

Interventional Endoscopy

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Good morning. I am Michael Wallace from the Mayo Clinic in Jacksonville, Florida. I have chosen 20 abstracts and what I'd like to do is organize this like a journal club. We will discuss at least 10 of them. The other 10 I've included in your booklet, but we've slotted enough time only to discuss 10 abstracts. I'm going to briefly summarize the abstracts and then give you my comments on it – how I read it, how I think it may be relevant to either practice or future practice and then let's just start an open discussion and questions.

The overall theme in this DDW in regards to interventional endoscopy has been a technology called NOTES which stands for Natural Orifice Transluminal Endoscopic Surgery. This is now the official name that's being given to what we've been calling transgastric surgery or intraperitoneal endoscopy. We've tried to come up with a standardized name so the ASGE, the AGA, and SSAT have decided to give it this name, NOTES. If you haven't been following this, there's now an official group of investigators in NOTES technology. Their abbreviation or acronym is NOSCAR and their Web site is www.noscar.org, so if you're interested in getting involved in this area, you can go to that Web site and join the group. There are a lot of ground rules that they've laid out. One of the important ground rules is that you have collaboration between a gastroenterologist and a surgeon. You have to have an animal laboratory at your facility to do this kind of research.

Abstract 225483: “Endoscopic anastomotic reduction after Roux-en-Y gastric bypass surgery: A potential treatment for weight regain”

The mechanisms of weight gain after gastric bypass surgery are not completely understood. At endoscopy, you often notice that the gastric pouch which was originally very small is now starting to get bigger. It is thought that some of the weight regain is due to this increased size of the gastric pouch. This paper from Chris Thompson, one of the leading groups in NOTES research, is one of the more straightforward approaches for interventional endoscopy. They used a standard Bard EndoCinch device in conjunction with an argon plasma coagulator, fibrin sealant and cytology brush to try to reduce the anastomotic luminal diameter between the gastroenteric bypass. They performed the procedure in 15 patients with weight gain after their gastric bypass surgery. Prior to the procedure, the lumen was 15-30 mm in diameter. After the procedure, the luminal diameter decreased to between 2 and 15 mm in size. Of the 15 patients, 11 were able to resume weight loss and four did not. Patients were followed for six months. Obviously, this is pilot work, though it looks like a promising method. Technically, this

approach is similar to closing other fistulas or leaks in the gastrointestinal tract. Instead of just suturing, you need to first denude the surface to get mucosa to mucosa sealing as opposed to serosal to serosal closure. You have to remove the epithelial lining. If you put two epithelial surfaces together, they will not fuse. They will maintain themselves in proximity but they will not fuse. They don't describe the details in the abstract, but I've talked to the author. They use the same technique everybody does in fistula closure. You excoriate the tissue in this case with a cytology brush. They then did argon plasma coagulation to further excoriate the tissue. They then put a fibrin sealant. You can use thrombin, cyanoacrylate, DERMABOND or superglue. Then they sutured it.

As I suggested, we use a similar approach to this for fistulas. The typical one is a post-anastomotic stricture after esophageal cancer surgery. The esophagogastric anastomosis breaks down and you get a fistula tract. Depending on the size of the fistula, you can manage it in different ways. The general principle is you have to first clean it up. We go in and debride all the necrotic material first; sometimes daily over several days or even a week or two. The patient is almost always in the hospital. Once we get all the necrotic material out, we denude the surface and try to close it. Typically, this is done with clips. I have not tried to suture a fistula closed, but you can close it with clips. We usually put a stent over those to seal it. My experience is you can get up to about 4-5 mm fistula closed with a clip. The ones that are really fibrotic are sometimes hard to appose. If you've got a really fibrotic area with thickened, heaped up walls, it's hard to get that tissue to oppose and in those cases, I'll inject glue, typically cyanoacrylate which is available as DERMABOND. DERMABOND is what the surgeons use or the ER physicians use to close lacerations. DERMABOND is not FDA approved for this indication. We include in our standard consent form that it's an off-label use.

Let's go to the next abstract.

Abstract 224819: "Natural orifice transluminal endoscopic surgery (NOTES) cholecystectomy: A transcolonic survival study in a porcine model"

Again, this is from Dr. Thompson's group at Harvard. They took adult Yorkshire pigs – these are standard farm pigs – and performed a cholecystectomy via a transcolonic approach hoping to get better survival results than with previous failed attempts at a transgastric approach. They highlight a number of important issues relevant to NOTES type surgery. They performed it after they sterilized the colon, used a sterilized scope, per anal antibiotics, Betadine rinse, and external Betadine scrub. The scope was introduced to about 15-20 cm from the anal verge, then a needle knife incision is made in the anterior wall of the colon, the abdominal cavity entered, the abdominal organs identified, the cystic duct and artery identified, and Endoclips used to ligate the cystic duct and the cystic artery. They were then able to pull the gallbladder off using hot biopsy forceps and used the coagulation forceps to dissect off the gallbladder and cut through the gallbladder and the cystic duct with hot snare cautery. They lavaged the area (standard surgical technique) and pulled the gallbladder out through the colon and closed the incision with Endoclips. They did this in five pigs. They were able to remove the gallbladder in all five. In four of them, they had generally successful outcomes. The pigs were survived for two weeks time and showed no signs of peritonitis or leak. In one pig, they were able to immediately see that they couldn't close the colonic hole and that pig was sacrificed at 48 hours because of apparent peritonitis. They did see some adhesions. They did necropsies on all of the remaining pigs and saw adhesions in the abdominal cavity. This is really a completely new area for endoscopy and for a lot of us it's very fascinating and interesting. It's probably not something we're going to be doing in our practices in the next five years, but we're certainly going to see a lot of research. There is a great deal of both individual and coordinated effort from the GI societies now to develop endoscopic surgery, research and training centers. Some of the basic principles of NOTES are incorporated in this study. First of all, sterile technique. This is quite different than what we do in normal endoscopy. Which approach, whether transgastric or transcolonic, is starting

to evolve. The initial procedures were all transgastric. We saw animal reports over the last couple of years - transgastric tubal ligation, transgastric oophorectomy, transgastric peritoneoscopy. The problem with all the upper GI applications after you make a needle knife incision in the stomach wall and cut through, you have to retroflex to look up at the gallbladder. You know how difficult it is to do any technical procedures in a retroflexed position. They tried to develop tools for what are called shape-locking technologies where you could put the scope in flexible position as we normally do, but then lock the scope into a rigid confirmation – a little bit like the scope stiffer but an extreme scope stiffer so that you could operate. In the early experience, particularly from this group, they were still unable to do a cholecystectomy from a transgastric approach. What's evolving is that the liver, gallbladder, and perhaps GE junction applications are probably going to be best accessed through a transcolonic approach. The lower GI, particularly the gynecological applications - tubal ligations, oophorectomies - are probably going to be most applicable from a transgastric approach. Appendectomies, although we haven't seen a publication yet, many of you have heard that a physician in India has performed a human appendectomy through a transgastric incision so this is certainly coming down the pike rather quickly. We are just beginning to see some of the reports of human cases. Most of this is now animal work.

This NOTES technology is technically transluminal, meaning you have to cross the lumen. There's a lot of related technologies and we will get into some of them - very aggressive endoscopic endoluminal therapies. They do include things like appendectomy. A group from Germany last year reported a technique for inverting the appendix into the colonic lumen and then closing that with an Endoloop. They put a suction catheter into the orifice of the appendix and applied very high suction to basically grab the walls and hold it back. They invaginated the appendix so to create a pseudopolyp and then closed that with an Endoloop detachable snare. This was in a normal appendix which is a very key issue because an inflamed appendix may not be as accessible. The same is true for diverticulitis. We're just starting to see some of the normal applications and the same for cholecystitis. Certainly, it is going to be more challenging to do these in a disease inflamed organ or tumor. I think some of the other applications that may come online sooner are, for example, endoluminal interventions you can do for a gastric stromal tumor. If you see a submucosal leiomyoma or stromal tumor, you can do a full thickness excision and have the ability to close that perforation. The same may be true for very large polyps or a T2 cancer in a non-surgical candidate. A group from England has even done lymph node removal through the esophagus. They made a perforation in the esophagus, went out and grabbed whole lymph nodes, pulled them into the esophageal lumen and did a lymphadenectomy. The whole technology here, I think is quite fascinating. At this point, I certainly wouldn't encourage you to adopt it into your practice, but if you want to get into this area, in a way it doesn't require a huge amount of effort. This is a research area that many of us could do. You need an animal laboratory if you work at a university or if you collaborate with a company. Many endoscopic companies have small animal research facilities. You do need a dedicated endoscope that is only for animal use. The FDA does not allow you to take your human endoscopes, use them in a pig, clean them and then bring them back to a human. You have to have an endoscope that is animal only and is never again used in a human. Maybe you have an old endoscope, or you can get one of the endoscope companies to donate a scope. There's going to be a lot of technical issues to work out. There are many small questions – where to make the incision, they chose 15-20 cm from the anal verge. Is that the best place? You could compare the site they used to using the transverse colon or another site; this is just one application. They don't comment on what gas they use here. I think many of them are using CO2 insufflation just as a laparoscopic surgeon would, but because you don't have an external hole they have been able to maintain good insufflation pressures. I've seen a couple of other papers that are just looking at insufflation pressures and how to monitor insufflation pressures. What pressures do you need? At some point, do either respiratory compromise or high intraperitoneal pressures develop or do you decrease venous return to the heart because of venocaval pressures? So there are a lot of technical issues that need to be studied in this and we probably will have some sort of pressure monitoring device like laparoscopic surgeons have to keep the intraperitoneal pressure at a safe level.

Abstract 226096: “Transcolonic endoscopic abdominal exploration”

This is again from Dr. Thompson’s group. The goal was to see if transcolonic peritoneoscopy could identify abdominal organs and still have animal survival. This is really just an alternative method of transcolonic peritoneoscopy. They took six pigs done under general anesthesia. They went through the rectum, sterilized or semi-sterilized the colon with an antibiotic suspension, a Betadine lavage, a sterile scope, went in through the same site 15-20 cm from the anal verge and explored the abdomen and showed that they could close the colon. They closed it with endoscopic clips or Endoloops. It’s not entirely clear how they closed with Endoloops. As you know it can be harder to close a wide perforation with the clips. One technique that people have done is to put clips around the perimeter of the incision to give you an anchor and then put an Endoloop outside of those clips so that they catch at the base of the clips and then just cinch the Endoloop down. It’s not actually physically anchored in the jaws; it just catches on the outside. Once you catch the clip and enough tissue, it will presumably cause closure.

Another possible technique is to use a suturing tool in the rectum. One of the other techniques is to use little T-tabs. It’s basically a suture with a little metal T at the end of it. You take a simple needle, like the sclerotherapy needle, punch the suture through the wall, push the T tab out, pull the needle out, and the T tab stays on the serosal side. In theory, you could punch a suture on one side of the hole, and punch a suture on the other side of the hole. Then you’ve got two sutures and you can use a knot tie or a little clamp. All of these tools are really in development right now. The device companies, the endoscope companies are investing quite a bit in developing some of these tools. Paul Swain developed a little T tab and they’ve been using it in his laboratory. Obviously, we’re using borrowed devices that aren’t perfect for these indications but this is new stuff and you use what you can get off the shelf. I’m sure that better, more customized, better-suited devices will be coming pretty quickly.

In this study, the peritoneal cavity was accessed through the colonic incision without difficulty. They were able to visually inspect all of the organs very quickly, three minutes. The lower pelvic organs were not consistently visualized. This seems to be a theme that’s emerging. We talked about this before. If you need to see the pelvic organs, you need to come from the stomach. If you need to see the liver, gallbladder, pancreas, or stomach, you need to come from the colon. One thing that was a little bit disturbing is the necropsies that they did afterwards. They are seeing adhesions in virtually all of the pigs. We saw that in the last one, they had adhesions. We like to think that transluminal endoscopic surgery would be less invasive, a little safer than laparoscopy. At least based on these initial experiences, it doesn’t avoid adhesions. Whether these are clinically relevant adhesions is not clear. It looks so far that no matter how you enter the peritoneum, you’re going to cause some adhesions. There’s a fair amount of basic research and pharmacologic research going into prevention of adhesions, using anti fibrotic installations to minimize these adhesions. That may not apply here, but at least at the moment it looks like we’re not going to get around the problem of adhesions just by going in through the rectum or the stomach. It actually appears that they are seeing more adhesions with a colonic approach compared to a gastric approach. I’m not quite sure why that is. It may be that it’s a less sterile environment and you’re just introducing more bacteria and inflammation in the peritoneum. I’m really not sure. That’s been one of the initial observations I saw just looking at some of the transgastric approaches. They didn’t report adhesions in their earlier transgastric studies but in both of these transcolonic studies they have reported adhesions.

The severely adhered peritoneum is going to present the same problems to transoral or transluminal approaches that it would to a laparoscopic approach. We know that the laparoscopic surgeons have to convert to open less and less than they used to, but will if you have dense adhesions. I think a lot of the inflammatory diseases are going to be difficult to manage, so acute appendicitis, acute cholecystitis, acute diverticulitis, this is probably not going to be the ideal approach to those. My impression is that it’s going

to be most useful for early cancers, pre-cancerous lesions, carcinoids or stromal tumors where you need to get a full thickness resection. If you have pancreatic cancer, we know that CT and even US miss some peritoneal studding. You could potentially do a very quick peritoneostomy. If you do it through EUS, look at the tumor, make a little incision in the stomach, look around and make sure there's no peritoneal studs and then close it and come out. That might pick up the 5% of people that still go to the OR that have metastatic disease. The initial ones will be fairly simple applications, easily removable tumors and just diagnostic inspection.

In addition, the preps probably have to be very pristine. I suspect we're going to have to do very aggressive colonic preps. You've probably seen recently, the FDA alert on phosphosoda preps. In a patient like this, you're likely going to give them 2 gallons of GoLYTELY instead of a gallon. They're also doing a lot of intraluminal, this Betadine lavage, the Cefazolin lavage. We'll need to do more of a surgical prep than what we do now.

We're going to change gears a little bit from NOTES activity to some photodynamic therapy. If you follow the photodynamic therapy (PDT) literature, these are the long-term outcomes of the original Overholt trial. The trial was the only prospective, randomized, placebo controlled trial of photodynamic therapy for early neoplasia in Barrett's esophagus. This was the trial that led to the FDA approval for photofrin PDT in Barrett's.

Abstract 218978: "Squamous overgrowth in a 5-year randomized phase III trial of photodynamic therapy using porfimer sodium in ablation of high-grade dysplasia in Barrett's esophagus"

This is now a five-year analysis looking at the prevalence of squamous overgrowth in Barrett's. We all have heard that if you ablate the esophagus with either PDT, argon plasma, multipolar electrocautery, and now cryotherapy, there's this risk of Barrett's underneath squamous epithelium that we can't see and thus can't target or biopsy. This is probably the ideal situation to look at this. We have a prospective, randomized, controlled trial so these patients were randomized to either PDT with omeprazole or omeprazole alone. The omeprazole alone just got the very intensive surveillance program. Everybody else got ablated with PDT and then followed by surveillance. One of the more impressive things as you read this is the number of biopsies these patients are getting. They got every three-month endoscopies, four quadrant, jumbo biopsies. They didn't mention it, but I assume that they were doing these every centimeter. After the first year, they went to every six months for five years. One hundred and thirty eight patients, 23,473 biopsies. That's a lot of biopsies. Squamous overgrowth was the same in the PDT arm as it was for the placebo arm. We have always thought that if you had squamous overgrowth, if you wanted to re-epithelialize the esophagus with squamous tissue, you had to first ablate it. The dogma has been, ablate it, and then let it regrow in an acid free environment. This clearly shows that it doesn't matter if it's ablated or not, it's just the acid free environment that seems to promote the squamous overgrowth. I see in my practice that people who are on very high dose PPIs, you start to see squamous islands. We see some patients with short segment Barrett's that we can't find the Barrett's anymore. The most interesting findings in this study, to me, were that you got squamous overgrowth with high dose PPIs without ablation.

The point that they were trying to make is that even though there was hidden Barrett's underneath squamous epithelium, there was never a lesion hidden under the squamous that wasn't also detectable in the visible Barrett's. Look at the last sentence in the RESULTS section – "In no patient was the highest grade of neoplasia per endoscopy found exclusively beneath squamous mucosa." They did find high-grade dysplasias under squamous. They don't mention the details, but I know in the study they found a few cancers underneath squamous epithelium. In all of those patients, there was also the same level of high-grade dysplasia or cancer in the visibly apparent Barrett's.

So are we reassured or does the fact that you get overgrowth in PPI patients make surveillance a false reassurance?

It does make surveillance difficult, however the good news from this study is that if you go in and you biopsy a visibly apparent Barrett's, you're going to find the neoplasia that may reside in subsquamous. At least according to this study, you shouldn't miss it. When I do surveillance on these patients, I always look at their original endoscopy report. If their Barrett's was 35-40 cm and I go in and see squamous epithelium covering most of 35-40 cm, I still do my routine Barrett's surveillance from 35-40 cm. Whether there is squamous epithelium or columnar epithelium, I just biopsy where the Barrett's originally was and I do it the same way that I do if I don't see the Barrett's; take four quadrant biopsies. In these patients, I do it every centimeter with jumbo forceps. There's a paper here from our group using the narrow band imaging scope which shows that you can see the subsquamous Barrett's epithelium using a narrow band imaging scope. It looks like that allows you to see the white epithelia, but you can see a villiform pattern underneath the white epithelium. It's white with a villous pattern underneath it so you can see where the Barrett's epithelium is. It's just covered with a whitish curtain. Narrow band imaging is a technology where instead of using white light endoscopy, it uses a very focal band of blue light. They put a filter over the light source so that you just get a blue light instead of blue, green, red, yellow, the whole range of white light. It has two effects. As a general principle, the shorter the wave length of light, the less deep it goes into the tissue. Just like ultrasound waves, short frequency ultrasound goes in only superficially; long wave length ultrasound or light goes deeper into the tissue. What you get with blue light is you see only the very surface layer, maybe a millimeter deep instead of looking at a whole thick slab. We don't appreciate it when we look at tissue. When you shine a bright light on tissue, you think you're looking at the surface, but you're really looking at a slab of tissue at least a centimeter or two thick. You're seeing the surface, you're seeing the collagen underneath it, you're seeing even some muscle in there and it's all merged into one slab. If you use a short wave length light, you see just the surface epithelium. That highlights the surface topography. The other effect of blue light is because hemoglobin absorbs in the blue range, that's why it appears red, the blood vessels absorb almost all of the light that hits them so they appear black. You see a much higher contrast between non-vascular areas and vascular areas. It allows you to see very fine capillaries, what they call interpapillary capillary loops. You can see these tiny little capillaries that run in between the villi. The combination of those two – very thin sliced almost tomographic imaging plus the increased contrast between the vascular and non-vascular areas allow you to see the mucosal and vascular detail that we can't see with just a normal white light. Its application in monitoring post PDT may not be critical. They're suggesting it's not critical to use any special technique. Just biopsy where you see the Barrett's.

They don't report the cancer outcomes in this particular study, but they showed in original data that there was a lower risk of developing cancer in the PDT group compared to the omeprazole group. I think many places have used PDT as an acceptable treatment modality for high-grade dysplasia. You still have options of surveillance but to me this study has moved us away from the surveillance alone approach. I now opt for ablative technology or surgery in almost all of these patients.

So if a person is a good surgical candidate do you still pick PDT?

Certainly surgery is still a very good option. Remember, you have 2 or 3% mortality from surgery. If it's a young, healthy patient, many of those end up choosing surgery. A lot of the ones referred for PDT have already made up their minds. If someone comes into our practice with high-grade dysplasia, we force them to at least meet with the thoracic surgeon and offer that option. They meet with our PDT endoscopist and our thoracic surgeon. Because we are a referral center for PDT, they've virtually always made up their mind and it's very rare that we reverse that but we at least offer it to them. I think both are quite reasonable options but the older they are, the higher their surgical mortality, the more we favor PDT.

What about BARRX?

We've just started using the BARRX. BARRX is a balloon that has a radiofrequency sheet of metal that is on the outside of the balloon. You blow up the balloon, put it in tight contact with the esophagus, and then apply radiofrequency energy. It is the same technology that was used in Stretta. This is a mucosal surface ablative method. So far, I've been quite impressed with our experience and the initial data. It gives you a lot more control of the depth of injury. All of these mucosal ablative technologies whether it's the cryotherapy, liquid nitrogen applicator, all the old burning technologies that we tried with gold probes and APC, create a very fine line between burning too deep and getting stricturing and not burning enough and getting Barrett's undergrowth. All of the technologies we've seen so far have crossed to one side of that line. PDT generally burns quite deep and if you give the full energy, you get a lot of stricturing. If you don't burn enough, you get this undergrowth. Most of the APC impact technologies do not burn deep enough. The mucosal stripping technologies generally cause stricturing but no Barrett's undergrowth. The BARRX so far seems to have achieved the best balance between stricturing and squamous overgrowth. We really have seen very little stricturing in the BARRX trial. Cryotherapy appears to be going a little too deep at least in the first 10 patients, 30% stricture. So the BARRX looks promising but I will hold my judgment on all of these technologies. Remember we got burned with some of the GERD therapies that looked very promising early on and now look much less promising. I would continue to watch carefully. If you have a busy practice like this, I think BARRX is a reasonable alternative to PDT. We're starting to offer it as an alternative. We don't have nearly the experience that we do with photodynamic therapy, which is the only ablative technology that's been subject to a prospective randomized sham controlled trial.

Abstract 220723: “Cryoablation of Barrett’s Esophagus (BE)”

This is a new device which basically applies liquid nitrogen to a small insulated delivery tube. They did 20 patients, 10 that they treated hemi-circumferentially, so half the esophagus. It's not written in the abstract, but I called Mark Johnston and he told me that they would treat half the side, bring them back four to six weeks later and then treat the other half. In the circumferential group, they treated the whole circumference. What they saw in the trade off was more treatment sessions in the hemi-circumferential group, twice as many endoscopies but maybe less stricture. In the fully circumferential group, the down side was stricture. In three of the 10 patients, they saw stricture or dysphagia developing with a stricture. Again, this is the trade off; if you burn too deep you get stricturing. There's not much data here on squamous overgrowth but this technology seems to be a little more on the side of deep injury, so it's probably going to have less squamous overgrowth and it's going to have more stricture. Like the cautery methods, my own impression is that it's going to be a bit hard to control the depth of injury. You spray liquid nitrogen onto the surface like a dermatologist sprays on a wart so you really can't control a lot of the depth of injury, but it appears to be a fairly deep injury.

Abstract 225165: “A sham-controlled study of the influence of radiofrequency deliver (The Stretta Procedure) on symptoms, acid exposure, and distensibility of the gastro-oesophageal junction in GORD patients”

We've got three studies that have to do with Stretta. This first one really looked at physiologic responses. As we've seen in virtually all of the GERD therapy studies, there were improved symptoms but no change in acid exposure and no change in lower esophageal sphincter (LES) pressure. What they did show from a physiologic difference is a decrease in the GE junction compliance. There's a debate as to whether Stretta causes a stricture or just a change in the muscular compliance. The way they tried to address that was they gave sildenafil – Viagra. Viagra is a smooth muscle relaxant and they speculated that if this changed the compliance, then it's not a stricture, it's not a fixed tightening, in fact it did change the compliance.

There was decreased compliance after Stretta, but it was reversible with Viagra. That tells you that it's not a fixed stricture somehow inducing some spasm or just a decreased overall compliance. It's not translating into changes in resting LES pressure and it's not resulting in changes in pH exposure. To me, it was an interesting physiologic observation. The bottom line is based on the sham controlled trial, all we really see are symptom responses and no pH or LES pressure responses, although an increase or decrease in the compliance may be valuable, but there are decreases – these transient lower esophageal sphincter relaxations that may be valuable. Whether it changes the neurosensory physiology so that we just feel less pain even in the setting of acid exposure is still a viable explanation for the Stretta effect. I must say my enthusiasm for Stretta has been quite tempered in the last couple of years. We're looking more at some of these full thickness plicator devices and suturing technologies that would get serosa to serosal coverage. We still do a little bit of Stretta but very little. Our volume has dropped off dramatically in the last couple of years.

The next two are both Stretta trials that come to different conclusions. Unfortunately, both are uncontrolled trials. They had long-term before and after data, but they don't have a placebo arm.

Abstract 223036: “Long-term 5-year follow up of the Stretta procedure for treatment of reflux disease”

This showed no long-term benefit at five years. There was really no significant improvement compared to baseline and reflux symptoms, quality of life and acid exposure. What this tells us is long-term, five year follow up data on what initially may have looked beneficial, shows that at five years these patients don't seem to be overall improved. Nine of 13 patients required on going acid suppression. Eight of the 13 were at or above their pretreatment levels of acid suppression.

Abstract 217443: “Long-term results of radiofrequency energy delivery for the treatment of gastroesophageal reflux disease sustained improvements in symptoms, quality of life and drug use at 4-year follow up”

This trial is arguably a better designed trial. They had larger numbers, higher rates of follow-up, and more precise measurements that showed some benefit. They showed that symptoms improved at long-term follow up – in this case four years. Quality of life improved. Use of antisecretory medications was reduced from 100% to 29.4% at 12 months and only 12% were continuing at 36 months and 13-14% were on antisecretory medicines at 48 months. These two trials disagree. I've read through as much as I could to try to figure out why one trial shows no benefit whatsoever at five years and this trial seems to show some benefit at four years. The bottom line is both of these are uncontrolled trials. I think without a sham-controlled arm, I interpret all of these studies with caution. One sham controlled study we have from Corley, et al., published a couple of years ago in *Gastroenterology* showed no clear benefit except for symptom response. People feel better after Stretta but they've got the same acid, the same LES pressure. My judgment is still suspended on Stretta and I haven't been recommending it to my patients until we get a better device.

Abstract 223898: “7 or 10 Fr, with low or high volume epinephrine? A single center prospective randomized control trial in acute non-variceal upper gastrointestinal bleeding (AUGIB)”

This is a nice trial by Dr. Schade at the University of Georgia which looked at a very practical question. If you have an acute upper GI ulcer bleed with a visible vessel, does it matter if we use 7 or 10 French cautery? Does it matter if you use a lot of epinephrine or a little epinephrine? The way I was taught was 10 ccs of epinephrine and a 10 French gold probe. This is a nice study design. It's called a 2 x 2 factorial design. If you want to answer two questions at the same time, you randomize people to both the 7 vs. 10 French and then within those groups you randomize them to high epinephrine and low epinephrine so you

have four treatment groups. In the end, you can consolidate and compare both outcomes. You lose a little bit of statistical power, but you answer two questions at the same time. Overall, it is a much more efficient design. A lot of drug trials have done these 2 x 2 to look for interactions between drugs. The short answer is bigger was better and more was better. The group that had the best overall outcome was the 10 French high dose epinephrine. High dose was 35 ccs of epinephrine versus 10 ccs. There was a statistically significant difference in the bleeding rates in the 10 French high dose trial. This is a study that may change my practice a little bit by going from 10 ccs of epinephrine to 35 ccs. They don't mention any complications from 35 ccs.

A general read on the GI bleeding, ulcer management literature over the last five years is more treatment seems to be better. We saw that two treatments are better than one when we looked at clips plus burn or injection plus clips or injection plus burn versus solo therapy. Virtually all the trials have shown more is better. Two treatments were better than one. Some preliminary evidence now shows that maybe even three treatment - clips, injection, and burn - is better than two. This trial, the same thing. The bigger the probe, the more epinephrine you inject, the better outcomes. The practical issue is it probably means to be prepared to have a therapeutic endoscope every time you go down with a big bleed so that you can put down a 10 French gold probe. I always tell the nurses if I get called in the middle of the night to get the two channel upper endoscope and I start every upper GI bleed case now with a two channel upper endoscope with the therapeutic channel - a 10 French channel.

Thank you all for coming.

Abstracts Discussed

225483: Endoscopic Anastomotic Reduction after Roux-en-Y Gastric Bypass Surgery: A Potential Treatment for Weight Regain. *Derek G Fong, David B Lautz, Christopher C Thompson*

Background and Aims: The mechanisms leading to weight regain after Roux-en-Y Gastric Bypass (RYGB) are not clearly understood. Dilatation of the gastrojejunal (GJ) anastomosis is a structural complication of the surgical pouch that may contribute to weight regain. The aim of this study was to examine our experience with endoscopic anastomotic reduction to effect weight loss after RYGB surgery. **Methods:** Between November 2003 and June 2005, thirty-eight endoscopic anastomotic reductions were performed at our institution. These procedures were performed using a Bard EndoCinch suturing device in conjunction with argon plasma coagulation, fibrin sealant, and tissue excoriation with a cytology brush. Fifteen patients with six month follow-up data were identified and included in this analysis. Patients with other upper GI pathology and early iterations of technique were excluded. **Results:** The GJ anastomotic size prior to reduction ranged from 15 to 30 mm in diameter (mean size 23.4 mm) with the post procedure size ranging from 2 to 15 mm in diameter (mean size 6.57 mm). Eleven of the patients lost weight following the procedure while four of the patients did not experience any weight change and one patient experienced weight gain. Mean percent excess weight loss at six months ranged from a gain of 9.6% to a loss of 56.8% (percent mean excess weight loss 14.2%). Three of the patient's who did not lose weight were found to have dilation of their GJ anastomosis at follow-up endoscopy and a second reduction was performed within eight months of the initial procedure. Two of the patient's who did not lose weight were known to be noncompliant with dietary restrictions. There were no serious complications from the procedure. Symptomatic complaints from the procedure were self limited and included sore throat, abdominal discomfort, and nausea. **Conclusions:** Endoscopic anastomotic reduction may be a useful treatment option for weight regain in selected patients after RYGB. Endoscopic anastomotic reduction appears feasible and safe, and is associated with variable weight loss. The durability of weight loss and the need for subsequent anastomotic reductions will need to be explored with additional prospective randomized studies.

224819: Natural Orifice Transluminal Endoscopic Surgery (NOTES) Cholecystectomy: A Transcolonic Survival Study in a Porcine Model. *Reina D Pai, Derek G Fong, Douglas S Fishman, David W Rattner, Christopher C Thompson*

Background and Aim: Transgastric cholecystectomy has been reported in two non-survival studies which detail substantial technical limitations and only a 33% success rate when limited to one gastric exit site despite the use of a multiple channel locking endoscope. The aim of this study was to demonstrate feasibility and evaluate technical limitations of a transcolonic approach to cholecystectomy. **Methods:** Under general anesthesia, adult Yorkshire pigs were prepped with multiple tap water enemas, per-anal instillation of an antibiotic and betadine rinse, and external betadine scrub. A sterile dual-channel endoscope (Olympus™) was introduced through the anus and advanced through a 2 cm, anterior, trans-colonic incision created by a needle knife approximately 15 - 20 cm from the anal verge. Upon completion of intra-abdominal exploration and identification of all major upper abdominal organs, the cystic duct and artery were dissected and ligated with endoclips. Dissection of the gallbladder away from the liver was achieved using hot biopsy forceps, snare tip, prototype endoscopic scissors and an insulated-tip needle knife. The gallbladder was successfully removed with hot snare cautery. The gallbladder fossa was then lavaged with sterile water, re-examined and additional cautery or endoclips were applied for hemostasis or closing of defects. At the conclusion of each procedure, the colonic incision was closed using endoloops and/or endoclips. **Results:** The animals were survived for two weeks followed by elective termination and necropsy. Four of the five animals flourished in the post-operative period demonstrating appropriate feeding and activity patterns as well as stable weights or weight gains. The colonic incision site in all 4 animals healed completely, however external adhesions were appreciated. In the last animal complete closure of the colonic incision site was not possible and a small 4mm residual defect remained. The animal was survived for 48 hours but then sacrificed due to concerns of peritonitis. Pathology from all 5 subjects subsequently confirmed the resected organs as gallbladders. **Conclusions:** The transcolonic approach provides improved visual exposure of the gallbladder and scope stability when compared to the transgastric approach. This study demonstrates the technical feasibility of transcolonic organ resection via a single incision. The one complication appeared secondary to inadequate incision closure and not related to the organ resection. For this approach to be translated to humans, a sterile conduit, secure closure device and better instruments for triangulation are necessary.

226096: Transcolonic Endoscopic Abdominal Exploration. *Derek G Fong, Reina D Pai, Christopher C Thompson*

Background and Aims: Although a transcolonic endoscopic approach to access the peritoneal cavity has been previously described by our group, the ability to systematically identify abdominal organs with animal survival has not been reported. The aim of this study was to determine the ability to evaluate abdominopelvic organs using a transcolonic approach in a survival study design. **Methods:** Six female Yorkshire pigs weighing 25 to 30 kg were used in this study. Under general anesthesia, the rectum was lavaged with multiple tap water enemas. After endoscopic confirmation that the distal colon was free of particulate matter, a cefazolin suspension was instilled for 10 minutes followed by a betadine lavage. Colonic incision was performed over

the anterior colonic wall at a distance of 15 cm to 20 cm from the anus. A sterilized Olympus upper endoscope was then passed through the incision and endoscopic abdominal exploration was performed. The incisions site was closed using endoscopic clips, endo-loops, as well as a novel closure device. **Results:** The peritoneal cavity was accessed through the colonic incision without difficulty. The stomach, liver, gallbladder, spleen, small bowel, and colon were identified in all of the animals in under 3 minutes. The lower pelvic organs were not consistently visualized. All of the animals survived 14 days without apparent sequelae before elective sacrifice. At necropsy, the colonic incision sites were completely closed and well healed from the luminal surface. From the serosal aspect, salpingocolonic and cystocolonic adhesions were identified in 5 of 6 animals. The development of adhesions are in contrast to our previous findings with transgastric endoscopy. There was no evidence of organ injury or peritonitis. **Conclusions:** This study demonstrates the ability of transcolonic abdominal exploration to successfully evaluate major organs in the upper abdomen. In contrast to the transgastric route, a transcolonic approach provides en face orientation to organs in the upper abdomen and allows for better visualization and scope stability. Therapeutic interventions in the upper abdomen including organ resection may therefore be technically easier using a transcolonic approach.

218978: Squamous Overgrowth in a 5-year Randomized Phase III Trial of Photodynamic Therapy using Porfimer Sodium in Ablation of High-Grade Dysplasia in Barrett’s Esophagus. *Mary Bronner, Shari Taylor, Bergein Overholt, Kenneth Wang, Steven Burdick, Charles Lightdale, Michael Kimmey, Hector Nava, Michael Sivak, Norman Nishioka¹ Hugh Barr² Chad Davis, Norman Marcon, Marcos Pedrosa, Michelle Depot*

PURPOSE: Squamous overgrowth may obscure the endoscopic extent of Barrett’s epithelium. Although squamous overgrowth has never been rigorously studied, it has been speculated that photodynamic therapy (PDT) increased the risk of subsquamous metaplastic glands. Consequently, its true diagnostic significance was assessed following PDT with porfimer sodium plus 20 mg omeprazole BID [PORPDT] versus 20 mg omeprazole BID [O alone] in patients with high-grade dysplasia (HGD) in Barrett’s esophagus (BE) in a large randomized trial. **METHODS:** Patients were randomized (2:1) to PORPDT or to O alone. Patients on PDT received 2 mg/kg i.v. of POR followed by endoscopic laser light exposure of Barrett’s mucosa at a wavelength of 630 nm within 40-50 hours up to a maximum of 3 courses administered at least 90 days apart. Starting at baseline, every 3 months patients underwent 4-quadrant jumbo biopsies of their pre-treatment Barrett’s length until four consecutive quarterly follow-up results were negative for HGD and then biannually up to 5 years or treatment failure. Biopsies were taken at 2-cm intervals and centrally processed for standardized histologic interpretation by GI pathologists blinded to treatment assignment and patient identity. **RESULTS:** There were 138 patients and 23,473 total biopsies in PORPDT and 70 patients with 10,160 total biopsies in O alone. Occurrence of squamous overgrowth was similar for PORPDT relative to O alone both per patient (31% vs. 33%) and per biopsy (1.2% vs. 2.2%). In no patient was the highest grade of neoplasia per endoscopy found exclusively beneath squamous mucosa. **CONCLUSIONS:** This 5-year large randomized trial with a rigorous surveillance biopsy program documents that squamous overgrowth occurrence is similar following either PORPDT or O alone. This trial confirms that squamous overgrowth is not detrimental to the longer-term safety of PORPDT.

220723: Cryoablation of Barrett’s Esophagus (BE). *Mark H Johnston, Brooks D Cash, John D Horwhat, Lavonne R Johnston, Cathy A Dykes, Halisha S Mays*

Background: The aim of this study was to explore the safety and efficacy of circumferential relative to hemi-circumferential cryoablation using an endoscopic low pressure liquid N2 device (CryMed Tech. Inc, Baltimore, MD) in BE. **Methods:** Twenty patients with BE were enrolled. The first 10 (group I) were treated hemi-circumferentially. The next 10 patients (group II) were treated circumferentially. In both groups 4 cm segments were treated at a time. Each area was frozen for 20 seconds, followed by thaw and then re-frozen for 20 seconds. **Results:** The mean age for both groups was 58. The mean BE length, pre-cryo, for group I was 4.5 cm, and for group II 2.7 cm. Post cryo the mean BE length for group I was 0.3 cm and for group II was 0 cm. The mean number of treatments for group I was 4.8 versus 2.1 in group II. There was no sub-squamous specialized intestinal metaplasia (SIM) for either group at 6 months follow-up for whom there was data. There were no serious complications. Group II experienced more transient chest discomfort and dysphagia (see table). Both patient discomfort and dysphagia completely resolved. No patient developed an esophageal stricture. **Conclusion:** Preliminary results indicate that circumferential cryoablation compared to hemi-circumferential is similarly efficacious with respect to reversal of BE and absence of subsquamous SIM. It requires less than half the treatments of hemi-circumferential treatment but at the cost of increased patient discomfort.

Table I

Pt#	Age	BE length (cm) pre-cryo	BE length (cm) post-cryo	F/U (mo)	# Cryos	SIM at 6 mo	Pain post-cryo	Dysphagia
1	56	4	1	32	5	+	-	-
2	51	1	0	31	6	-	-	-

3	72	8	2	31	8	+	-	-
4	74	5	0	26	5	-	-	-
5	57	8	0	25	5	-	-	-
6	60	4	0	20	1	-	-	-
7	57	4	0	20	6	+	-	-
8	53	3	0	20	4	+	+	-
9	53	4	0	20	5	-	-	-
10	50	4	0	19	3	-	+	-
11	64	6	0	15	1	-	+	-
12	62	1	0	10	2	-	+	-
13	52	3	0	10	4	-	+	+
14	59	7	0	10	4	p	-	-
15	61	2	0	8	1	-	+	+
16	41	1	0	9	1	-	+	+
17	59	1	0	9	1	p	-	-
18	67	1	0	8	2	+	-	-
19	56	4	0	8	4	p	+	-
20	61	1	0	8	1	+	+	-
mean	H=58 C=58	H=4.5 C=2.7	H=0.3 C=0.0	H=24 C=10	H=4.8 C:2.1	H=40% C=29%	H=20% C=70%	H=0% C=30%

H=hemi-circumferential; C=circumferential; p=pending; mo=months

225165: A Sham-Controlled Study of the Influence of Radiofrequency Delivery (The Stretta Procedure) on Symptoms, Acid Exposure and Distensibility of the Gastro-Oesophageal Junction in GORD Patients. *Joris Arts, Philippe Caenepeel, Rita Devos, Lieselot Holvoet, Daniel Sifrim, Toni Lerut, Paul Rutgeerts, Jozef Janssens, Jan Tack*

Several studies, including one sham-controlled study, have reported symptom relief in gastro-oesophageal reflux disease (GORD) patients treated with radiofrequency delivery (Stretta procedure) at the gastro-oesophageal junction (GOJ). The mechanism underlying this improvement is unclear as changes in pH monitoring are often inconsistent. Recently, it was proposed that decreased distensibility of the GOJ is involved in the symptomatic improvement observed after the Stretta procedure (Arts DDW 2005). The aim of the present study was to investigate the effect of Stretta on symptoms, acid exposure and GOJ distensibility in a double-blind randomised cross-over design. Methods: Consecutive GORD patients underwent two upper gastrointestinal endoscopies with 3 months interval, during which active or sham Stretta treatment was performed in a randomised double-blind fashion. The endoscopic procedure was performed by a team which was otherwise not involved in the follow-up of these patients. Before the start of the study and 3 months after the first treatment, they underwent symptom assessment, endoscopy, manometry, 24h esophageal pH monitoring and a barostat distensibility test of the GOJ before and after administration of 25 mg of sildenafil. Symptom scores, acid exposure, lower esophageal sphincter (LES) pressure and GOJ compliance data (mean±SEM) were compared using Student's t test. Results: 22 GORD patients (17 females, mean age 47±12) participated in the study; 11 received Stretta first and 11 sham first. Three months after initial sham treatment, symptom score (16.8±2.6 vs. 17.7±2.3, NS), acid exposure (9.0±1.3 vs. 7.5±1.8 % time, NS), LES pressure (15±2 vs. 13±1 mmHg, NS) and GOJ compliance (14.1±4.5 vs. 12.8±3.0 ml/mmHg, NS) were not significantly altered. Three months after initial Stretta procedure, no changes were observed in esophageal acid exposure (16.3±4.8 vs. 16.5±2.7% time, NS) and LES pressure (11.9±1.1 vs. 13.0±2.2 mmHg, NS). In contrast, symptom score was significantly improved (12.6±1.1 vs. 7.5±1.8, p<0.05) and GOJ compliance was significantly decreased (15.8±2.5 vs. 8.3±2.5 ml/mm Hg, p<0.05). After administration of sildenafil, an esophageal smooth muscle relaxant, GOJ compliance after Stretta was normalised to pre-Stretta level (13.2±1.4 vs. 13.2±2.8 ml/mmHg, NS), which rules out GOJ fibrosis as an underlying mechanism. Conclusion: In this sham-controlled study, Stretta was associated with improvement of GERD symptoms, decreased GOJ compliance and unchanged acid exposure or LES pressure. Decreased GOJ compliance, which reflects altered LES neuromuscular function, may contribute to symptomatic benefit by decreasing refluxate volume.

223036: Long-term 5-year Follow-up of the Stretta Procedure for Treatment of Reflux Disease. *Rebecca J Ryan, Suresh Sivanesan, William C Tam, Mark N Schoeman, John Dent, Richard H Holloway*

We have shown previously that radiofrequency (RFe) treatment of reflux disease (Stretta) reduces reflux symptoms, medication use and esophageal acid exposure over a 12-month follow-up (Gastroenterology 2002;122:A47). However, data on long-term efficacy are limited. **Aims:** To assess whether improvement in symptoms, medication usage, and esophageal acid exposure is sustained over a 5 year follow up period. **Methods:** Twenty patients (10M, 10F) with GERD (heartburn, %pH<4 >4%, ± h/o erosive esophagitis within 6 mths) underwent endoscopy, 24h ambulatory pH monitoring and symptom assessment (SF-36, GERD-HRQoL, dysphagia score) before and 6 months after RFe treatment. All patients were dependent on acid suppressant therapy before RFe; therapy was stopped after RFe and restarted only if symptoms relapsed. Thirteen patients (6M, 7F) were available for follow-up at 5 years (56-63 mo) after treatment. These patients underwent re-evaluation with endoscopy, 24h ambulatory pH monitoring and symptom assessment (SF-36, GERD-HRQoL, dysphagia score). **Results:** At 5 years, 9 of the 13 patients required ongoing acid suppression: 8 at or above the pre-treatment level; 1 had also undergone fundoplication. Only 4 patients were off therapy but all had mild symptoms. Two patients had mild (LA-A or B) erosive esophagitis but more severe than at entry; the remainder were endoscopy-negative. Esophageal acid exposure and scores for reflux symptoms and quality of life at 5 years were not statistically different from those pre-treatment or at 6 months post-treatment (Table, median (IQR)). **Conclusions:** The beneficial effects of the Stretta procedure that are apparent at short-term follow up are not sustained over 5 years. The role of the Stretta procedure in the management of reflux disease requires re-evaluation.

Median (IQR)	Pre-treatment	5 Years post-treatment
%time pH <4 (Total)	10.9 (8.0, 12.8)	6.7 (4.7, 11.5)
GERD QoL	14.0 (3.0, 20.0)	13.0 (7.0, 15.0)
SF-36 (Physical)	38.6 (34.6, 48.3)	50.2 (47.4, 52.6)
SF-36 (Mental)	50.0 (43.2, 56.2)	54.7 (51.9, 57.0)

217443: Long-Term Results of Radio Frequency Energy Delivery for the Treatment of Gastroesophageal Reflux Disease Sustained Improvements in Symptoms, Quality of Life and Drug Use at 4-Year Follow-Up. *Alvaro Reymunde, Nilda Santiago Ponce*

The aim of this study was to evaluate the efficacy of the Stretta procedure for GERD patients based on symptom control, quality of life and medication use. All patients underwent careful evaluation to document the diagnosis of GERD. Also, the patients symptoms were assessed using standardized validated tools complemented by patient diaries and symptom logs with use of visual analog scale including GERD Symptom Score. A Quality of Life in Reflux and Dyspepsia scale was used to assess patients quality of life related to reflux disease on a scale of 0-5 with higher numbers indicating better disease control. Medication use assessment was performed, patients were specifically queried about the use of all acid reflux medications including proton pump inhibitors, H2 receptor antagonists, antacids and promotility agents. This testing was repeated 12, 36 and 48 months following the Stretta procedure. Results: 83 consecutive patients; 65men (78%) and 17 women (22%) have reached follow-up of 48 months. Complete, matched data sets for 80 patients (96.4%) are reported with assessments at baseline and 12, 36 and 48 month follow-up; three patients were lost to follow-up. No serious complications were associated with the Stretta procedure. All results were statistically significant at all timepoints. GERD symptom scores improved from a mean score of 2.7 at baseline to 0.3 at 36 months and 0.6 at 48 months. 68.67% of patients showed complete resolution of symptoms with scores of 0 (p<0.001). The mean quality of life scores improved from 2.4 at baseline to 4.6 at 36 months, 4.3 at 48 months (p<0.001). Use of anti-secretory medications in patients following Stretta was reduced from 100% of patients using prescription anti-secretory medication at baseline to 29.4% of patients at 12 months and 12.1% of patients at 36 months and 13.75% of patients at 48 months (p<0.001). No patient who was previously on PPI BID returned to this requirement following the Stretta procedure. 90.2% of patients on PPI or H2RA levels pre-procedure had reduced their medication to none at all. 88.75% of patients had complete elimination of the need for anti-secretory medications or a reduction in their medication usage and significant improvement in both symptom score and QOL measures. Our study demonstrates the Stretta represents a durable modality that can be offered to patients suffering from persistent GERD as a clinically viable treatment for the relief of symptoms and requirement for ongoing medical management or the potential need for an invasive surgical procedure.

223898: 7 or 10Fr, with Low or High Volume Epinephrine? A Single Center Prospective Randomized Control Trial in Acute Non-Variceal Upper Gastrointestinal Bleeding (AUGIB). *Subbaramiah SRIDHAR, Sherman Chamberlain, Sreeram Parupudi, Sankar Sethuraman, Dharma Thiruvaiyaru, Urias Cuartas, Lynda Roach, Robert Schade*

Background: Endoscopic injection of epinephrine (1:10,000) together with thermocoagulation is considered highly effective for AUGIB. We compared the efficacy of low (10 ml) or high volume (35ml) epinephrine followed by 7 or 10Fr BICAP probe. Methods: A total of 197 pts., mean age 63.4(SD+16.6) who shared common demographic details with endoscopically confirmed AUGIB (Forrest I & II) were prospectively randomized to one of 4 effective treatment groups; high vol epi +10Fr (A, n=58), high vol epi +7Fr (B, n=47), low vol epi +10Fr (C, n=36), & low vol epi + 7 Fr (D, n=56). All endoscopic

procedures were performed within 6- hr. of admission by a single endoscopist (S, S). The outcome variables of interest were: rebleeding incidence, need for surgery, no. of hospital days & no. & duration of coagulations. Results: 113 DUs, 77GUs & 7 MW tears noted. 67 pts. took NSAIDs: 18, 17, 15 & 17 in A, B, C & D. The no. of rebleeding incidences (<48hrs) were 2,3,4 &13 in gps. A, B, C & D respectively. Only 1 pt in A required surgery for rebleeding when compared to 6 in D. The mean no. of coag. & duration (5.4, 7.7sec SD + 1.1, 2.1) were also low in A when compared to other groups. Using logistic regression analysis, the odds of rebleeding was significantly lower in A when compared to D (ref. to table). Using multivariate ANOVA, ICU & ward days in non-NSAID users were sig. lower in A than in D (P<0.01), but there was no difference between the two groups in NSAID users & among C, B & A for all pts. No. of coag. & duration in sec. were sig. fewer in A when compared to other groups(P< 0.01) in all pts. Conclusion: In our study 10Fr coagulation probe with high vol. epinephrine was associated with significantly reduced rebleeding risk and lower no. of coag. & duration. However, there was no sig. difference between the groups with respect to need for surgery for rebleeding. This therapy, when compared to 7Fr coagulation with low vol. epinephrine, was also superior in reducing hospital stay in non-NSAID users. Use of large probe with high volume epinephrine should be standard therapy when dealing with AUGIB for minimizing morbidity and costs.

Rebleeding Risk (Logistic regression)

Rebleeding	Wald Chi-square	P-value	Odds-ratio(95%CI)
Gp A vs D	9.132	0.003	0.035 (.004,.30)
Gp B vs D	5.812	0.016	0.185 (.047,.72)
Gp C vs D *NSAID	6.750	0.009	0.043 (.004,.46)
NSAID use	12.250	0.001	8.101 (2.5,26.1)

*Interaction between NSAID & groups C vs. D

223913: The Usefulness of Endoscopic Submucosal Dissection (ESD) for the Treatment of Premalignant and Malignant Gastric Neoplasm. *Sun-Taek Choi, Tae-Nyeun Kim, Jung-Hoon Lee, Jong-Ryul Eun, Jun-Hwan Kim, Byung-Ik Jang, Heon-Ju Lee*

Background/Aims; Minimally invasive treatment such as endoscopic mucosal resection (EMR) is widely used as a treatment for gastric neoplasm. But, it is difficult to obtain en bloc resection in case of large lesion with a conventional EMR techniques. Recently, ESD is reported to be a promising method to resect the lesion as an en bloc. The purpose of this study was to evaluate the efficacy and safety of ESD. Methods; 78 patients referred for ESD between September 2004 and November 2005 were studied prospectively. ESD was performed using IT-knife or needle knife after submucosal injection of saline-epinephrine solution. The en bloc resection rate, complete resection rate and associated complications were recorded. Results; 83 lesions were removed by ESD in 78 patients. Indications were adenoma 56.6%, dysplasia 9.6%, adenocarcinoma 33.7%. 3 cases of scar like mucosal lesion were resected (two cases; adenocarcinoma, one case; adenoma). The median size of the lesion and the resected specimen was 15.0 mm, 24.8 x 18.0 mm, respectively. The en bloc resection rate and complete resection rate were 95.2%, 91.6%, respectively. Complication rate for bleeding after ESD was 18%. 11 cases(73%) of bleeding were notified during early second look endoscopy within the first 24 hours. Hemostasis was achieved in all cases in response to endoscopic therapy. One case of perforation underwent an operation because the specimen spilt on the peritoneal cavity. The mean length of procedure time and hospitalization were 40 minutes, 5.5 days, respectively. Post-ESD histopathology was adenoma 47%, dysplasia 12%, adenocarcinoma 41%. ESD resulted in upgrading of pathologic staging to adenocarcinoma or dysplasia in 22%. Conclusions; ESD has high en bloc and complete resection rate in gastric neoplasm. ESD is associated with perforation and a high risk of bleeding, sufficient experience and endoscopic treatment technique are essential. Early second look endoscopy within 24 hours may be helpful to prevent bleeding from ESD. ESD changes pathologic diagnosis in a significant number of patients. Long-term follow up results of ESD are needed.

226620: Success of Argon Plasma Coagulation for Management of Gastric Antral Vascular Ectasia. *Kuldip S Banwait, Madhusudhan R Sanaka, Kuntal M Thaker, Karl Kwok, Stephanie Moleski, David Assis, Thomas Kowalski, David Loren*

Background: The gastric antral vascular ectasia (GAVE) syndrome is an uncommon cause of anemia and GI bleeding. A subset of patients with GAVE will require endoscopic thermal ablation to manage bleeding complications and argon plasma coagulation (APC) has increasingly become the therapeutic modality of choice. We hypothesize that the success of thermal ablation may be affected by the coexistence of portal hypertensive gastropathy and present what we believe to be the largest reported experience using APC for the management of GAVE. Aims: The aims of this study were to evaluate the efficacy of APC in treating GAVE in a large patient cohort and to assess the impact of portal hypertensive gastropathy on the clinical success of ablation therapy. Methods: A retrospective review of all EGD reports from a single tertiary care hospital was performed between 2000 and 2005. All patients in whom GAVE was diagnosed based upon endoscopic findings were included in the analysis. The clinical presentation, number of treatment sessions with APC, response to therapy, and clinical recurrence

were recorded. The chi square test and Students t-test were used where appropriate. Results: 24,349 upper endoscopies were performed during the study period of which 133 (0.55%) patients were diagnosed with GAVE. The mean age of affected individuals was 65.2 yrs (range 34-99) compared to 57.7 yrs for the entire cohort. Women comprised 62.5% of affected individuals and represented 56.3% of all patients undergoing upper endoscopy. The most common presentation was GI bleeding (35.5%) followed by anemia (30.9%). Of patients with GAVE, 17.3% (23/133) were diagnosed with coexistent portal hypertensive gastropathy. 69/133(51.9%) of affected patients underwent ablation therapy with APC with a mean of 2.2 sessions per patient (median=2). 34/69 patients (49.3%) required only a single ablative session to manage bleeding or anemia. Of those requiring multiple sessions, the mean number was 3.5 (median=3, range=2-12). The mean interval between sessions was 6.3 months. When patients were stratified according to the coexistence of portal hypertensive gastropathy there was no significant difference in the percent of patients requiring therapy or the mean number of sessions required. No procedure related complications were observed. Conclusions: APC is a safe and effective treatment modality for the management of GAVE. The coexistence of portal hypertensive gastropathy does not appear to affect clinical outcomes of those requiring ablative therapy. Our results are similar to those of the previously reported smaller cohorts of patients with GAVE treated with APC.

Additional Reading: Interventional Endoscopy

222111: Double Balloon Enteroscopy - A Useful Diagnostic Tool? Analysis of a Large, Non-Selected Cohort of Patients Regarding Success and Complications of Double Balloon Endoscopy. *Christian Maaser, Hansjoerg Ullerich, Karin Menzel, Dirk Domagk, Andreas Luegering, Wolfram Domschke, Torsten Kucharzik*

Aim: Double balloon enteroscopy has become one of the most innovative diagnostic new tool for the examination of the small bowel also allowing therapeutic interventions. The aim of this analysis was the evaluation of the success on one hand and potential risks on the other hand in a large cohort of non selected patients of one endoscopic center. Methods: We evaluated all examinations performed in our center starting November 2004 until mid November 2005, which resulted in a total of 215 examinations. Endoscopies were performed with the double balloon enteroscope Fujinon EV EN-450F. The examinations were performed by a team of 4 experienced endoscopists. Results: Indications for double balloon endoscopy have been obscure/occult gastrointestinal bleeding in 94 patients, suspected Crohn s disease in 18, strictures in 13 and suspected neoplasias in 14 patients. Overall we detected angiodysplasias in 32 cases, of which the most prominent ones were successfully treated with argonplasma coagulation in 17 patients. In 9 out of 18 cases suspected Crohn s disease was verified endoscopically and histologically. In 10 patients previously unknown neoplasias were detected. These included a tubulo-villus adenoma, a carcinoid tumor, three gastrointestinal stromal cell tumors (GIST), and intramural neurofibromatosis. Furthermore in 2 patients Peutz-Jeghers polyps were successfully resected during double balloon enteroscopy. In addition to the examination of the small bowel we used the double balloon technique to reach the Papilla Vateri successfully in 5 patients that presented with a Y-Roux anastomosis and cholangitis. By using the double balloon technique we were able to successfully perform papillotomies and dilatations leading to successful drainages of the bile ducts. Regarding complications we recorded minor symptoms such as postinterventional abdominal pain or mildly, temporarily elevated temperatures in about 10% of all patients. However non of the double balloon enteroscopies led to any major complications, e.g. perforations, bleeding or pancreatitis, Conclusion: Double balloon enteroscopy in this large, non-selected cohort showed to be an effective and save procedure. The clear advantage of this new technique is the possibility for therapeutic interventions, e.g. coagulation of angiodysplasias, polypectomies and balloon dilatation of Crohn s disease strictures.

225143: The Effect of Scheduled Second Endoscopy Against Intravenous High Dose Omeprazole Infusion As An Adjunct To Therapeutic Endoscopy In Prevention of Peptic Ulcer Rebleeding - A Prospective Randomized Study. *Philip W Chiu, Henry Joeng, Catherine Choi, Kwok Hung Kwong, Siu Ho Lam*

Background From our randomized study, scheduled second endoscopy reduces rebleeding in bleeding peptic ulcers [GUT 2003.52: 1403-7]. Intravenous high dose omeprazole infusion is another strategy established to reduce rebleeding. This study aimed to compare second endoscopy against intravenous omeprazole infusion in prevention of ulcer rebleeding. Patients and Method We recruited patients who had bleeding peptic ulcer with endoscopic stigmata of acute bleeding, visible vessel or adherent clot and hemostasis achieved on primary endoscopy. One group (2nd OGD) received scheduled second endoscopy 16-24 hours after initial haemostasis, and further therapy applied if endoscopic stigmata persisted as above. Another group (PPI) received high dose adjunctive omeprazole infusion. Those patients that developed rebleeding would receive operation if further endoscopic therapy failed. The outcome measures included rebleeding, transfusion, length of stay, and mortality. Results From 2003 to 2005, 335 patients presented with bleeding peptic ulcers. After endoscopic haemostasis, 164 eligible patients were randomized, 84 to PPI group and 80 to 2nd OGD group. 8 (9.4%) in the PPI group and 5 (6.3%) in the 2nd OGD group sustained rebleeding (Chi square test $p = 0.43$; RR = 0.63, 95% CI 0.19 - 2.03). There is no difference in the probably of rebleeding within 30 days upon Kaplan Meier statistics (Log rank test $p = 0.54$) (Fig 1). The number of patients that required surgery for rebleeding was 4 (4.8%) in PPI group and 1 (1.3%) in 2nd OGD group ($p = 0.36$; RR = 0.25, 95%CI 0.03-2.32). There was no difference in the hospital stay, ICU stay, transfusion or mortality between the two groups. Conclusion Both

scheduled second endoscopy and adjunctive high dose omeprazole infusion are effective strategy in prevention of peptic ulcer rebleeding after therapeutic endoscopy.

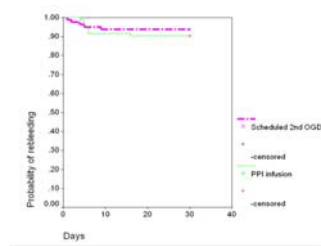


Fig 1

217224: Early Is Good; Is Very Early Better? Does Endoscopy Within 6 Hours of Presentation Improve Outcomes in High-Risk Patients Presenting with Acute Non-Variceal Upper Gastrointestinal Bleeding (ANVUGIB). *Leila Keyvani, Laura E Targownik, Sanjay K Murthy, Shanua Leeson*

Background: ANVUGIB is a serious cause of morbidity and mortality and is associated with a 5-10% case-fatality rate. The evidence to date suggests that performance of endoscopy within 24 hours of presentation reduces the risk of rebleeding and mortality in patients presenting with ANVUGIB. However, it is unclear whether performing endoscopy very early within this 24 hour window provides any additional benefit. The benefits of performing very early endoscopy would likely be most pronounced in high-risk patients, including the elderly, those with evidence of shock on presentation, and patients with a history of severe co-morbid illness. Therefore, we sought to determine if there were significant differences in outcomes between high-risk ANVUGIB patients who undergo endoscopies within 6h of presentation (“very early”) or between 6h and 24h from presentation. (“early”). Methods: We performed a retrospective review of all patients with ANVUGIB who presented to one of our two tertiary care medical centers in Winnipeg, Manitoba between 1999-2004. We selected the patients who were high risk based on their having a clinical Rockall score ≥ 3 . We separated subjects into two comparator groups based on whether they received endoscopy “very early” (≤ 6 hrs) or “early” (6-24 hrs). The primary outcome measure was any adverse outcomes (re-bleeding, need for surgery, mortality, readmission within 30 days of ANVUGIB). The secondary outcomes include the length of hospital stay, and receiving a blood transfusion more than 24h following the initial endoscopy. Results: 221 patients with a clinical Rockall score ≥ 3 underwent endoscopy within 24 hours of presentation. Of these high risk patients, 79 had “very early” endoscopy whereas 142 underwent “early” endoscopy. There were no significant differences in the baseline characteristics between the comparator groups. Patients receiving “very early” endoscopy were significantly more likely to have undergone endoscopic hemostasis (50% “very early” vs. 36% “early”, $p=0.01$). There were no differences in the incidence of adverse outcomes (25% vs. 22%, $p>.02$). Patients undergoing “very early” endoscopy were significantly more likely to have a hospital stay exceeding 5 days (64% “very early” vs. 49%, $p=.032$). Conclusion: There is no difference in the rate of adverse outcomes in high risk ANVUGIB patients who undergo “very early” endoscopy and “early” endoscopy, though patients receiving “very early” endoscopy are more likely to require both endoscopic hemostasis and longer stays in hospital. The optimal timing of endoscopy within first 24 hours should be confirmed in well designed randomized controlled trial setting.

218737: Screening Colonoscopy with Confocal Laser Endomicroscopy (CLE) for In Vivo Diagnosis of Colorectal Neoplasias. *Ralf Kiesslich, Martin Goetz, Arthur Hoffman, Katharina Lammersdorf, Constantin Schneider, Michael Vieth, Manfred Stolte, Peter R Galle, Markus F Neurath*

Introduction: Confocal laser endomicroscopy (CLE) allows subsurface, microscopic imaging of living cells in colonic tissue in vivo. The aim of the present study was to assess the potential of in vivo confocal laser colonoscopy for prediction of histology during screening colonoscopy for colorectal cancer. Methods: Patients with informed consent designated for screening colonoscopy were enrolled in the study and underwent total colonoscopy with CLE (Optiscan, Australia; Pentax, Japan; excitation of 488nm argon ion laser; detection >515 nm; optical slice thickness $7\mu\text{m}$; lateral resolution $0.7\mu\text{m}$; frame rate 0.8 or 1.6 frames/sec with 1024×1024 or 1024×512 pixels). After reaching the cecum, a fluorescent contrast agent (fluorescein) was administered intravenously. During withdrawal of the endoscope, standardized locations (right, transverse colon, rectum) and every circumscribed lesion was examined by using the confocal microscope (fluorescence technique), afterwards biopsies were taken. Confocal images were graded according to the confocal pattern classification for the presence of neoplastic changes and compared with final histology. Results: 280 patients were included in the study. 112 colonic lesions (34 non-neoplastic, 65 adenomas, 9 adenomas with high-grade dysplasia, 4 cancers) larger than 5mm could be endoscopically diagnosed. By the use of CLE, different cellular structures, capillaries and connective tissue limited to the mucosal layer could be identified. Neoplasia could be prospectively predicted by the use of confocal pattern classification with high accuracy (Sensitivity 98.7%; Specificity; 94.1%; Accuracy: 97.3%). All patients developed a transient discoloration of the skin after fluorescein application. However, no further side effects were noted. Conclusions: In this largest prospective study on CLE carried out so far, confocal laser endomicroscopy (CLE) emerged as a safe and well tolerated additional diagnostic option for screening colonoscopy.

Endoscopically identified colonic lesions can be microscopically graduated during ongoing colonoscopy and neoplasias can be predicted with high accuracy. Thus, in vivo histology can be used to target endoscopic therapy or biopsies.

221701: The Aer-O-Scope™ OmniVision system, a 360° Panoramic View of the Colon. Douglas Rex, Thomas Roesch, Bernard Levin, Jorje Pfefer, Nadir Arber

The Aer-O-Scope™ (GI View, Ramat Gan, Israel) is a disposable, miniaturized, self-propelling, self-navigating, endoscope. In a recent human study the cecum was reached in 10 of 12 patients (Vucelic et al, Gastro 2006). The Aer-O-Scope™ includes an advanced vision system with two simultaneous scanning views that provide complete coverage of the entire surface of the colon. A standard front view system (90° forward view) is similar to a conventional endoscope, while a novel and unique imaging system provides a 360° panoramic view of the colonic surface, both in front and behind the scanner device (the OmniView) [Fig. 1]. The OmniView mechanism enables detailed inspection of the entire colon surface area, including those areas behind mucosal folds where polyps may be missed. The electro-optical capsule size is 15 mm OD x 1.5mm long containing a CMOS based digital camera. Its spatial resolution is greater than 1mm within the FOV and the depth of view is from contact up to ~100mm which is adequate for all segments of the insufflated colon. The tip is embedded within a low pressure hydrophilic coated vehicle balloon. This balloon has two functions: it is the moving part of the Aer-O-scope, propelled by gas pressure and it also serves as the imaging center of the device. The capsule is covered by a transparent dome containing the optical lenses protruding from the balloon's front end. White LED's with automatic intensity control provide illumination. The OmniVision system was tested in thirty young female pigs. In all of the Aer-O-scope examinations clear and sharp visualization of the colonic mucosa, similar to that obtained during conventional colonoscopy, was achieved. High resolution images from the digital video camera were received, processed and displayed in real time on a PC screen and digitally recorded.

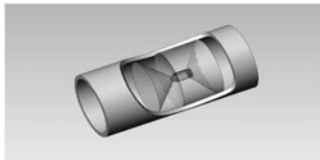


Fig. 1: Simultaneous Frontal and OmniVision Fields of View [FOV]

226090: Clinical Utility of Narrow Band Imaging (NBI) Endoscopy in Patients with Gastroesophageal Reflux Disease (GERD). Prateek Sharma, Amit Rastogi, Ajay Bansal, Srinivas R Puli, Sharad Mathur

Background : NBI is a novel imaging technique that uses narrow band filters (415, 445, 500 nm) and higher intensity blue light (smaller wavelength-less penetration) to show details of esophageal mucosal and vascular patterns. Aim: To compare findings seen only on NBI in pts with GERD and controls and to calculate sensitivity and specificity of these findings for GERD diagnosis. Methods: Reflux pts and controls without GERD symptoms filled 2 validated questionnaires (GERQ and RDQ). Then, distal esophagus was examined by white light followed by using NBI endoscope(Olympus GIFQ240Z, and 115 X) by a single investigator. Features seen only by NBI were noted:number, dilation and tortuosity of intra-papillary capillary loops (IPCL), micro erosions (ME), increased vascularity at squamocolumnar junction (SCJ), columnar islands (CI) in distal esophagus (CI) and ridge villous pattern (R/V) below squamocolumnar junction. NBI images were then evaluated by another blinded endoscopist. IPCLs were classified as increased, dilated or tortuous and other findings noted to be present or absent. Findings were compared using Fisher's exact test; sensitivity and specificity of findings individually and in combination for GERD diagnosis were calculated. Results:72 pts were prospectively evaluated (mean age 60 yrs,67 males)- 48 GERD and 24 controls. NBI revealed a striking contrast of squamous and columnar mucosa at SCJ. Increased number, dilation and tortuosity of IPCLs, presence of micro-erosions and increased vascularity at SCJ were significantly higher in GERD pts compared to controls (Table 1). Accuracy of their combinations are shown in Table 2. Conclusion: NBI shows details of mucosa and vascularity in distal esophagus - IPCLs, micro erosions and increased vascularity at SCJ being significantly higher in GERD pts vs. controls. Also, distinctive features like increased number, dilation or tortuosity of IPCLs have a high accuracy for GERD diagnosis. These findings support an emerging role of NBI in GERD diagnosis

Table 1

	GERD	Controls	p	Sens.	Specificity
ICPL Increased	65.2 % (30/46)	15.3 % (4/26)	0.0005	65.2%	84.6%
ICPL tortuous	83.7 % (36/43)	38.4 % (10/26)	0.001	83.7%	61.5%
ICPL Dilated	81.4 % (35/43)	15.3 % (4/26)	<0.0001	81.4%	84.6%
ME	50 % (23/46)	0 % (0/26)	<0.0001	50%	100%
SCJ	43.4 % (20/46)	7.6% (2/26)	0.006	43.4%	92.3%

R/V	23.9% (11/46)	11.5% (3/26)	0.36	23.9%	88.4%
CI	39.1 % (18/46)	34.6%(9/26)	0.08	39.1%	57.7%

Table 2

	Sensitivity	Specificity
Increased or Dilated or Tortuous IPCL	88.7%	61.5%
Increased + Dilated + Tortuous IPCL	60.5%	92.3%
Increased or Dilated or Tortuous IPCL or ME	93%	61.5%
Increased + Dilated + Tortuous IPCL + ME	32.6%	100%

221924: Image Registered Gastroscopic Ultrasound (IRGUS): 3D Registration of Endoscopic Ultrasound and CT Improves Efficiency and Structure Identification over Standard Endoscopic Ultrasound. *Christopher C Thompson, Nicholas Stylopoulos, Raul San-Jose Estepar, Eigil Samset, Randy Ellis, William Brugge, Kirby G Vosburgh*

INTRODUCTION Although Endoscopic Ultrasound (EUS) is a useful tool for the diagnosis and staging of abdominal and thoracic diseases, it has not been maximally adopted by gastroenterologists. This is due in part to the long learning curve and the lack of confidence in ultrasound interpretation. To overcome these hurdles, we have designed and implemented IRGUS, a novel system that links preprocedure CT with real-time EUS imaging. **MATERIAL AND METHODS** IRGUS aligns preprocedure CT images with real time EUS imaging so that the CT image corresponds to the oblique EUS plane. The operators are also provided with a novel 3D display and important spatial cues that show them how the plane of the EUS is oriented relative to the patient’s anatomy. In this study, novice and expert gastroenterologists were asked to perform an in vivo EUS examination of anesthetized pigs, identifying 8 key anatomic structures in a 5-minute period using traditional EUS and IRGUS. A sensor that was mounted on the echoendoscope allowed the tracking and recording of the motion of the scope during the task. These recordings were then used to calculate the efficiency of performing the exam, which is based on a set of kinematic parameters that we have used and validated in previous studies. At the conclusion of the tasks, participants completed a questionnaire. **RESULTS** Using conventional EUS, novices identified 29% of the structures and experts 50%, within the allotted time. Using IRGUS these rates increased significantly to 71% and 80% respectively (P<0.0001). IRGUS had the largest impact on the localization and identification of the right lobe of the liver and the right kidney. IRGUS also had a statistically significant benefit in assisting novices to identify the pancreatic body and tail. In the questionnaire, all participants rated IRGUS as superior to EUS. The analysis of kinematic data showed that IRGUS increased efficiency of conventional EUS by improving the economy of movements (path length), the smoothness of motion and the response orientation of the operator. **CONCLUSIONS** IRGUS is superior to conventional EUS in the localization and identification of anatomic structures and in various kinematic measures. It enhances procedural efficiency of both experts and novices and allows direct CT confirmation of structures and lesions. This novel technology has the capability of expanding the applications of conventional EUS and may allow for broader adoption beyond its current use. Portions of this work are sponsored by the US Department of the Army. The information does not necessarily reflect the position of the government and no official endorsement should be inferred.

219316: Prospective Comparison of Routine Cytology (RC), Digital Image Analysis (DIA), and Fluorescence in Situ Hybridization (FISH) in Patients Undergoing Endoscopic Ultrasound Guided Fine Needle Aspiration (EUS FNA). *Michael J Levy, Jonathan E Clain, Amy C Clayton, Kevin C Halling, Gavin C Harewood, Benjamin R Kipp, Elizabeth Rajan, Lewis R Roberts, Thomas J Sebo Mark D Topazian, Kenneth K Wang, Maurits J Wiersema, Gregory J Gores*

Background: Prior studies indicate enhanced diagnostic accuracy for DIA and FISH versus RC when evaluating biliary strictures. These tumor markers have never been applied to EUS FNA specimens. We hypothesize that these molecular markers incorporate generic targets capable of identifying a broad spectrum of malignancy. **Aim:** To compare the diagnostic accuracy of DIA and FISH to RC for a broad spectrum of pathologies sampled during EUS FNA. **Methods:** We prospectively evaluated pts with known or suspected malignancy by RC, DIA, and FISH. For clinical purposes, presence of malignancy by either DIA or FISH (DIA/FISH) was considered diagnostic. However for study purposes separate confirmation of malignancy was required for diagnosis. Pts with benign disease were followed at least 12 months and charts were reviewed to determine the accuracy. **Results:** 39 pts were enrolled and each diagnostic test performed upon samples collected from 42 sites to evaluate lymphadenopathy (n=19), solid pancreatic mass (n=12), cystic pancreatic lesion (n=7), esophageal or gastric wall mass (n=3), and thyroid mass (n=1). Malignancy was detected in 30/42 pts, including esophageal squamous cell carcinoma, esophageal adenocarcinoma, gastric adenocarcinoma, pancreatic adenocarcinoma, pancreatic mucinous cystic neoplasia, intraductal papillary mucinous neoplasia, metastatic forearm sarcoma, small cell lung cancer, non small cell lung cancer, thyroid follicular

carcinoma, malignant gastrointestinal stromal tumor, melanoma, adenocarcinoma of unknown primary, and lymphoma. The sensitivity, specificity, and accuracy of DIA/FISH versus RC for detection of malignancy were 97%, 100%, 98% versus 87%, 100%, 90% respectively. (Table 1) No false positive results occurred for DIA or FISH. The one failed diagnosis for DIA/FISH was in a patient with a malignant gastrointestinal stromal tumor. DIA/FISH correctly identified dysplasia or malignancy in 5 pts with cytology interpreted as benign, atypical, or suspicious. The final diagnosis in these pts was pancreatic adenocarcinoma

(n=3), esophageal squamous cell carcinoma (n=1), and IPMN (n=1). No complications were identified. **Conclusion:** Our findings suggest that in pts undergoing EUS FNA that DIA and FISH have a higher diagnostic accuracy than RC. These data suggest that these tumor markers incorporate generic targets as suggested by the high diagnostic sensitivity in this cohort of pts with diverse pathologies.

	DIA/FISH	RC
Sensitivity	97%	87%
Specificity	100%	100%
Accuracy	98%	90%

220868: Safety of Fine Needle Aspiration (FNA) during Endoscopic Ultrasound (EUS): A Prospective Study.
 Mohammad Al-Haddad, Catherine M Hodgens, Robin D Toton, Seth A Gross, Kyung W Noh, Surakit Pungpapong, Timothy A Woodward, Michael B Wallace, Massimo Raimondo

Background: FNA is commonly performed in conjunction with EUS procedures. There is limited prospective data on complication rates. Hypothesis: In prospective assessment, FNA is a safe procedure with limited complications in a high volume EUS referral center. Methods: Approximately 1200 patients undergo EUS at Mayo Clinic Jacksonville on annual basis for different indications. Of those, about 40% will undergo FNA. Between April and October 2005, 230 patients who underwent EUS- FNA were included in this study. These patients were screened for post-procedural complications including abdominal pain, nausea, vomiting, fever, gastrointestinal bleeding and dysphagia. Complications were assessed on day 0 by direct examination and at day 30 by a telephone call. Inquiries were made about emergency room visits or hospitalizations during the same period of time. Results: Table 1 demonstrates location of FNA for all patients (n=230). Complete follow up information was obtained on 207 patients (90%). -Day 0: Three patients were admitted to the hospital for observation. Two patients had abdominal pain after pancreatic cyst FNA and one was observed after mediastinal lymph nodes FNA for chest pain. All three patients were discharged within 24 hours of admission. There was no requirement of blood transfusion and no evidence of pancreatitis or infection in any of the hospitalized patients. One patient reported to the ER after EUS-FNA and was sent home on oral analgesics after appropriate evaluation. -Day 30: Four patients expired during the first month after EUS from primary disease process (3 had pancreatic cancer and one had lung cancer). Five patients were hospitalized for planned elective surgeries during the same period of time. There was no unplanned morbidity or mortality attributable to EUS-FNA. Conclusion: FNA is a safe intervention in patients undergoing EUS in high volume academic center with post procedural self-limited complication rate of 1%.

Table 1

FNA by Location	n=230
Pancreatic masses and cysts	103
Mediastinal masses and lymphadenopathy	74
Abdominal and pelvic lymphadenopathy	20
Gastroduodenal submucosal masses	8
Liver	7
Rectal	3
Miscellaneous	15