Bioprosthetic Valve Fracture During ViV TAVR

A step-by-step practical guide for performing BVF to facilitate ViV TAVR.

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Recent studies have demonstrated the safety and efficacy of valve-in-valve transcatheter aortic valve replacement (ViV TAVR) as an alternative to reoperation for patients with failed bioprosthetic surgical valves (BSVs). These data have led to the approval of ViV TAVR by the FDA for patients with a failed aortic bioprosthesis who are at high risk of complications related to reoperation.[1,2]

In the VIVID registry, 1-year survival after ViV TAVR was 83.2%. However, survival was significantly lower among patients with small BSVs and those with predominant surgical valve stenosis.[3] These worse clinical outcomes were likely driven by suboptimal postprocedural hemodynamics after ViV TAVR.[1-3] Indeed, mean gradients > 20 mm Hg indicate severe prosthesis-patient mismatch, which has been observed in up to 32% of patients undergoing ViV TAVR.[3] The risk of prosthesis-patient mismatch is higher in ViV TAVR because the transcatheter heart valve (THV) is constrained by the BSV sewing ring and the maximum achievable effective orifice area (EOA) is limited by the true internal diameter (ID) of the BSV. Although optimal THV selection and precise positioning may improve procedural results,[4-7] prosthesis-patient mismatch can occur with any THV and despite optimal deployment.

Bioprosthetic valve fracture (BVF) is a method to facilitate ViV TAVR in which the surgical valve ring is fractured with high-pressure balloon inflation, allowing for more optimal THV expansion, thus significantly improving postprocedural gradients and EOA.[7-9] The safety and efficacy of BVF have been demonstrated in multiple case series. However, the long-term impact of BVF on clinical outcomes and THV durability is still to be determined.[7-9] In this article, we focus on a step-by-step practical guide for performing BVF to facilitate ViV TAVR.

PREPROCEDURAL EVALUATION

Bioprosthetic Valve Type and Size

Patients who are expected to benefit the most from BVF are those with small BSVs (labeled valve size ≤ 21 mm) and/or stenosis as the mechanism of BSV failure, who are at risk for prosthesis-patient mismatch and high residual transvalvular gradients after ViV TAVR.[3,7] It is to be determined if patients with larger BSVs (labeled valve size > 21 mm) or intermediate transvalvular gradients (10–20 mm Hg) after ViV TAVR stand to benefit from BVF. In theory, because BVF results in more optimal expansion of the THV, BVF may also result in more optimal leaflet function and enhanced durability in all patients who undergo ViV TAVR.

Bench testing and clinical experience have demonstrated that many BSVs can be fractured, and others can be stretched or remodeled, which will be discussed later in this article. BSVs that can consistently be fractured include Magna (Edwards Lifesciences), Magna Ease (Edwards Lifesciences), Mitroflow (Sorin Group), Mosaic (Medtronic), newer-generation Perimount (Edwards Lifesciences), and Biocor Epic (Abbott). BSVs that cannot be fractured but can be remodeled are the Trifecta (Abbott), Carpentier-Edwards standard and supra-annular (Edwards Lifesciences), Inspiris (Edwards Lifesciences), and older-generation Perimount (Edwards Lifesciences). Finally, some valves, such as the Hancock II (Medtronic) and Avalus (Medtronic), cannot be fractured or remodeled (Table 1).[7,9-11] The fracture pressure for BSVs with alloyed metal ribbon rings (eg, Magna, Magna Ease) is higher (18–24 atm) compared to valves with a polymer ring (eg, Biocor Epic, Mosaic, Mitroflow; 8–12 atm).[7,9,12] It has been suggested that BVF results in an increase of 3 to 4 mm in the ID of the surgical valves with labeled valve sizes of 19 and 21 mm, respectively.[9,12]

THV Selection

THV selection for ViV TAVR is guided by the true ID of the bioprosthetic valve rather than the labeled surgical valve size.[13] The true ID can be obtained from the manufacturer or from the "ViV Aortic" phone application developed by UBQO Ltd. and Dr. Vinayak Bapat. Because BVF results in expansion of the bioprosthetic valve ring,

TABLE 1. BIOPROSTHETIC VALVES THAT CAN BE FRACTURED OR REMODELED WITH HIGH-PRESSURE BALLOON INFLATION AND THOSE THAT CANNOT[11]	
Valves that can be fractured	Biocor Epic, Mosaic, Magna, Magna Ease, Mitroflow, and newer-generation Perimount valves
Valves that can be remodeled	Trifecta, Carpentier-Edwards standard, Carpentier-Edwards supra-annular, older-generation Perimount, and Inspiris valves
Valves that cannot be fractured or remodeled	Hancock II and Avalus valves

THV selection should be based on the anticipated 3- to 4-mm increase in the true ID. For example, a 21-mm Magna BSV has a true ID of 19 mm and an expected ID of 22 to 23 mm after BVF. Thus, a 23-mm THV should be well expanded after BVF and have a better hemodynamic profile compared to a 20-mm THV.

The question remains whether to use a THV that can be optimally expanded after BVF or to up-size to a larger THV (a 26-mm THV as opposed to the 23-mm THV in the previous example), hoping to achieve a larger EOA and superior hemodynamics. Bench testing has suggested that a larger prosthesis, even if expanded to a less than nominal diameter, may result in a more favorable transvalvular gradient.[14] However, in a recent retrospective multicenter study of 75 patients treated with ViV TAVR and BVF, upsizing the THV did not result in a difference in final mean gradient or EOA after BVF.[15] Additionally, THV type was not associated with any difference in the final mean gradient after BVF,[15] contrary to previous data suggesting that the incidence of high residual gradients after ViV TAVR is lower with CoreValve (Medtronic), which has supra-annular leaflets, than with Sapien (Edwards Lifesciences), which has intra-annular leaflets.[2,3,14,16,17] These findings suggest that if there is any hemodynamic downside to using intra-annular THVs during ViV TAVR, it may be overcome by performing BVF and optimally expanding the THV.

BVF Balloon Selection

During bench testing studies, BVF was performed using noncompliant balloons sized 1 mm larger than the labeled valve size.[9,10] Although BVF can be performed using smaller balloons (ie, any balloon larger than the true ID of the bioprosthetic valve), this may result in less optimal expansion of the TAVR prosthesis and negatively affect valve hemodynamics.[12] In a recent retrospective study, performing BVF after ViV TAVR and using a noncompliant balloon that was at least 3 mm larger than the true ID of the surgical valve were independent predictors of achieving a lower final transvalvular gradient.[15] These findings are likely related to more optimal THV expansion. Importantly, if BVF is performed after CoreValve implantation, it is only safe to use a balloon that is at most 2 mm larger than the THV waist (the waist is 20, 22, 23, and 24 mm, respectively, for CoreValve Evolut Pro/R [Medtronic] 23-, 26-, 29-, and 34-mm THVs). Ideally, the proximal shoulder of the balloon should be placed distal to the waist of the CoreValve during BVF. In the previously used example, the 21-mm Magna valve should be fractured with a 22- or 23-mm balloon if a 23-mm Sapien valve is used, or a 22-mm balloon if a 23-mm CoreValve is used. The most frequently used balloons are True Dilatation (BD Interventional) and Atlas Gold (BD Interventional). The size (and presence of calcification) of the left ventricular outflow tract, coronary sinuses, and sinotubular junction should also be carefully assessed when evaluating a patient for suitability for BVF and selecting the size of the balloon that is used.

INTRAPROCEDURAL CONSIDERATIONS AND TECHNIQUE

Given the prolonged pacing run that is required during BVF, it may be advisable to perform these procedures under general anesthesia. In addition, general anesthesia provides a more controlled environment during the procedure and allows for more rapid treatment in case of complications.[18] If general anesthesia is utilized, we also recommend using transesophageal echocardiography guidance, which is useful in demonstrating adequate THV expansion and leaflet excursion, in addition to detecting potential complications early.

Whether BVF is optimally performed before or after implantation of the TAVR prosthesis is not clear. Fracture of the bioprosthetic ring prior to ViV TAVR may be justified to avoid subjecting the THV to high-pressure balloon inflation. On the other hand, this strategy may increase the risk of embolization of debris from the degenerated BSV and acute valvular insufficiency leading to hemodynamic compromise. We perform ViV TAVR prior to BVF, which allows for assessment of the postimplantation hemodynamic profile before deciding whether BVF should be performed. Furthermore, if BVF is performed after ViV TAVR, the high-pressure inflation ensures optimal expansion of the THV. However, there is concern that BVF performed within the implanted THV may also lead to acute or subacute leaflet damage, affecting long-term durability.[9,15,18] In a multivariable analysis of 75 BVF cases, performing BVF after implantation of ViV TAVR was an independent predictor of lower final mean transvalvular gradient, presumably due to more optimal expansion of the THV with this strategy.[15]

Optimizing THV implantation depth is very important for minimizing residual gradients, and the intention to

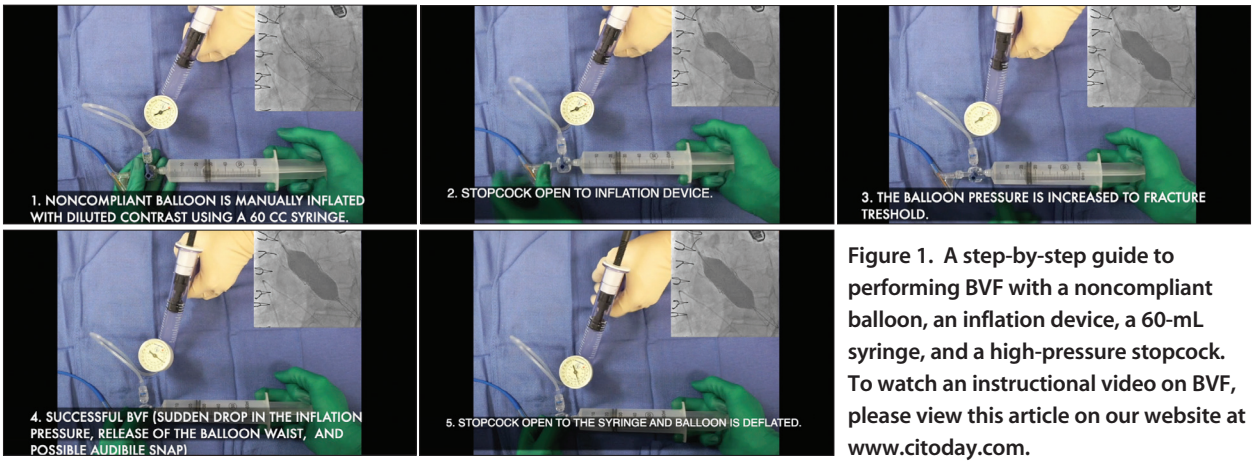

Figure 1. A step-by-step guide to performing BVF with a noncompliant balloon, an inflation device, a 60-mL syringe, and a high-pressure stopcock. To watch an instructional video on BVF, please view this article on our website at www.citoday.com.

perform BVF to facilitate ViV TAVR should not change the depth of implantation. High implantation in relation to the valve frame results in more favorable hemodynamic results.[5,6,17,19]

Bioprosthetic Valve Fracture

To perform BVF (Figure 1; Table 2), the following equipment is needed: (1) a noncompliant balloon (True Dilatation balloon or Atlas Gold balloon are most commonly used); (2) a high-pressure stopcock; (3) an inflation device; and (4) a 60-mL syringe filled with diluted contrast.

During rapid ventricular pacing, the noncompliant balloon is inflated by hand using the 60-mL syringe with diluted contrast. The stopcock is then opened to the inflation device and the balloon pressure is increased to the fracture threshold. BVF is noted by a sudden drop in the inflation pressure on the inflation device gauge, which is frequently accompanied by an audible snap. The balloon is then removed and examined to ensure that the drop in inflation pressure was not secondary to balloon failure or rupture. Successful BVF is noted fluoroscopically as release of the balloon waist, but this is not always obvious. The valve is assessed with echocardiography, and repeat hemodynamic measurements are obtained to ensure optimal expansion of the THV and satisfactory drop in the transvalvular gradient. If the mean gradient is still elevated and the valve was not fractured, the maneuver can be carefully repeated. If gradients remain elevated after successful BVF, postdilation to further expand the THV may be performed with hand inflation of a slightly larger balloon if the anatomy permits.

Bioprosthetic Valve Remodeling

Not all BSVs can be fractured with high-pressure balloon inflation. Bioprosthetic valve remodeling (BVR) is a technique similar to BVF in which high-pressure balloon inflation is performed to allow for better expansion of the THV inside the surgical valve.[20] BSVs that can be remodeled include Trifecta, Carpentier-Edwards standard and supra-annular, Inspiris, and older-generation Perimount (Table 1).[11]

TABLE 2. BVF/BVR: EQUIPMENT NEEDED AND A STEP-BY-STEP GUIDE

EQUIPMENT
▪ Noncompliant balloon (True Dilatation or Atlas Gold balloons are most commonly used)
▪ High-pressure stopcock (attached to the balloon port, the inflation device, and the syringe)
▪ Inflation device
▪ 60-mL syringe filled with diluted contrast
STEPS
1. The noncompliant balloon is appropriately positioned (Sapien: balloon centered on the valve; CoreValve: proximal shoulder of the balloon distal to the THV waist)
2. Rapid ventricular pacing is initiated
3. With the stopcock open to the syringe, the noncompliant balloon is inflated by hand injection using a 60-mL syringe with diluted contrast
4. The stopcock is opened to the inflation device
5. Using the inflation device, the balloon pressure is increased to the fracture threshold (for BVF) or until the balloon and valve are fully expanded (for BVR)
6. Successful BVF (sudden drop in the inflation pressure, release of the balloon waist, possible audible snap)
7. The balloon is deflated and removed, pacing is stopped

Abbreviations: BVF, bioprosthetic valve fracture; BVR, bioprosthetic valve remodeling; THV, transcatheter heart valve.

The frame and ring of the Carpentier-Edwards, older-generation Perimount, and Inspiris BSVs are stretchable. BVR in these valves is performed using high-pressure balloon inflation of an appropriately sized balloon for optimal THV expansion, similar to BVF. In doing this, the balloon pressure should be increased until the balloon and THV waist are eliminated. On the other hand, BVR in the Trifecta valve results in oblique distortion of the valve posts, but the valve ring does not stretch. To perform BVR in a Trifecta valve, a balloon 2 to 4 mm larger than the true ID of the valve is typically inflated to intermediate pressure (10–14 atm), allowing for better expansion of the THV and improved hemodynamic profile.

Complications

In the largest published clinical study of BVF to date, there were few complications. Two patients had periprocedural cerebrovascular events (day 3 and day 4 after the procedure), with complete resolution of neurologic deficits. Whether these events were related to BVF or just a consequence of ViV TAVR itself cannot be determined. Two patients had severe THV regurgitation after BVF and were successfully treated with placement of a second THV. One patient developed severe mitral regurgitation with flail anterior leaflet and was successfully treated with transcatheter mitral valve repair.[15] THV migration, iatrogenic perimembranous ventricular septal defect, and delayed coronary obstruction have also been reported.[18] It is important to acknowledge that the clinical experience is early and other theoretical risks exist, including annular rupture, aortic root injury, conduction anomalies, and paravalvular leak; however, none have been reported in published case series.[7,8,21]

The risk of coronary obstruction in ViV TAVR is a significant concern, and its incidence was reported to be as high as 3.5% during early experience in the VIVID registry.[22] This risk can be anticipated by measuring the virtual THV-to-coronary distance on CT. It has been suggested that a virtual THV-to-coronary distance of < 4 mm infers a high risk for coronary obstruction.[23] Other risk factors for coronary obstruction include narrow coronary sinuses, low coronary artery height, bulky bioprosthetic valve leaflets, and type of BSV (ie, those with leaflets mounted external to the valve frame).[22] If the risk of coronary obstruction is high, coronary protection measures should be considered. Whether BVF increases the risk of coronary artery obstruction during ViV TAVR is unknown.

CONCLUSION

BVF as an adjunct to ViV TAVR is safe and effective. It allows for optimal THV expansion and improved hemodynamic profile, particularly in small, stenotic BSVs. Many surgical valves are amenable to BVF, while some others can be stretched or remodeled. However, the long-term outcomes of BVF and BVR and their effect on THV durability are yet to be determined. ■

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