



Long-Term Outcomes After Treatment With a Paclitaxel-Coated Balloon Versus Balloon Angioplasty

Insights From the PEPCAD-DES Study (Treatment of Drug-eluting Stent [DES] In-Stent Restenosis With SeQuent Please Paclitaxel-Coated Percutaneous Transluminal Coronary Angioplasty [PTCA] Catheter)

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ABSTRACT

OBJECTIVES The intention this PEPCAD-DES (Treatment of Drug-eluting Stent [DES] In-Stent Restenosis With SeQuent Please Paclitaxel Eluting Percutaneous Transluminal Coronary Angioplasty [PTCA] Catheter) study update was to demonstrate the safety and efficacy of paclitaxel-coated balloon (PCB) angioplasty in patients with DES-ISR at 3 years.

BACKGROUND In the PEPCAD-DES trial late lumen loss and the need for repeat target lesion revascularization (TLR) was significantly reduced with PCB angioplasty compared with plain old balloon angioplasty (POBA) in patients with drug-eluting stent in-stent restenosis (DES-ISR) at 6 months. We evaluated whether the clinical benefit of reduced TLR and major adverse cardiac events (MACE) was maintained up to 3 years.

METHODS A total of 110 patients with DES-ISR in native coronary arteries with reference diameters ranging from 2.5 mm to 3.5 mm and lesion lengths ≤ 22 mm were randomized to treatment with either PCB or POBA in a multicenter, randomized, single-blind clinical study. With a 2:1 randomization, 72 patients were randomized to the PCB group and 38 patients to the POBA group. At baseline, there were lesions with at least 2 stent layers in PCB (52.8%, 38 of 72) and POBA (55.3%, 21 of 38) patients.

RESULTS At 36 months, the TLR rates were significantly lower in the PCB group compared with the POBA control group (19.4% vs. 36.8%; $p = 0.046$). Multiple TLRs in individual patients were more frequent in the POBA group compared with the PCB group (more than 1 TLR: POBA, 13.2%; PCB, 1.4%; $p = 0.021$). The 36-month MACE rate was significantly reduced in the PCB group compared with the POBA group (20.8% vs. 52.6%, log-rank $p = 0.001$).

CONCLUSIONS PCB angioplasty was superior to POBA for the treatment of DES-ISR patients in terms of MACE and TLR for up to 36 months. There was no late catch-up phenomenon. (Treatment of Drug-eluting Stent [DES] In-Stent Restenosis With SeQuent® Please Paclitaxel Eluting Percutaneous Transluminal Coronary Angioplasty [PTCA] Catheter [PEPCAD-DES]; [NCT00998439](https://doi.org/10.1016/j.jcin.2015.07.023)) (J Am Coll Cardiol Intv 2015;8:1695-700) © 2015 by the American College of Cardiology Foundation.

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**ABBREVIATIONS
AND ACRONYMS**

- DES** = drug-eluting stent(s)
- DES-ISR** = drug-eluting stent in-stent restenosis
- LLL** = late lumen loss
- MACE** = major adverse cardiac event(s)
- PCB** = paclitaxel-coated balloon catheter
- PES** = paclitaxel-eluting stent(s)
- PES-ISR** = paclitaxel-eluting stent in-stent restenosis
- POBA** = plain old balloon angioplasty
- TLR** = target lesion revascularization

In the PEPCAD-DES (Treatment of Drug-eluting Stent [DES] In-Stent Restenosis With SeQuent Please Paclitaxel Eluting Percutaneous Transluminal Coronary Angioplasty [PTCA] Catheter), late lumen loss (LLL) and the need for repeat target lesion revascularization (TLR) at 6 months were significantly reduced with paclitaxel-coated balloon (PCB) angioplasty as compared with plain old balloon angioplasty (POBA) for drug-eluting stent in-stent restenosis (DES-ISR) (1). However, LLL in the PCB population was higher than other reported LLL findings after PCB angioplasty in bare metal stent ISR (2-5) and DES-ISR (6-8). This difference may be explained with the inclusion of restenotic DES with different antiproliferative drugs. Moreover,

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the initial DES implantation in complex lesions with a high risk of restenosis such as multiple stent layers (Table 1) may also have contributed to the higher level of LLL. In this paper, the long-term clinical outcomes 3 years after initial treatment and additional findings are reported as well as whether the efficacy of PCB is different in paclitaxel-eluting stent (PES) restenosis or non-PES restenosis, whether PCB angioplasty is equally effective in single-layer versus multilayer DES-ISR, and whether there is a difference between diabetic and nondiabetic patients with DES-ISR when treated with PCB versus POBA.

METHODS

PATIENT POPULATION. From November 2009 to April 2011, 110 patients with restenosis of sirolimus-eluting stents, everolimus-eluting stents, or paclitaxel-eluting stents (PES) in a native coronary artery with the indication for percutaneous coronary intervention were randomized to treatment with either PCB or POBA in a multicenter, randomized, clinical single-blind study. With a 2:1 randomization, 72 patients were treated with PCB and 38 patients with POBA. Patients with sirolimus-eluting Cypher stent ISR (Cordis, Warren, New Jersey) or Yukon stent ISR (Translumina, Hechingen, Germany), everolimus-eluting Xience stent ISR (Abbott Vascular, Abbott Park, Illinois), or paclitaxel-eluting Taxus stent ISR (Boston Scientific, Natick, Massachusetts), with a reference vessel diameter of 2.5 to 3.5 mm and a lesion length less than 22 mm were included.

The inclusion and exclusion criteria, as well as the study design and the study procedure were reported previously (1). The protocol was approved by all ethics committees. All patients gave written informed consent.

Patients were scheduled for a 6-month angiographic follow-up and clinical follow-up at 12 and 36 months. Angiographic measurements were done with the CAAS 5.7 software (Pie Medical Imaging BV, Maastricht, the Netherlands) in the core lab of the University of Ulm, Ulm, Germany (9,10).

A major adverse cardiac event (MACE) was defined as a composite of cardiac death, myocardial infarction attributed to the target vessel, TLR, or a target vessel total occlusion. TLR was defined as the composite of TLR by means of percutaneous coronary intervention or coronary artery bypass grafting. Biochemical evidence of myocardial necrosis was defined as creatine-kinase myocardial band ≥ 3 times the upper normal limit or a total creatine kinase ≥ 3 times the upper normal limit whenever creatine-kinase myocardial band was not available. Clinical follow-up at 36 months was done by a telephone call with the patient, the patients' relatives, or the primary physician. A priori-defined subgroup analyses were based on paclitaxel-eluting stent in-stent restenosis (PES-ISR) versus non-PES-ISR, single-layer versus multilayer DES-ISR, and diabetic versus nondiabetic patients. Focal patterns of in-stent restenosis were defined as Mehran classes IA through ID, whereas diffuse patterns were described by Mehran classes II through IV (11).

STATISTICAL ANALYSIS. Based on the Satterthwaite *t* test, a superiority test hypothesis was formulated.

TABLE 1 Selected Basic Demographic Characteristics and Angiographic Outcomes From the Initial Publication (1)

	PCB (n = 72)	POBA (n = 38)	Pearson's Chi-Square p Value
Baseline cardiovascular risk factors			
Age, yrs	69.8 ± 10.8	64.0 ± 11.3	0.02
Male	52 (72.2)	26 (68.4)	0.68
Diabetes mellitus	26 (36.1)	13 (34.2)	0.84
Baseline angiographic data			
≥2 stent layers	38 (52.8)	21 (55.3)	0.80
Reference vessel diameter, mm	2.29 ± 0.51	2.30 ± 0.52	0.95
Minimal lumen diameter, mm	0.66 ± 0.40	0.62 ± 0.44	0.58
Mehran classification: focal	47 (65.3)	25 (65.8)	0.20
Mehran classification: diffuse	25 (34.7)	13 (34.2)	0.41
Angiographic outcomes at 6 months			
Angiographic follow-up	64 (88.9)	31 (81.6)	0.29
Late lumen loss target lesion, mm	0.43 ± 0.61	1.03 ± 0.77	<0.001
Late lumen loss total segment, mm	0.32 ± 0.55	0.99 ± 0.44	<0.001

Values are mean ± SD or n (%).
PCB = paclitaxel-coated balloon; POBA = plain old balloon angioplasty.

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