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Transcatheter implantation of balloon expandable bioprosthesis for large bicuspid aortic valve: case report

Implante transcater de bioprótese balão-expansível em válvula aórtica bicúspide e de grandes dimensões: relato de caso

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ABSTRACT – Transcatheter aortic valve implantation is one of the main treatment strategies for severe symptomatic aortic valve stenosis. The expansion of indications for low surgical risk patients has been based on recent studies. In this scenario, a younger population with bicuspid aortic valves is expected to be more frequently submitted to transcatheter valve replacement, given this anatomic profile is generally associated with larger aortic rings. There is no consensus on the best technique to use on these cases. We describe the implantation of an Edwards SAPIEN 3 prosthesis on a patient with a bicuspid aortic valve and large ring, and report the in-hospital follow-up.

Keywords: Aortic valve stenosis; Transcatheter aortic valve replacement; Aortic diseases; Bioprosthesis; Heart valve prosthesis

RESUMO – O implante transcater de válvula aórtica é uma das principais estratégias de tratamento da estenose aórtica grave sintomática. Estudos recentes embasaram a expansão das indicações para pacientes com baixo risco cirúrgico. Nesse contexto, espera-se que uma população mais jovem e portadora de válvulas aórticas bicúspides seja mais frequentemente submetida à terapia valvar transcater, pois esse perfil de anatomia está em geral associado a anéis aórticos de maiores dimensões. Não há consenso sobre a melhor técnica a ser empregada nesses casos. Descrevemos um implante com Edwards SAPIEN 3 em paciente com válvula aórtica bicúspide e anel grande, demonstrando sua evolução intra-hospitalar.

Descritores: Estenose da valva aórtica; Substituição da valva aórtica transcater; Doenças da aorta; Bioprótese; Próteses valvulares cardíacas

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is one of the major treatment strategies for severe symptomatic aortic stenosis (AS). Its use has grown fast since the first case was performed in France, in 2002, and its inclusion in guidelines on the topic, in 2008.¹ Randomized clinical trials have confirmed the safety and efficacy in moderate and high surgical risk patients.^{2,3} In 2019, indications were expanded to low-risk patients, based on studies showing non-inferiority and even superiority in relation to surgical treatment.^{4,5}

Roughly 80% of individuals with severe AS are estimated to belong to this low surgical risk group. Thus, a substantial increase in demand for TAVI in coming years is expected. Patients with bicuspid aortic valve (BAV) are among them. The latter is considered the most frequent congenital heart disease, with an estimated prevalence of 1.3%, occurring preferably in males (3:1). Clinical manifestations occur around the fifth or sixth decades of life.⁶

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Aortic disease, pronounced calcifications and large and eccentric aortic rings are more common in individuals with BAV, which add difficulties to planning and performing procedures, given there is no consensus on the best strategy to be adopted. When the choice is an expandable balloon device, the maximum value of the aortic ring area within manufacturer recommendations for Edwards SAPIEN 3 prosthesis (S3; Edwards Lifesciences, Irvine, California, USA) 29mm should be 683mm².

The present report aims to show technical aspects of implanting a S3 prosthesis above, different from manufacturer recommendations for a patient with BAV and large aortic ring, and also present in-hospital clinical results.

This study was evaluated and approved by the Research Ethics Committee of Universidade Metodista de Piracicaba (protocol 4.126.537, CAAE 33356920.9.0000.5507).

CASE REPORT

The patient was a 78-year-old male, 1.67m tall and weighed 74kg (body mass index 26.5), with a history of hypertension, diabetes mellitus and chronic renal failure (serum creatinine of 1.38mg/dL, estimated clearance of 55.11mL/minute). He was submitted to coronary artery bypass graft (CABG) in 2010, and received a left internal mammary artery anastomosis for the left anterior descending artery and saphenous vein grafts for right coronary artery and marginal left branch.

The patient complained of breathlessness at minimal exertion, compatible with heart failure functional class III according to the New York Heart Association (NYHA). The transthoracic echocardiography revealed severe AS, with a valve area of 0.5cm², maximum and medium pressure gradients of 88mmHg and 59mmHg, respectively, mild mitral regurgitation, and reduced ejection fraction estimated at 38%. The electrocardiogram showed left chamber overload, without atrioventricular blocks or intraventricular conduction disorders. Cardiac catheterization showed patent surgical grafts.

The case was discussed by the local Heart Team and, due to the moderate surgical risk (Society of Thoracic Surgeons – STS score – 4.9% for mortality and 23.1% for morbidity-mortality), low risk for TAVI (TVT score of 1.99%) and to the presence of pervious surgical grafts, the choice was TAVI.

Computed tomography angiography (Figure 1) revealed a Sievers 1 type BAV, with fusion of commissures between right and left cusps, pronounced and large calcification of the raphe and large aortic ring, with an area of 822.4mm², perimeter of 103.3mm and mean diameter of 32.4mm (36.9x27.9mm). The left ventricle (LV) outflow tract had larger measures, with an area of 911.5mm², perimeter of 108.6mm and mean diameter of 34.4mm. The region located 4mm above the ring, in the intercommissure plane, was smaller, with an area of 695mm² and perimeter of 99mm (tapered configuration). The ascending aorta had a maximum diameter of 34.5mm, the left coronary artery was at a

height of 14.7mm and the right coronary artery, at 20mm. The Valsalva sinus had a mean diameter of 33.3mm. There was pronounced calcification in the entire aortic root (Figure 2). Vascular accesses in the ileo-femoral region had slight calcifications, little tortuosity and diameters >8mm to the right and >7mm to the left.

NC: non-coronary cuspid; RC: right cuspid; LC: left cuspid.
Figure 1. Computed tomography angiography with aortic ring measurements.

Figure 2. Distribution of calcium in the aortic root.

The procedure was performed under general anesthesia with orotracheal intubation and transesophageal echocardiogram; puncture of femoral artery and vein to the left, with insertion of 7F and 6F introducers and passage of temporary transvenous 5F pacemaker, and protection of contralateral access with guidewire 0.018"x300cm (V-18™, Boston Scientific, Marlborough, MA, USA). The main access was the right common femoral artery, with pre-closure of the orifice with two Perclose Proglide™ (Abbott Vascular, USA) devices and passage of a Commander system 16F eSheath (Edwards Lifesciences, Irvine, California). Systemic heparinization was performed (100IU/kg), crossing

the valve with an AR 2 5F catheter and straight tip Teflon guidewire; positioning of the Lunderquist DC (Cook Medical) guidewire in the LV; predilation with semicomplacent Commander 25x40mm balloon and S3 29mm implant (fast stimulation by the pacemaker at 180bpm) with 3mL above nominal volume of the balloon. A high implant was chosen, with the lower limit of the central mark of the balloon positioned higher than usual in relation to the ring (Figure 3). After the implant, patent coronary arteries and minimum paraprosthetic regurgitation (PR) were observed, both on the aortography and on the echocardiography (Figure 4).

Figure 3. Aortic valve transcatheter implant. (A) High positioning of bioprosthesis. (B) Angiographic result.

Figure 4. Echocardiographic result. Arrow indicating trivial paraprosthetic regurgitation. (A) Long axis of aorta. (B) Transverse axis of aorta.

Manometry did not reveal gradient between LV and aorta. The mean gradient on the echocardiogram was 5mmHg, and the choice was not to post-dilate. We did not observe conduction disorders, and the temporary pacemaker was immediately removed, as were the catheters and 0.018" guidewire, after checking there were no vascular complications on the angiogram. After hemostasis of all accesses, the patient was extubated in the cath lab and sent to the stepdown Cardiology Unit. Serial electrocardiogram monitoring did not show any alterations. The transthoracic echocardiogram corroborated the intra-procedural findings of low gradient and minimal PR. The patient was discharged within 48 hours, taking aspirin, 100mg a day and clopidogrel 75mg a day.

DISCUSSION

The approach to patients with BAV and larger aortic rings will probably become more frequent in coming years, given the growing demand for TAVI, and recent expansion of its indication for low surgical risk patients. This kind of anatomy poses technical challenges and questions on late development, since there are still no prospective randomized studies specifically dedicated to this condition.

A meta-analysis including 758 patients with BAV submitted to TAVI did not show an increase in mortality in this scenario, when compared to procedures performed on tricuspid valves.⁷ However, other outcomes were more frequent in a 30-day follow-up, with an incidence of moderate to severe PR of 12.2%, and need for a pacemaker implantation reaching 17.9% of cases. On the other hand, a recent retrospective analysis of 5,412 TAVI for BAV, in which 3,705 of the procedures were performed with second generation devices, as is the case of S3, showed an expressive decrease in moderate to severe residual aortic insufficiency (2.7%) by using more contemporary implants.⁸

Regarding BAV planning, there is no consensus on computed tomography angiography measurements. There are basically two ways of measuring: at the level of the ring, as usual, or supra-annular, at the level of leaflets or commissures. Studies have suggested that ring measurement be used routinely and that the supra-annular be integrated into the assessment of questionable cases with borderline areas, or when the inter-commissure measurement is lower than the annular (tapered configuration).^{9,10} When there is raphe (Sievert 1 and 2 classification), the BAV implant has a unique aspect as to implant fixation. Unlike a tricuspid aortic valve, in which the anchorage zone involves the ring and the LV outflow track, fixation involves the ring and the raphe plane.

There is also no consensus on the level of oversizing required by computed tomography angiography. The structure of a S3 can be over-expanded to beyond what is recommended by the manufacturer (683mm²), and without reaching the ring area at issue. A higher volume applied to the balloon, assuring hyperexpansion of the prosthesis, but still maintaining undersizing of roughly -10.1% in relation

to the area of the ring, did not make PR more likely, nor 1-year mortality for patients with large aortic rings, in a sample including 26.7% of BAV.¹¹

In the present report, with a nominal diameter of S3, we would reach undersizing of -21.08% in relation to the ring, taking into account the formula:

$$\text{oversizing} = (649/\text{ring area} - 1) \times 100$$

By using an additional 3mL to the balloon, undersizing remained at -6.08%. The same line of thought applied to the intercommissure region, 4mm above the ring, would reach an undersizing of -6.61%, but with the additional 3mL to the balloon, it remained at +8.39%. Therefore, we integrated the ring measurement to the intercommissure measurement, since it was the case of non-usual format and size. PR at the end of the procedure was minimal both by the transesophageal echocardiography and the aortography.

By expanding the bioprosthesis with volumes above recommended, one should bear in mind the risk of ring rupture, prosthesis embolization and central regurgitation caused by any possible leaflet coaptation failure. Even by considering that S3 leaflets are larger than their predecessors, SAPIEN XT, there is information in the literature that allows expecting the occurrence of central regurgitation in 2.9% of patients within the first 30 days, and 11.6% within 1 year, albeit without increase in mortality or worsening of pressure gradient.¹²

Hyperexpansion and consequent loss of leaflet coaptation can lead to worsening of hemodynamic performance of S3, deterioration of leaflets and, in theory, to reduction in durability.¹³ However, there are no conclusive data on durability of hyperexpanded prostheses in patients with large rings after 1 year, which would be essentially important when approaching younger individuals with longer life expectancy.

The case discussed herein is technically challenging, taking into account the morphology and size of the aortic valve. However, through the meticulous analysis of computed tomography angiography during planning and appropriate implant technique, with predilation, and a high implant and hyperexpansion, we attained excellent immediate results, without adverse events in the in-hospital period. While large anatomy-dedicated devices are not commercially available, the present report suggests the technique described be used in specific cases, maintaining an appropriate safety and efficacy profile.

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None.

DISCLOSURE OF CONFLICTS OF INTEREST

Vinícius Esteves works as proctor in bioprosthesis implant for Edwards Lifesciences and Medtronic. The other authors declare they have no conflicts of interest.

CONTRIBUTION OF AUTHORS

Conception and design of the study: JFBT, VE, GFC and RCSP; data collection: JFBT, VE, MKMC, WGN and PTT; data interpretation: JFBT and VE; writing of the text: JFBT, VE and LAG; approval of the final version to be published: JFBT, GFC, RCSP, LAG, PTT, WGN, MKMC and VE.

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