JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 9, NO. 15, 2016

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jcin.2016.05.030

TRANSLATIONAL

Valve Type, Size, and Deployment Location Affect Hemodynamics in an In Vitro Valve-in-Valve Model

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ABSTRACT

OBJECTIVES The purpose of this study was to optimize hemodynamic performance of valve-in-valve (VIV) according to transcatheter heart valve (THV) type (balloon vs. self-expandable), size, and deployment positions in an in vitro model.

BACKGROUND VIV transcatheter aortic valve replacement is increasingly used for the treatment of patients with a failing surgical bioprosthesis. However, there is a paucity in understanding the THV hemodynamic performance in this setting.

METHODS VIV transcatheter aortic valve replacement was simulated in a physiologic left heart simulator by deploying a 23-mm SAPIEN, 23-mm CoreValve, and 26-mm CoreValve within a 23-mm Edwards PERIMOUNT surgical bioprosthesis. Each THV was deployed into 5 different positions: normal (inflow of THV was juxtaposed with inflow of surgical bioprosthesis), −3 and −6 mm subannular, and +3 and +6 mm supra-annular. At a heart rate of 70 bpm and cardiac output of 5.0 l/min, mean transvalvular pressure gradients (TVPG), regurgitant fraction (RF), effective orifice area, pinwheeling index, and pullout forces were evaluated and compared between THVs.

RESULTS Although all THV deployments resulted in hemodynamics that would have been consistent with Valve Academic Research Consortium-2 procedure success, we found significant differences between THV type, size, and deployment position. For a SAPIEN valve, hemodynamic performance improved with a supra-annular deployment, with the best performance observed at +6 mm. Compared with a normal position, +6 mm resulted in lower TVPG (9.31 ± 0.22 mm Hg vs. 11.66 ± 0.22 mm Hg; $p < 0.01$), RF (0.95 ± 0.60% vs. 1.27 ± 0.66%; $p < 0.01$), and PI (1.23 ± 0.22% vs. 3.46 ± 0.18%; $p < 0.01$), and higher effective orifice area (1.51 ± 0.08 cm^2 vs. 1.35 ± 0.02 cm^2; $p < 0.01$) at the cost of lower pullout forces (5.54 ± 0.20 N vs. 7.09 ± 0.49 N; $p < 0.01$). For both CoreValve sizes, optimal deployment was observed at the normal position. The 26-mm CoreValve, when compared with the 23-mm CoreValve and 23-mm SAPIEN, had a lower TVPG (7.76 ± 0.14 mm Hg vs. 10.27 ± 0.18 mm Hg vs. 9.31 ± 0.22 mm Hg; $p < 0.01$) and higher effective orifice area (1.66 ± 0.05 cm^2 vs. 1.44 ± 0.05 cm^2 vs. 1.51 ± 0.08 cm^2; $p < 0.01$), RF (4.79 ± 0.67% vs. 1.98 ± 0.36% vs. 0.95 ± 1.68%; $p < 0.01$), PI (29.13 ± 0.22% vs. 6.57 ± 0.14% vs. 1.23 ± 0.22%; $p < 0.01$), and pullout forces (10.65 ± 0.66 N vs. 5.35 ± 0.18 N vs. 5.54 ± 0.20 N; $p < 0.01$).

CONCLUSIONS The optimal deployment location for VIV in a 23 PERIMOUNT surgical bioprosthesis was at a +6 mm supra-annular position for a 23-mm SAPIEN valve and at the normal position for both the 23-mm and 26-mm CoreValves. The 26-mm CoreValve had lower gradients, but higher RF and PI than the 23-mm CoreValve and the 23-mm SAPIEN. In their optimal positions, all valves resulted in hemodynamics consistent with the definitions of Valve Academic Research Consortium-2 procedural success. Long-term studies are needed to understand the clinical impact of these hemodynamic performance differences in patients who undergo VIV transcatheter aortic valve replacement. (J Am Coll Cardiol Intv 2016;9:1618–28) © 2016 by the American College of Cardiology Foundation.

Valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) has emerged as a treatment for high surgical risk patients with failing aortic surgical bioprostheses (1,2). Recently, the Food and Drug Administration has approved both balloon-expandable (SAPIEN XT, Edwards Lifesciences, Irvine, California) and self-expanding (CoreValve, Medtronic, Dublin, Ireland) transcatheter heart valves (THV) for this indication in the United States. Although VIV-TAVR may restore valve function and improve symptoms, adverse events such as increased post-procedural gradients (28.4%), coronary obstruction (3.5%), device malpositioning (15.0%), and valve leaflet thrombosis (4%) have been reported (3–6). A lack of understanding of how VIV deployment location affects THV hemodynamics may explain some of these untoward events.

Current sizing and deployment recommendations are on the basis of reference guides that use valve true internal diameters for THV size selection. As a consequence, commonly used guides, such as the VIV Aortic app (7) and the THV manufacturer's instructions for use (IFU) for deployment in native aortic valves can recommend a different THV size for the same surgical bioprosthesis size (refer to the Online Appendix). At this time, no evidence-based industry sizing or positioning guidelines for VIV-TAVR exist, although it is approved by the U.S. Food and Drug Administration. Furthermore, recent studies suggest that in cases of extreme oversizing of the THV, a supra-annular deployment can result in superior hemodynamics for a balloon-expandable valve in a small bioprosthesis than in the deployment location recommended by the existing guidelines (8–10). In the current study, we investigate whether the drastic effects of supra-annular deployment seen in a small bioprosthesis were still present when there was less prosthesis-patient mismatch. We performed an in vitro study to better understand THV hemodynamics according to valve type, degree of oversizing, and deployment location for balloon- and self-expanding VIV-TAVR.

METHODS

FLOW LOOP. This study was conducted in a validated pulse duplicator (**Figure 1**) that simulates physiologic and pathophysiologic conditions of the heart (11). A noncalcified surgical bioprosthesis was mounted into an idealized rigid acrylic chamber designed to simulate the aortic sinus and ascending aorta (**Figure 2**). The chamber dimensions were based off of published average anatomic measurements (12,13). The aortoventricular angle in the left heart simulator is 0°, which is the standard configuration for in vitro TAVR testing for Food and Drug Administration submissions. The flow rate and the aortic and ventricular pressures were tuned to physiologic levels through a lumped systemic resistance and compliance and measured through a custom data acquisition system. The working fluid was a 3.5-cSt saline-glycerine solution (approximately 36% glycerine by volume in 0.9% NaCl) to match the kinematic viscosity of blood. Further details of the flow loop are provided in our previous publication (8).

VALVE MODELS AND DEPLOYMENT. A 23-mm Edwards PERIMOUNT surgical bioprosthesis was implanted in the in vitro model. This surgical bioprosthesis type and size was chosen because it is the among the most commonly encountered in general practice (14,15). In addition, this surgical valve type and size has multiple recommended THV sizes depending on the guidelines used. For the VIV-TAVR model, THV size selections were on the basis of the recommendations by the VIV app and IFU for deployment in native aortic valves. For the 23-mm Edwards PERIMOUNT, both guidelines recommend a 23-mm SAPIEN valve, but the VIV app recommends a 23-mm CoreValve Evolut and the IFU recommends a 26-mm CoreValve. In the current study, a 23-mm SAPIEN, a 26-mm CoreValve, and a 23-mm CoreValve Evolut were deployed within a 23-mm Edwards PERIMOUNT surgical bioprosthesis in the following 5 positions: normal (0 mm; bottom of the THV stent aligned with the bottom of the surgical bioprosthesis sewing ring, as indicated by the ViV Aortic app); −3 and −6 mm below the normal position; and +3 and +6 mm above the normal position (**Figure 3**).

ABBREVIATIONS AND ACRONYMS

EOA = effective orifice area
GOA = geometric orifice area
IFU = instructions for use
PI = pinwheeling index
PVL = paravalvular leak
RF = regurgitant fraction
TAVR = transcatheter aortic valve replacement
THV = transcatheter heart valve
TVPG = transvalvular pressure gradient
VIV = valve-in-valve

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Manuscript received February 18, 2016; revised manuscript received May 13, 2016, accepted May 16, 2016.