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Chapter

The Current Perspectives in Valve-in-Valve Transcatheter Aortic Valve Replacement

Takashi Murashita

Abstract

The increased use of bioprostheses in aortic valve replacement has led to increased number of patients with structural valve degeneration. Since reoperation for failed bioprostheses carries a high risk, a valve-in-valve transcatheter aortic valve replacement has become an attractive alternative treatment. However, there remains technical challenges and controversies in this field. Herein, we discuss the current perspectives in valve-in-valve transcatheter aortic valve replacement.

Keywords: transcatheter aortic valve replacement, valve-in-valve, failed bioprostheses

1. Introduction

The use of bioprosthetic valves in aortic valve replacement (AVR) has been increasing, even in younger patients [1]. In the meantime, the indication of transcatheter aortic valve replacement (TAVR) has been expanding as well. Since reoperation for degenerated prosthetic valve carries a high risk, a valve-in-valve TAVR has become an attractive alternative treatment. The most recent guidelines stated that valve-in-valve TAVR is recommended as class IIa indication for "severely symptomatic patients with bioprosthetic aortic valve stenosis judged by the heart team to be at high or prohibitive risk of reoperation, and in whom improvement in hemodynamics is anticipated" [2]. However, technical challenges exist in valve-in-valve TAVR. In this chapter, we discuss the current perspective of valve-in-valve TAVR and its associated risks and benefits.

2. Indications of valve-in-valve TAVR

2.1 Outcomes of redo aortic valve replacement

The use of bioprosthetic valve in AVR has been expanding. That will inevitably lead to increased number of patients who need re-aortic valve replacement for degenerated bioprostheses. Redo aortic valve replacement carries a higher operative risk compared to primary aortic valve replacement.

Kaneko et al. investigated 3,380 patients from The Society of Thoracic Surgeons database who underwent elective, isolated redo aortic valve replacement (AVR) after a previous AVR [3]. The operative mortality was 4.6%, and the incidence of

Study	Year	Number of pts	Key outcomes
Dvir et al. [4]	2014	459	Thirty-day mortality; 7.6%. Thirty-day stroke rate; 1.7%. One-year survival rate; 83.2%. Patients who had stenosis had worse 1-year survival in comparison with regurgitation. Patients with small valves had worse 1-year survival in comparison with intermediate or large valves.
Tuzcu et al. [5]	2018	1150	Thirty-day mortality; 2.9%. Thirty-day stroke rate; 1.7%. Thirty-day heart failure hospitalization rate; 2.4%. One-year survival rate; 88.3%. Patients in the valve-in-valve TAVR group had higher post-TAVR mean gradient, but less moderate or severe aortic regurgitation compared to native-valve TAVR group. Post-TAVR gradients were highest in small SAVRs and stenotic SAVRs.
Webb et al. [6]	2017	365	Thirty-day mortality; 2.7%. Thirty-day stroke rate; 2.7%. One-year survival rate; 87.6%. Mean transaortic gradient was 17.6 mm Hg, and effective orifice area was 1.16 cm^2 at 1 year.
Webb et al. [7]	2019	365	Three-year survival rate; 67.3% Aortic valve re-replacement was required in 1.9%. Mean transaortic gradient was 16.6 mm Hg at 3-year follow-up. Effective orifice area was 1.15 cm^2 at 3-year follow-up. Moderate to severe aortic regurgitation was 2.5% at 3 years. New York Heart Association functional class improved, with 90.4% in class III or IV at baseline and 14.1% at 3 years.
Neupane et al. [8]	2018	227	Thirty-day mortality; 5%. Thirty-day major stroke rate; 2%. Permanent pacemaker implantation; 9%. Valve-in-valve TAVR and re-SAVR had similar thirty-day mortality, and similar rates of stroke, myocardial infarction, and acute kidney injury requiring dialysis.
Pibarot et al. [16]	2018	1168	Thirty-day mortality; 10.3% in severe PPM, 4.3% in no or moderate PPM. Adjusted one-year survival rate; 80.7% in severe PPM, 89.1% in no or moderate PPM. Patients with pre-existing severe PPM more frequently harbored high post-procedural gradients.

Study	Year	Number of pts	Key outcomes
Deeb et al. [26]	2017	227	Thirty-day mortality; 2.2%. Thirty-day major stroke rate; 0.4%. One-year survival rate; 85.4%. Moderate aortic regurgitation occurred in 3.5% of patients at 30 days and 7.4% of patients at 1 year, with no severe aortic regurgitation. The rate of new permanent pacemaker implantation was 8.1% at 30 days and 11.0% at 1 year. The mean valve gradient was 17.0 ± 8.8 mm Hg at 30 days and 16.6 ± 8.9 mm Hg at 1 year. Factors significantly associated with higher discharge mean aortic gradients were surgical valve size, stenosis as modality of surgical valve failure, and presence of surgical valve prosthesis patient mismatch.
de Freitas Campos Guimarães et ak [27]	2018	116	Thirty-day mortality; 6.9%. Three-year survival rate; 74.1%. Average mean transaortic gradients remained stable up to 5-year follow-up. Clinically relevant structural valve degeneration occurred in 3%, and 15.1% had subclinical structural valve degeneration.
Goztek et al. [28]	2018	342	Thirty-day mortality; 5.4%. Permanent pacemaker implantation; 6.8%. Valve-in-valve TAVR was associated with higher incidence of PPM, higher paravalvular leaks and higher mean postoperative aortic valve gradients compared to re-SAVR.

TAVR: transcatheter aortic valve replacement; SAVR: surgical aortic valve replacement; PPM: prosthesis-patient mismatch.

Table 1.
Previous studies which reported the clinical outcomes of valve-in-valve TAVR.

mortality, morbidity, stroke, postoperative aortic insufficiency mild or greater, pacemaker implantation and vascular complications was higher in redo AVR group compared to primary AVR patients.

2.2 Outcomes of valve-in-valve TAVR

Overall the outcomes of valve-in-valve TAVR have been reported to equivalent or better compared to those of redo surgical AVR.

The Valve-in-Valve International Data (VIVID) reported the outcomes of valve-in-valve TAVR for 459 patients in 55 centers [4]. The thirty-day mortality was 7.6%. Overall one-year survival rate was 83.2% Patients with bioprosthetic stenosis had worse 1-year survival compared with the patients with bioprosthetic regurgitation. Patients with small valves had worse 1-year survival compared to intermediate or large valves.

The Transcatheter Valve Therapy (TVT) Registry showed that unadjusted 30-day mortality after valve-in-valve TAVR was 2.9%, and it was better than that of native valve TAVR (4.8%) [5].

The PARTNER (Placement of Aortic Transcatheter Valves) 2 trial showed that 30-day mortality was 2.7%, stroke was 2.7%, major vascular complication was 4.1%, conversion to surgery was 0.6%, coronary occlusion was 0.8%, new pacemaker insertion was 1.9%, and one year all-cause mortality was 12.4% [6]. Recently 3-year outcomes after valve-in-valve TAVR in the Partner 2 registry was published [7]. The mean age of the patients was 78.9 ± 10.2 years. At 3 years, the estimate all-cause mortality was 32.7%. Quality of life of the patients improved compared to baseline.

Neupane et al. conducted a meta-analysis of the previously reported studies to determine outcomes after valve-in-valve TAVR and redo AVR [8]. Their analysis showed no difference in 30-day mortality between valve-in-valve TAVR and redo AVR for failed bioprosthetic aortic valve.

Previous studies which reported the clinical outcomes of valve-in-valve TAVR are listed in **Table 1**.

3. Complications in valve-in-valve TAVR

3.1 Prosthesis-patient mismatch

Valve-in-valve TAVR could cause prosthesis-patient mismatch especially when there was severe bioprosthetic valve stenosis. It was also pointed out that valve-in-valve TAVR was an independent predictor of valve hemodynamic deterioration (defined as an increase in mean aortic valve gradient ≥10 mm Hg) [9].

Herrmann et al. reviewed 62,125 patients in the Society of Thoracic Surgeons/American College of Cardiology TVT registry and reported that severe prosthesis-patient mismatch occurred in 12% [10]. Patients with severe prosthesis-patient mismatch had higher mortality rate compared to patients with moderate or no prosthesis-patient mismatch.

On the contrary, Dvir et al. reported that severe prosthesis-patient mismatch occurred in 31.8% of patients surviving aortic valve-in-valve TAVR [4]. However, one-year survival was not affected by having severe prosthesis-patient mismatch.

The long-term transaortic gradient has not been reported. In the Partner II registry, mean transaortic gradient was 16.6 mmHg at 3-year follow-up [7].

3.2 Coronary obstruction

Coronary obstruction is a rare, but life-threatening complication associated with TAVR. Its incidence in native valve TAVR was reported as less than 1% [11]. However, it occurs more frequently in valve-in-valve TAVR.

Ribeiro et al. reviewed 1,612 patients from the Valve-in-Valve International Data Registry [12]. Coronary obstruction occurred in 37 patients (2.3%), and the 30-day mortality was 52.9% among the patients who had coronary obstruction. Coronary obstruction happened more frequently in stented valves with externally mounted leaflets or stentless valves compared to stented valves with internally mounted leaflets.

Multiple detector computed tomography is a standard diagnostic modality in the planning of TAVR [13]. A virtual transcatheter valve to coronary ostium distance <4 mm is considered a high risk of coronary obstruction [12].

In the case of anticipated high risk of coronary obstruction, a placement of a coronary guidewire with coronary balloon or undeployed stent in the targeted

coronary arteries before deploying TAVR is a good option for coronary protection, since the emergent percutaneous coronary intervention for coronary obstruction is challenging. Ribeiro et al. reported that percutaneous coronary intervention was successful only in 81.8% [11].

Delayed coronary obstruction is a rare complication following TAVR that accompanies with high in-hospital mortality. Jabbour et al. reported that the incidence of delayed coronary obstruction was 0.22% in 17,092 TAVR procedures and the overall in-hospital mortality was 50% [14]. Percutaneous coronary intervention was successful only in 68.8%. It occurred more frequently after valve-in-valve TAVR compared to native valve TAVR (0.89% vs. 0.18%) and it occurred more frequently in self-expandable valves compared to balloon-expandable valves (0.36% vs. 0.11%).

3.3 Self-expandable valve versus balloon-expandable valve

Self-expanding valves are usually associated with lower postprocedural gradients. Rogers et al. reported that hemodynamics of self-expandable valves were superior to that of balloon-expandable valves in patients with small aortic annulus [15].

In the meantime, Dvir et al. reported that elevated postprocedural gradients were happened more frequently in balloon expandable valves compared with self-expandable valves [4].

Pibarot et al. reported that pre-existing prosthesis-patient mismatch of the failed surgical valve was strongly and independently associated with increased risk for mortality following valve-in-valve TAVR [16]. Elevated pressure gradients are seen in more than 70% of patients who present with baseline prosthesis-patient mismatch if treated with balloon-expandable valves.

The optimal deployment height would be important to avoid postprocedural high gradients. Simonato et al. reported that lower gradients and greater effective orifice areas were achieved with higher deployment positions than lower deployment in vitro study [17]. Hatoum et al. reported that supra-annular axial deployment is associated with lower pressure gradients, and sub-annular deployment is associated with more favorable sinus hemodynamics [18].

When severe prosthesis-patient mismatch is present, a self-expanding device in a supra-annular position would be the preferred treatment strategy. Dvir et al. suggested an implant depth of up to 3 mm for the self-expandable valve; Evolut (Medtronic, Minneapolis, Minnesota), and up to 20% frame depth for the balloon-expandable valve; SAPIEN 3 (Edwards Lifesciences, Irvine, California) [19].

3.4 Structural valve deterioration after TAVR

Bioprosthetic valve dysfunction happens both in surgical AVR and TAVR. However, bioprosthetic valve dysfunction is a broad term that encompasses structural and non-structural valve deterioration [20]. It is very important to distinguish between two of them. Structural valve deterioration is the principal etiological factor, and it can lead to irreversible valve dysfunction, whereas non-structural valve deterioration includes reversible dysfunction such as valve thrombosis or endocarditis.

The long-term durability of valve-in-valve TAVR has been unknown. One of the longest follow-up data was reported from Partner II registry [7]. Among 337 patients who could be followed for 3 years, 5 patients underwent repeat aortic valve replacement for aortic valve dysfunction after valve-in-valve procedure. Moderate hemodynamic valve deterioration occurred in 2 out of 160 patients

(1.3%), and severe hemodynamic valve deterioration also occurred in 2 out of 160patients (1.3%) at 3 years.

3.5 Valve thrombosis

Valve thrombosis following TAVR has been increasingly recognized. Valve thrombosis is associated with reduced leaflet motion, and leads to high chance of strokes and transient ischemic attacks. Subclinical leaflet thrombosis is manifested by either hypo-attenuated leaflet thickening or reduced leaflet motion [21].

Del Trigo et al. reported that the incidence of valve hemodynamic deterioration following TAVR was 4.5% in 1,521 patients, and a valve-in-valve procedure was an independent predictor for valve hemodynamic deterioration [22].

Vahidkhah et al. analyzed computational three-dimensional models for the surgical aortic valve and transcatheter aortic valve [23]. They found that geometric confinement of the transcather aortic valve by the leaflets and the frame of the degenerated bioprosthesis that circumferentially surround the transcatheter aortic valve stent increased the blood residence time on the leaflets, which could act as a permissive factor in the leaflet thrombosis after valve-in-valve TAVR.

3.6 Antiplatelet/anticoagulation therapy after TAVR

The optimal antiplatelet/anticoagulation management after TAVR has been controversial [20, 24].

Most of the societies such as American Heart Association and Society of Thoracic Surgeons recommend lifelong-aspirin and 6 months of Clopidogrel after TAVR. In terms of anticoagulant therapy, it may be considered in patients with chronic atrial fibrillation or other indications. Vitamin K antagonist may be considered in the first 3 months after procedure in patients at risk for atrial fibrillation or valve thrombosis.

Overtchouk et al. reviewed 11,469 patients in French registry, and found that anticoagulation decreased the risk of bioprosthetic valve dysfunction, whereas chronic renal failure and prosthesis size ≤23 mm were associated with the risk of bioprosthetic valve dysfunction [25].

4. Conclusions

The valve-in-valve TAVR has provided satisfactory outcomes for degenerative bioprosthetic aortic valve. It is recommended with class IIa indication in high risk patients for redo surgical AVR. However, physicians need to understand technical challenges in valve-in-valve TAVR such as residual high pressure gradient, prosthesis-patient mismatch and coronary obstruction. The long-term durability of valve-in-valve procedure remains unknown. Moreover, anticoagulation management and superiority between self-expandable and balloon-expandable valves have been controversial.

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