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EDITORIAL

Transcatheter aortic valve implantation with a mechanical-expandable device: when perfection is hung on a 'wire'

Corrado Tamburino* and Marco Barbanti

Division of Cardiology, Ferrarotto Hospital, University of Catania, Catania, Italy

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This editorial refers to 'Safety and efficacy of a repositionable and fully retrievable aortic valve used in routine clinical practice: the RESPOND study'[†], by V. Falk *et al.*, on page 3359.

Since the first-in-human transcatheter aortic valve implantation (TAVI) performed by Alain Cribier in 2002, this innovative procedure has had widespread recognition as the treatment of choice for severe aortic stenosis in inoperable patients and as a reasonable alternative to conventional surgical aortic valve replacement in patients with intermediate and high surgical risk.[1]

In the last 15 years, TAVI technology has gone from strength to strength, transforming a challenging intervention into a standardized, simple, and streamlined procedure.[1,2] The development of the so-called 'new-generation' TAVI devices have profoundly contributed to this successful journey, by incorporating features to reduce the delivery catheter profile, facilitate deployment, and enable repositioning and retrieval capability.[3]

The Lotus valve (currently from Boston Scientific, Marlborough, MA, USA, and formerly from Sadra Medical, CA, Los Gatos, USA) can be easily considered the precursor of the new-generation TAVI devices. Being implanted for the first time by Buellesfeld and colleagues in 2007,[4] this technology has literally shown the way to an entire generation of new TAVI devices, being the first to incorporate an external sealing membrane to fill paravalvular gaps and make it possible to reposition the prosthesis before complete release.

The safety and efficacy of the Lotus valve was originally demonstrated in the REPRISE I[5] and REPRISE II[6] studies, and more recently confirmed by several national registries[7–9] and the REPRISE III randomized trial.[10]

This issue of the journal offers the readers the acute results of the RESPOND (Repositionable Lotus Valve System – Post-Market Evaluation of Real World Clinical Outcomes) study, a prospective, open-label, single-arm, multicentre, post-market registry enrolling 1014 'all-comer' patients undergoing TAVI with the Lotus valve.[11]

The study was well designed and rigorously performed. In addition, this is the largest experience to date evaluating the outcomes of TAVI with the Lotus valve. The incorporation of independent medical review for clinical endpoints and the core laboratory for paravalvular leak assessment are other quality elements of the registry.[11]

The patient population enrolled in this study is elderly and mostly at intermediate risk, reflecting current clinical indications for TAVI. Device-related complications were extremely rare. The authors reported a 98.1% peri-procedural success rate (successful vascular access, device delivery, and deployment of the Lotus valve, and successful retrieval of the delivery system). Repositioning of the valve was attempted in 29% of patients and was successful in 99.0%. Valve dislocation, and implantation of two valves occurred only in five cases (0.5%).

At 30 days, the mortality rate was 2.6%; the rates of cerebrovascular accidents and major vascular complications were 3.0% and 3.4%, respectively. These latter are well in line with the rates observed in the most recent TAVI series.[12]

Valve performance was extraordinarily favourable, further legitimizing the Lotus valve as the 'best-in-class' among the entire spectrum of transcatheter aortic valves in terms of paravalvular leak. Moderate or severe paravalvular aortic regurgitation was seen in <1% of patients, and mild leak was also infrequent, being reported in 7.7% of patients.

However, such a favourable performance came at a non-negligible price. Approximately one-third of patients in RESPOND developed conduction disturbances needing permanent pacemaker implantation. This rate is at least double compared with other new-generation transcatheter aortic valves,[12] and compares favourably with what has been observed in previous series with the Lotus valve.[5–10]

The opinions expressed in this article are not necessarily those of the Editors of the *European Heart Journal* or of the European Society of Cardiology.

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* Corresponding author. Division of Cardiology, Ferrarotto Hospital, Via Citelli 1, University of Catania, Catania, Italy. Tel: +39 095 7436103, Fax: +39 095 7436105, Email: tambucor@unict.it

To sum up, we are facing a transcatheter aortic valve that has virtually abolished the issue of paravalvular leak, approaching the rates seen in surgical bioprostheses, but which must deal with an unacceptable incidence of conduction disturbances (*Figure 1*). Historically, pacemaker implantation and left bundle branch block (LBBB) have been considered as minor complications of TAVI, primarily because the target population was typically old and at high or prohibitive risk. However, with gradual adoption of TAVI in younger and lower risk patients, and with the assimilation of new evidence supporting the negative effects of definitive pacing and LBBB on mid-term clinical and echocardiographic outcomes,[13,14] avoidance of conduction disturbances after TAVI has become a priority.

To explain these findings, we must analyse in depth the key features of the Lotus valve and its releasing mechanism. The prosthesis system consists of a trileaflet bovine peri-cardial valve supported on a braided nitinol frame that expresses high radial force to its landing zone [aortic annulus and left ventricular outflow tract (LVOT)]. As previously mentioned, the frame is covered with a seal at the inflow segment that adapts to aortic root irregularities. In addition, this is the only TAVI device that is fully recapturable and repositionable even after the valve has been fully deployed, which on the one hand promotes a more accurate and precise final positioning, but on the other potentially increases the number of maoeuvres at the level of the aortic root and the LVOT.

Therefore, the high rate of high-degree atrioventricular block probably derives from a combination of high radial force and the interaction of the valve with the conduction system and the LVOT during deployment, which are also plausibly the key features for the perfect sealing of the Lotus valve.

What is the solution for this dilemma? A recent study suggested that while maintaining the sealing capability of the valve, the pacemaker rate can be minimized if the necessary attention is given to both the implantation depth (≤5 mm) and the rate of LVOT oversizing (<10%).[15] In addition, the newer generation Lotus Edge (Boston Scientific) and the Depth Guard™ technology are already at an advanced stage of development. In particular, the latter consists of a new valve release mechanism that is properly designed to reduce LVOT (and conduction system) interaction by minimizing the depth of the valve during deployment.

It must be said that Boston Scientific recently announced a voluntary removal of all Lotus TAVI devices from global commercial and clinical sites. The action was a response to reports of the premature release of a pin connecting the Lotus valve to the delivery system. It was believed that the issue is caused by excess tension in the pin mechanism introduced during the manufacturing process. The company expects to bring the Lotus valve platform back to Europe and other relevant international markets by the last quarter of 2017.

In conclusion, since 2007 the Lotus valve has experienced an extraordinary development in terms of technology advancements and clinical evidence. Type of deployment and valve design are unique among the spectrum of TAVI devices. If the joint efforts of operators and manufacturer succeed in addressing the current issues of pacemaker implantation and release mechanism, this valve is destined to carve out a significant role in the competitive TAVI landscape.

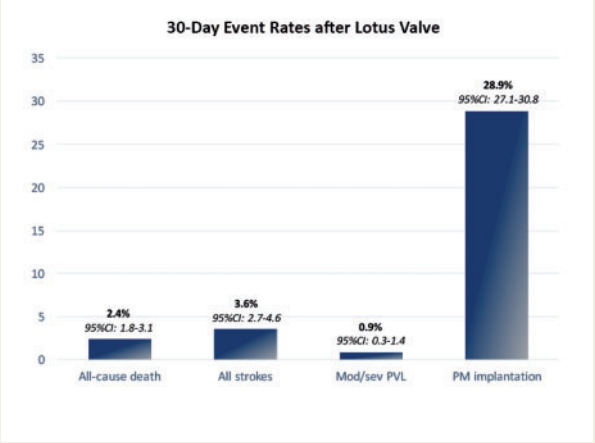

Figure 1 Major outcomes of the Lotus valve. Estimates are derived from a weighted meta-analysis of seven studies including 2359 patients from REPRISE I, REPRISE II, REPRISE III, UK Lotus Experience, RELEVANT, NORDIC Lotus-TAVR Registry, and RESPOND. Reported are cumulative rates for each outcome (pooled measures were calculated assuming a DerSimonian and Laird random effects model weighted by inverse variance incorporating both between- and within-study variance) and 95% confidence intervals (CIs). Mod/sev, moderate/severe; PM, pacemaker; PVL, paravalvular leak.

Conflict of interest: C.T. received speakers honoraria from Medtronic Inc., St Jude Medical, and Symetis. M.B. is a consultant for Edwards Lifesciences.

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