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# Predictive Factors, Efficacy, and Safety of Balloon Post-Dilation After Transcatheter Aortic Valve Implantation With a Balloon-Expandable Valve

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**Objectives** This study sought to evaluate the predictive factors, effects, and safety of balloon post-dilation (BPD) for the treatment of significant paravalvular aortic regurgitation (AR) after transcatheter aortic valve implantation (TAVI).

**Background** Very few data exist on BPD after TAVI with a balloon-expandable valve.

**Methods** A total of 211 patients who underwent TAVI with a balloon-expandable valve were included. BPD was performed after TAVI if paravalvular AR $\geq$2 was identified by transesophageal echocardiography. Clinical events and echocardiographic data were prospectively recorded, and median follow-up was 12 (6 to 24) months.

**Results** BPD was performed in 59 patients (28%), leading to a reduction in at least 1 degree of AR in 71% of patients, with residual AR $<$2 in 54% of the patients. The predictors of the need for BPD were the degree of valve calcification and transfemoral approach, with valve calcification volume $>$2,200 and $>$3,800 $mm^3$ best determining the need for and a poor response to BPD, respectively. Patients who underwent BPD had a higher incidence of cerebrovascular events at 30 days (11.9% vs. 2.0%, p = 0.006), with most (83%) events within the 24 h after the procedure occurring in patients who had BPD. No significant changes in valve area or AR degree were observed at follow-up in BPD and no-BPD groups.

**Conclusions** BPD was needed in about one-fourth of the patients undergoing TAVI with a balloon-expandable valve and was successful in about one-half of them. A higher degree of valve calcification and transfemoral approach predicted the need for BPD. BPD was not associated with any deleterious effect on valve function at mid-term follow-up, but a higher rate of cerebrovascular events was observed in patients who had BPD. (J Am Coll Cardiol Intv 2012;5:499–512) © 2012 by the American College of Cardiology Foundation

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Transcatheter aortic valve implantation (TAVI) has been associated with excellent hemodynamic results, but residual aortic regurgitation (AR), usually secondary to paravalvular leaks, occurs very frequently (1). Although residual AR after TAVI is usually trivial or mild, moderate or severe AR occurs in about 10% of cases (5% to 17%), and this has been associated with worse acute and mid-term outcomes (2–4). The presence of a severely calcified native aortic valve might prevent the complete sealing of the paravalvular space, and a higher degree of native valve calcification has already been identified as a predictor of moderate to severe residual AR after TAVI (5,6).

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Balloon post-dilation (BPD) has been proposed as an option to reduce the degree of paravalvular AR by obtaining a better expansion of the stent containing the transcatheter valve. In 2 previous studies, BPD was used in about one-fourth of the patients after TAVI with the self-expandable CoreValve system (Medtronic, Inc., Minneapolis, Minnesota), and paravalvular AR was improved in most of the patients (7,8). However, very few data exist on the incidence of BPD after TAVI with a balloon-expandable valve (9), and no data are available on the predictors of the need for and the success of BPD in such cases. Furthermore, it is unknown whether by further stretching the stent prosthesis against the aortic annulus, BPD might be associated with a higher rate of periprocedural TAVI complications, such as cerebral embolism or new conduction disturbances leading to the need for pacemaker implantation. Finally, BPD might be associated with potential damage to the valve prosthesis leaflets, leading to more rapid deterioration and structural failure of the transcatheter valve. The purpose of this study, therefore, was to evaluate the incidence and predictors of the need for BPD after TAVI with a balloon-expandable valve and the effects and potential acute and mid-term complications associated with it.

**Abbreviations and Acronyms**

**AR** = aortic regurgitation
**BPD** = balloon post-dilation
**CI** = confidence interval
**CT** = computed tomography
**MLD** = minimal lumen diameter
**OR** = odds ratio
**ROC** = receiver-operating characteristic
**TAVI** = transcatheter aortic valve implantation
**TEE** = transesophageal echocardiography
**TF** = transfemoral

## Methods

**Study population and TAVI procedures.** A total of 211 patients with severe symptomatic aortic stenosis underwent TAVI with a balloon-expandable valve (Edwards Sapien or Sapien XT, Edwards Lifesciences, Inc., Irvine, California) at our institution. Selection of transfemoral (TF) or transapical approaches was based on the appropriateness of the iliofemoral arteries. All procedures were performed under general anesthesia, and transesophageal echocardiography (TEE) was used in all cases. The size of the valve prosthesis was selected on the basis of aortic annulus measurements obtained by TEE. A 23-mm valve was selected if aortic annulus was between 17 and 21 mm, a 26-mm valve if aortic annulus was between 22 and 25 mm, and a 29-mm valve (only available in the last 6 months of the study period) if aortic annulus was between 25 and 27 mm. A 20-mm valve was implanted in a single patient with an aortic annulus of 17.5 mm. Balloon aortic valvuloplasty was systematically performed before valve implantation. After valve deployment, a careful evaluation of the presence, location (paravalvular, transvalvular), and severity of AR was performed using short- and long-axis TEE views. Semi-quantitative grading of AR was performed using color Doppler imaging according to the number of jets, the jet width in central jets, and the circumferential extent of the jet(s) in paravalvular AR (10,11). AR was classified as follows: 0 = absent, 1 = trace-mild, 2 = mild-to-moderate, 3 = moderate-to-severe, and 4 = severe (10). BPD was systematically performed in cases of significant paravalvular AR defined as AR ≥2. The first BPD was performed with the same balloon of the valve prosthesis and adding 0.5 ml of saline to the total volume used for valve prosthesis deployment. After BPD, the presence and degree of AR was evaluated again by TEE. A second BPD was performed at the discretion of the physician responsible for the procedure if paravalvular AR ≥2 persisted after the first BPD. This second BPD was performed using the same balloon and adding an extra 0.5 ml of saline to the total volume used for the first BPD. The presence, location, and degree of AR were re-evaluated by TEE, but no further post-dilation was performed irrespective of the result obtained with this second BPD. The BPD was considered successful if the degree of residual AR was reduced by at least 1 degree with global residual AR <2. If significant paravalvular AR persisted after BPD and was graded as >2, the implantation of a second valve was considered if valve prosthesis malpositioning (too aortic or ventricular) was suspected as evaluated by TEE. To further evaluate the effects of BPD, the diameter of the valve prosthesis frame was measured before and after each BPD on the mid-esophageal long axis (approximately 120°) of the ascending aorta at 3 different levels perpendicular to stent axis: ventricular level; valve level; and aortic level (Fig. 1). The minimum measurement obtained was considered as the valve prosthesis minimal lumen diameter (MLD). These measurements were performed offline by 2 cardiologists not involved in the procedure and unaware of the clinical data.

Procedural success and periprocedural complications were defined on the basis of the Valve Academic Research Consor-

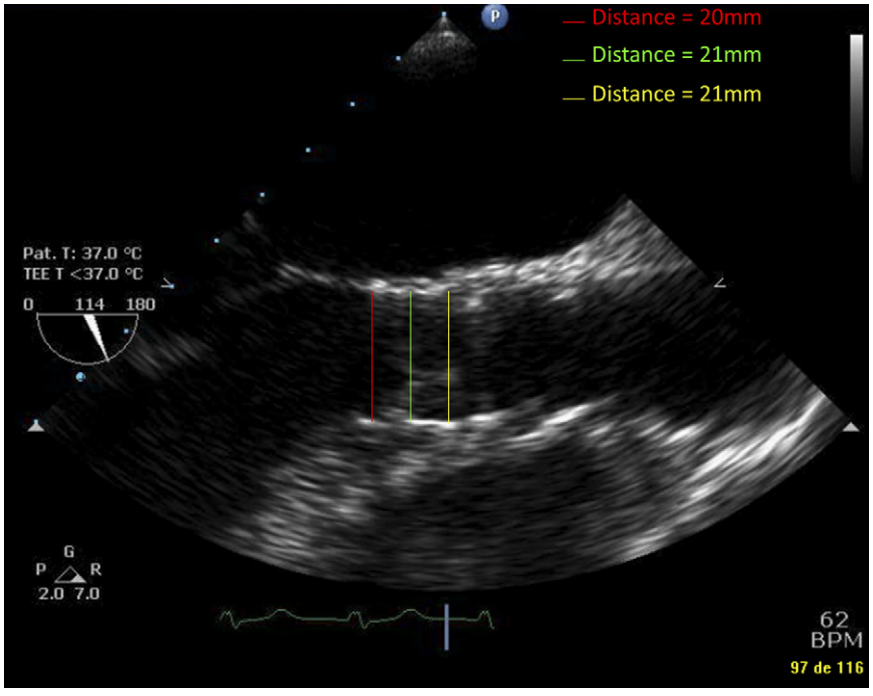


**Figure 1. MLD of the Valve Prosthesis**

Diameter measurements of the valve prosthesis frame (transesophageal echocardiography [TEE] images, long-axis view) at 3 different levels (ventricular, mid, aortic). The smallest measurement was defined as the minimal lumen diameter (MLD) of the valve prosthesis.

tium criteria (12). Cerebrovascular events were further classified as acute (within the 24 h after the procedure or upon awakeness from general anesthesia) or subacute (between 24 h and 30 days after TAVI). Baseline, procedural, and hospitalization data (including all data on BPD) were prospectively collected and entered in a dedicated TAVI database. All procedures were performed under a compassionate clinical use program approved by Health Canada (Ottawa, Ontario, Canada), and all patients provided written informed consent for the procedures.

**Follow-up.** Patients were followed by clinical visits at 1-, 6-, and 12-month follow-ups, and then yearly. The New York Heart Association functional class and clinical events, including the need for reintervention due to structural failure of the valve, were recorded and prospectively entered in the TAVI database. Clinical events were defined on the basis of the Valve Academic Research Consortium definitions. No patient was lost at follow-up and median follow-up was 12 (6 to 24) months.

**Echocardiography evaluation.** Transthoracic echocardiography examinations were systematically performed at baseline, at hospital discharge, at 6 months, and at 1 year. All examinations were analyzed by experienced technicians blinded to clinical data and supervised by a cardiologist at the Echo Core Lab of the Quebec Heart and Lung Institute. Transvalvular gradients and valve effective orifice area measurements were performed after the methods previously described by Clavel et al. (13). The severity of AR was evaluated using the multiparametric approach proposed in the American Society of Echocardiography/European Association of Echocardiography guidelines (10,11).

**Computed tomography: analysis of valve calcification.** A total of 134 patients underwent thoracic computed tomography (CT) without contrast injection before the procedure. The CT images of the aortic valve were analyzed offline in the Cardiac CT Core Lab of the Quebec Heart and Lung Institute by experienced technicians blinded to clinical data and supervised by a cardiologist. Three-dimensional multiplanar reconstruction was performed to examine the aortic valve in-plane (2-mm slice thickness, 2 to 5 slices per valve for full coverage) and precisely measure leaflet calcifications defined as pixels >130 Hounsfield units (TeraRecon, San Mateo, California). Aortic valve leaflet calcium volumes ($mm^3$) were determined using the modified Simpson technique (14).

**Statistical analysis.** Continuous variables are expressed as mean ± SD or median (interquartile range 25th to 75th percentile) depending on variable distribution. Group comparisons were analyzed using Student *t* test or Wilcoxon rank-sum test for continuous variables, and chi-square-test or Fisher exact test for categorical variables. The variables associated with significant AR (≥2) and the need for BPD,

and those associated with successful (vs. unsuccessful) BPD were determined by univariate analysis and those variables with p value <0.05 were entered in a logistic regression analysis to determine the independent predictors of the need for BPD. The univariate normality assumptions were verified with the Shapiro-Wilk tests. Receiver-operating characteristic (ROC) curve analysis was performed to discriminate power of the degree of valve calcification as determined by CT for the need and success of BPD. The maximum sum of sensitivity and specificity was used as the criterion to

**Table 1. Baseline Characteristics of the Study Population (N = 211) According to the Need for BPD**

| Variables | All (N = 211) | BPD | | p Value |
|---|---|---|---|---|
| | | Yes (n = 59) | No (n = 152) | |
| Baseline variables | | | | |
| Age, yrs | 79 ± 8 | 80 ± 8 | 79 ± 8 | 0.891 |
| Male | 86 (40.8) | 30 (50.9) | 56 (36.8) | 0.086 |
| BMI, kg/m$^2$ | 27 ± 5 | 27 ± 6 | 26 ± 5 | 0.213 |
| Diabetes | 77 (36.5) | 21 (35.6) | 56 (36.8) | 0.626 |
| Dyslipidemia | 173 (82.0) | 53 (89.8) | 120 (79.0) | 0.065 |
| Hypertension | 188 (89.1) | 51 (86.4) | 137 (90.1) | 0.464 |
| Chronic atrial fibrillation/flutter | 47 (22.3) | 12 (20.3) | 35 (23.0) | 0.717 |
| Coronary artery disease | 135 (63.9) | 37 (62.7) | 98 (64.5) | 0.873 |
| Prior CABG | 83 (39.3) | 22 (37.3) | 61 (40.1) | 0.755 |
| Cerebrovascular disease | 46 (21.8) | 14 (23.7) | 32 (21.1) | 0.711 |
| Peripheral vascular disease | 79 (37.4) | 22 (37.4) | 57 (37.5) | 1.00 |
| COPD | 62 (29.4) | 17 (28.8) | 45 (29.6) | 1.00 |
| eGFR <60 ml/min | 140 (66.4) | 38 (64.4) | 102 (67.1) | 0.694 |
| Logistic EuroSCORE, % | 24.9 ± 15.2 | 23.6 ± 15.3 | 25.4 ± 15.2 | 0.501 |
| Porcelain aorta | 57 (27.0) | 15 (25.4) | 42 (27.6) | 0.863 |
| Frailty | 38 (18.0) | 12 (20.3) | 26 (17.1) | 0.690 |
| Echocardiography data | | | | |
| LVEF, % | 54 ± 15 | 56 ± 13 | 53 ± 15 | 0.282 |
| Mean aortic gradient, mm Hg | 40 ± 16 | 45 ± 16 | 38 ± 16 | 0.006 |
| Aortic valve area, cm$^2$ | 0.63 ± 0.19 | 0.60 ± 0.15 | 0.64 ± 0.20 | 0.140 |
| Aortic regurgitation | | | | |
| Grade 1 | 65 (30.8) | 16 (27.1) | 49 (32.2) | 0.499 |
| Grade 2 | 80 (37.9) | 26 (44.1) | 54 (35.5) | |
| Grade 3 | 18 (8.5) | 7 (11.9) | 11 (7.2) | |
| Grade 4 | 6 (2.8) | 1 (1.7) | 5 (3.3) | |
| Aortic annulus diameter, mm | 21 ± 2.1 | 21 ± 2.0 | 21 ± 2.2 | 0.212 |
| Mitral regurgitation ≥3 | 53 (25.1) | 13 (22.0) | 40 (26.3) | 0.930 |
| CT data—valve calcification | | | | |
| Calcium aortic valve volume, mm$^3$ | 2,152 (1,343–3,479) | 3,369 (2,250–4,665) | 1,822 (1,260–2,749) | <0.0001 |
| Procedural data | | | | |
| Approach | | | | |
| Transfemoral | 65 (30.8) | 26 (44.1) | 39 (25.7) | 0.013 |
| Transapical | 146 (69.2) | 33 (55.9) | 113 (74.3) | |
| Prosthesis size | | | | |
| 20 mm | 1 (0.5) | 1 (1.7) | 0 | 0.062 |
| 23 mm | 121 (57.6) | 28 (48.3) | 93 (61.2) | |
| 26 mm | 80 (38.1) | 28 (48.3) | 52 (34.2) | |
| 29 mm | 8 (3.8) | 1 (1.7) | 7 (4.6) | |
| Ratio diameter prosthesis size/ diameter aortic annulus | 1.15 (1.12–1.21) | 1.15 (1.09–1.18) | 1.15 (1.13–1.21) | 0.211 |

Values are mean ± SD, n (%), or median (IQR).

BMI = body mass index; BPD = balloon post-dilation; CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; CT = computed tomography; eGFR = estimated glomerular filtration rate; EuroSCORE = European System for Cardiac Operative Risk Evaluation; IQR = interquartile range; LVEF = left ventricular ejection fraction.

identify an optimal cutoff point in the ROC analysis. An analysis of variance for repeated measures was performed to test for equal means at different times (baseline; discharge; and 6, 12, and 24 months) for mean gradient and valve area values, and a 2-way analysis of variance for repeated measures with interaction was used to compare the changes at different time points between groups (BPD vs. no BPD). Mixed effects ordinal regression was performed to test for significant changes in AR over time. Cumulative outcomes at 2-year follow-up were assessed by Kaplan-Meier estimates and compared using the log rank test. The results were considered significant with p values $<0.05$. All analyses were conducted using the statistical package SAS (version 9.2, SAS Institute Inc., Cary, North Carolina).

## Results

The clinical, echocardiographic, and procedural characteristics of the study population are presented in Table 1.

**Effects and predictors of BPD.** Paravalvular AR occurred in 161 patients (76%) immediately after valve prosthesis implantation as evaluated by TEE and was graded as follows: grade 1 (48%), grade 2 (11%), grade 3 (15%), and grade 4 (2%). The location of the AR jet was posterior, anterior, and both anterior and posterior in 71%, 17%, and 18% of the patients, respectively (Fig. 2). In the short-axis view, the AR jet was localized between 9 and 3 o'clock in 79% of the cases (Fig. 2). In patients with AR $\geq$2, the localization of AR jet was posterior, anterior, and both anterior and posterior in 65%, 4%, and 31% of the patients, respectively. In the short-axis view, the AR jet was localized between 9 and 3 o'clock in 84% of the cases. A first BPD was performed in the 59 patients with paravalvular AR $\geq$2 after valve prosthesis implantation and was successful (reduction of $>$1 degree with residual AR $<$2) in 28 patients (47%). Ten of the 31 patients with unsuccessful BPD underwent a second BPD, which was successful in 4 of them. Overall, the grade of the paravalvular leak was reduced by at least 1 grade in 42 patients (71%), remained the same in 15 patients (26%), and deteriorated in 2 patients (3%). BPD was considered successful in 32 patients (54%), and the degree of paravalvular AR after BPD was 0 in 9 patients, grade 1 in 23 patients, grade 2 in 18 patients, grade 3 in 7 patients, and grade 4 in 2 patients (Fig. 3). The circumferential extent of the paravalvular leak measured in the short-axis view was reduced from 16 $\pm$ 10% to 8 $\pm$ 7% (p = 0.001), and the number of paravalvular jets before and after BPD decreased from 1.4 $\pm$ 0.4 to 1.0 $\pm$ 0.6 (p = 0.053) (Fig. 4). A total of 13 patients (22%) had central AR grade 1 after valve prosthesis implantation, and the degree of central AR did

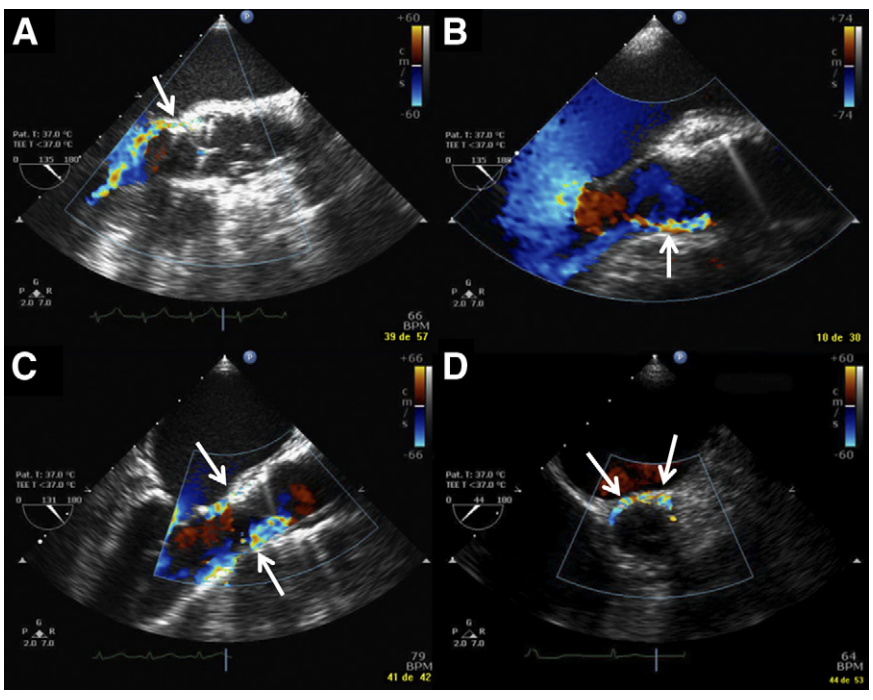


**Figure 2. TEE Images of Paravalvular AR After Valve Implantation**

Examples of paravalvular leak location after valve prosthesis implantation as assessed by procedural TEE in long-axis view (posterior **[A],** anterior **[B],** posterior and anterior **[C]**), and in short-axis view (between 9 and 3 o'clock **[D]**). **White arrows** indicate the location of the paravalvular leak. AR = aortic regurgitation; TEE = transesophageal echocardiography.

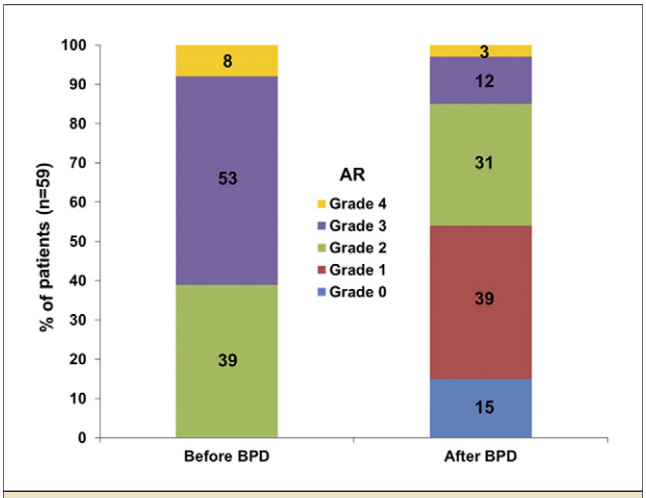


**Figure 3. Paravalvular AR Before and After BPD**

Degree of paravalvular aortic regurgitation (AR) before and after balloon post-dilation (BPD).

not increase in any patient after BPD. After BPD, the stent MLD increased from 19.4 ± 1.9 mm to 21.1 ± 1.8 mm ($p < 0.0001$) (Fig. 5). The mean absolute increase in stent MLD with BPD was 1.76 mm (95% confidence interval [CI]: 1.45 to 2.06 mm, $p < 0.0001$), which represented a mean percent increase of 9.3% (95% CI: 7.6% to 11.1%). The mean absolute increase in stent MLD was higher in those cases with a reduction of at least 1° in paravalvular AR (1.91 mm, 95% CI: 1.59 to 2.24 mm vs. 1.31 mm, 95% CI: 0.55 to 2.06; $p = 0.026$) (Fig. 5).

In 5 patients, valve prosthesis malpositioning was suspected and a second valve was implanted after the first (4 patients) or second BPD (1 patient). Paravalvular AR after valve-in-valve implantation was significantly reduced in all patients, and residual paravalvular AR was grade 1 in 3 patients and grade 2 in 2 patients.

Baseline and procedural characteristics of the patients grouped according to the need for BPD are shown in Table 1. In the multivariable analysis, the independent predictors of BPD after TAVI were a larger volume of calcium (odds ratio [OR] per 500 $mm^3$ increase: 1.26, 95% CI: 1.11 to 1.44, $p = 0.001$) and transfemoral approach (OR: 2.49, 95% CI: 1.03 to 5.97, $p = 0.042$). A calcium volume cutoff of 2,242 $mm^3$ best predicted the need for BPD with a sensitivity of 78% and specificity of 65% (area under the ROC curve: 0.74, 95% CI; 0.65 to 0.84, $p < 0.0001$).

Baseline and procedural characteristics of the patients who needed BPD, grouped according to the response to

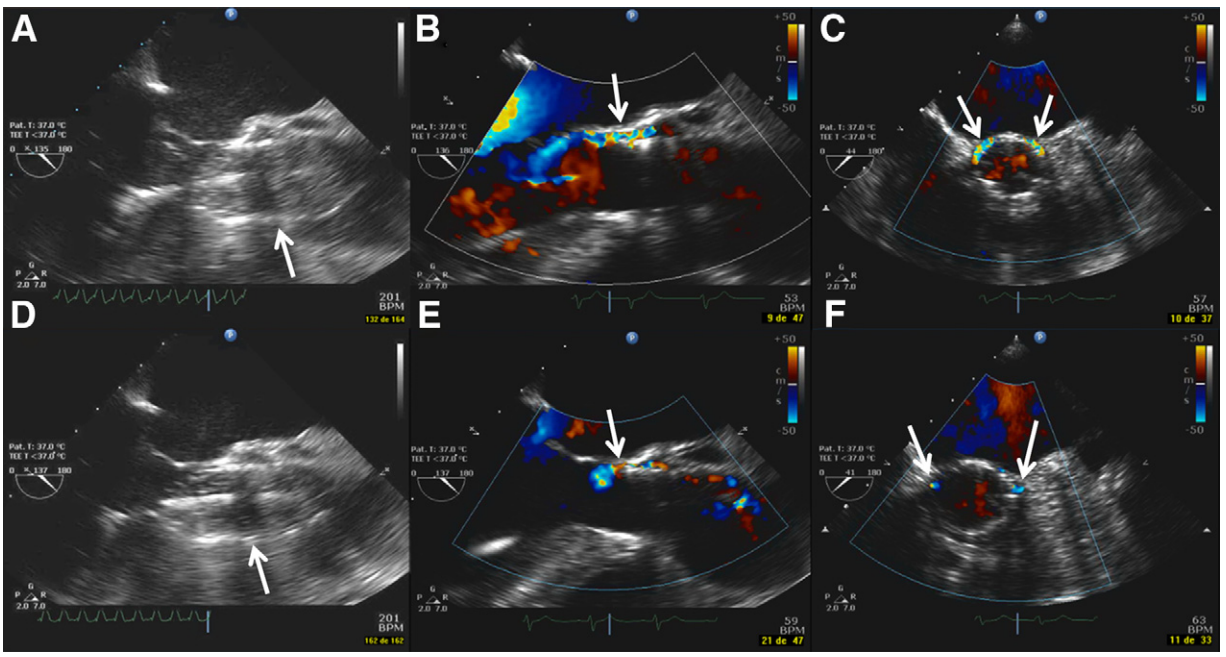


**Figure 4. Successful BPD**

Paravalvular AR as assessed by TEE (long- and short-axis views). **(A)** TEE images (long-axis view) of valve prosthesis implantation. **White arrow** indicates balloon inflation. **(B)** TEE images (long-axis view) immediately after valve implantation. **White arrows** indicate the paravalvular leaks. The degree of AR was evaluated as 2+. **(C)** TEE images (short-axis view) immediately after valve implantation. **White arrows** indicate the paravalvular leaks. **(D)** TEE images (long-axis view) of BPD with a slightly larger balloon (adding 0.5 ml of volume to the balloon used for valve prosthesis implantation). **White arrows** indicate balloon inflation. **(E)** TEE images (long-axis view) immediately after BPD. **White arrows** indicate the paravalvular leaks. Note the reduction of the number and extent of paravalvular leaks. **(F)** TEE images (short-axis view) immediately after BPD. **White arrows** indicate the paravalvular leaks. Note the reduction of the number and extent of paravalvular leaks. Abbreviations as in Figures 1 to 3.

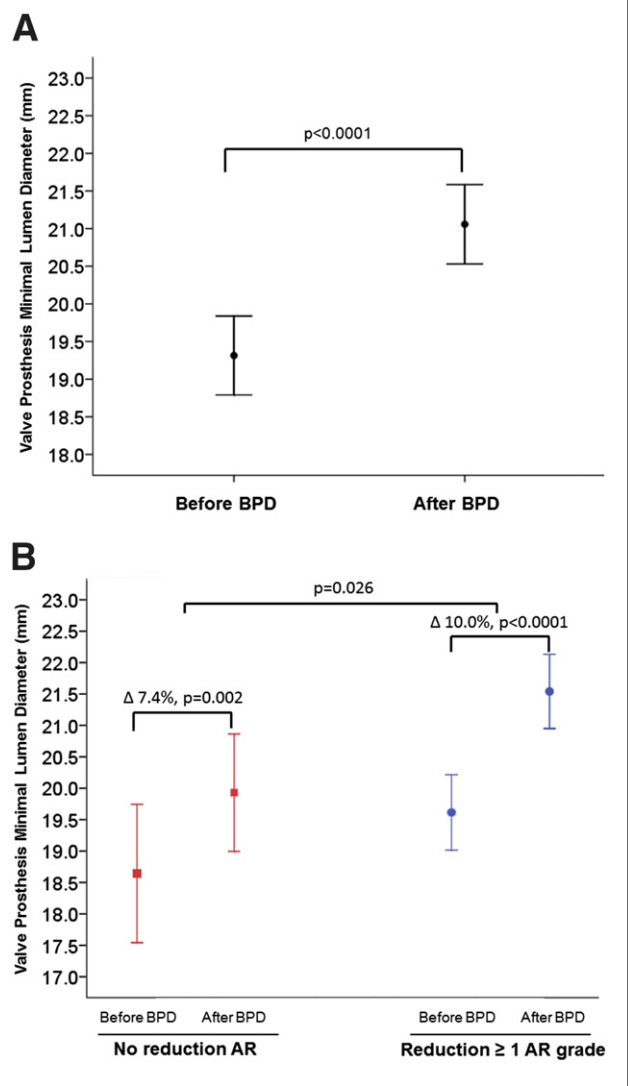


**Figure 5. Valve Prosthesis MLD**

**(A)** Valve prosthesis frame MLD before and after BPD. **(B)** Valve prosthesis frame minimal diameter before and after BPD, according to the decrease of at least 1 degree in AR. Abbreviations as in Figures 1 to 3.

BPD (successful vs. unsuccessful) are shown in Table 2. The degree of valve calcification was the only variable associated with unsuccessful BPD ($p = 0.034$). Valve calcification volume cutoff of 3,874 $mm^3$ best predicted the occurrence of significant AR (≥2) that did not respond to BPD, with a sensitivity of 82% and specificity of 60% (area under the ROC curve: 0.71, 95% CI: 0.54 to 0.88, $p = 0.033$).

**Clinical outcomes.** The 30-day and late outcomes of the study population, grouped according to the need for BPD after valve prosthesis implantation, are shown in Table 3. The need for BPD was associated with a tendency toward a higher rate of new left bundle branch block, but no differences in the rate of new pacemaker implantation were observed between groups. BPD was associated with a higher rate of cerebrovascular events after the procedure (11.9% vs. 2.0%, $p = 0.006$), and these differences were mostly due to a higher incidence of acute (within the first 24 h) cerebrovascular events in the BPD group (8.5% vs. 0.7%, $p = 0.007$), with no differences between groups in the rate of subacute (>24 h) cerebrovascular events (3.4% vs. 1.3%, $p = 0.312$). Baseline and procedural characteristics of the patients, grouped according to the occurrence of cerebrovascular event at 30 days are shown in Table 4. A greater volume of valve calcification ($p = 0.028$) and BPD ($p = 0.006$) were the 2 variables associated with a higher rate of cerebrovascular events at 30 days.

No differences were observed between groups regarding late outcomes (Table 3). The Kaplan-Meier survival curves for the BPD and no-BPD groups are shown in Figure 6. The survival curves depending on the occurrence of AR ≥2 immediately after the procedure are shown in Figure 7.

**Valve hemodynamics.** There were no differences between BPD and no-BPD groups in mean residual gradient and valve area after TAVI (13 ± 6 mm Hg vs. 12 ± 7 mm Hg, $p = 0.156$; 1.45 ± 0.28 $cm^2$ vs. 1.45 ± 0.35 $cm^2$, $p = 0.943$). No significant changes were observed in mean transvalvular gradient and aortic valve area over time in the BPD and no-BPD groups (Fig. 8). The degree of residual AR as evaluated by transthoracic echocardiography at hospital discharge and during the follow-up period in the BPD and no-BPD groups is shown in Figure 8. The BPD group exhibited a higher rate of residual AR ≥2 (36% vs. 8%, $p < 0.001$) at hospital discharge. The degree of residual AR remained stable over time in the 2 groups. No cases of structural failure of the valve occurred during the follow-up period in any of the groups. Changes in left ventricular ejection fraction over time are shown in Figure 9.

## Discussion

About one-fourth of the patients undergoing TAVI with a balloon-expandable valve needed BPD because of paravalvular AR ≥2 immediately after valve prosthesis implantation. BPD was associated with a reduction of AR by at least 1 degree in 71% of the patients and final AR <2 in 54%. A higher degree of valve calcification and transfemoral approach predicted the need for BPD, and the degree of valve calcification also determined its success, with a valve calcium volume cutoff of >3,800 $mm^3$ best determining a poor response to BPD. BPD was associated with a higher rate of cerebrovascular events, with most strokes in patients who had BPD occurring immediately after or within the first 24 h after the TAVI procedure. BPD was not associated with any significant increase in central AR acutely or at follow-up, and no deterioration in valve hemodynamics

**Table 2. Baseline and Procedural Characteristics According to the Success of BPD**

| Variables | Successful BPD | | p Value |
|---|---|---|---|
| | Yes (n = 32) | No (n = 27) | |
| Baseline variables | | | |
| Age, yrs | 80 ± 9 | 80 ± 7 | 0.909 |
| Male | 15 (46.8) | 15 (55.6) | 0.604 |
| BMI, kg/m$^2$ | 28 ± 6 | 27 ± 5 | 0.503 |
| Diabetes | 14 (43.7) | 7 (25.9) | 0.181 |
| Dyslipidemia | 28 (87.5) | 25 (92.6) | 0.678 |
| Hypertension | 29 (90.6) | 22 (81.5) | 0.450 |
| Chronic atrial fibrillation | 8 (25.0) | 4 (14.8) | 0.518 |
| Coronary artery disease | 19 (59.4) | 18 (66.7) | 0.599 |
| Prior CABG | 10 (31.3) | 12 (44.4) | 0.418 |
| Cerebrovascular disease | 8 (25.0) | 6 (22.2) | 1.00 |
| Peripheral vascular disease | 13 (40.6) | 9 (33.3) | 0.599 |
| COPD | 9 (28.1) | 8 (29.6) | 1.00 |
| eGFR <60 ml/min | 20 (62.5) | 18 (66.7) | 0.790 |
| Logistic EuroSCORE, % | 23.7 ± 17.1 | 23.5 ± 13.8 | 0.968 |
| Porcelain aorta | 11 (34.4) | 4 (14.8) | 0.133 |
| Frailty | 6 (18.7) | 6 (22.2) | 0.757 |
| Echocardiography data | | | |
| LVEF, % | 56 ± 14 | 56 ± 11 | 0.952 |
| Mean aortic gradient, mm Hg | 48 ± 16 | 41 ± 15 | 0.072 |
| Aortic valve area, cm$^2$ | 0.59 ± 0.12 | 0.62 ± 0.17 | 0.448 |
| Aortic regurgitation | | | |
| Grade 1 | 9 (28.1) | 7 (25.9) | 0.697 |
| Grade 2 | 16 (50.0) | 10 (37.0) | |
| Grade 3 | 3 (9.4) | 4 (14.8) | |
| Grade 4 | 0 (0) | 1 (3.7) | |
| Aortic annulus diameter, mm | 21 ± 2.0 | 21 ± 2.0 | 0.957 |
| Mitral regurgitation ≥3 | 9 (28.1) | 4 (14.8) | 0.398 |
| CT data—valve calcification | | | |
| Calcium aortic valve volume, mm$^3$ | 2,925 (2,099–3,848) | 4,081 (3,169–5,281) | 0.034 |
| Procedural data | | | |
| Approach | | | |
| Transfemoral | 14 (43.8) | 12 (44.4) | 1.00 |
| Transapical | 18 (56.3) | 15 (56.6) | |
| Prosthesis size | | | |
| 20 mm | 1 (3.1) | 0 (0) | 0.579 |
| 23 mm | 14 (43.7) | 14 (53.8) | |
| 26 mm | 17 (53.1) | 11 (42.3) | |
| 29 mm | 0 (0) | 1 (3.8) | |
| Ratio diameter prosthesis size/diameter aortic annulus | 1.14 (1.09–1.20) | 1.15 (1.11–1.18) | 0.975 |

Values are mean ± SD, n (%), or median (IQR).
Abbreviations as in Table 1.

(valve area, mean gradient) was observed up to 2-year follow-up.

**Frequency and effectiveness of BPD.** Very few data exist on the use of BPD to reduce the degree of paravalvular AR after TAVI. After the implantation of a self-expandable valve, the rate of BPD has been between 10% and 30%, with a reduction in the degree of AR in 60% to 81% of the patients (7,8). However, to date there have been no data on the usefulness of BPD after TAVI with a balloon-expandable valve. The present study shows that BPD was performed in up to 28% of the cases after the implantation of a balloon-expandable Edwards valve due to the occurrence of significant paravalvular AR. In accordance with previous studies with self-expandable valves, the degree of

**Table 3. 30-Day and Late Clinical Outcomes According to BPD**

| | All (N = 211) | BPD | | p Value |
|---|---|---|---|---|
| | | Yes (n = 59) | No (n = 152) | |
| 30-day outcomes | | | | |
| New left bundle branch block* | 55 (40) | 21 (51) | 34 (36) | 0.092 |
| New permanent pacemaker | 17 (8.0) | 5 (8.5) | 12 (7.9) | 0.890 |
| Myocardial infarction | 2 (1.0) | 0 (0) | 2 (1.3) | 1.00 |
| Highest CK-MB levels, μg/l | | | | |
| Transapical approach | 22.1 (16.2–33.2) | 20.6 (17.4–31.2) | 22.6 (16.1–35.8) | 0.641 |
| Transfemoral approach | 9.8 (6.9–14.6) | 8.4 (6.1–13.2) | 10.7 (7.3–17.1) | 0.315 |
| Cerebrovascular event | 10 (4.7) | 7 (11.9) | 3 (2.0) | 0.006 |
| ≤24 h | 6 (2.8) | 5 (8.5) | 1 (0.7) | 0.007 |
| >24 h to 30 days | 4 (1.9) | 2 (3.4) | 2 (1.3) | 0.312 |
| TIA | 1 (0.5) | 1 (1.7) | 0 (0) | 0.279 |
| Stroke | 9 (4.3) | 6 (10.2) | 3 (1.9) | 0.016 |
| Minor | 4 (1.9) | 3 (5.1) | 1 (0.7) | 0.067 |
| Major | 5 (2.4) | 3 (5.1) | 2 (1.3) | 0.135 |
| Death | 20 (9.5) | 6 (10.2) | 14 (9.2) | 0.799 |
| Late outcomes (>30 days) | | | | |
| Months follow-up | 12 (6–24) | 12 (7–24) | 12 (6–23) | 0.608 |
| New permanent pacemaker | 8 (3.8) | 2 (3.4) | 6 (3.9) | 0.849 |
| Myocardial infarction | 1 (0.5) | 0 (0) | 1 (0.7) | 1.00 |
| Cerebrovascular event | 5 (2.4) | 1 (1.9) | 4 (2.7) | 1.00 |
| TIA | 4 (1.9) | 1 (1.9) | 3 (2.0) | 1.00 |
| Stroke | 1 (0.5) | 0 (0) | 1 (0.7) | 1.00 |
| Minor | 0 (0) | 0 (0) | 0 (0) | — |
| Major | 1 (0.5) | 0 (0) | 1 (0.7) | 1.00 |
| Death | 34 (16.2) | 6 (10.2) | 28 (18.5) | 0.152 |
| Death or stroke | 33 (18.3) | 5 (10.9) | 28 (20.9) | 0.184 |
| Cumulative outcomes | | | | |
| New permanent pacemaker | 25 (11.8) | 7 (11.9) | 18 (11.8) | 0.996 |
| Myocardial infarction | 3 (1.4) | 0 (0) | 3 (1.9) | 0.561 |
| Cerebrovascular event | 15 (7.1) | 8 (13.6) | 7 (4.6) | 0.034 |
| TIA | 5 (2.4) | 2 (3.4) | 3 (1.9) | 0.621 |
| Stroke | 10 (4.7) | 6 (10.2) | 4 (2.6) | 0.031 |
| Minor | 4 (1.9) | 3 (5.1) | 1 (0.7) | 0.067 |
| Major | 6 (2.8) | 3 (5.1) | 3 (2.0) | 0.352 |
| Death | 54 (25.7) | 12 (20.3) | 42 (27.8) | 0.296 |
| Death or stroke | 63 (30.0) | 18 (30.5) | 45 (29.8) | 1.00 |

Values are n (%) or median (IQR). *Patients at risk = 136, after excluding 75 patients with previous left bundle branch block or pacemaker.
CK-MB = creatine kinase-myocardial band; TIA = transient ischemic attack; other abbreviations as in Table 1.

AR was reduced by at least 1 degree in 72% of the cases, but the BPD was considered successful (final residual AR <2) in about one-half of the patients. BPD was able to reduce not only the extent of the leaks, but also the total number of leaks in those patients with multiple leaks after TAVI. Interestingly, Takagi et al. (7) used an undersized balloon with respect to the valve prosthesis size for BPD, whereas a slightly oversized balloon (0.5 to 1 ml of additional volume) was used in the present study. This translated into a significant increase in the MLD of the valve prosthesis as measured by TEE in all patients, and a higher degree of lumen diameter increase was associated with a lesser grade of residual paravalvular AR. Importantly, the use of a slightly oversized balloon was not associated with any increase in central AR and there were no cases of aortic annulus rupture.

**Predictors of BPD.** A higher degree of valve calcification and the use of the TF approach were found to be independent predictors of significant AR after TAVI, leading to the need for BPD. The amount of valve calcification has been found to be a predictor of significant AR after TAVI with self-expandable and balloon-expandable valves (5,6). Indeed, Schultz et al. (8) showed that a higher degree of aortic

**Table 4. Baseline Characteristics of the Study Population According to the Occurrence of Cerebrovascular Events at 30 Days**

| Variables | 30-Day Cerebrovascular Event | | p Value |
|---|---|---|---|
| | Yes (n = 10) | No (n = 201) | |
| Baseline variables | | | |
| Age, yrs | 80 ± 4 | 79 ± 8 | 0.865 |
| Male | 6 (60.0) | 80 (40.0) | 0.323 |
| BMI, kg/m$^2$ | 28 ± 6 | 26 ± 5 | 0.441 |
| Diabetes | 6 (60.0) | 71 (35.3) | 0.175 |
| Dyslipidemia | 9 (90.0) | 164 (81.6) | 0.694 |
| Hypertension | 10 (100) | 178 (89.0) | 0.606 |
| Chronic atrial fibrillation/flutter | 1 (10.0) | 46 (22.9) | 0.464 |
| Coronary artery disease | 3 (30.0) | 132 (65.7) | 0.038 |
| Prior CABG | 3 (30.0) | 80 (40.0) | 0.743 |
| Cerebrovascular disease | 3 (30.0) | 43 (21.4) | 0.457 |
| Peripheral vascular disease | 3 (30.0) | 76 (37.8) | 0.747 |
| COPD | 3 (30.0) | 59 (29.4) | 1.00 |
| eGFR <60 ml/min | 8 (80.0) | 132 (65.7) | 0.501 |
| Logistic EuroSCORE | 14.7 ± 11.7 | 25.2 ± 15.2 | 0.126 |
| Porcelain aorta | 5 (50.0) | 52 (25.8) | 0.138 |
| Frailty | 0 (0) | 38 (18.9) | 0.214 |
| Echocardiography data | | | |
| LVEF, % | 57 ± 14 | 54 ± 15 | 0.528 |
| Mean aortic gradient, mm Hg | 49 ± 25 | 40 ± 15 | 0.091 |
| Aortic valve area, cm$^2$ | 0.64 ± 0.20 | 0.63 ± 0.19 | 0.879 |
| Aortic regurgitation | | | 0.465 |
| Grade 1 | 2 (20.0) | 63 (31.3) | 0.428 |
| Grade 2 | 5 (50.0) | 75 (37.3) | |
| Grade 3 | 0 | 18 (8.9) | |
| Grade 4 | 1 (10.0) | 5 (2.5) | |
| Aortic annulus diameter, mm | 21 ± 2.5 | 21 ± 2.1 | 0.409 |
| Mitral regurgitation ≥3 | 3 (30.0) | 50 (24.8) | 0.155 |
| CT data—valve calcification | | | |
| Calcium aortic valve volume, mm$^3$ | 4,080 (3,884–5,085) | 2,121 (1,341–3,369) | 0.028 |
| Procedural data | | | |
| Approach | | | |
| Transfemoral | 2 (20.0) | 63 (31.3) | 0.727 |
| Transapical | 8 (80.0) | 138 (68.7) | |
| Prosthesis size implanted | | | |
| 20 mm | 0 | 1 (0.5) | 0.309 |
| 23 mm | 6 (60.0) | 115 (57.2) | |
| 26 mm | 2 (20.0) | 78 (38.8) | |
| 29 mm | 1 (10.0) | 7 (3.5) | |
| Ratio diameter prosthesis size/diameter aortic annulus | 1.12 (1.08–1.18) | 1.15 (1.12–1.21) | 0.089 |
| BPD | 7 (70.0) | 52 (25.9) | 0.006 |

Values are mean ± SD, n (%), or median (IQR).
Abbreviations as in Table 1.

leaflet calcification determined the need for BPD after the implantation of a self-expandable valve. The present study shows that the degree of valve calcification is also the most important factor determining the need for BPD after the implantation of a balloon-expandable valve. In a step further, it was also shown that the severity of valve calcification was associated not only with the need for but also with the success of BPD, with a calcium leaflet volume cutoff of >3,800 mm$^3$ best determining a nonoptimal result of BPD. A greater amount of valve calcification likely precludes the complete sealing of the paravalvular space, and this seems to be so irrespective of the degree of valve

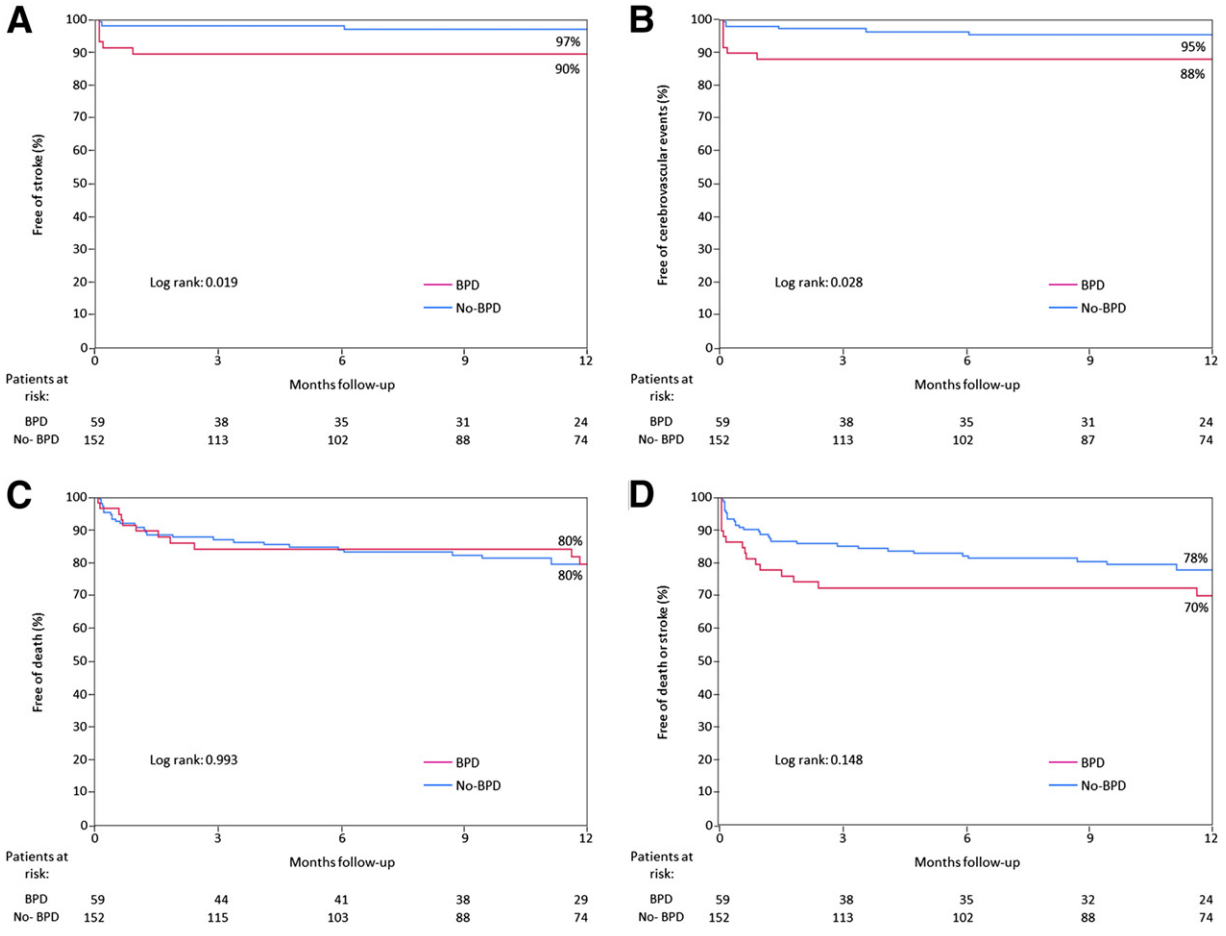


**Figure 6. Kaplan-Meier Survival Curves at 1-Year Follow-Up Depending on BPD After TAVI**

**(A)** Percentage of patients free of stroke. **(B)** Percentage of patients free of cerebrovascular events. **(C)** Percentage of patients free of death. **(D)** Percentage of patients free of stroke or death. BPD = balloon post-dilation; TAVI = transcatheter aortic valve implantation.

oversizing. The confirmation of these results in future studies would add highly clinically relevant information for the evaluation of potential candidates for TAVI. Interestingly, the use of the TF approach was also a predictor for the need of BPD after TAVI. In the TF approach, the position of the valve prosthesis before valve expansion by inflation of the balloon is nearly systematically very eccentric (usually in the outer curve of the ascending aorta), whereas in the transapical approach, the valve can be positioned more centrally and coaxially with respect to the aortic annulus (15). One might wonder if the position of the valve prosthesis before deployment might have an influence into the uniform and complete covering of the aortic annulus after valve implantation. Importantly, the TF approach did not influence the results of BPD after TAVI.

**Safety of BPD.** No studies to date had specifically evaluated the acute and long-term safety of BPD during TAVI procedures. The present study has shown that BPD was not associated with a higher rate of myocardial infarction or pacemaker implantation, though there was a tendency toward a higher rate of new left bundle branch block in patients who had BPD. The use of a slightly larger balloon for BPD might translate into a greater mechanical stress on the ventricular septum and potential damage to the left bundle branch system, and future studies will have to further evaluate the possible relation between BPD and conduction disturbances. BPD was associated with a higher rate of cerebrovascular events after TAVI (up to 11.9%), with most strokes in BPD patients occurring immediately after the procedure. Transcranial Doppler studies have shown that cerebral emboli during TAVI procedures mostly occur during the interaction of the valve prosthesis and the native calcified aortic valve (i.e., valve positioning and implantation), but the effect of BPD was not evaluated in these studies (16,17). The dislodgment of calcific particles from

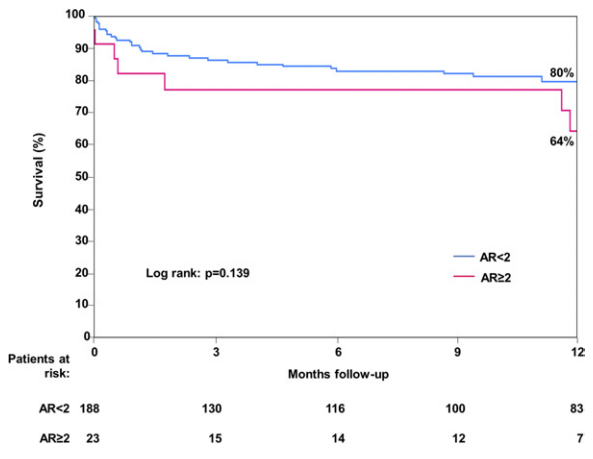


**Figure 7. Survival Curves at 1-Year Follow-Up, According to Residual AR**

Survival curves at 1-year follow-up, depending on the presence of residual AR ≥2 after TAVI (as evaluated by TEE at the end of the procedure). Abbreviations as in Figures 1, 2, and 6.

the native aortic valve might be favored by BPD, especially if we consider that the patients who needed BPD exhibited a higher degree of native valve calcification. In a substudy of the PARTNER (Placement of Aortic Transcatheter Valve) trial, Miller et al. (18) showed that a smaller valve area, which usually correlates with a higher degree of valve calcification (19,20), was the only predictive factor of stroke early after the TAVI procedure. However, no information about the rate of BPD was provided in the PARTNER trial (21). The results of the present study suggest that there is a relation between BPD and acute cerebrovascular events after TAVI, but future studies, including a larger number of patients, will have to determine whether this association is due to the BPD per se, to the amount of valve calcification, or both.

The potential effects of BPD on mid- to long-term valve function were not known. The present study showed that BPD was not associated with any deleterious effect on valve hemodynamics as measured by echocardiography up to 1-year follow-up. Indeed, no patient had a significant increase in central AR during the follow-up period. These results strongly suggest that BPD has no negative effect on valve function at mid-term follow-up, and future studies will have to confirm these results at long-term follow-up.

**Study limitations.** Although TEE images during the TAVI procedures were obtained by experienced operators using a systematic view sequence and a standardized approach, we cannot exclude the possible occurrence of inaccurate estimation of the degree of AR after valve prosthesis implantation. In particular, the fact that TEE images were not validated in an echo core laboratory, the exclusive use of semiquantitative color Doppler parameters to evaluate the degree of AR during the periprocedural period, and to the very short time allocated for interpretation of the images during the procedure might have led to errors in AR grading. However, only 12 patients (7.9%) classified as having an AR <2 by procedural TEE at the end of the procedure had an AR = 2 at hospital discharge as evaluated by multiparametric approach in the Echo Core Lab (agreement in the evaluation of AR degree in 92.1% of the patients). Calcium data were available only in two-thirds of the patients, and this might have led to an underestimation of the importance of this variable on the prediction of BPD and clinical events, such as stroke after TAVI. Also, potential underestimation of the aortic annulus by echocardiography has been suggested by some studies using CT angiography for aortic annulus sizing (1), and despite of the absence of differences in prosthesis/annulus ratio between BDP and no-BPD groups, we cannot

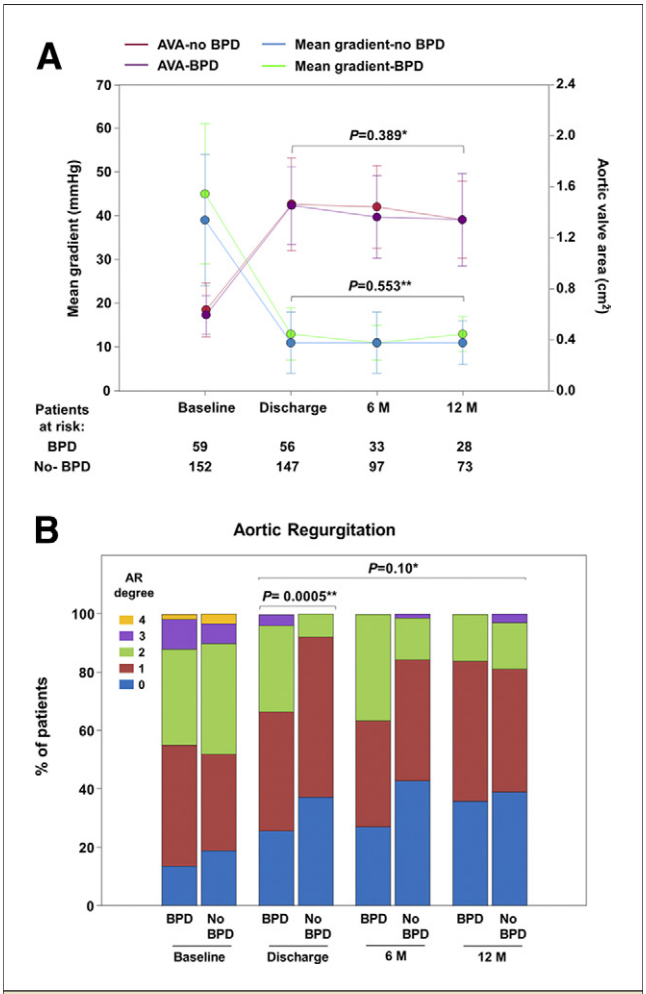


**Figure 8. Valve Hemodynamics During the Follow-Up Period**

(**A**) Mean transvalvular gradients and aortic valve areas over time for BPD and no-BPD groups. *AVA changes over time between BPD and no BPD groups; **mean gradient changes over time between BPD and no BPD groups. **(B)** Proportion of patients with post-procedural AR in BPD and no-BPD groups. No change in the frequency and degree of AR was observed during the follow-up in both groups. *AR changes over time between BPD and no BPD groups; **AR at discharge between BPD and no BPD groups. Abbreviations as in Figures 2 and 3.

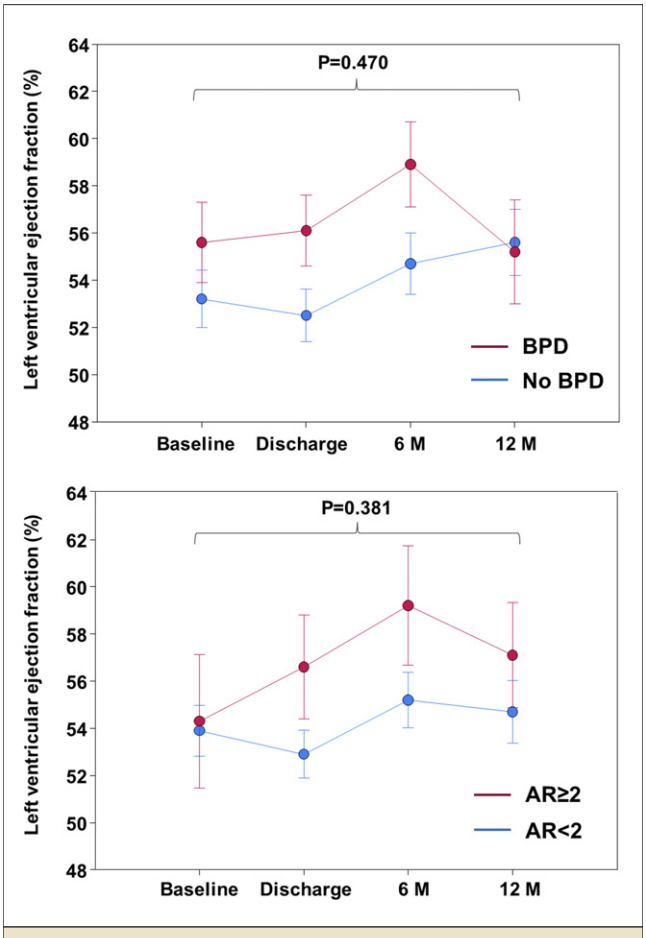


**Figure 9. Changes in LV Function Over Time After TAVI**

**(A)** Left ventricular (LV) ejection fraction changes over time for BPD and no-BPD groups. **(B)** LV ejection fraction changes over time, depending on the presence of residual AR ≥2 at hospital discharge. Abbreviations as in Figures 2, 3, and 6.

exclude a role for valve undersizing in some patients who required BPD. The relatively small number of clinical events after the TAVI procedure precluded performing a multivariate analysis to test the association between BPD and cerebrovascular events. Future studies, including larger number of patients and clinical events will have to further evaluate the association between BPD and stroke.

## Conclusions

BPD with a slightly larger balloon was performed in about one-fourth of the patients after TAVI with a balloon-expandable valve due to the occurrence of significant paravalvular leaks. BPD was associated with some decrease in the extent and/or number of leaks in about two-thirds of the patients, with one-half of them exhibiting no or trivial or mild AR at the end of the procedure. The degree of valve calcification and TF approach were the predictive factors of BPD, and a leaflet calcification volume of >3,800 $mm^3$ best predicted a poor BPD result. Whereas BPD was not associated with any deleterious effect on valve function at mid-term follow-up, a higher incidence of stroke early after the TAVI procedure was observed in those patients undergoing BPD. The results of this study show the very positive hemodynamic effects associated with BPD and strongly suggest that BPD should probably be systematically performed in those patients with significant paravalvular leaks after valve prosthesis implantation. However, the potential safety issue of cerebrovascular events associated with BPD needs to be further evaluated in larger studies in the future. The use of embolic protection devices might be of particular importance in such cases to prevent the beneficial effects of BPD being offset by a higher rate of cerebral embolism.

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**Key Words:** balloon post-dilation ■ stroke ■ transapical ■ transcatheter aortic valve implantation ■ transcatheter aortic valve replacement ■ transfemoral.