Update on Chronic Carotid Sinus Stimulation with an Implantable Device to Treat Resistant Hypertension

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Carotid Bifurcation is Central to Autonomic Control

The Carotid Sinus Baroreflex As Therapeutic Target

Stimulating Carotid Sinus Baroflex Slows Heart Rate and Reduces Elevated Blood Pressure

Effect of Carotid Sinus Baroflex Stimulation in 21 Patients with Resistant Hypertension

Heart Rate Variability

Low Frequency
High Frequency

Wustmann, Hypertension 2009; 54:S10
Effect of Carotid Sinus Baroflex Stimulation on Vascular Stiffness

- HR-adjusted Augmentation Index: 49%
- LV Wasted Work: 23,257 dyne-s/cm²
- Buckberg SEVR: 138%
- Ejection Duration: 34%
- Reflected Wave Timing: 109ms

Stimulation

- HR-adjusted Augmentation Index: 23%
- LV Wasted Work: 8,151 dyne-s/cm²
- Buckberg SEVR: 216%
- Ejection Duration: 25%
- Reflected Wave Timing: 173ms

Rheos Hypertension Pivotal Trial Design

- Trial Hypothesis: BAT is Safe and Effective for the Treatment of Resistant Hypertension
- Prospective randomized double-blind trial
  - 322 patients at 49 sites
  - 55 roll-in patients / 265 randomized (2:1)
- Co-primary endpoints
  1. Short Term Acute Response
  2. Long Term Sustained Response
  3. Short Term Procedural Adverse Events
  4. Short Term Hypertension Therapy Adverse Events
  5. Long Term Device Adverse Events

Long Term Data in Resistant HTN

- Screening
- Baseline

Change in SBP using BpTRU (mmHg, +/- SE)

- 1 Year
- 2 Year
- 3 Year
- 4 Year
- 5 Year
- 6 Year

Change in DBP using BpTRU (mmHg, +/- SE)

- 1 Year
- 2 Year
- 3 Year
- 4 Year
- 5 Year
- 6 Year

Rheos Pivotal Trial Extended Follow-up SBP

- Baseline
- 1 Year
- 2 Years
- 3 Years
- 4 Years

Rheos Pivotal Trial Extended Follow-up DBP

- Baseline
- 1 Year
- 2 Years
- 3 Years
- 4 Years
- 5 Years
Rheos Pivotal Trial LV Remodeling

Rheos Study Demonstrated Left Ventricular Reverse Remodeling with BAT

- 60 Patients from Rheos study enrolled in echocardiography sub-study
- Study assessed changes in left ventricular mass index (LVMI) after 12 months of active therapy
- At 12 months of BAT, average reduction of LVMI was 15 g/m² (p < 0.01) to normal range

Barostim neo

Unilateral Barostim neo™ Efficacy Results

- N = 30
- p-value < .001

Six Patients were Previously Treated with Renal Denervation

Effects of Barostim neo™ on Kidney

- N=23
Barostim included in ESH/ESC guidelines as an option to treat resistant hypertension

2013 ESH/ESC Guidelines for the management of arterial hypertension

The Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and the European Society of Cardiology (ESC)

A Controlled Trial of Renal Denervation for Resistant Hypertension


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Update on Carotid Sinus Stimulation

- Carotid sinus stimulation lowers blood pressure, induces positive ventricular remodeling and improves renal function
- RHEOS trial at 5 years demonstrated that chronic carotid sinus stimulation produces a durable decrease in blood pressure. HDE
- Barostim neo device easier to implant and is effective in lowering blood pressure
- Barostim neo pivotal trial for heart failure to start January 2016

Renal Denervation TCT meeting 2015

Long-Term (24-Month) Blood Pressure Results of Catheter-Based Renal Artery Denervation: SYMPLECTIC HTN-3 Randomized Controlled Trial.

Renal Artery Denervation for Hypertension Not Effective in the Long Term

SAN FRANCISCO -- October 14, 2015 -- Renal artery denervation has no lasting effect on blood pressure reduction, according to a study presented here at the 2015 Transcatheter Cardiovascular Therapeutics (TCT) meeting.