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The Increasing Incidence of IBD and the Use of Biosimilars

Dr. Cheeley:
The increasing incidence of inflammatory bowel disease, or IBD, has redirected the healthcare system's focus towards safe and affordable pharmacological interventions, but with the number of biosimilars now available, there is still hesitancy to use them in clinical practice.

Welcome to *GI Insights* on ReachMD. I'm your host, Dr. Mary Katherine Cheeley. And joining me today to talk about the use of biosimilars for the treatment of IBD is Dr. Shubha Bhat. Dr. Bhat is a Clinical Pharmacist in the Digestive Disease Institute at the Cleveland Clinic.

Dr. Bhat, thanks for joining me today.

Dr. Bhat:
Happy to be here. Thank you.

Dr. Cheeley:
Let's jump right in. I love the topic of biosimilars, so let's talk about the common ones that are being used for IBD these days.

Dr. Bhat:
Yeah, definitely. So currently, biosimilars are only available for infliximab and adalimumab, and these are the two most used biologics in IBD treatment. Also, we have about four FDA-approved infliximab biosimilars, but there's only three that are actually available for patient use. One of the pharmaceutical companies have produced two biosimilars. Instead of marketing both, they just decided to go with one. From an adalimumab standpoint, we have nine FDA-approved biosimilars right now, and all of these should be available for your patient use before the end of 2023. And actually, there's another commonly used biologic, which is ustekinumab, and the patent for this medication is expiring this month in September, so we anticipate that there will be a launch of ustekinumab biosimilars likely in 2025 per the agreement that's been made with the pharmaceutical company, as well as from the reference ustekinumab and the ustekinumab biosimilars.

Dr. Cheeley:
So let's take a step a little bit back in the process. Can you help describe for me the research behind the safety and efficacy for biosimilars to their reference products?

Dr. Bhat:
Oh, certainly. So when biosimilars were first introduced to gastroenterologists practicing in IBD, they had many concerns, primarily because biosimilars were being studied in rheumatologic conditions but were being approved for use in Crohn's disease and ulcerative colitis based on this data, and this process known as extrapolation. And I will say that one interesting feature is that there was a lot of practice differences between rheumatology and gastroenterology in regards to how we position, use, and monitor biologic medicine. At

the end of the day, we simply do not have a ton of medication options in IBD compared to rheumatology.

But going back to the positive extrapolation, it worked because biosimilar manufacturers need to demonstrate biosimilarity, meaning that the biosimilar products are entirely similar in structure and function to the reference product. Moreover, the active ingredient remained the same, and biosimilars also are subjected to a vigorous quality assurance process.

Fortunately, we do have a lot of studies now that have evaluated biosimilars in IBD, and those all confirmed that biosimilars are safe, effective, and do not result in worsening patient outcomes. I would like to also give a kudos to our colleagues in Europe because they have published a lot of this data given that biosimilar adoption in Europe has been a lot more successful when you compare it to biosimilar adoption status here in the United States.

Dr. Cheeley:
So based on your personal opinion, do you think we use enough biosimilars, especially in IBD?

Dr. Bhat:
Oh, that's definitely a great question, and I hate to say this, but unfortunately, no. And I will say that this insufficient utilization of biosimilars is really not just applicable to IBD but to other conditions as well. And for one example, we just had a launch of biosimilars in ophthalmology and one condition that this is approved for would be neovascular age-related macular degeneration, so that's another condition that's probably not releasing a ton of biosimilar use.

But going back to the positive biosimilar adoption and implementation has not really been well received or implemented within the United States, and I think you can agree, but there's a lot of complexities to this. There is litigation issues happening that's delaying the launch of these biosimilars. There's rebate traps in which the manufacturers are negotiating with the pharmacy benefit managers on the back end for pricing. There's formulary management that not everyone has the same formulary, whether that's the institution or the payer.

And then just look at the amount of payers that we have available. There's a ton of them. So not only that, there's also other stakeholders that are involved in the biosimilar adoption and implementation process. So we have the gastroenterologist and the patient. And interestingly, there was a report that was recently released by Cardinal Health that focused on biosimilars, and we have strongly identified that at least 93 percent of gastroenterologists surveyed are at least somewhat comfortable prescribing adalimumab biosimilar specifically, but it's interesting to note that the current concerns are not necessarily on efficacy or safety but just general impact of biosimilars on gastroenterology care, and moreover, the patient out-of-pocket costs.

So in summary, I think there's a lot of factors that really affect biosimilar utilization. And honestly, not all the pieces have lined up perfectly to allow for sufficient utilization, and at the end of the day, most of the utilization is really being driven by payers.

Dr. Cheeley:
I agree with that. I would say it's the same in our practice. We have providers that are used to the reference products, so that's what they reach for first, but then the payer comes in and says, "Well, I'm not going to pay you for that infliximab. I'll pay you for this one." And so it just starts this cycle, which then providers get frustrated with because now they're two weeks behind and starting a patient on something that really could make a difference. Do you notice the same thing in your practice?

Dr. Bhat:
Yes, this is definitely a pain point. But I think with biosimilars, there's a lot of great utilization and rationale for them, but yes, I think that the practical application when it comes to it at the end of the day in terms of navigating the logistics of switching patients or starting patients on a medication and doing a prior authorization process and then finally getting them on the correct product, yes, this is definitely, I think—and just a sidebar, I think that this is why pharmacists are definitely needed in this capacity, and so I think we have a lot of great impact when it comes to navigating that biosimilar landscape.

Dr. Cheeley:
I couldn't agree more. Just figuring out which product is right for the patient clinically and then payer-wise what you can actually get is right where you can find your friendly neighborhood clinical pharmacist to help you navigate that.

For those just tuning in, you're listening to *GI Insights* on ReachMD. I'm Dr. Mary Katherine Cheeley, and I'm speaking with Dr. Shubha Bhat about the use of biosimilars in treating IBD.

So let's turn our attention to the patient perspective. In your clinical practice, what are the questions that you're getting from patients about biosimilars? And then how do you specifically go back and counsel them and help them understand the difference between the products?

Dr. Bhat:
Oh, so I love this question because I have been counseling and educating about biosimilars for several years now, and I hate to say, but hands down the number one question and concern is the worry about the switching process, and it's always in the context of going from a reference to a biosimilar. And particularly, in a patient that is actually stable on treatment and has concerns, they're worried about the risk of receiving subpar treatment. And it also doesn't help that this is often a payer-mandated practice and patients are informed about this out of the blue—they get a letter in the mail—or they're at the point of trying to get their medication only to find out that for whatever reason the insurance isn't going to approve it anymore. And so this is why I can't emphasize this enough, but proactive education is so important. And I talk to patients about what a biosimilar is, what the benefits and rationale are for switching, and I also cover the logistic side and try to mitigate any questions or concerns that they might have. And I will also add this, that I do take the opportunity to mention biosimilars when I can, even if it's not applicable to patients at that moment because I honestly believe that knowledge is power.

Dr. Cheeley:
So are there any times where we should be proactively switching from a biologic reference product to a biosimilar in your opinion?

Dr. Bhat:
So I think, as you and I have been talking, the common theme that's been reoccurring is the fact that this is really a payer-driven process right now, and most of the switches, which is occurring when there's a formulary change or an update, and I think that, honestly, at the end of the day, in most clinical scenarios, the switch is totally fine. There's not usually a concern for it. And I would love for this to proactively happen, but it's not going to be a large-scale conversion unless it's being driven by the payer or institution.

Dr. Cheeley:
Yeah, I agree. What do you think about the future of biosimilars? What research needs to be done? Where do you see them falling into practice in the future for us?

Dr. Bhat:
Oh, I wish I had a crystal ball for the question. I could say that the answer would be that we successfully align practicing with Europe why biosimilar utilization is fantastic, and we're finally reaping the benefits of what biosimilars have to offer.

But going back to your question about the research, I think that now that we have established the efficacy and safety of biosimilars, we're not so concerned about that anymore, and moreover, that data continues to be supported by real-world evidence, so I think we're past that stage of questioning what biosimilars can do and what benefit they can offer.

But I really think now we can pivot more to the implementation and adoption side to start to look at what the barriers are, how do we overcome these barriers. And, Dr. Cheeley, I don't know if it's the same for you, but one of the things that I noticed a lot of us struggle with is that we say that the benefit of biosimilars is supposed to be from a cost-saving perspective, especially for patients, but I can tell you hands down even from a clinician side we're not necessarily seeing the cost savings, and so how much cost savings is actually happening, and where is that money being funneled into because is it being funneled into lowering premiums? Is it being funneled into developing new drugs? Where exactly is that cost savings going?

And so I think if we even had concrete data to highlight the benefits of biosimilars, actually the real-world impact, I think that this will really help biosimilar adoption go a long way.

Dr. Cheeley:

This has been such an amazing discussion. I'm so grateful for you being here. Thank you so much for talking to me about the biosimilar options for our patients with IBD. Thank you to my guest, Dr. Shubha Bhat, for joining me and providing great insight on this topic.

Dr. Bhat, it was so lovely speaking with you.

Dr. Bhat:
I appreciate it. Thank you.

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