

Operative management after transcatheter aortic valve replacement

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ABSTRACT

With broadening applications of transcatheter aortic valve replacement (TAVR) and increasing use in intermediate- and low-risk patients, the incidence of surgical re-interventions after TAVR is growing. Transcatheter heart valves suffer from similar long-term complications as surgical heart valve prostheses that require surgical re-intervention, including endocarditis and structural valve deterioration. Catastrophic periprocedural complications — such as annular or aortic rupture requiring urgent surgical intervention — may also occur during TAVR procedures. This review summarizes the current knowledge on indications, methods, and outcomes of cardiac operations after TAVR, with a focus on how to improve results in a rapidly growing patient population.

Key words: aortic stenosis, cardiac surgery, surgery, TAVI, TAVR

INTRODUCTION

Introduction of transcatheter aortic valve replacement (TAVR) represented a paradigm shift in the management of aortic stenosis. Although initially developed for use in non-operable or high-risk patients, TAVR applications continue to broaden, and both recent American and European guidelines endorse TAVR for intermediate- and select low-risk patients [1, 2]. In the European guidelines [2], TAVR is primarily recommended in older patients (≥ 75 years), or in those who are high-risk (Society of Thoracic Surgeons Predicted Risk of Operative Mortality [STS-PROM]/EuroSCORE II $> 8\%$) or unsuitable for surgery (recommendation class I, level of evidence A), while surgery is recommended for younger patients who are low-risk for surgery (< 75 years and STS-PROM/EuroSCORE II $< 4\%$), or in patients who are operable and unsuitable for transfemoral TAVR (recommendation class I, level of evidence B). For the large group of patients remaining in between, an individual decision should be made on a case-by-case basis (recommendation class I, level of evidence A) [2]. In the American guidelines [1], TAVR is the first choice for individuals > 80 years of age or for younger patients with

a life expectancy < 10 years and no anatomic contraindication to a transfemoral approach (recommendation class I, level of evidence A), while surgery is recommended for patients who are < 65 years old or have a life expectancy > 20 years (recommendation class I, level of evidence A). For patients who are 65–80 years old and have no anatomic contraindication to transfemoral TAVR, the decision between surgery and TAVR should be made individually, taking into account the expected patient longevity and valve durability [1].

Since its advent in 2002, TAVR has been applied to more than 300 000 patients worldwide and with technical progress, the procedural safety profile is excellent [3–5]. However, transcatheter heart valves (THV) suffer from similar long-term complications as surgical heart valve prostheses that require surgical re-intervention, including endocarditis and structural valve deterioration (SVD). Catastrophic procedural complications requiring urgent surgical intervention, although very rare [6], may also occur during TAVR procedures [7]. With the ever-increasing number of patients worldwide undergoing TAVR procedures, particularly in younger and lower-risk patients, the number of patients requiring

conventional surgery following TAVR is expected to grow exponentially. Patients with previous TAVR may also need cardiac surgery due to other non-aortic valve-related indications [8]. Furthermore, the results of surgical management of post-TAVR patients have thus far been discouraging [9]. This review, therefore, summarizes the literature and expert opinions on the indications, methods, and outcomes of operative management after TAVR, with a focus on how to improve on disappointing results in this rapidly growing patient population.

PATIENT PROFILE AND INDICATIONS

Similar to operative interventions in patients with failed transcatheter edge-to-edge repair [10, 11], the patient profile post-TAVR is generally unfavorable for conventional surgery. Most patients that currently require operative management after TAVR (either urgent or elective) had a high operative risk at the baseline procedure, which is further elevated by the presence of complications (both acute complications, such as annular rupture or aortic dissection, or chronic complications, like SVD or paravalvular leaks).

Several studies have examined the incidence of surgical re-intervention post-TAVR. The overall incidence of operative interventions after TAVR was 0.4% in Michigan state as reported by Brescia et al. [12], 1% in a report by Fukuhara et al. from the University of Michigan [13], and 1.2% in a report by Muensterer et al. from Munich [14]. Jawitz et al. [15] in an analysis of the STS database estimated that the incidence of surgery after TAVR in the US is 0.3% nationwide. Based on the STS-ACC TVT Registry of TAVR, Carroll et al. reported an emergency conversion rate (from TAVR to open heart surgery) of 0.4% [6]. A recent meta-analysis of 10 studies including 1690 patients undergoing a TAVR explant estimated the overall incidence of operative interventions at 0.4% (95% confidence interval [CI], 0.2%–0.6%) [9]. The true incidence is difficult to calculate, however, and is likely underestimated by these reports. Furthermore, it is important to note that the number of patients requiring surgery post-TAVR is expected to markedly increase in the future, as an ever-increasing number of non-high-risk patients with extended life expectancies undergo these procedures. While the rate of acute complications requiring emergency sternotomy will likely be stable and low (the incidence is similar in high- and non-high-risk patients) [6], the number of patients surviving until “chronic” complications (e.g. SVD, endocarditis, etc.) develop will be higher.

Patients presenting for surgery after TAVR currently represent a high-risk group with mean age >70 years, frequent STS-PROM >8% and a history of previous cardiac operations with sternotomy (Table 1) [9]. The calculated risk is significantly higher at reoperation than at index TAVR [16], and more than 60% of patients present for surgery with New York Heart Association class III/IV heart failure [9]. The STS-PROM reported in the literature ranges from 4.8% to 11.6% (Table 1), with Yokoyama and colleagues reporting an average of 8.1% in their meta-analysis [9]. The median

time between TAVR and operative management reported by Yokoyama and colleagues was 9.4 months [9], which is slightly longer than in our experience (7 months) [16]. The average time from TAVR to operative intervention reported in the literature ranges from 2.5 to 27.6 months (Table 1).

The most common indication for surgery is infective endocarditis (38%), followed by SVD (28%), and paravalvular leaks (14%) [9], especially in patients with anatomy not favorable for transcatheter management. Tarantini et al. proposed a helpful division of THV failure modes resulting in the indications for intervention following TAVR into four groups: (1) the SVD group (wear and tear, leaflet disruption, flail leaflet, leaflet calcification, strut deformation or fracture); (2) the non-SVD group (including abnormalities not intrinsic to the THV, such as paravalvular leaks, prosthesis-patient mismatch, positioning issues, etc.); (3) the THV thrombosis group; and (4) the THV endocarditis group [17]. Notably, the majority of operated patients require additional procedures at the time of TAVR explanation (Table 1). In our experience, these most commonly include aortic surgery (i.e. root repair and/or ascending aorta repair), mitral valve repair, and coronary artery bypass grafting (CABG) [16]. Yokoyama et al. [9] also reported that aortic surgery was the most common concomitant procedure, followed by mitral valve repair/replacement and CABG. Hence, in the reoperative setting post-TAVR, the aortic valve problem is usually not isolated. Notably, even if THV function is normal, some patients may require interventions due to other problems not solved by TAVR. In the Mayo Clinic experience, many patients undergoing an open heart operation after previous TAVR present with structural mitral or tricuspid valve problems and normal THV function (unpublished data). In a recent analysis of the STS Database, Fukuhara and colleagues [8] identified 666 cases of non-aortic valve surgeries after TAVR, which included mostly CABG (42.5%) and mitral valve procedures (38.7%). Importantly, more than half of these operations involved redo sternotomy [8].

EMERGENCY SURGERY AFTER TAVR

Cardiac surgery is an essential task of the Heart Team, and the cardiopulmonary bypass-capable operating room should be immediately available or on standby [1, 2]. While acute complications requiring emergency surgery are uncommon, they do occur. In a recent study from our center (Leipzig), we found that emergency surgery was required in 1.1% of TAVR patients with a decreasing incidence over time (from 3.5% in years 2006–2010 to 1.8% in years 2011–2015, to 0.4% in years 2016–2020) (Marin-Cuartas et al., submitted manuscript). Carroll et al. reported that the rate of conversions to open surgery with cardiopulmonary bypass during TAVR in the STS-ACC TVT Registry has steadily decreased from 1.4% in 2012 to 0.4% in 2019, and was similar across the patient risk strata [6].

Indications for emergency operations due to TAVR complications may include obstruction of coronary ostia,

Table 1. Studies reporting operative management of TAVR recipients

Publication	Number of patients	Age	Indications				Prior sternotomy	Time from TAVR to surgery (months)	Concurrent cardiac procedures	Calculated risk of mortality ^{a,b}	Observed mortality	O/E ratio
			Structural valve deterioration	Non-structural valve deterioration indications								
				Paravalvular leak/aortic regurgitation	Implantation failure/valve migration	Aortic stenosis/PPM						
Yokoyama et al., 2021 (meta-analysis) [9]	1690	73.7	27.7%	14.2%	12.7%	9.1%	37.6%	52.9%	8.1% ^a	16.7%	2.1	
Fukuhara et al., 2020 [56]	782	74.0	6.5%	21.5%	27%	20.2%	17.7%	55.9%	8.5% ^a	13.1% (19.4%) ^c	1.54	
Fukuhara et al., 2022 [57]	483	72.8	5.8%	16.1%	30.2%	18.2%	20.5%	62.7%	4.8% ^{a,d}	18%	2.2 ^d	
Baptat et al., 2021 [58]	269	72.7	15.2%	16.7%	3.7%	6.3%	43.1%	54.6%	5.0% ^a	13.1%	2.6	
Hirji et al., 2020 [49]	227	73.7	79.3%	—	—	—	20.7%	12.8%	90/227 prohibitive/high 137/227 high/intermediate risk ^a	13.2%	—	
Vitanova et al., 2022 [59]	196	73.5	21.4%	17.3%	4.1%	10.7%	42.9%	37.8%	5.1% ^a	9.6%	1.9	
Jawitz et al., 2020 [15]	123	77	11.4%	15.5%	10.6%	10.6%	9.8%	8.1%	8.8%	17.1%	1.9	
Yun et al., 2022 [60]	59	70	36%	24%	14%	3.4%	17%	79%	5.5% ^a	8.5%	1.5	
Brescia et al., 2021 [12]	46	73.0	10.9%	39.2%	34.8%	4.3%	13.0%	65%	8.9% ^a	20%	2.2	
Fukuhara et al., 2022 [61]	37	73.0	29%	35%	21%	11%	8%	84%	8.3% ^a	15%	1.8	
Fukuhara et al., 2021 [62]	34	74.9	—	50%	18%	38%	12%	68%	7.7% ^a	15%	1.9	
Marin-Cuartas et al., 2022 [16]	28	76	3.6%	10.7%	10.7%	3.6%	67.8%	60.7%	11.6% ^b	14.3%	1.2	
Fukuhara et al., 2021 [63]	28	72	39%	43%	—	—	7%	65%	8.5% ^a	15%	1.8	
Muensterer et al., 2022 [14]	31	76.3	3.2%	32.3%	6.5%	3.2%	51.6%	30.8%	5.9% ^a	25.8%	4.4	
Fukuhara et al., 2021 [13]	17	73.0	23.5%	41.2%	23.5%	—	5.9%	35.3%	9.9%	11.8%	1.2	

^aSTS-PROM. ^bLogistic EuroSCORE. ^cThe first value is given for patients with available STS-PROM (n = 283), the value in brackets for all patients. ^dn = 157, O/E calculated for patients with available STS-PROM only. Abbreviations: TAVR, transcatheter aortic valve replacement

valve migration (either retrograde into the ventricle or antegrade into the distal aorta), aortic dissection [7], aortic and/or annular rupture (Figure 1A), and heart perforation. Operative mortality in this setting is high and related to patients' risk profile. We found that in-hospital mortality was 62.1% in high-risk patients and 12.5% in low/intermediate-risk patients, while the one-year survival rate was 38% in high-risk patients vs. 88% in low- or intermediate-risk patients requiring emergency surgery after TAVR (unpublished data).

Data from the European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI), including 27 760 TAVR procedures reported the incidence of emergency cardiac surgery secondary to TAVR complications as 0.76%–0.98% [18]. The proportions of different THV types requiring emergency surgical management were similar in this report, and the most common reasons for operation were ventricular perforation (28.3%), followed by annular rupture (21.2%), valve migration/embolization (12.7%), and aortic dissection (11.8%) [18]. In this report, in-hospital mortality was 46.0% and was the highest in the case of annular rupture (62%). Fewer than 25% of urgently operated patients were alive at 1 year post-surgery [18]. However, the prognosis may change in the future with increased TAVR application in younger and lower-risk patients, who would have a higher chance of surviving an emergency operation.

INFECTIVE ENDOCARDITIS

Infective endocarditis (IE; Figure 1B and D–F) complicates TAVR with a similar incidence to surgical aortic valve replacement, ranging from 0.3%–1.9% per patient-year [19–22]. Comparison of balloon-expandable and self-expandable THVs showed no differences in IE rates [23]. The most commonly reported pathogens are *Enterococci* and *Staphylococcus aureus*, followed by *Streptococci* and coagulase-negative *Staphylococci* [24, 25]. The majority of cases occur in the first year after TAVR [26]. A multicenter registry reported in-hospital mortality of 41.8% and a 2-year mortality rate of 66.7% in IE complicating TAVR [27]. A study by Mangner et al. showed that mortality is modulated mostly by IE severity at diagnosis [28], yet TAVR recipients are less likely to receive surgical treatment (50% in the case of surgical prosthetic valve IE [29, 30] vs. 10.8% in THV IE [28]).

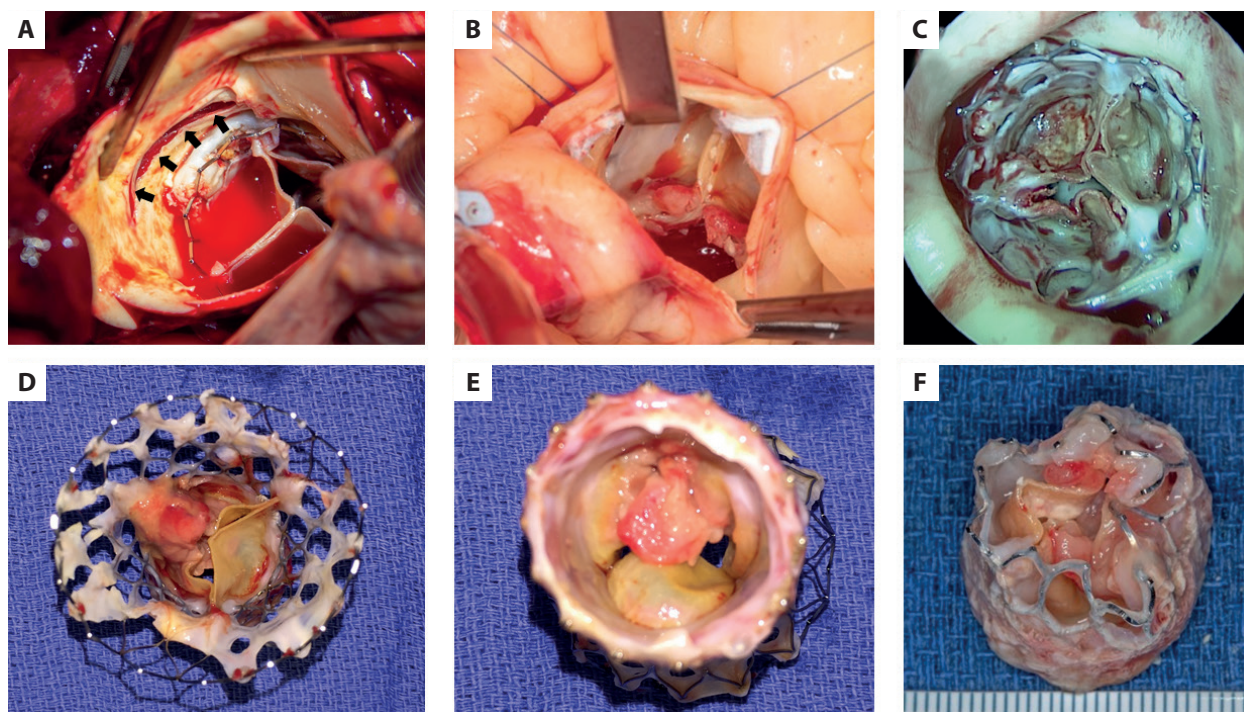


Figure 1. Representative images of intraoperative views during transcatheter valve explantation. **A.** Emergency surgery due to aortic rupture (black arrows) following Sapien 3 valve implantation. **B.** Intraoperative view of a Sapien 3 valve with endocarditis, aortotomy at the usual level. **C.** Intraoperative view of a Sapien 3 valve with structural valve deterioration 7 years after implantation. **D.** CoreValve prosthesis with endocarditis after explantation seen from the aortic side, and **E.** from the ventricular side. **F.** An explanted Sapien 3 valve with endocarditis. The stent frame was fractured to facilitate removal

TAVR recipients suffering from IE are usually elderly with multiple comorbidities and atypical presentations, with up to 20% of patients presenting without fever [20, 23, 27]. IE can present as THV obstruction, which may be difficult to differentiate from THV thrombosis [31]. Furthermore, stent frame presence impedes leaflet visualization on echocardiography, and the vegetations may be present within the stent frame or outside of the prosthesis, without leaflet involvement. This may lead to failure in vegetation detection on transesophageal echocardiography (TEE) in up to 60% of patients [23, 24, 27, 32]. An analysis from the Mayo Clinic showed that TEE was diagnostic for THV IE in only 47% of cases, while TTE was diagnostic in only 18% [31]. Combined multimodal imaging including computed tomography and positron emission tomography is therefore commonly required.

The cornerstone of treatment of TAVR IE is antimicrobial therapy which follows the same principles as for infected surgical prostheses [33]. Surgical indications are the same as for conventional post-surgical prosthesis patients (i.e. acute heart failure secondary to valvular dysfunction, uncontrolled infection, and/or embolic episodes). While operative management is the preferred treatment strategy for such patients, it should ideally be done in a center experienced in complex reoperations and aortic surgery. Data from a multicenter registry in Germany showed that the incidence of root surgery was 14.5% during operations for THV IE [34], which is not more common than in native

aortic valve IE (16.8%) [35]. The incidence of root abscess is also not different in IE after TAVR and conventional surgical valve replacement [36]. The decision to operate should be weighed against the surgical risk profile of the patient and made within the confines of an endocarditis team [37].

More than 60% of patients undergoing surgery for THV IE develop at least one complication such as stroke, acute kidney injury, or heart failure [21, 27, 28]. Interestingly, the incidence of stroke or systemic embolism events is higher in balloon-expandable valves (possibly due to different distribution of vegetations), but the incidence, timing, and etiology of IE are similar irrespectively of the type of THV [23]. The mortality rates for TAVR IE are high, ranging from 16 to 36% for in-hospital mortality and 41–59% at 1-year [20, 25–27]. Notwithstanding, the results of operative management of TAVR IE are not significantly different than those of surgical valve IE [36]. In the report of the ESC-EORP EURO-ENDO (European Infective Endocarditis Registry), the strongest predictor of mortality in IE was not performing surgery when indications were present [38]. Hence surgery should always be considered as a possible option for patients meeting criteria for surgery.

STRUCTURAL VALVE DETERIORATION

SVD (Figure 1C) is a degenerative process gradually leading to prosthetic valve dysfunction due to stenosis (40%), regurgitation (30%), or a combination of stenosis and regurgitation (30%) [39]. Significant discrepancies in the definition

of SVD between reports make comparisons of SVD rates between surgical and transcatheter valves difficult [40, 41]. For example, Aldati et al. showed that there is no difference in SVD rates between TAVR and surgery when using the Valve Academic Research Consortium-2 (VARC-2) criteria, but SVD rates are higher after surgery in the same cohort if the European Association of Percutaneous Cardiovascular Interventions (EAPCI) criteria are applied [42]. Data on THV SVD are also limited by the evolving technology and current TAVR population characteristics. Most previously treated TAVR patients are elderly, multimorbid, and have limited life expectancy, hence the number of patients available for long-term follow-up studies is limited [40]. In the 5-year results of the PARTNER-1 trial, Kappadia and Mack reported no SVD [43, 44], but in a meta-analysis of 8914 patients included in observational studies, Foroutan et al. reported a pooled incidence of 0.28 per 100 patients/year in TAVR recipients [45]. Pibarot reported that among PARTNER-2 trial participants, the second-generation SAPIEN XT balloon-expandable valve had a higher 5-year rate of SVD compared with surgical valves (1.6 vs. 0.6 per 100 patient-years, respectively), whereas the third-generation SAPIEN 3 was comparable [46]. Among patients included in the NOTION Trial, the SVD rate after TAVR was 5% at 6 years [47] but increased significantly to 14% at 8 years [48]. Longer-term data will be emerging as an increasing number of intermediate- and low-risk patients with longer life expectancies are being treated with TAVR.

TECHNICAL ASPECTS OF VALVE EXPLANTATION

Surgery post-TAVR is frequently performed as a re-sternotomy procedure, with 14%–47% of patients having undergone previous cardiac operations, most commonly CABG [13, 16, 49]. The surgical approach must therefore account for the increased technical demands associated with re-sternotomy such as adhesions and risk of injury to mediastinal structures. The presence of patent bypass grafts is particularly important since the grafts should not be injured and because they can complicate myocardial protection during the procedure [50]. After the exposure of the valve, some technical aspects are specific to the type of implanted THV (see below), and almost 90% of patients receive a bioprosthetic valve [9].

Balloon expandable valves

The low profile of an Edwards Sapien valve (Edwards Lifesciences, Irvine, CA, US), the most commonly implanted balloon-expandable device, usually spares coronary ostia from obstruction and allows aortotomy at the usual site [16]. Our preferred technique in Leipzig is to crimp the valve with two-needle holders, placed at 8 and 12 o'clock on the valve stent facing the surgeon [16]. The instruments are then pushed inwards and turned towards each other, allowing folding of the valve. The maneuver can be

repeated along different parts of the stent circumference if needed, which is followed by blunt dissection from the annulus. Badiu and colleagues [51] described a technique with passing of heavy silk ties through the opposite frame cells of the upper valve stent. When the ties are tightened up in the center, the valve can be crimped [51]. Nakazato and colleagues reported a technique involving cutting the whole stent in one line until the bottom of the frame so that the radial force is released, and the valve is dissected circumferentially with electrocautery [52]. At the Mayo Clinic, we use a similar "spam can" technique, with vertical transection of the stent followed by rolling it onto itself with a Kocher clamp. In general, removal of balloon expandable devices is usually relatively straightforward and most of the time does not require root replacement.

Self-expanding valves

The most commonly implanted self-expanding THV is CoreValve/Evolut (Medtronic, Minneapolis, MN, US), which has an hourglass-shaped stent and high profile. The landing zone usually stretches from the left ventricular outflow tract (LVOT) to the ascending aorta, and the frame can be endothelialized and incorporated into the aortic wall, leading to the potential for injury of the root, coronaries, and ascending aorta [16]. Furthermore, the high stent level forces the surgeon to make a transverse aortotomy in the aorta much higher than usual, complicating exposure of the aortic root and LVOT. Ice slush can facilitate extraction by restoring nitinol stent flexibility, but in many cases, aortic repair or even total aortic root replacement is necessary. Bruschi et al. reported using polypropylene sutures passed through the uppermost frame cells of the stent, which were passed through a tourniquet and inserted inside the outflow cone of the CoreValve delivery system, allowing the surgeon to "recapture" the prosthesis [53]. Tully et al. [54] reported using a piece of 3/8 inch tubing for the same purpose, but a small cylindrical valve sizer may be equally effective, and this is our preferred technique. The prosthesis can usually be safely removed using an "endarterectomy" technique, peeling the valve stent off the aortic wall [55].

Another example of this design is Symetis Accurate Neo THV (Boston Scientific, Marlborough, MA, US). This self-expanding THV has three distinctive stabilization arches within the frame, which stabilize it in the aorta during deployment. Due to the occasional proximity of coronary ostia, removing the upper part of the stent may also be difficult. Our technique of choice is to tie the arches together with a silk tie and pass the tie through a cylindrical valve sizer (e.g. 19-mm ATS Medtronic valve sizer), using it as a crimping device. Sharp hooks pointing towards the sinotubular junction and the ascending aorta are present in the lower crown, below the tissue valve. These hooks may damage the aortic wall during valve extirpation, requiring aortic repair or, occasionally, total root replacement.

SURGICAL OUTCOMES

The reported operative (30-day) mortality rates are relatively high for these patients, ranging from 8.5%–25.8% (Table 1), which is in part due to the high-risk profile of the patients and the increased incidence of IE. In a meta-analysis of 1690 patients undergoing surgery post-TAVR, the 30-day mortality rate was 16.7% [9]. This disappointing mortality rate was more than 2-fold higher than the STS-PROM score for the patient group and irrespective of the presence of endocarditis. The observed mortality rate in other studies is generally higher than predicted, with O/E ratios of approximately 2 (Table 1). These increased O/E ratios are in striking contrast to reoperations after mitral valve transcatheter edge-to-edge repair failure [10, 11]. In the Leipzig experience, the O/E ratio was 1.2 [16]. Also, non-aortic valve operations in TAVR recipients are associated with poor outcomes, with O/E ratios of 1.8 for isolated CABG, 1.8 for isolated mitral valve repair, and 1.7 for isolated mitral valve replacement [8]. These disappointing results underline the need for improved surgical results in patients undergoing surgery post-TAVR. In addition, these results should be considered during lifetime management discussions with patients with aortic stenosis and during signing informed consent for TAVR procedures, particularly with younger or lower-risk patients.

FUTURE PERSPECTIVE

TAVR adoption in the lower-risk younger populations is growing rapidly both in Europe and the US. Surgeons will therefore be increasingly faced with TAVR explantation procedures, where the results have thus far been uniformly disappointing. Cardiac surgeons affiliated with TAVR programs should be adequately trained to tackle these complex procedures, which frequently involve concomitant root and aortic surgery. Heart Teams should plan initial interventions in such a way as to facilitate future repeat procedures, both transcatheter and surgical, especially in younger and lower-risk patients. Finally, the Heart Team should play an essential role in the management of patients requiring surgery post-TAVR.

Article information

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