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Released: 06/02/2026
Valid until: 06/30/2027
Time needed to complete: 2h 08m

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Putting It All Together: A Practical IBD Treatment Selection Primer

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Dr. Iroku:
Welcome. I'm delighted to be joined by Dr. Rubin and Dr. Dolinger for a rapid-fire discussion on case-based management in IBD. In this episode, we're going to put everything you've learned into real-world practice. We're going to move quickly through a few real-world scenarios and show how management changes when the case changes, whether that's comorbidity, prior drug failure, infection risk, or treatment goals. Let's jump right in.

Let's start with a 28-year-old with newly diagnosed moderate to severe ulcerative colitis. She has bloody stools, urgency, elevated CRP, and extensive colitis on colonoscopy. You've ruled out an infection. Dr. Rubin, what's your first move?

Dr. Rubin:
Well, it's important to recognize that you started by telling us this was a patient with moderately to severely active ulcerative colitis. But our clinician colleagues should recognize that when they see the patient with ulcerative colitis, they need to determine if she's moderately or she's moderately to severely active.

You gave it away when you said that this patient was having active symptoms but also extensive colitis. So one of the major messages needs to be that when you diagnose somebody with moderately to severely active ulcerative colitis, you should choose a treatment that's going to address moderately to severely active UC. And what I mean by that is avoid thinking that you're going to be able to use courses of steroids repeatedly and then back down to mesalamine in a patient who's that sick.

You should embrace the therapies we know work and think carefully about using a treatment up front that's going to get the patient into remission, maybe even avoid steroids altogether. And at this stage, it might be a therapy like vedolizumab, the alpha-4 beta-7 anti-integrin, or even an S1P receptor modulator like ozanimod or etrasimod. Of course, it's also reasonable to think about some of our other treatment options. But for the starter, that might be where I would go.

Dr. Iroku:
Dr. Dolinger, what if it's a case where it is mild to moderate disease, what would you do differently with your approach?

Dr. Dolinger:
Yeah, I think in those cases where mesalamine is a real option for those patients, I like to use rectal steroids and to give them some form of topical relief if they're willing. I mean, you can judge when a patient's willing to use rectal steroids or not and get that sense, because that's really what drives symptoms. If you can heal that rectum and that sigmoid colon, or at least provide some sense of relief,

then that buys you a little bit of time.

And once they're feeling better, it gives you a chance to see if an oral mesalamine option may be a great approach for them. Whether it's sustainable or not, it's hard to predict that early, but I think in those cases it's really an option. You don't need to necessarily jump to a more advanced therapy or more targeted therapy at that point.

Dr. Rubin:
I agree completely, and I would just add that teaching patients that the majority of their symptoms are coming from the bottom is a nice way to educate them about why a rectal therapy might be a good choice up front and to explain how to do it, of course.

Dr. Iroku:
And for our patients who are interested with a holistic approach, Dr. Dolinger, are there any approaches that you tend to use in your patient population?

Dr. Dolinger:
Yes. As a pediatrician, most parents are hesitant to give their children an advanced therapy that targets the immune system, and they want some form of control with a diet or natural approach.

I tell them it's hard for diet to affect inflammation when it's far from the colon, but we do have nutraceuticals or natural approaches that can definitely provide relief of inflammation and help our therapies work faster. Two of them are curcumin plus QingDai, or CurQD, and another is coconut water. Actually, these studies are well tested, and you've seen in randomized trials that they do well for patients, not alone but in conjunction with other therapies. And they can really be an adjunctive approach and give patients that sense of control that they're desiring.

Dr. Rubin:
I have this similar conversation with adults, by the way. People are interested in understanding this. I just want to put in context that I try to think that everyone we're taking care of is a holistic approach to their management. So when patients say, “I want a holistic approach,” I say, well, that's also what we want for you.

I would also remind everyone that mesalamine is an extract from willow tree bark, and so you can help patients understand that some of our therapies actually are coming from nature in different ways. They just have good evidence to back them up, just like the CurQD strategy or the coconut—what is it, coconut water?

Dr. Dolinger:
Coconut water.

Dr. Rubin:
That's what I haven't used in the adults yet, but I'm learning from you, Mike. But nonetheless, I think it's important. It's also important to recognize that regardless of what we use, we still want to make sure we're achieving our goals.

Dr. Iroku:
Alright, so we're back in the universe where the patient has moderate to severe disease. Dr. Rubin, you've chosen your vedolizumab or an anti-IL-23 inhibitor. Is that what you chose?

Dr. Rubin:
I actually said an S1P receptor modulator. I think IL-23 is absolutely reasonable as well, and certainly the data would support that option.

Dr. Iroku:
And so, Dr. Dolinger, when do you want to bring your patient back? And what are you looking for to make sure that along the way your goals of therapy are being met in this patient population?

Dr. Dolinger:
Yeah, I want to make sure that that patient feels better within the first 2 weeks of starting a therapy. And if they're really sick and they have a high CRP, that gives me an alarm flag. When I see that CRP elevated in colitis, then maybe I want to check in with them even a little sooner. Within 1 week, we should start to see some form of symptomatic response, and it could be a telehealth. We don't necessarily need to inconvenience their life to bring them back or check in with a mid-level provider. But when they are that sick and they have moderate to severe ulcerative colitis, in particular, we'll know very shortly if they're moving in the right direction.

And when I do bring them back within 2 weeks, we use ultrasound in the office here, and this is where I would plug ultrasound as a way to see actual healing of the bowel wall in response to therapy. And we may use calprotectin if we don't have ultrasound as a surrogate that early as well to see some percentage change going down. As long as our patient is feeling better, then we know we're on the right

track.

Dr. Rubin:
Yeah, I agree completely. If you look at clinical trials, the data we have for all of our current therapies in this category of moderate to severe disease, or even mild to moderate disease, demonstrates that patients often feel better within 2 to 4 weeks of the first dose or the first doses of their treatment. And so it's reasonable to tell a patient that you might be feeling better, you definitely shouldn't be getting worse.

In my practice we have intestinal ultrasound as well, although I recognize many of our colleagues don't. I also will arrange for a calprotectin, but I usually wait until about 6 weeks to get the calpro, just so I've given them a little more time. But that doesn't mean that I'm waiting that long to know if they're feeling better. And I often will say to them, I'd like to hear from you in 2 weeks to know you're on the right track, but if you're feeling worse when you start this, please reach out sooner.

Dr. Iroku:
How much of a delay in response, Dr. Rubin, is enough to make you think we need to switch course?

Dr. Rubin:
Yeah, that's a great question, and it's a very frequent one, especially after you get through the inertia of explaining the therapy, having a patient or the parents of the child agree to start the therapy, and then getting the insurance approval. By the time you get through all that, you don't want to give up too soon, but you also don't want to drag it along too long.

And I would say to you that after 12 weeks for ulcerative colitis, if you haven't had a measurable improvement—either the symptoms are significantly better or the calprotectin or CRP is 50% better, or in the case of intestinal ultrasound we see a bowel wall thickness that's at least 25%-50% improved—you need to move on.

The concept of delayed remission or delayed response, which is included in clinical trials where you go an additional 12 weeks or an additional 6 weeks, is an important one. But you should acknowledge in the real world that the patient has to be improving. It's not that you're waiting 12 weeks and they're not better at all and then you go another 12 weeks.

And I recognize that in the real world that means going back to the drawing board or adding another therapy or doing something else, but that's what we need to do. We don't want the patient suffering unnecessarily for 6 months before we make a change.

Dr. Iroku:
Dr. Dolinger, are you doing any reinductions or adjustment of frequency of your maintenance therapy?

Dr. Dolinger:
Yeah, I think similar to Dr. Rubin, it’s a difference between trial and real world, that when you have a patient who you just got onto this therapy, you put a herculean effort in. They clearly have a measurable response—especially in symptoms—to induction, and then you lose some of that response where there's a flare and there's no infections. And you rule things out during maintenance, before cycling to the next therapy, which your patient fears they're going to go through therapies; and maybe we just didn't get it right from the beginning and always try and take a humble approach that we don't know. We don't have a precision test that drives that specific patient's inflammatory bowel disease, and we use all our factors to predict what we think the best and safest therapy is. But if we got it partially right, maybe they needed a higher dose, and maybe they needed a higher dose for longer. Maybe they weren't a patient who would have been in the clinical trial. And so I do give them that reinduction, or I shorten that interval when maybe the data doesn't support that if they did okay from the beginning.

Dr. Iroku:
Alright, so let's switch diseases. Now we have a 14-year-old in your field, Dr. Dolinger, 1 of your pediatric patients, who has Crohn's disease and now she has postprandial pain, weight loss, and imaging suggesting a stricture. What's your first thought?

Dr. Dolinger:
My first thought is, is this inflammatory, or is this a majority fibrotic or scarred stricture, and what's driving her symptoms? If this is really, truly scarred—and we use ultrasound combined with other cross-sectional imaging and endoscopy to try and figure that out—then I really do drive them to surgery early, because I think you're going to have disease for 80 years, maybe. Hopefully, we'll cure it, but we need to do the right thing now and not cycle through a therapy that's not going to work. So that's how I kind of approach that strategy.

Any difference in your approach, Dr. Rubin?

Dr. Rubin:
Well, in an adult, if it's inflammatory—so I do agree, you want to try to figure out whether it's a fibrotic or just a stenotic inflammation—

then I like the IL-23 as a first-line therapy in that setting. I do think inhibiting that target is a good one, and we recognize, of course—and this is an important message, especially in Crohn's—treat early with effective therapy and make sure that you hit them with the right treatment as soon as possible.

Dr. Iroku:
Alright. Now there's no stricture, and she has atopic dermatitis. Does that change your plan, Dr. Rubin?

Dr. Rubin:
Well, atopic dermatitis and IBD are interesting to consider together. Eczema is a common problem, and we know, for example, that JAK inhibition treats atopic dermatitis extremely well. TNF does not. So I will use this as a reason to choose an early use of upadacitinib in that setting. And I like that therapy both for the Crohn's and for the atopic dermatitis. And I won't go through other therapies; I'll start with that treatment. And I think because of the atopic dermatitis, it's completely reasonable to do so.

Dr. Iroku:
Dr. Dolinger, she's on her JAK-STAT inhibitor. Many years have passed. She's an adult. She's about to get married and conceive. Any change in your plan in that scenario?

Dr. Dolinger:
Yeah, absolutely. And like Dr. Rubin said, I like to think of the skin as a window into the gut and the biology, and so I choose that treatment as well for that choice and that reasoning.

But for the long-term option in pregnancy and life planning, I think we know we're going to get off this if we get you in deep remission. I think we can usually pivot then to an IL-23 therapy, or even potentially, if we've been in deep remission for years, use natural approaches, diet-based approaches, to keep things healed—not if we were severe from the start, but if they had a more mild to moderate approach without a stricture, as you said. And patients want that, and we could always restart upadacitinib, which is different than our other therapies, and it should be potentially as effective as before.

Dr. Rubin:
Okay. The key is monitoring, right? So if you de-escalate therapy or change the treatment, whether you're going to an IL-23 or whether you're going to consider an enteral nutrition strategy, I do want to emphasize the importance of monitoring at short intervals, so you don't lose track of what's going on.

Dr. Dolinger:
Yeah, and then we recently had a few cases like this, and we had disease recur early within 3 months, and the patient knew, “This strategy didn't work for me.” They wanted to prove it to themselves, and then they jumped to a therapy, and they got back into remission with healing. And it’s sometimes giving them that control back allows that kind of shared understanding and buy-in for the long term.

Dr. Rubin:
Yeah, I'm glad you said that. I would just add that currently, when the patients work their way up to therapy—so they go through other treatments before they finally land on a JAK or something that's working—if you withdraw it, they may bounce back sooner. But the better we get at treating early and getting people into remission early, the more we can actually consider options of de-intensification of therapy.

Dr. Iroku:
Alright, so we just made our way through a pandemic. But let's say your patient just has a regular endemic flu. What are you doing with your JAK-STAT inhibitor or other advanced therapies? Dr. Rubin?

Dr. Rubin:
That's a great question. It comes up all the time of course. My general rule of thumb is that if they have a fever over 101, we hold the JAK inhibitor for a few days and we let them restart when they're no longer febrile, when they're feeling better. Reminder that the half-life of upadacitinib and tofacitinib is short enough that it's out of the system quickly, and it can be restarted and be up to speed again fast when you need it.

Your other therapies have a long half-life, so stopping an IL-23 inhibitor or vedolizumab or even a TNF inhibitor, unless it's immediately due while they're sick, doesn't have much rationale.

Same thing goes for people having elective surgery, by the way. When our colleagues who are performing orthopedic surgery or dental procedures want to stop medicines for weeks and weeks, that doesn't necessarily fit the scenario.

Dr. Iroku:

So we've had an amazing conversation. Thank you, Dr. Dolinger. Thank you, Dr. Rubin. And thank you all for joining us in this episode.

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