Keynote Lecture Series

Bioprosthetic valve fracture: a practical guide

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Valve-in-valve transcatheter aortic valve replacement (VIV TAVR) is currently indicated for the treatment of failed surgical tissue valves in patients determined to be at high surgical risk for re-operative surgical valve replacement. VIV TAVR, however, often results in suboptimal expansion of the transcatheter heart valve (THV) and can result in patient-prosthesis mismatch (PPM), particularly in small surgical valves. Bioprosthetic valve fracture (BVF) and bioprosthetic valve remodeling (BVR) can facilitate VIV TAVR by optimally expanding the THV and reducing the residual transvalvular gradient by utilizing a high-pressure inflation with a non-compliant balloon to either fracture or stretch the surgical valve ring, respectively. This article, along with the supplemental video, will provide patient selection, procedural planning and technical insights for performing BVF and BVR.

Keywords: Surgical aortic valve replacement; transcatheter aortic valve; replacement; valve in valve; bioprosthetic valve fracture (BVF)

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Introduction

Heart teams are increasingly utilizing valve-in-valve transcatheter aortic valve replacement (VIV TAVR) to manage failed bioprosthetic surgical valves beyond the currently approved Food and Drug Administration indication for high-risk surgical patients only (1,2). An Achilles' heel of VIV TAVR, particularly in small surgical valves, is the potential for patient-prosthesis mismatch (PPM). The risk of severe PPM, typically defined as a residual transvalvular gradient >20 mmHg, is higher following VIV TAVR since the transcatheter heart valve (THV) is constrained by the surgical valve's true internal diameter (ID). In addition, suboptimal expansion of the THV following VIV TAVR may result in pin-wheeling of the THV leaflets and premature THV degeneration (3,4).

While the short-term results of VIV TAVR have generally been good, the observed one-year mortality following VIV TAVR in the Valve-in-Valve International Data (VIVID) Registry was significantly higher in patients with small surgical valves (labeled surgical valve size ≤21 mm) compared to intermediate (≥23 and ≤25 mm) or large (≥27 mm) surgical valves (25% *vs.* 18% *vs.* 7%, P=0.001), respectively (5). PPM may be responsible for this finding, with pre-existing PPM of the failed prosthetic valve an independent predictor of increased mortality after VIV TAVR (6). Strategies to improve the hemodynamic results of VIV TAVR and reduce the risk of PPM include; implanting the THV high in the surgical valve, since lower implantation depths can result in suboptimal leaflet function and increase the risk of high residual transvalvular gradients (7-10). In addition, utilizing a supra-annular THV, particularly in small surgical valves, can also minimize the risk of PPM. Unfortunately, PPM has occurred with a wide variety of THV's and despite a perfect implantation technique (8,11-13).

Bioprosthetic valve fracture (BVF) (14,15) and bioprosthetic valve remodeling (BVR) (16,17) are techniques to facilitate VIV TAVR, in which a high-pressure balloon inflation is performed using a non-compliant balloon to either fracture the surgical valve ring or stretch the surgical

valve ring or posts, permitting more optimal expansion of the THV and thereby, mitigating the risk of PPM following VIV TAVR. *In vitro* testing of bioprosthetic surgical valves has demonstrated that most, but not all, can be fractured or remodeled (14,16). In addition, clinical experience has demonstrated the safety and efficacy of BVF/BVR in reducing PPM following VIV TAVR (13-15,18). Finally, the reduction in transvalvular gradients following BVF appears durable at one-year follow-up, although the impact this may have on mortality and THV durability remains unknown (19). Achieving successful and safe results with BVF/BVR requires a clear understanding of the procedure, which this article and supplementary video will provide.

Bioprosthetic fracture set up

When first considering BVF/BVR, it is necessary to accurately identify the surgical valve and determine if it can be fractured or remodeled. Aortic surgical valves that can be fractured (along with their fracture threshold) include the Magna (22-24 Atm, Edwards Lifesciences), Magna Ease (18 Atm, Edwards Lifesciences), Perimount 2800 (20 Atm, Edwards Lifesciences), Mitroflow (12 Atm, Sorin Group), Mosaic (10 Atm, Medtronic), and Biocor Epic (8, Atm, Abbott) (14). Surgical valves that can be remodeled or stretched, but not fractured, include; Trifecta (Abbott), Carpentier-Edwards standard and supra-annular (Edwards Lifesciences), Inspiris (Edwards Lifesciences) and, Perimount 2700 (Edwards Lifesciences) (16,17). Finally, surgical valves that cannot be fractured or remodeled include the Hancock II (Medtronic) and Avalus (Medtronic) surgical valves (14).

BVF is performed using the following equipment: (I) a non-compliant balloon [True Dilatation or Atlas Gold (Bard, Murry Hill, NJ, USA) are the most commonly used]; (II) a high-pressure stopcock and tubing; (III) an indeflator and; (IV) a 60-mL syringe with dilute contrast (20). After initiating rapid ventricular pacing, the non-compliant balloon is rapidly filled with dilute contrast from the 60 mL syringe and then pressurized using the indeflator until fracture occurs. Confirmation of fracture can be challenging; observing in real time the waist of the balloon release at the time of fracture or listening for an audible snap, are unreliable. The best confirmation that BVF has occurred includes observing an acute drop in the indeflator pressure near the fracture threshold for the surgical valve and feeling a vibration or shutter through the shaft of the non-compliant balloon.

The pressures required to achieve BVF go well beyond the rated burst pressure of current non-compliant balloons (21). Balloon failure occurs in approximately 10% of cases and can mimic successful BVF with a drop in indeflator pressure. If the indeflator pressure acutely drops prior to reaching the predicted BVF fracture threshold, balloon failure has likely occurred. Balloon failure can be from rupture, which is always apparent, or more commonly, from a pin hole leak, occurring where the catheter enters or exits the balloon. A balloon failure from a pin hole leak will cause an acute drop in the indeflator pressure and mimic valve fracture. Pin hole leaks, unlike ruptures, do not cause a vibration in the shaft of the non-compliant balloon thus, a drop in the indeflator pressure without a vibration felt in the balloon shaft indicates balloon failure, not fracture. In addition, if the indeflator pressure drops acutely below the anticipated fracture threshold for a given surgical valve and continued inflation does not result in a pressure increase, then balloon failure has also likely occurred from a pin hole leak. If balloon failure is confirmed by removing and examining the balloon under pressure, then a new balloon should be prepped and BVF performed again.

The variability in fracture thresholds among surgical valves is directly related to the material used in the surgical valve frame. Recently, it has come to our attention that the Mosaic valve has been manufactured with two different materials and behaves differently during BVF depending on the material used to manufacture the frame. In our initial bench testing, the frame of the Mosaic valve was made of Delrin (acetal homopolymer resin) which is easily fractured at approximately 10-12 ATM (14). Although reported by Medtronic, it is not widely known that Mosaic valves have also been manufactured using the high-performance thermoplastic polyetheretherketone (PEEK) (personal communication, Medtronic). PEEK, when used in large amounts, such as in Medtronic's Avalus valve, cannot be fractured. However, the smaller amount used in the Mosaic valve, while still not allowing it to be fractured, does allow it to be stretched. During BVF on a Mosaic valve, if the fracture threshold is reached (~10-12 ATM) and nothing has happened then the frame may be made of PEEK; continue to increase the inflation device pressure and at about 18 ATM, the valve frame will begin to stretch. Continue the inflation to approximately 22 ATM at which point maximum expansion should be obtained.

THV valve/balloon selection

Initial *in vitro* testing demonstrated that BVF results

in an increase of 3–4 mm in the internal diameter of surgical valves with labeled valve sizes of 19 and 21 mm, respectively (14). Additional bench testing (unpublished) has demonstrated that expansion of 5 mm can be achieved in larger labeled valve sizes (23 and 25 mm) and clinical experience (13,16) suggests that a 6 mm increase in diameter can be obtained following BVF in larger (≥27 mm) surgical valves. The selection of balloon size when performing BVF is an important consideration in achieving optimal outcomes and is dependent on understanding how much expansion will occur following BVF. Although BVF can be performed with any balloon larger than the true ID of the surgical valve, this will result in higher fracture pressure, less optimal expansion of the TAVR prosthesis and may negatively impact valve hemodynamics. In a recent retrospective study, the use of a balloon that was at least 3 mm larger than the true ID of the surgical valve was an independent predictor of a lower final transvalvular gradient (18). Our prior advice to use a balloon 1 mm larger than the labeled valve size is no longer appropriate, rather, the balloon size should be determined by the THV used, the true ID of the surgical valve and its anticipated increase in diameter following fracture, the anatomy of the aortic root and LVOT, and the location of the coronary arteries.

Using non-compliant balloons to perform BVF that are larger than previously recommended may allow more optimal expansion of the THV to its nominal size and/or allow placement of a larger than previously recommended THV. Assuming the virtual valve to coronary (VTC) distance supports BVF, the following example illustrates the concept of using a larger balloon to fully expand the THV. For example, if the true ID of the failing surgical valve was 19 mm we would anticipate a 3–4 mm increase in diameter following BVF and would select a 23 mm THV for VIV TAVR. In the case of a 23 mm Sapien, we would then perform BVF with a 23 mm non-compliant balloon in order to fully expand the 23 mm THV. With a Sapien, the BVF balloon can be right sized to the THV (i.e., a 26 mm balloon can be used safely in a 26 mm Sapien). If in the prior example a 23 mm CoreValve was implanted both balloon size and balloon placement during BVF are critical to avoiding injury to the THV leaflets (14). With CoreValve, it is only safe to use a balloon that is at most 2 mm larger than the 'constrained area' of the THV and to position the shoulder of the balloon below the level of the constrained area on the CV (14). Thus, the largest balloon that should be used during BVF with a 23 mm CV is 22 mm, a 26 mm CV is 24 mm and a 29 mm CV is 25 mm.

This example illustrates how 'upsizing' or placing a larger THV than recommended might be accomplished assuming coronary obstruction was not in play. If, for example, VIV is being performed on a larger surgical valve with a true ID of 21 mm, you would anticipate an increase in diameter following BVF of 4–5 mm. Therefore a 26 mm Sapien THV could be implanted and fractured with a 26 mm non-compliant balloon or a 26 mm CoreValve could be implanted and fractured with an appropriately positioned 24 mm balloon.

Coronary obstruction is an elemental risk during VIV TAVR and this risk is augmented by the addition of BVF (22,23). Mitigating this risk requires a detailed understanding of the anticipated expansion of the surgical valve following BVF and its effect on the VTC distance as well as the risk of sequestration at the sinotubular junction. Determining the 'virtual' THV to coronary distance with a virtual valve and anticipating the ~4 mm increase in diameter of the surgical valve following BVF is an important procedural planning step for avoiding coronary obstruction. The use of coronary protection strategies to avoid coronary obstruction are sometimes needed during VIV TAVR even without the addition of BVF.

Bioprosthetic fracture: before or after VIV TAVR

The timing of BVF, either before or after TAVR, remains controversial (3). While performing BVF after VIV TAVR provides the most optimal expansion of the THV, it does expose the THV to the high-pressure balloon inflation, which could cause acute or subacute injury to the THV, impacting durability. On the other hand, performing BVF first may increase the risk of embolization of debris from the degenerated surgical valve and cause acute valvular insufficiency leading to hemodynamic instability. The timing of BVF and the potential effect of high-pressure balloon inflation on Sapien 3 THV leaflets was evaluated in an accelerated leaflet calcification animal model (24). No acute THV injuries and no difference in leaflet calcification were noted between the BVF before and after groups (P=0.8).

Our recommendation is to perform BVF after VIV TAVR, which we feel is safer and also, ensures optimal expansion of the THV. In the case of balloon expandable THV's, the compliant delivery balloon is not robust enough to fully expand the THV in the already fractured surgical valve (14). When BVF is performed after TAVR with a balloon expandable THV, the non-compliant balloon both

fractures the surgical valve and fully expands the already implanted THV (14). In the case of a self-expanding THV, *in vitro* bench testing suggested it was capable of full expansion in a previously fractured non degenerated surgical valve (14). *In vivo* however, the self-expanding THV may not have enough radial force to fully expand a degenerated and calcified surgical valve, even if already fractured (18). When using a self-expanding THV, if BVF is performed first a high-pressure balloon inflation may still be required to achieve optimal expansion of the THV although at a lower pressure than was required to fracture the surgical valve initially (18). In a multivariable analysis of 75 BVF cases, performing BVF after performing VIV TAVR was an independent predictor ($P<0.0001$) of lower final mean transvalvular gradient, presumably due to more optimal expansion of the THV (18).

One question that is often asked is whether BVF can be performed weeks or even months after the initial VIV TAVR if transvalvular gradients are noted to be increasing. Assuming that rising gradients are not felt to be related to leaflet thrombosis, anecdotal reports suggest that late BVF (up to one year) can be successfully performed for patients who experience deterioration in initially favorable valve hemodynamics following VIV TAVR (20,25,26). While failure to optimally expand the THV at the initial VIV TAVR might be corrected with delayed BVF, the damage to the leaflets that may have occurred in the interim is unlikely to be reversed by delayed BVF, potentially leading to premature failure of the THV. This raises the question as to whether BVF should be performed in all VIV cases where the surgical valves can be fractured regardless of the final mean gradient, in order to optimally expand the THV; this is our current practice.

BVF was initially conceived as a solution to high residual gradients following VIV TAVR however, optimal expansion of the THV may be just as important. Suboptimal expansion of a THV following VIV TAVR may lead to leaflet dysfunction and 'pin wheeling', which may decrease THV durability (4). Pin-wheeling refers to the 'pleated' appearance of the free edges of the redundant leaflets caused by under expansion of the valve (27). Pinwheeling which is often seen in the leaflets of a constrained THV may result in premature degeneration of the bioprosthetic leaflets, even in the setting of normal residual transvalvular gradients (26,28). Bench testing has demonstrated that BVF reduces pinwheeling through optimal expansion of the THV (3). We currently perform BVF on all valves that can be fractured where the THV is not optimally expanded even if residual gradients are not high in order to optimize leaflet function. This might provide a THV durability benefit in all patients who undergo VIV TAVR, regardless of the size of the surgical valve or risk of PPM. However, this hypothesis will require further study and longer follow-up.

Safety of BVF

Complications have been reported following BVF which have included annular rupture, acute damage to the THV, damage to the mitral valve, THV embolization, iatrogenic ventricular septal defect, atrioventricular (AV) block requiring permanent pacemaker, coronary artery obstruction and stroke (29). Annular rupture is a significant concern with BVF but has been rarely reported (18). The ability to fracture and expand a surgical valve without injury to the native annulus is likely related to the fact that most surgical valves are implanted supra-annular rather than intra-annular and, that calcium is debrided from the annulus and left ventricular outflow tract (LVOT) at the time of surgery allowing expansion of the surgical valve into the aortic sinuses. However, the anatomy of the aortic root and LVOT must be assessed before BVF is considered. We do not recommend BVF in valves implanted intra-annularly, such as rapid deployment valves, or in patients that have had a root replacement or formal root enlargement. In many instances, complications occurred early in the BVF experience and could have been avoided with more appropriate BVF technique as outlined previously. In a recent report from twenty-one experienced TAVR centers who performed BVF in seventy-five patients, there were no coronary occlusions, no annular ruptures and no new pacemakers with durability of results persistent at one-year (18,19).

Bioprosthetic fracture: future studies

While the focus of BVF has been in the aortic space, BVF may have utility in VIV pulmonary, mitral and tricuspid cases as a means to potentially reduce the incidence of VIV induced PPM (17,30-34). Although bench studies and clinical experience with BVF in the aortic position is known, particularly in small surgical valves, this knowledge may not extrapolate to larger valves that are frequently used in the tricuspid and mitral position. While safety concerns and efficacy with BVF in VIV mitral and tricuspid cases requires further study, there are also practical concerns to doing BVF in these larger valves.

Currently, the largest non-compliant balloon available for performing BVF has a diameter of 28 mm. In the aortic position, the availability of balloon sizes is adequate, as even in the largest surgical aortic valves, the true ID is exceeded by the true ID of the non-compliant balloon. This, however, is not the case with mitral and tricuspid valves, where the true ID of the surgical valve is often larger than the largest non-compliant balloon. While the bench top use of a 'kissing balloon' technique to fracture larger surgical valves is feasible, it is not very clinically practical (14). In addition to not having large enough balloons, the manufacturing parameters for non-aortic surgical valves are often dissimilar to their matched aortic counterparts. For example, a 27 mm aortic Magna Ease has a true ID of 25 mm and can be fractured with a 28 mm non-compliant balloon. On the other hand, a 27 mm mitral Magna Ease has a true ID of 26 mm and while it has a similar-looking metal ring to the aortic valve, it is actually slightly thicker (personal communication, Edwards) and, cannot be fractured with current balloons. Industry support from THV and balloon manufactures is needed to better understand such limitations of BVF and to optimize the procedure (35).

Conclusions

BVF, as an adjunct to VIV TAVR, appears safe when performed correctly and results in an unconstrained THV with improved hemodynamics, particularly; in small surgical valves thus, reducing the risk of severe PPM. Where feasible, we perform BVF in all cases regardless of the presence or severity of the residual gradient following VIV TAVR to optimally expand the THV. However, the BVF's effect on THV durability and long-term clinical outcomes requires further investigation. The expansion of BVF into the VIV mitral and tricuspid space, where even small reductions in gradients may yield significant benefits, is the next frontier that is just beginning to be explored.

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Footnote

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