Editorial

Transcatheter aortic valve implantation with the repositionable and fully retrievable Lotus Valve System™

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Provenance: This is an invited Editorial commissioned by the Section Editor Lei Zhang (Department of Vascular Surgery, Changhai Hospital, Second Military Medical University, Shanghai, China).

Comment on: Falk V, Wöhrle J, Hildick-Smith D, *et al.* Safety and efficacy of a repositionable and fully retrievable aortic valve used in routine clinical practice: the RESPOND Study. Eur Heart J 2017. [Epub ahead of print].

Submitted Jul 28, 2017. Accepted for publication Aug 10, 2017.
doi: 10.21037/jtd.2017.08.78
View this article at: http://dx.doi.org/10.21037/jtd.2017.08.78

Introduction

Transcatheter aortic valve implantation (TAVI) has become a therapeutic alternative for patients presenting with severe symptomatic aortic stenosis and considered either at high (1,2) or intermediate preoperative risk (3,4) for surgical aortic valve replacement (SAVR). Recent recommendations found that transfemoral TAVI, in comparison to SAVR, results in lower mortality and acute kidney injury at 2 years, and may reduce stroke rates (5). Over the past 15 years, several transcatheter devices have been tested and evolved to decrease access site complications with smaller profile delivery systems, decrease pacemaker rates, and avoid the risk of coronary obstruction and significant paravalvular leakage (PVL) (6-9).

The Lotus Valve System (Boston Scientific Corporation, Natick, MA, USA) consists of a braided nitinol wire frame with three bovine pericardial leaflets mounted on a pre-shaped delivery catheter (10). The valve is deployed via controlled mechanical expansion, which enables predictable and precise placement. The lower half of the Lotus Valve™ is surrounded by an adaptive seal, a polymer membrane designed to fill the space between the native annulus and the prosthetic valve frame, thereby reducing PVL (10). The Lotus Valve function can be assessed in the fully expanded position prior to release. Partial or full recapturing/repositioning of the valve, or full retrieval, is possible at any point prior to uncoupling and release (10).

In this editorial, we refer to the RESPOND (Repositionable Lotus Valve System-Post-Market Evaluation of Real World Clinical Outcomes) study recently published in the *European Heart Journal*. Falk and colleagues (11) report the results of a prospective, open-label, single-arm, multi-centre, post-market registry, to confirm the safety and efficacy of the Lotus Valve™ in a larger "all-comers" population at 30-day and 1-year follow-up.

Main findings

Study population, 30-day mortality and stroke

A total of 996 patients were included. The mean age was 80.8±6.5 years, 51% were female, with a mean predicted operative mortality risk of 6.0±6.9% and 8.0±8.4% as assessed by the Society of Thoracic Surgeons score and logistic EuroSCORE-II, respectively. Clinical end-points were reported upon the Valve Academic Research Consortium (VARC)-2 definitions (12). The device was successfully implanted in 98.1% of the 1,016 intention-to-treat population. Among these 996 as-treated patients, 99.7% had correct positioning of one valve in the proper anatomical location. Repositioning of the valve was attempted in 29.2%, and was successful (i.e., partial or complete re-sheathing of the Lotus Valve™ in the catheter and redeployment in a more accurate position within the aortic valve annulus) in 99%.

The length of hospital stay was 7.3±5.9 days. The 30-day all-cause mortality was 2.6% and 2.2% in the intention-to-treat and as-treated populations, respectively. The overall 30-day stroke rate was 3%, and 2.2% was considered disabling stroke. Strokes were judged not related to repositioning of the valve.

Acute valve performance and paravalvular sealing

Post TAVI, a significantly decrease in mean aortic valve gradient (from 37.7±15.2 mmHg at baseline to 10.8±4.6 mmHg at discharge) and increase in effective orifice aortic valve area (from 0.7±0.2 cm^2 at baseline to 1.8±0.4 cm^2 at discharge) was observed. Importantly, PVL was absent or trace in 92% of patients, 7.7% of patients showed mild PVL, 0.3% of patients moderate PVL and none presented with severe PVL. The Lotus Valve™ device seals the aortic annulus adjusting to the patient's anatomy with the mechanically expandable frame, and these results are equivalent or compare favorably to recent reports using different second-generation TAV devices (6,8,9,13,14). The results of the REPRISE II (Repositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus Valve System Evaluation of Safety and Performance) Study Extended Cohort (15) showed that the independent predictors of mild/moderate PVL included the ratio of device area to annulus area, left ventricular outflow tract (LVOT) calcium volume, and annulus area. Interestingly, the rates of mild/moderate PVL were 17.5%, 2.9%, and 3.2%, with 0–5%, 5–10%, and >10% annular oversizing by area, respectively, suggesting therefore that optimal valve oversizing to minimize PVL is >5% by area.

Need for permanent pacemaker implantation (PPI)

PPI was required in 34.6% of cases who did not have a pacemaker at baseline. This result is not surprising since studies with Lotus Valve™ have consistently reported high (30–36%) rates of PPI (*Table 1*). In the United Kingdom Experience (24), the incidence of new left bundle brunch block was 55% and 32% of the patients required PPI after Lotus Valve™ implantation (24). These rates are higher than those reported in studies with the self-expanding Accurate TA (8) and Acurate Neo (9) devices (Symetis, S.A., Ecublens, Switzerland/Boston Scientific, Marlborough, MA, USA) that is 5–10% and CoreValve (Medtronic, Inc., Minneapolis, Minnesota, USA), that is 15–26% (2,4,25-27). The Lotus Valve™ is shorter than the CoreValve prosthesis; therefore, one might expect a lower frequency of conduction disorders. However, to anchor the prosthesis within the aortic annulus, the inflow portion of the Lotus Valve™ protrudes into the LVOT thereby damaging the conduction system (28). Notably, an implantation depth of ≤6 mm was associated with a lower incidence of PPI compared with deeper implants with CoreValve (29); however, the UK experience with the Lotus Valve™ showed a mean implantation depth of 5.7±3.2 mm in the overall cohort. Hence, implantation depth was not found a predictor of PPI (24). Based on its mechanically expansion, the radial force of this device may be greater than the CoreValve™. Importantly, the issue of requiring PPI after TAVI is of concern since it has been shown to be an independent predictor of long-term mortality (30). Moreover, since TAVI is nowadays being performed in intermediate and lower risks patients, hence, younger subjects exhibiting a longer life spam, PPI may predispose to pacing-induced cardiomyopathy. Long-term clinical outcomes as well as valve durability (31) are therefore needed with this device. *Table 1* summarizes data on clinical outcomes in Boston Scientific-sponsored trials using the Lotus Valve™.

Potential utilities of the Lotus Valve™ beyond the treatment of native aortic stenosis

The safety and feasibility of TAVI for the treatment of non-calcified pure aortic valve regurgitation has been previously reported (32,33). Certainly, the absence of aortic valve and/or annulus calcification to anchor the newly implanted bioprosthesis may contribute to valve malposition or migration needing a second valve (32,33). The use of a repositionable and completely retrievable Lotus Valve™ system permits a well-controlled and safe procedure, thus, it may provide advantages over the first-generation devices in cases of pure aortic regurgitation and/or absence of calcium (34). Data on TAVI in bicuspid aortic valve stenosis is still limited, with significant rates of post-procedural moderate-to-severe PVL (35). In these cases, the mechanically deployed Lotus Valve™ may also provide a valuable alternative (36). Finally, the Lotus Valve™ may also be an option for transcatheter valve-in-valve treatment of failed surgical bioprosthesis (37). Such speculations would nevertheless be off-label use of the Lotus Valve™ device.

Future perspectives for the device

The RESPOND study was conducted using the first-

Table 1 Summary data of Lotus clinical outcomes in Boston Scientific-Sponsored Trials

Study	Death all-cause	Death cardiac	Stroke non-disabling	Stroke disabling	Bleeding LT or disabling	AKI stage 2 or 3	New PPM*	Valve thrombosis	Repeat procedure for valve dysfunction	Mean gradient, mmHg	Moderate or severe PVL
30 days											
REPRISE I (10); N=11; Binary rates	0	0	NR	9.1[a]	18.2	NR	36.4	NR	0	11.7±3.0	0
REPRISE II/II Extension (16); N=250; Binary rates	4.0	3.6	4.0	2.8	7.2	2.8	28.9	0	0	11.7±6.8	0.6
RESPOND (11); N=987; Binary rates	2.6[b]	2.0	NR	2.2	2.2	1.7	30.0	0.4	0.1	10.8±4.6[c]	0.3[c]
REPRISE III—Lotus arm (17); N=607; Binary rates	2.5	NR	NR	2.0	8.0	2.5[d]	29.1	NR	NR	12.0±6.1	NR
1 year											
REPRISE I (10); N=11; Binary rates	0	0	NR	9.1[a]	18.2	NR	36.4	NR	0	15.4±4.6	0
REPRISE II/II Extension (16); N=250; Binary rates	11.6	7.6	4.8	3.6	9.2	2.8	32.5	1.2	0	12.5±5.4	0
RESPOND (18); N=988; Binary rates	12.0[b]	7.5	NR	4.0	3.5	1.7	32.0	0.8	0.2	10.8±5.1	0.4
REPRISE III—Lotus arm (17); N=607; Binary rates	11.9	7.7	NR	3.6	9.9	NR	NR	1.5	0.2	12.3±5.8	2.0
2 years											
REPRISE I (19); N=11; KM rates	0	0	NR	9.1[a]	18.2	NR	36.4	NR	0	15.5±4.4	0
REPRISE II/II Extension (20); N=250; KM rates	19.1	9.5	4.9	4.7	10.7	2.8	35.1	1.3	0	12.2±6.0	0
3 years											
REPRISE I (21); N=11; KM rates	10.0	0	NR	9.1[a]	18.2	0	36.4	NR	0	15.6±4.4	0
REPRISE II (22); N=120; KM rates	23.1	12.3	6.0	4.5	7.8	3.4	35.4	0	0	11.3±5.2	0
4 years											
REPRISE I (23); N=11; KM rates	27.3	NR	NR	9.1[a]	18.2	0	36.4	NR	0	15.6±4.6	0

Values are percentages or mean ± standard deviations. *, Rate includes all enrolled patients in the denominator. [a], Major stroke; [b], intention-to-treat population (N=1,014) per-protocol (as safety primary endpoint); [c], pre-discharge rate per-protocol. 30-day visit not mandated per protocol; [d], ≤7 days. AKI, acute kidney injury; LT, life-threatening; NR, not reported; PVL, paravalvular leakage; PPM, permanent pacemaker; KM, Kaplan-Meier.

generation "classic" Lotus Valve™, which is no longer available on the market. The valve that is currently on the market in Europe is the Lotus Edge™ valve system, which incorporates new design features such as Depth Guard™ technology, designed to reduce LVOT interaction, minimizing the depth of the valve during deployment, a simplified locking mechanism, and a more flexible delivery catheter. The Depth Guard™ feature and increased catheter flexibility were intended to reduce the higher rates of PPI seen with classic Lotus device. Two small studies were conducted to evaluate these features: the RESPOND Extension and the Lotus Edge Feasibility Study. Preliminary (unpublished) data from both studies show a significant reduction in PPI rates (data from Boston Scientific).

Conclusions

TAVI with the repositionable, fully retrievably and mechanically deployed Lotus Valve system is safe, achieving optimal annular sealing with a remarkably low incidence of residual paravalvular aortic regurgitation, but at a cost of increased PPI rate. Future studies will help RESPOND the question around the need for PPI with this device.

Acknowledgements

The authors want to specially thank Vicki M. Houle, PhD and Ms Tamara Blair, from Boston Scientific Corporation, for the help in manuscript proofreading.

Footnote

Conflicts of Interest: Dr. Bagur has received speaking and consulting fees from Boston Scientific. Dr. Choudhury and Dr. Mamas have no conflicts of interest to declare.

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Cite this article as: Bagur R, Choudhury T, Mamas MA. Transcatheter aortic valve implantation with the repositionable and fully retrievable Lotus Valve System™. J Thorac Dis 2017;9(9):2798-2803. doi: 10.21037/jtd.2017.08.78

