopic Ultrasound-Guided Fine Needle Aspiration

**Eun Young Kim**

Department of Internal Medicine, Catholic University of Daegu School of Medicine, Daegu, Korea

## THE LIMITATION AND PERSPECTIVE OF EUS-FNA

EUS-FNA has become an essential diagnostic tool and almost routinely performed to evaluate submucosal lesions and stage esophageal, gastric, rectal, and pancreaticobiliary malignancies in many hospitals. However the reported accuracies of EUS-FNA vary according to the locations and characteristics of the lesions. Reported sensitivities of EUS-FNA differ vastly based on performers' skill and equipments used. EUS-FNA is a difficult technique to become proficient with a prolonged learning curve.[3] Therefore, one of the drawbacks of EUS-FNA is that the results are operator-dependent and endosonographer's experience is a crucial factor. Every endosonographer who wants to improve their diagnostic yield should be diligent on getting useful technical tips from experts. In ad-

Related to target lesion (location, size, characteristics, presence of fibrosis or chronic pancreatitis)

Technical details (type of needle used, aspiration method, number of passes, material processing)

Involved personnel (endoscopist expertise, presence of on-site experienced cytopathologist)

Clin Endosc 2012;45:115-116

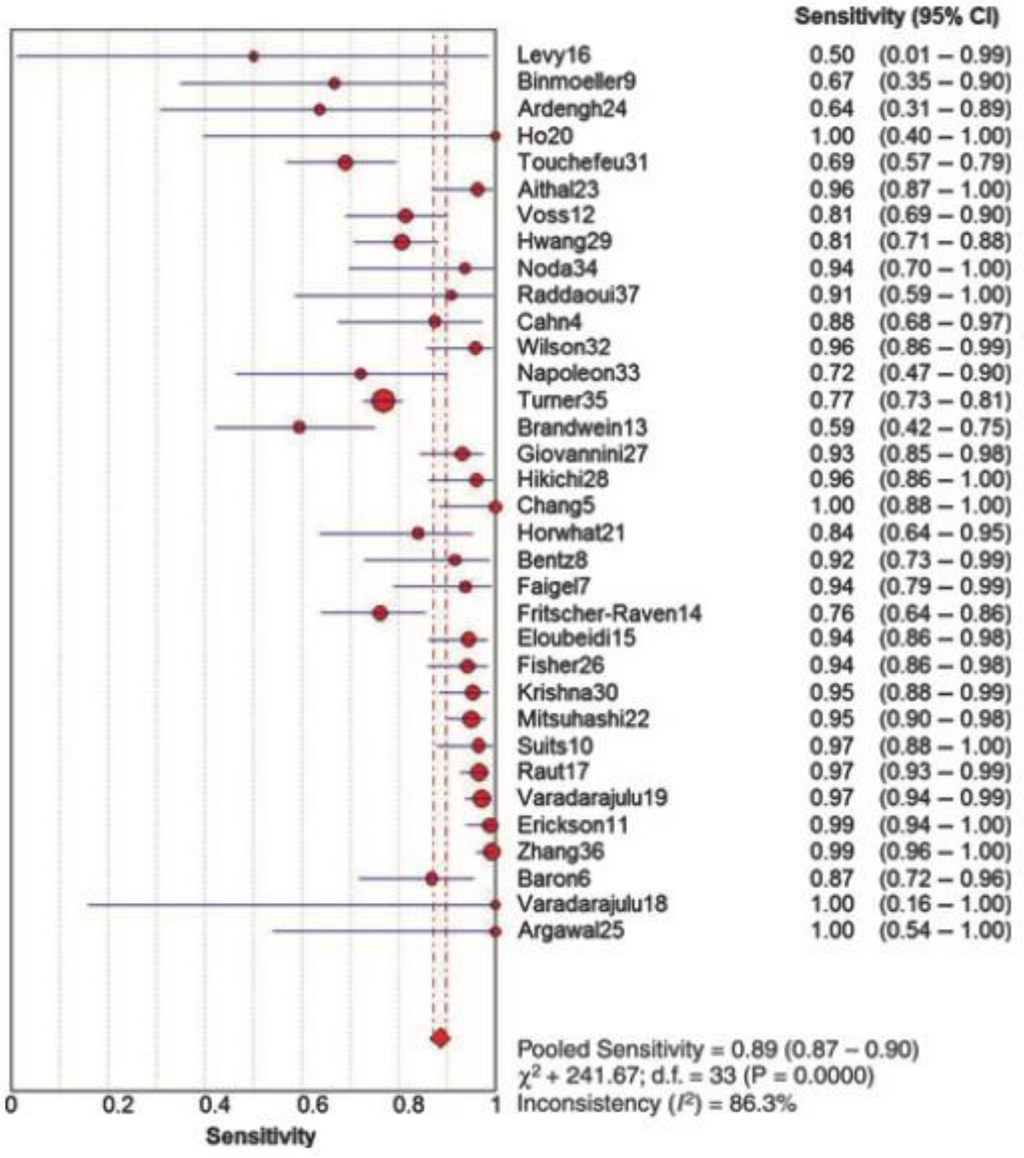
# The presence of a cytopathologist increases the diagnostic accuracy of endoscopic ultrasound-guided fine needle aspiration cytology for pancreatic adenocarcinoma: a meta-analysis

S. Hébert-Magee*, S. Bae†, S. Varadarajulu‡, J. Ramesh‡, A. R. Frost*, M. A. Eloubeidi‡ and I. A. Eltoum*

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**Results:** We included 34 distinct studies (3644 patients) in which EUS-FNA for a solid pancreatic mass was evaluated. The pooled sensitivity and specificity for EUS-FNA for pancreatic ductal adenocarcinoma was 88.6% [95% confidence interval (CI): 87.2–89.9] and 99.3% (95% CI: 98.7–99.7), respectively. The LR+ and LR– were 33.46 (95% CI: 20.76–53.91) and 0.11 (95% CI: 0.08–0.16), respectively. The meta-regression model showed rapid on-site evaluation (ROSE) ($P$ = 0.001) remained a significant determinant of EUS-FNA accuracy after correcting for study population number and reference standard.

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Cytopathology 2013, **24**, 159–171



*Original Article*

# Randomized non-inferiority trial comparing diagnostic yield of cytopathologist-guided versus seven passes for endoscopic ultrasound-guided fine-needle aspiration of pancreatic masses

***Results:*** Total of 142 patients were randomized with 73 in the cytopathologist arm and 69 in the seven-passes arm. Diagnostic yield for definite diagnosis was 78.3% with seven passes and 78.1% with cytopathology guidance. With an absolute difference 0.2%, 95% CI −14.4 to 14.6, carrying out seven passes was non-inferior to cytopathologist-guided EUS-FNA. There was no significant difference in complications or time to carry out FNA. A median of five passes were done with ROSE. Median cost with onsite cytopathology was significantly higher than carrying out seven passes ($1058 [958, 1445] *vs* $375 [275, 460], $P < 0.001$).

***Conclusions:*** Diagnostic yield for carrying out seven passes during EUS-FNA into solid pancreatic masses is non-inferior with lower charge compared to cytopathologist guidance.

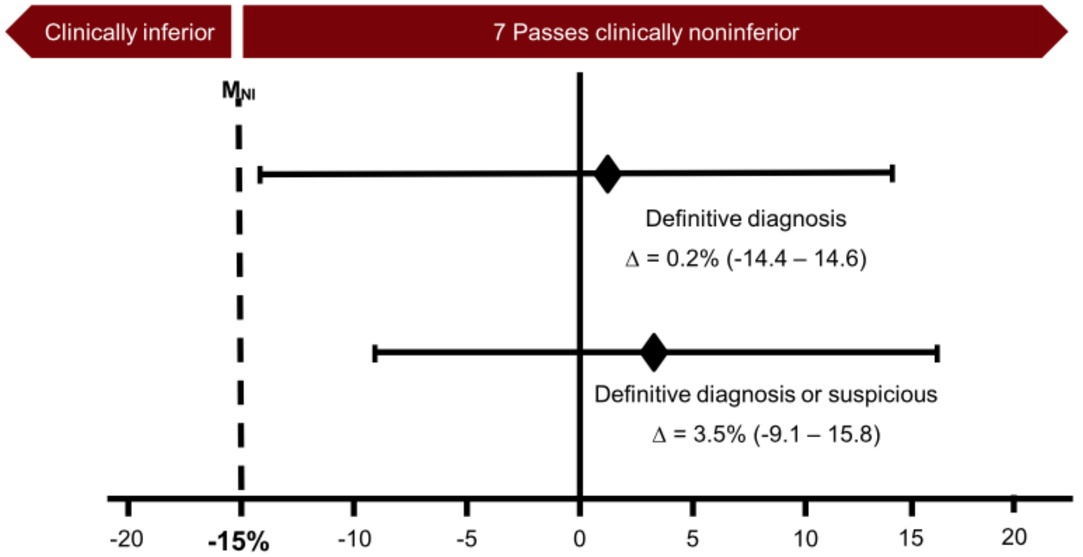


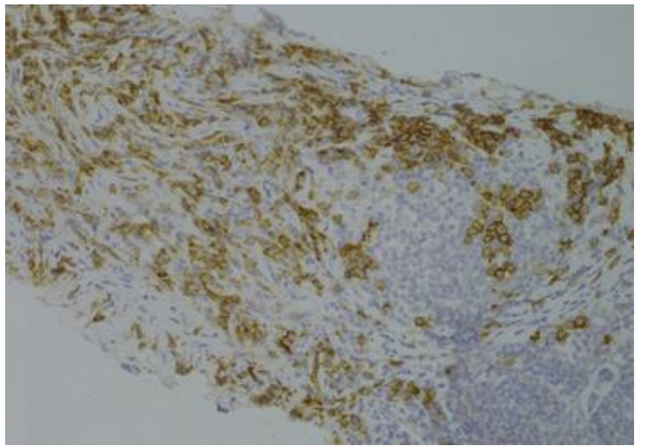

**Figure 1** Non-inferiority analysis demonstrating performance of seven passes compared to cytopathologist guidance during endoscopic ultrasound-guided fine-needle aspiration of solid pancreatic masses. $M_{NI}$, non-inferiority margin.

Core biopsy specimens for assessing architectural features may be essential for:

- diagnosing certain neoplasms (well differentiated adenocarcinoma, assessing the grading of the NET by determining the Ki-67 proliferation index, lymphoma, SEL, mts)
- Autoimmune pancreatitis



Core tissue allows performing various immunohistochemical staining and novel molecular analysis that can be used to tailor personalized therapies



# Virtual microdissection identifies distinct tumor- and stroma-specific subtypes of pancreatic ductal adenocarcinoma

Richard A Moffitt[1], Raoud Marayati[1], Elizabeth L Flate[1], Keith E Volmar[2], S Gabriela Herrera Loeza[1], Katherine A Hoadley[1,3], Naim U Rashid[1], Lindsay A Williams[1,4], Samuel C Eaton[5], Alexander H Chung[5], Jadwiga K Smyla[1], Judy M Anderson[6], Hong Jin Kim[1,7], David J Bentrem[8,9], Mark S Talamonti[10], Christine A Iacobuzio-Donahue[11], Michael A Hollingsworth[6] & Jen Jen Yeh[1,5,7]

Received 2 June; accepted 17 August; published online 7 September 2015; doi:10.1038/ng.3398

# Organoid Profiling Identifies Common Responders to Chemotherapy in Pancreatic Cancer FREE

Hervé Tiriac; Pascal Belleau; Dannielle D. Engle ; Dennis Plenker ; Astrid Deschênes ; Tim D. D. Somerville; Fieke E. M. Froeling; Richard A. Burkhart; Robert E. Denroche; Gun-Ho Jang; Koji Miyabayashi; C. Megan Young; Hardik Patel; Michelle Ma; Joseph F. LaComb; Randze Lerie D. Palmaira; Ammar A. Javed; Jasmine C. Huynh; Molly Johnson; Kanika Arora; Nicolas Robine; Minita Shah; Rashesh Sanghvi; Austin B. Goetz; Cinthya Y. Lowder; Laura Martello; Else Driehuis; Nicolas LeComte; Gokce Askan; Christine A. Iacobuzio-Donahue; Hans Clevers; Laura D. Wood; Ralph H. Hruban; Elizabeth Thompson; Andrew J. Aguirre; Brian M. Wolpin; Aaron Sasson; Joseph Kim; Maoxin Wu; Juan Carlos Bucobo; Peter Allen; Divyesh V. Sejpal; William Nealon; James D. Sullivan; Jordan M. Winter; Phyllis A. Gimotty; Jean L. Grem; Dominick J. DiMaio; Jonathan M. Buscaglia; Paul M. Grandgenett; Jonathan R. Brody; Michael A. Hollingsworth; Grainne M. O'Kane; Faiyaz Notta; Edward Kim; James M. Crawford; Craig Devoe; Allyson Ocean; Christopher L. Wolfgang; Kenneth H. Yu; Ellen Li; Christopher R. Vakoc; Benjamin Hubert; Sandra E. Fischer; Julie M. Wilson; Richard Moffitt; Jennifer Knox; Alexander Krasnitz; Steven Gallinger ; David A. Tuveson

**ABSTRACT** Pancreatic cancer is the most lethal common solid malignancy. Systemic therapies are often ineffective, and predictive biomarkers to guide treatment are urgently needed. We generated a pancreatic cancer patient-derived organoid (PDO) library that recapitulates the mutational spectrum and transcriptional subtypes of primary pancreatic cancer. New driver oncogenes were nominated and transcriptomic analyses revealed unique clusters. PDOs exhibited heterogeneous responses to standard-of-care chemotherapeutics and investigational agents. In a case study manner, we found that PDO therapeutic profiles paralleled patient outcomes and that PDOs enabled longitudinal assessment of chemosensitivity and evaluation of synchronous metastases. We derived organoid-based gene expression signatures of chemosensitivity that predicted improved responses for many patients to chemotherapy in both the adjuvant and advanced disease settings. Finally, we nominated alternative treatment strategies for chemorefractory PDOs using targeted agent therapeutic profiling. We propose that combined molecular and therapeutic profiling of PDOs may predict clinical response and enable prospective therapeutic selection.

**SIGNIFICANCE:** New approaches to prioritize treatment strategies are urgently needed to improve survival and quality of life for patients with pancreatic cancer. Combined genomic, transcriptomic, and therapeutic profiling of PDOs can identify molecular and functional subtypes of pancreatic cancer, predict therapeutic responses, and facilitate precision medicine for patients with pancreatic cancer.
*Cancer Discov; 8(9); 1112–29.* *©2018 AACR.*

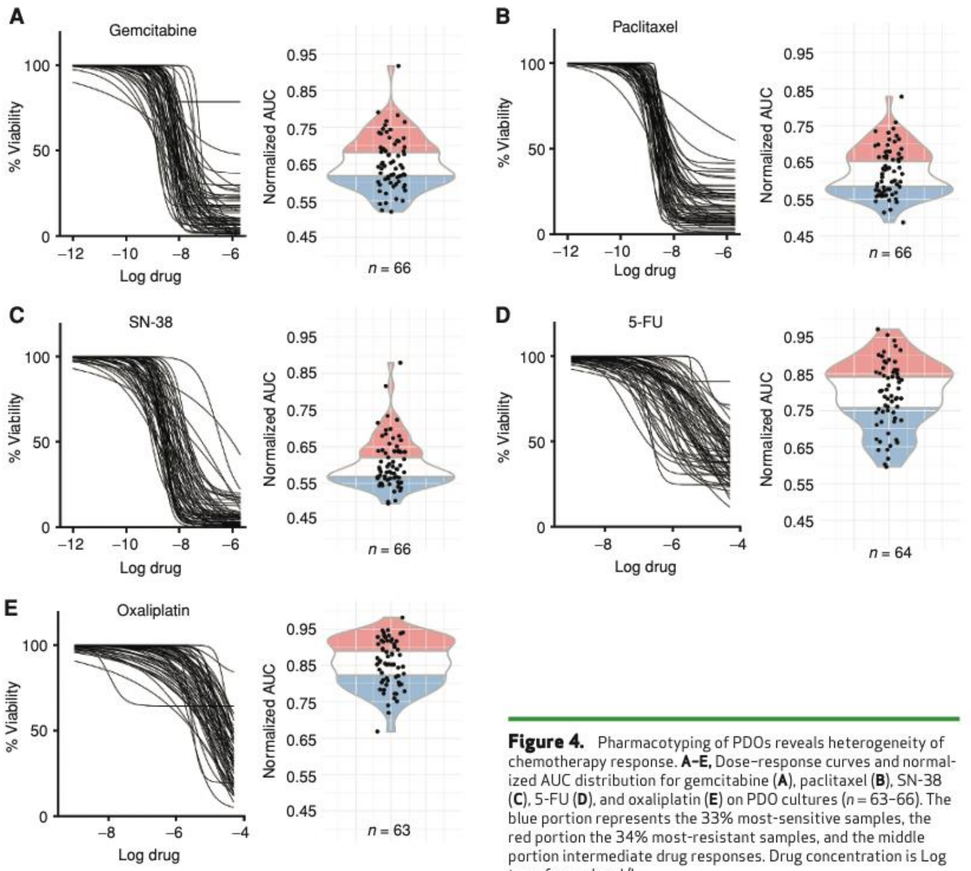



**Figure 4.** Pharmacotyping of PDOs reveals heterogeneity of chemotherapy response. **A–E,** Dose–response curves and normalized AUC distribution for gemcitabine (**A**), paclitaxel (**B**), SN-38 (**C**), 5-FU (**D**), and oxaliplatin (**E**) on PDO cultures ($n = 63$–66). The blue portion represents the 33% most-sensitive samples, the red portion the 34% most-resistant samples, and the middle portion intermediate drug responses. Drug concentration is Log transformed mol/L.

## Assessment of the technical performance of the flexible 19-gauge EUS-FNA needle

**Shyam Varadarajulu, MD,[1] Ji Young Bang, MD, MPH,[1] Shantel Hebert-Magee, MD[2]**

Birmingham, Alabama, USA

GASTROINTESTINAL ENDOSCOPY Volume 76, No. 2 : 2012

| Pts | Histologic specimen % | Histologic Diagnosis % |
|---|---|---|
| 32 | 94.7 | 92.1 |

## Ki-67 grading of nonfunctioning pancreatic neuroendocrine tumors on histologic samples obtained by EUS-guided fine-needle tissue acquisition: a prospective study

**Alberto Larghi, MD, PhD,[1] Gabriele Capurso, MD, PhD,[2] Antonella Carnuccio, MD, PhD,[1,2] Riccardo Ricci, MD, PhD,[3] Sergio Alfieri, MD,[4] Domenico Galasso, MD,[1] Francesca Lugli, MD,[5] Antonio Bianchi, MD,[5] Francesco Panzuto, MD, PhD,[2] Laura De Marinis, MD,[5] Massimo Falconi, MD,[6] Gianfranco Delle Fave, MD,[2] Giovanni Battista Doglietto, MD,[4] Guido Costamagna, MD, FACG,[1] Guido Rindi, MD, PhD[3]**

Rome, Italy

GASTROINTESTINAL ENDOSCOPY Volume 76, No. 3 : 2012

| Pts | Histologic specimen % | Histologic Diagnosis % |
|---|---|---|
| 30 | 93.3 | 83.3 |

## Use of Samples From Endoscopic Ultrasound–Guided 19-Gauge Fine-Needle Aspiration in Diagnosis of Autoimmune Pancreatitis

TAKUJI IWASHITA,* ICHIRO YASUDA,* SHINPEI DOI,* NOBUHIRO ANDO,* MASANORI NAKASHIMA,* SEIJI ADACHI,* YOSHINOBU HIROSE,‡ TSUYOSHI MUKAI,§ KEISUKE IWATA,§ EIICHI TOMITA,§ TAKAO ITOI,‖ and HISATAKA MORIWAKI*

**First Department of Internal Medicine, ‡Department of Clinical Pathology, Gifu University Hospital, Gifu; §Department of Gastroenterology, Gifu Municipal Hospital, Gifu; ‖Department of Gastroenterology and Hepatology, Tokyo Medical University, Tokyo, Japan*

CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 2012;10:316–322

| Pts | Histologic specimen % | Histologic Diagnosis % |
|---|---|---|
| 44 | 93.1 | 43.2 |

# EUS tissue acquisition: From A to B

**Bojan Kovacevic[1], Peter Vilmann[1]**
[1]Gastro Unit, Division of Endoscopy, Herlev and Gentofte Hospital, Copenhagen University, Herlev, Denmark

| **Type** | **FNA** | **FNB** | | | | | |
|---|---|---|---|---|---|---|---|
| **Needle generation** | | **First** | **Second** | **Third** | | | |
| **Needle Tip** |  |  |  |  |  |  |  |
| **Commercial name** | Many different available | Quick-Core | ProCore (reverse bevel) | SharkCore | Acquire | ProCore (forward-facing bevel) | TopGain |
| **Available sizes** | 19 – 25G | 19G | 19, 22, 25G | 19, 22, 25G | 22, 25G | 20G | 19, 22, 25G |

# EUS-guided trucut needle biopsies in patients with solid pancreatic masses: a prospective study

**Alberto Larghi, MD, PhD, Elizabeth C. Verna, MD, Stavros N. Stavropoulos, MD, Heidrun Rotterdam, MD, Charles J. Lightdale, MD, Peter D. Stevens, MD**

*New York, New York*

***Results:*** **Pancreatic tissue was obtained in 17 of the 23 patients (74%), including all patients in whom the transgastric approach was used. No acute or long-term complication was observed. Histopathologic evaluation revealed pancreatic cancer in 12 patients. CT-guided biopsy specimens were obtained in 4 of the 5 patients with a negative EUS-guided trucut needle biopsy result; two were positive for adenocarcinoma. Overall diagnostic accuracy was 61%. Subgroup analysis of the 16 patients in whom EUS-guided trucut needle biopsy was successful and who were available for follow-up revealed a diagnostic accuracy of 87.5%.**







Pancreatic tissue samples in 74% of the patients, with a diagnostic accuracy of 87% and high rate of failures (40%) when the procedure was performed through the duodenum.

This technically demanding and cumbersome to use needle has failed to reach widespread use outside of tertiary care centers

**(Gastrointest Endosc 2004;59:185-90.)**

# EchoTip ProCore® HD Ultrasound Biopsy Needle

## Feasibility and yield of a new EUS histology needle: results from a multicenter, pooled, cohort study

Julio Iglesias-Garcia, MD, Jan-Werner Poley, MD, Alberto Larghi, MD, PhD, Marc Giovannini, MD, PhD, Maria Chiara Petrone, MD, Ihab Abdulkader, MD, PhD, Genevieve Monges, MD, PhD, Guido Costamagna, MD, PhD, Paolo Arcidiacono, MD, Katharina Biermann, MD, PhD, Guido Rindi, MD, PhD, Erwan Bories, MD, Claudio Dogloni, MD, PhD, Marco Bruno, MD, PhD, J. Enrique Dominguez-Muñoz, MD, PhD

Volume 73, No. 6 : 2011 GASTROINTESTINAL ENDOSCOPY

## Feasibility and yield of a novel 22-gauge histology EUS needle in patients with pancreatic masses: a multicenter prospective cohort study

Alberto Larghi · Julio Iglesias-Garcia · Jan-Werner Poley · Geneviève Monges · Maria Chiara Petrone · Guido Rindi · Ihab Abdulkader · Paolo Giorgio Arcidiacono · Guido Costamagna · Katharina Biermann · Erwan Bories · Claudio Doglioni · J. Enrique Dominguez-Muñoz · Cesare Hassan · Marco Bruno · Marc Giovannini

*Surgical Endoscopy* **27**, 3733–3738 (2013)

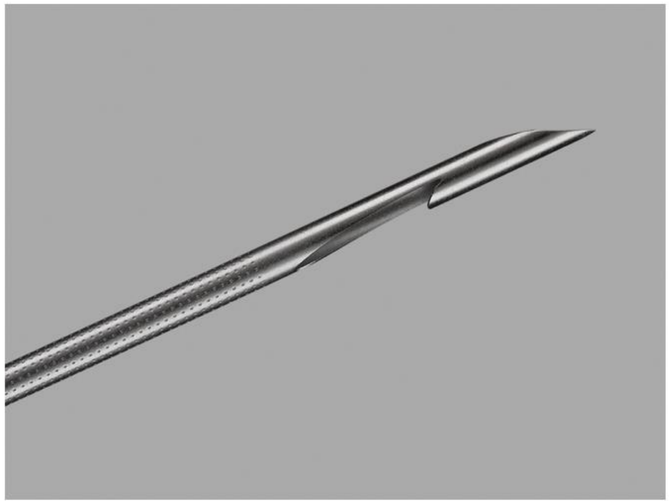
## High single-pass diagnostic yield of a new 25-gauge core biopsy needle for EUS-guided FNA biopsy in solid pancreatic lesions

Takuji Iwashita, MD, PhD,[1] Yousuke Nakai, MD, PhD,[1] Jason B. Samarasena, MD,[1] Do Hyun Park, MD, PhD,[1] Zesong Zhang, MD,[2] Mai Gu, MD, PhD,[2] John G. Lee, MD,[1] Kenneth J. Chang, MD[1]

Orange, California, USA

Volume 77, No. 6 : 2013 GASTROINTESTINAL ENDOSCOPY



| Needle | Pts | Histologic specimen % | Histologic Diagnosis % |
|---|---|---|---|
| 19 | 47 | 95.7 | 89.3 |
| 22 | 61 | 90.2 | 88.5 |
| 25 | 50 | 32 | 87 |

# A meta-analysis comparing ProCore and standard fine-needle aspiration needles for endoscopic ultrasound-guided tissue acquisition

Ji Young Bang[1], Robert Hawes[2], Shyam Varadarajulu[2]

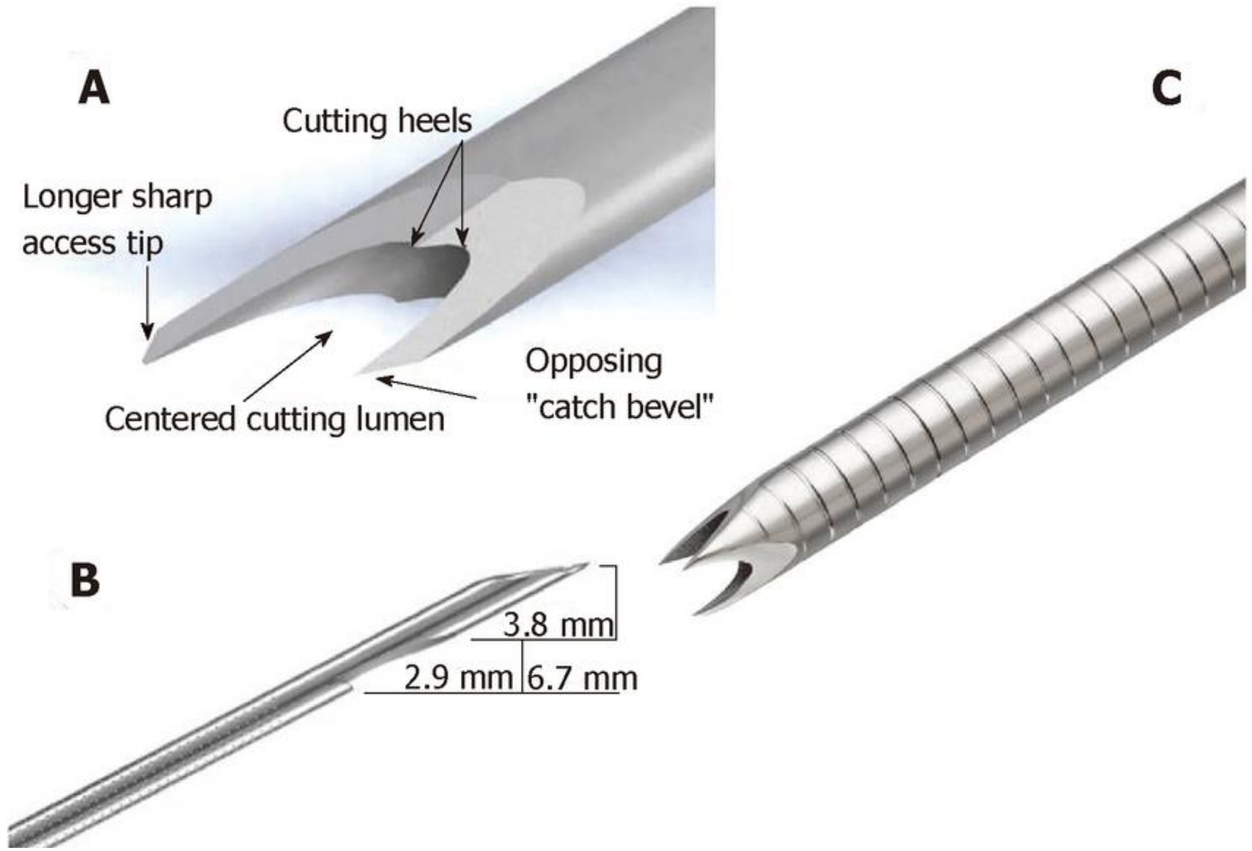
[1] Division of Gastroenterology and Hepatology, Indiana University, Indianapolis, Indiana, United States
[2] Center for Interventional Endoscopy, Florida Hospital, Orlando, Florida, United States

**Table 4** Summary of outcome measures in meta-analysis comparing the ProCore biopsy needle with standard fine-needle aspiration needles.

| Outcome Measure | Patients, n | | Pooled estimate, mean % (95 %CI) | | Pooled OR (95 %CI) | *P*value |
|---|---|---|---|---|---|---|
| | ProCore | FNA | ProCore | FNA | | |
| Diagnostic adequacy | | | | | | |
| All masses | 167 | 167 | 75.2 (52.2 to 92.4) | 89.0 (78.9 to 96.1) | 0.39 (0.081 to 1.85) | 0.234 |
| Pancreatic masses | 140 | 140 | 69.5 (42.5 to 90.7) | 89.7 (77.1 to 97.6) | 0.26 (0.043 to 1.53) | 0.136 |
| Diagnostic accuracy | | | | | | |
| All masses | 390 | 390 | 85.8 (75.2 to 93.8) | 86.2 (78.0 to 92.7) | 0.88 (0.60 to 1.30) | 0.530 |
| Pancreatic masses | 287 | 287 | 87.0 (75.9 to 95.1) | 85.3 (75.1 to 93.2) | 1.12 (0.65 to 1.92) | 0.687 |
| Histological core tissue | | | | | | |
| All masses | 401 | 399 | 77.7 (71.7 to 83.2) | 76.5 (66.1 to 85.5) | 0.94 (0.51 to 1.73) | 0.847 |
| All masses[1] | 178 | 176 | 75.2 (68.6 to 81.4) | 67.4 (44.7 to 86.4) | 1.42 (0.39 to 5.18) | 0.595 |
| Pancreatic masses | 286 | 286 | 79.2 (69.6 to 87.3) | 83.1 (77.7 to 87.9) | 0.87 (0.44 to 1.75) | 0.700 |
| Pancreatic masses[1] | 166 | 166 | 75.8 (66.8 to 83.8) | 80.1 (68.9 to 89.3) | 0.84 (0.28 to 2.54) | 0.757 |
| Mean no. of passes for diagnosis | | | | | | |
| All masses | 217 | 215 | – | – | −1.18[2] (−1.79 to −0.58) | <0.001 |
| Pancreatic masses | 129 | 129 | – | – | −1.03[2] (−1.57 to −0.50) | <0.001 |
| Adverse events | | | | | | |
| All masses | 462 | 460 | 2.0 (0.52 to 4.4) | 2.1 (0.50 to 4.7) | 0.96 (0.37 to 2.54) | 0.941 |
| Pancreatic masses | 347 | 347 | 2.4 (0.62 to 5.2) | 2.1 (0.49 to 4.7) | 1.1 (0.40 to 3.0) | 0.864 |

**Conclusions:** Current data do not demonstrate a significant difference between the ProCore and standard FNA needles for sample adequacy, diagnostic accuracy or acquisition of a core specimen. However, the ProCore needle establishes the diagnosis with fewer passes.

Endoscopy 2016; 48: 339–349




Designs:

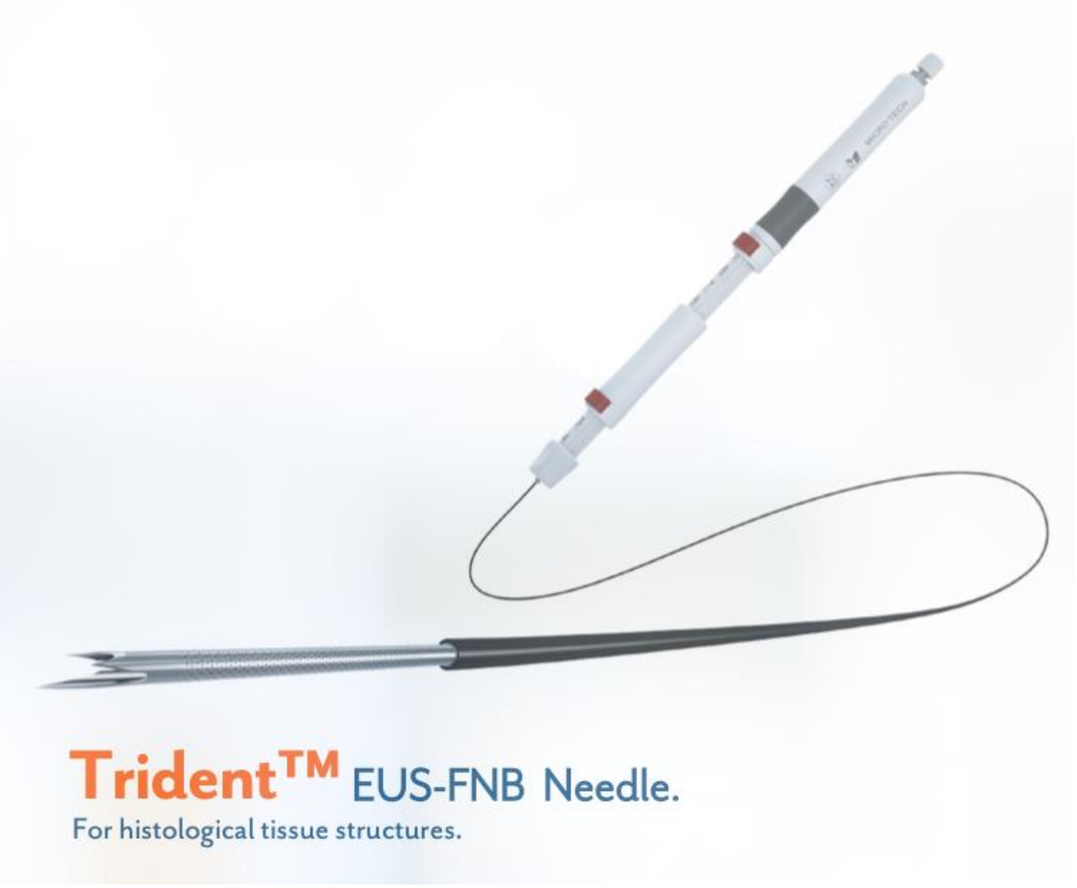
- ✓ Fork shaped Tip: cutting needle with a fork shape distal tip including 6 cutting edges and an opposing bevel (SharkCore – 19G, 22G, 25G, Medtronic)
- ✓ Anterograde core trap: modified Menghini type needle with a beveled side slot near needle tip (ProCore 20G, Cook)
- ✓ Franseen tip geometry: endo cutting needle with a crown shaped distal tip (Acquire, 25G, 22G, Boston Scientific)

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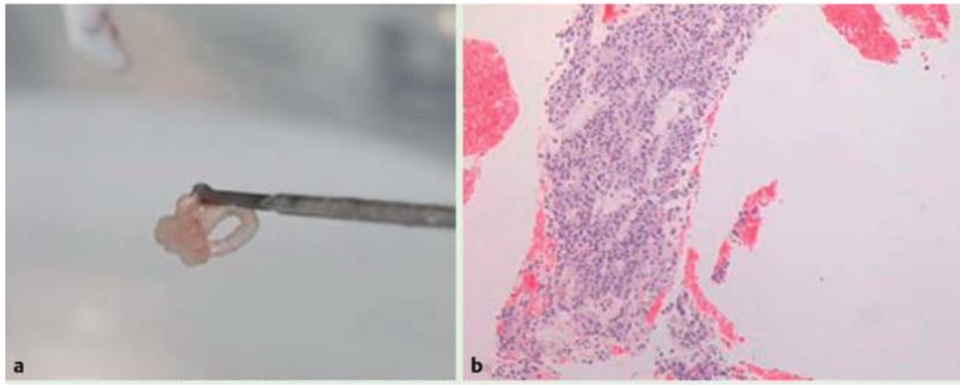


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# Initial experience with a novel EUS-guided core biopsy needle (SharkCore): results of a large North American multicenter study

Christopher J. DiMaio[1], Jennifer M. Kolb[1], Petros C. Benias[2], Hiral Shah[3], Shashin Shah[3], Oleh Haluszka[4], Jennifer Maranki[4], Kaveh Sharzehi[4], Eric Lam[5], Stuart R. Gordon[6], Sarah M. Hyder[6], Pavlos Z. Kaimakliotis[7], Satya B. Allaparthi[7], Frank G. Gress[8], Amrita Sethi[8], Ashish R. Shah[8], Jose Nieto[9], Vivek Kaul[10], Shivangi Kothari[10], Truptesh H. Kothari[10], Sammy Ho[11], Manhal J. Izzy[11], Neil R. Sharma[12], Rabindra R. Watson[13], V. Raman Muthusamy[13], Douglas K. Pleskow[14], Tyler M. Berzin[14], Mandeep Sawhney[14], Emad Aljahdi[14], Marvin Ryou[15], Clarence K. Wong[16], Parantap Gupta[17], Dennis Yang[1], Susana Gonzalez[1], Douglas G. Adler[18]




| Lesion type | n | Median number of passes for pathology (range) | Diagnostic yield, pathology (n, %) | Adverse events (n) |
|---|---|---|---|---|
| Pancreas | 136 | 2 (1 – 10) | 70/81 (86) | 5 (2 pancreatitis, 3 pain) |
| Subepithelial mass | 28 | 2 (1 – 5) | 13/15 (87) | |
| Lymph node | 51 | 2 (1 – 4) | 26/28 (93)* | 2 (pain) |

| | 25-gauge n (%) | 22-gauge n (%) |
|---|---|---|
| Pancreas | | |
| Cytology | 27/37 (73) | 51/61 (84) |
| Pathology | 17/20 (85) | 50/58 (86) |
| Subepithelial tumor | | |
| Cytology | 3/4 (75) | 12/15 (80) |
| Pathology | 0/1 (0) | 12/13 (92) |
| Lymph node | | |
| Cytology | 9/12 (75) | 18/25 (72) |
| Pathology | 2/2 (100) | 22/23 (96) |

Endoscopy International Open 2016; 04: E974–E979

# Endoscopic ultrasonography-guided biopsy using a Franseen needle design: Initial assessment

Ji Young Bang,† Shantel Hebert-Magee,† Muhammad K. Hasan, Udayakumar Navaneethan, Robert Hawes and Shyam Varadarajulu

**Table 1** Procedure details and outcomes of patients who underwent EUS-guided FNB ($n$ = 30)

| | | |
|---|---|---|
| Technical success, *n* (%) | | 29 (96.7) |
| Diagnostic adequacy on ROSE, *n* (%)† | | 28 (96.6) |
| No. passes for onsite diagnosis | Mean (SD) | 1.5 (1.2) |
| Diagnostic cell block, *n* (%) | | 29 (96.7) |
| Total tissue area ($mm^2$) | Mean (SD) | 6.27 (10.1) |
| Diagnostic accuracy, *n* (%) | | 29 (96.7) |
| Adverse events, *n* (%) | | 1 (3.3) |

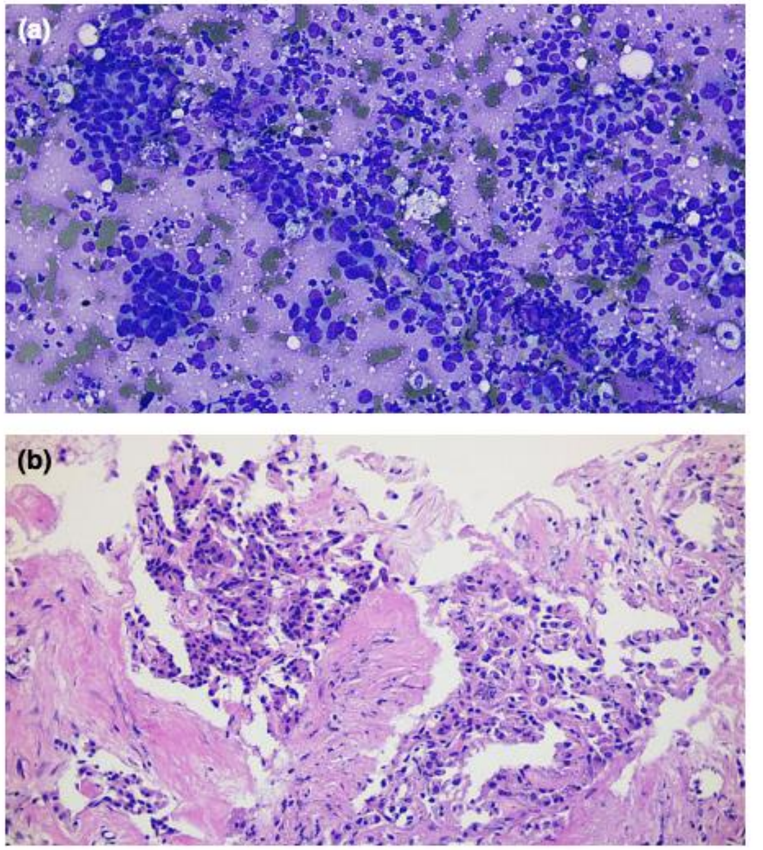



**Figure 2** Rapid onsite evaluation of an endoscopic ultrasound-guided fine-needle biopsy specimen of a pancreatic head mass reveals malignant cells (a; Diff-Quik staining, 200×) with the corresponding cell block demonstrating adenocarcinoma (b; H&E staining, 200×).

***Conclusion:*** Preliminary data suggest that the Franseen needle yields diagnostic material for ROSE and histology in >95% of patients.

# EUS-guided fine needle biopsy sampling using a novel fork-tip needle: a case-control study

**Pujan Kandel, MD,[1] Ghassan Tranesh, MD,[2] Aziza Nassar, MD,[2] Russell Bingham,[1] Massimo Raimondo, MD,[1] Timothy A. Woodward, MD,[1] Victoria Gomez, MD,[1] Michael B. Wallace, MD, MPH[1]**

Jacksonville, Florida, USA

**TABLE 3. Technical characteristics of EUS-FNA/FNB-SC**

| Characteristics | FNB (n = 39) | FNA (n = 117) | *P* value |
|---|---|---|---|
| Number of passes | | | .01* |
| Median (range) | 2 (1-6) | 4 (1-7) | |
| Pass number, no. (%) | | | .001† |
| ≤2 | 31 (80) | 16 (14) | |
| >2 | 8 (20) | 101 (86) | |

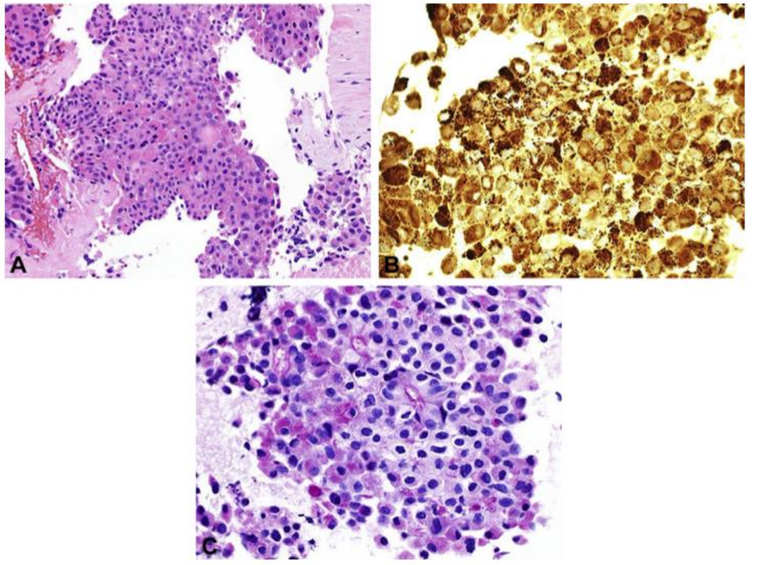



**Figure 2.** Pictomicrograph illustrations of adequate pancreatic biopsy specimens obtained by FNB-SC needle(acinic cell carcinoma). **A,** H&E, orig. mag. × 20. **B,** Trypsin immunostain, orig. mag. × 40. **C,** PAS stain, orig. mag. × 40.

**TABLE 4. Multivariate analysis**

| Groups | Total (n = 156) | Histology score (≥3) (n = 104) | Univariate odds ratio (95% CI), *P* value | Multivariate odds ratio (95% CI), *P* value |
|---|---|---|---|---|
| FNA | 117 | 67 (59%) | Reference | Reference |
| FNB | 39 | 37 (95%) | 12.9 (2.98-56.49), .01 | 11.30 (3.14-76.68), .01 |

*CI,* Confidence interval.

# A Multicenter comparative trial of a novel EUS-guided core biopsy needle (SharkCore™) with the 22-gauge needle in patients with solid pancreatic mass lesions

Mariam Naveed, Ali A. Siddiqui[1], Thomas E. Kowalski[1], David E. Loren[1], Ammara Khalid[1], Ayesha Soomro[1], Syed M. Mazhar[1], Joseph Yoo[1], Raza Hasan[1], Silpa Yalamanchili[1], Nicholas Tarangelo[2], Linda J. Taylor[2], Douglas G. Adler[2]

**Table 2. Operating characteristics of individual EUS needles**

| Operating characteristics | Technique of EUS tissue acquisition | | *P* |
|---|---|---|---|
| | 22-gauge standard FNA needle (*n*=973) (%) | 22-gauge SharkCore™ FNB needle (*n*=115) (%) | |
| Sensitivity (95% CI) | 91.5 (89.6-93.4) | 98.0 (94.0-100.0) | 0.077 |
| Specificity (95% CI) | 97.6 (94.2-100.0) | 87.5 (64.6-100.0) | 0.18 |
| PPV (95% CI) | 99.7 (99.4-100.0) | 98.0 (94.0-100.0) | 0.989 |
| NPV (95% CI) | 53.7 (45.7-61.7) | 87.5 (64.6-100.0) | 0.0001‡ |
| Diagnostic accuracy (95% CI) | 92.0 (90.3-93.8) | 96.5 (91.7-100.0) | 0.167 |

FNB: Fine-needle biopsy, CI: Confidence interval, PPV: Positive predictive value, NPV: Negative predictive value. ‡: Statistically significant

**Table 3. Per pass analysis**

| Pass on which diagnosis made | SharkCore needle (*n*=115) (%) | Standard needle (*n*=973) (%) | OD (95% CI) | *P* |
|---|---|---|---|---|
| 1 | 84 (73.4) | 184 (18.9) | 0.08 (0.04-0.15) | <0.001 |
| 2 | 22 (18.8) | 175 (18) | 0.95 (0.49-2) | 0.867 |
| 3 or more | 9 (7.8) | 582 (59.8) | 17.53 (7.01-56.49) | <0.001 |

CI: Confidence interval, OD: Odds ratio

# Fork-tip needle biopsy versus fine-needle aspiration in endoscopic ultrasound-guided sampling of solid pancreatic masses: a randomized crossover study

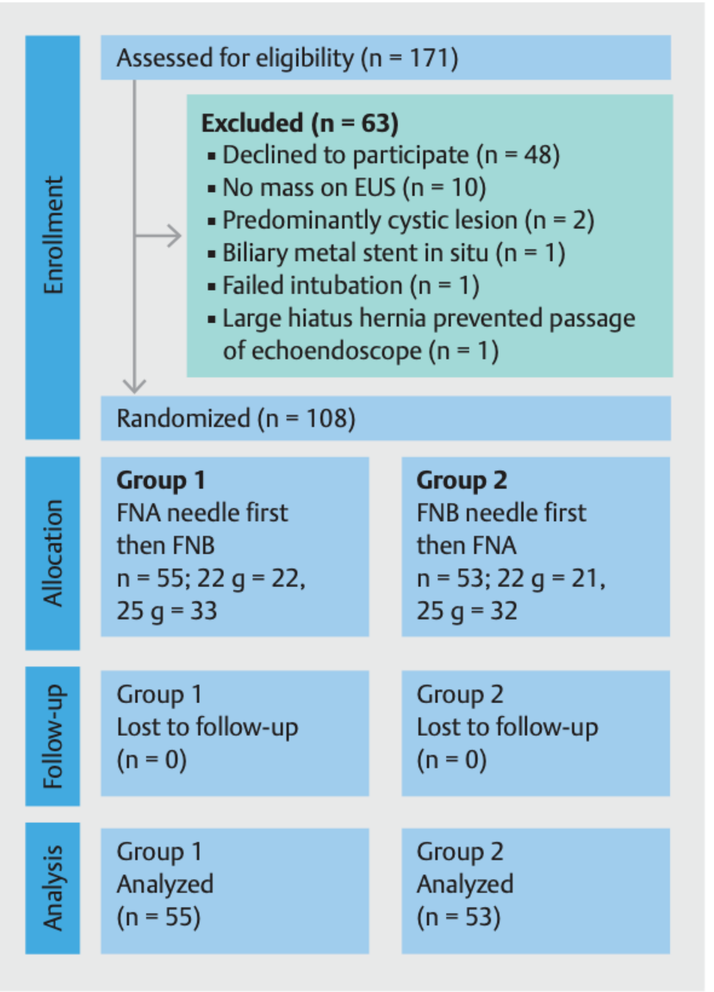
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Authors
Kofi W. Oppong[1,2], Noor L. H. Bekkali[3], John S. Leeds[1,4], Sarah J. Johnson[5], Manu K. Nayar[1], Antony Darné[5], Mark Egan[5], Paul Bassett[6], Beate Haugk[5]

▶ **Table 3** Diagnostic performance.

| Outcome | FNB | | FNA | | NxP Interaction[1] | Effect of needle type | |
|---|---|---|---|---|---|---|---|
| | n/N | % (95 %CI) | n/N | % (95 %CI) | *P* value | OR (95 %CI)[2] | *P* value |
| Diagnosis of malignancy | | | | | | | |
| ▪ Accuracy | 91/108 | 84 (76 to 91) | 81/108 | 75 (66 to 83) | 0.26 | 3.41 (1.12 to 10.4) | 0.03 |
| ▪ Sensitivity | 75/92 | 82 (72 to 89) | 65/92 | 71 (60 to 80) | 0.25 | 3.23 (1.12 to 9.38) | 0.03 |
| ▪ Specificity | 16/16 | 100 (79 to 100) | 16/16 | 100 (79 to 100) | – | – | – |
| ▪ Positive predictive value | 75/75 | 100 (94 to 100) | 65/65 | 100 (94 to 100) | – | – | – |
| ▪ Negative predictive value | 16/33 | 48 (31 to 66) | 16/43 | 37 (22 to 53) | 0.78 | 1.62 (0.64 to 4.10) | 0.31 |
| Specific diagnosis | | | | | | | |
| ▪ Accuracy | 85/108 | 79 (70 to 86) | 69/108 | 64 (54 to 73) | 0.13 | 4.79 (1.67 to 13.7) | 0.004 |
| ▪ Accuracy[3] | 10/16 | 63 (35 to 85) | 4/16 | 25 (7 to 52) | – | – | – |

FNB, fine-needle biopsy; FNA, fine-needle aspiration; NxP, needle by period; CI, confidence interval; OR, odds ratio.
[1] Analysis to examine whether the differences between needles varied depending on whether they were used first or second.
[2] OR calculated as odds for FNB relative to odds for FNA.
[3] Analysis based on patients with a benign final diagnosis only.

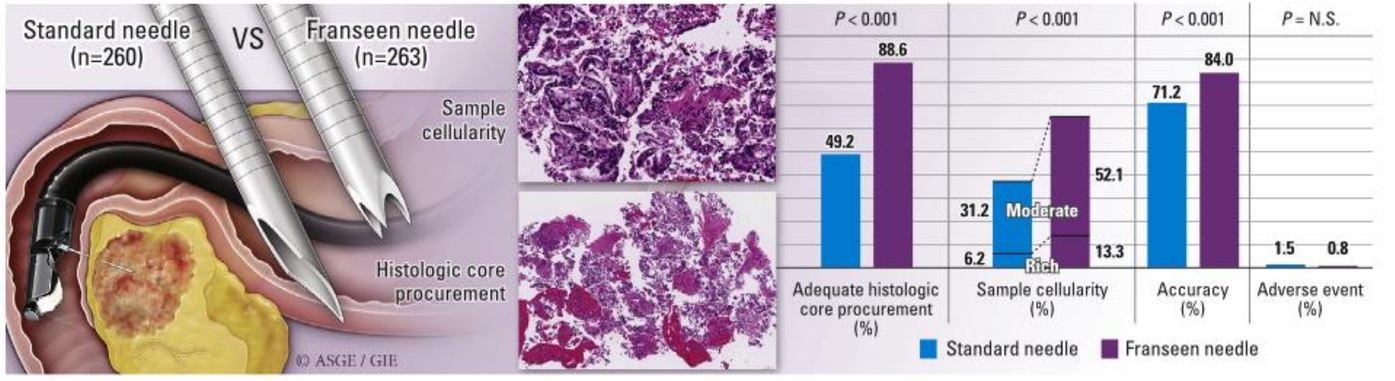



▶ **Fig. 1** CONSORT study flow diagram. Enrollment and outcomes. CONSORT, Consolidated Standards of Reporting Trials; FNA, fine-needle aspiration; FNB, fine-needle biopsy.

# Comparison of 22-gauge standard and Franseen needles in EUS-guided tissue acquisition for diagnosing solid pancreatic lesions: a multicenter randomized controlled trial (CME)

Masahiro Itonaga, MD,[1] Satoru Yasukawa, MD,[2] Nobuyasu Fukutake, MD,[3] Takeshi Ogura, MD,[4] Masanori Asada, MD,[5] Toshio Shimokawa, PhD,[6] Osamu Inatomi, MD,[7] Yoshitaka Nakai, MD,[8] Hideyuki Shiomi, MD,[9] Hiroko Nebiki, MD,[10] Azumi Suzuki, MD,[11] Koh Kitagawa, MD,[12] Satoshi Asai, MD,[13] Masaaki Shimatani, MD,[14] Tsuyoshi Sanuki, MD,[15] Akira Kurita, MD,[16] Mamoru Takenaka, MD,[17] Motoyuki Yoshida, MD,[18] Noriyuki Hoki, MD,[19] Hiroaki Yasuda, MD,[20] Hirotsugu Maruyama, MD,[21] Hisakazu Matsumoto, MD,[22] Akio Yanagisawa, MD,[23] Masayuki Kitano, MD[1]

## GRAPHICAL ABSTRACT




| | | Standard needle group (n=260) | Franseen needle group (n=263) | 0.1 Franseen needle better 1.0 Standard needle better 10 | OR [95%CIs] | p-value |
|---|---|---|---|---|---|---|
| Lesion size | ≤ 20mm | 29/60 (48.3%) | 49/65 (75.4%) | | 0.309 [0.133, 0.694] | *0.003* |
| | > 20mm | 150/200 (75.0%) | 169/198 (85.4%) | | 0.516 [0.298, 0.879] | *0.012* |
| Location of lesion | Head | 75/109 (68.8%) | 90/106 (84.9%) | | 0.394 [0.187, 0.799] | *0.006* |
| | Body or tail | 104/151 (68.9%) | 128/157 (81.5%) | | 0.502 [0.284, 0.879] | *0.012* |
| Puncture site | Stomach | 106/154 (68.8%) | 132/161 (82.0%) | | 0.486 [0.275, 0.847] | *0.009* |
| | D1 | 32/43 (74.4%) | 35/45 (77.8%) | | 0.833 [0.276, 2.489] | *N.S* |
| | D2 | 41/62 (66.1%) | 51/56 (91.1%) | ← 0.053 | 0.194 [0.053, 0.589] | *0.002* |

Odds ratio

# Randomized trial comparing fork-tip and side-fenestrated needles for EUS-guided fine-needle biopsy of solid pancreatic lesions

Stefano Francesco Crinò, MD,[1] Marco Le Grazie, MD,[1] Erminia Manfrin, MD,[2] Maria Cristina Conti Bellocchi, MD,[1] Laura Bernardoni, MD,[1] Anna Granato, MD,[1] Francesca Locatelli,[3] Alice Parisi, MD,[2] Serena Di Stefano, MD,[1] Luca Frulloni, MD, PhD,[1] Alberto Larghi, MD, PhD,[4] Armando Gabbrielli, MD[1]

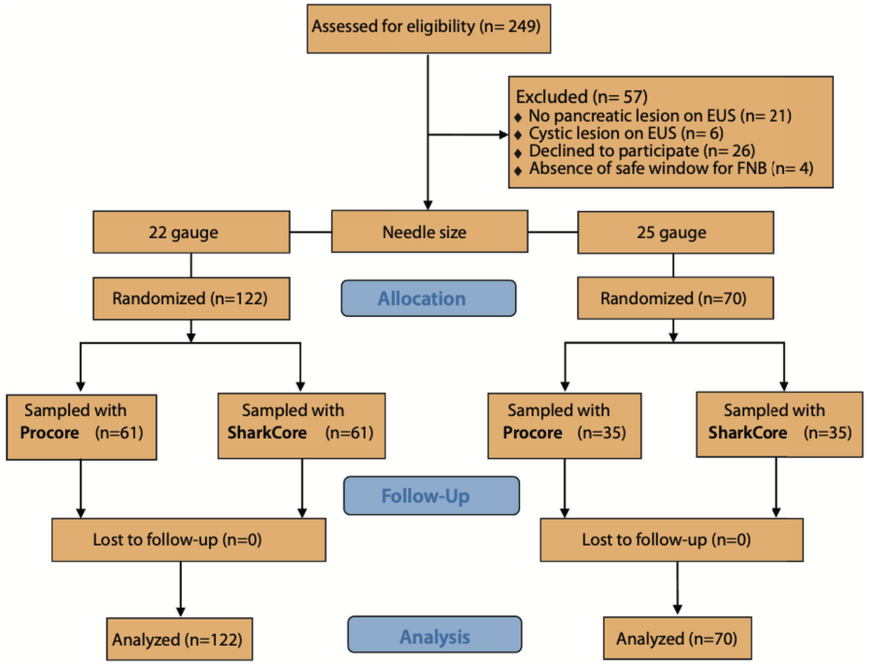



**Figure 2.** CONSORT flowchart of the study.

**TABLE 3. Histologic procurement yield and diagnostic accuracy of the 2 needles**

| Outcome | Side-fenestrated needle | Fork-tip needle | *P* value |
|---|---|---|---|
| Overall population (N = 96 per arm) | | | |
| Histologic yield, n/N (%)* | | | |
| 1 pass | 58/96 (60.4) | 89/96 (92.7) | .0001† |
| 2 passes | 63/96 (65.6) | 93/96 (96.9) | .0001† |
| 3 passes | 76/96 (79.1) | 96/96 (100) | .0001† |
| Diagnostic accuracy, % (95% CI) | | | |
| 1 pass | 78.1 (68.5-85.9) | 85.4 (76.7-91.8) | .262† |
| 2 passes | 89.6 (81.7-94.9) | 90.6 (82.9-95.6) | 1.00† |
| 3 passes | 91.7 (84.2-96.3) | 92.7 (85.5-97) | 1.00† |

# Comparison of a 22-gauge Franseen-tip needle with a 20-gauge forward-bevel needle for the diagnosis of type 1 autoimmune pancreatitis: a prospective, randomized, controlled, multicenter study (COMPAS study)

Akira Kurita, MD, PhD,[1] Satoru Yasukawa, MD,[2] Yoh Zen, MD, PhD,[3] Kenichi Yoshimura, PhD,[4] Takeshi Ogura, MD, PhD,[5] Eisuke Ozawa, MD, PhD,[6] Yoshinobu Okabe, MD, PhD,[7] Masanori Asada, MD, PhD,[8] Hiroko Nebiki, MD, PhD,[9] Minoru Shigekawa, MD, PhD,[10] Tsukasa Ikeura, MD, PhD,[11] Takaaki Eguchi, MD,[12] Hirotsugu Maruyama, MD,[13] Toshiharu Ueki, MD, PhD,[14] Masahiro Itonaga, MD, PhD,[15] Shinichi Hashimoto, MD, PhD,[16] Hideyuki Shiomi, MD, PhD,[17] Ryuki Minami, MD,[18] Noriyuki Hoki, MD,[19] Mamoru Takenaka, MD, PhD,[20] Yoshio Itokawa, MD,[21] Norimitsu Uza, MD, PhD,[22] Shunpei Hashigo, MD,[23] Hiroaki Yasuda, MD, PhD,[24] Ryoji Takada, MD,[25] Hideki Kamada, MD,[26] Hirofumi Kawamoto, MD, PhD,[27] Hiroshi Kawakami, MD, PhD,[28] Ichiro Moriyama, MD, PhD,[29] Koichi Fujita, MD,[30] Hisakazu Matsumoto, MD,[31] Keiji Hanada, MD, PhD,[32] Tadamasa Takemura, PhD,[33] Shujiro Yazumi, MD, PhD[1]

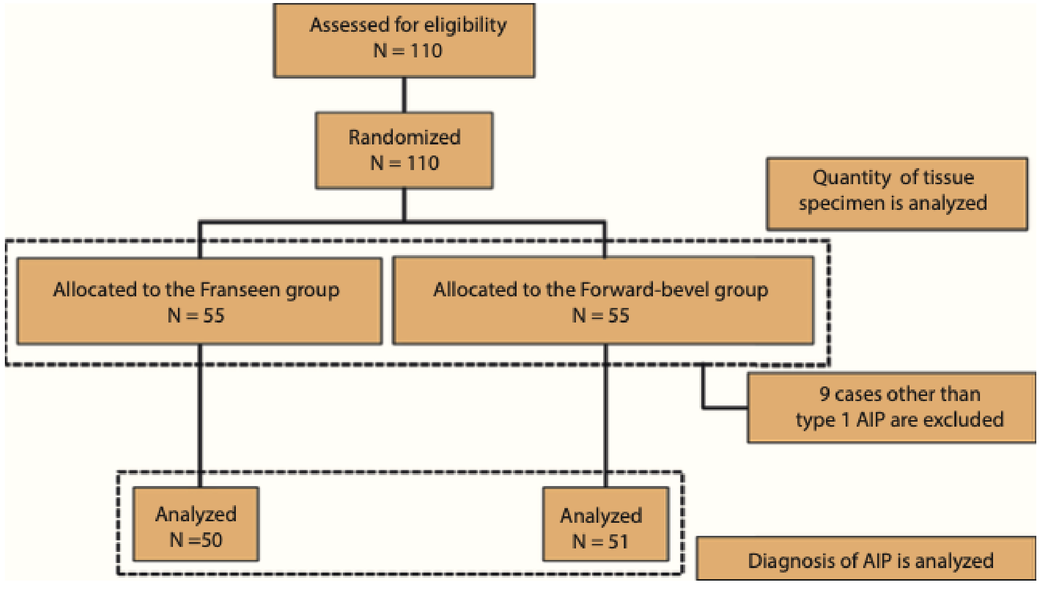



**Figure 1.** Flow diagram of the enrolled patients. *AIP*, Autoimmune pancreatitis.

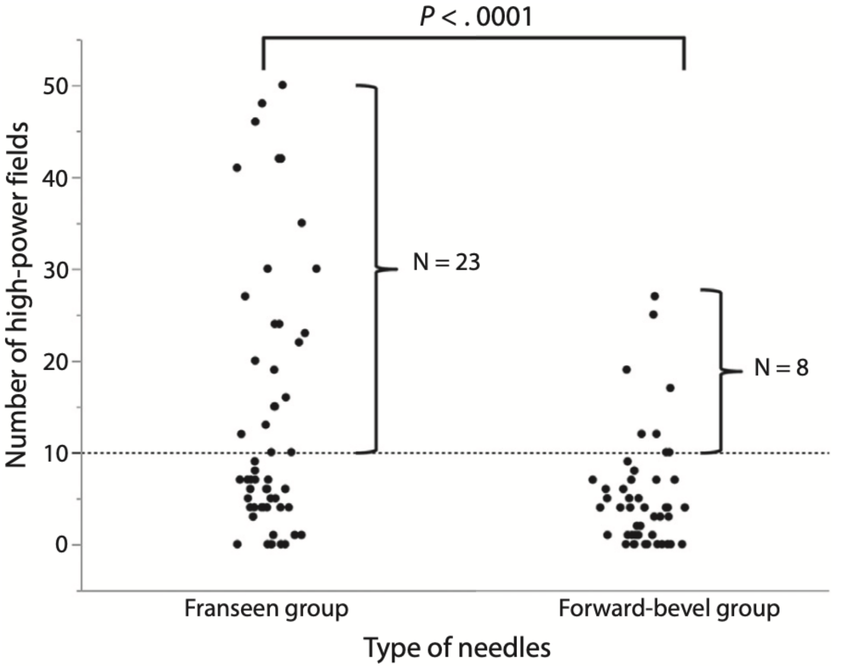
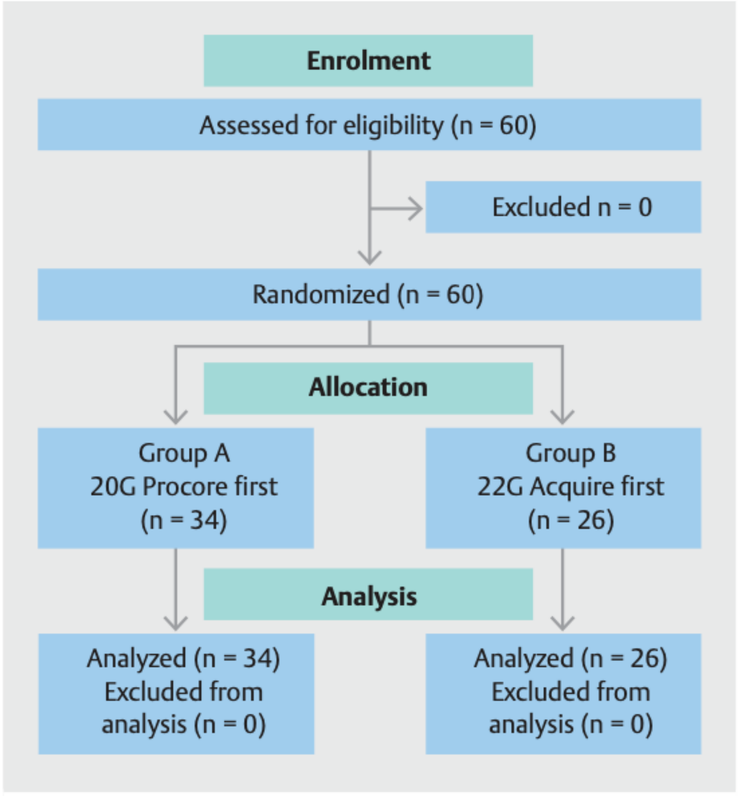



**Figure 2.** Comparison of the amount of acquired tissue area by high-power fields (HPFs). An optimal amount of tissue (≥10 HPFs) was obtained in 23 subjects in the Franseen group and in 8 subjects in the forward-bevel group, respectively ($P = .0027$).

**Conclusions:** The 22-gauge Franseen needle should be routinely used for histologic diagnosis of type 1 AIP.
(Clinical trial registration number: UMIN 000027668.) (Gastrointest Endosc 2020;91:373-81.)

# 22G Acquire vs. 20G Procore needle for endoscopic ultrasound-guided biopsy of pancreatic masses: a randomized study comparing histologic sample quantity and diagnostic accuracy

Authors
David Karsenti[1], Laurent Palazzo[2], Bastien Perrot[3], Jacqueline Zago[4], Anne-Isabelle Lemaistre[5], Jérôme Cros[6], Bertrand Napoléon[7]




▶ **Table 3** Comparison of quantity of histologic material obtained, and diagnostic adequacy and accuracy between a single pass with the two needles.

| | Acquire 22G[1] (n = 60) | Procore 20G[1] (n = 60) | *P* value |
|---|---|---|---|
| Cumulative length of tissue core biopsies per needle pass, mean (95 %CI), mm | 11.4 (9.0 – 13.8) | 5.4 (3.8 – 7.0) | <0.001 |
| Cumulative surface area of tissue core biopsies per needle pass, mean (95 %CI), $mm^2$ | 3.5 (2.7 – 4.3) | 1.8 (1.2 – 2.3) | <0.001 |
| Diagnostic adequacy[2] (95 %CI), % | 100 (94 – 100) | 82 (70 – 90) | 0.001 |
| Diagnostic accuracy (95 %CI), % | 87 (75 – 94) | 67 (53 – 78) | 0.02 |
| Sensitivity for adenocarcinoma (95 %CI), % | 83 (59 – 92) | 63 (48 – 77) | 0.06 |
| Sensitivity for neuroendocrine neoplasm (95 %CI), % | 100 (72 – 100) | 82 (48 – 87) | 0.50 |
| Sensitivity for autoimmune pancreatitis (95 %CI), % | 100 (16 – 100) | 50 (1 – 99) | >0.99 |
| Sensitivity for chronic pancreatitis (95 %CI), % | 100 (3 – 100) | 100 (3 – 100) | >0.99 |

Endoscopy 2020; 52: 747–753

# Comparing Needles and Methods of Endoscopic Ultrasound–Guided Fine-Needle Biopsy to Optimize Specimen Quality and Diagnostic Accuracy for Patients With Pancreatic Masses in a Randomized Trial

Ji Young Bang,* Konrad Krall,‡ Nirag Jhala,§ Charanjeet Singh,‡ Mohamedtaki Tejani,‖ Juan Pablo Arnoletti,¶ Udayakumar Navaneethan,* Robert Hawes,* and Shyam Varadarajulu*

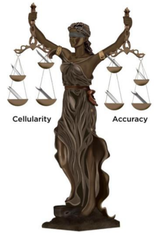



**Table 4.** Diagnostic Performance of Biopsy Samples for Each Technique, With Comparison Between the Needles

| Technique | Operating characteristic | Needle type: Reverse-bevel | Menghini-tip | Franseen | Fork-tip | *P* value |
|---|---|---|---|---|---|---|
| All lesions | | | | | | |
| All techniques | Sensitivity, % (95% CI) | 61.0 (49.6–71.6) | 72.8 (62.6–81.6) | 91.6 (83.4–96.5) | 96.3 (89.4–99.2) | <.001 |
| | Specificity, % (95% CI) | 100 (80.5–100) | 100 (59.0–100) | 100 (75.3–100) | 100 (75.3–100) | .999 |
| | PPV, % (95% CI) | 100 (92.9–100) | 100 (94.6–100) | 100 (95.3–100) | 100 (95.3–100) | .999 |
| | NPV, % (95% CI) | 34.7 (21.7–49.6) | 21.9 (9.3–40.0) | 65.0 (40.8–84.6) | 81.3 (54.4–96.0) | <.001 |
| | Accuracy, % (95% CI) | 67.7 (57.5–76.7) | 74.7 (65.0–82.9) | 92.7 (85.6–97.0) | 96.8 (90.9–99.3) | <.001 |
| Pancreatic neoplasia only | | | | | | |
| All techniques | Sensitivity, % (95% CI) | 64.1 (52.4–74.7) | 74.4 (64.2–83.1) | 93.8 (86.2–98.0) | 98.7 (93.1–100) | <.001 |
| No suction | Sensitivity, % (95% CI)[a] | 53.8 (33.4–73.4) | 60.0 (40.6–77.3) | 96.3 (81.0–99.9) | 96.2 (80.4–99.9) | <.001 |
| Stylet retraction | Sensitivity, % (95% CI)[a] | 65.4 (44.3–82.8) | 76.7 (57.7–90.1) | 92.6 (75.7–99.1) | 100 (86.8–100) | .003 |
| Suction | Sensitivity, % (95% CI)[a] | 73.1 (52.2–88.4) | 87.7 (69.3–96.2) | 92.6 (75.7–99.1) | 100 (86.8–100) | .022 |

# Randomized trial comparing the Franseen and Fork-tip needles for EUS-guided fine-needle biopsy sampling of solid pancreatic mass lesions

**Ji Young Bang, MD, MPH, Shantel Hebert-Magee, MD, Udayakumar Navaneethan, MD, Muhammad K. Hasan, MD, Robert Hawes, MD, Shyam Varadarajulu, MD**

Orlando, Florida, USA

GASTROINTESTINAL ENDOSCOPY Volume 87, No. 6 : 2018

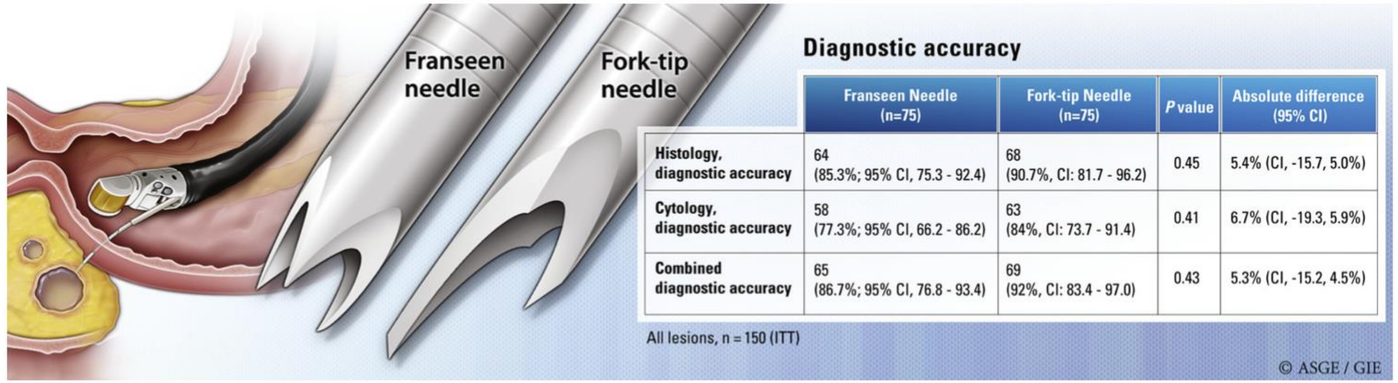
| | Franseen needle | Fork-tip needle | *P* value |
|---|---|---|---|
| ROSE, diagnostic adequacy | 47 (94.0) | 49 (98.0) | .317 |
| ROSE, total no. of passes for diagnostic adequacy* | | | .317 |
| Mean (SD) | 1.04 (.20) | 1.04 (.20) | |
| Median | 1 | 1 | |
| IQR | 1-1 | 1-1 | |
| Range | 1-2 | 1-2 | .317 |
| 1 | 45 (95.7) | 47 (95.9) | |
| 2 | 2 (4.3) | 2 (4.1) | |
| Specimen bloodiness | | | .819† |
| Mild | 14 (28.0) | 15 (30.0) | |
| Moderate | 23 (46.0) | 25 (50.0) | |
| Severe | 13 (26.0) | 10 (20.0) | |
| Diagnostic cell block | 48 (96.0) | 46 (92.0) | .317 |

**Conclusions:** There was no significant difference between Franseen and Fork-tip needles in yielding histologic tissue. Given their ability to yield diagnostic cell block in greater than 90% of patients, the new-generation fine-needle biopsy needles may obviate the need for ROSE. (Clinical trial registration number: NCT02910960.)

# Randomized controlled trial comparing the Franseen needle with the Fork-tip needle for EUS-guided fine-needle biopsy CME

Munish Ashat, MD,[1] Jagpal S. Klair, MD,[1] Sydney L. Rooney, MD,[2] Sagar J. Vishal, MD,[2] Chris Jensen, MD,[2] Nadav Sahar, MD,[1] Arvind R. Murali, MD,[1] Rami El-Abiad, MD,[1] Henning Gerke, MD[1]

## GRAPHICAL ABSTRACT



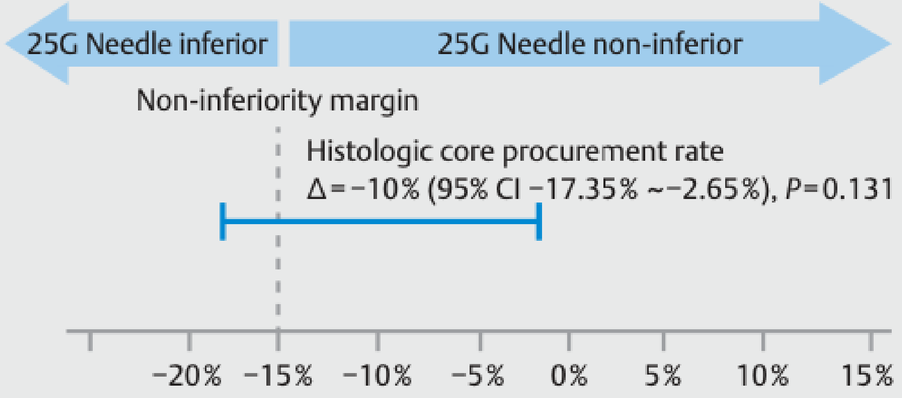

| | Franseen Needle (n=75) | Fork-tip Needle (n=75) | *P* value | Absolute difference (95% CI) |
|---|---|---|---|---|
| Histology, diagnostic accuracy | 64 (85.3%; 95% CI, 75.3 - 92.4) | 68 (90.7%, CI: 81.7 - 96.2) | 0.45 | 5.4% (CI, -15.7, 5.0%) |
| Cytology, diagnostic accuracy | 58 (77.3%; 95% CI, 66.2 - 86.2) | 63 (84%, CI: 73.7 - 91.4) | 0.41 | 6.7% (CI, -19.3, 5.9%) |
| Combined diagnostic accuracy | 65 (86.7%; 95% CI, 76.8 - 93.4) | 69 (92%, CI: 83.4 - 97.0) | 0.43 | 5.3% (CI, -15.2, 4.5%) |

| | Franseen needle (N = 75), n (%; 95% CI) | Fork-tip needle (N = 75), n (%; 95% CI) | *P* value |
|---|---|---|---|
| Pancreatic lesions (n=75) | 39 | 36 | |
| Histology, diagnostic accuracy | 35 (89.7; 75.8-97.1) | 34 (94.4; 81.3-99.3) | .68 |
| Cytology, diagnostic accuracy | 34 (87.2; 72.6-95.7) | 31 (86.1; 70.5-95.3) | 1 |
| Combined diagnostic accuracy | 36 (92.3; 79.1-98.4) | 34 (94.4; 81.3-99.3) | 1 |
| Nonpancreatic solid lesions (n = 75) | 36 | 39 | |
| Histology, diagnostic accuracy | 30 (83.3; 67.2-93.6) | 34 (87.2; 72.6-95.7) | .75 |
| Cytology, diagnostic accuracy | 24 (66.6; 49-81.4) | 32 (82.1; 66.5-92.5) | .18 |
| Combined diagnostic accuracy | 31 (86.1; 70.5-95.3) | 33 (84.6; 69.5-94.1) | 1 |

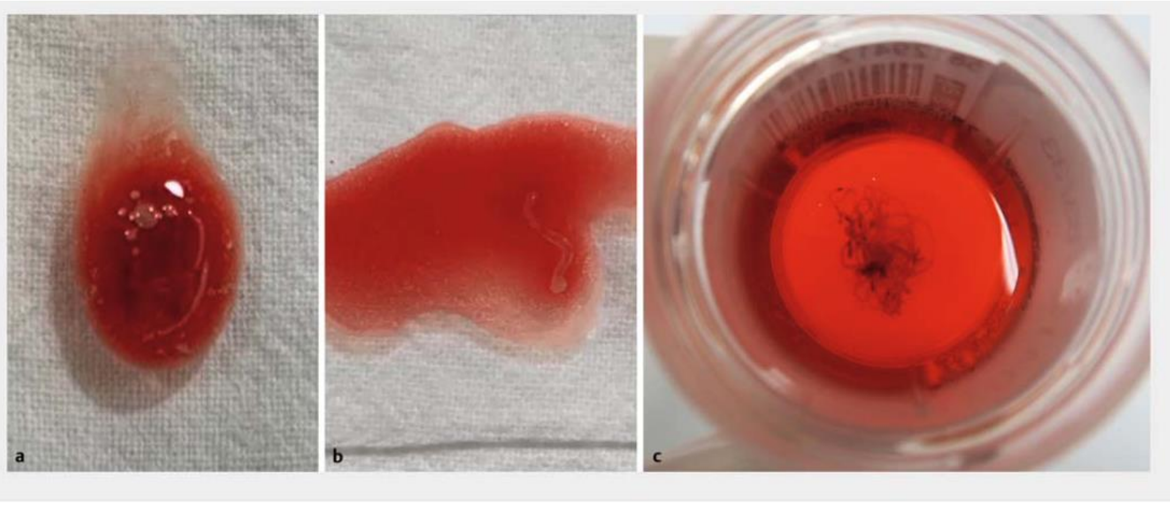
**Conclusions:** There was no significant difference in the performance of the Franseen needle versus the Fork-tip needle. Both needles achieved a high yield of histologic tissue samples and high diagnostic accuracy. (Clinical trial registration number: NCT03672032.) (Gastrointest Endosc 2021;93:140-50.)

# A comparison between 25-gauge and 22-gauge Franseen needles for endoscopic ultrasound-guided sampling of pancreatic and peripancreatic masses: a randomized non-inferiority study

Authors
Dongwook Oh[1], Joonseog Kong[2], Sung Woo Ko[1], Seung-Mo Hong[2], Hoonsub So[1], Jun Seong Hwang[1], Tae Jun Song[1], Sung Koo Lee[1], Myung-Hwan Kim[1], Sang Soo Lee[1]




▶ **Fig. 3** Non-inferiority analysis demonstrating the histologic core procurement rate of a 25-gauge Franseen needle compared with that of a 22-gauge needle.




| Characteristics | Type of needle | |
|---|---|---|
| | 22 gauge (n = 70) | 25 gauge (n = 70) |
| Sensitivity (95 %CI) | 100 % (94.3 %–100 %) | 98.4 % (91.5 %–99.9 %) |
| Specificity (95 %CI) | 100 % (59.0 %–100 %) | 85.7 % (42.1 %–99.6 %) |
| Overall accuracy (95 %CI) | 100 % (94.9 %–100 %) | 97.4 % (90.1 %–99.7 %) |

**Conclusions** The 25G Franseen needle was inferior to the 22G needle in histologic core procurement. Therefore, for cases in which tissue architecture is pivotal for diagnosis, a 22G needle, which procures relatively higher quality specimens than the 25G needle, should be used.

Endoscopy 2021; 53: 1122–1129

# Randomized trial comparing the 25G and 22G Franseen needles in endoscopic ultrasound-guided tissue acquisition from solid pancreatic masses for adequate histological assessment

Takeshi Tomoda,[1,3] Hironari Kato,[1] Yuuki Fujii,[1] Tatsuhiro Yamazaki,[1] Kazuyuki Matsumoto,[1] Shigeru Horiguchi,[1] Koichiro Tsutsumi,[1] Hirofumi Inoue,[4] Takehiro Tanaka,[4] Toshiharu Mitsuhashi[2] and Hiroyuki Okada[1]

**Table 4** Diagnostic efficacy of 22G vs. 25G Franseen needle

| | 25G needle | | 22G needle | | Difference (95% CI)[a] | *P*-value for equality |
|---|---|---|---|---|---|---|
| | *n*/*N* | % (95% CI) | *n*/*N* | % (95% CI) | | |
| Sensitivity | 72/84 | 85.7 (76.7 to 91.6) | 75/84 | 89.3 (80.9 to 94.2) | –3.6% (–9.9% to 2.8%) | 0.180[b] |
| Specificity | 4/4 | 100 (51.0 to 100) | 4/4 | 100 (51.0 to 100) | — | — |
| Positive predictive value | 72/72 | 100 (94.9 to 100) | 75/75 | 100 (95.1 to 100) | — | — |
| Negative predictive value | 4/16 | 25.0 (10.2 to 49.5) | 4/13 | 30.8 (12.7 to 57.6) | –5.8% (–38.6% to 27.1%) | 0.730[c] |
| Accuracy | 76/88 | 86.4 (77.7 to 92.0) | 79/88 | 89.8 (81.7 to 94.5) | –3.4% (–9.5% to 2.7%) | 0.180[b] |

**Table 2** Outcome of endoscopic ultrasound-guided sampling and histologic findings in each group

| | 25G group | 22G group | Adjusted difference (95% CI) | *P*-value | |
|---|---|---|---|---|---|
| | *n* = 88 | *n* = 88 | | Noninferiority | Superiority/equality |
| Primary endpoint | | | | | |
| Adequate tissue acquisition rate | 62 (70.5%) | 69 (78.4%) | –6.6% (–8.8% to –4.5%) | <0.001 | 0.999 |
| Secondary endpoints | | | | | |
| High-quality tissue acquisition rate | 22 (25.0%) | 40 (45.5%) | –22.7% (–24.1% to –21.2%) | 0.999 | |

***Conclusions:*** The 25G Franseen needle showed a noninferior adequate tissue acquisition and similar diagnostic performance compared to that of the 22G Franseen needle. However, a 15% noninferiority margin was high for clinical use; thus, further consideration is needed (Clinical Trial Registry no. UMIN000034596).

# Comparative diagnostic performance of end-cutting fine-needle biopsy needles for EUS tissue sampling of solid pancreatic masses: a network meta-analysis (CME)

Paraskevas Gkolfakis, MD,[1] Stefano Francesco Crinò, PhD,[2] Georgios Tziatzios, PhD,[3] Daryl Ramai, MD,[4] Apostolis Papaefthymiou, MD,[5] Ioannis S. Papanikolaou, PhD,[3] Konstantinos Triantafyllou, PhD, Prof,[3] Marianna Arvanitakis, PhD,[1] Andrea Lisotti, MD,[6] Pietro Fusaroli, PhD,[6] Benedetto Mangiavillano, PhD,[7] Silvia Carrara, MD,[8,9] Alessandro Repici, PhD, Prof,[8,9] Cesare Hassan, PhD, Prof,[8,9] Antonio Facciorusso, PhD[2,10]

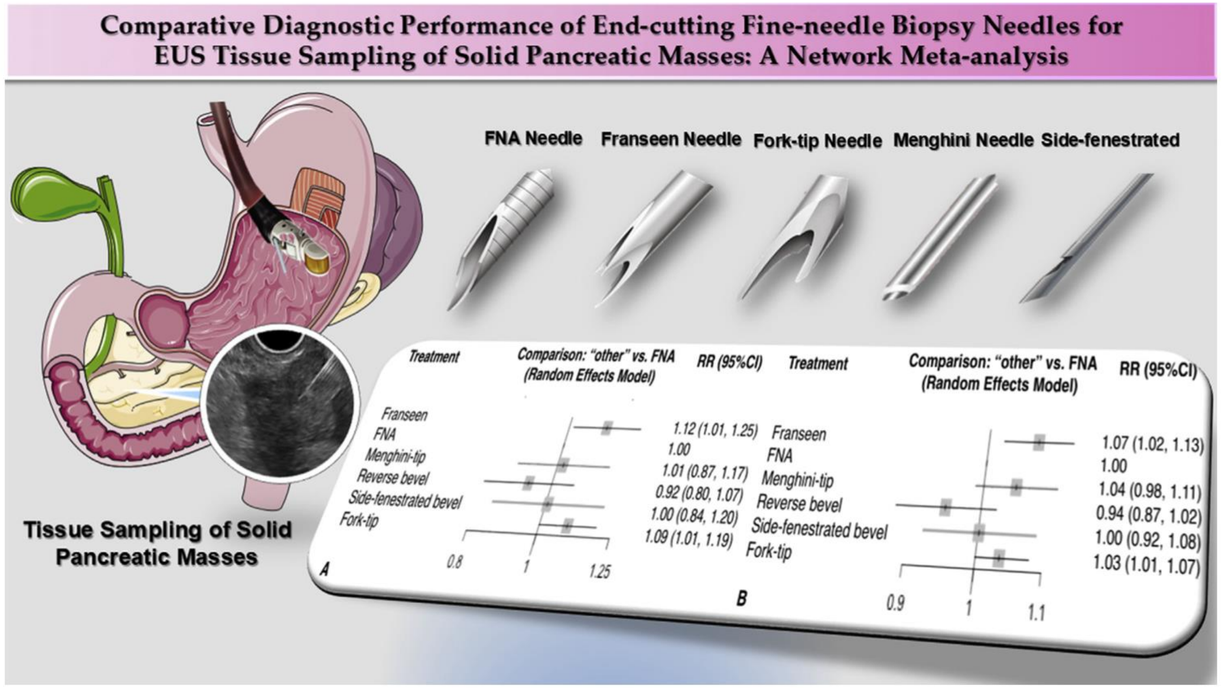



**TABLE 3. Surface under the cumulative ranking score for diagnostic accuracy and sample adequacy**

| Diagnostic accuracy | | Sample adequacy | |
|---|---|---|---|
| **Franseen** | **.89** | **Franseen** | **.94** |
| Fork-tip | .76 | Fork-tip | .73 |
| Menghini | .53 | Menghini | .69 |
| Reverse bevel 20-gauge | .37 | Reverse bevel 20-gauge | .37 |
| FNA | .29 | FNA | .26 |
| Reverse bevel | .27 | Reverse bevel | .23 |

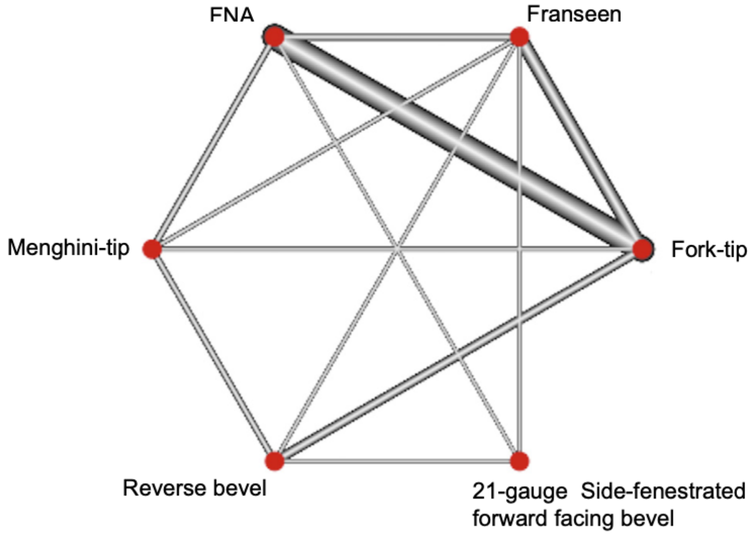



**Figure 2.** Network of included studies with the available direct comparisons between needles for EUS-guided sampling of pancreatic lesions. The size of the nodes and the thickness of the edges are weighted according to the number of studies evaluating each treatment and direct comparison, respectively.

Franseen and Fork-tip needles, particularly 22-gauge size, showed the highest performance for tissue sampling of pancreatic masses, with low confidence in estimates.

None of the tested needles was significantly superior to the other FNB devices or to FNA needles when rapid onsite cytologic evaluation was available.

# Endoscopic ultrasound (EUS)-guided fine needle biopsy alone vs. EUS-guided fine needle aspiration with rapid onsite evaluation in pancreatic lesions: a multicenter randomized trial

Authors
Yen-I Chen[1], Avijit Chatterjee[2], Robert Berger[3], Yonca Kanber[4], Jonathan Wyse[5], Eric Lam[6], Ian Gan[7], Manon Auger[4], Sana Kenshil[2], Jennifer Telford[6], Fergal Donnellan[7], James Quinlan[2], Gregory Lutzak[8], Fatma Alshamsi[2], Josee Parent[1], Kevin Waschke[1], Adel Alghamdi[1], Jeffrey Barkun[9], Peter Metrakos[9], Prosanto Chaudhury[9], Myriam Martel[1], Alastair Dorreen[2], Kristen Candido[1], Corey Miller[5], Viviane Adam[1], Alan Barkun[1], George Zogopoulos[9], Clarence Wong[8]

▶ **Table 3** Diagnostic characteristics for sampling of solid pancreatic lesions with endoscopic ultrasound (EUS)-guided fine-needle biopsy (EUS-FNB) alone or EUS-guided fine-needle aspiration (EUS-FNA) with rapid onsite evaluation of cytopathology (ROSE). All results are shown as percentages (95 % confidence intervals).

| | All | EUS-FNB | EUS-FNA + with ROSE | *P* value |
|---|---|---|---|---|
| Accuracy | 92.8 % (89.4 %–96.1 %) | 92.2 % (86.6 %–96.9 %) | 93.3 % (88.8 %–97.9 %) | 0.72 |
| Sensitivity | 93.1 % (88.9 %–96.1 %) | 92.5 % (85.7 %–96.7 %) | 96.5 % (93.0 %–98.6 %) | 0.46 |
| Specificity | 100.0 % (79.4 %–100.0 %) | 100.0 % (63.1 %–100.0 %) | 100.0 % (63.1 %–100.0 %) | > 0.99 |
| Positive predictive value | 100.0 % | 100.0 % | 100.0 % | |
| Negative predictive value | 51.6 % (39.6 %%–63.5 %) | 50.0 % (33.9 %–96.9 %) | 53.3 % (35.6 %–70.3 %) | |

**Conclusion** EUS-FNB alone is non-inferior to EUS-FNA + ROSE and is associated with fewer needle passes, shorter procedure time, and excellent histological yield at comparable cost.

Endoscopy 2022; 54: 4–12

# Endoscopic Ultrasound–guided Fine-needle Biopsy With or Without Rapid On-site Evaluation for Diagnosis of Solid Pancreatic Lesions: A Randomized Controlled Non-Inferiority Trial

Stefano Francesco Crinò,[1] Roberto Di Mitri,[2] Nam Q. Nguyen,[3] Ilaria Tarantino,[4] Germana de Nucci,[5] Pierre H. Deprez,[6] Silvia Carrara,[7] Masayuki Kitano,[8] Vanessa M. Shami,[9] Gloria Fernández-Esparrach,[10] Jan-Werner Poley,[11] Francisco Baldaque-Silva,[12] Takao Itoi,[13] Erminia Manfrin,[14] Laura Bernardoni,[1] Armando Gabbrielli,[1] Elisabetta Conte,[2] Elettra Unti,[15] Jeevinesh Naidu,[3] Andrew Ruszkiewicz,[16] Michele Amata,[4] Rosa Liotta,[17] Gianpiero Manes,[5] Franca Di Nuovo,[18] Ivan Borbath,[6] Mina Komuta,[19,20] Laura Lamonaca,[7] Daoud Rahal,[21] Keiichi Hatamaru,[8] Masahiro Itonaga,[8] Gianenrico Rizzatti,[22] Guido Costamagna,[22,23] Frediano Inzani,[24] Mariangela Curatolo,[24] Daniel S. Strand,[9] Andrew Y. Wang,[9] Àngels Ginès,[10] Oriol Sendino,[10] Marianna Signoretti,[11,25] Lydi M. J. W. van Driel,[11] Karoly Dolapcsiev,[26] Yukitoshi Matsunami,[13] Schalk van der Merwe,[27] Hannah van Malenstein,[27] Francesca Locatelli,[28] Loredana Correale,[1] Aldo Scarpa,[14,29] and Alberto Larghi[22,23]

Gastroenterology 2021;161:899–909

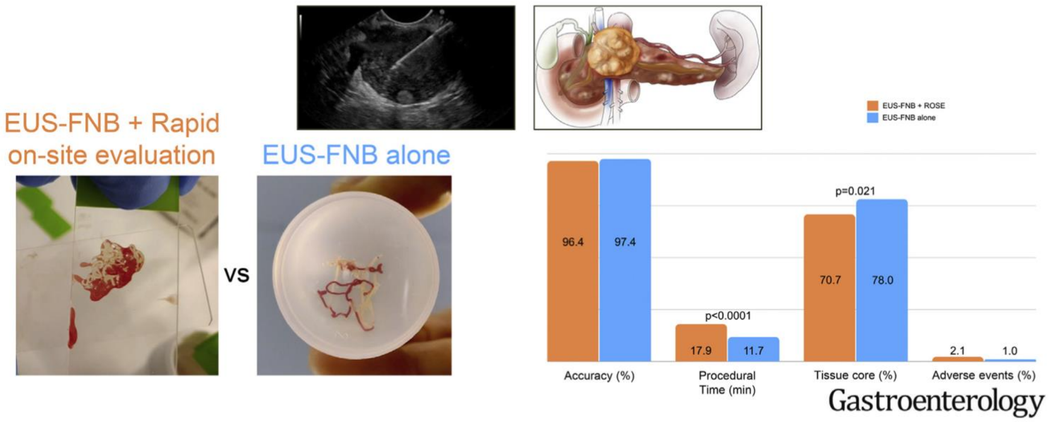



**Table 4.** Comparison of Operating Characteristics by Needle Type

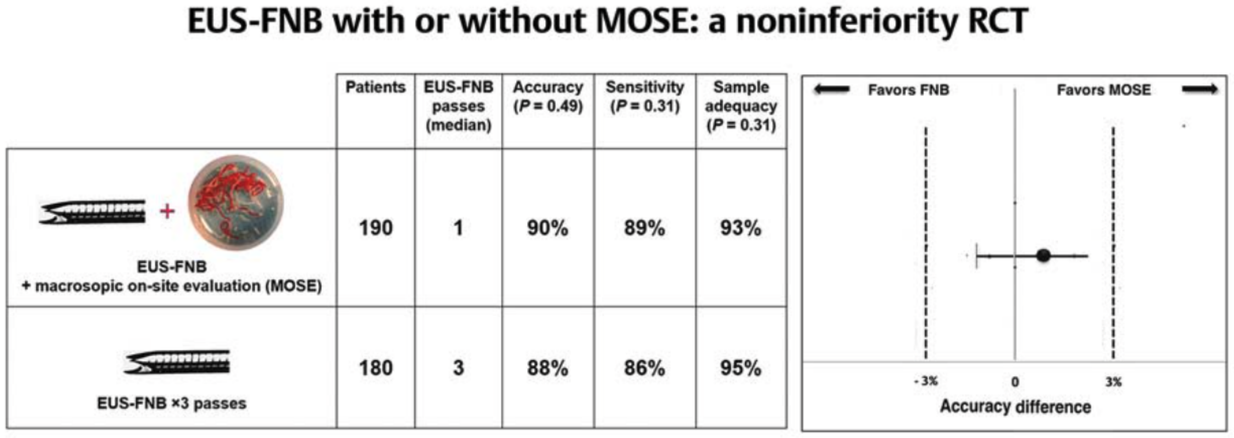
| Needle | Accuracy % (95% CI) | Core Procurement[a] % (95% CI) | Blood Contamination[b] % (95% CI) | Adverse Events n (%) |
|---|---|---|---|---|
| ProCore 20G (157) | 93.6 (88.6–96.9) | 68.2 (60.3–75.4) | Little, 32.5 (25.3–40.4)<br>Medium, 44.0 (36.2–51.7)<br>High, 23.5 (16.9–30.2) | 2 (1.3) |
| SharkCore 22G (163) | 98.8 (95.7–99.8) | 73.0 (65.5–79.7) | Little, 52.1 (44.5–60.0)<br>Medium, 25.8 (19.1–32.5)<br>High, 22.1 (15.7–28.4) | 5 (3.2) |
| Acquire 22G (451) | 97.3 (95.4–98.6) | 76.9 (72.8–80.8) | Little, 40.6 (36.0–45.3)<br>Medium, 42.8 (38.2–47.4)<br>High, 16.6 (13.2–20.0) | 5 (1.1) |

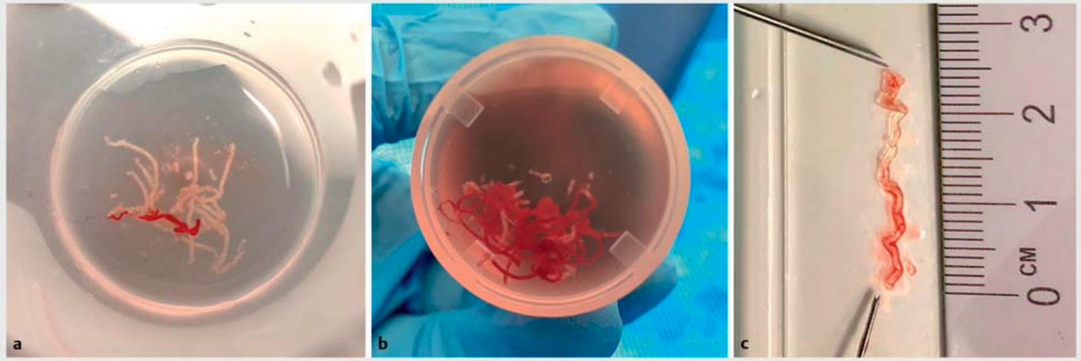
**Table 2.** Diagnostic Measures of EUS-FNB+ROSE and EUS-FNB Alone for Evaluation of SPLs

| | EUS-FNB+ROSE (n = 385) | | EUS-FNB Alone (n = 386) | | |
|---|---|---|---|---|---|
| Diagnostic Measures | % (n/N) | 95% CI | % (n/N) | 95% CI | *P*[a] |
| Sensitivity[b] | 96.0 (359/373) | 93.5–97.7 | 97.3 (361/371) | 95.1–98.7 | .324 |
| Specificity | 100 (12/12) | 73.5–100 | 100 (15/15) | 78.2–100 | NS |
| Positive predictive value | 100 (359/359) | 99.0–100 | 100 (361/361) | 99.0–100 | NS |
| Negative predictive value | 46.2 (12/26) | 26.6–66.6 | 60.0 (15/25) | 38.7–78.9 | .738 |
| Accuracy[b] | 96.4 (371/385) | 94.0–98.0 | 97.4 (376/386) | 95.3–98.8 | .396 |

# Endoscopic ultrasound-guided fine-needle biopsy with or without macroscopic on-site evaluation: a randomized controlled noninferiority trial

Authors
Benedetto Mangiavillano[1,2], Stefano Francesco Crinò[3], Antonio Facciorusso[4], Francesco Di Matteo[5], Carmelo Barbera[6], Alberto Larghi[7], Gianenrico Rizzatti[7], Silvia Carrara[8], Marco Spadaccini[8], Francesco Auriemma[1], Carlo Fabbri[9], Cecilia Binda[9], Chiara Coluccio[9], Gianmarco Marocchi[9], Teresa Staiano[10], Maria Cristina Conti Bellocchi[3], Laura Bernardoni[3], Leonardo Henri Eusebi[11], Giovanna Grazia Cirota[11], Germana De Nucci[12], Serena Stigliano[5], Gianpiero Manes[12], Giacomo Bonanno[13], Andrew Ofosu[14], Laura Lamonaca[1], Danilo Paduano[1], Federica Spatola[1], Alessandro Repici[2,8]



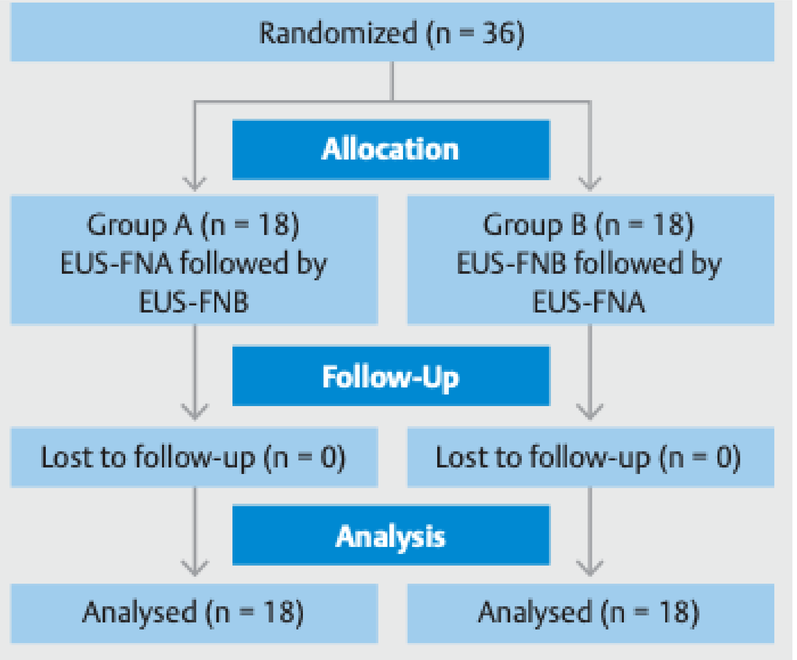



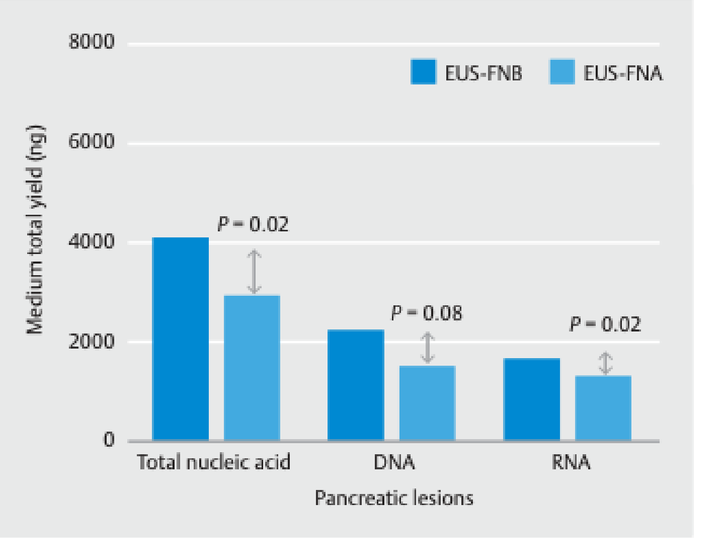

▶ **Fig. 1** Representative images of the macroscopic on-site evaluation (MOSE) technique showing: **a** a container with a small amount of saline containing an adequate sample consisting of several long worm-like white pieces of tissue; **b** fragmented specimens with white cores of uncertain aggregate length; **c** specimens transferred to a slide, with the white/yellowish cores aligned and measured using a ruler.

| | EUS-FNB with MOSE (n = 190) | EUS- FNB without MOSE (n = 180) | *P* value |
|---|---|---|---|
| Accuracy, n (%) [95 %CI]* | 171 (90.0 %) [84.8 % to 93.9 %] | 158 (87.8 %) [82.1 % to 92.2 %] | 0.49 |
| Sample adequacy, % (95 %CI) | 93.1 % (88.6 % to 96.3 %) | 95.5 % (91.4 % to 98.0 %) | 0.31 |
| Sensitivity, % (95 %CI)[1] | 88.8 % (83.1 % to 93.1 %) | 86.3 % (79.9 % to 91.2 %) | 0.31 |
| Specificity, % (95 %CI) | 100 % (83.2 % to 100 %) | 100 % (83.2 % to 100 %) | 0.89 |
| Positive predictive value, % | 100 % | 100 % | > 0.99 |
| Negative predictive value, % (95 %CI) | 51.3 % (40.8 % to 61.7 %) | 47.6 % (38.1 % to 57.3 %) | 0.15 |
| Adverse event rate, n (%) | 5 (2.6 %) | 2 (1.1 %) | 0.28 |

# Comparison of tissue and molecular yield between fine-needle biopsy (FNB) and fine-needle aspiration (FNA): a randomized study

Authors
Ravishankar Asokkumar[1], Chin Yung Ka[1], Tracy Loh[2], Lim Kah Ling[3], Tan Gek San[2], Hao Ying[4], Damien Tan[1], Christopher Khor[1], Tony Lim[2], Roy Soetikno[1,5]




▶ **Fig. 5** Quantification of nucleic acid obtained by the two needles. EUS-FNB provided significantly more nucleic acid than EUS-FNA. EUS-FNB yielded significantly more RNA and a trend towards an increased amount of DNA.

**Conclusion** The 22G EUS-FNB provides more histological core tissue and adequate nucleic acid yield compared to 22G EUS-FNA. In this study, the diagnostic performance was similar between the needles

Endoscopy International Open 2019; 07: E955–E963

# EUS-FNA for solid lesions: An idea whose time has passed?

**Daryl Ramai[1], Douglas G Adler[2]**
[1]Department of Gastroenterology and Hepatology, University of Utah Health, Salt Lake City, UT, USA; [2]Center for Advanced Therapeutic Endoscopy, Porter Adventist Hospital/PEAK Gastroenterology, Denver, Colorado, USA

To this end we ask: should FNB be the standard of care for EUS guided tissue acquisition? Is it time to close the chapter on FNA?

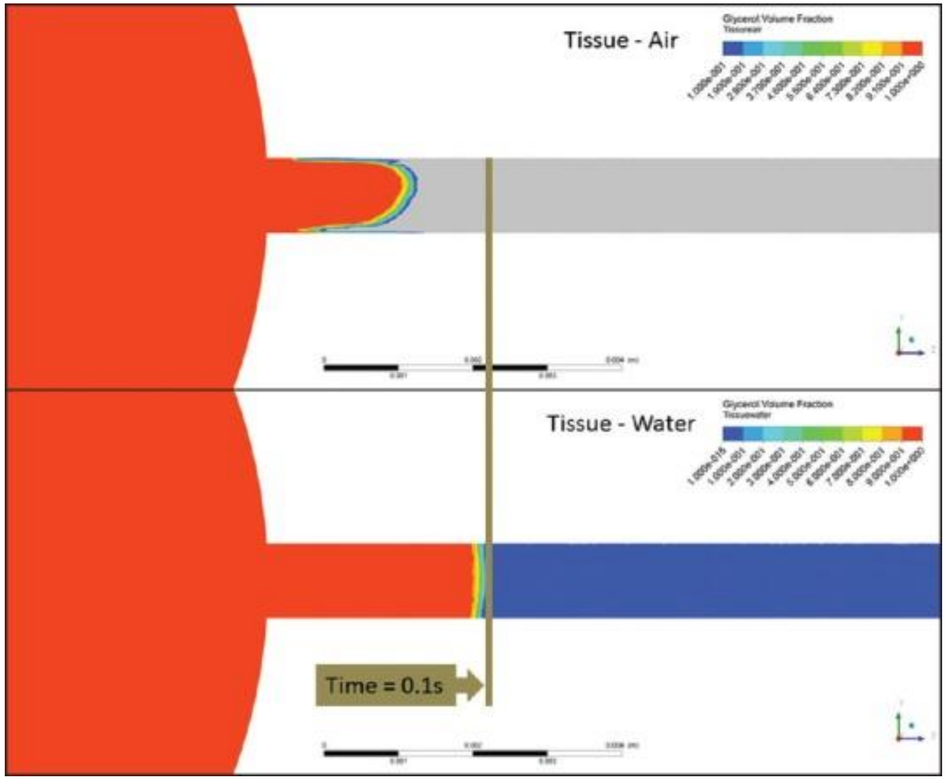
However, FNB represents a more effective approach at targeting solid lesions with the benefit of higher accuracy, being cost-effective, does not require ROSE, and yields adequate sampling to conduct personalized medicine including genetic analysis. Given these promising features, is it time to forgo EUS-FNA? When it comes to the sampling of solid lesions, FNB has largely become the *de facto* standard of care. FNA should, with rare exceptions, be limited to the sampling of cystic lesions.

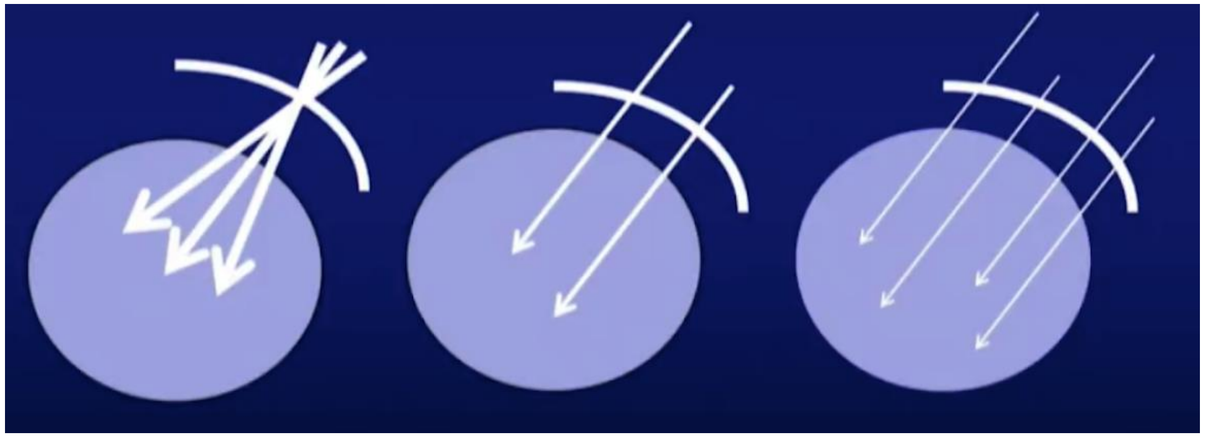



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# TECHNIQUES IN SAMPLING

- The use and type of suction
  - Standard suction (with a 10 or 20-mL syringe)
  - “High pressure suction” (with a 50-mL syringe)
  - Wet suction/hybrid technique
  - Slow-pull
- The use of stylet
- Multipass vs Funning



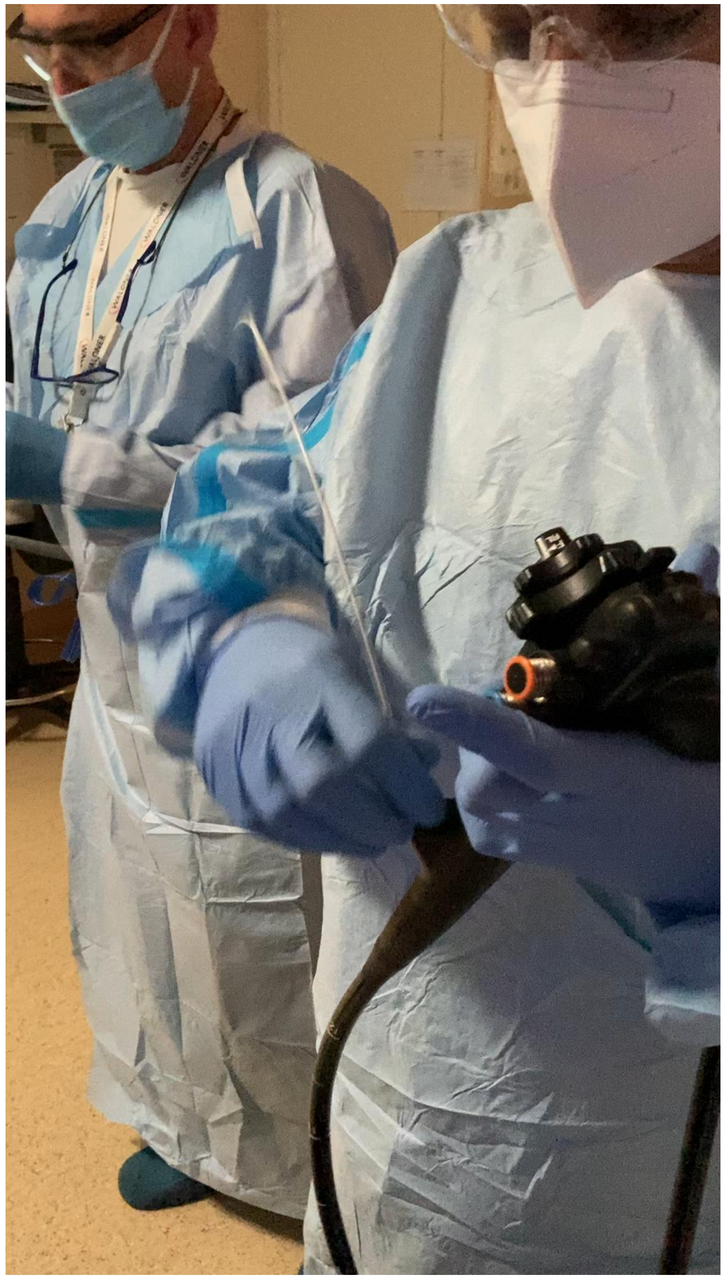



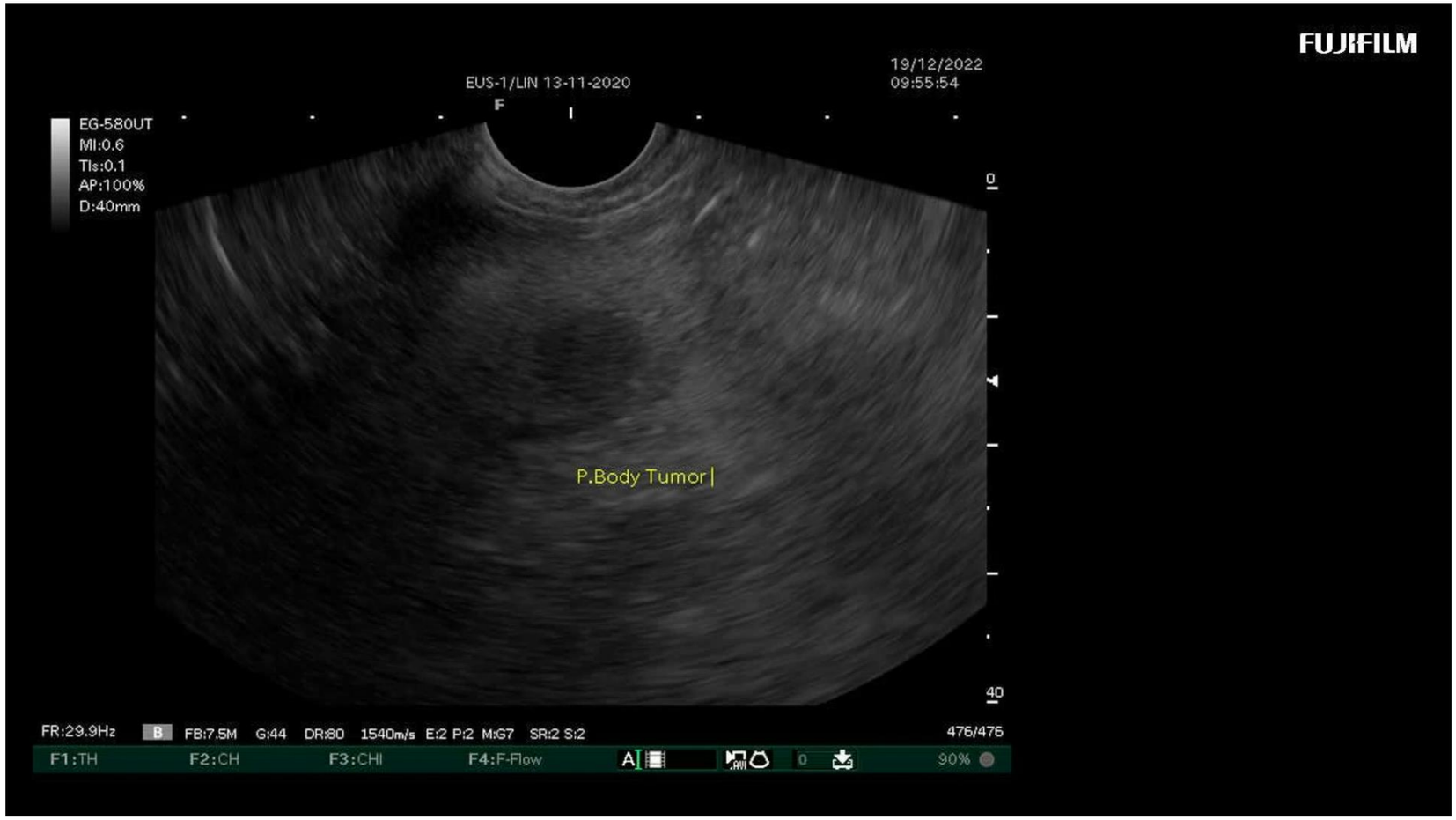
# Fine Needle Biopsies of Solid Pancreatic Lesions: Tissue Acquisition Technique and Needle Design Do Not Impact Specimen Adequacy

Antonio Mendoza Ladd[1,2] · Nancy Casner[3] · Sundar V. Cherukuri[4] · Cesar Garcia[5] · Osvaldo Padilla[6] · Alok Dwivedi[7] · Nawar Hakim[6]

**Table 3** Outcome comparison by tissue acquisition technique

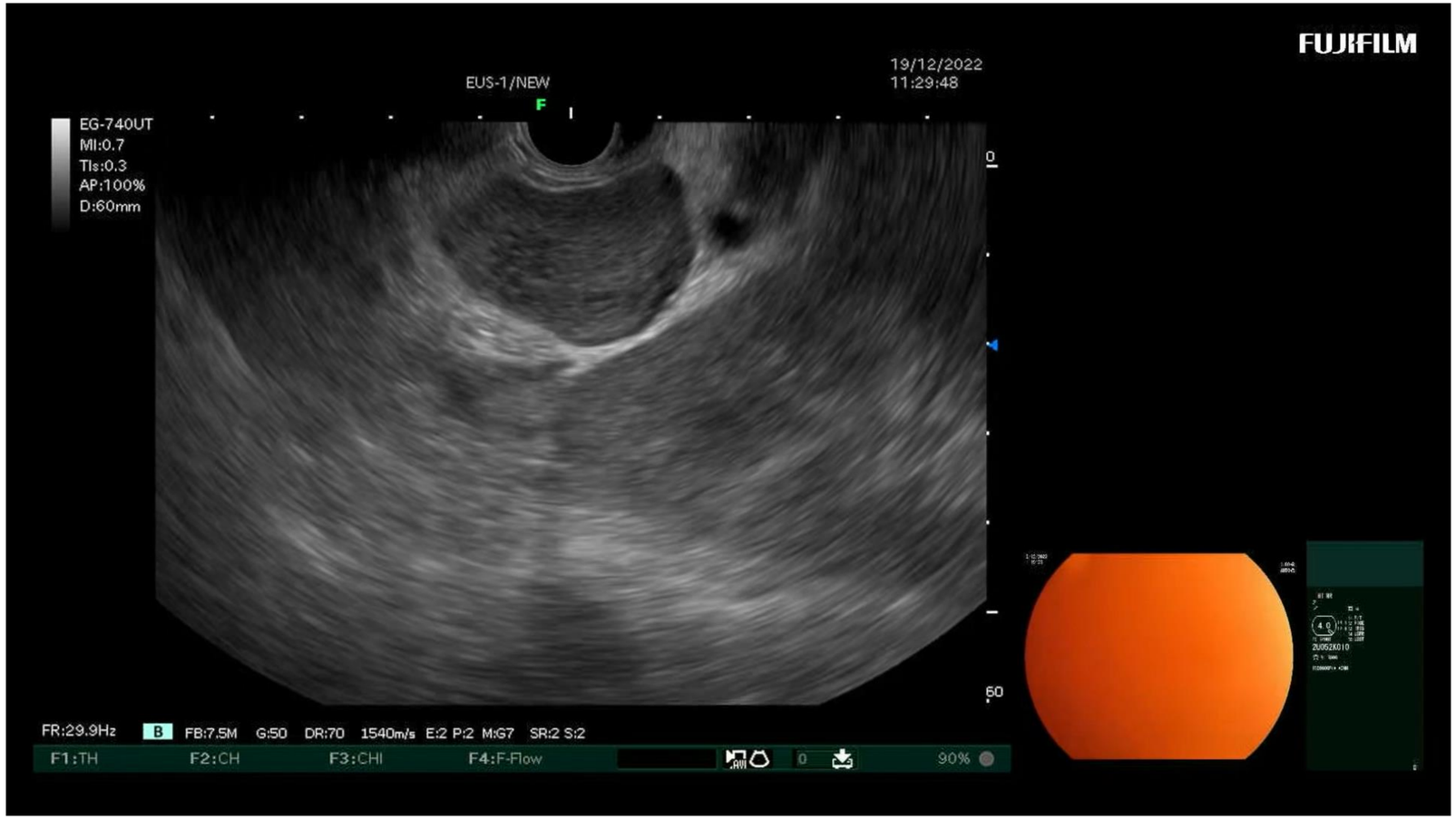
| Outcome | Overall | DS | WS | SP | *p* value |
|---|---|---|---|---|---|
| | 55 | 20 | 17 | 18 | |
| Cellularity Score *N*, (%) | | | | | 0.18 |
| 2 | 10 (18%) | 2 (10%) | 5 (29%) | 3 (17%) | |
| 3 | 23 (42%) | 6 (30%) | 8 (47%) | 9 (50%) | |
| 4 | 19 (35%) | 11 (55%) | 4 (24%) | 4 (22%) | |
| 5 | 3 (5%) | 1 (5%) | 0 (0%) | 2 (11%) | |
| Cellularity Score, mean (SD) | 3.27 (0.83) | 3.55 (0.76) | 2.94 (0.75) | 3.28 (0.89) | 0.081 |
| Blood contamination *N*, (%) | | | | | 0.41 |
| 1 | 54 (98%) | 19 (95%) | 17 (100%) | 18 (100%) | |
| 2 | 1 (2%) | 1 (5%) | 0 (0%) | 0 (0%) | |
| Diagnostic pass # *N*, (%) | | | | | 0.45 |
| 1 | 24 (44%) | 11 (55%) | 6 (35%) | 7 (39%) | |
| 2 | 16 (29%) | 5 (25%) | 7 (41%) | 4 (22%) | |
| 3 | 12 (22%) | 3 (15%) | 3 (18%) | 6 (33%) | |
| 4 | 1 (2%) | 0 (0%) | 1 (6%) | 0 (0%) | |
| 5 | 1 (2%) | 1 (5%) | 0 (0%) | 0 (0%) | |
| 6 | 1 (2%) | 0 (0%) | 0 (0%) | 1 (6%) | |




FUJIFILM
EUS-1/LIN 13-11-2020
19/12/2022
09:55:54
F
I
EG-580UT
MI:0.6
TIs:0.1
AP:100%
D:40mm
0
40
P.Body Tumor
FR:29.9Hz
B
FB:7.5M
G:44
DR:80
1540m/s
E:2 P:2 M:G7
SR:2 S:2
476/476
F1:TH
F2:CH
F3:CHI
F4:F-Flow
90%






FUJIFILM
EUS-1/NEW
19/12/2022
11:29:48
EG-740UT
MI:0.7
TIs:0.3
AP:100%
D:60mm
0
60
FR:29.9Hz
B
FB:7.5M
G:50
DR:70
1540m/s
E:2 P:2 M:G7
SR:2 S:2
F1:TH
F2:CH
F3:CHI
F4:F-Flow
90%

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