Use of sirolimus-coated balloon in de novo lesions; Mid-term follow-up from a single-centre registry

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Introduction: Use of drug coated balloons (DCBs) in coronary intervention is escalating and the guidelines recommend its use in restenotic lesions. However, recent data suggest it can also be considered in a subset of de-novo lesions especially; small vessels, ostium of an important side-branch and in patients unable to tolerate dual antiplatelet therapy for a prolonged period. Most DCBs used elute Paclitaxcel, but there is no data on Sirolimus eluting DCB, which is the drug of choice in currently available drug eluting stents. In this study, we report outcomes from the use of a Sirolimus coated balloon (SCB) in de novo coronary lesions.

Methods: We retrospectively analysed all patients treated with an SCB between April and December 2018. Results are reported as cardiac death, target vessel myocardial infarction (TVMI), target lesion revascularisation (TLR), target vessel revascularisation (TVR) and MACE (combination of cardiac death, target vessel MI and TLR).

Results: During the study period, 351 patients (with 414 lesions) with de novo lesions were treated with an SCB. The mean age of patients was 65.6±11.5 years, 275 (78%) were male and 39% (n=212) had diabetes. Most lesions treated were in the LAD/diagonal system (n=173, 42%). Predilatation was performed in 98% (405 lesions). Bailout stenting (with a drug eluting stent) was required in 7% lesions (n=30), of which 11 were due to dissections and 19 were due to recoil >50% following DCB use. The mean diameter and length of DCBs were 2.47 mm and 26 mm respectively.

During a median follow-up of 322-days (11-months) cardiac death was reported in 8 patients (2.3%). Target vessel MI was in 3%; n=10, TLR and TVR per lesion were 8% (n=34) and 9% (n=37) respectively. The MACE rate was 11%. There were no documented cases of acute vessel closure.

Conclusion: The mid-term outcome from the first ever study on sirolimus coated balloons in de novo lesions appears promising with low rates of hard endpoints with no documented cases of acute vessel closure. The MACE rates appear promising, although we need longer follow-up which is ongoing and we will be able to report outcomes from even longer follow-up during the presentation.

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