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"Assessment of effectiveness and security in high pressure postdilatation of bioresorbable vascular scaffolds during percutaneous coronary intervention. Study in a contemporary, non-selected cohort of Spanish patients"

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ABSTRACT

Objectives: To determine security and benefits of high pressure postdilatation (HPP) of bioresorbable vascular scaffolds (BVS) in percutaneous coronary intervention (PCI) of complex lesions whatever its indication is.
Background: Acute scaffold disruption has been proposed as the main limitation of BVS when they are overexpanded. However, clinical implications of this disarray are not yet clear and more evidence is needed.
Methods: A total of 25 BVS were deployed during PCI of 14 complex lesions after mandatory predilatation. In all cases HPP was performed with NC balloon in a 1:1 relation to the artery. After that, optical coherence tomography (OCT) analyses were performed.
Results: Mean and maximal postdilatation pressure were 17 ± 3.80 and 20 atmospheres (atm) respectively. Postdilatation balloon/scaffold diameter ratio was 1.01.
A total of 39,590 struts were analyzed. Mean, minimal and maximal scaffold diameter were respectively: 3.09 ± 0.34 mm, 2.88 ± 0.31 mm and 3.31 ± 0.40 mm. Mean eccentricity index was 0.13 ± 0.05. ISA percentage was 1.42% with a total of 564 malapposed struts. 89 struts were identified as disrupted, which represents a percentage of disrupted struts of 0.22%.
At 30 days, none of our patients died, suffered from stroke, stent thrombosis or needed target lesion revascularization (TLR).
Conclusions: NC balloon HPP of BVS at more than 17 atm (up to 20 atm) is safe during PCI and allows to achieve better angiographic and clinical results.

1. Introduction

New bioresorbable scaffold technology has become the great revolution in interventional cardiology. These scaffolds consist on a polymeric backbone of poly-L-lactic acid which is coated by another polymeric layer in which is embedded the antiproliferative drug. They offer all the benefits of a DES in addition to a great advantage: by two years after their implantation, the scaffolds are not more present in the coronary artery [1]. Furthermore, the artery can recover its vasomotility and compliance. Nevertheless, one limitation has been proposed for these devices: they are at risk of disruption when they are overexpanded. Clinical implications of this disarray are not yet clear.

2. Methods

2.1. Patient population

In this all-comers prospective study we included fourteen patients admitted to our centre for percutaneous coronary intervention (PCI)

Abbreviations: PTCA, percutaneous transluminal coronary angioplasty; DES, drug-eluting metallic stents; BVS, bioresorbable vascular scaffold; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; TLR, target lesion revascularization; DAPT, dual antiplatelet treatment; NC balloon, non-compliant balloon; ISA, incomplete strut apposition; LLL, late luminal loss.

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from June to December 2015. A total number of 14 lesions were treated with 25 bioresorbable vascular scaffolds (BVS) deployed.

Each patient must has been treated with a minimum of one BVS, independently of what the indication for coronary revascularization was. In fact, PCI is accepted either in the setting of an acute coronary syndrome (with or without ST segment elevation) or in stable coronary artery disease.

We report baseline clinical and angiographic characteristics of the 14 patients (14 lesions treated) in addition to OCT baseline analyses of the 25 BVS deployed. Moreover, all patients have undergone a 30-day clinical follow up, and half of them have also been interviewed three months after intervention.

Regarding to anatomical lesions characteristics, we only excluded lesions when minimum vessel diameter was less than 2 mm or when maximum vessel diameter exceeded 4 mm. Other exclusion criteria include: heparin or aspirin intolerance, high risk of bleeding (patients under chronic anticoagulation treatment, with previous history of life-threatening bleeding or with coagulation diseases), patients expected not to be able to maintain long dual antiplatelet treatment(DAPT) and terminal disease with life-expectancy less than a year.

2.2. Devices and optical coherence tomography

In our study we only used the Abbot bioresorbable scaffold (Abbott Vascular, Santa Clara, California): the Absorb 1.1 BVS. This device consists on a polymeric backbone of poly-L-lactic acid which is coated by another polymeric layer. This external layer is the one which supports and controls the everolimus eluting process. The scaffold is available in different diameters (2.5, 3.0, 3.5 mm) and lengths (15, 18, 23 and 28 mm), and we have chosen the most appropriate ones according to each lesion characteristics. Radial tension of this bioresorbable device is comparable to previously described radial tension in most bare metal stents. Its strut thickness has been quantified in 156 μm and its mean contact area with the vessel is 25% [1].

Intravascular imaging evaluation has been performed by a frequency-domain OCT analysis. We used the Lunawave Coronary imaging console® (Terumo Corp., Tokyo, Japan) and the FastView Catheter®(Terumo Corp. Tokyo, Japan). This catheter is advanced distally to the scaffold area at least 5 mm and then, it is automatically pulled back with simultaneous infusion of 4–10 mL of iodinated contrast at a rate of 3-5 ml/s. In very large stented artery segments, consecutive pullbacks can be performed in order to allow an adequate assessment of the treated segment. We performed the pullback at a 20 mm/s speed. In each pullback the achieved frame rate was 160 frames /sec.

2.3. Procedure

Scaffold size was selected according to visual and QCA assessment and, if more than one scaffold were needed, they must be implanted overlapping. According to current recommendations, all lesions must be predilatated with semicompliant balloons before scaffold deployment. In addition to this, all devices were postdilatated at high pressure with a non-compliant (NC) balloon in a 1:1 relationship. In our cathlab two brands of non-compliant balloons are available: Open NC® super High Pressure PTCA balloon Sismedical AG Winterthur Switzerland and NC Trek® Coronary Dilatation Catheter Abbott Vascular Sta. Clara California. A minimum pressure of, at least, 10 and 12 atm were used to achieve minimum diameter of each balloon. Maximal expected diameter for 3 mm and 3.5 mm Open NC balloon were 3.36 mm and 3.78, maximal expected diameter for 3 and 3.5 mm NC Trek balloon were 3.21 and 3.78 mm respectively. Election of posdilatation balloon was defined by its availability at the moment of the PCI. After that, OCT analyses were performed as it was explained above.

In our study we enrolled patients with indication of PCI either in the setting of an acute coronary syndrome or for chronic coronary artery disease. Primary PCI was performed by an on-call group of interventional cardiologists, according to current guidelines. Thrombus aspiration was not mandatory in all culprit lesions and GP IIbIIIA inhibitors could be used in a bail-out indication.

All percutaneous coronary interventions have been performed under unfractioned heparin treatment. At discharge, dual antiplatelet therapy was mandatory with aspirin and a P2Y12 inhibitor (ticagrelor, prasugrel or clopidogrel). Of note, in line with current guidelines, new generation P2Y12 inhibitors should be used after PCI in acute coronary syndrome.

2.4. OCT offline analysis

The OCT analysis was performed with the off-line software provided by Terumo® (Terumo Corp., Tokyo, Japan). We measured 1 mm distally and proximally out of the stented vessel segment, and the total scaffolded segment. Each millimeter of the pullback contains 8 frames.

In the 1 mm proximal and distal to the BVS edge we measured for each frame: lumen and vessel area and diameter. These data allowed us to calculate mean lumen and vessel area and mean, maximum and minimum lumen and vessel diameters.

For each frame along the scaffolded segment of the vessel, we measured all parameters mentioned above, in addition to scaffold area and diameter.

Automatically, Terumo software provided us plaque area, maximum and minimum plaque thickness and eccentricity index. OCT baseline analysis has been done according to previous literature [2–5] in offline setting. We defined lumen area as delimitated by the endoluminal surface of the struts. In case of malapposed struts were present, at that angular section of the vessel, lumen area would be delimitated by the endoluminal wall of the vessel. Scaffold area was measured thanks to the circumference formed by the points in the middle of the black core of each strut. Vessel area has been described based on the circumference marked by external elastic membrane. In those cases where this membrane was not so clear in first pullback, we performed additional pullbacks until its correct visualization. Incomplete strut apposition (ISA) was considered when axial distance between the abluminal surface of struts and the endoluminal surface of the vessel wall was larger than strut thickness (in our case: 156 μm) [6].

Acute scaffold disruption was diagnosed when two struts were in the same angular sector of the lumen either if they were in contact ("stacked struts", Fig. 1) or if they were one above the other but with a space between them ("overhung struts"). In addition to this, isolated malapposed struts (Fig. 2) were also considered as a mark of scaffold disruption when they were alone in lumen, with no connection with the stent circumference [7,8].

Thanks to all previous data we calculate all the following parameters: percentage of ISA (defined as the percentage of malapposed struts from the total of struts) [6] and percentage of disrupted struts from the total number of struts.

2.5. Study endpoints

Primary endpoint: to determine the percentage of disrupted struts after postdilatation of a BVS in percutaneous coronary intervention (PCI).

Secondary endpoints: to determine the percentage of malapposed struts after postdilatation, and rates of mortality, stroke or target lesion revascularization (TLR) at 30 days.

2.6. Statistical analyses

In this report we include results from both strut-level and lesion-level analyses. Continuous variables were expressed as mean and standard deviation while categorical variables are presented as a