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

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and


on behalf of the SPYRAL HTN-OFF MED Trial Investigators
Disclosures

• **Consultant** – Abbott/St. Jude, Astra, Medtronic, Servier, Vifor
• **Grant support** – Medtronic, Servier, German Research Foundation (DFG)
## SPYRAL HTN – OFF MED
### Study Organization

<table>
<thead>
<tr>
<th>Executive Committee</th>
<th>Data Safety Monitoring Board</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI: Michael Böhm, MD (Homburg/Saar, Germany)</td>
<td>Chairman: Bernard J. Gersh, MB, ChB, DPhil, FRCP (Rochester, MN, USA)</td>
</tr>
<tr>
<td>PI: David E. Kandzari, MD (Atlanta, GA, USA)</td>
<td>John A. Ambrose, MD (Fresno, CA, USA)</td>
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<tr>
<td>PI: Kazuomi Kario, MD (Tochigi, Japan)</td>
<td>Phyllis August, MD, MPH (New York, NY, USA)</td>
</tr>
<tr>
<td>PI: Raymond R. Townsend, MD (Philadelphia, PA, USA)</td>
<td>Michael Parides, BSc, MSc, PhD (New York, NY, USA)</td>
</tr>
<tr>
<td>Felix Mahfoud, MD (Homburg/Saar, Germany)</td>
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</tr>
<tr>
<td>Stuart Pocock, PhD (London, United Kingdom)</td>
<td><strong>Clinical Event Committee</strong></td>
</tr>
<tr>
<td>Michael A. Weber, MD (Brooklyn, NY, USA)</td>
<td>Chairman: Clive Rosendorff, MD, FRCP, FACC (Bronx, NY, USA)</td>
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<td>Ladan Golestaneh, MD (Bronx, NY, USA)</td>
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<td></td>
<td>Steven Marx, MD (New York, NY, USA)</td>
</tr>
<tr>
<td>Study Sponsor</td>
<td>Michele H. Morkrzycki, MD (Bronx, NY, USA)</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Joel Neugarten, MD, PhD, DSc (Bronx, NY, USA)</td>
</tr>
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</table>
## SPYRAL HTN – OFF MED

### Study Organization – Core Laboratories

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<thead>
<tr>
<th>Study Function</th>
<th>Core Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiographic Core Laboratory</td>
<td>Beth Israel Deaconess Medical Center, Inc.</td>
</tr>
<tr>
<td>Blood Core Laboratory</td>
<td>ACM Global Laboratory</td>
</tr>
<tr>
<td>Central Registration and Randomization Center</td>
<td>ICON Clinical Research</td>
</tr>
<tr>
<td>Clinical Events Committee (CEC)</td>
<td>Cardiovascular Research Foundation</td>
</tr>
<tr>
<td>Data Safety Monitoring Board (DSMB)</td>
<td>Cardiovascular Research Foundation</td>
</tr>
<tr>
<td>Drug Testing Core Laboratory</td>
<td>Klinische Toxikologie Universitätsklinikum des Saarlandes</td>
</tr>
<tr>
<td>Imaging and File Upload</td>
<td>Medidata</td>
</tr>
<tr>
<td>MRA/CTA Core Laboratory</td>
<td>Cardiovascular Core Lab, Morristown Medical Center</td>
</tr>
<tr>
<td>Renal Artery Duplex Ultrasound Core Laboratory</td>
<td>VasCore – The Vascular Ultrasound Core Laboratory</td>
</tr>
</tbody>
</table>
SPYRAL HTN Clinical Program

Background

- Up to one-third of adults have hypertension
  - Increased risk of cardiovascular events and stroke
  - Many patients remain uncontrolled
- Renal denervation therapy (RDN) targets the sympathetic nervous system
- SYMPPLICITY HTN-3 trial failed to demonstrate a significant blood pressure lowering effect of RDN
- Sub-analyses suggested:
  - Variance in medication adherence
  - Incomplete denervation of the renal arteries
  - Inclusion of patients with isolated systolic hypertension
SPYRAL HTN Clinical Program

Background

SPYRAL HTN-ON MED and SPYRAL HTN-OFF MED studies:

• Proof of concept trials

• Designed to demonstrate the ability of RDN to influence blood pressure in uncontrolled hypertension

## SPYRAL HTN Clinical Program

### Addressing Confounding Factors

Identified from SYMPLICITY HTN-3

<table>
<thead>
<tr>
<th>RX</th>
<th>Patients</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medications</strong></td>
<td>Drug changes and variable patient adherence</td>
<td>Heterogenous study population</td>
</tr>
<tr>
<td><strong>SYMPLICITY HTN-3</strong></td>
<td>Off and On Med studies with drug compliance testing</td>
<td>Excluding isolated systolic hypertension patients</td>
</tr>
</tbody>
</table>

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SPYRAL HTN
Global Trial Center Locations

21 Recruiting Sites in:
• USA
• Europe
• Japan
• Australia
SPYRAL HTN Clinical Program
Study Device: 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

Screening visit 1
- Office BP
- Drug naïve or medications D/C

Screening visit 2
- Office BP (Baseline)
- 24-hr ABPM
- Drug testing

2-week safety check
- OSBP ≥ 180

Screen failure
- ABPM SBP ≥ 140 to < 170
- Office SBP ≥ 150 to < 180
- Office DBP ≥ 90 mm Hg

Randomization / Procedure
- Renal denervation

Sham control
- ABPM Office BP
- Drug testing

Follow-up every 2 weeks
- Unblinding

*Only for patients discontinuing anti-hypertensive medications
SPYRAL HTN – OFF MED
Key Patient Eligibility Criteria

Inclusion
1. Patient is either:
   A. Not on antihypertensive medications, OR
   B. Permitting discontinuation of drug therapy
2. Office SBP ≥150 and <180 mm Hg
3. Office DBP ≥90 mm Hg
4. Systolic 24-hour mean ABPM ≥140 and <170 mm Hg

Exclusion
1. Ineligible renal artery anatomy (accessory arteries allowed)
2. eGFR <45 mL/min/1.73m²
3. Type 1 diabetes mellitus or type 2 diabetes mellitus with
   HbA1C >8.0%
4. Secondary causes of hypertension

SPYRAL HTN – OFF MED
Blinding Procedure & Efficacy

- All patients underwent renal angiography
- Conscious sedation
- Sensory isolation (e.g., blindfold and music)
- Lack of familiarity with procedural details and expected duration
- Assessed by blinding questionnaire at discharge and 3 months:

<table>
<thead>
<tr>
<th>Time</th>
<th>Blinding Index</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge</td>
<td>0.65</td>
<td>(0.56, 0.75)</td>
</tr>
<tr>
<td>3 Months</td>
<td>0.59</td>
<td>(0.49, 0.70)</td>
</tr>
</tbody>
</table>

Blinding Index >0.5 indicates successful blinding.
SPYRAL HTN – OFF MED
Patient Flowchart

353 patients enrolled and assessed for eligibility

342 patients at screening visit 1

271 patients at screening visit 2

80 patients randomized

11 patients did not meet all eligibility criteria

RDN group
N = 38 patients (ITT)

38 patients at 3-month follow up

Office BP Measurement
n = 37/38 (97.3%)

24-hour BP Measurement
n = 35/38 (92.1%)

Sham control group
N = 42 patients (ITT)

42 patients at 3-month follow up

Office BP Measurement
n = 41/42 (97.6%)

24-hour BP Measurement
n = 36/42 (85.7%)

71 excluded:
36 with office BP out of range
7 unwilling to discontinue anti-HTN meds
28 miscellaneous

191 excluded:
99 with office BP out of range
49 with ABPM out of range or not enough readings
20 with ineligible renal anatomy
23 miscellaneous
### SPYRAL HTN – OFF MED

#### Patient Baseline Characteristics

<table>
<thead>
<tr>
<th>Mean ± SD or % (N)</th>
<th>RDN (N = 38)</th>
<th>Sham Control (N = 42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>55.8 ± 10.1</td>
<td>52.8 ± 11.5</td>
</tr>
<tr>
<td>Male</td>
<td>68.4% (26/38)</td>
<td>73.8% (31/42)</td>
</tr>
<tr>
<td>BMI (kg/m(^2))</td>
<td>29.8 ± 5.1</td>
<td>30.2 ± 5.1</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>88.8 ± 16.6</td>
<td>90.9 ± 19.1</td>
</tr>
<tr>
<td>Diabetes (type 2)</td>
<td>2.6% (1/38)</td>
<td>7.1% (3/42)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>10.5% (4/38)</td>
<td>23.8% (10/42)</td>
</tr>
<tr>
<td>Obstructive sleep apnea</td>
<td>7.9% (3/38)</td>
<td>7.1% (3/42)</td>
</tr>
<tr>
<td>Peripheral artery disease</td>
<td>2.6% (1/38)</td>
<td>0% (0/42)</td>
</tr>
<tr>
<td>Coronary artery disease(^\dagger)</td>
<td>0% (0/38)</td>
<td>4.8% (2/42)</td>
</tr>
<tr>
<td>Stroke and transient ischemic attack(^\dagger)</td>
<td>2.6% (1/38)</td>
<td>0% (0/42)</td>
</tr>
<tr>
<td>Myocardial infarction / acute coronary syndrome(^\dagger)</td>
<td>0% (0/38)</td>
<td>2.4% (1/42)</td>
</tr>
</tbody>
</table>

\(^\dagger\)These events occurred >3 months before randomization.

\(P = NS\) for differences in all baseline characteristics.
SPYRAL HTN – OFF MED
Baseline Blood Pressure

<table>
<thead>
<tr>
<th>Mean ± SD</th>
<th>RDN</th>
<th>Sham Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office measurements</td>
<td>N = 38</td>
<td>N = 42</td>
</tr>
<tr>
<td>Office SBP (mm Hg)</td>
<td>162.0 ± 7.6</td>
<td>161.4 ± 6.4</td>
</tr>
<tr>
<td>Office DBP (mm Hg)</td>
<td>99.9 ± 6.8</td>
<td>101.5 ± 7.5</td>
</tr>
<tr>
<td>Office heart rate (bpm)</td>
<td>71.1 ± 11.0</td>
<td>73.4 ± 9.8</td>
</tr>
<tr>
<td>24-hour measurements</td>
<td>N = 37</td>
<td>N = 42</td>
</tr>
<tr>
<td>Mean 24-hour SBP (mm Hg)</td>
<td>153.4 ± 9.0</td>
<td>151.6 ± 7.4</td>
</tr>
<tr>
<td>Mean 24-hour DBP (mm Hg)</td>
<td>99.1 ± 7.7</td>
<td>98.7 ± 8.2</td>
</tr>
<tr>
<td>Mean 24-hour heart rate (bpm)</td>
<td>72.3 ± 10.9</td>
<td>75.5 ± 11.5</td>
</tr>
</tbody>
</table>

*P = NS for differences in all baseline characteristics.*
### SPYRAL HTN – OFF MED

#### Procedural Details

<table>
<thead>
<tr>
<th>Mean ± SD</th>
<th>RDN (N = 38)</th>
<th>Sham Control (N = 42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of main renal arteries treated per patient</td>
<td>2.2 ± 0.5</td>
<td>NA</td>
</tr>
<tr>
<td>Number of branches treated per patient</td>
<td>5.2 ± 2.5</td>
<td>NA</td>
</tr>
<tr>
<td>Total number of ablations per patient</td>
<td>43.8 ± 13.1</td>
<td>NA</td>
</tr>
<tr>
<td>Main artery ablations</td>
<td>17.9 ± 10.5</td>
<td>NA</td>
</tr>
<tr>
<td>Branch ablations</td>
<td>25.9 ± 12.8</td>
<td>NA</td>
</tr>
<tr>
<td>Treatment time (min)</td>
<td>57.1 ± 19.7</td>
<td>NA</td>
</tr>
<tr>
<td>Contrast volume used (cc)</td>
<td>251.0 ± 99.4</td>
<td>83.3 ± 38.5</td>
</tr>
</tbody>
</table>
### SPYRAL HTN – OFF MED

**Medication Adherence**

<table>
<thead>
<tr>
<th>% (n)</th>
<th>RDN</th>
<th>Sham Control</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>No anti-HTN drug identified by drug testing:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At baseline</td>
<td>92.1% (35/38)</td>
<td>88.1% (37/42)</td>
<td>0.72</td>
</tr>
<tr>
<td>At 3 months</td>
<td>94.3% (33/35)</td>
<td>92.7% (38/41)</td>
<td>1.00</td>
</tr>
<tr>
<td>At baseline and 3 months</td>
<td>88.6% (31/35)</td>
<td>82.9% (34/41)</td>
<td>0.53</td>
</tr>
<tr>
<td>Patients meeting escape criteria (n)</td>
<td>2</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

Drug testing of Urine and Serum by tandem HPLC and Mass Spectroscopy.
**SPYRAL HTN – OFF MED**

**Blood Pressure Change from Baseline to 3 Months: 24-Hr ABPM**

<table>
<thead>
<tr>
<th>Systolic</th>
<th>Diastolic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline BP (mmHg)</td>
<td>154</td>
</tr>
<tr>
<td>n</td>
<td>35</td>
</tr>
</tbody>
</table>

**BP Change from baseline to 3 months (mmHg)**

- **Systolic**
  - -5.5 mmHg
  - (-9.1, -2.0)
  - \( P = 0.003 \)

- **Diastolic**
  - -4.8 mmHg
  - (-7.0, -2.6)
  - \( P < 0.001 \)

**RDN**

- \( \Delta -5.0 \text{ mmHg} \)
  - (-9.9, -0.2)
  - \( P = 0.04 \)

**Sham**

- \( \Delta -4.4 \text{ mmHg} \)
  - (-7.2, -1.6)
  - \( P = 0.002 \)
**SPYRAL HTN – OFF MED**

**Blood Pressure Change from Baseline to 3 Months: Office BP**

<table>
<thead>
<tr>
<th>Baseline BP (mmHg)</th>
<th>Systolic</th>
<th>Diastolic</th>
</tr>
</thead>
<tbody>
<tr>
<td>162</td>
<td>161</td>
<td>100</td>
</tr>
<tr>
<td>n = 37</td>
<td>n = 41</td>
<td>n = 37</td>
</tr>
</tbody>
</table>

**BP Change from baseline to 3 months (mmHg)**

- **Systolic**
  - **RDN**
    - Baseline: 162 mmHg
    - Change: -10.0 mmHg
    - P < 0.001
    - Range: (-15.1, -4.9)
  - **Sham**
    - Baseline: 161 mmHg
    - Change: -2.3 mmHg
    - P = 0.24
    - Range: (-6.1, 1.6)

- **Diastolic**
  - **RDN**
    - Baseline: 100 mmHg
    - Change: -5.3 mmHg
    - P < 0.001
    - Range: (-7.8, -2.7)
  - **Sham**
    - Baseline: 101 mmHg
    - Change: -0.3 mmHg
    - P = 0.81
    - Range: (-2.9, 2.2)

**Overall**

- Systolic: Δ -7.7 mmHg
  - Range: (-14.0, -1.5)
  - P = 0.02
- Diastolic: Δ -4.9 mmHg
  - Range: (-8.5, -1.4)
  - P = 0.008
## SPYRAL HTN – OFF MED

### Safety Results at 3 Months

<table>
<thead>
<tr>
<th>%</th>
<th>RDN  (n = 38)</th>
<th>Sham Control (n = 42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>New myocardial infarction</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Major bleeding (TIMI(^1))</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>New onset end stage renal disease</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Serum creatinine elevation &gt;50%</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Significant embolic event resulting in end-organ damage</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Vascular complications</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hospitalization for hypertensive crisis/emergency</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>New stroke</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

\(^1\)TIMI definition: intracranial hemorrhage, \(\geq 5\)g/dl decrease in hemoglobin concentration, a \(\geq 15\)% absolute decrease in hematocrit, or death due to bleeding within 7 days of the procedure.
SPYRAL HTN – OFF MED

Limitations

• Proof of concept trial, not prospectively powered for statistical significance

• Antihypertensive drugs were detected in the blood/urine of some patients despite off-med protocol
  – Results in the modified ITT and PP populations were consistent
  – Similar results observed after adjustment for baseline blood pressure (ANCOVA) in all groups

• No practical methods to verify nerve destruction

• Results may not be generalizable to other RDN technologies
# SPYRAL HTN Clinical Program

## Advances of SPYRAL HTN Compared to SYMPLICITY HTN-3

<table>
<thead>
<tr>
<th>Medications</th>
<th>Patients</th>
<th>Procedure</th>
</tr>
</thead>
</table>
| **SYMPLICITY HTN-3** | ▪ 5.1 prescribed anti-HTN drugs at randomization  
▪ No drug adherence testing | ▪ Resistant hypertension patients (OSBP 180 ± 16)  
▪ No diastolic cutoff | ▪ Mono-electrode, sequential ablation system  
▪ Mostly inexperienced operators without proctoring  
▪ Main artery RDN only  
▪ Ablations per pt: 11.2 ± 2.8 |
| **SPYRAL HTN OFF MED** | ▪ No anti-HTN drugs at time of randomization  
▪ Drug adherence testing by serum and urine | ▪ Moderate hypertension patients (OSBP 162 ± 7)  
▪ Excluding ISH patients (ODBP 101 ± 7) | ▪ Four-electrode, simultaneous ablation system  
▪ Highly experienced operators with proctoring  
▪ Main + branches RDN  
▪ Ablations/patient: 43.8 ± 13.1 |
Conclusions

- **Biologic proof of principle** for the efficacy of renal denervation

- **Clinically meaningful blood pressure reductions** at 3 months
  - In mild to moderate hypertensive patients treated with RDN
  - In the absence of anti-hypertensive medications compared to sham control

- **No major safety events**
  - Despite a more complete denervation procedure that extended into renal artery branch vessels

- The results of this feasibility study will inform the design of a larger pivotal trial
Catheter-based renal denervation in patients with uncontrolled hypertension in the absence of antihypertensive medications (SPYRAL HTN-OFF MED): a randomised, sham-controlled, proof-of-concept trial


*Townsend et al, Lancet. Published online 28 Aug 2017
SPYRAL HTN – OFF MED

We thank patients, investigators, committee members and staff for their outstanding contribution!

Thank you for your attention!
<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Sub-Investigator</th>
<th>Centre</th>
<th>Location</th>
<th>Patients Randomized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michael Böhm, MD</td>
<td>Felix Mahfoud, MD</td>
<td>Klinik für Innere Medizin III,Universitätsklinikum des Saarlandes</td>
<td>Homburg/Saar, Germany</td>
<td>14</td>
</tr>
<tr>
<td>Konstantinos Tsioufis, MD</td>
<td>Dimitrios Tousoulis, MD</td>
<td>University of Athens, Hippokration Hospital</td>
<td>Athens, Greece</td>
<td>10</td>
</tr>
<tr>
<td>Roland Schmieder, MD</td>
<td>Axel Schmid, MD</td>
<td>Universitätsklinikum Erlangen</td>
<td>Erlangen, Germany</td>
<td>8</td>
</tr>
<tr>
<td>James W. Choi, MD</td>
<td>Cara East, MD</td>
<td>Baylor Jack and Jane Hamilton Heart and Vascular Hospital</td>
<td>Dallas, TX, USA</td>
<td>6</td>
</tr>
<tr>
<td>Debbie L. Cohen, MD</td>
<td>Robert Wilensky, MD</td>
<td>Hospital of the University of Pennsylvania</td>
<td>Philadelphia, PA, USA</td>
<td>6</td>
</tr>
<tr>
<td>Anthony Walton, MD</td>
<td>Ingrid Hopper, PhD</td>
<td>The Alfred Hospital and Monash University</td>
<td>Melbourne, Australia</td>
<td>6</td>
</tr>
<tr>
<td>David P. Lee, MD</td>
<td>Adrian Ma, MD</td>
<td>Stanford Hospital &amp; Clinics</td>
<td>Stanford, CA, USA</td>
<td>5</td>
</tr>
<tr>
<td>Philipp C. Lurz, MD</td>
<td>Karl Fengler, MD</td>
<td>University of Leipzig – Heart Center</td>
<td>Leipzig, Germany</td>
<td>4</td>
</tr>
<tr>
<td>Justin Davies, MD</td>
<td>Neil Chapman, MD</td>
<td>Imperial College Healthcare Trust</td>
<td>London, United Kingdom</td>
<td>3</td>
</tr>
<tr>
<td>Kazuomi Kario, MD</td>
<td>Satoshi Hoshide, MD</td>
<td>Jichi Medical University Hospital</td>
<td>Tochigi, Japan</td>
<td>3</td>
</tr>
<tr>
<td>Joachim Weil, MD</td>
<td>Tolga Agdirlioglu, MD</td>
<td>Sana Cardiomed Heart Center</td>
<td>Lübeck, Germany</td>
<td>3</td>
</tr>
</tbody>
</table>
## SPYRAL HTN – OFF MED
### Participating Centers – II

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Sub-Investigator</th>
<th>Centre</th>
<th>Location</th>
<th>Patients Randomized</th>
</tr>
</thead>
<tbody>
<tr>
<td>David Kandzari, MD</td>
<td>Dariush Bahrami, MD</td>
<td>Piedmont Atlanta Hospital</td>
<td>Atlanta, GA, USA</td>
<td>2</td>
</tr>
<tr>
<td>Manesh Patel, MD</td>
<td>Laura Svetkey, MD</td>
<td>Duke University Medical Center</td>
<td>Durham, NC, USA</td>
<td>2</td>
</tr>
<tr>
<td>Andrew S.P. Sharp, MD</td>
<td>Tony Watkinson, MD</td>
<td>The Royal Devon and Exeter Hospital</td>
<td>Exeter, UK</td>
<td>1</td>
</tr>
<tr>
<td>Chandan M. Devireddy, MD</td>
<td>Janice Lea, MD</td>
<td>Emory University School of Medicine</td>
<td>Atlanta, GA, USA</td>
<td>1</td>
</tr>
<tr>
<td>Jiro Aoki, MD</td>
<td>Kengo Tanabe, MD</td>
<td>Mitsui Memorial Hospital</td>
<td>Tokyo, Japan</td>
<td>1</td>
</tr>
<tr>
<td>George Dangas, MD</td>
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</table>

**TOTAL IN CURRENT ANALYSIS:** 80
SPYRAL HTN – OFF MED
24-Hr Blood Pressure

Results from matched datasets for baseline and 3 months.

24-Hr SBP (mm Hg)

Δ = -5.5 ± 10.3
P = 0.003

n = 35

Δ = -5.0 (-9.9, -0.2)
P = 0.04

n = 35

Δ = -0.5 ± 10.1
P = 0.76

n = 36

n = 36
SPYRAL HTN – OFF MED
Office Blood Pressure

Results from matched datasets for baseline and 3 months.
SPYRAL HTN – OFF MED
Blood Pressure Change from Baseline to 3 Months

24-hr SBP
Baseline BP (mmHg) 154 152
n = 35 n = 36
24-hr DBP
Baseline BP (mmHg) 100 99
n = 35 n = 36
Office SBP
Baseline BP (mmHg) 162 161
n = 37 n = 41
Office DBP
Baseline BP (mmHg) 100 101
n = 37 n = 41

BP Change from baseline to 3 months (mmHg)

-5.5 (-9.1, -2.0) P = 0.003
-0.5 (-3.9, 2.9) P = 0.76
-4.8 (-7.0, -2.6) P < 0.001
-0.4 (-2.2, 1.4) P = 0.65
-10.0 (-15.1, -4.9) P < 0.001
-2.3 (-6.1, 1.6) P = 0.24
-5.3 (-7.8, -2.7) P < 0.001
-0.3 (-2.9, 2.2) P = 0.81

Δ -5.0 mmHg (-9.9, -0.2) P = 0.04
Δ -4.4 mmHg (-7.2, -1.6) P < 0.001
Δ -7.7 mmHg (-14.0, -1.5) P = 0.002
Δ -4.9 mmHg (-8.5, -1.4) P = 0.008

RDN  Sham

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