Systematic review of transcatheter aortic valve replacement after previous mitral valve surgery

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Reported combinations of transcatheter aortic valve replacement valves implanted with previous mitral prostheses.

Central Message

This systematic review suggests that transcatheter aortic valve replacement can be performed safely and successfully in patients with mitral valve prostheses.

See Editorial Commentary page 66.

Supplemental material is available online.

Only case reports or small case series reporting the outcomes of patients with previous mitral valve (MV) surgery undergoing transcatheter aortic valve replacement (TAVR) are available.¹ We performed a systematic review to evaluate the feasibility, procedural risks, and outcomes of TAVR in patients with previous MV surgery.

METHODS

A systematic review of reports of TAVR in patients with previous MV surgery was registered on the PROSPERO database (CRD42017070707) and conducted according to PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines. We searched the PubMed/MEDLINE and EMBASE databases for relevant articles from inception to August 1, 2017. In addition, references from key manuscripts were searched manually in a backward snowballing fashion for additional

articles. Please refer to [Appendix E1](#) for details regarding the methodology of this study.

RESULTS

We identified 37 reports of 137 patients (24 case reports and 13 case series, range 2-40 patients; see [Appendix E1](#) for supplemental references). Mean age was 75.0 ± 9.6 years, and 101 patients (74%) were female. A median Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) of 9.9% (interquartile range: 8.9%-16.6%) was reported. MV surgery occurred 13.4 ± 6.0 years before

TAVR Valve		Mitral Prosthesis				
		Ring	Mechanical Monodisk	Mechanical Bileaflet	Mechanical Ball-in-Cage	Bioprosthesis
Self-expanding	CoreValve	2	11	13	2	4
	Evolut R			4	1	2
	JenaValve		1	1		1
	ACURATE-TA			1		
	ACURATE-neo			1		
Balloon-expandable	SAPIEN	1	3	14		6
	SAPIEN XT	3	1	11		2
	SAPIEN 3	1	3		1	1

FIGURE 1. All reported combinations of self-expanding and balloon-expandable TAVR valves implanted in the presence of pre-existing mitral prostheses and annuloplasty rings. Only specifically documented combinations are included (N = 91). TAVR, Transcatheter aortic valve replacement.

TABLE 1. Reported cases of interference between transcatheter aortic valve prosthesis and pre-existing mitral valve prosthesis

Study	Acuity	Complication	Outcome
Testa and colleagues ²	Acute	Acute, severe MR after CoreValve deployment requiring snaring of TAVR prosthesis into ascending aorta with resolution of MR	Successful repeat TAVR 2 mo later
Acar and colleagues ³	Acute	Complete heart block and interference between SAPIEN XT valve with MV prosthesis; left atrium thrombus; cardiogenic shock	Death
Squiers and colleagues ⁴	Acute	Single-tilting disc MV prosthesis impinged by tissue from aortomitral curtain after post-deployment dilation of SAPIEN 3 valve; hemodynamic deterioration requiring conversion to SAVR	Discharge home on postoperative day 8
Poulin and colleagues ⁵	Chronic	Six months after TAVR with SAPIEN XT, presents with flail MV bioprosthesis anterior leaflet causing severe MR and heart failure; necropsy suggests deformation of MV leaflet due to cyclic contact with stent edge of the TAVR prosthesis	Death

MR, Mitral regurgitation; TAVR, transcatheter aortic valve replacement; MV, mitral valve; SAVR, surgical aortic valve replacement.

TAVR. MV replacement was performed in 130 (95%) patients, including 103 (75%) mechanical valves and 27 (20%) bioprostheses, and MV repair was performed in 7 (5%). Aortic annulus to MV prosthesis distance was reported in 48 (35%) patients, with an overall mean of 6.2 ± 2.9 mm; 6.7 ± 2.8 mm for mechanical prostheses, 4.6 ± 3.3 mm for bioprostheses, and 4.3 ± 1.5 mm for annuloplasty rings.

Approaches were 90 (66%) transfemoral, 37 (27%) transapical, 6 (4%) transaortic, 3 (2%) trans-subclavian, and 1 (<1%) transcarotid. Both balloon-expandable and self-expanding TAVR valves were used for a variety of MV prostheses (Figure 1). Complications directly related to the interaction of the TAVR and MV prostheses were reported acutely in 3 (2%) patients and delayed in 1 (<1%) (Table 1).²⁻⁵ Of 65 patients without a previous pacemaker, 13 (20%) required pacemakers postprocedurally. Paravalvular leak (PVL) was evaluated in all reports and identified in 54 (40%) patients: grade 1 in 45 (34%); and grade 2 in 9 (7%). Two (1.5%) patients died before discharge. No significant differences in outcomes, including in-hospital mortality, new pacemaker, and PVL, were identified among TAVR valves, procedural approach, or MV prostheses.

DISCUSSION

Our systematic review identified 137 reported cases of TAVR after MV surgery. This procedure appears to be feasible and safe for balloon-expandable and self-expanding TAVR valves with a variety of MV prostheses. However, rare instances of TAVR valve underexpansion and intraventricular prosthesis-prosthesis clash have been reported. These cases were associated with severe complications, including death and conversion to SAVR.³⁻⁵ In the majority of reported cases, however, no complications related to direct conflict between the TAVR and MV prostheses were documented, and TAVR in patients with previous MV repair was uniformly successful. Given the extreme- to high-risk nature of these patients (median

STS-PROM, 9.9%), the in-hospital mortality of 1.5% appeared excellent.

Current “real-world” data from the Transcatheter Valve Therapy (TVT) Registry demonstrates that 11.8% of TAVR patients require a pacemaker within 30 days.⁶ Therefore, the 20% rate of new pacemaker implantation in our study may be increased as compared with all patients. The TVT registry does not document echocardiographic data, so the “real-world” rate of PVL after TAVR is difficult to ascertain. In recent prospective trials, moderate or worse PVL has been documented before discharge in 2% to 3% of patients.⁷ Given our review encompasses all TAVR valves, we cannot determine whether the increased rate of moderate or worse PVL (9%) was primarily due to the presence of MV prostheses or simply a reflection of PVL rates associated with older TAVR valves.

This report is subject to several limitations. We may have missed eligible reports, although we attempted to maximize our search’s sensitivity. Although the majority of reported cases document acceptable results, the true incidence of adverse outcomes may be greater, given understandable hesitation to publish poor outcomes and enthusiasm to report positive results. Finally, our review includes many cases in the early era of TAVR. However, no signal was present to suggest that modern TAVR prostheses or the TF approach were associated with different outcomes than earlier generation valves and/or alternative approaches.

In summary, this systematic review of TAVR in patients with previous MV surgery suggests the procedure can be performed safely and successfully. This procedure is associated with increased technical challenges and only should be performed by experienced TAVR implanters. A prospective study or registry is necessary to confirm these findings.

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APPENDIX E1

A systematic review of reports of transcatheter aortic valve replacement (TAVR) in patients with previous mitral valve (MV) surgery was conducted according to PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines¹ and registered in the PROSPERO database (CRD42017070707) (Table E1). We performed a search of the PubMed/MEDLINE and EMBASE databases for relevant articles from inception to August 1, 2017. All articles with the terms {"transcatheter aortic valve implantation," "TAVI," "transcatheter aortic valve replacement," OR "TAVR"} AND {"mitral valve," "mitral prosthesis," "mitral replacement," OR "mitral repair"} located in the title, abstract, or key words were identified to maximize the sensitivity of the search. Additionally, references from key manuscripts were manually searched in a backward snowballing fashion for additional articles.

Included articles had to meet the following criteria: (1) reporting outcomes of TAVR, (2) in human subjects who had previously undergone mitral valve surgery, and (3) written in English. Any peer-reviewed article meeting these criteria, from case reports to randomized control trials, were eligible for inclusion. Exclusion criteria included articles written in a language other than English, reports of concomitant mitral valve surgery and TAVR (ie, a single surgery addressing both valves), or reports regarding a procedure other than TAVR. The resulting list of citations, minus duplicates, was screened at the title/abstract level by a single author (J.J.S.) to identify potentially pertinent studies. At this stage, articles that lacked original data or focused on topics not covered in this review were removed. The full texts of all remaining manuscripts were retrieved for independent assessment by 2 authors (J.J.S., J.M.D.) (Figure E1). Agreement regarding inclusion after full text assessment was 100% between the independent authors.

Patient-specific data including demographics, MV prosthesis type, interval between MV surgery and TAVR, preoperative risk scores, preoperative imaging results, TAVR characteristics (including valve type, size, and delivery route), TAVR complications (including pacemaker placement, TAVR dysfunction, and MV dysfunction), and in-hospital mortality was collected from published reports and tabulated using Excel (Microsoft Corp, Redmond, Wash). Continuous data are reported as mean $\pm$ standard deviation in variables with normal distribution and median $\pm$ interquartile range in non-normally distributed variables. Categorical data are reported as count (percentage). The primary outcomes of interest were in-hospital

mortality and TAVR complications. Subgroup analyses stratified by TAVR valve type (self-expanding vs balloon-expanding) and MV prosthesis type (mechanical vs bioprosthesis vs ring) were performed.

On the basis of the preliminary literature review, the authors expected that the risk of bias of included studies was likely to be high, given that the eligible reports included primarily case reports and small case series with the intent to highlight exceptionally good results or specifically to publish bad results as a warning to others. Confidence in the strength of the body of evidence generated by this systematic review was assessed with GRADE criteria,² and given the limited level of evidence available in eligible reports, we assigned a grade of "low quality" (ie, further research is likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate) to this report. Nevertheless, we planned to proceed with the investigation given the limited data currently available regarding TAVR in patients with previous MV surgery for 2 main reasons: first, to summarize what is currently known about this procedure; and second, to motivate larger prospective study and/or a registry specific to this procedure.

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FIGURE E1. Flow-diagram of the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) systematic review process.

TABLE E1. PRISMA checklist

			Information reported		
Section/topic	No.	Checklist item	Yes	No	Line number(s)
Administrative information					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	X		Main text line 2
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	X		N/A
Registration	2	If registered, provide the name of the registry (eg, PROSPERO) and registration number in the Abstract	X		Supplement line 4
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	X		Main text line 4-30
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	X		Supplement lines 43-48
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A	N/A	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	X		Main text line 35
Sponsor	5b	Provide name for the review funder and/or sponsor	N/A	N/A	N/A
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A	N/A	N/A
Introduction					
Rationale	6	Describe the rationale for the review in the context of what is already known	X		Main text lines 52-53
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to PICO	X		Main text lines 53-54
Methods					
Eligibility criteria	8	Specify the study characteristics (eg, PICO, study design, setting, time frame) and report characteristics (eg, years considered, language, publication status) to be used as criteria for eligibility for the review	X		Supplement lines 11-21
Information sources	9	Describe all intended information sources (eg, electronic databases, contact with study authors, trial registers, or other gray literature sources) with planned dates of coverage	X		Supplement lines 11-21
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	X		Supplement lines 4-9
Study records					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	X		Supplement line 26
Selection process	11b	State the process that will be used for selecting studies (eg, 2 independent reviewers) through each phase of the review (ie, screening, eligibility, and inclusion in meta-analysis)	X		Supplement lines 11-21
Data collection process	11c	Describe planned method of extracting data from reports (eg, piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	X		Supplement lines 22-26
Data items	12	List and define all variables for which data will be sought (eg, PICO items, funding sources), any pre-planned data assumptions and simplifications	X		Supplement lines 22-26

(Continued)

TABLE E1. Continued

Section/topic	No.	Checklist item	Information reported		Line number(s)
			Yes	No	
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	X		Supplement lines 29-31
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	X		Supplement lines 32-42
Data					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	X		Supplement lines 26-28
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (eg, I^2 , Kendall's tau)	X		Supplement lines 26-28
	15c	Describe any proposed additional analyses (eg, sensitivity or subgroup analyses, meta-regression)	X		Supplement lines 29-31
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	N/A	N/A	N/A
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (eg, publication bias across studies, selective reporting within studies)	X		Supplement lines 32-42
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (eg, GRADE)	X		Supplement lines 32-42

PICO, Participants, interventions, comparators, and outcomes.