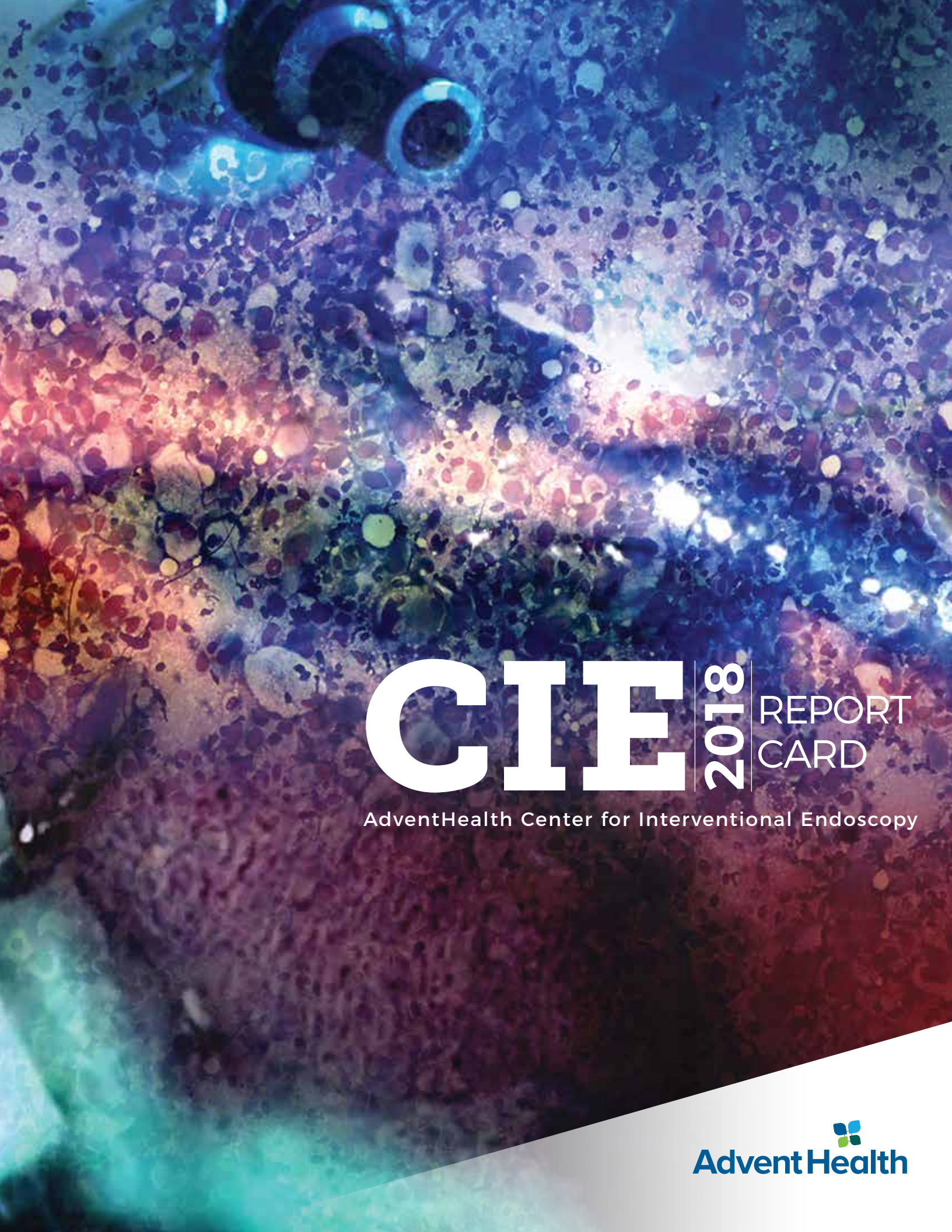


CIE 2018 REPORT CARD

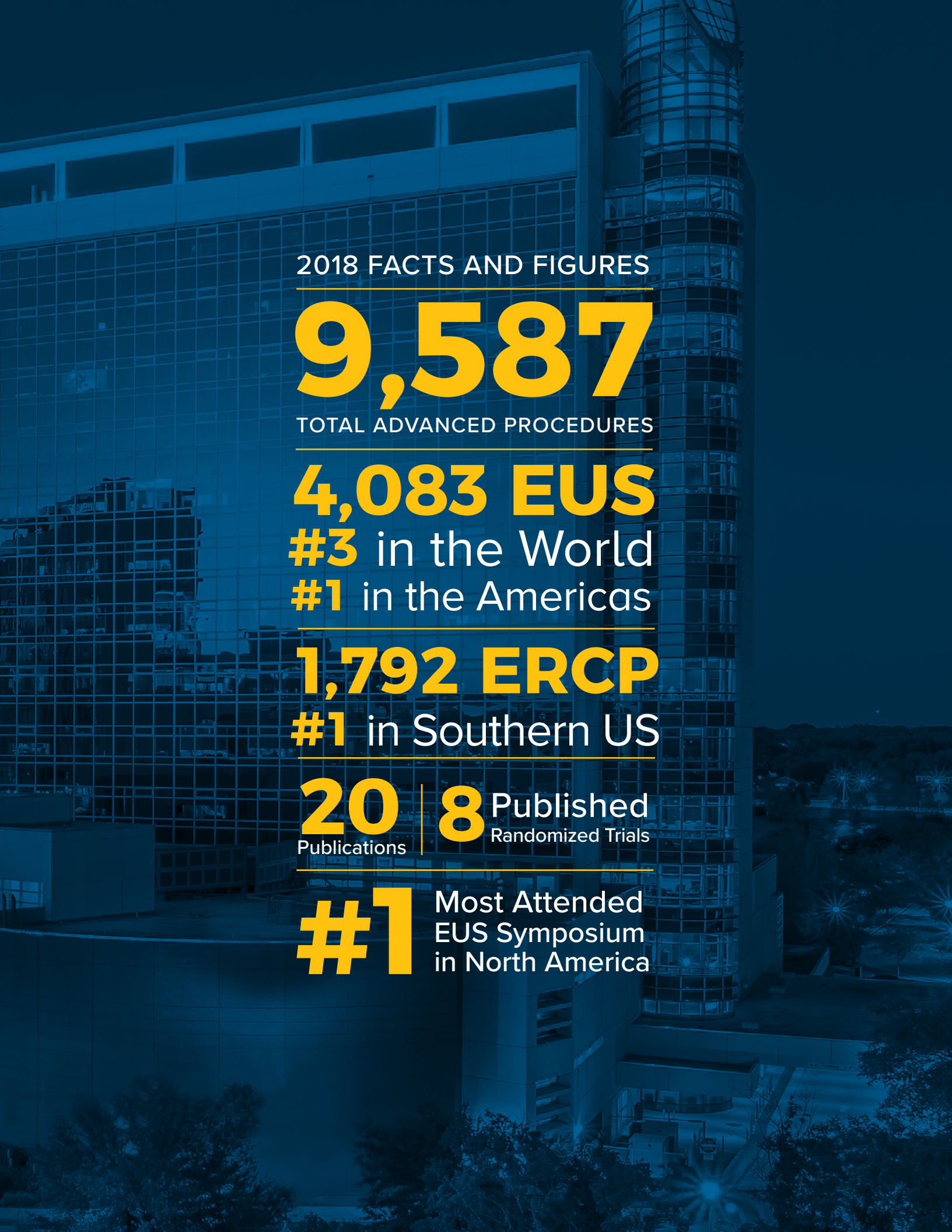
AdventHealth Center for Interventional Endoscopy

AdventHealth

CIE 2018

The AdventHealth Center for Interventional Endoscopy (CIE) is a state-of-the-art unit providing tertiary level care for patients with complex digestive diseases.

The CIE physicians are well-rounded and trained in the latest advanced techniques and procedural services available for the treatment of digestive disorders. Our team advances collaborative research not only within the Adventist Health System but globally to further the treatment and knowledge of digestive diseases.


2018 FACTS AND FIGURES
9,587
TOTAL ADVANCED PROCEDURES
4,083 EUS
#3 in the World
#1 in the Americas
1,792 ERCP
#1 in Southern US
20
Publications
8
Published
Randomized Trials
#1
Most Attended
EUS Symposium
in North America

“A vast amount of specialized procedures are performed at the renowned and top-ranked AdventHealth’s Center for Interventional Endoscopy.

The highly sought after services are not only available to our local residents, but 55 percent of the patients coming to the center are from out of the area – including outside the United States. This is a testament to the center’s high level of health care offered in Central Florida...and we are pleased to have such medical expertise in our region.”

- Orange County Mayor | Jerry L. Demings

2018 REPORT CARD

AdventHealth Center for Interventional Endoscopy

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OVERVIEW FROM PHYSICIANS

Dear Colleagues,
I am pleased to present the annual report card of the AdventHealth Center for Interventional Endoscopy (CIE). The annual report outlines our procedure volume, clinical outcomes, research portfolio, educational initiatives, scientific presentations and other significant milestones achieved in 2018.

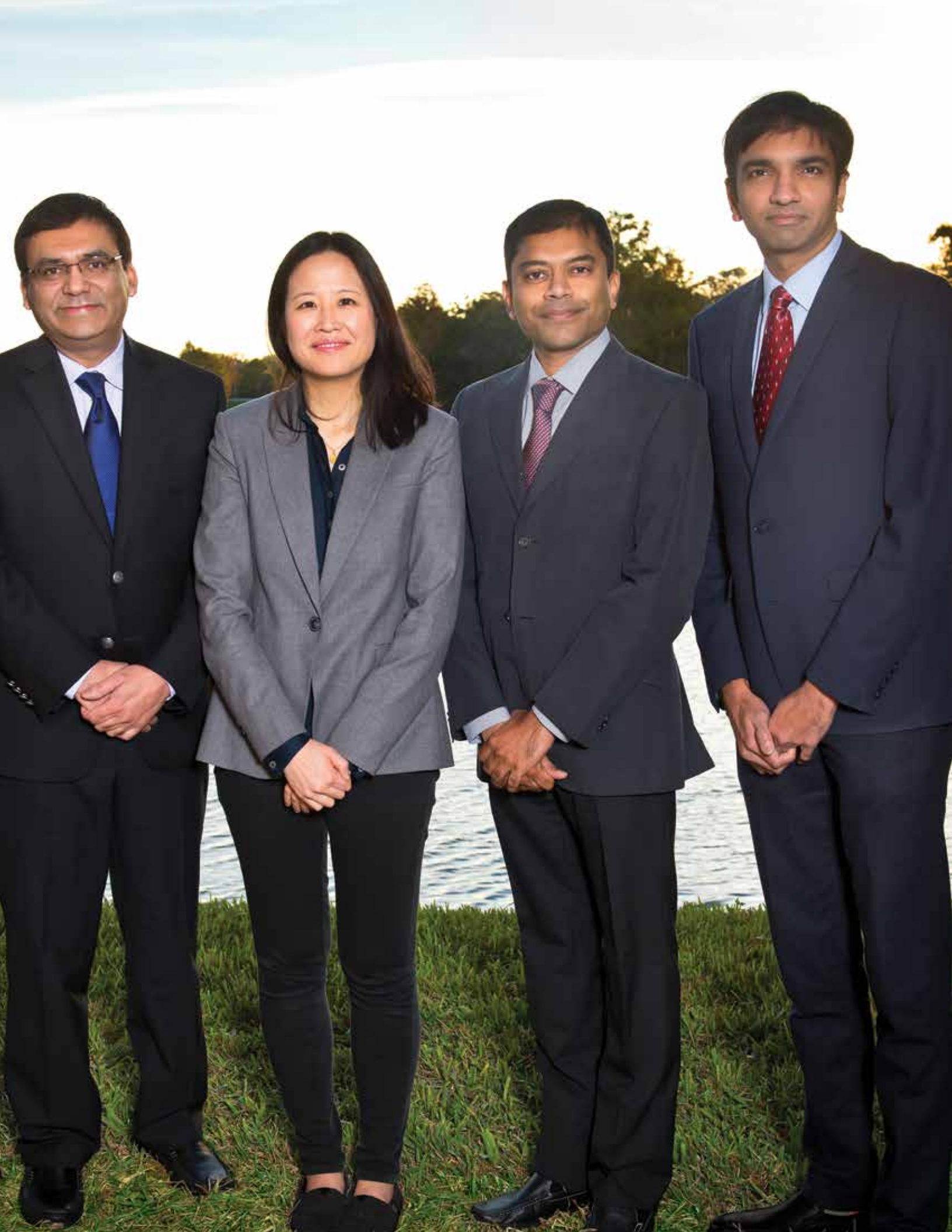
In 2018, we performed 9,587 complex endoscopic procedures that included 4,083 endoscopic ultrasound (EUS) examinations. CIE improved its ranking as the third largest EUS unit in the world and retained its status as the largest volume EUS program in North America. Our ERCP volume reached 1,792 and we performed more than 900 endoscopic mucosal resection procedures. Our third space endoscopy program continues to expand with the performance of submucosal tunneling endoscopic resection procedures and we added submucosal dissection to our portfolio in 2018.

We concluded 8 randomized trials and the CIE faculty published 20 peer-reviewed manuscripts in 2018. The 4th edition of our textbook ENDOSONOGRAPHY was successfully released at the Orlando Live Endoscopy symposium which was attended by 315 delegates from 28 countries.

As CIE continues to expand and grow, I invite you to visit our unit in person and give us the opportunity to share our vision with you.

Sincerely,

Shyam Varadarajulu
Medical Director
AdventHealth Orlando
Center for Interventional Endoscopy



AdventHealth Center for Interventional Endoscopy

STAFF

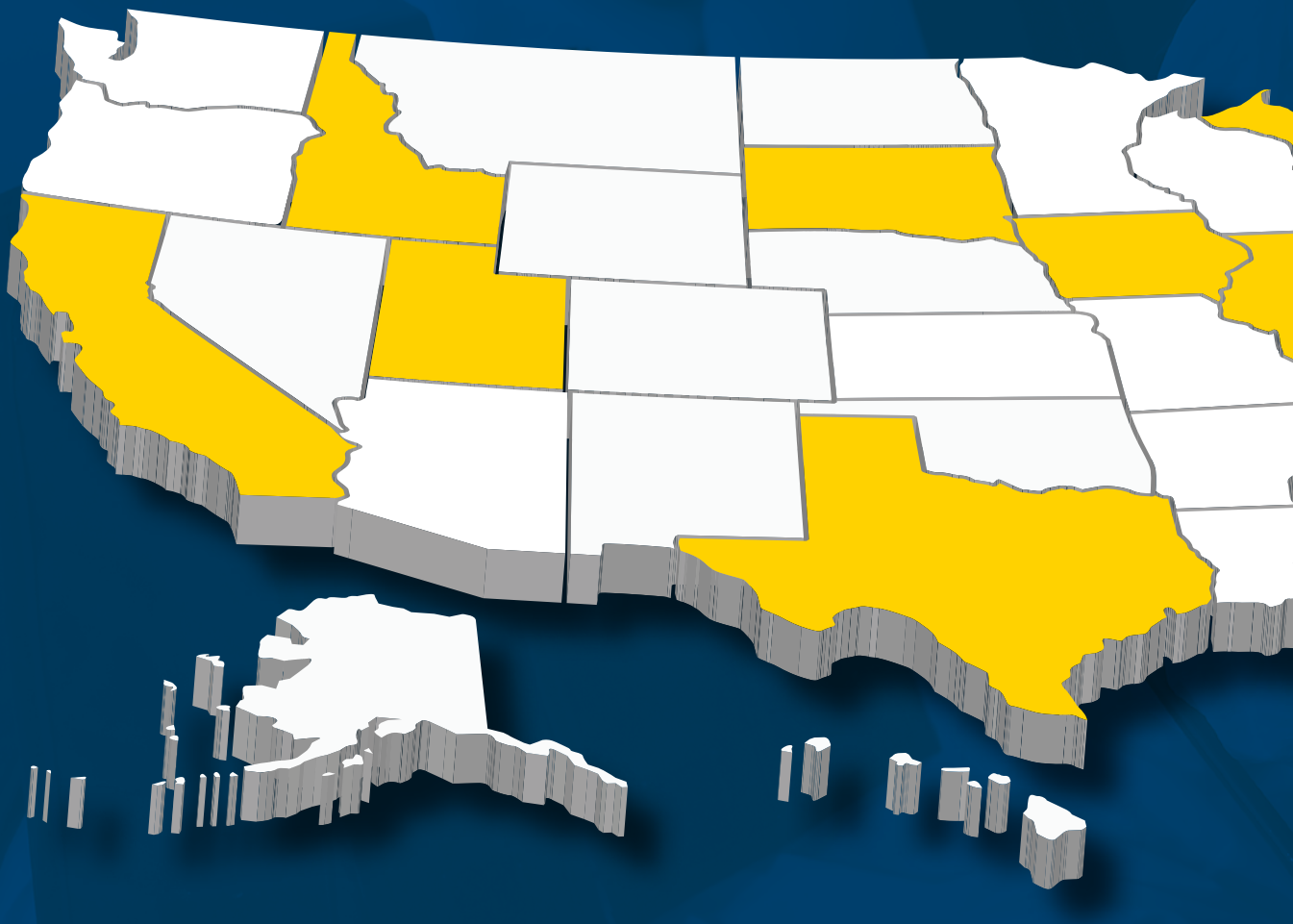
"I not only received exceptional treatment at the hands of great doctors but was cared for deeply by staff who are committed to excellence in patient care."

- Robert De Santis | Orlando, FL

PATIENT REFERRAL STATISTICS

Patients are referred to CIE for expert care from across the United States as well as internationally. In 2018, patients were referred nationally from 23 states as well as from 12 countries. More than 55% of patients treated at CIE originated from outside the Tri-County area.

MORE THAN 55% of patients treated at CIE originated from outside the Tri-County area.



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

8,108 Total Patients

23 States | **93** Patients

8,000 Florida Patients

Tri County 3,515 | Non-Tri County 4,485

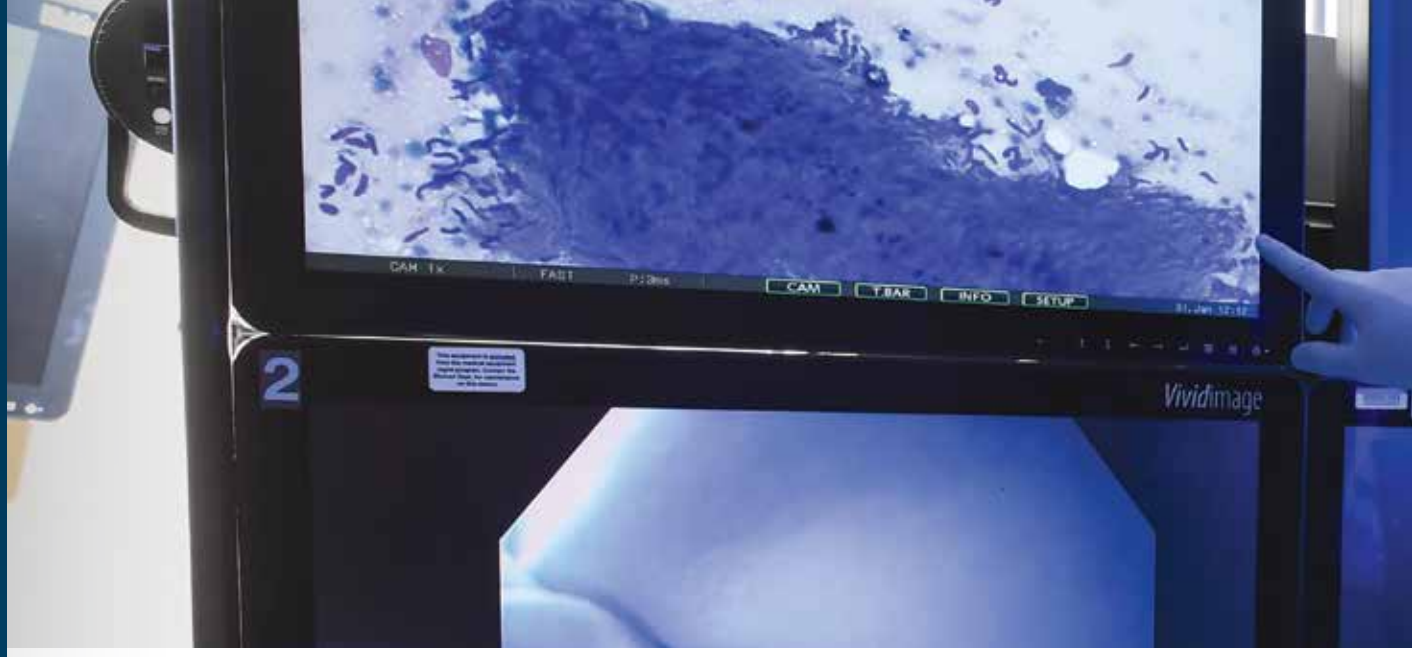
15 International Patients

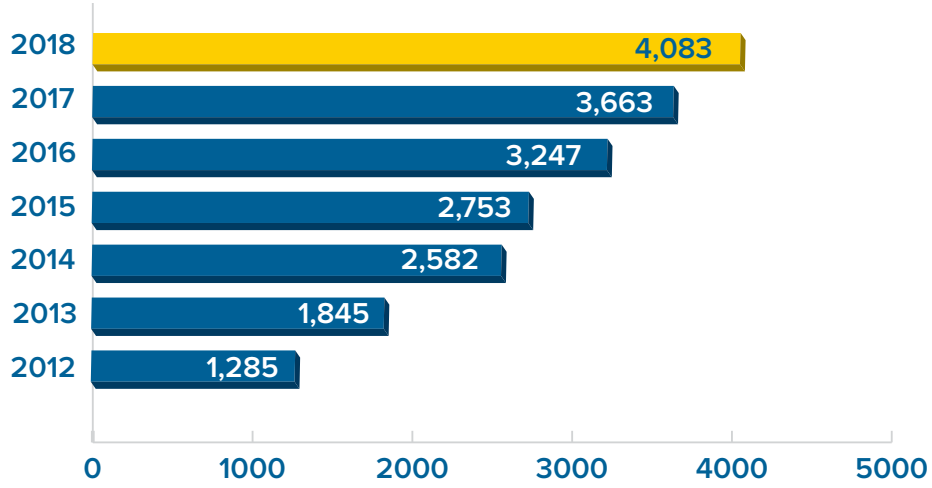
"The CIE team is an excellent resource for health care professionals in Florida. The team is always available to offer their support and expertise to my patients with complex endoscopic challenges.

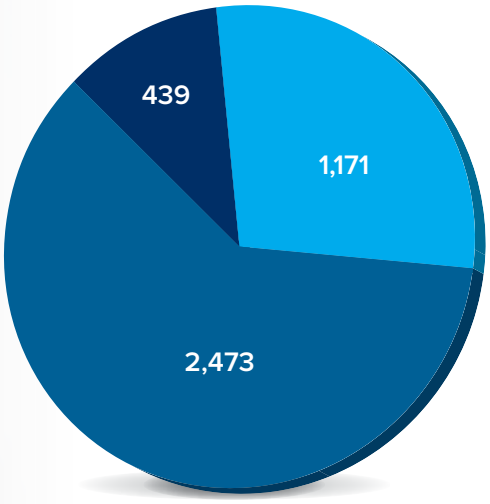
I always felt that my patients were well cared for by the very best team in the world. Each patient returning from CIE always has a wonderful experience to share."

- Dr. Christina Covelli | Gastroenterologist

ENDOSCOPIC ULTRASOUND PROGRAM







Tissue Acquisition

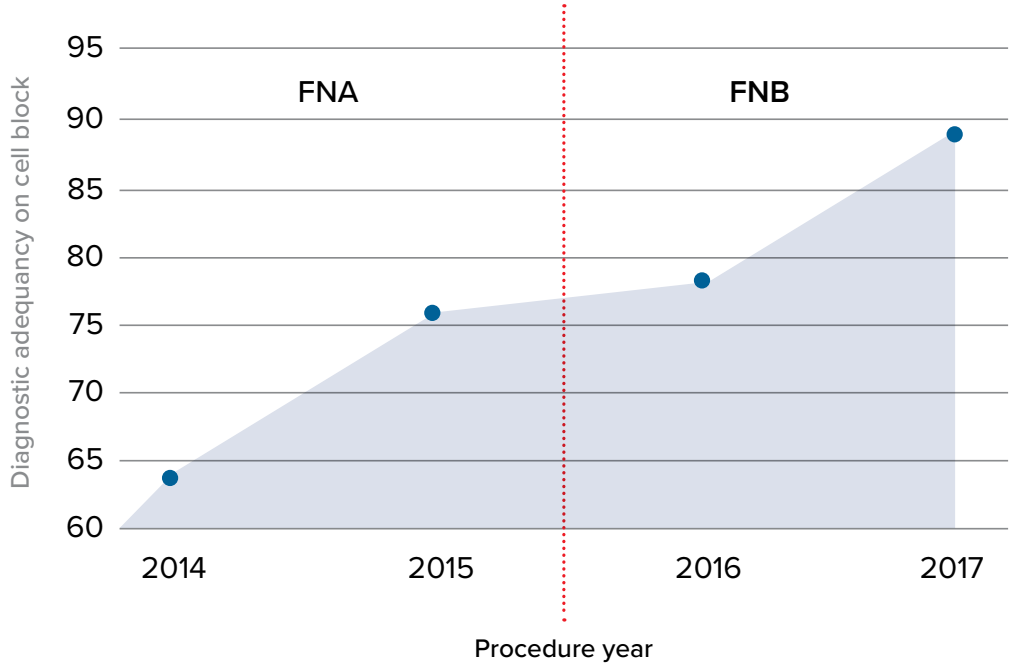
Diagnostic

Interventions

Interventions	
Pancreatic Fluid Collection Drainage	116
Biliary and/or Pancreatic Ductal Drainage	34
Celiac Plexus Interventions, Ablations, Fiducial Placements	227
Others	62

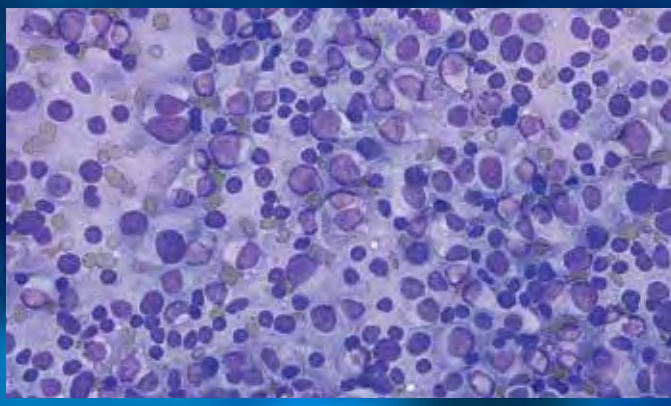
Research

Tissue acquisition in patients with solid mass lesions using endoscopic ultrasound is undergoing transition from fine needle aspiration (FNA) to fine needle biopsy (FNB). Cytological aspirates procured at FNA are suboptimal for molecular profiling, difficult for the differentiation of complex neoplasms and require the expertise of a trained cytopathologist for diagnostic interpretation. More importantly, the outcomes of FNA are reliant on onsite assessment of the specimen, a resource that is limited in availability. When the FNA specimen is processed offsite by cell block preparation the diagnostic yield is oftentimes suboptimal at less than 80%. The newly designed biopsy needles yield histological tissue that can overcome the above limitations. In an audit of 3,020 patients who underwent EUS-guided sampling of solid mass lesions using the FNA or FNB needle, our team demonstrated that the diagnostic yield for off-site assessment by cell block was greater than 90% for FNB needles compared to only 70% for FNA needles. Additionally, molecular profiling and ancillary studies could be reliably performed on all samples procured using the FNB needle. These findings were presented at the United European Gastroenterology Week 2018 in Vienna.



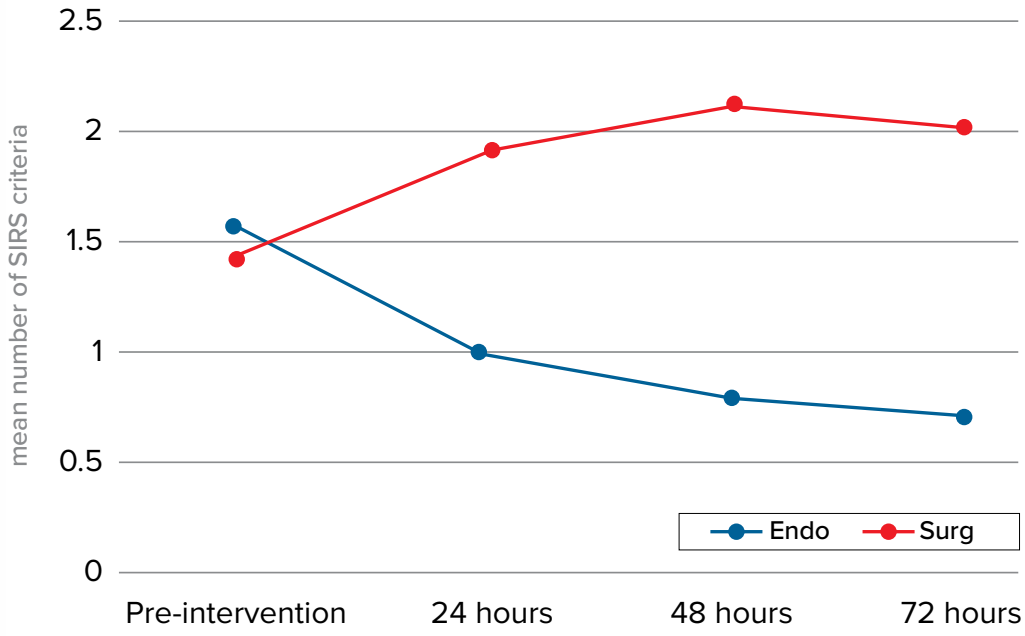
Increased diagnostic yield on cell block when using FNB needles

Where is EUS-guided tissue acquisition destined in the next 5-years? With an onsite diagnostic yield exceeding 90% using the newer generation FNB needles, it is important to optimize procedural techniques so that outcomes can be standardized across centers. In a randomized trial of 352 patients with pancreatic masses we demonstrated that the use of suction at tissue procurement can be counterproductive. However, more technical refinements tailored to specific needle types may be needed to further optimize the clinical outcomes of tissue acquisition.

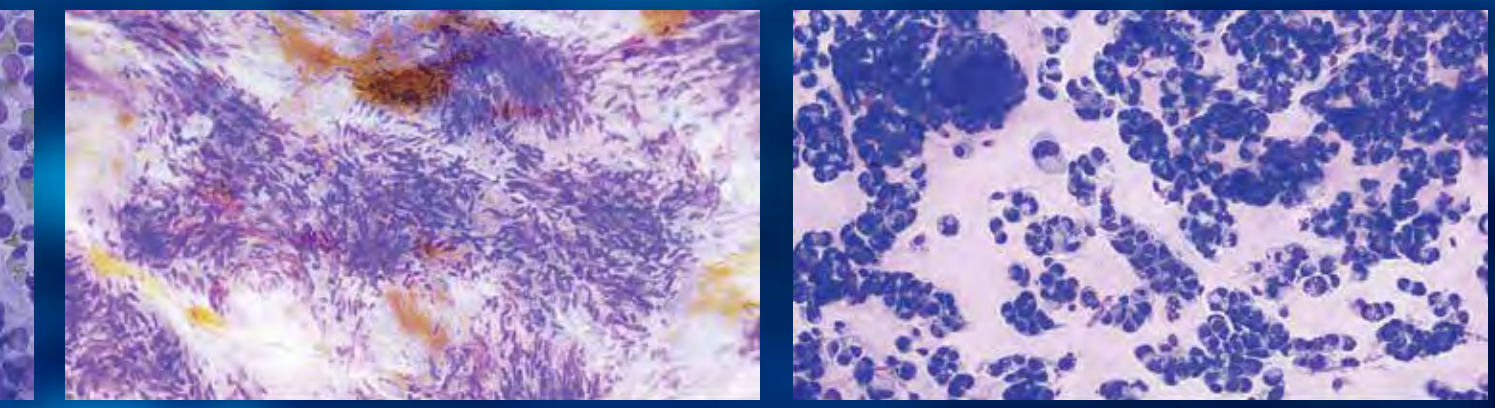


Tissue samples procured using new generation histology needles.

Interventional EUS has achieved significant milestones in the past five years particularly pertaining to the management of pancreatic fluid collections (PFCs) and biliary ductal drainage. In a landmark randomized trial (MISER) our team has shown that endoscopy is superior to minimally invasive surgical techniques for the treatment of infected necrotizing pancreatitis. The composite of major complications and the systemic inflammatory response syndrome (SIRS) scores were significantly less for the endoscopic approach. Additionally, the endoscopic transluminal approach has been technically simplified by the recent development of single-step drainage technique using the lumen-apposing metal stent platform. However, one burning question remains: does endoscopic necrosectomy at index intervention yield better outcomes than a step-up approach that incorporates transluminal drainage followed by necrosectomy on *as required basis?* To investigate this question the CIE team has assembled an impressive team of international centers in Asia and Europe to conduct a randomized trial that will commence in 2019.



Improved SIRS with endoscopic approach in infected necrotizing pancreatitis



"The clinical expertise and excellence in diagnostic and interventional EUS is exemplified not only by an exceptional number of more than 4,000 procedures per year, but also by the fact that the CIE is leading in some of the most innovative EUS studies being conducted around the globe."

- Marco Bruno, MD, PhD | Erasmus Medical Center | The Netherlands

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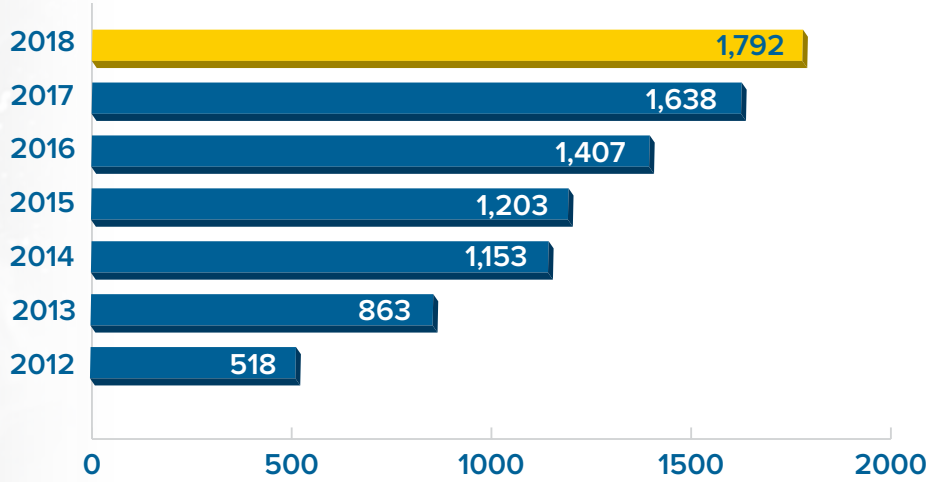
Biliary drainage observations from two randomized trials (Seoul, S. Korea and CIE, Orlando-Florida) conducted in 2018 show that the outcomes of EUS are not inferior to trans-papillary drainage at ERCP. However, these investigations were conducted at high-volume referral centers. Whether these superior outcomes can be replicated at non-tertiary units is unclear. Additionally, we do not know whether the extra-hepatic or intra-hepatic approach is superior and if the development of dedicated devices will further advance the technique.

Technological innovation included the development of a forward-view echoendoscope around 7 years ago, but experience has been limited. Whether the forward-view echoendoscope will be particularly valuable for specific indications such as sampling of hilar masses or drainage of complex fluid collections adjacent to the proximal stomach is unclear. We aim to advance the field of interventional EUS by addressing these questions via hypothesis-driven, well-designed, randomized trials.

ERCP PROGRAM

Procedure Volume



Adverse Events

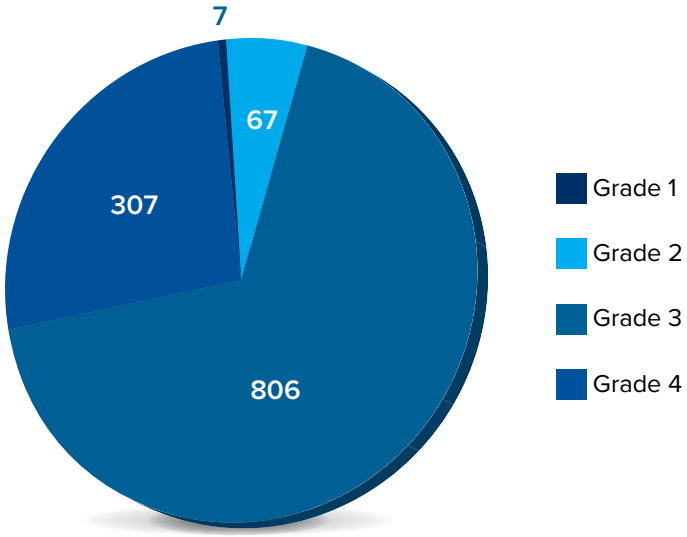
Death	0
Perforation	1
Bleeding	4
Cholangitis	7
Pancreatitis	39

ERCP Outcomes

Technical Success	1,771
Technical Failures	21
Altered Anatomy	14
Failed Cannulation	7

Procedures by ASGE Complexity Level

Single-operator Cholangioscopy = 133



"The scientific investigations conducted by the faculty at the Center for Interventional Endoscopy are outstanding.

Their experience is tremendous and their work is highly accomplished particularly on interventions in walled-off necrosis and disconnected pancreatic duct syndrome. I hope that their academic productivity will continue to increase and flourish in the years ahead."

- Santhi Swaroop Vege, MD | Mayo Clinic, Rochester

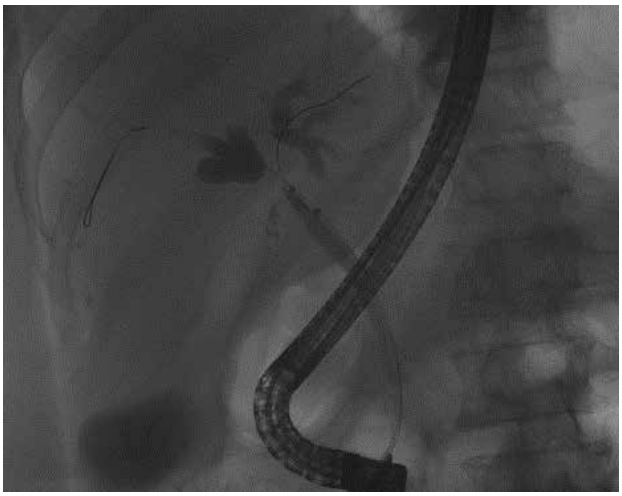
Research

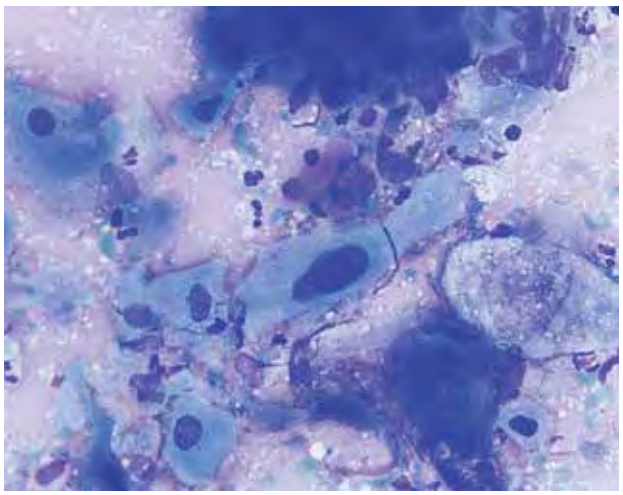
Strictures in the bile duct are difficult to evaluate as diagnosing an underlying malignancy can be technically challenging. While EUS-guided FNA is ideally suited for evaluating distal bile duct strictures, proximal strictures are more difficult to evaluate and sample by EUS. Cholangioscopy-guided biopsy is a promising modality for diagnosing malignancy in patients with indeterminate biliary strictures. Meta-analysis of published studies reveals a diagnostic accuracy of 65-80% depending on the presence or absence of underlying sclerosing cholangitis. However, the ideal technique of tissue acquisition and specimen processing is unclear. In a randomized trial of 60 patients with indeterminate biliary strictures we demonstrated that by performing three biopsies a diagnostic accuracy of 90% can be achieved using the off-site specimen processing technique.

Biomarkers are actively being investigated as a noninvasive method for diagnosing cancer. In a prospective study supported by a grant from the American College of Gastroenterology, Dr. Uday Navaneethan is exploring the role of lipidomics in differentiating benign from malignant biliary strictures. The findings of the study may be particularly relevant for patients with biliary strictures in the setting of primary sclerosing cholangitis to diagnose or exclude underlying malignancy.

Stones in the bile duct can be difficult to treat when large in size and if the diameter of the stone exceeds that of the distal bile duct. Although large balloon sphincteroplasty and cholangioscopy-guided laser lithotripsy are two common rescue techniques, it is unclear which modality is superior. In an attempt to develop a treatment algorithm, a randomized trial was conducted comparing balloon sphincteroplasty and laser lithotripsy for treatment of large bile duct stones measuring more than 12mm in size. Our study demonstrated that a stone-duct size ratio ≥1.2 and not using laser lithotripsy were significantly associated with treatment failure.

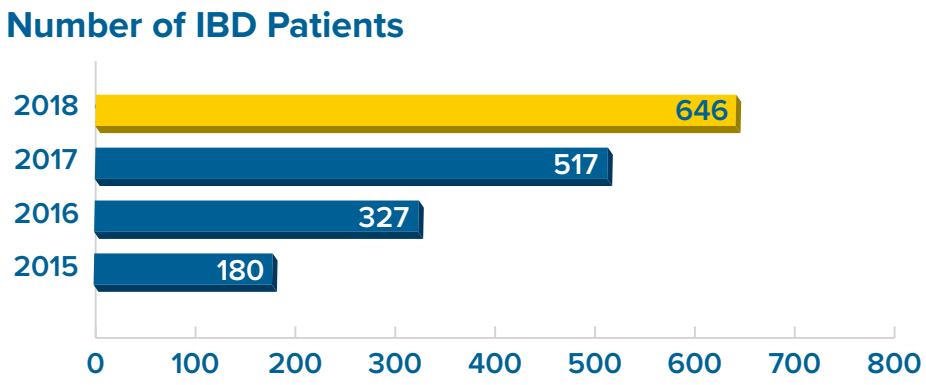
An **NIH-funded multicenter randomized trial** evaluating the role of indomethacin in post-ERCP pancreatitis is currently underway. CIE is one of nine centers across the United States participating in this study and has enrolled the second largest number of study participants to-date.





Evaluation of biliary stricture at single-operator cholangioscopy.

INFLAMMATORY BOWEL DISEASE PROGRAM



The mission of the program is to provide the highest quality of care for patients with inflammatory bowel diseases (IBD) by adopting a multidisciplinary approach.

The IBD multidisciplinary team comprises a medical gastroenterologist, colorectal surgeons, dietitians, pathologists, radiologists, psychologists/psychiatrists and wound care (stoma) specialists who work together to deliver evidence-based, comprehensive care to our patients. Our clinical trial developmental program enables us to improve existing therapies and provide novel treatment for patients with ulcerative colitis and Crohn's disease.

Additionally, at CIE, we place special emphasis on the endoscopic management of IBD complications that include strictures, fistulae and leaks. We utilize chromoendoscopy and confocal imaging to investigate early-stage neoplasia and offer endoscopic mucosal resection as a treatment option.

New Initiatives

- Global Interventional IBD Group: CIE is part of an international subspecialty group that coordinates clinical, educational, and investigational endoscopy-based research trials for patients with IBD.
- Clinical Trials: Our research team comprises four study coordinators and one IBD specialist who is the principal investigator. The team coordinates 15 studies that include both investigator-initiated and pharmaceutical-sponsored (phase 2 to 4) investigations.

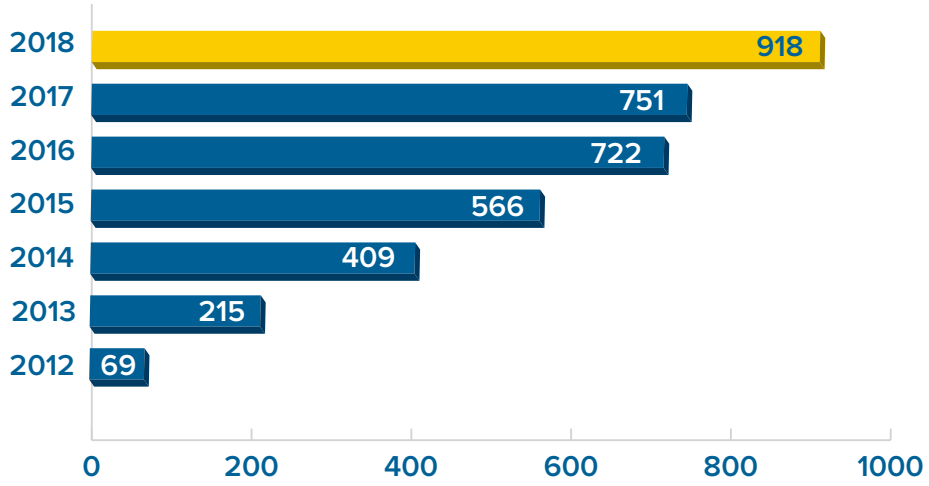
- IBD Board: Modeled on functioning of the tumor board, the IBD program conducts periodic review of challenging cases with input from the IBD specialist, colorectal surgeons, radiologists and pathologists to coordinate medical, endoscopic and surgical management. The IBD board facilitates excellence in patient management via multidisciplinary evaluations.
- Endoscopic stricturotomy is being offered recently as a treatment option for patients with refractory luminal strictures.

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.

RESECTION AND THIRD SPACE ENDOSCOPY PROGRAM

Endoscopic Mucosal Resection (EMR) Procedures



Tunneling

Myotomy

Mucosal Resection

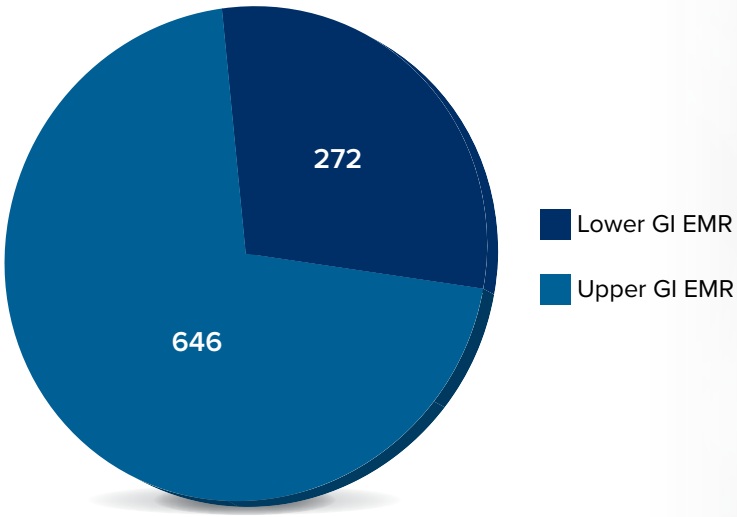
Submucosal Dissection

The number of endoscopic mucosal resection (EMR) procedures performed at CIE has steadily increased to almost 1,000 procedures per year – 67% of procedures involve the upper GI tract, and the number of EMRs performed for laterally spreading duodenal lesions has increased significantly over the past five years. In 2018, the endoscopic submucosal dissection portfolio was initiated by Drs. M. Hasan and J.Y. Bang and 28 procedures have been performed to date.

The Third Space Endoscopy program was started in late 2017 with Dr. J. Y. Bang performing the first Per-oral Endoscopic Myotomy (POEM) procedure. Subsequently, 27 procedures have been performed at CIE that include Submucosal Tunneling Endoscopic Resection (STER).

Research

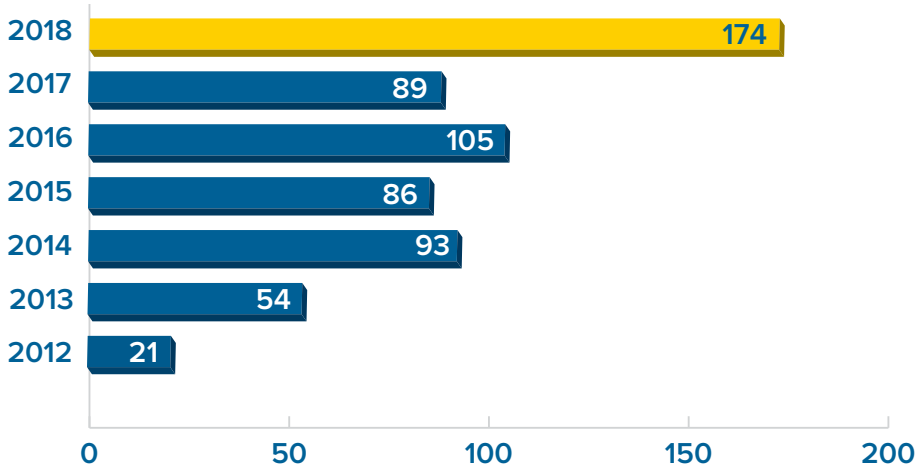
CIE was part of a multi-center United States trial that compared prophylactic clip placement versus conservative management after the removal of large colon polyps. The study demonstrated that prophylactic clips were particularly beneficial when placed after removal of large right sided colon polyps as they decreased the rates of post-procedure bleeding.



LUMINAL INTERVENTIONS PROGRAM

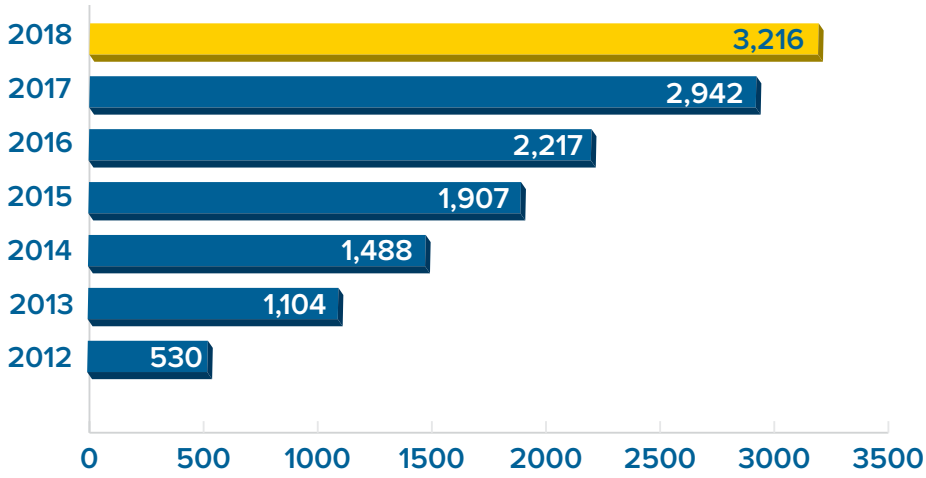
Radiofrequency Ablation

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.



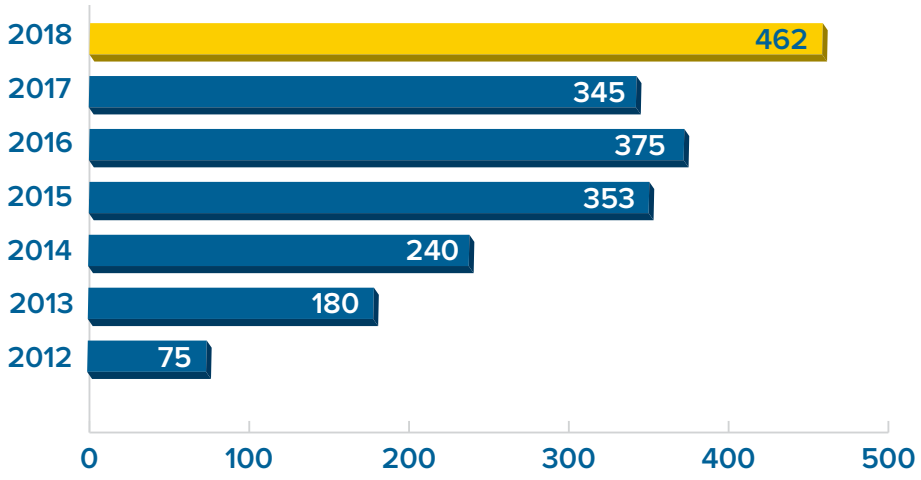
Other Interventions

- 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, and treatment of small bowel strictures and polyps.
- Clinical trials evaluating the utility of motorized spiral enteroscope will commence in 2019.



Digestive Diseases Week 2018 | Washington, DC

- Ji Young Bang, Udayakumar Navaneethan, Muhammad Hasan, Bryce Sutton, Robert Hawes, Shyam Varadarajulu. Superiority of EUS-guided RFA over CPN for palliation of pain in pancreatic cancer in a randomized trial.

Pancreas Club Annual Meeting | Washington, DC

- Ji Young Bang, Pablo Arnoletti, Udayakumar Navaneethan, Muhammad Hasan, Robert Hawes, Shyam Varadarajulu. Minimally Invasive Surgery versus Endoscopy Randomized (MISER) Trial for Necrotizing Pancreatitis.

United European Gastroenterology Week | Vienna, Austria

- Ji Young Bang, Udayakumar Navaneethan, Muhammad Hasan, Konrad Krall, Robert Hawes, Shyam Varadarajulu. Optimizing outcomes of single operator cholangioscopy (SOC)-guided biopsies: Results of a randomized trial.
- Ji Young Bang, Sachin Kirtane, Konrad Krall, Udayakumar Navaneethan, Muhammad Hasan, Robert Hawes, Shyam Varadarajulu. Changing trend in EUS-guided tissue acquisition: In memoriam - FNA, birth - FNB.

Honors and Awards

United European Gastroenterology Week, Vienna, Austria

The study “Changing trend in EUS-guided tissue acquisition: In memoriam - FNA, birth - FNB” was honored at the United European Gastroenterology Week 2018 with a Travel Award.

Annual Meeting of Florida Gastroenterologic Society

James L. Borland, Sr., Memorial Award presented to Dr. Robert Hawes

RESEARCH IN 2018

EUS-Related Studies

Multicenter randomized trial comparing direct endoscopic necrosectomy versus step-up transluminal interventions (DESTIN) in infected necrotizing pancreatitis.
Primary Aim: Compare rate of reinterventions between treatment groups.

Randomized trial comparing EUS and radiology-guided percutaneous liver biopsy techniques.
Primary Aim: Compare diagnostic adequacy and histological characteristics between techniques.

Prospective evaluation of the utility of forward-view echoendoscope.
Primary Aim: Evaluate the utility of the echoendoscope for specific diagnostic and therapeutic interventions.

Endoscopic ultrasound guided liver biopsy using a 19-gauge fine needle biopsy needle.
Primary Aim: To determine the diagnostic adequacy of the liver biopsy specimen obtained using a 19-gauge FNB needle.

Registry for Endoscopic Ultrasound (EUS) evaluation of pancreatic cysts.
Primary Aim: Prospective database to study the natural history of pancreatic cyst lesions.

EUS-Guided pancreatic cyst ablation.
Primary Aim: To maintain data on all patients undergoing EUS-guided ablation of pancreatic cysts using paclitaxel and gemcitabine and to assess its treatment efficacy.

Registry of endoscopic management of pancreatic fluid collections (PFCs).
Primary Aim: Prospective database to study the algorithm-based 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 ductal clearance 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.

Results of ERCP in sphincter of Oddi dysfunction (RESPOND).
Primary Aim: Assessment of symptom response following ERCP in sphincter of Oddi dysfunction.

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.

"AdventHealth's Center for Interventional Endoscopy continues to distinguish itself as one of the world's premier centers for therapeutic endoscopy.

It all begins with a patient-centric approach of providing timely and compassionate world-class care. It then blossoms into a wide spectrum of innovation which culminates in a portfolio of top-notch research such as the MISER trial which transforms our approach to patient care."

- John J. Vargo II, MD, MPH, FASGE | President-Elect | American Society for Gastrointestinal Endoscopy

A Prospective Multicenter Cohort Study Evaluating The Association Between Competency In Trainees And Clinical Outcomes In ERCP: The Act-ERCP Study.
Primary Aim: To assess the relationship between trainee skills (overall, technical and cognitive) and clinical outcomes (technical success and adverse events).

Lipidomics, Proteomics and Volatile Organic Compounds Biomarkers in Bile and Serum.
Primary Aim: To identify and evaluate proteomics, lipidomics, micro-RNAs and VOCs changes in blood and bile that may give specific indications of malignant cell metabolism in cancer. By extensive characterization of these tumor-specific changes, we aim to determine their usefulness as biomarkers in the early diagnosis of cancer.

Bariatrics-Related Study

Randomized, Double-Blind, Sham-Controlled, Prospective, Multi-Center Pilot Study to Evaluate the Safety and Effectiveness of Duodenal Mucosal Resurfacing (DMR) Using the Revita™ System in the Treatment of Type 2 Diabetes (T2D).
Primary Aim: To assess the safety of the Fractyl Revita™ System for the treatment of subjects with T2D suboptimally controlled on 2 oral antidiabetic medications; to assess the effect of DMR versus Sham procedures on glycemic endpoints 24 weeks after the procedure; to assess the effect of DMR on glycemic endpoints 48 weeks after the randomized procedure for durability of effect determination.

IBD-Related Studies

Entyvio (vedolizumab) long-term safety study: An international observational prospective cohort study comparing vedolizumab to other biologic agents in patients with Ulcerative Colitis (UC) or Crohn's Disease (CD).
Primary Aim: 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.
Primary Aim: To determine the effect of triple combination therapy with an anti-integrin (vedolizumab IV), a TNF antagonist (adalimumab SC), and an immunomodulator (oral methotrexate) on endoscopic remission at Week 26.

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: To evaluate the efficacy of JNJ-64304500 to reduce the CDAI score from baseline. To evaluate the safety of JNJ-64304500.

RESEARCH IN 2018

GS-US-419-3895: A Phase 3, Double-blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Crohn's Disease.
Primary Aim: To evaluate the efficacy of filgotinib as compared to placebo in establishing clinical remission by PRO2 at Week 10.

GS-US-418-3898: A Combined Phase 2b/3, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Safety and Efficacy of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Ulcerative Colitis
Primary Aim: To evaluate the efficacy of filgotinib as compared to placebo in establishing EBS remission at Week 10.

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: 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.

GS-US-419-3896 - A Long Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Crohn's Disease.
Primary Aim: To observe the long-term safety of filgotinib in subjects who have completed or met protocol specified efficacy discontinuation criteria in a prior Gilead-sponsored filgotinib treatment.

GS-US-418-3899 - A Long Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Ulcerative Colitis.
Primary Aim: To observe the long-term safety of filgotinib in subjects who have completed or met protocol specified efficacy discontinuation criteria in a prior Gilead-sponsored filgotinib treatment.

An open label, long term safety trial of BI 655130 treatment in patients with moderate to severely active ulcerative colitis who have completed previous BI 655130 trials.
Primary Aim: To evaluate the long-term safety and efficacy of BI 655130 in patients with moderate to severely active ulcerative colitis, who have completed treatment in previous trials.

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: 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 and who are Week 6 non-responders.

Phase 2/3, Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Subject with Moderately to Severely Active Crohn's Disease.
Primary Aim: To evaluate the clinical efficacy of guselkumab in participants with Crohn's disease; To evaluate the safety of guselkumab.

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: To evaluate the efficacy of filgotinib, when compared to placebo, in establishing clinical remission 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: To 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); To 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).

CLINICAL TRIALS	SPONSOR
Multicenter randomized trial comparing direct endoscopic necrosectomy versus step-up transluminal interventions (DENSTIN) in infected necrotizing pancreatitis.	AdventHealth
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	AdventHealth
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
Results of ERCP in sphincter of Oddi dysfunction (RESPOND).	Sponsor
A Prospective Multicenter Cohort Study Evaluating The Association Between Competency In Trainees And Clinical Outcomes In ERCP: The Act-ERCP Study	Sponsor
Randomized trial examining the impact of pancreatic duct stent placement in patients with acute necrotizing pancreatitis in the prevention of walled-off necrosis.	AdventHealth
Randomized, Double-Blind, Sham-Controlled, Prospective, Multi-Center Pilot Study to Evaluate the Safety and Effectiveness of Duodenal Mucosal Resurfacing Using the Revita™ System in the Treatment of Type 2 Diabetes.	Sponsor
Comparison of On-Site versus Off-Site Evaluation of Cholangioscopy-Guided Biopsies of the Bile Duct	AdventHealth
Lipidomics, Proteomics, Micro RNAs and Volatile Organic Compounds Biomarkers in Bile and Serum in the Diagnosis of Malignant Biliary Strictures	Sponsor
Registry of endoscopic management of pancreatic fluid collections (PFCs)	AdventHealth
Outcomes in the management of pancreatic fluid collection	Advent Health
Registry for Endoscopic Ultrasound (EUS) Evaluation of Pancreatic Cysts	AdventHealth
EUS-guided pancreatic cyst ablation	AdventHealth
A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of HUMIRA® (Adalimumab) in Patients with Moderately to Severely Active Ulcerative Colitis (UC)	Sponsor
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
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
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
GS-US-419-3895: A Phase 3, Double-blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Crohn's Disease	Sponsor
GS-US-418-3898: A Combined Phase 2b/3, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Safety and Efficacy of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Ulcerative Colitis	Sponsor
GS-US-419-3896 - A Long Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Crohn's Disease	Sponsor
GS-US-418-3899 - A Long Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Ulcerative Colitis	Sponsor
An open label, long term safety trial of BI 655130 treatment in patients with moderate to severely active ulcerative colitis who have completed previous BI 655130 trials	Sponsor

PUBLICATIONS IN 2018

Peer-Reviewed Publications

Bang JY, Hebert-Magee S, Navaneethan U, Hasan MK, Hawes RH, Varadarajulu S. EUS-guided fine needle biopsy of pancreatic masses can yield true histology. GUT 2018; 67: 2081-84

Bang JY, Navaneethan U, Hasan MK, Hawes RH, Varadarajulu S. Endoscopic Ultrasound-guided specimen collection and evaluation techniques affect diagnostic accuracy. Clin Gastroenterol Hepatol 2018; 16: 1820-1828

Bang JY, Wilcox CM, Navaneethan U, Hasan MK, Peter S, Christein JD, Hawes RH, Varadarajulu S. Impact of Disconnected Pancreatic Duct Syndrome on the Endoscopic Management of Pancreatic Fluid Collections. Ann Surg 2018; 267: 561-568

Teoh AYB. Dhir V, Kida, M, Yasuda I, Jin ZD, Seo DW, Almadi M, Ang TL, Hara K, Hilmi I, Itoi T, Lakhtakia S, Matsuda K, Pausawasdi N, Puri R, Tang RS, Wang HP, Yang AM, Hawes R, Varadarajulu S et al. Consensus guidelines on the optimal management in interventional EUS procedures: results from the Asian EUS group RAND/UCLA expert panel. GUT 2018; 67: 1209-1228

Bang JY, Navaneethan U, Hasan MK, Sutton B, Hawes R, Varadarajulu S. Non-superiority of lumen-apposing metal stents over plastic stents for drainage of walled-off necrosis in a randomised trial. Gut. 2018 [Epub ahead of print]

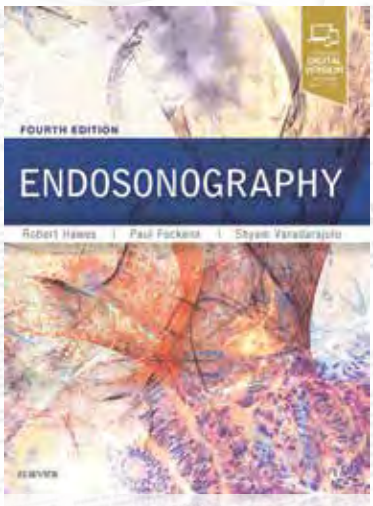
Bang JY, Arnoletti JP, Holt BA, Sutton B, Hasan MK, Navaneethan U, Feranec N, Wilcox CM, Tharian B, Hawes RH, Varadarajulu S. An Endoscopic Transluminal Approach, Compared to Minimally Invasive Surgery, Reduces Complications and Costs for Patients With Necrotizing Pancreatitis. Gastroenterology 2018 [Epub ahead of print]

Ali S, Hawes RH, Kadkhodayan K, Rafiq E, Navaneethan U, Bang JY, Varadarajulu S, Hasan MK. Utility of rapid onsite evaluation of touch imprint cytology from endoscopic and cholangioscopic forceps biopsy sampling (with video). Gastrointest Endosc 2018 [Epub ahead of print]

Bang JY, Kirtane S, Krall K, Navaneethan U, Hasan M, Hawes R, Varadarajulu S. In memoriam: Fine-needle aspiration, birth: Fine-needle biopsy: The changing trend in endoscopic ultrasound-guided tissue acquisition. Dig Endosc. 2018 [Epub ahead of print]

Reza, JA, Fruchter A, Varadarajulu, S, Arnoletti JP. A large intussuscepting gastric lipoma. J Gastrointest Surg 2018; 22: 1299-1300

Bang JY, Navaneethan U, Hasan MK, Hawes RH, Varadarajulu S. Stent placement by EUS or ERCP for primary biliary decompression in pancreatic cancer: a randomized trial (with videos). Gastrointest Endosc 2018; 88: 9-17



We take pride in highlighting our rate of abstract-to-manuscript conversion which nears 100%. Publication of scientific findings in high-impact peer-reviewed clinical journals is one of our top priorities.

The 4th edition of ENDOSONOGRAPHY was released in August 2018 at Orlando Live Endoscopy by Dr. K. R. Palaniswamy, Senior Consultant in Gastroenterology, Apollo Hospitals, India.

Bang JY, Sutton B, Hawes RH, Varadarajulu S. EUS-guided celiac ganglion radiofrequency ablation versus celiac plexus neurolysis for palliation of pain in pancreatic cancer: a randomized controlled trial (with videos). Gastrointest Endosc. 2019; 89: 58-66

Guda NM, Muddana V, Whitcomb DC, Levy P, Garg P, Cote G, Uc A, Varadarajulu S et al.

Recurrent Acute Pancreatitis: International State-of-the-Science Conference with Recommendations. Pancreas 2018; 47: 653-666

Bang JY, Hebert-Magee S, Navaneethan U, Hasan MK, Hawes RH, Varadarajulu S. Randomized trial comparing the Franseen and Fork-tip needles for EUS-guided fine-needle biopsy sampling of solid pancreatic mass lesions. Gastrointest Endosc 2018; 87: 1432-1438

Bang JY, Varadarajulu S. Stent Tracker app: Novel method to track patients with indwelling lumen-apposing metal stents Endoscopic Ultrasound 2018; 7: 69-70

Bang JY, Varadarajulu S. How the Experts Do It: Step-by-Step Guide. Gastrointest Endosc Clin N Am 2018; 28: 251-260

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

Rex, DK, Sieber M, Lehman GA, Webb D, Schmitt B, Kressel AB, Bang JY et al. A double-reprocessing high-level disinfection protocol does not eliminate positive cultures from the elevators of duodenoscopes. Endoscopy 2018; 50: 588-96

Kumar N, Abu Dayyeh BK, Lopez-Nava Breviere G, Galvao Neto MP, Sahdala NP, Shaikh SN, Hawes RH et al. Endoscopic sutured gastroplasty: procedure evolution from first-in-man cases through current technique. Surg Endosc 2018; 32: 2159-2164

Bang JY, Bourke MJ. Selection of EMR and ESD for Laterally Spreading Lesions of the Colon. Curr Treat Options Gastroenterol 2018; 16: 376-385

Bang JY, Varadarajulu S. EUS-guided biliary drainage versus ERCP for the primary treatment of malignant distal biliary obstruction: time for a large randomized study. Response Gastrointest Endosc 2018; 88: 572

Bang JY, Varadarajulu S. No difference does not always mean equivalent. Response; Gastrointest Endosc 2018; 88: 573-74

Bang JY, Varadarajulu S. EUS-Guided Fine Needle Tissue Acquisition for Pancreatic Solid Lesions: Are We at the End of Fine Needle Aspiration? Reply. Clin Gastroenterol Hepatol 2018; 16: 1362

ORLANDO LIVE ENDOSCOPY

AUGUST 29-31 | 2018

This three-day event was attended by 315 delegates from 28 countries. 11 international faculty from 7 countries performed 42 procedures that were transmitted live. In addition to didactic lectures, a self-assessment program and an industry-sponsored symposium were conducted as part of the convention. The hands-on lab was attended by 130 delegates and a didactic session on bariatrics was led by Dr. Vivek Khumbari from Johns Hopkins University. The symposium received a delegate rating of 4.8 on a scale of 0 to 5.

315 delegates from 28 countries attended

11 international faculty from 7 countries performed 42 procedures that were transmitted live

130 delegates attended a hands-on lab

2nd Annual
ROBERT FULBRIGHT MEMORIAL LECTURE

Introduction by Kari Vargas
Chief Operating Officer | AdventHealth Orlando

ROBERT FULBRIGHT MEMORIAL LECTURE was delivered by Professor Michael Bourke from Sydney, Australia.

CONFERENCE ATTENDEES

COUNTRIES REPRESENTED AT ORLANDO LIVE ENDOSCOPY 2018

Argentina
Australia
Belgium
Bolivia
Brazil
Canada
Chile
China
Colombia
Costa Rica
Czech Republic
Denmark
El Salvador
Germany
Greece
India
Israel
Japan
Kenya
Mexico
Paraguay
Peru
Russian Federation
Saudi Arabia
Thailand
The Netherlands
United Kingdom
United States

EDUCATIONAL SYMPOSIUMS

4th Annual Clinical Updates in Inflammatory Bowel Disease

April 21, 2018 | Orlando, Florida

This one-day event had an attendance of 203 delegates. It provided participants a comprehensive education in inflammatory bowel disease evaluation and management. The program covered six major topics:

1. Treatment options for the medical management of ulcerative colitis.
2. Understand the role of surgery in the management of complications of Crohn's disease.
3. How to evaluate, manage and monitor treatment of patients with IBD.
4. Management of IBD in women.
5. Diagnosing colon dysplasia/cancer in IBD patients and use of chromoendoscopy.
6. Peri-operative management of IBD.

Faculty (from left to right):
Bo Shen, MD, Miguel Regueiro, MD,
Francis Farraye, MD, Udayakumar Navaneethan, MD,
Raymond Cross, MD, Edward Loftus, MD and
Yehuda Chowers, MD

For more information regarding future events, visit AHCIEevents.com.

6TH ANNUAL ORLANDO LIVE EUS 2019

August 28-30 | 2019

AdventHealth Nicholson Center
Celebration, FL

Invited Faculty

Pierre H. Deprez,
MD, PhD | Belgium

Tomas Hucl, MD, PhD
Czech Republic

Takao Itoi, MD, PhD,
FACG, FASGE | Japan

Nirag C. Jhala,
MD, MIAC | USA

Darshana Jhala, MD,
B MUS, FCAP | USA

Michael Levy, MD
USA

Fauze Maluf-Filho,
MD, PhD, FASGE | Brazil

Jayapal Ramesh, MD
United Kingdom

Thomas Rosch, MD, PhD
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