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Assessing IBD with Intestinal Ultrasound and Exploring Ongoing Research

Dr. Buch:
Welcome to *GI Insights* on ReachMD. I'm your host Dr. Peter Buch, and today we're joined by Dr. David Rubin, who is a Professor of Medicine at the University of Chicago Pritzker School of Medicine and a leader in inflammatory bowel disease research and treatment. He'll be discussing best practices for utilizing intestinal ultrasound to assess inflammatory bowel disease.

Dr. Rubin, welcome to the program.

Dr. Rubin:
Hey, Peter. I'm so happy to be here with you, and I'm really grateful for the opportunity to talk about this topic.

Dr. Buch:
We're so happy that you're joining us. So, Dr. Rubin, to start us off, how do you use intestinal ultrasound in your practice?

Dr. Rubin:
Well, let's start by just reminding everyone what intestinal ultrasound is. This is an approach to visualizing the intestines using a transabdominal ultrasound probe that is designed to be performed at the bedside, point of care, and provides real-time information of what is actually happening in the bowel. The two main parameters we measure are bowel wall thickness, which is probably the most important one—a thickened bowel is inflamed or has some chronic inflammation—and the second parameter is color Doppler where we see blood flow, and increased blood flow is associated with inflammation. So what we've been able to incorporate and we've learned from our colleagues in Europe who have been doing this for years before us is the opportunity to assess a patient at the bedside in clinic in real time to know whether they're inflamed or not, when they're having symptoms whether it's truly from inflammation, or it may be something else, which we, of course, know happens. And separately, we have a clinic that is just an ultrasound clinic where my partners who do IBD but don't do scanning can also refer their patients, and they have these exams performed.

Dr. Buch:
And what are the benefits of using ultrasound to assess inflammatory bowel disease?

Dr. Rubin:
Well, there's a couple things that this has really brought to our clinics and to our patients. The first one is just the obvious, which is that by getting an answer right away, it doesn't require that the patient handles their own stool or that we're waiting for a result that comes back from a lab, or that the patient has to be prepped and have a scope or wait, and then have a scan that requires interpretation by a radiologist, and therefore, we have the information we need to make decisions in real time.

Now the separate issue about this that I think is really an important and interesting one is that it enables the patient to actually see their bowel at the same time. So the way this is set up is it's done right at the bedside. The patient turns their head to the right, and they can see the screen that the sonographer is using, and we routinely point out their bowel and we say, "Here's where your stricture is," or

"Here's an inflamed bowel." And what we've learned from patients—and a number of studies have emphasized this—is that it helps them visualize what's happening in their body, it helps them understand why they're taking their medicines, it helps remind them why they need to be on therapy, and I think it's been a really important advance in communicating to patients about their disease process.

Dr. Buch:
And you made me think about one other thing is having both inflammatory bowel disease and irritable bowel syndrome at the same time. Would you address that?

Dr. Rubin:
Yeah. So, Peter, that's a really important point, and I'm glad you brought it up, which is that one of the other areas that we've come to appreciate, and it's evolving, and I think your listeners should know is that full thickness improvement or healing has a better outcome than just endoscopic healing or radiologic healing. When you know that the bowel wall from the serosa all the way through to the mucosa is normal in its thickness that actually has better clinical outcomes, lower likelihood of relapse, than when you know that it's just endoscopically healed. And so the value of seeing that and knowing that that exists has actually changed how we interpret an irritable bowel. We used to say that 50 percent of people who were in remission might experience some overlap of a hypersensitive, or what we could call an irritable or functional bowel disorder, but now what we started to realize is some of those people we would label as having an irritable bowel, if you actually do an intestinal ultrasound, you find out that they actually are walking around with bowel wall thickness that might better explain their problem, and therefore, it's not actually a functional issue, it's a subsequent secondary functional problem, but there's an underlying transmural inflammatory issue. So it's actually opened our eyes to a completely new way to think about a common problem.

Dr. Buch:
Such a powerful tool. So let's now talk about limitations. What are the limitations?

Dr. Rubin:
Well, the first thing we have to acknowledge is that, as much as we value this, there are some things we don't know yet and we haven't proven, so we'd like to make sure that we understand that using this in routine practice is changing outcomes. The second one is understanding whether it's cost-effective. The machines themselves vary in price from 50,000 to more commonly over a hundred thousand dollars. There is reimbursement and a billing code for limited abdominal ultrasound and Doppler ultrasound that can be applied, and so far has been providing some reimbursement, and so we think that it's a cost-affordable test, but cost-effectiveness has to do with whether it changes outcomes in a way that ultimately leads to better outcomes, and we'd like to know that.

And we don't learn this in the United States as part of our routine training. In Europe, they learn intestinal ultrasound and ultrasound techniques in part of their residency training. It's just built in. Here we have to start from scratch with our well-meaning colleagues and teach them this, and then they have to gain enough experience so that they have some level of competency. And how we define competency and experience is evolving.

We've been borrowing and then working in close conjunction with the International Bowel Ultrasound Group. Their strategy of training, which requires hands-on training and supervision is also unproven, and certainly not something that we've really been able to study properly yet in the United States healthcare system. So there's a variety of different challenges we still face.

Dr. Buch:
For those just tuning in, you're listening to *GI Insights* on ReachMD. I'm Dr. Peter Buch, and I'm speaking with Dr. David Rubin about the use of ultrasound for inflammatory bowel disease.

Now, Dr. Rubin, how does intestinal ultrasound compare with CT and magnetic resonance enterography when assessing inflammatory bowel disease?

Dr. Rubin:

So whenever we have a new monitoring tool or diagnostic tool, we want to compare it to the industry or standard practice tools and tests. I'll start by saying that the gold standard in IBD for diagnosis and assessment has been colonoscopy and increasingly, biopsy assessment, but when we compare it to other cross-sectional imaging studies, like CT enterography and MR enterography, the good news is to know that ultrasound has an equivalent or even better sensitivity—and after a patient's already diagnosed with IBD—specificity than CT and MRE. It's significantly less expensive, and it is in the places where it's available often a test that takes less time to do and is also a test that is more available than waiting for a scheduled imaging exam. In the United States, it's astonishing when you look at the price or at least the charges for MR enterography and CT enterography and you compare them to the ultrasound, so from that point of view, it's superior.

But in terms of even diagnosing complications of IBD, like an abscess or a fistula, as you gain experience in performing intestinal ultrasound, you can find these with high degrees of sensitivity and enable quite a bit of information. We're trying to teach our colorectal surgeons to be comfortable with the ultrasound findings before they do surgery. We are when we know what we're looking at, and we're just teaching them that what we see can be as good or even better than what we find on the imaging studies that they're used to, but this is a learning curve, as with all new things, and we're trying to get the word out, which is why I'm grateful to you that we're talking about it today.

Dr. Buch:
And now looking at the STARDUST substudy on ustekinumab, how might this help to optimize treatment?

Dr. Rubin:
So STARDUST was a treat-to-target study of ustekinumab in moderate to severe Crohn's disease, and the hypothesis of this study was that if you used endoscopy to assess the bowel inflammation and adjusted the dose of ustekinumab—and the way we did that in the study is you decreased the interval of the injections—you would be able to drive patients to a greater degree of healing and endorse the need for higher doses of ustekinumab. Now having said that, the primary endpoint of the study, which was the endoscopic response at 48 weeks, was not different between those who had the endoscopically driven dose changes from those who had standard of care adjustments based on symptoms, and although there was a numeric difference, it wasn't statistically significant.

Now STARDUST was also unique because it was the first study that had an intestinal ultrasound substudy, and in a number of the patients who participated in the trial, they performed intestinal ultrasounds at intervals throughout the trial to assess the transmural thickness and healing of the bowel. Unlike the primary endpoint, the transmural healing was actually demonstrated to improve as the dosing of the ustekinumab was increased, so it actually provided a different objective endpoint that suggested it might be a better measure of success of the therapy to just the endoscopy. Now having said that, it is a substudy. It wasn't powered to show statistical difference. But what I like about the STARDUST substudy was the fact that it started to identify the use of intestinal ultrasound as a tool we might use in future clinical trials.

It's offered us some new options for our patients, but it also provides us with new insight into the pathophysiology of the disease process. And what we're starting to realize is our newer treatments for IBD have healing rates that are happening much sooner than we thought.

Now why is that relevant? Well, it tells us that the patient's likely to be doing better, but it also gives us new insights into when we might make treatment changes, and it also provides us with new insights about when we can assess that a treatment is working or not, so we can move on to other options sooner, and it all gets back to this issue of making somebody feel better and helping them stay better in a more durable way. So ultrasound has given us a noninvasive window of knowing how the bowel responds to therapy and how the disease process may work in ways that we had not thought possible before. And so future clinical trials are expected to include intestinal ultrasound, and I think we're going to start to understand a lot more about what's going on in our patients when we do that.

Dr. Buch:
In the last few moments of our discussion, Dr. Rubin, can you share any ongoing research with our audience?

Dr. Rubin:
There are some really innovative studies that are happening right now. Similar to what the STARDUST substudy suggests, using ultrasound to drive a treat-to-target strategy I think is going to be very revealing and helpful. We're doing a study now like that, but we're

also using ultrasound to characterize ulcerative colitis as a transmural disease. We have realized that although traditionally we talk about ulcerative colitis as a mucosally limited disease, actually, we've come to realize that it actually is transmural more often than not, and it impacts on response to therapy, so ultrasound is a way to measure that and to document response to treatment and whether it improves outcomes.

And we're now even doing some creative things. We just published a case report where we used a handheld ultrasound probe that syncs to your digital device, like your mobile phone or your tablet, and we taught a nonmedical patient to scan himself. He had severe colitis, put him on a new therapy, and after we gave him a simple lesson in the clinic, he went home and scanned himself with this handheld device every day and sent us screenshots of his bowel wall thickness, and we were able to measure how he was doing with his treatment in days rather than weeks and know exactly how he was doing. So we are now rolling that out in a bigger study to see if we can have patient-driven scanning that might guide therapy and provide even more information in a quicker way, so lots of exciting and interesting things happening.

Dr. Buch:
I want to thank my guest, Dr. David Rubin, for updating us about intestinal ultrasound for IBD. Dr. Rubin, thanks so very much for being here today.

Dr. Rubin:
It's really been my pleasure, and I appreciate the opportunity to talk about it, and I hope that your listeners will know a little bit more about ultrasound and some of them will take it up.

Dr. Buch:
For ReachMD, I'm Dr. Peter Buch. To access this and other episodes in this series, visit *GI Insights* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening.