Denervación renal por radiofrecuencia en pacientes de Alto Riesgo Cardiovascular: resultados y evidencia actual

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The SPYRAL HTN clinical program

With the largest and longest real-world experience

SPYRAL HTN program

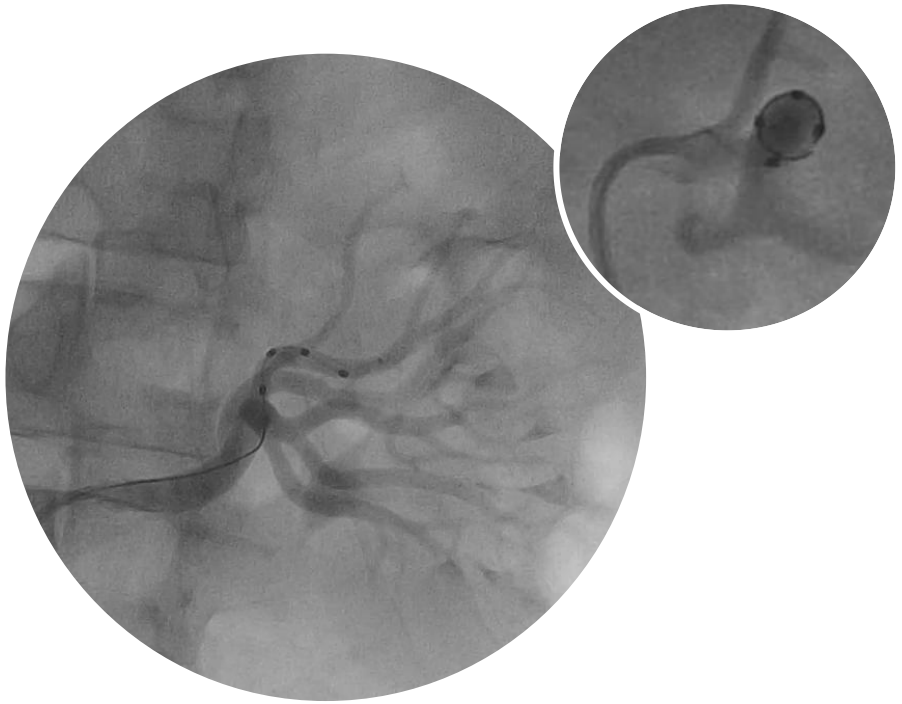
*>4000 **patients** in 4 sham-controlled RCT's and real-world evidence*

SPYRAL HTN-OFF MED Pilot[1]
(2017)

SPYRAL HTN-ON MED Pilot[2]
(2018)

SPYRAL HTN-OFF MED Pivotal[3]
(2020)

SPYRAL HTN ON MED Full Cohort[4]
(2023)



Global SYMPLICITY Registry (GSR)/GSR DEFINE[5,6]

[1] Townsend, et al. Lancet. 2017;390:2160-2170.
[2] Kandzari DE, et al. Lancet. 2018;391:2346-2355.
[3] Böhm M, et al. Lancet. 2020;395:1444-145.

[4] Kandzari DE, et al. J Am Coll Cardiol. 2023;82:1809–1823 .
[5] Mahfoud F, et al. Outcomes following radiofrequency renal denervation according to antihypertensive medications: subgroup analysis of the Global SYMPLICITY Registry DEFINE. EuroPCR 2023.
[6] Data includes both Symplicity Flex and Symplicity Spyral catheters.

Definición de alto riesgo cardiovascular

GSR DEFINE analysis

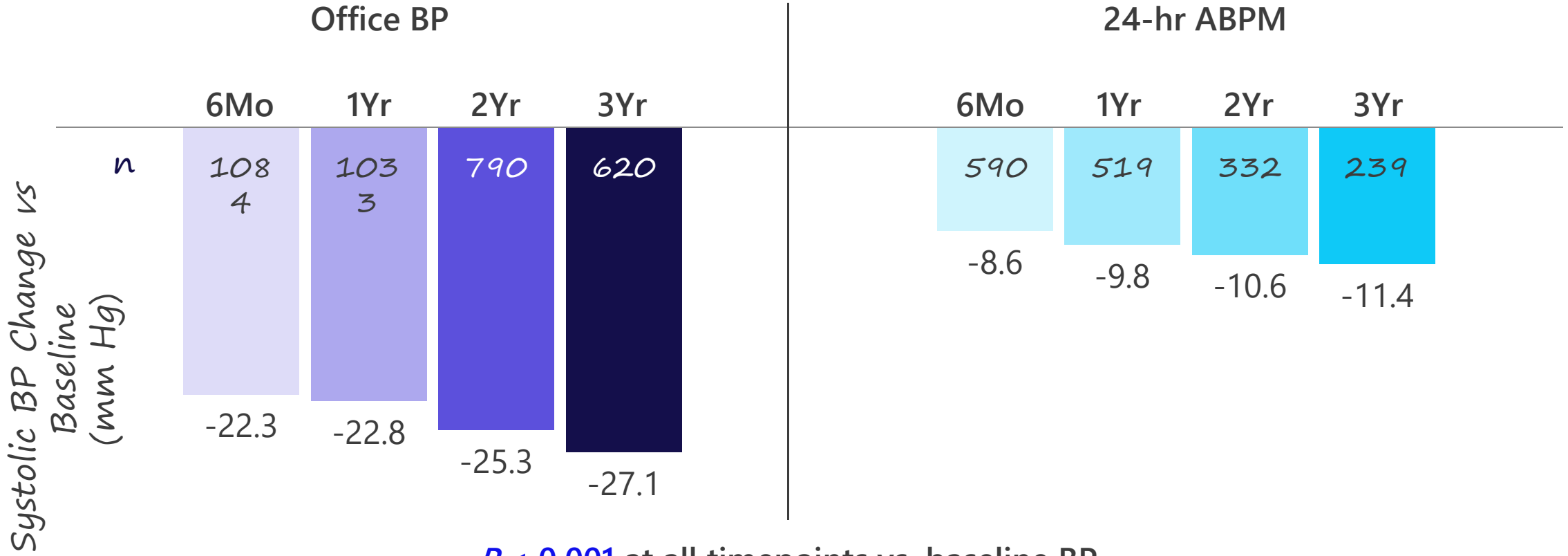
Other risk factors: - eGFR<60 - Diabetes mellitus - Hypercholesterolemia - Previous MI - Left ventricular hypertrophy - Previous stroke	Hypertension grading (office BP, mmHg)			
	High normal SBP ≥130 or DBP ≥ 85	*Grade 1* SBP ≥140 or DBP ≥ 90	*Grade 2* SBP ≥160 or DBP ≥ 100	*Grade 3* SBP ≥180 or DBP ≥ 110
None				X
≥ 2			X	X
≥ 3		X	X	X
CKD (eGFR<60) and / or diabetes mellitus	X	X	X	X

Rodriguez et al. ESC 2022.
Adapted from Williams B, et al. *Eur Heart J.* 2018;39:3021–3104; based on available data collected in GSR.

GSR data is conducted outside of the US and data includes both Symplicity Flex and Symplicity Spyral catheters

Sustained BP reductions through 3 years in higher CV risk patients

GSR DEFINE



P **< 0.001 at all timepoints vs. baseline BP**

Baseline BP **180** ± 23 mmHg

Baseline BP **160** ± 19 mmHg

Rodriguez et al. ESC 2022.

Note: patient numbers reflect who had completed follow-up at the time of analysis.

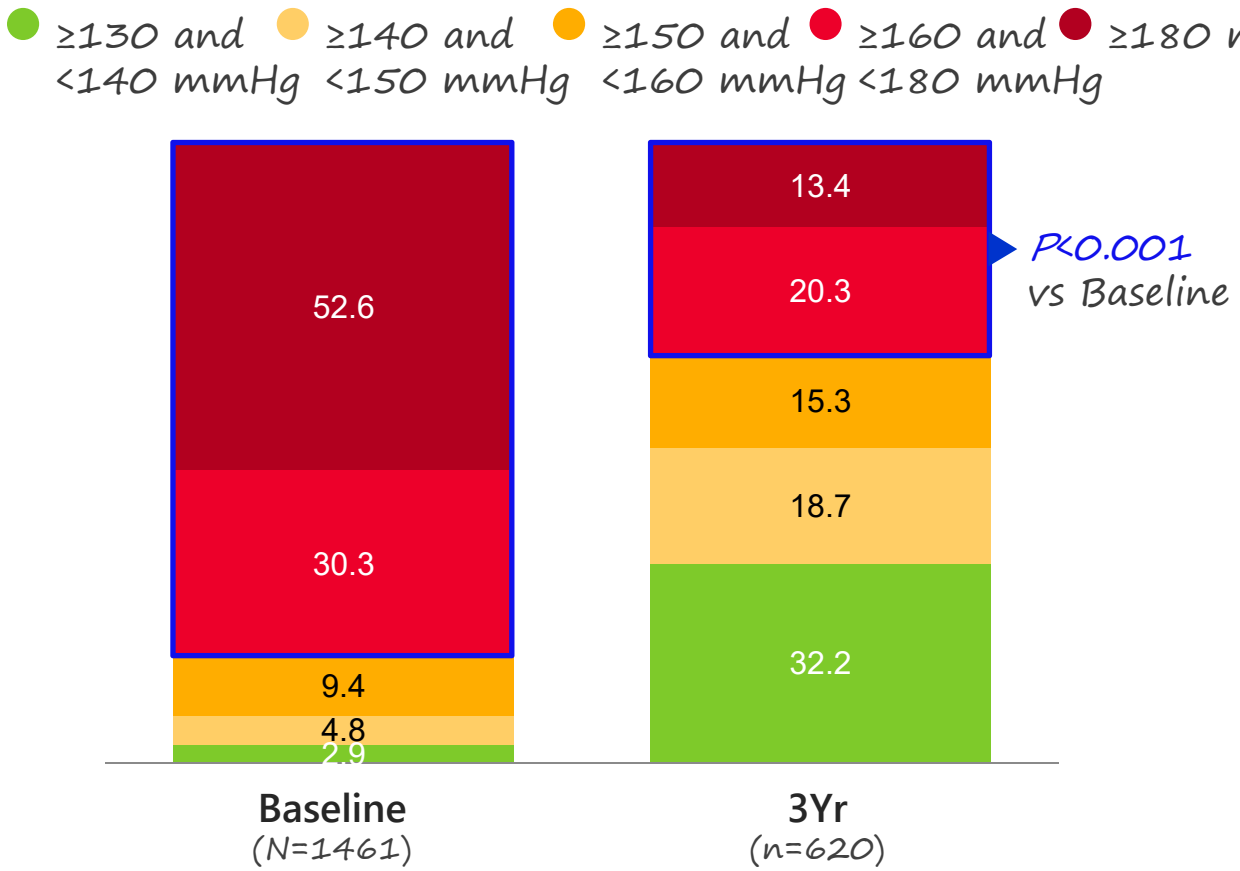
Kandzari et al. Circ Cardiovasc Qual Outcomes. 2023;16:e008997. DOI: 10.1161/CIRCOUTCOMES.122.008997

GSR data is conducted outside of the US and data includes both Symplicity Flex and Symplicity Spyral catheters

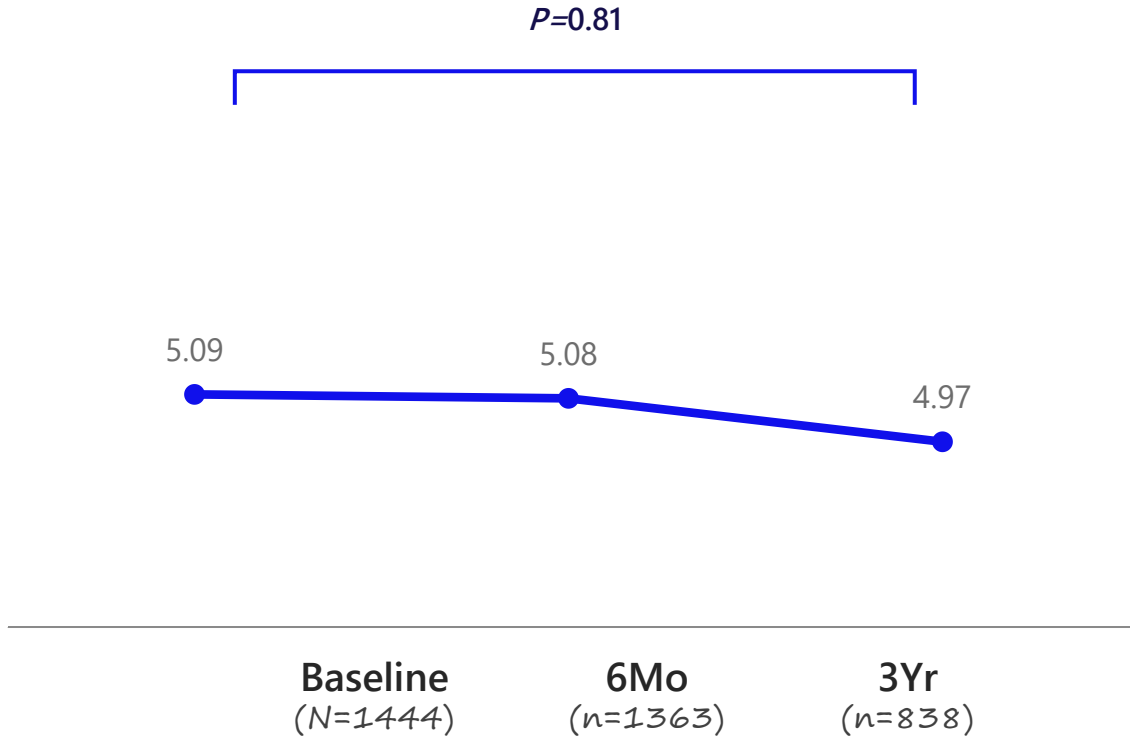
BP distribution in higher CV risk patients in GSR DEFINE

Independent of number of medications

Office Systolic BP Distribution
(% Patients)



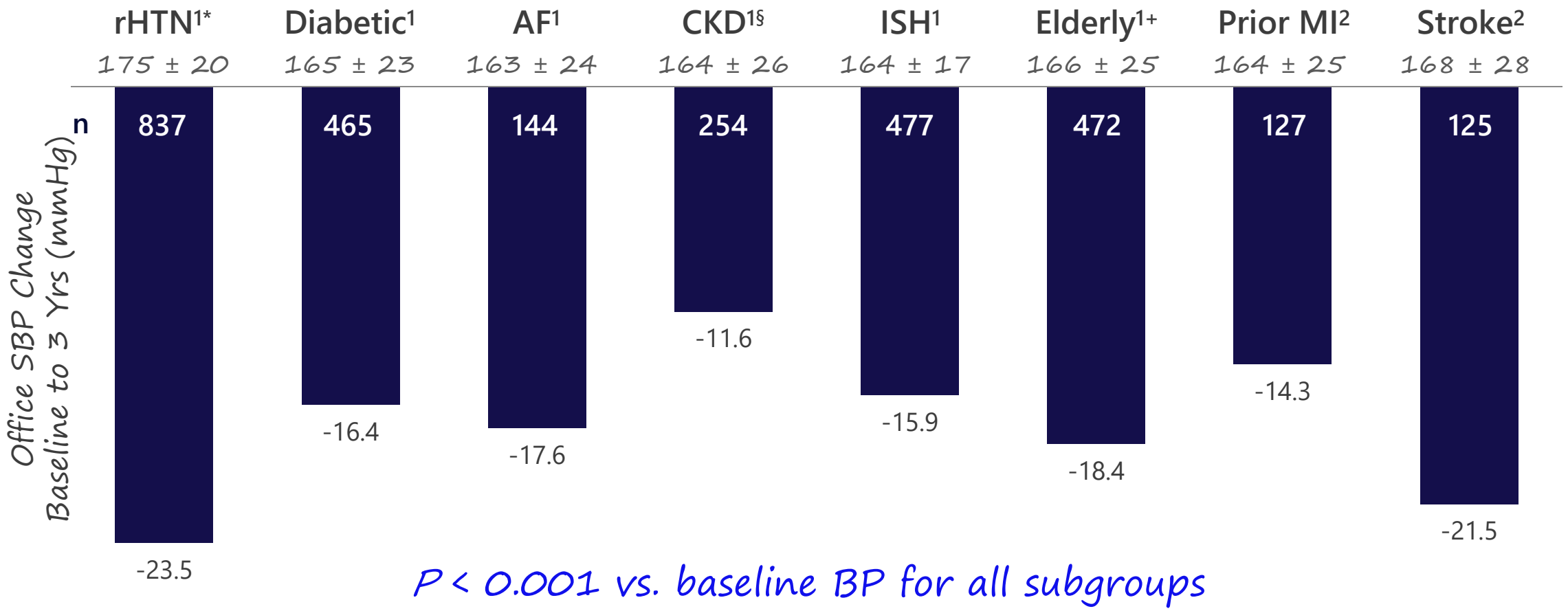
Anti-HTN Medications
(mean number)



Rodriguez et al. ESC 2022.
Note: patient numbers reflect who had completed follow-up at the time of analysis.
GSR data is conducted outside of the US and data includes both Symplicity Flex and Symplicity Spyral catheters

RDN reduced BP in a variety of patient subgroups

Office SBP reductions at 3 years in GSR DEFINE



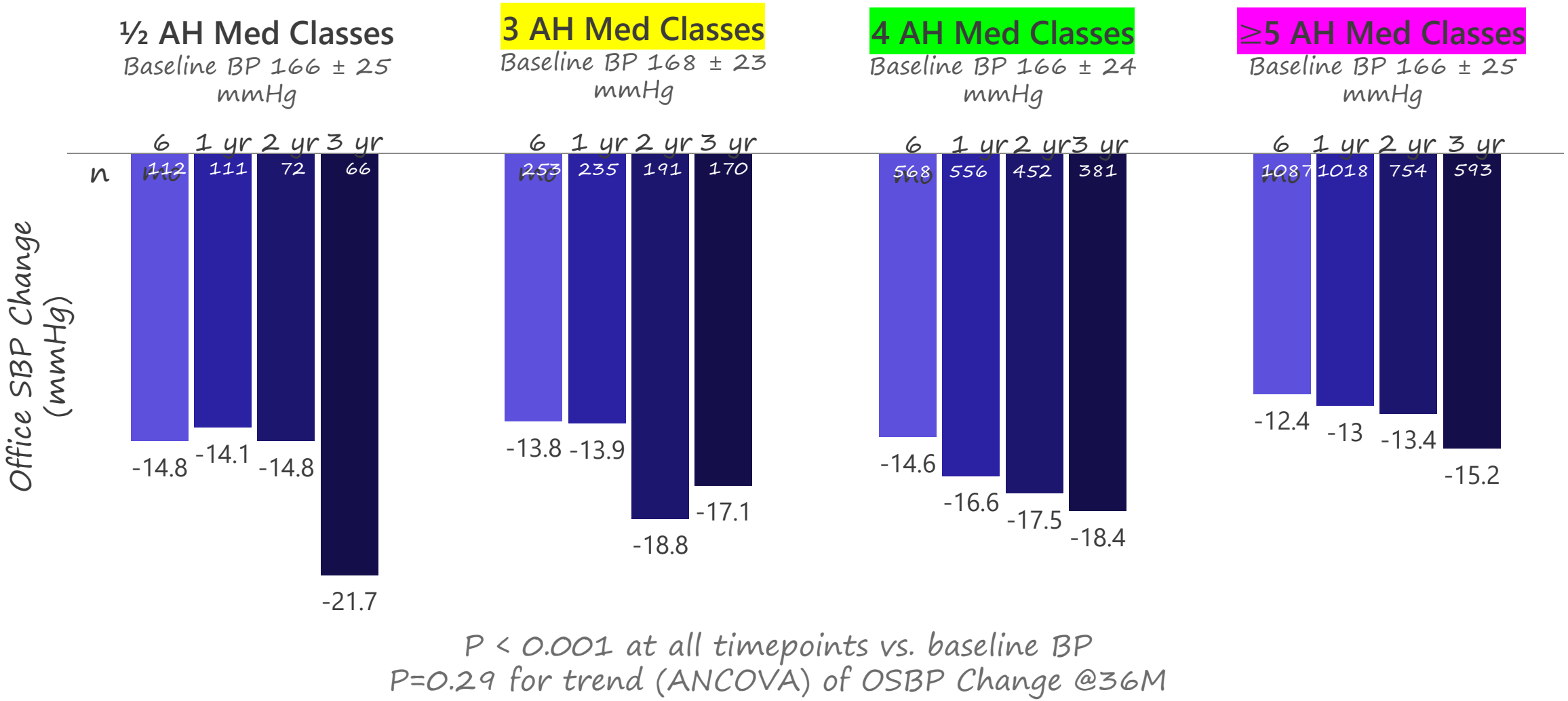
P < 0.001 vs. baseline BP for all subgroups

[1] Mahfoud F, et al. *J Am Coll Cardiol*. 2020;75:2879-2888.
[2] Mahfoud F, et al. ESH 2022.
* Resistant hypertension defined as OSBP>150 mmHg, ≥3 anti-hypertensive medications
§ CKD defined as eGFR <60ml/min/1.73m^2.
+ Elderly defined as ≥ 65 years old

GSR data is conducted outside of the US and data includes both Symplicity Flex and Symplicity Spyral catheters

BP reductions observed regardless of baseline medication classes

OSBP change by number of anti-hypertensive (AH) medications in GSR DEFINE



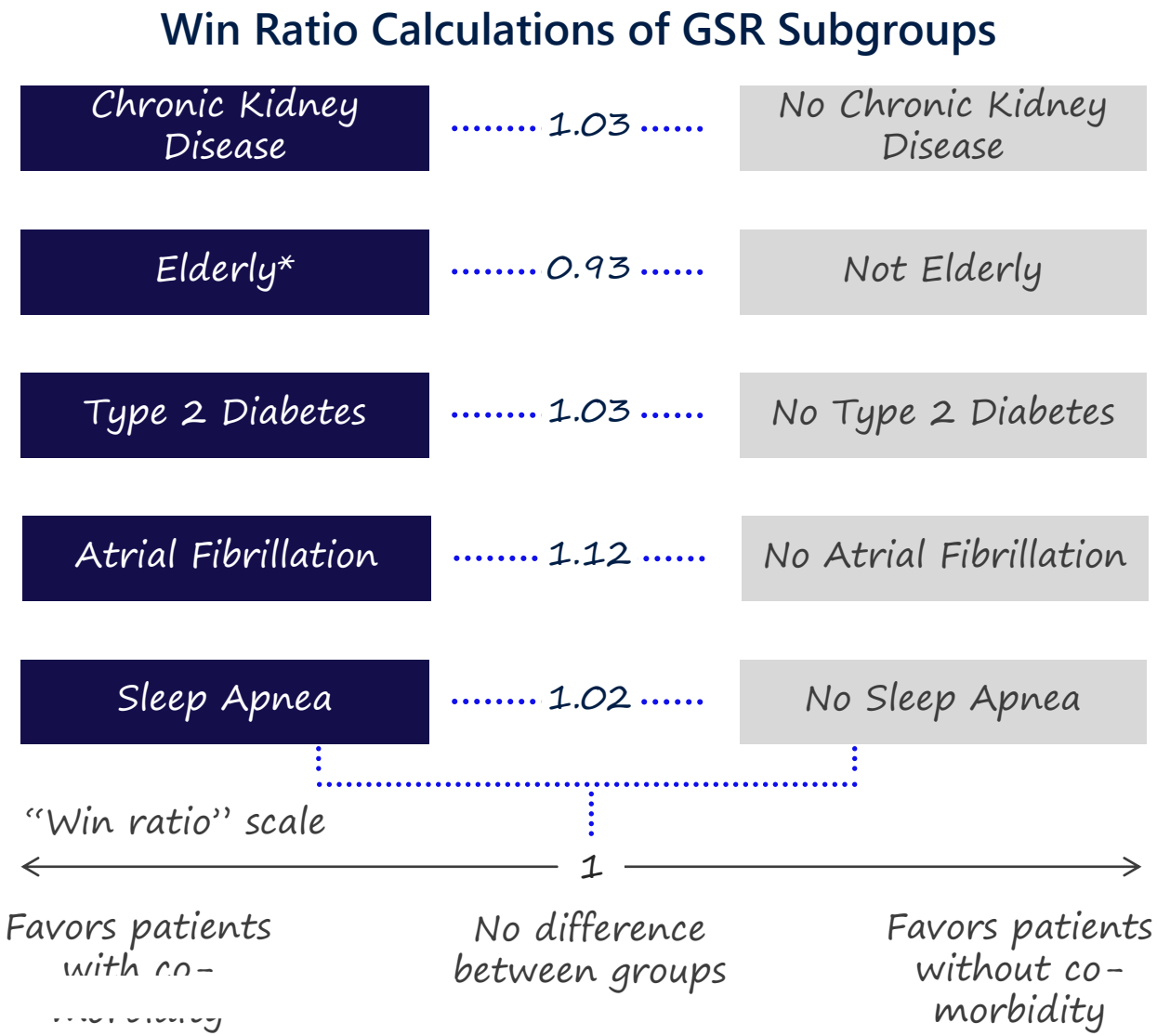
P < 0.001 at all timepoints vs. baseline BP
P=0.29 for trend (ANCOVA) of OSBP Change @36M

Mahfoud F, et al. PCR e-Course 2020.

GSR data is conducted outside of the US ad data includes both Symplicity Flex and Symplicity Spyral catheters

RDN benefits patients with or without multiple co-morbidities

Win ratio analysis of GSR DEFINE



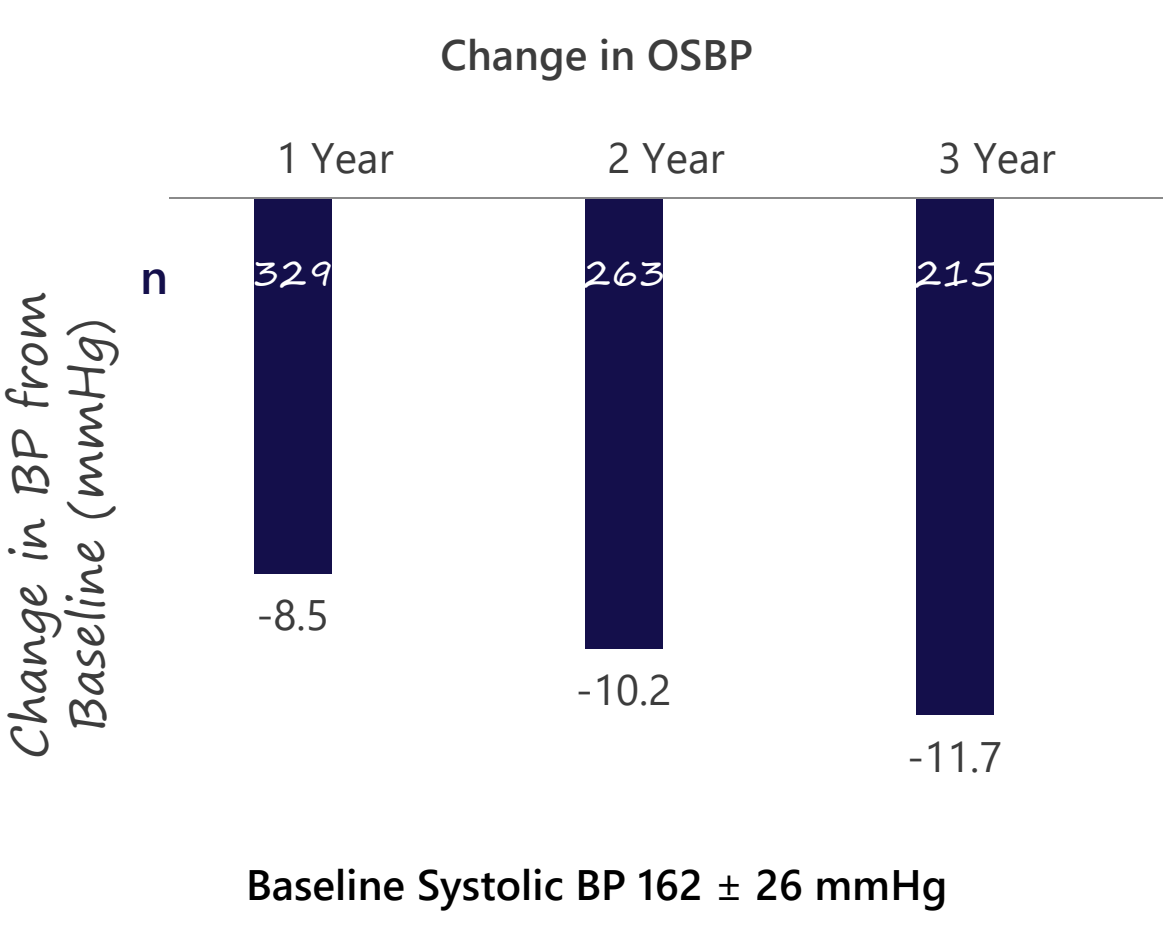
* Elderly ≥65 years.

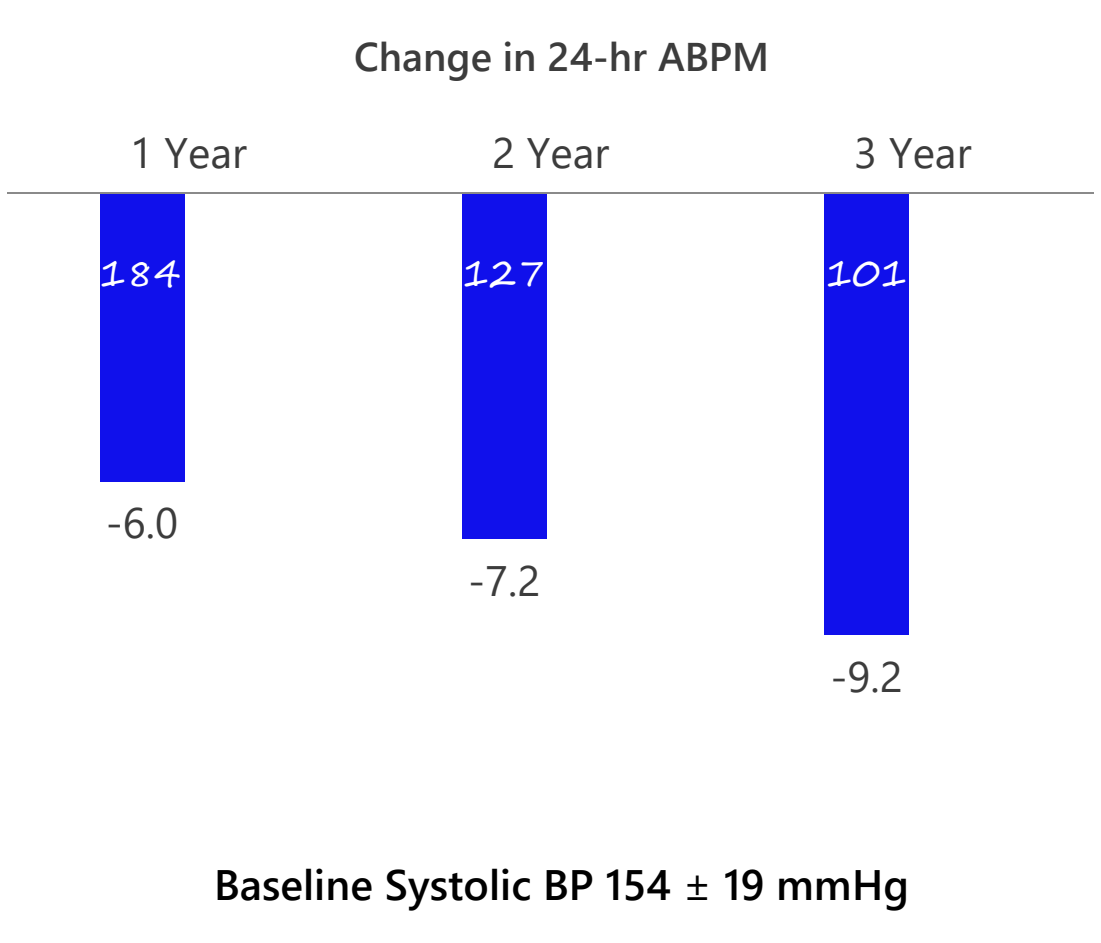
[1] Mahfoud F, et al. EuroPCR 2021.

[2] Mahfoud F, et al. ESC 2021.

BP reductions observed in CKD (eGFR<60) following RF RDN

Global SYMPLICITY registry (GSR) DEFINE results out to 3 years



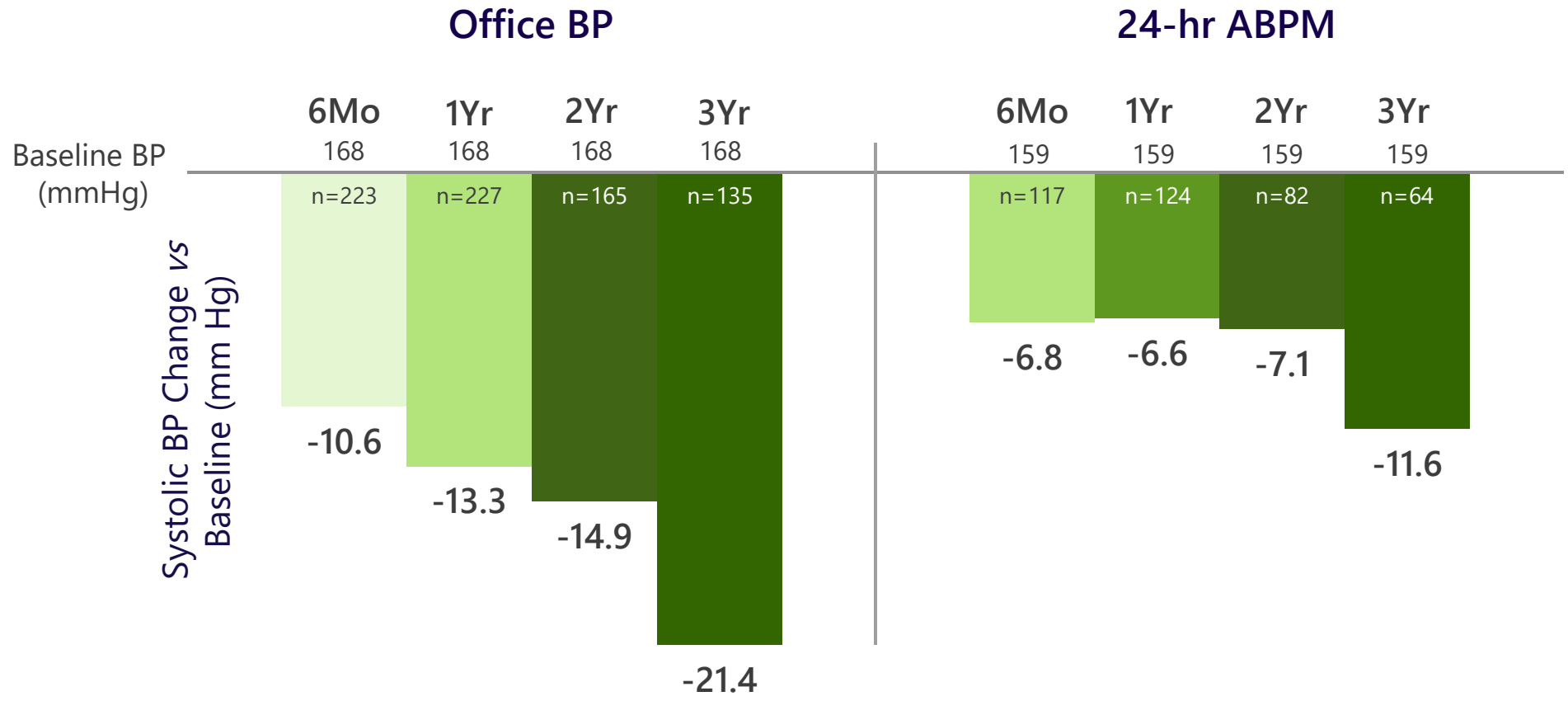


P < 0.001 at all timepoints vs. baseline BP

Ott C, et al. *Nephrol Dial Transplant*. 2022;37(2):304-310.

Stroke patients had sustained long-term BP reductions after RDN

GSR DEFINE systolic BP reductions through 3 years



Schlaich et al. ESH 2025.

P < 0.0001 at all timepoints vs. baseline BP

Recommendations in 2018 version	Class[a]	Level[b]	Recommendations in 2024 version	Class[a]	Level[b]
Use of device-based therapies is not recommended for the routine treatment of hypertension, unless in the context of clinical studies and RCTs, until further evidence regarding their safety and efficacy becomes available.	III	B	To reduce BP, and if performed at a medium-to-high volume centre, catheter-based renal denervation may be considered for resistant hypertension patients who have BP that is uncontrolled despite a three BP-lowering drug combination (including a thiazide or thiazide-like diuretic), and who express a preference to undergo renal denervation after a shared risk-benefit discussion and multidisciplinary assessment.	IIb	B
			To reduce BP, and if performed at a medium-to-high volume centre, catheter-based renal denervation may be considered for patients with both increased CVD risk and uncontrolled hypertension on fewer than three drugs, if they express a preference to undergo renal denervation after a shared risk-benefit discussion and multidisciplinary assessment.	IIb	A
			Due to a lack of adequately powered outcomes trials demonstrating its safety and CVD benefits, renal denervation is not recommended as a first-line BP-lowering intervention for hypertension.	III	C
			Renal denervation is not recommended for treating hypertension in patients with moderately to severely impaired renal function (eGFR <40 mL/min/1.73 m^2) or secondary causes of hypertension, until further evidence becomes available.	III	C

2024 ESC Guidelines for the management of elevated blood pressure and hypertension