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Stent strut ablation with rotational atherectomy device (Rotablator™) for restenosis treatment. Analysis and late follow-up

Ablação de hastes de stents para tratamento de reestenose com equipamento de aterectomia rotacional (Rotablator™).
Análise e seguimento tardio

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ABSTRACT – The widespread use of bare metal stents as from 1995 led to the appearance of a new entity called in-stent restenosis, and the severe concomitant calcification of the vessels is a challenge for the interventional cardiologist. In this scenario, rotational atherectomy has risen as a therapeutic rescue approach to manage this situation, using trephines to eliminate the underexpanded and non-expandable coronary stents. However, comprehensive data on the long-term efficacy or results of the procedures have not been published yet. We report a case of rotational atherectomy in stent restenosis, followed by percutaneous coronary intervention with implantation of a new stent to treat a calcified in-stent lesion.

Keywords: Stents; Drug-eluting stents; Percutaneous coronary intervention; Atherectomy, coronary

RESUMO – O uso generalizado de stents metálicos a partir de 1995 levou ao aparecimento de uma nova entidade denominada reestenose intra-stent, sendo a calcificação grave concomitante dos vasos um desafio ao cardiologista intervencionista. Nesse contexto, a aterectomia rotacional surgiu como uma possibilidade terapêutica de resgate para lidar com essa situação, utilizando-se o poder dos trépanos para eliminar os stents coronários subexpandidos e não dilatáveis. No entanto, ainda não foram publicados dados abrangentes sobre a eficácia ou o resultado em longo prazo desses procedimentos. Relatamos um caso de aterectomia rotacional em reestenose de stent seguida de intervenção coronária percutânea com implante de novo stent para tratamento de lesão calcificada intra-stent.

Descritores: Stents; Stents farmacológicos; Intervenção coronária percutânea; Aterectomia coronária

INTRODUCTION

Percutaneous coronary intervention (PCI) has become an important tool for treating coronary artery disease (CAD) since the 1990s.^{1,2} From its introduction and application to an increasing number of patients, two main adverse factors associated to the method have been identified: stent thrombosis and in-stent restenosis (ISR), and the ISR rates have been reported to be between 20% to 35%, with clinical and angiographic variables as risk factors.³

Binary ISR is defined as the recurrence of the lesion with $\geq 50\%$ obstruction of the vessel lumen in the treated segment (inside the stent and at the edges, with 5mm before and after it). This concept was based on physiological studies, which revealed impairment of coronary flow reserve from this degree of obstruction on.³ The evolution of devices, especially with the emergence of stents, led to a significant growth in the use of PCI in the last three decades with excellent results; ISR, however, still occurs, despite the evolution of drug-eluting stents.¹

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Rotational atherectomy (RA) with subsequent stenting is the contemporary method of choice for managing non-crossable and/or non-expandable coronary lesions.⁴ Published case reports have described an unconventional application of RA — the use of trephines to eliminate underexpanded and non-expandable coronary stents, as a rescue method to manage this problem. However, comprehensive data on the long-term efficacy or results of the procedures have not yet been published.⁴

Rotational atherectomy is a rotational system with an oval shaped burr encrusted with 5µm diamonds of various sizes, connected to a compressed air turbine, which rotates at high speed. Due to its high-speed rotation, the mechanism of action of RA consists in grinding the calcified atheromatous plaque into microscopic particles with consequent debulking. By reducing the volume of the residual plaque after PCI, the procedure minimizes one of the most important predictive factors for ISR, as demonstrated by several studies with intravascular ultrasound (IVUS) imaging.⁵ Therefore, RA, initially described in 1986, resurges with the purpose of minimizing the consequences of inappropriate expansion and/or mal-apposition of the implanted device.⁶

The main angiographic factors associated with greater incidence of identified ISR are lesions in thin vessels, long lesions (>20mm), tortuous segments, thrombus, ostial lesions, venous grafts (bypass grafts), highly calcified vessels, chronic occlusions, and bifurcations. In addition, factors related to the procedure are also fundamental, such as the degree of post-procedural residual stenosis and, specifically in the case of stent deployment, poor expansion, which is easily identifiable by intracoronary imaging methods.³

The rationale for using RA in highly calcified areas, prior to stent implantation, is based on the assumption that it will reduce the risk of acute occlusion, by creating a more regular lumen, with less barotrauma; the risk of ISR, by increasing luminal gain and reducing the residual plaque; and the risk of stent thrombosis, by a better expansion and apposition of the device. In addition, highly calcified lesions can pose a special threat to drug-eluting stents, as they may damage the polymer lining and hinder the consequent diffusion of the antiproliferative agent in the vessel wall, leading to a reduced efficacy of the device.⁶

The main indications for RA are ostial lesions, with high primary success; diffuse extensive lesions (10mm to 20mm), with 94% success rate, with complication rate greater than 6%, and restenosis rate of 45%; lesions that cannot be crossed or dilated with a balloon catheter; restenotic lesions; calcified lesions; elastic lesions; lesions located in the distal segment.⁷ Therefore, RA is an adjuvant method that prepares the lesion before the stent implantation, improves the result of the procedure, especially with the use of the latest generation of drug-eluting stents.

The objective of this study is to report a case of ISR treated by PCI with ablation of the stent struts with an RA equipment (Rotablator™) for treating a restenosis caused by

a hypoexpansion mechanism due to a juxtaposed calcified lesion. The Research Ethics Committee of the *Hospital de Urgências de Goiânia* approved this study (CAAE: 94882318.7.0000.0033).

CASE REPORT

A 62-year-old female patient with coronary artery disease (CAD) was admitted to our cath lab on February 2nd, 2011, with stable angina refractory to optimized medical therapy. She was referred for myocardial perfusion scintigraphy, which showed ischemia in the territory of the left anterior descending artery (LAD), corresponding to 19% of myocardial mass. As past medical/surgical history, on May 30, 2005, the patient underwent coronary angiography that showed a 70% proximal obstruction in the LAD, and on June 13, 2005, a PCI was performed with a 2.75mmx32mm paclitaxel-eluting stent. Due to the recurrence of angina symptoms, a new hemodynamic study was carried out on December 1st, 2008, which demonstrated a 95% in-stent focal restenotic lesion in the LAD, and a new PCI was performed on December 12, 2008 with the implantation of a 3.0mmx24mm Supralimus™ drug-eluting stent.

On April 16, 2009, a new study was performed, which showed an 80% in-stent focal restenotic lesion in the LAD. At that time, IVUS was performed, showing the presence of ISR by a mixed mechanism (in-stent neointimal proliferation and poor expansion of the struts in the distal third of the two previously implanted stents, due to a significant underlying fibrotic lesion at the site). Based on the IVUS analysis, a balloon angioplasty was performed to relieve the symptoms, with an important residual lesion remaining, on April 22, 2009. Coronary artery bypass graft was indicated, and left internal mammary (LIMA) artery to LAD anastomosis was performed on June 19, 2009. On February 2, 2011, based on a myocardial scintigraphy that showed ischemia in the anterior wall, a new coronariography was performed, which revealed 70% ISR in LAD, and occlusion of the LIMA graft (Figure 1A).

Therefore, on May 9, 2011, the first RA in LAD was performed with 1.25- and 1.75mm sequential burrs (Figure 1B), followed by angioplasty without stenting (Figure 1D). IVUS showed the persistence of poor expansion of previously implanted stents, therefore a new stent was not implanted (Figure 1C). At the time, we did not have a guide catheter with enough diameter to use large diameter trephines. Due to an additional recurrence of angina symptoms, a new PCI was performed on February 16, 2012, guided by IVUS (Figure 2A). Therefore, a new RA was performed with a 2.5-mm burr (Figure 2B) with a JL 9F catheter, followed by the implantation of a 3.0x38mm Promus® stent (Figures 2C and 2D).

During the patient's clinical follow-up, CAD medication was optimized. Regarding her lipid profile, our goal was to reach a low-density lipoprotein cholesterol (LDL-c)

level $<50\text{mg/dL}$, since she was a very high cardiovascular risk patient. During follow-up, the mean LDL-c level was $105.92\text{mg/dL} \pm 27.38$ and on February 12, 2020, it reached 78mg/dL . However, despite the non-pharmacological and therapeutic guidelines regarding high potency statins, the patient did not reach the goal advocated by the Updated Brazilian Dyslipidemia and Atherosclerosis Prevention Guidelines — 2017.⁸

During follow-up, a hemodynamic study was carried out on March 5, 2013, which did not demonstrate signi-

ficant obstructions, only the presence of a mild in-stent proliferation in the stent implanted in the LAD. Coronary angio-computed tomographies were also performed on May 7, 2014 and September 22, 2016, which revealed a patent stent in LAD, apparently without ISR, and, on April 10, 2019, which demonstrated a stent without restenosis in LAD, with a mild calcified ostial plaque. On February 14, 2020, a new hemodynamic study was carried out, which evidenced maintenance of the results (Figures 3A and 3B).

Figure 1. Hemodynamic study (2011). (A) Pre-percutaneous transluminal coronary angiography study showing 70% in-stent restenosis lesion in the proximal third of the anterior descending artery and graft occlusion. (B) Use of non-compliant balloon. (C) Analysis with intracoronary ultrasound showing persistence of poor expansion of the implanted stent. (D) Result of Pre-percutaneous transluminal coronary angiography with no implantation of a new stent.

Figure 2. Hemodynamic study (2012). (A) Pre-rotational atherectomy study. (B) Use of 2.5-mm burr with JL 9F catheter. (C) Implantation of 3.0x38-mm drug-eluting stent. (D) Result: adequate expansion of the new stent.

Figure 3. Hemodynamic study (2020). (A) Evidence of a patent stent in the left anterior descending artery. (B) Evidence of a patent stent in the left anterior descending artery.

DISCUSSION

Despite being an unconventional technique for treating ISR, RA has been shown to be safe and effective in the percutaneous treatment of lesions with extreme calcification, which requires the ablation of the stent struts previously implanted to ensure an adequate expansion of the new stent, demonstrating it to be a successful procedure with a favorable clinical course in late follow-up, as in the case reported here.

Currently, severe vessel calcification is one of the significant challenges faced by the interventional cardiologist, not only due to the greater difficulty in advancing and implanting stents along the calcified vessels, but also due to a greater number of complications that may occur in this anatomy. In these patients, RA is truly the only available technique capable of preparing the vessel for stent delivery, particularly if the calcium distribution is superficial.⁵

New techniques and devices have been used to overcome the obstacle posed by lesions with high calcium burden and to increase success rates, such as use of microcatheters, catheters and guidewires that are more rigid and with other conformations, a second guidewire in parallel (*buddy wire*), anchor ballooning, atheroablative techniques, such as laser or Rotablator™, and other devices, like Tornus®.⁹

Historically, patients with ISR present with stable symptoms, with no direct impact on important unfavorable clinical outcomes. Despite the evolution of platforms, polymers and drug elution, stents are not yet free from ISR, which still has an incidence of slightly over 10% in several clinical series. In this scenario, some therapeutic modalities, such as balloon angioplasty with metal structures (cutting/scoring), neointimal ablation with laser or RA, and also drug-eluting balloon angioplasty may be options in the management of these lesions. In addition, the use of IVUS and optical coherence tomography is essential in the mechanistic assessment of ISR-promoting factors to individually determine the best approach for these lesions.¹⁰

In 2009, Zanuttini et al. published a case report similar to the one we reported here, whose patient had a stent with a type II subocclusive restenosis, according to the Mehran's classification system, in the proximal third of the LAD. Percutaneous coronary intervention was performed in association with IVUS, which showed lack of expansion of the prosthesis associated with in-stent neointimal hyperplasia. Then, an attempt was made to expand the prosthesis, using a non-compliant balloon catheter, without success. Rotational atherectomy was then decided, with a progressive increase in the burr size (1.75 to 2.25mm), with satisfactory expansion, and a significant increase in the stent area. At one-year follow-up, the patient remained asymptomatic, with no adverse cardiac events and with no signs of ischemia in the stress echocardiogram.¹¹

The value of RA in patients with ISR was evaluated in two randomized trials. The ROSTER study,¹² a randomized clinical trial on RA *versus* balloon angioplasty for ISR treatment, showed that RA reduced the amount of residual tissue

in the stent and the rate of revascularization of the target lesion at follow-up, compared with balloon angioplasty alone. In contrast, the ARTIST trial¹³ compared balloon angioplasty *versus* RA for ISR treatment, and found lower rates of ISR, greater safety and superior clinical results, in the group that used balloon angioplasty alone.

A third study, conducted in patients with ISR, showed greater acute luminal gain after PCI with Excimer laser coronary atherectomy, in complex lesions, in which the long-term clinical results were favorable.¹⁴

Also on the adoption of RA in extremely calcified lesions, which for a time was relatively abandoned as a therapeutic option, the 2013 ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial, conducted with 240 patients with complex calcified native coronary lesions, randomized 120 patients undergoing percutaneous RA treatment, followed by the implantation of a paclitaxel-eluting stent, and 120 patients undergoing only percutaneous treatment with paclitaxel-eluting stenting (standard treatment). The primary endpoint was in-stent late lumen loss at 9 months. The results showed greater success in the RA group (92.5% versus 83.3%; $p=0.03$). At 9 months, in-stent late lumen loss was greater in the RA group (0.44 ± 0.58 versus 0.31 ± 0.52 ; $p=0.04$), despite an initially higher acute gain lumen (1.56 ± 0.43 versus 1.44 ± 0.49 mm; $p=0.01$).¹⁵

To clarify the best strategy for treating ISR cases, an elegant meta-analysis was published in 2015, including almost 6,000 patients with a 6 to 12-month follow-up. The primary outcome studied was percentage stenosis at follow-up, and the secondary outcome included binary restenosis, target lesion revascularization rates, myocardial infarction or death. All modalities included balloon angioplasty alone, debulking techniques, brachytherapy, use of bare metal stents, drug-eluting stents and drug-coated balloons. The use of a new everolimus-eluting stent implant was considered statistically superior to all other modalities, both for the primary outcome and for the rates of binary restenosis and revascularization of target lesion.¹⁶

Therefore, although debulking techniques, such as RA, are not considered routine treatment for ISR, they can be considered as a pre-treatment option for non-dilatable ISR lesions, especially those resulting from severely underexpanded stents or in-stent calcified neoatherosclerosis,¹⁷ as in the case reported here.

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DISCLOSURE OF CONFLICTS OF INTEREST

The authors declare there are no conflicts of interest.

CONTRIBUTION OF AUTHORS

Conception and design of the study: FPB, AMJ, RD and GG; data collection: DFRR, HLG and FPB; data interpretation: DFRR, FPB and GG; writing of the text: DFRR, HLG and GG; approval of the final version to be published: DFRR, HLG, FPB, AMJ, RD and GG.

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