

Comparison of clinical outcomes after treatment with a sirolimus-coated balloon in patients with coronary lesions in small vessels versus large vessels

BRIGUORI C.

Clinica Mediterranea, NAPLES, ITALY

AIMS

To compare the clinical outcomes of the patients with small coronary vessels (SV) versus patients with large coronary vessels (LV) after PCI with the **sirolimus-coated balloon DEVOIR**.

METHODS

Patients from a real-world population with small vessels (RVD ≤ 2.75 mm) and with large vessels (RVD ≥ 3 mm) were enrolled in this non-randomized, prospective multicentre study. The primary endpoint of the study was major adverse cardiac event (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).

STUDY DEVICE

The CE marked **DEVOIR** drug-coated balloon comprises of a semi-compliant balloon catheter coated with **sirolimus** drug ($1.27\mu\text{g}/\text{mm}^2$ of balloon surface).

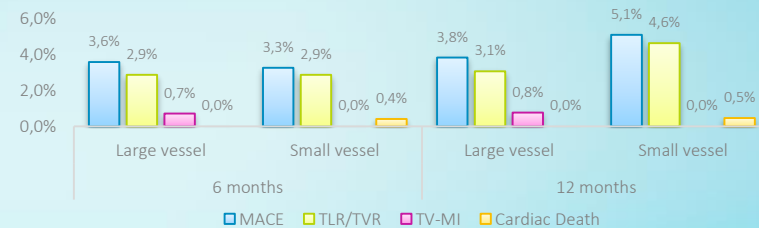
PATIENTS CHARACTERISTICS

| | Large vessel | Small vessel |
|------------------------|--------------|--------------|
| Patient, n | 141 | 252 |
| Age, years | 61.0 | 59.3 |
| Male, % | 83.7 | 80.2 |
| Hypertension, % | 48.9 | 44.1 |
| Diabetes, % | 48.2 | 42.9 |
| History of CAD, | | |
| -Previous MI, % | 46.1 | 22.6 |
| -Previous PCI, % | 75.9 | 39.7 |
| -Prior CABG, % | 8.5 | 5.2 |
| Renal insufficiency, % | 5.0 | 2.8 |
| Multivessel CAD, % | 7.8 | 5.6 |
| Clinical presentation, | | |
| -Stable angina, % | 48.9 | 48.0 |
| -ACS, % | 48.9 | 47.2 |
| Target vessel, | | |
| -LAD | 43.4 | 49.6 |
| -LCx | 18.5 | 26.3 |
| -RCA | 32.9 | 13.2 |

PROCEDURE CHARACTERISTICS

| | Large vessel | Small vessel |
|--------------------------|-----------------|------------------|
| Length, mm | 22.7 \pm 7.13 | 21.93 \pm 7.02 |
| Diameter, mm | 3.14 \pm 0.27 | 2.40 \pm 0.27 |
| Device per patient | 1.21 | 1.13 |
| Balloon alone therapy, % | 92.2 | 93.3 |
| Procedural success, % | 99.3 | 99.6 |

CLINICAL RESULTS



CONCLUSIONS

The results suggest that the use of the DEVOIR sirolimus-coated balloon is associated with **good clinical outcomes whether in small or large vessel lesions**. There was no significant difference reported between the two groups in terms of MACE.