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Intravascular lithotripsy providing femoral vascular access as adjuvant therapy to transcatheter aortic valve implantation

Litotripsia intravascular proporcionando acesso vascular femoral como terapia adjuvante à substituição de valva aórtica transcateter

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ABSTRACT – We describe a transcatheter aortic valve implantation in a patient with multiple comorbidities, including important bilateral iliac stenosis and severe aortic stenosis, with high surgical risk, in whom femoral access was contraindicated due to subocclusive stenosis of the common iliac artery and intense calcification. A new endovascular treatment modality was employed by intravascular lithotripsy with a balloon cathether Shockwave®, which enabled treating the common iliac artery together with the valve implantation, allowing to advance a deployment system of a self-expandable aortic valve prosthesis, with good results and successful procedure.

Keywords: Lithotripsy/methods; Aortic valve; Aortic valve stenosis; Heart valve prosthesis implantation/methods; Iliac artery; Percutaneous peripheral endovascular intervention

RESUMO – Descrevemos uma substituição valvar aórtica transcateter em um paciente com múltiplas comorbidades, incluindo estenose ilíaca bilateral importante e estenose aórtica grave, com risco cirúrgico elevado, em que o acesso femoral seria contraindicado, pela estenose ilíaca comum suboclusiva e intensa calcificação. Foi utilizada uma nova modalidade de tratamento endovascular por meio de litotripsia intravascular com cateter balão Shockwave®, que possibilitou a realização do tratamento da artéria ilíaca comum adjuvante à substituição valvar, permitindo o avanço do sistema de liberação de uma prótese valvar aórtica autoexpansível, com ótimo resultado e sucesso do procedimento.

Descritores: Litotripsia/métodos; Valva aórtica; Estenose valvar aórtica; Implante de prótese valvar cardíaca/métodos; Artéria ilíaca; Intervenção percutânea endovascular periférica

INTRODUCTION

The femoral approach for percutaneous transcatheter aortic valve implantation (TAVI) was introduced in 2006 and is considered the first option, for its practical employment and broad use. The vascular complications are severe adverse events directly associated with increase in mortality. According to the definition by the Valve Academic Research Consortium (VARC), the major and minor vascular complications are observed in 5% to 23.3% and 5.6% to 28.3% of procedures, respectively.[1]

The femoral approach is more often used in patients submitted to TAVI due to its easiness of use, safety and effectiveness. However, in 15% to 20% of candidates to TAVI, this approach is not accessible due to presence of diffuse atherosclerotic disease, calcification, tortuosity or small diameter of vessels. For such cases, there are several alternative approaches, such as transsubclavian, transaortic, transapical, transcarotid, transseptal and transcaval.[1]

We describe the case of a patient with multiple comorbidities, including subocclusive bilateral iliac stenosis and severe aortic stenosis, scheduled for TAVI due to

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high surgical risk, and initial contraindication for femoral access for severe iliac stenosis. Since a new treatment modality was available, by means of intravascular lithotripsy (IVL), it was possible to perform iliac treatment together with TAVI, allowing to advance the deployment system of a self-expandable aortic valve prosthesis, with good results and procedural success.

CLINICAL CASE

An 82-year-old white male patient, with severe aortic stenosis, presenting with symptoms of heart failure, New York Heart Association (NYHA) functional class II. He presented with multiple comorbidities, including hypertension, type 2 diabetes mellitus, obesity, dyslipidemia, stroke 6 years ago, chronic obstructive pulmonary disease, former smoker, total hip replacement on the right side, atrial fibrillation and on oral anticoagulant agent (apixaban), valvular cardiomyopathy and chronic arterial insufficiency due to significant bilateral iliac stenosis. Six years ago he underwent percutaneous coronary intervention in the mid-third of the left marginal branch with placement of drug-eluting stent, and currently with no significant coronary lesions.

Diagnostic methods

Electrocardiography showed atrial fibrillation and complete right bundle branch block. Echocardiography showed severe aortic valve stenosis, aortic valve area of 0.54cm^2, aortic transvalvular gradient with mean of 36.6mmHg and peak of 51.6mmHg, and left ventricle ejection fraction of 60%.

Computed tomography angiography revealed significant stenosis on the bifurcation of the common iliac artery, with intense calcification and area of 0.36cm^2 (Figure 1). Calcified aortic valve with valve perimeter of 87mm, valve area of 555mm^2, large aortic valve sinuses (34×35×36mm), left ventricle outflow track of 18×27mm, and sinotubular junction of 30×31mm. Based on the measures, a self-expandable prothesis Evolut R 34mm (Medtronic®, Santa Rosa, CA, USA) was chosen.

Procedure

The case was discussed with the Heart Team, since the patient had high surgical risk, and it was chosen to perform an elective percutaneous valvar treatment. Patient was submitted to a minimalist TAVI procedure, with conscious sedation and local anesthesia. Primary access through the left femoral artery (6F, later changed to 16F), and secondary access via the right femoral artery (6F). First, two devices Perclose ProGlide® (Abbott Vascular, Santa Clara, CA, USA) were pre-implanted, and unfractioned heparin 100U/kg was administered.

The catheter Pigtail 6F was passed through the right femoral access, and angiography showed calcification and significant stenosis at the bifurcation of the common iliac artery (Figure 2A). Guidewire BMW 0.014 (Abbott Vascular, Santa Clara, CA, USA) was passed and the IVL balloon catheter (Shockwave® Medical Inc., Fremont, CA, USA) was introduced through the iliac lesion (Figures 2B and 2C). The IVL balloon catheter was inflated at 4atm and four cycles of treatment were performed, successfully applying 20 shockwaves in each cycle. The left femoral sheath was changed to 16F, the guidewire 0.035" Supra Core (Abbott Vascular, Santa Clara, CA, USA) was passed through the aortic valve. The following steps were perfomed: Pigtail 6F catheter passage, hemodynamic measures, guidewire 0.035" Safari extra-small (Boston Scientific, MA, USA), and aortic valve pre-dilation using an aortic valvoplasty balloon catheter True® Dilatation 18×45mm (Bard Peripheral Vascular, Inc., Tempe, AZ, USA), with no complications. Next, the self-expandable prothesis delivery system Medtronic® Evolut R 34mm was passed through the left femoral access, the sheath 16F was removed, and the in-line sheath of the valve system was used (sheathless); crossing the previously treated iliac lesion presented no difficulty. TAVI was successfully performed (Figure 3A). The final angiography

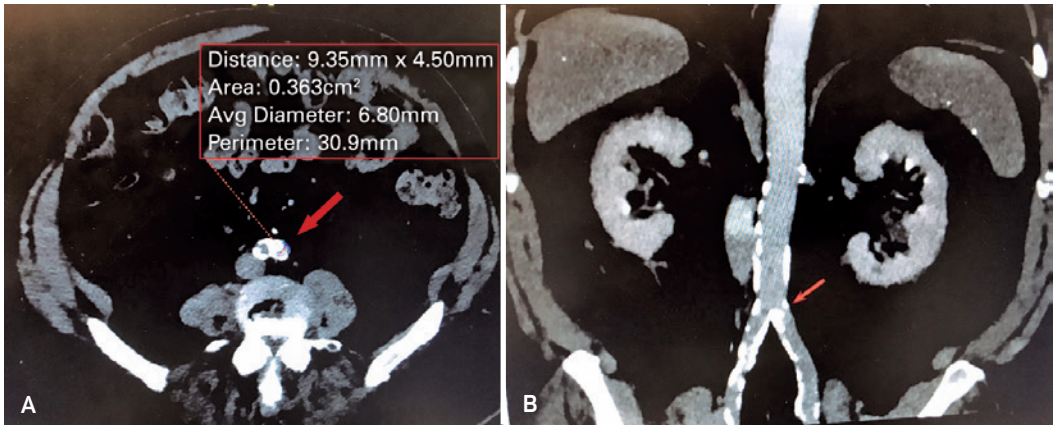

Figure 1. Computed tomography angiography. (A) Significant stenosis of the common iliac artery with intense calcification (arrow), cross section. (B) Significant stenosis of the common iliac artery with intense calcification (arrow), longitudinal section.

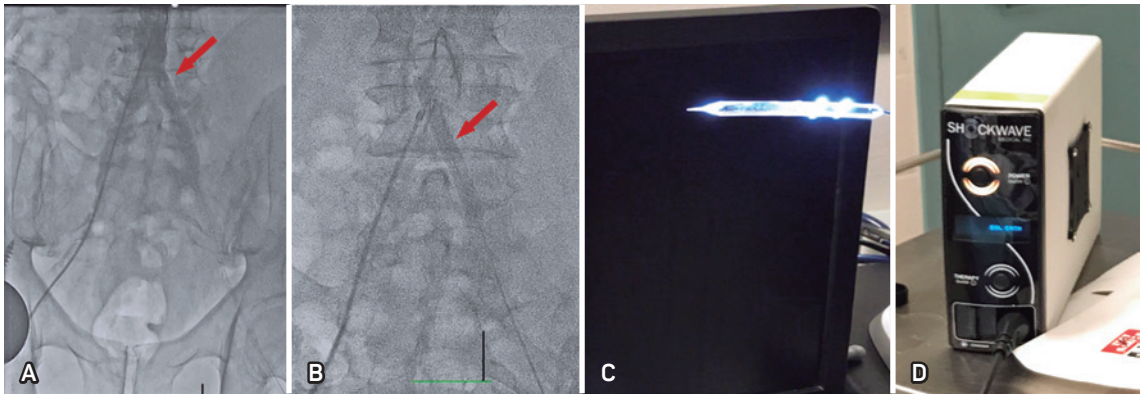

Figure 2. Angiography. (A) Angiography showing calcification and significant stenosis at the bifurcation of the common iliac artery (arrow). (B) Angiography showing treatment of the common iliac artery with inflation of intravascular lithotripsy balloon catheter Shockwave® (arrow). (C) Intravascular lithotripsy balloon catheter Shockwave®. (D) Shockwave® console.

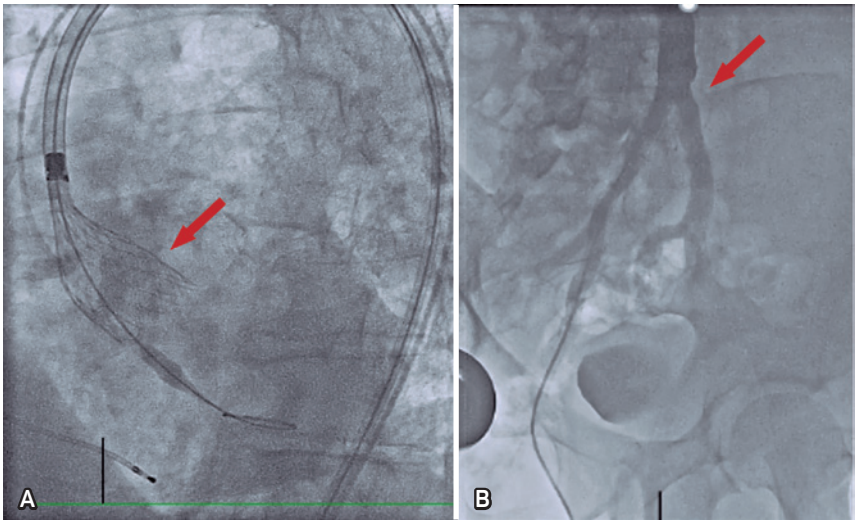

Figure 3. Angiography. (A) Deployment (arrow) of the self-expandable prothesis CoreValve Evolut R 34mm (Medtronic®, Santa Rosa, CA, USA). (B) Result at the bifurcation of the common iliac artery after treatment with intravascular lithotripsy (arrow).

demonstrated procedure success of IVL (Figure 3B). Left femoral hemostasis was carried out with the vascular repair devices previously implanted; on the right femoral artery, Angio-Seal® 6F (Terumo® Interventional Systems) was successfully used for the same purpose. The patient was discharged on the following day, and admission went uneventfully.

DISCUSSION

The present case demonstrated the choice of the vascular access site for patients submitted to TAVI should be individualized, according to the patient's characteristics and selection criteria, such as images, technical aspects and clinical results.[2] The evaluation of the access site in patients candidate to TAVI is crucial to prevent vascular complications. Vessel size, calcification and tortuosity in the iliac-femoral axis are important determinants of risk for complications related to insertion of the sheath.[1] In the case described, we chose the sheathless technique, which uses only the sheath of the self-expandable valve prosthesis, and does not employ the large sheath 20F that would be required for the 34-mm prosthesis and more likely to have vascular access complications.

The new IVL method Shockwave® is already marketed in Europe and the United States to treat peripheral vascular diseases, and allows using the femoral approach for most of those patients in whom this access is contraindicated, especially in calcified stenotic lesions. This technology combines balloon catheter from angioplasty with potent sound waves, similar to that used for renal calculi.[3,4]

The lithotripsy catheter transducers emit sound-wave pulses inside the vessels to break superficial and deep calcifications before inflating the angioplasty balloon.[5,6] In the present case, IVL was essential for the procedure, changing a formal contraindication to femoral approach

(artery extremely calcified with luminal subocclusion) into a procedure that is technically simpler, safe, successful and without complications.

Several alternative accesses are available, but all are technically more difficult and present greater risks.[2] Peri-procedural myocardial lesion in patients submitted to non-femoral TAVI has been already demonstrated.[7] In addition, transapical approach is associated to significantly larger myocardial lesions, and presents higher apical bleeding rates and major access-related complications, with greater risk of forming apical aneurysm, ventricular rupture, and late arrhythmias, mainly in frail elderly patients, like the individual herein described.[8,9]

Therefore, IVL provided adequate approach to perform TAVI in a fast, safe and efficient manner, with no need for surgery to obtain alternative accesses, and enable treatment of the patient as per the minimalist protocol, with early discharge in less than 24 hours after the procedure, which might not be possible in case of an alternative surgical access.[10] Hence, IVL is a new important tool in the scenario of challenging peripheral vascular accesses.

FUNDING SOURCE

None.

CONFLICTS OF INTEREST

The authors declare there are no conflicts of interest.

CONTRIBUTION OF AUTHORS

Conception and design of the study: LAPD and GFA; data collection: AM and CB; data interpretation: GFA; writing of the text: LAPD; approval of the final version to be published: GFA.

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