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Treatment of coronary in-stent restenosis with sirolimus-coated balloon catheter

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AIMS

Evaluation of the safety and efficacy of the sirolimus-coated balloon **DEVOIR** in patients with coronary **In-Stent Restenosis** (ISR).

METHODS

177 patients with coronary ISR were treated with the sirolimus-coated balloon DEVOIR in a prospective, multicentre and post-marketing study. The primary endpoint of the study was the rate of major adverse cardiac event (MACE), which is defined as the composite of cardiac death, target-vessel myocardial infarction (TV-MI) and target lesion/vessel revascularization (TLR/TVR) at one year. To date, 162 (91.5%) patients completed one-year clinical follow-up.

STUDY DEVICE

The CE marked **DEVOIR** drug-coated balloon comprises of a semi-compliant balloon catheter coated with **sirolimus** drug (1.27µg/mm^2 of balloon surface).

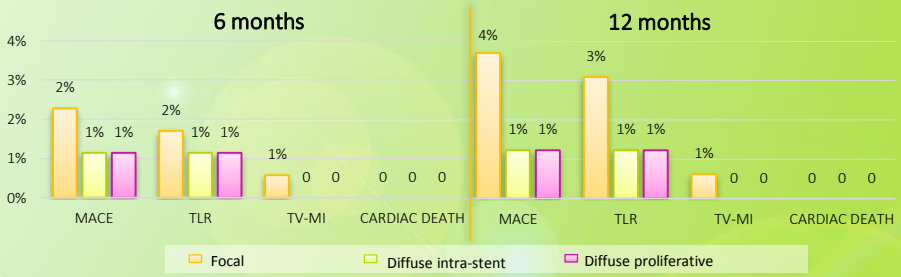
PATIENT CHARACTERISTICS

Patient, n	177
Age, years	60.24±9.08
Male, %	79.7
Hypertension, %	50.3
Diabetes, %	53.1
History of CAD,	
-Previous MI, %	55.9
-Prior CABG, %	7.9
Renal insufficiency, %	5.7
Left ventricular dysfunction, %	6.2
Clinical presentation,	
-Stable angina, %	50.9
-ACS, %	46.3
Target vessel,	
-LAD, %	47.6
-LCx, %	21.7
-RCA, %	28.0

LESION AND PROCEDURE CHARACTERISTICS

PROCEDURE/BALLOON		ISR PATTERN		TYPE OF STENT ISR	
Length, mm	22.54±7.12	Focal, %	60.3	DES, %	79.9
Diameter, mm	2.88±0.38	Diffuse intra-stent, %	18.5	BMS, %	11.1
Device per patient	1.22	Proliferative, %	9.0	BVS, %	1.1
Balloon alone therapy,%	92.1	Total occlusion, %	9.5	Unknown,%	7.9

CLINICAL RESULTS PER ISR TYPE



CONCLUSIONS

The use of sirolimus-coated balloon DEVOIR for the treatment of coronary ISR is **safe and effective** with a **low rate of events** up to one-year clinical follow-up whether the types of ISR pattern.