Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/cme/tackling-fluid-overload-in-patients-with-heart-failure-novel-approaches-to-remote-monitoring/15311/

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

Tackling Fluid Overload in Patients with Heart Failure: Novel Approaches to Remote Monitoring

Announcer:
Welcome to CME on ReachMD. This activity, titled "Tackling Fluid Overload in Your Heart Failure Patients: Novel Approaches to Remote Monitoring" is provided by Medtelligence.

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

Dr. Butler:
Heart failure remains a major global public health burden. Today, we are discussing strategies that can reduce hospital readmissions and improve patient care.

This is CME on ReachMD. I am Dr. Javed Butler.

Dr. Boehmer:
And I'm Dr. John Boehmer.

Dr. Butler:
John, great to have you today. Let's approach this topic first by discussing the signs and symptoms of fluid overload, of congestion—just sort of a broad overview of what fluid overload looks like in patients with heart failure, why should we care about it, what is the rationale that we should be monitoring pulmonary fluid levels in our patients?

Dr. Boehmer:
Well, thank you, Javed, and as you point out, much of the issue with heart failure is when patients become congested, they become volume-overloaded, and this leads to a number of symptoms. The obvious one is when they become edematous, and many patients can monitor the swelling in their feet and ankles, can also monitor their weights to see the weight going up, and can manage that. The more insidious one is when they develop pulmonary congestion. This can occur without a great deal of weight gain and leads to very distressing symptoms, but many times they can't really detect a big change in how they're breathing until such time as they're in distress. Once they're in distress, they typically report to the emergency department, and typically in the emergency department they're admitted to the hospital, and that begins the cycle of hospitalization due to decompensation. And then once they're discharged, they're still at increased risk for being rehospitalized.

Dr. Butler:
So if I sort of interpret what you're saying, is that by the time there are clinically manifest symptoms, it might be just too late, and patients tend to kind of ignore milder symptoms, and by the time they cannot bear it, it's too late and they come to the emergency room, and that's where their prognosis is poor and all the issues related to hospitalization. But if we can potentially figure out ways where we can find these congestion issues much earlier in the course, is that a fair way of thinking about it?

Dr. Boehmer:
Absolutely. I'm not sure if it's that they ignore symptoms or they're just not sure that their breathing is changing. It comes on slowly many times, and we used to talk about flash pulmonary edema. The truth is, when we monitor people more closely, we find that there are signals that date back many days to weeks prior to a hospitalization for heart failure. So this builds up slowly over time, and patients don't notice an abrupt change, so it's just like yesterday almost. So that when they reach the point where they're really working to

breathe, and they know that things are bad, that's what we used to call the flash, but that's just the very end of the sequence of getting worse leading up to a heart failure hospitalization.

Dr. Butler:
Yeah, you know, I mean, I sort of grew up in an era for training where you used to give these recommendations to the patients to weigh themselves on a daily basis, and I think that's still a pretty good recommendation. The problem is that the commercial scales that we have are not very accurate, and just depending on your, sort of, what you have eaten, your bowel habits, your clothes you are wearing, and all that kind of stuff, there is enough variation that precision becomes very difficult with just weight monitoring, so we need something which is a little bit more precise per se. But there are subtle changes that if we could detect those subtle changes earlier, maybe we can intervene earlier on and improve the patient's prognosis.

So with that said, now that we have a little bit of a better understanding of fluid overload, its various different manifestations, and the need to detect it a little bit earlier, can you tell us a little bit about device-based monitoring systems and the potential impact that it can have on hospitalization, rehospitalization rates?

Dr. Boehmer:
Well, thanks for that question, Javed. We know that treating weights and symptoms is helpful and it's still guideline-recommended therapy. But we can do better than that, because there are many times that it's not picked up by weights. The patients are uncertain about their symptoms.

So there are a number of remote monitoring systems available, and what they do and what they've taught us over the years is that there are changes in either the hemodynamics or other measures, such as respiration rate, heart rate, the heart sounds, thoracic impedance, that occur days to weeks prior to an episode of worsening heart failure. And if we can manage those, it becomes the preemptive, presymptomatic treatment of heart failure so that we don't wait until the patient is dyspneic and in extremis and then coming to the hospital where they'll surely be admitted. So this gives us a window, an opportunity to treat before you get to that stage.

Dr. Butler:
So in a way, if I paraphrase what you just said, is that, you know, you don't treat diabetes waiting for polyurea to occur and then figure out what to do with it. So you're just looking at some objective measure that there is congestion coming up and that you need to act.

For those just tuning in, you're listening to CME on ReachMD. I am Dr. Javed Butler, and here with me today is Dr. John Boehmer. We are discussing novel approaches to the remote monitoring of fluid overload in our patients with heart failure.

Can you tell us a little bit about some of the trials that you've been involved in, specifically about the BMAD trial, and what was that trial trying to figure out, and what did it find?

Dr. Boehmer:
Well, this was a very interesting clinical trial with a novel wearable device, and it gets to the patient population that's at highest risk and those that were just hospitalized for worsening heart failure. That population has a very high risk of rehospitalization that begins the day they leave the hospital, and it takes several months for it to go down to a more typical risk of heart failure hospitalization. So this was a study that enrolled patients who were recently discharged from the hospital—within the past 10 days—and it was not a randomized controlled trial. It's important to understand the trial design. It is a controlled comparator trial, where there were 2 arms, and a clinical site would either be the treatment arm or the control arm. In the treatment arm the wearable device that can measure thoracic fluid content using radiofrequency energy and the radar range from the left midaxillary line—the data were available to the investigators and they could share them with the patients. In the control group, the investigators and patients were blinded to the data, and there were alerts sent out when the thoracic fluid measurement had increased to more than 3 times the standard deviation of the baseline, and then the clinician would have the opportunity to interact with the patient to treat them. So because it's a concurrent controlled clinical trial and not a randomized control trial, you have to be a little careful about whether the groups are balanced. And there's also some risk of having some bias entered into the trial in that some sites may treat very differently than other clinical sites.

However, in this clinical trial, the inclusion criteria were very, very open, as mentioned, is for patients recently hospitalized and there was no ejection fraction criteria. The only exclusions were related to them having another disease that limited their 1-year prognosis unrelated to their heart failure or the presence of a left ventricular assist device, or anticipated to start dialysis within the next 90 days. And, the 2 groups were compared to each other with a primary endpoint set as the Kaplan-Meier event-free survival for heart failure hospitalization. So it was really looking at the risk of rehospitalization for worsening heart failure.

The 2 groups included 257 patients in the treatment group and 265 in the control. There were a few patients excluded initially because they didn't meet criteria or withdrew before data were collected. And that left 245 and 249 subjects in both groups respectively. The

baseline characteristics were generally well matched. And then coming to the results, importantly the relative risk reduction over 90 days for the risk of rehospitalization for heart failure was reduced by 38% in the group that was the intervention group, where the investigators and the patients would have access to the data. And that's an absolute reduction of 7% at 90 days, so 7% of people who received the intervention and had access to the data did not have a heart failure rehospitalization, whereas in comparison to the control group, they would have had a heart failure rehospitalization—or a number needed to treat of 14.3. We also looked at a combined endpoint that is typically looked at in clinical trials of time to first event, heart failure hospitalization, ER visit or death. That had a similar 38% reduction, and importantly, quality of life as measured by the KCCQ [Kansas City Cardiomyopathy Questionnaire] questionnaire improved in both groups, but the overall improvement in the treatment group was 12 points higher than in the control group, and we generally think that a change of 5 points on a KCCQ questionnaire is clinically meaningful. So they had a clinically meaningful improvement in quality of life beyond that seen in the control group. So in terms of heart failure rehospitalization, which was really the driver for the trial, and quality of life questionnaire, there was more improvement when the investigators had access to the subjects' data and could share it with them.

Dr. Butler:
Very nice. So let's now sort of put what we have learned into practice by looking at some of the cases to help our audience understand. What sort of patient population may benefit from fluid level monitoring? I mean, is this something for people with, you know, really low GFR [glomerular filtration rate] and super high risk? Should we be waiting for hospitalization? Do you think that the future trials should be looking at patient population early on so that you can prevent the index hospitalization?

Dr. Boehmer:
Well this device is available clinically at this time, and we're incorporating it into our program for patients in transitional care from hospital to home. We look at patients in terms of their risk, and one of the metrics we look at is the change in NT-proBNP from admission to discharge. That's been identified in the guidelines as one of the risk factors you can look at to identify a high-risk population. And those that don't have a 30% or greater reduction in NT-proBNP from admission to discharge are clearly at higher risk, and we're utilizing it in a high-risk population such as that. We also have a preference to use it in patients who have CKD [chronic kidney disease]. As you know, when we're dosing diuretics and we're monitoring renal function and electrolytes following a hospitalization, any change in renal function may lead a clinician to go back on the dose of diuretic. Many times, the opposite is necessary. The patient is more congested and you need to actually increase the dose of diuretic. But we don't have that objective data at home.

I refer to our ICUs as the data ocean, whereas they go home and they have very little data coming back to us, so they're out in the data desert then. And it's there that we need some objective data to help guide us and tell us do they need more or less diuretic at that period of time? Because the renal function might be telling us one thing, but the total volume in the patient, if we can measure it objectively, would tell us another.

Dr. Butler:
You know, we have focused so much on evidence generation, but not necessarily on implementation strategies and how to use the therapies that we have more effectively to improve patient outcomes. So it is so nice to see these sort of studies coming out that are more focused on improving patient outcomes and in a sense not necessarily just a traditional trial, but how to manage patients more effectively. So I certainly learned a lot. But, John, before we wrap do you want to give us one take-home message for our audiences?

Dr. Boehmer:
Yeah, I think the take-home message is that we now have a tool that is wearable that can be used for short-term. Many of the implantable devices are really lifelong and long-term monitoring, and it utilizes a lot of our resources to continue monitoring those patients. This is a good application for short-term use. It has clinical trial data behind it, as well as data demonstrating it can measure what it's purported to measure. So another tool is available that can be utilized in your high-risk populations to assist you in the standard management of heart failure.

Dr. Butler:
Well, John, thank you very much, but unfortunately, that's about the only time we have for today. So I really, really want to thank our audience members for listening and, John, thank you so much for joining me and sharing all of your valuable insights both as a clinician as well as somebody who knows the data inside out. It was really, really good speaking with you today.

Dr. Boehmer:
Well, thank you very much, Javed. It's been a pleasure, and it is an exciting time in the field of heart failure, where more tools and treatments are available, and how to implement them becomes the new adventure.

Announcer:

You have been listening to CME on ReachMD. This activity is provided by Medtelligence.

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