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TRANSCATHETER AORTIC VALVE IMPLANTATION: ACUTE AND 6-MONTH OUTCOMES OF THE FIRST LEBANESE EXPERIENCE AND A LITERATURE REVIEW

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ABSTRACT • Background : Transcatheter aortic valve implantation (TAVI) has recently emerged as a therapeutic alternative for high-risk surgical patients with severe symptomatic aortic valve stenosis and has been shown to improve clinical outcomes and reduce all-cause mortality in the PARTNER Trial. However, there is still no published data on similar outcomes in the Lebanon. **Objectives :** The aim of the study is to evaluate the immediate and short-term results of transfemoral (TF) and transaortic (TAo) TAVI done in Lebanon with 6 months follow-up. **Methods :** From July 2012 till March 2015, 10 consecutive high-risk and intermediate risk patients with severe symptomatic AS underwent TAVI using Edwards SAPIEN valve. The mean age was 79.4 ± 6.9 years, logistic EuroSCORE 12.56 ± 11.78 and mean STS 5.71 ± 2.44. Patients were equally distributed among genders (50%). The mean ejection fraction (EF) was 50.0 ± 14.9% and mean AV area 0.61 ± 0.1 cm^2; mean aortic valve gradient (mAVG) 45.6 ± 20.2 mmHg, and AV annulus size 21.8 ± 1.8 mm. **Results :** TF approach was performed in 9 patients (90%) and TAo in 1 patient (10%). All valves (17 size 26 mm and 25 size 23 mm) were implanted successfully. The overall 6-month survival was 80%. Grade I paravalvular aortic regurgitation (AR) was present in 60% of the patients; grade II in 10% while none of the patients developed AR with grade III or VI. The post-procedural mean aortic valve gradient (mAVG) was 9.77 ± 3.31 mmHg; EF was 52.5 ± 11.9% and immediate postoperative complications included only one case of new-onset arrhythmia (AV Block). After 6 months, one patient died of cardiac arrest following a massive pulmonary embolism while another patient died from a fatal stroke following infective endocarditis affecting the valve prosthesis. **Conclusion:** TAVI is a feasible technique for intermediate/high risk AS with high success rate and acceptable complications.

Keywords: transcatheter aortic valve implantation (TAVI), aortic stenosis, PARTNER

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INTRODUCTION

Aortic valve replacement (AVR) is the mainstay of treatment of symptomatic aortic stenosis (AS). This surgery has proven to offer improvement in symptoms and quality of life in patients who are candidates for thoracic surgery [1]. However, aortic valve surgery carries significant risks especially for patients with severe comorbidities such as cerebrovascular disease, coronary artery disease (CAD) and chronic kidney or pulmonary disease; hence many patients are not candidates for such major surgery [2]. Percutaneous aortic valvulotomy was developed as a minimally invasive measure by inflating balloon catheter placed inside the valve, in order to treat inoperable patients with severe AS who cannot undergo AVR [3]. However, this procedure is still not indicated for most patients with aortic stenosis according to the most recent ACC/AHA (American College of Cardiology/American Heart Association) 2006 guidelines as it only offers palliative treatment or is used as a bridge to surgical AVR for hemodynamically unstable patients [4].

Subsequently, transcatheter aortic valve replacement (TAVR) or implantation (TAVI) was developed as an alternative noninvasive technique to treat patients with severe symptomatic aortic stenosis and very high estimated surgical risk.

In this study, we describe the first experience of TAVI procedure for severe symptomatic AS in Lebanon. We describe the first registry in Lebanon to prospectively assess the conditions of ten patients who underwent a TAVI operation and were followed up for a minimum of six months in order to evaluate the safety of this procedure by checking the postoperative survival and the complications resulting from it.

MATERIAL AND METHODS

This is a prospective study of 10 patients who underwent TAVI at our center, the Lebanese American University Medical Center-Rizk Hospital (LAUMC-RH), between July 2012 and March 2015. All patients were diagnosed with severe symptomatic aortic stenosis and a status of high or intermediate surgical risk. None had a failing bioprosthesis. Decision for the procedure was conjoint between interventional cardiologists, cardiac surgeons, anesthesiologists, radiologists and the patients. The study was approved by the Institutional Review Board (IRB) and the LAUMC-RH. All the study subjects provided their informed consent, and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki. Echocardiography was per-

formed on all patients to confirm severe aortic stenosis defined by an aortic valve area of less than 1 cm^2 and a mean aorto-ventricular gradient of more than 40 mmHg.

When decision for TAVR is made, the preoperative work-up will include Doppler arteriography, coronary arteriography, aortoiliofemoral angiography, computed tomography to determine the aortic annular valve size, and a transthoracic ultrasound (TTE). The choice of valve size and access route (whether transfemoral, transapical or transaortic) will be made based on a composite evaluation of all the individual radiologic data of every patient. The role of computed tomography in TAVR preoperative work-up is based on the Society of Cardiac Computed Tomography (SCCT) expert consensus document on MDCT imaging before TAVR. CT will provide valuable information in regard to the small, medium and large diameters of the aortic annulus, the extent of aortic calcification and the distance between left main coronary and aortic annulus [5]. If the latter is less than 10 mm, there is an increased risk of coronary obstruction post procedure. Peripheral vascular imaging done by angiography will provide crucial evaluation of the aorta to exclude the presence of an abdominal aneurysm, kinking of the aorta or large thrombi protruding into the lumen, or complex atheromas. The presence of these factors is a contraindication for transfemoral approach [6]. Also the ascending aorta should be assessed for calcification as calcium may interfere with puncture of the aorta if the transaortic route is to be performed [5].

Inclusion criteria

Severe AS was defined as an aortic valve area (AVA) of less than 1.0 cm^2, a mean aortic-valve gradient of 40 mm Hg or more, or a peak aortic-jet velocity of 4.0 m per second or more. All the patients had New York Heart Association (NYHA) symptoms greater than class II.

Patients' comorbidities and surgical risk was evaluated based on the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) and the Society of Thoracic Surgeons (STS) risk of mortality score. An STS Score ≥ 8 and a logistic EuroSCORE ≥ 20% are considered high surgical risk patients. Patients with intermediate surgical risk have an STS Score between 3 and 8 and EuroSCORE of 0 to 20.

All patients in this study received the Edwards SAPIEN valve (Edwards LifeSciences, Irvine, Calif.), and were considered either intermediate or high-risk surgical patients. Regarding the choice of valve diameter adequate to avoid post-procedural paravalvular aortic regurgitation (AR), the 23 mm valve would be used if preoperative transesophageal echocardiographic (TEE) showed an aortic annulus between 18 and 21 mm, and the 26 mm valve would be used if the aortic annulus were between 22 and 25 mm.

Exclusion criteria

The major exclusion criteria indicated by the expert consensus document included: severe AR (> 3+), bicuspid, unicuspid or non-calcified aortic valve and a native aortic annulus size < 18 mm as measured by echocardiography or is > the largest annulus size for which a TAVI device is available (29 mm) [7]. Also excluded from the study were patients with hypertrophic cardiomyopathy with or without obstruction, severe mitral regurgitation or severe pulmonary hypertension with right ventricular dysfunction, a left ventricular ejection fraction (LVEF) < 20%, any echocardiographic finding suggestive of endocarditis, chronic kidney disease/end-stage renal disease (CKD/ESRD) and any recent acute coronary syndrome (ACS) within the past six months prior to enrollment. Regarding the access route, patients with iliofemoral disease, insufficient femoral artery diameter, or aortic dissection were all excluded from the transfemoral (TF) approach.

Delivery techniques, preoperative and postoperative management

All patients received the SAPIEN valve through the TF approach except one patient who had the procedure through the TAo route. Preoperative management involved preparations for treatment of volume depletion, positive inotropic agents in patients with low cardiac output (CO), inhaled nitric oxide in severe pulmonary hypertension and managing any emergency cardiopulmonary bypass. Perioperative management includes general anesthesia with a temporary pacing lead, warming to avoid hypothermia, anticoagulation with heparin administration (5,000 IU bolus) after placement of standard sheaths (target bleeding time of 250-300 seconds) and monitoring by arterial line and TEE [7]. Postoperative management includes chronic administration of antithrombotic therapy, with dual antiplatelet therapy (aspirin and clopidogrel) at first six months followed by lifelong aspirin intake, as recommended by US FDA [8,9]. Figures 1 & 2 show intraoperative images of two patients who underwent the procedure successfully.

Definitions of outcomes

Procedural success was defined as a successful implantation of the Edwards SAPIEN valve with no death or life-threatening complication. Furthermore, intraoperative TTE monitoring and Doppler echocardiogram should document a functional valve and aortic paravalvular regurgitation less than grade 2. Also major complications were monitored immediately post procedure as patients were admitted to the coronary care unit.

The efficacy and safety of the TAVI procedure including its complications were assessed with clinical follow-up and series of echocardiographic data before discharge, at 30 days, at 3 months and finally at 6 months post procedure.

Statistical analysis

Continuous variables are described as mean ± SD, and dichotomous or nominal variables are described as numbers and percentages. Statistical analyses were performed using SPSS (version 22.0 for Windows, SPSS Inc., Chicago, Illinois).

For all comparisons, a p value < 0.05 was considered statistically significant.

Baseline characteristics

Baseline clinical and echocardiographic characteristics of the study population are shown in Table I. The approach for TAVI was TF in 9 patients (90%) and TAo in one (10%). The mean patient age was 79 ± 7 years, and the mean logistic EuroSCORE and STS risk scores were 12.56 ± 11.78% and 5.71 ± 2.44%, respectively. Our patients had a high coronary artery disease prevalence
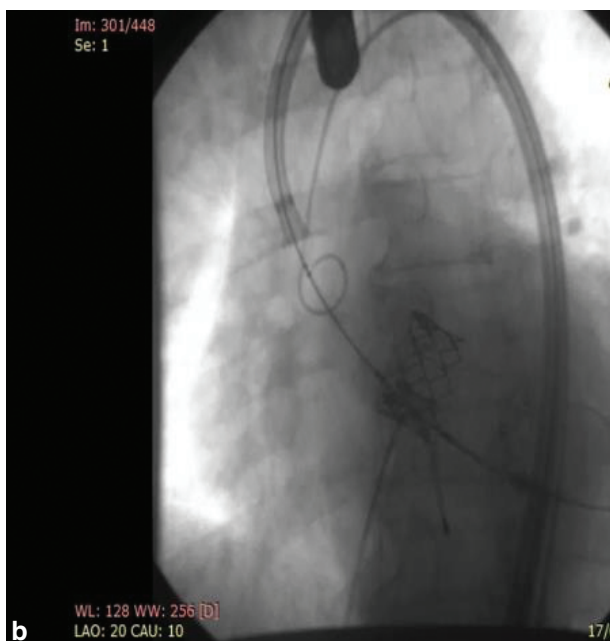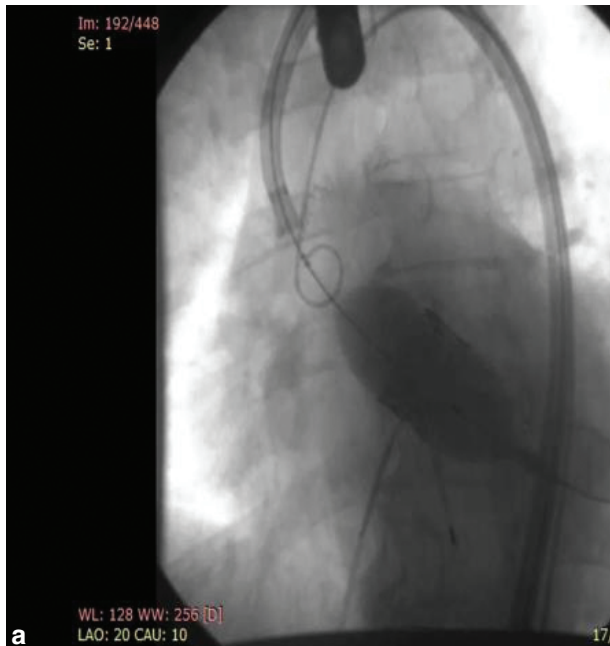
FIGURES 1a & 1b. A 76-year-old male patient (Case #1) with an AVA of 0.5 cm² and a mAVG of 60 mmHg is receiving the balloon expandable TAVI bioprosthesis.

(80%), with a mean logistic EuroSCORE of 12.56%, pulmonary disease prevalence of 20% and peripheral vascular disease prevalence of 10%.

Procedural characteristics and clinical outcomes

The procedural characteristics and clinical outcomes are defined in Tables II and III. Procedural success was achieved in all 10 patients (100%). All valves (four size 26 mm and five size 23 mm) were implanted without severe periprocedural complications or death, and the mean hospital stay was 6.7 days. The only complication that occurred within the first 24 hours of the procedure was an atrioventricular (AV) block that required placement of a permanent pacemaker.

Follow-up and 6-month outcomes

The 6-month outcomes of the procedure are summarized in Table III. Two out of the 10 patients: the first (Case #3) with a EuroSCORE of 39 and who had undergone TAVI with TAo approach died three months after the operation, attributed to severe pulmonary embolism, and the second patient (Case #9) suffered a fatal stroke following infective endocarditis affecting the bioprosthesis. Hence, our procedural 6-month mortality rate was 20%.

None of the other 8 patients experienced stroke or myocardial infarction as well as vascular complication, new onset atrial fibrillation and emergency open-heart surgery during 6 months post-operation (Table III). One of the patients who was free of post-TAVR complications (no stroke, MI, AV block) underwent hip replacement therapy which was well tolerated in terms of cardiac function, while another patient presented with multiple episodes of acute decompensated heart failure and recurrent pulmonary edema and eventually showed clinical improvement. Other hospitalizations included pneumonia and infective endocar-
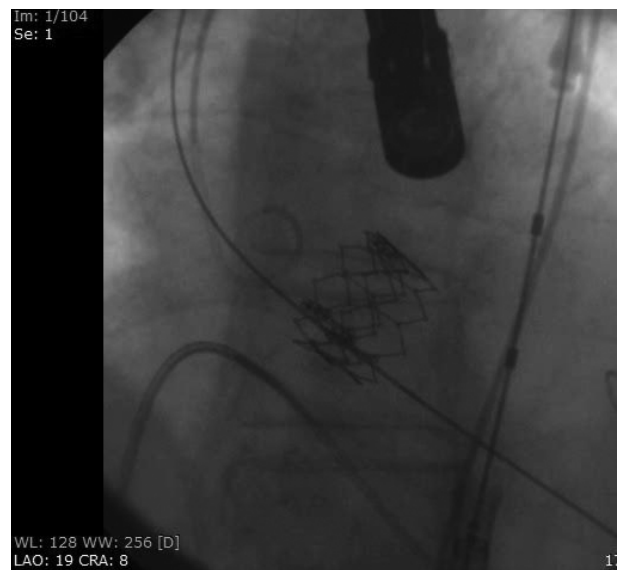
FIGURE 2. An 86-year-old female (Case #2) with an AVA of 0.7 cm² and a mean AVG of 50 mmHg has a TAVI bioprosthesis implanted with resultant decrease in mAVG to 8 mmHg.

Variable	All patients (N = 10)	Transfemoral (N = 9)	Transaortic (N = 1)
Age (years)	79.4 ± 6.9	80.3 ± 6.6	79
Male	5 (50)	4 (44)	1 (100)
Logistic EuroSCORE	12.56 ± 11.78	9.62 ± 7.69	39
NYHA class			
I or II	0	0	0
III or IV	10 (100)	9 (100)	1 (100)
Diabetes	2 (20)	2 (22)	0
Coronary artery disease	8 (80)	7 (77.8)	1 (100)
Prior percutaneous coronary intervention	2 (20)	2 (22)	0
Prior coronary artery bypass grafting	4 (40)	3 (33.3)	1 (100)
Cerebrovascular disease	0	0	0
Peripheral vascular disease	1 (10)	1 (11.1)	0
Pulmonary disease	2 (20)	2 (22)	0
Atrial fibrillation	3 (30)	3 (33.3)	0
Permanent pacemaker	0	0	0
ECHOCARDIOGRAPHIC FINDINGS			
Mean aortic gradient (mmHg)	45.6 ± 20.2	48.4 ± 19.2	20
Aortic valve area (cm²)	0.6 ± 0.1	0.6 ± 0.1	0.7
Left ventricular ejection fraction (%)	49 ± 14	51 ± 13	30

TABLE I — BASELINE CHARACTERISTICS OF THE STUDY POPULATION *

*Unless not applicable values are expressed as n (%)
EuroSCORE: European System for Cardiac Operative Risk Evaluation   **NYHA**: New York Heart Association

ditis. Additionally, there was a significant improvement in the NYHA class after 6 months follow-up, where 33.33% of patients converted from class II to class III.

Acute and 6-month echocardiographic findings
Echocardiographic findings at baseline, 24-hours and 6-months following the procedure, are shown in Table II. Among patients who underwent TAVI, the mean aortic valve gradient decreased from 45.1 ± 20.5 mmHg to 9.77 ± 3.31 mmHg at discharge ($p < 0.001$ for both). At 6-month follow-up assessment, the improvement in mean gradient remained significant. The post-24 hours procedural LVEF was 52.5 ± 11.9%. These values remained stable after 6 months of follow-up. Moreover, there was a significant improvement in MR grade (all < II) in all 10 patients. On the other hand, paravalvular AR post-TAVI was generally mild AR (angiographic grade ≥ 1) and was present in 90% of patients at discharge. None of the patients had more than moderate (grade 2) AR at 6-month follow-up.

Antithrombotic management
Regarding the antithrombotic treatment pre- and post-TAVI, six patients were already taking aspirin (ASA) prior to the TAVI procedure, and two were receiving dual anti-platelet therapy (DAPT) with aspirin and clopidogrel, while one patient was not on any antithrombotic treatment (ATT). After the procedure, all patients were placed on DAPT for 6 months and continued on lifelong ASA, while three patients with chronic atrial fibrillation were placed on different antithrombotic regimens after the procedure. One patient (case #6) was placed on triple antithrombotic therapy (aspirin, clopidogrel and warfarin) for six months and continued on warfarin while another patient (case #9) was continued on warfarin alone after the procedure. A third patient (case #10) with paroxysmal atrial fibrillation was in sinus rhythm post-op and hence was placed on the standard DAPT.

DISCUSSION

Although balloon valvuloplasty was developed to offer symptomatic relief for inoperable patients with severe AS, restenosis almost always occurred within 1-2 years, and it did not change the dismal prognosis of the disease [10]. Therefore, TAVI has emerged to replace balloon valvuloplasty as a successful alternative to surgical AVR with favorable short-term and long-term efficacy and safety. There are two current market leaders which are available to physicians for implantation in candidate patients: the Medtronic CoreValve device, delivered through a femoral, subclavian, or direct aortic approach, and the balloon-expandable valve, the Edwards SAPIEN valve by Edwards Lifesciences, a stainless steel cage that has three pericardial leaflets sewn onto the cage, implanted via a TF or TA approach. This procedure is currently approved in more than 50 countries including the US, where it gained FDA approval for use in inoperable patients in November 2011, and for high-risk patients in October 2012 [11]. The Medtronic CoreValve received FDA approval on January 17, 2014 [12].

A major clinical trial investigating the efficacy and safety of TAVI was the Placement of Aortic Transcatheter

Valve 1 (PARTNER 1) trial, which compared clinical outcomes in patients with severe symptomatic AS who were randomized to receive either conventional therapy (surgical AVR in cohort A or percutaneous aortic valve valvuloplasty in cohort B) or transcatheter implantation of an Edwards SAPIEN valve. The trial results showed a lower 1-year mortality rate of 30.7% versus 50.7%, 2-year mortality rate of 43.4% versus 68%, and 5-year (71.8% versus 93.6%) mortality rates for the TAVI group, compared to the group receiving balloon valvuloplasty [10]. In addition there was improvement of NYHA functional class at 1 and 2 years in cohort B of the trial [10]. Furthermore, the TAVI group had lower transvalvular AR rates at 30 days (11.8 versus 16.9%) and 1 year (10.5 versus 15.2%) compared to balloon valvotomy [10]. On the other hand, the outcomes of TAVI compared to surgical AVR were done in cohort A of the PARTNER trial; the results show similar mortality rates and frequencies of stroke, MI, endocarditis between TAVI and surgical groups at 30 days, 2 years and 5 years post procedure [13-15].

Compared with the PARTNER trial [10], our patients have higher coronary artery disease prevalence (80% versus 67.6%), but our cohort tended to be younger with a lower logistic EuroSCORE (12.56% versus 26.4%), pulmonary disease (20% versus 41.3%) and peripheral vascular disease (10% versus 30.3%). In our registry, the immediate procedural success rate was 100% with no acute complication (Table II), and none of patients required emergency surgical AVR or hemodynamic support. Moreover, the mean pressure gradient decreased by 78.7% at 6-months follow-up compared to 75.1% decrease in the PARTNER trial [10]. The reported procedural success of TAVI is approximately 90%-95%, but some patients may require multiple valve implantation or conversion to surgical AVR due to periprocedural complications of aortic dissection or rupture and valve embolization, migration and leakage [10,16-17]. In this cohort, the short-term (3 months) mortality rate was 10%, which is similar to that found in the Taiwanese study [13] (10%) and Italian registry 12.2% [14]. In the PARTNER 1A cohort, 30-day mortality was 5.2% while it was 5% in the PARTNER 1B cohort [10,18].

The most common encountered complications of TAVI are vascular in origin including bleeding or thrombotic events, and this may be due to the large access sheaths that are required to insert this delivery system. The PARTNER trial has shown that TAVI caused more vascular complications (17.0%) when compared to standard surgical AVR group (3.8%) in addition to high paravalvular AR [18]. Besides, stroke and transient ischemic attack are other alarming complications with higher rates in TAVI compared to surgical AVR and balloon valvuloplasty, as shown by the PARTNER 1A trial [18,19] (5.5 versus 2.4% at 30 days and 8.7 versus 4.3% at one year) and PARTNER 1B trial [10] (6.7 versus 1.7% at 30 days and 13.8 versus 5.5% at 2 years).

Our study shows a similar stroke rate (10%), with one case of fatal stroke (case # 9), and the stroke was caused by

TABLE II   BASELINE PROCEDURAL OUTCOMES

Case	Age	Gender	Logistic EuroSCORE	STS score	Annular size TTE (mm)	TEE (mm)	CT Scan (mm)	Type	Valve size (mm)	area (cm²)	Mean gradient (mmHg)	EF (%)	NYHA class
#1	76	M	19	2.89	22	23	22	E.S XT	26	60	0.5	0.25	III
#2	86	F	3	7.33	21	21	22	E.S XT	23	50	0.7	0.6	III
#3	71	M	39	5.7	23	24	24	E.S	26	20	0.7	0.3	III
#4	82	F	2.6	6.47	20.5	21	21-23	E.S	23	42	0.6	0.65	III
#5	88	M	9.8	11.28	21	22	22	E.S	23	42	0.7	0.45	III
#6	72	F	11	5.61	19	20	22	E.S XT	23	20	0.6	0.6	III
#7	71	M	5.5	3.1	21	22	22	E.S XT	26	72	0.5	0.6	III
#8	87	F	5	3.99	18	20	18	E.S XT	23	30	0.8	0.6	III
#9	76	M	5.7	6.25	19	20	20	E.S XT	23	35	0.8	0.6	III
#10	85	F	25	4.5	22	25	22	E.S XT	26	80	0.5	0.35	III
Mean	78.7 ± 6.6		12.56 ± 11.8	5.71 ± 2.44						45.1 ± 20.5	0.6 ± 0.1		

TFA: transfemoral approach. ...TAoA: transaortic approach   M: male   F: female   TEE: transesophageal echocardiogram
TTE: transthoracic echocardiogram   CT: computed tomography   E.S : Edwards SAPIEN Valve

				TABLE III	POST-PROCEDURAL OUTCOMES FOLLOWING HOSPITAL DISCHARGE	
Case	Mean gradient (mmHg)	Aortic insufficiency	Ejection fraction	Follow-up (months)	Events	NYHA
# 1	9	1	40-45	30	None	II
# 2	8	1	70	27	None	II
# 3	4.5	1.5	36-40	3	Cardiac death at 3 months	NA
# 4	17	1	65	18	Hip replacement 5 months ago	II
# 5	11.58	1.5-2	40-50	22	Pneumonia requiring ICU 1 week post procedure. Intubation for 5 days	III
# 6	9	1	40	17	Multiple hospitalizations for ADHF, recurrent pulmonary edema	III
# 7	8	< 1	> 70	17	None	IV
# 8	8	1	> 55	7	None	III
# 9	11.63	1	40-55	6	Infective endocarditis affecting the valve at 5 months. CVA leading to death from emboli while receiving antibiotics	III
# 10	11	2	50	6	Underwent successful hip replacement surgery after 5 months	III

ADHF: acute decompensated heart failure   **ICU**: intensive care unit   **NA**: not applicable

an embolus originating from an infected TAVI bioprosthesis. The total vascular complication rate was approximately 12%, and 72.7% are due to access-related vascular complication especially in the TF group [20]. Our study group did not experience any major vascular complication (no distal embolization, femoral-iliac artery dissection or rupture, or aortic dissection or rupture), and this may account for the low mortality rate after 6-months follow-up, as this complication is a significant prognostic factor of the 30-day mortality [21]. Another common complication is heart block occurring post-TAVI and necessitating permanent pacemaker implantation, where approximately 4 to 7% patients needed a new pacemaker for irreversible atrioventricular block [10,17]. In our study population, one patient (10%) (case #3) developed a new-onset arrhythmia (AV block) post-TAVI that required a permanent pacemaker, but none of the patients had a new-onset atrial fibrillation, advanced atrioventricular block, or right bundle branch block at 6 months.

Paravalvular AR is a common complication occurring in about 85% patients post-TAVI [19], similar to our results that show mild paravalvular AR in 90% of patients immediately post-TAVI and persisted after 6 months follow-up. Our study showed zero incidence of new-onset moderate to severe paravalvular AR (grade > 2) at all phases of follow-up, which was superior to other international clinical trials that report new-onset paravalvular AR rate exceeding 10-22%, both at 30-day and 1-year follow-up [10,22-23].

In our study, one mortality case occurred with the only patient who underwent TAVI through the TAo approach (case #3). This patient selected for the TAo approach had the highest surgical risk per his EuroSCORE (39), with a higher incidence for multiple comorbidities and worse vessel condition. This more favorable survival rate with the transfemoral approach is also evident in the study by Webb

et al. [24], reporting the 30-day mortality to be lowest in the transfemoral group (8.0%). The second mortality case (case #9) died from a fatal stroke following infective endocarditis affecting the Edwards SAPIEN valve. Infective endocarditis post-TAVI is a rare complication reported in the literature and associated with high mortality in any TAVI cohort [25]. The heart failure symptoms were significantly reduced or maintained stable after TAVI, and 3 out of 10 patients NYHA function class were decreased to Class II after 6-months follow-up. The persistence of heart failure in case #7 is due to the presence of moderate to severe mitral regurgitation (MR), which causes increased left ventricular end diastolic pressure (LVEDP) and decreased cardiac output despite the presence of non-stenotic aortic valve. Moreover, mild MR can also be the factor behind the persistence of most patients in NYHA class III at 6-months follow-up. However, neither age nor NYHA functional classes were significantly associated with survival in a univariate analysis according to the U.K. TAVI registry [18]. Moreover, the high 6-months survival rate in our study (80%) may be attributed to the favorable left ventricular function and AR profile post-TAVI, and LVEF and the presence of moderate/severe AR remained the only independent predictors of mortality in the multivariate model according to the U.K. TAVI registry [18]. Another reason for the low mortality after 6 months in our study group is the relatively low average logistic EuroSCORE (< 20) and STS score (3-8). In fact, it was shown that EuroSCOREs in the range of 30 to 35 were good predictors of 30-day mortality, and those in the transfemoral group with a preoperative EuroSCORE < 20 had higher 30-day survival than those with preoperative EuroSCORE ≥ 20 (94.6% versus 93.3%) [13].

It is noteworthy that there is no difference in survival outcome between patients with EuroSCORE of 0-21

and 21-40; thus the EuroSCORE proves to be a poor predictor of clinical outcomes in TAVR [23]. The results of the U.K. TAVI registry confirmed that the 30-day mortality was not significantly different between the group with a logistic EuroSCORE > 40 and that with a logistic EuroSCORE of 0 to 20 and 21 to 40 cohorts [18]. Hence, inclusion criteria for patients is expanding to include patients who are not in-operable or at high-risk. In one prospective multicenter, nonrandomized Canadian and German study involving 255 intermediate surgical risk patients (with STS score between 3 and 8%) who underwent TAVI and matched with patients undergoing surgical AVR, a similar mortality rate was noted in both groups (7.8 versus 7.1% after 30 days and 16.5 versus 16.9% after 1 year, respectively) [26].

Review of antithrombotic treatment

Given the periprocedural bleeding and postprocedural thrombotic events, there is a need to balance these risks by establishing an appropriate antithrombotic regimen before, during, and after TAVI. General recommendations for pre-operative management include intravenous heparin during valve implantation, and postoperative management include chronic administration of ATT, with dual antiplatelet therapy (DAPT), aspirin and clopidogrel, followed by life-long aspirin, provided no contraindications [7,27,28]. The current recommendations for ATT in patients undergoing TAVI consist of aspirin (ASA) 75-100 mg daily indefinitely, with concomitant clopidogrel 75 mg daily for a duration range between 1 to 6 months. Clopidogrel 300 mg loading is given if the patient had not already been maintained on clopidogrel [29,30]. Using a monotherapy strategy versus DAPT reduced life threatening and major bleedings without increasing the risk of stroke and myocardial infarction [31].

About one-third of patients undergoing TAVI have an underlying AF and are maintained on oral anticoagulants (OAC), usually warfarin [27]. These patients either receive triple antithrombotic therapy (TAT) (warfarin with aspirin and clopidogrel) or warfarin with 1 antiplatelet or warfarin alone [27,32]. In patients with CAD and chronic AF on triple therapy prior to TAVI, post procedure TAT is continued for 3 to 6 months, followed by vitamin K antagonist (VKA) plus ASA. If a patient has preceding percutaneous coronary intervention (PCI) with stent implantation and still requiring antiplatelet therapy, post-procedural ATT includes 3-6 months of TAT, followed by VKA plus clopidogrel, followed by lifelong VKA monotherapy [33]. Starting directly with VKA plus clopidogrel has also been used in those with high risk of bleeding and was associated with the smallest number of bleeding events in the early post-procedural setting [33]. In new-onset atrial fibrillation after TAVI warranting anticoagulation according to the CHADS2 score, some hospitals replace ASA by OAC. If patients previously on DAPT prior to TAVI, and then develop AF, continuing one antiplatelet in addition to adding OAC is considered. The decision to continue clopidogrel rather than ASA in addition to the OAC was guided by the presence of a recent stent [34].

Strengths and Limitations

Overall, TAVI has emerged as a safe and efficacious alternative technique for patients with severe symptomatic aortic stenosis who are not candidates for surgical AVR. The short-term outcomes after TAVI for these high-risk and intermediate risk patients with severe aortic stenosis in this first TAVI case series in Lebanon were encouraging. Similar to other international, multicenter studies, the results of our study show a high survival rate at 6 months (80%). The limitation of this study is the small number of patients included, given that insurance companies in our country do not cover for this relatively new and expensive procedure, thus hindering the patient recruitment.

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