

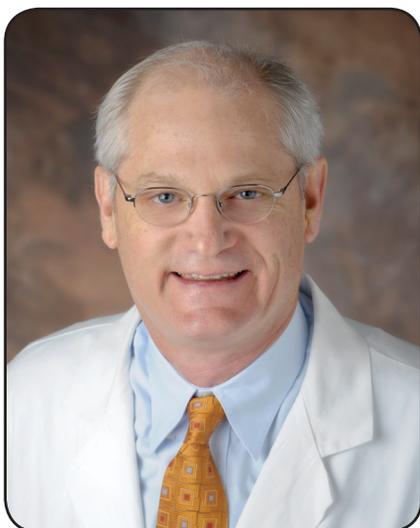


**SECOND ANNUAL  
CENTER FOR  
INTERVENTIONAL ENDOSCOPY  
REPORT CARD 2013**



**FLORIDA HOSPITAL**  
*Center for Interventional Endoscopy*  
*The skill to heal. The spirit to care.®*

## The Center For Interventional Endoscopy



**Robert Hawes, MD**

Medical Director  
Institute for Minimally Invasive Therapy



**Shyam Varadarajulu, MD**

Medical Director  
Center for Interventional Endoscopy



**Muhammad K. Hasan, MD**

Director  
Advanced Endoscopy Fellowship

### Administrative Staff

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Brittany Collins, Practice Manager  
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Amy Logue, Clinical Research Nurse  
James Clancy, ARNP  
Renay Crowe, Executive Assistant  
Laura Silva, Coder

Sara O'Brien, Patient Care Coordinator  
Tanja Wittig, Patient Care Coordinator  
Camille Ortiz, Patient Care Coordinator  
Joscelyn Pankey, Referral Coordinator

## Dear Colleagues

The Center for Interventional Endoscopy (CIE) at Florida Hospital, was created as a state of the art center, integrating therapeutic endoscopy with minimally invasive surgery to provide the highest quality care for patients with complex digestive diseases. The CIE physicians are trained in the most advanced techniques and procedural services available for the treatment of digestive disorders. The CIE team fosters collaborative research not only at Florida Hospital, but throughout the world to further the treatment and knowledge of digestive diseases. Our goal is to be a center of excellence, providing world class clinical care, cutting-edge clinical research and training the next generation of endoscopists and minimally invasive surgeons.

We are pleased to provide our second annual report card outlining the clinical research and educational milestones achieved in CIE through 2013. We look forward to the center continuing to grow and fulfill its mission to serve patients and provide state of the art therapeutic endoscopy and minimally invasive surgical services.

Sincerely,

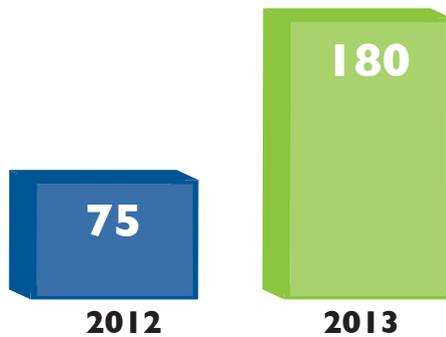
Muhammad Hasan, MD  
Robert Hawes, MD  
Shyam Varadarajulu, MD





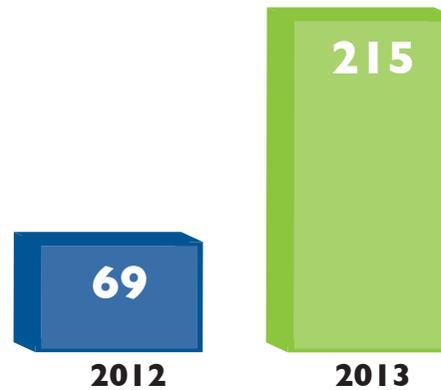
# Advanced Procedures

## Double-Balloon Enteroscopy



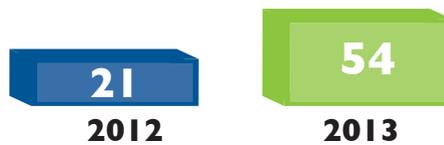
▶ 140% INCREASE

## Endoscopic Mucosal Resection



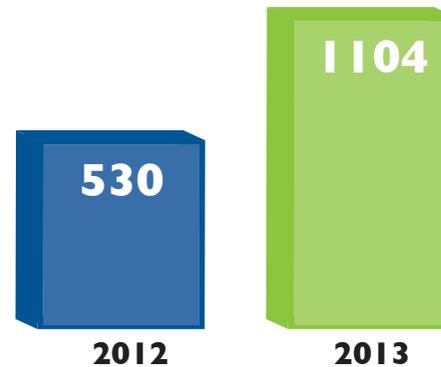
▶ 212% INCREASE

## Radio Frequency Ablation



▶ 158% INCREASE

## Other Interventions

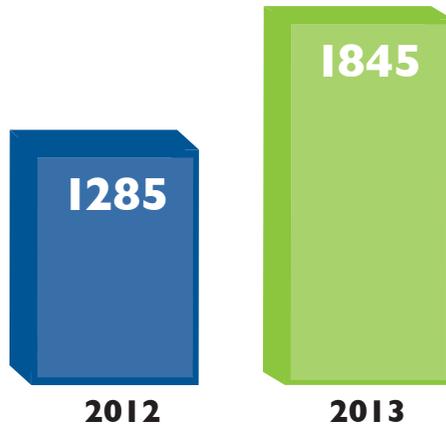


▶ 108% INCREASE

- ▶ Endoscopic Suturing
- ▶ Ovesco Clip
- ▶ Luminal Stenting
- ▶ Peg-J Tube
- ▶ Colonoscopy
- ▶ EGD

▶ The Nine Points Optical Coherence Tomography program for detection of early Barretts neoplasia has recently been instituted at CIE.

## EUS Procedure Volume



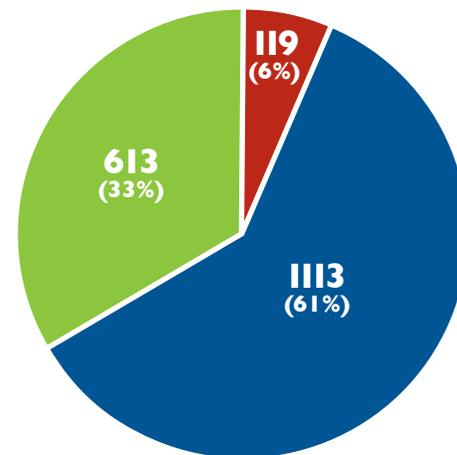
▶ **44% Increase In Annual EUS Volume**

- Diagnostic
- FNA
- Interventions

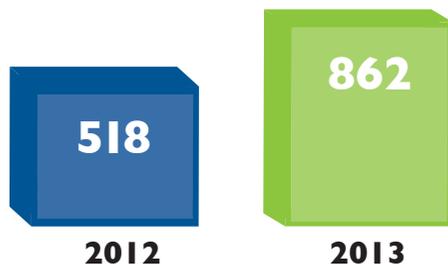
### Interventions Volume

- ▶ Celiac Plexus Interventions = **62**
- ▶ Drainage of Pancreatic/Pelvic Fluid Collection = **44**
- ▶ Ductal Drainage = **4**
- ▶ Others = **9**

- ▶ Published over 100 manuscripts on EUS and EUS-guided fine needle aspiration (EUS-FNA)
- ▶ Editors of the textbook Endosonography
- ▶ Developed an I-phone APP dedicated towards EUS education



## ERCP Procedure Volume



▶ **66% Increase In Annual ERCP Volume**

▶ The CIE pancreaticobiliary service offers advanced procedures including cholangioscopy, intraductal ultrasound and sphincter of oddi manometry. The program will soon initiate biliary RFA for palliation of advanced tumors.

### 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

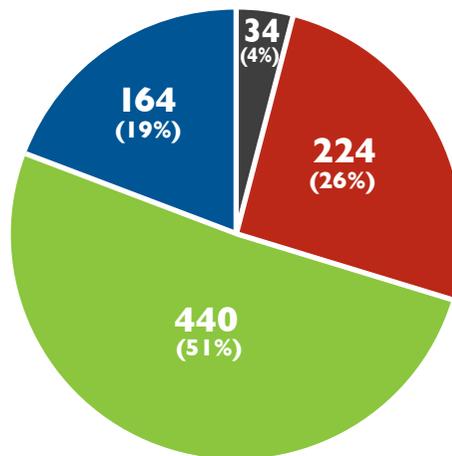
### Grade 3:

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 = 848 (98%)
- ▶ Technical Failures = 14 (1.6%)
  - ▶ Altered Anatomy = 10
  - ▶ Failed Cannulation = 4
- ▶ Complications = 28 (3%)
  - ▶ Perforation = 0
  - ▶ Bleeding = 4 (0.5%)
  - ▶ Pancreatitis = 15 (1.7%)
  - ▶ Cholangitis = 9 (1%)

# Research In 2013

## Research Highlights

The CIE team has concluded four randomized trials pertaining to EUS-guided tissue acquisition and published more than 25 manuscripts in 2013. Ongoing clinical investigations include randomized trials in endoscopic mucosal resection, cholangioscopy-guided tissue acquisition, comparison of biliary endoprosthesis for preoperative biliary decompression and optimizing techniques for celiac plexus interventions. CIE has also established a new clinical research program on optical coherence tomography to improve the outcomes of patients with Barrett's esophagus.

## Active Clinical Trials

- ▶ Prophylactic Octreotide to Prevent Post Duodenal EMR and Ampullectomy Bleeding  
*Primary aim: Determine whether the prophylactic administration of Octreotide reduces the risk of post duodenal EMR or ampullectomy bleeding.*
- ▶ Safety of Endoscopic Resection of Large Colorectal Polyps: A Multicenter Randomized Trial  
*Primary aim: Determine role of prophylactic clipping in prevention of post EMR delayed bleeding.*
- ▶ 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: Compare the rate of symptomatic esophageal strictures in patients receiving placebo versus oral prednisone.*
- ▶ 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.*
- ▶ 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 CSEMS or plastic stents.*
- ▶ 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.*
- ▶ 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 tissue acquisition.*
- ▶ Relationship Between Endoscopic Ultrasound Staging and Degree of Stricture in Esophageal Cancer  
*Primary aim: To correlate EUS staging (T) with stricture tightness at endoscopy.*
- ▶ Palliation of Biliary Neoplasms with the Cook Evolution Biliary Stent System  
*Primary aim: Evaluate the use of the Evolution® Biliary Stent System (uncovered) for palliation of malignant neoplasms in the biliary tree.*

## Concluded Clinical Trials

- ▶ A Randomized Trial Evaluating the Number of Passes Required for Diagnostic Cell Block During EUS-FNA of Solid Pancreatic Mass Lesions  
*Primary aim:* To compare the rate of complications when performing two versus four EUS-FNA passes of solid pancreatic mass lesions.
- ▶ 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 19 and 25-gauge needles for FNA of solid pancreatic mass lesions greater than 35mm.
- ▶ Comparison Between the 19 and 22-gauge Needles for Core Tissue Procurement During EUS-guided FNA Procedures  
*Primary aim:* To evaluate the ability of the needles to procure core tissue for molecular marker studies.
- ▶ Randomized Trial Comparing 19 and 25-gauge Needles for Endoscopic Ultrasound-guided Fine Needle Aspiration (EUS-FNA) of Solid Pancreatic Mass Lesions  
*Primary aim:* To compare the median number of passes required to establish diagnosis and ability to procure histological core using the 19 and 25-gauge needles for FNA of solid pancreatic mass lesions.
- ▶ Comparing Heparinized and Non-Heparinized 25-gauge Needles for Endoscopic Ultrasound-guided Fine Needle Aspiration of Solid Pancreatic Mass Lesions  
*Primary aim:* To compare the number of passes required to establish the diagnosis using heparinized and non-heparinized needles for FNA of solid pancreatic masses.
- ▶ Randomized Trial Comparing Endoscopic Ultrasound-guided Celiac Plexus Neurolysis (EUS-CPN) and Sham Therapy for Palliation of Pain in Pancreatic Cancer  
*Primary aim:* To evaluate the efficacy of EUS-CPN and analgesic therapy (Group one) in pain relief of patients with unresectable pancreatic cancer when compared with analgesic therapy alone (Group two).
- ▶ Prospective Comparison of Two EUS Processors for Imaging of the Pancreas  
*Primary aim:* To compare the quality of imaging between the Aloka 10 and Olympus EU-ME 2 processors.

## Upcoming Clinical Trials

- ▶ Multicenter Randomized Trial Comparing Endoscopy and Surgery for Minimally Invasive Treatment of Walled Off Pancreatic Necrosis  
*Primary aim:* To compare the rates of complications between the treatment cohorts.
- ▶ User Evaluation of a Novel Motorized Spiral Enteroscope in Patients Scheduled to Undergo Small Bowel Enteroscopy: A Prospective Multicenter Trial  
*Primary aim:* Evaluate the efficacy of the spiral enteroscope for the treatment of small bowel disorders.

## Peer-Reviewed Publications in 2013

- ▶ Varadarajulu S, Rana SS, Bhasin DK. Endoscopic Therapy for Pancreatic Duct Leaks and Disruptions. *Gastrointest Endosc Clin N Am.* 2013; 23:863-92.
- ▶ Varadarajulu S, Bang JY, Sutton BS, Trevino JM, Christein JD. Equal Efficacy of Endoscopic and Surgical Cystogastrostomy for Pancreatic Pseudocyst Drainage in a Randomized Trial. *Gastroenterology.* 2013; 145:583-90.
- ▶ Varadarajulu S, Hawes RH. The Changing Paradigm in EUS-guided Tissue Acquisition. *Gastrointest Endosc Clin N Am.* 2014; 24:1-7.
- ▶ Varadarajulu S, Hawes RH. EUS-guided Biliary Drainage: Taxing and Not Ready. *Gastrointest Endosc.* 2013; 78:742-3.
- ▶ Varadarajulu S, Hasan MK, Bang JY, Hebert-Magee S, Hawes RH. Endoscopic Ultrasound-guided Tissue Acquisition. *Dig Endosc.* 2013; 28. doi: 10.1111/den.12146.
- ▶ Varadarajulu S. A Hybrid Endoscopic Technique for the Treatment of Walled-off Pancreatic Necrosis. *Am J Gastroenterol.* 2013; 108:1015-7.
- ▶ Hasan MK, Hawes R, Varadarajulu S. Gastric Heterotopic Pancreas Abscess Leading to Gastric Outlet Obstruction. *Gastrointest Endosc.* 2013; 78:550-1.
- ▶ Hébert-Magee S, Hawes RH, Varadarajulu S. Is It Time to Take a Pass on the Increased Number of Passes in EUS-FNA? *Dig Dis Sci.* 2013; 58:3068-9.
- ▶ Hébert-Magee S, Bae S, Varadarajulu S, Ramesh J, Frost AR, Eloubeidi MA, Eltoun IA. The Presence of a Cytopathologist Increases the Diagnostic Accuracy of Endoscopic Ultrasound-guided Fine Needle Aspiration Cytology for Pancreatic Adenocarcinoma: A Meta-analysis. *Cytopathology.* 2013; 24:159-71.
- ▶ Hébert-Magee S, Varadarajulu S, Frost A, Ramesh J. Primary Pancreatic Leiomyosarcoma: A Rare Diagnosis Obtained by EUS-FNA Cytology. *Gastrointest Endosc.* 2014.
- ▶ Hébert-Magee S. Basic Technique for Solid Lesions: Cytology, Core, Both? *Endosc Ultrasound* 2014;3:28-34.

- ▶ Bang JY, Wilcox CM, Trevino J, Ramesh J, Peter S, Hasan M, Hawes RH, Varadarajulu S. Factors Impacting Treatment Outcomes in the Endoscopic Management of Walled-off Pancreatic Necrosis. *J Gastroenterol Hepatol.* 2013; 28:1725-32.
- ▶ Bang JY, Hawes RH, Varadarajulu S. Objective Evaluation of a New Endoscopic Ultrasound Processor. *Dig Endosc.* 2013; 25:554-5.
- ▶ Bang JY, Varadarajulu S. Metal Versus Plastic Stent for Transmural Drainage of Pancreatic Fluid Collections. *Clin Endosc.* 2013; 46:500-502.
- ▶ Bang JY, Varadarajulu S. Procore and Flexible 19-gauge Needle Can Replace Trucut Biopsy Needle? *Clin Endosc.* 2013; 46:503-505.
- ▶ Bang JY, Magee SH, Ramesh J, Trevino JM, Varadarajulu S. Randomized Trial Comparing Fanning with Standard Technique for Endoscopic Ultrasound-guided Fine Needle Aspiration of Solid Pancreatic Mass Lesions. *Endoscopy.* 2013; 45:445-50.
- ▶ Teoh AY, Ng EK, Chock A, Swanstrom L, Varadarajulu S, Chiu PW. Asian-Chinese Patient Perceptions of Natural Orifice Transluminal Endoscopic Surgery Cholecystectomy. *Dig Endosc.* 2013 6. doi: 10.1111/den.12192.
- ▶ Lim LG, Lakhtakia S, Ang TL, Vu CK, Dy F, Chong VH, Khor CJ, Lim WC, Doshi BK, Varadarajulu S, Yasuda K, Wong JY, Chan YH, Nga ME, Ho KY. Factors Determining Diagnostic Yield of Endoscopic Ultrasound Guided Fine Needle Aspiration for Pancreatic Cystic Lesions: A Multicenter Asian Study. *Asian EUS Consortium. Dig Dis Sci.* 2013; 58:1751-7.
- ▶ Kongkam P, Ang TL, Vu CK, Dy FT, Yasuda K, Rerknimitr R, Varadarajulu S, Dhir V, Chong VH, Zhen DJ, Wong JY, Ho KY. Current Status on the Diagnosis and Evaluation of Pancreatic Tumor in Asia with Particular Emphasis on the Role of Endoscopic Ultrasound. *Asian Consortium of EUS. J Gastroenterol Hepatol.* 2013; 28:924-30.

# Abstracts Selected For Presentation At Digestive Disease Week (DDW) 2014

## Podium Presentations

- ▶ Hasan M, Ramesh J, Bang JY, Holt B, Logue A, Hawes RH, Varadarajulu S. Multicenter Randomized Trial Comparing the 19-gauge and 25-gauge Needles for EUS-guided FNA of Large Solid Pancreatic Mass Lesions. ASGE Topic Forum.
- ▶ Roy A, Kim M, Hawes RH, Varadarajulu S. The Clinical and Financial Implications of Failed Hemostasis in Gastroduodenal Ulcer Bleeding. ASGE Topic Forum.

## Poster Presentations

- ▶ Varadarajulu S, Holt B, Hasan M, Bang JY, Logue A, Tamhane A, Hawes RH, Hebert-Magee S. Impact of an Intensive, Short-Term, Training Program in Cytopathology for Endosonographers.
- ▶ Varadarajulu S, Holt B, Hasan M, Bang J, Logue A, Hawes RH, Hebert-Magee S. The 25-gauge FNA Needle: Good for Onsite But Poor for Offsite Evaluation? Results of a Randomized Trial.
- ▶ Hebert-Magee S, Varadarajulu S, Corpus G, Eberwein E, Krall K, Logue A, Chang C-C. Molecular Analysis of EUS-FNA of the Pancreas: Is There a Better Needle?
- ▶ Bang JY, Hawes RH, Varadarajulu S. Innovations in Interventional EUS: Is the USA Fading Fast?
- ▶ Bang JY, Hawes RH, Varadarajulu S. Critical Assessment of the Choice of Endoprosthesis for Transmural Drainage of Pancreatic Fluid Collections.
- ▶ Bang JY, Hasan M, Hawes RH, Varadarajulu S. EUS-guided Tissue Acquisition: Meta-analysis Comparing the ProCore and Standard FNA Needles.
- ▶ Bang JY, Wilcox CM, Christein JD, Hasan M, Arnolett JP, De La Fuente S, Hawes RH, Varadarajulu S. Endoscopic Report Card of a 10 Year Experience in 100 Patients with Walled-off Pancreatic Necrosis.
- ▶ Piramanayagam P, Bang JY, Varadarajulu S, Palaniswamy KR. What is the Impact of a One Week, Intensive, Hands on EUS Training Program on Tissue Acquisition?
- ▶ Ramesh J, Kim H, Reddy K, Varadarajulu S, Wilcox CM. Pancreatic Stent Caliber Does Not Impact Post ERCP Pancreatitis Rates in Patients with Confirmed Sphincter of Oddi Dysfunction.
- ▶ Ramesh J, Reddy K, Kim H, Varadarajulu S, Monkemuller K, Trevino J, Baig K, Wilcox CM. Low Risk of Post-ERCP Pancreatitis in Patients Undergoing Pancreatography to Evaluate Ductal Integrity.
- ▶ Dhir V, Itoi T, Khashab M, Park DH, Teoh A, Attam R, Messallam A, Varadarajulu S, Maydeo A. Multicenter Comparative Evaluation of Endoscopic Placement of Expandable Metal Stents for Malignant Distal CBD Obstruction by ERCP or EUS-guided Approach.
- ▶ Khashab M, Fabbri C, Messallam A, Varadarajulu S, Tarantino I, Modayil R, Perez-Miranda M, Romagnuolo J, De La Serna C, Dhir V. Prospective Multicenter International Study on EUS-guided Biliary Drainage for Patients with Distal Malignant Biliary Obstruction and Failed ERCP.

## Educational Initiatives

### International Symposiums

#### ▶ 18th Annual Advanced Endoscopy Update - May 21-23, 2013

- ▶ Two days of international faculty utilizing didactics, video and live case demonstrations, provided a complete update of gastrointestinal endoscopy. 200 delegates from 24 countries attended the meeting.

#### ▶ 1st Annual Orlando Live EUS - September 11-13, 2013

- ▶ 194 delegates from 19 countries attended the meeting. 80 attended the hands-on lab, and 41 procedures were performed during the two days of live endoscopy sessions. The second annual Orlando Live EUS will be held **September 3-5, 2014**.

### Regional Symposiums

#### ▶ Clinical Challenges in Pancreatic Disease - January 12, 2013

- ▶ One-day CME program focused on cutting-edge endoscopic and surgical techniques for the management of pancreatic disease. 75 delegates from around the state of Florida attended the meeting.

### Tutorials

- ▶ EUS Cytopathology Interface Workshop: 5 programs involving 30 physicians, 11 states and Latin America
- ▶ EUS Preceptorships: 6 programs involving 24 physicians and 11 states
- ▶ Cholangioscopy Course: 3 programs involving 8 physicians and 5 states
- ▶ RFA Course: 2 programs involving 10 physicians and 4 states

### Visiting Professorships by CIE Physicians

- ▶ Belgium
- ▶ Brazil
- ▶ Canada
- ▶ China
- ▶ Germany
- ▶ India
- ▶ Japan
- ▶ Malaysia
- ▶ Mexico
- ▶ Netherlands
- ▶ Pakistan
- ▶ Romania
- ▶ Russia
- ▶ Thailand
- ▶ United Arab Emirates

### Attendee Countries



Argentina	Kenya
Australia	Korea, Republic
Brazil	Malaysia
Canada	Mexico
China	Netherlands
Columbia	Pakistan
Denmark	Romania
Ecuador	Russian Federation
France	Saudi Arabia
Germany	Spain
Guatemala	Thailand
Hong Kong	United Arab Emirates
India	United Kingdom
Israel	United States
Italy	Venezuela
Japan	

## Advanced Endoscopy Training



### Queen Elizabeth II Diamond Jubilee Scholarship

**Bronte Holt, MD.**, from the Center for Interventional Endoscopy (CIE) at Florida Hospital has been awarded the prestigious Prime Minister's Queen Elizabeth II Diamond Jubilee Scholarship. This scholarship is the most coveted of the Australian Government's Endeavour Awards. "The Endeavour Scholarships and Fellowships are internationally competitive scholarships which promote knowledge, education links and enduring ties between Australia and its neighbors," said Hon Christopher Pyne, Minister for Education of Australia.

The Prime Minister's Queen Elizabeth II Diamond Jubilee Scholarship is awarded to a high achieving Australian female student who will contribute to the advancement of women's leadership in Australia. The award provides financial support for a top Australian female postgraduate and/or postdoctoral fellow to undertake study and/or research towards an Australian-enrolled PhD, or to undertake postdoctoral research within a participating country, in any field of study.

Thanks to this scholarship, Dr. Holt, who is originally from Australia, will be able to continue her PhD research in the United States. "I am honored to be the recipient of this scholarship," said Dr. Holt. "This scholarship is an incredible opportunity to further my research in minimally invasive and novel endoscopic techniques for the diagnosis and management of premalignant and early-stage cancers of the gastrointestinal tract at the Florida Hospital CIE."

### ASGE Cook Medical Don Wilson Award

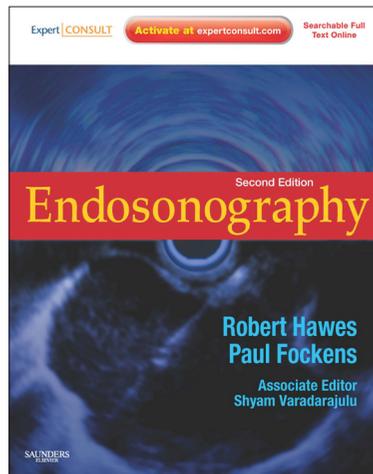
**Chirag Shah, MD.**, from KEM Hospital in Mumbai (Bombay), India, has been selected by the American Society for Gastrointestinal Endoscopy (ASGE) to be the recipient of the 2014 Cook Medical Don Wilson Award. As part of the award, Dr. Shah will be provided a \$7500 educational grant to support three months of his training at CIE during which he will participate in clinical research and other educational initiatives.



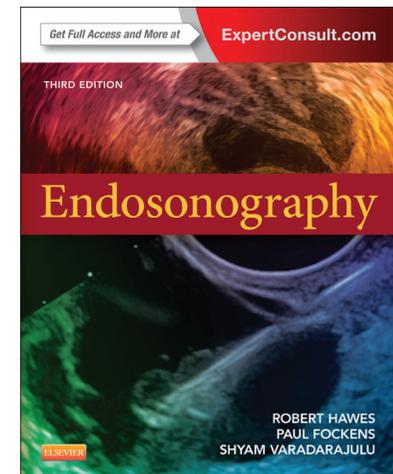
## Educational Resources



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 9000 registered users from 79 countries.



The textbook, Endosonography, edited by Drs. Hawes, Fockens and Varadarajulu, is dedicated to EUS education and is the most widely read textbook on EUS in the world. The book also has an online component in which literature review is posted on a quarterly basis.



The 3rd edition edited by Drs. Hawes, Fockens and Varadarajulu, is expected to be released in September 2014.

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