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Overexpansion of the SAPIEN 3 Transcatheter Heart Valve

An Ex Vivo Bench Study

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ABSTRACT

OBJECTIVES This study assessed the effect of overexpansion beyond labeled size (diameter) of transcatheter heart valves through an ex vivo bench study.

BACKGROUND Transcatheter heart valves function optimally when expanded to specific dimensions. However, clinicians may sometimes wish to overexpand balloon-expandable valves to address specific clinical challenges. The implications of overexpansion have assumed considerable importance, and objective information to guide practice is limited.

METHODS We evaluated SAPIEN 3 transcatheter heart valves (Edwards Lifesciences, Irvine, California). Valves (diameters of 23, 26, and 29 mm) were expanded to nominal dimensions, and then incrementally overexpanded with balloons sized 1-, 2-, and 3-mm larger than the recommended diameter. Valves underwent visual, microcomputed tomography, and hydrodynamic evaluation at various degrees of overexpansion.

RESULTS SAPIEN 3 valves with labeled diameters of 23, 26, and 29 mm could be incrementally overexpanded to midvalve diameters of 26.4, 28.4, and 31.2 mm, respectively. With overexpansion, there was visible restriction of the valve leaflets, which was particularly evident with the smaller valves. After maximal overexpansion of a 26-mm valve a leaflet tear was observed. High-speed video demonstrated impaired leaflet motion of both the 23- and 26-mm valves and hydrodynamic testing documented a regurgitant fraction for the 23- and 26-mm valves above accepted international standards. The maximally overexpanded 29-mm SAPIEN 3 still had relatively normal leaflet motion and excellent hydrodynamic function. Durability was not specifically evaluated.

CONCLUSIONS Overexpansion of balloon-expandable valves is possible. However, excessive overexpansion may be associated with impaired hydrodynamic function, acute leaflet failure, and reduced durability. Smaller valves may be at greater risk with overexpansion than larger valves. Overexpansion is best avoided unless clinical circumstances are compelling. (J Am Coll Cardiol Intv 2018;11:1696–705) © 2018 by the American College of Cardiology Foundation.

A number of transcatheter heart valves (THVs) are available for the treatment of severe aortic stenosis, each with distinctly different design features (1). The SAPIEN 3 (S3) valve (Edwards Lifesciences, Irvine, California) is currently the most commonly used THV, with 20-, 23-, 26-, and 29-mm labeled diameters available. The manufacturer recommends deployment of this balloon-expandable

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THV with a specified inflation volume of diluted contrast to achieve the nominal expanded diameter for each size of THV. The manufacturer states that extensive testing has demonstrated that expansion to these exact dimensions allows for optimal valve hydrodynamic function and durability.

However, there are clinical situations where optimal valve function and durability must be balanced against competing concerns, such as annular rupture due to calcification or paravalvular regurgitation due to a THV that is "too small." Clinicians might desire a THV intermediate in size between the nominal diameters available from the manufacturer. To accomplish this end, underfilling or overfilling of the delivery system balloon outside of the manufacturers recommendations is common (2,3). The terms *soft* or *hard* are commonly used. There are also other clinical situations where clinicians may wish to overexpand the THV beyond nominal diameter such as in patients with large annuli or more recently during valve-in-valve transcatheter aortic valve replacement where bioprosthetic valve fracture is also performed (3–7). The consequences of THV overexpansion in the long term remains unknown.

We sought to assess the effects of overexpanding the S3 valve beyond labeled size (diameter) through an ex vivo bench study.

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METHODS

VALVES. The valves tested were a 23-, 26-, and 29-mm S3 THV. The S3 THV is made of a cobalt-chromium alloy frame, bovine pericardial leaflets and an adaptive polyethylene terephthalate fabric seal at the inflow level of the valve. The 23-, 26-, and 29-mm S3 valves have expanded heights of 18, 20, and 22.5 mm, respectively, when fully expanded as per manufacturer specifications (8).

OBJECTIVES. In this study, we assessed if the S3 THV could be successfully overexpanded to varying degrees beyond nominal size (diameter). We also assessed the effect of overexpansion on valve/leaflet integrity and function. The achieved diameter by underfilling and overfilling the valve delivery balloon by approximately 10% compared with nominal volume (ml) was also assessed. Nominal size was defined as the labeled diameter size of the THV as per the manufacturer.

Delivery system. Dilatations were first performed using the transfemoral Edwards Commander delivery system (Edwards Lifesciences) alone without a THV to understand the effect of underfilling or overfilling. The delivery system for each valve size were first deployed with nominal volume (17 ml for the 23-mm, 23 ml for the 26-mm, and 33 ml for the 29-mm THVs) and balloon measurements made using scientific digital calipers at the midpoint of the balloon. This step was repeated 10 times to assess for intraobserver variability, and a mean nominal diameter was calculated. Each delivery system was then under and overfilled by ~10% volume (±1 ml for the 23-mm, ±2 ml for 26-mm, and ±3 ml for 29-mm delivery systems), and balloon measurements were made using calipers. This step was also repeated 10 times and a mean diameter of the delivery balloon diameter recorded for both underfilling and overfilling.

Ex vivo overexpansion. The transfemoral delivery system for each valve size (23, 26, and 29 mm) was used to expand the THV to nominal size (diameter) using the manufacturers recommended nominal filling volume. Overexpansion of the valves was performed in a sequential manner with incremental dilatations of 1 mm up to a maximum of 3 mm above nominal size (i.e., a 23-mm S3 was overexpanded to 24, 25, and 26 mm). True Dilatation balloon valvuloplasty catheters (Bard Vascular, Tempe, Arizona) of various sizes (24, 25, 26, and 28 mm) were used to overexpand the transcatheter heart valves. The True Dilatation balloon is noncompliant allowing high pressure balloon inflation with a consistent balloon diameter. For dilatations where an appropriate sized True Dilatation balloon was not available, a Z-Med II balloon (NuMED, Hopkinton, New York) was used. The Z-Med II is a compliant valvuloplasty balloon, and digital calipers were used to measure the Z-Med balloons to ensure the appropriate balloon diameter was achieved.

Imaging. At nominal size and with each 1 mm of incremental overexpansion, multimodality imaging was performed. High-resolution photography was performed at the same magnification and same fixed camera height. Micro computed tomography (microCT) was performed both at nominal size and for each 1 mm of valve overexpansion. All images were performed using the Nikon XT H 225 ST microfocus X-ray tomography system (Nikon Metrology, Cambridge, Canada) (Figures 1A and 1B).

MEASUREMENTS. Measurements were made using microCT at the inflow, middle, and outflow of the valve (Figure 1B). Inflow of the valve was at the level of the adaptive polyethylene fabric seal. Axial measurements were made using the center of each valve strut as a marker (Figure 1D) to measure diameter (midstrut diameter [MSD]) and area (midstrut valve

ABBREVIATIONS AND ACRONYMS

CT = micro computed tomography

DID = derived inner diameter

DIVA = derived inner valve area

DOD = derived outer diameter

DOVA = derived outer valve area

ISO = International Organization for Standardization

MSD = midstrut diameter

MSVA = midstrut valve area

S3 = SAPIEN 3

THV = transcatheter heart valve