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A sirolimus-coated balloon in the treatment of coronary lesions in patients with acute coronary syndrome

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AIMS

Evaluation of the clinical outcomes of sirolimus-coated balloon **DEVOIR** in patients with acute coronary syndrome (ACS) in a real-world setting.

METHODS

In this real-world observational study, 188 patients with ACS were enrolled (201 lesions).

The primary endpoint of the study was major adverse cardiac events (MACE) rate at 12 months. MACE was defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI) and target lesion/vessel revascularization (TLR/TVR).

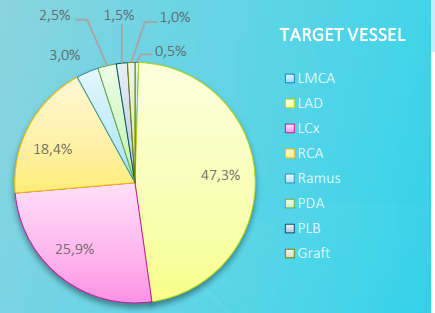
One year follow-up was completed in 89.4% of the patients to date. The study clinical follow-ups are on-going.

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

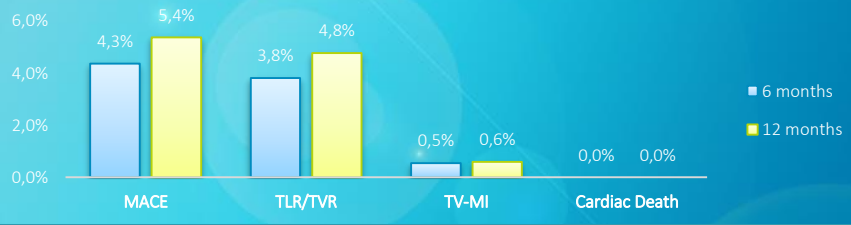
Patient, n	188
Age, years	59.54 ± 9.90
Male, %	80.3
Hypertension, %	47.3
Diabetes, %	43.1
History of CAD,	
-Previous MI, %	35.1
-Previous PCI, %	51.1
-Prior CABG, %	5.3
Renal insufficiency, %	4.8
Multivessel CAD, %	6.9
Clinical presentation,	
-Unstable angina, %	64.4
-Non-STEMI, %	12.2
-STEMI, %	23.4



PROCEDURE CHARACTERISTICS

Length, mm	22.15±7.47
Diameter, mm	2.71±7.47
Inflation pressure, atm	12.17±4.90
Inflation time, sec	58.41±8.13
Device per patient, mean	1.16
Balloon alone therapy, %	93.1
Procedure success, %	100.0

CLINICAL RESULTS



CONCLUSIONS

The results showed that treatment of patients presenting ACS is **safe and effective** with the DEVOIR sirolimus-coated balloon. Indeed, a **low rate of MACE** with no cardiac death was reported at one-year.