

Is Transcatheter Aortic Valve Implantation Still Effective in Nonagenarians?

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ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) has become the preferred therapeutic method for elderly patients presenting with severe symptomatic aortic stenosis (AS). Most TAVI procedures are performed in patients between 75–85 years of age. A few publications exist on TAVI in patients over 90 years, yet the outcome and complication rates are inconsistent.

Objectives: To identify all patients with AS who underwent TAVI between 2019 and 2020, specifically those age > 90 years at the time of the TAVI.

Methods: We reviewed the Maccabi Healthcare Services database for all severe/critical AS patients who underwent TAVI between 2019 and 2020, specifically those age > 90 years at the time of TAVI. These patients were compared to all patients aged 80–89 years who underwent TAVI during the same time. Follow-up ended on 31 December 2022. We compared mortality and complications rates in nonagenarians vs. those 80–89 years and evaluated the change in left ventricular ejection fraction before and after the procedure.

Results: We identified 36 nonagenarians who underwent TAVI during the study period, mean age 92.3 years, male:female ratio 15:21. During a mean follow-up period of 3 years, 44% of nonagenarians died, 26% of the control patients died ($P < 0.01$).

Conclusions: TAVI in nonagenarians is feasible. Total mortality during follow-up was significantly higher in nonagenarians. Overall complication rates were also higher in nonagenarians, mostly due to vascular complications. Left ventricular dysfunction appeared to improve after TAVI, even in nonagenarians.

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expanded to patients at lower age and risk groups, with mid- and long-term results at least equal, if not better than surgery [3–5]. Recently these favorable results have been extended over 10-year follow-up periods [6]. Parallel to these developments, significant improvement in technology and expertise have occurred, and TAVI has been performed on patients with more advanced age groups, including nonagenarians. Several previous publications have focused on the short- and mid-term results in this very old population; however, the outcomes of these studies have been inconsistent [7–11]. Maccabi Healthcare Services offers health insurance coverage for over 2.7 million individuals. The digital medical database of Maccabi is considered to be highly accurate. We carefully reviewed the medical records, including comprehensive clinical and echocardiography results, of all patients with severe aortic stenosis, age ≥ 90 years who underwent TAVI during the 2-year study period. We compared these results to those of patients 80–89 years old who underwent TAVI during the same time period.

PATIENTS AND METHODS

We carefully screened our digital database to identify all patients who had undergone TAVI for severe/critical aortic stenosis (AS) during 2019–2020. TAVI was performed at all public hospitals and one private hospital. All of the hospitals were licensed to perform TAVI and had been performing the procedure routinely.

All licensed hospitals have an active cardiovascular surgical department to back these procedures. Patients had been selected based on good physical, mental, and emotional status and all candidates had been approved for TAVI in dedicated heart teams, which included a cardiac surgeon.

All procedures were performed by highly experienced teams, using the most advanced technology and valves at the time of the procedure. In all but one case, femoral

Transcatheter aortic valve implantation (TAVI) for patients with severe symptomatic aortic stenosis is a rapidly growing interventional cardiology procedure. Starting with the monumental PARTNER studies [1,2] on inoperable and high-risk patients, the indications have

approach was possible, based on dedicated computed tomography (CT) scan images, and performed accordingly. All but one of the nonagenarians had transfemoral access. In one case apical access was used.

The senior operator for each procedure selected the type of valve: balloon or self-expandable. All procedures were performed for symptomatic patients with severe/critical AS based on current guidelines [12,13]. For all patients, detailed clinical evaluation, electrocardiogram, high-end echocardiography/Doppler, and TAVI-oriented advanced CT scan including aortic calcium score had been performed and reviewed by expert heart teams who agreed that the patient needed TAVI. Cardiac catheterization or coronary imaging by CT had been performed for each patient prior to TAVI, percutaneous coronary intervention was performed as indicated.

For the current analysis, those with younger than 80 years of age were excluded. Of those remaining, the cohort was divided into two groups: patients 90 years and older (study group) and patients between 80 and 89 years of age (control group). Both groups were followed up for total mortality and major adverse events until 31 December 2022 (on average 3 years). All mortality cases were confirmed through the official site of the Ministry of Health. All hospital admissions and data on complications were carefully reviewed. An attempt was made, through the family physicians, to evaluate the functional status of all survivors. Echocardiography reports including calculation of left ventricular ejection fraction (LVEF), peak and mean aortic gradients, and calculated valve area and indexed area, based on the continuity equation before TAVI and within 2–3 months follow-up were reviewed in all available studies. Statistical analysis was performed using the unpaired *t*-test, $P < 0.05$ was considered statistically significant.

The study was approved by the official Maccabi Healthcare Services institutional review board. No patient contact or contact with families was permitted; therefore, the need for informed consent was waived.

RESULTS

The study group included 36 patients, age 90+ years, mean age 92.3 years, 15 males and 21 females, who underwent TAVI during 2019–2020. Table 1 summarizes the mortality and complications data of these individuals from both groups.

All patients had symptomatic severe/critical AS, and all were in good general clinical condition and coherent. All had been evaluated and approved by dedicated heart

Table 1. Mortality and major complications

	Control group, n=283	Study group, n=36	P-value
Age in years	80–89	90+	
Mortality: over 3 years	74 (26.1%)	16 (44.4%)	< 0.01
Mortality: 30 days	4 (1.4%)	1 (2.7%)	
Peri-procedural	3 (1%)	1 (2.7%)	
Complications: vascular	15 (5.3%)	7 (19%)	< 0.05
Complications: cardiac	2 (0.7%)	1 (2.7%)	
Pacemaker implantation	36 (12.7%)	5 (13.8%)	
Moderate aortic insufficiency	3 (5.9%)	2 (5.5%)	
Neurologic	2 (0.7%)	3 (8.3%)	
No significant complications	226 (61.1%)	18 (50%)	

teams in each center and all had signed informed consent before the TAVI procedure (unrelated to the current study). The control group represents the typical candidate for TAVI: Age 80–89, mean age 83.4 years. This group included 283 patients, male/female 143/140, who underwent TAVI during the same time period. The clinical profile and risk factors of both groups are presented in Table 2. There was no significant difference between the two groups.

Table 2. The clinical profile and risk factors of both groups

	Control group, n=283	Study group, n=36
Age, in years	80–89	90+
Malignancy	130 (42.2%)	15 (41.7%)
COPD	39 (13.3%)	7 (19.4%)
Hypertension	129 (43.3%)	11 (30.6%)
Diabetes	97 (33%)	12 (33.3%)
Myocardial infarction	39 (13.3%)	4 (11.1%)
IHD	145 (49.3%)	19 (52.8%)
Previous cardiac catheterization	97 (33%)	12 (33.3%)

COPD = chronic obstructive pulmonary disease, IHC = ischemic heart disease

MORTALITY

The primary endpoint was all-cause mortality [Table 1]. Over a mean follow up of 3 years post-TAVI, 16/36 nonagenarians (44.4%) died, 1 peri-procedure. In contrast, 74/283 patients (26.1%) from the control group ($P < 0.01$) died, 4

within 30 days, 2 peri-procedure. The cause of death for 3/16 of the study group (18.7%) was related to the valve procedure. In the control group, it was 3/74 (6.3%), $P < 0.01$.

MAJOR COMPLICATIONS

Nonagenarians presented with the following complications: three major vascular complications, including right coronary artery occlusion, severe femoral bleeding closed with stent graft (2 each); cardiogenic shock (1); endocarditis (3); cerebrovascular accident (2); and pacemaker implantation (4), including 1 before TAVI, and migration of valve to the aorta and successful implantation of a second TAVI (1).

The control group presented with the following complications: bleeding false aneurysm (1); endocarditis with brain emboli (1); significant bleeding related to medical therapy (clopidogrel) (2), brain (1), GI (1); pacemaker implantation (4).

There was an overall increased rate of major vascular complications in the nonagenarians. Those without complications appeared to have improved clinically after the procedure by at least 1 HYHA FC class.

ECHOCARDIOGRAPHIC DATA

For all patients in both groups, TAVI resulted in a significant drop in aortic pressure gradient following the procedure, 9/36 nonagenarians had had moderate to severe LV dysfunction (LVEF < 40%) before TAVI. In 8 of these 9 patients LVEF improved/normalized after TAVI 58/283 patients from the control group had had LV dysfunction prior to TAVI, 23/58 improved/normalized post TAVI [Table 3].

Table 3. The recovery of LVEF

LVEF	Control group, n=85	Study group, n=36
LVEF improved (> 10%)	9 (10%)	9 (25%)
LVEF deteriorated (> 10%)	0	6 (17%)
LVEF unchanged (± 10%)	76 (90%)	21 (58%)

LVEF = left ventricular ejection fraction

DISCUSSION

Based on the Israel Central Agency for statistics and supported by the World Health Organization, the average life expectancy in Israel in 2019 was 82.9 years, 81 for men and close to 84 for women. Life expectancy for those individuals reaching 90 years of age was 93.4 years, and for those reaching 80 it was 89.3 years. These statistics apply to the general population, and do not represent outcomes of patients with symptomatic severe/critical AS. Based on med-

ical literature, their life expectancy is significantly shorter: mortality is up to 12 times higher than those of similar age without AS [12,13]. Furthermore, as shown in Table 1 most mortality cases were not peri-procedural or within 30 days of the procedure. Table 2 shows that the clinical background and risk factor profile of these two groups were not significantly different despite the almost 10-year age difference.

Matta and colleagues [14] published their experience in a large cohort of nonagenarians undergoing TAVI and compared these results to those younger than 90 years old undergoing TAVI. Of a total of 1336 patients undergoing TAVI 250 were nonagenarians (18%), mostly close to 90 years (mean age 91.8 years). They showed that in-hospital mortality in nonagenarians was significantly higher (5.2%) in contrast to 2% in those undergoing TAVI at a younger age. They also showed that major complications, in particular vascular complications, were more frequent in nonagenarians than younger patients, 9.2% vs. 6.7%, respectively.

These results concur with a study published earlier by Arsalan and co-authors [15], one of the largest prospective multicenter registry comparing 3773 nonagenarians to 20,252 patients < 90 undergoing TAVI. This study assessed death rate but also cerebrovascular accidents, re-hospitalization due to heart failure, myocardial infarction, re-intervention, and quality of life at 30 days and 1 year. They also showed higher mortality rates in nonagenarians than those undergoing TAVI at a younger age: 30 days: 8.8% vs. 5.9%; $P < 0.001$; 1 year: 24.8% vs. 22.0%; $P < 0.001$. However, when corrected by STS risk scores, no significant difference was found between groups. Galata and Afilalo [16] summarized the risks versus benefits of TAVI in patients over age 90 years. They presented published studies on this topic. The average 30-day and 1-year mortality was 5.5% and 23%, respectively. Our results support these observations with respect to the overall incidence of death in nonagenarians in contrast to younger individuals undergoing TAVI. Our results, however, indicate that mortality, although high in nonagenarians, 16/36 (44.4%) over 3 years, was largely unrelated to TAVI or even AS, but rather due to infection/malignancy and other causes that may result in mortality in elderly individuals. These observations concur with data from Arsalan et al. [15].

A major issue that is obvious after reading all published studies and supported by our results: age by itself is not necessarily a major factor in predicting success/failure of TAVI, but rather the overall physical/mental state of the individual TAVI candidate, and likely the availability for adequate femoral approach. The issue of frailty is well emphasized in several studies [17].

Interestingly, for those with reduced LV function before TAVI, which had likely been caused at least partially by severe AS, LV function appeared to improve following TAVI in nonagenarians as well as those at age 80–89.

There is little doubt that the combination of severe AS and severe LV dysfunction presents a significant risk and challenge for the clinician. The recovery of LV function was more frequent in the nonagenarians (25%) [Table 3]. In some cases, the improvement grew from severe LV dysfunction to near normal function. One possible explanation is that the nonagenarians were followed clinically and by electrocardiography more frequently, and the deterioration of LV function was noticed earlier and therefore early unloading of the afterload from the left ventricle by performing TAVI prevented/reduced irreversible myocardial fibrosis.

LIMITATIONS

The retrospective analysis, relatively small number in the nonagenarians group, and no detailed follow-up of each patient were limitation. Nevertheless, we believe that these data are of clinical importance when considering such a major procedure for well-selected nonagenarians with severe/critical AS. Our follow-up of 3 years is one of the longest recorded and includes echocardiographic data showing improved LV function after TAVI in those with reduced LVEF prior to the procedure, even at age over 90 years.

KEY LEARNING POINTS

TAVI is regularly performed in patients with severe aortic stenosis with equal or even better results than cardiac surgery. There are several publications that discuss patients undergoing TAVI who are older than 90 years of age. The immediate and longer follow-up results have been inconclusive. Our study adds important data, due to a follow-up period of 3 years in individuals who have undergone TAVI. After the procedure, 25% of nonagenarians improved LV function. Our results show that although TAVI is feasible in this particular population, overall mortality and serious vascular complications are frequent compared patients 10 years younger who had undergone TAVI during the same time period.

CONCLUSIONS

TAVI in well-selected patients with severe/critical AS appears to be feasible even in nonagenarians, but both all-cause mortality and significant vascular complications are more frequent than in younger patients. Each patient should be carefully evaluated for physical and mental stability, with emphasis on frailty.

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