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CLINICAL STUDY

# Use of Bioresorbable Vascular Scaffold technology in treating coronary bifurcation lesions: A report about long-term clinical results and review of available literature

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**ABSTRACT**
INTRODUCTION: BVS proved safe in humans. ABSORB trials showed them performing similar to Drug Eluting Stents in simple coronary interventions. We assessed a registry of 63 patients with bifurcation lesions, treated by BVS and followed their outcomes up-to 5 years.
METHODS: Patients who satisfied the inclusion criteria were included. Data about contact information, baseline characteristics, findings of coronary angiogram, details of their interventional treatment; short and long-term outcomes up till 5 years was collected.
RESULTS: Acute feasibility of implantation in bifurcation was high (98 %). Rate of stent thrombosis, acute or sub-acute, was 3.1 %. Rate of re-intervention was 38 %. The average time for an event to occur was 1.6±0.8 years. Over 5 years, 56 % had developed MACE. Patients with MACE were more likely females, hypertensive, smokers, with acute presentations (p=NS), and diabetic (72 % vs 33 % non-diabetic; p=0.002). Patients treated with hybrid strategy of BVS and DES were more likely to develop MACE (64 % vs 49 % for others; P=ns). Patients treated by simple provisional stenting were less likely to develop MACE (45 % vs 60.5 %; p=ns). The average SYNTAX score of MACE patients was 27 vs 20; p=0.06). Diabetes was independently associated with MACE. Hypertension was of borderline statistical significance (2-sided Log rank for Hypertension p=0.06, for Diabetes p=0.01).
DISCUSSION: The use of multiple stenting strategies to treat true bifurcation lesions using BVS is feasible with low rate of serious adverse events, albeit on the long run, the rate of re-intervention is high and stringent follow up is required *(Tab. 7, Fig. 3, Ref. 37)*. Text in PDF *www.elis.sk.*
KEY WORDS: Bioresorbable Vascular Scaffold technology, coronary bifurcation lesions, humans, ABSORB trials, Drug Eluting Stent, coronary interventions.

## Introduction

In 1977, balloon angioplasty by Andreas Gruntzig heralded the beginning of interventional treatment of patients with coronary artery disease (1). Bare Metal Stents (BMS) demonstrated the second large leap in its timeline. In the BENESTENT trial (2), BMS reduced the need for second coronary angioplasty. The increasing incidence of instent restenosis became a major issue with BMS (3). The next revolution was the Drug Eluting Stents (DES). The RAVEL study along with others (4, 5) showed that late luminal loss was reduced in the sirolimus DES stent group, translating into a 26 % reduction in recurrent revascularization. This was offset with early and late stent thrombosis in the first generation DES (6, 7). In an attempt to resolve this issue, further research was carried out leading to the advent of Bioresorbable scaffold technology (BVS). It was proven safe and feasible in humans (8). The ABSORB trial (9) showed that BVS was capable of performing similarly to other DES in selected patients. Its crossing profile at 1.4 mm was comparable to the BX Velocity stent. Radial strength at 37 degrees Celsius was similar to that of the MULTILINK stent (10). Its balloon delivery system was also the same as that used by Abbott for MULTI LINK, VISION and XIENCE V stents. Previous trials reported on efficacy of BVS in simple lesions (11, 12, 13). The efficacy of BVS in bifurcations has not been validated. This was initially a frowned upon due to fears of scaffold fracture. Numerous operators have reported on their use of BVS in bifurcations but the long-term outcomes were lacking. In this study we aimed to examine the short and long-term efficacy of BVS to treat true bifurcation lesions with side branches > 2.0 mm.

## Methods

Consecutive patients presenting for intervention, who satisfied the inclusion criteria were included into a registry. Data about baseline characteristics, findings of coronary angiogram,

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and details of treatment using BVS; as well as outcome during their hospital stay, medications at discharge and follow up data were collected. MACE consisted of a composite of recurrence of symptoms deemed due to ischemia, hospital re-admissions, or repeat procedures, and death till date of contact.

*Inclusion criteria*
– Patient consents to take part in the registry.
– Patient consents to undergo PCI to treat his disease.
– Patient's age between 18 and 75 years of age.
– Presenting as chronic stable angina or acute coronary syndrome including Unstable Angina, NSTEMI or STEMI.
– Presence of bifurcation lesion, described by Medina classification, necessitating use of stents for which BVS will be used alone, or in combination with another type of DES or Drug Eluting Balloons (DEB).

*Exclusion criteria*
– Inability to give Informed consent.
– Presenting with Cardiogenic shock.
– Inability of patient to use anti-platelets medications (aspirin and clopidogrel or ticagrelor) for predetermined period of 12 months.
– Patient's inability to follow up with physician.
– Patient being or suspected of being pregnant.
– Patient's life expectancy less than 6 months.
– Known allergy to contrast agent or to the material of which the scaffold is made.
– Deemed not feasible by operator to successfully treat the lesion with use of BVS

*Implantation technique*

Every patient was evaluated during the diagnostic angiogram. Standard views acquired in cath lab were used to evaluate the entire coronary tree. When a bifurcation was being evaluated, at least two orthogonal views where utilized to asses severity of disease and feasibility of an endovascular treatment. Whenever feasible, endovascular imaging in form of IVUS or OCT were utilized. A Bifurcation had to involve one major side branch > 2.0 mm in diameter, which if lost would result in significant patient morbidity such as chest pain, rising cardiac enzymes, and/or long-term myocardial damage. Heavily calcified or extremely tortuous lesions, and trifurcations were excluded. Main vessel and side branch had to be capable of accommodating at least a size 2.5 stent. Treatment strategy always included double wiring, initial pre-dilatation, stenting and final post-dilatation. All lesions had to be prepared with ballooning in a 1:1 ratio and in many instances an initial kissing balloon strategy was utilized to attain maximal initial diameter for easier implantation. Pre-dilatation utilized semi compliant balloons at nominal pressures and if deemed not well prepared then non-compliant balloons were used. Stenting strategies included main branch stenting and provisional side branch stenting as required. Side branch re-crossing and only kissing balloon, or stenting of both main and side branch using different strategies, but mainly TAP (T and protrusion) and also mini-crush. Stenting would involve at least one BVS, but can also contain a combination of a BVS and DES (Hybrid). Every stent is post-dilated separately at high pressures of 20 atmospheres, followed by a kissing balloon inflation (FKB) at nominal pressures, and a proximal optimization technique (POT) using a shorter non-compliant balloon. Whenever an imaging technique was utilized, a final image-run was done to document final result. Patient had to be admitted at same center for overnight observation.

*Clinical follow up*

Patients where then followed for up to 5 years. For those who were lost to follow up, their last known follow up was documented and used but they were not enrolled in further analysis. Whenever feasible patients were personally interviewed or contacted through phone. Their medical files were interrogated for recurrence of cardiac ischemia, including evidence from ECG or Lab results. Reports from other treating centers; visits to ER where all used to decide about emergence of endpoints (MACE). All deaths were considered to be cardiac-related unless a non-cardiac cause was known. Target lesion revascularization was defined as revascularization within 5 mm of the scaffold. Revascularization was defined as ischemia-driven if it was related to a repeat admission with chest pain deemed as Acute Coronary Syndrome (ACS); if there was evidence of a positive functional test suggestive of ischemia in the territory served by target vessel, or there were electrocardiogram changes suggestive of ischemia in the target vessel territory and FFR (fractional flow reserve) of the target vessel showed a ratio 0.80 or less. MI was defined according to the latest MI definition and stent (scaffold) thrombosis according to Academic Research Consortium criteria (14).

*Statistical analyses*

Quantitative variables are presented as mean value with Standard Deviation, or median (inter-quartile range). Dichotomous variables are presented as n (%) prevalence or incidence. Univariate analyses were used to evaluate the relationship between clinical outcome in the follow up period and various clinical, procedural and angiographic variables. To select co-variates independently associated with the outcome (cardiac-related death, hospital readmission for acute coronary syndrome or other cardiac emergencies, repeat vascularization, chest pain recurrence), statistically significant univariate predictors were reassessed by multivariate logistic regression analysis, with values for inclusion and elimination set at $p < 0.05$).

## Results

From 2012 till 2015, out of 341 cases treated at our center with BVS, there were 63 patients with significant bifurcation who satisfied the eligibility criteria and were enrolled in the registry. All these patients were treated fully or partially using BVS Cases with single branch involvement where excluded (Medina: 0.0.1/0.1.0/1.0.0) (Tab. 2).

The mean age of these patients was 58.2 years. 87.5 % of patients where men. 87 % of patients were from UAE or nearby Gulf countries. 70 % had Hypertension, more than half were Dia-

**Tab. 1. Baseline demographics of 63 patients enrolled in registry.**

| Baseline Demographics Study population (n = 63) | |
|---|---|
| Age (years) | 58±12 |
| Sex (male) | 55 (87.3 %) |
| Ethnicity (Arab) | 55 (87.3 %) |
| Hypertension | 44 (69.8 %) |
| Family history of coronary artery disease | 1 (1.6 %) |
| Smoker | 30 (47.6 %) |
| Diabetes | 36 (57.1 %) |
| Dyslipidemia | 48 (76.2 %) |
| Chronic Kidney Disease | 1 (1.5 %) |
| Obesity | 7 (11.1 %) |
| No. of patients who needed CABG post-procedure | 1 (1.6 %) |
| Left ventricular ejection fraction ( %) | 48±11 |
| Syntax score | 23±8 |

**Tab. 2. Procedural characteristics.**

| | |
|---|---|
| Presentation: Chronic Stable Angina/Staged PCI | 20 (31.7 %) |
| Presentation: Acute Coronary syndrome (UA/NSTEMI/STEMI) | 43 (68.3 %) |
| True Bifurcation (Medina 1.1.1) | 42 (66.7 %) |
| Chronic Total Occlusion intervention | 4 (6.3 %) |
| Use of more than one stent | 38 (60.3 %) |
| Treatment using BVS only | 35 (55.6 %) |
| Hybrid with BVS used in main vessel | 55 (87.3 %) |
| Hybrid with BVS used in side branch | 8 (12.7 %) |

**Tab. 3. Optimization measures utilized.**

| | |
|---|---|
| Imaging using OCT or IVUS | 38 (60.3 %) |
| Use of Fractional Flow Reserve | 1 (1.6 %) |
| Use of Drug Eluting Balloon | 6 (9.5 %) |
| Use of Cutting Balloon | 8 (12.7 %) |
| Pre-dilation | 61 (96.8 %) |
| FKB | 40 (63.5 %) |
| POT | 36 (57.1 %) |
| Use of dedicated stent: BIOSS | 3 (4.8 %) |
| Use of dedicated stent: AXXESS | 2 (3.2 %) |

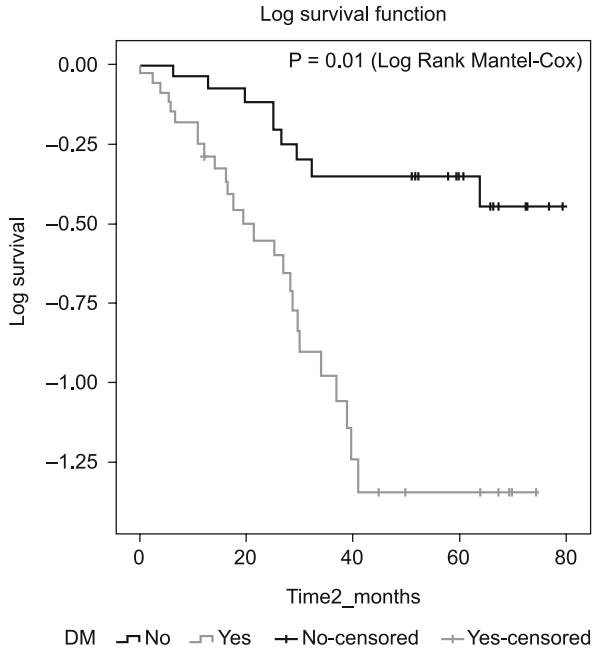


**Fig. 1. Kaiser Fissure survival curves free of MACE with and without Diabetes.**

betic (57 %) with 24 % using only insulin while the rest were on a combination or oral treatment. 76 % had Dyslipidemia, and 47 % were current or past smokers. 48.2 % had a history of myocardial infarction, and 24 % had a previous PCI performed. Eleven percent were morbidly obese (BMI > 35), while 1.5 % had a positive family history of early coronary artery disease. 15 % had a history of congestive heart failure. Peripheral vascular disease was known in 4 patients (7 %), and one patient had a history of CABG (1.5 %). Atrial fibrillation was present in 7 %, while chronic renal failure was known in 1.5 % (Tab. 1).

13 patients (20.6 %) had single vessel disease, 21 patients (33 %) had two vessels disease, while 29 patients (46 %) had triple vessel disease. Left main was involved in 2 patients (3 %). Four patients (6 %) had chronic total occlusion in treated vessel. Indication for the procedure was chronic stable angina or staged PCI in 20 patients (31.7 %), while it was Acute Coronary Syndrome in 43 patients (68 %); out of whom four patients (6 %) presented with STEMI. The average left ventricular ejection fraction was 48.2 %. The average Syntax Score was 22.5 and 66.7 % of treated bifurcations where "true bifurcations", i.e. the lesion involves significant stenosis (> 50 %) in both the Main vessel (MV) and the Side Branch (SB) (Medina: 1,1,1) (Tab. 2). 98 % of patients received pre-dilatation at 1:1 ratio at nominal pressures. Thirty three patients (52 %) had initial kissing balloon inflation. 8 patients (12.7 %) were prepared using cutting or scoring balloon. Average pre-dilatation balloon size was 3.1 ± 0.04, and length 16.3 ± 2.1 41 patients (63 %) had FKB and 36 patients (57 %) had POT; while 28 patients (43 %) had both maneuvers. Average balloon pressure utilized was 17.6 atm. During FKB, the average pressure was 8.3 atm. During POT, the average pressure was 12.8 atm (Tab. 3). The median total number of stents implanted was 2, with a minimal of one stent and maximal of six. 25 patients (40 %) required one stent, 33 patients (51 %) required 2 stents; while 6 patients (9.5 %) required 3 stents. The most prevalent strategy of stenting was provisional stenting (24 patients; 31.7 %. Another 4 patients (6 %) had Provisional followed by Drug Eluting balloon to side branch). Almost all stenting strategies where utilized including T stenting (7 patients; 11 %), T and protrusion (8 patients; 12.7 %), V stenting (5 patients; 8 %), Culotte (7 patients; 11 %), Minicrush (7 patients; 11 %) and a specifically adapted form of V stenting (skirt and trouser: 5 patients, 8 %), where initially proximal main branch is stented then both distal main and side branch are stented in a V fashion; starting from inside the initial stent (32) (Tab. 4, Figs 2 and 3). In 35 patients (55.6 %) a BVS only strategy was utilized; while a hybrid combination of BVS with DES or DEB was used in other 29 patients (44 %), out of which combining BVS to MV and DEB to side branch was utilized in 6 patients (9.5 %), a dedicated bifurcation stent was utilized in a minority of patients (3 patients using BiOSS, Balton, Poland; 2 patients used Axxess

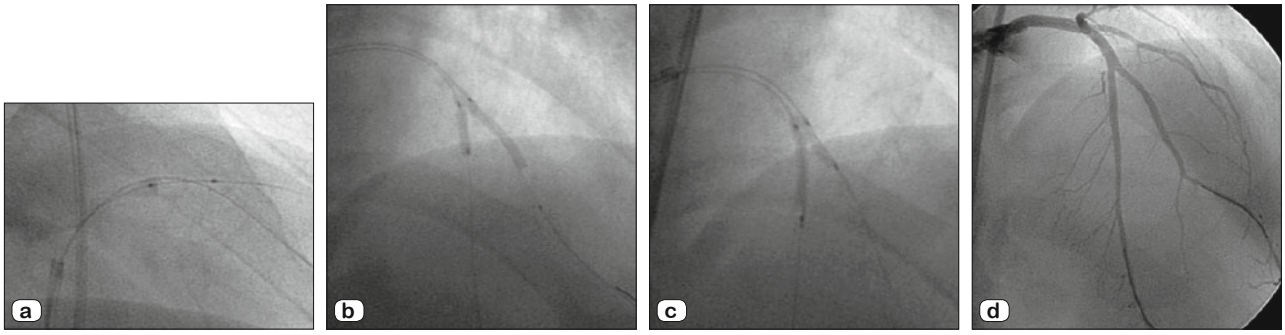


**Fig. 2. a) AP cranial of LAD& diagonal bifurcation (medina 1.1.1), b) Deploying 3.5x18 BVS in proximal LAD, c) Deployment of 2.5x28 BVS in diagonal, d) Deployment of 2.5x28 BVS into mid LAD, e) final result.**

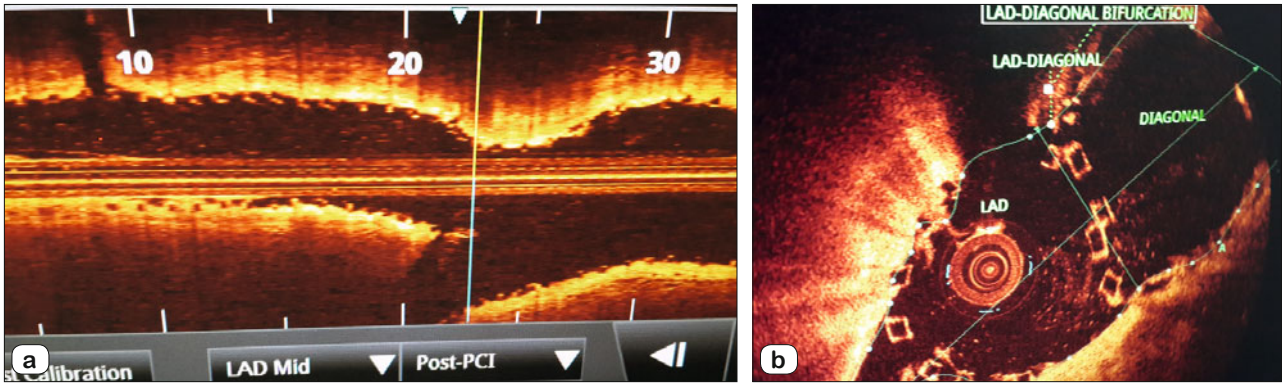


**Fig. 3. a) Longitudinal OCT image for pullback from mid back to proximal LAD, b) Cross sectional OCT image at neo-carina inside proximal BVS.**

Plus, Devax, California, USA). Forty-one patients (87 %) received BVS in main vessel, while DES stent was used in 8 patients (12.7 %). The treated bifurcation was Left Anterior descending / Diagonal bifurcation in 37 patients (58 %), Left Circumflex / Obtuse marginal in 15 patients (24 %), Right coronary artery / Posterior descending artery in 6 patients (9.5 %), and Left main / left anterior descending in 5 patients (8 %). 9 % the lesions were Ostial in position and 21 % showed up to moderate tortuosity (angulation up to 60 degrees). 6.3 % had a type C lesion which indicates a CTO, while 88 % where type B2 lesions and rest where B1. In 7 patient reason for intervention was Instent Restenosis (> 50 % stenosis in old stent). Intravascular imaging was utilized in 68 % of cases, mostly OCT (60.3 %, IVUS 7.7 %). Average main vessel size was 3.3 ± 3, lesion length was 14.1 ± 2.8. Average side branch size was estimated at 2.4 ± 0.2, and lesion length 8 ± 4. Average utilized BVS diameter was 3.3±0.5 and average implantation pressure was 13.8 ± 2.5. Average post dilatation balloon size was 3.3 ± 0.5, with an average inflation 18.3 ± 3.1 atm. The estimated acute gain was 1.6 ± 0.7. Radial access was used in 74 % of procedures, rest being femoral. In 68 % of cases 6F intervention-hardware was used. The most common guiding catheter used was EBU 3.5 (52 % of cases), followed by JR 3.5 (19 %) and AL1 (23 %) and AL2 (6 %). In 32 % additional hardware in form of mother-and-child

**Tab. 4. Stenting Techniques used.**

| | |
|---|---|
| Provisional Stenting | 20 (31.7) |
| T stent | 7 (11.1 %) |
| TAP | 8 (12.7 %) |
| Coulotte | 7 (11.1 %) |
| V stenting | 5 (7.9 %) |
| Skirt | 5 (7.9 %) |
| Mini-crush | 7 (11.1 %) |
| Provisional stenting and Drug Eluting Balloon (DEB) | 4 (6.3 %) |

**Tab. 5. Target vessels treated.**

| | |
|---|---|
| LM/LAD | 5 (7.9 %) |
| LAD/Diagonal | 37 (58.7 %) |
| LCx/OM | 15 (23.8 %) |
| RCA/Pda | 6 (9.5 %) |

**Tab. 6. Clinical outcome data through 5 years (Median follow up 3.87±0.68 years).**

| Outcome data | |
|---|---|
| Major adverse cardiovascular event | 35 (55.6 %) |
| All cause deaths | 5 (8 %) |
| Cardiac deaths | (4 %) |
| Required re-intervention | 24 (38 %) |
| Target Vessel Failure | 15 (24 %) |
| Target Lesion Failure | 11 (17 %) |
| Stent Thrombosis | 3 (4.6 %) |

**Tab. 7. Univariate logistic regression showing only presence of Diabetes as independently significant factor while Hypertension was borderline.**

| | No MACE (n=28) | MACE (n=35) | p |
|---|---|---|---|
| Male | 32 (58.2 %) | 23 (41.8 %) | 0.44 |
| Hypertension | 16 (36.4 %) | 28 (63.6 %) | 0.059 |
| Diabetes | 10 (27.8 %) | 26 (72.2 %) | **0.04** |
| Smoking History | 10 (33.3 %) | 20 (66.7 %) | 0.13 |
| Presentation: CSA/Staged PCI | 11 (55 %) | 9 (45 %) | 0.3 |
| Presentation: ACS | 17 (39.5 %) | 26 (60.5 %) | 0.3 |
| True bifurcation (Medina 1.1.1) | 16 (38.1 %) | 26 (61.9 %) | 0.2 |
| Provisional stenting | 11 (55 %) | 9 (45 %) | 0.3 |
| Treated using BVS only. | 18 (51.4 %) | 17 (48.6 %) | 0.3 |
| Syntax score | 21±8 | 23±8 | 0.4 |

technique was utilized (GuideLiner®, IL, US). In 3.5 % of cases strategy had to be abandoned while it was successfully executed in 96.5 %. Average procedure time was 44±19 minutes for LAD/D, 42 ±2 5 for LCx/OM and 40 ± 26 for RCA/PDA (Tab. 5).

*Outcome data*

All of the 63 patients were followed up to varying periods of time, with 59 cases being followed up the full period of time. Over the period of five years, 35 patients (55.7 %) had developed MACE. There were 5 deaths (8 %), two of whom had documented cardiac mortality, while 1 patient died due to sepsis, second patient died due to a road traffic accident, third patient died related to elderly age. A Repeat coronary angiogram was done in 24 patients (38 %). We had access to the angiograms or to the reports. Target vessel failure (TVF) was noted in 15 patients (24 %). 11 cases had Target lesion failure (TLF) (17 %) (Tab. 6). This was retreated by DES in BVS in 5 patients (8 %) and DEB in 2 patients (3 %). Four patients (6 %) had CABG, two of them were initially treated for lesions involving left main, while rest had initial LAD/D lesions. Two patients had a readmission with suspected ACS while no coronary angiogram was re-performed. Three patients (4.6 %) had BVS scaffold thrombosis. One patient had an early thrombosis before discharge while rest had late or very late event. One of the two cardiac deaths was related to the late stent thrombosis. Patients who developed MACE were more likely to be females (62.5 % vs 42 % males; p = NS), hypertensive (63.6 % vs 37 % nonhypertensives; p = 0.046), diabetic (72 % vs 33 % non-diabetic; p = 0.002), smokers (67 % vs 46 % nonsmokers; p = 0.07), had an acute presentation (ACS or UA: 0.5 % vs 45 % of patients presenting with chronic stable angina or for staged PCI; p = ns). Patient treated by a hybrid strategy of BVS and DES were more likely to develop MACE (64 % vs 49 % of patients treated using only BVS; P = ns). While patients treated by simple provisional stenting were less likely to develop MACE (45 % vs 60.5 % treated by more complex techniques; p = ns). The average SYNTAX score of patients developing MACE was 27 vs 20; p = 0.06) (Tab. 7). The average time for an event to occur was 1.6 ± 0.8 years. At the end of five years 38 % of patients continued to be on dual antiplatelet therapy, while 96.8 % were on it during first year. Being diabetic was independently associated with MACE. Hypertension was of borderline statistical significance (2-sided Log rank for Hypertension 0.06, for Diabetes 0.01) (Fig. 1).

## Discussion

Initial hypothesis for use of BVS in coronary bifurcations is that it would prevent permanent side branch obstruction as scaffolds are expected to be absorbed, which translates in a decline in risk of late stent thrombosis due to non-apposed SB struts15. Initial 'Instructions for use' of the ABSORB BVS advised against its use in lesions involving a SB > 2.5 mm. The fear was that in view of its 150 micron strut thickness, it would impede access to side branch and may fracture easily. Džavík et al reported on bifurcation bench testing of ABSORB BVS in synthetic arterial model16, using several stenting techniques; including provisional stenting with final kissing balloon (FKB), modified T-stenting with FKB, crush, mini-crush and culotte techniques. Using a 2.5 x 20 mm balloon in SB and 3.0 x 20 balloon in main vessel (8 atm), no mal-apposition or strut fracture was noted after implanting of 3.0x18 mm BVS Strut fracture was observed after FKB in T-stenting using a 3.0x18 mm BVS in MV and a 2.5x18 mm BVS in the SB. Mini-crush technique resulted in mild protrusion of BVS struts into the main vessel and a small area of malapposition between the carina and the two overlying scaffolds. Culotte technique showed thick circumferential two-layer scaffold wall in proximal segment of MB and a bulky BVS neocarina. The authors conclude that it is advisable to use provisional stenting in the majority of cases, with sequential NC balloon inflation in SB and MB and reserve FKB only if required. White et al also advocate restricted use of two-stent strategies17. Finet G et al (18) reported in the use of "re-POT" sequence during provisional stenting, comprised of proximal optimizing technique (POT), side branch inflation, and final POT, and compared BVS and DES (Xience V). Mean proximal expansion was 21.6 % for 2.5-mm and 23.6 % for 3.5-mm BVS devices, with only 1 strut fracture. Side branch ostium strut obstruction was greater with BVS scaffolds. BVS showed 2 % late recoil at 1 h, reaching 4 % by 24 h ($p < 0.05$). In an imaging registry of the ABSORB Cohort B (19, 20), a detailed 3D evaluation of the fate of 40 jailed SB 75) is present then a T stenting strategy is feasible. If FKB is to be used then at low pressures, so as not to distort BVS structure. Ormiston et al (23) reported on a "snuggling" technique, where only a small portion of SB balloon comes back in MB, and is inflated at 5 atm, to avoid BVS scaffold fracture. The use of hybrid techniques, where DES is used to treat SB is advised in complicated bifurcations where single provisional stenting with BVS is

not enough (22, 25). In another case report, Okamura et al (24) describes a patient with an initially peri-proceduraly obstructed SB. Serial OCT after 2-years showed reopened SB ostium with intimal bridges at neocarina. These persisted after absorption of the scaffold. Gogas et al (25) first describes side branch balloon dilatation of a LAD/second diagonal bifurcation treated by single ABSORB BVS in MB (Medina 1,1,1), then rewired and dilated SB with 1.5x12 balloon, with excellent end results. Grundeken et al (26) published a case report about implantation of BVS into LM (towards LAD), then LCx was rewired and dilated with a 2.0x20 then 2.5x15 Saphire balloons at 8 atm. OCT after implantation showed opening of the stent cells seen towards the LCx without disruption. Chan et al (27) published on his treatment of 23 bifurcation lesions and used FKB in a third of his cases. Naganuma et al (28) published his experience in treating 63 lesions with 71 % provisional stenting and 20 % systematic double stenting (14 cases), where he used hybrid stenting techniques in 5 cases. In his analysis the use of BVS was independently associated with later SB occlusion (Odds Ratio 2.09; 95 % 1.18–3.68). The European bifurcation club (29) favors the use of provisional single stent technique. Adequate lesion preparation and optimal sizing of ABSORB BVS is essential prior to scaffold placement. Sizing is based on proximal vessel diameter. Balloons > 0.5 mm larger than the BVS size are discouraged. Intravascular imaging, such as intravascular ultrasound (IVUS) or OCT, or online quantitative coronary angiography (QCA) is encouraged (29). After deployment, re-crossing and post-dilatation relies on the angiographic result and imaging. In cases of ostial pinching, with impaired TIMI flow, BVS re-crossing is advised towards the SB, through the most distal compartment to reduce incomplete stent apposition.

Our registry is to our knowledge the biggest and extends with the longest follow up. There was a high use of a two-stent strategy and the use of mainstream bifurcation techniques was liberal. The number of patients treated by any technique is low, hence we cannot draw conclusions about safety and applicability, only feasibility. The choice of technique remained up to the treating physician. In some cases, in order to preserve the integrity of BVS and avoid crush or fenestration, a V technique of two smaller BVS to start from inside a larger BVS was used (32). Every attempt was made to foresee and treat any misgivings of BVS and this is reflected by high use of OCT and IVUS and extended follow up to five years. The rate of MACE is high and it reflects real life results. The rate of serious adverse events, such as stent thrombosis, is reassuringly low, and in accordance with rates reported elsewhere (30). We were unable to prove that a simpler approach portends better long- term outcomes. Diabetes was the only variant that independently affected MACE. Yamawaki et al (31) showed that diabetes is associated with less lumen gain and higher late-loss with stenting using DES, due to inhomogeneous vascular healing. We hypothesize these remains true when using BVS

To conclude, the use of BVS to treat bifurcation lesions using multiple stenting techniques is feasible with low rate of serious adverse effects, albeit on the long run, the rate of re-intervention remains high. If such a strategy is utilized, then stringent follow up is mandatory. Larger registries will shed light on appropriate patient and lesion selection for this approach. Diabetes negatively impacts the long- term outcomes.

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