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REVIEW

Balloon aortic valvuloplasty review: the revenge during COVID-19 outbreak?

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ABSTRACT

Aortic stenosis is a highly prevalent cardiac valvular disease in adult population and increases with age. After symptoms onset in severe aortic stenosis, the prognosis begins to decline; however, new studies demonstrate an increased risk of death in patients with moderate disease. Although majority of patients with severe aortic stenosis are treated electively with surgical or transcatheter aortic valve replacement, not all patients are candidates for the interventions. Balloon aortic valvuloplasty can be used successfully as a bridge to definitive treatment or as palliative therapy in patients who are not candidates for either procedure. In this paper, we discuss and justify the current indications and contraindications for balloon aortic valvuloplasty. Additionally, the step-by-step procedure technique and most frequent complications are described. Moreover, we presented the safety and feasibility of balloon aortic valvuloplasty in 33 consecutive patients on a waiting list for transcatheter aortic valve replacement at 3 expert Italian centers during the first and second waves of COVID-19, when clinical priorities focused on hospitalized patients with pneumonia. The procedural success in this cohort of patients was achieved in 31 patients (94%). Out of the 33 patients enrolled, 15 underwent TAVR within 5±2 months from the valvuloplasty, and at 6-month follow-up a total of 2 patients died for end-stage heart failure.

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KEY WORDS: TAVR; SAVR; Covid-19 Pandemic; Aortic stenosis; Balloon Aortic Valvuloplasty.

Aortic stenosis (AS) is the second most common heart valve disease after mitral regurgitation; the main underlying cause of AS is calcific degeneration, typical in the older population, while congenital bicuspid and rheumatic diseases are less common, and generally occur in a younger population.[1] The prevalence of calcific aortic sclerosis is around 1-2% in patients under 65 years old and increases with age, reaching 9.8% in the range of 80 to 89 years.[2, 3] AS manifests with exertional dyspnea, angina, and less frequently with syncope and heart failure. It is a progressive disease and symptoms usually deteriorate along with the severity of the stenosis.[4] The prognosis is poor even in mildly symptomatic patients with severe AS unless left ventricular (LV) obstruction is relieved. The average survival rate in this scenario is 1 to 3 years after initial symptoms;[5] however, a recent observational study showed low sur-

vival rates with a markedly increased risk of death in patients with moderate (mean gradient >20 mmHg) AS.[6] Although most patients with severe AS are treated on an elective basis with either surgical aortic valve replacement (SAVR) or transcatheter aortic valve replacement (TAVR), not all patients are candidates for both procedures, and a delay in treatment has been associated with poor mid-term prognosis, higher mortality and recurrent hospitalization.[7] In addition, not all centers with catheterization laboratory have access to perform TAVR or SAVR.

Balloon aortic valvuloplasty

Historical evolution

Balloon aortic valvuloplasty (BAV) for AS dates back to 1986 when Cribier *et al*. introduced the concept reporting 44 elderly patients treated with this technique through the femoral artery in 34 and the brachial artery in 10 cases. They performed multiple inflations ranging from 10 to 240 seconds, and only one patient developed syncope during the procedure. The mean transvalvular pressure gradient fell from 76+/-25 mmHg to 30+/-13 mmHg (P<0.001). After dilatation, the final gradient was less than or equal to 40 mmHg in 37 cases and residual aortic regurgitation was only observed in only one case. Two patients died during hospitalization, without any other serious complications. With a mean follow-up of 6 months, there was an improvement in symptoms in the vast majority of cases and, in particular, syncopal and anginal attacks disappeared, but 4 patients remained in functional class III or IV after the intervention.[8] Initial enthusiasm around this technique, promoted as an alternative to SAVR in older AS patients, waned with subsequent large registries, which showed the inability of this procedure to alter the natural history of calcific AS and its associated procedural morbidity. For many years, BAV has been used as palliative treatment for short-term relief of symptoms in elderly, non-surgical patients.nThe first-in-human case of a percutaneous transcatheter aortic valve implantation through a trans-septal approach was presented by Cribier *et al*. in 2002.[9] The valve was composed of 3 bovine pericardial leaflets mounted within a balloon-expandable stent: this intervention rejuvenated and revived the dormant field of BAV, thanks to the need to predilate the stenosed valve to facilitate placement of the prosthesis.[9] Subsequently in 2011, after the publication of a registry from a German-Swiss-Brazilian investigators group, which showed the safety and feasibility of TAVR without predilation, resulting in similar efficacy to the standard TAVR approach, the rate of BAV was decreased again.[10] The DIRECTAVI study randomized 236 patients undergoing TAVR with balloon-expandable Edwards SAPIEN 3 to prior predilation *versus* no predilation prior to prothesis implantation, and investigators found the non-inferiority of this technique, however, 7 (5.8%) patients in the group without predilation required BAV to cross the valve, mainly due to severe valve calcification and bicuspid anatomy; this suggested the need for an adequate prior selection, based on patient characteristics.[11, 12] The same clinical trial mentioned above was unable to demonstrate a reduction in procedure time without predilatation. On the contrary, in a study from the Italian GISE registry, BAV before TAVR reduced procedural time, mainly with the Evolut (Evolut S.p.A., Castegnato, Brescia, Italy) and Portico devices (Abbott Laboratories, Chicago, IL, USA).[13] The global rate of BAV has possibly increased, but mainly due to the increase in the number of patients with severe AS treated percutaneously. BAV can be successfully used as a bridge to SAVR and TAVR, as demonstrated by a recent study in 3691 TAVR patients, of whom 1426 underwent BAV. Timing to TAVR was before discharge in 7.4%, within 30 days in 35%, between 31 and 90 days in 47%, between 91 and 180 days in 14%, and >180 days in 4%. Following propensity score-matched cohorts of patients undergoing direct TAVR *versus* those with prior BAV, in-hospital mortality during TAVR admission was similar (3.7% *vs*. 3.5%; P=0.91). Major complications, length of stay, and discharge disposition were also comparable. However, hospitalization costs were higher in the direct TAVR group.[14] BAV has also been used as palliative therapy in patients who have been denied SAVR or TAVR. One study analyzed the long-term

outcomes of 212 non-surgical patients with age ranging between 59 to 104 years who underwent BAV. Twenty-four percent of patients underwent a second BAV and 9% a third BAV. The Duration of symptom relief after the first, second, and third BAV procedures were 18±3, 15±4, and 10±3 months, respectively. The median survival rate after BAV was 35 months. Survival rates at 1, 3, and 5 years after the procedure were 64%, 28%, and 14% respectively. Patients with repeated BAV had higher 3-year survival rates than patients who underwent a single BAV procedure (P=0.01).[15]

Indications and contraindication for BAV

The ESC guidelines give an indication to BAV for patients with AS requiring urgent high-risk non-cardiac surgery and those with decompensated AS, however the full list of indications is broader (Table I).[7, 16] Indeed, it is recommended to suggest BAV after discussion with the Heart Team. Although most patients with AS will undergo SAVR or TAVR, a group of patients can be considered unsuitable for both procedures and then BAV may represent an alternative. High-risk patients who are considered for TAVR after SAVR exclusion, may be treated with BAV instead for various factors such as: inadequate arterial vascular access, inadequate annular size (<18 mm, >29 mm), elevated risk of coronary ostium obstruction and estimated life expectancy <1 year.[16] Moreover, in patients with acute presentation with cardiogenic shock and AS, a scenario in which TAVI represents a risky procedure, BAV can be the first choice; however, the prognosis in this group of patients is always poor. For patients at high risk, need for complex coronary intervention,[17] very low LV ejection fraction, and patients with hemodynamic instability, ventricular assist devices can be used simultaneously. In 2013 Megaly *et al*. showed the first case of BAV assisted by Impella.[18] Moderate to severe aortic regurgitation is the most common contraindication to for BAV, as well as active endocarditis, aortic tumors, vegetations and LV thrombus.

Table I.—*Indications for the treatment with balloon aortic valvuloplasty.*

Definitive treatment
Palliative purposes in high-risk patients not eligible to TAVR or SAVR after heart team discussion
Bridge to SAVR or TAVR
Acute heart failure due to severe AS without clinical improvement after medical and supportive therapy
When there is doubt as to the relative contribution of the AS to the patient's condition and symptoms; and there is improvement after the BAV
To assess improvement in left ventricular function in patients with low-flow low gradient AS and very low LVEF
Patients who require urgent high-risk non-cardiac surgery
Severely symptomatic pregnant women with AS

AS: aortic stenosis; BAV: balloon aortic valvuloplasty; LVEF: left ventricular ejection fraction; SAVR: surgical aortic valve replacement; TAVR: trans-catheter aortic valve replacement.

Procedure technique step by step

The procedure is usually carried out under conscious sedation and performed by experienced interventional cardiologists. The most common approach is retrograde, with passage of the guidewire through the ascending aorta, but a trans-septal approach can be performed as well. Procedural success can be defined as a reduction of 50% of trans-aortic gradient or after a satisfactory reduction in trans-aortic gradient (<30 mm Hg) and increase in valve area (≥25% *vs*. baseline). Rapid right ventricular pacing is not mandatory but is strongly recommended due to the reduction in LV stroke volume during balloon inflations, to stabilize the balloon in the aortic annulus. In a study, 51 patients were randomized to pacing or not during BAV and the authors found no difference in terms of efficacy and safety of the procedure, but tolerance was lower in the pacing group.[19] The pacing modality may vary, the standard being from the right ventricle, but pacing can also be obtained from the LV through the 0.035'' guidewire. In a study of 202 patients, LV pacing showed a lower radiation dose (0.16 *vs*. 0.28 Gy, P=0.02), shorter fluoroscopy (5.4 *vs*. 10.3 min, P=0.01) and overall procedure time (17 *vs*. 25 min, P=0.01) compared to RV pacing.[20] After aortic valvuloplasty there is a certain risk of persistent complete atrio-ventricular block, especially in those patients with wide QRS at baseline or any other pre-existing conduction abnormality. Complete atrio-ventricular block usually resolves within 12 to 24 hours but may be permanent in a small

portion of patients. Laynez *et al*. demonstrated in a cohort of 271 patients a risk of new conduction defects in 8.5% of patients,[21] but only 1.5%[4] required definitive pacemaker implantation; the main factor associated with the risk of postprocedural conduction abnormalities was balloon oversizing, when comparing the balloon/LV outflow tract diameter ratio (1.21 for the group with new conduction defects *vs*. 1.15 for the group without defects).[22] Transesophageal echocardiography (TEE) (especially with 3D imaging) measurement of the aortic annulus diameter has shown to be more accurate than transthoracic echo with studies comparing direct intraoperative measurement.[23] TEE is not inferior to computed tomography for preoperative aortic annulus sizing, but in patients with a pronounced oval-shaped annulus, the computer tomography seems to be more accurate.[21] From the clinical standpoint, for BAV transthoracic echo is more practical and less invasive and is the first choice in most patients. This is a stepwise approach to modern-era BAV:

• preprocedural imaging is usually non-invasive with transthoracic echocardiogram to measure LV-aortic gradients, LV ejection fraction and aortic annulus to choose the appropriate balloon size, which is often underestimated with this modality. Echocardiography also serves to exclude potential contraindications to the procedure, such as significant aortic regurgitation, thrombus in the LV and tumors (Figure 1). Final echocardiographic assessment is highly recommended to evaluate procedural success on top of invasive measurements, and to exclude aortic valve damage and significant residual regurgitation;

• venous access: right internal jugular vein or right femoral vein access is recommended to place the temporary pacemaker in the right ventricle (Figure 2);

• arterial access: most cases can be performed through the right femoral route but as mentioned above, right radial arterial access can be used safely and has the potential to reduce vascular complications. Modern BAV balloons allow an 8 Fr introducer for most sizes (Figure 2). At this stage the patient receives 5000 I.U. of heparin for anticoagulation;

• crossing the aortic valve: as for TAVR, an AL 1.0 diagnostic catheter should be the first choice, with a 0.035" guidewire to enter the LV under fluoroscopy guidance. Once the guidewire is into the LV, the catheter is gently advanced, and the guidewire withdrawn. Hemodynamic measurements should be performed. Finally, a

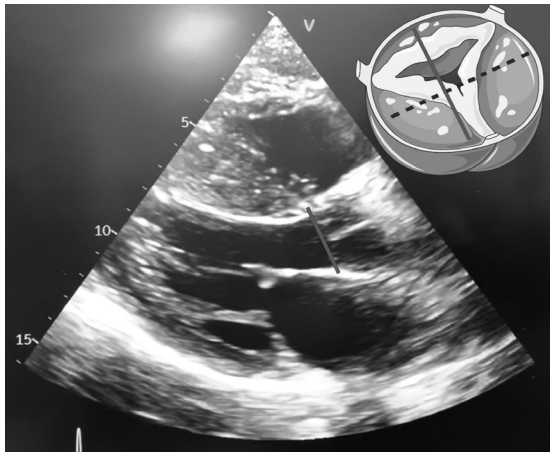


Figure 1.—Trans-thoracic echocardiographic parasternal long axis view. The dark grey line (red in the online version) indicates the measurement of the aortic annulus performed just at the leaflets' insertion site. On the right upper corner, a calcific aortic valve with severe stenosis shows the underestimation of the aortic annulus sizing with trans-thoracic echo. The dotted line (blue in the online version) shows the correct annulus size.

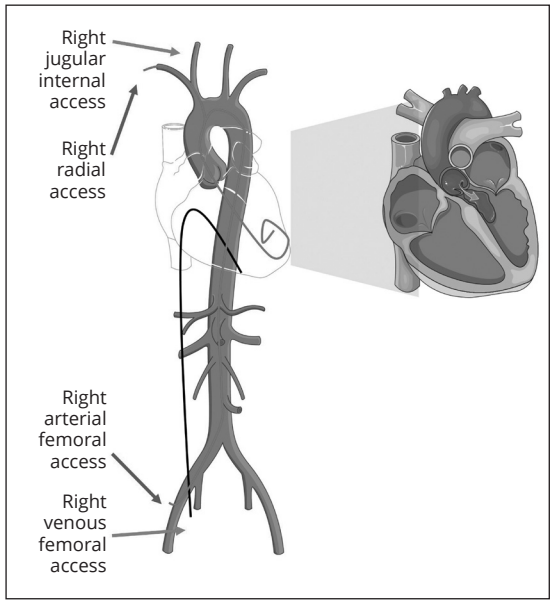


Figure 2.—Vascular access and complications of BAV.

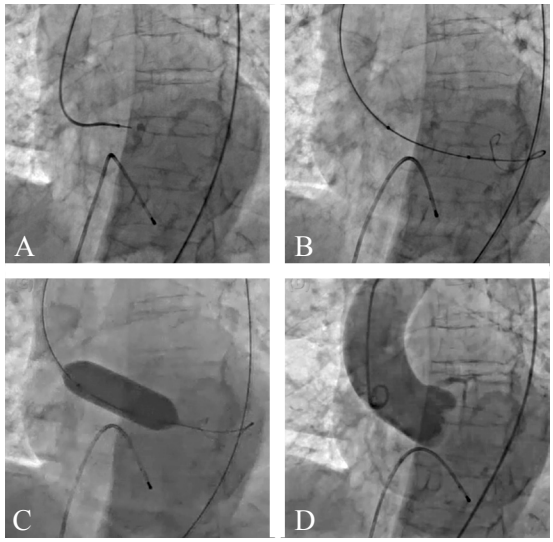


Figure 3.—BAV procedure: A) aortic valve crossing with AL1 catheter and straight guidewire, at the bottom a temporary pacemaker already in place; B) balloon positioning through the aortic valve; C) balloon inflation inside the aortic valve suffering some unintentional pullback but showing disappearance of the aortic "waist;" and D) final aortography showing good BAV result with mild aortic regurgitation.

stiff guidewire (*e.g.*, Amplatz super-stiff) with curve tip is placed into the LV and the catheter removed (Figure 3A);

• balloon selection: as mentioned before, the size of the balloon should be based on annulus diameter with a 0.9:1 or 1:1 balloon-to-annulus ratio.[24] In our experience, the balloon Valver ® (Balton, Poland) has a high profile with good deliverability and retraction;[25]

• positioning and preparation of the balloon: the balloon can be filled with contrast diluted at a ratio of 7-8:1, which allows the balloon to be visualized fluoroscopically, allowing fast inflation and deflation. A 50 mL syringe is attached. The catheter balloon is advanced to a position where the valve is between the 2 markers. For this step, either aortic valvular calcifications or echo are required (Figure 3B);

• right ventricular pacing starts at a rate of 180-220 beats/min just before balloon inflation and ends as soon as the balloon reaches peak inflation and is stabilized;

• balloon inflation: just after the increase in heart rate, the balloon is inflated to the desired pressure and according to the manufacturer's table, therefore the syringe is emptied, and hemodynamics is constantly assessed. During this phase, a decrease in systemic blood pressure is normally observed. Then, the balloon can be pulled toward the aortic root while it is deflated. Several inflations can be performed until the balloon indentation or "waist" disappears (Figure 3C). Some operators at this stage may decide to remove the guidewire and immediately assess intraventricular pressures with a diagnostic catheter. In case the operator secured another arterial access, an instantaneous pressure gradient can now be evaluated;

• final aortography in left-anterior oblique projection is recommended to evaluate complications such as the degree of aortic regurgitation and the (rare) possibility of annulus damage (Figure 3D).

Complications

The most frequent complications of BAV are vascular and related to the access site, and usually involve the arterial entry site. Significant vascular trauma, bleeding or arrhythmias occur in approximately 5% to 20% of patients,[26, 27] but newer generation balloons with lower profile and the use of a radial approach significantly reduced this complication. Embolic phenomena are infrequent, occurring in <1% of the cases. The need for permanent pacemaker after valvuloplasty is as low as 0.2%.[28] LV perforation, cardiac tamponade, valve annular rupture, and severe aortic regurgitation are rare (<0.5%) but serious complications[29, 30] (Figure 2). In addition, aortic valve leaflet rupture causing delayed left main coronary ostial obstruction has been described.[31] Moreover, a group of researchers recently published in this journal an interesting work of 24 patients demonstrating the safety and efficacy of BAV through the radial approach without any serious complication[32] and for cases where femoral access is not an option, bi-radial BAV using 2 balloons in a kissing fashion may be feasible.[33]

A COVID-19 recent clinical problem: and aortic stenosis

Out of the European regions, Lombardy was the first and one of the most affected during

COVID-19 outbreak. During the first, second and third pandemic waves in 2020 and 2021, clinical priorities were focused on the availability of beds in intensive care units or wards for patients infected with severe acute COVID-19 pneumonia.[34] This led to inadequate assistance for cardiovascular patients, including urgent and non-urgent valvular cases, which were deferred to an unpredictable waiting time. Although majority of patients with AS are treated on an elective basis either with SAVR or TAVR, a delay in treatment has been associated with worse mid-term outcomes, increased mortality, and recurrent hospitalization. Compared to 2019, in 2020 we observed a striking reduction in TAVR of 9% in Italy and of 20% in Lombardy (GISE 2020 data).

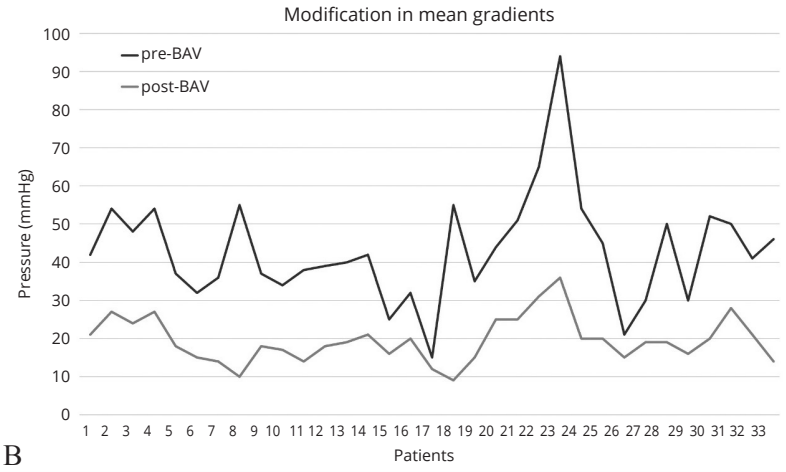
BAV-an option for patients with severe AS during the pandemic

BAV becomes a viable option to provide rapid, less invasive, and safe management to those patients who await definite treatment, without possibility to turn the clock back. In the COVID-19 era, the impossibility to warrant an efficient TAVR program in Northern Italy led to an increase in mortality in AS patients.[35] Thereafter, the BAV rate has increased in several centers in the region. We report the immediate and short-term outcome of patients scheduled for TAVR

Characteristics of the patients		Peri-procedural aspects	
Age, years (mean±SD)	86±5.5	Trans-radial access, no. (%)	13 (36)
Female sex, no. (%)	18 (55)	Aortic balloon size, mm (mean±SD)	20.5±1.8
Hypertension, no. (%)	25 (76)		
Diabetes Mellitus, no. (%)	8 (24)	Aortic balloon inflations (mean±SD)	2.8±0.9
Renal disease, no. (%)	5 (15)		
CAD and PCI, no. (%)	13 (39)	Final peak invasive gradient, mmHg (mean±SD)	29±14.1
NYHA class, no. (mean±SD)	2.53±0.7		
LVEF, % (mean±SD)	51±9.2	Final mean invasive gradient, mmHg (mean±SD)	16±6.2
EuroScore II (mean±SD)	7.3±2.4		
		Final peak echo gradient, mmHg (mean±SD)	35.4±12.3
		Final mean echo gradient, mmHg (mean±SD)	21.9±9.6
		Procedural success, no. (%)	

Pre-procedural echo parameters		Post-procedural complications	
Peak echo gradient, mmHg (mean±SD)	71±23.6	Aortic regurgitation, no. (%)	1 (3)
Mean echo gradient, mmHg (mean±SD)	44±14.7	Septic shock, no. (%)	1 (3)
Aortic anulus, mm (mean±SD)	20.8±2.8	Bleeding BARC type 2, no. (%)	2 (6)

A



B

Figure 4.—Patient characteristics, peri-procedural aspects and improvement in LV/Ao gradients after balloon aortic valvuloplasty. Ao: aortic; BARC: Bleeding Academic Research Consortium; CAD: coronary artery disease; LV: left ventricle; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention.

who, however, had to be treated with BAV during the first and second wave of COVID-19 pandemic in 2020 to bridge to a future TAVR.

Design and results

Between March and December 2020, a total of 33 patients underwent aortic valvuloplasty at 3 Italian TAVR expert centers. In the Figure 3A, B, we present the main patients' characteristics, the noninvasive (echo) and invasive periprocedural parameters, the procedural success and the postprocedure complications. There was a high percentage of females, an elderly population with significant comorbidities. The mean EuroScore II of 7.3±2.4 reflects the high risk of this cohort for SAVR. Concomitant coronaropathy was always completely revascularized with a median time of 3.2±0.9 days before valvuloplasty. The peak/mean echocardiographic gradients were 71±26 and 44±13 mmHg, respectively and the mean aortic anulus was 20.8±2.8 mm. Nine patients had a mean aortic gradient below 40 mmHg, and were classified as low-flow/low-gradient AS. As per our habits, no patient received anesthesia or sedation and we carried out the intervention with a trans-radial approach in one third of the patients. Final peak/mean invasive and echo gradients shown in Figure 3A, B, demonstrated a procedural success (final peak LV/Ao gradient <50%) in 94% of the cases.In one case BAV led to acute severe aortic regurgitation that was managed medically with diuretics and supportive measures with strict surveillance until TAVR (3 months later); we observed one case of septic shock, probably due to pneumonia and 2 Bleeding Academic Research Consortium type 2 hemorrhagic complications, managed with comfort measures and surveillance without the need for blood transfusions. Out of 33 patients enrolled, 15 underwent TAVR within 5±2 months of valvuloplasty, and at 6-month follow-up, 2 patients waiting definitive treatment died of end-stage heart failure.

Limitations of the study

Balloon valvuloplasty cannot be considered an alternative to TAVR; however, the current pandemic has shown some of the limitations of the Western European healthcare system, with a striking increase in cardiovascular deaths and a wicked reduction in facilities for complex cardiovascular interventions during the COVID-19 waves.

Conclusions

This study shows the safety and feasibility of BAV in patients on a (long) waiting list for TAVR and suggests some hints for the implementation of a BAV program: 1) the technique is easily adoptable in any catheterization laboratory; 2) is associated with acceptable short-term outcome (Figure 4); and 3) can be implemented as a mid-term bridge therapy to TAVR, or a definite one in case TAVR is not accessible or is very risky.

Key messages

- Balloon aortic valvuloplasty (BAV) remains as an important tool for definitive or bridging treatment of severe aortic stenosis in selected cases.
- BAV is safe, feasible and effective in high-risk patients awaiting definitive treatment with trans-catheter aortic valve replacement (TAVR) in special scenarios such as the COVID-19 outbreak.
- Periprocedural aspects of BAV should be focused on a minimalist approach: conscious sedation, noninvasive echocardiography, radial over femoral access, and retrograde approach.

References

1. Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. Lancet 2006;368:1005–11.

2. d'Arcy JL, Coffey S, Loudon MA, Kennedy A, Pearson-Stuttard J, Birks J, *et al.* Large-scale community echocardiographic screening reveals a major burden of undiagnosed valvular heart disease in older people: the OxVALVE Population Cohort Study. Eur Heart J 2016;37:3515–22.

3. Eveborn GW, Schirmer H, Heggelund G, Lunde P, Rasmussen K. The evolving epidemiology of valvular aortic stenosis. the Tromsø study. Heart 2013;99:396–400.

4. Lindman BR, Bonow RO, Otto CM. Current management of calcific aortic stenosis. Circ Res 2013;113:223–37.

5. Bach DS, Siao D, Girard SE, Duvernoy C, McCallister BD Jr, Gualano SK. Evaluation of patients with severe symptomatic aortic stenosis who do not undergo aortic valve replacement: the potential role of subjectively overestimated operative risk. Circ Cardiovasc Qual Outcomes 2009;2:533–9.

6. Strange G, Stewart S, Celermajer D, Prior D, Scalia GM, Marwick T, *et al.*; National Echocardiography Database of Australia contributing sites. Poor Long-Term Survival in Patients With Moderate Aortic Stenosis. J Am Coll Cardiol 2019;74:1851–63.

7. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, *et al.*; ESC/EACTS Scientific Document Group. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J 2022;43:561–6322.

8. Cribier A, Savin T, Saoudi N, Behar P, Rocha P, Mechmèche R, *et al.* [Percutaneous transluminal aortic valvuloplasty using a balloon catheter. A new therapeutic option in aortic stenosis in the elderly]. Arch Mal Coeur Vaiss 1986;79:1678–86. [French].

9. Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F, *et al.* Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation 2002;106:3006–8.

10. Grube E, Naber C, Abizaid A, Sousa E, Mendiz O, Lemos P, *et al.* Feasibility of transcatheter aortic valve implantation without balloon pre-dilation: a pilot study. JACC Cardiovasc Interv 2011;4:751–7.

11. Leclercq F, Robert P, Akodad M, Macia JC, Gandet T, Delseny D, *et al.* Prior Balloon Valvuloplasty Versus Direct Transcatheter Aortic Valve Replacement: Results From the DIRECTAVI Trial. JACC Cardiovasc Interv 2020;13:594–602.

12. Tchetche D, de Biase C, van Gils L, Parma R, Ochala A, Lefevre T, *et al.* Bicuspid Aortic Valve Anatomy and Relationship With Devices: The BAVARD Multicenter Registry. Circ Cardiovasc Interv 2019;12:e007107.

13. Giordano A, Corcione N, Ferraro P, Morello A, Conte S, Bedogni F, *et al.*; RISPEVA (Registro Italiano GISE sull'impianto di Valvola Aortica Percutanea) Study Investigators. Impact of Predilation Before Transcatheter Aortic Valve Implantation with New-Generation Devices. Cardiovasc Revasc Med 2019;20:1096–9.

14. Kawsara A, Alqahtani F, Eleid MF, El-Sabbagh A, Alkhouli M. Balloon Aortic Valvuloplasty as a Bridge to Aortic Valve Replacement: A Contemporary Nationwide Perspective. JACC Cardiovasc Interv 2020;13:583–91.

15. Agarwal A, Kini AS, Attanti S, Lee PC, Ashtiani R, Steinheimer AM, *et al.* Results of repeat balloon valvuloplasty for treatment of aortic stenosis in patients aged 59 to 104 years. Am J Cardiol 2005;95:43–7.

16. Williams T, Hildick-Smith DJ. Balloon aortic valvuloplasty: indications, patient eligibility, technique and contemporary outcomes. Heart 2020;106:1102–10.

17. Sacha J, Krawczyk K, Gawor M, Płonka J, Gierlotka M. Balloon aortic valvuloplasty, Impella insertion and complex coronary intervention: is this all feasible fully percutaneously via upper limb access? Postepy Kardiol Interwencyjnej 2021;17:126–8.

18. Megaly M, Jones P. Impella CP-assisted balloon aortic valvuloplasty. J Cardiol Cases 2016;14:49–51.

19. Dall'Ara G, Marzocchi A, Taglieri N, Moretti C, Rodinò G, Chiarabelli M, *et al.* Randomized comparison of balloon aortic valvuloplasty performed with or without rapid cardiac pacing: the pacing versus no pacing (PNP) study. J Interv Cardiol 2018;31:51–9.

20. Kleczynski P, Dziewierz A, Socha S, Rakowski T, Daniec M, Zawislak B, *et al.* Direct Rapid Left Ventricular Wire Pacing during Balloon Aortic Valvuloplasty. J Clin Med 2020;9:1017.

21. Kempfert J, Van Linden A, Lehmkuhl L, Rastan AJ, Holzhey D, Blumenstein J, *et al.* Aortic annulus sizing: echocardiographic versus computed tomography derived measurements in comparison with direct surgical sizing. Eur J Cardiothorac Surg 2012;42:627–33.

22. Laynez A, Ben-Dor I, Hauville C, Xue Z, Satler LF, Kent KM, *et al.* Frequency of cardiac conduction disturbances after balloon aortic valvuloplasty. Am J Cardiol 2011;108:1311–5.

23. Nishi T, Shibayama K, Tabata M, Kato N, Noguchi M, Okumura H, *et al.* Accuracy and usefulness of aortic annular measurement using real-time three-dimensional transesophageal echocardiography: comparison with direct surgical sizing. J Cardiol 2018;71:230–6.

24. Patsalis PC, Al-Rashid F, Neumann T, Plicht B, Hildebrandt HA, Wendt D, *et al.* Preparatory balloon aortic valvuloplasty during transcatheter aortic valve implantation for improved valve sizing. JACC Cardiovasc Interv 2013;6:965–71.

25. Bil J, Modzelewski P, Pawlak A, Gil RJ. Balloon aortic valvuloplasty with valver balloon catheter in adults with severe aortic stenosis as a bridge or palliative treatment. Wiad Lek 2021;74:1622–7.

26. Kefer J, Gapira JM, Pierard S, De Meester C, Gurne O, Chenu P, *et al.* Recovery after balloon aortic valvuloplasty in patients with aortic stenosis and impaired left ventricular function: predictors and prognostic implications. J Invasive Cardiol 2013;25:235–41.

27. Christodoulidis G, Yu J, Kini A, Dangas GD, Baber U, Melissa A, *et al.* Gender-specific outcomes after balloon aortic valvuloplasty: inhospital and long-term outcomes. Am Heart J 2015;170:180–6.

28. Khawaja MZ, Sohal M, Valli H, Dworakowski R, Pettit SJ, Roy D, *et al.* Standalone balloon aortic valvuloplasty: indications and outcomes from the UK in the transcatheter valve era. Catheter Cardiovasc Interv 2013;81:366–73.

29. Sakata Y, Syed Z, Salinger MH, Feldman T. Percutaneous balloon aortic valvuloplasty: antegrade transseptal vs. conventional retrograde transarterial approach. Catheter Cardiovasc Interv 2005;64:314–21.

30. Dall'Ara G, Santarelli A, Marzocchi A, Bacchi Reggiani ML, Sabattini MR, Moretti C, *et al.* Vascular complications after balloon aortic valvuloplasty in recent years: incidence and comparison of two hemostatic devices. Catheter Cardiovasc Interv 2018;91:E49–55.

31. Parekh A, Sengupta V, Hunyadi V, Ianitelli M, Zainea M. Aortic Valve Leaflet Rupture Causing Delayed Left Main Coronary Ostial Obstruction During Valvuloplasty Preceding TAVR. JACC Case Rep 2021;3:1822–7.

32. Medina DE Chazal HA, Seropian IM, Romeo F, Chiabrando JG, Valle Raleigh J, Berrocal DH, *et al.* Balloon aortic valvuloplasty through the novel transradial technique. Minerva Cardiol Angiol 2021;69:458–63.

33. ELJack AF, Hamandi M, Cubberley A, Potluri S, Szerlip M, Wang Z, *et al.* Bi-radial balloon aortic valvuloplasty as a bridge to gastric surgery in preparation for transcatheter aortic valve replacement in a patient with severe aortic stenosis and class III morbid obesity. J Am Coll Cardiol 2021;77:2458.

34. Grasselli G, Pesenti A, Cecconi M. Critical Care Utilization for the COVID-19 Outbreak in Lombardy, Italy: Early Experience and Forecast During an Emergency Response. JAMA 2020;323:1545–6.

35. Shreenivas S, Choo J, Answini G, Sarembock IJ, Griffin J, Smith JM, *et al.* TAVR During the COVID-19 Pandemic: The ACC/SCAI Consensus Statement. JACC Cardiovasc Interv 2020;13:1605–6.

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