SASCI

South African Society of Cardiovascular Intervention

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SASCI Endorsement of Bioresorbable Vascular Scaffolds

This comment does not have a corresponding ESC guideline section. SASCI has reviewed the Clinical Data for the ABSORB bioresorbable vascular scaffold and is of the opinion that this new therapy has a role to play in Interventional Cardiology.

Guided by the clinical safety and efficacy demonstrated by the Everolimus eluting stent in the SPIRIT family of clinical trials, ABSORB was designed to replicate the drug dose and drug eluting profile of the Xience family of Drug Eluting Stent (DES). Clinical data from ABSORB Cohort A, Cohort B & ABSORB Extend trials have demonstrated that ABSORB is able to revascularise the vessel safely and efficaciously and then fully resorbs over time. Historical comparison with Xience V has shown similar results between ABSORB & Xience V, explained by the similar drug release profile between the two devices.

- ABSORB uses the same drug dose density (100ug/cm2)
- Similar to Xience V, ABSORB releases approximately 80% of the total Everolimus in the first 90 days after implantation
- The controlled release of Everolimus in both Xience V and ABSORB contributes to the decrease in vessel tissue re-growth that can lead to restenosis.

Advantages of a bioresorbable scaffold over a metallic stent.

Unlike DES, ABSORB gradually uncages the vessel, which allows for restoration of natural vascular function in response to physiological stimuli (e.g. exercise)
Since ABSORB resorbs via a natural metabolic process (hydrolysis), leaving behind an unscaffolded vessel, future re-intervention options (e.g. stenting, CABG) remain available should such treatment become necessary over a patient's lifetime.
Since ABSORB is not a permanent implant, it also brings the following potential new benefits to the patients:

- Reduction in adverse events, such as stent/scaffold thrombosis (particularly very late scaffold thrombosis)
- Improvement in future treatment options:
  The treatment of complex multivessel disease and chronic total occlusion (CTO) frequently results in long stents. The use of a BVS may potentially allow any future percutaneous or surgical revascularization options should they be needed.[5]

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- The likelihood of chronic inflammation is decreased (particularly in patients with metal allergies or hypersensitivities)
- Positive vessel remodelling and restoration of vasomotion

Executive Summary of clinical data for the Absorb BVS:

- Revascularization comparable to a best in class DES, with late loss of 0.19 mm and 0.27 mm at 6 and 24 months respectively (ABSORB Cohort B)[1]
- Restoration of vasomotor function in Cohort B
  (19/33 patients had increasing MLD post Acetylcholine – Cohort B)[2]
- Possible late lumen gain (0.49 mm^2 increase in mean lumen area between 6 and 24 months – Cohort B)[1]
- Comparable safety and efficacy outcomes to a best in class DES

  - No Stent thrombosis (ST) in ABSORB Cohort A (5 year follow up)[1] and Cohort B (2 year follow up)[3]; 0.6% and 0.8% ST at 6 and 12 months respectively in ABSORB EXTEND[4]

  - Comparable major adverse cardiovascular events (MACE) rates (3.4% at 5 years (Cohort A)[1], 9.0% at 2 years (Cohort B)[3], and 3.0% at 6 months – Extend[4])

  - No new MACE between 1 and 3 years in ABSORB Cohort B, Group 1[4]

- Resorption of ABSORB has been shown on OCT, with restoration of the appearance of the endothelium at 5 year follow-up* (5 years – Cohort A)

Clinical Implications:

Noting the experimental and clinical data above, it is felt that the time is appropriate to make BVS available to South African patients both in the State and Private sector.

Clinical guidelines for use will be based on the recommendations of a European Advisory Board, endorsed by SASCI on a case by case basis.

SASCI recommends:

- Controlled roll out
- SASCI approved training modules
- Certification of all Cardiologists and Catheterization Labs
    - Theoretical component
    - Practical Component – supervision of 1st 3 cases
- Initial 6 month registry

References

[1] Serruys, PW. TCT 2011;
[2] Ormiston, J. TCT 2011;
[3] Dudek, D ABSORB Cohort B Trial, Evaluation of the Absorb Everolimus Eluting Bioresorbable Vascular Scaffold (Absorb BVS) in the Treatment of Patients with de novo Native Coronary Artery Lesions, 2-Year Clinical Results, ACC 2012 ;
[4] Bartorelli, A. An Interim Report on the 12-Month Clinical Outcomes from the First 250 Patients Registered, and An Interim Report on the 6-Month Clinical Outcomes from the First 500 Patients Registered, TCT 2012;
[5] Brugaletta et al Everolimus-eluting ABSORB bioresorpbable vascular scaffold: present and future perspectives: Expet Rev. Med. Devices 9(4), 327-338 (2012)