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Beyond GDMT: Timely Consideration of Barostim in Heart Failure

**Announcer:**
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**Dr. McCann:**
Improving the quality of life and overall symptom relief for our patients with heart failure with reduced ejection fraction, or HFrEF, is an important component of their care. Today, we're going to explore what clinicians can do when guideline-directed medical therapy, or GDMT, is insufficient and how medical devices such as Barostim can play an important role in heart failure treatment.

This is ReachMD, and I'm Dr. Patrick McCann.

**Dr. Mohan:**
And I'm Dr. Rajeev Mohan.

**Dr. McCann:**
We'd like to start by reviewing GDMT as it is the standard approach in managing patients with heart failure with reduced ejection fraction. It includes the 4 pillars of therapy, including evidence-based beta blockers, ARNIs or RAAS inhibitors, as well as mineralocorticoid receptor antagonists, and SGLT2 inhibitors. However, despite advancements in GDMT, a significant proportion of patients experience persistent heart failure symptoms and impaired functional status. This overall contributes to significant morbidity and mortality and decreased quality of life.

Dr. Mohan, what's your take on GDMT and improving quality of life and symptoms for patients with heart failure with reduced ejection fraction who are still experiencing symptoms?

**Dr. Mohan:**
Well, that's a great question. Our current conventional approach focuses primarily on optimizing pharmacologic GDMT before really considering device-based therapies. And what we know is that quality of life gains with GDMT are limited, and ultimately that's kind of one of the more important things for patients is their quality of life. So GDMT should include both a drug-based, but also a device-based, therapy consideration as they can work synergistically, rather than in competition with each other.

Historically, our focus on GDMT from a drug-based standpoint has been mainly based on the fact that these drugs have been developed over time, and they preceded the development of many of the devices that we have available to us today. The design and conduct of the clinical trials that led to the approval of device-based therapies, however, are just as important, focused primarily on quality of life for the patients.

So this approach of kind of focusing on drugs alone can have some shortcomings, particularly due to the fact that not all patients are able to get on the standard pillars of GDMT that we'd like for them to be on. It may be limited by factors such as intolerance, nonadherence due to certain side effects, but more often than not, it's due to cost or access from a lack of approval from insurance companies.

So really what we need is a personalized approach of sequencing heart failure therapies that includes both pharmacologic and device-based therapies.

**Dr. McCann:**
Completely agree with you, Dr. Mohan. I think we have found in our practice in tailoring the approach for our patients can sometimes be much more difficult than what is realized in clinical trials. Certainly, as you mentioned, the titration of GDMT can sometimes be limited by access as well as tolerance for patients. And truly, this is where I think device therapy has helped mitigate some of those challenges and improved overall quality of life.

When we look at Barostim therapy, we know that it's indicated for patients with NYHA Class III heart failure, as well as NYHA Class II with a recent decompensation and an ejection fraction of less than 35% as well as an NT-proBNP of less than 1600. I think that population certainly continues to have significant symptoms if they do not tolerate GDMT titration, and as a result, the device therapy can play an important role.

It's an implantable pulse generator that works alongside GDMT, and it delivers a continuous electrical stimulation to the carotid baroreceptors through a lead sutured on the carotid sinus. And that continuous electrical stimulation works to reduce heart failure symptoms by modulating the baroreceptor nerve activity and restoring baroreflex sensitivity, which rebalances the systemic autonomic control systems for the body.

For those just tuning in, you're listening to ReachMD. I'm Dr. Patrick McCann, and here with me today is Dr. Rajeev Mohan. We're discussing what you can do for your patients with heart failure when they're having symptoms despite GDMT.

The baroreceptor activation therapies are shown to improve quality of life. We know this from the BeAT-HF trial, as well as some additional data published in the post-approval studies and looking at patients that are on Barostim therapy. What are your thoughts about when to consider treatment with the device therapy for your patients?

**Dr. Mohan:**
That’s a good question. As you know, many of our patients, despite being on max tolerated doses of guideline-directed medical therapy, will continue to experience heart failure symptoms, impaired quality of life, and really reduced functional status. So for our patients, once we've got them started on treatment and we've up-titrated their doses to the maximum tolerated, we do relatively frequent reassessments to understand what their functional status is. And if after even as short of a time as 3 to 6 months of being on maximum therapy they are still symptomatic, those are the patients that we really think about moving on to the next step with respect to some sort of device-based therapy, or Barostim specifically.

Many of our chronic heart failure patients may also be on therapy, may have already been on therapy for a number of years, and they can still have some progressive declines over time. So those are another group of patients that we look at for considering initiation of advanced device-based therapies. So we want to make sure that those patients obviously are symptomatic enough, like you mentioned, Class II or Class III symptoms that are persistent. We want to make sure that we've optimized their medicines, and also considered other therapies such as cardiac resynchronization therapy, or CRT.

There is a figure that we’ll display here that shows kind of the different devices that we consider depending on what functional status the patients are in. So for Class II patients and Class III patients, it's really what was called BAT, or Barostim therapy. Now, we can also consider cardiac contractility modulation, or CCM, for patients that have an ejection fraction less than 45% who also remain symptomatic from their heart failure, but really indicated for patients with Class III heart failure.

And this has been shown to also improve quality of life, their 6-minute walk tests, and overall functional status. So that's really indicated for patients with an ejection fraction of 25% to 45%. But the data for that device seems to be more robust in terms of the response for patients who have an ejection fraction between 35% and 45%.

Now, going back to Barostim therapy, often clinicians may be hesitant to recommend this therapy to their patients, even if they're New York Heart Association Class II. But what we've seen is that these patients may still derive some benefit from this type of therapy by means of an improvement in their functional status. So it's really important for any patient with an ejection fraction of 35% or less who

are optimized on their therapy already to consider this type of device-based therapy.

So we really keep it on the radar for any patient who's having symptoms despite optimal medical therapy. Our main goal, of course, as I stated earlier, is to optimize their functional status and improve their quality of life.

**Dr. McCann:**
That's an excellent summary there, Dr. Mohan. And I think what you're getting at, really, is we're trying to determine are our heart failure patients getting the best outcome possible, understanding that this disease process is dynamic with the changing trajectory for our patients, and at times, the medical therapy may not be sufficient to improve their quality of life. And as a result now, these devices potentially have the possibility to alter the course of someone's heart failure.

Although we've made significant improvements in morbidity, we have not seen results yet to improve mortality. However, we do know from a number of ongoing studies that there have shown improvements in hospitalizations, and I think future studies will hopefully shine light on the potential for these devices to impact mortality. The clinical utility overall lies in the ability to address the persistent symptoms and improve the quality of life for our patients.

Well, this has been a wonderful conversation. Before we wrap up, Dr. Mohan, can you share your one take-home message with our audience?

**Dr. Mohan:**
Thanks, Dr. McCann. My final take-home message would be to really understand patient's functional status. And in any patient who remains symptomatic despite optimal medical therapy, we really should have a low threshold to consider these type of device-based therapies to help improve their functional status and overall quality of life.

**Dr. McCann:**
I completely agree with you, Dr. Mohan. I think every time a heart failure patient walks through the door, we should be completing an assessment of their quality of life and making sure that we are meeting the patient in their heart failure journey. And if the current therapies with medicines are insufficient to maintain an adequate quality of life for that patient, certainly we should be thinking about devices sooner rather than later.

Well, that's all the time we have today. So I want to thank our audience for listening. And thank you, Dr. Mohan, for joining me and sharing all of your valuable insights. It was great speaking with you today.

**Dr. Mohan:**
Thank you, Dr. McCann for the invitation.

**Announcer:**
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