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Small vessel caliber in-stent restenosis in diabetic patients; is drug coated balloon an efficacy treatment in this setting? A two centers experience

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Background & Aim: In the last years, drug coated balloon (DCB) has achieved significant results in the treatment of in-stent restenosis (ISR) and the last guidelines for myocardial revascularization suggest the use of DCB in the treatment of ISR of both bare metal stent (BMS) or drug eluting stent (DES). However, little is known about the safety and efficacy of small vessel caliber ISR treatment by DCB in diabetic patients. This study was conducted with an aim to find whether drug coated balloon as an efficacy treatment in small vessel caliber in-stent restenosis in diabetic patients.

Methods: Between 2011 and 2016 all the diabetic patients with ISR were enrolled in 2 Italian experts in DCB-PCI centers. Primary endpoint was the assessment of target lesion failure (TLF), defined as composite of myocardial infarction (MI), cardiac-death and target lesion revascularization (TLR) and second endpoint was the incidence of major adverse cardiac events (MACE) during the available follow up. 117 diabetic patients with ISR were enrolled and divided in two groups according to the vessel caliber: ≤2.75 mm (42 pz) vs. >2.75 mm (75 pz). All patients were treated with 2 different types of second-generation DCB (In. Pact Falcon, Medtronic-Invatec, Frauenfeld, Switzerland; and Pantera Lux, Biotronik, Bulach, Switzerland).

Results: At the longest available clinical follow up (average 19.7±14.2 months) the occurrence of TLF was 11.9% in the small vessel caliber group vs. 15.1% in the control group (p=0.86), with no significant differences in the incidence of MI (4.8% vs. 6.8%; p=0.92), TLR (7.14% vs. 8.2%; p=0.95) and there has been no cases of cardiac-death in both groups of patients. The incidence of target vessel revascularization (TVR) (11.9% vs. 10.9%; p=0.95) and MACE (11.9% vs. 13.7%; p=0.86) were slightly different between the two groups of patients and there has been no cases of stent thrombosis.

Conclusions: Our study suggests that the use of a second generation DCB for the treatment of a high risk population as the diabetic patients with small vessel caliber ISR, might be associated with an optimal long-term clinical follow up.

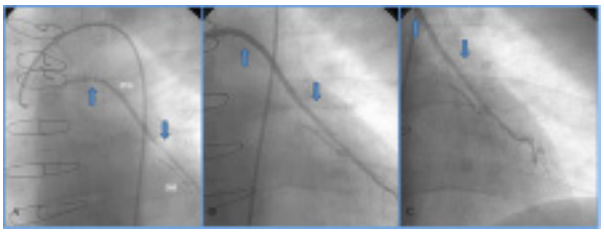

Figure 1: Two tandem ISR in saphenous vein graft to obtuse marginal branch (panel A, blue arrows). After pre-dilatation by a non-compliant balloon, DCB dilatation was performed with a final good result (panel B).

1 year angiographic follow up revealed a persistent good result (panel C).

Recent Publications

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2. Buccheri D, Piraino D, Andolina G, Cortese B (2016) Drug-Coated Balloon for Instent Restenosis in Patients at High Risk: Another Brick in the Wall of the Challenging Settings for Interventionists. Am J Cardiol 117(11):1859-61.
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4. Cortese B, Piraino D, Buccheri D, Alfonso F (2016) Treatment of bifurcation lesions with drug-coated balloons: A review of currently available scientific data. Int J Cardiol 220:589-94.

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