ADVANCES IN IBS

Current Developments in the Treatment of Irritable Bowel Syndrome

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New Ways to Evaluate for Evacuation Disorders



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G&H How do you feel the London classification and Rome V criteria have influenced the evaluation of patients with evacuation disorders and specifically dyssynergia?

ES The London classification has been actively looking at the standardization aspect of testing for evacuation disorders, particularly with anorectal manometry (ARM). With multiple different maneuvers that measure how well or not patients are able to defecate, standardization is important to help provide diagnosis and treatment more quickly, and to be able to have confidence in the results and replication of the results. The new Rome V criteria have focused on simplifying the diagnosis of dyssynergic defecation by reducing the number of tests required and broadening the symptom spectrum to include various stool types and sensory phenotypes. Beyond dyssynergic defecation, there can be weakness in the pelvic floor or sensory issues that make it difficult for patients to tell when they need to defecate. Sensory issues, such as when a patient feels the need to defecate a little bit more urgently than they typically should, are particularly interesting. Classically, the teaching is that increased or heightened sensation of the need to defecate is associated with diarrhea, which is not always true. A large study in the *American Journal of Gastroenterology* showed that at least one-third of patients with constipation have that sensation. It is also important to note that evaluation of evacuation disorders is simply dealing with the pelvic floor muscles themselves and is completely separate from testing for irritable bowel syndrome and other disorders of gut-brain interaction (DGBI), although there can be overlap of symptoms and the possibility of a coexisting evacuation disorder and DGBI. In my mind, pelvic floor testing focuses on the musculature and on spinal cord reflexes, and the physical changes that occur in the pelvic floor. Both sets of criteria, Rome being focused on the global picture of dyssynergia and London being more broadly focused on defecation disorders overall, are at least trying to standardize the field and make it hopefully slightly more accessible.

G&H What are some advantages and disadvantages of the standard or traditional assessments for evacuation disorders?

ES To start with, there may be no need for the test. My team at Dartmouth published a study showing that an empiric approach seems to work. For patients who are willing to try pelvic floor physical therapy (PT), do they need a test to tell them to do that? Contrary to what is written in the London classification and in the Rome consensus, many pelvic floor physical therapists, community gastroenterologists, and gynecologists do not anchor on test results. They anchor on talking with the patient and asking them what they want. The important nuance is that although the current classification systems and those in development are refining the science, testing might be more appropriate for patients who are seen in high-tech tertiary care centers, where the question is, what can we do for patients for whom everything else has failed? The broader picture is, for the patients who have not yet tried any PT, why not start there? That is one avenue.

The standard or traditional assessments for evacuation disorders have well-known inherent advantages and disadvantages. Digital rectal examination has the advantage of being low cost, quick, and easy to perform but is operator-dependent and subjective, whereas ARM and defecography are more labor-intensive and require trained technicians or specialists but provide more comprehensive results. Right now, in the gastroenterology community, the purpose of traditional assessments such as ARM is primarily to identify dyssynergic defecation. Although ARM

is a fairly high-tech test that requires training to learn, it has become much more accessible, with the London classification in particular, and more gastroenterologists have started to pick it up. Often, part of ARM is the rectal balloon expulsion test. A disadvantage of the test is that it uses a water-filled balloon, which can be difficult for patients to expel rectally and may not be the best mimic of stool. Another option that my colleagues Dr Jason Baker, Dr William Chey, and I codeveloped is a new rectal expulsion device called RED, which is a screening tool that can be used similarly at bedside, in the office, with the patient in a left lateral decubitus position; the difference is that it uses a foam-filled balloon. The test evaluates patients' ability to defecate and whether they have rectal hypersensitivity. Balloon expulsion tests are limited in that they do not provide as much information as more comprehensive testing. However, these tests are accessible to providers who may not need the full comprehensive evaluation, at least for an initial patient visit. This is where I think most patients who can benefit from RED are seen. Beyond the test results, use of RED may help physicians determine which patients are not good candidates for pelvic floor PT. That is where I think testing with RED or other such devices could be helpful and important. Not every patient is going to need pelvic floor PT or testing, frankly. Having this test is educational and enough for patients to know whether pursuing pelvic floor PT might make sense or may not be right for them, which is really helpful. It also can help foster conversation around what otherwise might seem like a difficult topic that really should not be.

G&H Why is being able to predict response to pelvic floor PT or biofeedback therapy important?

ES First, the point of anorectal function testing is not to identify the underlying cause. The point is that patients want to feel better. If they feel better, they can go about their everyday lives and do the things they really enjoy. If the anorectal function testing can help them get there, that is great. In another study, my team and I looked at whether RED, as a screening test, can predict patient outcome with community-based pelvic floor PT—not whether the patient needs PT, but rather if the patient can tolerate PT. We found that RED is able to identify patients for whom pelvic floor PT is unlikely to provide benefit. Being able to predict response to this therapy is important for several reasons. When patients see what the test looks like, and say no to pelvic floor PT, that is helpful. In this situation, patients can completely avoid something they do not want. When patients undergo the test and have, for example, a 9% or very low likelihood of response to pelvic floor PT, that is helpful because it saves patients from visits they may not benefit from. For these patients, other options can be explored. For patients who are already willing to go to pelvic floor PT and have a higher rate of response, this is validation that we are on the right track. Also, these patients will probably show up to PT, for which adherence is important. In our trial, the entry criteria for PT were, are the physical therapists treating the constipation in the pelvic floor where the problem is? There have been other studies looking at outcomes with PT in tertiary care populations. Our study evaluated patients with chronic constipation in the community setting who had no success with soluble fiber or an osmotic laxative. These patients underwent RED at an outpatient visit at general gastroenterology clinics and began pelvic floor PT within 2 weeks of the baseline anorectal function testing. Our study showed that predicting outcomes for patients in this setting is valuable. Separately, the patient with severe chronic constipation unresponsive after multiple visits with gastroenterologists or other specialists is a very different scenario.

There are rigorous clinical trials showing that biofeedback delivered with a machine is effective in patients with dyssynergic defecation, as it helps patients see what their muscles are doing as they are trying to defecate and can help patients relax. However, that is different from the PT setting where biofeedback is a component of pelvic floor PT, which is performed with digital maneuvers or with a device. There are differences between the two depending on use. There is community use that is more broadly applied to the general population and very specific use where the stakes are higher such as in a tertiary care center. Predicting response to biofeedback therapy has been studied and may be helpful, although most providers may recommend biofeedback therapy regardless. In a post hoc analysis of two biofeedback therapy studies, Dr Satish Rao and colleagues found that patients who used digital maneuvers were more likely to have success with biofeedback therapy and concluded that all patients with dyssynergic defecation should be offered this therapy irrespective of baseline findings. This appears to be the current practice. In speaking with the physical therapists who offer pelvic floor PT who we work with, they will perform and teach biofeedback to patients manually rather than use a device.

G&H What new tools are available to evaluate for evacuation disorders and how do they work?

ES One new tool I mentioned, RED, has been cleared by the US Food and Drug Administration. This is an office-based screening tool that uses a self-inflating foam balloon, which is inserted rectally by the physician or office staff. No bowel preparation is needed. The patient is asked to expel the balloon while laying on their side,

and how long it takes to expel the device can help identify whether the patient has an evacuation disorder. From a usability standpoint, the balloon is the same size as those used in balloon expulsion tests in tertiary care centers. If a patient cannot expel the balloon, the physician or office staff remove it. As a precaution, any anorectal testing should not be performed in patients with an anal fissure. RED was designed to fit easily into the gastroenterology clinic workflow, for gastroenterologists to be able to offer to their patients in the office a test that can help them with treatment decisions. Traditionally, our pelvic floor physical therapists have fairly high no-show rates possibly because patients are not adequately prepared for what to expect. This type of testing can help circumvent that issue and help patients choose what is right for them.

It is important to think about evacuation disorders earlier in the care paradigm.

G&H How can use of assessments such as RED transform the paradigm of chronic constipation management?

ES It is important to think about evacuation disorders earlier in the care paradigm. Pelvic floor evaluation is covered in the 2021 American College of Gastroenterology (ACG) clinical guidelines for managing benign anorectal disorders. However, in the 2023 joint practice guideline from the American Gastroenterological Association and ACG, which focused on over-the-counter laxative and prescription drug management of chronic idiopathic constipation, the accompanying clinical decision support tool has a step-by-step guide that includes when to consider evaluation for pelvic floor dysfunction. New to this algorithm was the consensus that pelvic floor evaluation does not have to start early, but it should be considered early. Basically, it does not have to be relegated to last line, and I think that aligns with what types of testing or treatment could be appropriate for a patient earlier in their care vs later. Based on our research and the work of others, clinicians should at the very least consider pelvic floor testing and rehabilitation.

G&H How could the care of patients with evacuation disorders be improved?

ES We should consider the meaningful clinical benefits of the tests we in this field are developing. In speaking with gastroenterologists when designing the RED study, we really tried to get to the heart of what patients and physicians care about, which is: Does the test change management? What is the next step? How can I help my patient get better? I would hope that more studies, at least device studies, aim to look at those questions and less about getting or needing the test itself. The reason that we developed RED was because anorectal function testing as it stands has lived for a long time in tertiary care medical centers. Often, it can take years before patients with an evacuation disorder, having gone through cycles of care, reach these big centers for testing. It is interesting because often the treatment is right down the street all along, and it was just a matter of connecting the dots. Thus, focusing on accessibility is really important and is why we hope RED makes an impact.

G&H What further research is needed in this area?

ES The ongoing efforts to standardize tertiary care tools are something we can look forward to. It is important for the various centers seeing diverse patient populations to share their different perspectives to try to improve how pelvic floor dysfunction is understood and how it can best be treated. I think there will be a lot of work on expanding this area in the next decade, which is exciting. Hopefully this will lead to increased recognition of these disorders in practice and earlier treatment.

Disclosures

Dr Shah has consulted for Laborie and Medtronic and has a patent with the University of Michigan for RED, which is licensed to NeurAxis.

Suggested Reading

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