

# Improvement of quality of life following transcatheter aortic valve implantation in the elderly: a multi-centre study based on the Polish national TAVI registry

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## Abstract

**Background:** Transcatheter aortic valve implantation (TAVI) is an effective therapeutic method for elderly high-risk patients with symptomatic severe aortic stenosis, not eligible for surgical treatment.

**Aim:** The aim of the study was to evaluate short-term changes in elderly people's quality of life following TAVI, based on the POL-TAVI registry.

**Methods:** One hundred and eighty-four octogenarians' and nonagenarians' samples from the POL-TAVI database were included in the study. The quality of life status was assessed with EQ-5D-3L questionnaire at baseline and after one-month follow-up.

**Results:** The mean of patients' age was 84 (80–93) years. Logistic EuroSCORE mean was 19.83% (3.48–83.94%), and trans-aortic mean gradient was 54.99 (19.0–149.0) mm Hg. At baseline, up to 24.50% of patients declared severe problems in performing usual activities. 13.60% felt extreme pain or discomfort; 9.80% were unable to wash and dress by themselves; 8.20% were extremely anxious or depressed; and 7.10% of the patients in the study were confined to bed. After 30 days the percentage of patients declaring severe problems in each dimension did not exceed 4.00%. The comparison between quality of life data at baseline and after one-month follow-up showed a significant improvement in each of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression ( $p < 0.001$ ). Patients' quality of life was increasing regardless of gender (female vs. male), the type of anaesthesia (general vs. local), and the type of procedure (TA vs. TF).

**Conclusions:** Short-term quality of life in the elderly subjects was significantly improved after one-month follow-up following TAVI.

**Key words:** aortic valve stenosis, elderly, transcatheter aortic valve implantation, quality of life

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## INTRODUCTION

Severe aortic stenosis is considered to be the most common valvular heart disease in the elderly and is associated with reduced quality of life (QoL) and increased mortality [1].

The definition of 'elderly population' in medical literature has changed from  $> 70$  years, through  $> 75$  years, to now  $> 80$  years of age. The life expectancy of the elderly is still expanding at the cost of larger number of patients

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requiring cardiovascular treatment. Elderly patients are usually the group of high-risk candidates for surgical aortic valve replacement (SAVR).

Until now, the SAVR procedure was the only effective therapeutic option for patients who suffered from symptomatic aortic stenosis. Unfortunately, on average one-third of patients were not eligible for this kind of treatment due to advanced age or co-morbidities [2].

Transcatheter aortic valve implantation (TAVI) is a modern, effective, and less invasive therapeutic method for high-risk patients. TAVI rapidly became an alternative to open heart surgery and now is the preferred therapy for inoperable patients. TAVI improves survival [3], with a lower mortality at one year [4], and is associated with both short- and long-term outcomes, including improved functional ability and general health-related quality of life (HRQoL) [5].

Elderly aortic stenosis sufferers present significant symptom burden, which includes exertional breathlessness, dizziness, chest pains, and syncope [6, 7]. According to the World Health Organisation definition of QoL, it is an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs, and their relationship to salient features of their environment [8]. Aortic stenosis symptoms may decrease physical, psychological, and social status [9], so QoL is an important parameter in the assessment of TAVI outcomes and should be a major expectation for the elderly patients undergoing this kind of treatment [10]. In previous studies, it has been shown that aortic stenosis has a significant impact on QoL status, which is greater than that associated with other long-term conditions, i.e. arthritis and lung diseases [11, 12]. Furthermore, in the case of the elderly population, and especially octogenarians and nonagenarians, the QoL status should be as important as the survival [13].

The aim of the study was to evaluate the short-term changes in QoL status in elderly patients undergoing TAVI procedure, which may be a predictor of patients' functioning in the future.

## METHODS

### *Study design*

The study was based on the multi-centre POL-TAVI database. POL-TAVI is the first Polish registry of patients with severe aortic stenosis, undergoing TAVI procedure.

Baseline data was collected during hospitalisation, and the 30-day follow-up interview was performed in an out-patient clinic setting. The data was subsequently entered into a dedicated electronic case report form.

For the needs of the study we singled out 184 samples of patients, above the age of 80 years, which underwent

the statistical analysis. The first step of data selection was to exclude from the whole registry (827 samples) all the patients below the age of 80 years, which gave us 468 samples, and the second step was to exclude patients who did not undergo the QoL interview after one month. Thus, we obtained 184 samples of patients.

### *Quality of life measurement*

The QoL status was assessed with a validated Polish version of the EQ-5D-3L descriptive system [14], a standardised measure of health status, developed by the EuroQol group [15]. The tool is commonly used as part of the follow-up interview for the purposes of the POL-TAVI registry. It contains the following five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels: no problems (level 1), some problems (level 2), and extreme problems (level 3).

The paper-and-pencil version of the EQ-5D-3L was used in the study and the patients had to fill the questionnaire out on their own or with the help of a family member or an interviewer (physician).

Health states were also converted into a single summary index by applying a formula that attaches values to each of the levels in each dimension. In the questionnaire there are 243 possible health states and each state is referred to in terms of a five-digit code. For example, state 11111 indicates no problems on any of the five dimensions, and the state 11233 indicates no problems with mobility and self-care, some problems with performing usual activities, extreme pain or discomfort, and anxiety or depression. In the study we used the value set available for the Polish population [16]. The Polish EQ-5D value set was obtained using a representative sample of the general population.

### *Statistical analysis*

Results were presented as percentages and frequencies (categorical variables) and means or medians where applicable (continuous variables). Continuous variables were assessed for normality using the Shapiro-Wilk test. Statistical significance was set at a p value of less than 0.05. The assessment of changes in categorical variables between baseline and follow-up data were performed using  $\chi^2$  test. Differences in continuous variables were analysed with the Wilcoxon signed-rank test. Statistical analysis was performed using STATISTICA 12.0 PL (StatSoft, Krakow, Poland).

## RESULTS

### *Characteristics of the study group*

Patients' characteristics and parameters at baseline are presented in Table 1. The variables are presented as frequencies (percentages) and means.

One hundred and sixty-eight patients underwent a procedure under general anaesthesia, and 16 patients under local

**Table 1.** Preoperative characteristics and parameters

| Variable                             | N = 184              |
|--------------------------------------|----------------------|
| Age [years]                          | 84 (80–93)           |
| Gender:                              |                      |
| Male                                 | 66 (35.9%)           |
| Female                               | 118 (64.1%)          |
| Body mass index [kg/m <sup>2</sup> ] | 27.27 (16.4–39.6)    |
| Logistic EUROscore [%]               | 19.83% (3.48–83.94%) |
| Hypertension                         | 152 (82.6%)          |
| Diabetes mellitus                    | 62 (33.7%)           |
| Chronic kidney disease               | 2 (1.1%)             |
| Previous MI                          | 50 (27.2%)           |
| Previous PCI                         | 52 (28.3%)           |
| Previous CABG                        | 19 (10.3%)           |
| NYHA:                                |                      |
| I                                    | 2 (1.1%)             |
| II                                   | 47 (25.5%)           |
| III                                  | 120 (65.2%)          |
| IV                                   | 15 (8.2%)            |
| LVEF [%]:                            |                      |
| < 30%                                | 4 (2.2%)             |
| 30–50%                               | 45 (24.5%)           |
| > 50%                                | 135 (73.4%)          |
| Transaortic peak gradient [mm Hg]    | 87.40 (35.0–171.0)   |
| Transaortic mean gradient [mm Hg]    | 54.99 (19.0–149.0)   |
| Aortic valve area [cm <sup>2</sup> ] | 0.64 (0.2–1.1)       |

CABG — coronary artery bypass grafting; LVEF — left ventricular ejection fraction; MI — myocardial infarction; NYHA — New York Heart Association; PCI — percutaneous coronary intervention

anaesthesia. A Medtronic CoreValve prosthesis was implanted in 95 patients, Edwards Sapien XT in 68 patients, Edwards Sapien in 10 patients, and the other type of prosthesis in 11 patients — 167 transfemoral (TF) and 17 transapical (TA). The mean hospital stay was nine days (Table 1).

### Quality of life

One hundred and eighty-four patients were included in the QoL study. At baseline, most patients with aortic stenosis presented a major impairment in HRQoL status and declared moderate or severe problems in each of the five dimensions. The comparison of frequency of problems for particular EQ-5D-3L dimensions between current study baseline results and Polish population norms [14] for the subpopulation of over 75-year-olds is shown in Table 2.

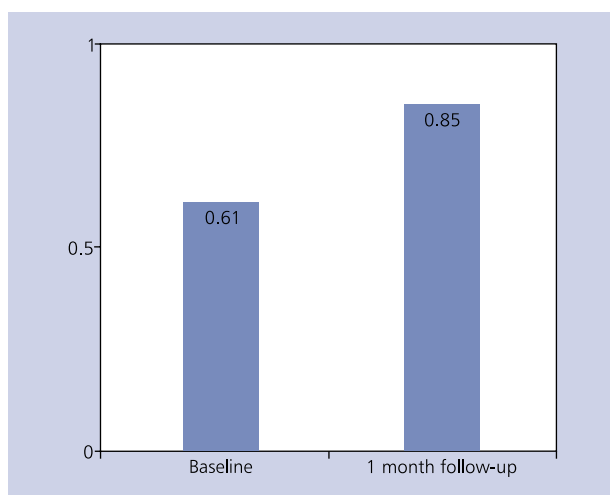
The analysis of baseline values compared to follow-up data at one month after TAVI, including EQ-5D-3L index value, showed a significant improvement of short-term QoL (Fig. 1–6;  $p < 0.001$ ).

EQ-5D-3L average index value at baseline was 0.61, and after 30 days it significantly increased to 0.85.

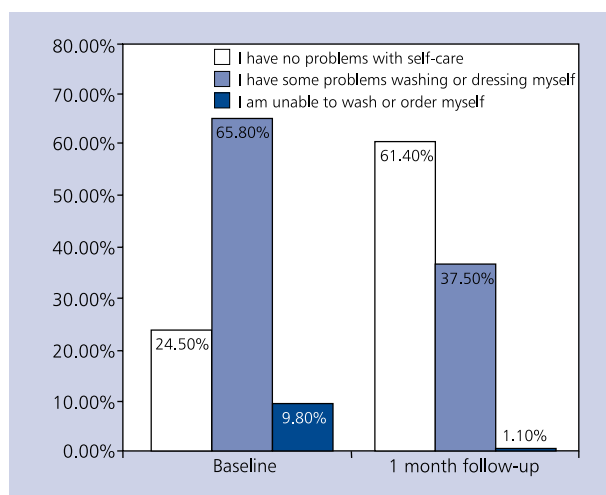
Before the TAVI procedure up to one fourth of patients declared severe problems in the EQ-5D questionnaire. Forty-five (24.50%) patients could not perform their usual daily activities; 25 (13.60%) patients felt extreme pain or discomfort; 18 (9.80%) patients were unable to wash and dress by themselves; 15 (8.20%) patients were extremely anxious or depressed; and 13 (7.10%) patients in the study were confined to bed. After one month the percentage of patients declaring severe problems oscillated from 0.50% (one patient) in pain or discomfort dimension to 3.30% (six patients) in the mobility and anxiety or depression dimensions.

**Table 2.** Comparison of frequency of problems for particular EQ-5D-3L dimensions between current study baseline results and Polish population norms for subpopulation over 75 years old

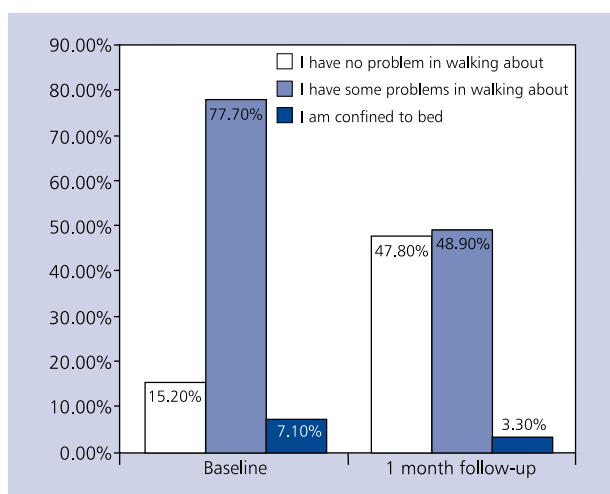
| EQ-5D-3L dimension | Level           | Polish population norms: | Current study baseline results: |
|--------------------|-----------------|--------------------------|---------------------------------|
|                    |                 | > 75 years old (n = 298) | > 80 years old (n = 184)        |
| Mobility           | No problems     | 29.2% (87)               | 15.2% (28)                      |
|                    | Some problems   | 68.8% (205)              | 77.7% (143)                     |
|                    | Confined to bed | 2.0% (6)                 | 7.1% (13)                       |
| Self-care          | No problems     | 59.4% (177)              | 24.5% (45)                      |
|                    | Some problems   | 36.6% (109)              | 65.8% (121)                     |
|                    | Unable to       | 4.0% (12)                | 9.8% (18)                       |
| Usual activities   | No problems     | 38.3% (114)              | 16.3% (30)                      |
|                    | Some problems   | 55.4% (165)              | 59.2% (109)                     |
|                    | Unable to       | 6.4% (19)                | 24.5% (45)                      |
| Pain/discomfort    | No              | 14.4% (43)               | 11.4% (21)                      |
|                    | Moderate        | 75.2% (224)              | 75.0% (138)                     |
|                    | Extreme         | 10.4% (31)               | 13.6% (25)                      |
| Anxiety/depression | No              | 39.6% (118)              | 33.2% (61)                      |
|                    | Moderate        | 57.4% (171)              | 58.7% (108)                     |
|                    | Extreme         | 3.0% (9)                 | 8.2% (15)                       |



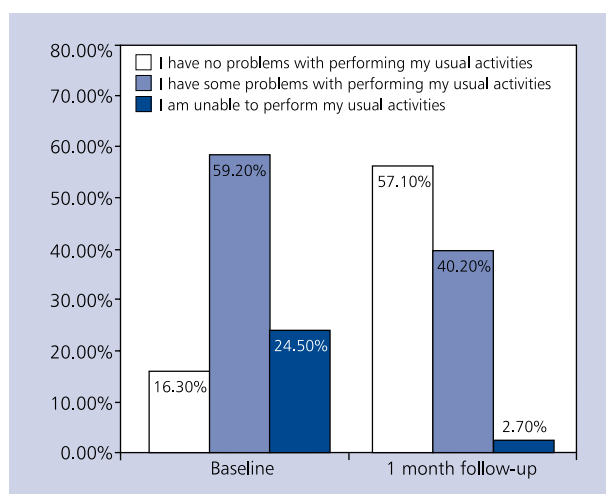
**Figure 1.** Results of the average EQ-5D-3L index value at baseline and one month after transcatheter aortic valve implantation



**Figure 3.** Results of the EQ-5D-3L questionnaire for self-care dimension at baseline and one month after transcatheter aortic valve implantation



**Figure 2.** Results of the EQ-5D-3L questionnaire for mobility dimension at baseline and one month after transcatheter aortic valve implantation



**Figure 4.** Results of the EQ-5D-3L questionnaire for usual activities dimension at baseline and one month after transcatheter aortic valve implantation

At baseline, 143 (77.70%) patients declared moderate problems in mobility; 138 (75.00%) in pain or discomfort; 121 (65.80%) in self-care; 109 (59.20%) in usual activities; and 108 (58.70%) in anxiety or depression. The percentage of patients declaring moderate problems in each of the five dimensions decreased after one-month follow-up. The frequencies oscillated from 90 (48.90%) patients still with moderate problems in mobility, 74 (40.20%) with problems performing daily activities, 69 (37.50%) of patients still had some problems in self-care, to 59 (32.10%) in pain or discomfort, and 44 (23.90%) in feeling anxious or depressed.

After one month the vast majority of patients claimed not to have any problems in EQ-5D dimensions. From 88 (47.80%) in mobility to 134 (72.80%) in anxiety and depression. Besides the ability to move and walk, in the four remaining dimensions the number of patients declaring no problems exceeded 50%.

We also compared baseline and one-month follow-up medians and average index values among males vs. females, patients under local vs. general anaesthesia, and TF vs. TA patients, but no significant differences between these groups were found.

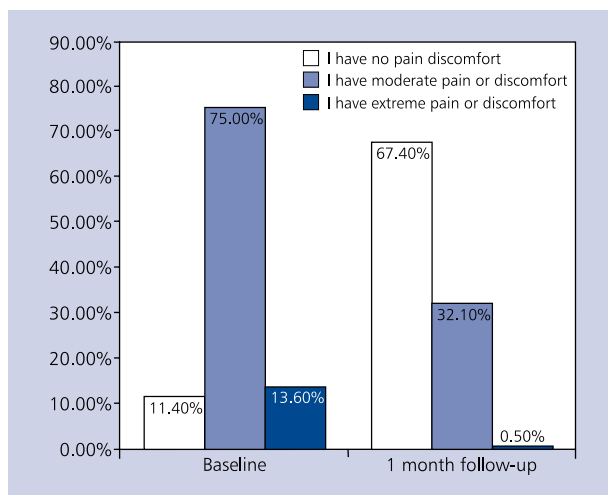


Figure 5. Results of the EQ-5D-3L questionnaire for pain or discomfort dimension at baseline and one month after transcatheter aortic valve implantation

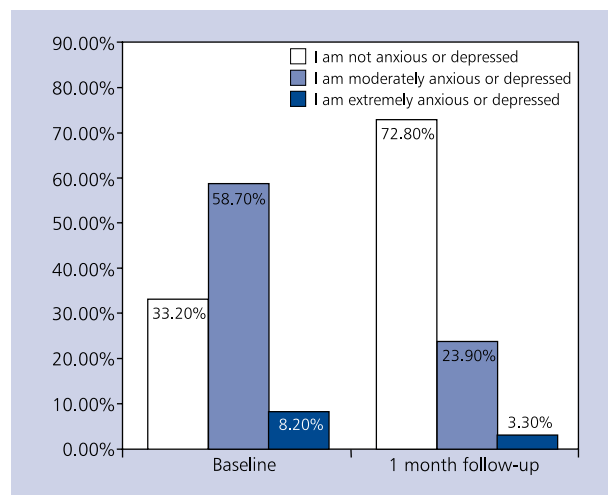


Figure 6. Results of the EQ-5D-3L questionnaire for anxiety or depression dimension at baseline and one month after transcatheter aortic valve implantation

Table 3. Baseline and one-month follow-up median and average EQ-5D-3L index values for all the patients in the study and among males vs. females, patients under local vs. general anaesthesia, and transfemoral vs. transapical patients

|                  | Gender    |      |           |      |          |      | Anaesthesia |      |           |      | Access    |      |          |      |
|------------------|-----------|------|-----------|------|----------|------|-------------|------|-----------|------|-----------|------|----------|------|
|                  | Total     |      | Female    |      | Male     |      | Local       |      | General   |      | TF        |      | TA       |      |
|                  | (n = 184) |      | (n = 118) |      | (n = 66) |      | (n = 16)    |      | (n = 168) |      | (n = 167) |      | (n = 17) |      |
|                  | B         | 30   | B         | 30   | B        | 30   | B           | 30   | B         | 30   | B         | 30   | B        | 30   |
| Mean             | 0.61      | 0.85 | 0.61      | 0.84 | 0.62     | 0.86 | 0.65        | 0.82 | 0.61      | 0.85 | 0.61      | 0.85 | 0.62     | 0.84 |
| SD               | 0.30      | 0.18 | 0.30      | 0.19 | 0.31     | 0.14 | 0.41        | 0.24 | 0.29      | 0.17 | 0.30      | 0.19 | 0.29     | 0.10 |
| Median           | 0.72      | 0.88 | 0.72      | 0.87 | 0.72     | 0.89 | 0.73        | 0.85 | 0.72      | 0.89 | 0.72      | 0.89 | 0.72     | 0.85 |
| 25 <sup>th</sup> | 0.55      | 0.79 | 0.55      | 0.77 | 0.55     | 0.79 | 0.72        | 0.72 | 0.55      | 0.79 | 0.55      | 0.79 | 0.66     | 0.74 |
| 75 <sup>th</sup> | 0.77      | 1.00 | 0.77      | 1.00 | 0.77     | 1.00 | 0.89        | 1.00 | 0.77      | 1.00 | 0.77      | 1.00 | 0.77     | 0.90 |

B — baseline; 30 — 30 days follow-up; SD — standard deviation; TA — transapical; TF — transfemoral

Medians and average EQ-5D index values in these groups are shown in Table 3.

### DISCUSSION

The present study shows that the HRQoL assessed with the EQ-5D-3L questionnaire, in Polish elderly patients who underwent TAVI procedure, was significantly improved in the short-term perspective. The analysis showed an improvement in both physical and mental health. After 30 days, patients reported increased mobility, self-care, and performance of usual activities and reduced pain, discomfort, anxiety, and depression. In spite of the satisfactory improvement in each dimension, the great increase occurred in pain/discomfort and anxiety/depression dimensions, in which lowest percentage of patients declared having extreme or moderate problems after the procedure. Nevertheless, one of the most important

results is a decreased percentage of patients declaring extreme problems in each dimension, and particularly in the usual activities dimension. In the majority of patients TAVI improved mental status and the ability to walk, take care of oneself, and perform daily activities, and reduced pain or discomfort to moderate or no problems.

The aim of this study was to emphasise the importance of TAVI short-term benefits. According to inoperable patients with a high risk of surgery, a rapid improvement of QoL is usually as important as the clinical outcomes and may predict further functioning. TAVI, as a less invasive and effective technique, primarily may shorten the period of recovery and quickly alleviate the symptoms of severe aortic stenosis.

Transcatheter aortic valve implantation outcomes, mainly physical functioning, including reduced pain and discomfort, which corresponds to mobility, self-care, and usual home

activities, in the short-term perspective is considered to be important, especially for the elderly group of patients. Increased mental health may be the result of the physical improvement, which is associated with independence, or equally may be the result of alleviated symptoms as well. However, a few studies showed less improvement of mental health. It may be speculated that it is difficult to affect mental status by a single TAVI intervention [17].

The results from the German TAVI registry [18] show a remarkable increase in QoL status of patients with severe symptomatic aortic stenosis who were treated with TAVI, measured with EQ-5D-3L. Interestingly, patients aged < 80 years had a lower QoL compared to those with age over 80 years before and after TAVI procedure. It confirms our findings that octogenarians and even nonagenarians are adequate candidates for TAVI procedure with a high probability of improving their QoL status.

A few studies, using EQ-5D-3L as an assessment method, also showed a significant improvement in QoL status after TAVI procedure. In the Bona et al. [19] study, after 30 days the TF-TAVI group reported fewer problems with usual activity and pain or discomfort, and higher EQ-5D index and Visual Analogue Scale (VAS) than the TA-TAVI group. The absolute improvements were larger in the TA-TAVI group. After one year there were no differences between groups in any EQ-5D domain. Elmalem et al. [20] observed that in high-risk group of patients with severe aortic stenosis, QoL and health status improved substantially at one month, and the improvement persisted six months after TAVI. Significant improvement occurred from baseline to one month of follow-up in the EQ-5D index value. After six-month follow-up three dimensions of the EQ-5D were significantly improved: usual activities, pain/discomfort and anxiety/depression which corresponds to our findings, where two of the listed dimensions presented the greatest improvement. Tokarek et al. [21] showed that TAVI improved QoL in peri-operative and 12 months of observation in comparison with mini-thoracotomy, mini-sternotomy, and SAVR patients.

The early QoL improvement was also shown in the study by Krane et al. [22]. Patients showed a major increase in physical components of QoL, although three months after TAVI the authors did not find any changes in mental status. Ussia et al. [23], as further evidence, showed a significant improvement in the physical and mental components of HRQoL as well, with a five-month follow-up, after TAVI procedure. Referring to the elderly, Bekeredjian et al. [24] observed a great improvement of general QoL status and physical functioning in octogenarians six months after TAVI.

Furthermore, several studies showed a significant improvement of QoL in intermediate and long-term perspective [17, 25–28]. Reynolds et al. [29] analysed 358 high-risk patients as a sub-study of the PARTNER trial. The authors showed

a remarkable improvement in HRQoL status after TAVI, compared to conservative treatment, at one-year follow-up.

In the present study, each of the five dimensions of the EQ-5D-3L questionnaire improved significantly in the short-term perspective, but despite the significant increase of seniors' QoL in the current study, there were still some patients who declared moderate or extreme problems in particular dimensions in 30 days of follow-up. In a comparison between Polish population norms for patients aged over 75 years [14] and the current study population at baseline, we observed that the percentage of patients with aortic stenosis declaring severe problems in each of EQ-5D dimensions was higher than in Polish population norms. The frequency of moderate problems was similar. QoL status in elderly patients is usually a result of cardiac and non-cardiac co-morbidities. The second may be the reason of only a partial improvement of QoL status in the elderly. TAVI reduces only certain symptoms, and some patients may require additional non-cardiac treatment in the future. Moreover, we can expect further improvement in a long-term follow-up. Because of their advanced age, some patients may need more time to notice the improvement.

Summarising, the TAVI procedure brings a lot of benefits to the elderly population, including octogenarians and nonagenarians, who need a rapid and effective intervention, with a shortened hospital stay. The TAVI procedure helps the elderly to improve their QoL in a short-term perspective, with a particular mention for physical status and general, usual functioning. It may also be a predictor of general QoL in the long-term perspective.

### *Limitations of the study*

The study is based on a multi-centre registry, and the number of patients included depends on the number of completed data and their quality. The VAS score could not be calculated because of the low number of data completed. An intermediate- and long-term assessment of QoL could also not be performed for the same reason. Another important limitation is the lack of a control group (i.e. SAVR patients) to compare with.

### **CONCLUSIONS**

In summary, short-term outcomes and a great improvement of QoL in the elderly Polish population with severe aortic stenosis was shown in the present study. The general QoL status and each of five dimensions of EQ-5D-3L increased significantly in one-month follow-up. The study shows that the TAVI procedure helps to improve QoL status and furthermore may be an adequate treatment method for both octogenarians and nonagenarians.

*Conflict of interest:* none declared

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# Poprawa jakości życia u pacjentów w wieku ponad 80 lat poddanych zabiegowi przezcewnikowej implantacji zastawki aortalnej: 30-dniowa obserwacja na podstawie danych z bazy POL-TAVI

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## Streszczenie

**Wstęp:** Przezcewnikowa implantacja zastawki aortalnej (TAVI) jest standardowym sposobem terapii stenozы aortalnej w populacji osób starszych, u pacjentów z grupy wysokiego ryzyka zdyskwalifikowanych z leczenia operacyjnego.

**Cel:** Celem badania była krótkoterminowa ocena jakości życia u pacjentów powyżej 80. rż., na podstawie wyników uzyskanych z wielośrodkowej bazy danych POL-TAVI.

**Metody:** Do analizy włączono dane obserwacyjne 184 pacjentów w wieku ponad 80 lat, pochodzące z bazy POL-TAVI, przebadanych za pomocą kwestionariusza EQ-5D-3L. Dane zebrano przed zabiegiem i podczas wizyty ambulatoryjnej 30 dni po zabiegu.

**Wyniki:** Średni wiek chorych wynosił 84 (80–93) lata. Przed zabiegiem średnia skali ryzyka Logistic EuroSCORE wyniosła 19,83% (3,48–83,94%), a średnia gradientu przez zastawkę — 54,99 (19,0–149,0) mm Hg. Przed implantacją 24,50% pacjentów zadeklarowało poważne problemy w wykonywaniu zwykłych, codziennych czynności; 13,60% towarzyszyło uczucie skrajnego bólu lub dyskomfortu; 9,80% nie było w stanie umyć się i ubrać samodzielnie; 8,20% odczuwało krańcowy niepokój i przygnębienie, a 7,10% badanych było zmuszonych do pozostawania na co dzień w łóżku. Po 30 dniach od zabiegu odsetek pacjentów deklarujących poważne problemy w każdym z wymiarów nie przekroczył 4,00%. Porównanie jakości życia chorych przed zabiegiem i podczas wizyty 30 dni po zabiegu wykazało istotną poprawę w zakresie zdolności do poruszania się, samoopieki, zwykłej działalności, odczuwanego bólu i niepokoju ( $p < 0,001$ ). Jakość życia pacjentów poprawiała się niezależnie od płci, rodzaju znieczulenia i rodzaju dostępu.

**Wnioski:** Stwierdzono, że wśród pacjentów powyżej 80. rż. poddanych zabiegowi TAVI znacząco poprawia się jakość życia w krótkoterminowej obserwacji.

**Słowa kluczowe:** jakość życia, stenoza aortalna, populacja osób starszych, przezcewnikowa implantacja zastawki aortalnej

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