Interventional Management of Complex Hypertension
Disclosures

• Disclosures
  - CryoLife - Consultant
  - Cordis - Consultant

• Some devices discussed are not approved by the FDA or currently available in the United States.
Outline

• “Resistant Hypertension” Impact and Pathophysiology
• Current Technology
• Current literature on Renal Stenting
• Mechanism of Renal Denervation
• History of Renal Denervation
• Current state of RDN
  – Outcomes Data
  – Current studies
• Future of RDN
  – Road to Patient Care
  – Indications
• Future Technology
• Economics of Therapy
Impact of Hypertension

• **Framingham Heart Study**
  – CHF related mortality 2.3-3x in Pt’s with HTN

• **Multiple Risk Factor Intervention Trial**
  – ↑RR 2.3-6.9 - CAD mortality
  – ↑RR 3.6 to 19.2 – stroke

• **JNC-7 - Benefit for anti-Hypertensive's:**
  – 35-40% reduction in CVA
  – 20-25% reduction in MI
  – >50% reduction in CHF
Impact of high normal blood pressure on the risk of cardiovascular disease

JNC-7 - Hypertension. Dec 2003;42(6):1206-52
Age-specific and age-adjusted prevalence of hypertension among adults aged 18 and over: US, 2009–2010

Age-adjusted awareness, treatment, and control of hypertension among adults with hypertension: US, 2007–2010

CDC - National Health and Nutrition Examination Survey
Global Impact

• Prevalence of adult HTN: 30.4% (66.9 million)
• Uncontrolled HTN: 53.5% of HTN patients (35.8 million)
• 85.2% of uncontrolled HTN patients had health insurance

• Worldwide Burden of Hypertension:
  – 7.6 million premature deaths each year attributed to high blood pressure
  – About 54% of stroke and 47% of ischemic heart disease attributable to high blood pressure
Past ideas of procedure/devices to control hypertension

- **CPAP devices** - hypertensive patients with obstructive sleep apnea
- **Direct electrical stimulation** of brain regions
- **Surgical neurovascular decompression** of the brainstem to overcome presumed vascular compression of bulbar regions that control sympathetic outflow and blood pressure
- **Carotid Arterial Baroreceptor modulation**
- **Renal artery stenting**
- **Radiofrequency catheter ablation** of the renal nerves
Rheos® Baroreflex Hypertension Therapy system

Figure 2. Anatomy of Baroreceptors
The renal stenosis results in a reduction of blood pressure within the kidney which compensates with a resultant rise in overall blood pressure, thus resulting in systemic hypertension.
Renal-artery stenting did not confer a significant benefit with respect to the prevention of clinical events when added to comprehensive, multifactorial medical therapy in people with atherosclerotic renal-artery stenosis and hypertension or chronic kidney disease.
End of an Era?

Predictors of outcome for renal artery stenting performed for salvage of renal function

J. Gregory Modrall, MD, a,b Carlos H. Timaran, MD, a,b Eric B. Rosero, MD, a,b Jayer Chung, MD, b Frank A. Arko III, MD, b R. James Valentine, MD, b G. Patrick Clagett, MD, b and Clayton Trimmer, DO, c

Dallas, Tex

Conclusions: The current study found that a steep decline in preoperative renal function portends a higher likelihood of renal salvage from RAS among patients with renal insufficiency. Incorporating this finding into patient selection may improve outcomes for RAS. (J Vasc Surg 2011;54:1414-21.)

- 72% - unchanged/worsening of renal function after stenting
- 28% experienced a improvement in renal function
Renal Sympathetic Innervation and Hypertension

Figure 2 Afferent and efferent sympathetic nerve fibers reach the kidneys along with the renal arteries. Increased sympathetic nervous outflow enhances renal renin release, reduces renal blood flow, and increases tubular sodium retention. Afferent nerve fibers connect the kidneys with the central nervous system. Activation of renal afferents elevates sympathetic nervous outflow to the kidney and other downstream organs.

**Note:** Reproduced from Percutaneous renal denervation: new treatment option for resistant hypertension and more?. Ewen S, Ukena C, Böhm M, Mahfoud F, 99, 1129–1134, copyright 2013 with permission from BMJ Publishing Group Ltd.
• Chronic Effect of Increased Sympathetic Nerve Activity
Anatomic Considerations

SPLANCHNIECTOMY FOR ESSENTIAL HYPERTENSION

RESULTS IN 1,266 CASES

Reginald H. Smithwick, M.D.
and
Jesse E. Thompson, M.D., Boston
### Table 2. Dates of Discovery of Antihypertensive Drugs or Drug Classes

<table>
<thead>
<tr>
<th>Year(s)</th>
<th>Antihypertensive Agent(s)</th>
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<tr>
<td>1900</td>
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<td>1931</td>
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<td>1947–1950</td>
<td>Ganglion blocking drugs</td>
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<td>Thiazide-type diuretics</td>
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<td>1950s</td>
<td>Hydralazine</td>
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<td>1973</td>
<td>β-Receptor blockers (eg, propranolol)</td>
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<td>1970s</td>
<td>Central α&lt;sub&gt;2&lt;/sub&gt; agonists (eg, clonidine)</td>
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<td>1975</td>
<td>Peripheral α&lt;sub&gt;1&lt;/sub&gt; receptor blockers (eg, prazosin)</td>
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<td>1977</td>
<td>ACE inhibitors (eg, captopril)</td>
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<td>1977</td>
<td>Calcium channel blockers (eg, verapamil, nifedipine)</td>
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<td>1993</td>
<td>Angiotensin II receptor blockers (eg, losartan)</td>
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<td>2000</td>
<td>Renin inhibitors (eg, aliskiren)</td>
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ACE indicates angiotensin-converting enzyme. Data derived from Freis.\textsuperscript{39}
Catheter Based Renal Sympathetic Denervation – **Simplicity** (Medtronic)

4-6 two minute treatments per artery

6F Guide Cath
Catheter Based Renal Sympathetic Denervation – **SYPHILICITY (Medtronic)**
Staged Clinical Evaluation

**Symplicity HTN-1**

First-in-Man

Series of Pilot studies

**Symplicity HTN-2**

EU/AU Randomized Clinical Trial

**USA**

Symplicity HTN-3
US Randomized Clinical Trial (upcoming)

**EU/AU**

Other Areas of Research:
Insulin Resistance,
HF/Cardiorenal,
Sleep Apnea, More
Catheter-based renal sympathetic denervation for resistant hypertension: a multicentre safety and proof-of-principle cohort study

Henry Krum, Markus Schlaich, Rob Whitbourn, Paul A Sica, Horst Sievert, Suku Thambar, William T Abraham, Murray B. Cook

June 2007

- 45 patients at five Australian and European centers with 1yr F/U
• 19 centers in Australia, Europe, and the United States
• 153 patients with catheter-based renal sympathetic denervation

<table>
<thead>
<tr>
<th>Baseline BP (mm Hg)</th>
<th>176/98 ± 17/15</th>
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<tr>
<td># of anti-HTN meds (mean)</td>
<td>5.1 ± 1.4</td>
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</table>
Procedure Details

- Median time from first to last ablation was 38 minutes – averaged 4 per artery

- No major complications
- 4 (3%) procedural complications
  - 3 groin pseudoaneurysms
  - 1 renal artery dissection
Symplicity HTN-1 Results

BP change (mm Hg)

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<tr>
<th>Time</th>
<th>Systolic</th>
<th>Diastolic</th>
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<tr>
<td>1 M</td>
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<td>24 M</td>
<td>-32</td>
<td>-14</td>
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(1 M (n=138), 3 M (n=135), 6 M (n=86), 12 M (n=64), 18 M (n=36), 24 M (n=18))
Follow-up

- **Renal vascular safety**
  - No abnormality at site if RF delivery in 61 pt who had renal CTA, MRA or duplex at 6 months
  - 1 progression of pre-existing stenosis (stented)

- **Renal function**
  - eGFR remained stable at 12 months with a change of -2.9 mL/min (N=64)

- **Other Side-effects**
  - No orthostatic hypotension
  - 1 patient with complaint of B/L flank pain for several months, 3 other patients reported intermittent or transient flank pain
• Prospective, randomized trial in 24 centers in Europe, Australia and New Zealand
• 106 patients randomized

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<th>RDN (n=52)</th>
<th>Control (n=54)</th>
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<tr>
<td>Baseline BP (mm Hg)</td>
<td>178/97</td>
<td>178/98</td>
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<tr>
<td># of Anti-HTN Meds</td>
<td>5.2 ±1.5</td>
<td>5.3 ±1.8</td>
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Circulation
Journal of the American Heart Association

Renal Sympathetic Denervation for Treatment of Drug-Resistant Hypertension: One-Year Results From the Symplicity HTN-2 Randomized, Controlled Trial
Murray D. Esler, Henry Krum, Markus Schlaich, Roland E. Schmieder, Michael Böhm and Paul A. Sobotka
for the Symplicity HTN-2 Investigators
Circulation. 2012;126:2976-2982
Symplicity HTN-2 Results

- 84% of RDN patients had ≥ 10 mmHg reduction in SBP
- 10% of RDN patients had no reduction in SBP
Follow-up

- **Renal function**
  - No significant difference in eGFR or serum Cr

- **Complications**
  - No major complications
  - Minor peri-procedural complications
    - 1 femoral artery pseudoaneurysm, 1 urinary tract infection, 1 extended hospital admission for assessment of paraesthesias, 1 case of back pain that was treated with analgesics and resolved after 1 month
    - 7 (13%) patients who underwent renal denervation had transient intraprocedural bradycardia requiring atropine; none had any sequelae

- **Renal Vascular safety**
  - 6-month renal artery imaging (n=43)
  - 1 patient had possible progression of RAS not requiring treatment
Renal Denervation in Patients with Uncontrolled Hypertension  

**Symplicity HTN-3**

- Multi-center, prospective, single-blind, randomized, controlled study of the safety and effectiveness of renal denervation in subjects with uncontrolled hypertension
- **Primary Endpoint** – Δ SBP at 6 months
- **Secondary Endpoint** - Δ avg 24-hr SBP at 6 months
- **Safety Endpoint** – MAE’s
Renal Denervation in Patients with Uncontrolled Hypertension **Symplicity HTN-3**

- Patient randomization – 530
- Enrollment Criteria
  - Avg office SBP ≥ 160 mmHg
  - ≥3 Anti-HTN meds (including a diuretic) at maximal tolerated dose
- All participants undergo renal angiogram
Renal Denervation in Patients with Uncontrolled Hypertension

Symplicity HTN-3

- Randomization is accomplished at the time of angiogram
- Enrolled between October 2011 - May 2013
- 535 patients
- 88 sites in the United States

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<th>RDN (n=364)</th>
<th>Sham (n=171)</th>
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<td># of Anti-HTN Meds</td>
<td>5.1 ±1.4</td>
<td>5.2 ±1.4</td>
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Results

Figure 1. Primary Efficacy End Point.
A significant change from baseline to 6 months in office systolic blood pressure was observed in both study groups. The between-group difference (the primary efficacy end point) did not meet a test of superiority with a margin of 5 mm Hg. The I bars indicate standard deviations.
Explanations

• 137 “Novice” Operators
  – 111 operators who did at least one procedure (31% did only 1 procedures)
  – 26 operators who did ≥5 procedures

• Good medical care
  – without a control group, the observed treatment effect may have been a result of trial participation, with the reduction in systolic blood pressure due to good care and a high degree of adherence to antihypertensive therapy as a result of close follow-up (i.e., the Hawthorne effect)
ClinicalTrials.gov
Find Studies > Search Results

122 studies found for renal denervation

Modify this search | How to Use Search Results

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<td>Hypertension; Heart Failure; Chronic Kidney Disease; Diabetes; Heart Rhythm Disorders</td>
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<td>Device: Renal denervation with Symplicity Flex Medtronic/Ardian; Device: Renal denervation with Enlighten St Jude Medical; Device: Renal denervation with Paradise Recor; Device: Renal denervation with V2 Vessix</td>
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<td>Renal Denervation in Patients With Chronic Heart Failure</td>
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April 2014
Distribution of Research

Colors indicate number of studies with locations in that region

Least - Most

Labels give exact study count
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Predictors of Response: RDN Device?

**EnligHTN** (St. Jude Medical)

EnligHTN-1: (n = 46)
ΔoSBP at 6 month: -26mmHg
Response Rate: 76%

**OneShot** (Covidien)

RHAS: (n = 8)
ΔoSBP at 6 month: -42mmHg
ΔoDBP at 6 month: -15mmHg

**Vessix V2** (Boston Scientific)

ReduceHTN: (n = 10)
ΔoSBP at 1 month: -30mmHg
ΔoDBP at 1 month: -11mmHg
Response Rate: 100% at 1 month

**Paradise** (ReCor)

REALISE: (n = 20)
Δ BP at 6 month: -21/9mmHg
Δ ABP at 6 month: -9/4mmHg
## Radiofrequency Ablation

<table>
<thead>
<tr>
<th>RF Catheters</th>
<th>Multi/Single electrode</th>
<th>Design</th>
<th>Catheter requirement</th>
<th>Irrigated?</th>
<th>Ablation Time per artery</th>
<th>CE Mark Approval</th>
<th>FDA Approved Clinical Trial</th>
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<td>Medtronic Symplicity™</td>
<td>Single</td>
<td>Catheter electrode</td>
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<td>2010</td>
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<td>Symplicity Spyral™</td>
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<td>RX* catheter</td>
<td>6F</td>
<td>Non-irrigated</td>
<td>1-2mins</td>
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<td>Basket</td>
<td>8F</td>
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<td>6-12mins</td>
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<td>Covidien OneShot</td>
<td>Multielectrode effect</td>
<td>OTW* Balloon</td>
<td>7F</td>
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<td>2mins</td>
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<td>Boston Scientific Vessix™ Renal Denervation System</td>
<td>Multi-electrode</td>
<td>OTW* Balloon</td>
<td>8F Guide Sheath</td>
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Figure 2. The next-generation Symplicity Spyral™ catheter combines the features of a 6 French compatible, 0.014” wire monorail system, enabling multi-electrode energy delivery and reduced anatomy manipulation.

Electrodes
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<th>Product</th>
<th>Preclinical</th>
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Renal Denervation in Moderate Treatment Resistant Hypertension

54 patients with a mean office BP of 151/83 mm Hg on at least 3 antihypertensives, including a diuretic.

- At 6 months, office BP was reduced by 13/7 mm Hg, and by 14/7 mm Hg in a subgroup (n = 36) with ambulatory BP monitoring
- Also at 6 months, BP was controlled (<140/90 mm Hg) in 51% of patients, while 61% had a ‘treatment response’ (≥10 mm Hg decrease in office systolic BP)
- Heart rate was reduced from 67 ± 11 bpm to 63 ± 10 bpm, but the change did not correlate with reduction in systolic BP

**Implications:** Renal denervation reduces BP in moderate drug-resistant hypertension, achieving goal of 140/90 mm Hg in about half of patients.


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*tctmd* The Source for Interventional Cardiovascular News and Education
Cost-Effectiveness and Clinical Effectiveness of Catheter-Based Renal Denervation for Resistant Hypertension

Benjamin P. Geisler, Abigail M. Garner, Jan B. Pietzsch, PhD
Menlo Park, California and Central Melbourne

Objective
Background
Methods
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Figure 1: Schematic Depiction of the Model

Patients enter the hypertensive state and follow one of the depicted pathways through the model until they eventually die.
ESRD = end-stage renal disease; HF = heart failure; MI = myocardial infarction.

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Conclusions

• Uncontrolled hypertension is a global epidemic that, for a significant portion of the population, is inadequately managed

• Renal Artery stenting does not appear to have superior efficacy to medical management

• Future studies on Renal Denervation are necessary for mainstream use