The use of paclitaxel coated balloon (PCB) in acute coronary syndrome of small vessel de novo lesions: an analysis of a prospective ‘real world’ registry

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Abstract

Background: Paclitaxel-coated balloon (PCB) angioplasty in small vessel de novo lesions has favourable outcome and appears to be an alternative to stent implantation. However there is limited data on its use specifically in small vessel acute coronary syndrome (ACS).

Methods: We analyse patients data from the SeQuEnt Please Small Vessel PCB only Registry. It was an international, prospective, multicentre registry which enrolled patients with de novo lesions of small vessel diameter (≤2.0, ≤2.75 mm). Patients were divided into the ACS group and the non-ACS group and comparison made between the two groups. The primary end-point was clinically driven target lesion revascularisation (TLR) at 9 months. Secondary end-points were acute technical success, 30-day and 9-month major adverse cardiac events (death, myocardial infarction or TLR) (MACE) and the occurrence of definite lesion and vessel thrombosis.

Results: A total of 447 patients were enrolled for this registry of which 105 (23.5%) patients were ACS (STEMI and NSTEMI). The procedural success rate was 98.1% in ACS group. The mean vessel diameter for the ACS and non-ACS group were 2.15 ± 0.36 and 2.14 ± 0.35 respectively. Similar mean lesion length of around 15.5 mm was recorded in both groups. Additional stenting was required in 9.3% ACS and 6.5% non-ACS, p = 0.308. Reasons for additional stenting were target lesion related dissection (57.6%) or non-target lesion stenosis (41.2%). More than half of the patients had 4 weeks of aspirin/clopidogrel (57.1% ACS, 60.5% non-ACS). No significant difference between the ACS and non-ACS groups with regards to the duration and types of DAPT during follow up. At 30-day, MACE rate were (0% ACS vs 0.3% non-ACS, p = 0.599). At 9 months TLR rates were (1.2% ACS vs 4.3% non-ACS, p = 0.180) and MACE rates (3.6% ACS vs 5.0% non-ACS, p = 0.601).

Conclusion: PCB in ACS with small vessel de novo lesions has low 30-day and 9-month TLR/MACE rates comparable to non-ACS small vessels. Thus it appears to be an alternative to stent implantation in the treatment ACS.

Keywords: Paclitaxel, Balloon angioplasty, Small vessels, Acute coronary syndrome, MACE

Background

Paclitaxel coated balloon (PCB) angioplasty has proven in the treatment of bare-metal and drug-eluting in-stent restenosis (ISR) (Scheller et al. 2006, 2008, 2012; Harbara et al. 2011; Byrne et al. 2013). The efficacy of PCB in treating small vessel de-novo lesions is also emerging with promising data so far (Ali et al. 2011; Zeymer et al. 2014). However, the data on PCB angioplasty specifically in acute coronary syndrome (ACS) is still lacking. Intravascular plaque rupture and thrombus formation in ACS

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