Bioresorbable vascular scaffolds in the routine clinical practice: long-term results

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ABSTRACT

Introduction and objectives: Recent publications suggest that bioresorbable vascular scaffolds (BVS) are associated with an excess of thrombotic complications. We present the real-world, long-term results of a series of patients who received the Absorb BVS (Abbott Vascular, United States).
Methods: A total of 213 consecutive patients who received at least 1 BVS between May 2012 and December 2016 were analyzed. The main objective of the study was the rate of target vessel failure, a composite endpoint of infarction or target vessel revascularization and cardiac death.
Results: Seventy-five per cent of the patients were men (mean age, 61.4 years). The most common cause for admission was non-ST-elevation myocardial infarction (53.52%). The median follow-up was 44 months [28 months], the rate of the primary endpoint was 6.57% for the first 24 months and 7.98% at the end of the follow-up. Regarding the device, there were 6 cases (2.81%) of thrombosis (definitive, probable or possible) and 10 cases (4.69%) of restenosis. Patients with a past medical history of diabetes mellitus (HR, 1.72; 95%CI, 1.01-2.95; P = .05) and/or chronic oral anticoagulation (HR, 5.71; 95%CI, 1.12-28.94; P = .04) had a higher risk of target vessel failure.
Conclusions: In this series of patients, the rate of target vessel failure was similar to the one previously described by randomized clinical trials. Events were more common during the first 2 years of follow-up and in the presence of greater cardiovascular comorbidity.

Keywords: Absorb. Bioresorbable scaffolds. Coronary angioplasty.

Armazones vasculares bioabsorbibles en la práctica habitual: resultados a largo plazo

RESUMEN

Introducción y objetivos: Las publicaciones sugieren que los armazones vasculares bioabsorbibles (AVB) conllevan un exceso de complicaciones trombóticas. Se describen los resultados en la vida real y a largo plazo de una serie de pacientes a los que se implantó un AVB Absorb (Abbott Vascular, EE.UU.).
Métodos: Se analizaron 213 pacientes consecutivos que recibieron al menos un AVB entre mayo de 2012 y diciembre de 2016. El objetivo principal del estudio fue la incidencia de fracaso del vaso diana, un evento compuesto que incluye infarto de miocardio, revascularización del vaso diana y muerte cardiaca.
Resultados: El 75% de los pacientes eran varones (edad media, 61,4 años). La causa más común de ingreso fue el infarto sin elevación del ST (53,52%). La mediana de seguimiento fue de 44 meses [28 meses]. La incidencia del evento primario fue del 6,57% durante los primeros 24 meses y del 7,98% al final del seguimiento. Respecto al dispositivo, hubo 6 casos (2,81%) de trombosis (definitiva, probable o posible) y 10 casos (4,69%) de reestenosis. Los pacientes con antecedentes de diabetes mellitus (HR = 1,72; IC95%, 1,01-2,95; p = 0,05) o con anticoagulación oral crónica (HR = 5,71; IC95%, 1,12-28,94; p = 0,04) tuvieron mayor riesgo de fracaso del vaso diana.

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Conclusiones: En esta serie de pacientes, la incidencia de fracaso del vaso diana fue comparable a la descrita previamente en ensayos clínicos aleatorizados. Los eventos adversos fueron más frecuentes en los primeros 2 años de seguimiento y en presencia de mayor comorbilidad cardiovascular.

Palabras clave: Absorb. Armazón vascular bioabsorbible. Angioplastia coronaria.

Abbreviations

BVS: bioresorbable vascular scaffold. **AMI:** acute myocardial infarction. **DES:** drug-eluting stent.

INTRODUCTION

Drug-eluting bioresorbable vascular scaffolds (BVS) were initially presented as a technological breakthrough to overcome the limitations and adverse events associated with permanent bare-metal stents, especially the development of neoatherosclerosis that is associated with a risk of thrombosis (0.2% per year) and secondary revascularization (2% to 3% per year).[1-3]

At the time, the implantation of a BVS was an innovative approach to treat coronary atherosclerosis by releasing the artery from a permanent metal jail and restoring the flow architecture. Also, it preserved parietal motility and its response to stimuli generated by coronary flow (shear stress). The Absorb (Abbott Vascular, United States)—a polymer everolimus-eluting scaffold with 157 μm-thick struts—was one of the first ones to be available in Spain and several clinical trials were conducted.[4-8] The excellent initial results led to the widespread use of this device for several clinical indications.[9-10] The Absorb BVS was approved by the U.S. Food and Drug Administration and obtained the CE marking certification in January 2011.[11]

However, the mid- and long-term data of the AIDA research group[12,13] on the Absorb were disappointing. They showed a higher rate of late scaffold thrombosis compared to the XIENCE (Abbott Vascular, United States) (3.5% vs 0.9%; hazard ratio [HR], 3.87; 95% confidence interval [95%CI], 1.78-8.42; $P < .001$), an everolimus-eluting stent (EES).[14,15] Therefore, the manufacturer stopped making the Absorb BVS and removed it from the market according to the European regulatory agency; however, some of these devices remain approved and are still available in Europe.[16]

Since the Absorb BVS was widely used in different clinical settings during market launch more than 7 years ago, the long-term follow-up results are available today. The objective of this study is to describe the incidence of long-term adverse events in a series of patients implanted with the Absorb BVS in different clinical settings of our multicenter registry.[17]

METHODS

Population, design, and definitions

The cases treated with percutaneous transluminal coronary angioplasty with at least 1 Absorb BVS in 3 hospitals between May 2012 and December 2016 were studied.[17] Implantation was performed to the discretion of the operator in charge.

The study primary composite endpoint was the target vessel failure rate, a composite event of target vessel revascularization, target vessel related acute myocardial infarction (AMI), and cardiac death.

The study secondary endpoint was the rate of the overall clinical endpoint including these adverse events: all-cause mortality, myocardial infarction, and all the new coronary revascularizations (including those of the non-target vessel).

The registry of the interventional cardiology unit of our hospital network was periodically reviewed every 6 to 12 months at the follow-up consultation at the interventional cardiology unit by a cardiologist. Also, it was completed through follow-up phone calls.

Statistical analysis

Data regarding quantitative variables are expressed as mean ± standard deviation and qualitative variables are expressed as percentages. Patients were grouped according to whether they had target vessel failure or not; inter-group averages were compared using the Student *t* test. Percentages were compared using the chi-square test. Kaplan-Meier analysis was conducted to estimate the likelihood of target vessel failure-free survival and BVS thrombosis and restenosis. Finally, the multivariate Cox regression analysis was conducted to study the survival function adjusted by different predefined variables: sex, age, cardiovascular risk factors, past medical history, clinical signs, size and length of the BVS implanted, overlapping of, at least, 2 BVSs, and use of intracoronary imaging modalities (optical coherence tomography [OCT] or intravascular ultrasound [IVUS]). Two-tailed $P \le$ values .05 were considered statistically significant in all tests. Data were analyzed using the statistical software package Stata IC 14 (StataCorp, United States).

RESULTS

Study population

Two hundred and thirteen consecutive patients implanted with, at least, 1 Absorb BVS between May 2012 and December 2016 were included. Table 1 shows the baseline clinical characteristics of these patients. Most of the participants were males (75.12%) with a mean age of 61.40 ± 12.74 years, and a high prevalence of dyslipidemia (62.44%) and smoking (65.26%). Diabetes mellitus was present in 23.94% and 21.60% had been previously treated with a percutaneous coronary intervention. The most common clinical presentation during recruitment was non-ST-segment elevation acute coronary syndrome (53.52%).

Index procedure of the bioresorbable vascular scaffold implantation

Table 2 shows the characteristics of the patients' index procedure. Two hundred and thirty-three coronary lesions were treated with

Table 1. Baseline clinical characteristics of patients and differences based on the primary endpoint

Characteristics	Patients who received BVS (n = 213)	Patients with BVS and target vessel failure (n = 17)	Patients with BVS without target vessel failure (n = 196)	P
Age (years)	61.40 ± 12.74	66.71 ± 9.62	61.14 ± 12.98	.07
Sex (male)	160 (75.12)	12 (70.59)	148 (75.51)	.65
Risk factors				
Diabetes mellitus	51 (23.94)	7 (41.18)	44 (22.45)	.06
Hypertension	118 (55.40)	11 (64.71)	107 (54.59)	.42
Dyslipidemia	133 (62.44)	13 (76.47)	120 (61.22)	.21
Active smoking	139 (65.26)	10 (58.82)	129 (65.82)	.56
Past medical history				
Chronic kidney disease	8 (3.76)	1 (5.88)	7 (3.57)	.63
LVEF < 30%	5 (4.5)	1 (5.88)	4 (2.04)	.55
Previous stroke or TIA	9 (4.2)	3 (17.65)	6 (3.06)	.01
Chronic oral anticoagulation	10 (4.69)	3 (17.65)	7 (3.57)	.01
Peripheral vascular disease	13 (6.10)	1 (5.88)	12 (6.12)	.96
Previous myocardial infarction	31 (14.55)	1 (5.88)	30 (15.31)	.29
Previous PCI	46 (21.60)	4 (23.53)	42 (21.43)	.84
Previous coronary artery bypass surgery	7 (3.29)	2 (11.76)	5 (2.55)	.04
Clinical presentation				
STEACS	31 (14.55)	4 (23.53)	27 (13.78)	.25
Non-Q-wave AMI type of NSTEACS	77 (36.15)	6 (35.29)	71 (36.22)	.66
Unstable angina type of SCASEST	37 (17.37)	3 (17.65)	34 (17.35)	.88
Stable angina or documented ischemia	68 (31.4)	4 (23.53)	64 (32.65)	.52

AMI, acute myocardial infarction; BVS, bioresorbable vascular scaffold; LVEF, left ventricular ejection fraction; NSTEACS, non-ST-segment elevation acute coronary syndrome; PCI, percutaneous coronary intervention; STEACS, ST-segment elevation acute coronary syndrome; TIA, transient ischemic attack.
Data are expressed as no. (%) or mean ± standard deviation.

an average 1.3 ± 0.3 lesions per patient. Implantation was successful in 99.5% of the cases but failed in 1 patient due to the difficulty advancing the device across the lesions. The patient required the implantation of a DES, which is why he was excluded from the analysis. Predilatation occurred in 89.3% of the cases and postdilatation in 33.5% of the cases. Intracoronary imaging modalities (OCT or IVUS) were used to optimize the BVS implantation in 86 patients (40.38%).

Clinical follow-up

The median follow-up was 44 months [28 months] with minimum times < 1 month. The primary composite endpoint of target vessel failure rate was 6.57% at the 24-month follow-up (table 3) and 7.98% at the end of the follow-up. Figure 1 shows the target vessel failure-free survival curve; at the 48-month follow-up it was 0.92 (95%CI, 0.87-0.95; P = .02). Regarding the secondary endpoint, the overall rate was 11.74% at the 24-month follow-up (table 3) and 17.84% at the end of the follow-up.

Figure 2 shows the rate of all adverse events depending on the time of clinical presentation. Regarding the primary endpoint, there were 3 (1.41%) cases of cardiac death, 4 (1.87%) cases of target vessel

related AMI, and 14 (6.57%) cases of target vessel revascularization. Regarding the secondary endpoint, there were 7 (3.29%) cases of all-cause mortality, 7 (3,29%) cases of AMI, and 31 (14.56%) cases of any coronary revascularizations. Finally, regarding the device, there were 6 (2.81%) cases of thrombosis (definite, probable, and possible) all reported within the first 12 months. Dual antiplatelet therapy was kept, at least, for 12 months in 157 (73.7%) patients and 1 patient with late definite thrombosis received dual antithrombotic therapy (acenocoumarol and clopidogrel). Similarly, there were 10 (4.69%) cases of BVS restenosis within the first 48 months of follow-up (figure 3).

Patients with target vessel failure had a higher prevalence of cerebrovascular disease (17.65% vs 3.06%; P = 0.01), chronic oral anticoagulation (17.65% vs 3.57%; P = .01), and previous coronary artery bypass graft surgery (11.76% vs 2.55%; P = .04). Similarly, there was a tendency towards a higher prevalence of diabetes mellitus in this group (41.18 vs 22.45%; P = .06) (table 1).

In the multivariate Cox regression analysis, a prior history of diabetes mellitus (HR, 1.72; 95%CI, 1.01-2.95; P = .05) and chronic oral anticoagulation (HR, 5.71; 95%CI, 1.12-28.94; P = .04) were identified as risk factors to develop target vessel failure at the follow-up. On the other hand, the use of intracoronary imaging

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Table 2. Characteristics of the index procedure and treatment

Characteristics	Patients who received BVS (n = 213)
Lesions treated per patient	1.3 ± 0.3
Number of devices per patient	1.2 ± 0.4
Total length of the device per patient (mm)	21.5 ± 13.5
Minimum device diameter per patient (mm)	2.75 ± 0.25
Device implantation	
At least 1 BVS	212 (99.5)
BVS only	204 (95.8)
Overlapping with at least 2 AVBs	20 (9.39)
Any DES	8 (3.8)
After BVS implantation failure	1 (0.5)
Procedural time (min.)	44 ± 23
Iodinated contrast used per procedure (mL)	161 ± 72
Predilatation of the first lesion treated	189 (88.7)
Procedural success	212 (99.5)
Lesions treated	
Total number	233
Predilatation	208 (89.3)
Postdilatation	78 (33.5)
0.5 mm postdilatation balloon plus BVS	21 (9.86)
Overall number of devices implanted	261
Overall number of devices per lesion	1.12 ± 0.4
Intracoronary imaging modality during implantation	
OCT or IVUS	86 (40.38)

BVS, bioresorbable vascular scaffold; DES, drug-eluting stent; IVUS, intravascular ultrasound; OCT, optical coherence tomography.
Data are expressed as no. (%) or mean ± standard deviation.

Table 3. Adverse events at the 2-year follow-up

Adverse event	Patients who received BVS 2-year follow-up (n = 213)
Clinical events	
All-cause mortality	5 (2.34)
Cardiac	3 (1.41)
Non-cardiac	2 (0.94)
All myocardial infarctions	6 (2.82)
During index procedure	2 (0.94)
Not during index procedure	4 (1.88)
Target vessel	3 (1.41)
Non-target vessel	1 (0.47)
Death or myocardial infarction	11 (5.16)
Any revascularization	18 (8.46)
Target vessel	11 (5.16)
Target lesion	11 (5.16)
Device thrombosis	3 (1.41)
Device restenosis	8 (3.76)
Any other vessel	7 (3.29)
Composite endpoint	
Target vessel failure	14 (6.57)
Overall clinical endpoint	25 (11.74)
Device thrombosis	
Definite	3 (1.41)
Probable	2 (0.94)
Possible	1 (0.47)

BVS, bioresorbable vascular scaffold.
Data are expressed as no. (%).

modalities (OCT or IVUS) during BVS implantation showed a clear tendency towards significance as a protective factor (HR, 0.33; 95%CI, 0.10-1.07; P = .06) (table 4).
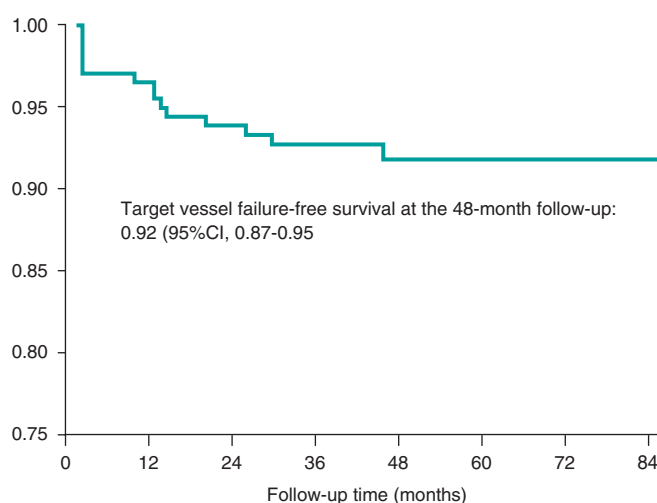
DISCUSSION

This study analyzed a consecutive series of patients who were implanted with, at least, 1 BVS in a high-volume setting and in real-life conditions. The primary composite endpoint of target vessel failure and the overall secondary composite clinical endpoint were similar to what had been reported by other previous randomized clinical trials on percutaneous coronary interventions.[18-22]
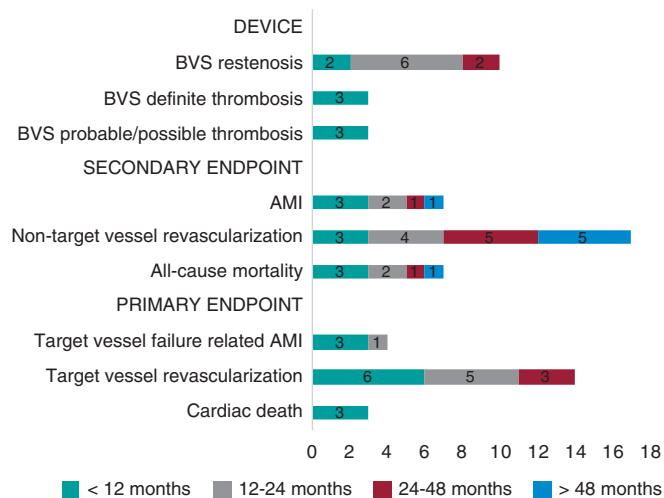
The AIDA clinical trial[20] confirmed the lower rate of target vessel failure related AMI from our series. In our study, the patients' baseline clinical characteristics and clinical presentation were similar to those of the population of the AIDA clinical trial. However, regarding the index procedure, the use of postdilatation was lower in our series. It has been reported that postdilatation

Figure 1. Kaplan-Meier survival curve for target vessel failure.

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Figure 2. Chart of adverse events based on the time of presentation after the index procedure. AMI, acute myocardial infarction; BVS, bioresorbable vascular scaffold.
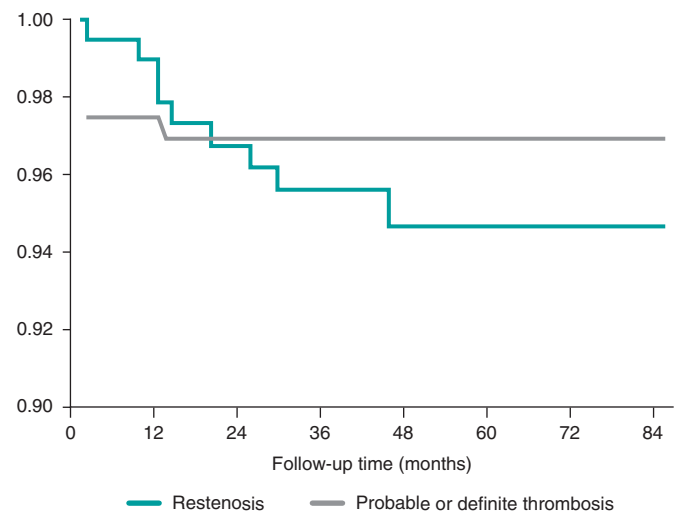
Figure 3. Kaplan-Meier survival curves for bioresorbable vascular scaffold restenosis and thrombosis.

Table 4. Factors associated with target vessel failure: Cox regression analysis

	Univariate analysis			Multivariate analysis		
	HR	95%CI	*P*	HR	95%CI	*P*
Past medical history						
Diabetes mellitus	1.72	1.04-2.86	.04	1.72	1.01-2.95	.05
Previous stroke or TIA	6.28	1.76-22.31	.01	1.94	0.40-9.23	.40
Chronic oral anticoagulation	5.34	1.51-18.97	.01	5.71	1.12-28.95	.04
Use of intracoronary imaging modalities during implantation						
OCT or IVUS	0.32	0.11-1.03	.06	0.33	0.10-1.06	.06

95%CI, 95% confidence interval; HR, hazard ratio; IVUS, intravascular ultrasound; OCT, optical coherence tomography; TIA, transient ischemic attack.

does not bring any additional benefits to the implantation of a BVS in the ST-segment elevation acute coronary syndrome clinical setting. If elevation is excessive it could even have deleterious effects when destructuring or tearing the nonmetallic structure of the scaffold.[23] The GHOST-EU registry[24] proved that the PSP strategy (predilatation, scaffold sizing, and postdilatation) was a predictor of cardiovascular events.

The right selection of the lesion plays a crucial role in the clinical performance of BVS. Most of the patients of this series showed acute coronary syndrome. It is feasible that patients with AMI may benefit the most from BVS treatments.[18] First, patients with acute coronary syndrome (with or without ST-segment elevation) often show a visible thrombus in the proximal segments and a less complex morphology with thin-cap fibroatheroma plaques and fewer calcified lesions. Secondly, aggressive antithrombotic therapy after an acute coronary syndrome may mitigate the rate of thrombotic complications.

Bioresorbable vascular scaffold thrombosis

A few studies have reported on a higher rate of BVS thrombosis associated with next-generation DESs,[25,26] especially all in off-label uses.[27] In our series, the definite or probable device thrombosis

occurred in a similar percentage of the patients to that previously reported.[12] Several mechanisms that may explain BVS thrombosis have been suggested including edge dissection, strut fracture, malapposition, and inadequate BVS sizing.[28] In our series there were 2 cases of subacute definite thrombosis. In the coronary angiography, the OCT performed confirmed the presence of some structural mechanism (underexpansion or malapposition) that favored it. Early presentation at the follow-up is consistent with what has already been reported.[29]

Similarly, we identified that the use of intracoronary imaging modalities (OCT or IVUS) during BVS implantation showed a clear tendency towards significance as a protective factor of target vessel failure as Caixeta et al.[30] had already confirmed in an international registry of 1933 patients. The recommendation here is to use intracoronary imaging modalities to optimize implantation and secure the correct apposition of the BVS, lack of underexpansion, and proper cover of the lesion.[31]

The main setback of the Absorb BVS is probably strut thickness and width (157 x 190.5 μm in 2.5 mm and 3.0 mm BVSs, and 157 μm x 216 μm in 3.5 mm BVSs), which can make the device more thrombogenic, especially when apposition is not the right one or expansion is incomplete. Today, ultra-thin drug-eluting stents (strut thickness < 70 μm) have lowered the risk of target lesion failure

to just 1 year compared to modern second-generation DESs thanks to fewer AMIs and stent thrombosis.[32] On this issue, the sirolimus-eluting MeRes100 BVS (Meril Life Sciences Pvt. Ltd., India) with thinner strut thickness (100 µm) confirmed the sustained efficacy and safety profile at the 2- and 3-year follow-up.[33]

Resistance to antiplatelet therapy can also be an important cause for BVS thrombosis.[34] Both acetylsalicylic acid and clopidogrel are effective antiplatelet drugs for the secondary prevention of cardiovascular events. Still their clinical efficacy varies from one individual to the next.[35] In our series, most of the patients remained on dual antiplatelet therapy for, at least, 12 months and there was 1 case of late thrombosis with dual antithrombotic therapy (acenocoumarol and clopidogrel). Due to his high bleeding risk, this last patient received dual antiplatelet therapy for the first 3 months; we do not know the international normalized ratio when the complication occurred, which is why the possibility of antiplatelet drug resistance cannot be discarded. However, the potential association between the BVS thrombosis and oral antiplatelet therapy had already been described.[36] We know that the selection of duration of antiplatelet therapy following the implantation of the Absorb BVS was difficult,[37] especially in anticoagulated patients because they are a population with comorbidities and high cardiovascular risk. Our data show that the implantation of the Absorb BVS in patients at high bleeding risk (including anticoagulated patients) shouldn't probably be recommended according to the consensus document reached by the European Society of Cardiology and the European Association for Cardio-Thoracic Surgery. This document does not recommend the use of the Absorb BVS in patients intolerant to prolonged dual antiplatelet therapy or who require oral anticoagulation.[16]

Bioresorbable vascular scaffold restenosis

The most common cause for target lesion revascularization was stent restenosis within the first 48 months of follow-up. The mechanisms involved in bioresorbable vascular scaffold restenosis that may occur in the same patient are varied.[38,39] The less intrinsic radial strength and its possible destructuring with an aggressive implantation may explain some of the early recurrences. In this study, aggressive implantation was less common since postdilatation with an up to 0.5 mm balloon combined with BVS implantation occurred in 9.86% of the cases. Also, postdilatation was not associated with restenosis at the follow-up. Also, it has been suggested that the slow resorption of the study device may have been associated with a significant spatial abnormality with loss of alignment of its structural elements, which favors restenosis.[40,41] The complete disappearance of the BVS from the vascular wall won't happen for another 3 years[6] and most cases of scaffold restenosis occurred within the first 2 years of follow-up.

Our study results show that there is a correlation between the history of diabetes mellitus and chronic oral anticoagulation and the development of target vessel failure. It is well-known that this past medical history elevates cardiovascular morbimortality and that the CHADS2 and CHA2DS2-VASc scores can be used to estimate the risk of adverse clinical events in patients with acute coronary syndrome.[42] In this sense, patients with a past medical history of diabetes mellitus, chronic oral anticoagulation, and coronary artery disease start with CHA2DS2-VASc scores of 4, that is, high risk of adverse clinical events.

Limitations

Selection bias was inevitable because, according to the operator's criterion, the clinical assessment that may have influenced the decision to implant a BVS maybe did not come from the database, which is a common problem with observational studies like this one. However, the study shows a pragmatic approach to the use of this device in the real world.

CONCLUSIONS

In this series of patients implanted with the Absorb BVS, the composite endpoint of target vessel failure and the overall clinical composite endpoint were similar to what had already been reported by randomized clinical trials. Adverse events were more common within the first 2 years of follow-up in case of greater cardiovascular comorbidity and without intracoronary imaging modalities (OCT or IVUS) during implantation. Although the BVS studied is not available anymore there other bioresorbable devices are in the pipeline.[16]

FUNDING

CONFLICTS OF INTEREST

The authors declared no conflicts of interest whatsoever.

WHAT IS KNOWN ABOUT THE TOPIC?

- The implantation of a BVS is an innovative approach for the management of coronary atherosclerosis because it releases the coronary artery from a permanent metallic jail and restores the vessel architecture.

- However, the Absorb BVS has a higher rate of thrombotic complications compared to modern DESs, which is why it was removed.

WHAT DOES THIS STUDY ADD?

- In our interventional cardiology network, the implantation of the Absorb BVS showed rates of target vessel failure that were similar to those previously described by randomized clinical trials.

- Target vessel failure occurred basically within the first 24 months in patients with diabetes mellitus or chronic oral anticoagulation. The use of intracoronary imaging modalities during implantation showed a tendency towards becoming a protective factor.

- Our results will contribute to the proper selection of patients eligible for BVS implantation and to the implantation technique as well.

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