Impact of Bioresorbable Scaffold Use on Procedural Features Compared with New-Generation Drug-Eluting Stents

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ABSTRACT

Introduction: Although bioresorbable scaffolds (BRS) are considered a new paradigm in stent technology, operators are often discouraged from implanting BRS because of increased strut thickness, reduced radial force, requirement for pre- and postdilatation of the lesions, and concerns about the risk of stent thrombosis. We compared procedure and fluoroscopy duration, cumulative radiation dose, and contrast agent volume among patients undergoing BRS or drug-eluting stent (DES) implantation.

Patients and Methods: One hundred thirty-four patients with a total of 165 coronary lesions, including 64 patients (78 lesions) with BRS and 70 patients (87 lesions) with DES, were selected. Clinical and procedural characteristics and angiographic features were calculated. Procedure and fluoroscopy time, volume of contrast medium, and cumulative radiation dose (Gy) were compared.

Results: The number of predilated and postdilated lesions was higher in the BRS group than in the DES group, although baseline lesion morphologies were similar. Stent diameters were comparable between the two groups. Larger postdilatation balloon sizes were chosen in the BRS group. Mean procedure time (45.4 ± 16.1 minutes vs. 38.3 ± 15.1 minutes; p= 0.010), volume of contrast medium (207.7 ± 80.7 mL vs. 154.7 ± 74.6 mL; p= 0.001), fluoroscopy duration (15.9 ± 6.6 minutes vs. 13.1 ± 6.6 minutes; p= 0.014), and radiation dose (1.80 ± 1.08 Gy vs. 1.44 ± 0.91 Gy, p= 0.037) were significantly higher in the BRS group than in the DES group.

Conclusion: BRS implantation leads to prolonged fluoroscopy, longer procedure duration, greater contrast volume, and higher radiation exposure compared with DES procedures.

Key Words: Coronary artery disease; percutaneous coronary intervention

Eriyebilen Stentlerin Prosedür Üzerine Olan Etkilerinin İlaç Kaplı Stentlerle Karşılaştırılması

ÖZET

Giriş: Artmış strut kalınlığı, azalmış stentin açılma kuvveti, stent takılmadan önce ve sonrasında balon yapma ihtiyacı, stent trombozu riskinde artış gibi birçok faktör operatörleri yenilikçi bir teknoloji olarak sunulan eriyebilen stentlerin (ES) kullanılmasında endişeye itmiştir. Bu çalışmada ES ile ilaç salınımlı stent (İSS) kullanılan hastalardaki işlem süresi ve floroskopi zamanı, opak miktarı ve radyasyon dozu karşılaştırılması hedeflenmiştir.

Hastalar ve Yöntem: Çalışmada koroner arter hastalığı tanısı alan 134 hastadaki 165 lezyon ele alınmış olup, bunlardan ES takılan 64 hastadaki 78 lezyon ile İSS takılan 70 hastadaki 87 lezyon dahil edilmiştir. İşlemle ilgili, klinik ve anjiyografik özellikler her grup için hesaplanmıştır. Her iki gruptaki prosedür ve floroskopi zamanı, kontrast miktarı ve toplam radyasyon dozu (Gy) karşılaştırılmıştır.

Bulgular: Başlangıç lezyon özellikleri her iki grupta benzer saptanmasına rağmen balon ile pre- ve post-dilatasyon anlamlı olarak ES takılanlarda daha yüksek saptandı. Stent çapları iki grupta da benzer iken ES grubunda postdilatasyon için daha yüksek çaplı balonlar tercih edildi. Ortalama işlem süresi (sırasıyla 45.4 ± 16.1 dakika ve 38.3 ± 15.1 dakika, p= 0.01), kontrast volümü (sırasıyla 207.7 ± 80.7 mL ve 154.7 ± 74.6 mL; p= 0.001), floroskopi zamanı (sırasıyla 15.9 ± 6.6 dakika ve 13.1 ± 6.6 dakika, p= 0.014), radyasyon dozu (sırasıyla 1.8 ± 1.08 Gy ve 1.44 ± 0.91 Gy, p= 0.037) ES grubunda İSS grubuna kıyasla anlamlı olarak daha yüksek bulunmuştur.

Sonuç: ES kullanımı İSS ile karşılaştırıldığında uzamış floro ve işlem süresi, artmış opak yükü ve radyasyon dozu ile ilişkilidir.

Anahtar Kelimeler: Koroner arter hastalığı; perkütan koroner girişim

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INTRODUCTION

Drug-eluting stents (DES), which inhibit cell proliferation as compared with bare metal stents (BMS), were introduced in 1999, followed by second-generation DES, which significantly reduce restenosis and target lesion revascularization (TLR) and are associated with a lower rate of stent thrombosis[1]. Despite these positive effects, the use of metallic DES has several disadvantages, such as vessel caging, diminished vasomotion, jailing side branches, preclusion of further bypass grafting, and foreign-body response that stimulates inflammation due to the implantation of permanent metallic material[2,3].

To overcome the limitations of DES, bioresorbable scaffolds (BRS) represent a new era of stent technology that elicits resorption of foreign material, promoting vasomotor tone of the vessel and providing regulation of coronary blood flow[4,5]. Advances in the development of BRS began with the introduction of the Absorb scaffold (Abbott Vascular, Santa Clara, CA, USA) and continued with at least 22 BRS devices, some of which are still under development[6].

Although BRS appear to be appealing alternatives to metallic stents, factors such as increased strut thickness, concerns regarding late or very late stent thrombosis, target-vessel revascularization, weaker radial strength, inferior deliverability, and suboptimal visualization under fluoroscopy have discouraged operators from using these devices[7].

The aforementioned features and specific technical implementation of BRS make these devices technically more demanding than DES deployment. The purpose of this study was to investigate procedure and fluoroscopy duration, cumulative radiation dose, and volume of contrast agent in patients treated with BRS compared with new-generation DES.

PATIENTS and METHODS

Ethics committee approval was received for this study from the Istanbul Medipol University Non-Interventional Clinical Researches Ethics Committee (10840098-604.01.01-E.199).

Patients

In this single-center retrospective study, we included a total of 134 patients with 165 lesions. Sixty-four patients with 78 lesions underwent single or multivessel percutaneous coronary intervention with an everolimus-eluting BRS device (n= 19; Absorb BRS; Abbott Vascular, Santa Clara, CA, USA) or the novolimus-eluting BRS device (n= 59; Elixir Medical Corporation) from February 2017 until January 2018, and 70 patients with a total of 87 lesions were treated with new-generation DES (Xience Pro, Abbott Vascular) from May 2018 until December 2018 at the Cardiology Clinic of Istanbul Medipol University. The inclusion criteria were stable coronary artery disease or unstable angina or non-ST elevation myocardial infaction and age ≥ 18 years. Major exclusion criteria were defined as acute ST-segment elevation myocardial infarction, hemodynamically unstable arrhythmias, left ventricular ejection fraction of 30%, lesions in arterial or saphenous vein grafts, or restenotic lesions in either BRS- or DES-implanted patients. The choice to implant a BRS or DES was left to the decision of the operator.

Baseline clinical and procedural characteristics were recorded for each case. Procedural time was defined as the time from the onset of guided catheter angiography to final angiography of the target vessel. Total air kerma at the interventional reference point (Ka, r, Gy) was the procedural cumulative air kerma (X-ray energy delivered to air) at the interventional reference point, which assessed the hazard at that specific location and was recorded for each procedure. Total fluoroscopy time was defined as the total length of time of fluoroscopic radiation exposure as measured during the period of coronary intervention.

Angiography Procedure and BRS Implantation

The recommended technique for BRS included adequate lesion preparation (P), appropriate sizing (S), and post dilatation (P), known as the PSP protocol. The goal was to achieve a final stenosis diameter of < 10% with a +0.5 mm noncompliant balloon inflated to high pressure (> 16 atm)[8].

The American College of Cardiology/American Heart Association (ACC/AHA) classification was used to define the lesions[9]. The size of the guide catheter was either 6 or 7 Fr. Lesion preparation using dedicated devices before stenting and after dilatation were left to the discretion of the operator.

Scaffold sizing was based on the visual evaluation of the vessel. The implantation of a scaffold was performed with a gradual increase in pressure of 1 atm every five seconds without exceeding the rated burst pressure. At this point, the balloon was deflated rapidly, and the same balloon was inflated again and kept at a nominal pressure for 15 to 30 seconds. Finally, a further angiogram was obtained to evaluate BRS expansion. Postdilatation was performed with noncompliant balloons with either the same size of BRS or a BRS that was 0.25- to 0.5 mm larger.

Quantitative coronary angiography (QCA) was performed using standard techniques with automated edge detection algorithms (CAAS 5.7.1, Pie Medical Imaging, Masstricht, The Netherlands) in the hospital's angiographic analysis center. Reference vessel diameter (RVD), minimal lumen diameter (MLD), lesion length, stenosis percentage, minimal lumen diameter after balloon (BminLD), final minimum lumen diameter (FminLD), and acute gain were measured. An upstream 300 mg loading dose of oral aspirin was followed by 100 mg aspirin daily in patients not receiving chronic aspirin treatment. Upstream loading doses of clopidogrel 600 mg, prasugrel 60 mg,

or ticagrelor 180 mg were followed by a daily maintenance dose of clopidogrel 75 mg or prasugrel 10 mg or a twice-daily dose of ticagrelor 90 mg for 12 months in thienopyridine-naive patients.

All patients were anticoagulated with unfractionated heparin during the procedure to achieve an activated clotting time of 250 seconds.

Statistical Analysis

SPSS 23.0 statistical software (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables were expressed as numbers and percentages. The Kolmogorov-Smirnov test was used to test normality of the distribution of continuous variables. Group means for continuous variables were compared using Student's t-test or Mann-Whitney U test, as appropriate. The association between categorical variables was compared using the chi-square test. Lesion morphology, predilatation use, and postdilatation use were compared between the BRS and DES groups. The results were demonstrated with a separate box-plot graphic. The accepted level of statistical significance was 0.05 for all comparisons.

RESULTS

Baseline Patient Characteristics

Baseline patient characteristics are shown in Table 1. Sixty four patients were treated by BRS, and 70 patients were treated by DES. Patients treated with BRS tended to be younger compared with patients treated with DES (57.4 ± 9.4 vs. 61.1 ± 11.0 years, respectively; p= 0.038). Most of the patients were male (89% in the BRS group, 80% in the DES group). Among the patients in the BRS group, 78% had hypertension, 37% had diabetes, 39% had prior myocardial infarction (MI), and 56% had stable angina. In the DES group, 56% had hypertension, 39% had diabetes, 37% had prior MI, and 69% had stable angina. The radial approach was the most preferred approach in both groups (80% vs. 83%, p= 0.667; BRS vs. DES groups, respectively). The mean left ventricular ejection fractions of the BRS- and DES-implanted patients were 52.9% ± 7.1% and 53.5% ± 8.2%, respectively. Laboratory findings in both groups mainly showed statistically similar results.

Lesion Characteristics

A total of 175 lesions in 134 patients were treated (Table 2). Approximately half of the BRS and DES were implanted in

Table 1. Demographic characteristics of the study population according to the stent/scaffold type

Variable	BRS (patients, n= 64)	DES (patients, n= 70)	p
Age (years)	57.4 ± 9.4	61.1 ± 11.0	0.038
Gender (male), n (%)	57 (89%)	56 (80%)	0.149
Hypertension, n (%)	50 (78%)	56 (80%)	0.574
Diabetes, n (%)	24 (37%)	27 (39%)	0.898
Hyperlipidemia, n (%)	39 (61%)	51 (73%)	0.142
Smoking, n (%)	40 (63%)	35 (50%)	0.145
Family history, n (%)	26 (41%)	22 (31%)	0.267
MI history, n (%)	25 (39%)	26 (37%)	0.819
Access site			0.667
Femoral	13 (20 %)	12 (17 %)	
Radial	51 (80 %)	58 (83 %)	
Clinical presentation			0.141
Stable angina, n (%)	36 (56%)	48 (69%)	
USAP/NSTEMI, n (%)	28 (44%)	22 (31%)	
Heart failure, n (%)	6 (9%)	7 (10%)	0.903
Ejection fraction (EF) (%)	52.9 ± 7.1	53.5 ± 8.2	0.654
Hemoglobin (g/dL)	13.03 ± 2.36	13.55 ± 1.80	0.154
Platelets	248.5 ± 115.6	242.3 ± 63.4	0.703
Creatinine	0.95 ± 0.21	0.98 ± 0.59	0.619

USAP: Unstable angina, NSTEMI: Non-ST elevation myocardial infarction.

Table 2. Angiographic characteristics of the lesions according to stent/scaffold type

Variable	BRS (lesions, n= 78)	DES (lesion, n= 87)	p
Vessels treated, n (%)			
LAD	43 (55)	50 (57)	0.677
CX	14 (18)	18 (21)	0.119
RCA	21 (27)	19 (22)	0.447
Type of lesion, n (%)			
A/B1	57 (73)	63 (72)	0.924
B2/C	21 (27)	24 (28)	0.924
Calcification	31 (40)	27 (31)	0.242

DES: Drug-eluting stent, BRS: Bioresorbable scaffold, LAD: Left anterior descending artery, CX: Left circumflex artery, RCA: Right coronary artery.

the left anterior descending artery as the target vessel [left anterior descending artery: n= 43 (55%), 50 (57%); left circumflex artery: n= 14 (18%), 18 (21%); and right coronary artery: n= 21 (27%), 19 (22%) in the BRS vs. DES groups, respectively].

More than 70% of lesions in both groups were categorized as types A and B1 per the ACC/AHA classification (73% in the BRS group and 72% in the DES group, p= 0.924). Calcification was recorded in 31 lesions (40%) in the BRS group and in 27 lesions (31%) in the DES group (p= 0.242).

Procedural Characteristics

The main procedural characteristics determined by QCA analyses are shown in Table 3. The mean RVD was similar in both groups (3.1 ± 0.4 mm in the BRS group, 3.1 ± 0.4 mm in the DES group, p= 0.256). The DES group had a lower MLD (0.75 ± 0.41 mm vs. 0.98 ± 0.46 mm, p= 0.001), higher stenosis percentage (75.1% ± 12.4% vs. 69.4% ± 12.3%, p= 0.004), and longer lesion length (21.3 ± 4.4 mm vs. 24.5 ± 7.4 mm, p= 0.001). Larger stent sizes were chosen in BRS-treated patients (3.09 ± 0.4 mm vs. 2.89 ± 0.4 mm; p= 0.001) despite similar reference vessel diameters. Longer stent lengths were favored in the DES group (24.9 ± 5.3 mm vs. 30.3 ± 8.9 mm; p< 0.001).

Balloon predilation and postdilatation were performed more frequently in the BRS group than in the DES group (100% vs. 75%; p< 0.001; 98% vs. 84%; p= 0.004, respec-

Table 3. Procedural characteristics measured by QCA

Variable	BRS	DES	p value
Reference vessel diameter (mm)	3.1 ± 0.4	3.1 ± 0.4	0.256
Minimum lesion diameter (mm)	0.98 ± 0.46	0.75 ± 0.41	0.001
Stenosis percentage (%)	69.4 ± 12.3	75.1 ± 12.4	0.004
Lesion length (mm)	21.3 ± 4.4	24.5 ± 7.4	0.001
Predilatation, n (%)	78 (100)	65 (75)	< 0.001
Predilatation balloon size (mm)	2.8 ± 0.5	2.5 ± 0.5	< 0.001
BminLD (mm)	2.2 ± 0.5	2.0 ± 0.5	0.045
Acute gain (mm)	2.0 ± 0.5	2.2 ± 0.5	0.017
Stent number per lesion	1.36 ± 0.56	1.41 ± 0.49	0.505
Stent diameter (mm)	3.09 ± 0.4	2.89 ± 0.4	0.001
Stent length (mm)	24.9 ± 5.3	30.3 ± 8.9	< 0.001
Postdilatation, n (%)	77 (98)	73 (84)	0.004
Postdilatation balloon size (mm)	3.3 ± 0.4	3.1 ± 0.4	0.036
FminLD (mm)	2.98 ± 0.40	2.97 ± 0.43	0.871

BminLD: Minimum lumen diameter after balloon predilatation, FminLD: Final minimum lumen diameter.

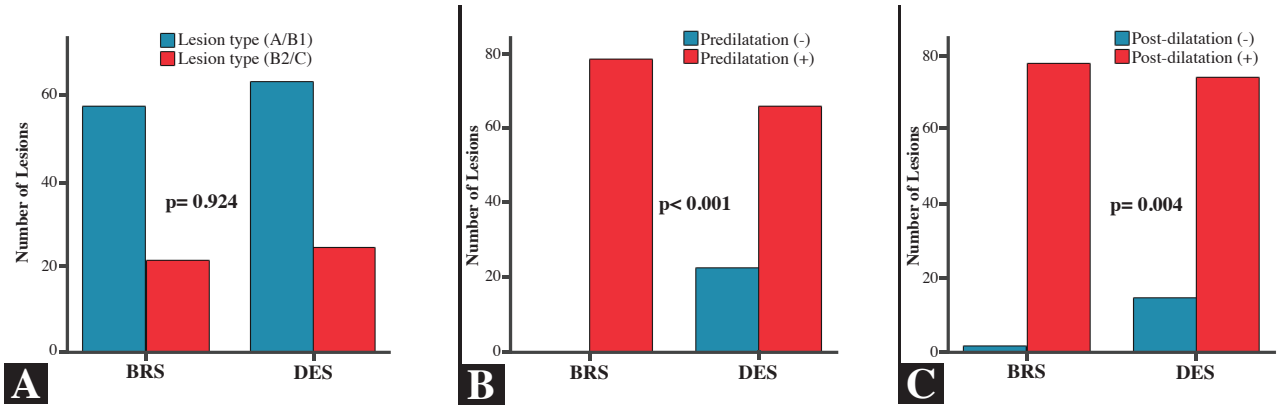

Figure 1. Comparison of lesion characteristics and pre- and postdilatation rates in BRS and DES groups. Percentage of lesion classification according to the ACC/AHA definition between the DES and BRS groups (A); comparison of predilatation (B) and postdilatation rates (C) in both groups.

Table 4. Procedural variables

Variable	BRS (patients, n= 64)	DES (patients, n= 70)	p
Fluoroscopy time (min)	15.9 ± 6.6	13.1 ± 6.6	0.014
Procedure time (min)	45.4 ± 16.1	38.3 ± 15.1	0.010
Contrast volume (mL)	207.7 ± 80.7	154.7 ± 74.6	0.001
Radiation dose (Gy)	1.80 ± 1.08	1.44 ± 0.91	0.037

tively), although both groups had similar lesion morphologies (Figure 1). Predilatation and postdilatation balloon sizes were also significantly higher in BRS-treated patients (2.8 ± 0.5 mm vs. 2.5 ± 0.5 mm; p< 0.001; 3.3 ± 0.4 mm vs. 3.1 ± 0.4 mm, p< 0.036; pre- and postdilatation, respectively).

Increased predilatation balloon calibers provided higher BminLD following predilatation in the BRS group as compared with the DES group (2.2 ± 0.5 mm vs. 2.0 ± 0.5 mm, p< 0.045, respectively). Of note, even longer lesion lengths in the DES group were present, and the average number of stents per lesion was similar in both groups (1.36 ± 0.56 in BRS patients and 1.41 ± 0.49 in the DES group).

The total procedure time, radiation dose, fluoroscopy time, and amount of contrast agent were all significantly greater in patients treated with BRS compared with those treated with DES, as shown in Table 4 (Figure 2).

DISCUSSION

In this study, BRS interventions appeared to have a longer procedure and fluoroscopy duration as well as increased amount of contrast agents and radiation dose compared with new-generation DES. The unique feature of the current study was that procedural aspects of BRS implantation focusing on procedure and fluoroscopy time, contrast volume, and amount of radiation exposure were investigated and compared with DES procedures.

Most evidence on BRS comes from studies that have used the Absorb BRS[10-12]. DESolve BRS is made from a poly-l-lactide polymer backbone similar to that of the Absorb BRS eluting anti-inflammatory novolimus, offering advantages such as a larger limit of expansion, with diminished strut fracture risk and self-correction of minor malapposition[13]. Some technical issues regarding the implantation technique have been reached by consensus and are applicable to both BRS methods used in our study[14,15]. The consensus suggested the use of the PSP protocol for BRS procedures, as data from studies advocate that rates of scaffold thrombosis could be reduced significantly if this approach is followed[8,16]. Previously published large-scale, randomized clinical trials and cohort studies reported variable rates of predilatation and postdilatation; interestingly, the rate of postdilatation was on average < 50%, with low intracoronary imaging[17,18]. Contrary to previously published data, we found that predilatation and postdilatation rates were higher in the BRS group compared with the DES group (predilatation 100% vs. 75% and postdilatation 98% vs. 84%). Our mean BRS length was longer than in previous studies[17]. It might be speculated that longer lesion lengths might have affected the operator's choice for higher pre- and postdilatation rates in the BRS group. However, even though lesion lengths were longer

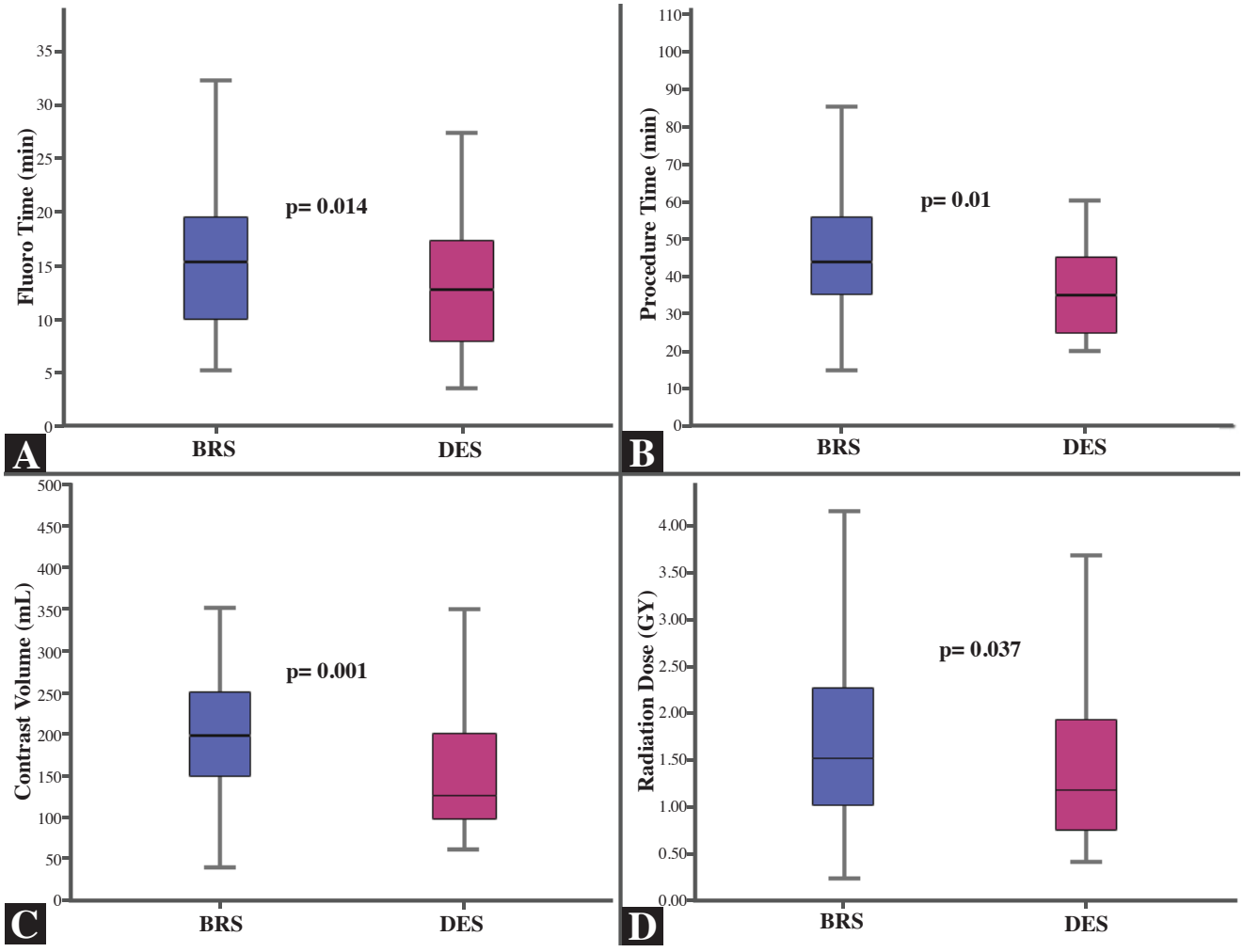

Figure 2. Association between procedural features in the study groups. Fluoroscopy time (A), procedure time (B), contrast volume (C), and radiation dose (D) of the BRS and DES procedures.

in the DES group, the average number of stents per lesion did not differ between the groups because of the available longer stent sizes in the DES group.

Operators have become more cautious when it comes to using BRS because of the above-mentioned drawbacks. In addition, increased strut thickness and inferior deliverability have made BRS implantation more challenging. However, despite these challenging and technically demanding issues, data on the duration of operation and fluoroscopy, contrast volume, and radiation dose during BRS deployment are scarce.

Sato et al. compared 96 patients treated with BRS and 96 matched controls treated with DES, both of whom had predominantly complex lesions[19]. They reported that primary endpoints including procedure time, total contrast medium administered, and fluoroscopy time were higher in the BRS group ($p< 0.001$, $p= 0.02$, and $p< 0.001$, respectively). Our data show that these outcomes can also translate into similar results even for patients with noncomplex lesion subsets. Wiebe et al. and Ozel et al. shared their data from a relatively small number of patients with chronic total occlusions regarding the amount of contrast volume and procedure and fluoroscopy time, but they did not conduct a comparison between BRS and DES groups[20,21]. Thus, this paper, which aimed to evaluate contrast load, radiation exposure, and duration of procedure and fluoroscopy, is of clinical importance for both operators and patients as it highlights the increased dose of radiation and contrast volume and longer procedural and fluoroscopy times in BRS-treated patients as compared with DES-treated patients.

In the current study, lesions in the DES group were longer than those in the BRS group. Hence, operators chose to implant significantly longer stents in the DES group. Unlike DES, commercially available scaffold sizes are also restricted. Although it might be expected that long stents selected for longer lesions with significantly most severe stenosis and lower predilatation

rates would increase the procedure times in DES group, there are several factors that make BRS deployment more demanding. Moreover, poor visualization of the scaffold markers as well as slow inflation time during BRS implantation also contributed additional time and excessive opaque use.

Because of this study's single-center design and retrospective nature, the current study is subject to selection and recall biases. Despite the relatively small sample size and the use of varied types of stents in the DES and BRS group, we believe that our study has sufficient power to reveal the observed differences in the procedural aspects between the BRS and DES groups.

Another limitation to our study was the lack of intravascular imaging (intravascular ultrasound/optical coherence tomography) for BRS and DES procedures to test radiation exposure, procedure time, and opaque load. However, Sato et al. did not find an association between intravascular imaging and longer procedural times[19]. Finally, we were unable to establish a relationship between BRS use and clinical outcomes, because long-term results were not evaluated in the current study.

CONCLUSION

BRS implantation results in a longer procedure and fluoroscopy duration. Excessive radiation exposure and opaque volume were observed in BRS-implanted patients. Awareness of ways to minimize the likelihood of contrast nephropathy as well as inappropriate excessive radiation use is of paramount importance during BRS procedures. Randomized trials are warranted to investigate radiation dose, procedural and fluoroscopy times of BRS devices, and the impact of these parameters on clinical outcomes.

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Informed Consent: Written informed consent was obtained from patients who participated in this study.

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Author Contributions: Concept/Design – BÇ; Analysis/Interpretation – BÇ; Data Collection – BÇ; Writing – BÇ; Critical Revision – BÇ; Final Approval – BÇ; Statistical Analysis – BÇ; Obtained Funding – BÇ; Overall Responsibility - BÇ

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