Successful treatment of recurrent carotid in-stent restenosis and drug-eluting balloon failure with a coronary bioresorbable vascular scaffold: A case report

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A B S T R A C T

INTRODUCTION: Carotid in-stent restenosis is associated with substantial risk of recurrent restenosis, even after drug-eluting balloon usage.

PRESENTATION OF CASE: We hereby report the case of a patient with recurrent carotid in-stent restenosis and drug-eluting balloon failure treated with a coronary bioresorbable vascular scaffold, achieving a satisfactory acute and long-term result, as disclosed by duplex ultrasound scan performed more than 1 year after the procedure.

DISCUSSION/CONCLUSION: While awaiting for external validation, this clinical vignette supports expanding the armamentarium of endovascular specialists focusing on carotid artery disease, while providing further proof of the safety and efficacy of current bioresorbable vascular scaffolds.

1. Introduction

Carotid artery stenting has become an established alternative to endarterectomy in the management of patients with significant carotid artery disease [1–4]. Despite remarkable improvements in technology, techniques, and ancillary medical therapy, complications and adverse events may still occur. In particular, in-stent carotid restenosis, while relatively uncommon, remains a challenging condition [2,5,6]. To date, a number of treatments for carotid in-stent restenosis have been proposed, with heterogeneous outcomes. The most favorable data, in terms of safety and efficacy, have been reported for drug-eluting balloons [2–9]. However, it remains unclear how to address recurrent restenosis despite prior drug-eluting balloon dilation. We hereby report the clinical vignette of a patient with recurrent carotid in-stent restenosis despite prior use of a drug-eluting balloon with a coronary bioresorbable vascular scaffold. This case may expand the armamentarium of endovascular specialists focusing on carotid artery disease, while providing further proof of the safety and efficacy of current bioresorbable vascular scaffolds.

2. Presentation of case

A 59-year-old woman was admitted for evidence at duplex ultrasound scan of significant in-stent restenosis in the right common and internal carotid artery. Her comorbidities were limited to dyslipidemia. Two years before, a carotid duplex ultrasound scan had been performed for the work-up of a transient ischemic attack, disclosing a significant stenosis of the ostium of the right internal carotid artery. She was then referred to another institution for carotid angiography, which confirmed the significant carotid stenosis, and underwent during the same procedure carotid angioplasty with implantation of an unspecified 7.0 × 40 mm open-cell self-expanding stent. Less than 6 months later, control duplex ultrasound scan disclosed severe in-stent restenosis, albeit without any symptom. She was thus referred to us for appropriate management.

After diagnostic angiography with a 6 French JR4 diagnostic catheter (VistaBrite, Cordis, Miami, FL, USA) highlighting diffuse in-stent restenosis involving both the common and internal carotid artery, a 7 French JR4 guiding catheter was placed in the proximal right common carotid artery via a 0.035˝ 260 cm Amplatz Super Stiff J-Tip Emerald guidewire (Cordis) (Fig. 1). Then, we deployed
an 7.0 mm Angioguard Rx filter (Cordis), and proceeded to predilation with a 3.0 × 20 mm Trek balloon (Abbott Vascular, Santa Clara, CA, USA), followed by a 5.0 × 40 mm Aviator Plus balloon (Cordis). Despite the apparently satisfactory angiographic result, we then opted for further postdilation with a 5.0 × 80 mm Legflow paclitaxel-eluting balloon (Cardionovum, Bonn, Germany) in order to minimize the risk of recurrent hyperplasia, achieving a good final angiographic result [10]. Periprocedural antithrombotic therapy included aspirin, clopidogrel, tirofiban and unfractioned heparin, whereas discharge antiplatelet therapy consisted of lifelong aspirin and clopidogrel for 6 months. A control duplex ultrasound scan was performed 6 months later. Despite the lack of symptoms, subocclusive recurrent restenosis was found, involving both the carotid bifurcation and the proximal internal carotid artery. The patient was thus admitted again to our institution.

As previously, after diagnostic angiography confirming the recurrent in-stent restenosis, we deployed a 7 French JR4 guiding catheter and a 7.0 Angioguard Rx filter (Fig. 2). Predilation was then performed with a 4.0 × 40 mm Ryujin Plus balloon (Terumo, Tokyo, Japan). Given the drug-eluting balloon failure, the promising data accrued so far for coronary bioresorbable vascular scaffolds even in complex lesions, and our favorable preliminary experience with extra-coronary applications of these devices [11,12], we chose to implant a 3.5 × 28 mm Absorb bioresorbable vascular scaffold (Abbott Vascular) in the distal common carotid artery and proximal internal carotid artery, placing the distal edge of the device well beyond the distal edge of the stent. This choice was mainly based on our goal of minimizing the risk of subsequent edge restenosis. We then postdilated the bioresorbable vascular scaffold and the rest of the original stent with a 4.5 × 30 mm Aviator Plus balloon, achieving a satisfactory final angiographic result. Periprocedural antithrombotic therapy included aspirin, clopidogrel, tirofiban and unfractioned heparin, whereas discharge antiplatelet therapy was based on lifelong aspirin and clopidogrel for 12 months.

The patient remained asymptomatic after discharge, and control duplex ultrasound scan was performed 6 and 13 months later (Fig. 3), without any evidence of restenosis. Specifically, after more than 12 months since the implantation of the bioresorbable vascular scaffold for recurrent in-stent restenosis and drug-eluting balloon failure, the metallic stent appeared largely patent, with faint signs of still incompletely resorbed scaffold struts, all devoid of significant restenosis (peak systolic velocity 120 cm/s, end-diastolic velocity 40 cm/s) (Fig. 3).

3. Discussion

Thanks to the pioneering efforts of many endovascular specialists from different disciplines, the introduction of key pieces of technology such as embolic protection devices and dedicated carotid stents, and landmark clinical trials, carotid artery stenting is now an established alternative to surgical endarterectomy in patients with significant carotid artery disease [1,2,5]. Much attention has been paid to the risk of post-procedural or long-term stroke after stenting, but restenosis is also a clinically relevant complication.

While carotid in-stent restenosis is relatively uncommon, it may pose technical challenges, especially when diffuse or subocclusive, and often recurs after repeat balloon dilation [2]. Accordingly, a number of approaches and devices have been proposed, including endarterectomy, cutting balloons, scoring balloons, endovascular atherectomy, drug-eluting balloons, and drug-eluting stents. No single one appears clearly best, as neointimal hyperplasia can often recur unless the stent is altogether removed surgically, a procedure which is also fraught with significant morbidity [2–9,13–18].
Bioresorbable vascular scaffolds have been recently devised and introduced into clinical practice for the treatment of coronary artery disease [19,20]. The most commonly used one is the Absorb device, which elutes everolimus, thus equaling a drug-eluting stent in terms of hyperplasia inhibition, while relying on a fully resorbable poly-L-lactic acid (PLLA) platform and polymer [21]. This balloon expandable device has proven non-inferior to second-generation drug-eluting stents, and has also been used successfully even in very complex coronary lesions, such as bifurcations, chronic total occlusions, and long lesions [21–24]. We have recently accrued a substantial expertise in using bioresorbable vascular scaffolds in both coronary and non-coronary lesions, including a preliminary experience with infra-inguinal implantation of these devices for superficial femoral artery disease or proximal popliteal artery disease [11,12].

Building upon such premises, we chose to implant a bioresorbable vascular scaffold to treat a recurrent carotid in-stent restenosis and drug-eluting balloon failure. Our acute and long-term results are quite novel, being unprecedented in the literature, and appear quite favorable. Moreover, they support the concept of considering the individualized off-label use of coronary bioresorbable vascular scaffolds for selected non-coronary lesions. More importantly, this clinical vignette highlights the remarkable effectiveness, versatility and safety of this technology, which
clearly merits further development, with the hope of eventually developing bioresorbable vascular scaffolds explicitly designed for non-coronary lesions [25,26]. In addition, its low profile ensures easy deliverability from any access site [27,28].

Despite such rationale and the favorable outcome of our patient, we do not advocate yet a widespread application of bioresorbable vascular scaffolds for the management of carotid in-stent restenosis. First, the bioresorbable vascular scaffold is more fragile than a metallic stent and may lead to a higher risk of embolization in comparison to a drug-eluting balloon, especially when forcefully post-dilated. While this risk remains limited during the procedure if embolic protection is adopted, embolization of relatively large strut fragments (150 μm) may occur before the device is fully endothelialized. Second, the balloon expandable design may be a distinct disadvantage in the carotid artery, where compression and crushing of the scaffold may occur. The presence of an external self-expandable stent may yet provide a certain amount of protection from this complication. Our 13-month follow-up based on duplex ultrasound scan, while adequate for most clinical purposes, cannot disclose or foresee complications or adverse events due to occur much later (e.g., 2 or 3 years after the procedure) and may have lower sensitivity than repeat angiography [29]. Nonetheless, this is unlikely, as after such period of time the scaffold will typically have already lost most of its radial support and drug-eluting properties, and will typically be completely endothelialized. Finally, whether invasive imaging may be required whenever bioresorbable vascular scaffolds are used remains open to debate [30].

4. Conclusion

While awaiting for external validation, this clinical vignette may expand the armamentarium of endovascular specialists focusing on carotid artery disease, while providing further proof of the safety and efficacy of current bioresorbable vascular scaffolds.

Conflicts of interest

Dr. Biondi-Zoccai has consulted for Abbott Vascular.

Sources of funding

None.

Ethical approval

None required.

Consent

Written informed consent was obtained from the patient for publication of this case report, as part of our routine consent for anonymized data collection for scientific purposes.

Author contribution

Drs. Giordano and Biondi-Zoccai are responsible for study concept and design, and data collection. Together with all other authors, they also participated to data analysis and interpretation, writing the paper, and approving its final version.

Guarantor

Dr. Biondi-Zoccai acts as study guarantor.

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