SYNCHRONIZED DIAPHRAGMATIC STIMULATION: DEVICE-BASED ACTIVITY ASSESSMENT IN CHRONIC HEART FAILURE PATIENTS

Peter Bauer,[1], Patricia Arand,[1], Hui Yu Sim,[1], Gregg Harris,[1], Marat Fudim,[2], Michael Mirro,[3]

[1] Viscardia, Inc., [2] Duke University, [3] Indiana University

Peter Bauer[1], Jack Cheng[1], Gregg Harris[1], Patti Arand[1], Marat Fudim[2], Michael Mirro[3]
[1] VisCardia Inc., Portland, Oregon
[2] Duke University, Durham, North Carolina
[3] Indiana University, Fort Wayne, Indiana

Synchronized Diaphragmatic Stimulation: Device-based Activity Assessment in Chronic Heart Failure Patients

Background:

Synchronized diaphragmatic stimulation (SDS), a device-based heart failure (HF) therapy to modulate intrathoracic pressure using a dedicated implantable system which delivers stimulation pulses to the diaphragm gaited with sensed cardiac activity, has been evaluated in a first-in-human study (NCT03484780). To allow monitoring and trending of patient status, the implanted device records accelerometer-based activity every 15 minutes to provide hourly averages for up to 90 days.

Objective:

To study the correlation of device-based activity measurements with other objective measurements of exercise tolerance, HF status and cardiac function.

Methods:

HF patients underwent laparoscopic implantation of the VisONE system comprised of a pulse generator and two bipolar sutureless, active fixation leads affixed to the inferior left and right hemispheres of the diaphragm. During the implant procedure, optimal locations and parameters for sensing the QRS complex and delivering SDS pulses were determined. The patients were evaluated at 3, 6 and 12 months post-discharge using standard chronic measures of cardiac function (LV ejection fraction (LVEF), LV end-systolic volume (LVESV), Short Form (36) Health Survey (SF-36), 6-minute walk test (6MWT)) and the device-based activity measurement.

Results:

Twenty patients were screened, and fifteen men were enrolled (100% ischemic etiology, 61 ± 7.3 y, LVEF 27.8 ± 5.6%, QRSd 114 ± 14.7 ms, NT-proBNP 1579 ± 756 pg/ml) and successfully implanted. For all patients a SDS stimulation level could be identified that caused imperceptible localized diaphragmatic contraction. Comparing discharge with SDS off to follow-up with SDS on, statistically and clinically significant improvements (mean of differences, discharge vs 12 months) were seen in 6MWT (37.1 m, p=0.004, see

figure), SF-36 role limitations physical score (19.2 au, p=0.006), LVEF (4.5 %, p=0.17), LVESV (with SDS off, -33.4 m/lm2, p=0.04) and activity (59.0 au, p=0.006).

CONCLUSION:
Device-based activity measurements with the VisOne system for Synchronized Diaphragmatic Stimulation are a reliable indicator of patient status and a useful tool for non-invasive patient monitoring.

Figure 1 Device-based daily activity data compared with exercise tolerance and LV ESV