

What is better for predilatation in bioresorbable vascular scaffold implantation: a non-compliant or a compliant balloon?

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ABSTRACT

Objective: The bioresorbable vascular scaffold system (BVS) is a fully absorbable vascular treatment system. In this study, we aimed to compare the periprocedural effectiveness and long term results of non-compliant balloon (NCB) and compliant balloon (CB) systems, which are used for predilatation before BVS implantation.

Methods: One hundred forty-six BVS-treated lesions from 119 patients were retrospectively analyzed in the study. Patients with acute coronary syndrome, stable angina and silent ischemia were included in the study. Lesions and patients were categorized into the NCB and CB groups according to the type of balloon used for predilatation. NCB was implemented on 72 lesions (59 patients) and CB was implemented on 74 lesions (60 patients). The two groups were compared on terms of procedural features and both in-hospital and 1-year clinical follow-up results. Chi-square and independent sample t test were performed for statistical analysis.

Results: There was no significant difference between the two groups in terms of patient characteristics and lesion properties. The number of postdilated lesions was significantly higher in the CB group. Procedure time, fluoroscopy time, and contrast volume were significantly lower in the NCB group. At follow-up, one patient had myocardial infarction in the CB group because of scaffold thrombosis and no mortality was observed.

Conclusion: Predilatation with NCB before BVS implantation reduces the need for postdilatation. In addition, use of NCB reduces the procedure time, fluoroscopy time, and contrast volume but had no effect on 1 year clinical follow-up results compared with CB.

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Keywords: bioresorbable vascular scaffold, predilatation, non-compliant balloon, compliant balloon

Introduction

ABSORB bioresorbable vascular scaffold (BVS) (Abbott Vascular, Santa Clara CA, USA), made by poly-L-lactic acid (PLLA), is a fully absorbable vascular system which is used to treat critical coronary stenosis. BVS provides transient scaffolding for the vessel to prevent acute vessel closure and recoil while eluting an antiproliferative drug to prevent neointimal hyperplasia.

BVS has some advantages over metallic stents. The vessel's vasomotor functions can more rapidly return to normal when no metallic cage remains in the vessel, and the use of BVS can facilitate the future percutaneous or surgical revascularization processes. BVS is feasible in coronary lesions with different and complex anatomy such as chronic total occlusions, bifurcations, small vessels, in-stent restenosis, and saphenous vein grafts (1-3).

ABSORB BVS has proved its efficacy in randomized trials. The first ABSORB trial demonstrated a low major adverse cardiac event rate at 3-year follow-up (4). According to a recently published multi-center ABSORB-II trial, BVS showed similar clinical outcomes to the new generation everolimus eluting metal stent at 1 year (5). Morphologically, both optical coherence tomography (OCT) and virtual histology intravascular ultrasound (VH-IVUS) examinations indicated a stable luminal diameter, a high rate of covered struts, and low restenosis at long term (6).

Balloon angioplasty is used as a main component of percutaneous coronary interventions (PCI) for predilatation of lesions before stent placement. Balloon dilatation is mandatory in tortuous and highly calcific lesions when direct stenting is impossible. Predilatation helps to avoid under deployment of the stent and underestimation of the vessel size (7-9). Although predilata-

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tion can raise the risk of dissection beyond the stenotic segment and lead to more distal embolization during PCI, it provides many advantages in specific lesion subsets.

In randomized trials, mandatory predilatation with a balloon according to the reference vessel diameter (RVD) was advised before BVS implantation, but the type of balloon for predilatation was not specified (10, 11).

In our study, we aimed to compare the non-compliant balloon (NCB) and compliant balloon (CB) for predilatation before BVS implantation in terms of procedural features and both in-hospital and 1-year clinical follow-up results.

Methods

Study population

One hundred forty-six coronary artery lesions of 119 patients who were admitted to Şifa University Cardiology Clinic between January 2013 and November 2013 were retrospectively analyzed in the study. Patients were categorized into NCB (59 patients) and CB (60 patients) groups. Our study was approved by the local ethics committee. All patients were aged 18 years or older and had a diagnosis of acute coronary syndrome, stable angina, and silent ischemia. Stenosis diameter was more than 50% but less than 100%. Patients with acute ST elevated myocardial infarction and a left ventricular ejection fraction below 30%, or patients who had restenotic lesions, chronic total occlusions, lesions located in the left main coronary artery, or lesions involving a major side branch were excluded. Lesions which were not optimally predilated with one type of balloon and needed a balloon switch were also excluded. The lesions were divided into two groups according to the type of balloon which was used for predilatation. NCB (NC TREK, Abbott Vascular, Santa Clara CA, USA) was implemented on 72 lesions, and CB (TREK, Abbott Vascular, Santa Clara CA, USA) was implemented on 74 lesions.

Technical considerations

Lesions were predilated with NCB or CB before BVS implantation. Diameters of the balloons were chosen according to RVD measurements. After predilatation, ABSORB BVS was implanted in each lesion. Postdilatation was performed with NCB at the physician's discretion if it was needed. Lesion characteristics and procedural properties [lesion length, stenosis value, predilatation balloon diameter, predilatation inflation pressure, postdilatation rate, BVS diameter, BVS length, pre and post procedure RVD, pre-procedure minimal lumen diameter (MLD), MLD after BVS implantation, post procedure MLD, procedure time, fluoroscopy time, and contrast volume] were analyzed and compared between the groups. RVD, lesion length, and MLD values were analyzed by quantitative coronary angiography (QCA) measurements. MLD measurements were done before and after BVS implantation, and if it is necessary, post-dilatations were performed and MLD was measured again after the complete procedure. The procedures were performed in our

institute by three experienced interventionalists. Operators performed both NCB and CB predilatation in a similar proportion of patients from each group.

Follow-up

First follow-up visits were made 1 month after each intervention. Following the first control, if there was no anginal recurrence or any other complaint thought to be related to intervention with the patient, 6-month and 1-year follow-up visits were made. During these follow-up visits, cardiovascular stress tests (treadmill test or myocardial perfusion imaging test) were routinely performed to explore if there was an ischemic situation associated with the intervention. Periprocedural myocardial infarction defined by elevation of cardiac troponin (cTn) values in patients with normal baseline values or a rise of cTn values >20% if the baseline values are elevated and are stable or falling. Coronary angiography and revascularization were performed as necessary. Extra visits were made in the case of anginal recurrence or any condition thought to be related to the intervention.

Statistical analysis

Data were described as mean and standard deviation for measurements. We used Kolmogorov-Smirnov as the test of normality. Chi-square test was performed for demographic and clinical characteristics. Independent sample t-test was performed to compare the lesion characteristics and procedural properties of the two groups. The level of statistical significance accepted was 0.05. Data were analyzed with the use of Statistical Package for the Social Sciences 17.0 software (SPSS IBM, Chicago, IL, USA).

Results

Patient characteristics, clinical presentation, lesion characteristics, and therapy at discharge were similar between the two groups. Mean age of the patients was 61.1 ± 9.4 years for the NCB group and 61.5 ± 9.6 for the CB group ($p=0.834$). More than half of the patients were diagnosed as having acute coronary syndrome. The rates of coronary risk factors were equal between the groups. The rates of radial intervention were similar. The severity of the lesions was uniform between the two groups (Table 1).

Among the procedural characteristics, lesion length, stenosis value, predilatation balloon diameter, predilatation inflation pressure, BVS diameter, BVS length, pre and post procedure RVD, and pre and post procedure MLD were similar between the two groups (Table 2).

The rate of postdilatation was significantly higher in the CB group (36.1% vs. 55.4%; $p=0.021$). Although post-procedure MLD values were similar between the groups, MLD values after BVS implantation and before postdilatation were significantly lower in the CB group (2.63 ± 0.32 vs. 2.48 ± 0.35 ; $p=0.010$) (Table 2).

Table 1. Clinical presentation and lesion characteristics

	NCB n=59, n=72 BVS (%)	CB n=60, n=74 BVS (%)	P
Patient characteristics			
Age, years	61.1±9.4	61.5±9.6	0.834
Male gender	53 (89.8)	47 (78.3)	0.132
Diabetes	20 (33.9)	23 (38.3)	0.614
Hypertension	48 (81.4)	48 (80)	1
Hyperlipidemia	28 (47.5)	34 (56.7)	0.361
Smoking	24 (40.7)	16 (26.7)	0.123
Chronic renal failure	3 (5.1)	2 (3.3)	0.679
Prior MI	27 (45.8)	28 (46.7)	1
Prior PCI	20 (33.9)	20 (33.3)	1
Prior CABG	6 (10.2)	11 (18.3)	0.295
Radial intervention	24 (40.7)	21 (35)	0.573
Clinical presentation			
Acute coronary syndrome	34 (57.7)	36 (60)	0.853
Stable angina	21 (35.6)	17 (28.3)	0.436
Silent ischemia	4 (6.8)	7 (11.7)	0.529
Lesion characteristics			
Target vessel			
LAD	39 (54.2)	31 (41.9)	0.185
CX	14 (19.4)	21 (28.4)	0.247
RCA	19 (26.4)	22 (29.7)	0.714
Lesion type			
A	16 (22.2)	22 (29.7)	0.348
B1	26 (36.1)	20 (27)	0.377
B2	28 (38.9)	32 (43.2)	0.617
C	2 (2.8)	-	0.241
Therapy at discharge			
ASA	58 (98.3)	59 (98.3)	1
Clopidogrel	55 (93.2)	56 (93.3)	1
Prasugrel	2 (3.4)	2 (3.3)	1
Ticagrelor	-	3 (5)	0.244
Statin	48 (81.4)	50 (83.3)	0.814
Beta-blocker	50 (84.7)	52 (86.7)	0.799
Chi-square test was performed CABG - coronary artery bypass graft; CB - compliant balloon; CX - circumflex artery; LAD - left anterior descending artery; MI - myocardial infarction; NCB - non compliant balloon; PCI - percutaneous coronary intervention; RCA - right coronary artery			

Procedure time (30±7.2 vs. 34±7.2; p<0.001), fluoroscopy time (8.5±2.3 vs. 9.9±2.5; p=0.001), and contrast volume (95.2±24.8 vs. 109.3±23.3; p=0.001) were significantly lower in the NCB group (Table 2).

During follow-up period at the hospital, no death and myocardial infarction were observed. Two patients from the CB group and one patient from the NCB group had angina during the

Table 2. Procedural characteristics

	NCB n=72 BVS	CB n=74 BVS	P
Lesion length, mm	20.3±4.9	19.4±5.1	0.304
Stenosis value, %	90.5±7.9	91.2±7.1	0.555
Predilatation balloon diameter, mm	2.8±0.4	2.7±0.4	0.274
Predilatation inflation pressure, mm Hg	14.6±1.4	14.5±1.2	0.588
Postdilatation rate	26 (36.1%)	41 (55.4%)	0.021
BVS diameter, mm	2.9±0.35	2.9±0.38	0.332
BVS length, mm	23.1±5	22.1±5.2	0.235
RVD-preimplantation, mm	2.4±0.28	2.4±0.32	0.651
RVD-post-implantation, mm	2.8±0.31	2.7±0.35	0.582
MLD-preimplantation, mm	0.79±0.13	0.8±0.13	0.130
MLD- after BVS implantation, mm	2.63±0.32	2.48±0.35	0.010
MLD-post-procedure, mm	2.7±0.31	2.7±0.34	0.875
Procedure time, min	30±7.2	34±7.2	<0.001
Fluoro time, min	8.5±2.3	9.9±2.5	0.001
Contrast volume, mL	95.2±24.8	109.3±23.3	0.001
Independent sample t-test was performed BVS - bioresorbable vascular scaffold; CB - compliant balloon; MLD - minimal lumen diameter; NCB - non compliant balloon; RVD - reference vessel diameter			

hospital stay, but there was no need for re-intervention. No acute BVS thrombosis was observed (Table 3).

At the end of the first year, no mortality was observed. Number of patients who had angina recurrence were similar between the NCB and CB groups (9 vs. 8; p=0.799). Target vessel revascularization rates were similar between the two groups (3.4% vs. 3.3%; p=1). No scaffold thrombosis was observed in the NCB group. One patient from the CB group had definite scaffold thrombosis after 5 months from the intervention (Table 3).

Discussion

There was no difference in the severity and location of lesions between our study groups. Total procedure time, fluoroscopy time, and contrast volume were found to be significantly lower with NCB. In addition, MLD after stent implantation was significantly lower and postdilatation rate was significantly higher in the CB group.

As the number of BVS interventions in recent years has begun to increase, some important facts about the implantation technique have become a current issue. Predilatation with a 1:1 sized balloon that matches the RVD, proper sizing of the vessel with novel devices like OCT and IVUS, and if necessary, high pressure postdilatation with an NCB are the most recommended technical points (12).

If the BVS is expanded beyond its limits, it has been shown to lose some of its radial strength and may fracture. Also, the

Table 3. Clinical outcomes between groups

	NCB n=59	CB n=60	P
In-hospital outcome			
Death	-	-	-
MI	-	-	-
Angina	1 (1.7%)	2 (3.3%)	1
CABG	-	-	-
TLR	-	-	-
TVR	-	-	-
Definite BVS thrombosis	-	-	-
Probable stent thrombosis	-	-	-
1 year outcome			
Death	-	-	-
MI	-	1 (1.7%)	1
Angina	9 (15.3%)	8 (13.3%)	0.799
CABG	-	-	-
TLR	-	1 (1.7%)	1
TVR	2 (3.4%)	2 (3.3%)	1
Definite BVS thrombosis	-	1 (1.7%)	1
Probable stent thrombosis	-	-	-
Independent sample t test was performed BVS - bioresorbable vascular scaffold; CABG - coronary artery bypass graft; CB - compliant balloon; MI - myocardial infarction; NCB - non-compliant balloon; TLR - target lesion revascularization; TVR - target vessel revascularization			

cross ability of the BVS is less than the newer generation of drug-eluting stents because of its thicker struts. Particularly, in highly calcific and tortuous lesions, predilatation with an appropriate balloon can facilitate the delivery of BVS. Although rigorous predilatation with an appropriate sized balloon is advised, there is no specific recommendation about the type of balloon in the literature.

In our study, longer procedure time, fluoroscopy time, and higher contrast volume with CB is primarily related to the higher postdilatation rate in this group. Lower MLD values, which were measured just after BVS implantation, indicate ineffective BVS expansion in the CB group. Ineffective expansion of the BVS after implantation leads to a need for postdilatation, and postdilatation raises the procedure time, fluoroscopy time, and contrast volume in the CB group. There have been different rates of postdilatation in previous BVS studies. According to the result of the ABSORB FIRST registry, procedural success rate was 97.9% with a postdilatation rate of 48.3%. Postdilatation rate was 49.9% in the GHOST-EU registry (12) and has reached 99.3% in some experienced centers (13). When we compare our results with previous studies, our postdilatation rate was lower (36.1%) in the NCB group and similar in the CB group (55.4%). The main reason for the reduced postdilatation rate with NCB is the more effective predilatation in this group. This facilitated the optimal BVS implantation and reduced the need of postdilatation. Another

important point was performing predilatation with high pressures. Our mean balloon inflation pressure was 14.6 ± 1.4 mm Hg for the NCB group and 14.5 ± 1.2 mm Hg for the CB group. Despite similar inflation pressures, NCB expands the lesion before implantation more effectively than CB.

After predilatation, we tried to choose the optimal BVS size according to RVD using QCA measurements. We believe that appropriate QCA measurement provides more optimal BVS sizing and lowers the need for postdilatation. This is also similar to a finding in a previous trial which showed that QCA assessment increases appropriate vessel size selection for BVS (14). RVD and MLD values before and after the procedure were statistically equal between the two groups, but MLD values just after BVS implantation were significantly lower in the CB group. We believe that NCB cracks the atherosclerotic plaque more strongly and predilates the lesion more effectively than CB. According to our experience, cross ability of BVS after predilatation is also higher if NCB is used.

We want to test the predilatation capability of two different types of balloon on the same type of lesions. Therefore, we included the patients with acute coronary syndrome but excluded the patients with ST segment elevated myocardial infarction. Because the characteristics and severity of the underlying coronary plaque cannot be estimated in ST segment elevated myocardial infarction before predilatation, the results could be misleading.

Besides QCA measurements, IVUS and OCT are strongly recommended for both proper sizing of the BVS and controlling the apposition of the BVS after implantation (15). However, the rate of IVUS and OCT use is not very high in routine clinical practice. Most centers conduct only a visual assessment in order to evaluate the success of implantation. In a recently published real world registry data, (12) including 1189 patients who underwent BVS placement, the rate of IVUS and OCT use was only 14.4% and 13.8%, respectively. Some OCT studies, which recruited patients from randomized trials, reported high rates of scaffold malapposition rates between 37% and 66% (16). Another study shows that despite an optimal angiographic result, 28% of the scaffolds examined require further intervention after OCT review (15). We did not use OCT or IVUS in our patients. This seems to be a limitation, but we believe that effective QCA assessment can guide the implantation and help choose the optimal BVS size. However, OCT is an excellent tool for screening the coronary endothelial surface and delineating scaffold apposition, under expansion, edge dissection, and tissue prolapse. Therefore, performing routine OCT can detect ineffective implantation more sensitively and can raise the need for postdilatation.

Among our patient groups, there were no serious complications observed during the hospital stay. One patient from the NCB group and two patients from the CB group had angina after intervention but none had clinical significance.

At the end of the first year, no mortality was observed in our study group. There was no scaffold thrombosis in the NCB

group. Only one patient from the CB group had scaffold thrombosis and myocardial infarction after 5 months from the intervention. Patient who had scaffold thrombosis discontinued the dual antiplatelet therapy early (4 months after the intervention). Therefore, scaffold thrombosis is thought to be unrelated to the implantation technique. This patient was successfully treated by balloon angioplasty; number of patients who had angina recurrence was also similar between the groups. TVR rates were similar between the two groups (3.4% vs. 3.3%; $p=1$) and parallel with the results of recent data (12). The type of balloon used for predilatation has no effect on long term clinical outcomes.

Although use of NCB for predilatation has no effect on clinical outcomes according to our study, performing predilatation with NCB could decrease the risk of contrast induced nephropathy by lowering the amount of contrast volume and could be advantageous for the operators via shortening the procedure time and radiation dose.

Although randomized trials of BVS show encouraging results, some negative results have been reported at the real world registry data. According to the GHOST-EU registry (12), the cumulative incidence of BVS thrombosis rate was 2.1% at 6 months after implantation. This rate is higher than the second generation drug-eluting stents and at an equivalent level to the first generation drug eluting stents. Because most of the thrombotic events occurred within 30 days of implantation in this registry, technical issues at the time of the implantation are very critical for the avoidance of complications. We had not experienced any acute scaffold thrombosis in our patient groups. Effective predilatation with NCB; optimal vessel sizing with QCA, OCT, or IVUS; and performance of postdilatation in case of malapposition will reduce thrombotic complications and improve clinical outcomes.

Study limitations

Our study has some limitations. Not using IVUS or OCT to decide on postdilatation is a limitation. In particular, OCT is strongly recommended for determining stent malapposition and under-expansion. However, in actual practice, BVS implantations are usually made only by visual assessment and the rate of OCT use is very low in most centers. Because QCA assessment provides a quantitative approach, it is superior to visual assessment, and the use of QCA was an advantage in our study. Although operators were experienced in BVS implantation, there may have been differences between them in interventional approaches independent of the choice of balloon, and this could have affected the procedure time and fluoroscopy time. Retrospective and non-randomized design of our study is a disadvantage to compare the outcomes. Prospective and randomized studies with large number of patient groups will be more valuable to compare the adverse clinical outcomes and target lesion revascularization rates.

Conclusion

Predilatation with NCB before BVS implantation reduces the need for postdilatation compared with predilatation with CB. Use of NCB also reduces the procedure time, fluoroscopy time, and contrast volume but has no effect on clinical follow-up results.

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