

# Three-year safety and efficacy in the Global Symlicity Registry: Impact of anti-hypertensive medication burden on blood pressure reduction

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## Potential conflicts of interest

**Speaker's name : Felix Mahfoud**

I have the following potential conflicts of interest to declare:

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Global SYMPPLICITY  
Registry

## Why this study?

- The Global SYMPPLICITY Registry (GSR) documents the long-term safety and effectiveness of the Symplicity™ renal denervation (RDN) system in a real-world patient population with uncontrolled hypertension
- The registry has enrolled to date >2860 patients treated with RDN and includes 3-yr follow-up for >2500 patients
- RDN has been proposed for application in patients prescribed multiple antihypertensive drug classes
- Therefore, we evaluated the impact of medication burden on BP lowering effect of RDN



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# GSR Clinical Trial Design

**Prospective, open-label, single-arm, multi-center, all-comer observational study**

**3000 consecutive patients with uncontrolled hypertension or other conditions associated with increased sympathetic activity treated with Symplicity™ (Flex or Spyral) RDN system**

Follow-up	3Mo	6Mo	1Yr	2Yr	3Yr
<i>FU available to date:</i>					
Pts treated with Symplicity Flex™		2231	2226	2211	2207
Pts treated with Symplicity Spyral™		516	472	381	323
<b>Total</b>		<b>2747</b>	<b>2698</b>	<b>2592</b>	<b>2530</b>

NCT01534299

Böhm M, Hypertension 2015



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## Baseline Patient Information

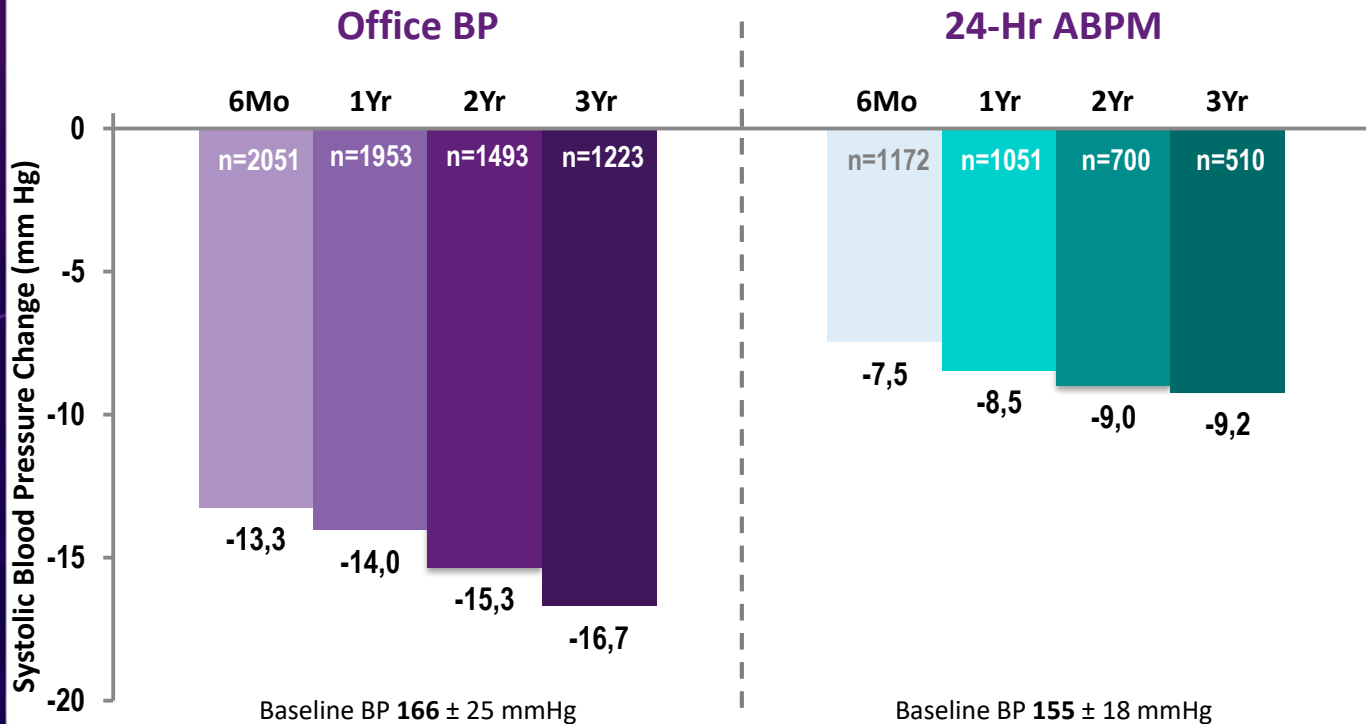
% or mean $\pm$ SD	All patients (N=2747)
Age (years)	61 $\pm$ 12
Male gender	57.9
History of cardiac disease	47.0
Atrial fibrillation	12.3
Diabetes, type 2	38.2
CKD (eGFR $<$ 60ml/min/1.73m <sup>2</sup> )	20.7
Obstructive sleep apnea	11.4
Current smoking	9.8
Office systolic BP (mmHg)	166 $\pm$ 25
24-Hr systolic BP (mmHg)	155 $\pm$ 18
Number of anti-HTN medication classes	4.6 $\pm$ 1.4



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# Blood Pressure Reduction Over 3 Years



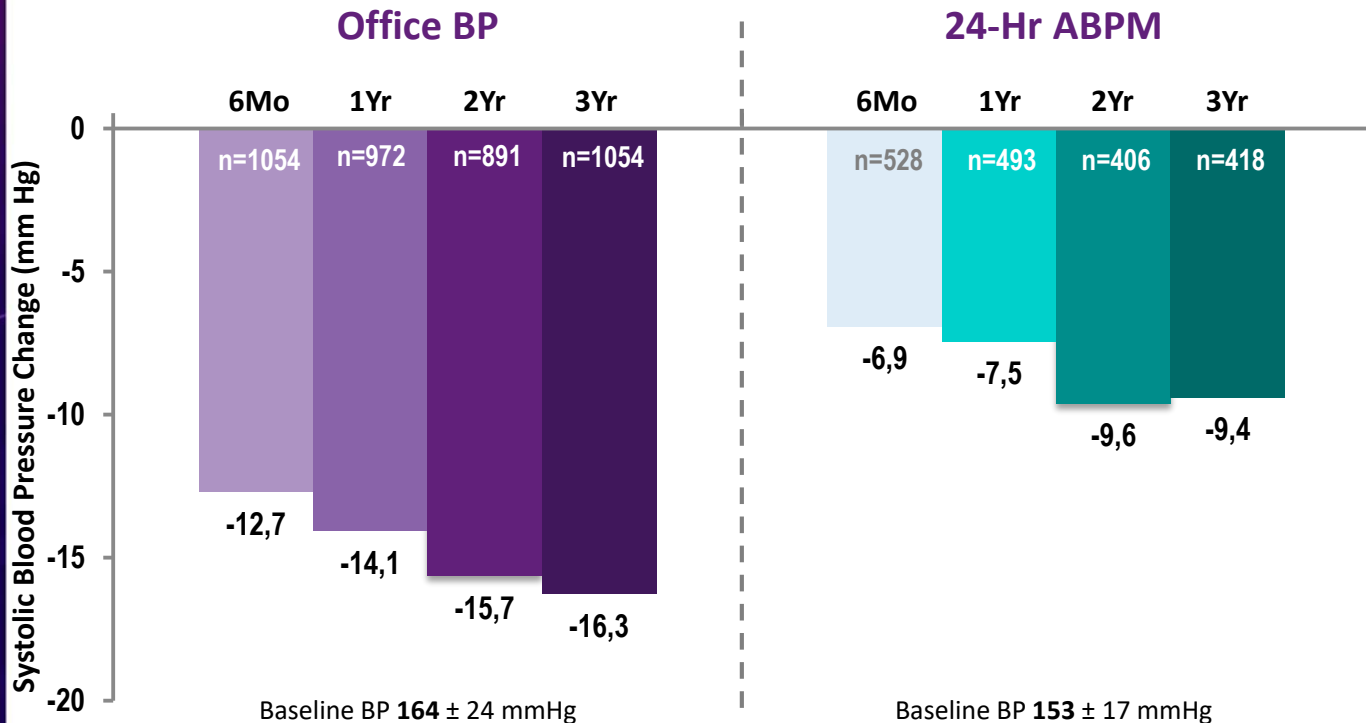
**$P < 0.001$  at all timepoints vs. baseline BP**



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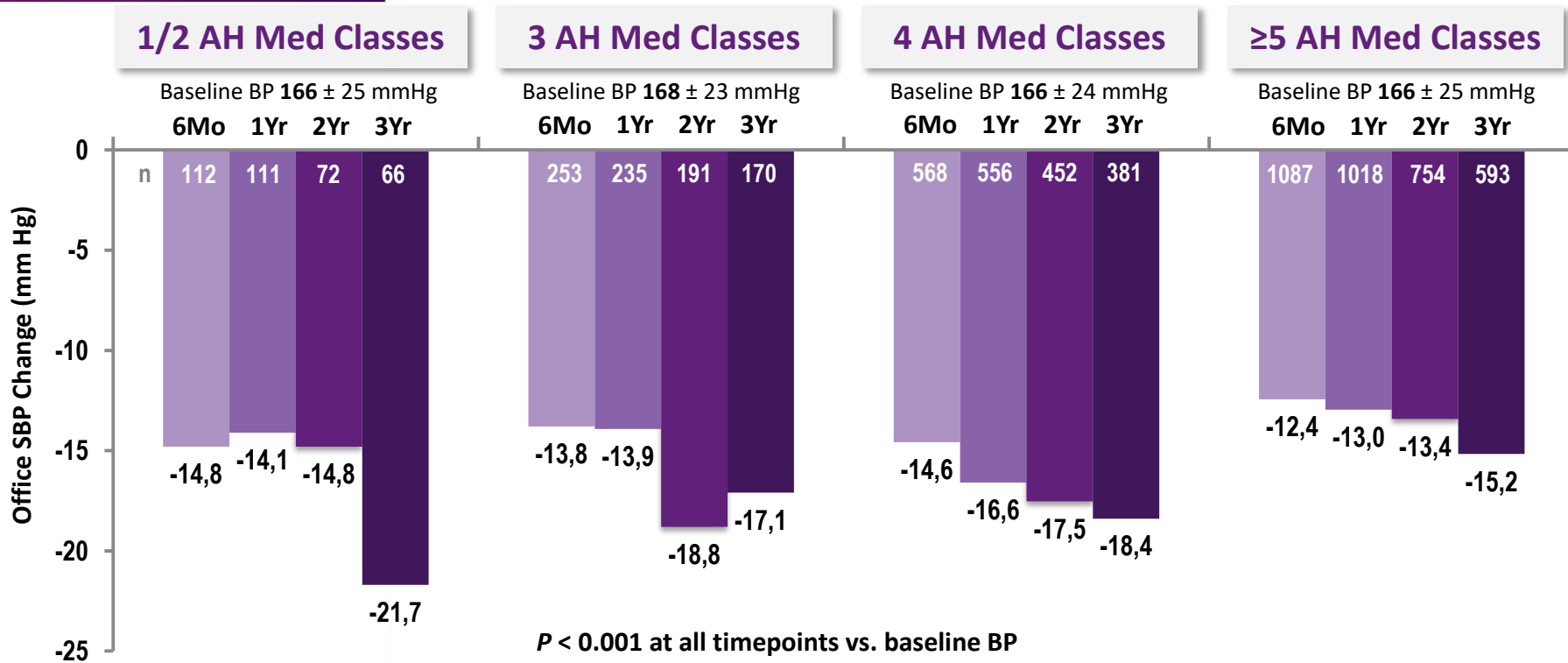
## Blood Pressure Reduction (Matched Patients)



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

Matched analysis based on patients with baseline, 6-month and 3-year Office BP measurements.

# OSBP Change by Number of Medications



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



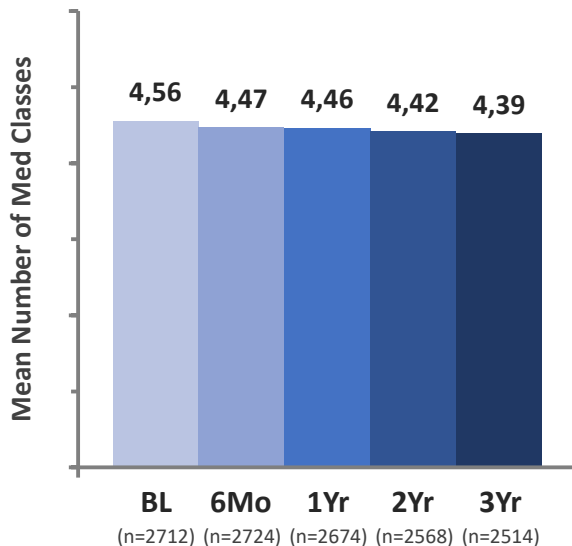
# BP Reduction Independent of Medications



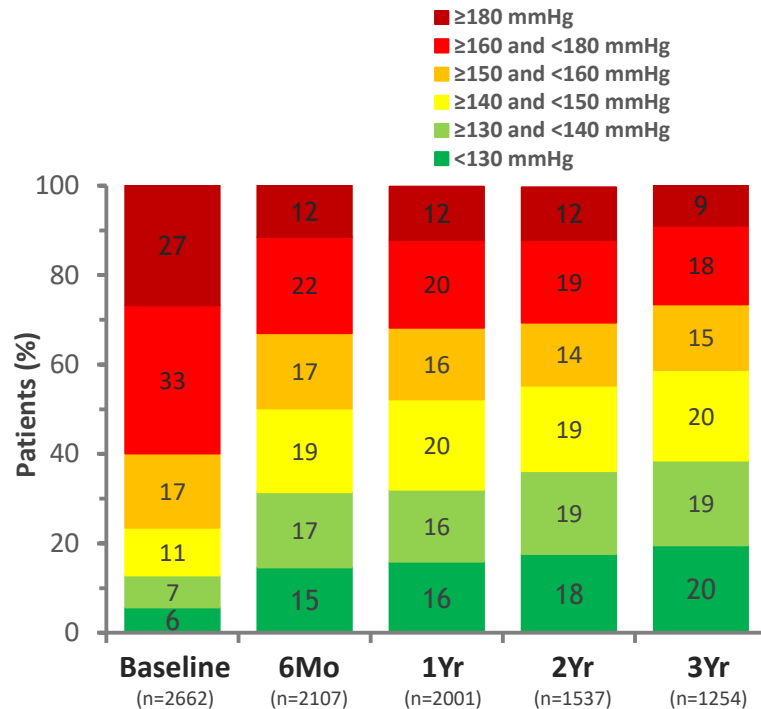
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## Number of Medications



## Office Systolic BP Distribution





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## Safety Events at 3 Years

<b>%</b>	<b>All patients (n=1784)</b>
<b>Death</b>	<b>5.5</b>
<b>Cardiovascular death</b>	<b>2.9</b>
<b>Myocardial infarction</b>	<b>2.5</b>
<b>Stroke</b>	<b>4.5</b>
<b>End-stage renal disease</b>	<b>1.8</b>
<b>Creatinine elevation &gt;50%</b>	<b>1.4</b>
<b>New renal artery stenosis &gt;70%</b>	<b>0.3</b>
<b>Hospitalization for new onset heart failure</b>	<b>4.0</b>
<b>Hospitalization for AF</b>	<b>3.5</b>
<b>Hospitalization for HTN crisis</b>	<b>3.1</b>



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## Conclusions

- The Global SYMPPLICITY Registry is the **largest real-world study** of renal denervation therapy and has enrolled over 2860 patients to date
- GSR continued to show **excellent safety** of the Symplicity™ RDN system, with only 0.3% renal artery stenosis and other clinical event rates within the expected range for hypertensive patients
- RDN decreased blood pressure **independent of baseline antihypertensive medication burden** and without increasing medication burden over time
- RDN resulted in **significant and clinically meaningful reductions** in both office and 24-hr blood pressure that were sustained out to 3 years post-procedure, demonstrating the **durability** of RDN



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