ABSORB EXTEND: AN INTERIM REPORT ON THE 24-MONTH CLINICAL OUTCOMES FROM THE FIRST 450 PATIENTS ENROLLED

Poster Contributions
Hall C
Monday, March 31, 2014, 9:45 a.m.-10:30 a.m.

Session Title: Bioresorbable and Drug-Eluting Balloon Technologies
Abstract Category: 41. TCT@ACC-i2: Coronary Intervention: Devices
Presentation Number: 2109-281

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Background: The safety and performance of the Absorb Bioresorbable Vascular Scaffold (Absorb) (Abbott Vascular, Santa Clara, CA) has been previously established in 131 patients from Cohort A and Cohort B of the First-in-Man ABSORB trial. Results out to 3 years have been presented in 100 patients from the ABSORB Cohort B trial. At 36 months, the MACE rate was 10.0%, with no scaffold thrombosis reported. ABSORB EXTEND was initiated as a global continued access study (outside of the US) to expand experience with the Absorb to different geographies. Additionally, patients were treated for longer coronary lesions than those in the ABSORB trial using either longer scaffold lengths or planned overlap of the Absorb.

Methods: ABSORB EXTEND is a prospective, single-arm, open-label clinical study that has enrolled a total of 814 subjects from up to 100 sites. Included were patients with lesions ≤ 28 mm in length and reference vessel diameter of 2.0 - 3.8 mm (as assessed by on-line QCA or IVUS). Treatment of a maximum of two de novo native coronary artery lesions, each in a different epicardial vessel, was permitted.

Results: Interim 24-month data in the first 250 ABSORB EXTEND study patients has been previously presented. Patients included 35% with unstable angina, 29% with prior MI and 25% with diabetes mellitus. The mean RVD was 2.58 mm and mean lesion length was 11.7 mm. In these 250 patients, the MACE and TVF rates were 7.3% and 8.1% respectively. Long-term, 24-month follow-up data will be available for approximately 450 patients in March 2014 and will provide substantial data on the long-term safety and performance of the Absorb in a larger population of patients, including those with planned overlapping and dual vessel treatment. Clinical composites and component end points will be presented out to 24 months.

Conclusions: Long-term outcomes in approximately 450 patients at 24 months (the largest patient cohort reported at this time point to date) from ABSORB EXTEND will provide further insight into the safety and efficacy of the Absorb in patients with longer lesions.