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<https://reachmd.com/programs/cme/treatment-for-primary-biliary-cholangitis-whos-on-first-whos-on-second/16647/>

Time needed to complete: 55m

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Treatment for Primary Biliary Cholangitis: Who's on First, Who's on Second?

Announcer:

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

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Dr. Rabiee:

This is CME on ReachMD, and I'm Dr. Atoosa Rabiee. Here with me today is Dr. Kris Kowdley.

We want to talk about once we arrive at the PBC diagnosis, what do providers need to know about treatment options?

Dr. Kowdley:

So to start with, it's important for our treaters and clinicians to know that first-line therapy is ursodeoxycholic acid. It was approved in 1997, has been around now for decades, and has really changed the natural history of PBC. As we can see, the number of liver transplants for PBC has continuously declined. We see a number of patients can achieve biochemical normalization with ursodeoxycholic acid alone.

But it's not a specifically targeted therapy. About 40% to 50% of patients do not achieve our therapeutic goal with ursodeoxycholic acid, so we need to consider second-line treatments. In the US the only FDA-approved second-line treatment is obeticholic acid. In 2021, the AASLD [American Association for the Study of Liver Diseases] treatment guidelines for PBC also recommended that off-label use with a fibrate could be considered for patients, so that's another option for second-line treatment.

But there still remains an unmet need. Fibrates do have a black box warning as far as liver and kidney and they're not approved by the FDA in the US. Obeticholic acid is an effective therapy in 40% to 50% of patients. Alkaline phosphatase levels can be reduced, but it has a liability of causing pruritus, which is dose related and can be limiting for many patients and may potentially have adverse effects on lipids.

Important to consider that treatment is lifelong, it's not curative, and we're not trying to eliminate the disease, but trying to control the disease. We also want to focus on symptom burden. Pruritus and fatigue are very important considerations for patients, and I think historically we've not had effective therapies to manage those.

So in terms of where we are in the current standard of care, urso is first-line therapy. After 6 months to no later than 1 year after urso therapy, a patient's biochemical response and symptom burden should be assessed, and then second-line therapy can be considered, either with the FDA-approved obeticholic acid or with off-label use with fibrates at the present time. And then as far as considering triple therapy, I think that's something that should be discussed probably with an expert and in the context of the patient's stage of disease and overall risk of progression. It is important to keep in mind that as far as itch is concerned, which can affect up to 60% of patients or more with PBC at some point, that UDCA does not really have any effect on pruritus and obeticholic acid can make itching worse. So second-line therapies that both alleviate symptoms and modify disease remain an important goal for future treatment.

Dr. Rabiee:

Thank you so much.

Announcer:

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