Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist

IMAGING EDUCATION

From Theory to Practice: The Value of Physician-to-Physician Education in Adopting Contemporary PCI

With Karim M. Al-Azizi, MD, FACC, FSCAI, FESC; Interventional Cardiology and Structural Heart Disease; Medical Director, Cardiac Catheterization Laboratories; Associate Program Director, Cardiology Fellowship, The Heart Hospital – Baylor Scott & White Health; Clinical Assistant Professor, Texas A&M University College of Medicine

The burden of coronary artery disease is steadily increasing in the general population, due to an aging comorbid population and increase in disease complexity at the vessel level. To address this, new technologies, techniques, and multidisciplinary collaboration are allowing percutaneous coronary intervention (PCI) to evolve into a standardized workflow approach known as "contemporary PCI."

continued on page 16

In This Issue

HEART FAILURE CARE

Novel Device for Heart Failure With Reduced Ejection Fraction (HFrEF) Patients: Baroreflex Activation Therapy With Barostim

CLD talks with Christina H. Economides, MD, MM, FSCAI.

Interventional cardiologist Dr. Christina Economides shares her experience treating patients with Barostim™ (Baroreflex Activation Therapy). The majority of her patients who have received Barostim have improved their functional and exercise capacity.

continued on page 10

IMAGING SYSTEMS

Bringing the Cutting-Edge Technology of the ARTIS icono Imaging System to a Small Community Hospital

CLD talks with Vijay S. Iyer, MD, PhD, FACC, FSCAI.

Olean General Hospital is a small community hospital located in Olean, New York, but its cath lab does not think 'small' — according to the New York State Department of Health, Olean handles 1% of all ST-elevation myocardial infarction (STEMI) cases in the state.[1,2] Despite its rural location, Olean General Hospital maintains equivalent outcomes to nearly all of the cath labs in New York State while treating patients of a similar acuity.[1] Staffed with outstanding team members and supported by an excellent EMS crew, the Olean General Hospital cath lab has done approximately 5000 catheterizations and 1500 percutaneous coronary interventions (PCIs) since opening in 2013, and offers implantable cardioverter-defibrillators, peripheral vascular disease intervention, and dialysis grafts. Here, Dr. Vijay Iyer discusses the value provided by the lab's ARTIS icono imaging system (Siemens Healthineers).

continued on page 14

Continued from cover

Novel Device for Heart Failure With Reduced Ejection Fraction (HFrEF) Patients: Baroreflex Activation Therapy With Barostim

CLD talks with Christina H. Economides, MD, MM, FSCAI.

What is the role of the baroreceptors in heart failure with reduced ejection fraction (HFrEF) patients?

Baroreceptors are a type of mechanoreceptor stimulated by the absolute level of and changes in arterial pressure. The autonomic nervous system and cardiovascular homeostasis are normally regulated by baroreceptors, which are extremely abundant in the walls of the carotid sinuses and in the wall of the aortic arch. They send sensory information, primarily via cranial nerves IX and X, to the brain via the afferent pathway. This information is processed and then exits the brain via the efferent parasympathetic and sympathetic pathways to the end organs: the heart, kidneys, and vascular system.

Unfortunately, baroreflex sensitivity is reduced in heart failure patients, meaning they have a reduced response to changes in blood pressure. This leads to an imbalance in the autonomic nervous system resulting in increased sympathetic tone. At the end organ level, this translates to increased heart rate, increased left ventricular remodeling, decreased diuresis, increased renin secretion, decreased vasodilation, and increased blood pressure. This chronic state of elevated sympathetic tone creates a vicious, self-perpetuating cycle which leads to more heart failure; this is the crux of the problem.

Can you tell us more about Baroreflex Activation Therapy?

Baroreflex Activation Therapy, or Barostim (CVRx), provides continuous stimulation of the carotid baroreceptors, thus restoring the balance of the autonomic nervous system (Figure 1).

Barostim is implanted by a cardiothoracic/vascular surgeon. The procedure involves a generator implant in the chest, very similar to a pacemaker generator, and a lead that is tunneled over the clavicle. The end of the lead has a 2 mm electrode which is sutured on the outside of the carotid sinus, supplying continuous electrical signaling to the baroreceptors. It is important to note that the Barostim System is completely extravascular. A carotid artery evaluation is required to ensure that the patient has at least one carotid artery with no significant stenosis (<50%), no ulcerative plaque, and a bifurcation below the level of the mandible.

What is the data for this therapy?

The Baroreflex Activation Therapy for Heart Failure (BeAT-HF) clinical trial[1] was the landmark study that led to FDA approval of Barostim (Figure 2 shows symptom improvement at 6-month follow-up). BeAT-HF was a prospective, randomized, controlled trial in patients with HFrEF. Patients were randomized to either guideline-directed medical therapy (GDMT) alone or GDMT and Barostim.

Figure 1. The Barostim System (CVRx).
View an animation: https://barost.im/MOA

"Beyond anything, patients living with heart failure need and want improved quality of life."

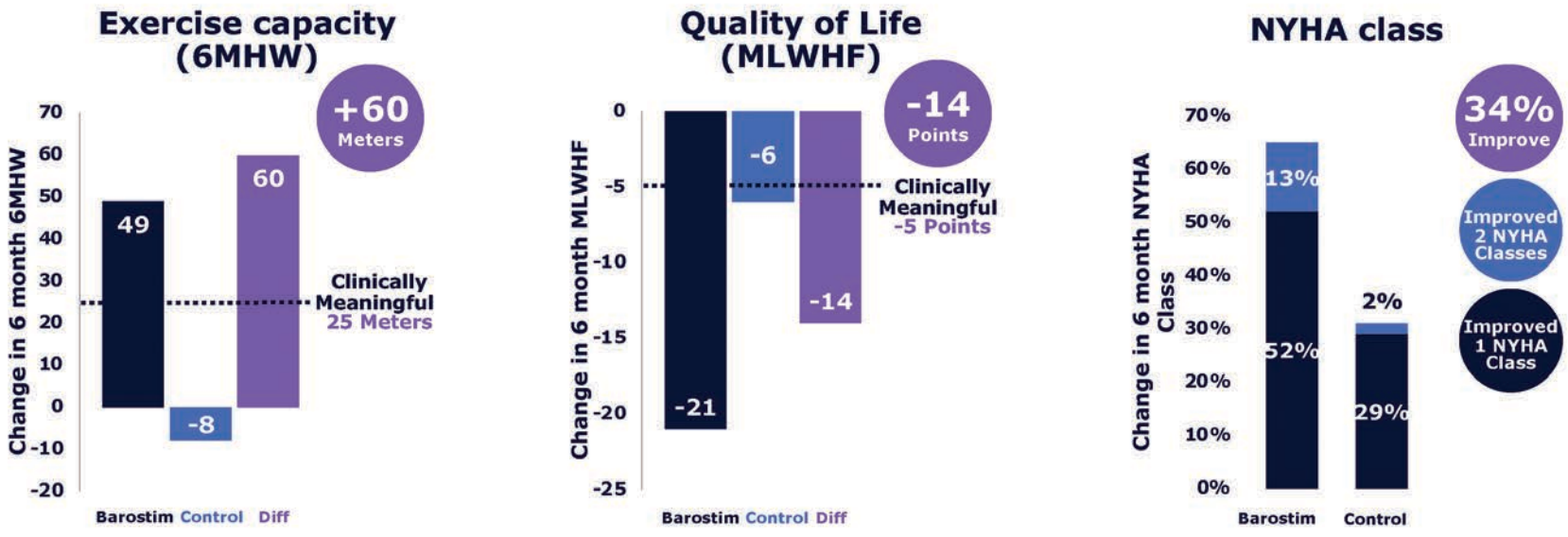

Figure 2. BeAT-HF clinical trial results: symptom improvement at 6 months.[1]

Source: Zile MR, et al. J Am Coll Cardiol 2020; 76:1-13. doi:10.1016/j.jacc.2020.05.015

Barostim Indications for Use

- NYHA III or NYHA II with recent history of NYHA III on GDMT*
- LVEF ≤35%
- NT-proBNP <1600 pg/mL
- Not indicated for CRT**

*Guideline-directed medical therapy (GDMT) according to 2022 AHA/ACC/ESC guidelines
**Or not receiving adequate response from existing CRT device

NYHA = New York Heart Association; LVEF = left ventricular ejection fraction; CRT = cardiac resynchronization therapy; AHA/ACC/ESC = American Heart Association/American College of Cardiology/European Society of Cardiology

Figure 3. Barostim indications, based on the BeAT-HF clinical trial.[1]

Which patients are candidates for this procedure?

In general, patients with New York Heart Association (NYHA) class II or III HF, an ejection fraction below 35%, and who have refractory HF symptoms despite GDMT are candidates, and those who are not candidates for cardiac resynchronization therapy (CRT) (Figure 3).

Patients to consider may fall into the following categories:

- Patients with implantable cardioverter defibrillators (ICDs) who are symptomatic despite GDMT.
- CRT non-responders, meaning they already have CRT, which is a biventricular device, and they are not responding well.
- Patients with have recurrent hospitalizations for congestive heart failure or who have a current hospitalization for congestive heart failure.
- Patients who are at maximally-tolerated GDMT but cannot be appropriately up-titrated to the target dose, or are having difficulties performing meaningful daily activities due to heart failure symptoms. Activities may include showering, making the bed, cooking, climbing the stairs in their own home, walking a couple of blocks, walking across the street to the doctor's office, shopping in the mall or market, playing with children or grandchildren, golfing, gardening, and traveling. What can these patients actually do on a day-to-day basis?

The last point above is meant to remind us of the reality our patients are experiencing. These are basic, standard activities of daily living that those of us who don't have heart failure take for granted.

Can you tell us about your experience referring patients for Barostim? Have you seen any changes in patients' activity and quality of life?

I have seen many of my patients increase their exercise capacity and resume some of their previous physical activities. One gentleman was referred to me after having had six congestive heart failure admissions and eight thoracenteses over 19 months. He was on maximally tolerated GDMT and was admitted with syncope. Since receiving a Barostim two years ago, he has not been readmitted again with heart failure and is no longer using metolazone. He improved from NYHA class III to NYHA class I-II. He's even able to play low-level soccer with his grandkids.

The majority of my patients who have received Barostim have not been readmitted with congestive heart failure and are more active — that is the most important feedback I have received from my patients and their families.

At what point do you start to think about offering Barostim to your patients and what is the patient pathway?

As a cardiologist and an interventional cardiologist, I often encounter these patients in the clinic or cath lab. We need to follow the usual pathway for CHF evaluation and treatment. It is important to evaluate the etiology of their cardiomyopathy, ensure revascularization as indicated, initiate and titrate GDMT, and offer CRT if applicable. If the patient continues to suffer from heart failure symptoms or is unable to tolerate GDMT at the target dose, they may be candidates for Barostim.

Is there a benefit to identifying patients earlier?

As with most things in medicine, it is always a good idea to develop a plan and talk to the patient about options earlier, whether that is CRT, an implantable cardioverter-defibrillator (ICD), or Barostim, in conjunction with their GDMT. We don't want to wait for repeat CHF hospital admissions. These heart failure patients never truly go back to baseline after each exacerbation; their new baseline is usually lower than where they started (Figure 4). Every time a patient gets readmitted for a congestive heart failure admission, they never truly bounce back to where they were prior to being admitted. They take five steps back and then maybe a few steps forward, but then they are readmitted, and they take seven steps back and then a few steps forward. Readmission takes something away from congestive heart failure patients, every single time.

How do you present this therapy to patients?

Lay people don't know what a baroreceptor is, much less the intricate details of the autonomic nervous system. I start by telling them there are two different types of nervous systems. There is the somatic nervous system where, for example, I tell myself to dial a phone number, I then pick up the phone, and I am able to accomplish that task. Then there is the autonomic nervous system, which involves involuntary things like my heart rate, which I have no significant control over. I then say that the autonomic nervous system itself has two major parts. There is the sympathetic, which allows me to run away if someone happens to walk in with a python, and then there is the

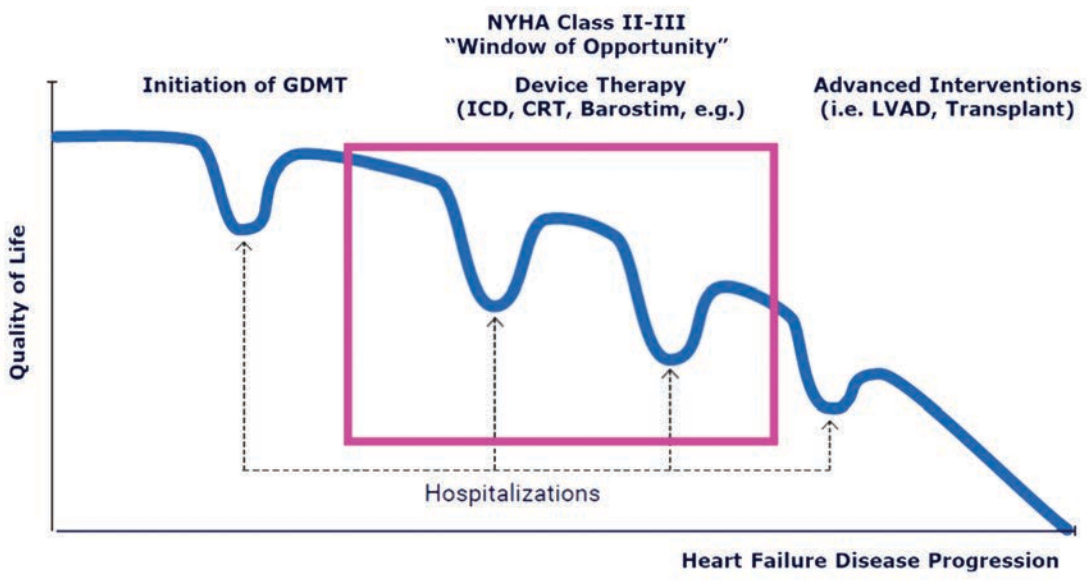

Figure 4. Heart failure disease progression. Physicians need to plan for these patients.

Modified from Greenhalgh T, et al. Understanding heart failure; explaining telehealth - a hermeneutic systematic review. BMC Cardiovasc Disord. 2017 Jun 14; 17(1): 156. doi:10.1186/s12872-017-0594-2

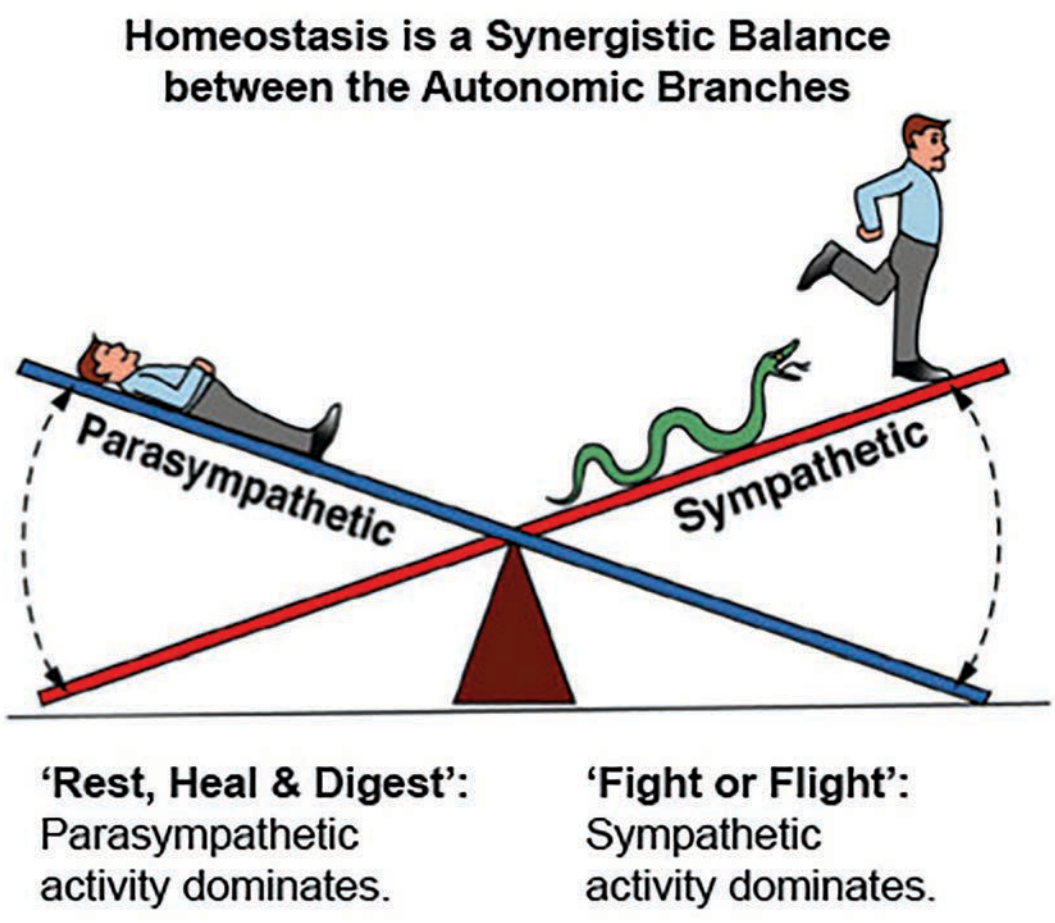

Figure 5. A visual aid when explaining Barostim. *Image copyright 2007 Pearson Education/Benjamin Cummings*

parasympathetic, an example of which is after a Thanksgiving meal where we are in 'rest and digest' phase, during which the parasympathetic system directs most blood flow to the abdomen so that we can digest our food.

I explain that in congestive heart failure, the sympathetic nervous system, the fight-or-flight response, is chronically activated. This activation is a vicious cycle, because it leads to increased fluid retention, shortness of breath, and more issues controlling blood pressure and diuresis. I tell the patient our goal is to move them more to the parasympathetic side. Depending on how much I think the patient is understanding, I might say that the reason the sympathetic side is winning out is because their baroreceptors are not functioning properly.

One of our most important responsibilities as physicians is to convey what is in our minds to patients in a way they can understand. I often use a seesaw as a visual aid, to help patients understand more easily (Figure 5). The sympathetic side is up, and the parasympathetic side is down, and with Barostim, I tell them, we are trying to flip the seesaw the other way around.

Why do you think other interventional cardiologists and general cardiologists should know more about Barostim?

Anyone who is a cardiologist is seeing congestive heart failure patients. There is no way to avoid it; it is ubiquitous. Hospitals and physicians alike are all coming under intense scrutiny because congestive heart failure is one of the biggest users of medical dollar expenditure, so every time we readmit a patient, it equals money out. Why are patients being readmitted? Is it because they are not taking their meds? Is it because they are eating bags of chips or fast food every day? Is it because GDMT has not been prescribed? Is it because the patient is just so far advanced that nothing is going to help? The answer is yes to all of the above. It is all of those reasons.

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More importantly, we need as many tools as are available to help our patients feel better. Congestive heart failure is incredibly hard on patients. Patients will come in and say, "I'm short of breath walking three steps from my bed to my bathroom." That is a horrible way to live.

Beyond anything, patients living with heart failure need and want improved quality of life. ■

This article is sponsored by CVRx.

Reference

1. Zile MR, Lindenfeld J, Weaver FA, et al. Baroreflex activation therapy in patients with heart failure with reduced ejection fraction. *J Am Coll Cardiol*. 2020 Jul 7; 76(1): 1-13. doi:10.1016/j.jacc.2020.05.015

Further Reading

1. Molina-Linde JM, Cordero-Pereda D, Baños-Álvarez E, et al. Efficacy and safety of baroreflex activation therapy for heart failure with reduced ejection fraction: systematic review. *ESC Heart Fail.* 2023 Jul 31. doi:10.1002/ehf2.14473

To learn more about Barostim, scan here to visit the CVRx website:

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