

Subject Area: Cardiothoracic Surgery

## **Postoperative Quality of Life Improvement: TAVI vs. Mini-sternotomy Tissue Valve Insertion in elderly patients with significant aortic stenosis**

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## ORIGINAL STUDY

# Postoperative quality of life improvement: Trans-catheter aortic valve implantation versus mini-sternotomy tissue valve insertion in elderly patients with significant aortic stenosis

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## Abstract

**Background:** Postoperative improvements in the quality of life represent a master scale for procedural success, particularly in elderly patients with cardiac conditions.

**Objectives:** To detect positive changes in quality of life for elderly candidates with significant calcific aortic stenosis treated by aortic tissue valve insertion, either through trans-catheter aortic valve implantation (TAVI) or mini-sternotomy aortic valve replacement (AVR).

**Patients and methods:** A prospective study was done on 88 patients above 65 years with severe calcific aortic stenosis. They sought treatment at the National Heart Institute in Cairo, Egypt between March 2020 and July 2022. All patients underwent aortic tissue valve replacement. Eight candidates were removed from the study as they did not complete the follow-up period due to death or due to other reasons. 40 patients had TAVI and the other 40 had surgical AVR through a minimally invasive approach (mini-sternotomy AVR). The study assessed the quality of life of all participants using the [RAND 36-Item Health Survey version 1.0 Questionnaire]. This was performed a day pre and three months post-operatively. Data were collected and compared.

**Results:** Patients who underwent the TAVI procedure showed significant positive changes in physical task difficulties ( $15.03 \pm 9.76$  vs.  $6.32 \pm 7.21$ ;  $P < 0.001$ ), emotional task difficulties ( $15.05 \pm 11.95$  vs.  $9.18 \pm 6.04$ ;  $P = 0.007$ ), and mental health outcomes ( $0.99 \pm 10.43$  vs.  $10.45 \pm 15.23$ ;  $P < 0.001$ ) compared with those who underwent surgical mini-AVR. However, the two groups had no significant differences as regards the pain scores, level of vitality, social and physical functions, and degrees of general health before and after surgery.

**Conclusion:** Early scores of quality of life regarding patients who received TAVI were noticeably better than those who underwent mini-AVR.

**Keywords:** Calcific aortic stenosis, Mini-aortic valve replacement, Quality of life improvement, Trans-catheter aortic valve implantation

## 1. Introduction

**A**ortic calcific stenosis in the old population represents a serious cardiac condition with a poor prognosis and increased risks of sudden death

if not treated properly. Surgical aortic valve replacement (SAVR) was considered the standard technique for treating such cases with low mortality and accepted morbidity rates on long-term follow-up. However, elderly cardiac patients with

Received 20 December 2023; revised 28 December 2023; accepted 10 January 2024.  
Available online 19 February 2024

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<https://doi.org/10.59299/2537-0928.1062>

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associated diseases are more liable to perioperative complications and may be considered unfit or inoperable candidates.

Recently, Trans-catheter aortic valve insertion (TAVI) has been widely applied as an alternative therapeutic approach for elderly patients with significant aortic stenosis suffering from other associated diseases and are considered risky surgical patients. This technique was first presented by Cribier and colleagues [1,2]. The TAVI can be achieved either through the femoral artery which is called the retrograde trans-femoral approach (TF) or through the apex of the heart (ante-grade trans-apical approach) (TA) [3].

Quality of life is a personal interpretation of one's overall well-being, which can vary based on socio-cultural factors [4]. Assessing the positive changes in a patient's quality of life after surgery through a comprehensive evaluation of his psychomotor and social performance is considered a reliable indicator of a patient's overall health status [5].

There are multiple ways to assess changes in life quality after surgery, including the Short form-36 questionnaire. This scale is commonly used and provides valuable insights into patients' quality of life who have undergone surgical or percutaneous techniques of the heart. The Short form-36 is a simple and accessible test that yields important information [6].

This questionnaire is made up of 36 questions that focus on 8 different aspects of health. These include physical activity, social involvement, task limitations due to physical or emotional issues, mental performance, vitality status, pain, and general status. The questions in the SF-36 ask about the health gains and drawbacks over the past 4 weeks. Each question is given a score and the outcomes are then translated into values ranging from zero to one hundred. There are limited pieces of information available about how TAVI affects patients' quality of life as few studies have raised this issue after TAVI.

Our study focused on assessing the improvement in life quality for patients above the age of 65 who underwent mini-AVR or TAVI procedures for severe calcific aortic stenosis at our institute. To measure their life quality, we used the questionnaire before the procedure and 3 months after surgery or intervention.

## 2. Patients and methods

Between March 2020 and July 2022 Following the ethical committee agreement and after obtaining written consent from all candidates. 88 consecutive adult patients who were over 65 years old and had severe calcific aortic stenosis were studied

prospectively at the National Heart Institute, Cairo, Egypt. All patients underwent aortic tissue valve replacement. Eight candidates were eliminated from our research as they did not complete the follow-up due to either mortality or other reasons. Candidates were then divided into two groups, the first had 40 candidates with Trans-catheter aortic valve implantation (TAVI) and the second had another 40 candidates with mini-sternotomy surgical AVR. After being fully informed, the candidates were briefed about the research and signed an informed consent.

A pre-operative assessment of all patients was done using computed tomography (CT) angiography to explore the aortic anatomy and to exclude the presence of porcelain aorta, penetrating ulcers, aortic aneurysms and to evaluate the suitability of arterial access for catheterization. Careful history-taking, physical examination and pre-operative routine investigations were performed. The obtained data were used to score patients according to the European System for Cardiac Operative Risk Evaluation (Euro-SCORE II) risk scoring system II, with the least operative risk defined as EuroSCORE less than 4 %, moderate risk as 4–8 %, and the highest as greater than 8 %. The decision regarding candidate enrollment in either of the study groups was taken by a hospital committee consisting of consultant cardiologists, cardiothoracic, anesthesiologists and radiologists after studying each case separately.

Eligibility for patient enrollment was: Adult patients aged 65 years old or above with isolated severe calcific aortic stenosis, and an ejection fraction of 35 % or more. We excluded: redo patients, patients with associated cardiac conditions, associated aortic aneurysms, congenital bicuspid aortic valves, recent strokes or TIA, renal impairment (creatinine >3 mg/dl), low ejection fraction patients below 35 %, and mortality cases.

Severe aortic stenosis (AS) was identified based on the parameters utilized in the Placement of Aortic Trans-Catheter Valve (PARTNER) Trial [7]. These parameters include an aortic effective orifice area less than 0.8 cm<sup>2</sup> [or valve area index <0.5 cm<sup>2</sup>/m<sup>2</sup>], a mean aortic gradient greater than 40 mm Hg, or a peak aortic jet velocity of greater than 4 m/s' [7] Leon MB et al.

### 2.1. Procedures

The approach for minimally invasive AVR was the partial upper sternotomy approach, which was used in all patients who underwent minimal access surgery. Femoral arterial cannulation was used to provide an adequate space during AVR through the small mini-sternotomy incision. Cannulation of the right atrium with a double-stage single venous

cannula and insertion of a left ventricular vent via Rt. Superior pulmonary vein and through mitral valve were performed in all surgical patients. As regards TAVI, the procedure was performed through a trans-femoral approach in all patients using standard techniques. All patients had their aortic valve replaced by a tissue valve. SAVR using Aortic stented bio-prosthetic valve CROWN PRT (LivaNova Canada Corp. Burnaby, Canada) or Hancock II Aortic bio-prosthesis (Medtronic Inc., Minneapolis, MN, USA) and TAVI using the Medtronic CoreValve Evolute R System (Medtronic Inc., Minneapolis, MN, USA) or Boston Scientific ACURATE neo 2 Aortic Valve System (Boston Scientific, Marlborough, Massachusetts, U.S.). Both procedures were performed under general anesthesia. Intensive care unit (ICU) admission for at least one day with early discharge of uncomplicated patients was a target throughout the study. Preoperative, operative, and post-operative data were collected and analyzed.

## 2.2. Quality of life assessment

The life quality of 40 candidates who received AVR and 40 candidates who were subjected to TAVI was measured and evaluated using the RAND 36-Item Health Survey version 1.0 Questionnaire. The questionnaire was given to the patients a day pre and three months postoperatively, and their outcomes were noted. Patients had the option to

complete the questionnaire either alone or with the assistance of their relatives.

## 2.3. Statistical analysis

The following statistical analysis was used to study quantitative and qualitative variations among groups. The analysis was conducted using IBM SPSS version 22.0 software on an IBM personal computer. The statistical types used were descriptive and analytic statistics.

Descriptive statistics were used to present continuous variables as Mean ( $\pm$ ), Standard Deviation (SD), and Percentage (%), while categorical variables were expressed in number and frequency.

Analytic statistics included the use of Student's *t*-test to study quantitative variation among the groups, and the chi-square test ( $\chi^2$ ) was applied to study qualitative variation. In both cases, a *P* value below 0.05 was considered significant.

## 3. Results

The mean age in the surgical group which had 40 patients was ( $67.77 \pm 2.01$  years) with 55 % diabetics, 60 % hypertensive, and 50 % smokers. NYHA classification showed 70 % in class II, 27.5 % in class III, and 2.5 % in class IV. The mean ejection fraction was  $52.00 \pm 9.01$  % and EuroSCORE II was  $5.87 \pm 1.20$  % (Table 1).

The TAVI group had 40 patients with a mean age of  $74.52 \pm 6.37$  years. Most patients were diabetic

Table 1. Comparison between surgical aortic valve replacement and trans-catheter aortic valve implantation groups.

	Surgical aortic valve replacement group (No = 40)	Trans-catheter aortic valve implantation group (No = 40)	<i>P</i> value
Age (y)	$67.77 \pm 2.01$	$74.52 \pm 6.37$	0.001*
Sex			
Male	22 (55.0 %)	19 (47.5 %)	0.502
Female	18 (45.0 %)	21 (52.5 %)	
DM			
Yes	22 (55.0 %)	28 (70.0 %)	0.165
No	18 (45.0 %)	12 (30.0 %)	
Hypertension			
Yes	24 (60.0 %)	29 (72.5 %)	0.237
No	16 (40.0 %)	11 (27.5 %)	
Smoking			
Yes	20 (50.0 %)	17 (42.5 %)	0.500
No	20 (50.0 %)	23 (57.5 %)	
NYHA			
II	28 (70.0 %)	10 (25.0 %)	0.002*
III	11 (27.5 %)	24 (60.0 %)	
IV	1 (2.5 %)	6 (15.0 %)	
Ejection fraction (%)	$52.00 \pm 9.01$	$49.10 \pm 10.71$	0.193
EuroSCORE II (%)	$5.87 \pm 1.20$	$12.65 \pm 1.71$	0.001*

DM, Diabetes Mellitus; NYHA, New-York Heart Association.

\* indicates statistically significant.

(70 %), hypertensive (72.5 %), and some were smokers (42.5 %). 25 % were in NYHA class II, 60 % in class III, and 15 % in class IV. The average ejection fraction was  $49.10 \pm 10.71$  %, and the mean EuroSCORE II was  $12.65 \pm 1.71$  %. Statistical Significance was noticed in age ( $P = 0.001$ ), NYHA classification ( $P = 0.002$ ), and EuroSCORE II ( $P = 0.001$ ) (Table 1).

Some statistically significant variations among the studied groups were detected, including the pre-operative role disabilities values ( $P > 0.001$ ), post-operative role difficulties values ( $P = 0.040$ ), pre-operative mental health values ( $P > 0.001$ ), and post-operative mental health values ( $P = 0.007$ ). In the SAVR group, there were significant statistical

differences between pre-operative and post-operative scores for physical function, role disabilities, general health, vitality, social function, and role difficulties. Similarly, in the TAVI group, also statistically significant variations among pre and post-operative values for physical function, role disabilities, general health, vitality, social function, role difficulties, and mental veracity were observed (Table 2, Fig. 1).

The study found that the physical task difficulty values in the pre-operative period were higher in the surgical compared with the TAVI group ( $34.91 \pm 6.21$  vs.  $29.42 \pm 3.58$ ;  $P < 0.001$ ). On the other hand, no significant variations were observed in the post-operative physical task difficulty values. The

Table 2. Evaluation of the short form-36 score in surgical aortic valve replacement and trans-catheter aortic valve implantation groups.

	Surgical aortic valve replacement	Trans-catheter aortic valve implantation	P value 1
Physical function			
Pre-operative	29.31 ± 4.98	27.01 ± 5.53	0.054
Post-operative	40.34 ± 7.12	38.91 ± 9.29	0.442
Difference	11.03 ± 7.31	11.90 ± 8.64	0.628
P value 2	<0.001*	<0.001*	
Role disabilities (physical)			
Preoperative	34.91 ± 6.21	29.42 ± 3.58	<0.001*
Postoperative	41.23 ± 5.82	44.45 ± 9.21	0.065
Difference	6.32 ± 7.21	15.03 ± 9.76	<0.001*
P value 2	<0.001*	<0.001*	
Pain			
Pre-operative	43.78 ± 5.53	41.67 ± 4.81	0.072
Postoperative	43.91 ± 9.12	43.92 ± 8.39	0.995
Difference	0.13 ± 9.99	2.25 ± 9.68	0.338
P value 2	0.938	0.145	
General Health			
Preoperative	29.13 ± 2.13	29.78 ± 3.23	0.291
Postoperative	44.34 ± 6.42	47.88 ± 13.13	0.129
Difference	15.21 ± 7.11	18.10 ± 14.02	0.248
P value 2	<0.001*	<0.001*	
Vitality			
Preoperative	41.56 ± 3.52	43.02 ± 3.33	0.060
Postoperative	49.01 ± 5.19	49.92 ± 7.11	0.515
Difference	7.45 ± 5.45	6.90 ± 7.29	0.703
P value 2	<0.001*	<0.001*	
Social function			
Preoperative	26.56 ± 2.54	28.04 ± 4.14	0.057
Postoperative	37.69 ± 5.32	38.26 ± 11.73	0.780
Difference	11.13 ± 6.92	10.22 ± 11.88	0.676
P value 2	<0.001*	<0.001*	
Role difficulties (Emotional)			
Preoperative	31.71 ± 4.02	29.81 ± 5.12	0.068
Postoperative	40.89 ± 5.11	44.86 ± 10.89	0.040*
Difference	9.18 ± 6.04	15.05 ± 11.95	0.007*
P value 2	<0.001*	<0.001*	
Mental health			
Preoperative	38.22 ± 5.67	34.36 ± 4.01	<0.001*
Postoperative	37.23 ± 9.13	44.81 ± 14.78	0.007*
Difference	0.99 ± 10.43	10.45 ± 15.23	<0.001*
P value 2	0.561	<0.001*	

AVR, aortic valve replacement; TAVI, trans-catheter aortic valve insertion.

\* Indicates statistical significance.

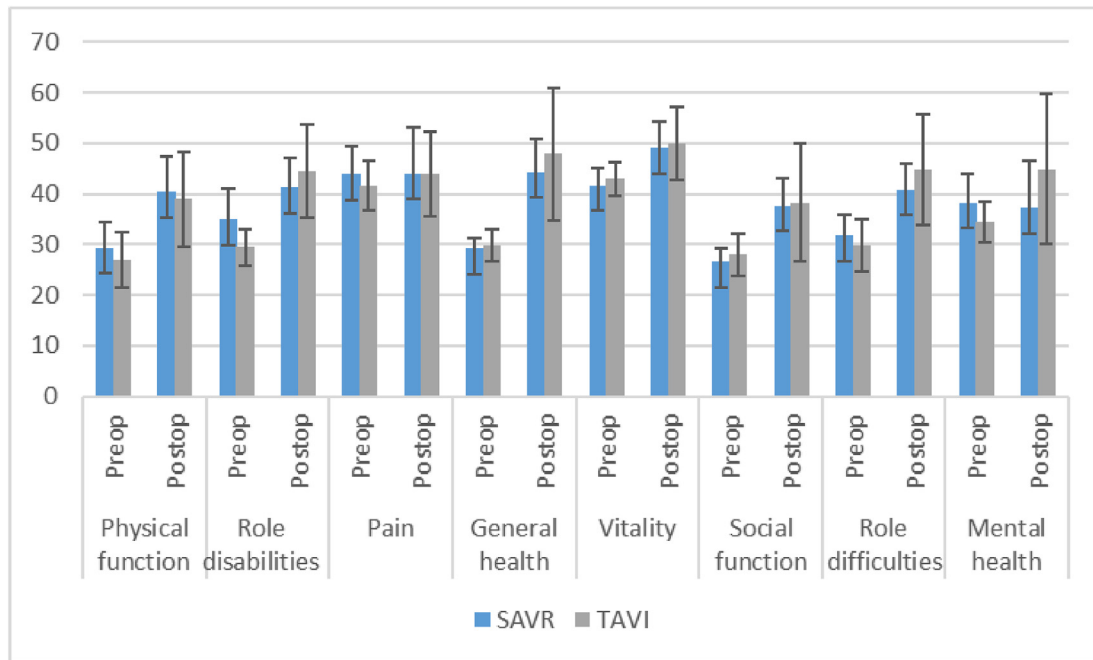


Fig. 1. Shows Short Form 36 questionnaire outcomes. blue bars represent surgical aortic valve replacement, grey bars represent trans-catheter aortic valve implantation, and error bars represent standard deviation.

TAVI group showed higher significant levels of improvement in the physical task difficulty values compared with the surgical group ( $15.03 \pm 9.76$  vs.  $6.32 \pm 7.21$ ;  $P < 0.001$ ) (Table 2, Fig. 1).

During the pre-operative period, no significant distinction was detected between both groups regarding emotional task limitations values. However, in the post-operative period, the TAVI group experienced a significantly higher value of betterment compared with the surgical group ( $15.05 \pm 11.95$  vs.  $9.18 \pm 6.04$ ;  $P = 0.007$ ) (Table 2, Fig. 1).

The pre-operative mental veracity of patients in the surgical group was notably better than that of the TAVI candidates ( $38.22 \pm 5.67$  vs.  $34.36 \pm 4.01$ ;  $P < 0.001$ ). However, the positive change in this particular parameter after surgery was significantly greater in the TAVI group than in the surgical group ( $0.99 \pm 10.43$  vs.  $10.45 \pm 15.23$ ;  $P < 0.001$ ) (Table 2, Fig. 1).

#### 4. Discussion

Minimally invasive replacement of aortic valve (Mini-AVR) and TAVI are less invasive alternatives to conventional surgical AVR, avoiding complete sternotomy. risky candidates with significant calcific stenosis may benefit from these less traumatic approaches.

On the other hand, patient satisfaction and Improvements in post-operative quality of life are

crucial indicators of procedural success, in particular, this is relevant for elderly patients who suffer from cardiac conditions.

In our study, the nonsurgical group of patients with severe calcific aortic stenosis showed a greater improvement in post-operative physical and emotional task limitation values. Despite greater levels of pre-operative mental health values observed in the surgical group, the nonsurgical group exhibited a significant improvement in this particular parameter postoperatively. Other parameters that determine the quality of life improvement, such as pain, vitality status, social and physical functions, and general health values, showed no significant differences between the studied candidates. Also, both TAVI and AVR patients showed significant improvement in aortic stenosis symptoms as well as improvement in general health conditions, this was similar to the Kocaaslan C et al. study [8]. Furthermore, we used the transe-femoral approach in all TAVI candidates, several studies reported shorter recovery times and improved quality of life associated with this technique [9].

Kocaaslan and colleagues. had similar results to our study, showing greater levels of life quality improvement postoperatively in TAVI patients compared with AVR patients. This can be attributed to the TAVI group's trans-femoral approach, which avoids any surgical incisions [8]. however, other

studies have indicated that Patients who undergo a trans-apical approach for TAVI have similar levels of post-operative life quality improvement in comparison to those who undergo conventional AVR. Despite a small incision being made in the chest during the trans-apical approach, the lack of expected improvement in the patient's quality of life compared with classic AVR may be due to the more severe and longer-lasting pain following the thoracotomy incision. Which can result in more limitations for the patients [9]. According to a study done by Bekeredian and colleagues they observed that patients who underwent TAVI procedure had the most quality of life improvement in their physical functions while experiencing the least improvement in reducing body pain, they also noticed that TAVI patients aged over 80 years had a positive impact on their mental health well-being. In our study, the TAVI group showed the highest benefit in general health status and the lowest was in pain relief. In addition, TAVI was found to have a significant positive impact on patient's mental health status [10].

Krane and colleagues have studied 99 TAVI patients prospectively, they found that patients' quality of life and NYHA functional capacity increased significantly 3 months after TAVI compared with the pre-operative period [11].

Patients who are 70 years old and above may experience limitations in their activities due to their old age. Long and colleagues compared the quality of life in candidates with a mean age above 70 who underwent tissue valve AVR before and 6 months after surgery using the SF-36 Questionnaire, positive changes were observed in physical function, social function, physical activity-related task limitation, vital condition, and health status. However, the research also found that 82 % of patients' dyspnea has improved dramatically after the relief of aortic stenosis. These findings go line in line with our study [12].

Sundt and colleagues conducted a study on patients aged 80 years or older who underwent AVR, the study revealed a significant improvement in functional abilities after surgery regardless of age. The majority of patients have experienced improvements in general condition and mental veracity status, social functions, emotional well-being, and pain relief. This demonstrates the positive impact of AVR on overall patients' well-being [13]. In our study, all parameters showed significant positive changes in patients of the mini-AVR group, except for pain and mental health.

Awad and colleagues have reported that there is no significant difference in mortality rates between

the first month and first year after TAVI or AVR procedures for candidates with significant stenosis and associated diseases, regardless of whether the cause of death was cardiac or due to other factors [14].

Gonçalves and colleagues performed a study that compared the life quality scores of candidates who underwent TAVI and AVR procedures. They found that although the TAVI candidates had a better life quality in the first month, both groups had a similar life quality after observing patients for 6–12 months. The surgical candidates have caught the TAVI group as time passes. This suggests that both procedures can provide similar long-term benefits, we observed the same pattern in our study [15].

We believe that studies conducted in the first month after AVR may not yield accurate results as patients are still in the recovery phase. Our research has shown that the quality of life for patients undergoing mini-AVR improves significantly after a two-month recovery period, this may be attributed to the progressive wound and sternal healing.

#### 4.1. Limitations and recommendations

Our study is limited to the few numbers and early stages of patients who underwent TAVI and mini-AVR procedures. Also, we used the post-operative quality of life improvement as a primary outcome which is a subjective measurement, other objective evaluations of post-operative outcomes including effective orifice area and durability of the replaced valve are needed in future studies.

We evaluated the patient's life quality using the SF-36 Questionnaire, which is a simple and comprehensible form. This form also assesses patient's dependency on others in their daily lives. However, we did not administer other tests like hospital anxiety and depression scales, which added to the limitations of this study.

#### 4.2. Conclusion

According to our early results, participants who underwent TAVI showed greater progress in their life quality parameters compared with those who received mini-AVR. This is likely because TAVI is a noninvasive technique which lacks cardiopulmonary bypass.

#### Conflicts of interest

There are no conflicts of interest.

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