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# Improvements in quality of life in septuagenarians versus octogenarians undergoing trans-catheter aortic valve replacement

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**Abstract**

**Background** Very elderly patients represent a distinct patient group in clinical setting in terms of a decision for trans-catheter aortic valve replacement (TAVR) when one considers the potential improvement in the quality of life (QoL) on one hand and the benefit to risk ratio on the other. This study aimed to compare functional and QoL outcomes of TAVR between octogenarians and septuagenarians. **Methods** This prospective cohort study included 136 elderly patients (70 to 89 years of age), who underwent transfemoral TAVR due to degenerative aortic stenosis. Patients were allocated into one of the following age groups: septuagenarians ($n$ = 67) and octogenarians ($n$ = 69). Preoperative and early postoperative clinical parameters were recorded. In addition, QoL of the patients was evaluated using SF-36 questionnaire preoperatively and six month postoperatively. **Results** Groups were similar in terms of early postoperative mortality and morbidity parameters. The mean New York Heart Association (NYHA) class improved after TAVR in both groups. In addition, all SF-36 norm-based scale and SF-36 summary scale scores improved significantly in both groups during the postoperative period. Postoperatively, physical functioning, general health and physical component summary scores were significantly better in the septuagenarian group ($P$ = 0.02, 0.01, 0.03, respectively). **Conclusion** Although the improvement in the QoL in terms of physical health was more marked in septuagenarians than in octogenarians, substantial benefits on the QoL and particularly on mental health seem to justify re-consideration of TAVR indications in the very elderly.

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**Keywords:** Elderly; Octogenarians; Quality of life; Septuagenarian; Trans-catheter aortic valve replacement

## 1 Introduction

Although surgical aortic valve replacement represents the standard management in symptomatic severe aortic stenosis,[1] it is also associated with an increased risk of morbidity and mortality in the elderly and in subjects with co-existing conditions.

A recently introduced and viable alternative to standard therapy in high-risk patients with severe symptomatic aortic stenosis is the trans-catheter aortic valve replacement (TAVR),[2] which is superior to standard medical therapy in terms of cardiovascular and all-cause mortality with lower re-hospitalization rates, and improved functional status in patients with inoperable aortic stenosis.[3] In conjunction with the improvement in functional status recovery of cardiac symptoms, quality of life (QoL) also improves after TAVR.

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The incidence of aortic valve stenosis increases with age, with a reported prevalence of 2.5% and 8.1% in those aged 75 and 85 years, respectively.[4] In aortic stenosis that occurs in the 8th decade of life decision to perform a TAVR is a challenging one due to the common occurrence of comorbid conditions and decreased life expectancy. On the other hand, a major expectation from TAVR in the elderly is not only a successful clinical and procedural outcome, but also improved QoL. Therefore, patients in their 8th decade of life represent a distinct patient group in clinical setting in terms of a decision for TAVR when one considers the potential improvement in the QoL on one hand and the benefit to risk ratio on the other.

In the present study, the impact of TAVR, for which cardiac surgeons may be less reluctant to perform in the 8th decade, was compared in patients in their 7th decade of life versus 8th decade of life.

## 2 Methods

### 2.1 Patients

This prospective cohort study included 136 patients, who

underwent transfemoral TAVR due to symptomatic degenerative aortic stenosis at Bezmialem Vakif University hospital between September 2012 and September 2014. Patients between 70 and 89 years of age with severe native calcific aortic stenosis with an indexed aortic valve area of < 0.6 cm/m$^2$, aortic annulus diameter of 19–27 mm, ascending aortic diameter of < 45 mm and logistic EuroSCORE greater than 15% were included. Exclusion criteria were as follows: > grade 3 aortic failure, a history of acute myocardial infarction (MI) within one month of study participation, renal failure (creatinine > 3 mg/dL), need for chronic dialysis, hemodynamic or respiratory failure (mechanical ventilation or inotropic support), hypertrophic obstructive cardiomyopathy, echocardiographic presence of intracardiac mass, thrombus, or vegetative, severe mitral failure, and a life expectancy of less than 12 months due to comorbid conditions. For the purpose of the analysis, patients were allocated into one of the following groups based on their age at the time of admission: patients in their 70 s ($n$ = 67; septuagenarians) and those in their 80 s ($n$ = 69; octogenarians). Study protocol was approved by local ethics committee and informed consent was obtained from all patients who agreed to participate in the study.

### 2.2 Preoperative procedures

Prior to TAVR, demographical, clinical, and echocardiographic data of all patients were collected and recorded. In addition, Short Form Health Survey (SF-36) was completed preoperatively by 119 patients (57 in the octogenarian group and 62 in the septuagenarian group).

### 2.3 TAVR procedure

TAVR was performed trans-femorally and under general anesthesia or under local anesthesia and deep sedation. Patients received a loading dose of pre-procedural clopidogrel (300 mg) and aspirin (100 mg), and 100 IU/kg heparin during the procedure. A temporary pacemaker lead was inserted into the right ventricle through the femoral vein. An Amplatz Extra Stiff Guide Wire was advanced into to the apex of the left ventricle through the femoral artery via an 18-F sheath. A balloon valvuloplasty was carried out on the aortic valve with ventricular pacing at a rate of 80–200 beats/min, and the device was implanted. An aortic valve prosthesis was inserted in the native aortic annulus under fluoroscopic guidance. After optimal opening was achieved, aortic root was visualized. Aortic valve and pericardium were also visualized with transthoracic echocardiography, followed by the trans-catheter delivery of a prosthetic heart valve. Dual antiplatelet chemotherapy (100 mg of acetylsalicylic acid and 75 mg of clopidogrel) were given to all patients for the first three months following intervention and they were all prescribed life-long aspirin treatment (100 mg/day).

### 2.4 SF-36 QoL questionnaire

SF-36, originally developed and introduced by the Rand Corporation in 1992, is a generic measure and comprehensive questionnaire for evaluating QoL.[5] Kocyigit performed the first Turkish validity and reliability study of SF-36 in 1999, and found a Cronbach's alpha coefficient ≥ 0.70.[6] SF-36 includes items regarding patient perception of changes in their health in the last four weeks and the previous year and comprises 36 items that evaluates the following physical and mental domains: physical functioning (PF), role-physical (RP), body pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and mental health (MH). Each scale is transformed directly into a 0–100 scale; a lower score indicates a worse health status. SF-36 has two summary scales, called the mental component summary (MCS) and the physical component summary (PCS). PCS includes PF, RP, BP, and GH, whereas the MCS includes VT, SF, RE, and MH. The PCS and MCS are standardized to reflect a general population mean of 50 and a standard deviation (SD) of 10.

### 2.5 Follow-up

In addition to early postoperative assessments, patients were also followed-up for 6 months for clinical outcomes. At month 6, a follow-up SF-36 questionnaire could be completed by 101 patients (48 in the octogenarian group and 53 in the septuagenarian group), who therefore had both preoperative and postoperative SF-36 data. Clinical results and changes in health-related QoL in the two study groups were analyzed.

### 2.6 Statistical analysis

The SPSS version 20.0 software was used for all statistical analyses. Data are presented as mean ± SD or $n$ (%), where appropriate. Normality of distribution was evaluated using Kolmogorov-Smirnov test. For inter-group comparisons of quantitative data, independent sample $t$-test or Mann-Whitney $U$ test was used. For intra-group comparisons (preoperative versus postoperative data), paired samples $t$ test or Wilcoxon signed rank test was used. Chi-Square or Fisher's exact test was used for the comparison of qualitative data. A $P < 0.05$ was considered an indication of statistical significance.

## 3 Results

Table 1 shows baseline characteristics of the patients.

**Table 1. Baseline characteristics of patients.**

| | Octogenarians (*n* = 69) | Septuagenarians (*n* = 67) | *P* |
|---|---|---|---|
| Age, yrs | 83.7 ± 2.8 | 75.1 ± 2.2 | 0.000 |
| Females | 42 (60.8%) | 42 (62.6%) | 0.73 |
| Diabetes | 20 (28.9%) | 21 (31.3%) | 0.84 |
| Hypertension | 48 (69.5%) | 47 (70.1%) | 0.85 |
| Dyslipidemia | 10 (14.4%) | 11 (16.4%) | 0.61 |
| COPD | 25 (36.2%) | 28 (41.7%) | 0.56 |
| Peripheral vascular disease | 17 (24.6%) | 16 (23.8%) | 1.0 |
| Coronary artery disease | 44 (63.7%) | 44 (65.6%) | 1.0 |
| Cerebrovascular disease | 2 (2.8%) | 3 (4.4%) | 0.65 |
| Serum creatinine >1.5 mg/dL | 12 (17.3%) | 10 (14.9%) | 0.65 |
| Atrial fibrillation | 15 (21.7%) | 14 (20.8%) | 1.0 |
| Previous MI (< 90 days) | 2 (2.8%) | 3 (4.4%) | 0.29 |
| Preoperative critical condition | 6 (8.6%) | 1 (1.4%) | 0.058 |
| Prior CABG | 7 (10.1%) | 11 (16.4%) | 0.31 |
| Aortic mean gradient, mmHg | 49.7 ± 14.3 | 48.7 ± 13.3 | 0.69 |
| Aortic valve area, $cm^2$ | 0.66 ± 0.16 | 0.75 ± 0.12 | 0.008 |
| LVEF, % | 53.9% ± 9.3% | 48.6% ± 14.4% | 0.11 |
| PAB (> 60 mmHg) | 13 (18.8%) | 8 (11.9%) | 0.26 |
| Logistic EuroSCORE | 22.5% ± 3.4% | 19.8% ± 3.8% | 0.000 |

Data are presented as mean ± SD or *n* (%). CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; EuroSCORE: European System for Cardiac Operative Risk Evaluation; LVEF: left ventricular ejection fraction; MI: myocardial infarction; PAB: pulmonary arterial pressure.

The two age groups did not differ with regard to clinical and laboratory parameters except for a significantly lower aortic valve area (0.66 ± 0.16 *vs*. 0.75 ± 0.12 $cm^2$, $P = 0.008$) and a higher logistic EuroSCORE (22.5% ± 3.4% *vs*. 19.8% ± 3.8%, $P < 0.001$) among octogenarians.

### 3.1 Clinical and QoL outcomes

Table 2 shows the comparison of the two age groups with regard to early postoperative clinical outcomes. Groups were similar in terms of early postoperative mortality and morbidity parameters. The mean New York Heart Association (NYHA) class improved after TAVR in both groups: decreased from 2.95 ± 0.70 to 1.81 ± 0.46 in the octogenarian group and from 2.92 ± 0.50 to 1.94 ± 0.39 in the septuagenarian group ($P < 0.001$ for both).

Overall, 57 (82.6%) and 48 (69.5%) patients in the octogenarian group completed the questionnaire preoperatively and postoperatively, whereas 62 (92.5%) and 53 (79.1%) patients did so in the septuagenarian group, respectively. Table 3 shows comparison of the groups with regard to changes in QoL (SF-36). All SF-36 norm-based scale (PF, RP, BP, GH, VT, SF, RE, and MH) and SF-36

**Table 2. Comparison of the groups with regard to early postoperative clinical outcomes.**

| | Octogenarians (*n* = 69) | Septuagenarians (*n* = 67) | *P* |
|---|---|---|---|
| 30-day mortality | 5 (7.2%) | 6 (8.9%) | 0.71 |
| Postoperative stroke | 4 (5.7%) | 2 (2.9%) | 0.42 |
| Need for pacemaker | 4 (5.7%) | 2 (2.9%) | 0.42 |
| Vascular complications | 8 (11.5%) | 6 (8.9%) | 0.61 |
| Pericardial tamponade | 2 (2.8%) | 0 | 0.16 |
| Transfusion, U | 1.59 ± 1.51 | 1.79 ± 2.57 | 0.58 |
| Postoperative hospital stay, days | 7.6 ± 8.0 | 6.9 ± 6.7 | 0.68 |
| Postoperative mean aortic gradient, mmHg | 5.4 ± 1.8 | 5.1 ± 2.0 | 0.35 |
| Postoperative mild aortic insufficiency | 5 (7.2%) | 3 (4.4%) | 0.49 |

Data are presented as mean ± SD or *n* (%).

**Table 3. Comparison of the groups with regard to changes in quality of life (SF-36).**

| | | Octogenarians (*n* = 69) | Septuagenarians (*n* = 67) | $P^a$ |
|---|---|---|---|---|
| PF | Preop | 28.64 | 29.04 | 0.51 |
| | Postop | 38.25 | 47.62 | 0.02 |
| | $P^b$ | 0.000 | 0.000 | |
| RP | Preop | 29.40 | 30.80 | 0.10 |
| | Postop | 46.62 | 48.75 | 0.44 |
| | $P^b$ | 0.000 | 0.000 | |
| BP | Preop | 41.40 | 43.84 | 0.15 |
| | Postop | 54.63 | 55.26 | 0.65 |
| | $P^b$ | 0.000 | 0.000 | |
| GH | Preop | 25.14 | 27.78 | 0.001 |
| | Postop | 42.65 | 49.24 | 0.01 |
| | $P^b$ | 0.000 | 0.000 | |
| VT | Preop | 29.08 | 32.48 | 0.000 |
| | Postop | 47.14 | 50.25 | 0.18 |
| | $P^b$ | 0.000 | 0.000 | |
| SF | Preop | 23.50 | 25.66 | 0.07 |
| | Postop | 46.36 | 42.72 | 0.32 |
| | $P^b$ | 0.000 | 0.000 | |
| RE | Preop | 30.04 | 32.14 | 0.35 |
| | Postop | 43.26 | 47.95 | 0.26 |
| | $P^b$ | 0.000 | 0.000 | |
| MH | Preop | 36.38 | 39.96 | 0.01 |
| | Postop | 44.50 | 45.35 | 0.65 |
| | $P^b$ | 0.000 | 0.000 | |
| PCS | Preop | 28.56 | 28.84 | 0.68 |
| | Postop | 42.66 | 48.25 | 0.03 |
| | $P^b$ | 0.000 | 0.000 | |
| MCS | Preop | 33.72 | 34.38 | 0.67 |
| | Postop | 47.61 | 47.14 | 0.89 |
| | $P^b$ | 0.000 | 0.000 | |

Data are presented as mean value. $P^a$: *P* value for inter-group comparisons; $P^b$: *P* value for intra-group comparison (preoperative versus postoperative). BP: bodily pain; GH: general health; MCS: mental component summary; MH: mental health; PCS: physical component summary; PF: physical functioning; Postop: post-operation; Preop: pre-operation; RE: role-emotional; RP: role-physical; SF: social functioning; VT: vitality.

summary scale (MCS and PCS) scores improved significantly in both groups during the postoperative period, compared to the preoperative assessments ($P$ = 0.000). Preoperatively GH, VT, and MH scores were significantly higher in the septuagenarian group than in the octogenarian group ($P$ = 0.001, 0.000, and 0.01, respectively), whereas the two groups were similar with regard to other quality life parameters. Postoperatively, PF and GH scores were significantly higher in the septuagenarian group than in the octogenarian group ($P$ = 0.02 and 0.01, respectively). Although the MCS score was similar across the groups, the PCS score was higher in the septuagenarian group than in the octogenarian group ($P$ = 0.03). Other tested QoL parameters did not differ between the two groups postoperatively.

## 4 Discussion

Octogenarian and septuagenarian subjects undergoing TAVR achieved similar clinical outcomes in our study. Furthermore, a significant improvement in all QoL parameters was noted in both age groups as compared to preoperative assessments.

TAVR has been reported to afford a higher probability of patient survival compared with more traditional medical therapy in inoperable or high-risk patients.[7] Improved survival was mostly accounted for by the decrease in mortality and re-hospitalization rates and improvement in functional capacity.[8] TAVR has demonstrated superiority over standard medical therapy regarding cardiovascular and all-cause mortality, lower re-hospitalization rates, and improved functional status in patients with inoperable aortic stenosis. One-year all-cause mortality rates reported in the placement of aortic transcatheter valves trial for TAVR and standard medical therapy were 30.7% and 50.7%, respectively, and corresponding 5-year all-cause mortality rates in the respective groups were 71.8% and 93.6%.[3] Others found a 30-day mortality rate of 6%–10% after TAVR.[9] Similarly, we observed a 30-day mortality rate of 7.2% ($n$ = 5) in octogenarians and 8.9% ($n$ = 6) in septuagenarians, without a significant difference between the two age groups in terms of early mortality rates.

As a procedure that is performed more frequently among the elderly, outcome of TAVR is expected to include extended life expectancy and improved health-related QoL. Several factors such as the severity of the aortic stenosis, co-morbid conditions, anatomical suitability of the patient, general prognosis, patient preference as well as the improved QoL are important factors in the decision to perform TAVR in the older patients.

Effects of TAVR on functional capacity and QoL has also been investigated[9] on the basis of observations suggesting that improved QoL is paralleled by increases in patients' functional capacity.[10] Previous studies utilizing SF-36 as a measure of the QoL reported positive effects of TAVR on physical and mental health-related QoL.[11,12] Krane, *et al*.[13] observed most pronounced improvements in PF and PCS domains of SF-36, with no significant changes in RE, SF, MH, or MCS. These authors also reported no change in mental health parameters other than vitality, probably due to the presence of comorbid conditions in the elderly population. A review on post-TAVR QoL found a more marked improvement in physical health parameters of SF-36 than in mental health parameters.[8]

On the other hand, the relative importance of life expectancy and patient age with respect to comorbid conditions are increased in this age group, particularly among octogenarians. In this regard, it may be worth to mention that several studies found significant improvements after TAVR even in the very advanced age groups.[11–13] For example, Biermann, *et al*.[14] observed even a higher degree of improvement after TAVR among patients > 80 years of age than those less than 80 years of age. In the present study, significant improvements in the overall and summary SF-36 scores six months postoperatively were seen versus preoperative figures both in octogenarian and septuagenarian groups. The improvement in QoL was significantly better only for PF, GH, and PCS in septuagenarians than in octogenarians.

Current understanding regards very advanced age as a partial obstacle to improvement in the QoL. On the other hand, although younger patients tend to perform better in terms of physical improvement following invasive interventions, they may also experience an age-related difficulty for accepting their health conditions and may be inclined to experience future depression with an anticipation of the recurrence of the disease(s).[15] While the rate of clinical improvement may be slower in the elderly owing to comorbidities and increased occurrence of post-interventional complications, they may be in a more favorable position than their younger counterparts with respect to psychological or mental improvement. For instance, an improvement in exercise capacity leading to recuperation of autonomy to carry out daily activities of living may, from an advanced age's perspective, represent a major improvement in the QoL. In other words, there may be a differential perception of disease and improvement among elderly and other age groups. Thus, a reconsideration may be given to perform a TAVR for patients who are deemed too old for such a procedure, not only due to potential functional and clinical improvements that may occur following the intervention, but

also due to expected improvement in the QoL that is at least equivalent to that in younger patients.

### 4.1 Limitations

Single-center nature and small sample size of our study limit the generalizability of our results. Another limitation that should be mentioned involves the use of a single life-quality scale, i.e., SF-36 for QoL assessments.

### 4.2 Conclusions

TAVR was associated with a significant improvement in clinical parameters and the health-related QoL in both age groups consisting of elderly individuals. Although, the improvement in the QoL in terms of physical health was more marked in septuagenarians than in octogenarians, substantial benefits on the QoL and particularly on mental health seem to justify re-consideration of TAVR indications in the very elderly.

## References


1 Zajarias A, Cribier AG. Outcomes and safety of percutaneous aortic valve replacement. *J Am Coll Cardiol* 2009; 53: 1829–1836.

2 Salinas P, Moreno R, Lopez-Sendon JL. Transcatheter aortic valve implantation: Current status and future perspectives. *World J Cardiol* 2011; 3: 177–185.

3 Leon MB, Smith CR, Mack M, *et al*. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010; 363: 1597–1607.

4 Carabello BA, Paulus WJ. Aortic stenosis. *Lancet* 2009; 373: 956–966.

5 Stewart AL, Hays RD, Ware JE, Jr. The MOS short-form general health survey. Reliability and validity in a patient population. *Med Care* 1988; 26: 724–735.

6 Kocyigit H, Aydemir O, Fisek G. Reliability and validity of the Turkish version of Short Form-36. *Ilac ve Tedavi Dergisi* 1999; 12102–12106.

7 Holmes DR, Jr., Mack MJ, Kaul S, *et al.* 2012 ACCF/AATS/SCAI/STS expert consensus document on transcatheter aortic valve replacement: developed in collabration with the American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Failure Society of America, Mended Hearts, Society of Cardiovascular Anesthesiologists, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. *J Thorac Cardiovasc Surg* 2012; 144: e29–e84.

8 Kim CA, Rasania SP, Afilalo J, *et al*. Functional status and quality of life after transcatheter aortic valve replacement: a systematic review. *Ann Intern Med* 2014; 160: 243–254.

9 Amonn K, Stortecky S, Brinks H, *et al*. Quality of life in high-risk patients: comparison of transcatheter aortic valve implantation with surgical aortic valve replacement. *Eur J Cardiothorac Surg* 2013; 43: 34–41.

10 Gurvitch R, Webb JG. Life after transcatheter aortic valve implantation: quality still matters. *Heart* 2010; 96: 1083–1084.

11 Georgiadou P, Kontodima P, Sbarouni E, *et al.* Long-term quality of life improvement after transcatheter aortic valve implantation. *Am Heart J.* 2011; 162: 232–237.

12 Kleczynski P, Bagienski M, Sorysz D, *et al.* Short- and intermediate-term improvement of patient quality of life after transcatheter aortic valve implantation: a single-centre study. *Kardiol Pol* 2014; 72: 612–616.

13 Krane M, Deutsch MA, Piazza N, *et al.* One-year results of health-related quality of life among patients undergoing transcatheter aortic valve implantation. *Am J Cardiol* 2012; 109: 1774–1781.

14 Biermann J, Horack M, Kahlert P, *et al.* The impact of transcatheter aortic valve implantation on quality of life: results from the German transcatheter aortic valve interventions registry. *Clin Res Cardiol* 2015; 104: 877–886.

15 Grimaldi A, Figini F, Maisano F, *et al.* Clinical outcome and quality of life in octogenarians following transcatheter aortic valve implantation (TAVI) for symptomatic aortic stenosis. *Int J Cardiol* 2013; 168: 281–286.