Angiographic Results and 1-Year Clinical Outcomes from the SABRE Trial Published

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Angiographic results and 1-year clinical outcomes of the SABRE (Sirolimus Angioplasty Balloon for Coronary In-Stent Restenosis) trial were published in JACC: Cardiovascular Interventions, October 2017.

ABSTRACT.

Objectives
The aim of this first-in-human study was to assess the safety and effectiveness of the Virtue sirolimus-eluting balloon in a cohort of patients with in-stent restenosis (ISR).

Background
Angioplasty balloons coated with the cytotoxic drug paclitaxel have been widely used for ISR treatment. The Virtue® angioplasty balloon (delivers sirolimus in a nanoencapsulated liquid formulation. This clinical trial is the first to examine a sirolimus-eluting balloon for ISR.

Methods
In this prospective, single-arm feasibility study at 9 European centers, 50 ISR patients were treated with the Virtue balloon. Angiographic measurements at 6 months are reported, along with 12-month clinical follow-up.

Results
Procedural success in the intention-to-treat population was 100%. The primary safety endpoint was target lesion failure (TLF) (cardiac death, target vessel myocardial infarction, and clinically driven target lesion revascularization) assessed at 30 days (0%, n = 50). The primary performance endpoint was in-segment late lumen loss (LLL) at 6 months (0.31 ± 0.52 mm; n = 47). Secondary 6-month endpoints include binary restenosis (19.1%), diameter stenosis (30.3 ± 19.9%), and major adverse cardiac events (MACE) (10.2%, n = 49). In the 36-patient per-protocol population (excluding major protocol violations and previously stented ISR), LLL was 0.12 ± 0.33 mm at 6 months. Clinical outcomes at 1 year for the intention-to-treat group were 12.2% TLF and 14.3% MACE and for the per-protocol population were 2.8% TLF and 2.8% MACE.

Conclusions
This first-in-human study showed excellent procedural success for the Virtue Sirolimus-eluting balloon, 6-month LLL rates in line with current stent-free ISR treatment options, and clinical outcomes that warrant further evaluation in dedicated randomized studies.

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