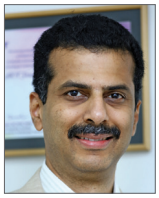
AsiaIntervention 2016;2:82-92

Technical considerations and practical guidance on the use of bioresorbable vascular scaffolds in the Asia-Pacific region: recommendations from an Asia Pacific Expert Group meeting 2015



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KEYWORDS

- Absorb
- Asian
- bioresorbable vascular scaffold

Abstract

Aims: Although the use of the bioresorbable vascular scaffold (BVS) in percutaneous coronary intervention (PCI) has been under investigation in clinical trials and real-world settings since its launch in 2010, these reports have come largely from the perspectives of European patients and physicians. Patient characteristics and physician preferences often differ in the Asia-Pacific region with respect to device implantation techniques, lesion complexity, access to intravascular imaging and patient management strategies. This has led to the need for a consensus on recommendations for deployment in Asia-Pacific populations. This document therefore serves as an overview of region-customised recommendations describing the best practices for these populations, in order to achieve more consistent and optimal clinical outcomes.

Methods and results: A comprehensive multiple choice questionnaire was disseminated to 28 interventional cardiologists from 13 countries in the Asia-Pacific region. The collated survey results then provided a backdrop to detailed discussion at a scientific meeting, the goal of which was accurate evaluation and understanding of the current BVS implantation and patient management practices of this group of physicians. Critical information from the discussions at the meeting was then compiled to generate technical recommendations, the purpose of which is to educate other cardiologists, both in the region and globally.

Conclusions: Practices, tips and techniques for the successful use of the Absorb BVS (A-BVS) in Asia were examined and used to assemble key recommendations that would foster confidence and encourage wider implementation of the device in the region. This included considerations for lesion selection, predilatation, deployment, post-dilatation, antiplatelet therapy, and management of complications. Additionally, the techniques used by interventional cardiologists in the Asia-Pacific region for specific complex lesion subtypes were also discussed.

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SUBMITTED ON 18/03/2016 - REVISION RECEIVED ON 22/08/2016 - ACCEPTED ON 27/08/2016

DOI: 10.4244/AsiaInterv_V2I2A20

Background and introduction

Important advances have been made in the last thirty years in the management and treatment of cardiovascular disease, through the use of coronary artery bypass, balloon angioplasty and other surgical and percutaneous interventions. However, as heart disease continues to be the leading cause of death globally[1], the approach to its management must be regularly updated and optimised. Over 75% of deaths from cardiovascular disease now occur in low- and middle-income countries[2], with the Asia-Pacific region accounting for nearly 50% of the worldwide burden of mortality[3].

Bioresorbable vascular scaffolds (BVS) represent a significant advance in coronary interventional technology. Although guidelines exist for the use of BVS in European patients[4], no specific recommendations are available for the Asia-Pacific region. This document therefore seeks to provide clarity on the best practices for the implementation of the Absorb BVS (A-BVS) (Abbott Vascular, Santa Clara, CA, USA) in percutaneous coronary intervention (PCI) in Asian patients, by leveraging the combined clinical experiences and professional opinions of 28 of the region's interventional cardiologists ("the authors").

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The A-BVS has undergone extensive preclinical testing[5] and clinical evaluation in Europe in simple coronary lesion settings[6,7] and has received the CE mark of approval (2010). It is now used increasingly in complex clinical settings such as ST-segment elevation myocardial infarctions (STEMI), long lesions, chronic total occlusions (CTO) and bifurcations.

Survey methodology

Twenty-eight interventional cardiologists from 13 countries in the Asia-Pacific region (Australia, New Zealand, Thailand, Malaysia, Vietnam, Singapore, Taiwan, Indonesia, India, China, Hong Kong, Japan and South Korea) who had prior experience with the implantation of coronary stents were invited to complete a survey. Briefly, the detailed survey comprised both quantitative and qualitative questions to determine the level of their experience and expertise with coronary scaffold technology and, in particular, their usage of the A-BVS device. The primary results of the survey have been published elsewhere[8]. Following the completion of the survey, the physicians gathered at a meeting sponsored by the device manufacturer (Abbott Vascular) in Singapore in April 2015. This meeting was also attended by the company's own representatives. The goal of the meeting was to understand the rationale and motivation behind the physicians' responses, in order to provide a more accurate perspective of scaffold delivery practices by physicians in the region. Importantly, the information derived from discussions during the meeting was used to drive recommendations for A-BVS deployment and use in the Asia-Pacific region, based on the collective experience of these physicians. The goal was to allow further education of physicians in these countries who are either new to, less experienced with, or encountering problems with the implementation of the A-BVS in their own practice. The following is a detailed account of the discussions at the meeting.

Potential benefits of BVS

Asia-Pacific interventional cardiologists perceived the A-BVS as effective in restoring the treated vessel's natural architecture and functionality, and potentially lowering long-term adverse event (AE) rates compared to drug-eluting stents (DES). Its most significant benefit is its temporary nature, allowing vessel enlargement through expansive vascular remodelling upon its disappearance. Many authors suggested that a scaffold would only be needed for three to six months to treat the lesion, and a temporary device that disappeared completely after two to three years was ideal.

BVS use would preserve future treatment options, such as coronary artery bypass graft (CABG) surgery in patients with progressive coronary artery disease (CAD) and replace the use of full-metal jackets with full-polymer ones in diffuse lesions (the so-called endoluminal bypass). It was also considered potentially beneficial for patients with diabetes mellitus and for young patients who might suffer from progressive and often aggressive CAD, and thus require repeat reinterventions. In such recurrent disease, implantation of additional BVS is feasible. In cases of in-scaffold restenosis (ISR), the use of metal-over-metal could be avoided by using BVS instead. With no permanent metal implant, concerns over very late stent thrombosis (ST) could potentially be reduced in the long term, especially beyond the time of complete resorption. In principle, the administration of long-term dual antiplatelet therapy (DAPT) may also be unnecessary beyond the period of resorption, although this would need to be confirmed in longer-term trials. BVS can also be used with computed tomography (CT), which is emerging as a non-invasive approach for evaluating patients with CAD **(Table 1)**.

Table 1. Perceived benefits of BVS.

Twenty-eight interventional cardiologists from countries in the Asia-Pacific region were asked to state the advantages of implanting BVS compared to alternatives such as drug-eluting metallic stents.	
Benefits of BVS as perceived or experienced by Asian interventional cardiologists	
Restores vessel's natural architecture and function	Could potentially reduce risk of late adverse events beyond the time of complete resorption
Temporary implant	Restores vasomotor function
Capping off of vulnerable plaques	Late lumen gain
Preserves future therapeutic options	Avoids full-metal jacket in diffuse lesions
Use of multiple BVS is beneficial for recurrent or progressive disease	May avoid need for long-term DAPT
Avoids metal-over-metal in ISR cases	Allows imaging, e.g., CT

Possible reasons for heterogeneous clinical outcomes

Utilisation of A-BVS varied among the authors, with one of the major concerns being the incidence of acute or subacute ST. Success with BVS was thought to be primarily dependent on adequate lesion preparation and post-dilatation **(Table 2)**. Authors agreed that

Table 2. Reasons for heterogeneous clinical outcomes.

Authors were asked to consider the problems faced in their own practices with A-BVS deployment, in order to understand the reason for heterogeneous clinical outcomes.
Possible reasons for heterogeneous clinical outcomes
Irregular use of post-dilatation
Inadequate lesion preparation
Operator inexperience with new device
DAPT non-compliance or discontinuation
Residual stenosis, suboptimal procedural result
Inadequate post-dilatation pressures
Operator skill
Incorrect vessel sizing
DAPT resistance

a large majority of the ST observed in the early post-market experience appeared to be due to a lack of or inadequate post-dilatation, or inadequate vessel and scaffold sizing. A smaller proportion is due to DAPT discontinuance, interruption or resistance.

General recommendations for BVS implantation

PATIENT AND LESION SUITABILITY

Ideal lesions for physicians to begin A-BVS implantation practices would be simple, straightforward, focal ones, e.g., type A/B1 lesions without heavy calcification or a major side branch (SB). The authors recommend successfully treating at least 20 simple lesions before attempting more complex ones (e.g., long diffuse lesions, CTOs, bifurcations). Only confident operators should attempt tortuous, extremely angulated and heavily calcified lesions. Left main (LM) and SB implantations should also be avoided initially, or until more suitable A-BVS sizes become available.

At the beginning of their practice, physicians should learn the "feel" of A-BVS deployment (i.e., pushability, strut flexibility) prior to progressing to more complicated lesions. The use of imaging techniques such as optical coherence tomography (OCT) is especially helpful when treating such lesions. For calcified lesions, the use of cutting balloons and rotablation is important in lesion preparation **(Table 3)**.

Due to the device's relative newness in the Asia-Pacific region (or unavailability so far, as in Japan and China), and the need to master implantation techniques, it is important that newer operators understand the patient and lesion types that may not benefit from A-BVS. Ideal lesions for treatment with A-BVS would be those which can be optimally expanded. Complex lesions would require more preparation and post-dilation and operator experience, and include heavily calcified lesions, long vein grafts, and true ostial lesions in either the right coronary artery or LM that are also fibrotic.

A-BVS may be less beneficial to elderly patients with numerous metallic implants. Operators must consider the currently available device lengths and diameters, expansion limits and profiles during deployment in challenging settings (e.g., in small vessels and tapering arteries). Patients who cannot be prescribed or comply with DAPT should not be treated with A-BVS.

Table 3. General guidelines for BVS implantation.

The 28 authors surveyed listed their personal experience and learning from the use of the A-BVS in their own patients to create a set of general guidelines for new users of the device.	
General guidelines for BVS implantation	
Lesions to begin with	Simple
	Focal
	A/B1
	Not heavily calcified
Lesions to progress to	Long, diffuse lesions
	STEMI/ACS
	Simple bifurcations
	CTOs
Lesions or cases to avoid	Heavily calcified
	Long vein grafts
	True ostial lesions
	Larger than 4 mm
	Smaller than 2.25 mm
Tools & techniques to use	Imaging (IVUS, OCT) when necessary/available
	Plaque modification (with cutting balloons, Rotablator™)

PREDILATATION AND SIZING

Vessel sizing and scaffold selection, lesion preparation and intravascular imaging are important pre-implantation considerations **(Figure 1)**. Proper scaffold selection is essential and depends on accurate target vessel sizing, for example, by intravascular imaging (IVUS and OCT), especially for complex lesions. However, due to the cost and limited availability of intravascular imaging, some authors preferred visual estimation against a catheter or predilatation balloon, quantitative coronary angiography or a pre-procedural CT coronary angiogram. For angiography, either proximal, interpolated or distal vessel reference diameters may be used for sizing. Sizing could also be facilitated by prior administration of nitrates. To determine whether an A-BVS could be advanced across a tough lesion, the lesion could be initially crossed and sized using a winged or deflated non-compliant balloon. Predilatation to the same size as the vessel (1:1), or to slightly less, could be performed with a non-compliant balloon dilatation catheter, especially if the lesion does not open with a semi-compliant balloon. Direct A-BVS implantation may rarely be performed in acute coronary syndromes (ACS) after thrombus aspiration.

For lesion preparation, predilatation with a non-compliant balloon was the most preferred method. For severely calcified lesions, the use of a cutting or scoring balloon or rotablation was highly advised. The authors recommended that the maximum amount of residual stenosis before scaffold implantation be at least less than 40% and, ideally, less than 20%.

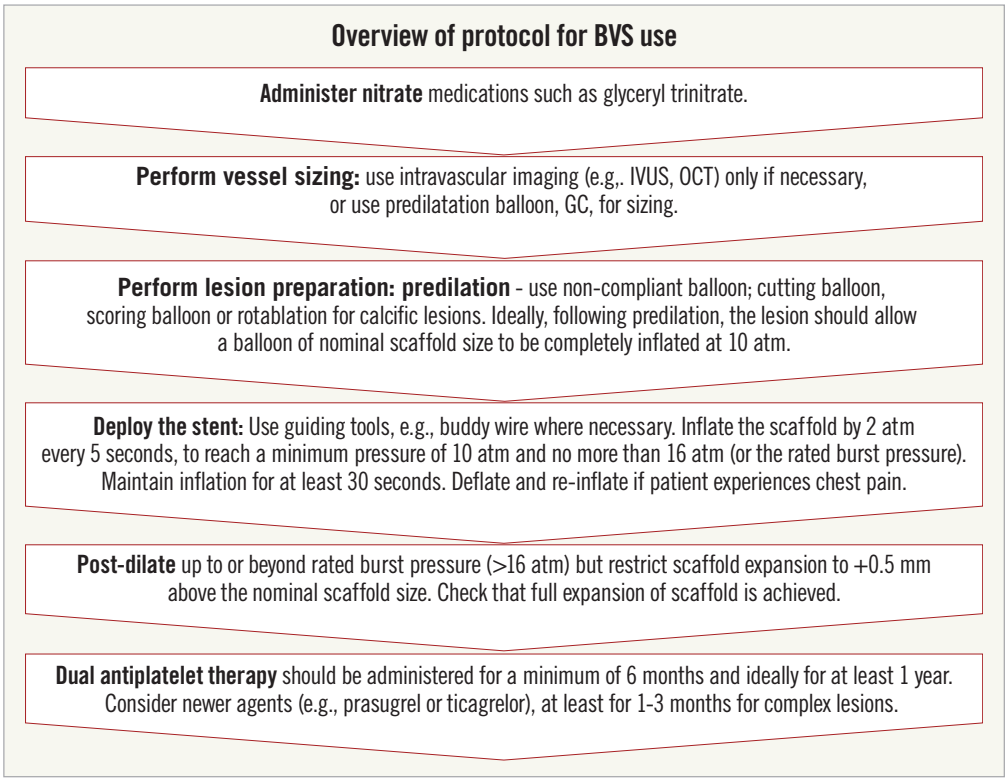

Figure 1. *Flow chart of treatment algorithm. Key steps in the deployment of the A-BVS device are summarised, following in-depth discussions by the authors to derive practical guidance on the most important aspects for practice.*

DEPLOYMENT: SCAFFOLD IMPLANTATION AND LESION CROSSING

The use of guidance tools can be integrated into BVS deployment practice. Buddy wires are often used to assist with tracking BVS deployment, as are GuideLiners® (Vascular Solutions Inc., Minneapolis, MN, USA), extra support wires or mother-and-daughter catheters. Optimal expansion and slow, gradual inflation during deployment were the most critical factors in ensuring successful implantation **(Figure 1)**. Although the scaffold should not be excessively overexpanded beyond its limits, expansion must be optimised. Balloon inflation should be maintained for at least 30 seconds and up to one minute, with pressures of 11-16 atm. Physicians must also be mindful of risking edge dissections, especially when deploying at very high pressures. To avoid this, the use of 8-10 atm for inflation was recommended by some authors, although expansion up to rated burst pressures is feasible.

The use of overlapping scaffolds may be necessary to ensure full coverage of the lesion and area treated by the balloon. The manufacturer recommends that the scaffolds be overlapped by at least 1 mm and up to 4 mm, to prevent gap-related restenosis. Overlapping should be performed by placing the balloon marker bands of the second A-BVS device on the inside of the first, already deployed scaffold, before expansion. This prevents gaps occurring between scaffolds.

Where possible, marker-to-marker overlapping should be used, although marker-over-marker and scaffold-to-scaffold techniques are also used. Precision is essential to avoid geographic miss. Physicians must understand that malapposition occurs more frequently at overlapping regions and calcified lesions. Overlapping A-BVS should also be avoided in small vessels.

POST-DILATATION: SCAFFOLD OPTIMISATION AND INTRAVASCULAR IMAGING

Post-dilatation using a high-pressure non-compliant balloon is recommended by both the manufacturer and the authors. The authors suggest a post-dilatation balloon that is slightly larger (by 0.25 to 0.5 mm) than the selected A-BVS device. Non-compliant balloons should be inflated to a maximum pressure of 15-20 atm, but expansion must be kept to no greater than 0.5 mm above the nominal scaffold diameter **(Figure 1)**. Higher pressures may be required in tough fibrocalcific lesions. The preferred duration for post-dilatation balloon inflation is 15-30 seconds but, depending on lesion complexity and the patient's tolerance to pain, inflation for either 31-60 seconds or less than 15 seconds may be preferred. Physicians are advised that balloon expansion *in vivo* differs from that shown in compliance charts.

ADJUNCTIVE ANTITHROMBOTIC THERAPY (DAPT)

DAPT recommendations currently in use by cardiologists in the Asia-Pacific region are adapted from those formulated by the American College of Cardiology, the American Heart Association and/or the European Society of Cardiology, for Caucasian patients.

East Asian patients may have different drug responses, and this must be considered when devising PCI strategies for ACS. These differences include ethnic-specific proclivities for thrombogenicity and bleeding, and a different window of time for optimal DAPT efficacy.

East Asian patients may have risk profiles for both thrombosis and bleeding which differ from Western populations[9]. In Asia, DAPT is usually prescribed for at least one year for complex lesions, with patients often maintained on DAPT long-term as secondary prevention. If clopidogrel therapy was initiated and resistance subsequently detected, transition to ticagrelor or prasugrel would be necessary. This highlights the necessity of customising DAPT prescriptions to the patient's clinical and genetic profile to ensure safety and efficacy.

For stable angina patients, a period of six months to one year or one to two years of DAPT **(Table 4)** was preferred. In ACS presentations, namely NSTEMI and STEMI, the authors were divided almost equally between durations of six months, six months to one year, one to two years, or more than two years, and there was no agreement on the optimal duration of DAPT. For patients with complex lesions such as CTO, long lesions or bifurcations, longer DAPT duration should be considered. In patients with ACS or STEMI, prasugrel or ticagrelor was preferred over clopidogrel **(Table 4)**.

If long-term OCT data in humans (in excess of three years) successfully confirm the total resorption of A-BVS, then there might be no need for long-term DAPT, i.e., beyond 2.5-3 years. More general descriptions of antiplatelet strategies and best practices for East Asian patients are available in recently published reviews[10].

Table 4. DAPT duration preferences for the treatment of A-BVS-implanted patients with stable angina, complex lesions, NSTE-ACS and STEMI complex lesions by authors surveyed for this manuscript.

In general, more authors chose either six months to one year or one to two years, rather than choosing up to six months or more than two years. Usage of prasugrel or ticagrelor was also surveyed.	
Rank order of preferred DAPT durations for cardiovascular indications treated with A-BVS	
Stable angina (1: most preferred, 4: least preferred, *: tie)	
Up to 6 months	2*
6 months - 1 year	1*
1 - 2 years	
More than 2 years	2*
Complex lesions (bifurcations, long, CTO) (1: most preferred, 4: least preferred)	
Up to 6 months	4
6 months - 1 year	1
1 - 2 years	3
More than 2 years	2
NSTE-ACS and STEMI (1: most preferred, 4: least preferred)	
Up to 6 months	4
6 months - 1 year	1
1 - 2 years	3
More than 2 years	2
Use of prasugrel or ticagrelor (%)	
Patient lesion type	% of authors who prescribe prasugrel or ticagrelor
NSTE-ACS or STEMI	66
All patients regardless of symptoms	26
N/A (physician only prescribes clopidogrel)	8

Recommendations for specific lesion subsets

LONG LESIONS

To avoid full-metal jackets in long lesions, the use of A-BVS is attractive, especially in young patients with long, diseased left anterior descending arteries (LAD), when options for future surgery need to be preserved and the anastomotic site must remain metal-free. Pre-implantation imaging is helpful for initial assessments in long lesions, as well as in the evaluation of tapering in such vessels. Imaging can help choose between implanting a single scaffold (using the interpolated diameter), or using two scaffolds instead. When sizing long lesions in tapering vessels, two scaffolds of different sizes may be used. Two different non-compliant balloons, one to treat the distal site, and a larger one to treat the proximal site, may also be used.

The treatment of long lesions with BVS requires suitable support (e.g., at least 7 Fr guide catheter, buddy wires, etc.) and meticulous vessel preparation **(Table 5)**. For deployment, the distal scaffold should be implanted first and all scaffolds should be optimally expanded. In general, implanting scaffolds distally to proximally is recommended. However, proximal A-BVS deployment can also be performed first when accurate placement is essential, e.g., in ostial lesions that require overlap and avoidance of a large side branch. This can be followed by post-dilatation and subsequent crossing with a distal scaffold.

Table 5. Factors to consider for the use of A-BVS in long lesions.

Treatment of long lesions with A-BVS	
Imaging	Assess extent of taper
	Verify possibility of use of 1 interpolated size scaffold
	Verify need for 2 different-sized scaffolds
Sizing	If >1 mm disparity, use 2 different-sized scaffolds
	Use interpolated diameter
	Use 2 different-sized non-compliant balloons
Preferred tools and techniques	Use good guide support
	Prepare vessel thoroughly
	Marker-to-marker overlap
Issues to note	If using multiple BVS, ensure precise positioning and optimal inflation
	Avoid or minimise scaffold overlap
	Overlap is not recommended in smaller vessels (<2.5 mm)

For overlapping, marker-to-marker was the most recommended approach. Ideally, the distal scaffold is deployed first, and the marker of the A-BVS scaffold checked to ensure appropriate overlap with the marker of the proximal scaffold balloon. When implanting full-polymer jackets, overlap should be minimal, and the technique of scaffold-to-scaffold placement (edge-to-edge) can be used. With small vessel diameters, layering of thick struts may compromise the lumen; therefore, overlap of A-BVS is not recommended in smaller vessels (<2.5 mm) **(Table 5)**.

CHRONIC TOTAL OCCLUSION (CTO)

As most CTOs are long lesions, using A-BVS keeps them free from full-metal jacketing for future surgical interventions. However, A-BVS is best avoided in certain CTO-associated lesions, e.g., heavily calcified lesions. The use of subintimal dissection and re-entry techniques for A-BVS in CTO is feasible. The regular use of invasive imaging techniques (IVUS and OCT) is advocated for BVS selection and follow-up in CTOs. In addition, when long CTOs are treated with overlapping BVS, optimal implantation can be verified with intravascular imaging during the index procedure, and at follow-up.

At six-month follow-up, the CTO-ABSORB pilot study[11] of BVS in 35 CTO lesions demonstrated the safety of A-BVS in this setting, as there were no MACE events in that study. Importantly, this trial emphasised adequate lesion preparation in these lesions to facilitate BVS expansion.

THROMBOTIC LESIONS (e.g., ACS, STEMI)

Real-world data from Singapore show that A-BVS can safely be used in patients with STEMI undergoing primary PCI[12]. The European multicentre randomised TROFI-II trial[13] demonstrated that stenting of culprit lesions with Absorb in the setting of STEMI resulted in a nearly complete arterial healing, which was comparable with that of the XIENCE EES at six months. In thrombotic lesions, using A-BVS may prevent late malapposition. Moreover, the greater intimal coverage afforded by the struts of A-BVS may potentially reduce distal embolisation. In younger patients with ACS and STEMI, the use of A-BVS can restore long-term vasomotion, lumen gain and vessel remodelling. Although the authors felt that A-BVS was appropriate for thrombotic lesions, the need for larger trials and more long-term data was emphasised.

To size STEMI lesions, the proximal reference diameters should be used after restoring flow and size recovery of the vessel following thrombus aspiration and nitrate treatment. Optimal sizing could be achieved using a larger balloon, although some oversizing (the largest scaffold that can be tolerated by the vessel) may be necessary. Imaging was also recommended to assist in determining the level of thrombus burden or whether plaque rupture had occurred.

The authors advised using the proximal reference marker, and deploying the scaffold slowly and gradually, to slightly higher than nominal pressures, visually verifying expansion, and performing post-dilatation to ensure optimal proximal apposition. Aggressive post-dilatation (over 14-16 atm) was generally not recommended due to the risk of no reflow, which can be minimised by thorough thrombus aspiration and/or intracoronary glycoprotein IIb/IIIa administration **(Table 6)**.

Direct scaffolding of STEMI lesions should only be performed if the level of plaque burden and proximal and distal vessel segments can be clearly seen following thrombus aspiration, and the

Table 6. Factors to consider for the use of A-BVS in thrombotic lesions (ACS, STEMI).

Treatment of thrombotic lesions with A-BVS		
Techniques	Prepare lesion:	Thorough thrombus aspiration
		Restore flow to vessel
	Sizing:	Use proximal reference diameter
		Size after restoring flow to vessel
	Implantation and post-dilatation:	Deploy scaffold slowly
		Implant a slightly oversized or largest size scaffold possible
		Direct scaffold only if thrombus aspiration is optimal, vessel is clearly visible and lesion is short, with little residual stenosis
		Avoid aggressive post-dilatation, >14-16 atm is not recommended
DAPT recommendations	1 year of DAPT is advised, e.g., one year of clopidogrel	
	Preload with DAPT	
	Use newer drugs or change to ticagrelor or prasugrel	
	Start with combinations such as aspirin and ticagrelor or prasugrel	
Issues to note	Reference vessel may be difficult to observe and size	
	Undersizing may occur	
	Plaque morphology may be unclear	
	Plaque resists expansion or ruptures	
	Risk of no reflow can be minimised by thrombus aspiration and/or intracoronary GP IIb/IIIa administration	

lesion is short with minimal residual stenosis. This would ensure that the lesion is sized accurately and thoroughly covered by the scaffold. Concerns included highly fibrotic and expansion-resistant plaques, or situations where the morphology of the plaque is unclear, especially if direct scaffolding with A-BVS is planned.

The consensus on the duration of antiplatelet therapy in thrombotic lesions following A-BVS implantation was one year of DAPT, with preloading and the use of newer thienopyridine medications such as ticagrelor or prasugrel. The manufacturer currently advocates at least six months of DAPT. Asia-Pacific interventional cardiologists preferentially use prasugrel and ticagrelor for ACS and STEMI. In complex lesions in general, the threshold for using prasugrel and ticagrelor tends to be lower. Patients can also begin with ticagrelor or prasugrel with aspirin but change to clopidogrel and aspirin during the first year, or after one year.

Potential issues with the use of A-BVS in thrombotic lesions include inflammation, spasm, occlusion and difficulties in visualising the vessel reference, which would affect vessel sizing. Importantly, these factors are also similarly present with the use of DES. Patients in cardiogenic shock should not be treated with A-BVS, since proper vessel sizing is time-consuming and may jeopardise the patient.

CALCIFIED LESIONS

Since significant calcification probably disrupts intimal physiology, vasomotor benefits following A-BVS may be limited in calcified lesions. Such compromised physiology may also impair local delivery of drugs to the calcified lesion; therefore, lesion preparation is essential. In calcific settings, overstretching the device can cause adventitial strain; therefore, lesion preparation is an essential first step and will determine the extent of expansion that can be achieved. However, BVS can provide long-term benefits if proper apposition and scaffold expansion are achieved. In order to use A-BVS, the level of calcifications must be no more than mild to moderate.

The use of cutting or scoring balloon or rotablation is recommended for lesion preparation. High-pressure dilatation with a non-compliant balloon (over 20 atm) can be performed to attempt full balloon expansion (preferably a 1:1 balloon:artery ratio). Where possible, no residual stenosis should persist. After lesion preparation, imaging (OCT or IVUS) is useful to assess the level of residual calcification, and whether it spans the entire circumference of the vessel, or is focal or eccentric. IVUS can determine if the calcification has cracked following balloon dilatation, which would make it more suitable for A-BVS. Besides sizing, IVUS can also be used post implantation to verify that, in all arterial segments, the implanted A-BVS is well expanded, and all struts circumferentially and longitudinally well apposed. Analysis of the lesion by CT angiography prior to the implantation procedure is also helpful in calcified lesions. The CT angiogram provides information on the extent and distribution of calcification **(Table 7)**.

BIFURCATIONS

In bifurcation lesions, the use of A-BVS over DES would prevent long-term stent jailing of the side branch. However, this lesion type should be treated by operators with significant expertise and experience. Due to the discrepancy between proximal and distal vessels, the operator should select the proximal vessel diameter

Table 7. Guidelines and considerations for the treatment of calcified lesions with the A-BVS.

Treatment of calcified lesions with A-BVS		
Techniques	Lesion preparation:	Use balloon dilatation to crack calcified plaque
		Cutting balloon, scoring balloon or rotablation can also be used on plaques
		Attempt to achieve no residual stenosis
	Imaging & sizing:	Use imaging for assessment of plaque density and distribution
		Use imaging for vessel sizing
		Size artery using non-compliant balloon to get 1:1 dimensions
		CT angiography may be helpful in assessing extent and distribution of calcium
	Deployment and post-deployment:	Gentle manipulation must be used for deployment
		Use high-pressure dilatation (>20 atm) with non-compliant balloon
		Use IVUS imaging to confirm that struts are well apposed, concentric and exposed
Issues to note	Overstretching can cause adventitial straining	
	Suboptimal deployment increases restenosis and thrombosis risk	
	Compromised DAPT delivery to calcified lesion	
	Not for highly calcified lesions	
	Disruption of intimal physiology	
	Early restenosis	
	Strut disruption/fractures if forcefully deployed	
	Lower vasomotor benefits	
	Diabetic patients may have more restenosis	

for scaffold sizing for bifurcation lesions, keeping in mind the limits of post-dilatation of the scaffold. Adequate imaging should be strongly considered, to establish vessel size and plaque distribution. If the distal vessel is small, it is critical not to oversize and risk distal vessel edge dissection; therefore, two overlapping scaffolds should be considered where possible, particularly in highly tapered vessels.

The use of kissing dilatation should also be minimised, and single, provisional scaffolding is the recommended strategy. Sequential non-compliant balloon inflations in the side branch and subsequently in the main branch may be used. Another option is to use snuggle balloon dilatation with two non-compliant balloons, and minimal overlapping of the balloons. While the use of final kissing balloon dilatation is generally not preferred, in selected cases low-pressure kissing balloon dilatation can be cautiously performed, preferably with imaging guidance.

Recommended strategies include the provisional 1-scaffold technique[14] with a side branch balloon, and the 2-scaffold technique with either TAP (with two BVS, or one BVS and one DES) or T stenting. If the anatomy is suitable for Medina 0,1,1 bifurcations, the V-scaffold technique is advocated. The "keep it open" approach is recommended for bifurcations with the side branch under 2.5 mm. If pinching of the side branch is significant, sequential balloon dilatation with low pressures (<10 atm) is advised, beginning with the side branch and finishing with the proximal optimisation technique (POT) in the main vessel. Kissing balloon dilatation with low pressures may be used, while a drug-eluting balloon (DEB) can be used for treatment of the side branch.

To treat the side branch, ballooning or DEBs could be used if the side branch is less than 2.5 mm in diameter. For wider side branches, either a DES or a BVS could be used, depending on the degree of angulation, diffuseness of disease or extent of calcification. To facilitate side branch treatment, the main branch BVS must be post-dilated optimally first, followed by gradual dilatation of the side branch through the struts using a balloon not more than 2.5 mm in diameter, after which a second BVS may be deployed in the side branch. The POT approach can also be used, as long as the expansion limits of the A-BVS are respected.

Post-procedure imaging, particularly with OCT, provides useful information on malapposition, underexpansion, scaffold fracture, edge dissection and side branch ostium, and should be strongly considered. Overdilatation of A-BVS in the main vessel can lead to issues including scaffold fracture, especially during proximal optimisation and final upsizing in the proximal vessel with an oversized balloon. Culotte or traditional crush techniques should generally be avoided in bifurcations. Ormiston et al[15] have shown in bench studies that dilatation through the side of an A-BVS scaffold displaced struts from the side branch lumen, but caused main branch malapposition opposite the side branch, main branch scaffold narrowing beyond the side branch, and protrusion of struts into the side branch. Scaffold distortion was corrected by main branch post-dilatation or by mini-kissing balloon post-dilatation (mini-KBPD). When 3.0 mm diameter balloons were used for side branch dilatation or mini-KBPD in 3.0 mm A-BVS, strut fracture did not occur at or below inflation pressures of 10 and 5 atm, respectively. Above these thresholds, the likelihood of strut fracture increased with increasing pressure. The clinical implications of scaffold fractures in bifurcations remain unclear, and use of a 3 mm balloon for side branch dilatation is not advocated by the manufacturers. Other considerations include malapposition, recrossing and calcifications. Scaffold malapposition in proximal vessels and/or severely tapered vessels may occur; therefore, the use of imaging techniques to assess vessel size and plaque distribution is recommended. When recrossing an implanted BVS with a second A-BVS is difficult, the authors advise using a short metallic DES. Calcification may impact on A-BVS deliverability (e.g., to side branches) and, in such situations, it must be used carefully or not used at all.

Management of complications

Data on the incidence of periprocedural scaffold thrombosis are conflicting; however, there is general consensus that the occurrence of such events is often related to suboptimal deployment. To treat early or late scaffold thrombosis, the preferred approach is plain balloon angioplasty with or without thrombectomy, followed by DES implantation (especially in cases of BVS fracture confirmed by OCT), and lastly by implantation of a new A-BVS. Also, the authors suggested administering glycoprotein inhibitors to dissolve the thrombus, since aggressive post-dilatation may also induce slow flow or no flow.

In dealing with in-scaffold restenosis (ISR), substantial plaque prolapse or associated thrombus is sometimes seen within the scaffold by IVUS/OCT. Since the occurrence of ISR after A-BVS implantation is still relatively uncommon, the best treatment strategy has not been evaluated. Use of a drug-eluting balloon or plain balloon angioplasty in this setting has the potential advantage of "leaving nothing behind", especially if the restenosis is early. Occasionally a second A-BVS has also been used in this setting for the same reason. However, many experts choose to treat restenosis following A-BVS with a metallic DES.

Limitations

This document was drafted based on the opinion of twenty-eight interventional cardiologists. Where there were differences of opinion, consensus was arrived at through thorough discussion. The opinions here reflect experience with optimal deployment and short-term outcomes. While all authors were comfortable with deploying A-BVS in simple lesions and patients, caution was recommended for more complex lesions where data are more limited. Long-term clinical studies are currently under way, and will help confirm whether such recommendations translate to the best long-term outcomes. A few pivotal trials have been published since the meeting; while the authors did not have the opportunity to discuss these, the additional trials are referenced in the discussion section below.

Summary of recommendations and discussion

BVS is generally regarded as the technology of the future by the authors and, in six to eight years, is expected to be widely used in the majority of cardiac catheterisation laboratories. Ongoing randomised controlled trials comparing A-BVS to the XIENCE stent include ABSORB II, III, CHINA, and JAPAN as well as ABSORB IV which is actively enrolling. In patients from Europe and New Zealand, ABSORB II[16] has thus far demonstrated comparable clinical event rates of A-BVS to XIENCE at one year, with reduced rates of angina, nitrate use and revascularisation in BVS-treated patients. ABSORB JAPAN, which compared A-BVS to XIENCE EES in Japanese patients with a maximum of two *de novo* target lesions in separate coronary arteries, has met the primary clinical and secondary angiographic endpoints of target lesion failure at one year and angiographic in-segment late lumen loss at 13 months, respectively[17]. Updated data from randomised controlled studies, including the large cohort (>2,000 patients) in ABSORB III at one year[18], demonstrated comparable target lesion failure and adverse event rates between the A-BVS and the XIENCE scaffold (TLF 7.8% vs. 6.1%, p<0.007), thus meeting the study's primary endpoint goals. The ABSORB China trial, which also compared A-BVS to XIENCE and was conducted to support device approval in China[19], achieved the one-year non-inferiority primary endpoint of in-segment late loss in 480 Chinese patients (A-BVS 0.19±0.38 mm vs. XIENCE 0.13±0.38 mm, p=0.01). In a patient-level, pooled meta-analysis of the above four randomised trials of 3,389 patients with stable coronary artery disease or a stabilised acute coronary syndrome, A-BVS event rates of composite patient-oriented and device-oriented adverse events did not differ at one-year follow-up compared with the XIENCE EES[20]. Together, these results indicate that A-BVS is non-inferior to the current best-in-class XIENCE metallic stent. Further results are anticipated from longer-term follow-up of these randomised trials.

In a prospective, real-world Australian study[21] of 152 lesions in 100 patients, A-BVS was associated with low rates of target lesion revascularisation, myocardial infarction, and scaffold thrombosis at 12 months. This was attributed to a strategy of meticulous lesion preparation, routine post-dilation, and 12 months of dual antiplatelet therapy. This Asia-Pacific experience supports the recommendations for optimising lesion preparation and post-dilatation procedures. Other real-world European studies have addressed the heterogeneity in patient outcomes reported by previous studies. In one small all-comers study by Costopoulos et al[22], where A-BVS-treated patients were lesion-matched to XIENCE-treated patients, no ST was detected. In that study, because post-dilatation was performed in >90% of A-BVS-treated patients and maximum inflation pressure was 21 atm, a reasonable inference is that high-pressure post-dilatation contributed to low to no adverse events. In another European study, the POLAR ACS study[23] in which post-dilatation was performed in 81% of patients, only one case of myocardial infarction (MI), attributed to scaffold thrombosis, was detected at one year. A single incidence of target lesion revascularisation (TLR) was observed, leading the investigators to conclude that the use of BVS for the treatment of acute coronary syndrome patients was both safe and effective. The controversial GHOST-EU trial[24] included all-comers with a fairly complex disease profile; the overall post-dilation rate in that report was only 52.3%, and the ST rate was 1.9% at six months and 2.0% at one year. More recently, however, a propensity-matched analysis of GHOST-EU patients versus those from the XIENCE V USA registry showed that the combined rate of ischaemic events at one year was low and not significantly different to matched patients treated with XIENCE EES[25]. Importantly, in a recent European all-comers registry, scaffold thrombosis could be significantly reduced with optimised implantation[26], a strategy now widely recognised as critical to the best clinical outcomes and lowest adverse event rates.

A summary of the recommendations of the group is as follows. Initial experience with A-BVS should consist of simple lesions and patients, such as type A/B1 lesions, the absence of heavy calcification and the avoidance of major side branches. A learning curve of approximately 20 procedures was considered reasonable, after which operators might expand their use to more complex lesion and patient types. Vessel sizing and scaffold selection, lesion preparation and intravascular imaging were emphasised as important pre-implantation considerations. Proper scaffold selection is essential and depends on accurate target vessel sizing, for example, by intravascular imaging, especially for complex lesions. However, due to the cost and limited availability of IVUS and OCT, many authors preferred visual estimation, quantitative coronary angiography or a pre-procedural CT coronary angiogram. Adequate predilatation to the same size as the vessel (1:1) is critical, if necessary with a non-compliant balloon catheter. Cutting or scoring balloons or rotablation were strongly recommended for calcified lesions. Post-dilatation was strongly recommended using non-compliant balloons inflated to a maximum pressure of 15-20 atm, or higher if necessary, with expansion limited to 0.5 mm above the nominal diameter of the scaffold. A period of six to 12 months of DAPT was considered ideal for simple lesion and patient types, whereas 12 months or longer was recommended for complex lesions. Many authors preferred newer $P2Y_{12}$ inhibitors, namely ticagrelor or prasugrel, especially in ACS and STEMI patients. These recommendations are very similar to those from Europe by Tamburino et al, in which consensus criteria for patient and lesion selection, BVS implantation and optimisation, use of intravascular imaging guidance, approach to multiple patient and lesion scenarios, and management of complications, were identified[4]. The authors noted that the current A-BVS device has thicker struts than current-generation DES, and noted that future generations of the device with a thinner strut profile would probably be easier to use, with a potential for even better clinical outcomes.

This document highlights how the current practice and experience of Asia-Pacific interventional cardiologists mirror those in Europe, regardless of lesion complexity. It is expected that long-term clinical trial data will support the present results, potentially showing improvements in long-term efficacy and safety over DES.

Acknowledgements

The authors express their appreciation to Ogilvy CommonHealth Asia Pacific, for manuscript writing and editorial assistance. The content of this publication reflects the opinions and clinical experiences of the experts.

Funding

Abbott Vascular USA supported the Asia-Pacific Thought Leaders Forum meeting and the creation of guidelines for the use of Absorb in the region. Authors' transportation to, and accommodation at the meeting site, were supported by Abbott Vascular. Funding for this manuscript was also provided by Abbott Vascular.

Conflict of interest statement

K. Sudhir and C. Simonton are employees of Abbott Vascular. The other authors have no conflicts of interest to declare.

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