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DEAR COLLEAGUES

The Center for Interventional Endoscopy (CIE) at Florida Hospital was instituted in 2012 as a state of the art unit integrating therapeutic endoscopy with minimally invasive surgery to provide the highest quality of care for patients with complex digestive diseases.

Three years since inception and 18 months since the new unit was inaugurated, CIE is officially the number one endoscopic ultrasound unit in the United States by volume performing 2582 procedures. We are also the largest ERCP unit in the state of Florida and our total interventional procedural volume is 5500. Since 2012 we have published 79 per-reviewed manuscripts, 33 alone in 2014. Our research portfolio is vibrant with 8 ongoing randomized trials, 4 prospective clinical trials and few others to commence in 2015.

I am pleased to provide the 3rd annual report card outlining the endoscopy procedural volume, clinical outcomes, research and educational milestones achieved in 2014. We look forward to the center continuing to grow and fulfill its mission by providing world class clinical care, performing 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
- Total Number of Patients: 4,707
- Total Florida Patients: 4,569
  - Tri-County: 2,274
  - Non Tri-County: 2,295
- Out-of-state patients: 130
- International patients: 8
- Countries: Virgin Islands, Saudi Arabia, Germany, India, Canada, Costa Rica, Mexico, Uruguay
- 34 states
CIE is conducting randomized trials comparing endoscopy and surgery for treatment of walled-off necrosis and identifying the best techniques for tissue acquisition.

The textbook Endosonography edited by the CIE physicians has 95% of readership market share and the EUS APP is used by more than 12,500 users in 108 countries.

**Interventions Volume**
- Celiac Plexus Interventions = 79
- Drainage of Pancreatic Fluid Collections = 89
- Ductal Drainages = 9
- Others = 12

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ERCP PROCEDURE VOLUME

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 GRADE

ERCP OUTCOMES:
- Technical Success = 1153 (98.8%)
- Technical Failures = 14 (1.2%)
  • Altered Anatomy = 8
  • Failed Cannulation = 6
- Complications = 23 (2.1%)
  • Perforation = 1 (0.08%)
  • Bleeding = 5 (0.4%)
  • Pancreatitis = 6 (1.4%)
  • Cholangitis = 11 (0.9%)

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

Randomized trials are in progress comparing techniques for management of large bile duct stones, evaluating metal and plastic stents for preoperative biliary decompression and identifying the best technique for tissue acquisition in biliary strictures.
Clinical trials evaluating the utility of Motorized Spiral Enteroscope in Small Bowel Diseases will commence in 2015.

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

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Clinical trials on resection of Barrett's Dysplasia and Duodenal/Ampullary Lesions are underway.

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Active Clinical Trials

- Minimally Invasive Surgery vs. Endoscopy Randomized (MISER) Trial for symptomatic walled-off necrosis
  Primary aim: To identify the optimal interventional approach for treatment of symptomatic or infected walled off pancreatic necrosis by comparing the incidence of major complications and mortality between endoscopy and surgery.

- Randomized trial comparing suction vs no suction for Endoscopic Ultrasound-guided Fine Needle Aspiration (EUS-FNA) of solid pancreatic mass lesions using 22G and 25G Needles
  Primary aim: To compare the proportion of diagnostic cell block obtained during EUS-FNA of solid pancreatic mass lesions between 22G and 25G needles with and without suction.

- Multicenter randomized trial comparing covered metal and plastic stents for preoperative biliary decompression in pancreatic cancer
  Primary aim: Compare the rates of complications in patients with pancreatic cancer undergoing preoperative biliary decompression using covered metal or plastic stents.

- Comparison of onsite versus offsite evaluation of Cholangioscopy-guided biopsies of the bile duct
  Primary aim: To compare the diagnostic accuracy between onsite and offsite assessment of cholangioscopy-guided bile duct biopsies.

Research Highlights

- 19 patients have been enrolled in the MISER Trial comparing treatment options in walled-off pancreatic necrosis with no procedure-related mortality.
- Clinical trials focusing on EUS and cholangioscopy for tissue acquisition are in progress.
- Clinical trials are being conducted to minimize procedure-related complications and other morbidity when performing endoscopic mucosal resection.
- A new protocol to ablate pancreatic cyst neoplasms using alcohol and paclitaxel, under EUS-guidance, will be started in 2015. Additionally, novel biomarkers to determine the biological behavior of pancreatic cysts are being evaluated.
- Randomized trial comparing techniques for management of large bile duct stones are underway.
- Prophylactic Octreotide to prevent post-duodenal EMR and ampullectomy bleeding
  Primary aim: To evaluate the prophylactic administration of 5 days of Octreotide on reducing the risk of post-duodenal EMR or ampullectomy bleeding in patients with duodenal and ampullary adenomas.
- Reduction in symptomatic esophageal stricture formation post-two stage complete Barrett’s excision for high grade dysplasia or early adenocarcinoma with short-term steroid therapy: A randomized, double-blinded, placebo-controlled, multicenter trial
  Primary aim: To compare the rate of symptomatic esophageal strictures in patients receiving placebo versus oral prednisone.
- Lipidomics, proteomics, micro RNAs and volatile organic compounds (VOCs) biomarkers in bile and serum in the diagnosis of malignant biliary strictures
  Primary aim: To identify and evaluate proteomics, lipidomics, micro-RNAs and VOCs changes in blood and bile to determine their usefulness as biomarkers for the early diagnosis of cancer.
Safety of endoscopic resection of large colorectal polyps: A randomized trial  
**Primary aim:** To examine whether clip closure of the mucosal defect after endoscopic mucosal resection (EMR) of large polyps will reduce the risk of delayed bleeding.

High resolution optical imaging of esophageal tissue using the NvisionVLE imaging system registry  
**Primary aim:** To evaluate the NvisionVLE for examination of the esophagus.

### Completed Clinical Trials

- A Randomized trial comparing the number of passes required for diagnostic cell block during EUS-FNA of solid pancreatic mass lesions  
  **Primary aim:** To compare the rate of diagnostic cell block when performing 2 versus 4 EUS-FNA passes of solid pancreatic mass lesions.

- EUS-Guided biliary drainage: A prospective feasibility multicenter trial  
  **Primary aim:** To determine the safety and effectiveness of EUS-guided biliary drainage following a failed ERCP.

- Endoscopic Ultrasound-guided liver biopsy: A multicenter trial  
  **Primary aim:** To assess the number of complete portal triads (CPT) and specimen length in liver biopsies obtained with the EUS-liver biopsy technique.

- Relationship between endoscopic ultrasound staging and degree of stricture in esophageal Cancer  
  **Primary aim:** To correlate EUS staging (T) with stricture tightness at endoscopy.

- Evaluation of injection techniques in Endoscopic Ultrasound-Guided Celiac Plexus Neurolysis (EUS-CPN)  
  **Primary aim:** To evaluate the efficacy of EUS-CPN in subjects who experience a sympathetic response during injection when compared with subjects who do not experience sympathetic response during injection.

- Randomized trial comparing 19 and 25 Gauge needles for Endoscopic Ultrasound-Guided Fine Needle Aspiration (EUS-FNA) of solid pancreatic mass lesions greater than 35mm  
  **Primary aim:** To compare the median number of passes required to establish diagnosis using the 19G and 25G needles for FNA of solid pancreatic mass lesions greater than 35mm.

- Palliation of biliary neoplasms with the Cook evolution biliary stent system  
  **Primary aim:** To collect data on the use of the Evolution biliary (uncovered) stent system for palliation of malignant neoplasms in the biliary tree.

- Assessment of an endoscopic Ampullectomy model  
  **Primary aim:** To assess proceduralists’ confidence in performing an Ampullectomy after training in the model.
## Status of Active Clinical Trials

<table>
<thead>
<tr>
<th>Name of the Trail</th>
<th>Sponsor</th>
<th>Design</th>
<th>Enrollment Goal</th>
<th>Current Enrollment</th>
</tr>
</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>19</td>
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<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>
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<td>13</td>
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<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>53</td>
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<tr>
<td>Randomized Trial Comparing 22 and 25 G Needles for Pancreatic Mass FNA with and without suction</td>
<td>Florida Hospital</td>
<td>Randomized</td>
<td>352</td>
<td>85</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>20</td>
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<tr>
<td>Reduction in Symptomatic Esophageal Stricture Formation Post-Two Stage Complete Barrett’s Excision for High Grade Dysplasia or Early Adenocarcinoma with Short-Term Steroid Therapy: A Randomized, Double-Blinded, Placebo-Controlled, Multicenter Trial</td>
<td>Florida Hospital</td>
<td>Randomized</td>
<td>126</td>
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<tr>
<td>Safety of Endoscopic Resection of Large Colorectal Polyps: A Randomized Trial</td>
<td>UAMC Vermont Multi-Center</td>
<td>Randomized</td>
<td>&gt;20</td>
<td>16</td>
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<tr>
<td>Prophylactic and emergent treatment of gastric varices with n-butyl cyanoacrylate (Histoacryl)</td>
<td>Florida Hospital</td>
<td>Registry</td>
<td>None</td>
<td>9</td>
</tr>
<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>Pending</td>
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<tr>
<td>EUS-Guided Drainage: A Prospective Feasibility Multicenter Trial</td>
<td>John Hopkins</td>
<td>Prospective</td>
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<tr>
<td>High Resolution Optical Imaging of Esophageal Tissue Using the Nvision VLE Imaging System Registry</td>
<td>NinePoint</td>
<td>Registry</td>
<td>100</td>
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</tbody>
</table>
Peer-Reviewed Publications


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Abstracts selected for presentation at DDW 2015

SUBMISSION HIGHLIGHTS

TOTAL SUBMISSIONS = 18

- EUS-related submissions = 8
- ERCP-related submissions = 7
- Endoscopic resection-related submissions = 2
- IBD-related submission = 1

Podium Presentations


Poster Presentations


Holt BA, Hawes R, Tharian B, Varadarajulu S. Assessment of an endoscopic Ampullectomy model.


**Video Presentations**

International Symposiums

- **2nd Annual Orlando Live EUS 2014 – September 3-5, 2014**
  Orlando Live is the single largest EUS related symposium in the United States. 144 delegates from 17 countries attended the meeting last year. 83 attended the hands-on lab and 42 procedures were performed during the two days of live endoscopy sessions. Eight expert faculty from 7 countries demonstrated live procedures. The overall delegate rating of the symposium was 4.8 in a scale of 0 to 5.

- **The 3rd Annual Orlando Live EUS will be held September 2-4, 2015**

- **1st Annual Orlando Live EMR 2014 - September 26, 2014**
  Live case demonstrations, didactics and video presentations were incorporated in the symposium that involved one international and one domestic faculty who demonstrated live procedures. 22 Delegates from 3 Countries attended the meeting.

Regional Symposiums

- **Endoscopic Intervention in Pancreaticobiliary Diseases, Tampa, January 2014**
  This one-day CME program focused on endoscopic interventions in pancreaticobiliary diseases that was attended by 75 Physicians from the state of Florida. The National invited faculty included, Dr. Martin Freeman and Dr. Joseph Elumzer.

- **Challenges in Clinical Endoscopy, Miami, November 15, 2014**
  This one-day CME program focused on cutting-edge endoscopic techniques in challenging diseases. Twenty-five delegates from around the state of Florida attended the meeting. Two national faculty were invited, Dr. Issac Raijman and Dr. Paul Tarnasky, to speak at the meeting.

- **Florida Hospital CIE Visiting Professorship, October 2014**
  Dr. Lee Swanstrom, former President of SAGES, was the Visiting Professor for 2014. Dr. Swanstrom is a world-renowned laparoscopic surgeon from the Legacy Health System in Portland, Oregon. Dr. Swanstrom lectured on the fading boundaries between surgery and endoscopy and the impact of healthcare reform on the minimally invasive treatment of digestive diseases.

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: 4 programs involving 16 physicians from 10 states
- RFA Preceptorships: 4 programs involving 25 physicians from 9 states

Visiting Professorships by CIE Physicians

- Austria
- India
- Belgium
- Pakistan
- China
- Netherlands
- Italy
- Canada
- Japan
- Republic of Korea
CONFERENCE ATTENDEE’S FOR 2014 BY COUNTRIES
ASGE to honor Dr. Robert Hawes, with the Rudolf Schindler Award at DDW 2015

The American Society for Gastrointestinal Endoscopy (ASGE) will confer Dr. Robert Hawes its highest honor, the Rudolf Schindler Award, at the Digestive Diseases Week in Washington DC in May 2015. The award is granted periodically to an ASGE member whose accomplishments in endoscopic research, teaching and/or service to the ASGE, exemplify the standards and traditions of Rudolf Schindler, MD, founder of the American Gastroscopic Club, the forerunner of ASGE. Dr. Hawes is one of the early pioneers of Endoscopic Ultrasound and has personally supervised or mentored more than 250 gastroenterology trainees, both domestic and international, over a career span of nearly four decades. He has authored more than 350 original articles, 75 textbook chapters, demonstrated in more than 300 live endoscopy meetings worldwide and has participated in the innovation of several cutting-edge endoscopic technologies. He was also the President of the ASGE from 2005-2006.

ADVANCED ENDOSCOPY TRAINING

Dr. Ashley Canipe

Dr. Ashley Canipe completed her medical school and internal medicine residency at the Emory University in Atlanta, Georgia. She underwent Gastroenterology Fellowship at Vanderbilt University in Nashville, Tennessee just prior to moving to Orlando. Dr. Canipe plans to stay in Florida and pursue private practice after she completes her advanced endoscopy training later this year.

Dr. Benjamin Tharian

Dr. Benjamin Tharian, MD graduated MBBS from the Government Medical College, Trivandrum, India, Medical Residency from the Ipswich Hospital NHS Trust, United Kingdom, and Gastroenterology Fellowship from the Hope Hospital in Manchester, United Kingdom. He is also Board Certified in Gastroenterology in Australia. After completion of advanced endoscopy fellowship at CIE in June 2015, he will be joining the University of Arkansas in Little Rock as an interventional endoscopist.
The EUS App, developed by Doctors Varadarajulu, Fockens and Hawes, is dedicated to education in endoscopic ultrasound (EUS). The app is compatible with all mobile devices. There are more than 12,600 registered users from 108 countries.

The 3rd edition edited by Drs. Hawes, Fockens and Varadarajulu, was released at the EUS 2014 Symposium in Chennai, India.

A supplement dedicated to EUS-Guided Tissue Acquisition was published by Elsevier in January 2014.

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