Transcatheter mitral valve implantation versus conventional redo surgery for degenerated mitral valve prostheses and rings in a multicenter registry

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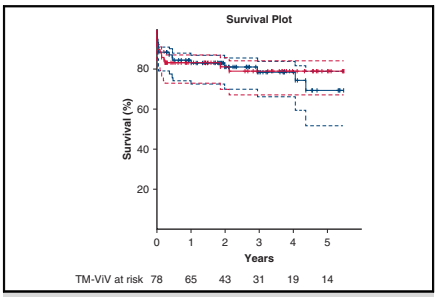
ABSTRACT

Objectives: Degeneration of mitral prostheses/rings may be treated by redo surgery, and, recently, by transcatheter valve-in-valve/ring implantation. This multicenter registry presents results of transcatheter valve-in-valve and repeat surgery for prostheses/rings degeneration.

Methods: Data provided by 10 German heart centers underwent propensity score-matched retrospective analysis. The primary endpoint was 30-day/midterm mortality. Perioperative outcome was assessed according to the Mitral Valve Academic Research Consortium criteria. Further, the influence of moderate or greater tricuspid regurgitation (TR) on 30-day/midterm mortality was analyzed.

Results: Between 2014 and 2019, 273 patients (79 transcatheter mitral valve-in-valve [TM-ViV] and 194 redo mitral valve replacement [Re-MVR]) underwent repeat procedure for mitral prosthesis/ring degeneration. Propensity score matching distinguished 79 patient pairs. European System for Cardiac Operative Risk Evaluation (EuroSCORE) II-predicted risk was 15.7 ± 13.7% in the TM-ViV group and 15.0% ± 12.7% in the Re-MVR group ($P = .5336$). TM-ViV patients were older (74.73 vs 72.2 years; $P = .0030$) and had higher incidence of atrial fibrillation (54 vs 40 patients; $P = .0233$). Severe TR incidence was similar (17.95% in TM-ViV vs 14.10%; $P = .1741$). Sixty-eight TM-ViV patients previously underwent mitral valve replacement, whereas 41 Re-MVR patients underwent valve repair ($P < .0001$). Stenosis was the leading degeneration mechanism in 42 TM-ViV versus 22 Re-MVR patients ($P < .0005$). The 30-day/midterm mortality did not differ between groups. Moderate or greater TR was a predictor of total (odds ratio [OR], 4.36; $P = .0011$), 30-day (OR, 3.76; $P = .0180$), and midterm mortality (OR, 4.30; $P = .0378$), irrespective of group.

Conclusions: In both groups, observed mortality was less than predicted. Redo surgery enabled treatment of concomitant conditions, such as atrial fibrillation or TR. TR was shown to be a predictor of total, 30-day, and midterm mortality in both groups. (J Thorac Cardiovasc Surg 2022;■:1-7)



Similar survival in both treatment groups within first 4 years of follow-up (95% CI).

CENTRAL MESSAGE

Transcatheter mitral valve-in-valve procedure for DMVP/R is a valuable alternative to surgery in selected patients.

PERSPECTIVE

Considering moderate or greater TR a predictor of increased mortality in patients undergoing repeat procedure for DMVP/R, additional tricuspid valve reconstruction upon redo surgery or transcatheter tricuspid valve intervention might improve outcome.

See Commentary on page XXX.

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Abbreviations and Acronyms

DMVP/R = degenerated mitral valve prostheses/rings
EuroSCORE = European System for Cardiac Operative Risk Evaluation
MVR = mitral valve replacement
MVARC = Mitral Valve Academic Research Consortium
PS = propensity score
PSM = propensity score matching
Re-MVR = repeat mitral valve replacement
TM-ViV = transcatheter mitral valve-in-valve
TR = tricuspid regurgitation

Implantations of valve reconstructive rings and/or bioprostheses are the most frequently performed procedures in adult patients requiring mitral valve surgery. According to the German Heart Surgery Annual Report 2018, among 6222 isolated mitral valve procedures, 64% were valve reconstructions and 29% were implantations of biological implants, with an overall mortality of approximately 4%.[1] Reconstructed valves and biological prostheses allow for avoidance of permanent anticoagulation therapy. However, a number bioprostheses and reconstructive rings might degenerate within a few years of the procedure.[2] Repeat surgery for mitral valve prosthetic degeneration is related to elevated perioperative risk.[3,4] Recently, an off-label use of transcatheter valve-in-valve in the mitral position has emerged as a less invasive option. However, contemporary results have been presented mostly in a form of cumulative reports from multicenter groups, because the method has not yet become a routine treatment.[5]

This multicenter registry compared early and midterm results of repeat mitral valve replacement (Re-MVR) and transcatheter mitral valve-in-valve (TM-ViV) implantations for degenerated mitral valve prostheses/rings (DMVP/R). For the purpose of outcome evaluation, the Mitral Valve Academic Research Consortium (MVARC) criteria were implemented.[6]

We sought to determine whether the prognosed risk in DMVP/R patients corresponded with observed mortality. Further, we tried to distinguish the differences in risk profile between Re-MVR and TM-ViV patients and their influence on early and midterm outcome, and, particularly, mortality. In addition, we analyzed the impact of moderate or greater tricuspid regurgitation (TR) on early and midterm mortality.

METHODS

Ten German cardiac surgery centers of the Arbeitsgemeinschaft Leitender Krankenhausärzte (Study Group of Chief Surgeons) participated in this multicenter registry and provided data of 273 patients with DMVP/R, treated either with TM-ViV (79 patients) or with Re-MVR (194 patients) between 2014 and 2019. Patients with prosthetic endocarditis and failing mechanical prostheses were excluded. In-hospital records were analyzed retrospectively with use of propensity score (PS)-matching to improve data homogeneity. Information regarding midterm results and mortality was obtained from patients' general practitioners or referring cardiologists per telephonic questionnaire. Study data provided by participating centers were subsequently transferred to an independent statistical institute for analysis. Each participating center received approval from their local ethic committee for conduction of the study in its current form.

The primary study endpoint was defined as 30-day and midterm mortality. Perioperative outcome according to the MVARC criteria[6] constituted the secondary study endpoint.

Procedural Aspects

In TM-ViV patients, 73 procedures were performed through transapical and 6 through transfemoral or trans-septal approach. The size of transcatheter prosthesis was predefined by dimensions of degenerated valve prosthesis and/or reconstructive rings.

Among redo surgery patients, 69 underwent median sternotomy and 10 were operated on through right-sided minimally invasive thoracotomy. Upon repeat procedure, degenerated valve implants were entirely excised.

Statistical Analysis

The primary study goal was to detect outcome differences between patients with previously implanted and degenerated valve prosthesis/rings treated with TM-ViV compared with Re-MVR. Secondary the relevance of prognostic factors for outcome parameters should be investigated. Because of data heterogeneity a PS was calculated using logistic regression of TM-ViV and Re-MVR cases in the total population with 12 relevant factors (Table 1). For each of the 79 TM-ViV patients a nearest Re-MVR neighbor was detected using optimized stepwise iteration (R [R Foundation for Statistical Computing]; proc matchit; optimal; 1:1) resulting in 158 cases to be analyzed. To illustrate the degree of balance achieved standardized mean differences (Wilson effect size calculator) were calculated for all PS-matched and further baseline variables using the original and the PS sample. A love plot was generated with all PS variables before and after matching.

The statistical analysis of the PS-matched sample (N = 158) used descriptive methods and tests in an explorative manner. No alpha adaption took place with respect to the explorative character of the tests. Analysis was conducted using Systat 13 (Systat Software, Inc).

The outcome was measured according to mortality (30 days, 1 year, and total), MVARC criteria, and procedural parameters (listed in Table 2). Mortality and MVARC criteria for both treatment groups were compared using χ^2 tests (or Fisher test in case of small numbers). Additionally time to death was analyzed using Kaplan–Meier plots, Log rank test (Breslow–Gehan), and Cox regression with PS value as covariate. The procedural parameters were checked for normality using Shapiro–Wilk tests, reported as median and interquartile range with Mann–Whitney test results in case of significant deviation from normality. As preplanned by the study team 5 prognostic factors (sex, age, TR, European System for Cardiac Operative Risk Evaluation [EuroSCORE] II, renal insufficiency) were integrated in mortality models using logistic regression to estimate their influence on mortality (especially greater than moderate TR) and to adapt the effect of the other factors and both treatment groups. Odds ratios with confidence interval and *P* value were estimated for this purpose. The models contain relevant correlations because EuroSCORE II takes age, sex, and renal function already into account. Thus, the model was reduced to significant factor (greater than moderate TR), EuroSCORE II, and treatment. As a result of the analyses the predictive relevance of 3 further factors (atrial fibrillation, stenosis, and size of prosthesis) was discussed between authors and an ad hoc outcome analysis with analog methods conducted.

TABLE 1. Preoperative characteristics and risk profiles

		Sample after PS matching				Original sample	
		TM-ViV	Re-MVR	Total	Total	Re-MVR	Total
N		79	79	158	158	194	273
Parameter	Set	Mean	Mean	SMD	*P* value	Mean	SMD
Age, y	PS	74.73	72.23	0.2888	.0030	65.44	0.8390
Male sex	PS	0.4051	0.4177	−0.0287	.8716	0.5670	−0.3605
EuroSCORE II, %	PS	0.1568	0.1504	0.0485	.5336	0.1368	0.1407
Creatinine, mg/dL	PS	1.4051	1.3568	0.0522	.0386	1.2699	0.1690
TR severity	PS	1.3846	1.2548	0.1292	.1762	1.1277	0.2523
Moderate or greater TR		0.4050	0.3670		.1741		
Diabetes mellitus	PS	0.2785	0.2532	0.0715	.7187	0.2320	0.1352
Adipositas	PS	0.2785	0.2405	0.1092	.5861	0.2062	0.2184
COPD	PS	0.1519	0.1392	0.0563	.8215	0.1289	0.1053
GFR, mL/min	Other	46.5	54.7	−0.4375	.0097	62.48	−0.7741
LV-EF, %	Other	0.5278	0.5253	0.1007	.7969	0.5225	0.1207
NYHA I	Other	0.6709	0.7333	0.0838	.5636	0.7433	0.1011
NYHA II	Other	0.2911	0.2133			0.2032	
NYHA III-IV	Other	0.0380	0.0533			0.0535	
Previous CABG	Other	0.2911	0.3165	−0.0662	.7294	0.2474	0.1227
Previous AVR	Other	0.2532	0.1266	0.4685	.0425	0.1134	0.5375
Afib	Other	0.6835	0.5063	0.4106	.0233	0.4536	0.5271
PHT	Other	0.6582	0.5190	0.3194	.0753	0.4227	0.5331
Prosthetic stenosis	Other	0.7848	0.3418	1.0746	<.0001	0.3144	1.1432

Variables used for PS matching and additional variables (other) binary variables coded as 0 = No, 1 = Yes. *P* values for Mann–Whitney and χ^2 test. *PS*, Propensity score; *TM-ViV*, transcatheter mitral valve-in-valve; *MVR*, mitral valve replacement; *SMD*, standardized mean difference; *EuroSCORE*, European System for Cardiac Operative Risk Evaluation; *TR*, tricuspid regurgitation; *COPD*, chronic obstructive pulmonary disease; *GFR*, glomerular filtration rate; *LV-EF*, left ventricular ejection fraction; *NYHA*, New York Heart Association; *CABG*, coronary artery bypass grafting; *AVR*, aortic valve replacement; *Afib*, atrial fibrillation; *PHT*, pulmonary hypertension.

RESULTS

Study group consisted of 273 patients with DMVP/R, who underwent repeat mitral valve procedures. Of them, 79 were treated with TM-ViV implantations, and 194 underwent Re-MVR. To improve data homogeneity, a PS matching (PSM) was implemented, leading to formation of 79 matched patient pairs. The following presented data is a summary of results after PSM (Figure 1).

Regarding baseline characteristics, there were several differences between groups. Mean age was 74.73 years in the TM-ViV and 72.23 years in the Re-MVR group ($P < .0030$). There were 32 (40.51%) male patients in the TM-ViV group, compared with 33 (41.77%) in the Re-MVR group ($P = .8716$).

Perioperative risk was calculated with use of the EuroSCORE II. TM-ViV patients presented with EuroSCORE II of 15.7%, compared with 15.0% in the Re-MVR group ($P < .5336$). Before PSM, there were differences regarding distribution of EuroSCORE II-defined risk subgroups between both study cohorts (low risk = EuroSCORE II <4%, intermediate risk = EuroSCORE II 4%-8%, and high risk = EuroSCORE II >8%). Within the TM-ViV group, 69.62% of patients belonged to the high-risk population (EuroSCORE II >8%), compared with 50% of patients in the Re-MVR group ($P = .0057$). Preoperative renal function, assessed according to creatinine and glomerular filtration rate, was reduced in the TM-ViV group: mean creatinine value was 1.41 mg/dL versus 1.36 mg/dL ($P = .0386$), and glomerular filtration rate was 54.7 versus 46.5 ($P < .0097$).

TR of any severity was present in 83.33% of TM-ViV patients versus 70.51% in Re-MVR patients. Moderate or greater TR affected 36.7% of Re-MVR and 40.5% of TM-ViV patients ($P = .1741$). Atrial fibrillation was seen in 54 patients (68.35%) of TM-ViV and in 40 (50.63%) Re-MVR patients ($P = .0233$). Pulmonary hypertension, defined according to guidelines of the European Society of Cardiology,[7] existed in 52 (65.82%) TM-ViV patients and 41 (51.90%) Re-MVR patients ($P = .0753$).

In most patients (n = 68) in the TM-ViV group mitral valve replacement (MVR) was a primary mitral

TABLE 2. Procedural parameters, mortality, and MVARC outcome criteria

	TM-ViV			Re-MVR			
	N	Median	IQR	N	Median	IQR	*P* value
Procedural criteria							
Procedure duration, minutes	79	75.0	30.0	79	240.5	118.0	<.01
Prosthesis size, mm	79	27.5	3.0	79	29.9	2.0	<.01
Ventilation time, hours	79	0.0	5.0	79	14.5	13.0	<.01
ICU length of stay, d	79	2.0	3.0	79	3.0	5.0	.02
Length of hospital stay, d	79	13.0	12.0	79	14.0	12.8	.26
Mortality		Count	%		Count	%	
30-Day mortality	79	11	14.1	79	10	12.7	.81
1-Year mortality	79	13	16.7	79	13	16.7	1.00
Total mortality	79	18	22.8	79	15	19.0	.56
Cardiovascular cause of death	12	8	66.7	14	11	78.6	.67
MVARC Criteria							
Stroke/transixent ischemic attack	79	2	2.5	79	4	5.2	.44
Postoperative MI	79	1	1.3	79	3	3.8	.37
Life-threatening bleeding	79	2	2.5	79	12	15.2	.01
Renal replacement therapy	79	10	12.7	79	16	20.3	.20
Atrial fibrillation	79	19	24.1	79	29	37.7	.07
PM implantation	79	3	3.8	79	13	16.5	.02
Paravalvular regurgitation	79	5	6.3	79	0	0.0	.03
Prosthesis dysfunction	65	2	3.1	65	0	0.0	.25

TM-ViV, Transcatheter mitral valve-in-valve; *MVR*, mitral valve replacement; *IQR*, interquartile range; *ICU*, intensive care unit; *MVARC*, Mitral Valve Academic Research Consortium; *MI*, myocardial infarction; *PM*, pacemaker.

intervention (86.08%), compared with 36 (46.75%) of the Re-MVR patients ($P < .0001$). The predominant mechanism of mitral valve prosthesis and/or ring dysfunction in the TM-ViV group was stenosis (in 62 patients, 78.48%), compared with 27 patients (34.18%) in the Re-MVR group ($P < .0001$). The degeneration mechanism did not influence total, early, and midterm mortality. A summary of preoperative characteristics is presented in Table 1.

Duration of procedure was the only comparable intraoperative parameter, because TM-ViV patients did not require cardiopulmonary bypass. In TM-ViV patients the procedure lasted in average 75 versus 240.5 minutes in the Re-MVR group ($P < .01$).

In the TM-ViV group, in 71 patients transcatheter prosthesis was implanted in valve and in 7 patients in ring. Afterward prostheses were implanted: Edwards Lifesciences Sapien XT in 28, Sapien in 6, and Sapien 3 in 45 patients. During Re-MVR, the following concomitant procedures were performed: tricuspid valve reconstruction in 11, ablation in 4, atrial septal defect closure in 1, aortic valve replacement in 5, coronary artery bypass in 4, and left atrial appendage closure in 5 patients. The average size of the implanted prosthesis was smaller in the TM-ViV group: 27.55 mm versus 29.90 mm in the Re-MVR group ($P < .01$).

TM-ViV patients required shorter intensive care unit stay (2 days), compared with Re-MVR group representatives (3 days; $P = .02$). Ventilation time was shorter in the TM-ViV group, too: 0.0 hours versus 14.5 hours in Re-MVR patients ($P < .01$). The median duration of in-hospital stay was longer in the Re-MVR group (14 days), versus 13 days in TM-ViV patients, ($P = .26$).

The incidence of postoperative infections was 12 (15.2%) in the TM-ViV and 9 (11.4%) in the Re-MVR group ($P = .4820$). Six patients in the TM-ViV and 5 in the Re-MVR group suffered from pneumonia.

Within 30 days of the procedure, 11 patients (14.1%) in the TM-ViV group and 10 patients (12.7%) in the Re-MVR group died ($P = .81$). One year after the procedure, 2 patients in the TM-ViV and 3 patients in the Re-MVR group were lost ($P = 1.0$). A total of 18 patients (22.8%) in the TM-ViV group and 15 patients (19%) in the Re-MVR group died after the procedure ($P = .56$; Figure 2). Intra- and postoperative results are summarized in Table 2.

Perioperative outcome, assessed according to MVARC criteria, is presented as follows:

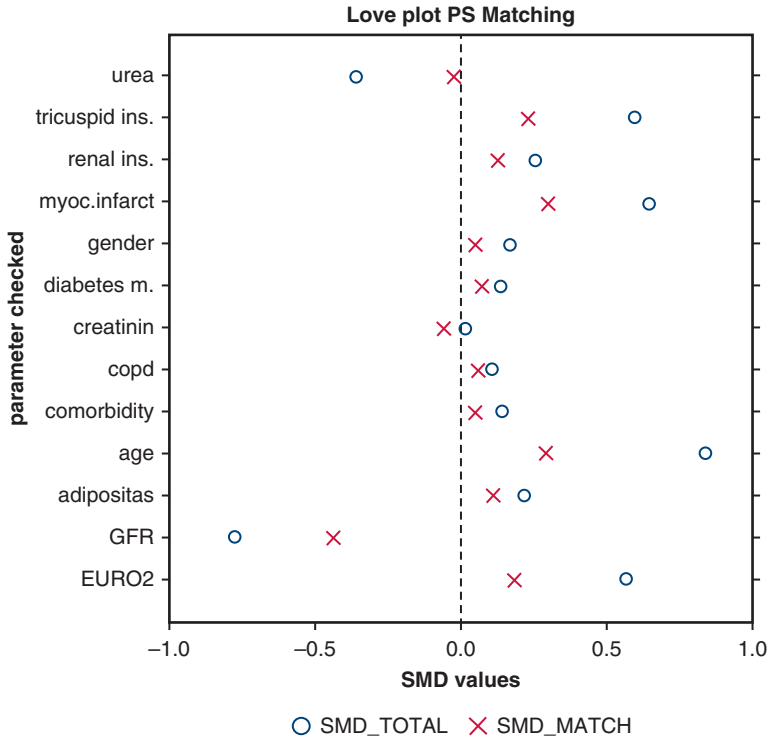

FIGURE 1. Love plot for propensity score (*PS*) variables. The reduction of baseline data heterogeneity by PS matching is shown. The allocation of standardized mean difference (*SMD*) is closer to 0 (homogeneity) after PS matching (*red crosses*; matched sample [*SMD_MATCH*]) than before (*blue circles*; original sample [*SMD_TOTAL*]) for each of the 13 PS variables. *GFR*, Glomerular filtration rate; *EURO2*, European System for Cardiac Operative Risk Evaluation II.

- Two patients (2.5%) in the TM-ViV group and 4 (5.2%) in the Re-MVR group suffered from postoperative transient ischemic attack or stroke ($P = .44$).
- Postoperative myocardial infarction occurred in 1 patient (1.3%) of the TM-ViV group and in 3 (3.8%) patients in the Re-MVR group ($P = .37$).
- Life-threatening bleeding occurred in 2 patients (2.5%) of the TM-ViV group and 12 patients (15.2%) of the Re-MVR group ($P = .01$). There was no case of periprocedural lethal bleeding in the study cohort.
- Postoperative/postprocedural renal replacement therapy was necessary in 10 patients (12.7%) in the TM-ViV group and in 16 patients (20.3%) in the Re-MVR group ($P = .2$).
- The incidence of postoperative atrial fibrillation was lower in the TM-ViV group (19 patients; 24.1%), compared with in the Re-MVR group (29 patients; 37.7%; $P = .07$).
- Thirteen patients in the Re-MVR group (16.5%) required permanent pacemaker versus 3 patients (3.8%) of the TM-ViV group ($P = .02$).

Regarding procedural/device success, no patient in the Re-MVR group but 5 in the TM-ViV group (6.3%) had paravalvular insufficiency detected upon predischarge echocardiography ($P = .03$). Perioperative prosthesis dysfunction occurred in 2 TM-ViV patients and in none of the Re-MVR patients ($P = .25$). One patient in the TM-ViV group required conversion to surgery. Presence of moderate or greater TR has been shown to be an independent predictor of increased total (odds ratio, 2.21; $P = .0001$), 30-day (odds ratio, 2.70; $P = .0124$), and midterm mortality (odds ratio, 4.30; $P = .0378$) in the entire cohort (correlation between moderate or greater TR and mortality is presented in Table 3). The average duration of follow-up was 4.5 years.

DISCUSSION

According to the Annual Report of the German Society for Heart, Vascular, and Thoracic Surgery from 2019, in 77 German heart surgery centers approximately 6500 isolated mitral valve operations were performed, with a total mortality of 3.4%. In 65% of cases the mitral valve was repaired with a mortality of 0.8%, compared with MVR, which was associated with a mortality of 8.2%. A small group of 152 patients underwent transcatheter MVRs. Perioperative mortality in this group was 9.2%.[8] Repeat mitral valve surgery for any reason carried even higher 30-day mortality of 11%,[4] which is self-explanatory considering challenges inherent to reoperation, high frailty, and endocarditis as a major indication for redo procedures.[9]

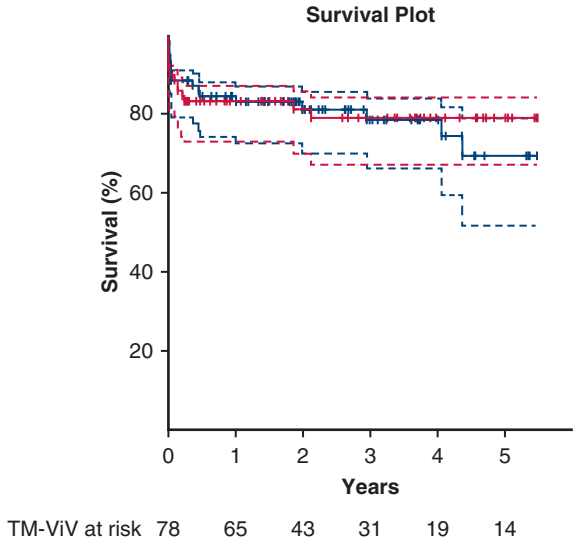

FIGURE 2. Kaplan–Meier plots. The nearly identical survival of both treatment groups during the first 4 years of follow-up is shown. Transcatheter mitral valve-in-valve (*TM-ViV*) patients survived less frequently after that period. Within follow-up, the number of cases declined and the CIs widened after 4 years, so that no difference in survival occured. *Blue* indicates TM-ViV; *red* indicates redo mitral valve replacement; *dotted* lines indicate 95% CI.

Therefore, in patients with prohibitive perioperative risk, the TM-ViV procedure has recently emerged as an alternative to redo surgery. Current guidelines of the European Society for Cardiology provide a IIb indication for transcatheter mitral valve-in-valve implantation in selected patients with DMVP/R.[10] In the contemporary setting, for transcatheter MVR inverted transcatheter aortic prostheses have been used. To date, transcatheter implants specifically dedicated for mitral valve implantation are not commercially available, although several devices have recently been tested in preclinical and clinical settings.[11,12] First in-human transcatheter mitral valve implantation for treatment of native mitral valve stenosis was reported in 2013.[13]

Bearing in mind the previously-mentioned Annual Report of the German Society for Heart, Vascular, and Thoracic Surgery, it becomes clear that transcatheter MVR remains a developing branch in cardiovascular medicine. Because 77 German cardiac surgery centers perform a full spectrum of valvular surgery, an average annual number of transcatheter MVRs in each center is <2. Similarly, in the presented registry, the number of procedures at the level of 1.3 per center per year reflected development of this method. Currently, repeat surgical MVR constitutes a benchmark for TM-ViV implantation as a procedure performed routinely.[9] To date, results of TM-ViV have been mostly presented in the form of multicenter reports.[14,15]

To our knowledge, this is the first German registry to present early and midterm outcomes in patients who underwent repeat procedures (conventional or transcatheter), for DMVP/R. In the presented registry, PSM was implemented to improve data homogeneity. As a result, 79 patient pairs were created and the differences in baseline risk profiles eliminated. Although study participants remained a high-risk population, the allocation to both treatment groups depended on type and mechanism of implant dysfunction rather than on predicted risk. Transcatheter valve-in-valve implantation might be considered a valuable alternative in selected patients, compared with redo surgery. In patients who require repeat mitral valve procedures, transcatheter valve-in-valve implantation effectively addresses mitral prosthesis degeneration as a leading clinical problem and

TABLE 3. Special mortality risks

Analysis	Parameter	Estimate	SE	95% CI limits		*P* value
				Lower	Upper	
Cox regression survival time	PS value	2.34	0.86	0.68	4.02	.0068
	Treatment	−0.17	0.37	−0.89	0.56	.6516
Logistic regression total mortality			Odds ratio			
	TR greater than moderate	5.13	2.21	2.20	11.94	.0001
	EuroSCORE II	11.24	16.19	0.67	189.38	.0932
	TM-ViV	1.21	0.51	0.53	2.75	.6485
Logistic regression 30-d mortality			Odds ratio			
	TR greater than moderate	5.05	2.70	1.77	14.40	.0024
	EuroSCORE II	40.00	63.08	1.82	879.98	.0193
	TM-ViV	1.07	0.53	0.40	2.82	.8986

CI, Confidence interval; *SE*, standard error; *PS*, propensity score; *TR*, tricuspid regurgitation; *EuroSCORE*, European System for Cardiac Operative Risk Evaluation; *TM-ViV*, transcatheter mitral valve-in-valve.

offers a focused solution. However, compared with redo surgery, the transcatheter procedure does not allow for simultaneous treatment of coexisting conditions, such as other valvular lesions, coronary stenoses, or atrial fibrillation. However, addressing all concomitant disorders upon repeat procedure in, at least potentially, more vulnerable transcatheter populations would probably lead to increased perioperative mortality and complication rate. Apparently, high-risk patients benefit from significantly shorter procedure and ventilation time and intensive care unit length of stay, despite unaddressed concomitant diseases. Thus, evaluation of potential hazards and future benefits in accordance with calculated perioperative risk is crucial in patients scheduled for repeat mitral valve procedure for prosthesis degeneration.

Most patients referred for transcatheter valve implantation presented with stenosis as a leading mechanism of prosthetic degeneration. As for native mitral valve stenosis, in which interventional treatment is a preferred treatment modality,[10] in stenosis of biological mitral valve prostheses the transcatheter procedure was shown to be a favored option. The role of surgery is limited to cases with mitral valve anatomy unfavorable for transcatheter therapy or to patients with major contraindications.[10] As shown by our results, individuals with stenotic mitral valve prostheses are characterized with elevated risk due to advanced age and comorbidities, similar to patients with native mitral valve stenosis.[16] Regarding the average size of implanted prosthesis, redo surgery allowed for implantation of bigger prostheses, which is self-explanatory because the dimension of transcatheter implants is already predefined and limited by the size of the previously implanted valve. Although not analyzed in this registry, smaller sizes of transcatheter prostheses could be related to higher transvalvular gradients, corresponding to postoperative functional mitral stenosis, as described in the literature.[17]

Transcatheter valve-in-valve implantation might leave a significant paravalvular regurgitation behind, especially if degenerated annuloplasty rings are treated.[14] In the presented registry, there were only 7 patients who underwent a repeat transcatheter procedure for failing annuloplasty ring. Among them, in 4 patients paravalvular postoperative regurgitation was detected. In a recent study, transcatheter valve-in-ring implantation was associated with suboptimal results in terms of higher rates of postprocedural stenosis and regurgitation.[15] Especially the presence of postimplantation regurgitation correlated with increased mortality at 4 years. As mentioned by Simonato and colleagues,[15] in most cases oval shape of currently available transcatheter aortic prosthesis implanted in the mitral position does not match the elliptical shape of degenerated ring. However, in contrast to results reported by Yoon and Simonato, in our study paravalvular regurgitation corresponded neither with increased early and nor midterm mortality. It needs to be emphasized that a limited number of patients affected by postoperative paravalvular regurgitation did not allow for reasonable analysis of its effect on peri- and postoperative outcome. In the presented registry, the overall rate of paravalvular regurgitation was higher among transcatheter patients, compared with their surgical counterparts, although without correlation to increased morbidity or mortality.

Among concomitant disorders, preoperative moderate or greater TR significantly influenced 30-day mortality in both groups. The overall number of TM-ViV patients affected by TR of any severity was higher compared with the Re-MVR group. Current risk stratification systems, such as EuroSCORE, do not incorporate TR as a risk factor in preoperative evaluation. Nevertheless, development of functional TR constitutes one of the advanced consequences of pathophysiological processes resulting from left-sided valvular lesions. In a population of patients undergoing cardiac surgery of any kind, presence of functional, significant TR substantially increases mortality.[18] Concomitant TR intervention during surgery for left-sided valve lesions improves outcome.[18] In addition, performance of a TR procedure at the time of mitral valve surgery does not increase perioperative risk and mortality.[19] In high-risk patients undergoing transcatheter intervention for native mitral valve insufficiency, additional transcatheter tricuspid repair was reported to be beneficial in terms of reduced mortality, compared with an isolated mitral procedure.[20]

In the presented registry, there was clear evidence for moderate or greater TR to be an independent predictor for increased total, 30-day, and midterm mortality, irrespective of treatment. Because only 11 patients in the Re-MVR (and none in the TM-ViV) group underwent simultaneous tricuspid repair, the question whether concomitant tricuspid intervention might have influenced early and midterm outcome remained unanswered.

CONCLUSIONS

Repeat intervention for DMVP/R is associated with increased perioperative risk. Currently, redo surgery constitutes treatment of choice, despite known challenges inherent to this type of procedure. In this context, TM-ViV implantation might be an attractive alternative in patients with high or prohibitive risk. Although not capable of complete treatment of coexisting comorbidities, transcatheter therapy focusing solely on mitral prosthesis offers a benefit resulting from limited invasiveness. Of all concomitant cardiac disorders, accompanying degeneration of mitral prosthesis, TR is an independent predictor of increased total, 30-day, and midterm mortality. Future studies on larger populations and with longer follow-up should facilitate directing therapies in these patients.

Study Limitation

The presented study has few limitations. As a multicenter registry, it has a retrospective character with 2 major resulting consequences.

Regarding allocation to treatment group, certain selection bias becomes apparent. In fact, there was no possibility to randomly assign patients to treatment groups. However, a decision to decline surgery and to choose a potentially less invasive method was always made upon individual, multidisciplinary assessment by the heart team in each participating center.

The inability to present uniform echocardiographic data is another weakness of this registry. Again, it is related to the retrospective and multicenter character of the study. Each participating center received preoperative echocardiographic workup of various quality/accuracy from general practitioners, referring cardiologists, etc. Any post hoc updates to already obtained echocardiographic reports were impossible.

Regarding procedural aspects in surgical groups, treatment of concomitant TR (11 patients) or atrial fibrillation (4 patients) was performed in a limited number of patients. Thus, reasonable statistical analysis of clinical benefit of simultaneous procedures was not possible. The decision to abandon concomitant ablation or tricuspid annuloplasty might have been related to certain technical difficulties upon repeat procedure.

To our best knowledge, this is the first German registry to present and compare results of TM-ViV/ring implantation versus redo surgery for DMVP/R. Further studies are warranted to establish clear indications for treatment in this special patient group.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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