

Implantable Device To Stimulate The Carotid Sinus Nerve of Hering and Treat Intractable CHF and Hypertension (The Barostim System): Current Clinical Status

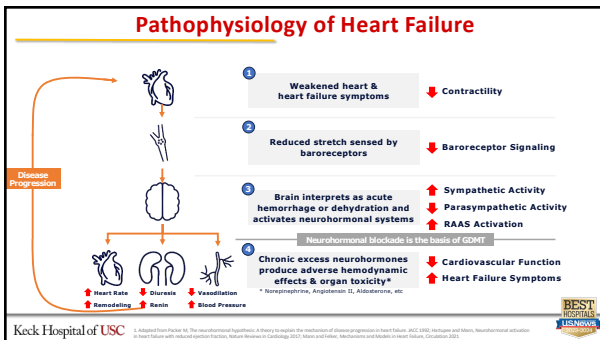
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Disclosures

Member of Scientific Executive Committee of CVRx which Manufactures Barostim

Keck Hospital of USC



Patients with HF Have Poor Quality of Life

Class II/III heart failure significantly decreases patients' physical and social well-being

- 66%** have mobility problems
- 68%** report pain or discomfort
- 76%** find usual activities difficult
- 50%** have anxiety or depression

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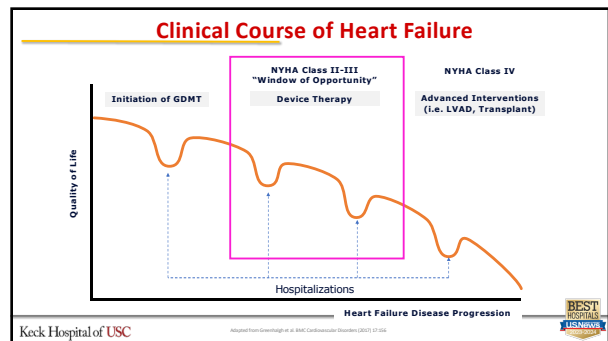
Goal Directed Medical Therapy

GDMT achieves significant improvement in mortality and morbidity, but only modest improvement in exercise capacity

CRT can improve exercise capacity, mortality and morbidity in HFrEF, but only about 30% of patients are indicated

Addressing these remaining needs in the HFrEF patient population will require a different approach

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Barostim System Elements

Barostim was designed to deliver electrical stimulation to carotid baroreceptors to increase baroreceptor signaling

Implantable Pulse Generator (IPG) & Carotid Sinus Lead

Wireless Programmer

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Barostim Stimulates the Carotid Baroreceptors

	Heart Failure	Barostim
Baroreceptor Signaling	↓	↑
Sympathetic Activity	↑	↓
Parasympathetic Activity	↓	↑
Heart Failure Symptoms	↑	?

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Barostim Targets the Neurohormonal Pathways

1 Weakened heart & heart failure symptoms ↓ Contractility

2 Reduced stretch sensed by baroreceptors ↓ Baroreceptor Signaling

3 Brain interprets as acute hemorrhage or dehydration and activates neurohormonal systems

↑ Sympathetic Activity
↓ Parasympathetic Activity
↑ RAAS Activation

4 Chronic excess neurohormones* produce adverse hemodynamic effects & organ toxicity

↓ Cardiovascular Function
↑ Heart Failure Symptoms

* Norepinephrine, Angiotensin II, Aldosterone, etc.

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Cardiology, Vascular Surgery Collaboration

Patient(s) Identified

Referral to Design Specialist - EP

Referral to HF

Referral to EP

Pre-admission workshopping

Sent to surgical office for AIC

Sent to surgical office for AIC

Vascular Surgeon
5,000 global implants
80% by Vascular Surgeons

Pre-admission workshopping

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Surgical Considerations

- Vascular Surgeon**
 - Surgical skill set
 - Intimate knowledge of carotid anatomy
- Verify at least one artery is adequate for implant, based on**
 - Accessibility of the bifurcation
 - Absence of ulcerative carotid plaques
 - Less than 50% carotid atherosclerosis (stenosis)
 - Based on prior experience, right side is recommended
- IPG placement: IPG should be placed ipsilateral to the neck incision, however the IPG may be placed contralateral if needed**
 - NOTE: Consideration should be given to the need for future CRM device on the left side

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Barostim Implant Technique

Small Incision in Neck

Electrode sutured to Carotid Artery

Lead tunneled to pectoral pocket

Lead connected to device and placed in pocket

Incision in neck closed

Pocket incision closed

Expose the anterior surface of carotid sinus bulb bifurcation

Outpatient Procedure

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Barostim BeAT-HF Results

ESC European Society of Cardiology
ESC Heart Failure Journal 2024; 17(1): 1-10

RESEARCH ARTICLE

Baroreflex activation therapy in patients with heart failure and a reduced ejection fraction: Long-term outcomes

Michael R. Zile¹, JoAnn Lindenfeld², Fred A. Weaver³, Faiz Zaman⁴, Elizabeth Gale⁵, Tyson Ragan⁶, and William T. Abraham⁷

Major Adverse Neurologic and Cardiovascular Event (MANCE) free rate of 97%

BeAT-HF Results

2024 ESC Heart Failure Journal 17(1): 1-10

Decrease in HF Hospitalizations Post Barostim

HOPE4HF publication¹

Fewer hospitalizations in the 6 months post- vs. 6 months pre-Barostim implant

¹There was a significant reduction in the rate of HF hospitalization from pre- to post-enrollment in the treatment group¹

USC Keck ACC abstract²

Fewer hospitalizations in the 12 months post- vs. 12 months pre-Barostim implant*

*BAT therapy with maximally tolerated doses of all four classes of GDMT is associated with reduced hospitalization rates 1-year post-therapy compared to GDMT alone²

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Barostim Summary

- Leverages carotid baroreceptor physiology
- Straightforward surgical procedure
- Low complication rate
- Improves HF patient's Quality of Life
- Lowers overall mortality
- Clinical application for treatment of Hypertension

2024 ESC Heart Failure Journal 17(1): 1-10

Conclusions

- Barostim is an effective therapy in treating symptoms of heart failure through stimulation of the carotid sinus.
- Implantation of Barostim is a straightforward extravascular procedure performed by vascular surgeons
- The implant procedure is attended by low perioperative and long-term complications

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