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Is bioresorbable vascular scaffold acute recoil affected by baseline renal function and scaffold selection?



Haci Murat Gunes *, Filiz Kizilirmak Yılmaz, Tayyar Gokdeniz, Gultekin Gunhan Demir, Ekrem Guler, Gamze Babur Guler, Oğuz Karaca, Beytullah Cakal, Ersin İbişoğlu, Bilal Boztosun

Medipol University, Faculty of Medicine, Cardiology Department, Istanbul, Turkey

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ABSTRACT

Objective: The aim of the present study was to investigate the relationship between glomerular filtration rate (GFR) and acute post-scaffold recoil (PSR) in patients undergoing bioresorbable scaffold (BVS) implantation. *Methods:* We included 130 patients who underwent everolimus-eluting BVS device (Absorb BVS; Abbott Vascular, Santa Clara, CA, USA) or the novolimus-eluting BVS device (Elixir Medical Corporation) implantations for single or multi-vessel disease. Clinical, angiographic variables and procedural characteristics were defined and pre-procedural GFR was calculated for each patient. Post-procedural angiographic parameters of each patient were analyzed. Primary objective of the study was to evaluate the effect of GFR on angiographic outcomes after BVS implantation while secondary objective was to compare post-procedural angiographic results between the two BVS device groups.

Results: Baseline clinical characteristics and angiographic parameters were similar between the two BVS groups. Post-procedural angiographic analysis revealed significantly lower PSR in the DESolve group than the Absorb group (0.10 \pm 0.04 vs. 0.13 \pm 0.05, p: 0.003). When PSR in the whole study population was evaluated, it was positively correlated with age, tortuosity , calcification and PBR as there was a negative correlation between GFR. Besides GFR were found to be independent predictors for PSR in all groups and the whole study population. Conclusion: In patients undergoing BVS implantation, pre-procedural low GFR is associated with increased post-procedural PSR. Calcification, age, PBR, dyslipidemia and tortuosity are other independent risk factors for PSR. DESolve has lower PSR when compared with Absorb.

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1. Introduction

Percutaneous coronary intervention (PCI) has made substantial progress in the last decades with the introduction of bare metal stents (BMS), drug-eluting stents (DES) and a newcomer to the field, bioresorbable vascular scaffolds (BVS) [1]. The main benefits anticipated by the use of biocompatible materials include gradually reduced inflammatory and fibrotic response through resorption mechanism and reconstruction of normal vessel wall structure [2]. BVSs have been developed to overcome difficulties related with DES technology; including side-branch occlusion, late adverse events, inability of by-pass grafting to stented segments and limited image resolution with computed tomography or magnetic resonance imaging modalities, in addition to their capability of restoring normal vessel vasomotion [1]. BVSs have been developed to overcome these difficulties related with DES

technology. BVSs remain within the vessel long enough to provide protection against subacute closure, wall recoil and restenosis. Besides it has the potential to reduce problems such as very late stent thrombosis and the need for prolonged dual antiplatelet therapy. More aggressive lesion preparation is required due to singular design and composition of BVSs [3]. Similarly, it was shown that plaque composition, morphology and burden were effective factors for BVS expansion and eccentricity [4]. Increased final luminal diameter of target vessel is associated with improved long-term patency after PCI and lower recurrence rates [5–7]. Stent recoil is one of the major mechanisms responsible for suboptimal stent expansion and severe residual lesion post-PCI [8,9]. Danzi et al. detected significantly greater acute recoil of the BVS in comparison with everolimus-eluting stents and also correlation between recoil percentage and residual stenosis after predilatation in patients treated with BVS [10]. The relationship between renal impairment (RI) and coronary artery disease is well established [11,12]. Complex coronary artery disease, left main coronary artery disease, ostial lesions, multi-vessel disease and heavily-calcified lesions are more common in patients with RI than those without RI [13,14]. Budoff et al. demonstrated a powerful and graded relationship between

^{*} Corresponding author at: Medipol University Hospital, Cardiology Department, TEM Avrupa Otoyolu Göztepe Çıkışı No: 1 Bağcılar, 34214 İstanbul, Turkey. E-mail address: haci.gunes@medipol.com.tr (H.M. Gunes).

lower glomerular filtration rate (GFR) and increased coronary artery calcifications (CAC) [15].

In this study we aimed to examine the relationship between preprocedural GFR and acute post-scaffold recoil (PSR) in patients treated with BVS.

2. Methods

2.1. Study population

In this cross-sectional and single-center study, we included 135 patients with single or multi-vessel disease undergoing PCI with everolimus-eluting BVS device (Absorb BVS; Abbott Vascular, Santa Clara, CA, USA) or the novolimus-eluting BVS device (Elixir Medical Corporation) between January 2013 and December 2015 in Medipol University. PCI could not be performed due to inability to cross the lesion with stent in 5 patients with single lesion (2 in LAD, 2 in Cx and 1 in RCA). We included total 130 patients. Baseline clinical, angiographic variables and procedural characteristics were defined.

Eligible patients were those with reference vessel diameter (RVD) ≥2.25 mm, stentable lesions, stable coronary artery disease or unstable angina or non-ST segment elevation myocardial infarction. All treated lesions consisted of stenosis >50% but less than 100% vessel occlusion in native coronary arteries with thrombolysis in myocardial infarction (TIMI) flow grade ≥1. Major exclusion criteria were defined as acute ST-segment elevation myocardial infarction, hemodynamically unstable arrhythmias, left ventricular ejection fraction (LVEF) <30%, lesions in arterial or saphenous vein grafts and restenotic lesions. No restrictions were applied regarding the number of treated lesions and vessels, implanted stents or lesion length. The patients were asked for their permission about implantation of one or more BVSs and in the case of DES or BMS.

2.2. Procedures

All interventions were performed according to current PCI standards including mandatory predilatation and pressures under rated burst pressure. Post-dilatation or additional stent implantation was left to the discretion of the operator. Predilatation was performed at the same diameter of RVD and post-dilatation balloon was selected with a diameter of 0.5 mm larger than implanted BVS diameter. Upstream 300 mg loading dose of oral aspirin was followed with 100 mg daily aspirin in patients not receiving chronic aspirin treatment. Upstream loading dose of clopidogrel 600 mg, prasugrel 60 mg or ticagrelor 180 mg was followed with daily maintenance dose of clopidogrel 75 mg, prasugrel 10 mg or ticagrelor 90 mg bid for 12 months in thienopyridine-naive patients. None of the patients received glycoprotein IIb/IIIa inhibitors.

2.3. Study objectives and definitions

Primary objective of the study was to evaluate the effect of GFR on angiographic outcomes after BVS implantation. Secondary goal was to compare post-procedural angiographic results between the BVS device types (Absorb and Elixir Medical Corporation). Pre-procedural GFR was estimated by the use of the Modification of Diet in Renal Disease (MDRD) equation [16]. Quantitative coronary angiography (QCA) was performed using standard techniques with automated edge-detection algorithms (version 1.4) in the hospital's angiographic analysis center. Scaffold segment and peri-scaffold segment (5 mm proximal and distal to the scaffold edge) were analyzed for each patient. Minimal luminal diameter (MLD), lesion length, RVD and percent diameter stenosis (DS) were calculated. In addition to baseline images, four images of post-PCI cine frames were analyzed (Fig. 1). Two images were acquired while predilatation balloon catheter was at the highest pressure, fully expanded and after balloon deflation was followed with nitroglycerine

injection. The other two images were acquired while post-dilatation balloon (or scaffold balloon instead) was at the highest pressure, fully expanded and after balloon deflation was followed with nitroglycerine injection. These images were analyzed from the same angiographic projection in order to minimize foreshortening.

2.4. Angiographic parameters

2.4.1. Calcification

Calcification was identified as readily apparent radiopacity within the vascular wall at the site of the stenosis, and was classified as moderate (radiopacity noted only during the cardiac cycle before contrast injection), and severe (radiopacity noted without cardiac motion before contrast injection and generally compromising both sides of the arterial lumen) [17].

2.4.2. Tortuosity

Coronary lesion is defined as severely tortuous when it satisfies the following criteria: one or more bends of 90° or more, or three or more bends of 45–90° proximal to the diseased segment. Lesions out of these criteria were defined as moderate [18].

2.4.3. Predil, diameter

Predil, diameter is defined as the balloon diameter for predilatation.

2.4.4. Postdil. diameter

Postdil. diameter is defined as the balloon diameter for postdilatation.

2.4.5. BMLD₁ (balloon mean lumen diameter₁)

BMLD₁ (balloon mean lumen diameter₁) is defined as the mean lumen diameter measured during inflation of predilatation balloon.

2.4.6. BMLD₂ (balloon mean lumen diameter₂)

 $BMLD_2$ (balloon mean lumen diameter₂) is defined as the mean lumen diameter measured after deflation of predilatation balloon.

2.4.7. PBR (post-balloon recoiling)

PBR (post-balloon recoiling) is defined as recoiling ((BMLD $_1$ – BMLD $_2$) / BMLD $_1$) after predilatation.

2.4.8. SMLD (scaffold mean lumen diameter)

SMLD (scaffold mean lumen diameter) is defined as the mean lumen diameter measured during inflation of post-dilatation balloon or scaffold balloon (when post-dilatation was not performed).

2.4.9. FMLD (final mean lumen diameter)

FMLD (final mean lumen diameter) is defined as the mean lumen diameter measured after deflation of post-dilatation balloon or scaffold balloon (when post-dilatation was not performed).

2.4.10. PSR (post-scaffold recoil)

PSR (post-scaffold recoil) is defined as recoiling ((SMLD - FMLD) / SMLD) after scaffold implantation.

2.4.11. Statistical analysis

SPSS 23.0 statistical software (SPSS Inc., Chicago, IL, USA) were used for statistical analysis. Continuous variables were expressed as mean \pm standard deviation (SD) or median and interquartile range as appropriate. Categorical variables were expressed as percentages. The Kolmogorov–Smirnov test was used to test normality of distribution of continuous variables. Group means for continuous variables were compared with the use of Student's t-test or the Mann–Whitney U test, as appropriate. Pearson or Spearman correlation analysis was used for assessing correlation between PSR and clinical and procedural variables of patients in all BVS population and each BVS type (Absorb,

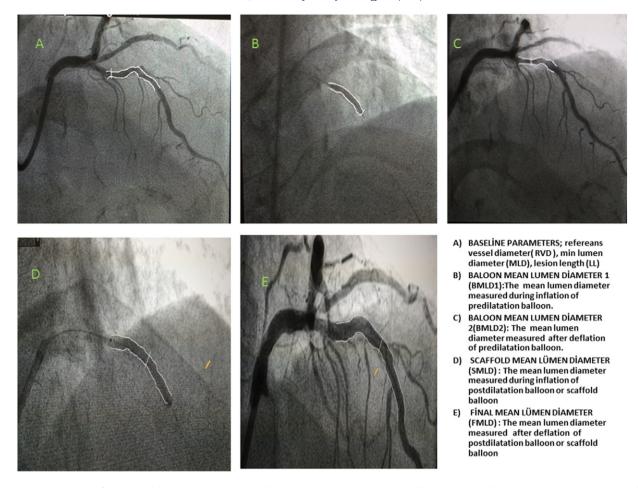


Fig. 1. A) Baseline parameters; reference vessel diameter (RVD), min lumen diameter (MLD), lesion length (LL). B) Balloon mean lumen diameter 1 (BMLD₁): the mean lumen diameter measured during inflation of predilatation balloon. C) Balloon mean lumen diameter 2 (BMLD₂): the mean lumen diameter measured after deflation of predilatation balloon. D) Scaffold mean lumen diameter (SMLD): the mean lumen diameter (FMLD): the mean lumen diameter (FMLD): the mean lumen diameter measured after deflation of post-dilatation balloon or scaffold balloon.

Elixir Medical Corporation) depending on Gaussian distributions. Stepwise multivariate linear regression analysis involving significant parameters in univariate analysis was performed to find independent predictors of PSR in all BVS population and each BVS type. A p value of ≤ 0.05 was considered statistically significant.

3. Results

A total of 130 patients underwent 162 BVS implantations consisting of Absorb (n:131 80.9%) and DESolve (n:31, 19.1%). Femoral access was used in 111 (85.4%) patients and radial access was used in 19 (14.6%) patients. Baseline characteristics and clinical data of both groups are shown in Table 1. Mean age of the study population was 59 ± 11 and male gender was 82%. Patients with stable angina and unstable angina were 111 (85%) and 19 (14%), respectively. Mean LVEF of the patients was $56\pm10\%$ and mean GFR was 88 ± 23 ml/min/1.73 m². There was no difference between scaffold groups with regard to baseline clinical characteristics.

Similarly, there were no differences among two scaffold groups in terms of angiographic characteristics of the patients (Table 2). Preprocedural and in-scaffold post-procedural QCA data of patients in each scaffold group were shown in Table 3. Pre-procedural QCA parameters were not different among two groups. Scaffold diameter was significantly higher in the DESolve group than the Absorb group (3.1 \pm 0.3 vs. 2.9 \pm 0.3, p: 0.037). PBR in the DESolve group was lower than the Absorb group (0.17 \pm 0.06 vs. 0.20 \pm 0.07, p: 0.005). FMLD was significantly higher in the DESolve group than the Absorb group (3.08 \pm 0.41 vs. 2.84 \pm 0.4, p: 0.005). PSR was lower in the

DESolve group than the Absorb group (0.10 \pm 0.04 vs. 0.13 \pm 0.05, p: 0.003).

Table 4 shows the correlation analysis between PSR and clinical and procedural variables. When the patients in the whole study population were taken into consideration, PSR was positively correlated with age (r: +0.147, p: 0.006), tortuosity (r: +0.146, p: 0.024), calcification (r: +0.364, p < 0.001) and PBR (r: +0.364, p < 0.001) while it was negatively correlated with GFR (r: -0.342, p < 0.001). In the Absorb group, there was a positive correlation between PSR and age (r: +0.252, p: 0.001), calcification (r: +0.438, p: 0.001) and PBR (r: +0.475,

Table 1Baseline clinical characteristics.

	Total n = 130	Absorb Group n = 107	DESolve Group n = 23	p value
Age, years Male gender, n (%) Hypertension, n (%) Diabetes mellitus, n (%) Current smoker, n (%) Dyslipidemia, n (%) Initial clinical	59 ± 11 107 (82) 81 (62) 57 (43) 60 (46) 99 (76)	59.7 ± 11.3 86 (80) 66 (61) 50 (46) 47 (43) 79 (73)	59 ± 11.8 21 (91) 15 (65) 7 (30) 13 (56) 20 (87)	0.772 0.174 0.473 0.115 0.192 0.141
presentation, n (%) Stable angina Unstable angina LVEF (%) GFR (ml/min/1.73 m²)	$111 (85)$ $19 (14)$ 56 ± 10 88 ± 23	94 (87) 13 (12) 55.9 ± 11.1 87.6 ± 24.5	17 (73) 6 (26) 57.5 \pm 6.7 91.8 \pm 20.7	0.087 0.105 0.508 0.444

LVEF: left ventricular ejection fraction, GFR: glomerular filtration rate.

Table 2 Angiographic characteristics.

	Total	Absorb Group	DESolve Group	p value
Treated vessel, n (%)				
LAD	86 (53.0)	71 (54.2)	15 (48.4)	
LCX	32 (19.8)	25 (19.1)	7 (22.6)	0.737
RCA	38 (23.5)	30 (22.9)	8 (25.8)	
LM	6 (3.7)	5 (3.8)	1 (3.2)	
Lesion classification ^a A/B1/B2/C, %	38/34/10/18	40/30/10/20	29/48/10/13	0.875
Calcification moderate/severe, %	60/40	59/40	65/35	0.686
Tortuosity moderate/severe, %	88/12	87/13	94/6	0.534

^a According to the American College of Cardiology/American Heart Association lesion classification. LAD: left anterior descending coronary artery; LCX: left circumflex coronary artery; LM: left main coronary artery RCA: right coronary artery.

 $p\!<\!0.001),$ and as PSR was found to have a negative correlation with and GFR (r: $-0.489,\,p\!<\!0.001).$

In the DESolve group PSR was positively correlated with dyslipidemia (r: +0.511, p: 0.003), calcification (r: +0.569, p: 0.001) and PBR (r: +0.522, p: 0.003) as it was negatively correlated with GFR (r: -0.551, p: 0.001).

Parameters having significant correlation with PSR in the total group and each BVS group in the univariate analysis were included in the multivariate analysis. Table 5 shows the multivariate analysis of independent predictors for PSR. In the Absorb group, PBR (p < 0.001), GFR (p : 0.001) and calcification (p < 0.001), were found to be independent predictors for PSR, and dyslipidemia (p : 0.001), PBR (p : 0.004), and GFR (p : 0.003) were independent predictors for PSR in the DESolve group. In the whole study population, PBR (p < 0.001), GFR (p < 0.001) and calcification (p < 0.001) were independent predictors for PSR.

4. Discussion

In this study we aimed to investigate the relationship between preprocedural GFR and post-procedural PSR in patients undergoing BVS implantation.

- Pre-procedural GFR was found to be independent predictor for PSR after BVS implantation in both scaffold groups. The lower GFR was associated with the higher PSR.
- II. In the whole study group, PBR and calcification were the other independent predictors for PSR. Other independent predictors for PSR were PBR and calcification in the Absorb group; dyslipidemia, PBR in the DESolve group, respectively.
- III. When post-procedural parameters of both groups were

compared, we detected lower PSR in the DESolve group than the Absorb group with statistically significant difference.

There is a growing number of BVS implantations in patients undergoing PCI. More aggressive lesion preparation is required because of design and composition characteristics of BVSs [3]. Furthermore, in contrast with metal stents aggressive post-dilatation can lead scaffold fractures in BVS use [19]. Shaw et al. demonstrated that BVS expansion and eccentricity were highly affected by plaque composition, morphology and burden; consequently lower scaffold eccentricity index and scaffold expansion index are associated with greater calcified plaque area and thickness [4].

Patients with RI have more complex and advanced coronary artery disease, hence a higher peri-procedural risk for PCI [11]. Cardiac death and MI after PCI with DES was 2-folds more common in patients with moderate/severe RI than those without; however stent thrombosis, DES affectivity or angiographic outcomes were not affected by RI [20]. Nevertheless, the relationship between RI and angiographic outcomes after BVS implantation has not been investigated so far. We investigated the relationship between pre-procedural GFR and BVS recoil. We detected that pre-procedural GFR was an independent predictor for PSR both in each scaffold group and the whole study group. This finding may be related with increased calcified plague burden in coronary arteries of patients with low GFR. It is not always possible to visualize coronary calcifications in coronary angiographic images. Since it is impractical to use imaging methods such as optical coherence tomography (OCT) or intravascular ultrasound (IVUS) in daily practice, GFR might serve as a simple and useful tool for prediction of angiographic outcomes after BVS. Other independent predictors for PSR were

Table 3 Procedural data.

	Total n = 162	Absorb Group n = 131	DESolve Group n = 31	p value
Pre-procedural QCA				
Lesion length, mm	24 ± 10	24 ± 11	25 ± 9	0.792
RVD, mm	3.1 ± 0.4	3.1 ± 0.3	3.2 ± 0.4	0.128
DS, %	69 ± 9	68 ± 7	71 ± 11	0.410
MLD, mm	0.9 ± 0.3	0.9 ± 0.2	0.9 ± 0.3	0.688
In-scaffold post-procedural QCA				
Predil. diameter	2.8 ± 0.3	2.8 ± 0.3	2.8 ± 0.3	0.833
Postdil, diameter	3.5 ± 0.7	3.0 ± 0.7	3.2 ± 0.7	0.176
Scaffold length, mm	25 ± 4	25 ± 4	26 ± 3	0.201
Scaffold diameter, mm	3.0 ± 0.3	2.9 ± 0.3	3.1 ± 0.3	0.037
BMLD _{1.} mm	2.9 ± 0.3	2.9 ± 0.4	2.9 ± 0.3	0.686
BMLD ₂ , mm	2.3 ± 0.3	2.3 ± 0.3	2.4 ± 0.3	0.069
PBR	0.20 ± 0.07	0.20 ± 0.07	0.17 ± 0.06	0.005
FMLD, mm	2.89 ± 0.41	2.84 ± 0.4	3.08 ± 0.41	0.005
SMLD, mm	3.31 ± 0.44	3.28 ± 0.43	3.45 ± 0.44	0.065
PSR	0.12 ± 0.05	0.13 ± 0.05	0.10 ± 0.04	0.003

BMLD₁: balloon mean lumen diameter 1. BMLD₂: balloon mean lumen diameter 2. DS: diameter stenosis; FMLD: final mean lumen diameter, MLD: minimum lumen diameter; PBR: post-balloon recoiling, Postdil. diameter: post-dilatation balloon diameter. PFR: post-scaffold recoil. QCA: quantitative coronary angiography; RVD: reference vessel diameter, SMLD: scaffold mean lumen diameter.

Table 4Association between PSR and clinical, procedural variables of patients.

Variables	Total	Absorb Group	DESolve Group r (correlation coefficient)/P value	
	r (correlation coefficient)/P value	r (correlation coefficient)/P value		
Age	+0.147/0.006	+0.252/0.004	+0.036/0.849	
Male gender	-0.095/0.141	-0.142/0.106	-0.185/0.320	
Hypertension	+0.074/0.250	+0.075/0.395	+0.232/0.208	
Diabetes mellitus	+0.004/0.953	+0.018/0.819	+0.073/0.696	
Dyslipidemia	+0.008/0.900	+0.067/0.450	+0.511/0.003	
LVEF	-0.086/0.131	-0.184/0.076	-0.284/0.122	
Tortuosity	+0.146/0.024	+0.169/0.053	+0.251/0.173	
Calcification	+ 0.364/< 0.001	+0.438/0.001	+0.569/0.001	
Lesion length	+0.050/0.355	+0.024/0.783	+0.105/0.574	
RVD	-0.034/0.526	-0.051/0.561	-0.002/0.993	
Predil. diameter	+0.015/0.810	+0.068/0.441	+0.105/0.575	
Postdil. diameter	+0.041/0.481	+0.044/0.621	+0.121/0.516	
Scaffold diameter	-0.037/0.537	-0.023/0.799	-0.034/0.857	
Scaffold length	+0.037/0.560	+0.013/0.880	+0.195/0.292	
PBR	+0.364/<0.001	+0.475/<0.001	+0.522/0.003	
DS	+0.005/0.930	+0.129/0.143	+ 0.253/0.169	
MLD	+0.003/0.953	+0.113/0.198	+0.203/0.272	
GFR	-0.342/<0.001	-0.489/<0.001	-0.551/0.001	

DS: diameter stenosis; LVEF: left ventricular ejection fraction, GFR: glomerular filtration rate, MLD: minimum lumen diameter; Postdil. diameter: post-dilatation balloon diameter; PBR: post-balloon recoiling; Predil. diameter: predilatation balloon diameter; PSR: post-scaffold recoil; RVD: reference vessel diameter, SMLD: scaffold mean lumen diameter.

calcification, PBR, dyslipidemia. Danzi et al. reported significant correlation between BVS recoil and residual stenosis after predilatation in their study [10]. Onuma et al. showed that high balloon/artery ratio (>1.1) was predictive for high recoil [21]. Absorb BVS was used in both studies as we included DeSolve BVS additionally. Stent recoil is a combined consequence of elastic recoil and radial force and it may be affected by procedural characteristics such as lesion features and RVD, stent oversizing and balloon compliance [21,22]. All parameters which we found to be associated with PSR are also factors interacting with coronary lesion characteristics, therefore it is natural to obtain these results.

ABSORB trial demonstrated that acute recoiling of BVS was higher than that of everolimus-eluting stent used in SPIRIT I and SPIRIT II [23]. BVS revision 1.1 was developed in order to improve scaffold characteristics and extend mechanical stability by making alterations in strut pattern design. We detected that PSR was significantly lower in the DESolve group than the Absorb group. To our knowledge, there is no study comparing DESolve and Absorb BVS in terms of PSR. Lower PSR in the DESolve group in comparison with the Absorb might be related to lower PBR values in the DESolve group. DESolve is a new BVS shown to have a short bioresorbation period and capability of expansion at high pressures without strut fractures [24]. Strut design pattern and different scaffold characteristics may be related with these findings; however, further studies are warranted in this field to investigate these factors in detail.

Table 5Multivariate analysis of independent predictors of PSR in all groups.

Absorb Group	p value	Beta
Age	-	-
PBR	< 0.001	0.274
GFR	0.001	-0.277
Calcification	< 0.001	0.289
DESolve Group		
Dyslipidemia	0.001	0.416
PBR	0.004	0.369
GFR	0.003	-0.385
Calcification	=	_
Total		
Age	-	
PBR	< 0.001	0.319
GFR	< 0.001	-0.267
Calcification	< 0.001	0.275
Tortuosity	-	-

DS: diameter stenosis; GFR: glomerular filtration rate; PBR: post-balloon recoiling; PSR: post-scaffold recoil

5. Study limitations

The main limitations of this study are small sample size and non-randomized design. All measurements were made angiographically so more precise and useful results could be obtained with imaging techniques such as OCT and IVUS. However, QCA is a practical non-invasive method providing useful information about vessel and lesion characteristics and angiographic data. DES was not selected as control group regarding findings in a recent study which had already established superiority of DES over BRS in acute recoil. Lack of follow-up after the procedure is another limitation of our study.

6. Conclusion

In patients undergoing BVS implantation, pre-procedural low GFR is associated with increased post-procedural PSR. Calcification, PBR, dyslipidemia are other independent risk factors for PSR. DESolve has lower PSR when compared with Absorb BVS. Employment of pre-procedural GFR might serve as a practical and useful parameter for prediction of BVS efficacy.

Conflict of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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