

Long-term safety and efficacy of renal denervation in the Global SYMPPLICITY Registry using the Symplicity Spyral catheter

Tzung-Dau Wang, MD, PhD*, Markus Schlaich, MD, Felix Mahfoud, MD, Bryan Williams, MD, Luis Ruilope, MD, PhD, Krzysztof Narkiewicz, MD, PhD, Martin Fahy, MS, Giuseppe Mancina, MD, PhD, Michael Böhm, MD

***Cardiovascular Center and Divisions of Cardiology/Hospital Medicine, Dept of Internal Medicine, National Taiwan University Hospital and National Taiwan University College of Medicine, Taipei City, Taiwan**

Disclosure

- Within the past 12 months, I, Tzung-Dau Wang or my spouse/partner, have had a financial interest/arrangement or affiliation with Omron and Medtronic.

Background

- Catheter-based renal denervation (RDN) therapy targets overactivity of the sympathetic nervous system to treat hypertension.
- Results from recent randomized sham-controlled clinical trials¹⁻³ have demonstrated the safety and efficacy of RDN.
- Long-term safety and durability of the procedure in real-world patients is important for clinical implementation.
- The **Global SYMPPLICITY Registry** is the largest collection of real-world patients treated with **radiofrequency RDN** for uncontrolled hypertension documenting data on long-term safety and effectiveness of the Symplicity™ RDN system.

¹ Townsend RR, et al. *Lancet*. 2017;390:2160-70.

² Kandzari DE, et al. *Lancet*. 2018;391:2346-55.

³ Böhm M, et al. *Lancet*. 2020;395:1444-51.

Global SYMPPLICITY Registry Clinical Trial Design

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

3,000 consecutive patients with uncontrolled hypertension
or other conditions associated with increased sympathetic activity treated with
the Symplicity™ (Flex or Spyral) RDN system

Follow-up visits:	3Mo	6Mo	1Yr	2Yr	3Yr
Pts treated with Symplicity Flex™	2231	2226	2211	2207	
Pts treated with Symplicity Spyral™	641	595	470	383	
Follow-up eligible to date:	2872	2821	2681	2590	

Focus of current
analysis

Global SYMPLICITY Registry

Baseline Patient Characteristics

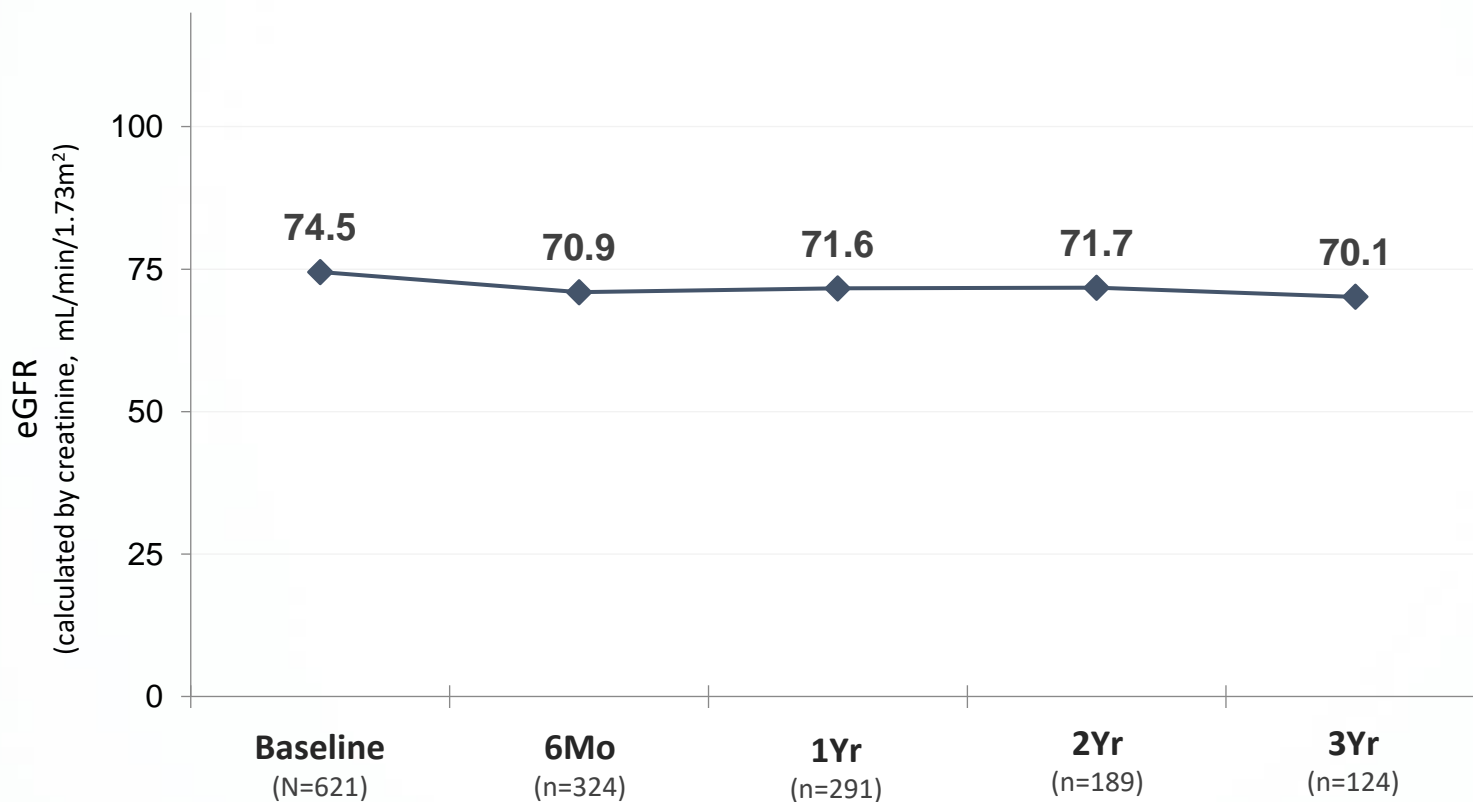
% or mean \pm SD	All patients N = 2,872	Spyral Patients N = 641
Age (years)	61 \pm 12	61 \pm 12
Male gender	57.8	56.9
History of cardiac disease	47.0	42.5
Atrial fibrillation	12.4	11.4
Diabetes, type 2	37.8	37.2
CKD ¹	20.5	19.1
Obstructive sleep apnea	11.1	12.9
Current smoking	9.9	9.8
Office systolic BP (mmHg)	166 \pm 25	168 \pm 25
24-Hr systolic BP (mmHg)	154 \pm 19	156 \pm 20
Number of AH meds	4.6 \pm 1.4	4.6 \pm 1.5

¹ Chronic Kidney Disease (CKD) defined as eGFR <60ml/min/1.73m².

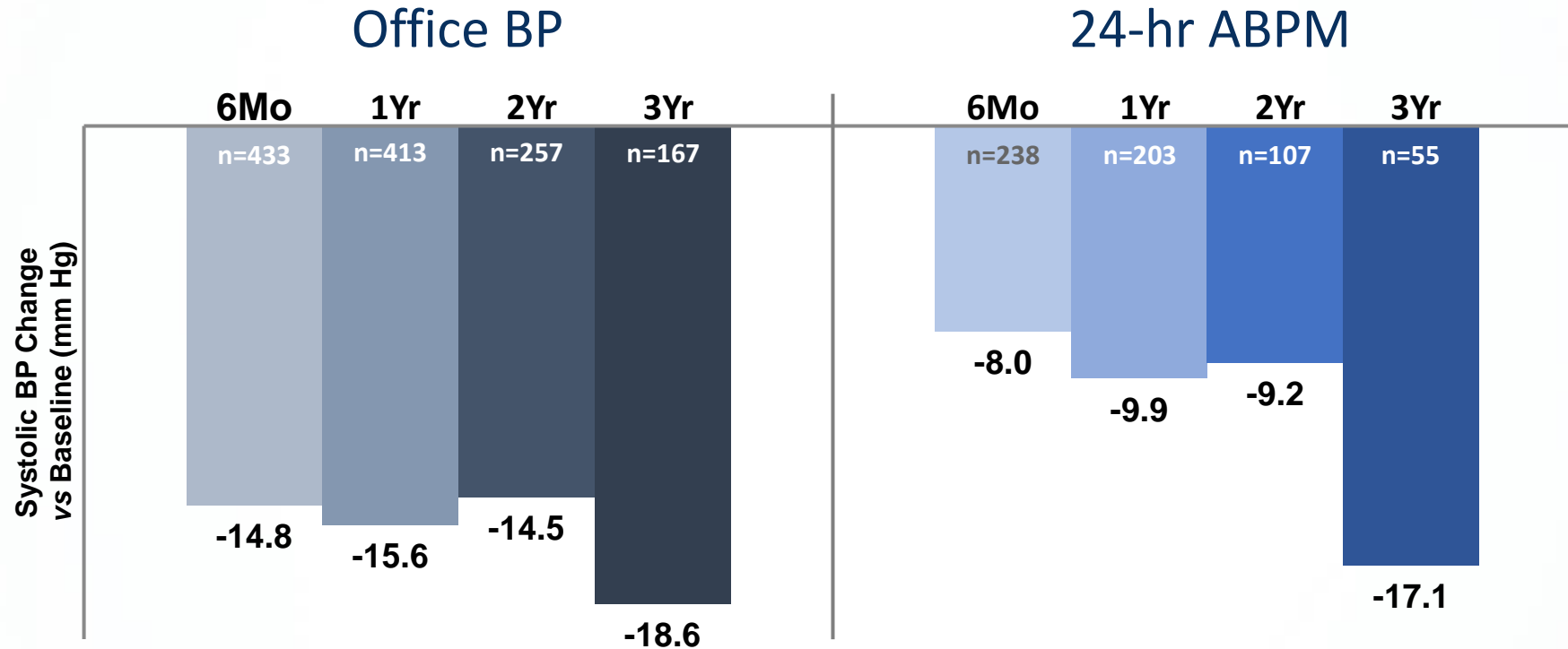
Global SYMPLICITY Registry: Spyral Patients Safety Results

%	6 Months (n=592)	1 Year (n=543)	2 Year (n=367)	3 Year (n=249)
Death	0.3	1.1	4.6	6.0
Cardiovascular death	0.0	0.6	1.6	1.6
Myocardial infarction	0.0	0.0	0.5	0.8
Stroke	1.4	2.0	4.1	6.8
End-stage renal disease	0.2	0.6	1.4	2.4
Creatinine elevation >50%	0.0	0.0	0.0	0.0
New renal artery stenosis >70%	0.0	0.0	0.0	0.0
Hospitalization for new onset heart failure	1.0	1.3	3.0	5.2
Hospitalization for AF	0.2	0.4	1.1	2.4
Hospitalization for HTN crisis	1.2	1.7	2.5	4.0

Global SYMPLICITY Registry: Spyral Patients Stable Renal Function



Global SYMPLICITY Registry: Spyral Patients Sustained Blood Pressure Reduction



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

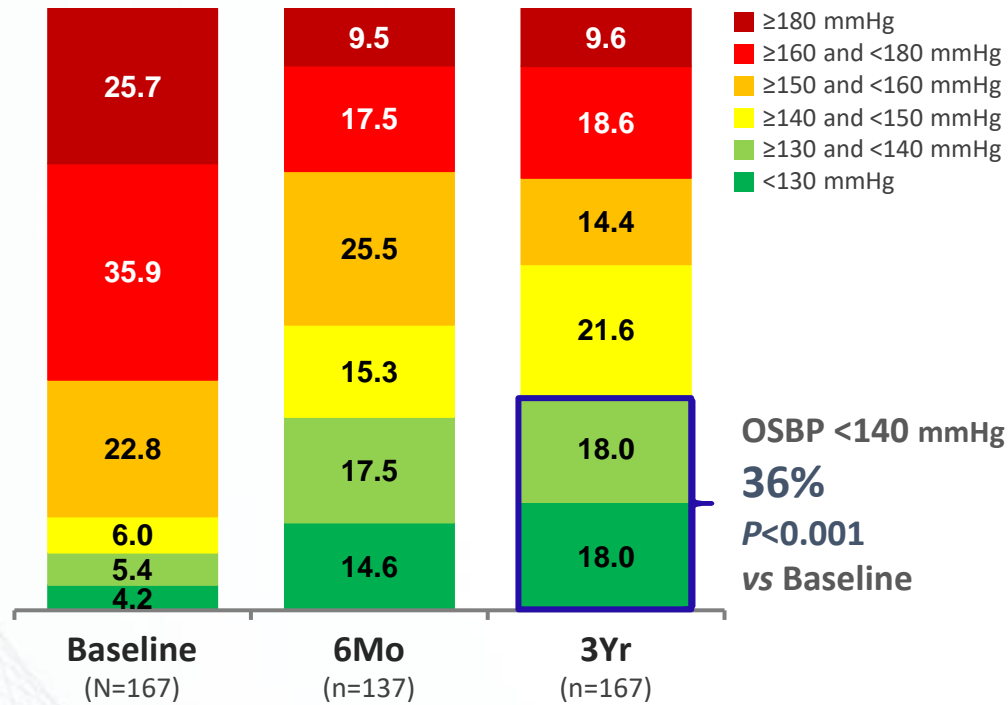
Baseline BP **168** ± 25 mmHg

Baseline BP **156** ± 20 mmHg

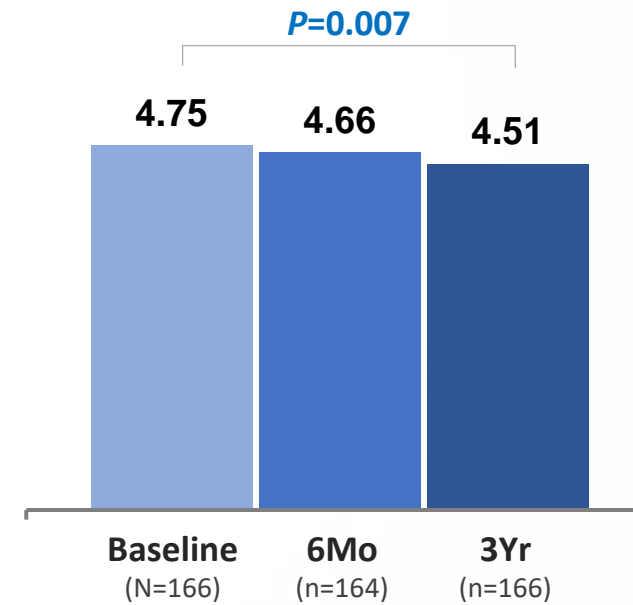
Note: patient numbers reflect who had completed follow-up at the time of analysis.

Global SYMPLICITY Registry: Spyral Patients BP Reduction Independent of Medications

Office Systolic BP Distribution
(% Patients)



Mean Number of Medications



Among 167 matched patients, 36% of patients achieved BP under control independent of medications: the mean number of med classes reduced from 4.75 at baseline (n=166) to 4.51 at 3 years (n=166, *P*=0.007).

Conclusions

Patients treated in Global SYMPLICITY Registry using the latest generation Symplicity Spyral RDN system:

- Represented a **broad, real-world population** including patients with multiple co-morbidities
- **No** short- or long-term **safety concerns** following RDN have been observed
 - No instances of renal artery stenosis or re-intervention
 - Renal function changes within the expected range for hypertensive patients
- **Clinically significant “always on” reductions** in Office and 24-hour BP that were **sustained** over 3 years without increase in number of medications