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Post-dilation with non-compliant balloon for optimization of outcomes after implantation of self-expandable transcatheter bioprosthesis

Pós-dilatação com balão não complacente para otimização do resultado após implante de bioprótese transcateter autoexpansível

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ABSTRACT – Valve-in-valve procedures are likely to become increasingly frequent with the aging of the population and the increasing number of surgical bioprostheses implanted. More than 50% of these implanted valves have small diameters, which hinders the good expansion of transcatheter devices, leading to higher final gradients. Therefore, post-dilation is required to optimize implantation of the new device. Compliant balloons have limitations and a higher potential to rupture when used for this purpose. We describe a case of a valve-in-valve procedure using a non-compliant balloon for post-dilation of the implanted transcatheter device in a bioprosthesis with a small ring.

Keywords: Aortic valve/surgery; Heart valve prosthesis implantation/trends; Transcatheter aortic valve replacement/methods/methods; Bioprosthesis

RESUMO – Os procedimentos de *valve-in-valve* devem ser cada vez mais frequentes, com o envelhecimento da população e o aumento do número de implantes de biopróteses cirúrgicas. Mais de 50% dessas próteses implantadas apresentam diâmetros pequenos, dificultando a boa expansão dos dispositivos transcateteres, levando a maiores gradientes finais. Dessa forma, existe a necessidade de pós-dilatação, visando à otimização do implante do novo dispositivo. Os balões complacentes utilizados apresentam limitações e maior potencial de ruptura para essa finalidade. Descrevemos o caso de um procedimento de *valve-in-valve* com utilização de balão não complacente para pós-dilatação do dispositivo transcateter implantado em uma bioprótese com anel pequeno.

Descritores: Valva aórtica/cirurgia; Implante de prótese de valva cardíaca/tendências; Substituição da valva aórtica transcateter/métodos; Bioprótese

INTRODUCTION

The use of surgical bioprostheses to treat symptomatic severe aortic stenosis has been growing, in detriment of metallic prostheses, due to the need for permanent anticoagulation. These devices, despite all technology involved, have as a major limitation the fact that they deteriorate over time and, therefore, they need to be replaced.

Conventional surgical aortic valve replacement is one of the therapeutic alternatives, but a considerable number of patients have high surgical risk and, therefore, indicating a new procedure may not be an option. In this context, transcatheter aortic valve implantation (TAVI) appears as a treatment alternative for these cases, and the procedure is known as "valve-in-valve" (ViV).[1,2]

Studies show that approximately 50% of surgically implanted bioprostheses have small diameters (<21mm), and this anatomical feature prevents the adequate expansion of transcatheter devices, leading to high gradients (mismatch) at the end of the procedure. The international multicenter registry Valve-in-Valve showed survival rates

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over 80% after 1-year follow-up for patients subjected to this technique.[3] However, there was considerable mismatch (31%), since patients with a mean gradient over 20mmHg at the end of the procedure had poorer clinical outcomes.

With increasing life expectancy of the population, evolution of transcatheter devices and greater experience of operators, the number of ViV procedures for correction of degenerated bioprostheses is expected to grow. However, it is essential that outcomes be optimized aiming at lower residual gradients.

In this context, we describe the case of a ViV procedure using a non-compliant balloon for post-dilatation of the implanted transcatheter device in a bioprosthesis with a small ring.

CASE REPORT

An 87-year-old male patient, 55kg, 1.62m (body mass index – BMI – 20.9), with past history of hypertension, dyslipidemia, chronic obstructive pulmonary disease secondary to prior smoking, non-dialysis chronic renal disease (creatinine clearance 37mL/min) and previous heart surgery for aortic valve replacement, in 2007 (Braile 21 bioprosthesis).

The patient had dyspnea upon light exertion (heart failure Functional Class III-IV as per New York Heart Association–NYHA) and had had two recent hospitalizations for pulmonary congestion, reversed with intravenous diuretic and therapy optimization. A transthoracic echocardiography was performed, showing the bioprosthesis in aortic position with thickened leaflets, reduced opening and mobility, and moderate eccentric prosthetic valve regurgitation. On Doppler, the peak systolic gradient was 70mmHg and the mean systolic gradient, 46mmHg, with an aortic valve area of 0.8cm^2 and pulmonary artery systolic pressure of 71mmHg.

The case was discussed in a meeting of the multidisciplinary heart team and, considering the high surgical risk (Society of Thoracic Surgeons – STS – score of 11.95% for mortality, 43.19% for morbidity and mortality, and EuroSCORE 2 of 20.69%), the patient was included in a screening program for TAVI. Cardiac catheterization did not show the presence of obstructive coronary artery disease, and confirmed a high peak gradient between the left ventricle and the aorta (65mmHg), as well as a size mismatch between the surgically implanted bioprosthesis and the patient's aorta (Figure 1).

The computed tomography angiography showed that the inner diameters of the bioprosthesis were small, 17.6×13.6mm, with a perimeter of 46mm and an area of 182mm^2 (Figure 2). There was discreet calcification, the ascending aorta was 46.5mm in its largest diameter, the left and right coronary arteries were 20.6mm- and 24.2mm-apart from the aortic valve plane. The sinus of Valsalva had a mean diameter of 34.1mm and there was no calcification in the left ventricle outflow track (LVOT). The femoral iliac system had discreet calcification, with little tortuosity and diameters >6mm bilaterally.

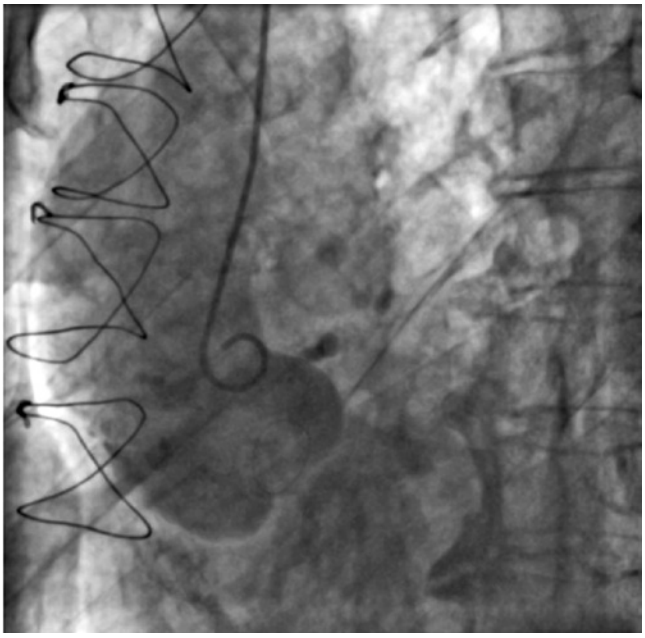

Figure 1. Aortography showing major diameter mismatch between the ring of the surgical bioprosthesis and the root of the aorta.

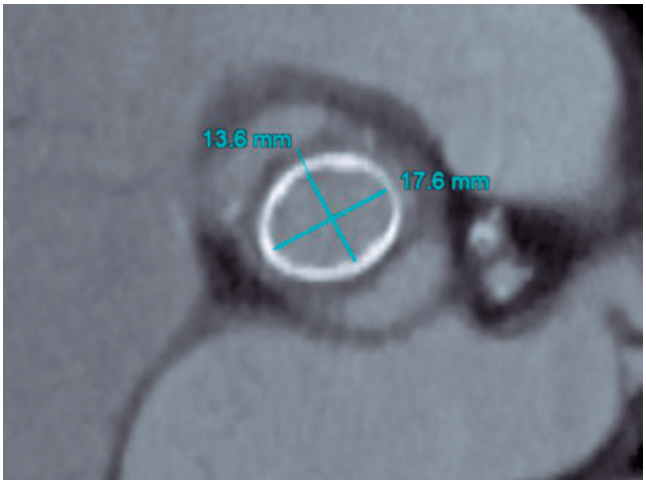

Figure 2. Computed tomography angiography showing the surgical ring with small diameters.

Procedure

The planning and strategy of the procedure were previously discussed and performed as follows: general anesthesia with orotracheal intubation, considering that the procedure was also guided by transesophageal echocardiography; antibiotic prophylaxis (cefazoline 2g intravenously); provisional 5F transvenous pacemaker placed in the interventricular septum using a 6F valved introducer sheath (the lateral line was used as the central venous access, avoiding

an additional venous puncture) into the right internal jugular vein; secondary access through the left femoral artery with a 7F introducer sheath; contralateral protection with a 0.018x300cm guidewire; main access in right femoral artery, with two Perclose Proglide® devices and a 18F Sentrant® introducer sheath; heparinization (100 IU/kg); crossing of the aortic bioprosthesis to the left ventricle with a 5F AL1 diagnostic catheter and a straight-tip Teflon-coated guidewire; Lunderquist® guidewire positioned at the tip of the left ventricle; implantation of a 23-mm Evolut™ R self-expandable bioprosthesis using as reference the radiopaque mark of the previously implanted surgical ring and echocardiographic images.

After implantation of the bioprosthesis, there was no central and/or periprosthetic aortic regurgitation, but the gradient between the left ventricle and the aorta was 45mmHg on manometry, and the peak and mean gradients were 50 and 31mmHg on echocardiography. The procedure chosen was post- dilation with an 18×40mm Atlas® Gold non-compliant balloon, insufflated to 14atm, when a sudden drop in pressure was seen on the gauge (with a specific high pressure insufflator provided by the manufacturer), with rapid stimulation by the provisional pacemaker at 180bpm (Figure 3). Manometry showed a drop in the peak gradient to 20mmHg, and gradients on the echocardiography of 26/12mmHg (Figure 4). After removal of catheters, guidewire and the 18F introducer sheath, the main access was successfully closed with suture devices, with no bruising and/or bleeding.

The patient was extubated in the room and sent for recovery in intensive care unit. The electrocardiogram did not show any changes when compared to the previous exam, and the provisional pacemaker was immediately removed. The patient had good clinical progression,

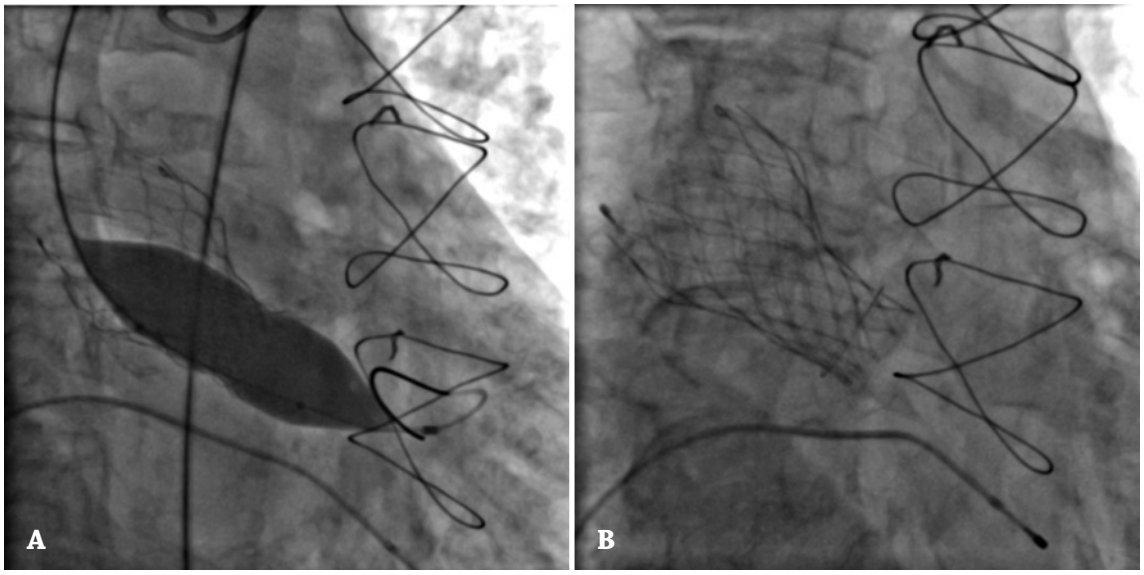

Figure 3. Percutaneous bioprosthetic aortic valve implantation. (A) Post-dilation of the 23-mm Evolut™ R bioprosthesis with 18x40mm Atlas® Gold non-compliant balloon to 14 atm; (B) final image of the implanted bioprosthesis.

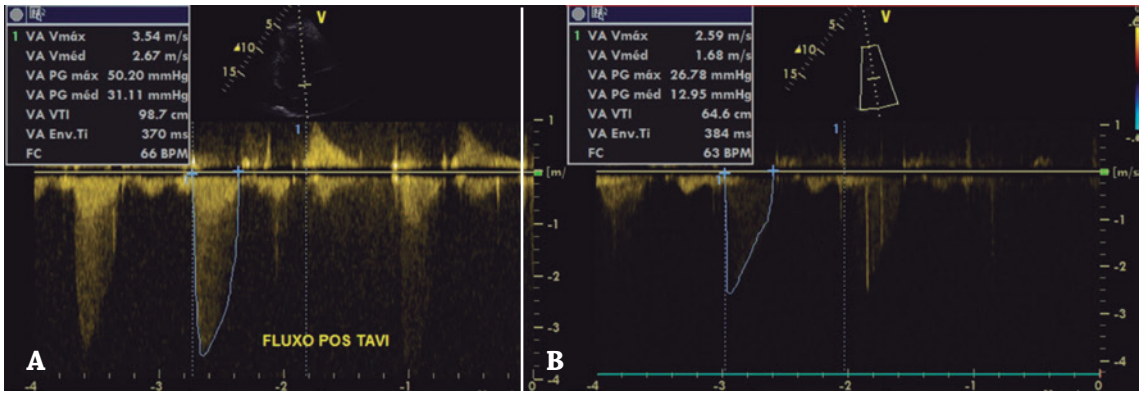

Figure 4. Aortic transvalvular gradient. (A) Echocardiographic control showing gradient after implantation of the transcatheter prosthesis; (B) major drop in gradient after balloon dilation.

with no access-related complications and no significant abnormalities in blood tests, and was discharged to go home 48 hours after the procedure. In the 3-month follow-up, the patient was in functional class I, with tapering and later withdrawal of diuretic therapy, with no need for new procedures.

DISCUSSION

ViV procedures will become increasingly frequent due to aging of the population, with an increased number of surgical bioprostheses implanted.[4] More than 50% of these implanted prostheses have small diameters, which hinders the good expansion of transcatheter devices, consequently leading to higher gradients at the end of the procedures. Therefore, there is a need for post-dilation, with the view to optimize implantation of the new device.[5,6] Compliant balloons have limitations and a higher likelihood to rupture when used for this purpose.

In vitro tests showed that not all bioprostheses can be fractured.[7] The technique usually employs a TRUE® Balloon or an Atlas® Gold (whereas only the latter is available in Brazil) non-compliant balloon, 1mm larger than the inner diameter of the bioprosthesis. Johansen et al.[8] and Chakravarty et al.[9] described their initial experiences with post-dilations using high-pressure, non-compliant balloons for ViV cases in degenerated surgical bioprostheses with small rings. Both reported good outcomes, with a significant drop in gradients and absence of complications. The purpose of the technique is to optimize the outcomes of the procedures by using a non-compliant balloon, insufflated to high pressures through hyperexpansion and/or fracturing of the ring of the previously implanted bioprosthesis. The authors described cases of ring fracture in prostheses that are rarely used or even unavailable in Brazil.

In this case report, we described this type of approach in a national Braile 21 bioprosthesis, with an inner diameter of approximately 17mm, which is widely used in the national market; however, its hyperexpansion or potential fracture have not been reported in the literature. It is a biologic, organic prosthetic valve, composed of porcine aortic valve cusps treated with glutaraldehyde and preserved with 4% formaldehyde. This treatment confers it appropriate resistance, flexibility and absence of antigenicity. The bioprosthesis is built on a polyacetal base lined with bovine pericardium, over which the previously treated porcine cusps are mounted. A special stainless steel wire, externally inserted into the support ring, reinforces the consistency of the base of the ring and allows for identification of the bioprosthesis position inside the patient through a simple radiographic examination. As described by the manufacturer, the surgical ring in this device is reinforced with a stainless steel wire, which prevents it from fracturing, even with the use of high-pressure, non-compliant balloons. Thus, the mechanism used for optimization of procedural outcomes was hyperexpansion, and not rupture of the bioprosthesis ring.

In this case, we chose to implant a transcatheter valve, measure the gradient and, finally, perform the post-dilation. This is an interesting aspect, because some authors report a different technique using the high-pressure, non-compliant balloon before implanting the new bioprosthesis, even in the presence of circulatory support.[10] The controversy is due to the fact that dilation before implantation of the bioprosthesis may lead to major hemodynamic impairment, followed by clinical deterioration, whereas aggressive post-dilation after implantation of the new bioprosthesis could, in theory, damage the leaflets of the device, although there are no supporting publications in this sense. Further studies and case reports are needed so that we can establish better strategies involving this technique. We conclude that post-dilation using high-pressure, non-compliant balloons can be used as an alternative in cases of ViV in small-ring prostheses to optimize outcomes.

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None.

CONFLICT OF INTEREST

The authors declare there are no conflicts of interest.

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