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Don't Forget, There's an Itchy Patient Behind Those Numbers

Announcer:
Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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Ms. Goacher:
Hey, everyone. I'm Elizabeth Goacher, and this is CME on ReachMD. Thanks for joining us today. I'm going to be discussing the impact of PBC, that's primary biliary cholangitis, related pruritus on the health-related quality of life and management strategies.

So we know in PBC, there's not just the biochemical pieces and the radiologic pieces and the histologic pieces; it's important in this illness to think about these other manifestations, in particular, itching. We know that itching is significantly impactful on these patients. We also know that itching is unrelated to their disease severity. So you can have people that have nearly normal numbers biochemically and on paper look like they're quite good, but in the real world they are scratching themselves to death. We know that up to 80% of patients with PBC report significant itch at some point in their life. And this was also associated with reduced scores on health-related quality of life.

So in the UK-PBC Consortium, which had over 2,000 patients, the patients who had more significant itching, we were also able to see that that significant itching was having a downstream impact on quality of life. This also impacts their sleepiness. You're itching and you're itching at night. You're not getting good rest, and this itching is fatiguing. Just being an itchy person wears you out. Just like pain, right? It's another symptom. Itching can be wearisome. So this leads to fatigue. So it's not just the itching, but what is driving, in addition to what fatigue you might have from the baseline disease.

We know that we need to try and focus on this for patients, too, because many patients report that they are not being asked of this; they're not being asked about their itchiness. They go see their PBC provider, they're asked about all kinds of things, like their color of their eyes and whether they're swelling, but nobody's asking them how bad they're itching.

So how do we assess itching? So we have the Visual Analog Scale, which is one way where you just, on a slider, where am I with my scores, 0 being no itch, 10 being the highest or worst imaginable itch, and anything over 5 counting as severe. This is important when we're thinking about what's severe, because that's some of the scales that are reported in clinical trials is anything over the 5 being a severe degree of itch.

There's a 5-D Itch scale, which is the 5 domains of duration, degree, direction, disability, distribution. This is a very quick and easy scale. It's very easy to answer these questions for patients. They often have an app that they can use. It may not be something you want to use for real time, but you may want to use periodically in your clinical assessment.

And then the PBC-40, which is a long form that has domains on all kinds of areas: pain, fatigue, itch, quality of life questions like how much engagement you are, and social engagement. It's a longer form but there are specific questions that are just 3 that are targeted toward itching. And these might be something that you could easily employ in your clinical practice. These you answer never, rarely,

sometimes, most of the time, always, or did not apply. Did itching disturb my sleep? I itched so much, I made my skin raw. I felt embarrassed because of my itching.

And even if it's just 1 of those tools or 2 of those questions that you use on a regular basis, that's an easy way for you in your brain to try and assess that. And if you put it down graphically so you can quantify it for the next visit, and then you can reference it back. Just some suggestions to think about how we can start engaging these tools, which are quite lengthy in some places, especially the clinical trials in our clinical practice.

When we think about itching and management of itching, there's been some long-established guidelines. A lot of these come out of the UK-PBC Consortium as well, and their guidance, non-pharmacological measures make sense, like use moisturizers, dry skin itches more, make sure you're thinking about cool showers instead of hot showers because hot showers cause more inflammation and more skin surface losing of moisture which then feeds the dryness, right? Fragrance-free soaps, detergents, things that your dermatologist would have you do to help you take care of your skin, avoiding irritating fabrics like wool or itchy, scratchy things.

When it comes to pharmacologic management of itching and pruritus, well established that the first-line agent is cholestyramine, and this is something you can use 4 g up to four times a day. It's a powder, kind of cumbersome, might have side effects, but it's the mainstay and works really well for the patients that can use it. Second-line therapy includes rifampin, naltrexone, and sertraline, all of which have data to support pruritus reduction.

It's important to know that first-line treatment for PBC often does not improve, and especially there's actually no relationship that we know of between ursodiol and pruritus improvement. Multiple areas where urso has been used, we can see it doesn't help itching, and we know this is true from our PBC patients. Think about the patients that are entering the clinical trials for novel agents, for second-line agents, 40% of them are reporting moderate to severe itching at baseline. And these are patients who are already on ursodiol, right? So this is a significant proportion of people who are on therapy with ursodiol but still itching. So we know it's out there.

We do know that itching was addressed in both the elafibranor and seladelpar trials. We saw that in the phase 2, even as soon as the phase 2 data, they both had some improvement in itching. We saw specifically in response the phase 3 for seladelpar, that they met their endpoint and we had a statistical significance and improvement over placebo. When it came to elafibranor, they also had trends toward improvement, but it did not meet their statistical endpoint. They did meet it in the PBC-40 and the 5-D Itch, but did not in the NRS scale, which was with a prespecified endpoint. But we know that both of these agents can be associated with improvement in itching, just depending on how you look at the data.

Thinking about the future, it's exciting to have our new agents really looking at itching and looking at pruritus specifically. Then we have upcoming, where thinking about new agents, including the ileal bile acid transporters. These are linerixibat, maralixibat, and volixibat. So stay tuned. These are not prime time, but things you may see soon at a clinic near you.

So it's been great talking with you. I appreciate spending some time. Nice to see you on ReachMD CME talking about PBC pruritus.

Announcer:_
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