JACC: CARDIOVASCULAR INTERVENTIONS VOL. ■, NO. ■, 2018

PUBLISHED BY ELSEVIER

The Effect of Post-Dilatation on Outcomes in the PARTNER 2 SAPIEN 3 Registry

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ABSTRACT

OBJECTIVES The purpose of this study was to understand the effects of balloon post-dilatation on outcomes following transcatheter aortic valve replacement with the SAPIEN 3 valve.

BACKGROUND Hemodynamics and outcomes with balloon post-dilatation for the SAPIEN 3 valve have not been previously reported.

METHODS The effects of balloon post-dilatation (BPD) in 1,661 intermediate (S3i cohort) and high surgical risk (S3HR cohort) patients with aortic stenosis enrolled in the PARTNER (Placement of Aortic Transcatheter Valves) II, SAPIEN 3 observational study on outcomes, as well as procedural complications, were assessed.

RESULTS 208 of 1,661 patients (12.5%) had BPD during the initial transcatheter aortic valve replacement. Baseline characteristics were similar except BPD had higher STS score ($p < 0.001$), significantly less % oversizing ($p = 0.004$), significantly more ≥moderate left ventricular outflow tract calcification ($p = 0.005$), and severe annular calcification ($p = 0.006$). BPD patients had no increase in permanent pacemaker, annular rupture, or valve embolization. Following transcatheter aortic valve replacement, BPD patients had significantly larger aortic valve area (1.72 ± 0.41 cm^2 vs. 1.66 ± 0.37 cm^2; $p = 0.04$) with no significant difference in prosthesis-patient mismatch ($p = 0.08$) or transvalvular aortic regurgitation ($p = 0.65$), but significantly more paravalvular regurgitation ($p < 0.01$). There was no significant difference in 30-day or 1-year outcomes of all-cause death ($p = 0.65$ to 0.76) or stroke ($p = 0.28$ to 0.72). However, at 1 year, there was a significantly higher incidence of minor stroke in BPD patients ($p = 0.02$). Adjusting for baseline differences, including calcium burden, minor strokes were no longer significantly different between the BPD and NoBPD groups ($p = 0.21$).

CONCLUSIONS BPD is performed more frequently in patients with lower % oversizing and greater calcium burden. BPD is not associated with procedural complications or an increase in 1-year adverse events of death, rehospitalization, or stroke. (J Am Coll Cardiol Intv 2018;■:■–■) © 2018 by the American College of Cardiology Foundation.

Numerous studies have shown an association between post-procedural paravalvular regurgitation (PVR) and increased late mortality (1–3), generating intense interest in determining predictors or treatment of this complication. Re-ballooning or balloon post-dilatation (BPD) of the transcatheter heart valve (THV) after implantation has been proposed as an effective method to reduce

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ISSN 1936-8798/$36.00 https://doi.org/10.1016/j.jcin.2018.05.035

ABBREVIATIONS AND ACRONYMS

BPD = balloon post-dilatation

CT = computed tomography

EOA = effective orifice area

LV = left ventricular

NoBPD = no balloon post-dilatation

PPM = prosthesis-patient mismatch

PVR = paravalvular regurgitation

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

TTE = transthoracic echocardiography

post-transcatheter aortic valve replacement (TAVR) PVR (4–6). Potential procedural risks of BPD include THV migration or injury, trauma to the conduction system, rupture of the membranous septum or aorta, and cerebrovascular embolism (5–7). We have previously shown that with a first-generation SAPIEN valve (Edwards Lifesciences, Irvine, California), BPD is associated with reduced rates of moderate or severe prosthesis-patient mismatch (PPM) with no evidence for short-term structural deterioration of the balloon-expandable transcatheter valve (8). BPD, however, was associated with a greater incidence of early stroke with no significant association between BPD and mortality, a finding supported by earlier investigations (6). Evaluation of registries (9) and trial data (10) outcomes of BPD with the CoreValve system (Medtronic, Minneapolis, Minnesota) have not shown significant neurological adverse outcomes, but did show significantly greater acute kidney injury (10). In addition, the need for BPD was nearly 2 times that for the first-generation SAPIEN valve (12% for SAPIEN vs. 24% for CoreValve).

The third-generation SAPIEN 3 has a new construct that allows for less oversizing (11), more precise positioning (12), and less PVR (13) than prior iterations. Some of these factors may contribute to greater or lesser usage of BPD as a method for reducing intraprocedural PVR. This study will attempt to characterize the patients receiving BPD with the SAPIEN 3 valve and relate this additional intervention to procedural and long term outcomes.

METHODS

STUDY DESIGN AND PATIENTS. The PARTNER (Placement of Aortic Transcatheter Valves) 2 SAPIEN 3 trial incorporated 2 parallel prospective, multicenter, active treatment cohorts of patients with symptomatic (New York Heart Association functional class II or greater), severe aortic stenosis. The S3HR cohort comprised patients considered to be inoperable or high-risk candidates for surgery, as defined by an STS-PROM (Society of Thoracic Surgeons Predicted Risk of Mortality) score of at least 8% and/or by the determination of a multidisciplinary heart team that included at least 1 cardiac surgeon and 1 interventional cardiologist. The S3i cohort comprised patients who were considered to be intermediate-risk candidates for surgery, as defined by STS-PROM score between 4% and 8% or by determination of a multidisciplinary heart team.

The 30-day and 1-year frequencies of all-cause mortality, cardiovascular mortality, rehospitalization, stroke, major vascular complications, major bleeding, myocardial infarction, acute kidney injury, and need for permanent pacemaker were documented according to Valve Academic Research Consortium-2 endpoint definitions (14). An analysis of neurologic events (major defined as a modified Rankin scale score of $\geq$2, minor as $<$2) was performed at the time of the event and adjudicated retrospectively by the clinical events committee.

TRANSTHORACIC ECHOCARDIOGRAPHIC DATA. Patients underwent transthoracic echocardiography (TTE) at baseline, discharge, 30 days, and 1 year as evaluated by PARTNER II S3 Core Lab Consortium at Québec Heart & Lung Institute (Quebec City, Canada), MedStar Health Research Institute (Hyattsville, Maryland), and Cardiovascular Research Foundation (New York, New York). The process of image reproducibility, analysis, and quality assurance has previously been described (15). Methodology for quantifying chamber size and function was measured using American Society of Echocardiography guidelines for chamber quantification (16). Central, paravalvular, and total aortic regurgitation was measured using an integrative grading scheme (17) as none, trace, mild, moderate, or severe. The effective orifice area (EOA) was indexed to body surface area and derived from

Lifesciences, for which she received no direct compensation. Dr. Weissman has received research grants from Boston Scientific, Edwards, Medtronic, Abbott, and LivaNova; and has had a core lab contract with Edwards Lifesciences, for which he received no direct compensation. Dr. Thourani has been a consultant for Edwards Lifesciences. Dr. Herrmann has received grants to his institution from Edwards Lifesciences, Medtronic, St. Jude Medical, Boston Scientific, Bayer, Corvia, the University of Laval, and Abbott Vascular; and has been a consultant for Edwards Lifesciences. Dr. Webb has been a member of the PARTNER Trial Executive Committee for which he received no direct compensation; and has been a consultant for Edwards Lifesciences. Dr. Leon has been a member of the PARTNER Trial Executive Committee for which he received no direct compensation. Dr. Kodali has been a consultant for Edwards Lifesciences, Merrill Lifesciences, and Claret Medical; has served on the advisory boards of Abbott Vascular, Biotrace Medical, Dura Biotech, Thubrikar Aortic Valve, Duratech, and VS Medtech; and has equity in Thubrikar Aortic Valve, Dura Biotech, and Biotrace Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received February 8, 2018; revised manuscript received May 17, 2018, accepted May 18, 2018.