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ORIGINAL ARTICLE

Effects of aggressive predilatation, sizing, and postdilatation strategy for coronary bioresorbable vascular scaffolds implantation

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Abstract

Background: The results of the recent Amsterdam Investigator-Initiated Absorb Strategy All-Comers trial showed that the predilatation, sizing, and postdilatation (PSP) technique did not lower the long-term rates of scaffold thrombosis and adverse events. We evaluated the impact of aggressive PSP bioresorbable vascular scaffold (BRS) implantation on the short- and long-term clinical outcomes.

Methods: From June 2014 to December 2016, 150 patients with BRS implantation were enrolled and received successful percutaneous coronary intervention (PCI), of whom 104 received aggressive PSP technique (high-pressure predilatation and lesion preparation in addition to the traditional PSP technique). Short- and long-term outcomes were compared.

Results: All patients underwent successful PCI and BRS implantation with final Thrombolysis in Myocardial Infarction grade 3 flow. The baseline and procedure characteristics were similar in both groups. Debulking techniques were used in 13 (8.7%) patients. Intracoronary imaging modalities were used in 73 (48.7%) patients. After BRS implantation, no adverse events were observed within 30 days in both groups. During the mean follow-up period of 2.98±0.77 years, 12 (8.0%) patients experienced major adverse cardiovascular events (MACEs), including one cardiovascular death (0.6%), three nonfatal myocardial infarction (2.0 %), and 11 target-vessel revascularization (7.3 %). Multivariate Cox regression analysis showed that aggressive PSP remained an independent protective factor for MACEs. Moreover, the use of intracoronary imaging and rotablation atherectomy was associated with better clinical outcomes.

Conclusion: Lesion preparation by aggressive PSP in BRS implantation was associated with better long-term clinical outcomes.

Keywords: Coronary artery disease; Myocardial infarction; Percutaneous coronary intervention

1. INTRODUCTION

Drug-eluting stents (DESs) are used as the current standard of care in percutaneous coronary intervention (PCI).[1,2] Metallic devices still have various well-recognized limitations, including permanent metallic vessel cages that induce endothelial dysfunction, in-stent restenosis resulting in the occurrence of neo-atherosclerosis, late stent thrombosis, and vasomotion restrictions.[3–6] Bioresorbable vascular scaffolds (BRSs) have been designed to be a promising solution for the long-term persistence of metallic stents in treating coronary artery diseases.[7,8] Although several large randomized controlled trials (RCTs) have demonstrated that polymeric BRSs have 1-year clinical outcomes similar to those of new-generation DESs, at least one large, randomized study has shown that BRSs were associated with a higher incidence of device-related thrombosis than metallic stents.[9] As BRSs are thicker (150 μm), have lower radial strength, and have more expansion limitations than DESs due to the characteristic limitation of the material,[10–13] more delicate implantation techniques have been suggested to optimize the performance of current-generation BRSs,[14] reduce the risk of early scaffold thrombosis, and yield favorable long-term outcomes. Recent studies have emphasized the optimal preparation of the lesion and carefully choosing lesions before BRS implantation.[15,16] Moreover, the use of the traditional PSP technique (ie, the use of optimal predilatation, proper vessel and device sizing, and optimal postdilatation) has been shown to be associated with better scaffold expansion and a lower risk of thrombotic events.[17] However, the role of aggressive predilatation in coronary lesions before BRS implantation has been less addressed. Therefore, this study was designed to retrospectively

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compare the short- and long-term clinical outcomes of BRS implantation using the aggressive PSP technique (aggressive predilatation [balloon diameter/vessel or scaffold diameter ≥ 1:1 ratio and pressure ≥ rated burst pressure (RBP)] with non-compliance (NC) balloon plus aggressive high-pressure post-dilatation with NC balloon) with those of BRS implantation using the traditional PSP technique.

2. METHODS

2.1. Study population

From June 2014 to December 2016, all consecutive patients with documented significantly stenotic coronary lesions (defined as stenosis diameter of ≥70%) who were undergoing PCI with BRS (ABSORB, Abbott Vascular, Santa Clara, California) implantation were enrolled. Moreover, patients with acute coronary syndrome, including ST-elevation myocardial infarction (MI) and non–ST-elevation MI, were included. The clinical exclusion criteria included patients with left main disease, bifurcation lesions with large side branches, acute decompensated congestive heart failure, acute and chronic infections, autoimmune diseases, malignancy with expected life span of <1 year, and unstable hemodynamic status. The baseline and procedural characteristics, medical history, clinical examination, operative records, and clinical outcomes were extracted from medical chart review. The estimated glomerular filtration rate (eGFR) was calculated according to the Modification of Diet in Renal Disease equation.[18] Chronic kidney disease was defined as an eGFR of ≤60 mL/min per 1.73 m^2. The study protocol was approved by the Institutional Review Board of Taipei Veterans General Hospital.

2.2. Procedural details

BRSs were implanted using either the traditional or aggressive PSP technique. The traditional PSP technique consisted of lesion preparation, proper scaffold sizing, and postdilatation.[19] In contrast, in the aggressive PSP technique group, all patients received aggressive high-pressure predilatation and postdilatation. Preparing calcified lesions using cutting balloon/rotablation atherectomy and an intracoronary imaging method (ie, intravascular ultrasound [IVUS] or optical coherence tomography [OCT]) was encouraged and left to the discretion of operators. BRSs were deployed by slow balloon inflation with 2 atm every 5 seconds, and the final inflation pressure was held for 20 seconds in the scaffold. Final aggressive high-pressure post-dilatation is mandatory in both the aggressive and traditional PSP technique groups. In case of multiple scaffold implantations per lesion, the marker-to-marker or scaffold-to-scaffold technique was used to minimize the overlap of the scaffolds.[20] All patients underwent successful PCI, which was defined as residual stenosis of <30% angiographically observed with final coronary Thrombolysis in MI (TIMI) grade 3 flow and without major complications. Dual antiplatelet drugs were started after the procedure, and all patients received aspirin (100 mg/day) indefinitely and clopidogrel (300-mg loading dose, and 75-mg maintenance dose per day) for at least 12 months. Medications for treating angina pectoris (ie, calcium channel blockers, beta-blockers, and nitrates) were continued.

2.3. Follow-up and study endpoints

All patients were followed up by medical chart review and telephone contact. The endpoints included 30-day and long-term cardiovascular (CV) death and major adverse cardiovascular events (MACEs), including ischemia-driven target-vessel revascularization (TVR), nonfatal MI, and CV death after the index procedure. TVR was defined as >50% angiographic restenosis of the target vessel needing intervention for previously treated vessels. Nonfatal MI was defined as the presence of new significant Q waves in at least two electrocardiography leads or symptoms compatible with MI associated with an increase in creatinine kinase-MB fraction ≥3× the upper limit of the reference range.[21] CV death was diagnosed as any death with definite CV causes or any death not clearly attributed to a non-CV cause. The occurrence of scaffold thrombosis was classified as definite, probable, or possible according to the Academic Research Consortium criteria[22] and were considered acute (within 24 hours), subacute (within 30 days), late (after 30 days and within 12 months), and very late (after 1 year).

2.4. Statistical analysis

All analyses were performed using Statistical Package for the Social Sciences (version 20; IBM Corporation, Armonk, NY). All data were expressed as means and standard deviations for numeric variables and as numbers (percentages) for categorical variables. Comparisons of continuous variables between groups were performed using Student *t* test. Categorical data between two groups were compared using the chi-square test or Fisher exact test. 30-day CV death, 30-day MACE, long-term CV death, and long-term MACE of both groups were estimated using the Kaplan-Meier method and compared using the log-rank test. A univariate Cox regression model was developed first for age, diabetes mellitus (DM), aggressive PSP technique, and hypertension, and in multivariate Cox regression analysis, we adjusted for age and associated comorbidities. The hazard ratio and 95% confidence interval were calculated. Differences with p values of <0.05 were considered statistically significant.

3. RESULTS

3.1. Baseline and angiographic characteristics

From June 2014 to December 2016, 150 patients who underwent successful PCI with BRS implantation were included retrospectively, and the aggressive PSP technique was applied in 104 patients, whereas the traditional PSP technique was applied in the remaining 46 patients. The baseline characteristics of both groups are shown in Table 1. No significant differences in the baseline characteristics were observed between the two groups. Moreover, the angiographic characteristics of both groups are summarized in Table 1. Nearly half of lesions (n = 62, 41.3%) were class B2/C complex lesions according to the American College of Cardiology/American Heart Association classification criteria, including six cases of chronic total occlusion (CTO) lesions and 10 cases of moderate-to-heavy calcifications. No significant differences in the angiographic characteristics were observed between both groups.

All patients underwent successful PCI with BRS implantation with final TIMI grade 3 flow. The procedural characteristics are summarized in Table 2. The mean total length of implanted scaffolds was 26.2 ± 12.3 mm in the aggressive PSP technique group, whereas it was 27.2 ± 11.2 mm in the traditional PSP technique group (p = 0.072). BRS overlapping using the marker-to-marker or scaffold-to-scaffold technique was performed in 42 patients (28%). Debulking techniques (ie, cutting balloon and/or rotablation atherectomy) were used in 13 patients (11 patients in the aggressive PSP technique group (10.6%) and two patients in the traditional PSP technique group (4.3%); p = 0.122) (Table 2). OCT before and after scaffold implantation was performed to evaluate vessel lumen diameter and stent apposition in 16 patients (10.6%), and IVUS was performed in 57 patients (38.0%). In total, intracoronary imaging modalities were used in 73 patients (56 patients in the aggressive PSP technique group [53.8%] and 17 patients in the traditional PSP technique group [37.0%]; p = 0.616) (Table 2). All patients in both groups

Table 1

Baseline characteristics and angiographic findings of the enrolled patients stratified by the presence or absence of the aggressive PSP technique[a]

Variables	Aggressive PSP technique (N = 104)	Traditional PSP technique (N = 46)	*p*
Age, y	58.0 ± 11.2	58.1 ± 10.1	0.962
Male	98 (94.2%)	31 (67.4%)	0.423
Hypertension	60 (58.0%)	20 (43.4%)	0.823
Hypercholesterolemia	38 (36.5%)	17 (40.0%)	0.928
Diabetes mellitus	28 (26.9%)	12 (26.1%)	0.963
Current smokers	42 (40.4%)	13 (28.2%)	0.412
Previous MI	3 (2.9%)	0 (0%)	0.086
Previous CABG	0 (0%)	0 (0%)	
DAPT 12 months	98 (94.2%)	32 (69.6%)	0.416
LVEF, %	51.3 ± 10.8	51.2 ± 8.2	0.322
Creatinine, μmol/L	1.2 ± 0.3	1.3 ± 0.4	0.146
Target vessels			0.923
LM	0 (0.0%)	0 (0.0%)	
LAD	37 (35.6%)	15 (32.6%)	
LCX	18 (17.3%)	7 (15.2%)	
RCA	49 (47.1%)	14 (30.4%)	
AHA/ACC lesion classification			0.924
A/B1	58 (55.8%)	20 (43.4%)	
B2/C	46 (44.2%)	16 (34.8%)	
Ositum lesion	3 (2.9%)	0 (0.0%)	0.086
Bifurcation	2 (1.9%)	0 (0.0%)	0.118
CTO	5 (4.8%)	1 (2.2%)	0.161
Moderate-to-heavy calcification	8 (7.7%)	2 (4.3%)	0.328

AHA/ACC = American Heart Association/American College of Cardiology; CABG = coronary artery bypass surgery; CTO = chronic total occlusion; DAPT = dual antiplatelet agent; LAD = left anterior descending artery; LCx = left circumflex artery; LM = left main coronary artery; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PSP = predilatation, sizing, and postdilatation; RCA = right coronary artery.

[a]Aggressive PSP technique: high-pressure predilatation and postdilatation.

received NC balloon catheters for postdilatation. All patients in the aggressive PSP technique group received NC balloons for predilatation and postdilatation, whereas only nine patients (19.6%) in the traditional PSP technique group received NC balloons for predilatation with either a lower balloon–artery ratio or a lower inflation pressure.

Table 2

Procedural characteristics of the enrolled patients stratified by the presence or absence of the aggressive PSP technique[a]

Variables	Aggressive PSP technique (N = 104)	Traditional PSP technique (N = 46)	*p*
Debulking technique			0.122
Cutting balloon	9 (8.6%)	2 (4.3%)	
Rotablation	2 (1.9%)	0 (0.0%)	
Imaging device			0.616
IVUS	42 (40.4%)	15 (32.6%)	
OCT	14 (13.5%)	2 (04.3%)	
Scaffold characteristics			
Scaffold diameter, mm	3.0 ± 00.5	3.0 ± 00.5	0.992
Scaffold length, mm	26.2 ± 12.3	27.1 ± 11.2	0.072
Predilatation characteristics			
B/S diameter ratio	1.09 ± 0.11	0.99 ± 0.10	0.021
With NC Balloon	104 (100%)	9 (19.6%)	<0.001
Postdilatation characteristics			
B/S diameter ratio	1.12 ± 0.12	0.98 ± 0.10	<0.01
With NC balloon	104 (100%)	46 (100%)	0.999

B/S = balloon/scaffold; IVUS = intravascular ultrasound; NC = noncompliant; OCT = optical coherence tomography; PSP = predilatation, sizing, and postdilatation.

[a]Aggressive PSP technique: high-pressure predilatation and postdilatation.

3.2. Short- and long-term clinical outcomes

After BRS implantation, no adverse events were observed within 30 days in both groups. During the mean follow-up period of 2.98 ± 0.77 years (median: 2.93 years, interquartile range: 2.40–3.62 years), 12 patients had MACEs (8.0%), including one case of CV death (0.6%), two cases of nonfatal MI (1.3 %), and 11 cases of TVR (7.3%) (Table 3). Fig. 1 shows the cumulative survival curves free of MACEs determined using the Kaplan-Meier method in patients divided according to scaffold implantation strategies, with the outcome being significantly better in those patients using the aggressive PSP technique (p = 0.041) than in those using the traditional PSP technique. One patient suddenly died 1 year after the index procedure. Two patients had non–ST segment elevation MI at the 323rd (traditional PSP technique group) and 372nd (aggressive PSP group) postoperative days, respectively. Furthermore, using the aggressive PSP technique during BRS implantation was significantly associated with less risk of in-scaffold restenosis and TVR than using the traditional PSP technique (p = 0.014) (Table 3). One patient in the traditional PSP technique group had late scaffold thrombosis (2.2%), whereas no scaffold thrombosis occurred in the aggressive PSP technique group (p = 0.131) (Table 3).

After adjusting for age, hypertension, DM, imaging modality, and debulking technique, multivariate Cox regression analysis showed that the aggressive PSP technique remained an independent protective factor against MACEs (p = *0.001*) (Table 4). Moreover, the use of intracoronary imaging and rotablation atherectomy was associated with better clinical outcomes (Table 4).

4. DISCUSSION

4.1. Main findings

In this study, we found that aggressive predilatation along with the traditional PSP technique for BRS implantation might be associated with better clinical outcomes. Our findings address the importance of optimal lesion preparation before BRS implantation.

Table 3

Short- and long-term outcomes of the enrolled patients stratified by the presence or absence of the aggressive PSP technique[a]

	Aggressive PSP technique (N = 104)	Traditional PSP technique (N = 46)	*p*
30-day outcomes			
MACE	0 (0.0%)	0 (0.0%)	NA
Cardiac death	0 (0.0%)	0 (0.0%)	NA
MI	0 (0.0%)	0 (0.0%)	NA
TVR	0 (0.0%)	0 (0.0%)	NA
Def/Pro scaffold thrombosis	0 (0.0%)	0 (0.0%)	NA
Long-term outcomes			
MACE	5 (4.8%)	7 (15,2%)	0.030[a]
Cardiac death	0 (0.0%)	1 (02.2%)	0.131
Nonfatal MI	1 (1.0%)	1 (02.2%)	0.551
TVR	4 (3.8%)	7 (15.2%)	0.014[a]
Def/Pro scaffold thrombosis	0 (0.0%)	1 (02.2%)	0.131

Def/Pro scaffold thrombosis = definite/probable scaffold thrombosis; MACE = major adverse cardiovascular events; MI = myocardial infarction; NA = not available; PSP = predilatation, sizing, and postdilatation; TVR = target-vessel revascularization.

[a]Aggressive PSP technique: high-pressure predilatation and postdilatation.

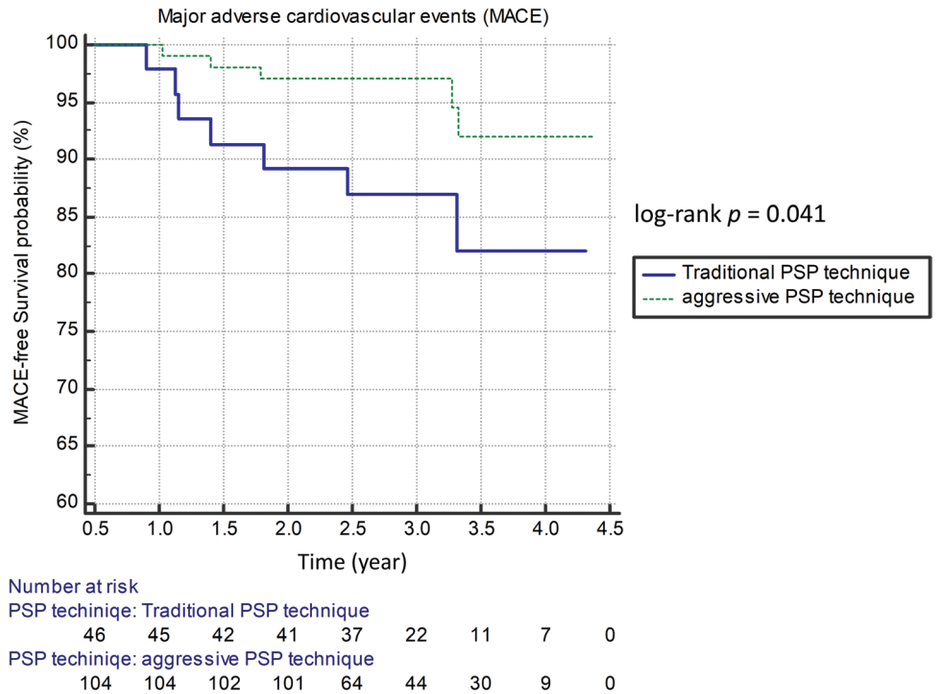

Fig. 1 The Kaplan-Meier survival curve showed that patients in the aggressive PSP* technique group had a significantly lower risk of long-term major adverse cardiovascular events (p = 0.041). *Aggressive PSP technique: high-pressure predilatation and postdilatation. MACE = major adverse cardiovascular events; PSP = predilatation, sizing, and postdilatation.

4.2. BRS and long-term clinical outcomes

BRSs have been designed to overcome the problems related to long-term persistence of metallic stents implanted in coronary arteries.[7,8] However, several RCTs comparing polymeric BRSs with new-generation DESs have found no significant differences in clinical outcomes between BRSs and DESs after 1 year.[23–25] Moreover, recent studies have shown that BRSs were associated with a higher incidence of device-related thrombosis than metallic stents.[26,27] The possible causes of BRS-related thrombosis are related to incomplete lesion coverage, underdeployment, mal-apposition, thick stent struts (eg, the 150-μm struts in the ABSORB scaffold), nonembedded and nonabsorbed scaffold struts in complex lesions, and late structural discontinuity or device dismantling.[28–32]

Table 4

Cox regression analysis on long-term MACE of the enrolled patients stratified by the presence or absence of the aggressive PSP technique[a]

	Univariate		Multivariate (forward stepwise)	
Variables	**HR (95% CI)**	***p***	**HR (95% CI)**	***p***
Aggressive PSP technique	0.158 (0.041-0.612)	0.008	0.083 (0.018-0.376)	0.001
Age	1.003 (0.950-1.059)	0.918	1.012 (0.850-1.062)	0.818
Hypertension	1.782 (0.225-2.719)	0.699	1.886 (0.365-2.889)	0.722
DM	1.106 (0.285-4.288)	0.884	1.112 (0.765-4.638)	0.786
Image modality	0.158 (0.031-0.804)	0.026	0.283 (0.069-0.881)	0.042
Debulking technique	0.232 (0.021-0.845)	0.028	0.266 (0.046-0.866)	0.046

DM = diabetes mellitus; HR = hazard ratio; MACE = major adverse cardiovascular events; PSP = predilatation, sizing, and postdilatation.

[a]Aggressive PSP technique: high-pressure predilatation and postdilatation.

Due to the mechanical characteristics of BRSs, Stone et al,[17] who analyzed major ABSORB studies, have found that BRS scaffold implantation using the traditional PSP technique (the use of predilatation, proper sizing, and postdilatation) may reduce the risk of adverse cardiovascular events. Better scaffold expansion, thus reducing the risk of thrombotic events, has been speculated as the main reason why the traditional PSP technique is associated with better clinical outcomes. Recently, two-year results of the Amsterdam Investigator-Initiated Absorb Strategy All-Comers Trial (AIDA) have shown that BRSs might be associated with a significantly increased risk of scaffold thrombosis and target-vessel MI compared with everolimus-eluting metallic stents. Intriguingly, the sub-study analysis of the AIDA trial focused on the effects of specific implantation strategies (eg, traditional PSP technique) and has found that lesions undergoing scaffold implantation using the optimal PSP implantation technique did not have lower rates of scaffold thrombosis and TVR than scaffold-treated lesions that did not meet the PSP criteria.[33]

4.3. Aggressive lesion predilatation for BRS implantation

Adequate lesion preparation is always required not only for scaffold delivery but also for optimal and symmetrical scaffold expansion, consequently avoiding stent underexpansion.[14,15,34,35] Therefore, optimal and/or aggressive predilatation may have played a more important role in BRS implantation, as aggressive predilatation can overcome greater vessel compliance, enabling full scaffold expansion, consequently avoiding excessive localized surface area coverage and polymer volume occupancy. Puricel et al[36] have reported that the implantation of a scaffold using a "BRS-specific implantation strategy," which emphasizes lesion preparation more than the traditional PSP technique (predilatation pressure ≥ RBP), might significantly reduce the incidence of scaffold thrombosis and improve long-term results up to 3 years.[20] Furthermore, Tanaka et al[12] implanted BRSs using a

dedicated strategy, which was based on the following principles: (1) aggressive lesion preparation, defined as >1:1 in size with the vessel diameter and implanted scaffold, and (2) high-pressure postdilatation, defined as nonoversized NC balloon (scaffold/balloon diameter 1:1) at high pressure (≥20 atm). The results showed that the cumulative target lesion failure rates were 7.9% at 1 year and 11.6% at 2 years. Definite/probable scaffold thrombosis occurred in three patients (1.2% at 1 and 2 years, respectively). This study adopted the similar dedicated strategy but using a slightly higher lesion–balloon ratio (1:1–1:1.5) in the aggressive PSP technique group. Debulking techniques, including balloon cutting and rotablation, were also used as needed in selected highly calcified lesions and were identified as an independent protective factor for better clinical outcomes. Moreover, the use of intracoronary imaging modalities was associated with better clinical outcomes. Taken together, previous reports and our results all addressed the importance of optimal lesion preparation before BRS implantation, which is significantly associated with long-term clinical outcomes.

Several limitations of this study must be addressed. First, this study was a single-center observational study with a limited sample size. Second, the angiographic follow-up rate of the study population was relatively low, incomplete angiographic follow-up-related potential bias might have a substantial impact on the long-term clinical outcomes in both groups. Finally, the operators were experienced in the use of metallic stents and have long experience with image-guided PCI. Therefore, aggressive PSP implantation skill was excellent; however, it was not applicable to other doctors with a lower amount of PCI experience.

In conclusion, aggressive predilatation and lesion preparation in addition to the traditional PSP technique for BRS implantation might improve long-term clinical outcomes.

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