Bioprosthetic Valve Fracture to Facilitate Transcatheter Valve-in-Valve Implantation

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Background. Valve-in-valve transcatheter aortic valve replacement is less effective in small surgical bioprostheses. We evaluated the feasibility of bioprosthetic valve fracture with a high-pressure balloon to facilitate valve-in-valve transcatheter aortic valve replacement.

Methods. In vitro bench testing on aortic tissue valves was performed on 19-mm and 21-mm Mitroflow (Sorin, Milan, Italy), Magna and Magna Ease (Edwards Lifesciences, Irvine, CA), Trifecta and Biocor Epic (St. Jude Medical, Minneapolis, MN), and Hancock II and Mosaic (Medtronic, Minneapolis, MN). High-pressure balloons Tru Dilation, Atlas Gold, and Dorado (C.R. Bard, Murray Hill, NJ) were used to determine which valves could be fractured and at what pressure fracture occurred.

Results. Mitroflow, Magna, Magna Ease, Mosaic, and Biocor Epic surgical valves were successfully fractured using high-pressure balloon 1 mm larger than the labeled valve size whereas Trifecta and Hancock II surgical valves could not be fractured. Only the internal valve frame was fractured, and the sewing cuff was never disrupted. Manufacturer’s rated burst pressures for balloons were exceeded, with fracture pressures ranging from 8 to 24 atmospheres depending on the surgical valve. Testing further demonstrated that fracture facilitated the expansion of previously constrained, underexpanded transcatheter valves (both balloon and self-expanding) to the manufacturer’s recommended size.

Conclusions. Bench testing demonstrates that the frame of most, but not all, bioprosthetic surgical aortic valves can be fractured using high-pressure balloons. The safety of bioprosthetic valve fracture to optimize valve-in-valve transcatheter aortic valve replacement in small surgical valves requires further clinical investigation.

T transcatheter aortic valve replacement (TAVR) is an effective treatment for patients with severe symptomatic aortic valve stenosis who are at intermediate or high risk for surgical aortic valve replacement [1–4]. In addition, the treatment of failing surgical bioprostheses with VIV TAVR is currently approved by the Food and Drug Administration for appropriately selected patients after heart team evaluation. Although VIV TAVR is becoming more common, data from the Valve-in-Valve International Data (VIVID) Registry demonstrate that high residual gradients (>20 mm Hg) are more common and 1-year mortality higher after VIV TAVR in patients with small and intermediate-size surgical valves as compared with larger surgical valves [5]. In addition to the negative impact of high residual gradients after VIV TAVR in small valves, the failure of a transcatheter valve to fully expand to its intended size may have long-term consequences on transcatheter valve durability.

Bioprosthetic valve fracture (BVF) using a high-pressure balloon (HPB) to facilitate expansion of the transcatheter valve has been reported in isolated cases [6–8]. To date, however, there has been no systematic bench testing of surgical tissue valves to determine which valves can be fractured or the balloons and pressures needed to accomplish this procedure. In addition, the ability to optimize transcatheter valve expansion to the manufacturer’s specifications with BVF is unknown.

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Material and Methods

Aortic tissue valves commercially available in the United States were used in this study and included Mitroflow (Sorin, Milan, Italy), Magna and Magna Ease (Edwards Lifesciences, Irvine, CA), Trifecta and Biocor Epic (St. Jude Medical, Minneapolis, MN), and Hancock II and Mosaic (Medtronic, Minneapolis, MN). Both 19-mm and 21-mm labeled valve sizes were tested for each valve, with the exception of Biocor and Hancock II valves, which are not available in a 19-mm size. Commercially available HPBs were used to determine which valves could be fractured and at what pressure fracture occurred. Fluoroscopy and video documented the testing. Pittsburgh digital calipers (Harbor Freight) with an accuracy ±0.2 mm were used for all measurements.

High-pressure balloon inflation was performed utilizing Tru Dilation and Atlas Gold balloons (C.R. Bard, Murray Hill, NJ) with a single-balloon technique (Fig 1A). The balloon size selected for attempted fracture was 1 mm larger than the labeled surgical valve size (ie, a 21-mm valve was fractured with a 22-mm balloon). The true internal diameter of the valve was not used to determine balloon size. For valves that failed to fracture with a single balloon (owing to balloon rupture), an additional attempt was made using a “kissing” double balloon technique (Fig 1B) with two Dorado balloons (C.R. Bard) whose combined diameter was 1 mm larger than the labeled valve size (ie, in a 21-mm valve, 10-mm and 12-mm Dorado balloons were utilized). Finally, if the double balloon technique was unsuccessful in fracturing the sewing ring, then serially larger balloons to 26 mm were used to attempt fracture.

The setup for HPB inflation using an Encore inflator (Boston Scientific, Marlborough, MA) is illustrated in Figure 2. The technique consisted of placing the balloon within the surgical prosthesis and inflating to its maximum by hand injection using a syringe, then finishing the high-pressure inflation with the indeflator. The BVF was characterized by a release of the balloon waist and a sudden drop in the inflation pressure on the indeflator gauge (Video 1). The BVF was often accompanied by an audible snap (Video 2). The threshold pressure required to achieve BVF was recorded in atmospheres (atm). Fluoroscopy of the fractured prosthesis was performed to demonstrate the architecture of the valve components and the mechanism of structural failure. When the fracture site could not be visualized fluoroscopically (Biocor Epic and Mitroflow), the Dacron (C.R. Bard) fabric covering the valve frame was removed to better visualize the fracture site.

To determine how transcatheter valves would expand within fractured valves, 23-mm Evolut R (Medtronic) and 23-mm Sapien XT and Sapien 3 (Edwards Lifesciences) transcatheter valves were deployed in both intact and fractured 21-mm Magna surgical valves and digital calipers were utilized to measure transcatheter valve dimensions.

Funding

Surgical tissue valves used in this study were requested from all manufacturers and provided without charge from Sorin, Medtronic, and St. Jude; Edwards’ surgical tissue valves were obtained from surgical stock. The HPBs used in this study were obtained from catheterization laboratory stock. Transcatheter valves in this study were obtained from surgical stock or from valve clinic samples used for patient and fellow education.

Results

Figure 3 summarizes the bench testing results of using HPB inflation to perform BVF. The Mitroflow, Magna, Magna Ease, Biocor Epic, and Mosaic valves were successfully fractured using both Tru Dilation and Atlas Gold balloons, whereas Trifecta and Hancock II surgical bioprostheses could not be fractured using any HPB inflation technique (balloon rupture occurred before fracture during all attempts). Although all valves with plastic stent frames could be fractured, the ability to fracture valves with metal in their frames varied. The metal frame of the Hancock II and the titanium frame in the Trifecta prevented fracture, whereas the Elgiloy alloy (cobalt-chromium-nickel-molybdenum) in the Magna

Fig 1. (A) High-pressure balloon (HPB) inflation was performed with a single-balloon technique. Balloon size was 1 mm larger than the labeled surgical valve size. If HPB inflation with a single balloon did not result in valve ring fracture, then an additional attempt was made using (B) a “kissing” double balloon technique with two Dorado balloons (C.R. Bard, Murray Hill, NJ) whose combined diameter was 1 mm larger than the labeled valve size.
and Magna Ease could be fractured. Inflation pressure required for BVF ranged from a low of 8 atm (Biocor Epic) to a high of 24 atm (Magna) but was the same with either Tru Dilation or Atlas Gold balloons (Fig 3); the manufacturer’s rated burst pressures for HPBs were exceeded in all scenarios. Larger prosthesis diameter did not have an effect on the threshold required for BVF. The pressures reported to fracture each surgical valve reflect the surgical valve being fractured without a transcatheter valve in place.

After HPB inflation, the fracture point in the surgical valve was easily palpated through the intact Dacron sewing cuff. In all fractured valves, only the valve frame was fractured, and the Dacron sewing cuff was never torn or disrupted. The rigid frame in some valves is radiopaque and on fluoroscopy during BVF of a Magna (Video 3), Magna Ease (Video 4), and Biocor Epic, a single point of fracture was observed. In contrast, Mosaic and Mitroflow valves have radiopaque markers within the sewing ring but the valve frame itself is not visible under fluoroscopy. After fracture of both of these valves, the Dacron sewing ring was removed, demonstrating a single fracture point, as illustrated with the Mitroflow valve in Figure 4.

Deployment of a 23-mm self-expanding Evolut R (optimal inflow expansion 23 mm) in an intact 21-mm Magna surgical valve resulted in constraint of the transcatheter valve to 19 mm, which represents the true internal diameter of the surgical valve (Figs 5A–D). However, when the same 23-mm Evolut R was deployed in a fractured 21-mm Magna surgical valve, the transcatheter valve expanded to its intended diameter of 23 mm (Figs 5E–G).

Similarly, when a 23-mm balloon expandable Sapien XT valve (optimal expansion 23 mm) was deployed in an intact 21-mm Magna surgical valve, the transcatheter valve was constrained by the surgical valve and expanded only to 19.1 mm (Figs 6A, 6B). After deployment of the 23-mm Sapien XT in a fractured 21-mm Magna surgical valve using only the compliant delivery balloon, the transcatheter valve remained slightly underexpanded at 22.3 mm (Fig 6C). Optimal expansion to 23 mm was accomplished after dilating the valve using a 24-mm noncompliant balloon with high pressure inflation (Fig 6D).

We performed similar bench testing using a 23-mm Sapien 3 deployed in both an intact and fractured 21-mm Magna surgical valve. After BVF, optimal expansion of the Sapien 3 valve to its intended size of 23 mm occurred only after dilating the valve using a 24-mm noncompliant balloon with high pressure inflation. After BVF of 19-mm and 21-mm surgical valves, an increase in

Fig 2. (A) Initial setup for high-pressure balloon (HPB) inflation consists of a large syringe, inflator, and high-pressure tubing and stop cock. (B) The HPB is rapidly filled with a syringe (1) and then the stopcock (2) is turned to allow the inflator to further pressurize the balloon to desired atmospheres. Successful valve fracture is characterized by a sudden drop in the pressure on the inflator gauge and often accompanied by an audible snap.
diameter of 3 mm and 4 mm, respectively, can be achieved; the intact, unbroken Dacron sewing appears to limit any greater expansion. Larger (23 mm to 27 mm) surgical valves were not tested. The utility of this bench testing is illustrated by the following case.

**Clinical Scenario**

A 76-year-old man with a history of surgical aortic valve replacement 8 years earlier presented with New York Heart Association functional class IV heart failure in conjunction with a failing 21-mm Magna surgical valve. Echocardiography demonstrated an ejection fraction of 45% with a mean transvalvular gradient of 49 mm Hg. Cardiac catheterization demonstrated no indication for coronary revascularization. The Society of Thoracic Surgeons surgical mortality risk score was 12.2%, and the heart team recommended VIV TAVR using a 23-mm Evolut R transcatheter valve.

The VIV TAVR was successfully performed percutaneously through transfemoral access using general anesthesia. Transesophageal echocardiography demonstrated no valvular insufficiency; however, postimplant hemodynamics demonstrated a residual mean gradient of 30 mm Hg. The transcatheter valve was postdilated with a 20-mm Tru Dilation balloon using manual inflation with a syringe, with a reduction of the mean gradient to 24 mm Hg. Considering the persistent high residual gradient, BVF was successfully performed using a 22-mm Tru Dilation balloon with HPB inflation, with fracture occurring at 24 atm. Hemodynamics after BVF demonstrated a reduction
of the mean transvalvular gradient to 5 mm Hg. There were no intraoperative or postoperative complications, and the patient was discharged to self-care on postoperative day 1. Computed tomography without contrast 1 month after the procedure demonstrated a fully expanded transcatheter valve within the fractured valve ring (Fig 7).

Comment

This report represents the first systematic bench testing documenting the ability to use commercially available HPBs to perform BVF on most, but not all, commercially available bioprosthetic valves. Testing demonstrates that during HPB inflation the valve ring fractures while the Dacron sewing cuff remains intact, mitigating the potential for cardiac injury due to exposed metal or plastic. Although transcatheter valves deployed in intact surgical tissue valves are clearly constrained (and thus underexpanded), both balloon expandable and self-expandable transcatheter valves appear to fully expand to their intended dimensions when deployed in fractured surgical valves.

Although the results with VIV TAVR are reasonable considering the patient population, results from the Valve-in-Valve International Data Registry demonstrated overall 1-year survival of only 83.2% [5]. Key patient variables that were associated with greater 1-year mortality included small surgical bioprostheses and valve failure mode of stenosis rather than insufficiency [5]. The difference in 1-year mortality after VIV TAVR in patients with small, intermediate, and large surgical valves (74.8% [27 of 84] versus 81.8% [26 of 118] versus 93.3% [7 of 80], respectively; p = 0.001) was attributed in part to suboptimal postprocedural hemodynamics in patients with small and intermediate sized surgical valves.

Prosthesis-patient mismatch (PPM) may play an important role in outcomes after VIV TAVR, particularly when performed in small surgical valves, as VIV TAVR further decreases the orifice of the surgical bioprosthesis.
In the aortic position, severe PPM is defined by an indexed effective orifice area of less 0.65 cm²/m²—a finding that was identified in 32% of patients surviving aortic VIV TAVR [5]. The presence of PPM is prognostically important, as PPM results in higher valve gradients and may increase perioperative and overall mortality [11]. In addition to the negative impact of high residual gradients after VIV TAVR in small and intermediate sized valves, the failure of a transcatheter valve to expand to its optimal size may have long-term consequences with respect to transcatheter valve durability.

In patients with small surgical valves with prosthetic stenosis, optimal therapy would involve reoperation with placement of a larger valve if PPM was a contributing factor. Root enlargement procedures are significant operations, particularly in patients thought to be at high risk for repeat surgery. Conventional techniques for avoiding high residual gradients after VIV TAVR include using a supraannular transcatheter valve and avoiding a deep implant [5]. These techniques appear only moderately effective, and therefore a new approach is needed to improve clinical outcomes with VIV TAVR, particularly in small surgical valves [5]. The BVF using a HPB to facilitate further expansion of the transcatheter valve and thus maximize its effective orifice area has been previously reported in isolated cases [6–8]. The initial experience with this technique was in treating failed right ventricular outflow tract conduits constructed with Edwards bioprostheses [8]. Additional cases of failed aortic and tricuspid bioprostheses have also been reported [6, 7]. The early clinical utility of this idea has been demonstrated in children with implantation of a surgical valve that is amenable to catheter-based enlargement as the child grows [12]. Finally, the potential value of this concept is reflected in ongoing device development by industry with patents already issued for surgical heart valves for adults adapted for postimplant expansion to accommodate transcatheter valves [13]. Despite these promising case reports and small series, ours is the first study to perform systematic bench testing of current surgical tissue valves to determine which valves can be fractured and the balloons and pressures needed to accomplish this procedure.

Our ex vivo study has yielded important observations, but also has raised many questions regarding the safety and optimal procedural technique for VIV TAVR in conjunction with BVF. Bench testing was performed on pristine valves; pannus and calcification that would be encountered with a degenerated surgical valve may alter the response to BVF during VIV TAVR. Concern is also warranted regarding the potential for BVF to cause aortic
root rupture or coronary artery occlusion. Further clinical studies will be required to address these concerns but prudence would suggest that heavily calcified aortic roots or preexisting concerns for coronary occlusion might preclude performing BVF. Knowledge of how the surgical valve was implanted (eg, whether supraannular or intraannular) may be important. Fracturing and expanding a surgical valve that was implanted in the supraannular position may offer a superior risk-benefit profile when compared with treatment of a surgical valve that was positioned in the native annulus.

Whether self-expanding or balloon expandable transcatheter valves are better suited for this application is unknown. One difference between devices is that the radial force of a self-expanding valve appears to be adequate to allow optimal expansion of the transcatheter valve inside a fractured surgical valve without requiring additional after dilation. Conversely, the delivery balloon used to expand and deploy the Sapien XT and Sapien 3 was not robust enough to fully deploy the valve in a fractured surgical valve, and a noncompliant balloon was required to postdilate and optimize transcatheter valve expansion. The findings from this bench testing may have implications for the selection of surgical prosthesis in patients undergoing initial surgical aortic valve replacement and for transcatheter valve selection for patients undergoing subsequent VIV TAVR.

Another unanswered question is whether BVF should be done before or after placing the transcatheter valve. Prior case reports have reported success with fracturing the surgical valve before TAVR [9–11]. During bench testing, BVF was performed first, followed by deployment of the transcatheter valve. When deployed in a fractured surgical valve, the self-expanding valve expanded to its intended diameter without need for postdilation. On the contrary, when balloon expandable valves were deployed in a fractured surgical valve, the delivery balloon was insufficient to fully expand the transcatheter valve and postdilation with a noncompliant balloon was required. Because of concerns for performing balloon valvuloplasty in a degenerated bioprosthetic valve (eg, leaflet tears leading to severe aortic insufficiency), in our clinical case, we performed BVF after implantation of the transcatheter valve. It is crucial to...
have an understanding of transcatheter valve anatomy, particularly when performing BVF after implanting a self-expanding transcatheter valve. The Medtronic self-expanding valve has a narrowed area where the commissures are attached to the nitinol frame, known as the “constrained area” (Fig 8A). When using a HPB larger than the diameter of the constrained area, care is required to avoid trauma to the transcatheter valve that could lead to severe valvular insufficiency. Our current practice and the technique used during bench testing is to keep the superior shoulder of the balloon below the constrained area during BVF to minimize the chance of tearing the leaflets (Fig 8B).

In our study, successful BVF was consistently achieved using HPBs 1 mm larger than the labeled valve size. However, BVF may only require the use of balloons that are slightly larger than the inner diameter of the prosthesis. Theoretically, the use of smaller diameter balloons for BVF may minimize trauma to the aortic annulus and minimize the risk of complications; however, the use of smaller balloons may require higher fracture pressures than are reported in this study, and may result in less optimal expansion of the TAVR prosthesis, which may impact valve hemodynamics and valve durability.

Finally, it is important to note that the long-term consequences of suboptimal expansion of transcatheter valves during VIV TAVR and how BVF may impact that are unknown. Although BVF may allow optimal expansion of the transcatheter valve, thus potentially decreasing the incidence of PPM and residual high gradients after VIV TAVR, its incorporation into routine clinical practice will require further study. Whether all surgical valves, regardless of size, should be fractured to optimize transcatheter valve expansion is a provocative question. Although larger surgical valves can be successfully treated with VIV TAVR with better hemodynamic results, the transcatheter valves when deployed into even large surgical valves remain constrained and not optimally expanded. The effect of suboptimal expansion of a transcatheter valve, regardless of whether it is in a small, intermediate, or large surgical valve, on the long-term durability of the transcatheter valve is unknown. The application of this technique to larger patient populations will need to be carefully studied in clinical trials to determine its safety and utility.

In conclusion, bench testing demonstrates that the frame of some surgical tissue valves can be fractured using HPB inflation. The use of this technique, however, outside of carefully controlled studies is not recommended. The safety of BVF to facilitate transcatheter VIV procedures, particularly in small surgical valves, to circumvent high residual gradients and optimally expand transcatheter valves requires further clinical investigation.

References