

Incidence, Outcomes and Predictors of Aortic Regurgitation After Transcatheter Aortic Valve Replacement in Al Azhar University Hospitals and National Heart Institute, Egypt

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Abstract

Background: Aortic regurgitation (AR), which has ill-defined predictors and an unknown long-term influence on outcomes, is a significant transcatheter aortic valve replacement (TAVR) constraint.

Objective: this research aimed to assess the prevalence, identify predictors, and evaluate the outcomes of aortic regurgitation following trans catheter aortic valve implantation (TAVI).

1. To calculate the prevalence of aortic regurgitation in elderly patients receiving trans catheter aortic valve implantation who have severe symptomatic aortic stenosis.
2. To determine aortic regurgitation risk factors after trans catheter aortic valve implantation.

Methods: From November 2017 to November 2020, this prospective observational study was done in the National Heart Institute on severe aortic valve stenosis patients above 65 years who were candidates for aortic valve replacement from the outpatient department.

Results: LVEF significantly improved. Compared to before TAVI (55.08 ± 9.71), LVEF elevated to 58.9 ± 8.8 ($P < 0.001$). Twenty-five patients (83.3%) showed class III/IV, four patients (13.3%) showed class II, and one patient (3.3%) showed class I before TAVI. While after TAVI, three patients (10%) only showed NYHA class III/IV, six patients (20 %) in class II, and 21 patients (70%) improved to be in class I. The left ventricular mass index mean was 158 ± 32.37 before TAVI and 133.50 ± 21.96 after TAVI ($p < 0.001$). Compared to before TAVI (0.75 ± 0.2), mean aortic valve area was improved to 2.0 ± 0.2 following TAVI ($P < 0.001$). A significant reduction

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Received Date: 07-29-2022

Accepted Date: 09-09-2022

Published Date: 09-18-2022

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in the mean pressure gradient from 47 ± 11.08 mmHg across the native valve prior to TAVI to 10.28 ± 3.21 mmHg across the prosthetic valve following TAVI ($P < 0.001$).

Expert commentary: The clinical and results of TAVR devices were clearly outlined in literature study. The study showed a high incidence of pacemaker implantation with Core valve and aortic regurgitation. This information strongly supports the need for a randomized trial with sufficient power to compare the most recent self-expandable valve generation to balloon expandable valves. In the 2019 PARTNER 3 prospective randomized trial, it was discovered that, when compared to surgical management, low-risk patients (defined as STS 4%) had a lower risk of the composite outcome of stroke, death, and rehospitalization at 1 year. Additionally, it was shown that TAVR had a lower risk of stroke and required less time in the hospital (3 days as opposed to 7, $P < 0.001$) than surgery [1]. In addition, despite an elevated permanent pacemaker implantation rate, the 2019 Medtronic Evolut Transcatheter Aortic Valve Replacement revealed no inferiority for composite all-cause stroke and death, as well as a statistically significant decrease in the rates of life-threatening bleeding, acute kidney injury and atrial fibrillation, compared with SAVR at 30 days following the procedure [2].

Conclusion: According to the study in high-risk patients with severe symptomatic aortic stenosis, TAVI is alternative, viable, safe, and successful therapy compared to traditional open-heart surgery.

Keywords: Transcatheter Aortic Valve Replacement; Aortic stenosis; Transcatheter Aortic Valve Implantation; Paravalvular Aortic regurgitation.

Introduction

Transcatheter Aortic Valve Replacement (TAVR) is a rapidly developing technology. Patients with severe symptomatic aortic valve stenosis may choose transcatheter aortic valve implantation (TAVI) over surgery (AS), who face a significant risk of surgery [3,4]. TAVR exceeded expectations by reducing deaths and enhancing life quality in high-risk surgical aortic valve replacement patients [5]. A common complication of TAVR is Aortic regurgitation (AR), with unknown etiologies and clinical effects. According to the form of evaluation (angiography vs. echocardiography, quantitative vs. semi-quantitative), AR incidence following TAVR ranges from 40% to 67% [6,7] for negligible to mild cases and from 7% to 20% for moderate to extreme cases. Valve regurgitation that is clinically significant following TAVR is poorly

characterized and is a matter of critical concern at the moment. even a mild paravalvular leak is a negative prognostic factor [8]. The scant yet evidence underscores the importance of further analysis and identifying modifiable variables to decrease the paravalvular leak. This study is aimed to estimate incidence, detect predictors and outcomes of aortic regurgitation after transcatheter aortic valve implantation.

- 1) To estimate the incidence of aortic regurgitation among elderly patients with severe symptomatic aortic stenosis undergoing transcatheter aortic valve implantation.
- 2) To determine factors associated with aortic regurgitation following TAVI.

Subjects and methods

From November 2017 to November 2020, this prospective observational study was done in the National Heart Institute on severe aortic valve stenosis patients above 65 years who were candidates for aortic valve replacement from the outpatient department. Inclusion criteria were: Mean gradient >40 mmHg, Aortic valve area <1 cm², Peak velocity >4 m/s and Peak gradient >65 mmHg all as detected by echocardiography. Also, ascending aorta diameter 3 cm over the annulus maximum 45 mm, aortic valve annulus diameters from 20 to 26 mm and iliac and femoral arteries diameter above 7 mm all as detected by multi-slice CT also in TAVI population were included. Exclusion criteria for patients were: Iliac, femoral, or aortic disease impairing catheterization, carotid or vertebral arteries obstruction more than 70%, aortic aneurysm, mitral valvular insufficiency more than mild degree, cerebrovascular accidents or myocardial infarction within one month, left ventricular or atrial thrombus, atrial fibrillation, sepsis or active endocarditis, history of aortic valve replacement, hypersensitivity or contra-indication to any medication used in the study, congenital aortic valve (Bicuspid, unicuspid, etc.), previously conduction defects, and supra-aortic and sub-aortic stenosis. This study included 30 patients (11 female and 19 male) with a mean age of 73.98 ± 8.40 years. Patients were classified into two subgroups according to valve implantation type:

A. Group 1: Core Valve (self-expandable valve) included 15 patients (10 male and 5 Female).

B. Group 2: Edwards SAPIEN (balloon-expandable valve) included 15 patients (9 Male and 6 Female).

All patients gave written informed consent, and the ethical research committee of the faculty of medicine, Al-Azhar University, approved the study. The work has followed the Declaration of Helsinki for studies involving humans.

Methods

All participants underwent history, clinical examination, blood tests, electrocardiogram (ECG), chest radiography, transthoracic echocardiogram, coronary angiography. Multi-slice computed tomography (CT) was done for patients in the TAVI group. Post-procedural monitoring for conduction disturbances and arrhythmias was done for all patients. Continuous rhythm screening for up to 72 hours was advised to maximize the diagnosis of arrhythmias. One and six months after hospital discharge, echocardiographic and clinical follow up were done. In all patients at each temporal step, twelve leads ECG were collected to record conduction disorders.

Statistical analysis

Data analysis was done using IBM SPSS 23.0 (Chicago, USA) and NCSS 11 (Kaysville, USA). Qualitative data were presented as numbers and percentages. Quantitative data were presented as mean \pm standard deviation (SD). Significant differences between groups were determined using Independent-samples t-test, Mann-Whitney U test or Chi-square (χ^2)

test or Fisher Exact test appropriately. P-value <0.05 was considered significant.

Results

This study was done in the cardiology department, Cardiology department, and National Heart Institute in the period from November 2017 to November 2020. The study involved 30 patients with serious symptomatic AS, 11 of whom were females (36.6%) and 19 of whom were males (63.3%). The mean age was 74 years and ranged from 68 to 82 years. Patients were classified into two subgroups according to the valve used:

- A. Group 1: Core Valve (self-expandable valve) included 15 patients (10 male and 5 Female).
- B. Group 2: Edwards SAPIEN (balloon-expandable valve) included 15 patients (9 Male and 6 Female).

As shown in Table 1, more than half of the patients (53.3%) were diabetics. About two-thirds (63.3%) were hypertensives. One-third had COPD. Only 10% had a history of cerebrovascular disease. Only 6.6% had a history of malignancy. One-third of the patients (33.3%) were smokers. Majority of the patients (56.6%) had ischemic heart disease history. Only 16.6% had a history of MI. Less than one-quarter had PCI or underwent CABG (23.3% for each). Most patients (83.3%) had creatinine clearance >60 ml/min. Just 13.2% had a chronic kidney disease history with <60 ml/min creatinine. Only one patient (3.3%) was on dialysis. Impaired functional capacity was observed in all patients; only one patient (3.3%) showed NYHA I, four (13.3%) showed NYHA II, and 25 patients (82.5%) showed NYHA III/IV. The EUROSCORE II of the patients ranged from 15% to 21%, with a mean of $18.1 \pm 1.96\%$.

Baseline data	Range	Mean \pm S D
Age (years)	67-82	74.0 \pm 8.4
Risk factors	No	%
DM	16	53.3
HTN	19	63.3
Smoking	10	33.3
PAD	6	20
COPD	9	30
Gender	No	%
Male	19	63.3
Female	11	36.6
History		
Cerebrovascular accidents	3	10
Malignancy	2	6.6
Creatinine clearance "Renal function"	N	%
>60 ml/min	25	83.3
<60 ml/min	4	13.3
Dialysis	1	3.3
Ischemic heart disease	N	%
SCAD	17	56.6

Elmaksoud TRA | Volume 3; Issue 3 (2022) | Mapsci-JCCR-3(3)-065 | Research Article

Citation: El Hefny ES, Atia MA, Mosaad MA, Elmaksoud TRA. Incidence, Outcomes and Predictors of Aortic Regurgitation After Transcatheter Aortic Valve Replacement in Al Azhar University Hospitals and National Heart Institute, Egypt. J Cardiol Cardiovasc Res. 2022;3(3):1-20.

DOI: [https://doi.org/10.37191/Mapsci-JCCR-3\(3\)-065](https://doi.org/10.37191/Mapsci-JCCR-3(3)-065)

MI	6	16.6
PCI	7	23.3
CABG	7	23.3
NYHA class	N	%
I	1	3.3
II	4	13.3
III/IV	25	83.3
EURO SCORE II	Range	Mean ± SD
	15-21	18.1 ± 1.96%

Table 1: Risk factors and demographics of the studied patients.

Procedural outcome

Edwards SAPIEN valve was used in 15 patients (50%). Among them, the size of the valve used was 23mm in 5 patients (16.6%) and 26 mm in 10 patients (33.3%). In the other 15 patients (50%), we used the Core Valve revolving

system. Among them, the size of the valve used was 26 mm in 12 patients (40.0%), 29 mm in 2 patients (6.6%), and 31 mm in one patient (3.3%). Two valves (29 mm and 31 mm) were used in one patient (CoreValve, valve in valve) Table (2).

Type	N	%	Size	N	%
Edwards SAPIEN valve	15	50	23	5	16.6
			26	10	33.3
Core valve	15	50	26	12	40
			29	2	6.6
			31	1	3.3

Table 2: Type of included TAVI valves.

The majority of patients (96.6%) had a successful procedure. We used the right femoral artery (RFA) as the default approach in 25 patients (83.3%), the left femoral artery (LFA) in 5 patients (16.7%) due to significantly diseased (RFA) Table 3.

The ProGlide closure device in 17 patients (56.6%) was used, while the surgical closure was used in 13 patients (43.3%). Regarding hospital complications, aortic regurgitation was found as one of inhospital complications. As shown in Table 3, more than two-thirds of the patients (43.3%) showed prosthetic aortic regurgitation of grade 0 (non to trace). Half of the patients (50%) had a mild degree (grade I). Only 6.6% showed a moderate degree

(grade II). No severe degree was reported (grade III and IV). The incidence of post procedural AR was significantly increased in (Core valve subgroup) than (Edwards Sapien valve subgroup) ($p=0.006$). No mortality was reported. One patient (3.3%) showed cerebrovascular stroke. No myocardial infarctions were reported. Regarding bleeding, only 13.3% showed minor bleeding. Major bleeding was reported in two patients (6.6%). No life-threatening bleeding was reported. Regarding vascular complications, minor and major vascular complications were reported (6.6% for each). No new AF was reported. In one patient, one permanent pacemaker was inserted during TAVI itself.

Neither valve migration nor shift to urgent surgery was reported. In one patient with moderate to severe AR, another valve was put during the procedure (Core valve with size 31). There were no statistically significant

differences between CoreValve group and Edwards SAPIEN valve group as regards post-TAVI inhospital complications, while rate of complications was less among Edwards Sapien subgroup (Table 3).

Procedural outcome	No.	%
Success	29	96.6
Approach site	No.	%
Right Femoral artery	25	83.3
Left femoral artery	5	16.7
Closure device	No.	%
Proglid	17	56.6
Surgical closure	13	43.3
Prosthetic aortic regurgitation	No.	%
Non to trace	13	43.3
Mild	15	50
Moderate	2	6.6
Severe	0	0
CVA	1	3.3
Vascular complications	No.	%
Minor	2	6.6
Major	2	6.6
Bleeding	No.	%
Minor	4	13.3
Major	2	6.6
Life threatening	0	0
Permanent pacemaker	1	3.3
Valve in valve	1	3.3

Table 3: Procedural outcome after TAVR.

Six months outcome

On six months follow up postoperative, AR as total represented more than half of the patients (15/27,55.5%) had paravalvular prosthetic aortic regurgitation of grade 0 (none to trace). More than one-third of patients (10/27,37%) had a mild degree (grade I), only two patients (2/27,7.5%) showed a moderate degree (grade II), and no severe prosthetic aortic regurgitation (grade III and

grade IV) was reported in all patients Table 4. Edwards Sapein valve was significantly associated with low incidence of post TAVI (AR) compared to Core Valve. Mortality due to non-cardiovascular causes was reported in one patient due to cancer head of the pancreas (1/28,3.5%), while no mortality due to a cardiovascular cause was reported Table 4. No more patients have been developed cerebrovascular accidents or myocardial

infarction. No more patients have been developed new atrial fibrillation, and no more patients underwent insertion of a permanent pacemaker. No more patients developed valve migration, thrombosis, or need valve surgery Table 4. More than half of the study participants (16/27,59.2%) had mitral regurgitation of grade 0 (none to trace). Mild

mitral regurgitation (grade I) was found in 11/27 patients (40.8%). About three-quarters of patients (20/27,74%) were found with NYHA functional class I at six months. Only 5/27 and 2/27 patients were found to have NYHA functional class II and III/IV at six months, respectively Table 4.

Death	N	%
Total	01/28	3.5
Non-cardiac	01/28	3.5
Cardiac	0	0
Prosthetic regurgitation	N	%
Non to trace	15/27	55.5
Mild	10/27	37
Moderate	02/27	7.5
Re-hospitalization	01/27	3.7
Mitral regurgitation	N	%
Non to trace	16/27	59.2
Mild	11/27	40.8
NYHA functional class	N	%
I	20/27	74
II	05/27	18.5
III/IV	02/27	7.5

Table 4: Outcome after six months in the studied patients.

Clinical difference between before and after TAVI

Before TAVI, 25 patients (83.3%) were in NYHA class III/IV, four patients (13.3%) were

in class II, and one (3.3%) was in class I. After TAVI, three patients (10%) only were in NYHA class III/IV, six (20%) were in class II, and 21 (70%) improved to be in class I.

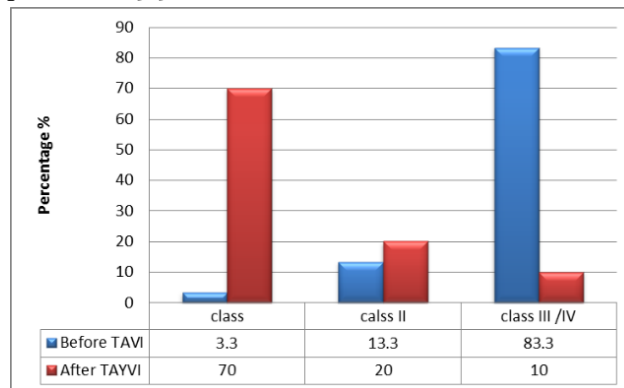


Figure 1: Pre and post TAVI NYHA functional class.

Echocardiographic findings pre and post TAVI.

As shown in table 5, Before TAVI, only 10% had moderate AR (grade II), more than half of the participants (57.7%) had mild AR (grade I), and one-third of the patients (33.3%) showed non to trace AR (grade 0). This improved post-TAVI; only 6.6% showed moderate AR (grade II) ($P < 0.017$), half of the patients (50%) showed mild AR (grade I), more than one-third (43.3%) showed non to trace AR (grade 0), and severe AR was not reported (grade III and IV) ($P < 0.001$). Post-TAVI left ventricular ejection fraction mean increased to 58.88 ± 8.79 compared to pre-TAVI measure (55.08 ± 9.71 , $P < 0.001$). Left ventricular end-systolic volume mean decreased to 33.41 ± 14.33 post-TAVI compared to 44.08 ± 13.21 before TAVI ($P = 0.036$). Regarding left ventricular end-diastolic volume mean, it decreased post-

TAVI to 92.96 ± 16.97 compared to 108.88 ± 19.21 before TAVI ($P < 0.001$).

The left ventricular mass index decreased post-TAVI to 133.50 ± 21.96 compared to 157.93 ± 32.37 before TAVI. Also, there was an improvement in aortic valve area mean (1.96 ± 0.18) compared to 0.75 ± 0.15 before TAVI. Furthermore, the means of mean and maximal pressure gradient over the aortic valve significantly declined. P values were < 0.001 for these parameters. Pulmonary arterial systolic pressure mean decreased to 25.1 ± 11.1 compared to 45.30 ± 16.88 before TAVI ($P = 0.016$). Before TAVI, about two-thirds of the patients (60%) had mild MR (grade I), and more than one-third (40%) showed non to trace MR (grade 0). Post TAVI, 14 patients (46.7%) had mild (grade I) MR and 16 (53.3%) showed non to trace MR (grade 0) ($P = 0.017$) Table 5 and Figure 3.

	Pre TAVI		Post TAVI		P-value
	No.	%	No.	%	
Aortic regurgitation					
Non to trace	10	33.3	13	43.3	<0.001
Mild	17	66.7	15	50	<0.001
Moderate	3	10	2	6.6	0.017
Echo parameters	Range	Mean \pm SD	Range	Mean \pm SD	
ESV(ml)	36.3-68.2	44.1 \pm 13.2	33.6-51.3	41.4 \pm 14.3	0.036
EDV(ml)	78.3-119.0	108.9 \pm 19.2	56.7-104.5	93.0 \pm 17.0	<0.001
EF(%)	36-70	55.1 \pm 9.7	38-73	58.9 \pm 8.8	<0.001
Valve area (cm ²)	0.44-1	0.74 \pm 0.16	1.51-2.5	2.0 \pm 0.18	<0.001
Maximum PG (mmHg)	89-163	93.2 \pm 18.7	May-36	20.0 \pm 5.90	<0.001
Mean PG (mmHg)	43-87	47.1 \pm 11.1	20-Mar	10.3 \pm 3.20	<0.001
PAP(mmHg)	21-97	45.30 \pm 16.88	23-66	25.1 \pm 11.1	<0.001
Mass index	111-243	159.15 \pm 31.26	88-186	133.50 \pm 21.96	<0.001
Mitral regurgitation	N	%	N	%	
Non to trace	12	40	16	53.3	0.017
Mild	18	60	14	46.7	0.017

Table 5: Echocardiographic finding Pre and post Transcatheter Aortic Valve Implantation.

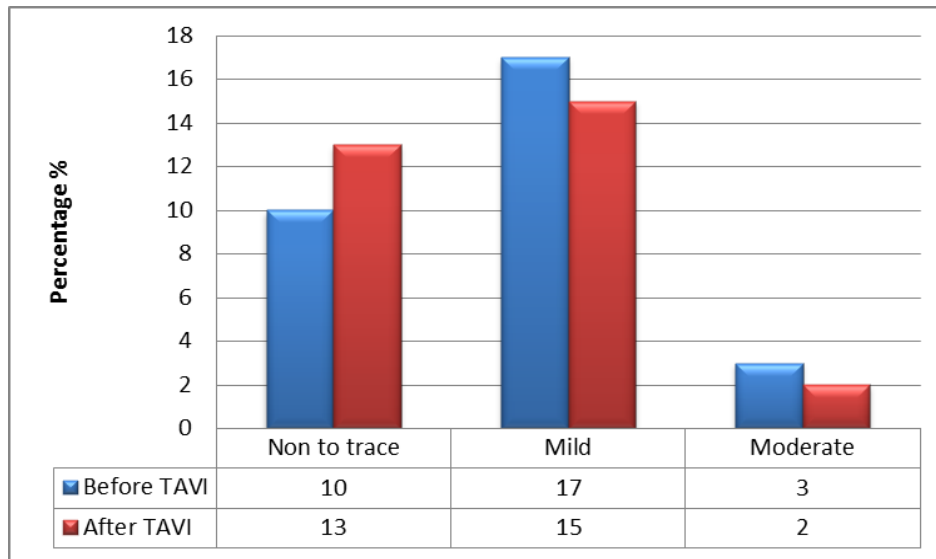


Figure 2: Aortic regurgitation (AR) Grades pre and post-TAVI.

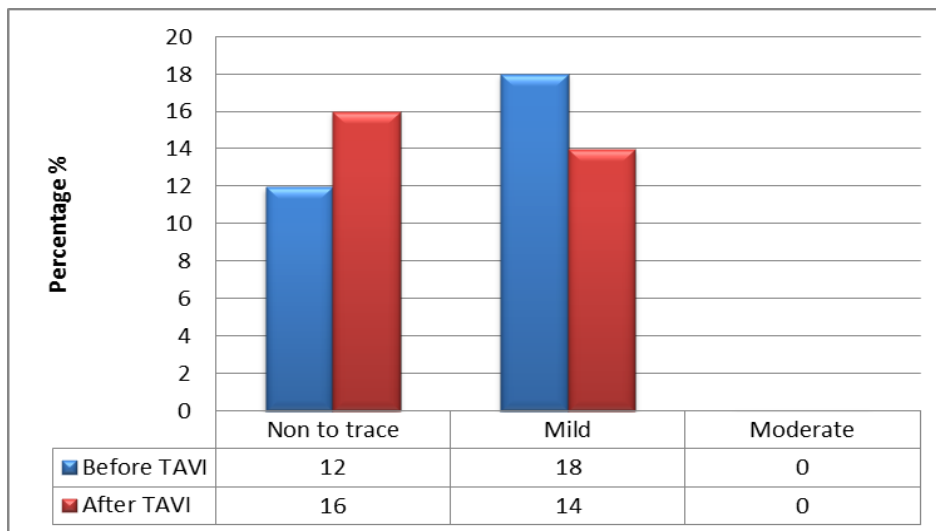


Figure 3: Mitral regurgitation (MR) Grades pre and post-TAVI.

Outcome according to valve type subgroup (procedural & post-procedural)

In 15 patients (50%), we used the Core Valve (subgroup I), and for 15 patients (50%), the Edwards SAPIEN valve was used (subgroup II). The procedure success rates were 93.3 and 100% for subgroups I and II, respectively (P=0.8). In one patient (6.6%) of subgroup I

and during the procedure, another valve was implanted due to moderate to severe paravalvular regurgitation. In subgroup II, no second valve was used. (P=0.8). For either type of valve, no valve migration or referral for urgent surgery occurred.

No death occurred with both types of valves during the procedure itself. One patient in

subgroup I experienced a cerebrovascular stroke compared to none in subgroup II. (P=0.866)

In sub-group I and II, minor bleeding was reported in 20% and 13.3%, respectively. (P=0.9). Regarding major bleeding, it was reported in 6.6% and 13.3% in groups I & II, respectively (P=0.7). Both groups did not experience life-threatening bleeding.

Only two patients in subgroup I showed minor vascular complications (13.3%), while in subgroup II, it occurred in one patient (6.6%) (P=0.8). Both subgroups I & II experienced major vascular complications (13.3% and 6.6%, respectively) (P=0.7).

Due to CHB and during TAVI itself, only one patient in the subgroup I underwent pacemaker implantation.

Six months outcome

In more than one-third of the patients of subgroup I (38.4%), non-to trace paravalvular regurgitation (grade 0) was reported. In subgroup II, it was found in more than two-thirds of the patients (71.4%). (P=0.7). Near half of subgroup, I patients (46.1%) showed mild paravalvular regurgitation (grade I), while it was found in about one-quarter of the subgroup II patients (28.6%) (P=0.64). Moderate paravalvular regurgitation (grade II) was reported in two patients (15.2%) in subgroup I compared to no patients in subgroup II. (P=0.8). The severe form (grade III and IV) was not reported in both subgroups. Only two patients in subgroup I died

at six months (13.3%). One was caused by a cardiac event, and the other was caused by a non-cardiac event. In subgroup II, mortality was reported in one patient (6.6%) due to a non-cardiac event (P=0.7).

In subgroups I and II, stroke was reported in one patient of each sub-group (P=0.6).

In subgroup I, only one patient (6.6%) experienced myocardial infarction. In subgroup II, no MI was reported. (P=0.8). Two patients of each subgroup (13.3%) experienced new AF (P=0.8). Four patients (26.6%) in subgroup I had permanent pacemaker insertions done, one of which was done during TAVI. It was carried out for one patient (6.6%) in subgroup II (P=0.55). Re-hospitalization was reported in only one patient in each of the sub-groups I and II. (P=0.6).

In general, significant differences were noted regarding different parameters and outcomes in the two subgroups Core Valve was significantly implanted deeply in the LVOT than Edwards SAPIEN valve (7.9 ± 2.4 mm vs 4.5 ± 1.1 mm, $p < 0.001$) and also had significantly larger size than Edwards SAPIEN valve (28.5 ± 1.36 mm vs 23.5 ± 1.1 mm, $p < 0.001$). Also, patients in the Core Valve subgroup had significant larger aortic annulus diameters, QRS duration, and IVS thickness than those in the Edwards SAPIEN subgroup.

	Core Valve	EDWARDS SAPIEN	P-value
	(Subgroup I)	(subgroup II)	
	N / %	N / %	
Procedural success	14/15(93.3%)	15/15(100 %)	0.869
Second valve	1/15(6.6%)	0/15(0.0%)	0.866
Paravalvular regurgitation			
Non to trace (grade 0)	5/13(38.4 %)	10/14(71.4 %)	0.708
Mild (grade I)	6/13(46.1 %)	4/14(28.6 %)	0.64
Moderate (grade II)	2/13(15.2 %)	0/14(0.0 %)	0.866
Severe (grade III-IV)	0(0 %)	0(0 %)	1
Stroke	1/15(6.6%)	1/15(6.6%)	0.612
Vascular complications			
Minor	2/15(13.3 %)	1/15(6.6 %)	0.964
Major	2/15(13.3%)	1/15(6.6 %)	0.794
Bleeding			
Minor	3/15(20%)	2/15(13.3%)	0.964
Major	1/15(6.6 %)	2/15(13.3%)	0.794
Life threatening	0/15(0.0%)	0 /15(0.0 %)	1
Six months outcome			
Mortality (Total)	2/15(13.3 %)	1/15(6.6 %)	0.794
Cardiac	1/15(6.6%)	0/15(0.0 %)	0.866
Non-cardiac	1/15(6.6%)	1/15(6.6%)	0.602
Stoke	1/15(6.6 %)	1/15(6.6 %)	0.602
MI	1/15(6.6 %)	0/15(0.0 %)	0.866
New onset AF	2/15(13.3 %)	2/15(13.3 %)	0.825
Permanent pacemaker	4/15(26.6 %)	1/15(6.6 %)	0.55
Rehospitalization	1/13(7.6%)	1/14(6.6%)	0.602

Table 6: Outcome according to valve type included in the study.

Discussion

TAVR is a rapidly developing procedure. In individuals with severe symptomatic aortic valve stenosis, it serves as an alternative to surgery (AS). who undergo surgery at a high risk [3,4].

TAVI is the treatment of choice for non-operable aortic stenosis patients and a good substitute for those at high or moderate surgical risk. However, the occurrence of some periprocedural complications remains a

concern [5]. Aortic paravalvular leak (PVL) is a common TAVI complication. It is related to elevated mortality and occurring more frequently with TAVI than with surgical AVR [9].

Aortic regurgitation (AR) is a common TAVR complication. AR incidence post-TAVR ranges from 40% to 67% and from 7% to 20% for trivial to mild and for moderate to severe leaks, respectively [6,7]. it would be of high clinical relevance to determine the predictive

factors of aortic regurgitation after TAVI procedures.

Our study reported a smaller size of the prosthesis lead to improper apposition on the native valve, and large aortic annulus was important in prediction of PVR post TAVI. A smaller annulus size is considered defensive against PVL presence, which is explained by the annulus greater congruence with THV. Greater annulus measurements were correlated with more than mild (AR) [10]. Due to the need for a larger post-dilatation balloon, which may cause leaflet distortion, the REVIVAL trial results showed that a wider aortic annulus was a stronger indication of post-TAVI central aortic regurgitation than PVL [11]. Hagar, et al. [12] reported a larger aortic annulus were commonly associated with \geq mild PVL [12]. Also, a meta-analysis study reported that under prosthesis sizing in relation to annulus size was the main predictive factor of PVL [13]. As the prosthesis size was always bigger than that of the annulus, Hagar, et al. researchers [12] found no statistically significant link between these parameters and the occurrence of PVL, which can be avoided by using the right oversizing [10]. Wong, et al. [14] found that elliptical aortic annulus was a predictor of PVL after TAVI. However, several other studies demonstrated no correlation [13,15].

According to our research, considerable aortic valve calcification increases the probability of PVR following TAVI, and the location of the calcification plays a significant role in this prediction. According to Hagar et al,[12] mild PVL is related with higher aortic valve calcification in all regions. Additionally,

it was discovered that calcifications in the body of leaflets were more predictive of PVL than calcifications at the tip, which were less so. Additionally, it appears that cusp calcifications were more important than commissure calcification in predicting PVL.

In our study found that implantation depth is other risk factor for incidence of AR post TAVI especially for core valve because of this valve is larger and need a higher range of implantation depth in comparing with Balloon expandable valve. aortic regurgitation was more with Core Valve than Edwards Sapien valve also moderate (AR) observed with Core Valve subgroup and not with Edwards Sapien valve subgroup, Core Valve was significantly implanted deeply in the LVOT than Edwards Sapien valve (7.9 ± 2.4 mm vs 4.5 ± 1.1 mm, $p < 0.001$) and also had larger size than Edwards SAPIEN valve (28.5 ± 1.36 mm vs 23.5 ± 1.1 mm, $p < 0.001$). lead to reducing the sealing provided by the tissue skirt and leaks above the skirt. Also, patients in the Core Valve subgroup had larger aortic annulus diameters, QRS duration, and IVS thickness compared to those with Edwards SAPIEN subgroup. According to Athappan, et al. [13], mild aortic regurgitation occurred following the implantation of self-expanding and balloon-expanding valves, respectively, at a rate of 16% and 9%. According to univariate analysis, the type of prosthesis had no effect on PVL prediction. Multivariate analysis, on the other hand, showed that the type of prosthesis (Self-Expanding vs. Balloon Expanding prosthesis) was a predictor of PVL [12]. The study reported that other cause for AR following TAVI is the patient /Prosthesis mismatch (PPM), the incidence of (PPM)

occurred more with Balloon than with Self Expandable valve (overall PPM, 27% vs. 20%, $p < 0.01$). In relation to patient's body size, when the size of prosthetic valve is too small, PPM resulting in high trans-prosthetic gradients and revealed negative impact on both long- and short-term outcomes [16,17]. Pibarot, and others, [27] Before TAVR, it is recommended to size the valve properly using gated transesophageal echocardiography or CT since it appears to decrease PPM frequency [18]. Additionally, after TAVI, decreased severe PPM incidence and improved valve hemodynamics are brought on by the absence of a sewing ring and a constant radial force [19].

According to Okuno, et al. [20], regardless of annulus area, a balloon Expandable valve is linked to a higher frequency of PPM than a self-Expandable valve (severe PPM, 15.6% vs. 6.7%, $P < 0.01$; overall PPM, 46.9% vs. 33.5%, $P < 0.01$). A lower grade of TAV oversizing seemed to be the key element linked to PPM [21]. One potential cause of AR following core valve implantation is the left ventricular outflow tract excessive angulation relative to the ascending aorta, which impairs the self-expanding prosthesis ability to form a tight seal and close the paravalvular cavity. In these cases, balloon post-dilation and a larger oversizing, as compared to the Edwards valve, can resolve the Core Valve under expansion. Balloon post-dilation, on the other hand, has been associated with an increased risk of stroke [22].

Also following core valve implantation, other AR factors is an incomplete device extension and subsequent impairment of the Core Valve

apposition to the native annulus and left ventricular outflow tract have been involved [13].

Another critical factor in minimizing AR when using the Core Valve is the implantation height. Due to the valve non cylindrical nature, implantation depth defines the effective valve diameter in the annulus. Sealing of the Core Valve at the virtual ring stage, especially in larger annuli, is based on a high implantation rate to take advantage of the valve lower diameter [13]. Marwan, et al. [23] demonstrated that annulus calcification was a significant predictor of PVL. Additionally, no difference was noted between PVL and non-PVL patients regarding commissure calcification [23].

In our study, the prevalence of moderate aortic regurgitation was 6.6%, while the majority of patients (43.3%) had no detectable paravalvular aortic regurgitation or mild form (50%). No serious aortic resurge was reported. (Yun et al., 2019) reported the incidence of moderate/severe AR at 30 days with Medtronic core valve and SAPIEN XT valve was (7% and 3%) respectively [24]. Hagar et al, [12] reported the incidence of \geq mild PVL was (29.3%) after the procedure. (5.5%) Of them, had moderate PVL and (0.7%) had severe PVL was severe in 2 patients [12]. According to France 2 registry, paravalvular aortic regurgitation rate was 46.0%, 16.1%, and 0.8% for grades I, II, and III, respectively [25].

The current study proved that TAVI significantly expands the area of the aortic

valve (1.96 ± 0.18 compared to 0.75 ± 0.15 prior to TAVI). This was in line with the findings of the initial TAVI experiment conducted in Egypt, which showed a post-procedural AVA of 2.0 ± 0.1 [26].

Our findings indicated a significant reduction in the mean pressure gradient across the aortic valve from 47 ± 11.08 mmHg across the native valve prior to TAVI to 10.28 ± 3.21 mmHg across the prosthetic valve following TAVI ($P < 0.001$).

SAPIEN 3 BE found mean transvalvular gradient of 13.7 ± 5.6 mmHg with enhanced aortic valve area (AVA) of 1.7 ± 0.4 cm², and a rate of moderate/severe PVR of 0.6% at 1 year [27]. This was consistent with the results from the PARTNER 3 trial. SE TAVs indicated greater frequencies of moderate-severe PVR but showed lower mean transvalvular gradients. In the SAVI TF registry and PORTICO-I trial, the mean transvalvular pressure gradient was reported to be 7.3-8.6 mmHg, with an AVA of 1.8-2.0 cm², and moderate/severe PVR rate of 2.6-3.6% at 1 year using Portico SE, ACURATE neo-TF and Evolut R/Evolut PRO valves [28,29].

Studies comparing BE and SE valves head-to-head have largely supported these conclusions. Despite the ACURATE neo's superior performance) transvalvular mean gradient 7 vs 11 mmHg [30], the randomized SCOPE I trial's failure to confirm the ACURATE neo-TF SE valve non-inferiority in comparison with the SAPIEN 3 BE valve was significantly attributable to the higher moderate/severe PVR prevalence rate. In contrast to these results, the SOLVE-TAVI

study verified the parity of the Evolut R SE and SAPIEN 3 BE devices at 30 days in terms of moderate/severe PVR (3.4% vs. 1.5%, $p=0.01$) and mean transvalvular gradient >20 mmHg (2.0% vs. 3.3%, $p=0.09$) [31].

As compared to ACURATE novo SE and Evolut R valves, SAPIEN 3 BE had higher transvalvular gradients (9.87.5 vs. 6.12.4 vs. 8.43.5 mmHg, $p=0.01$) and a lower rate of more-than-mild PVL (18.7% vs. 47.9% vs. 45.8%, $p=0.01$) [32].

This research revealed that paravalvular aortic regurgitation (PAR) was not detectable (grade 0) in 5/15 patients (33.3%) in subgroup I but was detected in 8/15 patients (53.3%) in subgroup II. ($p=0.7$). Mild paravalvular aortic regurgitation (grade I) was detected in 8/15 patients (53.3%) in subgroup I and 7/15 patients (46.6%) in subgroup II. ($P=0.64$). In subgroup I, two patients (13.2%) experienced moderate paravalvular regurgitation (grade II), while no moderate paravalvular aortic regurgitation (grade II) was noted in subgroup II. ($p=0.8$) In neither group were there any patients with serious paravalvular aortic regurgitation (grade III-IV).

In the CHOICE experiment, the rate of non to trace PAR (grade 0) was 49.2% and 66.1% in the core valve and in the Edwards SAPIEN groups, respectively. More than one-third of the patients (45%) experienced mild paravalvular aortic regurgitation (grade I) with the Core Valve and about one-third (32.2%) with the Edwards SAPIEN ($P=0.8$). Only 5.8% and 0.8% experienced moderate severity (grade II) PAR in the Core Valve group and Edwards SAPIEN group,

respectively. Severe PAR (grade III) occurred in 0.8% in the Edwards SAPIEN group compared to none in the Core Valve group [33].

Our findings are consistent with the CHOICE trial regarding paravalvular aortic regurgitation rate in grades 0 and 1 but were inconsistent with those of the CHOICE trial regarding grades 3 and 4. Yun, et al. [24] reported that moderate or more severe PVR after TAVR occurred in (4%) in the Medtronic Core Valve subgroup with MCV and in (2%) in the Sapien valve subgroup [24].

The current study demonstrated that there was an improvement in NYHA functional class. Prior to TAVI, one patient (3.3%) was in class I, four (13.3%) were in class II, and 25 (83.3%) were in class III/IV. Following TAVI, 21 patients (70%) had functional class I, six patients (20.0%) had class II, and three patients (10%) showed class III/IV ($P < 0.001$).

This was in line with the findings reported by Sylvia, et al. [34]. In contrast to preoperatively (72%), 20% of patients had NYHA class III-IV at 30 days [34].

This research demonstrated the LVEF, significantly improved after TAVI (58.9 ± 8.8 vs. 55.1 ± 9.7) ($P < 0.001$). This is similar to the PARTNER II experiment, which demonstrated an improvement in mean EF at 30 days (53.9 ± 13.1 vs. 57.9 ± 10.1) ($P < 0.001$) [35].

The current research recorded a procedural success rate of 96.6% in 29 patients, was 93.6 and 100% for subgroup I and II, respectively ($p=0.8$). which appears to be equivalent to

other reports, such as, the CHOICE trial results, device success rate with Medtronic Core valve and Sapein XT valve was (86% and 90%) [33]. But there were no differences in rehospitalization for heart failure (HF) (7.4 vs 12.8%, $p=0.19$) stroke (9.1 vs 3.4%, $p=0.11$) and all-cause mortality (17.4 vs 12.8%, $p=0.37$), between the 2 TAVI types at 1 year [33]. The first Egyptian experience with TAVI was conducted on ten participants using the Edward's Sapien valve and demonstrated a 100% success rate [26]. (Yun, et al. 2019) reported the device success rate was 90% for SXT, 83% for Lotus, and 86% for MCV ($p=NS$) [24]. Our study reported no mortality was reported during the procedure in comparison to other studies.

Our research revealed that one patient (6.6%) of each subgroup experienced stroke ($P=0.6$). In this meta-analysis, reported that balloon-expandable valves were associated with a higher incidence of any stroke compared with self-expanding valves. Large observational study showed that higher rate of stroke occurred more frequently with self-expandable valve than with Balloon expandable valve which was observed by higher rate of stroke with new generation of self-expandable valve [36]. Contrary to these finding, Elgendy, et al. [37] showed that stroke occurred more frequently with balloon expandable than with self-expandable valve [37]. Also, in the SOLVI TAVI trial the balloon expandable valve associated with a higher rate of any stroke than with self-expandable valve [31].

At six months, two patients (13.3%) in subgroup I died, one from a cardiac event and

the other from a non-cardiac event. One patient (6.6%) in subgroup II died from a non-cardiovascular cause. These results were similar to those from the reported CHOICE trials. It was reported that all-cause mortality was 5.1% in the group with the self-expanding valve and 4.1% in the balloon-expandable group at 30-days [32]. In our research, only one patient (3.3%) needed a second valve due to an unsatisfactory outcome with the first valve (Core valve size 29) as a result of a relatively serious paravalvular leak. In other patients, a single valve per patient was used.

This is similar to what has been recorded in other studies. Yun, et al. [24] found the (9%) patients with Medtronic core valve and (4%) patients with SAPIEN XT required implantation of a second valve due to initial implant embolization to the ascending aorta or mispositioning [24]. According to the CHOICE study, second valve implantation (transcatheter valve-in-valve) was also more common in the self-expandable group (5.8%) than in the balloon-expandable group (0.8%) (P=.03) [33].

Hamilton, et al. recent, meta-analysis [38] reported the results of BE versus SE TAVs used in the context of valve-in-valve (VIV) TAVR procedures. In terms of 1-year all-cause mortality (12.6% vs. 10.3%), they discovered no changes [38]. The same is true for Ochiai, et al. [39], who discovered no variation in 30-day (2.7% vs. 0.0%, p=NS)

VIV TAVR clinical outcomes versus redo SAVR in failing bioprosthetic aortic valves are compared by Al-Abcha, et al. in their study [40]. There were 12 observational studies

totaling 8430 participants. The risk of the rate of moderate to severe paravalvular leakage, permanent pacemaker implantation, myocardial infarction, cardiovascular mortality, and all-cause mortality were shown to be comparable between VIV TAVR and redo SAVR. Al-Abcha, et al. data, however, showed that the VIV group had lower rates of major bleeding, stroke, procedural mortality, and 30-day mortality.

According to the current study, only five patients (16.6%) experienced minor bleeding, three patients (10%) experienced major bleeding, and no life-threatening bleeding occurred. This was similar to the results recorded by Yun, et al. [24] found the major or life-threatening bleeding among (Medtronic Core valve was 2%, and SAPIEN XT was 5%), at 30 days post TAVI [24].

According to the current study, a minor vascular complication, as well as major vascular complication, were experienced by three patients (10%). Yun, et al. [24] reported that major vascular complications among (Medtronic Core valve was 1%, and SAPIEN XT was 5%); At 30 days post TAVI [24].

Four patients (13.3%) experienced new AF; one developed it shortly after the TAVI, the current study discovered that 2/15 patients (13.3%) in subgroup I and 2/15 patients (13.3%) in subgroup II developed new-onset AF (P=0.8). two developed it late in the hospital stay, and one developed AF at 30 days. Full heart block resulted in the requirement for permanent pacemakers in five patients (16.6%), four of whom had the Core valve and one of whom had the Edwards SAPIEN valve.

In a recent, extensive study of Bisson et al. [41] they showed higher PPI rates than previously reported, reporting the better of SAPIEN XT/3 Balloon Expandable TAVs (21.9/20.7%) versus CORE VALVE/Evolut R Self Expandable valve (25.5/24.3%) at 30 days, with no differences between new and previous generation devices [41]. In comparison to the SAPIEN 3 BE valve, the Evolut R SE valve had a greater rate of PPI at 30 days, according to the SOLVE-TAVI trial (23.0% vs. 19.2%). However, in the SCOPE I RCT, the outcomes for the SAPIEN 3 BE and ACURATE neo-SE valves were identical (9.3 vs.10.1% respectively, $p=0.79$) [32]. One patient (10%) had a permanent pacemaker implanted in the first TAVI trial in Egypt [26].

Our analysis found a 6.6% re-hospitalization rate for patients with heart failure, which was similar to the CHOICE experiment, which found a 4.3% re-hospitalization rate at 30 days in the self-expandable valve group but none in the balloon-expandable valve group [33]. For both valves, no procedural deaths were reported in our study, and this was consistent with the CHOICE trial [33].

According to this study, no valve migration or referral for urgent surgery was reported. At six months, this analysis found that myocardial infarction occurred in 1/15 patients (6.6%) in subgroup I, but not in any patients in subgroup II. ($p=0.8$). This contrary to the CHOICE experiment, which found that MI occurred at a rate of 0.8% in the Edwards SAPIEN valve category, while no mortality was reported in the Core Valve group ($P=0.99$) [33].

In the current study, readmission incidence was 6.6%, and all were due to heart failure, with 1/15 patient (6.6%) in subgroup I and another 1/15 patient (6.6%) in subgroup II ($p=0.6$). This is in line with the CHOICE trial; the readmission rate at 30 days was 4.3% in the self-expandable valve group and none in the non-expandable valve group [33].

Study Limitations

Our analysis has some shortfalls related to the small sample size. The limited patient population has a detrimental effect on the rate of complications and the validity of the research results. Also, the long follow-up durations are needed to capture enough events to reveal more meaningful patterns in the data.

Conclusion

In conclusion, 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. Aortic regurgitation (AR), mostly of the paravalvular type, is thought to be the most common and typical problem with transcatheter valves. It has also been found to be a strong and independent predictor of death from all causes and heart disease after TAVI. It is recommended to increase the sample size of future studies to best describe the value and significance of the results. Randomized controlled study is needed for a better evaluation of the outcome of TAVI for high-risk patients with severe symptomatic aortic stenosis. This study should include those with intermediate risk as well. For a better

assessment of the risk before surgery, a scoring system made just for TAVI should be looked for.

Conflict of Interest

No conflict of interest.

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Acknowledgement

The authors are appreciated the cooperation of all the patients who participated in the study.

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