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Health-related quality of life following transcatheter aortic valve implantation using transaortic, transfemoral approaches and surgical aortic valve replacement—a single-center study

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Abstract

Objective To evaluate short- and long-term changes in quality of life (QoL) in patients undergoing transcatheter aortic valve implantation (TAVI) and to assess differences in patient QoL when using the TAVI transaortic (TAVI TAo) approach compared with the transfemoral approach (TAVI TF) and surgical aortic valve replacement (SAVR). **Methods** Ninety-seven patients were assessed. Thirty-two patients underwent TAVI TAo, 31 underwent TAVI TF and 34 patients underwent SAVR. QoL was assessed using the EQ-5D-3L questionnaire at baseline, after one month and one year. **Results** Mean patient age was 80 years (range, 61–92 years) and the mean logistic EuroSCORE was 12.45% (range, 1.39%–78.98%). Declared health state at baseline was significantly lower in TAVI TF ($P < 0.001$) and after one month there were no differences between the three groups ($P = 0.99$). After one year, SAVR patient results of the EQ-5D-3L index value were lower in comparison to both TAVI patient groups ($P < 0.05$). The analysis also showed significant differences between the results of EQ-5D-3L index value over the one month and one year follow-up (TAVI TAo, $P < 0.001$; TAVI TF, $P < 0.05$; SAVR, $P < 0.05$). In all groups, the values significantly increased after one-month and one-year of follow-up in comparison to baseline value. Significant differences were also demonstrated between Visual Analogue Scale values (VAS). **Conclusions** A significant improvement in QoL was observed in all three patient groups. Regardless of the TAVI approach, EQ-5D-3L and VAS values were significantly increased after one-month and one-year follow up; the SAVR patients however, reported lower health status when compared to the TAVI patients.

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Keywords: Aortic valve stenosis; Aortic valve replacement; The elderly; Transcatheter aortic valve implantation; Quality of life

1 Introduction

With an aging population, the number of patients presenting with symptoms of aortic stenosis (AS) is increasing.[1–4] Since its introduction, transcatheter aortic valve implantation (TAVI) has become a well-established procedure for correcting severe symptomatic AS in elderly patients at high risk for surgery and it is now globally recognized as an effective alternative to open heart surgery.[5–7]

Over recent years, growing experience with TAVI has been accompanied by the development of several alternative vascular approaches.[6] Although the choice of approach depends mainly on the patient's clinical characteristics and the physician's preference, most centers today use the 'transfemoral first' (TAVI TF) approach as this is generally considered to be a less invasive method for high-risk patients[8–10] and approximately 70% of TAVI procedures are performed using this approach.[11] However, there are a number of contraindications for TAVI TF, including the presence of severe peripheral atherosclerosis and physiological abnormalities of the vasculature,[12,13] thus necessitating an alternative access route.

While the transapical (TA) TAVI approach is commonly used as a second-line option for patients who are ineligible for TAVI TF,[14] it also has limitations: it is not recommended for patients with multiple comorbidities (which include chronic lung disease and poor left ventricular function) and it may also be associated with an increased risk of

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bleeding complications.[15–18] Therefore, the transaortic approach (TAVI TAo) has been proposed as an alternative to both TAVI TF and TAVI TA.[19–21] TAVI TAo involves insertion of the catheter via an upper reversed L-ministernotomy—a safe and well-established procedure in classic cardiac surgery—followed by valve implantation through the ascending aorta.[12,21,22] Advantages of this procedure include greater visibility for the surgeon and allows a more rapid recovery time for most patients.[22]

Elderly patients with AS and a typical symptom burden that includes exertional dyspnea, dizziness and syncope represent the typical target population for TAVI.[23–25] These patients generally experience a reduction in physical, psychological and social functioning and wellbeing, leading to a reduction in quality of life (QoL).[26] Alongside clinical outcomes, QoL is a crucial factor for these patients, and improvement in QoL should be considered as if not more important than increased survival.[27] Despite the wealth of studies showing a rapid and significant improvement in QoL following TAVI,[28–31] there remains a lack of evidence on QoL outcomes following TAVI TAo. The aim of this study, therefore, was to compare short- and long-term changes in the QoL status of patients undergoing TAVI TAo, TAVI TF and surgical aortic valve replacement (SAVR).

2 Methods

2.1 Patients and study design

In this prospective, single-center study, conducted between 2014–2017 at the Medical University of Gdańsk in Poland, patients with severe symptomatic AS were assigned to TAVI TAo, TAVI TF or SAVR procedure by the local Heart Team, which included a cardiac surgeon, an interventional cardiologist and a cardiologist. All TAVI patients were ineligible for open heart surgery. SAVR patients were chosen randomly from among all patients over the age of 70 years, while patients with abnormalities of the vasculature were ineligible for TAVI TF and were therefore assigned to TAVI TAo. Patients who required an additional surgical procedure, such as coronary artery bypass or another valve replacement or repair, were excluded from the study. All the patients were able to and signed an informed consent form. The study design was approved by the Bioethics Committee of the Medical University of Gdańsk.

Baseline evaluation of all patients included physical examination, laboratory testing, and assessment of aortic annulus diameter, aortic topography, and ascending aorta morphology by computed tomography angiography. Health-related QoL was assessed at baseline, at one-month and one-year post-surgery using the EQ-5D-3L instrument. The one-month and one-year follow-up interviews were conducted over the telephone or in the outpatient clinic.

2.2 TAVI procedure

The local heart team in a hybrid operating room equipped with an accessible heart-lung machine performed all TAVI procedures.

Transaortic implantations were performed under general anesthesia. An upper L-ministernotomy down to the second or third intercostal space was performed. Implantation spot was secured with two purse string sutures. Pre-dilatation was mandatory in all cases. The position of the prosthesis was confirmed using a contrast medium. After implantation, a further bolus of contrast medium was given to assess the position of the valve and allow simultaneous estimation of paravalvular leak (PVL) and coronary status. The decision of whether to carry out post-dilatation was made after estimating the shape of the valve and after quantification of PVL. Procedure was completed after hemostasis and placement of a single chest tube. Sternum was closed by placement of 2 or 3 stainless steel wires. Patients were extubated 2–3 h after admission to intensive care unit.

Transfemoral implantations were done under local anesthesia without sedation. Vascular access was performed percutaneously and, in all cases, percutaneous vascular closure devices were used. Valve positioning and implantation control was similar to the transaortic access.

2.3 SAVR procedure

All procedures were performed under general anesthesia using a median sternotomy. Cardiopulmonary bypass was established with ascending aortic cannulation and right atrial venous cannulation, flow rate of 2.4–2.8 L/min per square meters and a perfusion pressure of 60–80 mmHg were used. Procedures were performed under mild hypothermia (30–32°C). Crystalline cardioplegia delivered direct ostial or retrograde provided myocardial protection. The left ventricle was vented via the right upper pulmonary vein. The native aortic valve was resected with removal of annular calcifications, in all cases, a biological prostheses was implanted. Procedure was completed after careful hemostasis and chest tubes were placed to control postoperative bleeding. Sternum was closed by standard stainless steel wires. Patients usually were extubated 6–8 h after admission to intensive care unit.

2.4 Health-related QoL

The EQ-5D is a standardized measure of health-related QoL.[32] It consists of five dimensions, namely mobility,

self-care, usual activities, pain/discomfort and anxiety/depression. Each of these dimensions has three levels (3L) indicating no problems (level 1), some problems (level 2) and extreme problems (level 3). In this study, health-related QoL was assessed using a validated Polish version of the EQ-5D-3L.[33] Patients were asked to complete the paper-and-pencil questionnaire either on their own or with the help of a family member or the interviewer, if needed. There are 243 possible health states in the EQ-5D-3L questionnaire and each of them is referred to by a five-digit code. For example, state 11111 indicates no problems in any of the five dimensions, while the state 12233 indicates no problems with mobility, some problems with self-care and usual activities, and extreme pain/discomfort and anxiety/depression. The health states were converted into a single summary index using a formula that attaches values to each level in each dimension. Health-related QoL was also assessed using the Visual Analogue Scale (VAS) of the EQ-5D-3L, in which a score of 100 indicates perfect health and 0 indicates the worst imaginable health.

2.5 Statistical analysis

Categorical data are presented as frequencies (percentages); continuous variables are presented as means or medians, as applicable, and were assessed for normality using the Shapiro–Wilk test. Changes in categorical variables between baseline and follow-up were assessed using the χ^2 test. $P < 0.05$ were considered significant. Differences in continuous variables were analyzed using the nonparametric Kruskal–Wallis ANOVA (independent variables) and Friedman's ANOVA (dependent variables). Multivariate post-hoc tests were also performed. Statistical analyses were performed using STATISTICA 12.0 PL (StatSoft, Krakow, Poland).

3 Results

3.1 Patients

A total of 97 patients were included in the study; 32 patients underwent TAVI TAo, 31 underwent TAVI TF and 34 received SAVR. All patients were included in the analysis. Patient demographics and characteristics at baseline are presented in Table 1.

3.2 Health-related QoL

The percentages (frequencies) of patients experiencing problems in EQ-5D-3L dimensions at baseline, one-month and one-year are shown in Table 2.

3.3 EQ-5D-3L

Table 3 shows EQ-5D-3L index values at baseline, one-month and one-year according to patient group (TAVI TAo, TAVI TF and SAVR). At baseline, the total population had a markedly depressed QoL, as demonstrated by a mean EQ-5D-3L index of 0.64 ± 0.33.

Table 1. Patient demographics and baseline characteristics.

Variable	TAVI TAo, *n* = 32	TAVI TF, *n* = 31	SAVR, *n* = 34	Total, *n* = 97
Age, mean (range)	81 (65–88)	81 (61–92)	77 (71–83)	80 (61–92)
Female	18 (56.3%)	20 (64.5%)	25 (73.5%)	63 (64.9%)
LVEF				
< 30%	1 (3.1%)	1 (3.2%)	-	2 (2.1%)
30%–50%	3 (9.4%)	14 (45.2%)	6 (17.6%)	23 (23.7%)
> 50%	28 (87.5%)	16 (51.6%)	28 (82.4%)	72 (74.2%)
EuroSCORE, mean (range)	15.1 (1.8–68.6)	14.2 (1.4–79.0)	8.4 (4.3–29.2)	12.5 (1.4–79.0)
Diabetes	7 (21.9%)	13 (49.9%)	7 (20.6%)	27 (27.8%)
Hypertension	27 (84.4%)	26 (83.9%)	23 (67.7%)	76 (78.4%)
Atrial fibrillation	4 (12.5%)	8 (25.1%)	4 (11.8%)	16 (16.5%)
Previous MI	3 (9.4%)	11 (35.5%)	5 (14.7%)	19 (19.6%)
Previous CABG	-	5 (16.1%)	-	5 (5.2%)
Previous PCI	4 (12.5%)	6 (19.4%)	3 (8.8%)	13 (13.4%)
NYHA				
II	8 (25%)	7 (22.6%)	12 (35.3%)	27 (27.8%)
III	21 (65.6%)	15 (48.4%)	22 (64.7%)	58 (59.8%)
IV	3 (9.4%)	9 (29%)	-	12 (12.4%)

Data are *n* (%) unless otherwise stated. CABG: coronary artery bypass graft; IQR: interquartile range; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association Functional Classification; PCI: percutaneous coronary intervention; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation with transaortic approach (TAVI TAo) or transfemoral approach (TAVI TF).

Table 2. Frequency of patients reporting problems in EQ-5D-3L dimensions at baseline, one month and one year (all patient groups).

Dimension	Level	Baseline	One month follow-up	One year follow-up
Mobility	No problems	12 (12.4%)	63 (64.9%)	65 (67.0%)
	Some problems	74 (76.3%)	32 (33.0%)	29 (29.9%)
	Confined to bed	11 (11.3%)	2 (2.1%)	3 (3.1%)
Self-care	No problems	69 (71.1%)	84 (86.6%)	89 (91.8%)
	Some problems	25 (25.8%)	12 (12.4%)	7 (7.2%)
	Unable to	3 (3.1%)	1 (1.0%)	1 (1.0%)
Usual activities	No problems	57 (58.8%)	75 (77.3%)	87 (89.7%)
	Some problems	36 (37.1%)	21 (21.7%)	9 (9.3%)
	Unable to	4 (4.1%)	1 (1.0%)	1 (1.0%)
Pain/discomfort	No	7 (7.2%)	57 (58.8%)	48 (49.5%)
	Moderate	67 (69.1%)	39 (40.2%)	48 (49.5%)
	Extreme	23 (23.7%)	1 (1%)	1 (1%)
Anxiety/depression	No	26 (26.8%)	74 (76.3%)	73 (75.3%)
	Moderate	62 (63.9%)	23 (23.7%)	22 (22.7%)
	Extreme	9 (9.3%)	-	2 (2%)

Data are presented as *n* (%) unless other indicated.

Table 3. EQ-5D-3L index values at baseline, one month and one year according to patient group.

		TAVI TAo *N* = 32	TAVI TF *N* = 31	SAVR *N* = 34	Total *N* = 97
Baseline	Mean ± SD	0.69 ± 0.29	0.45 ± 0.41	0.75 ± 0.19	0.64 ± 0.33
	Median [IQR]	0.78 [0.59–0.84]	0.72 [0.28–0.77]	0.82 [0.82–0.82]	0.80 [0.46–0.82]
One month	Mean ± SD	0.88 ± 0.17	0.88 ± 0.17	0.91 ± 0.08	0.89 ± 0.14
	Median [IQR]	0.93 [0.79–1.00]	0.91 [0.84–1.00]	0.89 [0.84–1.00]	0.90 [0.84–1.00]
One year	Mean ± SD	0.88 ± 0.27	0.92 ± 0.11	0.86 ± 0.11	0.89 ± 0.18
	Median [IQR]	0.93 [0.87–1.00]	1.00 [0.89–1.00]	0.84 [0.82–0.89]	0.89 [0.84–1.00]

IQR: interquartile range; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation with transaortic approach (TAVI TAo) or transfemoral approach (TAVI TF).

Kruskal–Wallis ANOVA confirmed significant differences between the three patient groups at baseline ($H_{(2,97)}$ = 17.76, P = 0.0001) and at one year ($H_{(2,97)}$ = 10.82, P = 0.0045). Multiple-comparison tests were used to confirm the differences. At baseline, EQ-5D-3L index values were significantly lower for patients in the TAVT TF group than for those in either the TAVI TAo group (P = 0.006) or the SAVR group (P < 0.001). Between-group differences were also found at one year, when index values for the SAVR were significantly lower than for the other two patient groups (P = 0.04 *vs*. TAVI TAo; P = 0.01 *vs*. TAVI TF) (Figure 1).

Further analysis focused on dependent samples. Friedman's ANOVA found significant differences between EQ-5D-3L index values at baseline and at one-month and one-year for all three procedures (TAVI TAo, $\chi^2_{(2, 32)}$ = 21.49, P < 0.001; TAVI TF, $\chi^2_{(2, 31)}$ = 44.12, P < 0.001; SAVR $\chi^2_{(2, 34)}$ = 40.51, P < 0.001). Multiple comparison tests were used to determine the differences between baseline and both follow-up time points (Figure 2).

3.4 Visual analogue scale

Similar analyses were performed for the EQ-5D-3L Visual Analogue Scale (Table 4). Analysis by Kruskal-Wallis ANOVA showed significant differences between the three groups at baseline ($H_{(2,97)}$ = 25.63, P < 0.001), after one-month ($H_{(2,97)}$ = 30.23, P < 0.001) and after one-year ($H_{(2,97)}$ = 39.53, P < 0.001). Multiple-comparison tests were performed to assess the differences between the groups.

At baseline, significant differences in VAS scores were found between the TAVI TAo and TAVI TF groups (P = 0.03) and between the TAVI TAo and SAVR groups (P < 0.001). At one-month and one-year, VAS scores were significantly lower in the SAVR group than in both the TAVI TAo and TAVI TF groups (P < 0.001 for all comparisons) (Figure 3).

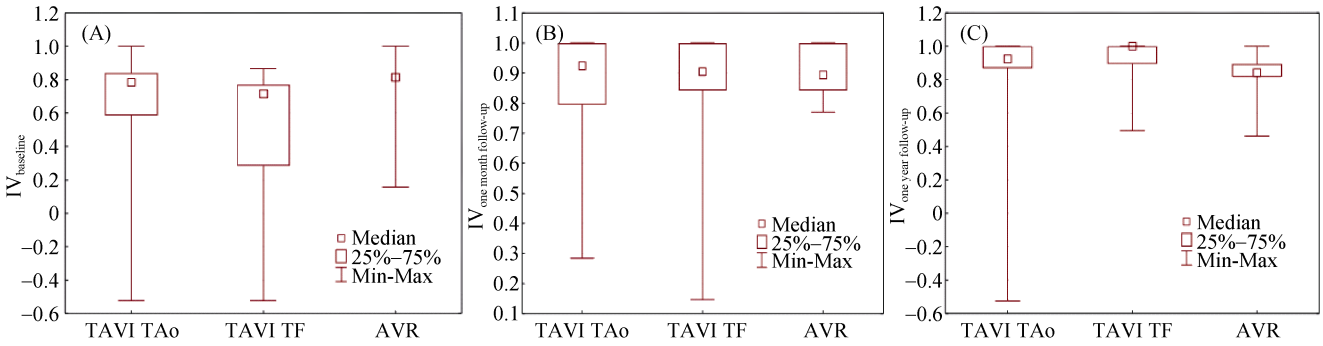

Figure 1. Comparison of EQ-5D-3L index values at baseline (A), one month (B) and one year (C) in TAVI-TAo, TAVI TF and AVR groups. AVR: aortic valve replacement; TAVI: transcatheter aortic valve implantation with transaortic approach (TAVI TAo) or transfemoral approach (TAVI TF).

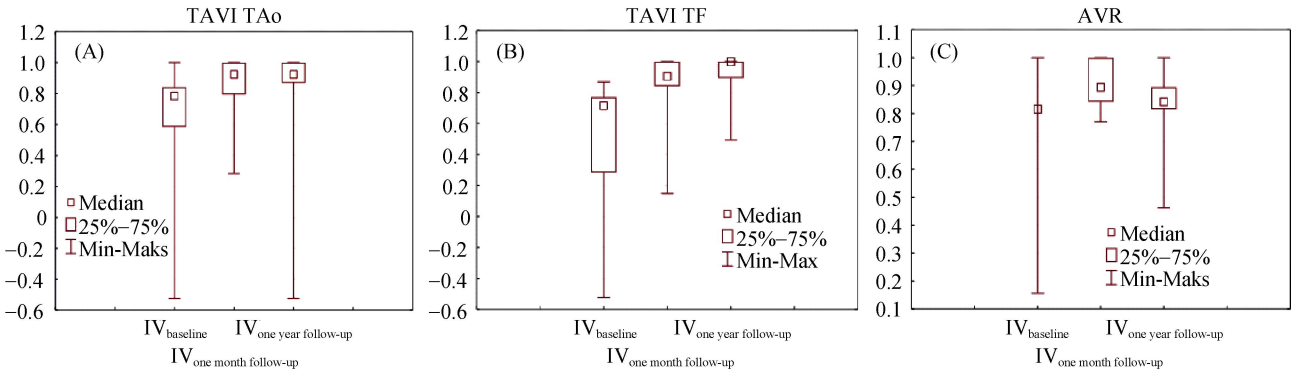

Figure 2. Comparison of EQ-5D-3L index values in TAVI-Tao (A), TAVI-TF (B) and AVR (C) groups at baseline, after 1-month and 1-year follow-up. AVR: aortic valve replacement; TAVI: transcatheter aortic valve implantation with transaortic approach (TAVI TAo) or transfemoral approach (TAVI TF).

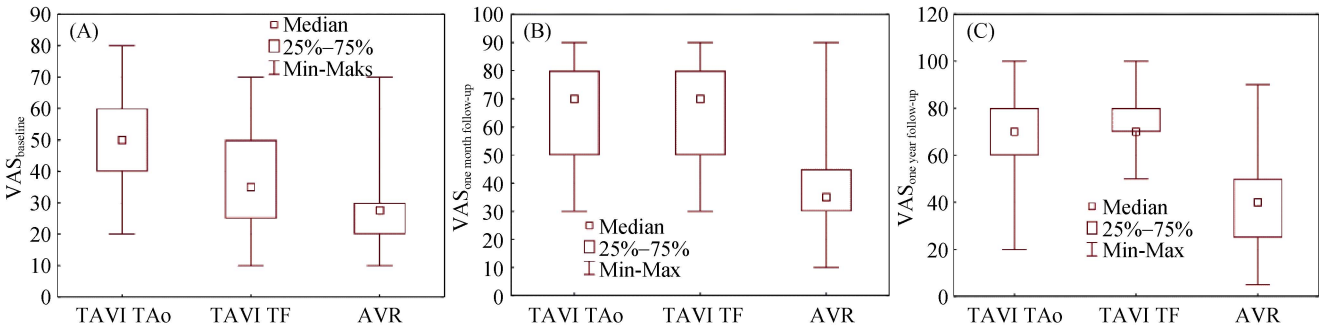

Figure 3. Comparison of EQ-5D-3L VAS results at baseline (A), one-month (B) and one year (C) in TAVI-TAo, TAVI TF and AVR groups. AVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation with transaortic approach (TAVI TAo) or transfemoral approach (TAVI TF).

Analysis of dependent samples showed significant differences in EQ-5D-3L VAS scores at one-month and one-year *vs*. baseline in all patient groups (TAVI-TAo, $\chi^2_{(2, 32)} = 31.45$, $P < 0.001$; TAVI-TF, $\chi^2_{(2, 31)} = 48.65$, $P < 0.001$; AVR $\chi^2_{(2, 34)} = 32.91$, $P < 0.001$). Again, multiple comparison tests were used to confirm these differences (Figure 4).

4 Discussion

Patients with severe AS commonly have symptoms of angina, syncope, dyspnea and/or heart failure and without rapid medical intervention they face a life expectancy of 2–3 years.[23–25] Interventions for AS, which are usually se-

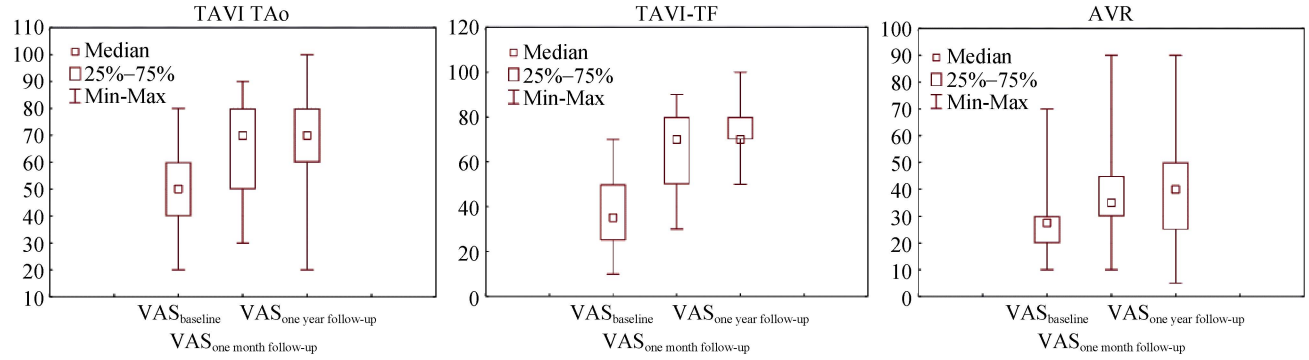

Figure 4. Comparison of EQ-5D-3L VAS results in TAVI-TAo, TAVI-TF and AVR groups at baseline, after 1-month and 1-year follow-up. AVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation with transaortic approach (TAVI TAo) or transfemoral approach (TAVI TF); VAS: Visual Analogue Scale values.

Table 4. EQ-5D-3L VAS scores at baseline, one month and one year according to patient group.

		TAVI TAo *N* = 32	TAVI TF *N* = 31	SAVR *N* = 34	Total *N* = 97
Baseline	Mean ± SD	49.1 ± 13.9	38.2 ± 15.8	29.4 ± 12.9	38.7 ± 16.3
	Median [IQR]	50.0 [40.0–60.0]	35.0 [25.0–50.0]	27.5 [20.0–30.0]	35.0 [25.0–50.0]
One month	Mean ± SD	65.9 ± 18.1	64.7 ± 17.8	41.8 ± 17.1	57.1 ± 20.8
	Median [IQR]	70.0 [50.0–80.0]	70.0 [50.0–80.0]	35.0 [30.0–45.0]	50.0 [40.0–80.0]
One year	Mean ± SD	70.6 ± 16.6	73.4 ± 11.2	40.3 ± 20.8	60.9 ± 22.6
	Median [IQR]	70.0 [60.0–80.0]	70.0 [70.0–80.0]	40.0 [25.0–50.0]	70.0 [45.0–80.0]

IQR: interquartile range; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation with transaortic approach (TAVI TAo) or transfemoral approach (TAVI TF).

lected as a result of the patient's clinical characteristics and the physician's expertise, include SAVR and TAVI, with different access routes for TAVI including TAVI TF, TAVI TA and, more recently, TAVI TAo.[10] There is substantial evidence in the literature of the feasibility, safety and mortality benefits of TAVI and the QoL associated with TAVI TA and TAVI TF,[5,28–31] but to the best of our knowledge there is little information about the QoL associated with the TAVI TAo approach.

This study showed that patients in the SAVR, TAVI TF and TAVI TAo treatment groups had significant improvements in QoL in all parameters assessed by the EQ-5D-3L questionnaire between baseline and one-month of follow-up and baseline and one-year of follow up. The biggest improvements were seen in the mobility, pain/discomfort and anxiety/depression dimensions. This data is in line with previous QoL studies showing that TAVI via different access routes was associated with an improvement in QoL.[28,34–36] Patients treated with SAVR, TAVI TF and TAVI TAo also had increased VAS values after one-month and one-year follow up. Compared with TAVI TF and TAVI TAo, patients in the SAVR group showed an improved in QoL but reported a lower overall health status.

In this study, intervention for AS resulted in a comparatively small increases in QoL for the self-care and usual activities dimensions. Patients with AS are typically elderly,[4] which mirrors the median age of patients across all groups in this study (80 years, range 61–92 years). In the general population, increased age and service use (including visits to healthcare practitioners) are significantly associated with transitions to sheltered accommodation.[37] It is realistic to consider that patients at the elderly age of the spectrum in this study likely have assistance for their care and have a reduced number of daily activities. Keeping this in mind, the impact of TAVI on these aspects of their lifestyles may be less apparent.

While all interventions were associated with an overall improvement in QoL, our study showed that TAVI TF and TAVI TAo provided more improvement in QoL compared with SAVR. The selection of patients for treatment with SAVR in this study was random. Interestingly, the baseline characteristics showed that patients in SAVR group were generally younger, with a lower EuroSCORE value and had a higher number of patients with NYHA class II and III (compared with the TAVI TF and TAVI TAo groups which had nine and three patients with NYHA class IV, respec-

tively). Although we have not reported data on the vascular characteristics of individual patients and how this may have influenced the choice of treatment intervention, the overall demographic data could suggest that patients in the SAVR group were medically fitter than those in the TAVI TF and TAVI TAo groups. With reference to this hypothesis, it may be possible that treatment with TAVI TF and TAVI TAo is medically more advantageous than SAVR as it is associated with a greater improvement in QoL in our specific patient population. The impact of TAVI on QoL is well documented,[38,39] and our findings that TAVI is associated with better patient outcomes in terms of QoL compared to SAVR is also supported by other studies.[5,40]

Some dimensions of the EQ-5D-3L questionnaire, including mobility (where patients reported being confined to bed), pain/discomfort (moderate) and anxiety/depression (either no anxiety/depression or extreme anxiety/depression) showed that QoL was better at one-month follow up compared to one-year follow up. A study by Hiltrop, *et al*.[41] reported similar findings—treatment with TAVI resulted in a significant improvement in QoL in the short-term, but as follow up time increases, the QoL data becomes similar to baseline values. Longer-term follow up in our study would determine whether the values in these QoL dimensions also become closer to baseline values or plateau at one-year.

4.1 Limitations of the study

The findings of our study are based on data from a single center and, although our population is currently one of the largest populations reporting on this issue, the patient size is still quite small. As a result, the data from this study should be interpreted with caution.

There is currently no aortic stenosis-specific questionnaire that exists to assess QoL. The EQ-5D questionnaire is a general questionnaire that assesses various aspects of the patient's life to put a numerical value on their quality of life and has been widely used in the cardiology field in patients with heart failure, those undergoing heart transplants and for patients in rehabilitation programs.[42–45] The EQ-5D model used in this study was the EQ-5D-3L version, which assesses mobility, self-care, usual activities, pain/discomfort and anxiety/depression, using the three levels (no problems, some problems and extreme problems), is currently one of the best available tools to measure QoL in these patients.

The TAVI procedure is associated with a relatively high (about 15%) one-year mortality[46] and, as a result, the proportion of patients with available data will diminish over time. As expected, the study shows that the TAVI TAo procedure improves QoL, but this data is based on the surviving (and potentially fitter) patients. The data, however, can be considered to be representative of the clinical picture in patients post the TAVI procedure.

4.2 Conclusions

Aortic stenosis is a debilitating condition that significantly impacts patient's quality of life. Intervention is provided to these patients with the aim of improving their health and wellbeing—both in terms of increasing their ability to perform day-to-day activities and increasing their life expectancy. Assessing the impact of different interventions on the patient's QoL will help clinicians to make informed decisions about the best possible treatment approaches for their patients.

Conflict of interest

The authors declare that they have no conflict of interest.

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