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ORIGINAL RESEARCH

Early outcomes of transapical mitral valve implantation versus surgical replacement in matched elderly patients at intermediate surgical risk

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ABSTRACT

BACKGROUND: Data comparing transcatheter mitral valve implantation (TMVI) with surgical mitral valve replacement (SMVR) are lacking.

AIMS: This study sought to compare the 30-day Valve Academic Research Consortium (VARC)-3 device success of TMVI with that of SMVR.

METHODS: Matching protocol combined exact matching (sex, atrial fibrillation, previous surgical aortic valve replacement [SAVR] or coronary artery bypass grafting [CABG]), coarsened exact matching (age) and propensity score matching (body mass index, mitral valve pathology and concomitant tricuspid regurgitation).

RESULTS: A total of 40 Tendyne TMVI and 80 SMVR patients with similar baseline characteristics were analysed (TMVI vs SMVR): age (78 years [interquartile range {IQR}75; 80] vs 78 years [IQR 73; 80]; p=0.8), female (60% vs 60%; p=1.0), atrial fibrillation (67.5% vs 63.7%; p=0.8), previous SAVR (12.5% vs 10.0%; p=0.8), previous CABG (20.0% vs 16.2%; p=0.8), body mass index (25.54 kg/m² vs 25.24 kg/m²; p=0.7) and valve pathology (mitral regurgitation: 70.0% vs 73.8%, mitral stenosis: 7.5% vs 3.8%, and mixed disease: 22.5% vs 22.5%; p=0.6). Most baseline characteristics not included in the matching model were balanced among the TMVI/SMVR cohorts: European System for Cardiac Operative Risk Evaluation (EuroSCORE) II (5.8% [IQR 2.9; 7.5] vs 4.2% [IQR 2.4; 6.8]; p=0.3) and Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score (5.2% [IQR 3.2; 8.6] vs 4.1% [IQR 3.3; 6.1]; p=0.076). Coronary artery disease (67.5% vs 32.5%; p<0.001) and previous percutaneous coronary intervention (47.5% vs 25.0%; p=0.023) differed among groups. Mitral VARC (MVARC) device success at 30 days was achieved in 82.5% of patients after TMVI and 57.5% of patients after SMVR (p=0.04). MVARC procedural success at 30 days was 75.0% after TMVI versus 52.5% after SMVR (p=0.07). Thirty-day mortality (2.5% vs 3.8%; p=0.47), technical success (97.5% vs 97.5%; p=1.0), major bleeding (17.5% vs 18.7%; p=0.087), stroke (5.0% vs 4.9%; p=1.0) and postoperative haemodialysis (7.5% vs 5.2%; p=0.4) were similar in both groups.

CONCLUSIONS: Patients with intermediate surgical risk, according to STS-PROM and EuroSCORE II, demonstrated higher rates of MVARC device at 30 days after TMVI compared to 30 days after SMVR. Rates of survival and procedural success, neurological, renal and bleeding complications were similar. Transfusion count and length of stay were lower after TMVI. For elderly patients at intermediate risk, a TMVI eligibility assessment may be considered.

KEYWORDS: mitral regurgitation; mitral valve disease; transapical

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Transcatheter mitral valve implantation (TMVI) is a less invasive treatment for patients who are ineligible for surgery or at a high surgical risk. While multiple TMVI devices are under investigation in clinical trials, the Tendyne mitral valve system (Abbott) is currently the only commercially available device, having received European conformity (CE) approval in 2020. TMVI with the Tendyne device achieves a sustained elimination of mitral regurgitation at 2 years and a reduction of rehospitalisation for heart failure symptoms[1]. The role of TMVI compared to edge-to-edge repair and mitral valve surgery is not yet well defined. The SUMMIT trial is currently randomising patients to TMVI with the Tendyne device or mitral valve edge-to-edge repair (ClinicalTrials.gov: NCT03433274). The initial trial design – randomising subjects to TMVI with Tendyne or surgical mitral valve replacement (SMVR) – was modified to the current protocol when edge-to-edge repair received U.S. Food and Drug Administration (FDA) approval. In this study, we aim to compare the early outcomes of TMVI using the Tendyne device with those of SMVR.

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Impact on daily practice

In this retrospective study, transcatheter mitral valve implantation achieved higher Mitral Valve Academic Research Consortium device and procedural success compared to surgical mitral valve replacement (SMVR). These are promising data for an evolving technology which is being developed as a complementary therapy to mitral edge-to-edge repair and SMVR. Future randomised trials are required to confirm our findings.

Methods

The study was approved by the local ethics committee (2023-359-S-KH) and was conducted in accordance with the Declaration of Helsinki.

PATIENTS AND DATA COLLECTION

Patients who underwent TMVI with the Tendyne mitral valve system were identified from the institutional TMVI database. To obtain a control group with comparable baseline characteristics, all patients who underwent SMVR between 2000 and 2022 were identified from our institutional database. Tricuspid valve repair was the only approved concomitant procedure among the SMVR cohort in the current analysis. Of the 1,278 identified patients, we excluded patients who had received mechanical valves, patients who had undergone emergency mitral valve surgery, patients with infective endocarditis of the mitral valve, and patients with previous mitral valve operations. Subsequently, 504 SMVR patients remained, of whom 454 had a complete dataset eligible for matching. These patients were matched at a rate of 1 TMVI patient to 2 SMVR patients using a combination of exact, coarsened exact and propensity score matching. The detailed matching protocol is described in the statistical analysis section of this article.

Thirty-day outcomes were reported according to Mitral Valve Academic Research Consortium (MVARC) recommendations[2]. All patients provided informed consent for the procedure.

TMVI WITH THE TENDYNE MITRAL VALVE SYSTEM

TMVI was performed with transoesophageal echocardiography (TOE) guidance via transapical access under general anaesthesia. Cutting of the anterior mitral valve leaflet (MitraCut technique) was executed as previously described if left ventricular outflow tract obstruction (LVOTO) caused by a long and poorly tethered anterior mitral valve leaflet (AML) was anticipated[3]. After achieving an intra-annular position of the sealing body, the Tendyne valve was fully released from the catheter, and the tether was anchored to the apical pad. For a more detailed description of the Tendyne implantation procedure, please refer to **Supplementary Appendix 1**.

SURGICAL MITRAL VALVE REPLACEMENT

SMVR was performed after a full sternotomy or a left anterolateral minithoracotomy. Under cardiopulmonary bypass and cardioplegic cardiac arrest, mitral valve replacement with or without tricuspid valve repair was performed with a biological mitral valve prosthesis.

STATISTICAL ANALYSIS

Continuous variables are reported as mean±standard deviation (SD) or median (interquartile range [IQR]) and were compared using the Student's t-test. Categorical variables are reported as numbers (percentage) and were compared using the chi-square test or Fisher's exact test. In-hospital events are reported as incidence (percentage) and presented as odds ratios (ORs) with 95% confidence intervals (CIs). Mortality, stroke, and other safety outcomes at 30 days were calculated using logistic regression or g-computation, and results are presented as ORs or risk ratios (RRs) with 95% CIs. A 2-tailed p-value of <0.05 was considered to indicate statistical significance. Statistical analyses were performed using R software (R Foundation for Statistical Computing).

For matching, a limited set of variables was used: the only included variables were those which had a complete data set in the institutional database. The matching procedure was a combination of exact matching, coarsened exact matching and propensity score matching. Sex, atrial fibrillation and previous surgical aortic valve replacement (SAVR) or coronary artery bypass grafting (CABG) were exactly matched. Coarsened exact matching using 3-year intervals was used for patient age. Mitral valve pathology, body mass index (BMI) and concomitant tricuspid regurgitation were matched by propensity score. For the subset of patients with previous

Abbreviations

LV	left ventricle	**SMVR**	surgical mitral valve replacement	**TOE**	transoesophageal echocardiography
LVOT	left ventricular outflow tract	**STS-PROM**	Society of Thoracic Surgeons Predicted Risk of Mortality	**TMVI**	transcatheter mitral valve implantation

SAVR or CABG, the matching protocol was less stringent in propensity score matching for age and mitral valve pathology and less stringent in exact matching for sex due to the small number of suitable patients in the surgical database. For the distribution of variables before and after matching, please refer to **Supplementary Table 1**. After matching, all pre- and postoperative variables were reviewed, and operative risk scores were recalculated for the matched patients to ensure optimal data quality. Differences in 30-day mortality and MVARC combined endpoints between the groups were calculated using g-computation. The outcome model used for g-computation was a logistic regression model that included all variables used for matching, as well the variables "diabetes mellitus" and "coronary artery disease", which were unbalanced among the two groups after matching. The model was used to calculate the average treatment effect on the treated (ATT), using cluster-robust standard error. In particular, the R packages "MatchIt" and "marginaleffects" (R Foundation for Statistical Computing) were used for matching and g-computation.

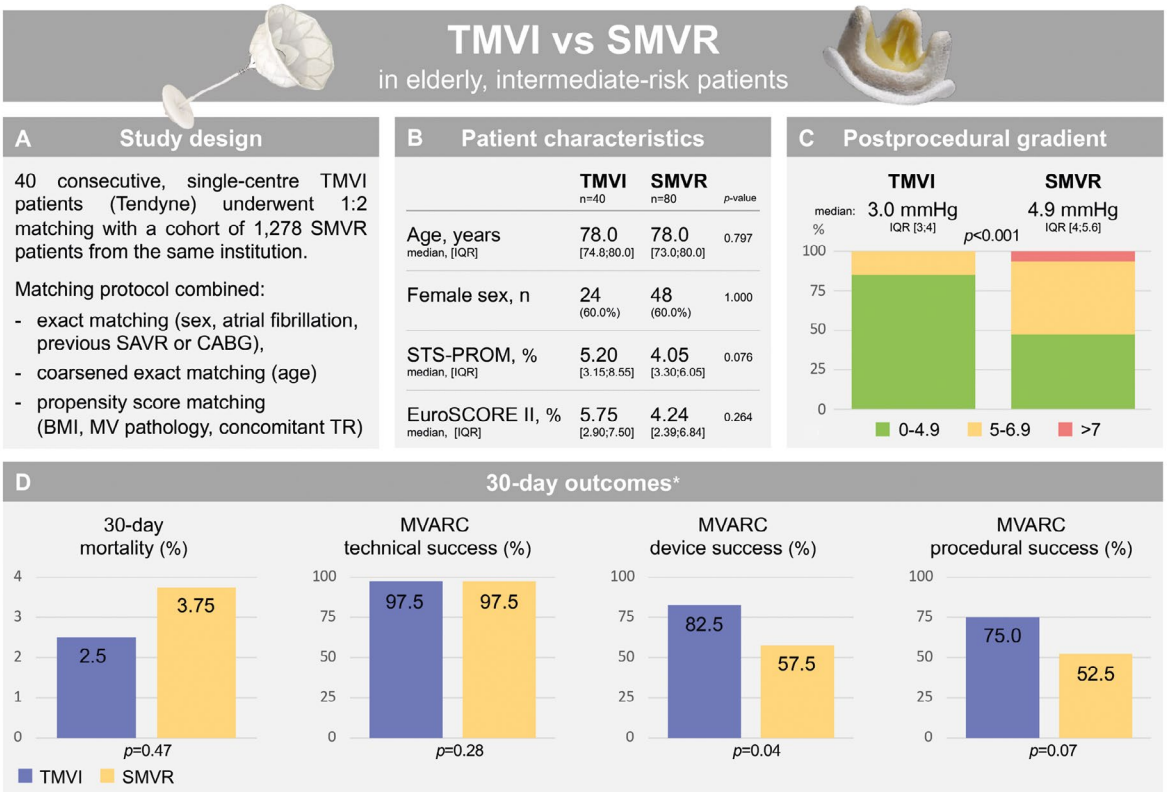
Results

Between June 2020 and May 2023, 40 patients underwent TMVI with the Tendyne device at the German Heart Center Munich. Among 1,278 patients undergoing SMVR between 2000 and 2022 at our department, the 1:2 matching protocol was performed as mentioned above and resulted in 80 SMVR patients serving as a control group **(Central illustration)**. Of these, 24 patients (30%) had received concomitant tricuspid valve repair.

The baseline variables **(Figure 1, Table 1)** included in the matching protocol were well balanced among the groups (TMVI vs SMVR): mean age (78 years [IQR 75; 80] vs 78 years [IQR 73; 80]; p=0.797), female sex (60% vs 60%;

EuroIntervention — Central **Illustration**

Outcomes of transcatheter mitral valve implantation versus surgical mitral valve replacement in matched elderly patients.



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**p-values were calculated using g-computation (ATT). A) Study design, B) baseline patient characteristics, C) postprocedural transvalvular gradient and D) 30-day outcomes. ATT: average treatment effect on the treated; BMI: body mass index; CABG: coronary artery bypass grafting; EuroSCORE: European System for Cardiac Operative Risk Evaluation; IQR: interquartile range; MV: mitral valve; MVARC: Mitral Valve Academic Research Consortium; SAVR: surgical aortic valve replacement; SMVR: surgical mitral valve replacement; STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; TMVI: transcatheter mitral valve implantation; TR: tricuspid regurgitation*

p=1.0), atrial fibrillation (67.5% vs 63.7%; p=0.839), previous SAVR (12.5% vs 10.0%; p=0.785), previous CABG (20.0% vs 16.2%; p=0.799), BMI (25.54 kg/m² vs 25.24 kg/m²; p=0.723) and mitral valve pathology (mitral regurgitation: 70.0% vs 73.8%, mitral stenosis: 7.5% vs 3.8% and mixed disease: 22.5% vs 22.5%; p=0.648). Most baseline characteristics not included in the matching model were also balanced **(Table 1)**; among these were left ventricular ejection fraction (p=0.07), pulmonary hypertension (p=0.998), previous myocardial infarction (p=1.0), creatinine levels (p=0.259), chronic obstructive pulmonary disease (COPD; p=1.0), European System for Cardiac Operative Risk Evaluation (EuroSCORE) II (p=0.264) and Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM; p=0.076). Differences among the groups (TMVI vs SMVR) were seen for aetiologies of mitral regurgitation (MR; primary MR: 45.0% vs 69.0%, secondary MR: 17.5% vs 2.5%, mixed aetiology: 27.5% vs 22.5%; p=0.01), diabetes mellitus (27.5% vs 11.2%; p=0.046), prevalence of coronary artery disease (67.5% vs 32.5%; p<0.001) and previous percutaneous coronary intervention (47.5% vs 25.0%; p=0.023).

PROCEDURAL DATA

The procedure time for SMVR (median: 217 min [IQR 180; 265], isolated SMVR: 205 min [IQR 176; 252], SMVR and tricuspid repair: 239 min [IQR 209; 286]) was significantly longer than that for TMVI (median: 112 min [IQR 97; 140]; p<0.001). An SMVR with a full sternotomy was performed in 76 patients; a right-sided anterolateral minithoracotomy was performed in 4 patients. Inotropic support was administered in all SMVR procedures and in 27.5% of TMVI procedures (p<0.001). In the SMVR group, 24 patients (30%) received concomitant tricuspid valve repair, while no tricuspid valve procedures were performed in the TMVI group (p<0.001).

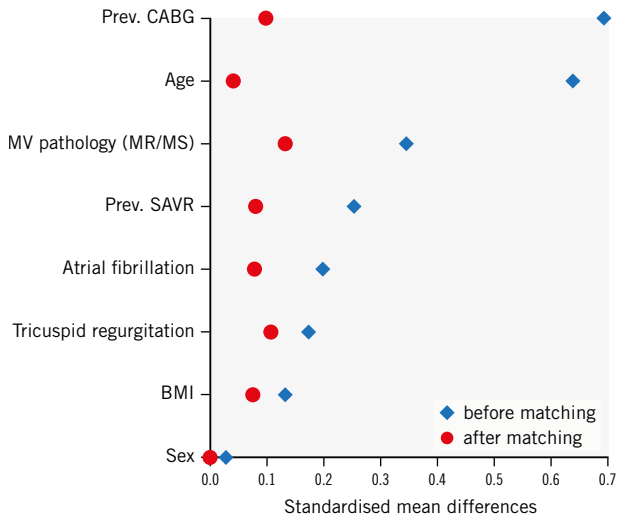

Figure 1. *Love plot. Squares and circles depict the standardised mean differences of variables before and after matching. Only variables included in the matching protocol are shown. BMI: body mass index; CABG: coronary artery bypass graft; MR: mitral regurgitation; MS: mitral stenosis; MV: mitral valve; prev.: previous; SAVR: surgical aortic valve replacement*

In 2 TMVI patients, a simultaneous transcatheter aortic valve implantation was performed (1 transapical, 1 transfemoral). A MitraCut of the AML was executed in 2 procedures prior to Tendyne implantation. Apical bleeding required a femoral cardiopulmonary bypass and unloading of the left ventricle to achieve haemostasis in 1 procedure. Throughout all the TMVI procedures, there was no embolisation of the Tendyne valves, no retrieval of the prosthetic valve was required and no intraprocedural LVOTO occurred; the mean left ventricular outflow tract (LVOT) gradient measured 6.7±6.3 mmHg. MVARC technical success was similar after TMVI (97.5%) and after SMVR (97.5%; p=0.28) **(Table 2)**.

IN-HOSPITAL AND 30-DAY OUTCOMES

Table 2 shows 30-day mortality rates and MVARC composite endpoints. MVARC device success at 30 days was achieved in 82.5% of patients after TMVI and in 57.5% of patients after SMVR (p=0.04).

MVARC procedural success at 30 days was achieved in 75% of patients after TMVI and in 52.5% of patients after SMVR (p=0.07) **(Central illustration)**. **Table 3** displays the clinical outcome at 30 days after TMVI and SMVR and the single endpoints defining MVARC device and procedural success. Patients had shorter lengths of stay in the intensive care unit (p<0.001) and in hospital (p=0.004) after TMVI compared to SMVR. The red blood cell transfusion count was lower after TMVI compared to after SMVR (p<0.001). The transprosthetic mitral gradient **(Figure 2)** measured 3 mmHg (IQR 3; 4) after TMVI and 4.9 mmHg (IQR 4.0; 5.6) after SMVR (p<0.001). Trace (TMVI 5%, SMVR 0%) and mild paravalvular leakage (TMVI 5%, SMVR 0%) differed among the groups (p=0.005). The mean LVOT gradient after TMVI measured 4.5 mmHg [IQR 3.0; 9.3]. Thirty-day mortality, major bleeding complications, stroke, and renal failure requiring haemodialysis were comparable among groups.

One patient developed a significant LVOTO after TMVI which was related to the systolic anterior motion of the anterior mitral valve leaflet and required LVOT stent-graft implantation on day 21 after the procedure.

Discussion

This is the first study comparing TMVI with the Tendyne mitral valve system to SMVR. The main findings of our study are as follows:

- TMVI achieved higher MVARC device success at 30 days compared to SMVR.
- Thirty-day mortality was comparable after TMVI (2.5%) and SMVR (3.8%).
- Bleeding complications (Bleeding Academic Research Consortium >Type 3a), stroke and renal failure were similar after TMVI and SMVR.
- Intensive care unit length of stay and hospital length of stay were shorter after TMVI than SMVR.

SURVIVAL

Thirty-day mortality after SMVR has been reported at 4.0% in younger patients (mean age 69 years) suffering from secondary mitral regurgitation (SMR) and between 9.2% and 19.0% in elderly patients (mean age 78-83 years) with

Table 1. Baseline characteristics.

	SMVR n=80	TMVI n=40	*p*-value
Baseline - patient characteristics			
Female	48 (60.0)	24 (60.0)	1.000
Age, years	78.0 [73.0; 80.0]	78.0 [74.8; 80.0]	0.797
BMI, kg/m^2	25.2±3.97	25.5±4.01	0.723
GFR, ml/min	55.0 [45.5; 75.0]	50.0 [41.8; 70.5]	0.469
Creatinine, mg/dl	1.10 [0.90; 1.30]	1.20 [0.90; 1.42]	0.259
Diabetes mellitus	9 (11.2)	11 (27.5)	0.046
Hypertension	64 (80.0)	26 (65.0)	0.118
Coronary artery disease	26 (32.5)	27 (67.5)	0.001
Myocardial infarction	17 (21.2)	8 (20.0)	1.000
Atrial fibrillation	51 (63.7)	27 (67.5)	0.839
Previous stroke	7 (8.75)	6 (15.0)	0.355
COPD	17 (21.2)	8 (20.0)	1.000
STS-PROM, %	4.05 [3.30; 6.05]	5.20 [3.15; 8.55]	0.076
EuroSCORE II, %	4.24 [2.39; 6.84]	5.75 [2.90; 7.50]	0.264
Baseline - echocardiography			
MV disease			0.649
Regurgitation	59 (73.8)	28 (70.0)	
Stenosis	3 (3.75)	3 (7.50)	
Mixed	18 (22.5)	9 (22.5)	
MR grade			0.435
None-mild	6 (7.5)	5 (12.5)	
Moderate	6 (7.5)	2 (5.0)	
Severe	68 (85.0)	32 (80.0)	
MR aetiology			0.010
Primary	55 (68.8)	18 (45.0)	
Secondary	2 (2.5)	7 (17.5)	
Mixed	18 (22.5)	11 (27.5)	
LVEF			0.071
≥50%	63 (78.8)	25 (62.5)	
41-49%	4 (5.0)	7 (17.5)	
≤40%	12 (15.0)	8 (20.0)	
LVEDD, mm	51.5±10.4	53.3±8.94	0.505
Systolic PAP, mmHg	47.0 [40.0; 63.0]	48.5 [38.2; 66.0]	0.988
Baseline – previous cardiac procedures			
MV edge-to-edge repair	3 (3.75)	0 (0)	0.550
PCI	20 (25.0)	19 (47.5)	0.023
CABG or SAVR	20 (25.0)	10 (25.0)	1.000
CABG	13 (16.2)	8 (20.0)	0.799
SAVR	8 (10.0)	5 (12.5)	0.758

Data are presented as n (%), median [Q1; Q3] or mean±SD. BMI: body mass index; CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; EuroSCORE: European System for Cardiac Operative Risk Evaluation; GFR: glomerular filtration rate; LVEDD: left ventricular end-diastolic diameter; LVEF: left ventricular ejection fraction; MR: mitral regurgitation; MV: mitral valve; PAP: pulmonary artery pressure; PCI: percutaneous coronary intervention; Q1: first quartile; Q3: third quartile; SAVR: surgical aortic valve replacement; SD: standard deviation; SMVR: surgical mitral valve replacement; STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; TMVI: transcatheter mitral valve implantation

predominantly primary mitral valve disease[4-8]. Comparison of previously reported mortality data with the 3.8% short-term mortality of our SMVR cohort is biased by the younger age of the SMR patients and by the rates of concomitant aortic valve or CABG procedures, which ranged from 34% to 48% and 55% to 75%, respectively, in previous studies[4-8].

Mortality at 30 days after TMVI with the Tendyne device was 2.5% in our cohort, whereas previous studies

Table 2. Thirty-day mortality and MVARC composite endpoints.

	SMVR n=80	TMVI n=40	Risk ratio (95% CI)	*p*-value
30-day mortality	3 (3.75)	1 (2.50)	0.66 (0.21-2.07)	0.47
Technical success	78 (97.5)	39 (97.5)	0.98 (0.93-1.02)	0.28
Device success	46 (57.5)	33 (82.5)	1.38 (1.01-1.89)	0.04
Procedural success	42 (52.5)	30 (75.0)	1.37 (0.96-1.95)	0.07

Data are presented as n (%). Risk ratios were calculated using g-computation. CI: confidence interval; MVARC: Mitral Valve Academic Research Consortium; SMVR: surgical mitral valve replacement; TMVI: transcatheter mitral valve implantation

reported higher 30-day mortality ranging from 6% to 10.2% and 12%[9-11]. These patients were younger (mean age 75 years[9-11]), showed a higher prevalence of SMR (89%, 69% and 37%) and had a higher STS-PROM score (6.5%, 7.7% and 7.8%) while still resulting in an intermediate operative risk profile[9-11].

IN-HOSPITAL ADVERSE EVENTS AFTER TMVI AND SMVR

The stroke rate (5%, n=2) of our TMVI cohort at 30 days was higher than the 2-3% reported in previous TMVI studies[9-11]. It is worthy of note that 1 patient from our cohort had suffered at least 2 strokes prior to TMVI, significantly increasing his perioperative stroke risk[12]. The occurrence of perioperative stroke after TMVI was similar to that in the SMVR control group (4.9%) and comparable to previously reported SMVR data ranging from 3.1% to 5.0%[4-6].

Renal failure requiring haemodialysis has been reported to be considerably higher (13.0% to 19.6% of patients) after SMVR compared to after TMVI (5% to 8% of patients)[6,7,9,11]. Our data (7.5% of TMVI patients vs 15.2% of SMVR patients) are in line with these findings. However, the difference in renal failure between TMVI and SMVR patients did not reach statistical significance.

In our study, the occurrence of MVARC major bleeding complications was comparable between the TMVI (17.5%) and SMVR (18.7%) cohorts. For TMVI, 2 previous studies reported a rate of 20% for major bleeding events, similar to our results[9,10]. The TENDER registry reported lower rates of major bleeding complications (11%)[11]. Previous SMVR studies have not reported bleeding complications following standardised definitions. They indicate either total volume of red blood cell transfusion, the rethoracotomy rate or the bleeding complication rate[6-8].

We found that hospital length of stay was significantly shorter after TMVI than after SMVR (9.0 days vs 12.5 days). Compared to our data, previous studies reported longer stays after TMVI (11 days) and after SMVR (13 days to 19 days), indicating an overall pattern of faster recovery after TMVI compared to SMVR[5,6,9]. Potential economic advantages, and higher patient acceptance and satisfaction need further analyses.

Table 3. Clinical outcome at 30 days.

	SMVR n=80	TMVI n=40	*p*-value
Length of stay			
ICU LOS, days	5.0 [2.5; 7.0]	1.0 [1.0; 4.75]	0.001
Hospital LOS, days	12.5 [9.75; 16.0]	9.0 [7.0; 13.0]	0.004
Adverse events			
30-day stroke	3 (4.9)	2 (5.0)	1.000
Bleeding			0.087
BARC Type 3a	2 (2.7)	5 (12.5)	
BARC Type 3b	6 (8.0)	1 (2.5)	
BARC Type 4	6 (8.0)	1 (2.5)	
RBC transfusion, units	2.0 [2.0; 4.0]	1.0 [0.0; 2.0]	<0.001
Major cardiac structural complications*	4 (5.0)	1 (2.5)	0.663
Renal failure requiring HD	12 (15.2)	3 (7.5)	0.367
Severe heart failure†	4 (5.0)	2 (5.0)	1.000
Prosthetic valve malposition	0 (0)	0 (0)	1.000
Unplanned surgical intervention‡	8 (10.0)	0 (0)	0.051
Myocardial infarction	0 (0)	0 (0)	0.000
MR >1	1 (1.25)	1 (2.5)	1.000
Transmitral gradient >5 mmHg	23 (28.75)	5 (12.5)	0.066

Data are presented as n (%) or median [IQR]. *Major cardiac structural complication including cardiac perforation resulting in death, life-threatening bleeding, haemodynamic compromise or tamponade, or requiring unplanned surgical or percutaneous intervention. †Severe postoperative heart failure, hypotension, or respiratory failure. ‡Unplanned surgical or interventional procedure related to the device or access procedure. BARC: Bleeding Academic Research Consortium; HD: haemodialysis; ICU: intensive care unit; IQR: interquartile range; LOS: length of stay; MR: mitral regurgitation; RBC: red blood cells; SMVR: surgical mitral valve replacement; TMVI: transcatheter mitral valve implantation

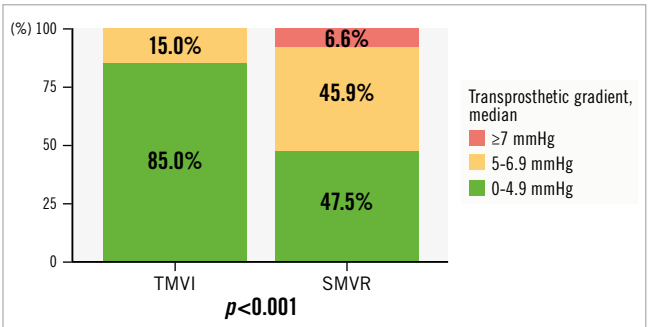

Figure 2. *Transprosthetic gradient after TMVI and SMVR. SMVR: surgical mitral valve replacement; TMVI: transcatheter mitral valve implantation*

At the end of the procedure, MVARC technical success was 97.5% for both TMVI and SMVR. Previous studies with the Tendyne device report >95% technical success rates, in line with our findings[9,10,11]. The MVARC composite endpoints, device success and procedural success, were achieved more often at 30 days after TMVI compared to 30 days after SMVR. Procedural success at 30 days was 75% in our TMVI cohort, which is comparable to the 80% procedural success rate reported from the TENDER registry[11]. To date, only sparse data exist regarding the outcomes with dedicated TMVI devices. In the early feasibility study, successful implantation of the 35 Fr transseptal Intrepid device (Medtronic) was reported in 14 of 15 patients[13]. Technical success among 30 patients treated with the transseptal HighLife device (HighLife Medical) was 90%[14]. The EVOQUE TMVR system (Edwards Lifesciences) achieved 93% technical success in the first 14 patients treated with the device[15]. The CHOICE-MI registry included 229 patients treated with 10 dedicated TMVI devices and reported a rate of 95.2% for technical success[16].

CURRENT TMVI CHALLENGES AND FUTURE PERSPECTIVES

In the treatment of mitral valve disease, the role of TMVI alongside other treatment modalities needs to be defined more clearly. TMVI is currently limited to patients who are unsuitable for surgery and who present with a mitral valve morphology that is ineligible for edge-to-edge repair. Currently, a significant number of patients are ineligible for TMVI as mitral valve devices either would not cover the mitral annulus dimensions or would reduce the LVOT area to below the threshold that can cause LVOTO. This study is the first to compare TMVI with SMVR. Clearly, prospective randomised studies comparing TMVI and SMVR are needed to confirm these initial findings. The SUMMIT trial, which is currently enrolling patients, aims to compare TMVI using the Tendyne system with edge-to-edge repair of the mitral valve.

Several transcatheter mitral valve systems with a transseptal delivery route are currently under clinical investigation and might broaden the clinical use of TMVI after achieving the relevant authorities' approval. Additional long-term TMVI data on valve durability are required for future discussion on TMVI as a potential substitute for SMVR in elderly patients.

Limitations

Several limitations need to be addressed regarding this study. First, the retrospective nature of this study has inherent biases. The 20-year period of SMVR patient inclusion optimised the patient selection to the matching protocol, but patient outcome might be biased because of modifications or improvements in postoperative care. There was no prespecified protocol, and only observational data could be included in the analysis. Data completion and revision, including operative risk score calculation, were partially conducted after matching, for the matched collective only. Thus, matching was performed on a parsimonious dataset. This resulted in some imbalances of variables not included in matching, namely MR aetiology, diabetes and coronary artery disease. According to these variables, patients receiving TMVI were slightly more unwell. However, considering other variables which were added after matching, such as EuroSCORE II or the glomerular filtration rate, the populations appear to be reasonably matched. The echocardiographic results were not core laboratory adjudicated, and serial echocardiography studies at discharge and at 30 days were only available for a limited number of patients. Follow-up is currently limited to 30 days to ensure the completeness of follow-up.

A rigid TMVI screening protocol which is predominantly driven by four-dimensional computed tomography (CT) and focuses on intracardiac anatomy and morphology results in a highly selected TMVI patient cohort. As the decision to opt for SMVR is not based on CT imaging, potential differences in intracardiac anatomy and morphology (i.e., mitral valve annulus size, mitral annulus calcification) among groups are not subject to retrospective analysis. MVARC criteria were developed to standardise outcome reporting after interventional mitral valve procedures, and their applicability to SMVR needs future evaluation.

Conclusions

Patients with intermediate surgical risk, according to STS-PROM and EuroSCORE II, demonstrated higher rates of MVARC device at 30 days after TMVI compared to 30 days after SMVR. Rates of survival and procedural success, neurological, renal and bleeding complications were similar. Transfusion count and length of stay were lower after TMVI. For elderly patients at intermediate risk, a TMVI eligibility assessment may be considered.

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Conflict of interest statement

H. Ruge serves as a physician proctor for and is an advisory board member of Abbott. M. Krane is a physician proctor and a member of the medical advisory board for JOMDD; a physician proctor for Peter Duschek; a medical consultant

for Evotec and Moderna; and has received speaker honoraria from Medtronic and Terumo. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Appendix 1. Detailed description of TMVI with the Tendyne mitral valve system.

Supplementary Table 1. Patient characteristics before and after matching.

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Supplementary data

Supplementary Appendix 1. Detailed description of TMVI with the Tendyne mitral valve system.

Patient evaluation included transoesophageal echocardiography (TEE) and 4D computerised tomography in all patients. Echocardiography measured left ventricular ejection fraction, enddiastolic and endsystolic diameter of the LV, length of the anterior mitral valve leaflet (AML), AML distance to the interventricular septum and AML tethering to the lateral wall of the LV. CT data acquired in systole and diastole were analysed using the 3mensio software (3mensio Medical Imaging, Bilthoven, the Netherlands). Valve size selection was based on mitral annulus dimensions. Simulating a virtual Tendyne valve implantation in 3mensio, the neo left-ventricular outflow tract (neo-LVOT) was measured. To prevent left-ventricular outflow tract obstruction after TMVI, a neo-LVOT >250 mm^2 was aimed for. TMVI was executed under general anaesthesia with TEE guidance and hemodynamic monitoring with pulmonary artery, aortic and left ventricular catheterisation. Prior to incision, perpendicular trajectory to the mitral annulus was confirmed by transthoracic echocardiography. Left anterolateral thoracotomy was performed via a ~7 cm incision. After placing two Teflon-reinforced pledged U-stitches with 3-0 MH Prolene, the left ventricle was punctured, and a guidewire was advanced to the left atrium (LA). A Fogarty catheter was then advanced from the apex of the LV to the LA to rule out any entanglement of the wire with the subvalvular apparatus. Balloon valvuloplasty of the mitral valve was performed with a 28 mm TRUE DILATATION balloon (Bard vascular, USA) if indicated. Cutting of the anterior mitral valve leaflet (MitraCut) was executed as previously described, if LVOTO caused by long and poorly tethered AML was anticipated[3]. The Tendyne mitral valve system was advanced through the apex of the LV until the proximal end of the delivery catheter could be identified in the LA. Then, the guidewire and inflatable dilator were removed, and the valve was partially exposed from the catheter. 3D en-face TEE view confirmed the alignment of the D-shaped Tendyne stent frame to the native mitral annulus. Subsequently, the valve was fully released from the catheter and pulled in the mitral annulus guided by TEE with intercommissural view and LVOT cross-plane. Mitral valve gradient and paravalvular regurgitation were assessed with TEE. After exclusion of a significant LVOT obstruction using invasive pressure gradients and TEE, the delivery catheter was removed, and the tether-wire was connected to the apical pad delivery system. After achieving haemostasis at the LV puncture site, the apical pad was advanced to the epicardium and tether tension was adjusted to the patient´s haemodynamics. Patients were either extubated in the hybrid operating room or intensive care unit. Oral anticoagulation with Marcumar was initiated after chest tube removal and prescribed for at least 6 months.

Supplementary Table 1. Patient characteristics before and after matching.

	Pre-matching			Post-matching		
	SMVR n=454	TMVR n=40	p-value	SMVR n=80	TMVR n=40	*p*-value
Female gender	266 (59%)	24 (60%)	1.000	48 (60%)	24 (60%)	1.000
Age (years)	70.16±10.45	76.70±5.85	<0.001	76.66±5.30	76.70±5.85	0.973
BMI	27±9	25±4	0.127	25±4	25±4	0.723
Pathology			0.001			0.649
– MR	399 (88%)	28 (70%)		59 (73.8%)	28 (70%)	
– mixed	25 (6%)	9 (22.5%)		18 (22.5%)	9 (22.5%)	
– MS	30 (7%)	3 (7.5%)		3 (3.75%)	3 (7.5%)	
Previous CABG	20 (4%)	8 (20%)	<0.001	13 (16.2%)	8 (20%)	0.799
Previous SAVR	28 (6%)	5 (12.5%)	0.25	8 (10%)	5 (12.5%)	0.758
Atrial fibrillation	263 (58%)	27 (68%)	0.315	51 (64%)	27 (68%)	0.839
Tricuspid regurgitation	197 (43%)	14 (35%)	0.388	24 (30%)	14 (35%)	0.678