Clinical Research in Cardiology
https://doi.org/10.1007/s00392-025-02744-y

ORIGINAL PAPER

Safety and effectiveness of oscillatory whole-body vibration training on exercise capacity and physical performance in aortic valve stenosis patients prior to transcatheter aortic valve implantation: a randomized clinical trial

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Received: 3 June 2025 / Accepted: 11 August 2025

Abstract

Background Exercise training is generally discouraged in patients with severe symptomatic aortic stenosis (AS) undergoing transcatheter aortic valve implantation (TAVI) due to safety concerns. However, whole-body vibration (WBV) exercise could offer a novel approach to improve exercise capacity and quality of life, though its effects remain unclear in this population.

Methods Thirty patients with AS scheduled for TAVI were prospectively and randomly assigned to either the WBV group (12 sessions, 30 min each over 4 weeks) or a control group. Assessments of cardiopulmonary exercise testing (CPET), 6-min walking distance (6MWD) and health-related quality of life (HRQoL) questionnaires were conducted at baseline (V1), one day before TAVI (V2) and at short-term follow-up (V3). WBV was conducted between V1 and V2.

Results For the analysis at V1 and V2 16 patients in the WBV group and 14 in the control group were included. Mean age was 79.7 ± 5.22 years, with a mean aortic valve area of 0.75 ± 0.21 cm^2. Peak V'O_2 increased by 0.3 mL*min^{-1}*kg^{-1} in the WBV group versus a decrease of − 1.4 mL*min^{-1}*kg^{-1} in the control group (difference, 1.7 mL*min^{-1}*kg^{-1}; 95% CI, [0.2 to 3.2], $p = 0.03$). Peak power improved by 5.1 W in the WBV group compared to a decline of − 4.5 W in the control group (difference, 9.6 W; 95% CI, [2.1 to 17.1], $p = 0.01$). The WBV group also showed a non-significant improvement in 6MWD (34 m vs. − 8 m in the control group; difference, 42 m; 95% CI, [-10 to 93], $p = 0.11$). No serious adverse events occurred in the WBV group

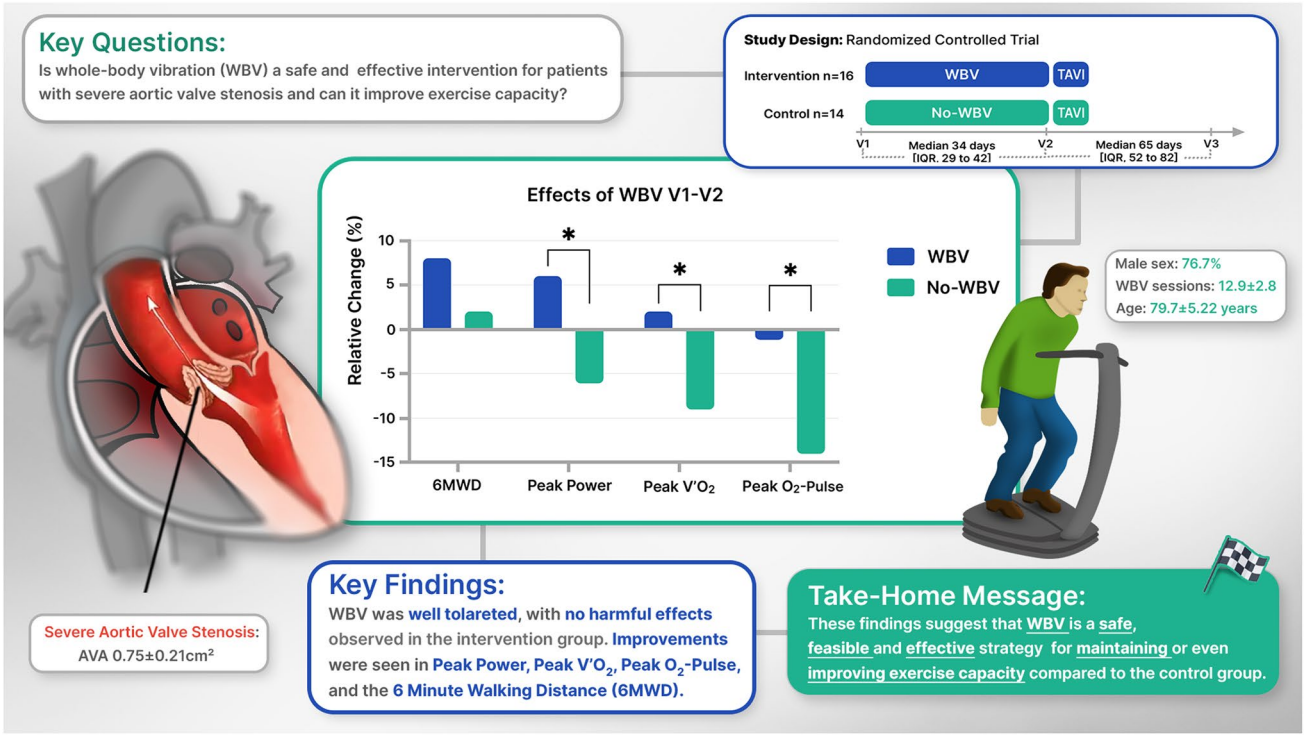
Conclusion This pilot study demonstrated that a WBV exercise program is feasible, safe, and showed potential to preserve exercise capacity as well as physical performance in AS patients scheduled for TAVI.

Johannes Klaus and Felix Gerhardt share the first authorship of this work.

Extended author information available on the last page of the article

Published online: 22 September 2025

Graphical Abstract



Keywords Transcatheter aortic valve implantation · Aortic valve stenosis · Peak V'O_2 · Endurance capacity · Oscillatory whole-body vibration

Abbreviations

6MWD	6-minute walking distance
AS	Aortic valve stenosis
CFS	Clinical Frailty Scale
CI	Confidence interval
CPET	Cardiopulmonary exercise testing
CRT	Chair rising test
ESC	European Society of Cardiology
HRQoL	Health related quality of life
IQR	Interquartile range
RER	Respiratory exchange ratio
SD	Standard deviation
SF-36	36-Item Short Form Health Survey
TAVI	Transcatheter aortic valve implantation
V'O_2	Oxygen uptake
WBV	Whole-body vibration

Introduction

Severe symptomatic aortic valve stenosis (AS) is a prevalent heart disease in the elderly, often associated with substantial morbidity and mortality [1, 2]. A lower fitness level, as indicated by a reduced peak oxygen uptake (peak V'O_2), is a strong predictor of mortality in this cohort [3]. Transcatheter aortic valve implantation (TAVI) is the preferred treatment for symptomatic AS in patients over 75 years [4]. Despite optimal postprocedural hemodynamic results, many TAVI patients experience limited improvements in functional capacity, with the lack of physical performance improvement emerging as an independent predictor of mortality at follow-up [5].

Supervised exercise training is effective in improving exercise capacity, clinical status, and health-related quality of life (HRQoL) and has been shown to improve outcomes in various cardiac conditions [6]. Pressler et al. demonstrated in a randomized study that eight weeks of endurance and resistance exercise training significantly improved peak V'O_2, muscle strength, and quality of life components in patients following TAVI treatment compared to usual care [7]. Similar findings have been reported in numerous observational and randomized studies [8].

The European Society of Cardiology (ESC) guidelines state that competitive or recreational sports/exercise of moderate and high intensity are not recommended in patients with severe symptomatic AS, based on a low level of evidence [9]. Gati et al. reported that very limited data exist on the effects of intensive exercise on valvular

heart disease and postulated that the accompanying adrenergic surges and increased hemodynamic load on the heart may have several potential consequences in patients with valvular heart disease [10].

Previous observational, non-randomized studies have evaluated either solely resistance training or a combined aerobic exercise and resistance exercise training programs in patients with AS and found a significant improvement in patients' activities of daily living [11, 12]. A randomized study evaluated the effect of pre- and intensified postprocedural physiotherapy on the primary composite endpoint of mortality and rehospitalization at 90 days, finding no significant difference between the intervention and control groups [13].

Poor physical performance and reduced exercise capacity are well-established predictors of adverse prognosis in patients undergoing TAVI, in individuals with cardiovascular risk factors, and in the general population [14–17]. WBV showed to be a promising exercise entity to improve physical performance and exercise capacity in patients with pulmonary arterial hypertension [18].

Data on exercise programs for patients with severe AS pre-TAVI are scarce and recommendations on whether to participate in sports programs are based on a low level of evidence [9].

Therefore, more data is needed on the safety, utility, and efficacy of pre-TAVI physical training in severe AS patients, focusing on six-minute walking distance (6MWD), cardiopulmonary exercise testing (CPET), muscle power, and HRQoL.

Thus, we examined the potential role of oscillatory WBV training as a preventive and potentially home-based physical exercise to improve exercise capacity in patients with severe AS in a prospective randomized pilot study.

Methods

Study design and patient population

The Galileo-AKS (AKS = ger. Aortenklappenstenose = eng. aortic valve stenosis) trial was a prospective, randomized, controlled, open-label trial that included patients with symptomatic severe AS (including low-flow, low-gradient, paradoxical low-flow, and high-gradient AS), who were scheduled for elective TAVI after a multidisciplinary heart team evaluation at the University Hospital Cologne. The trial protocol was approved by the local ethics committee and was conducted in accordance with the principles of the Declaration of Helsinki. Both written and oral informed consent were obtained from all patients. The trial was registered at the German Clinical Trials Register (DRKS00027542).

Patients with stable medical conditions for at least four weeks were randomly assigned in a 1:1 ratio to undergo oscillatory WBV training or to a control group. The inclusion and exclusion criteria are listed in Supplementary Tables 1 and 2. Participants were only enrolled if they were deemed physically able to perform the training intervention, based on the subjective clinical judgment of the supervising physician. No predefined objective fitness criteria were applied. The study was designed to enroll 30 patients, based on the pilot study design. A randomization sequence was generated for patients 1–30, with assignments placed in sealed envelopes by an independent individual. Envelopes were opened only after written consent and review of inclusion/exclusion criteria by the study physician. At the time of enrollment, 646 patients received TAVI for severe AS, 33 of those were eligible and consent to participate in the study. The number of potential participants, who were eligible but declined to participate was not documented.

At that point, both the study physician and the patient were aware of the allocation. Blinding was not possible as patients knew their group assignment. After three dropouts from the control group, three additional patients were randomized, resulting in 16 patients in the WBV group and 14 to the control group (Fig. 1). The baseline examination (V1) was conducted 4 weeks prior to TAVI, with a second assessment (V2) one day before TAVI and a short-term follow-up (V3) post-TAVI to assess performance changes and any adverse short-term events. Between V2 and V3, neither group received a specific exercise program.

Only patients in the intervention group received whole-body vibration (WBV) training between V1 and V2, while the control group did not. According to the exclusion criteria, participants in both groups were prohibited from engaging in other rehabilitation programs and were instructed to maintain their usual physical activity without initiating additional sports programs.

Oscillatory whole-body vibration

Oscillatory WBV was performed using a side-alternating Galileo Med35 platform (Novotec Medical GmbH, Pforzheim, Germany), with a vibration frequency of 28 Hz and a peak-to-peak displacement of 2 mm [18, 19]. The exercise program and platform settings are detailed in Supplementary Table 3. The standardized exercise program consisted of 12 to 16 sessions, each lasting 30 min over 4 weeks, and was supervised by experienced medical staff. Six exercises were performed for 2 min each, increasing to 3 min after the 8th session. Initially, all patients completed their sessions under supervision at the University Hospital Cologne, which required frequent visits and limited patient inclusion, as a logistical barrier. To address this issue, the protocol was adapted after one third of the included patients, to allow

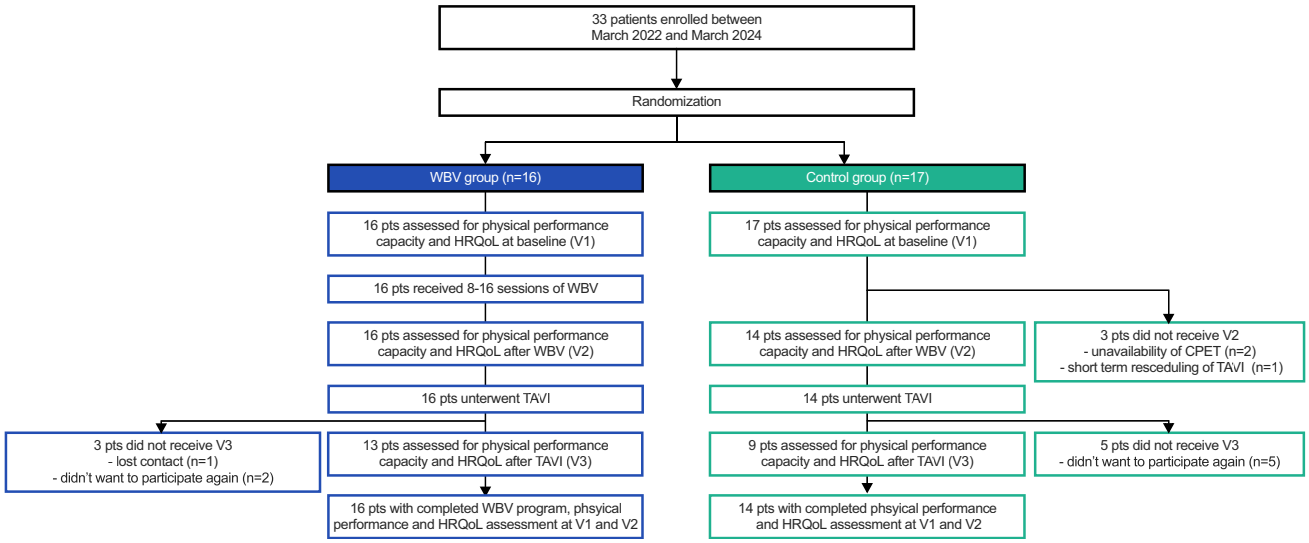


Fig. 1 Flowchart

home-based training. A fully supervised training program would have ensured maximum adherence control but was not feasible for all participants. To balance feasibility and adherence monitoring, a hybrid approach was used, with home-based training allowed only after participants had demonstrated correct and safe exercise execution in at least two supervised sessions. To further ensure proper execution, patients recorded each session and received regular follow-up via telephone.

Cardiopulmonary exercise testing

CPET was performed on a semi-upright cycle ergometer using a ramp protocol [20]. Exercise workload was increased using a ramp protocol (15 W/min or 10 W/min) after a 1-min warm-up at 20 W, until physical exhaustion or the achievement of the termination criterion as recommended by current standards [20, 21]. The following standard parameters were measured during serial bicycle spiroergometry: heart rate, blood pressure, respiratory exchange ratio (RER), peak oxygen consumption (peak V'O_2).

Clinical tests

The 6-Minute Walking Distance (6MWD) test was conducted according to guideline recommendations [22]. The Chair Rising Test (CRT) measured the time taken for patients to stand and sit five times without using their hands or arms for support, with a chair height ensuring 90° angles at the hips and knees. Furthermore, frailty was assessed via Rockwood's Clinical Frailty Scale (CFS) [23].

Health-related quality of life

The 36-Item Short Form Health Survey (SF-36) was used to assess HRQoL. This patient-reported questionnaire evaluates eight domains: physical functioning, role limitations due to physical health, role limitations due to emotional problems, social functioning, bodily pain, mental health, vitality and general health. Scores for each domain range from 0 to 100, with lower scores indicating greater disability [24].

Study endpoints

The primary endpoint was change in physical performance assessed by CRT, peak power in CPET, and 6MWD at V1, V2, and V3. Secondary endpoints were pulmonary function, peak V'O_2, HRQoL, frailty, and length of hospital stay.

Statistical analysis

Continuous variables are presented as mean ± standard deviation. Categorical variables are reported as absolute frequencies and percentages. Comparisons of categorical variables were conducted using Fisher's exact test. For continuous variables, non-parametric tests (Wilcoxon signed-rank test for paired samples, Mann–Whitney U test for independent samples) were applied when at least one group did not meet normality assumptions, as assessed by the Shapiro–Wilk or Kolmogorov–Smirnov test. Otherwise, parametric tests (t-test or paired t-test) were performed. To illustrate the difference in change between groups, the 95%-CI is displayed in addition to mean change. Due to the exploratory nature

and small sample size of this hypothesis generating pilot study, no formal correction for multiple testing was applied [25, 26]. Analyses were limited to pairwise comparisons between two time points (V1–V2 and V2–V3), conducted within and between groups for each outcome separately. More complex models (e.g., mixed effects) were considered but deemed inappropriate due to dropouts, normal and non-normal distributions, and limited feasibility of multivariable adjustment. Additionally, Cohen's d was evaluated for V1-V2, to determine effect size.

Two-sided p-values < 0.05 were considered statistically significant. Statistical analyses were performed using GraphPad Prism, Version 10.4.1 and R, Version 4.5.1.

Results

Baseline characteristics

A total of 33 patients were randomized, 30 completed both baseline and pre-TAVI assessments, and follow-up was available for 22 patients. Recruitment began in March 2022, with the final examination completed in May 2024 (Figs. 1, and 2).

The mean age was 79.7 ± 5.22 years, the mean body mass index was 25.8 ± 3.3 kg/m^2, and the mean aortic valve area was 0.75 ± 0.21 cm^2.

Demographic, clinical, and echocardiographic characteristics were similar between the two groups, except for a significantly higher prevalence of type 2 diabetes in the WBV group ($p = 0.007$, Table 1).

Our trial with a limited number of patients is the first randomized study to investigate oscillatory WBV in patients with severe AS providing a comprehensive assessment of CPET parameters.

At baseline (V1), the mean overall CPET results were as follows: peak power of 80 ± 26 W ($p = 0.52$), peak V'O_2 of 15.7 ± 4.2 mL*min^{-1}*kg^{-1} ($p = 0.79$), and peak RER of 0.93 ± 0.08 ($p = 0.87$). The mean 6MWD was 418 ± 100 m ($p = 0.50$), while the mean CRT was 11.2 ± 5.6 s ($p = 0.61$). The values for each group are presented in Table 2. Mean respiratory exchange ratio was 0.93 indicating sufficient effort in most patients.

HRQoL assessed with SF-36 showed higher scores in the WBV group for physical functioning ($75.3 \pm 19.8\%$) compared to the control group ($61.1 \pm 26\%$), though the difference was not statistically significant ($p = 0.10$).

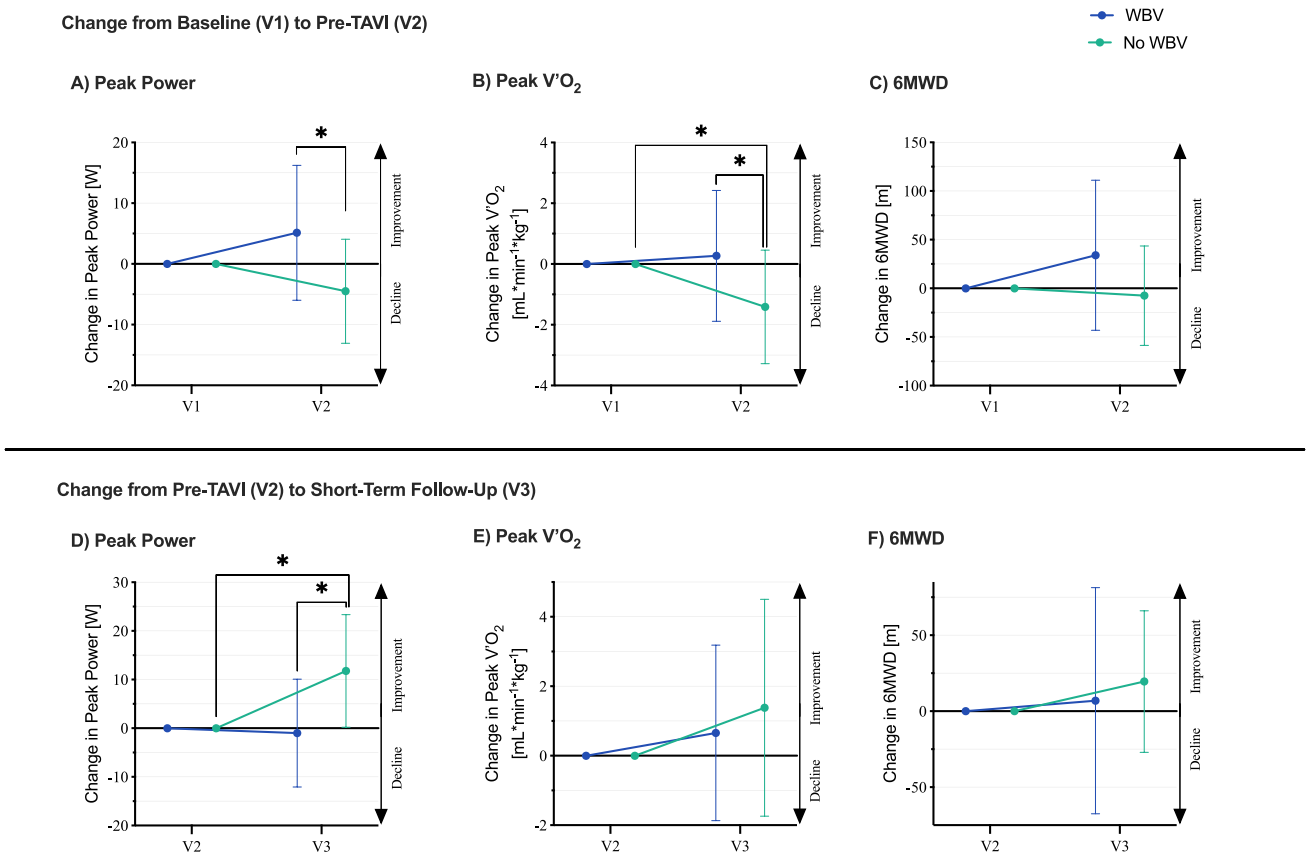


Fig. 2 Effect of WBV

Table 1 Demographic and clinical characteristics at baseline

	WBV, $n=16$	Control, $n=14$	p-value
Clinical characteristics			
Age, years	78.8 ± 4.8	80.7 ± 5.7	0.13
Body-mass-index, kg/m^2	26.4 ± 3.7	25.2 ± 2.9	0.31
New York Heart Association I/II	12 (75.0%)	8 (57.1%)	0.44
Male sex	13 (81.3%)	10 (71.4%)	0.67
Known history of smoking	5 (31.3%)	2 (14.3%)	0.40
Clinical Frailty Scale	2.69 ± 0.79	3 ± 1.18	0.76
Pre-procedural echocardiography			
Left ventricular end diastolic diameter, mm	45.8 ± 6.3	44.5 ± 7.7	0.62
Interventricular septum diameter, mm	13.5 ± 2.5	13.2 ± 3.5	0.81
Stroke volume index, mL/m^2	35.5 ± 7.4 [a]	38.3 ± 8.4	0.35
Peak aortic gradient, mmHg	66.6 ± 17.3 [a]	67.6 ± 21.5 [c]	0.90
Mean aortic gradient, mmHg	41.5 ± 9.7	41.5 ± 12.1	0.99
Peak aortic velocity, m/s	4.06 ± 0.53	4.07 ± 0.67	0.96
Aortic valve area, cm^2	0.74 ± 0.20	0.75 ± 0.21	0.98
Left ventricular ejection fraction > 50%	13 (81.3%)	12 (85.7%)	> 0.99
Cardiovascular risk factors			
Hypertension	12 (75%)	11 (79%)	> 0.99
Diabetes Mellitus Type 2	9 (56%)	1 (7%)	**0.007
Dyslipidemia	9 (56%)	7 (50%)	> 0.99
Coronary Artery Disease	4 (25%)	7 (50%)	0.26
Known history of atrial fibrillation	8 (50%)	7 (50%)	> 0.99
Previous permanent pacemaker	2 (13%)	2 (14%)	> 0.99

Parameters are presented as mean ± standard deviation or absolute (relative) frequency. If sample size differs from the value stated above, this is indicated with a superscript letter. The corresponding adjustment is specified in the legend, Significant differences are indicated as follows: * < 0.05//** < 0.01,

Mean ± SD or Frequency (%); WBV = Whole Body Vibration Training; a: $n=15$; b: $n=13$; c: $n=12$

Overall frailty determined by CFS was 2.83 ± 0.99 with no significant difference between the groups ($p=0.76$).

All patients underwent TAVI via transfemoral access. The following valves were implanted: 15 SAPIEN valves (6 × S3 29 mm, 9 × S3 Ultra 23/26 mm), 13 Evolut valves (R, PRO +, FX: 3 × 26 mm, 9 × 29 mm, 1 × 34 mm), and 2 ACURATE neo2 valves (1 × Medium, 1 × Large). The median interval was 34 days [IQR, 29 to 42] between V1 and V2 and 65 days [IQR, 52 to 82] between V2 and V3.

Results (V1 to V2)

Patients in the WBV group completed a mean of 12.9 ± 2.8 trainings sessions. Table 2 presents the within-group and between group changes from baseline (V1) to pre-TAVI (V2) assessment. Peak power improved in the WBV group (5.1 ± 11.1 W, $p=0.08$, Cohen's $d=0.46$), whereas the control group experienced a non-significant decline (−4.5 ± 8.6 W, $p=0.07$, Cohen's $d=-0.52$), resulting in a significant between-group difference favoring the WBV group (9.6 W, 95% CI [2.1 to 17.1], p = 0.014, Cohen's $d=0.96$).

Peak $V'O_2$ (−1.4 ± 1.9 ml*min^{-1}*kg^{-1}, $p=0.017$, Cohen's $d=-0.75$) significantly declined in the control group and significant changes between the groups, favoring WBV (1.7 ml*min^{-1}*kg^{-1}, 95% CI [0.2 to 3.2], p = 0.032, Cohen's $d=0.83$) were observed. Notably, RER was higher at V2 in the WBV group (0.97 ± 0.12) compared to the control group (0.91 ± 0.08), though the difference was not statistically significant ($p=0.15$).

$V'O_2$ at first ventilatory threshold was only achieved by 5 patients at V2. Therefore, no analyses were performed. 6MWD showed non-significant improvements (34 ± 77 m, $p=0.10$, Cohen's $d=0.44$) in the WBV-group with a similar trend in the CRT (−0.8 ± 2.1 s, $p=0.17$, Cohen's $d=-0.36$), whereas the control group exhibited a non-significant decline (Table 2). The mean change in 6MWD between the groups was not significant, although a numerical trend, favoring the WBV group was observed (42 m, 95% CI [−10 to 93], $p=0.11$, Cohen's $d=0.62$).

Table 2 Comparison of spirometry, spiroergometry, clinical tests and SF36 before and after WBV

	WBV ($n=16$)				Control ($n=14$)				WBV—Control ($n=30$)	
	V1[a]	V2[a]	Difference [a]	p value	V1[a]	V2[a]	Difference [a]	p value	V2-V1[b]	p-value
Spirometry										
FVC, L	2.98 ± 0.91	2.98 ± 0.77	−0.01 ± 0.45	0.96	2.84 ± 0.94	2.60 ± 0.82	−0.23 ± 0.37	***0.034**	0.23 [−0.08 to 0.53]	0.15
FEV1, L	2.15 ± 0.67	2.03 ± 0.68	−0.12 ± 0.44	0.28	1.77 ± 0.51	1.74 ± 0.62	−0.03 ± 0.28	0.72	−0.1 [−0.4 to 0.2]	0.85
Spiroergometry										
Peak Power, W	83.3 ± 31.4	88.4 ± 35.7	5.1 ± 11.1	0.08	76.9 ± 20.0	72.4 ± 24.3	−4.5 ± 8.6	0.07	9.6 [2.1 to 17.1]	***0.014**
Peak V'O_2, mL*min^{-1}*kg^{-1}	15.5 ± 4.7	15.8 ± 5.6	0.3 ± 2.2	0.62	15.9 ± 3.7	14.5 ± 4.1	−1.4 ± 1.9	***0.017**	1.7 [0.2 to 3.2]	***0.032**
Peak RER	0.93 ± 0.1	0.97 ± 0.12	0.04 ± 0.1	0.14	0.92 ± 0.06	0.91 ± 0.08	−0.01 ± 0.04	0.21	0.05 [−0.01 to 0.11]	***0.038**
Peak O_2-Pulse, mL	11.1 ± 3.4	11.0 ± 3.4	−0.1 ± 1.6	0.85	11.7 ± 3.1	10.1 ± 2.4	−1.6 ± 1.7	****0.004**	1.6 [0.3 to 2.8]	***0.016**
Clinical Tests										
6MWD, m	429 ± 101	463 ± 155	34 ± 77	0.10	404 ± 101	413 ± 125 (13)	−8 ± 51 (13)	0.60	42 [−10 to 93] (29)	0.11
Borg RPE	11.3 ± 2.6	10.9 ± 2.1	−0.3 ± 1.8	0.50	12.6 ± 2.8	13.2 ± 2.6 (13)	0.8 ± 2.2 (13)	0.23	−1.1 [−2.6 to 0.4] (29)	0.31
CRT, s	10.7 ± 3.5	9.9 ± 4.2	−0.8 ± 2.1	0.17	11.7 ± 7.4	12.2 ± 6.2 (13)	0.2 ± 3.8 (13)	0.95	−0.9 [−3.2 to 1.4] (29)	0.41
CFS	2.7 ± 0.8	2.6 ± 1.1	−0.1 ± 0.6	0.69	3.0 ± 1.2	2.9 ± 1.2	−0.1 ± 0.5	> 0.99	−0.1 [−0.5 to 0.4]	0.87
HRQoL—SF36										
Physical functioning, %	75.3 ± 19.8	76.6 ± 16.1	1.3 ± 17.5	0.87	61.1 ± 26	56.4 ± 30.2	−4.6 ± 15.4	0.28	5.9 [−6.5 to 18.3]	0.34
Physical role limitations, %	45.3 ± 44.9	51.6 ± 46.1	6.3 ± 25.0	0.47	35.7 ± 42.4	44.6 ± 48.2	8.9 ± 37.5	0.50	−2.7 [−26.2 to 20.9]	0.77
Emotional role limitations, %	87.5 ± 34.2	87.5 ± 29.5	0 ± 32.2	> 0.99	69.1 ± 44.3	85.7 ± 32.3	16.7 ± 40.8	0.25	−16.7 [−44 to 10.7]	0.27
Vitality, %	52.5 ± 20.7	55.6 ± 20.2	3.1 ± 14.7	0.41	53.9 ± 19.7	51.4 ± 19.7	−2.5 ± 8.9	0.31	5.6 [−3.6 to 14.9]	0.22
Mental health, %	83.8 ± 13.5	77.8 ± 17.8	−6.0 ± 9.6	***0.022**	70.9 ± 21.1	69.7 ± 22.2	−1.1 ± 12.2	0.24	−4.9 [−13 to 3.3]	0.70
Social functioning, %	92.2 ± 12	90.6 ± 16.8	−1.6 ± 11.1	0.78	84.8 ± 26	75 ± 34	−9.8 ± 22.6	0.19	8.3 [−4.8 to 21.3]	0.53
Bodily pain, %	87.3 ± 21.4	87.0 ± 21.1	−0.3 ± 10.1	0.97	81.6 ± 32.7	78.4 ± 34.3	−3.2 ± 10.8	0.50	2.9 [−4.9 to 10.7]	0.51
General health, %	62.5 ± 19.5	63.2 ± 21.3	0.7 ± 12.3	0.83	60.0 ± 22.0	55.0 ± 21.1	−5.0 ± 11.6	0.13	5.7 [−3.3 to 14.7]	0.20

*$p < 0.05$; ** $p < 0.01$; [a] Mean ± Standard deviation; [b] Difference of the Mean Difference [95%-CI]; (sample size) WBV—Whole body vibration training; FVC – Forced vital capacity; FEV1 – forced expiratory volume in one second; Peak V'O_2 – Peak oxygen uptake; RER – respiratory exchange ratio; O_2-Pulse – amount of oxygen uptake per heartbeat; 6MWD – six-minute walking distance; Borg RPE – Borg rate of perceived exertion; CRT – chair rising test; CFS – clinical frailty scale; HRQoL – Health related quality of life; SF36 – Short form 36

One patient who was part of the WBV group, identified as an outlier, experienced a − 154 m decline due to a recent cold. After adjustment, the between-group difference was significant (54 m, 95% CI [10 to 98], $p = 0.018$, Cohen's $d = 0.87$; Supplement Table 4). There were no within-group or between-group differences in quality-of-life measures between V1 and V2, except for a reported decline in mental health in the WBV group (Table 2). Mean hospital stay post-TAVI was similar between both groups (WBV: 5.4 ± 3.9 days vs. control: 5.9 ± 4.6 days, $p = 0.46$). The exercise intervention and control protocols, including training and CPET, were completed without any serious adverse events. Given the predominance of male participants, we conducted a subgroup analysis for women only. The results were similar among females compared to the overall cohort (Supplement Table 5).

Follow-up (V2 to V3)

Short-term follow-up (V2 to V3) was available for 13 patients (81.3%) in the WBV group and 9 (64.3%) in the control group. Following the TAVI procedure, the WBV group did not continue exercise training.

Both groups demonstrated improvements in peak V'O_2 (WBV-group 0.7 ± 2.5 mL*min^{-1}*kg^{-1}, $p = 0.37$; control group 1.4 ± 3.1 mL*min^{-1}*kg^{-1}, $p = 0.36$), and peak O_2-Pulse (WBV: 1.6 ± 2.9 mL, $p = 0.07$; Control: 1.2 ± 2.8 mL, $p = 0.24$), along with a reduction in perceived physical exertion (WBV: −1.3 ± 2.5, $p = 0.09$; Control: −2.2 ± 2.2, $p = 0.015$), as reflected by lower Borg scale scores, which was significant in the control group. The control group showed a notable increase in peak power (11.8 ± 11.6 W, $p = 0.016$), while the WBV group experienced a slight decline. This led to a significant between-group difference (−12.8 W, 95% CI [−23.0 to −2.6], $p = 0.017$). Apart from that, no significant between group differences in change were seen. In the intervention group, two patients developed third-degree atrioventricular block requiring permanent pacemaker implantation, and one patient experienced a stroke; all events occurred as complications of the TAVI procedure. No periprocedural complications were observed in the control group.

Discussion

Our pilot study investigated the effects of an oscillatory WBV intervention on physical performance, motor function, and endurance parameters in patients with severe symptomatic AS scheduled for TAVI. The main findings of our small-scale pilot study can be summarized as follows: (I) exercise performance, as assessed by peak V'O_2 and peak power, remained stable in the WBV group but declined in the control group; (II) analyses of the 6MWD and CRT suggested potential improvements in the WBV group; and (III) no serious adverse events occurred in the WBV group.

At baseline, physical performance was comparable between groups. Frailty did not differ significantly between groups and was classified as low in both, based on CFS levels [27, 28]. Between V1 and V2, the intervention showed improvements, whereas the control group declined, likely reflecting short-term training effects and progressive preprocedural deterioration. Between V2 and V3, improvements were observed only in the control group, possibly because the loss of training-induced effects in the intervention group outweighed the physiological benefits of TAVI, resulting in a relative decline. In contrast, the control group, with no prior training benefit to lose, showed a plausible improvement in physical performance.

While regular exercise is broadly recommended for most patients, caution is often advised for patients with symptomatic severe AS, while there is a lack of robust clinical data on this topic, as reflected in the ESC guidelines with a C level of evidence [9]. To date, Sasaki et al. conducted a non-randomized study evaluating bodyweight resistance exercise training in 78 patients with symptomatic AS as part of a cardiac rehabilitation program. Participants completed a median of 6 training sessions (IQR, 5–9). The authors reported no adverse increases in heart rate or blood pressure, along with improvements in activities of daily living [12]. Similarly, Arai et al. reported outcomes in 18 patients with severe AS admitted to a rehabilitation ward for physical disability. Their exercise training program included both resistance and aerobic training. Three patients died, and another three were transferred to another hospital for reasons unrelated to exercise, while the remaining 12 demonstrated improved daily living activities [11]. Furthermore, Weber et al. investigated the effects of an individualized ambulatory physiotherapy program conducted daily for at least two weeks before TAVR in a single center randomized controlled trial (training group, $n = 58$; control group, $n = 50$). The intervention included inspiratory muscle training (4 × 5 min/day) and a minimum of 30 min of walking below the threshold of subjective exhaustion. Inspiratory muscle strength significantly increased before TAVR in the intervention group, with no significant change in the control group [13].

We observed a modest increase in peak V'O_2 in the WBV group, whereas the control group exhibited a progressive decline in the period before TAVR. A previous pilot study conducted at our center demonstrated the safety and feasibility of WBV training in patients with severe pulmonary arterial hypertension, showing improvements in exercise tolerance, maximal oxygen uptake, and quality of life [18]. There is more study data on exercise programs post-TAVI. Pressler et al. investigated post-TAVI exercise effects in a

Table 3 Comparison of Spirometry, Spiroergometry, Clinical tests and SF36 before and after TAVI

	WBV ($n=13$)				Control ($n=9$)				WBV—Control ($n=22$)	
	V2[a]	V3[a]	Difference [a]	*p* value	V2 [a]	V3 [a]	Difference [a]	*p* value	V3-V2[b]	*p*-value
Spirometry										
FVC, L	3.00 ± 0.80	3.26 ± 0.78	0.26 ± 0.48	0.08	2.62 ± 0.98	2.81 ± 1.24	0.19 ± 0.51	0.30	0.07 [−0.38 to 0.51]	0.76
FEV1, L	2.08 ± 0.72	2.31 ± 0.62	0.24 ± 0.28	***0.011**	1.74 ± 0.77	1.89 ± 0.77	0.15 ± 0.33	0.21	0.09 [−0.18 to 0.36]	0.51
Spiroergometry										
Peak Power, W	88.1 ± 35.0	87.1 ± 30.7	−1.0 ± 11.1	0.75	79.7 ± 24.7	91.4 ± 26.4	11.8 ± 11.6	***0.016**	−12.8 [−23 to 2.6]	***0.017**
Peak V'O_2, mL*min^{-1}*kg^{-1}	15.8 ± 6.2	16.5 ± 5.0	0.7 ± 2.5	0.37	15.4 ± 3.4	16.8 ± 3.5	1.4 ± 3.1	0.36	−0.7 [−3.2 to 1.8]	0.61
Peak RER	0.97 ± 0.13	0.96 ± 0.06	−0.01 ± 0.1	0.64	0.93 ± 0.08	0.93 ± 0.08	−0 ± 0.04	0.93	−0.01 [−0.09 to 0.06]	0.81
Peak O_2-Pulse, mL	11.0 ± 3.7	12.5 ± 4.9	1.6 ± 2.9	0.07	10.6 ± 2.5	11.7 ± 4.2	1.2 ± 2.8	0.24	0.4 [−2.2 to 2.9]	0.54
Clinical Tests										
6MWD, m	458 ± 139	464 ± 111	7 ± 74	0.74	433 ± 109	453 ± 108	20 ± 47	0.24	−13 [−71 to 46]	0.66
Borg RPE	10.8 ± 2.3	9.5 ± 2.8	−1.3 ± 2.5	0.09	12.8 ± 2.9	10.6 ± 3.2	−2.2 ± 2.2	***0.015**	0.9 [−1.3 to 3.1]	0.39
CRT, s	10.8 ± 4.2	10.3 ± 4.4	−0.5 ± 1.5	0.29	11.3 ± 4.5	10.3 ± 3.7	−1 ± 3.4	0.50	0.5 [−1.7 to 2.8]	0.62
CFS	2.5 ± 1	2.2 ± 0.8	−0.2 ± 0.4	0.25	2.7 ± 1	2.7 ± 1.1	0 ± 0.5	> 0.99	−0.2 [−0.7 to 0.2]	0.37
HRQoL—SF36										
Physical functioning, %	76.5 ± 16.3	81.2 ± 20.9	4.6 ± 16.1	0.21	63.3 ± 30.5	76.1 ± 27.2	12.8 ± 31.9	0.31	−8.2 [−29.6 to 13.3]	0.44
Physical role limitations, %	48.1 ± 45.0	63.5 ± 42.8	15.4 ± 63.4	0.44	47.2 ± 47.5	66.7 ± 45.1	19.4 ± 32.5	0.13	−4.1 [−52.2 to 44.1]	0.83
Emotional role limitations, %	84.6 ± 32.3	84.6 ± 37.6	0 ± 49.1	> 0.99	77.8 ± 37.3	88.9 ± 33.3	11.1 ± 23.6	0.50	−11.1 [−48 to 25.8]	0.45
Vitality, %	56.9 ± 20.6	58.8 ± 23.6	1.9 ± 17.5	0.70	60.6 ± 16.1	67.8 ± 22.8	7.2 ± 17.0	0.24	−5.3 [−20.9 to 10.3]	0.83
Mental health, %	80.6 ± 15.2	84.3 ± 15.4	3.7 ± 13.4	0.48	71.1 ± 24.7	76.0 ± 21.2	4.9 ± 26.7	0.55	−1.2 [−19.1 to 16.7]	0.78
Social functioning, %	88.5 ± 18	96.2 ± 10.7	7.7 ± 14.9	0.13	75 ± 37.5	87.5 ± 25	12.5 ± 32.5	0.38	−4.8 [−26.1 to 16.5]	0.97
Bodily pain, %	91.5 ± 16.2	81.7 ± 25.0	−9.8 ± 24.4	0.25	77.5 ± 30.1	76.9 ± 25.2	−0.6 ± 36.5	0.75	−9.3 [−36.2 to 17.7]	0.77
General health, %	63.2 ± 21.3	68.1 ± 20.8	4.9 ± 26.5	0.52	56.1 ± 23.0	61.7 ± 20.9	5.6 ± 24.4	0.51	−0.6 [−23.9 to 22.6]	0.96

*$p < 0.05$; ** $p < 0.01$; [a] Mean ± Standard deviation; [b] Difference of the Mean Difference [95%-CI]; (sample size) WBV—Whole body vibration training; FVC – Forced vital capacity; FEV1 – forced expiratory volume in one second; Peak V'O_2 – Peak oxygen uptake; RER – respiratory exchange ratio; O_2-Pulse – amount of oxygen uptake per heartbeat; 6MWD – six-minute walk distance; Borg RPE – Borg rate of perceived exertion; CRT – chair rising test; CFS – clinical frailty scale; HRQoL – Health related quality of life; SF36 – Short form 36

randomized trial and reported a significant net increase of 3.7 mL*min^{-1}*kg^{-1} in peak V'O_2 compared with the control group [7]. This difference may be attributable to both variations in training protocols, as they applied a combined endurance and resistance training and increased the endurance training on cycle ergometers, and our relatively unfit cohort, with a low peak V'O_2 at baseline. Similarly, Hu et al. reported a significant improvement in peak V'O_2 albeit slightly lower, which is likely attributable to differences in training regimens as well [29].

Additionally, minor changes are important as poor physical fitness is a well-established modifiable risk factor, and higher fitness levels are associated with lower all-cause mortality [30]. Previous studies have demonstrated that higher maximal oxygen uptake is associated with lower cardiac mortality and morbidity in both healthy individuals [17] and patients with cardiovascular disease [31]. Furthermore, Dhoble et al. [3] demonstrated that patients with moderate to severe AS have significantly reduced peak V'O_2 and that higher peak V'O_2 is independently associated with improved survival, regardless of SAVR status. In our study, both groups exhibited a non-significant increase in peak V'O_2 from V2 to short-term follow-up, a finding that partially aligns with the results reported by Bellander et al. in patients undergoing SAVR for AS [32]. However, it is important to note that most patients in our cohort did not reach the first ventilatory threshold.

Our study contributes to the existing literature by demonstrating measurable improvements in 6MWD and peak power, comparable to previous findings in patients with pulmonary hypertension [18]. These results add to the growing body of evidence suggesting that such benefits are achievable even in patients with AS prior to TAVI. Following TAVI, Hu et al. reported improvements in the 6MWD with moderate-intensity continuous training, whereas Pressler et al. found no significant differences [7, 29]. In TAVI patients, Abdul-Jawad Altisent et al. reported that 72% improved in 6MWD at 6 months, while lesser improvement was associated with worse clinical outcomes [5].

Similarly, CRT showed a trend toward improvement, underscoring the importance of motor function, particularly given that only one third of patients in our cohort were non-frail. Frailty—defined by grip strength, gait speed, serum albumin, and activities of daily living—is a significant predictor of increased mortality following SAVR or TAVI [33].

We observed no significant within-group or between-group differences in HRQoL questionnaires, except for mental health, within our limited study cohort, which contrasts with the findings of Pressler et al. in patients undergoing exercise after TAVR [7]. Furthermore, while we detected no differences in HRQoL between groups, improvements in mobility and daily activities following TAVI are well documented [34, 35].

Importantly, we observed no adverse events, and WBV exercise appeared to be both safe and well tolerated. This aligns with findings from Saeed et al., who reported that exercise testing in patients with asymptomatic moderate or severe AS is both safe and feasible [36] as well as with findings from previous studies regarding patients with symptomatic AS [11–13]. Our findings support previous evidence demonstrating improved exercise capacity following TAVI and provide a foundation for larger multicenter trials to further evaluate this approach.

Study limitations

Several limitations of this study should be noted. First, the analysis included only 30 patients, predominantly male, from a single center, which limits the generalizability of the findings and underscores the need for further research. Second, the extended recruitment period likely resulted in participation being limited to patients willing to enroll, introducing potential selection bias. Third, the home-based training was unsupervised, relying on patient adherence to the protocol. Fourth, blinding of participants and study staff was not performed. This represents a potential source of bias, particularly for subjective outcomes. Fifth, the relatively low number of training sessions per participant may have influenced the observed effects. Sixth, the low RER at V2 in the control group suggests that this group may have performed less intense CPET, and the presence of outliers could affect effect size estimates. Seventh, the intervention was limited to 12 sessions over less than two months, precluding conclusions about the long-term effects on hard endpoints such as major adverse cardiovascular events. Eighth, we did not control for other physical activities performed during the study period, although such activities were not recommended by the study protocol. Ninth, the value of questionnaires in assessing physical activity was limited by highly variable patient responses (Table 3).

Conclusions

This small-scale pilot study suggests that oscillating vibration training is safe and may improve cardiopulmonary exercise capacity. Notably, most exercise parameters declined in the control group, indicating a potential role in mitigating deconditioning in patients with AS. Consistent with prior evidence, these findings support the feasibility and potential benefit of tailored interventions in this population.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00392-025-02744-y.

Acknowledgements The study was not sponsored. The authors acknowledge the use of automated assistive writing technologies for proofreading.

Funding Open Access funding enabled and organized by Projekt DEAL. This research received no external funding.

Data availability The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Conflict of interest/disclosures E. Kuhn reports consultancy and personal fees from Medtronic, Edwards Lifesciences, Boston Scientific, and Abbott. S. Baldus reports lecture fees from Abbott, Edwards Lifesciences, AstraZeneca, and JenaValve Technology; he received research grants from Abbott and AstraZeneca; and participates as a principal investigator in clinical trials sponsored by AstraZeneca and Abbott. C. Hohmann reports lecture/consultancy fees and/or travel grants from Bayer, Daiichi Sankyo, Edwards Lifesciences, Johnson & Johnson, MSD, and Pfizer. M. Adam reports grants and personal fees from Medtronic, and personal fees from Abbott, JenaValve Technology, Edwards Lifesciences, Boston Scientific, and Meril. H. Wienemann reports consultancy fees and travel grants from JenaValve Technology. All other authors declare no conflict of interest.

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