Mechanisms and prediction of aortic regurgitation after TAVI

Anna Sonia Petronio*, MD; Cristina Giannini, MD, PhD; Marco De Carlo, MD, PhD

Cardiac Thoracic and Vascular Department, University of Pisa, Pisa, Italy

Abstract

It has been demonstrated that moderate to severe paravalvular leak (PVL) after transcatheter aortic valve implantation (TAVI) procedures are related to impaired long-term prognosis. Anatomical and procedural factors influence the frequency and severity of PVL. Anatomical predictors of this complication are: annulus dimensions and shape, calcium distribution, angle between the ascending aorta axis and the left ventricular outflow tract ($\angle$LVOT-AO). Procedural predictors: prosthesis-size-annulus mismatch, valve depth deployment and the acquired experience of the centre. An effort has to be made to optimise valve sizing and deployment.

Introduction

Since transcatheter aortic valve implantation (TAVI) emerged as an alternative therapy for patients with severe aortic valvular stenosis who are inoperable or high-risk candidates for surgical aortic valve replacement, several technical improvements have been achieved positively affecting clinical results. Nevertheless, there are a few yet important complications of TAVI that have to be resolved in order to warrant wider use of this procedure. Paravalvular leak (PVL) has been frequently described for both types of percutaneous valves currently available, the balloon-expandable Edwards SAPIEN™ (Edwards Lifesciences, Irvine, CA, USA) and the self-expanding CoreValve® (Medtronic, Minneapolis, MN, USA). Paravalvular regurgitation is trivial or mild in the majority of cases, but

moderate to severe PVL is reported in the 15% to 40% range, considerably higher than after surgical aortic valve replacement[1-7].

Moderate to severe PVL can have important consequences on patient safety and long-term outcome, leading to haemodynamic deterioration, left ventricular (LV) remodelling and aortic valve re-intervention. While in the early experience of TAVI few data were reported on the mechanisms and clinical impact of PVL, recently important observations have been published from the PARTNER randomised trial and from the Italian and German TAVI national registries identifying PVL as an independent predictor of late mortality[2,8,9]. We recently presented the results of a study investigating the role of PVL on a wide population of CoreValve recipients from the Italian CoreValve Registry showing a negative impact of moderate/severe PVL at discharge on late mortality, identifying its anatomical and procedural predictors[10].

Multiple mechanisms leading to PVL after TAVI have been recently proposed and can be grouped as anatomical-demographic and procedural **(Table 1)**.

Anatomical-demographic characteristics

The native calcified valve is compressed by the new aortic valve prosthesis against an irregularly shaped aortic annulus and, as opposed to surgery, it is not possible to have its direct measurement and sizing. The different shapes of the aortic annulus and the amount and/or distribution of calcium together with leaflet thickness

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Corresponding author: Head, Cardiac Catheterisation Laboratory, Cardiothoracic and Vascular Department, Ospedale di Cisanello, IT-56124 Pisa, Italy. E-mail: as.petronio@gmail.com

can modify the position and expansion of the stented valves. Some authors demonstrated that the presence of heavy and very eccentric calcifications can lead to underexpansion of the prosthesis, with possible malfunction[7,10]. The two bioprostheses have different behaviours, as the balloon-expandable valve can modify and partially compress the calcium, while the self-expanding valve, which has a supra-annular position of the valve leaflets, will conform its in-flow portion to the annulus shape. Occasionally, in heavily calcified valves, balloon post-dilatation after valve deployment is needed to fully expand the prosthesis and immediately reduce PVL. Post-dilatation can be easily performed, but in some circumstances can cause complications, such as structural damage to the new valve. In addition, the more the shape veers off the circular –and the larger the area – the more the prosthesis fails to completely cover the valve orifice. A large aortic annulus is more common in patients with a large body surface area, and as a consequence it is more easily found in males, which was indicated in some studies as predictive of PVL[1-3,6]. The extreme of all these anatomic features is found in bicuspid aortic valves, which are still considered a relative contraindication to TAVI. Although there are only a few reported cases in the literature, immediate and mid-term results are encouraging in selected patients. Aortic annular diameters, which are too large for currently available transcatheter valves, and the asymmetric distribution of calcification may preclude the full expansion of the prosthesis, increasing the risk of PVL in patients with bicuspid aortic valves. Recently, it has been suggested that the supra-annular position, in particular using the CoreValve prosthesis, may attenuate the impact of the geometric deformation observed at the level of the native aortic annulus[12]. However, data currently available do not allow satisfactory comparisons between the two types of prosthesis in these particular patients.

Another anatomical factor that has been investigated, especially for the CoreValve, is the angle between the axes of the ascending aorta axis and of the LV outflow tract (∠LVOT-AO)[5]. A wider angle, leading to the anatomic configuration referred to as "horizontal aorta", can influence the expansion of the self-expanding stent, decreasing its radial force and interfering with valve expansion and sealing of the stent to the wall. The current recommendations for implantation of the Medtronic CoreValve prosthesis indicate an angle root of up to 70° except for the right subclavian (>30°) which is indicated for more vertical anatomies. In any case a wide angle can negatively affect the alignment of the balloon-expandable prosthesis with the plane of the aortic annulus.

Procedural mechanisms

Related to annulus shape, dimensions and valve calcifications, a procedural factor leading to PVL is the annulus-prosthesis-size mismatch. Previous studies on surgical aortic valve replacement indicated this circumstance as a predictor of paravalvular regurgitation. Regarding TAVI, a Cover Index ([prosthesis diameter - annulus diameter]/prosthesis diameter) ×100) has been proposed, that relates to the severity of PVL[1,3]. To avoid annulus-prosthesis-size mismatch, it is important to measure the annulus size accurately

Table 1. Most common independent predictors of moderate/severe PVL after TAVI reported in literature.

Anatomical-demographic predictors			
Authors	Larger annulus dimension	Asymmetric calcium distribution	Wider ∠LVOT-AO
Detaint[1]	NS	NS	---
Sherif[5]	NS	NS	*
Abdel-Wahab[2]	*	NS	---
Takagi[6]	*	---	---
Gripari[11]	NS	* (between right and non-coronary cusps)	---
Procedural predictors			
Authors	Prosthesis-size-annulus mismatch	Low valve deployment	Acquired experience of the centre
Detaint[1]	*	---	*
Sherif[5]	---	*	---
Abdel-Wahab[2]	---	---	*
Takagi[6]	NS	*	---
Gripari[11]	*	---	---
* significant; NS: not significant; ---: not evaluated			

during the TAVI screening protocol. Until recently, only two valve sizes were available for each TAVI device; the increase in the choice of valve dimensions will certainly reduce the rate of PVL in the near future. However, it seems reasonable for any prosthesis diameter, to slightly oversize the new prosthesis to reduce this complication.

The manoeuvres during prosthesis deployment can also affect PVL. The most important, specific to the CoreValve system, is the depth of deployment[3,5]. While for the balloon-expandable valve the level of deployment is critical to avoid prosthesis migration, for the self-expanding valve a low position can lead to PVL by two mechanisms: (1) the presence of a "secondary" annulus-prosthesis-size mismatch, not related to undersizing of the prosthesis; (2) direct blood passage from the aorta into the left ventricle over the upper limit of the valve skirt when the latter is below the aortic annulus. Some anatomical characteristics can favour low CoreValve deployment, including a large aortic annulus, at the limit of technical TAVI feasibility, a dilated left ventricle with a wide LV outflow tract, and a wide ∠LVOT-AO. Correct valve sizing is crucial, particularly in these circumstances, although recent improvements in the delivery catheter and implantation technique have made deployment more precise. Interestingly, the rates of low implantation and of moderate/severe PVL are lower in high-volume centres[1,2].

Conclusions

Knowledge of the mechanisms of PVL and of its impact on patient outcome warrants a careful evaluation of the anatomy of the ventricle-aortic continuity, as well as precise prosthesis sizing. Moreover, all continuing efforts to improve TAVI technology and techniques are necessary, in order to improve valve deployment and to allow for valve repositioning.

Conflict of interest statement

A.S. Petronio is a Clinical Proctor for Medtronic. C. Giannini and M. De Carlo have no conflicts of interest to declare.

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Online data supplement

Moving image 1. Transoesophageal images showing a heavy aortic valve calcification (A); which influenced the occurrence and location of PVL after TAVI (B).

Moving image 2. Transoesophageal images showing a very deep implantation resulting in a PVL; the covered skirt has been situated below the native annulus, which allows blood to regurgitate through the holes of the uncovered portion of the stent.