A Single Center, Real World Experience of Drug-Eluting Balloon Use in the Treatment of Instent Restenosis and Diffuse Coronary Artery Disease

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Background: Drug-eluting balloons (DEB) are emerging as an alternative treatment for coronary stenoses when scaffolding is undesirable. We report a real world, single center experience of DEB usage over a 19-month period in the treatment of in-stent restenosis (ISR) and de novo coronary artery disease.

Methods: Consecutive patients treated with the In.Pact FalconTM (Medtronic Inc., Minneapolis, MN, USA) paclitaxel eluting balloon as part of a coronary revascularization strategy between May 2009 and December 2010 were retrospectively studied. Patients were classified into primary complications of death, myocardial infarction (MI) and target vessel revascularization (TVR) at a minimum of 6 months follow-up. Secondary outcomes were in-segment restenosis and the individual components of the primary composite.

Results: A total of 122 lesions were successfully treated in 75 patients. The mean age was 66.6±2.9 years and 89.3% were male. The majority of patients (85.3%) had stable angina, and 62.7% had triple vessel disease. The predominant indication for DEB use was ISR (62.7%), with diffuse disease (34.7%) and focal, small vessel disease (2.6%) accounting for the remainder. 77.3% of lesions were classified as ACC/AHA B2 or C, and 30.0% involved a bifurcation. A mean of 1.5±0.8 DEB were used per patient. Balloon stenting was required in 25.8% of lesions, 19.3% for angiographic optimization before the DEB application of a de-novo strategy in the setting of PPCI for STEMI. The use of a bare metal stent in terms of 9-month target lesion revascularization.

Conclusion: The primary endpoint was a composite of all death, non-fatal MI and clinically driven target vessel revascularization (TVR) at 6 months. All reported device-related serious adverse effects were adjudicated by an independent clinical events committee (CEC).

Results: Results of the 600 consecutively enrolled DELUX patients are presented. Four hundred thirty-two men (78.0%) and 168 female (28.0%) with a mean age of 66.5 ± 11.1 years have been enrolled. Two hundred four patients (34.0%) were diabetics and 52.0% (n=312) had a history of previous MI. The majority of patients presented with stable angina by unstable angina (n=196, 32.7%). A total of 644 lesions were treated, including 568 (88.2%) in-stent restenotic (ISR) lesions (51.9% bare metal stent-ISR (n=295), 46.5% drug eluting stent-ISR (n=264), 1.5% unknown stent types (n=9)). Two hundred sixty-nine (41.8%) ISR lesions were diffuse (Mehran class II), but in 29 cases (4.5%) a total occlusion (Mehran class IV) was treated. Device success rate was 98.7%. The preliminary MACE rate (hierarchical) at 6 months was 5.6% (13 all death (2.9%), 5 non-fatal MI (1.1%) and 7 clinically driven TVR (1.6%).

Conclusion: Treatment with the Pantera Lux Paclitaxel Releasing Balloon showed excellent acute and mid term performance in an international real world setting. The majority of treated lesions were in-stent restenotic lesions with almost equal distribution between bare metal stents and drug eluting stents. Efficacy and safety are demonstrated by low revascularization rates and low non-fatal MI rate.

Native Coronary Stenosis

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Background: Paclitaxel-coated balloons (DEB) could represent a promising alternative to drug-eluting stent (DES) in the treatment of coronary stenosis. The aim of our study was to compare 9-month restenosis rate between a strategy of predilatation with a paclitaxel eluting balloon (PBB) (Eluta, Aachen Resonance, Aachen, Germany) followed by bare-metal CoCr stent implantation (Prokinete, Biotronik, Berlin, Germany) (PBB+CoCr-stent group) versus implantation of everolimus-eluting stent (Xience, Abbott Vascular, Redwood City, CA) (DES group) in the treatment of de-novo stenosis in native coronary artery.

Methods: The study, randomized, single center, was planned to enroll 366 patients, 188 patients per arm, with stable angina, undergoing percutaneous coronary intervention of a de-novo stenosis less than 15mm in length in a native coronary artery. Primary endpoint, in a non inferiority study design, was 9-month binary angiographic restenosis. Combined antiplatelet treatment was to be continued for 3 months in PBB+CoCr stent group and 12 months in DES group.

Results: The study was stopped after enrollment of 125 patients, 59 in the DEB group and 66 in the DES group, due to excess of Target Lesion Revascularization (TLR) in the PEB group (14% in the PEB vs 2% in DES group; p=0.001). No significant differences in terms of clinical or angiographic characteristics were observed among the two study groups. No stent thrombosis occurred in both study groups.

Conclusion: In the treatment of de-novo coronary stenosis, a strategy of predilatation with Eluta PEB prior to bare-metal CoCr stent implantation was significantly inferior to implantation of Xience stent with a 9-month target lesion revascularization.