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Effective PH Care: Do We Need To Rethink Best Practices for Patient Follow-Up?

Dr. McLaughlin:
So, effective PH care, do we need to rethink best practices for patient follow-up? I really need to emphasize that the goal of treatment of PAH is getting to patients at low risk, to getting the patients in the green zone, and as many of the variables in the green zone as we can get. And we have many tools to do that now, as well.

Combination therapy has been shown to be effective in treating PAH, and as part of all of the treatment guidelines. Currently, commercially, we have three pathways that we target, the nitric oxide cyclic GMP pathway, the endothelin pathway, and the prostacyclin pathway, and we have over a dozen FDA-approved therapies that are either oral, inhaled, or parenteral. And it's important to consider how combination therapy can be used to optimize care in clinical practice.

Now, the initial therapeutic approach is important, because most patients I think should start on combination therapy. In some patients, a very small proportion of patients, primarily those with idiopathic, heritable, and anorexic or drug and toxin-induced pulmonary arterial hypertension may respond to calcium channel blockers, and we identify those patients based on how robustly they respond to an acute vasodilator, such as inhaled nitric oxide at the time of their initial right heart catheterization. And of course, if they respond, drop the mean pulmonary pressure by at least 10 in the setting of a normal cardiac output. Those patients might be appropriate to treat with calcium channel blockers, but that's step one. Step two is you need to follow them clinically, and see if they improve to functional class one or two with just the calcium channel blockers, without the need for additional therapy. Those patients, very privileged patients may have a great long-term outcome with a simple, inexpensive, well tolerated therapy. But of course, those patients are very few and far between. The majority of patients will be non-responders to acute vasoreactivity testing. And those who are in the low or intermediate risk group, we generally treat with oral combination therapy, with an ERA and a PDE5, and there's a vast amount of data about how effective that combination therapy is as initial treatment for PAH. Some patients with PAH were not included in those clinical trials, for example, those with portal pulmonary hypertension, or those with many risk factors for diastolic dysfunction. And sometimes we go a little more gingerly in those patients, we start with monotherapy, and we reassess them a little more carefully before starting a second therapy. Of course, those patients who are treatment-naive, and fall into the high-risk category, we generally use initial combination therapy that includes a parenteral prostacyclin.

Let's say you do that, and the initial therapy does not get the patient to low-risk status, then we need to do something different. Remember, I said that the last part of the algorithm the reassessment part is actually the most important part of the algorithm. It's doing a structured follow-up and assessing risk after the first treatment choice that you made. And if the initial treatment approach results in something other than low-risk status, we need to do something more. If they're still at intermediate risk, we need to escalate, perhaps to triple combination therapy. If they're still at high risk, or they've progressed to high-risk, then we for sure need to do something more, and that probably includes a parenteral prostacyclin therapy. If you're successful, if that second treatment step gets you to the low-risk status, that's great, but then, remember, you need to continue the structured follow-up. The goal is to attain and maintain low-risk status, which requires continued structured follow-up. If after the second step the patient is not at low risk, if they're still at intermediate or high, then one needs to escalate to maximal medical therapy that includes a parenteral prostacyclin. And patients on follow-up with a low-risk status who deteriorate, this is why structured follow-up is so important, cause sometimes the disease can progress. If they deteriorate to intermediate or high-risk, they should be treated with more aggressive therapy. You need to escalate to double or triple or maximal

combination therapy.