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Hybrid metal/scaffold-jacket versus full-metal jackets in left anterior descending coronary artery diffuse disease: Differences in radiation exposure and fluoroscopic/procedural times☆

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ABSTRACT

Background/purpose: Bioabsorbable vascular scaffolds (BVS) are made from a radiolucent material. Their multiple implantations on a single long diffused segment requires a specific technique with imaging magnification, which could cause an increase in dose delivered during percutaneous coronary intervention (PCI) procedure. We aimed to identify differences in radiation dose, fluoroscopy and procedural times in Hybrid DES+ multiple BVS (Absorb, Abbott Inc., USA) implantation (hybrid metal/scaffold jacket) versus multiple III generation Drug-eluting stents (DES) (full-metal jacket) in patients with long and diffuse coronary artery disease of the left anterior descending (LAD) coronary artery.

Methods/materials: Patients with long and diffuse LAD disease were enrolled in a registry from 1st February 2015 to 1st February 2017. Patients treated with hybrid DES/BVS (at least three) jacket ($n = 72$ procedure) were compared with a 2:1 matched cohort of exclusive multiple overlapped DES (full-metal jacket) patients in the same period ($n = 114$ procedures).

Results: Patients had similar baseline characteristics due to matching. Radiation exposure (6035.7 ± 2846.8 vs 4251.1 ± 1787.3 cGy $*$ cm^2, $p < 0.0001$, $\Delta = 1784.5 \pm 1055.6$), fluoroscopy time ($16.2 \pm 4.5$ vs 9.1 ± 2.4, $p < 0.0001$) and procedure time (64.2 ± 18.5 vs $5\ 8.7 \pm 13.5$, $p = 0.02$) were higher in patients treated using hybrid metal/scaffold jacket compared that regular full-metal jacket.

Conclusion: The use of hybrid metal/scaffold jacket for the treatment of long and diffuse disease of LAD is associated with a higher fluoroscopy time and radiation exposure compared to full-metal jacket, quantifiable in approximately 35%.

1. Introduction

Over the last years, bioresorbable scaffolds (BRS) and particularly the everolimus-eluting Absorb Bioresorbable vascular scaffold (BVS) (Abbott Vascular, Santa Clara, CA, USA) have suggested to have the potential to drastically improve the interventional approach to coronary artery disease (CAD) [1]. Despite several improvements in both the design and technology of drug-eluting stents (DES) and related improvement in long-term outcome of CAD patients, the implantation of full metal jacket stents remains associated with some limitations [2]. Indeed, the prolonged contact with a metallic or polymeric foreign material can stimulate both inflammatory and thrombotic reactions, accelerating the neoatherosclerosis process and the subsequent risk of in-stent restenosis (ISR) [3]. In this setting, BVS are becoming a very promising alternative to DES in CAD patients, thanks to their property of "leaving nothing behind". This aspect seems to be very helpful especially in the treatment of diffuse disease of left descending coronary artery (LAD) unsuitable for surgical treatment. However, the implantation of a single or overlapped BVSs needs very careful lesion preparation and implantation which may be associated with a longer procedural time and maybe a subsequent increased x-ray exposure when compared to DES. Doubtless, the assessment of advantages and disadvantages, not

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only from an interventional point of view, but also in terms of radiations use in fundamental to ensure a net benefit for patients. However, data about this issue in current medical literature are scant. In the present manuscript, we sought to evaluate the influence of a hybrid DES+ multiple BVS implantation (hybrid metal/scaffold jacket) on radiation exposure compared to multiple drug-eluting stents (DES) (full-metal jacket) in daily clinical practice.

2. Material and methods

2.1. Study design

Between the 1st February 2015 and 1st February 2017, we prospectively enrolled patients undergoing percutaneous coronary intervention (PCI) due the presence of a long, diffuse and hemodynamically significant disease of the LAD which was unsuitable for cardiac surgery.

Patients treated using a drug eluting stent (Promus Premiere, Boston Scientific, Galway, Ireland) at the LAD-D bifurcation plus multiple BVS (Absorb, Abbot Vascular, Santa Clara, CA, USA) for the mid and distal portion of the LAD were compared with a 2:1 matched cohort (n = 114) of exclusive DES-treated patients, with the same extent of CAD, in the same period. Demographics, cardiovascular risk factors, Canadian Cardiovascular Score Class and angiographic characteristics (number of endovascular lesions and severity according to the SYNTAX score) were analyzed by a Heart team composed by an interventional cardiologist, a clinical cardiologist and the referral cardiac surgeon. Exclusion criteria for full-scaffold jacket were: age > 60 year-old, acute myocardial infarction of the indexed vessel, left main stenosis > 50%, diameter of mid-distal portion < 2.25 mm after nitro-glycerine coronary injection (200 μg), severe calcification of the mid-distal portion of the LAD not amenable to adequate lesion preparation, life-expectance less than 2 years and clinical comorbidities which did not allow an adequate double antiplatelet regimen for 12-month after the interventional procedure. All patients signed the informed consent and the Department board Committee approved the study.

3. PCI protocol

All patients received an intravascular ultrasound (IVUS) evaluation of the LAD diameter and lesion length by pre-dilation using non-compliant balloons (Sprinter NC or Euphora, Medtronic, Minneapolis, MN, USA). The BVS or DES size was subsequently selected based on IVUS findings with a 1:1 ratio at nominal atmospheres (atm) with increasing pressure until the rated burst pressure was reached or until the residual stenosis by QCA was less than 10%. BVS patients subsequently received a post dilation of BVS with non-compliant balloons not exceeding 0.5 mm of the scaffold diameter at 20 atm while DES patients received a post-dilatation with non-compliant balloons of diameter up to 1.5 mm exceeding the stent diameter. Finally, patients of both groups were evaluated another time with IVUS and an eventual further post-dilatation with non-compliant balloons not exceeding 0.5 mm of the scaffold diameter at 20 atm could be performed until a residual stenosis of less than 10% was obtained or if a strut malposition was observed. Angiographic success was defined as a residual stenosis < 20% by visual analysis in the presence of a Thrombolysis in Myocardial Infarction (TIMI) 3 flow grade. The treatment of LAD-D site was performed according the European Bifurcation Club recommendations [5]. During PCI, patients were anticoagulated with unfractionated heparin (a bolus of 40 U/kg and additional heparin to achieve an activated clotting time of 250–300 s). A twelve-month Prasugrel or Ticagrerol treatment and the use of aspirin lifelong were recommended.

4. LAD anatomy

The LAD was divided into the following segments for the stents implantation:

a. LAD-D: LAD proximal + 10 mm distally from the first diagonal branch with diameter > 2 mm.
b. LAD II 10: mm distally to the first diagonal branch with diameter > 2 mm from the exit of the vessel from the sulcus arteriosus
c. LAD III: from the sulcus to the apex.

5. Overlapping technique

5.1. Hybrid strategy

As we previously described [4], we adopted a modified overlapping technique, called edge-to-edge technique, to possibly minimize the ISR rate or thrombosis in the short-term. More specifically, the balloon of the BVS was lined up not with the deployed scaffold marker beads, which should result in a 1 mm overlapping (standard overlapping), but at the edge of the deployed scaffold marker beads, which should result in less than 1 mm (minimal overlapping) or no overlapping (edge-to-edge). Conversely, the overlapping between DES and BVS was performed:

a) Lining-up the balloon marker of the implanting DES with the second marker beads of the deployed scaffold in scaffolds 3.5 mm, in whom the marker is placed 1.4 mm inside from the outer edge proximally, which should result in less than 1 mm or no overlapping;
b) Lining-up the balloon of the implanting DES with the edge of the deployed scaffold marker beads in scaffold 2.5–3.0 mm inside from the outer edge proximally, which should result in less than 1 mm or no overlapping.

5.2. DES strategy

Mutiple DES implantation has been performed using standard overlapping technique with maximum 1 mm overlapping using routine DES of the operator's choice (Promus Premier, Boston Scientific, Galway, Ireland; Orsiro, Biotronik, Bulack, Switzerland; Resolute Integrity, Medtronic Inc., Galway, Ireland).

6. IVUS protocol

Intravascular ultrasound examination was performed using the 3F Opticross coronary IVUS catheter (Boston Scientific, Fremont, CA, USA) and automatic pull-back system (0.5 mm/s). On-line ultrasound assessment was performed in diastole. IVUS images were recorded after the administration of 100–200 mg of nytroglycerin. The ultrasound catheter was advanced 0.5 mm beyond the lesion/stent and was pull back to a point 0.5 mm proximal the lesion/stent using monitorized transducer pullback at 0.5 mm/s. The lumen cross sectional area (CSA) at the interface of the blood and the stent, at multiple levels (at least three) and the smallest area was chosen. The proximal and distal reference lumen areas, diameters were also measured by manual planimetry. To reduce the variability, all IVUS measurements were repeated, and the average of two values was used in the analysis. Routine measurements were recorded pre- and post-stent implantation.

7. Radiological protocol and radiation exposure

All the procedures have been performed using the GE Medical System Innova 3100 20″-20″ Flat Panel in all cases. An estimation of the effective dose has been obtained from the measurements of the dose-area product (DAP), which is a measure of stochastic risk and correlates very well with peak skin dose for the posterior-anterior and lateral exposures [6–7].

In all patients low detail of the image at 12.5 image/s has been used. In hybrid metal/scaffold jacket, maximum magnification of the image for at maximum 5 s has been used to properly line up the markers. No particular magnification has been used during full-metal jacket procedure. The radiation exposure of patients treated with hybrid metal/scaffold jacket or with full-metal jacket was measured using dose area product (DAP)

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