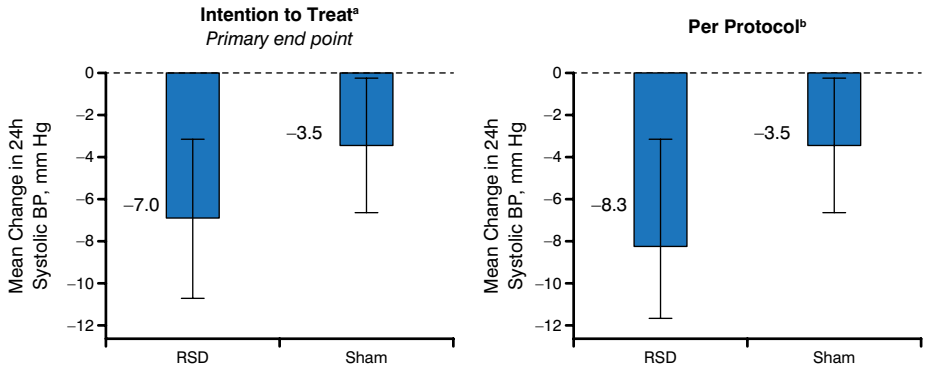
Figure 2. Primary End Point Results




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.

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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

Table 1. Cardiac MRI Results at Day 3 to 5

| MRI Assessments | Control (n = 20) | Hypothermia (n = 26) | *P* Value |
|---|---|---|---|
| Time from PCI, d | 4 (3-4) | 4 (3-5) | .53 |
| LV myocardial mass, g | 125.5 (109.5-135.5) | 123 (107-142) | .80 |
| Area at risk, g | 35.1 (20.4-50.5) | 34.2 (26-51.6) | .56 |
| Area at risk, % LV mass | 26.8 (16.7-40.6) | 26.1 (22.7-34.4) | .69 |
| Infarct mass, g | 20.8 (10.9-27.6) | 22.2 (15.6-30.1) | .44 |
| Infarct mass/area at risk, % | 55.8 (43.8-67.2) | 67.3 (48.9-73.3) | .36 |
| Myocardial salvage, % | 44.2 (32.8-56.2) | 32.7 (26.7-51.1) | .36 |
| **Primary Efficacy End Point Infarct size, % total LV mass** | **16.1 (10.0-22.2)** | **17.2 (15.1-20.6)** | **.54** |
| MVO, g | 0 (0-0.2) | 0 (0-0.7) | .57 |
| MVO, % total LV mass | 0 (0-0.2) | 0 (0-0.5) | .64 |
| LV end-diastolic volume, mL | 161 (137.5-172) | 159 (125-191) | .80 |
| LV end-systolic volume, mL | 83.3 (66.8-102) | 81.9 (71-119) | .63 |
| LV stroke volume, mL | 75.2 (61.4-81.5) | 75.4 (61.1-84) | .78 |
| LV ejection fraction, % | 46.3 (42.6-50.6) | 43.3 (37.4-52) | .37 |
| Abnormal wall motion score | 8 (4-11.5) | 8 (6-10) | .52 |

LV, left ventricular; MRI, magnetic resonance imaging; MVO, microvascular obstruction; PCI, percutaneous intervention.

artery infarct ($P = .11$), and symptom onset to hospital arrival ≤ 3 hours ($P = .17$) or > 3 hours ($P = .39$).

The primary safety composite end point occurred in 21.4% of hypothermia patients vs 0.0% of controls ($P = .02$). There were no significant differences between the hypothermia and control groups in the major adverse cardiac event (MACE) and stent thrombosis rates.

Limitations of this study included the sample size, which was not powered for efficacy. The study was unblinded. Both nonanterior and anterior infarcts were included. The level of optimal cooling before PCI is unknown. Long-term follow-up was not available.

Controlled systemic hypothermia through automated peritoneal lavage may be rapidly established in patients with evolving STEMI undergoing primary PCI at the expense of a modest increase in door-to-balloon time, concluded Dr Stone. In this trial, peritoneal hypothermia was associated with an increased rate of adverse events without reducing infarct size.

## ELA Useful in Treatment of Femoropopliteal ISR

Written by Brian Hoyle

Use of excimer laser atherectomy (ELA) as an adjunct to percutaneous transluminal angioplasty (PTA, also known as balloon angioplasty) is superior to PTA alone in patients with peripheral artery disease (PAD) who experience artery narrowing following stent implantation (in-stent restinosis [ISR]).

The results from the Randomized Study of Laser and Balloon Angioplasty Versus Balloon Angioplasty to Treat Peripheral In-Stent Restenosis [EXCITE ISR; NCT01330628] randomized trial were described by Eric J. Dippel, MD, Genesis Heart Institute, Davenport, Iowa, USA.

Treatment of PAD using stent implantation to retain arterial diameter is effective but ISR occurs in 30% to 40% of cases in the 2 years following the procedure. ISR is typically treated with PTA; however, the recurrence of ISR is common following PTA.

The prospective, randomized EXCITE ISR trial was undertaken to evaluate the safety and efficacy of ELA used along with PTA vs PTA alone in treating femoropopliteal ISR. Most ELA procedures used a dedicated laser atherectomy catheter (Turbo-Elite). The inclusion and exclusion criteria of the trial were designed to randomize patients frequently encountered during clinical practice (Table 1).

The trial randomized 250 patients in whom lesions were suitable. Patients were randomized 2:1 to receive ELA + PTA (n = 169) or PTA (n = 81). The primary safety end point of 30-day major adverse events (death, unplanned major amputation, revascularization of the lesion) was assessed in 155 and 73 patients in the ELA + PTA and PTA group, respectively. The primary efficacy end point (6-month freedom from clinically proven target lesion revascularization [TLR]) was assessed in 117 ELA + PTA patients and 56 PTA patients.

Baseline demographics concerning age, sex, clinical parameters, and lesion assessments were similar, with the exception of more extensive calcification in the ELA + PTS group (27% vs 9%; $P = .002$).