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FIRST-IN-HUMAN VISIONE HEART FAILURE STUDY: ASYMPTOMATIC DIAPHRAGMATIC STIMULATION FOR CHRONIC HEART FAILURE WITH REDUCED EJECTION FRACTION: CASE REPORT

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Spotlight on Special Topics

FIRST-IN-HUMAN VISONE HEART FAILURE STUDY: ASYMPTOMATIC DIAPHRAGMATIC STIMULATION FOR CHRONIC HEART FAILURE WITH REDUCED EJECTION FRACTION: CASE REPORT

Poster Contributions
Posters Hall_Hall A
Sunday, March 29, 2020, 3:45 p.m.-4:30 p.m.

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Background: Asymptomatic Diaphragmatic Stimulation (ADS) is a novel device-based HF therapy under investigation. ADS gated with the cardiac cycle transiently modulates intrathoracic pressure, thereby enhancing pre- and afterload, and stroke volume. It is hypothesized that ADS improves cardiac function and exercise tolerance in HFrEF patients.

Methods: HFrEF patients (15) underwent laparoscopic implantation of the VisONE ADS system (NCT03484780). Post-implant stimulation levels imperceptible to the patient are determined. At discharge, ADS therapy is turned on. Measures of cardiac function, HF status, QoL and adverse events are assessed every 3 months for 12 months.

Results: Results are presented from an initial patient receiving ADS therapy for 6 months. A male patient on optimal medical therapy (age 56, EF 30%, NYHA II); capture threshold confirmed visually during implant was 1.5V@0.4 ms (patient perception threshold when conscious 3.5V@0.4 ms). The patient was discharged without complications with ADS active. From discharge to 6 month f/u all relevant measures improved: NT-proBNP (1784 vs. 910 pg/ml); 6MWT (309 vs 347 m); HR (85 vs 75 bpm); SF36 summary score (44.4 to 58.2); and device-based activity (46 vs 96 a.u.).

Conclusion: This case study highlights the promise of ADS by demonstrating significant improvements to key heart failure measures without therapy related adverse events. Entire cohort results pending study completion and final statistical analysis.

