used in patients with complex lesions. The objective of the Comparison of Everolimus- and Biolimus-Eluting Stents With Everolimus-Eluting Bioresorbable Vascular Scaffold Stent trial [EVERBIO II; NCT01711931], presented by Stéphane Cook, MD, University of Fribourg, Fribourg, Switzerland, was to compare the efficacy of the BVS with the best-in-class new generation DESs—the everolimus-eluting stent (EES PROMUS ELEMENT) and biolimus-eluting stent (BES BIOMATRIX FLEX).

Patients with stable coronary artery disease (CAD) or acute coronary syndrome (ACS) undergoing percutaneous intervention (PCI) were randomized to the EES (n = 80), BES (n = 80), or BVS (n = 78). Clinical follow-up took place at 1, 6, 9, and 12 months and 2 and 5 years, with angiography at 9 months. The primary end point was in-stent late lumen loss (LLL) at 9 months. Secondary end points were in-segment LLL, patient-oriented major acute cardiac events (MACE; death, myocardial infarction [MI], and target vessel revascularization [TVR]), device-oriented MACE (cardiac death, MI, and target lesion revascularization), and stent thrombosis.

There were no significant differences in baseline characteristics between the 3 groups. No significant difference was observed in the cumulative frequency of in-stent LLL between the EES and BES groups combined (EES/BVS; 0.25 ± 0.36 mm) and the BVS group (0.28 ± 0.39 mm; $P = .30$). At nine months, there was no significant difference in the cumulative frequency of in-stent LLL between the EES (0.24 ± 0.32 mm), BES (0.25 ± 0.41 mm), and BVS (0.28 ± 0.39 mm) groups.

Stratified analysis found no significant differences in in-stent LLL between the EES/BES and BVS groups in patients with or without diabetes, ACS, or complex lesions.

In-segment LLL was significantly more frequent with the BVS (0.30 ± 0.44 mm) vs the EES/BES (0.19 ± 0.42 mm; $P = .03$). Stratified analysis found no significant differences in in-segment LLL between the EES/BES and BVS groups in patients with or without diabetes, ACS, or complex lesions.

There were no significant differences in dual antiplatelet therapy (DAPT) use in the EES/BES vs BVS, EES vs BVS, and BES vs BVS groups. No significant differences were observed in clinical outcomes at 9 months, including device-oriented MACE, patient-oriented MACE, TVR, and stent thrombosis, in the EES/BES vs BVS, EES vs BVS, and BES vs BVS groups.

This study had several limitations. It was not powered for noninferiority or to detect differences in clinical event rates. The study was performed in a single center with uniform procedural strategies that limit generalizations to other centers. Additionally, the investigators did not address the effect of the BVS on thrombotic risk.

In a patient population with minimal exclusion criteria and using LLL as an early and robust marker for restenosis, the BVS demonstrated satisfactory angiographic and clinical outcomes compared with the EES/BES. In-segment LLL was slightly but significantly higher with the BVS compared with the EES/BES. A possible explanation for this difference may be the modest and transient constrictive effect at the scaffold edges [Gogas B et al. *JACC Cardiovasc Interv.* 2012]. These results reinforce the authors' primary hypothesis of DES superiority within 6 to 12 months. The optimal DAPT duration after BVS implantation is not known.

Similar 12-Month BP Reductions With Renal Denervation and Sham Procedure

Written by Toni Rizzo

The Renal Denervation in Patients With Uncontrolled Hypertension trial [SYMPLICITY HTN-3; NCT01418261] was the first randomized, blinded, sham-controlled clinical trial of renal denervation for treatment-resistant hypertension. The 6-month results confirmed the safety of renal denervation but the primary efficacy end point was not met [Bhatt DL et al. *N Engl J Med.* 2014]. In addition to the blinding and sham control, post hoc analyses have identified potential factors that may account for the negative results, including the patient population and procedural variability. Deepak L. Bhatt, MD, MPH, Brigham and Women's Hospital, Boston, Massachusetts, USA, presented the 12-month post hoc analysis of the SYMPLICITY HTN-3 trial.

After 2 screening visits, potential subjects with refractory hypertension underwent renal angiogram and eligible patients were randomized to renal denervation (n = 364) or a sham procedure (n = 171) [Bhatt DL et al. *N Engl J Med.* 2014]. Medication changes were not permitted for 6 months. The primary efficacy end point of office systolic BP (SBP) at 6 months was significantly reduced from baseline in the denervation (n = 353; $P < .001$) and sham (n = 171; $P < .001$) groups but was not significantly different between the 2 groups ($P = .26$).

All clinicians and patients were unblinded to randomization after the 6-month evaluation. Sham control patients were permitted to crossover to renal denervation following the 6-month primary assessment if they continued to meet the study inclusion criteria. Study follow-up will continue for up to 5 years.

A total of 322 patients (91%) in the denervation group completed the 12-month postdenervation follow-up.

Among the sham patients, 101 crossed over to renal denervation; of these, 93 (96.9%) completed the 12-month postdenervation follow-up. A total of 48 sham patients (77%) completed the 12-month follow-up.

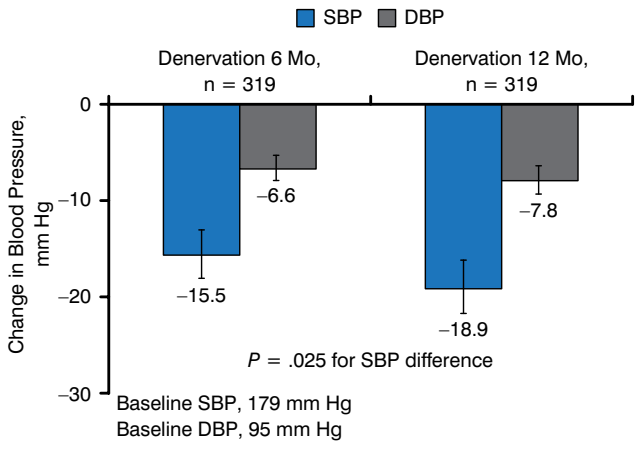
SBP and diastolic BP (DBP) reductions from baseline in the denervation group were –15.3 and –6.6 mm Hg, respectively, at 6 months ($P < .001$) and –18.9 and –7.8 mm Hg ($P < .001$), respectively, at 12 months. SBP and DBP reductions from baseline in the crossover group at 6 months were –17.7 and –7.1 mm Hg, respectively. In matched denervation patients (n = 319), the changes in office SBP and DBP at 6 months were –15.5 and –6.6 mm Hg, respectively, and –18.9 and –7.8 mm Hg, respectively, at 12 months ($P = .025$ for SBP difference; Figure 1).

SBP and DBP reductions from baseline in the noncrossover sham group were 32.9 and 13.3 mm Hg, respectively, at 6 months ($P < .001$) and 21.4 and 8.2 mm Hg, respectively, at 12 months ($P < .001$; Figure 2).

Figure 3 shows the relationship between office SBP changes and number of ablations attempted for combined denervation patients at 6 months.

The 12-month results of the SYMPLICITY HTN-3 trial are consistent with the previously reported 6-month findings. The safety of renal sympathetic denervation was maintained, but BP reductions were similar to those in patients receiving the sham procedure. The positive correlation of the total number of ablations and the circumferential pattern of ablations on systolic BP reduction was maintained and enhanced with the addition of the 6-month crossover subject data. These post hoc observations suggest hypotheses related to optimization of the denervation procedure that may inform the design of future renal denervation trials.

Figure 1. Change in Office BP at 6 and 12 Months for Matched Denervation Patients

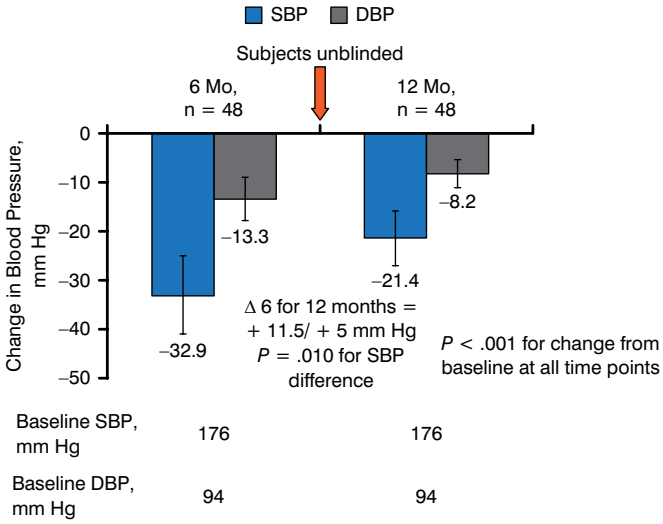


BP, blood pressure; DBP, diastolic blood pressure; RDN, renal denervation; SBP, systolic blood pressure; SE, standard error.

BP changes are vs patient baseline, not RDN vs Control. Error bars = 1.96 SE.

Reproduced with permission from DL Bhatt, MD.

Figure 2. Change in Office BP at 6 and 12 Months for Noncrossover Sham Patients

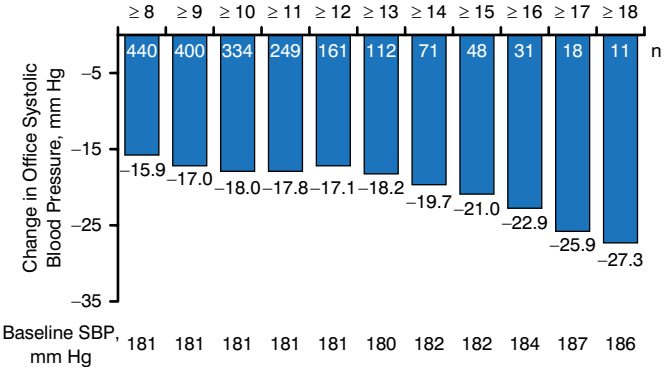


BP, blood pressure; DBP, diastolic blood pressure; RDN, renal denervation; SBP, systolic blood pressure; SE, standard error.

BP changes are vs patient baseline, not RDN vs Control. Error bars = 1.96 SE.

Reproduced with permission from DL Bhatt, MD.

Figure 3. SBP Changes and No. of Ablations Attempted at 6 Months



SBP, systolic blood pressure.

Denervation and crossover subjects combined.

Reproduced with permission from DL Bhatt, MD.