Morbidity and mortality in a cohort of individuals undergoing rotational atherectomy for extremely calcified lesions

Morbimortalidade em uma coorte de indivíduos submetidos à aterectomia rotacional por lesões extremamente calcificadas

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ABSTRACT – Background: The treatment of coronary arteries with heavily calcified or chronically occluded lesions has the lowest success rates when they undergo a percutaneous procedure. A strategy to reduce the volume of calcified lesions, which was part of the rescue technique to treat non-balloon dilatable stenoses, has evolved to an approach of primary lesion preparation for subsequent stenting. **Methods:** This is a retrospective analysis of data related to rotational atherectomies performed in complex, high-risk patients, for treating extremely calcified lesions with drug-eluting stent implantation, obtained from the Tasy Electronic Medical Record, between 2012 and 2016. **Results:** A cohort of 138 individuals was followed up after rotational atherectomy between 2012 and 2016. The most frequently observed risk factors were hypertension (87%), dyslipidemia (69%), diabetes mellitus (44%), and sedentary lifestyle (72%). A total of 244 vessels were treated, 179 of which with the aid of rotational atherectomy, and 308 drug-eluting stents were implanted. The SYNTAX II score was 22.4 ± 11.5 , with 18% of individuals classified as high risk (>33 points); femoral arterial access was employed in 76.8%. Lesion transposition was achieved in 98% of cases. Angiographic success was achieved with stenting in 98% of procedures. The length of hospital stay was 2.6 ± 3.7 days. In-hospital mortality was 4%, and 4-year mortality was 14.5%. Long-term follow-up was performed by phone calls up to 4 years after the procedure. Ninety-seven percent of patients maintained regular use of dual antiplatelet therapy. Only 42% reported regular exercise. Angina pectoris was reported by 13% of individuals. **Conclusion:** Rotational atherectomy showed a low occurrence of adverse events in the immediate and late phases, leading to a high success rate of stent implantation in complex lesions.

Keywords: Atherectomy, coronary; Coronary disease; Vascular calcification; Length of stay; Mortality

RESUMO – Introdução: O tratamento de artérias coronárias com lesões intensamente calcificadas ou cronicamente ocluídas tem as menores taxas de sucesso quando elas são submetidas a procedimento percutâneo. Uma estratégia de redução de volume das lesões calcificadas, que fazia parte da técnica de resgate para tratamento de estenoses não dilatáveis por balão, evoluiu para uma abordagem de preparação da lesão primária, para posterior implante do stent. **Métodos:** Trata-se de análise retrospectiva de dados relacionados a aterectomias rotacionais realizadas em pacientes complexos e de alto risco para tratamento de lesões extremamente calcificadas com implante de stent farmacológico, obtidos do Prontuário Eletrônico do Paciente Tasy, entre os anos de 2012 e 2016. **Resultados:** Uma coorte de 138 indivíduos foi acompanhada após aterectomia rotacional entre os anos de 2012 e 2016. Os fatores de risco mais frequentemente observados foram hipertensão (87%), dislipidemia (69%), diabetes melito (44%) e sedentarismo (72%). Foram tratados 244 vasos, dos quais 179 com auxílio de aterectomia rotacional, e implantados 308 stents farmacológicos. O escore SYNTAX II foi $22,4 \pm 11,5$, com 18% dos indivíduos classificados como de alto risco (>33 pontos); acesso arterial femoral ocorreu

em 76,8%. A transposição da lesão foi alcançada em 98% dos casos. O sucesso angiográfico foi obtido com o implante de stent em 98% dos procedimentos. O tempo de internação hospitalar foi de $2,6 \pm 3,7$ dias. A mortalidade intra-hospitalar foi de 4%, e a mortalidade em 4 anos foi de 14,5%. O seguimento tardio foi realizado por ligações telefônicas até 4 anos após o procedimento. Dentre os pacientes, 97% mantiveram o uso regular de terapia antiplaquetária dupla. Apenas 42% relataram exercícios regulares. *Angina pectoris* foi relatada por 13% dos indivíduos. **Conclusão:** A aterectomia rotacional apresentou baixa ocorrência de eventos adversos nas evoluções imediata e tardia, levando à alta taxa de sucesso do implante de stent em lesões complexas.

Descritores: Aterectomia coronária; Doença das coronárias; Calcificação vascular; Tempo de internação; Mortalidade

INTRODUCTION

Calcification is part of the natural history of atherosclerosis. Marked calcification of an atherosclerotic lesion may result in stent underexpansion, even after predilatation with a high-pressure balloon.¹

New technologies and the evolution of previously employed methods have gained importance in preparation of calcified arteries. The current armamentarium includes rotational atherectomy (RA) that modifies the plaque; use of the cutting/scoring balloon, which has proven to be superior to conventional balloons for causing fracture, compression, and redistribution of the calcified plaque, besides increasing local elasticity of the vessel; orbital atherectomy using centrifugal force; the Excimer laser, which causes small erosions and dissections in the plaque; and conventional semi-compliant or non-compliant balloons. Within this context, the use of adjunctive tools to effectively prepare the lesions has been the most effective and safe means to achieve success, and sustained long-term results in interventions in calcified arteries.²

The revival of RA in the era of drug-eluting stents (DES), particularly in very complex calcified lesions, underscores the importance of plaque modifications before the DES can be successfully introduced, precisely positioned, and deployed to exert the desired effects. The RA acts according to the principle of “differential cutting” and “orthogonal displacement of friction”, by selectively eliminating the inelastic fibrocalcified plaques and sparing the adjacent elastic tissue. The microcrystals embedded in the burr break the calcified plaque into microscopic particles (5 to 10 μ m in diameter), smaller than red blood cells, which are carried downstream and removed from circulation by the reticulo-endothelial system. This selective ablation of the fibrocalcified plaque produces a smooth, polished luminal surface to facilitate stent placement and expansion. By ablating part of the plaque volume, less pressure is required to achieve greater balloon expansion.³

Thus, RA is a very useful and effective tool in complex lesions with high calcification burden, and it is the most often used atheroablative technique in this scenario (5% to 6% of cases).⁴ Its main indication is for situations when it is not possible to cross the lesion with a balloon catheter and/or stent, or when complete expansion of the balloon catheter is not obtained during pre-dilation.⁵ Among the complications reported, dissections, slow-flow, distal embolization, abrupt vessel closure, and perforation stand out.⁶

The percutaneous treatment of severely calcified coronary lesions involves several technical difficulties that can significantly influence success at the end of the procedure.⁷

This study aimed to evaluate the incidence of complications in complex higher-risk patients (CHIP) undergoing RA for extremely calcified lesions with DES.

METHODS

We conducted a retrospective analysis of data on RA in complex and higher-risk patients, for treatment of extremely calcified lesions with DES implantation, in the city of Aparecida de Goiânia (GO, Brazil) from 2012 to 2016. Data collection was performed at *Hospital Encore* using the Tasy platform (<http://healthit.grupomidia.com>). Tasy Electronic Medical Records from January 2012 to June 2016 were analyzed. For the late four-year follow-up, data was collected over the phone.

Categorical variables were expressed as absolute numbers and percentages. Continuous variables were expressed as mean $\pm$ standard deviation. Microsoft Excel 365®, version 2016 software was used for data tabulation.

The Research Ethics Committee of the *Hospital de Urgências de Goiânia*, linked to *Plataforma Brasil*, approved the present study (CAAE: 94882318.7.0000.0033).

RESULTS

The sample consisted of 138 patients. The baseline characteristics of the sample are shown in table 1. There were 179 vessels treated by RA, with high rates of lesion transposition and successful DES implantation. The data of the procedures are described in table 2. The main access was the femoral artery. The left anterior descending artery was the vessel more often approached in the sample.

Regarding in-hospital follow-up, the data are presented in table 3. The average length of stay was 2 to 3 days. The in-hospital adverse events were observed in 14.5% of sample; in that, myocardial infarction (MI) and dissections of vessels submitted to RA were most common. The in-hospital mortality was 4.3%.

Table 1. Clinical characteristics (n=138)

Variable	
Age, years	71.4±10.6
Sex, male	88 (63.8)
BMI	26.9±4.6
Creatinine clearance, mL/min/1.73m ²	69.6±38.0
LVEF, %	59.7±14.2
Hypertension	121 (87.6)
Dyslipidemia	96 (69.8)
Smoking	29 (20.9)
Positive family history	65 (47.3)
Obesity	30 (21.7)
Sedentary lifestyle	99 (72.1)
Diabetes mellitus	61 (44.2)

Results expressed by mean±standard deviation or n (%).
BMI: body mass index; LVEF: left ventricular ejection fraction.

At the late 4-year follow-up, as shown in table 4, contact over the phone was successful in 62.9% of sample. Among the patients contacted, most reported maintaining regular use of dual antiplatelet therapy (DAPT), but less than half of them were exercising regularly (42%). Readmissions occurred in less than 10% of them, and cardiovascular diseases ranked as the first cause. Although limited by the high number of losses to telephone follow-up, mortality at late follow-up was 14.5%.

DISCUSSION

In this study, RA proved to be effective as an adjuvant technique in treatment of extremely calcified coronary lesions, with high rates of success in transposition of lesions and in DES implants (Figure 1). In-hospital mortality of the sample was 4.3%, and the main adverse events were MI, dissections of vessels submitted to RA, and occasional arterial perforation.

Although RA is necessary for treating severely calcified coronary lesions, the incidence of complications is relevant. In the ROTAXUS study (2012), 240 patients with calcified lesions were randomized to RA before stenting or standard procedure (paclitaxel stenting), showing higher procedural success and better acute luminal gain in the RA group (92.5% versus 83.3%; $p=0.03$), but with significant late loss over the course of months. Despite promising results, the judgment of this trial is limited, due to the 8% crossover rate and exclusion of more severe calcified lesions.⁸

In a retrospective study of 253 patients undergoing RA to treat complex coronary lesions, the mortality rates were 0.8% and 0.4% at hospital and late three-year follow-up, respectively. The main acute adverse outcomes were dissections and perforations, while MI and restenosis predominated in the late stages.⁹

Table 2. Characteristics of the procedures (n=138)

Variable	
Access route	
Right femoral	106 (76.8)
Right ulnar	1 (0.7)
Right radial	31 (22.5)
Total vessels treated	244
Mean SYNTAX score	22.4±11.5
SYNTAX Classification	
Low	80 (57.9)
Intermediate	33 (23.7)
High	25 (18.4)
Number of vessels treated with RA	179 (100.0)
1	125 (69.6)
2	50 (28.1)
3	4 (2.2)
Arteries treated with RA	179 (100.0)
Diagonal branch	1 (0.7)
Left anterior descending	105 (58.5)
Right coronary	36 (20.0)
Posterior ventricular	3 (1.5)
Left circumflex	13 (7.4)
First diagonal	4 (2.2)
Left main coronary artery	13 (7.4)
First marginal	3 (1.5)
Posterior descending	1 (0.7)
Number of burrs used	142 (100.0)
1	136 (95.6)
2	6 (4.4)
Number of DES used	
1	52 (17.0)
2	137 (44.4)
3	98 (31.9)
4	21 (6.7)
DES implanted per patient	2.3±0.8
Transposition of lesion by RA	176 (98.6)
Success in DES implantation	176 (98.6)
In-stent restenosis	3 (2.2)
Burr size, mm	142 (100.0)
2.15	13 (9.0)
2	30 (21.1)
1.75	66 (46.6)
1.5	22 (15.8)
1.25	11 (7.5)
Mean stent diameter, mm	3.5±0.4
Mean lesion extension, mm	42.7±23.9
Burr/vessel ratio	0.5±0.1/1
Percentage of stenosis	85.6±10.9
Use of vascular closure device	30 (21.7)

Results expressed by n (%) or mean±standard deviation.
AR: rotational atherectomy; DES: drug eluting stent.

Table 3. In-hospital outcomes (n=138)

Variable	
Days of hospitalization	2.6±3.7
In-hospital adverse events	22 (14.5)
Myocardial infarction	3 (2.1)
Dissections in vessels submitted to RA	6 (3.4)
Arterial perforations	3 (1.2)
Periprocedural stroke	1 (0.7)
Pneumonia	1 (0.7)
RotaWire® fracture with tip buried between stent and vessel	1 (0.7)
Hematoma in access site	3 (2.2)
Renal failure	2 (1.4)
Burr entrapment	2 (1.4)
Mortality	6 (4.3)

Results expressed as mean±standard deviation or n (%).
RA: rotational atherectomy.

Table 4. Outcomes observed at the mean 4-year follow-up (n=138)

Variable	
Successful contacts over the phone	83 (62.9)
Regular use of DAPT	81 (97.0)
Regular exercise	35 (42.0)
How many times a week you exercise	3.9±1.8
Chest discomfort or pain	11 (13.0)
Readmissions during the period	7 (8.2)
Cardiovascular cause	6 (83.3)
Other causes	1 (16.7)
Mortality	12 (14.5)
Cause of death	
ARF	4 (33.3)
Sepsis	1 (8.3)
Sudden death	1 (8.3)
PO cardiac surgery	1 (8.3)
Decompensated COPD	1 (8.3)
MI	1 (8.3)
Do not know	3 (25.0)

Results expressed as mean±standard deviation or n (%).
DAPT: dual antiplatelet therapy; ARF: acute renal failure; PO: postoperative; COPD: chronic obstructive pulmonary disease; MI: myocardial infarction.

Encouraging results were presented in PREPARE-CALC, in which 200 patients were randomized to treatment with either RA or modified balloons. A higher success rate was achieved with RA (98% *versus* 81%, respectively), mainly driven by balloon crossing failure, with no significant difference in late luminal loss at 9 months. Periprocedural complications were low and similar in both groups, probably due to highly experienced operators.¹⁰

A study conducted in nine large Australian hospitals over an 8-year period, by Couper et al., reported 16,577 percutaneous coronary interventions, with 1.0% of patients (n=167; 214 lesions) undergoing RA. The results showed that patients undergoing RA were older (71.0±9.7 *versus* 64.4 ± 11.9 years; p<0.01), with higher prevalence of diabetes (37.7% *versus* 23.8%; p<0.01) and renal failure (56.6% *versus* 33.4%; p<0.01). There was no significant difference in procedural success (94.6% *versus* 95.5%; p=0.57) and dissection (6.1% *versus* 4.8%; p=0.39), as well as in no-reflow rates, whether transient (4.4% *versus* 2.8%; p=0.23) or persistent (0% *versus* 0.7%; p=0.23). Importantly, in the present study, individuals undergoing RA had an increased risk of death at 12 months (6.6% *versus* 3.6%; p=0.04). There was no significant difference in major adverse cardiovascular events (MACE) at 12 months between the groups after adjustment for univariate predictors (OR=1.00; 95%CI 0.93-1.08). In addition, there was no significant difference in 30-day MACE (6.0% *versus* 5.1%; p=0.62) or 30-day mortality (2.4% *versus* 1.8%; p=0.54) between the groups.¹¹

Ai et al. evaluated 127 patients with moderately or severely calcified coronary lesions treated with RA, divided into two groups, according to the type of balloon after RA and before DES implantation: RA + Cutting Balloon Group and RA + Plain Balloon Group. The results showed the lumen diameter was significantly larger in the RA + Cutting Balloon Group than in the RA + Plain Balloon Group (1.57±0.46mm *versus* 1.10±0.40mm; p<0.001). Final lumen diameter was also larger in the RA + Cutting Balloon Group compared to the RA + Simple Balloon Group (2.81±0.41mm *versus* 2.60±0.25mm; p=0.039). Moreover, patients receiving RA and Cutting Balloon tended to have greater final luminal gain (2.15±0.48mm *versus* 1.95±0.47mm; p=0.132). At the one-year follow-up, the RA + Cutting Balloon strategy was shown to be safe, did not increase the rate of MACE, and was associated with a lower risk of in-stent restenosis (OR=0.136; 95%CI 0.020-0.936; p=0.043).¹²

Chen et al. published a retrospective study of 293 patients undergoing RA to treat severely calcified, non-dilatable, and balloon uncrossable lesions. They observed a higher rate of side-branch perforation and contrast-induced nephropathy in the group undergoing RA in the main vessel and side-branches, as compared to the group undergoing RA only in the main vessel. However, there was no statistical difference in the long-term MACE rate between both subgroups at a mean follow-up of 25 months.¹³

In the study by Sakakura et al. with 2,635 percutaneous coronary interventions, RA was employed in 11.7% of cases. The main complications related to the procedure were periprocedural MI (2.9%) and vessel perforation (1.3%).¹⁴ In the international prospective registry of Bouisset et al. conducted in eight European countries and 19 centers, with 966 patients treated by percutaneous coronary intervention with RA, clinical success was observed in 91.9% of procedures. The rate of in-hospital MACE, defined as cardiovascular death, MI, target lesion revascularization,

Figure 1. Example of rotational atherectomy procedure. (A) Right coronary artery with extremely calcified lesion and proximal occlusion on angiography. (B) Application of rotational atherectomy. (C) Result after rotational atherectomy. (D) Result after drug-eluting stent implantation.

stroke, and coronary artery bypass graft surgery, was 4.7%. Factors independently associated with the occurrence of MACE at one year were female sex, renal failure, acute coronary syndrome upon admission, decreased left ventricular ejection fraction, and presence of significant left main coronary artery injury.¹⁵

Our study has important limitations that should be emphasized. Since this is a retrospective study with data collected from analysis of medical records, the results are susceptible to selection and information bias. The late follow-up over the phone was extremely impaired (37.1% inefficiency), because many numbers contacted were no longer active. Thus, the data of late follow-up presented here cannot be extrapolated to the general population submitted to RA, and have only an informative character, considering the patients successfully contacted.

CONCLUSION

Rotational atherectomy showed a low occurrence of adverse events in the immediate and long-term follow-up, leading to a high success rate of stenting in complex lesions. There have been substantial technological advances in treatment of calcified coronary lesions in recent years, with increased procedural success and fewer periprocedural complications. However, in clinical practice, all devices dedicated to treatment of calcified lesions, especially rotational atherectomy, are underutilized due to increased operational risk in inexperienced hands and substantially high costs.

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None.

DECLARATION OF CONFLICTS OF INTEREST

The authors declare having no conflicts of interest.

CONTRIBUTION OF AUTHORS

Conception and design of the study: FBA, MLP and GG; data collection: FBA and DFR; data interpretation: MLP, AMJ, FHF, FPB, AGA and MWN; text writing: DFR e HLG; approval of the final version to be published: FBA, DFR, HLG, MLP, AMJ, FHF, FPB, AGA, MWN and GG.

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