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Comparison of the Clinical Outcomes in High-Risk Patients with Severe Aortic Stenosis Undergoing Transfemoral Aortic Valve Implantation Using SAPIEN XT and LOTUS Valve

SAPIEN XT ve LOTUS Kapakları Kullanılarak Transfemoral Aort Kapak İmplantasyonu Uygulanan Yüksek Riskli Aort Darlığı Olan Hastalarda Klinik Sonuçların Karşılaştırılması

Serkan ASLAN,[a]
Mehmet GÜL,[b]
Hüseyin Altuğ ÇAKMAK,[c]
Aydın Rodi TOSUN,[b]
Derya ÖZTÜRK,[b]
Hulusi SATILMIŞOĞLU,[b]
Ender ÖNER,[b]
Ali Kemal KALKAN,[b]
Aydın YILDIRIM,[b]
İhsan BAKIR[b]

[a]Clinic of Cardiology, Medicana Hospitals Bahcelievler,
[b]Clinic of Cardiology, Istanbul Mehmet Akif Ersoy Thoracic-Cardiovascular Surgery Training and Research Hospital, İstanbul
[c]Clinic of Cardiology, Bursa Mustafa Kemal Paşa Government Hospital, Bursa

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Yazışma Adresi/*Correspondence:*
Serkan ASLAN
Medicana Hospitals Bahcelievler, Clinic of Cardiology, İstanbul, TURKEY/TÜRKİYE
serkanaslan84@hotmail.com

ABSTRACT Objective: The aim of this study was to compare the procedural, 30-day, and one-year follow-up Valve Academic Research Consortium-2 (VARC-2) defined outcomes using either the LOTUS valve or the conventional the SAPIEN XT valve. **Material and Methods:** 50 patients (25 with LOTUS and 25 with SAPIEN XT) with severe symptomatic aortic stenosis undergoing transcatheter aortic valve implantation (TAVI) were included in this study. We evaluated the procedural outcomes, early safety, and clinical efficacy endpoints of patients who were treated with the LOTUS or the SAPIEN XT valve delivered via the transfemoral route. **Results:** Accordingly, the Valve Academic Research Consortium-2-defined safety endpoints within 30 days and combined efficacy endpoints at one-year follow-up were the same in both groups (p=0.569, p=0.529, respectively). The need for permanent pacemaker implantation in the LOTUS group was higher than in the SAPIEN XT group at 30 days (20% vs. 8%, p=0.221, respectively) and at one-year (24.0% vs. 16%, p=0.480, respectively). Echocardiography upon discharge demonstrated that trivial or mild paravalvular leakage in SAPIEN XT patients was significantly higher than in LOTUS patients (52% vs. 24%, p=0.041, respectively). Moderate or severe paravalvular leakage was observed in only one patient in a SAPIEN group. **Conclusion:** 30 days and one-year follow-up results according to Valve Academic Research Consortium-2 were similar in both groups. The permanent pacemaker rate was higher in LOTUS group despite an insignificant difference between the groups. LOTUS was associated significantly lower rate of trivial or mild paravalvular leakage compared with the SAPIEN XT. TAVI with LOTUS valve was associated with no moderate or severe paravalvular leakage and a low rate of mild paravalvular leakage.

Keywords: Aortic valve stenosis; heart valve prosthesis implantation; pacemaker, artificial

ÖZET Amaç: Bu çalışmanın amacı LOTUS kapak ve SAPIEN XT kapak sistemlerinin 'Valve Academic Research Consortium-2' (VARC-2) kriterlerine göre prosedürel, 30. gün ve 1 yıllık klinik sonuçlarını karşılaştırmaktır. **Gereç ve Yöntemler:** Transkateter aort kapak implantasyonu (TAVİ) uygulanan şiddetli semptomatik aort darlıklı 50 hasta (25 LOTUS ve 25 SAPIEN) bu çalışmaya dahil edildi. LOTUS veya SAPIEN XT kapak ile transfemoral TAVİ uygulanan hastalarda prosedürel, erken güvenlik ve klinik etkinlik sonlanım sonuçları değerlendirildi. **Bulgular:** "Valve Academic Research Consortium-2" kriterlerine göre, 30 günde güvenlik ve 1 yıllık klinik etkinlik sonlanım noktalarında iki grup arasında fark saptanmadı (p=0,569, p=0,529, sırasıyla). Kalıcı pil gereksinimi LOTUS kapakta, SAPIEN XT kapağa göre 30 gün (%20 vs. %8, p=0,221, sırasıyla) ve 1 yıllık (%24,0 vs. %16, p=0,480, sırasıyla) takiplerde daha fazla gözlendi. Ekokardiyografik incelemede eser ve hafif paravalvuler kaçak SAPIEN XT hasta grubunda LOTUS hasta grubuna kıyasla anlamı olarak daha fazla gözlendi (%52 vs. %24, p=0,041, sırasıyla). Orta ve ileri paravalvuler kaçak sadece SAPIEN grubunda bir hastada görüldü. **Sonuç:** 30 gün ve yıllık takiplerde iki kapak arasında "Valve Academic Research Consortium-2" kriterlerine göre sonlanım noktaları açısından fark saptanmadı. Kalıcı kalp pili oranı gruplar arasında anlamlı bir farklılık olmamasına rağmen LOTUS grubunda daha yüksek idi. LOTUS SAPIEN XT ile karşılaştırıldığında eser ve hafif paravalvüler kaçak anlamlı derecede düşük oranda ilişkilidir. TAVI'de LOTUS'un orta veya şiddetli paravalvüler kaçak oranı daha düşük bulunmuştur.

Anahtar Kelimeler: Aort kapak stenozu; kalp kapağı protezi implantasyonu; kalp pili, yapay

Transcatheter aortic valve implantation (TAVI) has become a viable alternative for the treatment of severe symptomatic aortic stenosis (AS) in selected patients who are poor candidates for surgical valve replacement.[1-4] Although TAVI appeared to be associated with favorable clinical results and a lower risk of periprocedural complications, there is an increased risk of moderate-to-severe paravalvular aortic leakage (PVL) with first generation devices. In addition, atrioventricular conduction disturbances, and access-related complications could be identified as important factors regarding the post-procedural outcomes.[1,5] Driven by these concerns, rapid innovation of novel TAVI devices and implantation techniques would help to prevent device-specific intra- and post-procedural complications.

As one of these innovations, the self-expanding LOTUS valve system (Boston Scientific Corporation, Marlborough, MA) has been designed for transfemoral access.[6-8] However, the clinical data regarding second-generation TAVI valves are very limited. There has been an adoption of new devices such as the LOTUS at some centers, to date, there have been no systematic head-to-head comparisons for LOTUS and SAPIEN XT.

The Valve Academic Research Consortium-2 (VARC-2) document has provided further standardization of endpoint definitions for studies evaluating the use of TAVI, which will lead to improved comparability and interpretability of the study results, supplying an increasingly growing body of evidence with respect to TAVI.[9]

The aim of this study was to compare 30-day and one-year outcomes defined by VARC-2 after TAVI with LOTUS versus SAPIEN XT prosthesis.

MATERIAL AND METHODS

STUDY DESIGN AND PATIENT SELECTION

This prospective study enrolled 50 consecutive patients including 23 males and 27 females with a mean age of 77.2±8.6 years from April 2014 to June 2015. Selection of the LOTUS or SAPIEN XT device was randomized. All patients had symptomatic severe calcific AS, with an initial aortic valve area (AVA) of < 1.0 cm^2 (or an AVA index of < 0.6 cm^2/m^2) and a mean pressure gradient of >40 mmHg or a jet velocity of >4 m/s, as measured by transthoracic echocardiography (TTE). All patients had New York Heart Association (NYHA) functional Class III or IV. The patients were deemed high risk based on a Society of Thoracic Surgery (STS) score of ≥10%; a logistic EuroSCORE of ≥20%; or agreement by consensus at a meeting of the heart team, which included an interventional cardiologist and a cardiothoracic surgeon, to the effect that frailty and/or coexisting comorbidities would be associated with a high surgical risk. The study's exclusion criteria were as follows: a congenital unicuspid or bicuspid aortic valve, acute myocardial infarction, transient ischemic attack, or stroke within the previous 6 months. Additional exclusion criteria were a prosthetic valve, a prosthetic ring in any position, more than moderate (>3+) mitral regurgitation or aortic regurgitation, untreated clinically significant coronary artery disease and a documented left ventricular ejection fraction (LVEF) below 25%. The study complied with the Declaration of Helsinki, and the trial protocol was approved by the Institutional Ethics Committee of the hospital (2015-21).

DEVICES

In our practice, we initially performed TAVI with the SAPIEN XT in 2010. We then added the LOTUS valve after it was approved in early 2014.[10] A proper and detailed pre-procedural evaluation was performed for all patients. Valve selection was determined according to aortic annulus dimensions.

SUITABILITY OF THE SAPIEN XT

The annular dimension criteria for the SAPIEN XT device were evaluated by multiple detector computed tomography (MDCT), including mean diameter, area, and perimeter (19-22 mm, 300-380 mm^2, and 60.0-69.0 for the 23-mm device; 23-25 mm, 415-490 mm^2, and 72.0-78.5 mm for the 26-mm device; and 26-28 mm, 530-620 mm^2, and 81.5–88.0

mm for the 29-mm device, respectively). The annulus to coronary ostium height was considered to be >10 mm.

SUITABILITY OF THE LOTUS

The annular dimension criteria for the LOTUS device were evaluated by MDCT, including mean diameter, area, and perimeter (20–23 mm, 350–420 mm^2, and 66.0–73.0 for the 23-mm device; 23–25 mm, 420–500 mm^2, and 73.0–79.0 mm for the 25-mm device; and 25–27 mm, 500–580 mm^2, and 79.0–85.0 mm for the 27-mm device, respectively). The annulus to coronary ostium height was considered to be >10 mm.

PROCEDURES

All TAVI procedures were performed in a catheterization laboratory under general anesthesia. The standard approach for both valves was through the transfemoral route with greater diameter and less tortuosity, if feasible. Access was gained using a percutaneous closure device (Prostar XL, Abbott Vascular, Redwood City, CA) or a surgical cutdown. Two sheaths were placed in the contralateral femoral artery and femoral vein for placement of a pigtail catheter in the aorta and a pacemaker lead in the right ventricle, respectively. In SAPIEN XT group, balloon predilatation was performed in all of the patients with rapid ventricular pacing. In LOTUS group, balloon predilatation was only performed in five patients with rapid ventricular pacing due to severe calcific aortic valve. Finally, valve position was assessed by contrast aortography and if the valve was positioned successfully, the prosthesis was released. After the procedure, daily aspirin (100 mg) and clopidogrel (75 mg) were required for 6 months and recommended indefinitely.

STUDY ENDPOINTS

All patients were evaluated in the follow-up after TAVI. All clinical endpoints of this study were defined according to the VARC-2 document, which provides further standardization of endpoint definitions for studies evaluating the use of TAVI. In VARC-2, early safety at 30 day follow-up is defined as a composite of all-cause mortality, all stroke, life-threatening bleeding, acute kidney injury (stage 2 or 3), coronary artery obstruction requiring intervention, major vascular complications, or repeat procedures for valve-related dysfunction. The combined efficacy endpoint at one-year follow-up is defined as a composite of all-cause mortality, stroke, need for hospitalization due to worsening heart failure, and valve-related dysfunction. Other outcomes were identified as the need for permanent pacemaker implantation, trivial, mild, moderate and severe PVL. "Device success" is defined as the absence of procedural mortality, correct positioning of a single prosthetic heart valve into the proper anatomical location, and intended performance of the prosthetic heart valve. Valve-related dysfunction refers to a mean aortic valve gradient >20 mmHg, a peak velocity >3 m/s, an effective orifice area <0.9–1.1 cm^2, a Doppler velocity index of <0.35 m/s, and severe prosthetic valve regurgitation. In previous research, other TAVI-related complications have been evaluated, including conversion to open surgery, coronary obstruction, cardiac tamponade, conduction disturbances and arrhythmias, endocarditis, valve thrombosis, valve malposition, and TAV-in-TAV deployment.

STATISTICAL ANALYSIS

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 21.0 (IBM Corp., Armonk, NY). Data were expressed as mean ± standard deviation for continuous variables, and as numbers with corresponding percentages for categorical variables. They were analyzed with the Student t test. The paired sample test was used to compare the pre- and post-procedural results. Categorical variables were compared using the Chi-square test or Fisher's exact test. For all comparisons, $p<0.05$ was considered statistically significant.

RESULTS

BASELINE CHARACTERISTICS

The baseline demographic characteristics of the patients are summarized in Table 1. All patients had

TABLE 1: Demographic and clinical parameters of the patients at baseline.

Patient characteristics	All patients (n=50)	SAPIEN XT (n=25)	LOTUS (n=25)	P values
Age (years)	77.2 ± 8.6	78.1 ± 7.2	76.3 ± 9.8	0.446
Female	27 (54)	14 (56)	13 (52)	0.777
Logistic EuroSCORE (%)	24.2 ± 12.1	23.1 ± 13.6	25.4 ± 10.5	0.502
STS score (%)	8.2 ± 5.2	8.3 ± 5.6	8.1 ± 5.0	0.897
BMI (kg/m^2)	27.8 ± 4.6	27.8 ± 4.7	27.9 ± 4.5	0.903
Hyperlipidemia	25 (50)	10 (40)	15 (60)	0.157
Hypertension	39 (78)	19 (76)	20 (80)	0.733
Diabetes	25 (50)	10 (40)	15 (60)	0.157
NYHA class III or IV	50 (100)	25 (100)	25 (100)	1.000
Previous percutaneous coronary intervention	19 (38)	12 (48)	7 (28)	0.145
Previous aortocoronary bypass graft	13 (26)	4 (16)	9 (36)	0.107
Cerebrovascular event	6 (12)	5 (20)	1 (4)	0.082
Creatinine (mg/dL)	1.1 ± 0.6	1.0 ± 0.4	1.2 ± 0.80	0.144
HGB (g/dL)	11.8 ± 2	11.7 ± 1.6	12.1 ± 2.3	0.759
LVEF	53 ± 12.4	53.6 ± 13.4	52.4 ± 11.6	0.737
Sinus rhythm	37 (74)	18 (72)	19 (76)	0.747
Effective orifice area (cm^2)	0.81 ± 0.18	0.82 ± 0.17	0.81 ± 0.19	0.815

Data are given as mean ± standard deviation or as number (%). STS: Society of Thoracic Surgeons; BMI: body mass index; NYHA: New York Heart Association; HGB: hemoglobin; LVEF: left ventricular ejection fraction.

severe symptomatic AS (i.e., mean AVA, 0.81±0.18 cm^2; mean transaortic gradient, 49.0±12.2 mmHg). Between April 2014 and June 2015 patients (N = 50) were treated with the repositionable LOTUS valve (N = 25) or the Edwards SAPIEN XT valve (N = 25). Baseline data were similar between the two groups.

PROCEDURAL OUTCOMES

The main procedural variables of the study population are summarized in Table 2. Twenty five patients were included in both groups. The most commonly used implant was the 26-mm valve (74%) in SAPIEN XT group and the 25-mm valve (60.0%) in LOTUS group. Device success was achieved in 49 (98%) patients. No procedural deaths occurred within the first 72 hours after TAVI in either group. In one patient in SAPIEN XT group, implantation was unsuccessful due to valve malposition in the sinus of valsalva, resulting in severe PVL as determined using angiography and echocardiography. TAV-in-TAV was performed successfully in this patient. One patient had cardiac tamponade (categorized as life-threatening bleeding according to the VARC-2). This occurred immediately after the deployment of the 26-mm SAPIEN XT and prompt pericardiocentesis successfully stabilized the patient. Stroke occurred in two patients. The first patient, in LOTUS group, suffered an ischemic stroke that was diagnosed on clinical grounds alone on the day of TAVI. The other patient was in SAPIEN XT group and had an ischemic stroke 2 days after TAVI; the diagnosis was confirmed through a brain computed tomography (CT) scan.

Among all of the patients, 30 patients (60%) had no post-procedural PVL, whereas 19 patients had trivial or mild PVL (38%). Except for 1 patient in SAPIEN XT group, a score of moderate or severe PVL was not observed in either group. TAV-in-TAV was performed successfully in this patient due to severe PVL. There were also significant differences between in SAPIEN XT and LOTUS groups in terms of trivial or mild PVL (p=0.041). LOTUS was associated with a lower rate of trivial or mild PVL.

There were no significant differences in intra- and post-procedural data or adverse outcomes be-

TABLE 2: The procedural characteristics and postprocedural outcomes.

Variables	SAPIEN XT (n=25)	LOTUS (n=25)	P value
Aortic valve prosthesis size			
SAPIEN XT 23 mm SAPIEN XT 26 mm SAPIEN XT 29 mm	5 (20) 16 (74) 4 (16)		
Lotus 23 mm Lotus 25 mm Lotus 27 mm	7 (28) 15 (60) 3 (12)		
Predilatation	25 (100)	7 (28)	**<0.001**
Arterial hemostasis (percutaneous: prostar XL)	23 (92)	22 (88)	0.637
Device success	24 (96)	25 (100)	0.312
Procedural mortality	0 (0)	0 (0)	-
Conversion to open surgery	0 (0)	0 (0)	-
Coronary obstruction	0 (0)	0 (0)	-
Cardiac tamponade	1 (4)	0 (0)	0.312
Valve malpositioning	1 (4)	0 (0)	0.312
TAV-in-TAV deployment	1 (4)	0 (0)	0.312
Post-procedure paravalvular regurgitation			
Trivial or mild	13 (52)	6 (24)	0.041
Moderate or severe	1 (4)	0 (0)	0.312
Post-procedure peak aortic gradient (mmHg)	17.5 ± 11.8	19.8 ± 6.3	0.399
Post-procedure aortic mean gradient (mmHg)	9.8 ± 6.1	12.1 ± 4.3	0.141
Data are given as mean ± standard deviation or as number (%)			

tween in SAPIEN XT and LOTUS groups (Table 2). The echocardiographic parameters are summarized in Table 3, and these were similar between the two groups.

VARC-2 OUTCOMES AT 30 DAYS AND ONE-YEAR

Table 4 summarizes the 30-day and one-year outcomes. At the 30-day follow-up, three deaths had occurred. Two patients in SAPIEN XT group died in the first week after TAVI because of pneumonia and subsequent sepsis and cardiogenic shock, respectively. Meanwhile, one patient in LOTUS group died 3 days after TAVI because of stroke, according to the VARC-2. Stage 2 or 3 acute kidney injury developed in five (10%) patients after 72 hours, two patients in SAPIEN XT group and three patients in LOTUS group, two patients had to be dialyzed temporarily. There was no coronary artery obstruction or valve-related dysfunction requiring a repeat procedure within 30 days.

In six patients, access-related vascular injury leading to life-threatening or major bleeding occurred. These vascular complications consisted of four percutaneous closure device failures resulting in perforation or dissection requiring surgery, one retroperitoneal bleeding after 1 day, and one occlusion of the common femoral artery requiring surgery. There were no significant differences between the groups in terms of vascular complications, major or life-threating bleeding, acute kidney injury, need for PPM, major stroke, and myocardial infarction at the 30-day follow-up. Early safety endpoints within 30 days as defined by VARC-2 were similar between groups (p=0.569).

Between 30 days and one-year, two more deaths with no-related to valve occurred because of recurrent infection and multiple organ failure from sepsis in LOTUS group. One patient in SAPIEN XT group died because of congestive heart failure. A one-year cumulative all-cause mortality rate was 12%. One patient in SAPIEN XT group had an ischemic stroke 5 months after discharge;

TABLE 3: Transthoracic echocardiography data.

Parameters	SAPIEN XT	LOTUS	P-value
	Baseline		
Peak aortic velocity (cm/s)	4.4 ± 0.9	4.2 ± 0.8	0.386
Peak aortic gradient (mmHg)	78.5 ± 17.7	72.6 ± 14.0	0.199
Mean aortic gradient (mmHg)	50.8 ± 13.5	47.2 ± 10.7	0.293
LVEF (%)	53 ± 13	52 ± 11	0.737
	Postprocedure		
Peak aortic velocity (cm/s)	2.1 ± 0.4	2.2 ± 0.5	0.695
Peak aortic gradient (mmHg)	17.5 ± 11.8	19.8 ± 6.3	0.399
Mean aortic gradient (mmHg)	9.8 ± 6.1	12.1 ± 4.3	0.141
LVEF (%)	54 ± 10	53 ± 10	0.717

Data are given as mean ± standard deviation. LVEF: left ventricular ejection fraction.

TABLE 4: Clinical outcomes of the study patients at 30 days and one-year.

Outcomes	Overall (n: 50)	SAPIEN XT (n: 25)	LOTUS (n: 25)	P value
30 days clinical outcomes				
All-cause mortality	3 (6)	2 (8)	1 (4)	0.552
Vascular complications (access side)				
Major	6 (12)	3 (12)	3 (12)	1.000
Minor	14 (28)	8 (32)	6 (24)	0.529
Bleeding				
Life-threating/disabling	5 (10)	3 (12)	2 (8)	0.637
Major	13 (26)	9 (36)	4 (16)	0.107
Acute kidney injury				
Stage 1	10 (20)	4 (16)	6 (24)	0.480
Stage 2 or 3	5 (10)	2 (8)	3 (12)	0.637
Post-procedure permanent pacemaker	7 (14)	2 (8)	5 (20)	0.221
Major stroke	2 (4)	1 (4)	1 (4)	1.000
Myocardial infarction	0 (0)	0 (0)	0 (0)	-
Early safety endpoint at 30 days	22 (44)	12 (48)	10 (40)	0.569
One-year cumulative clinical outcomes				
All-cause mortality	6 (12)	3 (12)	3 (12)	1.000
Cardiac mortality	1 (2)	1 (4)	0 (0)	0.312
All stroke	3 (6)	2 (8)	1 (4)	0.552
Requiring hospitalizations for worsening heart failure	7 (14)	4 (16)	3 (12)	0.684
Valve related disfunction	0 (0)	0 (0)	0 (0)	-
Permanent pacemaker	10 (20)	4 (16)	6 (24)	0.480
The combined efficacy endpoint at one-year	14 (28)	8 (32)	6 (24)	0.529

Data are given as number (%)

the diagnosis was confirmed through a brain CT scan. Seven patients required rehospitalization for heart failure (NYHA IV). The PPM incidence rate was higher in LOTUS group than in SAPIEN XT group despite an insignificant difference between the groups (at 30 day, 20.0% vs. 8%, p=0.221; at one-year, 24% vs. 16%, p=0.480, respectively). No valve-related dysfunction, including the presence of severe prosthesis regurgitation, was observed within one-year.

The VASC-2 defined clinical efficacy endpoints, which included all-cause mortality, cardiac mortality, major stroke, required hospitalization for worsening heart failure, need for prosthesis-patient mismatch (PPM), and valve-related dysfunction at one-year, showed no significant differences between the groups. The VASC-2-defined combined efficacy endpoints at the one-year follow up were accordingly the same in both groups (p=529).

DISCUSSION

This is the first study to compare early safety endpoints at 30 days and combined efficacy endpoints at one year, defined according to VARC-2, after TAVI at a single center with either the SAPIEN XT valve or the LOTUS valve in high-risk patients with severe AS. The overall device success rate of 98% is encouraging, and suggests that with careful planning and appropriate techniques, immediate procedural success can be achieved in most patients in whom the procedure is attempted.

While the rate of PPM was higher in LOTUS group, the rate of PVL was more common in SAPIEN XT group. Trivial or mild PVL was signif-

icantly higher in SAPIEN XT group, however, PPM did not reach statistical significance in the present study. Other clinical outcomes, including acute device success, access-related complications, and mortality were similar between the two groups.

TAVI has emerged as an alternative to surgical aortic valve replacement for symptomatic patients with severe AS and very high or prohibitive operative risk. Although TAVI has proven to be a less invasive treatment for high-risk patients with AS, it may be associated with potentially severe complications.[11-14]

A recent meta-analysis including 11,210 patients from 41 studies demonstrated that the need for PPM ranged from 1% to 51%, with a median of 28% using the CoreValve device and 6% with the Edwards SAPIEN device.[15] In the REPRISE I study, which included 11 patients treated with the 23-mm LOTUS device, the need for PPM implantation arose in 36% of cases (N=4/11).[7] Meanwhile, in the REPRISE II study, which included 120 patients treated with the 23- or 27-mm valve, the need for PPM was evident in 29% of cases.[8]

LOTUS implantation is frequently associated with atrioventricular block requiring PPM.[7,8] This is possibly because of greater expansion into the left ventricular outflow tract with compression of the septal conduction pathways, extensive metal burden, and the fact that this valve is longer than the SAPIEN XT valve, leading to deeper settlement.

In a previous study conducted by Wöhrle et al, the LOTUS valve and SAPIEN 3 valve, which are second generation valves were compared. Authors reported no significant difference in terms of clinical and procedural outcomes except for the need for PPM.[16] PPM was more frequently required with the LOTUS compared with the SAPIEN 3 (26.9% vs. 3.8%, p<0.003, respectively). In another study conducted by Gooley et al, the LOTUS valve and CoreValve were compared. Authors reported that the rate of new pacemaker insertion was greater in LOTUS group than CoreValve group (28% vs. 18%), although not statistically different.[17] In the present study, there was no significant difference the rate of requirement for PPM in the two groups. PPM was required more frequently in LOTUS group than in SAPIEN XT group at 30 days (20% vs 8%, p=0.221, respectively) and one-year (24% vs 16%, p=0.480, respectively).

We would expect to reach statistical significance in terms of the rate of PPM placements if the number of patients were increased. The need for a PPM was detected less in SAPIEN 3 than in LOTUS valves in the study of Wöhrle et al. In our study, a first-generation SAPIEN XT and second-generation LOTUS valve were compared. It can be said that the SAPIEN 3 is more advantageous in terms of the need for post-procedure PPM according to our results and those of Wöhrle et al.[16]

Accumulating data have linked device failure and more- than-mild PVL after TAVI with significantly increased late mortality after TAVI.[1] This complication was more frequent with the first-generation valves, as the new-generation systems are less likely to be associated with moderate-to-severe PVL. The Lotus is totally repositionable, even when fully expanded in the final position by virtue of its deployment and coupling mechanism. In addition, the presence of an adaptive seal around the outer aspect of the lower valve frame appears to reduce PVL by occupying residual interstices between the frame and native annulus.[7,8]

Gooley et al. reported that in comparison of LOTUS versus CoreValve groups, there was significant difference in terms of post-procedural PVL.[17] Furthermore, Wöhrle et al reported that in a comparison of LOTUS and SAPIEN 3 groups, there was no post-procedural moderate or severe PVL. The rate of mild PVL was insignificant in both groups (23% vs 15%, p = 0.40, respectively).[16] Although the present study used the SAPIEN XT rather than the SAPIEN 3, our findings were very similar. Moreover, except for the need for a TAV-in-TAV procedure due to valve malposition resulting in severe PVL, no patient in our series had post-procedural severe PVL. 13 patients in SAPIEN XT group (52%) and 6 patients in LOTUS group (24%) had trivial or mild PVL among all of the patients. While

the rates of trivial or mild PVL were higher with the SAPIEN XT group compared with the LOTUS group, there were significant differences between the two groups in terms of trivial or mild PVL (p = 0.041).

As expected, the results of these two studies showed the superiority of second-generation LOTUS valves in terms of PVL.

LIMITATIONS OF THE STUDY

As this was a single-center study involving a small number of high-risk patients in both groups, it may not be sufficient to compare the results for the two different valve types. Another limitation in our study was that we had less experience with the LOTUS device than with the SAPIEN XT technology, which had already been implemented for 5 years in our institution. We achieved excellent results despite being in the learning curve period.

CONCLUSION

In this study, TAVI with the repositionable LOTUS valve and the balloon-expandable SAPIEN XT valve resulted in similar early safety and combined efficacy outcomes. Although the results were not significant, the LOTUS valve was associated with a higher rate of requiring a PPM compared with the SAPIEN XT. Device success according to VARC-2 was similar between the two groups. The second-generation LOTUS device was associated with a significantly lower rate for trivial or mild PVL compared with first generation transcatheter valves. The results of this study showed the superiority of second-generation LOTUS valves in terms of PVL. The clinical significance of these differences will need to be tested in larger randomized trials.

Conflict of Interest

Authors declared no conflict of interest or financial support.

Authorship Contributions

Idea/Concept: Mehmet Gül, Serkan Aslan; **Design:** Mehmet Gül, Serkan Aslan; **Control/Supervision:** Aydın Yıldırım; **Data Collection and/or Processing:** Serkan Aslan, Muhammet Hulusi Satılmışoğlu, Hüseyin Altuğ Çakmak, Ali Kemal Kalkan, Derya Öztürk, Ender Öner; **Literature Review:** Serkan Aslan, Derya Öztürk, Hüseyin Altuğ Çakmak, Aydın Rodi Tosun; **Writing the Article:** Serkan Aslan, Mehmet Gül; **Critical Review:** Aydın Yıldırım, İhsan Bakır.

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