Mitral valve-in-valve hemodynamic performance: An in vitro study

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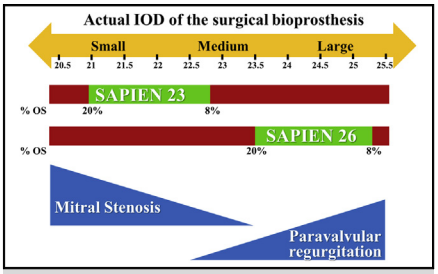
ABSTRACT

Objectives: The valve-in-valve (VinV) procedure may be used in high-risk patients with failed mitral surgical bioprostheses. The objective of this in vitro study was to assess the hemodynamic function of different VinV configurations.

Methods: A double activation duplicator was used to test 11 valve configurations (surgical bioprostheses alone) and 15 VinV configurations (Sapien [Edwards Lifesciences, Irvine, Calif] implanted within the surgical bioprosthesis) under 8 different hemodynamic conditions. The internal orifice diameter (IOD) of the surgical bioprosthesis was measured with a Smartscope (OGP Multi Sensor Measuring Instruments, Singapore).

Results: The VinV procedure was associated with significant deterioration in antegrade hemodynamic parameters compared with valve configuration (effective orifice area, 1.51 ± 0.21 cm^2 vs 1.65 ± 0.37 cm^2; $P < .001$ and regurgitant fraction, $11.5\% \pm 7.2\%$ vs $4.8\% \pm 3.8\%$; $P < .001$). Among the 120 tested experimental VinV situations, moderate or greater mitral stenosis occurred in 52 situations and mild or greater regurgitation occurred in 28 situations. The IOD of the surgical bioprosthesis was the main independent determinant of effective orifice area and regurgitant fraction. An IOD < 22 mm was associated with higher risk of significant mitral stenosis, particularly when the oversizing was >20%, and IOD > 23 mm was associated with higher risk of paravalvular regurgitation when oversizing was <8%.

Conclusions: This in vitro study shows that VinV within mitral surgical bioprostheses provides satisfactory hemodynamic results in the majority of patients. However, significant mitral stenosis is more likely to occur when the IOD of the surgical bioprosthesis is <22 mm, and particularly when the percentage of oversizing is >20%. Significant paravalvular regurgitation is rare and occurs with larger IODs and lower percentage of oversizing (8%). (J Thorac Cardiovasc Surg 2016;151:1051-9)



Decision aids schema for SAPIEN (Edwards Lifesciences, Irvine, Calif) size choice for optimal valve-in-valve assembly hemodynamic results with IOD and percentage of oversizing thresholds for optimal choice of Sapien size for a failed mitral bioprosthesis. For Sapien 23, Sapien 20 could be considered for internal orifice diameter <21 mm and oversized >20% (*red section on the left of the green bar for Sapien 23*). Similarly, Sapien 29 could be considered for internal orifice diameter >25.3 and oversized <8% (*red section on the right of the green bar for Sapien 26*).

Central Message

A small IOD (<22 mm) is associated with higher risk of mitral stenosis, particularly when the percentage of oversizing is >20%.

Perspective

The actual provided IOD and in vitro hemodynamic results of the different VinV assemblies may be useful to select the most appropriate size of Sapien transcatheter heart valve (Edwards Lifesciences, Irvine, Calif) for a given surgical bioprosthesis to optimize the hemodynamic performance of the VinV procedure. Further studies are needed to extend these results to other models and sizes of all currently implanted prostheses.

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The valve-in-valve (VinV) procedure consists of implanting a transcatheter heart valve within another dysfunctional transcatheter or surgical bioprosthetic valve.[1,2] The VinV procedure provides a valuable alternative for patients with a failed surgical bioprosthetic valve who are at high risk for repeated surgery.[3-7] The only approved transcatheter valves allowing VinV procedure in the mitral position are the Sapien or Sapien XT balloon expandable valves

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Abbreviations and Acronyms

%OS = percentage oversizing
AUC = area under the curve
EOA = Effective orifice area
IOA = internal orifice area
IOD = internal orifice diameter
mTPG = mean transvalvular pressure gradient
RF = regurgitant fraction
VinV = valve-in-valve

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(Edwards Lifesciences, Irvine, Calif).[8] The VinV procedure within failed surgical bioprostheses remains an off-label use of transcatheter valves and there is no precise recommendation about which model and size of transcatheter valve should be used for which model of surgical bioprosthesis.

There have been very few in vitro hemodynamic studies of VinV in normal or failed surgical bioprostheses[9-11] and these studies were limited to either Sapien valves deployed within Carpentier-Edwards bioprostheses or home-made transcatheter valves deployed within various surgical bioprostheses.

The objectives of this in vitro study were to assess the hemodynamic performance of the VinV procedure using the Sapien valve within several different types and sizes of surgical mitral bioprostheses and under various hemodynamic conditions; and to determine which factors related to the transcatheter valve, the surgical bioprosthesis, or the hemodynamic conditions have a significant effect on the hemodynamic outcome of the VinV procedure.

METHODS

Experiment Conditions

A double activation pulsed duplicator, previously described by Tanné and colleagues,[12] was used for this study (Figure E1). The fluid used was a water glycerol solution with temperature fixed at 37°C and viscosity fixed at 3.8 ± 2 cP. Eight different hemodynamic conditions (Table 1) were tested for each valve (surgical bioprosthesis is tested alone) and VinV configuration (transcatheter deployed in surgical bioprosthesis) (Table E1) by varying the following parameters: mitral flow volumes (70 or 90 mL), heart rate (45, 70, and 120 bpm), mitral flow profiles (E/A wave velocity ratio of 0.5, 1.0, and 1.5), and mean aortic pressure (40, 100, and 160 mm Hg).

Tested Valve and VinV Configurations

Two main categories of valve and VinV configurations (Table E1) were tested in the mitral position of the pulse duplicator: Surgical bioprostheses alone (valve configuration) and VinV using a Sapien prosthesis deployed within different models and sizes of surgical bioprosthesis (VinV configuration).

Valve configuration. Surgical bioprostheses included 1 model of pericardial bioprostheses (Manufactured by Edwards Lifesciences) and 2 models of porcine bioprostheses (Manufactured by St Jude Medical, St Paul, Minn, and Medtronic Inc, Minneapolis, Minn). Several sizes were tested for each model (Figure E2 and Table E1), leading to 11 valve configurations. The 3 tested models had different designs: Edwards' model had a low straight sewing ring and small struts, the St Jude model had a bombed sewing ring with large strut, and the Medtronic model had a straight high sewing ring and large struts. The 11 surgical valves tested in this study had normal function and had never been implanted. Eighty-eight different valve experimental situations (ie, 11 valve configurations × 8 hemodynamic conditions) were thus performed.

VinV configuration. Cheung and colleagues[13] suggest selecting the Sapien valve size according to the surgical bioprosthesis internal orifice diameter (IOD) provided by the manufacturer and reduced by 10%; that is, the Sapien 23 is implanted in bioprostheses having an IOD < 21.5 mm and the Sapien 26 is implanted in bioprostheses with an IOD between 21.5 and 24.5. In the present study, the actual IOD of the surgical bioprosthesis was measured with a Smartscope (OGP Multi Sensor Measuring Instruments, Singapore) (Table E1, *C*). The size of the Sapien prosthesis was chosen according to the actual IOD: the Sapien 23 was used when the IOD was <22 mm and a Sapien 26 was used when the IOD was between 23 and 25 mm. In cases of IOD between 22 and 23 mm both the Sapien 23 and the Sapien 26 were tested. We also did this additional experiment when there was report in the literature of use of both Sapien sizes for a given model and size of bioprostheses. In total, 15 different VinV configurations were tested (Table E1) and for 4 of them, we tested both Sapien sizes, resulting in 120 VinV experimental situations (15 VinV configurations × 8 hemodynamic conditions). Percentage of oversizing (%OS) was calculated from the nominal orifice area of the Sapien valve when fully deployed (4.15 cm^2 for Sapien 23 and 5.31 cm^2 for Sapien 26) and measured internal orifice area (IOA) of the surgical bioprosthesis: %OS = 100 × [SAPIEN nominal area−IOA]/IOA.

The implantation procedure of the assembly was performed outside of the simulator before introducing it into the pulsed duplicator (Figure E2, *E* and *F*). Positioning of the SAPIEN valve within the surgical bioprosthesis was performed as recommended in Ferrari[14] and Webb and colleagues[7]; that is, the atrial border of the Sapien valve stent was positioned 1 to 2 mm above the sewing ring of the bioprostheses (Figure E2, *F*). Axial positioning was adjusted to align Sapien leaflet junctions with bioprosthesis leaflet junctions for each VinV configuration. Balloon inflation pressure was fixed at 8 bar.

Measurement of Hemodynamic Parameters

The diastolic and systolic flow volumes were measured by an electromagnetic flowmeter (Probe 95 [Carolina Medical, East Bend, NC], internal diameter 30 mm, accuracy ± 2 mL/min) located 5 mm upstream of the mitral valve. From the flowmeter measurements, the closing volume (backflow volume during the closure of the valve), leakage volume (backflow volume when the prosthesis is closed), and total regurgitant volume (sum of closing and leakage volumes) were calculated. The regurgitant fraction (RF) was calculated as RF = 100 × (regurgitant volume/diastolic flow volume).

Pressures were measured in the left atrium, the left ventricle, the pulmonary circulation, and the aorta using 4 pressure catheters (Millar MPR 500 [Millar Sensor System Solution, Houston, Tex]; accuracy range, ±0.5%; −50 to 300 mm Hg). Transprosthetic flow velocity was measured by continuous wave Doppler. Mean transvalvular pressure gradients (mTPGs) were deduced from Doppler measurements. The effective orifice area (EOA) was calculated with the use of the continuity equation method by dividing the diastolic flow volume measured by the flowmeter by the time velocity integral of the transprosthetic flow velocity envelope obtained by Doppler.