Case Report

Minimally-invasive strategy for transcatheter implantation of second-generation Lotus™ aortic valve system

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ABSTRACT

Transcatheter aortic valve implantation is a well-established therapy in patients with severe aortic stenosis. There has been a progressive improvement in device technology associated with increased experience of the interventionists, resulting in safer procedures with better outcomes. The first second-generation device approved in Brazil, Lotus™ Valve System (Boston Scientific Corporation, Natick, USA), incorporates several of these new characteristics. This report describes the first two cases, both successfully performed in the country, carried out under local anesthesia and conscious sedation.

Introduction

Transcatheter aortic valve implantation (TAVI) is currently a viable treatment option for patients with severe symptomatic aortic stenosis (AoS) considered inoperable or at high risk for complications related to conventional surgical valve replacement. This technique has shown consistent results, with a significant reduction in mortality compared to drug therapy in inoperable patients,1 and with mortality rates similar to those of conventional surgery in high-risk patients.2 However, complications inherent to the procedures can impair the short and mid-term outcomes, limiting the use of this technique.

Correct positioning of the first-generation devices available in Brazil at the level of the aortic valve annulus can be quite challenging, being one of the main limitations of the technique; furthermore, valve displacement can lead to severe complications, including coronary occlusion.3 Incomplete prosthesis apposition may occur in the presence of significant amounts of calcium, in highly elliptical anatomies, or with suboptimal implantation, resulting in paravalvular regurgitation (PVR);4,5 it has been associated with increased mortality in several longitudinal studies.

With technological development, several improvements have been achieved in the devices, as well as in anesthetic management. The authors describe herein the first two procedures per-
formed in Brazil using a second-generation device, the Lotus™ Valve System (Boston Scientific Corporation, Natick, USA) for percutaneous treatment of AoS performed under local anesthesia and conscious sedation.

Case reports

Case 1

An 88-year-old female patient was admitted at Hospital Brasil (Santo André, SP, Brazil) for congestive heart failure, with New York Heart Association functional class (NYHA) IV. The patient had a history of hypertension, diabetes mellitus, and coronary artery disease with angioplasty and drug-eluting stent implantation for lesion in the left anterior descending artery in 2014, and moderate AoS. The transthoracic echocardiography (TTE) at admission showed severe AoS; due to her advanced age and comorbidities, a percutaneous treatment was indicated. Contrast computed tomography was performed to evaluate the aortic root, valve annulus, and vascular access (Table 1).

The procedure was performed under local anesthesia, conscious sedation, and without the need for transesophageal echocardiography. Heparin was administered at a dose of 150 IU/kg, in order to achieve an activated clotting time between 300 and 350 seconds. Initially, the right femoral arterial access was achieved with a 7 F sheath for contralateral protection with a 0.018 × 300 cm guidewire. The main arterial access was achieved percutaneously from the left femoral artery, using two Perclose Proglide® devices (Abbott Vascular, Redwood City, USA), followed by an 18 F sheath. Right femoral venous access was achieved percutaneously for implantation of a temporary pacemaker in the right ventricle. Subsequently, an aortography was performed to identify the view with the alignment of the three cusps on the same plane, which was used to release the prosthesis. The basal peak-to-peak transvalvular aortic gradient was 83 mmHg. A rigid 0.035° Safari® Pre-Shaped TAVI Guidewire (Boston Scientific Corporation, Natick, USA) was maintained in the left ventricle and an 18 × 40 mm valvuloplasty Cristal® balloon (Balt, Montmorency, France) was advanced over this guidewire, positioned in the aortic valve, and inflated to its nominal diameter under pacemaker-induced tachycardia. Next, a number 23 Lotus™ Aortic Valve System was advanced over the rigid guidewire and positioned at the level of the valve annulus. After angiograms were performed for position adjustment, the device was released. The angiographic control showed no regurgitation, whereas manometry showed no systolic transvalvular gradient (Fig. 1). The TTE performed at the end of the procedure confirmed the absence of aortic regurgitation, a peak gradient of 18 mmHg and a mean gradient of 8 mmHg. The patient was transferred to the room the next day and was discharged 4 days after the procedure.

Case 2

An 87-year-old female patient was admitted at Hospital São Luiz, Unidade Morumbi (Sao Paulo, SP, Brazil) for congestive heart failure (CHF) in NYHA functional class IV. She had a long-term diagnosis of severe AoS, having repeatedly refused surgical treatment. Due to the high surgical risk and in accordance with the patient’s preference, it was decided to perform a percutaneous treatment. Contrast CT was performed to evaluate the vascular access, as well as the aortic valve and aortic root geometry (Table 1).

The procedure was performed under local anesthesia, conscious sedation, and without the need for transesophageal echocardiography. Initially, heparin was administered (150 IU/kg), and right femoral access was achieved with a 7 F sheath (contralateral protection). The main arterial access was achieved percutaneously from the left femoral artery, using two Perclose Proglide® devices (Abbott Vascular, Redwood City, USA), followed by an 18 F sheath. A temporary pacemaker was implanted through the right femoral vein. An aortography was performed to identify the view with the alignment of the three cusps on the same plane, which was used to release the prosthesis. The basal peak-to-peak transvalvular aortic gradient was 90 mmHg. Valvuloplasty using an 18 × 40 mm Cristal® balloon (Balt, Montmorency, France) was performed before the implantation of a number 23 Lotus™ Aortic Valve System, both advanced over the 0.035° Safari® rigid guidewire and positioned at the level of the valve annulus. After angiograms were performed for position adjustment, the device was released. Angiographic control and the final TTE showed no regurgitation. The post-procedural peak and mean gradients were 15 mmHg and 9 mmHg, respectively. The patient left the intensive care unit after 48 hours and was discharged 5 days after the procedure.

Discussion

The Lotus™ valve system has been recently introduced in Brazil for the treatment of severe symptomatic AoS. This is a bovine pericardial
bioprosthesis with three leaflets attached to a nitinol mesh structure, with a radiopaque marker in a system mounted on a catheter for introduction and retrograde release through the femoral artery (Fig. 2). The valve is released by controlled mechanical expansion. It is pre-attached to a delivery system and features early leaflet operation, which contributes to a controlled and precise initial positioning, repositioning, or complete withdrawal at any time prior to release, even when 100% expanded, as in the case of malaposition or unfavorable complications (e.g., coronary occlusion). It has a single external adaptive seal made of polyurethane/polycarbonate, designed to adapt to irregular anatomical surfaces, occluding interstices between the prosthesis and the degenerated calcified leaflet material at the aorto-ventricular interface, thus minimizing PVR. There is no need for pacemaker-induced tachycardia during implantation. It is available in 23 mm (18 F sheath), 25 mm, and 27 mm (both with 20 F sheath).

Its unique characteristic of early leaflet operation, even before being completely released, associated with the lack of need for rapid ventricular pacing by a pacemaker and its capacity to be fully recaptured after implantation and before its release, are characteristics that prioritize its choice for less invasive strategies, using local anesthesia and conscious sedation.

The REPRISE II (RePositionable Percutaneous Replacement of Ste-notic Aortic Valve Through Implantation of Lotus Valve System: Evaluation of Safety and Performance) clinical trial, a prospective, multicenter, single-arm study in high-risk surgical patients with severe AoS, demonstrated the safety and efficacy of the procedure during successful valve implantation in all 120 patients, while achieving the primary outcome of device performance (mean gradient < 18 mmHg at 30 days), with low mortality (4.2%) and incapacitating stroke (1.7%) rates, as well as absence of embolization, ectopic release of the valve, or implantation of an additional valve. Additionally, it showed marked functional class improvement (91% were in functional class I or II, at 30 days) with low rate of significant PVR (moderate PVR occurred in 1.0%, and severe PVR in none of the patients).

General anesthesia has some disadvantages, such as the cardiodepresant effect of general anesthetics, which can cause cardiovascular instability during anesthesia induction and during the procedure, particularly hypotension and bradycardia, and, consequently, the need for vasoconstrictors, which may be deleterious in patients with severe AoS. Local anesthesia, in turn, prevents uncontrolled hemodynamic rate of general anesthetics, which can cause cardiovascular instability during anesthesia induction and during the procedure, particularly hypotension and bradycardia, and, consequently, the need for vasoconstrictors, which may be deleterious in patients with severe AoS. Local anesthesia, in turn, prevents uncontrolled hemodynamic instability during anesthesia induction and during the procedure, particularly hypotension and bradycardia, and, consequently, the need for vasoconstrictors, which may be deleterious in patients with severe AoS.

In conclusion, the cases described in this study demonstrate the performance of a prosthesis that allows greater stability during the procedure, accurate placement (with correction at any stage prior to its release), and adaptive seal with the potential to minimize PVR (and also decrease the need for TTE). Furthermore, this prosthesis enables the use of less invasive techniques, such as local anesthesia and conscious sedation.

Funding source
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Conflicts of interest
The authors declare no conflicts of interest.

References

Figure 2. (A) Nitinol mesh structure. (B) Central radiopaque positioning marker. (C) Locking mechanism. (D) Bovine pericardium. (E) Adaptive Seal™.