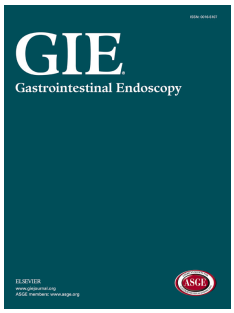

Standardization of EUS imaging and reporting in high-risk individuals of pancreatic adenocarcinoma: consensus statement of the Pancreatic Cancer Early Detection Consortium (PRECEDE)

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Standardization of EUS imaging and reporting in high-risk individuals of pancreatic adenocarcinoma: consensus statement of the Pancreatic Cancer Early Detection Consortium (PRECEDE)

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Background and Aims. Pancreatic ductal adenocarcinoma is an aggressive disease most often diagnosed after local progression or metastatic dissemination, precluding resection and resulting in a high mortality rate. For individuals with elevated personal risk of the development of pancreatic cancer, EUS is a frequently used advanced imaging and diagnostic modality. However, there is variability in the expertise and definition of EUS findings among gastroenterologists, as well as lack of standardized reporting of relevant findings at the time of examination. Adoption of standardized EUS reporting, using a universally accepted and agreed upon terminology, is needed.

Methods. A consensus statement designed to create a standardized reporting template was authored by a multidisciplinary group of experts in pancreatic diseases that includes gastroenterologists, radiologists, surgeons, oncologists, and geneticists. This statement was developed using a modified Delphi process as part of the Pancreatic Cancer Early Detection Consortium (PRECEDE) and >75% agreement was required to reach consensus.

Results. We identified reporting elements and present standardized reporting templates for EUS indications, procedural data, EUS image capture, and descriptors of findings, tissue sampling, and for postprocedural assessment of adequacy.

Conclusions. Adoption of this standardized EUS reporting template should improve consistency in clinical decision making for individuals with elevated risk of pancreatic cancer by providing complete and accurate reporting of pancreatic abnormalities. Standardization will also help to facilitate research and clinical trial design by using clearly defined and consistent imaging descriptions, thus allowing for comparison of results across different centers.

Introduction

Despite improved survival due to significant advances in prevention and treatment of many other solid malignancies, pancreatic cancer continues to carry a very high mortality and is expected to soon become the second leading cause of cancer-related deaths.[1] Most cases of pancreatic ductal adenocarcinoma (PC) are identified late in the course of the disease, when there is limited efficacy of current treatment options.[2] Given the high mortality and the current lack of a low-cost, broadly available imaging or noninvasive screening tool for early detection, population-based screening is not feasible. Although cystic lesions, in particular mucinous lesions, represent potential precursors to cancer, the majority of PC does not arise from these lesions.[3] In the absence of high-risk precursors on imaging or early detection biomarkers, identification of genetic, familial and personal risk factors allows the most effective way to identify individuals at elevated risk of PC who should be candidates for surveillance.[4]

In the last few years, multiple genetic syndromes and germline mutations have been associated with an increased risk of PC.[5-8] Several studies have also suggested that even in the absence of a known or recognized genetic syndrome or germline mutation, familial clustering of pancreatic and other cancers may increase the risk of PC.[9, 10] To date, the majority of surveillance in these individuals is done by a combination of cross-sectional and EUS-based imaging.

EUS has emerged as either the preferred modality for surveillance or a complementary modality to cross-sectional imaging. Most studies in high-risk individuals found that EUS identified a greater number of pancreatic abnormalities, with a greater sensitivity for small solid lesions (defined as either <2 cm or <1 cm in greatest diameter) than MRI.[11,12] MRIs generally have a greater sensitivity in identifying cystic lesions.[13] However, many of these studies are difficult to extrapolate to current day practice as both cross-sectional and EUS imaging quality and technology has evolved significantly. An important limitation of EUS is its dependence on the procedural expertise of the endoscopist, with the majority of published studies to date performed by high-

volume experts. Although cross-sectional imaging is much less reliant on radiologist expertise, it is worth noting that nearly all studies have been performed at tertiary care centers and there is some variability in examination interpretation. However, even among expert endosonographers, a high interobserver variability was seen when comparing pancreatic parenchymal findings in familial pancreatic cancer kindreds.[14] In contrast to cross-sectional imaging, the ability to re-read EUS examinations is highly limited because most are not recorded. Therefore, most high-volume surveillance programs and published guidelines currently recommend alternating cross-sectional imaging with EUS during surveillance.[15]

The goal of this consensus statement is to provide practical guidance on the EUS examination performed in individuals at high risk for PC and to standardize the reporting of findings. The goal of standardization is to reduce operator dependence and interobserver variability and to increase the opportunity to perform analogous comparisons. It is not our objective to define or develop guidance on the frequency or choice of modality used for surveillance, which has been previously published.[16] Adoption of procedural standards and reporting templates should enhance the performance of high-quality examinations, aid image analysis, and most importantly provide more reliable and accurate information to high-risk individuals and their clinical care team over time. This consensus statement addresses the integration of the appropriate descriptive terms of pancreatic findings, suggests a lexicon to be used in reporting to avoid confusion in terminology, and provides a structured template to improve completeness of EUS reporting in surveillance examinations in high-risk individuals for PC.

METHODS

This Consensus Statement was developed by a multidisciplinary expert panel assembled in the PRECEDE consortium. The PRECEDE Consortium consists of members from 36 pancreatic centers worldwide with expertise and a multidisciplinary focus in the care of individuals at

elevated risk for pancreatic cancer. First, areas of need were identified during the initial meeting of the consortium members which consists of multiple specialities (gastroenterology, surgery, genetics, oncology) on December 5, 2018. This group defined the objective as standardization of reporting and documentation (including image capture) of EUS examination in patients at high risk for pancreatic cancer. An objective was defined to establish standardization of descriptors or variables collected before the procedure (preprocedural), details, terminology, and image-capture obtained during the procedure (procedural) and reporting of biopsy or aspiration results (postprocedural). The Consortium also felt a standardized procedural adequacy assessment should be included (postprocedural). Subsequently an EUS focus group was assembled consisting of expert gastroenterologists who perform >200 pancreatic EUS per year, and representatives from pancreatic surgery, genetics and cross-sectional imaging who all have a publication record of peer-reviewed publications in the field and represent geographic diversity and practice. One author (T.A.G.) performed a Medline search of relevant literature between 2010 and 2020, and 3 members of the group (T.A.G., J.F.F., M.B.W.) assembled the initial list of variables to include in the reports. Subsequently all variables were considered, and their definition were sent out to all members of the EUS working group who were asked to accept or reject the variables. Because much of the terminology used was qualitative and the goal was not a formal practice recommendation but rather generation of a standardized document, members were asked to Accept/Reject rather than rate the variables. Only those where >90% of responders accepted were included. These variables are shown in **Supplementary Table 1.** These descriptors were then shared the entire group of PRECEDE Consortium members from different specialties to assure a broad applicability and adequacy. Members were asked to Agree/Reject/Accept with Revision each variable or descriptor (Round 1). All variables or descriptors that were rejected by more than 20% of consortium members were excluded (no consensus) and all statements with one or more suggestion were revised (Consensus after revision). In a final round (Round 2), the members of the EUS working

group were asked to vote on all variables and their descriptor which applicable on a modified Leikert scale (scale of 1-7). For most statements, this was done to assess agreement regarding inclusion of variables and where appropriate agreement regarding definition of variables was also assessed. Only those variables with >75% of Agree/Disagree or Strongly Agree/Disagree were included as having reached a consensus.

STANDARDIZATION AND TEMPLATES

Indications for EUS in High-Risk Individuals

Individuals who undergo surveillance for PC generally fall into 1 of 2 categories: those with a known germline mutation or syndrome associated with an increased risk of pancreatic cancer and those who are members of familial PC kindreds without known mutations but with several family members with the disease. In the majority of these cases, only an EUS examination of the pancreas is indicated. However, there are certain syndromes that are associated with other upper GI malignancies and therefore endoscopic examination of the gastric or duodenal mucosa and the ampulla may be necessary. The latter conditions include Lynch syndrome, Peutz-Jeghers syndrome, and familial adenomatous polyposis (FAP). The risk of PC in some of these conditions, albeit significant, is actually lower than the risk of other GI malignancies (ie, Lynch syndrome and FAP). Therefore, in these cases, a detailed description after an endoscopic screening protocol is necessary. In **Table 1** we summarize current indications for performing pancreatic screening in high-risk individuals and highlight the specific mutations or syndrome that may require additional endoscopic screening.

Procedural Data Collection

There are no specific equipment or sedation recommendations for performing EUS examination on high-risk individuals. However, in an effort to minimize interprocedural variability, we recommend using similar equipment among multiple procedures. Regarding the use of radial or linear EUS, some have suggested the use of linear EUS after radial EUS, but a head-to-head

comparison of these modalities has not been performed. Overall, we recommend the use of linear EUS for image capture and base our standardization on linear EUS views; however, recognize that individual preference and published data would also support the use of linear EUS after a radial EUS examination. Given the need for a detailed examination, most experts recommend performing an EUS examination with the patient under deep sedation.[18] The length of time required to examine the pancreas or a minimum procedure length has not been established and although future research may define a minimum examination time, we did not reach consensus on the need to include this.

Currently, there is no consensus on whether EUS procedures should be performed after cross-sectional imaging or instead of cross-sectional imaging and there is some heterogeneity in this practice even at high-volume surveillance programs.[19] In fact, there are significant variations in the utilization of EUS as a primary surveillance tool, adjunct or complimentary test. Most U.S. programs use alternating imaging by MRI and EUS; however, a significant number of European screening algorithms rely more exclusively on EUS[15]. Given certain biases that either practice may introduce, we recommend documenting results or significant pancreatic findings on CT/MRI performed within 12 months of the EUS procedure. To accurately collect all procedural data, we recommend collecting the information using the template in **Supplementary Table 2.**

Description and Standardization of EUS findings

EUS Pancreatic Image Capture Documentation

One of the most difficult aspects of standardizing EUS procedures arises from the operator-dependent nature of this procedure and lack of uniform recommendations for image capture. With the evolution of digital image processing and the promise of artificial intelligence approaches to diagnosis, a standardization of certain “views” during the EUS examination is essential. Such a standardized image capture approach will help clinicians compare examinations at different points in time, ensure that optimal image analysis is performed, define incomplete or suboptimal imaging, and reduce omissions in image capture.

Guidelines for standardization of transabdominal ultrasound imaging and documentation of colonoscopy images[21], as well as the EUS station-based approach[22] to EUS imaging serve as examples on how to standardize image capture and documentation. We propose the following views (either image or video format) be obtained and saved in every procedure with documentation of pancreatic duct (PD) and common bile duct (CBD) measurements (**Supplementary Table 3**). Examples of these views are shown in **Figure 1**.

Pancreatic Parenchyma

Nearly all of the parenchymal descriptive terms used to identify early pancreatic changes are adapted from the chronic pancreatitis literature, where some histologic correlates have been established for these sonographic abnormalities. The Rosemont criteria formalized the use of these descriptors and many of these can be identified in high-risk individuals.[23] However, the neoplastic histologic correlates of many of these changes are not as well established. Certain changes such as microcystic changes, atrophy and lobularity have been shown to correlate directly with PanIN lesions identified in corresponding tissue, whereas other changes (hyperechoic foci, strands) are of less-certain significance or may only correlate with associated fibrosis.[23]

Recognition and identification of pancreatic parenchymal changes are challenging, and studies have shown that even among experts significant interobserver variability exists between the nomenclature and terminology used.[14] However, the observations made in a patient do appear stable and consistent between multiple procedures.[24, 25] These studies suggest that the sonographic changes noted are stable and persistent and it is the nomenclature that needs more definite standardization.

In **Table 2,** we summarize the most commonly used parenchymal descriptors, provide a definition of these terms as well as presumed or documented histologic correlates both in inflammatory and neoplastic diseases. The accompanying **Figure 2** depict examples of these changes and abnormalities. Quantitative assessment and distribution throughout the pancreas of

these abnormalities may have significant impact on individuals with elevated risk and should be tracked longitudinally and documented, as shown in **Table 2**.

Main Pancreatic Duct

The development of pancreatic duct strictures or focal and diffuse dilation may serve as one of the most concerning early neoplastic changes in the pancreas. The main PD diameter at the head (HOP), body (BOP), and tail (TOP) of the pancreas should be measured and documented in the EUS report. The normal PD diameters in the HOP, BOP, and TOP are approximately 3 to 4, 2 to 3, and 1 to 2 mms in diameter, respectively. In cases where the MPD is dilated, examination of the ampulla is indicated to (1) evaluate for the presence of an ampullary lesion; and (2) evaluate for mucin extrusion seen with intraductal papillary mucinous neoplasm (IPMN) involvement (ie, "fish-mouth" papilla). In all cases with dilation of the MPD and when a main duct IPMN is suspected, we recommend image capture of the ampulla (if necessary using a duodenoscope) after 5 to 10 seconds of suctioning to demonstrate any possible mucin extrusion. If a focal narrowing in the MPD is appreciated, images at the level of the duct transition from non-dilated to dilated segment should be saved, with particular attention to parenchymal abnormalities at this level (**Table 3**).

Assessment of MPD wall thickening or wall calcification should be made at the level of stricture or distal to it with optimal endosonographic imaging (ie, parallel rather than vertical to the horizontal plane). In certain cases, imaging after secretin injection may help accentuate pancreatic duct stricture.[26] However, the routine use of secretin to identify pancreatic duct strictures and cystic communication with the MPD is not presently recommended and our group did not find this necessary to include in a standardized reporting.

Solid Lesions

Identification of solid lesions in patients undergoing surveillance EUS is uncommon, with a range of detection from 1% to as high as 20%, depending on the population screened.[13, 27-31] In the majority of cases, a solid mass is associated with a neoplasm (ie, adenocarcinoma,

neuroendocrine tumor, etc) but may indicate some benign conditions as well (ie, splenule, focal inflammation, microcystic serous cystadenoma). In **Table 4,** we provide a template for reporting solid lesions in the pancreas during an EUS examination. Reporting of biopsy techniques and results is discussed below.

Cystic Lesions

Pancreatic cystic lesions, especially mucinous cystic lesions, represent an important and frequent premalignant lesion identified in the pancreas during a screening examination. There is considerable debate whether these lesions have a different significance in high-risk individuals versus individuals in the general population. Most studies to date have shown that cystic lesions are more frequently identified in high-risk individuals, but do not appear to have a more rapid progression towards malignancy than cystic lesions identified in non-high-risk individuals.[13, 32] On the other hand, there appears to be a correlation between the frequency of identifying cystic lesions, even microcysts without PD communication and an increased risk of concurrent PanIN.[33-37] We recommend collecting detailed information on all cystic lesions identified in the pancreas in order of the lesion with the greatest size (greatest cross-sectional diameter). In patients with multiple cysts, most studies have shown that the dominant cyst is most likely to progress; however, multifocality has been shown in some studies (but not in others) to be associated with risk of progression.[37-39] Hence, we recommend detailed characterization of the largest cystic lesion or the one with the most worrisome feature(s), the number of cysts identified and their distribution in the pancreas (**Table 4)**.

Peripancreatic Lymph Nodes

The identification of enlarged peripancreatic lymph nodes should prompt a careful search for a pancreatic or per-pancreatic mass. The significance of enlarged peripancreatic lymph nodes in the absence of a known or suspected malignancy in the pancreas is not clear. General EUS practice guidelines recommend fine needle aspiration (FNA) of lymph nodes greater than 1 cm. However, lymphadenopathy (of undefined size) is one of the worrisome features associated with

suspected IPMN-associated malignancy and hence in patients with pancreatic cysts particular attention should be given to lymph nodes. We recommend documenting the location and size of any lymph node found and using standard EUS descriptors to characterize them (**Supplementary Table 4**).

EUS-Guided Tissue Sampling and Documentation

Biopsy of solid lesions and pancreatic parenchyma

Indications for biopsy of the pancreas in high-risk individuals includes the finding of a solid mass and biopsy of the pancreatic parenchyma at the site of a MPD stricture. In rare cases, focal changes in pancreatic parenchyma on EUS may also prompt a biopsy. There has been significant evolution in biopsy technologies in EUS-guided sampling and downstream tissue analysis. However, neither the size nor a specific needle design has conclusively been associated with greater downstream therapeutic benefit or superior tissue yield.[40] We recommend the use of a core needle biopsy (size range, 19- to 25-gauge) for solid masses when this is deemed safe and feasible by the endoscopist. Biopsy specimens containing tissue cores are optimal for downstream testing of molecular and immunohistochemical markers as tissue architecture is preserved. We recommend placing the majority of the specimen in formalin fixative for cell block, to preserve tissue architecture. However, in cases when rapid on-site evaluation (ROSE) is not available, we recommend placing some biopsy material in a liquid cytological fixative to increase the diagnostic yield. In certain settings, fresh tumor analysis may be required as part of a research protocol.

Aspiration and biopsy of pancreatic cysts

The threshold to obtain fluid aspirates in high-risk individuals with cystic lesions may be different from average risk individuals and some have advocated aspiration of any cyst >1 cm. [41-48] However, this recommendation is based on limited data and is more aggressive than most societal recommendations for the management of cystic lesions. The primary objective with small

cystic lesions without worrisome features (which may not undergo EUS according to societal guidelines) is to distinguish non-neoplastic (ie, pseudocysts) cysts from benign (serous cystadenomas and others) or mucinous lesions, including IPMNs and mucinous cystadenomas (MCNs).

We recommend using an FNA needle for cyst fluid aspiration. Given the viscosity of mucinous cyst fluid, a larger caliber needle (19-gauge, 22-gauge) is preferred when feasible. The stiffness of the 19-gauge needle may preclude FNA in the head of pancreas although some newer, more flexible needles may resolve this. For lesions >2 cm in diameter, consideration can be given to obtaining a microforceps biopsy (MFB). The use of MFB has been reported to increase the yield of diagnosing cyst type in equivocal cases.[32] The benefit of MFB is less certain in distinguishing high-risk from lower-risk premalignant mucinous cysts but these studies are underway. In addition, there is insufficient safety data to recommend the routine use of this modality in cyst diagnosis and therefore this is largely left at the discretion of the proceduralist. However, templates data acquisition should include collecting this information to better define outcomes with MFB procedures.

Major advances have been made in the analysis of cyst fluid and using this information to understand the risk of these lesions. These include CEA, glucose, amylase, and DNA, miRNA, RNA and protein-based biomarkers.[42] Currently, none of these are endorsed by societal guidelines to risk stratify cystic lesions, but a combination of biochemical and molecular markers (especially DNA sequencing) has shown promise in improving the accuracy of distinguishing intermediate from high-risk cysts. Information regarding the acquisition of these markers in cyst fluid biomarkers should be documented; however, a standard recommendation for their use in high-risk individuals cannot be made at this time. The template for reporting EUS-guided biopsy results is provided in **Supplementary Table 5.**

Postprocedural Evaluation and Assessment of EUS Examination Quality

To enhance standardization of EUS procedures and confirm the adequacy of the examination, we have included a statement regarding examination adequacy in the reporting

template. The quality and adequacy of an EUS examination may be affected by the operator, equipment function, adequacy of sedation, body habitus, imaging quality and anatomic alterations and abnormalities. Capturing this information is critical when comparing EUS examinations at different time points and in determination of the optimal surveillance modality. In **Table 5**, a template to describe the overall adequacy of the examination is provided.

Structured Reporting Template

The goal of a structured reporting template is to standardize the approach, description and documentation of abnormalities identified in the pancreas during an EUS examination in high-risk individuals. It is well recognized that a significant number of procedures performed in high-risk individuals will not identify any abnormalities. Therefore, we recommend using a template that allows for a quick and easy way to report the absence of findings and expand on specific details as identified. In the appendix, we provide a structured questionnaire that we use for data collection and that can be readily adopted by other centers (**Appendix 1**).

DISCUSSION

The purpose of this consensus statement is to provide a guide and a template for performing and reporting EUS in individuals at high risk of developing PC. This is an evolving cohort that is likely to enlarge as new pathogenic alterations that confer risk for PC are identified. The overall goal is to be able to offer the least invasive and most accurate surveillance modality to this high-risk group of patients, and to this date, surveillance relies on imaging. EUS imaging of the pancreas is an accurate, frequently performed procedure in this patient population and is unique in its ability to offers the simultaneous opportunity to biopsy any abnormality found.

Although this statement was developed specifically for EUS performed for screening purposes, we believe the format and template will be useful in standardizing all pancreatic EUS reporting. Although several guidelines exist regarding indications and techniques of EUS-guided sampling, there remains a gap in the definition of minimum image acquisition and assessment of

adequacy and quality of the pancreatic EUS examination. The lack of standardization of the EUS reports and image capture has hindered the ability to better compare findings across institutions and practitioners over time, thereby limiting the ability to understand the significance of reported findings. This is particularly important for screening EUS, where the evolving role of novel imaging methods and potentially the use of artificial intelligence for image processing is likely to hold great promise in recognizing more impactful precursors and leading to a path of more quantitative assessment.

Therefore, the members of the PRECEDE Consortium developed these guidelines to bridge the gap and standardize the performance of EUS examination and terminology used to describe changes identified in the pancreas at the time of EUS. The templates presented here are well-suited to be incorporated into reporting software, which will likely be needed to accomplish broad adoption and use. Standardization of EUS reporting will lead to an improvement in the quality of care for individuals at high risk for developing pancreatic cancer, which may ultimately have an impact on pancreatic cancer mortality.

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Figure Legends:

Figure 1. Recommended EUS pancreas views. A-D are views best obtained with endoscope positioned in the proximal stomach. A, Region of the aorta and celiac axis (CAX). **B,** Tail of pancreas at the level of the left kidney and approaching the spleno-renal angle. **C,** Body of the pancreas with SA and SV. **D,** Right lateral view of the neck of the pancreas. **E-H** are views obtained best from the duodenal bulb. **E,** Region of the ampulla of Vater and HOP. Measurements of the proximal PD and distal CBD. **F,** View of the portal vein, CBD and HOP. **G,** Region of the portal confluence and HOP. **H,** NOP/genu and PD medial to portal confluence. (CBD, Common bile duct; PD, pancreatic duct; HOP, head of pancreas; NOP, neck of pancreas; SMV, superior mesenteric vein; SA, splenic artery; CAX, celiac axis).

Figure 2. EUS imaging of common pancreatic parenchymal changes. A, Hyperechoic strands are bright, >5 mm in length and often have subtle hypoechoic shadows. **B,** Parenchymal calcifications are hyperechoic or bright with unequivocal hypoechoic shadowing. **C,** Hyperechoic foci are bright, <5 mm in length often without obvious shadowing. **D,** Lobularity is often described as honeycombing appearance of hypoechoic cystic areas and slightly more hyperechoic areas. The areas of the pancreas can be almost mass like. **E,** Multiple cysts are noted in the pancreas with thin septations and without an associated mass. **F,** A distinct area of hyperechogenicity is noted and is consistent with focal fatty infiltration (*yellow arrows*). **G,** Significant dilation of the MPD without filling defect or wall abnormalities. **H,** Relative atrophy of the pancreatic parenchyma around a somewhat dilated main pancreatic duct. (BOP, Body of pancreas; MPD, main pancreatic duct).

TABLES

Table 1. Common indications for screening EUS examination of the pancreas

Indication	Procedural recommendation
Known genetic mutations associated with pancreatic cancer risk (*BRCA2*, *BRCA1*, *PALB2*, *ATM*, *CDKNA*/*p16*) Familial PC without known germline mutation	EUS examination of the pancreas
Peutz-Jeghers syndrome (*STK11*) Lynch Syndrome (*MLH1/MSH2/MSH6, EPCAM, PMS2*)	EUS examination of the pancreas and EGD of gastric/duodenal mucosa
Familial adenomatous polyposis (*APC*)	EUS examination of the pancreas, EGD of the gastric/duodenal mucosa & examination of the ampulla using one of the following: (1) distal attachment cap on a standard upper endoscopy, (2) side-viewing duodenoscope, or (3) echoendoscope

Table 2. Pancreatic parenchyma evaluation and proposed histologic/neoplastic correlates

EUS parenchymal abnormality	Description of finding	Distribution of pancreatic changes	Possible histologic correlate in chronic pancreatitis	Possible neoplastic correlate
Hyperechoic foci	Small (< 5 mm) distinct reflectors	HOP/TOP/BOP/ throughout gland	Fibrosis	
Hyperechoic strands	String or line-like (>5 mm) distinct reflectors	HOP/TOP/BOP/ throughout gland	Fibrosis	
Lobularity	Rounded homogenous lobules separated by bright strands	HOP/TOP/BOP/ throughout gland	Fibrosis	PanIN
Microcysts	< 5 mm cysts without MPD communication	HOP/TOP/BOP/ throughout gland		Enlarged branch duct with PanIN
Atrophy	Reduction of pancreatic parenchyma >50%	HOP/TOP/BOP/ throughout gland	Atrophy	Acinar cell loss that may correlate with PanIN
Calcification	Hyperechoic lesion with acoustic shadowing	HOP/TOP/BOP/ throughout gland	Parenchymal calcification	
Heterogeneity	Differences in the echogenicity of one geographic area from another (excluding ventral/dorsal split)	HOP/TOP/BOP/ throughout gland	Edema, inflammation	PanIN/ infiltration
Solid lesion	Solid lesion with different echogenicity from the pancreas parenchyma	HOP/TOP/BOP/ throughout gland	Focal inflammation/necrosis	Neoplasm/Splenule Focal Inflammation
Fatty pancreas	Bright or hyperechoic pancreas	HOP/TOP/BOP/ throughout gland		

Table 3. Main pancreatic duct evaluation

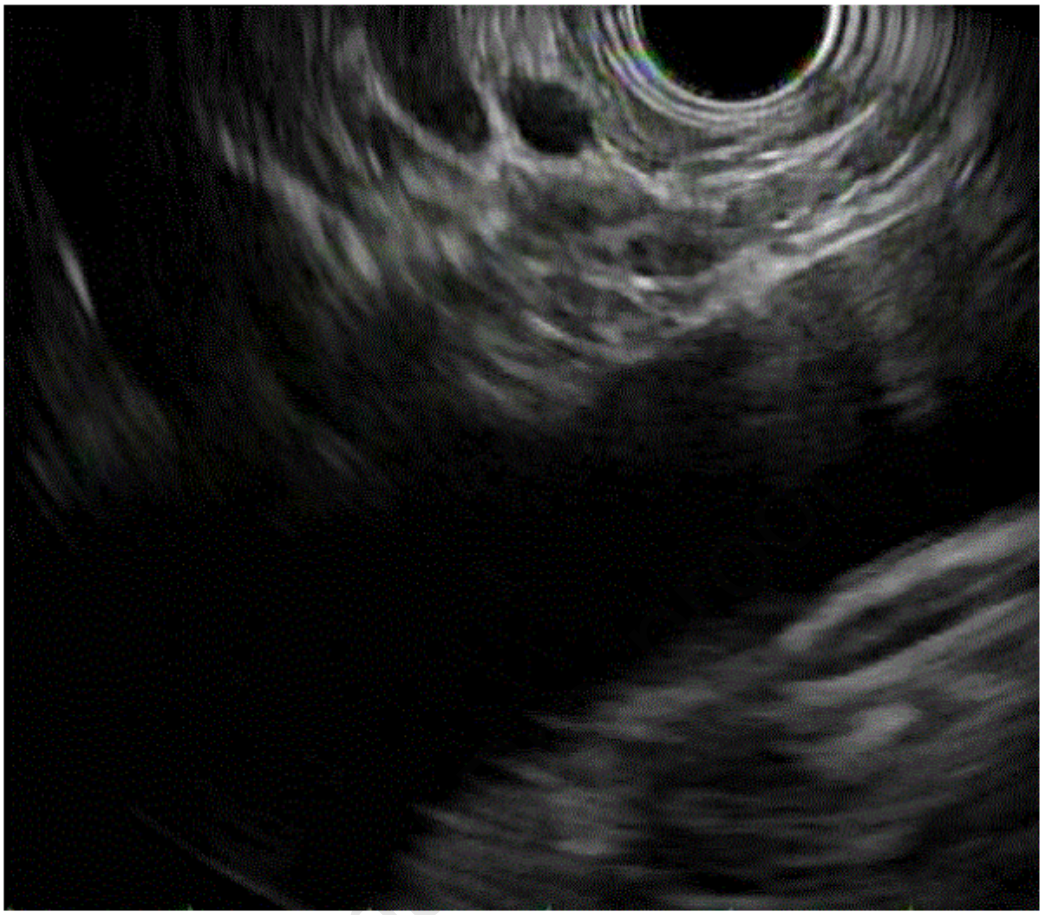
MPD diameter (mm)	HOP	BOP	TOP
MPD stricture	No	Yes, no associated parenchymal changes	Yes, associated parenchymal changes at transition
Where is MPD stricture identified?	HOP	BOP	TOP
MPD wall abnormalities	No	Yes, Wall thickening	Yes, Increased echogenicity
MPD filling defect	No	Yes, hyperechoic shadowing	Yes, hyperechoic nonshadowing
Ampulla abnormalities	No	Yes, abnormal mucosa	Yes, fish mouth

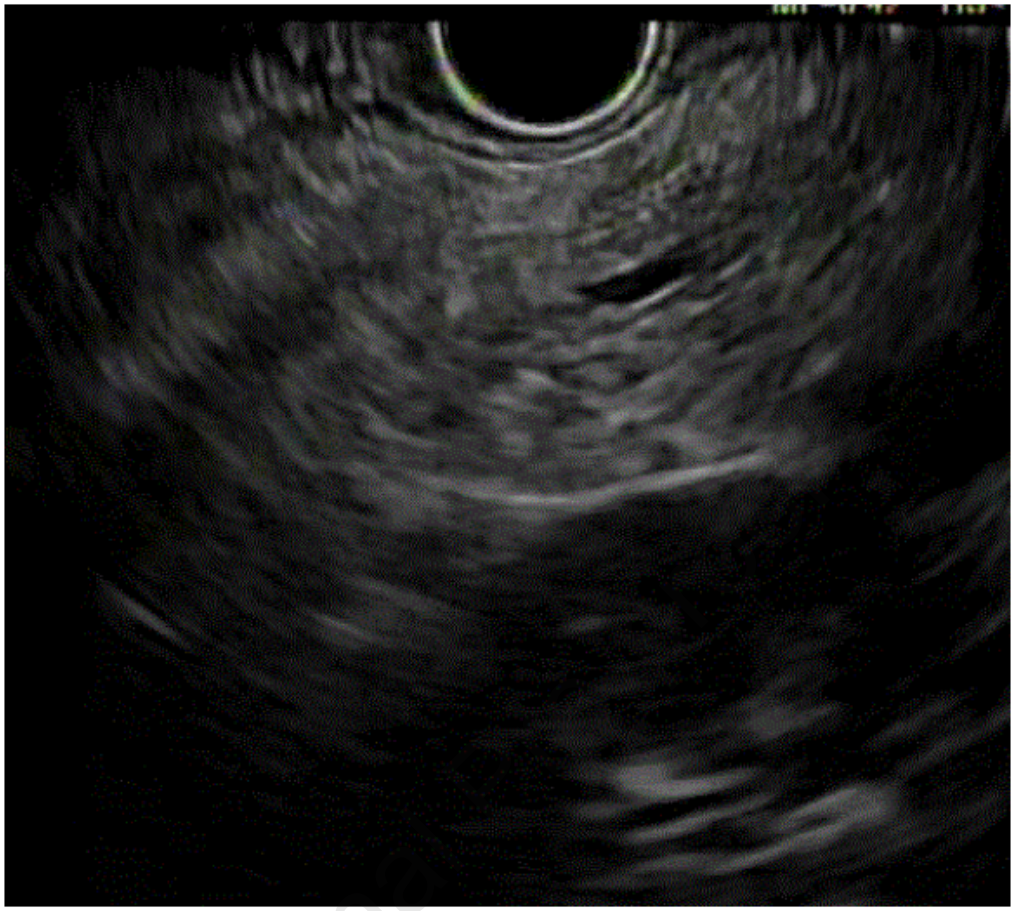
Table 4. Solid and cystic pancreatic lesion evaluation

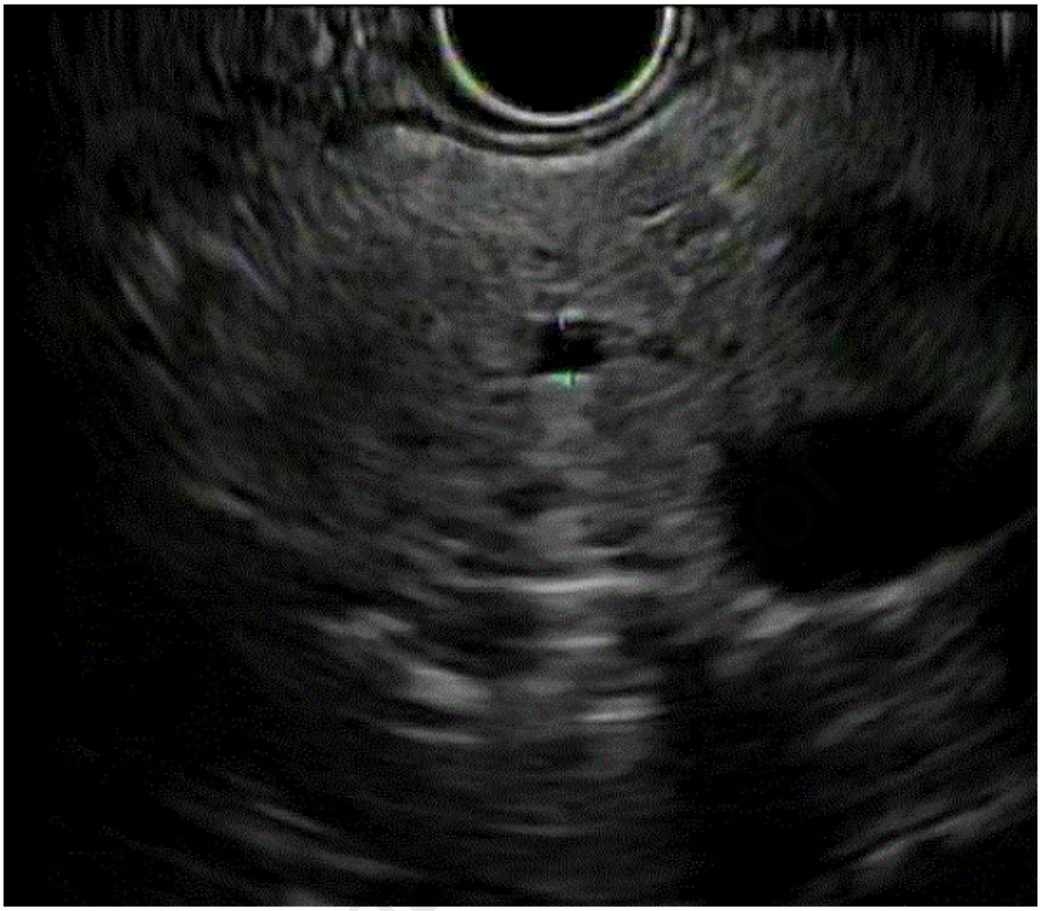
Solid lesions					
Location of mass	HOP	BOP	TOP		
Largest diameter (mm)					
Second diameter (mm)					
Echogenicity	Hypoechoic	Hyperechoic			
Cystic component	Yes	No			
Invasion	No	Yes - Vascular	Yes - adjacent structures		
Upstream MPD dilation	Yes	No			
Upstream atrophy	Yes	No			
EUS Impression	Adenocarcinoma	NET	Splenule	Focal inflammation	Other
Biopsy	Yes	No			
Cystic lesions					
Total number of cysts identified					
Location of dominant cyst	HOP	BOP	TOP		
Additional cyst location	HOP	BOP	TOP		
Largest cyst diameter (mm)					
Second diameter (mm)					
Septations	Yes	No			
No. of compartments					
Enhancing cyst wall	Yes	No			
Solid component	Yes	No			
Mural nodule	Yes	No			
Communication PD	Yes	No			
Upstream PD dilation	Yes	No			
Upstream atrophy	Yes	No			
Dominant cyst EUS impression	IPMN	MCN	SCA	PC	Other
Additional cysts/largest diameter					
Additional cysts with any worrisome features (WF)	Yes	No			
Additional cyst EUS impression	IPMN	MCN	SCA	PC	Other

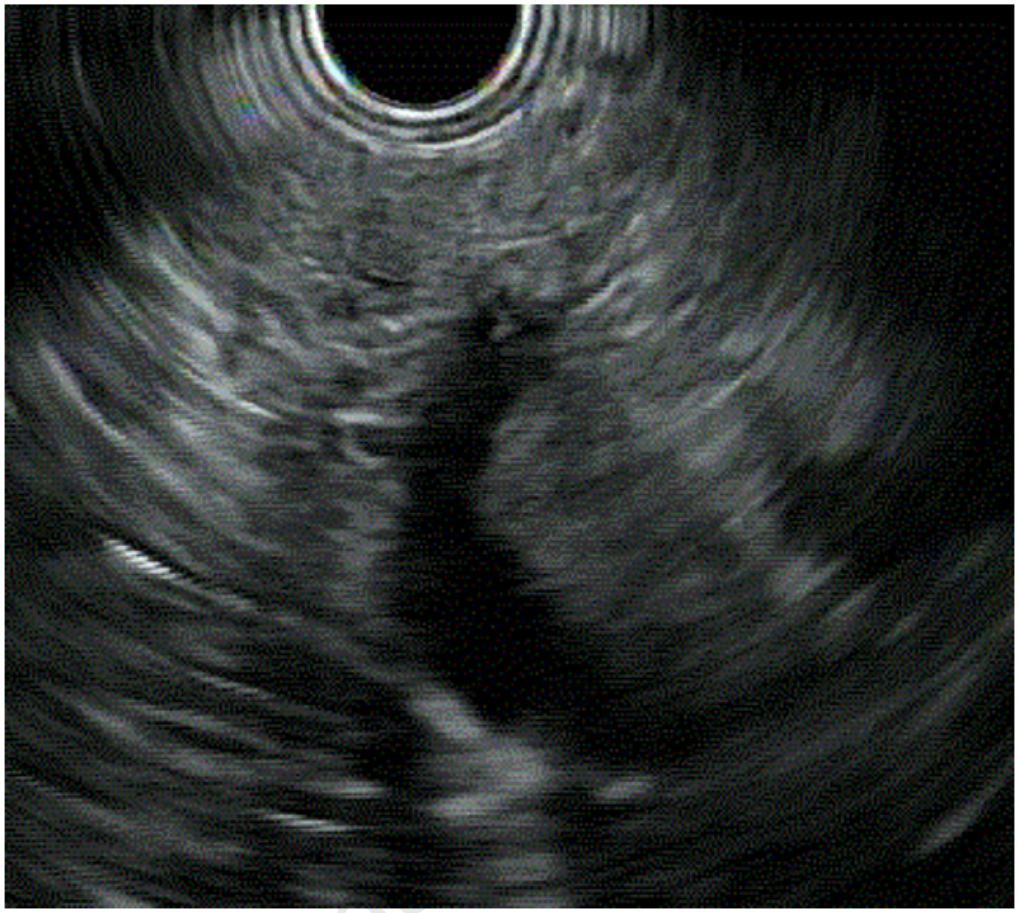
Table 5. Evaluation of EUS adequacy

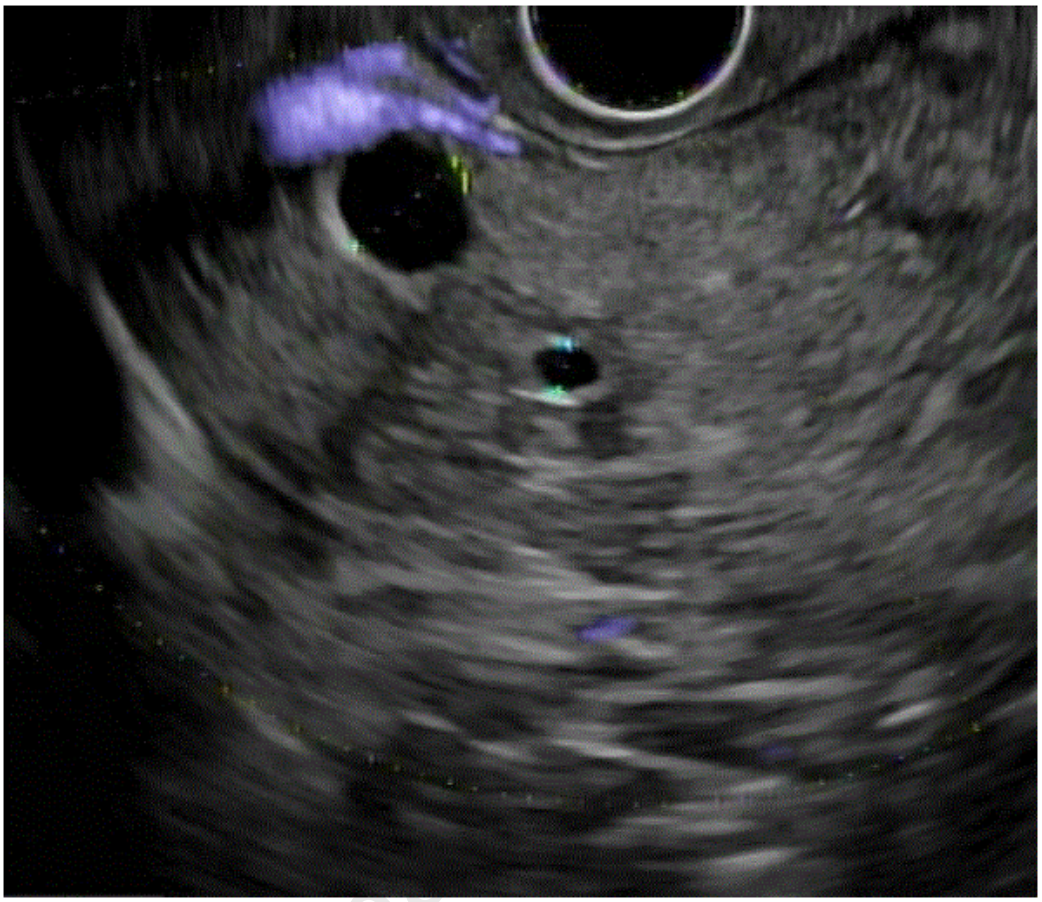
Questions about EUS adequacy			
What would you rate the adequacy of the procedure?	Adequate procedure	Inadequate or partially adequate procedure due to prior surgery (Whipple procedure, Pancreatectomy, Gastric Bypass, Billroth II, other)	Inadequate or partially adequate procedure due to anatomy image quality or acquisition
What would you rate the overall ability to make recommendations based on EUS imaging?	Good	Intermediate	Poor
Would you recommend that EUS is an adequate procedure for continued surveillance?	EUS is adequate, if indicated or standard of practice	Cross-sectional imaging is preferred as the EUS examination is partial adequate or inadequate	
What is the overall impression of the EUS examination?	Normal	Abnormalities of uncertain significance	Worrisome or significant abnormalities that require further investigation or heightened surveillance
If this is a surveillance examination and prior EUS is available for comparison, which statement applies	N/A (no prior examination)	No significant change is noted	Compared with prior EUS examination and imaging findings, significant changes are noted

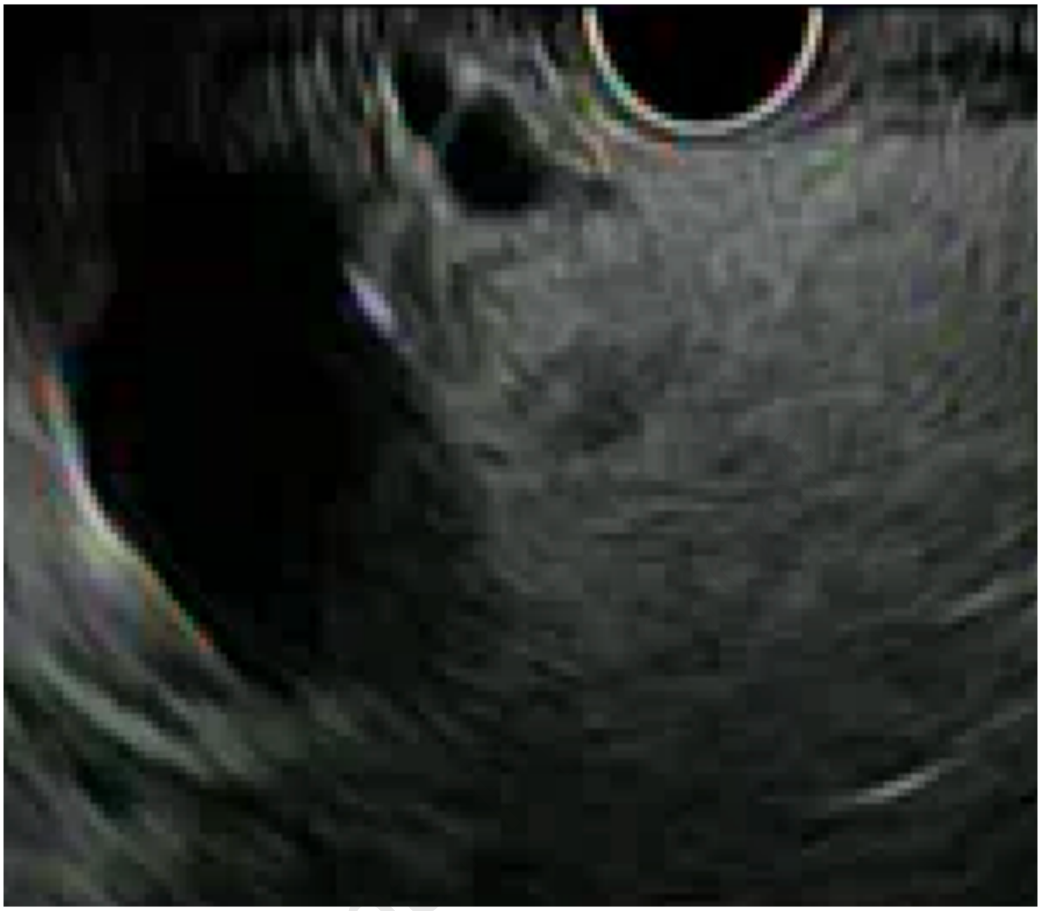


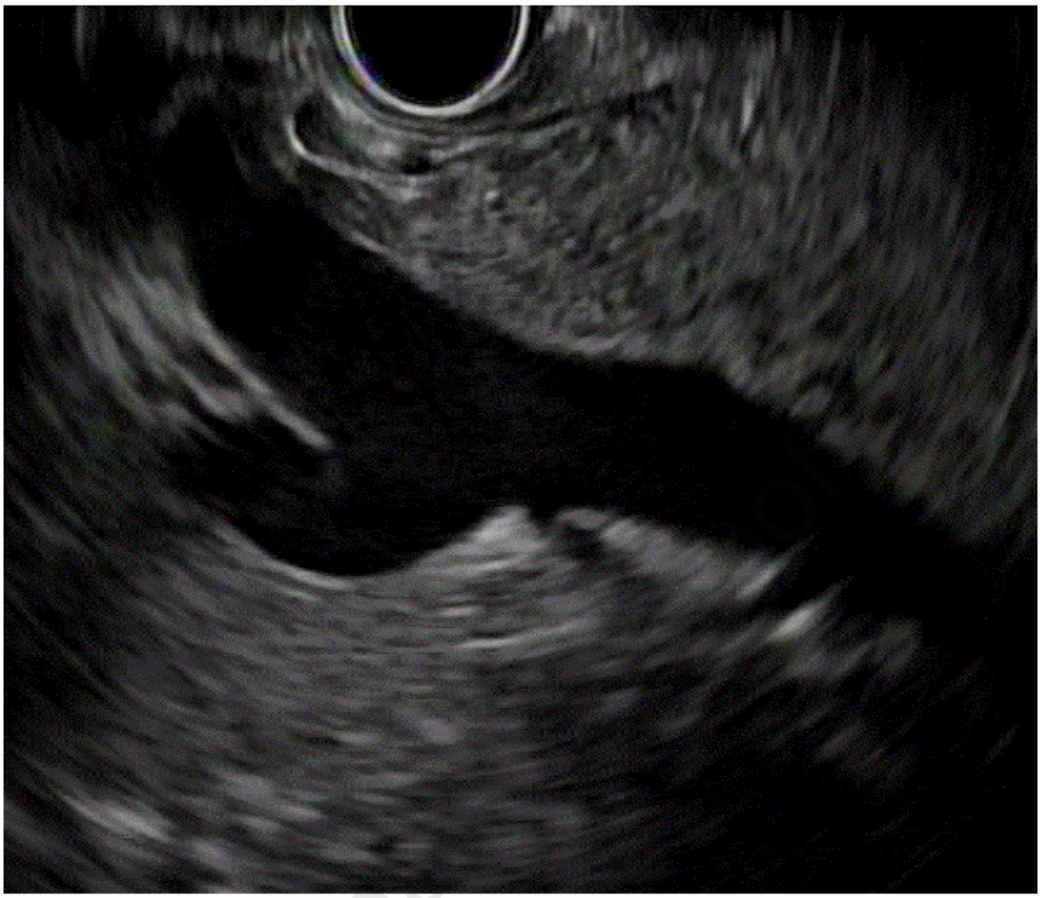


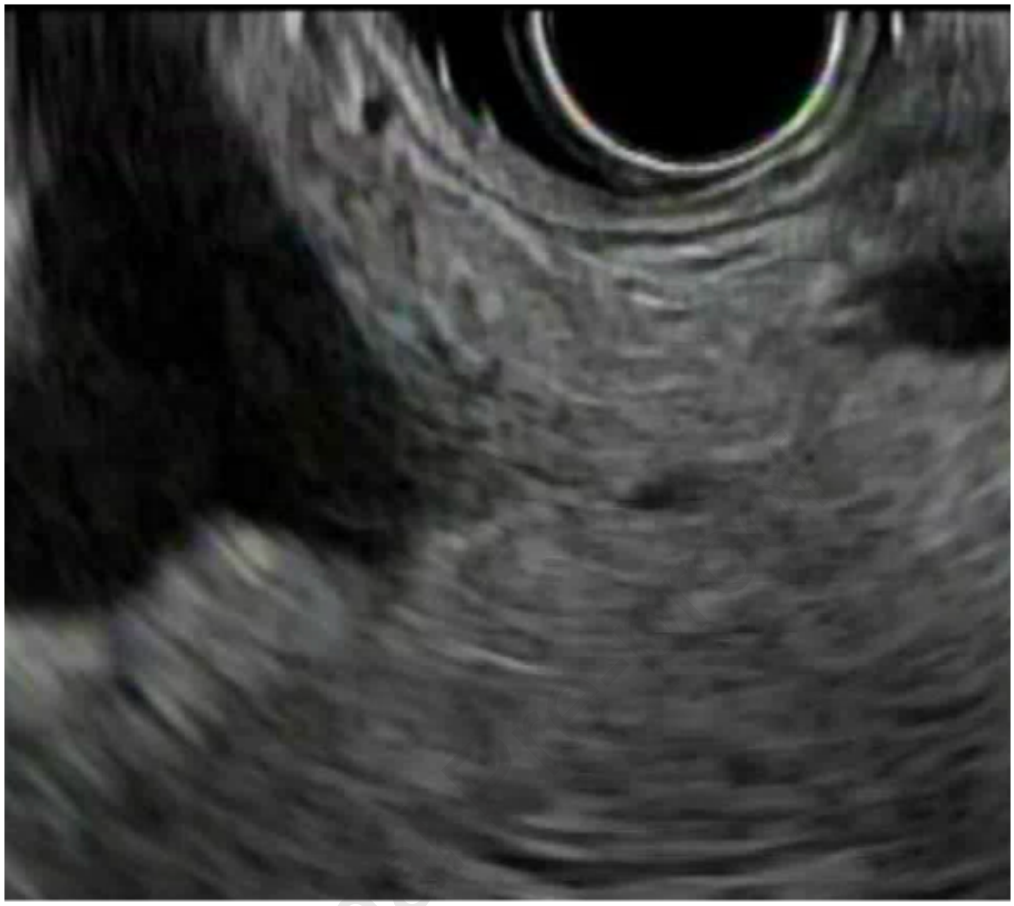


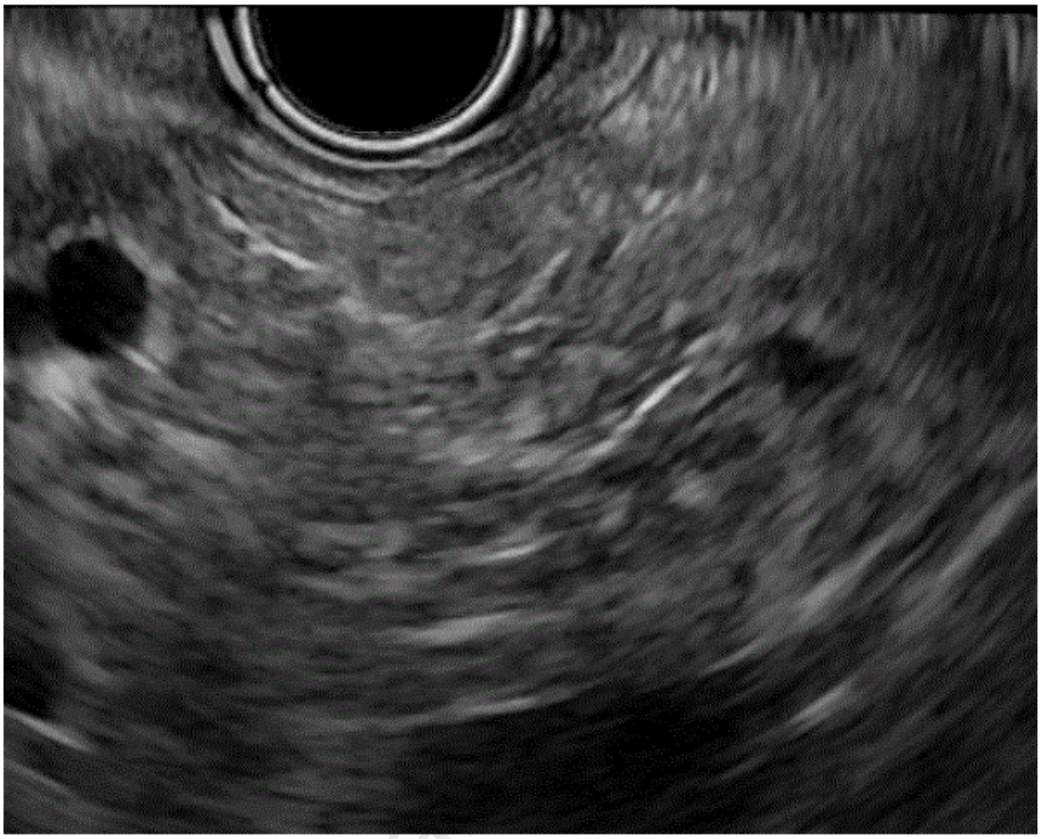


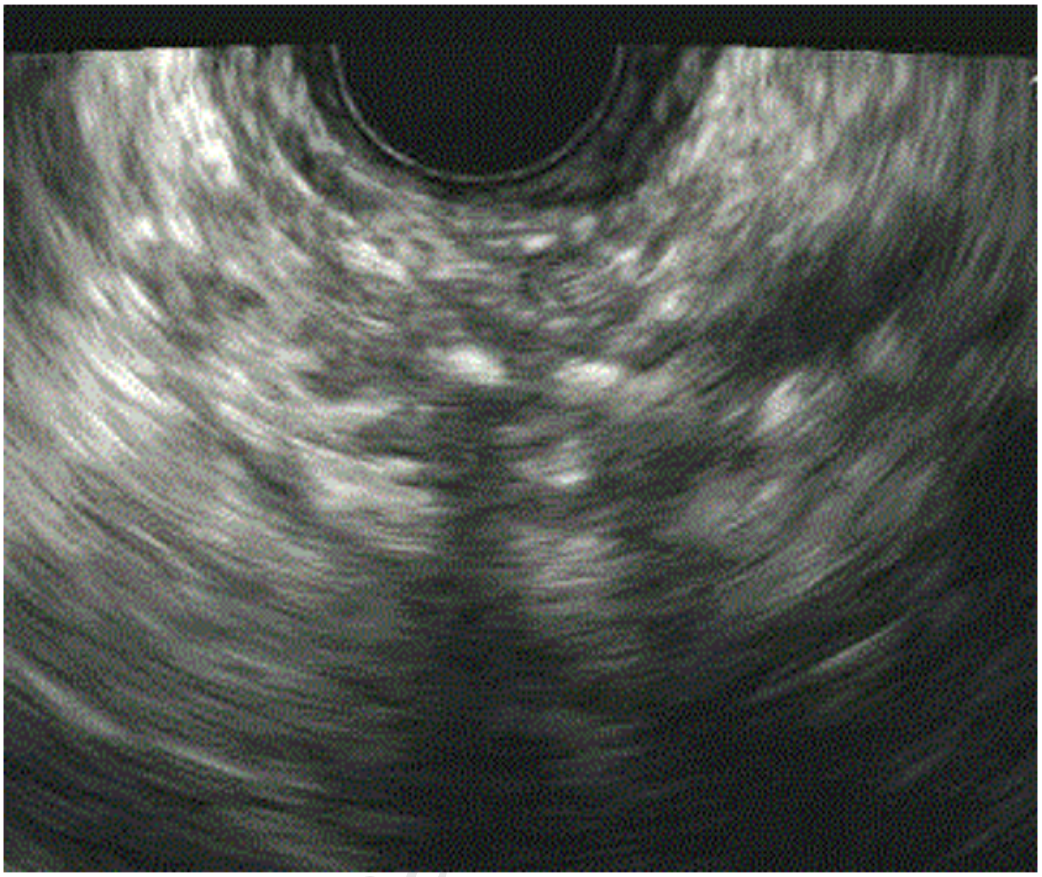


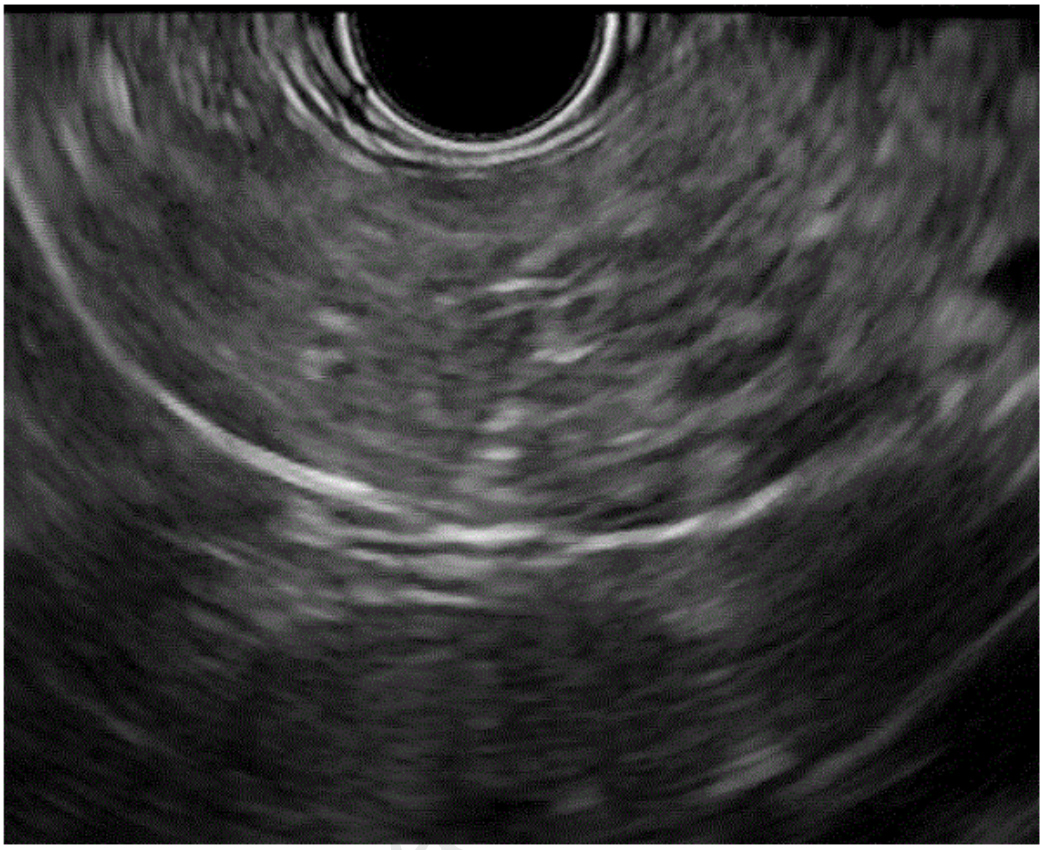


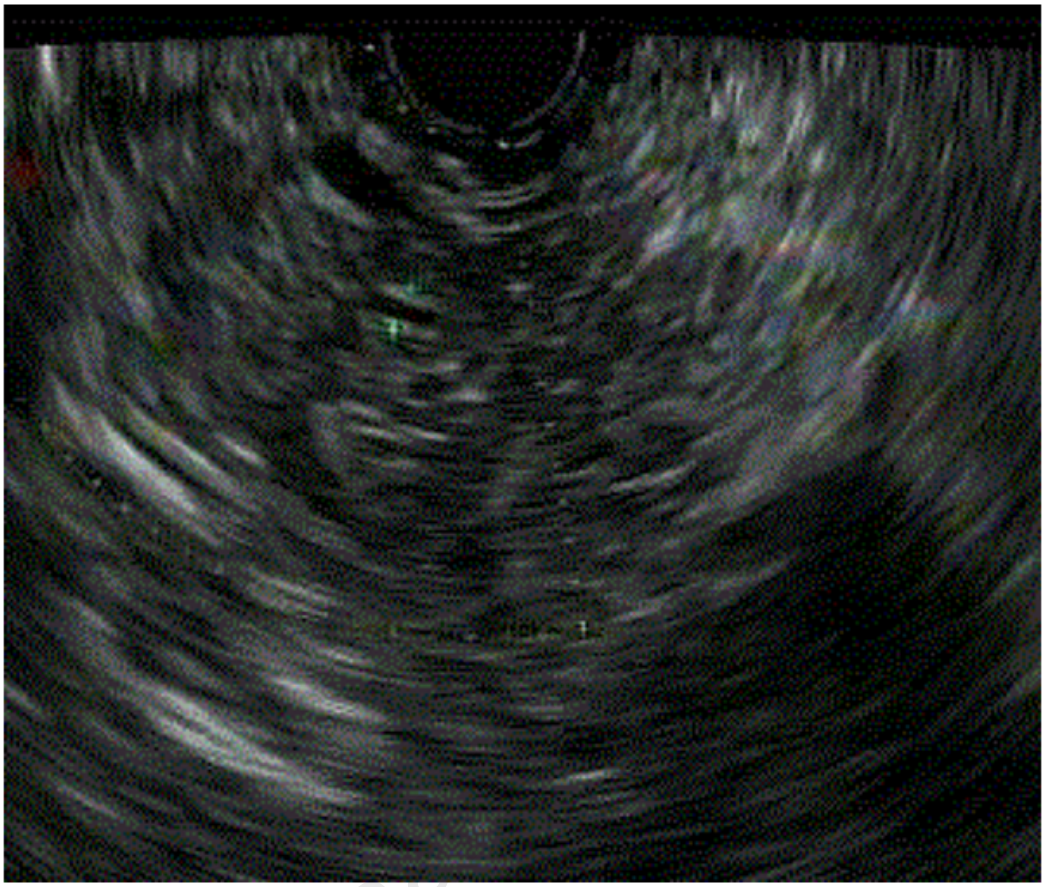


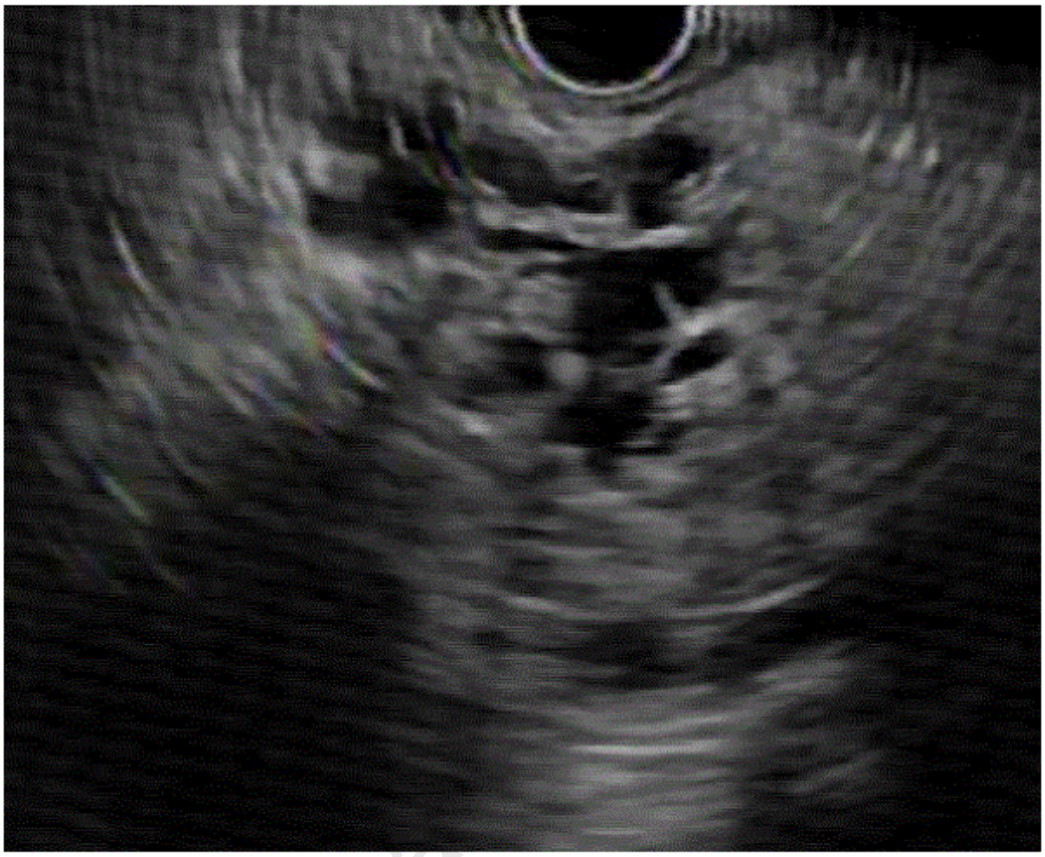


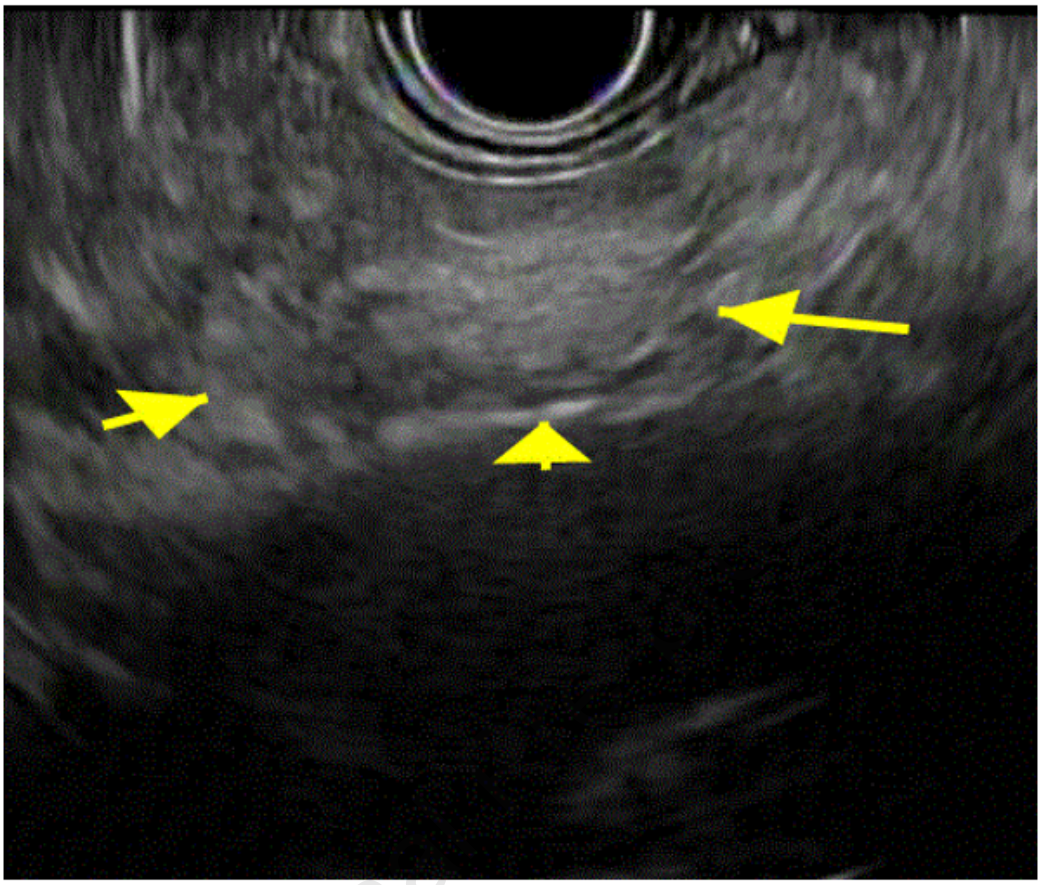


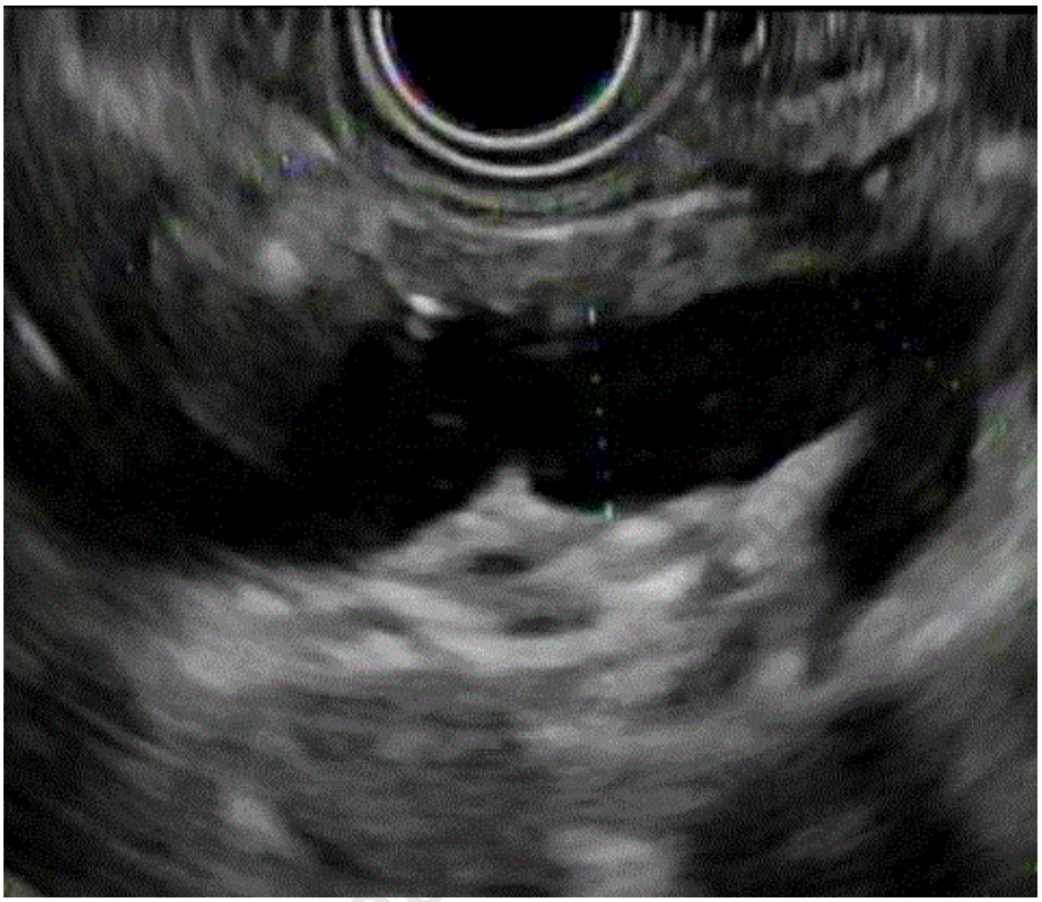


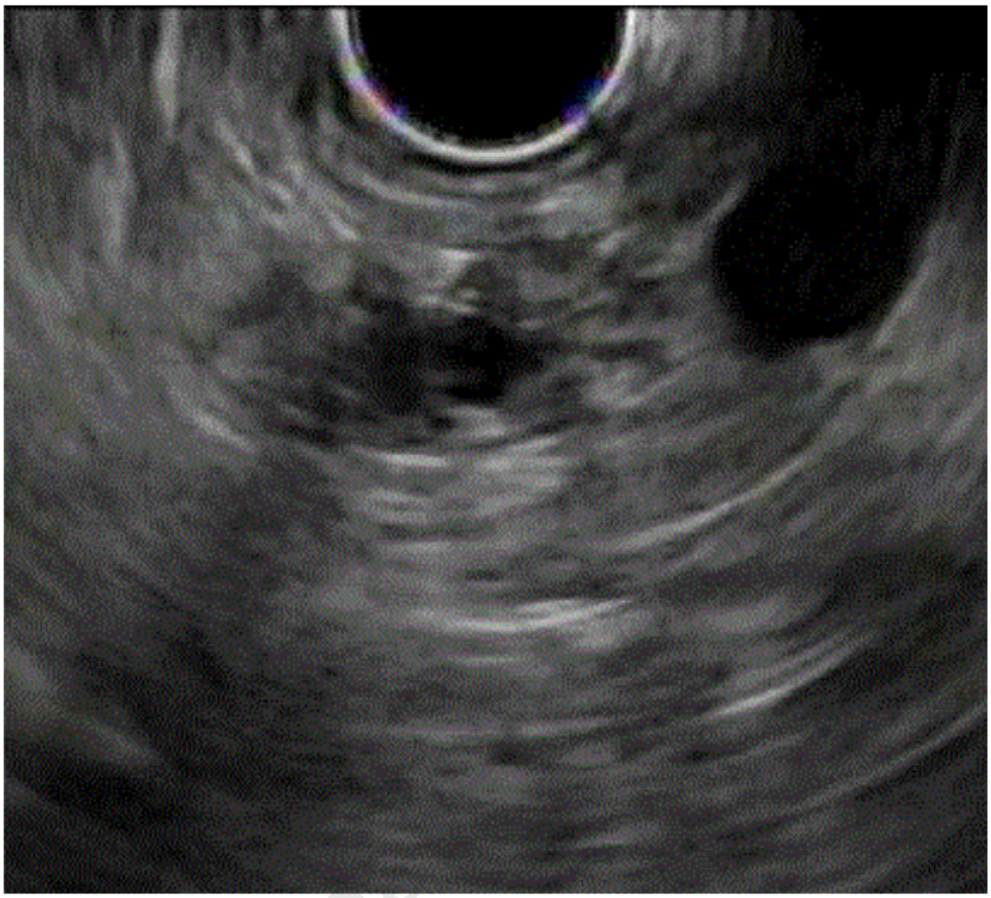












Supplementary Table 1. Results of consensus process on inclusion of variables, descriptors and definitions.

Category	Statement		Round 1	Round 2 Recomendation	Round 2 Descriptor	Round 2 Definition	% Strongly Agree + Agree Recommendation	% Strongly Agree + Agree Descriptor	% Strongly Agree + Agree Definition
PRE	Known genetic mutations associated with pancreatic cancer risk (BRCA2, BRCA1, PALB2, ATM, CDKNA/p16)		Accepted	Consensus			87.50%		
PRE	Familial PC without known germline mutation		Accepted	Consensus			87.50%		
PRE	Hereditary Pancreatitis		Rejected				87.50%		
PRE	Peutz-Jeghers syndrome (STK11) Lynch Syndrome (MLH1/MSH2/MSH6, EPCAM, PMS2)		Accepted	Consensus			87.50%		
PRE	Familial adenomatous polyposis (APC)		Accepted	Consensus			75%		
PRE	Indication for EUS procedure		Revised	Consensus			87.50%		
PRE	Indication for EGD		Accepted	Consensus			100%		
PRE	EUS Processor used		Accepted	No Consensus			62.50%		
PRE	EUS Exam		Accepted	Consensus			87.50%		
PRE	EUS procedure time (EUS scope in- scope out time)		Accepted	No Consensus			62.50%		
PRE	Sedation		Accepted	Consensus			87.50%		
PRE	Prior CT w/ IV contrast or MRI within 12 months		Revised	No Consensus			62.50%		
PRE	If prior imaging, abnormal pancreatic imaging		Accepted	Consensus			87.50%		
PROCEDURE	Duodenal Bulb	Distal CBD/Proximal PD/Ampulla view (Fig 1A)	Accepted		Consensus	Consensus		100%	100%
PROCEDURE	Duodenal Bulb	Porta hepatis (HA, PV, CBD) (Fig 1B)	Accepted		Consensus	Consensus		100%	100%
PROCEDURE	Duodenal Bulb	Pancreas parenchyma, portal confluence (Fig 1C)	Revised		Consensus	Consensus		87.50%	100%
PROCEDURE	Duodenal Bulb	Pancreas parenchyma (NOP/genu), region of SMV (Fig 1 D)	Accepted		Consensus	Consensus		87.50%	87.50%
PROCEDURE	Gastric Fundus	Celiac axis, SMA, Aorta (Fig 2A)	Accepted		Consensus	Consensus		87.50%	100%
PROCEDURE	Gastric Fundus	Tail of pancreas view with spleno-renal angle (Fig 2B)	Revised		Consensus	Consensus		100%	87.50%
PROCEDURE	Gastric Fundus	Body of pancreas view at level of SA, SV (Fig 2C)	Accepted		Consensus	Consensus		87.50%	87.50%
PROCEDURE	Gastric Fundus / Body	Right lateral pancreas margin (PD towards HOP) (Fig 2D)	Accepted		Consensus	Consensus		100%	87.50%
PROCEDURE	Hyperechoic foci	Small (< 5mm) distinct reflectors	Accepted		Consensus	Consensus		100%	87.50%
PROCEDURE	Hyperechoic strands	String or line-like (>5mm) distinct reflectors	Accepted		Consensus	Consensus		100%	100%
PROCEDURE	Lobularity	Rounded homogenous lobules separated by bright strands	Accepted		Consensus	Consensus		100%	100%
PROCEDURE	Microcysts	< 5mm cysts without MPD communication	Revised		Consensus	Consensus		100%	87.50%
PROCEDURE	Atrophy	Reduction of pancreatic parenchyma > 50%	Accepted		Consensus	Consensus		87.50%	75%
PROCEDURE	Calcification	Hyperechoic lesion with acoustic shadowing	Accepted		Consensus	Consensus		100%	100%
PROCEDURE	Heterogeneity	Differences in the echogenicity of one geographic area from	Revised		Consensus	Consensus		75%	75%
PROCEDURE	Solid Lesion	Solid lesion with different echogenicity from the pancreas p	Accepted		Consensus	Consensus		100%	100%
PROCEDURE	Fatty Pancreas	Bright or hyperechoic pancreas	Revised		Consensus	Consensus		100%	100%
PROCEDURE	MPD diameter (mm)		Accepted		Consensus		100%		
PROCEDURE	MPD stricture		Accepted		Consensus		100%		
PROCEDURE	Where is MPD stricture identified?		Accepted		Consensus		100%		
PROCEDURE	MPD filling defect		Accepted		Consensus		87.50%		
PROCEDURE	Ampulla abnormalities		Accepted		Consensus		87.50%		
PROCEDURE	Location of Mass		Accepted	Consensus			100%		
PROCEDURE	Largest Diameter (mm)		Accepted	Consensus			100%		
PROCEDURE	Second Diameter (mm)		Accepted	Consensus			100%		
PROCEDURE	Echogenicity		Accepted	Consensus			100%		
PROCEDURE	Cystic component		Accepted	Consensus			100%		
PROCEDURE	Invasion		Accepted	Consensus			100%		
PROCEDURE	Upstream MPD dilation		Accepted	Consensus			87.50%		
PROCEDURE	Upstream Atrophy		Accepted	Consensus			75%		
PROCEDURE	EUS Impression		Accepted	Consensus			75%		
PROCEDURE	Biopsy		Accepted	Consensus			100%		
PROCEDURE	Total number of Cysts Identified		Accepted	Consensus			87.50%		
PROCEDURE	Dominant Cyst (largest) Location		Accepted	Consensus			100%		
PROCEDURE	Additional Cyst Location		Accepted	Consensus			100%		
PROCEDURE	Largest Cyst diameter (mm)		Accepted	Consensus			100%		
PROCEDURE	Second Diameter (mm)		Accepted	Consensus			75%		
PROCEDURE	Septations		Accepted	Consensus			87.50%		
PROCEDURE	# Compartments		Accepted	Consensus			87.50%		
PROCEDURE	Enhancing Cyst Wall		Accepted	Consensus			87.50%		
PROCEDURE	Solid Component		Accepted	Consensus			100%		
PROCEDURE	Mural Nodule		Accepted	Consensus			100%		
PROCEDURE	Communicaiton PD		Accepted	Consensus			100%		
PROCEDURE	Upstream PD dilation		Accepted	Consensus			100%		
PROCEDURE	Upstream Atrophy		Accepted	Consensus			100%		
PROCEDURE	Dominant Cyst EUS Impression		Revised	Consensus			87.50%		
PROCEDURE	Additional Cysts / Largest Diameter		Accepted	Consensus			87.50%		
PROCEDURE	Additional Cysts with any Worrisome Features (WF)		Accepted	Consensus			100%		
PROCEDURE	Additional Cyst WF		Accepted	Consensus			100%		
PROCEDURE	Additional Cyst EUS Impression		Accepted	Consensus			87.50%		
PROCEDURE	Location		Accepted	Consensus			87.50%		
PROCEDURE	Number		Accepted	Consensus			87.50%		
PROCEDURE	Size - Greatest Diameter		Accepted	Consensus			100%		
PROCEDURE	Shape		Revised	Consensus			75%		
PROCEDURE	Echogenicity		Accepted	Consensus			87.50%		
PROCEDURE	Biopsy Method		Accepted	Consensus			100%		
PROCEDURE	Needle Size		Accepted	Consensus			100%		
PROCEDURE	Acquisition		Accepted	No Consensus			37.50%		
PROCEDURE	Needle manufacturer		Accepted	No Consensus			50%		
PROCEDURE	Number of passes		Accepted	Consensus			87.50%		
PROCEDURE	Microforceps biopsy (MFB; Moray bx)		Accepted	Consensus			100%		
PROCEDURE	Cytology Result		Accepted	Consensus			100%		
PROCEDURE	Histology Result		Accepted	Consensus			100%		
PROCEDURE	Cyst Fluid Analysis		Accepted	Consensus			100%		
POST	What would you rate the adequacy of the procedure?	Adequate / Inadequate / Partially Adequate	Revised	Consensus	Consensus			87.50%	87.50%
POST	What would you rate the overall ability to make recom	Good / Intermediate / Poor	Accepted	Consensus	Consensus			75%	87.50%
POST	Would you recommend that EUS is an adequate proce	EUS is adequate / Cross sectional imaging is preferred	Revised	Consensus	Consensus			87.50%	75%
POST	What is the overall impression of the EUS exam?	Normal / Abnormalities of uncertain significance / Worriso	Revised	Consensus	Consensus			100%	87.50%
POST	If this is a surveillance exam and prior EUS is available	No prior exam / No significant change / Significant change	Accepted	Consensus	Consensus			75%	87.50%

Supplementary Table 2. Procedural documentation for patients undergoing screening EUS

Indication for EUS procedure	Known germline mutation (list)/ Familial PC
Indication for EGD	Protocol (no specific indication)/Risk of GI neoplasm/Other (symptoms, etc)
EUS exam	Radial+Linear/Linear
Sedation	Conscious Sedation/Propofol Sedation/ General Anesthesia
If prior imaging, abnormal pancreatic imaging	Yes/No/N/A

Supplementary Table 3. Recommended pancreatic EUS image capture

Endoscopic Position	EUS view	Measurement
Duodenal Bulb	Distal CBD/Proximal PD/Ampulla view (Fig 1A)	Measurement of proximal PD, distal CBD
Duodenal Bulb	Porta hepatis (HA, PV, CBD) (Fig 1B)	CBD
Duodenal Bulb	Pancreas parenchyma, portal confluence (Fig 1C)	MPD
Duodenal Bulb	Pancreas parenchyma (NOP/genu), region of SMV (Fig 1 D)	MPD
Gastric Fundus	Celiac axis, SMA, Aorta (Fig 2A)	
Gastric Fundus	Tail of pancreas view with spleno-renal angle (Fig 2B)	MPD
Gastric Fundus	Body of pancreas view at level of SA, SV (Fig 2C)	MPD
Gastric Fundus/Body	Right lateral pancreas margin (PD towards HOP) (Fig 2D)	MPD

(CBD: Common bile duct; MPD: main pancreatic duct; HA: hepatic artery; PV: portal vein; SMA: superior mesenteric artery; SMV: superior mesenteric vein; SA: splenic artery; SV: splenic vein; T/B/HOP: tail/body/head of pancreas)

Supplementary Table 4. Peripancreatic lymph node evaluation

Location	
Number	
Size – greatest diameter	
Shape	Round/oval/triangular/irregular
Echogenicity	Hypoechoic /Hyperechoic

Supplementary Table 5 EUS-guided aspiration or biopsy

Biopsy Method	Fine-Needle Aspiration (FNA)	Fine Needle Biopsy (FNB)		
Needle Size	19G, 22G	20G	22G	25G

Microforceps biopsy (MFB; Moray bx)	Yes	No		
Cytology Result				
Histology Result				
Cyst Fluid Analysis	Amylase/CEA/Mutational Analysis/Glucose/Other			

Endoscopic ultrasound (EUS)
Pancreatic Cancer Early Detection Consortium (PRECEDE)
Pancreatic ductal adenocarcinoma (PC)
Familial Adenomatous Polyposis (FAP)
Pancreatic duct (PD)
Main pancreatic duct (MPD)
Common bile duct (CBD)
Head of pancreas (HOP)
Body of pancreas (BOP)
Tail of pancreas (TOP)
Intraductal papillary mucinous neoplasm (IPMN)
Fine needle aspiration (FNA)
Rapid on-site evaluation (ROSE)
Mucinous cystadenomas (MCNs)