ADVANCES IN IBS

Current Developments in the Treatment of Irritable Bowel Syndrome

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What Is New in the Rome V Criteria for Disorders of Gut-Brain Interaction?

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G&H How did the Rome Foundation choose the name of disorders of gut-brain interaction? Does this name assign too much emphasis to the brain?

JT The answer to the second part is definitely no. Any symptom is felt in the brain. Historically, these disorders were called functional gastrointestinal (GI) disorders, and functional has a connotation in many languages of being feigned or imagined. Over the years, a lot has been learned about the pathophysiology of these disorders. Many factors play a role, including altered motility, hypersensitivity, low-grade inflammation, responses to diet and food intake, bile acid processing, changes in the gut microbiota, but also comorbidity, like anxiety, depression, and altered central processing of symptoms. For all patients who can have any of these abnormalities in a different degree, it is necessary to have a term that encompasses the full spectrum, and I think gut-brain interaction covers it.

There are a few important points to mention. One is that the term was not invented; it was developed using a Delphi discussion at the end of Rome IV. It was carried by the participants there who were selected based on their status in the field and their international distribution. Second, it is gut-brain—it is the gut that triggers the symptoms, and the brain that feels them. This is a very important sequence. There was an International Society of Brain-Gut Disorders, but gut-brain was chosen because that is the direction. This is not a duality, or saying this is imagined, it actually explains what is happening. The clearest example is in irritable bowel syndrome (IBS). Over the last 10 years, there has been a revolution with response to the diet low in fermentable oligo-, di-, monosaccharides, and polyols (FODMAPs). In my center, we see an 80% to 85% response. That seems as peripheral as one could get. Diet? That really should not be the brain. However, when FODMAPs are given to healthy volunteers and to patients with IBS, and the substrate is examined under magnetic resonance imaging to see how they induce symptoms (distension of the small bowel, fermentation, gas formation, and accumulation in the bowel), it is exactly the same between healthy volunteers and patients, but the patients have symptoms at that point and the healthy volunteers do not. Something is happening in the periphery. It is a change in the perception pathway that drives symptoms in the patient and not in the healthy volunteers. There are some people who are very negative about the term, but it covers the full scientific understanding of the pathophysiology and how symptoms are arising, and it is in line with treatment targets. Treatment with diet, probiotics, antibiotics, motility-modifying drugs, or with gut-directed behavioral therapies can work. Disorder of gut-brain interaction (DGBI) encompasses the spectrum of what we are dealing with in the Rome Foundation.

G&H What have been some of the limitations of using standard Rome criteria? How has the Rome criteria been revised to address these issues?

JT Originally, the Rome criteria were driven from a research angle to select patients for clinical trials. An analysis in 1988 by Dr Kevin Klein looked at all the available trials in IBS and concluded that there was no evidence of efficacy of the treatments studied, but all of

the trials used different definitions to select the patients, and different endpoints, and so on. One aim of the Rome Foundation has been to develop criteria to help investigators identify, study, and establish efficacy, or lack of efficacy, of certain treatments in a group that can be reproduced across the world. Initially, the criteria were somewhat strict in terms of the type of symptoms, their frequency, and duration. As the Rome Foundation moved into epidemiologic research, the 6-month duration aspect was maintained as very important. In clinical practice, especially in parts of the world with low-threshold access to medical care, people will not wait 6 months before they see a physician for abdominal symptoms. Because of that, the Rome IV clinical criteria were published that emphasizes the symptom pattern, which needs to be retained but does not require a strict frequency cutoff. For example, the Rome criteria describe functional dyspepsia as fullness after meals 3 days a week. For a patient who has this 2 days a week, but it is really bothersome, the diagnosis can be made without waiting 6 months. A clinician who is confident that there is a symptom pattern and no missed classical organic disease behind it can make the diagnosis. The Rome V clinical criteria are omitting the frequency and duration thresholds and saying that bothersomeness is sufficient. Second, Rome V is much more clinical practice–oriented. There is now an algorithm for managing IBS, which was not in the previous iterations, as well as an extensive algorithm for upper GI symptoms. For instance, the practitioner does not need to do an upper endoscopy in every patient with upper GI symptoms but rather use clinical judgment, looking at alarm and risk factors, and then decide, yes or no, whether endoscopy is needed to make the diagnosis. By embedding clinical practice guidelines and stepwise algorithms for diagnosis and treatment recommendations, the Rome V criteria have come closer to clinical practice.

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G&H What are some of the important changes in the content and classification of DGBIs for Rome V?

JT The most dramatic change has been in the criteria for pediatric DGBIs, which have been completely restructured. There was an age cutoff–based subdivision—neonates and toddlers vs children and adolescents. Pediatric DGBIs are now categorized as upper and lower GI disorders, implementing some of the adult diagnosis into pediatric practice, and they include a vast number of feeding difficulty–related DGBIs that are very prevalent in pediatric gastroenterology and are dominating many of the clinical pictures.

The adult disease classification has become much more scientific. By scientific, I mean that a lot was learned from the Rome IV global epidemiology study, which surveyed more than 73,000 adults from 33 countries. In each country, in a representative segment of the adult population, there were prevalences, overlap, and impact of these disorders. The findings helped steer some of the novel criteria or adapt them into the adult criteria. The dictum was that any change needs to be based on evidence. The Rome Foundation also conducted a Rome V epidemiology study before finalizing the current criteria. Some of the provisional Rome V definitions were adjusted based on the results of this Rome V global epidemiology study.

G&H How will having separate frameworks for research and clinical diagnostic criteria improve management of DGBIs?

JT Management should not improve from the scientific framework because this has always been available. The Rome Foundation has credible legacy here. If someone asks how patients are selected for a study on treatment outcome in a DGBI, the US Food and Drug Administration will say to use the Rome criteria. The European Medicines Agency and Japan's Pharmaceuticals and Medical Devices Agency will say the same. To some extent, however, the clinical arena has not fully followed. Clinicians may know that Rome criteria exist but may not use them in clinical practice. There are now 34 adult and 22 pediatric DGBIs. Clinicians do not need to memorize all of them, but the frequent ones, they should know. For that, the criteria are now easier, which should help clinicians make a confident diagnosis. The outcome of patients is excellent once they are diagnosed with a DGBI, but this is not always clearly communicated. There are two reasons for this. One is a lack of easy-to-use, effective medications, which has to do with the difficulty of selecting the patients and evaluating the outcome, which the Rome Foundation is addressing. The second is clinician uncertainty: it sounds like IBS, but am I really sure there is not a hidden ischemia in the GI tract? Clinicians are sometimes hesitant to confirm a diagnosis of IBS. Making criteria easy-to-use and accessible in an app or in tools clinicians are already using online

and having them embedded in electronic medical records should make the difference. This is not being done to see only the number of Rome-based diagnoses increase; this is needed to achieve better care. A patient who receives a diagnosis also receives a level of understanding and comfort that comes with clarity of unexplained symptoms. I think it is an important step to name the condition, rather than say, "it is nothing." To the patient, it is not nothing. Having a diagnosis alleviates anxiety and doubt and prevents patients from feeling the need to obtain a second, third, or fourth opinion.

G&H Could you describe how the diagnostic criteria for adults and pediatrics were defined?

JT Criteria development has become much more interactive and bidirectional. This has been very fruitful in helping define adult and pediatric criteria. The pediatric committee, for instance, joined with the gastroduodenal committee, which I was on, to listen to our ideas and implemented them in some of the pediatric gastroduodenal disorder definitions. The same was done for IBS, for rumination, and so on, and this interaction worked both ways. For instance, abdominal migraine, which has been around in pediatrics for a long time, has been added to the adult DGBI criteria. This addition was based on findings of a soon-to-be-published epidemiology study, which applied the newly developed adult abdominal migraine criteria to an adult population and found that the condition is not negligible but rather is prevalent, important, and impactful.

G&H Why was the new diagnosis abelchia added?

JT With abelchia, or inability to belch, the tricky part is that not all patients will voluntarily say, "I cannot belch." They may present with discomfort behind the chest bone, pain, or rumbling noises. Some report feeling extremely bloated after meals or inability to tolerate food or food avoidance owing to discomfort, but they may not offer that they cannot belch unless asked. Inability to belch confirmed by the patient is a key part of the diagnosis, but patients may present with other conditions. There are a few reasons why adding abelchia is important. First, it covers an unrecognized clinical entity. Second, epidemiology shows this is not so rare but rather fairly prevalent. Third, there is a mildly invasive, well-tolerated effective treatment for the condition. This is based on findings of a triple-blind sham-controlled study, which was presented at Digestive Disease Week 2026 by Dr Karlien Raymenants from my group. In the study, 25 patients were injected with botulinum toxin in the upper sphincter, and 25 patients were injected with placebo. At the 12-week follow-up, 88% in the active group had a response vs 4% in the placebo group. Although the pathophysiology is not fully understood, the treatment appears to have high efficacy in these patients.

G&H Has anything changed specifically related to IBS?

JT The term *pain related to the bowel pattern* has been changed to *pain or discomfort*. In parts of the world, especially Asia and in Hispanic countries, people clinically diagnosed with IBS are more likely to say they have discomfort. In retrospect, this change reflects better international representation and is multiculturally and multilinguistically correct. The frequency rating also has been changed from once a week to 3 times a month; this does have an impact and is based on previous epidemiologic analyses. Two more connotations have been added that are very important. One is that pain should not be exclusively or predominantly related to the menstrual period. This is to help avoid missing endometriosis and is another example of a change informed by pediatrics. One study of adolescents with IBS found that in some patients, pain fluctuated very strongly over the menstrual period and was probably dysmenorrhea or endometriosis. Second, there is a stipulation that the pain of IBS should not be continuous (day in and day out); it should be occasional because there is another entity, centrally mediated abdominal pain syndrome, characterized by continuous pain. These changes are clinically relevant small refinements. They will by no means decrease in a large number the proportion of IBS cases seen in daily practice but should help clinicians identify the occasional presentation that is not IBS.

For DGBIs, the biopsychosocial approach means that clinicians go beyond the strict diagnosis.

G&H What is the biopsychosocial approach to management of patients with DGBIs?

JT Let me first say that the application of this can and should be used in any part of medicine, also for organic disease. For DGBIs, the biopsychosocial approach means that clinicians go beyond the strict diagnosis. For instance, suppose you have two patients who are women in their

40s with a history of IBS with diarrhea (IBS-D). One is very careful when she goes to restaurants but can function at work and never has to stay home because of diarrhea. The other says sometimes it is so bad that she needs to stay home several days from work and when she thinks she might get it, she does not go out and has become so anxious about her bowels starting again that at times she wakes up in the middle of the night in panic. Both women have IBS-D. The approach to each patient will be totally different. The first patient may need a soft diet or a locally acting drug, whereas for the second patient, the clinician might consider a complex diet, a neuromodulator, gut-directed behavioral therapy, and perhaps a physiological measurement. Further history is important because it is known, for instance, that patients with childhood trauma have a likelihood of having disordered defecation. The biopsychosocial model looks at the entirety of the patient, including their social network and the impact and comorbidity of their symptoms.

G&H What are the new treatment recommendations, including gut-brain psychotherapies?

JT Taking full stock of what has happened over the last decade, there have been a few revolutions of therapies with established efficacy. The first is cognitive behavioral therapy, which is now addressed in a Rome section called Gastropsych. A second one has been the low-FODMAP diet revolution, and this is still evolving. There is a Diet and Nutrition section, where dietitians across the world provide recommendations on not only the low-FODMAP diet but others as well. The third new recommendation is for our section on Complementary and Integrative Medicine. There is evidence that certain herbal medicines, for instance, have safety and efficacy, and in some areas of the world, these are extremely popular. Anorectal biofeedback is another treatment modality for which a Rome section is providing standardization and guidance. While staying scientific and evidence-based, in addition to the standard pharmacotherapy, the Rome committees have embraced these novel treatment tracks and provided hints on where to use them. This expansion of choices for clinical management allows for more targeted treatment. Having said that, some refinement is lacking. At some point, it would be nice to have a clinical decision tree for best choice of therapy. Currently, the science is not there, but the armamentarium clinicians can offer is now much broader, and therapy choice remains a guided interaction with the patient. The patient chooses at the end what is acceptable based on the input and information from the clinician.

G&H Is there anything else you would like to highlight about Rome V or a potential Rome VI?

JT There are definitely things that can be done differently in Rome VI. One gap is in overlapping conditions. We always aim to treat, describe, and analyze pathophysiologically and diagnostically these conditions as though they are single conditions, but there is a lot of overlap. For instance, of functional dyspepsia patients, 30% to 40% likely have overlapping IBS. There is no reason why the disease concepts such as altered sensitivity and motility would stop at the end of the stomach and not involve the rest of the intestine. It has been a struggle making strong recommendations on where to go first. This is one of the agendas that Rome will address on the way to Rome VI, which is luckily 10 years away. At the end of every chapter in the Rome consensus, there are agendas for future research. This is the third Rome iteration I have been involved in, and with each iteration, the agendas have stayed mostly the same because no one is doing this research. This is why we created the Rome Foundation Research Institute to conduct epidemiologic, pathophysiologic, and interventional research. This is one of the ways we can potentially advance the science of DGBIs and that should have an impact on Rome VI.

Disclosures

Professor Tack has given scientific advice to Adare Pharma Solutions, Alfasigma, Enterra Medical, Falk Foundation, ProMed, Recordati, Takeda, Trubion Pharmaceuticals, and Tsumura; has received research support from Biohit and ProMed; and has served on the speakers' bureau for Abbott, Biocodex, Mayoly, Menarini, ProMed, Reckitt-Benckiser, Schwabe, Takeda, Thai Meiji, and Trubion Pharmaceuticals. He is the current president of the Rome Foundation.

Suggested Reading

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