

Transfemoral aortic valve implantation with the repositionable Lotus valve for treatment of patients with symptomatic severe aortic stenosis: results from a single-centre experience



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KEYWORDS

- aortic regurgitation
- aortic stenosis
- Lotus
- TAVI
- VARC-2

Abstract

Aims: The aim of the study was to evaluate the procedural and 30-day results for the repositionable Lotus valve in patients undergoing transfemoral aortic valve implantation in a single-centre experience.

Methods and results: We prospectively enrolled 110 patients with severe symptomatic aortic stenosis (NCT02162069). All procedures were performed without general anaesthesia by the transfemoral approach. Patients were followed for 30 days. Patients received the 23 mm (n=20), 25 mm (n=43) or 27 mm (n=47) Lotus device. Mean oversizing in relation to annulus or left ventricular outflow tract (LVOT) did not differ among groups. There was no residual moderate or severe aortic regurgitation. The rate of mild aortic regurgitation was low at 9.1%. There was no valve embolisation, no need for a second valve and no conversion to surgery. The need for a new pacemaker implantation due to complete (third degree) or type II (Mobitz) second degree atrioventricular block was 24.1%, excluding patients with previously implanted devices. Within 30 days the rates of all-cause mortality and stroke were low.

Conclusions: In patients with severe aortic stenosis, transfemoral TAVI with the repositionable Lotus valve was associated with a high rate of device success, no moderate or severe residual aortic regurgitation, low rates of major vascular complications and mortality within 30 days.

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Introduction

Transcatheter aortic valve implantation (TAVI) for treatment of symptomatic patients with severe aortic stenosis was associated with a lower long-term mortality compared with patients undergoing surgical valve replacement¹. With first-generation TAVI prostheses, residual paravalvular aortic regurgitation (AR) after TAVI has been identified as a significant independent predictor of acute and long-term mortality². Furthermore, valve positioning could not be completely controlled, leading in some cases to severe complications such as valve embolisation or the need for a second valve implantation.

The Lotus™ valve (Boston Scientific, Marlborough, MA, USA) incorporates two dedicated design features to obtain optimised post-procedural results. First, the mechanically deployed valve can be repositioned to achieve an optimal valve positioning. Even after final placement in the annulus, the valve can still be completely retrieved, which should eliminate the risk of valve embolisation and the need for implantation of a second valve. Second, an adaptive outer seal minimises residual paravalvular AR (**Figure 1**). Published data with the Lotus valve do not include the full range of available sizes³⁻⁵ and are mainly limited to single case reports⁶⁻⁸.

We evaluated periprocedural safety, post-procedural results including residual AR, device success and outcome within 30 days according to the second Valve Academic Research Consortium criteria⁹ for the repositionable and retrievable Lotus valve in a patient population with symptomatic severe aortic stenosis undergoing transfemoral TAVI.

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Methods

We prospectively evaluated the safety and efficacy of the Lotus valve in 110 patients with symptomatic severe aortic stenosis including the 23, 25 and 27 mm valve sizes. Valve implantation was

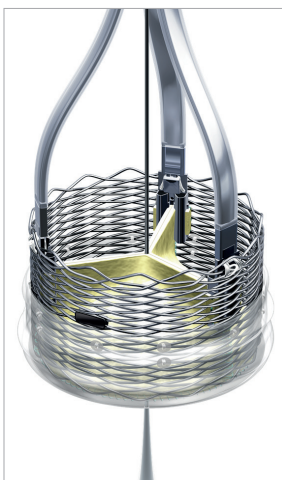


Figure 1. The Lotus valve. The repositionable, mechanically deployed Lotus valve with an adaptive seal at the outer side of the distal frame to reduce paravalvular aortic regurgitation.

performed in a hybrid catheterisation lab without general anaesthesia by the transfemoral approach as described elsewhere^{7,8,10}. Severe aortic stenosis was documented by echocardiography and cardiac catheterisation with an aortic valve area (AVA) ≤ 1 cm² or an indexed AVA ≤ 0.6 cm²/m². Patients were at intermediate to high risk for surgical valve replacement based on a Society of Thoracic Surgeons (STS) score for mortality or had relevant comorbidities with contraindications to surgical valve replacement, e.g., porcelain aorta, frailty or history of chest radiation. The Heart Team including cardiologists and heart surgeons made the decision for TAVI. Written informed consent was obtained from each patient. The study was approved by the local ethics committee (ClinicalTrials.gov NCT02162069).

Pre-procedural 256 multislice computed tomography was used for sizing in all patients. Measurements were obtained using dedicated software (3mensio 7.0 software; Pie Medical Imaging, Maastricht, The Netherlands). Aortic cusp calcification was assessed according to Rosenhek¹¹. Eccentricity index was calculated as $1 - (\text{minimum diameter of annulus}/\text{maximum diameter annulus})$. Oversizing or undersizing was calculated as $\% \text{oversizing} = (\text{Lotus valve nominal area}/\text{annular area by computed tomography} - 1) * 100$. Nominal areas for the 23, 25 or 27 mm Lotus valve were 415.5, 490.6 and 572.5 mm² according to the manufacturer's instructions for use. The presence of LVOT calcification was defined as moderate or severe as defined by Barbanti et al¹².

We studied the full range of available Lotus sizes including 23, 25 and 27 mm devices which allowed us to address the outcome of the Lotus valve in a general TAVI population. The 23 mm (25 mm; 27 mm) Lotus valve size was implanted in patients with a diameter of the annulus between 20 and 23 mm (23-25 mm; 25-27 mm). In addition, the distance between annulus and coronary ostia had to be >10 mm and the femoral and iliac arteries had to accommodate the 18 or 20 Fr delivery sheath. Puncture of the femoral artery was performed under fluoroscopic guidance during antegrade angiography. The femoral access was pre-closed with two ProGlide devices (Abbott Vascular, Santa Clara, CA, USA). The Lotus valve was implanted under fluoroscopic guidance without rapid pacing after predilation as described elsewhere^{8,10}. Appropriate valve positioning was achieved by positioning the posts (distal part of the locking mechanism) over a predetermined landing plane.

AR after TAVI was analysed by standardised aortography^{10,13}. Aortography for AR assessment was performed after complete release of the Lotus valve and after withdrawal of the Safari™ wire (Boston Scientific) by a pigtail catheter from the left ventricle. In all cases, the pigtail catheter for aortography was placed directly on top of the Lotus valve. AR and measurement of pressure gradients by transthoracic echocardiography (TTE) was carried out one to three days after TAVI. AR was graded none, trace, mild, moderate or severe as described elsewhere^{10,14,15} and differentiated into valvular and paravalvular. Post-procedural TTE was performed by cardiologists specialised in non-invasive imaging. Operators implanting the Lotus valves did not perform post-procedural TTE.

Post-procedural outcome was analysed according to the VARC-2 criteria⁹. Patients were followed for 30 days.

Statistical analysis

For statistical analyses, the Statistica software, version 10 (StatSoft, Inc., Tulsa, OK, USA) was used. Pre-procedural data and post-procedural results were compared among the three different valve sizes. The primary outcome measure was device success according to VARC-2 criteria, defined as the absence of procedural mortality and correct positioning of a single prosthetic heart valve into the proper anatomical position and intended performance of the prosthetic heart valve. Secondary endpoints were all-cause mortality at 30 days, disabling and non-disabling stroke, life-threatening bleeding, major vascular injury and new pacemaker insertion due to second degree (type II) or third degree atrioventricular block. All endpoints were defined according to VARC-2 criteria. Continuous variables are expressed as mean±one standard deviation and were compared with ANOVA testing. Categorical variables are presented as counts and percentages and differences between proportions were calculated by using the chi-squared test. A value of $p < 0.05$ was considered statistically significant.

Results

Between January 2014 and July 2015 the Lotus valve was successfully implanted in all 110 patients. Baseline, procedural and follow-up data at 30 days were available for all patients. Patients had multiple comorbidities including porcelain aorta, pulmonary disease or reduced left ventricular function, as displayed in **Table 1**. The American Society of Anaesthesiologists score for perioperative risk was 3.6 ± 0.6 ; the STS predicted risk of operative mortality was 6.5 ± 4.6 and 15.5 ± 14.1 by logistic EuroSCORE estimates. Mean EuroSCORE II was $7.0 \pm 7.4\%$ with 82 (74.5%) patients being at intermediate risk. There was no difference among groups

regarding the number of patients who were at high or intermediate risk based on EuroSCORE II (23 mm Lotus valve 75.0%; 25 mm valve 67.4%, 27 mm valve 80.9%; $p=0.34$). A history of cardiac surgery was present in 10% and atrial fibrillation in 38% of patients. The majority of patients (82%) were severely symptomatic with NYHA Class III or IV. There was no difference regarding baseline clinical data or baseline aortic valve parameters among the 23, 25 or 27 mm population (**Table 1**, **Table 2**).

Measurements of the annulus and LVOT parameters were significantly different for the three valve sizes with a perimeter-derived diameter of the aortic annulus of a mean of 22.8 mm for the 23 mm group ($n=20$), 24.8 mm for the 25 mm group ($n=43$) and 26.6 mm for the 27 mm group ($n=47$) (**Table 3**). The distance from the annulus to the left or right coronary ostium was shortest in the 23 mm population and longest in the 27 mm group. There was no difference in the rate of oversizing in relation to the annulus among the three valve sizes, ranging from 8.5% to 9.0%. In addition, there was no difference in the rate of oversizing in relation to the LVOT, ranging from 9.7% to 11.4% (**Table 3**). Calcifications of aortic cusps and LVOT calcifications were similar among the three groups.

PROCEDURAL RESULTS AND FOLLOW-UP

The Lotus valve was successfully implanted in all 110 patients by transfemoral access without general anaesthesia. Due to the option to reposition the Lotus valve, there was no need for a second valve and no valve embolisation. Partial resheathing was used in 21.8% and complete resheathing in 11.8% of patients. There was no procedural death, no coronary obstruction, annular rupture or need for conversion to surgery. Moderate or severe AR after valve release in the final position was completely absent in all three groups assessed by aortography and echocardiography (**Table 4**). On TTE after TAVI, the rate of mild AR was 9.1% (one valvular, nine paravalvular). There was a significantly higher rate of mild AR in

Table 1. Baseline clinical characteristics.

	Lotus (all)	Lotus 23 mm	Lotus 25 mm	Lotus 27 mm	p-value
Number of patients	110	20	43	47	
Age, years	81.1±5.4	80.7±6.2	81.4±5.2	81.0±5.2	0.88
Female	50.9% (56)	95% (19)	55.8% (24)	27.7% (13)	<0.001
BMI (kg/m ²)	26.8±4.8	26.6±4.7	26.0±4.5	27.5±5.2	0.36
Diabetes mellitus	22.7% (25)	10% (2)	25.6% (11)	25.5% (12)	0.32
Severe chronic renal failure	32.7% (36)	10% (2)	39.5% (17)	36.2% (17)	0.05
Coronary artery disease	62.7% (69)	70% (14)	58.1% (25)	61.7% (29)	0.51
History of MI	17.3% (19)	20% (4)	14.0% (6)	19.2% (9)	0.76
History of cardiac surgery	10% (11)	10% (2)	11.6% (5)	8.5% (4)	0.89
Peripheral or cerebral vascular disease	21.8% (24)	15% (3)	25.6% (11)	21.3% (10)	0.63
History of stroke or intracerebral bleeding	8.2% (9)	10% (2)	14.0% (6)	2.1% (1)	0.12
Pulmonary disease	60.9% (67)	55% (1)	60.5% (26)	63.8% (30)	0.72
Atrial fibrillation	38.2% (42)	15% (3)	41.9% (18)	44.7% (21)	0.06
Permanent pacemaker	27 (11.5%)	5% (1)	2.3% (1)	17.0% (8)	0.04
Logistic EuroSCORE	15.5±14.1	14.1±10.9	17.5±18.1	14.3±10.9	0.50
STS for mortality	6.5±4.6	6.1±4.0	7.5±5.2	5.7±4.0	0.14

Values are mean±SD or n (%). BMI: body mass index; MI: myocardial infarction

Table 2. Baseline aortic valve parameters.

	Lotus (all)	Lotus 23 mm	Lotus 25 mm	Lotus 27 mm	p-value
Number of patients	110	20	43	47	
Transthoracic echocardiography					
AVA, cm ²	0.75±0.17	0.72±0.16	0.77±0.18	0.75±0.17	0.64
Indexed AVA, cm ² /m ²	0.28±0.06	0.28±0.06	0.28±0.07	0.26±0.06	0.32
Mean aortic gradient, mmHg	35.8±6.8	41.0±16.9	36.0±16.3	33.4±17.1	0.27
Maximum aortic gradient, mmHg	62.9±25.5	71.3±25.5	63.2±24.8	59.2±26.3	0.24
Moderate/severe AR	9.1% (10)	5% (1)	9.3% (4)	10.6% (5)	0.77
Systolic pulmonary artery pressure, mmHg	40.5±13.9	40.0±11.8	44.5±16.4	37.1±11.5	0.11
Cardiac catheterisation					
AVA, cm ²	0.68±0.20	0.60±0.15	0.71±0.24	0.69±0.19	0.38
Indexed AVA, cm ² /m ²	0.24±0.06	0.23±0.06	0.26±0.08	0.24±0.06	0.54

Values are mean±SD or n (%). AR: aortic regurgitation; AVA: aortic valve area

patients with LVOT calcification compared to patients without calcification of the LVOT (25% versus 5.6%, $p<0.01$), as detailed in **Figure 2**. The residual mean aortic gradient by echocardiography did not differ among groups and was a mean of 12.1 ± 4.6 mmHg. The rate of device success was high at 95.5%, with no difference among groups (**Table 4**). All patients without device success had slightly elevated mean aortic gradients >20 mmHg as assessed by echocardiography (22 mmHg [n=2], 23 mmHg [n=2] or 32 mmHg [n=1]). In patients with device failure, there was no difference with respect to oversizing in relation to annulus or LVOT, LVEF,

eccentricity index or presence of LVOT calcification compared with patients with device success.

The rate of major vascular complications was 4.5% with no need for surgical repair. All five cases with major vascular complications were related to closure device failure in combination with a drop in haemoglobin of more than 3 g/dl. Although there was no statistical difference regarding the occurrence of major vascular complications among groups, all five patients with major vascular complications were treated with the 25 or 27 mm Lotus valve requiring the larger sheath.

Table 3. Baseline computed tomographic parameters.

	Lotus (all)	Lotus 23 mm	Lotus 25 mm	Lotus 27 mm	p-value
Number of patients, N	110	20	43	47	
Aortic annulus diameter, mm					
Area-derived diameter	24.5±1.8	22.2±1.2	24.0±1.0	26.0±1.1	<0.001
Perimeter-derived diameter	25.2±2.0	22.8±1.2	24.8±1.9	26.6±1.1	<0.001
Area, mm ²	474±68	387±43	454±40	531±43	<0.001
Oversizing, mean%	8.7±9.5	8.7±11.5	9.0±9.2	8.5±9.1	0.98
Perimeter	79.1±5.8	72.9±6.7	77.2±3.4	83.4±3.5	<0.001
Maximum diameter	27.3±2.1	24.9±1.7	26.9±1.5	28.8±1.5	<0.001
Minimal diameter	21.9±1.9	19.9±1.8	21.4±1.4	23.0±1.4	<0.001
Eccentricity index	0.20±0.06	0.20±0.08	0.20±0.06	0.20±0.06	0.95
Severe aortic cusp calcification	80.9% (89)	70% (14)	83.7% (36)	83.0% (39)	0.52
Distance (mm) of annulus to					
Left coronary ostium	14.1±9.3	12.9±1.4	14.1±2.5	14.6±2.8	0.038
Right coronary ostium	17.0±11.7	15.4±1.6	16.9±2.4	17.7±2.7	0.003
LVOT, mm					
Calcification	18.2% (20)	15% (3)	23.3% (10)	14.9% (7)	0.003
Area-derived diameter	22.4±2.1	21.7±1.7	23.9±1.6	25.9±1.3	<0.001
Perimeter-derived diameter	25.1±2.2	22.6±1.7	24.6±1.6	26.7±1.5	<0.001
Area, mm ²	471±81	387±85	449±60	527±53	<0.001
Oversizing, mean%	10.1±14.5	11.4±20.9	11.1±14.8	9.7±10.8	0.88
Perimeter	79.0±6.9	72.1±6.9	77.4±4.9	83.9±5.1	<0.001
Maximum diameter	28.3±2.5	25.7±1.9	27.9±1.8	29.7±2.3	<0.001
Area sinotubular junction, mm ²	662±162	507±124	645±130	744±152	<0.001
Area at coronary ostia, mm ²	807±177	669±96	771±158	900±171	<0.001

LVOT: left ventricular outflow tract

Table 4. Procedural data.

		Lotus (all)	Lotus 23 mm	Lotus 25 mm	Lotus 27 mm	p-value
Number of patients, N		110	20	43	47	
Non-general anaesthesia		110 (100%)	20 (100%)	43 (100%)	47 (100%)	--
General anaesthesia		0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
Correct placement		110 (100%)	20 (100%)	43 (100%)	47 (100%)	--
Cardiopulmonary bypass		0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
AR by aortography	None/trace	95.5% (105)	95% (19)	100% (43)	91.5% (43)	0.21
	Mild	4.5% (5)	5% (1)	0% (0)	8.5% (4)	
	Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
	Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Balloon post-dilation		0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
Implantation of >1 valve		0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
Adjunctive PCI		0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
Coronary obstruction		0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
Annular rupture		0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
Conversion to surgery		0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
AR by echocardiography	None/trace	90.9% (100)	95% (19)	88.4% (38)	91.5% (43)	0.37
	Mild	9.1% (10)	5% (1)	11.6% (5)	8.5% (4)	
	Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
	Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Mean aortic gradient, mmHg		12.1±4.6	13.5±3.2	11.7±5.3	11.8±4.3	0.32
Device success		95.5% (105)	100% (20)	93.0% (40)	95.7% (45)	0.46
Fluoroscopic time, min		24.3±7.8	24.6±4.4	22.7±8.8	25.7±7.8	0.21
Contrast amount, mL		99±35	101±37	94±34	105±34	0.36

Values are mean±SD or n (%). AR: aortic regurgitation; PCI: percutaneous coronary intervention

The need for new pacemaker insertion due to type II (Mobitz) second degree atrioventricular block or complete (third degree) atrioventricular block was 18.1% and did not differ among groups. Implantation depth did not differ between patients with and without the need for permanent pacemaker implantation. Median oversizing in relation to the annulus was 7.6% and median oversizing in relation to LVOT 10.8%. For both calculations of oversizing, the need for pacemaker implantation was 21.8% (n=12/55) for

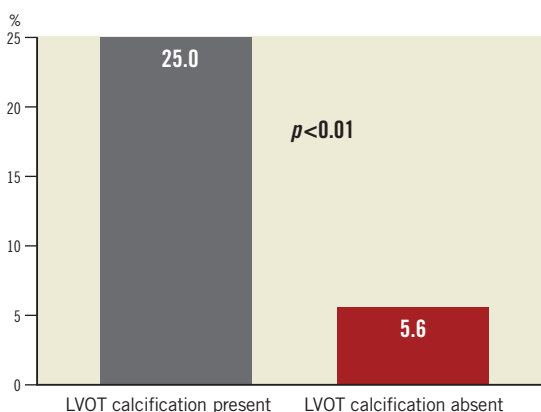


Figure 2. Post-procedural mild aortic regurgitation. There was a significantly higher rate of post-procedural mild aortic regurgitation in relation to calcification of the left ventricular outflow tract.

patients below the median versus 14.6% (n=8/55) for patients above the median (p=0.32). There was a significantly higher need for pacemaker implantation in patients with calcification in the LVOT compared to patients without LVOT calcification (35.0% versus 14.4%, p=0.03) (Figure 3). The need for permanent pacemaker implantation in patients without a permanent pacemaker before TAVI was 24.1% (n=20/83).

The early safety endpoint at 30 days was met in 10% and was similar among groups (Table 5), with no difference in the rates of all-cause mortality (0.9% for total population) or disabling (2.7% for total population) and non-disabling stroke (0.9% for total population). Three out of four strokes occurred within 24 hours after valve implantation; the fourth stroke occurred three days after the procedure.

Discussion

We were able to demonstrate a high rate of device success and low rates of mortality and stroke within 30 days according to VARC-2 criteria for the Lotus valve in symptomatic patients undergoing transfemoral TAVI. With all valve sizes, there was no residual moderate or severe paravalvular AR, with a similar rate of oversizing in relation to the annulus and LVOT. Based on the option to reposition the Lotus valve, there was no valve embolisation and no need for a second valve.

Residual AR after TAVI is a significant independent predictor of long-term mortality^{2,16}. The risk of moderate or severe

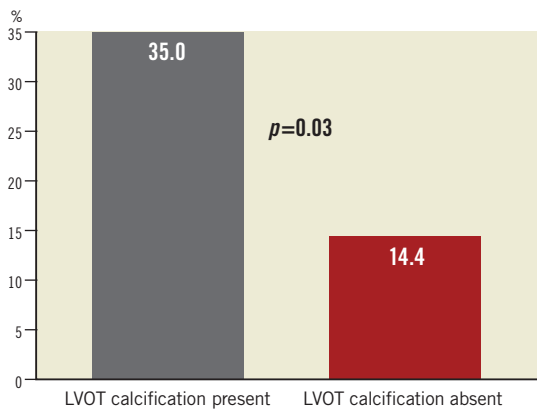


Figure 3. Need for permanent pacemaker implantation. The need for permanent pacemaker implantation was significantly higher in patients with calcification of the left ventricular outflow tract compared with patients without calcification of the left ventricular outflow tract.

AR with balloon-expandable TAVI prostheses ranged between 5 and 10%¹⁵⁻¹⁷, and was up to 18% for self-expanding TAVI prostheses even after post-dilation¹⁵. In early experiences with the Lotus valve, moderate AR was reported in up to 4.0%^{3-5,10}. The Lotus valve has been designed to eliminate post-procedural AR by an adaptive seal and by the unique delivery technique, which makes it possible to reposition and to completely retrieve the valve¹⁸. We report a single-centre experience including the full available range of valve sizes (23, 25 and 27 mm), demonstrating the elimination of moderate or severe residual AR for this first-generation repositionable TAVI device. In addition, there was no need for post-dilation. In the very first Lotus experience using the 23 mm device, the rate of moderate or severe AR in 11 patients was 0% and the rate of mild AR 18.2%³. In the REPRISSE II CE mark multicentre study including 120 patients

treated with the 23 and 27 mm device, the rate of paravalvular moderate or severe AR at discharge was 2.0% and the rate of mild AR 13.1%⁴. Numbers were 2% and 6% in a single-centre experience including 50 Lotus cases with 23 and 27 mm devices, respectively⁵. We observed mild AR in 9.1% with no difference among the three valve sizes, with a similar rate of oversizing in relation to the annulus and LVOT. There was a significantly higher rate of mild AR in patients with LVOT calcification. The presence of LVOT calcification has been shown to be an independent predictor of moderate AR in patients undergoing TAVI with other valve types^{12,19}.

Device success with the Lotus valve was high at 95.5%. All patients without device success showed an elevated mean aortic pressure gradient on echocardiography. All valves were correctly positioned and there was no procedural mortality or cardiac perforation. There was no conversion to surgery and no need for a second valve. In other Lotus valve series, device success was similar at 95.3%⁴ and 96%¹⁰, except for a single-centre experience reporting 84% in 50 patients⁵.

The need for pacemaker implantation with the Lotus valve was 36% in REPRISSE I (23 mm devices) and 29% in REPRISSE II (23 and 27 mm devices). The indication for pacemaker implantation was third degree atrioventricular block in 88% of patients in REPRISSE II, resulting in a need for pacemaker implantation due to total atrioventricular block of 25.2% for the total population. With three Lotus valve sizes available, the need for pacemaker implantation due to second (type II) or third degree atrioventricular block was 24.1% in our population, excluding patients with previously implanted devices. The presence of LVOT calcification significantly correlated to the need for pacemaker implantation. The need for pacemaker implantation with the Lotus valve was higher compared with balloon-expandable valves^{10,17,20,21} but similar to the rates reported with self-expanding valves^{15,22}. The need for pacemaker implantation was not associated with

Table 5. Clinical outcome at 30 days.

	Lotus (all)	Lotus 23 mm	Lotus 25 mm	Lotus 27 mm	p-value
Number of patients, N	110	20	43	47	
Early safety endpoint at 30 days	10% (11)	5% (1)	9.3% (4)	12.8% (6)	0.36
All-cause mortality	0.9% (1)	0% (0)	2.3% (1)	0% (0)	0.46
Disabling stroke	2.7% (3)	5% (1)	4.7% (2)	0% (0)	0.32
Non-disabling stroke	0.9% (1)	5% (1)	0% (0)	0% (0)	0.10
Acute kidney injury – stage 2/3	1.8% (2)	0% (0)	2.3% (1)	2.1% (1)	0.80
Life-threatening bleeding	2.7% (3)	0% (0)	2.3% (1)	4.3% (2)	0.61
Major vascular complications	4.5% (5)	0% (0)	4.7% (2)	6.4% (3)	0.52
Valve dysfunction requiring a repeat procedure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
Endocarditis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
Valve thrombosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	--
Myocardial infarction	0% (0)	0% (0)	0% (0)	0% (0)	--
Surgical repair	0% (0)	0% (0)	0% (0)	0% (0)	--
Pacemaker implantation*	18.2% (20)	15% (3)	25.6% (11)	12.8% (6)	0.27

Values are mean±SD or n (%). *Indication for pacemaker based on second degree (type II) or third degree atrioventricular block.

long-term sequelae^{22,23}. However, a higher need for permanent pacemaker implantation with the repositionable Lotus valve in contrast to balloon-expandable aortic valves could have a negative impact in younger patients or in patients with reduced left ventricular function.

The low mortality rate of 4.2% within 30 days observed in REPRIS II⁴ was confirmed in our population. The rate of disabling and non-disabling stroke was 3.6% in 110 patients and lower compared to the rate of 5.9% in REPRIS II and of 4.9% in the CoreValve High Risk Study¹. Three out of four strokes occurred within 24 hours after valve implantation. Whether the overall stroke rate can be reduced by the use of protection devices has to be studied further.

Patients treated with the 23 mm Lotus valve were predominantly female with a low rate of diabetes mellitus. The presence of diabetes mellitus in female patients may limit the use of the 23 mm Lotus valve due to the need for an 18 Fr delivery sheath. In REPRIS II, the rate of major vascular complications was lower at 2.5% in 120 patients⁴ in contrast to 4.5% in our population of 110 patients. The use of the 25 and 27 mm Lotus valve was more frequent in our population at 82% compared with about 50% in REPRIS II. For implantation of the 25 and 27 mm Lotus valve, the diameter of the sheath is larger compared to the size for implantation of the 23 mm Lotus valve. The higher usage of the larger sheath in our population in contrast to REPRIS II could have had an impact on the occurrence of major vascular complications due to a higher risk for closure device failure.

Limitations

There was no use of embolic protection to reduce the risk of periprocedural cerebral embolic events. There was no external echo core lab, although cardiologists specialised in non-invasive imaging not performing TAVI procedures performed TTE.

Conclusions

In patients with severe aortic stenosis, transfemoral TAVI with the repositionable Lotus valve was associated with a high rate of device success, no moderate or severe residual aortic regurgitation, low rates of major vascular complications, mortality and stroke within 30 days.

Impact on daily practice

Transfemoral aortic valve implantation with the repositionable Lotus valve is associated with a high rate of device success. With the use of the Lotus valve there is a low risk of moderate or severe residual aortic regurgitation due to the option to reposition and even retrieve the valve. In addition, there was no need for a second valve and no conversion to surgery.

Conflict of interest statement

The authors have no conflicts of interest to declare.

References

- Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM, Gleason TG, Buchbinder M, Hermiller J Jr, Kleiman NS, Chetcuti S, Heiser J, Merhi W, Zorn G, Tadros P, Robinson N, Petrossian G, Hughes GC, Harrison JK, Conte J, Maini B, Mumtaz M, Chenoweth S, Oh JK; U.S. CoreValve Clinical Investigators. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med*. 2014;370:1790-8.
- Athappan G, Patvardhan E, Tuzcu EM, Svensson LG, Lemos PA, Fraccaro C, Tarantini G, Sinning JM, Nickenig G, Capodanno D, Tamburino C, Latib A, Colombo A, Kapadia SR. Incidence, predictors and outcomes of aortic regurgitation after transcatheter aortic valve replacement: meta-analysis and systematic review of literature. *J Am Coll Cardiol*. 2013;61:1585-95.
- Meredith IT, Worthley SG, Whitbourn RJ, Antonis P, Montarello JK, Newcomb AE, Lockwood S, Haratani N, Allocco DJ, Dawkins KD. Transfemoral aortic valve replacement with the repositionable Lotus Valve System in high surgical risk patients: the REPRIS I study. *EuroIntervention*. 2014;9:1264-70.
- Meredith Am IT, Walters DL, Dumontel N, Worthley SG, Tchétché D, Manoharan G, Blackman DJ, Rioufol G, Hildick-Smith D, Whitbourn RJ, Lefèvre T, Lange R, Müller R, Redwood S, Allocco DJ, Dawkins KD. Transcatheter aortic valve replacement for severe symptomatic aortic stenosis using a repositionable valve system: 30-day primary endpoint results from the REPRIS II study. *J Am Coll Cardiol*. 2014;64:1339-48.
- Gooley RP, Talman AH, Cameron JD, Lockwood SM, Meredith IT. Comparison of Self-Expanding and Mechanically Expanded Transcatheter Aortic Valve Prostheses. *JACC Cardiovasc Interv*. 2015;8:962-71.
- Van Mieghem NM, Rodriguez-Olivares R, Kappetein AP, de Jaegere PP. Transcatheter Lotus valve implantation in a regurgitant SAPIEN 3 valve. *EuroIntervention*. 2015;11:356.
- Wöhrle J, Rodewald C, Rottbauer W. Transfemoral aortic valve implantation in pure native aortic valve insufficiency using the repositionable and retrievable Lotus valve. *Catheter Cardiovasc Interv*. 2016;87:993-995.
- Seeger J, Gonska B, Rodewald C, Rottbauer W, Wöhrle J. Bicuspid Aortic Stenosis Treated With the Repositionable and Retrievable Lotus Valve. *Can J Cardiol*. 2016;32:135.e17-9.
- Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, Brott TG, Cohen DJ, Cutlip DE, van Es GA, Hahn RT, Kirtane AJ, Krucoff MW, Kodali S, Mack MJ, Mehran R, Rodés-Cabau J, Vranckx P, Webb JG, Windecker S, Serruys PW, Leon MB. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *J Am Coll Cardiol*. 2012;60:1438-54.
- Wöhrle J, Gonska B, Rodewald C, Trepte U, Koch S, Scharnbeck D, Seeger J, Markovic S, Rottbauer W. Transfemoral aortic valve implantation with the repositionable Lotus valve compared with the balloon-expandable Edwards Sapien 3 valve. *Int J Cardiol*. 2015;195:171-5.

11. Rosenhek R, Binder T, Porenta G, Lang I, Christ G, Schemper M, Maurer G, Baumgartner H. Predictors of outcome in severe, asymptomatic aortic stenosis. *N Engl J Med.* 2000;343:611-7.
12. Barbanti M, Yang TH, Rodés Cabau J, Tamburino C, Wood DA, Jilaihawi H, Blanke P, Makkar RR, Latib A, Colombo A, Tarantini G, Raju R, Binder RK, Nguyen G, Freeman M, Ribeiro HB, Kapadia S, Min J, Feuchtner G, Gurtvich R, Alqoofi F, Pelletier M, Ussia GP, Napodano M, de Brito FS Jr, Kodali S, Norgaard BL, Hansson NC, Pache G, Canovas SJ, Zhang H, Leon MB, Webb JG, Leipsic J. Anatomical and procedural features associated with aortic root rupture during balloon-expandable transcatheter aortic valve replacement. *Circulation.* 2013;128:244-53.
13. Sellers RD, Levy MJ, Amplatz K, Lillehei CW. Left retrograde cardioangiography in acquired cardiac disease: technic, indications and interpretations in 700 cases. *Am J Cardiol.* 1964;14:437-47.
14. Zoghbi WA, Chambers JB, Dumesnil JG, Foster E, Gottdiener JS, Grayburn PA, Khandheria BK, Levine RA, Marx GR, Miller FA Jr, Nakatani S, Quiñones MA, Rakowski H, Rodriguez LL, Swaminathan M, Waggoner AD, Weissman NJ, Zabalgoitia M; American Society of Echocardiography's Guidelines and Standards Committee; Task Force on Prosthetic Valves; American College of Cardiology Cardiovascular Imaging Committee; Cardiac Imaging Committee of the American Heart Association; European Association of Echocardiography; European Society of Cardiology; Japanese Society of Echocardiography; Canadian Society of Echocardiography; American College of Cardiology Foundation; American Heart Association; European Association of Echocardiography; European Society of Cardiology; Japanese Society of Echocardiography; Canadian Society of Echocardiography. Recommendations for evaluation of prosthetic valves with echocardiography and doppler ultrasound: a report from the American Society of Echocardiography's Guidelines and Standards Committee and the Task Force on Prosthetic Valves, developed in conjunction with the American College of Cardiology Cardiovascular Imaging Committee, Cardiac Imaging Committee of the American Heart Association, the European Association of Echocardiography, a registered branch of the European Society of Cardiology, the Japanese Society of Echocardiography and the Canadian Society of Echocardiography, endorsed by the American College of Cardiology Foundation, American Heart Association, European Association of Echocardiography, a registered branch of the European Society of Cardiology, the Japanese Society of Echocardiography, and Canadian Society of Echocardiography. *J Am Soc Echocardiogr.* 2009;22:975-1014.
15. Abdel-Wahab M, Mehilli J, Frerker C, Neumann FJ, Kurz T, Tölg R, Zachow D, Guerra E, Massberg S, Schäfer U, El-Mawardi M, Richardt G; CHOICE investigators. Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. *JAMA.* 2014;311:1503-14.
16. Kodali S, Pibarot P, Douglas PS, Williams M, Xu K, Thourani V, Rihal CS, Zajarias A, Doshi D, Davidson M, Tuzcu EM, Stewart W, Weissman NJ, Svensson L, Greason K, Maniar H, Mack M, Anwaruddin S, Leon MB, Hahn RT. Paravalvular regurgitation after transcatheter aortic valve replacement with the Edwards sapien valve in the PARTNER trial: characterizing patients and impact on outcomes. *Eur Heart J.* 2015;36:449-56.
17. Schymik G, Lefèvre T, Bartorelli AL, Rubino P, Treede H, Walther T, Baumgartner H, Windecker S, Wendler O, Urban P, Mandinov L, Thomas M, Vahanian A. European experience with the second-generation Edwards SAPIEN XT transcatheter heart valve in patients with severe aortic stenosis: 1-year outcomes from the SOURCE XT Registry. *JACC Cardiovasc Interv.* 2015;8:657-69.
18. Meredith IT, Hood KL, Haratani N, Allocco DJ, Dawkins KD. Boston Scientific Lotus valve. *EuroIntervention.* 2012;8:Q70-4.
19. Buellesfeld L, Stortecky S, Heg D, Gloekler S, Meier B, Wenaweser P, Windecker S. Extent and distribution of calcification of both the aortic annulus and the left ventricular outflow tract predict aortic regurgitation after transcatheter aortic valve replacement. *EuroIntervention.* 2014;10:732-8.
20. Nazif TM, Dizon JM, Hahn RT, Xu K, Babaliaros V, Douglas PS, El-Chami MF, Herrmann HC, Mack M, Makkar RR, Miller DC, Pichard A, Tuzcu EM, Szeto WY, Webb JG, Moses JW, Smith CR, Williams MR, Leon MB, Kodali SK; PARTNER Publications Office. Predictors and clinical outcomes of permanent pacemaker implantation after transcatheter aortic valve replacement: the PARTNER (Placement of AoRtic TraNscathetER Valves) trial and registry. *JACC Cardiovasc Interv.* 2015;8:60-9.
21. Généreux P, Head SJ, Van Mieghem NM, Kodali S, Kirtane AJ, Xu K, Smith C, Serruys PW, Kappetein AP, Leon MB. Clinical outcomes after transcatheter aortic valve replacement using valve academic research consortium definitions: a weighted meta-analysis of 3,519 patients from 16 studies. *J Am Coll Cardiol.* 2012;59:2317-26.
22. Khatri PJ, Webb JG, Rodés-Cabau J, Fremes SE, Ruel M, Lau K, Guo H, Wijeyesundera HC, Ko DT. Adverse effects associated with transcatheter aortic valve implantation: a meta-analysis of contemporary studies. *Ann Intern Med.* 2013;158:35-46.
23. Erkapic D, De Rosa S, Kelava A, Lehmann R, Fichtlscherer S, Hohnloser SH. Risk for permanent pacemaker after transcatheter aortic valve implantation: a comprehensive analysis of the literature. *J Cardiovasc Electrophysiol.* 2012;23:391-7.