Is Trifecta safe for small valve size from mid-term outcome?

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Research Article

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Abstract

Background: Several studies have reported a high structural valve deterioration (SVD) rate for the Trifecta valve. We analyzed the midterm outcomes of the Trifecta valve and risk factors for early SVD.

Methods: We retrospectively reviewed 110 patients who underwent Trifecta implantation between January 2012 and December 2017.

Results: We encountered seven cases of Trifecta valve failure. We performed redo aortic valve replacements in five patients and transcatheter aortic valve replacements in two patients. The free rate of SVD was 96.1% at five years and 92.6% at seven years. The mean pressure gradient and peak velocity in the first postoperative echocardiogram in patients with SVD were higher than those in patients with SVD. The SVD-free rates of the 19 mm valve and other valves were 93% and 95.6% at five years and 89.6% vs. 95.6% at seven years, respectively. Although not statistically significant, the 19 mm valves tended to be SVD. Noncoronary cusp tears were seen in all patients who underwent a redo surgery.

Conclusions: The most common cause of SVD was noncoronary cusp tear. Patients with a high postoperative mean pressure gradient are at a high risk of SVD. The small size of the Trifecta for a small annulus or Valsalva sinus may be a risk factor for early SVD.

Background

The Trifecta valve (Abbott Vascular, Santa Clara, CA) was introduced for commercial use in 2010 and was approved in 2012 in Japan. Excellent hemodynamic performance and durability have been reported through midterm follow-ups [1, 2]. The excellent hemodynamics are due to an expansive valve design with a bovine pericardial sheet externally mounted on a titanium stent. However, some recent studies have reported early SVD in leaflet tears [2–12]. Fukuhara et al. reported that the rate of SVD was higher in the Trifecta group (n=508) than in the non-Trifecta group (n=550) (13.3% vs. 4.6%; P=.010) [13]. However, the cause and risk factors of early SVD remain unknown.

Japanese patients have smaller body sizes and aortic annuli than Western patients [14]. Therefore, we used a small size of Trifecta at a high rate to avoid prosthesis-patient mismatch (PPM). There are limited reports of valve durability and SVD of small-sized Trifecta, which is implanted into the small aortic annuli of Japanese patients. In this study, we analyzed the midterm outcome of the Trifecta valve and the risk factors for early SVD.

Methods

Patients data

We retrospectively reviewed 110 patients who underwent implantation of Trifecta at the Kobe City Medical Center General Hospital between January 2012 and December 2017. Our institutional review

board approved this study (No. zn210902). Informed consent was obtained from all patients. The valves were implanted using standard methods through a full median sternotomy approach in all patients. Trifecta valves were implanted in a supra-annular position using interrupted horizontal mattress pledgeted suture or intra-annular position using simple interrupted sutures. We tied sutures with fingers and kept a holder on the prosthesis. All patients were administered antiplatelet therapy and anticoagulant therapy for three months after Trifecta valve implantation.

Echocardiographic assessment

All patients underwent transthoracic echocardiography preoperatively and one week after Trifecta valve implantation at predischarge. Follow-up echocardiography was performed annually.

Structural valve degeneration (SVD) was defined as a mean transvalvular gradient of >40 mmHg, an increase in the mean transvalvular gradient of more than 20 mmHg, severe intra-prosthetic aortic regurgitation, or new or worsening (>2+/4+) gradient from baseline [15]. Prosthetic valve endocarditis, valve thrombosis, PPM without loss of valve function, and isolated paravalvular leak were not considered SVD.

Statistical Analysis

Continuous variables are presented as the mean±SD, and categorical variables are presented as proportions and absolute numbers. Differences between groups were analyzed with an unpaired t-test or Mann-Whitney U test for continuous variables and a χ^2 test or Fisher's exact test for categorical variables. P-values less than 0.05 were considered statistically significant. Time to event was determined as the number of months between the date of operation and the date of follow-up or the date of death. Survival and SVD rates were evaluated using a Kaplan-Meier survival analysis and log-rank test. Statistical analyses were performed using the JMP software (version 14.1.0; SAS Institute, Cary, NC, USA).

Results

Patients characteristics and operative data

The patient clinical characteristics are shown in Tables 1 and 2. The valve lesion in the first valve replacement included aortic stenosis (AS) (n= 77), aortic regurgitation (AR) (n=21), and aortic stenosis and regurgitation (ASR) (n= 12). Concomitant surgeries included mitral valve replacement (n=23), tricuspid valve plasty (n=22), coronary artery bypass graft (n=22), maze procedure (n=10), and myectomy (n=4). The prosthesis label size was 19 mm (n=47), 21 mm (n=44), 23 mm (n=12), and 25 mm (n=7). Trifecta valves were implanted in a supra-annular position (n=30) and an intra-annular position (n=70).

Follow-up results

The mean follow-up was 66 months. The clinical follow-up rate was 92.7%. The 1-, 3-, and 5-year cumulative survival rates were 95.5%, 90.9%, and 85.2%, respectively. Seven patients (6.4%) had SVD, and

all patients required redo surgeries. The free rate of SVD was 96.1% at five years and 92.6% at seven years (Figure 2).

Clinical characteristics of SVD group

Table 4 presents the clinical details of the SVD group. Mean valve durability was 40±27 months.

The primary pathologies of the aortic valve were AS (n=6) and ASR (n=1). Trifecta valve sizes were 19 mm (n=5) and 21 mm (n=2). The reoperation indications for SVD were AS (n=1), AR (n=5), and AsR (n=1). Five patients had redo surgical aortic valve replacements (SAVR) with another prosthesis. No complications occurred. Two patients underwent transcatheter aortic valve replacement (TAVR) without any complications.

Comparison between SVD and non-SVD

Tables 1 and 2 show comparisons of baseline and operative characteristics between the seven patients with SVD and the other patients. The valsalva sizes tended to be smaller in patients with SVD. The mean pressure gradient and peak velocity were higher and the effective orifice index(EOAI) was lower in patients with SVD than in patients with no SVD. There were no significant differences in the other perioperative variables between the SVD and no-SVD groups.

Comparison between 19 mm vs. other valves

Figure 3 shows the SVD-free rates of the 19 mm valves (n=47) and other valves (n=63). The SVD-free rates of the 19 mm and other valves were 93% and 95.6% at five years and 89.6% vs. 95.6% at seven years, respectively. Although not statistically significant, the 19 mm valves tended to have SVD.

Gross pathologic findings

We evaluated the failure valves of five patients who underwent SAVR pathologically. The cause of the AR disorder was a cusp prolapse caused by a tear of a leaflet along with the stent post in all patients. The cusp was detached from the stent post at the commissure of the right coronary cusp (RCC) and the noncoronary cusp (NCC) (n=4), left coronary cusp (LCC), NCC(n=1), or RCC and LCC (n=1). In one patient, the cusp was detached at both the RCC-NCC and RCC-LCC commissure.

In one patient, the RCC-LCC and LCC-NCC commissures adhered to the sinus of Valsalva, and there was a tear at the RCC-NCC commissure on its contralateral side, and a Pannus formation under the valve was seen in two patients (Figure 4).

Discussion

We reported seven cases of early SVD among 110 Trifecta valve implantations performed between 2012 and 2017 at our single center. In our study, the free rate of structural valve degeneration was 92.6% at seven years, similar to outcomes of other reports [13].

Previous studies have shown that a high postoperative mean pressure gradient and PPM are related to structural valve degeneration [16–18]. In our study, the mean pressure gradient and peak velocity in the first echocardiography were higher in patients with SVD. The most common cause of SVD was a noncoronary cusp tear. Previous studies have reported similar pathological findings. We estimate that the high mean pressure gradient increases the hemodynamic stress on the externally mounted leaflet, and the stress may be particularly high on the NCC commissures. This stress could lead to leaflet tears. Patients with a high mean pressure gradient and peak velocity should be closely monitored.

Subvalvular Pannus formations were observed in two patients. The pannus forms due to surgical injury leading to thrombus formation, release of cytokines, and deposition of inflammatory cells [19]. Two patients with pannus formations in our study underwent reoperation for aortic regurgitation. Excessive pannus formation may confer hemodynamic stress to the leaflet.

In one patient, the RCC-LCC and LCC-NCC commissures adhered to the sinus of Valsalva.

Attachment to the Valsalva sinus restricts leaflet movement and incomplete leaflet coaptation. It is probable that the externally mounted leaflet design of the Trifecta valve leads to the attachment of the Valsalva sinus, resulting in limited leaflet motion and valve insufficiency. A previous report showed the same pathological findings [3]. They reported that a small aortic root was predisposing factor. In our study, the Valsalva size tended to be smaller in patients with SVD, although the difference was not significant. Cleveland et al. reported that oversizing of bioprosthetic valves resulted in an increased pressure gradient, and the Trifecta valve was more sensitive to oversizing than other bioprosthetic valves due to the externally mounted leaflet design [20]. Implanting the oversized Trifecta valve in the small annulus may interfere with the expansion of the bioprosthesis, narrowing the EOAI, and creating accelerated blood flow. In addition, implanting the Trifecta in a small sinus of Valsalva may stress the outer-mounted valve. We used Trifecta valves in older adults, especially in patients with small annuli. Thus, we used 19 mm valves with a higher frequency (43%) than those used in previous studies [13, 21]. Although there were no statistically significant differences in our small sample, the SVD-free rate of the 19 mm valves tended to be higher. This result raises the possibility that the small size of Trifecta for a small annulus or Valsalva sinus may be a risk factor for early SVD. We used Trifecta vavles for patients with a small annulus because the Trifecta has good hemodynamic performance. However, this strategy conversely caused SVD. It may be better to consider the enlargement of the annulus rather than using an externally mounted leaflet valve.

This study had several limitations. Our analysis was retrospective and limited to a small number of patients. Although multivariate analysis is necessary to analyze the risk factors, statistically valid multivariate analysis was difficult due to the small sample size. More well-designed and large studies are essential to understand the mechanism of early Trifecta valve failure. Follow-up echocardiographic studies were performed in a variety of clinical settings.

Conclusion

In conclusion, although the midterm outcome of the Trifecta valve is acceptable, some patients need redo surgeries due to early SVD. The most common cause of SVD was noncoronary cusp tear. Patients with a high postoperative mean pressure gradient are at a high risk of SVD, so they should be closely followed up. A smaller sized Trifecta valve for a small annulus or Valsalva sinus may be a risk factor for early SVD.

Declarations

Ethics approval and consent to participate: Our institutional review board approved this study (No. zn210902) .

Consent for publication: Informed consent was obtained from all patients.

Availability of data and materials: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Conflict of Interest: All authors declare that they have no conflict of interest.

Author's contributions: TW analyzed the patient data and was a major contributor in writing manuscript. All authors critically revised the manuscript, approved the manuscript to be published, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Tables

Tables 1 to 4 are available in the Supplementary Files section

Figures

Figure 1

Kaplan-Meier survival curve after Trifecta valve implantation.

Figure 2

Free rate of structural valve degeneration after Trifecta valve implantation.

Figure 3

Free rate of early Trifecta valve failure. comparison between 19 mm valve vs others.

Figure 4

Photographs of Trifecta valves (Abbott Vascular, Santa Clara, CA).

A) 81-year-old man with moderate-severe aortic regurgitation. The valve durability was 49 months. There was a large tear at the stent post between the noncoronary cusp and right coronary cusp.

B) 77-year old woman with severe aortic regurgitation. The valve durability was 19 months. There was a partial tear of the noncoronary cusp.

C) 72-year old woman with severe aortic regurgitation. The valve durability was 4 months. The subvalvular pannus formation was seen.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- TrifectatableJCTS.pdf