



The role of transcatheter aortic valve replacement in the patients with severe aortic stenosis requiring major non-cardiac surgery

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Abstract

Severe aortic stenosis (AS) is considered as an independent risk factor for perioperative cardiac complications of non-cardiac surgery. Surgical aortic valve replacement should be considered before non-cardiac surgery in patients with symptomatic severe AS. However, recently, transcatheter aortic valve replacement (TAVR) has emerged as an alternative approach for selected AS patients. We sought to determine the safety and efficacy of TAVR in preparation for major non-cardiac surgery. From our retrospective database, seven patients who underwent TAVR in preparation for major non-cardiac surgery were identified, and their clinical and hemodynamic data were collected. After TAVR, a significant reduction in the mean transaortic pressure gradient from 54.0 (Interquartile range (IQR) 47.5–64.5) to 18.0 (IQR 12.5–19.0) mmHg ($p=0.016$) and an increase in the calculated aortic valve area from 0.6 (IQR 0.6–0.7) to 1.3 (IQR 1.1–1.5) cm² ($p=0.022$) were noted. Non-cardiac surgery included lung segmentectomy and lymph node dissection, lung lobectomy, ileocecal resection, partial colectomy, partial nephrectomy, nephroureterectomy, laparoscopic nephrectomy, and laparoscopic nephroureterectomy. All the initial non-cardiac surgeries were performed without cardiac complications, under general anesthesia, 37 (IQR 32–74) days after TAVR. Two of the patients eventually needed additional non-cardiac surgery, which was performed uneventfully without the need for additional AS treatment. TAVR was an effective and safe procedure that might reduce the risk of general anesthesia and major non-cardiac surgery in severe AS.

Keywords Valvular heart disease · Aortic valve stenosis · Transcatheter aortic valve replacement · Non-cardiac surgery

Abbreviations

| | |
|------|--|
| AS | Aortic stenosis |
| BAV | Balloon aortic valvuloplasty |
| BNP | Brain natriuretic peptide |
| DAPT | Double antiplatelet therapy |
| EF | Ejection fraction |
| IQR | Interquartile range |
| SAVR | Surgical aortic valve replacement |
| STS | Society of Thoracic Surgeons |
| TAVR | Transcatheter aortic valve replacement |

Introduction

Patients with severe aortic stenosis (AS) are at increased risk for perioperative cardiac complications from non-cardiac surgery. Kertai et al. reported that the risk of cardiac complications in patients with AS undergoing non-cardiac surgery was approximately 30% [1]. The risk of mortality in patients with severe AS undergoing intermediate or higher-risk surgery has been estimated to be approximately 6–10% [2–4]. Therefore, when AS patients requiring elective major non-cardiac surgery have indications for surgical aortic valve replacement (SAVR), preoperative SAVR is recommended [5, 6].

However, patients who are not suitable for SAVR because of frailty or other comorbidities are occasionally encountered. In addition, SAVR might not be optimal for patients with malignancy since extracorporeal circulation during the procedure could increase the risk of cancer dissemination by immunosuppression, although the evidence regarding this is controversial [7–11]. Generally, percutaneous balloon aortic

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valvuloplasty (BAV) was considered for these patients [12, 13]. However, the efficacy of BAV, in general, and for preparation for non-cardiac surgery is uncertain because of the associated high complication and recurrence rates [14–18]. Recently, transcatheter aortic valve replacement (TAVR) has emerged as an alternative treatment for severe AS for surgical intermediate to high-risk patients [19–21]. In the current study, we reported our experience with TAVR as the preoperative management of non-cardiac surgery for severe AS patients who were unsuitable for SAVR.

Materials and methods

Subjects

Between December 2013 and March 2018, 145 patients received TAVR at our hospital. Of these patients, seven patients required TAVR before major non-cardiac surgery including intermediate and high-risk procedures according to 2014 ESC/ESA guidelines on non-cardiac surgery [20]. The risk of SAVR in these patients was assessed based on a risk model developed by the Society of Thoracic Surgeons (STS). Three of these patients were intermediate-risk patients with an STS score of 4–8%, and the others were low-risk patients with an STS score of <4%. All seven patients had malignancy. Life expectancy of each patient was estimated longer than 1 year if the malignancy was treated properly. Invasive treatment for severe AS before non-cardiac surgery was recommended for these patients because they were all symptomatic and had indications for SAVR or TAVR. We decided for TAVR because of their advanced age, moderate risk for SAVR, or malignancy after discussing with our heart team, involving interventional cardiologists, cardiac surgeons, and anesthesiologists. Although four of them were at low risk with an STS score <4%, not SAVR but TAVR was selected to avoid the possible risk of cancer dissemination due to extracorporeal circulation during SAVR. Initial non-cardiac surgery was performed under general anesthesia for all patients within half a year after TAVR. Moreover, two of them eventually had to undergo additional non-cardiac surgery. All patients have provided written consent to publish their features and the identities of these patients have been protected.

TAVI procedure

All patients were prescribed 100 mg of aspirin. Procedural anticoagulation was achieved with administration of unfractionated heparin maintaining an activated clotting time of > 250 s. Procedures were all performed under general anesthesia. Only one of the seven patients underwent TAVR via the transapical approach; the transfemoral approach

was employed for the rest. Four patients were treated with a 23-mm SAPIEN XT (Edwards Lifesciences, Irvine, CA, USA), and three were treated with a 20-mm or 23-mm SAPIEN 3 (Edwards Lifesciences, Irvine, CA, USA). For the transapical approach, valve-in-valve implantation was performed due to the inappropriate low-positioning implantation of the first valve, which caused moderate-to-severe aortic regurgitation. In one of the cases with the transfemoral approach, post-dilatation was required due to moderate aortic regurgitation as a result of incomplete apposition.

Measurements

Hemodynamic data including transaortic pressure gradient and ejection fraction (EF) with echocardiography were assessed before and after the procedure. The aortic valve area was calculated using the continuity equation. Brain natriuretic peptide (BNP) values were measured before TAVR and before non-cardiac surgery, except in a case where BNP was not measured before non-cardiac surgery because the procedure was performed relatively soon after TAVR.

Statistical analysis

Clinical data are expressed as median values and interquartile ranges (IQR). Comparison between groups was performed with the Wilcoxon-signed rank sum test. A *p* value of < 0.05 was considered significant. Statistical analyses were performed using EZR software (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).

Results

Clinical and hemodynamic data

The clinical data of the seven patients are shown in Table 1. The study group consisted of a man and six women. Their median age was 79 (IQR 76–84) years. They were all symptomatic with New York Heart Association functional class II. Three were treated with conservative medical therapy for heart failure and one was treated not only with medications, but also with percutaneous BAV before TAVR. The other three patients were not treated for severe AS. No patient had a previous history of myocardial infarction, stroke, syncope, or angina pectoris. Only one had significant coronary artery disease with > 75% stenosis in the middle left anterior descending artery as revealed by pre-procedure coronary angiography. One patient had moderate aortic regurgitation, while the others had trace or

Table 1 Clinical data of seven patients undergoing TAVR before non-cardiac surgery

| Patient no. | Age | Sex | STS score | TAVI procedure | Diagnosis | Non-cardiac procedure | Days after TAVI |
|-------------|-----|-----|-----------|----------------|---|--|-----------------|
| Case 1 | 77 | F | 5.667 | TA XT 23 mm | Renal cell carcinoma | Laparoscopic nephrectomy | 132 |
| Case 2 | 74 | F | 2.095 | TF XT 23 mm | Urothelial carcinoma | Nephroureterectomy | 34 |
| Case 3 | 75 | M | 2.845 | TF XT 23 mm | Lung carcinoma | Segmentectomy Lymph node dissection | 44 |
| Case 4 | 85 | F | 4.600 | TF XT 23 mm | Renal cell carcinoma Colon carcinoma | Partial nephrectomy Ileocecal resection | 195 12 |
| Case 5 | 79 | F | 3.990 | TF S3 20 mm | Recurrence of carcinoma Lung carcinoma | Partial colectomy Lobectomy | 462 37 |
| Case 6 | 91 | F | 5.843 | TF S3 20 mm | Renal cell carcinoma | Laparoscopic nephrectomy | 104 |
| Case 7 | 82 | F | 3.357 | TF S3 23 mm | Urothelial carcinoma | Laparoscopic nephroureterectomy | 29 |

F female, *M* male, *STS* society of thoracic surgeons, *TA* trans apical approach, *TF* trans femoral approach, *XT* SAPIEN XT valve (Edwards Lifesciences, Irvine, CA, USA), *S3* SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA, USA)

mild aortic regurgitation. No patient had a bicuspid valve or other significant valvular heart diseases.

The hemodynamic outcome and values of EF and BNP are shown in Table 2. All patients had preserved EF and there were no significant changes in each patient between pre-procedure and post-procedure. After TAVR, there was a significant decrease in the mean systolic transaortic gradient from 54.0 (IQR 47.5–64.5) to 18.0 (IQR 12.5–19.0) mmHg ($p=0.016$) and a significant increase in the calculated aortic valve area from 0.6 (IQR 0.6–0.7) to 1.3 (IQR 1.1–1.5) cm² ($p=0.022$). A relative decrease in BNP levels from 150.7 (IQR 92.8–220.6) to 71.6 (IQR 52.0–90.0) pg/mL ($p=0.094$) was also observed after TAVR.

Complications

There was no adverse event including death, stroke, myocardial infarction, major vascular complication, acute kidney injury, or conduction abnormalities associated with TAVR. All patients had only trace to mild paravalvular aortic regurgitation following valve implantation.

Non-cardiac surgical procedures

The diagnosis and required non-cardiac surgery are also summarized in Table 1. All seven patients underwent initial non-cardiac surgery uneventfully under general anesthesia 37 (IQR 32–74) days after TAVR. According to 2014 ESC/ESA guidelines on non-cardiac surgery, initial non-cardiac

Table 2 Echocardiographic data and brain natriuretic peptide in seven patients undergoing TAVR

| Patients case no. | EF (%) | Mean transaortic gradient (mmHg) | | Calculated aortic valve area (cm ²) | | BNP (pg/mL) | |
|-------------------|------------------|----------------------------------|------------------|---|---------------|--------------------|------------------|
| | | Pre | Post | Pre | Post | Pre | Post |
| Case 1 | 59 | 33 | 14 | 0.7 | 1.0 | 237.6 | 90.8 |
| Case 2 | 69 | 62 | 19 | 0.6 | 2.0 | 150.7 | 50.2 |
| Case 3 | 78 | 54 | 19 | 0.8 | 1.6 | 18.8 | 7.3 |
| Case 4 | 62 | 51 | 11 | 0.6 | 1.4 | 203.6 | N/A |
| Case 5 | 74 | 80 | 30 | 0.6 | 1.1 | 133.4 | 57.3 |
| Case 6 | 73 | 67 | 18 | 0.5 | 1.1 | 433.7 | 92.9 |
| Case 7 | 66 | 44 | 11 | 0.7 | 1.3 | 52.2 | 85.9 |
| Median (IQR) | 69.0 (64.0–73.5) | 54.0 (47.5–64.5) | 18.0 (12.5–19.0) | 0.6 (0.6–0.7) | 1.3 (1.1–1.5) | 150.7 (92.8–220.6) | 71.6 (52.0–90.0) |

EF ejection fraction (before TAVR), *BNP* brain natriuretic peptide, *Pre* before TAVR, *Post* after TAVR, *IQR* interquartile range

surgery included two high-risk procedures; a lobectomy and a segmentectomy of the lung, and five intermediate-risk procedures; an ileocecal resection, a nephroureterectomy, two laparoscopic nephrectomies, and a laparoscopic nephroureterectomy [20].

Case 3 was diagnosed with renal cell carcinoma after initial non-cardiac surgery and underwent additional partial nephrectomy 195 days after TAVR. Case 4 was diagnosed with recurrence of the colon carcinoma and underwent additional partial colectomy 462 days after TAVR. Both procedures were of intermediate-risk. In both cases, no additional treatment for severe AS was required preoperatively. The

perioperative management with antiplatelet therapy in these seven patients is summarized in Fig. 1.

Preoperative management other than TAVR

In the same period, 2 patients (Case 1', 2') with symptomatic AS required SAVR before non-cardiac surgery, and only one patient (Case 3') with symptomatic AS had to undergo non-cardiac surgery (distal gastrectomy) without any invasive treatment due to active bleeding from gastric adenocarcinoma. There were no patients who underwent BAV as preoperative management in this period. The clinical data of these patients are summarized in Table 3.

| | Antiplatelet therapy | Period of antiplatelet therapy discontinuation | | Total days |
|----------------------------|----------------------|--|-----------------------|------------|
| | | Pre-operative period | Post-operative period | |
| Case 1 | Aspirin | 8 days | 8 days | 16 days |
| | Clopidogrel | 15 days | 8 days | 23 days |
| Case 2 | Aspirin | 8 days | 1 day | 9 days |
| Case 3 | Aspirin | 8 days | 4 days | 12 days |
| Case 4 | Aspirin | Continued throughout the entire period | | 0 days |
| Case 5 | Aspirin | 8 days | 6 days | 14 days |
| Case 6 | Aspirin | 6 days | 7 days | 13 days |
| Case 7 | Aspirin | 7 days | 5 days | 12 days |
| | Clopidogrel | 14 days | 5 days | 19 days |
| Additional surgery (Case3) | Aspirin | 8 days | 6 days | 14 days |
| Additional surgery (Case4) | Aspirin | 5 days | 5 days | 10 days |

Fig. 1 Case 1 and 7 were treated with dual antiplatelet therapy including aspirin and clopidogrel. Case 1 discontinued aspirin and clopidogrel for 17 days and 24 days, respectively, and Case 7 discontinued aspirin and clopidogrel for 12 days and 19 days, respectively, in the perioperative period. Case 2, 3, 5, and 6 were treated with single antiplatelet therapy with aspirin, which was discontinued for 9 (Case 2), 12 (Case 3), 14 (Case 5), and 13 days (Case 6), respectively. All these patients (Case 1, 2, 3, 5, 6, and 7) were treated with

continuous intravenous infusion of unfractionated heparin with a target activated partial thromboplastin time of 1.5–2.5 times the control value during the perioperative period. Case 4 was treated with single antiplatelet therapy with aspirin, which was continued throughout the perioperative period. For the additional surgeries, Case 3 and 4 discontinued aspirin, which was replaced with unfractionated heparin for 14 and 10 days, respectively

Table 3 Clinical data of patients not undergoing TAVR before non-cardiac surgery

| Patient no. | Age | Sex | STS score | Management before non-cardiac surgery | Diagnosis | Non-cardiac surgery | Days After SAVR |
|-------------|-----|-----|-----------|---------------------------------------|------------------------------|---------------------|-----------------|
| Case 1' | 82 | M | 3.017 | SAVR Magna 21 mm | Lumber spinal canal stenosis | Laminectomy | 45 |
| Case 2' | 70 | M | 6.383 | SAVR Mosaic 25 mm | Gastric adenocarcinoma | Distal gastrectomy | 105 |
| Case 3' | 71 | M | 2.380 | Medical therapy | Gastric adenocarcinoma | Distal gastrectomy | N/A |

M male, STS Society of Thoracic Surgeons, SAVR surgical aortic valve replacement, N/A not applicable

Indication for SAVR was also carefully discussed with the heart team. Case 1' was 82-year-old male who was scheduled for laminectomy for lumbar spinal canal stenosis. We decided for SAVR because of the low risk of SAVR (STS score: 3.017%) and a bicuspid aortic valve. Case 2' was 70-year-old male who was scheduled for distal gastrectomy for gastric adenocarcinoma. Although this patient had malignancy, we decided for SAVR because TAVR was contraindicated due to hemodialysis and BAV was also contraindicated due to moderate aortic valve regurgitation. The SAVR procedures were performed with cardiopulmonary bypass under general anesthesia. Procedural anticoagulation was achieved with administration of unfractionated heparin maintaining an activated clotting time of > 400 s. Case 1' was treated with 21-mm Magna Ease (Edwards Lifesciences, Irvine, CA, USA) and case 2' was treated with 25-mm Mosaic (Medtronic, Minneapolis, MN, USA). Case 1' underwent laminectomy 45 days after SAVR. During the perioperative period of non-cardiac surgery, he discontinued warfarin for 25 days with continuous intravenous infusion of unfractionated heparin with a target activated partial thromboplastin time of 1.5–2.5 times the control value. Case 2' underwent distal gastrectomy 105 days after SAVR. At this time, he had already completed the first 3 months of warfarin therapy after bioprosthetic valve replacement.

All patients including case 3' underwent non-cardiac surgery uneventfully, and no thrombotic event was observed during perioperative period.

One-year clinical outcomes

All patients except for Case 7 completed 1-year clinical follow-up after the first intervention (TAVR, SAVR, or non-cardiac surgery). During the follow-up period, Case 3' underwent SAVR uneventfully 46 days after distal gastrectomy. Otherwise, there were no clinical events including death, re-hospitalization due to heart failure, thrombotic event, and re-intervention for AS. Case 7 did not have any of these clinical events either over 300 days.

Discussion

TAVR in preparation for non-cardiac surgery compared to BAV or SAVR

Previously, for patients who were unsuitable for SAVR, percutaneous BAV was the only option for preparation for non-cardiac surgery. However, several important limitations exist regarding BAV use. First, the improvement of the transaortic pressure gradient and aortic valve area is limited, and consequently, persistent severe AS remains in many cases. [16] Second, serious complications including stroke, aortic

regurgitation, myocardial infarction, and access-site-related vascular complications have been reported in approximately 20% or more of patients [14, 16, 22]. Finally, restenosis and clinical deterioration occur in most cases within 6–12 months and repeat procedures are usually required in these cases [14, 17]. In a report including 15 patients who underwent BAV in preparation for non-cardiac surgery, there were five early adverse events including one fatality and two SAVR before any additional procedures required were performed [12]. TAVR is now widely accepted as an ideal treatment for intermediate to high-risk patients with severe AS. In TAVR, the improvement of AS is more satisfactory and fewer complications are noted compared to BAV. Moreover, TAVR is less invasive than SAVR, which could shorten the time to non-cardiac surgery. The possibility of cancer dissemination due to extracorporeal circulation for patients with malignancy might be avoided as well since it is not generally required in TAVR.

Therefore, TAVR might be optimal as a preparatory treatment for non-cardiac surgery.

Risk of cancer progression due to extracorporeal circulation

There have been several studies investigating the association between extracorporeal circulation and cancer progression [7–11]. Although the results are inconsistent and inconclusive possibly due to heterogeneity of patients (e.g., cancer type, stage, therapy), some of the studies suggested adverse effects of extracorporeal circulation on cancer progression [8–10]. Namely, it has been reported that cardiovascular surgery with extracorporeal circulation decreases immune capacity and thus may be associated with cancer progression [22]. Therefore, it might be better to avoid extracorporeal circulation in patients with malignancy.

Guideline recommendation

In the current guidelines for non-cardiac surgery from the European Society of Cardiology and European Society of Anesthesiology, TAVR is listed as an alternative approach for patients who are at high risk for valvular surgery [20]. However, there are only a few case reports of combined TAVR and endovascular repair of abdominal aortic aneurysm, and a few reports of TAVR in patients requiring major non-cardiac surgery [23, 24].

Perioperative antiplatelet therapy cessation in TAVR patients

One of the major concerns of preoperative TAVR is the safety of the early cessation of antiplatelet therapy prior to major surgery. Current guidelines recommend a dual

antiplatelet therapy (DAPT) with low-dose aspirin and clopidogrel for at least 3–6 months after TAVR [5, 6]. These recommendations are currently based on expert consensus without reliable clinical evidence. The main purpose of antithrombotic therapy in TAVR patients is prevention of thrombotic events including myocardial infarction and stroke. Although some data have already shown that single antiplatelet therapy, compared to DAPT, did not increase the risk of thrombotic events, there are no data regarding complete cessation of antiplatelet therapy after TAVR [24–26].

Our experiences

To date, the efficacy and safety of TAVR as preparation for major non-cardiac surgery has not been well studied. Our experience with these seven patients showed that TAVR may serve as an optimal treatment option in the preoperative management of patients with severe AS who require major non-cardiac surgery. All seven patients were safely treated with TAVR and underwent major non-cardiac surgery under general anesthesia without a delay in the planned schedule. None of our seven patients had adverse cardiac events such as a clinical worsening of heart failure during the perioperative period. Two patients required additional major non-cardiac surgery and underwent them uneventfully, without requiring additional treatment for severe AS. During the perioperative period, eight of nine procedures were performed with a complete cessation of antiplatelet therapy, which was substituted with unfractionated heparin for 13 (IQR 11–14) days. However, no thrombotic events were observed in these patients.

Study limitations

Our study has several limitations worth noting. First, the present study was a retrospective observational study with a small number of patients and does not have statistical power to detect the efficacy of TAVR in preparation for non-cardiac surgery. Second, the study was not randomized regarding the use of medical therapy, BAV, SAVR, and TAVR in AS patients requiring non-cardiac surgery. Moreover, we had only a few patients treated with medical therapy or SAVR in the same period. Thus, any potential benefits of TAVR as perioperative management compared to medical therapy, BAV, or SAVR are unclear. Our study only suggests feasibility of TAVR before major non-cardiac surgery and further study is needed to clarify this issue. Third, our study includes only low or intermediate-risk patients with an STS score of < 8%. Therefore, the results might not be applicable to TAVR patients in general. However, we believe this small study will provide new insights into the preoperative management of AS before major non-cardiac surgery.

Conclusion

This study suggests that TAVR is a safe and effective approach that could reduce the risk of general anesthesia and major non-cardiac surgery in patients with severe AS. Further investigation is needed to clarify the safety and efficacy of TAVR as preoperative management for major non-cardiac surgery in patients with severe AS.

Compliance with ethical standards

Conflict of interest Dr. Tanabe receives honoraria from Edwards Lifesciences, and Medtronic. Dr. Yokozuka receives honoraria from Edwards Lifesciences. Other authors report no conflicts of interest.

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