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Original Article

Transcatheter aortic valve replacement among heart transplant recipients with donor aortic valve diseases: a systematic review of the literature

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Abstract: Background: Despite high surgical risk among heart transplant (HTx) recipients, who develop aortic valve diseases (AVD), transcutaneous aortic valve replacement (TAVR) has been scarcely reported as a viable option in this patient population. Methods: A systematic review was conducted to identify studies reporting the outcomes of HTx recipients who developed AVD of the donor heart and underwent TAVR. Studies were eligible if they provided individual-level data for HTx recipients, who underwent TAVR on the donor heart. Review articles, editorials or commentaries, studies lacking original data, or those reporting surgical valve replacement for AVD in HTx recipients were excluded. Results: A total of 15 case reports, encompassing 15 patients, describing characteristics and outcomes of HTx recipients undergoing TAVR were included. These included 13 males and 2 females with an average age of 63.6±15 years. The indications for HTx were non-ischemic dilated cardiomyopathy, ischemic cardiomyopathy and ischemic dilated cardiomyopathy in 42.9%, 35.7%, and 21.4% of the patients, respectively. The main indication for aortic valve replacement (AVR) among HTx recipients was aortic stenosis (73.3%). The transcutaneous approach was preferred over surgical AVR due to high surgical risk in > 50% of the patients. Both pre-TAVR transvalvular pressure gradient and the peak aortic pressure gradient decreased after the TAVR. Paravalvular leak was minimal/none to mild in all the patients post-TAVR. Most patients had an uneventful post-TAVR recovery with no recurrence of the symptoms or echocardiographic finings at a median follow-up of 6 months. Conclusions: TAVR seems to be a viable option for HTx recipients who develop donor aortic valve diseases. However, there is a paucity of knowledge on the long-term survivability of the replaced aortic valves and the clinical and echocardiographic outcomes of HTx recipients undergoing TAVR.

Keywords: Heart transplant, HTx, cardiac transplantation, donor heart, aortic valve diseases, transcatheter aortic valve replacement, TAVR

Introduction

Due to ongoing advances in the surgical techniques and development of targeted immunosuppressive regimens over the past decades, survivability has steadily increased among patients receiving heart transplant (HTx) [1, 2]. This has caused HTx recipients to develop late comorbidities such as vasculopathy or valvular diseases more commonly [3-5]. While right-sided heart valve diseases more likely result from hemodynamic changes in pulmonary vasculature, left-sided valvulopathies mainly arise from atrial structural changes or ventricular dysfunctions [6, 7]. Regardless of the underlying etiology, which is multifactorial in many cases, re-intervention among HTx recipients, who develop aortic valve diseases (AVD) poses certain risk factors including but not limited to multiple comorbidities, immunosuppression, redo-sternotomy, and anticoagulation challenges after aortic valve replacement (AVR) or repair.

Transcatheter aortic valve replacement (TAVR) has proved to be a viable alternative to surgical AVR in high-risk patients with AVD or a compa-

rable option in moderate-to-low risk counterparts [8-11]. Nevertheless, the utility of TAVR has not been studied among HTx recipients who develop AVD. Hence, we aimed to systematically review the current literature on the studies reporting the peri-procedural outcomes of TAVR among HTx recipients who developed donor AVD and underwent TAVR.

Methods

Study design

A systematic review of the literature was performed by inquiring PubMed/Medline, Scopus, Embase and Google Scholar to identify studies reporting on the outcomes of TAVR among HTx recipients since inception to 12/20/2022. The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) were followed throughout the literature review, study selection, and data curation [12]. The following combination of keywords was used as MeSH Terms and free-text words: "transcatheter", "aortic valve", "heart transplant*", and "cardiac transplant*".

Literature review and eligibility criteria

The title and abstracts of the retrieved articles were screened for potential relevancy. The full texts of the relevant articles were reviewed in-depth for eligibility. Studies were eligible if they were presenting original data for HTx recipients who underwent TAVR for the native aortic valve in the donated heart. Review articles, editorials or commentaries, and studies providing data on surgical/operative valve replacement techniques were excluded.

Outcome measures

Eligible studies were reviewed for data extraction using a predetermined data spreadsheet. This included the lead author's name, publication date, study type, sample size, country of patient's residence, demographics, clinical presentation at the time of AVD diagnosis, peri-TAVR clinical and diagnostic work-up, peri-procedural outcomes, and follow-up. When available, the time interval was also obtained for the elapsed period between HTx, AVD diagnosis, TAVR, and follow-up outcomes.

Data collection and descriptive statistics

Using individual data from each study, descriptive analysis was performed using Stata/BE 17 for windows (StatCorp LLC, College Station, TX, USA). Data is presented as mean ± standard deviation (SD) and number (percentage) as appropriate. As there was not sufficient data available, an inferential statistical analysis was not feasible to perform.

Results

Literature review

A total of 15 case reports encompassing 15 patients were included in this systematic review [13-27]. **Figure 1** depicts our systematic approach to the literature review and study selection following the PRISMA guidelines. All the studies were case reports of patients who had received HTx and later underwent TAVR due to the donor AVD. Almost half of the cases were from US (4 patients, 26.7%) [15, 16, 22, 26] and UK (3 patients, 20%) [14, 20, 21]. Publication timeframe ranged from 2010 [25] to 2022 [20] with an average of less than a case per year. All the extracted data are available in the Supplementary Materials.

Demographics and clinical characteristics of HTx recipients who underwent TAVR

Out of 15 HTx recipients, 13 patients were male (86.7%) and 2 patients were female (13.3%). The average age of the HTx recipients at the time of AVD diagnosis was 63.6±15 years (min: 25 and max: 80). The time interval between HTx and TAVR ranged from 15 weeks to 34 years with an average of 16.5±7.8 years. The main indication for HTx was non-ischemic dilated cardiomyopathy (6 patients, 42.9%), ischemic cardiomyopathy (5 patients, 35.7%), and ischemic dilated cardiomyopathy (3 patients, 21.4%).

Postoperative outcomes of HTx recipients

Graft rejection was reported in 2 patients after HTx, one case within 15 weeks postoperatively [18] and another one after 3 years [17]. One patient was a case of redo-HTx due to biventricular malfunctioning of the initial donor heart [19]. Three donated hearts (20%) had bicuspid donor aortic valve [14, 16, 22]. Allograft vasculopathy occurred in 7 HTx recipients (53.8%), out of which 3 patients (42.8%) underwent percutaneous coronary interventions; two patients with a stenotic lesion in the left anterior descending artery, one patient in the

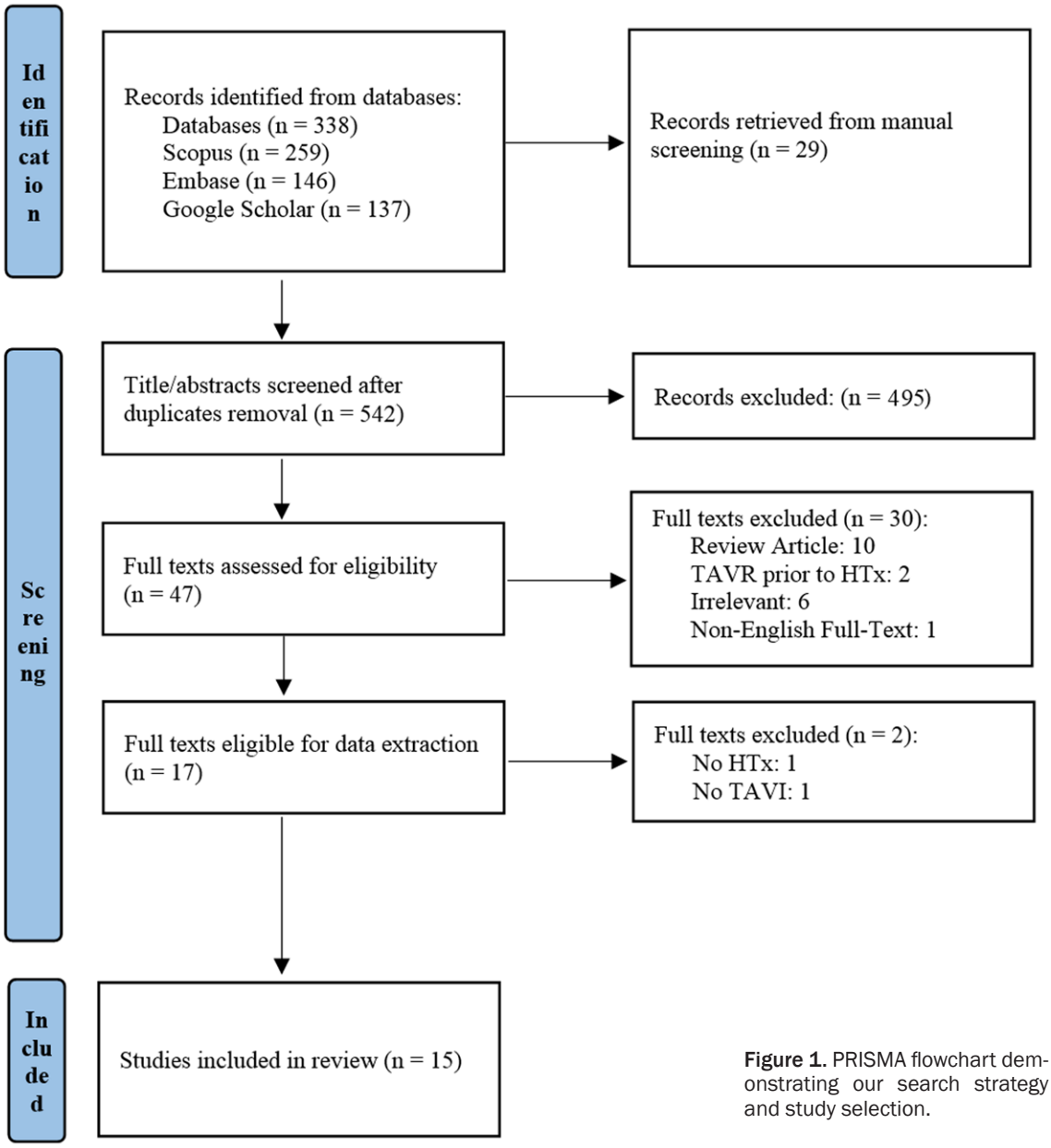

Figure 1. PRISMA flowchart demonstrating our search strategy and study selection.

left circumflex artery, and 4 patients with diffuse vasculopathy not plausible for stenting. Characteristics of the HTx recipients and the donor heart are presented in **Table 1**.

Clinical characteristics of HTx recipients with AVD

Initial presentation of the patients with donor AVD were progressive dyspnea on exertion (10 patients, 66.7%), acute pulmonary edema (1 patient, 6.7%), feeling of illness (1 patient, 6.7%), and echocardiographic findings of AVD (aortic stenosis, increased peak aortic pressure, and reduced ejection fraction) during routine post-HTx follow-up (3 patients, 20.1%). All the patients had established comorbidities with CKD being the most common one (8 patients, 53.3%), followed by hypertension (7 patients, 46.7%) and hyperlipidemia (4 patients, 26.7%). The main indications for aortic valve replacement (AVR) were aortic stenosis (11 patients, 73.3%), aortic regurgitation (3 patients, 20%), or both (1 patient, 6.7%). The indications for TAVR over a surgical AVR were high surgical risk (9 patients, 60%), poor medi-

Table 1. Characteristics of of heart transplant (HTx) recipients who developed aortic valve diseases in their donor heart

Author	Year	Country	Gender	Age at AVD (yrs)	HTx to TAVR interval (yrs)	Indication for HTx	Age at HTx	Bicuspid AV	Graft Rejection
Ezad	2022	UK	Male	61	34	IDC	27	No	No
Beale	2020	USA	Male	45	22	IC	23	Yes	No
Wallen	2020	USA	Male	80	24	IC	56	No	No
Avula	2019	USA	Male	69	19	NIC	54	No	No
Akleh	2018	UK	Male	77	23	IDC	54	Yes	No
Julien	2017	USA	Male	73	13	NIC	60	Yes	No
Margale	2017	Australia	Male	65	12	IC	53	No	No
Ahmad	2016	Denmark	Female	25	14	NIC	11	No	No
Kyranis	2016	Australia	Male	68	12	IC	56	No	No
Gopalamurugan	2014	UK	Male	60	20	N/A	40	No	No
De Praetere	2013	Belgium	Male	77	18	IC	59	No	No
Zanuttini	2013	Italy	Male	75	14	NIC	61	No	No
Chandola	2012	Canada	Female	45	0.26	NIC	45	No	3 years
Bruschi	2010	Italy	Male	67	9	NIC	58	No	15 weeks
Seiffert	2010	Germany	Male	67	14	IDC	53	No	No

Yrs: Years; AVD: Aortic valve diseases; HTx: Heart transplantation; TAVR: Transcutaneous aortic valve replacement; N/A: Not available; IDC: Ischemic dilated cardiomyopathy; IC: Ischemic cardiomyopathy; NIC: Non-ischemic cardiomyopathy; DOE: Dyspnea on exertion; Echo: Echocardiographic; EF: Ejection fraction.

cal condition (1 patient, 6.7%), and a history of a redo-HTx (1 patient, 6.7%). The preference for TAVR over SAVR was unclear in 4 patients (26.7%). The Society of Thoracic Surgeon risk for patients with high surgical risk for AVR ranged between 7.03% and 20.39% while the European System for Cardiac Operative Risk Evaluation Score (EuroSCORE) ranged from 26.74% to 36%. The peri-procedural clinical characteristics of HTx recipients are summarized in **Table 2**.

Peri-procedural outcome measures of HTx recipients with AVD undergoing TAVR

Pre-TAVR echocardiographic evaluation of HTx recipients showed an average ejection fraction (EF) of 35.6%±17.3 (range: 21% to 70%), an aortic valve area (AVA) of 78.4±18.5 mm^2 (range: 50 to 100 mm^2), a mean aortic transvalvular pressure gradient of 36±15.1 mmHg (range: 17 to 52 mmHg), a peak aortic pressure gradient of 66.4±20.9 mmHg (range: 32 to 87 mmHg), and a peak velocity of 4.5±0.5 m/s (range: 4 to 4.9 m/s) (**Table 3**).

All TAVRs were performed through a transfemoral approach except one case, which was accomplished via a left anterior mini-thoracotomy to access the left ventricular apex [25]. The size of the implanted prosthetic valves ranged from 23 mm to 34 mm with the most common valve size being 29 mm (5 patients, 38.5%), 26 mm (4 patients, 30.8%), and 25 mm (2 patients, 15.4%). The average post-TAVR mean and peak aortic pressure gradients were 9.9±5.5 mmHg and 16±8.8 mmHg, respectively. Paravalvular leak was mild in 3 patients (20%) and minimal or none in the remaining cases.

The average length of the hospital stay ranged from 2 days to 18 days with an average of 5.5±5 days. Hospital course was uneventful in all but three patients; two patients developed a 3rd degree atrioventricular block requiring pacemaker implantation [16, 27] and one patient required upgrade of the single-chamber pacemaker to a dual-chamber pacemaker due to bradycardia with Mobitz type 2 atrioventricular block noted prior to TAVR [14].

Patients were followed up from 1 to 18 months with a median of 6 months, with no recurrent symptomatology or abnormal echocardiographic findings. There was no reported mortality during the follow up period of this study.

Due to the limited number of cases and a heterogeneity in the reported echocardiographic parameters, an inferential analysis was not plausible to perform. However, post-HTx and pre-TAVR echocardiographic parameters were depicted against the time interval between HTx and TAVR, which demonstrated no relationship between AVA, mean or peak pressure gradient, and peak velocity with the time elapsed since HTx (**Figure 2**).

Discussion

Our literature review found 15 reported cases of TAVR among HTx recipients who developed AVD after heart transplantation. The results show that TAVR is a safe option for AVR with acceptable clinical and echocardiographic outcomes, at least in the short-term.

The average time interval from HTx to TAVR was 16 years with the main indication for AVR to be severe or symptomatic aortic stenosis; of these, three cases (20%) had a bicuspid donor aortic valve. Allograft vasculopathy occurred roughly in half of the patients and a similar proportion had an established CKD. Routine echocardiography was able to identify about 20% of the patients with AVDs before clinically significant symptomatology. TAVR was preferred over SAVR due to a high surgical risk profile among HTx recipients with multiple comorbidities. On average, pre-TAVR EF, AVA, aortic transvalvular pressure gradient, peak aortic pressure gradient, and peak velocity were 35.6%, 78.4 mm^2, 36 mmHg, 66.4 mmHg, and 4.5 m/s, respectively. Following TAVR, mean and peak aortic pressure gradients reduced to 9.9 mmHg and 16 mmHg, respectively. The implanted prosthetic valve size ranged between 23 mm and 34 mm with 29-mm being the most common valve size used for TAVR on the donor heart. Paravalvular leak was mild or none in all the patients. The average length of hospital stay was 5.5 days and clinically uneventful in the majority of the cases. Of the 3 cases with post-TAVR in-hospital complications, de-novo and recurrent heart blocks occurred in 2 patients and 1 patient, respectively. At a median follow-up of 6 months, no patient developed any symptoms suggesting recurrent AVD or had any abnormal findings on surveillance echocardiog-

Table 2. Peri-procedural clinical characteristics of heart transplant recipients undergoing transcutaneous aortic valve replacement

Author/Year	Presentation at AVD	Comorbidity	Allograft Vasculopathy/Stent	Indication for AVR	Surgical Risk Score
Ezad/2022	DOE	CKD	No	AS	
Beale/2020	DOE	HTN, HLP, CKD, arrhythmia, SCC	Yes/LAD	AS	STS score: 12.9%
Wallen/2020	DOE	HTN, CKD	No	AS	
Avu/2019	DOE	HTN	No	AS	
Akleh/2018	DOE	HTN, HLP, CKD, arrhythmia	No	AS	STS score: 7.03%
Julien/2017	DOE		No	AS	STS score: 8.02%
Margale/2017	DOE	HTN, HLP, CKD, DM, MM, obesity, OSA, smoking	Yes	AS	Euro score: 30%
Ahmad/2016	Echo finding (increasing peak aortic pressure)		Yes	AS	
Kyranis/2016	DOE			AS	STS score: 20.39%
Gopalamurugan/2014	Echo finding (reducing EF)	Arrhythmia		AR	
De Praetere/2013	DOE		Yes	AS and AR	Euro score: 26.74%
Zanuttini/2013	DOE	HTN, CKD, COPD, previous thoracic surgery	Yes/LCA	AR	Euro score: 36%
Chandola/2012	Feeling unwell	CKD	No	AR	
Bruschi/2010	Acute pulmonary edema	CKD, chronic HCV	Yes	AS	
Seiffert/2010	Echo finding (aortic stenosis)	HTN, HLP, and smoking	Yes/LAD	AS	STS score: 29%

AVD: Aortic valve diseases; AVR: Aortic valve replacement; AS: Aortic stenosis; AR: Aortic regurgitation; Echo: Echocardiographic; DOE: Dyspnea on exertion; HTN: Hypertension; HLP: Hyperlipidemia; COPD: Chronic obstructive pulmonary diseases; HCV: Hepatitis C virus; SCC: Squamous cell carcinoma; CKD: Chronic kidney diseases; DM: Diabetes mellitus; MM: Multiple myeloma; OSA: Obstructive sleep apnea; LAD: Left anterior descending artery; LCA: Left circumflex artery; STS: Society of Thoracic Surgeon.

Table 3. Peri-procedural echocardiographic findings of heart transplant recipients undergoing transcutaneous aortic valve replacement

Author/Year	Pre-TAVR						TAVR	Post-TAVR				LOS	Hospital Course	Follow-up
	EF	AVA	AD	PAV	MAG	PAG		EF	MAG	PAG	Para-valvular Leak			
Ezad/2022			33				34-mm Evolut R						N/A	N/A
Beale/2020				4.7	52		Balloon expandable transcatheter valve		8			6	3rd degree AV Block	N/A
Wallen/2020	70%					77	29-mm Medtronic evolute		22		Mild	2	Uneventful	
Avula/2019							N/A					2	Uneventful	
Akleh/2018	50%	90	25			65	29-mm Edwards Sapien 3		12	14		2	Single-chamber Pacemaker Upgraded to Dual-chamber	1
Julien/2017							26-mm Sapien 3		13	27	None	2	Uneventful	
Margale/2017	21%	89		4			25-mm Lotus valve						Uneventful	18
Ahmad/2016		100			44	71	23-mm Edwards Sapien 3		11	20		3	Uneventful	1
Kyranis/2016	21%	70		4.9	44		25-mm Lotus Valve	30%	10		None	4	Uneventful	
Gopalamurugan/2014							26-mm CoreValve					2	Uneventful	12
De Praetere/2013	25%	90			17	32	26-mm Edwards-Sapien pericardial valve				Minimal	6	Uneventful	6
Zanuttini/2013	40%		24				29-mm CoreValve	50%	10	16	Mild	18	3rd degree AV Block and Afib	
Chandola/2012	23%						A 29-mm CoreValve		1	3	None		N/A	
Bruschi/2010	35%	50				87	A 29-mm CoreValve	36%	6		Mild	12	Uneventful	4
Seiffert/2010		60	25		23		26-mm Edwards Sapien pericardial valve		6		Trivial	7	Uneventful	1

TAVR: Transcutaneous aortic valve replacement; EF: Ejection fraction; AVA: Aortic valve area; AD: Aortic diameter; PAV: Peak aortic velocity; MAG: Mean aortic valve gradient; PAG: Peak aortic gradient; LOS: Length of hospitalization.

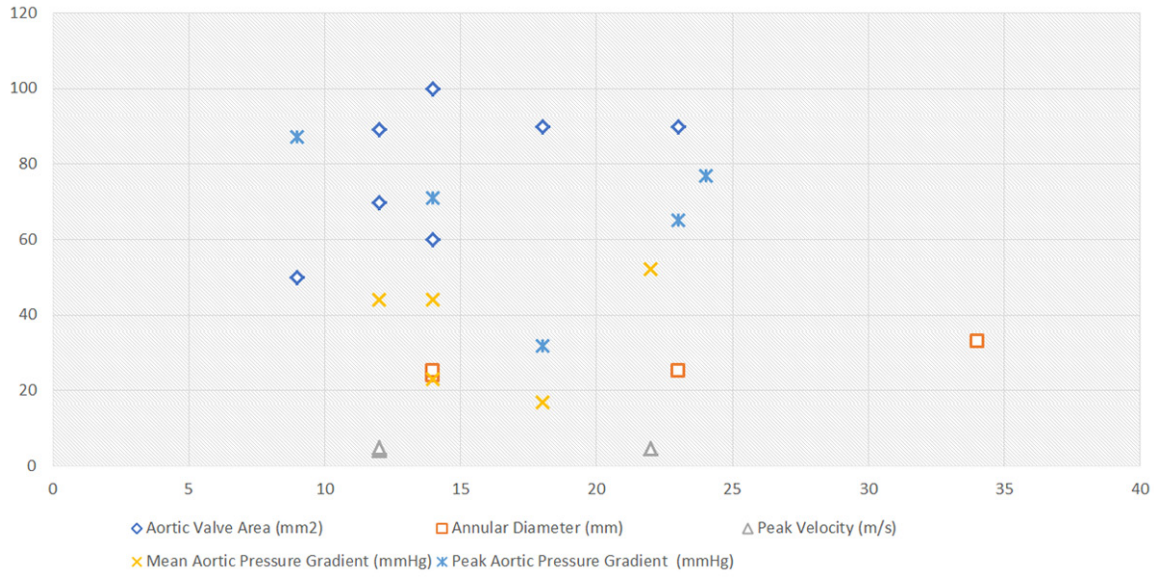

Figure 2. Echocardiographic parameter in cardiac allograft recipients prior to transcutaneous aortic valve replacement and their association with time elapsed since heart transplantation.

raphy. There was no mortality reported among HTx recipients in relation to TAVR on the donor heart.

Transcatheter valve replacement technology has revolutionized the art of treatment for AVD, first among high-risk [11], and later, among low-to-intermediate surgical risk patients [8, 10], thanks to the enhanced design of the transcatheter devices and the increasing experiences of the structural heart interventionalists. Due to multiple underlying comorbidities, lifelong immunosuppression, and pos-transplant complications, HTx recipients constitute a uniquely high risk population of patients among which TAVR has been scarcely performed and its clinical and echocardiographic outcomes are vastly unknown [28-30]. However, with the increase in the longevity of donated hearts and HTx recipients, the incidence of the AVD in the donor heart is expected to rise; which can be a result of the tri-leaflet valve calcification [15, 20, 27] or a stenosis of the native bicuspid aortic valve [14, 16, 22, 31]. Additionally, due to the ongoing lengthening of HTx waiting list, donor hearts with existing valvular diseases are now being considered, on a case-by-case basis, eligible for transplantation [32-35]. Saito et al. reported a case of a 21-year-old woman with dilated cardiomyopathy who was suffering from repeated complications of left ventricular assist device (LVAD) and was finally matched with a donor heart 853 days after LVAD implantation [36]. The donor heart was of marginal quality in the way that it had mild aortic stenosis due to calcification of the congenital bicuspid aortic valve. The stenotic valve was replaced, prior to HTx, with a 21-mm ON-X mechanical valve, due to its durability. Other cases of pre-HTx aortic valve replacement [37] or repair [38] have been reported with normal left ventricular function or with left ventricular hypertrophy [39]. It is noteworthy that although benchmark repair/replacement of the donor AVD have saved the donated heart for transplantation, recognition of an impaired left ventricular function in the setting of donor valvular diseases will lead to the exclusion of the heart from donation. Additionally, while aortic valve repair or replacement with a bioprosthetic valve might seem a feasible solution to optimize the quality of a marginally accepted donor heart for transplantation, AVR with mechanical aortic prosthesis confers additional risk of bleeding due to the required anticoagulation with warfarin in patients who will require serial endomyocardial biopsy following transplantation. On the contrary, AVR with a bioprosthetic valve would likely be associated with an increased risk of re-intervention due to the superior longevity of the allografted heart compared to the replaced/repaired aortic valve. Nevertheless, the type of

aortic valve for AVR in donor hearts should be selected with the consideration of the long-term anticoagulation requirement with mechanical valves versus shorter durability and the need to valve-in-valve reintervention with bioprosthetic valves.

The first case of AVR after heart transplantation was described by Goenen et al. in 1989 in a 28-year-old male, which was performed surgically 31 months after HTx [31]. The patient had one moderate episode of rejection 10 weeks after HTx. The donor heart was described to be enlarged in size with a bicuspid AV and a dilated ascending aorta. The second case of post-HTx AVR was in a 32-year-old women who developed infective vegetative endocarditis, leading to AV insufficiency, requiring an urgent surgical AVR [40]. However, it was only in 2010, when the first case of AVR via a trans-apical approach was introduced in a 67-year-old male, 14 years after HTx [25]. Further cases of post-HTx TAVR have been performed through a trans-femoral approach [13-24, 26, 27]. Transfemoral TAVR has been shown to be superior to trans-apical approach in terms of post-procedural complications, and length of hospital stay and cost [9, 41]. This might explain the adoption of transfemoral approach among patients undergoing TAVR especially HTx recipients who develop post-HTx AVD and require a non-surgical AVR approach. However, efforts are being made to develop alternative access options for patients requiring TAVR but with contraindications for traditional transfemoral route.

Valvular diseases are less common than vasculopathy among donor heart, possibly due to their better endurance against the degenerative process than the coronary vasculature [6, 7]. However, when intervention is required, HTx recipients should be considered a special population of patients with particular risk profiles. Compared to the surgical approach, TAVR lacks the operative risk associated with surgical AVR, which includes the burden of thoracotomy and cardiopulmonary bypass, delayed wound healing due to immunosuppression, and multiple comorbidities complicating general anesthesia. On the contrary, TAVR confers a higher risk of heart block, endovascular trauma, valve dislodgment, embolic events, and coronary arteries ostia obstructions [42, 43]. Without mid-term and long-term data available, it remains unclear what the ideal options are for HTx recipients who develop symptomatic AVD of the donor heart.

Limitations

The main limitation of this systematic review is the scant data in the literature regarding therapeutic options for AVD among HTx recipients. This is applicable to both TAVR and surgical AVR. However, with increasing survival of HTx recipients, the cumulatively incidence of AVD requiring AVR will be on the rise. Additionally, the majority of HTx recipients who underwent TAVR were followed for only a shorter period after their procedure with long-term data lacking on the survivability of the replaced valve or post-procedural outcomes. It also remains to be determined if benchmark repair of the aortic valves in marginally accepted donor heart or a more vigorous screening approach utilizing modernized imaging techniques will improve the outcomes of AVR among HTx recipients, especially in the years to come.

Conclusion

TAVR seems to be a safe therapeutic option for HTx recipients who develop AVD after heart transplantation. However, mid-term and long-term data are lacking on the survivability of the transplanted valve or the clinical outcome of the patients undergoing TVAR. Comparison of the long-term outcome of TAVR with that of surgical AVR would be substantially valuable but challenging to accomplish, in part due to relatively low diagnostic rate of AVD among donor hearts at this time.

Disclosure of conflict of interest

None.

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