brought to you by 🔏 CORE

CRT-1

Paclitaxel Drug-coated Balloon For The Treatment Of Drug-eluting Stent In-stent Restenosis: Subanalysis Results Of The Valentines I Trial

Joshua P Loh,¹ Pieter R Stella,² Giuseppe Sangiorgi,³ Sigmund Silber,⁴ Stefanic Stahnke,⁵ Rembert Pogge von Strandmann,⁵ Zhenyi Xue,¹ Rebecca Torguson,¹ Ron Waksman¹

¹MedStar Washington Hospital Center, Washington, DC; ²University Medical Center Utrecht, Utrecht, Netherlands ³University of Rome, Rome, Italy ⁴Heart Center at the Isar, Munich, Germany ⁵Eurocor GmbH, Bonn, Germany MedStar Washington

Background: In the Valentines I trial, treatment of coronary in-stent restenosis was effective and safe with the second-generation $DIOR^{\oplus}$ paclitaxel drug-coated balloon (DCB). We analyzed the effect of DCB treatment on patients with drug-eluting stent (DES) restenosis.

Methods: Valentines I trial prospectively enrolled 250 patients with ISR. Of these, 74 patients (29.6%) had DES restenosis. Patients underwent balloon angioplasty followed by DCB treatment. Clinical outcomes of patients with paclitaxel DES restenosis (34 patients with 41 lesions) and -limus (sirolimus, everolimus and zotarolimus) DES restenosis (42 patients with 43 lesions) treated with DIOR® DCB were compared.

Results: Baseline characteristics were similar in both groups. There were more diffuse pattern of restenosis in paclitaxel DES compared to -limus DES restenosis (50% vs. 26.8%, p=0.032). Number of DCB used per patient (1.07 each group), mean DCB diameter (2.95mm vs. 3.02mm), mean DCB length (26.7mm vs. 22.5mm) and bailout stenting (2.6% vs. 4.7%) were similar in both groups (p=NS). At mean follow-up of 231 ± 43 days, major adverse cardiac events was 0% in the paclitaxel DES restenosis and 23.8% in the -limus DES restenosis (p=0.002), the difference contributed mainly by less target vessel revascularization (0 vs. 18.6%, p=0.006) (Table).

Conclusion: In the Valentines I trial, the use of paclitaxel DCB was more effective in patients with paclitaxel DES restenosis compared to -limus DES restenosis, achieving better mid-term clinical outcomes. This suggests the efficacy of localized paclitaxel delivery to overcome paclitaxel resistance but not -limus resistance due to different mechanisms of DES failure.

Clinical outcomes at follow-up

	Paclitaxel DES restenosis (patients, n=34; lesions, n=41)	Limus DES restenosis (patients, n=41; lesions, n=43)	P value
Major adverse cardiac events	0	10 (23.8%)	0.002
Death	0	1 (2.4%)	1.00
Myocardial infarction	0	1 (2.4%)	1.00
Vessel thrombosis	0	2 (4.8%)	0.50
Target lesion revascularization	0	6 (14.0%)	0.027
Target vessel revascularization	0	8 (18.6%)	0.006

The State Of The Excimer Laser For Coronary Intervention In The Drug-eluting Stent Era

CRT-2

Salem Badr, Itsik Ben-Dor, Israel Barbash, Sa'ar Minha, Hironori Kitabata, Joshua Loh, Lakshmana Pendyala, Rebecca Torguson, Fang Chen, William Suddath, Lowell Satler, Augusto Pichard, Ron Waksman Medstar Washington Hospital Center, Washington, DC

Objectives: This study aimed to determine how Excimer laser coronary atherectomy (ELCA) performs in the drug-eluting stent (DES) era.

Background: For more than 20 years, ELCA has been used for coronary intervention. With developments in the coronary intervention field, the role of ELCA is in question. **Methods:** The study includes 119 patients with 124 lesions who underwent percutaneous coronary intervention (PCI) with ELCA in our institution from January 2004 to May 2011. **Results (Table):** The main indications for ELCA use were saphenous vein graft (SVG) (45 lesions), acute myocardial infarction (AMI) (7 lesions), chronic total occlusion (CTO) (32 lesions). In-stent restenosis (ISR) (15 lesions), and calcified de-novo lesions (25 lesions). High success rates were recorded for the SVG, AMII, CTO, ISR, and calcified lesion indications (91.1%, 85.7%, 93.8%, 86.7%, and 80%; respectively). ELCA related complications were reported in 10 patients (8%); four dissections, three no-reflow phenomenon, two perforations, and one thrombus formation.

Conclusion: ELCA is an alternative solution with an acceptable performance in the treatment of complex coronary lesions not ideally suitable for balloon angioplasty.

	Saphenous vein graft lesion (n=45)	Acute myocardial infarction (n=7)	Chronic total occlusion (n=32)	In-stent restenosis (n=15)	Calcified lesions (n=25)
ELCA success®	41 (91.1%)	6 (85.7%)	30 (93.8%)	13 (86.7%)	20 (80%)
Angiographic success¥	42 (93.3%)	7 (100%)	29 (90.6%)	14 (93.3%)	21 (84%)
Balloon non-crossable	2.0 (4.4%)	0	23 (71.9%)	2.0 (13.3%)	14 (56%)
Complications:					
Dissection	0	0	3 (9.4%)	1 (6.7%)	0
Perforation	0	0	1 (3.1%)	0	1 (4.0%)
No-reflow	0	0	0	1 (6.7%)	2 (8.0%)
Thrombus formation	0	0	1 (3.1%)	0	0

*ELCA success was defined as the laser catheter crossing the entire length of the stenotic lesion determined by angiographic evidence of the catheter tip in the artery distal to the stenosis. ¥Angiographic success was defined as <50% residual stenosis after laser and adjunctive therapy</p>

CRT-3

Catheter-based Renal Denervation with the Symplicity[™] System Provides Safe and Durable Blood Pressure Reduction out to Three Years

David E Kandzari,¹ Henry Krum²

¹Piedmont Heart Institute, Atlanta, GA; ²Monash University/Alfred Hospital, Melbourne, Australia

Background: The Symplicity[™] renal denervation catheter uses low power radiofrequency energy to ablate the renal artery nerves and has been shown to lower blood pressure (BP) in patients with treatment-resistant hypertension. Continued follow-up of patients who have undergone renal denervation (RDN) is essential to establish the long-term safety and effectiveness of this procedure.

Methods: The open-label Symplicity HTN-1 study enrolled 153 patients with severe resistant hypertension (systolic BP \geq 160 mm Hg in the presence of \geq 3 antihypertensive