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Underexpansion and Ad Hoc Post-Dilation in Selected Patients Undergoing Balloon-Expandable Transcatheter Aortic Valve Replacement

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Objectives This study sought to assess the clinical outcomes and hemodynamic performance associated with a strategy of underexpanding balloon-expandable transcatheter heart valves (THV) when excessive oversizing is a concern.

Background Transcatheter aortic valve replacement depends on the selection of an optimally sized THV. An undersized THV may lead to paravalvular regurgitation, whereas excessive oversizing may lead to annular injury.

Methods Patients (n = 47) who underwent transcatheter aortic valve replacement with an intentionally underexpanded THV (balloon-filling volume reduced ~10%) were compared with consecutive control patients who had nominal THV balloon deployment (n = 87). Pre- and post-procedural computed tomography imaging and echocardiography were performed to assess THV stent expansion and hemodynamics.

Results Underfilling resulted in THV underexpansion that was maximal at the THV inflow (85.0 ± 7.4% vs. 102.5 ± 6.2%, $p < 0.001$), in study versus control groups, respectively. The study group received larger THV, although annular injury was not observed. Post-dilation was required in 10.6% and 4.6% of patients of the study and control groups, respectively ($p = 0.165$). Echocardiographic THV area, gradient, paravalvular regurgitation, and in-hospital outcomes were similar.

Conclusions Intentionally underexpanding balloon-expandable THV by underfilling the deployment balloon did not adversely affect procedural clinical outcomes, THV gradients, or THV areas. A strategy of underexpansion, with post-dilation as necessary, might play in role in reducing the risk of annular injury and paravalvular regurgitation in selected patients. (J Am Coll Cardiol 2014;63:976–81) © 2014 by the American College of Cardiology Foundation

Transcatheter aortic valve replacement (TAVR) requires an optimally sized transcatheter heart valve (THV). Undersizing may result in paravalvular regurgitation (PVR) or device migration, whereas excessive oversizing may result in atrioventricular block, coronary obstruction, peri-aortic hematoma, mitral valve injury, septal rupture, or root rupture (1,2).

Computed tomography (CT) imaging can help optimize balloon-expandable THV size selection and reduce PVR (1,3). However, balloon-expandable valves are currently only available in a limited number of sizes. Patients with "borderline" annular dimensions, where the annular dimensions support transitioning from a smaller to a larger valve, represent a particular challenge. For example, when transitioning from a 23-mm to a 26-mm THV, the implant diameter increases by 3 mm or 13%, perimeter by 9.42 mm or 13%, and cross-sectional area by 1.15 cm^2 or 28%.

Routine balloon-expandable deployment results in THV inflow diameters slightly below the stated nominal THV

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diameter (1,3). In vitro analysis shows that reducing balloon-fill volumes by ~10% results in only minor hemodynamic functional changes. We hypothesized that using a strategy of underexpansion with ad hoc post-dilation as necessary when selecting a THV that would result in annular area oversizing >20% (or >10% with adverse root features) might reduce the risk of annular injury without increasing the rate of significant PVR.

Abbreviations and Acronyms

CT = computed tomography
PVR = paravalvular regurgitation
TAVR = transcatheter aortic valve replacement
THV = transcatheter heart valve

Methods

Forty-seven consecutive patients with severe aortic stenosis who underwent TAVR with an intentionally underexpanded Sapien type THV (Edwards Lifesciences Inc., Irvine, California) at St. Paul's Hospital, Vancouver, Canada, and Aarhus University Hospital, Aarhus, Denmark, were included in this prospective study. For comparison, a historical cohort of 87 consecutive patients who had undergone balloon-expandable TAVR with nominally filled deployment balloons at St. Paul's Hospital (control group) was identified. All patients underwent pre- and post-procedure CT and echocardiographic imaging (Online Appendix).

The manufacturer's recommended nominal filling volume of the deployment balloons for the 20-, 23-, 26-, and 29-mm Sapien XT were 11, 17, 22, and 33 ml for the NovaFlex delivery system (Edwards Lifesciences) and (no Ascendra 20-mm system is available), 16, 20, and 30 ml for the Ascendra delivery system (Edwards Lifesciences). Our strategy was to underexpand THV when transitioning from a smaller to a larger implant by underfilling the deployment balloon ~10%. Consequently, at the discretion of the operator, 20-, 23-, 26-, and 29-mm balloons were underfilled up to 1, 2, 3, and 4 ml, respectively (Fig. 1).

The study cohort then was divided in 3 subgroups (Groups A, B, and C) according to the percentage of volume reduction from the THV balloon (Fig. 1). Criteria for intentional balloon underfilling were >20% area oversizing as determined from pre-procedural CT or >10% area oversizing with adverse root features (left ventricular outflow tract calcification, shallow sinuses of Valsalva, extreme age, previous chest irradiation, female sex, relatively small body size).

Statistical analysis and definitions. Continuous variables are reported as mean ± SD and categorical variables as percentages. Continuous variables were tested for a normal distribution (QQ plot) and compared by the Student *t* test. For comparison of >2 continuous parametric variables, an analysis of variance was used. Categorical variables were compared by the Fisher exact or chi-square tests. Bonferroni adjustment was used when appropriate. All tests were

	Balloon volume	1 ml underfilled	2 ml underfilled	3 ml underfilled	4 ml underfilled
Novaflex					
20-mm THV	11 ml	-9.1%	-18.2%*	-27.3%*	-36.4%*
23-mm THV	17 ml	-5.9%	-11.8%	-17.6%*	-23.5%*
26-mm THV	22 ml	-4.5%	-9.0%	-13.6%	-18.2%*
29-mm THV	33 ml	-3.0%	-6.1%	-9.1%	-12.1%
Ascendra					
23-mm THV	16 ml	-6.3%	-12.5%	-18.8%*	-25.0%*
26-mm THV	20 ml	-5.0%	-10.0%	-15.0%	-20.0%*
29-mm THV	30 ml	-3.3%	-6.7%	-10.0%	-13.3%
Group A (3-7%)					
Group B (9-10%)					
Group C (11-15%)					

Figure 1 THV Balloon Volumes

Percentages of volume reduction across the different transcatheter heart valves (THV) and delivery systems according to the degree of underfilling. *Not recommended.