Original Article

Health-related quality of life after minimal-invasive treatment of aortic valve stenosis in the elderly

Terézia B. Andrási[1]^, Celine Schellenberg[1], Alina Vasiloi[1,2], Alannah C. Glück[1]

[1]Department of Cardiac and Cardiovascular Surgery, Philipps University of Marburg, Marburg, Germany; [2]Department of Geriatric Medicine, Bürgerspital Solothurn, Solothurn, Switzerland

Contributions: (I) Conception and design: TB Andrási, AC Glück; (II) Administrative support: A Vasiloi; (III) Provision of study materials or patients: AC Glück, C Schellenberg, A Vasiloi; (IV) Collection and assembly of data: AC Glück, C Schellenberg; (V) Data analysis and interpretation: AC Glück, TB Andrási; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Terézia B. Andrási, MD, PhD, MEBCTS. Department of Cardiac and Cardiovascular Surgery, Philipps University of Marburg, Baldingerstrasse 1, 35041 Marburg, Germany. Email: terezia.andrasi@med.uni-marburg.de.

Background: Although transfemoral transcatheter aortic valve implantation (TF-TAVI) offers superior early outcome over open surgical aortic valve replacement (SAVR) in the elderly, a comparison of TF-TAVI with surgery performed through partial upper mini sternotomy (PUMS) hasn't yet been validated. The aim of the present study is to evaluate the clinical outcome and quality of life of patients subjected to TF-TAVI and open surgical aortic valve replacement through partial upper mini sternotomy (PUMS-SAVR).

Methods: Baseline, procedural and post-treatment data of 197 consecutive patients: 137 TF-TAVI and 60 PUMS-SAVR treated at Philipps University of Marburg, were retrospectively collected. The propensity score method was used to create two groups in a 1:1 fashion. Questionnaire assessment (SF36_LQ) of quality of life of the matched patients was carried out at the ambulant routine control presentation. A competing risk regression model is used to evaluate the impact of the clinical outcome on health-related quality of life (HrQoL).

Results: After propensity matching, TF-TAVI remained associated with lower procedural time (136±50 *vs.* 298±36 min, P<0.01), intensive care unit stay (2.68±2.70 *vs.* 4.29±2.43 days, P<0.01), transfusion of packed red cell units (0.46±2.05 *vs.* 1.60±2.00 U, P=0.02) and higher heart block (42.86% *vs.* 0%, P<0.01) and permanent pacemaker implantation rates (14.29% *vs.* 0%, P=0.05) compared to PUMS-SAVR. TF-TAVI is associated with less complains, superior HrQoL (excellent 40% and very good 60% *vs.* very good 100% in PUMS). Partial sternotomy is the main predictor of the inferior HrQoL, with the regression coefficient of −1.11 (95% confidential interval, −1.503 to −0.726; R^2=0.324, P<0.0001). Transfusion (P=0.26), paravalvular leakage (0.618), pacemaker implantation (P=0.19) and delirium (P=0.92) did not influence HrQoL after the minimal-invasive treatment of aortic valve stenosis in elderly patients.

Conclusions: Although PUMS-SAVR offers better technical outcomes with less permanent pacemaker implantation and less paravalvular leakage than TF-TAVI, it is still associated with more need for transfusion, longer ventilation—and intensive care unit—times, and prolonged hospital stay. In the elderly, PUMS-SAVR achieves inferior quality of life compared to TF-TAVI. Partial sternotomy reveals as the strongest risk factor of perceived health-level post-treatment. It remains to be revealed whether fast-track open heart surgery that maintains a fully intact sternum and allows immediate postoperative extubation—as performed through video-assisted mini-thoracotomy or thoracoscopic robotic procedures with percutaneous cannulation - should be favored against PUMS-SAVR.

Keywords: Aortic; stenosis; mini-sternotomy; transcatheter valve implantation; quality of life; patient satisfaction

Submitted Sep 26, 2023. Accepted for publication Jan 26, 2024. Published online Apr 10, 2024.
doi: 10.21037/jtd-23-1509
View this article at: https://dx.doi.org/10.21037/jtd-23-1509

^ ORCID: 0000-0001-7808-9226.

Introduction

The progressing aging of the population results in an increased need for aortic valve procedures due to degenerative disease (1).

While mortality has decreased thanks to improvements in both surgical and catheter-based techniques (2), recent studies (3,4) endorse the measurement of health-related quality of life (HrQoL) as a component of patient evaluation to support indication for therapy, and shed decision-making and quality monitoring of the aortic valve treatment.

Various techniques of minimal-invasive surgical aortic valve replacement (SAVR) are applied at this time, with the partial upper mini-sternotomy (PUMS) extended in a J-shape or T-shape into one or both fourth intercostal spaces being used the most (5,6).

Given the fact that the impact of the operation on patient's life is not merely limited to these biological and clinical aspects, a more adequate assessment would include the areas of physical, psychological and social parameters.

Beyond mortality and morbidity, HrQoL assessment is of paramount importance not only to guide patient-centered clinical decision-making, but also to estimate the efficacy of the treatment modalities.

Both PARTNER trial compared (7) and the CoreValve Pivotal trial (8) compared transcatheter aortic valve implantation (TAVI) to full sternotomy and revealed significantly superior HrQoL with TAVI.

Although to date, clinical trials have been conducted to compare open surgical aortic valve replacement through partial upper mini sternotomy (PUMS-SAVR) to full sternotomy (9-12) and full sternotomy to transfemoral transcatheter aortic valve implantation (TF-TAVI) (6,7,13), there have been no studies selectively comparing clinical outcomes and HrQoL of PUMS-SAVR *vs.* TF-TAVI.

Beyond the clinical parameters, the domains quantified in the health status assessment include physical limitations, symptom frequency, subjective health level, and social limitation. Since HrQoL is a reliable instrument that has been validated in patients suffering from aortic valve stenosis (AVS), the SF36_LQ questionnaire is considered highly responsive to clinically meaningful changes (3,6,7,12) and thus, significant for our study.

The aim of the present study is to evaluate the clinical outcome and quality of life of elderly patients subjected to TF-TAVI and PUMS-SAVR by using propensity score matching. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1509/rc).

Highlight box

Key findings
- In the elderly, open surgical aortic valve replacement through partial upper mini sternotomy (PUMS-SAVR) is associated with inferior quality of life compared to transfemoral transcatheter aortic valve implantation (TF-TAVI).
- Partial sternotomy reveals as the strongest risk factor of perceived health-level post-treatment.

What is known and what is new?
- The superior early outcome of TF-TAVI over open surgical aortic valve replacement (SAVR) through full sternotomy has been demonstrated in the elderly.
- Although PUMS-SAVR offers better technical outcomes with less permanent pacemaker implantation and less paravalvular leakage than TF-TAVI, it is still associated with more need for transfusion, longer ventilation time, more delirium and prolonged hospital stay.

What is the implication, and what should change now?
- Favoring fast-track open heart surgery performed through video-assisted mini-thoracotomy or thoracoscopic robotic procedures with percutaneous cannulation, that maintains a fully intact sternum and allows immediate postoperative extubation is advisable in surgical patients, instead of PUMS-SAVR.

Methods

Study design

This is an independent (not industry-supported), single-blind, single-center observational study that compares two treatment groups: patients undergoing treatment of AVS by PUMS-SAVR or TF-TAVI. The exclusion criteria were prior stroke with persistent neurological impairment, dementia, motoric dysfunction of any cause, previous ascending aortic surgery and prior atrioventricular valve surgery.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This retrospective study was approved by the institutional review board at the Philipps University of Marburg (No. ek_mr_110221_Wensauer-2). The need for patient consent was waived off owing to the retrospective nature of the study.

Patients

From the 758 consecutive patients with severe aortic stenosis treated at Philipps University of Marburg between

Table 1 Preoperative data

Variables	Total cohort			Propensity matched		
	TF-TAVI (n=137)	PUMS-SAVR (n=60)	P	TF-TAVI (n=35)	PUMS-SAVR (n=35)	P
Age (years)	78.6±6.5	66.3±7.0	<0.01	73.9±5.2	70.1±4.6	<0.01
BMI (kg/m^2)	27.6±4.7	30.5±6.7	<0.01	29.2±4.9	29.3±4.1	0.91
Male	77 (56.2)	40 (66.7)	0.21	23 (65.7)	22 (62.9)	>0.99
Diabetes mellitus	45 (32.8)	14 (23.3)	0.24	13 (37.1)	12 (34.3)	>0.99
COPD	14 (10.2)	8 (13.3)	0.62	5 (14.3)	6 (17.1)	>0.99
Post-malignancy	37 (27.0)	9 (15.0)	0.07	7 (20.0)	6 (17.1)	>0.99
Atrial fibrillation	51 (37.2)	6 (10.0)	<0.01	6 (17.1)	5 (14.3)	>0.99
Myocardial infarction	12 (8.8)	1 (1.7)	0.11	3 (8.6)	1 (2.9)	0.61
AVA (cm^2)	0.8±0.3	0.8±0.3	0.84	0.9±0.3	0.8±0.2	0.12
Max PG (mmHg)	64.7±21.2	79.5±21.9	<0.01	65.3±25.0	75.7±20.3	0.10
Mean PG (mmHg)	37.3±12.8	46.7±156	<0.01	38.2±15.1	43.2±16.7	0.28
Bicuspid valve	1 (0.7)	19 (31.7)	<0.01	1 (2.9)	8 (22.9)	0.03
Aortic regurgitation I°	81 (59.1)	32 (53.3)	0.27	20 (57.1)	21 (60.0)	>0.99
LV-EF (%)	50.4±7.9	53.8±6.9	<0.01	52.1±5.1	55±7.3	0.06
Diastolic dysfunction	67 (48.9)	17 (28.3)	<0.01	13 (37.1)	11 (31.4)	0.80
Systolic PAP (mmHg)	38.8±14.9	38.0±13.6	0.88	35.6±10.5	36.4±6.7	0.88

Values represent mean ± standard error of mean for continuous variables and absolute numbers and percentages (in brackets) for categorical variables. TF-TAVI values are compared against corresponding PUMS-SAVR values. P value <0.05 of is considered statistically significant. TF-TAVI, transfemoral transcatheter aortic valve implantation valve implantation; PUMS-SAVR, open surgical aortic valve replacement over partial upper mini-sternotomy; BMI, body mass index; COPD, chronic obstructive pulmonary disease; AVA, aortic valve area; PG, pressure gradient; I°, slight; LV-EF, left ventricular ejection fraction; PAP, pulmonary artery pressure.

June 2019 and June 2022, 195 patients fulfilling the inclusion and exclusion criteria of our study underwent TF-TAVI using Edwards or Medtronic prosthesis.

To derive a surgical control group, we identified 60 patients treated with PUMS-SAVR aged 75 years or older, from the hospital records, out of the total of 337 aortic valve replacement procedures treated by PUMS-AVR for aortic stenosis during the same period.

To compare accurately TF-TAVI with PUMS-SAVR, a logistic regression model (propensity scoring) was used to generate two groups of each 35 patients, 1:1 matched based on the following variables: age, gender distribution, diabetes, arterial hypertension, kidney disease, chronic obstructive pulmonary disease, atrial fibrillation and prior coronary surgery. Patients with microbiologically ascertained valve endocarditis (6 cases) were excluded from the propensity matching.

Baseline data of the unmatched and matched groups are presented in *Table 1*. The outcome of heart surgery is evaluated by objective clinical and paraclinical parameters, including echocardiographic cardiac function parameters, morbidity and mortality.

The patient-perceived health status post-treatment was assessed at 6 months after treatment using the SF36_LQ questionnaire.

Outcome measures

The primary outcome measures are technical success and early revisions.

The secondary outcome measures are in-hospital atrioventricular block requiring pacemaker implantation and the mortality at 1-year follow-up.

The tertiary endpoint measure is to detect differences in HrQoL between PUMS-SAVR and TF-TAVI and to identify risk factors for lower perceived health level, as evaluated by the SF36_LQ questionnaire.

Statistical analysis

Data are presented in absolute numbers and percentages for categorical variables and mean values and standard deviations for continuous variables. Categorical variables were compared by means of chi-square test and Fischer's exact test. Continuous variables were compared by *t*-test. Statistical significance was 2-sided tested with an alpha level of 5%. Multiple linear regression models with stepwise variable selection was used to identify independent risk factors for the perceived health level, starting with all variables showing a P value <0.02 in previous univariate analyses.

All statistical analysis were performed using the SPSS statistical package (SPS Inc., Chicago, IL, USA), Version 11.0 for Windows.

Results

Baseline characteristics

The baseline characteristics and clinical data of the unmatched and of the propensity-matched groups are summarized in *Table 1*. The propensity matching and the results of the selection of the 70 matched patients are depicted in *Figure 1*.

Treatment and clinical outcome

The intraoperative and postoperative data are presented in *Table 2*. Operative times differed significantly between the two groups, remaining higher in the open surgical group also after propensity matching (136±50 *vs.* 298±56 min, P<0.01). In the TAVI group, procedural success was achieved in all patients, however, aortic dissection occurred in 5 of all 137 cases (3.65%), and 1 patient (2.86%) of the matched group. In the PUMPS-SAVR group, valve implantation was successful in all cases without complications and the need for conversion to full sternotomy. Surgical revision for bleeding was performed in 9.49% and 6.67% in the unmatched (P=0.59) and 2.86% and 8.57% in the matched (P=0.61) TF-TAVI and PUMS-SAVR groups, respectively. Thus, the postoperative complications did not differ significantly between TF-TAVI and PUMS-SAVR (*Table 2*). However, the surgically treated patients required more packed red blood cell (PRBC) and fresh frozen plasma (FFP) transfusion when compared to TF-TAVI in the propensity-matched cohort. Although the PUMS-SAVR patients also required longer ventilation time (P<0.01) and ICU stay (P=0.01) than TF-TAVI patients, the hospital stay was similar in the two groups.

Echocardiographic evaluation

Echocardiography at discharge revealed good hemodynamic function of the implanted valves in both groups. Transvalvular pressure gradients were slightly lower in TF-TAVI patients of the entire cohort (P<0.01), and became comparable to PUMS-SAVR in the propensity-matched subgroups (10.52±3.37 *vs.* 11.80±5.67 mmHg, P=0.31). In the entire TF-TAVI cohort, 51.67% of the unmatched patients and 40.00% of the matched patients had some degree of paravalvlar leakage, whereas in the PUMS-SAVR group no paravalvular leakage was observed, however transvalvular aortic regurgitation was present in 29.82% and 28.75% in the unmatched and matched groups, respectively.

The echocardiography also revealed that TF-TAVI patients suffered more from diastolic dysfunction, mitral and tricuspid valve regurgitation, as well as from high pulmonary pressures than the PUMS-SAVR patients (*Table 2*). After propensity matching, only tricuspid regurgitation (60% *vs.* 31.43%, P=0.03) and higher pulmonary pressure (42.56±14.90 *vs.* 31.21±7.88 mmHg, P=0.03) remained more pronounced in TF-TAVI compared to PUMS-SAVR, respectively.

New-onset of atrioventricular block was assessed in 40.88% of the TF-TAVI and 1.67% of the PUMS-SAVR unmatched patients (P<0.01) and 42.86% and 0% of the matched patients, respectively (P<0.01). Pacemaker implantation was required in 18.25% of the TF-TAVI and 1.67% of the PUMPS-SAVR patients (P<0.01).

Mortality rates did not differ between TF-TAVI (5.11%) and PUMS-SAVR (1.67%) at follow-up, respectively (P=0.44).

HrQoL after treatment

The SF36_LQ questionnaire assessed post-procedural satisfaction of patients undergoing treatment of the AVS. It analyzed 9 dimensions of satisfaction with the treatment: (I) perceived health level after treatment; (II) perceived health level compared to the pre-treatment level; (III) limitations in mobility; (IV) physical limitations in daily work and activity; (V) mental limitations in daily work and

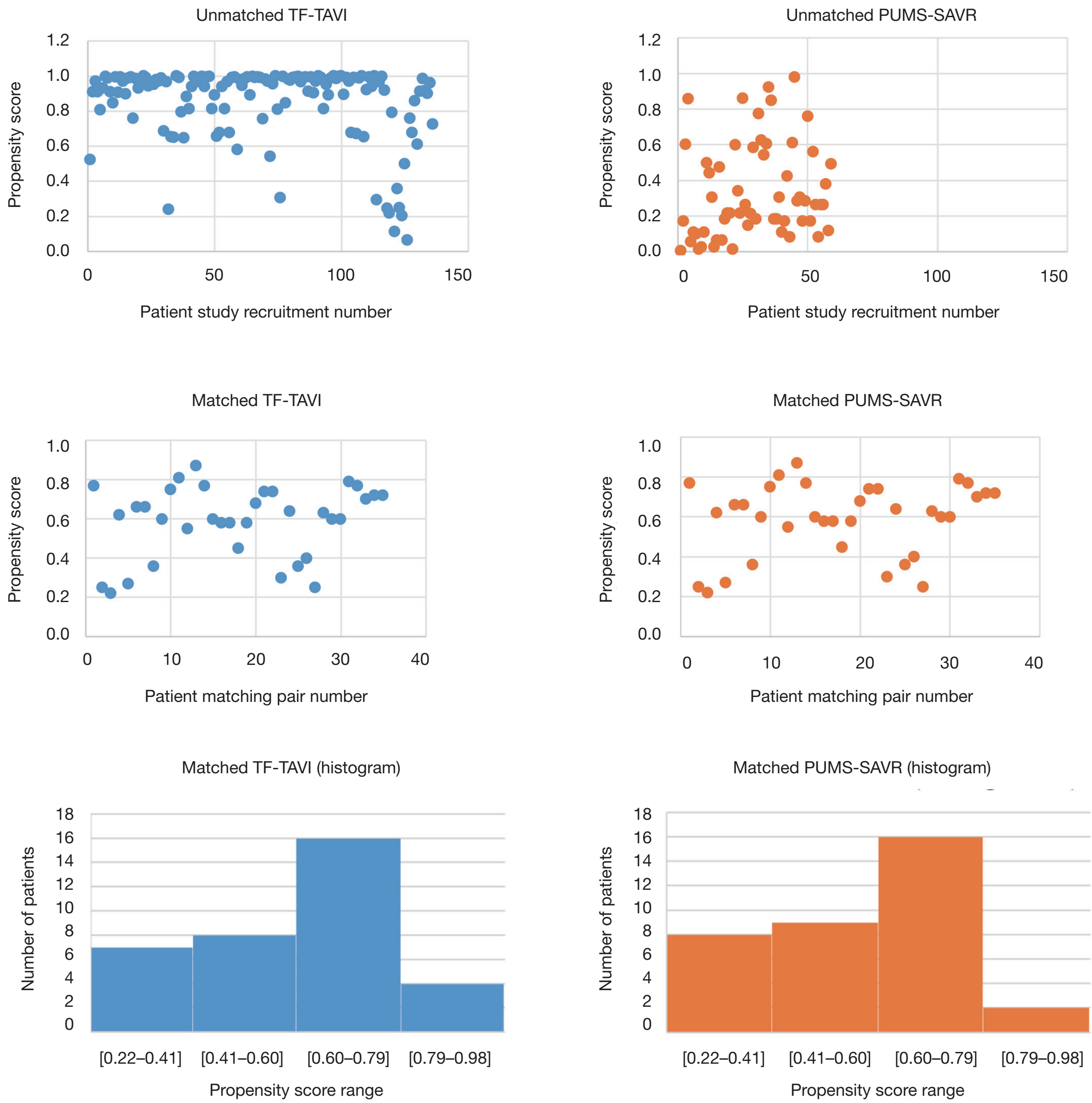

Figure 1 The propensity scores in the entire patient groups and in the matched subgroups are depicted. The histograms present the distribution of the propensity scores in the matched subgroups. TF-TAVI, transfemoral transcatheter aortic valve implantation; PUMS-SAVR, open surgical aortic valve replacement performed through partial upper mini sternotomy.

activity; (VI) limitations in social activity; (VII) pain; (VIII) limitations in daily activity due to pain, and (IX) emotional condition. The main findings are reproduced in *Figure 2*.

Whereas TF-TAVI patients described "excellent" outcomes in almost every dimension indicating great improvements in HrQoL, PUMS-SAVR patients expressed only a "very good" outcome in most of the cases.

Patients in the PUMS-SAVR also expressed more dissatisfaction related to emotional and physical complains after treatment in comparison to the TF-TAVI treatment group (*Figure 3*). On average, 25.46% (maximal value less than 50%) of the PUMS-SAVR patients and 14.75% (maximal value less than 30%) of the TF-TAVI patients reported complains after treatment. This difference was not

Table 2 Treatment and outcome

Variables	Total cohort			Propensity matched		
	TF-TAVI (n=137)	PUMS-SAVR (n=60)	P	TF-TAVI (n=35)	PUMS-SAVR (n=35)	P
Treatment time (min)	134±53	297±50	<0.01	136±50	298±56	<0.01
AVA (cm^2)	2.09±0.25	1.9±0.28	0.08	2.21±0.12	1.80±0.22	0.06
Max PG (mmHg)	18.66±8.34	22.79±9.33	<0.01	21.07±6.24	22.77±10.72	0.46
Mean PG (mmHg)	9.43±4.36	11.97±5.03	<0.01	10.52±3.37	11.80±5.67	0.31
V_{max} (m/s)	2.22±0.54	2.33±0.33	0.34	2.38±0.57	2.26±0.36	0.50
PVL (%)	62 (45.26)	17 (28.33)	<0.01	14 (40.00)	10 (28.57)	0.45
Heart block (%)	56 (40.88)	1 (1.67)	<0.01	15 (42.86)	0	<0.01
PPM (%)	25 (18.25)	1 (1.67)	<0.01	5 (14.29)	0	0.05
MVR (%)	86 (62.77)	26 (43.33)	<0.01	22 (62.86)	15 (42.86)	0.15
TVR (%)	72 (52.55)	25 (41.67)	0.09	21 (60.00)	11 (31.43)	0.03
LV-EF (%)	49.33±8.18	51.15±4.97	0.12	51.38±5.49	51.8±5.62	0.75
Diastolic dysfunction	54 (39.42)	10 (16.67)	<0.01	10 (28.57)	4 (11.43)	0.13
Systolic PAP (mmHg)	38.34±11.85	22.09±8.65	<0.01	42.56±14.90	31.21±7.88	0.03
Bleeding (%)	13 (9.49)	4 (6.67)	0.59	1 (2.86)	3 (8.57)	0.61
Aortic dissection (%)	5 (3.65)	0	0.19	1 (2.86)	0	0.99
AMI (%)	1 (0.73)	0	1	0	0	>0.99
TIA/stroke (%)	3 (2.19)	0	0.55	0	0	>0.99
Pneumonia (%)	15 (10.95)	1 (1.67)	0.04	1 (2.86)	1 (2.86)	>0.99
Delirium (%)	6 (4.38)	4 (6.67)	0.73	0	4 (11.42)	0.11
PRBC transfusion (U)	1.05±2.99	1.30±2.49	0.57	0.46±2.05	1.60±2.00	0.02
FFP transfusion (U)	0.49±2.37	4.53±4.41	<0.01	0.49±2.55	4.91±5.36	<0.01
Intubation (days)	0.83±3.06	1.52±1.03	0.10	0.20±0.65	1.59±0.84	<0.01
ICU stay (days)	3.45±4.85	3.97±2.00	0.43	2.68±2.70	4.29±2.43	0.01
Hospital stay (days)	11.81±6.24	13.42±4.26	0.07	11.51±5.75	13.66±3.56	0.06
FU-mortality (%)	7 (5.11)	1 (1.67)	0.44	0	0	>0.99

Data are presented as mean ± standard error of mean for continuous variables and number and percentage in brackets for categorical variables. P value <0.05 is statistically significant. TF-TAVI, transfemoral transcatheter aortic valve implantation valve implantation; PUMS-SAVR, open surgical aortic valve replacement over partial upper mini-sternotomy; AVA, aortic valve area; PG, pressure gradient; V_{max}, maximal velocity; PVL, paravalvular leakage; PPM, permanent pacemaker; MVR, mitral valve regurgitation; TVR, tricuspid valve regurgitation; LV-EF, left ventricular ejection fraction; PAP, pulmonary artery pressure; AMI, acute myocardial infarction; TIA, transient cerebral ischemic attack; PRBC, packed red blood cell; FFP, fresh frozen plasma; ICU, intensive care unit; FU, follow-up.

statistically significant (P=0.371). Similarly, perceived health level after treatment (*Figure 3*) was described as "excellent" in 11.4% *vs.* 8.5% (P=0.991) and as "very good" to "good" taken together, in 80% *vs.* 74.3% (P=0.77) of the TF-TAVI and PUMS-SAVR patients, respectively. However, in the independently stratified quantification as it is depicted in *Figure 3*, 34.29% of the TF-TAVI patients reported "very good" health level *vs.* 0% "very good" health level found in the PUMS-SAVR group (P<0.0001) and 42.85% of the TF-TAVI patients reported "good" health level *vs.* 77.14 %

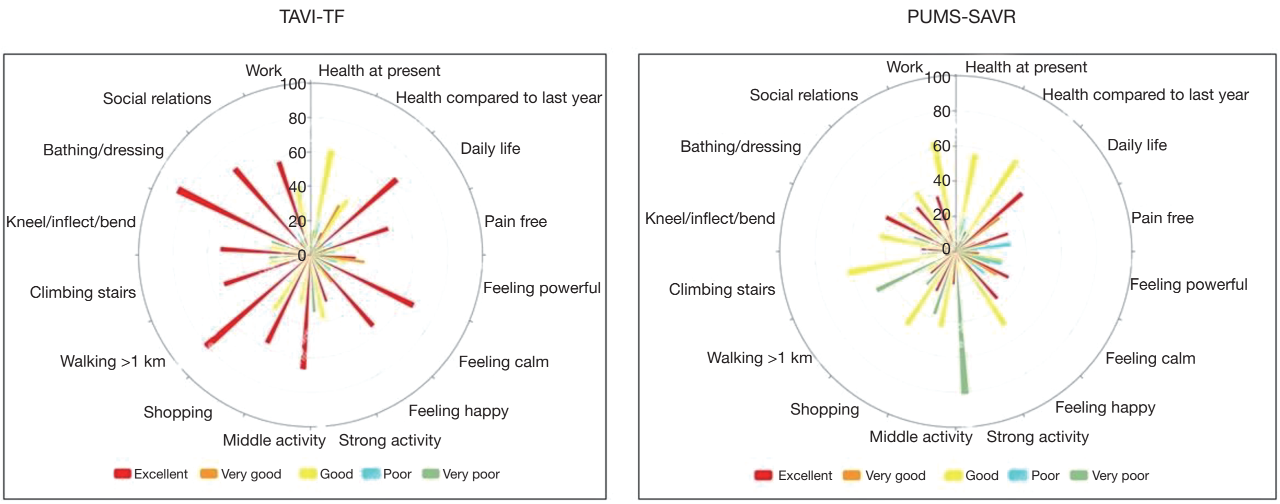

Figure 2 Health-related quality of life after TF-TAVI and PUMS-SAVR treatment. Sixteen health-related quality of life parameters are quantified based on a 5-grade scale from very poor to excellent and graphically depicted as percentages of the evaluated patient number. A scale of percentages from 0% to 100% is depicted on each artwork at 12 o'clock. TF-TAVI, transfemoral transcatheter aortic valve implantation; PUMS-SAVR, open surgical aortic valve replacement performed through partial upper mini sternotomy.

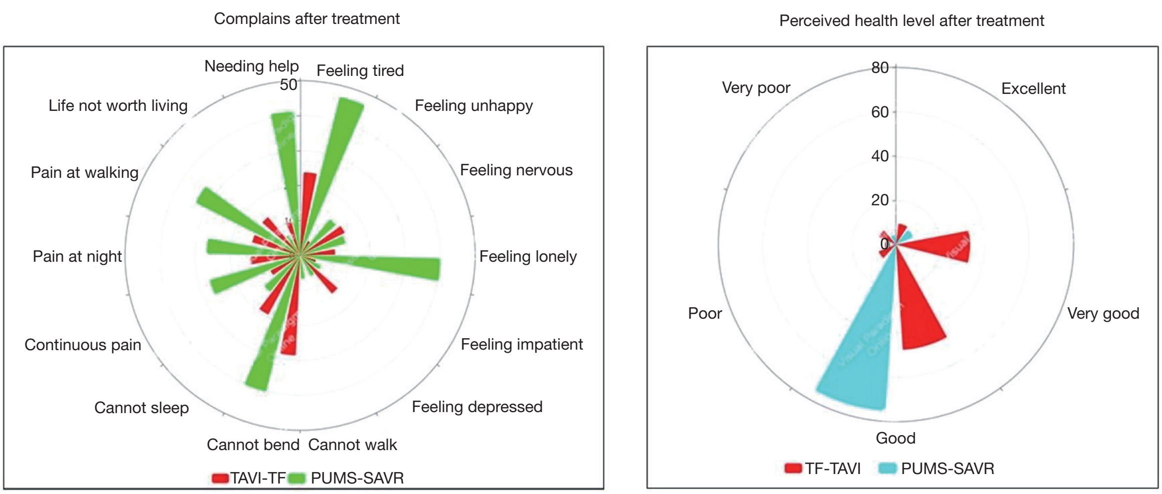

Figure 3 Comparison of patient satisfaction after TF-TAVI and PUMS-SAVR treatment. Post-treatment complains and the perceived health level are represented in percentages of the evaluated patient number. Scales of percentages from 0% to 50% and from 0% to 80% are depicted on the artworks at 12 o'clock. TF-TAVI, transfemoral transcatheter aortic valve implantation; PUMS-SAVR, open surgical aortic valve replacement performed through partial upper mini sternotomy.

"good" health level found in the PUMS-SAVR group (P<0.01). These findings reflect more satisfaction in the TF-TAVI group compared to PUMS-SAVR.

The univariate linear regression analysis of the data from the propensity-matched patient cohort revealed intervention time, HLM time, partial sternal incision (PUMS) and heart block as factors significantly influencing HrQoL after the treatment of the AVS (*Table 3*).

The multivariate linear regression analysis revealed partial sternal incision (PUMS) as the only detrimental factor (R^2=0.324, power 0.855, P<0.0001) influencing HrQoL after AVS treatment (*Table 3*).

Table 3 Factors influencing quality of life after AVS treatment in the propensity matched cohort

Perceived quality of life *vs.*	Univariate linear regression				Multivariate linear regression (R=0.57, R^2=0.324)			
	Slope	95% CI	R^2	P value	Slope ± SE	95% CI	VIF	P value
Sternal incision (PUMS)	−1.11	−1.503 to −0.726	0.325	<0.0001	−1.11±0.23	−1.566 to −0.659	1.28	<0.0001
PRBC transfusion	0.06	−0.049 to 0.176	0.018	0.26	0.011±0.05	−0.008 to 0.111	1.08	0.82
Paravalvular leakage	−0.13	−0.622 to 0.372	0.004	0.61	−0.025±0.22	−0.469 to 0.419	1.11	0.91
Heart block	−0.54	−1.066 to −0.016	0.058	0.04	0.006±0.28	−0.491 to 0.615	1.46	0.82
Permanent pacemaker	−0.16	−1.507 to 0.307	0.025	0.19	−0.029±0.45	−0.929 to 0.871	1.34	0.94
Delirium	−0.05	−1.064 to 0.973	0.0001	0.92				

P value <0.05 is statistically significant. AVS, aortic valve stenosis; R, coefficient of regression; R^2, coefficient of determination; CI, confidential interval; SE, standard error of regression slope; VIF, variance inflation factor; PUMS, partial upper mini-sternotomy; PRBC, packed red blood cell.

Discussion

To the best of our knowledge, this is the first study that compares clinical treatment and quality of life outcomes between TF-TAVI and PUMS-SAVR in a propensity-matched patient cohort suffering from AVS.

The analysis demonstrated that in the elderly, minimally invasive SAVR over partial upper mini-sternotomy is a safe and well-tolerated procedure associated with less heart block and better valve functional outcomes compared to TF-TAVI.

In our evaluation, early all-cause mortality did not differ between the groups, which is in agreement with previous findings (14-17). However, long-term mortality was not assessed in this study. In respect thereof, although 5-year mortality of TF-TAVI as demonstrated by the PARTNER-2 trial (15) is low, mortality is a consequence of structural valve degeneration and paravalvular leakage (7,15) in that study. Accordingly, we also found a higher incidence of PVL in the TF-TAVI group than in PUMS-SAVR, which is thought to be related to the removal of the native calcified valve and lower mechanical stress on the valve leaflets after surgical valve replacement (16,17). Transforming high-degree AVS into a low-degree aortic valve insufficiency by means of less-invasive TF-TAVI treatment seems to confer the patients a feeling of clinical health improvement, especially in the early post-treatment period, which explains the findings of the HrQoL questionnaire in our study. Although in our study a relatively high incidence of central valve regurgitation was documented in the PUMS-SAVR group, pulmonary pressure and tricuspid regurgitation were considerably lower after PUMS-SAVR than after TF-TAVI. Recently, Tokarek *et al.* (13) reported better LV-EF after TF-TAVI than after surgery. Otherwise, in our study, PUMS-SAVR retained a superior functional outcome, which persisted also after the propensity matching. Whereas the pulmonary pressure, the incidence of heart block and the amount of transfusion remained higher in the TF-TAVI group also after the propensity matching, the ventilation time and the ICU stay were higher in the PUMS-SAVR group. Owing to the small sample size produced by the matching process, the superior outcome of PUMS-SAVR versus TF-TAVI in terms of hemodynamic performance and pacemaker implantation was lost in the matched cohort. Since frailty is playing an increasing role in determining surgical risk in the aging population, we would not confer extraordinary importance on the age difference in the propensity-matched subgroups.

Nonetheless, patients value the importance of the outcome of certain events differently from clinicians and researchers (18,19) and patients-centered end-points truly reflect clinical relevance.

Thus, with accumulating evidence of feasibility and safety, as well as reduced rates for early mortality and postoperative morbidity of both TF-TAVI and PUMS-SAVR, additional outcome parameters, such as HrQoL, are of paramount importance in the evaluation of treatment efficacy.

To date, this is the first nonrandomized study to report on HrQoL outcomes in patients undergoing PUMS-SAVR compared to TF-TAVI in a propensity-matched elderly population.

The HrQoL of our patients, as determined using the SF36_LQ assessment tool, is significantly better after TF-TAVI compared to PUMS-SAVR (*Figure 2*).

When looking at the subdomains, patients receiving TF-TAVI described pain level, mobility capacity, psychologic condition, feelings and social interactions after treatment, as "excellent". In contrast, patients receiving PUMS-SAVR described the subdomains merely as "good", and as presented in *Figure 2*, "strong activity" was "very poor" in this surgical subgroup.

These findings slightly differ from the results revealed in other studies (17,18). One explanation is given by the different timing of the evaluations: whereas our evaluation is documenting findings at 6 months after treatment, other studies focused on the evaluation at 1 and 5 years after treatment (7,8,20-22). It is conceivable that in the long-term PUMS-SAVR may offer a superior quality of life, however in our cohort of elderly patients with shorter life expectancy, the evaluation at 6 months might be more relevant.

On average, 25.46% (maximal value less than 50%) of the PUMS-SAVR patients and 14.75% (maximal value less than 30%) of the TF-TAVI patients reported complains after treatment, and this difference was not statistically significant (P=0.371).

When comparing the level of the perceived quality of life, improvements were also less pronounced in the PUMS-SAVR than in TF-TAVI, with the TF-TAVI patients reporting mainly a "very good" and "good" outcome and most PUMS-SAVR patients reporting "good" outcome (*Figure 3*).

These findings are in agreement with the findings of the PARTNER trial (cohort A), showing that patients eligible for TF-TAVI demonstrated significant HrQoL benefit at 1 month when compared to conventional SAVR. In contrast, patients treated via the transapical approach demonstrated no benefits over conventional SAVR at any time point (6). Lange *et al.* (3) further explained that the reduced HrQoL benefits of transapical TAVI are caused by the greater repeat hospital admission. However, in our study no differences in hospital stay and early mortality were assessed between the interventional and surgical groups.

Although patient characteristics and procedural complications have been both described as influencing post-procedural recovery after AVS treatment, predictive factors for the HrQoL have been inconsistent.

Gonçalves *et al.* (20) and Fairbairn *et al.* (22) showed that female sex and the presence of peripheral vascular disease are independent predictors of lower HrQoL at 1 year. In contrast, procedure-related multiple small cerebral infarcts occurring in 77% of their patients were not associated with altered health status (22).

Krane *et al.* (23) found that female sex and a mitral valve regurgitation degree greater than mild were predictive of lower HrQoL improvements after TF-TAVI.

Apart from these findings, Taramasso *et al.* (21) observed no association between either patient demographics or baseline comorbidities and the degree of functional improvement after treatment, and revealed instead that residual moderate to severe PVL, and periprocedural stroke were being each associated with less HrQoL improvements after TF-TAVI.

The analysis of our propensity-matched data shows a lower impact of baseline comorbidities on HrQoL and strengthens the evidence that periprocedural characteristics are powerful predictors of patient satisfaction (*Table 3*).

By applying this model, the linear regression analysis revealed four predictors of HrQoL after AVS treatment, from which three: sternal incision, intervention-time and HLM-time are related to PUMS-SAVR, whereas only one, the heart block occurs more often in association with TF-TAVI.

The predominant impact of surgery on HrQoL early after treatment is further confirmed by the multivariate regression analysis, revealing PUMS as the only significant predictor for lower patient satisfaction in our study (*Table 3*).

Although PUMS-SAVR offers better technical outcome with less pacemaker implantation rate and less PVL than TF-TAVI, it is still associated with more need for transfusion, longer ventilation and ICU times, and prolonged hospital stay (*Table 2*). These factors seem to sum up and strengthen the impact of surgery on the post-treatment HrQoL after PUMS-SAVR.

Limitations

Our study certainly has its limitations, the most evident of which is represented by the small number of the patients selected in the propensity-matched group. Furthermore, the two treatment groups remained different in age also after the propensity matching.

Second, this is a retrospective study investigating the HrQoL evaluation performed at 6 months after treatment. HrQoL evaluations at baseline and at a later post-treatment time point were not available. Third, there were some variations in the time-period from treatment to the post-treatment echocardiographic evaluation as well as to the time-point of the HrQoL evaluation. Fourth, we performed multivariate analysis and matched cohort analysis, but the retrospective study design could have selection bias and residual cofounding. Fifth, we had no data on prescriptions after discharge; therefore, we could not exclude the possibility of changes in analgesics and heart insufficiency medication at the time of the HrQoL evaluation.

Conclusions

Although PUMS-SAVR offers better technical outcome with less PPM and less PVL than TF-TAVI, it is still associated with more need for transfusion, longer ventilation- and ICU times, and prolonged hospital stay.

In the elderly, PUMS-SAVR achieves the inferior quality of life compared to TF-TAVI, and partial sternotomy reveals as the strongest risk factor of less-satisfactory health level after PUMS-SAVR compared to TF-TAVI.

Future studies are necessary to reveal whether fast-track open-heart surgery that maintains the sternum intact and allows immediate postoperative extubation—as performed through video-assisted mini-thoracotomy or thoracoscopic robotic procedures with percutaneous cannulation—should be favored against PUMS-SAVR.

Acknowledgments

Funding: None.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1509/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1509/dss

Peer Review File: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1509/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1509/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This retrospective study was approved by the institutional review board at the Philipps University of Marburg (No. ek_mr_110221_Wensauer-2). The need for patient consent was waived off owing to the retrospective nature of the study.

References

1. Carabello BA, Paulus WJ. Aortic stenosis. Lancet 2009;373:956-66.
2. Brown JM, O'Brien SM, Wu C, et al. Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database. J Thorac Cardiovasc Surg 2009;137:82-90.
3. Lange R, Beckmann A, Neumann T, et al. Quality of Life After Transcatheter Aortic Valve Replacement: Prospective Data From GARY (German Aortic Valve Registry). JACC Cardiovasc Interv 2016;9:2541-54.
4. Lauck SB, Yu M, Ding L, et al. Quality-of-Life Outcomes After Transcatheter Aortic Valve Implantation in a "Real World" Population: Insights From a Prospective Canadian Database. CJC Open 2021;3:1033-42.
5. Svensson LG. Minimally invasive surgery with a partial sternotomy "J" approach. Semin Thorac Cardiovasc Surg 2007;19:299-303.
6. Moustafa MA, Abdelsamad AA, Zakaria G, et al. Minimal vs median sternotomy for aortic valve replacement. Asian Cardiovasc Thorac Ann 2007;15:472-5.
7. Reynolds MR, Magnuson EA, Wang K, et al. Health-related quality of life after transcatheter or surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results from the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial (Cohort A). J Am Coll Cardiol 2012;60:548-58.
8. Arnold SV, Reynolds MR, Wang K, et al. Health Status After Transcatheter or Surgical Aortic Valve Replacement

in Patients With Severe Aortic Stenosis at Increased Surgical Risk: Results From the CoreValve US Pivotal Trial. JACC Cardiovasc Interv 2015;8:1207-17.
9. Dogan S, Dzemali O, Wimmer-Greinecker G, et al. Minimally invasive versus conventional aortic valve replacement: a prospective randomized trial. J Heart Valve Dis 2003;12:76-80.
10. Aris A, Cámara ML, Montiel J, et al. Ministernotomy versus median sternotomy for aortic valve replacement: a prospective, randomized study. Ann Thorac Surg 1999;67:1583-7; discussion 1587-8.
11. Mächler HE, Bergmann P, Anelli-Monti M, et al. Minimally invasive versus conventional aortic valve operations: a prospective study in 120 patients. Ann Thorac Surg 1999;67:1001-5.
12. Bonacchi M, Prifti E, Giunti G, et al. Does ministernotomy improve postoperative outcome in aortic valve operation? A prospective randomized study. Ann Thorac Surg 2002;73:460-5; discussion 465-6.
13. Tokarek T, Sobczyński R, Dziewierz A, et al. Clinical outcomes in patients after surgical and transcatheter aortic valve replacement. Pol Arch Med Wewn 2015;125:755-64.
14. Sayed A, Almotawally S, Wilson K, et al. Minimally invasive surgery versus transcatheter aortic valve replacement: a systematic review and meta-analysis. Open Heart 2021;8:e001535.
15. Makkar RR, Thourani VH, Mack MJ, et al. Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement. N Engl J Med 2020;382:799-809.
16. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med 2019;380:1695-705.
17. Conradi L, Seiffert M, Treede H, et al. Transcatheter aortic valve implantation versus surgical aortic valve replacement: a propensity score analysis in patients at high surgical risk. J Thorac Cardiovasc Surg 2012;143:64-71.
18. Stolker JM, Spertus JA, Cohen DJ, et al. Rethinking composite end points in clinical trials: insights from patients and trialists. Circulation 2014;130:1254-61.
19. Ahmad Y, Nijjer S, Cook CM, et al. A new method of applying randomised control study data to the individual patient: A novel quantitative patient-centred approach to interpreting composite end points. Int J Cardiol 2015;195:216-24.
20. Gonçalves A, Marcos-Alberca P, Almeria C, et al. Quality of life improvement at midterm follow-up after transcatheter aortic valve implantation. Int J Cardiol 2013;162:117-22.
21. Taramasso M, Latib A, Cioni M, et al. Quality of life improvement is maintained up to two years after transcatheter aortic valve implantation in high-risk surgical candidates. EuroIntervention 2012;8:429-36.
22. Fairbairn TA, Mather AN, Bijsterveld P, et al. Diffusion-weighted MRI determined cerebral embolic infarction following transcatheter aortic valve implantation: assessment of predictive risk factors and the relationship to subsequent health status. Heart 2012;98:18-23.
23. Krane M, Deutsch MA, Piazza N, et al. One-year results of health-related quality of life among patients undergoing transcatheter aortic valve implantation. Am J Cardiol 2012;109:1774-81.

Cite this article as: Andrási TB, Schellenberg C, Vasiloi A, Glück AC. Health-related quality of life after minimal-invasive treatment of aortic valve stenosis in the elderly. J Thorac Dis 2024;16(4):2274-2284. doi: 10.21037/jtd-23-1509

