

EDITORIAL COMMENT

Treatment of Small Surgical Valves

Clinical Considerations for Achieving Optimal Results in Valve-in-Valve Procedures*



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Worldwide, there is growing experience with transcatheter treatment of failed bioprosthetic valves, and technical considerations are evolving (1,2). The main issues observed during the early days of valve-in-valve (VinV) implantations were transcatheter heart valve (THV) malposition, life-threatening coronary obstruction, and elevated post-procedural gradients (3). Device malposition is becoming less common due to a better understanding of the fluoroscopic landmarks of surgical valves (4,5). Optimal screening and prevention of coronary obstruction has made these adverse events less frequent as well (6). Currently, the main limitation of VinV procedures in the aortic position is residual stenosis, which is associated with poor clinical outcomes and limited durability (7).

RESIDUAL STENOSIS: THE ACHILLES' HEEL OF AORTIC VINV IMPLANTATION

Data from the VIVID (Valve-in-Valve International Data) registry reveals that 32% of VinV procedures have severe prosthesis-patient mismatch immediately after valve implantation (7). Similar suboptimal results have been verified in U.S. VinV trials using SAPIEN XT (Edwards Lifesciences, Irvine, California) and CoreValve (Medtronic, Minneapolis, Minnesota). Poor post-procedure hemodynamics are unacceptable, because elevated gradients will translate into worse clinical outcomes (8). In addition, operators are limited in treating severe stenosis after VinV by

having a smaller effective orifice area with each additional valve implanted inside of a failing one (i.e., “Russian doll” phenomenon). Therefore, all clinicians involved in VinV should be made aware of techniques that can decrease the risk of elevated post-procedural gradients after aortic VinV, especially in procedures involving small surgical valves.

Unfortunately, many of the failed surgical valves are small: 379 of 1,349 aortic VinV in the VIVID registry (28%) were labeled size ≤ 21 mm (September 2015), similar to earlier analyses (7). In the surgical arm of the PARTNER trial, approximately one-half of the patients that underwent aortic valve replacement were implanted with a small valve (9). Small bioprostheses may fail earlier than larger ones, making future VinV implantation challenging. Inside these small valves there is limited space for THV expansion, and the risk of having significant stenosis post-implantation is exceedingly high. In addition, patients’ survival and symptom improvement is limited (7).

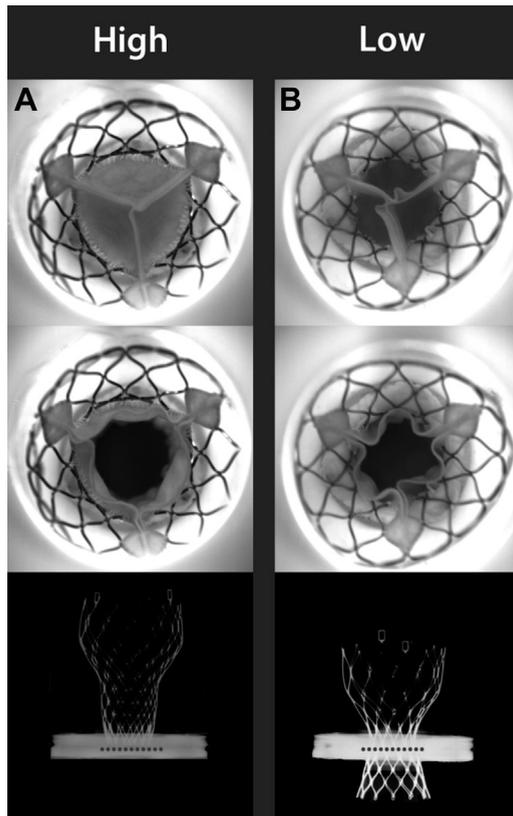
CLINICAL CONSIDERATIONS IN PATIENTS WITH SMALL SURGICAL VALVES

A crucial step in assessing a candidate for VinV with a failed small surgical valve is confirming that the observed elevated gradients across the bioprosthesis are a result of degeneration and not merely related to the small size of that surgical valve (i.e., severe prosthesis-patient mismatch of the surgical valve itself) (1,2). Patients with high, but relatively stable, gradients across that valve, observed early after the original surgical implantation and without obvious signs of leaflet degeneration, might not be ideal candidates for VinV. Selected patients with true failure of their small surgical valves could benefit from redo surgery with removal of the bioprosthesis and

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FIGURE 1 Influence of Valve-in-Valve Implantation Depth on Effective Orifice Area



Implantation of a 23-mm CoreValve Evolut (Medtronic, Minneapolis, Minnesota) inside of a 19-mm label sized Epic (St. Jude Medical, St. Paul, Minnesota) in different depths. The high position (A) results in a larger effective orifice area after valve-in-valve implantation in comparison with the low position (B).

targeted implantation of a larger device or aiming for a specific surgical implant associated with improved hemodynamics.

If VinV in a small bioprosthesis is deemed necessary, then selection of the most appropriate THV device is crucial. Although virtually all THV devices are underexpanded when implanted into small and intermediate-sized surgical valves, there are THVs that are less prone to having poor hemodynamics after VinV (3). It is suggested, from both in-vivo and in-vitro evaluations, that supra-annular position of the functional portion of the THV device is beneficial (3,7,10-13) (Figure 1). However, there are devices with limited ability to safely function above the plane of the surgical valve. Nevertheless, it becomes clear that all devices will achieve lower post-procedural gradients the higher they are implanted. The main concern

is that an excessively high position will result in unacceptable regurgitation and may lead to device dislodgement. Therefore, researchers and engineers should search for a “sweet spot” in which gradients are lowered while safety is not jeopardized. Each THV device may have a specific target position that is associated with optimal hemodynamics (14). It is conceivable that some devices with inherent supra-annular position may have a longer target zone for implantation than those that act relatively intra-annular.

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In this issue of *JACC: Cardiovascular Interventions*, Midha et al. (15) have performed in vitro assessment, implanting a 23-mm SAPIEN XT (Edwards Lifesciences) inside of a small surgical valve, #19 Perimount. These were performed in 4 different positions from intra-annular to exceedingly supra-annular position (up to 8 mm above the ring of the surgical valve). Although these extremely high positions are not conventionally utilized in clinical cases and are considered off-label (positions can be observed in Figure 3 of the paper by Midha et al. [15]), the results are of interest: the higher the position, the lower the post-procedural gradients. However, the higher the position, the least amount of force was required to pull the implanted device, and therefore, the risk for device dislodgement would be unacceptably high. These results highlight the need to continue searching for the optimal zone of implantation during VinV procedures.

FUTURE DIRECTIONS

In this exciting and growing era of VinV procedures, there are still many unknowns with regard to the optimal treatment of small surgical valves. Clinical data should continue to be analyzed and evaluated for whether VinV in small surgical valves is clinically justified and cost-effective. The optimal position for each THV device that will provide reasonable post-procedural gradients without affecting surgical safety should be defined (14). The effect of implantation of very small THV devices (20 mm in size) should be further explored as well. Eventually, novel surgical valves, with an advanced structure dedicated for VinV treatment, may result in better hemodynamics post-implantation.

In conclusion, residual stenosis is the Achilles' heel of aortic VinV procedures. Poor hemodynamic results are especially common in cases performed in small surgical valves. Exceedingly high transcatheter valve position is associated with better

hemodynamics but may increase the risk of device dislodgement. Physicians and engineers should continue to work together and further explore how to optimally position different THV devices inside failing surgical valves.

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