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Surgical Explantation of Transcatheter Aortic Valve Bioprostheses: A Statewide Experience

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ORIGINAL ARTICLE

Surgical Explantation of Transcatheter Aortic Valve Bioprostheses

A Statewide Experience

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BACKGROUND: Despite the rapid adoption of transcatheter aortic valve replacement (TAVR) since its initial approval in 2011, the frequency and outcomes of surgical explantation of TAVR devices (TAVR-explant) is poorly understood.

METHODS: Patients undergoing TAVR-explant between January 2012 and June 2020 at 33 hospitals in Michigan were identified in the Society of Thoracic Surgeons Database and linked to index TAVR data from the Transcatheter Valve Therapy Registry through a statewide quality collaborative. The primary outcome was operative mortality. Indications for TAVR-explant, contraindications to redo TAVR, operative data, and outcomes were collected from Society of Thoracic Surgeons and Transcatheter Valve Therapy databases. Baseline Society of Thoracic Surgeons Predicted Risk of Mortality was compared between index TAVR and TAVR-explant.

RESULTS: Twenty-four surgeons at 12 hospitals performed TAVR-explants in 46 patients (median age, 73). The frequency of TAVR-explant was 0.4%, and the number of explants increased annually. Median time to TAVR-explant was 139 days and among known device types explanted, most were self-expanding valves (29/41, 71%). Common indications for TAVR-explant were procedure-related failure (35%), paravalvular leak (28%), and need for other cardiac surgery (26%). Contraindications to redo TAVR included need for other cardiac surgery (28%), unsuitable noncoronary anatomy (13%), coronary obstruction (11%), and endocarditis (11%). Overall, 65% (30/46) of patients underwent concomitant procedures, including aortic repair/replacement in 33% (n=15), mitral surgery in 22% (n=10), and coronary artery bypass grafting in 16% (n=7). The median Society of Thoracic Surgeons Predicted Risk of Mortality was 4.2% at index TAVR and 9.3% at TAVR-explant (P=0.001). Operative mortality was 20% (9/46) and 76% (35/46) of patients had in-hospital complications. Of patients alive at discharge, 37% (17/37) were discharged home and overall 3-month survival was 73±14%.

CONCLUSIONS: TAVR-explant is rare but increasing, and its clinical impact is substantial. As the utilization of TAVR expands into younger and lower-risk patients, providers should consider the potential for future TAVR-explant during selection of an initial valve strategy.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: aortic valve ■ aortic valve insufficiency ■ aortic valve stenosis ■ cardiac surgical procedures ■ Michigan ■ reoperation ■ transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) is an established alternative to surgical aortic valve replacement (SAVR) for patients with severe symptomatic aortic stenosis, with a growing body of evidence demonstrating the short- and intermediate-term durability of current TAVR devices.[1,2] TAVR has rapidly

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WHAT IS KNOWN

- Repeat transcatheter aortic valve replacement (TAVR) procedures for failed TAVR valves (redo TAVR) have been performed in ≈0.3% to 0.4% of patients.
- Patients with unsuitable anatomy or other contraindications to redo TAVR may undergo surgical explantation of TAVR bioprostheses in conjunction with surgical aortic valve replacement (TAVR-explant).

WHAT THE STUDY ADDS

- By linking data from the Society of Thoracic Surgeons Adult Cardiac Surgery Database and Transcatheter Valve Therapy Registry at Michigan hospitals, this study provides the age of failed TAVR valves and characterizes concurrent coronary and valvular pathology at both the time of index TAVR and TAVR-explant.
- The most common indications for TAVR-explant procedures were procedure-related failure, paravalvular leak, and the need for other cardiac surgery.
- The most common contraindications to redo TAVR in patients undergoing TAVR-explant were the need for other cardiac surgery, unsuitable noncoronary aortic root anatomy, coronary obstruction, and endocarditis.

Nonstandard Abbreviations and Acronyms

ACSD	Adult Cardiac Surgery Database
CABG	coronary artery bypass grafting
MR	mitral regurgitation
SAVR	surgical aortic valve replacement
STS-PROM	Society of Thoracic Surgeons Predicted Risk of Mortality
TVT	transcatheter valve therapy
VIV	valve-in-valve

advanced from its original use in patients at prohibitive surgical risk to those at low risk over the past decade.[3,4] Since the inception of TAVR, an increasing number of patients are requiring procedures for failed TAVR valves. Initial reports of repeat TAVR for failed TAVR valves (eg, redo TAVR) define an incidence of 0.33% to 0.40%[1,2] and a large international series recently reported excellent short-term outcomes at 30 days and 1 year for patients undergoing redo TAVR.[2]

However, these redo TAVRs were performed in select patients with suitable anatomy, whereas the number of TAVR valves requiring surgical explantation and SAVR (TAVR-explant) due to unsuitable anatomy or other contraindications to redo TAVR was not reported. In addition, long-term outcomes after redo TAVR are unknown and the clinical impact of TAVR-explant to address TAVR valve dysfunction has not been well described. An analysis of the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD) described TAVR-explant procedures as rare but morbid compared with similar patients undergoing primary SAVR.[5] However, these data only extend to March 2015, and more contemporary single-center[6] and STS ACSD[7] analyses have shown that the majority of TAVR-explants have occurred more recently. A different national analysis of Medicare beneficiaries found an incidence of 0.2% and comparable 30-day mortality to other series but ends in 2017 and lacks clinical detail for concomitant surgical procedures, such as aortic repair.[8] Furthermore, none of these national analyses include procedural data from the index TAVR.[5,7,8] Merging clinical data from the index TAVR and subsequent TAVR-explant is essential to fully characterize the lifetime management of aortic stenosis in these patients.

Therefore, we linked data from the STS ACSD and Transcatheter Valve Therapy (TVT) Registry through a statewide quality collaborative to (1) define the frequency of TAVR-explant in Michigan and (2) report the indications for and outcomes after TAVR-explant. We hypothesize that the frequency of TAVR-explantation will be comparable to published rates and that older explanted TAVR valves will be associated with more frequent and complex concomitant procedures.

METHODS

Data Sources

Clinical data for surgical TAVR-explant procedures were collected from the STS ACSD through the Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative, developed in 2001 as a cardiac surgeon-led quality collaborative embedded in the Michigan Society of Thoracic and Cardiovascular Surgeons including all 33 nonfederal hospitals performing cardiac surgery in Michigan.

Clinical data for TAVR procedures were collected through Michigan TAVR, a collaboration between the Michigan Society of Thoracic and Cardiovascular Surgeons and Blue Cross Blue Shield Cardiovascular Consortium. The Michigan TAVR Coordinating Center receives quarterly data for Michigan from the STS/American College of Cardiology TVT Registry.

This University of Michigan Institutional Review Board deemed this study to be exempt from review (HUM00185363), and the requirement for informed consent was waived. These data cannot be made available due to data use restrictions. Additional details pertaining to analytic methods are available from the corresponding author upon reasonable request.

Patient Population

Patients undergoing SAVR and with a documented prior TAVR procedure or documented TAVR valve explant between January 1, 2012 and December 31, 2019, in Michigan were identified from the STS ACSD (n=58). From these, 15 patients who underwent redo TAVR and 1 undergoing heart transplantation after prior TAVR were excluded. The total number of

TAVRs performed during the same period was collected from the TVT Registry and used as the denominator for frequency. An additional 4 patients undergoing TAVR-explant procedures between January and June 2020 were included to total 46 patients with TAVR-explant in the final population (Figure 1).

STS dates of birth, sex, height, race/ethnicity, and date of primary TAVR (if known) were used to develop an algorithm to match STS records of TAVR-explant operations to TVT Registry records for index TAVR procedures. In total 91% (42/46) of patients were successfully linked. Reasons for unsuccessful matching may include index TAVRs performed in a different state or enrollment in a trial at the time of index TAVR. Date of primary TAVR was available for 96% (44/46) of patients.

Surgical Explantation of TAVR Bioprostheses

Surgical technique for TAVR-explant procedures was determined according to surgeon preference. Circumferential device neoendotheliazation was often present in older valve explants, and careful dissection was required to avoid structural injuries to the aorta, anterior mitral leaflet, and the membranous septum (Figure 2A through 2D).

Explanted prostheses were either self-expanding (Medtronic, Inc, Minneapolis, MN; n=29, 71%) or balloon-expandable (Edwards Lifesciences, Irvine, CA; n=12, 29%) devices and unknown in 5 patients. The surgical technique of early (<1 year) and late (>1 year) explantation of both self-expanding and balloon-expandable devices has been described previously.[6,9]

Definitions and Outcomes

The primary outcome was operative mortality, defined as death during the hospitalization or within 30 days after TAVR-explant. A subgroup analysis included STS Predicted Risk of Mortality (PROM) for isolated SAVR, which was reported at index TAVR in 91% (42/46), TAVR-explant in 72% (33/46), and available at both initial TAVR and TAVR-explant in 67% (31/46).

Secondary outcomes included time to TAVR-explant, index TAVR echocardiographic data, need for concomitant procedures during TAVR-explant, in-hospital complications, discharge location, 30-day readmission, and all-cause mortality. Individual in-hospital complications included permanent stroke, reoperation for bleeding, new renal failure, postoperative atrial fibrillation, and new permanent pacemaker placement. Echocardiographic data before and after index TAVR was collected from the TVT Registry. Late TAVR-explant occurred >1 year after the initial TAVR procedure and early explant occurred <1 year from initial TAVR, as defined previously.[2,6]

Indications for TAVR-explant were collected from the STS ACSD versions 2.73, 2.81, and 2.9 and could include >1 per patient (Appendix in the Data Supplement). Patients with a need for other cardiac surgery indication also met ≥1 valve-related indications for TAVR-explant. Indications failed repair and sizing/position issue as defined in the STS ACSD were combined and categorized as procedure-related failure to encompass devices that failed either during the index TAVR or afterward for reasons directly related to the procedure. Patient TVT and STS data were used by the authors to determine contraindications to redo TAVR for 74% (34/46) of patients, which also sometimes included >1 per patient.

Statistical Analysis

Normally distributed continuous variables are expressed as mean±SD, and non-normally distributed variables are expressed as median (interquartile range). Bivariate comparisons utilized

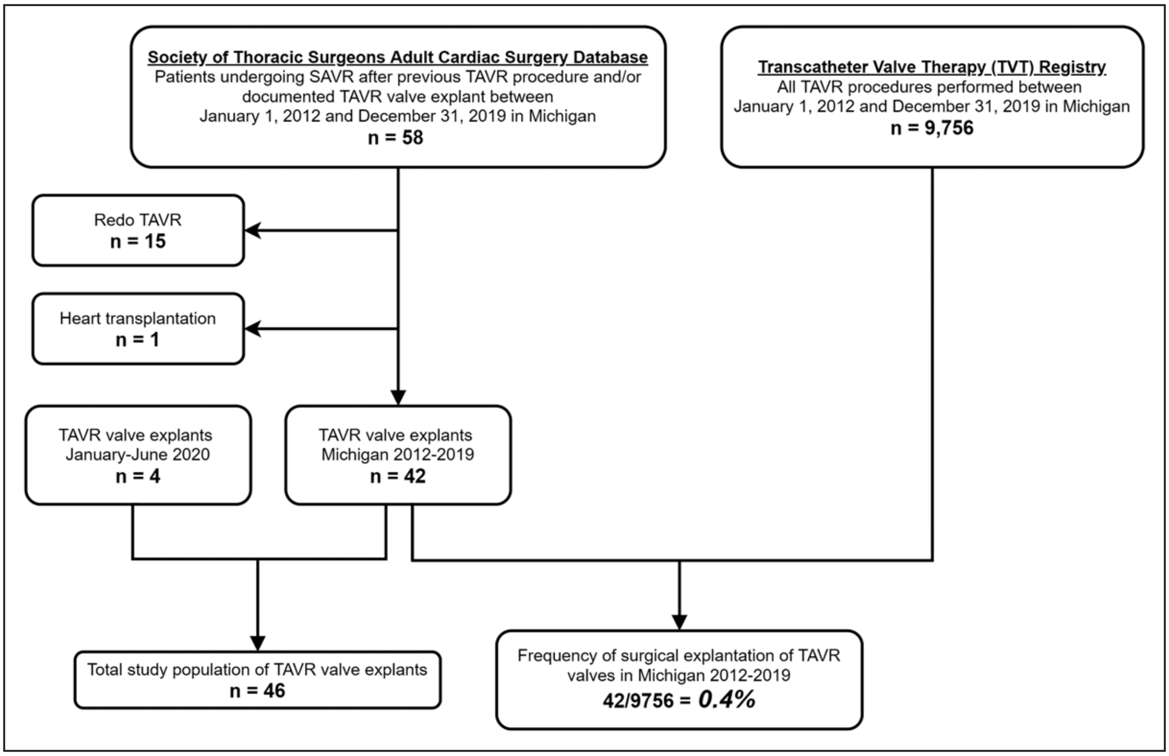

Figure 1. Flow diagram of patient population.
SAVR indicates surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement; and TVT, transcatheter valve therapy.

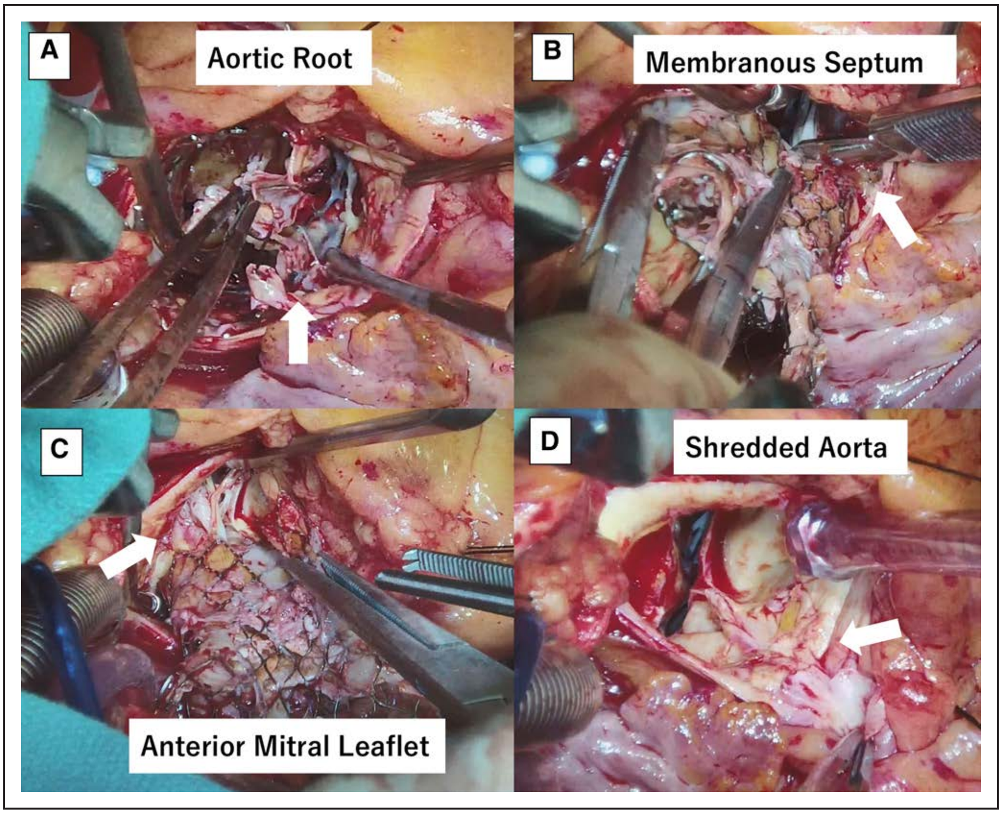

Figure 2. Intraoperative images of a 3-y-old transcatheter aortic valve replacement (TAVR) self-expanding valve explant.
A, Denuded aortic intima due to severe endothelialization. **B**, Severely adherent stent cage to the membranous septum. **C**, Severely adherent stent cage to the anterior mitral leaflet and chordae tendinae. **D**, Disintegrated right coronary sinus after the TAVR valve removal.

paired, 2-tailed *t* tests for normally distributed continuous variables, Wilcoxon rank-sum tests for non-normally distributed continuous variables, and Fisher exact tests for categorical variables.

A spaghetti plot displayed STS-PROM at initial TAVR and TAVR-explant and medians were compared with the Wilcoxon rank-sum test. Time-to-event survival analyses were performed using the log-rank test and Kaplan-Meier estimates with corresponding 95% CIs. Two time-to-event analyses were performed: cumulative frequency of TAVR-explant from date of index TAVR with TAVR-explant treated as a failure event and cumulative survival after TAVR-explant.

$P<0.05$ (2-tailed) were considered statistically significant. Analyses were conducted using Stata 16.0 (StataCorp LLC, College Station, TX).

RESULTS

TAVR-Explant Frequency

The frequency of TAVR-explant between 2012 and 2019 was 0.43% (42/9756), and the number of TAVR-explants increased annually from 1 in 2013 to 17 in 2019 (Figure 3), whereas the number of TAVR procedures also increased from 141 in 2012 to 2404 in 2019 (Figure I in the Data Supplement). Among 157 cardiac surgeons at 33 hospitals in Michigan, 15% (n=24) of surgeons at 36% (12/42) of hospitals performed ≥1 TAVR-explant (median, 1; range, 1–12 per surgeon).

Patient Characteristics

Mean age was 73±8 years, and 33% (n=15) were female (Table 1). At the time of TAVR-explant, 50% (n=23) had chronic lung disease, 43% (n=20) a history of cerebrovascular disease, 15% (n=7) prior stroke, and 28% (n=13) a permanent pacemaker. Mean left ventricular ejection fraction was 50±14%, 14% (n=6) of patients had undergone a prior coronary artery bypass grafting (CABG), 11% (n=5) had a porcelain aorta, and 7% (n=3) had a history of mediastinal radiation.

Eighty-seven percent (34/39) of patients presented with New York Heart Association functional class III/IV heart failure. Among those with available STS-PROM (n=33), 58% (n=19) were at high surgical risk (>8%). The overall median STS-PROM at TAVR-explant was 8.9% (5.4–18.2), which was higher for late versus early explants (14% [7.3–33.6]) versus 6.5% [3.8–17.3]; $P=0.13$; Table 1); however, this did not reach statistical significance.

Index TAVR Data

Data from the index TAVR were available for 91% (42/46) patients (Table I in the Data Supplement). Most presented with New York Heart Association III/IV (n=31) symptoms and the 2 most common indications for TAVR

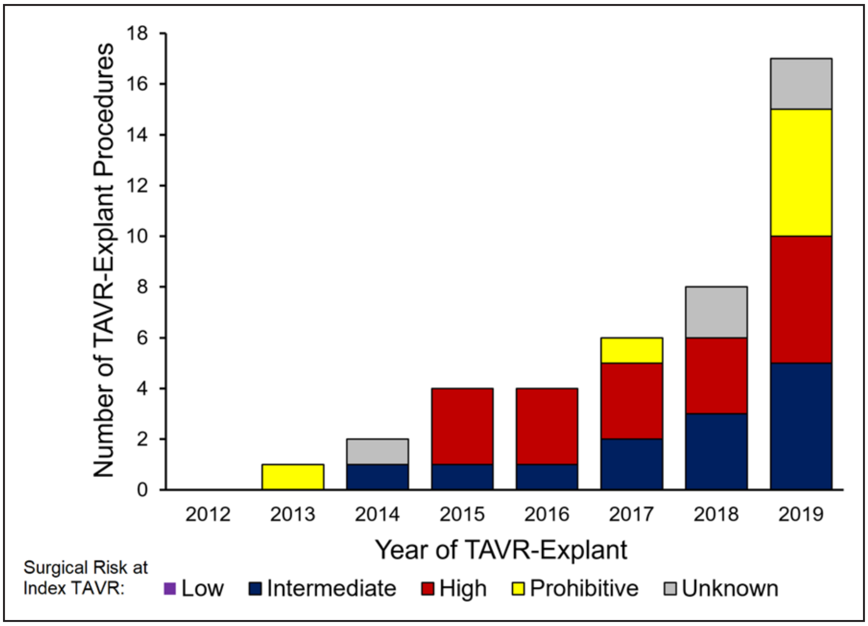

Figure 3. Number of transcatheter aortic valve replacement (TAVR)–explants per year.
Each year is stratified by patient risk at index TAVR (low, intermediate, high, or prohibitive).

were primary aortic stenosis (n=26, 63%) and failed bioprosthetic valve requiring valve-in-valve (VIV) procedures (n=14, 33%). Thirty-three percent of patients (n=14) were classified as intermediate risk for surgery at time of TAVR, 48% (n=20) were high risk, and 19% (n=8) were prohibitive/extreme risk.

Between 2012 and 2019 in Michigan, 40.3% (3935/9756) of TAVR devices implanted were self-expanding, whereas 59.2% (5771/9756) were balloon-expandable. Among eventual TAVR-explants, 71% (n=29) had a self-expanding device implanted at the index TAVR, whereas 29% (n=12) patients received a

Table 1. Patient Characteristics at Time of TAVR-Explant

Characteristic	Overall (n=46)	Early explant (<1 y, n=28)	Late explant (>1 y, n=16)	*P* value
Age, y	73±8	75±8	71±8	0.15
Female sex	15 (33)	6 (21)	8 (50)	0.09
Hypertension	41 (89)	23 (82)	16 (100)	0.14
Diabetes	16 (35)	8 (29)	7 (44)	0.34
Dialysis	6 (13)	4 (14)	2 (13)	1.00
Chronic lung disease	23 (50)	12 (43)	9 (56)	0.53
Cerebrovascular disease	20 (43)	13 (46)	6 (38)	0.75
Prior stroke	7 (15)	5 (18)	2 (13)	1.00
Permanent pacemaker	13 (28)	9 (32)	4 (25)	0.74
Peripheral vascular disease	9 (20)	6 (21)	3 (19)	1.00
Previous myocardial infarction	17 (37)	10 (36)	7 (44)	0.75
Body mass index, kg/m^2	30.9±8.0	28.3±8.1	34.1±6.3	0.018
Left ventricular ejection fraction	50±14%	51±15%	49±13%	0.69
Porcelain aorta	5 (11)	2 (7)	3 (19)	0.34
History of mediastinal radiation	3 (7)	0	3 (19)	0.042
Prior CABG	6 (14)	3 (12)	3 (19)	0.66
NYHA class III/IV (n=39)	34 (87)	19 (83)	13 (93)	0.63
STS predicted risk of mortality, median (interquartile range) [n=33]	8.9% (5.4–18.2)	6.5% (3.8–17.3)	14.0% (7.3–33.6)	0.13
Low (<4%)	6 (18)	5 (26)	1 (8)	0.44
Intermediate (4–8%)	8 (24)	5 (26)	3 (23)	0.44
High (>8%)	19 (58)	9 (47)	9 (69)	0.44

Values are expressed as n (%), mean±SD, or median (interquartile range). CABG indicates coronary artery bypass grafting; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons; and TAVR, transcatheter aortic valve replacement.

balloon-expandable device. Due to intraprocedural positioning errors, a second self-expanding TAVR device was implanted in 3 patients during the index TAVR procedure.

On preTAVR echocardiogram, 5% (n=2) patients had mitral stenosis, 32% (n=13) had moderate or worse mitral regurgitation (MR), and 23% (n=9) had moderate or worse tricuspid regurgitation. Post-TAVR echocardiogram showed mild paravalvular leak in 21% (n=8) of patients and moderate paravalvular leak in 15% (n=5), whereas the rest had none.

Indications for TAVR-Explant and Operative Data

The most common indications for TAVR-explant included procedure-related failure (35%), paravalvular leak (28%), need for other cardiac surgery (26%), and endocarditis (13%; Figure 4A and Figures II and III in the Data Supplement). Contraindications to redo TAVR included need for other cardiac surgery (28%), unsuitable noncoronary anatomy (13%), risk of coronary obstruction (11%), endocarditis (11%), and were unknown in 26% (n=12) of patients (Figure 4B). Unsuitable noncoronary anatomy included prior VIV procedures in 4 patients and an oversized annulus perimeter in 2 patients, precluding redo TAVR. In the subgroup analysis of 31 patients with complete STS-PROM scores, the median STS-PROM was significantly higher at TAVR-explant (9.3% [5.6–18.8]) compared with index TAVR (4.2% [2.5–8.9]; *P*=0.001, Figure 5).

Among patients with known procedure dates (n=44), the median time between TAVR and TAVR-explant was 139 (3–611) days (Figure 6), including 11 patients (25%) who underwent emergent/urgent conversion to TAVR-explant and SAVR on the same day as the index TAVR. All other patients (33/44, 75%) underwent TAVR-explant during a subsequent hospitalization after index TAVR. Sixty-one percent of patients (n=28/46) had undergone at least one previous sternotomy, more frequently among late versus early explants (81% [13/16] versus 46% [13/28], *P*=0.030). A higher proportion of late explants underwent elective procedures, whereas more early explants were emergent (Table 2). Median cardiopulmonary bypass and cross-clamp times were 165 (131–235) and 121 (95–174) minutes, respectively. Seventy-eight percent of patients (n=36) received a stented bioprosthesis, whereas 4% (n=2) received a stentless bioprosthesis and 7% (n=3) a mechanical valve.

Sixty-five percent of patients (n=30) underwent concomitant procedures during TAVR-explant, including 33% (15/46) undergoing aortic repair/replacement, 22% (10/46) mitral repair/replacement, and 16% (7/46) CABG. Among the 15 patients who underwent a concomitant aortic procedure (n=11 explants of self-expanding devices and n=4 balloon-expandable), 12 underwent ascending repair/replacement (n=9 self-expanding and n=3 balloon-expandable), 7 aortic root repair/replacement (n=6 self-expanding and n=1 balloon-expandable), and 3 aortic arch procedures. A higher proportion of late versus early explants underwent concomitant procedures (88% versus 50%, *P*=0.021; Table 2).

Among patients undergoing nonaortic concomitant procedures with TVT index TAVR data available, 55% (5/9) who underwent concomitant mitral surgery had moderate or worse MR at the time of TAVR, 60% (3/5) undergoing tricuspid repair had moderate or worse tricuspid regurgitation, and 60% (3/5) undergoing CABG had significant coronary disease.

Postexplant Outcomes

Mortality in the hospital or within 30 days was 20% (9/46), including 45% (5/11) among patients emergently/urgently converted on the same day as index TAVR. Median postoperative length of stay among those discharged alive was 11 (9–17) days. In total 76% (35/46) of patients had at least one postoperative in-hospital complication, including 37% (17/46) with new postoperative atrial fibrillation, 23% (9/40) new renal failure, 11% (5/46) reoperation for bleeding, 6% (2/33) new permanent pacemaker placement, and 4% (2/46) permanent stroke. Among those alive at discharge, 37% (17/37) were discharged to home and 30-day readmission was 27% (10/37). Postoperative outcomes did not statistically differ between early versus late TAVR-explants (Table 3). TAVR-explants who had undergone prior VIV procedures for failed bioprosthetics had a 0% (0/14) operative mortality, 64% (9/14) had at least one in-hospital complication, 71% (10/14) were discharged home, and 30-day readmission was 14% (2/14).

All-cause mortality was 33% (15/46) at median 14.1 (2.8–40.8) months follow-up after index TAVR and 1.8 (0.7–6.5) months after TAVR-explant. Estimated survival after TAVR-explant was 73±14% at 3 months, 68±15% at 6 months, and 56±20% at 12 months (Figure IV in the Data Supplement).

DISCUSSION

This is the first study using multicenter registry data to comprehensively describe patients undergoing TAVR-explant by linking TVT Registry TAVR procedural and STS ACSD surgical TAVR-explant data. Collectively, these data indicate that TAVR-explants are rare but increasing in frequency, often require concomitant cardiac surgery, and confer significant operative mortality and morbidity.

Prior analyses have described redo TAVR with an incidence of 0.4%[1] and 0.33%,[2] with a recent international registry analysis reporting an excellent 5.4% 30-day mortality among patients with early (<1 year)

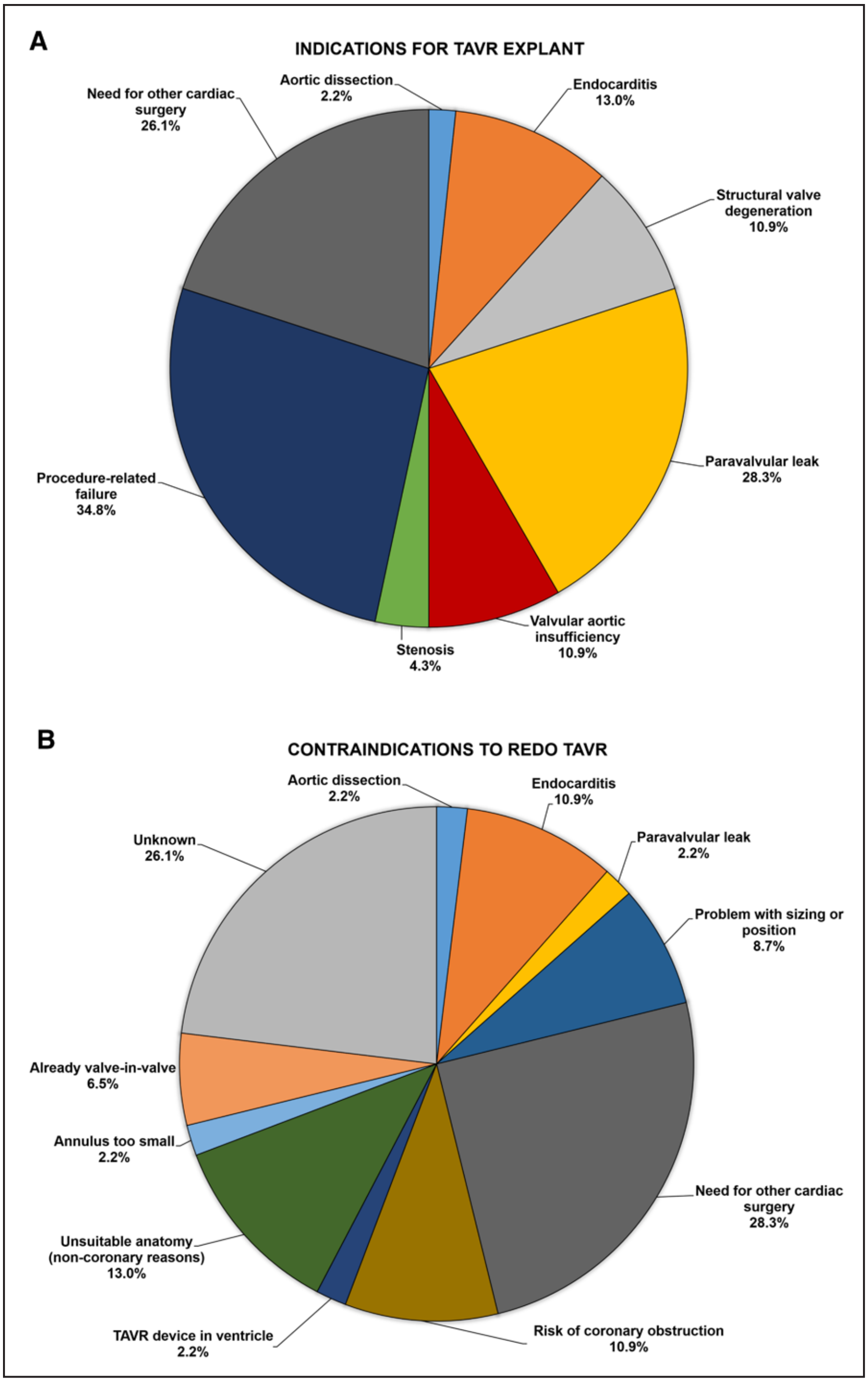

Figure 4. Procedure indications and contraindications.
A, Indications for transcatheter aortic valve replacement (TAVR)–explant. **B**, Contraindications to redo TAVR. TAVR-explant indications were available for all patients, while contraindications to redo TAVR were determined for 34/46 (74%) patients. Some had more than one indication or contraindication. Patients with a need for other cardiac surgery also met ≥1 valve-related indications for TAVR-explant.

valve dysfunction and 1.4% among those with late (>1 year) dysfunction prompting redo TAVR.[2] However, these analyses are restricted to transcatheter registry data and do not address the population of patients with TAVR with contraindications to redo TAVR. The 0.4% frequency in this study suggests that TAVR-explant may be at least as common as redo TAVR. Tang et al[10] established an interesting model which estimated that redo TAVR after Sapien 3 TAVR would be unfeasible in 21.4% of cases. However, the model focuses specifically on the risk of coronary obstruction based on leaflet or stent frame interaction with coronary arteries. The overall feasibility of redo TAVR is likely lower than predicted through this model since the analysis could not consider progression of thrombus, leaflet thickening, and calcification of the native/prosthetic valve or the aortic root over time, potential device constraint of the second TAVR valve, and progression of other synchronous/de novo cardiac pathologies. These factors cannot be appreciated on intraoperative angiogram at the time of index TAVR.[6,11] In addition, the requirement for concomitant procedures common in this, and prior[7] studies presents another contraindication to redo TAVR. Future analyses should evaluate both redo TAVR and TAVR-explant within the same

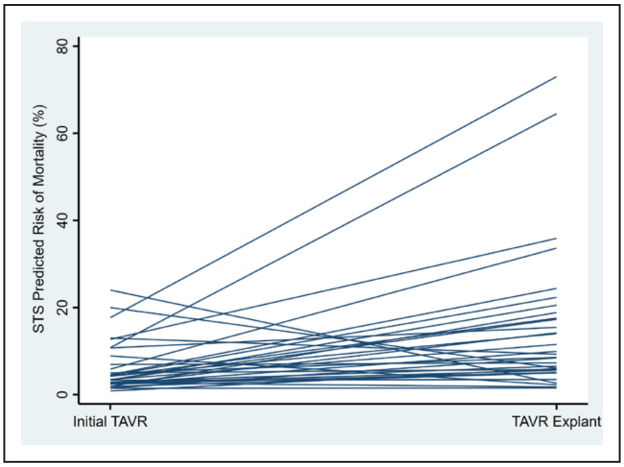

Figure 5. Society of Thoracic Surgeons (STS) Predicted Risk of Mortality (PROM) at index transcatheter aortic valve replacement (TAVR) and TAVR-explant.
An STS-PROM was available at both times in 67% (31/46) of patients.

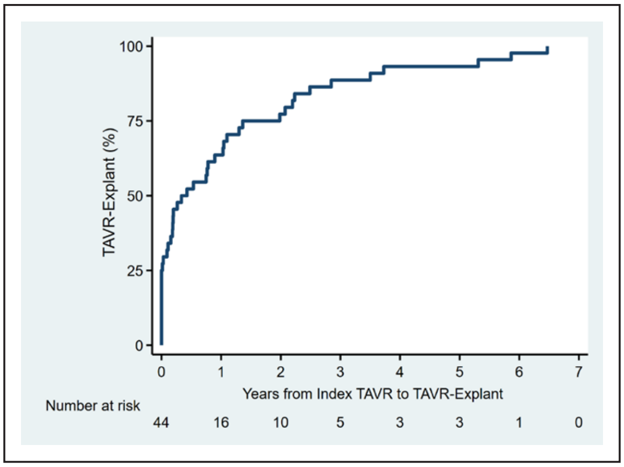

Figure 6. Time to valve failure from index transcatheter aortic valve replacement (TAVR) to TAVR-explant.
Two patients (2/46, 4%) were excluded due to an unknown date of index TAVR.

dataset to fully characterize the incidence, indications, and outcomes of transcatheter or surgical reintervention for failed TAVR valves.

Other studies have described TAVR-explants using surgical databases[5,7] or Medicare data.[8] Interestingly, in an STS ACSD analysis between 2011 and 2015,[5] only 7% of patients underwent root replacement, 2.4% mitral replacement, and 5.7% CABG concomitant to TAVR-explant, compared with 33% who underwent concomitant aortic procedures, 22% mitral, and 16% CABG in this series. These drastic differences may indicate that TAVR-explant procedures became more complicated after 2015, this series may include a higher proportion of late explants, or that regional differences exist between our state and national data. Additionally, 33% of patients in the current study underwent TAV-in-SAV VIV procedures before subsequently requiring TAVR-explant, whereas the STS ACSD database analysis does not include data from the index TAVR and the number of VIV procedures is unknown.[5]

A more updated STS ACSD analysis including TAVR-explants between 2011 and 2018 found a 19.4% 30-day mortality among 782 patients, higher among patients undergoing concomitant procedures (23.8%) versus isolated SAVR (14.8%; P=0.002).[7] In contrast to the 2011 to 2015 study with rare concomitant procedures,[5] the authors reported ascending aortic or root replacement in 25.6%, mitral surgery in 21.1%, and CABG in 15.6%, which were comparable to the current study. Notably, these analyses were unable to define TAVR-explant frequency due to data limitations, although Jawitz et al[5] estimated a 0.3% TAVR-explant incidence. Although one prior study has analyzed data from index TAVR and TAVR-explant within the same dataset and reported a 1.0% TAVR-explant frequency, this was a single-center study with only 17 patients.[6] Because the majority of patients in this and prior studies were high-risk when faced with TAVR-explant, we hypothesize that the incidence of TAVR-explant reported here and elsewhere likely underestimates the incidence of failed TAVR valves since some patients were likely not offered redo TAVR or TAVR-explant due to their extremely high-risk status.

Another recent analysis of TAVR-explant procedures in Medicare beneficiaries from 2012 to 2017 found an incidence of 0.2%.[8] The authors reported 8.4% underwent concomitant CABG and 4.4% other valve procedures and a similarly high mortality at 13.2% and 17.6% at 30 and 90 days, respectively.[8] However, these data are limited to Medicare beneficiaries and most importantly do not fully capture concomitant procedures at TAVR-explant, such as aortic repair. Given that the rates of concomitant procedures and specifically aortic repair/replacement were 65% and 33% in this study and 55.9% and 25.6% in the nationally-representative STS ACSD analysis,[7] capturing these data are important to inform lifetime management of severe aortic stenosis patients and we question whether these patients may have received incomplete therapy at their index TAVR.

Prior multicenter analyses have notably not included TAVR procedural and echocardiographic data, which are essential to understanding why TAVR valves fail and differentiating between concomitant pathologies, such as MR, tricuspid regurgitation, or coronary disease being present at the time of TAVR versus developing in the interval between TAVR and TAVR-explant. In this study, 55% (5/9) of patients who underwent concomitant mitral surgery had moderate or worse MR at the initial TAVR. As prior studies have shown, both mitral stenosis[12] and MR[13] left untreated at index TAVR are associated with higher mortality. Furthermore, the majority of patients who underwent

Table 2. TAVR-Explant Operative Data

Characteristic	Overall (n=46)	Early explant (<1 y, n=28)	Late explant (>1 y, n=16)	*P* value
Redo sternotomy	28 (61)	13 (46)	13 (81)	0.030
Operative status				
Elective	20 (43)	9 (32)	10 (63)	0.025
Urgent	18 (39)	11 (39)	6 (38)	0.025
Emergent/salvage	8 (17)	8 (29)	0	0.025
Cardiopulmonary bypass time, min	165 (131–235)	159 (131–234)	193 (131–253)	0.62
Cross-clamp time, min	121 (95–174)	120 (85–155)	153 (105–184)	0.20
Circulatory arrest	5 (11)	5 (18)	0	0.14
Explanted device type				
Balloon-expandable	12 (26)	9 (32)	3 (19)	0.19
Self-expanding	29 (63)	16 (57)	13 (81)	0.19
Unknown	5 (11)	3 (11)	0	0.19
Explanted device size, mm	29 (26–34)*	29 (26–34)	27.5 (23–31)	0.17
Explanted device age, d	139 (3–611)*	37 (0–109)	809 (486–1320)	<0.001
Implanted prosthesis				
Stented bioprosthesis	36 (78)	21 (75)	13 (81)	0.49
Stentless bioprosthesis	2 (4)	2 (7)	0	0.49
Mechanical valve	3 (7)	1 (4)	2 (13)	0.49
Other	5 (11)	4 (14)	1 (6)	0.49
Implant device size, mm	25 (23–27)	25 (23–27)	23 (23–25)	0.11
Concomitant procedures	30 (65)	14 (50)	14 (88)	0.021
Annular enlargement	5 (11)	1 (4)	4 (25)	0.06
Mitral	10 (22)	3 (11)	6 (38)	0.06
Coronary artery bypass grafting	7 (16)	2 (7)	3 (19)	0.34
Tricuspid	6 (13)	4 (15)	2 (13)	1.00
Aortic procedure	15 (33)	7 (26)	8 (50)	0.19
Root repair/replacement	7 (15)	2 (7)	5 (31)	0.08
Ascending repair/endarterectomy	12 (26)	7 (25)	5 (31)	0.73
Arch	3 (7)	3 (11)	0	0.29
Ventricular septal defect repair	1 (2)	1 (4)	0	1.00
Multiple concomitant procedures	8 (17)	2 (7)	5 (31)	0.08
Intra-aortic balloon pump	3 (7)	2 (7)	1 (6)	1.00
ECMO	4 (9)	3 (11)	1 (6)	1.00

Values are expressed as n (%) or median (interquartile range). ECMO indicates extracorporeal membrane oxygenation; and TAVR, transcatheter aortic valve replacement.

*n=44 patients.

concomitant tricuspid repair and CABG had moderate or worse tricuspid regurgitation or significant coronary disease, respectively, at the time of index TAVR. Given the median number of TAVR-explants per surgeon was 1, we expect an associated learning curve (particularly with older TAVR valves), which may contribute to the high reported mortality and morbidity rates. Additionally, the need for other cardiac surgery at time of TAVR-explant was present in >25% of patients and may result from incomplete therapy of synchronous cardiac pathology at the initial intervention.

These data raise a concern for the appropriateness of TAVR as a first valve strategy in younger, healthier patients who inevitably outlive the lifespan of their TAVR valves. With recent favorable outcomes after TAVR in low-risk patients[3,4] and the subsequent Centers for Medicare and Medicaid National Coverage Decision which may double the number of hospitals eligible to perform TAVR,[14] the number of TAVR procedures performed in low-risk patients is expected to increase substantially. Although a 0.4% TAVR-explant frequency reinforces similarly low incidences reported with TAVR-explant in Medicare (0.2%)[8] and redo TAVR data (0.33%),[2] this study importantly does not include any patients undergoing TAVR-explant who were deemed low-risk at their index TAVR.

Table 3. Postoperative Outcomes by Timing of TAVR-Explant

Characteristic	Overall (n=46)	Early (<1 y, n=28)	Late (>1 y, n=16)	*P* value
Operative mortality	9 (20)	6 (21)	3 (19)	1.00
ICU length of stay, h	113 (47–209)	112 (52–172)	146 (45–229)	0.57
In-hospital complication, %	35 (76)	20 (71)	13 (81)	0.72
Permanent stroke	2 (4)	2 (7)	0	0.53
Reoperation for bleeding	5 (11)	2 (7)	3 (19)	0.34
New renal failure*	9 (23)	4 (17)	4 (29)	0.43
Atrial fibrillation	17 (37)	11 (39)	5 (31)	0.75
New pacemaker†	2 (6)	0	2 (17)	0.14
Postoperative length of stay, d‡	11 (9–17)	10 (8–16)	12 (9–25)	0.23
Discharge location‡				
Home	17 (37)	9 (39)	8 (67)	0.16
Extended/transitional care/rehab	19 (41)	14 (61)	4 (33)	0.16
Nursing home	1 (2)	0	0	0.16
30-day readmission‡	10 (27)	5 (23)	5 (42)	0.44
All-cause mortality	15 (33)	9 (32)	6 (38)	0.75
Follow-up after TAVR-explant, mo	1.8 (0.7–6.5)	1.6 (0.4–11.0)	2.0 (0.9–5.3)	0.97

Values are expressed as n (%) or median (interquartile range). ICU indicates intensive care unit; and TAVR, transcatheter aortic valve replacement.

*n=40 without end-stage renal disease preoperatively.

†n=33 without a permanent pacemaker preoperatively.

‡n=37 patients alive at discharge.

Limitations

This study has several limitations. First, it is descriptive, with a relatively small sample size. However, this is the only registry analysis providing linked STS and TVT data, which provides unique insights into TAVR-explants which cannot be obtained from STS ACSD or Medicare data alone. Second, insights into operative technique are limited in this database study. However, we include important procedural data from both the TAVR and TAVR-explant procedures and have previously published on TAVR-explant technique in significant detail.[6,9] Third, the granularity of TAVR-explant indications is limited to data reported in the STS ACSD, which is a limitation of registry studies. Fourth, follow-up is short for recent TAVR procedures, which comprise the majority of TAVRs performed. As a result, future analyses may show that TAVR-explants occur at later times than represented in these data.

Conclusions

TAVR-explant is a rare, but clinically significant procedure required for some patients with failed TAVR valves. These procedures carry a higher risk of surgical mortality than at the time of index TAVR and two-thirds of patients in this series required concomitant cardiac surgical procedures at the time of TAVR-explant. As the widespread adoption of TAVR continues and the number of younger, lower-risk patients become TAVR candidates, providers should consider these data in the context of lifetime management to determine the best initial valve strategy for severe aortic stenosis patients.

ARTICLE INFORMATION

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Supplemental Materials

Expanded Methods
Table I
Figures I–IV

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