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Comprehensive Review

Balloon Aortic Valvuloplasty in the Modern Era: A Review of Outcomes, Indications, and Technical Advances

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ABSTRACT

Balloon aortic valvuloplasty (BAV) improves the hemodynamics and symptoms of patients with severe aortic stenosis in the short term with low rates of complications, but has not been shown to be an effective destination therapy. Our pooled analysis of >14,300 patients from studies published between January 1, 1991, and April 31, 2022, reported intraprocedural mortality and in-hospital mortality rates as 1.94% (95% CI, 1.39%-2.59%) and 6.02% (95% CI, 4.83%-7.32%), respectively. Hence, BAV is primarily indicated as a bridge to aortic valve replacement/decision with secondary uses as bridge to noncardiac surgery and palliative therapy. Recent advancements in alternative access sites, balloon catheters, and lithotripsy for BAV have opened opportunities for expanded use and further improvements in complication rates. As the utilization of BAV has continually increased since the advent of transcatheter aortic valve replacement, reexamining the role and outcomes of BAV in the era of transcatheter aortic valve replacement has become increasingly important. This review focuses on the outcomes, indications, advances, and technical considerations for BAV.

Introduction

Balloon aortic valvuloplasty (BAV) was introduced in 1986 by Cribier as an alternative to surgical aortic valve replacement (SAVR) in elderly patients with severe aortic valve stenosis (sAS).[1] Early experiences with BAV indicated a limited effect on patient survival with a significant risk of morbidity and mortality, leading to tampered enthusiasm and limited utilization as a palliative measure in patients without a surgical option.[2,3] In the past 2 decades, the advent of transcatheter aortic valve replacement (TAVR) has led to a renewed interest of BAV as a bridge to TAVR in patients with underlying medical illnesses that could eventually resolve but currently precludes them from TAVR. Recent data indicate that the utilization of BAV has soared since the introduction of TAVR, particularly in the United States.[4] The indications, risks, benefits, and safety of BAV have accordingly come under greater scrutiny once again in the contemporary TAVR era.

In concert with the rapid dissemination of TAVR, operator comfort with large bore access and percutaneous femoral access has improved in recent years. Concomitantly, there have been significant advances in technology and technique with changes in balloon catheters, ventricular pacing strategies, and arterial access sites over the past 2 decades.[5-7] These changes have increased the viability of BAV since its introduction. However, data are conflicted on the efficacy of BAV as a bridge to TAVR, and the success of TAVR lends the question of what role BAV should have in contemporary practice.[8] In this review, we will explore the outcomes of BAV, the modern use of BAV in the era of TAVR, recent advances in BAV technology, and technical considerations.

Outcomes after BAV

The procedural efficacy of BAV may be objectively evaluated through changes in preprocedural and postprocedural transaortic valve pressure gradients and aortic valve area (AVA) using invasive hemodynamics and noninvasive echocardiography. There is extensive evidence that BAV effectively decreases the peak-to-peak aortic valve (AV) gradients in patients with severely calcified aortic stenosis (AS).[9,10] This decrease in the transvalvular pressure gradient has been shown to persist for at least 30 days postprocedure and correlates with major improvements in symptoms related to heart failure.[11] A contemporary study examining the safety and efficacy of BAV in 612 patients at a quaternary care center across a range of presentations (including those who were treated in the intensive care unit [ICU], hospitalized with decompensated heart failure, and presented in the outpatient setting)

Abbreviations: AS, aortic stenosis; AVA, aortic valve area; BAV, balloon aortic valvuloplasty; BVF, bioprosthetic valve fracture; LFLG-AS, low-flow low-gradient aortic stenosis; PVL, paravalvular leak; RVP, rapid ventricular pacing; sAS, severe aortic stenosis; TAVR, transcatheter aortic valve replacement; VIV, valve-in-valve.

Keywords: aortic valve stenosis; balloon aortic valvuloplasty; outcomes; transcatheter aortic valve replacement.

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tracked post-BAV survival, adverse events, invasive hemodynamic measures (invasive peak-to-peak left ventricular to aorta gradient and AVA), and immediate postprocedural echocardiographic parameters. Many of these patients underwent TAVR following BAV, with a median follow-up of 307 days. It was found that BAV improved peak-to-peak and mean AV gradients regardless of the acuity of patient illness, with a consistent hemodynamic benefit among patients in the outpatient, ward, and ICU settings with no intergroup differences. Notably, the hemodynamic and symptomatic benefits of BAV extended to critically ill patients with cardiogenic or septic shock, resulting in clinical improvements and survival to hospital discharge for most ICU patients who otherwise might have expired.[12]

Despite the success of BAV in short-term stabilization and symptomatic relief of the sickest patients, BAV has not been shown to be an effective long-term treatment option. For patients who are unable to undergo TAVR as destination therapy owing to a procedural or clinical impediment, there is recurrence of sAS at 6-12 months after standalone BAV and a considerably higher rate of 1-year mortality compared with those of patients subjected to TAVR or SAVR.[10,11] Overall, data support that BAV can temporarily get the sickest patients with sAS "out of trouble," allowing more time for clinical improvement or diagnostic evaluation to better assess which patients will benefit from permanent aortic valve replacement (AVR).

Pooled analysis of outcomes

Reassuringly, BAV seems safe with low rates of procedural complications and short-term mortality.[9,12,13] A retrospective multicenter study following up acute and long-term outcomes of 811 patients with sAS who underwent BAV as destination therapy, bridge to TAVR, and bridge to SAVR found relatively low rates of 30-day all-cause death and major bleeds with no significant intergroup differences.[13] To further quantify the rates of procedural complications after BAV in contemporary practice, we performed a random-effects pooled analysis of 25 studies consisting of >14,300 patients. The PubMed online database was queried for studies that reported on intraprocedural mortality, in-hospital mortality, stroke, major vascular events, transfusion/major bleeding events, pacemaker implantation, myocardial infarction, and acute aortic regurgitation (AR) after BAV from January 1, 1991, to April 31, 2022. The full method of the pooled analysis is detailed in the Supplementary Material.

Notably, the rates of intraprocedural death, stroke, major vascular events, and acute AR were 1.94%, 1.27%, 4.77%, and 1.31%, respectively (Figures 1-4). Rates of these and other complications with their 95% confidence intervals in the pooled analysis are detailed in Table 1. The forest plots of the pooled analysis for the rate of in-hospital death, major bleeding events, pacemaker implantation, and myocardial infarctions are reported in Supplemental Figures S1-S4, respectively.

Comparison of BAV and TAVR

Using the Nationwide Inpatient Sample data from 2004 to 2013, Alkhouli et al[4] examined the safety of propensity-matched groups of patients who underwent BAV and TAVR. Notably, there were no significant differences in procedural and in-hospital mortality between these 2 groups, but BAV was associated with less pacemaker implantations and blood transfusions than TAVR. Furthermore, BAV was associated with lower resource utilization and length of hospital stay than TAVR. BAV may have lower mortality for critically ill patients with sAS and shorter hospital stays than TAVR, making BAV a safer option for high-risk patients.

These data indicate that BAV is effective in temporary relief of sAS with significant decreases in mean transaortic valve pressure gradients

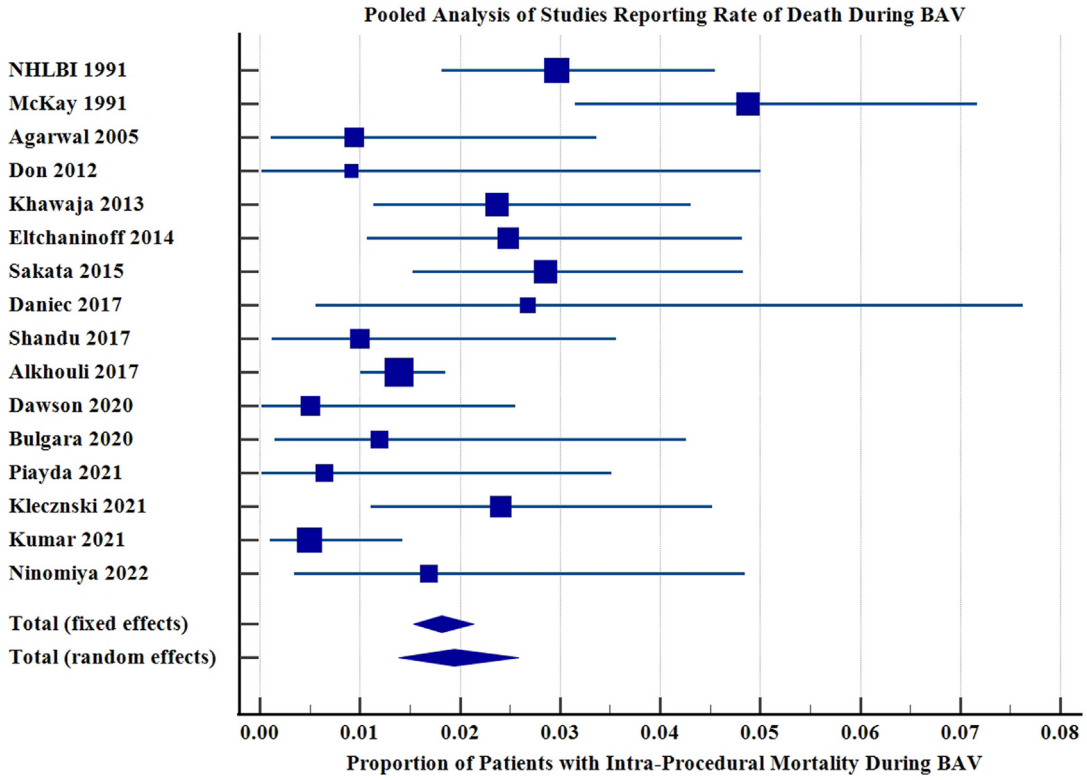


Figure 1.
Forest plot of pooled analysis of studies reporting rate of death during BAV. On pooled analysis of 16 studies including 7880 patients, the rate of intraprocedural deaths during BAV was 1.94% (95% CI, 1.39%-2.59%). BAV, balloon aortic valvuloplasty.

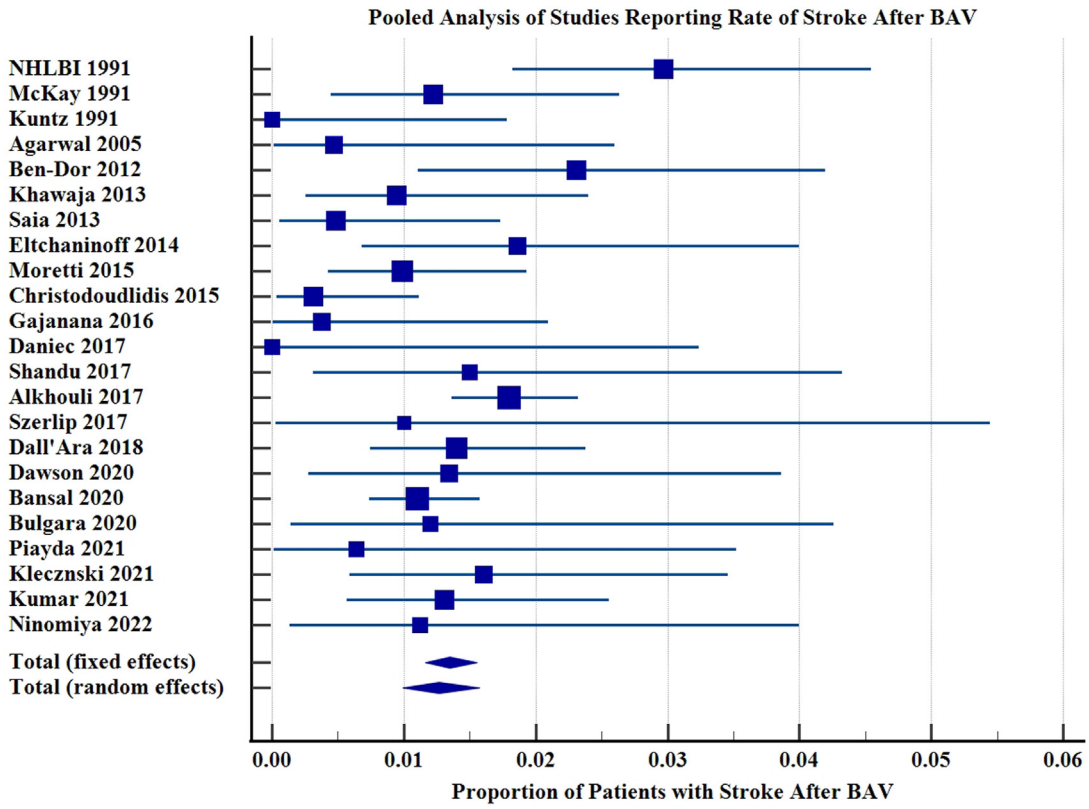


Figure 2.
Forest plot of pooled analysis of studies reporting rate of stroke after BAV. On pooled analysis of 23 studies including 13,751 patients, the rate of stroke after BAV was 1.27% (95% CI, 0.99%-1.57%). BAV, balloon aortic valvuloplasty.

and improvement of symptoms. In the hands of a skilled operator, BAV is procedurally safe and should be considered as a feasible short-term treatment option for high-risk patients or those in extenuating circumstances. However, BAV is not a durable treatment option of sAS and is not suitable as a destination therapy in patients who can safely undergo TAVR.

Role of BAV in the TAVR Era

Bridge to permanent AVR (TAVR/SAVR)

American College of Cardiology/American Heart Association and European Society of Cardiology guidelines indicate BAV as a bridge to TAVR/SAVR and noncardiac surgery in hemodynamically unstable patients.[14,15] The contemporary indications for BAV are outlined in the Central Illustration and Figure 5. In patients for whom BAV is intended as a bridge to TAVR, one should consider obtaining femoral access on the side not intended for TAVR, use of as small of a sheath as possible, avoiding collagen-based closure devices—particularly if the same side is needed for TAVR, and completion imaging of the femoral artery such as angiography of the common femoral artery to assess for dissection or computed tomography (CT) angiography of the abdomen/pelvis.

As previously mentioned, BAV may help stabilize patients with comorbid medical issues or those critically ill or as a diagnostic and therapeutic maneuver in patients in whom the contribution of AS to their symptoms is uncertain. BAV has a low rate of procedural complications and reasonable effectiveness in ameliorating symptoms out to 6 months.[10,11] However, BAV as an isolated destination therapy is associated with valve restenosis and poorer long-term outcomes than AVR.[11] BAV as a bridge to TAVR is generally considered safe. Recent data indicate that among patients who underwent BAV with subsequent TAVR or SAVR, mortality rates were low and in line with patients who underwent TAVR or SAVR alone.[8,16] In addition, BAV does not necessarily lead to a delay in the time to receiving TAVR, as Kumar et al[12] showed that the time to TAVR was generally similar among patients regardless of if they underwent BAV or not.

BAV as a bridge to TAVR may be performed safely in patients with low-flow low-gradient aortic stenosis (LFLG-AS). A study found that BAV as a bridge to TAVR in 16 patients with LFLG-AS resulted in a reduction in the peak gradient by 4.0 mm Hg, an increase in the ejection fraction by 6.4%, and similar 30-day and 1-year mortality rates as the 22 patients with high-gradient aortic stenosis (HG-AS) within the study population.[17] In addition, the rates of periprocedural and postprocedural complications were similar between the HG-AS and LFLG-AS groups. Further research with larger sample sizes will be needed to confirm the safety and efficacy of BAV as a bridge to TAVR in the setting of LFLG-AS. However, a single-center retrospective study demonstrated that using the mean pressure gradient as a surrogate for BAV success may not be adequate for patients with LFLG-AS, suggesting that the measures of success for BAV in the setting of LFLG-AS may need refinement.[18] Although BAV as a bridge to TAVR has shown positive outcomes in treating HG-AS, LFLG-AS presents as another distinct clinical scenario in which BAV as a bridge to TAVR may be considered.

Although direct TAVR has been shown to be effective even among critically ill patients, TAVR is a more expensive procedure than BAV, and resource utilization is higher despite having similar short-term mortality as BAV.[4] A recent meta-analysis evaluating device success and complications for patients undergoing direct TAVR or TAVR with systematic

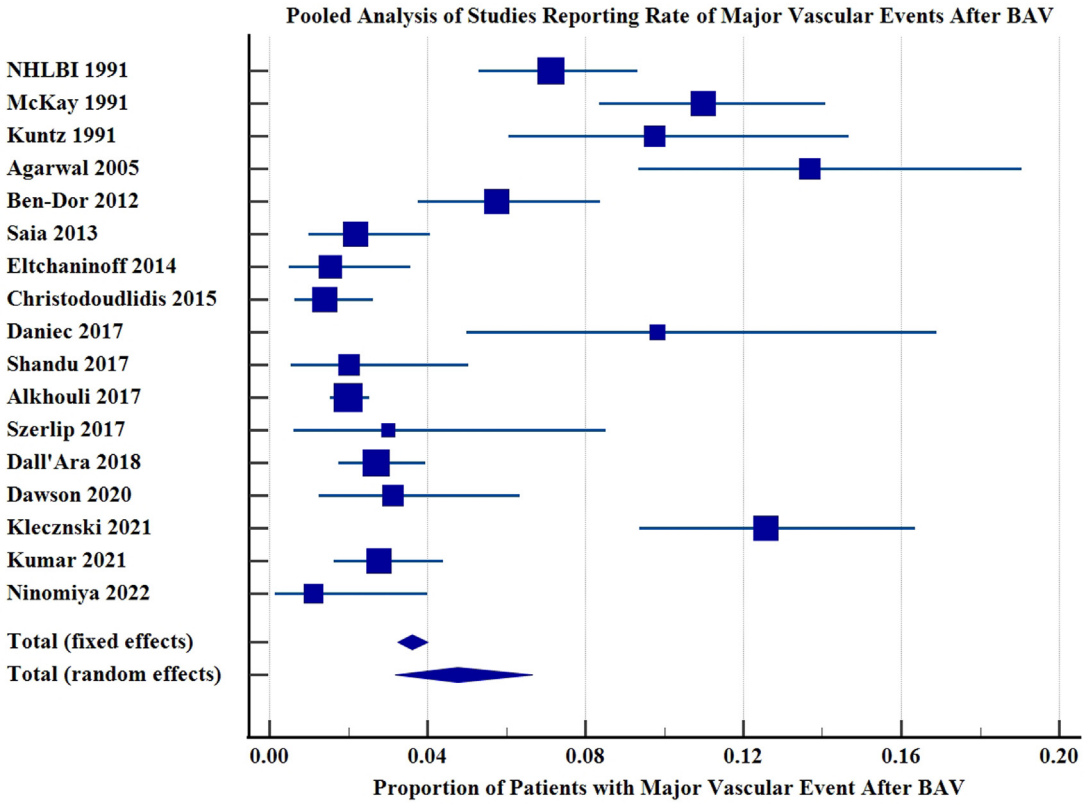


Figure 3.
Forest plot of pooled analysis of studies reporting rate of major vascular events after BAV. On pooled analysis of 17 studies including 9297 patients, the rate of major vascular events after BAV was 4.77% (95% CI, 3.18%-6.66%). BAV, balloon aortic valvuloplasty.

BAV before showed that there were no significant differences between the 2 groups regarding the rates of device success, 30-day mortality, stroke, pacemaker implantation, and acute kidney injury (AKI).[8] However, there is evidence that TAVR may lead to greater reductions in readmissions of patients for decompensated heart failure and cardiogenic shock than in those treated with urgent BAV not offered TAVR in a timely fashion.[16] BAV is not required in most patients and should be reserved for patients who are unable to undergo TAVR owing to temporary medical contraindications, when the contribution of sAS to patient condition is in question or when the severity of AS is ambiguous—but patients could subsequently be offered TAVR in a timely fashion.

Bridge to urgent or high-risk noncardiac surgery

The management of patients with sAS who require high-risk noncardiac surgery remains difficult. The presence of sAS is well known to be associated with an increased risk of perioperative and postoperative complications from noncardiac surgeries,[19,20] but the optimal management of AS is not well defined.[21] BAV can be performed for patients with severe symptomatic AS in whom AVR would involve high risk, would involve difficult recovery, or could not be offered expeditiously enough before an emergent noncardiac surgery.[14,15] Calicchio et al[22] conducted a study in which BAV as a bridge to noncardiac surgery led to symptomatic improvement and was well tolerated, although the sample size and follow-up time were limited. However, another study conducted across 2 centers with a larger sample population found that BAV did not significantly improve the clinical outcome in comparison with conservative management of sAS for patients requiring noncardiac surgery at the 1-month follow-up.[23] These findings illustrate that BAV as a bridge for urgent/high-risk noncardiac surgery may temporarily improve hemodynamics in the short term but may not be particularly beneficial for clinical outcomes after noncardiac surgery. Furthermore, these studies emphasize the importance of careful patient selection for performing BAV as a bridge to urgent/high-risk noncardiac surgeries. Conservative management may be particularly reasonable in patients with normal N-terminal pro–B-type natriuretic peptide, without symptoms of AS, or in whom BAV is a high risk. However, there are no data on the use of BAV for preoperative optimization of patients with asymptomatic sAS before noncardiac surgery, despite this being a common reason for performing BAV, and additional studies are needed in this area. Nevertheless, these studies are limited in scope, and further research is required to characterize the true utility of BAV as a bridge to noncardiac surgeries.

Critically ill patients who are not currently candidates for TAVR

Patients with critical illness due to cardiogenic shock or noncardiac issues may not be appropriate for TAVR. In a recent study among patients treated with TAVR in the United States between 2014 and 2017, preceding cardiogenic shock was associated with high 30-day mortality (19.1%) post-TAVR. This was despite high rates of procedural success, indicating that the degree of shock drives mortality in this population rather than procedural complications.[24] For critically ill patients, BAV presents as a possible alternative to stabilize patients with cardiogenic shock before TAVR. In a separate study, ICU patients with cardiogenic shock who underwent BAV before TAVR showed similar rates of 1-year mortality as patients with lower severity illness, and most ICU patients who underwent BAV survived to hospital discharge.[12] These support the role of BAV as a temporizing agent to bridging critically ill patients who are not immediately able to undergo TAVR and may lead to better

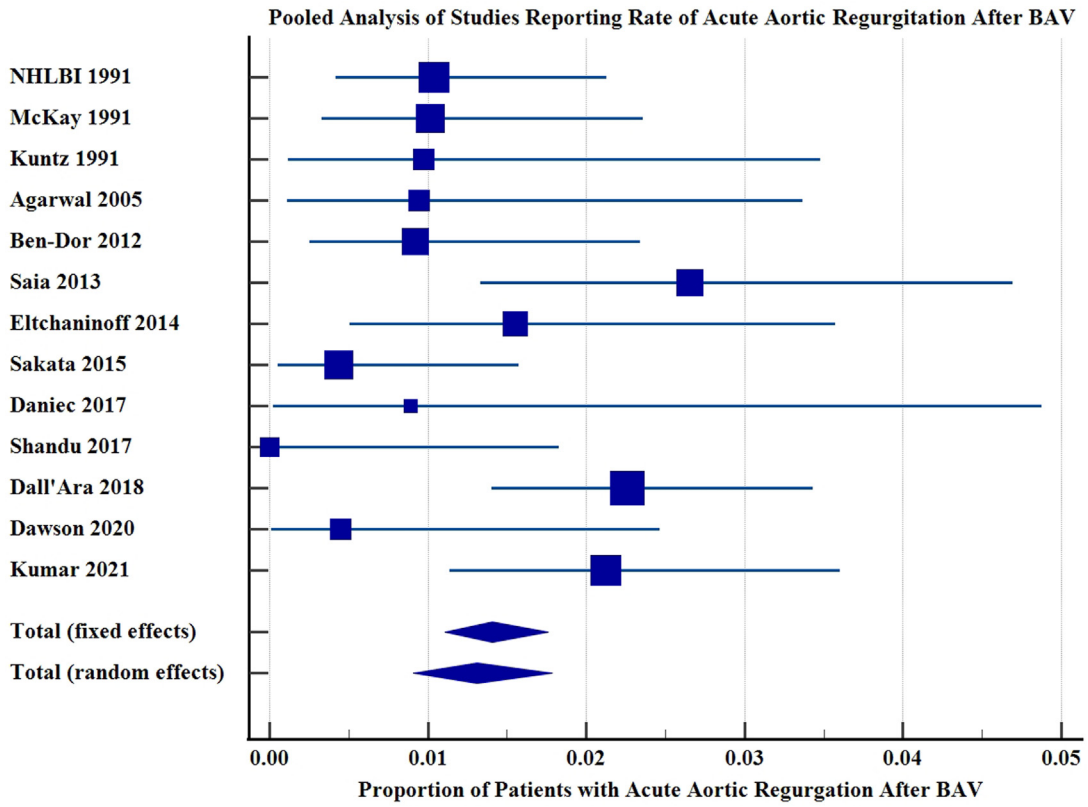


Figure 4.
Forest plot of pooled analysis of studies reporting rate of severe acute aortic regurgitation after BAV. On pooled analysis of 13 studies including 5289 patients, the rate of severe acute aortic regurgitation after BAV was 1.31% (95% CI, 0.91%-1.78%). BAV, balloon aortic valvuloplasty.

utilization of resources than performing TAVR in all of such critically ill patients.

Furthermore, BAV can be performed in patients with sAS who present with comorbidities that are likely to resolve or cancer that is not prognosticate. Although research in these patient populations is limited, there are some preliminary studies that point toward case-by-case assessment for BAV use in these patients. A recent case report described an elderly patient with a history of AS with recent suspicion of COVID-19 who had rapid deterioration of clinical and hemodynamic stability, necessitating BAV as a bridge to TAVR. The patient's COVID-19 PCR test was confirmed with negative results after BAV, and the patient was discharged safely.[25] This case illustrates how BAV is an option for temporary relief of heart failure from sAS when TAVR is contraindicated, as in the case for suspicion of infections such as COVID-19. In addition, a preliminary study with a very limited sample size found that BAV decreased the operative risk for noncardiac surgeries with minimal complications in cancer patients.[26] BAV may be performed after case-by-case assessment after evaluating the risks involved with sAS and performing percutaneous coronary intervention in the setting of infection or cancer.

Table 1. Complication rates from BAV in pooled analysis of contemporary studies.

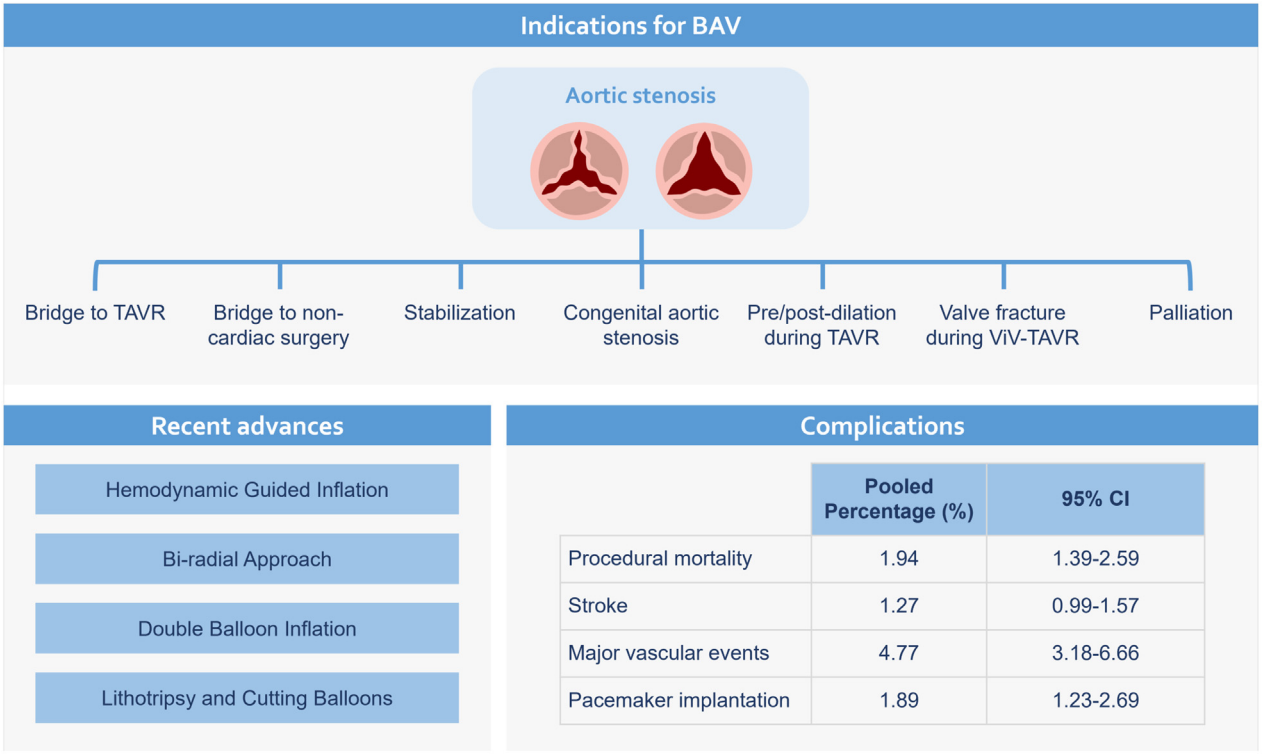
	No. of Patients	No. of Studies	Pooled percentage of complications	95% CI
Intraprocedural mortality	7880	16	1.94	1.39-2.59
In-hospital mortality	11,290	15	6.02	4.83-7.32
Stroke	13,751	23	1.27	0.99-1.57
Major vascular events	9297	17	4.77	3.18-6.66
Transfusion/major bleeding events	8523	16	5.79	2.87-9.64
Pacemaker implantation	7808	13	1.89	1.23-2.69
Myocardial infarction	4818	11	0.69	0.24-1.36
Acute aortic regurgitation	5289	13	1.31	0.91-1.78

Major vascular events defined by VARC-2 criteria, Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) definitions, vascular injury requiring surgery, or vascular access site complications. Major bleeding events defined by VARC-2 criteria, BARC-3 criteria, or bleeding requiring transfusion.
BARC-3, Bleeding Academic Research Consortium-3; BAV, balloon aortic valvuloplasty; VARC-2, Valve Academic Research Consortium-2.

BAV as a palliative therapy

Patients who are unable to undergo AVR owing to frailty or elderly age with limited life expectancy may opt for BAV for short-term symptomatic relief. Among elderly patients with sAS and limited life expectancy, BAV has low rates of procedural complications and halves the time spent in the hospital for heart failure decompensation.[9] Moreover, improvements in symptoms persist for 1 and 3 months postprocedure, with some studies suggesting lower rates of mitral valve regurgitation than without BAV.[27]

There are limited data on the prognosis of patients treated with palliative BAV. In a large study, Kumar et al[12] showed that 1 year survival after BAV was ~50% for outpatients, 20% for inpatients without cardiogenic shock, and <10% for critically ill patients, with most mortalities occurring within 90 days of BAV.[12] These data may be useful in conversations of prognosis with patients using their degree of illness as a guide.



Central Illustration.
Main indications, complications, and advances of BAV. BAV, balloon aortic valvuloplasty; TAVR, transcatheter aortic valve replacement; ViV, valve-in-valve.

Congenital aortic stenosis

Traditionally, surgical aortic valvuloplasty (SAV) has been considered as the standard treatment for congenital AS. However, the effectiveness and safety of BAV in improving outcomes for pediatric patients with congenital AS has made it a promising and less-invasive treatment option. A 19-year single-center study showed that BAV is associated with significant decreases in the peak systolic gradient, with a mean period for reintervention of 46 months.[28] Another study showed that there was no significant difference between BAV and SAV regarding mortality and reintervention rates (1.3 years for SAV and 1.9 years for BAV) in the medium term.[29] Although 1 study suggested that SAV leads to greater AV gradient reduction, lower rate of postoperative aortic insufficiency, and lower rates of reintervention at 10 years when

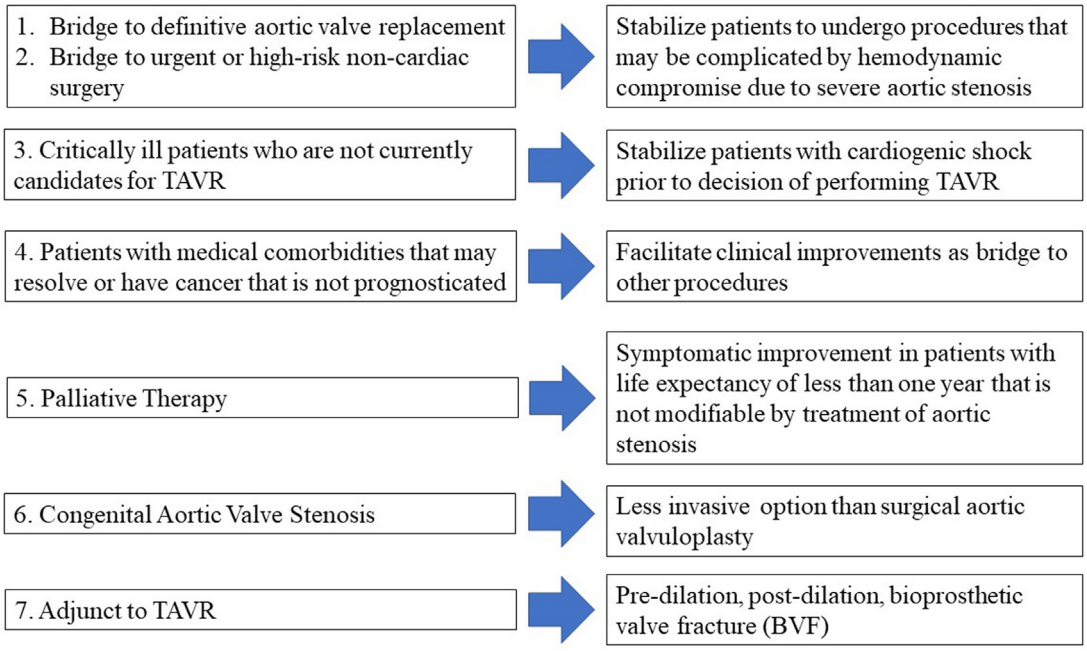


Figure 5.
Contemporary BAV indications and potential benefits. BAV, balloon aortic valvuloplasty; TAVR, transcatheter aortic valve replacement.

compared with BAV,[30] a meta-analysis of outcomes after BAV versus SAV for congenital AS showed that rates of AV regurgitation, late aortic insufficiency, and survival are similar between BAV and SAV.[31] Moreover, fetal balloon aortic valvuloplasty does not endanger the mother and negligibly affects the course of pregnancy and delivery.[32] BAV is a practical treatment option for patients with congenital bicuspid AS because it may delay or avoid surgery.

BAV as an adjunct to TAVR

BAV may be used as an adjunct to TAVR, as predilation or postdilation, and valve-in-valve (ViV) TAVR for bioprosthetic valve fracture (BVF). Historically, predilation using BAV was a mandatory step when performing TAVR to increase the orifice area of the AV for the passage of TAVR devices and to prevent paravalvular leak (PVL)/valve malposition with uniform prosthesis expansion.[33] Because of advances in TAVR protheses, predilation BAV for TAVR has been trending downward in utilization.[34] In addition, numerous studies and meta-analyses have established direct TAVR without predilation to be safe and feasible when compared with TAVR with predilation, narrowing the utility of BAV in adjunct with TAVR as predilation.[8,35,36] The potential risks of hemodynamic instability, longer procedural times, requirement for rapid pacing, AKI, and conduction disorders that are associated with predilation should also be considered when deciding on the TAVR strategy. Although clinical guidelines for predilation are lacking, a recent review outlined how valve sizing, anatomical considerations (such as AVA <0.4 cm^2, severe valvular calcification, congenital bicuspid valve, and aortic tortuosity), and prosthetic choice may influence the decision of choosing predilation TAVR over direct TAVR.[33] The use of predilation TAVR using BAV has decreased with the demonstration of the safety and efficacy of direct TAVR; however, predilation TAVR continues to have a role in cases with specific anatomical and prosthetic considerations.

Postdilation of TAVR is primarily used for reduction of PVL severity but may be used for optimizing the prosthesis frame expansion and mitigating patient-prosthesis mismatch.[37,38] PVL occurs with inadequate circumferential overlap between the prosthesis and annulus.[39] Numerous studies have shown that PVL is associated with poorer outcomes such as mortality and rehospitalization, but postdilation is able to safely reduce PVL and mitigate these outcomes.[40-43] Potential risks of postdilation include aortic annulus rupture, stroke, conduction disorders, valve embolization, and prosthesis damage. Although there are no specific guidelines for postdilation, general recommendations for postdilation include reduction of PVL in patients with grade III-IV PVL, observed on aortography and transesophageal echocardiography, with further consideration in patients with grade II PVL depending on the risks and benefits of the procedure.[33] Furthermore, postdilation is recommended for reducing valve gradients in the setting of high mean gradients (>20 mm Hg) and increasing effective orifice area. Postdilation proves to be particularly beneficial for patients with significant postprocedural PVL but comes with risks that need to be weighed against the benefits of postdilation.

BVF is performed to reduce patient-prosthesis mismatch after ViV TAVR. BVF entails inflation of a valvuloplasty balloon to fracture the sewing ring of the bioprosthetic valve (BPV), thereby permitting greater expansion of the BPV and transcatheter heart valve with an increased maximum effective orifice area.[44] Preliminary case series have shown that valvuloplasty balloons have been able to successfully fracture the BPV with hemodynamic benefit safely. Notably, combined clinical cases from 2 case series with 30 patients treated with ViV TAVR for failed BPV observed a reduction in the mean gradient from 41 to 11 mm Hg immediately after BVF and ViV TAVR, which was an improvement in effective orifice area from 0.75 to 1.7 cm^2, with no reports of perioperative death, coronary artery obstruction, annular rupture, PVL, or pericardial effusion.[44-46] Despite the promising foundation of BVF set by these case series, further studies focusing on the effect of long-term survival in patients at risk for patient-prosthesis mismatch and safety margins for operating in higher-risk patients will be crucial for refining BVF.

Procedural considerations

BAV is most often performed through femoral artery access; however, it may be performed through subclavian or axillary access, or brachial access in select patients. The procedure is guided with the use of fluoroscopy with or without transesophageal echocardiography (TEE) and is usually performed under conscious sedation, without the need for general anesthesia. An arterial sheath is advanced into the vessel of choice, typically varying in size between 8F and 14F catheter depending on the manufacturer and balloon size used. For example, the True Dilatation Balloon Valvuloplasty Catheters (BD Interventional) are indicated to have a catheter size of 11-14F, whereas the Z-Med II Balloon Dilatation Catheters (B. Braun Interventional) are indicated for 5-16F, necessitating the use of different-sized arterial sheaths to accommodate the different balloons. To reduce the risk of vascular complications and facilitate hemostasis, a Perclose Proglide (Abbott) device may be inserted before increasing the sheath size $>$8F (if needed), known as the "preclosure" technique. After vessel preclosure, the sheath may be upsized as large as needed, and when removed, the Perclose knot pushed down, achieving hemostasis even with sheaths larger than 8F. For sheaths 8F or smaller, the preclosure is not needed, and the Perclose device (or another vascular closure device) can be placed at the end of the procedure if desired to ensure stable arterial hemostasis.

After the sheath is secured and anticoagulation is achieved (typically with unfractionated heparin to a goal activated clotting time of 250-300 seconds), a guide wire is advanced across the AV. This is usually achieved with use of a short straight wire or hydrophilic glidewire and a 5F AL1 catheter, although operators vary in their approach. The guide wire should be aligned with the aortic orifice and may require either clockwise or counterclockwise rotation of the catheter. Once the guide wire is correctly positioned and has crossed the aortic AV, the coronary catheter can be advanced into the left ventricular (LV) cavity. The difference in LV pressure to femoral arterial pressure is usually determined with simultaneous transduction of the pigtail catheter and side port of the femoral arterial sheath, whereas measurements of central aortic pressures and LV pressure can be obtained with the use of an alternative dual-lumen pigtail catheter. Then, the catheter is exchanged for a stiff exchange length guide wire, such as an Amplatz Extra or Superstiff wire (Boston Scientific), which is positioned in the LV for passage of the aortic balloon across the aortic annulus. Typically, a right anterior oblique projection of the superstiff guide wire is suitable for minimizing interactions with the mitral valve apparatus.

Balloon size is determined by preprocedural transthoracic echocardiography (TTE), TEE, or CT imaging by assessment of the aortic annulus diameter. In addition, 3D preprocedural assessments of the aortic annulus through CT for TAVR has been shown to be important for deployment angle, evaluating vessel adequacy for access, and catching incidental findings such as coronary artery occlusion and extracardiac findings.[47]

The general rule for safety and efficacy is to size at a maximum of 1:1 from the average left ventricular outflow tract (LVOT) diameter based on a CT image, and $\leq$2.0 mm over the TTE or TEE diameter. However, most operators start 10%-20% smaller than the measured LVOT or annular size. Conservative sizing is advised for patients with mild AR, and BAV should be avoided in patients with at least moderate AR before the procedure. In addition, calcification of the LVOT or small sinotubular junction may limit BAV sizing. The indication for BAV may

also affect the balloon sizing. For example, balloon sizing may be more aggressive for destination therapy when compared with predilation in TAVR. Although a gated cardiac CT is not necessary to size BAV, if available, it can be a tremendous resource because it allows for a better definition of LVOT calcification, LVOT and annular sizing, and access planning.

In practice, BAV balloons are typically filled with a dilute mixture of no more than 50% contrast and 50% saline, which not only allows for visualization on fluoroscopy but also permits rapid inflation and deflation. Semicompliant balloons generally have lower profiles and require smaller arterial sheaths. However, they have less predictable inflation diameters and lower rated burst pressures in comparison with noncompliant balloons. To assist with balloon placement, rapid ventricular pacing (RVP) may be initiated at 160-220 bpm when the balloon is situated across the aortic annulus. This will decrease the cardiac output to minimize the displacement forces on the balloon. Under the guidance of fluoroscopy, the operator should confirm that the position of the balloon is unchanged with RVP. Then, the balloon can be rapidly inflated and deflated across the aortic annulus in a matter of seconds, after which RVP is discontinued. Furthermore, the aortic balloon should be withdrawn into the ascending aorta with return of systemic blood pressure. Importantly, patients with right ventricular dysfunction, severe pulmonary hypertension, or cardiogenic shock may not tolerate rapid pacing. In these situations, BAV may be attempted without pacing, and pacing added if the balloon is too mobile or the result ineffective, and the patient tolerates the initial inflation.

The device success of BAV is typically determined by a reduction in the mean transaortic valvular gradient. An ideal outcome is a reduction of the LV-aortic gradient to <50% of the original gradient. Alternatively, in patients who also have a Swan-Ganz catheter in place, an increase in AVA to a value >1.0 cm^2 is considered a success. Care should be given to assure that there is no significant increase in AR, which is suggested by a drop in aortic diastolic pressure and/or increase in LV end-diastolic pressure or observed on procedural echocardiography or aortography. The procedural end point may depend on the circumstances of the case.

The transvalvular gradient may be confirmed with the use of echocardiography (TTE or TEE) or pigtail catheter. Operators may opt for further balloon inflation; however, blood pressure should return to baseline before continued balloon inflation. After ballooning, hemostasis is achieved in the aforementioned manner. Protamine may be administered if needed. Once the procedure is completed, the patient may be discharged the same day if the procedure is uncomplicated or the following day after a repeat echocardiogram, and consideration for bridge or destination therapy should be reviewed in the clinic in 4-6 weeks.

Advances in BAV

BAV is conventionally performed using the transfemoral retrograde approach with heparin administration after insertion of an 8-14F sheath, dictated on the balloon size and brand. Use of the Perclose Proglide (Abbott) in a preclosure fashion has allowed percutaneous closure with use of larger bore catheters. Despite this, the risks of bleeding with femoral access have prompted interest in the use of other access sites, particularly in patients with lower extremity peripheral artery disease (PAD) that may preclude femoral access. Brachial artery access is perhaps the most well-documented alternative access route.[48] This generally requires the use of a smaller BAV balloon through an 8F sheath or retrograde double BAV with bilateral brachial access and simultaneous inflation of 2 balloon catheters. With this method, the effective balloon size is determined as two-thirds of the sum of the total balloon sizes. This double-balloon BAV approach has been shown to be effective in decreasing the mean transaortic valve gradient and may be a reasonable option for patients with extensive PAD through bilateral femoral access with smaller sheaths.[49] Recently, there has been increased interest in a transradial approach to BAV. This transradial approach is achieved with bilateral radial access with a 5F or 6F sheath and the use of 2 mini-BAV balloons (eg, Cristal Balloon; Balt Extrusion) inflated simultaneously. This strategy has been shown to be a safe and effective alternate access site for elderly patients with AS.[50] Transradial access through mini-BAV is associated with low rates of vascular complications and symptomatic improvement in patients with AS.[51] With the utilization of alternate access sites, BAV can be performed in a broader population because operators can avoid small-caliber femoral arteries or arteries with tortuous anatomy.

The Inoue balloon has shown relative success for BAV and presents several unique technical advantages. The Inoue balloon, which has 3 stages of balloon changes when inflated, was initially introduced in 1984 for mitral valvuloplasty in patients with symptomatic mitral stenosis.[52] Since then, the Inoue balloon has been adapted for aortic valvuloplasty with relative success and novel applications. In a study of 405 patients with sAS, BAV performed using the Inoue balloon through an antegrade, transseptal approach with multiple inflation of gradually increasing dilation size was shown to significantly improve mean transaortic valve pressure gradients and clinical symptoms.[53] Furthermore, the antegrade approach has been shown to result in decreased rates of vascular complications owing to the use of venous access as opposed to arterial access and can be considered in select patients.[54] Although the antegrade approach with the Inoue balloon is technically more difficult for operators to perform, its benefits regarding vascular complications provide yet another feasible, or in some circumstances preferred, access site for BAV.

Rapid ventricular pacing is a commonly used during BAV and TAVR to temporarily decrease cardiac output, assisting operators in balloon placement. Multiple and prolonged RVP use is associated with increased likelihood of developing atrial fibrillation, AKI, and hypotension and increased short-term mortality and 1-year mortality.[55] RVP has not been associated with BAV efficacy or safety, but it does promote balloon stability during BAV.[4] RVP may be particularly important for patients during a bilateral brachial or radial approach. However, avoiding RVP use may minimize adverse events and improve patient outcomes after BAV if the balloon can be kept stable during the procedure. A single-center retrospective study examining the outcomes of retrograde Inoue balloon BAV without RVP found that it was both safe and feasible for elderly patients with AS when compared with conventional BAV with RVP.[56] Furthermore, nonocclusive balloons provide another encouraging option for BAV because they may be used without RVP and allow for continuous blood flow with every step of inflation. In a study of nonocclusive BAV including 27 patients, there were low procedural complications and no increase in procedural time.[57]

Intravascular lithotripsy (IVL) enables vascular access for percutaneous interventions in patients with calcified PAD. A prospective case study of patients undergoing IVL for iliac or femoral arterial access showed that IVL was able to disrupt calcification to allow for safe passage of large bore sheaths, expanding eligibility for TAVR procedures.[58] Although IVL is primarily used to enable vascular access for TAVR, it opens the door for applications to BAV for patients with PAD. Furthermore, the development of a transcatheter debridement device that takes advantage of low-intensity ultrasound waves for lithotripsy of calcified AVs has shown relative success in humans ex vivo and adult pigs in vivo.[59] This cutting-edge technology is promising and may alter the role of BAV in the treatment of sAS in the future.

Conclusion

BAV is a safe and feasible therapy for the short-term treatment of patients with sAS. Although TAVR has redefined the role of BAV in the management of sAS, BAV remains useful as a temporizing measure primarily aimed at short-term stabilization and relief of symptoms in patients who may eventually be candidates for TAVR after resolution of their acute issue. With continual advances in BAV regarding access sites and balloon catheters, BAV use may extend to higher-risk patients.

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Ethics statement and patient consent

No primary data was collected for this review, and as such, institutional review board and ethics approval was not required. As this review did not involve the collection of primary data from human subjects, informed consent from patients was not required.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2023.101002.

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