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Status Of Renal Denervation And Other New Invasive Catheter-Based Treatments For Drug Resistant Hypertension

Horst Sievert, Ilona Hofmann, Laura Vaskelyte, Sameer Gafoor, Predrag Matić, Markus Reinhart, Bojan Iovanovici, Kolja Sievert, Iris Grunwald, Nalan Schnelle
CardioVascular Center Frankfurt - CVC, Frankfurt, Germany

Disclosures

Physician name: Horst Sievert
Company: Abbott, Ablative Solutions, Ancona, Heart, Bioventrix, Boston Scientific, Carag, Cardiac Dimensions, Celonova, Cibiem, Cguard, Comed B.V., Contego, CVRx, Edwards, Gardia, Hemoq, InspireMD, Kona Medical, Lifetech, Maquet Getinge Group, Medtronic, Occlutech, pfm Medical, Recor, St. Jude Medical, Terumo, Trivascular, Vascular Dynamics, Venus, Veryan
Relationship: Consulting fees, Travel expenses, Study honoraria

Devices for Renal Denervation

- Radiofrequency catheters
  - Spiral - Medtronic
  - St. Jude Medical
  - Cordis
  - AngioCare – Terumo
  - Vena
- Radiofrequency balloons
  - Vessix – Boston
- Microwave
  - DenervXooled
- Drugs
  - Mercator
  - Northwind
  - Ablative Solutions
  - Kippronat Hospital, Athens
- Radiation
  - Best Medical Int.
  - CyberHeart (CyberKnife)
- Ultrasound
  - Recor Medical
  - CardioSonic
  - Kona

Most of them are still in the post Earthquake state of shock
Jan 9, 2014

ESC 2017: The resuscitation of renal denervation

Investigation of catheter-based renal denervation in patients with uncontrolled hypertension in the absence of antihypertensive medications:
Three-month results from the randomized, sham-controlled, proof of concept SPYRAL HTN-OFF MED Trial

Prof. Dr. Michael Böhm
Klinik für Innere Medizin II, Universitätsklinikum des Saarlandes, Homburg/Saar, Germany

Medtronic

FOR IMMEDIATE RELEASE
MEDTRONIC ANNOUNCES U.S. RENAL DENERVATION STUDY MEETS PRIMARY EFFICACY ENDPOINT WHILE MEETING PRIMARY SAFETY ENDPOINT

MINNEAPOLIS—January 9, 2014—Medtronic, Inc. (NYSE:MDT) today announced that its U.S. pivotal trial in renal denervation for treatment-resistant hypertension, VITALITY HTN-3, failed to meet its primary efficacy endpoint. The trial met its primary safety endpoint, and the trial’s Data Safety Monitoring Board (DSMB) concluded that there were no safety concerns in the study.
SPYRAL HTN
Symplicity Spyral™ Catheter

- Multi-electrode catheter with quadrantic vessel contact for simultaneous ablation in up to 4 electrodes
- 60-second simultaneous energy delivery
- Vessel diameter range: 3 – 8 mm
- Flexible catheter allows branch treatment
- 6F guiding catheter compatible

SPYRAL HTN – OFF MED

- Study Design
  Randomized, sham-controlled, single-blinded trial

The Resuscitation: SPYRAL HTN – OFF MED
Blood Pressure Change from Baseline to 3 Months: Office BP

Lessons learned from SPYRAL HTN

- Renal denervation with radiofrequency does work!
- The effect is less pronounced than hoped
  - partially due to a huge variation in response
- Most patients would still need medical therapy

Any news about other renal denervation technologies?
Ablative Solutions
PeriVascular Renal Denervation (PVRD)

- Ethanol or other agents

Tim Fischell 2013

Change in Office Blood Pressure

<table>
<thead>
<tr>
<th>Blood Pressure mm Hg</th>
<th>1 Month (N=16)</th>
<th>6 Months (N=16)</th>
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</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>175</td>
<td>153</td>
</tr>
<tr>
<td>SBP</td>
<td>151</td>
<td>151</td>
</tr>
<tr>
<td>DBP</td>
<td>95</td>
<td>87</td>
</tr>
<tr>
<td>Reduction in systolic OBP at 6-Month = -24 ± 21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction in diastolic OBP at 6-Month = -12 ± 21</td>
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</tbody>
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Other device based approaches

- Baroreceptor stimulation  
- Carotid bulb expansion (Mobius)  
- Carotid body ablation  
- Pacemaker  
- Median nerve stimulation  
- AV fistula (Rox Coupler)

Other device based approaches (cont.)

- Not catheter-based
- Covered in this session

What is the Carotid Body?

- A small cluster of cells with chemoreceptors
- Located near the carotid bifurcation
- Detects changes in:
  - Partial pressure of oxygen and CO₂
  - pH
  - Temperature
- Activation of the carotid body increases ventilation and blood pressure

Other device based approaches

- Other device based approaches
- Not catheter-based
- Covered in this session

1, 3 and 6 Months Blood Pressure Reduction

1, 3 and 6 Months Blood Pressure Reduction

Complete Case Analysis

(12-Month Paracrine Study)
Surgical Carotid Body Removal – BP Results

Transvenous Ablation

6 Month ABPM Results

Carotid Body Function Testing – Potential Screening Method

Conclusion

- Spiral HTN has proven that renal denervation does work!
- It is less effective than we had expected
- There is potential for better results with:
  - new denervation technologies
  - Improved patient selection – who are the responders?
  - technologies to monitor the ablation effect
- The positive results of Spiral HTN will boost other innovations including non-renal approaches

Thank you for your attention