DOCTORAL THESIS

Feasibility and safety of transradial balloon aortic valvuloplasty in patients with severe aortic stenosis

（重症大動脈弁狭窄症患者に対する経橈骨動脈大動脈弁拡張術の有用性と安全性）

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ORIGINAL ARTICLE

Feasibility and safety of transradial balloon aortic valvuloplasty in patients with severe aortic stenosis

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Abstract

Balloon aortic valvuloplasty (BAV) was developed as a technique to treat aortic stenosis (AS) and is associated with significant improvements in aortic valve area and trans-aortic valve gradient in the early and immediate periods after the procedure. BAV is commonly performed using a trans-femoral retrograde approach; however, trans-femoral access is associated with frequent access-site bleeding. Among 146 patients with symptomatic severe AS who were treated with BAV in our institution, 123 patients received BAV treatment via a trans-radial approach using a 7-Fr Glidesheath. The balloon size was 16–20 mm for all patients. Echocardiograms were obtained before and after BAV. Patients who received BAV alone ($n = 119$) were followed up for 3 months, and major adverse events (stroke, re-hospitalization for heart failure, and death) and procedural complications were recorded. At post-procedural echocardiography, the mean trans-valvular gradient (49.7 ± 21.5–42.5 ± 17.6 mmHg; $p < 0.0001$) was reduced significantly. All patients in this study did not die or require valve surgery within the first 7 days after BAV. Successful BAV was obtained in 45.6% of the patients. No patients had severe aortic insufficiency or BAV access-site bleeding. Three patients died suddenly and 4 patients were readmitted for heart failure. Trans-radial BAV is safe and may be useful as a bridging therapy for trans-catheter aortic valve replacement or surgical aortic valve replacement.

Keywords Aortic stenosis · Balloon aortic valvuloplasty · Transradial access

Introduction

Balloon aortic valvuloplasty (BAV) was developed as a technique to treat aortic stenosis (AS) and was first performed in 1985 [1]. BAV is associated with significant improvements in aortic valve area and trans-aortic valve gradient in the immediate and early-term post-procedure, although significant restenosis of the valve occurs in 60% of patients at 6 months [2, 3]. BAV is commonly performed using local anesthesia and a trans-femoral retrograde approach. Trans-femoral access is associated with major vascular complications due to the need for large-diameter sheaths. Patients with severe AS suitable for trans-catheter aortic valve replacement (TAVR) are elderly, frail, and have a bleeding tendency. A major mechanism of bleeding in AS is represented by acquired type 2A von Willebrand syndrome, which is characterized by a quantitative deficiency of high molecular weight multimers of von Willebrand factor [4]. The pathogenesis of Heyde's syndrome, which is associated with calcific aortic stenosis and gastrointestinal bleeding due to angiodysplasia, involves an acquired von Willebrand factor deficiency secondary to aortic stenosis in elderly patients with concomitant gastrointestinal bleeding [5]. As a result, several studies reported that the incidence of major vascular complications was as high as 6–14% in the BAV technique [6]. On the other hand, trans-radial artery access is associated with fewer vascular access-site complications and has been shown to reduce major bleeding and mortality as compared with the trans-femoral approach in the setting of

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percutaneous coronary interventions for acute coronary syndrome [7–9]. Therefore, we aimed to investigate the feasibility and safety of a systematic trans-radial approach for BAV.

Methods

Patient population

From March 2017 through September 2021, among 146 patients with symptomatic severe AS who were treated with BAV in our institution, we retrospectively analyzed 124 patients who received BAV treatment via a trans-radial approach. Patients had a high-risk profile for surgical aortic valve replacement and at least one of the following: advanced age; congestive heart failure; low left ventricular ejection fraction (LVEF); critical conditions; moderately/severely frail; preoperative status of percutaneous coronary intervention; bridge to major non-cardiac surgery. Patients with the following conditions were excluded from this study: hemodialysis, cardiogenic shock, abnormal Allen test results, or severe tortuosity of the radial artery, which precluded radial access (Fig. 1). Pre- and post-procedural LVEF, maximum and mean trans-aortic gradients, aortic valve area (AVA), and the degree of aortic regurgitation (AR) were obtained from echocardiographic evaluations. LVEF was measured using Simpson's method, trans-aortic gradient was calculated using the simplified Bernoulli equation, and AVA was calculated using the continuity equation. Ninety-six percent patients underwent standard TAVR screening procedures including 3-dimensional computed tomography (3D CT) to assess the dimensions and morphologies of the aortic valve and aorta as well as peripheral access vessels. This study complied with the principles of the Declaration of Helsinki and was approved by the institutional review board

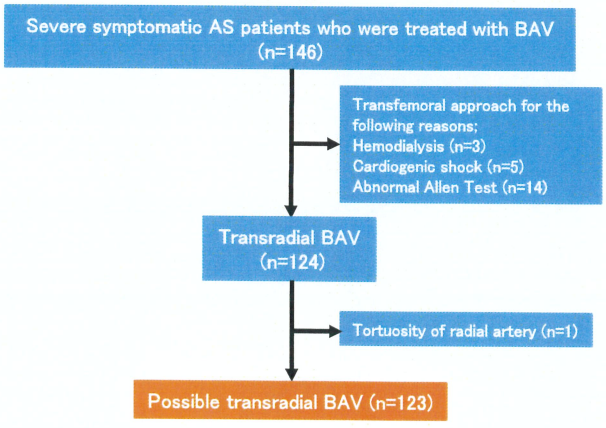

Fig. 1 Patients inclusion flow chart. *AS* aortic stenosis, *BAV* balloon aortic valvuloplasty

at Yokohama City University Graduate School of Medicine (B191200047) and was conducted in accordance with the guidelines of our institutional ethics committees. All patients participated this study unless the patient opted out.

Trans-radial BAV procedure

All procedures were performed by a trans-radial retrograde approach using a 7 French (Fr) Glidesheath Slender (Terumo, Tokyo, Japan). This is a thin-walled radial sheath that combines an inner diameter compatible with any 7-Fr guiding catheter with an outer diameter smaller than current 7-Fr sheaths [10]. The other side of the radial artery was used for pressure monitoring of simultaneous trans-aortic gradients with a pigtail catheter using a 5 Fr trans-radial sheath. A diagnostic 5 Fr pigtail catheter (Goodman, Nagoya, Japan) was placed in the right-coronary cusp. Temporary pacing was performed using an appropriate femoral vein, and contralateral access was prepared before August 2018 for emergency situations using a 3-Fr or 4-Fr sheath. All patients received 4000 UI of unfractionated heparin after insertion of all sheaths. A 5 Fr diagnostic Amplatz left curve 1 or a Judkins right curve 4 catheter (Goodman, Nagoya, Japan) was delivered up to the aortic valve and used to direct a 260 cm 0.035 in. straight tip-fixed core guidewire through the stenotic valve orifice. Once the catheter was advanced over the orifice, the straight guidewire was replaced by the shaped spring wire, and the pigtail catheter was placed in the left ventricle. The mean trans-aortic gradient was measured before and after valvuloplasty by recording the aortic and left ventricle pressures. After measuring pressure, a Safari guidewire (Boston Scientific, MA, USA) was inserted into the pigtail catheter. The balloon sizes were 7-Fr compatible 16–20 mm VACS II (OSYPKA, Rheinfelden, Germany) in all cases. 18- and 20-mm balloons were available from December 2020 and July 2021, respectively. Appropriate balloon size was defined as minimum lumen diameter of aortic valve annulus measured by 3D CT minus 1 mm and used to select balloon size from December 2020. 20-mm balloon was used during TAVR in the present study. To stabilize the balloon position across the aortic valve before balloon inflation, the right ventricle was paced at a high rate (180–200 bpm). Pacing was continued until the balloon was deflated. The number of balloon inflations was one to three times in all patients. At the end of the procedure, protamine sulfate was administered to most patients to facilitate hemostasis. The successful BAV was defined as (1) 25% increase in AVA by echocardiography and (2) absence of death or valve surgery within the first 7 days after procedure.

Procedural complications [worsening aortic insufficiency, permanent pacemaker and BAV access-site and non-access-site bleeding according to the Bleeding Academic Research Consortium (BARC) criteria] were recorded. Major adverse

events included stroke, re-hospitalization for heart failure and cardiovascular death during 3 months of follow-up.

Statistical analysis

Continuous variables are expressed as means ± standard deviations. Categorical variables are presented as numbers and percentages and were compared by Chi-square tests. Continuous clinical variables among the three groups were compared by analysis of variance (ANOVA). Paired tests were analyzed by paired Student's *t* tests. Paired ordinal data including AR severity were evaluated using the Bowker test. A p value of < 0.05 was considered to indicate statistical significance. All analyses were performed using JMP® 15 software (SAS Institute Inc., Cary, NC, USA).

Results

Baseline characteristics

Baseline characteristics of the population are shown in Table 1. The mean age of the patients was 84.7 years, and 36% were male. Overall, 42% of the patients had coronary artery disease, and 8% of them had previous cerebrovascular accidents. Our study cohort represents a typical population of symptomatic patients with AS at high risk for open-heart surgery and suitable for TAVR [Society of Thoracic Surgeons (STS) score: 8.9 ± 6.3%, logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE): 13.7 ± 9.65%]. The mean annulus size was 408.1 mm^2.

Procedural characteristics

In one patient, there was a need to cross over to femoral access because of tortuosity of the radial artery. Thus, BAV via trans-radial access was feasible in 99% of patients in our study population (Fig. 1). 16-, 18-, and 20-mm balloons were used in 106, 13, and 4 patients, respectively (Fig. 2). In this study, 20-mm balloon was used trans-radially during TAVR procedure when self-expandable trans-catheter heart valve did not expand well and required balloon dilatation using 20-mm balloon. Mean rapid pacing time was 8.8 s. Multiple inflations were performed in 114 patients (92%). After BAV, mean trans-aortic gradient as assessed by catheterization decreased significantly (54.5 ± 22.9–42.6 ± 18.9 mmHg; $p < 0.0001$) (Fig. 3). The mean interval between pre-procedural echocardiography and the BAV procedure was 30 days and that between post-procedural echocardiography and the BAV procedure was 19 days. On comparing baseline and post-procedural echocardiographic data, AVA increased from 0.62 ± 0.22 to 0.74 ± 0.20 cm^2 ($p < 0.0001$), and mean trans-valvular gradient decreased significantly (49.7 ± 21.5–42.5 ± 17.6 mmHg; $p < 0.0001$) (Fig. 4). We divided the patients into three groups according to the tertile of annulus area measured by 3D CT: tertile 1 (low tertile), annulus area of $< 365 mm^2$; tertile 2 (intermediate tertile), annulus area of 365–427mm^2; and tertile 3 (high tertile), annulus area of $> 427 mm^2$. In all three groups, mean trans-valvular gradient at post-procedural echocardiography decreased significantly

Table 1 Baseline characteristics

Variable	$n = 123$
Age, years	84.7 ± 4.9
Male gender, *n* (%)	45 (36)
BMI, kg/m^2	22.1 ± 3.8
Risk factors	
Hypertension, *n* (%)	105 (85)
Diabetes, *n* (%)	37 (30)
Dyslipidemia, *n* (%)	71 (57)
Smoker, *n* (%)	10 (8)
Clinical history	
Prior MI, *n* (%)	10 (8)
Prior PCI, *n* (%)	20 (16)
Prior CVA, *n* (%)	10 (8)
COPD, *n* (%)	43 (34)
CAD, *n* (%)	52 (42)
Clinical presentation	
Angina pectoris, *n* (%)	17 (13)
Syncope, *n* (%)	5 (4)
Dyspnea, *n* (%)	104 (84)
Admission due to CHF, *n* (%)	73 (59)
STS Score, %	8.9 ± 6.3
Logistic EuroSCORE, %	13.7 ± 9.65
Annulus area, mm^2	408.1 ± 78.1

Values are expressed as mean ± SD or *n* (%)

BMI body mass index, *MI* myocardial infarction, *PCI* percutaneous coronary intervention, *CVA* cerebrovascular accidents, *COPD* chronic obstructive pulmonary disease, *STS* Society of Thoracic Surgeons, *EuroSCORE* European System for Cardiac Operative Risk Evaluation

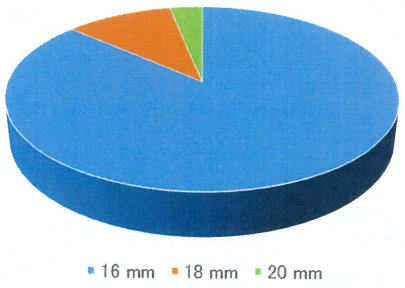

Fig. 2 The distribution of balloon size

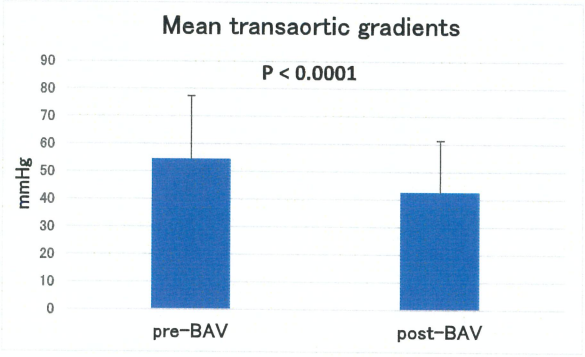

Fig. 3 Mean transaortic gradients pre- and post-BAV obtained by catheterization. Mean transaortic gradient by recording of aortic and left ventricle pressures before and after BAV. *BAV* balloon aortic vavuloplasty

(tertile 1: 51.7 ± 21.8–43.6 ± 19.4 mmHg; $p < 0.0001$; tertile 2: 50.2 ± 19.8–43.3 ± 16.7 mmHg; $p < 0.0001$; tertile 3: 46.5 ± 23.4–39.5 ± 17.2 mmHg; $p < 0.0001$). There was no significant difference in the reduction of mean trans-valvular gradient among the three groups ($p = 0.593$) (Fig. 5). We calculated relative expansion of balloon by quantitative angiography using actual balloon diameter as the reference ([minimum balloon diameter/actual balloon diameter] × 100) and compared among the three groups stratified by the tertiles of annulus area (Fig. 6). In each tertile, relative balloon expansions were 88.5 ± 7.63%, 88.9 ± 6.84% and 88.5 ± 6.77%, respectively. There were no significant differences among the three groups. Overall, LVEF significantly improved (61.1 ± 16.1–64.0 ± 14.0%; $p = 0.019$). All patients in this study did not die or require valve surgery within the first 7 days after BAV. Successful BAV was obtained in 45.6% of the patients. No patient had severe AR after BAV. Access-site bleeding was not observed in any patient. However, non-access-site bleeding according to BARC-3 criteria was observed in 6 patients (4%). Fourteen patients (11%) had radial artery occlusion at the BAV access site.

Major adverse events

One patient died of sepsis 1 month after BAV and 3 patients died suddenly 2 and 3 months after BAV, respectively. Four patients were readmitted with heart failure after BAV (Table 2).

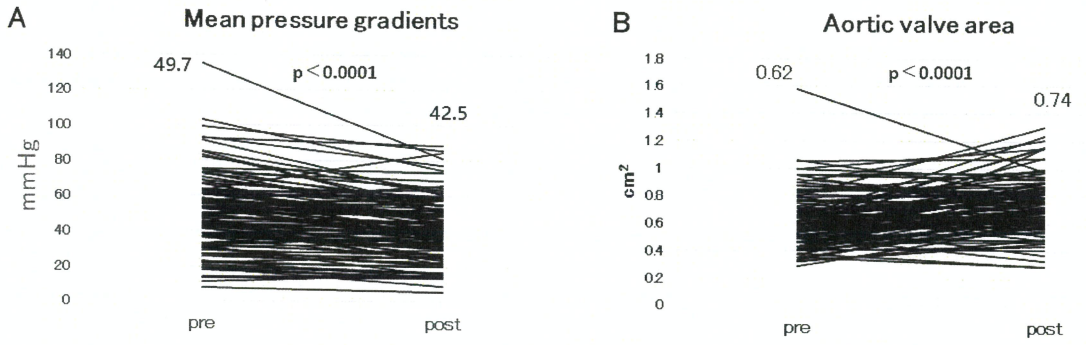

Fig. 4 Echocardiographic data pre- and post-BAV. Mean pressure gradients pre- and post-BAV (**A**), and aortic valve areas pre- and post-BAV (**B**). *BAV* balloon aortic valvuloplasty

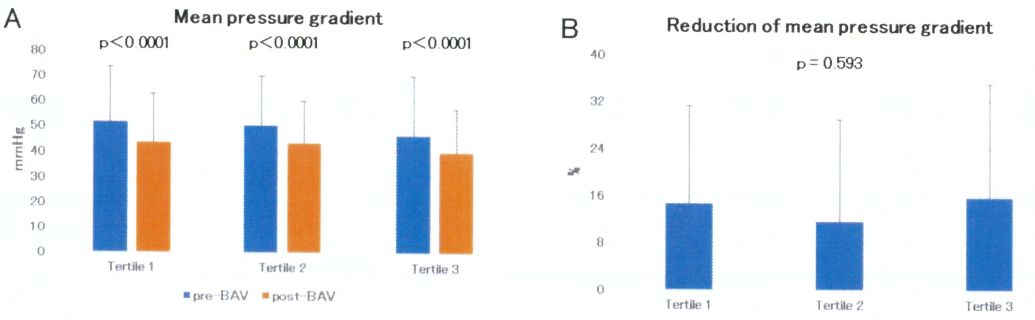

Fig. 5 **A** Mean pressure gradient by echocardiography pre- and post-BAV in each groups according to the tertile of annulus area. **B** Comparison of reduction of mean pressure gradient among the groups

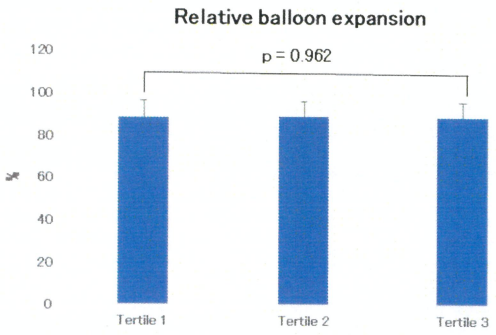

Fig. 6 Comparison of relative balloon expansion by quantitative angiography among the 3 groups stratified according to the tertile of annulus area

Table 2 Major adverse events and procedural complications

Variable	
Major adverse events	$n=119$
Cardiovascular death, *n* (%)	3 (2)
Stroke, *n* (%)	2 (1)
Re-hospitalization due to HF, *n* (%)	4 (3)
Procedural complications	$n=123$
Worsening AR, *n* (%)	0 (0)
Permanent pacemaker, *n* (%)	0 (0)
BAV access-site occlusion, *n* (%)	14 (11)
BAV access-site bleeding (BARC-3), *n* (%)	0 (0)
Non-access-site bleeding (BARC-3), *n* (%)	6 (4)

Values are expressed as *n* (%)

AR aortic regurgitation, *BARC* Bleeding Academic Research Consortium, *BAV* balloon aortic valvuloplasty, *HF* heart failure

Discussion

This study evaluated the use of 16–20 mm diameter balloon for the trans-radial treatment of symptomatic severe AS. Our main findings showed that in a high-risk cohort, BAV using a 16–20 mm balloon via the radial artery was feasible in 84% of all AS patients who received BAV in our hospital. Furthermore, trans-radial BAV was performed in 99% of patients in whom radial puncture was attempted. Trans-radial BAV resulted in reasonable hemodynamic and clinical improvements, while reducing the risk of access-site vascular complications.

7-Fr-transradial BAV as a possible safer bridge-to-TAVR option

It is well known that BAV does not improve the survival rates of patients with severe AS [11]. BAV may improve symptoms [3], but the recurrence rate is high. Safian et al. performed BAV in 170 patients who had symptomatic AS. During 9 months of follow-up, 44 patients had recurrence of symptoms and 25 patients died [12]. In the present study, we used a 16-mm balloon for all patients until November 2020 because this balloon size was maximum for a 7-Fr sheath during the study period. This balloon size may not be appropriate for all patients. However, 18- and 20-mm balloons were available and the overall change in AVA in our study (0.62 ± 0.22–0.74 ± 0.20 cm^2) was similar to that in previous studies. Compared with baseline echocardiography, the mean trans-valvular gradient decreased significantly 1 month after the procedure irrespective of the annulus size and severity of valve calcium. In the National Heart Lung and Blood Institute Balloon valvuloplasty Registry, the AVA increased from 0.5 to 0.8 cm^2 using commonly a 20 or 23 mm balloon [3], whereas Liberman et al. reported an increase in AVA from 0.5 to 0.7 cm^2 using balloons with progressively larger effective diameters [11]. In either study, the balloon size was larger than that in our study.

BAV alone suffers a lack of durability, such as early recoil [13] and the inflammatory and fibrous cellular response of valves, resulting in restenosis [14] commonly occurs within 6 months. Eltchaninoff et al. suggested that in TAVR patients, BAV could often serve diagnostically to confirm the potential benefit of TAVR and as a treatment to palliate symptoms while patients were screened and awaiting definitive therapy [15]. In our study, TAVR was performed within 3 months when possible, and there were only 3 patients with recurrence of valve restenosis who were readmitted for heart failure before TAVR. Therefore, trans-radial BAV is useful option as a bridge to TAVR.

Safety

Ben-Dor et al. reported that serious adverse events, such as intra-procedural death, stroke, severe aortic regurgitation, and vascular complications, are frequent after BAV and occur in more than 15% of patients. Vascular complications requiring intervention account for half of all events, occurring in 7% of patients [6]. In our study, the incidence of non-access-site bleeding according to the BARC-3 criteria was 4%. All cases of non-access-site bleeding were caused by a femoral artery access site using 3- or 4-Fr sheath, which was prepared for backup for extracorporeal membrane oxygenation. Therefore, major bleeding may occur even with a small diameter sheath in the setting of BAV in patients with symptomatic AS. Since August 2018, we have changed

our strategy to perform BAV without femoral artery access prepared for extracorporeal membrane oxygenation. After we changed our strategy, none of the 88 patients had non-access-site bleeding according to BARC-3 criteria. Older age, female gender, renal failure, and low body mass index were reported to be associated with a higher rate of major vascular complications during or after trans-femoral coronary interventions [16]. This is particularly relevant for patients who are typical candidates for TAVR because of high age and frailty [17]. Avoidance of femoral access allows patient mobility soon after the procedure [17]. However, the disadvantage of a trans-radial approach relates to vascular tortuosity in elderly patients. This can usually be managed, but sometimes requires conversion to a femoral approach [18]. When we started this study, we performed BAV using right radial artery. However, in some cases, we have difficulty to perform BAV because we felt resistance to deliver the balloon due to aortic tortuosity. After we changed our strategy via left radial artery, we could easily perform BAV without resistance in most patients. Therefore, 82% patients received BAV via left radial artery. In one patient, we could not advance guidewire to the aorta because of severe tortuosity of bilateral radial artery. Transradial access reduced bleeding and mortality as compared with transfemoral access in patients with acute coronary syndromes, which have been associated with significantly increased bleeding [19, 20]. AS has been reported to be associated with coagulation impairment related to bleeding tendency [21]. In this report, bleeding occurred approximately in 20% of severe AS patients during 6 months before surgery. Therefore, the present study proved the feasibility of transradial BAV with low complication rate and supports the use of transradial access in patients with AS.

Jalava et al. reported that acute heart failure caused by severe AS was associated with increased risk of mortality and morbidity even after SAVR and TAVR [22]. Eugene et al. assessed 40 patients with severe AS accompanied by acute heart failure and showed that rescue BAV followed by TAVR or SAVR was safe and improved prognosis [23]. Although TAVR is safe in patients with chronic heart failure, we believe that BAV followed by TAVR was attractive option in the setting of acute decompensated heart failure.

Significant coronary artery disease (CAD) is commonly encountered in patients with severe AS being evaluated for TAVR. However, timing of revascularization of severe CAD is still unclear especially in patients with severe calcified lesion requiring rotablation. Goel et al. reported that patients with severe AS and LVEF $\leq$ 30% and STS score $\geq$ 10% before the era of TAVR were at a high risk of 30-day mortality after percutaneous coronary intervention (PCI) [24], suggesting that BAV concomitant with PCI or BAV followed by staged PCI may have a role. In our study, we performed PCI after BAV in 45 of 123 patients. During PCI procedure, hemodynamic status was stable in most cases.

Tumscitz et al. reported safety and feasibility of transradial BAV using a 9-Fr sheath [25]. However, 20% of patients had radial artery occlusion at 1 month in that study. This sheath size was deemed too large and possibly inappropriate for patients with a small physique. The present study is the first to use a 7-Fr Glidesheath Slender during the transradial procedure, and this technique may overcome limitations of the commonly used femoral approach, such as access-site bleeding due to the need for large-diameter sheaths. Aminian et al. assessed the feasibility and safety of the 7-Fr Glidesheath Slender for transradial percutaneous coronary intervention, and the rate of radial artery occlusion at 1 month was 4.8%, which was the lowest reported rate so far for a 7-Fr radial sheath [10]. In the present study, the occurrence of radial artery occlusion (11%) was higher than that reported by Aminian et al. In previous studies, the incidence of radial artery occlusion varied widely from 0.8 to 38% [26–28]. Garg et al. reported that female sex, diabetes, and lower body mass index were predictors of radial artery occlusion [29]. In our study, the ratios of females were higher and body mass index was lower than in previous studies [27, 28]. In all patients, we could retrieve a balloon into the radial sheath without excessive resistance after balloon dilatation.

Study limitations

There are several limitations in this study. Our results represent the experience of a single center with a small number of patients. However, our sample size is the largest so far to demonstrate the feasibility of transradial BAV. A larger randomized trial comparing transradial with transfemoral BAV is required to ultimately prove the superiority of transradial over trans-femoral BAV. Although the transvalvular gradient and AVA have improved, the use of a 16-mm balloon might be undersized in most patients. If appropriate balloon size was defined as minimum lumen diameter of aortic valve annulus measured by 3D CT minus 1 mm, 71% of the patients require > 16 mm balloon. 7-Fr compatible 18-mm and 20-mm balloons were commercially available from December 2020 and July 2021, respectively. Currently, 90% of our patient population would be covered by 16–20 mm balloon. In addition, acute AR occurred after BAV with a larger-size balloon in 1.5–2.0% of patients [3, 15, 30], which was not observed in the present population. Therefore, the small-size balloon used in this study may be adequate given the balance between the safety and efficacy of BAV with backup for TAVR or surgical aortic valve replacement within several months. The incidence of non-access bleeding from the femoral artery was high even with placement of a smaller

sheath. Therefore, a strategy without any sheath placement is needed to avoid femoral artery bleeding.

Conclusion

The present study demonstrated that systematic trans-radial BAV was feasible with the abolition of access-site bleeding and a low rate of radial artery occlusion. Transradial BAV may be a useful bridging therapy for trans-catheter aortic valve replacement or surgical aortic valve replacement.

Declarations

Conflict of interest The authors have no conflict of interest to declare.

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Ⅰ　主論文

Feasibility and safety of transradial balloon aortic valvuloplasty in patients with severe aortic stenosis

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Ⅱ　副論文

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Ⅲ　参考論文

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