

Assessment of cognitive functions and quality of life in patients scheduled for transcatheter aortic valve implantation: a pilot study

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Transcatheter aortic valve implantation (TAVI) is an innovative and effective treatment for patients with symptomatic severe aortic stenosis (AS). In particular, TAVI offers a treatment option for elderly patients with very high surgical risk, who are disqualified from surgical aortic valve replacement (SAVR) [1]. An improvement in long-term outcomes and quality of life (QoL) after TAVI has been confirmed by several studies [2–6]. Importantly, an exponential increase in the number of TAVIs is expected over the next decade. It is related to the aging of the population in Europe and the growing number of geriatric patients who will be possible candidates for TAVI. Apart from mortality, QoL and both mental and functional status are important instruments in assessing patient-specific outcomes of therapeutic interventions, especially in the population with limited life expectancy [7]. Measures of morbidity and mortality are not able to elucidate life-specific information on physical, emotional, and mental well-being but can be supplemented with the patient's perception of recovery after the intervention [7]. However, there are specific changes in cognitive functioning, connected with aging [8]. Neuropsychological evaluation of cognitive functions and QoL assessment are helpful 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 elderly patients seems to be necessary.

We sought to evaluate QoL in regard to both mental and functional status among patients with symptomatic severe AS scheduled for TAVI.

Here we summarize our initial results of 100 consecutive patients with symptomatic severe AS and high surgical risk or contraindications for SAVR. The periprocedural risk was evaluated with the STS PROM scale and EuroSCORE II. Patients were admitted for TAVI qualification to the Second Department of Cardiology and Cardiovascular Interventions in Krakow between 2016 and 2017. Patient screening and selection were performed by a multidisciplinary Heart Team. The study is planned to be held in three steps: assessment before the treatment, 2 weeks and 6 months after TAVI. The full data (2-week and 6-month steps) are in the process of collection. Due to the time-consuming procedure, the necessity to create appropriate methods of patient qualification, and some difficulties with fast data collection, we decided to present the first step results in this paper. An evaluation of a larger population with 6-month follow-up is planned. Exclusion criteria included: lack of informed consent, severe dementia, severe somatic state preventing participation in the study, eyesight deficits which make it impossible to fill in the questionnaires, and hearing deficits which make it impossible to answer the questions asked during the interview. During the qualification process, all the procedures were performed by an expe-

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rienced cardiologist. In addition, each patient was examined by a neuropsychologist highly qualified in work with cardiologic patients. Patients were asked to take part in a psychological interview concerning demographic data, previous mental problems, family life and current life situation with a special interest in everyday life skills and abilities. The Mini-Mental State Examination Scale (MMSE), self-reported EQ-5D-3L questionnaire, and the Lawton Instrumental Activities of Daily Living (IADL) scale were collected. MMSE was used for cognitive function evaluation with typical cut points [8]. The differences in QoL between patients with stable ((MMSE) \geq 24 points) and decreased (MMSE \leq 23 points) cognitive functioning were examined. All patients provided written informed consent to participate in the study. The protocol was approved by the local ethics committee (decision no. 122.6120.39.2015). The study followed the ethical principles for clinical research based on the Declaration of Helsinki with later amendments.

Standard descriptive statistics were used. Quantitative variables were described using mean and standard deviation. Categorical variables were presented as counts and percentages. The level of statistical significance was set at $p < 0.05$. The Mann-Whitney U test (for non-normal distribution of data) or unpaired (two-sample) Student's t -test (for normally distributed data) was applied for continuous variables. The χ^2 test was used for categorical (nominal and dichotomous) variables. The association between the values of MMSE and IADL was assessed by Pearson's correlation coefficients. All analyses were carried out with Statistica 12 (StatSoft, Inc. Tulsa, OK, USA).

A total of 100 consecutive patients (66 males and 34 females; mean age: 82 ± 5 years) with symptomatic severe AS and very high surgical risk or contraindications for SAVR were enrolled. Mean MMSE score in the group with stable cognitive functioning was 26.9 ± 1.9 points while in the group with dementia symptoms it was 19.2 ± 3.1 points. Patients with MMSE ≥ 24 were younger (81.2 ± 5.3 vs. 84.2 ± 4.0 years, $p = 0.001$), with longer education (10.5 ± 5.3 vs. 6.6 ± 2.9 years, $p = 0.001$) and better orientation in time and place (9.5 ± 0.8 vs. 6.6 ± 2.8 points, $p = 0.001$). In patients with decreased MMSE, memory skills (3.6 ± 1.5 vs. 5.3 ± 0.9 points, $p = 0.001$) and language functions (3.15 ± 1.1 vs. 3.8 ± 0.6 points, $p = 0.001$) were lower in comparison to patients with preserved mental status. There was no difference between groups in QoL assessment using the EQ-5D-3L questionnaire and the VAS scale (Table I). Therefore, general evaluation of self-care, usual activities, pain and discomfort, anxiety and depression is not enough to describe and differentiate patients' abilities to cope with treatment duties and tasks in the context of the mental state. Also, patients' subjective point of view in the context of their well-being (assessed with the VAS) is not a sufficient predictor of differences in patients' functioning between the group with stable and decreased cognitive functioning. Such

daily activities as using the phone, walking, cooking, managing medications and managing finances are distinctive for patients' ability to be independent in everyday life and well adapted to treatment situations. These factors are evaluated in the IADL scale and can be helpful in qualification procedures for TAVI. Particular results of these dimensions describing daily functioning are presented in Table I. A moderate positive correlation between MMSE and the IADL scale was observed ($r = 0.45$, $p = 0.006$) (Figure 1). It proves that mental state is an important factor connected with daily activities. Patients with higher scores in the MMSE have a higher chance of returning to their daily activities and coping well with self-care after TAVI treatment, too.

We confirmed that the MMSE test is appropriate for general cognitive functioning measurement in elderly patients with severe symptomatic AS qualified for TAVI. The differences between patients with cognitive decline (MMSE ≤ 23 points) in orientation in time and place, memory skills and language functions are consistent with the previous studies [9, 10]. Thus, MMSE can be used in the qualification process for TAVI. However, the method of MMSE data interpretation requires a detailed analysis. In some studies functional independence was related to the level of education: a higher level of education corresponded to a higher level of self-reliance [8]. We found in our study that the algorithm for the calculation of results in the MMSE proposed by previous studies is probably inadequate [11]. The correction for age and education suggested by the authors of the algorithm gave statistically false results. Years of education did not accurately represent the mental state of our patients. A possible reason is that in our study many of the patients were not educated enough due to World War II to use this algorithm appropriately. Thus, we decided to evaluate the raw results, which is recommended in some cases [12]. Furthermore, chronic heart failure (CHF) as a result of severe AS could have an influence on the value of MMSE [13]. The association between cognitive impairment and stage of CHF seems to have clinical importance [13]. Mental status decline affects both the QoL and clinical evolution of the stage of CHF [13]. Furthermore, it has a detrimental effect on the interaction between physician and patients as well as compliance with recommended treatment.

Evaluation of QoL seems to be an important index as frequently not a reduction in mortality but an improvement in daily life comfort is considered most desirable by the patients themselves. Regarding QoL and daily living, the IADL questionnaire was found to be relevant and useful. On the other hand, EQ-5D-3L, which is a standardized generic measure of health state widely used in diverse patient populations, showed low sensitivity, which potentially influenced the results. Therefore the use of EQ-5D-3L in our further studies seems to be debatable as the IADL questionnaire may provide more comprehensive information about the patients' functioning.

Table I. EQ-5D-3L Questionnaire and IADL scale mean values in comparison between patients with stable (MMSE \geq 24 points) and decreased (MMSE \leq 23 points) cognitive functioning level

Variable	MMSE \geq 24 points	MMSE \leq 23 points	P-value
Mobility EQ-5D-3L:			0.3
None (0)	20.37%	22.58%	
Moderate (1)	75.93%	64.52%	
Extreme (2)	3.70%	12.90%	
Self-care EQ-5D-3L:			0.2
None (0)	75.93%	61.29%	
Moderate (1)	22.22%	38.71%	
Extreme (2)	1.85%	0.00%	
Usual activities EQ-5D-3L:			0.3
None (0)	55.56%	41.94%	
Moderate (1)	42.59%	51.61%	
Extreme (2)	1.85%	6.45%	
Pain/discomfort EQ-5D-3L:			0.2
None (0)	25.93%	16.13%	
Moderate (1)	62.96%	58.06%	
Extreme (2)	11.11%	25.81%	
Anxiety/depression EQ-5D-3L:			0.9
None (0)	44.44%	38.71%	
Moderate (1)	42.59%	48.39%	
Extreme (2)	12.96%	12.90%	
Total score EQ-5D-3L [points]	3.3 \pm 1.6	3.6 \pm 2.3	0.4
EQ Visual Analogue Scale	50.6 \pm 19.6	54.4 \pm 18.1	0.4
IADL using phone:			0.005
Dependent (1)	0.00%	21.88%	
Need help (2)	12.96%	21.88%	
Independent (3)	87.04%	56.25%	
IADL walking:			0.001
Dependent (1)	14.81%	40.63%	
Need help (2)	31.48%	34.38%	
Independent (3)	53.7%	25.00%	
IADL shopping:			0.2
Dependent (1)	24.07%	31.25%	
Need help (2)	18.52%	31.25%	
Independent (3)	57.41%	37.5%	
IADL cooking:			0.007
Dependent (1)	0.00%	6.25%	
Need help (2)	12.96%	34.38%	
Independent (3)	87.04%	59.37%	
IADL basic house work:			0.02
Dependent (1)	11.11%	21.88%	
Need help (2)	31.48%	40.63%	
Independent (3)	57.41%	37.5%	
IADL laundry:			0.06
Dependent (1)	9.43%	21.88%	
Need help (2)	24.53%	37.50%	
Independent (3)	66.04%	40.62%	

Table I. Cont.

Variable	MMSE \geq 24 points	MMSE \leq 23 points	P-value
IADL managing medications:			0.007
Dependent (1)	5.56%	25.00%	
Need help (2)	11.11%	21.88%	
Independent (3)	83.33%	53.12%	
IADL managing finance:			0.002
Dependent (1)	0.00%	21.88%	
Need help (2)	14.81%	9.38%	
Independent (3)	85.19%	68.74%	
IADL total score [points]	20.8 \pm 3.1	16.1 \pm 6.3	0.007
IADL using phone	0%	100%	0.003
IADL walking	38.1%	61.9%	0.007
IADL shopping	56.52%	43.48%	0.5
IADL cooking	0%	100%	0.06
IADL basic house work	46.15%	53.85%	0.2
IADL laundry	46.15%	53.85%	0.2
IADL managing medications	27.27%	72.73%	0.009
IADL managing finance	0%	100%	0.003

MMSE – Mini Mental State Examination. EQ-5D-3L – The questionnaire is composed of 5 questions, each scoring 0–2 points. A higher score represents a lower quality of life. The Visual Analogue Scale was scored 0–100% – the higher the score, the higher the quality of life. IADL (Instrumental Activities of Daily Living) questionnaire was scored 1–3 points – the higher the score, the fewer the problems with a particular activity.

Our results showed which aspects of QoL are an easy and quick way to evaluate patients who will profit from the treatment and a group of patients who will not gain any benefits. Furthermore, in the follow-up, we plan to assess whether TAVI influences cognitive functions and QoL in time.

Both functional and cognitive assessment can provide objective data to assist with targeting individualized diagnostic needs and the plan for treatment. Most of the proposed mental state and QoL indices confirmed predictive ability in the process of qualification for TAVI. Our results are consistent with recent reports on the impact of frailty on 12-month mortality after TAVI [14]. Such assessments can help to identify a group of patients who will not benefit from TAVI and who should receive conservative treatment instead. Mental and QoL evaluation can also guide the physicians to focus on the patient's baseline capabilities, facilitating early recognition of changes and symptoms that may signify a need for a medical work-up [15]. Comprehensive medical and psychological evaluation is useful in selection of patients for TAVI. Multidisciplinary evaluation in the qualification process gives the fullest description of the clinical situation of the candidate for TAVI. An important aspect for further consideration is the postulate that the psychologist should always be a member of the TAVI qualification team.

The most important limitation of this single-center prospective observational study is the relatively small sample size. On the other hand, this study represents a comprehensive analysis of consecutive “real-world” patients undergoing TAVI. There are limitations linked to

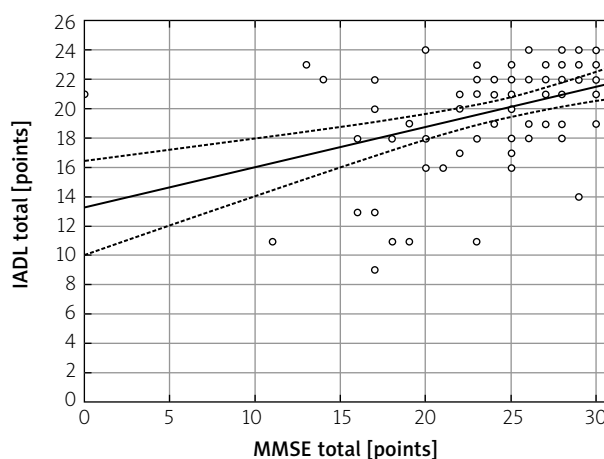


Figure 1. Correlation between IADL and MMSE total points ($r = 0.45$, $p = 0.006$)

the tool for QoL assessment. EQ-5D-3L is questionnaire with low sensitivity. Also, the analysis did not include disease-specific questionnaires; only generic instruments were used.

In conclusion, we confirm the relationship between mental health and QoL in patients scheduled for TAVI. Thus, it may stress the value of the assessment of cognitive and everyday life functioning with validated methods during qualification for TAVI. A comprehensive evaluation may be useful to avoid futility of TAVI and to predict outcomes

Conflict of interest

The authors declare no conflict of interest.

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