ORIGINAL ARTICLE

Clinical and angiographic outcomes at more than 1 year after treatment of chronic total occlusions with the everolimus-eluting bioresorbable vascular scaffold

Kronik tam tıkanma lezyonlarının everolimus salgılayan "bioresorbable vascular scaffold" ile tedavisinin bir yıllık takipte klinik ve anjiyografik sonuçları

Aylin Hatice Yamaç, M.D., Abdülkadir Yıldız, M.D., Meherrem Nasifov, M.D., Ahmet Taştan, M.D.,[#] Nemat Bashirov, M.D., Ömer Göktekin, M.D.

Department of Cardiology, Bezmialem Foundation University, İstanbul, Turkey
[#]Department of Cardiology, Şifa University Hospital, İzmir, Turkey

ABSTRACT

Objective: Treatment of chronic total occlusion (CTO) with everolimus-eluting bioresorbable vascular scaffold (BVS) is safe and effective at short-term follow-up (FU). The current study investigated clinical and angiographic outcomes after treatment of CTO with BVS at >1 year.

Methods: Thirty patients who underwent successful recanalization of 35 CTOs were included in this study. Quantitative coronary angiography (QCA) was performed at median FU period of 402 days. Clinical endpoints analyzed included all-cause mortality, cardiac death, non-fatal target vessel myocardial infarction, target vessel revascularization (TVR), symptom-driven target lesion revascularization (TLR), and BVS thrombosis.

Results: QCA analysis revealed in-scaffold minimal luminal diameter of 2.14±0.50 mm and late lumen loss (LLL) of 0.38±0.54 mm. One cardiac death, 5 cases with TVR, and 3 cases with TLR were detected at median FU time of 542 days. No BVS thrombosis was observed.

Conclusion: The Absorb BVS was safe and effective in the treatment of CTO with acceptable LLL at mid-term FU, comparable to drug eluting stents.

ÖZET

Amaç: Kronik tam tıkanma (KTT) lezyonlarının everolimus salgılayan eriyen stentler (bioresorbable vascular scaffold - BVS) ile tedavi edilmesi kısa dönem takipte güvenilir ve etkilidir. Bu çalışma KTT lezyonlarının BVS ile tedavisinin bir yıllık klinik ve anjiyografik sonuçlarını araştırmayı hedeflemektedir.

Yöntemler: Bu çalışmaya 35 KKT lezyonu başarıyla tedavi edilen 30 hasta alındı. Kantitatif koroner anjiyografi (KKA) ortalama 402 günlük takip süresi sonucunda yapıldı. Primer sonlanım noktaları tüm nedenlere bağlı ölüm, kardiyak ölüm, hedef damara bağlı ölümcül olmayan miyokart enfarktüsü, hedef damar revaskülarizasyonu (HDR), semptom oluşturan hedef lezyon revaskülarizasyonu (HLR) ve BVS trombozu olarak belirlendi.

Bulgular: Kantitatif koroner anjiyografi analizinde minimal lümen çapı 2.14±0.50 mm, geç lümen kaybı 0.38±0.54 mm olarak ölçüldü. Ortanca 542 günlük takip süresince bir kardiyak ölüm, beş HDR ve üç HLR saptandı. BVS trombozu gelişmedi.

Sonuç: KTT tedavisinde Absorb BVS kullanımı orta dönem takipte güvenilir ve etkilidir. Geç lümen kaybı ilaç salınımlı stentler ile benzer bulunmuştur.

There is limited data on clinical and angiographic outcomes following implantation of bioresorbable vascular scaffold (BVS) in patients with complex coronary lesions, and in particular, chronic total occlusion (CTO) with indication for revascularization.

As BVS provides temporary scaffolding with concomitant everolimus drug delivery, there might be some putative benefits in comparison with metallic stents. CTO treatment with BVS would avoid risks associated with "full metal jackets," including late re-

Received: March 31, 2016 *Accepted:* September 05, 2016

Correspondence: Dr. Aylin Hatice Yamaç. Adnan Menderes Bulvarı (Vatan Cad.), 34093 Fatih, İstanbul, Turkey.
Tel: +90 212 - 691 52 62 e-mail: haticeyamac80@yahoo.de

© 2016 Turkish Society of Cardiology

stenosis and thrombosis.

Resorption of scaffold restores pulsatility, cyclical strain, physiological shear stress, and mechanotransduction.[1] Additional benefits include no restrictions on future percutaneous or coronary artery bypass grafting (CABG).

Further, when scaffolds are resorbed, normal bifurcation anatomy, flow, and vascular function will be restored, while jailed side branches (SBs) will be liberated.

A 5-year clinical and functional multi-slice computed tomography angiographic follow-up (FU) study after coronary implantation of Absorb BVS (Abbott Vascular, Inc., Santa Clara, CA, USA) in patients with de novo coronary artery disease reported low event rate and suggested sustained safety of the device.[2]

However, information about angiographic FU data of Absorb BVS in CTO lesions is sparse.

Procedural feasibility of CTO treatment with BVS was demonstrated in our recent study, marked by acceptable clinical outcome at short-term FU.[3] Present study was investigation of clinical and angiographic outcomes at >1 year after treatment of CTO with Absorb BVS.

METHODS

A total of 30 consecutive patients who underwent successful recanalization of CTO with BVS between March 6, 2013 and March 29, 2015 in the Department of Cardiology of the Bezmialem Foundation University were included in the study. CTO was defined as thrombolysis in myocardial infarction (TIMI) grade 0 flow with estimated duration of occlusion of >3 months. Indications for revascularization included angina or equivalent, and/or evidence of myocardial ischemia. Patients were anticoagulated with unfractionated heparin using initial bolus of 70–100 U/kg and subsequent boluses targeted to activated clotting time of >300 seconds throughout the intervention. Patients were eligible if reference vessel diameter (RVD) was between 2.5 and 4.0 mm. There was no restriction with regard to lesion or occlusion length. Treatment strategy was to cover occluded segment and stenotic segment proximally and distally to occlusion with 1 or more BVSs. Postdilatation was mandatory to ensure optimal expansion and apposition. Dual antiplatelet therapy of acetylsalicylic acid 100 mg per day and clopidogrel 75 mg per day or ticagrelor 90 mg twice daily was prescribed for at least 12 months. Ticagrelor was mainly preferred in difficult or complicated cases, some of which resulted in target vessel revascularization (TVR) or target lesion revascularization (TLR). Clinical FU was conducted every 6 months.

Abbreviations:

AS	*Area stenosis*
BMS	*Bare metal stent*
BVS	*Bioresorbable vascular scaffold*
CABG	*Coronary artery bypass grafting*
CTO	*Chronic total occlusion*
DS	*Diameter stenosis*
DES	*Drug-eluting stent*
FU	*Follow-up*
IQR	*Interquartile range*
IVUS	*Intravascular ultrasound*
LAD	*Left anterior descending artery*
LCX	*left circumflex coro¬nary artery*
LLL	*Late lumen loss*
MACE	*Major adverse cardiovascular event*
MI	*Myocardial infarction*
MLA	*Minimal lumen area*
MLD	*Minimal lumen diameter*
OCT	*Optical coherence tomography*
PCI	*Percutaneous coronary intervention*
QCA	*Quantitative coronary angiography*
RCA	*Right coronary artery*
RVD	*Reference vessel diameter*
SB	*Side branches*
TIMI	*Thrombolysis in myocardial infarction*
TLR	*Target lesion revascularization*
TVR	*Target vessel revascularization*

Every patient provided written informed consent for procedure and subsequent anonymous FU data analysis for clinical research purposes. Ethics committee of the Bezmialem Foundation University approved the study.

Patient selection

Patients aged between 18 and 80 years, with 1 or more CTO, presenting with angina symptoms or equivalent, and/or reversible ischemia were included in the study.

Principal exclusion criteria included myocardial infarction (MI) in the territory of target CTO within 30 days or within 3 days in other territory, renal failure with serum creatinine level >3 mg/dL, other comorbid conditions with life expectancy <2 years, contraindication for aspirin or clopidogrel therapy, and women with childbearing potential. Cases with severe calcification or tortuous vessels were also excluded.

Angiographic success was defined as residual in-scaffold diameter stenosis (DS) <30%, with TIMI flow grade 3 without occlusion of significant SBs, flow-limiting dissection, distal embolization, or angiographic evidence of thrombus. Procedural success was defined as composite endpoint of angiographic success without associated major, in-hospital, clinical complications (e.g., death, MI, stroke, emergency

CABG). Periprocedural MI was defined as elevation of cardiac biomarkers (creatine kinase-myocardial band 5 times upper limit of normal, troponin 5 times upper limit of normal).

Clinical follow-up parameters

Median FU was 542 days (interquartile range [IQR]: 175–961 days). Clinical endpoints analyzed included all-cause mortality; cardiac death; and major adverse cardiovascular event (MACE), such as non-fatal target vessel MI, TVR, symptom-driven TLR, or BVS thrombosis.

FU MI was diagnosed based on increase of cardiac troponins above 99th percentile upper reference limit with at least 1 of the following observations: symptoms of ischemia; changes in electrocardiogram, i.e., new or presumed new significant ST-T changes, new left bundle branch block, or development of pathological Q-waves; imaging evidence of new loss of viable myocardium or new regional wall motion abnormality; or identification of intracoronary thrombus by angiography. Symptom-driven TLR consisted of repeat percutaneous coronary intervention (PCI) or CABG to treat luminal stenosis in scaffold or within 5 mm border proximal or distal to scaffold implanted at indexed procedure in presence of angina symptoms and/or MI.

Angiography and quantitative coronary angiography analysis

Coronary arteriography was performed according to standard procedures[4] using consecutive single-plane orthogonal projections of target lesion. Quantitative coronary angiography (QCA) was performed with the Cardiovascular Angiography Analysis System (CAAS) II (Pie Medical Imaging BV, Maastricht, The Netherlands).[5] Small radiopaque markers at the ends of the stent helped with localization of the radiolucent device for definition of in-scaffold segment. The following QCA parameters were computed before and after BVS implantation and at FU angiography: occlusion length, minimal lumen diameter (MLD) and area, and RVD.

Optical coherence tomography

Time-domain optical coherence tomography (OCT) examinations were performed using well-validated, non-occlusive technique.[6] Briefly, after wiring artery with guidewire as described, Dragonfly Duo imaging catheter (LightLab Imaging, Inc., Westford, MA, USA) was advanced distally to implanted stent and during continuous contrast media flush (Visipaque, iodixanol, GE Healthcare, Chicago, IL, USA), automatic pullback was performed.

OCT images were obtained along region of interest, which was the implanted stent plus 5 mm both proximal and distal. Off-line analysis was performed after careful recalibration of acquired images along reconstructed longitudinal segment. Mean proximal and distal RVD, in-scaffold MLD, minimal lumen area (MLA), DS and area stenosis (AS) were obtained along region of interest using automated algorithm.

Statistical analysis

Continuous variables were presented as mean (standard deviation) or median (interquartile range). Categorical variables were presented as number (percentage). Differences in proportions were tested with chi-square test, and differences in continuous variables were tested with Student's t-test. Statistical analysis was performed using SPSS software (SPPS Statistics 20; IBM Corp., Armonk, NY, USA).

RESULTS

Population and lesion characteristics

Baseline characteristics of the patients are provided in Tables 1 and 2.

Thirty patients were treated with Absorb BVS for single CTO, while 5 patients underwent PCI for double CTO. Mean age was 57.8±9.6 years and 86.7% of the population was male. Three patients had suffered previous MI and 2 patients had undergone previous CABG. Nine patients had triple-vessel disease, while double-vessel disease was found in 14 patients, and 5 patients had single-vessel disease. Majority of lesions involved the right coronary artery (RCA) (40.0%), followed by the left anterior descending artery (LAD) (34.3%), and the left circumflex coronary artery (LCX) (25.7%). Most lesions were localized in proximal section of target vessel (51.4%), while 28.6% of cases consisted of mid-portion lesions, 14.3% ostial, and 5.7% distal lesions.

Occlusion length >20 mm was observed in majority of cases (57.1%), 11 cases had blunt stump, and 8 lesions were characterized by moderate to severe calcification.

Table 1. Patient demographics and clinical characteristics (n=30)

	n	%	Mean±SD
Age (years)			57.8±9.6
Male	26	86.7	
Cardiovascular risk factors			
Hypertension	24	80.0	
Hypercholesterolemia	17	56.7	
Diabetes mellitus	1	3.3	
History of Smoking	12	40.0	
Family history of CAD	10	33.3	
Cardiac history			
Previous myocardial infarction	3	10.0	
Previous PCI	4	13.3	
Previous coronary artery bypass grafting	2	6.7	
Number of diseased vessels			
1	5	16.7	
2	14	46.7	
3	9	30.0	
Left ventricle ejection fraction			50.2±6.4
Comorbidities			
Chronic renal failure	0		
Chronic obstructive lung disease	2		
Prior stroke	0		

CAD: Coronary artery disease; LV: Left ventricle; PCI: Percutaneous coronary intervention.

Table 2. Angiographic lesion characteristics (n=35)

	n	%
Target vessel		
Left anterior descending artery	12	34.3
Left circumflex artery	9	25.7
Right coronary artery	14	40.0
Lesion location		
Ostial	5	14.3
Proximal	18	51.4
Mid portion	10	28.6
Distal	2	5.7
Side branch at occlusion	5	14.3
Provisional stenting	3	8.6
Double stenting	2	5.7
T-stenting	1	2.9
Mini crush	1	2.9
Occlusion length >20 mm	20	57.1
Blunt stump	11	31.4
Moderate to severe calcification	8	22.9

Procedural characteristics

Procedural characteristics of lesions can be seen in Table 3. Antegrade approach was applied in 32 CTOs. Majority of these lesions were treated with single wire crossing. Parallel wire technique was conducted 5 times. In 3 cases treated via retrograde approach, reverse-CART technique was used.

In total, 75 Absorb BVS were implanted. All implantations were successful, with angiographic success rate of 97.1%. No MIs occurred after procedures.

Predilation was performed with balloon diameter of 2.5±0.8 mm and mean maximum inflation pressure of 13.8±2.7 atm.

Mean scaffold length was 58.3±23.3 mm (range: 18–102 mm) with mean of 2.3±0.9 scaffolds per lesion (range: 1–4 scaffolds) and diameter of 3.2±0.4 mm (range: 2.5–3.5 mm). Postdilation was performed in all patients with mean balloon diameter of 3.4±0.4 mm and inflated to a maximum pressure of 16.8±4.1 atm.

There were 5 SBs at occlusion site, consisting of 2 obtuse marginals (both first obtuse marginal) and 3 diagonal vessels (2 first diagonals, 1 second diagonal).

Provisional stenting was performed 3 times: Double-stent strategy was applied in 2 cases and double-BVS strategy was used with T-stenting technique in 1 case. One mini-crush procedure was performed with hybrid strategy using drug-eluting stent (DES) for the SB.

Quantitative coronary angiography

The results of QCA analysis are provided in Table 4. Baseline analysis revealed mean lesion occlusion length of 40.07±17.52 mm with proximal RVD of 3.02±0.39 mm and distal RVD of 2.13±0.54 mm.

Directly after BVS deployment, in-scaffold MLD was measured at 2.51±0.51 mm, in-scaffold DS at 13.19±5.88% and in-scaffold AS was measured at 22.07±5.33%. At median FU time of 402

Table 3. Procedural variables

	n	Mean±SD
Bilateral injection	32	
Approach type		
Antegrad	32	
Retrograd	3	
Mean balloon diameter at predilatation (mm)		2.5±0.8
Inflation pressure (atm)		13.8±2.7
No of total ABSORB BVS	75	
No of ABSORB BVS per CTO		2.3±0.9
Mean scaffold length (mm)		58.3±23.3
Mean scaffold diameter (mm)		3.2±0.4
Mean balloon diameter at postdilatation (mm)		3.4±0.4
Inflation pressure (atm)		16.8±4.1
Microcatheter	28	
Stiff guidewires	27	
Special technique		
Parallel wire	5	
Reverse CART	3	

BVS: Bioresorbable vascular scaffold; CART: Controlled antegrade and retrograde subintimal tracking; CTO: Chronic total occlusion.

Table 4. Quantitative coronary angiography results

	Mean±SD
Baseline quantitative coronary angiography	
Proximal reference diameter (mm)	3.02±0.39
Distal reference diameter (mm)	2.13±0.54
Lesion length (mm)	40.07±17.52
Post-procedural quantitative coronary angiography	
In-scaffold minimal lumen diameter (mm)	2.51±0.51
In-scaffold minimal diameter stenosis (%)	13.19±5.88
In-scaffold minimal area stenosis (%)	22.07±5.33
Follow up quantitative coronary angiography	
In-scaffold minimal lumen diameter (mm)	2.14±0.50
In-scaffold minimal diameter stenosis (%)	20.69±13.04
In-scaffold minimal area stenosis (%)	36.73±16.69
Late lumen loss (mm)	0.38±0.54

SD: Standard deviation.

days, QCA revealed MLD of 2.14±0.50 mm, DS of 20.69±13.04%, and AS of 36.73±16.69%. Late lumen loss (LLL) was calculated at 0.38±0.54 mm.

Optical coherence tomography

Results of OCT analysis are presented in Table 5. Six RCA cases, 3 LCX cases, and 1 LAD case were analyzed at FU with OCT. Two patients had double CTO. One patient with LCX lesion had TLR (79% AS), while another patient with RCA lesion had VR proximal to stented segment. Average in-scaffold MLD was measured at 2.56±0.47 mm. Excluding the case with TLR, AS ranged from 17.1% to 36.0%.

Clinical parameters and follow-up data

Clinical outcome parameters can be found in Table 6. Median FU was 542 days (IQR: 175–961 days).

Overall analysis of all patients revealed no in-hospital MACE. At FU there was 1 cardiac death, 3 cases with TLR, and 5 cases with TVR. Restenosis was treated with repeat BVS implantation. Furthermore, there was no MI or scaffold thrombosis during FU up period.

DISCUSSION

In this study, we have demonstrated that treatment of even long CTOs (mean occlusion length: 42.67±21.62 mm; mean scaffold length per CTO: 58.3±23.3 mm) with Absorb BVS show acceptable angiographic and clinical outcome results at mid-term FU.

In this kind of lesion, delayed endothelialization with DES, especially if stent is suboptimally implanted, may be associated with higher and longer-term risk of stent thrombosis. In addition, "full metal jacket" may jail some significant SBs and may inhibit future surgical revascularization.

A recent study has shown that even for long lesions covered by BVS (109 visible SB analyzed in 35 CTO

Table 5. Optical coherence tomography at follow-up (n=8 patients, 10 CTOs)

Patient	Age	Gender	Culprit vessel	BVS (n)	Balloon predila-tation (mm)	BVS size (mm)	Balloon postdila-tation (mm)	Side-branch dilata-tion	Side branch stent	FU (days)	MACE	Mean Prox. Ref. vessel diameter (mm)	Mean Dist. Ref. vessel diameter (mm)	Min. in scaffold lumen diameter (mm)	Min. in scaffold lumen area (mm^2)	Lumen diameter stenosis (%)	Area stenosis (%)
1	41	Male	LCX	2	2.0x30	2.5x28 3.5x12	3.25x15	NO	NO	376	NO	3.26	2.36	2.19	4.56	41.4	34.0
2a	55	Male	RCA	1	2.0x20 2.5x12 3.0x20	3.5x28	4.0x15	NO	NO	517	NO	4.27	3.01	3.58	11.74	28.7	27.6
2b	55	Male	LCX	2	2.0x20 3.0x20	3.0x28 3.5x18	3.25x15 3.5x15	NO	NO	517	TLR	4.39	2.70	2.34	4.83	69.5	79.0
3	66	Male	RCA	2	3.0x12	3.0x28 3.5x12	3.5x12	NO	NO	781	NO	3.14	2.08	2.42	4.79	20.3	28.6
4a	49	Male	LCX	1	3.0x12	3.5x28	3.5x15	YES	NO		NO	3.04	2.30	2.36	5.10	31.3	34.9
4b	49	Male	RCA	2	3.0x12	3.5x28 3.5x18	3.5x12	NO	NO	527	Dissection	3.39	3.02	2.74	6.35	27.7	25.7
5	55	Male	RCA	4	2.0x20 2.5x20 3.0x15 3.5x15	3.0x28 3.5x28 3.5x28 3.5x18	3.5x15	NO	NO	745	NO	3.28	2.70	2.56	6.55	22.7	36
6	60	Male	LAD	3	2.0x30 3.5x28 3.5x12	3.0x28 3.5x15	3.0x15	YES	YES	332		3.41	1.94	1.83	3.25	37.6	31.7
7	54	Male	RCA	1	2.5x15	3.5x28	4.0x15	NO	NO	716		3.65	3.20	2.77	7.50	20.3	21.9
8	61	Male	RCA	2	2.5x30 3.0x15	4.0x15 3.5x28		NO	NO	217		3.81	2.94	2.85	9.25	13.2	17.1

BVS: Bioresorbable vascular scaffold; CTO: Chronic total occlusion; FU: Follow-up; LAD: Left anterior descending artery; LCx: Left circumflex artery; RCA: Right coronary artery.

Table 6. Clinical events and MACEs in hospital and on follow-up.

	In hospital		Total follow up	
	n	%	n	%
Overall death	0	0	1	3.0
Cardiac death	0	0	1	3.0
Target vessel myocardial infarction	0	0	0	0
Target vessel revascularization	0	0	5	14.3
Target lesion revascularization	0	0	3	8.6
Bioresorbable scaffold thrombosis	0	0	0	0

Median clinical follow-up time: 542 days (interquartile range: 175-961).

cases), where incidence of SB occlusion might have been expected to be higher, only low rate of 6.4% was observed.[7]

In the present study, all SBs on occlusion side, which were either treated provisionally or with double-stent strategy, including mini-crush and T-stenting techniques, were patent without significant restenosis.

Finally, absence of permanent metal endoluminal prosthesis should allow the vessel to regain its physiological properties. In this context, an OCT study conducted 5 years after elective first-in-man BVS implantation revealed favorable tissue response with late luminal enlargement and SB patency.[8] All struts had disappeared and been integrated within the neointima and underlying plaque, forming a homogeneous, signal-rich, low-attenuating layer.[8]

One of the frequent concerns regarding use of BVS in complex lesion subset like CTOs is that due to thicker struts of Absorb BVS (currently 157 μm in comparison to around 70–85 μm with current-generation DES), limited distensibility with risk of scaffold fracture might be assumed to occur in comparison to DES. Regarding deliverability and deployment, in our study, all lesions were multiple predilated (2.7 balloons per CTO). Further, to overcome difficulties in steerability/trackability, we routinely exchanged CTO wire with extra-support guidewire (Grand Slam; Asahi Intecc Co. Ltd., Aichi, Japan) through a microcatheter after crossing the CTO lesion. To increase deliverability of BVS, particularly when angulation comes into play, use of anchoring balloon or application of GuideLiner (Vascular Solutions, Inc., Minneapolis, MN, USA) or Guidezilla (Boston Scientific Corp., Marlborough, MA, USA) guiding catheter extensions might be a solution, as described in our previous publication.[3]

Data about angiographic and clinical outcome analysis of BVS use in CTO cases are sparse; the CTO-ABSORB pilot study has reported good, non-invasive, angiographic and clinical outcome results of CTO PCI7. Multi-slice computed tomography performed at baseline and at 6 to 8 months revealed only 2 cases with in-scaffold stenosis, and no other adverse events were observed. Rate of MACEs was lower compared with the current study; however, clinical observation period and time until angiography were shorter, especially if we consider that in our study, with exception of 1 TLR and 1 TVR, remaining MACEs occurred after FU period of 6 months (Table 6). Thus, longer observation periods are of great importance to state efficacy and safety of Absorb BVS for CTO more precisely.

Majority of studies on BVS enrolled patients with relatively simple lesions, thus one-to-one comparison between BVS use in this lesion subset and CTOs might not be accurate: The ABSORB Cohort B trial, which recruited 101 patients with single or 2-vessel de novo disease, had only 1 case of TVR at 6 months FU. LLL was only 0.19±0.18 mm, with similar results at 2-year FU (0.27±0.20 mm). Although after 6 months there was significant reduction in MLA on intravascular ultrasound (IVUS), as compared with baseline ($p<0.005$), the scaffold area gradually increased with longer observation time.[9,10] At 3-year FU, there were 7 cases (7%) of ischemia-driven TLR, MACE rate was 10.0%, and there were no instance of scaffold thrombosis.

Heterogeneous outcomes have been reported from registries recruiting patients with more complex lesions compared with ABSORB II study. In the Gauging Coronary Healing with Bioresorbable Scaffolding Platforms in Europe (GHOST-EU) registry, a total of 1189 patients who underwent PCI with implantation of 1 or more BVS in 10 high-volume European centers were recruited. Patients with acute coronary syndromes, calcified lesions, CTO, or complex bifurcation lesions were also included. Technical success was achieved in 99.7% of cases. Target lesion failure occurred in 67 of 1189 patients at median of 109 days (IQR: 8–227 days) after implantation.[11]

In the current study, TLR rate was 8.6%, TVR was observed in 14.3% of cases, and no scaffold thrombosis occurred; 1 cardiac death was documented.

Clinical outcome parameters between DES and BVS in CTO treatment seem to be comparable. A metanalysis examined efficacy and safety of DES and bare metal stent (BMS) use in CTO PCI.[12] Pooled analysis (n=3992) revealed MACE rate of 13.51% in DES group and 28.13% in BMS group. TVR occurred in 11.71% of DES-treated patients and 23.95% of BMS-treated patients. Restenosis rate was significantly decreased with DES use: 10.65% in DES group and 36.83% in BMS group (p<0.001).

LLL analyses of DES in CTOs have yielded similar results to those obtained in present study. Tian et al. reported 1-year LLL of 0.46±0.68 mm after DES implantation in angiography-guided cases, whereas in IVUS-guided cases, LLL was markedly decreased (0.28±0.48 mm).[13] Thus, routine IVUS guidance might improve the results obtained in this study, as determination of scaffold size before implantation and malapposition post deployment might be stated precisely.

Conclusion

Current study has demonstrated acceptable angiographic and clinical mid-term results of Absorb BVS use in CTO lesions, comparable to DES. Furthermore, use of Absorb BVS might avoid risks associated with "full metal jackets" in long lesions, such as stent thrombosis, might allow for possible future coronary bypass surgery and restoration of vessel's physiological properties.

Clinical and imaging FU at future time points with more patients is required to fortify utility of current findings.

Limitations of the study

This study had small sample size and was not randomized. Lack of OCT evaluation at index procedure was also a limitation.

Conflict-of-interest issues regarding the authorship or article: None declared

REFERENCES

1. Latib A, Costopoulos C, Naganuma T, Colombo A. Which patients could benefit the most from bioresorbable vascular scaffold implant: from clinical trials to clinical practice. Minerva Cardioangiol 2013;61:255–62.
2. Onuma Y, Dudek D, Thuesen L, Webster M, Nieman K, Garcia-Garcia HM, et al. Five-year clinical and functional multislice computed tomography angiographic results after coronary implantation of the fully resorbable polymeric everolimus-eluting scaffold in patients with de novo coronary artery disease: the ABSORB cohort A trial. JACC Cardiovasc Interv 2013;6:999–1009.
3. Goktekin O, Yamac AH, Latib A, Tastan A, Panoulas VF, Sato K, et al. Evaluation of the Safety of Everolimus-Eluting Bioresorbable Vascular Scaffold (BVS) Implantation in Patients With Chronic Total Coronary Occlusions: Acute Procedural and Short-Term Clinical Results. J Invasive Cardiol 2015;27:461–6.
4. Judkins MP. Selective coronary arteriography. I. A percutaneous transfemoral technic. Radiology 1967;89:815–24.
5. Gronenschild E, Janssen J, Tijdens F. CAAS. II: A second generation system for off-line and on-line quantitative coronary angiography. Cathet Cardiovasc Diagn 1994;33:61–75.
6. Pawlowski T, Prati F, Kulawik T, Ficarra E, Bil J, Gil R. Optical coherence tomography criteria for defining functional severity of intermediate lesions: a comparative study with FFR. Int J Cardiovasc Imaging 2013;29:1685–91.
7. Vaquerizo B, Barros A, Pujadas S, Bajo E, Estrada D, Miranda-Guardiola F, et al. Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study. EuroIntervention 2015;11:555–63.
8. Karanasos A, Simsek C, Gnanadesigan M, van Ditzhuijzen NS, Freire R, Dijkstra J, et al. OCT assessment of the long-term vascular healing response 5 years after everolimus-eluting bioresorbable vascular scaffold. J Am Coll Cardiol 2014;64:2343–56.
9. Diletti R, Farooq V, Girasis C, Bourantas C, Onuma Y, Heo JH, et al. Clinical and intravascular imaging outcomes at 1 and 2 years after implantation of absorb everolimus eluting bioresorbable vascular scaffolds in small vessels. Late lumen enlargement: does bioresorption matter with small vessel size? Insight from the ABSORB cohort B trial. Heart 2013;99:98–105.

10. Serruys PW, Onuma Y, Garcia-Garcia HM, Muramatsu T, van Geuns RJ, de Bruyne B, et al. Dynamics of vessel wall changes following the implantation of the absorb everolimus-eluting bioresorbable vascular scaffold: a multi-imaging modality study at 6, 12, 24 and 36 months. EuroIntervention 2014;9:1271–84.
11. Capodanno D, Gori T, Nef H, Latib A, Mehilli J, Lesiak M, et al. Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry. EuroIntervention 2015;10:1144–53.
12. Colmenarez HJ, Escaned J, Fernández C, Lobo L, Cano S, del Angel JG, et al. Efficacy and safety of drug-eluting stents in chronic total coronary occlusion recanalization: a systematic review and meta-analysis. J Am Coll Cardiol 2010;55:1854–66.
13. Tian NL, Gami SK, Ye F, Zhang JJ, Liu ZZ, Lin S, et al. Angiographic and clinical comparisons of intravascular ultrasound- versus angiography-guided drug-eluting stent implantation for patients with chronic total occlusion lesions: two-year results from a randomised AIR-CTO study. EuroIntervention 2015;10:1409–17.

Keywords: Bioresorbable vascular scaffold, chronic total occlusion, late lumen loss

Anahtar sözcükler: Bioresorbable vascular scaffold; geç lümen kaybı; kronik tam tıkanma.