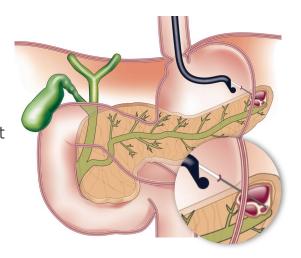
Pancreatic Cysts*

Cellvizio®

Real-time Differentiation

Problem statement

 Many patients with pancreatic cysts do not get a definitive diagnosis after an Endoscopic Ultrasound-guided Fine Needle Aspiration (EUS-FNA) procedure



Current solution and limitations

Although EUS-FNA is currently common practice, its sensitivity for cystic lesions diagnosis is low:

- Cytology has a sensitivity up to 40%¹
- Carcino-Embryonic Antigen (CEA) improves sensitivity to 75%¹, potentially leaving many patients with malignant cysts

Cellvizio images³

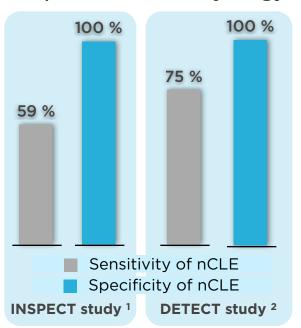


Intraductal Papillary Mucinous Neoplasm (IPMN)



Serous Cystadenoma

Detection of mucinous pancreatic cysts Higher diagnostic yield of nCLE compared to CEA or cytology¹



Potential Cellvizio advantages

Clinical studies have demonstrated that Cellvizio can facilitate^{2,3,4}

- The differentiation between mucinous and non-mucinous pancreatic cysts during EUS-FNA procedures
- The quick identification of patients who need surgery
- The reduction of unnecessary diagnostic procedures



App Notes© Mauna Kea Technologies, April 2012 V1.01

Cellvizio[®]



Designed to combine the most advanced imaging technology with ergonomics for ease of use and patient comfort.

Better patient care is our aim

References

- 1. Brugge W. at al., Diagnosis of Pancreatic Cystic Neoplasms: A Report of the Cooperative Pancreatic Cyst Study, Gastroenterology, 2004.
- 2. Waxman, I., Aslanian, H.R., Konda, V.J., Siddiqui, U.D., Wallace, M.B. First Assessment of Needle-based Confocal Laser Endomicroscopy (nCLE) During EUS-FNA Procedures of the Pancreas. GIE, In Press.
- 3. Konda V, An International, Multi-Center Trial on Needle-Based Confocal Laser Endomicroscopy (nCLE): Results From the In Vivo CLE Study in the Pancreas With Endosonography of Cystic Tumors (INSPECT), poster at DDW 2012
- 4.Nakai Y, Chang K, Diagnosis of Pancreatic Cysts: Endoscopic Ultrasound, Through-the-Needle Confocal Laser-Induced Endomicroscopy and Cystoscopy Trial (DETECT Study), oral presentation at DDW 2012

Confocal MiniprobesTM are intended to be used during standard endoscopy procedures. Once connected to the Cellvizio® system, Confocal MiniprobesTM are inserted through the lumen of endoscopes or endoscope accessories to provide imaging through direct contact of their distal tip with tissues within or adjacent to the gastrointestinal and respiratory tracts.

The Cellvizio System is a regulated Medical Device CE marked (Class IIa - NB : LNE/G-MED) and FDA cleared. Please consult labels and instructions for use.

* The AQ-FlexTM 19 Confocal MiniprobeTM has not been cleared by the FDA

