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Clinical Outcomes among Patients with Severe Aortic Stenosis Treated with Transcatheter Aortic Valve Implantation: A Single Center Experience

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Abstract

Background: Transcatheter aortic valve implantation (TAVI) has become an appealing treatment option in elderly patients with aortic stenosis, especially in patients with increased surgical risk.

Aim of Study: To report local expertise, clinical outcomes, and 6-month follow-up of patients undergoing TAVI.

Patients and Methods: This study is retrospective and prospective, conducted from January 2022 to May 2023. It included 151 patients treated with TAVI. However, 29 patients were missed during follow-up, to complete the study with 122 patients fulfilling the inclusion criteria.

Results: The mean age was 73.67±7.04 years, 52.5% were females, and 59% were low riskaccording to Euro Score II. Three valve platforms were used and Evolut R was the most common (78.6%). Survival rate at 30-days was 97.5%, and 96.7% at 6-months. Incidence of stroke was 1.6% at 1-month, permanent pacemaker implantation 6.6%, no acute kidney injury, 2 patients experienced vascular complications (1.6%), and no patients had more than mild paravalvular leakage. Regarding symptomatology, there was ahighly significant improvement at the 6-month follow-up in which the majority of patients became at NYHA I (91.8%) and II (7.4%) (p<0.001). The Euro quality of life questionnaire was used and revealed significant improvement in general health status in all five dimensions with an overall Euro-quality of life visual analogue scale (EQ-VAS) score of 62.48±4.99 at baseline and 84.92±7.33 at follow-up (p<0.001).

Conclusions: Our study demonstrated low rates of procedure-related complications, favorable short-term clinical outcomes, and a significant improvement in symptomatology and general health status.

Key Words: Aortic stenosis – Transcatheter aortic valve implantation – TAVI-registry – Valve Academic Research Consortium-3 – Self-expandable valves – Balloon-expandable valves.

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Introduction

WITH a prevalence of up to 4.6% in patients over 75 years old, aortic stenosis (AS) is currently the most frequent valvular heart disease in the elderly and the most common cause of adult valve surgery **[1].**

The typical course of AS starts with a prolonged latent asymptomatic period, and a lot of patients miss diagnosis **[2].** Once symptoms begin to appear, a rapid decline in survival rate is predicted. Unfor-

List of Abbreviations:

AF : Atrial fibrillation.
AKI : Acute kidney injury.
AS : Aortic stenosis.
BAV : Bicuspid aortic valve.
BEV : Balloon expandable valve.
BSA : Body surface area.
BVD : Bioprosthetic valve dysfunction.
CARRY : China aortic valve transcatheter replacement registry.
CBC : Complete blood count.
CrCl : Creatinine clearance.
CT : Computed tomography.
CVS : Cerebrovascular stroke.
DM : Diabetes mellitus.
ECG : Electrocardiogram.
EF : Ejection fraction.
EQ VAS score: Euro-quality of life visual analogue scale.
EQ-5D-5L questionnaire: Euro-quality of life 5 dimensions 5 levels questionnaire.
IHD : Ischemic heart disease.
IQR : Interquartile range.
LBBB : Left bundle branch block.
LV : Left ventricle.
LVEF : Left ventricular ejection fraction.
MI : Myocardial infarction.
MSCT : Multi-slice computed tomography.
NOTION : Nordic aortic valve intervention.
NYHA : New York Heart Association.
PARTNER: Placement of Aortic Transcatheter Valves.
PPM : Permanent pacemaker.
RBBB : Right bundle branch block.
SAVR : Surgical aortic valve replacement.
SEV : Self-expandable valve.
STS : Society of Thoracic Surgeons.
TAVI : Transcatheter aortic valve implantation.
THV : Transcatheter heart valve.
TTE : Transthoracic echocardiography.
VARC-3 : Valve Academic Research Consortium-3.
VHD : Valvular heart disease.
ViV : Valve-in-valve.

tunately, medical treatment plays a limited role, and valve replacement becomes the only treatment option to halt the decline in survival [3]. Because of age, multiple comorbidities, and poor general condition, surgical aortic valve replacement (SAVR) is considered high risk. Thus, a percutaneous approach represents an appealing treatment option for many patients [4].

Transcatheter aortic valve implantation (TAVI) is now the standard of care for the treatment of patients with AS in many centers worldwide, TAVI showed non-inferiority to SAVR in low-risk patients such as the PARTNER 3, NOTION 2, and the Evolut TAVR low-risk trial [5-7].

The Valve Academic Research Consortium-3 (VARC-3) updated guidelines intend to give definitions to clinical endpoints/complications after TAVI and include: Death; stroke;rehospitalization; hemorrhage; vascular; heart structure complications; acute kidney injury (AKI); heart blocks and arrhythmias; myocardial infarction (MI); bioprosthetic valve dysfunction (BVD); leaflet thickening and decreased leaflets excursion; valve thrombosis; patient-reportedhealth status; and composite endpoints [8].

Registries are thought to be a great resource for non-selected real-world patients, offering valuable information about short-, intermediate-, and long-term results as well as the affordability of different treatments [9].

Given the limited existing research on this topic in the Egyptian context, this study aimed to report local expertise, clinical outcomes, and 6-month follow-up of patients undergoing TAVI.

Patients and Methods

Our registry included patients retrospectively and prospectively. It included 151 patients who were treated with TAVI from January 2022 to November 2022 retrospectively and from November 2022 to May 2023 prospectively.

Out of the 151 patients, 119 were treated with the self-expandable Medtronic Evolut R valve, 18 with the balloon-expandable Edwards Sapien 3 valve, and 14 with the self-expandable Boston Acurate neo 2 valve. However, 29 patients were excluded due to failure of follow-up, and we completed the study with 122 patients.

All enrolled patients were diagnosed with symptomatic severe AS and the decision to undergo TAVI was taken by our local heart team committee. The study protocol gained approval by the local ethical committee. Each patient was given written informed consent and coded by numbers to preserve their confidentiality.

All patients were subjected to (at baseline, 1 month, and 6 months follow-up):

Clinical data:

Detailed history taking including age, sex, history of diabetes mellitus (DM), history of renal impairment or renal replacement therapy, and previous history of ischemic heart disease (IHD) or cerebrovascular stroke (CVS). Physical examination included weight, height, and body surface area (calculated using the Mosteller method), and general and local examination. Surgical risk scores: Euro-Score II [10] and STS scores [11] were calculated by our heart team for all patients.

Laboratory data:

Included Complete blood count (CBC), renal and liver functions, and pre-and post-procedural serum creatinine levels; serum creatinine was measured 1 day before the procedure, 48 hours after the procedure, and at day 7 (whether in-hospital or after discharge). Acute kidney injury (AKI) was defined according to VARC-3 8if at least one of the following occurred; an increase in serum creatinine ≥1.5–2.0 X from the baseline within 7 days, or an increase of ≥0.3mg/dL within 48 h of the index procedure.

ECG data:

Twelve lead surface ECG on admission & after intervention and at follow-up, we abided by the VARC-3 [8] to diagnose patients with new onset AF, or the occurrence of conduction disturbances as new-onset left bundle branch block (LBBB) or heart block or the need for permanent pacemaker implantation (PPM).

Transthoracic echocardiography (TTE):

All patients were subjected to a full TTE study using a Vivid E95 (GE health care) device with a 3.5 MHz transducer with an emphasis on the assessment of AS based on the recent guidelines from the European Association of Cardiovascular Imaging [12].

CT data (TAVI protocol):

MSCT (Multi-Slice Computed Tomography) with contrast was done to all patients using the Somatom Definition Siemens CT machine. The data was analyzed using the OsiriX MD by at least two TAVI operators based on the expert consensus document of the Society of Cardiovascular Computed Tomography (SCCT) [13].

TAVI Procedural data:

TAVI was done using the self-expandable valve (SEV) Evolut R or Acurate neo 2, or the balloon-expandable (BEV) Sapien 3 valve. The choice between the three platforms depended on two factors; firstly, the anatomical suitability of the patient, and secondly, the availability at our center, given that the Sapien 3 and Acurate neo 2 platforms were not readily available at all times.

All procedures were intended to be 'minimalistic', i.e. without general anesthesia, transesophageal echo, and vascular open access. All procedures were done under conscious sedation, local anesthesia, and a percutaneous approach using proglides as closure devices. The routine access was the common femoral artery, except for 4 patients in which the access was either left subclavian, left axillary, or right common carotid with planned surgical cutdown due to unsuitable femoral access. Pacing was done most commonly through a temporary pacemaker through transjugular or transfemoral access, and less commonly by left ventricular (LV) pacing over the stiff wire placed in the LV apex using alligator clamp electrodes and high voltage battery. If no conduction disturbances occurred during the procedure, we removed the pacemaker but left the venous sheath for 24 hours under monitoring, and were removed afterward if no signs of conduction disturbances. Predilatation was preplanned based on the CT data and was done routinely in the Sapien 3 and Acurate neo 2 platforms. We intended to routinely predilate in heavily calcified, bicuspid, and rheumatic valves. Post-deployment dilatation was done under rapid pacing if MPG was ≥10mmHg as assessed by TTE.

Clinical outcomes:

Data were collected based on theVARC-3 definitions including mortality, stroke, hospitalization, acute kidney injury (AKI), bleeding, vascular complications, coronary obstruction, myocardial infarction (MI), bioprosthetic valve dysfunctions (BVD), conduction disturbances, permanent pacemaker implantation (PPM).

Mortality was defined as either periprocedural mortality or early mortality. Periprocedural mortality is defined as death occurring during the procedure or within the first 30 days from the index procedure. Early mortality is death occurring >30 days and <1 year from the index procedure **[8]**.

Euro-quality of life 5 dimensions 5 levels (EQ-5D-5L questionnaire):

EQ-5D-5L is a standardized measure of health status developed by the EuroQol Group to provide a simple, generic measure of health for clinical and economic appraisal. The descriptive system comprises the following 5 dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The respondent is asked to indicate his/her health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the 5 dimensions.

Euro-quality of life visual analogue scale (EQ VAS score):

Records the respondent's self-rated health on a 20cm vertical, visual analogue scale with endpoints labelled 'the best health you can imagine' and 'the worst health you can imagine'. This information can be used as a quantitative measure of health as judged by the individual respondent **[14,15]**.

Statistical analysis: Version 23 of the Statistical Package for Social Science (IBM SPSS) was used to collect, edit, code, and enter data. When the quantitative data were determined to be non-parametric, they were given as the interquartile range (IQR) and the mean, standard deviations, and ranges when the data were parametric or median. Additionally, percentages and figures were used to represent qualitative characteristics. When the predicted count in any cell was less than 5, the Chi-square test and/or Fisher exact test were used to compare the qualitative data between the groups. The independent *t*-test was used to compare two independent groups with quantitative data and a parametric distribution; the Mann-Whitney test was used to compare a non-parametric distribution.

Results

One hundred twenty-two patients were enrolled, with a mean age of 73.67±7.04 years, 52.5% were females, 59% of the patients were at low surgical risk (n=72), 27.9% were at intermediate risk (n=34) and 13.1% were at high risk (n=16) according to Euro Score II. Fourpatients had surgical valve dysfunction (SVD) and planned for valve in valve (ViV) in which all received Evolut R 23mm, 5 patients were diagnosed with rheumatic heart disease-based on medical history, echocardiographic, and CT findings, and 18 patients were diagnosed with bicuspid aortic valve (BAV). Other demographic and clinical data can be seen in Table (1).

Regarding baseline laboratory, ECG, echocardiographic, and CT data, the mean hemoglobin level was 11.38±1.07mg/dl. The median creatinine clearance (CrCl) was 60.1ml/min. The majority of patients were in sinus rhythm, 18% had AF (n=22), and 8.2% had pre-existing RBBB (n=10). Echocardiographic data revealed that 20.49% (n=25) of patients had reduced Ejection fraction (EF),10.66% (n=13) of patients with low-flow, low-gradient AS with reduced EF, and1.6% (n=2) of patients with low-flow, low-gradient AS with preserved EF and average mean pressure gradient (MPG) 50.12±14 mmHg. Other echocardiographic data can be seen in Table (2) CT data revealed an average annulus mean diameter of 23.77±2.14mm, with 3 patients (2.46%) havinga small annulus ≤20 mm. Other studied CT parameters are shown in Table (3).

Procedural data of the studied patients revealed that 96 patients (78.6%) received the Medtronic Evolut R, 14 patients (11.4%) received the Edwards Sapien 3, and 12 patients (9.8%) received the Boston Acurate neo 2 valve as shown in Fig. (1). Most of the vascular access was through the transfemoral approachin 96.72% of patients (n=118), while transcarotid was done in 2 patients, and transsubcalvian

and transaxillary were done in 1 patient each due to extensive peripheral arterial disease. The averagedepth of implantation (DI) was 3.91±2.21mm measured by fluoroscopy in the cusp overlap view after implantation. Other procedural data can be seen in Table (4).

Our clinical endpoints were the changes in symptomatology and the occurrence of complications as defined by VARC-3. Regarding symptomatic improvement, our study revealed that the most limiting symptoms reported at baseline were shortness of breath, chest pain, palpitations, and fatigue. The majority of patients had NYHA III (73%) and IV (26.2%) at baseline and there was a highly significant improvement at 6 months follow-upin which the majority of patients became at NYHA I (91.8%) & II (7.4%) (p<0.001). And as regards laboratory data there was a significant improvement of CrCl at follow-up with a p-value of 0.011, as shown in Fig. (2) and Table (5).

As regards Echocardiographic data at follow-up, it revealed an average postprocedural MPG of 6.13±1.58mmHg. And, showed a significant improvement in EF with a p-value <0.001, even in the subgroup who had a pre-existing reduced EF. No patients acquired moderate or severe valvular leaks as shown in Table (6).

As regards clinical endpoints, our registry reported a 30-day survival rate of 97.5% and a six-month survival rate of 96.7%. Periprocedural mortality included 3 patients; 2 patients died in hospital after the procedure due to stroke, and 1 patient died after discharge and within the first 30 days due to an unknown cause which should be considered a cardiac cause according to VARC-3 definition of mortality. Incidence of stroke was 1.6% (n=2) at 1-month, Permanent pacemaker implantation was 6.6% (n=8), New onset LBBB occurred during the procedure in 18% (n=22), no acute kidney injury, and only 2 patients experienced vascular complications (1.6%), as shown in Fig. (3) and Table (7).

The EQ-5D-5L questionnaire revealed significant improvement of general health status in all five dimensions with an overall VAS score of 62.48±4.99 at baseline and 84.92±7.33 at follow-up (p<0.001) as shown in Fig. (4) and Table (8).

Table (1): Demographic data of the study population.

Parameters		Total number = 122
Age (years)	Mean ± SD (Range)	73.67±7.04 (55 – 90)
Sex	Female/Male	64 (52.5%) / 58 (47.5%)
BMI (kg/m^2)	Mean ± SD (Range)	30.32±6.35 (18.31 – 50.52)
BSA (m^2)	Mean ± SD (Range)	1.89±0.21 (1.35 – 2.47)
Euro Score II	Median (IQR)-(Range)	3.34 (1.99 – 6.42) - (0.84 – 42.7)
	<4% (low risk)	72 (59.0%)
	(4% - 9%) (intermediate risk)	34 (27.9%)
	>9% (high risk)	16 (13.1%)
STS score	Median (IQR)-(Range)	2.56 (1.76 – 4.7) - (0.66 – 16.98)
	<4%	88 (72.1%)
	(4% - 8%)	19 (15.6%)
	>8%	15 (12.3%)
Valve in Valve	N (%)	4 (3.27 %)
Smoking	Current smoker; N (%)	9 (7.4%)
	Ex-smoker: N (%)	9 (7.4%)
Diabetes Mellitus	N (%)	49 (40.2%)
Hypertension	N (%)	94 (77.0%)
Ischemic heart disease	N (%)	53 (43.4%)
Previous CABG	N (%)	12 (9.8%)
Cerebrovascular stroke	N (%)	9 (7.4%)
Chronic liver disease	N (%)	13 (10.7%)
Rheumatic heart disease	N (%)	5 (4.1%)
Bicuspid aortic valve	N (%)	18 (14.7%)

BMI: Body mass index. STS score: Society of Thoracic Surgeons.
BSA: Body surface area. CABG : Coronary artery bypass graft.

Table (2): Baseline laboratory, ECG, and Echocardiographic data.

		Total no. = 122
Baseline laboratory investigations		
Hemoglobin (mg/dl)	Mean ± SD (Range)	11.38±1.07 (9.3 – 14)
Creatinine clearance (ml/min)	Median (IQR) (Range)	60.1 (44 – 79) (13.19 – 140)
Baseline ECG data		
Atrial fibrillation	Permanent	11 (9.0%)
	Paroxysmal	11 (9.0%)
Pre-existing bundle branch block	LBBB	11 (9.0%)
	RBBB	10 (8.2%)
	IVCD	6 (4.9%)
PR interval (ms)	Mean ± SD (Range)	177.21±38.59 (120 – 320)
QRS width (ms)	Mean ± SD (Range)	103.28±26.80 (80 – 200)
Baseline ECHO		
EF (%)	Mean ± SD (Range)	59.10±14.62 (20 – 84)
	Reduced ejection fraction (<50%)	25 (20.5%)
SWT (mm)	Mean ± SD (Range)	12.65±1.92 (8 – 20.1)
SWT indexed (mm/m^2)	Mean ± SD (Range)	6.76±1.14 (4.29 – 10.66)
PWT (mm)	Mean ± SD (Range)	12.20±1.56 (8 – 18.2)
PWT indexed(mm/m^2)	Mean ± SD (Range)	6.54±1.04 (3.86 – 9.58)
LVEDD (mm)	Mean ± SD (Range)	50.55±7.05 (31 – 74)
LVEDD indexed (mm/m^2)	Mean ± SD (Range)	27.09±4.73 (16.65 – 46.54)
LVESD (mm)	Mean ± SD (Range)	33.76±8.22 (12 – 63)
LVESDi (mm/m^2)	Mean ± SD (Range)	18.18± 5.19 (6.57 – 37.73)
AV PPG (mmHg)	Mean ± SD (Range)	80.91±21.51 (35 – 171)
MPG (mmHg)	Mean ± SD (Range)	50.12±14.00 (20 – 95)
	Low gradient	15 (12.3%)
AVA (cm^2)	Mean ± SD (Range)	0.70±0.20 (0.2 – 1)
Aortic regurgitation grade	G0 N (%)	15 (12.3%)
	G1 N (%)	74 (60.66%)
	G2 N (%)	29 (23.77%)
	G3 N (%)	3 (2.46%)
	G4 N (%)	1 (0.8%)
RVSP	Mean ± SD (Range)	43.21±12.10 (20 – 86)
Low flow, Low gradient AS with reduced EF%	N (%)	13 (10.66)
Low flow, Low gradient AS with preserved EF%	N (%)	2 (1.6)

EF : Ejection fraction.
SWT : Septal wall thickness.
PWT : Posterior wall thickness.
LVEDD : Left ventricular end diastolic diameter.
LVESD : Left ventricular end systolic diameter.
AV : Aortic valve.
PPG : Peak pressure gradient.
MPG : Mean pressure gradient.
RVSP : Right ventricular systolic pressure.

Table (3): MSCT (Pre-TAVI protocol) data.

MSCT parameters		Total number = 122
Annulus mean Diameter (mm)	Mean ± SD (Range)	23.77±2.14 (18 – 28.4)
	18 – 20 (small annulus)	3 (2.46%)
	>20 – 23	46 (37.7%)
	>23 – 26	53 (43.44%)
	>26 – 30	20 (16.39%)
Annulus mean Diameter indexed (mm/m^2)	Mean ± SD (Range)	12.74±1.49 (7.59 – 17.48)
Annulus Perimeter (mm)	Mean ± SD (Range)	76. 67±6.65 (56.5 – 95)
Annulus Perimeter indexed (mm/m^2)	Mean ± SD (Range)	41.10±4.79 (23.83 – 56.6)
Annulus Area	Mean ± SD (Range)	444.98±77.55 (254 – 705.7)
Annulus Area Indexed (mm/m^2)	Mean ± SD (Range)	237.76±40.62 (107 – 377)
LMCA height	Mean ± SD (Range)	12.82±2.31 (8.8 – 20)
LMCA height indexed (mm/m^2)	Mean ± SD (Range)	6.89±1.44 (4.13 – 12.37)
RCA height	Mean ± SD (Range)	14.56±3.14 (8.6 – 26)
RCA height indexed (mm/m^2)	Mean ± SD (Range)	7.82±1.88 (4.45 – 14.21)
MS length	Mean ± SD (Range)	8.53±2.00 (4.2 – 14.4)
MS length Indexed (mm/m^2)	Mean ± SD (Range)	4.58±1.20 (2.02 – 8.68)
Grade of aortic valve Calcification	0	1 (0.8%)
	I	24 (19.7%)
	II	46 (37.7%)
	III	35 (28.7%)
	IV	16 (13.1%)
Basal Septal Calcification (presence or absence)	Yes	14 (11.5%)

LMCA: Left main coronary artery.
RCA : Right coronary artery.
MS : Membranous septum.

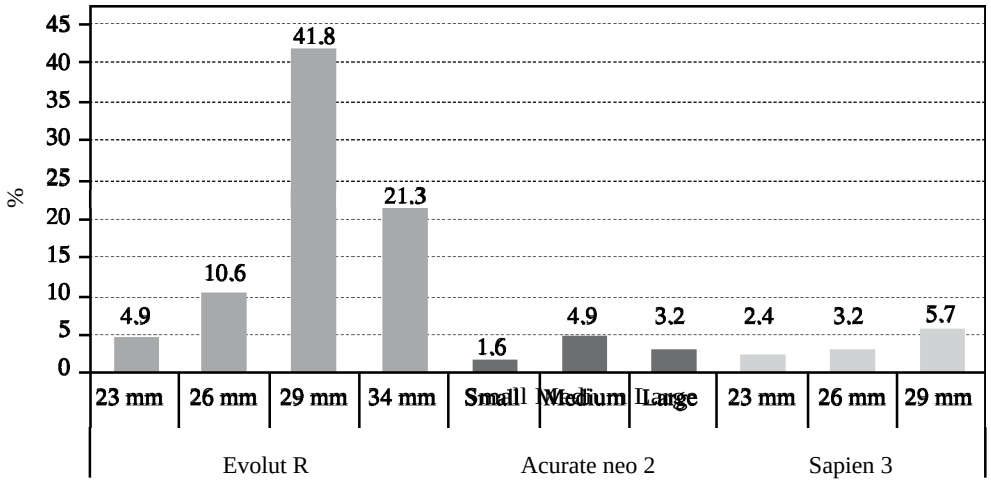

Fig. (1): Different valve platforms and sizes used among the study population.

Table (4): Procedural data of the studied patients.

Procedural data			Total no. = 122
THV type:			
Self-expandable	Evolut		
	(96 valves, 78.6%)	23 mm	6 (4.9%)
		26 mm	13 (10.6%)
		29 mm	51 (41.8%)
		34 mm	26 (21.3%)
	Acurate neo 2		
	(12 valves, 9.8%)	Small	2 (1.6%)
		Medium	6 (4.9%)
		Large	4 (3.2%)
Balloon expandable	Sapien 3		
	(14 valves, 11.4%)	23 mm	3 (2.4%)
		26 mm	4 (3.2%)
		29 mm	7 (5.7%)
Depth of implantation (mm)	Mean ± SD		3.91±2.21
Depth of implantation indexed (mm/m^2)	Mean ± SD		2.07±1.16
Pre-Dilatation	N (%)		58 (47.5%)
Post-Dilatation	N (%)		21 (17.2%)
DIMS	Mean ± SD		48.29±27.77
Vascular access	Trans-femoral		118 (96.72%)
	Non-trans-femoral	Trans-carotid	2 (1.6%)
		Trans-subclavian	1 (0.8%)
		Trans-axillary	1 (0.8%)
Approach	Percutaneous (using proglides)		118 (96.7%)
	Planned surgical cutdown		4 (3.27%)
	Conversion to surgical cutdown (failed closure device)		3 (2.5%)

THV: Transcatheter heart valve, DI: Depth of implantation, DIMS: Percentage of depth of implantation to membranous septum length.

Table (5): Clinical and laboratory parameters at baseline and 6 months follow-up.

Clinical parameters at baseline and 6 months follow-up					
Complaint	Baseline	At follow-up	Test value	*p*-value	Significance
Asymptomatic	1 (0.8%)	99 (81.1%)	162.734*	<0.001	HS
Dyspnea	36 (29.5%)	10 (8.2%)	18.110*	<0.001	HS
Chest pain	14 (11.5%)	0 (0.0%)	14.852*	<0.001	HS
Syncope	8 (6.6%)	0 (0.0%)	8.271*	0.004	HS
Palpitation	2 (1.6%)	1 (0.8%)	0.337*	0.562	NS
Fatigue	1 (0.8%)	10 (8.2%)	7.711*	0.005	HS
More than 1 symptom (dyspnea, angina, fatigue)	60 (49.2%)	2 (1.6%)	72.742*	<0.001	HS
NYHA classification:					
I	1 (0.8%)	112 (91.8%)	236.157*	<0.001	HS
II	0 (0.0%)	9 (7.4%)			
III	89 (73.0%)	0 (0.0%)			
IV	32 (26.2%)	1 (0.8%)			
Laboratory parameters at baseline and 6 months follow-up					
Hemoglobin (mg/dl):					
Mean ± SD	11.38±1.07	11.43±1.17	-1.064•	0.289	NS
Creatinine clearance (ml/min):					
Median (IQR)	60.1 (44 – 79)	66 (53 – 83)	-2.545#	0.011	S
Range	13.19 – 140	15 – 120			

p-value >0.05: Non-significant. *: Chi-square test. HS: Highly significant. SD: Standard deviation.
p-value <0.05: Significant. •: Independent *t*-test. NS: Non-significant. IQR: Inter-quartile range.
p-value <0.01: Highly significant. #: Mann-Whitney test. S: Significant. NYHA: New York Heart Association.

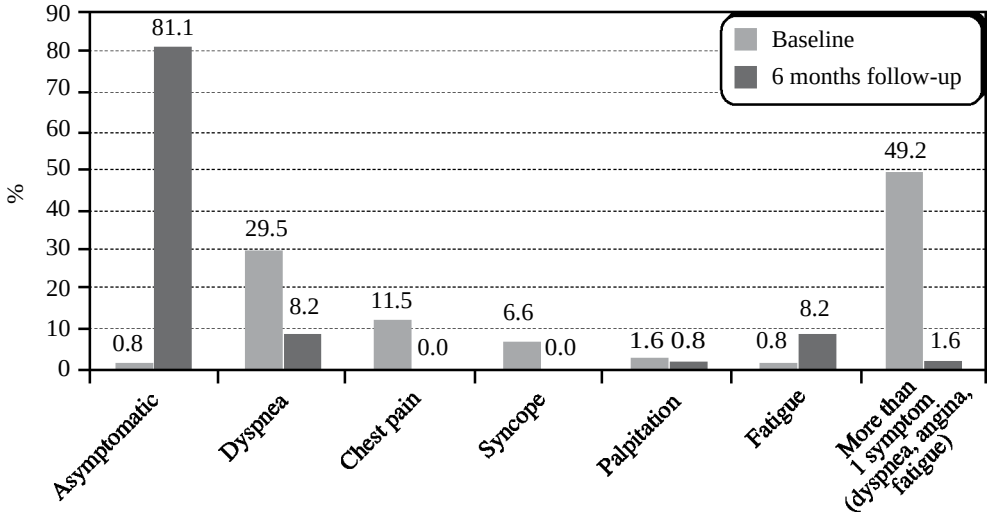

Fig. (2): Comparison between symptoms at baseline before TAVI and at 6 months follow-up.

Table (6): Echocardiographic data at baseline and 6 months follow-up.

Aortic valve Mean pressure gradient at baseline and 6 months follow-up					
MPG	Baseline		At follow-up		
Mean ± SD	50.12±14.00		6.13±1.58		
Post-procedure Degree of Paravalvular Leakage					
Degree of valvular leak at follow-up	No		105 (86.1%)		
	Mild		16 (13.1%)		
	Moderate		1 (0.8%)		
	Severe		0 (0.0%)		
LV ejection fraction at baseline and 6 months follow-up					
Ejection fraction	Baseline	At follow-up	Test value	*p*-value	Significance
Total:					
Mean ± SD	59.10±14.62	62.70±11.75	–7.012•	<0.001	HS
Reduced EF:					
Mean ± SD	33.44±8.42	42.16±8.40	–4.298•	<0.001	HS

p-value >0.05: Non-significant.
p-value <0.05: Significant.
p-value <0.01: Highly significant.
*: Chi-square test.
•: Independent *t*-test.
HS: Highly significant.
SD: Standard deviation.
EF: Ejection fraction.

Table (7): Clinical endpoints of the study population according to VARC-3.

Clinical endpoints of the study population according to VARC-3				
		Peri-procedural mortality	Early mortality	Total
Mortality	No	119 (97.5%)	118 (99.2%)	118 (96.7%)
	Cardiac	3 (2.5%)	0 (0.0%)	3 (2.5%)
	Non-cardiac	0 (0.0%)	1 (0.8%)	1 (0.8%)
		At 1 month	At 6 months	Total
Stroke	No	120 (98.4%)	120 (100.0%)	120 (98.4%)
	Yes	2 (1.6%)	0 (0.0%)	2 (1.6%)
Hospitalization	No	112 (91.8%)	95 (84.8%)	95 (77.9%)
	Cardiac	9 (7.4%)	6 (5.4%)	15 (12.3%)
	Non-cardiac	1 (0.8%)	11 (9.8%)	12 (9.8%)
Permanent pacemaker implantation	No	114 (93.4%)	113 (99.1%)	113 (92.6%)
	Yes	8 (6.6%)	1 (0.9%)	9 (7.4%)
New onset LBBB	No	100 (82%)	100 (100.0%)	100 (82%)
	Yes	22 (18%)	0 (0.0%)	22 (22%)
Acute kidney injury	No	122 (100.0%)	122 (100.0%)	122 (100.0%)
	Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)
Bleeding	No	115 (94.3%)	113 (98.3%)	113 (92.6%)
	Minor	7 (5.7%)	1 (0.9%)	8 (6.6%)
	Major	0 (0.0%)	1 (0.9%)	1 (0.8%)
Vascular complications	No	120 (98.4%)	120 (100.0%)	120 (98.4%)
	Pseudoaneurysm	1 (0.8%)	0 (0.0%)	1 (0.8%)
	Infection	1 (0.8%)	0 (0.0%)	1 (0.8%)
BVD at 1 and 6 months	No	122 (100.0%)		
MI at 1 and 6 months	No	122 (100.0%)		

LBBB: Left bundle branch block. AKI: Acute kidney injury. BVD: Bioprosthetic valve dysfunction. MI: Myocardial infarction.

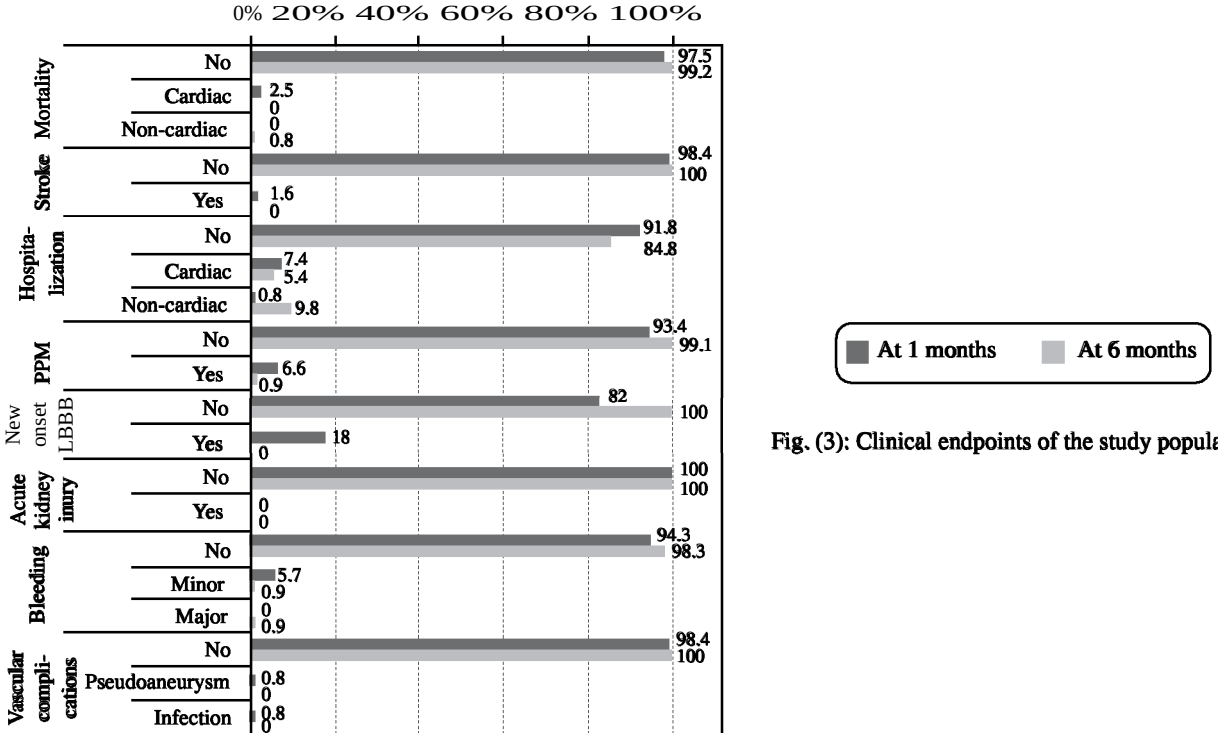

Fig. (3): Clinical endpoints of the study population.

Table (8): EQ-5D-5L questionnaire and EQ-VAS score at baseline and 6 months follow-up.

EQ-5D-5L questionnaire and EQ-VAS score						
		Baseline No. (%)	Follow-up No. (%)	Test value	*p*-value	Significance
Mobility	No problem	0 (0.0%)	84 (68.9%)	225.564*	<0.001	HS
	Slight	0 (0.0%)	33 (27.0%)			
	Moderate	13 (10.7%)	2 (1.6%)			
	Severe	75 (61.5%)	1 (0.8%)			
	Extreme	34 (27.9%)	2 (1.6%)			
Usual activities	No problem	0 (0.0%)	91 (74.6%)	225.018*	<0.001	HS
	Slight	1 (0.8%)	27 (22.1%)			
	Moderate	32 (26.2%)	1 (0.8%)			
	Severe	68 (55.7%)	1 (0.8%)			
	Extreme	21 (17.2%)	2 (1.6%)			
Self-care	No problem	0 (0.0%)	103 (84.4%)	212.243*	<0.001	HS
	Slight	9 (7.4%)	16 (13.1%)			
	Moderate	63 (51.6%)	0 (0.0%)			
	Severe	47 (38.5%)	1 (0.8%)			
	Extreme	3 (2.5%)	2 (1.6%)			
Pain/discomfort	No problem	0 (0.0%)	96 (78.7%)	202.878*	<0.001	HS
	Slight	13 (10.7%)	23 (18.9%)			
	Moderate	68 (55.7%)	0 (0.0%)			
	Severe	39 (32.0%)	1 (0.8%)			
	Extreme	2 (1.6%)	2 (1.6%)			
Anxiety/depression	No problem	2 (1.6%)	91 (74.6%)	167.253*	<0.001	HS
	Slight	34 (27.9%)	28 (23.0%)			
	Moderate	64 (52.5%)	0 (0.0%)			
	Severe	17 (13.9%)	0 (0.0%)			
	Extreme	5 (4.1%)	3 (2.5%)			
EQ VAS Score	Mean ± SD	62.48±4.99	84.92±7.33	–29.663•	<0.001	HS

p-value >0.05: Non-significant. *: Chi-square test. HS: Highly significant.
p-value <0.05: Significant. •: Independent *t*-test. EQ-5D -5L: (Euro-quality of life – 5 dimensions- 5 levels).
p-value <0.01: Highly significant. EQ-VAS: (Euro-quality of life visual analogue scale).

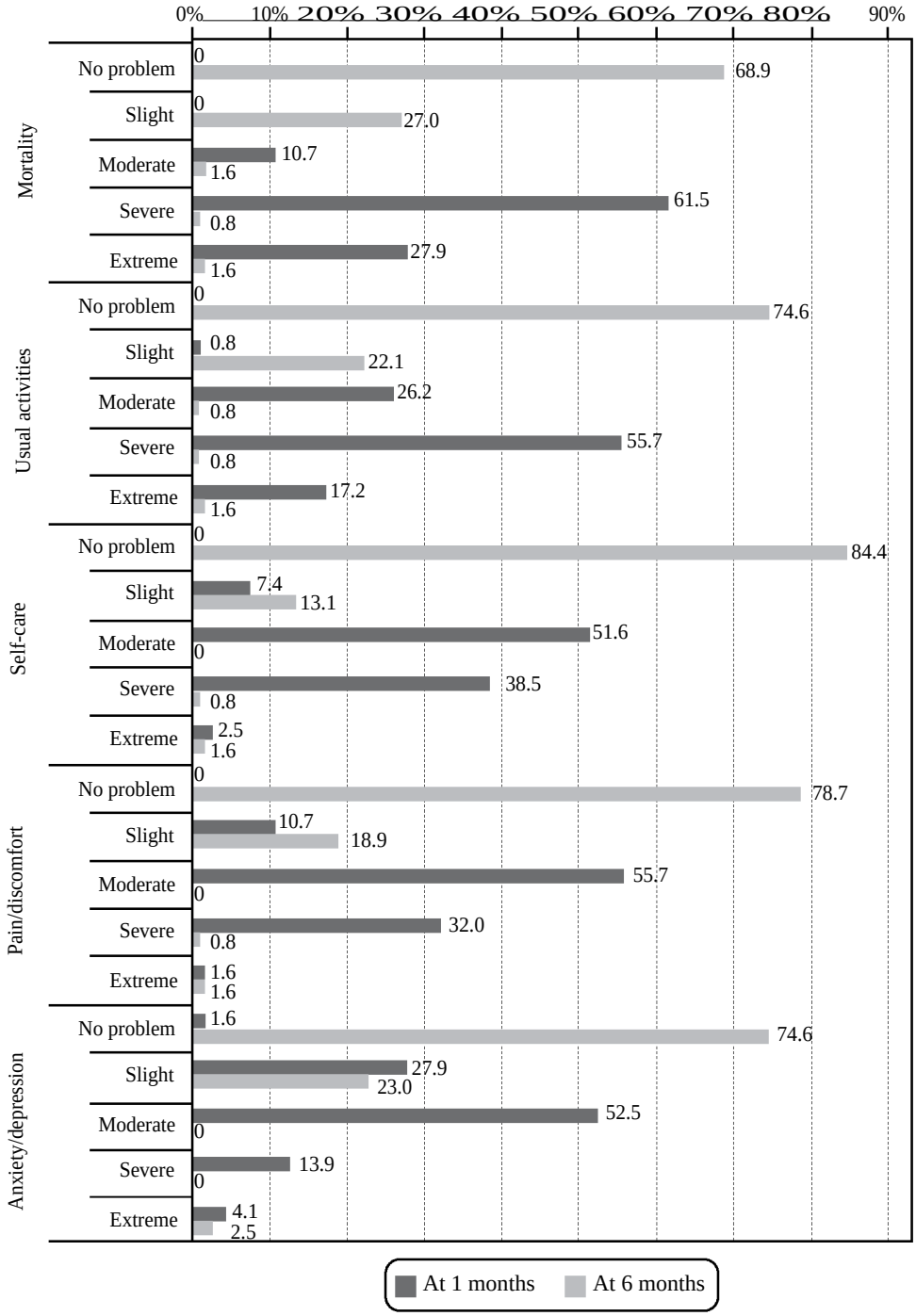

Fig. (4): Comparison between results of the EQ-5D-5L at baseline before TAVI and at 6 months follow-up.

Discussion

To our knowledge, this is the first Egyptian TAVI registry analyzing clinical outcome reporting based on the Valve Academic Research Consortium-3 (VARC-3) as a clinical endpoint. The ultimate goal of TAVI is not only to add years to patients' lives by reducing mortality rate but also to add life to their years by improving quality of life.

In our study, the median and interquartile ranges (IQR) for Euro II score & STS score were 3.34 (1.99 – 6.42) & 2.56 (1.76 – 4.7) respectively with about = 87% of patients at low & intermediate risk for cardiac surgery and only about = 13% of them at high risk for cardiac surgery, which comes in the context of the recent practice of the new low-risk TAVI era.

In our study, there were significant differences regarding patients' demographics compared to that of the Western populations. The main variations involved being relatively younger with mean age ± SD 73.67±7 years, 52.5% were females, higher BMI of

30.32±6.35kg/m^2, a higher percentage of diabetics 40.2% (N=49), and a lower Euro II & STS score of 3.34 (1.99 – 6.42) & 2.56 (1.76 – 4.7) respectively than that of UK TAVI *[16]* and Swiss TAVI registries *[17]*. In concordant with the Chinese CARRYTAVI registry *[18]* the mean age was 73.8±6.5 years and the mean STS-PROM score was 6.0 (3.7– 8.9).

The transfemoral approach was adopted in 96.72% (N=118) of our patients, which is higher compared to 74.1% in the United States and Japan TAVI registry *[19]*, 74.4% in the UK registry *[16]*, and nearly similar compared to (98.2%) in the Chinese CARRY registry *[18]*. This goes with the fact that transfemoral TAVI is easier and showed better results encouraging operators to use the femoral approach as the routine access, Moreover, we only encountered 4 patients with peripheral arterial disease and had unsuitable transfemoral approach.

The SEV platform (Evolut R) was implanted in 78.6% (N=96) of patients which is higher compared to 51.05% in the Egy-TVR registry *[20]* and 21.1% In the STS-ACC TVT registry *[21]* and 41.7% in the UK TAVI registry *[16]*. This could be attributed to the scarcity of the BEV in our center sometimes due to higher costs.

Balloon pre-dilatation & post-dilatation were performed in 47.5% (N=58) and 17.2% (N=21) respectively which is less in comparison with 50% (N=48) and 30.2% (N=29) in the Egy-TVR registry *[20]*, this could be attributed to the relatively younger age, lower risk, and less use of the BEV platform.

In our registry, the median CrCl and IQR were 60.1 (44-79) ml/min at baseline which shows significant improvement at 6 months follow-up 66 (53-83) ml/min with a ***p***-value of 0.011 which comes in concordant with Calça et al., study *[22]* which suggested an improvement in kidney function in patients with moderate to severe CKD after TAVI, and This outcome is probably due to better kidney perfusion post-procedure.

Based on echocardiography results, TAVI significantly improved the patient's hemodynamics. The mean pre- and post-procedural LVEFwere 59.10± 14.62 and 62.70±11.75% respectively with ***p***-value <0.001, also patients with reduced EF showed significant improvement with mean pre- and post-procedural LVEF of 33.44±8.42 and 42.16±8.40% respectively with ***p***-value <0.001. The mean pre- and post-procedural MPG were 50.12±14.00 and 6.13± 1.58mmHg respectively with ***p***-value <0.001, with more than 99% absence of > mild paravalvular leak. This comes concordant with echocardiographic assessment in the CARRY registry 18 in which the mean pre- and post-procedural LVEF were 53.3±14.1 and 55.8±11.8%, respectively (***p***<0.001). & The mean pre- and post-procedural MPG were 57.6±21.8 mmHg and 13.0±6.4 mmHg respectively (***p***<0.001).

Regarding death as the most objective and unbiased endpoint, our registry reported a 30-day survival rate of 97.5% and only 2.5% mortality at one month related to cardiac causes, and a 6-month survival rate of 96.7% with lower mortality rates compared to 4.5% in the CARRY registry *[18]*, 4.16% in Egy-TVR registry *[20]*, 7.1% in the UK TAVI registry *[16]* and 10.4% in a study by Rodés-Cabau et al., *[23]* which may be explained by the increased experience and technical advances in the devices in recent studies.

The overall hospitalization rate was 12.3% (N=15) due to cardiac causes, and 9.8% (N=12) due to non-cardiac causes, the cardiac causes were predominant at one month with a rate of 7.4% (N=9) mostly due to heart failure manifestations, and non-cardiac causes were predominant at six months with a rate of 9.8% (N=11) mostly due to chest infection, compared to 2.5% in Nilsson study *[24]*, this could be attributed to large number (N=2821) of participant in their study.

The stroke rate in our study was 1.6% (N=2) similar to the observed rate of 2.1% in the UK TAVI registry *[16]*, but lower than the PARTNER trial (6.1%) *[25]*. Unfortunately, both of our patients experienced in-hospital mortality after mechanical ventilation due to impaired consciousness levels.

The overall incidence of high-degree atrioventricular block resulting in permanent pacemaker implantation (PPM) was 7.4% (N=9) with 6.6% (N=9) in the first month, Evolut R was implanted in all of them, compared to 7.29% in Egy-TVR registry *[20]*, 11.8% in the STS-ACC TVT registry *[21]* and 12.4% in the UK TAVI registry *[16]*, which may be explained by the growing world-wide operator experience and technical advances to reduce such complication as using the cusp-overlap view and targeting percentage of depth of implantation from the membranous septum length <70% *[26]*.

We observed 1.6% vascular complications (N=2), compared to 1.1% in the CARRY registry *[18]*, 2.3% in the UK TAVI registry *[16]*, 7.1% in the STS-ACC TVT registry *[21]*, and 11.5% in the Egy-TVR registry *[20]*. Major bleeding occurred in only one patient (0.8%) at 6 months and was GIT bleeding compared to 0.5% in the CARRY registry *[18]*, and 8.4% in the STS-ACC TVT registry *[21]*, this could be attributed to accumulating experience and smaller sheath sizes with the newer valve designs.

It is promising to say we observed no cases of MI or BVD up to six months post-procedure compared to 0.2% in the CARRY registry *[18]*.

Regarding symptomatology, the most limiting symptoms related to heart disease reported at baseline were shortness of breath (SOB), chest pain, fatigue, and palpitations which show high significant improvement with 81.1% of patients (N=99) were

asymptomatic at follow-up with *p*-value <0.001, fatigue reported as the most limiting symptom at follow-up. Since this is a less specific symptom, it can be seen as being caused by advanced age or other diseases, and the majority of patients with NYHA III (73%) & IV (26.2%) at baseline show high significant improvement with the majority of patients at NYHA I (91.8%) & II (7.4%) at follow-up with a *p*-value <0.001, this comes in concordance with a study by Olsson et al., [27] *p*-value = 0.022, and Lefevre et al., (Euro-PARTNER) study [28] with 84.8% improvement of NYHA class.

Regarding the quality of life (EQ-5D-5L questionnaire), we observed improvement in all five dimensions (Mobility, Usual activities, Self-care, Pain/discomfort, Anxiety/depression), and overall EQ-VAS score showed improvement from 62.48 ± 4.99 at baseline to 84.92±7.33 at follow-up ($p<$ 0.001) which comes in concordant to Olsson et al with improvement from 50 (10-90) to 70 (25-100) with *p*-value = 0.00527.

Conclusions:

Our study demonstrated low rates of procedure-related complications, favorable short-term clinical outcomes, and a significant improvement in symptomatology and general health status.

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النتائج السريرية للمرضى الذين يعانون من التضيق الشديد بالصمام الأورطى وتم علاجهم بزراعة الصمام الأورطى عن طريق القسطرة: تجربة مركز واحد

زرع الصمام الأبهرى عبر القسطرة هو الآن معيار الرعاية للمرضى غير القابلين لاستبدال الصمام الأبهرى جراحيا وبديل صالح للجراحة للعديد من المرضى المعرضين لمخاطر عالية. وقد أظهرت عدم الدونية لاستبدال الصمام الأبهرى جراحيا فى المرضى الذين يعانون من مخاطر متوسطة لجراحة القلب.

الهدف من هذه الدراسة هو تقييم النتائج السريرية للمرضى الذين يخضعون لزراعة الصمام الأورطى. شملت دراستنا (١٥١) مريضا وتم تغيب ٢٩ مريضا أثناء المتابعة واستبعادهم بسبب عدم اكتمال البيانات وفشل المتابعة ، لإنهاء الدراسة مع (١٢٢) مريضاً.

يظهر سجلنا نتائج سريرية مواتية على المدى القصير فى مرضى زراعة الصمام الأورطى عن طريق القسطرة غير المختارين، وجدت الدراسة أن مرشحى زراعة الصمام الأورطى عن طريق القسطرة فى مصر كانوا أصغر سناً، ولديهم مخاطر أقل لجراحة القلب، وكان لديهم معدلات أقل من المضاعفات والوفيات بعد الإجراء مقارنة بسجلات جميع القادمين الدوليين الآخرين، مما يشير إلى أن الإجراء آمن ومفيد خاصة من خلال تراكم الخبرة والتقدم التقنى فى الأجهزة وليس فقط إضافة سنوات إلى حياة المرضى عن طريق تقليل الوفيات الناجمة عن جميع الأسباب ولكن أيضا إضافة الحياة إلى سنواتهم من خلال تحسين نوعية الحياة.