Drug eluting balloon: a real world three centers experience

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BACKGROUND The use of drug-eluting balloons (DEB) for the treatment of in-stent restenosis (ISR) and lesions in small vessels has not been extensively investigated in the real-life clinical practice. According to the most recent guidelines, the use of DEB is indicated only for the treatment of ISR. We aim to report a three-centers “all comers” registry on the safety and efficacy of DEB in the treatment of ISR and de novo coronary artery disease.

METHODS Consecutive patients treated with the In.Pact Falcon™ (Medtronic Inc., Minneapolis, MN, USA) paclitaxel-eluting balloon between January 2012 and November 2014 in the centers of Verona, Mirano and Savona were retrospectively analyzed in our registry. The measured clinical end-points were cardiac death, myocardial infarction (MI), target lesion revascularization (TLR), target vessel revascularization (TVR), while procedural success was defined as the ability to reach, cross and dilate a lesion with the study device, with a residual stenosis <30% and a final TIMI 3 flow in the culprit vessel. Primary end point of the study was the occurrence of major adverse cardiac events (MACE), defined as combination of cardiac death, MI, and TLR, at 12 and 24 months of follow up.

RESULTS A total of 167 lesions were successfully treated in 143 patients. The mean age was 67 ± 10 years, and 82.5% were males. The main risk factors were represented by hypertension and dyslipidemia while 39.4% of patients were diabetics. The 73.5% of the population had a prior PCI and the main indication for PCI was because of ACS (73.5% while 26.5% of patients suffered from stable angina). The predominant indication for DEB use was ISR (75%), mainly focal (34.1%), involving a DES in the 79% of cases. Procedural success was achieved in 97.6%. A mean of 1.1 ± 0.18 DEB were used per patient. Bailout stenting was required in 2 lesions. No events were recorded during the hospitalization. Long term follow up was available for 100% of the study population. The overall incidence of MACEs at 12 months was 5.6%, while at 24 months was 9.1%, with an overall event free survival of 85%. Of interest, the primary endpoint occurred in 18% of patients treated for de novo lesions, against a 5.7% of ISR patients (p=0.01). Patients presenting with focal restenosis had an incidence of events comparable to those with more aggressive restenotic pattern (diffuse or proliferative, p=0.71).

CONCLUSIONS Our results confirm the safety and efficacy at short and long term follow up of DEBs, especially in patients presenting with ISR. On the contrary, the use of DEB in de novo lesions is associated with a poorer clinical outcome. Larger trials are needed to confirm our data.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

KEYWORDS Drug-eluting balloon, Optical coherence tomography, Restenosis, in-stent

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Treatment of coronary artery disease with a new-generation drug-coated balloon: preliminary results from the Italian Elutax SV Registry

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BACKGROUND drug-coated balloons (DCB) have shown to be a valuable alternative to stents for the treatment of in-stent restenosis, and there is some initial evidence of their efficacy for the treatment of small coronary vessels. Newer generation DCB were developed to overcome the reduced deliverability of the previous generation of devices, warranting an effective drug delivery to the vessel wall. However, the vast majority of such devices still lack of reliability due to paucity of clinical data.

METHODS between 2012-2014 all patients intended to be treated with this type of DCB at 9 italian centers were enrolled in this retrospective registry. We did not have specific exclusion criteria. Coronary interventional procedures were performed following the Italian Position paper on DCB-PCI published in 2014. Primary outcome was the occurrence of target lesion revascularization (TLR) at the longest available follow up.

RESULTS we enrolled 247 consecutive patients/283 lesions, whose clinical, angiographic and procedural characteristics are depicted in Table. At the longest available clinical follow up (average 225 days, I.Q. ranges 67 days), 5 patients suffered a TLR, all but one managed with re-PCI (2 with another type of DCB, 2 with DES). We registered 2 cases of cardiac death (one for heart failure and one for fatal myocardial infarction related to another vessel), 4 non-cardiac deaths (2 malignancies and 2 intracranial hemorrhages) and no cases of target vessel myocardial infarction/thrombosis.

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