

Editorial

The repositionable Lotus™ valve system

O sistema de válvula reposicionável Lotus™

Transcatheter aortic valve implantation (TAVI) is an established therapeutic option for patients with severe and symptomatic aortic valve stenosis (AS) who are inoperable or at high risk for conventional surgery (surgical aortic valve replacement – SAVR).

The first randomized pivotal trials in the United States with the first generation TAVI prosthesis have shown a significant survival benefit for TAVI over SAVR in PARTNER B, and non-inferiority in PARTNER A. Current 5-year data of the PARTNER trials have demonstrated the long-term durability and even superior hemodynamic parameters of TAVI valves.^{1,2} The randomized CoreValve US trial, a “high-risk study” with the self-expanding TAVI prosthesis, reported a significant survival benefit in TAVI patients when compared with SAVR.³ In contrast to the PARTNER trial, the CoreValve US pivotal trial applies the best clinical practices, including computed tomography-based sizing and the use of an independent echocardiographic core lab.

Due to the advancing experience with the TAVI systems, including a learning curve and evolution of the systems, better results and lower rates of complications and mortality were achieved, as shown by the real-world data. The new TAVI systems (second-generation devices) allow for a more secure implantation, are easier to use, and present better anatomical adaptation. Therefore, even better results are to be expected with the new TAVI systems, and the risk of serious periprocedural complications and mortality will be further reduced. In the pivotal studies, the new valves are already showing better results than the first generation prostheses.⁴

The Lotus™ Valve System (Boston Scientific – Natick, USA) is one of the new generation devices. It is a mechanical expandable and repositionable TAVI system that includes a bioprosthetic aortic valve consisting of three bovine pericardial leaflets mounted into a nitinol frame. Three valve sizes are available: 23 mm, 25 mm, and 27 mm, covering an annulus range from 20 to 27 mm. Other advantages of the prosthesis include the adaptive seal around the inflow portion of the device, to minimize paravalvular leak (PVL), and the radiopaque marker for guided and precise implantation in the target anatomical position. The clinical results with this prosthesis have been previously described. Ongoing clinical and real world studies, such as the REPRISE (REpositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus™ Valve SystEm) III and RESPOND, expand the clinical dataset.^{5,6}

The article by Esteves et al. in this issue of the *Revista Brasileira de Cardiologia Invasiva* presents the initial experience in Brazil with the second-generation repositionable Lotus™ valve system, as well as the in-hospital outcomes. The study was designed as an observational, retrospective, and multicenter registry of high surgical risk patients treated with the Lotus™ Valve System. One patient underwent a valve-in-valve (VinV) procedure in degenerated bioprosthesis.

Despite the small number of patients in this study, the efficacy and safety of the repositionable retrievable Lotus™ Valve System in patients at high surgical risk with AS was demonstrated, with similar results when compared with other controlled studies and with-

out an apparent learning curve. Regardless of the sheath size (18 to 20 F) for the Lotus™ valve, a low vascular complication rate has been reported. Furthermore, the good outcome data in patients with complex anatomies indicates the feasibility and safety of this new TAVI device in real-world patients. Device success, defined in accordance with the Valve Academic Research Consortium (VARC-2)⁷ criteria, was achieved in 96.7%. There were no cases of valve migration, embolization, ectopic valve deployment, or TAV-in-TAV deployment. The VARC-defined combined safety rate was very high, with a non-device-associated mortality rate of 3.2% (one patient), no cases of stroke or moderate or severe aortic regurgitation. This is one of the greatest advantages of this prosthesis, as its structure with a strong axial force and adaptive seal appears to solve the problem of PVL. Another benefit is the option of repositioning, which allows for an optimal positioning to eliminate PVL.

However, some challenges still remain, such as the rate of pacemaker implantation due to the induced conduction disturbance. At the RESPOND study, this rate was 36.5%, being similarly high at 38.7% in the Brazilian experience.

The number of pre-dilatations was noteworthy in this study being used in 65% of the procedures. Post-dilatation was performed in one of the procedures. There is no evidence regarding the effect or advantages of pre-dilatation before TAVI, as it was mandatory in the initial studies. Therefore, expert opinions differ about the need of pre-dilatation in some patient subsets. However, it is a sensible step in cases with very highly calcified cusps, very high-gradient stenosis, or very small valve orifice area.

There is already continuous ambition and development to further optimize second-generation TAVI prosthesis, as well as to overcome the remaining challenges: the reduction of the sheath size and the reduction of atrioventricular (AV) conduction disturbances and pacemaker rate.

With the evolution of the devices, increasing improvement of procedural results, and further reduction of the mortality, there is a tendency to expand the indications to patients with intermediate risk. Subgroup analyses with TAVI in intermediate-risk patients have already shown equivalent results to SAVR in terms of mortality and valve function. We expect further trends and data with enthusiasm.

Conflicts of interest

Gerckens is proctor and consultant for Boston Scientific and Medtronic Inc. Yuecel declares no conflicts of interest.

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