A BOSTON SCIENTIFIC PUBLICATION

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ENHANCING PATIENT OUTCOMES. DELIVERING TOTAL VALUE.™

Boston Scientific named Best Endoscopy Innovations Company by *THE NEW ECONOMY* magazine

Innovative by Design:

The Resolution 360™ Clip delivers control

Close The Gap

Making a difference through education and awareness

A Message From Dave Pierce

With the introduction of the SpyGlass™ DS System and the AXIOS™ Stent System, 2015 was truly a year of breakthrough innovations for Boston Scientific's Endoscopy business. And others agreed. Last year we were named the "best endoscopy innovations company" by The New Economy Magazine. We're not in this business for notoriety, but it is certainly nice to be recognized for our work in developing innovative products and our commitment to "advancing science for life."

We are pleased that clinicians have embraced our new technologies and more pleased to learn that these devices are making a difference in patients' lives. It's why we are continually innovating, developing cutting-edge technologies as well as making incremental improvements to devices. We want to ensure physicians have what we consider to be the best devices and greatest treatment options in the industry.

Dr. Harsha Polavarapu and Boston Scientific sales representative Lauren Pennington at a colon cancer awareness event sponsored by Blessing Hospital in Quincy, Illinois. Boston Scientific supported over a dozen events throughout the U.S. during March in support of colon cancer awareness, helping educate approximately 1,000 people.

In 2016, we continue on our path of innovation with the introduction of the Resolution 360™ Clip. This new clip lets the physician choose who controls the rotation of the device and allows a one-to-one bi-directional response for controlled placement, enabling procedural accuracy and efficiency (p. 4).

In support of education and training, we developed the EndoSuite Learning Channel and Virtual Training Institute to provide access to physician-led educational videos from a laptop or mobile device. These are important new global resources, yet we remain committed to hands-on teaching and working closely with physicians to develop robust training programs. Earlier this year, we assembled a group of physicians to help us further develop training for the AXIOS Stent System (p. 5).

When it comes to generating awareness and improving access to care, our Close the Gap health equity programs are gaining momentum. Our work with the Colon Cancer Prevention Project of Kentucky and the First Ladies Health Initiative of Cincinnati are two great examples of our collaborations, as well as organizations that are making a difference in their communities (p. 2).

And we are making an impact in other ways. Working with the Colon Cancer Alliance, we founded the Blue Hope Financial Assistance program to provide individuals who qualify access to lower-cost screenings. In support of this year's Colon Cancer Awareness Month, we committed to donating up to $75k to the CCA (based on a percentage of select product sales during the month of March) to continue funding this program, allowing more people to get screened. As of March this year, 331 patients from across the U.S. were referred for screening assistance, resulting in three cancer diagnoses. Learn more by visiting the Colon Cancer Alliance www.ccalliance.org.

Our employees are doing their part too, — walking for causes and fundraising. Earlier this year, employees built 80 bicycles to donate to the children of U.S. military families (p. 6) who had recently been deployed. Working together, we can make a difference.

Read a survivor's story.

Dave Pierce
Senior Vice President, Boston Scientific
President, Endoscopy Division

In This Issue

HAPPENINGS

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Physician Case Studies

Closing the Gap in Screening and Treatment
for Gastrointestinal, Pulmonary Conditions

Boston Scientific assists local groups in mobilizing at-risk populations to screen for asthma and colon cancer, and educate on other diseases as part of its Close the Gap health equity program. Two successful initiatives are highlighted here. Boston Scientific's Endoscopy business hopes to collaborate with more hospitals and community organizations in 2016.

KENTUCKY GROUP ADDRESSES COLON CANCER DISPARITIES

THE COLON CANCER PREVENTION PROJECT began with one physician's passion to reverse the state's worst-in-the-nation outcomes for a 90% preventable disease, as well as offer support for patients diagnosed with it.

Learn about the Colon Cancer Prevention Project.

Dr. Whitney Jones, speaking at an event on colon cancer awareness.

IN A SINGLE WEEKEND IN 2003, Louisville pancreatic physician and therapeutic endoscopist Whitney Jones, M.D., saw three patients with advanced colon cancer. They all had health insurance. They should have been screened but had never been screened. The experience moved him to action, and he hasn't slowed down in 13 years.

Further researching the topic, he quickly discovered Kentucky's high risk factors of smoking and obesity coupled with "dismal" screening rates led to the state's status as a colon cancer hotspot. Jones said, "I just basically decided to do something about it."

That led to his founding of the nonprofit Colon Cancer Prevention Project in 2004, which has since grown to be a statewide advocacy group for colon cancer screening for underserved patient populations as well as a grassroots lobbying organization. It has won hard-fought reimbursement gains, most recently in 2015 for patients who go in for diagnostic colonoscopies, only to get hit with large bills when polyps are removed and the procedures are reclassified as therapeutic.

Boston Scientific joined his organization's efforts in 2014 to help increase cancer screenings, primarily among the underinsured and underserved populations. The support came under the aegis of Close the Gap, a Boston Scientific health equity initiative which aims to eliminate healthcare disparities in gastrointestinal and pulmonary disease. Boston Scientific took a customized approach in working with the Colon Cancer Prevention Project, working hand in hand with the organization's leadership and staff to support various screening events in the Louisville area and other awareness initiatives.

> "Dr. Jones has sparked passion in a lot of other people– he's not okay with the status quo. He gets fired up, and he doesn't get burnt out talking about it."
>
> — **Andrea Shepherd**
> Executive Director, Colon Cancer Prevention Project

TIME TO TALK ABOUT COLON CANCER: REMOVING THE TABOO

Colon cancer might not make for pleasant dinner conversation, yet Dr. Jones's group took on the task of educating Kentucky's general population — some of which includes Appalachian and urban poor hit the hardest by the disease — as well as healthcare providers, about the importance of screening for colon cancer, an often taboo topic.

"When I speak to a room of 100 people and ask, 'How many of you have or know someone who has colon cancer or has died from it?' half the people raise their hands," Jones said. So his goal became not only to raise awareness of the disease, but to get Kentuckians screened as early as possible.

To support these efforts, through grants, Boston Scientific contributed financially to a major initiative — a video documentary *Catching a Killer*, featuring a person from the local community getting their first screening colonoscopy. The program aired repeatedly on public television throughout the state. The company sponsored several other initiatives, including a 5k race with employee volunteers, the Colon Cancer Prevention Project's pledge program that resulted in over 600 African-Americans pledging to get screened, a new grant program that provides funding for innovative ideas to raise awareness in the region and a program for community health centers to educate physicians on screening trends as well as provide assistance to eliminate barriers to screening.

"Dr. Jones has sparked passion in a lot of other people — he's not okay with the status quo. He gets fired up, and he doesn't get burnt out talking about it," said Andrea Shepherd, executive director of the nonprofit. "Susan G. Komen got people talking about breast cancer when they just didn't before. We're seeing people more and more comfortable talking about colon cancer, and once you start talking about it, you see that this is such a common cancer."

MAKING AWARENESS WORK

Learn about colon cancer. Hear a survivor's story.

The Colon Cancer Prevention Project, among other statewide public and private entities, has made a measurable difference. In 1999, with Kentucky ranked 49th among U.S. states for its colorectal cancer screening rate with 34.7% of its population screened. By 2012, the state ranked 28th, with 65.9% screened. Today, Jones said, it's around 70%, which he describes as "unbelievable" for a southern U.S. state. "Boston Scientific shares our mission in getting people screened and fighting this disease, " Shepherd said.

A case study on the Kentucky Colon Cancer Prevention Project is featured in the April issue of Premier's Economic Outlook magazine.

Boston Scientific Sales Representative in Kentucky, Robert Kennedy (right) with colleagues at an event hosted by the Colon Cancer Prevention Project. Kennedy volunteered for Colon Cancer Prevention Project events during some of the organization's earliest days.

Dena Cranley, co-chair of the First Ladies Health Initiative of Cincinnati with husband and Cincinnati Mayor John Cranley, who lent his support by visiting several of the screening locations.

IN CINCINNATI, MAKING A DIFFERENCE SCREENING FOR ASTHMA

CHURCHES, LOCAL GOVERNMENT AND BUSINESSES TEAM up to screen underserved urban populations for many chronic conditions through the First Ladies Health Initiative of Cincinnati. Boston Scientific joined with the local chapter of the organization to help screen for asthma and lung cancer.

Learn about the First Ladies Health Initiative.

DENA CRANLEY, CINCINNATI'S "FIRST LADY" by virtue of being married to Mayor John Cranley, found out fairly quickly that she wasn't the only first lady in town. After calling New Prospect Baptist Church Pastor Damon Lynch III and inviting him to her husband's mayoral swearing-in, she learned that every African-American church had its own first lady, too.

"When I hung up the phone, I thought, wow, wouldn't it be great to get these ladies to come together and make a difference in the community?" Cranley said.

That first conversation led to a friendship between the pastor's wife Barbara Lynch and Dena Cranley. Lynch became co-chair of the First Ladies Health Initiative of Cincinnati, which met regularly at Cranley's home, and eventually swelled to about 30 first ladies and ambassadors. They discussed how they could improve health disparities in neighborhoods underserved by the healthcare system, which led to an idea both ambitious and complex, in terms of planning — hosting a family health day across the churches on the same day, inviting members of 28 local churches to health fairs at 18 locations, on the same day, and providing health screenings for such things as vision as well as tests for hypertension, HIV, hepatitis C, diabetes, asthma, lung cancer, and more.

Last October 11, Cranley, Co-chair Lynch and 27 other first ladies, along with a cast of more than 800 volunteers, pulled off the event, christened "First Ladies Health Day."

NOT JUST SCREENING, BUT TREATMENT, TOO

A physician and nurse staffed each location, in addition to each first lady (some locations hosted by two) and volunteers from local health systems, churches and 40 healthcare companies, such as Boston Scientific. Screening wasn't the end goal of First Ladies Health Day; patients whose screenings led to recommendations for follow-up care were contacted after the health day to make sure they followed through with appointments and treatment.

In total, more than **3,000 people** attended the First Ladies health fairs across Cincinnati. Some **2,000 attendees** — adults and children — took part in the screenings offered.

Boston Scientific volunteers focused on asthma and lung cancer screening. Four hundred attendees received information about asthma; 167 took a survey and 38 were referred for follow-up care with the interventional pulmonary team at the University of Cincinnati. About 70 patients were referred to the University of Cincinnati Cancer Institute for follow-up care, either CT scans or smoking cessation programs, based on their lung cancer screening at the health fair. As with other Close the Gap programs and events, Boston Scientific took a hands-on approach, tailoring its involvement to add the greatest value possible.

"Boston Scientific was very supportive," Cranley said. "It was a great day for our city, and it was partners like Boston Scientific that made it happen." She added that the partnership will likely grow. At the next fair they're planning, the First Ladies will add a colon cancer screening component to the health fairs — and Boston Scientific offered to support that pursuit, too.

(Continued on page 4)

Innovation in Design – *Reinventing the Clip*

Learn more about this new device.

As pioneers of the endoscopic hemoclip, Boston Scientific heeded the call for mechanical clipping. While the Resolution™ Clip remains the number one clip on the market, the company heard loud and clear that customers needed more: a clip that rotates. However, as innovative experts in the field, it wasn't enough to simply create a clip that rotates. The mission was to raise the bar and advance the technology to the next level.

INNOVATIVE THINKING

Boston Scientific set out to design a clip that would deliver controlled positioning and rotation without compromising the integrity and proven clinical performance of the Resolution Clip. It was understood early on that a control-wire-driven rotation mechanism would be more prone to manufacturing defects and a higher likelihood for whip and lag. "We saw an opportunity to build something that hadn't yet been achieved," explains Shawn Ryan, R&D technical team lead at the start of the Resolution 360™ Clip design project.

INVENTIVE DESIGN

The Resolution 360 Clip is uniquely designed with a 32-wire overbraid on top of the existing legacy coil with 16 wires braided in each direction, allowing for equivalent, one-to-one response in both clockwise and counterclockwise rotation. Furthermore, the ingenuity of the braided catheter allows for both nurse/technician-driven rotation at the handle grip interface and for physician-controlled catheter rotation at the biopsy cap.

Dennis Hubbard, R&D technical team lead on the project, explains: "We realized early on that providing control at the biopsy cap allows physicians to instantly manipulate and position the clip where they want without the added step and time of directing the nurse or technician on rotation." The Resolution 360 Clip is designed for control that enables procedural efficiency and accuracy.

CUSTOMER VALIDATION

It is not enough to assume you have the right product, therefore Boston Scientific conducted extensive customer testing throughout the development process. Early on, the company conducted a two-day evaluation lab gathering feedback from over 70 physicians from around the world. In the end, testing was conducted on over 350 prototypes by over 125 physicians, ensuring that the company formulated a clip that met the needs of the physician.

"A highlight of the project was hearing physicians tell me: You just showed me something that I didn't think could be achieved." says Ryan.

Closing the Gap in Screening and Treatment for Gastrointestinal, Pulmonary Conditions *(Continued)*

Learn about the First Ladies Health Initiative.

THINKING OF TAKING ON A PROJECT LIKE THIS IN YOUR COMMUNITY?

The complex rollout of health screenings for 2,000 people requires not only getting the word out to potential patient attendees, but a volunteer network to serve them. Cranley and local Boston Scientific sales representatives Lenny Saia and Amy Reed, who took part in the screening day, offer some advice for organizations hoping to duplicate the success of the Cincinnati First Ladies events. For these tips and how to collaborate with Boston Scientific, read the full article at www.bostonscientific.com/gastroservices.

If you have an idea for addressing health disparities in your community, email Boston Scientific at closethegap@bsci.com.

First Lady Regina Jenkins Lynch of New Prospect Baptist Church (left) and First Ladies Health Initiative of Cincinnati Co-chair, First Lady Barbara Lynch of New Jerusalem Baptist Church, with local baseball team mascot at one of the screening locations.

Physician Expertise and Best Practice Sharing:

Key Ingredients for Successful Outcomes

Managing Patients with Complications of Pancreatitis

When truly innovative technology comes along that enables a new solution or procedure, realizing its full potential to impact patient care requires more than just device training. That's why Boston Scientific brought together four leading pancreatico-biliary experts and early users of the AXIOS™ Stent and Electrocautery Enhanced Delivery System to share their experiences managing patients with complications of pancreatitis.

Watch an AXIOS System in-service video.

The AXIOS System is a ground-breaking technology enabling physicians to treat certain complications of pancreatitis endoscopically instead of surgically. These include symptomatic pancreatic pseudocysts and walled-off necrosis (WON) ≥ 70% fluid content.[1] Dr. Kenneth Binmoeller developed this technology, and Boston Scientific now has both the privilege and responsibility to bring it to physicians worldwide.

A MULTI-DISCIPLINARY APPROACH

Dr. Martin Freeman
Professor of Medicine and Director of GI Hepatology and Nutrition, University of Minnesota

[In our practice] all patients with severe pancreatitis are managed by a highly specialized multi-disciplinary team. It's a complex decision and a very dynamic process. We have weekly meetings to review all cases and the decision for intervention is made as a team.

Dr. Mustafa Arain
Advanced Endoscopic Pancreatico-biliary Gastroenterologist, University of Minnesota

These are complex patients with multi-organ involvement requiring a dedicated team of specialists… [who are] comfortable dealing with pancreatic disease, including necrotizing pancreatitis.

THE AXIOS SYSTEM

Dr. Mouen Khashab
Associate Professor of Medicine and Director of Therapeutic Endoscopy, Johns Hopkins Hospital

[AXIOS]is the first and only FDA-approved stent for endoscopic drainage of pancreatic psuedocysts and WON[1] and that is very important to us.

Dr. Chris Thompson
Director of Therapeutic Endoscopy, Brigham and Women's Hospital, Boston

I think efficiencies improve because when we are using the electrocautery enhanced system, we don't need to use a needle, wires or dilating balloons, and that really cuts down procedure time.

NEED FOR PHYSICIAN TRAINING

Dr. Mustafa Arain — *It is highly recommended that only physicians with advanced endoscopic skills, including therapeutic endoscopic ultrasound skill, perform these procedures.*

Dr. Mouen Khashab — *I advise starting with easier cases such as transgastric drainage of large pseudocysts before moving to more difficult transduodenal drainage or walled-off necrosis cases.*

Dr. Chris Thompson — *Physicians should make sure that they are methodical about getting trained and learning more about these patients if they don't have experience taking care of them.*

Endoscopic solutions offer a less-invasive treatment option and may also be associated with shorter hospital stays, and lower costs.[2]

To learn more about the AXIOS Stent System, go to **www.endosuite com**.

References:

1. The AXIOS Stent and Electrocautery-Enhanced Delivery System is indicated for transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size and walled off necrosis ≥ 70% fluid content.
2. Equal Efficacy of Endoscopic and Surgical Cystogastrostomy for Pancreatic Pseudocyst Drainage in a Randomized Trial, Varadarajulu S. et al. Gastroenterology 2013; 145:

New Stent Technology Offers Solution for

Patient with Symptomatic Pancreatic Fluid Collection

Ralph tells his story — watch the video.

Ralph Sexton has always enjoyed an active and busy lifestyle. He is a tenacious athlete, coming from a long and successful athletic career at Middlebury College, where he played both hockey and lacrosse. He instilled his passion for sports in both of his children who play Division I lacrosse for Notre Dame. Now 69 years old and living in the home he built, Ralph and his wife Valerie prefer rigorous yard work, house repairs, and putting in time at the gym and outdoors with their dog Lucky. But that all changed in April 2015 when Ralph was rushed to the emergency room feeling very ill. Tests revealed a large pancreatic fluid collection (PFC).

> "The biggest benefit was my doctor saying, 'This is going to make things better.' I feel much better. I'm back to work, back to my normal routine, activities and sports, and back to playing with Lucky." says Ralph.

While some patients with pancreatic pseudocysts are asymptomatic, others like Ralph experience severe pain, bloating and poor digestion. Over the next several weeks, Ralph was treated with varying results. He returned home for a week or two at a time, only to be rushed back to the emergency room at his local hospital with the same persistent symptoms. Finally, it was determined that Ralph would need an endoscopic intervention and was moved to an advanced facility for treatment.

In September 2015, Ralph learned about the AXIOS™ Stent and Electrocautery Enhanced Delivery System ("The AXIOS System") from his gastrointestinal team of physicians at a large academic medical center in Massachusetts. The physicians recommended a procedure in which the AXIOS System would be placed to drain his PFC. Once the procedure was performed, Ralph's PFC drained almost immediately. He began to feel like himself again, resuming daily activities and even scheduling trips to see his children's lacrosse games around the country.

Building Bicycles for Military Families is Company's Way of Giving Back

A service member with children who received bicycles at the event in Colorado.

During a recent sales meeting in Colorado, **more than 400 Boston Scientific employees built 80 bicycles to donate to military families** stationed in the Colorado Springs area. Over 30 families were invited to an event where ice cream was served and each child received a bicycle.

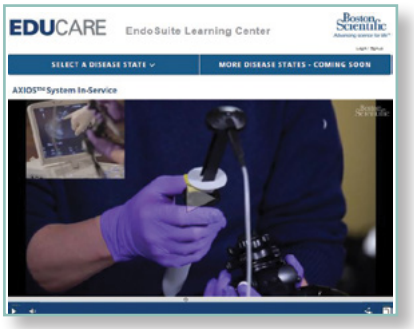
As a resident of Colorado, Mike Jones, vice president of sales for Boston Scientific's Endoscopy business, is well aware of the contributions and sacrifices made by military families in the region. "Our employees wanted to show their gratitude for veterans' service by helping to raise the spirits of kids whose parent or family member had recently been deployed," explained Jones. "It was wonderful to have an opportunity to give thanks to these men and women who serve our country, and the families who support them."

One parent expressed her gratitude by saying, "My family and I were completely humbled today by this loving act from complete strangers. My girls have never received such generosity or recognition for being military children. In their short lives (6 and 8), their dad has been gone for a total of five years and it has been extremely difficult for them. Thank you for showing us that they are remembered."

New Websites Deliver
Physician-led On-demand Learning

At Boston Scientific's Endoscopy business, training and education have always been a top priority. We have been funding and delivering high-quality, hands-on education programs for decades — from physician lectures to clinical device training and preceptorships. Not all clinicians, however, are able to take advantage of these programs due to travel costs, time away from their practices or programs not being available in some regions.

Virtual Training Institute



EndoSuite Learning Center

At the same time, there has been an increasing trend for on-demand education with almost **70%** of physicians using online videos for learning.[1] To meet this need and provide broader access to clinical education, we recently launched two new websites, the EndoSuite Learning Channel and the Virtual Training Institute.

These websites provide easy access to educational videos from virtually any laptop or mobile device anytime, anywhere. Clinicians can learn from experts in GI disease management through lectures, case reports and procedural techniques, clinical research updates, device training videos and more. Visitors can also register for updates and webcasts, sign up for hands-on programs, ask questions, provide feedback, contact a representative, upload a case and link to a variety of other resources.

Content is continually being updated so check back frequently and be sure to register to receive updates.

www.endosuite.com (for U.S. and CE Mark countries)
www.virtualtraininginstitute.com (for AMEA countries)

Get Connected Today!

THE ASGE RECOGNIZES BOSTON SCIENTIFIC FOR ITS ADVOCACY AND SUPPORT

Boston Scientific continues to partner with the American Society for Gastrointestinal Endoscopy (ASGE) and the GI specialty societies to advocate for patient access to much-needed endoscopy procedures by providing persuasive logic to support appropriate Medicare outpatient hospital payment. Over the past two years, Boston Scientific has successfully petitioned the Centers for Medicare and Medicaid Services to adjust payment for biliary, colonic and duodenal stenting as well as for endoscopic mucosal resection. The company's efforts have resulted in substantial increases in reimbursement for these procedures so that the payment provided more accurately reflects the associated costs. **— Statement provided by the ASGE**

For more information on GUIDEPOINT Reimbursement.

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Targeted specialist audiences, including PCPs, pediatricians, cardiologists, oncologists, gastroenterologists and OB/GYNs.

Peroral Endoscopic Myotomy

Learn more about this new device.

CASE PRESENTED BY:

PROFESSOR PRADEEP BHANDARI
MBBS, M.D., MRCP

Professor of Gastrointestinal Endoscopy
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth, UNITED KINGDOM

FERGUS CHEDGY, M.D.

Research Registrar
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth, UNITED KINGDOM

PATIENT HISTORY

A 61-year-old female presented to her local hospital with dysphagia, retrosternal chest pain and regurgitation (Eckardt score of 6). An upper gastrointestinal endoscopy demonstrated a dilated esophagus with significant food residue and resistance to passage of the endoscope at the gastroesophageal junction **(Figure 1)**. A barium swallow demonstrated typical appearances of achalasia with a severely dilated esophagus and sigmoid-like tortuosity **(Figure 2)**. Esophageal manometry studies confirmed Type II achalasia with an elevated, resting lower esophageal sphincter pressure of 26. The patient was initially treated at her local hospital with balloon dilatation of the lower esophageal sphincter and underwent two sessions of botulinum toxin. The patient's symptoms persisted and she was referred to our center for peroral endoscopic myotomy (POEM).

PROCEDURE

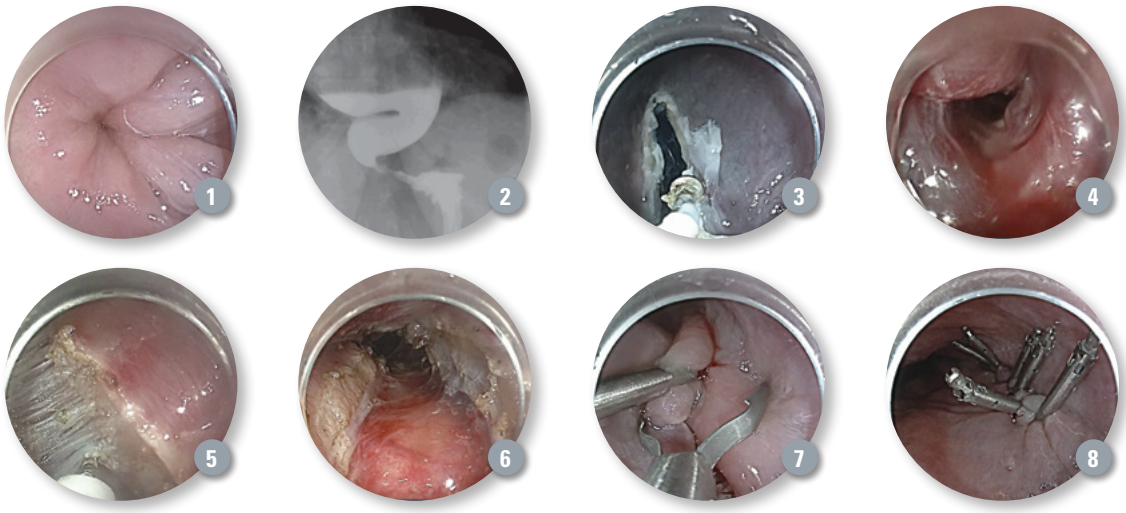
A submucosal injection of normal saline and indigo carmine was administered (adrenaline is avoided due to proximity to myocardium and risk of arrhythmias). An ESD-knife was used to create a 2.8mm mucosal incision to provide an entry point into the submucosa **(Figure 3)**. Gradual dissection of the submucosa was conducted to create a submucosal tunnel extending over 11cm in the esophagus and then 4cm into the stomach **(Figure 4)**. A long myotomy was performed of over 12cm **(Figures 5 and 6)**. Six Resolution 360™ Clips were used to close the mucosal incision **(Figures 7 and 8)**.

OUTCOME / POST PROCEDURE

The patient was admitted overnight for observation and discharged without complication. Post procedure, the patient's symptoms have completely resolved and she awaits repeat manometry testing.

CONCLUSION

This case highlights how the functionality of the Resolution 360 Clip can be used to close mucosal defects. **The rotational movement of the clip was easily employed by both the endoscopist and the nurse. The innovative design of this new clip allowed the physician to rotate the jaws themselves with one-to-one rotation, securing clip positioning and deployment to securely close the mucosal defect.**



Endoscopic Removal of a 6cm Pedunculated Adenoma of the Duodenum

CASE PRESENTED BY:

BRIDGER W. CLARKE, M.D.

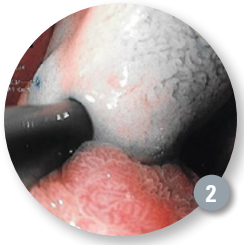
Director of Advanced Interventional Endoscopy
Jefferson Hospital
South Hills Gastroenterology Associates
Clairton, Pennsylvania, USA

PATIENT HISTORY

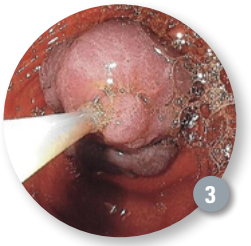
A 54-year-old male presented for upper endoscopy to evaluate acid reflux symptoms. Endoscopy revealed a large polypoid mass filling the pylorus and duodenal bulb **(Figure 1)**. Biopsies were obtained at that time, which revealed tubular adenoma with no evidence of invasive malignancy. Management options were discussed, including surgical and endoscopic resection. The patient opted for an initial attempt at endoscopic removal.

PROCEDURE

Propofol sedation was administered by an anesthesiologist. Endoscopic ultrasound was initially performed to further characterize the lesion. This demonstrated a 60mm heterogenous soft-tissue mass extending from the pylorus to the second portion of the duodenum. A thick stalk was identified consistent with a pedunculated polyp. There was no evidence of invasion into the duodenal wall on sonographic examination.

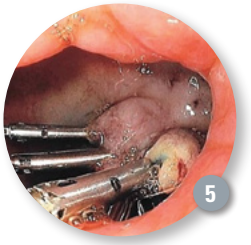


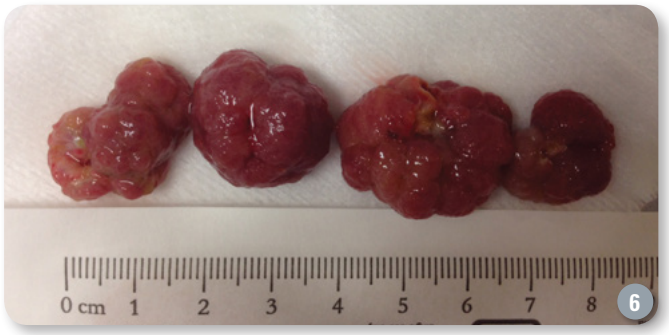
The echoendoscope was exchanged for a gastroscope and the stalk was identified arising from the posterior wall of the duodenal bulb. An Interject™ Single-Use Injection Therapy Needle Catheter was used for injection into the stalk and submucosal layer **(Figure 2)**. Piecemeal resection was then performed using a Captivator™ II 25mm Snare **(Figure3)**. Once the polyp was debulked, the snare was placed around the base of the stalk to complete the resection. The pedicle was examined following resection and a focus of arterial bleeding was visualized **(Figure 4)**. Four Resolution™ Clips were placed around the transected portion of the stalk, achieving good hemostasis **(Figure 5)**. The polyp specimens were then collected. The stalk and polyp were sent as separate samples to ensure the margin was evaluated **(Figure 6)**. Final pathology demonstrated tubulovillous adenoma and a clear margin.

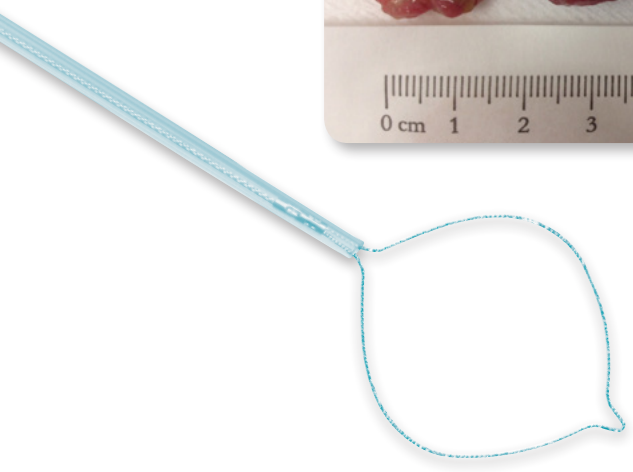


CONCLUSION

This case demonstrates a technique for endoscopic management of massive pedunculated polyps arising within the duodenum. **These widely available endoscopic devices were used to safely remove all precancerous tissue and effectively treat procedure-related bleeding, preventing the need for a larger surgical resection.**







Learn about hemostasis devices.

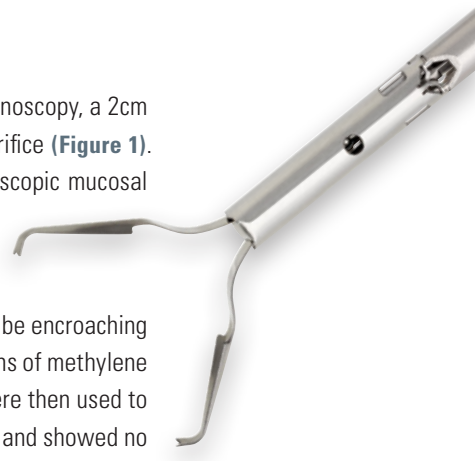
Learn about snares.

Using Hemoclips for Closure of a Complicated Endoscopic Mucosal Resection

CASE PRESENTED BY:

STEPHEN KIM, M.D.

Clinical Instructor of Medicine
David Geffen School of Medicine at UCLA
Los Angeles, California, USA



PATIENT HISTORY

A 63-year-old man underwent a routine colonoscopy for colorectal cancer screening. During the colonoscopy, a 2cm laterally spreading sessile polyp (Paris 0-IIa) was seen in the cecum adjacent to the appendiceal orifice **(Figure 1)**. Biopsies of the polyp were consistent with a tubular adenoma. The patient was referred for endoscopic mucosal resection (EMR).

PROCEDURE

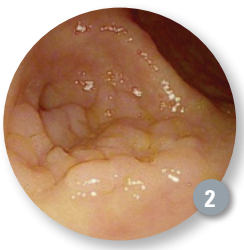
The previously identified large 2cm polyp was seen in the cecum. One edge of the polyp appeared to be encroaching on the appendiceal orifice **(Figure 2)**. The polyp was circumferentially lifted with submucosal injections of methylene blue and saline **(Figure 3)**. The Captivator™ II Single-Use Snares, 15 and 20mm stiff round snares, were then used to remove the polyp in two pieces **(Figure 4)**. The final endoscopic mucosal resection defect was 2.5cm and showed no evidence of residual polyp and no bleeding or perforation was seen **(Figure 5)**. Due to the orientation of the polyp and difficult scope position, the hemoclip closure of the EMR site was an arduous task. Ultimately, the EMR site was completely closed using careful placement of three Resolution 360™ Clips **(Figure 6)**.

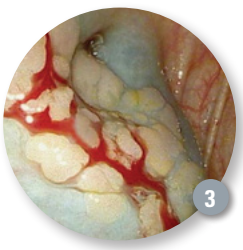
POST PROCEDURE

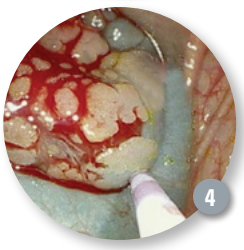
The patient tolerated the procedure without any complications. The final pathology of the polyp confirmed a tubular adenoma with no high-grade dysplasia. The patient will return in 12 months for a surveillance colonoscopy to ensure that there is no recurrent or residual polyp at the resection site.

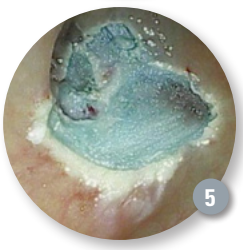
DISCUSSION

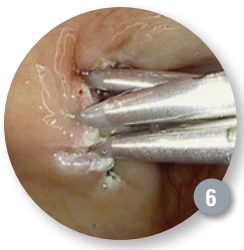
This case demonstrates the ability to effectively close a complicated EMR site using the new Resolution 360 Clip. Although the size of the polyp was only 2cm, the polyp was located in the cecum where there is an increased risk of post-procedural bleeding. However, closing this EMR defect was more complicated than initial appearance due to the orientation of the polyp and the difficult scope position. **The Resolution 360 Clip was pivotal in providing one-to-one control in order to position the clips in the exact alignment needed to close the defect.** Three clips were placed in zipper fashion to completely close the resection site. The patient did not experience post-polypectomy bleeding.











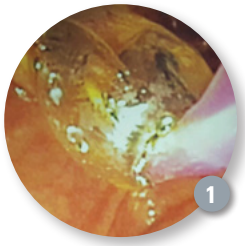
Learn more about the Resolution Clip.

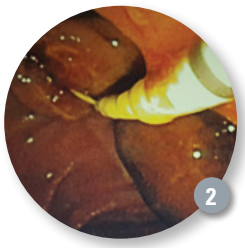
Removing Difficult Biliary Stones by Dilation-assisted Stone Extraction

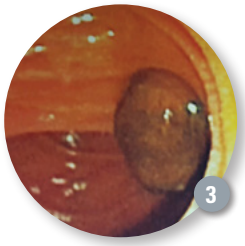
CASE PRESENTED BY:

JEREMY BARBER, D.O.

Mercy Health Muskegon
Muskegon, Michigan, USA







PATIENT HISTORY

The patient was a 56-year-old female who previously underwent laparoscopic cholecystectomy from a referring physician. The physician noted abnormal cholangiogram results, suggesting a large, distal filling defect in the bile duct. She was then referred to me for endoscopic retrograde cholangiopancreatography.

PROCEDURE

The patient was transported to the endoscopy suite with anesthesia provided by general endotracheal intubation. The patient was maintained in a semi-prone position. A TJF160 duodenoscope was inserted into the mouth, passed through the posterior pharynx, proximal, middle and distal esophagus. The scope was advanced through the GE junction into the stomach along the greater curvature, through the pylorus, duodenal bulb, and into the second portion of the duodenum. The scope was withdrawn into short position.

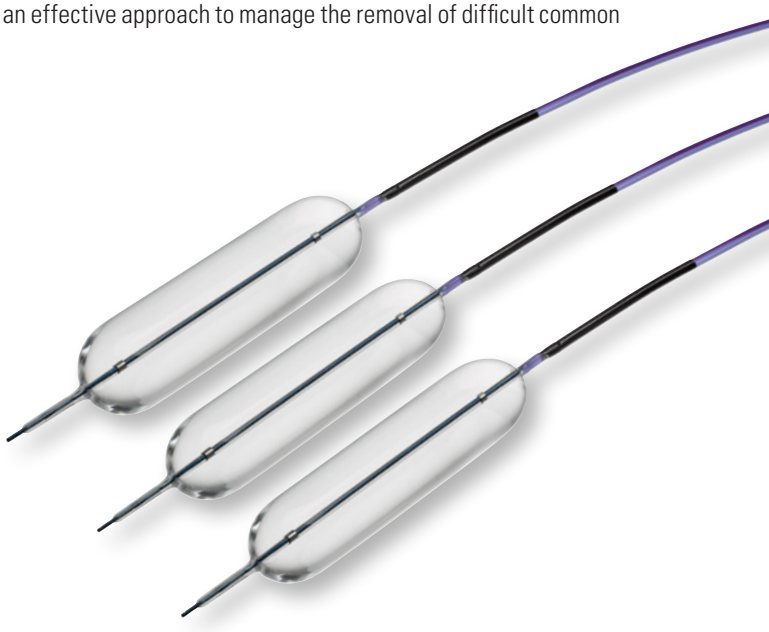
An Autotome™ RX 39 Cannulating Sphinctertome was loaded with a Jagwire™ .025" High Performance Guidewire and deep biliary cannulation **(Figure 1)** was achieved. A cholangiogram was performed which demonstrated a large filling defect in the distal duct. The duct was approximately 10-12mm with a 12mm filling defect. A large endoscopic sphincterotomy **(Figure 2)** was made. I then utilized a 10-12mm CRE™ Single-Use Wireguided Biliary Balloon Dilator and dilated the ampulla **(Figure 3)** up to 12mm as I knew I would then be able to pull the stone through the site. A large 12mm stone was delivered **(Figure 4)**. There was a large amount of pus behind the stone and the duct was then swept until it was clean.

The patient tolerated the procedure well and was transported to recovery in stable condition, placed on antibiotics and was monitored in the hospital until discharged stable the following day.

CONCLUSION

The DASE procedure using a CRE Single-Use Wireguided Biliary Balloon Dilator with a biliary indication (now called CRE PRO Wireguided Balloon Dilatation Catheter) is an effective approach to manage the removal of difficult common bile duct stones.

Learn about balloon dilatation.



Cholangioscopy-assisted Intrahepatic Duct Access and Electrohydraulic Lithotripsy: No Stones Left Unturned

CASE PRESENTED BY:

TAMAS A. GONDA, M.D.

Division of Digestive and Liver Diseases
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Columbia University Medical Center
New York, New York, USA

TINA H. PARK, M.D.

Division of Digestive and Liver Diseases
Department of Medicine
Columbia University Medical Center
New York, New York, USA

PATIENT HISTORY

A 77-year-old man with a history of heart transplant, cholecystitis and cholecystectomy ten years ago presented to our hospital with sepsis, Enterobacter bacteremia, and abnormal LFTs (AST 85, ALT 105, total bilirubin 1.3, alkaline phosphatase 223). An MRCP revealed dilated extrahepatic and intrahepatic bile ducts and multiple calculi and debris in segment VIII. Prior endoscopic retrograde cholangiopancreatography (ERCP) was successful in removal of stones from the common hepatic and common bile ducts, but right intrahepatic ducts could not be accessed for removal of intrahepatic ductal stones.

PROCEDURE

The patient underwent ERCP which demonstrated no filling defects in the common hepatic and bile ducts and in the left hepatic duct. Despite occlusion cholangiogram and multiple attempts at guidewire manipulation, contrast was not extended into the right system and access could not be gained **(Figure 1)**. A cholangioscope was used to explore the bifurcation. At the level of the right hepatic duct a trifurcation of the ducts was noted **(Figures 2 and 3)**. A cholangioscopy-guided cannulation of segment VIII revealed a slight narrowing and an upstream dilated duct segment with multiple intraductal stones **(Figures 4 and 5)**.

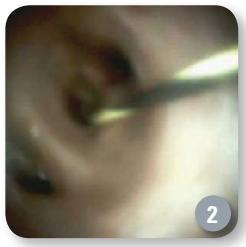
OUTCOME

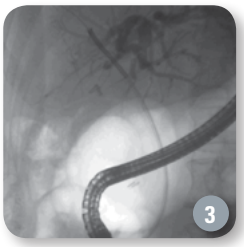
Despite dilation of this segment and attempts at a balloon sweep, the stones could not be removed. Cholangioscopy-assisted electrohydraulic lithotripsy (EHL) was applied and stones were fragmented **(Figure 6)**. The fragments were easily swept from this segment. After completion of stone extraction **(Figure 7)**, a stent was left in place. Due to successful stone extraction using cholangioscopy-assisted intrahepatic duct access and EHL, the patient may avoid repeat hospitalization for cholangitis and additional procedures, such as a repeat ERCP or percutaneous transhepatic cholangiography.

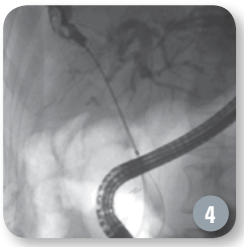
SUMMARY

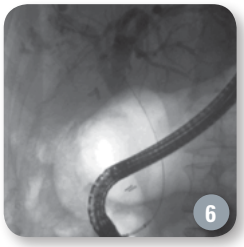
This case demonstrates the superior ability of cholangioscopy to guide access to liver segments that may not be otherwise accessible or visualized using standard cholangiogram. In addition, cholangioscopy provided direct visualization of the intraductal stones, allowing effective and efficient stone extraction when combined with EHL.

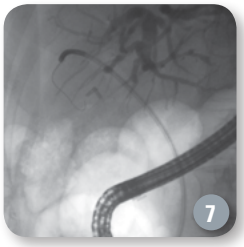
Watch EHL at work on CBD stones.











Exclusion of Cholangiocellular Carcinoma Using Cholangioscopy

CASE PRESENTED BY:

MARK ELLRICHMANN, M.D.

Interdisciplinary Endoscopy
Medical Department 1
University Hospital Schleswig-Holstein
Campus Kiel
Kiel, GERMANY

PATIENT HISTORY

A 74-year-old woman was referred for further evaluation of obstructive jaundice, fever and shivering. Lab tests revealed significantly increased cholestasis parameters. An abdominal ultrasound and MRI showed a solid obstruction of the left hepatic duct with significant cholestasis of the left liver lobe and the suspicion of a cholangiocellular carcinoma. The endoscopic retrograde cholangiography from the referring physician confirmed this suspicion **(Figure 1)** despite brush cytology showing only an unspecific inflammation of the bile duct. During this procedure a plastic stent was placed to ensure drainage.

PROCEDURE

We decided to perform a cholangioscopy using the SpyGlass™ DS System's SpyScope™ DS Access and Delivery Catheter to further differentiate the indeterminate stenosis of the left hepatic duct. Upon cholangioscopy we observed a regular surface of the common bile duct and the intrahepatic ducts of the right liver lobe. In contrast, the left hepatic duct was completely blocked by a solid plug consisting of mucus, fibrin and pus **(Figures 2 and 3)**. This plug was passed and the scope was further navigated up to the intrahepatic ducts of the left liver lobe that presented with a regular surface. The obstructing plug was then removed with a wire-guided basket and by irrigation with water applied under cholangioscopic control. Macroscopically, a circumscribed inflammation with a superficial erythema and a small central ulcer remained at the mucosa of the distal part of the left hepatic duct **(Figure 4)**. Targeted biopsies were taken with the SpyBite™ Biopsy Forceps for further evaluation. Due to a rapid flow of bile and contrast from the left liver lobe, no further stent placement was indicated.

Animation provides an overview on the SpyGlass DS System.

OUTCOME AND PATIENT FOLLOW-UP

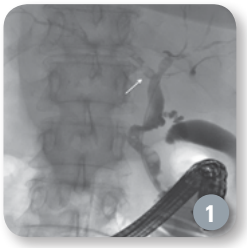
Histological examination of the retrieved tissue samples displayed a mild cholangitis without any signs of dysplasia or malignancy. Lab tests showed a significant decrease of cholestasis parameters and a normalization of C-reactive protein and white blood cells within two days after the procedure.

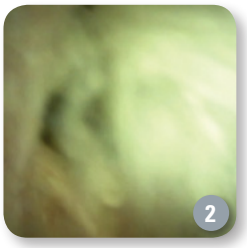
The ill-defined mass of the left hepatic duct completely vanished, with normalization of the diameter of the extra- and intrahepatic ducts of the left liver lobe proven by abdominal ultrasound three days after plug removal.

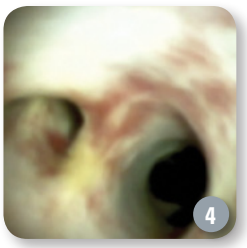
Twelve weeks thereafter the patient was readmitted for scheduled re-evaluation. Abdominal ultrasound was normal, lab tests showed normalized cholestasis parameters. The "2nd look" using cholangioscopy showed a regular surface of the previously inflamed area in the left hepatic duct, and no signs of inflammation or maligancy were observed **(Figures 5 and 6)**.

SUMMARY

Though the exact reason for this localized inflammation remains unclear, the presented case demonstrates the compelling necessity for a proper differential diagnosis in the management of intra- or extrahepatic strictures. In the era prior to direct and digital cholangioscopy, the patient would have been transferred to surgery for left hemihepatectomy. **Therefore, use of the SpyGlass DS System can help to precisely stratify patients to appropriate surgical therapy and can also help to avoid surgery if it is not necessary. Available data for the macroscopic distinction of benign and malignant biliary strictures are disappointing with a high interobserver variability. Nevertheless, definition of macroscopic criteria of malignancy in a multicenter study approach will help digital cholangioscopy to become the gold standard of intraductal diagnosis and intervention.**





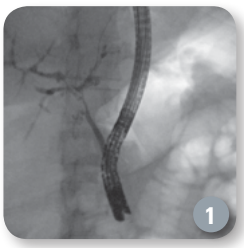


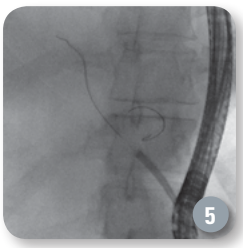
Diagnosis and Treatment of a Difficult CBD Stricture Using Digital Cholangioscopy

CASE PRESENTED BY:

NISHANT PURI, M.D.

Providence Sacred Heart Medical Center
Spokane, Washington, USA





PATIENT HISTORY

A 47-year-old female presented with a history of Crohn's disease. She was diagnosed around age 13. She is now in remission and on azathioprine. In addition, she has a history of primary sclerosing cholangitis (PSC), diagnosed in July 2014 by ERCP, which showed a central and right intrahepatic duct stricture and was treated with plastic stents for six weeks. She presented in December 2015 to the emergency room with epigastric pain radiating to her back. Her liver enzymes, which were normal before, were elevated with AST 435 U/L, ALT 249 U/L, alkaline phosphatase 315 U/L, and bilirubin 2.3 mg/dL. An MRI with MRCP was performed which showed left intrahepatic duct dilation and strictures with no evidence of calculi. An ERCP was performed to evaluate the stricture for dilation and stenting.

PROCEDURE

Deep common bile duct (CBD) cannulation was achieved using an 0.035" guidewire through a sphincterotome. Initial cholangiogram showed a stricture at the confluence of the hepatic ducts along with a filling defect. Dilation of the left intrahepatic duct consistent with PSC was also noticed **(Figure 1)**. Multiple balloon sweeps produced small stone fragments. The SpyGlass™ DS Direct Visualization System's SpyScope™ DS Access and Delivery Catheter was then introduced to examine the hilar stricture. Small stones were seen in the common bile duct. At the hilum, there was narrowing of the bile duct with congested and erythematous raised mucosa **(Figure 2)**. At the takeoff of the main right intrahepatic, there was a narrowing due to this hilar stricture and a 1cm stone was seen proximal to the stricture **(Figure 3)**. An additional stone measuring about 7mm was also seen in the left intrahepatic duct which was seen to be dilated on the initial cholangiogram **(Figure 4)**. Some pus was also seen in the intrahepatic ducts and CBD. An electrohydraulic lithotripsy catheter was then introduced and the stones were fragmented in rapid sequence.

Watch a video case study on assessing a bile duct stricture.

The ducts were then examined further using the SpyScope and determined to be free of stones. The SpyBite™ Biopsy Forceps were then introduced and biopsies of the hilar stricture were taken. On further examination of the ducts, pus was seen in a branch of the left intrahepatic duct.

A decision was then made to perform selective cannulation of that branch and the right posterior duct which had the stones. An 0.018" NovaGold™ Guidewire was then introduced into the left intrahepatic branch. Visualization of the diminutive duct using the SpyGlass DS System was of great help along with the flexibility and maneuverability of the guidewire, which was easily able to make the sharp turn in the left duct branch. A second 0.018" NovaGold Guidewire was then introduced through the SpyGlass DS System and placed selectively under direct visualization into the right intrahepatic duct **(Figure 5)**. Keeping both guidewires in place, the cholangioscope was removed and the guidewires secured. Balloon sweeps were then performed over each guidewire, delivering residual stone fragments and sludge. Two 7Fr X 9cm Advanix™ Biliary Stents were then placed over the 0.018" guidewires into the right and left intrahepatic ducts, respectively. Good bile duct flow was confirmed and the procedure was then terminated.

CONCLUSION

By using the SpyGlass DS System, the source of cholangitis and elevated liver enzymes was able to be established. A 1cm and a 7mm stone were able to be removed from the patient's intrahepatic ducts that were lying proximal to the stricture and were undetectable with MRI. Selective wire placement of left and right intrahepatic ducts took place under direct visualization using the SpyGlass™ DS System, which saved time on attempted cannulation using conventional ERCP with different guidewires. Using the selective cannulation technique under direct visualization may have prevented a failed cannulation and avoided a potential interventional radiology procedure for this patient.

Treating an OLT Anastomotic Stricture Using SEMS — Results after One Year

In the U.S., fully covered stents are not cleared for treatment of benign biliary strictures.

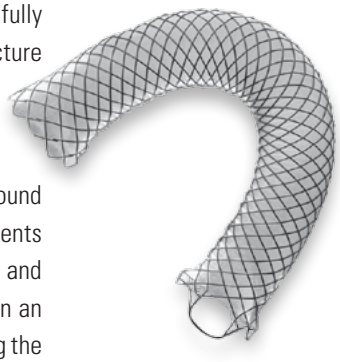
CASE PRESENTED BY:

ANGELO PAULO FERRARI, M.D., PH.D.
FERNANDA PRATA MARTINS, M.D., PH.D.

Hospital Israelita Albert Einstein
São Paulo, BRAZIL

INTRODUCTION

This case is presented of a post-orthotopic liver transplantation (OLT) stricture. The patient was treated with the fully covered WallFlex™ Biliary RX Stent System RMV. The cholangioscopy aspect of a post–OLT anastomotic stricture after one year is examined.



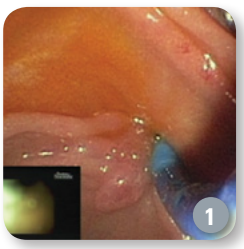
PATIENT HISTORY, PROCEDURE AND OUTCOME

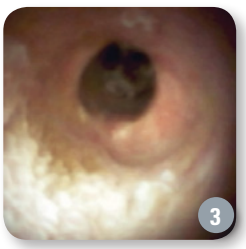
A 45-year-old male was referred with elevated levels from liver function tests (LFT) and an abdominal ultrasound showing dilated intrahepatic bile ducts two months after the OLT. According to this institution's protocol, such patients are referred directly for ERCP without further investigation. The stricture was found at the biliary anastomosis and treated with a 10mm x 60mm fully covered biliary stent after sphincterotomy. All of our patients are treated on an outpatient basis and discharged home in the same day. This patient returned after one year, asymptomatic. During the follow-up ERCP, spontaneous distal migration was noted and we performed a cholangioscopy with the SpyGlass DS System **(Figure 1)**. The proximal bile ducts looked normal **(Figure 2)** and the anastomosis showed a very short fibrotic ring with some papillary tissue around it and a suture knot could be seen **(Figures 3 and 4)**. A follow-up laboratory test was done to determine there was no stricture recurrence.

DISCUSSION

Endoscopy has been the first choice for the treatment of post-OLT anastomotic strictures. **In our experience, although the results with multiple plastic stents and metallic stents are similar, regarding treatment of post-OLT anastomotic strictures, metal stents may be a valid alternative for treatment of these strictures.**

Cholangioscopy with the SpyGlass DS System is new in Brazil, and this is the first case in which we were able to study the anastomotic aspect after successful treatment. The diagnosis could have been derived from radiographic images, but the SpyGlass DS System images provided more detail for the diagnosis.





First SpyGlass DS Case in Brazil.

Successful Biliary Drainage in a Benign Common Bile Duct Stricture Due to Chronic Pancreatitis

CASE PRESENTED BY:

JESÚS GARCÍA-CANO M.D., PH.D.

Department of Digestive Diseases
Hospital Virgen de la Luz
Cuenca, SPAIN

PATIENT HISTORY

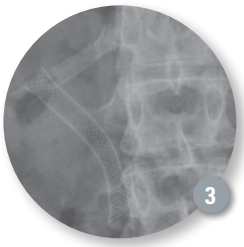
A 50-year-old male presented with jaundice. He had a long history of alcohol abuse. He also suffered from insulin-dependent diabetes. An MRCP **(Figure 1)** showed a stricture in the lower common bile duct (CBD) probably related to gross findings of chronic pancreatitis (CP). In fact, diffuse pancreatic atrophy was seen. Besides dilation in the main pancreatic duct, increased collateral venous circulation in the splenic vein was also observed. Surgical options were ruled out and ERCP biliary drainage was deemed the most appropriate choice.

PROCEDURE

A CBD deep cannulation ERCP showed a similar CBD stricture that was previously reported on MRCP. A medium-sized biliary sphincterotomy was performed and a 6cm long, 8mm wide WallFlex™ Biliary RX Fully Covered Stent was inserted. This diameter was chosen because a lower cystic duct insertion was also reported in the MRCP. The duodenal end of the stent was placed enough outside from the papillary orifice to allow an easy endoscopic extraction at a later ERCP procedure **(Figure 2)**.

POST PROCEDURE

No complications occurred after ERCP. On a radiograph taken the next day **(Figure 3)** the stent had fully expanded. The patient was scheduled for follow-up but did not attend appointments. Nine months after stent insertion he was admitted due to diabetes-related problems. A consultation was made by the endocrinologist in charge with the Digestive Department. The patient's liver biochemistry was normal and obstructive cholestatic pattern had completely subsided. Stent removal was accomplished during the ERCP by grasping the removal loop at the end of the stent. No clear signs of the former stricture were seen on cholangiography but due to poor patient compliance with follow-up schedules, a plastic 7Fr double pigtail stent was inserted.



Animation shows the steps for placing a metal stent.

DISCUSSION

The WallFlex Biliary RX Fully Covered Stent provided successful biliary drainage in this benign CBD stricture due to CP. Furthermore, the stent could be removed nine months after insertion with no signs of remaining stricture on the cholangiography. Poor compliance with follow-up schedules is common in some patients suffering from this condition. It reinforces the need for patients to undergo as few procedures as possible.

Placing a Pancreatic Stent to Drain the Pancreatic Duct

CASE PRESENTED BY:

MANKANWAL SINGH SACHDEV, M.D.

Director of Endoscopy
St. Joseph's Hospital and Medical Center
Assistant Professor of Medicine
Creighton University School of Medicine
University of Arizona - Phoenix
Co-Program Director Advanced Therapeutic Endoscopy Fellowship
Phoenix, Arizona, USA

PATIENT HISTORY

A 55-year-old female with longstanding bouts of recurrent acute pancreatitis presented with pain consistent with another flair-up. It was suspected that these symptoms were due to pancreatic divisum, which was diagnosed on outside ERCP and MRCP. The patient previously tried conservative measures, only to experience recurrent symptoms. Therefore, ERCP with minor duct cannulation and potential sphincterotomy was recommended. Previous ERCP established a complete divisum.

PROCEDURE

An ERCP and a cholangiogram were performed **(Figure 1)**. The minor papilla was then located with minimal difficulty. Using the pure wire-guided method, cannulation was achieved using a 0.035" Jagwire™ High Performance Guidewire. Once the wire was placed, a pancreatogram was performed **(Figure 2)**, which revealed a dilated major pancreatic duct and a normal-sized accessory duct. A sphincterotomy was performed and then a 5Fr 5cm single pigtail Advanix™ Pancreatic Stent (without a flange) was successfully placed across the minor papilla. The deployment catheter was well visualized and allowed for accurate placement using the radiopaque marker. **(Figures 3 and 4)**.

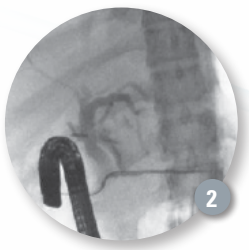
POST PROCEDURE

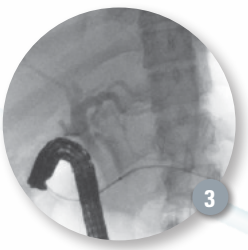
The patient experienced some initial discomfort, and then returned for a follow-up one month later. At that point all symptoms had resolved and she felt well. The stent had spontaneously migrated.

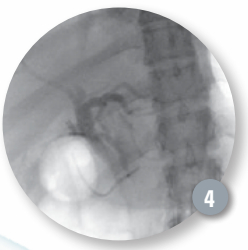
Learn about the Advanix Pancreatic Stent.

DISCUSSION

This case demonstrates that Advanix Pancreatic Stents are effective in the drainage of the pancreatic duct. The stent migrated after adequate therapy time.







EUS-guided Liver Biopsy for Benign Liver Disease

CASE PRESENTED BY:

MICHAEL SCHAFER, M.D.

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PATIENT HISTORY

In April of 2014, a 57-year-old female was referred by her primary care physician due to elevated liver function tests (LFT) found on routine lab work. She had a mild increase in her AST and ALT, 36 and 42, respectively. Her alkaline phosphatase and bilirubin were normal. A transcutaneous ultrasound of the abdomen was normal as was viral hepatitis serologies. She denied using alcohol, had no reported illicit drug use and has had no recent travel history,

A complete laboratory work-up revealed a positive F-actin antibody at 48 (19), but a negative ANA. She also had a positive anti-mitochondrial antibody at 107 (20). A percutaneous liver biopsy by interventional radiology was performed. A provisional diagnosis of primary biliary cholangitis was made and the patient was started on ursodeoxycholic acid. She did well until a year later when she was admitted to the hospital with nausea, vomiting, weight loss and pruritis. Labs on admission revealed an AST of 888 and ALT of 971, and alkaline phosphatase of 241 with a total bilirubin of 2.0.

PROCEDURE

An endoscopic ultrasound (EUS) was performed to rule out bile duct obstruction. There was an enlarged hilar lymph node compressing the bile duct, so an ERCP was performed to rule out frank obstruction. The ERCP was normal. It was decided to perform a second liver biopsy at this time under EUS guidance. An Expect™ Needle 19ga Flex was used. I find it to be the only useful needle if a right lobe sample is needed. I removed the stylet and flushed the channel with saline. I punctured the liver through the stomach for a left lobe sample and the duodenum for a right lobe sample. I usually get a left lobe sample. Once in the liver, I used suction and performed four actuations in the liver. I then flushed the sample directly into formalin with saline. Several core biopsy specimens were attained. The recovery time is typically 30 minutes post procedure, similar to a routine endoscopy.

OUTCOME / POST PROCEDURE

Based on the pathology findings, she was diagnosed with an autoimmune hepatitis/primary biliary cholangitis overlap syndrome. She was started on steroids and her liver function studies quickly normalized. Because of repeated elevations in her LFTs upon weaning steroids, she was transitioned to 6-mercaptopurine. She remains in remission.

CONCLUSION

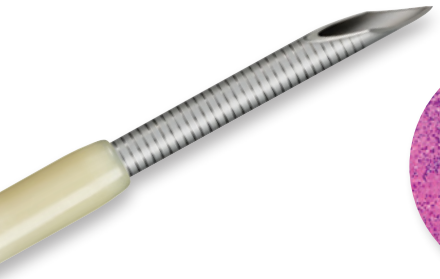
Out of more than 175 EUS liver biopsies performed, I have yet to have a complication. To date, I have ordered two bedside ultrasounds to rule out bleeding for post-procedure pain (both were normal), and four with non-diagnostic samples (all subsequently had cirrhosis-fragmented samples).

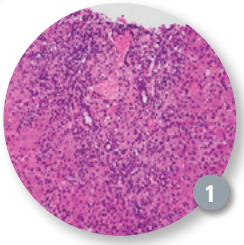
PATHOLOGY FINDINGS

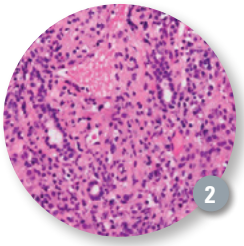
The specimen consisted of multiple (approximately 10) core needle biopsies ranging from 1.0 to 2.5cm in length. The samples were processed as per routine protocols in the surgical pathology laboratory and stained with hematoxylin and eosin, trichrome and other special stains.

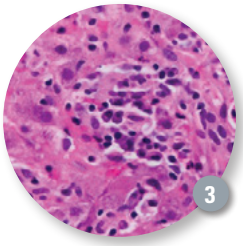
Upon microscopic examination, over twenty complete portal triads were present for examination. The portal areas were expanded by a chronic inflammatory infiltrate **(Figures 1 and 2)** consisting of lymphocytes and prominent plasma cells **(Figure 3)**. There was a moderate interface hepatitis and moderate lobular inflammation. The original bile ducts were present with patchy mild epithelial disarray. No florid duct lesions or granulomas were identified. There was no cholestasis. The trichrome stain showed portal, periportal and patchy bridging fibrosis. The histologic findings were consistent with autoimmune hepatitis.

In my experience, EUS liver biopsy samples provide excellent tissue samples and are actually superior to other methods of liver biopsy. EUS liver biopsies generally contain more biopsy cores with greater lengths and a wider diameter than other biopsy methods. They often contain 20 or more complete portal triads. The larger cores are less likely to break apart, allowing for better characterization of the overall hepatic architecture. **Biopsy yield from EUS liver biopsy specimens is more than adequate for diagnosis in most situations and, in my opinion, is actually superior to other methods of liver biopsy.**









Learn more about the Expect Needle.

Cystogastrostomy Using the AXIOS Stent and Delivery System

CASE PRESENTED BY:

JOSE M. NIETO, D.O., AGAF, FACP, FACG, FASGE

Chairman, Advanced Therapeutic
Endoscopy Center
Hospital Affiliation: Borland Groover Clinic
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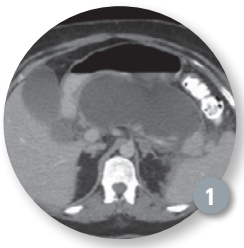
PATIENT HISTORY AND ASSESSMENT

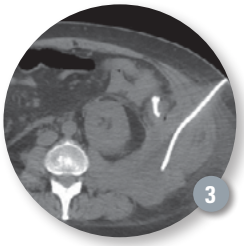
A 45-year-old female, with no past medical history, presented with acute necrotizing pancreatitis secondary to choledochalithiasis. Her lipase was greater than 2000, total bilirubin was 2.1, WBC was 23,000 and Hgb was 17. The patient developed an infected walled-off necrosis (WON) pancreatic fluid collection (10cm X 17cm) **(Figure 1)** four weeks after a pancreatitis endoscopic intervention was done. An endoscopic ultrasound (EUS)-guided cystogastrostomy using an AXIOS™ Stent and Delivery System 15mm x 10mm lumen apposing stent was placed **(Figure 2)**. An immediate necrosectomy was done using a cold snare and lavage with 33% hydrogen peroxide solution. Intravenous fluids and oral antibiotics were given to the patient for ten days. There was a second pancreatic fluid collection in the left pericolic gutter that required percutaneous drainage **(Figure 3)**.

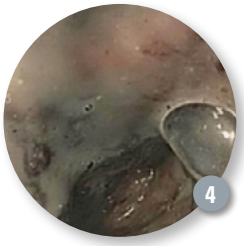


PROCEDURE

An EUS-guided placement of the AXIOS 15mm x 10mm lumen apposing stent was performed. A 19ga needle was used to puncture the cyst and drain fluid confirming an infected pancreatic fluid collection. An 0.035" guidewire was introduced into the cyst and watched under EUS guidance; fluoroscopy was not required. Then a needle knife was used to create a fistula between the stomach and cyst.

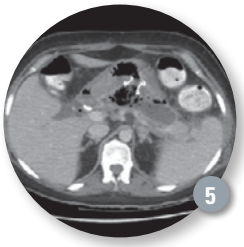
The new fistula tract was dilated to 4mm to allow passage of the AXIOS 15mm x 10mm Stent. The procedure was done entirely under EUS guidance and fluoroscopy was not required. Then the stent was dilated to 15mm to allow passage of an upper endoscope. A necrosectomy was performed **(Figure 4)** using a hexagonal cold snare and with repeated lavages of 33% H2O2 (hydrogen peroxide). The patient was brought back every week for repeated necrosectomy until the cyst had resolved. The patient required three necrosectomies for total resolution. The WON resolved completely after multiple endoscopic interventions. There was a small pancreatic fluid collection in the left pericolic gutter that was treated and resolved with an 8Fr peripheral drain. The patient was positioned in the standard left lateral recumbent position, and was sedated with propofol IV and fentanyl. The stent was placed in the body/tail of the pancreas **(Figure 5)** to drain the 10cm x 17cm WON. **The AXIOS Stent placement avoided surgical intervention in a patient who developed biliary necrotizing pancreatitis. There was complete resolution of the pancreatic fluid collection in eight weeks. There was a residual PFC in the left pericolic gutter that was resolved with peripheral drainage.**

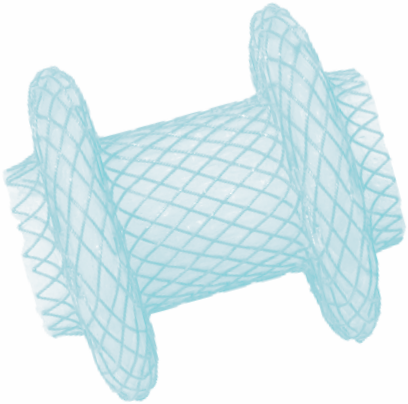




OUTCOME AND PATIENT FOLLOW-UP

The patient tolerated the initial and follow-up procedures very well and stayed in the hospital for seven days after the stent was placed. The patient was brought back weekly until there was complete resolution of the pancreatic fluid collection. Imaging confirmed complete PFC resolution and stent removals. The patient was started on pancreatic enzyme replacement, glucose control, and a regular balanced diet was recommended. One year later, the patient's pancreatic insufficiency has completely resolved and she no longer requires insulin.





Learn about interventional EUS.

A Test to Qualify a Candidate for Pancreatic Pseudocyst Drainage

Learn about interventional EUS.

CASE PRESENTED BY:

DONALD GARROW, M.D.

Fawcett Memorial Hospital
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INTRODUCTION

A pancreatic pseudocyst (PPC) is a collection of rich amylase fluid enclosed by a non-epithelialized wall. PPCs have a tendency to develop in 20%-40% of patients with acute and chronic pancreatitis.[1] Most PPC, will resolve on their own, but when PPCs persist for more than four weeks and are associated with clinical symptoms, surgical, percutaneous or endoscopic pancreatic pseudocyst drainage should be performed.[2]

It is important to screen patients for possible PPC drainage to discern a pancreatic pseudocyst from either a cystic lesion of the pancreas or possible pseudoaneurysms. Applying a test to qualify the patient prior to EUS-guided pseudocyst drainage with the AXIOS™ Stent and Electrocautery Enhanced Delivery System can improve patient selection in order to achieve optimal outcomes.

PATIENT HISTORY

We report a case of a 60-year-old with recurrent acute pancreatitis. There was a 2cm pseudocyst on imaging three months ago, which now is 8cm in the body of the pancreas, impinging on the stomach. The patient is symptomatic with epigastric pain, nausea and vomiting for over one week. There is a history of rheumatoid arthritis, recurrent acute pancreatitis, coronary artery disease and hypertension. Prior surgeries include a coronary artery bypass graft and appendectomy. Currently, the patient is on prednisone 10 mg daily, lortab 5/325 mg every six hours, and hydrocodone bitartrate and acetaminophen tablets 10 mg daily. There are no known drug allergies and the family history has not revealed any gastrointestinal disease, malignancy or liver disease in either parent or siblings. The patient has a history of alcohol abuse but quit six months ago, has a 30-year history of tobacco use, but none in two years.

Physical examination revealed fullness in the epigastric region with a palpable mass-like area in the right upper quadrant extending to the epigastric area 6cm by fingerbreadth. This area is tender to palpation. A CT scan of the abdomen reveals an 8.5cm pseudocyst in the body of the pancreas pressing on the lesser curvature of the stomach.

TEST FOR AXIOS STENT AND ELECTROCAUTERY ENHANCED DELIVERY SYSTEM

Applying the *Garrows Criteria* to the patient's history, we ask the questions below, for which we are seeking an answer of YES.

1. Greater than 6cm?
2. Adherence to wall less than 1cm?
3. Rule out pseudoaneurysm or cystic lesion?
4. Recurrent history of pancreatitis?
5. Obvious debris or necrosis?
6. Wall of the cyst encapsulated?
7. Symptoms associated with cyst?

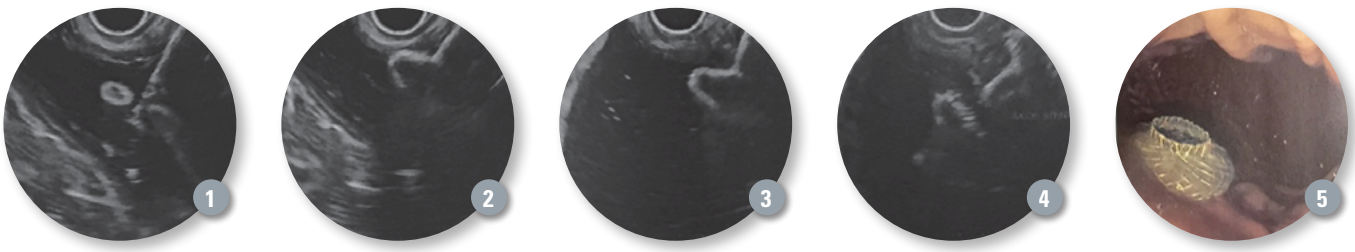
Based on the *Garrows Criteria*, the patient described above is a suitable candidate and concern for any misclassification of the cyst as a pseudoaneurysms or cystic lesions has been mitigated. Therefore, the patient was scheduled for an EUS with pancreatic pseudocyst drainage procedure.

PROCEDURE

During the procedure, the wall of the pseudocyst was measured under EUS to ensure adherence no less than 1cm and the Doppler ultrasound was used to ensure vessels were involved. An Expect™ 19ga Flex Needle was advanced into the cyst and a .025" guidewire was advanced into the cyst to provide a railroad track for the AXIOS Electro Cautery Enhanced (ECE) Delivery System. The AXIOS ECE System was advanced down the linear echoendoscope over the wire and the AXIOS catheter was advanced until the wall of the cyst began to tent on ultrasound. Using the electrosurgical generator and the required 3mm active cord, cautery was applied to the AXIOS System and it was advanced **(Figure 1)**, observing the swirling fluid gave us visual confirmation on endoscopic ultrasound. The first flange of the stent was then deployed **(Figure 2)** and the AXIOS catheter was pulled back to observe the stent changing shape under ultrasound. Once the shape of the stent changed **(football shape, Figure 3)**, the second flange of the stent was deployed **(Figure 4)**. Endoscopic confirmation of pancreatic fluid drainage and stent deployment were noted **(Figure 5)**.

CONCLUSION

Applying the *Garrows Criteria* to PPC may help appropriately select patients for EUS and PPC drainage.



1. Usatoff V, Brancatisano R, Williamson RC. Operative treatment of pseudocysts in patients with chronic pancreatitis. Br J Surg. 2000;87:1494–1499
2. Habashi S, Draganov PV. Pancreatic pseudocyst. World J Gastroenterol. 2009;15:38–47

AN INTERVIEW WITH

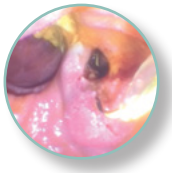
Muhammad K. Hasan, M.D.

Center for Interventional Endoscopy, Florida Hospital, Orlando

Watch a video clip on balloon endoscopy and dilating a GI tract stricture.

The Dilation-assisted Stone Extraction Technique

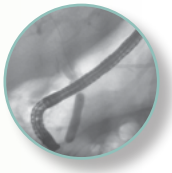
Q Dilation-assisted Stone Extraction or "DASE" can be an effective technique in the removal of difficult biliary stones. Can you provide an overview of how you utilize this technique in your practice?



Although a majority of stones may be retrieved using a standard balloon or basket after performing a biliary sphincterotomy, larger stones or stones in the setting of biliary anatomic variants can be difficult to extract. The technique of biliary dilation assisted stone extraction (DASE) can be indispensable in such circumstances.

At the Center for Interventional Endoscopy in Orlando we perform 1,250 ERCPs annually, of which one-third of the procedures are referred for stone disease. The majority have failed attempts at outside facilities. In almost 80% of such cases we are able to extract the stones using DASE without the need for other advanced interventions (i.e., mechanical lithotripsy, laser or EHL). Even in cases where advanced interventions may be required, DASE facilitates easier extraction of larger stone fragments, thereby minimizing trauma to the ampullary orifice and lowering the risk of adverse events (i.e., bleeding, pancreatitis and perforation). In my practice, before attempting other advanced techniques, I perform DASE. If stone extraction is still unsuccessful, then will I perform laser lithotripsy using the SpyGlass™ DS System, or other adjunct measures as required.

The following principles are critical for successful, safe and effective performance of DASE:



1. Although a complete biliary sphincterotomy may be unnecessary, at least a partial sphincterotomy is needed to guide the force of dilation toward the intraduodenal biliary segment in the direction of the sphincterotomy.
2. The size of the dilatation balloon is determined by the size of the stone and the diameter of the bile duct. The balloon size should not exceed the diameter of the intrapancreatic portion of the bile duct.
3. The balloon is positioned such that its midpoint is at the biliary sphincter and its direction is along the long axis of the bile duct. Gradual inflation must be performed under endoscopic and fluoroscopic monitoring in order to avoid entrapment of the stone between the balloon and bile duct wall. The balloon should be inflated with a diluted contrast medium to facilitate fluoroscopic monitoring. Although there is no specific limit on the duration, I maintain balloon inflation for 60 seconds to dissipate edema around the ampullary orifice as a measure to decrease the likelihood of developing pancreatitis.

Q Which patients are the best candidates for this technique? Why might you choose this technique over other stone removal methods?

DASE is performed when the size of the stone exceeds the diameter of the ampullary orifice and cannot be removed by conventional basket or balloon sweep, despite an adequate sphincterotomy. It is also useful in situations where the intrapancreatic bile duct is too narrow, tortuous or sigmoid-shaped and would not allow stone extraction without lithotripsy.

DASE is also very effective and safe in patients with:

- a. Coagulopathy or at high risk for bleeding (long-term anticoagulation or on anti-platelet agents) and
- b. When the ampulla is at the rim of a large diverticulum or intra-diverticular in location, making a large sphincterotomy unsafe.

Q How does DASE impact overall care and outcomes in ERCP?

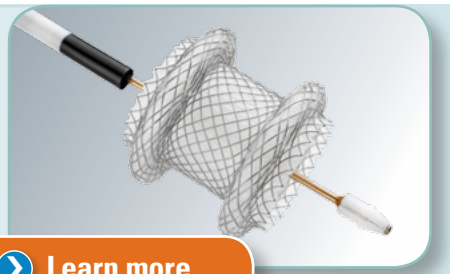
Technical difficulty with stone extraction can prolong procedural duration and increase the risk of adverse events such as pancreatitis, cholangitis, bleeding or perforation. DASE is a technique already validated by randomized trials and shown to be relatively safe, simple and an effective alternative for extraction of difficult bile duct stones, thereby precluding the need for advanced techniques or more complex interventions.

Learn more about this device.

The Boston Scientific CRE™ PRO Wireguided Balloon Dilatation Catheter is indicated for use in dilatation of the biliary tree and the Sphincter of Oddi with or without prior sphincterotomy. Sphincterotomy prior to the use of a balloon for dilatation of the Sphincter of Oddi is known as Dilation-assisted Stone Extraction, or DASE. ***Read more about this device on the back cover.***

News and New Devices

The **AXIOS™ Stent and Electrocautery Enhanced Delivery System** (the "AXIOS System") is now cleared for use in helping physicians manage two serious complications resulting from pancreatitis. The AXIOS System has been cleared for endoscopic management of symptomatic pancreatic pseudocysts and symptomatic walled-off necrosis (WON) of ≤ 30% solid.[1] There are two types of pancreatic pseudocysts (the pseudocyst and WON must be greater than 6cm in size and have an encapsulated wall) or fluid collections (PFCs) that occur in 5-16% of patients with acute pancreatitis and 20-40% of patients with chronic pancreatitis.[2] While some of these PFCs are asymptomatic and self-resolving, others cause severe symptoms and require treatment.



Learn more.

[1] Currently the only indications in the United States.

[2] *Safety and Efficacy of Endoscopic Ultrasound-Guided Drainage of Pancreatic Fluid Collections With Lumen-Apposing Covered Self-Expanding Metal Stents. Shah RJ, Shah JN, Waxman I, Kowalski TE, Sanchez-Yague A, Nieto J, Brauer BC, Gaidhane M, Kahaleh M. Clin Gastroenterol and Hepatol 2014 Oct 5 http://www.ncbi.nlm.nih.gov/pubmed/25290534.*

Learn more.

The **Resolution 360™ Clip** builds on the strong clinical and economic track record of the Resolution™ Clip with the added benefits of controlled one-to-one rotation, enabling faster, more accurate placement to reduce procedure time. Features include a unique braided catheter which allows for physician-controlled rotation along the catheter shaft and an innovative rotation control knob at the handle that allows for nurse/technician-controlled rotation while maintaining hand in handle.

The Boston Scientific **CRE™ PRO Wireguided Balloon Dilatation Catheter** is indicated for use in dilatation of the biliary tree and the Sphincter of Oddi with or without prior Sphincterotomy. Sphincterotomy prior to the use of a balloon for dilatation of the Sphincter of Oddi is known as Dilation-assisted Stone Extraction, or DASE. The CRE PRO Wireguided Balloon Dilatation Catheter features include:

- **Optimized Passability** — New balloon folding process for a lower profile, leading to consistent ease of passage through the scope.
- **Simplified Scope Compatibility** — Compatible with 2.8mm+ working channel endoscopes and 3.7mm+ working channel duodenoscopes. Smaller sizes (6-8, 8-10, 10-12, 12-15mm) are also compatible with 3.2mm working channel duodenoscopes.
- **Fluoroscopic Visualization** — Embedded RO markers facilitate balloon placement using fluoroscopy.

Learn more.

Watch the Alliance™ II Inflation/Lithotripsy Device in-service video.

The SpyGlass™ DS System Wins Award for Product Innovation. Members of the SpyGlass™ DS System's Research and Development team were recognized at the 53rd annual R&D 100 Awards in Las Vegas, Nevada. The awards honor the 100 most innovative technologies and services of the past year as determined by a panel of independent judges and editors from R&D Magazine. The SpyGlass DS System won the prestigious R&D 100 Award in the analytical/test category, in which there were more than 80 finalists.

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