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Hemodynamic and regurgitation after TAVI.

An in-vitro study.

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BACKGROUND - OBJECTIVES

Observations of EDWARDS SAPIEN prosthesis (ED SA) once deployed in vivo, shows a frequent elliptic geometry, which can cause inadequate transvalvular hemodynamic and the occurrence of valvular regurgitation (intra and/or para). This study aims to quantify in vitro, hemodynamic and valvular regurgitation of ED SA in circular and elliptic deployment conditions.

METHODS

A pulsed simulator reproducing human circulations was used. Balloon-expandable Edwards SAPIEN THVs 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) were measured by Doppler-echocardiography and the performance index ($100 \times \text{EOA}/\text{Annulus Area}$) was calculated. Paravalvular and transvalvular regurgitation were assessed by color doppler and leakage volume was quantified by flowmeter measurement.

RESULTS

The highest TVGM were observed for circular annulus 18 and 20 mm, respectively 17.7 and 12.2 mmHg, which was correlated with the lowest EOA (1.27 and 1.44 cm²). We observed a mismatch leaflets-stent for annulus 18 with plicature of leaflets. Hemodynamic parameters and mean PI (48.5 vs 43.2) were better with elliptic geometry than circular. No significant intraprosthesis regurgitation was observed. Just 1 paraprosthetic regurgitation occurred for the ED SA 26 in the elliptic annulus with largest EI (0.33), due to a gap between the stent of ED SA and the annulus.

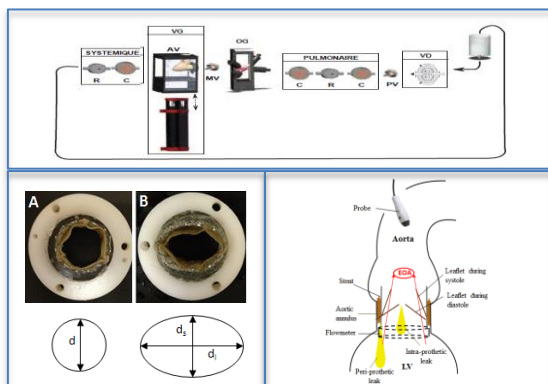


Figure 1. 1 : Pulsed simulator. 2 : ED SA implanted in circular and elliptic annulus. 3 : Study parameters.

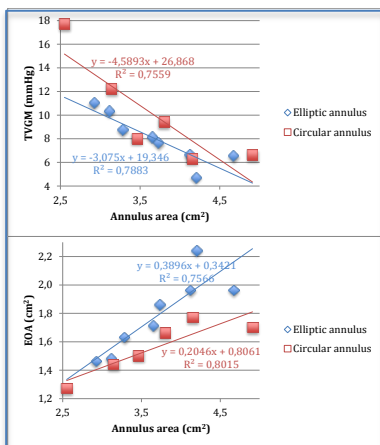
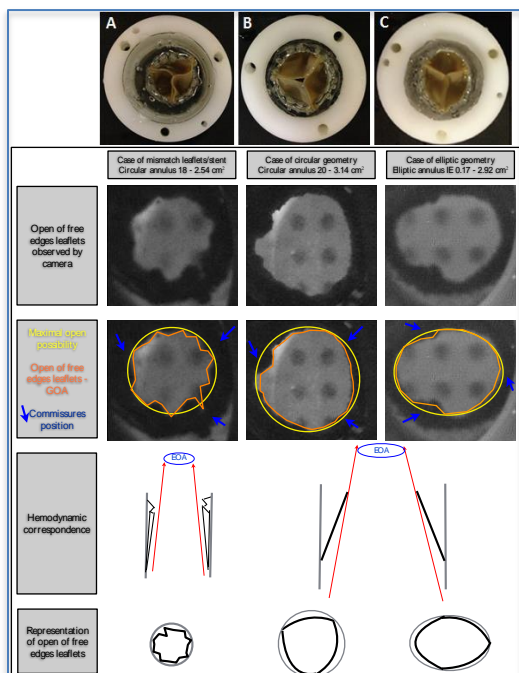


Figure 2. TVGM and EOA for Elliptic and Circular annulus according to annulus area



CONCLUSIONS

Hemodynamic parameters of ED SA obtained in vitro with elliptic geometry appear to be better than with circular. A "leaflets-stent mismatch" can occur in the case of undersizing in annulus with smaller area. No intra-prosthetic regurgitation occurred in circular and elliptic deployment.