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Current practices of Asia-Pacific cardiologists in the utilization of bioresorbable scaffolds

B.B. Chanana [a], Praveen Chandra [b], Jack Jun Cheng [c], Ron Dick [d], Hyeon-Cheol Gwon [e], M.S. Hiremath [f], Do Quang Huan [g], Anuruck Jeamanukoolkit [h], Tiemin Jiang [i], On-Hing Kwok [j], Michael C.L. Lim [k], Adrian F. Low [l], Rony Mathew [m], Samuel K. Mathew [n], Dougal McClean [o], Sunao Nakamura [p], Michael Nguyen [q], Shubin Qiao [r], Teguh Santoso [s], Sudheer Saxena [t], Carl Schultz [u], G. Sengottuvelu [v], Ashok Seth [w], Charles A. Simonton [x], Chee Siong Soo [y], Krishnankutty Sudhir [x,*], Cheng-Ting Tsai [z], Udayachalerm Wasan [aa], Alan Whelan [q], Chris Wong [j], Yee Guan Yap [ab]

[a] Maharaja Agrasen Hospital, New Delhi, India
[b] Medanta Medicity, Haryana, India
[c] Shin Kong Wu Ho-Su Memorial Hospital, Taipei, Taiwan
[d] Epworth Hospital, Melbourne, Victoria, Australia
[e] Samsung Medical Center, Seoul, Republic of Korea
[f] Ruby Hall Clinic, Pune, Maharashtra, India
[g] Heart Institute HCM, Ho Chi Minh City, Vietnam
[h] Police General Hospital, Bangkok, Thailand
[i] The Second Hospital of Tianjin Medical University, Tianjin, China
[j] Hong Kong Sanatorium & Hospital, Hongkong, China
[k] Mount Elizabeth Novena Hospital, Singapore, Singapore
[l] National University Hospital, Singapore, Singapore
[m] Lisie Hospital, Ernakulam, Kerala, India
[n] Lilavati Hospital, Mumbai, India
[o] Christchurch Hospital, Christchurch, New Zealand
[p] New Tokyo Hospital, Chiba, Japan
[q] Fiona Stanley Hospital, Murdoch, Australia
[r] Fuwai Cardiovascular Hospital, Beijing, China
[s] Medistra Hospital, Jakarta, Indonesia
[t] Max Hospital, New Delhi, India
[u] Royal Perth Hospital Campus, University of Western Australia, Australia
[v] Apollo Hospital, Chennai, India
[w] Fortis Escorts Heart Institute, India
[x] Abbott Vascular, Santa Clara, USA
[y] HSC Medical Centre, Kuala Lumpur, Malaysia
[z] Mackay Memorial Hospital, Taipei, Taiwan
[aa] King Chulalongkorn Memorial Hospital, Bangkok, Thailand
[ab] Prince Court Medical Centre, Kuala Lumpur, Malaysia

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ABSTRACT

Background & aims: Although Absorb Bioresorbable Vascular Scaffolds (A-BVS) are routinely used in the Asia-Pacific, there is little information on patient selection or deployment technique here. This document investigates the experiences of leading interventional cardiologists from the Asia-Pacific region with a focus on patient characteristics, deployment techniques and management.

Methods and results: A detailed questionnaire was distributed to 28 highly-experienced interventional cardiologists ('Authors') from 13 Asia-Pacific countries. The results were discussed at a meeting on patient selection, technical consideration, deployment practices and patient management. Potential patient benefits of Absorb compared to metallic DES, the learning curve for patient selection and preparation, device deployment, and subsequent patient management approaches are presented.

Conclusions: Current practices are derived from guidelines optimized for European patients. Differences in approach exist in the Asia-Pacific context, including limited access to imaging and frequency of occurrence of complex lesions. Nevertheless, the use of the Absorb BVS ('Absorb') in certain Asia-Pacific countries has flourished and practices here are continuing to mature.

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0167-5273/

1. Introduction

Bioresorbable drug-eluting scaffolds offer the benefits of complete resorption of the device, while effectively treating the lesion and restoring the vessel's native physiological properties and functions. Although trials of Absorb BVS [Abbott Vascular, Santa Clara, CA, USA] in patients with simple lesions are ongoing or completed, its 'Real World' use in the Asia-Pacific lacks documentation. In the ABSORB II randomized controlled trial [1] in patients from Europe and New Zealand, an interim analysis at 1 year demonstrated comparable clinical event rates of A-BVS to Xience™ (Abbott Vascular, Santa Clara, CA, USA). In the ABSORB Extend registry [2], an international continued access study that included Asia-Pacific sites, for the first 512 patients enrolled in the study, the composite endpoints of ischaemia-driven MACE and target vessel failure were 4.3% and 4.9% respectively, while ARC defined scaffold thrombosis for this population was 0.8% at one year. The recently completed ABSORB Japan trial [3] in patients with up to 2 de novo target lesions in separate coronary arteries met its primary clinical and secondary angiographic endpoint of non-inferiority in 1 year TLF and 13 month late loss for the Absorb BVS compared to the Xience EES. Likewise, the recently completed ABSORB China trial [4] met its primary angiographic endpoint of non-inferiority in 12 month late loss compared to Xience, and showed similar rates of TLF at 1 year. However, in general, Asian patients tend to have smaller vessels, more diffuse disease, more multivessel disease and higher rates of diabetes, resulting in different practice and results with the Absorb BVS. Hence, the practices of 28 expert interventional cardiologists in the region were analyzed, to obtain information on A-BVS use in real world practice.

2. Methods

2.1. Survey design

2.1.1. Objectives

The primary aim was to determine the current clinical knowledge of scaffold implantation by selected interventional cardiologists from the Asia-Pacific region, and understand their real-world use of Absorb. The incidence and management of complications and patient follow-up procedures were also examined.

2.1.2. Selection of physicians

To obtain comprehensive information on the use of the Absorb BVS in the region, interventional cardiologists were selected based on their experience in percutaneous coronary intervention (PCI) and their level of procedural expertise. Countries surveyed included Singapore, Malaysia, Vietnam, Thailand, Indonesia, Hong Kong, South Korea, Japan, China, Taiwan, India, Australia and New Zealand. The physicians had a combined experience of >400 annual PCI and an average of over 15 years of clinical experience.

2.1.3. Questionnaires

The questions facilitated an accurate, comprehensive and unbiased analysis of the current clinical practice and concerns of physicians performing interventional coronary scaffolding in Asian patients. Questions were categorized to evaluate the physician's expertise and real-world experience with scaffolds, clinical practice for scaffold deployment, and patient management. A survey was subsequently distributed to the panel of interventional cardiologists.

2.1.4. Survey methods

The list of questions was provided in a paper-based or secure-link, web-based format. Physicians subsequently discussed the results of the survey at a meeting and consented to the publication of their results.

2.2. Data analysis

Profiling of physicians was based on their expertise and experience with scaffold usage in Asia-Pacific patients. Questions were either quantitative or qualitative in nature. In qualitative questions, multiple responses could be selected, or personal opinions given. For quantitative questions, percentage scales were used to represent the physician's combined clinical experience, which were weighted as a percentage of total cases treated or total physician experience. Where possible, quantified answers were reported as a percentage of all responses received.

3. Results

3.1. Part 1. Physician demographics and personal experience with absorb

This study represents the expertise of highly qualified and skilled physicians. Twenty-eight interventional cardiologists from the Asia-Pacific region participated, 61% of whom have performed over 100 Absorb implantations (Fig. 1A). However while 44% have used Absorb for over 2 years, some (26%) have only a year of Absorb experience, and while 9% have used it in more than 50% of their cases, a third have used it in only 26–50% of cases (Fig. 1B, C).

Analysis of lesion complexity treated showed that STEMI (ST segment elevation myocardial infarction) patients comprised fewer than 10% of cases for 70% of authors (Fig. 2A). Use of Absorb in NSTEMI (non-STEMI) cases was variable, with 61% using it in under 25% of NSTEMI patients. Only 13% dealt with NSTEMI as a majority of their cases (over 50%, Fig. 2B). In addition, 35% indicated that over 60% of their Absorb-treated patients had stable angina (Fig. 2C).

Patients with Absorb often have multiple devices implanted during the index procedure. Here, fewer than 50% of authors have implanted multiple Absorbs in 25% of patients, while 37% have performed multiple implantations in 50% of patients. 48% of authors stated that fewer than 10% of patients receive both DES and Absorb implants during the index procedure, and only 4% do so in 60% of cases. 22% used dual implants in a quarter of their patients, while 26% did so in a quarter to half of cases. These differences may be due to lesion complexity

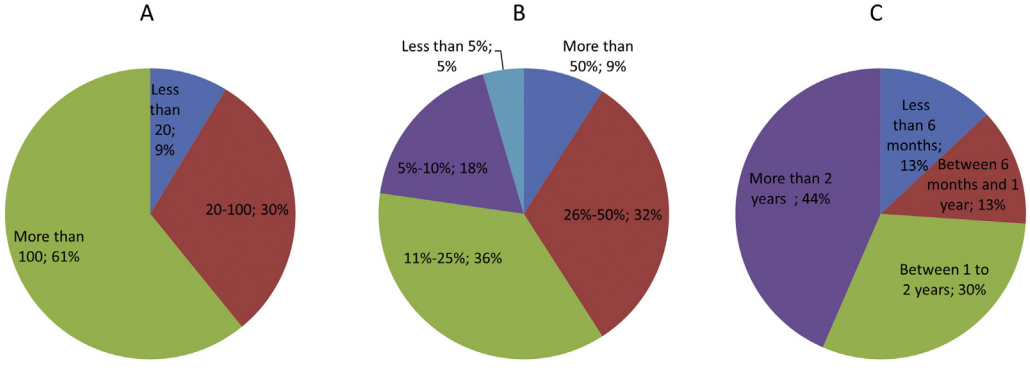

Fig. 1. Personal history with Absorb. (A) Percentage of authors and frequency of Absorb usage. Responses were grouped as follows: less than 20, 20–100, and more than 100 implants. (B) Percentage of authors and Absorb usage. Responses were grouped as <5%, 5–10%, 11–25%, 26–50% and >50%. (C) Frequency of Absorb use in a physician's personal PCI clinical experience. Responses were grouped according to the following categories. In all questions, the number of authors voting under each response group was calculated as a percentage of all respondents. Categories that received null replies (n = 0) were omitted from the graphical representation.

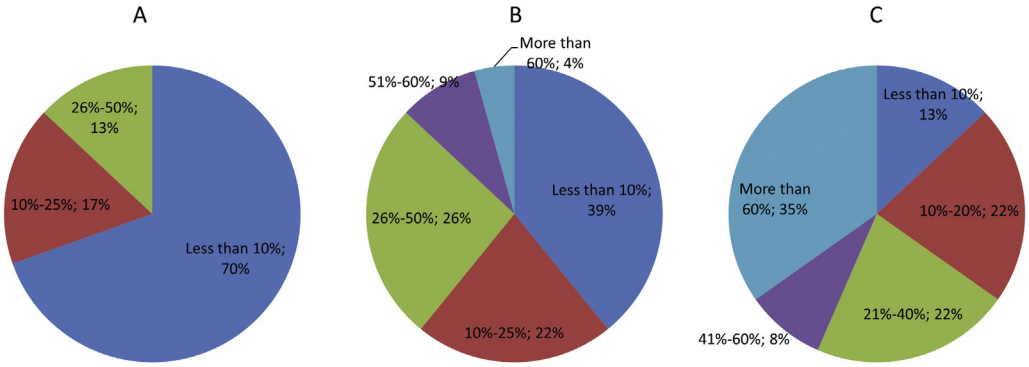

Fig. 2. Physician's experience with Absorb-lesion complexity. The frequency of patients with a particular lesion in each author's practice was grouped as follows: less than 10%, 10–25%, 26–50%, 51–60%, and more than 60%. (A) STEMI cases amongst patients with Absorb. Null responses were received for '51–60%' and 'more than 60%'. (B) Proportion of non-ST-segment elevation MI (NSTEMI) or unstable angina (i.e. ACS) cases amongst patients with Absorb. (C) Stable angina cases amongst patients with Absorb.

variations, however it also indicates a diversity of practice amongst interventional cardiologists in the region.

In real-world settings in the Asia-Pacific, Absorb was most frequently used for long lesions (longer than 20 mm), chronic total occlusions, bifurcations with side branches (SBs) larger than 2 mm, STEMI and distal lesions (Fig. 3). It was also used in thrombotic lesions, in-stent restenosis and heavily calcified lesions. It was less frequently used in coronary segments with large diameters (over 4 mm, which is over the expansion limit of the largest Absorb available, 3.5 mm), or in B2/C class lesions.

Intravascular ultrasound or optical coherence tomography (IVUS/OCT) guidance was sometimes used during BVS implantation to assess scaffold malapposition, vessel size, assess the lesion site, identify plaques, and check for edge dissection. IVUS/OCT was also used to assess complex PCI (e.g. bifurcations), clarify ambiguous angiographic results, deal with complications (e.g. scaffold thrombosis), and assist in postdilatation (Fig. 4).

Authors had concerns about the ease of Absorb deployment, including the inability to adequately verify deployment, risks of scaffold recoil, poor radio-opacity due to the polymer material of BVS, and increased ST. Patient-focused concerns included the patient's disease type and severity, and how they recovered after the procedure. Concerns also included factors such as patient age, device affordability, lesions in vessels exceeding the device's physical limit, highly complex lesions (e.g. heavy calcifications), ruptured plaques in acute MI, long-term outcomes and the risk of restenosis.

Potential issues with scaffold implantation that would influence the use of Absorb were thought to be strut thickness, ease of deployment, malapposition, scaffold fracture and SB occlusion (Fig. 5). The most cited potential advantages of Absorb use over metallic DES included the absence of metal, a potential reduction in long-term thrombosis (beyond 2.5 years), possibly a reduced need for prolonged dual antiplatelet therapy (DAPT), but importantly, artery remodeling, and restoration and recovery of physiologic and reactive vasomotor function following scaffold absorption. Additional benefits cited included scaffold disappearance, ease and possibility of future re-intervention procedures, feasibility of future bypass (CABG) surgery and of non-invasive imaging (Fig. 6).

There was some concern with the slightly thicker struts of the current generation of Absorb, a feature that might limit its use in smaller vessels. The current design characteristics were also perceived to make deployment in tortuous arteries difficult. Other factors raised included its short shelf life, the need for meticulous lesion preparation, and its cost which may be significant if guiding procedures or tools (e.g. OCT/IVUS) were routinely required.

To understand exactly how Absorb is used, the authors' predilatation, deployment and post-dilatation practices were surveyed.

3.2. Part 2a. Pre-dilatation vessel sizing and lesion preparation

Pre-dilatation vessel sizing and lesion preparation methods were assessed (Fig. 7). OCT was most frequently used for accurate vessel sizing prior to Absorb implantation, followed by quantitative coronary angiography and IVUS. Balloon dilatation and nitrate administration to assist with sizing, were also frequently used (Fig. 7A). Other methods

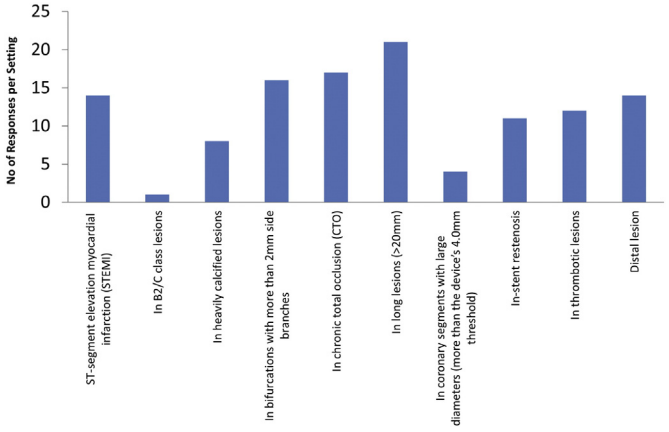

Fig. 3. Complex settings in which absorb is figure used. The frequency of each lesion type was graphically represented as relative distribution. Authors could select multiple responses (e.g. those CTO, bifurcations, long lesions and STEMI may not have selected B2/C lesions).

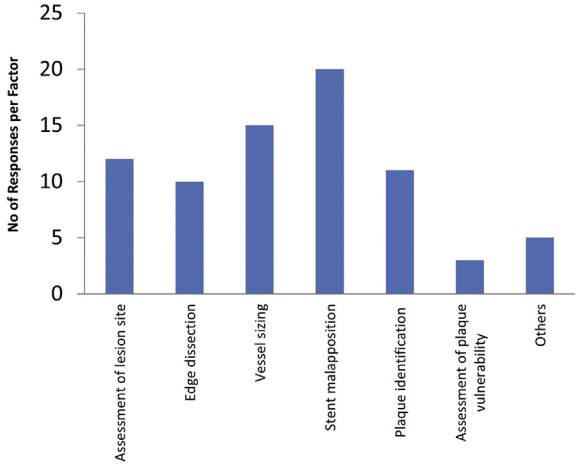

Fig. 4. Use of IVUS/OCT guidance during implantation. Authors indicated when they have used IVUS/OCT imaging as a guiding tool, and could select multiple responses.

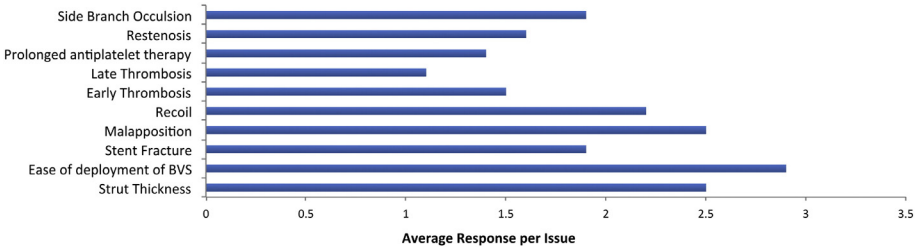

Fig. 5. Overall perception of the potential risks of Absorb. Response per issue was calculated by taking the average of the sum of the level of concern (Score 1 = no risk; Score 2 = some risk; Score 3 = significant risk; Score 4 = very significant risk) from all of the physicians.

included visual estimation ('eye-balling'), guide catheter (to estimate diameter, Dmax), balloon (to estimate length), pressure wire, and computed tomography (CT) angiogram to assess plaque characteristics and the severity of calcification.

The authors had no preferred reference vessel for angiography, and agreed that this depended on the vessel being treated (Fig. 7B). Equal numbers of authors chose either proximal Dmax or distal Dmax (~38% each), while ~24% chose the interpolated vessel reference. Authors favoring the interpolated diameter indicated that for a substantially tapered artery, the proximal vessel should be sufficiently expanded without distal overstretching, or device overstretching. Others felt that depending on the vessel diameter and the extent of tapering, the proximal vessel diameter should be used, otherwise the choice of vessel reference was unimportant. If saving a large side branch (SB) was the goal, distal Dmax was selected because overexpansion in the ostium of the distal main branch could compromise the SB. Here, distal Dmax for size optimization and finishing with proximal optimization, was preferred. The length of the required scaffold was an important consideration — a larger difference between proximal and distal would exist with a long scaffold, therefore the interpolated diameter would be used. If the scaffold required was shorter, the proximal diameter would be selected.

Predilatation balloon was the preferred method for lesion preparation before implantation followed by cutting balloon, rotational atherectomy, Scoreflex™ balloon (OrbusNeich, Hong Kong), scoring balloon and non-compliant balloon (Fig. 8A). 73% performed predilatation in over 90% of cases, with the remaining authors predilating in 61–90% of patients (Fig. 8B). Predilatation and lesion preparation were considered mandatory for some patients, e.g. renal failure patients, whose stiff lesions may not open even with BVS manipulation. Young patients with thrombus, or those who were relatively or totally disease-free in other arteries or segments, might not need predilatation. Thorough thrombus aspiration in such cases was recommended. Direct Absorb implantation was unpopular, with 85% of authors only doing so in ~10% of all acute coronary syndrome (ACS) patients (Fig. 8C).

For predilatation prior to implantation, 70% preferred non-compliant balloons, 17% preferred semi-compliant balloons and 13% chose scoring balloons (Fig. 9A). Scoring and cutting balloons were used in fewer than 10% of all cases by 50% of authors (Fig. 9B). Following predilatation, about 50% of authors aimed for less than 20% residual stenosis, while 39% aimed for less than 40% residual stenosis. The remaining aimed to completely open the predilatation balloon without indentations, without predilatation targets (Fig. 9C).

3.3. Part 2b. Deployment strategy

For proper implantation, 80% of authors inflated the Absorb by 2 atm every 5 s. However, 60% maintained inflation within the nominal size (Fig. 10A). Equal proportions of authors (45%) maintained inflation for either 60 s or 30 s, however 5% maintained inflation for less than 30 s (Fig. 10B). Balloon implantation pressures varied; 10% exceeded 16 atm (i.e. the rated burst pressure, RBP; Fig. 10C), 20% inflated to 11–12 atm, 30% inflated up to 13–14 atm, and a further 20% inflated to 15–16 atm. Only 15% inflated under 10 atm. For full expansion, 45% of authors reached the deployment RBP in 25% of cases, and 20% did in 75–100% of cases (Fig. 10D). 10% of authors inflated reached the RBP in 26–50% of cases, while 15% did this in 51–75% of cases.

With respect to overlap technique, the authors favored marker-to-marker (55%), followed by the marker-over-marker (30%) and scaffold-to-scaffold (5%) (data not shown).

In the case of "1,1,0", "1,0,0", or "0,1,0" bifurcation lesions (Fig. 11A), 25% of authors would deploy only one Absorb in the main vessel (MV), and 20% would implant one Absorb in the MV and fenestrate toward the SB. However, 45% would deploy one Absorb in the MV, and fenestrate only if the SB TIMI-flow was rated as less than 3, or disease was extensive (>75%). Importantly, many authors routinely implemented multiple strategies for bifurcations.

For bifurcation lesions, where one Absorb would be used in the main vessel, many authors preferred to also perform balloon dilatation in the SB, and implant a subsequent Absorb in the SB (using T or TAP technique). Others would deploy a DES in the SB, avoid using Absorb, or deploy an extra Absorb in the SB with mini-crush or culotte techniques (Fig. 11B).

3.4. Part 2c. Post-dilatation approach

Whilst postdilatation to or beyond the RBP upon deployment was crucial, only 50% of authors did so, but they did so in 75% of cases. The practice of postdilatation up to RBP by others varied widely (Fig. 12A). 55% of authors used a postdilatation balloon that was 0.25 mm larger

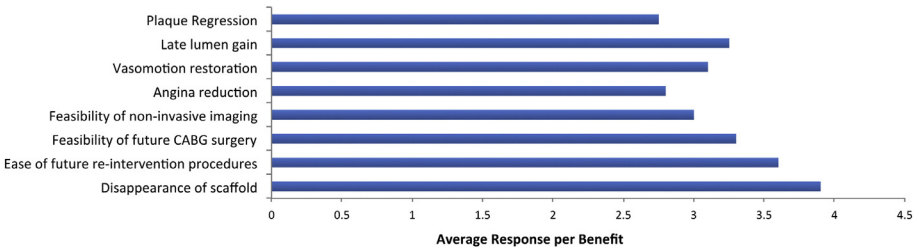

Fig. 6. Overall perception of the potential benefits of Absorb compared to metallic DES. Response per benefit was calculated by taking the average of the sum of the level of concern (Score 1 = no risk; Score 2 = some risk; Score 3 = significant risk; Score 4 = very significant risk) from all of the physicians.

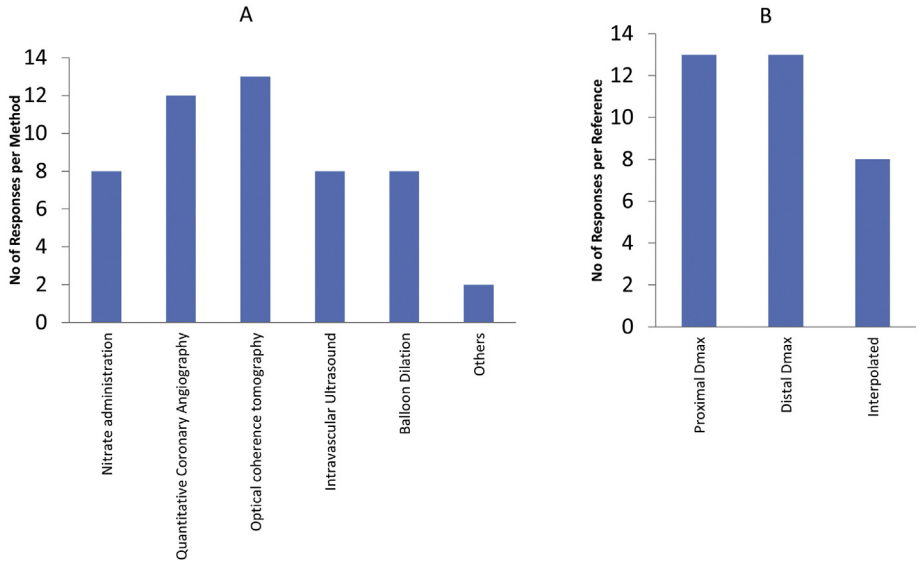

Fig. 7. Vessel sizing methods. (A) Preferred method. (B) Preferred reference vessel for assessing diameter. In each question, the authors could select multiple responses.

than Absorb, 15% used a balloon that was 0.5 mm larger, and 20% used the same-size balloon (Fig. 12B). The typical balloon pressure achieved by 70% of authors was greater than 15 atm, although lower pressures of 11–12 atm (5%), 13–14 atm (5%) and 15–16 atm (15%) were also used (Fig. 12C). Postdilatation pressures never dipped below 10 atm. Upon inflation, the balloon was maintained at pressure for 16–30 s by 40% of authors, 31–60 s by 25% of authors, and less than 15 s by 30% of authors (Fig. 12D).

Following implantation, 85% of authors aimed for less than 10% residual stenosis (Fig. 13A) and during deployment, 80% achieved less than 10% residual stenosis in over 50% of cases (Fig. 13B). 90% of authors could fully expand the Absorb in over 50% of cases, however 5% managed this in only 10% of cases (Fig. 13C).

Optimal wall apposition was achieved over 50% of the time by most authors (90%), whereas 5% achieved this in only 25% of cases (Fig. 14A). For complications and adverse events, 75% were unconcerned about acute scaffold recoil (which affected fewer than 5% of cases), with 15% observing recoil in up to 25% of cases and 5% observing this in 50% of cases (Fig. 14B). Whilst 45% were unconcerned about scaffold malapposition (Fig. 14C) as it was seen in fewer than 5% of their patients, 10% observed this in 50% of their patients. Others were concerned about edge dissection from the scaffold balloon dilatation to resolve malapposition, and preferred using shorter or larger balloons (0.5 mm) for postdilatation.

3.5. Part 2d. Imaging

To decide if specific lesion preparation was necessary, 36% of authors used pre-implantation intravascular imaging. During deployment, 48% used IVUS/OCT in over 50% of cases, 13% in 26–50% of cases, and 39% in 11–25% of cases (data not shown).

3.6. Part 2e. Dual antiplatelet therapy (DAPT)

In treating stable angina with Absorb, 5% of authors would prescribe long-term DAPT (over 2 years), while another 5% would prescribe short-term durations (up to 6 months). 35% of authors would prescribe intermediate durations (6 months–1 year), while 35% would

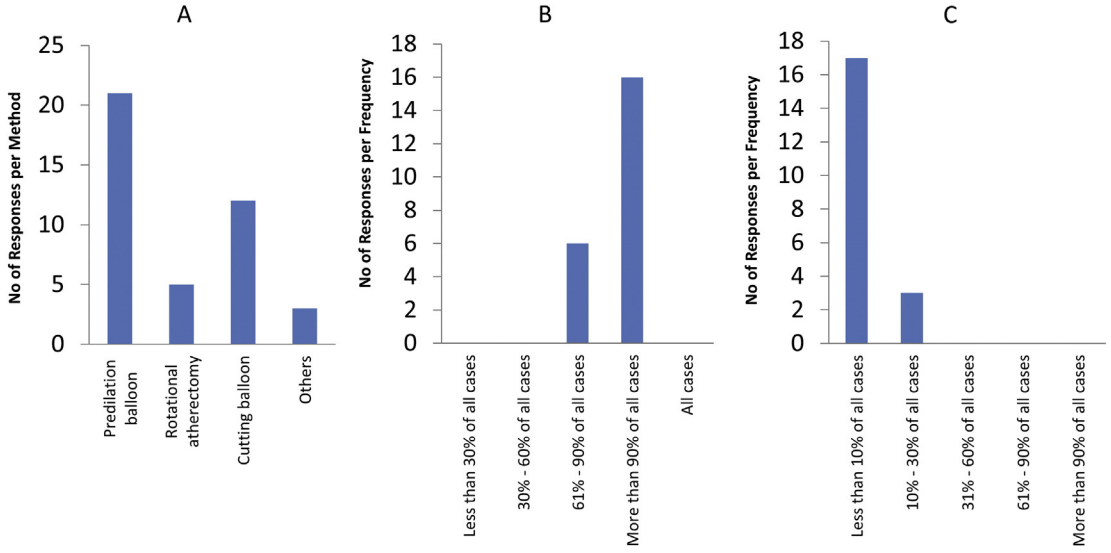

Fig. 8. Lesion preparation prior to implantation. (A) Coronary lesion preparation methods. Authors could select multiple responses. (B) Predilatation of lesion. (c) Direct implantation of BVS in ACS.

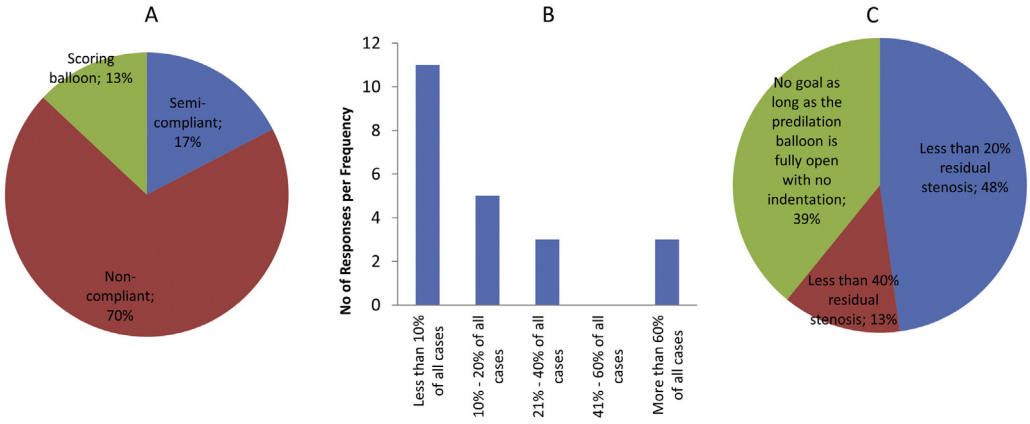

Fig. 9. Use of balloons for predilatation and subsequent goal. (A) Non-compliant balloons, scoring balloons and semi-compliant balloons are preferred for predilatation. Authors could select multiple responses. (B) Usage of scoring or cutting balloons. (C) Main goal of predilatation before implantation.

recommend DAPT for 1–2 years. For Non-ST-segment elevation and ACS (NSTE-ACS) and STEMI patients, short-term DAPT (up to 6 months) was recommended by 18% of authors, while intermediate durations (either 6 months to 1 year, or 1 to 2 years) were recommended by 25–30% of authors, and long-term DAPT was prescribed by 27%.

Absorb patients with other complex lesions (e.g. bifurcations, long lesions, CTO) would receive DAPT for 6 months–1 year. Patients with drug-eluting stents (DES) generally received short-term DAPT (6 months–1 year), or 1–2 years of DAPT. DAPT practices varied widely amongst the authors (due to cost and genetic resistance), however the use of clopidogrel or ticagrelor in combination with aspirin was similar. 26% would prescribe prasugrel or ticagrelor for all patients, regardless of clinical presentation. Occasionally, physicians would transition to other drugs, for example, in complex PCI (e.g. bifurcations), where the patient is initially treated with prasugrel or ticagrelor for 3 months, and subsequently transitioned to aspirin and clopidogrel.

3.7. Part 3. Follow-up and outcomes

Follow up in real world practice was generally clinical. Only 5% of authors routinely performed follow-up coronary angiography (CA) at 6–9 months following Absorb. 15% performed CA at 1 year, while 80% never used CA during follow-up. Routine intracoronary imaging was

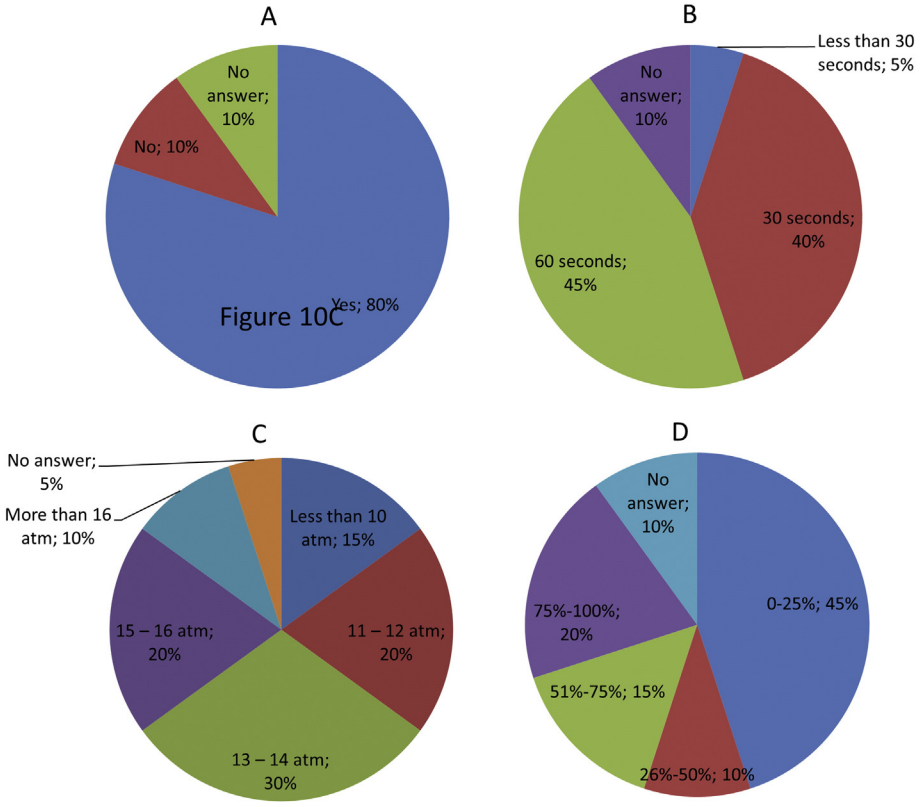

Fig. 10. Scaffold delivery balloon deployment. (A) Proportion of physicians that stayed within the nominal size. (B) Duration of balloon inflation and percentage of physicians that maintained the associated duration. (C) Typical Absorb balloon implantation pressure and percentage of physicians who achieved the associated pressures. (D) Proportion of physicians who deploy up to the RBP to achieve full scaffold expansion. The proportion for each pressure was grouped as follows: 0–25%, 26–50%, 51–75%, and 75–100%.

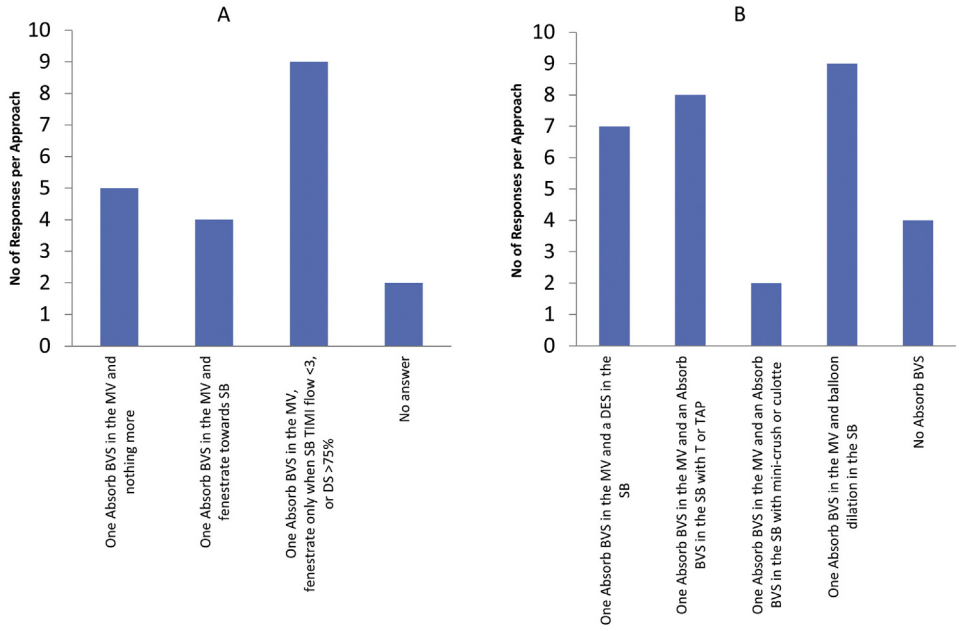

Fig. 11. Bifurcation strategies. (A) "1,1,0", "1,0,0" or "0,1,0" bifurcation lesions were treated with different approaches using Absorb. (B) Frequency of different approaches in the treatment of these bifurcation lesions. In both questions, the authors could select multiple responses.

performed at follow-up CA by only 30% of authors, while 10% did so selectively (Data not shown).

To treat ST (Fig. 15A), 40% preferred plain balloon angioplasty with or without thrombectomy, 28% chose DES implantation for OCT-determined BVS fracture, and 20% chose new Absorb implantation. In treating scaffold restenosis (Fig. 15B), DES implantation was most popular, followed by drug-coated balloon and DES implantation. New BVS implantation and plain balloon angioplasty were seldom used.

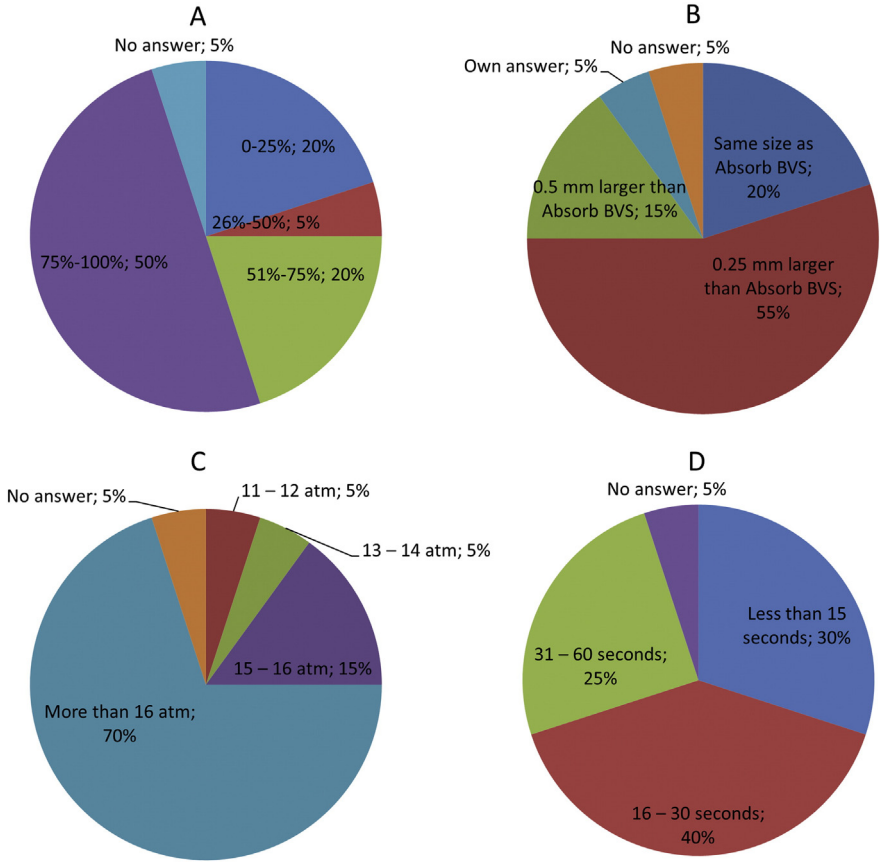

Fig. 12. Postdilatation balloon strategies. (A) Percentage of physicians that performed inflation of postdilatation balloon up to or beyond 16 atm. The responses were grouped as follows: 0–25%, 26–50%, 51–75%, and 75–100%. (B) Percentage of physicians that used postdilatation balloons greater than, or of similar sizes to the Absorb. Null responses (n = 0) were received for '1 mm larger than Absorb'. (C) Typical postdilatation balloon pressure used and percentage of physicians that achieved that. Null responses (n = 0) were received for 'less than 10 atm'. d) Duration of inflation of postdilatation balloon and percentage of physicians that maintain that duration.

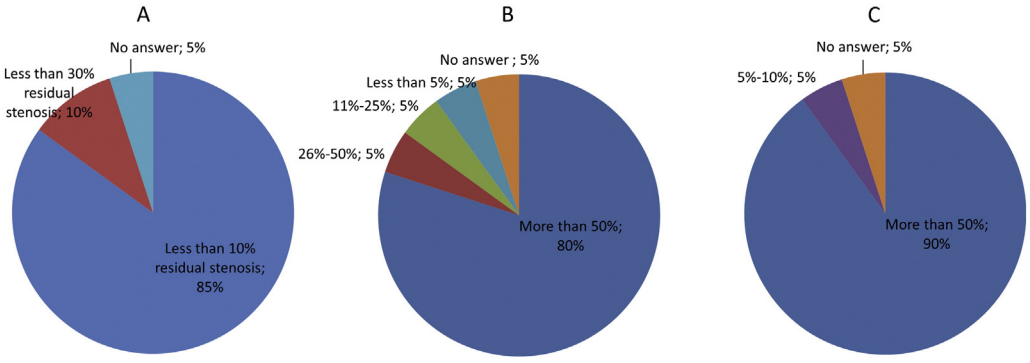

Fig. 13. Postimplantation goals of physicians. (A) Percentage of physicians with goals of achieving less than 10%, 30%, 40% or 50% residual stenosis. Null values (n = 0) were received for 'less than 30%' and 'less than 40%' residual stenosis. (B) Frequency of residual stenosis being less than 10%. The responses were grouped as follows: less than 5%, 5–10%, 11–25%, 26–50%, and more than 50% of the time. Null responses (n = 0) were received for '5–10% of the time'. (C) Typical postdilatation balloon pressure used and percentage of physicians that achieved that. The responses were grouped as follows: less than 5% of the time, 5–10%, 11–25%, 26–50 and more than 50% of the time. Null responses (n = 0) were received for 'less than 5%', '11–25%', and '26–50%' of the time.

4. Discussion and recommendations

Asia-Pacific cardiologists routinely treat a medley of coronary lesion types with metallic DES, and now increasingly with bioresorbable polymer-coated DES as well as fully-resorbable scaffolds. In this survey, interventional cardiologists provided their unique experiences and expertise on the treatment of Asian patients. This knowledge would help other cardiologists in the region, particularly those less experienced with bioresorbable scaffolds, or those experiencing difficulties in integrating this into their PCI.

While there were differences of opinion amongst the cardiologists surveyed, consensus was obtained in a number of areas. (1) Physicians should begin Absorb implantation with simple, straightforward, focal lesions, i.e. type A/B1 lesions without heavy calcification or a major side branch. Only after confidence has been gained (after ~20 procedures) should operators attempt tortuous, extremely angulated and heavily calcified lesions. (2) Proper scaffold selection depends on accurate vessel sizing. For simple lesions, this can be accomplished through visual estimation against a catheter or predilatation balloon, quantitative coronary angiography or a pre-procedural CT coronary angiogram; intravascular imaging (IVUS and OCT) is particularly useful in complex lesions. (3) Predilatation to the same size as the vessel (1:1) should be performed with a noncompliant balloon dilatation catheter, especially when a semi-compliant balloon is insufficient. (4) For calcified lesions, the use of cutting, or scoring balloon or rotablation was strongly recommended. (5) Postdilatation is strongly recommended using non-compliant balloons inflated to a maximum pressure of 15–20 atm, but expansion must be kept within 0.5 mm of the size limit. (6) In Asia, a period of 6 months–1 year of DAPT is usually prescribed for stable angina patients. For complex lesions, a year or longer is recommended, with a preference for ticagrelor or prasugrel especially in ACS and STEMI patients. These observations are similar to the report 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 [6].

The authors were concerned about Absorb deployment in difficult lesions, and emphasized rigorous lesion preparation and the use of accessory devices to ensure successful delivery. The current device with thicker struts is problematic for some physicians, and future generations of the device with a thinner strut profile would be welcomed. While there is an initial learning period to master scaffold delivery techniques, adoption of the Absorb is slowly increasing in Asia. It was the hope amongst many of the authors that the long term concerns that exist with DES, such as late thrombosis and reinfarction may be addressed by the use of Absorb.

Recent results from worldwide registries and randomized controlled clinical trials have shown short and medium-term safety of the Absorb BVS, as evidenced by comparable outcomes to Xience in several randomized clinical trials namely ABSORB II [1], ABSORB III [5], ABSORB Japan [3] and ABSORB China [4], and low event rates in most real world registries. Initial results from the GHOST-EU registry examining real world outcomes of BVS showed acceptable rates of TLF at six months, although the rates of early and midterm scaffold thrombosis, mostly clustered within 30 days, were not negligible [7]. However, more recently, in a propensity-matched comparison of the GHOST-EU and XIENCE V USA registries, cardiac death was less likely to occur in the Absorb group with a trend toward a reduction in myocardial infarction, while no differences in ischemia-driven target lesion revascularization or device thrombosis were detected between the Absorb BVS

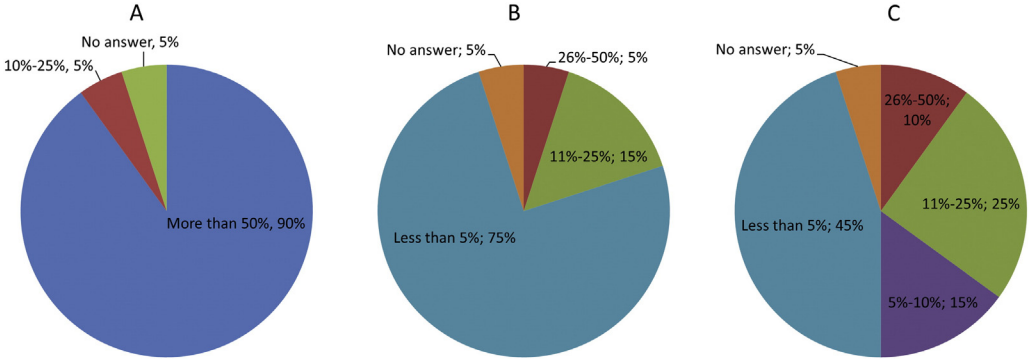

Fig. 14. Frequency of occurrence of adverse events and complications following absorb implantation. The responses to all questions were grouped as follows: less than 5%, 5–10%, 10–25%, 25–50% and more than 50% of all cases. (A) Optimal wall apposition. Null responses (n = 0) were received for 'less than 5%', '5–10%', and '25–50%' of cases. (B) Acute scaffold recoil. Null responses (n = 0) were received for '5–10%' and 'more than 50%' of all cases. (C) Scaffold malapposition. Null responses (n = 0) were received for 'more than 50%' of all cases.

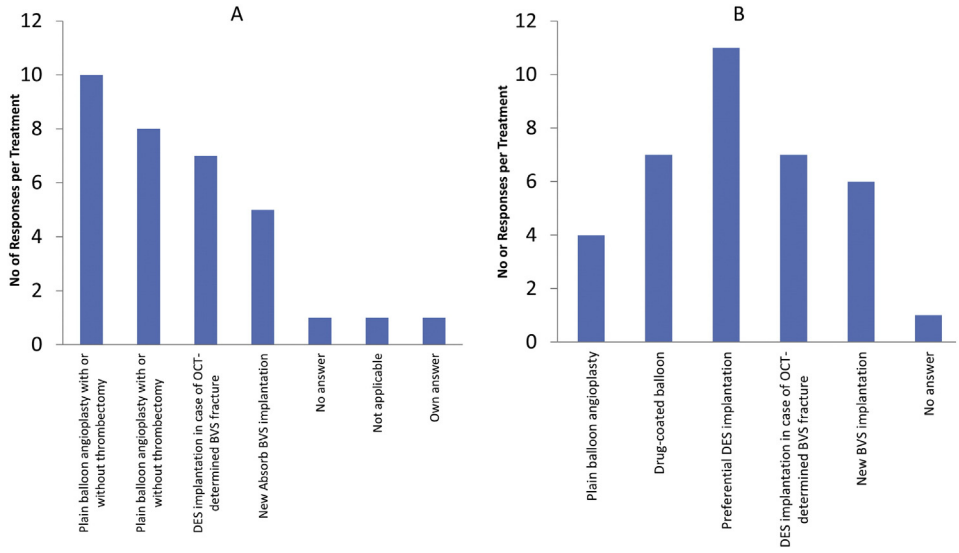

Fig. 15. Treatment of complications due to scaffold implantation. (A) Treatment of scaffold thrombosis. (B) Treatment of scaffold restenosis. In both questions, authors could select multiple responses.

and XIENCE EES [8]. One-year results from the ASSURE registry at 6 German centers suggest that bioresorbable vascular scaffolds for de novo coronary artery disease are associated with favorable clinical and functional outcomes in routine clinical practice despite a visually overestimated RVD [9]. Of note, in a recent all comers registry at 2 German and 2 Swiss Hospitals, the rate of scaffold thrombosis could be significantly reduced with optimized implantation [10], a strategy now recognized as being critical in obtaining the best clinical outcomes and lowest adverse event rates. The field would benefit from additional data on implantation techniques, lesion and patient selection, and their relationship to short and long-term event rates in patients from the Asia-Pacific, in order to more accurately profile usage patterns and clinical outcomes in this region.

Conflict of interest

K. Sudhir and CA Simonton are employees of Abbott Vascular, Santa Clara, California. Other authors report no relationships that could be construed as a conflict of interest.

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References

[1] P.W. Serruys, B. Chevalier, D. Dudek, A. Cequier, D. Carrié, A. Iniguez, M. Dominici, R.J. van der Schaaf, M. Haude, L. Wasungu, S. Veldhof, L. Peng, P. Staehr, M.J. Grundeken, Y. Ishibashi, H.M. Garcia-Garcia, Y. Onuma, A bioresorbable everolimus-eluting scaffold versus a metallic everolimus-eluting stent for ischaemic heart disease caused by de-novo native coronary artery lesions (ABSORB II): an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial, Lancet 385 (2015) 43–54.

[2] A. Abizaid, J. Ribamar Costa Jr., A.L. Bartorelli, R. Whitbourn, R.J. van Geuns, B. Chevalier, T. Patel, A. Seth, M. Stuteville, C. Dorange, W.F. Cheong, K. Sudhir, P.W. Serruys, ABSORB EXTEND investigators, The ABSORB EXTEND study: preliminary report of the twelve-month clinical outcomes in the first 512 patients enrolled, EuroIntervention 10 (2015) 1396–1401.

[3] T. Kimura, K. Kozuma, K. Tanabe, S. Nakamura, M. Yamane, T. Muramatsu, S. Saito, J. Yajima, N. Hagiwara, K. Mitsudo, J.J. Popma, P.W. Serruys, Y. Onuma, S. Ying, S. Cao, P. Staehr, W.F. Cheong, H. Kusano, G.W. Stone, ABSORB Japan Investigators, A randomized trial evaluating everolimus-eluting Absorb bioresorbable scaffolds vs. everolimus-eluting metallic stents in patients with coronary artery disease: ABSORB Japan, Eur. Heart J. 36 (2015) 3332–3342.

[4] R. Gao, Y. Yang, Y. Han, Y. Huo, J. Chen, B. Yu, X. Su, L. Li, H.C. Kuo, S.W. Ying, W.F. Cheong, Y. Zhang, X. Su, B. Xu, J.J. Popma, G.W. Stone, ABSORB China Investigators, Bioresorbable vascular scaffolds versus metallic stents in patients with coronary artery disease: ABSORB China Trial, J. Am. Coll. Cardiol. 66 (2015) 2298–2309.

[5] S.G. Ellis, D.J. Kereiakes, D.C. Metzger, R.P. Caputo, D.G. Rizik, P.S. Teirstein, M.R. Litt, A. Kini, A. Kabour, S.O. Marx, J.J. Popma, R. McGreevy, Z. Zhang, C. Simonton, G.W. Stone, ABSORB III Investigators, Everolimus-eluting bioresorbable scaffolds for coronary artery disease, N. Engl. J. Med. 373 (2015) 1905–1915.

[6] C1. Tamburino, A. Latib, R.J. van Geuns, M. Sabate, J. Mehilli, T. Gori, S. Achenbach, M.P. Alvarez, H. Nef, M. Lesiak, C. Di Mario, A. Colombo, C.K. Naber, G. Caramanno, P. Capranzano, S. Brugaletta, S. Geraci, A. Araszkiewicz, A. Mattesini, S.A. Pyxaras, L. Rzeszutko, R. Depukat, R. Diletti, E. Boone, D. Capodanno, D. Dudek, Contemporary practice and technical aspects in coronary intervention with bioresorbable scaffolds: a European perspective, EuroIntervention 11 (2015) 45–52.

[7] D. Capodanno, T. Gori, H. Nef, A. Latib, J. Mehilli, M. Lesiak, G. Caramanno, C. Naber, C. Di Mario, A. Colombo, P. Capranzano, J. Wiebe, A. Araszkiewicz, S. Geraci, S. Pyxaras, A. Mattesini, T. Naganuma, T. Münzel, C. Tamburino, Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry, EuroIntervention 10 (2015) 1144–1153.

[8] C. Tamburino, P. Capranzano, T. Gori, A. Latib, M. Lesiak, H. Nef, G. Caramanno, C. Naber, J. Mehilli, C. Di Mario, M. Sabaté, T. Münzel, A. Colombo, A. Araszkiewicz, J. Wiebe, S. Geraci, C. Jensen, A. Mattesini, S. Brugaletta, D. Capodanno, 1-year outcomes of everolimus-eluting bioresorbable scaffolds versus everolimus-eluting stents: a propensity-matched comparison of the GHOST-EU and XIENCE V USA registries, JACC Cardiovasc. Interv. 9 (2016) 440–449.

[9] J. Wöhrle, C. Naber, T. Schmitz, C. Schwencke, N. Frey, C. Butter, J. Brachmann, M. Ingwersen, A. Drabik, S. Markovic, D.G. Mathey, Beyond the early stages: insights from the ASSURE registry on bioresorbable vascular scaffolds, EuroIntervention 11 (2015) 149–156.

[10] S. Puricel, F. Cuculi, M. Weissner, A. Schmermund, P. Jamshidi, T. Nyffenegger, H. Binder, H. Eggebrecht, T. Münzel, S. Cook, T. Gori, Bioresorbable coronary scaffold thrombosis: multicenter comprehensive analysis of clinical presentation, mechanisms, and predictors, J. Am. Coll. Cardiol. 67 (2016) 921–931.