The ABSORB Cohort B Trial: Insights from Longitudinal Imaging Follow-up from Six Months to Three Years

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Background: The ABSORB Cohort B trial is a multicenter single-arm study assessing the safety and performance of the Absorb BVS (Abbott Vascular, Santa Clara) in 101 patients at 12 sites in the European and Asia Pacific regions. This Cohort was divided into 2 groups of patients: the first group (B1) underwent invasive imaging by means of QCA, IVUS, IVUS-VH and OCT at 6 and 24 months, whereas the second group (B2) underwent invasive imaging at 12 months, which will be repeated at 3 years.

Methods: Endpoints include: Ischemia-Driven MACE at 30 days, 6, 9 and 18 months, and yearly to 5 years; in-scaffold and in-segment late loss, changes in mean lumen diameter (vasomotion) at 6 months, 1, 2 and 3 years assessed by QCA; vessel area, mean and minimal scaffold area, mean and minimal lumen area at 6 months, 1, 2 and 3 years assessed by IVUS; strut area, lumen area, scaffold area, and neointimal area obtained with OCT at 6 months, 1, 2 and 3 years.

Results: Clinical data up to 2 years for the full cohort of 101 patients are currently available and show an ID-MACE rate of 9.0%. There were no scaffold thromboses up to 2 years. From 6 months to 2 years, the in-scaffold late loss in Group B1 increased from 0.16±0.18 to 0.27±0.20 on QCA, with an increase in neointima on OCT and IVUS. This value of 0.27mm in Group B1 at 2 years was similar as the late loss in Group B2 at 1 year (0.27mm ±0.32). This group is currently undergoing 3 year imaging follow-up. At 1 year, vasomotion test in Group B2 had demonstrated the transient dynamic plasticity of the scaffold, with 30 out to 32 tested patients showing signs of vasomotion. At 2 years, discontinuity of the scaffold allows further dynamic changes in vessel architecture, such as late lumen enlargement as suggested by the increase in mean scaffold area compared with baseline (+0.54±1.09 mm2 on intravascular ultrasound, P=0.003 and +0.77±1.33 m2 on OCT, P=0.016).

Conclusions: At 2 years, the dynamic vasomotion and the structural increase in the scaffold area suggest that the mechanical integrity of the Absorb BVS has subsided. The 3-year follow-up of Group B2 will be available at the time of the presentation. We will present a global update of the ABSORB Cohort B trial with imaging observations at 6 months and 1, 2 and 3 years.