

CARDIOVASCULAR SURGERY UPDATE

Next Generation Transcatheter Aortic Valve Systems: the Portico™ Valve

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ABBREVIATIONS

LVOT = left ventricular outflow tract
TAVR = transcatheter aortic valve replacement

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INTRODUCTION

Transcatheter aortic valve replacement (TAVR) is currently considered a valuable alternative for the treatment of severe symptomatic aortic stenosis patients who are inoperable or at excessively high surgical risk.¹ Although TAVR is associated with high success rates and relatively low morbidity and mortality, the incidence of procedural complications, namely paravalvular aortic regurgitation, conduction disturbances, vascular complications, stroke, etc. is higher than surgical aortic valve implantation, which is still considered the “gold standard” treatment. A large number of new bioprostheses is being designed and developed for TAVR in an effort to increase procedural safety and make this relatively novel technology available for low surgical risk patients.

THE PORTICO™ TISSUE VALVE

The Portico™ valve (St. Jude Medical Inc, St Paul, MN, USA) is the first fully re-sheathable and repositionable (until fully deployed) commercially available transcatheter aortic valve (Figure 1).^{2,3} The valve is made of bovine leaflets and porcine pericardial cuff that are treated with the Linx™ anticalcification treatment, which is also used on St. Jude Medical surgical tissue valves (i.e. Trifecta™).⁴ Portico is designed for leaflet coaptation in round and elliptical annulus configurations. For the moment, two sizes are commercially available, 23 mm and 25 mm for aortic annulus dimensions 19-21 mm and 21-23 mm, respectively. Two additional sizes (27 mm and 29 mm) are under clinical evaluation and are expected to become available soon.

PREVENTION OF PARAVALVULAR LEAKS

The Portico valve frame has large cells with less metal and more tissue. This configuration allows for easier access to the coronary ostia after TAVR and, most importantly, it is anticipated to decrease the frequency and the severity of paravalvular aortic regurgitation. The potential of a frame strut resting against a calcific nodule in the annulus section of the frame is minimized and the tissue can conform better around calcific nodules on the native valve leaflets.

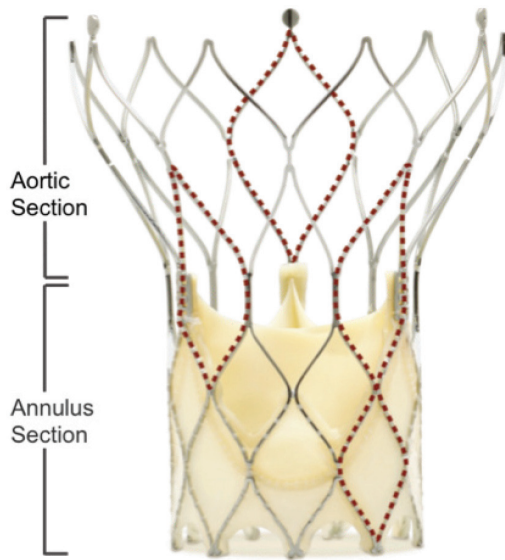


FIGURE 1. The Portico™ transcatheter heart valve. The valve frame has large cells in order to decrease the incidence of para-valvular leaks (by accommodating calcific nodules) and to facilitate access to the coronary ostia.

**NO HEMODYNAMIC INSTABILITY
DURING DEPLOYMENT**

The valve itself is sutured in the lowest part of the frame and is intended to function in an annular position (Figure 2). In fact, the valve leaflets function immediately after deployment of the distal part of the frame. This unique characteristic alleviates accuracy during implantation since there is no change in the patient's blood pressure. Also, there is no "parachute effect" during deployment and practically no need for rapid ventricular pacing.

**THE PORTICO DELIVERY SYSTEM
– LOADING AND RESHEATHING
FEATURES**

The delivery system currently available is designed for transfemoral approach via an 18F sheath. A shorter delivery system for transaortic/transsubclavian access is under clinical evaluation. The valve itself does not need special preparation or cold saline immersing before loading on the delivery system. Loading takes approximately two minutes, facilitating quick valve preparation in case of an emergency. Clockwise rotation of the release wheel is used during valve deployment. If needed, the valve can be fully resheathed by counterclockwise rotation of the wheel, provided that the valve is not fully released (up to 80-85% is acceptable). The time needed for a complete

resheath from 80%-deployment position is approximately 15 seconds. This means that in case of a valve "pop-out", which sometimes occurs with self-expanding devices, the valve can be resheathed and redeployed very fast, increasing patients safety. Also, this feature makes the Portico system user-friendlier in relation to other available TAVR systems. For example, in case of a relatively deep deployment of the distal part of the stent, there is no need to pull on the system; slight resheathing allows for partial valve recapture and deployment can start again at the intended depth.

PREVENTION OF HEART BLOCK

The Portico system has some special features to mitigate atrioventricular conduction block. The annulus section of the valve frame is not flared in order to avoid the trauma on the left ventricular outflow track (LVOT), which has been associated with heart block. In addition, the optimal depth of implantation for Portico is 4 mm below the aortic annulus, which is anticipated to further decrease the occurrence of conduction disturbances (Figure 2). Finally, the valve frame has almost equal radial strength in different degrees of expansion, which means that oversizing does not increase a lot compression of the LVOT, minimizing potential trauma.

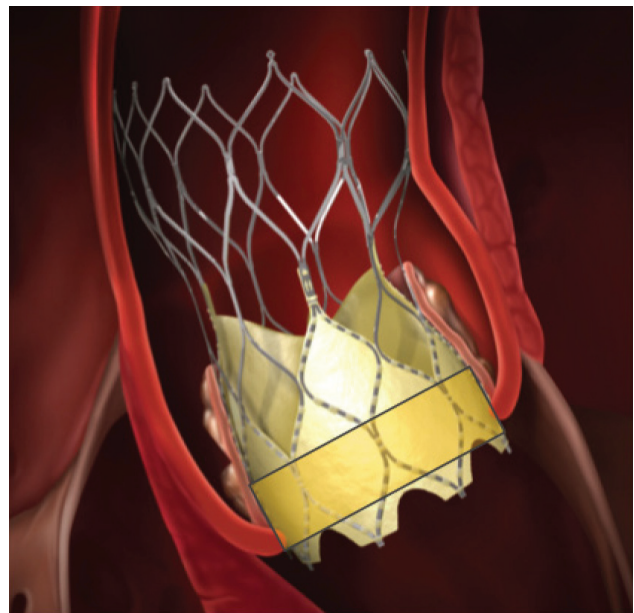


FIGURE 2. The ideal depth of implantation is 4 mm below the aortic annulus (range 1-9 mm, highlighted area). The non-flared annulus section of the valve and the minimal protrusion of the valve in the left ventricular outflow tract are expected to mitigate the occurrence of heart block and the need for pacemaker implantation.

RELATED STUDIES

Initial results in two small non-randomized studies were favorable.^{2,3} The Portico 23 mm valve was implanted in 10 and 11 patients in Ireland and Canada, respectively.^{2,3} Valve resheathing was used in 6 patients. Patients were followed for 6-12 months. There was no death, major stroke, new pacemaker implantation, myocardial infarction, or major vascular complication. There were 6 new left bundle branch blocks. Echocardiography assessment showed a sustainable increase in the valve effective orifice area. No patient had more than mild aortic regurgitation at follow-up.

CONCLUSIONS

New generation transcatheter aortic valves are expected to expand the indications for TAVR in low surgical risk patients. The Portico valve has several special features aiming to minimize the occurrence of paravalvular aortic regurgitation and heart block, to increase the accuracy of deployment

and to facilitate better implants. Naturally, favourable initial results should be confirmed in large randomized clinical trials.

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