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App-based assessment of memory functions in patients after transfemoral aortic valve replacement

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ABSTRACT

BACKGROUND Transfemoral aortic valve replacement (TAVR) is the standard treatment for elderly patients with aortic valve stenosis. Although safe and well-established, there is a risk of intraprocedural hemodynamic instability and silent cerebral embolism, which can lead to a decline in neurocognitive function and dementia. In clinical practice, comprehensive cognitive testing is difficult to perform. AI-assisted digital applications may help to optimize diagnosis and monitoring.

METHODS Neurocognitive function was assessed by validated psychometric tests using "Δelta -App", which uses artificial intelligence and computational linguistic methods for extraction and analysis. Memory function was assessed using the 'Consortium to Establish a Registry for Alzheimer's Disease' (CERAD) word list and digit span task (DST) before TAVR and before hospital discharge. The study is registered in the German Register of Clinical Trials (https://drks.de/search/de/trial/DRKS00020813).

RESULTS From October 2020 until March 2022, 141 patients were enrolled at University Hospital Heart Centre Brandenburg. Mean age was 81 ± 6 years, 42.6% were women. Time between the pre- and post-interventional test was on average 6 ± 3 days. Memory function before TAVR was found to be below average in relation to age and educational level. The pre-post TAVR comparison showed significant improvements in the wordlist repeat, $P < 0.001$ and wordlist recall test of CERAD, $P < 0.001$. There were no changes in the digital span test.

CONCLUSIONS Despite impaired preoperative memory function before TAVR, no global negative effect on memory function after TVAR was detected. The improvements shown in the word list test should be interpreted as usual learning effects in this task.

Cognitive performance is usually conceptualized in terms of functional domains such as memory, attention, language, or executive functions.[1] Cognitive impairments in the domains of attention and memory have been documented in patients with heart failure (HF).[2,3] Heart failure is caused by increased afterload and myocardial remodeling and is a multifactorial consequence in patients with severe AS.[4] Because of the considerable risk of open-heart surgery, transfemoral aortic valve replacement (TAVR) is the standard therapy in elderly patients at medium or high risk. In these patients, functional aspects, especially cognitive function, are of immense importance.[5] Several factors could affect cognition in TAVR patients. One key factor contributing to cognitive decline is cerebral hypoperfusion, which may be exacerbated by low cardiac output.[6] Studies show that low cardiac output is also associated with more rapid cognitive decline in patients with cardiovascular disease.[7,8] Moreover, intraprocedural hemodynamic instability during TAVR could lead to cerebral blood flow restriction, with the risk of organ-specific ischemia, micro-embolism or stroke, which are typical complications after TAVR.[9,10] On the other hand, improved cardiac output is associated with increased cerebral blood flow, particularly in the hippocampus,[11] and was associated with improved cognitive function after TAVR.[12] A recent meta-analysis showed that preexisting cognitive impairment was a significant risk factor for worse outcomes after TAVR.[13] Cognitive function appears to improve or stabilize after TAVR, particularly in patients with preexisting cognitive impairment.[14,15]

Digital neuropsychological testing may offer advantages over traditional paper-pencil testing because comprehensive cognitive testing is difficult to perform in clinical practice. Artificial Intelligence-powered digital applications may help optimizing diagnosis and monitoring. The aim of this study was to assess the cognitive functions of TAVR patients with a focus on changes in memory functions using a digital application (Δelta-app, KI-Elements, Germany) before and after TAVR.

METHODS

Patients

This prospective cohort study enrolled adult patients undergoing elective TAVR at the University Hospital Heart Center Brandenburg between October 2020 and March 2022. Inclusion criteria comprised patients with severe symptomatic aortic stenosis who were scheduled for TAVR and were classified as high surgical risk patients according to the European Society of Cardiology guidelines.[16] Exclusion criteria were emergency surgery, chronic dialysis, and lack of written informed consent for study participation.

A multidisciplinary valve team that included interventional cardiologists, cardiothoracic surgeons, and cardiovascular anesthesiologists was involved in the allocation of surgical or nonsurgical treatment for all patients. Three months after discharge, patients and general practitioners were followed up by telephone to collect quantitative data on subjective well-being, outcome, and outpatient laboratory values. Patient flow is shown in Figure 1.

The study was approved by local ethics committee (E-01-20191006) and is registered in the German Register of Clinical Trials (DRKS00020813).

TAVR procedure

The majority of patients were admitted on the day before the procedure. TAVR was performed in the hybrid catheterization laboratory under fluoroscopy guidance with the use of contrast media. The TAVR device was delivered through femoral approach in all patients. Procedures were performed under local anesthesia with conscious sedation or general anesthesia with endotracheal intubation. The prosthesis size was determined using preprocedural echocardiographic and multi-slice computed tomography angiogram findings. During TAVR, old valve is probed from the inside with a catheter. The calcified valve leaflets are pushed open while the artificial valve develops and replaces it.[17]

Neurocognitive Function Assessment

Neurocognitive function was assessed with validated tests (CERAD-WL and Digit Span Task, DST) using the “Δelta -App”. Δelta is a certified medical product that uses artificial intelligence (AI) and computational linguistic methods for extraction and language recognition. For human validation of the AI-assisted automated scoring, all test results were manually cross-checked by a trained psychologist. A third generation iPad Air from Apple with the operating system iPadOS 14.4 was used to conduct the test.

CERAD-Wordlist (WL-W/WL-A):

The CERAD Word list is a cognitive assessment tool that measures immediate (WL-W) and delayed (WL-A) memory for new and non-associated verbal information. It assesses the ability to learn and retain new words, which falls within the sub-domain of memory. In WL-W, ten words are presented acoustically one after the other in three rounds. The order of the words is changed in each round. After each

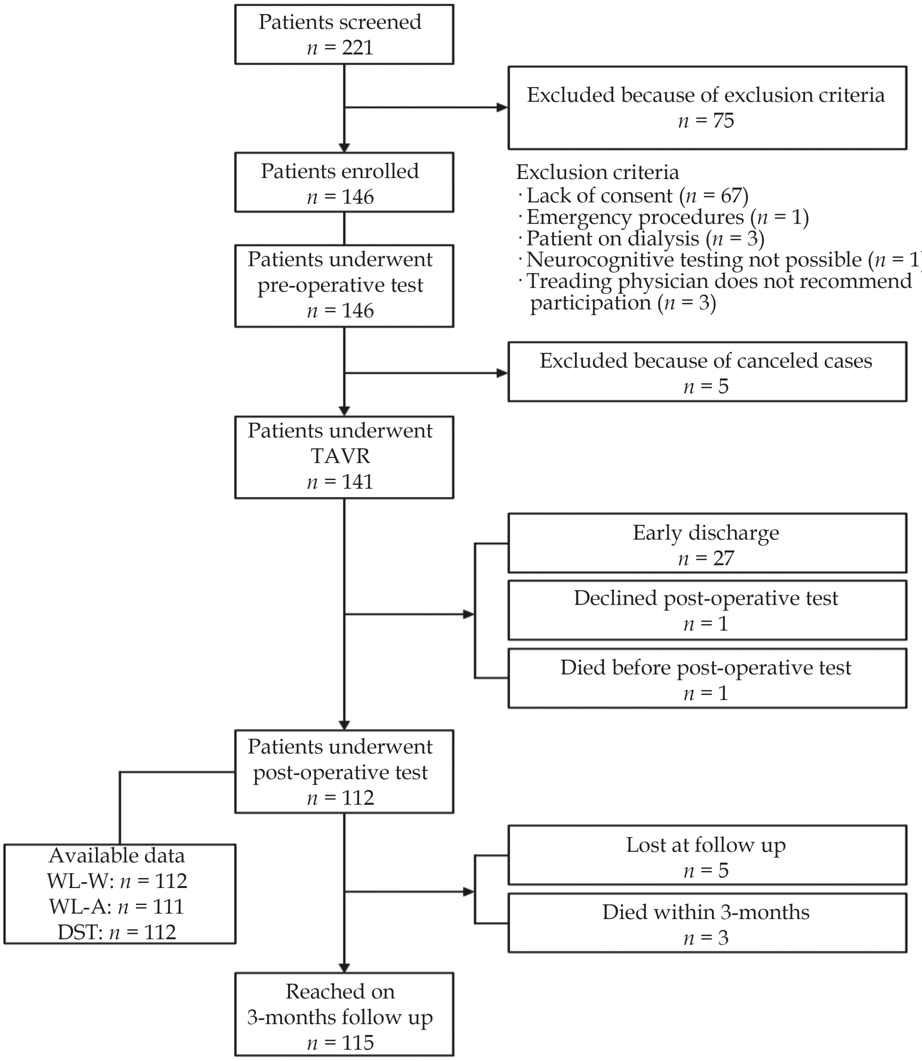

Figure 1 Patient flow through the study. TAVR: transfemoral aortic valve replacement.

presentation, patients were asked to repeat as many words as they remember, regardless of order. At the end of our cognitive test battery, patients were asked to name the ten words presented in WL-W without being preceded by another acoustic presentation (WL-A).

Digit-Span-Task

The Digit Span Test (DST) is a neuropsychological assessment tool, that measures short-term memory, verbal attention and working memory.[18]

In this test, patients repeated from memory an increasing number of digits in the given order. The first two rounds start with a digit span of two. If the sequence of digits is reproduced correctly in at least one of the two rounds, two more rounds follow in which the digit span is increased by one more digit. In the planned sixteen rounds, the digit range will be increased to nine. If the digit range was repeated incorrectly or not at all in both rounds, the last correct digit range was taken as the maximum digit range that this subject could remember correctly, and the test was over. Alternatively, the subject may repeat the digit sequence correctly in all rounds and reach a maximum digit range of nine.

Data Collection

Medical records were reviewed until hospital discharge. The following information was obtained: demographics, comorbidities, procedural characteristics including valve type and size, intra- and post-procedural complications during the index hospital stay (cardiac decompensation, need for packed red blood cells, sepsis, or septic shock), laboratory parameters, length of stay in hospital after TAVR, in-hospital mortality as well as discharge status. Rehospitalization within 90 days after discharge, 90-day mortality and major adverse cardiac events (MACE) were assessed by a questionnaire sent to the treating primary care physician. In addition, patients were interviewed 90 days after hospital discharge using a structured telephone interview (Appendix).

Statistical Analysis

Patients were divided into one of three groups according to age following CERAD norm data. For statistical analysis, a paired *t*-test and a two-way ANOVA as well as chi square test for pre- and postoperative changes according to age group was used. The basis for assigning the level of cognitive impairment followed the recommendation according to CERAD.[19] To estimate the cognitive status of the patients before TAVR, test scores were transformed into age-, sex- and education-corrected standardized scores as implemented in delta-app. Postoperative cognitive decline was defined as post-TAVR performance decrease of more than 1 SD compared with the score before (i.e., individual delta score post-TAVR minus pre-TAVR of > 1 SD) A *P* value of less than 0.05 was considered statistically significant. SPSS 29 (IBM, Armonk, NY, USA) was used.

RESULTS

From October 2020 to March 2022, 146 patients were enrolled, of whom 141 underwent TAVR. Mean age was 81 ± 6 years with a mean Euro-Score II of 10.41% ± 7.10%. Baseline characteristics are shown in Table 1. The mean time between preoperative cognitive assessment and TAVR was 2.0 ± 5.2 days; between TAVR and postoperative assessment 5.0 ± 3.1 days. The mean time between preoperative and postoperative cognitive assessment was 6 ± 3 days with minimum of 3 days and maximum of 31 days. A postoperative stroke was diagnosed in 2.8% cases, 3.5% suffered postoperative delirium and 14.9% required a pacemaker implantation after TAVR. The mean duration of hospital stay was 11 ± 6 days, 22.3% of patients were rehospitalized within 90 days. Overall, 3 patients died within 90 days, 5 patients within 180 days (Table 2).

Preoperative CERAD-Wordlist WL-W and WL-A in comparison to CERAD-comparison group

There was a significant decrease with age in memory function (Table 3). Regardless of the age group, significant pre-intervention impairment in memory function was evident in both WL-W and WL-A to the standard comparison group defined by Luck, *et al*.[20] Before implantation, adjusted for age and education level, TAVR patients had a significant lower memory function, compared to reported comparison group of healthy individuals (*Z*-value MW (SD), Table 3, Figure 2).

CERAD-Wordlist Pre- and Post-operative

In our study cohort there was a significant decrease in pre-interventional memory function with age, for WL-W ($P < 0.001$) and WL-A ($P = 0.023$). After TAVR-implantation, memory function increased in both tests: WL-W ($P < 0.001$) WL-A ($P < 0.001$) (Figure 3). This effect was independent of age.

Digit Span Pre- and Post-operative

The mean digit span was 5.39 numbers. There was no age-related effect in memory function in the DST-task, F= 1.68, $P = 0.191$. Also, no significant changes after TAVR could be found (Figure 4).

DISCUSSION

A major proportion of our study cohort had a severe impairment in memory function prior to TAVR implantation. Compared to other normative data with even more liberal criteria, where downward deviations are weighted less heavily,[20] our subjects perform comparatively poorly.

Particularly for high-risk and elderly patients, TAVR has become the standard of care. Recent research suggests, that TAVR is also suitable as a treatment option for patients with lower operative risk and its use is expected to increase in the future.[21,22]

After TAVR, WL-W and WL-A showed significantly better memory function. Such improvements are expected as learning effects and have been previously reported for this type of task.[23] A limitation to transferability is that, unlike the comparative psychometric validation data, our cohort underwent TAVR implantation as an additional interven-

Table 1 Baseline characteristics.

Patient characteristics	≤ 69 years	70–79 years	≥ 80 years	overall	*P*-value
Age, yrs	65 ± 4	76 ± 3	84 ± 3	81 ± 6	< 0.001
Female	2/8 (25%)	17/38 (44.7%)	41/95 (43.2%)	60/141 (42.6%)	0.578
Body mass index, kg/m^2	30 ± 6	29 ± 6	27 ± 5	28 ± 5	0.11
Smoker	3/7 (42.9%)	3/33 (9.1%)	10/95 (10.5%)	16/135 (11.9%)	0.03
EuroScore, %	7.32 ± 3.76	8.69 ± 6.12	11.43 ± 7.52	10.41 ± 7.10	0.06
Formal education, years	14 ± 2	10 ± 3	11 ± 4	11 ± 4	0.069
Comorbidities					
Arterial hypertension	6/8 (75%)	31/38 (81.6%)	77/95 (81.1%)	114/141 (80,9%)	0.908
Coronary heart disease	5/8 (62.5%)	25/38 (65.8%)	61/95 (64.2%)	91/141 (64.5%)	0.978
Atrial fibrillation	0/8 (0%)	7/38 (18.4%)	41/95 (43.2%)	48/141 (34.0%)	0.003
Peripheral vascular disease	2/8 (25%)	3/38 (7.9%)	6/95 (6.3%)	11/141 (7.8%)	0.167
Acute decompensated heart failure	1/8 (12.5%)	0/38 (0%)	4/95 (4.2%)	5/141 (3.5%)	0.183
NYHA-Classification	3 ± 1	3 ± 0	3 ± 1	3 ± 1	0.915
NYHA-Class I	0/8 (0%)	1/34 (2.9%)	1/90 (1.1%)	2/132 (1.5%)	
NYHA-Class II	2/8 (25.0%)	8/34 (23.5%)	18/90 (20%)	28/132 (21%)	
NYHA-Class III	5/8 (62.5%)	25/34 (73.6%)	65/90 (72.2%)	95/132 (71.3%)	
NYHA-Class IV	1/8 (12.5%)	0/34 (0%)	6/90 (6.7%)	7/132 (5.3%)	
Previous myocardial infarction	1/8 (12.5%)	3/38 (7.9%)	9/95 (9.5%)	13/141 (9.2%)	0.909
Stroke	0/8 (0%)	2/38 (5.3%)	7/95 (7.4%)	9/141 (6.4%)	0.677
Chronic kidney disease	3/8 (37.5%)	11/36 (30.6%)	40/95 (42.1%)	54/139 (38.8%)	0.479
Hypertensive heart disease	0/8 (0%)	8/38 (21.1%)	10/95 (10.5%)	18/131 (12.8%)	0.139
Hyperlipoproteinemia	4/8 (50%)	20/38 (52.6%)	39/95 (41.1%)	63/141 (44.7%)	0.456
Diabetes type II (insulin)	4/8 (50%)	11/38 (28.9%)	18/95 (18.9%)	33/141 (23.4%)	0.088
Chronic obstructive pulmonary disease	0/8 (0%)	5/38 (13.2%)	9/95 (9.5%)	14/141 (9.9%)	0.510
Previous PTCA	2/8 (25%)	13/38 (34.2%)	38/95 (40.0%)	53/141 (37.6%)	0.619
Previous CABG	2/8 (25%)	6/38 (15.8%)	6/95 (6.3%)	14/141 (9.9%)	0.087
Cardiac device	0/8 (0%)	1/38 (2.6%)	15/95 (15.8%)	16/141 (11.3%)	0.056
Laboratory parameters					
Serum creatinine, µmol/L	100 ± 26	93 ± 46	99 ± 33	97 ± 36	0.703
eGFR, ml/min	65 ± 27	69 ± 21	59 ± 19	62 ± 20	0.041
NT-proBNP, pg/mL	7398 ± 9023	2213 ± 3829	4274 ± 7083	39002 ± 6580	0.101
Hemoglobin, mmol/L	8.3 ± 1.0	8.1 ± 1.1	7.9 ± 1.0	8.0 ± 1.0	0.406
Echocardiographic parameters					
LVEF (%)	47 ± 14	50 ± 12	49 ±15	50 ±14	0.867
TAPSE (mm)	21 ± 5	20 ± 6	20 ± 5	20 ± 5	0.986
Procedural characteristics					
Valve type					0.011
Evolut R	4/8(50%)	14/36 (38.9%)	65/95 (68.4%)	83/139 (59.7%)	
Evolut Pro	0/8 (0%)	9/36 (35%)	16/95 (16.8%)	25/139 (18.0%)	
Sapien 3**	4/8 (50%)	13/36 (30.6)	13/95 (14.8%)	30/139 (21.6%)	
Balloon-expanding valve	4/8 (50%)	12/37 (32.4%)	13/95 (13,7%)	29/140 (20.7%)	0.006
Self-expanding valve	4/8 (50%)	25/37 (67.6%)	82/95 (86.3%)	111/140 (79.3%)	0.006
Pre-dilatation	7/8 (87.5%)	25/37 (67.6%)	64/95 (67.4%)	96/140 (68.6%)	0.494
Post-dilation	2/8 (25%)	7/37 (18.9%)	20/95 (21.1%)	29/140 (20.7%)	0.919
Valve-in-valve	1/8 (12.5%)	1/37 (2.7%)	4/95 (4.7%)	6/140 (4.3%)	0.462

CABG: coronary artery bypass grafting. Values are expressed as means ± SD or *n* (%).

Table 2 Process parameter and outcome grouped according to age.

Patient characteristics	≤ 69 years	70 – 79 years	≥ 80 years	Overall	*P*-value
Process parameter					
Time between (days)					
preoperative cognitive test an TAVR	1.9 ± 1.6	1.7 ± 1.5	2.0 ± 6.2	2.0 ± 5.2	0.677
TAVR and postoperative cognitive test	4.2 ± 1.3	5.1 ± 4.9	5.8 ± 1.3	4.5 ± 3.1	0.395
preoperative tests and tests post TAVR	5.8. ± 1.3	6.9 ± 5.1	5.8 ± 2.0	6.1 ± 3.3	0.211
Outcome					
Died within procedure	0/8 (0%)	0/38 (0%)	0/95 (0)%	0/141 (0%)	
Admission to intensive care	3/7 (42.9%)	3/35 (8.6%)	1/92 (1.1%)	7/134 (5.2%)	<0.001
AKI	3/5 (60%)	2/24 (8.3%)	13/66 (19.7%)	18/95 (18.9)	0.026
Hemodynamic relevant pericardial effusion	0/8 (0%)	1/38 (2.6%)	0/95 (0%)	1/141 (0.7%)	<0.001
Delir	1/8 (12.5%)	1/38 (2.6%)	3/95 (3.2%)	5/141 (3.5%)	0.366
Stroke	0/8 (0%)	1/38 (2.6%)	3/95 (3.2%)	4/141 (2.8%)	0.872
Pacemaker implantation	2/8 (25%)	3/38 (7.9%)	16/95 (16.8%)	21/141 (14.9%)	0.302
Bleeding requiring transfusion	1/8 (12.5%)	5/36 (13.9%)	4/95 (4.2%)	10/141 (7.1%)	0.134
Length of stay in hospital, days	16.5 ± 11.8	11.7 ± 5.7	10.8 ± 5.0	11.0 ± 6.0	0.026
Discharge status					
Home	8/8 (100%)	33/38 86.8%)	84/95 (88.4%)	125/141 (88.7%)	0.562
Rehabilitation	0/8 (0%)	2/38 (5.3%	3/95 (3.2%)	5/141 (3.5%)	0.718
Nursing-Home	0/8 (0%)	0/38 (0%)	1/95 (1.1%)	1/141(0.7%)	0.784
Other hospital	0/8 (0%)	3/38 (7.9%)	6/95 (6.3%)	9/141 (6.4%)	0.708
Died in hospital	0/8 (0%)	0/38 (0%)	1/95 (1.1%)	1/141 (0.7%)	0.784
Follow-up					
Died within 3 months	0/7 (0%)	0/36 (0%)	3/90 (3.3%)	3/133 (2.3%)	0.480
Rehospitalization within 3 months	1/6 (16.7%)	6/25 (24.0%)	16/72 (22.2%)	23/103 (22.3%)	0.927
MACE within 3 months	0/5 (0%)	2/19 (10.5)	2/58 (3.4%)	4/82 (4.9%)	0.403
Died within 6 months	1/7 (14.3%)	0/27 (0%)	4/60 (6.7%)	5/94 (5.3%)	0.222
Rehospitalization within 6 months	2/6 (33.3%)	5/34 (14.7%	10/81 (12.5%)	17/121 (14.1%)	0.281

Values are expressed as means ± SD or *n* (%). AKI: acute kidney injury; MACE: major adverse cardiac events; TAVR: transfemoral aortic valve replacement.

tion between pre- and posttest. However, the fact that there were no significant changes in DST underscores the likelihood, that the significant changes in CERAD were only learning effects. In conclusion, we can at least exclude a systematic negative effect of TAVR on deterioration of memory function as measured by WL-W/WL-A and DST with the "Δelta -App".

These findings are consistent with previous published data in this field, that could not show a systematic effect on global cognition after TAVR.[14,15] When applied to our methodology, this underlines the feasibility of assessing cognitive function in TAVR patients using established but digitized tasks, which has only been reported with a comparable test-battery in an unselected elderly population.[24] Given the lack of conclusive evidence and the potential for underdiagnosis and underreporting of adverse cognitive outcomes after TAVR, digital cognitive assessment may provide a robust methodology for future research or routine individualized measurement in patients undergoing TAVR. AI-assisted analysis offers the opportunity to lower the inhibition threshold for cognitive function assessment and facilitate the collection of these endpoints. An individual assessment of cognition seems particularly necessary. Talbot-Hamon *et al.* pointed out, that "by using mean scores, the larger pool of indi-

Table 3 Memory function depending on age group.

Age	≤ 69 years	70–79 years	≥ 80 years	*P*-value
Preoperative memory function				
WL-W-task, *n* = 146	*n* = 10	*n* = 46	*n* = 90	
Repeated words	16.10 ± 2.38	15.35 ± 3.50	13.17 ± 3.75	< 0.001
Repeated words *z*-value	–1.73 ± 1.10	–1.48 ± 1.15	–1.46 ± 1.11	0.769
WL-A-task, *n* = 145	*n* = 10	*n* = 46	*n* = 89	
Repeated words	3.20 ± 1.48	2.65 ± 2.30	1.79 ± 2.06	0.023
Repeated words *z*-value	-2.48 ± 1.01	-2.20 ± 1.21	-2.00 ± 1.09	0.351
DST, *n* = 146	*n* = 10	*n* = 46	*n* = 90	
Digit span	6.00 ± 1.25	5.39 ± 1.06	5.40 ± 0.95	0.191
Pre-post-operative comparison				
WL-W, *n* = 112	*n* = 5	*n* = 39	*n* = 68	
Change of mean repeated words (t1-t0)	2.00 ± 3.08	2.56 ± 2.81	1.90 ± 3.46	0.590
Changes in %	13.47% ± 19.59%	16.79% ± 19.67%	19.26% ± 32.82%	0.849
WL-A, *n* = 111	*n* = 5	*n* = 39	*n* = 67	
Change of mean repeated words (t1-t0)	0.40 ± 2.30	0.74 ± 1.67	0.94 ± 1.99	0.758
Changes in %	70% ± 186.58%	50.62% ± 121.83%	83.63% ± 166.09%	0.565
DST, *n* = 111	*n* = 5	*n* = 40	*n* = 68	
Change of mean repeated numbers (t1-t0)	–0.20	–0.05	0.06	0.748
Changes in %	–2.5 ± 13.4	0.46 ± 18.37	1.51 ± 15.46	0.846

Values are expressed as means ± SD for absolute data and as % and SD for relative values. DST: digit span test; WL-A: wordlist repeat; WL-W: wordlist recall.

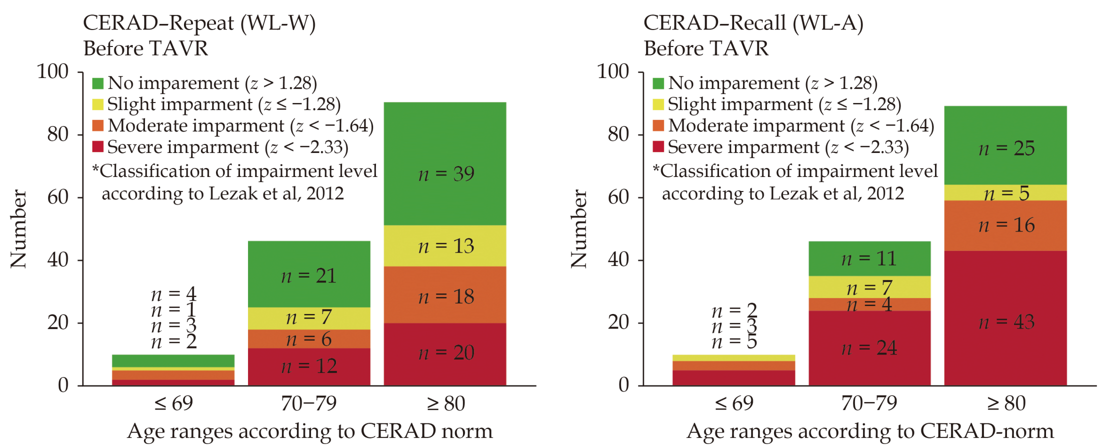

Figure 2 CERAD-wordlist repeat (WL-W) and wordlist recall (WL-A) before TAVR according to age groups. TAVR: transfemoral aortic valve replacement.

viduals with cognitive stability or improvement is likely to dilute and mask the small but clinically relevant subset of individuals with cognitive decline after TAVR".[25]

There are some limitations to our study. Unlike the original published version of CERAD, which uses a visual presentation of the wordlist, we used an auditory presentation of the wordlist in the "Δelta -App". Comparative studies have shown that working memory (i.e., word recall) did not show a visual superiority effect over auditory administration.[26] As a significant proportion of the age group had significant visual impairment and may have under-reported dyslexia that impaired visual comprehension–an auditory administration may be more appropriate for these older individuals. On

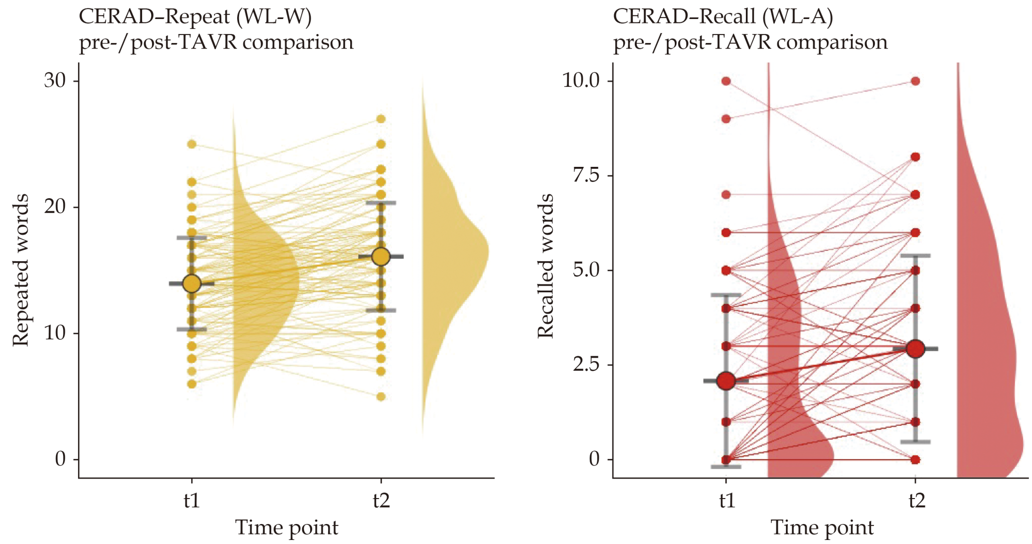

Figure 3 CERAD-wordlist repeat (WL-W) and wordlist recall (WL-A) in pre- and post-TAVR comparison. WL-W: $P < 0.001$, WL-A: $P < 0.001$. TAVR: transfemoral aortic valve replacement.

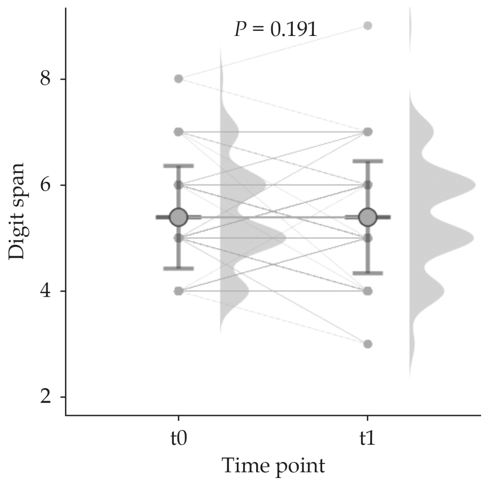

Figure 4 Digit-Span (DST) in pre- and post-TAVR comparison. TAVR: transfemoral aortic valve replacement.

the other hand, hearing impairments may also have had an impact on test performance. To counter this, each patient was asked before starting the word list whether auditive presentation could be understood clearly. Future research should verify advantages and disadvantages with a larger data set comparing visually and auditorily administered cognitive screening tests in high age TAVR-collectives.

In conclusion, a considerable proportion of the study population had significantly worse memory function before TAVR in contrast to the age-standardized comparison group. An overall negative effect of TAVR on memory could not be demonstrated.

DISCLOSURE

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Author contributions

Conceptualization: JN, AHF; Methodology: JN, AHF, CB, MH; Formal analysis and investigation: JN, MH Writing—original draft preparation: JN, AHF; Performance of experiments or therapy: JN, CB, MH; Writing—review and editing: MH, JS, GF, CB; Funding acquisition and Resources: JN, AHF; Supervision: AHF All authors approved the final manuscript.

Financial & competing interests' disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Ethics

This study was approved by the Ethics committee of the Brandenburg Medical School (MHB) E-01-20191006.

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