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The Channel

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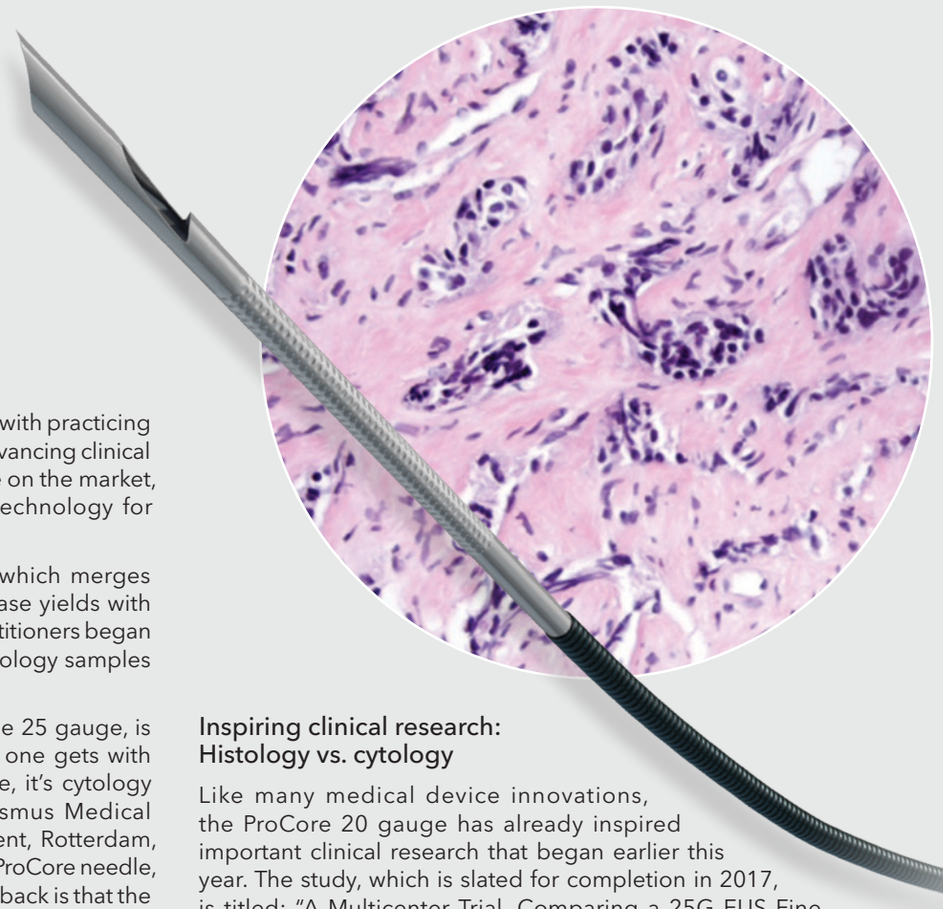
A new 20 gauge EUS needle balances flexibility and sample size



Cook Medical has led the EUS field by collaborating with practicing endosonographers who require devices with ever-advancing clinical capabilities. It began with the first contoured handle on the market, followed by patented, high-definition dimpling technology for enhanced needle visualization.

Recently, Cook pioneered the EchoTip ProCore, which merges histology and cytology, allowing clinicians to increase yields with potentially fewer needle passes. Soon, however, practitioners began requesting EUS needles that can obtain quality histology samples without sacrificing needle flexibility.

"On the one hand, the FNA needles, in particular the 25 gauge, is very easy to handle but the amount of tissue that one gets with that needle is relatively limited and also, of course, it's cytology material," said Prof. Marco Bruno, MD, PhD, Erasmus Medical Center, Gastroenterology & Hepatology Department, Rotterdam, Netherlands. "Whereas, with the recently introduced ProCore needle, you're able to get histological materials but the drawback is that the larger size needles are difficult to handle and a little bit stiff."

The desire by practitioners for increased needle flexibility without diminished sampling capacity led Cook's engineers and researchers to create the new 20 gauge EchoTip ProCore. This needle—soon widely available—gives endosonographers a new tool with the flexibility to accurately target small lesions while increasing valuable histological yields.

"The Cook 20 gauge EchoTip ProCore offers improved flexibility for those more difficult EUS-FNA biopsy approaches, with easy to-and-fro passage of the needle, along with a larger 20 gauge needle to yield histologic grade tissue for both diagnosis and ancillary studies," said James Farrell, MD, Interventional Endoscopy and Pancreatic Diseases Section of Digestive Diseases, Yale University School of Medicine.

According to Prof. Marc Giovannini, MD, PhD, Endoscopic Unit, Paoli-Calmettes Institute Marseilles, France: "Cytology is not enough in the diagnosis and treatment of all lesions. You need sufficient quality of material to correctly characterize tumors and conditions. The [20 gauge] EchoTip ProCore needle is a good compromise between the ease of use of a small needle and the quality of sample you can achieve with a bigger needle."

Inspiring clinical research: Histology vs. cytology

Like many medical device innovations, the ProCore 20 gauge has already inspired important clinical research that began earlier this year. The study, which is slated for completion in 2017, is titled: "A Multicenter Trial, Comparing a 25G EUS Fine Needle Aspiration (FNA) Device With a 20G EUS ProCore Fine Needle Biopsy (FNB) Device (ASPRO)." The study includes global participation by pathologists and will examine the histology-versus-cytology question.

"There has long been a lack of consensus amongst global pathologists as to when cytology is adequate and when histology information is also needed," Prof. Bruno said. "Theoretically, one would assume pathologists would prefer histological materials, not only because it's better to handle, more easy for them, but also because they're used to handling histological materials, particularly in peripheral clinics. In academics perhaps, pathologists are used to handling cytology material. But, in particular, in the community hospitals, pathologists are used to histological material. I think what's very interesting about this particular study is that we're going to compare the specimens we get from FNA and from FNB then blind the pathologists so that they truly are interpreting only the specimen sample that they see before them. We hope to finally get to an answer to the question: "Is it more preferable to get histology or is cytology enough?" ■

For more information about the 20 gauge EchoTip ProCore and its availability, please contact your local sales representative.

Clinical image courtesy of Priscilla van Riet, MD, Erasmus MC University Medical Center, Rotterdam, The Netherlands

In This Issue

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If you would like to submit material for *The Channel*, please email us at **thechannel@cookmedical.com.**

We welcome your comments and suggestions.

First experience with the new 20 Gauge EchoTip ProCore® FNB needle:

Diagnosis and staging of a pancreatic neuroendocrine tumor

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Background

Pancreatic neuroendocrine tumors (p-NET) comprise an intriguing disease entity posing clinicians with some interesting differential diagnostic challenges. Currently available imaging techniques can identify p-NETs in most cases, but histological confirmation is required to select the best management strategy. EUS-guided tissue sampling is the procedure of choice for preoperative tissue collection in p-NETs. To obtain a reliable diagnosis, pathologists require a tissue sample of sufficient size and quality that allows for the full range of diagnostic tests. Importantly, sample adequacy is influenced by several factors, including the type of device and sampling technique used.

Figure 1

Abdominal CT scan with contrast enhancement, showing a hypervascular, nodular lesion near the head of the pancreas (arrows).

Recently, a new EUS sampling device has been launched: the 20 gauge EchoTip ProCore FNB needle. This EUS needle is designed to combine the best features of currently available sampling tools; a large core size for optimal histological tissue acquisition, yet easy to be handled in anatomically challenging locations because it has a flexibility that approximates that of a 25 gauge needle. We share our first experience with the new ProCore FNB device in diagnosing and staging a pancreatic neuroendocrine tumor.

Case

A 73-year-old patient was referred to our outpatient department with complaints of weight loss (13 kg in 2 years), flushes and intermittent epigastric pain. Her medical history reported hypertension and de novo diabetes since 2014. Previously, the patient had undergone an abdominal CT scan, which showed a hypodense, nodular lesion in or near the head of the pancreas (*Figure 1*). Because of the suspicion of either a neuroendocrine tumor or enlarged peripancreatic lymph nodes, the patient was scheduled for EUS-guided tissue sampling under conscious sedation in an outpatient setting. On EUS, a hypoechogenic, hypervascular, contrast-enhancing lesion (9 x 12 mm) was observed, located in the head of

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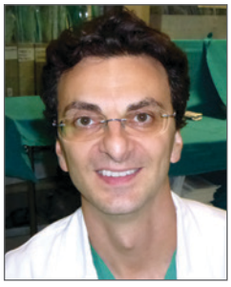
EUS-guided fine needle biopsy (EUS-FNB) with 25 gauge EchoTip ProCore® needle of a subepithelial lesion in the distal duodenum



Filippo Antonini, MD *Giampiero Macarri, MD*

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A 79-year-old patient underwent computed tomography scan for surveillance of colon cancer and discovered an incidental 2 cm mass located in the distal duodenum. An upper gastrointestinal endoscopy revealed a bilobated subepithelial lesion (SEL) in the distal part of a winding duodenum. An endoscopic ultrasound (EUS) revealed a homogenous hypoechoic well-circumscribed tumor, originating from muscle layer (*Figure 1a*).

Two separate attempts of tissue sampling on EUS-guided fine needle aspiration (FNA), using first a 22 gauge and subsequently a 25 gauge traditional needle, were inconclusive, for several reasons: first, the location and the technical complexity reaching the lesion; second, we encountered several difficulties in penetrating the lesion because the scope, extremely angulated, became stiffer, limiting angulation. Indeed, we decided to use a 25 gauge EchoTip ProCore needle (Cook Medical) for tissue sampling.

This needle considerably reduced the previously mentioned difficulties in penetrating the lesion (*Figure 1b*) and, more importantly, allowed us to obtain a good tissue sampling. Histological examination showed a group of spindled-shaped cells (*Figure 2a*). The immunohistochemistry was positive for CD117 and CD34 (*Figure 2b*) while negative for desmin, smooth muscle actin and S-100 expression. A diagnosis of gastrointestinal stromal tumor (GIST) was done and the patient underwent surgical resection.

Transduodenal EUS-FNA is technically challenging due to the angulated position that may be an obstacle to the advancement of the needle through the scope and in the targeted lesion. Moreover, to avoid instrument damage, frequently the scope had to be withdrawn into the stomach so the tip could be straightened. For these reasons, when the echoendoscope is located in the duodenum, FNA is usually performed using either 22 or 25 gauge needles while use of the 19 gauge is rare.

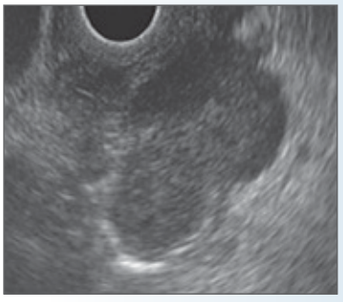

Figure 1a

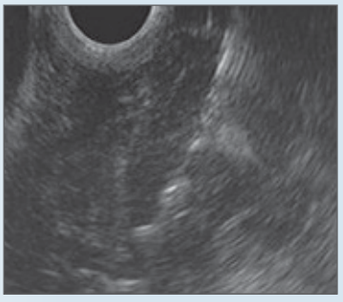

Figure 1b

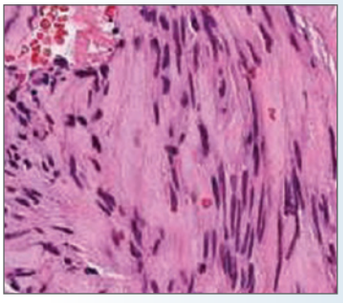

Figure 2a

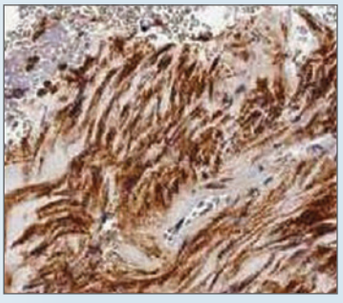

Figure 2b

For the diagnosis of SEL, usually adequate cytological sampling is needed, especially when immunehistochemical analysis is required. In these conditions, larger needles (19 or 22 gauge) should be preferred.

EchoTip ProCore needles have been conceived to obtain more tissue and ideally to provide histological specimens (core biopsies).

In our case, we were able to obtain histological diagnosis of a GIST located in the third part of a winding duodenum by using the smallest EchoTip ProCore needle available. This needle can be taken into consideration when larger needles fail to provide adequate tissue sampling of SEL located in the distal duodenum. ■

The positive collaborative experience of Wessex EUS Group regarding EUS in pancreatic cancer

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Pancreatic cancer is the tenth most common cancer in the UK[1]. Adenocarcinoma of the pancreas has a mean survival time of 11-12 months following surgical resection[2], but stage 3 (locally unresectable disease) has a survival of 6-11 months[3]. A pancreatic mass may also be a neuroendocrine tumour, or indeed a manifestation of a benign disease process such as autoimmune pancreatitis, both with different treatment modalities and better prognosis. Thus histological confirmation of any mass is now essential before treatment can be commenced.

Endoscopic ultrasound enables high-resolution imaging of the pancreas, bile duct and periampullary area and has been deemed the gold standard for both viewing and obtaining histology[4], where EUS is seen to give a higher diagnostic accuracy to CT-guided biopsy. Not only may histology be gained but also further information on nodal disease and invasion of vascular structures to optimise staging.

Key to success in pancreatic FNA is a high-sensitivity rate. Prior to 2012 there were two EUS centres in Wessex: Winchester for the Portsmouth, Southampton, Isle of Wight and Channel Islands network; and Bournemouth for Pool, Bournemouth and Salisbury. The central pancreatic centre and regional MDT is in Southampton. From 2012 both Portsmouth and Southampton became EUS centres and thus the Wessex EUS group was started in 2012 with a view to optimising EUS practice across the region using regional audit and standards and continuing collaborative working. The group has met three times a year to discuss techniques and audit results.

In 2013 the sensitivity for FNA in Winchester was 84%. This was in keeping with a UK Meta-analysis of 33 studies examining solid lesion EUS FNA tissue acquisition in 4,984 patients which showed a pooled sensitivity of 85%, increasing to 91% if suspicious atypia was included[5].

Following agreed standards and practices the sensitivity for pancreatic FNA increased to 96%[6]. The presence of rapid on-site evaluation with a technician in the room to prepare samples and a cytologist to give contemporaneous feedback of the sample obtained and a preliminary diagnosis has further increased sensitivity to 99%. This has generated a confidence in our practice and furthermore facilitates the patient pathway with both staging and diagnosis provided at the time of visit.

Dr. Harriet Gordon, pathologist Dr. Bryan Green and nurse Jun Wang.

High sensitivities have been demonstrated in large volume single operator centres where sensitivities of 92-97% have been reported[7,8]. The four Wessex EUS centres all work from a regional HPB MDT in Southampton, where pancreatic cases are discussed and EUS procedures requested. Each centre has two EUS operators, performing between 148 and 214 cases per annum. Our regional working demonstrates that smaller volume centres working within a regional network can achieve similar standards to high volume centres.

Finally the regional audit in 2013-14 histology results have shown that in those pancreatic lesions where unresectable malignancy was shown radiologically, while adenocarcinoma was confirmed in 67%, but there also confirmed neuroendocrine tumour in 20%, mucinous cystic tumour in 9%, and squamous cell carcinoma and spindle cell tumours were also seen.

Endoscopic ultrasound of the pancreas, with a view to FNA, is now the commonest indication for EUS in our practice. It seems likely that this will continue given that the information generated has improved to satisfactory standards.

Conflict of interest: *Cook Medical has kindly sponsored our Regional Networking Meetings since 2013.* ■

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Celebrating an endoscopy champion

Professor Norman Marcon named Officer of the Order of Canada

Prominent Toronto gastroenterologist Professor Norman Marcon, Director of Therapeutic Endoscopy at St. Michael's Hospital, was recently named an Officer of the Order of Canada, one of that nation's highest civilian honors. The Order of Canada, established in 1967, acknowledges outstanding achievement, dedication to the community and service to the country. In bestowing the honor, the Order recognized Prof. Marcon "for his contributions to the treatment of gastrointestinal diseases and for his work to disseminate the latest advances in therapeutic endoscopy."

Cook Medical is especially proud to congratulate Prof. Marcon on this prestigious accomplishment. In the early 1980s, Prof. Marcon worked closely with Cook's Endoscopy division co-founder Don Wilson to adapt radiological devices for endoscopic use, changing the field of gastroenterology forever.

The Channel recently asked three of Prof. Marcon's colleagues to reflect on his stellar career and lasting contributions to the field of medicine he loves.

Medal photo courtesy of Rideau Hall. ©Her Majesty The Queen in Right of Canada represented by the OSGG, 1992. Reproduced with permission of the OSGG, 2015.

Recognizing what we all already know

By Gary May, Gabor Kandel and Paul Kortan

No Division can be so fortunate as to have Norm Marcon as its leader.

At the Wellesley Hospital over three decades ago, two subspecialties were vying for recognition: respirology, which had developed an expertise in diaphragmatic pacing; and gastroenterology, which, under Norm Marcon, was focused on upper GI bleeding.

Invariably, patients with both problems were ill, requiring hospitalization, so whenever a consult was requested for either problem, the first step was to find a hospital bed for the ailing patient. However, there were never any beds to be had. The respirologists followed the rules, and waited for a bed to empty, generally a futile quest. But Norm ignored the setback: "Send the patient down," he would say. "Aren't we all lucky to be needed!"

Respirology was lauded by the hospital, their residents slept soundly, order reigned. Gastroenterology was shunned, their trainees up all night, entropy everywhere. But now—a generation later—Norm is renowned for his endoscopic management of upper GI tract bleeding, while diaphragmatic pacing is done elsewhere, if at all.

Norm succeeded for several reasons: realizing that moving ahead meant skirting around rules instead of following them, by uncanny instincts steering him to recognize without any doubt that the future lay in endoscopy and by innate leadership skills that stimulated others to follow him even when the road was hard.

And the road was difficult at the start. When Norm began his career, gastroenterology was an offshoot of internal medicine, a cerebral discipline focused on pathophysiology, its zenith capped by achievements such as understanding the metabolism of vitamin B-12. Diagnosis was mostly within the realm of radiology, and effective treatment was provided almost exclusively by surgeons, leaving to gastroenterologists the more mundane tasks of discussion, explanation and support. Gastroenterologists were "talk docs."

Norm was the first clinician in Canada to realize that the future lay elsewhere, namely in endoscopy. That passion began when he saw his first endoscope, a colonoscope prototype literally carried by Tetsuichiro Muto from Japan to St. Marks Hospital in London, England, where both Muto and Norm were fellows.

From that time on, with faultless decision-making, his professional eyes focused on one prize only: advancing the endoscopic management of bowel diseases. Nothing else mattered, virtually all other issues were a second priority.

He began by converting a Victorian-style, single-patient room at the Wellesley Hospital to a makeshift endoscopy suite, taking his place at the cutting edge of every advance in endoscopy since, culminating in his present expertise in endoscopic mucosal resection.

Along the way, he pioneered mucosal angiodysplasia, treating it with injection and banding; appreciating the potential of electrocoagulation to stop gut bleeding; and exploiting endoscopic technology to treat malignancies. He early on recognized the need for accessories.

Norman Marcon and Don Wilson

According to legend, it was he who convinced Don Wilson, one of the co-founders of what is now Cook Medical's Endoscopy division, to adapt the tools then being made for radiology to endoscopic use. Vacations consisted of visiting the masters in Europe to learn their skills.

Norm has never wavered in pursuing his vision, championing endoscopy in every available forum. At first, no one else saw the light. Hospitals found endoscopy too costly, colleagues saw it as too risky, patients were too frightened, surgeons threatened.

But with hundreds of talks, forum chairs, demonstrations, book chapters and articles, he inexorably convinced a reluctant world. His own research interest eventually focused on new methods of endoscopic visualization, especially auto-fluorescence and optical coherence tomography. Together with Brian Wilson, he made seminal contributions in this area.

Norm handpicked his Division. At the Wellesley Hospital, each Division member was first vetted as a resident in medicine, encouraged to train in the Toronto Gastroenterology Program, sent

The Therapeutic Endoscopy Group at St. Michael's Hospital: Gary May, Gabe Kandel, Norman Marcon and Paul Kortan

to study abroad, then eventually welcomed back as an equal. After three tries, however, he realized that his successor had to be found elsewhere. After scouring the world, he realized the future lay with Calgary's star, Gary May.

To accomplish all of this, Norm incessantly and single-handedly hounded administrators for the necessary resources, took all the risks, purchased every required instrument, found the patients—then generously shared credit equally with all of us. He prided himself on being part of a team. However the truth is that he did it all himself, even though he invariably claimed it was a group effort. There is no "I" in his "we" world.

All of this would be a feat worthy of an exemplary full-time academician. But Norm never lost sight of his patients. He has always been a full-time clinician, prioritizing clinical care in his day-to-day activities. He sees his in-patients daily, including weekends, phones them at home regularly after intensive endoscopic procedures to make sure they are well and is always on call for them. No wonder they have responded by funding both his research and fellowship programs.

Most of us strive to leave behind things better than before we arrived. Wherever Norm went, in everything he did, he built, developed, expanded and made things not just better but much better. Before Norm, the Wellesley Hospital had no academic gastroenterology; by the time it closed, endoscopy was its forte.

Before Norm, the St. Michael's endoscopy unit was an adjunct to its leadership in inflammatory bowel disease; since his arrival, the focus has switched to endoscopy, and St. Michael's is now recognized as one of the best units in North America. Before Norm, there was limited therapeutic endoscopy in Canada; now it is in the forefront. None of this would have happened without Norm. If evidence is ever needed to demonstrate that an individual makes a difference, Norm Marcon's career would be the ultimate proof. ■

Generations:

Continuing the legacy of the interventional ERCP pioneers

Horst Neuhaus

By Peter Cotton

We hope that you have enjoyed Volumes 1 and 2 of the project celebrating the Pioneers of Interventional ERCP as much as I have in helping to produce them. We asked those we featured to suggest some names of those they mentored in the early days to give us a broader perspective of the pioneers and the developments they fostered. Future editions of The Channel *will feature one of those special early "trainees" who have now become prominent in the field. Our Generations series starts with Horst Neuhaus, one of the many current leaders who were nurtured in the iconic Demling/Classen stable at Erlangen in Germany.*

Peter Cotton: We have interviewed Meinhard Classen for this project, obviously one of the foremost pioneers for Western countries. I was personally very motivated and stimulated by him in the early days. He suggested I should contact you to get some inside stories about some of the earlier days with him. How did you get started and when did you did first come across Meinhard?

Horst Neuhaus: I started medicine in Bonn and spent then one year of residency in surgery and then I changed my mind and decided on internal medicine. About 1983 I attended a meeting in Wiesbaden, which is still an annual event, which was organized by Meinhard—Endoscopy for the Internists. I was so much impressed at that time by the new inventions in endoscopy imaging and options for minimally invasive procedures, sphincterotomy and so on, that I decided to specialize in gastroenterology.

At that time Classen was of course the superstar and I was too shy to ask him directly if it would be possible to work in his unit, and by chance, I got a position in Ingolstadt, which is a city about fifty miles north of Munich. There was also another colleague of Meinhard's who was also from the famous unit in Erlangen, Professor Paul. He was the Chief of Gastroenterology and I was trained therefore in Ingolstadt. This was a large referral center and we did a study on ERCP and acute pancreatitis, which was still under discussion at the time. Then Classen became aware of my activities in Ingolstadt and he invited me to give a lecture in Munich. This was in 1987 and then

Horst with Fritz Hagenmuller

he asked me about my interests and he gave me the opportunity to join his team at the famous Department of Gastroenterology of the Technical University in Munich.

I became a member of the endoscopy team under the leadership of Meinhard and Fritz Hagenmueller. Both of them have become close friends of mine. Fritz left in 1990 and became chief in Hamburg. At that time, I became the chief of the endoscopy unit.

Fritz Hagenmuller

Cotton: How long did you stay in Munich?

Neuhaus: In 1995 I got the opportunity to become head of a department of internal medicine with special focus on gastroenterology in Dusseldorf. We established also a large tertiary referral center and became a Center of Excellence of the WEO. We have established the annual Dusseldorf International Endoscopy Symposium in February, which has expanded to attendance of 1,800 participants from over 40 different countries.

Cotton: I'd like to take you back to the earliest days. How did you first perform ERCP and why and where and who with?

Neuhaus: I did my first ERCP in Ingolstadt in 1985. I learned it from Professor Paul, of course, with a fiberscope with a teaching attachment and a dearth of appropriate guide wires. You know it well. It was much more difficult.

Cotton: Yes. It's too easy now I think, don't you?

Neuhaus: No, it's not too easy. It can still be very difficult, and everybody is interested to see cannulation of the papilla and that even experts may struggle.

Cotton: That's true.

Neuhaus: In cannulating the papilla, what was nice at that time was that the nurses couldn't watch us, so when you started with ERCP, you could tell them, "Well, the papilla is hidden behind the fold or a diverticulum." Nobody could check on you. Now they immediately notice if you are a good endoscopist or not.

Cotton: That's a good point. I'd like to take you onto another subject. I know that you became good friends with Don Wilson and with his wife Minda.

Horst with Don Wilson

17th Düsseldorf International Endoscopy Symposium, February 2015

Neuhaus: Of course, Don and Minda were also good friends of Meinhard and they came several times to Munich to visit him. I met both of them for the first time in the early nineties. Meinhard gave all of us always great opportunities. I organized and became secretary of the first biliary endoscopy symposium, which was a big challenge for me. At that time, Don and Minda came and we had a lot of good discussions. It was a very personal relationship and then they supported me very much in several respects. For example, they helped me to make contact to other colleagues and also, in particular, to Jean Brihay, who you know was the representative for Cook in Europe.

He invited me to attend workshops and to meet other colleagues. They were extremely helpful for this kind of networking so also to meet colleagues on a very personal level. When I moved to Dusseldorf, this was, of course, not easy here because at that time the center was not really known. Don and Minda visited me and gave me a lot of advice, and they supported me very much to establish our first international symposium. Really they pushed me and gave me the confidence to proceed.

It was not only the financial support but also the psychological background because they were very confident that our meeting would become successful. We became very good friends and Minda comes every year to our meetings. She is also a good friend of my wife, Silvia.

Cotton: We all owe Wilson-Cook, as it was called then, a great deal for their support in those earlier days. I didn't realize you trained a little bit in surgery. Did that help you in becoming a therapeutic endoscopist, or not relevant?

Neuhaus: It helps. I could even do a cholecystectomy in my first year, and I learned the attitude of surgeons and, of course, I learnt a lot about the anatomy. I did laparoscopies and, therefore, I realized that endoscopy is a wonderful mix between manual interventions and the full background of gastroenterology. I think even in these days, I still benefit because in terms of NOTES and more advanced procedures, I think the collaboration with surgeons becomes easier.

Cotton: As you know, I've been advocating that we should get rid of the distinction between internists and surgeons and develop a new training program for "digestivists." Do you think that will ever happen?

Neuhaus: I think it varies from country to country. In Germany surgeons also are becoming more and more interested in advanced endoscopy. They want to do POEM and other more advanced procedures. I'm skeptical if a new specialty can be established because the societies are so different, but nevertheless, they come closer as seen in our meetings. As you know, at the DDW, at the UEG week and at our German meeting, we always have surgeons involved in interdisciplinary sessions and training courses.

Cotton: DDW really doesn't include any significant number of surgeons. In the USA we have all these separate societies, which I think is a pity. But I do understand the power of the various societies and specialty boards.

Neuhaus: You know that in treatment of early cancer in the GI tract, it just depends on less than a millimeter of invasion of cancer if the disease is treated by surgeons or by endoscopists. This really shows that we should work close together and be more disease oriented.

Cotton: I agree with that entirely. Has that happened in Germany, that there is more multidisciplinary collaboration within the academic and major centers?

Neuhaus: Yes, I think so. In these days, the surgeons accept all the advanced interventions, which are done by gastroenterologists and endoscopists. There is no longer a fight or hesitation as in these old days. As you well know, Demling together with Classen had to do the first sphincterotomy under enormous pressure of the surgeons who threatened them.

Cotton: I remember those days. I was interested that both you and Meinhard became department chairs of internal medicine. Why was that necessary? Did that not interfere with your plans to be a great gastroenterologist and endoscopist?

Neuhaus: Well, these are the old structures in some departments and centers in Germany. The tendency is, of course, that you really specialize in gastroenterology or even in endoscopy only, as we can see in the US. In my situation it works very well because I have great co-workers who take care for the other specialties in internal medicine so that I can really focus on gastroenterology, and I can perform endoscopy every day for several hours. The future is, of course, that it's getting more and more specialized.

Cotton: As you may know, I've been very interested in quality and safety in endoscopy and I have some concerns about endoscopy in the United States, where there is very little in the way of quality control. Anybody can do anything and there's certainly some rather poor quality ERCP. How is the quality control in Germany in terms of these advanced procedures?

Neuhaus: The training of gastroenterology is over a period of three years. We do not have the specialization of a year for advanced endoscopy that I would prefer for ERCP, EMR and the more complex techniques. That means that even the gastroenterologist who has done only one hundred ERCPs or a few EMRs or so, can do when he wants any kind of advanced procedures. There is not enough control. But what we see also, patients are more and more referred to larger centers because nobody wants to undergo the risk of complications, which is higher in small-volume centers in complex cases.

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Cotton: So are the patients more informed now in making these decisions?

Neuhaus: Yes. Patients are more informed. For instance, we see patients who are already on the list for major surgery, e.g. for a papillary adenoma, and then they look into the internet and look for a second opinion and options of endoscopic treatment. This really changes the field.

Cotton: Let's talk about the past again for a little bit. Do you have any regrets about what you have done or not done in this field? Things you've missed out on or are you happy with everything?

Neuhaus: Not nearly, Peter. I regret a little bit that I discontinued my training in EUS when I was together with Thomas Roesch. As you know, EUS was introduced in Europe in Munich and Thomas became my successor when I left Munich in 1995, and he focused very much on EUS. I discontinued after some time because I thought it's too much to do ERCP, regular endoscopy and all advanced procedures, including percutaneous biliary interventions. I thought it's better to focus on these areas and not also to try to become an expert in EUS.

Thomas Roesch

But in these days, I regret a little bit when I see interventional EUS. I'm still thinking to learn it. Not to do difficult diagnostic procedures, as in pancreatic lesions, but for therapeutic interventions. As a good ERCPist you miss it a little bit.

Cotton: Right. That's the way the trend is happening with the advanced training in the United States. More and more people are wanting to embrace EUS and ERCP and EMR. In the past you were either an ERCPist or an EUSist. Their coming together, I think, is crucially important. Looking forward now, unlike retirees like myself and Meinhard, are there things that you would love to do that you can tell us about?

Giants of European endoscopy: Jacques Deviere (Brussels), Guido Costamagna (Rome), Meinhard Classen (Germany) and Horst Neuhaus

At the Beach meeting in Charleston with Marion and Peter Cotton

Neuhaus: Well, I'm still very much interested in new technologies, and we will be involved also in evaluation of new techniques, and we are in contact with some start-up companies. We work close together with other European centers, in particular in Amsterdam, Brussels, Hamburg, Lyon and Rome. The leading colleagues from these units, several co-workers and myself, we are very good friends. It is wonderful to collaborate. Of course, there is some competition but in fact we never had any problems to discuss who is the first author of multicenter trial or first evaluator of a new technology.

We always find a way to collaborate in research. In addition, I am still very much interested also in education, so we have regularly trainees here. I think it's very satisfying to train and also to teach in our own unit or at other departments. I also enjoy to travel to meetings and to teach young colleagues and to motivate them as Meinhard did for me.

Cotton: Well, we're going to have to wrap this up, Horst. Don't know if there's anything else you want to add? We started this by reflecting on our tremendous indebtedness to Meinhard for his vision and mentorship over the years. I'm sure you feel the same way as I do.

Neuhaus: Absolutely. He has always been a great mentor. As you also well know, many well-known endoscopists had such a mentor in the beginning of their careers.

Cotton: Yes, it is essential in life, as well as in endoscopy. Horst, thank you so much for your time and interesting reflections.

Neuhaus: It was a great pleasure. ■

Disclosure: *Dr. Peter Cotton is a paid consultant on the Generations series.*

Horst and Silvia visit Cook in Winston-Salem

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Inclusion, not exclusivity:

An update on new global design standards from GEDSA

Tom Hancock
Executive Director
GEDSA

A new global design standard from the International Organization for Standardization (ISO) for medical tubing connectors is currently being applied to enteral feeding devices in the marketplace. In this issue of The Channel, *we speak with Tom Hancock, a founder and executive director of the Global Enteral Device Supplier Association (GEDSA) about how that organization is helping the medical device industry transition to the new global design standards for enteral feeding connectors.*

The Channel: What is GEDSA and can you describe the organization's origin and mission?

GEDSA is the Global Enteral Device Supplier Association and it was formed officially on October 1, 2013. Unofficially, the conversation in the enteral device industry began some years ago, revolving around connector concerns and standardization.

The discussion at the time was primarily about what do these connectors look like. How do they fit together? How are they going to be compatible for the connections they are supposed to make and not compatible with the devices they are not supposed to be? Once that became defined, the questions began to be raised as to how will we introduce these new connectors to the marketplace and we started to get into conversations around that concern.

The feeding system has at least four components that must fit together to be complete, a bag or bottle that carries the nutrition, an administration set that connects to the bag or bottle to deliver nutrition, a feeding tube for patient access and then a syringe for bolus feeding, hydration, medication or aspiration. So, there are four primary pieces, if you will, to the puzzle of a feeding system that all have to work together. Those four components can often come from four different manufacturers.

Now, imagine if you are going to create a new connector and it's supposed to be universal, all the manufacturers will have to make sure they connect at the same time. That's where the members of GEDSA came up with this notion of having a synchronized launch plan where the new connectors would be introduced by different manufacturers to help ensure compatibility, avoid any disruption of therapy and improve patient safety.

I was actually working for Abbott Nutrition at the time and I was just another guy representing one of the manufacturing companies. We were kind of unofficially acting like a trade association. Then, as we got a little bit closer sometime early to mid-year, I approached the group and said "it appears there is an opportunity for a joint communication effort, aligning on common introduction timing and having someone lead that effort." And that's what ultimately turned into the GEDSA.

The Channel: What is your role with GEDSA and can you tell us about the organizational structure?

I am the executive director and a founder of the organization.

GEDSA is a federally tax exempt 501(c)(6) non-profit trade association. To be considered an official non-profit, you are required to have a board of directors and in so doing we also created a set of officer positions. So we have a chair, a vice chair, a treasurer and a secretary. Those are all elected positions, and then the board itself is made up of appointed positions.

When we set out to do this, we have always been about inclusion and not exclusivity. We did this because we are focused on a patient safety initiative that we all benefit from and the more companies that align to these standards, the safer the system will be. Therefore, we did not want to exclude any company from participating and help address this misconnection concern. To encourage full participation from the industry we needed a way to attract companies both large and small so it became apparent that we needed two levels.

We further delineated the membership between two categories: There are charter members and there are associate members. The two primary distinct differences are that charter members get a seat on the board for helping guide and lead the organization as a whole, as well as a primary position on all communication efforts. The associate-level members have a secondary position and no seat on the board.

The Channel: Can you explain the benefits supplied by GEDSA and also comment on collaboration with other interested organizations?

Some of the formal benefits are that we do have joint communication efforts because with these connector changes that are coming there's a lot to communicate. As you can imagine with a feeding system changing because of the connectors, you have to inform lots of personnel within the hospital. You have a doctor, a nurse, a pharmacist, supply chain personnel, risk managers, safety officers, administration, and the list goes on with who you would need to inform.

In a sense, we are helping to ensure that we have a single message, and we are doing a lot of work to help get that message out. We are doing that through the stayconnected2015.org website, brochures, press releases, articles, FAQs, webinars and live speaking engagements and conferences. I work with the Food and Drug Administration, the Association for the Advancement of Medical Instrumentation, the Joint Commission, the American Society for Parenteral and Enteral Nutrition and other key opinion leaders. We are all working collaboratively to develop a consistent message and raise awareness of the impending change.

There is a complete list of GEDSA members, supporting organizations and partner associations on the Stay Connected website, including A.S.P.E.N., ISMP, the Oley Foundation, NPSF and AHRMM.

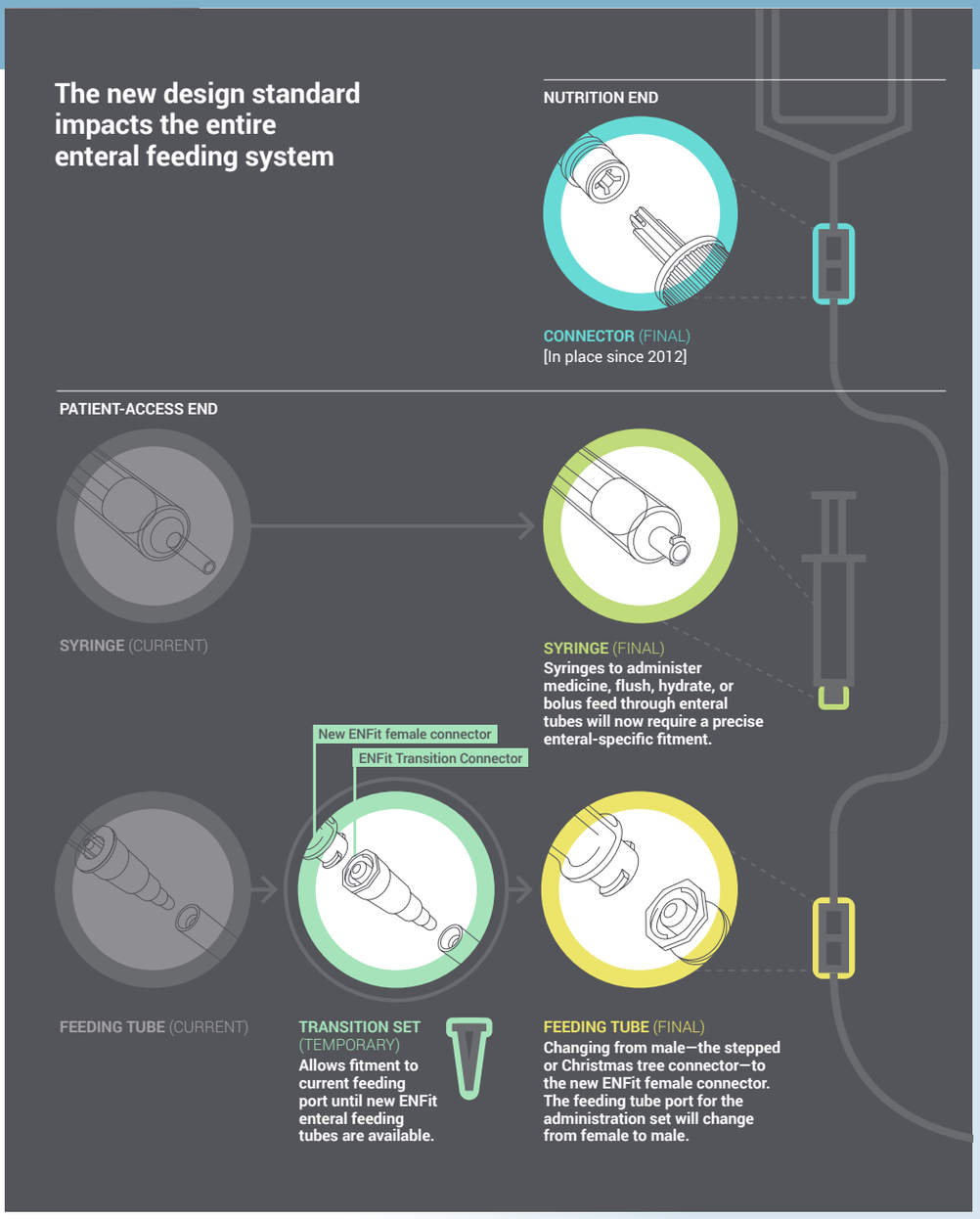
The Channel: How can clinicians and hospital staff learn more about your work?

I would certainly point them to the Stay Connected website first. It is intended to be a great resource for anyone whether you are a manufacturer, a sales rep, or a clinician anywhere on the healthcare continuum. We encourage everyone who visits the site to sign up for our Stay Connected email updates that provide the latest news and resources to aid in the transition. Another resource is gedsa.org, which provides more details on GEDSA membership and our contact information.

We also work through our partner associations and share articles in their publications and host webinars for their members. We also attend a lot of conferences, annual conventions and other trade shows because we feel the best way to communicate these changes is to physically show them. We hand out lots of brochures and wristlets. The wristlets are a neat way to demonstrate what the new connectors will look like along with a reminder to visit the website for more information. The Stay Connected brochures provide more background on this initiative, why we are doing this, what is the change going to look like and how we will transition the market.

The Channel: What can you share with the readership regarding the deadlines and objectives related to the transition?

There is one hard and fast deadline: January 2016. This deadline has been set by California legislation (Senate Bill 158; Assembly Bill 1867) that prohibits the use of intravenous, epidural or enteral feeding connections that would fit into a connection port other than the type for which it was intended.



To get the most up-to-date information on global Stay Connected timelines, go to www.stayconnected.org. For more information on GEDSA or to join, go to gedsa.org. (Brochure illustration courtesy of GEDSA.)

January 2016 is a hard deadline that our industry interprets as the market should be fully transitioned by then. That means we have to be way ahead of it in order to carefully transition the market. Technically, that's the only hard, fast deadline. The International Organization for Standardization (ISO) will set a loose deadline of three years after the official publication of the standard.

We, as an industry, because of the California legislation, are trying to get ahead of the published standard and so the California deadline supersedes the ISO standard and the publication. The other thing is that manufacturers view the conversion of California and the United States as the same, so the industry will not convert California as separate, different than other markets. Logistically, it would be incredibly challenging to manage the supply chain with two sets of products.

The Channel: Going forward, how does all the collaborative effort in this transition address patient and healthcare provider safety concerns?

I think that is really important. These enteral devices have to be able to connect to each other in order to have a safe environment for patients. Most importantly, they have to not connect with things they are not supposed to. The ISO design addresses that issue; however, the piece that is not discussed within the ISO process is the implementation piece. How are you supposed to do this and with unintended consequences?

Therefore, every single member and manufacturer and just about every clinician you speak to will say, "This is awesome. This is great that we are finally addressing this issue." But it doesn't come without a significant risk since, by design, the old connectors are not supposed to connect with the new connectors. There's a transition plan that we have temporarily put into place to make sure there is backwards compatibility.

Continued on page 15

Opening new Vistas for collaborative, peer-to-peer training

For more than 30 years, physician education and training has been an integral part of Cook Medical's overall mission to enhance patient care across the globe. The company's Vista Collaboration and Training Programs continue that tradition while also reflecting the company's long history of collaborating directly with clinicians.

Vista programs are peer-to-peer events in which the best and brightest instructors provide valuable training to physicians eager to improve their skills. The events produce a highly constructive, interactive environment for sharing best practices and advanced techniques.

A recently developed Vista program—Focus on ERCP Fundamentals Skills Theatre—brings endoscopy fellows together with world-renowned ERCP practitioners and instructors. In a stress-free, interactive environment—and using Cook's state-of-the-art ERCP Trainer—participants can acquire an essential practical understanding of basic pancreatobiliary anatomy, therapeutic techniques and ERCP devices. You can also expect to learn about scope movements, bile and pancreatic duct access, stone and stricture management therapies, and more.

Created through a collaboration between Prof. Guido Costamagna and Dr. Ivo Boškoski (Catholic University of Rome, Digestive Endoscopy Unit, Rome, Italy), the ERCP Trainer has proven to be an excellent tool to teach participants scope movement and manipulation, bile and pancreatic duct access, stone and stricture management therapies and more.

"One of the main problems in teaching ERCP to young endoscopists," said Prof. Costamagna, "is to make them understand the spatial relationship among the endoscope, the duodenum and, of course, the target of our examination, which is the papilla. So, the idea that Ivo [Boškoski] had some years ago was to build a homemade simulator, which is used to fix the endoscope in a stable, straight position like the one we commonly have in the duodenum. The goal was improving, with the manipulation of the endoscope, the ability of the trainee to be in the right relationship with the tip of the scope and the papilla."

A Model of Learning

The Channel spoke recently with Dr. Boškoski about the development of the new model and the skills it was specifically designed to teach young endoscopists.

The Channel: **What inspired your interest in developing the ERCP Trainer? What were your primary goals for the model training experience to accomplish?**

ERCP is a difficult exam also for experts. When I started learning ERCP, for me the most difficult thing was to understand movements and orientation. Then, at one stage when I became a tutor in ERCP, I noticed that most of the fellows had the same concerns as me before. I wanted to help them to understand what really was happening "outside the box," but it was difficult to explain it during real ERCP. One day I took some wires, parts from used accessories, tubes and sutures, and I made the ERCP Trainer that had a bile duct, pancreatic duct and different grades of ERCP difficulties. I was working night and day on it, and it was very exciting. But the most exciting thing came when the first two fellows tried it! They were so enthusiastic. Many things that were impossible to imagine before, now for them

were so obvious. And the most important thing came in the next days: both of the fellows were able to cannulate in the correct axis and to do many things that only few days before were difficult even to imagine for them, and they were not losing time in orientation in front of the papilla.

The Channel: **How does this model concept improve upon other ERCP training modalities with which you are familiar?**

This is a mechanical simulator that is compact, small and user friendly. This is the first all-in-one ERCP trainer that permits users to learn ERCP in the prone, supine and oblique positions, to learn all cannulation techniques and all types of interventions in the bile ducts and pancreatic duct. The most important things are that this teaches the correct axis on how "to stand" in front of the papilla and gives haptic feedback. This is an open model and this gives the possibility to understand what exactly happens "out of the box."

The Channel: **What benefits should trainees immediately expect from an initial training course with the model?**

During the first basic training courses, we saw fellows that had never touched a duodenoscope before and were unable to find the papilla, but after two days of training they were capable of stone extraction, metal and plastic stents placement, strictures resolution and so on. Basically, at the beginning, fellows learn the correct axis and correct movements: what to do in which situation.

The Channel: **Can the model be used to replicate difficult ERCP experiences and build understanding of techniques needed?**

Yes, the ERCP Trainer can replicate various degrees of difficulty and difficult cannulation scenarios. One of these is the semi-long position, difficult cannulations, low-papilla and so on. ■

For more information on Vista Collaboration and Training Programs, please contact your local Cook District Manager, Regional Manager or Field Product Specialist or visit: vista.cookmedical.com.

20 Gauge Echotip ProCore, continued from page 2

the pancreas (*Figure 2*). The patient had EUS-guided tissue sampling using the new 20 EchoTip ProCore FNB needle. The lesion was punctured from the duodenum (D2) and three consecutive needle passes were performed, using suction with a syringe. Excellent tissue samples were obtained from all three passes. Each pass contained both tissue cores and material for cytology. Immunohistochemical staining was performed (*Figure 3a and 3b*) and found positive for Pancreatin, CD 56, Synaptophysin, Chromogranin A, and the somatostatin receptor SSTR-2a. A proportion of mitotic cells between 3-20% (MIB-1 or Ki67) confirmed a pancreatic neuroendocrine tumor, grade 2.

Conclusion

In this patient with a neuroendocrine tumor in the head of the pancreas the 20 gauge EchoTip ProCore FNB needle provided a reliable tissue diagnosis to guide further management. The ultimate benefit of the 20 gauge EchoTip ProCore FNB needle is currently being tested in a large scale international study (ASPRO study) of which the results are eagerly awaited. ■

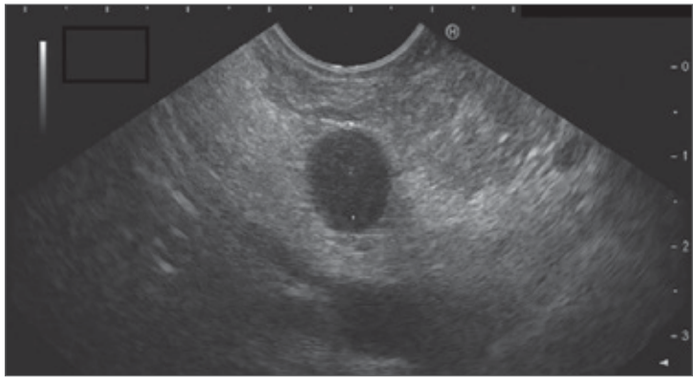


Figure 2

EUS procedure, showing a hypoechogenic mass (9 x 12 mm) between the pancreatic head and the uncinate process with sharp margins, before insertion of the FNB needle.

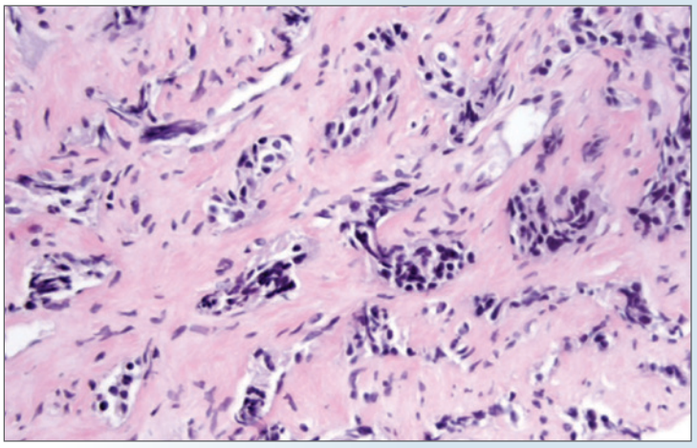


Figure 3a

Histology of a 20 gauge Echotip ProCore FNB biopsy. H&E staining of the tissue core showing nests of tumor cells imbedded in fibrous stroma.

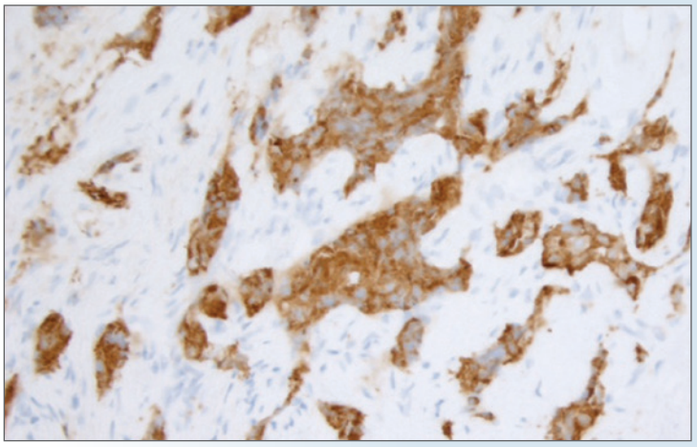


Figure 3b

Synoptophysin immunohistochemistry with strong positivity of tumor cells. Magnification x200. The final diagnosis is a neuroendocrine tumor in the head of the pancreas, grade 2.

Inclusion, Not Exclusivity, continued from page 13

If manufacturers didn't work together to: a) come up with a transition plan, b) decide to introduce the new connectors in the same time period and c) to make sure we are all saying the same thing, we would confuse our customers. If there weren't that type of collaboration, it would be mass confusion and worse. It would lead to disruption of therapy. The biggest single driver is patient safety, ensuring that we carefully transition the market without disruption of therapy.

So collaboration between the manufacturers is really important, as is collaboration with the various associations. We have been able to make a great connection with the folks at A.S.P.E.N., the American Society for Parenteral and Enteral Nutrition. That organization and in particular, Dr. Peggi Guenter has been a huge proponent of our efforts. They have helped lead the development of our FAQs and other training tools as well as lead the charge presenting these changes at various conferences and webinars.

The Joint Commission has been working with us and they recently released Sentinel Event Alert #53 to demonstrate the importance if these changes. The FDA is also available to provide guidance and answer questions for us. The Institute for Safe Medication Practices has also been strong contributor as has the Association for Advancement of Medical Instrumentation.

The Oley Foundation is another great collaborator. They are a patient care advocacy group and they are a very strong voice within that community. We are working with them to make sure that we have the right transition plan in place and we are addressing their issues and doing studies to make sure that when we make the transition it is suitable. They, too, are helping get the word out.

For medication administration concerns, we are working with the American Society of Health-System Pharmacists (ASHP). We have participated in their Medication Safety Collaborative, where we did a talk and a breakout session for hands-on training. So we are going to continue to foster that relationship to get the word out to pharmacists in the hospital setting. We are also working with the Walgreens of the world that deliver home infusion. They will also communicate the message through to their pharmacies at the community level.

So the collaboration just continues to build and we are continuing to create relationships with various associations that represent the various personnel and functions that we need to try to reach through hospitals, long-term care and home care settings. ■

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Advancing education and collaboration to improve patient care

For more than 30 years, physician education and training has been an integral part of Cook Medical's overall mission to enhance patient care across the globe. It's all part of our continuing commitment to education and professional development in endoscopy through Vista training programs.

For example, we recently began a new venture with the European Endoscopy Training Centre (EETC) in Rome, Italy. Collaborating with Professor Guido Costamagna and his local faculty and visiting faculty at Gemelli University Hospital, we are offering an ERCP Basic Training course for fellow endoscopists at the beginning of their ERCP career. The course will give fellows the opportunity to develop a comprehensive ERCP skillset.

And, in North America, look for the upcoming ERCP Skills Theatre for fellows, featuring Cook's ERCP devices, that will also include didactic lectures from top-level physicians.

For more information on these and other training courses from the Endoscopy division, please visit: vista.cookmedical.com

Vista℠ | Collaboration and Learning Program

Upcoming Events

MAY		
May 17-19	DDW	Washington, DC
May 17-19	SGNA	Baltimore, MD
May 29-30	UVA Liver Disease & Gastroenterology	Charlottesville, VA
May 29-31	JGES	Nagoya, Japan
JUNE		
June 4-5	Amsterdam Live	Amsterdam, The Netherlands
June 15-17	33rd GEEW – ERASME	Brussels, Belgium
JULY		
July 1-3	XXIV International Course Therapeutic Endoscopy	Sao Paulo, Brazil
July 16-19	Current Topics in Gastro & Hepato	Brewster, MA
July 27-29	VII Curso Internacional de Gastroenterologia y Endoscopia Terapeutica	Bogota, Colombia
SEPTEMBER		
Sept. 19-23	XLIII Congreso Nacional Endoscopia	Mazatlan, Mexico
Sept. 25-27	FGS	Orlando, FL
Sept. 25-27	EndoFest	Chicago, IL
Sept. 28-Oct. 2	Gastro 2015	Brisbane, Australia
OCTOBER		
Oct. 8-11	JDDW	Tokyo, Japan
Oct. 18-20	ACG	Honolulu, Hawaii
Oct. 24-28	UEG	Barcelona, Spain
NOVEMBER		
Nov. 21-25	XIV SBAD 2015	Curitiba, Brazil