ORIGINAL ARTICLE

Clinical outcomes in patients after surgical and transcatheter aortic valve replacement

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KEY WORDS

aortic stenosis, ministernotomy, minithoracotomy, propensity score

ABSTRACT

INTRODUCTION Transcatheter aortic valve implantation (TAVI) and minimally invasive aortic valve replacement (minithoracotomy and ministernotomy) have become a valuable alternative to conventional surgical treatment of severe aortic stenosis (AS) in high-risk patients.

OBJECTIVES The aim of the study was to evaluate long-term results and complications in patients with symptomatic AS treated with TAVI, surgical aortic valve replacement (SAVR), minithoracotomy, or ministernotomy.

PATIENTS AND METHODS A total of 173 patients with symptomatic AS were enrolled to the study between the years 2011 and 2013. Propensity scores were calculated for TAVI and each surgical method separately. Differences in clinical outcomes between patients treated with TAVI and those treated with surgical methods were adjusted for propensity scores using a logistic regression analysis and presented as adjusted odds ratios with 95% confidence intrervals.

RESULTS A median follow-up was 583.5 days (interquartile range, 298–736 days). Before aortic valve replacement (AVR), no significant differences in ejection fraction (EF) were observed between the groups. At 1 week after AVR, mean EF values were significantly higher in patients after TAVI in comparison with the other groups (TAVI, 50.2% ±13.1%; minithoracotomy, 44.1% ±13.4%; ministernotomy, 37.8% ±12.8%; SAVR, 40.3% ±12.5%; $P = 0.001$). There were no differences in the longest available follow-up mortality between the analyzed groups ($P = 0.8$). To our best knowledge, this is the first study comparing minithoracotomy, ministernotomy, and SAVR with TAVI in terms of long-term outcomes such as the longest available follow-up mortality, left ventricular (LV) function, complications after the procedure, and conduction disturbances and arrhythmias after the procedure.

CONCLUSIONS Patients undergoing TAVI show more beneficial long-term outcomes in comparison with patients undergoing minithoracotomy, ministernotomy, and SAVR and do not differ in terms of the longest available follow-up mortality. TAVI seems to have a more favorable effect on LV function and an increase in EF in comparison with the surgical methods.

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INTRODUCTION Aortic stenosis (AS) is the most common type of acquired valvular heart disease.[1,2] Its incidence increases with age, and from 3% to 9% of adults over 75 years of age develop AS.[3]

Transcatheter aortic valve implantation (TAVI) and minimally invasive aortic valve replacement (minithoracotomy and ministernotomy) have become attractive alternatives to conventional surgical treatment of severe AS in high-risk patients.[4,5] TAVI is considered a safe and effective treatment modality in elderly patients who are not eligible for surgery or who carry an unacceptably high perioperative risk to undergo surgical treatment.[6-9] TAVI is associated with faster

recovery and allows for earlier ambulation in comparison with conventional surgery.[10] The superiority of TAVI over medical therapy has been recently established by the PARTNER trial, and preliminary randomized data confirmed that TAVI is noninferior to surgical aortic valve replacement (SAVR) in terms of safety and effectiveness.[11] The clinical benefits of the above aortic valve replacement (AVR) treatment options have not been widely investigated. Therefore, the aim of this study was to evaluate long-term results in patients with symptomatic AS and treated with TAVI (using transfemoral access), ministernotomy, minithoracotomy, or SAVR.

PATIENTS AND METHODS This report represents a comparative retrospective 2-center registry. The study group consisted of 173 consecutive patients with severe symptomatic AS admitted from January 1, 2011, to December 31, 2013, to the 2nd Department of Cardiology and Cardiovascular Interventions and Department of Cardiovascular Surgery and Transplantology of Jagiellonian University Medical College in Kraków, Poland.

A preprocedural assessment of the included patients involved transthoracic and transesophageal echocardiography, carotid ultrasonography, spirometry, coronary angiography, and evaluation of peripheral access sites by arterial angiography or computed tomography angiography. Individual patient selection involved the assessment of risk level as well as feasibility and safety of the procedure. All patients were evaluated by a dedicated multidisciplinary heart team consisting of cardiac surgeons, interventional cardiologists, anesthesiologists, and radiologists expert in cardiovascular imaging. Clinical decision making was based on a multimodality screening assessment including the evaluation of surgical risk by logistic EuroSCORE and EuroSCORE II.[12] Additional risk criteria were porcelain aorta, advanced liver cirrhosis, severe neurological impairment, and frailty based on the physician's judgment.[12]

After the assessment by the multidisciplinary heart team, patients were allocated to 4 types of AS treatment (transfemoral TAVI, ministernotomy, minithoracotomy, or SAVR). To avoid operator-related influence on the outcome, all procedures were performed by the same team of experienced cardiac surgeons (SAVR, ministernotomy, minithoracotomy) or interventional cardiologists with cardiac surgeons (transfemoral TAVI). Ejection fraction (EF) was measured on the day of hospital admission, on the day of valve replacement after the procedure, and 1 week after the procedure. The definitions of complications were used according to the Valve Academic Research Consortium guidelines (VARC-2).[13] Adverse events were assessed at regular clinical follow-up visits at the hospital or by a standardized telephone interview. Medical history was systematically taken from all patients with suspected or confirmed events. Follow-up was performed perioperatively and 6, 12, and 24 months after the procedure. The analysis was done in the "intention-to-treat" manner. The protocol was approved by the local ethics committee. The study was conducted in accordance with the ethical principles for clinical research based on the Declaration of Helsinki with subsequent amendments.

Statistical analysis Standard descriptive statistical methods were used in the analysis. The normality of the data was assessed with the Shapiro–Wilk test. Quantitative variables were described using means and standard deviations or medians and interquartile ranges. Categorical variables were presented as percentages. A direct comparison between the groups was done using the χ^2 test for categorical variables. One-way analysis of variance with the post hoc Tukey test (for normal distribution with equal variance between the groups) or the Kruskal–Wallis test (for non-normally distributed data) was applied for quantitative variables. The effect of using TAVI versus surgical methods on mortality and other clinical outcome parameters was presented as odds ratios (ORs) and 95% confidence intervals (CIs). To adjust for possible selection bias, a propensity score[14] for each individual's likelihood of being treated with TAVI was calculated based on the following variables: sex, age, previous percutaneous coronary intervention, previous myocardial infarction, peripheral arterial disease, carotid stenosis, and logistic EuroSCORE. Propensity scores were calculated for individuals comparisons between TAVI and minithoracotomy, TAVI and ministernotomy, and TAVI and SAVR. Differences in clinical outcomes between patients treated with TAVI compared with those treated with surgical methods were adjusted for the propensity scores using a logistic regression analysis and presented as adjusted ORs with 95% CIs. The level of statistical significance was set at a P value of 0.05 or lower. All analyses were conducted with the STATISTICA v 10 software (StatSoft, Inc., Kraków, Poland).

RESULTS TAVI was performed in 39 patients (22.5%); ministernotomy, in 44 patients (25.5%); minithoracotomy, in 50 patients (29%); and SAVR, in 40 patients (23%). All procedures were performed electively. TAVI, SAVR, and ministernotomy were performed successfully in all cases. The type of the procedure was changed only in 1 patient, initially scheduled for minithoracotomy (successful in 98% of the cases), but during the intervention, it was changed to SAVR. The Edwards SAPIEN XT valve was implanted in 31 patients (79%), while the Medtronic CoreValve—in 8 patients (21%) allocated to the TAVI group. Transfemoral access was used in all patients undergoing TAVI. In contrast to other groups, patients undergoing TAVI were less frequently male (35.9%, 66%, 45.4%, and 55% for TAVI, minithoracotomy, ministernotomy, and SAVR, respectively; $P = 0.03$) and were significantly older (medican, 80 years [range, 73–83 years], 63 [54–73], 67

TABLE 1 Exercise tolerance measured according to the New York Heart Association classification at baseline and 1 week after treatment

NYHA class		TAVI (n = 39)	MT (n = 50)	MS (n = 44)	SAVR (n = 40)	*P* value
at baseline	I	3.3%	10.5%	13.3%	17.2%	0.0006
	II	22.6%	57.9%	60%	27.6%	
	III	54.8%	31.6%	26.7%	34.5%	
	IV	19.3%	0%	0%	20.7%	
at 1 week	I	78.1%	35.3%	52.8%	56.3%	0.03
	II	18.8%	47.1%	27.8%	28.1%	
	III	3.1%	17.6%	19.4%	15.6%	
	IV	0%	0%	0%	0%	

Abbreviations: MS, ministernotomy; MT, minithoracotomy; NYHA, New York Heart Association; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation

TABLE 2 Mortality in the study groups

Variable	TAVI (n = 39)	MT (n = 50)	MS (n = 44)	SAVR (n = 40)	*P* value
periprocedural mortality	0%	0%	2.3%	2.5%	0.5
in-hospital mortality	5.1%	2.0%	2.3%	2.5%	0.5
30-day mortality	7.7%	2.0%	2.5%	7.5%	0.4
6-month mortality	10.3%	6.0%	2.5%	7.5%	0.6
1-year mortality	10.3%	8.0%	2.5%	7.5%	0.7
longest available follow-up mortality	10.3%	8.0%	6.8%	7.5%	0.8

Abbreviations: see TABLE 1

[57–77], and 69.5 [58–75] for TAVI, minithoracotomy, ministernotomy, and SAVR, respectively; $P = 0.00001$). The TAVI group was at higher periprocedural risk of major complications (EuroSCORE: median, 8 points [range, 7–10 points], 2 [2–5], 4 [2–6], and 5.5 [3–6] for TAVI, minithoracotomy, ministernotomy, and SAVR, respectively; $P = 0.00001$; logEuroSCORE: median, 9.5% [range, 7%–14%], 2.7% [1.8%–3.8%], 4% [2.2%–7%], and 4.5% [2.3%–6.6%] for TAVI, minithoracotomy, ministernotomy, and SAVR, respectively; $P = 0.00001$; EuroSCORE II: median, 3.4% [range, 1.8%–5.4%], 1% [0.7%–1.4%], 1.2% [0.9%–1.6%], and 1.3% [0.8%–2.3%] for TAVI, minithoracotomy, ministernotomy, and SAVR, respectively; $P = 0.00001$). Patients treated with TAVI had a significantly shorter time of the procedure (121.5 ±43 min vs 267.8 ±73 min vs 237.6 ±31 min vs 214 ±41 min for TAVI, minithoracotomy, ministernotomy, and SAVR, respectively; $P = 0.00001$) and lower blood loss (15 ±43 ml, 253.6 ±284.37 ml, 280.9 ±145.6 ml, and 232 ±117.8 ml for TAVI, minithoracotomy, ministernotomy, and SAVR, respectively; $P = 0.00001$). Patients allocated to TAVI underwent significantly more percutaneous transluminal angioplasties (10.3%, 0%, 0%, and 0% for TAVI, minithoracotomy, ministernotomy, and SAVR, respectively; $P = 0.003$), percutaneous coronary interventions (35.9%, 10%, 11.4%, and 10% for TAVI, minithoracotomy, ministernotomy, and SAVR, respectively; $P = 0.002$), and coronary artery bypass grafting procedures (15.4%, 0%, 2.3%, and 5% for TAVI, minithoracotomy, ministernotomy, and SAVR, respectively; $P = 0.008$).

There were no significant differences between the groups in terms of previous carotid artery disease ($P = 0.08$), previous myocardial infarction ($P = 0.9$), previous carotid artery stenting ($P = 0.31$), blood transfusions during hospitalization ($P = 0.5$), complications during the procedure ($P = 0.06$), arrhythmias during the procedure ($P = 0.5$), and sudden cardiac arrest during the procedure ($P = 0.2$). Exercise tolerance was measured using the New York Heart Association (NYHA)classification. The results at baseline and 1 week after the treatment are presented in TABLE 1.

The median follow-up of all patients was 583.5 days (range, 298–736 days). There were no differences between the groups in periprocedural and in-hospital mortality rates or in 30-day, 6-month, 1-year, and total mortality (TABLE 2). A relative risk of total mortality after adjustment for the EuroSCORE, logEuroSCORE, EuroSCORE II, as well as age and sex was calculated for the TAVI and surgical groups using the logistic regresion analysis (TABLE 3). After adjustment for propensity scores using the logistic regresion analysis, patients in the TAVI group seemed to have rather lower total mortality in comparison with the surgical groups, but the difference was not significant (TABLE 3). Complications after the procedure are presented in TABLE 4. The measurements of EF at baseline, after the procedure, and 1 week after the procedure are presented in FIGURE 1. The rate of complications after the procedure and clinical

TABLE 3 Comparison between unadjusted and adjusted odds ratios for all-cause mortality at the longest available follow-up between the study groups

Odds ratio		TAVI vs MT	*P* value[a]	TAVI vs MS	*P* value[b]	TAVI vs SAVR	*P* value[c]
unadjusted		1.3 (0.3–5.6)	0.7	1.6 (0.3–7.5)	0.6	1.4 (0.3–6.8)	0.7
adjusted for	EuroSCORE, points	0.5 (0.06–3.3)	0.4	0.9 (0.1–5.5)	0.9	1.5 (0.3–9.2)	0.6
	logEuroSCORE, %	0.9 (0.2–5.2)	0.9	1.2 (0.2–7.5)	0.9	1.2 (0.2–7.1)	0.8
	EuroSCORE II, %	1.4 (0.3–7.1)	0.7	1.8 (0.3–0.2)	0.5	1.3 (0.3–7)	0.7
	age/sex	0.5 (0.08–2.6)	0.4	0.5 (0.08–3.1)	0.5	0.5 (0.07–3.8)	0.5
	propensity score	0.4 (0.04–3.3)	0.4	0.3 (0.03–1.9)	0.6	0.3 (0.04–2.8)	0.3

Data presented as odds ratio with 95% confidence interval.

a TAVI vs MT; **b** TAVI vs MS; **c** TAVI vs SAVR

Abbreviations: see **TABLE 1**

TABLE 4 Complications after the procedure

Variable	TAVI (n = 39)	MT (n = 50)	MS (n = 44)	SAVR (n = 40)	*P* value
complications in total	35.9	10	13.6	45	0.0002
conduction disturbances	23.1	2	4.6	10	0.004
new LBBB	7.9	0	0	0	0.01
new third-degree AV block	10.5	0	0	2.5	0.01
arrhythmias	18	0	2.3	10.3	0.004
new AF	7.7	0	0	2.5	0.07
retoracotomy	0	2	0	2.5	0.6
hydrothorax	10.3	2	6.8	17.5	0.07
pneumothorax	5.1	4	0	5	0.5
cardiac tamponade	7.7	2	0	0	0.07
paravalvular leak	2.6	0	0	0	0.3
local complication	2.6	0	0	2.5	0.5
hemodialysis	0	0	0	2.5	0.3
implanted valve regurgitation	0	0	0	2.5	0.3
pulmonary edema	2.6	0	0	0	0.3
bleeding	2.6	0	0	0	0.3
drainage, ml	87.9 ±485	450.9 ±343.9	397 ±229.2	829.2 ±787.4	0.0001
intra-aortic balloon contrapulsation	2.6	0	0	0	0.3
stroke/TIA	0	0	0	0	–
MI/cardiogenic shock	0	0	0	0	–
catecholamines	29	96.7	85.7	87.5	0.00001

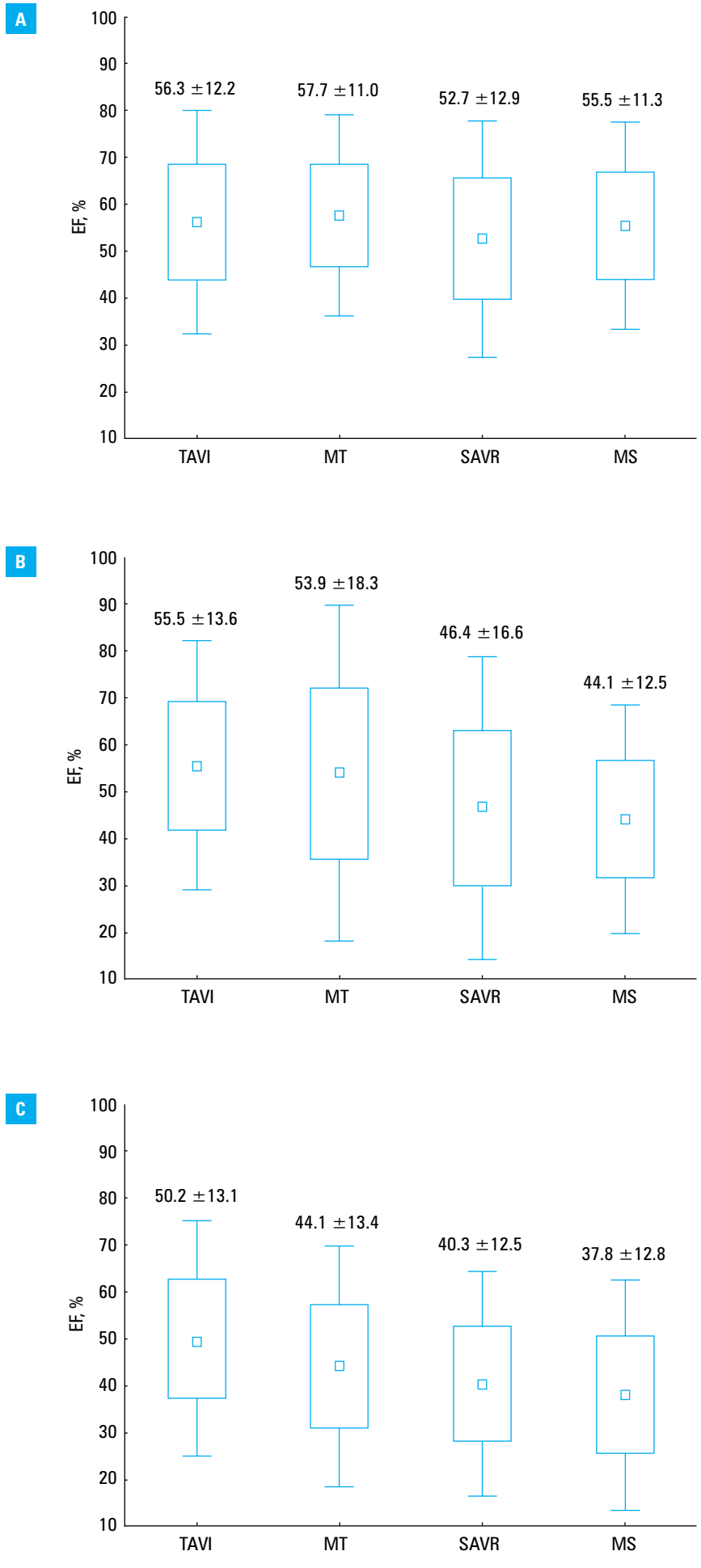
Data are presented as percentage of patients or mean ± standard deviation.

Abbreviations: AF, atrial fibrillation; AV, atrioventricular block; LBBB, left bundle branch block; MI, myocardial infarction; TIA, transient ischemic attack; others, see **TABLE 1**

outcomes for TAVI vs surgical options in the subgroups of patients matched using the propensity score are presented in **TABLE 5**. Laboratory results are presented in **TABLE 6**.

DISCUSSION Our study revelead no differences in the longest available follow-up mortality between patients undergoing TAVI in comparison with those subject to surgical methods such as minithoracotomy, ministernotomy, and SAVR. EF 1 week after the procedure was significantly higher in patients undergoing TAVI in comparison with those undergoing surgical treatment; therefore, TAVI seems to have a favorable effect on left ventricular (LV) function. Complications, conduction disturbances, and arrhythmias after the procedure were significantly more often reported after TAVI in comparison with minithoracotomy and ministernotomy, while there were no differences between TAVI and SAVR. To the best of our knowledge, this is the first study comparing minithoracotomy, ministernotomy, and SAVR with TAVI in terms of clinical results such as the longest available follow-up mortality, LV function, complications after the procedure, and conduction disturbances and arrhythmias after the procedure.

FIGURE 1
Echocardiography results:
A – EF before the procedure ($P = 0.2$);
B – EF after the procedure ($P = 0.01$);
C – EF 1 week after the procedure ($P = 0.001$)
Abbreviations:
EF, ejection fraction; others, see **TABLE 1**



There are no data comparing all 4 types of AVR. The PARTNER Cohort B study demonstrated that patients treated with TAVI had a lower mortality rate compared with those receiving standard medical therapy (medications or medications and balloon aortic valvuloplasty)—30.7% vs 50.7% (P <0.001).[15] The available data on TAVI versus SAVR for patients at a higher surgical risk show similar outcomes for both groups.[16] Previous publications reported that a 30-day mortality rate after TAVI ranged from 3.2% to 15.2%.[17] Our study showed a similar rate of all-cause mortality at 30 days in the TAVI group. In addition, no significant differences were observed between TAVI and surgical treatment options in terms of mortality at any time point of the follow-up. No significant differences between TAVI, minithoracotomy, ministernotomy, and SAVR were found in terms of mortality after the propensity score match. The similar mortality rates for TAVI and surgical treatment options could be due to an evolving device profile, appropriate patient selection by an experienced heart team, skillful operators, or the minimal invasiveness of TAVI.[17]

In the ADVANCE trial,[18] the all-cause mortality rates were low both at 30 days (4.5%) and at 12 months (17.9%).[19] The procedural success rate in the ADVANCE study was 97.8%, and the overall complication rate at 30 days was low.[19] In our study, patients treated with TAVI had a significantly higher total rate of complications after the procedure in comparison with the other groups. We also observed a higher risk of conduction disturbances and arrhythmias after the procedure. After the propensity score match, significant differences between TAVI, minithoracotomy, and ministernotomy were found in terms of complications, arrhythmias, and conduction disturbances after the procedure (TAVI vs minithoracotomy: 35.9% vs 10.3%, P = 0.007; 18% vs 0%, P = 0.005; 23.1% vs 2.6%, P = 0.007; respectively; TAVI vs ministernotomy: 35.9% vs 15.4%, P = 0.004; 18% vs 2.6%; P = 0.02, 23.1% vs 5.3%, P = 0.03; respectively). There were no significant differences in terms of the above complications between TAVI and SAVR (P = 0.5, P = 0.3, and P = 0.06, respectively).

An improvement in the NYHA class 1 week after the procedure was also comparable with the results at 30 days in the ADVANCE study. The 1-year mortality rates in our study compared favorably with the 1-year all-cause mortality rate of 24.2% in TAVI patients in the PARTNER trial (cohort A) and with the mortality rate of 18.9% in the transfemoral TAVI subgroup using the Edwards SAPIEN valve in the SOURCE registry.[6] These results might have been caused by the differences in the baseline risk level of our patients in comparison with the PARTNER trial (cohort A) and the SOURCE registry.

The recently reported CoreValve US Pivotal study, which included 471 high-risk patients implanted with the CoreValve prosthesis (Medtronic Inc, Minneapolis, Minnesota, United States), demonstrated that TAVI is associated with improved outcomes in this inoperable population.[4] TAVI is associated with a high possibility of major vascular complications, cerebrovascular events, or significant prosthetic valve aortic regurgitation (AR).[17] One serious bleeding complication after TAVI was reported in our study. The incidence of major vascular complications varies from 10.7% to 33.3% and depends on the access site, the clinical profile of the treated patients, and the size of the introducer sheaths.[4] A recent study demonstrated that during TAVI embolic debris are liberated from the native aortic valve and aorta and travel to cerebral circulation.[20] Most of the patients with new ischemic defects are asymptomatic; nevertheless, the incidence of stroke after TAVI reaches 6.7%.[19] In our study, neither stroke nor transient ischemic attack occurred. A severely stenotic and calcified aortic valve, the use of large delivery systems, and multiple manipulations during device implantation (ie, balloon postdilation and device repositioning) have been associated with an increased risk of debris embolization.[4]

New-onset atrial fibrillation (NOAF) may also promote embolus formation and embolization. The effectiveness of cerebral embolic protection devices in decreasing the risk of stroke has not been proved so far. NOAF is a frequent complication associated with TAVI with about half of the AF episodes occurring within 24 hours and more than 80%—within the first 3 days after the procedure.[21] NOAF is associated with an increased rate of cardioembolic events following the procedure. Amat-Santos et al[21] reported an incidence of NOAF reaching 31% of the patients with no prior chronic/paroxysmal AF, undergoing TAVI with a balloon-expandable valve by transfemoral or transapical approach. In PARTNER Cohort A, the incidence of NOAF within 30 days was 15% in patients with no prior AF.[21] Two-thirds of the patients included in the PARTNER trial underwent the procedure by transfemoral approach. The rate of NOAF was close to the rate of 16% observed by Amat-Santos et al[21] in a cohort of patients undergoing transfemoral TAVI. In our study, the incidence of NOAF after TAVI was 7.7%, with no statistical differences between the groups. After the propensity score match, no differences were found between TAVI and other groups (TAVI vs minithoracotomy, P = 0.08; TAVI vs ministernotomy, P = 0.08; TAVI vs SAVR, P = 0.3).

Older age, the use of the Medtronic CoreValve revalving system, the presence of right bundle branch block, a low placement of the prosthesis, a porcelain aorta, and valve oversizing are associated with conduction disorders that require pacemaker implantation.[4] There is evidence that conduction disorders have a negative effect on systolic LV function and on the patient's functional status.[4] A recent study demonstrated an incidence of new conduction disturbances after TAVI of up to 43%, the most common (35%) being the left bundle branch block (LBBB).[22] Other studies reported a similar incidence or higher.[23,24] A few

TABLE 5 Complications after the procedure and clinical outcomes after the propensity score match in the study groups

Variable	TAVI (n = 39)	MT (n = 50)	MS (n = 44)	SAVR (n = 40)	*P* value[a]	*P* value[b]	*P* value[c]
new third-degree AV block	13	0	0	2.6	0.02	0.02	0.08
catecholamines	29	96.7	86.5	89.7	0.00001	0.00001	0.00001
EF at 1 week, %	50.2 ±13.1	42 ±12	37.6 ±13.1	40.9 ±12.2	0.003	0.0005	0.003
CKMB, U/l	37 ±25	99.6 ±208	42 ±13.5	80.6 ±77.2	0.17	0.006	0.00001
troponin T, ng/ml	0.4 ±0.3	0.7 ±1	0.5 ±0.3	0.9 ±0.6	0.54	0.35	0.00006

Data are presented as mean ± standard deviation or percentage.

P value is adjusted for propensity match score.

a TAVI vs MT; **b** TAVI vs MS; **c** TAVI vs SAVR

Abbreviations: CKMB, creatine kinase-MB; others, see **TABLE 1**, **TABLE 4**, and **FIGURE 1**

TABLE 6 Laboratory results at baseline and after the procedure

Variable	TAVI (n = 39)	MT (n = 50)	MS (n = 44)	SAVR (n = 40)	*P* value
postprocedural CKMB, U/l	30 (22–37)	30 (24–81)	44 (35–56)	79 (41–76)	0.00001
postprocedural troponin T, ng/ml	0.4 (0.3–0.5)	0.3 (0.2–0.6)	0.4 (0.3–0.7)	0.9 (0.5–1)	0.00001
Hb at baseline, g/dl	12 ±2.1	11 ±1.7	12.6 ±1.8	13.6 ±1.4	0.00001
postprocedural Hb, g/dl	10 ±1.4	10.4 ±1.5	10.4 ±1.1	11.1 ±1.4	0.008

Data are presented as mean ± standard deviation or median (interquartile range).

Abbreviations: Hb, hemoglobin; others, see **TABLES 1** and **2**

series of 10 to 102 patients described new pacemaker implantation due to new-onset complete heart block (NOCHB) in 27% to 33% of the patients undergoing TAVI with CoreValve implantation and in 4% to 12%—with Edwards SAPIEN implantation.[25] A recently published analysis of 200 patients reported new pacemaker implantation due to NOCHB in 22% of the particpants.[25] Following SAVR, new-onset bundle branch block was reported in 16% to 32% of the patients and the need for permanent pacemakers—in 3% to 8% of the patients.[26] In our study, we reported a significantly higher risk of new LBBB and third-degree atrioventricular (AV) block in patients undergoing TAVI (**TABLE 4**). No significant differences in the risk of new LBBB were found between TAVI and surgical methods after the propensity score match (TAVI vs minithoracotomy, $P = 0.08$; TAVI vs ministernotomy, $P = 0.08$; TAVI vs SAVR $P = 0.3$). The rates of new third-degree AV block in TAVI as compared with surgical methods after the propensity score match are presented in **TABLE 5**.

TAVI seems to reduce LV afterload, increase LVEF, and promote LV remodeling. These changes have a beneficial effect on mitral valve performance. Several reports have shown a decrease in the severity of mitral regurgitation after TAVI.[4] In a study comparing LV function between patients undergoing transcatheter and surgical valve implantation, patients undergoing TAVI showed a better recovery of LVEF at 1 year.[27] In our analysis, as well as others that reported improvement in LVEF after TAVI, the Edwards SAPIEN valve was used for the procedure.[27] On the other hand, studies regarding TAVI with the CoreValve prosthesis did not demonstrate a significant improvement in LVEF after the implantation.[28] The different rates of conduction disturbances, in particular LBBB, could possibly explain the differences in LVEF after TAVI using Edwards SAPIEN versus TAVI using CoreValve implants.

In our study, no significant differences in EF before AVR were observed between the groups ($P = 0.2$). LVEF was significantly higher in TAVI patients after the procedure and 1 week after the procedure in comparison with patients undergoing SAVR, ministernotomy, and minithoracotomy (**FIGURE 1**). Significant differences between TAVI and surgical approaches in terms of EF assessed 1 week after the procedure were maintained even after the propensity score match (**TABLE 5**). Patients allocated to TAVI showed a significantly smaller decrease in the mean value of LVEF before AVR, after AVR, and 1 week after AVR in comparison with the other treatment options.

Moderate or severe paravalvular AR after TAVI is reported in around 15%.[4] Published data have shown that moderate or severe AR after TAVI is associated with worse outcomes and is an independent predictor of mortality.[4] In the PARTNER study, the presence of mild AR was associated with worse prognosis.[4] In our study, paravalvular AR was observed only in 1 patient. Myocardial injury (MI), defined as an elevated troponin level greater than 20 times the 99th percentile in patients with normal baseline levels is observed in most patients undergoing TAVI.[29] A recent study demonstrated an association between increased

cardiac enzyme levels and improvement in LVEF after TAVI.[29] A small study demonstrated no association between MI and mortality, and yet another study, including 119 patients, demonstrated that MI was an independent predictor of 30-day mortality.[29,30,31] Neither MI nor cardiogenic shock after the procedure was observed in our study. Biochemical markers of MI were significantly less elevated after TAVI in comparison with ministernotomy and SAVR (TABLE 6). Patients undergoing TAVI had similar levels of creatine kinase-MB and significantly higher levels of troponin T after the procedure in comparison with the minithoracotomy group (TABLE 6). The comparison of biochemical markers of MI between TAVI and surgical methods after the propensity score match is presented in TABLE 5. Significantly higher blood loss in surgical treatment options was probably connected with a higher need for blood transfusions and resulted in a significantly lower hemoglobin levels after the procedure in the TAVI group (TABLE 6).

Clinical risk models designed to predict outcomes following SAVR, such as the EuroSCORE, the EuroSCORE II, the logistic EuroSCORE, the Society of Thoracic Surgeons, and the Society of Thoracic Surgeons Predicted Risk of Mortality (PROM), have low accuracy in predicting mortality after TAVI.[4] Van Mieghem et al[32] proposed a new risk stratification model specially designed for patients undergoing TAVI, the so called SURTAVI model. It includes common risk factors and variables that seem to affect outcomes in patients undergoing TAVI, such as frailty, the presence of a porcelain aorta, complex chest deformity, previous extensive mediastinal radiation, and advanced liver failure, but it does not include anatomic features that have been associated with an increased risk of complications.[4] Further studies are needed to design an appropriate clinical prognostic model for risk assessment in patients undergoing TAVI.

Limitations The main limitation of this study is a nonrandomized design and 2-center retrospective data collection. A low total number of patients and small subgroups are also an important limitation. There is a potential bias caused by patients lost to follow-up. Finally, despite significant results, it would be interesting to see the results at longer follow-up in future studies.

Conclusions Our data showed that patients after TAVI have more beneficial long-term outcomes in comparison with patients undergoing ministernotomy, minithoracotomy, or SAVR. No differences were found in terms of the longest available follow-up mortality between the analyzed groups. TAVI seems to have a more favorable effect on LV function and an increase in EF in comparison with ministernotomy, minithoracotomy, and SAVR. These findings support the indication for TAVI in patients with contraindications to surgery (such as advanced age or multiple comorbidities). The available results indicate that TAVI is an acceptable alternative to surgery in selected high-risk patients. Further studies focusing on how to lower the rates of common complications are needed.

Contribution statement TT conceived the idea for the study and prepared the manuscript. DD, JS, ZS, AD, and RS contributed to the design of the research. TT, AD, ZS, and RS coordinated this research at all steps of the study. All authors were involved in data collection and follow-up of the patients. TT and AD conducted the statistical analysis. All authors participated in the analysis and interpretation of the data. All authors revised the manuscript critically for important intellectual content. All authors edited and approved the final version of the manuscript.

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ARTYKUŁ ORYGINALNY

Wyniki odległe po chirugicznej i przezskórnej wymianie zastawki aortalnej

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SŁOWA KLUCZOWE

ministernotomia, minitorakotomia, stenoza aortalna, wskaźnik skłonności

STRESZCZENIE

WPROWADZENIE Przezskórna implantacja zastawki aortalnej (*transcatheter aortic valve implantation* – TAVI) i minimalnie inwazyjna wymiana zastawki aortalnej (minitorakotomia i ministernotomia) stały się wartościową alternatywą dla klasycznej kardiochirurgicznej operacji u pacjentów obciążonych wysokim ryzykiem z ciężką objawową stenozą aortalną (*aortic stenosis* – AS).

CELE Celem pracy była ocena długoterminowych wyników i powikłań u pacjentów z objawową AS i leczonych za pomocą TAVI, operacyjnej wymiany zastawki aortalnej (*surgical aortic valve replacement* – SAVR), minitorakotomii lub ministernotomii.

PACJENCI I METODY 173 pacjentów z objawową AS zostało włączonych do badania w latach 2011–2013. Wskaźnik skłonności (ang. *propensity score*) został policzony osobno dla TAVI i każdej metody kardiochirurgicznej. Różnice w wynikach klinicznych pacjentów po TAVI w porównaniu z metodami chirurgicznymi zostały dostosowane do wskaźnika skłonności za pomocą analizy regresji logistycznej i zaprezentowane jako skorygowany iloraz szans z 95% przedziałem ufności.

WYNIKI Średnia długość obserwacji pacjentów wyniosła 583,5 dni (przedział międzykwartylowy: 298–736 dni). Przed wymianą zastawki aortalnej (*aortic valve replacement* – AVR) nie znaleziono istotnych statystycznie różnic między grupami w zakresie frakcji wyrzutowej (*ejection fraction* – EF). Tydzień po AVR stwierdzono istotnie statystycznie wyższą średnią wartość EF u pacjentów po TAVI w porównaniu z pozostałymi grupami (TAVI: 50,2% ±13,1%; minitorakotomia: 44,1% ±13,4%; minsternotomia: 37,8% ±12,8%; SAVR: 40,3% ±12,5%; p = 0,001). Nie stwierdzono różnic między grupami w zakresie śmiertelności w ciągu całego okresu obserwacji (p = 0,8). Według naszej wiedzy nasze badanie jako pierwsze porównało TAVI z minitorakotomią, ministernotomią i SAVR pod względem wyników odległych, takich jak śmiertelność w najdłuższym dostępnym okresie obeserwacji, funkcja skurczowa lewej komory, powikłania po zabiegu oraz zaburzenia przewodnictwa i rytmu po zabiegu.

WNIOSKI Pacjenci po TAVI mają korzystniejsze wyniki leczenia w porównaniu z minitorakotomią, ministernotomią i SAVR. Nie stwierdzono różnic między grupami w zakresie śmiertelności w ciągu całego okresu obserwacji. TAVI ma korzystniejszy wpływ na poprawę funkcji lewej komory i wzrost EF w porównaniu z metodami chirurgicznymi.

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