Transcatheter Aortic Valve Implantation: A Single-Center Experience of 300 Cases

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ABSTRACT: **Background:** Transcatheter aortic valve implantation (TAVI) has recently become an alternative to surgical aortic valve replacement in selected patients with high operative risk.

Objectives: To investigate the 30 day clinical outcome of the first 300 consecutive patients treated with transfemoral TAVI at the Tel Aviv Medical Center.

Methods: The CoreValve was used in 250 patients and the Edwards-Sapien valve in 50. The mean age of the patients was 83 ± 5.3 years (range 63–98 years) and the mean valve area 0.69 ± 0.18 cm^2 (range 0.3–0.9 cm^2); 62% were women.

Results: The procedural success rate was 100%, and 30 day follow-up was done in all the patients. The average Euro-score for the cohort was 26 ± 13 (range 1.5–67). Total in-hospital mortality and 30 day mortality were both 2.3% (7 patients). Sixty-seven patients (22%) underwent permanent pacemaker implantation after the TAVI procedure, mostly due to new onset of left bundle brunch block and prolonged PR interval or to high degree atrioventricular block. The rate of stroke was 1.7% (5 patients). Forty-one patients (13.7%) had vascular complications, of whom 9 (3%) were defined as major vascular complications (according to the VARC definition).

Conclusions: The 30 day clinical outcome in the first 300 consecutive TAVI patients in our center was favorable, with a mortality rate of 2.3% and low rates of stroke (1.7%) and major vascular complications (3%).

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KEY WORDS: transcatheter aortic valve implantation (TAVI), aortic stenosis, interventional cardiology, valvular heart disease, bioprosthetic heart valves

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Aortic stenosis is one of the most common valvular disorders worldwide, with an estimated prevalence of 4.6% among 75 year old patients [1] and up to 8% among 85 year olds [2]. Transcatheter aortic valve implantation has emerged as an alternative to surgical aortic valve replacement in high risk patients with severe symptomatic aortic stenosis [3]. More than 50,000 patients have been treated with TAVI worldwide since the procedure was first performed a decade ago [3], and 1500 in Israel [4]. A number of registries have described the outcome of these high risk patients treated with TAVI. The 30 day mortality rate reported in a recently published registry of 3195 TAVI patients from 34 centers in France was 9.7% [3]. Similar mortality rates were previously reported by other registries, ranging from 5.0 to 11.5% [5-8]. To date, more than 300 patients have undergone the TAVI procedure at the Tel Aviv Sourasky Medical Center in Israel. We report here the 30 day outcome and the complication rate in our first 300 TAVI patients.

PATIENTS AND METHODS

All patients who underwent TAVI by means of a percutaneous approach (transfemoral or transaxillary) between March 2009 and September 2012 at the Tel Aviv Medical Center were included in the present analysis. All had symptomatic aortic stenosis with aortic valve orifice area of < 0.9 cm^2 and all were considered high risk for valve surgery by our cardiologists and cardiac surgeons. Routine right and left cardiac catheterization with full hemodynamic evaluation was performed prior to TAVI to document the severity of the aortic stenosis and to identify and treat significant obstructive coronary artery disease. During the catheterization ascending aortography and bilateral ilio-femoral arteriography were performed. All patients underwent pre- and post-TAVI transthoracic or transesophageal echocardiogram. All TAVI procedures were performed by one team comprising three interventional cardiologists, using either the 18Fr CoreValve device (Medtronic, Minneapolis, MN, USA) or the Edwards-Sapien or Sapien XT heart valve system (Edwards Lifesciences, Irvine, CA, USA). During the procedure, an 18Fr delivery sheath was placed into either the femoral (in 293 cases) or subclavian (7 cases) artery. A temporary pacemaker was placed in the right ventricular apex, and a balloon valvuloplasty was performed under rapid

***The first two authors contributed equally to this study**

VARC = Valve Academic Research Consortium

TAVI = transcatheter aortic valve implantation

ventricular pacing followed by implantation of the valve (26 mm, 29 mm or 31 mm for CoreValve, and 23 mm or 26 mm for Edwards-Sapien XT valves). The femoral artery access was then closed by a big-hole closure device (Prostal XL, Abbott Vascular, Abbott Park, IL, USA). General anesthesia was used only in the first 12 patients; the remaining 288 patients received local anesthesia and deep sedation only.

COMPLICATION DEFINITIONS

Cerebrovascular accident and transient ischemic accident were defined according to the stroke diagnostic criteria detailed in the consensus report of the Valve Academic Research Consortium [9]. Briefly, the diagnostic criteria for stroke were rapid onset of a focal or global neurological deficit with at least one of the following:

- change in level of consciousness
- hemiplegia
- hemiparesis
- numbness or sensory loss affecting one side of the body
- dysphasia or aphasia
- hemianopia
- amaurosis fugax
- other neurological signs or symptoms consistent with stroke
- confirmation of the diagnosis required by a neurologist or a neurosurgeon and/or the findings on neuroimaging [9].

Vascular complications were defined according to the consensus report of the VARC [9]. Major vascular complications included:

- any thoracic aortic dissection
- access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, etc.) leading to death, the need for significant blood transfusions (≥ 4 units) or for an unplanned percutaneous or surgical intervention, or irreversible end-organ damage
- distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage.

Minor vascular complications were defined as:

- access site or access-related vascular injury not requiring unplanned percutaneous or surgical intervention and not resulting in irreversible end-organ damage
- distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage
- failure of percutaneous access site closure resulting in interventional or surgical correction and not associated with death, significant blood transfusions, or irreversible end-organ damage.

VARC = Valve Academic Research Consortium

STATISTICAL ANALYSIS

Continuous variables are presented as mean ± standard deviation and compared using the independent Student *t*-test. Non-continuous variables were compared using the Mann-Whitney test. A two-tailed P value < 0.05 was considered statistically significant. All analyses were performed with the SPSS 19.0 software (SPSS Inc., Chicago, IL).

RESULTS

A total of 300 consecutive patients were included in the analysis (185 women, 62%). The mean age of the cohort was 83 ± 5.4 years (range 63–98 years). Baseline clinical characteristics, including the European System for Cardiac Operative Risk Evaluation (Euro-score) are shown in Table 1. The mean aortic valve area was 0.69 ± 0.18 cm^2 (range 0.3–0.9 cm^2). Of the 300 TAVI procedures performed, 293 were via the transfemoral approach and 7 via the subclavian approach. The CoreValve was used in 250 patients and the Edwards-Sapien valve in 50 patients. Two patients underwent valve-in-valve implantation; both had previously undergone surgical biologic aortic valve replacement. Mean hospital stay was 8 ± 4.4 days (range 3–41 days). Thirty day follow-up data were completed for all 300 patients.

The procedural success rate was 100% and this was confirmed by echocardiographic measurement of the transvalvular gradient, which declined substantially and rapidly following

Table 1. Patients' baseline characteristics

No. of patients	300
Female gender	185 (62%)
Age	83 ± 5.4 yr (range 63–98)
Body mass index	27 ± 4.8
Hypertension	86%
Type 2 diabetes mellitus	33%
Hyperlipidemia	77%
Current smoker	4%
Peripheral vascular disease	10%
Coronary artery disease	57%
Previous myocardial infarction	16%
Previous CABG	18%
Chronic atrial fibrillation	17%
COPD	22%
Creatinine clearance	44 ± 19.9 ml/min (range 11–111)
Previous permanent pacemaker	8%
Euro-score	26 ± 13.1 (range 1.5–67)
Ejection fraction	55 ± 7.5%

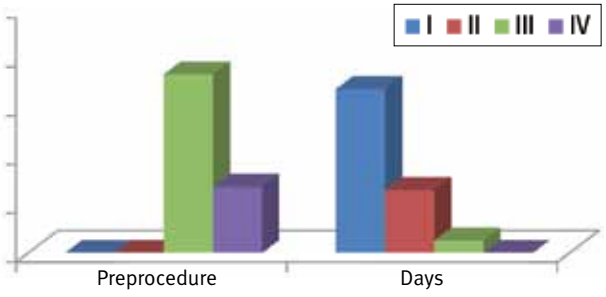
CABG = coronary artery bypass graft, COPD = chronic obstructive pulmonary disease, Euro-score = European System for Cardiac Operative Risk Evaluation

Table 2. Procedural results (300 patients)

	Baseline	In-hospital	30 days post-procedure
Peak transvalvular gradient (mmHg) (range)	78 ± 22 (20–150)	17 ± 7 (4–55)	15 ± 6 (5–46)
Mean transvalvular gradient (mmHg) (range)	47 ± 15 (11–91)	9 ± 4 (2–34)	8 ± 3.3 (2–26)
Functional capacity			92.7%
NYHA class 1/2	0		5%
NYHA class 3	73%		0
NYHA class 4	27%		(2.3% died)

NYHA = New York Heart Association

Figure 1. NYHA functional class before and 30 days after the TAVI procedure



the procedure. Measures of the severity of aortic stenosis at baseline, immediately post-procedure and 30 days post-procedure are presented in Table 2.

Baseline mean and peak transvalvular pressure gradients were 47 ± 15 and 78 ± 22 mmHg, respectively. Post-TAVI mean and peak gradients were 9 ± 4 and 17 ± 7 mmHg, respectively ($P < 0.001$ for each).

Prosthetic valve migration during the implantation process occurred with three TAVI procedures; all were resolved by successful implantation of a second valve through the first delivered valve.

New York Heart Association functional class improved significantly following valve implantation ($P < 0.001$) [Table 2 and Figure 1].

MORTALITY

There were no periprocedural deaths. Seven patients died during the hospital stay of the index procedure (in-hospital mortality rate 2.3%) due to severe aortic regurgitation in one, renal failure in one, a complicated ischemic cerebral event in one, and sepsis in two. There were no other deaths during the first 30 days after the procedure (i.e., the 30 day mortality was the same as the in-hospital mortality, 2.3%). Of the 184 patients who completed the 1 year follow-up, the 1 year mortality rate was 13% (total of 24 patients).

CVA AND VASCULAR COMPLICATIONS

Five patients (1.7%) suffered from stroke. Forty-one patients (13.7%) had vascular complications, of which 9 (3%) were defined as major according to the VARC definition. Four of these nine patients underwent vascular surgical procedures and one was treated with the insertion of a cover stent to the iliac artery. Three patients (1%) developed cardiac tamponade during the periprocedural period; all were successfully treated with drainage.

AV BLOCK

Sixty-seven patients (22%) underwent permanent pacemaker implantation after TAVI, 62 patients (24.8%) with the CoreValve and 5 (10%) with the Edwards-Sapien valve, mostly due to new-onset left bundle branch block and prolonged PR interval or high degree atrioventricular block.

PROCEDURE TIME AND CONTRAST MEDIA VOLUME

Mean radiation time for the cohort was 17 ± 6 minutes (range 8–43 minutes) and the mean contrast media volume delivered was 145 ± 43 ml (range 75–295 ml).

ANESTHESIA

The first 12 patients underwent the TAVI procedure with general anesthesia. The subsequent 288 patients (96%) underwent the TAVI procedure under local anesthesia and sedation only.

DISCUSSION

We report here the favorable outcome and low complication rates in the first 300 patients treated with percutaneous aortic valve implantation at the Tel Aviv Medical Center. The procedural success rate was 100%, with a 2.3% mortality rate at 30 days and a relatively low rate of complications.

Our results correlate with the reported high success and safety rates of transfemoral TAVI. In the PARTNER trial [10] the 30 day mortality rate in TAVI patients was 5%, major strokes were observed in 5% at 30 days and vascular complications in 30% of patients [10]. In the prospective multicenter French national TAVI (FRANCE 2) registry [3] of 3195 patients with an average age of 83 years and mean Euro-score of 22, the 30 day mortality rate was 9.7% and the 30 day stroke rate 3.4%. Almost 5% suffered from major vascular complications and 15.6% underwent pacemaker implantation [3]. Rodés-Cabau et al. [6] evaluated the acute and late outcomes of TAVI using the Edwards-Sapien valve. A total of 345 procedures (168 transfemoral, 177 transapical) were performed in 339 patients. The procedural success rate was 93.3% and the 30 day mortality rate 10.4% (the latter rising to 22.1% after a median follow-up of 8 months) [6]. In the SOURCE registry, Thomas and colleagues [7] followed 1038 TAVI patients

Table 3. Complications (300 procedures)

	No. of patients (%)
In-hospital mortality 30 day mortality	7 (2.33%) 7 (2.33%)
Myocardial infarction	0
Stroke (ischemic)	5 (1.66%)
Cardiogenic shock	3 (1%)
Cardiac tamponade	3 (1%)
Respiratory failure	7 (2.3%)
Major vascular Minor vascular	9 (3%) 32 (10.7%)
Sepsis	5 (1.66%)
New pacemaker	67 (22%)

enrolled at 32 European centers (the Edwards-Sapien valve was used in all patients, 575 with the transapical approach and 463 the transfemoral approach). The overall short-term procedural success was 93.8% and the 30 day mortality rate was 6.3% in the transfemoral patients and 10.3% in the transapical patients [7]. Dworakowski et al. [11] followed 151 patients with severe aortic stenosis who underwent TAVI with the Edwards-Sapien valve using the transapical (n=84, 56%) or transfemoral (n=67, 44%) approach. The procedural success rate was 98% and the post-procedural stroke rate 6%; complete atrioventricular block occurred in 5.3%, renal failure requiring hemofiltration in 9.3% and vascular injury in 8.6%; the overall 30 day mortality rate was 9.9% [11].

To elucidate the effects of the operators' learning curve on outcome we compared the complication rate between the first and the second half to the cohort. Our results show similar mortality and stroke rates among the first 150 patients (patients 1 to 150) and the second half of the cohort (patients 151 to 300). Table 3 summarizes the procedural complications.

It should be noted that in our cohort all the procedures were performed in the same medical center and by the same team. This might not reflect the situation in other medical centers and may explain the relatively low mortality and complication rate. Larger registries with a much longer follow-up are still needed to answer these unresolved questions.

CONCLUSIONS

Our study describes the favorable outcome and low complication rate in the first 300 patients treated with transcatheter aortic valve implantation in our institution. We report a procedural success rate of 100% and mortality rate of 2.3% at 30 days among this elderly and high risk population of patients undergoing TAVI.

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"The ability to simplify means to eliminate the unnecessary so that the necessary may speak"

Hans Hofmann (1880-1966), German-born American abstract expressionist painter. He believed that abstract art was a way to get at the important reality. In his youth Hofmann gravitated towards science and mathematics and developed and patented such devices as the electromagnetic comptometer, a radar device for ships at sea, a sensitized light bulb, and a portable freezer unit for military use

"Show me a hero and I will write you a tragedy"

F. Scott Fitzgerald (1896-1940), widely regarded as one of the greatest American writers of the 20th century. Fitzgerald is considered a member of the "Lost Generation" of the 1920s. He wrote four novels: *This Side of Paradise*, *The Beautiful and Damned*, *The Great Gatsby* (his most famous), and *Tender Is the Night*