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ORIGINAL RESEARCH

Repositionable Versus Balloon-Expandable Devices for Transcatheter Aortic Valve Implantation in Patients With Aortic Stenosis

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***Background*—**The safety and effectiveness of the fully repositionable LOTUS valve system as compared with the balloon-expandable Edwards SAPIEN 3 prosthesis for the treatment of aortic stenosis has not been evaluated to date.

***Methods and Results*—**All patients undergoing transcatheter aortic valve implantation with the Edwards SAPIEN 3 or the LOTUS valve system were included into the Swiss Transcatheter Aortic Valve Implantation Registry. An adjusted analysis was performed to compare the early clinical safety outcome according to the Valve Academic Research Consortium-2 definition. Between February 2014 and September 2015, 140 and 815 patients were treated with the LOTUS and the Edwards SAPIEN 3 valve, respectively. There was no difference in crude and adjusted analyses of the early safety outcome between patients treated with LOTUS (14.3%) and those treated with Edwards SAPIEN 3 (14.6%) (crude hazard ratio, 0.97; 95% CI, 0.61–1.56 [*P*=0.915]; adjusted hazard ratio, 1.03; 95% CI, 0.64–1.67 [*P*=0.909]). More than mild aortic regurgitation was <2% for both devices. A total of 34.3% of patients treated with LOTUS and 14.1% of patients treated with Edwards SAPIEN 3 required a permanent pacemaker (HR, 2.76; 95% CI, 1.97–3.87 [*P*<0.001]).

***Conclusions*—**The repositionable LOTUS valve system and the balloon-expandable Edwards SAPIEN 3 prosthesis appeared comparable in regard to the Valve Academic Research Consortium-2 early safety outcome, and the rates of more than mild aortic regurgitation were exceedingly low for both devices. The need for new permanent pacemaker implantation was more frequent among patients treated with the LOTUS valve. **(*J Am Heart Assoc*. 2016;5:e004088 doi: 10.1161/JAHA.116.004088)**

Key Words: aortic valve regurgitation • newer-generation devices • permanent pacemaker • transcatheter aortic valve replacement

Transcatheter aortic valve implantation (TAVI) has gained wide acceptance for the treatment of severe aortic stenosis among patients deemed to be at increased risk for surgical aortic valve replacement. Expansion of TAVI to lower risk patients is critically dependent on the refinement of early-generation devices to further reduce the risk of paravalvular regurgitation, device malposition, atrioventricular (AV) conductance disturbances, access-site complications, and periinterventional bleeding. Newer-generation devices feature external cuffs or internal skirts to seal the prosthesis to the

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Accompanying Table S1 and Appendix S1 are available at http://jaha.ahajournals.org/content/5/11/e004088/DC1/embed/inline-supplementary-material-1.pdf

A complete list of the Collaborators and Swiss Transcatheter Aortic Valve Implantation Registry Investigators can be found in the Supplemental Material.

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aortic annulus and reduce the risk of paravalvular regurgitation. Atraumatic, precurved, and steerable delivery catheter systems aim for a reduction of plaque embolization, and smaller catheter diameters mitigate the risk of access site complications and bleeding.[1]

The LOTUS valve system (Boston Scientific, Natwick, MA) is a novel, fully repositionable TAVI prosthesis that permits evaluation of the final configuration of the deployed valve, the degree of aortic regurgitation, as well as reduced coronary flow before detachment. Single-arm registries of the LOTUS valve showed high rates of procedural success and suggested substantially lower rates of paravalvular regurgitation compared with early-generation devices[2–4]; conversely, rates of AV conduction disturbances were relatively high, resulting in permanent pacemaker implantation in 1 in every fourth patient up to one in every third patient.[2,3]

The safety and effectiveness of the fully repositionable LOTUS valve system as compared with other newer-generation TAVI devices have not been evaluated to date. We therefore performed an adjusted comparison of the LOTUS valve system with the balloon-expandable Edwards SAPIEN 3 prosthesis in patients with aortic stenosis undergoing TAVI within the nationwide Swiss Transcatheter Aortic Valve Implantation Registry (NCT01368250).

Methods

Study Population

All patients undergoing TAVI procedures performed in Switzerland are consecutively captured in a nationwide, prospective cohort study (ClinicalTrials.gov NCT01368250).[5] For the purpose of the present analysis, we investigated all patients with severe aortic stenosis treated with the Edwards SAPIEN 3 prosthesis or the LOTUS valve system. Selection of TAVI candidates, device allocation, and periprocedural management was left to the discretion of the operators. All data were recorded in a Web-based database held at the Clinical Trials Unit of the University of Bern, Switzerland. The Swiss TAVI registry has been approved by the local cantonal ethics committee and the institutional review boards of all participating sites. All patients provided written informed consent for study participation and prospective follow-up assessment.

Devices

The LOTUS valve system consists of a single nitinol wire that is braided into a stent frame upon foreshortening and mechanical expansion. Positioning is facilitated by a radiopaque marker. The prosthesis is attached to the delivery system with 3 coupling fingers; buckles at the distal end connect to posts located at the commissures of the 3 leaflets upon shortening, and lock the valve in its final configuration. The stent frame accommodates a bovine pericardial valve and comes in 3 prosthesis sizes (23 mm, 25 mm, and 27 mm) fitting an annulus diameter ranging from 20 mm to 26 mm. An adaptive seal in the distal portion of the prosthesis and an outer sleeve have been designed to reduce paravalvular regurgitation. The LOTUS prosthesis is fully repositionable and allows for an assessment of the final result before detachment of the valve from the coupling fingers of the delivery system. The precurved delivery catheter has a diameter of 18 F to 20 F and is not steerable. The valve can be implanted without rapid ventricular stimulation and predilatation is not necessary in all cases. The LOTUS valve system received CE mark approval on October 28, 2013, and on July 14, 2014, for its 23/27 mm and 25 mm prosthesis, respectively, and since then has become available for commercial use and implantation in Switzerland.

The Edwards SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA) is the fourth iteration of the first balloon-expandable transcatheter aortic valve prosthesis. The stent frame houses a valve made of 3 modified pericardial tissue leaflets, and accommodates annulus sizes from 18 mm to 28 mm using 3 device sizes (23 mm, 26 mm, 29 mm). An outer sealing skirt in the distal portion of the prosthesis complements the inner PET skirt and aims at a reduction of paravalvular aortic regurgitation. The prosthesis is loaded on the delivery balloon in the abdominal aorta rendering the delivery catheter compatible with 14 F to 16 F. The Commander delivery catheter is steerable and has a wheel to fine-adjust valve positioning.[6] The Edwards SAPIEN 3 valve was introduced in Switzerland for implantation on January 27, 2014, and completely replaced the previously available Edwards SAPIEN XT prosthesis.

Definitions

Patients underwent transthoracic echocardiography before hospital discharge, and were contacted for clinical follow-up at 30 days. Standardized interviews, documentation from referring physicians, and hospital discharge summaries were used for the collection of clinical end points. All end points were defined according to the updated version of the Valve Academic Research Consortium (VARC2) definitions.[7] An independent clinical event committee adjudicated all events. The prespecified end point was the VARC2 early safety outcome, a composite of all-cause mortality, stroke, life-threatening bleeding, acute kidney injury stage 2 or 3, coronary obstruction requiring intervention, major vascular complication, and valve-related dysfunction requiring repeat procedure.

Statistical Analysis

Continuous data are reported as mean±SD, and categorical variables are reported as number (percentage) of patients. Events are reported as counts of first occurrence per (sub-) type of event within 30 days of follow-up (% of all patients). Event rates at 30 days were compared for patients treated with the LOTUS versus the Edwards SAPIEN 3 bioprosthesis using Cox regressions, censoring patients at death or lost to follow-up. Reported are crude hazard ratios (HRs; with 95% CIs) with *P* values from Wald chi-square tests, or continuity correct risk ratios with *P* values from Fisher exact tests in case of zero events. Multiple imputation of missing data was performed using chained equations (n=20 data sets generated) before the adjusted analyses. Details on the missing data are summarized in Table S1. Reported are adjusted HRs (95% CIs), with the two valves compared, adjusting for age, dyslipidemia, peripheral vascular disease, aortic regurgitation moderate or severe, aortic valve area, New York Heart Association class III or IV, and Society of Thoracic Surgeons (STS) predicted risk of mortality score. No adjusted analyses were performed if there were fewer than 5 events overall. The estimates of adjusted HRs from 20 data sets after multiple imputation of missing values were combined using Rubin's rule and presented with adjusted *P* values. Two-sided *P* values <0.05 were considered statistically significant. Stratified analyses of the following subgroups were performed: age (≥83 years versus <83 years—median), sex (female versus male), left ventricular ejection fraction (≤40% versus >40%), peripheral vascular disease (yes versus no), STS risk score (>4 versus ≤4), and *P* value for the interaction between subgroups and valve type. All analyses were performed with Stata version 14 (StataCorp, College Station, TX).

Results

Patient Population

Between February 4, 2014, and September 29, 2015, 140 patients were treated with the LOTUS valve system and 815 patients with the Edwards SAPIEN 3 prosthesis in 12 centers across Switzerland. Baseline characteristics are summarized in Table 1. Age, sex, medical history, and cardiovascular risk factors were well balanced between the two treatment arms. Compared with patients treated with the LOTUS valve system, patients treated with the Edward SAPIEN 3 prosthesis more commonly had peripheral vascular disease (15.5% versus 7.9%, *P*=0.01) and higher estimated surgical risk as assessed by the logistic EuroScore (18.9±14.8% versus 15.0±8.6%, *P*=0.018) and STS score (5.0±3.8% versus 4.1±2.4%, *P*=0.005).

Procedural Characteristics

Procedural characteristics are shown in Table 2. Although procedure time was comparable, the amount of contrast media was greater with the LOTUS valve system compared with the Edwards SAPIEN 3 prosthesis (177±77 mL versus 153±93 mL, *P*=0.004). Patients treated with Edwards SAPIEN 3 more commonly underwent femoral surgical access (12.6% versus 5.7%, *P*=0.018) and predilatation with balloon valvuloplasty (81.8% versus 31.4%, *P*<0.001). Device success was 77.1% among patients treated with the LOTUS valve and 75.7% among patients treated with the Edwards SAPIEN 3 prosthesis (*P*=0.713). There were no significant differences between the two devices with regards to transprosthetic gradient, patient prosthesis mismatch, or postprocedural aortic valve area, respectively (Table 3). Patients treated with the LOTUS valve more commonly had no aortic regurgitation after intervention (71.4% versus 53.2%, difference 18.3%; 95% CI, 9.4–27.1) (Table 2). Whereas 7 patients (0.9%) treated with the Edwards SAPIEN 3 prosthesis underwent valve in series implantation due to malpositioning, no case of valve malpositioning was reported in the LOTUS cohort (*P*=0.271).

Clinical Outcomes

The early VARC2 safety end point occurred in 14.3% of patients treated with the LOTUS and 14.6% of patients treated with the Edwards SAPIEN 3 prosthesis with no difference in crude (HR, 0.97; 95% CI, 0.61–1.56 [*P*=0.915]) and adjusted (HR, 1.03; 95% CI, 0.64–1.67 [*P*=0.909]) analyses (Figure 1). Individual components of the primary composite end point are summarized in Table 3. All-cause mortality at 30 days was 2.2% among patients treated with the LOTUS valve system, and 2.8% among patients treated with the Edwards SAPIEN 3 valve (adjusted HR, 0.75; 95% CI, 0.22–2.51 [*P*=0.636]). Estimated and observed mortality are illustrated in Figure 2. There were no significant differences between the two devices with regard to mortality, cerebrovascular accidents, myocardial infarction, vascular access site, and bleeding complications. While none of the patients in the LOTUS group experienced periprocedural myocardial infarction, 7 patients treated with the Edwards SAPIEN 3 prosthesis did (0.9%) (HR, 0.39; 95% CI, 0.02–6.79 [*P*=0.602]).

Despite a higher amount of contrast used in patients treated with the LOTUS valve, there were no differences with respect to acute kidney injury. The number of permanent pacemaker implantations was higher in patients treated with the LOTUS (34.3%) as compared with the Edwards SAPIEN 3 prosthesis (14.1%) (HR, 2.76; 95% CI, 1.97–3.87 [*P*<0.001]) (Figure 3). In a stratified analysis for the VARC2 early safety outcome, there were no significant interactions across major subgroups, with the exception of a positive effect for

Table 1. Baseline Characteristics

	LOTUS N=140	Edwards S3 N=815	Difference (95% CI)	*P* Value
Age, y	82.97±5.40	81.92±6.37	1.05 (−0.07 to 2.17)	0.065
Female sex, No. (%)	65 (46.4)	352 (43.2)	3.2% (−5.7% to 12.1%)	0.519
Body mass index, kg/m^2	26.64±4.77	26.95±5.27	−0.31 (−1.25 to 0.63)	0.516
Cardiac risk factors				
Diabetes mellitus, No. (%)	33 (23.6)	200 (24.5)	1.0% (−6.8% to 8.7%)	0.915
Dyslipidemia, No. (%)	80 (57.1)	392 (48.1)	−9.0% (−18.0% to −0.1%)	0.055
Hypertension, No. (%)	114 (81.4)	625 (76.8)	−4.6% (−12.2%; 2.9%)	0.273
Medical history				
Previous pacemaker implantation, No. (%)	15 (10.7)	80 (9.8)	−0.9% (−6.3% to 4.5%)	0.760
Previous myocardial infarction, No. (%)	21 (15.0)	122 (15.0)	−0.0% (−6.4% to 6.4%)	1.000
Previous cardiac surgery, No. (%)	14 (10.0)	114 (14.0)	4.0% (−2.1% to 10.1%)	0.228
Previous cerebrovascular accident, No. (%)	14 (10.0)	91 (11.2)	1.2% (−4.5% to 6.8%)	0.771
Clinical features				
Peripheral vascular disease, No. (%)	11 (7.9)	126 (15.5)	7.6% (1.3%–13.9%)	0.018
Chronic obstructive pulmonary disease, No. (%)	11 (7.9)	91 (11.2)	3.3% (−2.2% to 8.9%)	0.300
Coronary artery disease, No. (%)	85 (60.7)	477 (58.5)	−2.2% (−11.0% to 6.7%)	0.643
Left ventricular ejection fraction, %	56.13±12.13	55.14±14.44	0.98 (−1.79 to 3.76)	0.487
Aortic valve area, cm^2	0.66±0.22	0.71±0.23	−0.05 (−0.10 to −0.00)	0.046
Mean transvalvular aortic gradient, mm Hg	49.36±19.54	46.14±21.50	3.22 (−0.89 to 7.32)	0.125
Symptoms on admission				
NYHA class				0.061
NYHA I or II, No. (%)	58 (41.4)	255 (33.2)	8.2% (−0.4% to 16.7%)	0.066
NYHA III or IV, No. (%)	82 (58.6)	512 (66.8)	−8.2% (−16.7% to 0.4%)	0.066
CCS angina class	n=140	n=811		0.508
No angina, No. (%)	113 (80.7)	626 (77.2)	3.5% (−4.0% to 11.0%)	0.381
CCS I or II, No. (%)	21 (15.0)	131 (16.2)	−1.2% (−7.7% to 5.4%)	0.803
CCS III or IV, n (%)	6 (4.3)	54 (6.7)	−2.4% (−6.7% to 2.0%)	0.349
Risk assessment				
Log EuroScore, %	14.95±8.62	18.85±14.78	−3.90 (−7.14 to −0.67)	0.018
STS score, %	4.10±2.42	5.04±3.76	−0.93 (−1.58 to −0.28)	0.005

Values are expressed as means with SDs (*P* value from *t* tests) or counts (% of all patients; *P* value from Fisher or chi-square tests). CCS indicates Canadian Cardiovascular Society; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons.

treatment with the LOTUS valve among patients 83 years and older (*P* for interaction=0.030) (Figure 4).

Discussion

The key findings of our analysis can be summarized as follows.

1. In a nationwide prospective registry of patients undergoing TAVI, we found no differences for the primary end point, the early composite safety end point within 30 days between patients treated with the fully repositionable LOTUS valve system versus the balloon-expandable Edwards SAPIEN 3 prosthesis.
2. Rates of device success were comparable for both devices.
3. More than mild residual aortic regurgitation was exceedingly low with both devices.
4. Patients treated with the LOTUS valve system had a 2- to 3-fold increased risk of permanent pacemaker implantation compared with patients treated with the Edwards SAPIEN 3 prosthesis.

Table 2. Procedural Characteristics

	LOTUS N=140	Edwards S3 N=815	Difference (95% CI)	*P* Value
Procedure time, min	69.81±26.09	70.25±33.47	−0.44 (−6.40 to 5.52)	0.885
Amount of contrast, mL	177.10±77.06	152.59±93.34	24.51 (7.78–41.24)	0.004
General anesthesia, No. (%)	35 (25.0)	314 (38.5)	−13.5% (−22.1% to −4.9%)	0.002
Type of transfemoral access				0.018
Percutaneous, No. (%)	132 (94.3)	712 (87.4)	6.9% (1.2%–12.7%)	
Surgical, No. (%)	8 (5.7)	103 (12.6)	−6.9% (−12.7% to −1.2%)	
Concomitant procedure				
Percutaneous coronary intervention, No. (%)	12 (8.6)	50 (6.1)	−2.4% (−6.9% to 2.0%)	0.268
Device features				
Valve size				
23 mm	44 (31.4%)	216 (26.5%)		
25 mm	51 (36.4%)			
26 mm		351 (43.1%)		
27 mm	45 (32.1%)			
29 mm		248 (30.4%)		
Prior balloon aortic valvuloplasty, No. (%)	44 (31.4)	667 (81.8)	50.4% (43.3%; 57.6%)	<0.001
Device success, No. (%)	108 (77.1%)	617 (75.7%)	1.4% (−6.2% to 9.1%)	0.713
Valve in series, No. (%)	0 (0.0%)	7 (0.9%)	−0.9% (−2.4% to 0.7%)	0.271
Repeat unplanned intervention within 30 days	1 (0.7%)	11 (1.3%)	−0.6% (−2.6% to 1.4%)	0.533
Patient prosthesis mismatch, No. (%)				0.928
Insignificant	114 (81.4%)	661 (81.1%)	0.3% (−6.7% to 7.4%)	
Moderate/severe	26 (18.6%)	154 (18.9%)	−0.3% (−7.4% to 6.7%)	
Aortic regurgitation post-TAVI				<0.001
Grade 0, No. (%)	100 (71.4)	430 (53.2)	18.3% (9.4%–27.1%)	
Grade 1, No. (%)	39 (27.9)	369 (45.6)	−17.8% (−26.6% to −8.9%)	
Grade 2, No. (%)	1 (0.7)	10 (1.2)	−0.5% (−2.4% to 1.4%)	
Grade 3, No. (%)	0	0	na	
Postprocedure				
Mean transprosthetic gradient, mm Hg	10.29±6.10	9.51±5.10	0.79 (−0.17 to 1.74)	0.106
Aortic valve area, mm	1.78±0.61	1.75±0.53	0.03 (−0.10 to 0.16)	0.675
In-hospital course				
Any PRBC, No. (%)	11 (7.9)	111 (13.6)	5.8% (−0.2% to 11.8%)	0.074
Number of PRBC, median (interquartile range)	2.0 (1.0–4.0)	2.0 (2.0–3.3)	1.85 (0.03–3.68)	0.839
Overall in-hospital stay after TAVI, days	9.34±4.40	9.47±5.55	−0.13 (−1.10 to 0.84)	0.790

Values are expressed as means with standard deviations (*P* values from *t* tests) or counts (% of all patients; *P* values from Fisher tests or chi-square tests). PRBC indicates packed red blood cell; TAVI, transcatheter aortic valve implantation.

Newer-generation TAVI devices are characterized by improved device success as compared with early-generation devices primarily by a reduction of moderate or severe prosthetic valve regurgitation, which has consistently been associated with increased late mortality.[8,9] Documentation of moderate to severe aortic regurgitation has been reported in up to 14% of patients treated with early-generation devices,[8–10] and motivated the development of internal skirts and external cuffs to seal the prosthesis to the aortic annulus and reduce paravalvular regurgitation. Complimentary to technical refinements of the devices, dedicated imaging tools have been introduced allowing for precise device positioning within the

Table 3. Clinical Outcomes at 30 Days

	LOTUS N=140	Edwards S3 N=815	HR (95% CI)	*P* Value	Adjusted HR (95% CI)	Adjusted *P* Value
Early safety primary end point VARC2	20 (14.3)	119 (14.6)	0.97 (0.61–1.56)	0.915	1.03 (0.64–1.67)	0.909
Mortality, No. (%)	3 (2.2)	23 (2.8)	0.75 (0.22–2.49)	0.636	0.75 (0.22–2.51)	0.636
Cardiovascular Mortality, No. (%)	2 (1.5)	21 (2.6)	0.55 (0.13–2.33)	0.414	0.51 (0.12–2.21)	0.371
Cerebrovascular accident, No. (%)	6 (4.3)	25 (3.1)	1.40 (0.57–3.41)	0.461	1.42 (0.57–3.50)	0.448
Disabling stroke, No. (%)	3 (2.1)	9 (1.1)	1.93 (0.52–7.15)	0.322	2.01 (0.53–7.61)	0.304
Nondisabling stroke, No. (%)	3 (2.1)	11 (1.4)	1.58 (0.44–5.68)	0.480	1.59 (0.43–5.79)	0.485
TIA, No. (%)	0 (0.0)	5 (0.6)	0.53 (0.03–9.53)	1.000		
MI, No. (%)	0 (0.0)	9 (1.1)	0.31 (0.02–5.30)	0.371		
Periprocedural MI, No. (%)	0 (0.0)	7 (0.9)	0.39 (0.02–6.79)	0.602		
Spontaneous MI, n (%)	0 (0.0)	2 (0.3)	1.16 (0.06–24.03)	1.000		
Acute kidney injury, No. (%)	2 (1.4)	26 (3.2)	0.44 (0.10–1.86)	0.265	0.62 (0.14–2.67)	0.522
Stage 1, No. (%)	1 (0.7)	5 (0.6)	1.16 (0.14–9.94)	0.891	1.06 (0.12–9.55)	0.960
Stage 2, No. (%)	0 (0.0)	6 (0.7)	0.45 (0.03–7.94)	0.600		
Stage 3, No. (%)	1 (0.7)	15 (1.9)	0.38 (0.05–2.90)	0.353	0.61 (0.08–4.79)	0.642
Bleeding, No. (%)	17 (12.2)	131 (16.2)	0.74 (0.45–1.23)	0.246	0.79 (0.47–1.32)	0.368
Life-threatening bleeding, No. (%)	6 (4.3)	45 (5.5)	0.77 (0.33–1.81)	0.550	0.79 (0.33–1.87)	0.586
Major bleeding, No. (%)	8 (5.7)	59 (7.3)	0.78 (0.37–1.63)	0.512	0.81 (0.38–1.71)	0.572
Minor bleeding, No. (%)	3 (2.1)	28 (3.5)	0.62 (0.19–2.03)	0.425	0.75 (0.22–2.49)	0.633
Vascular access site and access-related complications, No. (%)	19 (13.6)	112 (13.8)	0.98 (0.60–1.60)	0.946	0.96 (0.59–1.58)	0.880
Major vascular complications, No. (%)	10 (7.2)	76 (9.3)	0.76 (0.39–1.47)	0.416	0.72 (0.37–1.41)	0.342
Minor vascular complications, No. (%)	8 (5.7)	32 (3.9)	1.45 (0.67–3.16)	0.344	1.45 (0.66–3.19)	0.357
Structural valve deterioration, No. (%)	0 (0.0)	1 (0.1)	1.93 (0.08–47.14)	1.000		
Repeat unplanned intervention, No. (%)	1 (0.7)	11 (1.4)	0.52 (0.07–4.04)	0.534	0.38 (0.05–3.04)	0.363
Valve-related dysfunction requiring intervention	0 (0.0)	3 (0.4)	0.83 (0.04–15.98)	1.000		
Valve in valve treatment, No. (%)	0 (0.0)	0 (0.0)				
Surgical revision, No. (%)	0 (0.0)	3 (0.4)	0.83 (0.04–15.98)	1.000		
Other, No. (%)	1 (0.7)	8 (1.0)	0.72 (0.09–5.73)	0.754	0.53 (0.06–4.32)	0.550
Permanent pacemaker implantation, No. (%)	48 (34.3)	113 (14.1)	2.76 (1.97–3.87)	<0.001	2.63 (1.86–3.73)	<0.001

Depicted are the number of first events within 30 days with percentage of all patients. All clinical outcomes were adjudicated, except for pacemaker implantations. Cox regressions reporting hazard ratios (HRs; with 95% CIs) or continuity corrected risk ratios (95% CIs) in case of zero events with Fisher exact *P* values. Adjusted HR from Cox regressions, adjusting for age, dyslipidemia, peripheral vascular disease, aortic regurgitation moderate or severe, aortic valve area, New York Heart Association class III or IV, and Society of Thoracic Surgery risk score (combining the estimates of 20 data sets using Rubin's rule because of missing data). Multiple imputation of missing data was performed using chained equations (n=20 data sets generated). There was no adjusted analyses if there were fewer than 5 events overall. MI indicates myocardial infarction; TIA, transient ischemic attack; VARC2, Valve Academic Research Consortium.

annular landing zone. In the Swiss TAVI registry, moderate or severe aortic regurgitation was documented in 0.7% and 1.2% of patients treated with LOTUS and Edwards SAPIEN 3, respectively. Our findings are consistent with the Repositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus Valve System: Evaluation of Safety and Performance (REPRISE) II study and the UK LOTUS registry, reporting moderate or severe aortic regurgitation in 1% and 0.8% of patients, respectively.[2,3] Reduction of paravalvular aortic regurgitation results from a combination of both, the full repositionability of the LOTUS valve allowing for an assessment of the result prior to deployment, and the prosthesis design with an adaptive seal in the distal portion and an outer sleeve.[6] A similarly low incidence of moderate to severe aortic regurgitation was documented with the Edwards SAPIEN 3 valve that has been refined by an external sealing cuff that mimics a parachute. The incidence of more than mild paravalvular regurgitation decreased from 5.3% to 1.3%

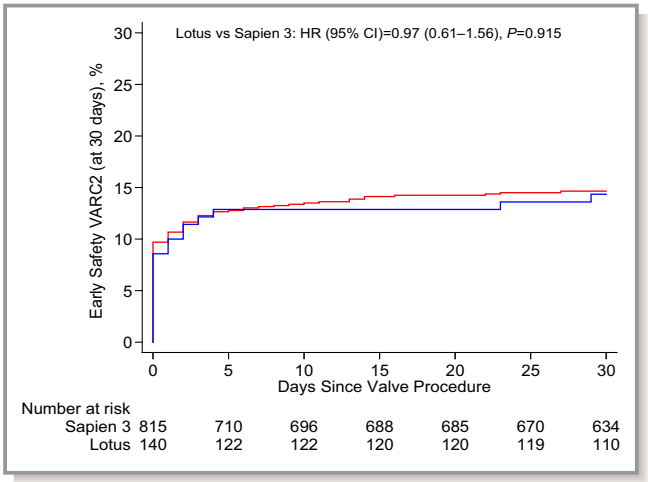

Figure 1. Kaplan–Meier estimates of the Valve Academic Research Consortium 2 (VARC2) early safety composite outcome at 30 days. The blue line relates to the LOTUS valve system; the red line relates to the Edwards SAPIEN 3 valve. HR indicates hazard ratio.

(*P*=0.04) as compared with its predecessor in a previous analysis from the Swiss TAVI registry including almost 600 patients.[11]

Rates of permanent pacemaker implantation amounted to 34% among patients treated with the LOTUS valve, and were 2- to 3-fold higher compared with patients treated with the Edwards SAPIEN 3 prosthesis. Comparable rates of AV conductance disturbances and permanent pacemaker implantation have been consistently reported in the REPRISE II study (28.6%) and the UK LOTUS registry (31.8%).[2,3] The effect of permanent pacemaker implantation after TAVI on long-term outcomes remains a matter of debate.[12,13] No difference in 1-year mortality was documented in patients with a previous permanent pacemaker, a new permanent pacemaker, or no pacemaker in a prospective registry of 353 patients from 2 institutions.[12] In contrast, permanent pacemaker implantation after TAVI was reported to be an independent predictor of 1-year mortality in an analysis of the Placement of Aortic Transcatheter Valves (PARTNER I) trial.[13] Moreover, permanent pacemaker implantation was associated with a longer duration of hospitalization and higher rates of repeat hospitalization at 1 year.[14] The degree of pacemaker dependency accompanied by ventricular dyssynchrony may reconcile the differential in clinical findings between studies. AV conductance disturbances along with pacemaker dependency after TAVI may be temporary rather than permanent in nature. In a small study of 36 patients with new pacemaker following implantation of a self-expandable prosthesis, more than half of the patients were pacemaker independent at a median follow-up of 12 months.[15]

The rates of the early composite safety end point were comparable between the two devices at 30 days. In line, there were no differences with respect to cardiovascular mortality, myocardial infarction, bleeding, or vascular access site complications. The observed mortality rate (LOTUS 2.2% versus SAPIEN 3 2.8%) was substantially lower as compared with the STS estimates. The overall incidence of stroke was 4.3% and 3.1% of patients treated with the LOTUS valve system and the Edwards SAPIEN 3 prosthesis, respectively. The incidence of stroke at 30 days was 5.9% in the REPRISE II study and 3.9% in the UK LOTUS registry,[2,3] while large nationwide TAVI registries reported stroke rates in the range

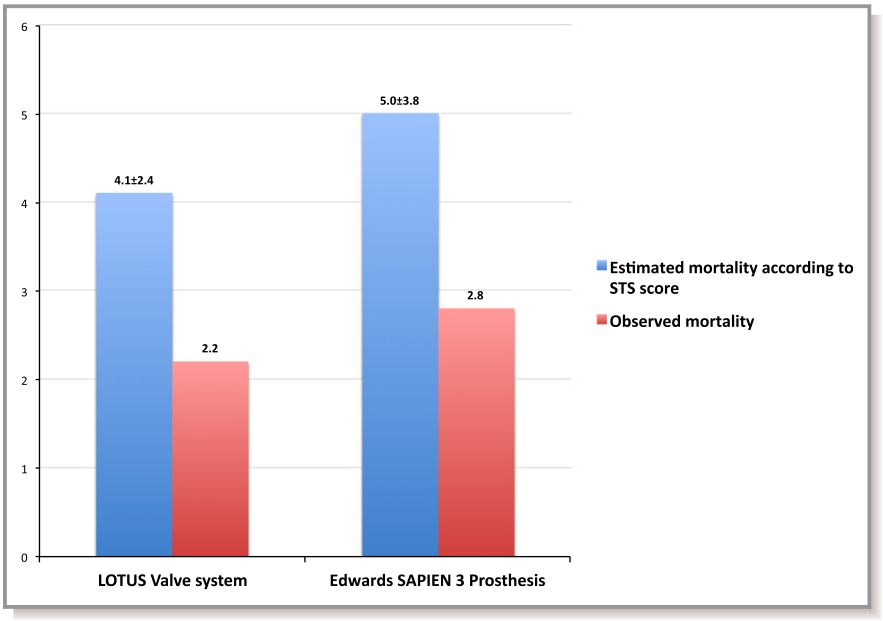

Figure 2. Bar graph of estimated and observed mortality at 30 days. Society of Thoracic Surgeons (STS) risk scores were used to estimate mortality at 30 days.

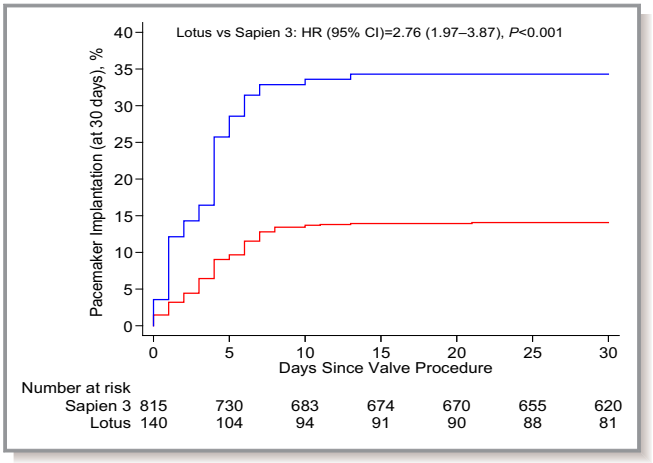

Figure 3. Kaplan–Meier estimates for permanent pacemaker implantation within 30 days. The blue line relates to the LOTUS valve system; the red line relates to the Edwards SAPIEN 3 valve. HR indicates hazard ratio.

of 1.5% to 4%.[9,11,16–19] Although the signal has to be interpreted with caution, several reasons may account for a potential difference in cerebrovascular events between the two devices. A significantly lower rate of prior balloon valvuloplasty among patients treated with the LOTUS valve as compared with the Edwards SAPIEN valve may affect the rates of stroke. In a small study of 87 patients, the volume of new cerebral ischemic lesions as assessed by diffusion-weighted magnetic resonance imaging was significantly higher among patients without as compared with patients with prior balloon aortic valvuloplasty.[20] In contrast, a recent meta-analysis of 18 studies with 2443 patients demonstrated a trend towards a reduced risk of clinically relevant stroke with direct TAVI. However, the findings should be interpreted with caution given the limitations of the nonrandomized studies included in the meta-analysis and the unadjusted nature of the summary measures used.[21] The effect of predilatation on clinical outcome is currently being investigated in the Transcatheter Aortic Valve Implantation Without Predilatation (SIMPLIFy TAVI) study (NCT 01539746) and the Balloon Expandable Transcatheter Aortic Valve Implantation Without Predilatation of Aortic Valve (EASE-IT) study (NCT02127580). Moreover, differences in the delivery catheter diameter, flexibility, and steerability may affect the risk of plaque abrasion in the aortic arch. Finally, full repositionability of the LOTUS valve may increase the inclination of repeated prosthesis placement, which, in turn, has been associated with an increased risk of stroke.[22]

Study Limitations

The present analysis has several limitations. First, there was no random allocation to treatment with the LOTUS valve or the Edwards SAPIEN 3 prosthesis, respectively. Although baseline characteristics between the two treatment arms were comparable, we cannot exclude selection of treatment according to concealed confounders. We used an adjusted analysis to correct for differences in baseline characteristics.

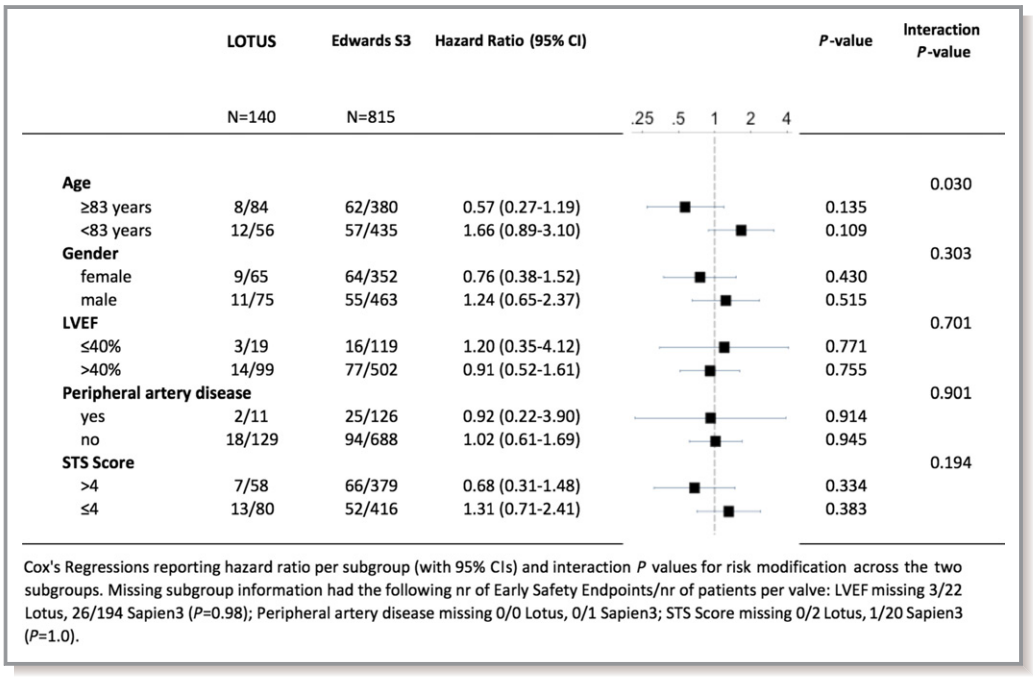

Figure 4. Stratified analysis for the Valve Academic Research Consortium 2 Early Composite Safety Outcome (based on crude hazard ratios). LVEF indicates left ventricular ejection fraction; STS, Society of Thoracic Surgeons.

Second, the number of patients included in the analysis was limited, and the duration of follow-up did not extend beyond 30 days. However, it constitutes the largest series reported to date and data are consistent with previously reported single-arm registries. Third, differences in balloon valvuloplasty prior to device implantation may have confounded the clinical results. However, our analysis reflects routine clinical practice with the 2 devices by experienced operators. Finally, implantation depth and oversizing have both been associated with an increased rate of conductance disturbances, respectively. Neither of which were prospectively documented in our registry.

Conclusions

In a nationwide registry, no statistical difference was found between the repositionable LOTUS valve system and the balloon-expandable Edwards SAPIEN 3 prosthesis with respect to the VARC2 early safety outcome for the treatment. Rates of moderate or severe aortic regurgitation are exceedingly low for both devices. The need for new permanent pacemaker implantation was more frequent among patients treated with the LOTUS valve.

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Disclosures

Dr Pilgrim serves as a consultant to St. Jude Medical, and received research contracts to the institution from Edwards Lifesciences and Symetis. Dr Nietlispach serves as consultant to Edwards Lifesciences and St. Jude Medical. Dr Tueller received speakers' fees from Edwards Lifesciences and travel expenses from Medtronic. Dr Toggweiler is a proctor for Symetis and received speakers' fees from Edwards Lifesciences and Medtronic. Dr Jeger serves as a consultant to St. Jude Medical and has received reimbursement for travel expenses from Medtronic, Boston Scientific, and Edwards Lifesciences. Dr Ferrari is a proctor for Edwards Lifesciences. Dr Noble serves as consultant for Medtronic. Dr Roffi received institutional research grants from Abbott Vascular, Boston Scientific, Biotronik, Biosensor, and Medtronic. Dr Huber is a proctor for Edwards Lifesciences and Consultant for Medtronic. Dr Windecker has received research contracts to the institution from Abbott, Boston Scientific, Biosensors, Cordis, Medtronic, and St. Jude. Dr Wenaweser serves as proctor for Medtronic, Edwards Lifesciences, and Boston Scientific and has received an unrestricted grant from Medtronic to the institution (University of Bern). All of the other authors have no conflicts of interest to declare.

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SUPPLEMENTAL MATERIAL

Table S1 **Missing Baseline Characteristics, Multiple imputation and Adjusted Analyses**

	Nr of missing values	Imputed	Used to impute***	Used for Adjusted Cox's Regression
Nr of patients	N = 955			
Age	0 (0.0%)	No	Yes	Yes
Sex	0 (0.0%)	No	Yes	No
Body mass index	3 (0.3%)	Yes	Yes	No
Cardiac Risk Factors				
Diabetes mellitus	0 (0.0%)	No	Yes	No
Dyslipidemia	0 (0.0%)	No	Yes	Yes
Hypertension	1 (0.1%)	Yes**	Yes	No
Past Medical History				
Previous pacemaker implantation	0 (0.0%)	No	Yes	No
Previous myocardial infarction	0 (0.0%)	No	Yes	No
Previous cardiac surgery	0 (0.0%)	No	Yes	No
Previous cerebrovascular accident	0 (0.0%)	No	Yes	No
Clinical Features				
Peripheral vascular disease	1 (0.1%)	Yes**	Yes	Yes
Chronic obstructive pulmonary disease	1 (0.1%)	Yes**	Yes	No
Coronary artery disease	0 (0.0%)	No	Yes	No
Aortic Valve Area (cm2)	241 (25.2%)	Yes	Yes	Yes
Mean transaortic gradient	104 (10.9%)	Yes	Yes	No
Aortic regurgitation grade moderate or severe	65 (6.8%)	Yes	Yes	Yes
Mitral regurgitation grade moderate or severe	50 (5.2%)	Yes	Yes	No
Symptoms on admission				
New York Heart Association (NYHA) Functional Class	48 (5.0%)	Yes	Yes	Yes
Canadian Cardiovascular Society Angina Class	4 (0.4%)	Yes	Yes	No

Risk Assessment				
STS Score	22 (2.3%)	Yes	Yes	Yes
Device				
Device size	0 (0.0%)	No	Yes	No
Primary Outcome				
Early Safety Endpoint	0 (0.0%)	No	Yes	No

** Single imputation with the mode. All other missing values were multiple imputated.

*** Chained equations.

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Repositionable Versus Balloon–Expandable Devices for Transcatheter Aortic Valve Implantation in Patients With Aortic Stenosis

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