XIII CONGRESO INTERNACIONAL DE CARDIOLOGIA

CARDIOLOGIA INTERVENCIONISTA - LII JORNADA ACCI-SOLACI

DE LA

PREVENCIÓN

A LA **INTERVENCIÓN**

8, 9 y 10 de octubre

Lugar:

INTERCONTINENTAL
SAN JOSÉ, COSTA RICA

Organiza:

ASOCAR
Asociación Costarricense de Cardiología

ASOCAR
Capítulo de Enfermería

ACCI

JORNADAS SOLACI

ESTUDIOS CLÍNICOS ACTUALIZADOS DE LA DENERVACIÓN RENAL

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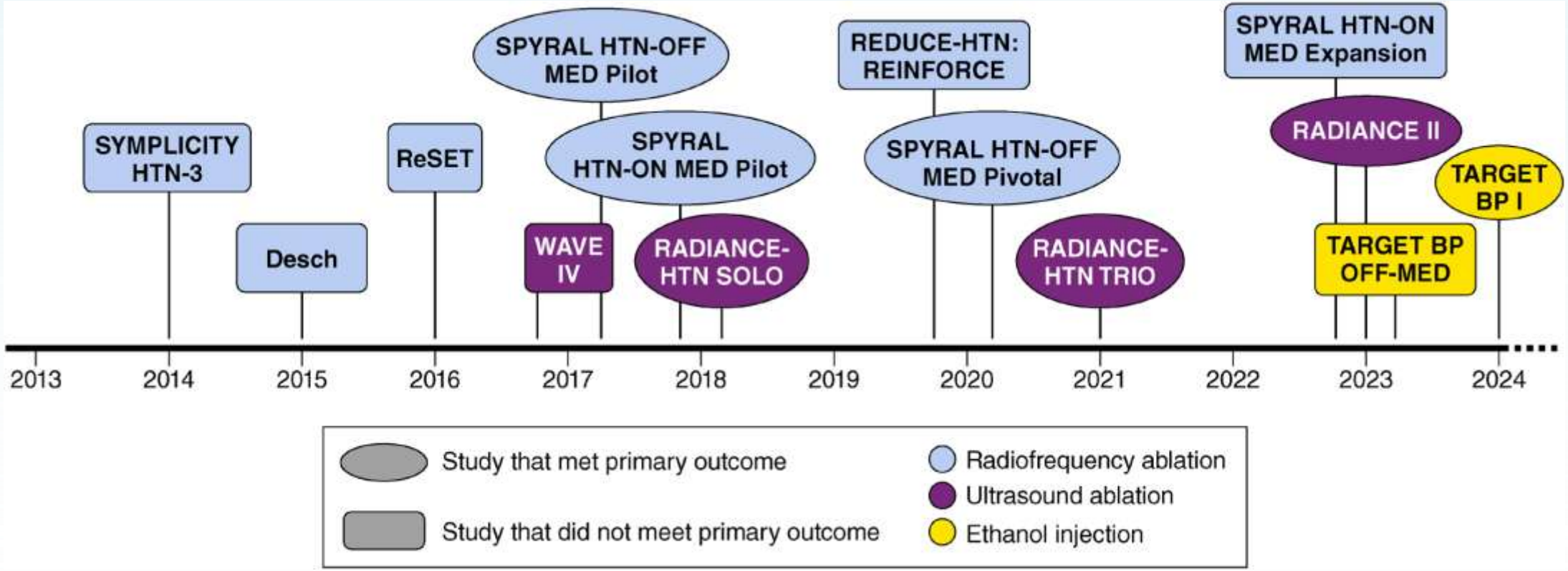
Una línea múltiples historias. . .



Hypertension. 2024;81:e135–e148. DOI: 10.1161/HYP.0000000000000240

Symplycity 3

Qué falló, por qué la inconsistencia ?

- Denervación subóptima e incompleta en algunos pacientes.
- Una adherencia cuestionable a la medicación.
- Altas tasas de cambios de fármacos durante el ensayo.
- La variabilidad en la técnica de medición de la presión arterial en los distintos sitios.

Pero el problema sigue…

Trial	Year of publication	Number of centers	Sample size (male, female)	Randomisation ratio	Catheter device	Inclusion criteria	Primary efficacy endpoint	Question and corresponding statistical analysis		BP reduction: RDN vs control group
SPYRAL HTN-OFF MED Pilot [32]	2017	21	80 (57, 23)	RDN vs sham (1:1)	Symplicity Spyral - multi-electrode RF	Uncontrolled office and 24-hour BP in the absence of antihypertensive drugs	Change in 24-hour SBP at 3 months	Comparison of 24-hour and office SBP changes at 3 months, adjusted for baseline measures within sub-groups.	ANCOVA	−5.5 (95% CI: −9.1 to −2.0) vs −0.5 mmHg (95% CI: −3.9 to 2.90); $p = 0.0414$
								Between group differences and BP differences from baseline to the 3-month and 6-month follow-up time.	Unpaired and paired *t*-test	
								Comparisons between treatment groups were made to exact tests for multilevel categorical variables.	Chi-square test	
SPYRAL HTN-ON MED Proof-of-concept [35]	2018	25	80 (67, 13)	RDN vs sham (1:1)	Symplicity Spyral - multi-electrode RF	Uncontrolled office and 24-hour BP on 1 to 3 antihypertensive drugs	Change in 24-hour SBP at 6 months	Comparison of 6-month BP changes, adjusted for baseline measures within sub-groups.	ANCOVA	−9.0 (95% CI: −12.7 to −5.3) vs −1.6 mmHg (95% CI: −5.2 to 2.0); $p = 0.006$
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SPYRAL HTN-OFF MED Pivotal [33]	2020	44	331 (220, 111)	RDN vs sham (1:1) with Bayesian adaptive design	Symplicity Spyral - multi-electrode RF	Uncontrolled office and 24-hour BP, in the absence of antihypertensive drugs	Change in 24-hour SBP at 3 months	Comparisons of BP changes between treatment groups, as well as pre-specified subgroup analyses, adjusted for baseline measures.	Bayesian ANCOVA	−4.7 (95% CI: −6.4 to −2.9) vs −0.6 mmHg (95% CI: −2.1 to 0.9); $p = 0.0005$
								Comparisons between treatment groups were made to exact tests for multilevel categorical variables.	Chi-square or Fisher's test	
								Between group differences and within group BP differences from baseline.	Unpaired and paired *t*-test	
RADIANCE-HTN SOLO [60]	2018	39	146 (85, 61)	RDN vs sham (1:1)	Paradise - US	Uncontrolled daytime ambulatory BP in the absence of antihypertensive drugs	Change in daytime ambulatory SBP at 2 months	Treatment interactions: baseline vs daytime ambulatory SBP for subgroups (ethnicity, age, sex, geography, baseline daytime ambulatory SBP, baseline office BP, and abdominal obesity).	Linear regression model (ANCOVA)	−8.5 ± 9.3 vs −2.2 ± 10.0 mmHg; $p = 0.0001$
RADIANCE-HTN TRIO [36]	2021	53	136 (109, 27)	RDN vs sham (1:1)	Paradise - US	Uncontrolled office and daytime ambulatory BP on a three-drug fixed-dose combination pill	Change in daytime ambulatory SBP at 2 months	Exploratory analyses of pre-specified subgroups: change in daytime ambulatory SBP at 2 months as the dependent variable.	Linear regression analyses	−8.0 (IQR − 16.4, 0.0) vs −3.0 mmHg (IQR − 10.3, 1.8); $p = 0.022$
									Unpaired t-test or	

Table 1 (continued)

Trial	Year of publication	Number of centers	Sample size (male, female)	Randomisation ratio	Catheter device	Inclusion criteria	Primary efficacy endpoint	Question and corresponding statistical analysis		BP reduction: RDN vs control group
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TARGET BP OFF-MED [29]	2023	25	106 (78, 28)	RDN vs sham (1:1)	Peregrine system - ethanol injection via microneedles	Uncontrolled office and 24-hour BP, in the absence of antihypertensive drugs	Change in 24-hour SBP at 2 months	Comparison of office and 24-hour BP changes at 8 weeks, 3 months, 6 months and 12 months, adjusted for baseline measures within sub-groups.	ANCOVA	−2.9 ± 7.4 ($p = 0.009$) vs −1.4 ± 8.6 mmHg ($p = 0.25$)
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SPYRAL HTN-ON MED Expansion [30]	2023	56	337 (270, 67)	RDN vs sham (1:1 for initial 106 patients, 2:1 for subsequent 231 patients)	Symplicity Spyral - multi-electrode RF	Uncontrolled office and 24-hour BP on 1 to 3 antihypertensive drugs	Change in 24-hour SBP at 6 months	Comparisons of BP changes between treatment groups, as well as pre-specified subgroup analyses, adjusted for baseline measures.	Bayesian ANCOVA	−6.5 ± 10.7 vs −4.5 ± 10.3 mmHg; $p = 0.12$
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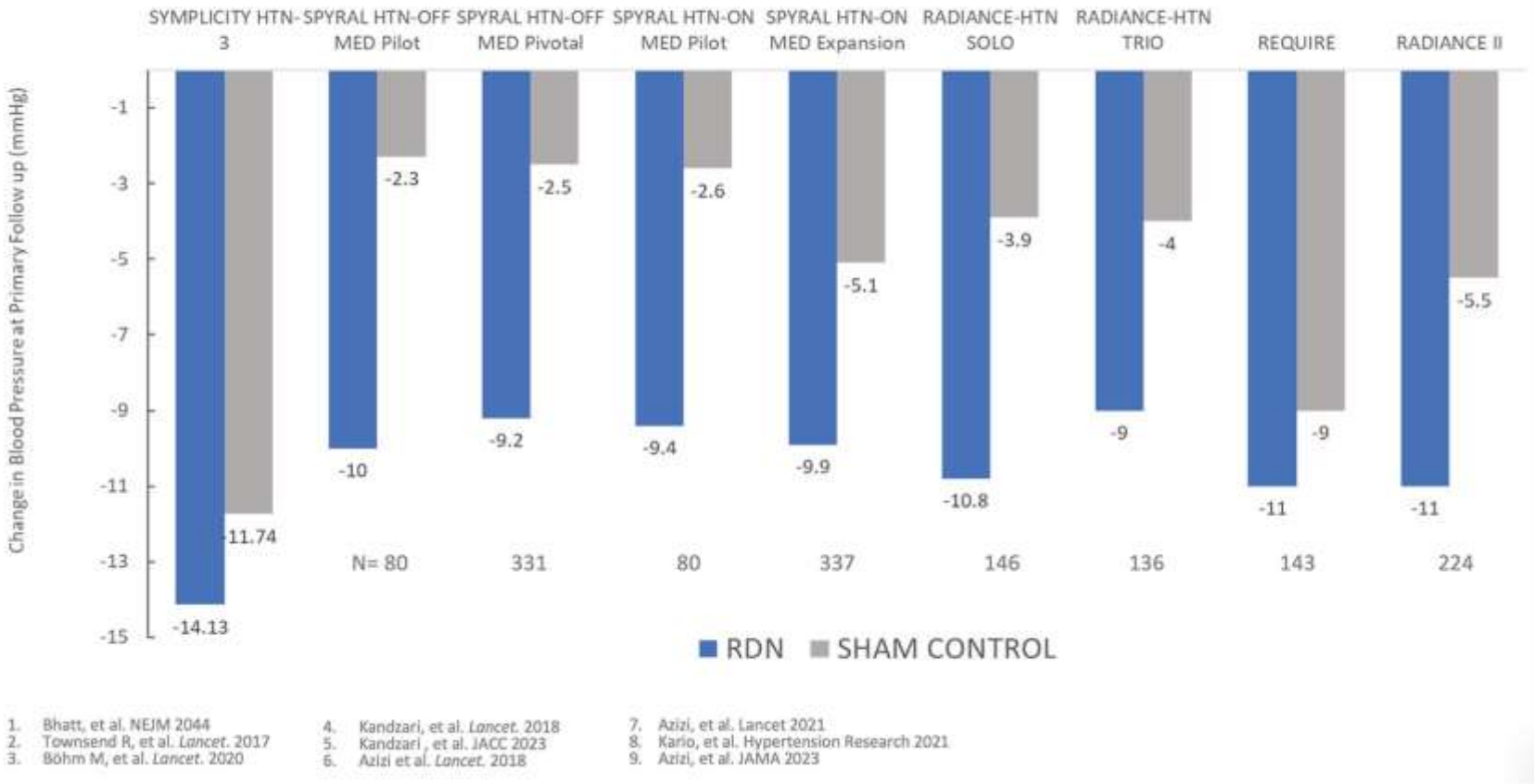
BP blood pressure, *RDN* renal denervation, *RF* radiofrequency, *US* ultrasound, *SBP* systolic blood pressure, *CI* confidence interval, *IQR* interquartile range

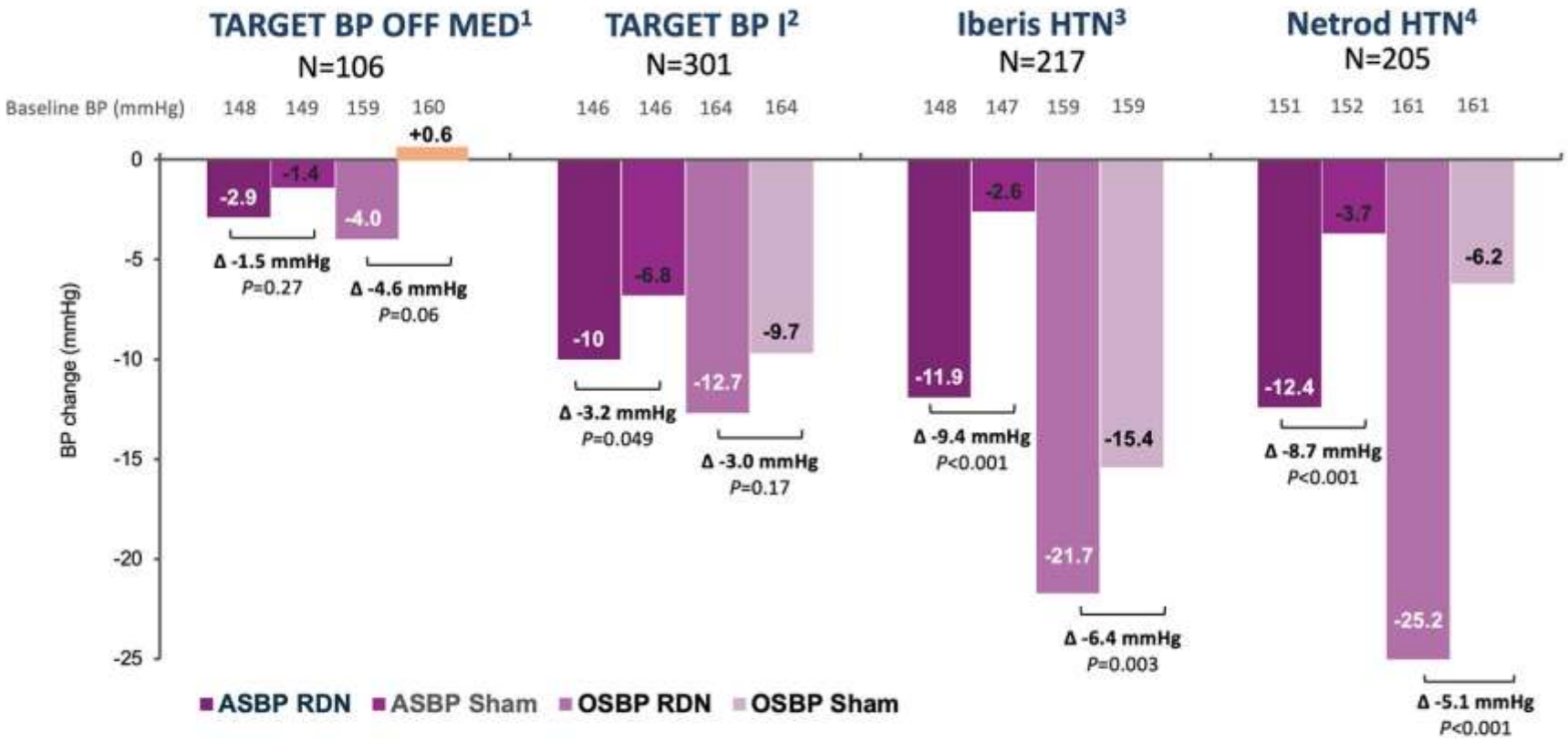
Figure 1. Multiple Sham Controlled RCTs Demonstrated Effectiveness of RDN
In Presence and Absence of Antihypertensive Medications



1. Bhatt, et al. NEJM 2044
2. Townsend R, et al. *Lancet*. 2017
3. Böhm M, et al. *Lancet*. 2020
4. Kandzari, et al. *Lancet*. 2018
5. Kandzari , et al. JACC 2023
6. Azizi et al. *Lancet*. 2018
7. Azizi, et al. Lancet 2021
8. Kario, et al. Hypertension Research 2021
9. Azizi, et al. JAMA 2023

Figure: Courtesy of David E. Kandzari, MD, FACC

Figure 2. 'Next Generation' RDN Sham-Controlled Randomized Trials



[1]Pathak et al. EuroIntervention 2023; [2]Kandzari et al. Circulation 2024; [3]Jiang et al. CIT 2023; [4]Zhou et al. EuroPCR 2023

Figure: Courtesy of David E. Kandzari, MD, FACC

Regresemos a lo básico. . .
Herramientas en estadística

PRUEBA T

La prueba *t* se utiliza para comparar dos muestras independientes que contienen variables continuas, asumiendo que los datos son paramétricos. Determinando si las diferencias son significativas o por azar.

Prueba de Wilcoxon

El uso de pruebas de Wilcoxon en la investigación , también puede ser valioso para evaluar diferencias significativas en variables continuas entre grupos, especialmente cuando se trata de datos que no se adhieren a los supuestos de distribución normal.

Análisis de covarianza (ANCOVA)
Compara las diferencias entre tres o más variables continuas, lo que permite controlar las variables de confusión que pueden ser continuas o discretas, suponiendo que los datos son paramétricos.
Lo que permite conocimientos más confiables y precisos sobre la efectividad y seguridad de la intervención.

Prueba de chi-cuadrado
Se utiliza para comparar diferencias entre dos o más muestras que contienen variables discretas. Se ha utilizado para hacer comparaciones entre grupos de tratamiento para pruebas exactas para variables categóricas como sexo y etnicidad

Prueba exacta de Fisher

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FUTURE
START

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