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Impact of Barostim on Heart Failure Hospitalization

Dr. Abraham:
This is CME on ReachMD, and I'm Dr. Jacob Abraham. Today I'm discussing the real-world analysis of healthcare utilization and reduction in hospitalizations associated with use of baro activation therapy for heart failure.

Healthcare utilization is a critical measure of the burden of heart failure on patients and the healthcare system. While guideline-directed medical therapy, or GDMT, is the cornerstone of treatment for patients with heart failure and reduced ejection fraction, we still know that about 1 in 4 patients who are treated with optimal GDMT will still experience a first or recurrent heart failure hospitalization, underscoring the need for additional novel therapies to prevent the progression of heart failure.

It's in this context that baro activation therapy may play an important role.

We know that a central mechanism of heart failure progression is neurohormonal activation, which is characterized by sympathetic activation and parasympathetic withdrawal.

Baro activation therapy consists of an implantable pulse generator that delivers continuous electrical activation of the carotid baroreceptors through a lead sutured on the carotid sinus. This stimulation increases baroreceptor signaling, which improves baroreceptor sensitivity and autonomic balance.

In the BeAT-HF trial, patients with an ejection fraction of less than or equal to 35% and an NT-proBNP level of less than 1600 pg/mL were randomized to receive medical treatment alone or medical treatment in addition to baro activation therapy. This study showed a reduction in NT-proBNP levels and an increase in 6-minute walk distance that resulted in FDA approval of the device.

In the post-market phase of the trial, baro activation had a neutral effect on cardiovascular death and heart failure hospitalization, but this trial was significantly impacted by the COVID-19 pandemic. Consequently, the impact of baro activation therapy on hospitalization remains unclear.

We therefore set out to assess the impact of baro activation therapy on hospitalization by leveraging the Premier Healthcare dataset, an all-payer database with a national, comprehensive, real-world electronic healthcare data that includes both inpatient and outpatient encounters. From over 300 million patients in the dataset who were collected between 2016 and 2023, we identified 306 patients who were implanted with a baro activation device.

In this study, healthcare utilization was defined as hospital visits resulting in either inpatient admission or emergency room visits. We then classified these visits as being due to all-cause, cardiovascular, or heart failure-related etiologies. Rates were compared 12 months before Barostim implantation and for the available follow-up duration after Barostim implantation.

Of the 306 patients who were implanted with baro activation therapy, the mean age was 66 ± 12 years. Approximately 1 in 4 patients were female and approximately 1 in 5 were African American. The pre- and post-implant follow-up periods were 306 and 586 patient-years, respectively. We found that mortality rates at 1 and 2 years post implant were 6.3% and 12.3%, respectively.

The main results of our paper are that treatment with baro activation therapy was associated with an 86% relative reduction in all-cause hospitalization, an 84% relative reduction in cardiovascular hospitalizations, and an 85% reduction in heart failure-related hospitalizations. Additionally, we identified significant reductions in the length of stay for hospitalizations in the 1 year post implant versus the 12 months pre implant of baro activation therapy.

The significant findings of our study are the large and meaningful reductions in hospitalization for all-cause, cardiovascular, and heart failure-related hospitalizations from this dataset. Of importance, these reductions in hospitalizations occurred across all categories, meaning that there was no shift from a heart failure hospitalization to another etiology of hospitalization. Additionally, we found that baro stimulation therapy was associated with reductions in length of stay of any cause.

And taken together, these findings suggest that baro activation therapy improves overall clinical stability in patients with heart failure. In both of these metrics, reduction in hospitalization and length of stay are critical when evaluating the cost of heart failure on large populations, such as the ones studied in our paper.

There are several important limitations of this study. First, there was no control group that did not receive baro activation therapy. Secondly, we lack details regarding the severity of heart failure in this population. Additionally, it is possible that there are other disease modification therapies that were applied, including treatment under advanced heart failure specialists, which could have been associated with improvements in heart failure that are independent of the device.

Finally, it is possible that the COVID-19 pandemic impacted the rate of heart failure hospitalization and all-cause hospitalization in this study; however, we note that 90% of the population were implanted and had follow-up in the years of 2021 to 2023, after the COVID-19 pandemic.

So in conclusion, we found that baro activation therapy was associated with significant reductions in all-cause, cardiovascular, and heart failure-related hospitalizations in this analysis of a large contemporary nationwide database. Clinicians should consider the use of device-based therapies when encountering patients with heart failure and reduced ejection fraction who continue to have limiting symptoms despite treatment with optimal guideline-directed medical therapy. Such device considerations should include baro activation therapy.