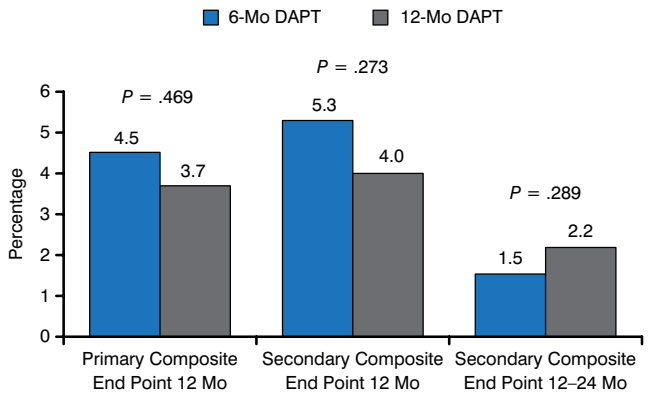
Figure 1. Primary and Secondary Composite End Points



DAPT, dual antiplatelet therapy.

Reproduced with permission from A Columbo, MD.

Table 1. Secondary End Points

	6-Month DAPT (n = 682)	12-Month DAPT (n = 717)	*P* Value
Cardiac mortality, %			
12 Months	0.7	0.4	.435
24 Months	0.9	0.8	.931
BARC bleeding, 3 or 5, %			
12 Months	0.6	1.1	.283
24 Months	0.7	1.1	.455
Myocardial infarction, %			
12 Months	2.3	2.1	.747
24 Months	3.1	2.6	.630
Stroke, %			
12 Months	0.9	0.3	.136
24 Months	0.9	0.4	.280
Definite/probable ST, %			
12 Months	0.3	0.4	.694
24 Months	0.4	0.4	.951
Possible ST, %			
12 Months	0.0	0.0	NS
24 Months	0.0	0.0	NS

BARC, Bleeding Academic Consortium Criteria; DAPT, dual antiplatelet therapy; NS, nonsignificant; ST, stent thrombosis.

Source: Colombo A et al. *JACC* 2014.

Table 2. Predictors of the Primary End Point

Variables in the Model	HR	95% CI	*P* Value
Age ≥75 years	2.211	1.234 to 3.962	.007
Stent type			.019
Endeavor Resolute vs Biomatrix/Xience/Promus	2.336	1.051 to 5.190	
Mean number of stents (for each unit increase)	1.410	1.128 to 1.741	.002
Mean stents length (for each 5 units increase)	1.383	1.135 to 1.685	.001
Mean stent size (for each 2.5 units increase)	1.326	1.106 to 1.590	.002
Diabetes mellitus			.069
NIDDM vs none	0.895	0.464 to 1.729	
IDDM vs none	2.349	1.080 to 5.106	
DAPT 6- vs 12-month	1.272	0.754 to 2.145	.367
Female sex	1.596	0.897 to 2.838	.111

DAPT, dual antiplatelet therapy; IDDM, insulin-dependent diabetes mellitus; NIDDM, non-insulin-dependent diabetes mellitus.

Source: Colombo A et al. *JACC* 2014.

stent implanted and stent number/length/size (Table 2). Interestingly, diabetes mellitus was only of borderline statistical significance in this trial.

Despite several study limitations, such as the lower than expected primary end point incidence and statistical power, Dr Colombo concluded that the 6-month DAPT is noninferior to the 12-month regimen in low-risk patients undergoing PCI with a 2G-DES.

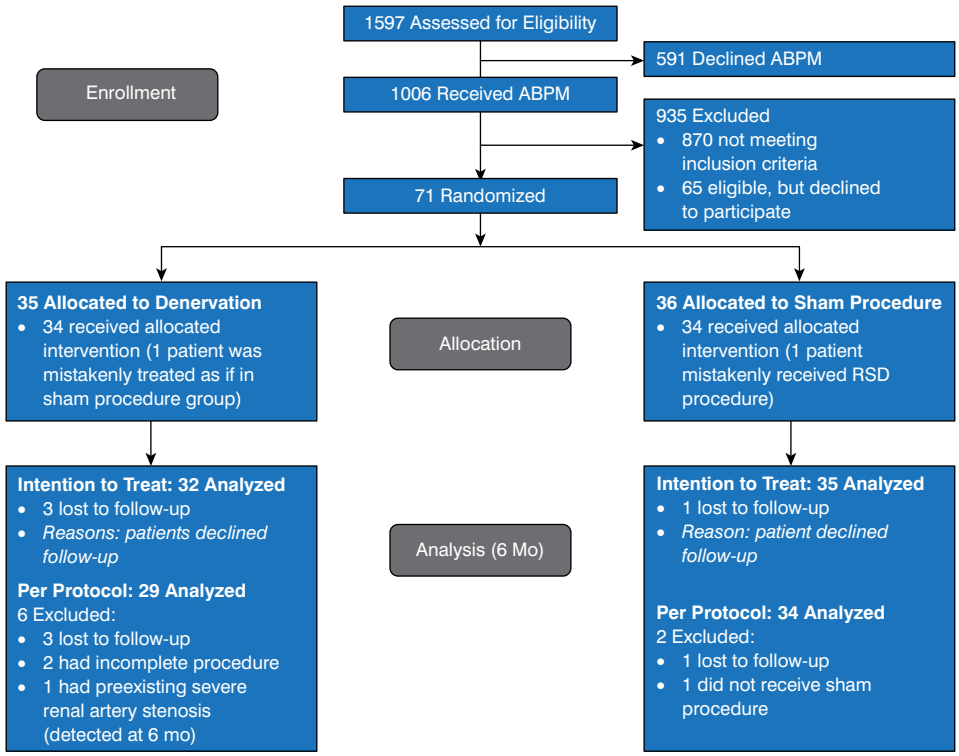
RSD Effective in Some Patients With Mildly Elevated BP

Written by Brian Hoyle

A small randomized study failed to demonstrate the superiority of renal sympathetic denervation (RSD) compared with medical therapy in achieving lowered blood pressure (BP). However, while systolic BP was decreased 6 months post denervation in all patients, the decrease was significant only for the per-protocol cohort. The findings, which are provocative rather than definitive, were reported by Steffen Desch, MD, University of Lübeck, Lübeck, Germany.

While percutaneous RSD might be effective in lowering BP in patients with severe resistant hypertension, the applicability when BP is only slightly elevated is unclear.

Figure 1. Flow Chart of the Study



ABPM, ambulatory blood pressure measurement; RSD, renal sympathetic denervation.

Reproduced with permission from S Desch, MD.

This study was designed to assess the issue. Seventy-one patients with resistant, yet only mildly elevated BP were randomized to RSD or a sham procedure. RSD used the Symplicity Flex Catheter for 4 to six 2-minute circumferential ablations in a distal-to-proximal direction for each renal artery. The procedures were done by experienced personnel who had performed at least 20 procedures prior to the study. The sham procedures consisted of an angiography of renal arteries as well as an invasive simulation of RSD. The surroundings and equipment were the same as for the genuine procedure. Intravenous saline was used instead of pain medication.

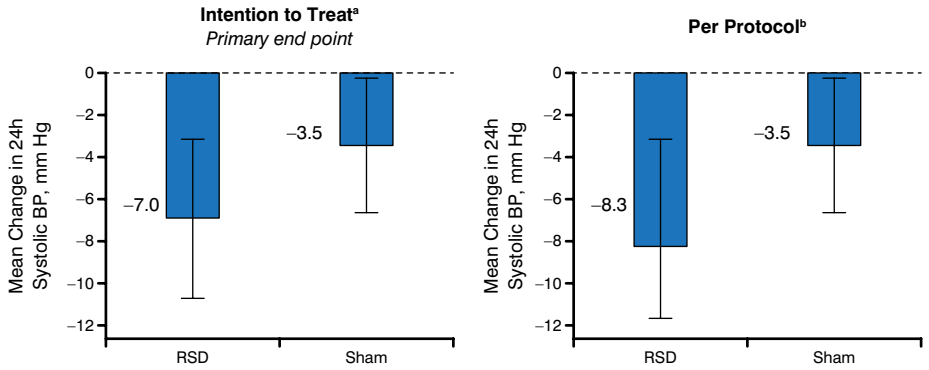
The inclusion criteria were a mean daytime systolic BP of 135 to 149 mm Hg determined from a 24-hour ambulatory BP measurement (ABPM) and/or mean daytime diastolic BP of 90 to 94 mm Hg, use of a stable antihypertensive regimen that had not been changed for the 4 weeks preceding study randomization that consisted of ≥ 3 drugs including an optimal dose of a diuretic, and age ≥ 18 to ≤ 75 years. Exclusion criteria were ABPMs less than or more than the prespecified mean systolic and diastolic BPs, anatomic restriction for RSD, glomerular filtration rate < 45 mL/min/1.73 m^2, any change in BP medication in the 4 weeks prior to randomization, and subject resistance to maintenance of the medication regimen. The primary end point was the change in 24-hour systolic BP at 6 months in the intention-to-treat (ITT) cohort.

Of the 1597 patients who were assessed, 71 were randomized to RSD (n = 35) or sham procedure (n = 36). At the 6-month analysis, the ITT population comprised 32 in the RSD group and 35 in the sham group; 29 and 34 patients in the per-protocol cohort, respectively (Figure 1).

The 2 groups were similar at baseline in demographic and clinical parameters, with the exception of age (64.5 ± 7.6 years in the RSD group, 57.4 ± 8.6 years in the sham group; $P < .001$). The groups were also comparable in baseline medications (diuretic, β-blocker, calcium channel blocker, and angiotensin-converting enzyme receptor blocker in order of prevalence).

The primary end point was not met, with no significant difference in mean change of 24-hour systolic BP

Figure 2. Primary End Point Results



BP, blood pressure; RSD, renal sympathetic denervation.

[a]P=.15 for between-group comparison; [b]P=.042 for between-group comparison; Error bars show 95% CI.

Reproduced with permission from S Desch, MD.

from baseline to 6 months in the ITT population (P=.15). The difference was significant in the per-protocol population, favoring RSD (P=.042; Figure 2).

Study limitations included small sample size, lack of assessment of medication adherence in the absence of urine analysis, and lack of an objective assessment of the success of blinding. Also, the finding of significance only in per-protocol patients necessitates further study to draw a definitive conclusion concerning the efficacy of RSD.

VELOCITY: Pre-PCI Hypothermia Increases Adverse Event Rate Without Reducing Infarct Size

Written by Toni Rizzo

The Evaluation of Ultrafast Hypothermia Before Reperfusion in STEMI Patients trial [VELOCITY; NCT01655433], presented by Gregg W. Stone, MD, Columbia University Medical Center, New York, New York, USA, assessed the feasibility, safety, and efficacy of systemic hypothermia induced by peritoneal lavage in patients with STEMI prior to primary percutaneous intervention (PCI). Patients with symptoms of STEMI between 30 minutes and 6 hours before presentation and ST-segment elevation ≥2 mm in ≥2 continuous electrocardiography (ECG) leads who were intended for PCI were randomized to PCI (n=26) or peritoneal hypothermia followed by PCI (n=28). Cardiac magnetic resonance imaging (MRI) was performed at 3 to 5 days and 30±7 days after PCI. Clinical follow-up took place at 30 days and 6 months after PCI.

An automated peritoneal lavage system was used to induce hypothermia to a core temperature of ≤34.9°C (target 32.5°C), maintained for 3 hours post PCI, after which the system initiated active rewarming and fluid drainage. The primary efficacy end point was infarct size assessed by cardiac MRI on day 3 to 5. The primary safety end point was the composite rate of death, re-infarction, ischemia-driven target vessel revascularization, major bleeding, sepsis, pneumonia, peritonitis, severe arrhythmia, or renal failure occurring within 30±7 days.

PCI was performed in 25 of 26 patients randomized to PCI without hypothermia. Peritoneal access was attempted in 26 of 27 patients randomized to hypothermia followed by PCI. One of the 28 patients did not have peritoneal access or PCI and underwent surgery for aortic dissection. Peritoneal access was successful and hypothermia established in 26 of the 27 patients in whom access was attempted. PCI was performed in 27 patients.

The goal temperature of ≤34.9°C before PCI was achieved in 24 of 27 patients in the hypothermia group (88.9%) at a median 17.0 minutes after cooling onset. There were no significant differences in angiographic and ECG outcomes between the hypothermia and control groups. Cardiac MRI results at day 3 to 5 demonstrated no significant differences between the hypothermia and control groups in any parameters, including infarct size (P=.54; Table 1).

A prespecified subgroup analysis found no significant difference in infarct size at day 3 to 5 between patients in the hypothermia and control groups with left anterior descending (LAD) artery infarct (P=.68), non-LAD