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Improving Symptoms in Patients with HFrEF Using Novel Device Therapy

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Dr. Raval:
Even when using optimized guideline-directed medical therapy, or GDMT, in patients with heart failure, worsening symptoms such as diminished exercise capacity, and functional status often result in reduced quality of life. However, using baroreflex activation therapy, or BAT, an implantable FDA-approved cardiac autonomic modulation device, there may be a window of opportunity to improve symptomatology in patients with NYHA [New York Heart Association] class II to III heart failure. Today, we'll review the clinical trial data showing the sustained and durable benefits of BAT and review patient selection criteria for its application in practice.

This is CME on ReachMD. And I'm Dr. Nirav Raval.

Dr. Panjrath:
And I am Dr. Gurusher Panjrath.

Dr. Raval:
So let's take a closer look at BAT. Let's discover what it is and why it works. Gurusher?

Dr. Panjrath:
Thanks, Nirav. That's a great question. But before we go into BAT, I think we need to revisit what happens in the body and how is our cardiovascular hemostasis maintained, and this is where the autonomic nervous system plays a key role. Autonomic nervous system, which is constituted by sympathetic and parasympathetic supply systems, they are key players in maintaining cardiovascular hemostasis including renal function, as well.

We know that in heart failure there's an imbalance between the parasympathetic as well as sympathetic supply, and this regulates the cardiovascular hemostasis. This has a deleterious effect on symptoms in patients with heart failure, their functionality, and their quality of life. Now the autonomic nervous system is controlled by different pathways, but one of the key pathways are the carotid baroreceptors.

So we know in heart failure that the carotid baroreceptors have decreased signaling. And this is where BAT therapy really comes into play. BAT increases the signaling with the carotid baroreceptors, thus rebalancing some of the sympathetic/parasympathetic imbalance. This in result has an effect on patient's symptoms, their disease activity, disease process, and quality of life. One of the unique things about BAT is this is an extravascular device. There is no part of the device which is in intravascular space. It has a generator similar to a pacemaker or defibrillator. And instead of a wire, which goes into the heart or intravascular space, everything is subcutaneous. The electrode, which really sends a signal, is under the skin, as well. So you really are not exposing any vascular territory at all.

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We know that even with optimized guideline-driven medical therapy and utilization of quadruple therapy, patients with NYHA class II and III heart failure are still symptomatic and have residual risk. What is the window of opportunity for patients? And how can we as providers improve the quality of life? Dr. Raval?

Dr. Raval:
It's a good question. Let's see if we can try and develop this window of opportunity. GDMT is really interesting, right? I mean, we've seen in the late '80s and '90s where things like ACE [angiotensin-converting enzyme] inhibitors and beta-blockers, ARBs [angiotensin receptor blockers], mineralocorticoid antagonists, have all come to be, really, part of the pantheon for heart failure. They all improve longevity, you know, so really, GDMT itself is not very controversial. There are a couple of issues, though. Adherence is relatively poor. We need to work with our patients, really, to make sure their adherence is better always. And also, you know, we're not able always to get to the target doses. And that may just be because, you know, blood pressure is relatively modest in some of these patients with class II, class III heart failure. So there's really a point where GDMT improves longevity, but it doesn't affect quality of life or exercise tolerance in a positive manner.

So really, we see this because GDMT only modestly affects these aspects in several well-done studies. So BAT may address some of these areas. So patients may get on some GDMT, as tolerated, or maximally tolerated, but it's not at a level that prescribers might be happy with. And adding BAT may allow for further improvement of blood pressure, which then allows for further improvement in guideline-directed medical therapy. So in a sense, BAT is like a bridge to further GDMT.

Switching gears for a second because we are used to taking care of devices and prescribing devices. And we should talk about the similarities of BAT and CRT [cardiac resynchronization therapy]. So we saw improvements in the CRT trials in 6-minute walk, quality of life, and NYHA class. And in the BAT population, we saw about 50 meter improvement in 6-minute walk. Similarly, quality of life, we saw an improvement by about 10 points in the Minnesota Living with Heart Failure classification, and about 65% improvement in NYHA class in the BAT group.

So we know that CRT, it's not controversial, something that we use, we know it works well. And we see similar or numerically potentially better improvement in the BAT population. What's interesting is that only 30% of people with NYHA II and III heart failure symptoms are CRT candidates. So what about the other 70%, right? We're still trying to develop this window of opportunity. This 70% is the unmet need. So as you develop your window of opportunity, you're really looking at patients that are on guideline-directed medical therapy, maximally tolerated. It may not be at target doses. We know that, but again, if you add BAT, you may be able to get that further along. You know, patients are not candidates for CRT, that's 70% of the people, really. Post-market, we've seen some interesting things as well. We've seen some good endpoints, additional endpoints such as the hierarchical win ratio, showing improvement in the BAT arm. We've also seen really interesting durable and sustained improvements in the quality of life, exercise capacity, NYHA classes that I saw out to even 24 months. So that's very reassuring in the real-world data as well.

Dr. Panjrath:
Those are really important points which you have made here. And, you know, I want to reemphasize that while pharmacologic therapy has been amazing in its mortality and heart failure hospitalization benefits, the quality of life and exercise capacity benefits have been modest. And patients do value both, and they want to feel better. They want to live longer. But importantly, they want to be better and be able to enjoy that quality of life which they deserve. And in this context, I think it's important to recognize that this is not an end-stage therapy. I think that's very important to realize that this is something which we shouldn't wait as our last rescue strategy if everything else fails. And I think, you know, to me, BAT is a truly disease-modifying therapy just because of the mechanism of action, what it does. And I think as you have said, we have a narrow window of opportunity; we shouldn't miss that. We should recognize those patients. Then they can truly benefit from [BAT] therapy.

Dr. Raval:
For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Nirav Raval, and here with me today is Dr. Gurusher Panjrath. We're discussing how to improve symptoms in patients with HFrEF [heart failure with reduced ejection fraction] using baroreflex activation therapy, or BAT.

Dr. Panjrath:
Now that we know how BAT works, what the benefits are, and when it should be considered, let's shift our focus to the clinic.

Nirav, tell us about your patients and how BAT fits into your heart failure treatment algorithm.

Dr. Raval:
So to give you an example, I have a 60-year-old female with a nonischemic cardiomyopathy, and she had it for about 4 years. Really didn't have any other pertinent medical history, but she really had class III heart failure with dyspnea, edema, orthopnea, classical PND

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[paroxysmal nocturnal dyspnea] episodes as well. And her LVEF [left ventricular ejection fraction] was 25% to 30%. Had a mildly dysfunctional RV [right ventricle], her LV [left ventricle] size was a little bit big at 6.8 cm. She had some valvular disease, mild MR [mitral regurgitation] and TR [tricuspid regurgitation]. Her blood pressure was around 100 systolic; heart rate was around 90. Now she had an ICD [implantable cardioverter-defibrillator] placed about 3 years ago. In fact, she was hospitalized recently, and that's how we actually got to know this individual, but she really didn't have any previous hospitalizations.

When looking at her GDMT, she was on maximally tolerated GDMT with bisoprolol 5 mg, sacubitril valsartan 24/26 BID and spironolactone 25 mg once daily. We felt that she was still symptomatic, and we implanted her as an outpatient, and she was sent home the same day. And interestingly enough, over the next 3 months, we saw an improvement in her functional status. She also had a reduction in her loop diuretic dose to achieve euvolemia, and she of course had no interval readmissions. Now over that 3 months, we saw an interesting phenomenon. We saw the blood pressure go up to about 115 systolic and heart rate came down slightly to around 80. And what that allowed us to do is to improve her further guideline-directed medical therapy. One interesting fact is that the implanting surgeon at the wound check called us to say, “Hey, you might want to call this patient because she was diuresing relatively fast,” and he wanted to make us aware so we could potentially alter her diuretics. And we do see that from time to time, we have this kind of improvement in patients from a diuretic perspective, at whatever dose of loop that they're on.

So this is really where I look at these patients. Again, the EF are less than 35%, non-CRT candidates, you know, maximally-tolerated GDMT, but they're still symptomatic.

Dr. Panjrath:
So I would echo your views. We have seen some tremendous and remarkable results early on, just like similar to your patient case. We have also observed similar benefits in terms of enhanced diuresis and have to cut down the diuretics after implantation. And what has happened is we also have noticed that we've been able to add on more medications or increase the titration of doses, which was not possible before they had the BAT implant.

So really, you know, going back to some of the things you mentioned before, that really is helping not only with its underlying pathophysiological underpinnings directed towards heart failure, but also helping with actual, active management of a patient in answering some of the GDMT benefits as well.

I think the key is having a frank conversation and a deep dive into the lives of our patients, understanding quality of life, what it means for them, what their real life looks like, endurance in performing their activities of daily living. And a lot of times in clinical practices, patients just are feeling fine. But when you really ask them in detail of how they are really coping up, the details come out. So spending that extra effort of understanding what the challenges are in the daily living can really uncover their limitations in activities.

Dr. Raval:
I think we need to look at treating the patients. As you say, you have to really get the symptoms out of them. And I think some of them are very personal: somebody may want to go into the grocery store, somebody may want to try and walk a golf course, what have you.

I like the way that you said that it is a disease-modifying device. So looking at treating these patients upstream, after they're on GDMT, is very, very important. I think will allow a plateauing or potentially an improvement in their heart failure symptoms and prevent them from or delaying worsening of heart failure that leads them on to things like ventricular assist devices or even heart transplantation.

Dr. Panjrath:
And there, I want to go back to what you said earlier about CRT, and I absolutely second it. This is not a replacement for CRT device; I think the CRT benefits are outstanding. So I think that's another group of people I feel we have seen benefit in, where they’re CRT non-responders, they’re clinically having symptoms, they have clinically limiting endurance as well as quality of life.

Dr. Raval:
Well, this certainly has been just an excellent conversation. But before we wrap up, Gurusher, can you share your one take-home message with our audience today?

Dr. Panjrath:
I think earlier is better, as it provides the opportunity to actually change the disease process, and to create an algorithm, which works for your system, to identify these patients, whether in focus device clinics, heart failure clinics, or during or post hospitalization so you can identify the right candidates early on.

Dr. Raval:
And I think my take-home message would be don't forget about the other 70%. For the 30% that might benefit from CRT, this is not controversial, please put the CRT in. But for the 70% of people that are not CRT candidates, consideration for BAT therapy in these

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patients earlier, as you pointed out, is something that we should all think about.

Unfortunately, that's all the time we have today, so I want to thank our audience for listening and thank you, Dr. Panjrath, for joining me and sharing all your valuable insights. It really was great speaking with you today.

Dr. Panjrath:
Thank you, Dr. Raval.

Announcer:
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