Renal Denervation in Patients With Uncontrolled Hypertension: Results of SYMPLICITY HTN-3 Trial

**History:** Due to their role in controlling blood pressure (BP), the renal sympathetic nerves have been identified as a potential treatment target for patients with resistant hypertension. Previous clinical trials of catheter-based renal denervation (RDN) have shown promising safety and efficacy results in this population.

**Questions to answer:** Is RDN safe and effective for patients who have systolic BP (SBP) ≥160 mmHg despite compliance with full tolerated doses of ≥3 antihypertensive medications of different classes?

**Trial Design**
- Prospective, randomized, single-blind, multicenter, sham-controlled study; N=535
  - Randomization: Renal denervation + baseline medications vs sham-control + baseline medications
  - F/U: SBP at 1, 3, and 6 mos; unblinding and renal artery imaging at 6 mos; total F/U will be 5 years

**Primary Endpoints**
1. Incidence of (a) major adverse events (MAEs) within 1 month and (b) renal artery stenosis in the first 6 months post-randomization
2. Change in office SBP from baseline to 6 months post-randomization

**Trial Results**

<table>
<thead>
<tr>
<th>Safety (MAE)</th>
<th>Efficacy (mm Hg)</th>
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<tr>
<td>RDN vs OPC*: 1.4% vs 9.8% (P&lt;0.001)</td>
<td>RDN vs sham: -14.13±23.93 vs -11.74±25.94</td>
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<td>RDN vs sham: 1.4% vs 0.6% (P=0.67)</td>
<td>Change relative to control:</td>
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<td>-2.39 (95% CI, -6.89 to 2.12; P=0.26)</td>
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**Take Away:** RDN demonstrated a favorable safety profile, but did not significantly reduce SBP in patients with uncontrolled hypertension despite adherence to antihypertensive medication regimens.

*OPC=objective performance criterion; based on historical data.

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