

## Original paper

# Changes in cognitive functions and quality of life in patients after transcatheter aortic valve implantation

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## Abstract

**Introduction:** Transcatheter aortic valve implantation (TAVI) has emerged as a therapeutic option for patients with severe aortic stenosis (AS). However, an association between cognitive functions (CF) and health-related quality of life (HRQoL) in TAVI patients is still unclear.

**Aim:** To assess the long-term changes in CF and HRQoL in elderly patients with AS after TAVI.

**Material and methods:** A total of 259 patients who underwent cardiological and psychological TAVI qualification were enrolled and divided into the normal ( $n = 174$ ) and impaired cognition group ( $n = 85$ ). CF and HRQoL characteristics assessed at baseline and 13 months were compared between groups. The analysis of multiple linear regression was performed to identify the association between HRQoL and CF and to assess the influence of TAVI on HRQoL.

**Results:** There was no difference in CF between baseline and follow-up. However, an improvement in attention functions and memory skills in the cognitively impaired group was noted at follow-up. In addition, HRQoL scores increased in both groups. An independent predictor associated with HRQoL was global CF ( $\beta = -213$ ,  $p = 0.01$ ), which explained 7% of CF variation. Improvements in all five dimensions of HRQoL, from 4.8% in self-care and up to 33.6% in pain/discomfort, were found. At follow-up, 60% of TAVI patients had improved health, 12% had worse health, 4% showed no change and 24% had a “mixed” change.

**Conclusions:** TAVI is associated with positive changes in the functioning of elderly patients at long-term follow-up.

**Key words:** cognitive functions, quality of life, elderly, aortic valve stenosis.

## Summary

Transcatheter aortic valve implantation (TAVI) has emerged as a therapeutic option for patients with severe aortic stenosis (AS). However, an association between cognitive functions (CF) and health-related quality of life (HRQoL) in TAVI patients is still unclear. The aim of the study was to assess the evolution of CF and HRQoL in the 13-month follow-up of the elderly with AS after TAVI. The long-term study results show mainly positive changes in functioning of the elderly after TAVI treatment.

## Introduction

During the last decade transcatheter aortic valve implantation (TAVI) has gained clinical acceptance and become an appealing therapeutic option for elderly patients with multiple comorbidities and disabilities, who are disqualified from surgical aortic valve replacement (SAVR) due to a very high surgical risk [1, 2]. Numerous randomized clinical trials comparing TAVI to SAVR have

proved a lower complications rate, including stroke and mortality associated with TAVI [3–5]. Furthermore, TAVI patients have beneficial long-term outcomes in comparison with minithoracotomy, ministernotomy and SAVR [6]. Once becoming symptomatic, severe aortic valve stenosis has a very poor prognosis [2], resulting in progressive deterioration. Impaired functional status, reduced health-related quality of life (HRQoL) and cognitive de-

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cline can be found simultaneously. Thus, the assessment of the impact of TAVI on psychological and functional domains, along with mortality and morbidity, is of predominant importance [7]. Previous studies reported conflicting results on the assessment of cognitive functions (CF) and HRQoL after TAVI.

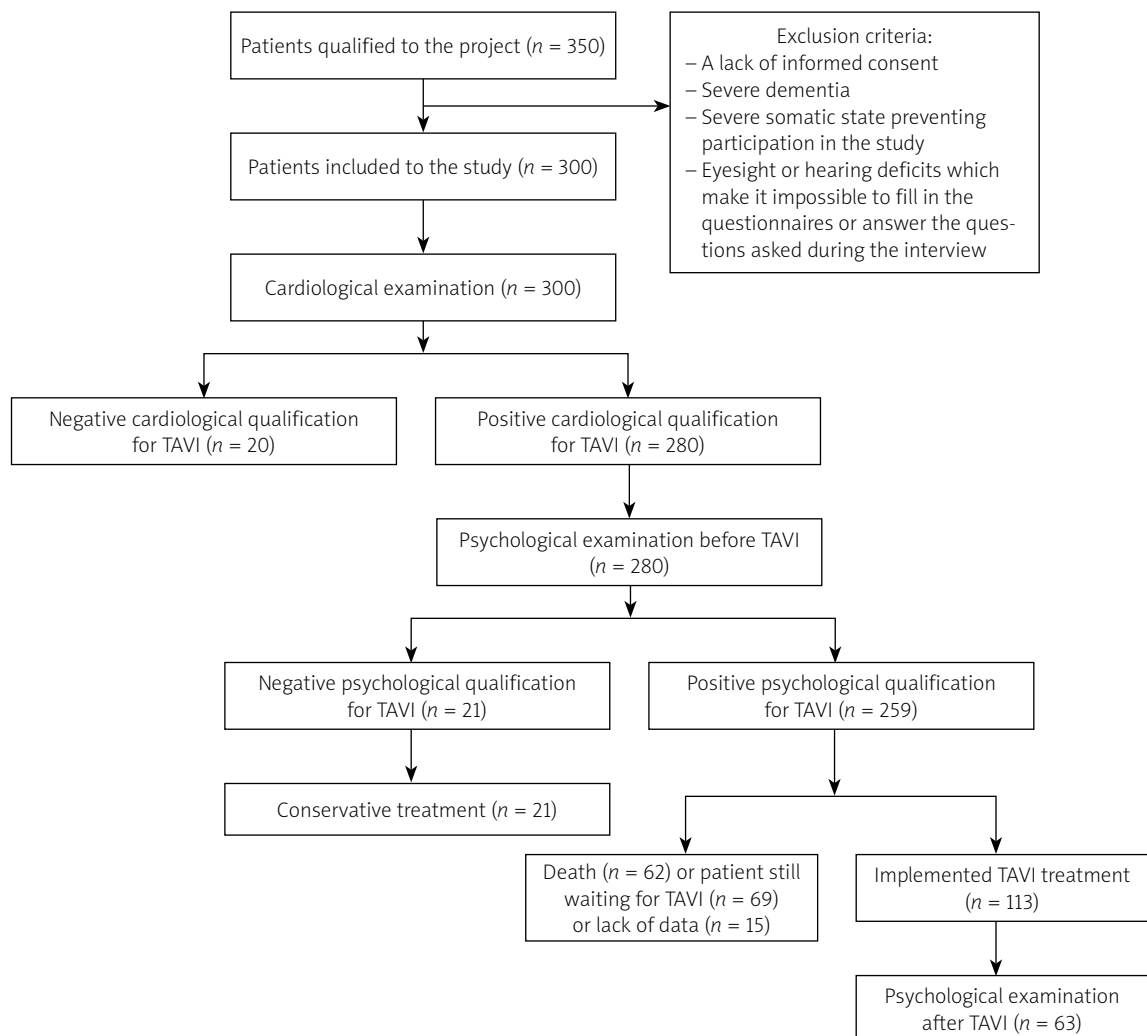
## Aim

We sought to assess the changes in CF and HRQoL in the long-term follow-up of patients with AS undergoing TAVI.

## Material and methods

Inclusion and exclusion criteria and the patients' flow chart are presented in Figure 1. All patients suitable for TAVI based on cardiological qualification underwent psychological assessment. Each of these patients was examined before TAVI by a neuropsychologist highly qualified in work with cardiologic patients. Patients were asked to take part in a psychological interview concern-

ing demographic data, previous mental problems, family life and current life situation with special interest in everyday life skills and abilities. The Mini-Mental State Examination Scale (MMSE) as well as self-reported EuroQol 5 dimensions questionnaire (EQ-5D-3L) and the Lawton Instrumental Activities of Daily Living (IADL) scale were collected. The differences in HRQoL between patients with stable (MMSE  $\geq 24$  points) and decreased (MMSE  $\leq 23$  points) CF were examined. Patients after successful TAVI were assessed again at 13 months after the procedure. According to principles based on Pareto Improvement in Welfare Economics – the Pareto Classification of Health Change [8, 9] we compared the results in EQ-5D-3L before and after the TAVI procedure. In this approach EQ-5D-3L health state is considered “better” than another if it is better on at least one dimension and is no worse in any other dimension. It is deemed to be “worse” than another if it is worse on at least one dimension and is no better in any other dimension. All patients provided written informed consent to participate in the study. The protocol was approved by the local ethics committee. The



**Figure 1.** Flow chart of patients with severe aortic stenosis qualified for transcatheter aortic valve implantation

study was provided with ethical principles for clinical research based on the Declaration of Helsinki with later amendments.

### Statistical analysis

Results are presented as number of patients (percentage) or mean  $\pm$  standard deviation. We compared participants' characteristics between the normal cognition and impaired cognition group. We used the unpaired *t*-test or Mann-Whitney *U*-test for continuous variables and the  $\chi^2$  test for categorical variables, as appropriate. Changes in the EQ-5D-3L questionnaire were analyzed using McNemar's test. The differences between baseline and follow-up responses in the VAS score were calculated with the Wilcoxon signed-rank test. Multiple linear regression analyses were performed to determine the association between HRQoL as a dependent variable and cognitive functioning as an independent variable adjusted for baseline characteristics, i.e. age, sex, education level. *P*-values below 0.05 were considered statistically significant. The statistical analysis was performed using Statistica 13 PL (StatSoft, Inc. Tulsa, OK, USA).

## Results

All the 259 patients included in the study were between 61 and 94 years old (mean age: 81.8  $\pm$  5.9 years)

and 61% of patients were female. Demographic and clinical characteristics of subgroups with different cognitive status are presented in Table I. Mean MMSE in the group with normal CF was 27.2  $\pm$  1.9 points while in the group with impaired cognition it was 20.2  $\pm$  2.9 points. There were also differences in the age (*p* = 0.01) and education level (*p* = 0.001). The average wait time of 4 to 5 months for TAVI was similar in both groups.

Changes from baseline to 13 months in quality of life, instrumental activities of daily living and cognitive assessment scores were assessed (Table II). EQ-5D-3L and VAS scale total score improved over time. Moreover, such factors as pain/discomfort and anxiety/depression in the whole study group improved (lower scores mean an improvement); pain/discomfort in the normal cognitive subgroup and impaired cognitive group also improved. On the other hand, the mobility dimension decreased in the whole study group and the normal cognitive subgroup. In IADL there was an improvement in managing medications in the whole group and in the normal cognitive subgroup (Table II).

The overall MMSE result did not differ between baseline and follow-up. In the MMSE subscales (orientation, memory, language functions, attention, visual and spatial skills) differences in subgroups depending on cognitive status were observed. There was improvement over time in attention functions and memory skills in the cognitive-

**Table I.** Clinical and demographic characteristics of participants (*n* = 261)

Parameter	Normal cognition ( <i>n</i> = 174)	Impaired cognition ( <i>n</i> = 85)	<i>P</i> -value
Age [years] <sup>1</sup>	80.8 $\pm$ 6.2	84.1 $\pm$ 4.5	0.01
Female <sup>2</sup>	106 (60)	54 (63)	0.7
Education level [years] <sup>1</sup>	10.2 $\pm$ 4.2	7.1 $\pm$ 3.1	0.001
Total TAVI wait time [months] <sup>1</sup>	4.2 $\pm$ 3.5	4.6 $\pm$ 3.6	0.8
Hypertension <sup>2</sup>	52 (91)	19 (83)	0.2
EF% before TAVI <sup>1</sup>	53.3 $\pm$ 13.4	53.9 $\pm$ 14.2	0.6
Diabetes mellitus <sup>2</sup>	20 (35)	7 (32)	0.8
Body mass index [kg/m <sup>2</sup> ] <sup>1</sup>	26.6 $\pm$ 4.6	26.1 $\pm$ 3.8	0.3
Chronic kidney disease <sup>2</sup>	18 (32)	7 (30)	0.9
Chronic obstructive pulmonary disease <sup>2</sup>	5 (9)	1 (5)	0.5
Asthma <sup>2</sup>	3 (5)	1 (5)	0.9
Coronary artery disease <sup>2</sup>	44 (77)	16 (7)	0.7
Carotid artery stenosis <sup>2</sup>	8 (15)	3 (13)	0.8
Current smoker <sup>2</sup>	1 (2)	0 (0)	0.7
EuroSCORE II <sup>1</sup>	6.1 $\pm$ 7.7	6.5 $\pm$ 8.3	0.6
STS risk score <sup>1</sup>	4.1 $\pm$ 2.2	3.8 $\pm$ 1.5	0.054

EF – ejection fraction, EuroSCORE II – European System for Cardiac Operative Risk Evaluation II, STS – Society of Thoracic Surgery risk score, TAVI – transcatheter aortic valve implantation. <sup>1</sup>Mean (standard deviation), <sup>2</sup>numbers (%).

ly impaired group (Table II). A multiple linear regression analysis was applied to assess the relationship between HRQoL and CF (Table III). Global cognitive performance (MMSE) was considered an independent variable and was adjusted for age, sex, and education level. The model explained 7% of variation in the EQ-5D-3L scores. MMSE

**Table II.** Baseline and 13-month follow-up quality of life, instrumental activities of daily living and cognitive assessment

Variable	All patients (n = 59)			Normal cognition (n = 39)			Impaired cognition (n = 20)		
	Baseline	Follow-up	P-value	Baseline	Follow-up	P-value	Baseline	Follow-up	P-value
Health-related quality of life:									
Mobility EQ-5D-3L	1.8 ±0.5	1.9 ±2.8	0.01	1.8 ±0.6	2.1 ±3.5	0.05	2.1 ±0.3	1.7 ±0.5	0.1
Self-care EQ-5D-3L	1.3 ±0.5	1.3 ±1.2	0.5	1.3 ±0.5	1.4 ±1.6	0.6	1.3 ±0.5	1.3 ±0.5	0.7
Usual activities EQ-5D-3L	1.4 ±0.6	1.3 ±0.5	0.2	1.4 ±0.6	1.1 ±0.4	0.06	1.4 ±0.6	1.5 ±0.6	0.8
Pain/discomfort EQ-5D-3L	1.9 ±0.5	1.3 ±0.5	0.001	1.9 ±0.6	1.4 ±0.6	0.05	2.1 ±3.4	1.3 ±0.5	0.01
Anxiety/depression EQ-5D-3L	1.8 0±.7	1.5 ±0.6	0.05	1.8 ±0.7	1.5 ±0.7	0.1	1.7 ±0.6	1.4 ±0.5	0.2
Total score EQ-5D-3L [points]	8.1 ±1.6	6.8 ±1.9	0.001	7.9 ±1.6	6.6 ±2.1	0.01	8.4 ±1.7	7.2 ±1.6	0.05
EQ Visual Analogue Scale	52.8 ±17.6	64.5 ±21.5	0.01	53.6 ±17.7	63.5 ±21.3	0.05	51.5 ±17.6	66.4 ±22.5	< 0.05
Instrumental activities of daily living:									
IADL using phone	2.7 ±0.6	3.2 ±2.6	0.2	2.9 ±0.2	3.6 ±3.2	0.368	2.3 ±0.8	2.5 ±0.8	0.8
IADL walking	2.2 ±0.8	2.5 ±0.6	0.1	2.4 ±0.7	2.6 ±0.7	0.525	1.8 ±0.8	2.3 ±0.6	0.07
IADL shopping	2.2 ±0.8	2.4 ±0.8	0.08	2.4 ±0.8	2.5 ±0.7	0.213	1.9 ±0.9	2.2 ±0.9	0.2
IADL cooking	2.8 ±0.5	2.6 ±0.7	0.4	2.9 ±0.4	2.7 ±0.6	0.162	2.5 ±0.7	2.5 ±0.8	1.0
IADL basic house work	2.4 ±0.6	2.6 ±0.6	0.2	2.5 ±0.6	2.7 ±0.6	0.418	2.2 ±0.6	2.5 ±0.7	0.2
IADL laundry	2.6 ±0.6	2.6 ±0.6	0.7	2.7 ±0.6	2.7 ±0.5	0.814	2.3 ±0.5		0.8
IADL managing medications	2.7 ±0.5	2.5 ±0.7	0.01	2.9 ±0.3	2.7 ±0.5	<0.05	2.5 ±0.8	2.1 ±0.8	0.1
IADL managing finance	2.7 ±0.6	2.8 ±0.5	0.8	2.9 ±0.2	2.9 ±0.3	0.576	2.4 ±0.9	2.6 ±0.8	0.4
IADL total score [points]	20.7 ±3.9	20.8 ±3.8	1.0	20.9 ±3.9	21.8 ±3.1	0.933	18.4 ±2.9	18.7±4.4	0.7
Cognitive assessment:									
MMSE total score [points]	24.9 ±3.8	25.1 ±4.6	0.7	27.2 ±1.9	26.7 ±2.6	0.2	20.7 ±2.9	22.1 ±6.1	0.3
MMSE orientation in time and place	9.2 ±1.3	9.3 ±1.4	0.3	9.7 ±0.5	9.7 ±0.5	0.6	8.1 ±1.8	8.4 ±2.1	0.4
MMSE memory skills	4.8 ±1.1	4.8 ±0.9	1.0	5.2 ±0.8	4.9 ±0.8	0.08	4.1 ±1.2	4.6 ±0.9	0.05
MMSE language functions	7.4 ±1.2	8.1 ±3.7	0.2	7.8 ±1.1	7.5 ±0.8	0.4	6.5 ±1.1	9.05 ±6.4	0.1
MMSE attention functions	3.2 ±1.6	3.2 ±1.4	0.7	3.8 ±1.3	3.6 ±1.4	0.24	1.9 ±1.3	2.5 ±1.2	0.05
MMSE visual and spatial skills	0.6 ±0.5	0.7 ±0.4	0.07	0.7 ±0.4	0.8 ±0.4	0.3	0.5 ±0.5	0.7 ±0.5	0.1

EQ-5D-3L – EuroQual 5-Dimension 3-Level, IADL – Instrumental Activities of Daily Living, MMSE – Mini Mental State Examination.

**Table III.** Analysis of multiple linear regression to EQ-5D-3L

Variable	Beta	P-value	R <sup>2</sup>	P-value
MMSE	-0.213	0.01	0.072	0.01
Sex (1 – female)	0.044	0.5		
Age	0.101	0.1		
Education level	0.005	0.9		

MMSE – Mini Mental State Examination.

was the only independent predictor associated with the EQ-5D-3L ( $\beta = -213, p = 0.01$ ).

EQ-5D-3L data before and after TAVI are presented in Figure 2. There was an improvement in EQ-5D-3L in all five dimensions: from 4.8% improvement in self-care, up to 33.6% in pain/discomfort. The rank of dimensions in terms of percentage changes from the biggest to the smallest improvement was as follows: pain/discomfort, mobility, usual activities, anxiety/depression, self-care. We found that 60% of TAVI patients had improved health, 12% had worse health, 4% had no change and 24% had a “mixed” change.

### Discussion

In this study, patients’ general CF level was stable at 13 months after TAVI. In a subgroup of cognitively impaired patients an increase in two dimensions was noted. HRQoL mainly improved, especially in the pain/discomfort and anxiety/depression aspects and in the scale of VAS on which a subjective evaluation of quality of life was performed. These findings suggest the impact of TAVI on mental function improvement.

The data showed that the impaired cognition subgroup’s mean age was significantly higher, and their education level was lower in comparison to the normal cognition group, with no differences in chosen medical factors, which is in accordance with our previous pilot study group characteristics [10]. Younger age and longer education time are the common protective factors against dementia which strengthen everyday life activity skills, independence and autonomy. Our results are in line with those proving preserved neurocognitive domains longitudinally after TAVI [11–14]. Musa *et al.* [11] in an observational two-center comparison found a decline in verbal memory and psychomotor speed at 30 days in a group of patients who received a second-generation Lotus valve. There was a higher incidence of silent cerebral micro-

infarction and a greater number of lesions per patient following Lotus compared with CoreValve, too. However, performance longitudinally at 1 year was preserved in all neurocognitive domains with either prosthesis. Other studies presented [14, 15] cognitive improvement after TAVI in patients with initially impaired preprocedural CF. Change in mental status was possibly related to hemodynamic improvement. Likewise, in a study by Pelletier *et al.* [12] in a subgroup analysis of patients who were cognitively impaired at baseline, a significant increase in their overall score was noted. In contrast, overall CF did not differ before TAVI as compared to 6 months following the procedure. Ciuca *et al.* [13] obtained data showing no significant differences in cognitive status from baseline up to 1-year follow-up. Finally, a meta-analysis by Khan *et al.* [16] showed preserved cognitive performance after TAVI, suggesting that this treatment is not detrimental to cognition.

In the more detailed analysis, we found that such cognitive domains as memory skills and attention functions improved after TAVI in the subgroup of patients with cognitive impairment. Cognitive improvement in the group of patients with cognitive impairment at baseline seems to be of great importance considering data indicating that cognitive impairment based on the MMSE score was an independent predictor of mortality at 1 year after TAVI [17]. Better memory and attention functions possibly also improve everyday communication and cooperation between an elderly patient and a caregiver in usual activities, self-care and other activities of daily living. Preserved cognitive performance after TAVI suggests effectiveness of this treatment, even though the incidence of silent cerebral microinfarctions, lesions and hypoperfusion in the central nervous system as side effects are mentioned in some studies [11, 14].

CF remained at the same level or improved in all TAVI patients in the 13-month follow-up. Hereby, the results of our study also confirm that TAVI can be protective

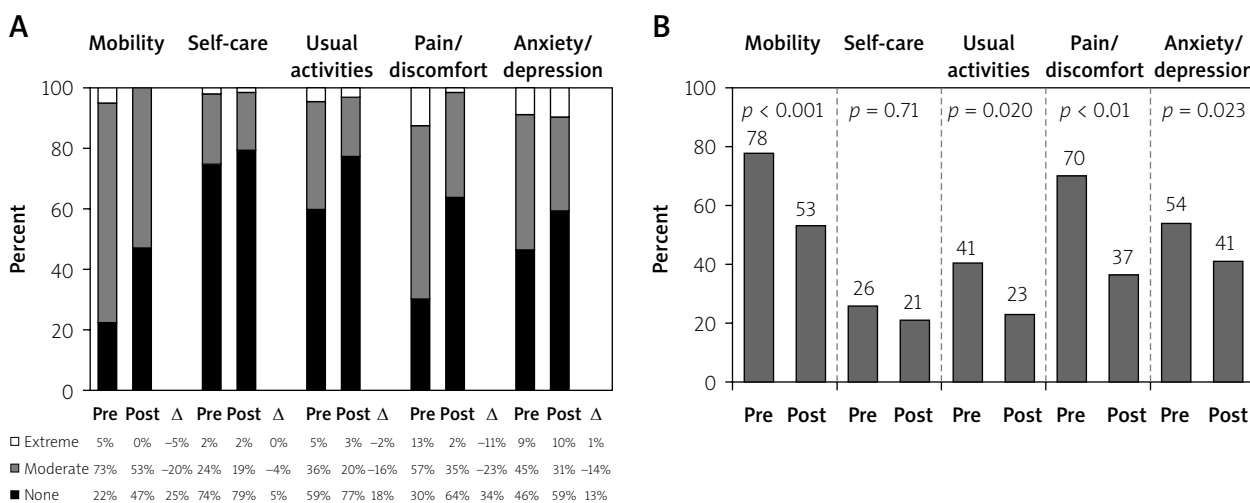


Figure 2. Proportions of patients reporting levels within EQ-5D-3L dimensions: pre- and post-TAVI

against the process of physiological aging of the central nervous system possibly due to improved hemodynamic functions. Measurement of general CF, as a factor of frailty, seems to be of a great importance in the evaluation of mortality and delirium risk after TAVI. Thus, it might be incorporated into the risk models for preoperative assessment. The frailty factors consist of e.g. general cognitive functioning, activities of daily living, and motor skills [16–19]. TAVI guidelines [1] advocated including frailty in the risk models as the Frailty Index was proved to be associated with delirium after TAVI and mortality [18–23].

In this study, all TAVI patients improved their global HRQoL measured with EQ-5D-3L in 13-month follow-up and no difference was found in the global HRQoL when measured with IADL. From the subjective patients' point of view, their quality of life level in the aspects of physical, emotional and psychological activity are at least as important as medical surgery results. Thus, we analyzed particular HRQoL dimensions and found that pain/discomfort and anxiety/depression decreased after the TAVI procedure. The available data on HRQoL in general and when measured in detail showed similar outcomes [2, 24, 25]. In the German Aortic Valve Registry Lange *et al.* [24] concluded that TAVI led to improvements in HRQoL, especially in terms of mobility and usual activities. However, there was a sizable group of patients who did not derive any HRQoL benefits. Several independent pre- and post-operative factors were identified as being predictive for less pronounced HRQoL benefits. Deutsch *et al.* [2] stated that TAVI significantly improved HRQoL in high-surgical-risk patients with severe AS with sustained effects up to 2 years. In a comprehensive literature review Ferrari *et al.* [25] stated that most studies reported a significant increase in HRQoL after TAVI, greater for physical aspects compared with psychological components, which persisted at mid and long-term follow-up. The author also mentioned that evaluation of quality of life in TAVI patients might be challenging. Similar results were obtained by Tokarek *et al.* [26]: global, physical and emotional dimension scores in HRQoL at 30 days from aortic valve replacement (AVR) presented significant improvement after TAVI in comparison with surgical methods 1 year after the procedure with no differences in somatic and emotional components. No differences were found in HRQoL 24 months after AVR. Also, Li *et al.* [27] in a systematic review of HRQoL changes in the long-term follow-up stated that this technique provides a promising therapeutic approach for elderly patients with severe symptomatic AS and high surgical risk.

Data from our study demonstrated significant improvement of HRQoL at follow-up after TAVI in comparison with surgical methods. However, the dimension mobility-walking of HRQoL decreased in time, which is the opposite result to other studies [18, 24]. We suppose that methods such as gait speed and Timed Up and Go tests

turned out to be more relevant than the subjective evaluation of mobility method in our study.

Results in HRQoL with the IADL scale showed an improvement in one dimension, managing medications, in the group of patients with a stable cognitive state. The ability to have control over medical treatment is important and helpful in the patients' daily living, especially when we take into consideration the multiple comorbidities they suffer from and the number of medications they are prescribed. In a previous pilot study of TAVI patients [10] we put stress on the fact that psychological evaluation of CF and HRQoL assessment is helpful and very often of great importance in the qualification process concerning clinical decisions and choice of treatment method. Furthermore, well-adjusted questionnaires are able to exclude those patients who cannot cooperate well enough during diagnostic procedures because of dementia. Identification of such patients would allow the Heart Team and treating physicians to better inform patients of their likely individual benefits from this procedure. Therefore, comprehensive medical and psychological evaluation of the elderly seems to be needed.

We believe that our findings support the use of TAVI as a therapeutic option in elderly patients who were denied surgery because of advanced age, multiple comorbidities and surgical risk.

The main limitation of this study is the small number of patients in the post-TAVI group. There is a potential bias caused by the patients lost during follow-up, too. Different and more relevant methods to measure mobility changes after TAVI, instead of the subjective evaluation method used in our study, should be considered.

## Conclusions

Long-term results after TAVI are associated with positive changes in functioning of elderly patients. These findings support the importance of mental status evaluation before the TAVI procedure. CF and HRQoL evaluation play an important role in TAVI qualification and the long-term observation process.

## Conflict of interest

The authors declare no conflict of interest.

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