Barostim™
Outsmart the heart

Publication Summary

Real world evidence demonstrates significant reduction in hospital visits with Barostim

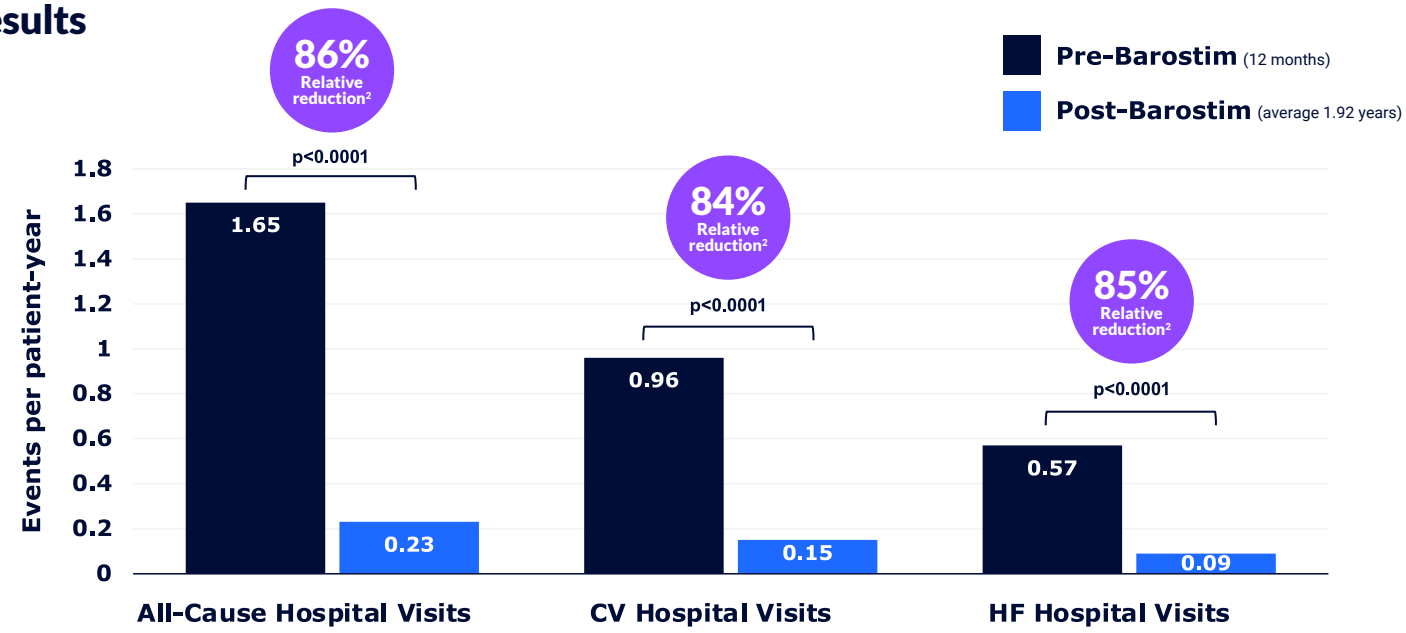
Key message

A retrospective analysis of a large real-world all-payer database demonstrated a statistically significant reduction in hospitalizations and emergency department visits following Barostim implantation.

Background

Healthcare utilization is a critical measure of the burden of heart failure (HF) on patients and the healthcare system. Heart failure with reduced ejection fraction (HFrEF) is a progressive disease, and patients remain at a significant risk of HF hospitalization, despite implementation of contemporary guideline directed medical therapy (GDMT). Analysis of real-world data from an all-payer database (Premier Healthcare Database[1]) identified 306 patients implanted with Barostim between 2016 and 2023 in the US.[2] Hospital visits (hospitalizations and emergency department encounters) categorized as all-cause, cardiovascular, and heart failure-related, were compared 12 months before Barostim implantation and for the available follow-up duration after Barostim implantation (average of 1.92 years).

Results



Barostim: Baroreflex Activation Therapy; CV: Cardiovascular; HF: Heart Failure.
Hospital Visits include hospitalizations and emergency department encounters.
Data from Premier Healthcare Database.[1]

Pre-Barostim duration: 12 months; Post-Barostim duration: 1.92±1.87 years (586 patient-years).
Rate ratio calculated by dividing post-implant event rate by pre-implant event rate.
P-values calculated from the negative binomial model.
*Hospital length-of-stay compares 12m pre-implant and 12 ± 3m post-implant; p<0.05

Conclusion

This analysis of a large all-payer database suggests that implantation of Barostim is associated with significant reductions in all-cause, cardiovascular, and heart failure hospital visits. While pre- vs. post-intervention hospitalization rates are not the same as efficacy compared to a contemporary control group, they are useful in describing real-world experience and consistency of results compared to prospective trials.

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Read the manuscript

Listen to the podcast

JCF Journal of Cardiac Failure

THE BRAIN→HEART CONTINUUM WITH PHILIP B. ADAMSON, MD

[1] Premier Healthcare Database: Data That Informs and Performs (White Paper). https://offers.premierinc.com/rs/381-NBB-525/images/PremierHealthcareDatabaseWhitepaper.pdf
[2] Abraham J, et al. Real-world analysis of healthcare utilization with baroreflex activation therapy for heart failure, J Card Fail 2025.

Important Safety Information

CAUTION: Federal law restricts this device to sale by or on the order of a physician. See Instructions for Use 900133-001 for a complete instruction for use and a description of indications, contraindications, warnings, precautions and adverse events.

Barostim™ Brief Summary for Physicians

The Barostim System is indicated for patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices), have a left ventricular ejection fraction of ≤ 35%, and a NT-proBNP <1600 pg/ml. Barostim delivers Baroreflex Activation Therapy for improvement of patients' heart failure functional status, six-minute hall walk, and quality of life.

Patients are contraindicated if they have bilateral carotid bifurcations located above the level of the mandible, baroreflex failure or autonomic neuropathy, uncontrolled symptomatic cardiac bradyarrhythmias, carotid artery stenosis greater than 50% caused by atherosclerosis, as determined by ultrasound or angiographic evaluation, ulcerative plaques in the carotid artery as determined by ultrasound or angiographic evaluation, known allergy to silicone or titanium.

Warnings include: only trained physicians may use this system, prescribing physicians should be experienced in the diagnosis and treatment of heart failure and should be familiar with the use of this system, blood pressure and heart rate should be monitored during Carotid Sinus Lead placement and when adjusting stimulation parameters intra-operatively, system programming post-implantation, should avoid the following: heart rate falls below 50 beats per minute (BPM), or systolic pressure falls below 90 mmHg, or diastolic blood pressure falls below 50 mmHg, or problematic adjacent tissue stimulation is noted, or undesirable interaction indicated by monitoring of any other implanted electrical device, or any other potentially hazardous patient responses are observed. For patients who currently have an implanted electrical medical device, physicians must verify compatibility with the implanted device during implantation of the system as well as whenever settings are changed in either implant. Interactions are more likely in devices that contain a sensing function, such as an implantable cardiac defibrillator or pacemaker. If an interaction is observed, the Barostim NEO and NEO2 should be programmed to reduced therapy output settings in order to eliminate the interaction. If necessary, change settings in the other implant only if the changes are not expected to negatively impact its ability to perform its prescribed therapy. During the implant procedure, if device interactions cannot be eliminated the Barostim System should not be implanted. Improper system implantation could result in serious injury or death. Do not use diathermy therapy including shortwave, microwave, or therapeutic ultrasound diathermy on patients implanted with the system. Patients should be counseled to stay at least 15 cm (6 inches) away from devices with strong electrical or magnetic fields such as strong magnets, loudspeaker magnets, Electronic Article Surveillance (EAS) system tag deactivators, arc welders, induction furnaces, and other similar electrical or electromechanical devices. This would include not placing items such as earphones in close proximity to the implanted pulse generator. The system may affect the operation of other implanted devices such as cardiac defibrillators, pacemakers, or neurological stimulation systems.

Precautions include: the system should be implanted and programmed carefully to avoid stimulation of tissues near the electrode or in the area of the IPG pocket. Such extraneous stimulation could involve the following: the regional nerves, causing laryngeal irritation, difficulty swallowing, or dyspnea, the cervical musculature, causing intermittent contraction, skeletal muscles, causing intermittent contraction around the IPG pocket. Proper sterile technique during implantation should be practiced and aggressive pre-operative antibiotics are recommended. Infections related to any implanted device are difficult to treat and may necessitate device explantation.

It is anticipated that subjects will be exposed to operative and post-operative risks similar to related surgical procedures involving the neck and/or a pacemaker implant. These risks and potential risks of chronic device based Barostim may include, but are not limited to: stroke, transient ischemic attack (TIA), systemic embolization, surgical or anesthetic complications, infection, wound complications, arterial damage, pain, transient, temporary or permanent nerve damage/stimulation, hypotension, hypertensive crisis, respiratory, exacerbation of heart failure, cardiac arrhythmias, tissue erosion/IPG migration, injury to baroreceptors, fibrosis, allergic reaction, general injury to user or patient, need for reoperation, secondary operative procedure, and death. Patients implanted with the system may receive Magnetic Resonance Imaging (MRI) only when all MR Conditional safety parameters are met as listed in the instructions for use.

For a list of all potential benefits and risks go to www.cvrx.com/benefit-risk-analysis/
For a list of all applicable patents, see www.cvrx.com/patent-marking.

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