Nita D¹, Parepa Irinel Raluca², Mazilu Laura², Suceveanu Andra-Iulia², Matei Luminita², Tuta Liliana-Ana²

"Bare Metal" Stent Placement Complications: Interventional Treatment

¹ Army's Center for Cardiovascular Disease "Acad. Vasile Cârdea" Bucharest

² Faculty of Medicine, University "Ovidius" of Constanta

ABSTRACT

The rapid implementation of stents in standard practice and expansion of the indication for their utilization also introduced a new problem: in-stent restenosis. Management of patients with restenosis after stent implantation is still considered an important clinical problem. Although balloon angioplasty is still one of the preferred strategies that provide satisfactory results and a low incidence of complication, repeat stenting with "drug eluting" stents or "drug balloon" angioplasty become a very attractive methods of treatment for selected lesions and patients.

Keywords: stent, in-stent restenosis, balloon angioplasty, drug eluting balloon

Daniel Nita

Department of Interventional Cardiology, Army's Center for Cardiovascular Diseases "Acad. Vasile Cârdea"
Plevnei Street no 134, Bucharest

email : danielnita23@yahoo.com

Introduction

Over the last decades, implantation of stents has become the treatment of choice for symptomatic coronary artery disease. This is mainly due to advances in interventional technique, lower rates of angiographic restenosis and improved clinical outcome when compared with conventional balloon angioplasty [1]. However, the permanent presence of metallic material in the vessel wall triggers a cascade of physiological events, which led to the description of a new pathology called "in-stent restenosis". Mechanism of in-stent restenosis include a large spectrum ranging from smooth muscle cell proliferation to neoatherosclerosis [2]. Angiographic restenosis is defined as the recurrence of stenosis >50% at follow-up angiogram [2]. Coronary angiography also allows a morphological classification of stent restenosis (pattern I, focal; pattern II, diffuse; pattern III, proliferative; pattern IV, occlusion) and may predict the need for repeat revascularization [3]. The field of interventional therapy of restenosis includes several options ranging from plain old balloon angioplasty, angioplasty with dedicated balloons up to stent re-implantation.

Balloon Angioplasty

„Plain old balloon angioplasty” (POBA)

involves a mechanic widening of the vascular lumen through a radial and longitudinal redistribution of atherosclerotic plaque (figure 1). Intravascular ultrasound examinations revealed two mechanisms by which POBA provides an optimal postprocedural luminal diameter. The first is that the neointimal tissue is compressed and crushed against the stent strut with a contribution of $\sim 44 \pm 28\%$. Along with this, an additional expansion of the stent during the procedure participates with $\sim 56 \pm 28\%$ to the final result [4]. One advantage of POBA is the fact that, for restenotic lesions, complications such as dissection, acute vessel occlusion or perforation appear exceptionally due to the protection offered by the stent already implanted [4,5]. One of periprocedural limitations of this method is neointimal tissue reintrusion („early lumen loss”) which may require in some cases re-implantation of a new stent [6]. Angiographic studies showed a rate of recurrence at 6 months almost double in case of diffuse lesions (≥ 10 mm) compared with focal lesions (63% versus 31%) [7]. Therefore, the favorable results obtained through POBA are suitable particularly for patients who present with focal restenosis [6].

Figure 1 Balloon angioplasty for focal restenosis in the stent implanted on anterior descending artery

„Cutting balloons” have longitudinal blades attached to the balloon surface capable to make controlled incisions in the neointimal tissue that

may facilitate its subsequent extrusion and better acute results. Moreover, they can eliminate „balloon slippage” phenomenon observed during classic angioplasty for fibrocalcific lesions („watermelon seeding” phenomenon) [6]. Some observations have shown that the use of „cutting balloons” is comparable to conventional angioplasty for the treatment of in-stent restenosis with a similar recurrence rate and a similar „late loss” at 6 months follow-up, but with a higher risk of postprocedural myocardial infarction [8]. According to current recommendations, the use of „cutting balloons” to avoid slippage phenomenon and injury to adjacent segments in case of resistant lesions has indication of class IIb [9].

„Scoring balloons” have small elements or nitinol-base spiral struts on the external surface that promotes contact with restenotic lesions and prevents slippage in complex coronary lesions [10, 11].

Drug-eluting balloons have been studied in recent years as an alternative to the stent placement. They have the advantage for immediate release of the active substance without the use of additional polymer, a homogeneous tissue distribution and greater flexibility in treating complex lesions. The ideal substance should be lipophilic with a rapid absorption rate and a high rate of tissue retention in the vascular wall. Paclitaxel has all these qualities in view of the fact that it rapidly binds to various cellular components with a lasting effect by alteration of the cytoskeleton structure [12]. The value of drug-eluting balloons was demonstrated by Paclitaxel-Coated Balloons Catheter for In-Stent Restenosis (PACCOCATH ISR I and II) trials that studied their effectiveness compared with POBA. Angiographic results at 6 months follow-up showed a late luminal loss reduction (LL) from 0,81 mm to 0,14 mm and a subsequent significantly reduced restenosis rate. At 5.4 ± 1.2 years follow-up, the rate of major cardiac events was significantly reduced in patients treated with drug-coated balloon (59.3% vs. 27.8%) [13]. Furthermore, Paclitaxel Eluting Balloon in Coronary Artery Disease (PEPCAD II) trial studied comparatively the performance of paclitaxel eluting balloons or stents for the treatment of in-stent restenosis. At 6 months follow-up, late loss and restenosis rate were reduced in the group of

patients treated with paclitaxel eluting balloon ($0,17 \pm 0,42$ mm vs. $0,38 \pm 0,61$ mm, respectively 2% vs. 7%). These results suggest that drug eluting balloons are at least as effective as the first generation of drug eluting stents (DES) [14]. In contrast, data from the RIBS V (Intra-stent restenosis of stents Bare Metal: paclitaxel-eluting everolimus-eluting stent vs balloon) trial have demonstrated the superiority of second generation DES in terms of angiographic parameters [15]. In conclusion, the use of coated balloons is a viable option for bare metal stents (BMS) restenosis treatment. Guidelines indication for their use is class IIa [9].

New stent placement for in-stent restenosis („sandwich technique”)

Reimplantation of a new stent (figure 2) is associated with a better angiographic result, a higher post-procedural lumen diameter and eliminates „early lumen-loss phenomenon” in comparison with POBA [6]. In favor of this statement were suggestive the results provided by RIBS I (Intra-stent Restenosis: Balloon Angioplasty Stenting Versus Elective) trial that compared the effectiveness of reimplantation BMS with POBA. According to them, minimal luminal diameter calculated immediately post-procedural is higher when a stent is implanted compared to that obtained by balloon dilation (2.77 ± 2.25 vs. 0.4 ± 0.5 mm) [16]. Additionally, although periprocedural results were higher with stent reimplantation, stent restenosis rate at 6 months follow-up was similar (38% vs. 39%). In contrast, in case of coronary arteries with diameter ≥ 3 mm or in case of „edge stent restenosis”, repeat stenting was found to be superior POBA regarding some long term follow-up results (in-stent restenosis occurrence 27% vs. 49%) [16]. Moreover, a number of studies demonstrate the benefit obtained by reimplantation of DES [17,18,19]. According to ISAR-DESIRE 1 (Intracoronary Stenting or Angioplasty for Restenosis Reduction - Drug Eluting Stents for In-Stent Restenosis) trial restenosis rate at 6 months follow-up was 21.7% in the group of patients treated with paclitaxel eluting stent, 14.3% for those treated with sirolimus eluting stent and 44.6% for patients treated only with „plain old balloon angioplasty” [17]. Favorable results were also obtained using the second generation of DES. For example, the use of

everolimus eluting stents is associated with a late loss of 0.35 ± 0.63 mm and a recurrence restenosis rate of only 12.22% at 9 months follow-up [19]. However, their use is still limited, mainly due to their relatively high cost. Frequently, despite all limitations, POBA continues to be the first option for patients with in-stent restenosis, stent reimplantation being reserved for cases with suboptimal outcome or in presence of complications such as total vessel dissection.

Figure 2: Reimplantation of stent at the origin of anterior descending artery for diffuse in-stent restenosis

Another treatment strategies

Brachytherapy is used in patients with in-stent restenosis due to its antiproliferative effects. During this treatment an effective dose of gamma and beta radiation is released to the target segment using various radioactive isotopes. As a result of its complicated logistics and rapid drug eluting stents implementation, this method has lost importance in the treatment of restenosis in BMS [9].

Rotational atherectomy involves debulking the intraluminal obstructive material with a diamond-tipped burr. The ARTIST (The Angioplasty versus Rotational Aterectomy for the Treatment of Diffuse In-Stent Restenosis) trial has compared rotational atherectomy followed by POBA as one option of

interventional treatment with POBA alone. Control angiograms showed a lower restenosis rate in the group treated only with balloon angioplasty[20]. Conversely, in different circumstances, when IVUS guidance and prolonged antiplatelet treatment were used, the ROSTER (Rotational Atherectomy versus Balloon Angioplasty for Diffuse In-Stent Restenosis) trial demonstrated superior results obtained with atherectomy followed by balloon dilation [21]. Currently, rotational atherectomy is used for preparing stent placement in case of heavily calcified or fibrotic lesions which are not prone to proper predilatation (Class IC) [9].

Conclusions

Restenosis after „bare metal” stent implantation is considered one of the most significant problem in percutaneous coronary intervention. Evidence from clinical studies recommends repeat stenting with DES and „drug eluting” balloon angioplasty as therapeutic modalities that provide the best clinical and imagistic results in these patients.

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