

Capsule Endoscopy

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Good morning. I'm Blair Lewis. We will cover every aspect of capsule endoscopy. I'm going to give an orientation to each of the abstracts before we talk about them.

If you are not aware, there is a conference called the ICCE – International Conference on Capsule Endoscopy that is held annually. In March, we had our fifth conference. In 2005, there were six consensus statements that were published in the October issue of *Endoscopy* (*Endoscopy* 2005; 37, 10:1060-4). A consensus statement is listed concerning inflammatory bowel disease and capsule endoscopy. It said, in essence, that capsule endoscopy is better than other modalities in identifying ulcers of the small intestine. It has potential for making a firm diagnosis in a patient with indeterminate colitis. It certainly has value in patients who have had unexplained abdominal symptoms which fits in with suspected Crohn's disease. It also said that we really need to have a scoring index to assess disease severity and mucosal disease severity. They also said that it may help and assess mucosal healing after therapy. So, capsule endoscopy may be a future tool to help us determine healing. It may also help us in determining disease recurrence in people who are post-op and it may help in people with a family history of inflammatory bowel disease who are asymptomatic. We may have learned more about the natural history of the disease. If somebody were to do a study in asymptomatic family members, we could actually see the onset of the disease. We have this concept that Crohn's disease starts as a mucosal disease. Early on, there is mucosal inflammation and then as the disease progresses, you get transmural inflammation and then you get transmural edema, and then you can have abscess formation, you can have stricturing, scarring, and all the rest. We've known since I was in my training in the 1980's that at the onset of symptoms, when there is a demonstrable change on a small bowel series, the average lag time is three years. There are patients out there who we classify right now as having IBS and some subset of those patients are going to actually have Crohn's disease. What we don't know is, if we make that diagnosis earlier, whether we can actually change their outcomes. If you're treating them symptomatically, before you make that final diagnosis, does that hurt them? Does that change them? Do you change the natural history of the disease? We do not know. Certainly, it's intriguing to think that if we can make the diagnosis earlier, we might actually change the disease progression and the natural history of the disease. That's where capsule actually fits in. Capsule can identify mucosal disease better than any other technology. That has actually been well-documented in multiple papers. We will go through a meta-analysis that will answer it for everybody. In 2005, the consensus statement actually defined suspected Crohn's disease. They tried to hammer down a guideline for future work. They said, choose two of either pain or diarrhea, iron deficiency anemia, elevated sedimentation (SED) rate or C-reactive protein (CRP), hypoalbuminemia, extraintestinal manifestations, family history, or abnormal serologies. They said pick two of those and you have suspected Crohn's disease and you should have a capsule endoscopy. Indeed, in 2006 the consensus actually took this to a whole different level; one that is so much more complex. It becomes a "Chinese menu" where you choose one from column A and one from one of the other columns

and it is very, very detailed, though quite user-unfriendly. In the interim, between the 2005 and 2006 consensus, there was a meta-analysis by Triester published in the *American Journal of Gastroenterology*. They looked at 11 studies comparing capsule to small bowel series, to CT angiography, and to colonoscopy with ileal intubation, to see how good capsule endoscopy was. Capsule endoscopy was superior to all those other methods. When it was compared to CT angiography as well as magnetic resonance (MR) enterography, capsule endoscopy was far and away better in diagnosing proximal disease, and it was about the same in diagnosing ileal disease. When you actually split the subgroups into patients who have known Crohn's disease and those who have suspected Crohn's disease, there was actually no difference in the yields. That brings us almost up to the present day. The consensus group, working in March, 2006, looked at all the previous literature and at that meta-analysis and said, "Well, there are problems with the literature." There's really no gold standard. We don't have a gold standard to diagnose Crohn's disease. You see an abnormal X-ray; you call it Crohn's disease. You get non-caseating granulomas on an ileal biopsy maybe once every five years. If you get that, you jump for joy but other than getting that, there is no gold standard. Most of the literature is retrospective in nature. The prospective studies are generally underpowered and the most important thing of all is that there is no scoring index. Nobody is working on the same playing field. For example, the famous paper that everybody quotes is based on a nationwide call in Israel for people who had suspected Crohn's disease. They said anybody with abdominal pain, diarrhea, iron deficiency anemia, negative small bowel series, negative colonoscopy, and negative upper endoscopy, send them to me and I will do capsule endoscopy. They collected 17 patients and did capsule. The report was that in 70% of those cases they found ulcerations and Crohn's disease. We don't actually know what he found. We don't know if he found a single ulcer, severe ulceration, disease activity, we have no idea of how to actually confirm the findings that the author states. We trust it, but we really are not talking a common language. So, the consensus for 2006 says that we definitely need a scoring index. We definitely need a definition of thresholds to make the diagnosis of Crohn's disease on capsule endoscopy. We have to correlate that index with other indices. At the same time, they also said that it was unlikely that you are going to be able to differentiate NSAID damage from Crohn's disease on capsule endoscopy. Most likely, you are not going to be able to know that, at least that's what the consensus indices say.

I want to stop and talk about the other indices that are out there. In clinical practice, we don't use indices but when you read the literature, everybody uses the Crohn's Disease Activity Index (CDAI); sometimes you'll read the short version of the CDAIs, a one-day determination instead of a seven-day determination. These are very subjective things. How many times you go to the bathroom over a week. I come from Sinai and we've all sat through discussions on what is a bowel movement. Is it just going to the bathroom and closing the door? Is it actually something coming out? Is it the urge to go? These conversations would last about an hour. When it comes to indices, those are subjective measures. Do you have pain? You don't have pain – so forth. The placebo response to those other measures was ridiculously high. As a matter of fact, the placebo response on CDAI in Crohn's disease studies is supposed to be between 15-16% and that's because when you put somebody into a study and you say, okay, we're going to call you twice a week to see how you are doing, they feel better. You give them a placebo and they feel better because you care about them. You're calling about them; you're following up with them. The placebo response on symptom scores is gigantic. When we're looking at mucosal healing versus the people's symptoms, there is generally no correlation. For example, there are scores in the literature that are strictly based on laboratory studies – sed rate, albumin, anemia, and stuff like that. There are several of those scores and they do not correlate with CDAIs. Never do. You have to have that in your head when people call and say does this endoscopic index, does this capsule endoscopy, correlate with the CDAI? It never will. Answer this for yourself, "Is it more important that the patient feels better or is it more important that the mucosal disease disappears?" First, you have to take a detailed history, call them, find out how they feel, and then you do a capsule endoscopy. It's totally different management. There's definitely a different approach to the way we deal with Crohn's disease. The other thing I should mention before we

get into the abstracts is retention rates. People are very concerned about putting capsules in patients who have Crohn's disease because they're worried about capsule retention. The big concern in Crohn's disease is that you are going to end up having capsule retention in somebody who would otherwise be treated medically. What that rate of retention is, nobody is really quite clear about. It has been reported to be between 0 and 13%. The numbers are actually quite small and the 13% number is when we put capsules in people with known Crohn's disease and suspected strictures. The bulk of these people, virtually all of these people, had a normal small bowel series. Small bowel series is not the way to clear it. That won't protect you from retention. We had to figure out some way of trying to screen these people ahead of time. Some people have said that CT enterography plays a role and there may be patency capsules. The problem with patency capsules from the articles that were published in the last year in *Endoscopy* is that the initial capsule had a plug at one end and the capsule was supposed to dissolve. As the capsule started to shrink and dissolve overnight, it would become soft enough that it would actually plug a stricture and you would get an acute obstruction. Patients would develop severe abdominal pain. There were two patients in one paper who actually ended up with small bowel obstruction and ended up having surgery. One person had emergency surgery and one finally passed the capsule. The thought was they've got to get a capsule that actually dissolves better. There's a new capsule that Given has devised called Agile™ recently approved by the FDA. Agile™ has two plugs at either end so when it dissolves, it dissolves quickly. That actually is going to be a great tool. Theoretically, what you can do is give it to the patient on their visit and say, "You will have a capsule a week from Thursday and four days before you come for your capsule, you're going to swallow this thing." When they come to the office that morning, you can actually scan them and see if it is actually in them. If it is still in them, you are going to have to take an X-ray to see if it is in their colon, maybe they are just constipated, but if it is still in them, you're not going to put a video capsule in them. Agile™ is going to be a tremendous help and I can actually see using it in other patients – people with chronic abdominal pain, who you think may have obstruction, but you're not sure.

There are two scores for capsule endoscopy that have been written. One is actually in abstract form from Dr. Niv that is in the recommended reading section. There is a real score that Given has agreed to put into RAPID 5 for its next software release. That is a scoring index that is based on splitting the small bowel passage time into quartiles and then there are different parameters that are going to get graded. There has been a group working on this for the past several years and the parameters have changed over time. When you read other papers such as the Niv scoring index, he grades things like edema and erythema. Early on, we realized that what you thought was red and what he thinks was red are different, and there was no great way of measuring redness or edema. There was such intraobserver variability that we threw it out very quickly. What we are left with are the parameters that are measured on this index. Villous appearance – whether or not the villi are normal and whether or not you think they are edematous. We've included something called denuded lesion because there is some thought that the loss of villi, these are pink center with pale borders, that they may be a harbinger of NSAID damage. We've left it in the index to do some studies to really see if we can differentiate NSAID damage. Maybe the pathophysiology of the ulcer is different, we don't know. Obviously, you are going to measure ulcers and finally stenosis. There are a variety of scales that are built into this number: extent of the lesions, how much of the bowel length is involved, the size, how much of the picture that you have of the worst ulcer is occluded by the ulcer. There are a variety of other descriptors that are built into the score. The idea is that with RAPID 5, this will be a pull down menu and you will be able to click on it and the score will actually appear. We are not up to having numbers in the score yet; we're just trying to lower intraobserver variability. There's actually going to be a prospective trial and we put scoring into a bunch of other trials to validate it.

That brings us up to where we are as we look at the abstracts.

Abstract 225505: “Mucosal healing in the small intestine detected by wireless capsule endoscopy”

This abstract is an extension of the ideas that I just presented to you. This is the concept of using capsule endoscopy to make sure that there is mucosal healing. They took patients (N=14) with known Crohn’s disease, who have had capsules, were treated with a variety of therapies whether it be steroids, azathioprine, methotrexate, infliximab and the rest, and then had repeat capsules. They improved CDAs – they went from an average of 316 to 139 and they reported that capsule endoscopy did not change. It did not show mucosal healing, especially in the steroid group. Again, no index. There is no index to measure. They just talk about specific lesions – cobblestoning, fissures, ulcers, aphthae, erythema, and strictures. I’ll just tell you that there is high intraobserver variability in cobblestoning; so we also took that out. There was no difference between aphthae and ulcers or mucosal breaks. These are all names for the same thing. In our heads, aphthae are little, round ulcers and ulcers are big, round ulcers – or irregular ulcers – but in essence they are the same. In nomenclature, they are the same. I think as we go through this we should realize that mucosal breaks are mucosal breaks no matter what. I don’t care what size or shape, unless there is an index to actually measure them.

This was very tempting, to say that capsules may be preventing you from mucosal healing, but this is so rudimentary, so early on and there is no index to accurately help you. Here they give you an index for the CDAI. They say CDAI improves. It should not surprise you that CDAI improves. I already told you, they’re in a study, they’re being measured, CDAI is always going to improve. Their numbers are small. What happens to the capsule, I don’t know. This is all so early. The idea is that people are pushing envelopes. People are starting to use the capsule in this regard and that’s the whole point. That’s the take away from that abstract.

Abstract 216360: “Wireless capsule endoscopy in suspected Crohn’s disease: Correlation of findings with IBD serology”

This abstract is by Jonathan Erber. He is trying to correlate capsule findings with IBD serologies. They’ve taken this a step further and are actually splitting patients into four different groups. Twenty-four patients had abdominal pain, diarrhea, guaiac positive stools and iron deficiency anemia. Twenty-four had pain and diarrhea, 11 pain only, and 23 indeterminate colitis. All had pan endoscopy and small bowel series. They try to define their capsule findings and split them into groups. There is no index, but it is a step further into that process. They define the capsule a definite for Crohn’s disease as having more than three ulcers, edema, nodularity, and/or stricture. They define a possible category, which is a single ulcer, edema, and nodularity, non-specific changes including erythema, edema and mucosal breaks. Mucosal breaks are ulcers, so I’m not really sure what that means. They go back to the four groups of patients who had capsules and group them into different capsule findings and looks at their serologies. This shows a very good association between the serologies and the capsule findings in the patients who had definite disease.

What you see at the end is that 84% of patients with positive serologies had definite or possible capsule findings. I was taught that serologies are just a tool to differentiate Crohn’s disease from ulcerative colitis, but they may play a role in making the diagnosis of Crohn’s disease. It actually goes against what the literature says. That’s okay, that’s what we do in practice. He’s actually trying to bolster that concept that we can use serology to actually make that diagnosis. And that goes back to suspected Crohn’s disease, where if you have positive abnormal serologies, you warrant a capsule to actually look inside and see. I think this is a step in the right direction. It’s pretty interesting and goes along with what we do in clinical practice.

Abstract 223829: “Is it possible to differentiate Crohn’s disease from NSAID-enteropathy by capsule enteroscopy?”

This comes from the home of NSAID enteropathy in England. They have a huge population of NSAID patients that they do capsule endoscopy on. The point of this is that you can’t really differentiate the two. In 2004, when we initially used the rudimentary capsule index to look at NSAIDs versus Crohn’s disease, they were very similar. There is a lot of overlap. You can’t look at severity of disease and say the more severe is Crohn’s, the less severe is not.

Abstract 224178: “M2A patency capsule in small bowel Crohn’s disease”

This is using the standard patency capsule, an ingestible, time-controlled, dissolvable capsule the same size as PillCam™. This is not the Agile™ system. This comes out of Italy where they’ve had certification for a long time at this point. It’s a small paper and does not compare to some of the bigger multicenter trials that have been reported, but I put this in to talk to you about patency. They used 16 patients with suspected Crohn’s disease. Ten of the 16 had abdominal pain and/or abdominal mass and five patients had diarrhea. One patient is not accounted for. All patients were integrated with small bowel series followed by the patency capsule. In some of these patients, they actually developed abdominal pain as well, as this capsule dissolved inside. Nobody became acutely obstructed and nobody required surgery. That is the hallmark take home from the French data: that people develop abdominal pain after patency, you don’t have to scan them, and you just can’t put a video capsule in them. If they develop abdominal pain, you know the stricture is so narrow that as this thing is dissolving, it’s having a hard time getting through the stricture and those are the people that should not get a video capsule. They say that it shows clinical utility in most patients, but it basically just tells you the same information you already knew. There’s nothing new here. This is the same old stuff, but it gave me an excuse to talk to you about patency. You can’t talk about IBD and capsule without talking about patency.

Question: You have a patient with Crohn’s disease and they have a stricture or they have edema and the capsule is blocked, what do you do?

Answer: There are no data on treatment for capsule retention. Retention is currently defined as having a capsule stuck in the small bowel for two weeks. If the capsule is still not passed after two weeks, then it is considered retained. I’ve done capsule studies that I thought would result in retention and in two weeks it’s gone. If retention is newly diagnosed, some people have given steroids. There is actually one report in the pediatric literature where they gave steroids and the capsule passed so you can certainly give a course of steroids. You could think about Remicade. Remicade now has a brand new black box warning around it. So, you may not want to use Remicade. Certainly you do not want to use Remicade as a one-time dose anyway because when you are pushed to Remicade, you should really be putting people on it chronically. People have talked about using double balloons, but if there is really a Crohn’s stricture, the chances of actually being able to dilate that through a double balloon from below and then extract the capsule with a basket would give me pause because of the risk of dilation although it can be done. There are tools that allow you to do that. You could also operate on the patient. When they did the initial studies on the patency capsule, the study centers would look for the worst of the worst – these horribly long strictures on small bowel series and put the patency capsule in those. In the beginning, it’s quite amazing because on X-ray it can look horrible and it can be all spasm and the patency capsule would just fly through those areas. There is absolutely no way to know. It actually took a long time to get enough patients for the patency capsule to be proven to be actually efficacious because of that.

This next abstract is also an eye-opening idea, a new concept.

Abstract 225797: “The role of capsule endoscopy in the evaluation of patients with unexplained growth failure”

The FDA has cleared capsule use in people over the age of 10. There are kids that can have growth failure because of unexplained reasons and IBD could be the cause. These authors looked at a group of patients. This was a retrospective study. There were eight kids that had growth failure and they all had normal small bowel series. They had normal upper endoscopies and colonoscopies. They put capsules in and five of the eight had multiple small bowel ulcerations due to Crohn’s disease. The thought is that if you can identify Crohn’s disease and you treat it, certainly you get rid of the growth failure and these kids start to grow. This is a new take on capsule endoscopy. This is an eye opening idea that capsule can be used again in these people with unexplained symptoms and you can diagnose Crohn’s disease early on.

Abstract 220503: “A novel diagnostic approach in patients with indeterminate colitis: Wireless capsule enteroscopy”

This is exactly what the consensus group said in 2005 and in 2006, that capsule could have a role in patients with indeterminate colitis. When you have patients that you’re not sure if it’s ulcerative colitis or Crohn’s colitis and you do a small bowel study and a capsule identifies ulcerations in the proximal bowel, you have Crohn’s. Capsule has been shown to identify ulcers in the proximal bowel in people with ileal Crohn’s disease. People debate whether or not knowing that increased extent of disease changes your management. If I know that the person already has ileitis and now I know that they have a couple of ulcers up in their jejunum, does that really change what I am going to do for their ileitis? Maybe, maybe not. In patients with indeterminate colitis, finding ulcerations upstream would actually confirm that diagnosis of Crohn’s disease and tell them they don’t have ulcerative colitis. That is exactly what this paper looks at. It is a small group, 11 patients. They were able to identify findings suggestive of Crohn’s disease in 36% of the patients. They actually stopped their patients from being on steroids for one month. I think everyone would agree that month is a great washout period if it’s actually true. They were able to find ileal inflammatory changes. Again, conceptual and could be used in that way.

The last two abstracts round it out in using capsule in suspected Crohn’s disease.

Abstract 226654: “The utility of wireless capsule endoscopy in the evaluation of suspected Crohn’s disease in the pediatric population”

This group from Milwaukee is trying to come up with a threshold to make that diagnosis. They say that diagnosis of Crohn’s disease is if you had more than three ulcers, and you are suspicious if you have less than or equal to three ulcers. The question is what is the threshold? Does one ulcer give the person a lifetime diagnosis of Crohn’s disease? Do two ulcers do it? These are answers we don’t know. We need more studies on normals. We need more studies on NSAIDs. The studies need to be prospective, and we need to be scoring the index in order to come up with this. Again, they used this in the pediatric population and they were actually able to come up with a diagnosis of Crohn’s disease. The point is trying to come up with an idea of how you make that diagnosis. What are people doing to grapple with this idea of capsule findings?

That goes on to the final abstract.

Abstract 211588: “Clinical outcome of patients submitted to capsule endoscopy for suspect Crohn’s disease”

This group divided their capsule findings into three groups – Group A was severe stricturing lesions mandating surgery (nobody would debate that), Group B was moderate inflammatory lesions that had to be investigated by invasive means, and Group C was minimal inflammatory changes including lymphoid hyperplasia of the terminal ileum which we would consider normal. They reported a sensitivity, specificity, positive and negative likelihood ratio of 93%, 84%, 5.8 and 0.08 for diagnosis of small bowel abnormalities suggestive for Crohn’s. They suggest that capsule doubles the pretest probability of having small bowel disease over clinical judgment and small bowel X-ray. Again, they are trying to somehow categorize severity of disease, trying to come up with a way of deciding who truly has Crohn’s disease and who does not.

All the papers are similar. We need a scoring index. Until then, we can’t really know what we are actually seeing, what is actually real and what is not real. Thank you for coming.

Abstracts Discussed

225505: Mucosal Healing in the Small Intestine Detected by Wireless Capsule Endoscopy. *Ruediger Schoo, Carsten Buenin, Johann Ockenga, Jutta Wirth, Jutta Weber, Guido Schachschal, RHerbert Lochs, Voderholzer Winfried*

Background: Wireless capsule endoscopy may be useful in the follow up of small intestinal Crohn's disease (CD) in order to detect healing of mucosal lesions. However, data on the follow up of patients with small intestinal CD are rare. Aim of our study was healing during standard therapy. Methods: Patients with active CD (CDAI > 200) were enrolled. Before the WCE-procedure all patients underwent gastroscopy, colonoscopy, small bowel radiology (CT-enteroclysis), and abdominal ultrasound. After exclusion of relevant strictures (< 1 cm diameter) by CT enteroclysis and a regular preparation like for colonoscopy, the patients underwent wireless capsule endoscopy. All capsule videos were evaluated by a standardized form that gave information about specific lesions for CD (cobblestoning, fissural ulcers, aphthae, erythema, strictures). After that, standard medical therapy was initiated. After 2 months, WCE, colonoscopy, and ultrasound were repeated. Results: So far, 14 patients have been examined (f/m = 7/7, 35, 1 ± 11.7 yrs). All Patients had a clinical improvement (CDAI 1: 316 ± 108.64, CDAI 2: 139.43 ± 87.9) after therapy with glucocorticoids and mesalazine (10 patients), azathioprine (2), infliximab (1) and MTX (1). After 2 months of therapy, there was no change with respect to the colonoscopic activity. Moreover, there was no change in kind and frequency of Crohn typical lesions seen in WCE in patients who received glucocorticoids. The patient on MTX had pathological lesions all over the small intestine. After treatment the extent was limited to the terminal ileum and the proximal lesions had disappeared. The one patient who were on azathioprine showed no change. The other patient had almost a complete disappearance of lesions. The patient who received infliximab had a remission of about 50% of his ulcerations. The only significant change was a minor change of results of abdominal ultrasound (p= 0,034). Conclusions: WCE is a suitable method for examining mucosal healing in CD. Standard therapy using glucocorticoids does not result in mucosal healing in the small intestine, although in patients who received an immunomodulatory or immunosuppressive medication (infliximab and azathioprine) the lesions got rare.

216360: Wireless Capsule Endoscopy in Suspected Crohn's Disease: Correlation of Findings with IBD Serology. *Jonathan A Erber, William F Erber, Sharon K Sagiv, Susan Sagiv*

INTRODUCTION: Wireless Capsule Endoscopy (WCE) provides direct visualization of mucosal abnormalities throughout the entire small intestine. IBD serologies have been shown to be a useful marker in IBD. The combination of WCE with IBD serologies may be the most sensitive means of diagnosing and identifying the extent and degree of small intestinal Crohn's disease (CD). METHODS: A retrospective analysis of 86 patients who underwent WCE with the PillCam Sb (Given Imaging, Yoqneam, Israel) for suspected CD between January 2003 and November 2005. 4 groups of patients were identified: 28 with abdominal pain, diarrhea, guaiac + stools, and iron deficiency anemia; 24 with abdominal pain and diarrhea; 11 with abdominal pain; 23 with indeterminate colitis. All patients underwent pan-endoscopy, most ileoscopy, and small bowel series. WCE studies were reviewed by 2 independent readers. Findings were classified as definite or possible for CD, non-specific, or normal. Definite findings included the presence of greater than 3 ulcers, numerous aphthous ulcers, edema, nodularity, and stricture. Findings considered as possible included the presence of a single aphthous ulcer with edema and nodularity. Non-specific inflammatory changes consisted of erythema, edema, nodularity, and mucosal breaks. IBD serologies (ASCA IgA, IgG, p-ANCA) were obtained from 52 patients. Patients on aspirin, clopidogrel, NSAIDs, or with known CD, were excluded. RESULTS: There were 53 females, 33 males; average age 47.4 (range 11-82). 9/28 patients with abdominal pain, diarrhea, guaiac + stools, and iron deficiency anemia had definite Capsule Endoscopy findings (4 with diffuse small intestinal involvement), 5 possible, 11 non-specific, 3 normal. 3/24 patients with abdominal pain and diarrhea had definite findings, 6 possible, 13 non-specific, 2 normal. 1/11 patients with abdominal pain alone had definite findings (diffuse small intestinal involvement), 2 possible, 8 non-specific. 4/23 patients with indeterminate colitis had definite findings, 6 possible, 7 non-specific, 6 normal. 84% (16/19) of patients with + IBD serologies had definite or possible capsule findings; 10/12 patients with definite findings had + markers; 6/15 with possible findings had + markers; 2/21 with non-specific findings had + markers; 1 with normal findings had + markers. Conclusion + WCE findings for CD strongly correlated with + IBD serologies. + WCE findings for CD were highest for patients with abdominal pain, diarrhea, guaiac + stools, and iron deficiency anemia. Combining WCE with IBD serologies improves the diagnostic staging of patients with CD. This may ultimately impact on therapy.

223829: Is it Possible to Differentiate Crohn's Disease from NSAID-Enteropathy by Capsule Enteroscopy? *Laurence P Maiden, Bjarni Thjodleifsson, Sam Adler, Winfried Voderholzer, Ingvar Bjarnason*

Background: Introduction of wireless Capsule Enteroscopy (CE) added a new dimension into the investigation of small bowel disease. It is emerging as a first line investigation for the detection of small bowel Crohn's disease. It also appears to be the investigation of choice for the diagnosis of NSAID-enteropathy, which affects over 50% of patients receiving these drugs long-

term. Furthermore NSAID-enteropathy is associated with serious outcomes (bleeding, perforation and obstruction) as frequently as NSAID-gastropathy. Indeed it has been suggested that certain NSAID-induced small bowel damage may be indistinguishable from that of Crohn's disease. **Aim:** To assess if it is possible to differentiate between Crohn's disease and NSAID-enteropathy by CE. **Methods:** The pathology recorded by CE from 18 patients with established small bowel Crohn's disease and 13 with NSAID-enteropathy were localised and quantitated by an established damage score (incorporating reddened (inflamed) folds, denuded areas, petechiae and mucosal breaks (erosions and ulcers)). Four experienced clinicians who had no knowledge of the clinical or demographic details of the patients read the images independently. Each made a diagnosis of Crohn's disease or NSAID-enteropathy ('definite' or 'likely'), based on their overall impression of the images. **Results:** There was a high rate of concurrence (over 95%) between the investigators regarding the localisation and type of damage. The number of denuded areas and petechia did not differ significantly between the diseases ($p < 0.1$). The median number of mucosal breaks (median 10 (range 1 - 26) for Crohn's disease and 2 (range 1-18) for NSAIDs) differed significantly ($p < 0.05$) between Crohn's disease and NSAID treated patients. However 3 (23%) patients with NSAID-enteropathy were incorrectly labelled as 'definite Crohn's disease' (3 of the 14 diagnosed as 'definite Crohn's disease') and 3 (17%) patients with Crohn's disease were incorrectly labelled as either 'definite' (1 of 9 diagnosed as 'definite') or 'likely' (2 of 4) NSAID-enteropathy. **Conclusions:** CE images of the small bowel show that NSAID-enteropathy has a similar range of pathology as seen in patients with Crohn's disease which further corroborates the importance of the small bowel in the overall gastrointestinal damage of NSAIDs. In the absence of a clinical history experienced CE image readers arrive at an incorrect diagnosis in 20% of cases.

224178: M2A Patency Capsule in Small Bowel Crohn's Disease. *Pietro Occhipinti, Silvia Saettone, Laura Broglia, Paolo Gorini, Ferruccio Rossi*

BACKGROUND: Pillcam is a noninvasive diagnostic tool for the study of entire small bowel. The small bowel is the most commonly affected site of Crohn's Disease (CD). Due to the risk of retention, CD is no yet completely established indication to Pillcam above all in pts with clinically suspected strictures. Traditional radiological methods offer some options though associated with false-negative results. The M2A Patency Capsule (M2APC) consists of an ingestible, time-controlled, dissolvable capsule with the same size as Pillcam. It is composed of a dissolving lactulose body surrounding a radio frequency identification tag, that can be relieved by a radio frequency scanner. **AIM:** To assess the ability and the safety of M2APC in detecting intestinal strictures in pts with suspected small bowel CD before undergoing Pillcam. **METHODS:** A total of 16 pts (8 Male and 8 Female, mean age 37 yrs) with suspected CD was studied: 10 pts with clinical pattern of recurrent cramping abdominal pain and/or abdominal mass and 5 pts with clinical pattern of diarrhoea. All pts were first investigated with a small bowel follow-through (BFT) and subsequently with ingested M2APC. The presence of M2APC was assessed with scanner after 36 hours and, if still present, after 48 and 72 hours. If M2APC was detected after 72 h or disintegrated in the stool, the test was considered "pathological" and the occurrence of a stricture was suggested. **RESULTS:** In 10/16 pts (9 pts with clinical pattern of recurrent cramping abdominal pain and/or abdominal mass and 1 pts with clinical pattern of diarrhoea) M2APC test was "pathological". Two of them complained abdominal pain and nausea, probably due to the blockage of M2APC, quickly improved probably for capsule dissolving. In 7/11 pts with clinical pattern of recurrent cramping abdominal pain and/or abdominal mass BFT showed no reduction of small bowel lumen. Pillcam was uneventfully performed in 6 pts with normal M2APC test, 2 of them with BFT-positive for small bowel stricture; in 5/6 pts Pillcame disclosed lesions indicative for CD. **CONCLUSION:** Our preliminary results indicate M2APC as a simple and safe test. M2APC should be used before undergoing Pillcam in pts with suspected small bowel CD and in particularly those clinically suspected for stenosis. Moreover M2APC seems to be a diagnostic tool more sensitive than BFT to detect small bowel functional strictures.

225797: The Role of Capsule Endoscopy in the Evaluation of Patients with Unexplained Growth Failure. *Libia Moy, Jeremiah Levine*

Background: Poor weight gain and growth can be caused by innumerable medical, nutritional, behavioral, psychological and environmental disease states. Although we know that 15 to 40% of children with Crohn's disease have growth failure, the diagnosis is not always readily apparent. Negative findings on routine serologic, radiographic and endoscopic diagnostic studies can result in significant delays before appropriate therapy can be instituted. Lack of a definitive diagnosis also frequently leads to additional and potentially costly testing in an attempt to identify the etiology of the poor growth. The aim of this study is to evaluate the role of the Capsule Endoscopy (CE) as part of the evaluation of older children and adolescents with unexplained growth failure. **Methods:** We retrospectively reviewed the records of all children with unexplained growth failure who underwent CE at Schneider Children's Hospital between August 2002 and November 2005. **Results:** Eight patients (4 males and 4 females, mean age of 12.1 ± 3.5 year old, mean weight of 30.6 ± 9.4 Kg) had CE studies to review. Laboratory studies including CBC, biochemistry profiles and celiac serologies were negative in all subjects. Only 1/8 had an elevated ESR. All had normal small bowel series performed prior to the CE. All had both endoscopically and histologically normal esophagogastroduodenoscopy and colonoscopy as well. In 5/8 subjects, multiple small bowel aphthous ulcerations consistent with Crohn's disease were identified by CE. Two subjects had normal CE and one had an incomplete CE study due to delayed passage of the capsule. **Conclusions:** Sixty three percent of older children and adolescents with unexplained growth failure and

normal small bowel series were found to have Crohn's disease involving the small intestine. To avoid further costly testing for possible endocrine or psychiatric causes of poor growth, CE should be considered as part of the armamentarium in evaluating children with severe unexplained growth failure.

220503: A Novel Diagnostic Approach in Patients with Indeterminate Colitis: Wireless Capsule Enteroscopy. *Raffaele Bennato, Francesco Manguso, Agesilao D'Arienzo, Giovanni Lombardi, Gianfranco De Dominicis, Francesco P D'Armiento, Oscar Nappi, Antonio Balzano*

BACKGROUND/AIMS: the term indeterminate colitis was indicative of inflammatory bowel diseases in which there were difficulties in distinguishing between Crohn's disease and ulcerative colitis in colectomy specimens (10-15% of cases). Today the significance of the term is more complex; it is linked not only to the histological findings but it is a clinic-pathological definition with many aspects not yet well characterized. Wireless capsule enteroscopy (WCE) is able to directly visualize the entire small bowel mucosa and identify superficial lesions. The aim of our study was to evaluate small bowel mucosa by WCE in patients with indeterminate colitis at the onset. **MATERIALS:** from October 2004 to November 2005, 11 patients (M/F:5/6; mean age 38.9 yrs, range 26-58) consecutively admitted to our two Units with a first diagnosis of indeterminate colitis, were enrolled. The selection was made in a population of patients with symptoms suggesting colonic inflammatory bowel disease by a ileocolonoscopy. Mucosal biopsies were collected in terminal ileum and in all colonic segments (at least three specimens in the cecum, every 20 cm and in the mucosal areas judged to be the most severely inflamed). Histological assessment was made by two pathologists who were blinded to each other's evaluation, according to guidelines of the British Society of Gastroenterology. Discordances were resolved by consensus. A WCE was performed by two blinded observers in all patients. Patients had not been using 5-ASA, salazopyrin, NSAIDs and corticosteroids for at least one month before the WCE. **RESULTS:** complete ileocolonoscopy was performed in all patients. In all cases there was not endoscopic and histological involvement of terminal ileum. Every patient well tolerated WCE. Outcome agreement between observers was 100%. In one case multiple small aphthous ulcers were observed, in another patient two jejunal isolated aphthas were found, in two cases WCE showed proximal segmental oedema and hyperemia. The overall percentage of ileal inflammatory findings was 36,4%. **CONCLUSIONS:** our study shows a small bowel inflammatory involvement, in particular of the bowel proximal to terminal ileum, in a high percentage of patients with indeterminate colitis, detected by wireless capsule enteroscopy. This novel safe diagnostic method seems to be able to find also signs of very mild ileal inflammation and could be used for a better classification of indeterminate colitis.

226654: The Utility of Wireless Capsule Endoscopy in the Evaluation of Suspected Crohn's Disease in the Pediatric Population. *Colm J O'Loughlin, Nathan Slinde, Subra Kugathasan*

Background & Aims: Wireless Capsule Endoscopy (WCE) allows direct visualization of the entire small intestinal (SI) mucosa and detection of mucosal lesions not identified by conventional endoscopic and radiographic studies. Little information is available regarding the utility of WCE in the investigation of SI disease in the pediatric population. The aim of this study is to evaluate the clinical utility of WCE in the detection of known or suspected SI crohns disease (CD) in children with non-confirmatory traditional diagnostic studies. **Methods:** Retrospective analysis of 24 consecutive pediatric patients undergoing WCE for suspected CD at a single center during a 16 month period. Suspicion of CD was based upon symptoms of chronic abdominal pain with at least two of the following additional criteria: chronic diarrhea, weight loss, anemia, occult blood loss, increased ESR, delayed growth or malnutrition. Conventional diagnostic testing including colonoscopy and small bowel series were non-diagnostic. The finding on WCE of multiple SI ulcers (> 3) was considered diagnostic of CD, ≤ 3 ulcers suspicious of CD and otherwise as normal. All patients received a 2 liter preparation with Polyethylene Glycol electrolyte lavage (PEG) the day prior to the procedure. **Results:** WCE identified small intestinal CD in 8 patients and was suspicious for CD in 4 patients. WCE identified small intestinal strictures in 3 patients (all in patients with known CD) which were not demonstrated on routine radiographic studies and multiple small intestinal ulcers in 5 additional cases. Unsuspected Celiac Sprue was documented in one case. These WCE findings resulted in changes in patient management. Ten of 24 (40%) had normal exams or non-specific findings. Capsule retention (NNE) occurred in 1 case (4%) despite prior normal small bowel radiographs and required surgical resection of the SI stricture. No adverse events occurred. Two patients required endoscopic capsule placement. **Conclusion:** WCE is a clinically useful technique for the identification of mucosal lesions in children with small intestinal CD undetected disease by conventional radiographic and endoscopic testing. Approximately half of the patients studied had normal exams excluding significant small intestinal mucosal disease. The risk of capsule endoscope (CE) retention appears to be increased in this subpopulation.

211588: Clinical Outcome of Patients Submitted to Capsule Endoscopy for Suspect Crohn's Disease. *Carlo M Girelli, Paola Porta, Francesco Rocca*

Capsule endoscopy (CE) has a diagnostic yield greater than radiology in the detection of subtle inflammatory changes of the small bowel mucosa, but their clinical significance is uncertain because of the lack of long term follow up studies. Aim of the study was to follow a cohort of patients with suspect Crohn's disease of the small bowel (SBCD) until a well established diagnosis in order to detect the clinical meanings of CE findings. From April 2002 to March 2005, we submitted to CE twenty-seven patients (11 males, 40±18 yrs) with abdominal pain and diarrhea lasting more than three months, and at least one of the following features: anemia, weight loss, fever, extra-intestinal manifestation(s) of inflammatory bowel disease. All subjects underwent an unremarkable pan-endoscopy, serology for celiac disease and intestinal radiologic studies inconclusive for small bowel abnormalities. By CE findings, patients were assigned to three groups; group A, severe stricturing lesions mandating surgery; group B, moderate inflammatory lesions further investigated by invasive means; group C, minimal inflammatory changes or normal findings (including lymphoid hyperplasia of the terminal ileum (LH)), clinically observed every three months until a final diagnosis was reached. Small bowel inflammatory lesions were found in 13 of 27 patients (diagnostic yield 48%). Three patients underwent surgery (group A) and SBCD was confirmed in two; the remainder had ileal adenocarcinoma, but was considered a true positive anyway. Group B consisted of five patients and SBCD was histologically confirmed in 4 (one false positive; ulcer and erythema of the terminal ileum not confirmed at ileoscopy and final diagnosis of relapsing appendicitis). Finally, group C consisted of nineteen patients with a median follow up of 21 months (range 15-27); within those with positive findings at CE, SBCD was confirmed by clinical improvement to oral budesonide in seven of 8; the false positive one had jejunal erythema and a final diagnosis of splenic lymphoma. Only one patient with LH later developed overt ileal SBCD (one false negative). Sensitivity, specificity, positive and negative likelihood ratio were 93%, 84%, 5.8 and 0.08, respectively. Assuming a pre-test probability of disease of 40%, CE determined a post-test probability of 79%. In our selected cohort, CE was a sensitive tool for the detection of small bowel abnormalities, doubling the pre-test probability of having a structural small bowel disease. Focal erythema and luminal debris may lower CE specificity. Patients with stricture are surgical candidates, whereas those with LH may later develop SBCD and a careful follow up is warranted.

213326: Entecavir Results in Continued Virologic and Biochemical Improvement and Hbeag Seroconversion Through 96 Weeks Of Treatment in Lamivudine-Refractory, Hbeag(+) Chronic Hepatitis B Patients (ETV-026). *Morris Sherman, Paul Martin, William M Lee, Cihan Yurdaydin, Jose D Sollano, James Vaughan, Robert G Hindes*

Background: In lamivudine (LVD)-refractory, HBeAg(+) chronic hepatitis B (CHB) patients, switching to entecavir (ETV) was superior to continued LVD at Week 48 for achieving histologic improvement, undetectable HBV DNA and ALT normalization. Long-term data for efficacy and safety through 96 weeks of treatment are reported here. Methods: 286 HBeAg(+) CHB patients who were refractory to current LVD therapy were randomized 1:1 to ETV 1.0 mg (N=141) or continued LVD 100 mg (N=145). At Week 48, patients who achieved Virologic Response (HBV bDNA <0.7 MEq/mL but positive for HBeAg) could continue blinded therapy through Week 96. A patient was a responder for a cumulative end point if the patient had a confirmed response (two sequential measurements) for the end point at any time during treatment. Results: 77 ETV-treated and 3 LVD-treated patients continued blinded therapy to a second year of therapy. In this cohort, the proportion of ETV-treated patients with HBV DNA <300 copies/mL increased from 21% at Week 48 to 40% at end of dosing, ALT normalization increased from 65% to 81% and mean HBV DNA reduction from baseline increased from 5.7 to 5.9 log₁₀ copies/mL. In a cumulative analysis of all treated patients, viral rebound with ETV resistance mutations occurred in 9% of patients through Week 96. The cumulative analysis of efficacy end points for all treated patients through Week 96 is presented in Table 1. The Week 96 cumulative safety profile of ETV was comparable to that for LVD. Conclusions: Through 96 weeks of treatment, ETV 1.0 mg results in continued clinical benefit in LVD-refractory HBeAg(+) patients as measured by the proportion of patients achieving an HBV DNA <300copies/mL, ALT normalization and HBeAg seroconversion. Patients treated for a second year experienced incremental benefit in viral load reduction and ALT normalization.

Table 1:

Cumulative Confirmed Virologic, Serologic, and Biochemical Endpoints Through Week 96 (%)			
	ETV 1.0 mg N=141	LVD 100 mg N=145	p-value
HBV DNA <300 copies/mL	30	1	<0.0001
HBeAg seroconversion	16	4	0.0011
ALT ≤1 x ULN	85	29	<0.0001

Additional Reading: Capsule Endoscopy

226667: Wireless Capsule Endoscopy (WCE) In Pediatric Gastroenterology Practice. *Khiet Ngo, Elizabeth Gendy, Marquelle Klooster, George Yanni, Manoj Shah*

Background and Purpose: The application of WCE in pediatric practice is growing rapidly. We share our experiences with WCE for various clinical indications in a pediatric gastroenterology practice. **Methods:** A review of medical records of patients <21 years of age undergoing WCE between January 2005 to October 2005 at our Children’s Hospital was conducted. **Results:** Forty-four patients were identified for the study (M:F 24:20, mean age 12 yr range 4-21yr). Symptoms leading to evaluation by WCE included persistent debilitating abdominal pain (31), GI bleeding (9), weight loss (9), and chronic diarrhea (11). Indications for WCE were grouped as shown in Table 1 along with the corresponding final diagnosis. Ten patients required endoscopic delivery of the capsule. The mean gastric transit time was 1hr while the mean small bowel transit time was 4.75hrs. Crohn’s disease was diagnosed based on the presence of mucosal ulcerations and/or inflammation. In 6 of 8 patients diagnosed with Crohn’s, prior evaluations were non-diagnostic (endoscopy with biopsy, small bowel follow through). Negative or normal findings were felt to be helpful in clinical decision making by the ordering physician. Six patients had incomplete studies (1 gastric retention, 2 did not reach the ileo-cecal valve by the end of the study with eventual passage of the capsule, 2 obscured images, and 1 retained capsule in a patient with known Crohn’s). **Conclusions:** 1. In our study population, performing WCE for the indication of suspected Crohn's Disease provided the highest positive yield (30%) when the clinical suspicion was high even with an otherwise unrevealing work-up. 2. WCE was non-diagnostic in patients evaluated for GI bleeding. 3. The knowledge of the absence of polyps or extent of small bowel involvement in other diseases contributed to patient management. 4. WCE was safely completed in the majority of pediatric patients studied. 5. Small bowel visualization time was adequate in the majority of patients.

Table 1. Indications & Final Diagnosis of Patients Undergoing WCE

Indication Groups	Final Diagnosis
Suspected Crohn's Disease	8Crohn's Disease, 2Duodenitis, 1Dysmotility, 1Enteritis, 1Erosion, 12Normal Study
Suspected Celiac Disease	3Normal Study
Evaluation of Polyposis	3Normal Study
Un-explained GI Bleeding	1Enteritis, 3Normal Study
Evaluation for PTLD	1Normal Study
Evaluation of Diseases Extent*	4Small Bowel Involvement, 3No small bowel involvement

*Known Crohn's Disease, Celiac Disease, Vascular Malformation, Autoimmune Enteropathy

219727: Does Preoperative Wireless Endoscopic Capsule Predict Long-Term Outcome After Ileal Pouch-Anal Anastomosis (IPAA)? *Stefanie J Schluender, Shahab Mehdizadeh, Eric A Vasiliaukas, Marla Dubinsky, Konstantinos A Papadakis, Andrew Ippoliti, Simon Lo, Stephan Targan, Phillip Fleshner*

PURPOSE: The extent of preoperative small bowel (SB) mucosal inflammation in ulcerative colitis may be an important predictor of outcome after IPAA. Although small bowel follow-through (SBFT) is the traditional method for assessing SB inflammation, wireless capsule endoscopy (WCE) appears to be more sensitive for the assessment of mucosal lesions than radiological testing. The purpose of this study was to investigate the value of preoperative WCE in predicting long-term outcome of IPAA in patients with ulcerative colitis or indeterminate colitis. **METHODS:** 24 patients undergoing WCE before having an IPAA over the 4-year period ending October 2005 were identified. Findings on WCE were classified as positive (erosions, ulcers, erythema), negative, or incomplete. SBFT was done in 20 patients and was classified as positive if ulcerations, mucosal blunting, or wall thickening was identified. Long-term outcome was assessed prospectively and included acute pouchitis (AP), chronic pouchitis (CP), or the development of Crohn’s disease (CD). Patients with AP, CP or CD were considered to have pouch inflammation (PI). **RESULTS:** WCE was positive (WCE+) in 8 patients (33%), negative (WCE-) in 12 patients (50%) and incomplete in 4 patients (17%). After a median length of followup of 15 months in the 20 patients with a complete WCE, AP was seen in 3 patients (15%), one patient (5%) developed CP and one patient (5%) developed CD. Within WCE+ patients, 1 (13%) developed AP and none developed CP or CD. Within WCE- patients, 2 (17%) developed AP, 1 (8%) developed CP, and 1 (8%) developed CD. PI rate for WCE+ patients (13%) was lower than WCE- patients (33%) (p=NS). SBFT was positive (SBFT+) in 3 patients (15%) and negative (SBFT-) in 17 patients (85%). Within SBFT+ patients, 1 (33%) developed AP and 1 (33%) developed CP. Within SBFT- patients, 2 (12%) developed AP and 1 (6%) developed CD. The PI rate for SBFT+ patients (67%) was higher than for SBFT- patients (18%)(p=0.1). There was no significant difference in overall PI rate between WCE+ and SBFT+ patients (p=0.1). **CONCLUSION:** Early observations from this study suggest that in UC or

IC patients undergoing IPAA, preoperative WCE+ does not appear to be associated with pouchitis. WCE may not confer any advantage over SBFT in assessing the risk of pouch inflammation after IPAA for patients with UC or IC.

223653: Long-term NSAID use and small bowel pathology: a cross-sectional quantification by capsule enteroscopy. L Maiden, A Seigal, I Bjarnason, B Birgisson, B Thjodleifsson, IT Bjarnason. *Laurence P Maiden, A Seigal, Ingi Bjarnason, B Birgisson, Bjarni Thjodleifsson, Ingvar Bjarnason*

Background & Aims: Capsule enteroscopy has shown small bowel mucosal breaks (erosions and ulcers) in 40% of volunteers taking the NSAID diclofenac (with a proton pump inhibitor) for 2 weeks, however the full range of pathology in a large group of long-term users has not been assessed. We undertook a capsule enteroscopy in 117 patients on long-term NSAIDs to assess the range of small bowel damage caused by these agents. **Methods:** Patients with established osteoarthritis, rheumatoid arthritis or low back pain who had been regularly taking any one NSAID for 3 months or longer underwent a capsule enteroscopy. Patients with known or suspected Crohn's disease, spondylarthropathy, including seronegative arthritides, and other small bowel pathologies were excluded as the gastrointestinal damage might not readily be distinguished from that of NSAIDs. Sixty healthy volunteers acted as controls. **Results:** The volunteers had no damage. 81 of the 117 (69%; $p < 0.001$) had evidence of intestinal pathology attributable to the drug on enteroscopy. Forty-one (35%) had more than one lesion concurrently. The commonest lesion seen was the denuded lesion in 47 (40%; $p < 0.001$). Forty-one (35%; $p < 0.001$) had red spots. Thirty-one (26%) demonstrated mucosal breaks, of which 1 was bleeding at the time of enteroscopy. Reddened folds were seen in 14 patients (12%; $p < 0.05$). Strictures without a mucosal break or bleeding were seen in 2 of the patients (2%; $p > 0.05$) and a further 2 patients revealed evidence of bleeding without an obvious source. **Conclusion:** Capsule enteroscopy demonstrates small bowel lesions in 69% of patients on long-term NSAID. Clinically significant pathology (mucosal break, stricture and bleeding) is detected by capsule enteroscopy in 30% of patients on long-term NSAIDs, which is greater than that seen in the stomach. This may explain why the serious outcomes (perforation, bleeds and obstruction) associated with NSAIDs from the upper and lower gastrointestinal tract are comparable.

216938: Assessment of a New Simple Capsule Endoscopy Crohn's Disease Activity Index (CECDAI). Eyal Gal, Alex Geller, Gerald Frase, Zohar Levi, Yaron Niv

Introduction: Capsule endoscopy (CE) (PillCam SB, Yoqneam, Israel) is a relatively new imaging tool for detection of small bowel pathology. It was found to be the most sensitive procedure for detection of small bowel Crohn's disease in several studies. Assessment of endoscopic severity of Crohn's disease by CE is not standardized and is limited by inter-observer variation in interpreting findings and assessing their severity. **Aim:** To develop and validate a new, simple CECDAI in order to grade the severity of small bowel CE findings. **Methods:** The small bowel was divided into proximal and distal segments according to transit time, and each segment was given a score according to the worst mucosal lesion, extent of disease and presence of strictures (Table). The segmental score is calculated by multiplying the inflammation score by the extent score and adding the stricture score (A x B + C). The final score is the sum of the 2 segmental scores so CECDAI = (A1 x B1 + C1) + (A2 x B2 + C2). Four experienced endoscopists (2 with experience in CE interpretation) reviewed 20 de identified, coded CE videos of Crohn's disease patients, and graded them according to CECDAI. Each examiner was blinded to the scores given by the others. The scores were compared by Spearman's correlation using SPSS for inter-observer variability. **Results:** Total CECDAI score correlation was 0.867 (0.700-1.000 = strong degree association, WHO classification, $P < 0.0001$). CECDAI in 20 patients range was 0 to 26. All examiners agreed that the score was simple to learn and apply, even for endoscopists with no specific CE experience. **Conclusions:** The CECDAI score is a simple score for assessing small bowel Crohn's disease by CE, and shows a low inter-observer variability between examiners with extensive endoscopic experience. **Table - CECDAI** A. Inflammation score 0=none 1= Mild to moderate edema/hyperemia/denudation 2= Severe edema/hyperemia/denudation 3= bleeding, exudate, apthae, erosion, small ulcer (up to 0.5cm) 4= moderate ulcer (0.5-2cm), pseudopolyp 5= large ulcer (>2cm) B. Extent score 0= none 1=Focal disease (single segment) 2=Patchy disease (multiple segments) 3=>Diffuse disease C. Narrowing score 0= none 1= single, passed 2= multiple, passed 3= obstruction **Segmental score Total score**

220957: Small Intestine Contrast Ultrasonography (SICUS) Versus Videocapsule Endoscopy (VCE) for Assessing Crohn's Disease Post-Operative Recurrence: A Prospective Longitudinal Study. Livia Biancone, Emma Calabrese, Rosa Maria Bozzi, Carmelina Petruzzello, Sara Onali, Micaela Cretella, Anna Caruso, Alessandra Geremia, Francesco Pallone

Background. Small intestine contrast ultrasonography (SICUS) is a non-invasive technique able to detect small bowel lesions in Crohn's Disease (CD). Videocapsule endoscopy (VCE) allows the visualization of the small bowel inner surface. As CD patients require endoscopic assessment after surgery, non-invasive techniques able to detect the postoperative recurrence may well be of use. The usefulness of SICUS and VCE for assessing the postoperative recurrence of CD is unknown. **Aims.** We aimed to investigate, in a prospective, longitudinal study, the usefulness of SICUS in comparison with VCE for assessing the postoperative recurrence of CD patients (pts) 1 year after ileo-colonic resection, when using conventional colonoscopy (CC) as gold standard. **Methods.** 14 CD pts (8 M, age range 25-64 yrs) undergoing ileo-colonic resection for CD were prospectively

followed up from July 2003 to November 2005. After surgery, all patients underwent clinical assessment (CDAI) every 3 months for 1 year. At 1 year, CD recurrence was assessed by 3 independent investigators by SICUS and CC, followed by VCE. CD recurrence was assessed by CC (Rutgeerts' score). SICUS was performed after PEG ingestion (375 ml). VCE was performed by using the M2A Given (11x26 mm) (median excretion time 28 hrs). Lesions compatible with recurrence assessed by SICUS and VCE were recorded. Results. No pts. showed side effects. At 1 year, all 14 patients were inactive (CDAI<150). In 1 pt, VCE was not performed due to an anastomotic stricture detected by CC. Comparison between the 3 techniques was therefore made in 13/14 pts. CC detected CD recurrence in 12/13 pts. Lesions compatible with recurrence were detected by SICUS in 13/13 pts (1 false positive) and by VCE in the same 12/13 pts showing endoscopic recurrence (12 true positives). CC detected recurrence at both the anastomosis and PA-ileum in 9/13 pts and at anastomosis only in 3/13 pts. Recurrence was detected by SICUS at both the anastomosis and PA-ileum in 10/13 (1 false positive) and at the anastomosis only in the same 3/13 pts detected by CC (3 true positives). VCE detected CD recurrence at both the anastomosis and PA-ileum in 7/13 pts (2 false negatives) and at the anastomosis only in 5/13 pts (2 false positives). VCE therefore appeared to appropriately detect the presence, but not the site of CD recurrence, which appeared better defined by SICUS. Conclusions. Present findings from a prospective longitudinal study suggest that SICUS and VCE represent alternative non-invasive technique for assessing CD recurrence in patients under regular follow-up after ileo-colonic resection. VCE use however requires the exclusion of stricturing recurrence.

225088: Capsule Endoscopy Diagnosed Small Bowel Ulceration: Is This Really Crohn's Disease? *Joanna Law, Scott Whittaker, Lawrence Halparin, Robert Enns*

Background: Capsule endoscopy (CE) is a means of evaluating the small intestine primarily for obscure GI bleeding (OGIB). We have noticed a small group of patients that have presented with OGIB (without NSAID use) with small bowel ulcerations. They had no signs or symptoms of Crohn's disease (CD) or in fact any other small bowel disorder (besides OGIB). We sought to evaluate this group of patients more thoroughly as we believe they represent a sub-set of CD that is unique from those with stenosing, fistulizing or ulcerating disease. Methods: All patients undergoing CE studies were reviewed with a prospectively collected database on patient demographics, indication for CE, previous investigations, transfusions, and management before and after CE. Patients were all followed long term after their CE studies. Results: 10 patients were identified from the database (of 410 CE) with small bowel ulcerations. Of the 10 patients (mean age 52, 60% men), 7 patients were referred because of suspected occult bleeding and 3 patients because of overt bleeding. The duration of symptoms was 12-24 weeks in one patient, greater than 24 weeks in 7 patients and not documented in 2 patients. None of the patients took NSAIDs, was on any anti-platelet agents, or had a history of inflammatory bowel disease, celiac disease or other vascular abnormalities. There were no associated masses. The ulcerations were distributed throughout the small bowel and were consistent with CD. No patient had other significant comorbid disorders to suggest vasculitis, ischemia, lymphoma or other small intestine abnormality. Additionally, 3 patients were from Southeast Asia (where CD is uncommon) and all patients lacked extra-intestinal manifestations of IBD. Over a follow up mean of 16 months, no patient has progressed with obstructive, fistulizing or other GI symptoms. All patients have remained with intermittent bleeding without progression of disease. No patients have undergone surgery. Conclusion: Through CE, we have found a small group of patients with OGIB with small bowel ulcerations (in absence of NSAIDs), which we have labeled as CD. This type of CD is unique in that there is no progression to stenosing, fistulizing or even small bowel symptoms (i.e. diarrhea) and the presentation and subsequent management is strictly one of bleeding. We believe that this represents a unique sub-set of CD with different presentation, progression, outcomes and likely management from other CD subtypes.

223608: Usefulness of the Capsule Endoscopy In the Study of the Inflammatory Bowel Disease : Preliminary Results. *Sara Galter, Begona Gonzalez, David Monfort, Elena Ricart, Dolors Gonzalez, Edgar Ayala, Carlos A Guarner, Ingrid Ordas, Joaquim Balanzo*

Introduction: Capsule endoscopy (CE) has been proved to be a new and useful tool in the study of the inflammatory bowel disease, as Crohn's Disease (CD) of the small bowel has long presented diagnostic difficulties. Patients with colon CD or indeterminate colitis (IC) are the best candidates, because intestinal lesions may lead to a change in the diagnosis or the management of the patient. Aim: Assess the usefulness of the capsule endoscopy in detecting small bowel disease in patients with Colon CD, IC or suspected CD, after a normal small bowel follow through (SBFT). Patients and methods: Since January 2004 until November 2005 we included 22 patients (8 males, 14 females) divided in different groups: established Colon CD (group 1, n=13), IC (group 2, n=7) and suspected CD (group 3, n=2). 20 of the 22 patients had a previous normal SBFT. After an intestinal preparation and 8 hours of fasting, the exploration was performed. Results: CE was normal only in 6/22 patients (27.2%) and pathological in 16/22 (72.8%). In group 1, the capsule showed lesions suggestive of CD in 7 patients (53%); in group 2, 5 patients had intestinal lesions, leading to a diagnosis change (70%) and in group 3, CD was confirmed in 1 case (50%). The cecum was reached in 90% of procedures and all capsules passed naturally. Conclusions: 1. Capsule endoscopy is effective in the study of Indeterminate Colitis, leading to a diagnosis of Crohn's Disease in 70%. 2. The examination of the intestinal extent of Crohn's Disease shows lesions in 7 patients (53%), although the clinical relevance needs to be assessed. 3. Capsule Endoscopy is superior to Small Bowel Follow Through in the detection of small bowel lesions.

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