



# CITE 2017

## REPORT CARD



FLORIDA HOSPITAL  
Colorado

EMERGENCY

# CIE 2017

The Center for Interventional Endoscopy (CIE) at Florida Hospital is a state-of-the-art center providing the highest quality care for patients with complex digestive diseases.

The CIE physicians are trained in the latest advanced techniques and procedural services available for the treatment of digestive disorders. Our team advances collaborative research not only at Florida Hospital, but throughout the world to further the treatment and knowledge of digestive diseases.

2017 FACTS AND FIGURES

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8288

Total Advanced Procedures

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3663 EUS

#4 in the world

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1638 ERCP

#1 in Southern US

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19 | 7 Completed  
Publications | Randomized Trials

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#1 Most Attended  
EUS Symposium  
in North America



“

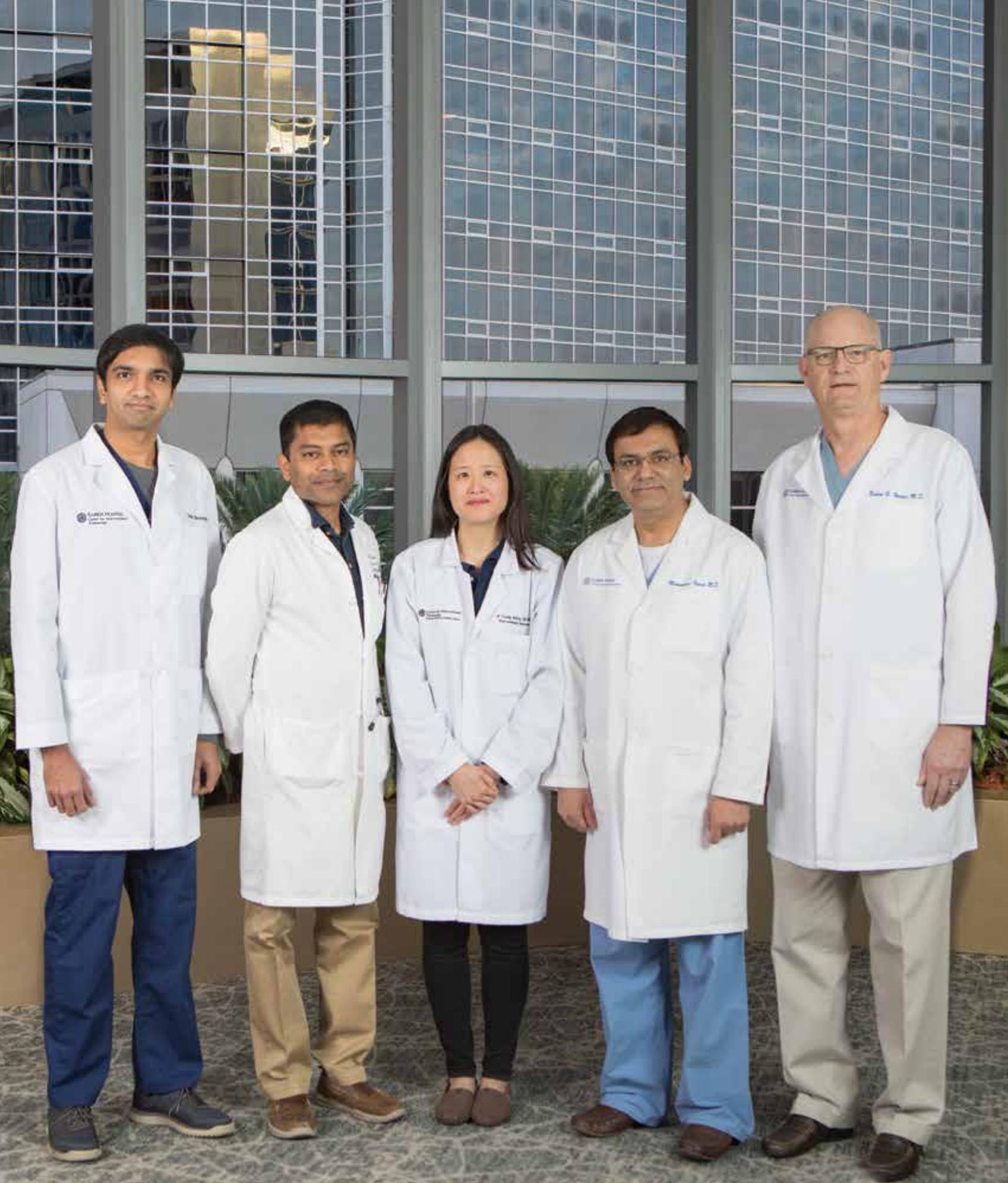
We're fortunate to have world-renowned healthcare options located throughout our city, including state-of-the-art facilities such as Florida Hospital's Center for Interventional Endoscopy.

Since its opening in 2013, the Center has been a referral destination for patients in Central Florida as well as nationwide. In addition to providing cutting-edge clinical research and innovative endoscopic procedures, it reinforces Orlando as a destination for gastroenterologists from around the world to learn and observe from our city's medical leaders.”

—Orlando Mayor, Buddy Dyer

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*Dr. Udayakumar Navaneethan, Dr. Shyam Varadarajulu, Dr. Ji Young Bang,  
Dr. Muhammad Hasan, Dr. Robert Hawes*

# OVERVIEW FROM PHYSICIANS

Dear Colleagues,

I am pleased to present the annual report card of the Florida Hospital Center for Interventional Endoscopy (CIE). The report card outlines our procedure volume, clinical outcomes, research portfolio, educational initiatives, scientific presentations and other significant milestones achieved in 2017.

In 2017, we performed 8288 complex endoscopic procedures that included 3663 endoscopic ultrasound (EUS) examinations. CIE retained its status as the largest volume EUS unit in North America for the fourth consecutive year making it the fourth largest EUS program in the world. Our ERCP volume reached 1638 and we performed more than 600 endoscopic mucosal resection procedures. The third space endoscopy program was successfully launched in 2017 with the performance of per-oral endoscopic myotomy (POEM) procedures.

We concluded 7 randomized trials and the CIE faculty published 19 peer-reviewed manuscripts in 2017. Three randomized trials presented at the United European Gastroenterology Week in Barcelona were recognized with first prizes and two studies were selected for plenary presentations at the World Congress of Gastroenterology in Orlando and the American Pancreatic Association Annual Meeting in San Diego.

A major upcoming highlight will be the Orlando Live Endoscopy symposium that will be held from August 29-31, 2018. We also expect to conclude three important randomized trials in 2018 and release the 4th edition of our textbook ENDOSONOGRAPHY.

I invite you to visit CIE in person and give us the opportunity to share our vision with you.

Sincerely



**Shyam Varadarajulu**

Medical Director

Center for Interventional Endoscopy

# FLORIDA HOSPITAL CENTER FOR INTERVENTIONAL ENDOSCOPY STAFF



“

I traveled 10,000 miles to be evaluated at CIE. I had a fantastic experience as the staff were very courteous, helpful, efficient, professional and the care was exceptional.”

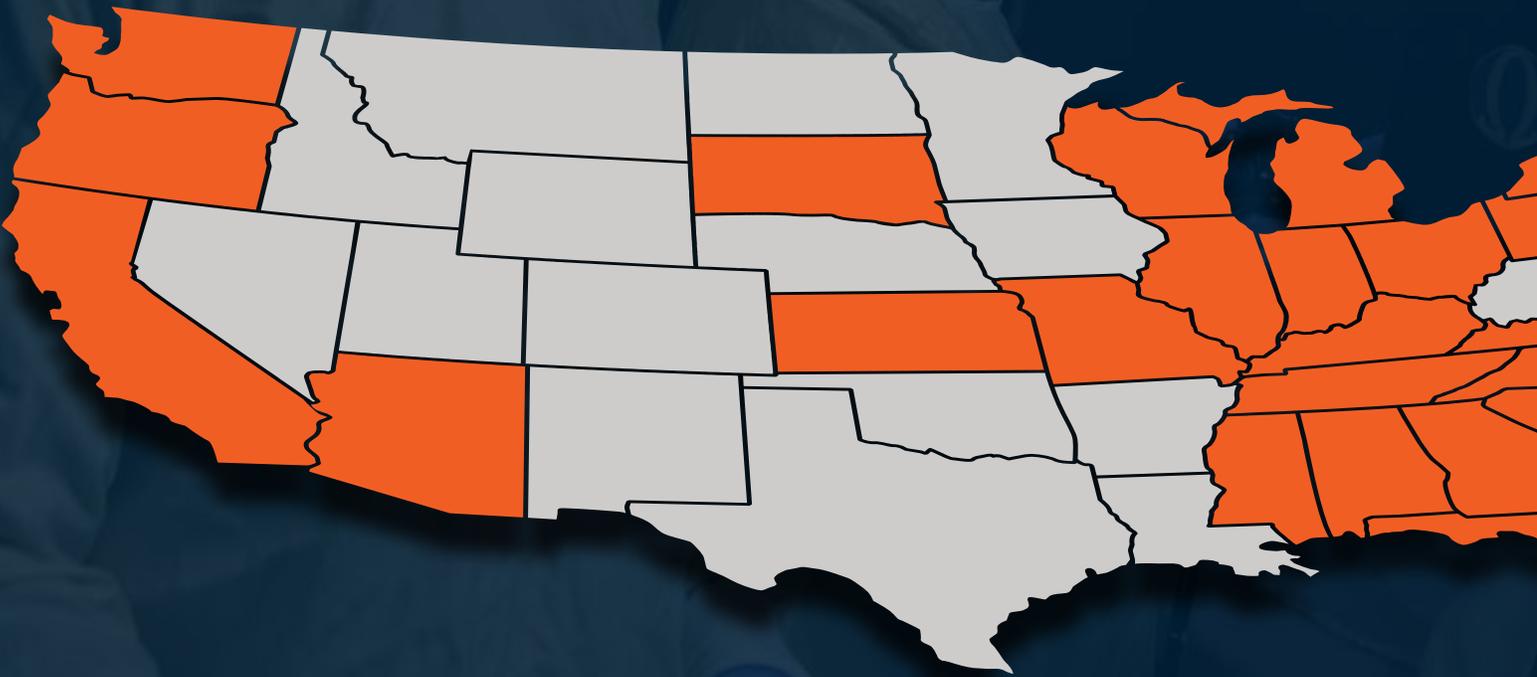
—Anu Aga  
Industrialist, Member of Parliament, India



# PATIENT REFERRAL STATISTICS

Patients are referred to CIE for expert care from across the United States as well as internationally. In 2017, patients were referred nationally from 30 states as well as from 13 countries.

**More than 50%** of patients treated at CIE originated from outside the Tri-County area.



For more information or to refer a patient, call (855) 341-3411.

Total Patients  
**6919**



**30**  
States  
Patients 109



Florida Patients  
**6797**



Tri County 2,555  
Non-Tri County 4,242

International  
Patients  
**13**



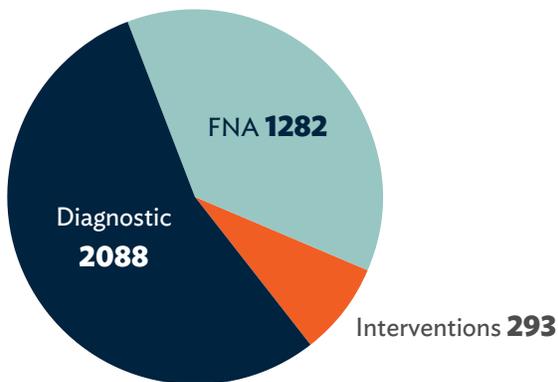
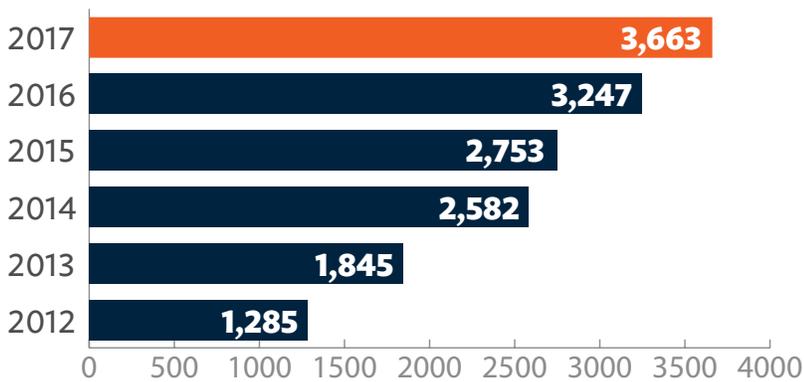
Our colleagues at Florida Hospital Center for Interventional Endoscopy (CIE) have created a valuable resource allowing for an efficient and near seamless referral of patients with complicated gastrointestinal disorders.

The team at CIE has become an invaluable asset providing expert care for my most complex patients. I am most pleased with the prompt and detailed responses outlining my patients' care while at CIE."

— Dr. Adel Daas  
Gastroenterologist  
Ormond Beach, Florida



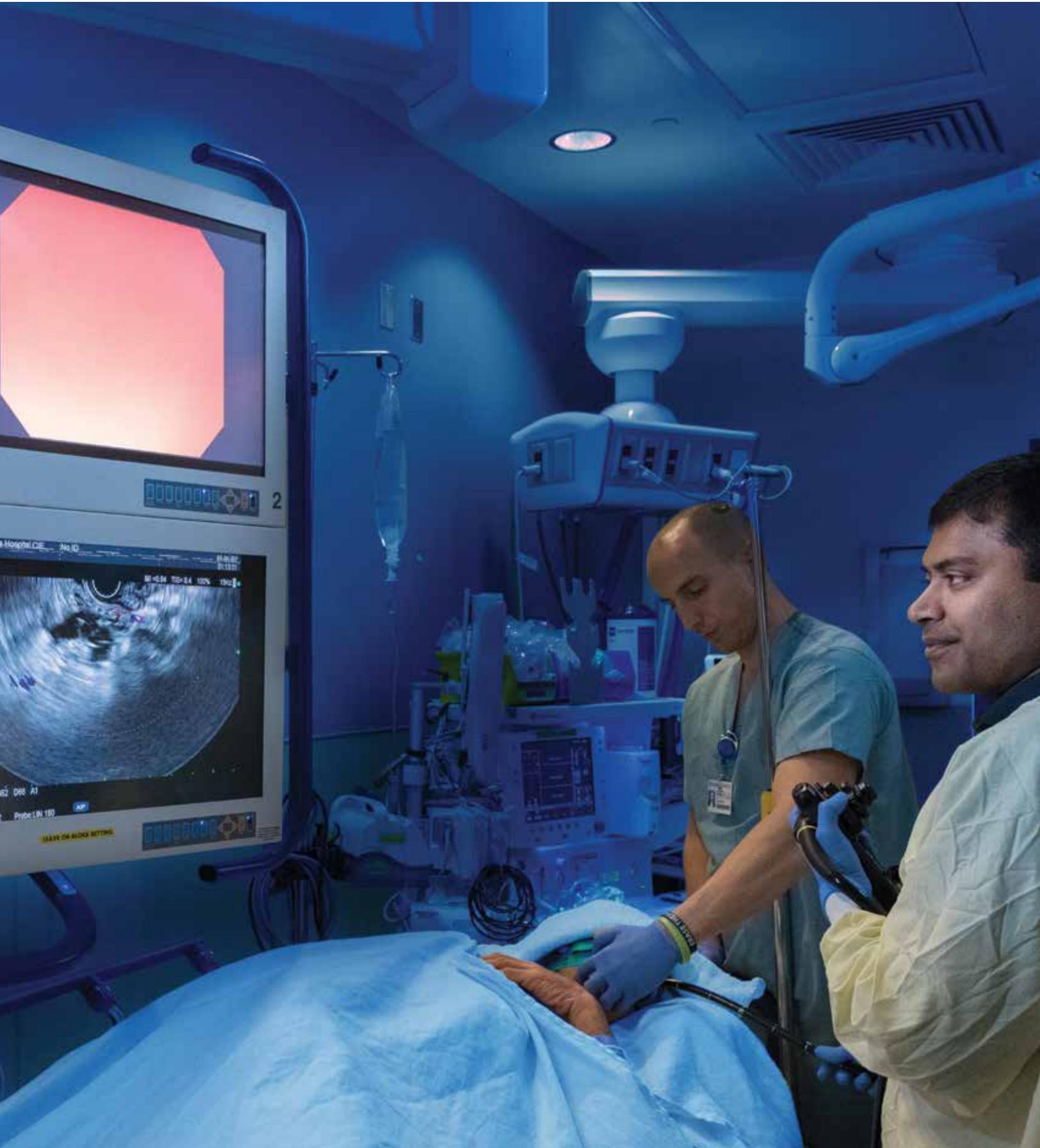
# ENDOSCOPIC ULTRASOUND PROGRAM

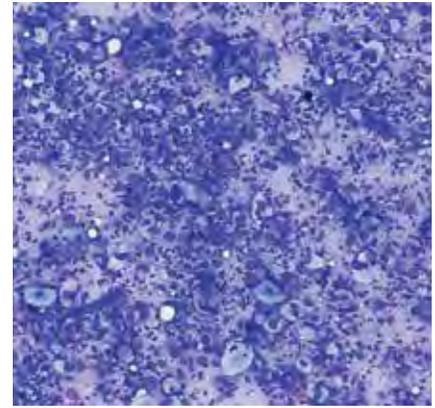
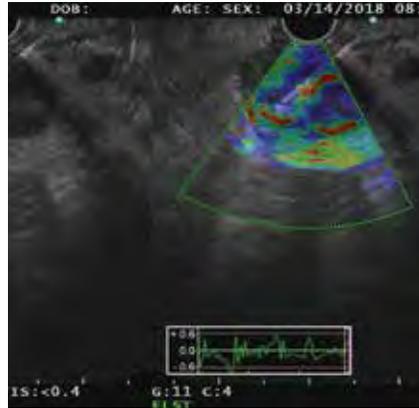
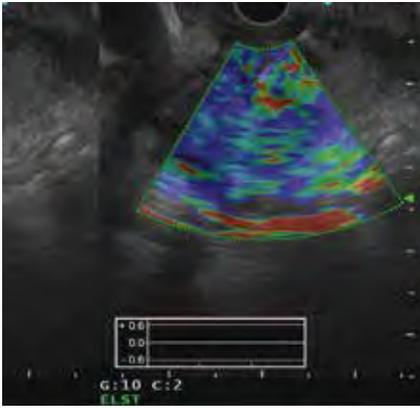


## Interventional Procedures

Celiac Plexus Interventions	92
Drainage of Pancreatic Fluid collections	102
Ductal Drainages	41
Cyst Ablation	9
Fiducial Placement	37
Others	12







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.

## RESEARCH

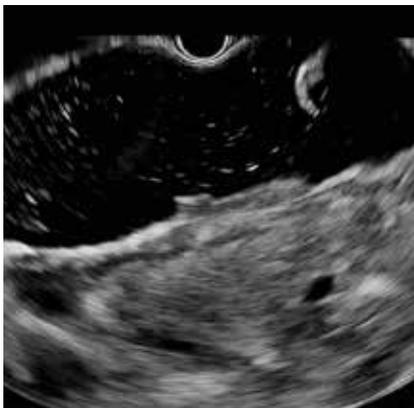
**Tissue Acquisition:** A randomized trial of 352 patients was conducted to identify the most optimal specimen processing technique in EUS-guided tissue acquisition. The study demonstrated that the 22G FNA needle when used in conjunction with suction increased specimen bloodiness and the number of passes needed to achieve onsite diagnostic adequacy. The study suggested that the 25G needle may be suboptimal for processing specimens offsite using the cell block technique. The study manuscript has been accepted for publication in *Clinical Gastroenterology and Hepatology*.

Recently, core biopsy needles have been developed for procuring histology grade tissue that was hitherto not possible using standard bevel FNA needles. In a randomized trial, the CIE faculty demonstrated that the Franseen-design core biopsy needle yielded significantly more histology-grade tissue than the FNA needle in patients with pancreatic cancer. This development may have significant implications for delivery of personalized therapy in pancreatic cancer. The study findings were published in *GUT*.

### **Necrotizing Pancreatitis:**

Endoscopic approaches are being increasingly used for treating acute necrotizing pancreatitis. The Minimally Invasive Surgery versus Endoscopy Randomized (MISER) Trial for the treatment of acute necrotizing pancreatitis was successfully concluded in 2017. The study demonstrated that the endoscopic treatment approach was associated with a lower rate of complications, better quality of life and was less costly than minimally invasive surgical treatment approaches. The study manuscript is currently undergoing peer-review.

Although Lumen-Apposing Metal Stents (LAMS) have been developed for the endoscopic treatment of walled-off necrosis, their advantage over plastic stents is unclear. In a randomized trial, the CIE team demonstrated that while the procedural duration when using LAMS is shorter there was no difference in other treatment outcomes, particularly adverse events, between patients treated with LAMS versus plastic stents. The study manuscript has been accepted for publication in *GUT*.



## NEW INITIATIVES

**Pancreatic cancer:** Abdominal pain is a common symptom of pancreatic cancer that has traditionally been treated with narcotic medications. However, narcotics induce side effects such as drowsiness and constipation. To overcome these limitations, EUS-guided celiac plexus neurolysis by injection of bupivacaine and alcohol has been offered as a treatment alternative but is effective in only

60-70% of patients. In a recent single blind randomized trial, the CIE team evaluated the role of EUS-guided Radiofrequency Ablation (RFA) as an alternative to celiac plexus neurolysis. The study demonstrated that patients undergoing EUS-RFA had significantly better pain relief than those treated by EUS-CPN. Given this promising data, EUS-guided RFA has been incorporated as a treatment option for managing pain in patients with pancreatic cancer.



## The MISER trial is a landmark study.

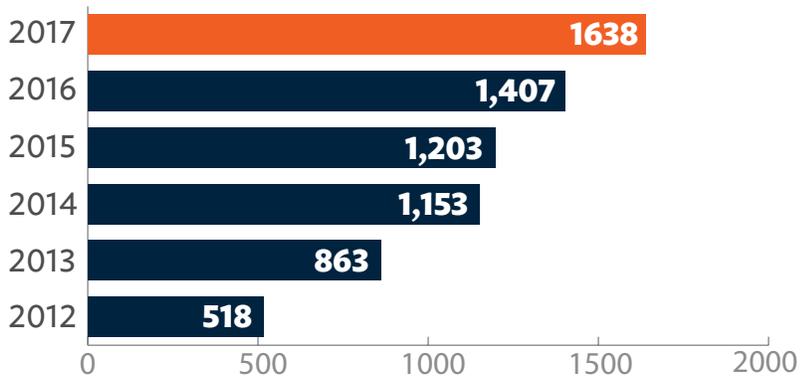
It is the first randomized trial comparing endoscopic therapy to minimally invasive surgical therapy for infected necrotizing pancreatitis to be conducted that includes state of the art endoscopic and minimally invasive surgical approaches, and includes realistic endpoints including pancreatic and entero-cutaneous fistulae. It shows that an endoscopic approach is superior in multiple aspects, including length of stay and cost, as well as other endpoints.”

—**Professor Martin L. Freeman M.D**  
*Chief, Division of Gastroenterology  
University of Minnesota*



**Shyam Varadarajulu**  
*Medical Director  
Center for Interventional  
Endoscopy*

# ERCP PROGRAM



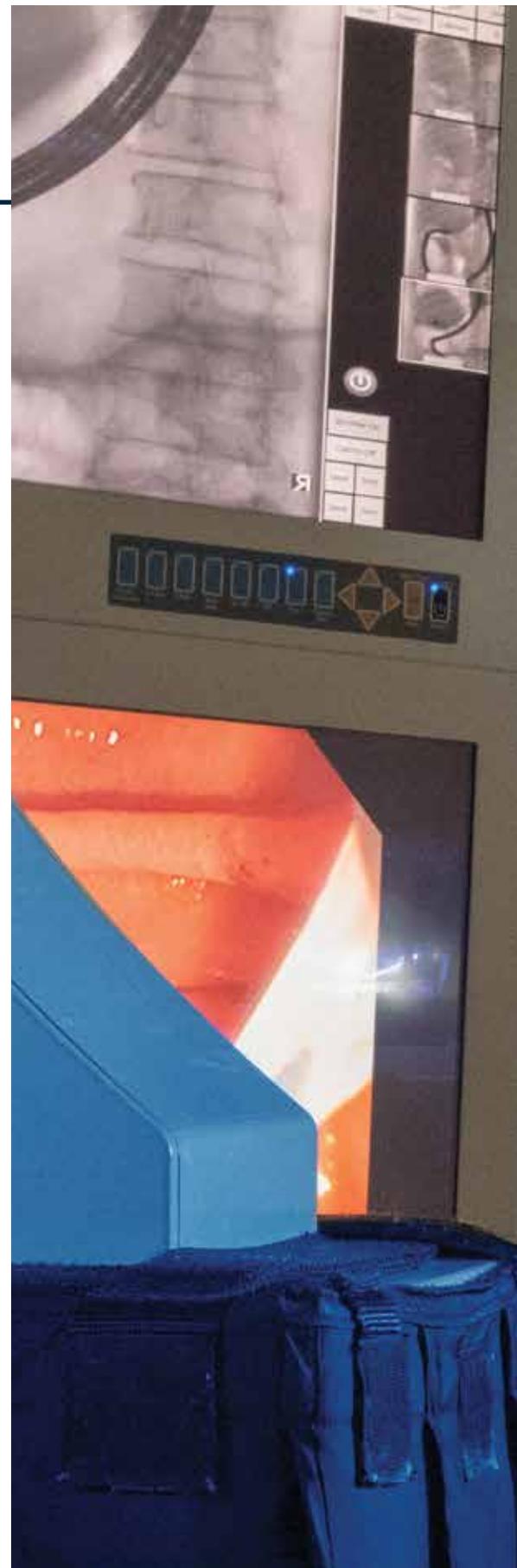
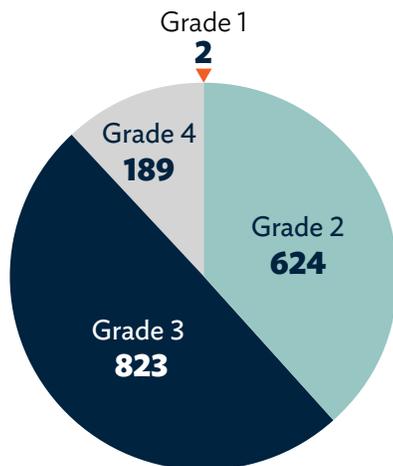
### ERCP outcomes:

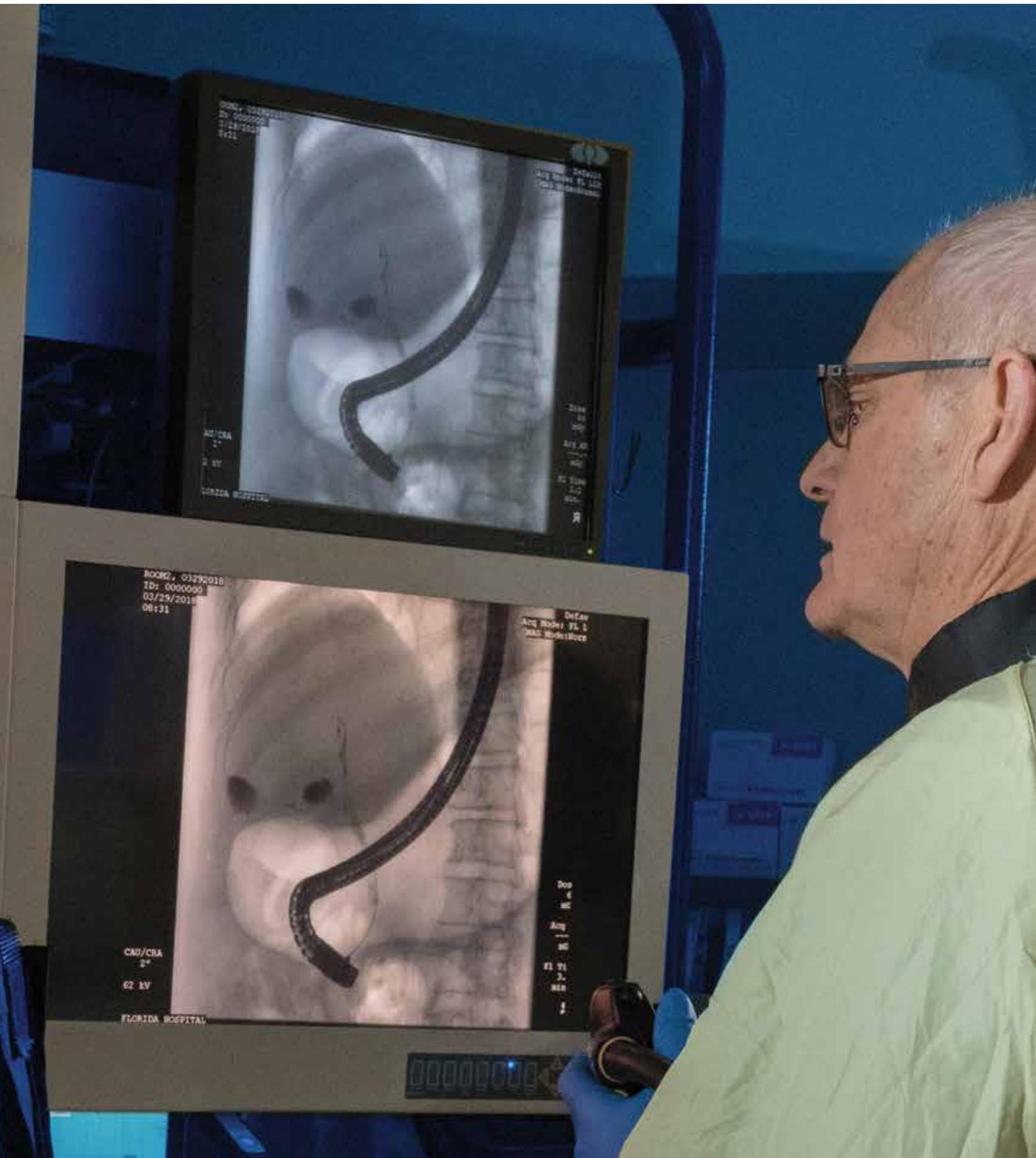
Technical Success	<b>1608</b>
Technical Failures	<b>24</b>
Altered Anatomy	<b>18</b>
Failed Cannulation	<b>6</b>

### Adverse events:

Perforation	<b>5</b>
Bleeding	<b>2</b>
Pancreatitis	<b>27</b>
Cholangitis	<b>16</b>
Death	<b>1</b>

### ERCP Volume by ASGE Complexity Level







## RESEARCH

**Pancreatic Cancer:** Although ERCP is the reference standard for the treatment of biliary decompression in pancreatic cancer; EUS-guidance has been increasingly used in challenging cases when ERCP fails. Most clinical investigations have evaluated the efficacy of EUS-guided biliary drainage only in the setting of a failed ERCP and in patients with locally advanced or metastatic cancer. In a recent randomized trial, the CIE team investigated the role of EUS-guided biliary drainage as primary treatment modality in patients with pancreatic cancer. The study demonstrated similar efficacy for both EUS and ERCP-based treatment approaches. Additionally, treatment by EUS-guided transmural stent placement did not preclude subsequent pancreaticoduodenectomy. The study manuscript has been accepted for publication in *Gastrointestinal Endoscopy*.

This study has important implications because the ability to utilize the same echoendoscope for both a diagnostic (FNA) and therapeutic (biliary drainage) intervention is likely to improve procedural efficiency and minimize

resource utilization. Additionally, therapy such as celiac plexus neurolysis for palliation of pain or fiducial placement for facilitation of radiotherapy can all be undertaken in a single treatment session using the same endoscope.

**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 has currently enrolled more than 300 patients 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.





Dr. Robert Hawes



Dr. Shyam Varadarajulu

## NEW INITIATIVES

### **Indeterminate bile duct strictures:**

Establishing a tissue diagnosis in patients with indeterminate bile duct strictures can be technically challenging. To increase diagnostic sensitivity, we utilize rapid onsite evaluation techniques for processing specimens procured using cholangioscopy-guided techniques. A randomized trial comparing onsite

and off-site specimen evaluation techniques is currently in progress.

The role of lipidomics in differentiating benign from malignant biliary strictures is currently under evaluation at CIE. This prospective investigation has been supported by a research grant awarded by the American College of Gastroenterology. More than 300 patients have been currently enrolled in this clinical trial.



**ERCP in gastric bypass:** Biliary and pancreatic interventions are undertaken using the double balloon enteroscope or by the placement of lumen-apposing metal stents via the gastric remnant to access the excluded stomach. Using a combination of approaches, our technical success rates for ERCP in this complex patient population approaches 90%.



## I congratulate the Florida Hospital CIE team

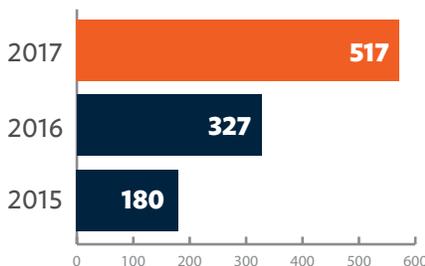
on performing this a landmark study in the continuing evolution of our management of patients with obstructive jaundice effectively and efficiently. “One stop” EUS-based diagnosis and management is certainly attractive. The only remaining question, as the authors acknowledge, is whether the excellent results can be replicated widely in community practice. If not, perhaps there is an argument for these, and more complex cases, such as hilar strictures, to be managed only at tertiary referral centers.”

—**Professor Peter B. Cotton, MD, FRCS, FRCP**  
*Medical University of South Carolina*

# INFLAMMATORY BOWEL DISEASE PROGRAM

The Inflammatory Bowel Disease (IBD) program that was established in 2015 at CIE and is a center of excellence devoted to the management of patients with complex ulcerative colitis and Crohn's disease. More than 500 patients with complex inflammatory bowel disease have been evaluated and undergone treatment through our IBD program.

Number of IBD Patients



## 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 for detection and resection of early-stage tumors.

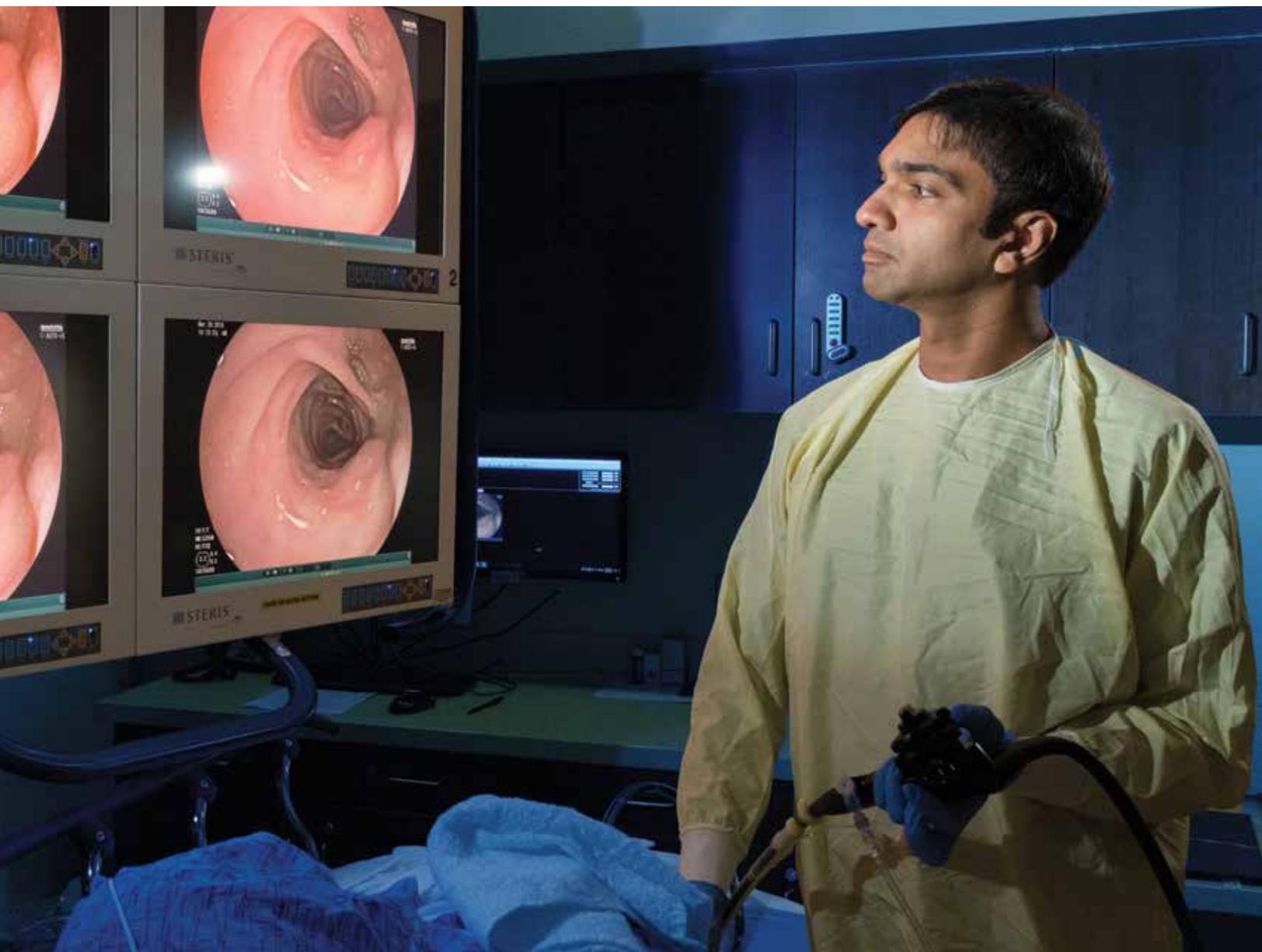
## Initiatives

- To improve the effectiveness for treating strictures in IBD, a novel endoscopic procedure called “needle knife stricturotomy” has been integrated within our clinical practice for treating refractory strictures in patients with inflammatory bowel disease.
- Given the limited treatment options in patients with IBD who have failed multiple biologic medications, clinical trials involving newer treatment options including oral small molecules are offered for patients with IBD.



## Annual Symposium in Inflammatory Bowel Disease

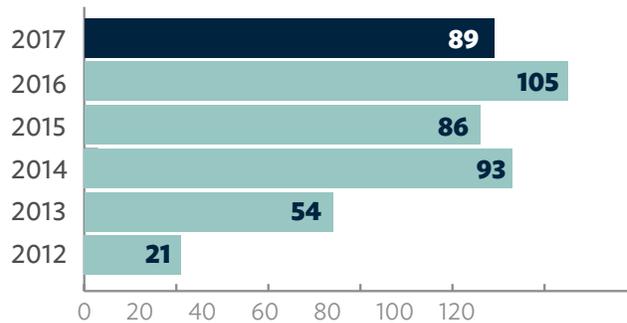
CIE hosts a nationally recognized annual symposium devoted to IBD in the month of April. The symposium draws experts from around the United States and Europe who share their expertise and explore the latest advances in the treatment of IBD.



# OTHER PROCEDURES

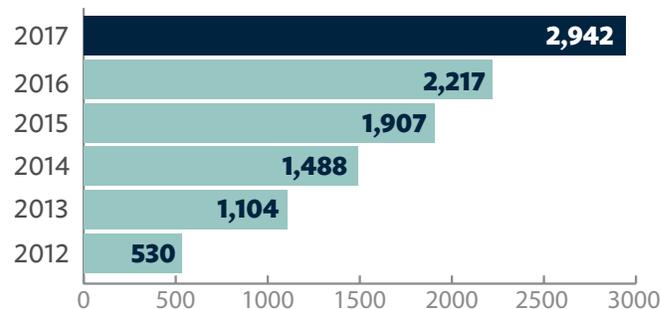
## RADIOFREQUENCY ABLATION

- 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.



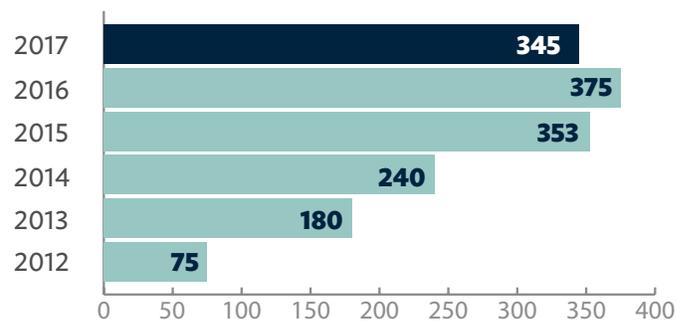
## OTHER INTERVENTIONS

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



## DOUBLE BALLOON ENTEROSCOPY

- CIE provides a wide range of diagnostic and therapeutic services that include management of small bowel bleeding, evaluation of inflammatory bowel disease, treatment of strictures and polyps.
- Clinical trials evaluating the utility of Motorized Spiral Enteroscope are expected to commence in 2018.







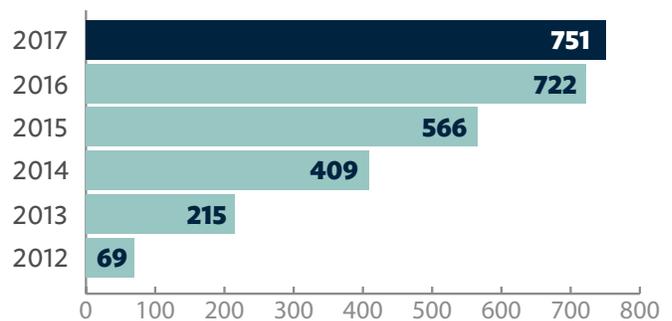
## NEW INITIATIVES

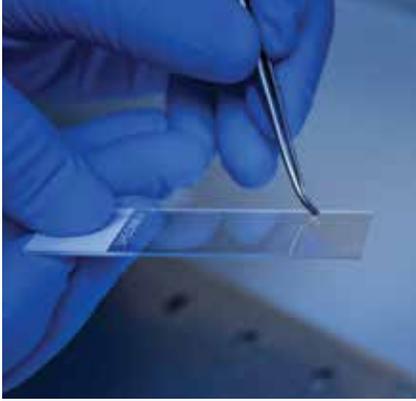
- Peroral Endoscopic Myotomy (POEM): POEM is currently offered as a treatment option for patients with achalasia cardia. CIE Faculty, Dr. Ji Young Bang, underwent hands-on training for two months in India and was subsequently proctored for the first three cases at CIE by Dr. Nageshwar Reddy and Dr. Pankaj Desai. The technique is a likely conduit to pursue other interventions such as submucosal tunneling endoscopic resection.
- Endoscopic Submucosal Dissection (ESD): ESD will be offered as a treatment option for patients with early-stage neoplasia from September 2018 onwards.



## ENDOSCOPIC MUCOSAL RESECTION

- Randomized trials evaluating the role of subcutaneous octreotide in prevention of bleeding after ampullectomy and endoscopic mucosal resection of large duodenal polyps are underway.





# RESEARCH IN 2017

## EUS-RELATED STUDIES

### **EUS-guided pancreatic cyst ablation**

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

### **Registry for Endoscopic Ultrasound (EUS) Evaluation of Pancreatic Cysts**

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

### **Registry for Endoscopic Management of pancreatic fluid collections**

*Primary Aim: Prospective database to study the management of pancreatic fluid collections*

## ERCP-RELATED STUDIES

### **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*

### **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*

## IBD-RELATED STUDIES

### **A Phase 2, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy and Safety of Filgotinib in the Treatment of Perianal Fistulizing Crohn's Disease**

*Primary aim: The primary objective of this study is to evaluate the efficacy of filgotinib as compared to placebo in establishing combined fistula response at Week 24*

### **A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of HUMIRA® (Adalimumab) in Patients with Moderately to Severely Active Ulcerative Colitis (UC)**

*Primary Aim: The primary objective of this Registry is to evaluate the long-term safety of HUMIRA® in moderately to severely active UC adult patients (18 years of age or older) who are treated per routine clinical practice*

### **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.**

*Primary Aim: The primary objective of this study is to assess the long-term safety of vedolizumab versus other biologic agents in patients with UC or CD*

**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**

*Primary Aim: The primary objective of this study is to determine the effect of triple combination therapy with an anti-integrin (vedolizumab IV), a tumor necrosis factor (TNF) antagonist (adalimumab SC), and an immunomodulator (oral methotrexate) on endoscopic remission at Week 26*

**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**

*Primary Aim: The primary objective of this study is to determine the effect of vedolizumab IV dose optimization on mucosal healing compared with the standard vedolizumab IV dosing regimen at Week 30 in subjects with UC and high vedolizumab clearance based on a predefined week 5 serum vedolizumab concentration threshold (<50 µg/mL) and who are Week 6 nonresponders*

**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**

*Primary Aim: The primary objectives to this study are to evaluate the efficacy of JNJ-64304500 to reduce the Crohn's Disease Activity Index (CDAI) score from baseline and to evaluate the safety of JNJ-64304500*

**Impact of Chromoendoscopy on outcomes in inflammatory bowel disease patients with a history of low grade dysplasia on white-light endoscopy**

*Primary Aim: The primary aim of the study is to evaluate the impact of chromoendoscopy and the long-term outcome of patients with low grade dysplasia detected on white-light endoscopy*

**A Phase 2/3, Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn's Disease**

*Primary Aim: The primary objectives of this study are to evaluate the clinical efficacy of guselkumab in participants with Crohn's disease and evaluate the safety of guselkumab*

**A Phase 2, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy and Safety of Filgotinib in the Treatment of Small Bowel Crohn's Disease (SBCD)**

*Primary Aim: The primary objective of this study is to evaluate the efficacy of filgotinib, when compared to placebo, in establishing clinical remission, defined as Crohn's disease activity index (CDAI) < 150, at Week 24*

**A Phase II/III Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Safety and Efficacy of BI 655130 Induction Therapy in patients with moderate-to-severely active ulcerative colitis who have failed previous biologics therapy**

*Primary Aim: The primary objectives of the studies are to: 1) prove the concept of clinical activity of BI 655130 in patients with moderate-to-severely active ulcerative colitis who have failed previous biologic treatments and to identify efficacious and safe dose regimens in Part 1 (Phase II), and 2) confirm efficacy and safety of BI 655130 in patients with moderate-to-severely active ulcerative colitis who have failed previous biologic treatments in Part 2 (Phase III)*



Research Team: Left to right: Callie Arnold, Robin Barron, Dr. Ji Young Bang, Millie Lopez, Cristina Campos

### ENTYVIO® Outcomes in Real-World Bio-naïve Ulcerative Colitis and Crohn's Disease Patients (EVOLVE)

*Primary Aim: Evaluate treatment patterns and clinical effectiveness of vedolizumab and other biologics in biologic naïve ulcerative colitis (UC) and Crohn's disease (CD) patients in a real world setting in the USA*

### Clinical and Laboratory Features Including Serum levels of Ustekinumab and Antibodies in Predicting Short-term and Persistent Remission in Crohn's Disease Patients

*Primary Aim: The primary aim of the study is to evaluate bio-markers and serum levels of Ustekinumab in predicting Short-term and Persistent Remission in patients with Crohn's Disease*

## RESECTION-RELATED RANDOMIZED STUDIES

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

*Primary Aim: Evaluate the role of subcutaneous Octreotide in preventing postresection bleeding in patients with duodenal and ampullary masses*

## 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*



## The study on 'ERCP vs EUS for palliation of distal malignant biliary obstruction'

by the Florida Hospital group in Orlando led by Dr. Shyam Vardarajulu is a ground-breaking study in endoscopic management of biliary decompression in pancreatic cancer that will lead to paradigm shift in clinical management.”



— **Professor Nageshwar Reddy**  
Chairman  
Asian Institute of Gastroenterology, India

## 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.

CLINICAL TRIALS	SPONSOR
Randomized trial comparing On-site versus Off-site evaluation of cholangioscopy-guided biopsies of the bile Duct	Florida Hospital
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
A randomized trial comparing covered metal and plastic stents for preoperative biliary decompression in pancreatic cancer	Florida Hospital
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	Sponsor
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 trial evaluating prophylactic Octreotide to prevent post-duodenal EMR and ampullectomy bleeding	Florida Hospital
Lipidomics, Proteomics and Volatile Organic Compounds Biomarkers in Bile and Serum	Florida Hospital
Endoscopic ultrasound-guided liver biopsy using a 22 gauge Fine Needle Biopsy needle	Florida Hospital
EUS-guided pancreatic cyst ablation	Florida Hospital
Registry for Endoscopic Management of Pancreatic Fluid Collections	Florida Hospital
Registry for Endoscopic Ultrasound (EUS) Evaluation of Pancreatic Cysts	Florida Hospital
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.	Sponsor
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	Sponsor
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.	Sponsor
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.	Sponsor
Clip vs. no clip to prevent post-EMR resection of large colon polyps.	Sponsor



# PUBLICATIONS IN 2017

## Peer-Reviewed Publications

Bang JY, Hasan MK, Navaneethan U, Hawes R, Varadarajulu S. Lumen-apposing metal stents (LAMS) for pancreatic fluid collection (PFC) drainage: may not be business as usual. *Gut*. 2017; 66: 2054-2056

Bang, JY, Hebert-Magee S, Navaneethan U, Hasan, MK. EUS-guided fine needle biopsy of pancreatic masses can yield true histology: results of a randomized trial. *Gut*. 2017. In Press

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*. 2017; 85: 773-781

Yachimski P, Varadarajulu S. Endoscopic Ultrasound-Guided Pancreatic Cyst Ablation: More Peril Than Promise? *Gastroenterology*. 2017; 153: 1183-1185

Roy A, Kim M, Hawes R, Varadarajulu S. The clinical and cost implications of failed endoscopic hemostasis in gastroduodenal ulcer bleeding. *United European Gastroenterol J*. 2017; 5: 359-364

Navaneethan U, Lourdasamy D, Gutierrez, NG, Zhu X, Vargo JJ, Parsi MA. New approach to decrease post-ERCP adverse events in patients with primary sclerosing cholangitis. *Endosc Int Open*. 2017; 5: E710-E717

Navaneethan U, Edminister T, Zhu X, Kommaraju K, Glover S. Vedolizumab Is Safe and Effective in Elderly Patients with Inflammatory Bowel Disease. *Inflamm Bowel Dis*. 2017; 23: E17

Navaneethan U, Njei B, Zhu X, Kommaraju K, Parsi MA, Vardarajulu S. Safety of ERCP in patients with liver cirrhosis: a national database study. *Endosc Int Open*. 2017; 5: E303-E314

Varadarajulu S, Lakhtakia S. Moving away from the tumor zone: A work in progress. *Dig Endosc*. 2017; 29: 35

Ali S, Asad U, Navaneethan U. An Unusual Cause of Recurrent Gastrointestinal Bleeding After Whipple's Surgery. *Gastroenterology*. 2017; 153: e1-e2

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

Bang JY, Hebert-Magee S, Hasan MK, Navaneethan U, Hawes R, Varadarajulu S. Endoscopic ultrasonography-guided biopsy using a Franseen needle design: Initial assessment. *Digestive Endoscopy*. 2017; 29: 338-346

Bang JY, Varadarajulu S, Letter to editor. *Gut*, 2017; 66: 1535

Bhatia V, Varadarajulu S. Endoscopic ultrasonography-guided tissue acquisition: How to achieve excellence. *Dig Endosc*. 2017; 29: 417-430

Feng Y, Navaneethan U, Zhu X, Varadarajulu S, Schwartz I, Hawes R, Hasan MK, Yang A. Prophylactic rectal indomethacin may be ineffective for preventing post-endoscopic retrograde cholangiopancreatography pancreatitis in general patients: A meta-analysis. *Dig Endosc*. 2017; 29: 272-280



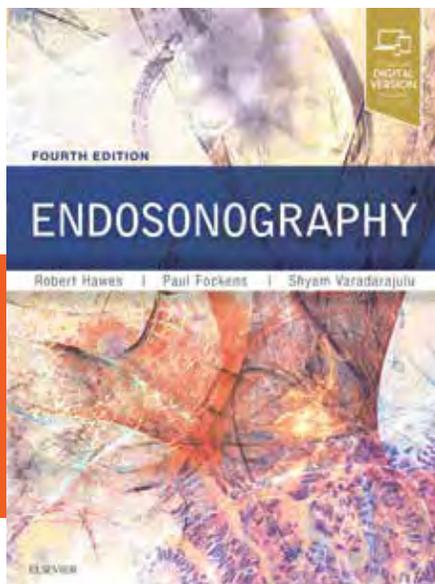
Hawes RH, Devière J. How I cannulate the bile duct. *Endoscopy*. 2018; 50: 75-77

Kadkhodayan K, Rafiq E, Hawes RH. Endoscopic Evaluation and Management of Gastric Stromal Tumors. *Curr Treat Options Gastroenterol*. 2017; 15: 691-700

Reza JA, Fruchter S, Varadarajulu S, Arnoletti JP. A Large Intussuscepting Gastric Lipoma. *J Gastrointest Surg*. 2017. In Press

Bang JY, Wilcox CM, Navaneethan U, Hasan MK, Peter S, Christein J, Hawes R, Varadarajulu S. *Ann Surg*. 2018 Mar;267(3):561-568

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.



- The 3rd edition of the textbook was 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 August 2018

# SCIENTIFIC PRESENTATIONS

## **Digestive Disease Week 2017, Chicago, Illinois**

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

## **World Congress of Gastroenterology at American College of Gastroenterology Meeting, Orlando, Florida**

Ji Young Bang, Pablo Arnoletti, Bronte Holt, Udayakumar Navaneethan, Bryce Sutton, C. Mel Wilcox, Nicholas Feranec, Muhammad Hasan, Robert Hawes, Shyam Varadarajulu. Minimally Invasive Surgery versus Endoscopy Randomized (MISER) Trial for Necrotizing Pancreatitis

## **Pancreas Club Annual Meeting, Chicago, Illinois**

Ji Young Bang, Udayakumar Navaneethan, Muhammad Hasan, Robert Hawes, Shyam Varadarajulu. Lumen-apposing metal stents (LAMS) for pancreatic fluid collection drainage: May not be business as usual

Ji Young Bang, Shantel Hebert-Magee, Udayakumar Navaneethan, Muhammad Hasan, Robert Hawes, Shyam Varadarajulu. Randomized trial comparing 22-gauge Franseen biopsy and 22-gauge aspiration needles for EUS-guided sampling of solid pancreatic mass lesions

## **American Pancreatic Association Annual Meeting, San Diego, California**

Ji Young Bang, Pablo Arnoletti, Bronte Holt, Udayakumar Navaneethan, Bryce Sutton, Mel C. Wilcox, Nicholas Feranec, Muhammad Hasan, Robert Hawes, Shyam Varadarajulu. Minimally Invasive Surgery versus Endoscopy Randomized (MISER) Trial for Necrotizing Pancreatitis

## **United European Gastroenterology Week, Barcelona, Spain**

Ji Young Bang, Pablo Arnoletti, Bronte Holt, Udayakumar Navaneethan, Bryce Sutton, Mel C. Wilcox, Nicholas Feranec, Muhammad Hasan, Robert Hawes, Shyam Varadarajulu. Minimally Invasive Surgery versus Endoscopy Randomized (MISER) Trial for Necrotizing Pancreatitis

Ji Young Bang, Shantel Hebert-Magee, Udayakumar Navaneethan, Muhammad Hasan, Robert Hawes, Shyam Varadarajulu. Randomized trial comparing 22-gauge Franseen biopsy and 22-gauge aspiration needles for EUS-guided sampling of solid pancreatic mass lesions



**Dr. Udayakumar Navaneethan**

## HONORS AND AWARDS

### American Pancreatic Association Annual Meeting, San Diego, California

The MISER trial presentation was recognized with a Travel Award

### The German Society for Gastroenterology Digestive & Metabolic Diseases

Endoscopy Award to Dr. Robert Hawes

### United European Gastroenterology Week, Barcelona, Spain

Three CIE studies were honored with first prizes in their respective categories at UEG Week: 1) Minimally Invasive Surgery versus Endoscopy Randomized (MISER) Trial for management of acute necrotizing pancreatitis, 2) Randomized trial comparing lumen-apposing metal versus plastic stents for drainage of walled-off necrosis, and 3) Randomized trial comparing the volume and histologic quality of the Franseen and standard bevel FNA needles for sampling of solid pancreatic masses

### World Congress of Gastroenterology at American College of Gastroenterology, Orlando, Florida

The ACG Auxiliary Award was presented for the study entitled Volatile Organic Compound Biomarker Signature in Bile to Distinguish Pancreatic Cancer from Chronic Pancreatitis: A Single Blinded Study

## LECTURESHIPS

Don Wilson Lecture EndoSwiss Live, Zurich, Switzerland was delivered by Dr. Robert Hawes.



# 5TH ANNUAL ORLANDO LIVE EUS





Orlando Live is the single largest EUS symposium in the United States. In 2017, **233 delegates** from **24 countries** attended this meeting. **Ten experts** from **9 countries** demonstrated **42 procedures** that were transmitted live. A hands-on lab had **106 attendees**. The symposium received a rating of **4.7 out of 5** from the delegates present.



# CONFERENCE ATTENDEES



- Argentina
- Australia
- Belgium
- Brazil
- Canada
- China
- Colombia
- Germany
- India

# COUNTRIES REPRESENTED AT THE 5TH ANNUAL ORLANDO LIVE EUS



Iran  
Japan  
Mexico  
The Netherlands  
Pakistan  
Peru  
Poland  
Romania  
Russia

South Africa  
Spain  
Tanzania  
United Arab Emirates  
United Kingdom  
United States

# EDUCATIONAL SYMPOSIUMS



*5th Annual Orlando Live EUS Faculty*

## **5th Annual Orlando Live EUS 2017** August 30 - Sept 1, 2017

The best attended North American symposium in EUS received a delegate rating of 4.7 on a scale of 0 to 5. There were five components to the symposium that provided participants a comprehensive education in endosonography: (a) Live cases demonstrating techniques in endoscopic ultrasound (EUS) procedures, (b) Didactic lectures focusing on disease management, (c) Literature update providing the latest information on research, (d) Self-assessment video quiz evaluating knowledge base and (e) Hands-on lab teaching procedural techniques in models.

The Orlando Live Endoscopy symposium will be held in Orlando from August 29–31, 2018. Moving forward the EUS and Endoscopy symposiums will alternate every other year.

## **Achieving Excellence in Clinical Endoscopy. St Petersburg, Florida** January 14, 2017

This one-day CME program focused on achieving excellence in clinical endoscopy. Over 110 delegates attended this one day symposium. The invited faculty were Michael Bourke (University of Sydney), Horst Neuhaus (Dusseldorf, Germany), Gregory Haber (Lenox Hill Hospital, New York) and Francis Farraye (Boston University School of Medicine).

## **Clinical Updates in Inflammatory Bowel Disease Orlando, Florida** April 22, 2017

This one-day CME program focused on clinical updates in Inflammatory Bowel Disease. There were 120 delegates attended the meeting. The 4 invited faculty invited to speak at this symposium were Dr. Shomron Ben-Horin (Tel-Aviv University), Dr. Bo Shen (Cleveland Clinic), Dr. John F. Valentine, MD (University of Utah HSC) and Dr. Raymond Cross (University of Maryland Medical Center).



*Clinical Updates in Inflammatory Bowel Disease*

## **Pancreas Update Winter Park, Florida** December 9, 2017

This one-day multidisciplinary CME symposium covered key issues in pancreatic diseases encompassing autoimmune and chronic pancreatitis, walled-off necrosis, pancreatic cysts and pancreatic cancer. The invited faculty were Suresh Chari (Mayo Clinic College of Medicine), Martin Freeman (University of Minnesota), Anne-Marie Lennon (Johns Hopkins University School of Medicine), Desiree Morgan (University of Alabama), Nageshwar Reddy (Asian Institute of Gastroenterology, India) and Nicholas Zyromski (Indiana University School of Medicine).

**For more information regarding future events, visit [FHGIEvents.com](http://FHGIEvents.com).**



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