Transcript Details

This is a transcript of a continuing medical education (CME) activity accessible on the ReachMD network. Additional media formats for the activity and full activity details (including sponsor and supporter, disclosures, and instructions for claiming credit) are available by visiting: https://reachmd.com/programs/cme/closing-arguments/14250/

Released: 10/28/2022
Valid until: 10/28/2023

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Closing Arguments

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

Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements as well as the learning objectives.

Dr. Krasuski:
Thank you to both attorneys today for your masterful presentation of evidence and to the witnesses, for your expertise and candor. Today, we have seen and heard multiple pieces of evidence that debate the question of whether all adult Fontan patients should be treated with group one PAH therapy. As demonstrated, this is not an easy question to answer. We are faced with a disease state that has very limited guidelines or universally accepted hemodynamic parameters to guide physicians' diagnosis and treatment of the patient. Therefore, the application of therapies is similarly without guidance, and the use of group one vasodilators in this patient group must almost be considered off-label. In addition, since not all Fontan patients may exhibit elevations in PVR over time, should we be automatically prescribing expensive group one medications when there is no clinical evidence of PAH? That is what you, the jury, must decide in a few moments. It will not be an easy decision. Dr. Aboulhosn, you may make your summary statement.

Dr. Aboulhosn:
Thank you, Your Honor. Ladies and gentlemen of the jury, we have shown through witness testimony and evidence that numerous studies, as well as our own personal experience as treating physicians, demonstrate the benefit of lowering pulmonary arterial resistance and transpulmonary gradient on multiple, multiple measures in Fontan patients, including V02, exercise capacity, and other parameters of a more normal life. Without this reduction in transpulmonary gradient and the congested flow that can harm the liver and other organs, patients are more likely to suffer eventual ventricular, hepatic, and renal damage and possible failure. For symptomatic patients in whom an increased pulmonary arterial resistance and an increased transpulmonary gradient is a factor for the failing Fontan physiology, there is clearly a rationale for the use of pulmonary vasodilators. The ERAs and the PDE5 inhibitors are safe, and they're effective in this and their utility in other forms of group one PAH. It's now well known that this is the case. Pulmonary vasodilators significantly improve the hemodynamics of Fontan patients. They reduce the NYHA functional class, and they increase the six-minute walk distance for Fontan patients. We're beginning to see more rigorous phase three trials, and that's great. That's great. We want more data. We want more evidence, but we don't want a bunch of body bags lined up along the road while we're waiting for that evidence to become Duke-worthy. We don't want that. The successful use of selective pulmonary vasodilators and/or a combination of these could potentially improve quality of life for these patients, who often present at a relatively young age with symptoms of heart failure and volume overload, and liver failure. With limited organ availability out there, and patient group here with increased medical and anatomic complexity for transplantation, including several prior surgeries and thoracotomies and collaterals and potential sensitization and so on and so forth, you know, anything that can help us push that clock back, defer listing, maintain acceptable functional status, give them good quality of life so that they can be with their families, they can be with their children. These group one medications may allow us to do that, and it's for these reasons, ladies and gentlemen of the jury, and more that we feel very strongly that all Fontan patients should be considered for, and they probably should also be receiving group one vasodilator therapy. Thank you.

Dr. Krasuski:

Thank you, Dr. Aboulhosn. Dr. Kay, you may make your summary statement.

Dr. Kay:
Thank you, Your Honor. It is premature to think that group one vasodilators should be applied to all Fontan patients. For symptomatic patients in whom we have an identified elevation of pulmonary pressures and transpulmonary gradient that is identified to be the cause for their worsening physiology, there's a clear rationale for the use of these therapies. Indeed, provisional data has shown benefit of these medications. I will not deny that, but these data are provisional. In addition, I can see there are likely a number of presymptomatic patients with Fontan physiology that have elevated transpulmonary gradients and may benefit from early initiation of this therapy, as has been shown in those with biventricular circulation. However, to date, the available trial data have neither yielded enough evidence to support routine use of pulmonary vasodilators in all Fontan patients, nor have they been helpful in defining subgroups of patients that may benefit from such therapies. As a result, guideline committees have not yet described critical values for Fontan patients in which hemodynamics define the threshold for which patients should get started on these therapies. One thing that is relatively clear is that the effective vasodilators in the adult Fontan patient really depends on where the patient starts from clinically. In addition to the absence of clarity of guidelines for treating Fontan patients, we must face realities that there are side effects and cost issues for some of group one medications, and we may yet see effects on other organs indirectly affected by the Fontan circulation. If you, as healthcare providers and our jurors practice evidence-based medicine to the benefit of your patients, you will recognize that at the current time, there is insufficient evidence to support broad use of group one medications in all Fontan patients. With that determination, we must await more, stronger clinical trial data that is used to support international peer-reviewed guidelines that determine the clinical management for the Fontan patient.

Dr. Krasuski:
Thank you, gentlemen. This now concludes the case. I turn the case over now to you, our jury, to determine whether, based on the presented evidence and arguments, should all adult Fontan patients be placed on PAH group one therapy? You will decide.

Announcer:
You have been listening to CME on ReachMD. This activity is jointly provided by Global Learning Collaborative (GLC) and TotalCME, Inc. and is part of our MinuteCME curriculum.

To receive your free CME credit, or to download this activity, go to ReachMD.com/CME. Thank you for listening.