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Reviewing a Vibrating Capsule for Chronic Constipation

Dr. Buch:

Welcome to *GI Insights* on ReachMD. I'm your host, Dr. Peter Buch. And today we'll be discussing a new therapy for chronic constipation with Dr. Eamonn Quigley. Dr. Quigley is the David M. Underwood Chair of Medicine in Digestive Disorders, a Professor of Medicine at Houston Methodist, and also a coauthor of the article, titled "Randomized Placebo-controlled Phase 3 Trial of Vibrating Capsule for Chronic Constipation," that is published in *Gastroenterology* just recently in 2023.

Dr. Quigley, welcome back to the program.

Dr. Quigley:

Great to be with you again. Thank you.

Dr. Buch:

It's great to work with you again, sir. So let's dive right in, Dr. Quigley. How does this vibrating capsule work for patients with chronic constipation?

Dr. Quigley:

So let me take through the details of this as much as we understand them. So basically, this is a capsule, which is about the same size as the PillCam or the SmartPill, or basically, a large vitamin tablet. So you get one of these; you place it in a little pod that's got a hole, which fits the capsule in the middle of it, and when you do that, you activate the capsule. Now what does that mean? That means that when you swallow the capsule, when it reaches the colon, it will begin to vibrate. Now when I say it reaches, it's timed for an average small bowel transit of, say, six hours. So it reaches the colon and begins to activate. That means that it vibrates at a certain frequency at a certain repetition rate over a certain period of time. By doing this, it actually stimulates the wall of the colon and stimulates peristalsis in the colon. That's the idea. Now is there evidence to support this? There is some. There are other studies, which have used a variety of other stimulating methods which have shown, actually, that this does occur, but that's the basic logic behind it.

Now the difficulty with this program, which I've actually been involved with for several years, has been to find the right parameters. In other words, what frequency to stimulate at how frequently that stimulation should be done and at what time of day should that be done. Those were all kind of worked out over the years until we came up with the protocol that appeared in this final study, which fortunately, was a positive study, but there isn't an animal model really for constipation or a whole animal model for constipation, so this all has to be done by trial and error in human studies.

Dr. Buch:

Perfect. And let's talk about safety and efficacy. Is a patency capsule worthwhile when we're thinking about this? I realize that the population is going to be different, but is a patency capsule worthwhile in this situation?

Dr. Quigley:

In developing this, the indications had been very carefully defined, and more importantly, those individuals who would not be suitable for this have been carefully defined, so anybody with dysphagia, anybody with gastroparesis, anybody with a history of intestinal surgery, anybody with a history of

complicated diverticular disease, or anybody with a history of Crohn's disease, for example, or any other disorder that could lead to stricturing in the small intestine is automatically excluded.

Now where the patency capsule comes in, as you know better than I do, is when you are dealing with, say, a Crohn's patient, for example, and you feel that they might benefit from a PillCam, so you do a patency capsule beforehand in the concern that there might be a stricture that might hold up the capsule. And we've all encountered this. If you follow the instructions carefully in terms of inclusion and exclusion criteria for the Vibrant capsule, you should not run into that trouble, so you should not need a patency capsule.

Dr. Buch:

Perfect. And how about any other safety and efficacy features that you'd like to talk about?

Dr. Quigley:

It has been remarkably safe to date. One of the good things about it is that it doesn't cause diarrhea. Like it either works and relieves your constipation or it doesn't work. There have not been any issues with the capsule getting stuck anywhere or causing problems. Some patients are aware of a mild sense of vibration when they take the capsule, but that didn't lead anybody to want to withdraw from the study at any time.

Dr. Buch:

Perfect. So could this treatment be more effective than other therapies currently being used?

Dr. Quigley:

Now that's a good question, which I'm not going to give you a complete answer to because we just don't have the data. So the study was done in people who had failed one or more traditional therapy, which would be diet, laxatives, stool softeners, etcetera, so we can say that it's at least as effective or more effective than that level of treatment. With regard to prescription medications, there has not been a direct comparison, so I cannot say that it's better than linaclotide, plecanatide, or tenapanor, or whatever, so I can't say that. However, if you just look at the data, the data looked pretty good, and they looked at response rates using similar outcome variables, which was FDA-mandated variables as other studies. The results were pretty good. And the other interesting thing, which came out from further analysis of the phase 3 study that you just mentioned, was that even in people who had severe constipation—by severe I mean people who had no bowel movement per week in the run-in period—they still responded.

Dr. Buch:

Thank you for sharing that. For those just tuning in, you're listening to *GI Insights* on ReachMD. I'm Dr. Peter Buch, and I'm speaking with Dr. Eamon Quigley about a vibrating capsule that's used to treat chronic constipation in patients.

So now, Dr. Quigley, how should clinicians address therapy for those who don't respond well to the capsule?

Dr. Quigley:

Well, it's like everything else. We've got a range of options for patients with constipation. I mentioned a number of prescriptions. Prosecretory agents are available. There's a pro motility agent in the form of prucalopride. And of course, then there are the traditional laxatives as well. What I tend to do myself in patients who don't respond to any single therapy is maybe to combine therapies. IBD people do this all the time. They combine biologics with different mechanisms of action, so if you apply that to constipation, you would maybe take a prosecretory agent and a prokinetic agent and combine those different mechanisms of action. I would also, in this situation, begin to look carefully at other factors. For example, is there significant dyssynergia going on? As you can imagine, if patients have significant dyssynergia with, say, puborectalis relaxation or failure of anal sphincter relaxation, that may not respond to a lot of conventional therapies and may require more specific evaluation and more specific therapy, such as in the form of biofeedback.

Dr. Buch:

And do you ever foresee this as particularly usefulness in patients with irritable bowel syndrome?

Dr. Quigley:

Yeah, that's a very interesting and provocative question. And let me explain to you about why I'm saying this. The vagus is actually much more of a sensory nerve than a motor nerve, and there is slightly tangential evidence from other areas that afferent traffic from the GI tract to the central nervous system may play a role in suppressing some symptoms. One example that comes up is gastric electrical stimulation, so-called gastric pacemaker, which actually doesn't pace make, and it actually does improve symptoms in people with gastroparesis or severe nausea and vomiting, but it actually doesn't accelerate gastric emptying.

And as you know, there are a number of technologies out there, which are being evaluated for afferent stimulation in a variety of conditions, so it is possible. It's purely theoretical. I have no data whatsoever to support this, but it is possible that you could get some benefit from irritable bowel syndrome. Of course, you would get benefit from the constipation effect in patients with IBS-C, but whether you might get some additional benefit in terms of sensory modulation is a possibility, but I don't have an answer to that. I think it's an intriguing idea. I think this capsule technology is fascinating.

Dr. Buch:

And lastly, Dr. Quigley, are there any other takeaways you would like to leave with our audience today?

Dr. Quigley:

The one takeaway I would like to mention, which has come up, this is now FDA approved, and it's now available. I think one of the things that people get very anxious about is not seeing the capsule coming out the other end, if you know what I mean, and you have to remind people that colon transit in people with constipation is very slow. It will pass. If you have no symptoms suggesting obstruction or any of that, you don't have to worry about it. Just let it pass. See if it works. If it works, great. It could be helpful to you.

Dr. Buch:

Well, with those final thoughts in mind, I want to thank my guest, Dr. Eamonn Quigley, for presenting this new treatment modality for chronic constipation.

Dr. Quigley, thanks so very much for joining us today.

Dr. Quigley:

Thank you very much.

Dr. Buch:

For ReachMD, I'm Dr. Peter Buch. To access this and other episodes in this series, visit ReachMD.com/GIInsights where you can Be Part of the Knowledge. Thanks for listening and see you next time.