NINE-MONTH OUTCOMES IN THE TREATMENT OF STENOTIC LESIONS IN DE NOVO NATIVE CORONARY ARTERIES IMPLANTED WITH PRESILLION/PRESILION PLUS STENT SYSTEM: RESULTS FROM THE PIONIR STUDY

i2 Poster Contributions
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Authors: Horst Sievert, Jeffrey J. Popma, Beth Israel Deaconess Medical Center, Boston, MA, United States

Background: The use of bare metal stents (BMS) has dropped precipitously since the introduction of drug-eluting stents (DES). Recent concern regarding the long-term safety of DES, specifically an increased risk of late stent thrombosis relative to BMS, has tempered the use of DES in favor of BMS. The objective of the PIONIR study is to assess the safety and effectiveness of the 2nd generation cobalt chromium Presillion and Presillion Plus bare metal stent systems in the treatment of de novo stenotic coronary artery lesions.

Methods: This is a non-randomized, multicenter, prospective, single arm study. A total of 278 patients were enrolled at 16 sites in Europe and Israel. Patients were included with stenosis ≥50%, lesions 2.5 mm to 4.0 mm in diameter, and ≤30 mm in length.

The primary endpoint is the incidence of target vessel failure defined as cardiac death, target vessel myocardial infarction, or clinically driven target vessel revascularization within 270 days post procedure, and will be compared with a BMS historical control reference. Secondary endpoints included clinically driven target lesion revascularization (TLR), target vessel revascularization (TVR), target vessel failure (TVF) and stent thrombosis at 30, 180, 270 and 360 days. Patients will be followed out to 1 year post index stenting procedure.

Results: Procedural and device success were achieved in 98.2% of all patients. At 30 days, one patient died and 6 suffered a myocardial infarction for a total TVF rate of 2.5%. To date, approximately 80% of patients have completed follow-up for the primary endpoint with a TVF rate of 10.7% and clinically driven TLR rate of 7.0%. Complete 9-month follow-up will be presented at time of ACC presentation.

Conclusions: Preliminary results with the use of the Presillion stent show promising safety and effectiveness results of this device compared to published data of other BMS and DES.