Percutaneous aortic valve replacement (part 3): Balloon counterpulsation of a novel temporary aortic valve

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Abstract
A previously published two-part study described an engineering design of a percutaneous aortic valve (PAV) replacement system, which utilizes a novel temporary aortic valve (TAV) support to improve procedural outcomes and safety. Conceptually, this investigational approach can promote accurate PAV placement, procedural hemodynamic stability, smaller catheter delivery system, reduction in PAV regurgitation, reduction in conduction and vascular complications. The balloon TAV can potentially facilitate the PAV replacement procedure by serving as the patient’s surrogate aortic valve while the native valve is pretreated and replaced. The original TAV is designed to function with an effective aortic stenosis and insufficiency in moderate ranges, which lessens from the patient’s more critical valve condition, should be well tolerated when the native valve becomes nonfunctional during the replacement process. Further optimization of the TAV’s hemodynamic profile could further improve the system’s overall performance and enhance the realization of a truly minimally invasive, cath lab-based PAV replacement procedure comparable to that of percutaneous coronary intervention. This study explores design permutations from the original published TAV, including varying the number of balloons and adding balloon counterpulsations, to improve upon its hemodynamic profile to better serve as the patient’s surrogate valve and the overall PAV replacement procedure.

Key words: Percutaneous aortic valve replacement, temporary aortic valve, controlled aortic stenosis, controlled aortic insufficiency, balloon counterpulsation, temporary valve counterpulsation

Introduction
The development of percutaneous aortic valve (PAV) replacement continues to be challenging and the notion of achieving a similar level of minimal invasiveness as percutaneous coronary intervention (PCI) remains elusive. To successfully replace the diseased aortic valve solely via catheter approach in the cath lab setting, several key obstacles must be overcome. Current models have highlighted some of the leading issues including positioning-related, deployment-related, vascular- and conduction-related complications (1–6). Continued developmental efforts have led to some current models to be used in high-risk, inoperable patients (7). A novel PAV and delivery system consisting of a built-in temporary aortic valve (TAV) has been conceptually developed and previously published in a two-part study (8,9). The TAV could take over the function of the native valve and could allow for optimal pretreatment of the native aortic valve and annulus such as valve debulking, modification and partial or complete removal prior to PAV implantation. Strategies for accurate positioning of the prosthetic valve and reduction in catheter size to lessen overall procedural complications have been described. The goal is to develop a fully cathlab based PAV replacement system that achieves similar minimal invasiveness of PCI.

The original (TAV) is mounted at the tip of the guide catheter, which is designed with a three-balloon system that can be readily deployed and retrieved (Figure 1) (8). In the inflated (deployed) position, the three-balloon temporary valve could create an effective moderate range aortic stenosis and regurgitation which should be well tolerated by the subject. Most importantly, the controlled aortic regurgitation
could prevent massive reversal of blood flow into the
deep bottleneck region during diastole when the native aortic
valve is removed or nonfunctional during the replace-
ment process, while allowing for diastolic coronary
filling. The TAV, therefore, has the advantage of
allowing for pretreatment of the native aortic valve
and annulus prior to implantation of the prosthetic
valve.

This study explores design options of the TAV
which could further optimize its function as a surro-
gate aortic valve. Adjustment and control of the
TAV’s effective aortic stenosis and regurgitation are
possible by varying the number of configured balloons
as well as counterpulsations of the balloon elements
in the TAV. These design maneuvers can alter the
cross-sectional gap-to-balloon area ratios to achieve
the desired hemodynamic profile. Optimized TAV
hemodynamics can better support the entire percu-
taneous aortic valve replacement procedure. The
hemodynamics profiles of various TAV balloon
configurations with and without counterpulsation
elements are presented.

**Material and methods**

To create an understanding of the gap-to-balloon
relationship in producing the optimal effective
mild-to-moderate range aortic stenosis and insuffi-
ciency of the temporary aortic valve, mathematical
calculations are performed on TAV models compris-
ing three to six balloons of the same sizes surrounding
the central catheter (Figure 2). The choice of
using the same size balloons is to ease calculation
and manufacturing complexities, though it is not a
requirement as long as the resultant cross-sectional
area of the gap: overall luminal aorta ratios are
between the recommended range of 25 to 60% (8).
Hence, balloons of various sizes and configurations
(non-circular) may be design options in future
developments.

To study the potential benefits of balloon counter-
pulsation and to further unload the temporary valve’s
effective stenosis, various balloon counterpulsation
permutations are explored as shown (Figure 2). Bal-
loon counterpulsation is defined as balloon inflation
during diastole and balloon deflation during systole similar to the timing cycle of the intra-aortic balloon pump (10). During TAV balloon counterpulsation, certain configurations may be potentially mechanically less stable, e.g. when all of the balloons counterpulsate, and may lead to some catheter fling. Unstable configurations, such as single or double balloon counterpulsation in the three-balloon TAV, three-balloon counterpulsation in the four-balloon TAV, three-balloon counterpulsation in the five-balloon TAV and four-balloon counterpulsation in the six-balloon TAV, are not considered in the calculations.

TAV permutations considered in the calculations are the following: Counterpulsation of all of the TAV balloons (the middle row of Figure 2), counterpulsation of the catercorner balloons in the four-balloon TAV (the remaining two as fixed supportive balloons), counterpulsation of the two opposing balloons in the five-balloon TAV (three remaining fixed supporting balloons) and counterpulsation of every other balloons in the six-balloon TAV (others as fixed support balloons) (the bottom row of Figure 2).

**Results**

Table I shows the relationship between the radius of the aorta (R) to the radius of the TAV balloons (r) and the radius of the central catheter (h) for the three-, four-, five- and six- balloon TAV configurations. As first reported in the original TAV study (8), the three-balloon TAV cross-sectional gap area: total area of the ascending aorta is calculated to be approximately 35%, which falls in the moderate range effective aortic stenosis and insufficiency during systole and diastole, respectively. As the number of balloons surrounding the central catheter increases, the balloon size becomes smaller as demonstrated by the increasing R: r ratio. Furthermore, as the balloon size becomes smaller, the center space becomes larger allowing for a larger lumen central catheter to be housed as shown by the decreasing R: h ratio. In the four-balloon

![Figure 2](image-url)
configuration, the diastolic gap area: total area ratio is lowered to 28% compared to the three-balloon TAV’s 35%, which decreases the effective aortic insufficiency. As the number of balloons increases, the diastolic gap area: total area ratio decreases further to 25% and 22%. While the effective TAV aortic insufficiency decreases with increasing number of balloons, the effective aortic stenosis increases to beyond critical range (gap: total area ≤25%) in the five- and six-balloon TAV. This would entail less effective aortic insufficiency by the TAV which may or may not be adequate for coronary perfusion during diastole, however, during systole the TAV’s effective aortic insufficiency will become significant.

The central catheter diameter is dependent on the size of the ascending aorta (as indicated by the R: h ratio) as well as the number of TAV balloons (Table I). For average size adult human ascending aorta (11), the central catheter-TAV can conceptually be fabricated to be as small as a 7-French system to as prohibitively large as >30-French.

Table II shows the effects of balloon counterpulsation when all (II A) or some (II B) of the TAV balloons are inflated-deflated timed to the cardiac cycle as described. When the TAV balloons are deflated during systole and inflated during diastole via balloon counterpulsation, it can alleviate or lower the degree of effective aortic stenosis while keeping the controlled effective aortic insufficiency unchanged. When all of the balloons of the TAV counterpulsate, the effective aortic stenosis is significantly reduced to negligible to very mild ranges as shown in Table II A. In the four-balloon configured TAV, counterpulsation of two selective cathercorner balloons while keeping the other two as fixed support decreases the effective aortic stenosis during systole to a gap area: total area ratio of 62.7%, as compared to 28% without counterpulsation. Similar improvement in the systole effective aortic stenosis is seen in the five- and six-balloon TAV with selective balloon counterpulsation as noted in Table II B, with the systole gap area: total area of 52.1% and 55.6%, respectively. Note that balloon counterpulsation is most relevant in the five- and six-balloon configurations where the effective aortic stenosis is at critical values. Hence, balloon counterpulsation may present a unique advantage over the fixed-balloon TAV system.

**Discussion**

This study has demonstrated the design potential to manipulate and control the TAV’s effective aortic stenosis and insufficiency by varying the number of balloons used to create the TAV and by adding balloon counterpulsation to lessen the systolic effective TAV stenosis. From the design standpoint, there are a variety of ways to create the optimal gap: total cross-sectional area ratio for the desirable effective TAV stenosis and insufficiency via non-circular vs. circular balloons, non-uniform vs. uniform balloons and non-balloon structures. The initial choice of using balloons of the same size in each TAV is to simplify mathematical modeling and manufacturing process. The choice of using inflatable balloons in the TAV is for its ease of deployment and removal. Another method to create a temporary valve has been explored (12).

In the TAV permutations, as the number of balloons increases in a given size ascending aorta, the size of the balloons will decrease as clearly demonstrated by the R to r ratio. The relationship between R and h will also influence the size of catheter used. Furthermore, the distance between the balloons and the center of the ascending aorta will also increase as

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**Table I. Comparative TAV configurations with fixed (Inflated) balloons.**

<table>
<thead>
<tr>
<th>Dimensional Relationship</th>
<th>3-Balloon TAV</th>
<th>4-Balloon TAV</th>
<th>5-Balloon TAV</th>
<th>6-Balloon TAV</th>
</tr>
</thead>
<tbody>
<tr>
<td>R: r ratio</td>
<td>R = 2.15 r</td>
<td>R = 2.41 r</td>
<td>R = 2.70 r</td>
<td>R = 3.0 r</td>
</tr>
<tr>
<td>R: h ratio</td>
<td>R = 14.29 h</td>
<td>R = 5.88 h</td>
<td>R = 3.85 h</td>
<td>R = 3.0 h</td>
</tr>
<tr>
<td>Gap: Area</td>
<td>35%</td>
<td>28%</td>
<td>25%</td>
<td>22%</td>
</tr>
<tr>
<td>TAV’s Effective AS</td>
<td>Moderate</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>TAV’s Effective AI</td>
<td>Moderate</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Estimated Central Catheter Size</td>
<td>7-Fr.</td>
<td>17-Fr.</td>
<td>26-Fr.</td>
<td>32-Fr.</td>
</tr>
</tbody>
</table>

As the number of balloons increases from 3 to 6, the balloons become smaller (increasing R: r ratio) and the space to house the central catheter gets larger (decreasing R: h ratio). In the five- and six-balloon configurations, the TAV’s systolic effective aortic stenosis reaches critical values of 25% and 22%, respectively. The ↑ arrows denote the relative degree of the TAV’s effective aortic stenosis and insufficiency as compared to the original three-balloon configuration. In general, as the number of balloons increases, the TAV’s effective aortic stenosis increases while its effective aortic insufficiency decreases. The estimated central catheter diameter tends to increase with the number of TAV balloons as shown.
the number of balloons increases. Hence, with more balloons in the TAV, there will be a larger space in the center of the ascending aorta to house a larger central catheter. In the fixed balloon TAV permutations, the effective aortic stenosis increases as the number of balloons increases, while the effective aortic insufficiency decreases accordingly. The TAV model permutations may allow for opportunity for catheter size fitting or tailoring based on the aortic size, the number of balloons on the TAV and the associated hemodynamic profile.

In the five- and six-balloon TAVs, the systolic effective aortic stenosis reaches the critical range of 25%, which is unacceptable in the replacement of severe aortic stenosis procedures. In these cases, balloon counterpulsation appears mandatory to alleviate the excessive TAV stenosis during systole. Also in the five- and six-balloon TAV configurations, the effective aortic insufficiency during diastole lowers toward mild range which is fabulous in preventing excessive regurgitation and congestive heart failure but could limit adequate coronary perfusion. The follow-on animal studies will be able to determine the relationship between the degree of TAV’s effective insufficiency and diastole coronary filling.

With the addition of balloon counterpulsation, it is found that the TAV’s effective aortic stenosis during systole can be significantly reduced, while the effective aortic insufficiency during diastole is unchanged. For all of the balloon configurations used in the calculations (three-, four-, five- and six-balloon TAVs), the systolic effective aortic stenosis is reduced to negligible ranges (when all balloons counterpulsate) to mild ranges (when selective balloons counterpulsate). This reduction in antegrade blood flow obstruction can further help to stabilize the patient during the percutaneous aortic valve replacement procedure. This is particularly true for the five- and six-balloon TAVs where the effective aortic stenosis is already in the critical range in the fixed balloon models. The tremendous relief of effective TAV stenosis by counterpulsating all of the balloons as shown in the middle row figures of Figure 2, while maintaining the same effective aortic insufficiency as the fixed-balloon models. 

Table II. Comparative TAV configurations with balloon counterpulsation.

<table>
<thead>
<tr>
<th>Dimensional Relationship</th>
<th>3-Balloon TAV</th>
<th>4-Balloon TAV</th>
<th>5-Balloon TAV</th>
<th>6-Balloon TAV</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Counterpulsation with all of the balloons.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gap: Area (systole)</td>
<td>99%</td>
<td>97%</td>
<td>93%</td>
<td>88%</td>
</tr>
<tr>
<td>Gap: Area (diastole)</td>
<td>35%</td>
<td>28%</td>
<td>25%</td>
<td>22%</td>
</tr>
<tr>
<td>TAV’s Effective AS (systole)</td>
<td>Negligible</td>
<td>Negligible</td>
<td>Very Mild</td>
<td>Very Mild</td>
</tr>
<tr>
<td>TAV’s Effective AI (diastole)</td>
<td>Moderate</td>
<td>Moderate (same as fixed)</td>
<td>Mild-Moderate (same as fixed)</td>
<td>Mild (same as fixed)</td>
</tr>
<tr>
<td>B Counterpulsation with selective balloons</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gap: Area (systole)</td>
<td>–</td>
<td>62.7%</td>
<td>52.1%</td>
<td>55.6%</td>
</tr>
<tr>
<td>Gap: Area (diastole)</td>
<td>35%</td>
<td>28%</td>
<td>25%</td>
<td>22%</td>
</tr>
<tr>
<td>TAV’s Effective AS (systole)</td>
<td>Moderate</td>
<td>Mild</td>
<td>Mild</td>
<td>Mild</td>
</tr>
<tr>
<td>TAV’s Effective AI (diastole)</td>
<td>Moderate</td>
<td>Moderate (same as fixed)</td>
<td>Mild-Moderate (same as fixed)</td>
<td>Mild (same as fixed)</td>
</tr>
</tbody>
</table>

A presents the significant relief of the effective TAV stenosis by counterpulsating all of the balloons as shown in the middle row figures of Figure 2, while maintaining the same effective aortic insufficiency as the fixed-balloon models. 

B presents the results of counterpulsating selective balloons of the TAV as shown in the bottom row of Figure 2. The TAV’s effective aortic stenosis during systole is significantly reduced while maintaining the the same effective aortic insufficiency as the fixed-balloon systems. The reduced effective TAV stenosis for the three-, four-, five- and six-balloon TAV are 99%, 97%, 93% and 88% respectively for counterpulsation of all balloons. The reduced effective TAV stenosis for the four-, five- and six-balloon TAV are 62.7%, 52.1% and 55.6% respectively for counterpulsation of selective balloons. These values are considered negligible to mild aortic stenosis, which is a significant improvement from the fixed-balloon TAV systems.
its function as mechanical and hemodynamic support for the percutaneous aortic valve replacement procedure. The presented mathematical calculations are limited to idealized models where the balloons stay circular, the ascending aorta has a circular circumference free of atherosclerotic irregularities, perfect contacts between balloons and the aortic wall without slippage, leakage or resonance vibrations. In reality, the balloon compliance may encroach upon the gaps, creating more than expected contacts with the aortic wall, and the gap: total cross-sectional area ratio may further be altered by the irregular aortic profile from disease conditions. Excessive and/or inadequate TAV-aortic wall contacts can occur. The greater degree of operating hemodynamics range afforded by adding balloon counterpulsation to the TAV may help to mitigate some of the challenges of a perfect TAV fit to the ascending aorta. Animal validations along with the theoretical model analyses are vital in developing TAV system into a successful supportive device in the overall PAV replacement procedure.

In conclusion, the ability to influence and adjust the TAV’s function is possible by varying the number of balloons utilized and implementing balloon counterpulsation. The eventual choice of device configuration will also depend on other factors such as the desirable guide catheter size and the required TAV hemodynamic profiles. The TAV balloon counterpulsation should not be confused with IABP counterpulsation in that the balloon volume of the TAV is significantly less (30–40cc in IABP vs. <3cc in TAV) (10) without full aortic occlusion and should be safe to use with the presence of aortic insufficiency. Similar to the hemodynamic support of IABP in high-risk percutaneous coronary interventions, however, the TAV can provide additional hemodynamic support to optimize patient safety and procedural outcome in PAV replacement. In addition, TAV support will allow for the development of tools and methods to pretreat the diseased aortic valve, which can further the development of PAV replacement toward an overall attractive procedure reaching beyond the high-risk subset to serve all patients in need.

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References