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Case Report

Bioresorbable vascular scaffold for coronary in-stent restenosis: A novel concept

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ABSTRACT

The management of patients with significant in-stent restenosis (ISR) with drug-eluting stent is still not well defined. Various treatment modalities include plain old balloon angioplasty (POBA), metallic stent, cutting or scoring balloon and drug-eluting balloon (DEB). Bioresorbable vascular scaffold (BVS) is the latest technology for the treatment of de novo coronary artery lesions. The use of BVS in ISR is based on the rationale of local drug delivery as achieved by DEB without the permanent bi-layer of metal and also stabilizes dissection flaps and prevents acute recoil as provided by metallic stent. To the best of our knowledge this is the first case report of the use of BVS in patient with ISR.

1. Introduction

The percutaneous coronary intervention (PCI) for treatment of de novo coronary artery disease is well established but the treatment of in-stent restenosis (ISR) in patients with drug-eluting stent (DES) is still a major clinical challenge. Various treatment modalities have been used for treatment of ISR ranging from plain old balloon angioplasty (POBA), metallic stent, cutting or scoring balloon to drug-eluting balloon (DEB). Here, we report a case of DES-ISR treated by using a Bioresorbable Vascular Scaffold (BVS) in patient with unstable angina.

2. Case report

A 40-year-old hypertensive and non-diabetic female was admitted to our department with gradually progressive angina for last 6 months. She had significant past history of anterior wall myocardial infarction two years prior to admission and underwent PCI to left anterior descending coronary artery (LAD) with sirolimus eluting stent through right transradial approach.12-lead electrocardiogram revealed Q waves with inverted T waves in anterior precordial leads suggesting old anterior wall myocardial infarction. Two-dimensional cross-sectional echocardiographic and Doppler examination revealed severe left ventricle systolic dysfunction (LVEF ~ 30%). In view of crescendo symptoms, after informed consent, coronary angiography was performed via left transradial access using 6 F hydrophilic introducer sheath and 5 F TIG 4.0 catheter, which revealed significant ISR in proximal segment of LAD (Panel A, B Fig. 1; S Video 1). Left circumflex coronary (LCX) and right coronary artery (RCA) were non obstructive. PCI of LAD was planned and left coronary ostium was engaged with 6F EBU guide catheter (Launcher, Medtronic, Inc., Minneapolis, MN). The lesion was crossed with 0.009-inch rotawire and

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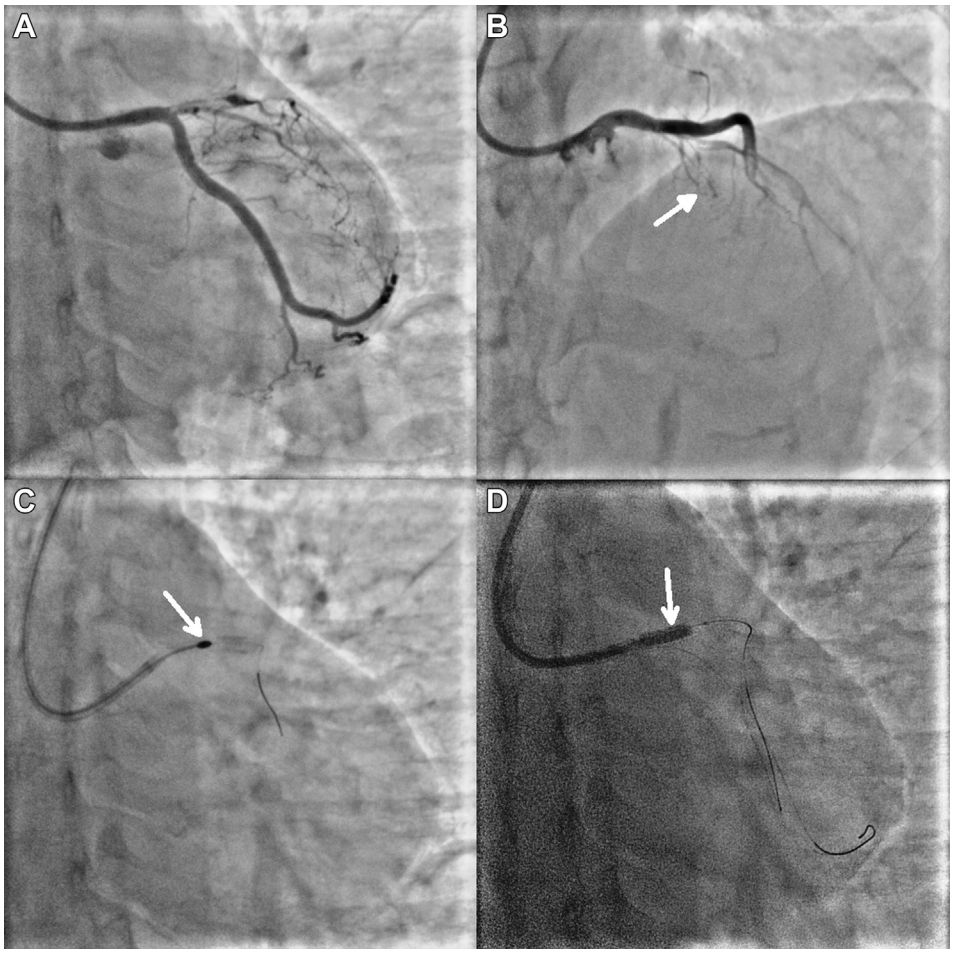

Fig. 1 – Left coronary angiogram in RAO caudal (Panel A) and AP cranial view showing significant ISR in proximal LAD (Arrow, Panel B). AP caudal view showing rotablation with 1.5 mm burr (Arrow, Panel C) and predilation with PTCA balloon dilatation catheter (Arrow, Panel D) (RAO, Right anterior oblique; AP, Anterio–posterior; ISR, In-stent restenosis; LAD, left anterior descending artery; PTCA, Percutaneous transluminal coronary angioplasty).

rotablation was performed using a 1.5-mm rotaburr (Boston Scientific, Boston, MA, USA) at 1,50,000 rpm (Arrow, Panel C Fig. 1; S Video 2). After rotablation, the lesion was crossed with 0.014-inch BMW guidewire (Abbott Vascular, Santa Clara, CA) and rotawire was removed. The lesion was pre-dilated with 2 × 10 mm Maverick PTCA balloon dilatation catheter (Boston Scientific, Boston, MA, USA) (Arrow, Panel D Fig. 1) after which, a 3.5 mm × 28 mm Absorb™ BVS (Abbott Vascular, Santa Clara, CA) was deployed with the help of two platinum markers at 10 atm with good angiographic result (Arrow, Panel A, B Fig. 2; S Video 3). Patient remained hemodynamically stable during the procedure and was asymptomatic at 1-month follow up.

Supplementary video related to this article can be found at http://dx.doi.org/10.1016/j.ihj.2014.05.016.

3. Discussion

The management of patients with ISR is still a major clinical challenge even in era of DES. Although the incidence of ISR is significantly reduced with the use of DES as compared to bare metal stent (BMS) but the absolute number of cases is increased with increase in the complex and multivessel PCI. Moreover, because of diverse etiology of DES-ISR the optimal treatment modality is difficult to determine.[1] The treatment option varies from using vascular brachytherapy (VBT), larger high-pressure balloon dilatation, same or different DES, cutting or scoring balloon and drug-eluting balloon (DEB) but still the optimum treatment strategy is undefined. The VBT is not used now-a-days because of better alternative options and radiation source related logistic issues.[2] The plain old balloon angioplasty (POBA) is mainly limited by frequent slippage of the balloon during inflation and high rate of recurrent restenosis as compared to DES.[3,4] This problem is overcome by using cutting or scoring balloon but has limitation because of its larger profile which makes it difficult to cross the stented segments especially when the ISR is diffuse. Even in focal ISR, DES is better than cutting balloon in terms of preventing late luminal loss and in preventing recurrent restenosis.[5] Outcomes of same drug DES implantation in focal DES-ISR are excellent although in patients with diffuse DES-ISR, a different

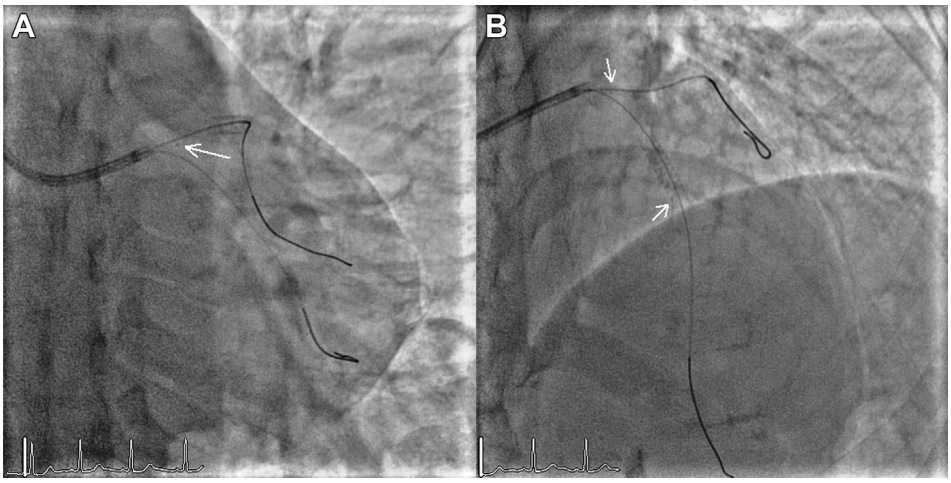

Fig. 2 – BVS platinum markers representing the edges of the scaffold are seen placed across the lesion in RAO caudal (Arrow, Panel A) and AP cranial view (Arrow, Panel B) confirming the proper position of the scaffold (BVS, Bioresorbable scaffold; RAO, Right anterior oblique; AP, Anterio–posterior).

drug DES provides better patency.[6] One of the major drawbacks of treatment of ISR with implantation of a stent inside a stent is the metal burden in that segment of the vessel. In large caliber coronary arteries, this strategy is fairly well tolerated, although in smaller caliber vessels where ISR is more likely to occur, metal burden is a limiting issue. DEB is a novel technique of local drug delivery without adding second layer of metal and hence has theoretical advantage over DES but is limited by failure to provide the mechanical scaffolding support to combat acute recoil and to cover dissection flaps.[7] BVS is the latest advance in the armamentarium of interventional therapies for treating de novo significant coronary artery disease. Recent data from trials have suggested many advantages of BVS over DES.[8] The rationale of using BVS in DES-ISR is based on the concept of repeat local drug delivery as achieved by DEB with the benefits of a scaffold to stabilize dissection flaps, and prevent acute recoil as provided by metallic stent, without the permanent bi-layer of metal, that in some vessels, may in and by itself create flow abnormality.[9]

4. Conclusion

This case is the first human experience demonstrating feasibility, and acute efficacy of BVS in a patient with DES-ISR. In view of its appealing biologic advantage, the efficacy and outcomes of a BVS based treatment strategy for DES-ISR need to be evaluated in comparison to other established PCI based therapies, such as repeat DES implantation, in a randomized setting.

Conflicts of interest

All authors have none to declare.

REFERENCES

1. Dangas GD, Claessen BE, Caixeta A, Sanidas EA, Mintz GS, Mehran R. In-stent restenosis in the drug-eluting stent era. *J Am Coll Cardiol*. 2010;56:1897–1907.
2. Torguson R, Sabate M, Deible R, et al. Intravascular brachytherapy versus drug-eluting stents for the treatment of patients with drug-eluting stent restenosis. *Am J Cardiol*. 2006;98:1340–1344.
3. Lemos PA, van Mieghem CA, Arampatzis CA, et al. Post-sirolimus-eluting stent restenosis treated with repeat percutaneous intervention: late angiographic and clinical outcomes. *Circulation*. 2004;109:2500–2502.
4. Chatani K, Muramatsu T, Tsukahara R, et al. Predictive factors of re-restenosis after repeated sirolimus-eluting stent implantation for SES restenosis and clinical outcomes after percutaneous coronary intervention for SES restenosis. *J Interv Cardiol*. 2009;22:354–361.
5. Song HG, Park DW, Kim YH, et al. Randomized trial of optimal treatment strategies for in-stent restenosis after drug-eluting stent implantation. *J Am Coll Cardiol*. 2012;59:1093–1100.
6. Mehilli J, Byrne RA, Tiroch K, et al. Randomized trial of paclitaxel versus sirolimus-eluting stents for treatment of coronary restenosis in sirolimus-eluting stents: the ISAR-DESIRE 2 (Intracoronary Stenting and Angiographic Results: drug Eluting Stents for In-Stent Restenosis 2) study. *J Am Coll Cardiol*. 2010;55:2710–2716.
7. Navarese EP, Austin D, Gurbel PA, et al. Drug-coated balloons in treatment of in-stent restenosis: a meta-analysis of randomised controlled trials. *Clin Res Cardiol*. 2013;102:279–287.
8. Onuma Y, Serruys PW. Bioresorbable scaffold. The advent of a new era in percutaneous coronary and peripheral revascularization? *Circulation*. 2011;123:779–797.
9. Waksman R, Pakala R. Drug-eluting balloon: the Comeback Kid? *Circ Cardiovasc Interv*. 2009;2:352–358.