radcliffe cardiology

Title: HFA 24: Cordella PA Sensor System in NYHA Class III HF Patients: PROACTIVE-HF
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Dr Michael Kiernan

"Hi, my name is Mike Kiernan at Tufts Medical Centre in Boston, Massachusetts, and I'll be speaking about the results of the PROACTIVE HF trial.

Class III Heart Failure Patients

Well, class three patients are patients who have a significant burden of residual symptoms, as well as a high risk of ongoing morbidity and mortality. So while they're generally too well or stable to consider something like a transplant or LVAD, these are patients who are not thriving and have, again, a high burden of risk, as well as poor quality of life and impaired functional capacity.

Cordella Sensor System

Sure, the Cordella sensor system is a novel system for monitoring ambulatory pulmonary artery pressure. So there are other systems that are currently available on the market. What's a little bit different about the Cordella system are two things. Number one, pulmonary artery pressure can be measured with a handheld sensor sitting in the seated upright position rather than lying on the bed, which may be a little bit user friendly and can lead to increased patient engagement and compliance.

Of course, this is not a therapy, so if the patient's not monitoring themselves, then we can't use that information to make decisions to improve outcomes. The other novel thing about the Cordella system, in contrast to other commercially available devices, is that it comes packaged with a broader suite of home disease monitoring technologies for vital sign monitoring. Namely, we don't just get the internal pulmonary artery pressures, we also have access to vital signs, including weight, blood pressure, and heart rate, that

we can use to paint a more comprehensive clinical picture of the patient to further guide clinical decision making.

PROACTIVE HF Trial Overview

Sure. So the PROACTIVE HF trial looked at the role of ambulatory PA pressure monitoring in patients with NYHA class three heart failure symptoms, and that was across the spectrum of ejection fraction included HFpEF, as well as HFrEF or low ejection fraction in patients who had a recent heart failure hospitalisation in the last twelve months and or elevated NT pro BNP levels greater than 800 to 1500, depending on if you had HFpEF versus HFrEF.

Key Findings

Well, so the key findings of the PROACTIVE study were, number one, that the system is safe as it relates to freedom from device implant complications as well as from sensor failure. Both of those were under 1%, so greater than 99% as it relates to freedom from, again, device related complications or sensor failure.

Number two was found to be effective in comparison to event rates treated in other clinical trials. In fact, the event rate for the composite endpoint of death or heart failure hospitalisation was less than half of that seen in other contemporary trials of PAP monitoring. Now, this was a single arm study, so you can't necessarily determine the effect size, but we created a performance goal.

Frankly, given the relative lack of equipoise, there's a lot of data that's emerged lately that we now feel very confident that these systems help to avoid the risk of rehospitalization in patients with symptomatic heart failure in class three. So, knowing what we know, we use historical treatment arm data to define a performance goal and the Cordella system met those endpoints in terms of efficacy of success.

Take Home Messages

So the key take home messages are, number one, ambulatory monitoring. Ambulatory PA pressure allows further titration and optimization in medical therapy.

Well, if I could say, there's another one key finding of the analysis that we present today, and that's that looking at specifically the role of PA pressure monitoring on changes in heart failure related medications. And what we learned is that patients at the time of enrollment of this study were, frankly, exceptionally well treated. They were already optimised on medical therapy.

Addressing Class III Heart Failure Needs

Which brings us back to your initial question about in terms of what are the gaps or needs of patients with class three heart failure. So, while the overall proportion of patients on GDMT was no different at six months, we were able to still see incredibly low event rates in this class three population. And what is that driven by? Well, that's driven by monitoring pulmonary artery pressure and then allowing us to, frankly, titrate diuretics to avoid congestive episodes that result in heart failure.

Future Directions

Well, there's the PROACTIVE HF 2 trial, and that's looking to broaden the population of patients that could potentially benefit from these monitoring systems into a potentially less sick cohort of patients, an enriched group of patients with class two symptoms who've had heart failure events or high pro BNP levels. So that's really where the field is moving as it relates to monitoring of ambulatory PA pressures. So we need more data in terms of a broader, more heterogeneous cohort of patients."