Surgical Therapy for Patients with Severe Aortic Stenosis in the Era of Transcatheter Aortic Valve Replacement

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Abstract: Aortic stenosis (AS) is the most common valvular heart disease and is most frequently recognized among elderly people. Surgical aortic valve replacement (SAVR) is the most effective therapy, but its indication is sometimes difficult, and is impossible for high operative risk patients. Transcatheter aortic valve replacement (TAVR) was recently approved in Japan for high risk and inoperable patients with severe AS. TAVR is a less invasive method because it does not require a cardiopulmonary bypass and is associated with excellent surgical outcomes. In Western countries, the indication of TAVR has already been extended to moderate operative risk patients with severe AS, and is going to be further extended to low risk patients. The number of patients undergoing TAVR is increasing progressively, and there are effective alternative therapies for patients with severe AS. Selection of these surgical methods will be important in the near future. In regard to low operative risk patients especially, not only operative mortality, but also long-term mortality and morbidity and quality of life should be taken into consideration. It is considered that some comorbidities in AS patients will be revealed to have an impact on surgical outcomes at the time when these surgical methods are selected. In this review, we examine end-stage renal disease on hemodialysis, functional tricuspid regurgitation, and sigmoid septum, and give an outline of what influence SAVR and TAVR have on the surgical outcomes of severe AS patients.

Keywords: aortic valve replacement, transcatheter aortic valve replacement, hemodialysis, functional tricuspid regurgitation, sigmoid septum.

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Introduction

Aortic stenosis (AS) is the most common valvular heart disease to require surgical treatment, and is most frequently recognized in elderly people [1, 2]. The number of patients with AS is expected to increase in the elderly societies of developed countries, including Japan [2, 3]. The number of patients undergoing isolated surgical aortic valve replacement (SAVR) increased annually until 2014, according to the annual review of the Japanese Society of Thoracic and Cardiovascular Surgery [1, 4]. SAVR is an effective therapy that can improve the prognosis of severe AS patients by preventing sudden death [5-8], although it always requires a cardiopulmonary bypass, which is sometimes harmful, especially for high risk patients. Some patients with severe AS are considered to be inoperable because of their high operative risk and comorbidity, resulting in being forced to take medical therapy only.

Transcatheter aortic valve replacement (TAVR) has

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been shown in clinical trials to improve the prognosis of patients with severe AS who are treated with conservative therapy instead of SAVR due to the high operative risk [9, 10], and with respect to short-term survival, it is at least equivalent to SAVR for high risk patients with severe AS [11, 12]. TAVR was approved in Japan in 2013 for high risk and inoperable patients with severe AS, and has been associated with sustained clinical and functional cardiac improvement [13]. Though the number of patients undergoing TAVR is increasing as rapidly in Japan as in Western countries, isolated SAVR with or without coronary aortic bypass grafting (CABG) (n = 9,472) has increased by 10.3% since 5 years ago (n = 8,589) [1]. The indication of TAVR in Western countries has been extended to intermediate risk patients with severe AS, and is going to be further extended to low risk patients [14–16]. The indication of TAVR in Japan is going to be extended to intermediate operative risk patients, and the number of patients undergoing TAVR is going to increase more rapidly in the near future because of its nature as a less invasive procedure.

Because TAVR can be an alternative surgical treatment for patients with severe AS, we have to determine which technique could be suitable to each AS patient on a case by case basis. When indication of TAVR is expanded to lower risk patients, it will be insufficient to base the selection of surgical methods on operative risk only. Some comorbidities will be revealed as a problem which could affect postoperative outcomes at the time of selection of such surgical methods. In this review, we examine end-stage renal disease on hemodialysis (HD), functional tricuspid regurgitation (TR), and sigmoid septum as such comorbidities, and discuss what influence each surgical method has on operative and postoperative outcomes in patients with severe AS.

End-stage renal disease on HD

Dialysis patients undergoing cardiac surgery are thought to have a higher risk for mortality than nondialysis patients, not only because renal failure itself is a major risk factor in cardiovascular surgery, but also because dialysis patients frequently have such comorbidities as peripheral vascular disease, cerebrovascular disease, hypertension, and diabetes mellitus [7, 17–19]. Rahmanian et al showed that dialysis patients undergoing cardiac surgery have an in-hospital mortality rate more than 3 times greater than that of non-dialysis patients (12.7% versus 3.6%) [20]. Leontyev et al reported that the in-hospital mortality of dialysis patients undergoing cardiac surgery was 15.3%, in which the independent predictors were combined mitral and aortic valve pathologic condition, chronic obstructive pulmonary disease, peripheral vascular disease, and left ventricular ejection fraction <30% [21]. They found differences in in-hospital mortality by types of operation, namely that of dialysis patients undergoing isolated CABG was 8.9%, but that of isolated valve surgery was 19.2% [21]. Postoperative outcomes are affected by the preoperative status of patients and associated comorbidities. The differences in operative results between studies seem due to differences in the patient status in each study, because dialysis patients have a wide spectrum of distribution of comorbidities.

SAVR for dialysis patients

The pathophysiology of valve disease in dialysis patients is related to chronic inflammation and disturbance in calcium-phosphate metabolism [22]. Valve disease is observed less common than coronary artery disease among such patients. Calcified aortic stenosis is the most common valvular disease, and is an independent risk factor for death in dialysis patients [23, 24]. SAVR has been a standard treatment for severe calcified AS, as well as for non-dialysis patients. SAVR could significantly improve the 5 year mortality rate in dialysis patients with severe AS to 60.6%, in comparison with that of dialysis patients with severe AS undergoing conservative therapy (75.5% at 5 year mortality). However, such improvement was not as effective in non-dialysis patients (18.7% in SAVR vs. 49.3% in conservative therapy) [8]. Regarding the in-hospital mortality of SAVR, a recent study from the United States analyzing a large cohort demonstrated that in-hospital mortality of dialysis patients undergoing SAVR was twofold higher than that of non-dialysis patients in the propensity-matched cohorts of dialysis versus non-dialysis patients (8.1% vs. 3.9%, p<0.001) [25]. In Japan, a single-center retrospective study reported that the crude 30-day mortality rate after SAVR
was 4.5% in dialysis patients, which was not significantly different from 1.9% in non-dialysis patients, but the overall mid-term survival was significantly worse in the dialysis patients (63% versus 85% at 5 years, and 35% versus 69% at 10 years) [26]. They found that age and concomitant diabetes mellitus were significant predictors of late death. In the University Hospital of Occupational and Environmental Health, the in-hospital mortality in dialysis patients undergoing SAVR \((n=40, \text{age: } 69.5\pm10.7 [32–83])\) was 10% (4 of 40 patients, 2 patients had pneumonia, 1 patient had low output syndrome, and 1 patient had sepsis), which was significantly higher than that of non-dialysis patients (1.1%). There were 15 deaths during the follow-up, in which 4 of the 15 patients experienced cardiac death (all of them had heart failure), and 11 experienced non-cardiac death (4 patients had pneumonia, 4 patients had sepsis, 1 patient had ischemic colitis, 1 patient had bladder cancer, and in 1 patient the cause was unknown). Their three-year survival rate was 69.8% (Fig. 1), which was compatible with these studies. The mid-term survival rate of dialysis patients after SAVR was significantly lower in patients aged \(\geq 70\) than in patients aged <70 (Fig. 2). Many dialysis patients with severe AS die from non-cardiac causes during follow-up, especially among elderly patients. Because they have more comorbidities, surgical treatment for valvular disease could not always improve their poor prognosis. 

The choice of prosthetic valve in dialysis patients is another problem, and is controversial. Because dialysis patients are considered to have poorer life expectancy than non-dialysis patients, a higher rate of bleeding events, and potentially more progression of calcification to bioprosthetic valve due to dysregulation in calcium metabolism and hyperphosphatemia resulting in progressive structural valve deterioration (SVD), it is difficult to apply the data obtained from non-dialysis patients. Even current American College of Cardiology/American Heart Association (AHA/ACC) guidelines for the management of patients with valvular heart disease do not mention the choice of prosthetic valve in dialysis patients [27]. Some papers have concluded that there was no significant difference in bioprosthetic valves in comparison with mechanical valves in dialysis patients, or were preferable to them primarily because of the limited life expectancy in dialysis patients [28,29]. Dialysis patients in Japan, however, have an extremely low mortality rate compared with those in the United States and Europe.

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\text{Fig. 1. Survival in all dialysis patients with severe AS undergoing SAVR (n=40). One-, 3-, and 5-year survival rate were 77.6\%, 69.8\%, and 41.0\%, respectively. AVR: aortic valve replacement, AS: aortic stenosis, SAVR: surgical aortic valve replacement.}
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The crude 1-year mortality rate from the start of dialysis among dialysis patients was 6.6% in Japan, 15.6% in Europe and 21.7% in the United States [30]. A single-center retrospective study from Japan mentioned that freedom from SVD was significantly lower in dialysis patients compared with non-dialysis patients (82% vs. 100% at 5 years; \( p < 0.001 \)), and that dialysis was the only significant predictor of SVD. They concluded that, regarding life expectancy and freedom from SVD, bioprosthetic valves could be considered for use [26].

**TAVR for dialysis patients**

TAVR has not been approved in Japan for dialysis patients who were excluded from pivotal clinical trials, although it has already been expanded to dialysis patients in Western countries. Several reports have been published about the outcomes of TAVR for dialysis patients compared with SAVR. Alqahtani et al reported that after propensity score matching, a twofold increase in in-hospital mortality was found for SAVR compared with TAVR (13.7% vs. 6.1%; \( p = 0.021 \)), and that patients who underwent TAVR had more pacemaker implantation (13.2% vs. 5.6%; \( p = 0.02 \)), significantly fewer blood transfusions, shorter length of hospital stay, and less non-home discharge [31]. Kobrin et al reported that TAVR in dialysis patients was associated with decreased 1-year survival rate compared with non-dialysis patients (57.4% vs. 77.4%; \( p < 0.01 \)), which was comparable with SAVR in high risk dialysis patients based on a propensity-matched comparison (60% vs. 63.6%) [32]. Vindhyal et al studied outcomes of TAVR and SAVR for dialysis patients with severe AS by a meta-analysis using 4 observational studies with a total of 966 patients. They found that the in-hospital mortality of patients who underwent TAVR was not significantly different than that of SAVR (8.1% vs. 10.3%), and that TAVR had a significantly shorter length of hospital stay and higher pacemaker implantation rate in dialysis patients [33]. An analysis of dialysis patients with severe AS, using the information derived from the National Inpatients Sample database, has shown that overall in-hospital mortality was high (9.9%), with no significant difference between the two groups (8% in TAVR vs. 10.3% in SAVR), and that TAVR was associated with a shorter length of stay, lower in-hospital complications (60.6% vs. 76%), and higher rate of home discharge.
(31.4% vs. 17.7%) [34].

It is unclear whether TAVR can improve in-hospital mortality compared with SAVR in dialysis patients with severe AS. Even in the TAVR group, the in-hospital complication rate was not very low, and the home discharge rate was not very high [34]. Though TAVR is considered to be a less invasive procedure than SAVR because of the lack of necessity of cardiopulmonary bypass or cardioplastic arrest, even TAVR might not be non-invasive enough for such high risk patients. It is necessary not only to clarify which procedures could be suitable for such high risk patients with severe AS, but also to identify which dialysis patients might, or might not, benefit from intervention.

Functional TR

It is well known that functional TR is associated with left-sided heart valve disease. It is considered to perform a correction for functional TR at the same time as left-sided heart valve surgery, because, in patients with functional TR, the residual TR often worsens to significant severity during long-term follow-up, which could cause an increase in late mortality and morbidity [35–38]. Tricuspid annuloplasty (TAP), which is safe and simple, is the standard procedure for functional TR. It does not cause an increase in mortality and morbidity, and does not lengthen the time for cardiopulmonary bypass or ischemia [36, 38]. Moreover, reoperation for severe and isolated TR after left-sided valve surgery is associated with a high perioperative mortality of 8.4% [1]. The recent AHA/ACC guidelines for the management of valvular disease recommends tricuspid valve surgery for patients with severe TR undergoing left-sided heart valve surgery (Class I; Level of evidence C) [27]. Even for patients with mild or greater functional TR, TAP can be beneficial if they have tricuspid annular dilatation and/or prior evidence of right heart failure (Class IIa; Level of evidence B) [27].

SAVR and concomitant TAP for severe AS patients with functional TR

Though the impact of concomitant TR on the mortality and morbidity in severe AS patients who undergo SAVR is known, the clinical and surgical therapy for patients with concomitant severe AS and TR is less understood. Guidelines for left heart valvular disease have mentioned how to treat concomitant TR, but most studies addressed the presence of mitral valve disease, as opposed to AS. Though there is a consensus that concomitant severe or moderate-to-severe TR could be surgically treated at the same time as SAVR according to the guidelines [27], the management of moderate or mild TR is still controversial because its clinical significance and natural history are still little known. Jeong et al reported that functional TR did not improve after SAVR in half of AS patients with TR greater than mild, and that freedom from cardiac death at 10 years was significantly lower in those with TR greater than mild than in those without TR (61.6% vs. 93.0%) [39]. Taramasso et al investigated 61 patients with severe AS associated with mild or moderate TR to evaluate the prognostic impact and late changes in the preoperative TR after SAVR, and found that preoperative untreated TR improved or remained stable in the majority of patients [40]. Yajima et al examined changes in untreated mild or moderate TR after SAVR and its long-term impact on outcome, and found that preoperative TR was aggravated after isolated SAVR, resulting in a high incidence of renal dysfunction and right heart failure, and that tricuspid annulus diameter index ($\geq 21$ mm/M$^2$) was a predictor of late significant TR [41].

The effects of TAVR on untreated functional TR

Several articles about operative outcomes of TAVR for patients with severe AS and functional TR have been reported. McCarthy et al reported from the Society of Thoracic Surgeon/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry that greater TR severity was associated with higher risk patients and increased mortality and readmission at 1 year postoperatively, especially for patients with severe TR and left ventricular ejection fraction greater than 30% [42]. Barvalia et al reported that the severity of TR is a strong independent parameter predictive of death at 30 days after TAVR [43]. In a recent report from the STS/ACC TVT registry about the development and validation of a clinical risk model for 30-day mortality after TAVR that included both standard clinical factors and pre-procedural status and frailty, more than moderate TR is one of the independent predictors associated with greater odds [44]. Fan
et al reported in meta-analysis including 9 retrospective studies that baseline moderate or severe TR as well as RV dysfunction could worsen all-cause death at 30 days after TAVR [45]. AS patients with significant TR undergoing TAVR are vulnerable to the influence of TR and RV failure because they cannot receive any tricuspid valve procedure at the same time as TAVR.

Comparison between SAVR plus TAP and TAVR alone

Taken together, significant functional TR in patients with severe AS could not only increase perioperative mortality and morbidity but also have a negative impact on the outcome during follow-up after SAVR or TAVR. Worku et al reported that baseline moderate-severe TR in patients with severe AS is frequently improved after undergoing TAVR [46]. Rozenbaum et al investigated the postoperative outcomes and RV function in a comparison between SAVR + TAP and TAVR for severe AS patients with moderate or greater TR. They found that TAP at the time of SAVR did not affect mortality compared with TAVR alone in an adjusted analysis, and that though SAVR with concomitant TAP and TAVR were associated with reductions in TR in patients with severe AS combined with severe TR, RV function improved after TAVR but not after SAVR with concomitant TAP 6 months after operations, probably due to vulnerability to the ischemic insult during cardiopulmonary bypass. They suggested that functional TR is a surrogate marker of poor prognosis but is not an independent target for intervention [47].

The mechanism of functional TR with AS was explained as the following five steps: 1) left ventricular end-diastolic pressure increasing due to aortic valve flow obstruction, myocardial hypertrophy and declining compliance; 2) an increase in left atrial pressure and pulmonary capillary pressure; 3) pulmonary vascular compliance declines, resulting in an increase in right ventricular (RV) end-diastolic pressure and RV dilatation; 4) RV failure and functional TR progression; and 5) volume overload and further progression of functional TR and RV failure. Both SAVR and TAVR can improve aortic valve flow obstruction and induce LV reverse remodeling, but can not improve such irreversible changes as pulmonary vascular change, RV dilatation and dysfunction [48]. However, TAP can have the effect of reducing RV volume overload due to TR, though it requires a cardiopulmonary bypass. A study by Rozenbaum is a retrospective analysis with the same short follow-up period as most other studies about TAVR. As transcatheter tricuspid annuloplasty has not yet been approved in Japan, it has to be decided which procedure should be indicated for patients with AS and significant TR, SAVR plus TAP, or TAVR alone. Considering that only the severity of TR and RV function would be insufficient at the time of decision making, it is necessary that operative risk and frailty should be taken into consideration. It is necessary to settle some questions about whether TAP can influence operative and long-term outcomes in patients with severe AS and significant TR, whether severity of functional TR is an adequate parameter to induce TAP, and what is the most reliable parameter to determine the indication for TAP.

Sigmoid septum

Sigmoid septum, which is one of the causes of left ventricular outflow tract (LVOT) obstruction [49], is a non-uniform pattern of hypertrophy in which basal interventricular septum (IVS) shows a greater degree of thickening than other regions, and is also characterized by a diminished angle between the basal IVS and the aorta [50–52]. Sigmoid septum is incidentally found in patients with older age and hypertension by echocardiography, and basically considered to be of little clinical importance, with a relatively benign prognosis [51–54]. Because AS develops mainly in the aged population, sigmoid septum is also common in patients with AS. Although an accepted definition of sigmoid septum has not been established yet, a commonly used definition is disproportionate thickening of the anterior ventricular septum relative to the posterior left ventricular free wall (septal-free wall ratio > 1.3) [54, 55], or a proximal focal area of localized septal hypertrophy > 50% thicker than the thickness of the septum at its mid-distal point [56].

SAVR for severe AS patients with sigmoid septum

Because there is no proper guideline about the indication for myectomy of the hypertrophic muscle in AS patients, it is still controversial whether or not concomitant myectomy for hypertrophic septal muscle
at the time of SAVR should be performed for severe AS patients with sigmoid septum. Kayalar et al reported that because a quantitative assessment of obstructive sigmoid septum in the setting of severe AS may be difficult and because concomitant myectomy is a safe and effective procedure without such additional complications as complete atroventricular (AV) block or iatrogenic ventricular septal perforation, surgeons should consider it for patients with a preoperative or intraoperative diagnosis of sigmoid septum, even though dynamic obstruction is not demonstrated [54]. Di Tommaso et al showed that in patients with AS and sigmoid septum who received SAVR with concomitant myectomy for the septum, the LV mass index regressed and LV diastolic function improved at 5 years of follow-up, compared to patients who received SAVR only [55]. They also recommended that surgeons should inspect the LVOT at SAVR because concomitant myectomy at SAVR is a safe and effective procedure [55]. In contrast, Fujita et al reported a case of sigmoid septum with LVOT obstruction treated by myectomy in which procedure was not effective, resulting in requiring mitral valve replacement and permanent pacemaker implantation by marked exacerbation of hemodynamics and complete heart block [57]. The authors suggested that myectomy might not be advisable in sigmoid septum. Though the mechanism of the formation of sigmoid septum has not been established yet, Yoshitani et al reported that augmented compression by longitudinally elongated ascending aorta to the interventricular septum may cause sigmoid septum, and that the shortening of the elongated ascending aorta could improve sigmoid septum. In this paper, they focused on the shortening of the ascending aorta by aortotomy and suturing in SAVR, which was not performed in TAVR, and found that SAVR as opposed to TAVR improves the interventricular septum-aorta angle, basal interventricular septum thickness and its functional impairment [51].

**TAVR for severe AS patients with sigmoid septum**

TAVR for severe AS patients with sigmoid septum is still challenging, though it is widely used. It is sometimes difficult to assess the pressure gradient in the LVOT precisely, because it would be very close to the stenotic aortic valve in cases of sigmoid septum. When the stenotic aortic valve is removed, the pressure gradient in LVOT is ‘unmasked’ and its residual pressure gradient ruins the early and late operative results. It is difficult to treat such a situation in the case of TAVR. In fact, in a PARTNER trial, patients with septal muscle obstruction in the LVOT were excluded from the study [9, 11]. Moreover, the instability of deployment of a transcatheter heart valve would sometimes happen when the hypertrophic septal muscle bulges into the LVOT and causes the transcatheter heart valve to be pushed out distally from the aortic annulus, so-called “watermelon seeding” [56, 58, 59]. In order to avoid this, deep implantation of the transcatheter heart valve could be applied, although it could potentially cause AV block because the stent of the heart valve could be moved close to the membranous septum. It has been reported that the presence of a sigmoid septum and deep implantation are independent risk factors for complete AV block following TAVR [56].

The degree of septal thickening of the sigmoid septum is often milder than that of hypertrophic cardiomyopathy [51, 54, 55]. The contribution of septal thickening to LVOT obstruction might be modest in the case of sigmoid septum, differing from HCM [49, 52]. Though further study is needed to make it clear whether concomitant myectomy at SAVR could be effective or not, a superior point of SAVR to TAVR is that aortotomy and suture could shorten the aorta and improve the sigmoid septum without myectomy, which is an indispensable procedure in SAVR. Although TAVR has the natural advantage of being a less invasive procedure, SAVR could have the advantage of the possibility of improvement for sigmoid septum without any additional procedure. Moreover, TAVR has a higher risk than SAVR of causing complete heart block in AS patients with sigmoid septum. Such characteristics should be taken into account when selecting the surgical treatment for such patients, especially for lower risk patients.

**Conclusion**

In this review, we discussed severe AS patients with hemodialysis, functional TR, or sigmoid septum. It is unclear whether TAVR could be a sufficiently non-
invasive procedure for dialysis patients with severe AS because of its still high in-hospital mortality and morbidity. The indication of surgical treatment including TAVR for dialysis patients should be determined carefully. For AS patients with functional TR, indication for TAP is important because TAVR cannot treat TR at the same time. It is still unclear what is the most reliable parameter to determine the indication for TAP. Although SAVR is a more invasive method than TAVR, it seems to have some advantage in treating AS patients with sigmoid septum. Further studies, including randomized clinical trials, are needed to determine which techniques could be suitable for AS patients, case by case. Because it has been only several years since TAVR can be clinically used, long-term outcomes, especially concerning SVD of the bioprosthetic valve of TAVR, are still insufficient. TAVR will become more important in selecting the suitable surgical method for each patient who has various clinical features.

Conflict of Interest

The authors declare that they have no conflicts of interest regarding the publication of this article.

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Surgical Therapy for Aortic Stenosis


TAVR時代の大動脈弁狭窄症の外科治療

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要旨：大動脈弁狭窄症（AS）は最も多く見られる心臓弁膜症であり、特に高齢者に多く認められる。手術の大動脈弁置換術（SAVR）は最も有効な治療法であるが、手術リスクの高い症例ではその適応は時に困難である。高リスク患者に対しては不可欠な時もある。近年では、わが国でもカテーテルの大動脈弁置換術（TAVR）が認可され、高リスク患者・手術不能患者に対して広く行われるように出てきている。TAVRは人工心肺を要さず低侵襲でありその手術成績も良好であるので、欧米ではすでに中リスク患者まで適応は広げられ、さらに低リスク症例にまで広げられようとされており、その症例数は著に増加してきている。ASに対する有効な治療法の選択肢が拡大したわけであるが、今後はこれらの手術法の選択が重要となってくる。特に低リスク患者では、手術死亡のみならず、遠隔成績や合併症、Quality of life まで考慮する必要がある。このとき、患者的併存症が治療成績に影響を与えることを考える必要がある。本稿ではその併存症として透析を要する慢性腎不全、機能的三尖弁逆流、S字状中隔を取り上げ、これらを合併するAS患者におけるSAVR、TAVRの治療成績について概説する。

キーワード：大動脈弁置換術、カテーテルの大動脈弁置換術、血液透析、機能的三尖弁閉鎖不全症、S字状中隔。