Committed to Excellence in Patient Care, Clinical Research and Education
Dear Colleagues,

I am pleased to present the 4th 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, Digestive Diseases Week (DDW) 2016 presentations and other milestones achieved in 2015.

CIE retained its status in 2015 as the number one center in Florida by volume - performing 6216 complex endoscopic procedures. Our endoscopic ultrasound (EUS) unit remained the largest volume center in the United States for the second consecutive year performing 2753 procedures. Our procedural volume was matched only by the number of clinical trials and publications which originated from CIE. Our faculty published 55 peer-reviewed manuscripts while 24 abstracts were accepted for presentation at DDW 2016. Given our large procedural volume, as evident from the DDW presentations, our clinical trials are mostly prospective, single center and very often randomized in design. The research program at CIE is robustly vibrant with 10 ongoing randomized trials and 6 prospective clinical trials. Endosonography, a textbook which was edited by the CIE faculty, was awarded the British Medical Association’s first prize for excellence in postgraduate medical education.

We look forward to CIE’s continued growth in the upcoming years by fulfilling its mission of providing world class clinical care, conducting cutting-edge clinical research and training the next generation of endoscopists and minimally invasive surgeons.

Sincerely,

Shyam Varadarajulu, MD
Medical Director
Center for Interventional Endoscopy
Robert Hawes, MD
Medical Director
Institute for Minimally Invasive Therapy

Shyam Varadarajulu, MD
Medical Director
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Xiang Zhu, Biostatistician
Patients are referred to CIE for expert care from across the United States as well as internationally. In 2015, patients were referred nationally from 37 states as well as from 8 countries. More than 50% of patients treated at CIE originated from outside the Tri-County area.
CIE is conducting randomized trials comparing endoscopy versus surgery and metal versus plastic stents for the treatment of walled-off pancreatic necrosis (WOPN).

The largest randomized trial involving 352 patients with pancreatic masses will be concluded in 2016. The diagnostic sensitivity of 22 versus 25 gauge needles is being compared while evaluating the utility of suction in EUS-guided sampling of pancreatic masses.

Excellence in clinical care coupled with cutting-edge clinical research helped make CIE the #1 Center in North America for the second consecutive year.

**Interventions Volume**
- Celiac Plexus Interventions = 159
- Drainage of Pancreatic Fluid Collections = 64
- Ductal Drainages = 10
- Others = 18

**Diagnostic** = 1671  
**FNA** = 831  
**Interventions** = 251
ERCP Procedure Volume

- CIE is conducting translational research studies to differentiate benign from malignant bile duct strictures - particularly in the setting of Primary Sclerosing Cholangitis (PSC).

- Randomized trials are ongoing at CIE comparing metal versus plastic stents for preoperative biliary decompression in pancreatic cancer and evaluating the utility of on-site cytopathology in single operated cholangioscopy-guided biopsies of indeterminate biliary strictures.

ERCP OUTCOMES:
- Technical Success = 1185 (98.5%)
- Technical Failures = 18 (1.5%)
  - Altered Anatomy = 10
  - Failed Cannulation = 8
- Complications = 34 (2.8%)
  - Perforation = 0 (0%)
  - Bleeding = 6 (0.5%)
  - Pancreatitis = 11 (.91%)
  - Cholangitis = 16 (1.33%)
  - Death = 1 (.08%)

ERCP VOLUME BY GRADE

GRADE 1:
- Biliary stent removal/exchange
- Diagnostic cannulation of ducts tissue sampling

GRADE 2:
- Biliary stone extraction <10 mm
- Treatment of bile leaks, treatment of extrahepatic strictures

GRADE 3:
- 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:
- Removal of internally migrated pancreatic stents, stones (>5 mm)
- Pseudocyst drainage or necrosectomy
- Ampullectomy
- ERCP after Whipple procedure/Roux-en-Y bariatric surgery

ERCP Volume by Year:
- 2012: 518
- 2013: 863
- 2014: 1153
- 2015: 1203

ERCP outcomes by grade:
- GRADE 1: 518 (48%)
- GRADE 2: 863 (75%)
- GRADE 3: 1153 (92%)
- GRADE 4: 1203 (100%)
Clinical trials evaluating the utility of Motorized Spiral Enteroscope in Small Bowel Diseases will commence in 2016.

Other Interventions

- EGD
- Colonoscopy
- Enteral Feeding Tubes
- Fistula Closure (suturing, clips)
- Luminal Stenting
- Glue Injection
Randomized trials evaluating the utility of subcutaneous octreotide in preventing bleeding after endoscopic mucosal resection of duodenal and ampullary masses are underway.

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.
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.

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 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:

The IBD program at CIE is a part of the Crohn’s and Colitis Foundation of America (CCFA) clinical research alliance, a group of select medical centers testing new drug therapies for ulcerative colitis and Crohn’s disease. Another highlight of the IBD program at CIE is its involvement in several clinical trials evaluating Crohn’s disease, ulcerative colitis and primary sclerosing cholangitis:

- Bio-markers in the early diagnosis of cholangiocarcinoma in primary sclerosing cholangitis.
- Research registry evaluating the utility of chromoendoscopy in IBD.
- Long term follow-up of patients on adalimumab for the treatment of patients with ulcerative colitis and Crohn’s disease.
- A Phase 3 study of Entyvio (vedolizumab) in patients with primary sclerosing cholangitis and ulcerative colitis.
- 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.

Annual Symposium Advances Understanding of 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 who share their expertise and explore the latest advances in the treatment of IBD.
Research Highlights

- Ten randomized trials and six prospective studies are currently in progress evaluating cutting edge endoscopic techniques or novel technologies.

- Our large procedural volume enables us to conduct well-designed, prospective, randomized, single-center, clinical trials.

- A major focus of CIE is to innovate and attempt to answer critically important questions in the field of gastrointestinal endoscopy.

Active Clinical Trials

- Minimally Invasive Surgery vs. Endoscopy Randomized (MISER) Trial for Symptomatic Walled-Off Pancreatic Necrosis
  
  **Primary Aim:** Compare the composite of adverse events between minimally invasive surgery and endoscopy for treatment of walled-off necrosis.

- Comparison of On-site versus Off-site evaluation of Cholangioscopy-guided Biopsies of the Bile Duct
  
  **Primary Aim:** Compare the diagnostic sensitivity of Rapid On-Site Evaluation (ROSE) 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:** Compare rate of adverse events prior to surgery.

- 22 Gauge Versus 25 Gauge: Suction-in, No-suction (SINS) Randomized Trial for EUS-FNA of Pancreatic Masses
  
  **Primary Aim:** Compare the rate of re-interventions to achieve treatment success between cohorts.

- Stent vs Indomethacin for Preventing Post-ERCP Pancreatitis: The SVI Trial - A Multicenter Randomized Noninferiority Clinical Trial of Rectal Indomethacin Alone vs. Indomethacin & Prophylactic Pancreatic Stent Placement for Preventing Post-ERCP Pancreatitis in High-Risk Cases
  
  **Primary Aim:** Compare the rate of post-ERCP pancreatitis between indomethacin versus pancreatic duct stenting and indomethacin.

- Registry for Endoscopic Ultrasound (EUS) Evaluation of Pancreatic Cysts
  
  **Primary Aim:** Prospective database to study the natural history of pancreatic cyst lesions

- Randomized trial comparing the use of single-operator peroral cholangioscopy-guided laser lithotripsy (POCLL) versus Endoscopic Balloon Sphincteroplasty (EBS) for removal of difficult bile duct stones
  
  **Primary Aim:** Compare the rate of re-interventions to achieve treatment success 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:** Compare the rate of endoscopic re-interventions between metal and plastic stents for walled-off necrosis.
- **EUS-guided pancreatic cyst ablation**
  *Primary Aim:* Registry to evaluate the role and utility of chemotherapeutic agents in pancreatic cyst ablation.

- **Safety of endoscopic resection of large colorectal polyps: A randomized trial**
  *Primary Aim:* Compare the rate of delayed bleeding complications in patients undergoing endoscopic resection of large polyps between:
  A) Closing the mucosal defect after resection (Clip group) and
  B) Not closing the mucosal defect after resection (No clip group).

- **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.

- **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.

- **Lipidomics, Proteomics and Volatile Organic Compounds Biomarkers in Bile and Serum**
  *Primary Aim:* 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.
<table>
<thead>
<tr>
<th>NAME OF THE TRIAL</th>
<th>SPONSOR</th>
<th>DESIGN</th>
<th>ENROLLMENT GOAL</th>
<th>CURRENT ENROLLMENT</th>
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</thead>
<tbody>
<tr>
<td>Minimally Invasive Surgery vs. Endoscopy Randomized (MISER) Trial for Symptomatic Walled-Off Pancreatic Necrosis</td>
<td>Florida Hospital</td>
<td>Randomized</td>
<td>102</td>
<td>42</td>
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<tr>
<td>Stent vs. Indomethacin Randomized (NIH) Trial for Preventing Post-ERCP Pancreatitis</td>
<td>Grant Sub-Award</td>
<td>Randomized</td>
<td>144</td>
<td>0</td>
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<tr>
<td>Comparison of On-Site versus Off-Site Evaluation of Cholangioscopy-Guided Biopsies of the Bile Duct</td>
<td>Florida Hospital</td>
<td>Randomized</td>
<td>66</td>
<td>19 FH</td>
</tr>
<tr>
<td>Multicenter Randomized Trial Comparing Covered Metal and Plastic Stents for Preoperative Biliary Decompression in Pancreatic Cancer</td>
<td>Florida Hospital</td>
<td>Randomized</td>
<td>114</td>
<td>73 (UAB and FH)</td>
</tr>
<tr>
<td>Randomized Trial comparing Fully Covered, Self-Expanding Metal Stent (FCSEMS) and Plastic Stents for EUS-guided Drainage of Walled-off Necrosis (WON)</td>
<td>Florida Hospital</td>
<td>Randomized</td>
<td>62</td>
<td>0</td>
</tr>
<tr>
<td>Randomized Trial Comparing 22 and 25 G Needles for Pancreatic Mass FNA</td>
<td>Florida Hospital</td>
<td>Randomized</td>
<td>352</td>
<td>352 (Complete)</td>
</tr>
<tr>
<td>Prophylactic Octreotide to Prevent Post Duodenal EMR and Ampullectomy Bleeding</td>
<td>Florida Hospital</td>
<td>Randomized</td>
<td>124</td>
<td>31</td>
</tr>
<tr>
<td>Safety of Endoscopic Resection of Large Colorectal Polyps: A Randomized Trial</td>
<td>VA Medical Center</td>
<td>Randomized</td>
<td>&gt;20</td>
<td>16</td>
</tr>
<tr>
<td>Randomized trial comparing Captiva-tor tissue cassettes vs. no cassettes for endoscopic mucosal resection (EMR) in esophageal carcinoma</td>
<td>Florida Hospital</td>
<td>Randomized</td>
<td>30</td>
<td>0</td>
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<tr>
<td>Lipidomics, Proteomics, Micro RNAs and Volatile Organic Compounds Biomarkers in Bile and Serum in the Diagnosis of Malignant Biliary Strictures</td>
<td>Florida Hospital</td>
<td>Prospective</td>
<td>500</td>
<td>78</td>
</tr>
<tr>
<td>Volumetric Laser Endomicroscopy Signal Heterogeneity Analysis in the Evaluation of Patients with Biliary Strictures-A Pilot Ex-Vivo Study</td>
<td>Florida Hospital</td>
<td>Pilot Ex-Vivo</td>
<td>10</td>
<td>3</td>
</tr>
</tbody>
</table>
Publications In 2015

Peer-Reviewed Publications


- Bang JY, Hawes R, Varadarajulu S. A meta-analysis comparing ProCore and standard fine-needle aspiration needles for endoscopic ultrasound-guided tissue acquisition. Endoscopy. 2015 [Epub ahead of print]


Publication Highlights

- We take pride in highlighting our rate of abstract-to-manuscript conversion which exceeds 90%.
- Our CIE faculty makes it a priority to publish scientific findings in high-impact peer-reviewed clinical journals.


- Teoh AY, Ho LK, Dhir VK, Jin ZD, Kida M, Seo DW, Wang HP, Yang AM, Binmoeller KF, Varadarajulu S. A multiinstitutional survey on the practice of endoscopic ultrasound (EUS) guided pseudocyst drainage in the Asian EUS group. Endosc Int Open. 2015


- Bang JY, Hawes RH, Varadarajulu S. EUS-guided tissue acquisition: things are not always what they seem. Gastrointest Endosc. 2015; 81:1300-1


- Bang JY, Hawes RH, Varadarajulu S. Do fluoroscopy systems influence the level of scatter radiation exposure during endoscopic procedures? Dig Endosc. 2015; 27:629


Navaneethan U. Gut Inflammation in Primary Sclerosing Cholangitis and Autoimmune Sclerosing Cholangitis-Contrasting Pattern of Liver-gut Cross Talk. EBioMedicine. 2015; 30; 2:1310-1


Modha K, Navaneethan U. Diagnosis and management of primary sclerosing cholangitis-perspectives from a therapeutic endoscopist. World J Hepatol. 2015; 18; 799-805


Tharian B, George N, Navaneethan U. Endoscopy in the Diagnosis and Management of Complications of Inflammatory Bowl Disease. Inflamm Bowel Dis. 2015, Dec 29. [Epub ahead of print]
Podium Presentations

- Bang JY, Hasan M, Navaneethan U, Hawes RH, Varadarajulu S. Lumen Apposing Metal Stents (LAMS) for Drainage of Pancreatic Fluid Collections (PFCs): When and for whom? ASGE Topic Forum


- Osterman M, Navaneethan U, Roblin X, Glover S, Popa MA, Wyant T, James A, Lasch K, Rosario M. Association of Vedolizumab Drug Concentrations at or Before Week 6 with Remission at Week 14 in Moderately to Severely Active Ulcerative Colitis Patients from GEMINI 1. AGA Topic Forum

Poster Presentations


Bang JY, Holt BA, Hasan M, Navaneethan U, Hawes RH, Varadarajulu S. EUS-based Step-up Treatment Approach is Associated with Better Systemic Inflammatory Response and Clinical Outcomes in Walled-off Necrosis


Njei B, McCarty TR, Varadarajulu S, Navaneethan U. Comparative Effectiveness of Endoscopic Retrograde Cholangiopancreatography (ERCP) Based Modalities for the Diagnosis of Cholangiocarcinoma (CCA) in Primary Sclerosing Cholangitis (PSC): A Systematic Review and Meta-analysis.


Advanced Endoscopy Fellows Course In EUS Cytopathology

The objective of this one-day program was to enable endosonographers to perform a self-assessment of specimens for diagnostic adequacy. Twelve fellows from academic medical centers across the United States participated in this workshop where the CIE faculty demonstrated 12 EUS-FNA procedures and the trainees were proctored on EUS-related cytopathology by Dr. Shantel Hebert-Magee.
3rd Annual Orlando Live EUS

Orlando Live EUS is the single largest EUS-related symposium in the United states. In 2015, 228 delegates from 20 countries attended this meeting. Eight experts from 7 countries demonstrated procedures and the 42 procedures performed during this symposium were transmitted live. A hands-on lab had 103 attendees. The overall delegate rating of the symposium was 4.8 on a scale of 0 to 5.
Conference Attendees

Countries Represented at Orlando Live EUS 2015

[Map showing countries represented with flags]
International Symposiums

- **3rd Annual Orlando Live EUS 2015—September 2-4, 2015**
  228 delegates from 20 countries attended the Third Annual Orlando Live EUS symposium from September 2-4, 2015. 220 delegates were practicing gastroenterologists and 8 were fellows in training. 42 procedures were performed during the two days of live endoscopy sessions. A hands-on lab was attended by 103 registrants. The most highly rated components of the symposium were the cytopathology and interventional sessions which received a 92% outstanding rating.

- **The 4th Annual Orlando Live EUS will be held September 7-9, 2016**

Regional Symposiums

- **Clinical Dilemma with Pancreatic Cysts, Orlando, February 2015**
  This one-day CME program focused on the Clinical Dilemma with Pancreatic Cysts and was attended by 25 physicians from around the state of Florida. The national invited faculty included Dr. William Brugge (Massachusetts General Hospital) and Dr. Desiree Morgan (University of Alabama at Birmingham).

- **Clinical Updates on Inflammatory Bowel Disease, Winter Park, April 2015**
  This one-day CME program focused on clinical updates on Inflammatory Bowel Disease. There were 45 delegates from around the state of Florida who attended the meeting. The two national faculty invited to speak at this symposium were Dr. David Binion (University of Pittsburgh) and Dr. Bo Shen (Cleveland Clinic).

Tutorials

- EUS cytopathology interface workshops: 6 programs involving 50 physicians from 17 states and Latin American Countries
- Spyglass Preceptorship: 4 programs involving 19 physicians from 9 states and The People’s Republic of China
- EUS Preceptorships: 9 programs involving 16 physicians from 10 states
- RFA Preceptorships: 4 programs involving 25 physicians from 9 states

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

Dr. Sameer Siddique, MD graduated from the Christian Medical College, Vellore in India. He then completed an Internal Medicine training program in the United Kingdom before moving to Philadelphia where he did his Internal Medicine Residency at the Albert Einstein Medical Center. Dr. Siddique completed his Gastroenterology Fellowship at the University of Missouri, Columbia prior to starting his advanced endoscopy fellowship at CIE.

Dr. Wesam Frandah

Dr. Wesam Frandah, MBChB, graduated with Honors from the University of Tripoli Medical School in Libya. He completed an Internal Medicine Residency at Texas Tech University Health Science Center in Lubbock and a Gastroenterology Fellowship at the University of Kentucky Medical Center in Lexington prior to joining CIE for his training in advanced endoscopy.

2015 Visiting Physicians

- Eduardo Turiani Houmeaux de Moura (Brazil)
- Khalid Moussa (Florida)
- Humberto Schwartz (Brazil)
- Shashi Kumar (Pennsylvania)
- Trupti Shinde (Florida)
- Maria Ana Jeanellee (Florida)
- Dr. A. C. Arun (India)
- Mala Nath (Florida)
- Paul Pickholtz (Florida)
- Luciano Henrique Lenz Tolentino (Brazil)
- Reza Fatemi (Iran)
- Frank Nakao (Brazil)
- Abdelkader Chaar (Florida)
- Wen-Hsin Huang (Taiwan)
- Pawan K Reddy (India)
- Saad Niaz (Pakistan)
- Choksi Mehul Jayprakash (India)
- Nair Vinayachandran (India)
- Jeffrey Walliz (Florida)
- Qi Wu (China)
- Zhiwu Lu (China)
- Zhiwu Lu (China)
- Hongbo Shan (China)
- Kumar Krishnan (Texas)
For more information regarding future events, visit FHClEvents.com or to refer a patient, call (855) 341-3411.