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STRUCTURAL

Impact of Balloon Post-Dilation on Clinical Outcomes After Transcatheter Aortic Valve Replacement With the Self-Expanding CoreValve Prosthesis

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ABSTRACT

OBJECTIVES The aim of this study was to assess the incidence and clinical impact of balloon post-dilation (BPD) after transcatheter aortic valve replacement (TAVR) with the CoreValve prosthesis (Medtronic Inc., Minneapolis, Minnesota).

BACKGROUND BPD is a widely adopted strategy to reduce the degree of paraprosthetic regurgitation in case of transcatheter heart valve underexpansion. However, controversies still remain regarding its real effectiveness and safety.

METHODS The ClinicalService (a nation-based data repository and medical care project) dataset was analyzed. All patients were dichotomized according to the need for BPD during the index procedure.

RESULTS Among 1,376 patients, BPD of the transcatheter heart valve was performed in 272 (19.8%). In 37% of cases, it was unsuccessful at reducing the paravalvular regurgitation to mild or less. No case of valve embolization, new intravalvular regurgitation, coronary occlusion, and aortic root injury occurred during BPD. There were no statistically significant differences between the 2 groups in the incidence of in-hospital all-cause and cardiovascular mortality, neurological events, myocardial infarction, bleeding, conversion to open-chest surgery, and the need for a permanent pacemaker. The need for BPD did not emerge as an independent risk factor for all-cause (adjusted hazard ratio [HR]: 1.33, 95% confidence interval [CI]: 0.81 to 2.19, $p = 0.264$) and cardiovascular (adjusted HR: 1.48, 95% CI: 0.74 to 2.97, $p = 0.265$) mortality at 1 year after the procedure. In addition, BPD did not predispose to higher odds of neurological events during 12 months after TAVR (HR: 0.92, 95% CI: 0.45 to 1.88, $p = 0.815$).

CONCLUSIONS This large study showed that BPD after TAVR was safe and not associated with increased rates of cerebrovascular events, mortality, myocardial infarction, and aortic root injury. (J Am Coll Cardiol Intv 2014;7:1014–21)

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Transcatheter aortic valve replacement (TAVR) has matured into a viable treatment alternative for patients with severe aortic stenosis at high-risk of conventional surgical aortic valve replacement (1,2). Although associated with excellent hemodynamic results, residual paravalvular regurgitation (PVR) occurs frequently with this procedure, having been reported in 80% to 96% of TAVR cases (3). Moderate or severe PVR occurs in ~10% to 15% of procedures, and this was observed to produce significantly worse outcomes (2,3).

Balloon post-dilation (BPD) has been shown to be a feasible and effective strategy to reduce significant PVR by enabling better expansion of the stent frame containing the biological valve and thus improved sealing (4). However, this technique is ineffective when PVR is caused by a "too high" or "too low" implantation, and some argue that post-dilation itself may potentially increase the risk of iatrogenic cerebrovascular events (5,6). However, these latter observations come from a few single-center studies with relatively small populations. The aim of this large multicenter analysis was to evaluate the prevalence of BPD after TAVR with a self-expanding prosthesis and its relative impact on clinical outcomes.

METHODS

PATIENT POPULATION. Starting in June 2007, all consecutive patients with severe aortic stenosis undergoing TAVR with the third-generation 18-French CoreValve device (Medtronic Inc., Minneapolis, Minnesota) at 7 Italian centers were prospectively included in the ClinicalService Project. This is a nation-based clinical data repository and medical care project aims to describe and improve the use of implantable devices in clinical practice in Italy. The project was approved by each site's institutional review board or medical director and conforms to the principles outlined in the Declaration of Helsinki. Each patient signed an informed consent for data collection and analysis. Clinical and echocardiographic follow-up were performed according to each center's clinical practice. Eligibility for TAVR was established at each center based on the consensus of a local multidisciplinary team, including clinical cardiologists, cardiac surgeons, and cardiac anesthesiologists. Sizing of the transcatheter heart valve (THV) was carried out by using multidetector computed tomography and an integration of echocardiography (transthoracic and/or transesophageal), angiography and simultaneous aortography during balloon valvuloplasty (7), according to each center's local practice. All the procedures were approved for compassionate use in patients considered at high risk of surgery. Clinical and echocardiographic follow-up were performed at 30 days and 1 year by clinical visits or telephone contacts. All events were site reported. Patients were dichotomized according to the need for BPD after release of the CoreValve prosthesis at the index procedure.

ABBREVIATIONS AND ACRONYMS

BPD = balloon post-dilation
CI = confidence interval
HR = hazard ratio
LBBB = left bundle branch block
PVR = paravalvular regurgitation
TAVR = transcatheter aortic valve replacement
THV = transcatheter heart valve
VASC = Valve Academic Research Consortium

PROCEDURE. Design features of the CoreValve prosthesis and technical details of the procedure were previously described (8–10). The CoreValve prosthesis, available in the 26-mm and 29-mm sizes and, starting September 2011 and August 2012, even in the 31-mm and 23-mm sizes, was implanted using the transfemoral, subclavian, and transaortic approaches with an 18-French delivery catheter, later improved by the use of the AccuTrak Stability Layer (Medtronic Inc.). All procedures were performed with patients under local anesthesia or general anesthesia and endotracheal intubation under fluoroscopic guidance. After prosthesis deployment, BPD was carried out under rapid pacing to reduce significant PVR or to optimize the frame expansion. Indications and technique of BPD were left to operators' practice. Intraprocedural quantification of PVR severity was carried out by using either echocardiography (Valve Academic Research Consortium criteria) or hemodynamic parameters according to the local institutional policies. The degree of PVR was further assessed by a transthoracic echocardiogram performed before discharge.

STATISTICAL ANALYSIS AND DEFINITIONS. Descriptive statistics are reported as mean ± SD for normally distributed continuous variables or as median and 25th to 75th percentile (interquartile range) otherwise. Normality of distribution was tested by means of the Kolmogorov-Smirnov test. Absolute and relative frequencies are reported for categorical variables. Continuous Gaussian variables were compared by means of a Student *t* test for independent samples, whereas skewed distributions

is on the Advisory Board of Medtronic and a consultant for Direct Flow Medical. Drs. Bedogni, Ettori, Bruschi, and Petronio are consultants for Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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