
Endoscopic ultrasound (EUS) with fine-needle aspiration (FNA) of pancreatic cystic lesions (PCL) is flawed by inadequate diagnostic yield. Needle-based confocal laser endomicroscopy (nCLE) utilizes a sub-millimeter probe that is compatible with an EUS needle and enables real-time imaging with microscopic detail of PCL. The aims of the In vivo nCLE Study in the Pancreas with Endosonography of Cystic Tumors (INSPECT) pilot study were to assess both the diagnostic potential of nCLE in differentiating cyst types and the safety of the technique. Eight referral centers performed nCLE in patients with PCL. Stage 1 defined descriptive terms for structures visualized by an off-line, unblinded consensus review. Cases were reviewed with a gastrointestinal pathologist to identify correlations between histology and nCLE. Stage 2 assessed whether the specific criteria defined in Stage 1 could identify pancreatic cystic neoplasms (PCN) including intraductal papillary mucinous neoplasms, mucinous cystic adenoma, or adenocarcinoma in an off-line blinded consensus review. A total of 66 patients underwent nCLE imaging and images were available for 65, 8 of which were subsequently excluded.
due to insufficient information for consensus reference diagnosis. The presence of epithelial villous structures based on nCLE was associated with PCN (P=0.004) and provided a sensitivity of 59%, specificity of 100%, positive predictive value of 100 %, and negative predictive value of 50%. The overall complication rate was 9% and included pancreatitis (1 mild case, 1 moderate case), transient abdominal pain (n=1), and intracystic bleeding not requiring any further measures (n=3). These preliminary data suggested that nCLE has a high specificity in the detection of PCN, but may be limited by a low sensitivity. The safety of nCLE requires further evaluation.