Sustained Functional Improvements from Endovascular Baroreflex Amplification (EVBA) in Symptomatic HFrEF

K. Piayda, K. Sievert, H. Sievert, T. Shaburishvili, I. Gogorishvili, M. Rothman, J Januzzi, J. Lindenfeld, G. Stone

BACKGROUND

Autonomic imbalance plays a key role in the development and progression of heart failure (HF). The MobiusHD® device (Vascular Dynamics, Irvine, CA) is a self-expanding, nitinol, open-cell endovascular implant that reshapes the carotid sinus and maintains pulsatility.

The EVBA approach provides autonomic modulation to reduce sympathetic overdrive and enhance parasympathetic activity to treat HFrEF patients. Results of a feasibility study for this approach have shown improvements in 24-month outcomes.

METHODS

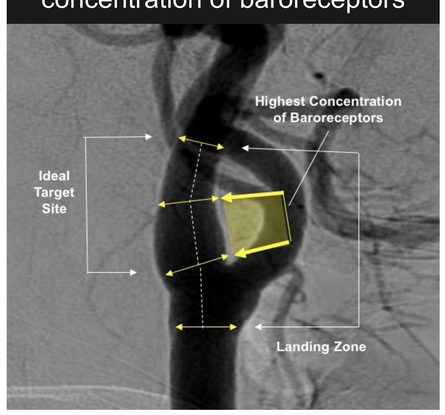
- 37 symptomatic HFrEF patients despite stable GDMT were treated with the MobiusHD device.
- Implants were placed in the carotid sinus using established techniques.
- Outcomes, including KCCQ OSS, rates of HF hospitalizations and responders in QoL scores (>5 and 10 pts), are provided for 23 patients with 24 months follow up.
- Hemodynamic data provide an assessment of mechanistic changes.

IMPLANT PROCEDURE

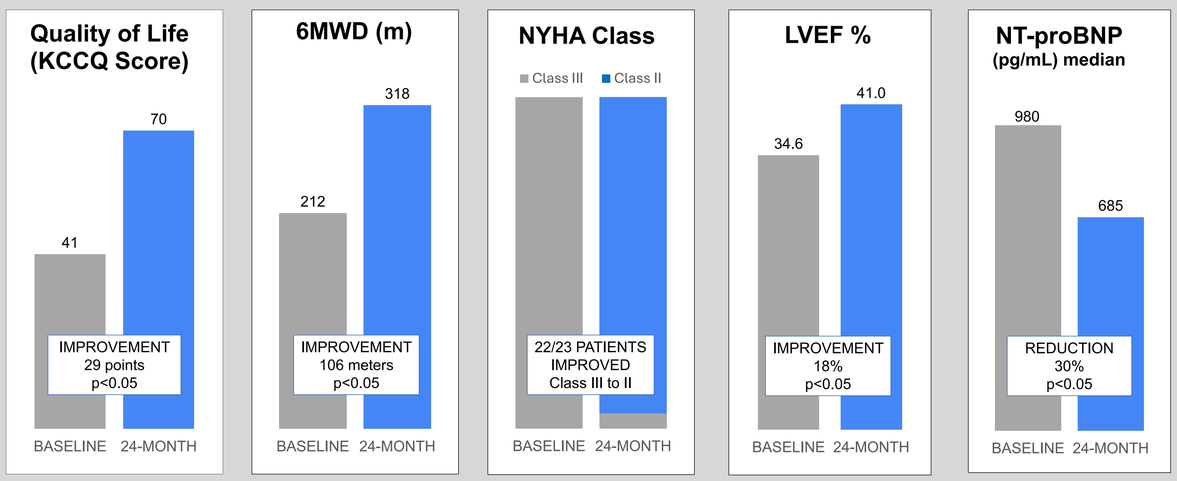
Pre-op imaging:
- Confirm plaque-free artery
- Confirm acceptable anatomy

Implantation:
- Standard access to carotid sinus
- Deploy implant in desired location

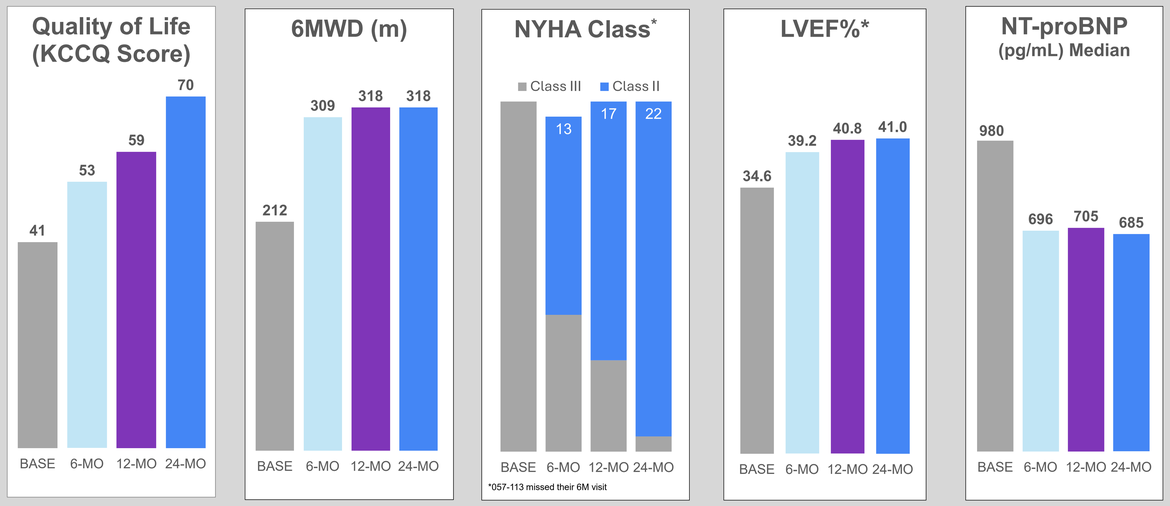
Targeting the site of highest concentration of baroreceptors



EVBA HF Feasibility Clinical Evidence
24-MONTH RESULTS (N=23)



Feasibility Results Over Time
6, 12 & 24-MONTH RESULTS (N=23)



MEASURE (MEAN)	BASELINE	6 MONTHS	12 MONTHS	24 MONTHS
HEART RATE	81.6 ± 14.2	75.4 ± 18.1	78.3 ± 16.7	74.3 ± 16.9
SYSTOLIC BP	128.9 ± 6.7	125.6 ± 8.4	122.8 ± 4.9	126.4 ± 9.6
DIASTOLIC BP	71.1 ± 5.5	77.9 ± 5.0	74.1 ± 4.4	73.0 ± 6.5
N=	23	22*	23	23

*057-113 missed their 6M visit

Disclosures:
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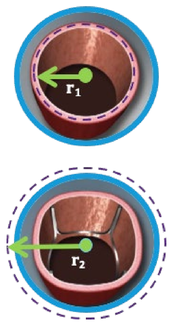
Contact:
Martin Rothman
Vascular Dynamics, Inc
mrothman@vasculardynamics.com

MECHANISM OF ACTION

Baroreceptors are activated by stretch, not pressure.

The rectangular-shaped MobiusHD implant creates a larger effective arterial radius (r2 > r1) and increases wall stretch/strain. Increased wall stretch amplifies the baroreflex mechanism.



RESULTS

Of 23 patients with 24 months follow up, the mean age was 60 ± 11 years and 70% were male. Stable medical therapy was maintained; 100% were on a diuretic, 96% a BB, 91% an ACEi/ARB/ARNI, and 83% an MRA.

- Improvements in KCCQ OSS from baseline were shown (p<0.05). KCCQ OSS improved at 6, 12, and 24 months by more than 5 pts in 83%, 87%, and 96%, and by more than 10 pts in 57%, 74%, and 91% of patients.
- In the 6 months prior to EVBA treatment, there were 10 HF hospitalizations in 9 patients (0.9/pt-yr). In the 6 months after EVBA treatment there were no HF hospitalizations.
- In the 24 months after EVBA treatment, there were 3 HF hospitalizations in 2 patients (0.07/pt-yr).
- During the follow-up period, HR trended lower and BP remained unchanged.

Of all 37 patients enrolled,
- In the 6 months prior to EVBA treatment there were 11 hospitalizations in 10 patients (0.6/pt-yr). In the 6 months after EVBA treatment there was one HF hospitalization in one patient (0.05/pt-yr).
- One patient withdrew and there were 3 deaths unrelated to the device at 161,191 and 691 days post-implantation. 10 have yet to complete 24 months follow up.

CONCLUSIONS

Patients with symptomatic HFrEF despite GDMT were treated with the MobiusHD device. Progressive improvements were sustained at 24 months follow up as evidenced by improved KCCQ OSS and lower rates of HF hospitalization. HR trended lower. Findings indicate a potentially clinically meaningful and durable benefit of the MobiusHD device in HFrEF. A randomized, sham-controlled trial is planned.