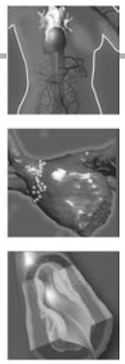

Balloon aortic valvuloplasty in elderly patients: a review and update

Calcific aortic stenosis is the most common valvular disease in the western world, with the prevalence increasing with age. Medical management of critical aortic stenosis is associated with high mortality and cost. While surgical valve replacement is ideal, high early morbidity and mortality limit its usefulness among patients with comorbid illness or advanced age. Balloon aortic valvuloplasty can be an important option that can be used as a bridge to definitive replacement or as palliative therapy. Fewer complications and easier recovery may make balloon aortic valvuloplasty a particularly attractive option for very elderly patients. Reducing the balloon profile reduces complications. A case series using a low-profile balloon with rapid inflation to achieve more effective force on calcified valves resulted in good short- and long-term outcomes. Future studies should seek longer-term data and investigate pathological changes following valvuloplasty.

KEYWORDS: aortic stenosis ■ balloon ■ calcific ■ replacement ■ transcatheter aortic valve implantation ■ valvuloplasty

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Calcific aortic stenosis (AS) is the most common valvular heart disease in the western world, with moderate-to-severe stenosis in approximately 3% of adults >75 years in the USA and Europe [1–3]. Severe, symptomatic AS cannot be treated medically. Medical management offers no therapy to prolong life and there are limited treatments to reduce symptoms in patients with severe AS [4]. Medical management is generally only used when severe comorbidity or patient preference precludes surgical or other invasive options. Definitive treatment of calcific AS is surgical valvular replacement [5]. Due to the elderly age of the typical AS population and frequent comorbidities, surgical options are often limited in patients with severe AS. Transcatheter aortic valve implantation (TAVI) may be considered for patients with severe, symptomatic AS who are not surgical candidates [6–10]. TAVI may be better tolerated than aortic valve replacement (AVR), with similar long-term survival. Balloon aortic valvuloplasty (BAV) often forms an integral part of TAVI treatment and is typically used as a bridge to definitive treatment or for symptomatic palliation. Since BAV has generally been linked with short-term benefits without long-term improvement in disease prognosis, it is generally not considered a definitive treatment for most adults with severe AS [11]. The purpose of this review is to explore current data on outcomes after AS treatment, with special attention to an expanded role for BAV in very elderly patients.

Methods

A literature search was performed through Medline to identify relevant articles published in English from January 2000 to September 2012, including in press articles available for prepublication review through to September 2012. Articles were identified by using the search terms: 'aortic stenosis', 'transcatheter aortic valve implantation', 'valve replacement' and 'valvuloplasty'. Additional articles were obtained by reviewing reference lists from identified articles and searching for additional related articles by authors of the initially identified articles. Both medical and surgical treatment options for AS were reviewed, with a focus on new data investigating long-term outcome after BAV.

Outcome after AS treatment

While AS would ideally be managed with valvular replacement, comorbid medical conditions often limit the feasibility of surgery among patients with AS, especially older patients. AVR has considerable early mortality (Table 1) [12–14], as well as a 1% per year incidence of bleeding requiring hospitalization due to necessary anticoagulation after replacement [15]. Furthermore, a series of 378 patients >65 years old undergoing AVR demonstrated that only 46% were discharged to home, with the remainder discharged to nursing homes or rehabilitation facilities [16]. TAVI may be better tolerated than AVR, with similar long-term survival (Table 1).

Older adults are typically only considered to be BAV candidates if they are unable to tolerate

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Table 1. Sample of outcome for aortic stenosis treatment.

Study (year)	Subjects	Mean age (years)	Mortality	Ref.
Surgical aortic valve replacement				
Kvidal *et al.* (2000)	2359 patients (concomitant CABG surgery in 917 patients)	65	5.6% mortality within 30 days postsurgery	[12]
Good long-term survival				
Brown *et al.* (2008)	166 symptomatic and 97 asymptomatic patients	70	Operative mortality was 2% for symptomatic patients and 1% for asymptomatic patients	[13]
10-year survival (64% for all)				
Dahl *et al.* (2012)	125 patients (concomitant CABG in 37 patients)	72	23% mortality over an average 4-year follow-up	[14]
TAVI				
Leon *et al.* (2010)	358 patients randomized to standard therapy (including BAV in 64%) or TAVI	83	6.4% mortality 30 days postsurgery	[6]
Rodés-Cabau *et al.* (2010)	345 patients	81	10.4% 30-day mortality	[7]
Thomas *et al.* (2010)	1038 patients	81	8.5% 30-day mortality	[8]
Smith *et al.* (2011)	699 high-risk patients randomized to TAVI or surgical replacement	84	6.5% 30-day mortality with surgery vs 3.4% with TAVI ($p = 0.07$) 1-year mortality was similar	[9]
Eltchaninoff *et al.* (2011)	249 high-risk patients	82	12.7% 30-day mortality	[10]
BAV as bridge to TAVI				
Kapadia *et al.* (2010)	90 consecutive patients	75	17% 30-day mortality 1-year survival of 44% after BAV alone and 78% after BAV followed by surgical replacement	[19]
Malkin *et al.* (2013)	33 consecutive patients		3% 30-day mortality 58% of patients responded to BAV and referred for definite replacement	[20]
Agarwal *et al.* (2005)	83 consecutive patients referred for TAVI 43 high-risk patients underwent BAV first	81	12% 30-day mortality after BAV plus TAVI vs 3% after TAVI alone; difference was predicted by baseline EuroSCORE	[21]

BAV: Balloon aortic valvuloplasty; CABG: Coronary artery bypass graft; TAVI: Transcatheter aortic valve implantation.

surgery or if BAV is used as a bridge to subsequent valve replacement [4]. For example, in a recent series of AS patients treated with BAV in the UK, BAV was used as palliative treatment for 41% of cases and as a bridge for TAVI (34%) or surgical replacement (13%) for the majority of other treated patients [17]. While early symptomatic improvement typically occurs, the number of serious complications is high (>10% of cases), with restenosis and clinical deterioration expected within 6–12 months [4]. Furthermore, *in vitro* studies show the presence of large calcific particles after valvuloplasty that can place patients at high risk of postprocedure coronary embolic events [18]. Therefore, BAV is often used as a bridge to valve replacement in symptomatic patients with severe AS (Table 1) [19–21].

BAV may also be repeated to prolong symptomatic control in patients for whom alternative treatments are not an option. Agarwal *et al.* reported outcome for 212 consecutive patients with severe AS who were not surgical candidates, but were treated with BAV [21]. During the mean 3-year follow-up, 51 patients underwent repeat BAV for symptomatic recurrence. The average time between procedures was 18 months between the first and second BAV, and 15 months between second and third BAV. Survival rates were 64% at 1 year, 28% at 3 years and 14% at 5 years.

Comparison among techniques

The PARTNER trial was a multicenter, randomized clinical trial in high-risk patients with severe AS that compared outcome with TAVI versus standard therapy. In this trial, Leon and colleagues reported data from 358 patients randomized to TAVI or standard care that included BAV [6]. After 1 year, the death rate was significantly higher after standard therapy (51 vs 31%; $p < 0.001$). In addition, assignment to

New York Heart Association (NYHA) class III or IV among survivors at 1 year was lower with TAVI compared with standard therapy (25 vs 58%; p < 0.001). A subsequent report of two studies from the PARTNER trial compared outcomes after AVR versus TAVI [22]. In one study, patients who were candidates for AVR were randomized to AVR or TAVI. In the other study, patients who were not candidates for AVR were randomized to TAVI or standard medical management [22]. The 1-year mortality was similar with AVR and TAVI, with TAVI superior to medical management. In both cohorts, however, TAVI was associated with significantly more vascular complications, including cerebrovascular accidents. The authors concluded that, although TAVI is beneficial for patients unable to undergo AVR, AVR should be the treatment of choice for those patients who are surgical candidates due to increased complications with TAVI.

Researchers from Washington Hospital Center (WA, USA) prospectively evaluated 900 patients with severe, symptomatic AS and high surgical risk who had been referred for TAVI [23]. Patients were divided into three groups: surgical valve replacement (n = 146), TAVI (n = 159) and medical management with palliative BAV (n = 595). Predicted mortality by EuroSCORE was 27% in those receiving surgical replacement, 42% with TAVI and 43% with medical management/BAV. Early mortality was similar among the three treatment groups (Figure 1). The 1-year survival was similar between surgical replacement and TAVI; survival was significantly worse with medical management/BAV (p < 0.001). This study does not directly compare treatments as patients were carefully screened, with lower risk patients selected for surgical replacement. These data, however, do support that, while medical management and BAV may result in short-term symptomatic benefits, they do not confer sufficient long-term survival benefits to be considered a definite treatment option. Both surgical replacement and TAVI appear to be acceptable options for high-risk patients with severe AS. Rajani *et al.* similarly reported the outcome of 85 patients with severe AS who were not surgical candidates (mean age: 81 years) who were subsequently treated with TAVI (n = 38) or medical management (n = 47; 14 of whom underwent BAV) [24]. Patients were followed for an average of 215 ± 115 days, with mortality being significantly higher among medically managed versus TAVI patients (28 vs 13%; p = 0.04).

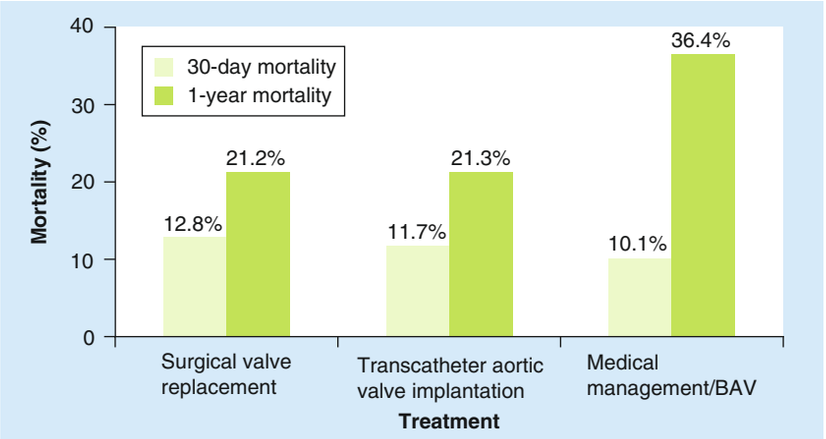

Figure 1. Mortality among treated patients with severe aortic stenosis.
BAV: Balloon aortic valvuloplasty.
Data taken from [23].

Dvir *et al.* recently published outcome results for high-risk AS patients (n = 343) at their center assigned to treatment with AVR, TAVI, BAV or medical management [25]. The 1-month mortality was similar with AVR (12%) and BAV (19%), and significantly lower with TAVI (3%) and medical management (4%). The 1-year survival was highest with TAVI (92 vs 71% with AVR, 62% BAV and 65% medications only; p < 0.001). NYHA class I or II was achieved at 1 year in 85% with TAVI, 63% with AVR, 18% with BAV and 21% with medical management.

Despite the limitations from the above studies, with treatment assignment generally based on clinical profile and patients with more impaired clinical status generally treated with less invasive treatment, these data do support the benefits of valve replacement when clinically feasible. While benefits from BAV are substantially less than from valve replacement, BAV may be an important option for patients with more severe disease and patients at higher risk of vascular complications associated with valve replacement.

Defining a role for BAV

Very elderly seniors may, in particular, be good candidates for valvuloplasty. A 30-day mortality has been reported in approximately 8% of patients >80 years old undergoing AVR [26,27] and 13% of seniors (average age: 82 years) undergoing BAV [28]. Mortality outcome, however, may not be the more important end point for older seniors. Octogenarians are particularly concerned about prolonged disability more than mortality [29], and the expected discharge to nursing home or rehabilitation center in over half of patients following AVR may be particularly concerning to very elderly patients [16]. The risk

of cerebrovascular and bleeding events after valve replacement may also reduce the acceptability of valve replacement for very elderly patients at higher risk of stroke and serious anticoagulation complications.

Reducing complications through lower profile balloons

BAV is typically accomplished using the femoral retrograde approach, although other vascular sites may be used. Typical arterial sheath size has varied between 12.5 and 16.5 French (F) to accommodate the balloon, which is typically 20–25 mm [30–33]. The balloon inflation duration reported in an early study evaluating BAV was between 15 and 260 s (mean: 40 s) [34], although inflation–deflation times subsequently decreased [1].

The balloon size may be an important factor in complication risk after BAV. A study from Washington Hospital Center showed a higher ratio of BAV size to left ventricular outflow tract diameter to be a significant risk factor for the development of cardiac conduction abnormalities after BAV [30]. The authors cautioned practitioners to select appropriately sized BAV balloons to avoid oversizing with increased complication risk. In a recent study, 423 patients (mean age: 81 years) underwent BAV, using balloon sizes from 10 to 28 mm (mode 20 mm) and access site gauges from 6 to 18 F (most commonly 9 and 12 F) [17]. Only 1% of patients required surgical vascular access repairs and 1.2% required transfusion of ≥2 units of packed red cells. 30-day mortality was 14%. The balloon size had a weak correlation with change in gradient achieved ($r = 0.27$; $p < 0.0001$), with no significant impact on mortality. In addition, access sheath gauge was not associated with the need for vascular intervention.

Other reports have also described successful treatment in higher risk patients with severe AS using lower profile balloons [35,36]. In a previously published series (n = 20 consecutive high-risk AS patients; mean age: 82 ± 8.5 years; logistic EuroSCORE: 19.7%), BAV was performed using a smaller profile Atlas® balloon (CR Bard, AZ, USA), designed to withstand higher pressures, that was rapidly inflated with a power injector [36]. Three balloon sizes (diameter × length) were used: 16 × 40, 18 × 40 and 20 × 40 mm. Balloons were inflated using a power injector at a rate of 18–25 ml/s at a 0 rise time to 16–18 atmospheres pressure, with each patient receiving two to three inflations. Rapid inflation should theoretically provide a greater force (force = mass × acceleration) that may enhance the valve-opening effect. A previous study demonstrated good efficacy and safety when using fast inflation and deflation times of <2 s [37]. Balloons were immediately deflated and removed following inflation. The total time for balloon inflation and withdrawal from the valve was <3 s. Average changes postprocedure were a 40% decrease in systolic gradient peak-to-peak pressure and a 30% increase in aortic valve

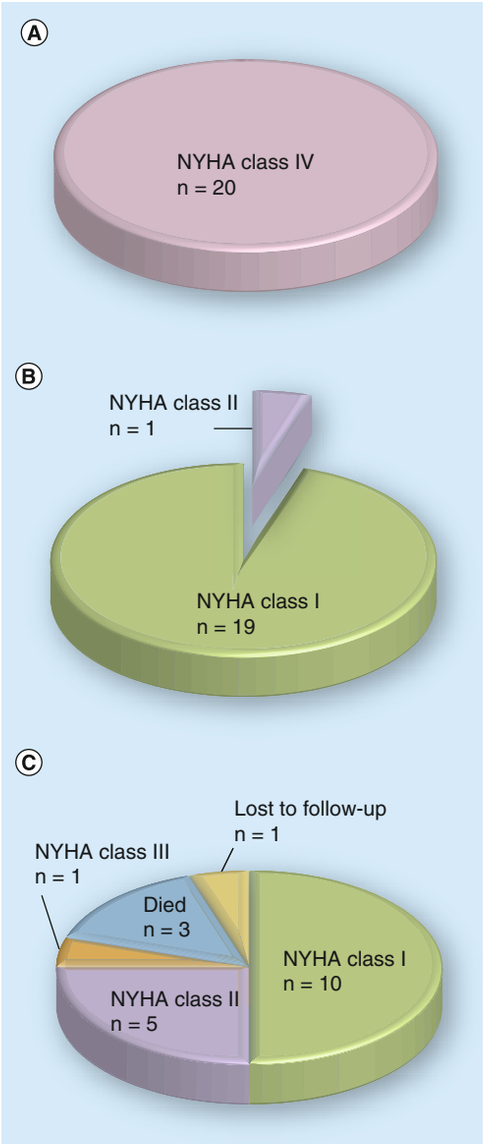

Figure 2. Short- and long-term New York Heart Association class assignment among patients treated with low-profile balloon aortic valvuloplasty procedure using rapid inflation. (A) Baseline NYHA categories, **(B)** 1 month postballoon aortic valvuloplasty and **(C)** 6 months post-balloon aortic valvuloplasty.
NYHA: New York Heart Association.
Data taken from [35].

area. A single patient experienced a procedural complication (pericardial tamponade) and one patient who had a prolonged hospitalization prior to the procedure developed *Clostridium difficile* colitis. There were no additional early complications. The 6-month survival and maintenance of cardiac improvement were good (Figure 2).

Since that report, 24 additional high-risk AS patients were treated with BAV using a low-profile balloon inflated with a power injector. The additional 24 patients were similarly high risk, with a mean EuroSCORE II of 25.2 ± 27.8% (range: 2.2–84.2%). The combined group of 44 total patients (20 from the original report and 24 new cases) has been followed for up to 1 year. Among this group of 44 patients, there were 25 males and 19 females, with a mean age of 80.2 ± 8.1 years. Average systolic peak gradient changed from 59.5 ± 21.5 to 35.4 ± 13.8 mmHg. Mean gradient decreased from 50.3 ± 16.7 to 33.2 ± 13.1 mmHg. Aortic valve area increased from 0.63 ± 0.17 to 0.97 cm^2. There was one procedural complication of pericardial tamponade (noted in the original published series, with no additional procedural complications among the additional 24 cases). There were no cerebrovascular events, patients requiring permanent pacemakers or bleeding requiring transfusion. All patients were classified as NYHA class IV at baseline. Class I or II were achieved by 93.2% at 30-days post-BAV, 75.0% after 6 months and 54.5% after 1 year (Figure 3). After 1 year, 22.7% were NYHA class III or IV and 18.2% of patients had died. This expanded sample further supports both good immediate outcome and maintenance of benefit among high-risk patients treated with low-profile BAV with rapid expansion.

Conclusion

Calcific AS is a common and disabling disease, especially in aging populations. Medical management is ineffective. While surgical valve replacement is ideal, this is often not an option for older patients or patients with significant comorbidity. BAV can serve an important role as a bridge to definitive replacement or as palliative therapy. Reducing balloon profile reduces complications, with good short- and long-term outcome shown in a case series using a low-profile, noncompliant balloon with rapid inflation to achieve more effective force on calcific valves.

Future perspective

As the population ages worldwide, prevalence of AS will probably increase, with an expanded need for safe and effective treatments, especially among older patients with comorbid illnesses. Elderly patients are particularly interested in improving quality of life and maintaining independence, rather than simply prolonging survival [29]. A small retrospective series reported outcome over a 10-year period among 26 elderly patients with severe AS treated with BAV (mean age: 86 years, range: 78–93 years). Survival was reported for 88% 6-months post-BAV, 64% after 1 year and 31% after 2 years [38]. Perhaps more significantly, event-free survival (no death and no hospital admissions for cardiac-related complications) was reported for

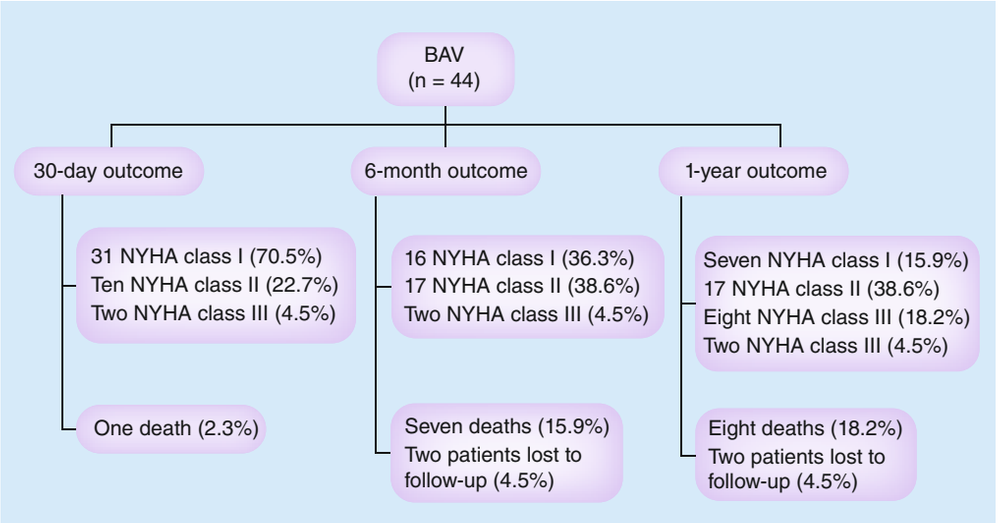

Figure 3. Cumulative outcome after low-profile balloon aortic valvuloplasty procedure using rapid inflation among 44 high-risk patients with aortic stenosis.
BAV: Balloon aortic valvuloplasty; NYHA: New York Heart Association.

77% at 6 months, 31% after 1 year and 16% after 2 years. Improving remaining quality of life and reducing hospitalizations are important outcomes to consider when recommending balloon therapy to very elderly patients.

Additional data showing long-term benefit from low-profile BAV may increase recommendations for using this as a more definitive treatment for high-risk patients, rather than simply using BAV as a bridge to replacement. BAV results in fractures of calcific deposits on aortic leaflets, with the development of scar tissue that can be seen microscopically [39]. Future studies may wish to explore the pathological changes occurring after valvuloplasty to help determine which patients may be most anticipated to benefit and if benefits may differ, based on the technique. For example, the rapid inflate, high pressure inflation method described above may be expected to produce a greater force to crack and breakdown calcified tissues [36]. Models may be developed to help verify whether this technique offers pathological advantages over more traditional BAV that might suggest it would be more appropriate for certain patient categories.

Financial & competing interests disclosure

GR Eles is a consultant for CR Bard. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Writing assistance was provided by DA Marcus. Funding for this was provided by the Allegheny General Hospital Interventional Cardiology Fund (Pittsburgh, PA, USA).

Executive summary

Epidemiology & impact

- Calcific aortic stenosis is the most common valvular disease in the USA and Europe, with the prevalence increasing with age.
- Average survival after symptoms begin is ≤3 years.

Medical management of aortic stenosis

- Medical management of aortic stenosis is associated with high mortality and cost.

Valve replacement

- High early mortality and other complications limit the use of definitive valve replacement, especially in elderly patients and in patients with comorbid diseases.

Balloon valvuloplasty

- Balloon aortic valvuloplasty is primarily used as a bridge to help improve status and reduce symptoms to make patients better candidates for more definitive treatment.
- Higher in-hospital mortality and expectation that over half of elderly patients treated with aortic valve replacement will be discharged to a nursing home or rehabilitation facility rather than to home may make valvuloplasty a more desirable option for older seniors.
- Reducing the balloon profile may reduce complications after valvuloplasty.
- Device improvement and procedure modification may improve long-term outcomes.

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