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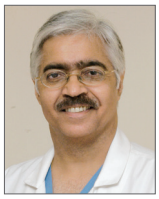
Bioresorbable scaffold use in the "real world" – mantras from the East



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The Absorb bioresorbable vascular scaffold (A-BVS) (Abbott Vascular, Santa Clara, CA, USA) represents a significant advance in the treatment of coronary artery disease. In use increasingly around the world, over the last year it has had to its credit three seminal trials (ABSORB China, ABSORB Japan and ABSORB III) which have demonstrated that A-BVS is as good as the best in class second-generation metallic drug-eluting stent (DES) both for safety and effectiveness at one year. These findings have also led to its approval in the USA two months ago. Over the last three years, clinical uptake of this revolutionary therapy has fluctuated between scepticism and optimism, confidence and caution and clarity and confusion – and all this because of the single fact that the A-BVS does not behave like the thin-strut, lower-profile user-friendly third-generation DES, which makes life so "simple" for the busy interventional cardiologist, even in complex lesions. The dreaded complication of stent thrombosis is also rare for DES as they are "technically forgiving" despite, in many instances, suboptimal implantation. The A-BVS is a "new device" and has a unique set of deployment and implantation characteristics, hence it requires its own set of "tips and tricks" for safe and effective implantation.

In this issue of AsiaIntervention, Sengottuvelu et al[1] publish a review of A-BVS use in the Asia-Pacific region. This review is important, especially as this region has a high prevalence of diabetes, and advanced and diffuse coronary artery disease in smaller vessels. Experience with the A-BVS is rapidly expanding in this region, and the lessons learnt by some of the experienced users and key opinion leaders provide not just insights, but important guidance for the interventional community at large for its safe and effective use. The document is originally based on a meeting which was convened in order to come up with a consensus around important "practice points". This meeting took place nearly a year and a half ago (April 2015), after GHOST-EU[2] had created an atmosphere of fear regarding higher scaffold thrombosis rates. Today, however, we are far wiser and certainly more confident. The document emphasises what we have said before:

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- Firstly, there is a learning curve and operators should gradually make the transition from simple to more complex cases. This helps the operator get the "feel" of the device, its crossability and deliverability characteristics, the nuances of gradual inflation, recrossing with balloons and wires, its appearance on intravascular imaging with OCT/IVUS, etc. After approximately 15-20 cases, one can then progress to more "real-world" complex cases.
- Secondly, meticulous attention to implantation techniques affects outcomes. Clearly the "seven mantras" to success with the BVS are strongly amplified in this document **(Figure 1)**. Of these, for me the most important is high-pressure post-dilatation of the scaffold with a 0.25 mm larger non-compliant balloon up to 18-20 atm. This optimises the expansion, enlarges the lumen and also embeds the thick struts into the vessel wall[3] resulting in low thrombosis rates and improved outcomes similar to the latest-generation DES[4].

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Seven "mantras" to success with BVS

1. Have good guide catheter and guidewire support
2. Size the vessel accurately after intracoronary nitroglycerine
3. Prepare the lesion well with near optimal size balloon dilatation
4. Deploy the BVS slowly and appropriately matched to the vessel size
5. Post-dilate with a 0.25 mm larger non-compliant balloon to high pressures
6. Use OCT/IVUS when in doubt regarding vessel size or result
7. Pay meticulous attention to antiplatelet therapy

Figure 1. *Seven "mantras" to success with BVS.*

– Thirdly, while I strongly recommend imaging by OCT in specific clinical scenarios such as for accurate sizing of large vessels to determine if they are greater than 4 mm (which would preclude the use of the A-BVS), for bifurcation lesions, where a two-scaffold strategy is deployed, for "full plastic jacket" and small vessels diffuse disease, the routine use of intravascular imaging is not necessary if high-pressure post-dilatation is routinely performed as advised above. One should keep in mind that intravascular imaging is not available at all centres and also adds to cost. The more practical philosophy is to "post-dilate all and image a few" rather than "image all and post-dilate a few".

Despite exciting technical promise and robust scientific proof, the uptake of the A-BVS will remain slow until those concerns which brought about this era of caution are further clarified in order to achieve confidence. There is also a reluctance related to the greater time and hardware spent in deploying an invisible device with meticulous, painstaking precision and a routine that requires post-dilatation interspersed with imaging – and all this in an age when we have become used to the rapid "deploy and done" technique with the latest-generation DES where we have no need to remember any "mantras". I would argue that the potential long-term benefits of this temporary scaffold are physiologically sound, and clinically attractive (though this will only be proven through ongoing, long-term studies). Therefore, really, what is a few more minutes of your time if it gives the patient a "lifetime".

Finally, the consensus regarding type and duration of DAPT therapy in the Asia-Pacific region remains unclear and seems to follow that of the West. This is despite the fact that many studies from the West show an increased incidence of clopidogrel resistance in patients of Asian origin. There are no systematic studies today regarding this from Asia. While this may not be so important for the "forgiving DES", it takes on a different and important connotation for the thick-strutted A-BVS where DAPT using the newer $P2Y_{12}$ inhibitors, at least initially, could be more predictable and safe in complex "real-world" patients. This is clearly an area for prospective investigation.

It is heartening that the initial clinical experience with first-generation BVS has led to the evolution of an "optimal technique" of BVS implantation which offers us third-generation DES-like safety and outcomes. Further refinements in technology, iterations in design, and the thinning of struts and pruning of costs would overcome many of the present limitations and concerns, hopefully making BVS the strategy of choice for most patients with coronary artery disease rather than just the select few.

Conflict of interest statement

A. Seth is a member, ABSORB, Global Advisory Board, Abbott Vascular.

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