

# **VIVA Highlights at TCT Asia Pacific 2016**

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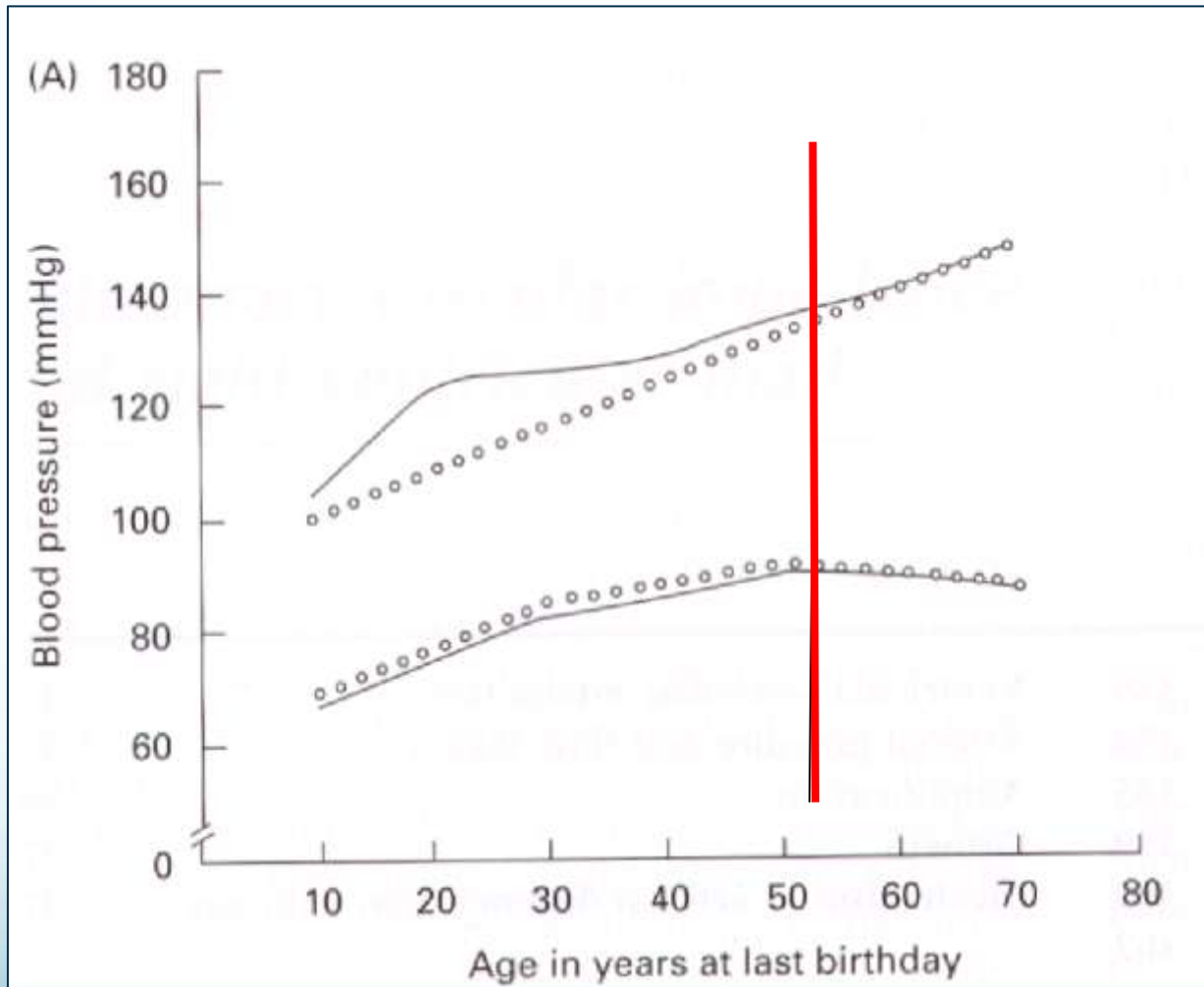
## **ROX: Changing How We Think About Hypertension**

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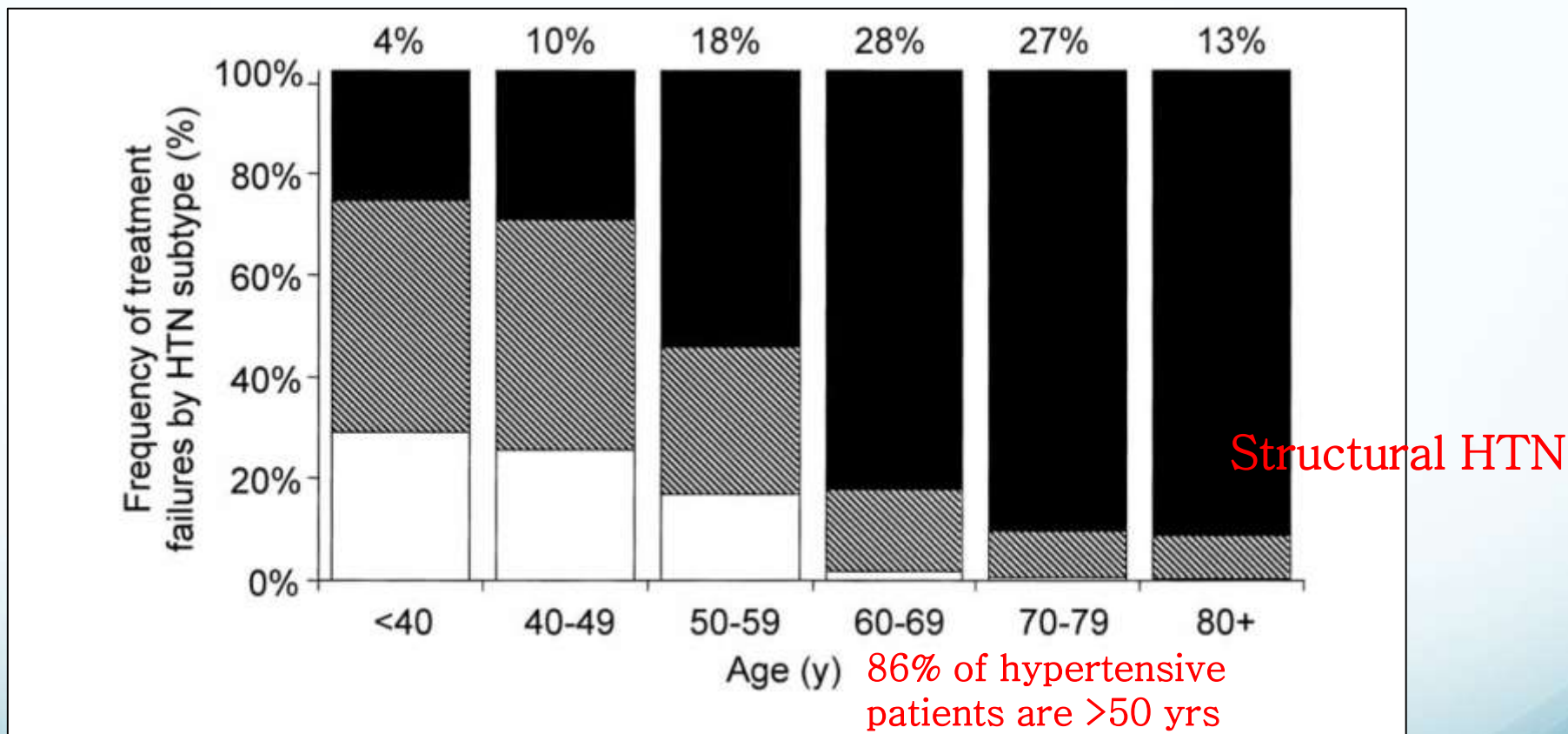
# Structural Hypertension

- Aortic elasticity buffers cardiac stroke energy by converting it to the potential energy in elastic recoil
- Aging, diabetes and chronic HTN accelerate the loss of aortic elastic tissue (a terminal and irreversible process)
  - Systolic blood pressure rises
  - Pulse pressure increases
  - Pulse wave velocity increases
  - Resistance to drugs and devices targeting reduction of resistance vessel tone which fail to reduce blood pressure
- Therefore, Structural Hypertension is an inherent consequence of aging: Isolated Systolic Hypertension (ISH)

# BP and Pulse Pressure Increase with Age

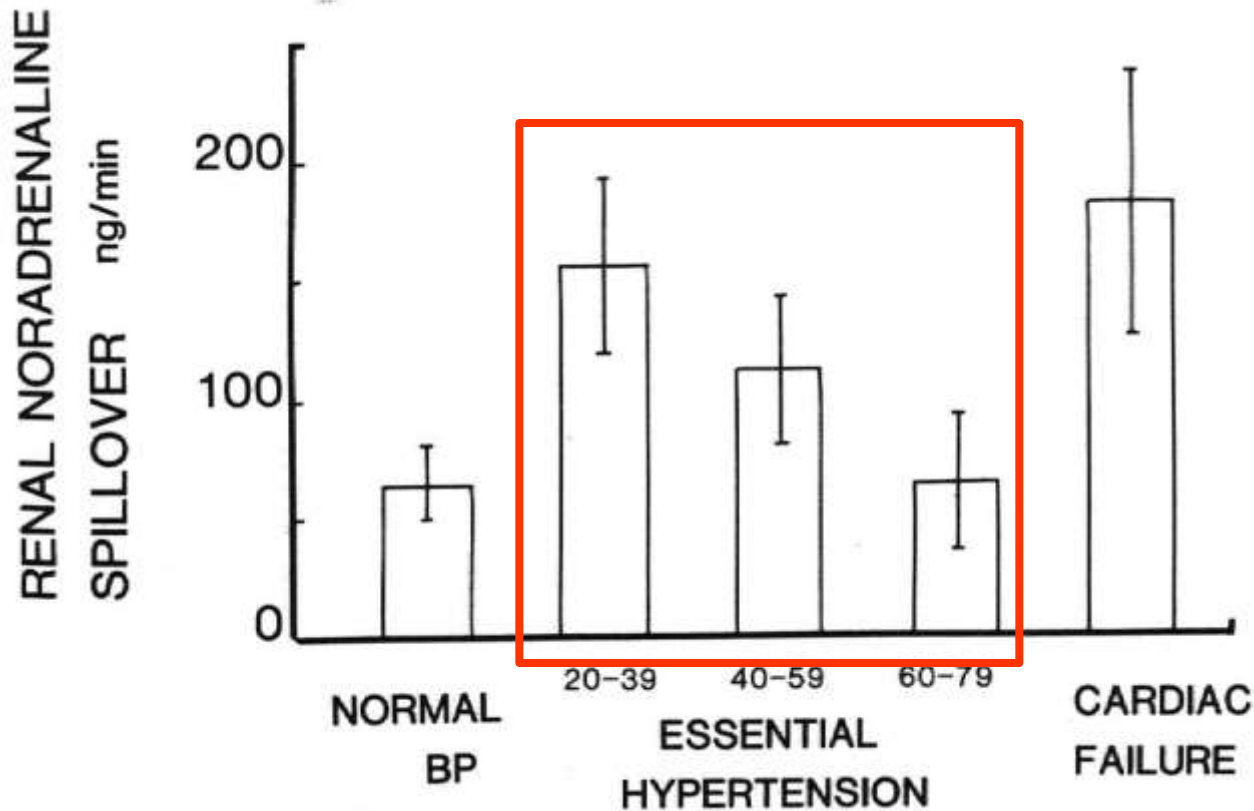


# The Majority of Hypertension is Structural: Isolated Systolic Hypertension



2001 NIH Data Base: Percentage of ISH as a function of age

# Renal Sympathetic Contribution to BP Declines with Age

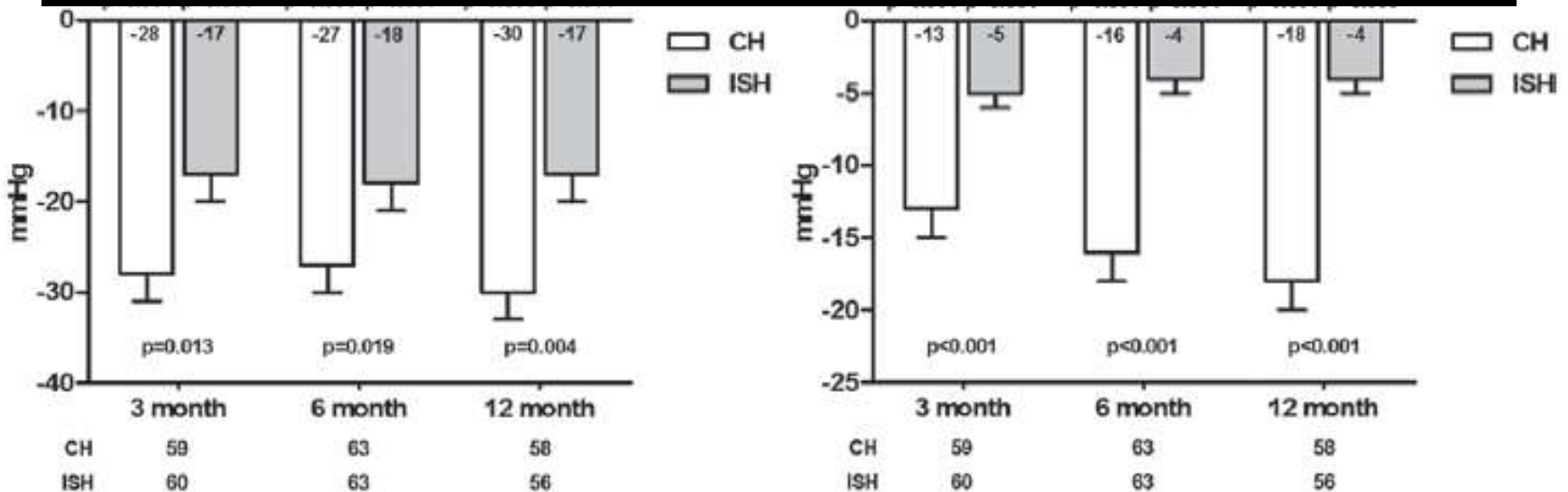


**FIG. 2.** The rate of release of noradrenaline from the kidneys to plasma in control subjects, patients with cardiac failure, and hypertensive patients of different ages is shown. Renal noradrenaline spillover was increased in cardiac failure and in patients with essential hypertension who were aged younger than 40 years ( $p < 0.01$ ). Mean and standard deviation are indicated.

# Original Article

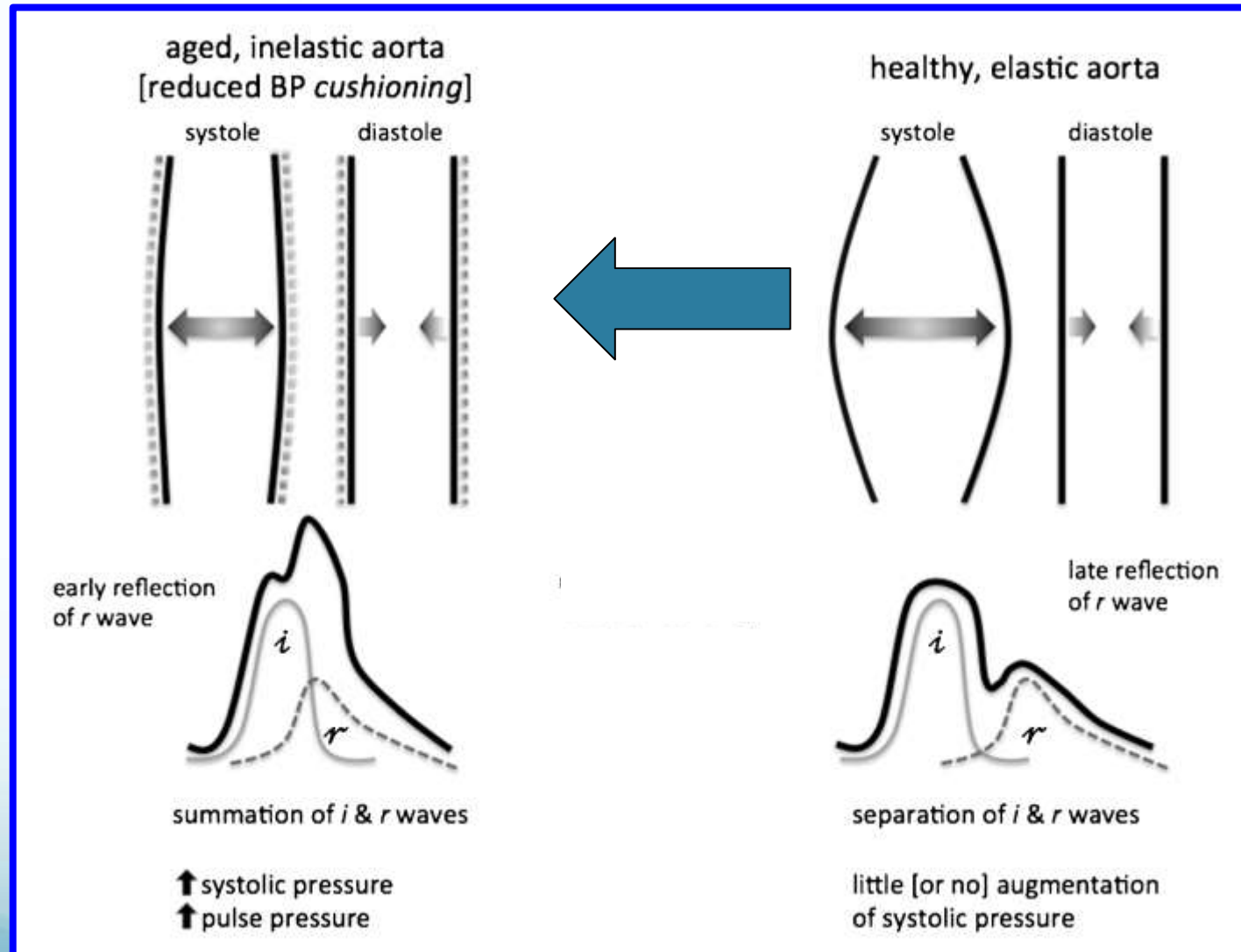
## Reduced Effect of Percutaneous Renal Denervation on Blood Pressure in Patients With Isolated Systolic Hypertension

**Non-responder (SBP <10 mmHg) rates:  
ISH = 37% v. CH = 21%**

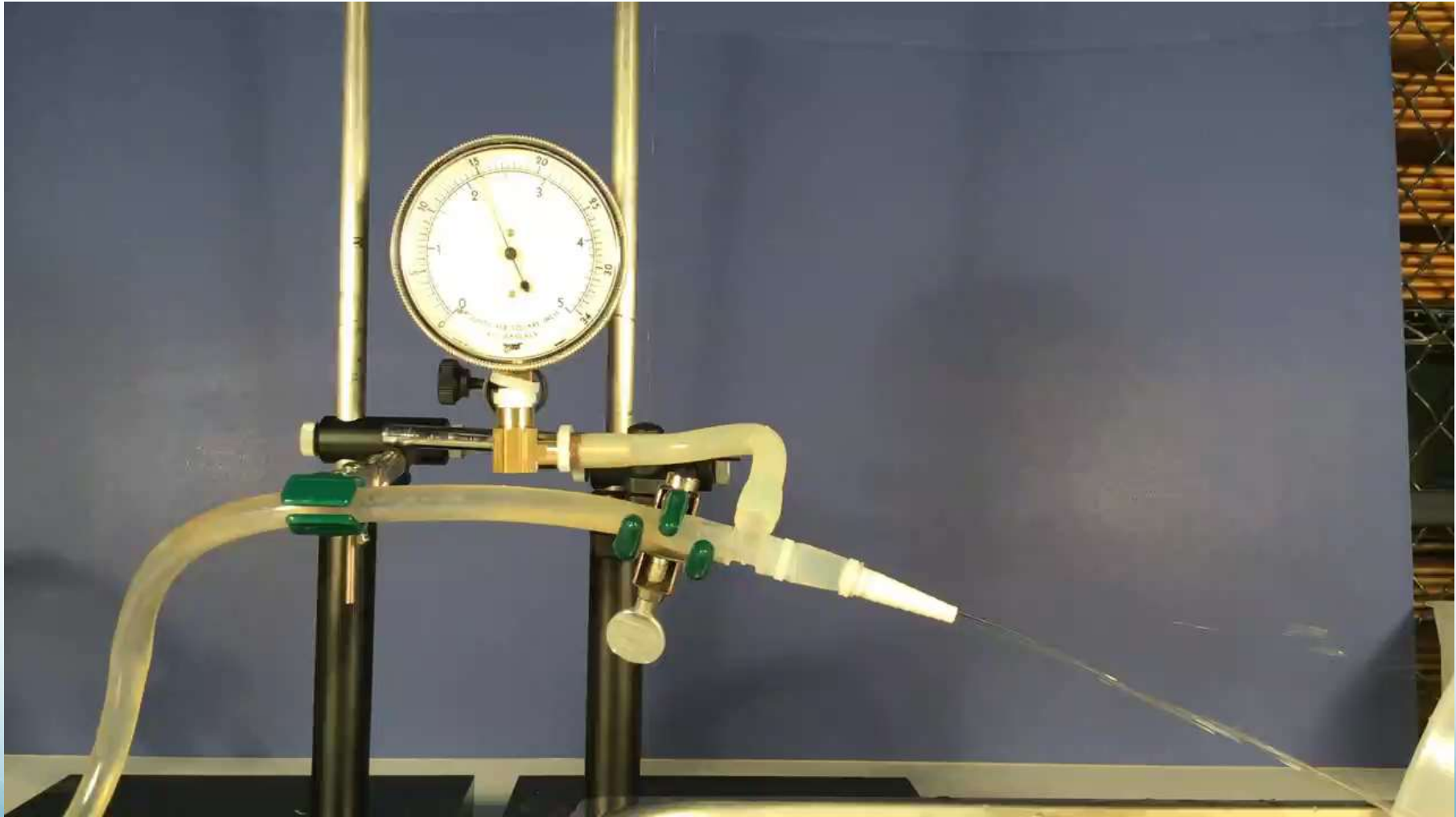


SBP/DBP OBP 12 mo. response to RDN in patients with ISH ( $\geq 140 / < 90$  mmHg) v. "Combined HTN" ( $> 140 / > 90$  mmHg)

# The Pathophysiology of Structural Hypertension

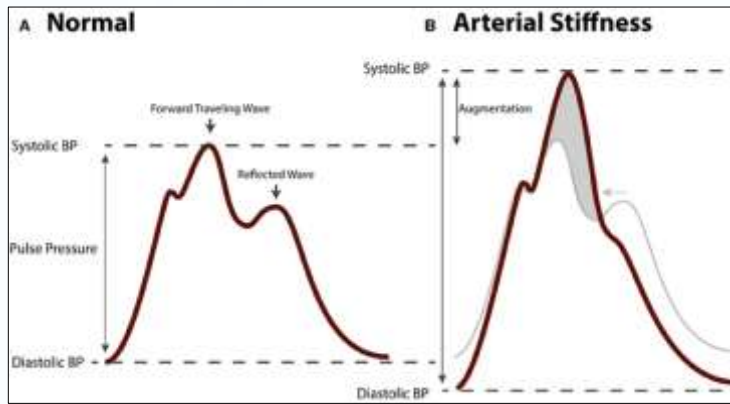


# Loss of Arterial Elasticity: Increased Peak Systolic Pressures & Unresponsiveness to Medications





# Reduction of Central Aortic Blood Volume Restores Windkessel Effect and Reduces Pistol Shot Waves



Circumferential STRESS  
N/cm<sup>2</sup>

**Inelastic Aorta:**  
Pistol shot wave forms  
Volume sensitivity  
Increases PWV

**Elastic Aorta:**  
Cushions pressures  
damps peak velocity

Circumferential STRAIN  
(aortic distension)

Aging, ISH



# ROX Medical

## The Solution for Structural Hypertension

**Central arteriovenous anastomosis for the treatment of patients with uncontrolled hypertension (the ROX CONTROL HTN study): a randomised controlled trial**

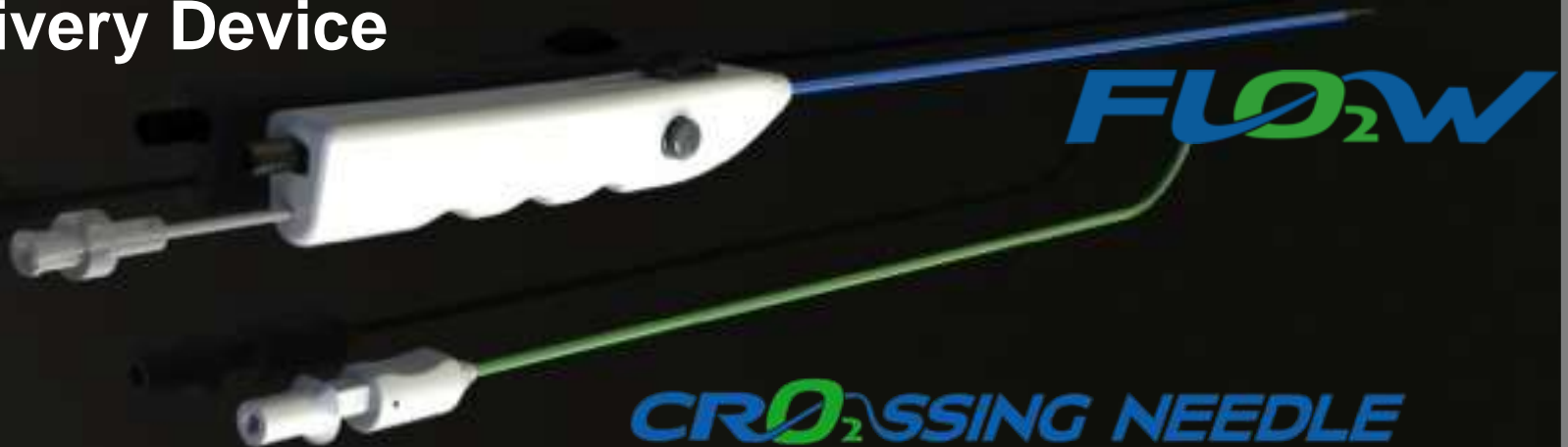
*Melvin D Lobo, Paul A Sobotka, Alice Stanton, John R Cockcroft, Neil Sulke, Eamon Dolan, Markus van der Giet, Joachim Hoyer, Stephen S Furniss, John P Foran, Adam Witkowski, Andrzej Januszewicz, Danny Schoors, Konstantinos Tsioufis, Benno J Rensing, Benjamin Scott, G André Ng, Christian Ott, Roland E Schmieder, for the ROX CONTROL HTN Investigators\**

# ROX Coupler

- Using a venous segment to reduce effective arterial volume without depleting the venous capacitance vessels:
  - Restores elasticity at lower filling volumes in aged vessels
  - Reduces mean pressure
  - Reduces BP variability
- Changing pulse wave propagation velocity reduces reflected pressure stacking

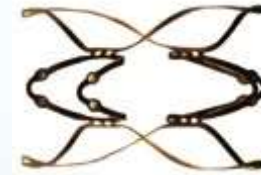
# The ROX Procedure Kit

Delivery Device



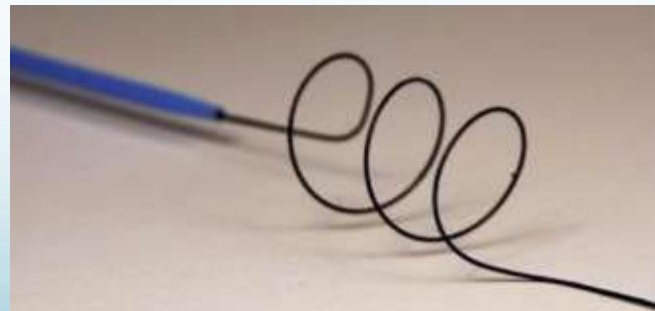
CO<sub>2</sub>UPLER

RADIOPAQUE NITINOL IMPLANT



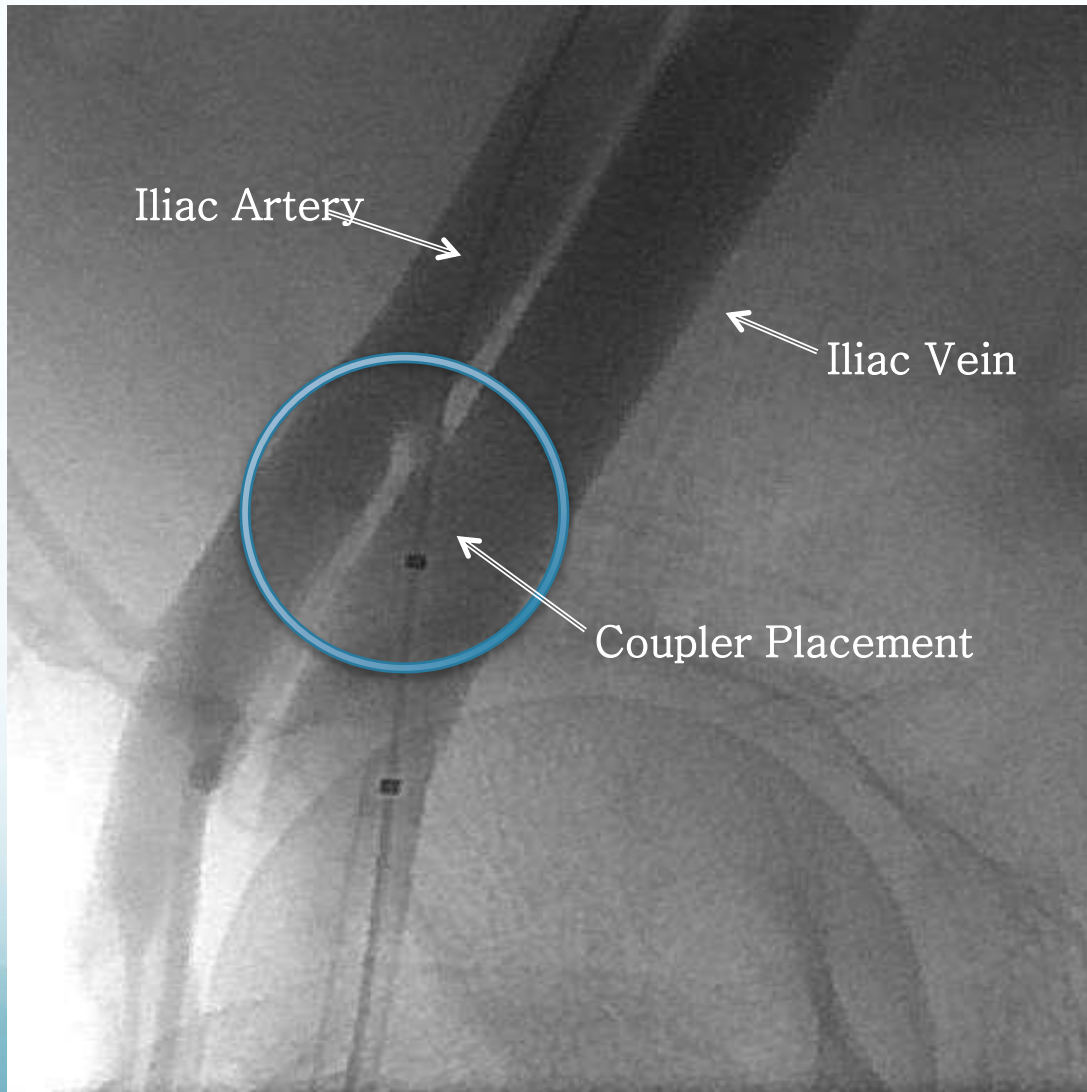
CROSSHAIR

ARTERIAL GUIDEWIRE



WIRE

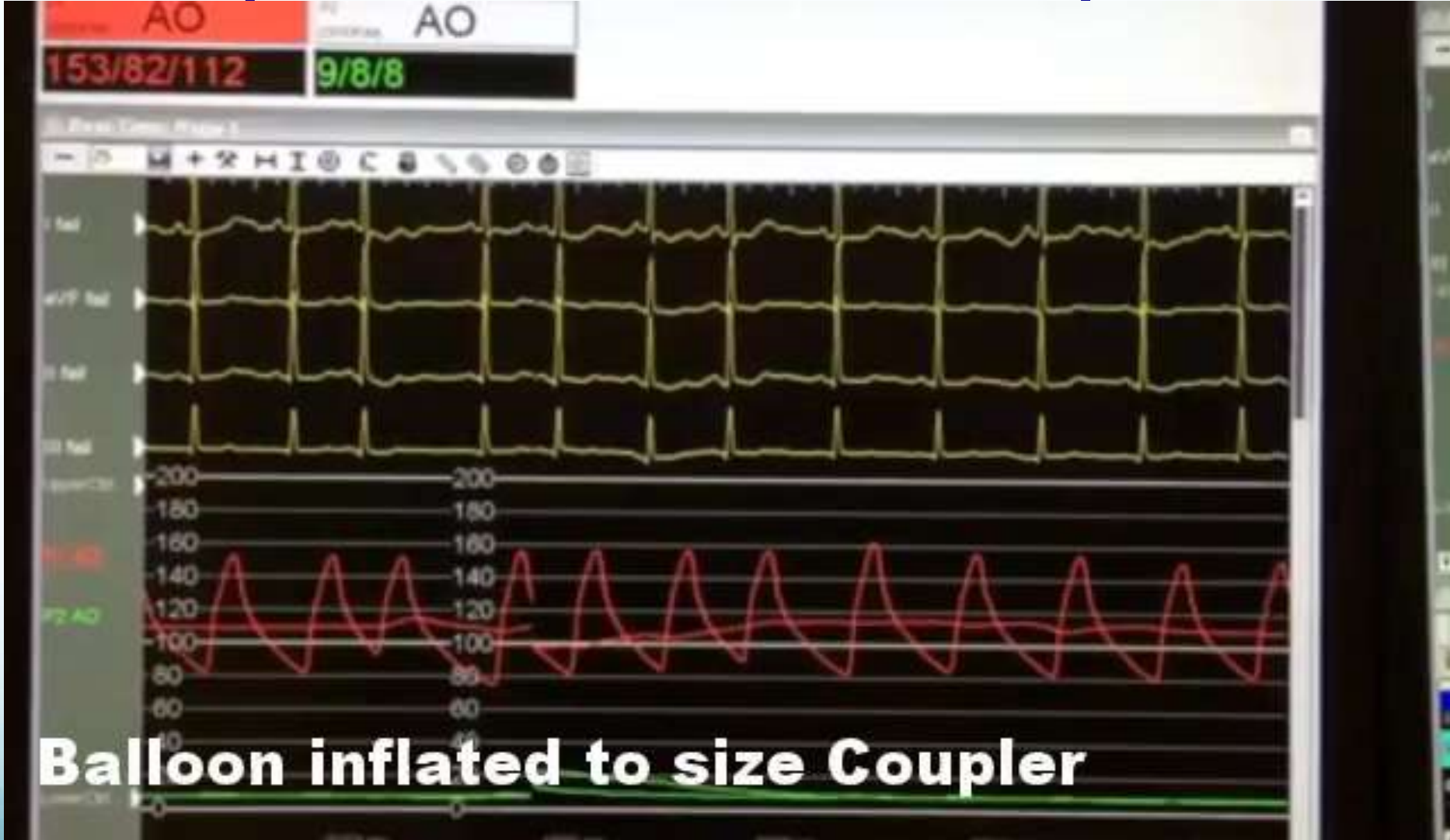
# Verified Placement of the ROX Coupler between Iliac Artery and Vein



- A cath lab procedure
- Completed <1 hr.
- Permits physician confirmation of procedural success while on the table...no 'Black Box'.
- Little variability in procedural technique
- Reversible using a covered arterial stent

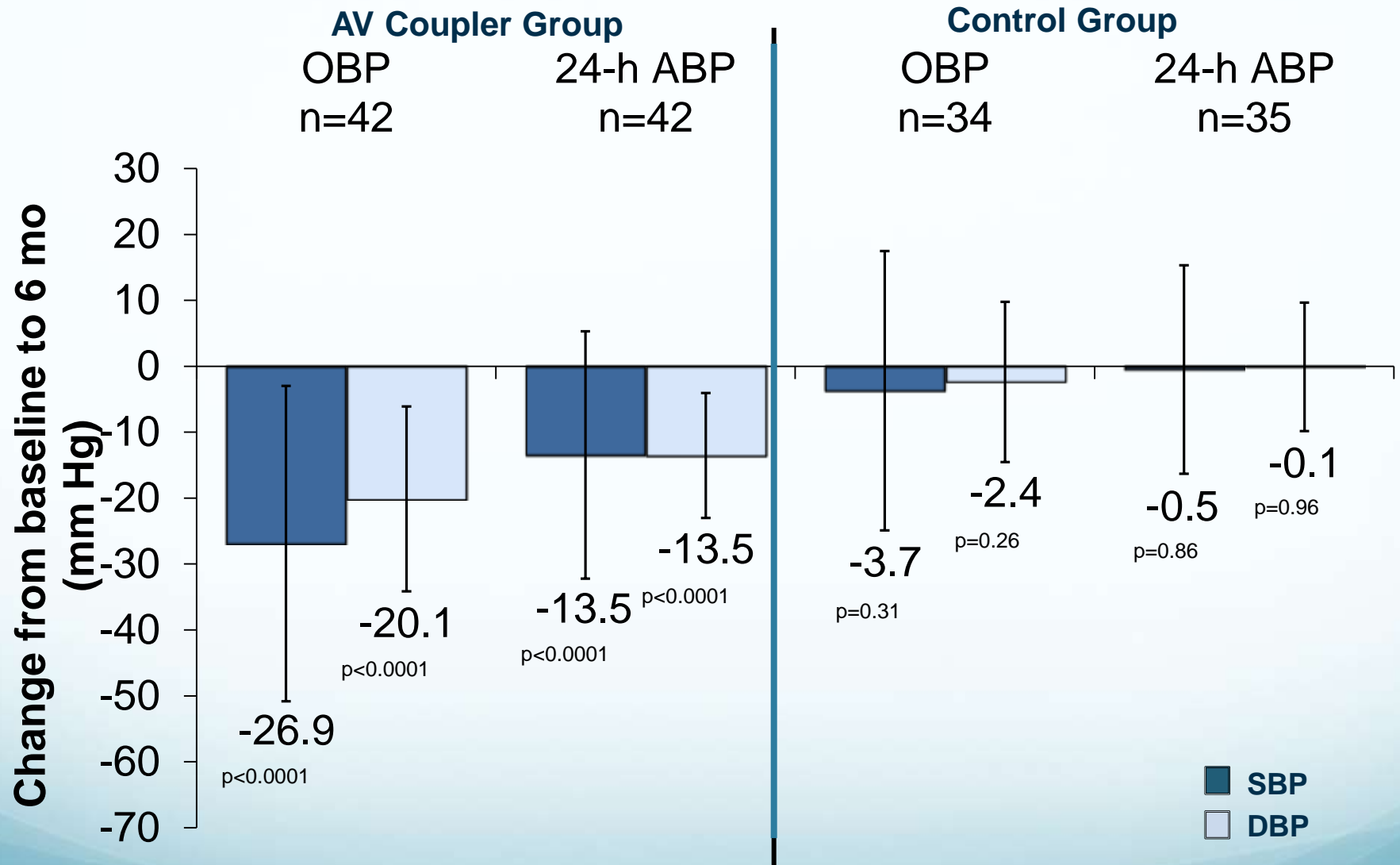
4mm anastomosis, 800cc/min flow

# Immediate, significant BP reduction upon placement of the ROX Coupler



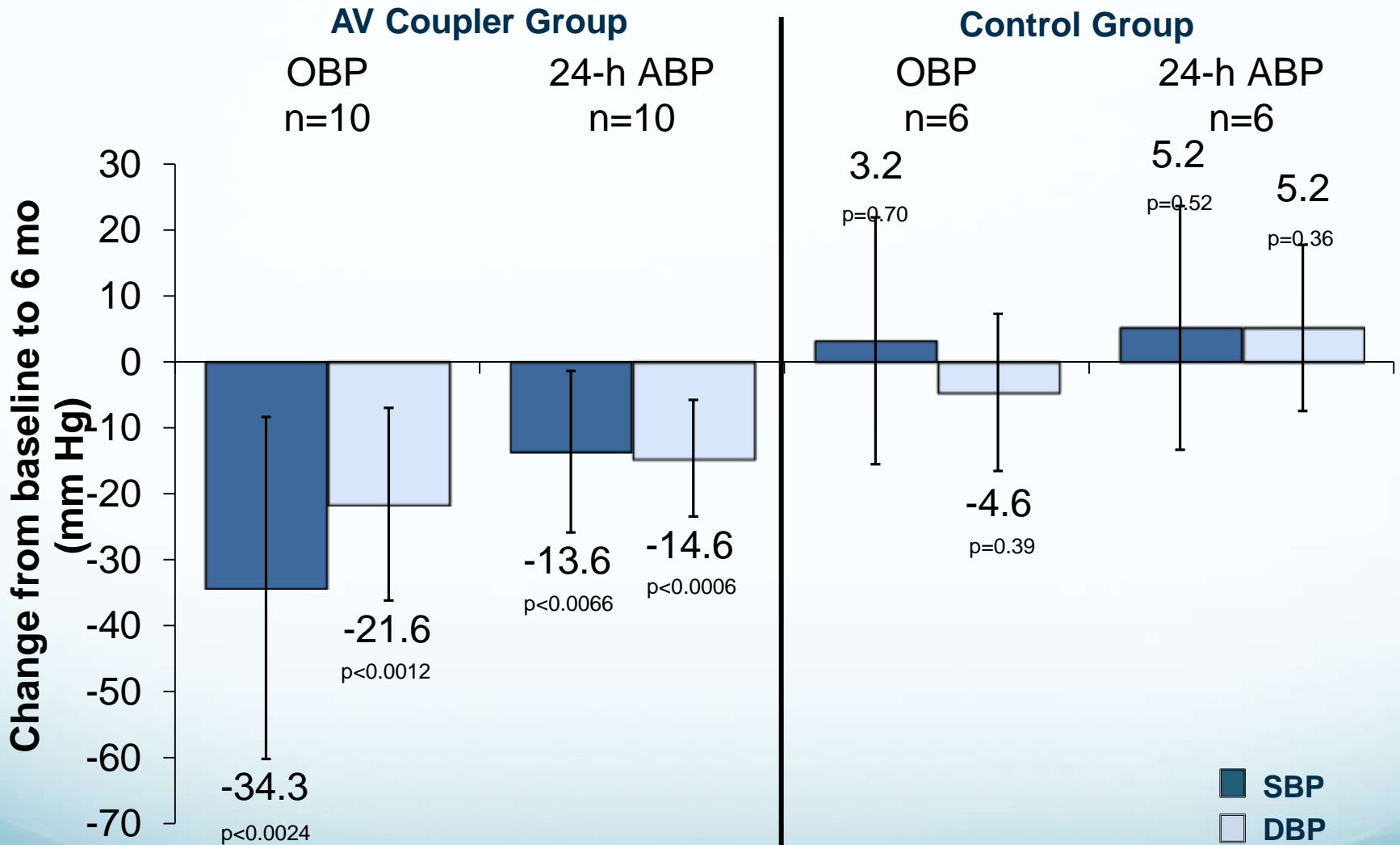
The immediate BP reduction eliminates the possibility of placebo, sham or Hawthorne effect

# Change in BP at 6 Months



Error bars are  $\pm 1$  Standard Deviation. ABP=ambulatory blood pressure. BP=blood pressure. OBP=office blood pressure.

# Change in BP at 6 Months: Prior RDN Subset



Error bars are  $\pm 1$  Standard Deviation. ABP=ambulatory blood pressure. BP=blood pressure. OBP=office blood pressure.



# Change in Antihypertensive Medications from Baseline to 6M (all available data)

	<b>ROX Coupler (n = 43)</b>	<b>Control (n = 34)</b>	<b>p-value</b>
<b>Increased HTN medication</b>	<b>4 (9.3%)</b>	<b>10 (29.4%) ↑</b>	<b>0.0359</b>
<b>Decreased HTN medication</b>	<b>11 (25.6%) ↓</b>	<b>2 (5.9%)</b>	<b>0.0309</b>

**Blood pressure analysis was done independent of medication changes**

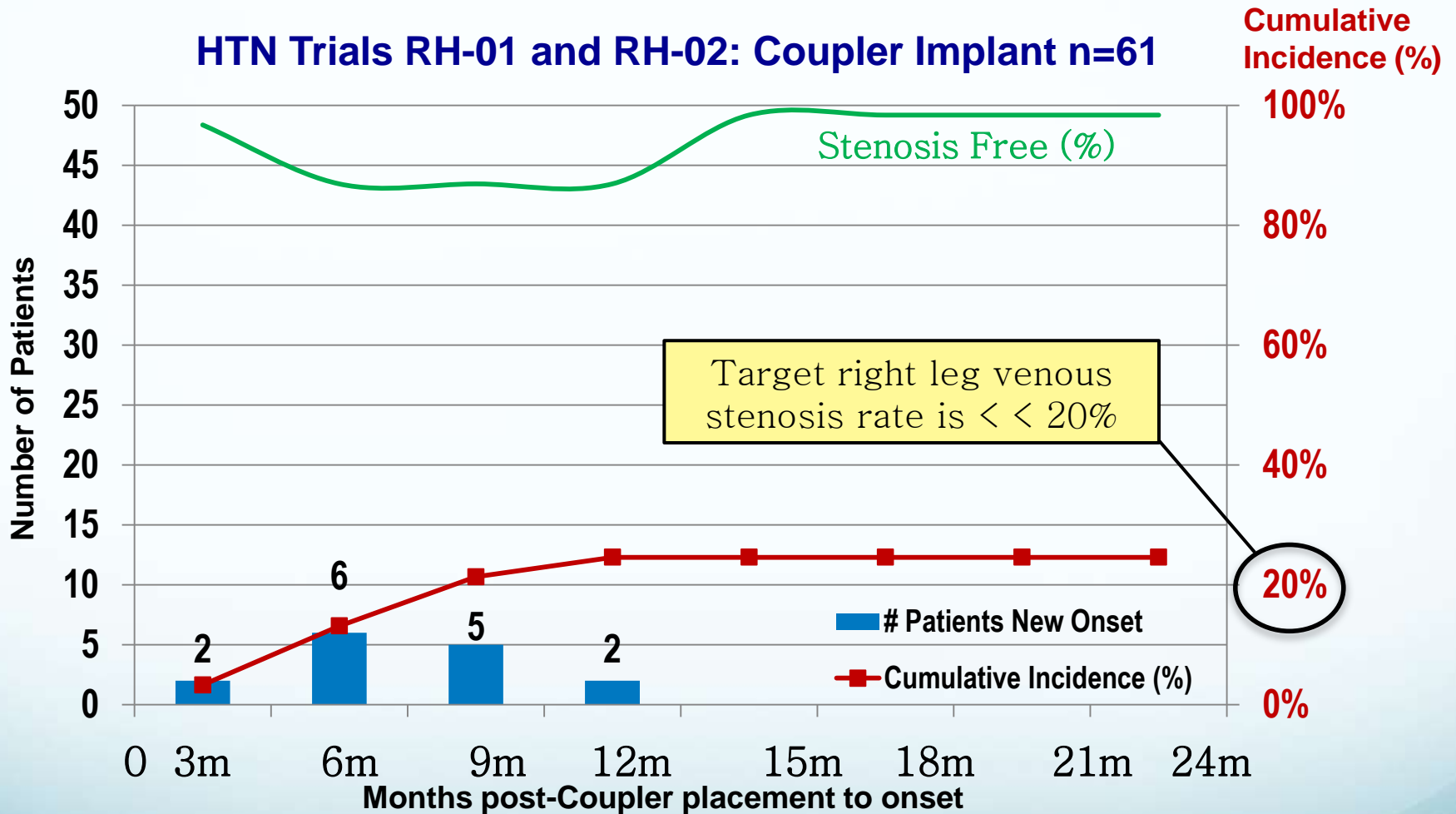
Hence, the true treatment effect maybe understated in the data

# ROX Coupler: Reduced Morbidity

Events related to <u>IMPROVEMENT</u> in BP	ROX Coupler (n = 42)		Control Group (n = 39)		p-value
<b>Non-serious events:</b>	Events	Patients	Events	Patients	
Hypotensive symptoms permitting reduction in antihypertensive meds	8	8 (19.0%)	0	0 (0%)	0.0056
<i>Desired medication reduction</i>					
Events related to <u>WORSENING</u> in BP	Events		Events		
<b>Serious events:</b>	Patients	Patients	Patients	Patients	
Hypertensive crisis	0	0 (0%)	5	3 (7.7%)	0.0225
<b>Non-serious events:</b>	<i>Reoccurring events and far worse than venous stenosis</i>				
Worsening BP requiring increase in medication	1	1 (2.4%)	4	4 (10.3%)	
<b>TOTAL</b>	1	1 (2.4%)	9	7 (17.9%)	0.0059

Not included above: one Control Group death related to hypertension at month 8

# Venous Stenosis Occurs within 12 months It is Less Common in the Right Iliac Vein



**Venous stenosis is half of the 40% Adverse Event (AE) rate for medications reported in the SPRINT Trial**

# ROX and v. RDN

## ROX

Procedure:

- Technically Verifiable
- Identical

Effect:

- Immediate, constant

Durability:

- Non-counter regulatory

Target Population:

- All adults

Treatment Failures:

- None known to date

## Renal Denervation

Procedure:

- A 'Black Box' procedure
- Variable denervation

Effect:

- Ill defined time course

Durability:

- ? nerves may regrow

Target Population:

Younger adults

Treatment Failures:

- Older
- ISH