



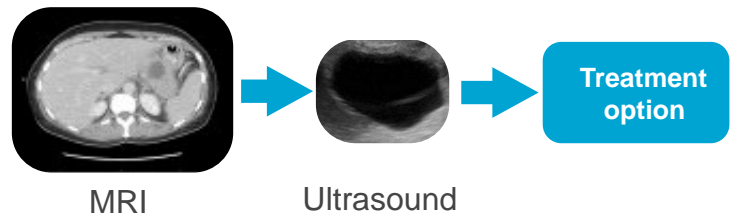
AN INFORMATIONAL GUIDE FOR PATIENTS ABOUT Endomicroscopy Benefits in Pancreatic Cysts

You have been diagnosed with a Pancreatic Cyst. This short guide will help you understand the different methods used to determine the best course of treatment. Along with a description of the different diagnostic options, there is a list of questions to help you prepare for a conversation with your physician. It is important to work closely with your physician for your diagnostic workup. Doing so could save you an unnecessary surgery or get you to a treatment sooner.

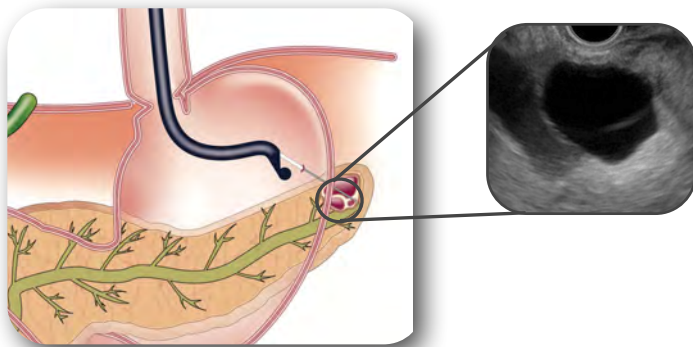
Who should you contact?

You will likely be referred to a pancreatic cyst specialist. This is most often a gastroenterologist who will want to provide further screening that can be used to classify the cyst, as either cancerous or pre-cancerous (i.e. mucinous), or benign (i.e. non-mucinous). Pre-cancerous and cancerous cysts are often surgically removed.

Most often, the gastroenterologist will want to perform an Endoscopic Ultrasound (EUS) procedure. Characterizations from the EUS procedure will determine the course of treatment.



What you need to know about Endoscopic Ultrasound (EUS)

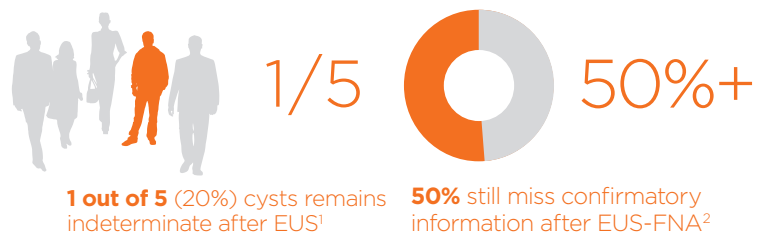


EUS is an imaging procedure during which a flexible endoscope is passed orally down to the stomach and duodenum. It allows the physician to visualize your pancreatic cyst.

During this procedure, the physician also has the ability to place a needle through the endoscope and into the cyst to collect samples of its inner contents (often fluid). This is referred to as EUS Fine Needle Aspiration (EUS-FNA).

Unfortunately 1 out of 5 cysts remain undefined after EUS¹ and 50% still miss clear diagnostic information after EUS-FNA².

Due to uncertain diagnosis, 60% of patients with benign pancreatic cysts undergo surgery which may not have been needed³.



What are your alternatives?

Luckily, with recent advances in medical imaging, there is a new technology that has been shown to improve diagnostic yield. **Suggested questions about needle-based Confocal Laser Endomicroscopy (nCLE) are listed on the following page.**

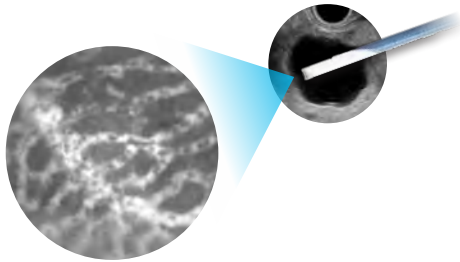
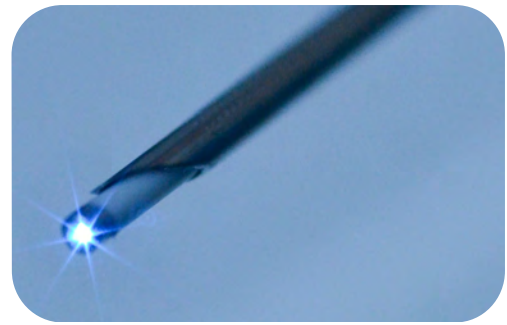
Learn more about pancreatic cysts & find a physician using nCLE today on diagnosingPancreaticCysts.com

References: 1.Brugge W. et al., Diagnosis of pancreatic cystic neoplasms: a report of the cooperative pancreatic cyst study, Gastroenterology 2004. 2.Van der Waaij. Cyst fluid analysis in the differential diagnosis of pancreatic cystic lesions: a pooled analysis. Gastrointest Endosc. 2005. 3.Jais B. et al. Serous cystic neoplasm of the pancreas: a multinational study of 2622 patients under the auspices of the International Association of Pancreatology and European Pancreatic Club (European Study Group on Cystic Tumors of the Pancreas). Gut 2015. 4.Ho C.K. et al. Complications of pancreatic surgery. HPB 2005;7:99-108. 5.Kotwall et al. National estimates of mortality rates for radical pancreaticoduodenectomy in 25,000 patients. Ann Surg Oncol 2002.

What is nCLE?

Needle-based Confocal Laser Endomicroscopy (nCLE)

nCLE or “Digital Optical Biopsy” is a safe way of looking at cells inside the body using a very small microscope. This microscope is a long, thin, flexible fiber-optic miniprobe which can be threaded down a needle. nCLE can be used to examine a pancreatic cyst to determine if signs of cancer are present- in real-time. The procedure is easy to perform, quick and yields the most accurate results available.



nCLE image of a benign cyst⁸

Published clinical trials have shown that nCLE provides high precision characterization of various types of cysts:

- Mucinous (potentially cancerous) cysts can be confirmed in about 80% of cases with very high specificity^{6,7}.

- Serous cystadenomas (benign) can be confirmed by nCLE in 7 cases out of 10, with very high specificity⁸.

Follow up studies are still ongoing.

This diagnostic accuracy is much higher than traditional fluid analysis and can influence the direction of patient care^{9,10}. For these reasons, nCLE has been adopted by leading physicians around the world in hundreds of hospitals.

Be prepared. Here are some questions to help you make an informed decision

- I read that success rates in diagnosing benign cysts vary significantly because they are difficult to diagnose, is that true?
- How would I know if my cyst is benign?
- Will you be using endomicroscopy?
- How can I be sure that I will not be sent to surgery if my condition does not require it?
- How can I be guaranteed quick results after my first procedure?
- For patients that have already undergone an indeterminate test: Where can I go to get an nCLE test?

The incidence of pancreatic cysts in the US population is estimated between 3% and 15%¹¹ but only 2% of cysts are malignant at diagnosis¹² and only very few degenerate into pancreatic cancer. Working closely with your physician to define the best diagnostic workup is important to pancreatic cancer early detection and treatment.

Learn more about pancreatic cysts & find a physician using nCLE today
on diagnosingPancreaticCysts.com

These statements and the associated reference to specific clinical studies, are not intended to represent claims of safety or effectiveness for detecting or treating any specific condition or disease state. Rather this information is intended to provide useful reference to selected published literature describing physician experiences with the associated clinical uses. These statements have not been reviewed, cleared, or approved by the U.S. FDA.

References: 6. Konda V.J. et al. A pilot study of in vivo identification of pancreatic cystic neoplasms with needle-based confocal laser endomicroscopy under endosonographic guidance. *Endoscopy* 2013. 7. Nakai Y. et al. Diagnosis of pancreatic cysts: EUS-guided, through the needle confocal laser-induced endomicroscopy and cystoscopy trial: DETECT study. *GIE* 2015. 8. Napoléon B, et al. A novel approach to the diagnosis of pancreatic serous cystadenoma: needle-based confocal laser endomicroscopy. *Endoscopy* 2014. 9. Van der Waaij. Cyst fluid analysis in the differential diagnosis of pancreatic cystic lesions: a pooled analysis. *Gastrointest Endosc.* 2005 10. Thosani N et al. Role of EUS-FNA based cytology in the diagnosis of mucinous pancreatic cystic lesions: a systematic review and meta-analysis 11. T.A. Laffan et. al. Prevalence of Unsuspected Pancreatic Cysts on MDCT *AJR Am J Roentgenol.* 2008. 12. Wu BU, Sampath K, Berberian CE et al. Prediction of malignancy in cystic neoplasms of the pancreas: a population-based cohort study. *Am J Gastroenterol* 2014.