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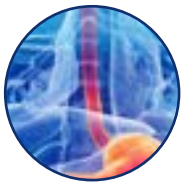
REAL-TIME IN VIVO CELLULAR IMAGING

Publications in Gastroenterology



GERD/BARRETT'S ESOPHAGUS

- Significantly higher per-patient pCLE pooled sensitivity, specificity, and NPV of 96%, 93%, 98%, compared to random biopsies

DeMeester S, et al. High definition probe-based confocal laser endomicroscopy review and meta-analysis for neoplasia detection in Barrett's esophagus. Techniques and Innovations in Gastrointestinal Endoscopy, 2022.

Meta-analysis on 9 studies, 688 patients and 1,299 lesions

- 2x more Barrett's Esophagus detected compared to Seattle protocol

Richardson C, et al. Real-time diagnosis of Barrett's esophagus: a prospective, multicenter study comparing confocal laser endomicroscopy with conventional histology for the identification of intestinal metaplasia in new users, Surgical Endoscopy, 2019.

172 patients with Barrett's Esophagus, 8 centers

- Improved the treatment plan in 36% of patients

Canto M I, et al. In vivo endomicroscopy improves detection of Barrett's esophagus-related neoplasia: a multicenter international randomized controlled trial. Gastrointestinal Endoscopy, 2013.

192 patients with Barrett's Esophagus, 5 centers

- 2x more dysplastic lesions detected compared to WLE
  1.7x more lesions detected compared to Narrow Band Imaging

Sharma P, et al. Real-time increased Detection of Neoplastic Tissue in Barrett's Esophagus with Probe-based Confocal Laser Endomicroscopy: Final results of a Multi-center Prospective International Randomized Controlled Trial. Gastrointestinal Endoscopy, 2011.

101 patients with BE, 5 international centers

- Associated with lower health services utilization of endoscopy, anesthesia, biopsy, ablation, and higher patient satisfaction.

Randhawa N, et al. The Relationship Between Patient Satisfaction and Use of Healthcare Services in Patients With Barrett's Esophagus Using Confocal Laser Endomicroscopy versus Standard of Care. ACG 2022 abstract.

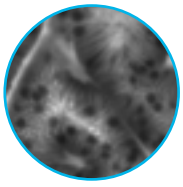
60 patients with Barrett's Esophagus, 5 centers

Other publications

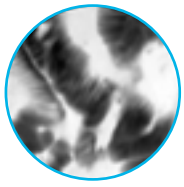
- Al-Mansour M R, et al. SAGES TAVAC safety and efficacy analysis confocal laser endomicroscopy. Surg Endosc, 2020.
- Xiong Y-Q, et al. Comparison of narrow-band imaging and confocal laser endomicroscopy for the detection of neoplasia in Barrett's Esophagus : A meta-analysis. Clinics and Research in Hepatology and Gastroenterol, 2018.
- Neumann H, et al. Confocal Laser Endomicroscopy for Diagnosis of Barrett's Esophagus. Frontiers in Oncology, 2012.
- Johnson E A, et al. Probe-Based Confocal Laser Endomicroscopy to Guide Real-Time Endoscopic Therapy in Barrett's Esophagus with Dysplasia. Case Report Gastroenterology, 2012.
- Bertani H, et al. Improved Detection of Incident Dysplasia by Probe-Based Confocal Laser Endomicroscopy in a Barrett's Esophagus Surveillance Program. Digestive Diseases and Sciences, 2012.
- Wallace M B, et al. Multicenter, randomized, controlled trial of confocal laser endomicroscopy assessment of residual metaplasia after mucosal ablation or resection of GI neoplasia in Barett's esophagus. Gastrointestinal Endoscopy, 2012.
- Gaddam S, et al. Novel Probe-Based Confocal Laser Endomicroscopy Criteria and Interobserver Agreement for the Detection of Dysplasia in Barrett's Esophagus. The American Journal of Gastroenterology, 2011.
- Konda V J, et al. Confocal Laser Endomicroscopy: potential in the Management of Barrett's Esophagus. Diseases of the Esophagus, 2010.
- Wallace M B, et al. Preliminary Accuracy and Interobserver Agreement for the Detection of Intraepithelial Neoplasia in Barrett's Esophagus with Probe-based Confocal Laser Endomicroscopy. Gastrointestinal Endoscopy, 2010.

Cellvizio® Image Patterns

Squamous Epithelium



Intestinal Metaplasia



Adenocarcinoma

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Publications in Gastroenterology

PANCREATIC CYSTS

→ 35% of patients with benign cysts prevented from any surveillance

Palazzo M, et al. Impact of needle-based confocal laser endomicroscopy on the therapeutic management of single pancreatic cystic lesions, Surgical Endoscopy, 2019. (CONTACT 2).

206 patients with cysts

→ nCLE identified mucinous PCLs with: high sensitivity of 98%, 94% specificity and 97% accuracy

Krishna S G, et al. Endoscopic Ultrasound-Guided Confocal Laser Endomicroscopy Increases Accuracy of Differentiation of Pancreatic Cystic Lesions, Clinical Gastroenterology and Hepatology, 2019.

144 patients with a suspected PCL (≥20 mm)

→ nCLE could reduce up to 23% of surgical interventions

Le Pen C, et al. A health economic evaluation of needle-based Confocal Laser Endomicroscopy for the diagnosis of pancreatic cysts. Endoscopy International Open, 2017.

→ Adding nCLE led to a net savings of $442,438 (mean: $4,757.40/patient)

Luthra A, et al. Cost-Benefit Analysis and Resource Implications of Endoscopy Ultrasound-guided Confocal Endomicroscopy in Pancreas Cysts, Techniques and Innovations in Gastrointestinal Endoscopy, 2021.

93 patients with cysts

→ EUS-TTNB and EUS-nCLE were better choices for the diagnosis of PCLs

Li SY, et al. Comparative Performance of Endoscopic Ultrasound-Based Techniques in Patients With Pancreatic Cystic Lesions: A Network Meta-Analysis. The American Journal of Gastroenterology, 2023.

A meta-analysis of studies comprising 3,641 patients with cysts

Other publications

- Machicado J D, et al. Accuracy and agreement of a large panel of endosonographers for endomicroscopy-guided virtual biopsy of pancreatic cystic lesions. Pancreatology, 2022.
- Singh R R, et al. Risk Stratification of Pancreatic Cysts With Confocal Laser Endomicroscopy. Gastro Hep Advances, 2022.
- Machicado J D, et al. High performance in risk stratification of intraductal papillary mucinous neoplasms by confocal laser endomicroscopy image analysis with convolutional neural networks (with video). Gastrointest Endosc, 2021.
- Napoléon B, et al. Confocal Endomicroscopy for the Evaluation of Pancreatic Cystic Lesions: A Systematic Review and an International Delphi Consensus Report. Endoscopy International Open, 2020.
- Al-Mansour, et al. SAGES TAVAC safety and efficacy analysis confocal laser endomicroscopy. Surg Endosc, 2020.
- Napoléon B, et al. Needle-based confocal laser endomicroscopy of pancreatic cystic lesions: a prospective multicenter validation study in patients with definite diagnosis, Endoscopy, 2018. (CONTACT 2)
- Napoléon B, et al. New horizons in the endoscopic ultrasonography-based diagnosis of pancreatic cystic lesions. World J Gastroenterol, 24(26), 2853–2866, 2018.
- Napoléon B, et al. A novel approach to the diagnosis of pancreatic cystadenoma: needle-based confocal laser endomicroscopy, Endoscopy, 2015. (CONTACT 1)
- Nakai Y, et al. Diagnosis of pancreatic cysts: EUS-guided, through-the-needle confocal laser-induced endomicroscopy and cystoscopy trial: DETECT study. Gastrointestinal Endoscopy, 2015.
- Konda V J A, et al. A pilot study of in vivo identification of pancreatic cystic neoplasms with needle-based confocal laser endomicroscoscopy under endosonographic guidance. Endoscopy, 2013. (INSPECT)

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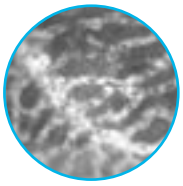
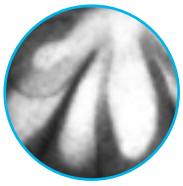
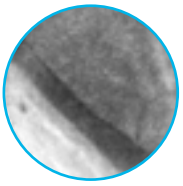


Serous cystadenoma



IPMN



Mucinous cystadenoma

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Publications in Gastroenterology

GASTRIC DISEASE

→ 96.9% sensitivity for the diagnosis of superficial gastric neoplasia with pCLE and biopsy versus 75% sensitivity with conventional biopsy

Bok G H, et al. The accuracy of probe-based confocal endomicroscopy versus conventional endoscopic biopsies for the diagnosis of superficial gastric neoplasia (with videos). Gastrointestinal Endoscopy, 2013.

46 patients - diagnosis of superficial gastric neoplasia - 1 center

→ pCLE classification of gastric pit patterns and vessel architecture could predict Atrophicgastritis, GIM and neoplasia with sensitivity of at least 89% and specificity of 99% with substantial inter-observer agreement (k:0.7)

Li Z, et al. New Classification of Gastric Pit Patterns and Vessel Architecture Using Probe-based Confocal Laser Endomicroscopy. J Clin Gastroenterol, 2015.

32 patients - surveillance of gastric intestinal metaplasia - 1 center

→ Pooled 92% sensitivity and 97% specificity for the diagnosis of gastric intestinal metaplasia with CLE

Zhang H-P, et al. The diagnostic value of confocal laser endomicroscopy for gastric cancer and precancerous lesions among Asian population: a system review and meta-analysis. Scand J Gastroenterol, 52(4), 382–388, 2017.

4000+ lesions - surveillance of gastric intestinal metaplasia - 23 studies

Other publications

- Lim L G, et al. Comparison of probe-based confocal endomicroscopy with virtual chromoendoscopy and white-light endoscopy for diagnosis of gastric intestinal metaplasia. Surgical endoscopy, 2013.
- Pittayanon R, et al. Flexible spectral imaging color enhancement plus probe-based confocal laser endomicroscopy for gastric intestinal metaplasia detection. Journal of Gastroenterology and Hepatology, 2013.
- Pittayanon R, et al. The learning curve of gastric intestinal metaplasia interpretation on the images obtained by probe-based confocal laser endomicroscopy (pCLE). Diagnostic and Therapeutic Endoscopy, 2012.
- Pittayanon R, et al. Role of Confocal Laser Endomicroscopy for the Detection of early Gastrointestinal Malignancy. Thai Journal Gastroenterology, 2011.

IRRITABLE BOWEL SYNDROME - FOOD INTOLERANCE

→ 69.5% of patients improved with food exclusion therapy and 13% were symptom-free according to CLE.

Gjini B, et al. Food intolerance in patients with functional abdominal pain: Evaluation through endoscopic confocal laser endomicroscopy. Endoscopy Int Open, 2023.

34 patients, observational study

→ More than 50% of patients with IBS could have an atypical food allergy, with negative results from skin tests and serologic analysis of immunoglobulin E.

Fritscher-Ravens A, et al. Many Patients With Irritable Bowel Syndrome Have Atypical Food Allergies Not Associated With Immunoglobulin E. Gastroenterology, 2019.

108 patients, prospective study

→ CLE showed a real-time response to food antigens in 22 of 36 patients.

Fritscher-Ravens A, et al. Confocal Endomicroscopy Shows Food-Associated Changes in the Intestinal Mucosa of Patients With Irritable Bowel Syndrome. Endoscopy Int Open, 2014.

COLORECTAL LESIONS

→ 100% sensitivity and NPV combination of pCLE and virtual chromoendoscopy for neoplastic recurrence

Shahid M W, et al. Diagnostic accuracy of probe-based confocal laser endomicroscopy in detecting residual colorectal neoplasia after EMR: a prospective study. Gastrointestinal Endoscopy, 2012.

92 patients - post-EMR control 3 international centers

→ 93.3% of neoplastic lesions accurately characterized

Wanders L K, et al. Diagnostic performance of narrowed spectrum endoscopy, autofluorescence imaging, and confocal laser endomicroscopy for optical diagnosis of colonic polyps: a meta-analysis. Lancet, 2013.

Meta analysis on 11 studies 1319 lesions

→ Real-time CLE, had a pooled sensitivity and specificity of 91% and 97% for characterization in patients with colonic IBD

Lord R, et al. Colonic lesion characterisation in inflammatory bowel disease: A systematic review and meta-analysis. World J Gastroenterol, 2018.

1491 patients (4674 polyps)

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Publications in Gastroenterology

INFLAMMATORY BOWEL DISEASES

- Increased epithelial gap density in IBD patients is an endoscopic predictor of relapse within 12 months

  Turcotte JF, et al. Increased Epithelial Gaps in the Small Intestine Are Predictive of Hospitalization and Surgery in Patients with Inflammatory Bowel Disease. Clinical and Translational Gastroenterology, 2012.

  41 patients (21 Crohn's disease and 20 Ulcerative Colitis), 1 center

- CLE allows for the early prediction of relevant clinical outcomes being hospitalization or surgery

  Tontini GE, et al. Prediction of clinical outcomes in Crohn's disease by using confocal laser endomicroscopy: results from a prospective multicenter study. Gastrointestinal Endoscopy, 2017.

  49 CD patients, 2 centers, retrospective study

- Severity of mucosal barrier dysfunction on pCLE resulted in significant reductions in the number, length of stay and total days of IBD-related hospitalizations

  Julia J. Liu et al. Personalized Inflammatory Bowel Disease Care Reduced Hospitalizations. Digestive Diseases and Sciences, 2019.

  >100 patients

- CLE barrier healing was highly accurate for predicting the further course of disease and exceeded endoscopic and histologic remission for predicting a survival free of major adverse outcomes

  Rath T, et al. Intestinal Barrier Healing Is Superior to Endoscopic and Histologic Remission for Predicting Major Adverse Outcomes in Inflammatory Bowel Disease: The Prospective ERIca Trial. Gastroentorlogy, 2022.

  181 patients (100 Crohn's disease and 81 Ulcerative Colitis), long-term prospective study

Other publications

- Al-Mansour MR, et al. SAGES TAVAC safety and efficacy analysis confocal laser endomicroscopy. Surg Endosc, 2020.
- Karstensen J, et al. Confocal laser endomicroscopy in ulcerative colitis: a longitudinal study of endomicroscopic changes and response to medical therapy (with videos). Gastrointestinal Endoscopy 2016.
- Musquer N, et al. Probe-based confocal laser endomicroscopy: A new method for quantitative analysis of pit structure in healthy and Crohn's disease patients. Digestive and Liver Disease, 2013.
- Liu JJ, et al. Increased Epithelial Gaps in the Small Intestines of Patients with Inflammatory Bowel Disease: Density Matters. Gastrointestinal Endoscopy, 2011.
- Neumann H, et al. Prospective Evaluation of the Learning Curve of Confocal Laser Endomicroscopy in Patients with IBD. Histology and Histopathology, 2011.
- Palma GD, et al. In-vivo Characterization of DALM in Ulcerative Colitis with High-Resolution Probe-based Confocal Laser Endomicroscopy. World Journal Gastroenterology, 2011.
- Neumann H, et al. Cancer Risk in IBD: How to Diagnose and How to Manage DALM and ALM. World Journal Gastroenterology, 2011.

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Healthy Mucosa

CD mucosal barrier dysfunction

Dysplasia/cancer