



FLORIDA HOSPITAL
Center for Interventional Endoscopy

REPORT CARD 2016

Committed to
Excellence in Patient Care,
Clinical Research and Education





FLORIDA HOSPITAL
Orlando

CENTER FOR
INVENTION
OSCOP



Shyam Varadarajulu, MD | Robert Hawes, MD | Shantel Hebert-Magee, MD | Ji Young Bang, MD, MPH
Udayakumar Navaneethan, MD | Muhammad K. Hasan, MD

OVERVIEW FROM PHYSICIANS

Dear Colleagues,

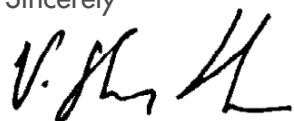
I am pleased to present the annual report card of the Florida Hospital Center for Interventional Endoscopy (CIE). This report card outlines our endoscopy procedure volume, clinical outcomes, portfolios on research and education, scientific presentations and significant milestones achieved in 2016.

Since the founding of CIE in 2012, within a short span of 5 years, significant progress has been made in fulfilling our core mission: provide high quality clinical care, conduct cutting-edge clinical research and train the next generation of endoscopists. In 2016, we performed 7248 complex endoscopic procedures of which 3247 were endoscopic ultrasound (EUS) examinations. For the third consecutive year, CIE has retained its status as the largest volume EUS unit in North America. Our ERCP volume exceeded 1400 and we performed more than 500 endoscopic mucosal resection procedures.

Our research portfolio remains robustly vibrant with 14 ongoing randomized trials and 6 prospective clinical studies evaluating cutting-edge endoscopic interventions or novel technology. The CIE faculty published 42 peer-reviewed manuscripts in 2016 with four abstracts being selected for podium presentations at the Digestive Diseases Week and the Pancreas Club Annual Meeting. Our research findings were published in high-impact journals such as the Annals of Surgery and GUT and recognized with awards at the United European Gastroenterology Week in Vienna and the Pancreas Club Annual Meeting in San Diego.

As we complete our first five years and begin the second phase of our mission that include initiation of novel procedural services, evaluation of new techniques in clinical trials and integration of digital technology in endoscopic education, we reaffirm our commitment to excellence in clinical care and in making CIE a model for innovation in clinical endoscopy.

Sincerely



Shyam Varadarajulu, MD

Medical Director

Center for Interventional Endoscopy



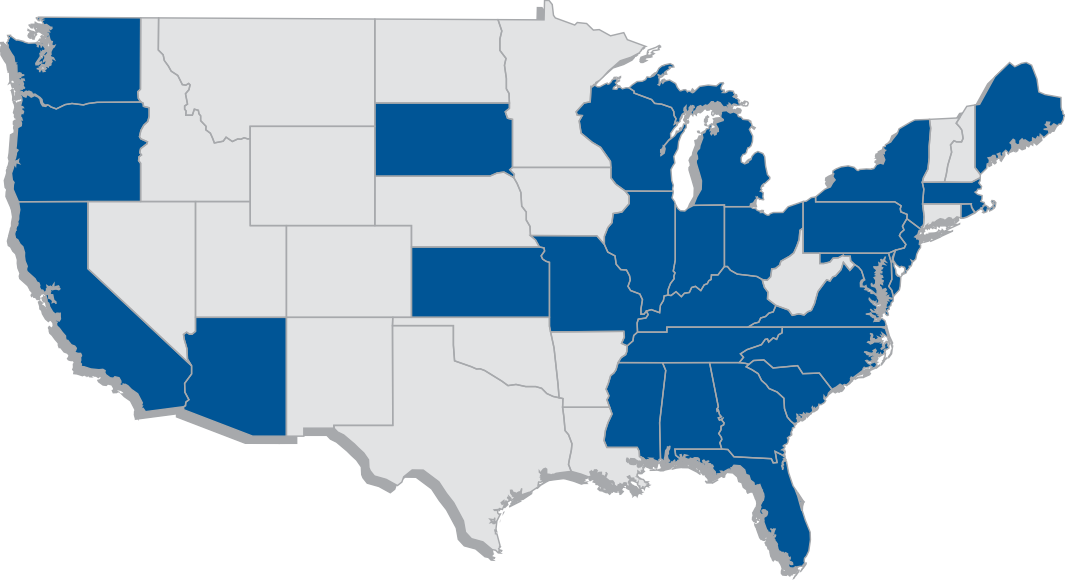
CIE STAFF

Craig Baker, Administrative Director
 Shyam Varadarajulu, MD, Medical Director
 Amy Metivier, ARNP
 Whitney Dailey, PA-C
 Mariel Madrideo, RN, Nurse Manager
 Heather Yount, RN, Assistant Nurse Manager
 Myles Wright, Practice Office Manager

Jason Jose, Program Manager
 Renay Crowe, Office Manager, Executive Assistant
 Robin Barron-Nelson, RN MSN CCRP,
 Clinical Research Manager
 Cristina Campos, Reserach Coordinator
 Xiang Zhu, Biostatistician
 Julie Hartung, Supervisor
 Lilly Sihabouth, Receptionist

Lisa Coon, Coder
 Talitha Rios, Medical Assistant
 Sara O'Brien, Patient Care Coordinator
 Tanja Wittig, Patient Care Coordinator
 Camille Ortiz, Patient Care Coordinator
 Elsa Barreira, Patient Care Coordinator
 Maria Nieves, Referral Coordinator

PATIENT REFERRAL STATISTICS



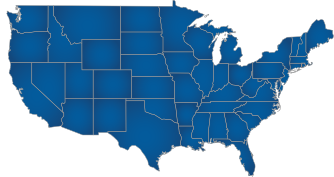
Patients are referred to CIE for expert care from across the United States as well as internationally. In 2016, patients were referred nationally from 30 states as well as from 7 countries. More than 50% of patients treated at CIE originated from outside the Tri-County area.



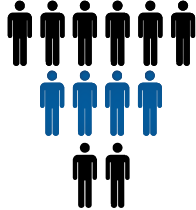
7243
TOTAL PATIENTS



7102
FLORIDA PATIENTS
Tri County: 3616
Non Tri-County: 3486



30
STATES

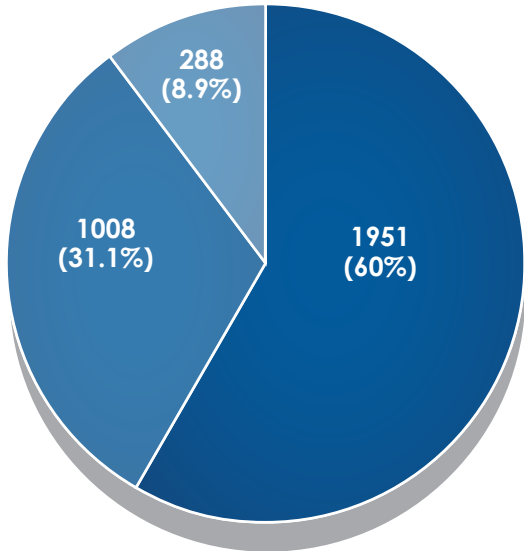
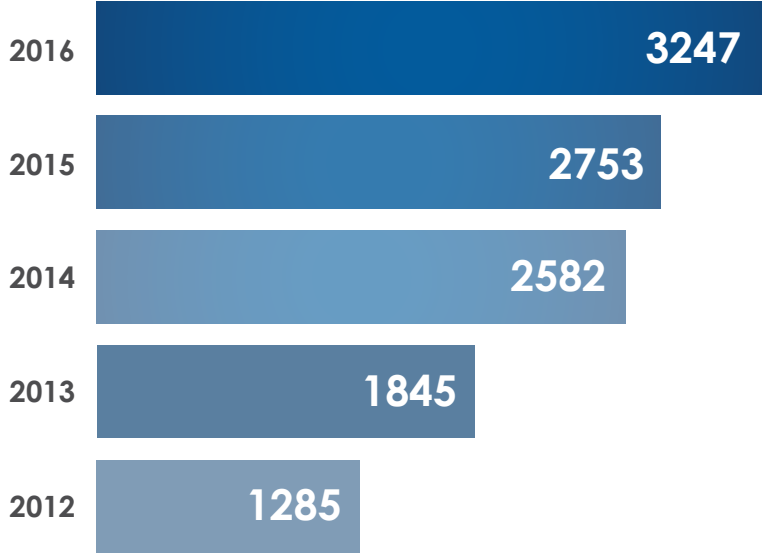


133
OUT-OF-STATE
PATIENTS



7
INTERNATIONAL
PATIENTS
Virgin Islands
Puerto Rico
Brazil
England
Spain
India
Venezuela

EUS PROCEDURE VOLUME



- Diagnostic = 1951
- FNA = 1008
- Interventions = 288

Interventional Procedures

- ▶ Celiac Plexus Interventions = 146
- ▶ Drainage of Pancreatic Fluid Collections = 106
- ▶ Ductal Drainages = 18
- ▶ Others = 18

ENDOSCOPIC ULTRASOUND PROGRAM

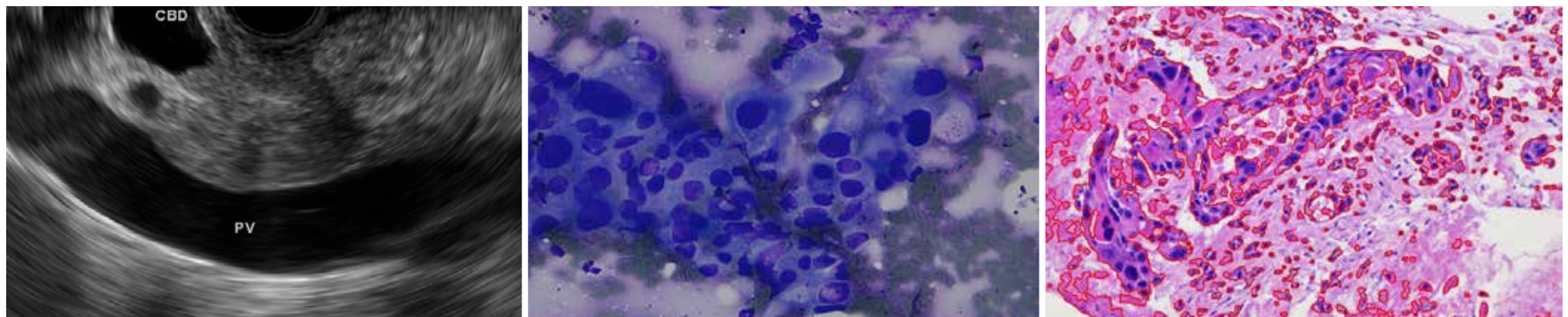
RESEARCH

- **Walled-off Necrosis (WON):** Randomized trials comparing endoscopy versus surgery and plastic versus lumen-apposing metal stents for the treatment of WON are in progress.
- **Tissue Acquisition:** The suction-in no-suction (SINS) four-arm randomized trial involving 352 patients with solid pancreatic masses was concluded in 2016. The study compared the 22 versus 25G needles and evaluated the role of suction. The overall diagnostic accuracy of EUS-FNA was found to be more than 98.5% at long-term follow-up. Another randomized trial comparing the Franseen biopsy and standard FNA needles for the sampling of pancreatic masses was recently concluded. The findings of this study will be presented at United European Gastroenterology (UEG) Week 2017.

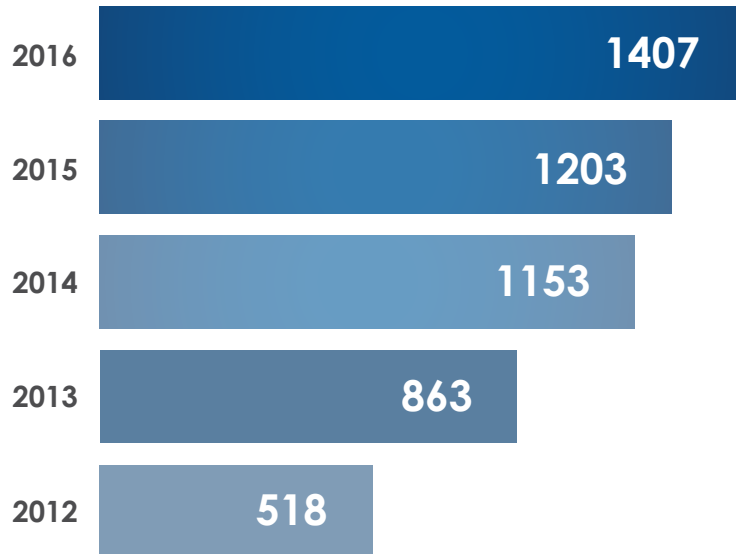
NEW INITIATIVES

- **Pancreatic Cyst Ablation:** Nearly 2% of patients undergoing cross-sectional imaging studies are found to have an incidental cyst in the pancreas and a significant proportion of these cysts are considered neoplastic. Given the poor outcomes of surgery in pancreatic cancer, it is important to identify and treat pancreatic cysts that are at high-risk for progression to malignancy. With the availability of needle-based confocal laser endomicroscopy and use of next generation sequencing we are now able to reliably risk-stratify patients. A EUS-based chemotherapeutic protocol has been introduced at CIE to treat high risk surgical patients who are at increased risk for progressing to cancer.
- **Tumor Ablation:** With the introduction of EUS compatible radiofrequency ablation (RFA) probes we are now able to perform ablation of tumors and celiac plexus nerves in patients with locally advanced pancreatic cancer. Most of these procedures are generally performed in a protocol-based clinical trial setting.

Recent studies at CIE have shown that neoplastic specimens procured at EUS-guided fine-needle biopsy can be quantified for tumor and desmoplastic stroma which are both critical for the delivery of molecular-based chemotherapy.



ERCP PROCEDURE VOLUME



ERCP VOLUME BY GRADE

Grade 1: 7

- Biliary stent removal/exchange
- Diagnostic cannulation of ducts and tissue sampling

Grade 2: 545

- Biliary stone extraction <10 mm
- Treatment of bile leaks, treatment of extrahepatic strictures

Grade 3: 678

- Biliary stone extraction >10 mm
- Minor papilla therapy
- Cholangioscopy
- Management of acute or recurrent pancreatitis, pancreatic strictures, or stones (< 5 mm)
- Treatment of hilar tumors, strictures
- Sphincter of Oddi Manometry

Grade 4: 177

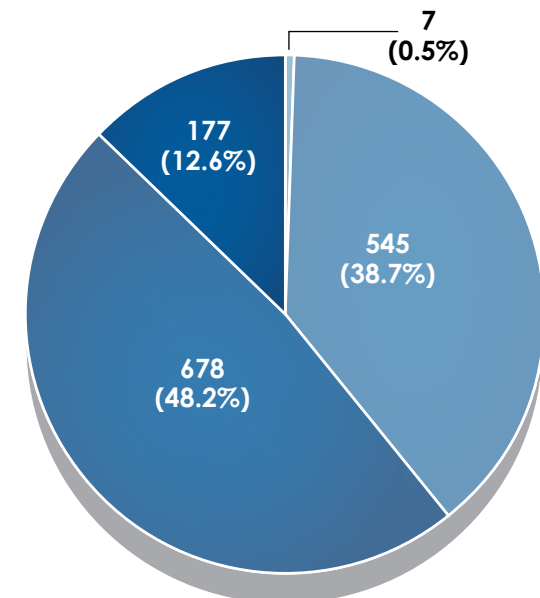
- Removal of internally migrated pancreatic stents, stones (>5 mm)
- Pseudocyst drainage or necrosectomy
- Ampullectomy
- ERCP after Whipple procedure/Roux-en-Y bariatric surgery

ERCP OUTCOMES:

- Technical Success = 1391 (98.9%)
- Technical Failures = 16 (1.1%)
 - Altered Anatomy = 11
 - Failed Cannulation = 5

ADVERSE EVENTS = 42 (2.9%)

- Perforation = 1
- Bleeding = 4
- Pancreatitis = 18
- Cholangitis = 19
- Death = 0



ERCP PROGRAM

RESEARCH

- **Pancreatic-biliary Malignancy:** The diagnosis and treatment of pancreatic and bile duct cancers are major areas of clinical and research focus at CIE. Given the suboptimal diagnostic sensitivity of cholangioscopy-guided biopsies, a randomized trial evaluating the concept of onsite cytology in detecting malignancy is currently in progress. Additionally, randomized trials comparing ERCP and EUS-guided drainage for malignant biliary obstruction are currently in progress.
- **Bile Duct Stones:** Treatment of large bile duct stones can be technically challenging. In order to determine the most effective treatment strategy, a randomized trial comparing balloon sphincteroplasty and cholangioscopy-guided laser is being conducted.
- **Biomarkers:** A Prospective study evaluating the role of lipidomics in differentiating benign from malignant biliary stricture is currently underway. Nearly 200 patients have been enrolled in this study to date. The findings of the study may be particularly relevant for patients with primary sclerosing cholangitis-induced biliary strictures.
- **Post-ERCP Pancreatitis:** CIE is a part of the NIH funded multi-center randomized trial evaluating the role of indomethacin in preventing post-ERCP pancreatitis.
- **Pancreatic Necrosis:** The role of pancreatic duct stenting in preventing disconnected pancreatic duct syndrome in patients with necrotizing pancreatitis is being investigated in a randomized trial.

NEW INITIATIVES

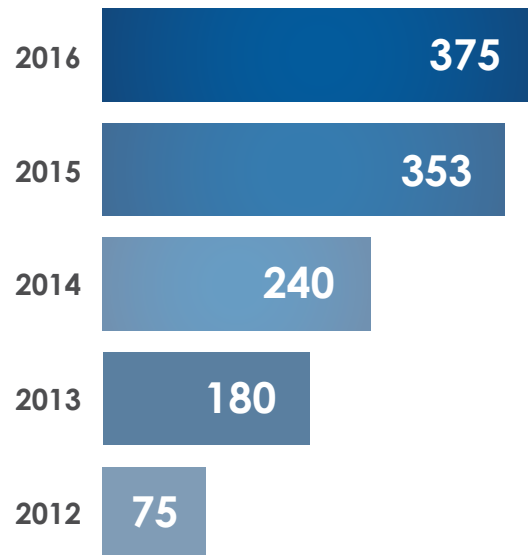
- **Advanced Imaging:** To improve the diagnostic work-up of indeterminate biliary strictures, both volumetric and confocal laser endomicroscopy have been integrated within our clinical practice.
- **Cholangiocarcinoma:** Given the limited treatment options, radiofrequency ablation (RFA) is being offered as a palliative therapy for patients with cholangiocarcinoma.



ADVANCED PROCEDURES

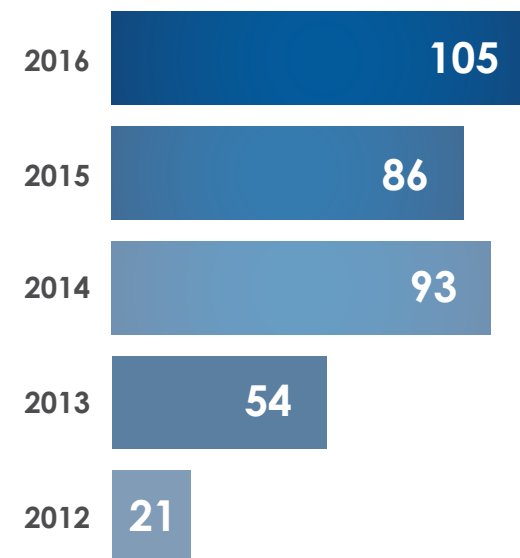
DOUBLE-BALLOON ENTEROSCOPY

- Clinical trials evaluating the utility of the Motorized Spiral Enteroscope in Small Bowel Diseases are expected to commence in 2017.



RADIOFREQUENCY ABLATION

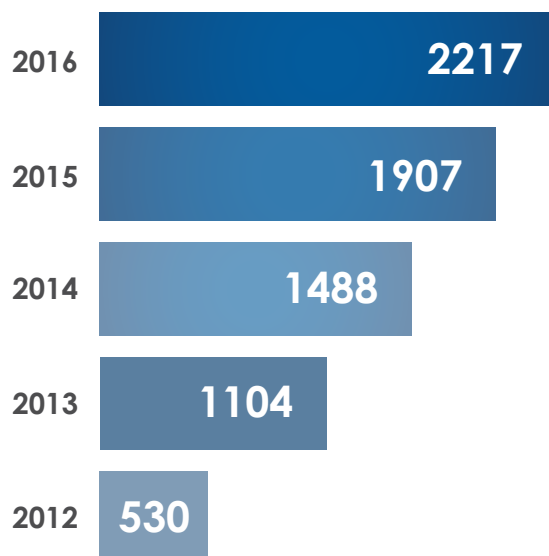
- Clinical trials evaluating the utility of Optical Coherence Tomography for identifying neoplasia in Barrett's esophagus, inflammatory bowel disease and indeterminate biliary strictures are in progress.
- A pilot study evaluating the utility of RFA in ablation of pancreatic and biliary tumors is in progress.



ADVANCED PROCEDURES

OTHER INTERVENTIONS

- EGD
- Colonoscopy
- Enteral Feeding Tubes
- Fistula Closure (suturing, clips)
- Luminal Stenting
- Glue Injection
- Zenker's Diverticulectomy



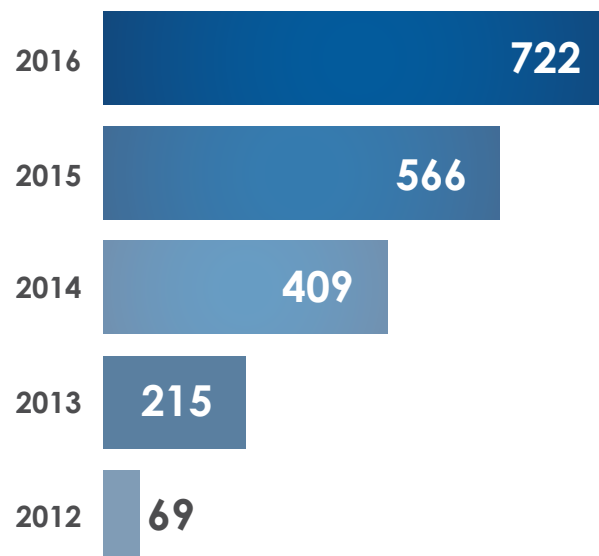
NEW INITIATIVES

- **Zenker's Diverticulectomy:** 18 patients with Zenker's diverticulum have been treated by endoscopic diverticulectomy in 2016.
- **Peroral Endoscopic Myotomy (POEM):** POEM will be offered as treatment option for patients with achalasia from June 2017.

ENDOSCOPIC MUCOSAL RESECTION INCLUDING POLYPECTOMY

RESEARCH

- Randomized trials evaluating the role of subcutaneous octreotide in prevention of bleeding after ampullectomy and endoscopic mucosal resection of large duodenal polyps are underway.
- Other randomized trials include the evaluation of tissue cassettes for EMR specimen collection and the role of prophylactic clips in preventing bleeding after endoscopic resection of large colon polyps.



RESEARCH IN 2016

EUS-RELATED RANDOMIZED TRIALS

Minimally Invasive Surgery vs. Endoscopy Randomized (MISER) Trial for Symptomatic Walled-Off Pancreatic Necrosis

Primary Aim: To compare the composite of adverse events between minimally invasive surgery and endoscopy for treatment of walled-off necrosis.

A Randomized trial comparing Endoscopic Ultrasound-guided biliary drainage (EUS-BD) and Endoscopic Retrograde Cholangiopancreatography (ERCP) for Malignant Distal Biliary Obstruction

Primary Aim: To compare the rates of adverse events between patients undergoing EUS-BD and ERCP for distal malignant biliary obstruction.

22 Gauge Versus 25 Gauge: Suction-in, No-suction (SINS) Randomized Trial for EUS-FNA of Pancreatic Masses

Primary Aim: To compare the 22 and 25G needles and to evaluate the role of suction between cohorts.

Randomized Trial comparing Fully Covered, Self-Expanding Metal Stent (FCSEMS) and Plastic Stents for EUS-guided Drainage of Walled-off Necrosis (WON)

Primary Aim: To compare the rate of endoscopic re-interventions between metal and plastic stents for walled-off necrosis.

Randomized trial comparing FNB and FNA needles for Endoscopic Ultrasound (EUS)-guided sampling of solid pancreatic masses

Primary Aim: To compare the total area, tumor-stroma ratio and molecular marker uptake in tissue procured using the FNA and FNB needles in patients undergoing EUS-guided sampling of pancreatic masses.

Randomized trial comparing two FNB needles for Endoscopic Ultrasound (EUS)-guided sampling of solid pancreatic masses

Primary Aim: To compare the total area of procured tissue between the two FNB needles in patients undergoing EUS-guided sampling of pancreatic masses.

ERCP-RELATED RANDOMIZED TRIALS

Stent vs Indomethacin for Preventing Post-ERCP Pancreatitis: The SVI Trial - A Multicenter Randomized Non-inferiority Clinical Trial of Rectal Indomethacin Alone vs. Indomethacin & Prophylactic Pancreatic Stent Placement for Preventing Post-ERCP Pancreatitis in High-Risk Cases

Primary Aim: To compare the rate of post-ERCP pancreatitis between indomethacin versus pancreatic duct stenting and indomethacin.

Randomized trial comparing the use of single-operator peroral cholangioscopy-guided laser lithotripsy (POC-LL) versus Endoscopic Balloon Sphincteroplasty (EBS) for removal of difficult bile duct stones

Primary Aim: To compare the rate of re-interventions to achieve treatment success between cohorts.



Ji Young Bang, MD, MPH
Director of Clinical Research

RESEARCH HIGHLIGHTS

- Fourteen randomized trials and six prospective studies are currently in progress evaluating cutting edge endoscopic techniques or novel technologies.
- Our large procedural volume facilitates the conduct of well-designed, prospective, randomized, single-center, clinical trials.
- A major focus at CIE is to innovate and attempt to answer critically important and critically relevant questions in the field of gastrointestinal endoscopy.
- The research unit at CIE is supported by a Research Manager and three full-time research coordinators.

Randomized trial examining the impact of pancreatic duct stent placement in patients with acute necrotizing pancreatitis in the prevention of walled-off necrosis

Primary Aim: To compare the incidence of walled-off necrosis between the pancreatic duct stent and no stent groups at 4-6 weeks post-index ERCP

Randomized trial comparing On-site versus Off-site evaluation of cholangioscopy-guided biopsies of the bile Duct

Primary Aim: To compare the diagnostic sensitivity of onsite (rapid onsite evaluation) versus standard-of-care techniques in the evaluation of indeterminate biliary strictures.

A randomized trial comparing covered metal and plastic stents for preoperative biliary decompression in pancreatic cancer

Primary Aim: To compare rate of adverse events between cohorts prior to surgery.

| CLINICAL TRIALS | SPONSOR | DESIGN | CURRENT ENROLLMENT |
|---|-------------------|-------------|--------------------|
| Minimally Invasive Surgery vs. Endoscopy Randomized (MISER) Trial for Symptomatic Walled-Off Pancreatic Necrosis | Florida Hospital | Randomized | 64 |
| Randomized trial comparing On-site versus Off-site evaluation of cholangioscopy-guided biopsies of the bile Duct | Florida Hospital | Randomized | 38 |
| A Randomized trial comparing Endoscopic Ultrasound-guided biliary drainage (EUS-BD) and Endoscopic Retrograde Cholangiopancreatography (ERCP) for Malignant Distal Biliary Obstruction | Florida Hospital | Randomized | 4 |
| Randomized Trial comparing Fully Covered, Self-Expanding Metal Stent (FCSEMS) and Plastic Stents for EUS-guided Drainage of Walled-off Necrosis (WON) | Florida Hospital | Randomized | 52 |
| A randomized trial comparing covered metal and plastic stents for preoperative biliary decompression in pancreatic cancer | Florida Hospital | Randomized | 28 |
| Randomized trial comparing two FNB and FNA needles for Endoscopic Ultrasound (EUS)-guided sampling of solid pancreatic masses | Florida Hospital | Randomized | 26 |
| Stent vs Indomethacin for Preventing Post-ERCP Pancreatitis: The SVI Trial - A Multicenter Randomized Non-inferiority Clinical Trial of Rectal Indomethacin Alone vs. Indomethacin & Prophylactic Pancreatic Stent Placement for Preventing Post-ERCP Pancreatitis in High-Risk Cases | MUSC - NIH | Randomized | 26 |
| Randomized trial comparing the use of single-operator peroral cholangioscopy-guided laser lithotripsy (POC-LL) versus Endoscopic Balloon Sphincteroplasty (EBS) for removal of difficult bile duct stones | Florida Hospital | Randomized | 25 |
| Randomized trial examining the impact of pancreatic duct stent placement in patients with acute necrotizing pancreatitis in the prevention of walled-off necrosis | Florida Hospital | Randomized | 1 |
| Randomized trial evaluating prophylactic Octreotide to prevent post-duodenal EMR and ampullectomy Bleeding | Florida Hospital | Randomized | 33 |
| Randomized trial comparing Captivator tissue cassettes vs. no cassettes for endoscopic mucosal resection (EMR) in esophageal carcinoma | Florida Hospital | Randomized | 18 |
| Randomized trial evaluating the safety of endoscopic resection of large colorectal polyps | VA Medical Center | Randomized | 46 |
| Randomized trial comparing celiac plexus neurolysis and radiofrequency ablation for palliation of pain in pancreatic cancer | Florida Hospital | Randomized | 0 |
| Lipidomics, Proteomics and Volatile Organic Compounds Biomarkers in Bile and Serum | Florida Hospital | Prospective | 181 |

RESECTION-RELATED RANDOMIZED TRIALS

Randomized trial evaluating prophylactic Octreotide to prevent post-duodenal EMR and ampullectomy Bleeding

Primary Aim: Evaluate the role of subcutaneous Octreotide in preventing post-resection bleeding in patients with duodenal and ampullary masses.

Randomized trial comparing Captivator tissue cassettes vs. no cassettes for endoscopic mucosal resection (EMR) in esophageal carcinoma

Primary Aim: Evaluate the utility of tissue cassettes in esophageal specimen preservation after endoscopic mucosal resection.

OTHER PROSPECTIVE STUDIES

Lipidomics, Proteomics and Volatile Organic Compounds Biomarkers in Bile and Serum

Primary Aim: To analyze the utility of various bile biomarkers including lipidomics, proteomics, micro-RNAs and VOCs of bile aspirated during ERCP in differentiating malignant from benign causes of biliary strictures.

Volumetric Laser Endomicroscopy Signal Heterogeneity for Detection of Dysplasia in Inflammatory Bowel Disease-A Pilot Ex-Vivo Study

Primary Aim: Evaluate the role of volumetric laser endomicroscopy in identifying dysplasia in inflammatory bowel diseases.

Volumetric Laser Endomicroscopy Signal Heterogeneity Analysis in the Evaluation of Patients with Biliary Strictures-A Pilot Ex-Vivo Study

Primary Aim: Evaluate the utility of volumetric laser endomicroscopy in identifying neoplasia in biliary strictures.

Registry for Endoscopic Ultrasound (EUS) Evaluation of Pancreatic Cysts

Primary Aim: Prospective database to study the natural history of pancreatic cyst lesions

Randomized trial evaluating the safety of endoscopic resection of large colorectal polyps

Primary Aim: The primary aim of the study is to compare the rate of delayed bleeding complications in patients undergoing endoscopic resection of large polyps between closing versus not closing the mucosal defect after resection.

EUS-guided pancreatic cyst ablation

Primary Aim: Registry to evaluate the role and utility of chemotherapeutic agents in pancreatic cyst ablation.

High Resolution Optical Imaging of Esophageal Tissue Using the Nvision VLE Imaging System Registry

Primary Aim: Evaluate the role of volumetric laser endomicroscopy in identifying dysplasia in Barrett's esophagus.

PUBLICATIONS IN 2016

PEER-REVIEWED PUBLICATIONS

Bang JY, Wilcox CM, Navaneethan U, Hasan MK, Peter S, Christein J, Hawes R, Varadarajulu S. Impact of Disconnected Pancreatic Duct Syndrome on the Endoscopic Management of Pancreatic Fluid Collections. *Ann Surg*. 2016 [Epub ahead of print]

Bang JY, Hasan M, Navaneethan U, Hawes R, Varadarajulu S. Lumen-apposing metal stents (LAMS) for pancreatic fluid collection (PFC) drainage: may not be business as usual. *Gut*. 2016 [Epub ahead of print]

Njei B, McCarty TR, Varadarajulu S, Navaneethan U. Cost utility of ERCP-based modalities for the diagnosis of cholangiocarcinoma in primary sclerosing cholangitis. *Gastrointest Endosc*. 2016 [Epub ahead of print]

Njei B, McCarty TR, Varadarajulu S, Navaneethan U. Systematic review with meta-analysis: endoscopic retrograde cholangio-pancreatography-based modalities for the diagnosis of cholangiocarcinoma in primary sclerosing cholangitis. *Aliment Pharmacol Ther*. 2016; 1139-1151

Wilcox CM, Seay T, Kim H, Varadarajulu S. Prospective Endoscopic Ultrasound-Based Approach to the Evaluation of Idiopathic Pancreatitis: Causes, Response to Therapy, and Long-term Outcome. *Am J Gastroenterol*. 2016; 111: 1339-48

Bang JY, Hasan MK, Navaneethan U, Sutton B, Frandah W, Siddique S, Hawes RH, Varadarajulu S. Lumen-apposing metal stents for drainage of pancreatic fluid collections: When and for whom? *Dig Endosc*. 2017; 29: 83-90

Feng Y, Navaneethan U, Zhu X, Varadarajulu S, Schwartz I, Hawes R, Hasan M, Yang A. Prophylactic rectal indomethacin may be ineffective for preventing post-endoscopic retrograde cholangiopancreatography pancreatitis in general patients: A meta-analysis. *Dig Endosc*. 2016 [Epub ahead of print]

Bang JY, Hebert-Magee S, Hasan MK, Navaneethan U, Hawes R, Varadarajulu S. Endoscopic ultrasonography-guided biopsy using a Franseen needle design: Initial assessment. *Dig Endosc*. 2016 [Epub ahead of print]

Navaneethan U, Hasan MK, Lourdasamy V, Zhu X, Hawes RH, Varadarajulu S. Efficacy and safety of endoscopic mucosal resection of non-ampullary duodenal polyps: a systematic review. *Endosc Int Open*. 2016; 4: E699-708

Bang JY, Varadarajulu S. Endoscopic Treatment of Walled-off Necrosis in Children: Clinical Experience and Treatment Outcomes. *J Pediatr Gastroenterol Nutr*. 2016; 63: e31-5

Bang JY, Navaneethan U, Hasan MK, Hawes RH, Varadarajulu S. EUS correlates of disconnected pancreatic duct syndrome in walled-off necrosis. *Endosc Int Open*. 2016; E883-9.

We take pride in highlighting our rate of abstract-to-manuscript conversion which exceeds 90%.

Publication of scientific findings in high-impact peer-reviewed clinical journals is one of our top priorities.

Bang JY, Varadarajulu S. Management of Hemorrhagic Walled-Off Necrosis Using the Multiple Transluminal Gateway Technique. *Am J Gastroenterol*. 2016; 111: 457

Bang JY, Hasan MK, Sutton B, Holt BA, Navaneethan U, Hawes R, Varadarajulu S. Intraprocedural increase in heart rate during EUS-guided celiac plexus neurolysis: Clinically relevant or just a physiologic change? *Gastrointest Endosc*. 2016; 84: 773-779



Bang JY, Varadarajulu S. Transmural drainage versus transpapillary stenting and transmural drainage: not an open and shut case...yet. *Gastrointest Endosc.* 2016; 83: 1046.

Khashab MA, Van der Merwe S, Kunda R, El Zein MH, Teoh AY, Marson FP, Fabbri C, Tarantino I, Varadarajulu S, Modayil RJ, Stavropoulos SN, Peñas I, Ngamruengphong S, Kumbhari V, Romagnuolo J, Shah R, Kalloo AN, Perez-Miranda M, Artifon EL. Prospective international multicenter study on endoscopic ultrasound-guided biliary drainage for patients with malignant distal biliary obstruction after failed endoscopic retrograde cholangiopancreatography. *Endosc Int Open.* 2016; 4: E487-96

Varadarajulu S, Bang JY, Hasan MK, Navaneethan U, Hawes R, Hebert-Magee S. Improving the diagnostic yield of single-operator cholangioscopy-guided biopsy of indeterminate biliary strictures: ROSE to the rescue? (with video). *Gastrointest Endosc.* 2016; 84: 681-7

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Bang JY, Ramesh J, Hasan M, Navaneethan U, Holt BA, Hawes R, Varadarajulu S. Endoscopic ultrasonography is not required for staging malignant esophageal strictures that preclude the passage of a diagnostic gastroscope. *Dig Endosc.* 2016; 28: 650-6

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Frاندah W, Siddiqui S, Navaneethan U, Chaar A, Hawes RH, Varadarajulu S, Hasan MK. Unusual cause of hemobilia. *Gastrointest Endosc.* 2016; 84:182

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Tharian B, Varadarajulu S, Hawes R. Drainage of obstructed gallbladder with use of lumen-apposing metal stent. *Gastrointest Endosc*. 2016; 83: 460-1

Roy A, Kim M, Hawes R, Varadarajulu S. Changing trends in tissue acquisition in malignant pancreatic neoplasms. *J Gastroenterol Hepatol*. 2016; 31: 501-5

Holt BA, Hawes R, Hasan M, Canipe A, Tharian B, Navaneethan U, Varadarajulu S. Biliary drainage: role of EUS guidance. *Gastrointest Endosc*. 2016; 83: 160-5

Hawes RH. Lessons Learned from Traditional NOTES: A Historical Perspective. *Gastrointest Endosc Clin N Am*. 2016; 26: 221-7

Asad-Ur-Rahman F, Abbass A, Majeed U, Navaneethan U. Melanoma Metastasizing to the Small Intestine: A Case Report Illustrating Symptomatic and Asymptomatic Involvement. *Cureus*. 2016; 8: e608

Navaneethan U. Diagnosis of cholangiocarcinoma in primary sclerosing cholangitis: finding a needle in a haystack. *Endoscopy*. 2016; 48: 417-8

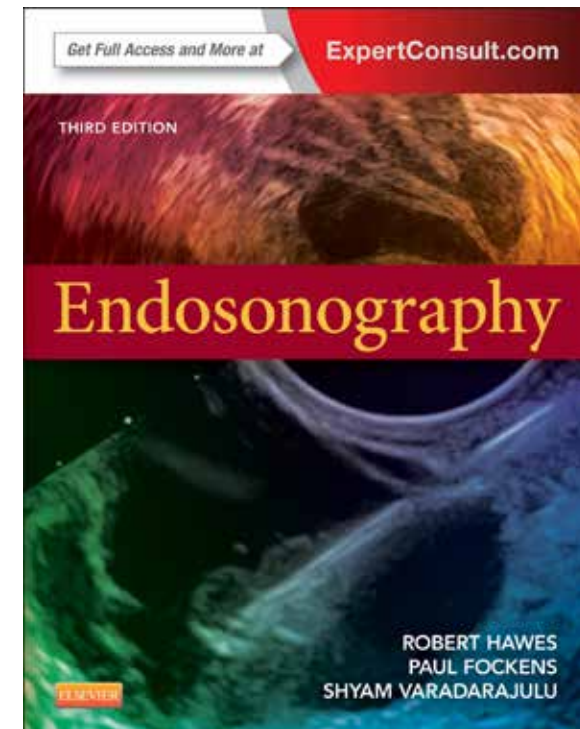
Tharian B, George N, Navaneethan U. Endoscopy in the Diagnosis and Management of Complications of Inflammatory Bowel Disease. *Inflamm Bowel Dis*. 2016; 22:1184-97

Navaneethan U, Rai T, Venkatesh PG, Kiran RP. Primary sclerosing cholangitis and the risk of colon neoplasia in patients with Crohn's colitis. *Gastroenterol Rep (Oxf)*. 2016; 4: 226-31

Navaneethan U, Venkatesh PG, Jegadeesan R, Lourdasamy V, Hammel JP, Kiran RP, Shen B. Comparison of outcomes for patients with primary sclerosing cholangitis associated with ulcerative colitis and Crohn's disease. *Gastroenterol Rep (Oxf)*. 2016; 4: 43-9

Chambers MR, Hasan MK, Hébert-Magee S. Pearls before bile: Primary squamous cell carcinoma of the gallbladder diagnosed on-site by endoscopic ultrasound-guided fine-needle aspiration. *Dig Endosc*. 2016; 28: 105

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ENDOSONOGRAPHY

- Best Selling textbook in the field of Endoscopic Ultrasound
- Awarded the first prize by the British Medical Journal in internal medicine category in 2016
- 4th Edition of the textbook is due for release in 2018

SCIENTIFIC PRESENTATIONS 2017

DIGESTIVE DISEASE WEEK

Navaneethan U, Grove D, Zhu X, Varadarajulu S, Dweik R. Volatile Organic Compounds in Bile Distinguishes Benign From Malignant Biliary Strictures: A Prospective Single Blinded Study

Navaneethan U, Feurer M, Villanueva F, Glover S. Impact of Chromoendoscopy on outcomes in inflammatory bowel disease patients with a history of low grade dysplasia on white-light endoscopy

Navaneethan U, Zhu X, Lourdasamy D, Shen B, Kiran RP. Colorectal Cancer Resection Rates in Patients with Inflammatory Bowel Disease: A Population Based Study

Navaneethan U, Zhang R, Zhu X, Hasan MK, Bang JY, Hawes RH, Vargo JJ, Varadarajulu S. Lipidomic Profiling of Bile in Distinguishing Benign From Malignant Biliary Strictures: A Prospective Single Blinded Study

Bang JY, Hebert-Magee S, Navaneethan U, Hasan M, Hawes R, Varadarajulu S. Randomized Trial Comparing the 22 and 25 gauge needles using the Suction-In and No-Suction (SINS) Techniques for EUS-guided FNA of Pancreatic Masses

PANCREAS CLUB

Bang JY, Hebert-Magee S, Navaneethan U, Hasan M, Hawes R, Varadarajulu S. Lumen-apposing Metal Stents (LAMS) for Pancreatic Fluid Collection (PFC) Drainage: May not be business as usual

Bang JY, Navaneethan U, Hasan M, Hawes R, Varadarajulu S. Randomized trial comparing the 22G Franseen biopsy and 22G aspiration needles for EUS-guided sampling of solid pancreatic mass lesions

CLINICAL RESEARCH AWARDS

American College of Gastroenterology (ACG) Clinical Research Award: Dr. Udayakumar Navaneethan awarded \$50,000 grant to pursue his research in Evaluation of Lipidomics, Proteomics and Volatile organic compounds in Plasma and Bile for Diagnosis of Biliary Strictures.

Pancreas Club: The clinical study evaluating the impact of disconnected pancreatic duct syndrome on endoscopic management of pancreatic fluid collections was awarded a research prize at the 50th Annual Pancreas Club Meeting in San Diego.

United European Gastroenterology Week: The randomized trial comparing the 22 and 25G needles and evaluating the role of suction in EUS-guided FNA of solid pancreatic masses was awarded a junior faculty travel scholarship at UEGW 2016 in Vienna, Austria.

INFLAMMATORY BOWEL DISEASE PROGRAM

The Inflammatory Bowel Disease (IBD) program that was established in 2015 at CIE is a center of excellence devoted to the management of patients with complex ulcerative colitis and Crohn's disease. There were 327 new patients with inflammatory bowel disease seen and followed in 2016.

Clinical Program:

The IBD program is comprised of a multidisciplinary team which includes a gastroenterologist (with specialized expertise in IBD), colorectal surgeons, nutritionists, radiologists, pathologists and pain management specialists who jointly deliver comprehensive care. A specific emphasis of our program is the management of IBD complications including strictures, fistulas, leaks and early-stage tumors by providing tertiary-level endoscopic treatment. Additionally, colon cancer surveillance is performed utilizing advanced technology such as chromoendoscopy.

IBD Research:

- Bio-markers in the early diagnosis of cholangiocarcinoma in primary sclerosing cholangitis.
- Long term follow-up of patients on adalimumab for the treatment of patients with ulcerative colitis and Crohn's disease.
- Entyvio (vedolizumab) long-term safety study: An international observational prospective cohort study comparing vedolizumab to other biologic agents in patients with ulcerative colitis or Crohn's disease.
- Safety of Entyvio (vedolizumab) in elderly patients with IBD.
- Impact of Chromoendoscopy on outcomes in inflammatory bowel disease patients with a history of low grade dysplasia on white-light endoscopy.
- A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of ABT-494 for the Induction of Symptomatic and Endoscopic Remission in Subjects with Moderately to Severely Active Crohn's Disease who have Inadequately Responded to or are Intolerant to Anti-TNF Therapy (Celeste).
- A Phase 2b, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of JNJ-64304500 in Subjects with Moderately to Severely Active Crohn's Disease.
- Vedolizumab 4006 (EXPLORER): An Open-Label, Phase 4 Study to Evaluate the Efficacy and Safety of Triple Combination Therapy with Vedolizumab, IV, Adalimumab SC, and Oral Methotrexate in Early Treatment of Subjects with Crohn's Disease Stratified at Higher Risk for Developing Complications.
- A Phase 4 Open-Label-Study to Evaluate Vedolizumab IV Dose Optimization on Treatment Outcomes In Non-responders With Moderately to Severely Active Ulcerative Colitis.
- Clinical and Laboratory Features Including Serum levels of Ustekinumab and Antibodies in Predicting Short-term and Persistent Remission in Crohn's Disease Patients.
- Open label study of Ustekinumab in patients with post-operative Crohn's disease.

Annual Symposium in Inflammatory Bowel Disease

CIE hosts a nationally recognized annual symposium devoted to IBD in the month of April. The symposium draws experts from around the United States and Europe who share their expertise and explore the latest advances in the treatment of IBD.



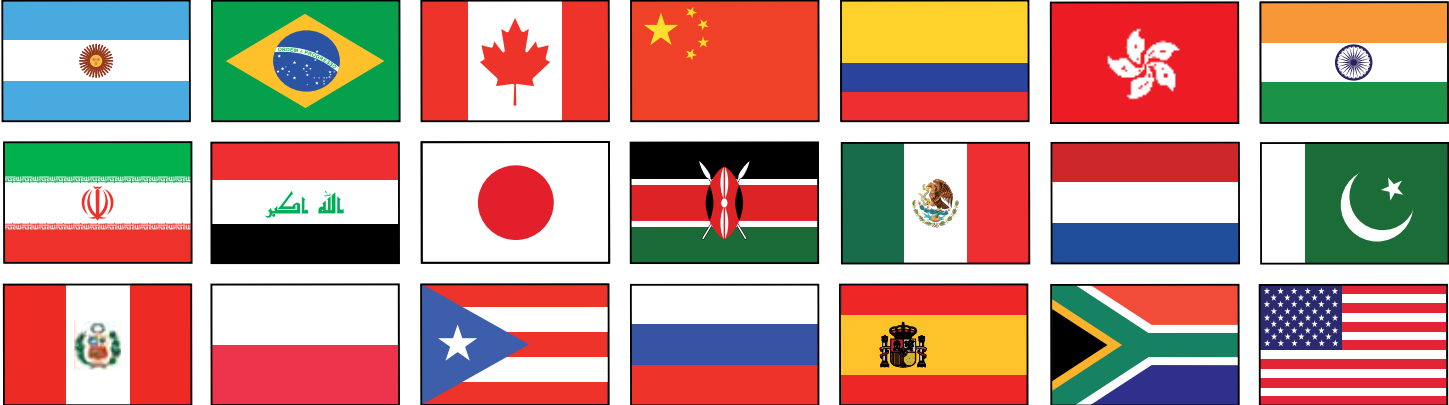
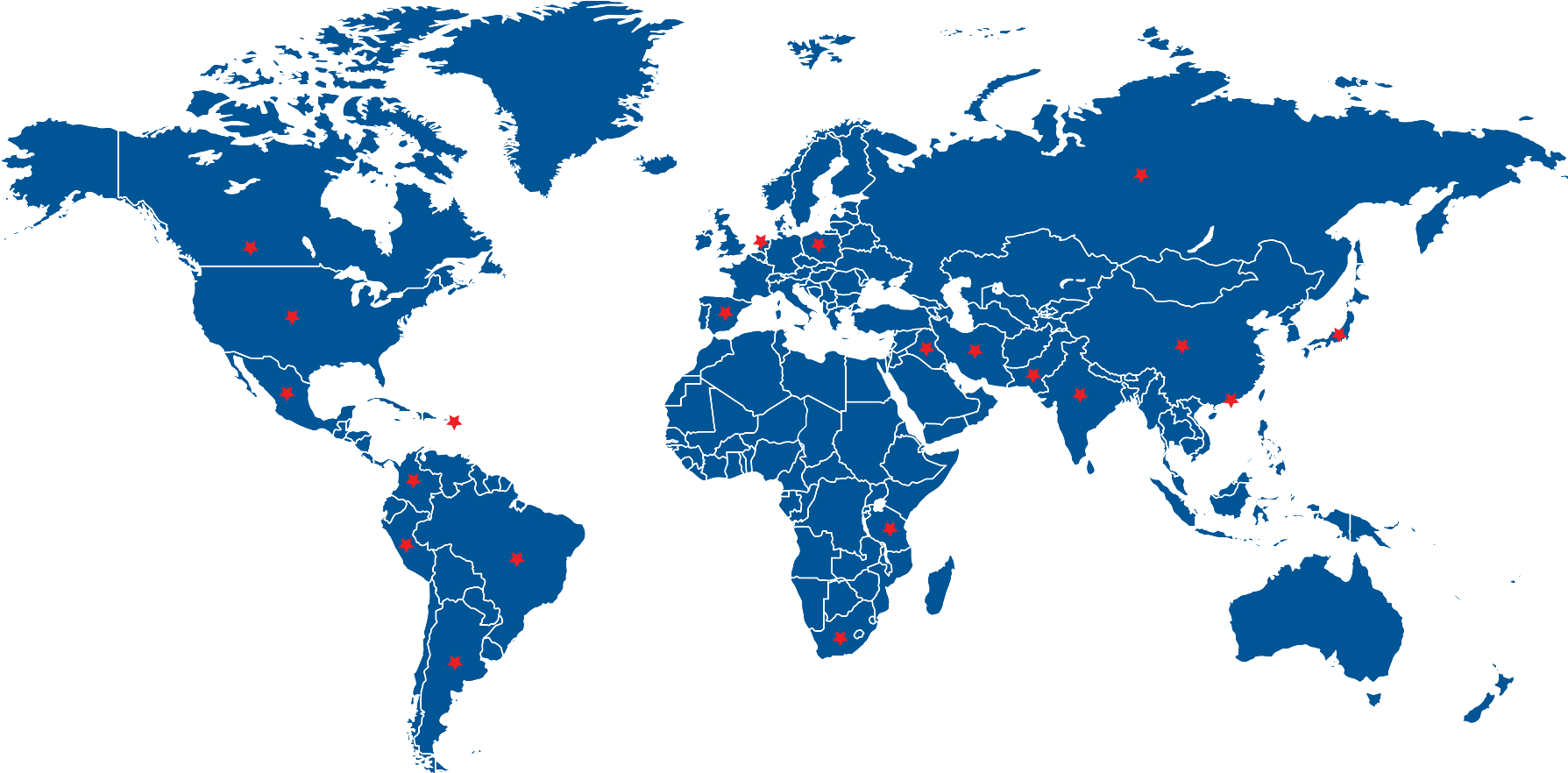
4TH ANNUAL ORLANDO LIVE EUS

Orlando Live EUS is the single largest EUS-related symposium in the United States. In 2016, 249 delegates from 21 countries attended this meeting. Nine experts from 8 countries demonstrated 42 procedures that were transmitted live. A hands-on lab had 106 attendees. The overall delegate rating of the symposium was 4.7 on a scale of 0 to 5.



CONFERENCE ATTENDEES

COUNTRIES REPRESENTED AT ORLANDO LIVE EUS 2016



EDUCATIONAL INITIATIVES

INTERNATIONAL SYMPOSIUMS

4th Annual Orlando Live EUS 2016, September 7-9, 2016

249 delegates from 21 countries attended the symposium. 219 delegates were practicing gastroenterologists, 5 were fellows-in-training and others were allied health personnel. Nine expert faculty from 8 countries demonstrated 42 live procedures at the symposium. The hands-on lab was attended by 106 attendees. The overall delegate rating of the symposium was 4.7 on a scale of 0 to 5.

The 5th Annual Orlando Live EUS symposium will be held from August 30 to September 1, 2017

REGIONAL SYMPOSIUMS

Symposium on Challenges in Clinical Endoscopy Palm Coast, Florida, January 2016

This one-day CME program focused on the Clinical Challenges in Endoscopy and was attended by 63 physicians from around the state of Florida. The International and National invited faculty included Dr. Horst Neuhaus (Evangelisches Krankenhaus Düsseldorf, Germany), Dr. Greg Haber (Lenox Hill Hospital, New York, NY) and Dr. Stephen Hanauer (Northwestern University, Chicago, Illinois).

Clinical Updates on Inflammatory Bowel Disease Winter Park, Florida, April 2016

This one-day CME program focused on clinical updates on Inflammatory Bowel Disease. There were 60 delegates from around the state of Florida who attended the meeting. The four national faculty invited to speak at this symposium were Dr. Miguel Regueiro (University of Pittsburgh), Dr. Bo Shen (Cleveland Clinic), Dr. Francis Farraye (Boston Medical Center) and Dr. Raymond Cross (University of Maryland Medical Center).

TUTORIALS

EUS cytopathology interface workshops: 5 programs involving 60 physicians from 20 states and Latin American Countries

Spyglass Preceptorship: 3 programs involving 21 physicians from 10 states

EUS Preceptorships: 10 programs involving 22 physicians from 13 states

RFA Preceptorships: 3 programs involving 33 physicians from 12 states

For more information regarding future events,
visit FHCIEevents.com or to refer a patient, call (855) 341-3411.



THE MARCH FORWARD...



Eric Stevens | Senior Executive Officer, Florida Hospital Orlando

CIE is a signature program at Florida Hospital that combines cutting-edge therapeutic endoscopy with world-class clinical research and education. CIE adds immense value to our institution by fulfilling a long-standing clinical need of this region. The program has exceeded all our expectations and benchmarks in its first five years. As CIE marches forward, we hope that this trajectory will soar towards greater goals and accomplishments.



Abel Biri | Vice President, Chief Operating Officer, Florida Hospital Orlando

When we set out to build CIE five years ago, we knew it would elevate the care in our community by bringing new services and cutting-edge technology. However, with their global reach in research, published medical literature and world-class education series, CIE has surpassed our expectations in their stated goal to become knowledge-generators in the field of minimally invasive therapies. As CIE continues to push the limits of an endoscope, I look forward to new minimally invasive, life-saving treatments they will bring locally as well as the global impact they will have on the next generation of interventional endoscopists.



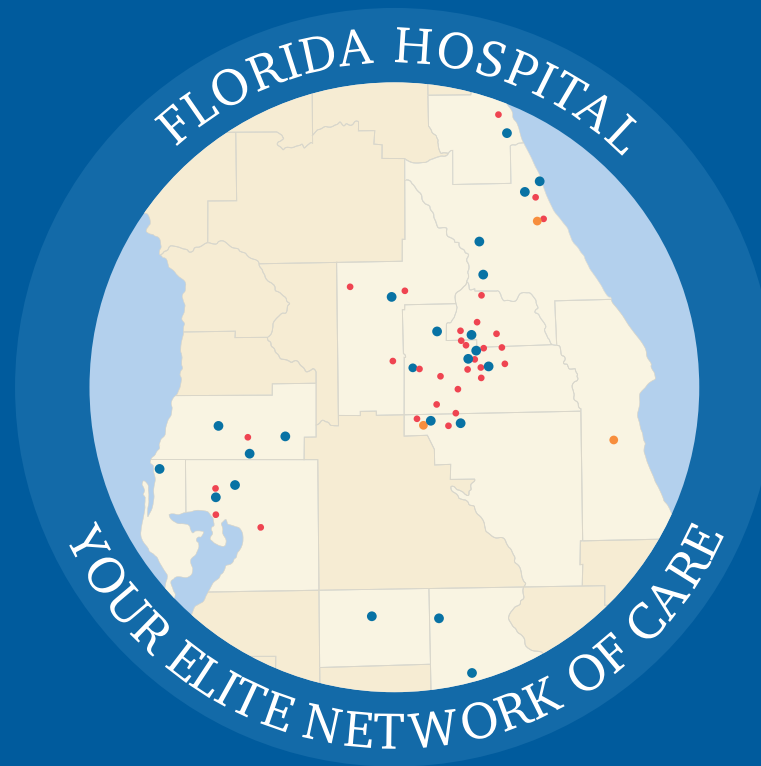
Karilynn Vargas | Vice President, Business Strategy & Innovation, Florida Hospital Orlando

The vision of the Center for Interventional Endoscopy was to create a Southeast destination for complex therapeutic endoscopy that complimented community-based needs with leading advanced endoscopic expertise. As we move into the future, we anticipate the continued focus of these highly skilled and internationally recognized therapeutic endoscopists to further their research and development of a training and innovation site for advanced endoscopic techniques. We envision the future to extend beyond gastroenterologists and build a unique general surgery competency through the use of flexible endoscopy in innovative therapies for GI diseases.



FLORIDA HOSPITAL
Orlando

CENTER FOR
INTERVENTIONAL
ENDOSCOPY



Florida Hospital is a trusted member of one of America's largest, not-for-profit healthcare systems.



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