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Effect of oversizing and elliptical shape of aortic annulus on transcatheter valve hemodynamics: An in vitro study☆

Erwan Salaun [a,1], Anne-Sophie Zenses [b,c,1], Morgane Evin [b,c], Frédéric Collart [d], Gilbert Habib [a], Philippe Pibarot [e,*], Régis Rieu [b]

[a] AP-HM, Hôpital Timone, Insuffisance Cardiaque et Valvulopathies, Marseille, France
[b] Aix-Marseille Université, CNRS, ISM UMR, 7287, Marseille, France
[c] Protomedlabs, Marseille, France
[d] AP-HM, Hôpital Timone, Chirurgie Cardiaque, Marseille, France
[e] Quebec Heart and Lung Institute, Laval University, Quebec, Canada

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ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) is often performed in patients with non-circular aortic annulus and in oversizing (OS) conditions. The impact of elliptical annulus shape and the consequences of oversizing/underdeployment on the hemodynamic performance are still debated.

Objective: This in-vitro study aims to assess and compare the valve hemodynamic performances of the Edwards SAPIEN transcatheter heart valve (THV) in the different current conditions of use: important oversizing in small circular annuli and in elliptical annuli, moderate oversizing in circular and in elliptical annuli of various degrees of eccentricity.

Methods: A pulsed cardiovascular simulator was used. Edwards SAPIEN 23 and 26 (mm) were implanted in different circular and elliptical annuli of various sizes and eccentricity. Transvalvular mean pressure gradients (TPGm), effective orifice area (EOA) after implantation of Edwards SAPIEN THV were measured by Doppler-echocardiography and the performance index (PI = 100 × EOA / Annulus Area) was calculated. Para and transvalvular regurgitation was assessed by color-Doppler and leakage volume was quantified by flowmeter measurement.

Results: For a given aortic annulus area, EOAs after implantation of Edwards SAPIEN THV were generally larger and TPGms lower with elliptical annuli compared to circular annuli. The PI was higher ($p = 0.047$) for elliptical ($48 \pm 3\%$) than for circular annuli ($43 \pm 5\%$). Paravalvular regurgitation occurred only in the case of the SAPIEN 26 implanted in the elliptical annulus with highest eccentricity.

Conclusion: The results of this in-vitro study suggest that the EOAs of Edwards SAPIEN are better in elliptical than in circular annuli. No transvalvular regurgitation occurred and only one paravalvular regurgitation was observed after implantation of SAPIEN 26 in the highly eccentric annulus.

1. Introduction

Transcatheter aortic valve implantation (TAVI) is currently the treatment of choice in patients with contraindication or/and high-risk for surgery [1,2,3]. The transcatheter heart valve (THV) is often implanted in patients with non-circular aortic annulus and several studies have reported that cross-sectional shape of the prosthesis stent after TAVI is not circular but rather elliptical or irregular [4,5]. Despite the fact that the stent deployment is often non-circular, the hemodynamic performance in terms of effective orifice area (EOA) and transvalvular mean pressure gradient (TPGm) are better than that of surgical bioprostheses [1,3]. However, in vitro study [6], numerical [7] and clinical studies [8] suggest that elliptical shape and eccentricity of the aortic annulus may lead to increased transvalvular and paravalvular regurgitation as well as mechanical stress on the leaflets. Nevertheless the impact of aortic annulus eccentricity on post-procedural regurgitation remains discordant. Indeed, other in vivo studies found no association between annulus index of eccentricity (IE) and the occurrence of paravalvular regurgitation [9,10]. Although THVs are generally used for the treatment of severe stenosis in patients with tricuspid aortic valves, it may also

Abbreviations: d_{mi}, minor axis diameter; d_{ma}, major axis diameter; EOA, effective orifice area; IE, index of eccentricity; OS, oversizing; PI, performance index; SV, stroke volume; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve; TPGm, transvalvular mean pressure gradients; VIV, valve-in-valve.

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

* Corresponding author at: Institut Universitaire de Cardiologie et de Pneumologie de Québec, 2725 Chemin Sainte-Foy, Québec City, Québec G1V-4G5, Canada.
E-mail address: philippe.pibarot@med.ulaval.ca (P. Pibarot).

[1] Both authors equally contributed to this work.

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be used for the treatment of stenosis in patients with bicuspid aortic valves, who often have more eccentric aortic annuli [11]. THV oversizing (OS) is generally used to prevent the risk of paravalvular regurgitation following TAVI. However, the impact of oversizing on valve hemodynamic performance and the hemodynamic consequences of oversizing/underdeployment are not well known. The aim of this in vitro study was to assess the effect of: i) aortic annulus shape, i.e. circular versus elliptical with various degrees of eccentricity and ii) THV oversizing on valve hemodynamic performance of the balloon-expandable Edwards SAPIEN.

2. Methods

2.1. Experimental model

The Edwards SAPIEN aortic valve prostheses of sizes 23 and 26 mm were tested on a previously described mock circulatory system [12]. Briefly, the mock circulatory system is an in-vitro simulation system including anatomically shaped silicone-made left heart cavities and aorta, and simulation of the pulmonary and systemic circulations. Systolic and diastolic phases of cardiac cycle were controlled through hydraulic activation of the left ventricle using a Vivitro piston pump (Vivitro Inc., Victoria, Canada). A gear pump simulated right ventricle ejection in the pulmonary circulation. Additional compliances and resistances were used as equivalent lumped model of both circulations. Both pump activation and signal acquisition were controlled by using LabVIEW 8.2 (National Instruments, Texas, USA) through use of a Compact RIO with FPGA controller and DAQ acquisition system. Controlling enables physiological flow through the aortic valve following the standards for heart valve testing in normal flow conditions (ISO 5840-part 3): stroke volume (SV) was maintained at 70 ml and heart rate was fixed at 70 bpm for a cardiac output of 5 $l \cdot min^{-1}$, mean aortic pressure was set at 100 ± 5 mm Hg. The circulatory fluid was a saline mixture of water (60%) and glycerol (40%) mimicking blood viscosity (4 ± 0.2 cP) and maintained at 37 °C.

2.2. Doppler echocardiographic measurements and studied variables

Doppler echocardiographic measurements were performed using an HDI 5000 (Philips). The 4 MHz probe of this system was applied at the surface of the aorta and oriented to obtain optimal alignment of the Doppler beam with the flow direction across the prosthesis. The transvalvular flow velocities were measured by continuous-wave Doppler. TPGms were calculated from velocity measurements using Bernoulli equation. Transvalvular flow rate was measured using an electromagnetic flowmeter Model 501 (Carolina Medical Electronics Inc., East Bend, USA) positioned immediately below the prosthesis and averaged over 100 cycles. Valve effective orifice area was determined by the continuity equation using the stroke volume measured by electromagnetic flowmeter and the velocity–time integral (VTI) obtained by continuous wave Doppler:

$$EOA = SV/VTI.$$

The performance index was adapted to THV and defined by the ratio EOA/theoretical orifice area, which actually reflects the performance of the THV according to the annulus area available to the Edwards SAPIEN deployment [13]. The performance index (PI) was calculated as follows:

$$PI = 100 \times EOA/Annulus\,Area.$$

CCD camera was used to analyze the opening kinetics of the leaflets.

2.3. Experimental conditions

Aortic annuli of different geometries (circular and elliptical) and different diameters were designed and made of silicon (SYLGARD 184) (Fig. 1). Silicon-made annulus allowed to reproduce annulus of aortic stenosis, whose tissue properties are presumably less compliant than normal aortic valve, and so close to those of a very calcified annulus [14].

The SAPIEN 23 and 26 THVs were deployed in circular aortic annuli of various diameters (18, 20, 21, 22, 23, and 25 mm) in order to test different degrees of THV oversizing (Table 1). The percentage of oversizing (%OS) was calculated using the following formula: $\%OS = 100 \times \frac{A_{THV} - A_{AoA}}{A_{AoA}}$ where A_{THV} is the cross-sectional area of the THV calculated from the label size of the THV (415.5 mm^2 for the SAPIEN 23 and 530.9 mm^2 for the SAPIEN 26) and A_{AoA} is the cross-sectional area of the aortic annulus. Mild oversizing was defined as %OS < 5%, moderate oversizing as %OS between 5 and 20%, moderate-to-severe oversizing as %OS between 21 and 35%, and severe oversizing as %OS ≥ 35% [15,16].

Four elliptical annuli were used for each size of prosthesis (Table 1):

- i) Three "*fixed short axis*" annuli; i.e. a minor diameter(d_{mi}) of 17.6 mm for the SAPIEN 23 and of 19.9 mm for the SAPIEN 26, with an increasing IE (0.17, 0.26, 0.33) that is an increasing major diameter (d_{ma}).
- ii) One "*combined elliptical annulus*"; i.e. with d_{mi} and d_{ma} corresponding respectively to the smallest and largest diameters selected for the circular annuli (d_{mi} = 18 mm and d_{ma} = 22 mm for the SAPIEN 23, and d_{mi} = 21 mm and d_{ma} = 25 mm for the SAPIEN 26), and an area close to that of the circular annulus with intermediate diameter.

The %OS for elliptical annuli was calculated using the same formula as for circular annuli (Table 1). The index of eccentricity was calculated as follows:

$$IE = 1 - d_{mi}/d_{ma}.$$

The THV was crimped onto the dedicated device composed of a balloon catheter specific to each THV size. Deployment of the crimped THV was performed by balloon inflation within the aortic

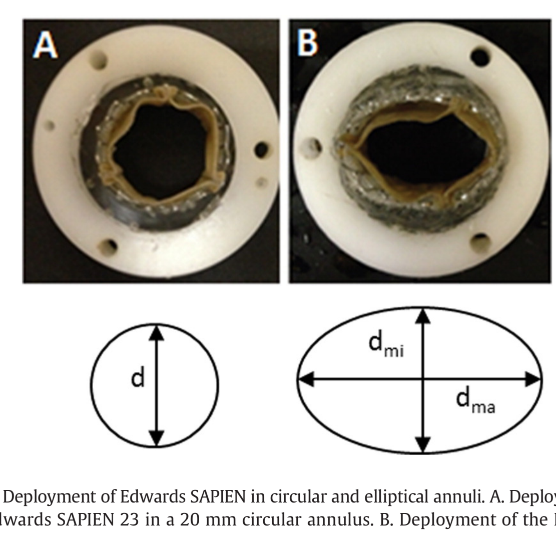

Fig. 1. Deployment of Edwards SAPIEN in circular and elliptical annuli. A. Deployment of the Edwards SAPIEN 23 in a 20 mm circular annulus. B. Deployment of the Edwards SAPIEN 26 in an IE 0.33 elliptical annulus (d_{mi} = 19.9 mm, d_{ma} = 29.9 mm). d = diameter, d_{ma} = major diameter of elliptical annulus, d_{mi} = minor diameter of elliptical annulus, IE = index of eccentricity.