Original article

Transfemoral aortic valve implantation with new-generation devices: the repositionable Lotus vs. the balloon-expandable Edwards Sapien 3 valve

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Background **New-generation transcatheter heart valves have been developed to reduce complications of transcatheter aortic valve implantation (TAVI). With this study we sought to compare procedural and 30-day outcomes of the new-generation repositionable Boston Scientific Lotus (Lotus) and the balloon-expandable Edwards Sapien 3 (ES3) transcatheter heart valves.**

Methods **A total of 315 patients with severe symptomatic aortic stenosis undergoing transfemoral TAVI with Lotus or ES3 included in two large Italian registries were considered for this analysis. After propensity matching, 93 matched pairs of patients were included. Outcomes were evaluated according to Valve Academic Research Consortium-2 definition at discharge and 30 days.**

Results **There were no differences in baseline characteristics, except for lower mean aortic gradient and larger mean aortic annulus in the ES3-treated patients. Valve Academic Research Consortium-2 defined device success was high and comparable between groups (97.8 for Lotus vs. 98.9% for ES3, $P = 0.09$). The frequency of moderate/severe paravalvular leak was low and similar for both devices (2.2 vs. 1.1%, $P = 0.10$). At 30 days, both groups showed low all-cause mortality (5.4 vs. 1.1%, $P = 0.10$) and rates of disabling stroke (3.2 vs. 1.1%, $P = 0.31$). New pacemaker implantation was more common after Lotus deployment (31.7 vs. 10.5%, $P < 0.001$).**

Conclusion **Transfemoral TAVI with both Lotus and ES3 resulted in favorable clinical and hemodynamic procedural and 30-day outcomes. Rates of significant paravalvular leak were low with both devices. The Lotus valve was associated with higher risk of pacemaker implantation.**

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Keywords: aortic stenosis, new-generation transcatheter heart valves, transcatheter aortic valve implantation

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Introduction

In the last decade, transcatheter aortic valve implantation (TAVI) has rapidly changed the way we treat symptomatic aortic stenosis first in inoperable, then in high-risk and intermediate-risk patients.[1–6] Despite the excellent TAVI results across the surgical risk spectrum, modest yet nonnegligible complications remain, including need for permanent pacemaker, paravalvular leak (PVL), stroke and vascular access complications. Although Heart Team approach and careful preprocedural imaging screening have mitigated these risks, advances in transcatheter heart valves (THVs) design have further improved TAVI safety and efficacy.[7] Innovations of new-generation THVs include the addition of an adaptable outer skirt to minimize the risk of PVL, the development of smaller introducers and delivery catheters to reduce vascular complications, the inclusion of steerable guiding catheters to optimize prosthesis positioning. Among new-generation THVs, the balloon-expandable Edwards Sapien 3 (ES3) and the repositionable Boston Scientific Lotus (Lotus) valves have shown favorable clinical and hemodynamic results.[8,9] However, reports comparing ES3 and Lotus valves are limited,[10] and no randomized study has yet been performed. Accordingly, the present propensity-matched study aimed to compare procedural safety and early efficacy of transfemoral TAVI with ES3 vs. Lotus in patients with severe symptomatic aortic stenosis.

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Methods

Patient population

The PUREVALVE (Padua University REVALVing Experience) registry is a large tertiary center registry in which data of all consecutive patients undergoing TAVI are prospectively collected. The RELEVANT (REgistry of Lotus valvE for treatment of aortic VAlve steNosis with Tavr) study is an Italian, prospective, multicenter, real-world registry of TAVI procedures performed using Lotus valve.[11] For the purpose of this analysis, all consecutive patients undergoing transfemoral TAVI with ES3 in the PUREVALVE registry ($n = 93$, from August 2013 to January 2017) were matched with patients ($n = 222$, from December 2013 and April 2016) undergoing transfemoral TAVI with the Lotus valve included in the RELEVANT study. Enrolled patients had symptomatic severe aortic stenosis, defined as aortic valve area (AVA) less than 1.0 cm^2 or AVA indexed less than 0.6 cm^2/m^2, and either a mean pressure transaortic gradient more than 40 mmHg or a jet velocity more than 4 m/s at transthoracic echocardiography (TTE). Surgical risk was calculated using the logistic EuroSCORE and the Society of Thoracic Surgery score.[12,13] Patients were candidate to TAVI by the local Heart Team on the basis of surgical risk score, as well as frailty and presence of comorbidities.[14,15] Exclusion criteria included a life expectancy of less than 1 year, congenital unicuspid or bicuspid aortic valve, severe peripheral artery disease (femoral artery lumen diameter <6.0 mm) favoring the transapical route for TAVI and valve-in-valve procedure. The study cohort complied with the Declaration of Helsinki and was approved by the local Ethics Committees, and all patients provided informed written consent before the procedure.

Preprocedural assessment

Patients were assessed by clinical evaluation, 12-lead ECG, TTE, coronary angiography and multidetector computed tomography (MDCT) of the aortic valve, the entire aorta and the iliofemoral system. Treatment of concomitant severely obstructive atherosclerotic disease of the proximal coronary vessels was performed at least 1 month before TAVI.

Study devices

The Edwards Sapien 3 (Edwards Lifesciences, Irvine, California, USA) is the latest evolution of the balloon-expandable Sapien family.[1,3,16] Compared with the previous generation, it has an improved geometry in the trileaflet bovine pericardial valve, a longer cobalt alloy frame with more open outlet cells and denser inlet cells, a polyethylene terephthalate fabric skirt sewn to the bottom portion of the interior and exterior of the frame, which provides an external circumferential seal to reduce PVL. Moreover, it has a lower profile expandable sheath (14–16 F), which enables transfemoral approach in even more challenging peripheral anatomies. A new steerable commander delivery system provides easier navigation in the aorta and more precise valve positioning. The device is available in three sizes: 23, 26 and 29 mm.[4]

The Boston Scientific Lotus (Boston Scientific, Natick, Massachusetts, USA) THV is a bioprosthetic bovine pericardial aortic valve attached to a nitinol frame of 19-mm height with a central radiopaque marker to aid positioning, incorporating a polymeric Adaptive Seal around the lower half of the inflow portion to minimize the risk of PVL by occupying any small interstices between the frame and native anatomy. Deployment of the valve is achieved via controlled mechanical expansion, during which the valve is unsheathed and the frame shortens while expanding radially to its final diameter. Rapid ventricular pacing is not required, as the valve functions early in the deployment phase, providing hemodynamic stability. This feature is particularly useful in patients with reduced left ventricular (LV) function.[17,18] Moreover, the valve is easily repositionable and fully retrievable, even when locked in its final position. This allows potential for removal in case of suboptimal device size or malposition. There are three available valve sizes: 23, 25 and 27 mm, with 18–20-F hydrophilic sheaths.[19]

Transcatheter aortic valve implantation procedure

All procedures were performed under general anesthesia or conscious sedation. Patients were premedicated with aspirin and clopidogrel. The introducer sheath was inserted preferably through the right femoral artery, and the access site was routinely preclosed with two Proglide devices (Abbott Vascular, Abbott Park, Illinois, USA). Using a crossover technique, the contralateral femoral artery was cannulated and a guide wire was positioned distal into the femoral artery to ensure a safe final access site closure. Once all arterial and venous accesses were established, anticoagulation was achieved with intravenous unfractionated heparin with a target activated clotting time of more than 250 s. The decision to perform balloon aortic valvuloplasty before valve deployment was left to operator's discretion. Valve deployment was performed according to manufacturer's instruction. Rapid ventricular pacing was not performed in case of Lotus valve implantation. Paravalvular regurgitation was assessed by aortography and transesophageal echocardiography as described elsewhere.[20] In case of moderate/severe regurgitation, the Lotus valve was repositioned, while the ES3 valve was postdilated.

Endpoints

The primary endpoint of the study was Valve Academic Research Consortium-2 (VARC-2) defined device success,[21] that is a composite endpoint that includes the absence of procedural mortality, correct positioning of a single valve in the correct anatomic position, and the absence of prosthesis-patient mismatch, moderate or greater aortic regurgitation, or mean aortic gradient more

than 20 mmHg. Secondary endpoints were 30-day VARC-2 early safety, all-cause mortality, major bleeding, major vascular access complication, new pacemaker implantation, disabling and nondisabling stroke.[21]

Statistical analysis

Quantitative variables were summarized as mean ± SD. Categorical variables were presented as counts and percentages. Control of confounders was undertaken by propensity score matching with 'nonrandom' R package to control selection bias based on possible clinical predictors of adverse events after TAVI. The propensity score was estimated with a logistic regression model including the following variables: age, sex, BMI, presence of coronary artery disease and logistic EuroSCORE and using a caliper of 0.2 times the SD of logit. Imbalance of the baseline patients' characteristics before and after matching was evaluated trough standardized differences (d). Postmatching comparison of the end-points between the two groups was performed with McNemar in case of cumulative incidence for all events at discharge and at 30 days. Analyses were performed using R software (version 3.3.1) and SAS 9.4.

Results

Baseline characteristics

Baseline characteristics of the two populations before propensity matching are reported in Table 1. Notably, the two groups differed in multiple baseline features. After propensity score matching was performed for the entire population ($n = 315$), there were 93 matched pairs of patients. Demographic and clinical characteristics of matched patients are depicted in Table 2. As expected, patients' demographics were comparable between matched groups. Baseline echocardiographic and MDCT parameters are shown in Table 3.

Table 1 Baseline characteristics before propensity matching

Patient characteristics	Lotus, $n = 222$	Sapien 3, $n = 93$	Standardized difference[a]
Age (years)	81.7 ± 6.1	79.9 ± 5.8	−0.44
Male	52 (48.7%)	56 (58.9%)	0.21
BMI (kg/m^2)	25.4 ± 4.6	26.3 ± 4.2	0.19
STS score	8.5 ± 4.3	8.7 ± 8.0	0.04
EuroSCORE	17.2 ± 10.2	15.3 ± 10.5	−0.17
Hypertension	164 (73.2%)	75 (80.6%)	0.46
Diabetes mellitus	61 (27.4%)	23 (24.7%)	−0.07
GFR (ml/min/m^2)	45.2 ± 21.6	49.2 ± 19.9	0.19
Coronary artery disease	79 (35.5%)	48 (51.6%)	0.33
Previous CABG	37 (16.6%)	11 (11.8%)	−0.14
Previous stroke	37 (39.8%)	8 (8.6%)	−0.24
Chronic pulmonary disease	76 (34.2%)	29 (31.2%)	−0.05
Atrial fibrillation	54 (24.3%)	25 (26.9%)	−0.24
Existing permanent pacemaker	28 (12.6%)	7 (7.5%)	−0.22
NYHA functional class			
I	0 (0.0%)	0 (0.0%)	0.25
II	102 (45.9%)	43 (46.1%)	
III	106 (47.7%)	46 (49.5%)	
IV	14 (6.3%)	4 (4.3%)	

Categorical and continuous data are presented as n (%) or mean ± SD, respectively. CABG, coronary artery bypass grafting; GFR, glomerular filtration rate; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons Score. [a]A value of 0.2 or less was considered indicative of a good balance.

Table 2 Baseline characteristics of matched populations

Patient characteristics	Lotus, $n = 93$	Sapien 3, $n = 93$	Standardized difference[a]
Age (years)	80.5 ± 7.0	79.8 ± 5.8	−0.10
Male	52 (55.9%)	54 (58.1%)	0.04
BMI (kg/m^2)	25.9 ± 4.6	26.3 ± 4.3	0.09
STS score	9.0 ± 5.2	8.7 ± 8.0	−0.04
LogEuroSCORE	15.9 ± 10.2	15.3 ± 10.5	−0.05
Hypertension	77 (82.8%)	75 (80.6%)	−0.12
Diabetes mellitus	26 (28.0%)	23 (24.7%)	−0.07
GFR (ml/min/m^2)	49.4 ± 23.4	49.3 ± 20.2	−0.01
Coronary artery disease	43 (46.2%)	48 (51.6%)	0.11
Previous CABG	15 (16.1%)	11 (11.8%)	−0.12
Previous stroke	12 (12.9%)	8 (8.6%)	−0.13
Chronic pulmonary disease	27 (29.0%)	29 (31.2%)	0.05
Atrial fibrillation	21 (22.6%)	25 (26.9%)	0.11
Existing permanent pacemaker	11 (11.8%)	7 (7.5%)	−0.18
NYHA functional class			
I	0 (0.0%)	0 (0.0%)	0.07
II	45 (48.4%)	43 (46.1%)	
III	42 (45.2%)	46 (49.5%)	
IV	6 (6.4%)	4 (4.3%)	

Categorical and continuous data are presented as n (%) or mean ± SD, respectively. CABG, coronary artery bypass grafting; GFR, glomerular filtration rate; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons Score. [a]A value of 0.2 or less was considered indicative of a good balance.

Procedural characteristics

The most frequently used valve sizes were the 26-mm ES3 and the 23-mm Lotus (Table 4). With the mechanically expandable Lotus valve, balloon predilation was significantly less frequent (50.1 vs. 65.3%, $P = 0.04$). Postdilation was never performed after Lotus implantation, while it was required in 5.3% of ES3 TAVI ($P = 0.02$). In 23.6% of Lotus procedures partial valve resheathing was performed to achieve good final valve positioning. Accordingly, procedural time was longer and contrast volume higher in the Lotus group.

Table 3 Preprocedural imaging data of matched populations

Transthoracic echocardiography	Lotus, $n = 93$	Sapien 3, $n = 93$	Standardized difference[a]
Aortic valve area (cm^2)	0.71 ± 0.22	0.80 ± 0.21	0.25
Aortic valve area indexed (cm^2/m^2)	0.40 ± 0.13	0.47 ± 0.12	0.24
Mean aortic gradient (mmHg)	47.8 ± 14.1	42.6 ± 16.9	−0.33
Peak aortic gradient (mmHg)	72.4 ± 28.0	62.8 ± 34.7	−0.30
Pulmonary artery pressure (mmHg)	39.6 ± 12.9	39.6 ± 15.0	−0.01
Left ventricular ejection fraction	53.2 ± 10.9	55.7 ± 12.3	0.19
>50%	63 (67.7%)	68 (73.1%)	
30–50%	21 (22.6%)	17 (18.3%)	
<30%	1 (1.1%)	5 (5.4%)	
Aortic annulus CT measurements			
Annular perimeter (mm)	79.4 ± 9.4	79.8 ± 12.6	0.32
Annular area (mm^2)	483 ± 133	510 ± 129	0.25
Area-derived diameter (mm)	24.1 ± 23.3	24.8 ± 2.1	0.19

Categorical and continuous data are presented as n (%) or mean ± SD, respectively. CT, computed tomography. [a]A value of 0.2 or less was considered indicative of a good balance.

Table 4 Procedural characteristics

	Lotus, $n=93$	Sapien 3, $n=93$	P value
Prosthesis size, mean	24.4 ± 1.6	25.3 ± 2.1	0.01
23 mm	45 (48.4%)	36 (38.7%)	
25 mm	29 (31.2%)	–	
26 mm	–	44 (47.3%)	
27 mm	19 (20.4%)	–	
29 mm	–	13 (14.0%)	
Preimplant BAV	47 (50.1%)	59 (65.3%)	0.04
Prosthesis postdilation	0 (0%)	5 (5.3%)	0.02
Partial valve resheathing	22 (23.6%)	NA[a]	–
Full valve resheathing	3 (3.2%)	NA[a]	
Full valve retrieval	1 (1.1%)	NA[a]	
Successful valve deployment	93 (100%)	93 (100%)	1.00
Procedural duration (mm)	107 ± 32	81 ± 22	<0.00
Contrast volume (ml)	241 ± 100	183 ± 72	<0.00

Categorical and continuous data are presented as n (%) or mean ± SD, respectively. BAV, balloon aortic valvuloplasty; NA, not available.

Outcomes

The VARC-2 defined device success (Table 5) was high and not different between groups (97.8 vs. 98.9%, $P=0.09$). Depicting the components of this outcome, the absence of procedural mortality was 100%, correct positioning of a single prosthesis was 100%, mean prosthetic valve gradient less than 20 mmHg was 100%, absence of prosthesis mismatch 100% in both groups. More than mild PVL was present in two patients of the Lotus and one patient of the ES3 group (Fig. 1). The two groups had similar rates of major vascular complications (2.2 vs. 3.3%, $P=0.16$). At 30 days, early safety endpoint was favorable in both groups (15.1 vs. 8.6%, $P=0.06$), with numerically higher all-cause mortality (5.4 vs. 1.1%, $P=0.10$) and rate of disabling stroke (3.2 vs. 1.1%, $P=0.31$) among Lotus patients. Of note, four deaths in the Lotus group occurred 3 weeks postdischarge and were not directly related to the procedure (two patients died of pneumonia, two after massive intracranial hemorrhage). New pacemaker implantation was more common with Lotus than ES3 valve (31.7 vs. 10.5%, $P<0.001$). Figure 2 shows the improvement in New York Heart Association (NYHA) functional class after TAVI, both at discharge and at 30 days. Hemodynamic valve performance in terms of mean pressure gradient and effective orifice area, as assessed by TTE, is reported in (Fig. 3).

Table 5 In-hospital outcomes

	Lotus, $n=93$	Sapien 3, $n=93$	P value*
Procedural mortality	0 (0%)	0 (0%)	1.00
Stroke	3 (3.2%)	1 (1.1%)	0.31
Disabling stroke	2 (2.2%)	1 (1.1%)	0.56
Major vascular access-related complication	2 (2.2%)	3 (3.3%)	0.16
Major bleeding	4 (4.3%)	4 (4.3%)	1.00
Conversion to sternotomy	0 (0.0%)	0 (0.0%)	1.00
Cardiac tamponade	1 (1.1%)	1 (1.1%)	1.00
Correct final positioning of a single valve	93 (100%)	93 (100%)	1.00
Valve migration/embolization	0 (0.0%)	0 (0.0%)	1.00
Procedural coronary obstruction	0 (0.0%)	0 (0.0%)	1.00
Aortic regurgitation (%)			
None/trivial	60 (64.5%)	67 (72.0%)	0.50
Mild	31 (33.3%)	25 (26.9%)	
Moderate	2 (2.2%)	1 (1.1%)	
New pacemaker implantation	24 (29.2%)	9 (10.5%)	0.001
Device success (VARC-2)	91 (97.8%)	92 (98.9%)	0.09

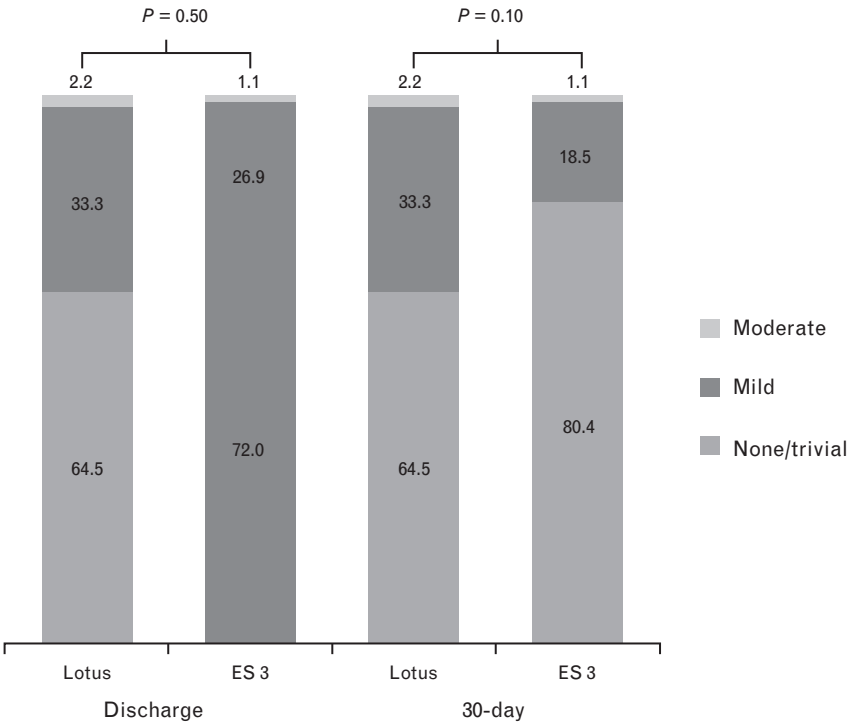
Data are presented as n (%). VARC-2, Valve Academic Research Consortium-2.

Discussion

The main findings of the present propensity-matched study on clinical outcomes and valve performance of TAVI patients treated with the Lotus and the ES3 are as follows: first, acute performance of both valves was favorable, with no procedural mortality and high device success; second, early safety at 30 days was similar between groups, with most deaths not TAVI-related; third, both valves showed good hemodynamic performance, with low rates of moderate/severe PVL; fourth, TAVI with the Lotus valve resulted in significantly higher rates of new pacemaker implantation.

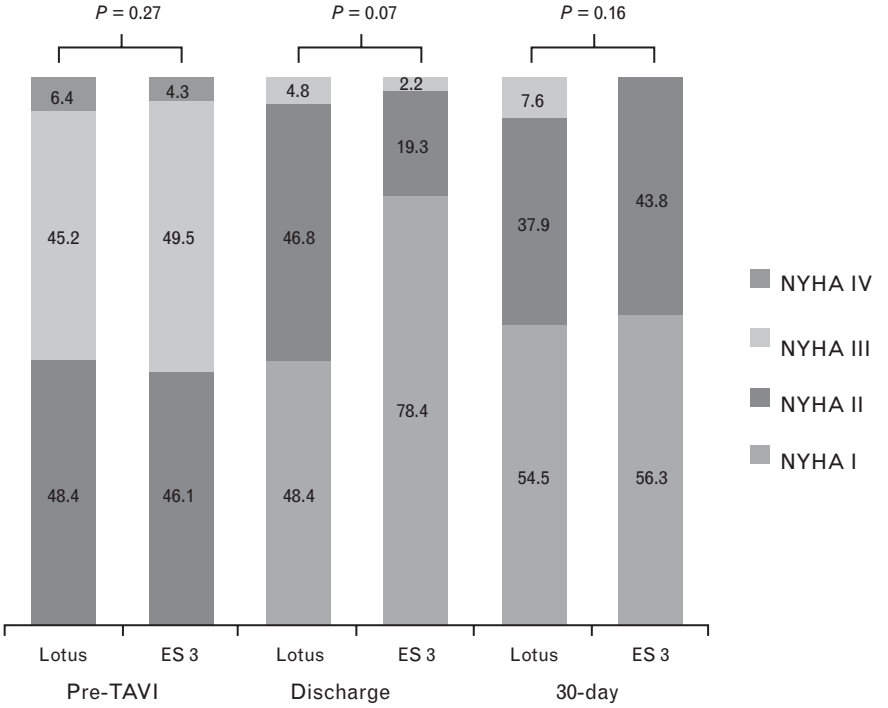
TAVI has rapidly become the treatment of choice in high-risk patients with severe symptomatic aortic stenosis, and guidelines recommendations are now equivalent to SAVR.[22,23] Among new-generation devices, which have been developed to overcome some pitfalls of TAVI, the Lotus valve has a peculiar mechanical expansion mechanism that allows it to be fully retrievable, redeployable and repositionable. In the recent randomized REPRISE III trial, the Lotus valve showed noninferiority for the 30-day safety and superiority for the 1-year efficacy endpoint compared with the self-expandable CoreValve and Evolut R (Fig. 4).[21] Notwithstanding, no randomized trial has yet compared Lotus with the balloon-expandable ES3. In our propensity-matched study, transfemoral TAVI with both devices resulted in good and similar acute and 30-day outcomes. In particular, VARC-2 defined device success was high and comparable between groups (97.8 vs. 98.9%, $P=0.09$), with no procedural death, no valve embolization nor coronary obstruction. The favorable acute performance of both devices translated into good clinical results at 30 days, with low mortality rates similar to other reports in the literature[1,24] and significant improvement in NYHA functional class compared with baseline. Stroke rate was also reassuring with both valves, consistently with the easier aortic arch navigation and lower valve manipulation granted by the improved design of new-generation THVs (with lower profile, flexible and steerable delivery catheters). Although the numbers are too small to draw any final conclusion, the two disabling strokes in the Lotus group occurred in patients in whom the valve was not repositioned. Therefore, it seems that Lotus repositioning was not correlated with an increased risk of cerebral embolic events. The low rate of prosthesis postdilatation, which has been linked to increased stroke rates,[25] might also have contributed to this favorable result.

Fig. 1



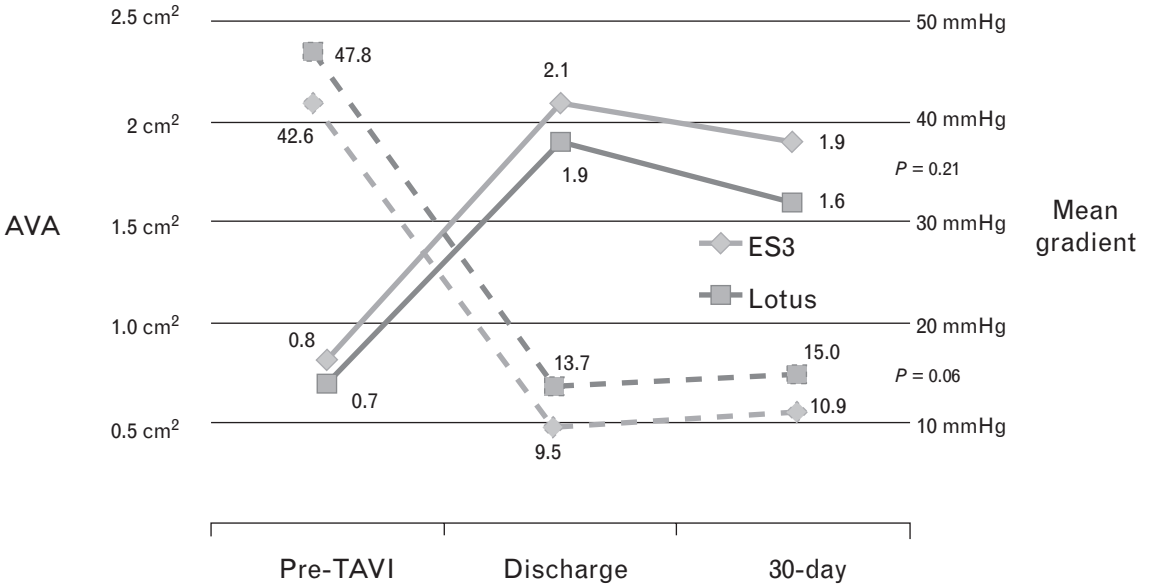
Degree of paravalvular leakage after transcatheter aortic valve implantation in the two groups at discharge and at 30 days. TAVI, transcatheter aortic valve implantation.

Fig. 2



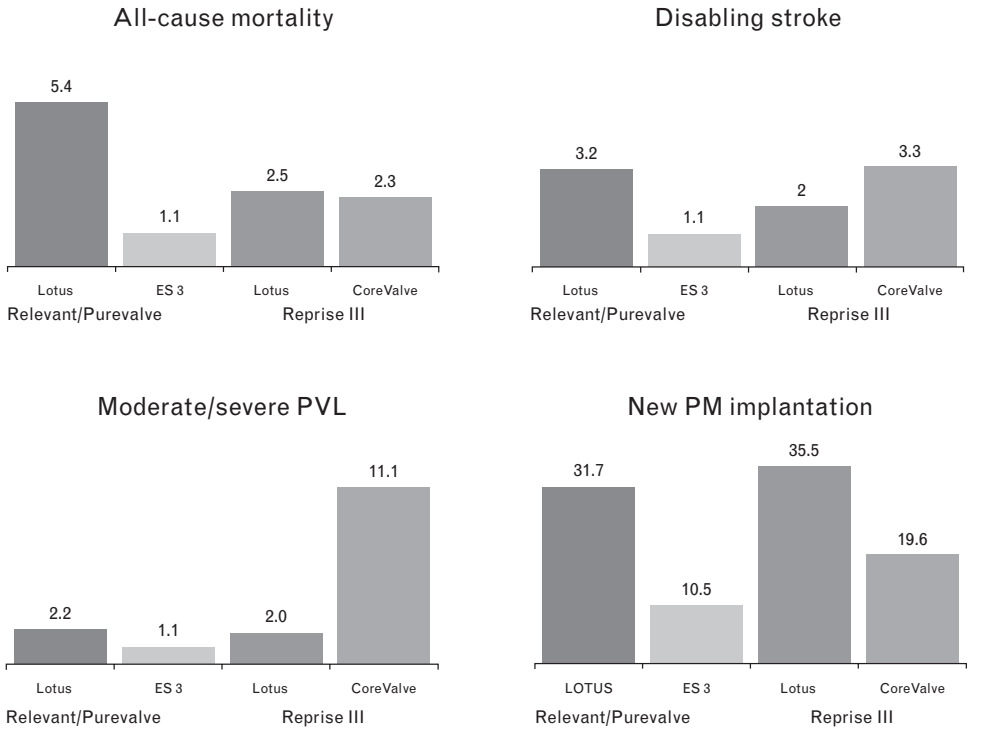
Improvement of New York Heart Association functional class after transcatheter aortic valve implantation. NYHA, New York Heart Association; TAVI, transcatheter aortic valve implantation.

Fig. 3



Change in aortic valve area and mean aortic pressure gradient throughout the study period in Edwards Sapien 3 and Lotus group, respectively. ES3, Edwards Sapien 3 valve.

Fig. 4



Comparison of 30-day all-cause mortality, disabling stroke, moderate/severe paravalvular leak and new pacemaker implantation in our propensity-matched study and in the REPRISE III trial. Numbers represent percentage of patients. PM, pacemaker; PVL, paravalvular leak.

Importantly, both valves showed low rates of significant PVL at discharge and at 30 days. In fact, the incorporated outer skirt and the repositionability of the Lotus system were designed to minimize the gap between TAVI and SAVR in postprocedural PVL,[2,26] granted that moderate/severe PVL has been associated with worse outcome.[27,28] To this regard, our results compared favorably with those of the REPRISE II–III[7,21] and SOURCE three registry.[9] Moreover, they showed a marked improvement over first-generation devices, which had significantly higher frequency of moderate/severe PVL (ranging from 4% with the balloon-expandable Sapien XT to 18% with the self-expandable CoreValve).[29–32] The favorable acute hemodynamic performance of both devices was sustained at 30 days. In particular, both valves showed low mean transprosthetic gradients and low rates of moderate/severe PVL throughout the follow-up period. Of note, the incidence of mild PVL was also considerably lower with both new-generation devices compared with previous generation THVs[26] and this might be important at longer term follow-up, given the controversial data on the influence of mild PVL on outcome of TAVI patients and its unknown effect on prosthesis durability.

Significantly, balloon aortic valvuloplasty was performed more frequently before implantation of ES3 than Lotus (65.3 vs. 50.1%, $P = 0.04$). Given the nonrandomized nature of the study, we cannot exclude that this discrepancy was due to difference in valve characteristics (such as extension of calcifications) between groups. Nevertheless, we recently demonstrated the safety and efficacy of Lotus valve implantation without routine balloon aortic valvuloplasty,[33] made possible by the mechanical expansion of the device, which is able to exercise sufficient radial force to overcome the resistance of even severe cusps calcifications. Valve repositioning was performed in 23.6% of Lotus procedures. Accordingly, procedural time and contrast volume were higher in the latter group compared with ES3. Moreover, none of the mechanical expandable devices vs. 5.3% of ES3 THVs underwent postdilatation.

Despite the larger sheath sizes of the Lotus compared with the ES3 valve (20–22 vs. 14–16 F), the rate of major vascular complications was similar between groups. This finding might be linked to the fact that patients with larger femoral vessels might have been scheduled for the Lotus valve, whereas subjects with more challenging peripheral anatomies are treated with the ES3 (Table 6).

Pacemaker implantation was more common with the Lotus than the ES3 valve (31.7 vs. 10.5%, $P < 0.001$). New pacemaker implantation rates after TAVI are known to be higher compared with balloon-expandable, but similar to self-expandable valves.[34–36] Our frequency of new pacemaker implantation was in line with findings from the REPRISE II (28.6%)[8] and III (35.5%), and UK Lotus registry (31.8%).[37] The nonnegligible pacemaker implantation rate with the Lotus valve system is probably secondary to the closed-cell design and the different profile of the prosthesis, leading to stronger interaction with the LV outflow tract (LVOT) and the underlying conduction system. Nevertheless, we cannot exclude that the higher incidence of pacemaker implantation among patients treated with the Lotus valve was influenced also by different degree and distribution of LVOT calcifications between the two groups. Even if the negative effect of right ventricular pacing on ventricular synchrony and hemodynamics is well known, the reported data on the impact of pacemaker on outcome after TAVI are conflicting.[38–41] However, with TAVI indication moving to lower risk and younger patients, it is likely that pacemaker implantation and ventricular asynchrony will adversely affect – if not mortality – at least physical performance of more active, younger patients.[42] To note, with the new-generation Lotus, which is shorter and leads to less LVOT interaction, pacemaker implantation rates seem to be substantially reduced.[43]

Table 6 Thirty-day outcomes

	Lotus, $n = 93$	Sapien 3, $n = 93$	P value*
Early safety (VARC-2 definition)	14 (15.1%)	8 (8.6%)	0.06
All-cause mortality	5 (5.4%)	1 (1.1%)	0.10
Stroke	4 (4.3%)	1 (1.1%)	0.32
Disabling stroke	3 (3.2%)	1 (1.1%)	0.31
Major bleeding	4 (4.3%)	3 (3.2%)	0.71
Aortic regurgitation (%)			
None/trivial	60 (64.5%)	74 (80.4%)	0.10
Mild	31 (33.3%)	17 (18.5%)	
Moderate	2 (2.2%)	1 (1.1%)	
New pacemaker implantation	26 (31.7%)	9 (10.5%)	<0.001
Hospitalization for CHF	0 (0%)	0 (0%)	1.00
Prosthetic valve endocarditis, thrombosis	0 (0%)	0 (0%)	1.00

Data are presented as *n* (%). CHF, congestive heart failure; VARC-2, Valve Academic Research Consortium-2.

Limitations

Despite being one of the largest studies comparing the Lotus and the ES3 valve, the present analysis is not powered for major clinical endpoints such as death and stroke. Although propensity matching was performed, this was not a randomized trial. It is therefore possible that unrecognized differences between groups (for instance, in anatomical characteristics) may have contributed to the choice of one valve over the other, and therefore may have affected the results. Another limitation is the absence of an independent clinical event adjudication committee and echo core lab. The Lotus valve was temporarily recalled in February 2017, following reports of problems with the device's delivery, and is expected to become available again in October 2017.

Conclusion

In appropriately selected high-risk patients, transfemoral TAVI with either the balloon-expandable ES3 or the

repositionable Lotus valve resulted in good clinical and hemodynamic outcomes. Rates of moderate/severe PVL are very low with both devices, while TAVI with the Lotus valve carries a higher risk of pacemaker implantation. These results need to be confirmed by larger randomized trials.

Acknowledgements

Conflicts of interest

G.T. received lecture fees from Edwards Lifesciences, and is proctor for Boston Scientific; the other authors have nothing to disclose.

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