

## Research Article

# The Benefit of Acute Early Cardiac Rehabilitation after Transcatheter Aortic Valve Implantation (TAVI)

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## Abstract

**Background:** Cardiac Rehabilitation (CR) has been shown to increase physical and cognitive performance and to improve quality of life. However, evidence concerning CR in frail patients after transcatheter aortic valve implantation (TAVI) is still limited. Thus, the aim of the present study was to investigate the effect of inpatient acute early cardiac rehabilitation in frail patients dependent on nursing care immediately after TAVI.

**Methods:** In this retrospective observational single-center cohort study, we included 12 consecutive TAVI patients referred for Acute Early Cardiac Rehabilitation (AECR) to the cardiac rehabilitation hospital Lippoldsberg between August 31<sup>st</sup> and December 31<sup>st</sup> 2021. The impact of AECR on 6-minute walking test distance (6-MWD), Body Mass Index (BMI), and performance in Activities of Daily Living (ADL) as measured by Katz Index and Barthel Index was evaluated.

**Results:** On admission, patients were characterized by advanced age (mean, 84.3±1.3 years), a high burden of comorbidities, severe impairment in ADLs (Katz Index 2.1±0.4, Barthel Index 40.2±5.5 points), but preserved cognitive function (mini-mental state examination 24.5±1.27 points). At time of AECR discharge, a significant improvement of 6-MWD (mean gain + 73±12m) and autonomy in ADLs (Katz Index: mean gain +2.3±0.4 points; P=0.0001; Barthel Index: mean gain +33±3points, P<0.0001) could be observed. Importantly, five individuals (42%) were independent from nursing care after AECR, whereas none had been before.

**Conclusions:** Acute early cardiac rehabilitation in frail octogenarians after TAVI is safe and significantly improves exercise capacity as well as functional autonomy in activities of daily living, also in individuals with initial severe disability.

**Keywords:** 6-minute Walking Test Distance; Acute Early Cardiac Rehabilitation; Exercise Capacity; Transcatheter Aortic Valve Implantation

## Abbreviations

AS: Aortic Stenosis; SAVR: Surgical Aortic Valve Replacement; TAVI: Transcatheter Aortic Valve implantation; CR: Cardiac Rehabilitation; 6-MWD: Six-Minute Walking Test Distance; AECR: Acute Early Cardiac Rehabilitation; BMI: Body Mass Index; ADL: Activities of Daily Living; VARC: Valve Academic Research Consortium; MMSE: Mini-Mental State Examination; SaO<sub>2</sub>: Oxygen Saturation; CAD: Coronary Artery Disease; CKD: Chronic Kidney Disease; COPD: Chronic Obstructive Pulmonary Disease; RBC: Red Blood Cell Count; RCT: RECOVER-TAVI; EF: Ejection Fraction; MI: Myocard Infarction; CABG: Coronary Artery Bypass Grafting

## Introduction

Severe Aortic Stenosis (AS) is one of the most common clinically relevant primary valve lesions and is associated with increased morbidity and mortality [1]. Due to the aging population, the prevalence is rapidly increasing. Surgical Aortic Valve Replacement (SAVR) or transcatheter treatment are the first-line therapies for the treatment of severe symptomatic AS. Transcatheter Aortic Valve

Implantation (TAVI) has been developed as an alternative to surgical valve replacement, especially for elderly, frail patients with multiple comorbidities and a high perioperative mortality [2,3]. Previous reports have already provided evidence that these vulnerable patients may benefit from Cardiac Rehabilitation programs (CR) after surgical [4-8] or percutaneous valve interventions [7,9-14]. CR is already recommended for cardiac conditions such as heart failure or myocardial infarction to maintain independence or facilitate reintegration into daily life [14-17]. CR has been shown to increase physical and cognitive performance, thereby improving quality of life and reducing mortality and hospital re-admissions [6-8,14,18-20]. Despite these promising data, cardiac rehabilitation after TAVI has not yet received a guideline recommendation. However, emerging scientific evidence suggests that CR in TAVI patients are safe [7,10] and improves exercise tolerance [9, 11-13] as well as quality of life [7,9,14]. To assess the aforementioned effects, established parameters such as six-minute walking test distance (6-MWD), Barthel index, body mass index, or various neurological follow-up parameters have been studied.

Nevertheless, there are still only few studies focusing on Acute Early Cardiac Rehabilitation (AECR) immediately after TAVI. Due to the minimally invasive nature of the procedure, TAVI patients are frequently characterized by advanced age, multiple comorbidities, and frailty. In such patient cohorts, the maintenance or recovery of independence in functional tasks of daily living is of utmost importance - for the individual person itself as well as for healthcare in common. Thus, the aim of the present study was to investigate the effect of inpatient acute early cardiac rehabilitation in frail patients dependent on nursing care immediately after TAVI. Therefore, the impact of AECR on 6-MWD, Body Mass Index (BMI), and performance in Activities of Daily Living (ADL) as measured by Katz Index and Barthel Index was evaluated.

## Materials and Methods

### Patient population and study design

In this retrospective observational single-center cohort study, we included 12 consecutive TAVI patients who were dependent on nursing care and referred for AECR to the cardiac rehabilitation hospital Lippoldsberg between August 31<sup>st</sup> and December 31<sup>st</sup> 2021. Study participants had been treated with transfemoral TAVI at the University Medical Center Goettingen immediately before AECR. Goettingen represents a high-volume TAVI-center, with at least 400 procedures per year. Patients' baseline characteristics were recorded before the intervention. Transfemoral TAVI was performed as previously described using standard techniques. Peri-procedural complications were evaluated according to the Valve Academic Research Consortium (VARC2)-recommendations [21].

### Ethics Approval and Consent to Participate

In accordance with the local ethics committee, all patients gave written informed consent for the TAVI procedure itself as well as for the use of their anonymized data for research purposes. The study was performed in accordance with the ethical standards defined in the Declaration of Helsinki.

### Acute Early Cardiac Rehabilitation Program

After transferal to the rehabilitation clinic, all patients attended a standardized three-week multicomponent inpatient AECR program including an educational interview on admission, physical therapy, neurophysiological co-assessment, nutritional counseling, and planning of post-discharge care. During the first physiotherapeutic session, the patients' training condition and resilience was evaluated by experienced physiotherapists. A six-minute walking test including documentation of the perceived exertion scale was performed in a long indoor corridor under repeat recordings of blood pressure, heart rate, breathing rate and SaO<sub>2</sub>. Cognitive function was assessed by the Mini-Mental State Examination (MMSE) test, a 30-point questionnaire including simple questions in a number of areas like orientation, registration, attention, calculation, recall, and language. Afterwards, patients participated in daily individual physiotherapeutic training units of 30 minutes duration including a combination of endurance and coordination training. Supplementary, they performed daily physical training on the seat bike (Motomed) with individually adapted duration and intensity to improve the individual aerobic capacity. During the second week of AECR, the supervised exercise program was expanded by other training methods like swimming,

bicycle ergometer and treadmill training, strength and muscle building. Each patient received at least 90 minutes of physical therapy per day. Individual therapeutic goals were defined and evaluated in weekly meetings with all therapists, nursing staff and physicians. Before discharge, the six-minute walking test was repeated.

At the beginning and the end of the AECR, patients' performance in activities of daily living was documented by evaluation of Katz Index and Barthel Index. The Katz Index assigns one point for complete independence in each of the six areas feeding, bathing, dressing, transferring, toileting, and urinary continence. Thus, a patient with a score of six points is independent from nursing care. The more precise Barthel Index measures the performance in 10 items on an ordinal scale with a given number of points assigned to each level of ranking. The maximum score of 100 points indicates complete independence.

### Statistical analysis

All data are presented as mean±SEM (software: GraphPad Prism Version 9.0). For pairwise comparisons, paired student's t-tests were used. Results with P<0.05 were considered as statistically significant.

## Results

### Patient characteristics

The 12 patients (4 men, 8 women) who underwent AECR after elective TAVI were characterized by advanced age (mean, 84.3±1.3 years) and a high burden of comorbidities like coronary artery disease (CAD, 41.7%), chronic kidney disease (CKD, 41.7%), hypertension (91.7%), chronic obstructive pulmonary disease (COPD, 16.7%), reduced ejection fraction <50% (41.7%), and prior stroke (25%). The calculated surgical risk as estimated by logistic EuroScore 1 (mean, 20.5±7.7%) indicated a high-risk cohort. At time of admission in the rehabilitation clinic, the majority of patients was severely impaired in activities of daily living, as documented by a mean Katz Index of 2.1±0.4 points and a mean Barthel Index of 40.2±5.5 points. None of the participants was independent from nursing care at the beginning of AECR. Cognitive function as estimated by MMSE was normal in most patients (mean, 24.5±1.27 points), except for two individuals with mild (MMSE 21 points) and moderate (MMSE 15 points) cognitive impairment. Mean six-minute walking test distance before AECR was 109±26 m (range, 0-250 m). Baseline characteristics of the cohort are displayed in table 1.

### Immediate post-TAVI course

The TAVI procedure had been successful in 11 of the 12 patients. No patient died peri procedurally, but conversion to SAVR had been necessary due to annular rupture with pericardial tamponade in one case. The 86-year-old woman needed transfusion of 6 RBC units and intermittent renal replacement therapy due to stage 3 acute kidney injury, but recovered quickly. One further patient experienced a severe access-related complication (femoral dissection with indication for surgical intervention), and stage 3 acute kidney injury also occurred in one further patient. All other procedure-related complications were of minor severity. However, conduction disturbances were the most common among the VARC2 defined complications (4 patients in total; new left bundle branch block in 2 patients, new third degree atrioventricular block in 1 patient, implantation of new permanent pacemakers in 2 patients). The mean length of acute hospital stay after

**Table 1:** Baseline characteristics; Values indicate n (%) or mean ± SEM. EF: Ejection Fraction; CAD: Coronary Artery Disease; MI: Myocard Infarction; CABG: Coronary Artery Bypass Grafting; CKD: Chronic Kidney Disease; PM: Pacemaker; COPD: Chronic Obstructive Pulmonary Disease; BMI: Body Mass Index; 6-MWD: 6-minute Walking Test Distance; MMSE: Mini-Mental State Examination.

Male Sex, n (%)	4 (33%)
Age, years	84.3±1.3
EF, %	52.7±2.9
EF <50%, n (%)	5 (42%)
CAD, n (%)	5 (42%)
Prior MI, n (%)	3 (25%)
CABG, n (%)	1 (8%)
CKD, n (%)	5 (42%)
Prior Pacemaker, n (%)	2 (17%)
Hypertension, n (%)	11 (92%)
Diabetes, n (%)	1 (8%)
Smoking, n (%)	1 (8%)
COPD, n (%)	2 (17%)
Prior stroke, n (%)	3 (25%)
Anemia, n (%)	4 (33%)
Logistic EuroScore 1, %	20.5 ± 7.7
BMI, kg/m <sup>2</sup>	25.7±1.2
6-MWD BL, m	109±26
MMSE BL, points	24.5±1.27
Katz Index BL, points	2.1±0.4
Barthel Index BL, points	40.2±5.5

TAVI was 6.5±1.7 days (range, 2-23 days).

**Effects of Cardiac Rehabilitation**

Mean length of AECR was 17.42±1.2 days (range, 13-29 days). The rehabilitation program proved to be safe: No complications occurred, and no transference to an acute care facility was necessary.

The six-minute walking test at baseline and discharge from cardiac rehabilitation could not be performed in 1 of the 12 patients due to severe coxalgia. At time of discharge, an improvement of

6-MWD could however be observed in all other 11 participants (mean, 109.2±26.2 m at baseline vs. 182.5±28.8 m at discharge, p<0.0002, Figure 1A). Importantly, even the 3 patients who had experienced severe TAVI complications (see above, one of them with the lowest baseline MMSE of 15 points) showed significant gain of walking distance.

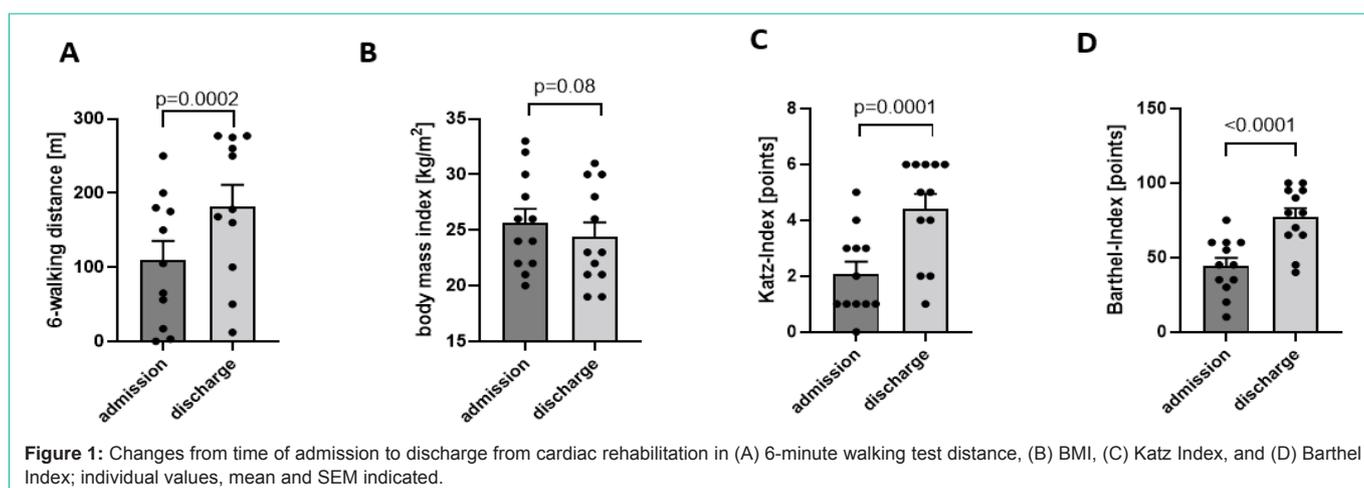
Additionally, we saw a tendency towards decreased BMI levels at time of discharge, but this finding did not reach statistical significance (25.67±1.19 kg/m<sup>2</sup> vs. 24.42±1.22 kg/m<sup>2</sup>, p=0.08; Figure 1B).

At the end of AECR, a substantial improvement of Katz Index (mean gain 2.3±0.4 points; P=0.0001) and Barthel Index (mean gain 33±3points, P<0.0001) (Figure 1 C+D) could be observed in every single patient. While no participant was independent in activities of daily living on admission, 5 persons regained autonomy during AECR and were discharged with a Katz Index of 6 and a Barthel Index >90 points. Importantly, all 12 patients could be discharged to their homes, no transferences to nursing homes were necessary.

**Discussion**

The results of our present study indicate that acute early cardiac rehabilitation in frail octogenarians after TAVI is safe and significantly improves exercise capacity (as measured by 6-MWD) as well as functional autonomy (as measured by Katz and Barthel Index), even in individuals with severe impairment at baseline. The described cohort combines several risk factors of adverse outcomes in terms of mortality and permanent dependence on nursing care: advanced age, high baseline comorbidity burden, high incidence of relevant TAVI-complications, and severe disability at time of rehabilitation admission.

Our findings are well in line with previous reports demonstrating gains in functional tasks, mobility and quality of life for TAVI patients after CR [8,11,12,22-24]. The six-minute walking test, performed according to current guidelines of the American Thoracic Society [25], is the most common tool to measure exercise capacity. In a meta-analysis including 292 TAVI and 570 SAVR patients, early cardiac rehabilitation was able to improve exercise tolerance and functional independence in both cohorts, without significant differences between TAVI and SAVR [7]. Of note, average increase in 6-MWD was three times greater than the minimum clinically



**Figure 1:** Changes from time of admission to discharge from cardiac rehabilitation in (A) 6-minute walking test distance, (B) BMI, (C) Katz Index, and (D) Barthel Index; individual values, mean and SEM indicated.

important difference previously defined for cardiac rehabilitation in CAD patients after percutaneous coronary interventions (+25m) [26].

In comparison with previous reports on 3-week CR in post-TAVI patients however, our own cohort exhibited markedly lower baseline 6-MWD (109±26 m; Russo et al. [12]: 241±95 m; Völler et al. [22]: 262±90 m; Zanettini et al. [9]: 210±87 m) as well as lower baseline Barthel Indices (40±6 points; Russo et al. [12]: 90±17 points; Zanettini et al. [9]: 84±21 points). Nevertheless, the mean absolute gain in 6-MWD at discharge was comparable between our cohort (+73±12 m) and the previous publications (Russo et al. [12]: 60±46 m; Völler et al. [22]: +74±90 m; Zanettini et al. [9]: +65±92 m), indicating a higher relative gain in our severely disabled patients. Moreover, the gain of functional autonomy as measured by mean increase of Barthel index was much more pronounced in our cohort (+33±3 points) if compared to other studies (Russo et al. [12]: +9±12 points; Zanettini et al. [9]: +11±16 points). This observation of relevant benefit from cardiac rehabilitation even in most vulnerable individuals is of utmost importance, since the avoidance of permanent dependence on nursing care is highly relevant for the individual person as well as for the health system in common.

Persevered cognitive function and absence of cachexia might however play a significant role, since both have been previously reported to predict rehabilitation-related gain in 6-MWD and quality of life in TAVI patients [11]. In line with these results, the majority of our own patients exhibited a normal cognitive function, and none showed underweight. Half of the cohort was even overweight with a BMI >25kg/m<sup>2</sup>, a rather protective factor in many studies on frail individuals. The insignificant weight loss we observed during CR was probably attributable to mobilization of persistent edema after treatment of severe AS rather than a result of nutritional changes.

To date, very few TAVI patients are included in randomized trials evaluating the effects of CR. Pressler et al. [10] randomized 30 patients after TAVI to an eight-week supervised rehabilitation program versus usual care. In the training group, significantly higher changes for peak oxygen uptake, muscular strength and quality of life, but not 6-MWD, could be observed. However, reassessment two years after the intervention documented loss of most differences between treatment groups, underlining the importance of ongoing exercise interventions [27]. In preparation of a multi-center RCT (RECOVER-TAVI) to support guideline development, a pilot study demonstrating the feasibility of recruiting TAVI patients into a randomized rehabilitation trial has already been published [28]. Since some previous reports even suggest a survival benefit for TAVI patients undergoing CR, such studies are urgently required to generate guideline-relevant outcome data. In a longitudinal cohort study of 1056 TAVI patients treated between 2008 and 2016, individuals who underwent post-TAVI cardiac rehabilitation had a significantly better 6-months survival than patients who voluntarily declined to participate [8].

## Conclusions

Acute early cardiac rehabilitation in frail octogenarians after TAVI is safe and significantly improves exercise capacity as well as functional autonomy in activities of daily living, also in individuals with initial poor performance. The six-minute walking test performs

as useful outcome measure also in this TAVI-specific patient cohort.

## Limitations

The present investigation represents a single-centre experience with a small sample size. However, we report on a very vulnerable cohort of patients characterized by a high prevalence of TAVI complications and severe functional impairment before AECC. Furthermore, the study lacks a control group. Since our hospital offers rehabilitation programs to all post-TAVI patients, a randomization to treatment versus control group seems inadequate though. Also, patient-related outcome measures (like quality of life questionnaires) were not included in the study. Further investigations and clinical trials are warranted in order to establish evidence-based cardiac rehabilitation programs that significantly improve the clinical outcome of TAVI patients beyond the procedure itself.

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