Bioresorbable Vascular Scaffolds

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Abstract Withdrawn

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ABSORB EXTEND: An Interim Report on the 24-month Clinical Outcomes from the First 250 Patients Enrolled

Robert J. Whitbourn

1St. Vincent Hospital Melbourne, Melbourne, Australia

Background: The safety and performance of the Absorb Biodegradable Vascular Scaffold (Absorb BVS) (Abbott Vascular, Santa Clara, CA) has been previously established in 111 patients from Cohort B 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 BVS 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 BVS.

Methods: ABSORB EXTEND is a prospective, single-arm, open-label clinical study that will enroll approximately 800 patients at up to 100 sites. Included are 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, is permitted.

Results: Interim 12-month data in the first 250 ABSORB EXTEND study patients have 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 4.4% and 4.8% respectively. Long-term, 24-month follow-up data will be available for these patients in October 2013 and will provide substantial data on the long-term safety and performance of the Absorb BVS 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 250 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 BVS in patients with longer lesions.

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First Report of the Four Year Clinical Results of the ABSORB Trial Evaluating the Absorb Everolimus Eluting Bioresorbable Vascular Scaffold in the Treatment of Patients with de Novo Native Coronary Artery Lesions

Bernard Chevalier

ICPS, Massy, France

Background: The ABSORB Cohort A trial results demonstrated the safety of Absorb BVS (Abbott Vascular, Santa Clara, CA, USA) in 30 patients with single de novo native coronary artery lesions, with a low long-term MACE rate at 5 years (3.4%) and no scaffold thrombosis. The ABSORB Cohort B trial, a continuation of that assessment with a modified Absorb BVS, enrolled 101 patients at 12 sites in European and Asia Pacific regions in 2009.

Methods: The patients of the ABSORB Cohort B trial were divided into 2 groups. Cohort B1 (45 patients) having imaging follow-up performed at 180 days and 2 years and Cohort B2 (56 patients) having imaging follow-up performed at 1 and 3 years. Key clinical endpoints include scaffold thrombosis, ischemia driven MACE (ID-MACE) and its components at 30 days, 6, 9 and 18 months, and 1, 2, 3, 4 and 5 years.

Results: In the ABSORB Cohort B trial, the mean age was 62 years, 72% of patients were male, 17% of patients were current tobacco users. Patients with diabetes: 17%, hypertension: 66%, hypercholesterolemia: 85%, family history of CAD: 55%, stable angina: 68%, of which 15% having stable angina with CCS class I or II, 10% unstable angina class I, 7% class II, 2% class III. In the ABSORB Cohort B trial, the mean age was 62 years, 72% of patients were male, 17% of patients were current tobacco users. Patients with diabetes: 17%, hypertension: 66%, hypercholesterolemia: 85%, family history of CAD: 55%, stable angina: 68%, of which 15% having stable angina with CCS class I or II, 10% unstable angina class I, 7% class II, 2% class III.

Conclusion: Four-year data are currently being collected. The long-term 4-year clinical results for Cohort B1 will be presented and will provide further insight into the long-term safety and efficacy of the Absorb BVS.
The appearance of jailed side branches post-procedure, at 6, 12, 24 and 36 months following implantation of bioresorbable vascular devices – Insights from the ABSORB Cohort B trial using three-dimensional optical coherence tomography

Yoshinobu Onuma1, Hector M. Garcia-Garcia2, Jacques Koolen3, Takashi Muramatsu4, Shimpie Nakatani5, John A. Ormiston6, Patrick W. Serruys7, Leif Thuesen8, Robert Van Geuns9, Robert J. Windecker10, Stephen Windecker11

1Thoraxcenter, Rotterdam, Rotterdam, 2Cardiology, Rotterdam, Zuid Holland, 3catharina hospital eindhoven netherlands, Eindhoven, Netherlands, 4Thoraxcenter, Erasmus Medical Center, Rotterdam, Netherlands, 5Sakurabashi-Watanabe Hospital, Osaka, Japan, 6Associate Professor, University of Auckland Medical School, Auckland, New Zealand, 7Thoraxcenter, Rotterdam, Rotterdam, Netherlands, 8Department of Cardiology, Aarhus University Hospital, Skejby, Denmark, Aarhus, Denmark, 9Erasmus MC, Rotterdam, Netherlands, 10St. Vincent Hospital Melbourne, Melbourne, Australia, 11Bern University Hospital, Bern, Switzerland

Background: Eterovin-luting ABSORB Bioresorbable vascular scaffolds consisted of poly-lactide are programmed to biodegrade approximately in three years. It is still unknown how the struts implanted in front of a side branch behave during biodegradation. The purpose of this study was to assess the fate of bioresorbable stents jailed side branch ostia at 6, 24 months (cohort B1) or at 12 and 36 months after implantation of the BVs (cohort B2), with three-dimensional (3-D) optical coherence tomography (OCT) reconstruction.

Methods: The ABSORB Cohort B trial is a multicentre single-arm trial to assess the safety and performance of the BVs. Four different OCT pullbacks were obtained at a pullback speed of 20 mm/s and 3-D rendering are computed. The area and the number of strut-free compartments at side branch ostium delineated by the BVs struts were evaluated. The endo- and abluminal coverages of the struts present at the ostium of sidebranch were quantified at 6, 12, 24 and 36 month follow-up.

Results: Serial 3D-OCT images were available in total 26 side branches (13 in cohort B1 and 13 in cohort B2). In the Cohort B1, the number of compartment and average ostium area free from jailed struts did not change from baselines to 6 months, but significantly reduced from 6 months to 2 years. In the Cohort B2, there was a similar reduction of the number of compartments and the ostium area from baseline to one year. However, from one year to 3 years, there was late enlargement of the sidebranch ostium area (1Y: 0.47±0.64mm2, 2Y: 0.68±0.38mm2) without changing the number of compartment. The thickness of the strut coverage was greater at the abluminal surface compared to endoluminal strut side at followup.

Conclusions: The ostial area jailed by bioresorbable scaffold decreased up to 2 years due to growing tissue between the struts, but late ostium area enlargement was observed at 3 years.

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Changes In Bioabsorbable Scaffold Geometry After Kissing Balloon Inflation In Bifurcated Coronary Lesions

Pedro Martin Lorenzo1, Medina Alonso2, SaiDiRe2,De Leo Javier3, Jose NovoaMedina4, Maueles Franco5, Manuel Furi6, Ofelia Soledad7, Suarez De Leo Jose8

1Hospital Universitario de Gran Canaria Dr. Negrín, Las Palmas de Gran Canaria, Spain, 2Hospital Universitario Reina Sofia, University of Cordoba, Cordoba, Spain

Background: In vitro and in vivo geometry of metallic single stent implantation in coronary bifurcated lesions after kissing balloon (KB) intervention, has been well studied. The same analysis of bioabsorbable vascular scaffolding (BVS) had not yet been reported. Our own in vitro observations with BVS showed integrity and no device fracture after KB inflation when ≤2.5 mm balloon diameter was inflated through the struts.

Methods: In our series, 80 coronary bifurcated lesions were treated with provisional BVS strategy. In 21 out of 80 lesions, we performed final KB inflation after BVS implantation. The reason for side branch (SB) intervention was ostial angiographic stenosis (present before BVS implantation in 14 lesions, and appearing after it in 7). IVUS studies were performed in 3 conditions: before treatment, immediately after BVS and after KB inflation. Measurements were performed at the proximal scaffold segment, before SB origin, under SB origin and at the distal segment. This study analyzes the ultrasonicographic (IVUS) findings after BVS implantation and after KB inflation. For KB technique, the balloon diameter inflated in the MV was always 0.5 mm minor than BVS diameter and the SB balloon diameter was 2 or 2.5 mm.

Results: BVS diameter was 3.10±0.39 mm and the mean inflation pressure was 15±1 atm. The MV balloon diameter was 2.8±0.3 mm (0.5 mm minor than BVS diameter in all cases). The SB balloon diameter was 2.3±0.2 mm and the inflation pressure of both balloons was 7±8 atm. Integrity of the device was always observed after KB. Good aposision of the proximal BVS and angiographic improvement of the SB origin was always obtained. Geometry of the BVS may be modified after KB technique, but not distorted. The table summarizes the findings.

<table>
<thead>
<tr>
<th>SB origin area</th>
<th>After BVS</th>
<th>After KB inflation</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>Proximal BVS area</td>
<td>7.48±1.73</td>
<td>7.95±1.19</td>
<td>0.03</td>
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<tr>
<td>Al at proximal stent</td>
<td>0.85±0.06</td>
<td>0.86±0.05</td>
<td>0.93</td>
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<tr>
<td>Before SB origin area</td>
<td>6.70±1.99</td>
<td>7.53±2.04</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Al at before SB origin</td>
<td>0.81±0.08</td>
<td>0.80±0.07</td>
<td>0.88</td>
</tr>
<tr>
<td>After SB origin area</td>
<td>6.03±1.76</td>
<td>5.89±1.67</td>
<td>0.77</td>
</tr>
<tr>
<td>After SB origin area</td>
<td>0.85±0.06</td>
<td>0.82±0.07</td>
<td>0.04</td>
</tr>
<tr>
<td>Distal BVS area</td>
<td>6.98±2.03</td>
<td>7.01±1.72</td>
<td>0.98</td>
</tr>
<tr>
<td>Al at distal BVS</td>
<td>0.84±0.06</td>
<td>0.84±0.05</td>
<td>0.75</td>
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</tbody>
</table>

Conclusions: Final KB inflation in bifurcated coronary lesions treated with BVS is feasible, without inducing fracture or important distortion of the scaffold.

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One-year Clinical Outcomes of Diabetic Patients Treated With Everolimus-Eleasing Bioabsorbable Vascular Scaffolds: A Pooled Analysis From the ABSORB Cohort B and the ABSORB EXTEND Trials.

Takashi Muramatsu1, Yoshinobu Onuma2, Robert J. Van Geuns3, Bernard Chevalier4, Tejas M. Patel5, Ashok Seth6, Roberto Diletti7, Hector M. Garcia-Garcia8, Cécile Dorange9, Susan Veldhoen10, Wai-Fung Cheong11, Robert J. Whitbourn11, Antonio L. Bartorelli12, Alexandre Abizaid13, Patrick W. Serruys14

1Thoraxcenter, Erasmus Medical Center, Rotterdam, Netherlands, 2ThoraxCenter, Rotterdam, Rotterdam, Netherlands, 3Sakurabashi-Watanabe Hospital, Osaka, Japan, 4Associate Professor, University of Auckland Medical School, Auckland, New Zealand, 5Thoraxcenter, Rotterdam, Rotterdam, Netherlands, 6Department of Cardiology, Aarhus University Hospital, Skejby, Denmark, Aarhus, Denmark, 7Erasmus MC, Rotterdam, Netherlands, 8St. Vincent Hospital Melbourne, Melbourne, Australia, 9Bern University Hospital, Bern, Switzerland

Background: This interim post-hoc analysis included 101 patients of the ABSORB Cohort B and the ABSORB EXTEND Trials.

Methods: The ABSORB Cohort B trial and the ABSORB EXTEND Trials.

Results: There were no significant differences in baseline patient demographics and lesion characteristics between diabetic and non-diabetic patients treated with the Absorb BVS, except for the prevalence of hypertension requiring medications (75.0% in diabetics vs. 61.4% in non-diabetics, p=0.004). The cumulative incidence of MACE did not differ between diabetic and non-diabetic patients treated with the ABSORB BVS at 1-year follow-up (3.7% vs. 5.1%, p=0.64). One patient out of 136 diabetic patients experienced definite late scaffold thrombosis (ST), whereas four ST events (1 definite and 1 probable subacute ST, and 1 definite and 1 possible late ST) were observed in the 415 non-diabetic patients. The incidence rate of definite/probable ST was thus 0.7% in diabetic group and 0.7% in non-diabetic group (p=1.0).

Conclusions: The results of this study are in line with the previous observations of diabetics versus non-diabetics patients when treated with the Absorb Bioresorbable Vascular Scaffolding (BVS) at 1-year follow-up.