

# Interim Analysis of the Protégé Paclitaxel-Eluting Balloon in Real-World Practice (PEARL) Registry

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## Introduction

Percutaneous coronary intervention (PCI) is often performed with implantation of a drug-eluting stent (DES) [1]. However, stent implantation may be less desirable for recurrent in-stent restenosis and for specific lesion characteristics such as small vessel disease and coronary ostia. Randomized controlled trials have shown promising results for the use of a drug-eluting balloon (DEB) in these indications [2-4], but data on DEB use in real-world practice are still scarce.

The Protégé DEB (Wellinq, Leek, the Netherlands) features an innovative balloon design in which the drug component is encapsulated in the balloon folds and is only exposed upon inflation. Hereby, DEB handling and tight lesion crossing will not lead to premature drug release. Predilation may not be required with this DEB as, besides a compliant version, the DEB is also available in a non-compliant version. The Paclitaxel-Eluting Angioplasty Balloon in the Real-World (PEARL) Registry aims to evaluate safety and efficacy of the Protégé DEB in real-world practice.

## Methods and Results

This interim analysis includes the first 200 consecutive patients in the registry. Patients were included in four hospitals in the Netherlands. Mean age was 65.7 ±10.6 years and 71% were men. Patients had a high

cardiovascular risk profile with diabetes in 25%, hypertension in 59%, history of myocardial infarction in 64%, and history of prior PCI in 89% and coronary artery bypass grafting in 19%. Indication for PCI was ST-elevation myocardial infarction in 10% and non-ST-elevation acute coronary syndrome in 35%. DEB was primarily used for in-stent restenosis in 73.5% of patients and for de novo lesions in 26.5% of patients.

A total of 242 lesions were treated with DEB with lesion distribution in the left main in 2%, left anterior descending in 39%, left circumflex in 20%, right coronary artery in 30% and bypass graft in 9%. The majority

of lesions had a high complexity with 34% classified as type B2 and 46% classified as type C. Mean lesions length was 21.0 ±17 mm and mean diameter was 2.8 ±0.7 mm. Predilation was performed in 67%. Non-compliant DEB was used in 38%. Average inflation time was 53±19 seconds at a mean atmosphere of 14±4 atm. DEB related procedural complications were low (6.5%), mostly consisting of coronary dissection (n=12). Bail-out stenting was required in 6.5%. Device failure only occurred in 2 patients (balloon burst). Final angiographic and clinical success was achieved in all patients.

None of the patients had a major adverse cardiac event (MACE) during hospitalization (Table 1).

	N=200
<i>In-hospital events</i>	
Composite MACE	0 (0%)
Procedural complications	
DEB related complications	13 (6.5%)
Bail-out stenting	13 (6.5%)
Device failure	2 (1.0%)
<i>Events at 6 months</i>	
Composite MACE	20 (10%)
Cardiac death	4 (2%)
Target vessel myocardial infarction	6 (3%)
Target lesion revascularization	10 (5%)

Table 1: Clinical outcomes after PCI with paclitaxel DEB

PCI: Percutaneous Coronary Intervention, DEB: drug-eluting balloon, MACE: Major Adverse Cardiac Events

At six months, MACE occurred in 20 patients (10.0%), consisting of target lesion revascularization (TLR) in 5%, target vessel myocardial infarction in 3%, and cardiac death in 2%.

## Discussion

When comparing data with that of randomized controlled trials [2-4], it should be noted that the patients in the PEARL registry seem to have a higher cardiovascular risk profile and more often present with acute coronary syndrome, lesions seem to have higher complexity and predilation was performed less frequently. Nevertheless, DEB success rate and MACE rate remain favorable. Limitations of this interim analysis include the relatively small sample size and the limited clinical follow-up period. The full PEARL registry is planned to include a larger patient cohort and two years of follow-up. This will also allow us to perform additional subgroup analyses.

## Conclusion

This interim analysis suggests that the use of the Protégé DEB is safe and effective for PCI of in-stent restenosis and denovo lesions.

## Conflicts of interest

A research grant was received for the set-up of the PEARL registry. The authors have no conflicts of interest to declare.

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