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Efficacy and safety of the Lotus Valve System for treatment of patients with severe aortic valve stenosis and intermediate surgical risk: Results from the Nordic Lotus-TAVR registry

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ABSTRACT

Background: Transcatheter aortic valve replacement (TAVR) has become an established therapeutic option for patients with symptomatic, severe aortic valve stenosis (AS) who are ineligible or at high risk for conventional valvular surgery. In Northwestern Europe, the TAVR technology is also increasingly used to treat patients with an intermediate risk profile.

Methods and results: The study was designed as an independent Nordic multicenter registry of intermediate risk patients treated with the Lotus Valve System (Boston Scientific, MA, USA; N = 154). Valve Academic Research Consortium (VARC)-defined device success was obtained in 97.4%. A Lotus Valve was successfully implanted in all patients. There was no valve migration, embolization, ectopic valve deployment, or TAV-in-TAV deployment. The VARC-defined combined safety rate at 30 days was 92.2%, with a mortality rate of 1.9% and stroke rate of 3.2%. The clinical efficacy rate after 30 days was 91.6% — only one patient had moderate aortic regurgitation. When considering only those patients in the late experience group (N = 79), the combined safety and clinical efficacy rates were 93.7% and 92.4%, respectively. The pacemaker implantation rate was 27.9% — this rate was 12.8% in case of a combined implantation depth <4 mm and a device/annulus ratio < 1.05.

Conclusions: The present study demonstrates the efficacy and safety of the repositionable, retrievable Lotus Valve System in intermediate risk patients with AS. The VARC-defined device success rate was 97.4% with a 30-day patient safety and clinical efficacy rate of more than 90%. Less than moderate aortic regurgitation was obtained in 99.4% of patients.

1. Introduction

Transcatheter aortic valve replacement (TAVR) has become an established therapeutic option for patients with symptomatic, severe aortic valve stenosis (AS), who are ineligible or at high risk for conventional surgical aortic valve replacement (SAVR) [1–4]. In Northwestern Europe, the TAVR technology is also increasingly used to treat patients with an intermediate risk profile — this practice was recently supported by results from the NOTION trial indicating that TAVR is also a viable option for patients with a lower risk profile [5].

In the REPRISE I feasibility study [6] and prospective, single-arm REPRISE II CE-Mark trial [7], the safety and effectiveness of the new Lotus Valve System was studied in patients with severe AS who are at high surgical risk. In the current study, we aimed to study the real-world performance of the Lotus Valve System in patients with an intermediate risk profile.

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2. Methods

2.1. Data collection

The study was designed as an independent, Nordic multicenter voluntary registry of patients with severe AS and an intermediate surgical risk profile treated with the Lotus Valve System. Intermediate risk was defined as a Society of Thoracic Surgeons (STS) risk score ≥3 and <8, or EuroSCORE II ≥2 and <10. The local Heart Team reviewed all patients, and TAVR was offered in case of intermediate-to-high surgical risk based on STS score and/or EuroSCORE in combination with frailty score (Katz ADL score, 5 meter walk time, grip strength, albumin). In total, 232 patients were treated with the Lotus TAVR system in eight Nordic TAVR centers — of these, 154 patients had an intermediate surgical risk profile. Data on baseline patient characteristics, procedural variables and outcomes, echocardiographic parameters, and Valve Academic Research Consortium (VARC)-defined 30-day clinical outcomes [8] were collected up to August 2015. Follow-up data on adverse events were censored in September 2015. An informed consent was obtained from each patient and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

2.2. Device description

The Lotus Valve System (Boston Scientific, MA, USA, Fig. 1) has been described previously [9]. Briefly, the system includes a bioprosthetic aortic valve consisting of three bovine pericardial leaflets attached to a braided nitinol frame with a radiopaque marker and a catheter-based system for introduction and retrograde delivery via the femoral artery. Three valve sizes are available: 23 mm, 25 mm, and 27 mm. The valve is pre-attached to the delivery system. The valve is designed to expand radially as the valve shortens during deployment. An adaptive seal surrounds the inflow portion of the device and is designed to minimize paravalvular leak (PVL). The device is introduced through a dedicated 20 to 22 Fr introducer sheath using conventional percutaneous catheterization techniques or via a surgical cut-down.

2.3. Procedural steps

The majority of procedures were performed by transfemoral approach. After crossing the stenotic aortic valve and, in some cases, balloon valvuloplasty, the Lotus Valve System catheter is advanced across the annulus over a stiff guidewire (0.035-in.) and positioned so that the tip of the catheter is just on the ventricular side of the annulus. Unsheathing is initiated by rotating the control knob of the handle counter-clockwise. During unsheathing, the once-elongated valve frame shortens and radially expands, and the radiopaque marker advances from its initial position and moves towards the aortic annulus. Once in the optimal position, the operator manipulates the catheter to maintain marker position in the sinus of Valsalva — approximately 5 mm distal to the aortic annulus. While maintaining marker alignment, the operator continues to unsheath the valve, resulting in radial expansion and anchoring within the aortic annulus. At this stage, aortography and/or echocardiography are typically performed to evaluate valve position. Based on these assessments, the decision is taken to resheath and reposition the valve in case of suboptimal positioning or to lock the valve when optimal positioning is achieved. Once the valve is locked in the desired position, the release process can begin by sliding the release window and rotating the release collar clockwise, resulting in the release of the valve from the delivery catheter. The delivery catheter is then resheathed and the device is retracted through the introducer sheath.

Post-procedural antithrombotic regime was dual antiplatelet therapy for three to six months followed by aspirin life-long. In case of atrial fibrillation or other indications for anticoagulation, warfarin and clopidogrel was given for three to six months followed by life-long warfarin.

2.4. Statistics

Categorical variables are reported as absolute values and percentages (%). Continuous variables are presented as means ± standard deviation (SD) or median and range for perimeter-derived aortic annulus diameter. For the early safety and clinical efficacy endpoint at 30 days, a separate analysis was performed in which the first fifteen Lotus TAVR procedures performed in every centre were categorized as early experience. This additional analysis resulted in early experience (N = 75) and late experience (N = 79) outcome data. All statistical analyses were performed with SPSS version 20 (IBM Corp., USA).

3. Results

3.1. Patient population

The study population consisted of 154 intermediate risk patients treated with the Lotus Valve System in eight different Nordic centres. Four centres contributed more than 20 cases, whereas the other four centres had a volume of 10 or less Lotus TAVR cases at the moment of data collection (see Supplementary File 1). Baseline characteristics of the study population are shown in Table 1. Mean age was 82.2 ±

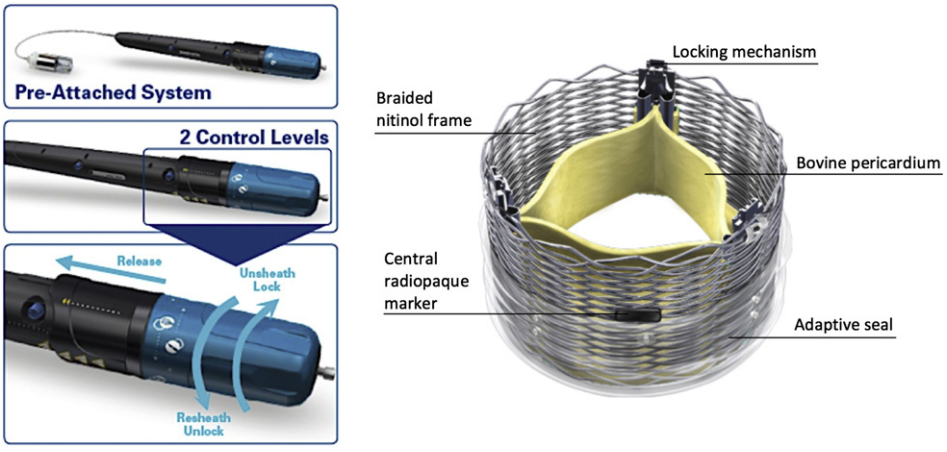


Fig. 1. The Lotus Valve System has three bovine pericardial tissue leaflets, a braided nitinol frame, a central radiopaque marker to aid positioning, and a polyurethane/polycarbonate outer seal designed to conform to irregular anatomic surfaces and minimize paravalvular leak. The braided structure shortens axially and expands radially during implantation and is locked in position using a post-and-buckle locking mechanism. This figure is used with permission from Boston Scientific, MA, USA.

Table 1
Baseline characteristics.

Procedural outcomes	Overall N = 154
Patient characteristics	
Age, years	82.2 ± 5.9
Female	90 (58.4%)
Arterial hypertension	114(74.0%)
Hyperlipidaemia	71 (46.1%)
Diabetes mellitus, medically treated	26 (16.9%)
Body mass index (kg/m^2)	26.7 ± 5.2
Previous myocardial infarction	31 (20.1%)
Previous PCI	31 (20.1%)
Previous CABG	23 (14.9%)
Peripheral vascular disease	17(11.0%)
Atrial fibrillation, history	53 (34.4%)
Cerebrovascular accident, history	18(11.7%)
Transient ischemic attack, history	13 (8.4%)
Chronic renal failure (eGFR <30 mL/min)	7 (4.5%)
COPD, moderate or severe	20 (13.0%)
Pulmonary hypertension	27 (17.5%)
NYHA functional class III-IV	128 (83.1%)
STS score	5.0 ± 2.8
EuroSCORE II	5.3 ± 3.1
Echocardiographic assessment	
LVEF, %	52.9 ± 13.0
Mean aortic valve gradient, mm Hg	47.9 ± 13.8
Peak aortic valve gradient, mm Hg	79.4 ± 21.2
Aortic valve area, cm^2	0.7 ± 0.2
Aortic regurgitation, moderate or severe	19 (12.3%)
Mitral regurgitation, moderate or severe	25 (16.2%)
Cardiac CT assessment	
Aortic annulus diameter*	24.2 [19.9–28.6]
Aortic valve calcification	
Mild	3 (1.9%)
Moderate	85 (55.2%)
Severe	66 (42.9%)
Porcelain aorta	12 (7.8%)

Values are mean ± SD, n (%), or median [range]. CABG, coronary artery bypass graft surgery; COPD, chronic obstructive pulmonary disease; eGFR, glomerular filtration rate; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons.
* Perimeter-derived aortic annulus diameter.

5.9 years, 58% were female, and 83% had dyspnea NYHA functional class III or IV. The mean STS score and EuroSCORE II were 5.0 ± 2.8 and 5.3 ± 3.1, respectively. The Lotus Valve System was used to treat 115 high-gradient (75%), 20 'classical' low-flow low-gradient (LFLG, 13%), and 19 paradoxical LFLG (12%) AS patients. Perimeter-derived aortic annulus diameters ranging from 19.9 mm to 28.6 mm were treated — the latter being a bicuspid aortic valve in which transcatheter heart valve undersizing is recommended.

3.2. Procedural characteristics and outcomes

The majority of Lotus TAVR cases were performed by transfemoral approach (N = 151; 98%) and three cases (2%) were performed by direct aortic approach. The three available device sizes 23, 25, and 27 mm were almost equally used in 47, 46 and 61 patients, respectively. Pre-dilatation was performed in 54 patients (35%), whereas post-dilatation was only needed in one single case. Overall fluoroscopy times were 26.4 ± 10.1 min with 95.1 ± 37.1 mL of contrast used (Table 2).

VARC-defined device success was obtained in 97.4% (150 out of 154 patients). A Lotus Valve was successfully implanted in all patients. There was no valve migration, embolization, ectopic valve deployment, or transcatheter aortic valve (TAV)-in-TAV deployment. Device failure was due to an immediate post-implant transvalvular gradient ≥20 mm Hg or peak velocity ≥ 3 m/s in three patients; in addition, one death occurred during the TAVR procedure because of dissection of the aortic arch with subsequent mediastinal bleeding (Table 2).

Table 2
Procedural characteristics & outcomes after TAVR with Lotus Valve.

Variables	Overall N = 154
General anesthesia	69 (44.8%)
Access route	
Transfemoral	151 (98.1%)
Direct aortic	3 (1.9%)
Valve size (mm)	
23	47 (30.5%)
25	46 (29.9%)
27	61 (39.6%)
Predilatation	54 (35.1%)
Postdilatation	1 (0.6%)
Contrast, mL	95.1 ± 37.1
Fluoroscopy time, min	26.4 ± 10.1
Aortic valve malpositioning	0 (0.0%)
Valve migration	0 (0.0%)
Valve embolization	0 (0.0%)
Ectopic valve deployment	0 (0.0%)
TAV-in-TAV deployment	0 (0.0%)
Device success (VARC-2)	150 (97.4%)
Absence of procedural mortality	153 (99.4%)
Successful access, delivery, deployment, and system retrieval	154 (100%)
Correct positioning of a single valve into proper location	154(100%)
Intended performance of prosthetic valve*	151 (98.1%)
Hospitalization length	
Intensive care unit	1.3 ± 2.5
Total hospitalization length	7.2 ± 4.6

Values are n (%) or mean ± SD. TAV, transcatheter aortic valve; VARC, Valve Academic Research Consortium.
* No prosthesis-patient mismatch and mean aortic valve gradient <20 mm Hg or peak velocity < 3 m/s, and no moderate or severe prosthetic valve regurgitation.

3.3. VARC-defined patient safety at 30 days

The 30-day mortality rate post-TAVR was 1.9% (N = 3) and the stroke rate was 3.2% (N = 5) with no association to pre-dilatation (N = 1/54 in the pre-dilatation group; p = 0.473). The composite of death and stroke occurred in seven patients (4.5%). VARC-defined major vascular complications were reported in four patients (2.6%). Three patients had a life-threatening bleeding due to femoral arterial access site bleeding (N = 1), aortic dissection with subsequent mediastinal bleeding (N = 1), and left ventricular perforation and cardiac tamponade (N = 1). Peri-procedural myocardial infarction or re-intervention was not reported. In conclusion, the VARC-defined combined safety rate at 30 days for our patient cohort was 92.2% (Table 3). When considering only those patients in the late experience group (N = 79), the combined safety rate at 30 days was 93.7%.

3.4. VARC-defined clinical efficacy after 30 days

Besides freedom from all-cause mortality and stroke at 30 days, the VARC-defined clinical efficacy rate also reflects the valve performance as well as clinical success rate. Echocardiography was performed according to local protocols, 30-days data were obtained in 117 patients (76.0%). The mean gradient decreased from an average of 48.4 ± 14.8 mm Hg to an average of 10.1 ± 3.9 mm Hg post-procedure at 30 days. The effective orifice area (EOA) at baseline was 0.7 ± 0.2 cm^2 and increased to 1.8 ± 0.6 cm^2 at 30 days (Fig. 2A). Aortic regurgitation at 30 days was mild or less in 153 patients (99.4%). One patient had moderate aortic regurgitation and none had severe aortic regurgitation (Fig. 2B). VARC-defined valve-related dysfunction was observed in two patients, namely the patient with moderate aortic regurgitation and one patient with a persistent mean transvalvular gradient of 24 mmHg (Table 3). Dyspnea NYHA functional class improved by at least 1 level in 87%, at least 2 levels in 48%, and 3 levels in 5% of patients. There were five patients (3.2%) with NYHA class III-IV after 30 days (Fig. 3). In conclusion, the VARC-defined clinical efficacy rate after 30 days was

Table 3
30-day outcomes.

Outcomes	Overall N = 154
Early safety at 30 days (VARC-2)	**142 (92.2%)**
All-cause mortality	3 (1.9%)
All stroke	5 (3.2%)
Major vascular complication	4 (2.6%)
Life-threatening bleeding	3 (1.9%)
Acute kidney injury > stage 2	2 (1.3%)
Coronary artery obstruction requiring intervention	0 (0.0%)
Repeat procedure for valve-related dysfunction	0 (0.0%)
Clinical efficacy after 30 days (VARC-2)	**141 (91.6%)**
All-cause mortality	3 (1.9%)
All stroke	5 (3.2%)
Valve-related dysfunction (mean gradient >20 mm Hg, EOA <0.9–1.1 cm^2 and/or DVI < 0.35 m/s, moderate or severe prosthetic valve regurgitation)	2 (1.3%)
NYHA III or IV	5 (3.2%)
New permanent pacemaker	**43 (27.9%)**
Third degree AV block	32 (20.8%)
Second degree AV block, type II	4 (2.6%)
New LBBB, symptomatic bradycardia	6 (3.9%)
Trifascicular block	1 (0.6%)

Values are n (%). AV, atrioventricular; EOA, effective orifice area; LBBB, left bundle branch block; NYHA, New York Heart Association; VARC, Valve Academic Research Consortium.

91.6%. When considering only those patients in the late experience group (N = 79), the clinical efficacy rate was 92.4%.

3.5. New permanent pacemaker (PM)

The rate of new PM implantation was 27.9% in the total study population (N = 43); reasons for PM implantation were third degree atrioventricular (AV) block (N = 32); second-degree AV block type II (N = 4), new left bundle branch block with symptomatic bradycardia (N = 6), and a trifasciculair block (N = 1). Neither 'implantation depth' nor 'device/annulus oversizing ratio' was an independent predictor of the need for permanent PM implantation (data not shown). However, the PM implantation rate was only 12.8% (5 out of 39 patients) in case of a combined implantation depth <4 mm and a device/annulus oversizing ratio <1.05 (Fig. 4).

4. Discussion

The major findings of this observational multicenter study of the Lotus Valve System for intermediate risk patients with severe AS were a VARC-defined device success rate of 97.4% and a 30-day patient safety rate of 92.2% with an all-cause mortality of 1.9%. Although direct comparison with other competitive transcatheter aortic valves is impossible due to differences in patient selection, we can state that these results are among the best ever reported for the TAVR technology. Outcomes obtained with the Sapien 3 and CoreValve transcatheter heart valve in intermediate risk patients can be found in Supplementary File 2 [10,11].

4.1. Lotus Valve System

In accordance with the recent REPRISE II study – a prospective, single-arm, multicenter study evaluating the Lotus Valve System in 120 high-risk AS patients [7] – the Lotus Valve was successfully implanted in all 154 patients, with no cases of valve embolization, ectopic valve deployment, or additional valve implantation. This result can be ascribed to the fact that the Lotus Valve (1) functions early in deployment — thereby minimizing the period of hemodynamic compromise and enabling a more controlled deployment, (2) can be recaptured and repositioned at any stage of the deployment process, which promotes a more accurate and precise final positioning, and (3) can be evaluated in its final position and fully functioning state before release from the delivery system. The fact that patients are hemodynamically stable throughout the whole procedure with no need for rapid pacing makes this valve a good choice to treat patients with severe AS and a poor left ventricular ejection fraction.

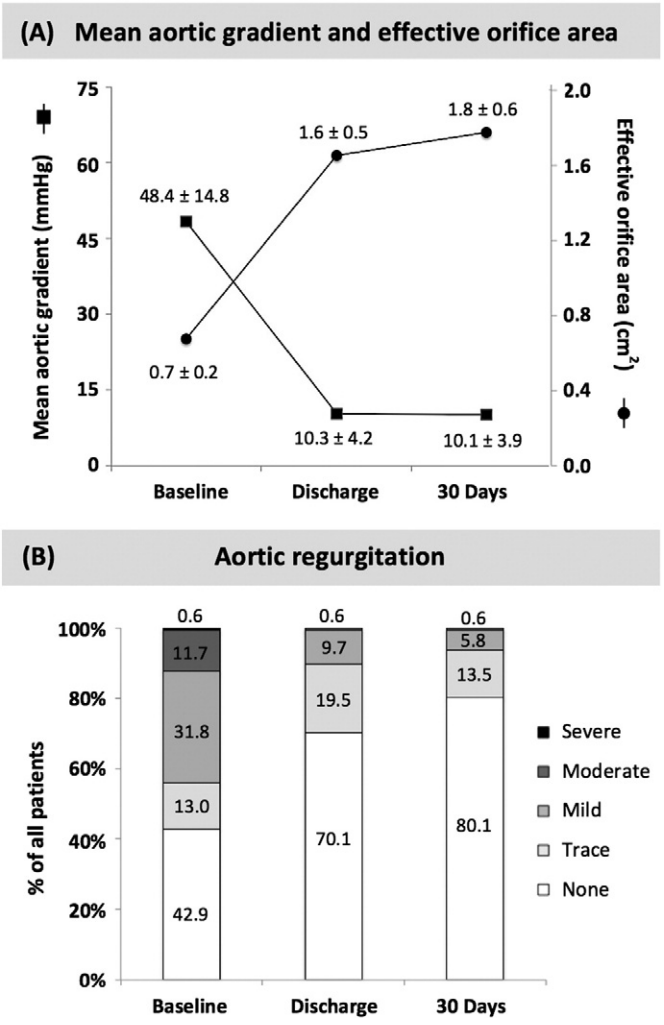


Fig. 2. Valve performance. (A) Mean aortic gradient (mm Hg) and effective orifice area (cm^2) as measured at baseline, at discharge, and 30 days after TAVR; values are mean ± SD. (B) Aortic regurgitation as evaluated at baseline, at discharge, and 30 days after TAVR; values are %.

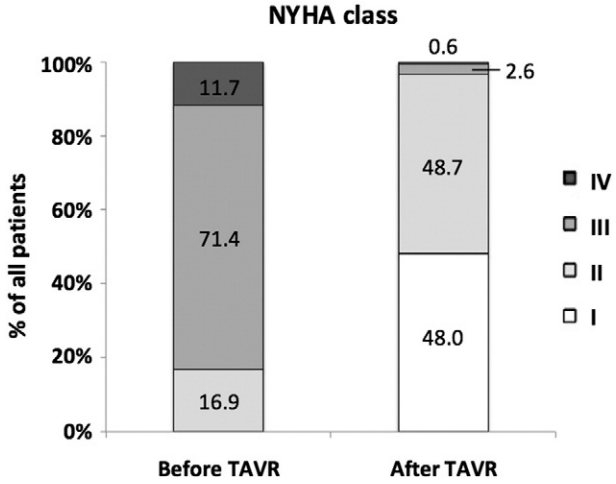
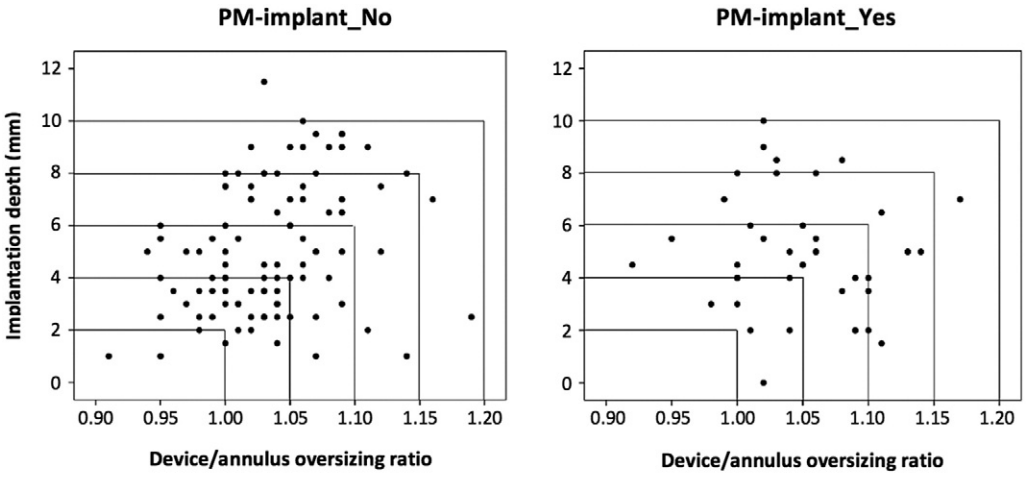


Fig. 3. New York Heart Association (NYHA) functional status as evaluated before TAVR and at 30 days after TAVR.



Implant depth, oversizing ratio – both criteria fulfilled	Patients with new PM/ total number of patients*	PM rate (%)
< 2mm, < 1.00	0/2	0.0%
< 4mm, < 1.05	5/39	12.8%
< 6mm, < 1.10	22/88	25.0%
< 8mm, < 1.15	34/121	28.1%
< 10mm, < 1.20	42/147	28.6%
Total study population	43/150	28.7%

Fig. 4. Permanent pacemaker (PM) implantation following Lotus TAVR. The scatter plots illustrate the relation between 'device/annulus oversizing ratio' and 'implantation depth (mm)' in patients without (left panel) and with need for permanent PM implantation (right panel). Device/annulus oversizing ratio = nominal Lotus valve size/perimeter-derived annulus diameter ratio. *There was missing data about implantation depth and/or annulus size in four patients.

4.2. All-cause mortality and stroke rate

Based on the NOTION trial, it could be anticipated that rates of all-cause mortality and stroke at 30 days would be ≤ 4% in this lower risk group [5]. In our Lotus TAVR population with an intermediate risk profile, the rate of all-cause mortality was 1.9% (N = 3). One patient died procedure-related due to dissection of the aortic arch with subsequent mediastinal bleeding, a second patient died within 24 hours after TAVR due to refractory heart failure, and a third patient died 7 days after TAVR following a major stroke. The overall stroke rate was 3.2% in our study population (N = 5) with three minor and two major strokes; one of the latter resulting in mortality. Three of the strokes were procedure-related, whereas two other strokes occurred in the first few days/weeks after TAVR and were most likely related to new-onset atrial fibrillation. As a comparison, the stroke rate in the high-risk Lotus TAVR group in the REPRISE II trial was 5.7% [7]. Although these rates are slightly higher than reported for other TAVR systems, these data do not support the hypothesis that re-sheathable TAVR systems could be associated with a higher stroke rate due to additional manipulation in the aortic annulus.

4.3. Vascular and bleeding complications

Despite the larger profile of the Lotus introducer sheaths (20 to 22 Fr) as compared to the sheaths utilized for CoreValve (18 Fr) and Sapien 3 (14–16 Fr, expandable) implantation, we only report a major vascular complication rate of 2.6% in our study population. Of course, these data should be interpreted carefully as patients with moderate to severe peripheral vascular disease and/or borderline iliofemoral access have typically not been selected for TAVR with the Lotus Valve System. Still, despite its larger size, the Lotus introducer sheath also has some features — such as the hydrophilic coating, coil reinforced Prebax™ shaft, and the silicone strain relief — which facilitate a smooth sheath entry/removal and provide resistance to kinking while enhancing trackability through challenging anatomies. For the next-generation Lotus Valve System, an expandable 14 Fr sheath has been announced; this is expected in 2016.

4.4. Aortic regurgitation

Confirming our daily clinical experience as well as the results from the REPRISE II trial [7], we report in this study that 30 days post-implant aortic regurgitation was none in 80.1%, trace/mild in 19.3%, and moderate in only 0.6% of the total study population. None had severe aortic regurgitation. These results may be ascribed to the adaptive seal designed to minimize the incidence of PVL as well as the ability to reposition and retrieve the valve in case of suboptimal implantation or prosthesis-patient mismatch. As a consequence, the Lotus Valve System is in many of the participating Nordic centers the first choice when treating heavily calcified AS with left ventricular outflow tract (LVOT) calcium as well as bicuspid aortic valve stenosis. In contrast to the Lotus Valve System, results obtained with the Sapien 3 and CoreValve show incidences of moderate to severe aortic regurgitation ranging from 4% to 20% [10,12]. The importance of this finding is reflected in a worse prognosis in those with residual moderate or greater aortic regurgitation [13,14].

4.5. New pacemaker implantations

The rate of new PM implantation in our population was 27.9%. Although this rate is dependent on multiple factors such as pre-existing right bundle branch block (RBBB) and the threshold for PM implantation in the different TAVR centers, we have to remark that in 32 out of 43 patients, the indication for PM implantation was a third-degree AV block. These results are in line with the REPRISE-II trial, which reported

a new PM rate of 28.6% [7]. This new PM rate with the Lotus Valve System is higher than those reported for other second-generation TAVR valves such as the Portico (10.4%), EvolutR (11.7%), Sapien 3 (13.2%), and Direct Flow (17.0%) systems [10,15–17]. However, more in-depth analysis demonstrates that this PM rate can be minimized if the necessary attention is given to both the implantation depth (<4 mm) and rate of oversizing (<1.05). In case of Lotus implantation at a depth <4 mm with an oversizing ratio <1.05, the calculated PM rate was only 12.8% (5/39 patients). Similar findings have been reported by Dr. Götberg at TCT 2015, demonstrating a PM rate of only 13.3% in case of early high deployment and a final high implant of the Lotus valve [18].

4.6. Study limitations

The main limitations of this study are the retrospective analysis, the fact that selection bias cannot be excluded, and that there was no endpoint adjudication. Although our study cohort is rather limited, it still includes more patients than most CE Mark trials for any new transcatheter heart valve. A final limitation of this study is the limited follow-up duration; however, previous studies describing the efficacy and safety of transcatheter heart valves have shown that results at 30 days and at 1 year following TAVR are largely in line.

5. Conclusion

The present study demonstrates the efficacy and safety of the Lotus Valve System in intermediate risk patients with symptomatic, severe AS. The Lotus Valve System is designed for a well-controlled TAVR procedure and allows assessment of the final valve function and possible reposition before final release. The VARC-defined device success rate was 97.4% in our study population with a 30-day patient safety rate of 92.2% and a clinical efficacy rate of 91.6%. Less than moderate aortic regurgitation was obtained in 99% of patients.

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Conflicts of interest

Leo Ihlberg, Henrik Bjursten, and Matthias Götberg are consultants for Boston Scientific. Lars Søndergaard received an unrestricted research grant from Boston Scientific. No other conflicts of interest.

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