ORIGINAL ARTICLE

Percutaneous aortic valve replacement (part 2): Miniaturization of the delivery system based on the novel temporary valve technology

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Abstract
Percutaneous aortic valve replacement remains an investigational procedure challenged by multiple key issues. In part 1 of this 2 part series, the issue of precise placement of the percutaneous aortic valve was addressed by a novel design of a delivery and deployment system. The design and use of a hemodynamics supporting temporary aortic valve was highlighted, which can stabilize the hemodynamic and local flow conditions for a more controlled and precise placement of the percutaneous aortic valve. In this part 2 study, the issue of vascular access complications is addressed. The current large French size catheter systems can cause significant vascular injuries; the catheter diameter must be reduced for this procedure to be safe and routine. The hemodynamic support of the temporary aortic valve system allows for the formulation of a novel approach to reduce the catheter-delivery system. The miniaturization strategies consist of pretreatment of the aortic annulus and assembly of the percutaneous aortic valve apparatus in a piecemeal fashion of smaller components. Each component would, therefore, require a smaller diameter delivery catheter. The combined strategies as described in this 2 part series aim at realizing the percutaneous aortic valve replacement as a routine, fully percutaneous and cath lab-based.

Key words: Percutaneous aortic valve replacement, temporary aortic valve, ablation stent system, reduction in catheter diameter/size, miniaturization of percutaneous aortic valve

Introduction
The percutaneous approach to aortic valve replacement is challenged by multiple key issues that currently frustrate the success of the procedure. It remains an investigational procedure rather than mainstay therapy for many patients who may benefit from it. These important factors include the accuracy of placement of the percutaneous aortic valve (PAV) at the aortic annulus to avoid damaging important adjacent structures and vascular complications resulting from the large size delivery system (1–6). A novel percutaneous temporary aortic valve system (TAV) was recently introduced to specifically address the issue of accurate PAV placement in the aortic annulus (7). A mathematical model of the TAV showed the device’s efficacy in controlling and supporting the local hemodynamics allowing time for a more accurate positioning of the PAV at deployment. Based on the TAV design, significant reduction in the diameter (French size) of the delivery catheter is possible. This study evaluates the potential for miniaturization strategy of the delivery system based on the TAV technology. The combination of the TAV hemodynamics support and the reduction in catheter size of the overall PAV system can finally bring this technology to mainstay therapy.

Material and methods
The percutaneous temporary aortic valve system was first described in part 1 of this 2-part series (7). The TAV is intended to temporarily substitute for the function of the native aortic valve during its replacement. By engineering design, the supported hemodynamics by the TAV can afford the operator invaluable time and patient stability to favorably modify the anatomy of the aortic annulus before the PAV implantation.
A more precise placement of the PAV is possible. The TAV support can also allow for a piecemeal assembly of the PAV at the aortic annulus, thereby lowering the guide-catheter's diameter because each PAV component would require a smaller delivery system.

**Temporary aortic valve system**

The TAV was described in detail in a prior study (7). A 3-supporting-balloon system is designed to situate at the distal end of the delivery guide catheter as previously described (Figure 1 A and B). In the inflated position, mathematical calculations demonstrated the effective moderate range aortic stenosis and insufficiency at the TAV, which are generated by the balloons and channels with the contacting aortic wall, and should be well tolerated by the subject when the native aortic valve is initially ablated (7). This feature can allow the subject to sustain relatively stable hemodynamics and quiescent flow conditions for the complete expansion of the aortic annulus (pre-dilation and pre-stenting) (see below and Figures 2 and 3) and the subsequent accurate placement of the PAV.

**Miniaturization strategies**

Because the TAV can allow the subject to have a temporary stable cardiovascular hemodynamic condition when the native aortic valve is ablated and no longer functional, an immediate deployment of a functional PAV is not

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*Figure 1.* Schematic illustration of the 3-balloon TAV system situated at the distal end of the delivery guiding catheter. When deployed in the ascending aorta as shown by cross sectional (A) and by longitudinal view (B), mathematical calculations of the resultant temporary AS and AI by TAV can afford the subject stable hemodynamics during the modification (pretreatment) of the aortic annulus and precise placement of the PAV.
The operator has time to carefully prepare the aortic annulus to accept the PAV. Furthermore, the support structure of the PAV would not have to serve as both the mechanical prop for the opening of the annulus and the framework for the tissue valve. The ablation stent(s) in the aortic annulus can modify the local geometry toward a favorable housing to receive the PAV, and can assume most, if not all, of the mechanical load (radial force) to maintain the desired annulus lumen. The framework for the PAV itself can therefore be smaller and less bulky serving only to structure the tissue valve. Miniaturization of the delivery system is, therefore, possible by focusing on the design strategies of the ablation stent system and the new PAV system.

Strategies in designing the ablation stent system (Figure 3) in the miniaturization effort focus on two areas: At the procedure level (Figure 3 A and B) and at the stent level (Figure 3 C and D). There is precedence to use multiple concentrically placed thinner stents to achieve sufficient radial force to overcome resistant luminal narrowing (8). Although each thinner stent may possess inadequate radial strength to eliminate residual stenosis, the addition of multiple stents can add to the overall amount of metal and radial support to achieve full luminal expansion (Figures 3 A and B). The advantage of using multiple thinner stents is to allow for reduction in diameter of the delivery system, because each stent would require a smaller guiding catheter.

The design of the ablation stents can also help to reduce the size of the delivery system and guiding catheter. The conventional coronary stent design is to avoid significant amounts of foreshortening. Foreshortening is defined as a reduction in length of the stent in the expanded state. In percutaneous coronary intervention, foreshortening can lead to unpredictable stent location, and is therefore considered an undesirable feature. In the PAV replacement procedure, however, an ablation stent designed with the deliberate foreshortening can have unexpected advantages. It allows for the axial (along the catheter length) distribution of metallic material in the crimped position (reduced profile), while the intended foreshortening can concentrate metallic support at the aortic annulus in the expanded state (Figure 3 C and D). An anchoring or centering mechanism will be necessary to ensure predictable stent location during deployment.

With the ablation stents bearing most of the mechanical load to maintain the aortic annulus lumen and geometry, the new PAV system can be fashioned to a lower profile system as well. The PAV itself can be without the bulky stent structure as seen in current models (Figure 4 A and B). The new PAV will only require a thinner framework to support the tissue valve alone, and can be packaged and delivered in a significantly reduced French-size guiding catheter. With the TAV support and the native aortic valve annulus sufficiently prepared by the ablation stents,
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the delivery and deployment of the new PAV can be precise and relatively uncomplicated (Figure 5).

Results

Based on the TAV technology, miniaturization of the PAV system is possible by innovative design of the ablation stent system and the new PAV system. The miniaturization is expected to be significant allowing for a truly percutaneous procedure. As shown in the previous study (7), the illustrated step-by-step procedure can be performed routinely with significant improvement in patient safety, success rate and resource management. At the completion of the procedure, the TAV system is withdrawn along with the guide wire. The final outcome is a well-placed PAV securely anchored inside an optimally modified housing of the ablation stents at the aortic annulus (Figure 6). Manual removal

Figure 3. Schematic illustration of the deployment of the valve ablation stent(s) at the aortic annulus. This creates an optimal housing for the annulus to receive a much reduced size PAV. With the utilization of thinner stent designs, the required diameter of the guiding catheter can be reduced. However, a thinner stent alone may not have adequate radial strength to fully eliminate residual stenosis at the aortic annulus (A); multiple thinner stents may be required to achieve adequate radial strength to prevent recoil of the native valve materials into the annulus lumen (B). A stent design with deliberate foreshortening can further lower the profile of the delivery system, and the guiding catheter diameter. This is achieved by optimal axial distribution of metallic material in the pre-deployed (crimped) state (C). At deployment, the stent will foreshorten at the aortic annulus concentrating the metallic element at the annulus where maximal load-bearing is needed (D).

Figure 4. Schematic comparison of the current PAV models with large and bulky supporting framework (A) and the new PAV model demonstrating a much reduced framework structure design for a smaller, lower profile delivery system (B).
Discussion

In this two-part series, a novel design of a potential technological advancement in PAV replacement is presented detailing the engineering basis and procedural steps. This new technology may help to realize the possibility of PAV replacement as a stand-alone, routine, entirely percutaneous and cath lab-based procedure.

Percutaneous aortic valve replacement can be likened to percutaneous coronary intervention (PCI) of complicated left main stenosis in the high-risk nature and potential for patient instability. Unlike percutaneous intervention of the left main artery, current
investigational systems do not possess capabilities for prophylactic protection and hemodynamic support. In patients with complex coronary disease and high risk factors, the operator has the option to support the hemodynamics by inserting an intra-aortic balloon pump (IABP) (9). The use of the TAV system for PAV replacement can be analogous to the IABP in high-risk PCI.

An essential aspect of this proposed system is the development of a temporary aortic valve serving as a transient hemodynamic support device. The resultant moderate range aortic insufficiency and stenosis at the TAV should be well tolerated by the subject as compared to the original severity of disease. Clinical limitations and patient selection in the use of the TAV system were discussed in part 1 (7). The temporary and relatively stable hemodynamic conditions achieved by the TAV can afford time to prepare (to pre-treat) the aortic annulus. Strategies for pre-treatment of the annulus may include the use of debulking devices (to be invented) and the use of the ablation stent system to achieve an optimally circular and unobstructed housing for the PAV as described. Distal embolic protection may also be relevant, especially if debulking options become available. Patients with the most difficult anatomy may be approached in this fashion. By utilizing multiple smaller profile ablation stents and minimizing the metal support of the PAV, the diameter of the delivery system can be significantly reduced. The patient can be left with a well-placed PAV in a secure housing with improved hemodynamics and only a band-aid at the femoral access site.

Further validation with animal and follow-on human models will be the necessary next steps in the development of this new technology.

References