



Manuscript ID

ZUMJ-1911-1626 (R1)

DOI

10.21608/zumj.2020.19760.1626

ORIGINAL ARTICLE

Predictors of Outcomes of Transcatheter Aortic Valve Implantation in Patients with Severe Aortic Stenosis

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Submit Date 2019-12-13

Revise Date 2019-12-31

Accept Date 2020-01-07

ABSTRACT

Background: Trans-catheter aortic valve implantation (TAVI) was appeared as a suitable alternative to surgical valve replacement for patients having severe aortic valve stenosis in the presence of other co-morbidities, which can make surgery a high-risk, this study aimed to assess the efficacy, early and after 6 months' outcome of trans-catheter aortic valve implantation in patients having severe aortic stenosis and at high operative risk for surgical valve replacement

Methods: 36 Patients with severe symptomatic aortic stenosis and high risk for conventional surgical aortic valve replacement admitted to National Heart Institute during the period from February 2013 till February 2019 were included in the study.

Results: Out of 36, None to trace prosthetic aortic regurgitation was found and no patients had severe prosthetic aortic regurgitation. After six months, 4 patients died. 4 patients (11.1%) developed CHB need PPM and 5 patients (13.9%) developed new LBBB

Conclusions: TAVI is a safe and effective procedure and can be considered as a viable alternative to conventional open-heart surgery in selected high-risk patients with severe symptomatic aortic stenosis

Keywords: Trans-catheter aortic valve Implantation, Aortic stenosis, aortic valve replacement



INTRODUCTION

TAVI is accepted as alternative to surgical valve replacement in patients with severe aortic stenosis and associated with adverse features (advanced age, impaired left ventricular function), or when surgery may be associated with unfavorable results [1]. In 2002, Cribier [2] did the first case by using a balloon expandable valve. Two devices are available in Europe, the balloon-expandable (Edwards SAPIEN_ prosthesis and the self-expandable (CoreValve) prosthesis. Multi-detector computed tomography (MDCT) is the chosen imaging modality, providing comprehensive details about an individual patient's anatomy. In particular, the aortic valve calcification degree is important anatomical factor affecting procedural results. Severe calcification of the aortic valve is associated with increased risk of annular rupture, conduction system disturbances [3], and residual aortic valve regurgitation [4]. TAVI succeeded in decreasing mortality and improving life quality in patients at prohibitive risk of surgical aortic valve replacement. These results

had earlier been supported by large prospective registries [5], there has been an exponential increase in TAVI procedures across the globe with speculations of its extension to a low-risk population. However, despite the progress made, many potential TAVI limitations need to be minimized before application this approach [6].

METHODS

36 Patients with severe symptomatic aortic stenosis and high risk for conventional surgical aortic valve replacement as predetermined according to the EUROSCORE II admitted to Zagazig university hospital and National Heart Institute during the period from February 2013 until February 2019 were included in the study. Consent of acceptance of sharing in our study was taken from each patient. The research ethical committee of Faculty of Medicine, Zagazig University approved our study. The study was carried out according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Inclusion Criteria: Patient with severe

symptomatic aortic stenosis and at high risk for valve surgery (Euro SCORE is 15 to 20%).

Exclusion Criteria: Femoral, iliac, or Aortic disease hampering catheterization, Aortic Aneurysm, Coagulopathy, Myocardial infarction or cerebro-vascular accidents within 1 month, Mitral valvular insufficiency of severe degree, Left ventricular or atrial thrombus, Previous aortic valve replacement, Sepsis or active endocarditis, Hypersensitivity or contra-indication to any medication used in the study, Congenital Aortic valve (Bicuspid and unicuspid), Supra-aortic and sub-aortic stenosis, Patients who had did trans-apical TAVI, Aortic Annular diameter < 19 mm or > 27mm or The patients with an expected life span less than 1 year due to comorbidities.

METHODS

The patients were subjected to full history taking, clinical examination, and imaging studies. Imaging studies included echocardiography, 12 lead surface ECG, multi-slice computed tomography (CT) scan and Aortography. Transthoracic echocardiography was used for assessment of Valve anatomy, valve calcification; Trans aortic jet velocity and left ventricular ejection fraction before and three months after the procedure using Simpson's method. During the procedure, trans-esophageal echocardiography (TEE) has been used for measuring the dimensions of the aortic root and the size of the aortic annulus to aid in accurate positioning of the prosthetic valve before deployment. We used TEE after TAVI to assess the presence and grade of para-valvular leak; we also assessed the patency of the coronary arteries and to exclude presence of complications. Multi-slice computed tomography (CT)-scan was done before TAVI to evaluate the aortic root, ascending and abdominal aorta and iliac-femoral axis for patients without contraindications. MSCT, also, provided greater appreciation of vessel size, tortuosity and calcific burden and measurement of the aortic valve annulus and measurement distance to the coronary ostium. Aortography was performed at the start of procedure and repeated to adjust the prosthesis in true place and to assess the coronary arteries patency and assess the presence and grade of aortic regurgitation and aortic dissection. Finally, follow up to the patients was done immediately after the procedure, during hospitalization, at 30 day and at 6-month duration.

Statistical analysis:

Data were analyzed using the Statistical Package for Social Sciences (SPSS) release 16. Data showing normal distribution were presented as the means and standard deviation. For comparison between the means of two groups, the t-test was used. The non-parametric values were tested using

the Mann–Whitney-U test. Qualitative data are represented by frequency and relative percentage and chi-square test was used for testing the association of the qualitative data. In all analyses, *P* values <0.05 were considered statistically significant.

RESULTS

This study was carried on 36 patients had severe symptomatic aortic stenosis and high risk for conventional surgical aortic valve replacement 17 females (47.2%), and 19 males (52.8%), their ages ranged from 65 to 81 years with a mean age 69.6 ± 3.7 . The mean of weight and BMI were 86.8 ± 13.2 and 29.4 ± 6.1 respectively (Table 1).

The data of overall outcomes are presented in Table 2. Four mortality (11.1%) occurred after the procedure. Two patients (5.6%) developed CVA, two patients (5.6%) developed myocardial infarctions. Eight patients (22.3%) developed bleeding (6 patients developed minor bleeding and 2 patients developed major bleeding), 4 patients (11.1%) developed minor vascular complications and 2 patients (5.6%) developed major vascular complications. 4 patients (11.1%) developed CHB need PPM and 5 patients (13.9%) developed new LBBB. Four patients (11.1%) developed new onset AF, no valve migration occurred. No urgent surgery was needed (Table 2).

The differences between deaths and survivors in terms of clinical history and status, ECG and echocardiographic data before TAVI are summarized in Table 3. There was a significant difference between deaths and survivors regarding PAD and IHD, NYHA functional class II and III & IV, creatinine clearance less than 60 ml/ min and EF (Table 3)

The differences between deaths and survivors in terms of overall outcomes are presented in table 4. There was a significant difference between deaths and survivors regarding major bleeding and major vascular complications (Table 4).

There was a significant difference between patients with AR and those without regarding aortic annulus, porcelain aorta (extensive calcification of the ascending aorta or aortic arch that can be completely or near completely circumferential) and used valve size while there was no significant difference regarding valve type (Table 5).

There was a significant difference between patients who developed disturbances of conduction system and those who didn't regarding RBBB while there was no significant difference regarding other ECG data. Also, there was a significant difference regarding valve type while there was no significant difference regarding valve size (more significant core valve) (Table 6).

Table (1): baseline demographic data of the whole study population.

Demographic data		All patients
Count (%)		36 (100%)
Gender		
Male		19 (52.8%)
Female		17 (47.2%)
Age (years)		
Mean ± SD		69.6 ± 3.7
Median (Range)		69 (65 – 81)
Weight (kg)		
Mean ± SD		86.8 ± 13.2
Median (Range)		86.5 (56 – 113)
BMI (kg/m ²)		
Mean ± SD		29.4 ± 6.1
Median (Range)		28.9 (17.8 – 41.0)
Clinical history		
HTN		25 (69.4%)
DM		14 (38.9%)
Smoking		12 (33.3%)
COPD		7 (19.4%)
PAD		8 (22.2%)
CVA		4 (11.1%)
IHD		16 (44.4%)
Cancer		2 (5.6%)
Mediastinal radiation		2 (5.6%)

Table (2): overall outcome of the whole study population.

Overall outcome	All patients
Count (%)	36 (100%)
Death	4 (11.1%)
CVA	2 (5.6%)
MI	2 (5.6%)
Bleeding	8 (22.3%)
Minor	6 (16.7 %)
Major	2 (5.6%)
Vascular complications	6 (16.7 %)
Minor	4 (11.1%)
Major	2 (5.6%)
Conduction disturbances	9 (25%)
CHB need PPM	4 (11.1%)
New LBBB	5 (13.9%)
New onset AF	4 (11.1%)
Valve migration	0 (0%)
Urgent surgery	0 (0%)

Table (3): Comparison between the deaths and survivors regarding clinical history and status, ECG and echocardiographic data before TAVI.

	Deaths	Survivors	Test	P-value (Sig.)
Count	4	32		
Clinical history				
HTN	3 (75%)	22 (68.8%)	‡ ^F	1.00 (NS)

	Deaths	Survivors	Test	P-value (Sig.)
Count	4	32		
DM	2 (50%)	12 (37.5%)	‡ ^F	0.634 (NS)
Smoking	3 (75%)	9 (28.1%)	‡ ^F	0.098 (NS)
COPD	2 (50%)	5 (15.6%)	‡ ^F	0.163 (NS)
PAD	3 (75%)	5 (15.6%)	‡ ^F	0.028 (S)
CVA	2 (50%)	2 (6.3%)	‡ ^F	0.053 (NS)
IHD	4 (100%)	12 (37.5%)	‡ ^F	0.031 (S)
Cancer	1 (25%)	1 (3.1%)	‡ ^F	0.213 (NS)
Mediastinal radiation	1 (25%)	1 (3.1%)	‡ ^F	0.213 (NS)
NYHA functional class				
NYHA II	0 (0%)	20 (62.5%)	‡ ^F	0.031 (S)
NYHA III & IV	4 (100%)	12 (37.5%)		
Renal functions				
Creatinine clearance < 60 mL/min	3 (75%)	6 (18.8%)	‡ ^F	0.041 (S)
EF (%)				
Mean ± SD	48.0 ± 16.1	58.3 ± 5.7	-2.676 *	0.011 (S)
AVA (cm ²)				
Mean ± SD	0.69 ± 0.21	0.72 ± 0.10	-0.454 *	0.653 (NS)
AV mean PG (mmHg)				
Mean ± SD	51.8 ± 14.9	54.9 ± 7.4	-0.704 *	0.486 (NS)
AR				
No AR	2 (50%)	8 (25%)	0.084 ‡	0.772 (NS)
Grade I	1 (25%)	21 (65.6%)		
Grade II	1 (25%)	3 (9.4%)		

Table (4): Comparison between the deaths and survivors regarding the overall outcome.

Overall outcome	Deaths	Survivors	Test	P-value (Sig.)
Count	4	32		
CVA	0 (0%)	2 (6.3%)	‡ ^F	1.00 (NS)
MI	0 (0%)	2 (6.3%)	‡ ^F	0.390 (NS)
Bleeding	3 (75%)	5 (15.6%)	‡ ^F	0.028 (S)
Minor	1 (25%)	5 (15.6%)	‡ ^F	0.535 (NS)
Major	2 (50%)	0 (0%)	‡ ^F	0.010 (S)
Vascular complications	3 (75%)	3 (9.4%)	‡ ^F	0.010 (S)
Minor	1 (25%)	3 (9.4%)	‡ ^F	0.390 (NS)
Major	2 (50%)	0 (0%)	‡ ^F	0.010 (S)
Conduction disturbances	1 (25%)	8 (25%)	‡ ^F	1.00 (NS)
CHB need PPM	1 (25%)	3 (9.4%)	‡ ^F	0.390 (NS)
New LBBB	0 (0%)	5 (15.6%)	‡ ^F	1.00 (NS)
New onset AF	1 (25%)	3 (9.4%)	‡ ^F	0.390 (NS)
AR	1 (25%)	15 (46.9%)	‡ ^F	0.613 (NS)
Valve migration	0 (0%)	0 (0%)	-	-
Urgent surgery	0 (0%)	0 (0%)	-	-

Table (5): Comparison between patients with AR and those without regarding the MSCT data and the procedural data.

MSCT data and procedural data	AR	No AR	Test	P-value (Sig.)
Count	20	16		
Aortic annulus (mm)				
Mean ± SD	23.6 ± 1.1	22.2 ± 0.8	4.301 *	<0.001 (HS)
Porcelain aorta				
No	14 (70%)	16 (100%)	‡ ^F	0.024 (S)
Yes	6 (30%)	0 (0%)		
Valve type				
CoreValve	11 (55%)	11 (68.8%)	0.707 ‡	0.400 (NS)
Edwads SAPIEN	9 (45%)	5 (31.3%)		
Valve size				
23 mm	5 (25%)	0 (0%)	9.000 ‡	0.029 (S)
26 mm	14 (70%)	10 (62.5%)		
29 mm	1 (5%)	5 (31.3%)		
31 mm	0 (0%)	1 (6.3%)		

Table (6): Comparison between patients who developed conduction disturbances and those who didn't regarding ECG and the Procedural data.

ECG & procedural data	Conduction disturbances	No conduction disturbances	Test	P-value (Sig.)
Count	9	27		
ECG data				
AF	1 (11%)	4 (14%)	‡ ^F	0.302 (NS)
LBBB	2 (22.2%)	4 (14.8%)	‡ ^F	0.627 (NS)
RBBB	4 (44.4%)	1 (3.7%)	‡ ^F	0.009 (S)
Valve type				
CoreValve	7 (78%)	15 (55%)	‡ ^F	0.041 (S)
Edwads SAPIEN	2 (22%)	12 (45%)		
Valve size				
23 mm	1 (11.1%)	4 (14.8%)	5.956 ‡	0.114 (NS)
26 mm	4 (44.4%)	20 (74.1%)		

DISCUSSION

TAVI is relatively a new line of treatment in interventional cardiology but it achieve more space in the past 20 years and the improving results allowed more use of TAVI for patients with severe symptomatic aortic stenosis and high risk surgical aortic valve replacement [7].

Improving the valve profile of the two commercially available valves with new generation of the Edward's valve (Sapien III) and the new version of the Core Valve (The Core-Valve Evolut R with EnVeO R delivery catheter) also reduced the complications especially the vascular complications and subsequent bleeding, both reduce the total and cardiovascular mortality.

Our study provides an easy and simplifying application for predicting TAVI procedure complications (death, para-valvular leak and

conduction disturbance). Our study included 36 patients with severe AS with mean age is 69.6 ± 3.7. 52.8% patients were males and 47.2% were females. The mean of weight and BMI were 86.8 ± 13.2 and 29.4 ± 6.1 respectively.

Our study found that there has been a significant difference among deaths and survivors regarding PAD. In agreement with our study, Fanaroff et al [8] showed that nearly 1 in every 4 patients undergoing TAVR via trans-femoral access, and nearly half of patients undergoing TAVR via non trans-femoral access, do have PAD. Patients having PAD undergoing trans-femoral TAVR reported a higher prevalence of death, readmission, MI, and bleeding during 1-year follow-up opposite to patients without PAD. However, among patients undergoing non trans-femoral TAVR, patients with PAD do not have a greater risk of 1-year death or

readmission than patients without PAD.

Our study reported that CAD was significant in death group. In agreement with our study, Dewey et al,[9] They reported the outcomes on 171 patients based on CAD status and found that presence of CAD was the most significant factor associated with 30-day and one year mortality. In disagreement with our study, Piotr Chodór et al,[10] showed that The short- and mid-term outcomes of TAVI patients with CAD, despite higher risk profile, did not differ from the outcomes of treatment in patients without CAD. Stefanini et al,[11] showed that it is the severity and complexity of coronary artery disease (higher Syntax scores) that showing more prognostic implications in the TAVR outcomes rather than mere presence of CAD. With assessing the clinical status of the patients in our study we found that death was more in group with NYHA III/IV. All patients in deaths group was NYHA III & IV while there were 12 patients (37.5%) in survival group with statistically significant difference among deaths and survivors regarding NYHA functional class. This was in concordance with The FRANCE-2 registry [12], which reported that NYHA functional class III/IV at baseline was found to be a predictor of late mortality in the current study and was associated with 1-year mortality.

There was also significant difference between deaths and survivors regarding the creatinine clearance less than 60 ml/min. This was concordant with Sinning et al. [13] who found that patients with CKD reported significantly higher frequencies of AKI, bleeding, in addition to mid-term mortality after TAVI and Post-procedural stroke.

Regarding our study, there was no significant difference between deaths and survivors regarding patients' Euro SCORE and STS score. This was discordant with Codner et al., [14] who assessed the mortality risk after TAVI in which there was a significant difference between deaths and survivors in patients with higher Euro SCORE and STS scores. Kofler et al, [15] who assessed The Euro SCORE II and the STS score as independent predictors of 30-day and cumulative mortality rates in patients undergoing TAVI, also stated that there was a statistically significant difference regarding patients' Euro SCORE, STS score between both survivor and deaths groups. Tamburino et al, [16] showed that the mean logistic Euro SCORE for patients who died was $24.9 \pm 15.1\%$ compared with $22.6 \pm 13.4\%$ for patients who survived ($P=0.13$). The discriminative facility of the logistic Euro SCORE to anticipate the risk for 30-day as well as 1-year mortality was limited. Wendt et al, [17] showed that The value of risk-scoring model (Euro

SCORE and STS score) might be further limited, in that these models have been created and assessed in different countries with differing attention on certain comorbidities and neglecting other several comorbidities. Accordingly, the different weighting of risk factors and co-morbidities within each model caused such variability in risk scoring. Our study showed a significant difference between deaths and survivors regarding EF%, as incidence of death was more in group with less EF%. The association between depressed LVEF and clinical outcomes post-TAVR is controversial. While some reports have revealed an association concerning depressed LVEF and poor results as Urena et al, [18]; others for example the PARTNER trial [19] failed to show this association. Variations in inclusion criteria and the cut off values used for defining low LVEF may explain these differences. Emerging evidences suggest that LVEF itself may not accurately represent the actual extent of myocardial dysfunction in patients with severe AS. Rather, a reduced trans-aortic flow may be a more important prognostic factor. Thus, several studies have identified a pre-procedural lower trans-valvular gradient as an important marker of poor outcomes post-TAVR [20]. More recently, a low-flow state (defined as stroke volume index ≤ 35 mL/m²) has been associated independently with a greater rate of mortality after TAVR irrespective of LVEF. In patients with depressed LVEF (LVEF $\leq 40\%$), aortic valve area ≤ 1.0 cm², and a low trans-valvular gradient (trans-valvular gradient < 40 mmHg), it remains very important to assess the presence/absence of contractile reserve as a means of further risk-stratification [21].

In the current study, we reported a significant difference between deaths and survivors regarding procedural vascular complications (VCs) and bleeding. This was in agreement with PARTNER study, which proved that major post-procedural VCs increased late mortality by more than 1.5-times [22]; as vascular complications have been associated with bleeding, blood transfusion, procedure prolongation, more contrast injection, renal impairment, infection and prolonged hospitalization.

There was a significant difference regarding the used valve size due to under sizing the valve in relation to aortic annulus size which lead to incomplete apposition of the prosthesis to aortic annulus, while there was no significant difference between patients with, versus those without, para-valvular AR concerning closure device, approach site or valve type. This was concordant to Stähli et al, [23]. In disagreement with our study, Hayashida et al, [24] showed the incidence of significant AR was more with the use of the Core-Valve. The

actual reason for this has not been identified; however, the fact that the operators were less experienced in the use of the Core-Valve (53 of 400 patients) may have had an impact on the higher incidence of significant AR in addition to the fact that the Core-Valve is generally used in patients with a larger annulus. This valve selection bias could have impacted these results.

Regarding ECG data, our study stated that there was statistically significant difference concerning RBBB while there was no statistically significant difference concerning AF and LBBB. Lenders et al, [25] stated that pre-existing RBBB and pre-existing 1st degree AV-block confirmed to be strong predictors of the need for new permanent pacemaker implementation.

In the present study there was a significant difference between patients who developed conduction disturbances and those who didn't regarding valve type (more significant Core-Valve) as Core-Valve prosthesis is progressively deployed from its ventricular side exerting high radial forces in the LVOT (often deeper than balloon-expandable valves). Erkapic and colleagues, [26] evaluated 32 studies (from April 2002 to April 2011). Among 2887 Edwards THV and 2371 Core-Valves, the incidence of a new pacemaker implant after TAVR was 6.5% and 25.8%, respectively (odds ratio [OR] 4.91, 95% confidence interval [CI] 4.12-5.86, $P < 0.001$). In seven non-randomized studies that implanted both Edwards THV and Core-Valve, the risk of a pacemaker implant was 3.7 times higher for Core-Valve than Edwards THV. A new onset of LBBB increased and the incidence of LBBB was almost 6 times higher after Core-Valve (29-65%) than Edwards THV implant (4-18%) [27].

CONCLUSION

Certain preoperative risk factors and postoperative complications can predict patients' outcome after TAVI. PAD, IHD, NYHA III/IV, renal impairment, low EF, post-procedural major bleeding and vascular complications are associated with higher mortality. Larger aortic annulus, porcelain aorta and smaller prosthesis size are associated with higher para-valvular leak. Patients with RBBB and Core-Valve implantation are associated with higher incidence of conduction disturbances and pacemaker implantation.

Conflict of Interest: None.

Financial Disclosures: None.

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To Cite

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