COOK® MEDICAL

The Channel

A COOK NEWS PUBLICATION ISSUE 2, 2010

Fusion® Dual Platform

THE LONG and THE SHORT of it

ERCP Product Line

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Associate Professor of Medicine
University of Florida

Wire guides are an indispensable part of ERCP. They are used to gain and maintain access to the desired duct, and provide a platform for insertion or withdrawal of various devices. Traditionally, long wire guides were exclusively used at the time of ERCP. The long length is dictated by the need to exchange various devices over the wire, and therefore the wire length should be, at minimum, twice the length of the device (the typical ERCP wire is 450 cm in length).

FUSION DUAL PLATFORM

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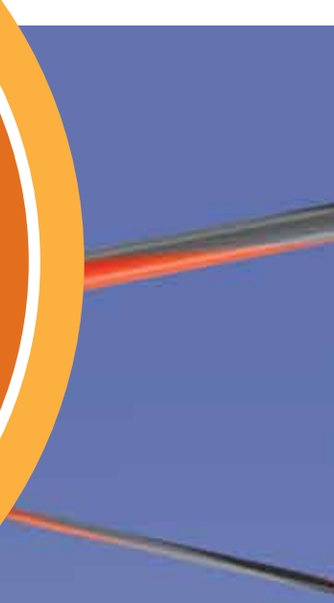
Performance of Long Wire FUSION Efficiency of Short Wire



A number of problems are attributed to the use of long wires:

- Longer exchange time, which can lead to increase of procedure and fluoroscopy time, and sedation requirements
- Need for excellent communication between physician and assistant
- Contamination from the long wire touching the floor
- Success of the ERCP is dependent on the availability of a highly trained assistant

To overcome the disadvantages of the long-wire system, three short-wire systems have been introduced. They share three essential elements: 1) shorter wire length ranging from 205 to 270 cm, 2) the ability to lock the wire in position during the device exchange and 3) the ability of the endoscopist to independently manage and manipulate the wire. The short-wire systems have some perceived advantages.

- Reduced device exchange, stent insertion, total procedure, and fluoroscopy times
- Maintaining stable ductile access
- Physician control of the wire may facilitate cannulation and reduce ampullary trauma, and decrease rate of post-ERCP pancreatitis

Unfortunately, the use of a short-wire system may impose insurmountable challenges in some situations:

- More complex cases where multiple exchanges are needed
- Advanced techniques are required, such as double wiring for hilar stricture
- When the ERCP devices are not used in typical order
- When non-ERCP devices are used at the time of ERCP, such as over the wire upper endoscopy dilation balloons

Fusion was created with the intent to overcome the shortcomings associated with the use of a short wire. Fusion is the only dual-platform ERCP product line that allows use of ERCP devices with a short wire or in an over-the-wire, long-wire manner.

ERCP remains the most complex endoscopic procedure and provides a particular challenge even for very skillful physicians. Therefore, a device system with a full range of capability combining the benefits of short-wire and long-wire platforms will be of great value.

I recently did a case at the University of Florida of a hilar stricture. Once the endoscope was positioned in the second portion of the duodenum, the papilla was found located deep on the side wall of a large duodenal diverticulum. That created a challenge with obtaining cannulation with standard devices. I selected to use the Fusion Omni sphincterotome. That gave me two distinct advantages: the ability to rotate the sphincterotome to accommodate the altered anatomy, and to take control over wire manipulation for precise cannulation.

After I achieved successful bile duct cannulation, the hilar structure was visualized; then deep-wire access was obtained to the right biliary system. I was able to access the right biliary system and then immediately inserted a second wire through the same sphincterotome and gained access to the opposite left side of the liver. To complete the procedure, I sequentially deployed two plastic stents, one in the right and the other in the left biliary branches.

I noted that Fusion carries some distinct advantages, including reduced device exchange, stent insertion and fluoroscopy times. It also provides for physician to control of the wire, which may lead to improved cannulation rate, decreased trauma to the ampulla and decreased risk of post-ERCP pancreatitis. In addition, physician wire control makes the success of ERCP less dependent on the availability of a highly trained assistant.

Finally, I concluded that Fusion provides trainees the opportunity to experience both the use of short wires and long wires as appropriate and ultimately prepare them for both options when moving into practice of their own.

Fusion Dual Platform: A Prospective, Randomized, Controlled Trial

A recently completed randomized control study, performed at the University of Florida, formally evaluated the performance characteristics of Cook Medical's Fusion Dual Platform ERCP product line. A total of 71 patients (38 male, 33 female), mean age of 60.3 years, were enrolled. The indications for the ERCP were biliary stones (N=38), obstructive jaundice (N=14), post-liver transplantation (N= 11) and chronic pancreatitis (N=7).

Fusion provided for a significantly faster mean device exchange time (125 seconds), compared with the long-wire system (177 seconds) ($p=0.05$). The mean stent insertion time (135 seconds) was significantly shorter with Fusion versus the long-wire system (254 seconds) ($p> 0.001$). A trend toward shorter procedure time, fluoroscopy time and cannulation time was also noted with Fusion. One incident of post-ERCP pancreatitis occurred in the Fusion group and two cases in the long-wire groups.

This first study evaluating Fusion has a number of strengths: 1) it is a prospective randomized controlled trial; 2) potential for bias was minimized by blinding the endoscopist to the study hypothesis and measured outcomes, and the person measuring the outcomes to the study hypothesis; 3) all procedures were done by the same physician, reducing confounding from variation in technical skills; 4) patients with various indications for ERCP were enrolled; and 5) the difference in device exchange and stent insertion times were not only statistically significant but also clinically significant (device exchange and stent insertion were faster on average by 52 and 119 seconds, respectively, for Fusion compared with the long-wire device). This latter point is particularly obvious in patients undergoing more complex ERCP procedures requiring multiple device exchanges or placement of multiple stents, in whom these efficiency advantages are magnified.

In conclusion, the study demonstrates that Fusion provides for significantly shorter device exchange and stent insertion times compared with traditional long-wire ERCP devices.

"Who's Who" of Endoscopists in Hong Kong for the 24th International Workshop on Therapeutic Endoscopy

Cyprian Tan

The 24th International Workshop on Therapeutic Endoscopy was held at the Prince of Wales Hospital in Hong Kong December 8-10, 2009. This high-powered annual workshop, organized by the Hong Kong Society of Digestive Endoscopy, began in 1985.

As usual, the international faculty list reads like a "who's who" of digestive endoscopists. Among the notables this year were Dr. Peter Cotton, Dr. Norman Marcon, Prof. Jacques Deviere, Prof. Horst Neuhaus and Dr. Nageshwar Reddy.

The workshop started off with the Minda and Don Wilson Lecture by Dr. Marcon on "Mucosal Resection: EMR or ESD – a Bit of Science – a Bit of Opinion." And, as has been customary for several years, Minda herself was there to grace the occasion.

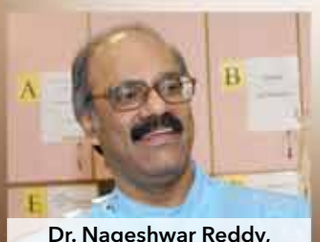
During the three days, the various faculty members performed many difficult and interesting procedures. Of particular interest were: bilateral hilar stenting; circumferential ESD for early tumor of the cardia; pancreatography and pancreatic ductal stone removal; and double biliary and duodenal stenting.

The meeting closed with a traditional Chinese banquet for all participants at the picturesque Aberdeen Marina Club.

Dr. Joseph Sung, Minda Wilson and Dr. Norman Marcon

Dr. Peter Cotton, Medical University of South Carolina, USA

Prof. Jacques Deviere, Erasme University Hospital, Brussels, Belgium



Dr. Nageshwar Reddy, Asian Institute of Gastroenterology, Hyderabad, India

Prof. Horst Neuhaus, Evangelic Hospital Düsseldorf, Düsseldorf, Germany

All Participants Were WINNERS at the 2nd Annual Interventional Endoscopy Course for GI Nurses & Technicians and Fellows

It's Vegas, baby! Yes, the 2nd Annual Interventional Endoscopy Course for GI Nurses, Technicians and Fellows took place at the one and only Caesars Palace, Las Vegas, Nevada. The course was held on February 26-28 with 192 participants representing 26 states, including eight participants from Hawaii.

The course began Friday afternoon with a warm welcome from Kathy Lamont, Director of the Gastroenterology Center at Northwest Community Hospital, Arlington Heights, IL, and **Dr. Willis Parsons**, Medical Director of Gastroenterology Center at Northwest Community Hospital. The course quickly shifted gears to education during the afternoon session, which was an update on gastrointestinal (GI) bleeding by Dr. Parsons. Dr. Parsons incorporated an interactive aspect into his presentation by rewarding participants with $10 casino chips for correct answers. His presentation included information related to variceal versus non-variceal bleeding, the appropriate therapies and devices that could be used to resolve the cause of bleeding, as well as alternate endoscopic techniques in helping to diagnose the source of bleeding.

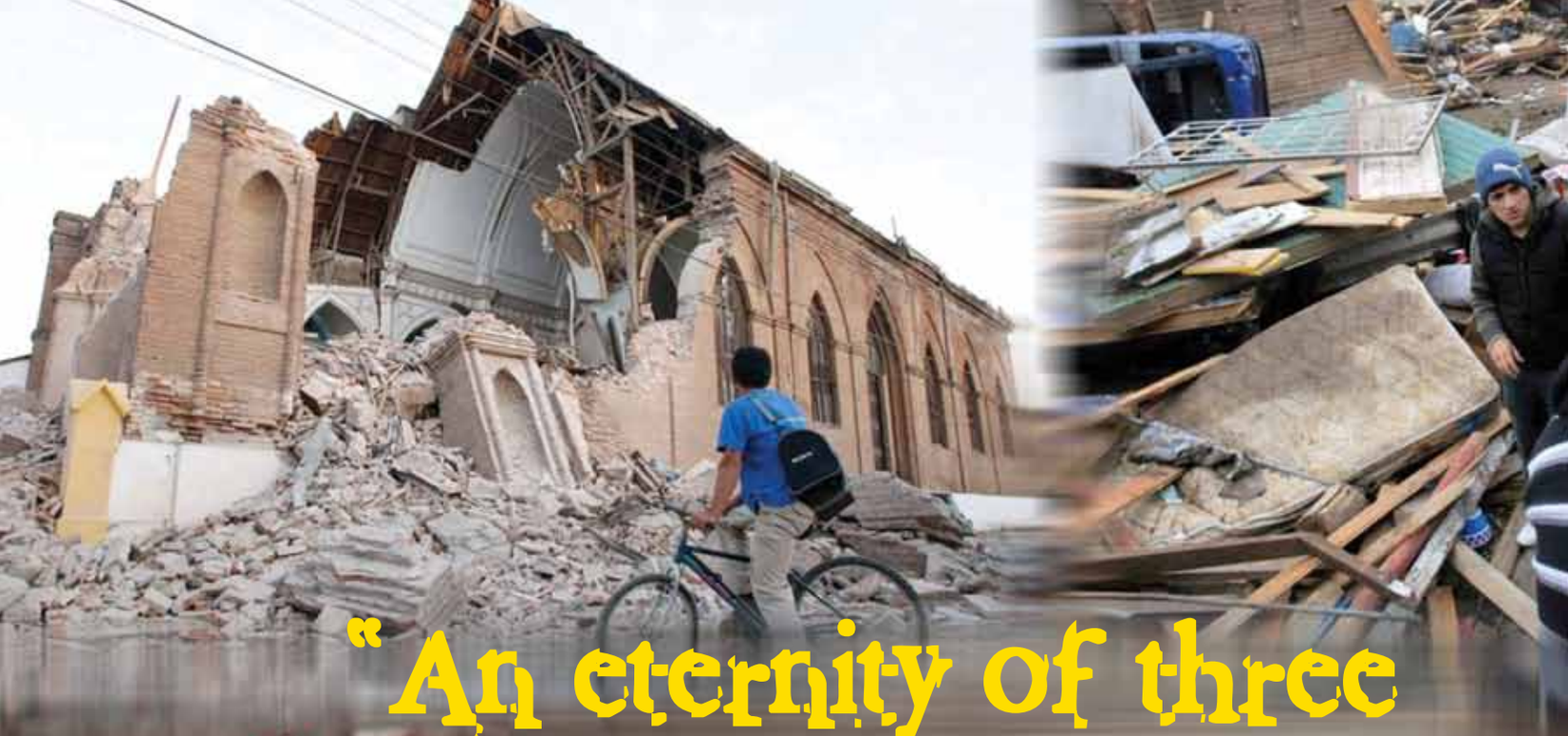
As the afternoon progressed, **Dr. Todd Baron**, guest speaker from the division of Gastroenterology and Hepatology, Department of Medicine, Mayo Clinic, Rochester, MN, discussed the indications for enteral self-expanding metal stents (SEMS), treatment options and case study information related to caring for the patient requiring an enteral SEMS.

At the close of the day, participants were challenged to an ERCP "fluoro quiz," which focused on the basics of interpreting fluoroscopic ERCP images. The normal anatomy of the pancreaticobiliary system was discussed and quickly followed by abnormal fluoroscopic imaging. The participant's goal was to determine the etiology of the patient's imaging abnormality.

During Saturday's session, participants had the opportunity to learn about other important GI related topics, such as the "ABC's of Anesthesia in the GI Lab," presented by Dr. Brian Cadre, Attending Anesthesiologist, Northwest Community Hospital, and "Surgical Intervention for Pancreatic Diseases," presented by Dr. Malcolm Bilimoria, Director of the Illinois Center for Pancreatic and Hepatobiliary Diseases, Northwest Community Hospital. As a bonus, various vendors were available for assisting with the hands-on sessions with the participants, giving them the opportunity to ask specific product-related questions as well as taking part in mock procedural simulations with the devices.

The last day of the course began with **Dr. Rameez Alasadi**, Center for Advanced Therapeutic Endoscopy, Northwest Community Hospital, giving an overview of "Endoscopic Ultrasound and Endoscopic Mucosal Resection (EMR)." Dr. Alasadi presented treatment modalities, which are safe and effective for more sensitive disease states, such as diagnosing suspicious lesions in the pancreas despite the size and location, celiac plexus neurolysis to alleviate chronic pain and EMR for diagnosing and treating superficial GI tract lesions.

Finally, as the meeting concluded, even those who did not do so well with "Lady Luck" in the casinos definitely went home with a wealth of knowledge on the latest in GI and ERCP updates. Those attending the entire session received a total of 16.25 contact hours for continuing education credit.



"An eternity of three intense minutes"

The February 27, 2010 Chilean earthquake

On Saturday, February 27, a massive, magnitude 8.8 earthquake struck near the coast of south-central Chile, shaking buildings and causing blackouts in parts of the capital Santiago, 200 miles (320 km) away.

The US Geological Survey said the earthquake struck 56 miles (90 km) northeast of the city of Concepcion at a depth of 34 miles (55 km) at 3:34 a.m. According to the USGS website, an earthquake of magnitude 8 or over is classified as a "great" earthquake that can cause "tremendous damage." Soon after, the Survey said the quake had generated a tsunami along the Chilean coast near the epicenter.

The Channel recently interviewed Dr. Juan Carlos Ayala and Cook Representative Victor Lira, who live in or near Santiago, to learn their personal experiences from the earthquake.

Dr. Ayala is an attending surgeon and endoscopist at both the Santiago Emergency Hospital and the Indisa Clinic of Santiago. Mr. Lira lives and works about 30 miles south of Santiago.

Where were you when the earth began to shake?

Dr. Ayala: I was sleeping in my house and I awoke to the movement of the bed. My wife and three children also were sleeping at home. I live 350 km away from the epicenter area, but the intensity recorded in Santiago was 8.6 degrees on Richter scale.

During the earthquake I experienced the "feeling of imminent death." It was a very scary feeling knowing you had no control over what was happening, "hearing" the earth move, the explosion of glass, screams of the people. We felt an eternity in those three very intense minutes, and later saw the vast destruction caused to thousands of people.

Victor Lira: I live with my wife, two daughters (23 and 16 years old) and three dogs. At 3:34 am on February 27 a tremendous sound and little movement woke us up (my wife and I). After some seconds, the sound and movement increased a lot and at this moment we decided to run with much difficulty (without balance) outside the house.

We have an open space in the front of the house that is defined as "our secure zone." At this moment, our most important concern was our daughters. The oldest was doing her professional summer work in another city 200 miles south of Santiago. The youngest was enjoying her last week on summer vacation with a friend's family at a beach 80 miles from Santiago.

What did you do immediately after the earthquake?

Dr. Ayala: Because of the quake, electricity and the phones stopped working. We only had news through a battery-powered radio. After the earthquake ended, I immediately looked for flashlights and shoes for my children and wife.

Once I checked the home and found no damage, we all went to the main room and heard the initial news, but for the next 24 hours, I never had access to images. Only after a day could I see the real extent of damage in different cities in Chile.

To my mind came the image of destruction and tragedy I saw in another earthquake in January 1999, in Colombia. At that time I felt sadness, fear and sorrow for the tragedy that thousands of people were living in areas of greatest destruction.

I also felt anxiety because I could not communicate with my family in Colombia. I knew they were worried and I had no way to call them. Fortunately a good friend from Cook Medical, engineer Andrés Aguirre, sent an e-mail to my Blackberry and I could answer him for help. He linked us from Winston-Salem to Colombia to my father and they could finally stay calm. Thanks again Andre! And Cook as usual ... helping solve problems!

After the earthquake, I was incommunicado for 12 hours as the signal from cell phones and landlines fell. We had no electricity in our home, just water and gas. The instructions via radio were to stay at home and avoid going out into the streets if it were not necessary.

Victor Lira: In the middle of the earthquake, all my neighborhood lost power, so I went back inside my house to get our mobile phones to call our daughters before the phone service went away. We tried many times to call, but the lines failed. Fortunately, many minutes later, I received a call from our oldest daughter. She was scared and crying, but explained that she was OK.

Because it was impossible to talk with our youngest daughter or with somebody from her friend's family at the beach, we decided to go for her. Fortunately, after 15 or 20 minutes, we received a call explaining that she was safe and on the highway traveling back to our home.

Did your house suffer any damages?

Dr. Ayala: There was extensive damage in Santiago city, but in our house, fortunately, we did not have personal or material damage, just some things fell to the floor without breaking.

Victor Lira: In our home, many things fell down; we lost some lamps, cups and dishes only. In our neighborhood, the earthquake only damaged the roof of some houses. But close to our home in a small village, farm workers lost their houses, and an old school and community hospital were destroyed, fortunately, without personal injuries.

Photos courtesy of
Dr. Juan Carlos Ayala

Did the tsunami affect you?

Dr. Ayala: The city of Santiago is 120 km from the coast, so the tsunami did not affect the city. But the pool at my house lost a quarter of its volume due to the force of the waves produced by earthquake. The pool's thermometer that usually floats on the surface hung from small rubber duck was found about three meters away over the garden's plants!

How do you rate emergency medical care in Chile?

Dr. Ayala: The quality of emergency medical care in Chile is very good, but unfortunately the coordination by the offices responsible for the disaster was inadequate and delayed some emergency responses.

When emergency personnel had the opportunity to deliver care, it was good. In addition, international aid teams and medical emergency hospitals in the places of greatest destruction provided adequate quality.

Victor Lira: Some big hospitals and community hospitals suffered structural damages. Twelve hospitals closed and the only medical services that were used are ones for war times, called modular hospitals. These were provided from Argentina, Brazil, Germany, China and the USA.

Were you and your colleagues able to help victims of the disaster?

Dr. Ayala: In our hospital's Endoscopy Unit, we doctors were available to assist if needed, but the biggest disaster site was 500 km from our city. So from that point of view, we did not have GI emergencies. In addition we could not move up due to damage of many bridges, which made it difficult to travel. Finally, there was no need to go to strengthen the doctors who were already on duty. Other hospitals – assisted by the police, navy, army and air force – sent doctors to the disaster area.

What messages would you like to send to the medical community in Chile?

Dr. Ayala: I compliment and congratulate the Chilean medical community for the professionalism with which they provided aid in the sites of major disasters. Also, I want to highlight the courage and commitment of medical students who voluntarily traveled to assist in various tasks.

The disaster makes me think more about how fragile life is, that it may end in a brief moment. After this experience, I think my life is not the same. Now I appreciate the miracle of life. I try to spend even more time with my family and thank God for every day that I get to live. Life is short, really short, and unfortunately we sometimes need certain experiences to wake up and open our eyes to appreciate what we have.

My advice to people at risk of facing an earthquake is that they always know the evacuation plan and security places, follow directions of people trained in disaster and remain calm.

As for tsunamis, have adequate training on escape routes to high places far from the sea, and have an emergency kit read, always with items such as flashlights and radio batteries.

Victor Lira: The real heroes in this disaster were the rescue personnel, and firemen ("bomberos" is the Spanish word) who work voluntarily without payment.

New Web-based Video Library Will Create a Community for EUS Practitioners

As the market's leading supplier of EUS devices, Cook Medical has worked closely for many years with some of the foremost endosonographers around the world. That collaboration, which has brought about the development of many innovative ultrasound diagnostic and more recently therapeutic tools, has also resulted in a new web-based video library designed specifically as a resource for EUS practitioners. The video library will soon be accessible by registering at Cook Endoscopy's home page.

One of the first contributors to the library is **Dr. Anand Sahai**, Associate Professor of Medicine and Chief, Division of Gastroenterology at the Centre Hospitalier de l'Université de Montréal in Canada. He says that visitors to the library "can expect to see a large number of cases in a relatively short time, featuring various endosonographers."

The library will be a useful resource for endosonographers of all degrees of experience. **Dr. Marc Giovannini**, Chief of the Endoscopy Unit at Paoli-Calmettes Institute in Marseilles, France, who is also featured in the video library's inaugural entry, said, "Many endosonographers who are just starting out performing EUS procedures asked us to develop a video library like this."

As the library increases in size, the EUS videos will be cross-referenced so that users can search for cases based on different variables – such as indication, lesion type, disease state and/or clinician. "The goal," said Dr. Sahai, "is to provide access to an ever-expanding selection of real-life EUS cases that show various endosonographers' approaches to common problems."

The EUS Video Library will also offer procedures performed by **Dr. Girish Mishra**, Associate Professor, Internal Medicine (Gastroenterology) and Director of Endoscopic Ultrasound Services at Wake Forest Baptist Medical Center in Winston-Salem, North Carolina; and **Dr. Mohamad Eloubeidi**, Associate Professor of Medicine at the University of Alabama – Birmingham (UAB), Division of Gastroenterology and Hepatology and Director of the UAB Endoscopic Ultrasound Program. And there will be many more EUS procedural videos to come.

The library is designed to create a community where endosonographers can learn new techniques and share their expertise. "Hopefully, the library will eventually lead to an EUS forum that allows discussion of the cases and interaction between users," Dr. Sahai said.

The ultimate goal for the library is to enhance patient care. Dr. Sahai concludes: "Increasing EUS experience and expertise should lead to better outcomes."

William R. Brugge, M.D.

David G. Forcione, M.D

Naz Janer, RN

Aman Ali, MD, Advanced Endoscopy Fellow, reviews a case with Dr. Forcione.

Digestive Heal

at Massachusetts General Hospital, Harvard Medical School

Collaboration for Patient Care and Cutting-Edge Research

At the prestigious Digestive Health Care Center at Massachusetts General Hospital, a teaching hospital for Harvard Medical School, more than 55 physician specialists and 65 nurses have created a successful patient-centered system. "Our collaboration is based on people with the same philosophy – to provide the best patient care possible," explains William R. Brugge, MD, Professor of Medicine, Harvard Medical School.

The third-oldest general hospital in the U.S. and the largest hospital in New England, Mass General is consistently ranked among the top five hospitals in the nation. The 900-bed medical center offers sophisticated diagnostic and therapeutic care in virtually every specialty and subspecialty of medicine and surgery. A leader in bridging innovative science with state-of-the-art clinical medicine, Mass General conducts the largest hospital-based research program in the country. A key facet of that program involves gastroenterology.

Over a century of gastroenterology experience

Massachusetts General has had a GI unit for more than 100 years. "The most dramatic growth occurred in the last 15 years, when we went from 10 to 38 staff gastroenterologists," Dr. Brugge said. "Within the GI section we have four pancreas and biliary physician specialists and five surgeons. We were the first in the Boston area to do EUS, ERCP and bile duct endoscopy. The team performs approximately 2000 advanced endoscopic procedures each year.

"Approximately 80 percent of our patients come from New England," said Dr. Brugge, "and the rest are referred from all areas of the US." In addition to the Center's reputation, a large referral base sends patients to Dr. Brugge and his colleagues because of their success in endoscopically diagnosing and treating many serious GI conditions, including pancreatic cysts, lesions, stones, cancers, and recurrent inflammation of the pancreas. Dr. Peter Kelsey, the Associate Director of Endoscopy, has pioneered the use of cholangioscopy. Dr. Brugge noted that another departmental strength is the efficient coordination and scheduling of GI procedures directed by Naz Janer, RN.

In addition to his patient care responsibilities, Dr. Brugge pursues several academic responsibilities. These include managing an endoscopic research lab and conducting a training program for Advanced Endoscopic Fellows. The Advanced Endoscopy Fellowship program has two Fellows a year and partners with the Brigham and Women's Hospital in Boston. "The Advanced Endoscopy fellows work closely with the 20 gastroenterology fellows in patient care, research projects, and writing," said Dr. Brugge. Dr. Brenna Bounds is the Director of Endoscopic Teaching and provides hands-on teaching of GI and Advanced Endoscopy Fellows.

Collaborating to solve complicated cases

David G. Forcione, MD, Instructor in Medicine at the Harvard Medical School, and attending physician in Interventional Endoscopy, recalled a recent case history of collaboration among the hospital's GI, General Surgery and Interventional Radiology groups.

A community hospital referred a 74-year-old patient for cholangitis resulting from stones. He had an extensive abdominal surgical history and was a poor candidate for conventional ERCP and for additional surgery. "Our unit became involved and diagnosed six stones in the patient's bile duct," Dr. Forcione recalled. "We collaborated with an interventional radiologist to place a catheter in the bile duct. Interventional endoscopy provided two sessions of electrohydraulic lithotripsy performed using a cholangioscope through the percutaneous catheter. The results were excellent. The stones were removed and the patient avoided surgery."

Dr. Brugge recalled another collaborative success story involving a patient who presented with pancreatitis and severe pain. "Following a CAT scan and blood test," Dr. Brugge said, "the patient was sent here for an evaluation. Endoscopic ultrasound and fine needle aspiration was used to evaluate the pancreas. Instead of finding pancreatitis, a pancreatic malignancy was identified. Using a team approach, the patient was evaluated within a day for surgery and chemotherapy."

LTH CARE

Reputation for research attracts expert specialists and advances patient care

The unit has attracted high-quality physicians who offer specialties and procedures not widely available elsewhere. "In the past, pancreatic surgery was generally unsuccessful. But now we have achieved much better, safer results in removing malignancies and benign lesions from the pancreas," explained Dr. Brugge.

Much of Dr. Brugge's research has focused on enhanced pancreatic cancer diagnosis. Working with Dr. Andrew Warshaw, a world-renowned pancreatic surgeon at MGH, the MGH GI group performed a number of studies in animals and realized the potential for endoscopic pancreatic biopsies. "We began those in 1995 and the procedure has proven to be very successful. Now we are using the same EUS procedure to inject ablative agents into the pancreas."

Since then, Dr. Brugge and his colleagues have developed a variety of endoscopic techniques to aspirate malignant and pre-malignant lesions of the pancreas, including cystadenomas, intraductal tumors and masses.

This work has national and international implications. MGH physicians organized and spearheaded a national cooperative pancreatic cyst study. Dr. Brugge noted: "We collaborated with the MGH Cytology and Chemistry Departments to detect cancer markers in pancreatic fluid. We found the best marker was Carcino Embryonic Antigen – or CEA."

In addition, the group discovered that injecting alcohol into pre-malignant pancreatic cysts could eliminate up to a third of cysts. "At first, many physicians were wary of this procedure; however, we found it is safe with carefully controlled techniques. A wide variety of pancreatic ablative agents have been investigated in the animal laboratory."

A new imaging technique with many promising applications

In a collaborative effort with the MGH Wellman Institute, physicians and engineers developed a new GI tract imaging procedure called Optical Coherence Tomography (OCT). The procedure has substantially improved diagnoses for Barrett's esophagus. Other possible uses for OCT are diagnosing bile duct malignancies and pancreatic cysts. "We are proud to be part of a test team that is bringing this procedure into the arena," said Dr. Brugge.

An important GI physician involved in the OCT studies is Dr. Norman Nishioka. "He has done a lot of work in Barrett's esophagus and has a large referral base," explained Dr. Brugge. "Through his work and that of his colleague, William Puricelli, RN, we are able to offer multiple forms of therapy, such as EUS, EMR, ablative therapy, radio frequency ablation, BARRx tool, cryotherapy and photodynamic therapy. Thus, we can offer many options for Barrett's dysplasia and early cancer."

A bright future of innovative therapies

Dr. Forcione, reflecting on the accomplishments of the unit, named some objectives: "Most of us want to redirect the focus from diagnosis to therapy. For example, implanting ERCP stents with therapeutic uses such as radiation emission and drug therapies. For EUS, we strive to enhance biopsies and therapies by ablation or injection."

Regarding endoscopic research focuses, Dr. Brugge wants the unit to pursue the benefits of natural orifice transendoscopic surgery, a relatively new concept in endoscopy. He notes that Drs. Sevde Cizginer and Brian Turner are already exploring endoscopic experiments through the esophagus to the lungs, heart and other areas.

"We believe that using the endoscope outside the stomach can not only access other organs, but also remove gallbladders and parts of the pancreas. Although this work is still experimental, I feel confident that collaboration with our GI surgeons will lead to further success," concluded Dr. Brugge.

MGH 1811 MASSACHUSETTS GENERAL HOSPITAL

National and International Recognition

The MGH Digestive Healthcare Center is recognized both nationally and internationally for groundbreaking research and outstanding patient care.

US News and World Report Honor Roll of America's Best Hospitals, 2009-2010

Last year, MGH was ranked fourth in the nation for treating digestive disorders.

American Nurses Credentialing Center Magnet Hospital

Magnet designation represents the highest honor available for nursing excellence and is achieved by only five percent of hospitals in the US.

Leapfrog Top Hospital

The Leapfrog Group's quality and safety survey is an important measure of a hospital's commitment to patients' well being.

Research at the MGH Digestive Healthcare Center

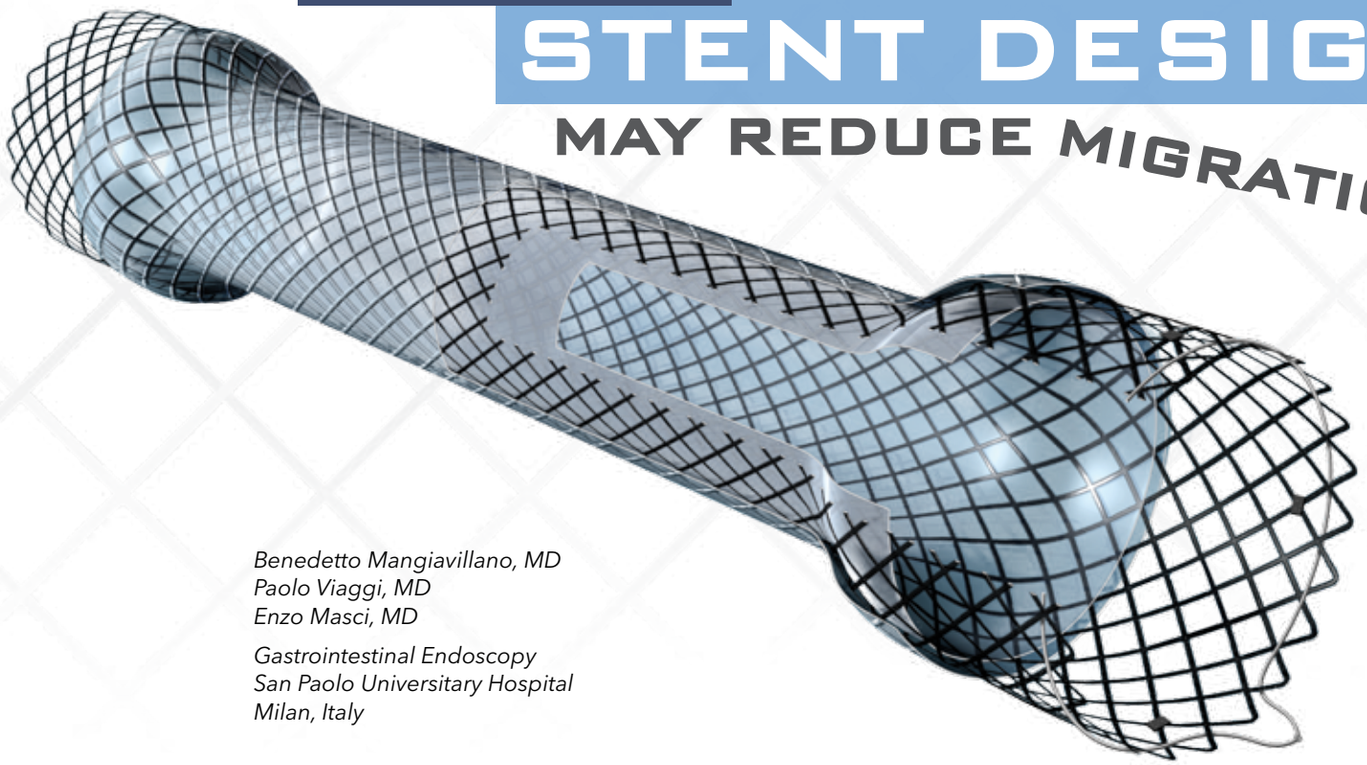
Important research topics that are actively investigated by the research faculty include:

Genetics
Obesity
Colon cancer
Development of the GI tract
Viral replication and injury
Origins of GI tumors
Epidemiology of digestive diseases
Inflammatory bowel disease
Minimally invasive surgery
Pancreatic research
GI epithelial biology

See "Harvard EUS Live 2009" on page 14.

ESOPHAGEAL EVOLUTION®
CASE STUDY

STENT DESIGN MAY REDUCE MIGRATION



Benedetto Mangiavillano, MD
Paolo Viaggi, MD
Enzo Masci, MD

Gastrointestinal Endoscopy
San Paolo Universitary Hospital
Milan, Italy

Figure 1
Esophageal X-ray showing the neoplastic stenosis

In November 2008, a 58-year-old patient, with a previous diagnosis of proximal squamocellular esophageal neoplasia with liver and lung metastasis, was referred to our attention because of rising of solid and semisolid food dysphagia. The patient was previously judged as non-eligible for surgery, and chemotherapy was started.

An esophageal X-ray was then performed, revealing a short proximal esophageal stenosis of about 1.5 cm length (Fig. 1). At the end of December 2008, the patient underwent GI upper endoscopy under deep sedation, confirming the neoplastic stricture with a residual lumen of 6 mm and a metallic esophageal stent (10 cm x 18-23 mm) was placed across the stenosis (Fig. 2). The patient started feeding 24 hours after the procedure and was discharged on the second day.

After one month the patient was newly referred to our unit because of dysphagia. A chest thorax plus abdomen X-ray was performed revealing the migration of the stent. A second metallic stent, with a larger diameter (9 cm x 22-27 mm) than the previous stent was placed across the neoplastic stricture. The patient started feeding 36 hours after the procedure without any complication, not referring more dysphagia, and was discharged on the third day.

A month and half later, the patient came back to our unit after developing, for the third time, dysphagia. A chest thorax plus abdomen X-ray was performed revealing the absence of the metallic esophageal stent.

Because of the dislocation of the two metallic stents and the short esophageal stenosis, we considered the insertion of a different esophageal metallic stent with a larger distal diameter because of its reported low rate of migration.

Under deep sedation the patient underwent esophagogastroduodenoscopy (EGD), confirming the absence of the previously placed esophageal stent. Then an Evolution esophageal stent (Evolution esophageal, 10 cm x 20-25 mm; Cook Medical) was released across the stricture (Fig. 3). No complications were observed during the procedure and 48 hours thereafter. The patient was allowed feeding 24 hours after the Evolution esophageal stent placement, and the dysphagia was solved. A chest X-ray was performed the day after procedure showed the correct stent placement.

Figure 2 (Left)
Chest X-ray showing the first metallic esophageal stent placed across the stricture

Figure 3 (Right)
Esophageal Evolution stent

Seven months later, in September 2009, the patient came back to our attention because of solid food dysphagia. A chest thorax X-ray revealed the correct position of the Evolution esophageal stent. An EGD was performed showing a neoplastic and inflammatory tissue overgrowing at the distal extremity of the Evolution stent, with a residual lumen of about 7 mm. We decided to attempt to solve the stenosis with a placement of a second Evolution esophageal stent (Evolution esophageal, 10 cm x 20-25 mm; Cook Medical) across the overgrowth tissue. No complications were encountered during this stent placement. An X-ray performed the day after revealed the correct position of the two stents and the feeding was started after the fluoroscopic control.

The patient died three weeks later because of poor clinical conditions.

After migration of the two previously placed esophageal metallic prostheses, we considered placing an Evolution esophageal stent because, as opposed to other metallic stents, the Evolution stents present the proximal and distal extremity with a larger diameter than the body and a major numbers of crowns, allowing to the stent to have best "anchorage" at the esophageal walls.

Stent migration is still a frequently occurring problem, particularly for distally located tumors.[1] The design of the stent is probably important in reducing stent migration. Two multicenter studies show that the stent design may play a role in stent migration, demonstrating how the combination of a larger flare at both ends reduces the stent migration rate.[2] Homs et al. showed that the self-expandable metal stent with a single proximal large flare presents a major migration percentage.[3]

If compared to other types of stents, the major radial force of the Evolution esophageal stent allowed reduced stent migration, despite the short length of the neoplastic stenosis.

Figure 4
Double esophageal Evolution stents

1. Sieresema PD, Marcon N, Vakil N. Metal stents for tumors of the distal esophagus and gastrici cardia. Endoiscopy 2003; 35:79-85

2. Verschuur EM, Repici A, Kuipers EJ, Steyerberg EW, Siersema PD. New design esophageal stents for the palliation of dysphagia from esophageal or gastric cardia cancer: a randomized trial. Am J Gastroenterol 2008; 103:304-12

3. Homs MY, Steyerberg EW, Kuipers EJ, van der Gaast A, Haringsma J, van Blankenstein M, Siersema PD. Causes and treatment of recurrent dysphagia after self-expanding metal stent placement for palliation of esophageal carcinoma. Endoscopy 2004;36:880-6

HARVARD EUS LIVE 2009

The Teaching and Training of Endoscopic Ultrasound

William R. Brugge, MD, Massachusetts General Hospital, Boston, MA

Dr. William R. Brugge

Introduction Didactic and hands-on training in endoscopic ultrasound is critical for the development of EUS skills in an endoscopist. What is the best way of teaching endoscopists how to perform FNA and therapeutic procedures with EUS. The Harvard EUS course provided a variety of methods for teaching physicians EUS FNA.

Background The Harvard EUS course has provided a forum for discussion of critical EUS issues for nearly 13 years. There are many unique aspects of the course, including a close collaboration between the Harvard teaching hospitals in the presentation of the three-day course. The most important goal of the course is to create many opportunities for the faculty and participants to learn together.

EUS Live 2009 The Harvard EUS course in 2009 was a three-day event featuring lectures, live demonstrations, hands-on demonstrations and an animal workshop. The course was attended by nearly 150 participants. A series of lectures from the Harvard faculty and invited speakers focused on the use of EUS in gastroesophageal malignancy, pancreatic lesions and sub-epithelial lesions. The live demonstrations took place at Massachusetts General Hospital and were delivered to a large screen at the Fairmont Copley Plaza Hotel. The audience was able to learn from the experts by watching the performance of difficult EUS procedures.

Interactive Sessions One of the unique aspects of the EUS Live program was an opportunity for the audience to interact with the faculty in a variety of forums. On the first night, a case presentation dinner was held for the audience and faculty. The faculty was asked to present their 'best' and 'worst' cases. Prizes were awarded to the best presentations. The course participants were able to ask questions of the presenters and vote on the best presentation.

The EUS Hands-on Demonstration On the second day, the participants had an opportunity to learn EUS procedures and techniques by performing hands-on procedures in a unique EUS phantom model. There were eight stations, each of which was staffed by a faculty member. The stations were devoted to a specific procedure such as pseudocyst drainage, node aspiration or probe endosonography. The Erlangen model used pig organs underwater for ultrasound transmission. A variety of 'lesions' were created in order to simulate 'real' disease. For example, gastric stromal cell tumors were created using muscle tissue.

The Final Exam For the first time, the course participants were asked to take a one hour multiple-choice examination in EUS. Drs. John Saltzman (Brigham and Womens' Hospital) and John DeWitt (Indiana University School of Medicine) administered exams in gastroesophageal lesions and pancreatic-biliary diseases. An audience response system provided the results of the participants' answers in "real time." The presenters discussed the correct answers and offered explanations for the various responses.

The Last Day The three-day event concluded with an animal lab experience. In five stations, the faculty was able to demonstrate EUS in live animals using a variety of EUS procedures. The participants performed many of the procedures under the careful monitoring of the faculty. The highlight of the workshop was the demonstration, for the first time in the US, of a cryotherm probe by ERBE. The probe was used to ablate pancreatic tissue.

Conclusions The close interactions between the faculty and the participants provided an exciting learning venue for all. Many of the faculty commented on how much they learned while teaching the participants. The participants can't wait for the course next year.

case presentation

Unusual Biliary Anatomy at ERCP

Dr. Raymond McCrudden and Dr. Earl Williams, Department of Gastroenterology
Dr. Arnie Drury and Dr. Sonya Snape, Department of Radiology
Royal Bournemouth Hospital, East Dorset, United Kingdom

A previously fit and well 84-year-old patient presented with new onset obstructive jaundice to his general practioner. On referral to hospital his blood tests showed a bilirubin rise of 101 (normal range – 17.00 µmol/l), an Alkaline phosphatase of 205 iu/L (30-150) and an Alt of 47 iu/L (- 35). A transabdominal ultrasound showed a shrunken gall bladder with at least three small stones but poor views of the common bile duct (CBD). A CT scan was therefore ordered which showed unusual anatomy consisting principally of two long hepatic ducts coursing down to the duodenum and joining just proximal to the ampulla to form a very short CBD. (Figure 1 & 2). The right hepatic duct was dilated to 19 mm and the left hepatic duct to 17 mm; both ducts contained soft tissue densities in the mid to distal portions. In the region where the two ducts unite, there was a further 19 mm soft tissue density immediately superior to the ampulla. An ERCP was ordered on the suspicion that these intraductal lesions were CBD stones.

At ERCP the two ducts were visualized sequentially after cannulation by cholangiography beginning with the left duct.

Omnipaque 240 mg diluted to 50/50 (5 ml contrast + 5 ml normal saline) was the contrast used for cholangiography. The left hepatic duct was cannulated and opacified first as seen in Figure 3. An FS-OMNI-35 sphincterotome, preloaded with .035" guide wire for cannulation of the first duct (right on the X-Ray), was incorporated; following sphincterotomy, the duct was cleared using an FS-QEB-XL-A extraction balloon (12 mm, 15 mm, 18 mm & 20 mm diameter). The right system was challenging to access, given the altered anatomy. The Fusion OMNI 21, preloaded with .021" guide wire, was used to cannulate the duct and stones were removed with the same extraction balloon. The procedure was completed with all stones cleared from both ducts. After balloon trawls of each duct, a balloon occlusion cholangiogram confirmed that the procedure was complete for each duct in turn.

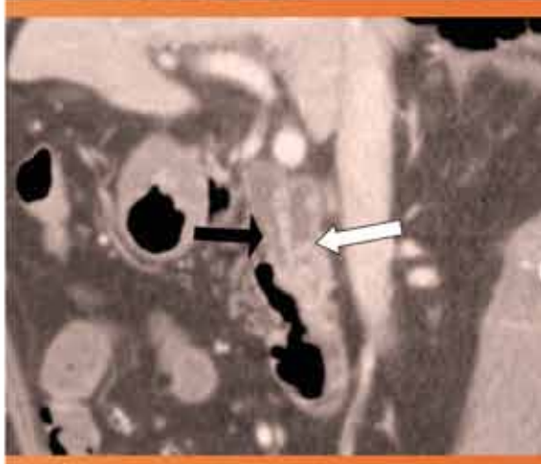


Figure 1
Axial CT image showing dilated left (black arrow) and right (white arrow) hepatic ducts, both containing gallstones.

Figure 2
Sagittal reconstructed CT image showing dilated left anterior (black arrow) and right posterior (white arrow) hepatic ducts, both containing gallstones, above a duodenal diverticulum.

Figure 3
Cholangiogram during ERCP demonstrating two long hepatic ducts which merge to form a short common bile duct at the ampulla. The cystic duct comes off from the mid right hepatic duct.

Discussion: Biliary and pancreatic duct anatomical variations are commonly reported at radiology though may not always be seen at ERCP. A variety of anomalies have been reported. The most common concerns the drainage of the right posterior duct (RPD) into the left hepatic duct (LHD) before its confluence with the right anterior duct (RAD). Another reported anomaly describes simultaneous emptying of the RPD, RAD and LHD into the common hepatic duct (CHD) leading into a "triple confluence." Three common variants of the cystic duct are described, such as the low cystic duct insertion into the distal extra hepatic bile duct (EHD); the medial cystic duct insertion, in which the cystic duct drains into the left side of the CHD and a parallel course of the cystic duct with the CHD, where the cystic duct runs closely parallel to the CHD for around 20 mm prior to insertion. The anatomical variation described here is rare. Clinical recognition of these variations is important in recognizing the different ducts present not only for ERCP but in other arenas, for example during hepatobiliary surgery or laparoscopic cholecystectomy.

Jean Brihay: 1933-2010

Jean Brihay, whom Prof. Jaques Devière calls "a towering figure in the world of endoscopy," passed away on April16, 2010. Jean, Cook Medical Endoscopy division's first International Sales Representative, dedicated much of his life to the field of gastroenterology. Over the course of 25 years, Jean made Cook Medical a major presence in the international marketplace, and achieved one of his greatest legacies: the development of "the endoscopic workshop."

Jean worked and collaborated with some of the world's most renowned gastroenterologists, including such notables as: Professors Nib Soehendra, Jacques Devière, Claude Liguory, Michel Cremer, Horst Neuhaus, Guido Costamagna, Kayse Huibregtse, Ibrahim Mostafa, and Doctors Marc Giovannini and Christopher Williams, among many others.

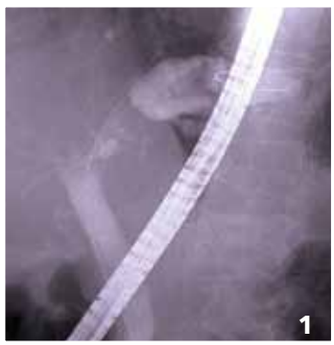
Jean took it upon himself to recruit established clinicians to mentor younger clinicians. The resulting classes evolved into vigorous, hands-on sessions. It was through these educational sessions that Jean achieved one of his greatest legacies – the development of "endoscopic workshops," which brought the "students" right into the procedure room, observing and working alongside expert physicians. "Jean created a true international network of therapeutic endoscopists," says Prof. Devière, "which dramatically influenced the international collaboration in Europe."

Jean's full and varied life and career would be difficult to sum up in a single sentence, but Prof. Devière comes as close as one can: "This gentleman is a towering figure in the world of endoscopy; a man that two generations of endoscopists will always remember for his education, generosity, humanism and professionalism."

All of us who knew Jean will miss his smile and his boisterous laughter, his enthusiasm and his passion. But most of all, we will miss his friendship.

What's Up Doc?

Jong H. Moon, MD, PhD
Digestive Disease Center, Division of Gastroenterology
Soon Chun Hyang University School of Medicine, Bucheon/Seoul, Korea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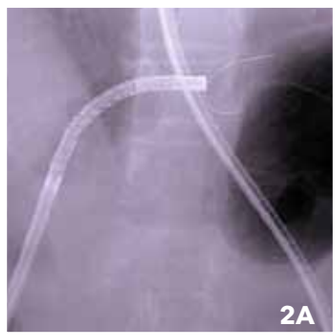
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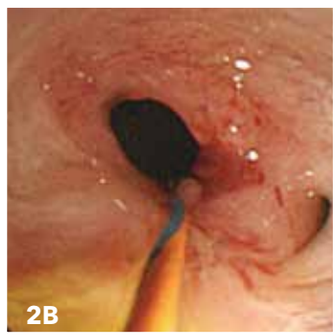

2B

A 63-year-old patient with acute cholangitis had persistent bile duct stricture and dilation on left hepatic duct after CBD stone removal (figure 1). We performed direct peroral cholangioscopy (POC) by using an forward-viewing endoscope to examine the strictured segment (figure 2 A, B). Much mucin was observed above the stricture (figure 3). Target biopsy under direct endoscopic visualization was done for the strictured lesion (figure 4). The patient underwent an extended left hepatectomy.

What is the diagnosis?

To confirm your diagnosis, click the newsletter button on endoscopy homepage of www.cookmedical.com <http://www.cookmedical.com>

We are looking for more submissions and welcome your participation. If you want to submit an image with a written case history and clinical explanation, please contact Kevin Chmura at kevin.chmura@cookmedical.com.


3


4

Japanese Digestive Disease Week 2009 attracts 17,000 participants

Cook Medical partnered with Medico's Hirata of Japan at the Japanese Digestive Disease Week 2009 (JDDW) to exhibit Cook's a wide array of GI devices such as EchoTip® Ultra Endoscopic Ultrasound needle with HDFNA™, Hercules® 3 Stage Dilation Balloon, 4,6,10 Shooter™ Saeed Multi-Band Ligator, Fusion® Biliary System, and Zilver®Biliary Self-Expanding Metal Stents.

JDDW was held from Wednesday, October 14 to Saturday, October 17 at the Kyoto International Conference Hall and Grand Prince Hotel in Kyoto. Since JDDW first began in 1993, it has been considered the major medical conference in Japan. There were approximately 17,000 participants through the term of the four-day meeting. Eight separate lectures took place at the exhibition booth throughout the four day meeting. Each booth lecture was conducted by an expert physician in the area of GI with an audience of anywhere from 30-50 participants. Booth lecture topics included EUS, wire guided cannulation, placement of metal and plastic stents, and esophageal balloon dilation.

Cook invited Dr. Roy Soetikno, Chief of GI Endoscopy at VA Palo Alto Health Care System (bottom left) to participate in a luncheon seminar titled "Interventional EUS-US Experience." There were approximately 250 participants that attentively listened to his lecture, which was followed by a question and answer session. Dr. Takao Itoi of Tokyo Medical University Hospital acted as the moderator of this successful seminar.

In addition to the EUS luncheon seminar, there was also an EUS-themed table discussion that Dr. Soetikno participated in with approximately 20 other Japanese physicians (bottom right). They shared the newest information and arguments in relation to EUS. All attendees walked away with a better understanding of the technological enhancements in the world of EUS.

NEWS FROM

SIGNEA

Society of International Gastroenterological Nurses and Endoscopy Associates

Highlights of GASTRO 09

Ulrike Beilenhoff, President of ESGENA, Pauline Hutson, Chair of BSG-EAG and Norah Connelly, President of SIGNEA.

Sarah Marshall and Val Pyor with the bowel screening program brochure.

Great poster on Computerization of Digestive Services by Natalia Bartolome, Quality Department, Hospital Del Mar, Spain.

Debbie den Boer BSN, RN, CGRN

Norah Connelly, President of SIGNEA, Ulrike Beilenhoff, President of ESGENA and Pauline Hutson, Chair of BSG-EAG were interviewed for the Gastro 09 newsletter that was distributed every day at the congress. All three gave a very concise and insightful summary of the goal and outcome of this combined, international conference. "It was bringing different professional cultures together."

SIGNEA's President, Norah Connelly said: "We believe that our association with Gastro 2009 will strengthen our relationships with colleagues worldwide. We have a wealth of international speakers that keep us abreast of new techniques and technology in the field as well as best-practice initiatives and research. There are varying degrees of societal cultures which shape the way practices operate around the globe."

About the conference, Ulrike Beilenhoff said: "The topics touch on clinical work as well as education and research, combining state-of-the-art lectures with free papers and posters, workshops and hands-on training."

"It is a great honour to be hosting the world conference," declared Pauline Hutson, chair of BSG-EAG. "The educational program for visiting nurses encompasses many aspects of gastroenterology and endoscopy and includes practical workshops and opportunities to update knowledge and skills."

The ESGE/OMED Learning Area was a haven for endoscopists and nurses as well as associates because these hands-on sessions were performed on biological models to practice skills. State-of-the-art equipment and accessories were used for the benefit of tutoring nurses and physicians. The DVD Learning Center was equally popular where teaching material and case studies were available on videos with headphones. Live demonstrations were broadcast from as far as Hyderabad, Rome and London.

The GI Gastro 2009 Nursing conference started with multiple 90-minute workshop sessions, covering topics such as: cleaning, disinfection and new drying guidelines, bowel preparation, the nurse's role in Crohn's disease, esophageal manometry and Bravo ph monitoring, biofilm transmission and many more.

and GI Nurses 09 Scientific Program

Entrance to the famous St. Mark's Hospital, London.

Van Pyor, Endoscopy Manager, took the group on a tour through her unit. (L–R) Rebeccah Chandler (USA), Debbie den Boer (SIGNEA) and Siriporn Ratanalert (Thailand).

Group of attendees from Jordan and Sudan with SIGNEA board members.

Dr. Lawrence Muscarella gave a very comprehensive lecture on "The risk of biofilms and transmission of Clostridium Difficile and other epidemiologically important infectious agents during GI endoscopy." He discussed the properties of biofilms, how they form and the different surfaces on which they may form. Reviewing the standard precautions, Dr. Muscarella emphasized the three primary modes of disease transmission and transmission-based precautions. Is GI endoscopy a risk factor for the transmission of biofilms? This is a very valid question and he discussed strategies to prevent the transmission of biofilms, C. Difficile and multi-drug-resistant-organisms during GI endoscopy. (See website myendosite.com)

The free paper and poster sessions give GI nurses and associates the opportunity to report on research and findings done in their own units and countries. Roaming through the exhibit hall, stopping by the vendor booths, handling and playing with the equipment and listening to the eager well trained vendor representatives is so much part of a great congress. This encompasses the whole learning process and we are grateful for the continuous support of our vendors.

A group of us visited the famous St. Mark's Hospital in Northwick Park, London, where director and manager Mrs. Val Pyor met us and showed us her very large endoscopy unit. Because of a live demonstration to the congress the next day, audio-visual engineers were working frantically to get all the cables laid and all the cameras in position. Val Pyor also introduced us to the St. Mark's Bowel Screening Centre where Sarah Marshall informed us of the cancer screening program.

SGNA's president, Terrie Vos honored Christiane Neumann, past president of ESGENA with a SGNA lifelong honorary membership for her contribution to GI endoscopy nursing.

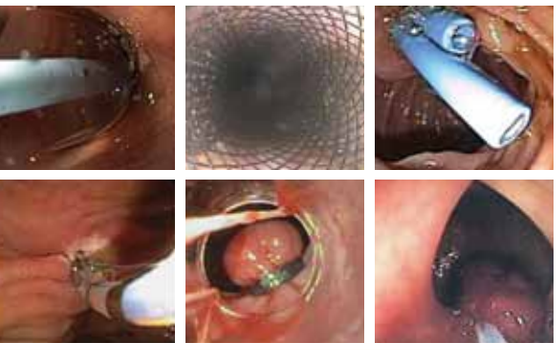
Beyond all the academics, education and hands-on training is the very important aspect of networking, and these conferences are havens for professional, collegial and personal friendships. It is always wonderful to observe the warm greetings and hugs when people meet each other again! It is great to be a GI nurse and belong to an organization like SIGNEA.

United Kingdom Gastrointestinal Nursing Journal editor, Annie Hall and colleague.

Above: Christianne Neumann with Terrie Vos, president of SGNA.

GI 360

EDUCATIONAL PROGRAMS



Cook Medical has long understood that optimal patient care is your focus, and it continues to be our focus as well. That's why for more than twenty years we have assisted healthcare professionals in learning the latest in endoscopic GI technology and related disease information.

That tradition continues as Cook Medical, in partnership with HealthStream (an accredited provider of continuing nursing education), offers three new educational activities:

Updates in Esophageal Cancer with Focus on Therapeutic Treatment Options

Updates in Esophageal Cancer with Focus on Diagnosis and Palliation

Updates in Enteral Feeding

We are pleased to announce that the American Board of Certification for Gastroenterology Nurses (ABCGN) has reviewed these educational activities and recognized them as providing GI specific content.

These activities are presented without charge by your Cook Medical district manager. Educational activity descriptions, objectives and the related accreditation information can be found at http://www.cookmedical.com/esc/educationResource.do?id=Educational_Activity.

Contact your Cook representative for more information or to arrange a presentation opportunity.

HealthStream®

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A continuing nursing education activity sponsored by HealthStream. Grant funds provided by Cook Medical.

UPCOMING EVENTS

SGNA	*Orlando, FL*	***May 2-4***
DDW	*New Orleans, LA*	***May 2-5***
Advanced Endoscopy Update	*Isle of Palms, SC*	***May 7-8***
UCI - ERCP Course	*Orange, CA*	***May 11-12***
ERCP Nurses Workshop - *Northwest Comm. Hospital*	*Arlington Heights, IL*	***May 14***
International Athens Live Endoscopy Course	*Athens, Greece*	***May 14-15***
EURO-EUS	*Tel Aviv, Lebanon*	***May 30-31***
UCI - ERCP Course	*Orange, CA*	***June 8-9***
ERCP Nurses Workshop - *Northwest Comm. Hospital*	*Arlington Heights, IL*	***June 11***
UCI - EUS Course	*Orange, CA*	***June 15-16***
GIHep 2010	*Singapore*	***June 17-20***
28th GEEW	*Brussels*	***June 21-23***
GO 2010	*Rosemont, IL*	***June 25-27***
UCI - ERCP Course	*Orange, CA*	***July 13-14***
UCI - EUS Course	*Orange, CA*	***July 20-21***
UF-Update in Viral Hepatitis, Liver Diseases & Gastro	*Clearwater Beach, FL*	***July 30-31***
ASGE - First Years Fellows	*Oak Brook, IL*	***July 31 - Aug 1***
ASGE - First Years Fellows	*Oak Brook, IL*	***Aug. 7-8***
UCI - ERCP Course	*Orange, CA*	***Aug. 10-11***
ASGE - First Years Fellows	*Oak Brook, IL*	***Aug. 14-15***
ASGE - First Years Fellows	*Oak Brook, IL*	***Aug. 21-22***
ERCP Nurses Workshop - *Northwest Comm. Hospital*	*Arlington Heights, IL*	***Aug. 27***
ASGE - First Years Fellows	*Oak Brook, IL*	***Aug. 28-29***
APDW 2010	*Kuala Lumpur, Malaysia*	***Sept. 19-22***

INSIDE *Joke*

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