COOK® MEDICAL

The Channel

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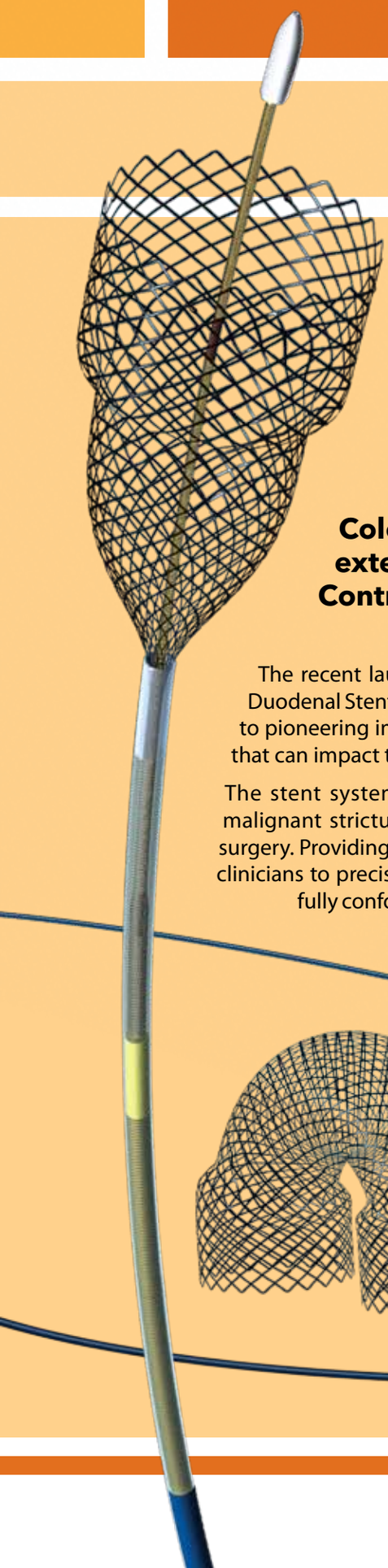

Commitment to Innovation

Colonic and Duodenal stent system extends Cook Medical line of innovative Controlled-Release Evolution devices

The recent launch of the Evolution® Controlled-Release Colonic and Duodenal Stent Systems reflects Cook Medical's continued commitment to pioneering important innovations in stent delivery and performance that can impact the quality of patient care.

The stent system was created specifically for clinicians confronting malignant strictures, gastric outlet obstruction or creating a bridge to surgery. Providing excellent control and maneuverability, Evolution allows clinicians to precisely deliver a stent that provides better wall apposition, fully conforms to the natural curves of the anatomy and potentially reduces post-placement risks.

COMMITMENT TO INNOVATION
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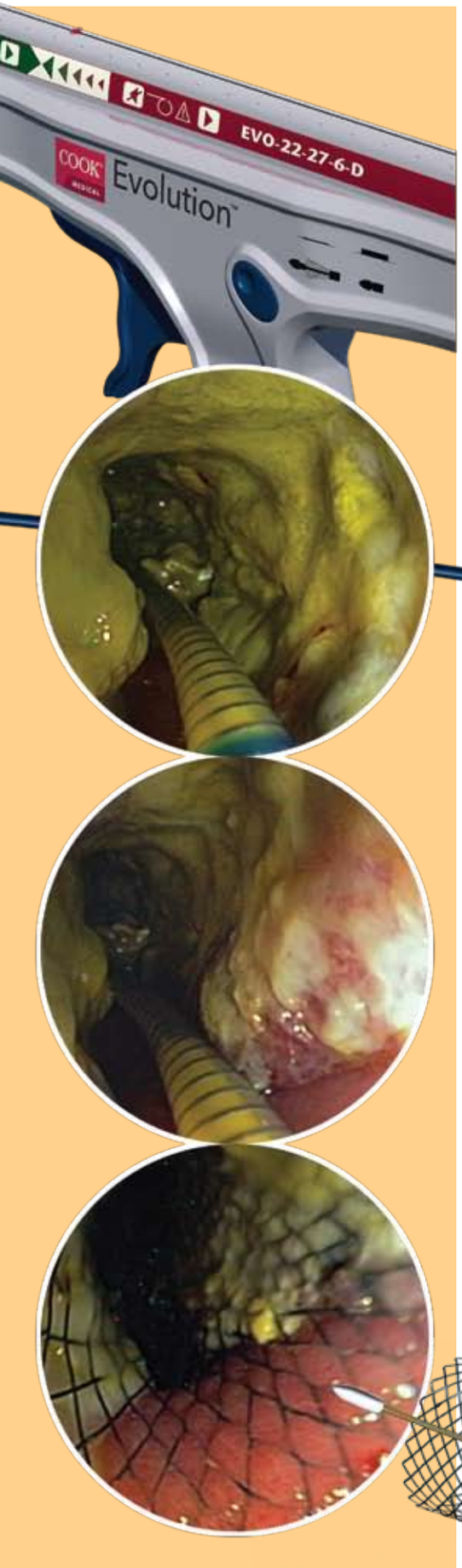


COMMITMENT TO INNOVATION

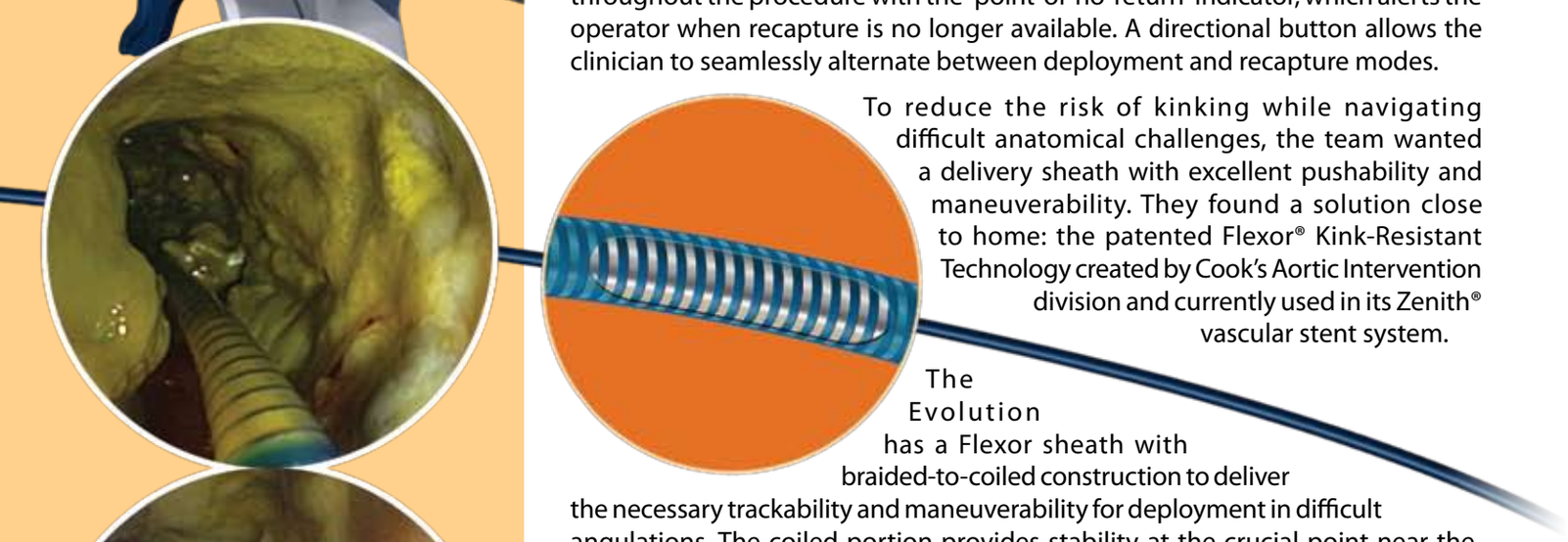
Continued from page 1

Evolutionary Security

What makes Evolution completely unique is the fact that it is the first and only stent delivery system that gives the clinician three important capabilities: the ability to deploy, recapture and/or reposition the stent. Its development is a major step forward in colonic and duodenal stenting, offering an innovative alternative to traditional deployment systems.

With each squeeze of the stent's trigger-based introducer, a proportional length of the stent is deployed or recaptured. Stent-placement progress is directly monitored throughout the procedure with the "point-of-no-return" indicator, which alerts the operator when recapture is no longer available. A directional button allows the clinician to seamlessly alternate between deployment and recapture modes.

To reduce the risk of kinking while navigating difficult anatomical challenges, the team wanted a delivery sheath with excellent pushability and maneuverability. They found a solution close to home: the patented Flexor® Kink-Resistant Technology created by Cook's Aortic Intervention division and currently used in its Zenith® vascular stent system.



The Evolution has a Flexor sheath with braided-to-coiled construction to deliver the necessary trackability and maneuverability for deployment in difficult angulations. The coiled portion provides stability at the crucial point near the proximal end of the stent. A rounded tip is designed to reduce trauma and to aid in traversing abnormal anatomy.

Thanks to Evolution's precise control and maneuverability, the ability to place the stent precisely the very first time is enhanced, potentially reducing the need for repeat procedures.

Evolutionary Design

In developing a new colonic and duodenal stents, the goal was to create a prosthesis that could potentially reduce post-placement risks. The result is the Evolution stent, constructed of thin gage, single-weave Nitinol, giving it more crowns (atraumatic looped ends) than its competitors. The increased number of crowns is due to the smaller size of the individual cells that make up the stent. This particular configuration delivers the flexibility and evenly distributed radial force that the team wanted. It is a design that facilitates better wall apposition, allowing the stent to conform to the natural curves of the anatomy while potentially reducing the risk of delayed perforation.

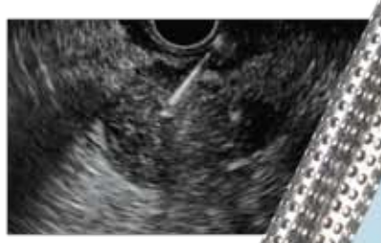
To reduce the risk of migration, the Evolution colonic and duodenal stents have proximal and distal flanges. Four radiopaque markers at each end of the stent provide visualization for accurate placement.

With the Evolution Controlled-Release Colonic and Duodenal Stent Systems, Cook has given the clinician new options to impact the efficiency of their procedures with the ultimate goal of improving the quality of life for their patients.

Not available in US; pending FDA 510(k) clearance.

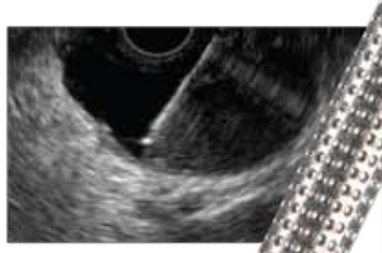
HDFNA: An important key to precision

A discussion with Docteur Christian Boustiere, President, Societe Francaise d'Endoscopic Digestive. (The French Society of Digestive Endoscopy)



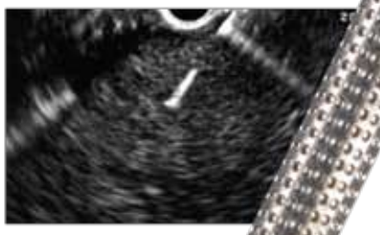
At Hopital Privé Saint Joseph in Marseille, three seasoned endoscopists, led by Docteur Christian Boustiere, perform more than 620 EUS examinations a year. And with more than 200 EUS procedures involving fine needle aspiration or interventional techniques, precise visualization is a critical need.

Fortunately for Dr. Boustiere, his St. Joseph colleagues, and their patients, greater visual precision came to France in September 2007 when the Digestive Endoscopy Unit began using the new EchoTip Ultra HDFNA. Dr. Boustiere, who is President of the French Society of Digestive Endoscopy, discussed the new needle.

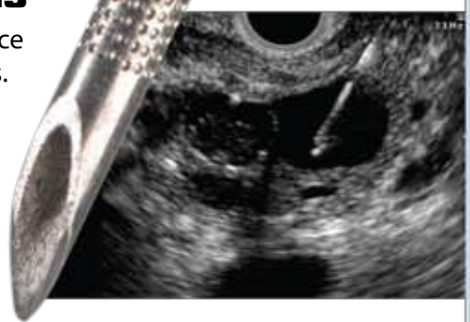


"At first, my colleagues and I were reluctant to change needles," recalls Dr. Boustiere.

"The old ones were already good. But when we discovered the new needle, we found it so much better and we have changed our opinions. This is not a gimmick."



"About 90% of our use is for diagnostic purposes," he explains. "During an EUS, my colleagues and I can see the tip of the needle much better now during a procedure. In the past, the needle could be difficult to visualize, because we are often working with more than 4 cm to the digestive wall. "



Improved aspiration, fewer passes, better yields

"With the new needle, however, we experience even greater precision," Dr. Boustiere says. For example, when I have big masses I need to choose the best sites of the tumor to aspirate. It is always difficult to place the needle in the tumoral part – the endoscopist needs very precise guiding. The HD needle helps enable that."

"In addition, at St. Joseph's we have experienced fewer passes," he continues.

"Thus, the time required to obtain specimens is clearly better, and we have improved our diagnostic yield. In addition, the greater clarity has resulted in fewer needle sticks."

"Recently, I had to perform a lower pancreatic needle aspiration through the glutonal wall. It was very difficult, and thus important to have a good view and control of the needle. Echo Tip HDFNA helped give me the precision I needed."

St. Joseph Hopital

- St. Joseph is a private foundation located in the center of Marseille.
- It is an important private medical center in France, with more than 850 beds.
- The hospital's physicians represent all specialties.
- The Digestive Endoscopy Unit performs 8000 examinations a year in 3 well-equipped rooms.
- For EUS, the endoscopists have access to a complete Olympus Aloka Alpha 5 system with 4 linear scopes and 2 electronic radial.
- Dr. Boustiere's Department is involved in EUS teaching.
- He is the co-director of the French University diploma of EUS.
- The Department also conducts research.

In the last year, Cook Medical's Endoscopy division has taken these waste reduction and reuse steps:

- Stocked all vending machines with plastic bottles and placed voluntary recycling stations in 18 campus locations.
- Switched to re-usable plastic pallets; damaged pallets are recycled.
- Installed automated paper towel dispensers which have reduced paper towel usage by 40-50%.
- Converted to 100% post-consumer recycled paper in copiers.
- Eliminated 40 desktop printing locations, resulting in reduced ink and energy use.
- Begun on-site fluorescent bulb grinding and collection of hazardous waste.
- Purchased production hairnets that are 100% recyclable.

To reduce energy/water usage, Cook Medical has:

- Implemented a four-day/10-hour production work schedule, aimed at reducing staff fuel consumption by 20%.
- Replaced all bottled water units with filtered tap water coolers.
- Made a 100% transition to fluorescent bulbs.
- Replaced all T12 fluorescents with T8 fluorescents. (The division projects a 20% reduction in total number of lights during transition.)
- Installed automatic light switches (ongoing).
- Begun placing auto-flush and faucet activators in all restrooms.
- Made extensive use of native drought-resistant landscaping on campus.

Cook Medical Environmental Action Pays Off in Several Green Ways

Over the last several years, an innovative team at Winston-Salem, NC–based Endoscopy division of Cook Medical, has used a multi-faceted program focused on reducing waste and achieving green improvements. Taking a practical approach to environmental stewardship, however, also improves customer satisfaction and yields dollar savings.

In addition, the program ties directly to the Cook corporate philosophy. "Our standards center on patient care and high ethics, and environmental stewardship is an important facet of that," says Bill Gibbons, President of Cook Endoscopy. "Although we started this program with that objective, we realized that we were achieving cost reductions as we got deeper into it. To me, environmental stewardship and revenue savings are totally compatible goals."

"We developed our own program, instead of hiring expensive consultants," explains Bryan Griswold, Plant Facilities Manager. "Basically, we put our heads together and followed a guideline of 'let's do what makes common sense.' As a bonus, we are also achieving some returns on investment. In fact, a new system goal calls for efforts that will pay for themselves in 12-18 months."

"The program also includes marketing successes," Gibbons adds. "We challenged our packaging staff to eliminate excess paperboard packing for our products delivered to hospitals worldwide; we were able to eliminate five tons of paperboard packaging a year. Because hospitals rank waste management as a significant issue, we've received positive feedback because of less cardboard and other packing waste."

Stepped-up recycling

In Winston-Salem, Cook Medical now recycles 100% of incoming cardboard boxes and tubes in its own recycling center. Built during the spring of 2008, the center already processes three tons of cardboard, plastic tubes, and plastic vending machine bottles monthly. "It is much less expensive than incineration, and is actually yielding a return," explains Griswold. "In addition, we have 26 paper shredding/recycling locations on our campus. We estimate we can recycle a ton of this paper a month.

"Our employees have certainly bought into our efforts," he continues. "For example, we began a vanpool a couple of years ago, and now have six vans, which carry 12-15 employees. We no longer need to build more parking spaces, and the employees are saving gas and vehicle maintenance dollars. Up to 25% of our manufacturing employees use the vanpool."

The program saves power – and dollars – even during after hours. Cook Medical created an automation system to reduce evening heating and air conditioning use. The team installed a building automation system called Tritium. Computer controlled, Tritium monitors everything from office lighting to parking lot lights.

Gastric mucosal resection video case creates interest

at British Society of Gastroenterology

In March 2008, Consultant Gastroenterologist, Dr. Anjan Dhar, DM, MD, FRCP, created significant interest at the British Society of Gastroenterology (BSG) with a video case involving a high-risk patient with a precancerous lesion of the stomach. Although endoscopic procedures to resect high grade gastric dysplasia are not unknown in Great Britain, the Duette® device he used, the relative efficiency of the device, and the shortened time for the procedure were unique.

His video case theme, "Mucosal Resection of high grade gastric dysplasia using the Duette mucosectomy device", shows the effectiveness and efficiency of the device for endoscopic mucosal resections in the stomach.

The patient featured in the case was a 78-year-old British male with a 15 mm precancerous stomach lesion, proven to be high-grade dysplasia on two previous biopsies. He was at high risk for a distal gastrectomy due to a complicated medical history of ischemic heart disease, advanced heart failure, diabetes mellitus, and chronic obstructive airways disease.

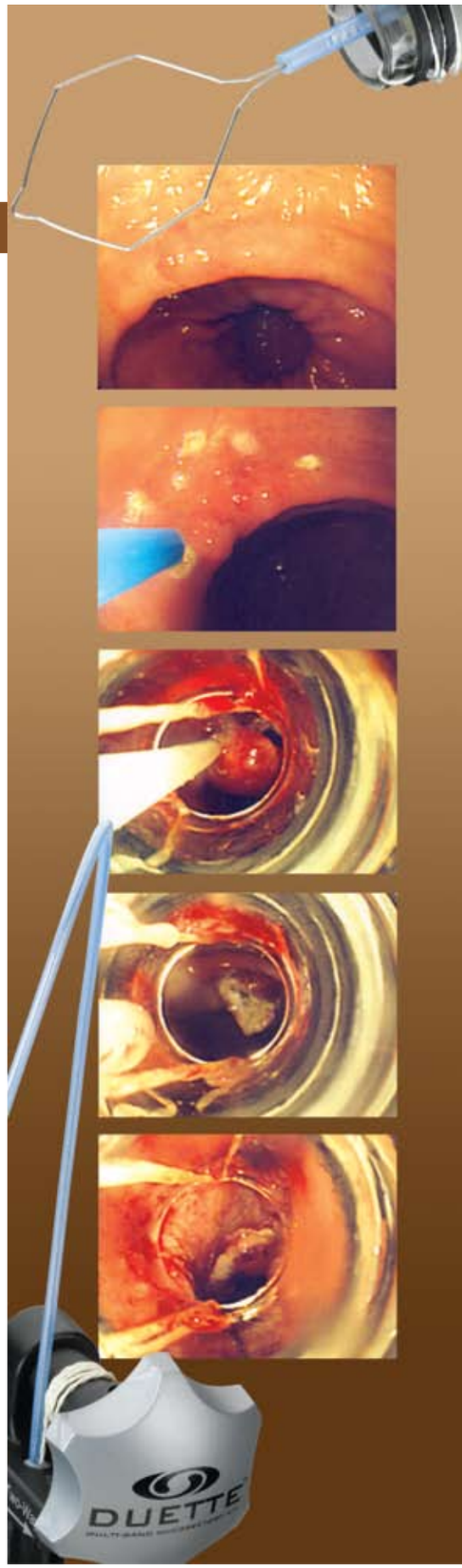
Dr. Dhar has been Consultant Gastroenterologist & Endoscopy (Training) Lead since 2004 at Bishop Auckland Hospital, one of three hospitals in the County Durham and Darlington NHS Foundation Trust in the Northeast of England. Opened in 2002, the 286-bed hospital serves a population of 120,000 in Northeast England. The hospital's Gastroenterology Department includes three Consultants, two Fellows-in-training and ten nurses.

Dr. Dhar holds a specialist registration in General Internal Medicine and Gastroenterology in the UK. In addition, he has served in Gastroenterology specialist roles in London, Oxford, and Oman, as well as in New Delhi, and Chandigarh, India. A Fellow of the Royal College of Physicians of the UK, he also is a member of American Gastroenterology Association, the British and the Indian Gastroenterology Associations.

Esophageal experience applied to stomach lesions

Dr. Dhar recalls the details of the gastric procedure: "We decided to extend the Duette technology to remove a gastric precancerous lesion approximately 15 mm in size. We essentially applied the same principle as in resecting lesions in the esophagus. We reasoned that if the gastric lesion was well demarcated, it was appropriate for endoscopy. Thus, the lesion could be resected endoscopically, avoiding major surgery.

"There were other UK centers doing endoscopic resections of the stomach," he noted. Specialists in Nottingham and Portsmouth have done approximately 20 cases, using the cap snare procedure. To Dr. Dhar's knowledge, however, the Durham stomach resecting case was the first in the Northeast of England using the Duette device.



GASTRIC MUCOSAL RESECTION VIDEO CASE

Continued on page 7

About Dr. Anjan Dhar

Dr. Anjan Dhar, who has published 40 research papers in his field, has expertise in the following endoscopic techniques:

- Esophageal variceal band ligation and sclerotherapy
- Esophageal bougie and balloon dilatation
- Esophageal metal and plastic/ biodegradable stent placement
- Peptic ulcer injection, electrocoagulation and haemoclip
- Argon Beam therapy for tumors
- Pecutaneous gastrostomy
- Advanced colonic polypectomy

His credentials include:

- Former reviewer for the Indian Journal of Gastroenterology
- Specialist FRCP (Edin), Royal College of Physicians of Edinburgh, United Kingdom
- DM (Gastroenterology) Postgraduate Institute of Medical Education and Research, Chandigarh, India
- MD (Internal Medicine) Postgraduate Institute of Medical Education and Research, Chandigarh, India
- Diplomate of the National Board, National Board of Examinations, New Delhi, India
- Commonwealth Fellowship in Gastroenterology, Association of Commonwealth Universities, United Kingdom, Oxford

Dr. Dhar has a total of 14 years experience in gastroenterology and endoscopy and has carried out over 5000 upper GI therapeutic endoscopies, 1000 colonoscopies with a caecal intubation rate of >90% and 300 ERCPs. He has performed emergency procedures for GI bleeding such as injection therapy, heater probe electrocoagulation, band ligation and Argon plasma coagulation.

GASTRIC MUCOSAL RESECTION VIDEO CASE

Continued from page 5

Benefits of applying the device

"The results were accomplished without open surgery, although the patient was under sedation," continues Dr. Dhar. "During the procedure we resected four segments, using four bands. From an endoscopist's perspective, there were several advantages of applying the Duette device during the stomach resection.

The device:

- **Uses a familiar technique from esophageal variceal banding**
- **Enables multiple banding without reloading**
- **Reduces the procedure time**
- **Takes advantage of vacuum suction**

"The patient remained in the hospital for 24 hours to assure there were no complications. He went home the following day. He required a two-day recovery period as opposed to several months for open surgery or 1-2 weeks for a standard medical laparoscopic procedure.

"In conclusion, I would like to acknowledge the support of my Endoscopy Sister, Ann Allan, RN. She and I found the Duette device to be quicker and easier to use than the cap method, which is more technologically demanding," said Dr. Dhar. "The total procedure required only 45 minutes.

"Best of all, when we looked at the histology of the resected area, there was complete resection with no evidence of early cancer remaining. A subsequent endoscopy at six months with biopsies indicates no evidence of early cancer. Thus, the procedure is potentially curative."

Questions following Dr. Dhar's BSG presentation

After the presentation of his video case to the BSG, interested professionals in the audience peppered Dr. Dhar with questions. These included:

Are there size limitations to stomach lesions using EMR?
Dr. Dhar: Japanese physicians have reported using EMR on stomach lesions up to 30 mm. This was possible using multiple bands. In our case, we resected a 15 mm lesion in four steps using four Duette bands.

Do stomach lesions require endoscopic ultrasound before resection?
Dr. Dhar: Yes, to determine the staging and depth of the lesions.

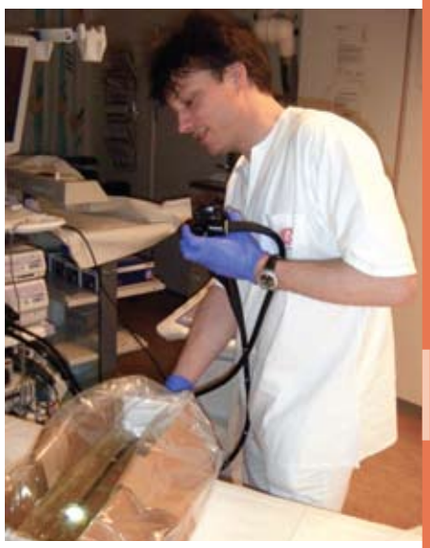
What is the risk of bleeding resulting from stomach lesion resections?
Dr. Dhar: It was not a major risk in the procedure due to the application of electrocauterization while resecting.

Successful ERCP/EUS workshop in Oslo, Norway

Lars Aabakken, course director

April 2-3, 2008, a hands-on workshop was organized by the department of GI Endoscopy, Rikshospitalet University Hospital, Oslo, Norway, in close collaboration with the Scandinavian Cook team.

The workshop was organized specifically for team-based hands-on training, and a total of 8 teams (doctor and nurse) were invited from all across Norway. The local team was headed by Chief of GI Endoscopy, Professor Lars Aabakken, and organizing nurse Gudrun Jonasdottir. The local faculty was strengthened by visiting faculty member Dr. Jan Verner Poley of Erasme Hospital, Rotterdam, who chaired the EUS sessions of the workshop.



On Wednesday, a total of 3 clinical cases were demonstrated, utilizing a variety of Cook accessories, for ERCP as well as for EUS procedures. Dr. Poley gave a highly practical lecture on the ins and outs of therapeutic EUS, while nurse Siv Furholm of the local faculty presented her comparative data on single use versus reusable accessories.

The course dinner was held at the private home of Prof. Aabakken, offering an excellent arena for networking and informal discussions, which are some of the main benefits of such courses However, all participants were freshly attending the next morning for more cases and talks, on EUS, ERCP techniques and a specific talk by nurse Anne Lysaker on nursing aspects of ERCP.

After lunch, hands-on sessions were organized using a locally developed gelatine-based model for EUS puncturing, and the standard Cook model for ERCP cannulation and exchange training.

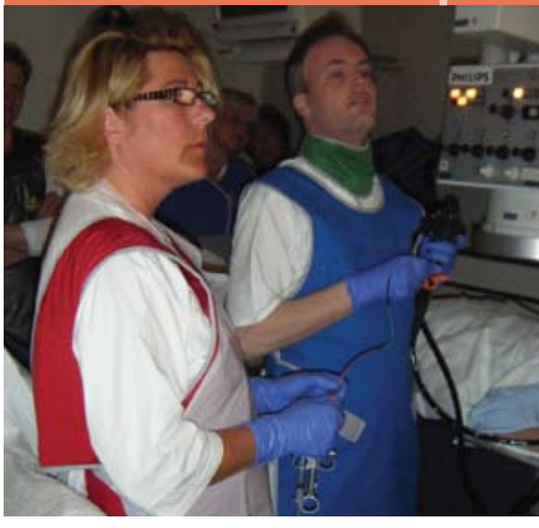
Provisional feedback from the participants was highly positive. Surely, small-scale meetings like this with a high level of interaction and the possibility to touch and feel the various accessories in a clinical context is the best way to introduce and familiarize endoscopists and assistant nurses with new technologies, facilitating in a major way the first attempts at real patients. We hope that this course can become an annual event, to improve the endoscopy network of Norway, as well as the position of Cook in the region. We also would not mind a repeat visit from Dr. Poley!

Main Cook organizer Lena Zimmergren was very content with the clinical performance and as well as the presentation on single use accessories given by specialist nurse Siv Furholm.

Dr. Jan Werner Poley was amazed with the authentic look and feel of the EUS puncture model.

The complete group – exhausted but content.

Lars Aabakken and assisting nurse Cecilie Crohn use the Omnitome to facilitate a difficult cannulation.



Oklahoma Gastroenterologist Dilates Eosinophilic Esop

Rhody Fawaz, M.D.

Comanche County Memorial Hospital endoscopy unit staff with Hercules balloon

In 2008, Comanche County (OK) Memorial Hospital Gastroenterologist Rhody Fawaz, M.D. treated a 25 year-old male patient who presented with painful eosinophilic esophagitis. Because of the esophageal stricture, the patient experienced severe and uncomfortable dysphagia.

Dr. Fawaz decided to treat the patient's stricture using a balloon dilator procedure. From his experience with this procedure, Dr. Fawaz expected that he would require multiple dilation efforts to achieve success. For this procedure, however, he had available the new Cook Medical Hercules 3 Stage Balloon Dilator. Designed to endoscopically dilate strictures of the esophagus with greater radial force than existing balloons could offer, the balloon has received FDA 510(k) clearance.

A single lumen catheter with a balloon mounted on the distal tip, Hercules is inflatable with water to three distinct and progressively larger size diameters to exert force on esophageal strictures resulting in stricture dilation.

"Balloons I had previously employed would have taken longer to dilate because they offered only up to 7 centimeters of inflation. The longer, stronger Hercules enabled one dilation, versus multiple dilations," said Dr. Fawaz.

Optimum strength through three phases

The Hercules balloon, offered in five sizes, each with three stages (see chart below), provides optimum strength for opening strictures that exhibit a high level of fibrosis. Cook Medical engineers, consulting with physicians globally, sought to improve patient outcomes by offering exceptional dilating strength to relieve patients' dysphagia.

The engineers used proprietary P.E.T. Flex™ technology to develop a strong, durable, yet stageable balloon dilator. P.E.T. is the same material found in water bottles and soft drink bottles. Rigid, with high tensile strength, the new material delivers enough compliance for stageability and the stiffness for radial force all in the same balloon.

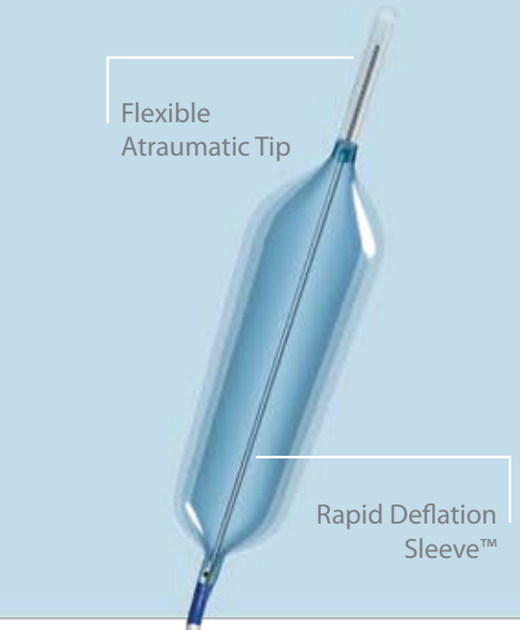
In fact, in bench testing, Hercules scored an average of 154% greater radial force than the competitor balloon at 18, 19 and 20 mm.

For Dr. Fawaz and his patient, the additional strength helped in reaching desired results. "The Hercules radial force meant we were able to achieve the exact level of dilation needed," he said. "Our endoscopy team used all three stages of the balloon, from 12 all the way up to 15 millimeters. The length of the procedure was about seven to eight minutes."

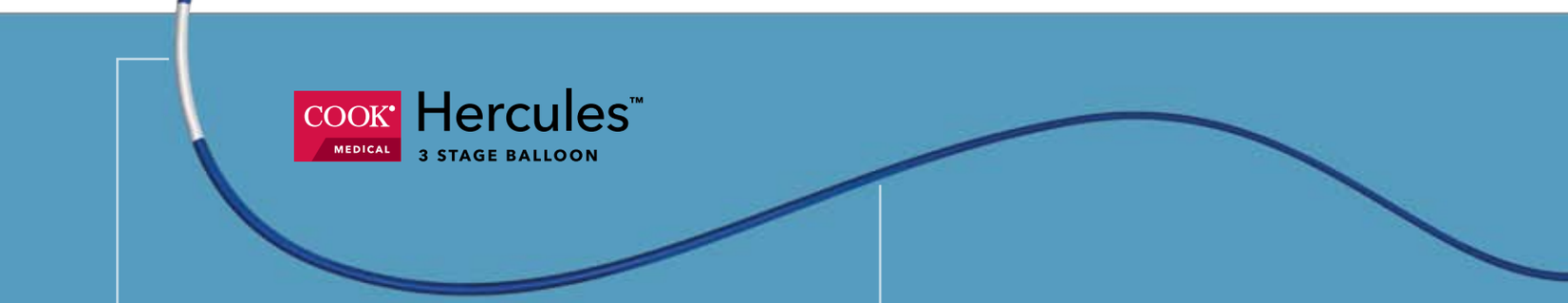
Features designed to promote accuracy

"It is often difficult for an endoscopist to estimate where the stricture starts," noted Dr. Kevin Casey of Rochester General Hospital, Rochester, NY. "For example, 'Am I at 17 mm?' There is insecurity regarding how well the balloon will dilate. We wonder 'Will it inflate to that size of the stricture?' "

To answer questions such as those, Cook Medical designed the balloon to inflate to three distinct and increasing diameters.



COOK MEDICAL Hercules™
3 STAGE BALLOON



hagitis Stricture With Hercules 3 Stage Balloon

All three sizes on the label and the device are printed with glow-in-the-dark labeling. "The balloon is very well visualized," noted Dr. Fawaz.

In creating a stageable balloon, the gold standard in esophageal dilation, P.E.T Flex technology again played a key role. Because the balloon dilates uniformly, endoscopists achieve the expected sizes. For example, should a procedure successfully dilate the stricture at the first stage (18 mm), there may be no need to continue.

In addition, based on preliminary market feedback, the Hercules balloon dilates to its intended target size and holds its position within stricture.

Rapid balloon withdrawal process saves time

In consulting with physicians during the Hercules development, Cook Medical learned that saving procedure time was a critical factor in every case. A major area of concern – the amount of time to deflate the balloon.

To allow more rapid deflation, Cook engineers placed a Rapid Deflation Sleeve inside the pre-lubricated Hercules balloon. In addition, they equipped Hercules with an Express Evacuation Catheter to increase the flow of water out of the balloon.

As a result, water is not trapped at the tip of the balloon, and can be pulled quickly into the syringe. "This is what you want to see," commented Dr. Casey.

In Hercules, rapid deflation* is achieved by simply applying negative pressure. When that is achieved, the balloon folds into a star shape. As the physician removes the device, the balloon twists around the catheter and is easily withdrawn through the scope channel. And even if removal begins prior to complete deflation, Hercules can easily be withdrawn into the endoscope.

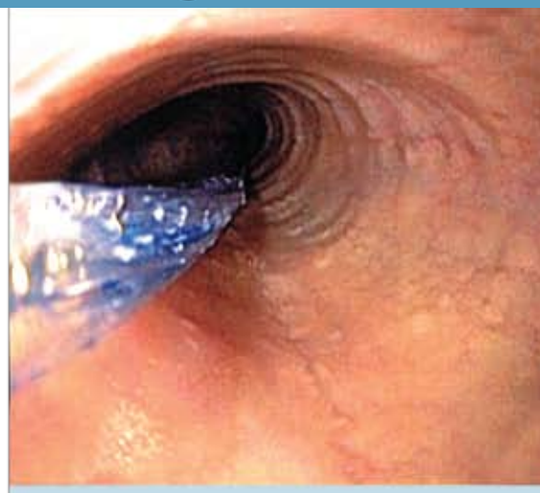
"The Hercules balloon was very easy to remove. We never had any problems with deflated balloon recovery," noted Dr. Fawaz.

Other improvements assist Endoscopists and their staffs

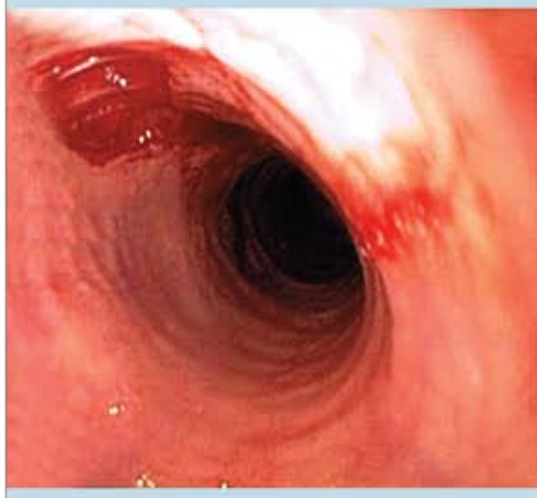
- The new balloon improves visualization. When placed in front of the light source of the endoscope, the balloon has a blue tint to it. The tint was part of the design plan to eliminate a portion of the glare created by musocal and fluid reflection caused by the light source.
- The atraumatic tip is firm enough for easy entry into the biopsy channel with the biopsy port cover in place. Yet the tip is still flexible enough to be atraumatic.
- The kink-resistant catheter provides greater push- and pull-ability. The Hercules balloon is easy to insert into the biopsy port and advance through the scope channel. A nitinol core gives it strength for removal.

"In the eosinophilic esophagitis case, the patient responded very well to the Hercules dilation procedure. He is doing great and appreciates being able to swallow again," concluded Dr. Fawaz.

* Using 60 cc syringe.



Eosinophilic esophagitis stricture prior to dilation



Stricture showing effects of successful dilation

Glow-in-the-dark Catheter Tag

ORDER NUMBER	GPN	INFLATED BALLOON DIAMETER
HBD-8-9-10	G31928	8-9-10 MM / 24-27-30 FR
HBD-10-11-12	G31925	10-11-12 MM / 30-33-36 FR
HBD-12-13.5-15	G31926	12-13.5-15 MM / 36-40.5-45 FR
HBD-15-16.5-18	G48732	15-16.5-18 MM / 45-49.5-54 FR
HBD-18-19-20	G31927	18-19-20 MM / 54-57-60 FR

NOTE: *Catheter size is 7 FR. Catheter length 180 cm. Minimum accessory channel 2.8mm.*

Coming Soon

The New Zilver 635 Self-Expanding Biliary Stent

All the benefits of the original Zilver…

- **Established patency performance** – The MOZART Study concluded: "The 10 mm Zilver and 10 mm Wallstent had similar patency rates for treating malignant obstruction below the bifurcation."[1] Stent patency performance impacts the number of re-interventions required post-placement and, therefore, patient outcomes.
- **Nonforeshortening** – Zilver's Nitinol construction and foreshortening characteristics provide stent placement precision and predictability, enhancing ease of deployment and accuracy. Nonforeshortening stent placement facilitates physician assurance of final stent position. "The proximal aspect may be placed accurately below any potential line of future resection."[2]

… on a new 6 FR introduction system:

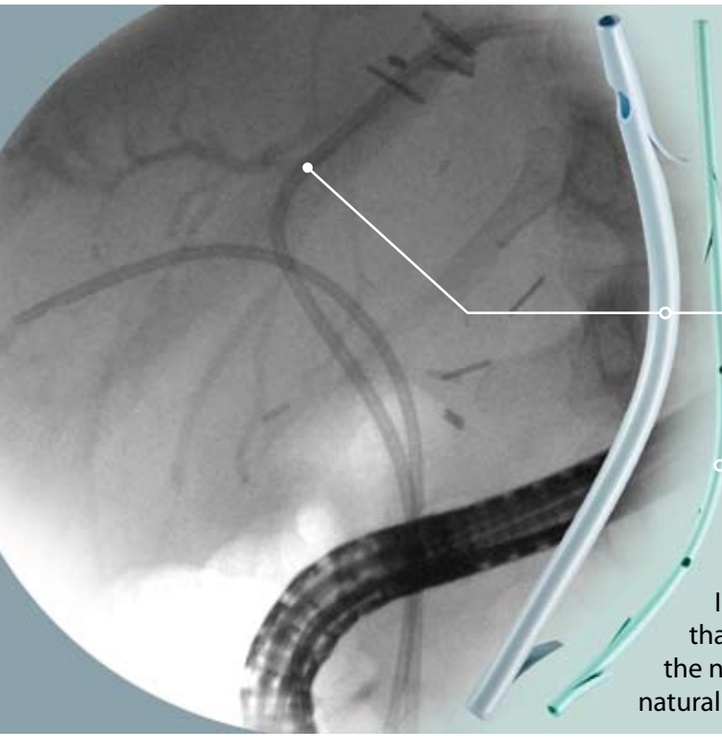
- **The smallest introducer available on the market** – A smaller introducer means potentially easier negotiation through tight or torturous anatomy.
- **Kink-resistant Flexor catheter** – patented coil-reinforced construction for optimal flexibility and maximum resistance to kinking or compression.
- **Improved "shelf-less" tip design** – engineered for smooth withdrawal of stent introducer through deployed stent.
- **Great visibility** – A radiopaque band incorporated within the sheath material identifies precise location of the distal tip for positioning accuracy, while an endoscopic marker on the inner catheter aids in identifying the proximal end location of the stent placement (this endoscopic marker should be referenced when placing a stent across the papilla).

1 Vittal, H., Howell, D.A., Sanders, M.K., Desilets, D.J., Kortan, P.P., May, G.R., et al. (2007). Mechanisms of Occlusion of Uncoated Self-Expanding Metal Biliary Stents (SEMS): Final Results of a Multi-Center Comparative Study. Gastrointestinal Endoscopy, 65, AB245.

2 Lawrence, C., Howell, D.A., Conklin, D.E., Stefan, A.M., Martin, R.F. (2006). Delayed pancreaticoduodenectomy for cancer patients with prior ERCP-placed, nonforeshortening, self-expanding metal stents: a positive outcome. Gastrointestinal Endoscopy, 61, 531.

Soft on Tissue, Strong on Results

Our best-selling stent designs are going soft … Sof-Flex®, that is!



Sof-Flex is a supple-yet-pliable kink-resistant material designed to gently maintain the shape of the duct instead of forcing the duct to take the shape of the stent. This is a new material option for Cotton-Leung® Biliary and Geenen® Pancreatic stent configurations.

Cotton-Leung Sof-Flex Biliary stents are designed with a tapered tip for smooth cannulation, and proximal and distal flaps to help minimize stent migration. The curved shape of the CLSO-SF is designed to adapt gently to shape of the bile duct.

Geenen Sof-Flex Pancreatic stents are available in two configurations. The GPSO-SF configuration has offset ductal and duodenal flaps (shown), while the GPSOS-SF features offset duodenal flaps. Both configurations have spiraled side holes spaced every 5mm for efficient pancreatic drainage.

See the Difference

In the right hepatic duct (left stent) is a standard polyethylene stent that alters the shape of the duct. In the left hepatic duct (right stent) is the new Cotton-Leung Sof-Flex Biliary Stent. See how the Sof-Flex stent naturally conforms to the anatomy of the duct.

Image courtesy of Martin Freeman, M.D., Professor of Medicine, Director of Pancreaticobiliary Endoscopy Fellowship, Codirector of Minnesota Pancreas & Liver Center, University of Minnesota & Hennepin County Medical Center, Minneapolis, MN

Fusion™ Marathon™

Anti-Reflux Biliary Stent

Kulwinder S. Dua
MD, DMSc, FRCP (Edin), FRCP (London), FACP, FASGE
Professor of Medicine
Division of Gastroenterology & Hepatology
Medical College of Wisconsin
Milwaukee, U.S.A.

Plastic biliary stents (PBS) were introduced in the 1970s and are still being used regularly for relieving bile duct obstruction. They are effective, easy to place, can be removed, and are relatively cheap. However, stent occlusion within a relatively short period continues to be a major issue with these stents. This requires frequent stent exchanges to prevent life-threatening complications like cholangitis. Not surprisingly, there has been a constant search for a stent that has the advantages of a plastic stent and yet remains patent for a longer time.

The exact mechanism(s) that lead to stent occlusion is not known. Larger diameter stents have better patency rates (e.g. 10FR stents versus 7FR stents) but the maximum diameter that can be used is limited by the endoscope channel (maximum possible 11.5FR). Expandable metal stents can expand up to 30FR (10mm) and remain functional for a longer time, but these stents are expensive and the majority of them cannot be removed as they tend to get embedded into the tissue. Another approach was to make PBS with material having the lowest friction co-efficient (Teflon®) or with hydrophilic coatings. However, unlike in-vitro studies, these stents did not show any advantage in prospective clinical trials. Similarly, changing stent designs like double-layered stents or stents with no side-holes were no different from standard PBS in clinical trials. Studies have also looked at the formation of a biofilm on the inner wall of the stent by adherence of host proteins and bacteria. The bioflim protects the bacteria against antimicrobial agents and bacterial glucuronidases and phospholipases action on bile components leads to biliary sludge formation. To reduce bacterial adherence and sludge formation, antibiotic and choleretic agents that help in bile flow have also been tried, either separately or in combinations. Unlike in vitro studies, clinical studies again did not consistently show significant benefits using these approaches.

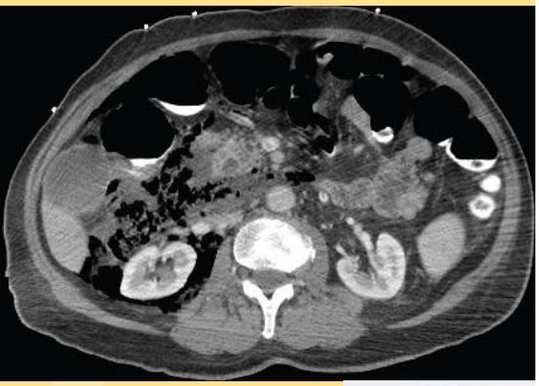
The muscle sphincter at the lower end of the common bile duct acts like a physiological barrier preventing dudeno-biliary reflux. Whenever stents are placed across the sphincter, this barrier effect is compromised and hence it is not surprising to find air in the biliary tree. Several studies done from the mid-1980s till recently have also shown duodenal contents like plant fibers in occluded PBS. Hence, there is enough evidence to support the occurrence of dudeno-biliary reflux when stents are placed in the biliary system across the sphincter. Whether dudeno-biliary reflux contributes towards stent occlusion was recently investigated using a new PBS that has an anti-dudeno-biliary reflux valve - the Fusion Marathon Anti-Reflux Biliary Stent.

The Fusion Marathon stent is a 10FR plastic biliary stent with a windsock-type valve at its duodenal end. This stent does not have side holes, thereby eliminating the

FUSION MARATHON *Continued on page 12*

What's Up Doc?

Welcome to a section in The Channel where we present a clinical image and ask you to participate.



Dr John Baillie

This abdominal CT scan was performed 6 hours after a "difficult" ERCP in a jaundiced, middle-aged man with presumed malignant biliary obstruction. A generous needle knife papillotomy failed to afford deep access to the bile duct. Following the procedure, the patient developed low back pain, more on the right than on the left, requiring narcotic analgesia. He was afebrile, and had a normal peripheral white blood cell count. His liver panel was unchanged. Amylase and lipase levels were normal. The patient's vital signs are stable and he's asking to eat.

What abnormality is present on the CT scan?

What caused this appearance?

What is the appropriate initial management?

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

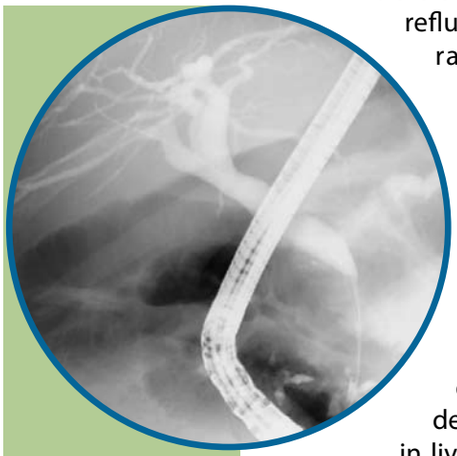
We are looking for more submissions and welcome your participation. If you want to submit an image with a written case history and clinical explanation, please contact Kevin Chmura at kevin.chmura@cookmedical.com.

FUSION MARATHON

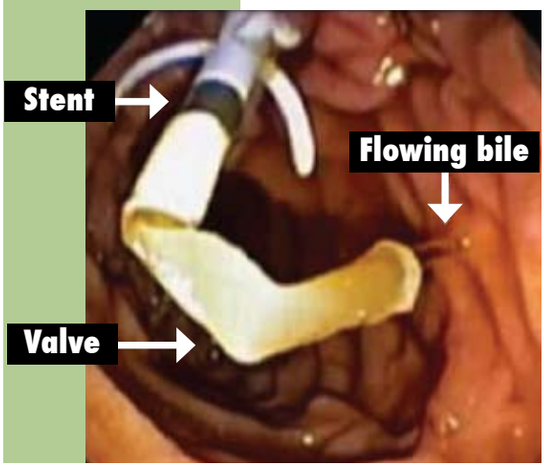
Continued from page 11

possibility of duodenal contents refluxing into the stent bypassing the valve. The stent is available pre-loaded on a Fusion Oasis delivery system that is compatible with the 0.035" short or long wire systems. Standard techniques are used to place the stent. Since it is important to select the right length of the stent in relation to the stricture as explained below, the stent is available is several length options.

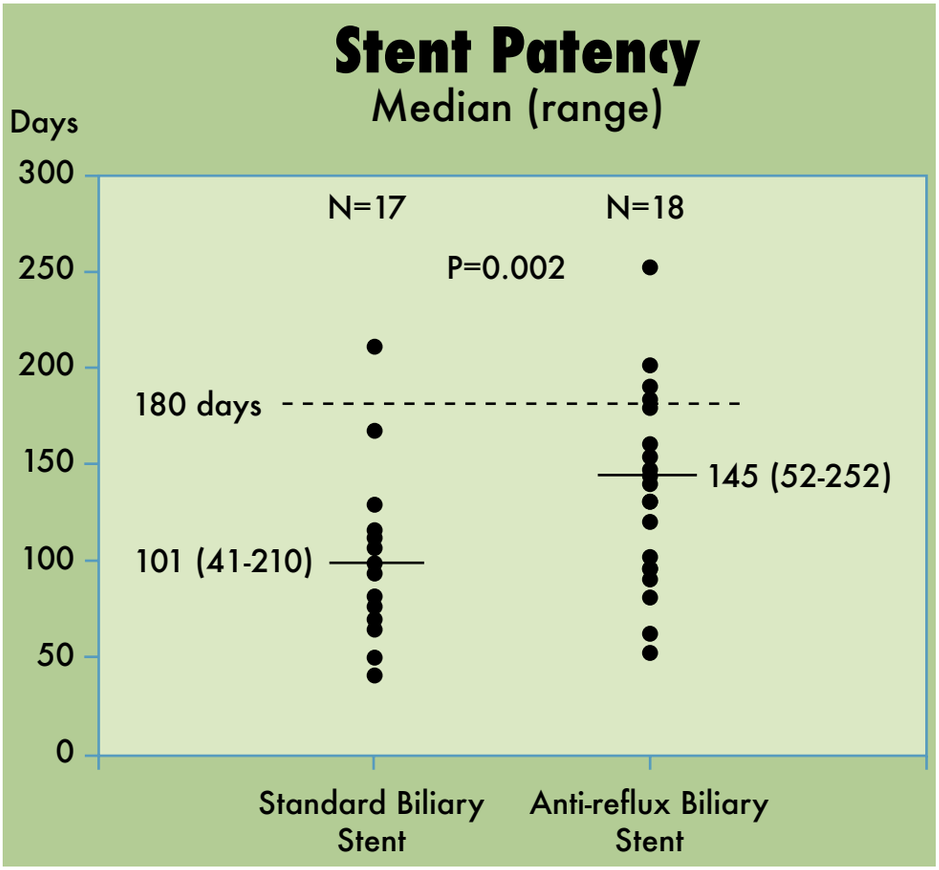
In-vitro studies have shown that the anti-reflux valve on the Fusion Marathon stent is capable of withstanding high pressure gradients and hence will reduce the likelihood of dudeno-biliary reflux. To determine if the addition of a valve to the stent increases the resistance to flow of bile into the duodenum, studies were done using ox bile that was perfused through the stent at various flow rates and results were compared with a standard stent of the same diameter and length. It was shown that not only did the valve not increase the resistance, but it facilitated forward flow by generating negative pressure by siphon effect.



To evaluate the impact of reducing duodeno-biliary reflux on stent patency rates, a prospective randomized study was conducted on patients with non-hilar malignant bile duct strictures. The primary end-point was the stent patency rate, measured as the duration in days from stent insertion to stent occlusion. Stent occlusion was defined as worsening jaundice, and/or worsening liver tests, and/or cholangitis with improvement of these after stent exchange. Secondary end-points analyzed were success in biliary decompression as measured by improvement in liver tests and complications. Results were compared between standard stents and Fusion Marathon stents. Thirty patients were randomized to the standard stent and 30 to the Fusion Marathon stent. Secondary to non-stent related issues and to those lost to follow up, in the final analysis, there were 24 patients in each arm. The majority of the patients had pancreatic cancer and both groups were similar with regards to age, gender, diagnosis, metastasis, and length of stent used. All stents were 10FR in diameter.



Seven of the 24 patients in the standard stent group and 6 of the 24 in the Fusion Marathon group died with progression of their disease without any evidence of stent occlusion. In the remaining patients (Standard 17; Fusion Marathon 18), the median patency for the Fusion Marathon stent was 145 days (range 52 to 252 days) which was significantly longer than what was observed for the standard PBS (median 101, range 41 to 210; P = 0.002, Figure 3). This difference was also significant when analyzed using a Kaplan-Meier plot. In 6 of the 18 patients (33%)



in the Fusion Marathon group, the stent remained patent for longer than six months compared to only one patient (5.8%) in the standard PBS group. Both type of stents were successful in significantly (P <0.001) reducing bilirubin levels within 4 weeks after placement compared to pre-placement values and there was no significant difference between the ability of the two stents in decreasing bilirubin levels. The stent migrated in two patients in each group (Standard PBS: external 1, internal 1; Fusion Marathon: external 2; internal none). All the 3 patients in whom the stent migrated externally had short strictures (around 1-2 cm long ampullary tumors) but had 7-cm long stents placed (shortest length available at the time). Since neither the standard stent (Tannenbaum®) nor the Fusion Marathon stent have side-holes, these 3 patients presented with acute stent occlusion as the duodenal end of the stent impacted against the opposite duodenal wall on external migration. Hence proper stent length selection is important to avoid external migration. The distance between the flaps on the stent should be no longer than 1 cm more than the distance between the upper end of the stricture and the ampulla. One patient in each group developed mild pancreatitis managed conservatively. There was no stent related mortality in either group.

In summary, as the Fusion Marathon Anti-Reflux Biliary Stent remains patent for a longer time compared to a standard stent, it does suggest that duodeno-biliary reflux may be contributing towards stent occlusion. The Fusion Marathon stent is as effective as a standard stent in reducing bilirubin levels suggesting that addition of a valve to the stent does not interfere with the primary function of the stent, namely forward flow of bile. As the complication rates are similar between the two type of stents, the anti-reflux valve appears to be safe. However, it is important to select the proper length of the stent to avoid external migration and impaction as explained above. The stent is now available in several lengths for proper selection of length.

Cook in the News....

"The FDA has granted 510(k) clearance for Cook Medical's Evolution Controlled Release Esophageal Stent System, a precision delivery device that deploys and recaptures the stent, possibly reducing the need for repeat procedures by placing the stent correctly the first time" – **Gastroenterology & Endoscopy News, July 2008**

"…Cook Medical has introduced the Evolution Controlled Release Esophageal Stent System, which was designed in collaboration with U.S. and European doctors…" – **DeviceLink.com, June 9, 2008**

"'This product is going to make a real difference; we think it's going to shake up the market… as a disruptive technology,'" – **Barry Slowey for Cook Medical, Medical Device Daily, June 10, 2008**

"'…easy to deploy…holds great promise…should have a significant impact in my practices..,'" – **Dr Willis Parsons on the Evolution Esophageal Stent System, Medical Device Daily, June 10, 2008**

"Evolution, including the stent and delivery system, is a major step forward in esophageal stenting, offering a new, improved alternative to the traditional push-pull deployment system" – **Dr Todd Baron on the Evolution Esophageal Stent System, EndoNurse.com, June 13, 2008**

"This new minimally invasive device from Cook Medical, called Evolution® Controlled Release Esophageal Stent System…should make care more compassionate, while improving the quality of life of patients" – **MedGadget.com, June 13, 2008**

"Battle-ready Cook is pricing Evolution at or below the competition to establish "cost-value leadership." - **The Gray Sheet, August 4, 2008**

NEWS FROM SIGNEA
Society of International Gastroenterological Nurses and Endoscopy Associates

Endoscopic Management of a Foreign Body in a Patient

with Hiatal Hernia and Gastroesophageal Reflux Disease

Oleg Poniatoff, MD, Andrew Zaynullin, MD, Sahatov Batyr PhD, Grehov Alex, MD, Ashgabat, Turkmenistan

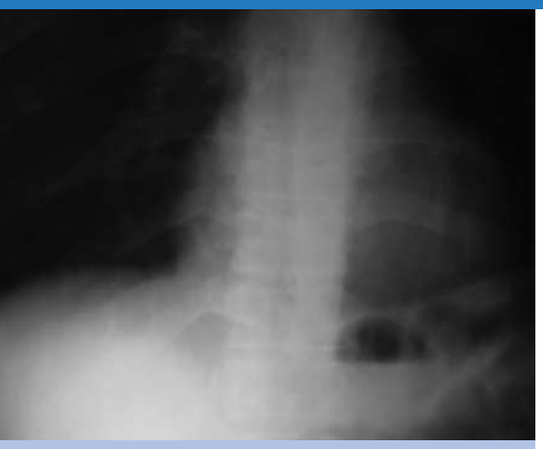


Fig 1 X-Ray overview in a patient with a foreign body.

Upper Endoscopy (UE) is considered the standard management for a "foreign body" (FB) in the gastrointestinal (GI) tract but few data describe its involvement in gastroesophageal reflux disease (GERD) and hiatal hernia (HH). GERD remains an interesting but incompletely understood entity in relation to the appearance of foreign bodies in the upper GI tract.

The current understanding of GERD include typical symptoms (heartburn, regurgitation, dysphasia) and atypical symptoms (i.e. globus sensation, FB feeling). The development of endoscopic and radiologic instruments and technology allows physicians to investigate GERD and HH more attentively. Specifically with regard to components of HH, important actions and interpretations are governed by conscious values. The combination of this research has significantly increased the possibility of investigating the risk factors for HH in the clinical setting as well as diagnostic GERD in patients with suspected FB, and thereby has modified the diagnostic and therapeutic approaches.

We present a case of a FB in the upper GI tract occurring in a patient with GERD and HH after endoscopy examination and the successful extraction by endoscopic forceps.

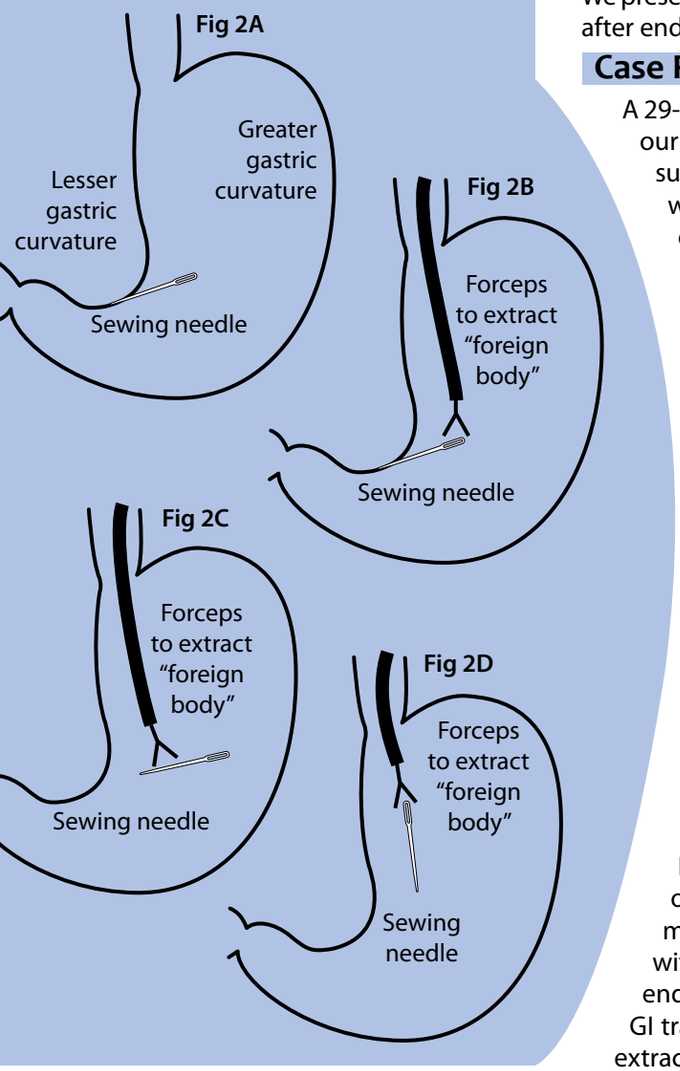
Case Report

A 29-year-old Turkmenistan man with a history of FB in the GI tract presented in our department for an emergency UE. He underwent an X-ray examination for a suspicion of FB in the GI tract because of an FB feeling in esophagus associated with epigastralgia. A chest and abdominal X-ray film showed swelling of the descending colon loops, particularly in the area of the splenic flexure. The X-ray overview has not shown the FB *(Fig 1)*.

During the upper endoscopy examination, the esophagus, stomach and duodenum were inspected. The patient tolerated topical oropharyngeal anesthesia well and is safe for office-based endoscopy. With this technique, the diagnosis of FB was confirmed. During the endoscopy a sewing needle was located in the area of the lesser gastric curvature projection at the depth of the antrum. The gastric lumen was flushed endoscopically with water to determine the eye of the needle, the only visible part that was 1cm long *(Fig 2A)*.

Presence of HH, inflammation of the tubular esophagus and traumatic alteration of the esophageal mucosa was observed. Reflux intensity included: mucosal edema, endoscopically visible erosive mucosa in the distal esophagus of 3 cm in length. Inflammation of esophageal mucosa was assessed according to the Los Angeles Classification indicative for GERD. The dotted erosion in the lower third of the esophagus was evidence of the traumatic damage caused by the FB. The HH was classified as large because its size was determined endoscopically as more than 4 cm and the protrusion into the esophagus was observed.

FB removal was done in 3 stages, beginning with fixing the visible part of the sewing needle *(Fig 2B)*. Evidence–based appraisal of endoscopic management for types of FB and their location provided the decision to withdraw the visible part of FB directly from the gastric wall by using flexible endoscopic forceps *(Fig 2C)*. To avoid traumatic damage or perforation in the GI tract, the FB was turned 45 degrees into the gastric cavity and successfully extracted through the esophageal cavity and mouth *(Fig 2D)*.



A follow-up UE obtained 3 days later confirmed the diagnosis of GERD. There was no evidence for the prior traumatic alteration which was previously caused by the FB. The small HH was seen endoscopically only in a retroflexed view.

The postoperative period was favorable and the patient was released from the hospital on day 3 without any complications.

Discussion

The FB database provides a unique opportunity to study the characteristics of patients with esophageal abnormalities and the practice patterns used in the management of these common endoscopic findings.

Despite endoscopic and surgical advances, a FB in the GI tract continues to be a clinically significant problem. Management of patients with a FB begins with a careful history to assess for alarming upper GI symptoms.

The incidence of esophageal FB is rising in Turkmenistan with the cultivation of the carpet weaving industry (when sewing needles are held in the mouth) and the careless eating of sturgeon (ingesting fish bones). Thus, ingestion of a FB is a common clinical problem in this region. These findings were consistent with GERD, HH and FB alterations in the GI tract. In this case pathologic findings were observed endoscopically before and after removal of the FB. These findings raise questions about HH and its size, which was observed in the initial UE and the endoscopy three days later. We suggest that the esophagus responds not only to intraluminal stimuli such as inflammation of esophageal mucosa, but also FB in the GI tract and the non HH region, all of which induce esophageal contraction. FB can be applied to distribution of HH risk factors. This case study shows that esophageal motility disorder may be the cause of GI foreign body impaction.

Disclosure

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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Beth Israel team honored to be first in the U.S. to place **Evolution** esophageal stent

On May 30, 2008, Beth Israel Medical Center, located in New York City, became the first hospital in the country to place the new Evolution esophageal stent. Dr. David Robbins, Director of Endoscopic Ultrasound, was proud that he and his team had the honor of being the first to place the Evolution stent. Dr. Robbins' patient, a 70-year-old man, previously had a competitor's self-expanding metal esophageal stent* placed.

Due to in-growth, the patient was in need of an esophageal stent that was covered and would not migrate. Cook's Evolution esophageal stent aided in the patient's comfort and eliminated the issues he had with the previous stent.

The team is looking forward to placing more Evolution esophageal stents. Dr. Robbins and his team were impressed with the ease and quickness of the procedure.

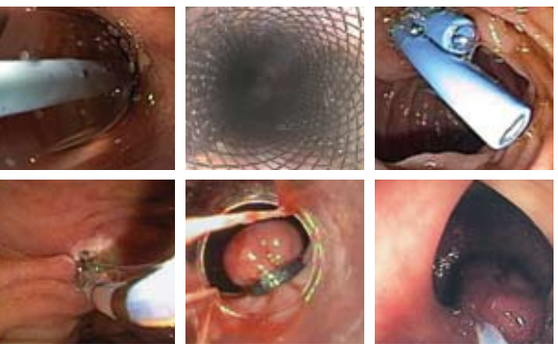
*"**The simplicity of the design**,"* said GI nurse Gillian Oleda, *"**made the procedure effortless**."*

Dr. Robbins added: *"**This stent is hot. It deploys like a Formula One race car**."*

*Ultraflex

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 educational activities:

Malignant Biliary Disease

Biliary Stone Management

Primary Sclerosing Cholangitis

These activities are presented without charge by your Cook Medical Representative, and each offers one contact hour. Educational activity descriptions, objectives, and the related accreditation information can be found at http://www.cookendoscopy.com/education/pages/edprograms.html

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

HealthStream® COOK® MEDICAL

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

UPCOMING EVENTS

10th International Workshop on Therapeutic Endoscopy	*Ciaro, Egypt*	***Nov 29 - Dec. 1***
UCI ERCP Hands-On Nurses Workshop	*Orange, CA*	***Dec. 8-9***
23rd International Workshop on Therapeutic Endoscopy	*Hong Kong, China*	***Dec. 9-12***
Amsterdam Live Endoscopy 08	*Netherlands*	***Dec. 15-16***
NYSGE	*New York, NY*	***Dec. 17-20***
		2009
Pancreatic & Biliary Endoscopy - Simon Lo	*Los Angeles, CA*	***Jan. 23-25***
XII International Course in Gastroenterology & Digestive Endoscopy	*Bogota, Columbia*	***Jan. 29-31***
11th International Symposium: Diagnostic & Therapeutic Endoscopy	*Düsseldorf, Germany*	***Feb. 6-7***
Rocky Mountain Interventional Endoscopy	*Denver, CO*	***Feb. 12-13***
Belgian Week of Gastroenterology	*Antwerp, Belgium*	***Feb. 12-14***
GI Nurses Interventional Course	*Las Vegas, NV*	***Feb. 20-22***
XXII Central American Gastroenterology & Endoscopy Congress	*Managua, Nicaragua*	***Mar. 18-21***
British Society of Gastroenterology	*Glasgow, Scotland*	***Mar. 23-26***

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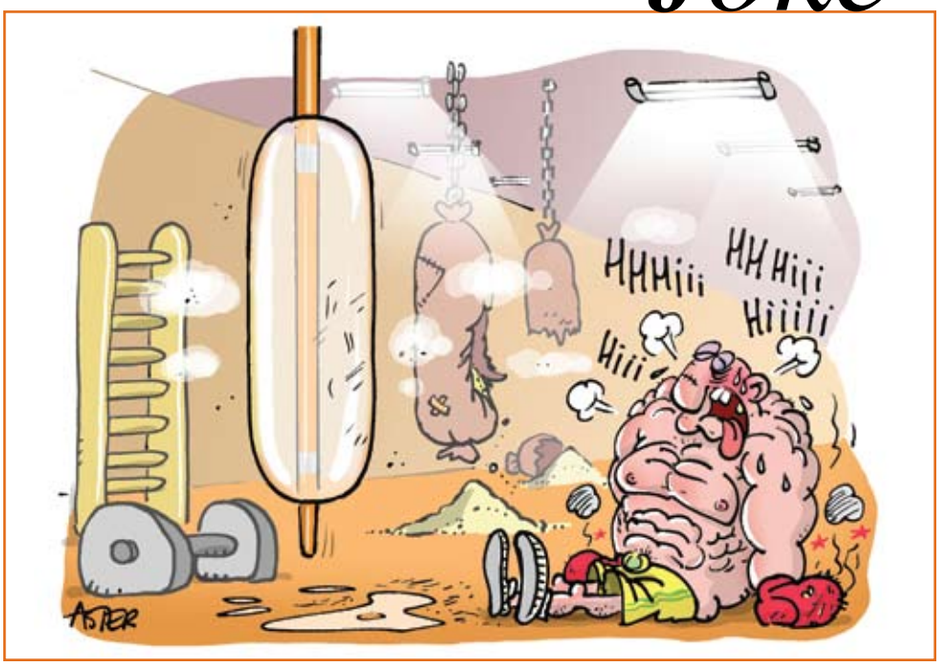
INSIDE *Joke*



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