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# Safety and efficacy of repeated balloon aortic valvuloplasty in patients with symptomatic severe aortic stenosis

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**Safety and efficacy of repeated balloon aortic valvuloplasty in patients with symptomatic severe aortic stenosis**

**Short title:** Outcomes of repeated BAV

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**ABSTRACT**

**Background:** Long-term outcomes of balloon aortic valvuloplasty (BAV) in patients with severe symptomatic aortic stenosis (AS) are poor, and this procedure needs to be repeated for selected cases.

**Aims:** To investigates the safety and efficacy of repeated BAV (reBAV).

**Methods:** We included consecutive patients who underwent reBAV in three Polish centers between 2010 and 2019. Baseline clinical, echocardiographic, procedural, and outcome data were analyzed.

**Results:** Thirty-five patients (median age 81.5 years, 57.1% women) who underwent reBAV were enrolled. In 42.9% of the patients, index BAV was considered a palliative treatment, and in 54.3% a bridge to definitive treatment. Index BAV decreased peak aortic valve gradient (pAVG) from a median of 78.0 mm Hg to 46.0 mm Hg ($P$ <0.001). After a mean of 255.8 days, reBAV was performed. In most cases (71.4%), the reason for reBAV was the worsening of heart failure symptoms and in 54.3% of patients, reBAV was still considered a palliative option. A decrease in pAVG max from a median of 73.0 mmHg to 45.0 mmHg ($P$ <0.001), comparable to the index BAV, was observed. The complications were numerically higher for repeated procedures. During the median (IQR) follow-up of 403.0 (152.0–787.0) days from the index procedure, 80.0% of the patients died.

**Conclusions:** Acute hemodynamic results of reBAV are comparable to those achieved during index BAV. However, reBAV may carry an increased risk of complications. Mortality after reBAV is high due to unfavorable risk profiles or delays in receiving definitive therapy.

**Key words:** aortic stenosis, balloon aortic valvuloplasty; complications; palliative care; outcomes;

## WHAT'S NEW?

Limited data exist on the effectiveness of repeated balloon aortic valvuloplasty in patients with severe symptomatic aortic stenosis who have previously undergone this treatment. In a group of 35 patients, we concluded that the acute hemodynamic results of the repeated procedure were comparable to those achieved during index balloon aortic valvuloplasty. However, mortality after repeated balloon aortic valvuloplasty was high due to unfavorable risk profiles or delays in receiving definitive therapy.

## INTRODUCTION

Nowadays, surgical aortic valve replacement (SAVR) and transcatheter aortic valve implantation (TAVI) are complementary treatment options for patients with severe symptomatic aortic stenosis (AS) [1–3]. The Heart Team selects the optimal mode of the intervention (SAVR or TAVI) based on the patient's age, life expectancy, comorbidities, anatomical and procedural characteristics, the relative risk of both procedures, as well as local experiences and resources [4]. Alternatively, balloon aortic valvuloplasty (BAV) may be considered a bridge to TAVI or SAVR in patients with decompensated AS and those with severe AS who require urgent high-risk non-cardiac surgery or in advanced heart failure also as a destination therapy or a bridge to recovery [4-6]. In this context, BAV could be used to verify whether patient frailty is related to valvular disease or not. Several studies have confirmed that this procedure is feasible and has acceptable safety [7–14]. However, contrary to TAVI, the long-term clinical and hemodynamic outcomes of BAV are relatively poor, and in selected cases, the procedure needs to be repeated [7, 8, 11]. On the other hand, there are limited data on the effectiveness of repeated BAV in patients who have previously undergone this treatment [7]. Thus, we sought to investigate the safety and efficacy of repeated BAV in patients with severe symptomatic AS.

## METHODS

We included 35 consecutive patients with severe symptomatic AS [aortic valve area (AVA) <1 $cm^2$, indexed AVA <0.6 $cm^2/m^2$ body surface area] who underwent repeated BAV in three Polish centers experienced in diagnostics and interventional treatment of AS between 2010 and 2019. After carefully considering absolute risk, profits, and planned further treatment, all patients were qualified for the procedure by an interdisciplinary group of specialists (Heart Team). The major contraindication for BAV was a baseline severe aortic regurgitation (AR) determined by transthoracic echocardiography (TTE). The procedure was guided by TTE and

fluoroscopy and the procedural technique of repeated BAV was virtually the same as for the initial intervention. Femoral access was used, starting with a 6F sheath and exchanging to the destination sheath depending on the balloon size. Anticoagulation was achieved with unfractionated heparin with activated clotting time between 250 and 300 seconds. Balloon catheters from Osypka Medical Inc. (Berlin, Germany) were used in most cases. Balloon sizes were chosen based on a minimal annulus diameter measured in TTE or computed tomography (CT) scans, if available. The exact positioning of the balloon during inflation was obtained by rapid ventricular pacing from either the 0.035" ultra-stiff guidewire inserted into the left ventricle or the temporary pacemaker inserted into the right ventricle. The number of balloon inflations was left to the operator's discretion. Usually patients underwent re-inflation if no complete balloon expansion nor desired gradient drop was achieved. The balloon was replaced with a larger device if, despite full inflation, wedging at the aortic valve was not achieved, and some movement of the balloon was visible. The procedure was considered successful if a transaortic gradient drop of more than 30% compared to the baseline was observed. Vascular access was closed with manual compression or Angio-Seal (Terumo, Tokyo, Japan) vascular closure device or ProGlide system (Abbott Vascular Inc, Menlo Park, CA, US), depending on the preference of operators and centers. Pre, post-BAV, and follow-up echocardiograms were performed by the same experienced echocardiographers using measurements of AVA (the continuity equation), peak (pAVG) and mean (mAVG) aortic valve gradients, degree of AR and left ventricular ejection fraction (LVEF) were based on Doppler and conventional 2-dimensional echocardiography. The transvalvular aortic gradient was measured just before and after each inflation while verifying the degree of aortic regurgitation.

Selected data were retrieved from retrospective institutional databases from each participating center and combined into a single database. The aforementioned echocardiographic parameters and baseline clinical and procedural data were analyzed. Baseline clinical data included age, gender, anthropometric parameters, comorbidities, dyspnea symptoms, and periprocedural risk assessed with the Logistic EuroScore and Society of Thoracic Surgeons risk score. Description of procedures focused on the number of inflations and balloon catheter size. Assessment of periprocedural complications included frequency of cardiac arrest, bleedings (pericardial, access site), ischemic stroke, atrio-ventricular conduction disturbances, and severe aortic regurgitation. During routine clinical follow-ups, data on all-cause mortality and receiving definitive treatment were collected. In addition, changes in the initial treatment strategy were noted.

**Statistical analysis**

Categorical variables are expressed as number of patients (percentages). Continuous variables are expressed as mean with standard deviation (SD) or median with interquartile range (IQR). The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to determine normal distribution. Differences between baseline and follow-up parameters were evaluated with paired Student's t-test or Wilcoxon signed-rank test for continuous variables and with the McNemar's test for categorical (nominal) variables, as appropriate. Differences between patients who died and survived were assessed with the independent samples Student's t-test or Mann-Whitney U test, and Fisher's exact test as appropriate. All tests were 2-tailed, and a *P* value <0.05 was considered statistically significant. All statistical analyses were performed with STATISTICA 13.3 (TIBCO Software Inc., Palo Alto, CA, US).

**RESULTS**

Thirty-five patients with severe symptomatic AS (median age 81.5 years, 57.1% women) who underwent repeated BAV were enrolled. Repeated BAVs constituted 4.4% of all BAV procedures performed during the study period. Data on baseline characteristics and echocardiographic assessment before index BAV are summarized in Table 1. In most patients (85.7%), acute decompensation was the primary reason for the index hospitalization. In 15 (42.9%) patients, BAV was considered a palliative treatment of AS, in 18 (51.4%) a bridge to TAVI, in 1 (2.9%) a bridge to SAVR, and in 1 (2.9%) was performed to alleviate the risk of non-cardiac surgery (Figure 1). The technical details of the procedure are shown in Table 2. BAV resulted in a decrease in pAVG from median 78.0 (60.0–104.5) mm Hg to 46.0 (34.0–70.0) mm Hg and in mAVG from median 47.0 (36.0–64.5) mm Hg to 30.0 (19.0–44.0) mm Hg (*P* <0.001 for both, Figure 2). A reduction of more than 30% in pAVG and mAVG was observed in 27 (77.1%) and 20 (57.1%) of patients, respectively. One access site bleeding and 1 complete heart block was observed (Table 2).

After a median (IQR) of 163.5 (78.0–412.0) days, repeated BAV was performed. In most cases (71.4%), the reason for repeated BAV was the worsening of heart failure symptoms, followed by angina symptoms in 8 (22.9%) patients and syncope in 2 (5.7%) patients. In 19 (54.3%) patients, BAV was considered a palliative treatment of AS, in 14 (40.0%) a bridge to TAVI, in 2 (5.7%) a bridge to SAVR. The median AVA was 0.5 (0.4–0.6) $cm^2$, and the median LVEF was 40.0 (22.5–50.0) %. The number of balloon inflations was comparable between repeated and index BAV. However, the mean balloon catheter size was higher for repeated BAV (Table 2). Repeated BAV resulted in a decrease in pAVG from median (IQR) 73.0 (49.0–

98.5) mm Hg to 45.0 (31.0–67.0) mm Hg ($P$ <0.001, Figure 2). A reduction of more than 30% in pAVG and mAVG was observed in 27 (77.1%) and 22 (62.9%) of patients, respectively. Acute reduction in pAVG and mAVG was comparable between the index and repeated BAV - index BAV vs. re BAV, median (IQR) ΔpAVG 30.0 (18.0–43.0) mm Hg vs. 20.0 (14.0–39.0) mm Hg; $P$ = 0.08; ΔmAVG 17.0 (11.0–27.0) mm Hg vs. 14.0 (7.0–20.0) mm Hg; $P$ = 0.44). The frequency of periprocedural complications was numerically higher for repeated BAV procedures (Table 2). The observed cardiac tamponade resulted in periprocedural death. There were 8 additional deaths during the hospital stay, with overall in-hospital mortality of 25.7%.

The final treatment allocation and outcomes are shown in Figure 1. Five (14.3%) patients underwent TAVI. Additionally, in 5 patients another BAV procedure was performed after a median (IQR) of 405.0 (373.0–687.0) days. Of them, in 3 (60.0%) patients, the reason for repeated BAV was worsening heart failure symptoms, and in 2 (40.0%) angina symptoms. In 4 (80.0%) patients, the procedure was considered the palliative treatment, and in 1 (20.0%) case was related to the need for urgent non-cardiac surgery. One periprocedural death occurred. Finally, during the median (IQR) follow-up of 403.0 (152.0–787.0) days from the index procedure, 28 (80.0%) patients died. No significant differences in baseline clinical characteristics between patients who survived and died at follow-up were found, except for a trend toward lower baseline systolic pulmonary artery pressure in survivors (Table 1). The first BAV resulted in a higher reduction of mAVG (median [IQR] 18.0 [17.5–38.5] mm Hg vs. 16.0 [10.0–24.0] mm Hg) in patients who survived, but with no difference in ΔpAVG (42.0 [28.5–52.0] mm Hg vs. 27.5 [18.0–42.5] mm Hg). No differences in the acute results of reBAV were observed between patients who survived and died at follow-up (median (IQR) ΔmAVG 14.0 (9.5-17.5) mmHg vs. 14.0 (7.5-26.0) mmHg and ΔpAVG 20.0 (20.0-25.0) mmHg vs. 20.5 (13.0-39.5) mmHg). Patients who survived were more likely to be treated with TAVI after repeated (4 (57.1%) vs. 1 (3.7%); $P$ = 0.003).

## DISCUSSION

The major finding of our study is that repeated BAV is feasible and has acceptable periprocedural risk. It may allow the achievement of acute hemodynamic results comparable to those gained during index BAV. However, mortality after repeated procedures remains high due to unfavorable risk profiles or delays in receiving TAVI or SAVR.

Previous studies have confirmed that BAV increased AVA and decreased pAVG and mAVG immediately after the procedure [7–14]. However, this effect lasts 1 month and gradually diminishes at 6–12 months to baseline values [11]. It may result in the recurrence of

AS severity and symptoms over longer time from BAV. On the other hand, this period might be sufficient for bridging to destination therapy (TAVI or SAVR) [10, 11, 14]. Additionally, a recovery in LVEF after BAV is frequently observed and may result in requalification from the palliative treatment to TAVI or SAVR in patients with severe AS. However, in systems with limited access to TAVI, even a period of several months might not be sufficient to receive definitive treatment. Thus, repeated BAV may allow additional time for a final treatment decision in selected patients [7]. Our study has confirmed a significant heterogeneity in clinical presentations and responses to BAV in patients with severe AS. Almost one-fourth of patients scheduled for palliative treatment at index BAV were requalified for bridging to TAVI at repeated BAV. On the other hand, almost half of the patients considered potential candidates for TAVI were requalified for palliative care due to limited response to treatment or additional findings during TAVI-related diagnostic workup. It should be stressed that despite favorable acute results of BAV, long-term mortality remained high, especially in patients in the palliative treatment cohort [8, 14]. What is more, this group of patients belongs to the elderly population with the largest burden of comorbidities. Thus, their expectations about the scope of treatment recommended by the guidelines must be considered when making therapeutic decisions. Importantly, we have previously confirmed a significant rate of non-cardiac deaths (approximately 15%) in those patients, which may be related to multiple comorbidities leading to the denial of definitive treatment in this group [14].

The procedural technique of repeated BAV was virtually the same as for the index procedure. However, operators were more likely to use larger balloon catheters during the repeated BAV. On the other hand, the observed reduction in pAVG and mAVG was comparable for the index and repeated procedure. In contrast, Bordoni et al. reported a lower efficacy in mAVG decrease and AVA increase between the first and second procedures [7]. The rate of periprocedural complications for index BAV was lower than reported in previous studies. It might be related to selection bias, as patients with periprocedural complications during index BAV were less likely to have repeated procedures and to be included in the present study. The risk of complications for repeated BAV was numerically higher than for the index BAV but still acceptable in terms of the findings of the previous studies. An increased risk of vascular complications is mainly related to large arterial sheaths (8–10 F) and concomitant peripheral arterial disease [14]. Also, the temporary pacemaker insertion might contribute to access-site-related complications and/or tamponade. It may be avoided using rapid ventricular pacing from the 0.035” ultra-stiff guidewire inserted into the left ventricle [13] or even with the no-pacing technique of BAV [15]. Interestingly, in the Bordoni et al. [7] study, patients

who experienced a vascular complication during the index BAV appeared somehow at higher risk of repeated complications, possibly in relation to the individual risk profile. Therefore, these patients may deserve particular attention during repeated procedures. In line with the previous studies [7], the incidence of severe acute aortic regurgitation and acute cerebrovascular events for repeated BAV was low. Thus, these observations may confirm the safety of multiple BAVs.

Luckily, increasing the availability of TAVI in Poland [16] may limit the need for BAV, particularly repeated BAV as a bridging strategy. However, BAV may still be considered in patients with severe symptomatic AS before intermediate or high-risk non-cardiac surgery in whom the TAVI and SAVR are unfeasible [4, 17]. On the other hand, Debry et al. [18], confirmed that patients with severe AS managed conservatively before urgent non-cardiac surgery are at high risk of events. However, a systematic invasive strategy using BAV does not significantly improve clinical outcomes. Interestingly, Kojima et al. [19] suggested that TAVI is a viable option even in patients with severe AS and active malignancies. Female gender, high body-mass index, NYHA class III/IV, atrial fibrillation, albumin levels, and cancer metastasis were predictors of mortality. Meanwhile, active cancer without metastasis was not associated with increased mortality rates. Thus, these findings suggest the validity of the TAVI option instead of BAV as a palliative treatment in patients with active malignancies, especially in patients without metastases and life expectancy <1 year due to non-cardiac causes [19]. However, such an approach may not be available in systems with limited access to TAVI [16].

The study is limited by retrospective data collection and small sample size. The proper assessment of possible predictors of mortality at follow-up was not possible. The definition of procedural success may differ from that reported in previous studies. Currently, due to increased access to TAVI, the need for repeated BAV, especially to bridge to TAVI, may be restricted. The procedures were performed in high-volume academic centers; thus, the findings may not apply to other settings.

In conclusion, the acute hemodynamic results of repeated BAV are comparable to those achieved during index BAV. However, repeated BAV may carry an increased risk of periprocedural complications. Mortality after repeated BAV is high due to unfavorable risk profile (palliative treatment) or delay in receiving definitive therapy.

**Article information**

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**Table 1. Baseline characteristics**

| **Variable** | **All (n = 35)** | **Survived (n = 7)** | **Died (n = 28)** | ***P*-value** |
|---|---|---|---|---|
| Age, years, median (IQR) | 81.5 (79.0-91.5) | 79.0 (78.5-80.5) | 82.0 (79.0-90.0) | 0.48 |
| Age ≥80 years, n (%) | 23 (65.7) | 4 (57.1) | 19 (67.9) | 0.67 |
| Female sex, n (%) | 20 (57.1) | 4 (57.1) | 16 (57.1) | 1.00 |
| Height, cm, mean (SD) | 162.1 (10.5) | 166.0 (12.5) | 163.0 (10.5) | 0.88 |
| Weight, kg, mean (SD) | 70.5 (14.3) | 66.7 (15.3) | 75.0 (19.5) | 0.95 |
| Body mass index, kg/m$^2$, mean (SD) | 26.8 (6.8) | 25.0 (9.3) | 28.2 (6.2) | 0.72 |
| Body surface area, m$^2$, mean (SD) | 1.8 (0.2) | 1.7 (0.2) | 1.8 (0.3) | 0.99 |
| Arterial hypertension, n (%) | 32 (91.4) | 7 (100.0) | 25 (89.3) | 0.60 |
| Diabetes mellitus, n (%) | 16 (45.7) | 4 (57.1) | 12 (42.9) | 0.68 |

| | | | | |
|---|---|---|---|---|
| Previous MI, n (%) | 19 (54.3) | 4 (57.1) | 15 (53.6) | 1.00 |
| Previous PCI, n (%) | 19 (54.3) | 5 (71.4) | 14 (50.0) | 0.42 |
| Previous CABG, n (%) | 5 (14.3) | 0 (0.0) | 5 (17.9) | 0.56 |
| eGFR, ml/min/1.73 $m^2$, mean (SD) | 54.8 (13.0) | 56.7 (10.4) | 53.0 (13.2) | 0.16 |
| Atrial fibrillation, n (%) | 18 (51.4) | 2 (28.6) | 16 (57.1) | 0.23 |
| Previous stroke, n (%) | 9 (25.7) | 1 (14.3) | 8 (28.6) | 0.65 |
| Carotid artery stenosis, n (%) | 2 (5.7) | 0 (0.0) | 2 (7.1) | 1.00 |
| Chronic obstructive pulmonary disease, n (%) | 5 (14.3) | 0 (0.0) | 5 (17.9) | 0.56 |
| Pacemaker, n (%) | 9 (25.7) | 1 (14.3) | 8 (28.6) | 0.65 |
| New York Heart Association class, n (%) | | | | 0.14 |
| II | 2 (5.7) | 0 (0.0) | 2 (7.1) | |
| III | 24 (68.6) | 7 (100.0) | 17 (60.7) | |
| IV | 9 (25.7) | 0 (0.0) | 9 (32.1) | |
| Logistic EuroSCORE, mean (SD) | 4.7 (4.4) | 3.0 (0.6) | 4.7 (4.2) | 0.80 |
| STS risk score, mean (SD) | 4.0 (1.8) | 3.7 (0.6) | 4.4 (2.1) | 0.37 |
| Peak AVG, mmHg, mean (SD) | 94.8 (28.9) | 95.3 (31.0) | 96.7 (35.0) | 0.68 |
| Mean AVG, mmHg, mean (SD) | 58.6 (17.8) | 63.7 (22.9) | 59.2 (21.5) | 0.46 |
| Aortic valve area, $cm^2$, median (IQR) | 0.5 (0.5-0.6) | 0.5 (0.4-0.6) | 0.5 (0.4-0.6) | 0.84 |
| Aortic regurgitation, n (%) | | | | 0.68 |
| None/trivial | 10 (28.6) | 1 (14.3) | 9 (32.2) | |
| Mild | 23 (65.7) | 6 (85.7) | 17 (60.7) | |
| Moderate | 2 (5.7) | 0 (0.0) | 2 (7.1) | |
| Severe | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Severe mitral regurgitation, n (%) | 3 (8.6) | 0 (0.0) | 3 (10.7) | 0.60 |

| | | | | |
|---|---|---|---|---|
| LVEF, %, median (IQR) | 49.0 (45.5-50.0) | 47.5 (40.0-55.0) | 42.5 (25.0-50.0) | 0.18 |
| sPAP, mm Hg, mean (SD) | 56.0 (19.0) | 36.7 (22.2) | 52.8 (16.4) | 0.06 |

Abbreviations: AVG, aortic valve gradient; eGFR, estimated glomerular filtration rate; IQR, interquartile range; LVEF, left ventricle ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention; SD, standard deviation; sPAP, systolic pulmonary artery pressure; STS, Society of Thoracic Surgeons

**Table 2. Procedural characteristics**

| Variable | Index BAV (n = 35) | ReBAV #1 (n = 35) | ReBAV #2 (n = 5) | P-value* |
|---|---|---|---|---|
| Wire pacing, n (%) | 7 (20.0) | 5 (14.3) | 1 (20.0) | 0.63 |
| Number of inflations, mean (SD) | 1.7 (0.6) | 1.5 (0.8) | 1.3 (0.5) | 0.33 |
| ≥2 inflations, n (%) | 21 (60.0) | 16 (45.7) | 2 (40.0) | 0.27 |
| Balloon catheter size, mm, mean (SD) | 21.9 (2.0) | 22.5 (1.9) | 23.0 (1.4) | 0.008 |
| Pericardial bleeding, n (%) | | | | — |
| mild | 0 (0.0) | 1 (2.9) | 0 (0.0) | |
| tamponade | 0 (0.0) | 1 (2.9) | 0 (0.0) | |
| Access site bleeding, n (%) | 1 (2.9) | 0 (0.0) | 0 (0.0) | — |
| Complete AV block, n (%) | 1 (2.9) | 1 (2.9) | 0 (0.0) | — |
| Cardiac arrest, n (%) | 0 (0.0) | 1 (2.9) | 0 (0.0) | — |
| Ischemic stroke, n (%) | 0 (0.0) | 1 (2.9) | 0 (0.0) | — |
| Severe aortic regurgitation, n (%) | 1 (2.9) | 2 (5.7) | 1 (20.0) | — |
| Any complication, n (%) | 3 (8.6) | 7 (20.0) | 1 (20.0) | 0.22 |

Abbreviations: AV, atrio-ventricular; BAV, balloon aortic valvuloplasty; SD, standard deviation

* for index BAV vs. repeated BAV #1

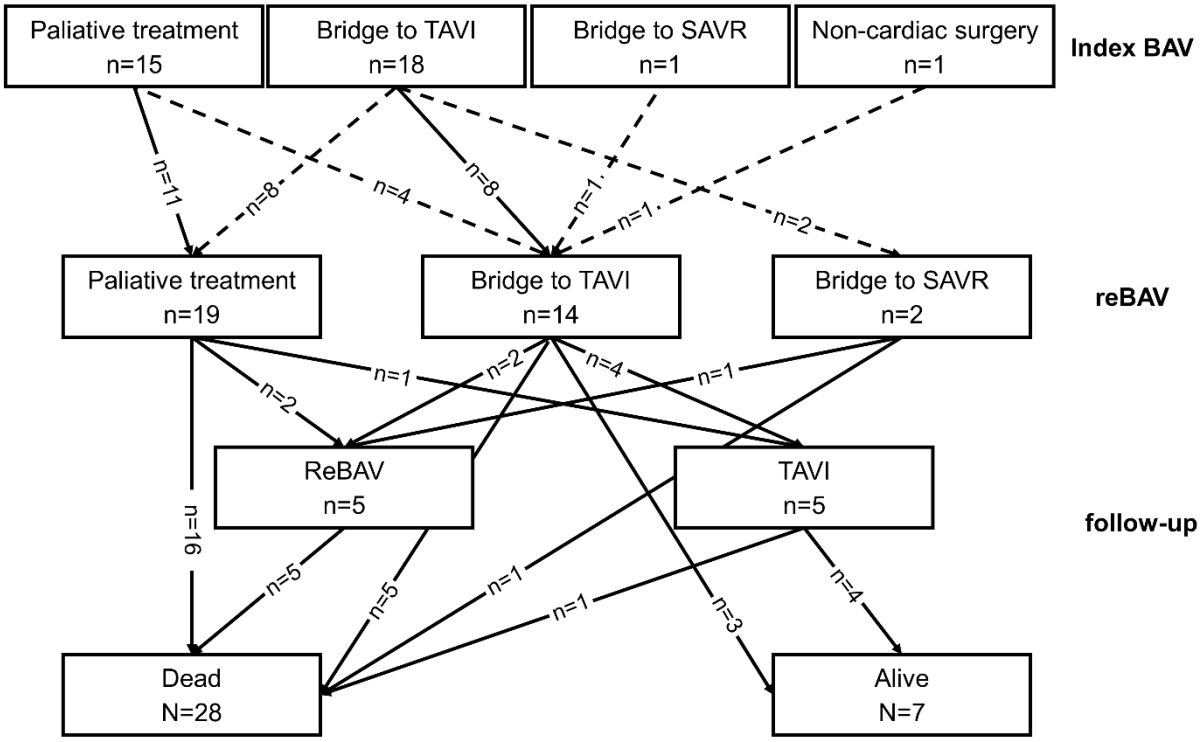


**Figure 1.** Assigned strategies before index and repeated balloon aortic valvuloplasty. Change in the initial treatment strategy marked with a dotted line

Abbreviations: BAV, balloon aortic valvuloplasty; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve replacement

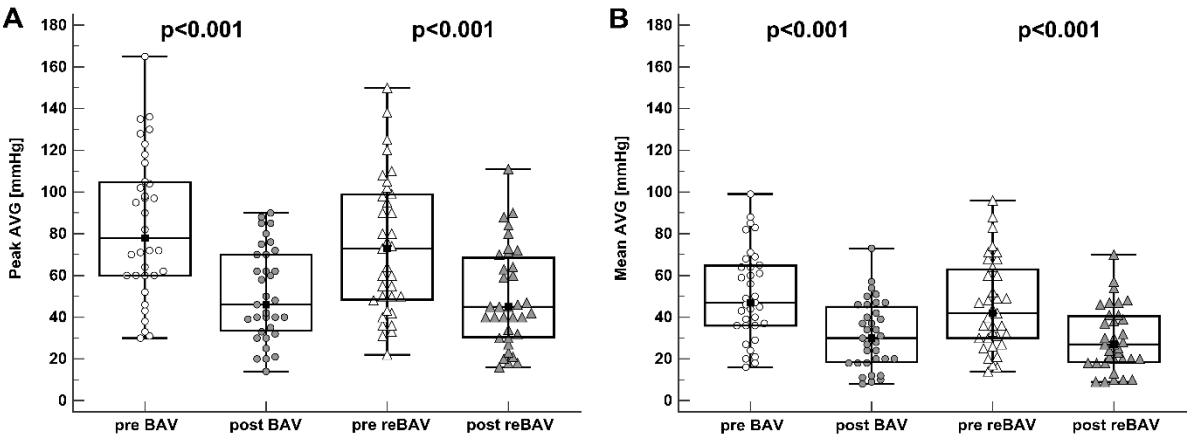


**Figure 2.** Peak (A) and mean (B) aortic valve gradient before and after index and repeated balloon aortic valvuloplasty. Data presented as median (interquartile range)

Abbreviations: AVG, aortic valve gradient; BAV, balloon aortic valvuloplasty