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%; $P = .002$).

Table 1. Inclusion and Exclusion Criteria

"Real World" Patients
No lesion length limit
Multiple stents allowed
Common stent fractures (Grades 1 - 3)
Popliteal stents included
Key Inclusion Criteria
ISR lesion ≥ 4 cm
Rutherford classification 1 - 4
RVD ≥ 5.0 mm and ≤ 7.0 mm
≥ 1 patent tibial artery
Key Exclusion Criteria
Target lesion extends > 3 cm beyond stent margin
Untreated inflow lesion
Grade 4 or 5 stent fracture
Follow-up
Discharge, 30 days, 6 months, and 1 year post procedure

ISR, in-stent restenosis; RVD, reference vessel diameter.
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Procedural success was significantly greater for and residual stenosis was significantly less in the ELA + PTA group (94% vs 83%; $P = .03$ and 5% vs 14%; $P = .02$). The need for TLR in the year following surgery was significantly less for those receiving ELA + PTA ($P < .003$). One-year survival and freedom from major adverse events was significantly higher in those receiving ELA + PTA ($P < .005$ and $P < .001$, respectively).

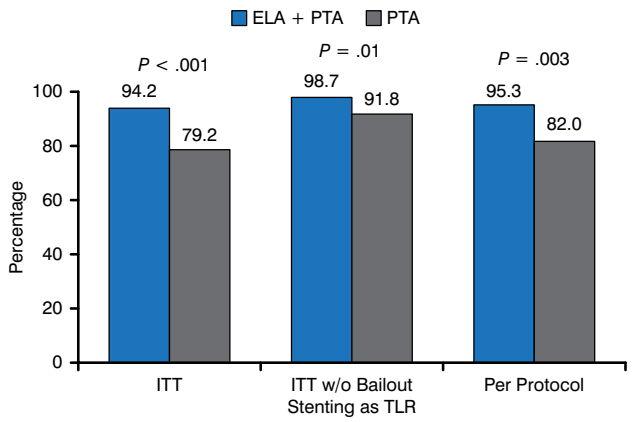
ELA + PTA compared with PTA alone was associated with less TLR (5% vs 16%; $P = .008$), dissection (8% vs 17%; $P = .03$), > Grade C (2% vs 7%; $P = .08$), bailout stenting (4% vs 11%; $P = .02$), thrombosis (1% vs 3%; $P = .25$), and abrupt closure (0% vs 1%; $P = .23$). PTA alone was associated with decreased embolization (8% vs 5%; $P = .47$).

The primary safety and efficacy end points significantly favored ELA + PTA (Figures 1 and 2).

The advantage of ELA + PTA over PTA held following a battery of subgroups included those based on age, diabetes, prior ISR, artery occlusion, artery diameter, lesion length, and other parameters.

Thus, ELA + PTA treatment of ISR was found to be superior to PTA for the treatment of femoropopliteal ISR involving complicated lesions. Large scale trials are needed to determine if this should be considered standard of care in patients with femoropopliteal ISR.

Figure 1. Primary Safety End Point



ELA, excimer laser atherectomy; ITT, intention-to-treat; PTA, percutaneous transluminal angioplasty; TLR, target lesion revascularization.
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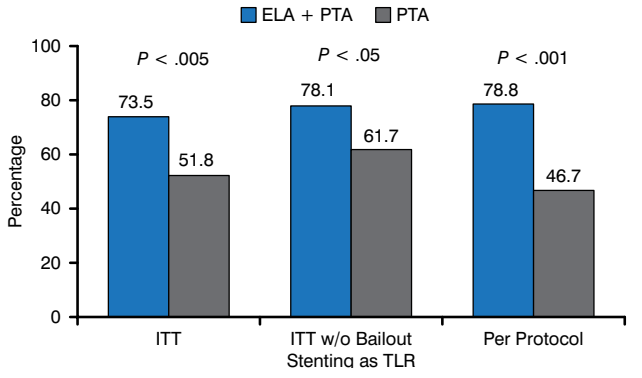
Figure 2. Primary Efficacy End Point



ELA, excimer laser atherectomy; ITT, intention-to-treat; PTA, percutaneous transluminal angioplasty; TLR, target lesion revascularization.
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Satisfactory Angiographic and Clinical Outcomes With the Everolimus-Eluting BVS

Written by Toni Rizzo

New generation drug-eluting stents (DESs) are increasingly efficient and safe. The ABSORB everolimus-eluting bioresorbable vascular scaffold (BVS) is thought to reduce long-term complications, including neoatherosclerosis and very late stent thrombosis. The effectiveness of the BVS has been demonstrated in patients with noncomplex lesions but it is increasingly being