Renal Sympathetic Denervation for,
Any updates after SIMPLICITY III?

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Hypertension

- Hazards of hypertension
- Difficult to treat due to multiple mechanisms
- Secondary HTN
Goal?

140/90

How to reach?

@CAF
Renal denervation
### Evidence

<table>
<thead>
<tr>
<th>Month</th>
<th>1 Month</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
<th>18 Months</th>
<th>24 Months</th>
<th>36 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-19/-9</td>
<td>-21/-10</td>
<td>-22/-10</td>
<td>-27/-14</td>
<td>NR</td>
<td>-29/-14</td>
<td>-31/-16</td>
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<tr>
<td></td>
<td>(n = 143)</td>
<td>(n = 148)</td>
<td>(n = 144)</td>
<td>(n = 132)</td>
<td></td>
<td>(n = 105)</td>
<td>(n = 34)</td>
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</table>

#### Symplicity HTN-1 [n = 153]

<table>
<thead>
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<th>Month</th>
<th>1 Month</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
<th>18 Months</th>
<th>24 Months</th>
<th>36 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-20/-7</td>
<td>-24/-8</td>
<td>-32/-12</td>
<td>-28/-10</td>
<td>-32/-12</td>
<td>-29/-10</td>
<td>NR</td>
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<tr>
<td></td>
<td>(n = 49)</td>
<td>(n = 49)</td>
<td>(n = 49)</td>
<td>(n = 47)</td>
<td>(n = 43)</td>
<td>(n = 40)</td>
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</table>

#### Symplicity HTN-2 [n = 106]

### Symplicity HTN-1 (2009)

[Graph showing blood pressure changes over time for Symplicity HTN-1 study]
Symplicity HTN-2 (2010)

2014

- Symplicity HTN-3
- Symplicity HTN-3 (12 month follow up)
- Global Symplicity Registry
Symplicity HTN-3 (2014)

- SYMPLICITY HTN-3 is the first prospective, multi-center, randomized, blinded trial.
- 535 patients underwent randomization.
- Renal denervation vs. sham procedure.
Symplicity HTN-3 (2014)

Blood pressure at 6 months was $-14.13 \pm 23.93$ mm Hg in the RDN group vs $-11.74 \pm 25.94$ mm Hg in the sham-procedure group.

- No significant reduction of systolic blood pressure in patients with resistant hypertension 6 months after RDN compared to control.

After 3 years of success

Failed
2014

- **Symplicity HTN-3**
- **Symplicity HTN-3** (12 month follow up)
- **Global Symplicity Registry**

Patient disposition: 6 months to 1 year

Crossover subjects were denervated after unblinding at 6 months if blood pressure criteria for treatment were met and subjects elected to proceed.

- **Sham-Control group** 171 subjects
  - Crossover 101 Subjects
    - 2 died
    - 3 withdrew
    - 96 eligible for 6M post-RDN follow-up
    - 93 Subjects (96.9%) 6M post-RDN follow-up
    - 48 Subjects (77%) 12M follow-up
  - Non-Crossover 70 Subjects
    - 2 died
    - 6 withdrew
    - 62 eligible for 12M follow-up

- **Denervation group** 361 Subjects
  - 4 died
  - 3 withdrew
  - 354 eligible for 12M follow-up
  - 322 Subjects (91%) 12M follow-up
2014

• Symplicity HTN-3

• Symplicity HTN-3 (12 month follow up)

• Global Symplicity Registry

Background

• The Global Symplicity Registry is a multi-center, prospective, non-invasive safety and procedural assessment in a worldwide population of patients.

• The registry will assess the long-term effect of RDN in real-life clinical practice.
  - Blood pressure
  - Conditions
  - Differences

• Follow-up results in the first 2,000 enrolled patients for 12 months are available.

• 245 international sites in 37 countries
• min. 10% randomly assigned to 100% monitoring
Procedural Details

<table>
<thead>
<tr>
<th></th>
<th>N=1000</th>
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<tbody>
<tr>
<td>Number of renal arteries</td>
<td>2.2 ± 0.5</td>
</tr>
<tr>
<td>Treatment time, min</td>
<td>50.4 ± 21.6</td>
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<tr>
<td>Number of ablations</td>
<td>13.5 ± 4.1</td>
</tr>
<tr>
<td>Number of 120 sec ablations</td>
<td>11.4 ± 3.5</td>
</tr>
<tr>
<td>Contrast volume used, cc (IQR*)</td>
<td>127.8 ± 81.1 (70, 160)</td>
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</tbody>
</table>

*25-75% intra-quartile range

Operator Experience in GSR

- 189 operators did 1,000 procedures

59% of interventionists performed >15 RDN procedures
Change in Office SBP for All Patients and SBP Subgroups

Baseline Office SBP

- In this "real world" patient population, patients demonstrated a substantial reduction in office and ambulatory SBP after RDN, performed by experienced operators, with a favorable safety profile.

Baseline SBP (mmHg) 164 ± 24 150 ± 6 167 ± 6 196 ± 14
What’s new?

• 1. New catheter system
• 2. Antomical

Our View of Renal Nerve Distribution Has Changed
Renal denervation is still under investigation with more understanding of the technique and improvement of the learning curve.

- Better renal anatomy understanding.
- More ablations needed including renal artery and branches.
- New catheter system
- SPYRAL-HTN trial.
THANK YOU