Subject Area:

Transcatheter aortic valve implantation vs surgical aortic valve replacement in high-risk patients with aortic stenosis

Emad Sarawy
National Heart Institute(NHI), emadsarawy@gmail.com

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Emad Sarawy

Department of Cardiothoracic Surgery, National Heart Institute(NHI), Cairo, Egypt

Abstract

Objective
The aim was to demonstrate whether transcatheter aortic valve implantation (TAVI) improves mortality and morbidity compared with standard surgical aortic valve replacement (SAVR) in high-risk patients requiring intervention for aortic valve stenosis (AS). Many patients with severe AS and coexisting morbidity are not candidates for surgical replacement of the aortic valve (AV). TAVI has been suggested as an alternative less invasive treatment for high-risk patients with AS.

Patients and methods
A total of 50 patients with high-risk severe AS for AV intervention were classified into: GROUp A, the TAVI group, including 25 patients who underwent AV replacement via the transcatheter femoral approach and group B, the SAVR group, including 25 patients who underwent standard SAVR via median sternotomy.

Results
Intraoperatively, procedure duration was 101.8 ± 10.6 and 191.2 ± 7.5 min in group A and B, respectively ($P < 0.001$). Major vascular complications occurred in 20% of patients in group A vs 0% of patients in group B ($P = 0.018$). Postoperative follow-up, mean ICU stay was 3 ± 2.4 and 4.8 ± 3.5 days in group A and group B, respectively ($P = 0.035$). In group A, 32% of patients needed permanent pacemakers. In group A, 12% of patients developed stroke or transient ischemic attacks. Paravalvular aortic regurgitation occurred in 36.3 and 4.5% of patients in group A and group B, respectively ($P = 0.009$).

Conclusions
In high-risk patients with severe AS, transcatheter and surgical procedures for aortic-valve replacement were comparable for survival at 3 months, although there were important differences in periprocedural outcomes.

Keywords: Aortic valve stenosis, sternotomy, transcatheter aortic valve implantation

INTRODUCTION

Aortic stenosis represents an important issue of public health because of its bad prognosis and high prevalence, strongly linked to the phenomenon of population aging. The severe form of aortic stenosis when symptomatic, has high mortality rates and is therefore an indication for valvular replacement [1,2].

Surgical aortic valve replacement (SAVR) is the standard of care in the treatment of affected patients by alleviating symptoms and improving survival. Despite favorable results even among high-risk patients, surgical replacement is not performed in up to one-third of eligible patients, due to advanced age, comorbidities, previous cardiac surgery, concomitant coronary artery disease, and patient refusal [3,4].

In 2002, transcatheter aortic valve implantation (TAVI) was introduced as an option for this patient group, and it has been shown to reduce mortality and length of hospital stay. Although TAVI was originally designed to treat such a group of severe aortic stenosis patients at prohibitive risk of open heart surgery,

Correspondence to: Emad Sarawy, MD,
11571 Mokattam city, Cairo, Egypt 01227345248
E-mail: emadsarawy@gmail.com

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nowadays it is being performed worldwide, even in lower risk population [5,6].

Studies of TAVI have primarily been observational registries without control populations. In particular, there is little knowledge on the comparative operative and perioperative mortality and morbidity of high-risk patients undergoing TAVI compared with a conventional surgical approach [7]. Our study compared 3-month mortality rates and morbidities of patients with high-risk aortic stenosis patients treated with TAVI against a group of high-risk aortic stenosis patients who were surgically treated when TAVI was an inappropriate option for them for various reasons, including coronary anatomy, aortic annulus and root anatomy, peripheral vasculature, patient preference, and lack of funding.

PATIENTS AND METHODS

This study was approved by the Ethics Committee of the National Heart Institute. This prospective study was conducted on 50 patients in the National Heart Institute and Dar Al Fouad Hospital from March 2016 to June 2019. Informed consent was taken from each patient. All patients had severe aortic valve stenosis (AS) and were listed for aortic valve (AV) intervention. They were considered of high surgical risk based on risk profiling after calculating the European System for Cardiac Operative Risk (EuroSCORE) and Society of Thoracic Surgeons Predicted Risk of Mortality (STS PROM). Patients were classified into two groups: group A TAVI, including 25 patients who underwent AV replacement via transcatheter femoral approach and group B, SAVR, 25 patients who underwent AV replacement via standard median sternotomy. The patients were assigned to either of the procedure according to the decision of the heart team, which was composed of a cardiologist, a cardiac surgeon, an anesthesiologist, and an intensivist. The team assessed the demographic characteristics, health status prior to intervention, comorbidities, and the technical suitability for TAVI.

Exclusion criteria for TAVI were bicuspid AV, concomitant ischemic heart disease requiring revascularization, left ventricular ejection fraction (EF) 20% or less, severe aortic regurgitation, and severe mitral regurgitation.

Patient's medical history including age, sex, New York Heart Association classification, and preoperative risk factors were recorded. Echocardiography was done for all patients and assessment was done for all patients before procedure and after 3 months. The echocardiographic study postoperatively was done to assess paravalvular aortic regurgitation that was graded using all available parameters, including the circumferential extent of aortic regurgitation (AR) from multiple parasternal short-axis views, in accordance with the Valve Academic Research Consortium recommendations [8]: mild, moderate, and severe when the circumferential extent was less than 10, 10–20, greater than 20%, respectively. When there was more than 1 jet, the values of all regurgitation jets of more than or equal to mild were added. Echocardiography was used for the

assessment of EF, diameter of the left ventricle and AV mean pressure gradient (PG).

All SAVR patients received a bioprosthesis with the specific type and size determined during the procedure, which was performed through a standard midline sternotomy with cardiopulmonary bypass and systemic hypothermia. Calcified AV was excised, followed by implanting a new valve, using interrupted Ethibond sutures with Teflon pledget circumferentially. Patients who underwent TAVI received the CoreValve self-expanding bioprosthesis (Medtronic, Minneapolis, Minnesota, USA), via femoral artery. Using fluoroscopy, a guidewire was advanced to the aorta and a sheath was sutured to the puncture site. A balloon was advanced to the AV and balloon aortic valvuloplasty was performed. The delivery system was then advanced and the stent with the valve was aligned along the balloon within the aorta. All available CoreValve sizes (23, 26, 29, or 31 mm) were used. The procedure was performed under general anesthesia. All TAVI and SAVR patients received similar periprocedural prophylactic antibiotics and postoperative antiplatelet and anticoagulation regimes.

The overall mortality during hospital stay from the intervention was the primary endpoint. Secondary endpoints included overall mortality within 3 months and the incidence of stroke, defined as any new persistent neurological deficit; vascular complications, defined as any access site complication requiring surgical or percutaneous treatment, incidence of myocardial infarction, permanent pacemaker insertion and red blood cell transfusion were recorded.

Statistical analysis

The data were collected, tabulated, and statistically analyzed by the Statistical Package for Social Sciences (SPSS version 22.0; IBM Corp., Armonk, New York, USA) on IBM compatible computer. Two types of statistics were use. Descriptive statistics such as percentage, mean, and SD and analytic statistics such as χ^2 test were used to study the association between two qualitative variables and Fisher's exact test was used to study the association between two qualitative variables and at least one cell of expected was less than 5. Student's t-test is a test of significance used for comparison between two groups having normally distributed quantitative variables. Mann–Whitney test (U) (nonparametric test) is a test of significance used for comparison between two groups having non-normally distributed quantitative variables and paired t-test was used as a test of significance used for one group of units that has been tested twice (a 'repeated measures' t-test), that is, between two related normally distributed quantitative variables.

RESULTS

Baseline characteristics

There was no statistical difference between the two groups as regards the demographic characteristics. The mean age of the patients in group A was 76.1 ± 2.9 vs 75.5 ± 1.9 years in group B ($P = 0.14$). In both groups, 14 patients were

men (56%) and 11 were women (44%), with no statistical significance ($P = 1$) (Table 1).

Also, the echocardiographic data of both groups was comparable with a mean EF in group A being 56 ± 5.8 vs 58 ± 4.2% in group B, with no statistical significance ($P = 0.61$). AV mean PG in group A was 50.2 ± 9 mmHg while in group B, it was 50.6 ± 8.7 mmHg, with no statistical significance ($P = 0.87$) (Table 2).

Procedural data

The mean procedure duration was significantly lower in the TAVI group 101.8 ± 10.6 vs the the SAVR group 191.2 ± 7.5 min, with statistical significance ($P < 0.001$). Major vascular complications, including pelvic vessels dissection, aortic dissection, and access site hematoma was higher in the TAVI group. These complications occurred in five (20%) patients in group A vs none (0%) in group B; this resulted in statistical significance ($P = 0.018$). Major bleeding that resulted in hemodynamic instability and warranted immediate inotropic support and/or blood transfusion occurred in five (20%) patients in group A, in contrast to one (4%) patient only in group B, with no statistical significance ($P = 0.082$) (Table 3).

Clinical outcomes

Regarding postoperative follow-up data, patients in group A required 2.2 ± 2.3 transfused blood units, while in group B, patients required 3.6 ± 2.1 units, with statistical significance ($P = 0.023$). The mean ICU stay was 3 ± 2.4 and 4.8 ± 3.5 days in group A and group B, respectively, which has resulted in statistical significance ($P = 0.035$). In group A, eight (32%) patients developed conduction abnormalities requiring permanent pacemaker vs two (8%) patients in group B, with statistical significance ($P = 0.034$). In group A, three (12%) patients developed stroke/transient ischemic attacks (TIAs), in contrast to no patients (0%) in group B, with statistical significance ($P = 0.037$) (Table 3).

As regards 3-months follow-up data; one (4.3%) patient needed repeat hospitalization for noncardiac reasons, while in group B, two (8.7%) patients needed repeat hospitalization. There was no statistical significance ($P = 0.55$) regarding 3-month mortality, one patient in each group (4.3%) passed away, with no statistical significance ($P = 1$) (Table 4).

Echocardiographic outcomes

Three-month follow-up echocardiographic data: AV mean PG was 9.6 ± 2.9 and 12.8 ± 1.6 mmHg in group A and group B, respectively. This was statistically significant ($P < 0.001$). Paravalvular aortic regurgitation occurred in eight (36.3%) patients and in one (4.5%) patient in group A and group B, respectively. This finding was statistically significant ($P = 0.009$) (Table 5).

DISCUSSION

Prognosis in patients with severe, symptomatic high-grade aortic stenosis is poor if treated medically. Surgical valve replacement can be done at low operative risk in patients

Table 1: Sociodemographic characteristics and anthropometric measurements of studied groups

Parameters	Group A (n=25) [n (%)]	Group B (n=25) [n (%)]	P
Age (years)			
Mean±SD	76.1±2.9	75.5±1.9	0.14
Sex			
Male	14 (56)	14 (56)	1
Female	11 (44)	11 (44)	
Cigarette smokers	10 (40)	8 (32)	0.55
BMI (kg/m²)			
Mean±SD	26.7±3.8	27.3±3.6	0.54
Diabetic on insulin	6 (24)	7 (28)	0.55
Hypertensive	15 (60)	20 (80)	0.12
Renal impairment with			
Creatinine level >2 mg/dl	3 (12)	2 (8)	0.63
Dyspnea			
NYHA class II	2 (8)	1 (4)	0.55
NYHA class III, IV	23 (92)	24 (96)	0.55
Angina			
CCS class II	5 (20)	7 (28)	0.5
CCS class III, IV	10 (40)	11 (44)	0.77
Logistic EuroSCORE	17.8±7.7	18.3±7.1	0.59
STS score	8.9±3.9	9.1±3.5	0.63

CCS, Canadian Cardiovascular Society; EuroSCORE, European System for Cardiac Operative Risk; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons

Table 2: Comparison between studied groups regarding pre-operative echo data

Parameters	Group A (n=25) (mean±SD)	Group B (n=25) (mean±SD)	P
LVEDD (cm)	5.2±0.3	5±0.5	0.07
LVESD (cm)	3.5±0.3	3.5±0.3	0.62
EF (%)	56±5.8	58±4.2	0.61
AV mean PG (mmHg)	50.2±9	50.6±8.7	0.87
AVA (cm)	0.7±0.2	0.6±0.2	0.16
Aortic root (cm)	2.9±0.4	3.1±0.4	0.11

AV, aortic valve; EF, ejection fraction; LVEDD, left ventricle end diastolic diameter; LVESD, left ventricle end systolic diameter; PG, pressure gradient; AVA, aortic valve area.

without significant comorbidities. However, with increasing age and increasing comorbidities surgical operative mortality has been reported to increase significantly [7].

Previously, SAVR was the only effective treatment, but after being introduced in 2002, TAVI became an option for certain patients with severe symptomatic AS that was considered inoperable or in patients at high risk for surgical complications [9].

More recently, observational studies have demonstrated acceptable mortality outcomes in low and intermediate risk patients [10,11]; however, few randomized clinical trials have been conducted in a high-risk patient population [12].

Table 3: Comparison between studied groups regarding procedure data and postoperative clinical outcomes

Parameters	Group A (n=25) [n (%)]	Group B (n=25) [n (%)]	P
Procedure duration (min) (mean±SD)	101.8±10.6	191.2±7.5	<0.001*
Procedure complications			
Major vascular complications	5 (20)	0	0.018*
Major bleeding	5 (20)	1 (4)	0.082
Inotropic support	15 (60)	10 (40)	0.19
Blood transfusion, number of units (mean±SD)	2.2±2.3	3.6±2.1	0.023*
ICU stay (days) (mean±SD)	3±2.4	4.8±3.5	0.035*
New-onset or worsening AF	3 (12)	6 (24)	0.26
Permanent pacemaker	8 (32)	2 (8)	0.034*
Acute Renal Injury	3 (12)	2 (8)	0.63
Stroke and/or TIAs	4 (16)	0	0.037*
Wound Infection	3 (12)	3 (12)	1
Hospital stay (days) (mean±SD)	6.8±2.5	7.4±3.8	0.54
Mortality	2 (8)	2 (8)	1

AF, atrial fibrillation; TIAs, transient ischemic attacks.*Statistically significant difference.

Table 4: Comparison between survivors in studied groups regarding 3-month postoperative data

Parameters	Group A (n=23) [n (%)]	Group B (n=23) [n (%)]	P
Repeat hospitalization	1 (4.3)	2 (8.7)	0.55
Dyspnea			
NYHA class II	2 (8.6)	1 (4.3)	0.55
NYHA class III, IV	0	0	1
Angina			
CCS class II	1 (4.3)	2 (8.6)	0.55
CCS class III, IV	0	0	1
Mortality	1 (4.3)	1 (4.3)	1

CCS, Canadian Cardiovascular Society; NYHA, New York Heart Association.

In our study, there was no significant difference between the two groups regarding the demographic data and preoperative comorbidities. There was also no significant difference between the two groups regarding preoperative left ventricular end-diastolic diameter (LVEDD) and left ventricular end-systolic diameter (LVESD) as well as EF. Our preoperative LV study is similar to that of Little et al.[13] who reported high surgical risk in their patients.

Our study showed that the mean procedure duration in group A was shorter than group B, with statistical significance. This finding was also reported by Thyregod et al. [12]. In their study, the mean procedure time in the TAVI group was 90.3 ± 38.6 and 177.2 ± 39.8 min in the SAVR group. However, less consumed time was reported in both procedures in their study and can

be attributed to more experience as well as a larger number of cases operated upon at the center where they conducted their study.

One more statistically significant operative finding in our study was major vascular complications whose incidence in group A was more than in group B. This finding coincides with Leon et al.[5] who reported 16.2% in the TAVI group and 1.1% in the SAVR group. Deeb et al.[14] had also endorsed the same finding in their study, reporting 7% in the TAVI group and only 2% in the SAVR group.

Regarding postoperative blood transfusion, patients in group A needed less blood transfusion than patients in group B, with statistical significance. Tamburino et al.[15] had also reported statistical significance when it came to comparing the mean number of transfused blood units in their two groups, with a mean of 2.3 ± 2.2 units in the TAVI group and 3.6 ± 3.6 units in the SAVR group.

Mean ICU stay in our study in group A was shorter than group B, with statistical significance. Stöhr et al.[7] in their study that they had conducted between 2008 and 2010, reported statistical significance as well, when they compared mean ICU stay. Patients in the TAVI group had a mean of 3.3 ± 3.1 days, while those in the SAVR group stayed in ICU for 6.6 ± 10.5 days. This can arouse mind that the more experience in care for those critical patients which was gained over the years in addition to advances in medical technology have contributed to shortening the ICU stay after either TAVI or SAVR. On the other hand, Tamburino et al.[15] had reported no statistical significance, comparing the mean ICU stay in TAVI and SAVR groups, though the ICU stay in their TAVI group was quite close to ours, with a mean of 3.2 ± 4.7 days. However, the mean ICU stay of patients in the SAVR group was 3.8 ± 7.7 days.

In our study, more patients in group A required postoperative permanent pacemaker insertion in eight (32%) patients than patients in group B two (8%) patients with statistical significance (P = 0.034). Thyregod et al.[12] had reported the same statistical significance, when they compared 34.1% of patients in the TAVI group to 1.6% in SAVR group, who necessitated postoperative permanent pacemaker insertion. D'Errigo et al.[6] had also reported 16% of patients in the TAVI group and 0.8% of patients in the SAVR group who needed permanent pacemaker insertion, resulting in statistical significance.

Stroke and/or TIAs have complicated the postoperative course of more patients in group A than patients in group B and this was of statistical significance. Smith et al.[16] had also described statistical significance when they compared the incidence of either postoperative stroke or TIAs in 5.5% of patients in the TAVI group and 2.4% of patients in the SAVR group. Kodali et al.[17] had also delineated in their study the incidence of stroke/TIAs in 8.7% and 4.3% of patients in TAVI and SAVR groups, respectively, with statistical significance.

Table 5: Comparison between survivors in studied groups regarding 3-month postoperative echo data

Parameters	Group A (n=22) (mean±SD)	Group B (n=22) (mean±SD)	P
LVEDD (mmHg)	5.1±0.3	4.9±0.4	0.061
LVESD (mmHg)	3.5±0.4	3.3±0.3	0.062
EF % (mmHg)	56.8±6.6	58.7±7	0.31
AV mean PG (mmHg)	9.6±2.9	12.8±1.6	<0.001*
Paravalvular aortic regurgitation [n (%)]	8 (36)	1 (4.5)	0.009*

AV, aortic valve; EF, ejection fraction; LVEDD, left ventricle end diastolic diameter; LVESD, left ventricle end systolic diameter; PG, pressure gradient.*Statistically significant difference.

The same number of patients in both groups had passed away, and this comparable rate between the two groups did not get any statistical significance. Leon et al.[5] had also found no statistical significance. The rate was 9% in their TAVI group and 2.8% in SAVR group. Stöhr et al.[7] had also described no statistical significance when they compared the mortality rates in TAVI and SAVR groups which were 12 and 7.6%, respectively. Leon et al.[5] and Stöhr et al. [7]. had attributed the early mortality to cardiac causes. In our study, we have also found that the cause of death of the four patients was persistent low cardiac output in spite of maximal inotropic support.

During the 3-month follow-up in our study, one patient in group A died of stroke, while another patient in group B died of cerebral hemorrhage. There was no statistical significance. Thyregod et al.[12] had found no statistical significance neither when they compared mortality in the two groups of their study, reporting 2.1% in TAVI group and 3.7% in SAVR group.

Regarding the 3-month follow-up echocardiography, AV mean PG in group A was less than that in group B and this has resulted in a statistically significant difference. This goes in agreement with Little et al.[13] who noted that TAVI had resulted in a lower AV mean PG (9.1 ± 3.5 mmHg), compared with the SAVR group (12.4 ± 7.4 mmHg). They had also reported a statistically significant difference comparing both groups. These observations are also consistent with D'Errigo et al.[6] who reported a mean AV mean PG of 10.8 ± 6.4 mmHg in TAVI group that was lower than the mean of 13.6 ± 8.6 mmHg in SAVR group, with statistical significance.

Regarding postoperative AV regurgitation in our study, more patients in group A experienced paravalvular regurgitation (eight patients, 36%) patients, than in group B only one (one patient, 4.5%). This resulted in a statistical significant difference. This may be due to the severe extensive calcification of those studied high-risk patients; in group B (SAVR) decalcification was done surgically before valve implantation, while in group A (TAVI), no decalcification and the valve got implanted over calcification leading to higher incidence of paravalvular leak and regurgitation.

These findings are consistent with D'Errigo et al.[6] who had reported the incidence of paravalvular regurgitation in 39.1% of patients in TAVI group and 11.2% in SAVR group, with statistical significance.

Limitations

Small sample size, was one of the limitations we encountered in our study as our trial aimed to compare TAVI vs SAVR and therefore excluded patients with significant coronary artery disease. The high cost of TAVI was a considerable reason that made several patients prefer to undergo conventional surgery, even though they were suitable candidates for TAVI.

Interobserver variability in the interpretation of echocardiographic finding was another limitation in our study, especially when evaluating the degree of postoperative paravalvular regurgitation.

Short-term follow-up in our study was considered a limitation as longer term studies will determine the long-term durability of transcatheter and surgical AVs and may reveal additional parameters associated with mortality hazard that were not significant at 3 months.

CONCLUSION

A 3-month follow-up of high-risk surgical patients with severe AS supports TAVI as an alternative to surgery. The two treatments were similar with respect to mortality, but paravalvular regurgitation, vascular complications, stroke/TIAs, and permanent pacemaker insertion were more frequent after TAVI.

Conflicts of interest
There are no conflicts of interest.

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