

# ***Denervación Renal Donde estamos hoy?***

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**Cardiólogo Intervencionista**



# Disclosure

- ✓ Consultant: Medtronic
- ✓ Proctoring fees: Medtronic

# Que esperamos de la Denervación Renal

- Adecuada reducción de Tensión Arterial
- Disminución del numero de No respondedores
- Disminución en la variabilidad de respuesta
- Menor variabilidad en la técnica
- **Mantener el perfil de seguridad!**

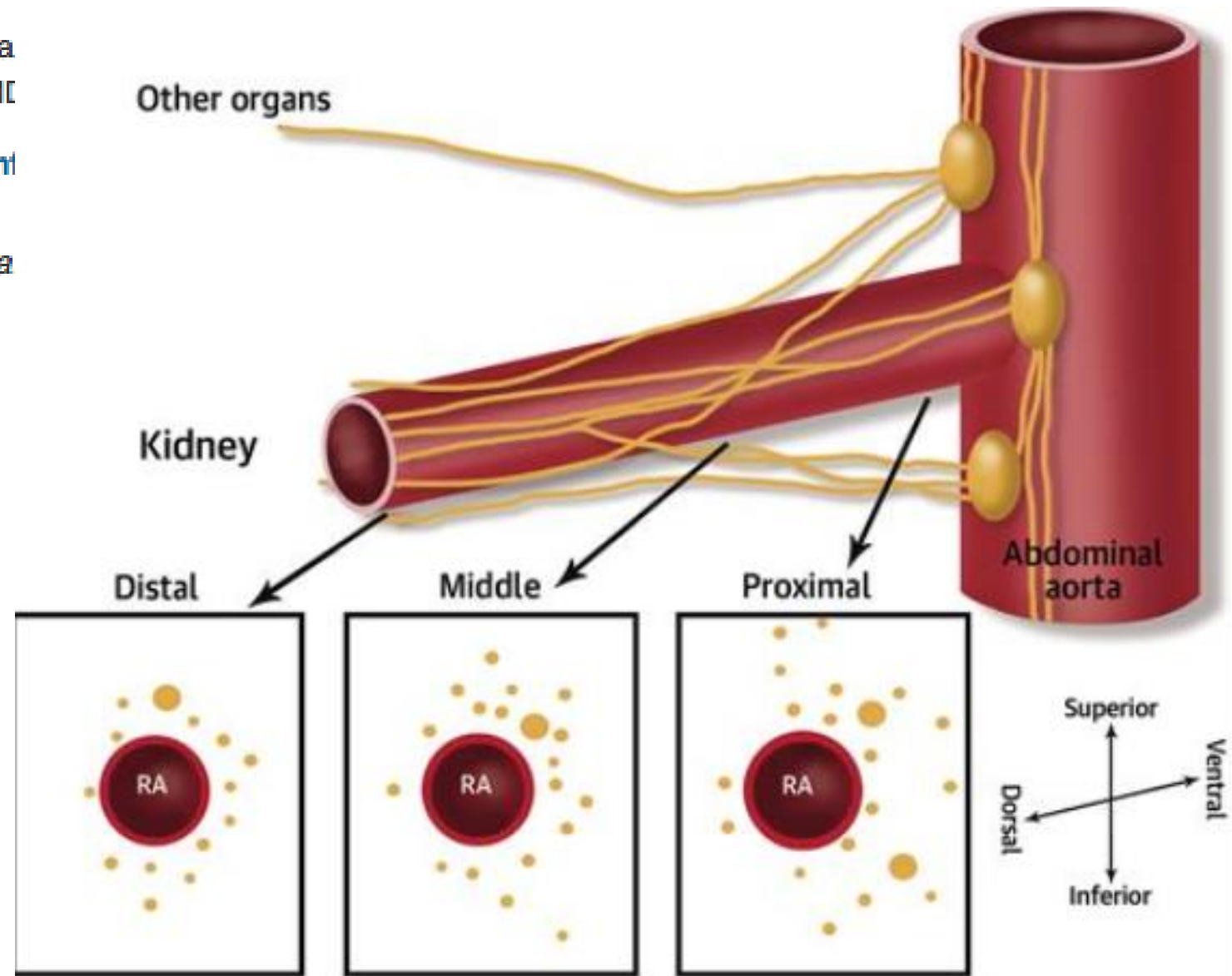
# Anatomic Assessment of Sympathetic Peri-Arterial Renal Nerves in Man

Kenichi Saka  
R. Fowler, MD

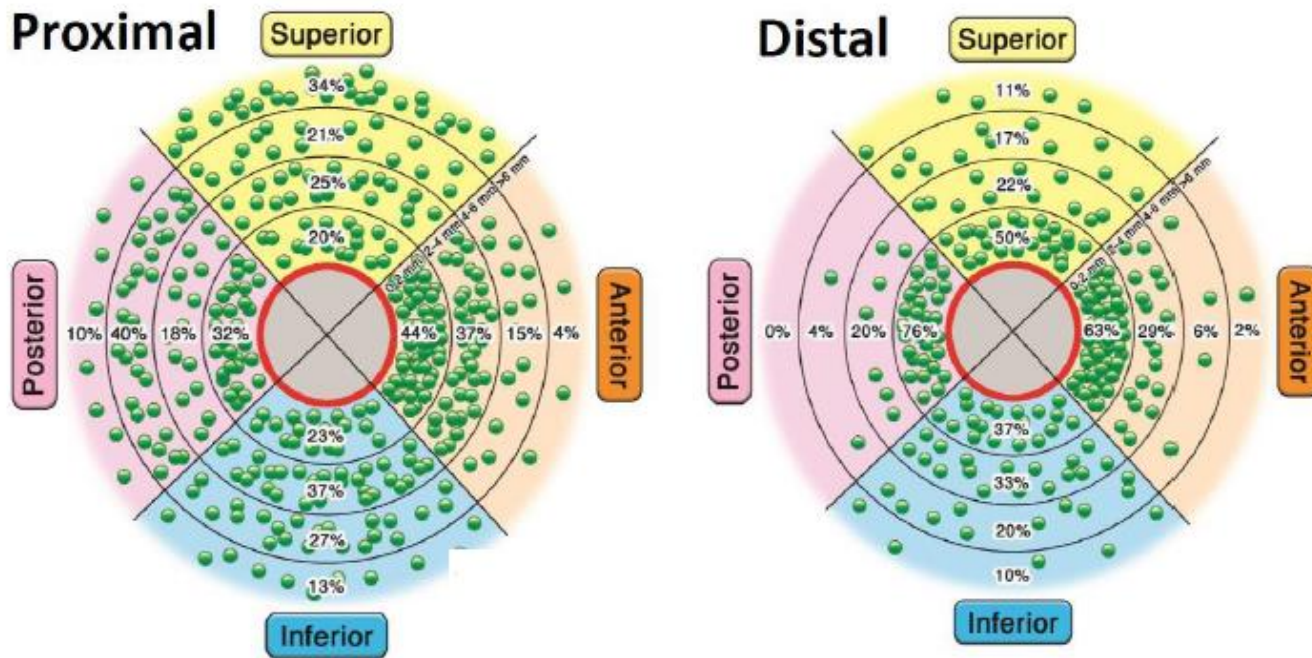
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*J Am Coll Ca*

MD\*; David

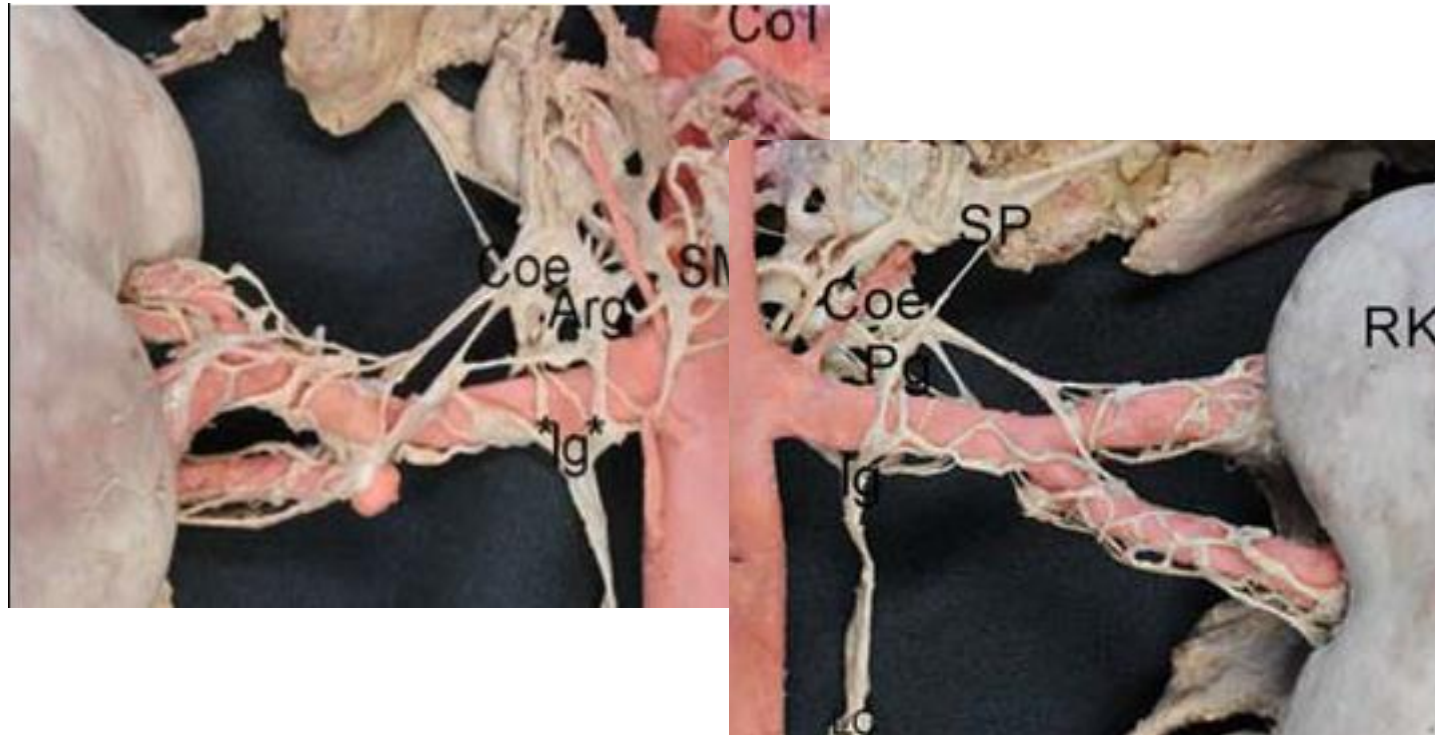


# Nervios del sistema simpático



Mahfoud F et al. JACC 2015

# Nervios del sistema simpático



# Optimization of the Treatment Methodology: a combined target approach to renal denervation



RF treatment of the Main Artery

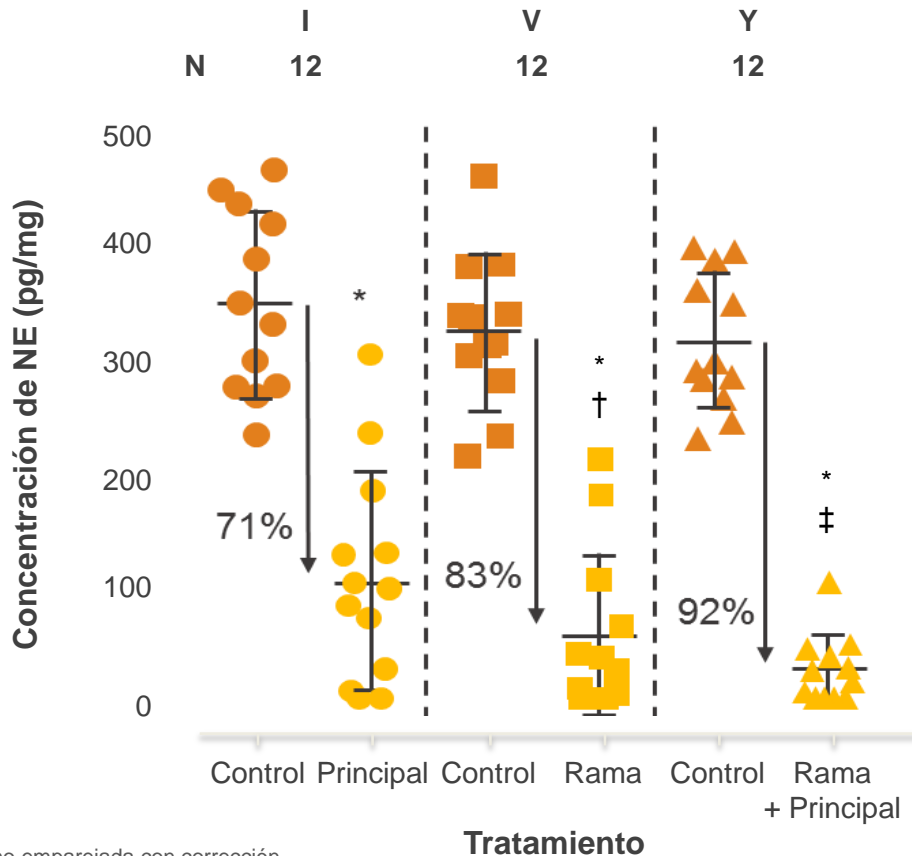


RF treatment of each Branch



RF treatment of the Main Artery  
and Branches

# El Tratamiento Combinado de la Rama y Arteria Principal Resultó en un Efecto Pre-Clínico Mayor y Más Constante



- El enfoque de tratamiento previo se centraba únicamente en la estructura principal de la arteria renal
- El Estudio IVY demostró un efecto del tratamiento estadísticamente mayor y más constante cuando la ablación se realiza tanto en la arteria renal principal como en sus ramas comparado con la ablación de la arteria renal principal únicamente.

Prueba t no emparejada con corrección de Welch v. control emparejado  
\* P < 0,0001

Prueba t no emparejada con corrección de Welch v. Principal

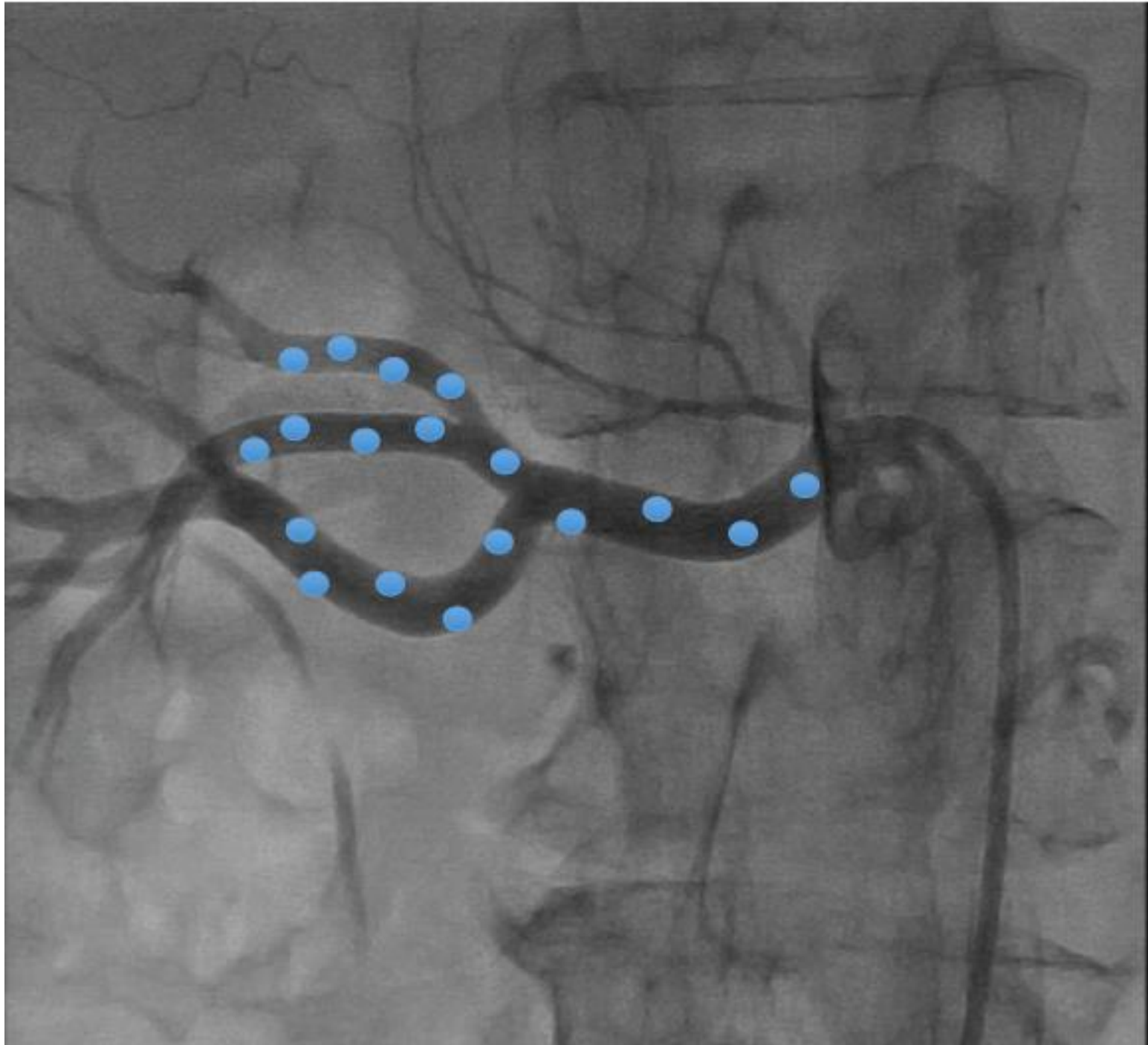
† P < 0,1966

‡ P < 0,0200

Melder et al. TCT 2014.

Nota: Se tomó a cada animal como su propio control en este estudio





# Six-month invasive safety assessment in humans of renal artery denervation using Simplicity Spyral applied in the main trunk and branches



Justin Davies, MBBS, PhD  
Interventional Cardiologist  
Hammersmith Hospital,  
Imperial College London



**Imperial College**  
London

# Symplicity Spyral

- 16 pacientes con ablación de arteria Renal principal y ramas
- Evaluar seguridad del procedimiento

# En promedio cada paciente recibió 24 ablaciones con RF

		Details of renal denervation (n=16)
<b>Left Kidney</b>		
	<i>Total number of ablations left renal artery</i>	9.5 ± 3.2
	<i>Average number of ablations left main renal artery</i>	4.5 ± 1.3
	<i>Average number of ablations distal branches left renal artery</i>	5.0 ± 2.7
<b>Right Kidney</b>		
	<i>Total number of ablations right renal artery</i>	13.1 ± 2.5
	<i>Average number of ablations right main renal artery</i>	4.8 ± 2.3
	<i>Average number of ablations distal branches right renal artery</i>	8.3 ± 2.7

# No hubo cambio en la anatomía de la arteria renal a 6 meses

PRE-RDN

POST-RDN

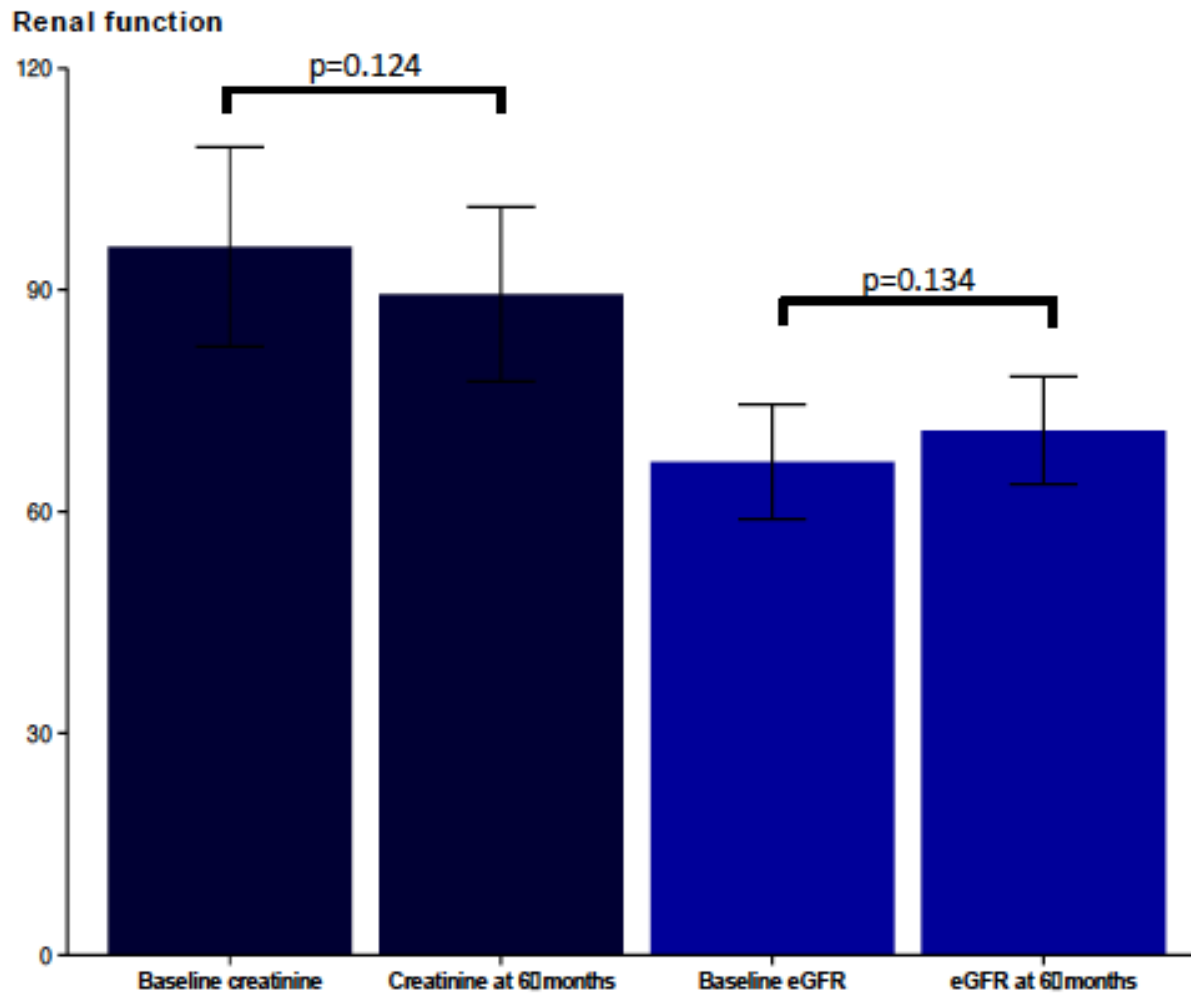
6 Months



# Las arterias renales se mantuvieron sin cambio en el seguimiento

- Sin disección
- Sin trombo
- Sin espasmo
- Sin estenosis

# Sin cambios en la función Renal



# Conclusión

- La Denervación Renal con el catéter Symplicity Spyral en el tronco de la arteria renal y sus ramas
  - Es posible
  - No está asociado con cambios anatómicos a 6 meses
  - Está asociada a función renal preservada a 6 meses de seguimiento





# The Nationwide United Kingdom Registry on Renal Denervation

Dr Andrew SP Sharp MD FRCP

Consultant Cardiologist and Honorary Senior Lecturer  
Royal Devon and Exeter Hospital and University of Exeter



# UK Renal Denervation Affiliation

- 253 cases
- Five different technologies
  - Symplicity Flex (204; 81%)
  - Symplicity Spyral (10; 4%)
  - St Jude Enlightn (26; 10%)
  - Boston Vessix (3; 1%)
  - Coviden Oneshot (10; 4%)
- Mean cases per centre - 15

# Follow-up Office BP data

Follow-up Office BP data (n=228; 90%)	Mean	SD*
Duration of follow-up	11.0	6.7
Systolic BP	163	28
Diastolic BP	93	19
Mean fall in cohort office SBP (mmHg)	22	29
Mean fall in cohort office SBP (mmHg)	9	19

# ABP follow-up

Follow-up ABPM data (n=177; 70%)	Mean	SD
Duration of follow-up	8.5	4.0
Daytime systolic BP	158	25
Daytime diastolic BP	91	17
Night-time systolic BP	145	26
Night-time diastolic BP	83	17
Mean fall in cohort daytime ABPM systolic BP (mmHg)	12	
Mean fall in cohort daytime ABPM diastolic BP (mmHg)	7	

# UK RDA

## *Medicamentos*

- 65% de los pacientes (n=165) no agregó ningún medicamento post RDN
- 36% de los pacientes ( 92 pac) redujeron al menos 1 medicamento post RDN
  - 18% 1 medicamento
  - 10% 2 medicamentos
  - 4% 3 medicamentos
  - 4% 4 medicamentos



# Long-term (3-year) safety and effectiveness from the Global SYMPLICITY Registry of renal denervation in a real world patient population with uncontrolled hypertension

Felix Mahfoud, MD<sup>1</sup>

M. Böhm<sup>1</sup>, K. Narkiewicz<sup>2</sup>, L. Ruilope<sup>3</sup>, M. Schlaich<sup>4</sup>, G. Mancia<sup>5</sup>  
on behalf of the GSR Investigators

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# Symlicity Renal Denervation System

## FLEX



- Single-electrode catheter
- 120-second energy delivery
- Vessel diameter range: 3–8 mm
- Deflectable 4F catheter
- 6F guide compatible



## SPYRAL



- Multi-electrode catheter with ablation in up to 4 electrodes simultaneously
- 60-second simultaneous energy delivery
- Vessel diameter range: 3–8 mm
- Over-the-wire 4F catheter facilitates branch treatment
- 6F guide compatible

# Global SYMPLICITY Registry (GSR) Clinical Trial Design

Prospective, open-label, single-arm, all-comer observational registry



10% randomly assigned to 100% monitoring



Follow-up available to date:

	3M	6M	1Y	2Y	3Y
Patients treated with Flex catheter		2206	2173	1747	467
Patients treated with Spyrax catheter		201	143		

\* Limited to resistant hypertension only



# Procedural Details



mean ± SD	Flex Patients N=2206	Spyral Patients N=201	P-value
Number of renal arteries treated	2.1 ± 0.4	2.1 ± 0.4	NA
Treatment time (min)	49.0 ± 20.7	30.9 ± 24.4	<0.001
Contrast volume used (cc)	128.7 ± 78.2	105.8 ± 76.9	<0.001
Number of ablations			
In all patients	13.4 ± 4.1	21.3 ± 9.6	<0.001
In patients with main vessel treatment only*	Not collected	19.9 ± 7.6 (n=151)	<0.001
In patients with main vessel and any branch treatment*	Not collected	<b>30.0 ± 14.0</b> (n=30)	

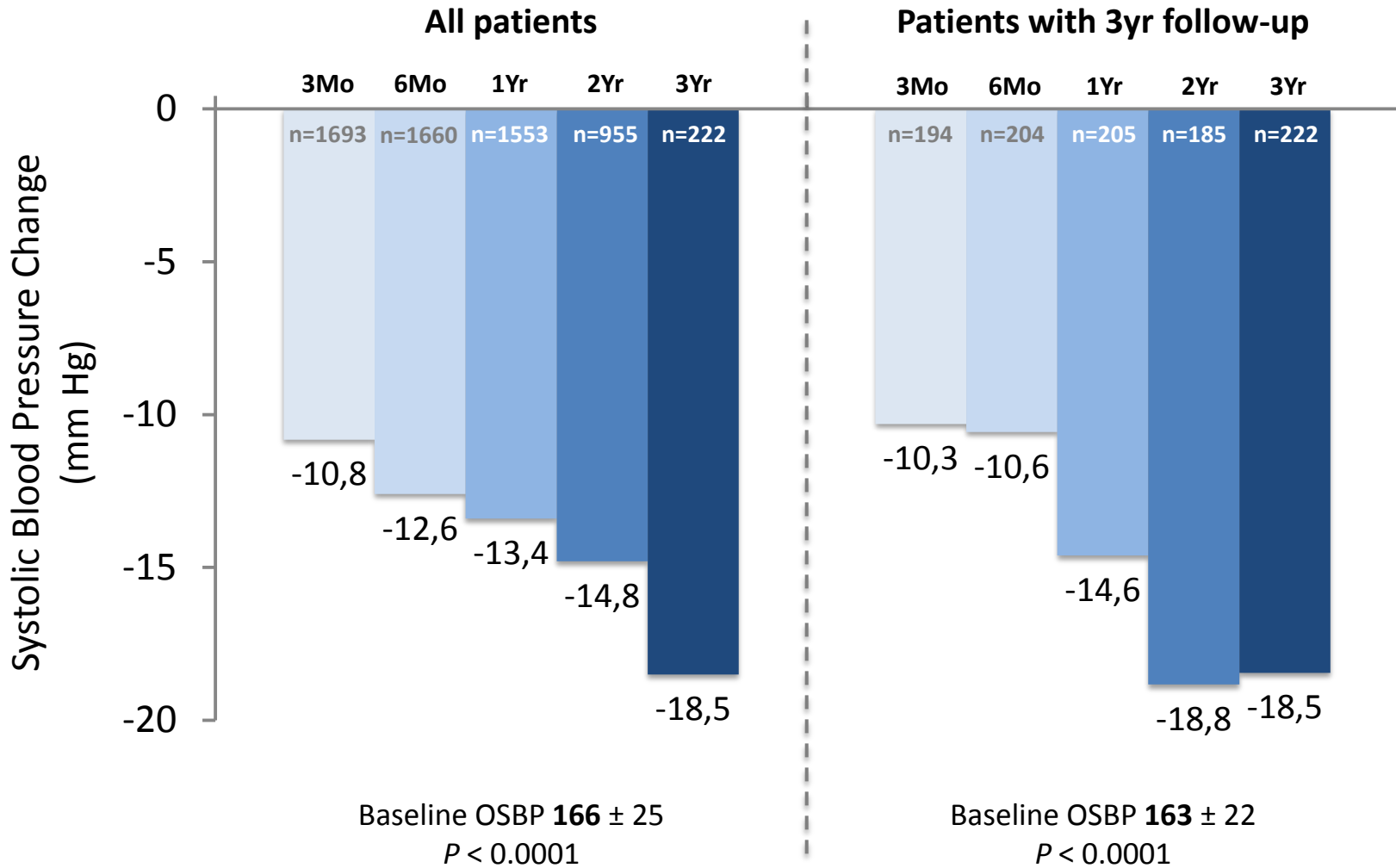
\*Site reported data. Branch treatment was not specified in the GSR study protocol and was performed at the discretion of the operator.



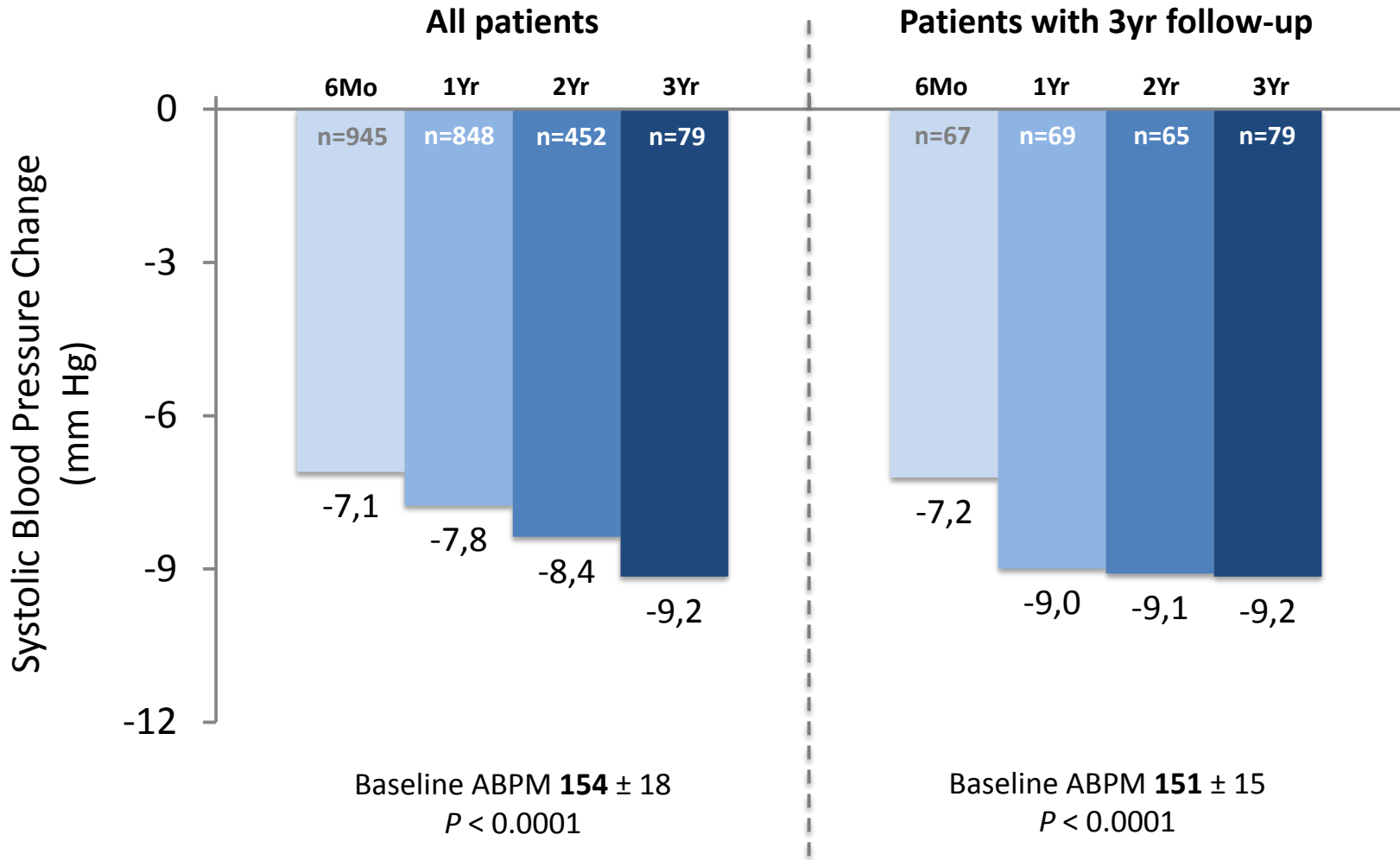
%	3 Months n=197	6 Months n=191	1 Year n=123
<b>Composite safety endpoint</b>	<b>0.5</b>	<b>1.6</b>	<b>4.1</b>
<b>Cardiovascular events</b>			
Cardiovascular death *	0.0	0.0	0.8
Stroke	1.0	2.1	4.1
Hospitalization for new onset heart failure	1.0	2.1	3.3
Hospitalization for atrial fibrillation	0.0	0.0	0.0
Hospitalization for hypertensive crisis/hypertensive emergency *	0.5	1.6	3.3
Myocardial infarction	0.0	0.0	0.0
<b>Renal events</b>			
New onset end-stage renal disease *	0.0	0.0	0.0
Serum creatinine elevation >50%	0.0	0.0	0.0
New artery stenosis >70% *	0.0	0.0	0.0
<b>Post-procedural events</b>			
Non-cardiovascular death	0.0	0.0	0.0
Renal artery reintervention *	0.0	0.0	0.0
Vascular complication *	0.0	0.0	0.0

\* Included in composite safety endpoint at 30 days

# Flex – Office Systolic BP Change



# Flex – 24h Ambulatory BP Change

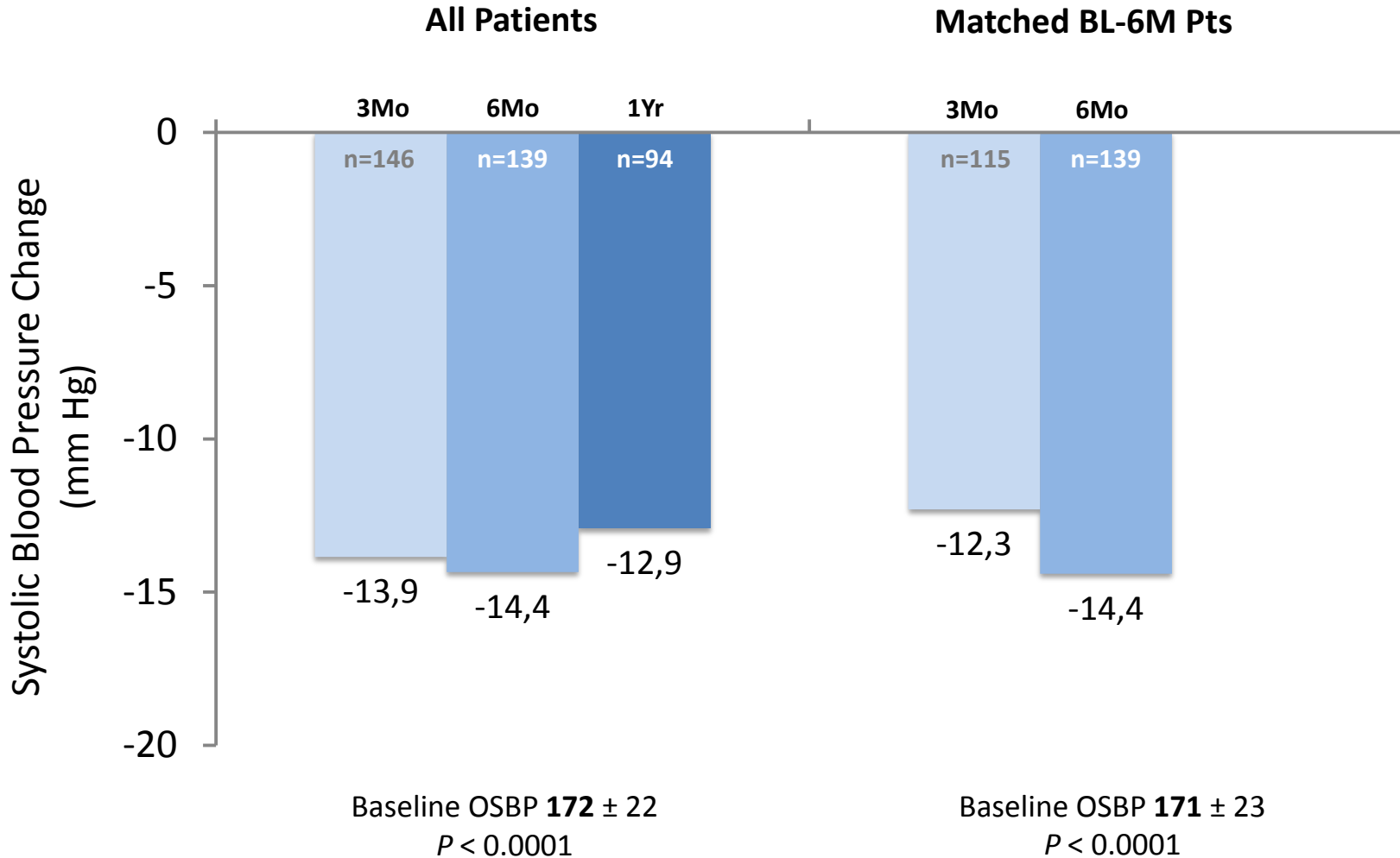


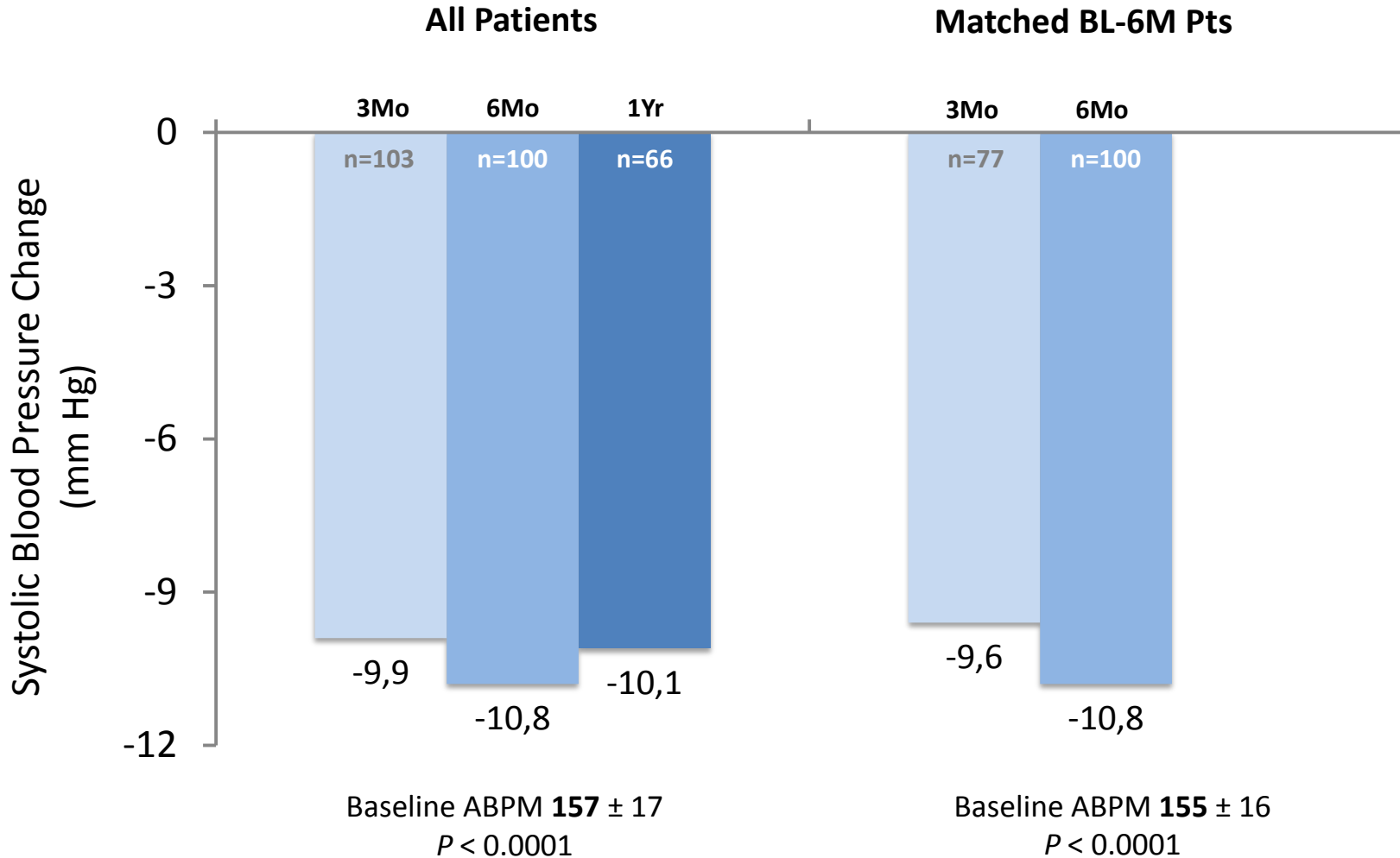
**SPYRAL**



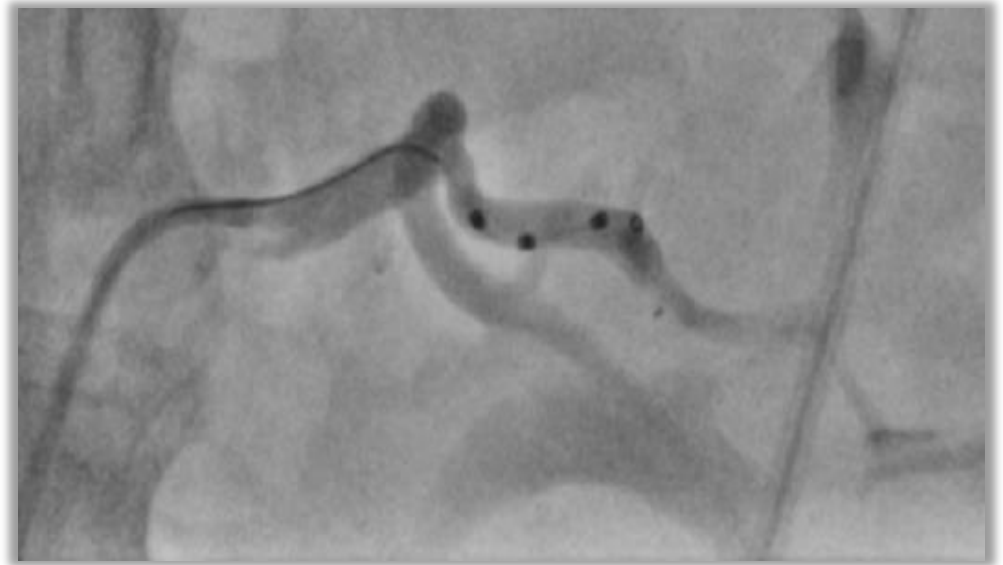
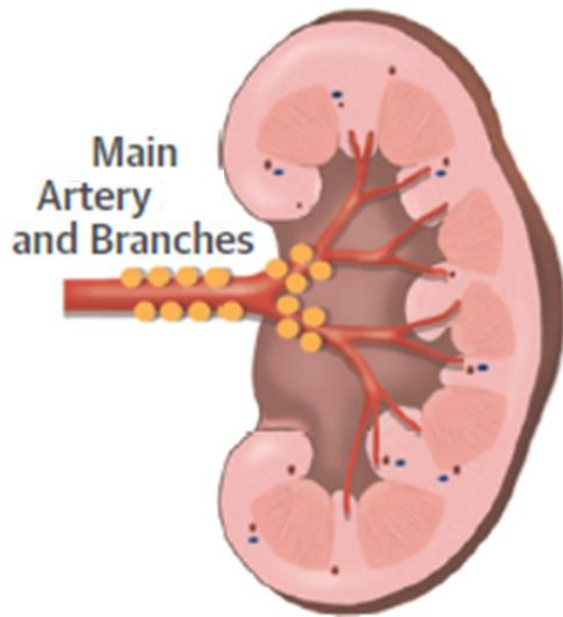
**BLOOD PRESSURE RESULTS**

# Spyral – Office Systolic BP Change





# Treatment of Main Renal Artery and Major Branches

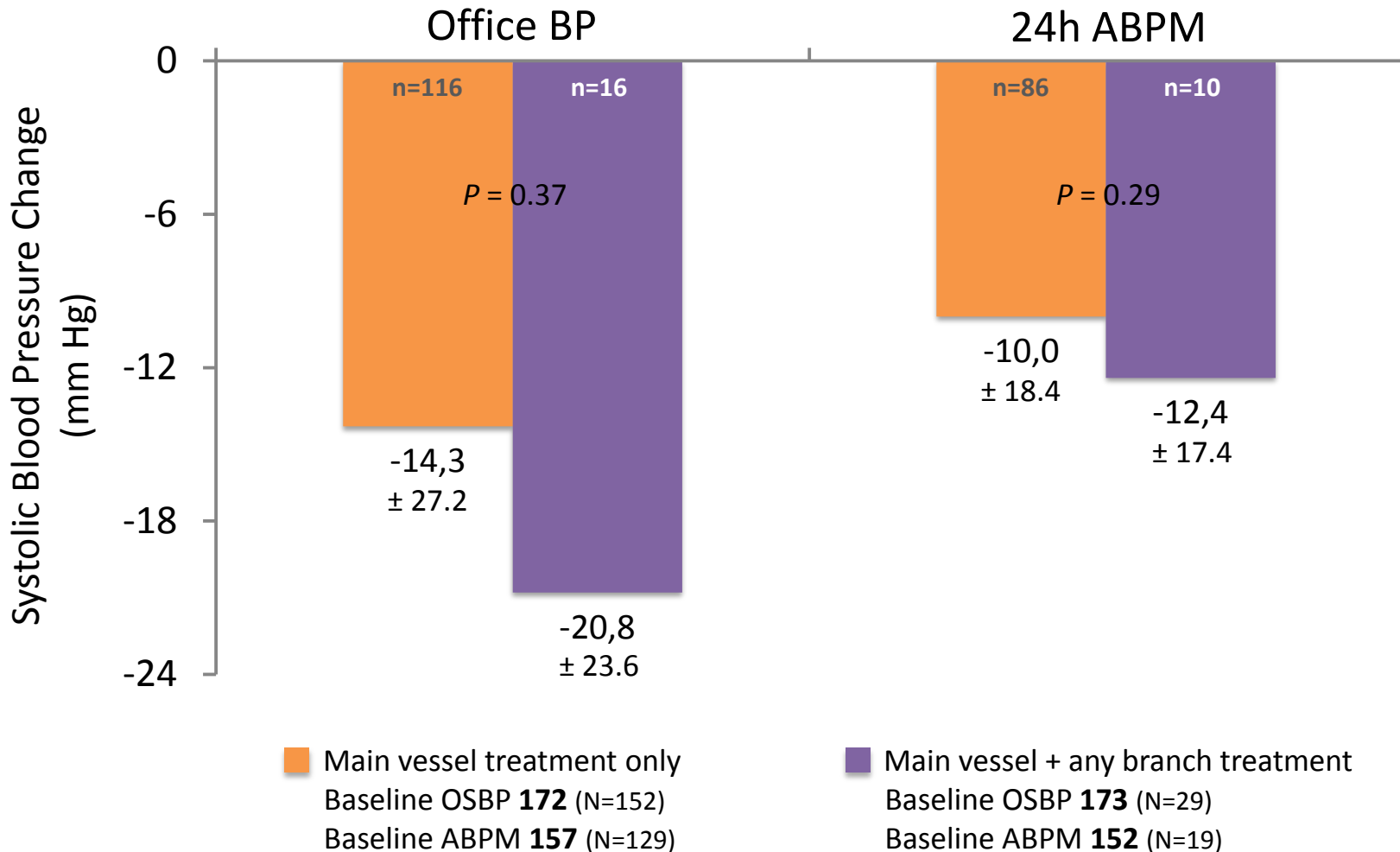






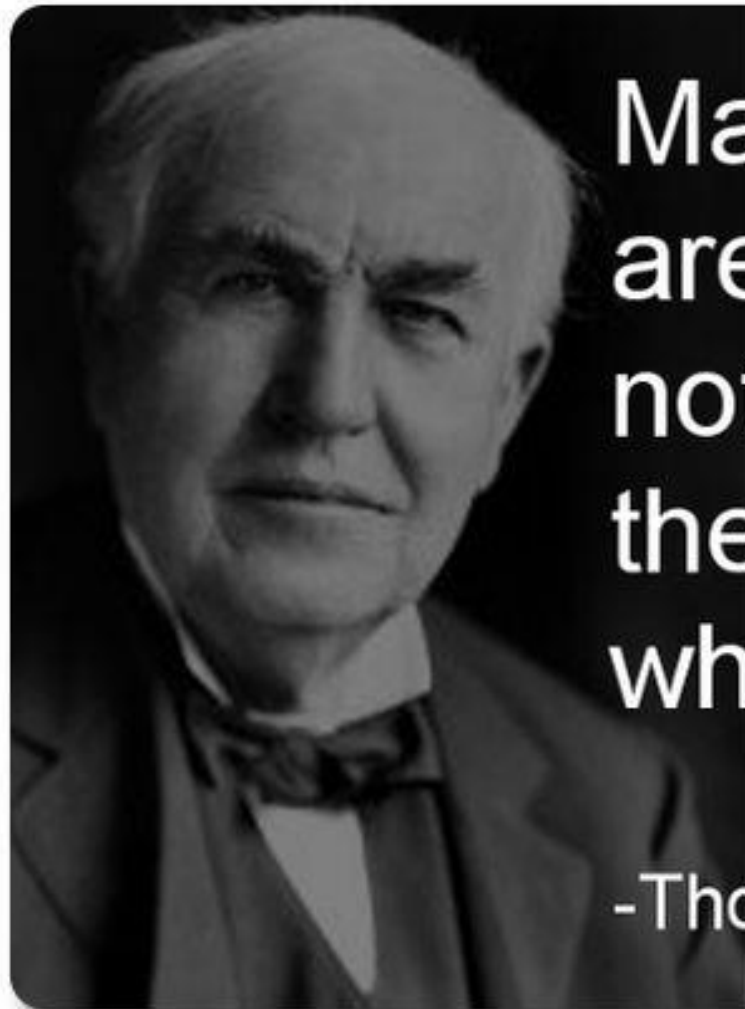
# Spyral – BP Change at 6 Months

## Subset: Renal Artery Branch Treatment



# Conclusión

- El Registro Global Symplicity tiene seguimiento a 3 años con la mayor cohorte de pacientes con sólidos datos de seguridad y eficacia.
- Existe nueva evidencia que nos orienta a cambios en la manera como realizabamos el procedimiento.
- Tratar las ramas ha demostrado ser seguro.
- Hay datos iniciales de mejor respuesta en la TA.
- Los estudios con y sin antihipertensivos nos permitirá comprender mejor el impacto de la medicación en la denervación renal y la estrategia de tratar en las ramas.



Many of life's failures  
are people who did  
not realize how close  
they were to success  
when they gave up.

-Thomas Edison



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CARACAS

GRACIAS

