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Long-Term Outcomes of Patients Presenting with Acute Coronary Syndrome and Implanted with Bioresorbable Scaffold

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ABSTRACT

A bioresorbable scaffold (BRS) has been used in the latest stages of stent technology and is a less-known material than drug-eluting stents (DES). In this study, we aimed to evaluate the long-term clinical outcomes of BRS in patients presenting with non-ST-segment elevation myocardial infarction (NSTEMI), a type of acute coronary syndrome (ACS).

39 patients and 53 lesions who applied to Istanbul Medipol University Faculty of Medicine Hospital between June 2015 and April 2016 with a diagnosis of NSTEMI and were treated with BRS were included in the study. The 4-year follow-up of the patients between 2016 and 2020 was recorded. Endpoints for the study were device success, treatment success, stent thrombosis, restenosis, and major adverse cardiac events (MACE).

Operations were performed with a device success rate of 98.1% and a treatment success rate of 98.1%. No death or stent thrombosis was detected in any patient, and target lesion revascularization (TLR) occurred in one patient. The total rate of MACE was found to be 1.9%. Complications developed in two patients during the procedure and hospitalization and in four patients during the 4-year follow-up.

If BRS are implanted by experienced surgeons in NSTEMI patients, it has been observed that the complication rate in the early period is low, and the complication rate increases depending on the type of stent chosen in the late period. To obtain better results, a BRS with good radial strength, thinner strut thickness, and rapid deployment should be achieved.

Keywords: Bioresorbable scaffolds, acute coronary syndrome, non-ST-elevation myocardial infarction

Introduction

Implanting stents to coronary artery lesions constitutes the main treatment for acute coronary syndrome (ACS), which is considered one of the most important causes of mortality and morbidity(1). Although the use of drug-eluting stents (DES) is considered the gold standard, there is a risk of persistent stent thrombosis or restenosis for years after percutaneous coronary intervention (PCI) due to a permanent vessel cage(2). Therefore, bioresorbable scaffold (BRS) technology has emerged due to the clinical disadvantages of DES, such as permanent side branch occlusion, restrictions on non-invasive imaging of the coronary arteries, and preventing the bypass graft from attaching to the stented area (1). Some studies have shown that BRS can be used safely in ACS patients, while others have shown that BRS increases scaffold thrombosis compared to DES (3,4). Nevertheless, BRS is an important success in interventional cardiology with its ability to restore endothelial function by providing complete absorption and its success in treating coronary lesions (5).

The use of BRS is generally preferred for patients presenting with ACS for a long life expectancy and, therefore, probably provides more benefits than other vascular treatments (2).

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In this study, we analyzed 1-and 4-year clinical outcomes of patients who had BRS implantation for ACS in our clinic.

Materials and Methods

Study Population: This study is a retrospective 4-year follow-up and monocentric enrollment of 39 patients hospitalized with non-ST-segment elevation myocardial infarction (NSTEMI) and treated with deployable stent implantation in PCI in the Cardiology Department of Istanbul Medipol University Faculty of Medicine between June 2015 and April 2016. For this study, ethical approval was obtained from the ethics committee of Medipol University Faculty of Medicine, and the informed consent of all patients was obtained with an informed consent form. Lesions suitable for PCI with a reference vessel diameter ≥ 2.50 mm and stenosis in the lesion area over 50% were preferred. The exclusion criteria for this study were left main coronary artery lesions, true bifurcation lesions (Medina 1,0,1, Medina 1,1,1, Medina 0,1,1), and conditions with stent requirements smaller than 2.5 mm and greater than 4.0 mm. There were no restrictions on the number of lesions and vessels treated, lesion length, or the number of implanted stents. Permission was obtained from patients to implant one or more dissolving stents and simultaneously insert drug-coated metal stents, depending on the surgeon's preference. After the operation, follow-up records of the patients during their emergency or routine outpatient clinic admissions were examined, and clinical follow-up was done by taking records over the phone. Control angiography was performed on patients requiring coronary angiography indications both in emergency admission and outpatient follow-up, and when required, percutaneous interventions were also recorded in the clinical follow-up of the patients.

Stents Used in the Study

ABSORB dissolving stent: It is made of polylactic acid polymer, 150 mm strut thickness, and has two radiopaque markers. It is accepted that it provides vascular support for six months and dissolves within three years. Different stents are available in 2.5 mm, 3.0 mm, and 3.5 mm wide and 18 mm, 23 mm, and 28 mm in length. Dissolving stents are coated with a polylactic acid polymer and everolimus. The total conveying system length is 145 mm and is compatible with a 0.014 mm guidewire and 6 F guide catheter.

DESolve dissolving stent: It is made of polylactic acid polymer, 150 mm strut thickness, and has two platinum markers. Different stents are available in 2.5 mm, 3.0 mm, 3.25 mm, 3.5 mm, and 4 mm width and 14 mm, 18 mm, and 28 mm in length. The dissolving stents are coated with a polylactic acid polymer and novolimus and contain 5 mcg of novolimus per mm on average. Most of the drugs are released for four weeks. The dissolving stents are designed to be absorbed within one year. The total delivery system length is 139 mm and compatible with a 0.014 mm guidewire and 6 F guide catheter (6).

Procedure: All interventions were performed according to current PCI standards, with mandatory pre-dilatation and stent implanting at a pressure not exceeding bursting pressure. Post-dilatation was applied to all patients. The specific treatment strategy, such as additional stent placement, was decided by the surgeon. The diameter of the pre-dilatation balloon was selected to be the same size as the reference vessel diameter, with the diameter of the post-dilation balloon equal to the implanted stent diameter or 0.5 mm greater than the stent diameter. Patients who did not receive chronic aspirin treatment were given 100 mg of oral aspirin daily, following a 300 mg loading dose before PCI. Patients who did not receive chronic therapy were given a loading dose of clopidogrel (600 mg) or prasugrel (60 mg) or ticagrelor (180 mg) before PCI, followed by a maintenance dose of clopidogrel (75 mg) or prasugrel (10 mg) or ticagrelor (90 mg bid) for 12 months. Any of the patients received glycoprotein IIb/IIIa inhibitors.

Study Endpoints and Definitions: The main purpose of this study was to analyze the success of the procedure after stent implanting, major adverse cardiovascular events (MACE) (cardiac death, peri/post-procedural myocardial infarction, stroke) during hospitalization or four years, and stent thrombosis rates.

Patients were invited for visits at 1, 6, and 12, 24, and 48 months. The patients who could not attend the visits were called via phone to find out whether they had any complications. During follow-up, all patients were evaluated using non-invasive and, if necessary, invasive tests. Death, myocardial infarction (MI), TLR, and stent thrombosis were monitored during the follow-up.

Statistical Analysis: This study data were analyzed using IBM SPSS (Version 23.0, SPSS Inc., Chicago, IL, USA). The distribution of continuous data was analyzed with the help of the Kolmogorov Smirnov test. Normally distributed

continuous variables were expressed as mean ± standard deviation, and non-normally distribution was stated as median (25th–75th percentiles). Categorical variables were expressed as numbers and percentages (%). The Chi-square test was used for categorical variables. Statistical significance was accepted as p-value < 0.05 in all analyzes.

Results

Thirty-nine patients were hospitalized with a diagnosis of NSTEMI, and a total of 53 lesion interventions were included in this study. The average age of the patients included in the study was 57.51 ± 13.28 of which 12.8% were women. Regarding classical risk factors, among the patients, 69.2% had hypertension, 41% had diabetes mellitus, 71.7% had hyperlipidemia, and 53.8% were active smokers or had a smoking history. Those with a family history of cardiac disease constituted 41%, 35.9% previously had MI, and the rate of patients with heart failure was 10.2%. Left ventricular ejection fraction (LVEF) mean (%) was 55.69 ± 9.06, mean creatine was 0.96 ± 0.21 (mg/dL), mean hemoglobin was 13.31 ± 2.59 (g/dL), the platelet ratio was calculated as 236.33 ± 53.30, and GFR was 94.51 ± 23.25 (ml/min/1.73 m2). Additionally, 79.4% of the patients were treated as new p2y12 inh., and these preparations were prescribed, and the patients were discharged. The basic demographic characteristics of the 39 patients included in the study are given in detail in Table 1.

The studied lesions of the vessels constitute 50.9% of LAD, 17% of CX, and 32.1% of RCA. The group with lesions in one vessel constituted 37.7%, the group with lesions in two vessels was 49.1%, and the group with lesions in three vessels included 13.2%. 33.9% of these lesions were Type A, 49.1% were Type B, and 17% were Type C lesions. Femoral access was applied to 15% of the lesions. 28.3% of the lesions were calcified, and 20.7% of the lesions had proximal segment tortuous. The operations were performed using 56.6% ABSORB and 43.4% DESolve stents. Stenosis percentages of the lesions were 83.16 ± 9.8, and the length of the lesions was calculated as 24.26 ± 10.57. The average size of the balloons used in pre-dilatation was 2.75 ± 0.43, and the mean of the post-dilatation balloons was 3.23 ± 0.42, while the stents were 3.1 ± 0.43 in size and 24.98 ± 4.42 in length. The preminimal lumen diameter was measured as 1.02 ± 0.5. After the balloon, the minimal lumen diameter was 1.87 ± 0.58, and after the stent, the diameter was 2.8 ± 0.47, as the reference diameter was 3.2 ± 0.42. The DS ratio of the lesions was 0.12 ± 0.07, and the acute gains were 1.77 ± 0.59. The characteristics of the 53 lesions included in the study are shown in Table 2.

Since 8 (15.1%) of the lesions were long segment lesions, overlap implantation of BRS was applied; also, in 1 (1.9%) lesion, BRS was implanted in the in-stent restenosis. Pre-dilatation and post-dilatation were performed using a non-compliant balloon in all patients. No debulking devices, such as scoreflex, cutting balloon, or rotablator, were required in any lesion.

While 2 (3.8%) lesions could be passed using a Guideliner (7 F Guideliner V3 Catheter, Vascular Solutions, Inc Galway/Ireland) support catheter, device success was detected as 98.1%. While all BRSs could be successfully advanced to the lesion area, more than 30% residual stenosis was detected in only one lesion. The success of the procedure was 98.1%.

Two patients lost to follow-up. Patient follow-up was carried out by either direct clinical examination or via phone call at 1st, 6th, 12th, 24th, 36th and 48th months, using a standard procedure for an average of 48 months. At the end of one year, a total of MACE 4 (10.8%), 2 (11.8%) patients in the ABSORB group, and 2 (10%) patients in the DESolve group were detected. However, during the 4-year period, the total MACE was determined as 8 (21.6%). There were 4 (23.5%) patients in the ABSORB group and 4 (20%) patients in the DESolve group, and there was no statistically significant difference (Table 3) (Figure 1).

Discussion

This retrospective study in which clinical outcomes of patients who are admitted with a diagnosis of NSTEMI and applied BRS that evaluated in respect to use of those stents was concluded as if the placement rules were followed, the clinical outcomes of BRSs for one year are similar to the previous results obtained with drug-eluting stents. In their four-year follow-up similar to the studies performed with elective revascularization patients, we found that the rate of restenosis increased depending on the type of stent. This study's data obtained from DESolve BRS on ACS usage showed that these stents are more reliable than ABSORB BRS.

In percutaneous coronary ıntervention (PCI) performed in patients with ACS, preferring stents with smaller diameters to normal sizes due to vasospasm and leading malposition due to

Table 1. Clinical and Demographic Characteristics of the Patients Included in the Study

Age Mean+SD	57.51 ± 13.28
Woman gender, n (%)	5 (12.8)
Hypertension n (%)	27 (69.2)
Diabetes n (%)	16 (41.0)
Hyperlipidemia, n (%)	28 (71.7)
Smoking, n (%)	21 (53.8)
Family history, n (%)	16 (41.0)
MI history, n (%)	14 (35.9)
Heart failure, n (%)	4 (10.2)
New p2y12 inh., n (%)	31 (79.4)
LVEF (%)	55.69 ± 9.06
Hemoglobin (g/dl)	13.31 ± 2.59
Platelet Mean+SD	236.33 ± 53.30
Creatine Mean+SD	0.96 ± 0.21
GFR (ml/min/1.73 m2)	94.51 ± 23.25

Table 2. Characteristics of Vessels and Lesions Included In The Study

Target vessel, n (%):	
LAD	27 (50.9)
CX	9 (17.0)
RCA	17 (32.1)
Count of vessel, n %	20 (37.7) / 26 (49.1) / 7 (13.2)
Type of lesion A/B/C, n %	18(33.9) / 26(49.1) / 9(17.0)
Punction site, n %	8 (15.0)
Calcification of lesion, n %	15 (28.3)
Tortuosity of proximal segment , n %	11 (20.7)
Type of stent, n %	30 (56.6)
Percentage of stenosis, %	83.16 ± 9.80
Lesion length, mm	24.26 ± 10.57
PTCA, predilatation size, mm	2.75 ± 0.43
Diameter of stent, mm	3.10 ± 0.43
Stent length, mm	24.98 ± 4.42
PTCA, postdilatation size, mm	3.23 ± 0.42
Preminimal lumen diameter	1.02 ± 0.50
Minimal lumen diameter, after PTCA	1.87 ± 0.58
Minimal lumen diameter, after stent	2.80 ± 0.47
Referance diameter	3.20 ± 0.42
Percentage DS	0.12 ± 0.07
Acute Gain	1.77 ± 0.49

thrombus formation under stent struts, these patients have a higher risk of early and late stent thrombosis than stable coronary patients (7,8).

Although the use of second-generation DES in patients with ACS is considered the gold standard nowadays, handicaps, such as the presence of a permanent metal cage in the long term, disruption of the flow due to the trapping of the side branch, and the loss of vasomotor tone of the vessel, have revealed the need for the development of BRSs (9,10).

Previous studies on the use of BRS in ACS are related to ABSORB BRSs, which were the first in daily use.

The EVERBIO-2 study is a randomized clinical study comparing the use of Everolimus-eluting DES and Biolimus-eluting DES with ABSORB BRS in ACS patients. The study's results reveal

Table 3. Clinical Outcomes

	0 (n=17)	1(n=20)	P
1 year			
All-cause death	0	0	NA
Cardiac death	0	0	NA
TV-MI	1(5.9)	1(5)	1
Definite scaffold thrombosis	0	0	NA
TVR	1(5.9)	3(15)	0.61
TLR	1(5.9)	2(10)	1
MACE	2(11.8)	2(10)	1
4 years follow-up			
All-cause death	0	0	NA
Cardiac death	0	0	NA
TV-MI, (%)	2(11.8)	2(10)	1
Definite scaffold thrombosis	1(5.9)	0	0.46
TVR	4(23.5)	5(25)	1
TLR	4(23.5)	3(15)	0.68
MACE	4(23.5)	4(20)	1

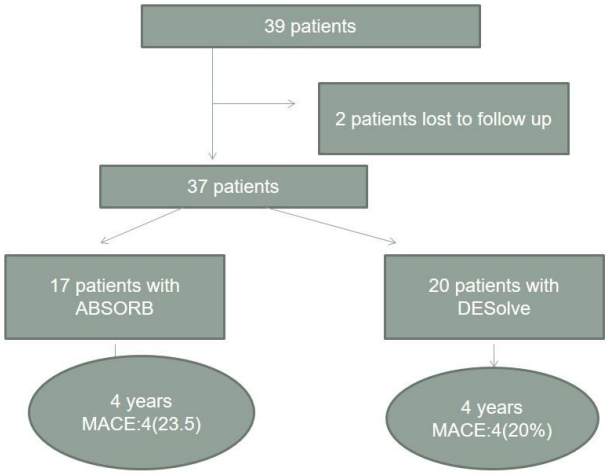

Fig 1. Patient population

that no difference was found in all three groups regarding late lumen loss at the 9th month, which was the primary endpoint of the study, and stent thrombosis was not observed in those with DES, while possible late stent thrombosis was found in one patient in the BRS group (11).

Another randomized study of the TROFI II trial, ABSORB, and Everolimus-eluting DES was compared in patients with ST-segment elevation myocardial infarction (STEMI). The primary endpoint was adjusted as the optical coherence tomography (OCT) evaluation of filling defects due to the presence of uncovered or malpositioned strut at the 6th month. Device-related cardiac events were also accepted as the secondary endpoint. In the TROFI II trial, better results were obtained quantitatively but not statistically in the primary outcome of the BRS group. While cardiac events were not observed in the DES group, subacute stent thrombosis was found in one patient (1.1%) in the BRS group (12).

In the POLAR-ACS study, which is one of the multi-center registry studies, MACE was found to be 2% in a 1-year follow-up (13). In the GHOST-EU study in which 47.4% of the patients were in the ACS group, the target lesion failure (TLF) was detected to be 4.4% in the 6th month, while TLF was found to be 8.5% in the AMC-PCI study. In the GHOST-EU study, the absolute or probable stent thrombosis rate was 2.1%, while it was 3% in the AMC-PCI and 0% in the ASSURE study (14,15,16). Similar to previous studies, major cardiac events (MACE) were detected as 1.8% in this study, and high procedural success was achieved.

Although the preliminary clinical trial results of the use of BRS in ACS patients are promising, some technical difficulties should be considered. Since BRS placement requires a different procedure from normal stent placement, pre-dilating first the lesion with a balloon in a one-to-one ratio, gradually inflating the scaffold, and then post-dilating with an appropriate diameter non-compliant balloon prolong the procedure time and increase the amount of contrast material. This may worsen the clinical picture of patients with unstable hemodynamics (17,18).

The most important problem in the early period after BRS application is stent thrombosis. The conditions that cause this clinical picture can be listed as the excessive strut thickness of the current stents (150 μm), proper lesion preparation due to vasoconstriction or thrombus, and the development of malposition due to the inadequate selection of the stent size. Although it has not been shown that its routine use is beneficial, there is information supporting the idea that manual thrombus aspiration devices can be safely used in ACS patients with thrombus lesions where BRS is used. Moreover, administering intracoronary nitrate to all patients and measuring the true vessel diameter may be a useful way (19,20). Intracoronary imaging techniques, such as intravascular ultrasound (IVUS) and OCT, can also help obtain the optimal stent size before the procedure. In addition, their uses may be beneficial since they provide information about post-procedure malposition, thrombus, and edge dissections (21).

Another important aspect of reducing MACE rates after BRS implantation is the selected antiplatelet agents and the duration of dual antiplatelet therapy (DAPT). While there is no DAPT usage period specified for BRSs in the current guidelines, it is recommended for use for one year in ACS (7). It is also recommended to choose acetylsalicylic acid (ASA), prasugrel, and ticagrelor, which are potent p2y12 inhibitors, based on the experience gained from the studies and expert opinion. In addition, since late stent thrombosis is more common in bioresorbable stents, it may be preferable to use DAPT for longer than one year, especially in patients with no high risk of bleeding (22).

If six months have passed since the interventions after thrombosis or restenosis of the bioresorbable stents, DES application is recommended since a significant part of the biodegradable stent will have degraded. In the early period of BRS thrombosis and restenosis, if malposition or inadequate expansion is the underlying cause, it is recommended to post-dilate with an appropriate non-compliant balloon (23). If the BRS is broken, DES is recommended; however, if there is an edge dissection, then BRS or DES is recommended. Patients with stable angina pectoris (SAP) were treated by performing a control angiography (CAG), and in-stent BRS restenosis was detected by applying DES after a long time following the first procedure.

Contrary to what was expected in the 3-year results of the ABSORB2 study by Serruys et al., ABSORB BRSs could not provide vasomotor reactivity superiority and non-inferiority in late lumen loss compared to DES, and MACE was observed more frequently in the ABSORB group (3). This situation increases the need for the development of a new generation of dissolving stents. Developing a dissolving stent that will disappear in a shorter time after adequate vascular support with a thinner structure can meet the expectations of the BRS ideal. In a study comparing second-generation DESs with thinner struts and first-generation DESs, it was determined that significantly better results were obtained in second-generation everolimus-eluting DESs, and second-generation DESs can be safely preferred when the overlap is applied, especially in long segment lesions.

When we examine the results of this study, several factors that make the results satisfactory are that the study is single-centered and that the operations are conducted by a single operator with experience in BRS. Applying appropriate pre-dilatation and post-dilatation in all patients is one of the factors that increase success. Intracoronary nitrate administration to all patients with appropriate clinical conditions before stent implantation is also an important factor in the promising results of this study.

It has been observed that if BRSs are performed by experienced operators in NSTEMI patients, the rate of complications in the early period is low, and the rate of complications increases depending on the type of stent chosen in the late period follow-up. To obtain better results, BRSs with good radial strength, thinner strut thickness, and that can dissolve in a shorter time should be developed.

Limitation: Patient's files were screened retrospectively, and angiography and QCA measurements were obtained from previously recorded data. If this study had been designed prospectively, follow-up could have been done more appropriately, and clinical outcomes between the two groups could have been compared by choosing patients with DES as the control group. Since this study was single-centered and included patients with ACS and implanted BRS."who applied with only ACS and implanted BRS, a few number of patients attended the study, which resulted in a small number of sample size. Although pre-dilation and post-dilation were applied to all patients in this study, the fact that intracoronary imaging techniques (intravascular ultrasound or fractional flow reserve) were not used to exclude malposition and edge dissection

after proper BRS selection and BRS placement is another limitation of this study.

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