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ANTHEM-HF study shows significant improvement in cardiac function with left or right vagus nerve stimulation

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Regulation of the autonomic nervous system with a device that delivers continuous, low-amplitude stimulation to the vagus nerve can significantly improve cardiac function and symptoms in patients with chronic heart failure, regardless of whether the device is implanted on the left or right vagus nerve, according to preliminary results presented today at ESC Congress 2014.

The ANTHEM-HF (Autonomic Neural Regulation Therapy to Enhance Myocardial Function in Heart Failure) was presented as a Hot Line at the congress, with simultaneous publication in the Journal of Cardiac Failure.

Left-sided vagal nerve stimulation (VNS) is a well-established treatment for epilepsy, however it has not previously been evaluated in heart failure patients, and the effects of left and right-sided VNS have not been directly compared in this patient population, explained the study's principal investigator Inder Anand, MD, DPhil, from the University of Minnesota Medical School, in Minneapolis, USA.

"Left-sided VNS could be an advantage in some heart failure patients because it can be combined with cardiac devices such as implantable cardioverter-defibrillators (ICDs) and cardiac resynchronisation therapy (CRT) devices, the vast majority of which are implanted on the left side of the thorax," he noted.

The study included 60 heart failure patients (aged approximately 51 years) with reduced ejection fraction, who were receiving optimal and stable pharmacological therapy.

Patients were randomised to receive a VNS device implanted on either the left (n=31) or right (n=29) side and stimulation to the vagus nerve was titrated over a 10-week period to determine the best-tolerated intensity.

Following titration, VNS was then delivered for six months at an amplitude of 2.0 (± 0.6) mA, and a constant frequency of 10 Hz.

The study showed significant improvement (mean 4.5%) from baseline in left ventricular ejection fraction (LVEF) among all patients, with no statistically significant differences between left- and right-sided VNS.

Improvement in left ventricular end systolic volume (LVESV) was not statistically significant.

There was also a mean improvement of 56 metres in the 6-Minute Walk Test, but this improvement was significantly less with left- compared to right-sided VNS (mean 34 vs 77 meters).

Minnesota Living with Heart Failure Questionnaire scores also improved by a mean of 18 points, with no significant difference between left- and right-sided VNS.

There was a similar rate of device-related adverse events in both groups, including transient mild dysphonia (voice alteration), cough, and oropharyngeal pain, which resolved during the study.

"These are consistent with device-related non-serious adverse events previously reported in epilepsy patients treated with VNS," noted Dr

Anand.

One patient with a history of carotid atherosclerosis suffered an embolic stroke during device implantation and died three days later.

"It is possible that manipulation of the common carotid artery in the neck during dissection of the vagus nerve caused plaque disruption or dislodged a thrombus," said Dr. Anand. "Avoidance of this procedure in patients with severe obstructive carotid disease is likely to minimise such occurrences."

ANTHEM-HF is the first clinical study to compare the feasibility and tolerance of left- and right-sided ART, and compare safety and efficacy measures, he concluded.

"This preliminary assessment shows promising results which need to be confirmed in a larger, controlled trial."

Provided by European Society of Cardiology

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