Featured Article

Clinical outcomes of TAVR explant stratified by original risk profile: insights from 110 TAVR explants

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Background: Reoperations after transcatheter aortic valve replacement (TAVR) are increasingly reported with consistently poor outcomes. This study aimed to analyze clinical outcomes of TAVR explantation stratified by the original risk profile at the time of TAVR.

Methods: We reviewed our single institutional series of 110 consecutive patients who underwent TAVR explant between 2013 and 2024. This cohort was stratified into low-risk (n=35), intermediate-risk (n=35), and high/extreme-risk (n=40) categories based on the original risk profile.

Results: Low-risk patients began to appear in 2018. By 2021, the number of low/intermediate-risk patients surpassed that of the high/extreme-risk group. Balloon-expandable valves were predominantly used in the low-risk group, whereas chronic kidney disease was more prevalent in the other groups. The majority of patients in each group had either structural valve deterioration (SVD) and/or non-SVD as the primary failure mechanism, with endocarditis accounting for 20% or less. Cardiopulmonary bypass/aortic cross-clamp times were longest in the high-/extreme-risk group. Overall, 75 (68.2%) patients underwent a concomitant procedure during TAVR explant, most commonly an aortic (n=39; 52.0%) and a mitral procedure (n=29; 38.7%). The high/extreme-risk group had the highest rates of concomitant procedures. Operative mortality improved significantly over time, dropping from 27.3% in Era 1 (2013–2017) to 5.6% in Era 3 (2022–2024) (P=0.049). The operative and one-year mortality rates were 8.6%, 8.6%, and 7.5% (P=0.98), and 17.1%, 8.6%, and 17.5% (P=0.48) in the low-, intermediate-, and high-/extreme-risk group, respectively. Conversely, the observed-to-expected mortality ratio (O/E ratio) was highest in the low-risk group (2.8 *vs.* 1.0 *vs.* 0.8; P<0.001).

Conclusions: Low-risk patients are emerging as the predominant group requiring TAVR explant. Despite the procedural simplicity and lower-risk profile, the operative mortality was comparable to higher-risk groups, and the O/E ratio was significantly higher in the low-risk group. Thoughtful reconsideration of the TAVR-first approach may be warranted for this population.

Keywords: Transcatheter aortic valve replacement (TAVR); surgical aortic valve replacement (SAVR); the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM)

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Introduction

Since the first commercial approval of transcatheter aortic valve replacement (TAVR) by the US Food and Drug Administration (FDA) in 2011, it has now become a standard for patients with severe aortic stenosis and appropriate anatomy (1-4). With a growing body of evidence demonstrating procedural safety, valve performance and excellent clinical outcomes (5). Consequently, over the past decade, TAVR has expanded from its original role in high/extreme-risk populations to those with low surgical risk (1-4). Presently, the Society of Thoracic Surgeons' Predicted Risk of Mortality (STS-PROM) score for surgical

aortic valve replacement (SAVR) is no longer considered a determinant of candidacy for TAVR. Furthermore, the indications for TAVR have broadened to include bicuspid valve pathology (6), and ongoing investigations are assessing its use for native aortic regurgitation (7).

Despite the rapid expansion of TAVR utilization, little is known about the fate of patients with failed TAVR valves. Earlier research has predominantly focused on the favorable aspects of TAVR, and our understanding of failing TAVR valves and necessary reinterventions has lagged behind the development of newer-generation TAVR valves, refinements in implantation techniques, and expansion of TAVR indications. Clearly, the implementation of TAVR has outpaced our understanding of the true long-term consequences of TAVR usage. There are two mainstay treatments for failed TAVR valves: redo-TAVR or TAVR explant. However, previous studies have reported the frequency and clinical outcomes from each treatment independently, and therefore, there was little insight related to the proportion and characteristics of each treatment among all-comers. Several reports have demonstrated consistently poor clinical outcomes after TAVR explant, attributed to the high-risk profile of TAVR recipients and high rates of concomitant procedures, most commonly aortic and mitral interventions (8,9). Of particular concern is the recent increase in post-TAVR cardiac reoperations following low-risk TAVR approval in 2019, as reported from an updated study of the STS Adult Cardiac Surgery Database (10). Considering the unfavorable outcomes associated with TAVR explant, there is a pressing need to avoid such scenarios. Consequently, inappropriate treatments, such as valve-in-valve TAVR in patients with severe prosthesis-patient mismatch and bilateral snorkel coronary stents in young patients, are observed in practice (11). While evidence regarding TAVR explant has accumulated in recent years, these investigations have predominantly relied on registry-based studies lacking detailed data (8,9). Thus, the true reasons for the amplified risk of TAVR explant remain unclear. In this report, we share insights from our extensive experience with TAVR explant by reviewing the stratified clinical outcomes based on the original risk profile at the time of TAVR implantation.

Methods

The University of Michigan Institutional Review Board approved all aspects of the study (HUM00190884; approved on August 6th, 2020). The approval included a waiver of informed consent.

Patients and study design

We retrospectively reviewed 2,659 consecutive patients who underwent TAVR at our institution between July 8th, 2011, and December 30th, 2023. Four patients with intraoperative death and five patients with intraoperative SAVR conversion were excluded. Among those included, 82 (3.1%) patients required aortic valve reinterventions, consisting of 54 TAVR explants and 28 redo-TAVRs. Additionally, 56 patients who received a TAVR procedure at a different center underwent TAVR explant at our institution, yielding a total of 110 patients with TAVR explant. While original TAVR implantation procedures were performed between 2011 and 2023, the TAVR explant procedures occurred between May 2013 and April 2024 in the present study. All patients were reviewed by our multidisciplinary structural heart team for treatment options, including redo-TAVR and other catheter-based therapies. This study group was stratified into low-risk (STS-PROM <4; n=35), intermediate-risk (STS-PROM 4–8; n=35), and high/extreme-risk (STS-PROM >8; n=40) categories, based on the documented original STS-PROM at the time of TAVR. Additionally, incremental risk factors not accounted for in the STS risk calculator (e.g., frailty, home oxygen therapy, liver disease, multiple sternotomies) that may increase the level of surgical risk were considered for risk stratification during heart team review at the time of TAVR (2). The patient cohort flow diagram is summarized in *Figure 1*. Abstracted data included patient demographics, clinical and treatment variables, perioperative and follow-up adverse events, and survival. Operative mortality was defined as mortality during the admission following a procedure. Structural valve deterioration (SVD), non-structural valve dysfunction (non-SVD), and echocardiographic variables were defined according to the Valve Academic Research Consortium-3 criteria (12). The TAVR explant difficulty index, as reported by the operating surgeon, was collected for all cases. The details of the grading system are described elsewhere (13). In brief, surgeons were asked to grade the difficulty of the TAVR explant using a scaling system consisting of the inability of standard cardioplegia delivery, the presence of chimney stents at the coronary ostia, and the degree of adhesions at four anatomic locations [sino-tubular junction (STJ), sinus of Valsalva, left ventricular outflow tract (LVOT), including the membranous septum,

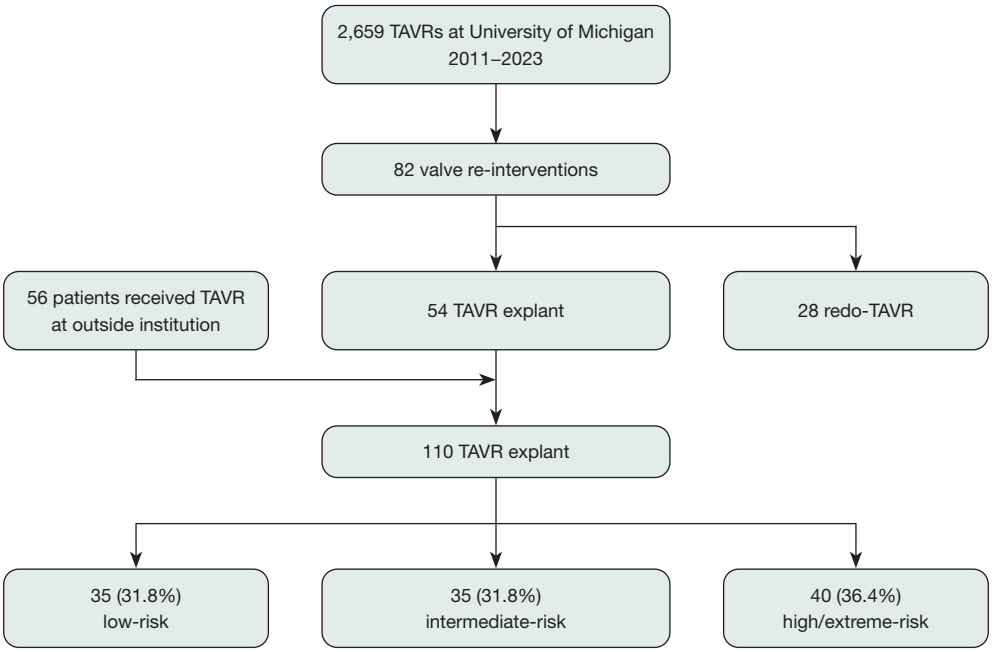

Figure 1 Flow diagram of patient cohort. TAVR, transcatheter aortic valve replacement.

and the anterior mitral leaflet]. TAVR explant difficulty was classified into the following difficulty indexes based on the scoring system: 0–1 (low), 2–3 (intermediate), and 4+ (high). Other clinical variables conformed to the corresponding STS definitions (14). We used the National Death Index database, medical record review, and a telephone survey to obtain long-term survival.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation for normally distributed variables and medians with interquartile range (IQR) for non-normally distributed variables. Categorical variables are presented as proportions and absolute numbers. Differences among groups were detected using the χ^2 test or Fisher's exact test for categorical variables and one-way analysis of variance or Kruskal-Wallis *H* test for continuous variables. Survival data were depicted using the Kaplan-Meier method and the log-rank test with corresponding 95% confidence intervals (CIs). A P value of <0.05 was considered statistically significant. All P values were the result of two-tailed tests. The statistical analyses were performed using SPSS 28.0 (IBM-SPSS Inc., Armonk, NY, USA) and Stata 14.2 (StataCorp, College Station, TX, USA).

Results

Trends of TAVR explant

The number of TAVR explant cases increased over time from 0–1 in 2011–2015 to 26 in 2023. Low-risk patients began to appear in 2018. Notably, the case volume of 20 as of April suggests an anticipated annual volume well above 50 in 2024 (*Figure 2*). The aggregate percentage of patients in the low/intermediate-risk group started exceeding that of the high/extreme-risk group in 2021. The latest breakdown was 85% and 15% in the original low/intermediate-risk and high/extreme-risk groups in 2024, respectively.

The TAVR explant procedure represented second (n=63; 57.3%), third (n=37; 33.6%), fourth (n=8; 7.3%), and firth (n=2; 1.8%) aortic valve intervention. Of these, 3 (2.7%) were TAVR explant cases after redo-TAVR (*Figure 3*).

Patient demographics

Patient demographics and clinical characteristics are shown in *Table 1*. STS-PROM at the time of the original TAVR was 2.0% (IQR, 1.8–2.4%), 5.0% (IQR, 3.6–6.9%), and 7.8% (IQR, 3.3–11.0%) in the low-, intermediate-, and high/extreme-risk groups, respectively. Notably, 30% to 40% of patients already had a permanent pacemaker.

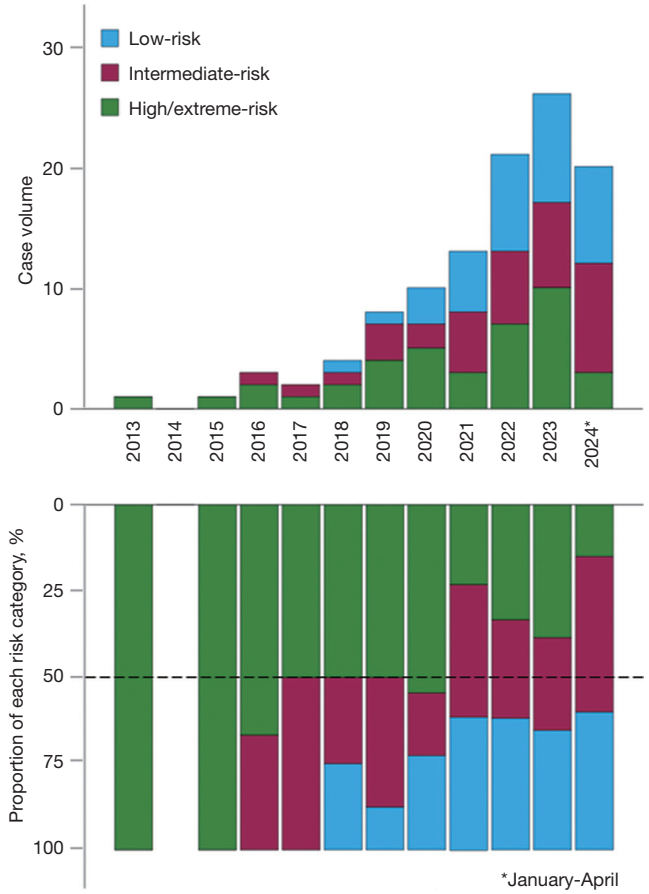

Figure 2 Trends of TAVR explant volume by year. The case volume increased over time from 0–1 in 2011–2013 to 26 in 2023. The case volume was 20 as of April for 2024. Low-risk patients began to appear in 2018. By 2021, the number of low/intermediate-risk patients surpassed that of the high/extreme-risk group. TAVR, transcatheter aortic valve replacement.

Balloon-expandable valves were more frequently used in the low-risk group, while chronic kidney disease was more prevalent in the intermediate- and high/extreme-risk groups. Age at the time of the original TAVR and TAVR explant, the time interval between TAVR implant and explant, the percentage of valve-in-valve TAVR, and the primary valve failure etiology were similar among groups. The majority of patients in each group had either SVD and/or non-SVD as the primary failure mechanism, with endocarditis accounting for 20% or less.

Operative data

The operative data is summarized in *Table 2*. There was no difference concerning the TAVR explant difficulty index or score among groups. Cardiopulmonary bypass and aortic cross-clamp times were longest in the high-risk group. Overall, 75 (68.2%) patients received a concomitant procedure at the time of TAVR explant, most commonly an aortic procedure (n=39; 52.0%) and a mitral procedure (n=29; 38.7%). The high-risk group had the most frequent concomitant procedure rates, attributable to aortic root replacement and mitral procedures.

Postoperative outcomes and follow-up

The postoperative outcomes are summarized in *Table 3*. The overall operative mortality, compared by era, showed significant improvement over time, decreasing from 27.3% in Era 1 (2013–2017) to 5.6% in Era 3 (2022–2024) (P=0.049) (*Figure 4*). The operative and 1-year mortality rates were 8.6%, 8.6%, and 7.5% (P=0.98), and 17.1%,

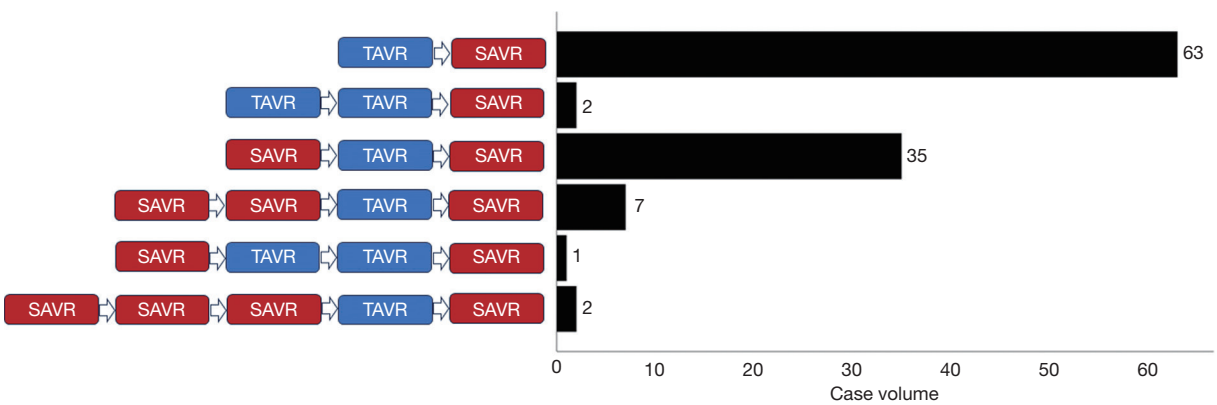

Figure 3 Sequence of aortic valve interventions in the present study cohort. TAVR, transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement.

Table 1 Patient demographics

Variables	Low-risk (n=35)	Intermediate-risk (n=35)	High/extreme-risk (n=40)	P value
Age at TAVR (years)	67 [58–74]	70 [64–78]	69 [59–76]	0.22
Age at TAVR explant (years)	70 [60–76]	73 [65–80]	72 [61–78]	0.21
STS-PROM at original TAVR	2.0 (1.8–2.4)	5.0 (3.6–6.9)	7.8 (3.3–11.0)	<0.001#
STS-PROM at TAVR explant	3.1 (2.5–6.6)	9.0 (4.6–12.4)	9.8 (6.0–20.0)	<0.001#
Native TAVR	25 (71.4)	19 (54.3)	21 (52.5)	0.20
ViV-TAVR	10 (28.6)	16 (45.7)	19 (47.5)	0.20
Female	10 (28.6)	9 (25.7)	13 (32.5)	0.81
Diabetes	15 (42.9)	18 (51.4)	16 (40.0)	0.59
Coronary artery disease	17 (48.6)	18 (51.4)	18 (45.0)	0.86
Chronic kidney disease	15 (42.9)	25 (71.4)	26 (65.0)	0.037#
Dialysis dependent	1 (2.9)	3 (8.6)	8 (20.0)	0.051
COPD	7 (20.0)	7 (20.0)	7 (17.5)	0.95
History of stroke	11 (31.4)	8 (22.9)	11 (27.5)	0.72
Moderate or severe pulmonary hypertension	7 (30.4)	6 (17.1)	10 (25.0)	0.70
Left ventricular ejection fraction (%)	55 [40–60]	50 [30–55]	55 [30–60]	0.41
NYHA Class III/IV	22 (62.9)	26 (74.3)	32 (80.0)	0.24
Permanent pacemaker	11 (31.4)	11 (31.4)	16 (40.0)	0.66
Implanted TAVR valve type				
Self-expandable	13 (37.1)	25 (71.4)	27 (67.5)	0.006#
Balloon-expandable	20 (57.1)	10 (28.6)	13 (32.5)	0.03#
Mechanically-expandable	2 (5.7)	0	0	0.11
TAVR valve size (mm)	26 [23–29]	29 [23–34]	29 [23–29]	0.50
Primary valve failure etiology				
SVD	14 (40.0)	9 (25.7)	14 (35.0)	0.44
Non-SVD	10 (28.6)	13 (37.1)	15 (37.5)	0.67
Mixed SVD + non-SVD	6 (17.1)	6 (17.1)	4 (10.0)	0.59
Endocarditis	5 (14.3)	7 (20.0)	7 (20.0)	0.82

Variables are expressed as numbers (percentages) or medians [interquartile range], as appropriate. # indicates statistically significant (P<0.05). TAVR, transcatheter aortic valve replacement; ViV-TAVR, valve-in-valve TAVR; COPD, chronic obstructive pulmonary disease; STS-PROM, Society of Thoracic Surgeons Predicted Risk of Mortality; NYHA, New York Heart Association; SVD, structural valve deterioration.

8.6%, and 17.5% (P=0.48) in the low-, intermediate-, and high-/extreme-risk group, respectively. In contrast, the O/E ratio was highest in the low-risk group (2.8 *vs.* 1.0 *vs.* 0.8; P<0.001).

The median follow-up period was 1.6 years (IQR, 0.5–3.0 years). Kaplan-Meier survival curve showed no difference among groups in the survival rate up to 2 years after TAVR explant (*Figure 5*). There have been no valve reinterventions except for 2 (1.8%) patients with endocarditis.

Table 2 Operative data

Variables	Low-risk (n=35)	Intermediate-risk (n=35)	High/extreme-risk (n=40)	P value
Redo sternotomy	13 (37.1)	18 (51.4)	23 (57.5)	0.20
Cardiopulmonary bypass time (min)	159 [109–245]	133 [115–200]	201 [153–254]	0.019#
Aortic cross-clamp time (min)	129 [87–205]	108 [83–142]	165 [109–193]	0.025#
TAVR explant difficulty index				0.19
Low	20 (57.1)	15 (42.9)	25 (62.5)	
Intermediate	10 (28.6)	18 (51.4)	12 (30.0)	
High	5 (14.3)	2 (5.7)	3 (7.5)	
TAVR explant difficulty index score	1 [1–3]	2 [1–2]	1 [1–2]	0.59
Isolated SAVR	15 (42.9)	13 (37.1)	7 (20.0)	0.045#
Concomitant procedures				
Aortic root enlargement	14 (40.0)	11 (31.4)	7 (17.5)	0.095
Any aortic repair	11 (31.4)	10 (28.6)	18 (45.0)	0.28
Aortic root replacement	8 (22.9)	4 (11.4)	15 (37.5)	0.031#
Total root replacement	4 (50.0)	3 (75.0)	9 (60.0)	0.70
Partial root replacement	4 (50.0)	1 (25.0)	6 (40.0)	0.70
Ascending aortic replacement	6 (17.1)	7 (20.0)	6 (15.0)	0.85
Mitral repair or replacement	8 (22.9)	5 (14.3)	16 (40.0)	0.035#
Commando procedure	2 (5.7)	1 (2.9)	5 (12.5)	0.25
Tricuspid repair or replacement	2 (5.7)	4 (11.4)	8 (20.0)	0.17
CABG	3 (8.6)	3 (2.7)	5 (12.5)	0.80
Ventricular septal defect repair	0	2 (5.7)	0	0.11
Pulmonary valve replacement	0	0	1 (2.5)	0.42
Mechanical circulatory support	2 (5.7)	1 (2.9)	2 (5.0)	0.84

Variables are expressed as numbers (percentages) or medians [interquartile range], as appropriate. # indicates statistically significant (P<0.05). TAVR, transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement; CABG, coronary artery bypass grafting.

Discussion

This study shared our updated experience with TAVR explant since our TAVR practice began in 2011. The primary findings of interest in this study were: (I) the number of TAVR explant in the originally low/intermediate-risk groups is increasing; (II) low-risk patients more frequently underwent simple isolated aortic valve replacement, while high-/extreme-risk patients underwent more complex operations along with the TAVR explant; (III) despite the simplicity of the procedure and risk profile in the low-risk group, the operative mortality and up to 2 years survival was similar among the three groups and the O/E ratio was significantly higher in the low-risk group; (IV) overall operative mortality after TAVR explant has improved over time.

The need for cardiac surgery after TAVR is becoming a more common entity, which may be potentially one of the most common cardiac operations in the near future. Bowdish *et al.* recently reported important observations from an STS Adult Cardiac Surgery Database study (10). First, the annual incidence of cardiac reoperation after TAVR is increasing, exceeding 6,500 cases, with the most rapidly growing operation being TAVR explant and SAVR, exceeding 3,500 cases as of 2023. Second, the rapid increase of post-TAVR cardiac surgery, particularly TAVR explant

Table 3 Postoperative outcomes

Variables	Low-risk (n=35)	Intermediate-risk (n=35)	High/extreme-risk (n=40)	P value
Operative mortality	3 (8.6)	3 (8.6)	3 (7.5)	0.98
O/E ratio	2.8	1.0	0.8	<0.001[#]
Length of hospital stay (days)	8 [5–21]	11 [8–14]	12 [9–21]	0.12
Stroke	1 (2.9)	1 (2.9)	2 (5.0)	0.85
Prolonged ventilation	12 (34.3)	13 (37.1)	20 (50.0)	0.33
Respiratory failure requiring tracheostomy	1 (2.9)	1 (2.9)	1 (2.5)	0.33
Renal failure requiring dialysis (n=98)*	6 (17.6)	0	4 (12.5)	0.053
Reoperation for bleeding	2 (5.7)	1 (2.9)	2 (5.0)	0.84
Permanent pacemaker (n=72)[†]	0	2 (8.3)	3 (12.5)	0.22
Readmission (n=101)[§]	7 (21.9)	7 (21.2)	13 (35.1)	0.33
1-year mortality (%)	6 (17.1)	3 (8.6)	7 (17.5)	0.48

Variables are expressed as numbers (percentages) or medians [interquartile range], as appropriate. [#] indicates statistically significant (P<0.05). *, among patients without preoperative dialysis; [†], among patients without permanent pacemaker preoperatively; [§], among patients survived to hospital discharge. TAVR, transcatheter aortic valve replacement; O/E ratio, observed-to-expected mortality ratio.

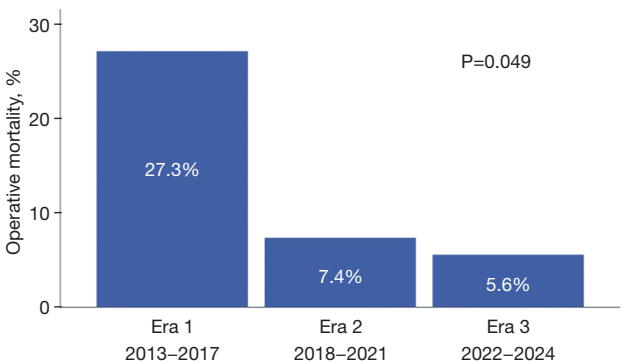

Figure 4 The overall operative mortality, compared by era, showed significant improvement over time, decreasing from 27.3% in Era 1 (2013–2017) to 7.4% in Era 2 (2018–2021) and 5.6% in Era 3 (2022–2024) (P=0.049).

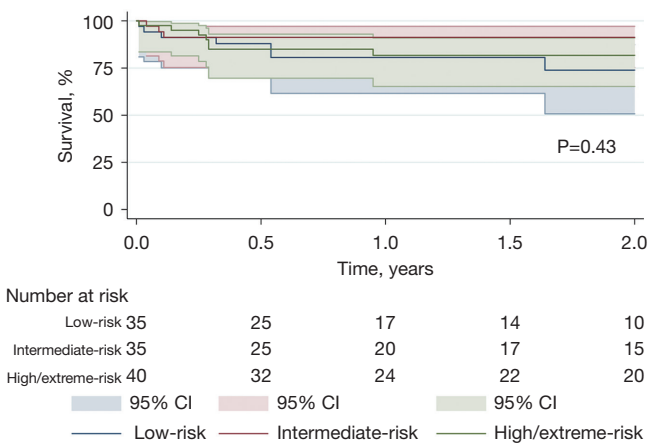

Figure 5 Kaplan-Meier survival curve depicting the estimated survival of each risk category group up to 2 years. CI, confidence interval.

scenarios, was observed after low-risk TAVR approval in 2019. Third, the observed operative mortality of TAVR explant is remaining high, with a mortality rate of 15.8% with a stroke incidence of 4.5%. In contrast to the dismal outcomes of TAVR explant, redo-TAVR continues to demonstrate favorable results. The most intense study was recently published by Makkar *et al.*, describing 1,320 redo-TAVR cases using balloon-expandable valves between 2011 and 2022 from the STS/American College of Cardiology Transcatheter Valve with 4.7% and 17.5% at 30 days and 1-year mortality (15). It is of critical importance to note that the redo-TAVR 1-year survival rate of 17.5% in this TVT registry study was numerically worse than our TAVR explant 1-year survival rate, which was 14.6% (*Table 3*). Compared with the propensity score-matched cohort of first time native TAVRs, the redo-TAVR outcomes were comparable. These results based on the real-world experience with redo-TAVR are promising, as our community have already implanted numerous numbers of TAVR valves including

patients who will outlive the durability of TAVR valves. However, the case volume of only 1,320 redo-TAVRs between 2011 and 2022 is indeed concerning, despite STS Database already having 2,764 TAVR explants within the same time period (10). It is speculated that TAVR explant scenario may be a more common pathway as post-TAVR valve reintervention than redo-TAVR. This statement is also supported by a report by the International EXPLANTORREDO-TAVR Registry (16). In this report, 396 patients underwent reinterventions, consisting of 181 (46%) with reoperations and 215 (54%) with redo-TAVR from 29 centers. This study was the first study revealing the two treatment pathways (redo-TAVR and TAVR explant) across the same centers. Importantly, there was a steep rising trend of case volume of TAVR explant after 2019. It appeared that redo-TAVR was initially more frequently performed before the low-risk TAVR approval. This trend subsequently changed that redo-TAVR and TAVR explant were performed with a fifty-fifty ratio between 2019–2021. More recently, TAVR explant is likely surpassing the redo-TAVR volume among patients needing post-TAVR reintervention. This assumption is in line with the case volume of the STS study (2,764 TAVR explants between 2012–2022) (10) and TVT Registry (1,320 balloon-expandable redo-TAVR between 2011–2022) (15).

Historically, TAVR explant has been considered a high-risk procedure. The present study is the first study that has demonstrated improving trend of postoperative outcomes following TAVR explant. However, this was not due to the increasing trend of more low-risk patients. In fact, the clinical outcomes in the low-risk group were highly concerning despite the less frequent concomitant procedure rates in this group. TAVR explant difficulty or explanted TAVR device type did not appear to have affected the outcomes. The TAVR explant difficulty index was similar among the three groups. There may be a perception by the surgeon that self-expandable TAVR explants are more technically challenging. However, the intermediate- or high/extreme-risk group with more frequent self-expandable TAVR presence did not show worse outcomes. The unfavorable outcomes were likely attributable to heightened burden of heart failure coupled with other related complications such as chronic kidney disease and pulmonary hypertension at the time of TAVR explant regardless of TAVR explant difficulty or explanted TAVR valve type, although the etiology of the higher mortality and failure-to-rescue rates observed were likely multifactorial and inconclusive due to the limited sample size. However, delayed intervention despite TAVR failure by continuously seeking non-surgical options or receiving incomplete non-surgical intervention is not a negligible factor in these circumstances. For instance, in the present series, three patients underwent redo-TAVR and subsequently required TAVR explant. Five patients underwent snorkel coronary stents at the time of TAVR and sustained immediate severe prosthesis-patient mismatch and TAVR explant. The Heart Team Approach concept remains of paramount importance not only for patients undergoing a TAVR for the first time, but also for patients with failing TAVR valves. These suboptimal non-surgical interventions are not helpful. In light of still rare occurrence of TAVR explant procedures, these patients should be evaluated at a tertiary center with experience for TAVR explant.

Study limitations

This study has several inherent limitations including its retrospective nature with small sample size. The TAVR-explant difficulty index has not been validated in a large series and it contains significant subjectivity in terms of each surgeon's perception of the severity of adhesions or surgeon experience in this particular procedure. The survival curves of these three groups (*Figure 5*) crossed, which could suggest a potential violation of the proportional hazards assumption, and the interpretation of the results require caution. We believe that this crossing may be partially attributed to the short follow-up period (2 years) and the small sample size (40 patients or less per group). In view of the large numbers of TAVR devices implanted worldwide, further investigation involving other institutions using standardized methodology is highly warranted to validate our results.

In summary, this study highlighted our updated single-institution experience with TAVR explant. This study represents the first study that demonstrated promising trend of improving outcomes after TAVR explant, although this was not because of the inclusion of more low-risk patients. Considering the concerning clinical outcomes of the low-risk group and the expected notable increase of TAVR explant case volume in the next decade, thoughtful reconsideration of the TAVR-first approach is highly warranted particularly for this population who will likely outlive the longevity of TAVR valves.

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Footnote

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Conflicts of Interest: S.F. serves as a consultant for Terumo Aortic, Medtronic, Edwards Lifesciences and Artivion. G.M.D. is a consultant and investigator for Medtronic. H.J.P. serves as a consultant for Medtronic Inc. G.A. serves as a consultant/advisory board member for Medtronic, Abbott, Edwards Lifesciences, and Cephea. The other authors have no conflicts of interest to declare.

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