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2020 Crohn's & Colitis Congress: How & When to Perform Disease & Drug Monitoring

Announcer:
You're listening to ReachMD. The following episode was produced in collaboration with the Crohn's & Colitis Foundation & the American Gastroenterological Association.

Here's your host, Dr. Matt Birnholz.

Dr. Birnholz:
Coming to you from the Third Annual Crohn's & Colitis Congress in Austin, Texas, this is ReachMD. I'm Dr. Matt Birnholz. Here with me today is Dr. Frank Scott, Assistant Professor of Medicine from the Crohn's & Colitis Center at the University of Colorado, and together we'll be reviewing the subject of a session, occurring at this congress focusing on disease and drug monitoring for IBD.

So, Dr. Scott, it's great to have you with us.

Dr. Scott:
Thank you so much for having me. It's a pleasure to be here at the congress, uh, always enjoy being here. It's a great opportunity to network—network with our colleagues and discuss the state of the art in terms of IBD care.

Dr. Birnholz:
It's great to have you here. Uh, so just to start off, why don't we cut right to the chase and then dive into the details afterwards.

What I'd love to know from a big picture perspective is what you think are the most important drivers for disease and drug monitoring for IBD in clinical practices today, because it's an always shifting target. What can you tell us about, uh, disease and drug monitoring for this particular disease, what you think right now and moving forward are the most important factors that we need to keep in mind?

Dr. Scott:
Fantastic question. I—I think, uh, we're at a really exciting time in IBD care wherein we not only have, uh, a wide armamentarium of new therapies that we can give to our patients, we—we also have new markers that are noninvasive that allow us to actually monitor disease activity, and we have growing bodies of evidence that suggest that monitoring these patients very closely potentially has the impact to change the course of disease.

Dr. Birnholz:
Interesting and fascinating. What—t are some of these markers if we just start to delve right into them?

Dr. Scott:
So, traditionally we've used endoscopic evaluation or cross-sectional imaging. And Endoscopic evaluation, unfortunately, is invasive, and it requires a prep by the patient, and it has potential risks associated with it, and it is also expensive. Uh, uh, an initial adjunct to that was cross-sectional imaging in the form of MR enterography or CT enterography, but those carry different risks and costs associated with them now as well. Uh, we are currently, uh, recommending that providers use a combination of things like C-reactive protein, which is a—a serum-based marker for inflammation, uh, widely available, inexpensive and with a growing body of evidence that suggests that you can trend that over time to determine whether or not patients are responding and whether or not they're about to have a flare, and also fecal calprotectin, which is a stool-based study, slightly less convenient to, uh, collect for the patient but much more sensitive to G—GI tract-specific inflammation.

Dr. Birnholz:

And their sensitivity, because you mentioned that, is high enough to have a good degree of confidence in being able to actually have predictive monitoring for flares, for instance?

Dr. Scott:
Absolutely. You know, in several meta-analyses we're talking sensitivity values that are greater than 80%, uh, for—for these specific markers. Now, the… There is always going to be the issue of whether or not they're specific. Uh, for example, if somebody has a GI, uh, infection, GI tract infection of some sort, uh, a fecal calprotectin may be falsely positive, it doesn't reflect their inflammatory bowel disease, but it does reflect, uh, that there's inflammation in the GI tract, but they are very sensitive for the GI tract inflammation. Uh, they also have a very high negative predictive value, which means if they're negative, we can feel fairly confident as clinicians that the cause of their current symptoms is not related to actual inflammation related to Crohn's or ulcerative colitis.

Dr. Birnholz:
Interesting. Well, you're getting to, um, another area that I'm really interested in here, which is what the adoption rate is among clinicians in terms of trying to establish best practices in monitoring and whether GI specialists or other specialists who are taking care of patients with IBD are following the best practices out there to get better predictive monitoring. What would you say the state of affairs is right now in clinical practice?

Dr. Scott:
I can't give you exact estimates with regards to adoption of, uh, algorithms such as treat-to-target, but I can say that there's a growing acceptance amongst especially the IBD expert community that this is what we should be moving towards, and, uh, events like the Crohn's & Colitis Congress serve as educational opportunities for providers that are not routine IBD experts to learn about these methods and—and to use them at a—at a higher frequency.

Dr. Birnholz:
Do you think that there might still be some improvements that could be made in the monitoring methods among specialists such as yourself in—whether it's in the private practice arena or in hospital systems—to foster better long-term outcomes for IBD patients?

Dr. Scott:
Absolutely, you know, I think the 2 main modalities right now that most IBD physicians and general gastroenterologists are concerned about is how do we select drugs, uh, for patients when we're, uh, beginning, uh, immunosuppressive therapy or—or steroid-sparing therapy and how do we, uh, most tightly monitor these patients to maximize the effect of these therapies. I think those are the 2 main avenues where there's still a lot of active research. We have some guidelines right now like treat-to-target, uh, which has been promoted heavily at this conference, uh, uh, appropriately so in my opinion, um, but we don't yet quite have, uh, directed biologic markers for what the right therapy is for the right patient at the right time.

Dr. Birnholz:
And just to catch our viewers and listeners up, uh, in terms of our audience regarding treat-to-target, can you just overview that for a minute—and, what kind of pull it's been getting at the Congress?

Dr. Scott:
I feel, you know, at—at the events that I've been at so far that, uh, people are generally in tune with this idea, and it's—it's gaining acceptance amongst the community. The general concept is that once we've started a therapy on somebody, uh, it's—you—you just don't start the medication and then just wait for them to come back and see how they're doing 6 months later. It involves a combination of—of recurrent symptomatic monitoring, uh, at 3 to 4 months as well as biochemical monitoring in the form of things like fecal calprotectin and CRP and modification of therapy if patients are not yet—uh, haven't yet experienced normalization of these, uh, biochemical values or with resolution of their symptoms. That allows a—a finer tuning of—of their medical therapy that prior to algorithms like treat-to-target wasn't available.

Dr. Birnholz:
Do you think that there might be a—and I'll put this speculatively, but I think the answer is almost a rhetorical question—any continuing barriers, be they technological, access- uh-driven or, um, patient adherence-driven towards being able to get to that sweet spot of being able to monitor patients continuously in the way that you were just describing from treat-to-target recommendations?

Dr. Scott:
I think so. You know, CRP would be, uh, 1 good example. It's—it's easy to draw. It can happen in the clinician's office or at a—any sort of standard laboratory, uh, but it doesn't have the same test characteristics as fecal calprotectin. Fecal calprotectin can be considerably more sensitive, but it requires a stool collection, which can be burdensome for patients. There's also some interesting data that suggests that it may vary based on what assay you're using. And there's not fantastic data with regards to what cutoff we should be

using in terms of a positive versus a negative value at this point. That's still a bit of a gray area in the—in research, and it may be assay-dependent and time—even time-of-day-dependent.

Dr. Birnholz:
Hmm, interesting. And what about drug level monitoring? What's in place right now, and what's potentially being looked down the future for more accurate drug level monitoring for patients?

Dr. Scott:
Sure. Therapeutic drug monitoring is a—has been a hot topic in inflammatory bowel disease and even other autoimmune disorders for a long period of time now over the last several years. I think the—in general the community is very comfortable with something we refer to as reactive monitoring. Reactive monitoring is when you assess drug levels and antibodies as a trough when somebody's had recurrence of symptoms. Uh, there's a wide body of literature that suggests that, uh, that is effective and helps guide your next selection of therapy for patients that are—are failing a therapy.

The slightly more controversial adaptation of therapeutic drug monitoring right now is proactive monitoring where patients, uh, have drug level testing done at, uh, when they're doing well, uh, but just after initiation of a drug or change in dosing of the drug. So clinically they're fine, but you still want to see where the drug level is and whether or not they develop an antibody and fine tune it if possible. Um, there's been 2 large retrospective clinical trials that have demonstrated that that may not add benefit, but there's a—a very large body of observational data that suggests that it is, and so that is a continued area of debate in the IBD field.

Dr. Birnholz:
And what about the role of pharmacogenomics in being able to establish accurate predictive measures for whether a patient will respond or not? Is there any place in that in IBD therapy right now?

Dr. Scott:
We're not there yet, but that is—that is the sort of golden ticket, if you will. Um, you know, we now for the first time over the last several years have developed not only 1 class of biologic therapy for inflammatory bowel disease but 2 additional FDA-approved classes. We're on the cusp of several additional agents being available and new classes of medications. The future therapy for... The future of therapy in inflammatory bowel disease is—is not just selecting a drug but figuring out what the right drug is for the right person. There's some really fascinating data with regards to various genetic analyses run on blood samples on baseline, uh, interleukin receptor levels, um, that may be of benefit, but it requires validation at this point.

Dr. Birnholz:
Well, Dr. Scott, before we go, any last parting takeaway thoughts regarding, uh, directions for this congress that you're excited about, um, this and other subjects therein?

Dr. Scott:
Uh, just to reiterate what I opened with, you know, I—I feel like it's a—it's an exciting time as an IBD-ologist to care for patients, because not only do we have a wide array of potential therapeutic options but we also have, uh, novel methods by which we can survey our patients and potentially improve the care that we provide, and we're beginning to see that not only are we improving clinical care but we're altering the course of disease, and that's pretty exciting stuff.

Dr. Birnholz:
That's great, perfect parting comments. We've only just brushed the surface of insights, I think, coming out of, uh, disease and drug monitoring, but, uh, what we've got from you at this Crohn's &, uh, Colitis Congress has been, uh, wonderfully informative. I can't thank you enough for your time.

Dr. Scott:
Thank you.

Dr. Birnholz:
For ReachMD, I'm Dr. Matt Birnholz. Thanks again for joining us, everyone.

Announcer:
This program was brought to you in collaboration with the Crohn's & Colitis Foundation & the American Gastroenterological Association. If you missed any part of this discussion, or to find others in this series, visit ReachMD.com/foundation, where you can be part of the knowledge.