Bioprosthetic Valve Fracture Improves the Hemodynamic Results of Valve-in-Valve Transcatheter Aortic Valve Replacement

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Background—Valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) may be less effective in small surgical valves because of patient/prosthesis mismatch. Bioprosthetic valve fracture (BVF) using a high-pressure balloon can be performed to facilitate VIV TAVR.

Methods and Results—We report data from 20 consecutive clinical cases in which BVF was successfully performed before or after VIV TAVR by inflation of a high-pressure balloon positioned across the valve ring during rapid ventricular pacing. Hemodynamic measurements and calculation of the valve effective orifice area were performed at baseline, immediately after VIV TAVR, and after BVF. BVF was successfully performed in 20 patients undergoing VIV TAVR with balloon-expandable (n=8) or self-expanding (n=12) transcatheter valves in Mitroflow, Carpentier-Edwards Perimount, Magna and Magna Ease, Biocor Epic and Biocor Epic Supra, and Mosaic surgical valves. Successful fracture was noted fluoroscopically when the waist of the balloon released and by a sudden drop in inflation pressure, often accompanied by an audible snap. BVF resulted in a reduction in the mean transvalvular gradient (from 20.5±7.4 to 6.7±3.7 mm Hg, $P<0.001$) and an increase in valve effective orifice area (from 1.0±0.4 to 1.8±0.6 cm^2, $P<0.001$). No procedural complications were reported.

Conclusions—BVF can be performed safely in small surgical valves to facilitate VIV TAVR with either balloon-expandable or self-expanding transcatheter valves and results in reduced residual transvalvular gradients and increased valve effective orifice area. **(*Circ Cardiovasc Interv*. 2017;10:e005216. DOI: 10.1161/CIRCINTERVENTIONS.117.005216.)**

Key Words: aortic stenosis ■ bioprosthesis ■ transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) has become an alternative, less invasive treatment option for patients at intermediate or high risk for surgical aortic valve replacement.[1–4] The treatment of failed surgical bioprosthetic valves with valve-in-valve (VIV) TAVR has also been reported; however, patients with small surgical bioprosthesis (≤21 mm in diameter) undergoing VIV TAVR seem to have higher residual gradients and higher late mortality than other patients undergoing VIV TAVR.[5] Because VIV TAVR further decreases the orifice of the previously implanted surgical bioprosthesis, these findings suggest that patient/prosthesis mismatch (PPM) may play an important role in outcomes after VIV TAVR.[6]

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PPM has typically referred to a situation in which the effective valve area after surgical valve replacement is less than that of a normal human valve.[7] In the aortic position, severe PPM is defined by an indexed effective orifice area of <0.65 cm^2/m^2, and the incidence of severe PPM after surgical aortic valve replacement ranges between 2% and 20%. A recent meta-analysis suggested that predictors of PPM after surgical aortic valve replacement include older age, female sex, hypertension, diabetes mellitus, renal failure, larger body surface area, larger body mass index, and the utilization of a bioprosthesis.[8] Furthermore, the presence of PPM is prognostically important because PPM results in higher valve gradients and increased perioperative and overall mortality.[8]

Isolated cases have previously been reported in which a bioprosthetic valve ring has been fractured using a high-pressure balloon inflation to facilitate VIV TAVR, to allow further expansion of the transcatheter valve to maximize the effective orifice area and minimize PPM.[9–11] We have previously reported results from bench testing that outline which bioprosthetic valves can and cannot be fractured.[12] In this article, we describe procedural results from a series of consecutive cases in which bioprosthetic valve fracture (BVF) was performed.

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WHAT IS KNOWN

- Patients with small surgical bioprostheses undergoing valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) seem to have higher residual gradients and higher late mortality than other patients undergoing VIV TAVR.
- Isolated cases have previously been reported in which a bioprosthetic valve ring has been fractured using a high-pressure balloon inflation to facilitate VIV TAVR.

WHAT THE STUDY ADDS

- Bioprosthetic valve fracture can be performed without complications in select patients undergoing VIV TAVR.
- Bioprosthetic valve fracture results in lower residual valve gradients and higher effective valve orifice areas.
- Bioprosthetic valve fracture can be successfully performed before or after VIV TAVR.

Methods

All patients in this series underwent VIV TAVR for bioprosthetic valve degeneration in accordance with the Food and Drug Administration indication for VIV TAVR and provided informed consent before the procedure. The cases were performed at 9 centers in the United States. Procedural and demographic data were deidentified and provided to the principal investigators at St Luke's Mid America Heart Institute in Kansas City, Missouri. The Institutional Review Board at St Luke's Mid America Heart Institute granted a waiver of informed consent and authorization for this study. Statistical analysis and article preparation was performed by the investigators at St Luke's Mid America Heart Institute.

The timing of BVF (ie, before or after implantation of the transcatheter valve) was at the discretion of the operators. In some cases, BVF was performed before VIV TAVR, to ensure that the ring could be successfully fractured before deciding which size transcatheter valve to implant. In most cases, BVF was performed after VIV TAVR, because of suboptimal hemodynamic results. BVF was performed by inflation of a high-pressure balloon positioned across the valve ring during rapid ventricular pacing. Successful fracture was noted fluoroscopically when the waist of the balloon released, and by a sudden drop in inflation pressure, often accompanied by an audible snap. Hemodynamic measurements and calculation of the valve effective orifice area were performed at baseline, immediately after VIV TAVR, and after BVF.

Statistics

Statistical analysis was performed using SPSS software (IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY). Continuous variables were expressed as means±SDs. Categorical variables were expressed as percentages or frequencies. The Shapiro–Wilk test demonstrated that the differences in measures were normally distributed. Therefore, comparisons of mean hemodynamic gradients and valve effective orifice area were performed using 2-sided paired *t* test. A *P* value of <0.05 was considered to be statistically significant for all analyses.

Results

Clinical Cases

A total of 20 patients were successfully treated with VIV TAVR and BVF. All patients survived the procedure, and there were no procedural complications, including no coronary occlusion or root rupture, no valvular or paravalvular aortic insufficiency, and no advanced atrioventricular block or pacemaker requirement reported after BVF. One patient experienced new left-sided weakness on postprocedural day 1 and was found to have a right posterior frontoparietal stroke in the area of a posterior branch of the middle cerebral artery, without acute hemorrhage or mass effect, from which he fully recovered. Patient characteristics and procedural data are summarized in the Table. The mean age of the patients was 76.4 years, and the Society of Thoracic Surgeons Predicted Risk of Mortality score was 8.4%. BVF was performed in patients undergoing VIV TAVR with both balloon-expandable (n=8) and self-expanding (n=12) transcatheter valves in Mitroflow (Sorin, Milan, Italy), Carpentier-Edwards Perimount, Magna and Magna Ease (Edwards Lifesciences, Irvine, CA), Biocor Epic and Biocor Epic Supra (St. Jude Medical, Minneapolis, MN), and Mosaic (Medtronic Inc, Minneapolis, MN) surgical valves. In most cases (15/20, 75%), operators chose to perform BVF after VIV TAVR, as opposed to beforehand. For patients in whom VIV TAVR was performed before BVF, the mean transvalvular gradient was reduced from 20.5±7.4 mm Hg after initial VIV TAVR to 6.7±3.7 mm Hg after BVF (P<0.001). Accordingly, the mean effective valve orifice area increased from 1.0±0.4 cm^2 after initial VIV TAVR to 1.8±0.6 cm^2 after BVF (P<0.001).

An example of procedural hemodynamics is depicted in Figure 1. The mean transvalvular gradient was improved from 36 mm Hg at baseline to 26 mm Hg after VIV TAVR and, finally, to 9 mm Hg after BVF. This corresponded to a valve effective orifice area of 0.8 cm^2 at baseline to 1.2 cm^2 after VIV TAVR and to 1.6 cm^2 after BVF. Figure 2 depicts fluoroscopic images from a clinical case after VIV TAVR, during BVF, and after BVF.

BVF results in a single fracture point in the surgical valve ring which can often be visualized on postprocedural imaging.[12] Figure 3 demonstrates a digital reconstruction of computed tomography in a patient who underwent VIV TAVR and BVF. Figure 3, left, demonstrates a single disruption of the surgical valve ring, and the Figure 3, right, demonstrates the obverse view with an otherwise intact surgical ring. Figure 4 depicts examples of fractured valve rings as viewed ex vivo, under fluoroscopy. In Movie I in the Data Supplement, a 21-mm Magna valve treated with a 23-mm CoreValve Evolut (Medtronic Inc, Minneapolis, MN) is fractured with a 22-mm True Dilatation Balloon (Bard, Murray Hill, NJ) at a pressure of 18 atm. In Movie II in the Data Supplement, a 21-mm Mitroflow valve treated with a 20-mm Sapien 3 (Edwards Lifesciences, Irvine, CA) is fractured with a 20-mm True Dilatation Balloon at a pressure of 18 atm.

Discussion

In this article, we report positive procedural outcomes of BVF in conjunction with VIV TAVR in 20 patients, which suggest that this may be a safe technique to optimize hemodynamic results in patients with small bioprosthetic valves. The potential of BVF to reduce the impact of PPM after VIV TAVR is promising. In the largest registry of patients undergoing VIV TAVR

Table. Clinical and Procedural Characteristics of Patients Undergoing Bioprosthetic Valve Fracture

Patient	Age, y	STS PROM	Surgical Prosthesis	Age of Surgical Prosthesis, y	True ID, mm	VIV TAVR, or BVF First?	TAVR Valve	TAVR Access	Baseline Mean Gradient, mm Hg	Baseline AVA, cm^2	Post-TAVR Mean Gradient, mm Hg	Post-TAVR AVA, cm^2	BVF Balloon	BVF Pressure (Rupture Threshold)	Post-BVF Mean Gradient, mm Hg	Post-BVF AVA, cm^2
1	72	15	19-mm Magna	9	17	TAVR	23-mm CV Evolut	TF	64	0.7	17	2.0	22-mm TRUE	12	7	2.2
2	77	4.2	23-mm Magna	10	21	TAVR	26-mm CV Evolut	TF	18	0.8	12	1.2	24-mm TRUE	16	4	2.4
3	76	3.1	23-mm Mosaic	9	18.5	TAVR	26-mm CV Evolut	TF	36	0.7	25	1.2	24-mm TRUE	10	3	1.7
4	70	14.3	21-mm Mitroflow	3	17	TAVR	20-mm Sapien S3	TC	54	0.4	15	0.9	20-mm TRUE	18	9	1.1
5	80	15	21-mm Mosaic	11	17	TAVR	23-mm CV Evolut	TF	60	0.6	29	0.75	20-mm TRUE	20	4	1.2
6	84	7.8	19-mm Magna	11	17	TAVR	23-mm CV Evolut	TF	40	0.6	22	0.75	20-mm TRUE	16	4	1.7
7	68	4.4	21-mm Magna	12	19	TAVR	23-mm CV Evolut	TF	44	0.72	31	1.02	22-mm TRUE	15	13	1.6
8	79	4	23-mm Carpentier-Edwards	16	20	TAVR	26-mm Sapien XT	TF	30	1.2	7	…	24-mm TRUE	15	3	3.3
9	67	8.2	25-mm Mitroflow	5	21	TAVR	26-mm Sapien XT	TF	24	1.0	11	…	26-mm TRUE	16	6	2.5
10	83	7	19-mm Mitroflow	8	15.5	BVF	20-mm Sapien S3	TF	63	0.6	…	1.02	20-mm Atlas Gold	16	…	2.2
11	83	8	21-mm Mitroflow	7	17	BVF	23-mm Sapien S3	TF	26	…	…	…	22-mm Atlas Gold	18	…	…
12	81	8	19-mm Mitroflow	7	15.5	BVF	20-mm Sapien S3	TF	64	0.6	…	…	20-mm Atlas Gold	15	…	…
13	62	…	21-mm Epic	…	16.5	TAVR	23-mm Sapien S3	TF	31	0.65	22	0.78	22-mm TRUE	7	6	1.8
14	62	…	19-mm Epic Supra	…	16.5	TAVR	20-mm Sapien S3	TF	39	0.5	23	0.84	20-mm TRUE	18	10	1.1
15	90	9.7	21-mm Magna	10	19	TAVR	23-mm CV Evolut	TF	40	0.5	25	0.9	22-mm TRUE	15	10	1.3
16	77	…	19-mm Perimount	14	17	TAVR	23-mm CV Evolut	TF	40	0.75	25	…	20-mm TRUE	20	5	…
17	75	7.3	21-mm Mosaic	9	16.5	BVF	23-mm CV Evolut	TF	40	…	…	…	22-mm TRUE	14	…	1.4
18	70	2.3	25-mm Mosaic	7	20.5	BVF	26-mm CV Evolut	TF	40	1.3	…	…	24-mm TRUE	14	…	1.7
19	85	4.1	23-mm Perimount	15	19	TAVR	23-mm CV Evolut	TF	46	0.5	24	0.85	24-mm VIDA	15	14	1.5
20	87	17	21-mm Mosaic	10	17	TAVR	23-mm CV Evolut	TF	39	0.8	10	2.0	22-mm TRUE	12	3	2.1
Mean	76.4	8.4		9.5	17.8				41.9±11.2	0.6±0.2	20.5±7.4	1.0±0.4			6.7±3.7	1.8±0.6
P value											<0.001*	0.002*			<0.001†	<0.001†

AVA indicates aortic valve area; BVF, bioprosthetic valve fracture; CV, CoreValve; ID, inner diameter; PROM, Predicted Risk of Mortality; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; TC, transcarotid; TF, transfemoral; and VIV, valve in valve.

**P* value refers to *t* test comparing groups at baseline and post-TAVR.

†*P* value refers to *t* test comparing groups post-TAVR and post-BVF.

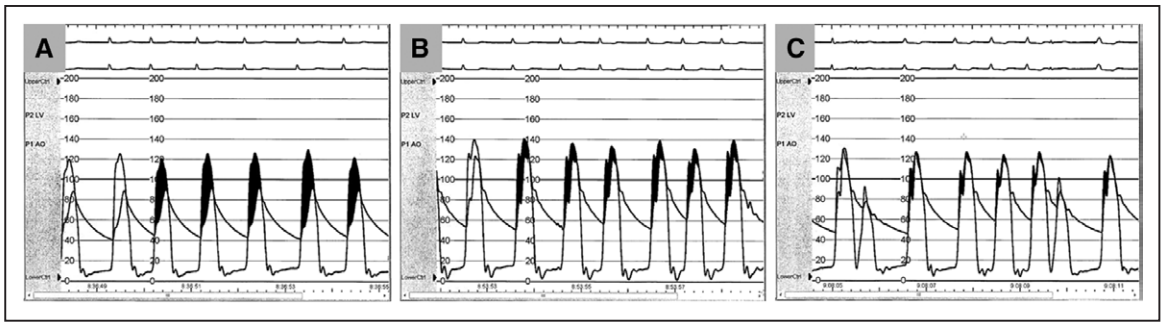

Figure 1. Example of procedural hemodynamics with valve-in-valve transcatheter aortic valve replacement (TAVR) and bioprosthetic valve fracture (BVF). **A**, Baseline hemodynamics demonstrating severe bioprosthetic aortic stenosis. Mean aortic valve gradient is 36 mm Hg; effective orifice area is 0.8 cm^2. **B**, Hemodynamics post-TAVR deployment demonstrating improved transvalvular gradient. Mean aortic valve gradient is 26 mm Hg; effective orifice area is 1.2 cm^2. **C**, Hemodynamics post-BVF demonstrating final transvalvular gradient. Mean aortic valve gradient is 9 mm Hg; effective orifice area is 1.6 cm^2.

to date, Dvir et al[5] reported a 38% incidence of severe PPM after VIV TAVR and a higher incidence of PPM in patients with smaller-sized surgical valves.[5] Importantly, 1-year mortality among patients with labeled valve sizes which were small (≤21 mm) and intermediate (>21 and <25 mm) was higher than in patients with larger (≥25 mm) surgical valves undergoing VIV TAVR. These data suggest that suboptimal postprocedural hemodynamics play an important role in long-term outcomes after VIV TAVR. BVF directly addresses this issue and has a dramatic effect on postprocedural gradients and effective valve orifice area in our series. Whether this technique improves long-term clinical outcomes remains to be seen.

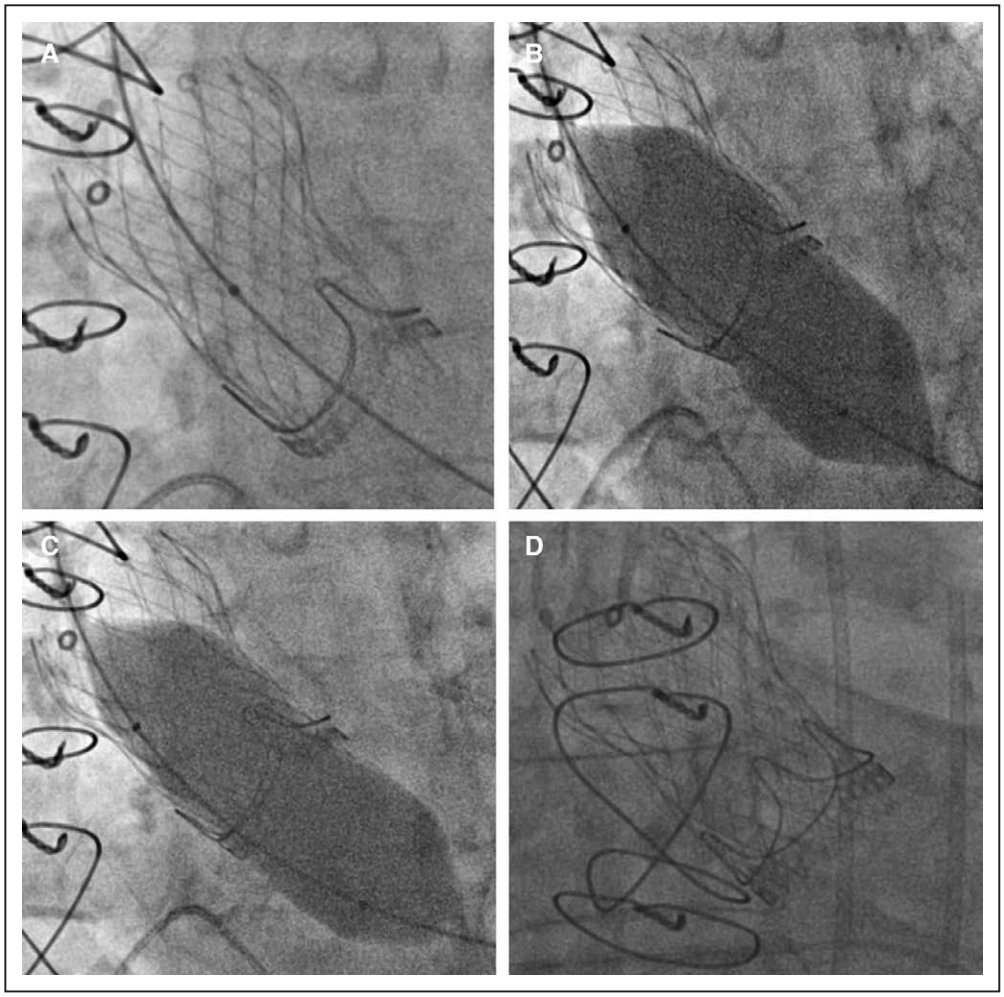

Figure 2. Fluoroscopic images of the stages of valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) followed by bioprosthetic valve fracture (BVF). **A**, Immediately after VIV TAVR. **B**, During BVF before fracture of surgical ring. Note the waist of the balloon at the level of the surgical valve ring. **C**, During BVF after fracture of surgical ring. Note the release of the balloon waist. **D**, Final fluoroscopic results.

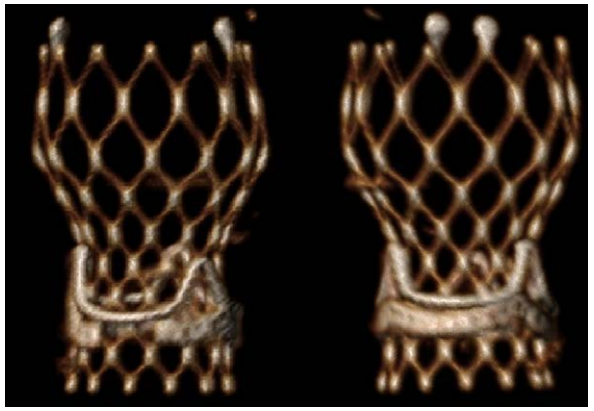

Figure 3. Computed tomography (CT) reconstruction of a patient who underwent valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) with a 23-mm CoreValve Evolut R in a 19-mm Edwards Magna, followed by bioprosthetic valve fracture (BVF). **Left**, Clear disruption of the surgical valve ring. **Right**, Obverse view.

An important question remains as to the timing of BVF, that is, before or after transcatheter valve implantation. There are potential advantages to both strategies. Fracture of the bioprosthetic ring before TAVR implant may allow for a larger-sized TAVR prosthesis to be used, whereas fracture of the bioprosthetic ring after TAVR implant may allow for further expansion of the TAVR valve itself.[12] In the former scenario, there remains concern regarding balloon dilatation of degenerated bioprosthetic valves, for fear of leaflet tearing and resultant aortic insufficiency, as well as the potential for dislodgement and embolization of debris. On the other hand, if BVF follows transcatheter valve implantation, the TAVR prosthesis itself is subjected to a high-pressure balloon inflation, which in some cases may cause acute structural damage or accelerated degeneration. In either scenario, BVF may reduce PPM and optimize hemodynamics by decreasing the residual aortic valve gradient during VIV TAVR. Whether the timing of BVF is a determinant of clinical outcomes remains to be seen.

The majority of cases in our clinical series were performed with balloons sized 1 mm larger than the labeled valve size, which has been demonstrated to be effective in bench testing.[12] However, BVF may only require the use of balloons which are larger than the internal diameter of the prosthesis. The use of smaller diameter balloons for BVF may minimize trauma to the aortic annulus and minimize the risk of complications. On the other hand, the use of smaller balloons may result in less optimal expansion of the TAVR prosthesis, which may impact valve hemodynamics. The long-term consequences of suboptimal expansion of TAVR prostheses, as is the case in VIV TAVR, are not fully understood.[13] Even if BVF is performed to optimize valve hemodynamics, it remains unclear whether satisfactory long-term outcomes after VIV TAVR can be best attained in a given patient by using a smaller TAVR valve which is fully expanded, or a larger TAVR valve which may not achieve full expansion (eg, a perfectly expanded 20 mm versus a suboptimally expanded 23 mm valve). Similarly, it remains unclear whether self-expanding or balloon-expandable transcatheter valves are better suited for this application. On the basis of bench testing, the radial force of a self-expanding valve seems adequate to achieve optimal expansion of the transcatheter valve inside a fractured surgical valve. On the other hand, Sapien XT and Sapien 3 valves deployed in a fractured surgical valve were underexpanded, and postdilatation with a noncompliant balloon was required to optimize the transcatheter valve expansion. Bench testing also suggests that the outer Dacron sewing ring of bioprosthetic valves results in a limit to how much further a valve can be expanded after BVF.[12] Therefore, further investigation is needed to determine optimal balloon sizing for BVF and optimal transcatheter valve selection when using this technique.

A final question that is raised by our results is the role of BVF in patients with larger surgical prostheses. Although these patients have a higher 1-year survival than patients with small surgical valves, as well as a lower incidence of PPM, after VIV TAVR, it is not known whether BVF of large prostheses will result in even further improvement in postprocedural hemodynamics and survival in these patients. There is some evidence to suggest that underexpansion of bioprosthetic valves may lead to early prosthetic deterioration because of folds in the bioprosthetic leaflets.[13] Therefore, an up-front strategy of BVF in all degenerated surgical valves could, in theory, improve outcomes for all patients undergoing VIV TAVR. Further clinical experience is required to provide insight on this novel technique.

Despite these initial promising results, there are several limitations to this study. Although no procedural complications were

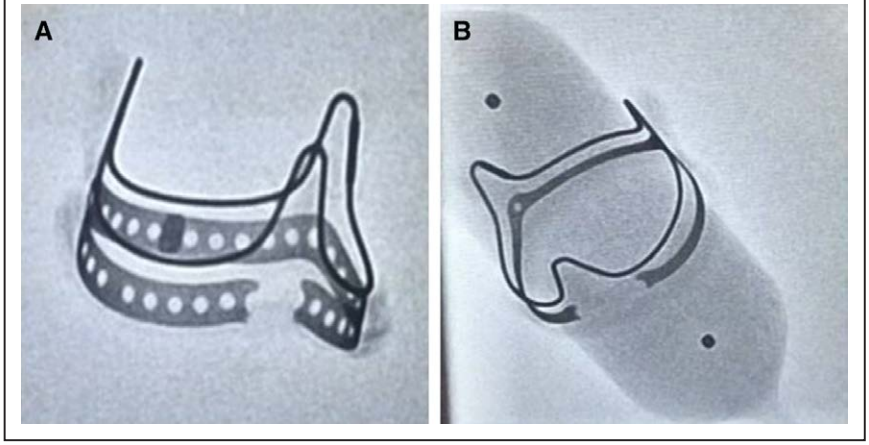

Figure 4. Ex vivo fluoroscopic images of fractured Magna (**A**) and Magna Ease (**B**) bioprosthetic valves.

observed with BVF in this small series, reasonable concerns remain regarding the potential for BVF to cause aortic root rupture or coronary artery occlusion, and a heavily calcified aortic root or anatomy predisposing to coronary occlusion might preclude the use of this technique. Because computed tomographic imaging was not routinely performed after BVF, subclinical injury to the aorta cannot be fully assessed. One patient in this series experienced a postprocedural stroke, but whether this complication was specifically related to BVF is unknown, and larger studies are needed to fully evaluate the safety of this technique. Previous work has demonstrated that although the majority of commercially available bioprosthetic valves can be fractured with high-pressure balloon inflation, some, such as the St Jude Trifecta and the Medtronic Hancock II, cannot be fractured.[12] Furthermore, the location of the previously implanted surgical valve (ie, supra-annular or intra-annular) may be important because BVF in a surgical valve that was implanted in the supra-annular position may offer a superior risk–benefit profile when compared with BVF of a surgical valve that was positioned in the native annulus. Further study of patient factors such as aortic root and coronary sinus dimension will be important to determine patient-specific limitations of BVF and avoid complications, and if concerns regarding such issues are present in a given patient, back-up cardiopulmonary support could be considered at the time of BVF.

Conclusions

BVF can be performed safely in small surgical valves to facilitate VIV TAVR with either balloon-expandable or self-expanding transcatheter valves and results in reduced residual transvalvular gradients and increased valve effective orifice area.

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References

1. Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM, Gleason TG, Buchbinder M, Hermiller J, Jr, Kleiman NS, Chetcuti S, Heiser J, Merhi W, Zorn G, Tadros P, Robinson N, Petrossian G, Hughes GC, Harrison JK, Conte J, Maini B, Mumtaz M, Chenoweth S, Oh JK; U.S. CoreValve Clinical Investigators. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med*. 2014;370:1790–1798. doi: 10.1056/NEJMoa1400590.
2. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Brown DL, Block PC, Guyton RA, Pichard AD, Bavaria JE, Herrmann HC, Douglas PS, Petersen JL, Akin JJ, Anderson WN, Wang D, Pocock S; PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med*. 2010;363:1597–1607. doi: 10.1056/NEJMoa1008232.
3. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, Thourani VH, Tuzcu EM, Miller DC, Herrmann HC, Doshi D, Cohen DJ, Pichard AD, Kapadia S, Dewey T, Babaliaros V, Szeto WY, Williams MR, Kereiakes D, Zajarias A, Greason KL, Whisenant BK, Hodson RW, Moses JW, Trento A, Brown DL, Fearon WF, Pibarot P, Hahn RT, Jaber WA, Anderson WN, Alu MC, Webb JG; PARTNER 2 Investigators. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. 2016;374:1609–1620. doi: 10.1056/NEJMoa1514616.
4. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Williams M, Dewey T, Kapadia S, Babaliaros V, Thourani VH, Corso P, Pichard AD, Bavaria JE, Herrmann HC, Akin JJ, Anderson WN, Wang D, Pocock SJ; PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med*. 2011;364:2187–2198. doi: 10.1056/NEJMoa1103510.
5. Dvir D, Webb JG, Bleiziffer S, Pasic M, Waksman R, Kodali S, Barbanti M, Latib A, Schaefer U, Rodés-Cabau J, Treede H, Piazza N, Hildick-Smith D, Himbert D, Walther T, Hengstenberg C, Nissen H, Bekeredjian R, Presbitero P, Ferrari E, Segev A, de Weger A, Windecker S, Moat NE, Napodano M, Wilbring M, Cerillo AG, Brecker S, Tchetche D, Lefèvre T, De Marco F, Fiorina C, Petronio AS, Teles RC, Testa L, Laborde JC, Leon MB, Kornowski R; Valve-in-Valve International Data Registry Investigators. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. *JAMA*. 2014;312:162–170. doi: 10.1001/jama.2014.7246.
6. Faerber G, Schleger S, Diab M, Breuer M, Figulla HR, Eichinger WB, Doenst T. Valve-in-valve transcatheter aortic valve implantation: the new playground for prosthesis-patient mismatch. *J Interv Cardiol*. 2014;27:287–292. doi: 10.1111/joic.12108.
7. Rahimtoola SH. The problem of valve prosthesis-patient mismatch. *Circulation*. 1978;58:20–24.
8. Dayan V, Vignolo G, Soca G, Paganini JJ, Brusich D, Pibarot P. Predictors and outcomes of prosthesis-patient mismatch after aortic valve replacement. *JACC Cardiovasc Imaging*. 2016;9:924–933. doi: 10.1016/j.jcmg.2015.10.026.
9. Brown SC, Cools B, Gewillig M. Cracking a tricuspid perimount bioprosthesis to optimize a second transcatheter sapien valve-in-valve placement. *Catheter Cardiovasc Interv*. 2016;88:456–459. doi: 10.1002/ccd.26507.
10. Nielsen-Kudsk JE, Christiansen EH, Terkelsen CJ, Nørgaard BL, Jensen KT, Krusell LR, Tang M, Terp K, Klaaborg KE, Andersen HR. Fracturing the ring of small Mitroflow bioprostheses by high-pressure balloon predilatation in transcatheter aortic valve-in-valve implantation. *Circ Cardiovasc Interv*. 2015;8:e002667. doi: 10.1161/CIRCINTERVENTIONS.115.002667.
11. Tanase D, Grohmann J, Schubert S, Uhlemann F, Eicken A, Ewert P. Cracking the ring of Edwards Perimount bioprosthesis with ultrahigh pressure balloons prior to transcatheter valve in valve implantation. *Int J Cardiol*. 2014;176:1048–1049. doi: 10.1016/j.ijcard.2014.07.175.
12. Allen KA, Chhatriwalla AK, Cohen DJ, Saxon JT, Aggarwal S, Hart AJ, Baron SJ, Davis R, Pak AF, Dvir D, Borkon AM. Bioprosthetic valve fracture to facilitate transcatheter valve-in-valve implantation [published online ahead of print June 29, 2017]. *Ann Thoracic Surg*. doi: 10.1016/j.athoracsur.2017.04.007. https://doi.org/10.1016/j.athoracsur.2017.04.007.
13. Grubitzsch H, Galloni M, Falk V. Wrinkles, folds and calcifications: reduced durability after transcatheter aortic valve-in-valve replacement. *J Thorac Cardiovasc Surg*. 2017;153:266–268. doi: 10.1016/j.jtcvs.2016.08.018.

Bioprosthetic Valve Fracture Improves the Hemodynamic Results of Valve-in-Valve Transcatheter Aortic Valve Replacement

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Bioprosthetic Valve Fracture Improves the Hemodynamic Results of Valve-in-Valve Transcatheter Aortic Valve Replacement

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Background—Valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) may be less effective in small surgical valves because of patient/prosthesis mismatch. Bioprosthetic valve fracture (BVF) using a high-pressure balloon can be performed to facilitate VIV TAVR.

Methods and Results—We report data from 20 consecutive clinical cases in which BVF was successfully performed before or after VIV TAVR by inflation of a high-pressure balloon positioned across the valve ring during rapid ventricular pacing. Hemodynamic measurements and calculation of the valve effective orifice area were performed at baseline, immediately after VIV TAVR, and after BVF. BVF was successfully performed in 20 patients undergoing VIV TAVR with balloon-expandable (n=8) or self-expanding (n=12) transcatheter valves in Mitroflow, Carpentier-Edwards Perimount, Magna and Magna Ease, Biocor Epic and Biocor Epic Supra, and Mosaic surgical valves. Successful fracture was noted fluoroscopically when the waist of the balloon released and by a sudden drop in inflation pressure, often accompanied by an audible snap. BVF resulted in a reduction in the mean transvalvular gradient (from 20.5±7.4 to 6.7±3.7 mm Hg, $P<0.001$) and an increase in valve effective orifice area (from 1.0±0.4 to 1.8±0.6 cm^2, $P<0.001$). No procedural complications were reported.

Conclusions—BVF can be performed safely in small surgical valves to facilitate VIV TAVR with either balloon-expandable or self-expanding transcatheter valves and results in reduced residual transvalvular gradients and increased valve effective orifice area. **(*Circ Cardiovasc Interv*. 2017;10:e005216. DOI: 10.1161/CIRCINTERVENTIONS.117.005216.)**

Key Words: aortic stenosis ■ bioprosthesis ■ transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) has become an alternative, less invasive treatment option for patients at intermediate or high risk for surgical aortic valve replacement.[1–4] The treatment of failed surgical bioprosthetic valves with valve-in-valve (VIV) TAVR has also been reported; however, patients with small surgical bioprosthesis (≤21 mm in diameter) undergoing VIV TAVR seem to have higher residual gradients and higher late mortality than other patients undergoing VIV TAVR.[5] Because VIV TAVR further decreases the orifice of the previously implanted surgical bioprosthesis, these findings suggest that patient/prosthesis mismatch (PPM) may play an important role in outcomes after VIV TAVR.[6]

See Editorial by McElhinney

PPM has typically referred to a situation in which the effective valve area after surgical valve replacement is less than that of a normal human valve.[7] In the aortic position, severe PPM is defined by an indexed effective orifice area of <0.65 cm^2/m^2, and the incidence of severe PPM after surgical aortic valve replacement ranges between 2% and 20%. A recent meta-analysis suggested that predictors of PPM after surgical aortic valve replacement include older age, female sex, hypertension, diabetes mellitus, renal failure, larger body surface area, larger body mass index, and the utilization of a bioprosthesis.[8] Furthermore, the presence of PPM is prognostically important because PPM results in higher valve gradients and increased perioperative and overall mortality.[8]

Isolated cases have previously been reported in which a bioprosthetic valve ring has been fractured using a high-pressure balloon inflation to facilitate VIV TAVR, to allow further expansion of the transcatheter valve to maximize the effective orifice area and minimize PPM.[9–11] We have previously reported results from bench testing that outline which bioprosthetic valves can and cannot be fractured.[12] In this article, we describe procedural results from a series of consecutive cases in which bioprosthetic valve fracture (BVF) was performed.

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WHAT IS KNOWN

- Patients with small surgical bioprostheses undergoing valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) seem to have higher residual gradients and higher late mortality than other patients undergoing VIV TAVR.
- Isolated cases have previously been reported in which a bioprosthetic valve ring has been fractured using a high-pressure balloon inflation to facilitate VIV TAVR.

WHAT THE STUDY ADDS

- Bioprosthetic valve fracture can be performed without complications in select patients undergoing VIV TAVR.
- Bioprosthetic valve fracture results in lower residual valve gradients and higher effective valve orifice areas.
- Bioprosthetic valve fracture can be successfully performed before or after VIV TAVR.

Methods

All patients in this series underwent VIV TAVR for bioprosthetic valve degeneration in accordance with the Food and Drug Administration indication for VIV TAVR and provided informed consent before the procedure. The cases were performed at 9 centers in the United States. Procedural and demographic data were deidentified and provided to the principal investigators at St Luke's Mid America Heart Institute in Kansas City, Missouri. The Institutional Review Board at St Luke's Mid America Heart Institute granted a waiver of informed consent and authorization for this study. Statistical analysis and article preparation was performed by the investigators at St Luke's Mid America Heart Institute.

The timing of BVF (ie, before or after implantation of the transcatheter valve) was at the discretion of the operators. In some cases, BVF was performed before VIV TAVR, to ensure that the ring could be successfully fractured before deciding which size transcatheter valve to implant. In most cases, BVF was performed after VIV TAVR, because of suboptimal hemodynamic results. BVF was performed by inflation of a high-pressure balloon positioned across the valve ring during rapid ventricular pacing. Successful fracture was noted fluoroscopically when the waist of the balloon released, and by a sudden drop in inflation pressure, often accompanied by an audible snap. Hemodynamic measurements and calculation of the valve effective orifice area were performed at baseline, immediately after VIV TAVR, and after BVF.

Statistics

Statistical analysis was performed using SPSS software (IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY). Continuous variables were expressed as means±SDs. Categorical variables were expressed as percentages or frequencies. The Shapiro–Wilk test demonstrated that the differences in measures were normally distributed. Therefore, comparisons of mean hemodynamic gradients and valve effective orifice area were performed using 2-sided paired *t* test. A *P* value of <0.05 was considered to be statistically significant for all analyses.

Results

Clinical Cases

A total of 20 patients were successfully treated with VIV TAVR and BVF. All patients survived the procedure, and there were no procedural complications, including no coronary occlusion or root rupture, no valvular or paravalvular aortic insufficiency, and no advanced atrioventricular block or pacemaker requirement reported after BVF. One patient experienced new left-sided weakness on postprocedural day 1 and was found to have a right posterior frontoparietal stroke in the area of a posterior branch of the middle cerebral artery, without acute hemorrhage or mass effect, from which he fully recovered. Patient characteristics and procedural data are summarized in the Table. The mean age of the patients was 76.4 years, and the Society of Thoracic Surgeons Predicted Risk of Mortality score was 8.4%. BVF was performed in patients undergoing VIV TAVR with both balloon-expandable (n=8) and self-expanding (n=12) transcatheter valves in Mitroflow (Sorin, Milan, Italy), Carpentier-Edwards Perimount, Magna and Magna Ease (Edwards Lifesciences, Irvine, CA), Biocor Epic and Biocor Epic Supra (St. Jude Medical, Minneapolis, MN), and Mosaic (Medtronic Inc, Minneapolis, MN) surgical valves. In most cases (15/20, 75%), operators chose to perform BVF after VIV TAVR, as opposed to beforehand. For patients in whom VIV TAVR was performed before BVF, the mean transvalvular gradient was reduced from 20.5±7.4 mm Hg after initial VIV TAVR to 6.7±3.7 mm Hg after BVF ($P<0.001$). Accordingly, the mean effective valve orifice area increased from 1.0±0.4 cm^2 after initial VIV TAVR to 1.8±0.6 cm^2 after BVF ($P<0.001$).

An example of procedural hemodynamics is depicted in Figure 1. The mean transvalvular gradient was improved from 36 mm Hg at baseline to 26 mm Hg after VIV TAVR and, finally, to 9 mm Hg after BVF. This corresponded to a valve effective orifice area of 0.8 cm^2 at baseline to 1.2 cm^2 after VIV TAVR and to 1.6 cm^2 after BVF. Figure 2 depicts fluoroscopic images from a clinical case after VIV TAVR, during BVF, and after BVF.

BVF results in a single fracture point in the surgical valve ring which can often be visualized on postprocedural imaging.[12] Figure 3 demonstrates a digital reconstruction of computed tomography in a patient who underwent VIV TAVR and BVF. Figure 3, left, demonstrates a single disruption of the surgical valve ring, and the Figure 3, right, demonstrates the obverse view with an otherwise intact surgical ring. Figure 4 depicts examples of fractured valve rings as viewed ex vivo, under fluoroscopy. In Movie I in the Data Supplement, a 21-mm Magna valve treated with a 23-mm CoreValve Evolut (Medtronic Inc, Minneapolis, MN) is fractured with a 22-mm True Dilatation Balloon (Bard, Murray Hill, NJ) at a pressure of 18 atm. In Movie II in the Data Supplement, a 21-mm Mitroflow valve treated with a 20-mm Sapien 3 (Edwards Lifesciences, Irvine, CA) is fractured with a 20-mm True Dilatation Balloon at a pressure of 18 atm.

Discussion

In this article, we report positive procedural outcomes of BVF in conjunction with VIV TAVR in 20 patients, which suggest that this may be a safe technique to optimize hemodynamic results in patients with small bioprosthetic valves. The potential of BVF to reduce the impact of PPM after VIV TAVR is promising. In the largest registry of patients undergoing VIV TAVR

Table. Clinical and Procedural Characteristics of Patients Undergoing Bioprosthetic Valve Fracture

Patient	Age, y	STS PROM	Surgical Prosthesis	Age of Surgical Prosthesis, y	True ID, mm	VIV TAVR, or BVF First?	TAVR Valve	TAVR Access	Baseline Mean Gradient, mm Hg	Baseline AVA, cm^2	Post-TAVR Mean Gradient, mm Hg	Post-TAVR AVA, cm^2	BVF Balloon	BVF Pressure (Rupture Threshold)	Post-BVF Mean Gradient, mm Hg	Post-BVF AVA, cm^2
1	72	15	19-mm Magna	9	17	TAVR	23-mm CV Evolut	TF	64	0.7	17	2.0	22-mm TRUE	12	7	2.2
2	77	4.2	23-mm Magna	10	21	TAVR	26-mm CV Evolut	TF	18	0.8	12	1.2	24-mm TRUE	16	4	2.4
3	76	3.1	23-mm Mosaic	9	18.5	TAVR	26-mm CV Evolut	TF	36	0.7	25	1.2	24-mm TRUE	10	3	1.7
4	70	14.3	21-mm Mitroflow	3	17	TAVR	20-mm Sapien S3	TC	54	0.4	15	0.9	20-mm TRUE	18	9	1.1
5	80	15	21-mm Mosaic	11	17	TAVR	23-mm CV Evolut	TF	60	0.6	29	0.75	20-mm TRUE	20	4	1.2
6	84	7.8	19-mm Magna	11	17	TAVR	23-mm CV Evolut	TF	40	0.6	22	0.75	20-mm TRUE	16	4	1.7
7	68	4.4	21-mm Magna	12	19	TAVR	23-mm CV Evolut	TF	44	0.72	31	1.02	22-mm TRUE	15	13	1.6
8	79	4	23-mm Carpentier-Edwards	16	20	TAVR	26-mm Sapien XT	TF	30	1.2	7	…	24-mm TRUE	15	3	3.3
9	67	8.2	25-mm Mitroflow	5	21	TAVR	26-mm Sapien XT	TF	24	1.0	11	…	26-mm TRUE	16	6	2.5
10	83	7	19-mm Mitroflow	8	15.5	BVF	20-mm Sapien S3	TF	63	0.6	…	1.02	20-mm Atlas Gold	16	…	2.2
11	83	8	21-mm Mitroflow	7	17	BVF	23-mm Sapien S3	TF	26	…	…	…	22-mm Atlas Gold	18	…	…
12	81	8	19-mm Mitroflow	7	15.5	BVF	20-mm Sapien S3	TF	64	0.6	…	…	20-mm Atlas Gold	15	…	…
13	62	…	21-mm Epic	…	16.5	TAVR	23-mm Sapien S3	TF	31	0.65	22	0.78	22-mm TRUE	7	6	1.8
14	62	…	19-mm Epic Supra	…	16.5	TAVR	20-mm Sapien S3	TF	39	0.5	23	0.84	20-mm TRUE	18	10	1.1
15	90	9.7	21-mm Magna	10	19	TAVR	23-mm CV Evolut	TF	40	0.5	25	0.9	22-mm TRUE	15	10	1.3
16	77	…	19-mm Perimount	14	17	TAVR	23-mm CV Evolut	TF	40	0.75	25	…	20-mm TRUE	20	5	…
17	75	7.3	21-mm Mosaic	9	16.5	BVF	23-mm CV Evolut	TF	40	…	…	…	22-mm TRUE	14	…	1.4
18	70	2.3	25-mm Mosaic	7	20.5	BVF	26-mm CV Evolut	TF	40	1.3	…	…	24-mm TRUE	14	…	1.7
19	85	4.1	23-mm Perimount	15	19	TAVR	23-mm CV Evolut	TF	46	0.5	24	0.85	24-mm VIDA	15	14	1.5
20	87	17	21-mm Mosaic	10	17	TAVR	23-mm CV Evolut	TF	39	0.8	10	2.0	22-mm TRUE	12	3	2.1
Mean	76.4	8.4		9.5	17.8				41.9±11.2	0.6±0.2	20.5±7.4	1.0±0.4			6.7±3.7	1.8±0.6
P value											<0.001*	0.002*			<0.001†	<0.001†

AVA indicates aortic valve area; BVF, bioprosthetic valve fracture; CV, CoreValve; ID, inner diameter; PROM, Predicted Risk of Mortality; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; TC, transcarotid; TF, transfemoral; and VIV, valve in valve.

**P* value refers to *t* test comparing groups at baseline and post-TAVR.

†*P* value refers to *t* test comparing groups post-TAVR and post-BVF.

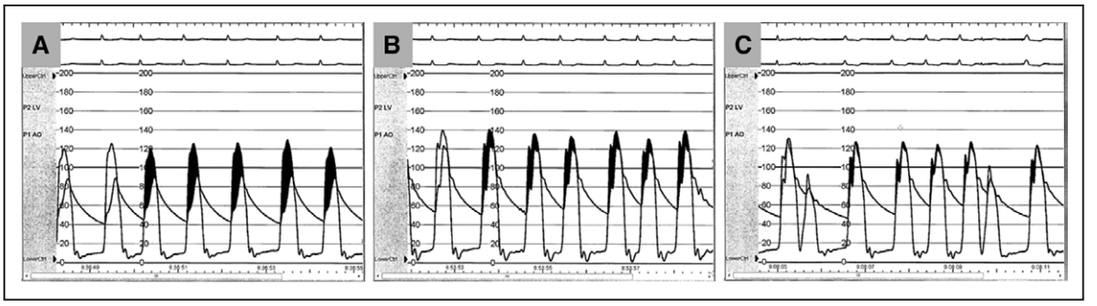

Figure 1. Example of procedural hemodynamics with valve-in-valve transcatheter aortic valve replacement (TAVR) and bioprosthetic valve fracture (BVF). **A**, Baseline hemodynamics demonstrating severe bioprosthetic aortic stenosis. Mean aortic valve gradient is 36 mm Hg; effective orifice area is 0.8 cm^2. **B**, Hemodynamics post-TAVR deployment demonstrating improved transvalvular gradient. Mean aortic valve gradient is 26 mm Hg; effective orifice area is 1.2 cm^2. **C**, Hemodynamics post-BVF demonstrating final transvalvular gradient. Mean aortic valve gradient is 9 mm Hg; effective orifice area is 1.6 cm^2.

to date, Dvir et al[5] reported a 38% incidence of severe PPM after VIV TAVR and a higher incidence of PPM in patients with smaller-sized surgical valves.[5] Importantly, 1-year mortality among patients with labeled valve sizes which were small (≤21 mm) and intermediate (>21 and <25 mm) was higher than in patients with larger (≥25 mm) surgical valves undergoing VIV TAVR. These data suggest that suboptimal postprocedural hemodynamics play an important role in long-term outcomes after VIV TAVR. BVF directly addresses this issue and has a dramatic effect on postprocedural gradients and effective valve orifice area in our series. Whether this technique improves long-term clinical outcomes remains to be seen.

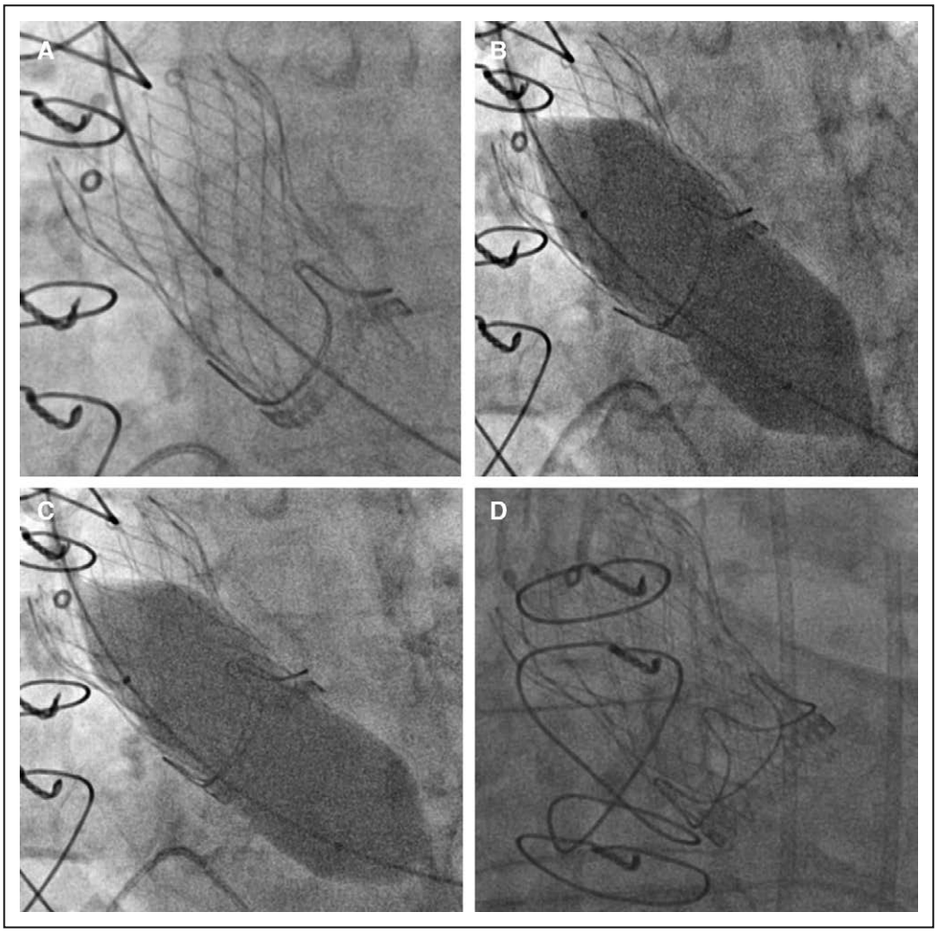

Figure 2. Fluoroscopic images of the stages of valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) followed by bioprosthetic valve fracture (BVF). **A**, Immediately after VIV TAVR. **B**, During BVF before fracture of surgical ring. Note the waist of the balloon at the level of the surgical valve ring. **C**, During BVF after fracture of surgical ring. Note the release of the balloon waist. **D**, Final fluoroscopic results.

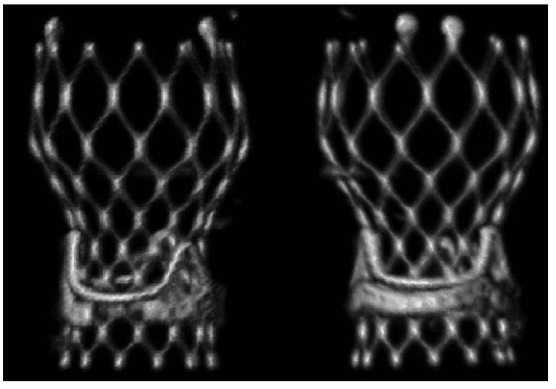

Figure 3. Computed tomography (CT) reconstruction of a patient who underwent valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) with a 23-mm CoreValve Evolut R in a 19-mm Edwards Magna, followed by bioprosthetic valve fracture (BVF). **Left**, Clear disruption of the surgical valve ring. **Right**, Obverse view.

An important question remains as to the timing of BVF, that is, before or after transcatheter valve implantation. There are potential advantages to both strategies. Fracture of the bioprosthetic ring before TAVR implant may allow for a larger-sized TAVR prosthesis to be used, whereas fracture of the bioprosthetic ring after TAVR implant may allow for further expansion of the TAVR valve itself.[12] In the former scenario, there remains concern regarding balloon dilatation of degenerated bioprosthetic valves, for fear of leaflet tearing and resultant aortic insufficiency, as well as the potential for dislodgement and embolization of debris. On the other hand, if BVF follows transcatheter valve implantation, the TAVR prosthesis itself is subjected to a high-pressure balloon inflation, which in some cases may cause acute structural damage or accelerated degeneration. In either scenario, BVF may reduce PPM and optimize hemodynamics by decreasing the residual aortic valve gradient during VIV TAVR. Whether the timing of BVF is a determinant of clinical outcomes remains to be seen.

The majority of cases in our clinical series were performed with balloons sized 1 mm larger than the labeled valve size, which has been demonstrated to be effective in bench testing.[12] However, BVF may only require the use of balloons which are larger than the internal diameter of the prosthesis. The use of smaller diameter balloons for BVF may minimize trauma to the aortic annulus and minimize the risk of complications. On the other hand, the use of smaller balloons may result in less optimal expansion of the TAVR prosthesis, which may impact valve hemodynamics. The long-term consequences of suboptimal expansion of TAVR prostheses, as is the case in VIV TAVR, are not fully understood.[13] Even if BVF is performed to optimize valve hemodynamics, it remains unclear whether satisfactory long-term outcomes after VIV TAVR can be best attained in a given patient by using a smaller TAVR valve which is fully expanded, or a larger TAVR valve which may not achieve full expansion (eg, a perfectly expanded 20 mm versus a suboptimally expanded 23 mm valve). Similarly, it remains unclear whether self-expanding or balloon-expandable transcatheter valves are better suited for this application. On the basis of bench testing, the radial force of a self-expanding valve seems adequate to achieve optimal expansion of the transcatheter valve inside a fractured surgical valve. On the other hand, Sapien XT and Sapien 3 valves deployed in a fractured surgical valve were underexpanded, and postdilatation with a noncompliant balloon was required to optimize the transcatheter valve expansion. Bench testing also suggests that the outer Dacron sewing ring of bioprosthetic valves results in a limit to how much further a valve can be expanded after BVF.[12] Therefore, further investigation is needed to determine optimal balloon sizing for BVF and optimal transcatheter valve selection when using this technique.

A final question that is raised by our results is the role of BVF in patients with larger surgical prostheses. Although these patients have a higher 1-year survival than patients with small surgical valves, as well as a lower incidence of PPM, after VIV TAVR, it is not known whether BVF of large prostheses will result in even further improvement in postprocedural hemodynamics and survival in these patients. There is some evidence to suggest that underexpansion of bioprosthetic valves may lead to early prosthetic deterioration because of folds in the bioprosthetic leaflets.[13] Therefore, an up-front strategy of BVF in all degenerated surgical valves could, in theory, improve outcomes for all patients undergoing VIV TAVR. Further clinical experience is required to provide insight on this novel technique.

Despite these initial promising results, there are several limitations to this study. Although no procedural complications were

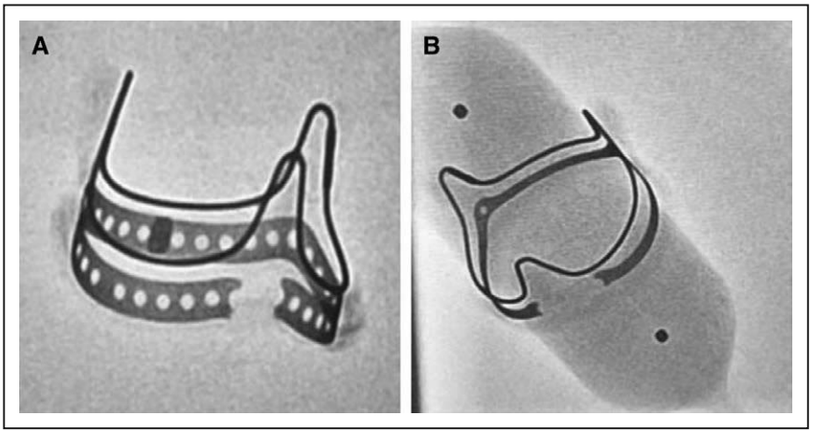

Figure 4. Ex vivo fluoroscopic images of fractured Magna (**A**) and Magna Ease (**B**) bioprosthetic valves.

observed with BVF in this small series, reasonable concerns remain regarding the potential for BVF to cause aortic root rupture or coronary artery occlusion, and a heavily calcified aortic root or anatomy predisposing to coronary occlusion might preclude the use of this technique. Because computed tomographic imaging was not routinely performed after BVF, subclinical injury to the aorta cannot be fully assessed. One patient in this series experienced a postprocedural stroke, but whether this complication was specifically related to BVF is unknown, and larger studies are needed to fully evaluate the safety of this technique. Previous work has demonstrated that although the majority of commercially available bioprosthetic valves can be fractured with high-pressure balloon inflation, some, such as the St Jude Trifecta and the Medtronic Hancock II, cannot be fractured.[12] Furthermore, the location of the previously implanted surgical valve (ie, supra-annular or intra-annular) may be important because BVF in a surgical valve that was implanted in the supra-annular position may offer a superior risk–benefit profile when compared with BVF of a surgical valve that was positioned in the native annulus. Further study of patient factors such as aortic root and coronary sinus dimension will be important to determine patient-specific limitations of BVF and avoid complications, and if concerns regarding such issues are present in a given patient, back-up cardiopulmonary support could be considered at the time of BVF.

Conclusions

BVF can be performed safely in small surgical valves to facilitate VIV TAVR with either balloon-expandable or self-expanding transcatheter valves and results in reduced residual transvalvular gradients and increased valve effective orifice area.

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References

1. Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM, Gleason TG, Buchbinder M, Hermiller J, Jr, Kleiman NS, Chetcuti S, Heiser J, Merhi W, Zorn G, Tadros P, Robinson N, Petrossian G, Hughes GC, Harrison JK, Conte J, Maini B, Mumtaz M, Chenoweth S, Oh JK; U.S. CoreValve Clinical Investigators. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med*. 2014;370:1790–1798. doi: 10.1056/NEJMoa1400590.
2. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Brown DL, Block PC, Guyton RA, Pichard AD, Bavaria JE, Herrmann HC, Douglas PS, Petersen JL, Akin JJ, Anderson WN, Wang D, Pocock S; PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med*. 2010;363:1597–1607. doi: 10.1056/NEJMoa1008232.
3. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, Thourani VH, Tuzcu EM, Miller DC, Herrmann HC, Doshi D, Cohen DJ, Pichard AD, Kapadia S, Dewey T, Babaliaros V, Szeto WY, Williams MR, Kereiakes D, Zajarias A, Greason KL, Whisenant BK, Hodson RW, Moses JW, Trento A, Brown DL, Fearon WF, Pibarot P, Hahn RT, Jaber WA, Anderson WN, Alu MC, Webb JG; PARTNER 2 Investigators. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. 2016;374:1609–1620. doi: 10.1056/NEJMoa1514616.
4. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, Tuzcu EM, Webb JG, Fontana GP, Makkar RR, Williams M, Dewey T, Kapadia S, Babaliaros V, Thourani VH, Corso P, Pichard AD, Bavaria JE, Herrmann HC, Akin JJ, Anderson WN, Wang D, Pocock SJ; PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med*. 2011;364:2187–2198. doi: 10.1056/NEJMoa1103510.
5. Dvir D, Webb JG, Bleiziffer S, Pasic M, Waksman R, Kodali S, Barbanti M, Latib A, Schaefer U, Rodés-Cabau J, Treede H, Piazza N, Hildick-Smith D, Himbert D, Walther T, Hengstenberg C, Nissen H, Bekeredjian R, Presbitero P, Ferrari E, Segev A, de Weger A, Windecker S, Moat NE, Napodano M, Wilbring M, Cerillo AG, Brecker S, Tchetche D, Lefèvre T, De Marco F, Fiorina C, Petronio AS, Teles RC, Testa L, Laborde JC, Leon MB, Kornowski R; Valve-in-Valve International Data Registry Investigators. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. *JAMA*. 2014;312:162–170. doi: 10.1001/jama.2014.7246.
6. Faerber G, Schleger S, Diab M, Breuer M, Figulla HR, Eichinger WB, Doenst T. Valve-in-valve transcatheter aortic valve implantation: the new playground for prosthesis-patient mismatch. *J Interv Cardiol*. 2014;27:287–292. doi: 10.1111/joic.12108.
7. Rahimtoola SH. The problem of valve prosthesis-patient mismatch. *Circulation*. 1978;58:20–24.
8. Dayan V, Vignolo G, Soca G, Paganini JJ, Brusich D, Pibarot P. Predictors and outcomes of prosthesis-patient mismatch after aortic valve replacement. *JACC Cardiovasc Imaging*. 2016;9:924–933. doi: 10.1016/j.jcmg.2015.10.026.
9. Brown SC, Cools B, Gewillig M. Cracking a tricuspid perimount bioprosthesis to optimize a second transcatheter sapien valve-in-valve placement. *Catheter Cardiovasc Interv*. 2016;88:456–459. doi: 10.1002/ccd.26507.
10. Nielsen-Kudsk JE, Christiansen EH, Terkelsen CJ, Nørgaard BL, Jensen KT, Krusell LR, Tang M, Terp K, Klaaborg KE, Andersen HR. Fracturing the ring of small Mitroflow bioprostheses by high-pressure balloon predilatation in transcatheter aortic valve-in-valve implantation. *Circ Cardiovasc Interv*. 2015;8:e002667. doi: 10.1161/CIRCINTERVENTIONS.115.002667.
11. Tanase D, Grohmann J, Schubert S, Uhlemann F, Eicken A, Ewert P. Cracking the ring of Edwards Perimount bioprosthesis with ultrahigh pressure balloons prior to transcatheter valve in valve implantation. *Int J Cardiol*. 2014;176:1048–1049. doi: 10.1016/j.ijcard.2014.07.175.
12. Allen KA, Chhatriwalla AK, Cohen DJ, Saxon JT, Aggarwal S, Hart AJ, Baron SJ, Davis R, Pak AF, Dvir D, Borkon AM. Bioprosthetic valve fracture to facilitate transcatheter valve-in-valve implantation [published online ahead of print June 29, 2017]. *Ann Thoracic Surg*. doi: 10.1016/j.athoracsur.2017.04.007. https://doi.org/10.1016/j.athoracsur.2017.04.007.
13. Grubitzsch H, Galloni M, Falk V. Wrinkles, folds and calcifications: reduced durability after transcatheter aortic valve-in-valve replacement. *J Thorac Cardiovasc Surg*. 2017;153:266–268. doi: 10.1016/j.jtcvs.2016.08.018.