Implantation of a vagus nerve stimulator for patients with heart failure with reduced ejection fraction: An educational video

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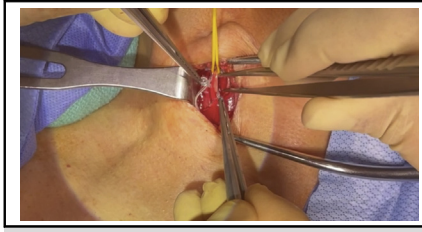
ABSTRACT

Objectives: Implantation and use of vagus nerve stimulation (VNS) systems is a proven treatment strategy for epilepsy and depression, and extensive research regarding vagal control of the heart has led to the idea of VNS as a potential adjunct treatment for heart failure with reduced ejection fraction (HFrEF). We describe our experience with the implantation of an investigational VNS system to manage patients living with HFrEF.

Methods: As part of the ongoing ANTHEM-HFrEF (Autonomic Regulation Therapy to Enhance Myocardial Function and Reduce Progression of Heart Failure with Reduced Ejection Fraction) Pivotal Study, a 67-year-old male patient with a history of ischemic cardiomyopathy was randomized to implantation of the VITARIA System (LivaNova Inc). The electrical lead requires no mapping for placement around the vagus nerve. The surgical procedure was completed uneventfully under general anesthesia, and the device was activated in the operating room after surgery.

Results: Following successful implantation and activation of the VNS system, the patient was discharged to home on the same day.

Conclusions: Current, ongoing studies, such as the ANTHEM-HFrEF Pivotal Study, are designed to determine the long-term effects of VNS on heart failure symptoms, hospitalization rates, and survival. The VNS-implantation procedure was straightforward. (JTCVS Techniques 2022;14:96-8)



Surgical implantation of vagus nerve stimulation system for autonomic regulation therapy.

CENTRAL MESSAGE

Vagus nerve stimulation for the delivery of autonomic regulation therapy is being investigated as a potential adjunct treatment for patients with heart failure with reduced ejection fraction.

PERSPECTIVE

Our goal is to share our technique with the surgical society. We provide a step-by-step guide on how to perform the implantation of a vagus nerve stimulator in patients with heart failure with reduced ejection fraction.

See Commentary on page 99.

Video clip is available online.

Heart failure (HF) is the leading cause of hospitalization in adults in the United States, with a heavy impact on health care costs.[1] Innovative device therapy is recognized as an additional modality that could alter the disease course.[2] Devices are in development to deliver autonomic regulation therapy (ART) using vagus nerve stimulation (VNS) to address the autonomic system imbalance that accompanies and aggravates chronic HF, as demonstrated by heightened sympathetic and reduced parasympathetic activity.[3] ART has the potential to reduce chronic heart rate, restore heart rate variability and baroreflex sensitivity, and suppress proinflammatory cytokines and arrhythmias,[4] which could translate to improved functional status and longevity.[5]

Earlier clinical studies of VNS (Autonomic Regulation Therapy for the Improvement of Left Ventricular Function and Heart Failure Symptoms [ANTHEM-HF], Increase of Vagal Tone in Heart Failure [INOVATE-HF], and NEural

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Abbreviations and Acronyms

ANTHEM-HFrEF = autonomic regulation therapy to Enhance myocardial function and reduce progression of heart failure with reduced ejection fraction
ART = autonomic regulation therapy
HF = heart failure
HFrEF = heart failure with reduced ejection fraction
VNS = vagus nerve stimulation

Cardiac TherApy foR Heart Failure [NECTAR-HF]) have collectively provided dose-ranging information that has informed the development of VNS for tolerability and improving cardiovascular symptoms and function in patients living with heart failure and reduced ejection fraction (HFrEF).[6-9] Improvements from baseline in heart rate, heart rate variability, 6-minute walk distance, New York Heart Association functional class, and quality-of-life have been reported.[9]

The ANTHEM-HFrEF (Autonomic Regulation Therapy to Enhance Myocardial Function and Reduce Progression of Heart Failure with Reduced Ejection Fraction) Pivotal Study is evaluating the investigational VITARIA System (LivaNova, Inc) for the treatment of patients with dilated cardiomyopathy of ischemic as well as nonischemic origin, reduced left ventricular ejection fraction, and clinical symptoms of advanced HF despite treatment with guideline-directed medical therapy.[10] We describe the first and successful implantation of a VNS system at our study site in a patient with HFrEF.

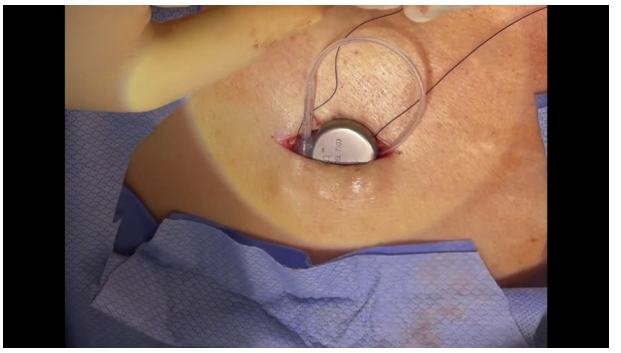
METHODS

The local institutional review board approved the ANTHEM-HFrEF Pivotal Study (HSC-MH-20-1197, March 13, 2021). Informed patient consent was obtained for participation in the study and publication purposes. The treatment team consisted of members from the anesthesiology, cardiothoracic surgery, and cardiology departments, a surgical proctor with previous experience in the implantation of VNS systems, and field clinical engineering support from the device manufacturer.

A 67-year-old male patient with a history of ischemic cardiomyopathy presented to the clinic in New York Heart Association stage II HF with chest pain and exertional shortness of breath and was randomized to implantation of the VITARIA System and treatment with ART in the treatment arm of the study. The study protocol leaves the choice of local, regional, or general anesthesia for implanting the VITARIA System to the implanting surgeon. This patient underwent VNS system implantation using general anesthesia. He was placed in the supine position with both arms tucked and the neck extended to the left (Video 1). The right neck was prepped and draped. Local anesthesia was injected, and a transverse incision was made over the midsternocleidomastoid muscle.

The platysma muscle was traversed with electrocautery, and dissection was carried down to the carotid sheath. The sternocleidomastoid was retracted laterally. The carotid sheath was opened, and the right cervical vagal nerve was identified posterior to the carotid artery. The nerve was meticulously dissected in a no-touch technique for a 3-cm length and isolated with a vessel loop. A skin incision was made in the anterior subclavicular region for the generator, and a pocket was developed and sized. A tunneling device was passed through the subcutaneous tissue from the upper incision to the lower one. The introducer was removed from the sheath, and the generator lead was passed through the sheath. The VNS lead was held in the center and wrapped around the vagus nerve 2 to 3 cm below the carotid artery bifurcation (Figure 1). The lead was connected to the generator and then tested by the manufacturer. The lead was secured to the sternocleidomastoid muscle with a permanent suture, leaving a few centimeters loop up in the neck to allow for bidirectional neck movement.

The generator was secured to the pectoralis fascia in the pocket with multiple absorbable sutures. The subcutaneous tissue was approximated, and the skin was closed.



VIDEO 1. This video describes how to implant a vagus nerve stimulator to manage patients with heart failure with reduced ejection fraction. Video available at: https://www.jtcvs.org/article/S2666-2507(22)00201-2/fulltext.

RESULTS

The implantation procedure had a duration of 66 minutes, was completed successfully, and there were no perioperative complications. The VNS was activated in the operating room after the completion of the procedure. During follow-up appointments, the postoperative assessment was uneventful. The investigational device has continued to

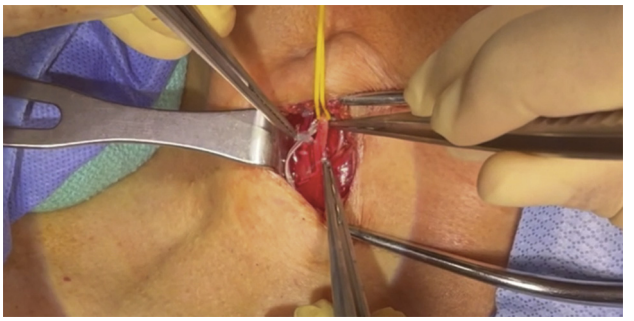


FIGURE 1. Vagus nerve stimulator insertion as a potential adjunct in managing patients with heart failure with reduced ejection fraction.

function properly, and VNS titration has been performed per the study protocol.

CONCLUSIONS

The concept of using VNS to modulate the autonomic nervous system, restore sympathovagal balance, and improve clinical outcomes has been evaluated in initial studies of patients who have HFrEF and persistent symptoms of advanced HF despite guideline-directed medical therapy.[6-8] The ongoing ANTHEM-HFrEF Pivotal Study aims to determine whether the delivery of ART using VNS will improve symptoms and function, quality of life, hospitalization rates, and survival of patients with HFrEF. The implantation of the VITARIA System was straightforward and is very similar to the implantation of VNS systems for the treatment of drug-refractory epilepsy or treatment-resistant depression. Implantation is possible in the ANTHEM-HFrEF Pivotal Study using local, regional, or general anesthesia, and placement of the electrical lead around the vagus nerve requires no mapping.

Conflict of Interest Statement

M.J. is site PI for the ANTHEM-HRrEF Pivotal Study sponsored by LivaNova (NCT03425422), a consultant for Medtronic Vascular, Inc, and a recipient of in-kind support from Boston Scientific Corporation. B.K. has received in-kind support from Edwards Lifesciences Corporation. The University of Texas Health Science Center at Houston does receive funds in relation to activities with the ANTHEM-HRrEF Pivotal Study. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: vagus nerve stimulator, heart failure