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Implementing a Multidisciplinary Approach to Heart Failure: Patient Identification and Treatment Using Novel Device Therapy

Announcer:
Welcome to CME on ReachMD. This activity, titled “Implementing a Multidisciplinary Approach to Heart Failure: Patient Identification and Treatment Using Novel Device Therapy” is provided by Medtelligence.

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Dr. Economides:
This is CME on ReachMD and I’m Dr. Christina Economides. Many patients with heart failure continue to have worsening symptoms and reduced quality of life despite guideline-directed medical therapy. How do we, as providers, use patient profiles to make treatment decisions that will lead to symptom and quality of life improvements? Join us today as we explore the multi-disciplinary approach to patient identification and treatment by different medical specialties.

This is CME on ReachMD and I’m Dr. Christina Economides.

Dr. Kenigsberg:
My name is Dr. David Kenigsberg and I’m a cardiac electrophysiologist in South Florida.

Dr. Howard:
And I’m Dr. Brian Howard. I am an advanced heart failure cardiologist in Atlanta, Georgia.

Dr. Economides:
Brian, let’s begin with you. Despite GDMT, many patients continue to have worsening symptoms and quality of life. As a heart failure specialist what do you recommend for these patients, and does it vary according to patient profile?

Dr. Howard:
Thank you. Yeah, so my job as a heart failure specialist is somewhat unique in that all I see, all day every day, is patients with heart failure. And those patients range from patients who have very mild forms of heart failure and sometimes asymptomatic cardiomyopathies that were picked up routinely based on abnormal EKGs, all the way to patients that are so sick they need mechanical pumps to support the heart or even cardiac transplant. And so, when I’m thinking about a heart failure patient, the first thing I want to think about is, is there anything reversible and, if so, trying to reverse that and then, if not, how sick is this patient? And do they need something very aggressive? Or can we do something that’s less aggressive and less risky to optimize their outcome and quality of life? And so, based on all the tools I have, I first start with medications in those patients that have reduced ejection fraction or a weaker heart. And then once the medications have been optimized, I then move on to devices and I think about all the device options, which we’ll get into. And then once those, kind of, lower risk minimally [invasive] device options have been exhausted, then we think about the more aggressive stuff like mechanical circulatory support and heart transplantation.

Dr. Kenigsberg:

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Yeah, as an electrophysiologist the referral of those patients for device therapy like CRT and other standard recommendations from heart failure specialists, we depend a lot on referral from general cardiology and heart failure specialists to identify these patients that could benefit from CRT. But the main frustration over many, many years is that there are a lot of patients with narrow QRS that do not benefit from CRT. And actually, in that patient population, CRT can cause desynchrony and worsening of heart failure symptoms. So for us, it's extremely helpful to work in conjunction with the other specialists to find the right patients that could benefit from device therapy in heart failure.

Dr. Howard:
And I fully agree with that comment. When I'm recommending a device for a particular patient, there's one thing that can be said for a device that's going to prevent sudden cardiac death. What patients really, really think about and talk about and what are probably more concerned about, generally speaking is, is it going to make them feel better? And I routinely have patients that are much more concerned with feeling better versus preventing sudden cardiac death and so, of course, the CRT has the ability to do both. The single chamber or the dual chamber ICD will prevent sudden cardiac death, but isn't necessarily going to improve quality of life.

And so, once I've optimized the medications, I've talked about prevention of sudden cardiac death and moved in a direction of an ICD if in line with the patient's goals of care. If the patient's not a CRT candidate or, even if they are, but they haven't responded well to CRT, then I'm thinking about devices like the CCM device, which is indicated for EFs of 25 to 45% and then the Barostim Neo device, which is indicated for EFs of less than 35%. And so, they're both devices that are typically right-sided implants. They're low risk devices, but in particular, the Barostim Neo device has very strong data associated with improvements in quality-of-life and that effect has been demonstrated in the clinical trial to be durable.

Dr. Economides:
Yeah. Just to add to what you were saying, Brian, it's about 70% of patients who don't meet a class I or class IIA indication for CRT and that's a huge, huge number of patients who need another option to improve their quality of life.

For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Christina Economides and here with me today are Dr. Brian Howard and Dr. David Kenigsberg. We're discussing the multi-disciplinary approach to identification and treatment of patients with heart failure.

So, David, as an electrophysiologist what can you tell us about the therapeutic options available for patients with heart failure?

Dr. Kenigsberg:
For years we had very good therapies to reduce patients' risk of sudden cardiac death and if they had a wide QRS those patients would benefit, especially true left bundle patients, from resynchronization therapy with CRT devices. But, in recent years, with the availability of Barostim device, and CCM, cardiac contractility modulation, we have other options that mainly focus on reducing heart failure symptoms and hospitalization from heart failure and those options are extremely important, as Brian said, to the patient.

Dr. Howard:
We were actually involved in the BeAT-HF clinical trial, so my longest patient with the device has had his over 6 years now, I think, almost 7 years. And I too have seen these, what I would call super-responders, which meaning, these patients are NYHA class III or IIIB, really just struggling with life, struggling with day-to-day activity, not necessarily actively dying, but just not living well and feeling well with their heart failure, and they get this device and a couple months later they're really just back to life.

Dr. Kenigsberg:
I want to mention, I said before, that we work hand-in-hand with cardiologists and especially heart failure specialists like yourself, Brian, to identify patients, but electrophysiologists follow a large number of device patients. And if we look at our patient population and we follow them in the device clinic, we can find patients that are candidates for this therapy, namely patients who are optimized, but still have symptoms with EFs less than 35%.

In addition, I myself have identified a lot of CRT non-responders. Now clearly, when someone's a CRT non-responder, you need to look for all the potential causes. Is the lead in the right place? Are we pacing from the right vector? Is the timing appropriate? Hopefully the lead is not placed apically. So, after we look at that, if the patient's still non-responding, then we can offer them the Barostim therapy, and they can improve.

The Heart Rhythm Society has a consensus document that says that we really shouldn't have more than 5 leads inside the heart. And if you think of someone with BiV ICD and you're adding 2 more leads for a device, that's 5 leads. That increases the risk of venous stasis and BVT potentially in the upper extremities, other congestive problems. When you think about the Barostim device, one thing that's appealing to me, as an implanter and an extractor, is that this device leaves no leads in the heart. This device leaves no leads inside the

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heart and, therefore, being a totally extravascular device, doesn't present the same problems as other devices that I have to put leads inside the body. And, I think, as a specialty and as a field, we're moving away from putting leads inside the body with leadless pacing and subcutaneous defibrillators. This is another type of therapy where we leave leads outside an extravascular, which reduces the risk of lead-related complications and the need for extraction in the case of device infection.

Dr. Howard:
One of the things that we've seen and I've talked to heart failure docs across the country is the way the Barostim Neo device works, of course, is based on regulation of the autonomic nervous system, and specifically, kind of, an increase in parasympathetic tone and a decrease in sympathetic tone facilitating natriuresis and vasodilatation, which is, of course, good for heart failure patients. And so, what we'll commonly see over time as we titrate up the output of the device, is auto-diuresis. So, patients are urinating more often, not always, but often urinating more and we'll actually end up coming down on the diuretic dose, the loop diuretics, and sometimes actually coming off the loop diuretics in some patients. And that's something I personally think is probably unique to the Barostim Neo; it's based on the mechanism of action.

So when I'm going back and forth between a patient, I'm thinking about those two things and, of course, the leads in the device, the extravascular component of the Barostim Neo device. All those things I think are very important.

And so, Christina, now that we've heard from an electrophysiologist and a lowly heart failure specialist, what's the interventional cardiologist's role in treating heart failure patients?

Dr. Economides:
So, my answer to this question is the following: We're in a place now where congestive heart failure's ubiquitous. You don't have to be a subspecialist cardiologist to be seeing these patients. Everyone is seeing these patients. If you're in medicine, you are seeing these patients no matter what field of medicine you're in.

In the BeAT-HF trial, when you look at the demographic of patients, the etiology of the heart failure in that trial was 65% coronary artery disease. So, that's especially in the United States, it is actually the main reason for heart failure with reduced ejection fraction.

And so, in that way, first and foremost I'm a cardiologist. I see plenty of general cardiology and cardiology consultation, but I do spend most of my time in the cath lab doing a lot of diagnostic angiography and then percutaneous intervention. So, we're, in many ways, especially with STEMI and non-STEMI, the first responders of meeting these patients who are going to go on to either improve their EF on medical therapy, only if it's non-ischemic, or with revascularization of one sort or another. And if they become our patients for the long-term, which most of them do, this is how I meet a lot of my heart failure patients. So, it's an interesting sort of paradox that's happened over the last, I don't know, 30 to 40 years that now patients are surviving their myocardial infarctions, but the incidence of heart failure is paradoxically increasing because they're surviving. So, that's my answer to that particular question.

For patients with multi-vessel coronary disease though, sadly sometimes, as you all know, time is of the essence and you can revascularize and maybe they're just not going to improve and there's plenty of also non-ischemics who don't improve and then the question becomes, what is the answer? How can we make them feel better? And so, that's really where this Barostim device comes in. Especially in NYHA class II/III where there's a window of opportunity to try to make them feel better.

I just want to briefly review the implant procedure. It involves suturing a single electrode on the carotid sinus outside of the vasculature, as was just discussed, through a small incision in the neck, similar to an endarterectomy exposure. The lead is tunneled over the clavicle and connected to a subcutaneously implanted pulse generator in a standard device pocket. The Barostim device is about the size of a pacemaker and the procedure takes about an hour or less. Patients can typically go home the same day and, as was said, there's no hardware in the heart or the vasculature. Currently the device is implanted by surgeons with experience in the carotid space, so that would include vascular surgeons or cardiothoracic surgeons.

Dr. Howard:
I have cases that are similar. We talk about these cases at conferences and what's really hypothesis generating to me is the change in heart failure trajectory that this device has probably provided this patient, right. With all those admissions and all that morbidity, that patient is probably headed toward the mortality in the near future if something doesn't change and so you've implanted a low-risk device that's safe and now he's really on a different trajectory.

Dr. Kenigsberg:
I wanted to mention a couple things. First off, most of these implantations worldwide are done by thoracic and cardiothoracic surgeons, although I myself do have experience with implantation of this device. And it can be safely and effectively done by a skilled electrophysiologist with experience working in the space.

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Another thing that I have noticed after implantation is that there's more room for me once the patient reaches steady state to up-titrate guideline-directed medical therapy, namely beta blockers. So not only do we get them off diuretics, which is helpful, we can also increase the other three pillars of heart failure therapy.

Dr. Economides:
Well, I want to thank our audience for listening and thank you both, Dr. Brian Howard and Dr. David Kenigsberg, for joining me and for sharing all of your valuable insights and expertise. It was great speaking with you today.

Dr. Howard:
This was a real pleasure discussing this topic that is extremely important to our heart failure patients with you two experts and I appreciate the opportunity to be here.

Dr. Economides:
Thank you.

Dr. Kenigsberg:
Thank you as well guys. My pleasure.

Announcer:
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