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CTA Assessment of Coronary Atherosclerotic Plaque Evolution after BVS Implantation – a Follow-up Study

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ABSTRACT

Background: Computed tomography angiography (CTA) occupies an important place in the evaluation of coronary atherosclerotic lesions, both before and after the implantation of bioresorbable stents (BVS), providing an accurate assessment of the treated lesions. **Aim of the study:** This study aims the prospective follow-up of atherosclerotic plaques electively treated with BVS implantation via CTA evaluation in terms of morphological and virtual histology aspects. **Material and methods:** This is a prospective observational study which enrolled 30 patients electively treated with BVS implantation, in whom CTA was performed after PTCA in order to assess the morphological and virtual histology aspects of coronary plaques. In order to evaluate the impact determined by pre- and post-implantation procedures, statistical analysis was performed among 6 subgroups. **Results:** After BVS implantation, a significant reduction was observed in terms of stenosis % (61.63 ± 12.63% in subgroup 1A vs. 24.41 ± 12.48% in subgroup 1B, p <0.0001) and eccentricity index (0.46 ± 0.24 in subgroup 1A vs. 0.43 ± 0.24 in subgroup 1B, p <0.0001). In terms of plaque components, there were significant differences with regard to lipid volume and lipid % (20.07 ± 15.67 mm^3 in subgroup 1A vs. 11.05 ± 10.83 mm^3 in subgroup 1B, p = 0.01), which presented a significant reduction after BVS implantation. The calcium score evaluated locally (82.97 ± 107.5 in subgroup 1A vs. 96.54 ± 85.73 in subgroup 1B, p = 0.25) and on the target coronary artery (148.2 ± 222.3 in subgroup 1A vs. 206.6 ± 224.0 in subgroup 1B, p = 0.10), as well as the total calcium score (377.6 ± 459.5 in subgroup 1A vs. 529.5 ± 512.9 in subgroup 1B, p = 0.32), presented no significant differences when compared with and without post-dilatation lesions. As far as CT vulnerability markers are concerned, the study groups presented significant differences only in terms of spotty calcifications (66.66% in subgroup 1A vs. 79.16% in subgroup 1B, p = 0.05) and low attenuation (37.5% in subgroup 1A vs. 20.83% in subgroup 1B, p = 0.01). **Conclusions:** Following the analysis of coronary artery plaques after the implantation of BVS, significant changes were noted both in the morphology of the atherosclerotic plaques treated with these devices and in the lumen and coronary wall.

Keywords: bioresorbable stent, CTA, elective treatment, coronary artery plaque

INTRODUCTION

Coronary computed tomography angiography (CTA) occupies an important place in the evaluation of coronary atherosclerotic lesions, both before and after the implantation of coronary bioresorbable vascular scaffolds (BVS).[1] This noninvasive examination, still more used as a complementary examination in patients with coronary artery disease next to invasive coronary angiography, offers major benefits in tracking bioresorbable stents.

Having the advantage of radiolucency and resorption over time, a BVS can be accurately evaluated with CTA after implantation, thus opening up a new era in the follow-up methods of these devices.[2,3]

Due to the possibility of evaluating BVS through coronary CTA, it is feasible to analyze the plaques and their structure through a post-processing software, dedicated to the analysis of atherosclerotic plaque composition, enabling the concurrent analysis of vulnerability characteristics as well as of the information related to the lumen and walls of the coronary arteries.[4] Details of plaque composition before stenting and its morphological characteristics under the implanted BVS can be obtained after the post-processing of CTA-acquired images.[5–8] A detailed analysis is obtained with the help of virtual histology, using a color code for the different components of the plaque: white for calcium, red for the necrotic core, light green for the fibrolipidic core, dark green for fibrous tissue. The final results are available in absolute values or as a proportion in the plaque.[9,10]

The implantation of bioresorbable stents requires a careful lesion assessment to determine the need for and extent of lesion preparation, and to select the size and length of the device. The use of conventional imaging as well as pre- and post-procedural intracoronary imaging techniques is encouraged to optimize the implantation and the subsequent monitoring of the device.[11]

Given their structure and mechanical properties, compared to the pharmacologically-treated metallic stents, bioresorbable scaffolds require a meticulous evaluation of the lesion and also the frequent use of pre- and post-dilatation. As a result, the duration of the procedure and the use of contrast substance increases.

It is recommended to dilate the lesion with a non-compliant balloon before BVS implantation, by targeting balloons with a diameter corresponding to the estimated diameter of the reference vessel. Orthogonal angiographic projections are required for viewing the entire expansion of the balloon, otherwise it is necessary to use other preparation techniques before implanting the BVS.[12] As a technical notion, pre-dilatation should be performed with a balloon of a size that is appropriate for the vascular diameter (ratio of 1:1). BVS should not be implanted in lesions that present suboptimal results after pre-treatment. If pre-dilatation results are not satisfactory, implantation of the bioresorbable stent will cause incomplete expansion associated with an increased risk for restenosis or in-stent thrombosis.[13]

Post-dilatation with a non-compliant high-pressure balloon should be performed routinely with a balloon diameter that exceeds the diameter of the device with a maximum of 0.5 mm. The expansive limit of the bioresorbable scaffold is 0.5 mm above the nominal diameter. A 3.2 mm bioresorbable stent should not be dilated above 3.5 mm, which is the size when the stent struts are prone to fracture. If the stent struts rupture, they will lead to subsequent complications that pose a potential cause of concern.[12]

Magnesium alloy bioresorbable stents present high radial force, which could expose it to fractures during expansion.[14] Although the radial force of bioresorbable stents has been reported to be comparable to that of metallic stents, this holds true if the bioresorbable stent is expanded within the limits of its size. If the bioresorbable stent is expanded beyond its size, it can lose its radial force and possibly fracture.[15]

The topic of implantation methodology and subsequent follow-up of bioresorbable scaffolds is still largely discussed in the field of interventional cardiology. Therefore, this study aims the prospectively follow-up patients with significant coronary atherosclerotic plaques who have been treated electively with BVS implantation, via coronary CTA evaluation.

MATERIALS AND METHODS

We performed a prospective observational study, which included 30 patients with stable and unstable angina, who underwent elective BVS implantation for significant coronary atherosclerotic lesions in the CardioMed Medical Center between January 2015 and March 2017. Data regarding the patients' medical history and clinical examination were collected, and the patients presented at 1, 6, or 12 months for follow-up visits.

Other inclusion criteria were age over 18 years, BMI <40 kg/m^2, signed written informed consent given by the patient. Exclusion criteria included STEMI or non-STEMI diagnosis, electric and hemodynamic instability at admission, known allergy for contrast agent, indication for long-term anticoagulant treatment, chronic kidney disease stage 4 or 5, end-stage disease with life expectancy below 1 year.

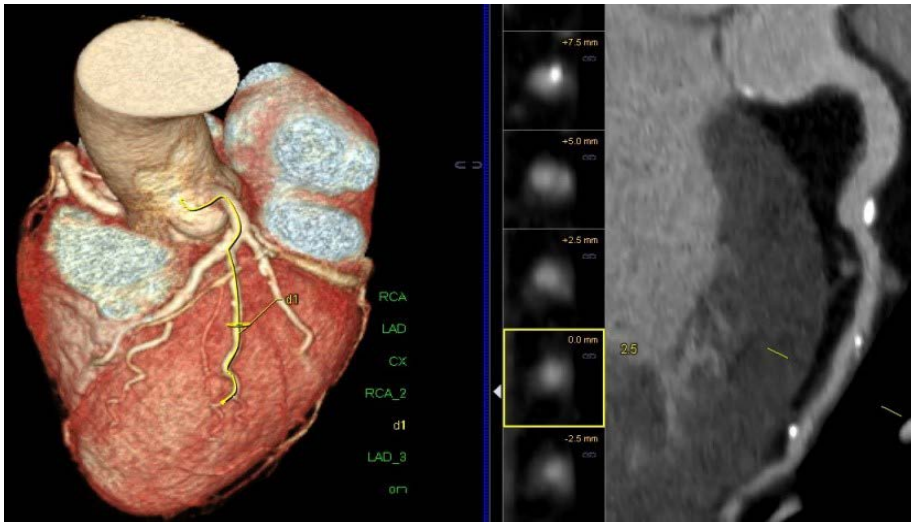

FIGURE 1. CTA of diagonal coronary artery 12 months after PTCA with BVS – no significant stenosis between BVS markers

All patients underwent CTA evaluation 12 to 24 months after PTCA in order to assess the morphological and virtual histology aspects of the coronary plaques. CTA was performed before and after BVS implantation for 16 patients and only after BVS implantation for 14 of the study subjects. In total, 48 coronary plaques were analyzed.

In order to evaluate the impact determined by the pre- and post-implantation procedures on the structure and morphology of the coronary artery, statistical analysis was performed in 2 subgroups, as follows:

- subgroup 1 – pre-implantation lesions (n = 48)
- subgroup 2 – post-implantation lesions (n = 48)

FIGURE 2. CTA of diagonal artery 12 months after PTCA with BVS, post-processed image with Syngo.via Frontier (Siemens AG, Erlangen, Germany) – no significant stenosis between BVS markers.

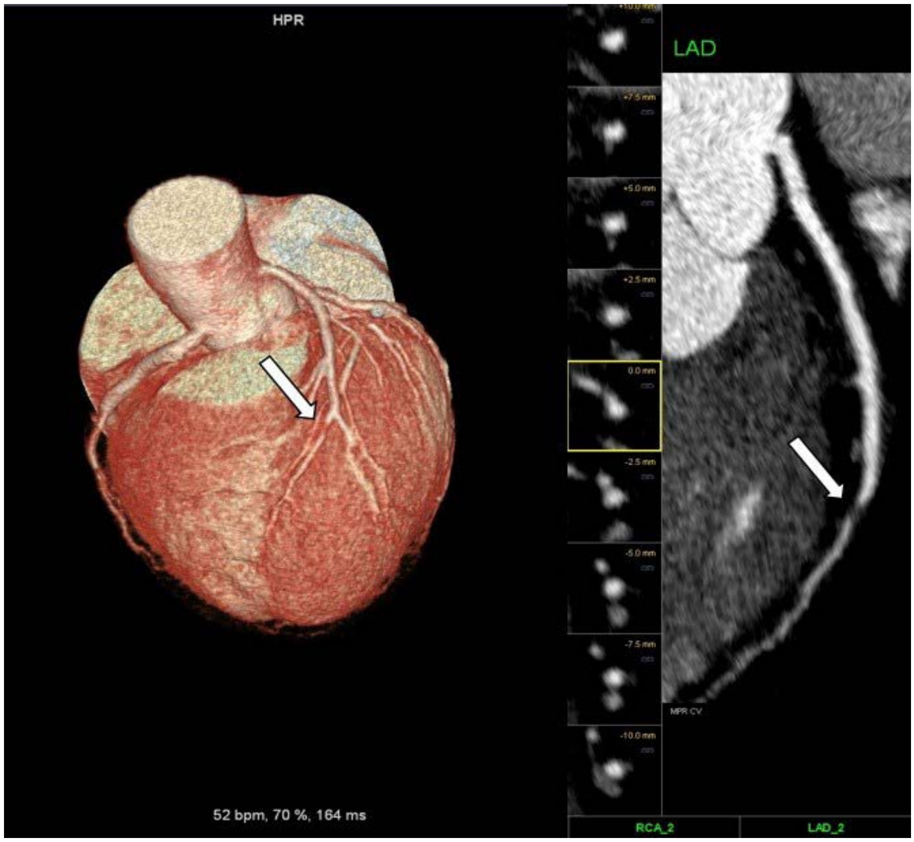

FIGURE 3. 128-slice CTA. Left anterior descending artery with critical stenosis in the third segment, before implantation of BVS

FIGURE 4. Coronary plaque analysis platform – Syngo.via Frontier software

CT scanning protocol

CTA evaluations were performed in the Laboratory of Advanced Research in Cardiac Multimodal Imaging of the Cardio Med Medical Center of Tîrgu Mureş, with a 64- and 128-slice dual-source CT (SOMATOM Definition, Siemens Healthcare), with the following technical characteristics: 64 × 0.5 mm and 128 × 0.6 mm detector rows, 330 ms rotation time, and a table feed of 0.2–0.4 mm per rotation.

Optimization of the CT scanning protocol consisted in a fasting period of 5–24 h prior to CT examination, avoidance of smoking, caffeine use or physical exercises before CT scanning. During CT image acquisition, a heart rate <60 bpm was obtained with the oral titrated administration of Metoprolol or Ivabradine 1 h prior to the CT scan.

Reconstruction of CT images and data analysis

CT image post-processing was performed with a dedicated research software, Syngo.via Frontier, using a Siemens workstation (Siemens AG, Erlangen, Germany). Figure 1 presents a coronary angiographic 128-slice CT scan, Figure 2 presents a detailed analysis of a coronary plaque and the BVS, and Figure 3 presents a critical stenosis of the left anterior descending artery before implantation of the BVS.

Plaque structure

A coronary plaque analysis platform was used to assess morphology and plaque composition (Figure 4). Plaque structure was evaluated according to the CT density of its main components: lipids (–100–30 HU), fibrotic tissue (30–400 HU) and calcifications (400–950 HU).

Statistical analysis

Statistical analysis was performed using GraphPad Prism 7 (GraphPad Software, San Diego, USA). Continuous variables were compared using Student's t-test for paired data or the Wilcoxon test when appropriate, and categorical data were compared using the Chi-square test. The statistical significance of the study was set at an alpha of 0.05.

Ethical approval

This study was carried out in accordance with the World Medical Association's Declaration of Helsinki. All patients gave written informed consent, and the study protocol was approved by the Ethics Committee of the University of Medicine and Pharmacy of Tîrgu Mureș (approval no. 338/17.11.2017) and the Ethics Committee of CardioMed Medical Center (approval no. 29/28.12.2017).

RESULTS

General characteristics of the study population

The mean age of study population was 58.35 ± 7.79 years, and 20% of the study subjects were over 65 years. With regard to gender distribution, 86.66% of the subjects were males (n = 26).

General characteristics of the study population and their cardiovascular risk factors are presented in Table 1. In terms of left ventricular dysfunction incidence, 70% of the subjects presented a left ventricular ejection fraction <55%, 63.33% were enrolled with a diagnosis of stable angina, and 36.67% were diagnosed with unstable angina.

After coronary CT evaluation, 43.33% of the subjects presented coronary artery disease (CAD) with lesions in a single vessel, 30% were diagnosed with 2-vessel disease, and 26.66% presented severe 3-vessel disease. From the treated lesions, pre-dilatation was performed in 80% of cases, while post-dilatation was carried out in 26.66% of cases.

Post-implantation CT analysis of coronary plaques

Morphological and virtual histology aspects of the analyzed coronary plaques after BVS implantation are presented in Table 2.

After BVS implantation, a significant reduction was observed in the degree of stenosis (61.63 ± 12.63% in subgroup 1 vs. 24.41 ± 12.48% in subgroup 2, p <0.0001) (Figure 5A) and the eccentricity index (0.46 ± 0.24 in subgroup 1 vs. 0.43 ± 0.24 in subgroup 2, p <0.0001) (Figure 5B).

TABLE 1. General characteristics and cardiovascular risk factors

	Mean value ± SD	%
Age, years	58.35 ± 7.79	
Age >65 years	6	20
Male gender	26	86.66
Female gender	4	13.43
EF <55%	21	70
Hypertension	25	80.64
Creatinine clearance	73.55 ± 18.12	
Diabetes Mellitus	6	20
Dyslipidemia	10	33.33
History of AMI	10	33.33

TABLE 2. Morphological and virtual histology aspects of analyzed coronary plaques

	Pre-BVS Mean value ± SD (95% CI)	Post-BVS Mean value ± SD (95% CI)	p value
Plaque length (mm)	18.69 ± 2.73 (17.54–19.85)	18.91 ± 2.87 (17.7–20.12)	0.64
% stenosis	61.63 ± 12.63 (52.02–66.69)	23.41 ± 12.48 (18.14–28.68)	<0.0001
Eccentricity index	0.46 ± 0.24 (0.36–0.57)	0.43 ± 0.24 (0.33–0.53)	<0.0001
Remodeling index	1.04 ± 0.2 (0.95–1.13)	1.09 ± 0.3 (0.96–1.21)	0.71
Vascular volume (mm3)	277.7 ± 86.36 (241.3–314.2)	283.7 ± 72.24 (253.2–314.2)	0.79
Lumen volume (mm3)	100.8 ± 33.68 (86.53–115.0)	128.2 ± 37.38 (112.4–144.0)	0.01
Dense calcium (mm3)	13.59 ± 17.36 (6.26–20.92)	16.07 ± 19.0 (8.0–24.09)	0.45
Dense calcium (%)	6.72 ± 7.79 (3.43–10.02)	8.98 ± 9.0 (5.15–12.82)	0.25
Necrotic core (mm3)	169.8 ± 63.7 (142.9–196.7)	143.6 ± 53.62 (121.0–166.2)	0.12
Necrotic core (%)	93.27 ± 7.79 (89.98–96.56)	91.0 ± 9.0 (87.17–94.84)	0.25
Fibro-fatty (mm3)	20.07 ± 15.67 (13.46–26.69)	11.05 ± 10.83 (6.47–15.62)	0.01
Fibro-fatty (%)	10.31 ± 6.24 (7.67–12.95)	6.46 ± 6.14 (4.05–9.24)	0.01
Fibrous (mm3)	114.8 ± 59.62 (119.6–170.0)	132.6 ± 50.97 (111.0–154.1)	0.44
Fibrous (%)	82.97 ± 7.74 (79.69–86.24)	84.26 ± 10.73 (79.73–88.79)	0.63
Calcium score – local	82.97 ± 107.5 (37.57–128.4)	96.54 ± 85.73 (60.34–132.7)	0.25
Calcium score – target coronary artery	148.2 ± 222.3 (54.37–242.1)	207.6 ± 224.0 (113.0–302.2)	0.10

In terms of plaque components, there were no significant differences between subgroup 1 and subgroup 2 regarding to the calcified volume (13.59 ± 17.36 mm³ in subgroup 1 vs. 16.07 ± 19.0 mm³ in subgroup 2, p = 0.45), % calcified (6.72 ± 7.79 in subgroup 1 vs. 8.98 ± 9.0 in subgroup 2, p = 0.25), necrotic core volume (169.8 ± 63.7 mm³ in subgroup 1 vs. 143.6 ± 53.62 mm³ in subgroup 2, p = 0.12), necrotic core % (93.27 ± 7.79 in subgroup 1 vs. 91.0 ± 9.0 in subgroup 2, p = 0.25), fibrotic volume (114.8 ± 59.62 mm³ in subgroup 1 vs. 132.6 ± 50.97 mm³ in subgroup 2, p = 0.44), or fibrotic % (82.97 ± 7.74 in subgroup 1 vs. 84.26 ± 10.73 in subgroup 2, p = 0.63), except for lipid volume and lipid % (20.07 ± 15.67 mm³ in subgroup 1 vs. 11.05 ± 10.83 mm³ in subgroup 2, p = 0.01) which presented a significant reduction after BVS implantation (Figure 6).

Regarding the calcium score evaluated locally (82.97 ± 107.5 in subgroup 1 vs. 96.54 ± 85.73 in subgroup 2, p = 0.25), at the level of the target coronary artery (148.2 ± 222.3 in subgroup 1 vs. 206.6 ± 224.0 in subgroup 2, p = 0.10), and the total calcium score (377.6 ± 459.5 in subgroup 1 vs. 529.5 ± 512.9 in subgroup 2, p = 0.32), there were no significant differences when comparing lesions with versus without post-dilatation (Figure 7).

Table 3 presents the comparative analysis between the pre- and post-BVS implantation aspects of the CTA evaluation combined with the image post-processing analysis in terms of CT vulnerability markers of the analyzed coronary plaques.

Regarding CT vulnerability markers, the study groups presented significant differences only in terms of spotty

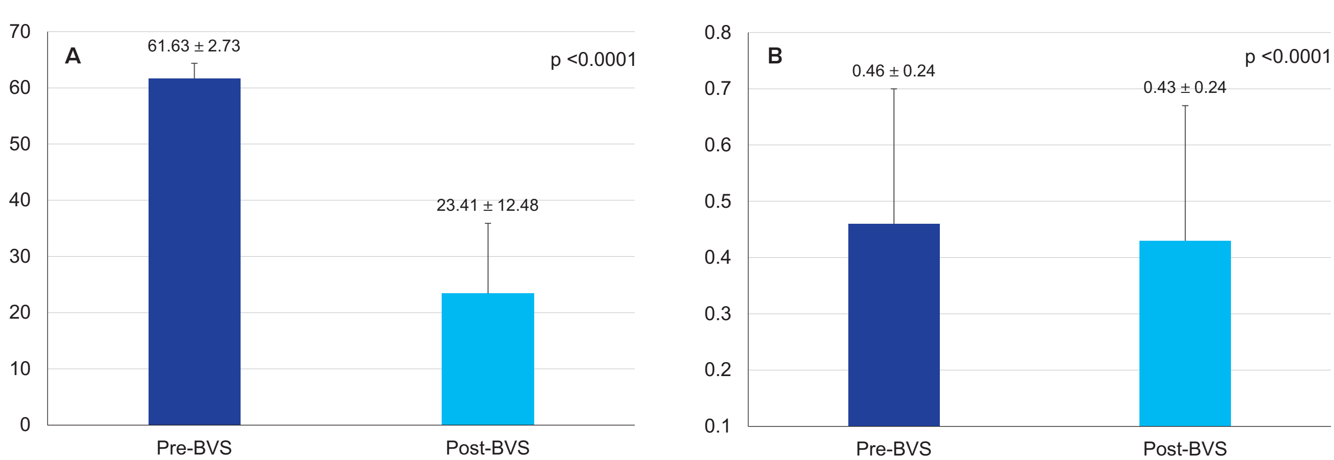

FIGURE 5. **A** – % stenosis mean value pre- and post-BVS implantation; **B** – Eccentricity index pre- and post-BVS implantation

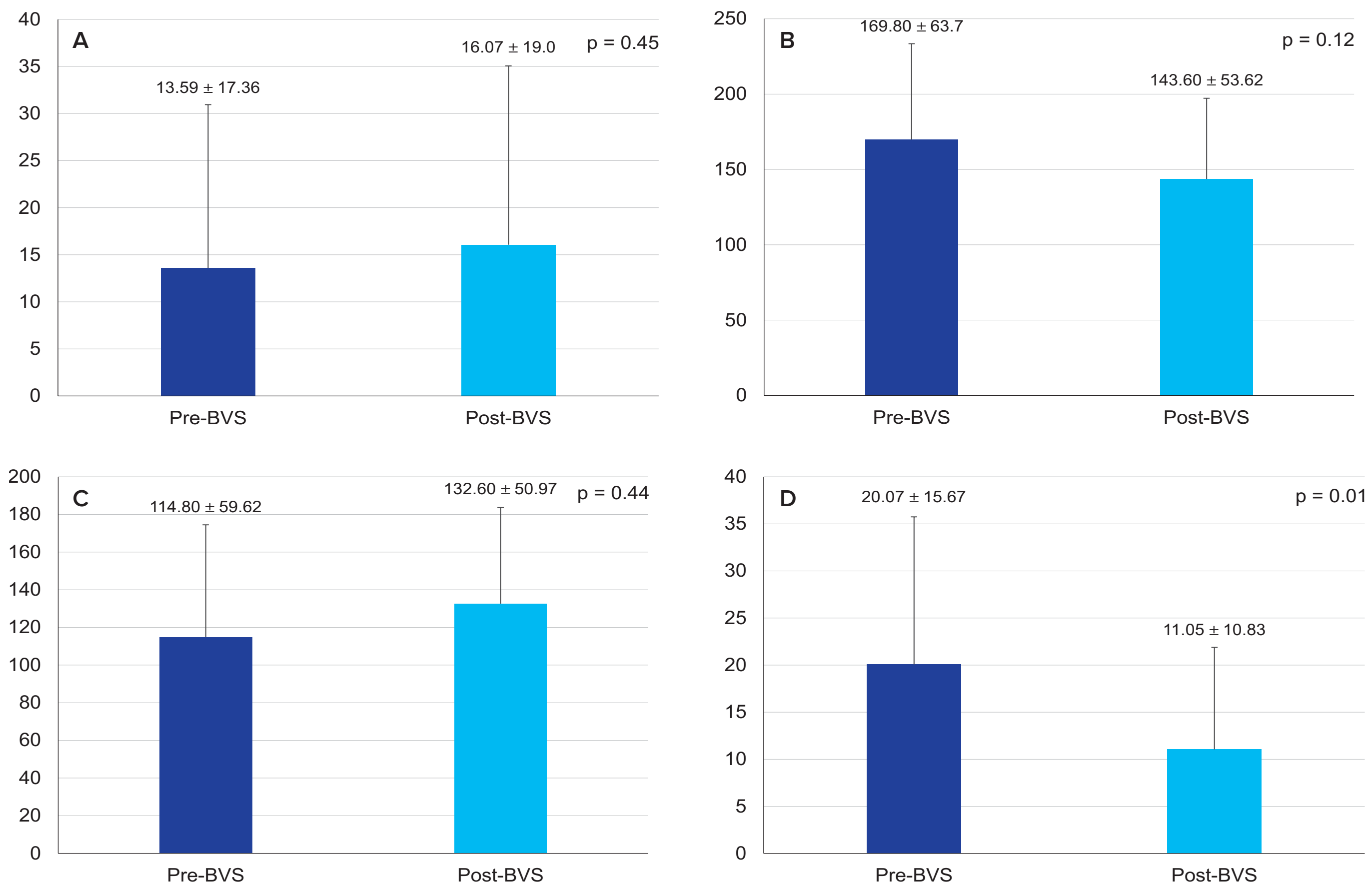

FIGURE 6. **A** – Calcified volume (mm³); **B** – Necrotic core volume (mm³); **C** – Fibrotic volume (mm³); **D** – Lipid volume (mm³)

calcifications (66.66% in subgroup 1 vs. 79.16% in subgroup 2, p = 0.05) and low attenuation (37.5% in subgroup 1 vs. 20.83% in subgroup 2, p = 0.01) (Figure 8).

DISCUSSIONS

Given that coronary atherosclerotic plaques, treated by implantation of bioresorbable scaffolds, can also be evaluated after the procedure using a noninvasive method, this could lead to the routine evaluation of these devices through coronary CT angiography. This way, the coronary CT angiography evaluation of BVS can highlight certain complications that may occur over time.[16,17]

The CTA evaluation of BVS is possible due to the special advantages of these structures, namely polymer resorption over time. All patients included in this study underwent BVS implantation, with a composition based on polymers. Regarding the radiological advantages, the radiotransparency of the device is worth mentioning, which facilitates the acquisition of coronary CT angiography, as well as subsequent image post-processing.[17–20]

The post-processing software dedicated to the detailed analysis of atherosclerotic plaque components enabled the analysis of important elements for a percutaneous procedure.

Another crucial element in a successful revascularization treatment using bioresorbable stents is the careful analysis of the target lesion. This thorough analysis, corroborated with noninvasive pre-interventional CT imaging, can contribute to the best revascularization approach of the atherosclerotic lesions.

Pre-dilatation techniques, implantation of the device, and its subsequent optimization by post-dilatation were elements evaluated in this study. When the first BVS had been implanted, there were no precise guidelines related to these procedural aspects; nevertheless, we monitored these aspects in this study. Although statistically significant differences were not obtained, differences in absolute values were observed for multiple parameters such as stenosis % (CT performed 12 to 24 months post-implantation showed less procedural stenosis in patients with pre-dilatation); the eccentricity index, the remodeling index, vascular volume, plaque volume, and necrotic core were lower among these patients. Following the in-

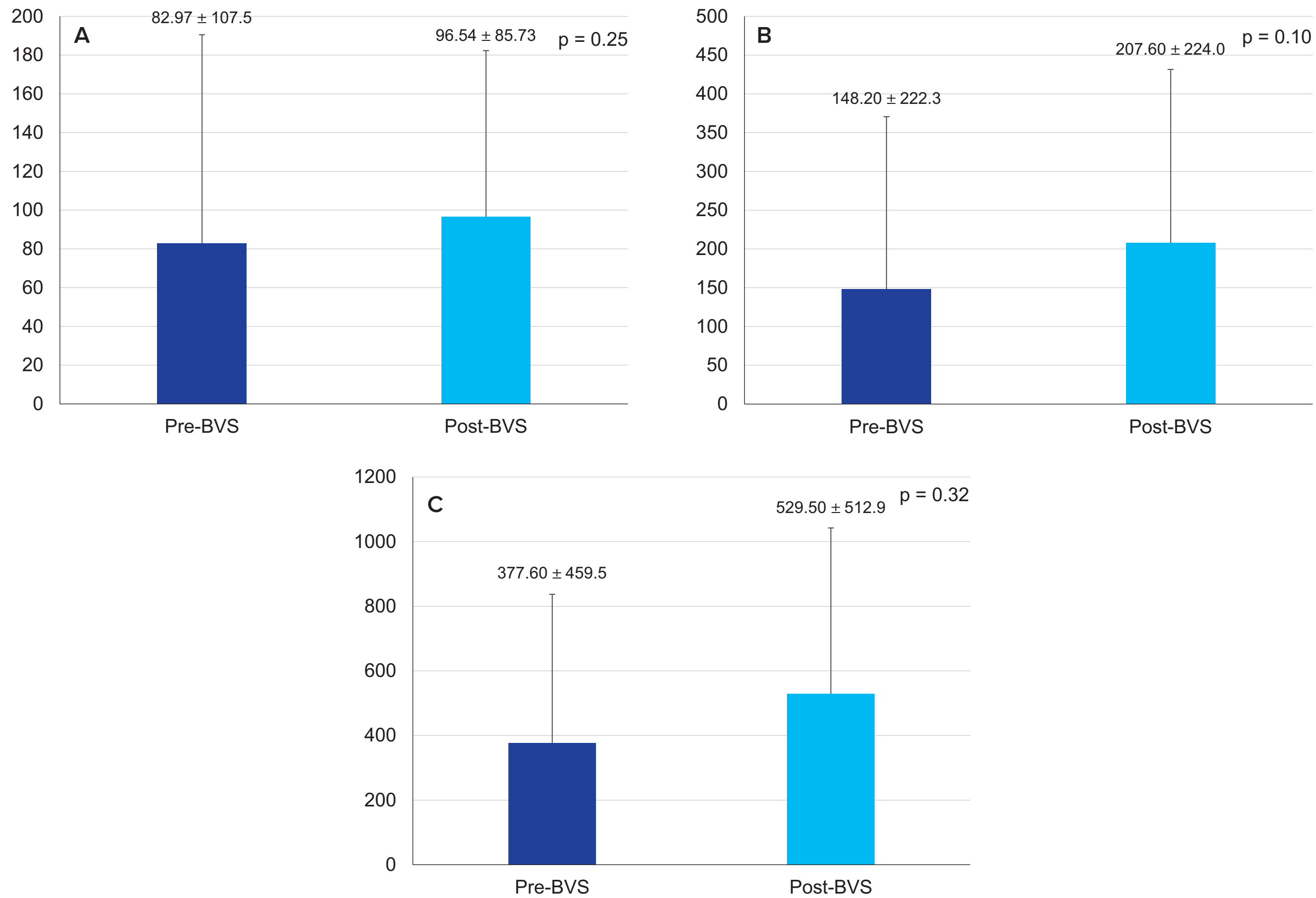

FIGURE 7. **A** – Local calcium score; **B** – Target lesion calcium score; **C** – Total calcium score

tervention, stent lumen was larger in patients with pre-dilatation.

Regarding patients who underwent post-dilatation of the bioresorbable stent versus patients without post-dilatation, except for statistically significant differences in vascular volume and lumen volume, differences in absolute stent-stenosis values were observed, which were lower in stents that have been post-dilated.

No randomized trials with specific, mandatory, predefined implantation techniques have been completed, based on the PSP concept (pre-dilation, dimensioning, and post-dilatation of the bioresorbable stent).[21] In this respect, the evaluation of these procedures can lead to new ideas, improvement, and mandatory implementation of certain specific techniques in the treatment of coronary atherosclerotic lesions with bioresorbable stents. It is recommended that the stents be implanted by trained and experienced operators in interventional cardiology.[22–24]

TABLE 3. CT vulnerability markers

	Pre-BVS (%)	Post-BVS (%)	p value
Positive remodeling	45.83	58.33	0.08
Spotty calcifications	66.66	79.16	0.05
Napkin-Ring sign	0	4.16	–
Low attenuation	37.5	20.83	0.01

CONCLUSIONS

During the analysis of coronary artery plaques after the implantation of bioresorbable scaffolds with noninvasive CT imaging techniques, significant changes were noted both in the morphology of the atherosclerotic plaques treated with these devices and in the lumen and coronary wall. The assessment of coronary atherosclerotic plaques and bioresorbable scaffolds via coronary CT angiography could become a novel follow-up method for these cases.

CONFLICT OF INTEREST

Nothing to declare.

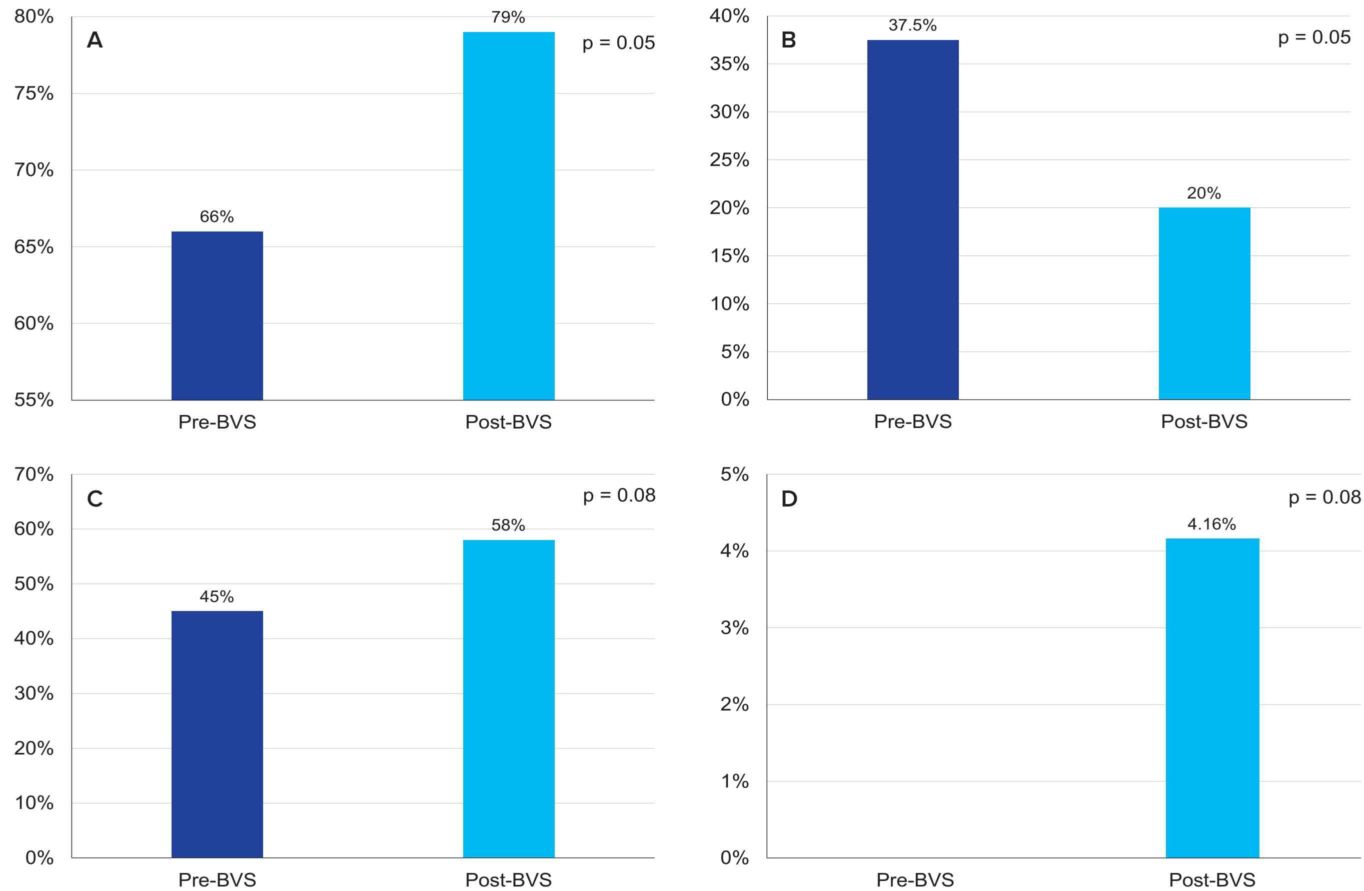

FIGURE 8. **A** – Spotty calcifications; **B** – Low attenuation; **C** – Positive remodeling; **D** – Napkin-ring sign

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