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Original article

Bioresorbable Vascular Scaffold for the Treatment of Coronary Bifurcation Lesions: Immediate Results and 1-year Follow-up

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ABSTRACT

Introduction and objectives: The treatment of coronary lesions with a bioresorbable vascular scaffold has been shown to be effective. However there is little information about its use in bifurcations. The aim of this study was to analyze the safety and efficacy of the bioresorbable scaffold in the treatment of coronary bifurcation lesions.

Methods: From January 2012 to January 2015, we used a bioresorbable vascular scaffold to treat 194 patients with 230 bifurcation lesions. The scaffold geometry was examined by intracoronary imaging techniques in 145 bifurcations (65%). In all, 78% of the bifurcations were evaluated angiographically during follow-up (computed tomography angiography in 138 and coronary angiography in 41).

Results: The most common clinical presentation was acute coronary syndrome (81%). The most frequent type of bifurcation was 1,1,1 (34%). A simple approach was the chosen strategy in 221 bifurcations (96%). In 90 of these lesions, the side branch was postdilated through the cells of the platform and, in 3 cases, strut fractures were observed in optical coherence tomography. Procedural success was achieved in all patients. There was 1 case of subacute thrombosis and 1 sudden cardiac death during the first month. The duration of angiographic follow-up was 7.3 ± 1.6 months and that of clinical follow-up, 14 ± 6 months. Twelve (5%) restenoses were documented and revascularized. During follow-up, 2 patients (1%) had an infarction in another territory and another 2 patients (1%) died; the remaining patients had a symptom-free follow-up. The incidence of thrombosis was 1.3%.

Conclusions: Treatment of bifurcation coronary lesions using a provisional approach is feasible and safe, with a low rate of adverse events.

Tratamiento de lesiones en bifurcaciones coronarias con armazón vascular bioabsorbible. Resultados inmediatos y al año de seguimiento

Palabras clave:
Stent bioabsorbible
Lesiones en bifurcación
Intervención coronaria percutánea

RESUMEN

Introducción y objetivos: El tratamiento de lesiones coronarias con armazón vascular bioabsorbible ha demostrado ser eficaz. Hay poca información sobre su uso en bifurcaciones. El objetivo de este estudio es analizar la seguridad y la eficacia de esta plataforma en el tratamiento de bifurcaciones coronarias.

Métodos: Desde enero de 2012 hasta enero de 2015, se trató con plataforma bioabsorbible a 194 pacientes con 230 lesiones en bifurcaciones coronarias. Se analizó con técnicas de imagen intracoronaria la geometría de 145 bifurcaciones (63%). El 78% de las lesiones se revaluaron angiográficamente (por tomografía computarizada, 138; por coronariografía, 41).

Resultados: La presentación clínica más habitual fue un síndrome coronario agudo (81%). El tipo de bifurcación más frecuente (34%) fue la 1,1,1. La estrategia simple fue de elección en 221 lesiones (96%). En 90 lesiones se posdilató la rama lateral a través de las celdillas, y por tomografía de coherencia óptica se observó fractura del dispositivo en 3 casos. Se obtuvo éxito del procedimiento en todos los pacientes. En el primer mes se documentó 1 trombosis subaguda y 1 muerte súbita. El tiempo de seguimiento angiográfico fue de 7,3 ± 1,6 meses y el del seguimiento clínico, 14 ± 6 meses. Se observaron 12 restenosis (5%). Durante el seguimiento, 2 pacientes (1%) tuvieron un infarto en otro territorio y otros 2 fallecieron (1%); los demás quedaron libres de síntomas. La tasa de trombosis fue del 1,3%.

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Conclusiones: El tratamiento de lesiones en bifurcaciones coronarias con armazón vascular bioabsorbible provisional es seguro y eficaz. Al seguimiento, había una tasa de eventos adversos baja.

Abbreviations

BVS: bioresorbable vascular scaffold
MV: main vessel
SB: side branch
SI: symmetry index
TLR: target lesion revascularization

INTRODUCTION

Treatment of coronary lesions using an everolimus-eluting bioresorbable vascular scaffold (BVS) (Absorb, Abbott Vascular; Santa Clara, California, United States) has been shown to be effective, with promising immediate and long-term results.[1–3] After its implantation, a process of hydrolysis commences that leads to the reabsorption of the platform, which may confer potential advantages over the new generations of bare metal stents. However, because of its distinctive features, the use of this new platform in bifurcations is still controversial. Coverage of the large branches by struts that are much thicker than bare metal stents is a cause for concern, as the formation of a neocarina following the resorption process has been reported.[4] On the other hand, given the features of the BVS, balloon dilatation through its cells can place the integrity of the platform at risk. For these reasons, bifurcation lesions were excluded from the initial clinical trials. Thus, there is little information on the use of Absorb in this scenario.[5,6] The purpose of this study was to evaluate the safety and efficacy of the BVS in lesions involving a coronary bifurcation and to analyze the changes produced in the platform geometry upon postdilatation of the side branch.

METHODS

In vitro tests with Absorb

The BVS struts are 157-μm thick and the crowns are joined together by 3 connectors. The potential expansion diameter of the cells is 3 mm for the platforms measuring 2.5 mm and 3 mm in diameter, and 3.6 mm for the 3.5-mm platform. Before undertaking our study of BVS in bifurcations, we performed a series of *in vitro* studies to analyze the behavior of the expanded platform after carrying out different postdilatation maneuvers through its cells. All the tests were carried out with the device submerged in serum at body temperature after it had been expanded at 14 atmospheres.

Patients

From January 2012 to January 2015, we used BVS to treat 556 patients with coronary artery disease who had 680 significant lesions. From this registry, we selected a sample of 194 patients who had been treated for 230 bifurcation lesions. During this same period of time, we treated 775 bifurcations with bare metal stents. We selected those lesions in which the proximal reference diameter was $\leq$ 4 mm and that of the side branch (SB) was $\geq$ 2 mm. We excluded patients older than 70 years, those with cardiogenic shock, and those who were unable to receive dual antiplatelet therapy for 1 year. Bifurcations with severe calcification documented on angiography were also excluded. In those cases in which maneuvers were performed for the postdilatation of the SB through the cells of the BVS, the platform geometry was analyzed by intravascular ultrasound or optical coherence tomography. After the procedure, serial creatine kinase and troponin determinations were carried out. Periprocedural myocardial infarction was defined in accordance with the latest consensus document from the Society for Cardiovascular Angiography and Interventions[7] and, for the definition of thrombosis, we followed the criteria of the Academic Research Consortium[8]. All the patients underwent clinical follow-up either at the hospital or by telephone. Computed tomography angiography was scheduled for at least 6 months after treatment to analyze the segment in which the BVS had been implanted. In contrast to bare metal stents, plastic is radiolucent and allows a detailed study of the lumenogram of the segment with the scaffold, which is indicated by the proximal and distal platinum markers. Coronary angiography was also performed when there were signs of clinical disease. We considered major adverse cardiovascular events during follow-up to include death, myocardial infarction, and target lesion revascularization (TLR).

Cardiac Catheterization and Implantation of the Bioresorbable Vascular Scaffold

Informed consent was obtained from all patients. The procedure involved the femoral approach and the use of 7 Fr or 8 Fr guide catheters. The decision to dilate the lesion or not prior to BVS was left to the operator's discretion.[9] The diameter of the Absorb scaffold system depended on the reference diameter proximal to the lesion. The strategy for gaining access to the lesion did not differ from that established after our experience with bare metal stents, and provisional BVS predominated. When subsequent dilatations were required, noncompliant balloons were used, the diameter of which never exceeded that of the BVS by more than 0.5 mm. Postdilatation of the device was performed when incomplete expansion of the BVS balloon was observed, or when intracoronary imaging studies showed, at the level of the minimal lumen area, a reduction in the area greater than 30% with respect to the point of maximum expansion. The procedure was considered to be successful when residual stenosis was less than 30% at the level of the BVS and, at the level of the SB, when a Thrombolysis In Myocardial Infarction grade 3 flow and a residual stenosis $\leq$ 50% was achieved. Angiographic measurements were obtained using the MEDIS system (CMS [Coronary Measurement System] 7.1, MEDIS; Leiden, The Netherlands), and were carried out off-line by an expert interventional cardiologist at the end of each procedure.

Intravascular Ultrasound

In 32 cases in which the platform was postdilated with the kissing balloon technique, an ultrasound study was carried out (Atlantis SR 2.5 Fr, 40 MHz, Boston Scientific; Natick, Massachusetts, United