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Evaluation of Patients with Severe Aortic Stenosis after TAVI with Self-Expandable vs. Balloon-Expandable Devices

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Abstract

Background: The introduction of transcatheter aortic valve implantation (TAVI) for the treatment of severe aortic stenosis (SAS) has expanded the therapeutic possibilities for successfully managing SAS in cases with intermediate and high surgical risks. However, the complications and outcomes of new devices have not been studied enough. Hence, the purpose of this study is to evaluate the midterm results of the Core Valve and Evolute R self-expandable (SE) devices versus the Edwards SAPIEN balloon-expandable (BE) devices. **Methods and Material:** This was a quasi-experimental study conducted in Tehran, Iran, from May 2012 to June 2017. SAS patients who were not ideal candidates for surgery were randomly assigned to either SE or BE groups. For each patient, a questionnaire, including four sections comprised of Basic characteristics, echocardiographic, angiographic, and Computed Tomography (CT) scan data was filled. TAVI was followed by echocardiography a week later and after three months they were reevaluated by another questionnaire. **Results:** The total number of patients was 60. The mean ages of patients undergoing the procedure with SE or BE devices were 81.2 ± 8 and 79.8 ± 7, respectively. Mortality occurred in 20% of the patients (5 cases in the SE group and 7 cases in the BE); mortality causes were 66.6 % cardiac and 33% non-cardiac. Moderate to severe Paravalvular leakage in both groups did not differ significantly. The mortality rate was 5 (41.6%) in the SE group versus 7 (58.3%) in the BE group ($P > 0.05$). **Conclusion:** In conclusion, the BE group

did not experience fewer paravalvular leaks in comparison with the SE. Morbidity and mortality between the BE and the SE groups did not differ significantly.

Keywords

TAVI, Balloon-Expandable Valves, Self-Expandable Valves, Mortality, Aortic Stenosis

1. Introduction

Transcatheter aortic valve implantation (TAVI) has been introduced as a new therapeutic option for patients diagnosed with severe aortic stenosis (SAS) at high risk for surgical operation [1] [2].

Transcatheter device development has been progressing rapidly during the past decade, and to date, this approach challenges surgical intervention as the preferred or the only option for managing symptomatic SAS [3].

Recent research has explored if TAVI remains an alternative to surgical aortic valve replacement (SAVR) when surgical risk is low. To date, two large randomized controlled trials have been carried out to evaluate TAVI in patients with moderate surgical risk; both have documented TAVI as non-inferior to SAVR regarding stroke and all-cause mortality, whilst benefiting from a lower tendency to new acute kidney injury, major bleeding, or atrial fibrillation [4] [5] [6].

Several new-generation devices for TAVI have been developed to overcome the limitations of the earlier ones [7]. Aortic prosthesis transcatheter placement requires either a self-expandable (SE) system (Medtronic Core Valve, Evolute R) or a balloon-expandable (BE) system (Edwards SAPIEN). Because the hemodynamic effects and complications of these valves are different and have not been studied enough, this study aims to evaluate the efficacy of these devices and compare their results and complications after midterm follow-up.

2. Methods and Materials

This study was quasi-experimental, as device selection was based on availability rather than randomization. The research took place at Rajaee Heart center and Dey clinic in Tehran, Iran. All patients with SAS who were at high risk for operation and were capable of undergoing TAVI from May 2012 to June 2017 were included in this study. Based on the availability of the devices and their indications for insertion, one patient went to either the BE group or the SE group. If severe calcification existed in the aortic valve (AV) or the left ventricular outlet, the BE device was preferred.

Since this was the starting point of the insertion of these types of devices in the AV, all patients who met the inclusion criteria and agreed to undergo TAVI instead of SAVR were included in the study.

The ethics committees of both participating centers approved this study. Additionally, all participants were provided with written informed consent for inclusion in the trial. TAVI candidates were only included in the study if they met all of the inclusion and none of the exclusion criteria. A questionnaire was given to each patient containing two sections: Section one was about the medical history and chief complications of patients, which was self-administered, while section two was about anatomical characteristics of the AV and annulus in echocardiography and multi-slice Computed Tomography (CT) scan which was filled out by a cardiologist. The inclusion criteria were comprised of 1) the presence of SAS, defined as a maximum AV area of 1 cm^2 or a maximum indexed AV area of 0.6 cm^2/m^2, and 2) clinical symptoms described as the functional class of two or higher based on the New York Heart Association (NYHA) classification.

Contraindications to SAVR were anatomic appropriateness for either transfemoral vascular access or transcatheter device.

Primary exclusion criteria were hemodynamic instability, transfemoral access contraindications, a native AV annulus of less than 20 mm, and active endocarditis history. Additional contraindications that were also used were hypersensitivity or other contraindications for Clopidogrel, Heparin, or Aspirin use; active infection in need of antibiotics, and upper gastrointestinal bleeding within 3 months prior to the intervention.

Patients' assessment was performed using transesophageal echocardiography, transthoracic echocardiography, left ventriculography, multi-detector CT scan, selective coronary angiography, as well as angiography of iliofemoral vessels and the aortic root for comprehensive evaluation of the aortic root anatomy in addition to the AV. Each multi-detector CT examination was evaluated locally by expert cardiac CT readers. 3D multidetector CT annular measurements included the mean, the minimum, and the maximum; perimeter, area, and diameter. The eccentricity index was used to describe annular eccentricity, defined as [1 – (minimum diameter/maximum diameter)]. The grading of the AV calcification was performed semi-quantitatively based on the observation of the amount of calcium on the Aortic valve by the echocardiographer: Grade (1) without calcification, Grade (2) mild calcification (small isolated spots), Grade (3) moderate calcification (multiple larger spots), and Grade (4) heavy calcification (all cusps extensively calcified). The outflow tract of the left ventricle was separately analyzed semi-quantitatively for the presence, location, and amount of calcification. To conduct TAVI, a multidisciplinary team comprised of a cardiac surgeon, an anesthesiologist, and an interventional cardiologist was responsible for the final decision.

The SE system included the Core Valve system and also the newer generation Evulote R valves, consisting of porcine pericardial tissue sewn to form a trileaflet valve mounted within a self-expanding hourglass-shaped nitinol frame. The prosthetic size was determined by the external diameter of the ventricular end.

The BE system included a cylindrical cobalt-chromium stent onto which 3

leaflets made of bovine pericardium were mounted. Edwards SAPIEN was used as the BE valve.

The selection of the device size was performed according to the sizing charts issued by the manufacturer; however, it was recommended by the steering committee to do the sizing based on 3D imaging and the multi-detector CT-based annular area preferably. The currently utilized transfemoral delivery system has 16-F through 20-F catheters.

The procedures were mainly carried out under sedation (no endotracheal intubation) with the aid of fluoroscopic guidance. Moreover, in all patients, transesophageal echocardiography was performed as the appropriate guidance. The SE valve positioning was performed in a controlled fashion, either under slow-rapid pacing or without pacing, with limited realignment potential.

The BE device was positioned under rapid pacing without the use of cardiopulmonary support. Complete preprocedural revascularization was performed in cases that were diagnosed with significant coronary artery disease.

2.1. Valve Function Assessment

After the deployment of the valve, the valve function assessment was carried out using transthoracic echocardiography, invasive hemodynamic measurements, and angiography.

After the wire was retrieved from the ventricle, the angiographic assessment was carried out with the aid of a 6- or 5-F pigtail catheter positioned in the implanted valve's superior segment above the cusps within the ascending aorta.

Aortographies were recorded in the 45˚ left anterior oblique and the 30˚ right projections over several cardiac cycles. The contrast amount was standardized to permit adequate angiographic evaluation (minimum of 25 mL with a flow rate of 20 mL/s). We semi-quantitatively assessed aortic regurgitation (AR) by the estimation of the circumference proportion: more than 20% was considered severe, 10% to 20% moderate, and up to 10% mild paravalvular AR [8] [9].

An experienced interventional echocardiographer performed the evaluation on-site. The invasive hemodynamic assessment involved measuring the aortic diastolic pressure, end-diastolic pressure of the left ventricle, and residual transprosthetic gradient. The dimensionless AR index was calculated as ([diastolic blood pressure − left ventricular end-diastolic pressure]/systolic blood pressure) × 100.

Throughout follow-up, the assessment of valve function was performed by transthoracic echocardiography at two prearranged sessions (24 hours, 90 days).

2.2. Follow-Up and Endpoints

Electrocardiography was conducted at multiple time points after valve implantation, including 1 hour after the procedure, 24 hours later, daily throughout the first week, and immediately prior to discharge. Additionally, blood tests were performed, including a complete blood count, as well as renal and liver function

tests, 24 hours after the procedure. During hospitalization and for one week after discharge, patients were closely monitored for any adverse events. Further follow-up visits were scheduled for 3 months to ensure continued monitoring of patient health.

The primary endpoint of the trial was *device success* as defined by the third Valve Academic Research Consortium document consisting of 1) technical success (immediate success of a procedure, which is measured at the time of leaving the procedure room and encompasses the true technical safety of the device and its delivery), 2) freedom from mortality, 3) freedom from surgery or intervention related to the device (excluding permanent pacemaker) or a major vascular or access-related or cardiac structural complication, and 4) intended performance of the valve (mean gradient < 20 mmHg, peak velocity < 3 m/s, Doppler velocity index ≥ 0.25, and less than moderate AR) [10].

The secondary endpoints were about the complications of device insertion such as complete heart block, pericardial effusion, atrial fibrillation, sepsis, vascular complications, myocardial infarction (MI), decompensated heart failure (DHF), and stroke that were compared between the two types of valves, immediately as well as after ninety days.

Immediate post-procedural AR assessment was performed as a criterion for the primary composite endpoint of this study via transesophageal echocardiography and angiography.

Continuous variables were compared using a two-sided unpaired t-test and noncontinuous variables were analyzed by ANOVA and the numbers were reported using mean ± SD.

There were no missing data on the primary endpoint.

A P-value < 0.05 was considered statistically significant and All tests were two-sided. No adjustment was made for the primary and secondary endpoint comparisons. Statistical analyses were carried out via SPSS software 16.

3. Results

The total number of patients was 60 (32 in the BE group and 28 in the SE group).

41 patients were included from Rajaee Heart Center, and 19 patients were included from Dey clinic. The mean age of patients who underwent TAVI for the SE group was 81.2 ± 8 years, and for the BE group was 79.8 ± 7 years.

According to **Table 1**, the basic characteristics of patients such as gender, age, height, body weight, diastolic and systolic blood pressure, and EuroSCORE and STS score in the SE group and the BE group were not significantly different (P > 0.05).

Past medical history of the two groups such as hypertension, the history of diabetes mellitus, ischemic heart disease (IHD), hyperlipidemia, cerebrovascular accident (CVA), and chronic kidney disease (CKD) did not have any significant differences (P > 0.05).

Table 1. Basic characteristics of patients.

	Balloon-expandable valve group (number/percent)	Self-expandable valve group (number/percent)	P-value
Age, mean (SD)	81.2 ± 8	79.8 ± 7	P = 0.556
Bodyweight	68.8 ± 2.1	70.6 ± 2.6	P = 0.453
Height	166.8 ± 9.7	163.6 ± 8.8	P = 0.974
Systolic blood pressure mmHg	125.2 ± 12.8 mmhg	122.2 ± 19.4	P = 0.213
Diastolic blood pressure mmHg	67.5 ± 18 mmhg	74.5 ± 14	P = 0.603
Women	7 (25%)	8 (25%)	P = 0.571
EuroSCORE II, median (IQR)	7.6 ± 3	5.2 ± 3	P = 0.747
Society of Thoracic Surgeons score, mean (SD)	5.1 ± 2.2	5.4 ± 2.6	P = 0.507
NYHA Class			P = 0.306
I	2	1	
II	5	8	
III	16	18	
IV	9	1	
Diabetes mellitus	12	4	P = 0.057
Coronary artery disease	11 (45%)	8 (47%)	P = 0.737
HLP	5 (8%)	6 (15%)	P = 0.399
Myocardial infarction	0	2 (11%)	P = 0.001
CABG	10 (41%)	8 (17%)	P = 0.001
Cerebral vascular disease	1	0	P = 0.121
Peripheral vascular disease	4	0	
Pulmonary disease	5 (28%)	2 (11%)	P = 0.372
Creatinine level, mean (SD),	1.11 ± 0.4	1.17 ± 0.5	P = 0.026
Severe chronic renal failure	5	1	P = 0.776
Atrial fibrillation	10 (35%)	10 (32%)	P = 0.695

NYHA = New York heart association; Hlp = hyper lipidemia; CABG = coronary artery bypass graft.

Echocardiography and CT scan findings of patients are illustrated in Table 2 and Table 3.

The mean ejection fraction (EF) in patients in the SE group was 40.23 ± 14 while in the BE group was 43.7 ± 10 (P = 0.733).

The mean pulmonary artery pressure (PAP) in the SE group was 40.7 ± 18 mmhg while in the BE group was 41 ± 13 mph (P > 0.05).

The mean aortic area, mean aortic gradient, eccentric index, and the mean and the maximum diameter of the aortic annulus did not vary significantly between the BE group and the SE group (P > 0.05).

Table 2. Transthoracic and transesophageal characteristics of patients before TAVI.

	Balloon-expandable valve	Self-expandable valve	P-value
Aortic valve area, mean (SD), cm^2	0.62 ± 0.15	0.77 ± 0.2	P = 0.860
Mean gradient, mean (SD), mmHg	51.46 ± 2.8	55 ± 6.4	P = 0.491
Eccentric index	1.2 ± 0.3	1 ± 0.5	P = 0.651
Ejection fraction, mean (SD), %	43.7 ± 10	40.23 ± 14	P = 0.733
Pulmonary artery pressure (PAP) mmHg	43 ± 14 mmHg	40 ± 14 MMHG	P = 0.803
Severe regurgitation;			
Aortic	2	0	P = 0.994
Mitral	1	1	P = 0.615
Tricuspid	0	1	P = 0.061
Systolic pulmonary artery pressure, mean (SD), mmHg	41 ± 13 mmhg	40.7 ± 18 mmhg	P = 0.455
Transesophageal echocardiography;			P = 0.736
Moderate leaflet calcification	2	0	
Severe leaflet calcification	14	13	
without leaflet calcification	0	1	

Table 3. CT scan characteristics of patients before TAVI.

Multidetector CT	Balloon-expandable valve	Self-expandable valve	P-value
Aortic annulus diameter, (SD), mm			
Maximum	3.4 ± 0.2	3.5 ± 0.2	0.931
Minimum	2.2 ± 0.4	2.5 ± 0.4	0.860
Mean	2.1 ± 0.26	2.3 ± 0.28	0.030
Area, mm^2	6.38	7.36	0.315
Eccentricity index	1.2 ± 0.37	1.2 ± 0.42	0.651
Degree of aortic cusp calcifications			0.678
Mild	3	0	
Moderate	2	1	
Severe	14	13	
Degree of LVOT calcifications			0.024
None	22	19	
Mild	3	4	
Moderate	0	1	
Severe	7	4	
Height, mean (SD), mm			
Coronary artery			
Left main (LAD)	14.6 ± 3	11.7 ± 1.6	0.550
Right	13.7 ± 1.5	10.1 ± 2.9	0.060
Common femoral artery diameter, mean (SD), mm			
Right	7.3 ± 2	7.5 ± 0.76	0.061
Left	6.6 ± 1.8	7.36 ± 0.39	0.16

Moderate to severe Aortic regurgitation immediately after angiography was found in 16% of patients in the self-expandable group versus 27% in the balloon-expandable group (P > 0.05).

On the other hand, echocardiography revealed that 40% of patients experienced moderate AR after one week in the SE group compared to only 23% of patients in the BE group (P > 0.05).

Outcomes and Procedural Details

Procedural details and outcomes are demonstrated in Table 4 and Table 5. The 26-mm valve was the most common valve used in the BE group (20, 62.5%), whereas in the SE group the most frequently implanted valve was the 29-mm valve (14, 50%).

There was only one case of in-hospital mortality. Mortality occurred in 12 (20%) cases (5 cases in the SE group and 7 cases in the BE group). The cause of mortality was 66.6 % (8 cases) cardiac (3 cases of MI, 2 cases of DHF, 3 cases of SCD) and 33% none cardiac (1 case of ICH, 2 cases of sepsis, 1 case of hepatic liver cancer).

Table 4. Procedural details.

	Balloon-expandable valve	Self-expandable valve	P-value
Balloon predilatation			
Valve size, mm			
23 mm	4	0	
26 mm	20	12	
29 mm	8	14	
30 mm	0	1	
34 mm	0	1	
Aortic regurgitation after initial valve Placement			0.957
None/trace	10	7	
MILD	18	15	
MODERATE	4	5	
SEVERE	0	1	
Valve snaring due to deep implant	0	1 (3%)	
Adjunctive percutaneous coronary intervention	0	0	
Procedural duration, mean (95% CI), min	67 ± 10.1 min	70 ± 12.5 min	
Fluoroscopy time, mean (95% CI), min	9 ± 2.5 min	10 ± 3.5 min	
Contrast amount, mean (95% CI), mL	200	220	
Implant of ≥2 valves	0	0	

Table 5. Procedural outcome.

	Balloon-expandable valve	Self-expandable valve
In-hospital procedural mortality	0	1
Final aortic regurgitation Angiography		
NONE	5	9
MILD	14	15
MODERATE	7	5
SEVERE	0	1
Echocardiography		
NONE/TRACE	12	5
MILD	14	10
MODERATE	6	12
SEVERE	0	1
Aortic regurgitation index, mean (95% CI) c	16%	20%
Coronary obstruction	0	0
Annular rupture	0	0
Device success	32 (100%)	27 (97%)

According to Table 6, no significant differences were found in the total mortality rate between the SE and the BE groups; the mortality rate was 5 (41.6%) in the SE group versus 7 (58.3%) in the BE group ($P > 0.05$).

Pneumonia led to hospital admission in one case from the BE group and two cases from the SE group ($P > 0.05$).

According to Table 7, severe pericardial effusion leading to urgent drainage of fluid from the pericardial space occurred in one patient in the BE group and one patient in the SE group ($P > 0.05$).

Complete heart block leading to the cardiac pacemaker occurred in 3 cases (10%) in the BE group and 6 cases (21%) in the SE group ($P > 0.05$).

No other significant difference was found between the two groups ($P > 0.05$).

4. Discussion

The therapeutic possibilities for successful management of severe AS have been expanded by the introduction of TAVI. Every year new devices are developed to treat these patients; however, the efficiency and complications of these devices, especially in the Middle East, have not been sufficiently studied. The present analysis is a quasi-experimental study that describes the outcomes of TAVI patients with the midterm follow-up using the self-expanding Core Valve System and the balloon-expanding Edwards SAPIEN device.

Table 6. Clinical outcome on the 90th day.

	Balloon-expandable valve	Self-expandable valve	
Death	7 (21%)	5 (17%)	0.184
Stroke	1 (3%)	1 (3%)	0.121
Myocardial infarction	3 (9%)	1 (3%)	0.001
Sudden cardiac death	2 (6%)	1 (3%)	0.642
decompensated heart failure	2 (6%)	4 (14%)	0.866
Sepsis	1 (3%)	2 (6%)	0.018
Major Vascular Complication	2 (6%)	2 (7%)	0.892
Major bleeding	2 (6%)	0	0.018
hemodialysis	0	3 (17%)	0.001
Repeat procedure for valve-related dysfunction	0	0	
Prehospitalization for heart failure	1 (3%)	3 (17%)	0.024
NYHA class improvement	13 (76%)	9 (69%)	0.234
New permanent pacemaker	3 (10.7%)	6 (20.6%)	
New atrial fibrillation	3 (17%)	1 (3%)	0.0001

Table 7. Morbidity during TAVI in the self-expandable and the balloon-expandable groups.

	Balloon expandable group	Self-expandable group	P-value
Pneumonia	2 (6%)	1 (3%)	P = 0.460
Decompensate HF	1 (3%)	3 (10%)	P = 0.866
GIB	0	1 (3%)	P = 0.147
MI	1 (3%)	0	P = 0.089
Vascular complication	2 (6%)	2 (7%)	P = 0.892
sepsis	0	1	P = 0.272
Pericardial effusion			P = 0.651
moderate	2 (6%)	0	
sever	1 (3%)	1 (3%)	
LBBB	2 (6%)	3	P = 0.037
RBBB	1 (3%)	1 (3%)	P = 0.0001
CHB	3 (10%)	6 (21%)	P = 0.259

GIB = gastro intestinal bleeding; MI = myocardial infarction; RBBB = right bundle branch block; LBBB = left bundle branch block; CHB = complete heart block.

Moderate to severe Paravalvular leakage in both groups did not differ substantially either by immediate aortography after the procedure or echocardiography after seven days.

In the Choice study, unlike our research, the self-expanding Core Valve cases had a higher occurrence of moderate to severe paravalvular leakage compared to

the balloon-expanding Edwards SAPIEN group [11].

The differences between the choice study with our study may be due to the use of Evolute R in the self-expandable group which had a lot less paravalvular leakage (only 2 out of 10 Evolute R valves had moderate to significant paravalvular leakage). Moreover, unlike the choice study, in our study paravalvular leakage did not decrease after one week. It seems that echocardiography, due to the lack of precision to detect paravalvular leakage, may influence the results (**Table 8**).

The success rate of devices used in the procedure was 97%, with only one failure due to the device not passing through a severely calcified aorta. The average fluoroscopic time and amount of contrast used were comparable to similar research conducted in Italy and Germany [11].

The most common causes of mortality were myocardial infarction and decompensated heart failure after valve implantation. Upon closer examination of **Table 9**, it becomes evident that while TAVI was performed on only 28 patients (46.6%) from 2016 onwards, only one mortality (3%) was reported in these cases ($P < 0.05$). This suggests that as the TAVI team gained more experience in recent years, the mortality rate dropped dramatically.

The higher rate of mortality in our study may be due to the higher age and EuroSCORE as well as the lower ejection fraction of our patients, especially at the beginning of the study. However, two out of the three sepsis cases that led to death sparked more attention to sterilization and hygiene management pre-procedurally, and also the use of more potent antibiotics during and after the intervention.

Table 8. Mortality causes in self-expandable and balloon-expandable groups.

	Balloon-expandable	Self-expandable
Myocardial infarction	3	0
Sudden cardiac death	2	1
Decompensated heart failure	1	1
Intracranial hemorrhage	0	1
SEPSIS	0	2
CANCER	1	0

Table 9. Mortality rate regarding time and center.

	NUMBER (PERCENT)	P-VALUE
Rajaee heart center/Dey clinic	5 (41.6%)/7 (58.4%)	P > 0.05
Male/Female	11 (91.67%)/1 (8.33%)	P > 0.05
Self-expandable/Balloon-expandable	5 (41.6%)/7 (58.4%)	P > 0.05
Cardiac/Non-cardiac	8 (66%)/4 (34%)	P > 0.05
<3 month/>3 months	6 (50%)/6 (50%)	P > 0.05
2016-2017 mortality out of 28 procedures	1 (3%)	P > 0.05
2012-2016 mortality out of 32 procedures	11 (34%)	P > 0.05

5. Study Limitation

The lack of standard imaging for detecting paravalvular leakage was one of the limitations of this study. Additional limitations were incomplete patient sheets as well as a lack of scheduled and regular patient follow-ups. Finally, as this research studied the patients who underwent TAVI for the first time after this procedure's introduction in Iran, our sample size and their complication rate were also limited.

6. Conclusions

In conclusion, the balloon-expandable group (Edwards SAPIEN) did not have decreased paravalvular leakage in comparison with the self-expandable group (Core Valve and Evolute R).

The morbidity and mortality rates between the balloon-expandable and the self-expandable groups did not differ significantly.

Recommendations

It is highly recommended to conduct a study with a larger sample size and a longer follow-up period. It is also suggested to use stronger antibiotics before and after the procedure. In case of any signs of infection, consulting with infectious disease specialists is advised. Accurate evaluation of patients, especially during the initial weeks following the procedure, with regard to signs of decompensated heart failure, through echocardiography and regular patient follow-up can lead to lower mortality and morbidity rates.

Ethics Approval

All patients participating in this study provided written informed consent and the study was approved by the ethical committees of both participating centers. The study was performed in accordance with the declaration of Helsinki.

Authors' Contribution

Mohammad Nourizadeh was responsible for the study concept and design. All authors intercepted the data, drafted the manuscript, approved the final manuscript, and agreed to be accountable for all aspects of the work.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

References

[1] Shrivastava, S., Shrivastava, S., Mumtaz, K. and Mostafa, J.A. (2022) Evolving Indications of Transcatheter Aortic Valve Replacement Compared to Surgical Valve Replacement: A Review of the Current Literature. *Cureus*, **14**, e23364. https://doi.org/10.7759/cureus.23364

[2] Mahmaljy, H., Tawney, A. and Young, M (2022) Transcatheter Aortic Valve Replacement. StatPearls. StatPearls Publishing, Treasure Island.

[3] Jørgensen, T.H., Thyregod, H.G.H., Ihlemann, N., Nissen, H., Petursson, P., Kjeldsen, B.J., *et al.* (2021) Eight-Year Outcomes for Patients with Aortic Valve Stenosis at Low Surgical Risk Randomized to Transcatheter vs. Surgical Aortic Valve Replacement. *European Heart Journal*, **42**, 2912-2919. https://doi.org/10.1093/eurheartj/ehab375

[4] Leon, M.B., Smith, C.R., Mack, M.J., Makkar, R.R., Svensson, L.G., Kodali, S.K., *et al.* (2016) Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. *The New England Journal of Medicine*, **374**, 1609-1620. https://doi.org/10.1056/NEJMoa1514616

[5] Reardon, M.J., Van Mieghem, N.M., Popma, J.J., Kleiman, N.S., Søndergaard, L., Mumtaz, M., *et al.* (2017) Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients. *The New England Journal of Medicine*, **376**, 1321-1331. https://doi.org/10.1056/NEJMoa1700456

[6] Ali, N., Patel, P.A. and Lindsay, S.J. (2018) Recent Developments and Controversies in Transcatheter Aortic Valve Implantation. *European Journal of Heart Failure*, **20**, 642-650. https://doi.org/10.1002/ejhf.1141

[7] Mas-Peiro, S., Weiler, H., Mohr, G.-L., Papadopoulos, N., Zeiher, A., Fichtlscherer, S., *et al.* (2018) TCT-780 First Direct Comparison of the Self-Expandable Portico versus the Balloon-Expandable Sapien 3 Device for Trans-Catheter Aortic Valve Replacement: A Case-Matched Cohort Study. *Journal of the American College of Cardiology*, **72**, B311. https://doi.org/10.1016/j.jacc.2018.08.2011

[8] Barbanti, M., Yang, T.-H., Rodès Cabau, J., Tamburino, C., Wood, D.A., Jilaihawi, H., *et al.* (2013) Anatomical and Procedural Features Associated with Aortic Root Rupture during Balloon-Expandable Transcatheter Aortic Valve Replacement. *Circulation*, **128**, 244-253. https://doi.org/10.1161/CIRCULATIONAHA.113.002947

[9] Leon, M.B., Piazza, N., Nikolsky, E., Blackstone, E.H., Cutlip, D.E., Kappetein, A.P., *et al.* (2011) Standardized Endpoint Definitions for Transcatheter Aortic Valve Implantation Clinical Trials: A Consensus Report from the Valve Academic Research Consortium. *Journal of the American College of Cardiology*, **57**, 253-269. https://doi.org/10.1016/j.jacc.2010.12.005

[10] Null, N., Généreux, P., Piazza, N., Alu Maria, C., Nazif, T., Hahn Rebecca, T., *et al.* (2021) Valve Academic Research Consortium 3: Updated Endpoint Definitions for Aortic Valve Clinical Research. *Journal of the American College of Cardiology*, **77**, 2717-2746. https://doi.org/10.1016/j.jacc.2021.02.038

[11] Abdel-Wahab, M., Mehilli, J., Frerker, C., Neumann, F.-J., Kurz, T., Tölg, R., *et al.* (2014) Comparison of Balloon-Expandable vs Self-Expandable Valves in Patients Undergoing Transcatheter Aortic Valve Replacement: The CHOICE Randomized Clinical Trial. *JAMA*, **311**, 1503-1514. https://doi.org/10.1001/jama.2014.3316