Endovascular Creation of an Iliac AV Fistula to Treat Resistant Hypertension

Rationale & Results of the ROX Coupler Device

Krishna Rocha-Singh, MD
Chief Scientific Officer
Prairie Heart Institute Saint John’s Hospital
Springfield, IL

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

Company
- Medtronic
- Medtronic, Alucent, Zimmer-BioMet, ROX Medical, SoundBite Medical
- PQ Bypass
- None
- Convergence Consulting, LLC
- Yes
- VIVA Board Member


Fryer et al NCHS Data Brief October 2017

Loss of Elastic Aortic Function Underlies Hypertension in Older Adults

Burt et al Hypertension 1995

The Pathophysiology of Structural Hypertension

The ROX Coupler is NOT commercially available in the United States. C/T/R/NI: Investigational device. Limited by Federal (or United States) law to investigational use. The ROX Coupler is CE marked for Hypertension and is commercially available in the European Union.
Fixed 4mm Diameter Arteriovenous Anastomosis ~ 800 cc shunt

Immediately, Verifiable On-the-Table Decline in BP

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ROX CONTROL HTN: Open-Label, Multicenter, Prospective, Randomized Controlled Trial

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ROX CONTROL HTN: 6 Mo. Results & Hypertension Related Events

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ROX CONTROL HTN Study: 12-Month OBP Results

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ROX CONTROL HTN Study: 12-Month ABPM Results

ROX CONTROL HTN Study: 12-Month ABPM Results

AV Coupler Associated Venous Stenosis:

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Venous Stenosis Occurrence – ROX HTN Randomized Trial

Venous Stenosis Occurrence – ROX HTN Randomized Trial
The US ROX HTN2 Trial Design

Impact of cAV Coupler Physiology on Trial Design

- 1:1 randomized sham controlled, double-blinded (patient and HTN physician) adaptive trial design
- Primary Endpoint: Change in mean 24 hr ABPM at 6 months
  --Secondary Endpoint: Change in mean OBP at 6 months
- Safety Endpoint: Procedural and AEs through 12 months

The US ROX HTN2 Trial Design: Key Inclusion Criteria

- Key Inclusion Criteria:
  --OBP ≥155 mmHg at all screening visits AND ≥160 at one visit; OR
  OBP ≥150 mmHg AND one ER visit or hospitalization in the past 12 months for antihypertensive crisis
- 24 hour ABPM ≥140 mmHg
- Site expertise in HTN diagnosis and treatment

The US ROX HTN2 Trial Design: Key Exclusion Criteria

- eGRF <45 mL/min/1.73m²
- Significant venous disease and/or PAD; a normal rest Right ABI is required
- Moderate/severe valvular disease
- LVEF ≤45%, mean PAP >25mmHg, PCWP >15 mmHg at time of right heart cath
- History of DVT/PE

US ROX HTN2 Trial: Next Steps

- The cAV Coupler is the first endovascular therapy which appears safe and effective in uncontrolled HTN consequent to loss of aortic elasticity...a growing population
- The ROX HTN2, a large randomized, double-blinded, sham controlled trial in uncontrolled hypertensive patients on a 'stable and consistent' antihypertensive regimen, maintained through 6-months will assess the safety and efficacy of this novel concept

END