

openheart Percutaneous balloon aortic valvuloplasty in the era of transcatheter aortic valve implantation: a narrative review

Thomas R Keeble,^{1,2} Arif Khokhar,^{2,3} Mohammed Majid Akhtar,⁴ Anthony Mathur,⁴ Roshan Weerackody,⁴ Simon Kennon⁴

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¹Department of Cardiology, Essex Cardiothoracic Centre, Basildon, UK

²Postgraduate Medical Institute, Anglia Ruskin University, Chelmsford, UK

³Department of Cardiology, Royal Brompton & Harefield NHS Trust, London, UK

⁴Department of Cardiology, Barts' Heart Centre, St. Bartholomews' Hospital, London, UK

Correspondence to
Dr Simon Kennon;
Simon.kennon@bartshealth.nhs.uk

ABSTRACT

The role of percutaneous balloon aortic valvuloplasty (BAV) in the management of severe symptomatic aortic stenosis has come under the spotlight following the development of the transcatheter aortic valve implantation (TAVI) technique. Previous indications for BAV were limited to symptom palliation and as a bridge to definitive therapy for patients undergoing conventional surgical aortic valve replacement (AVR). In the TAVI era, BAV may also be undertaken to assess the 'therapeutic response' of a reduction in aortic gradient in borderline patients often with multiple comorbidities, to assess symptomatic improvement prior to consideration of definitive TAVI intervention. This narrative review aims to update the reader on the current indications and practical techniques involved in undertaking a BAV procedure. In addition, a summary of the haemodynamic and clinical outcomes, as well as the frequently encountered procedural complications is presented for BAV procedures conducted during both the pre-TAVI and post-TAVI era.

INTRODUCTION

Percutaneous balloon aortic valvuloplasty (BAV) was widely adopted when first described by Cribier *et al*¹ in 1986, as a simple low-cost treatment strategy for patients with symptomatic severe aortic stenosis (AS) presenting in cardiogenic shock, or for symptom palliation in those considered too frail for conventional surgical aortic valve replacement (AVR) surgery. Its popularity waned however, as it emerged that restenosis and recurrence of symptoms were common after 6 months and mortality rates within a year of BAV were similar to those of an untreated conservatively managed population.²

In 2002, Cribier introduced his definitive solution for inoperable patients with severe AS—the first-in-man transcatheter aortic valve implantation (TAVI).³ Since then, the

PARTNER trials have demonstrated the superiority of TAVI in comparison to optimal medical therapy (OMT), which included the use of BAV. In patients not suitable for surgery, all-cause mortality after 1 and 5 years following TAVI was 30.7% and 71.8%, respectively, compared with 50.7% and 93.5% for those being treated with OMT.^{4 5} Similarly, in high-risk individuals, both the PARTNER and COREVALVE studies demonstrate that TAVI confers similar symptomatic and prognostic improvements when compared with conventional surgical AVR (table 1).^{6–8}

The evolution of TAVI into the treatment of choice for high-risk and inoperable patients with severe symptomatic AS has seen a resurgence in the numbers of BAV procedures being performed (figure 1). During a TAVI procedure, BAV may be undertaken prior to transcatheter heart valve (THV) deployment to facilitate catheter and valve delivery across the aortic annulus and may also be used to minimise the likelihood of coronary occlusion by the valve leaflets given the close proximity of the ostia of the coronary arteries to the annulus. BAV can play a role in accurately measuring aortic annular size in conjunction with transoesophageal echo (TOE) or CT.⁹ This is particularly useful in patients where the aortic annulus size falls in the cut-off between two suitable THV sizes and balloon valvuloplasty with a similar sized balloon has been used in some cases to assess the risks of coronary occlusion and guide choices of THV size for TAVI intraprocedurally. BAV may also be undertaken post-THV deployment intraprocedurally to improve valve expansion, in particular if there is a suggestion of significant paravalvular aortic regurgitation (AR) secondary to annular calcification and consequent sub-optimal THV expansion.

Increasingly, borderline patients with poor left ventricular (LV) systolic function, chronic obstructive pulmonary disease (COPD), advanced comorbidities and significant frailty who are deemed too high risk to undergo TAVI or AVR can undergo a BAV as a diagnostic tool to assess 'therapeutic response' to a significant reduction in transaortic valvular gradient with a view to a definitive procedure if a significant benefit can be demonstrated. Finally, as individual operator experience grows, BAV is likely to be offered more frequently in the context of the original indications for BAV, principally

Table 1 Comparison of mortality rates between TAVI and AVR from the PARTNER⁶ and COREVALVE^{7 8}

Follow-up period	TAVI (all-cause mortality) (%)	AVR (all-cause mortality) (%)
30 days (PARTNER) ⁶	3.4	6.5
1 year (PARTNER) ⁶	24.2	26.8
1 year (COREVALVE) ⁷	14.2	19.1
3 years (COREVALVE) ⁸	32.9	39.1

AVR, aortic valve replacement; TAVI, transcatheter aortic valve implantation.

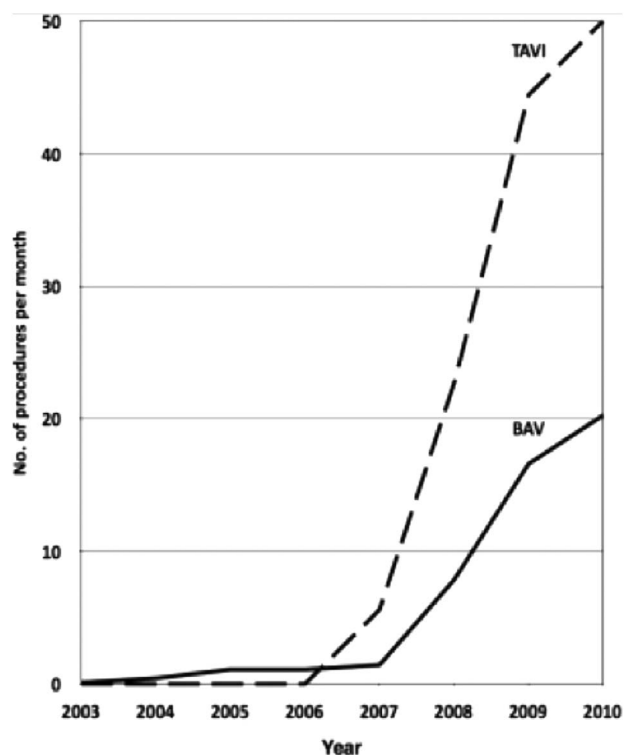


Figure 1 Number of balloon aortic valvuloplasty and TAVI procedures in the UK—the increase in stand-alone BAV mirrors the increase in TAVI (TAVI data from the 25 UK centres with TAVI programmes—British Cardiovascular Intervention Society 2011; BAV data from 14 study centres). Reproduced having obtained permission from corresponding author.¹⁵ BAV, balloon aortic valvuloplasty; TAVI, transcatheter aortic valve implantation.

cardiogenic shock and symptom palliation. Combined with an increasingly ageing population, the number of BAV procedures is set to increase further over the next few years.¹⁰

In one study of 99 patients with severe AS and impaired left ventricular ejection fraction (LVEF) who underwent TAVI, the role of BAV or dobutamine stress echocardiography (DSE) were compared on the ability to guide prognostic benefit post-TAVI. Those patients who had been identified to have contractile reserve on a preprocedural DSE had a lower mortality than those who did not have any reserve. DSE, however, was unable to predict those patients in whom LVEF would improve post-TAVI. Those patients with impaired Left Ventricular Systolic Function (LVSF) who underwent BAV and showed a subsequent improvement in LVSF were more likely to show an improved LVEF post-TAVI as well. The conclusion was that both DSE and BAV provided complementary data with regard to the likelihood of LVEF improvement post-TAVI together with mortality (both periprocedurally and longer term).¹¹

This narrative review discusses current guidelines and indications for BAV, the procedure itself with its risks and limitations, as well as contemporary and historical clinical outcomes.

CURRENT EUROPEAN AND AMERICAN GUIDELINE INDICATIONS FOR BAV

In the current European Society of Cardiology (ESC) guidelines (2012), BAV has a class IIb indication for use as a bridge therapy to TAVI or AVR in haemodynamically unstable patients at high risk for surgery, or in patients with symptomatic severe AS who require urgent non-cardiac surgery (level of evidence: C).¹² They additionally recommend considering BAV as a palliative measure in selected individuals not suitable for TAVI or AVR (table 2). Although the American Heart Association (AHA)/American College of Cardiology (ACC) guidance (2014) suggest that BAV may be considered as a bridge to TAVI or AVR for patients with severe symptomatic AS (class IIb,

Table 2 Summary of ESC¹² and AHA/ACC¹³ guidelines for the role of BAV in managing severe aortic stenosis

Indication for BAV in severe symptomatic aortic stenosis	ESC (2012)	AHA/ACC (2014)
As bridge therapy for <i>all</i> patients undergoing TAVI or AVR	×	✓
As bridge therapy for <i>haemodynamically unstable</i> patients undergoing TAVI or AVR	✓	✓
For patients requiring urgent non-cardiac surgery	✓	×
As a palliative procedure for symptomatic benefit	✓	×

AVR, aortic valve replacement; BAV, balloon aortic valvuloplasty; ESC, European Society of Cardiology; TAVI, transcatheter aortic valve implantation.

level of evidence: C), unlike the European guidance they do not recommend the use of BAV in patients undergoing urgent non-cardiac surgery or as palliation but do acknowledge that some patients report an improvement in their symptoms (table 2).¹³

Both guidelines advocate for decision-making to be undertaken by a multidisciplinary team (MDT), taking into account individual patient characteristics and comorbidities, prior to undertaking any procedures.

THE BAV PROCEDURE

BAV procedures should be undertaken in cardiac centres by experienced operators, following a detailed consent process, which highlights key risks associated with the procedure. The indication for BAV including as a palliative procedure, as a staged procedure prior to potential TAVI/AVR or to facilitate urgent intermediate or high-risk non-cardiac surgery should be clearly established prior to any intervention.

Procedural benefits and risks should be discussed with patients. Procedural risks include vascular damage requiring intervention or surgery (including haematoma, haemorrhage, pseudoaneurysm, dissection and vascular ischaemia), myocardial infarct, stroke, cardiac chamber perforation, tamponade requiring cardiothoracic surgery or pericardiocentesis, dysrhythmia, annular rupture, aortic dissection, emergency cardiothoracic surgery and mortality. Although contrast is used to prepare the aortic balloon, the procedure can be undertaken with minimal or no intravascular contrast use making it suitable in patients with advanced renal disease.

Patients excluded from BAV include those with metallic or bioprosthetic aortic valve (due to risk of fragmentation of prosthetic apparatus), active aortic valve endocarditis, those without severe AS, patients with pre-existing severe AR or patients with significant frailty and comorbidity unsuitable for any other aortic valve intervention and in whom BAV would not provide a significant change in quality or quantity of life. BAV may not be suitable either in those patients in whom aortic annular area is too small or too large for conventional balloon sizes although again this is likely to be rare given the variety of balloon sizes available. Patients with LV thrombus in situ, significant left main stem stenosis

or those with active bleeding that would prevent systemic heparinisation intraprocedurally are also contraindicated from BAV. Decision on BAV and any other aortic valve interventions are best made via the decision of a multidisciplinary 'heart team' meeting which ideally should involve interventional/structural cardiologists, imaging cardiologists (echo/CT), cardiothoracic surgeons and if appropriate physicians with interest in elderly care medicine (given the abundance of AS in patients with advanced age).

Prior to the BAV procedure, the operator should make a decision, ideally in conjunction with the patient and relatives about the ceiling of therapy to involve the patient if there is a significant or in particular catastrophic complication. Decisions need to involve whether a patient is a candidate for emergency sternotomy, cardiopulmonary bypass or surgery so that a clear plan can be made in case there is a procedural complication. Following on from this, as such, BAV should only take place in tertiary centres where the facility for 'bail-out' therapy including surgery/TAVI is available and where there is sufficient operator expertise in the procedure.

BAV PROCEDURAL CONSIDERATIONS

BAV can be undertaken under local or general anaesthetic using fluoroscopic guidance with or without the aid of TOE. Most procedures are performed using a standard retrograde technique (figure 2) via the femoral artery and rarely, in the presence of severe arterial disease, the brachial artery or subclavian artery (via arterial cut-down) can be used. The use of an antero-grade trans-septal approach has also been described in cases where retrograde arterial access is not possible.¹⁴

During BAV, an arterial sheath is percutaneously inserted, most commonly into the femoral artery. The size of the arterial sheath varies between 8 and 12 French depending on the aortic balloon size and manufacturer. For smaller arterial sheath sizes, a vascular closure device such as an Angioseal, Exoseal or Proglide may be deployed at the end of the procedure to achieve arterial haemostasis. For larger sheath sizes (usually >8 Fr sheaths), a Proglide or Prostar may need to be pre-deployed prior to arterial sheath insertion and

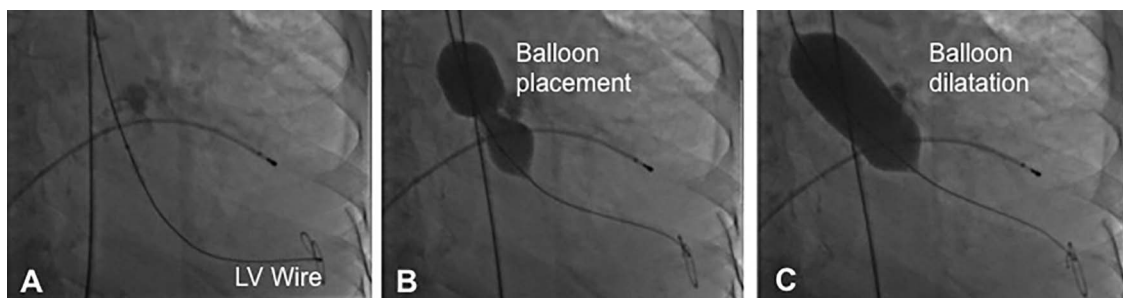


Figure 2 (A–C) Sequential angiographic images demonstrating placement of the wire, using the retrograde technique in the LV cavity (A), followed by balloon placement (B) and subsequent dilation within the calcified aortic valve (C). LV, left ventricular.

procedure initiation to allow suitable closure at the end of case. Furthermore, vascular complications can be minimised by the use of preclosure devices (Perclose, ProGlide or Prostar, Abott Vascular), appropriate pre-assessment of peripheral vascular status and use of micro-puncture techniques.

In most cases of BAV, venous access is also needed to facilitate temporary pacing wire (TPW) insertion for overdrive pacing to stabilise balloon positioning during inflation by decreasing the cardiac output and displacement forces on the balloon. With some non-compliant balloon profiles, overdrive pacing is not essential such as the 'True Dilatation' Balloon (Bard Vascular). If patients already have a permanent pacemaker in situ, then overdrive pacing via the permanent system is possible. TPWs can be inserted via the internal jugular vein, femoral vein or the subclavian vein. Advantages of internal jugular or subclavian TPW insertion include reduced risk of infection, Deep Vein Thrombosis (DVT) and allowing patient mobility in the postoperative period if the patient is pacing dependent. In a series of 423 patients, TPW use did not demonstrate any effect on either mortality or complication rates.¹⁵

Patients are systemically anticoagulated with heparin at 75–100 U/kg to achieve an Activated Clotting Time (ACT) of 250–300 s. Following this, a diagnostic catheter with the soft-tip straight end of a standard 0.035 guidewire is used to probe and cross the aortic valve. Typical catheters used to help direct the guidewire towards the aortic orifice include the Judkins Right 4 (JR4) or Amplatz Left 1 (AL1) but other catheters can be used including the Amplatz Left 2 (AL2—particularly where there is a horizontal aortic root/vertical configuration of the aortic valve) or Amplatz Right 1 (AR1) catheter. Gentle clockwise or anticlockwise rotation of the catheter may be needed to orientate the guidewire in line with aortic orifice. If the guidewire is unable to negotiate the aortic valve orifice, then a hydrophilic Terumo guidewire (Terumo, Kanagawa, Japan) may be used to help cross the aortic valve. The aortic valve can be crossed in the standard anteroposterior projection or a typically with 10–20° of Left Anterior Oblique (LAO) angulation may be applied to open up the aortic root and to provide the operator with an improved understanding of the orifice location.

Once a guidewire has crossed the aortic valve, then the coronary catheter can be advanced into the LV cavity and exchanged via a J-tipped long exchange guidewire to a pigtail catheter into the LV cavity. Simultaneous transduction of the pigtail catheter and the side port of the femoral arterial sheath will allow an assessment of differences in LV pressure to peripheral femoral arterial pressure and thereby an estimate of transvalvular gradient. An alternative is the use of a dual-lumen pigtail catheter which allows for the simultaneous measurement of central aortic pressures and LV pressures without the need for transducing a side port femoral sheath and is more accurate for assessing

central arterial/aortic pressures and is not contaminated by peripheral arterial disease as is the case for femoral arterial pressure transduction.

An exchange length 'superstiff' guidewire such as a preshaped Amplatz superstiff guidewire, Safari wire (Boston Scientific) or Confida wire (Medtronic) which have an atraumatic curve on their distal end can then be exchanged for the pigtail catheter and positioned at a suitable position in the LV apex to support passage of the aortic balloon across the annulus (figure 2). Ideally, the wire should be suitably placed in a position that does not interfere with the mitral valve apparatus and is not too arrhythmogenic in terms of ectopy inducing. An Right Anterior Oblique (RAO) projection can be used to ensure suitable apical positioning of the superstiff guidewire, and is desirable for minimising any interaction with the mitral valve apparatus.

Aortic balloon size is usually predetermined based on Trans-Thoracic Echocardiography (TTE), TOE or CT assessments of annular diameter. Most operators will size the aortic balloon closely to the measurement of the aortic valve annulus diameter upto a 1:1 ratio depending on clinical and echocardiographic and CT features such as the gradient across the valve, patient tolerability of procedure, presence of cardiogenic shock and calcification in the left ventricular outflow tract (LVOT) and valvular apparatus and degree of pre-existing AR. On TTE or TOE, the aortic annular diameter is measured from the aortic annulus measurement or LVOT measurement in systole in the parasternal long axis view and the balloon is sized accordingly up to a 1:1 ratio compared with annular diameter or at maximum a 10% oversize to the LVOT diameter. Balloon sizing tends to be more aggressive where BAV is used as a stand-alone therapy or as a diagnostic tool to assess therapeutic response to reduction in transaortic gradients, than when it is used for predilation in TAVI. It is important to ensure a balloon size smaller than the sinotubular junction diameter.

Aortic balloons typically range between 3 and 6 cm in length and have a variable diameter to fit different annular dimensions (figure 2). They are filled with a mixture of contrast and saline (usually in a ratio of 90:10 to appear radio-opaque on fluoroscopy and allow rapid deflation) and de-aired prior to use. They have a variable volume of 25–60 mL dependent on balloon diameter and length. Operators can use semicompliant (Tyshak II, Braun International Systems) or non-compliant aortic balloons (Z-Med, Braun International Systems; Maxi LD Balloon, Cordis Corporation). Semicompliant balloons tend to have a lower profile and therefore require smaller vascular access sheaths which helps with reduced vascular complications in this elderly cohort. The trade off, however, is that they have less predictable inflation diameters than the non-compliant balloons and have lower rated burst pressures.

Once the balloon is positioned across the aortic annulus, then overdrive pacing is started. Patients are usually overdrive paced at 180–220 bpm to allow a drop

in the stroke volume. Once a drop in transduced arterial blood pressure is demonstrated, the balloon position should be confirmed to be unchanged and then it should be rapidly inflated typically a few seconds (usually ~3 s) prior to rapid balloon deflation and discontinuation of overdrive pacing. The balloon should then be withdrawn into the ascending aorta from the aortic annulus to allow recovery of systemic blood pressure. The operator watches to ensure on fluoroscopy the appearance of a fully inflated balloon across the aortic annulus.

The different aortic balloons employed are designed to inflate to predictable diameters at set pressures. The increase in BAV procedures being performed has resulted in an evolution in the design of these balloons in order to improve both the safety and technical aspects of the procedure. Current generation balloons have changed from a cylindrical shape to an hourglass shape (V8: InterValve, NuCLEUS: NuMed, NuCLEUS-X: NuMed and Braun), to improve balloon positioning and stability during device inflation, whereby the shape is maintained throughout inflation reducing the likelihood of annulus rupture.

After balloon inflation the transvalvular gradient can be assessed on both echocardiography (TTE or TOE) as well as invasively by repositioning a pigtail catheter into the LV to decide on the need for further balloon inflations or an increment in balloon diameter to achieve a therapeutic effect with BAV which is usually a 40–50% reduction in peak aortic valve gradient with no significant increase in AR. Further balloon inflations should not take place until blood pressure has returned back to baseline. A significant increase in LV end diastolic

pressure or a drop in the aortic diastolic pressure is suggestive of haemodynamically significant AR.

On case completion, the operator can remove the arterial access (by vascular closure device or manual pressure if ACT<150 s) and the TPW can be removed depending on the likelihood of bradycardia development. The patient can then be recovered in a Coronary Care Unit (CCU) or monitored cardiac ward and can often be discharged the following day based on clinical state and a repeat echocardiogram to assess aortic valve area, gradients and any AR.

In an antegrade approach, there is a trans-septal puncture (via a trans-septal needle and Mullins sheath) and an extended wire loop that is from the right side of the heart, across the interatrial septum into the left side of the heart and across the aortic valve. An Inoue balloon (Toray) can be used to dilate the aortic annulus. While the antegrade approach reduces the need for large calibre arterial access in patients with peripheral vascular disease, it is associated with higher risk of damage to mitral valve apparatus.

Where patients are being considered for a bridge to definitive therapy, whether it is TAVI or AVR, they should be reviewed in clinic within 4–6 weeks to make a decision.

Procedural aims

During balloon dilation of the aortic valve, most operators aim for a reduction in mean transaortic valvular gradient of 50 mm Hg or 40–50% of the original gradient, with variations arising depending on clinical circumstances (figure 3A, B). Saia *et al*¹⁰ reported the complete

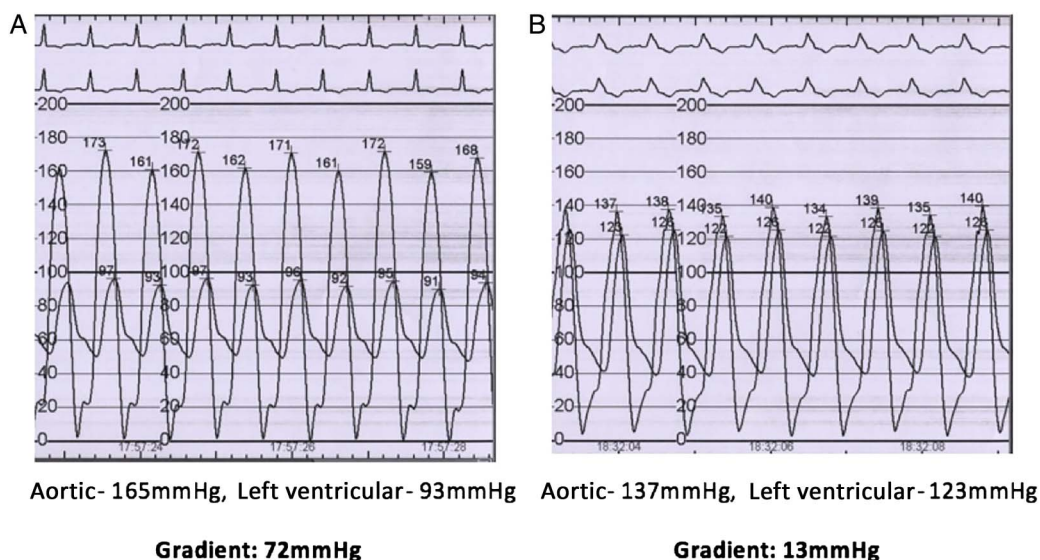


Figure 3 (A and B) Pressure tracings showing haemodynamic results pre-BAV (A) and post-BAV (B) procedure. Pre-BAV, there is a significant transvalvular gradient of 72 mm Hg and haemodynamically significant aortic stenosis. Post-BAV simultaneous aortic-LV pressure assessment demonstrates a significant reduction in transvalvular gradient to 13 mm Hg demonstrating therapeutic efficacy of the BAV. Incidentally, there is a new onset of Left Bundle Branch Block (LBBB) post-BAV in this patient as demonstrated by prolongation of the QRS duration on the rhythm strip on top. This may be a transient phenomenon and rate-related postburst pacing or may be permanent due to anatomical proximity of the AV node and conduction tissue to the aortic annulus. AV, atrioventricular; BAV, balloon aortic valvuloplasty; LV, left ventricular.

abrogation of the aortic pulse for a few seconds following three manual dilations as a sufficient end point. Subtle changes that may be evident post-BAV that suggest improved haemodynamics include an increase in aortic systolic arterial pressure and a rapid upstroke to arterial waveform. Any reductions in transvalvular gradient has to be off-set against the increased risk of AR and annular rupture from large and more aggressively sized balloon diameters or sequential dilations.

COMPLICATIONS POST-BAV

Patients can experience a variety of complications post including vascular haemorrhage (external haematoma, retroperitoneal haemorrhage), bradycardia (complete atrioventricular block, pauses), tamponade (from temporary wire insertion), aortic annular rupture, pump failure (acute LV systolic failure), severe AR, acute severe mitral regurgitation (from guidewire/pigtail entrapment of Mitral Valve (MV) apparatus or balloon disruption), coronary ischaemia or sustained tachyarrhythmia (Ventricular Tachycardia (VT)). It is important to treat hypotension promptly as this patient population tolerates hypotension particularly poorly and fall into a vicious cycle of hypotension and coronary ischaemia. Hypotension should be treated with intravenous fluid administration together with inotropes or vasopressors while the cause for hypotension can be identified immediately and treated. This usually involves an algorithm of possibilities assessed by live ECG analysis intraprocedurally, TTE (or TOE) to look for annular rupture, AR or tamponade, iliofemoral angiogram and aortogram on fluoroscopy to assess for contrast extravasation.

Vascular haemorrhage. This can be treated by a peripheral vessel occlusion balloon, replacement of lost intravascular volume with fluids and blood products, reversal of anticoagulation and surgery or peripheral vascular covered stenting if needed.

Bradycardia. Can be treated by intravenous atropine and temporary pacemaker wire use.

Tamponade. This complication can be treated with emergency pericardiocentesis, reversal of anticoagulation, intravascular filling with fluids and blood products and if ongoing bleeding then cardiothoracic surgery.

Severe AR: In certain cases, rescue manoeuvres can be used to mobilise a fixed cusp of the aortic valve.¹⁶ Otherwise inotropes, diuresis and stabilisation may be appropriate. Rapid pacing via the TPW may also limit the diastolic regurgitation. Generally significantly hypertrophied hearts (as in AS) do not tolerate acute AR well and in such cases urgent TAVI or surgery may be required.

Annular rupture. This has a very high mortality rate given the nature of the complication and most patients acutely deteriorate and die on table. If annular rupture is promptly recognised, then intravenous fluid therapy, treatment of tamponade and emergency cardiothoracic surgery, if appropriate is needed to maximise chances of survival.

HISTOPATHOLOGY OF AORTIC VALVE FOLLOWING BAV

The pathology of calcific AS in the elderly is due to fibrosis and calcification of the valve leaflets, which is sometimes associated with commissural fusion. These pathological changes render the valve rigid and immobile.

The mechanisms of successful percutaneous balloon dilation of the aortic valve described by Serruys and colleagues in 1993 include (1) cleavage or laceration of the dense collagenous valve stroma, (2) fracture and/or fragmentation of calcifications and (3) separation of fused commissures. They described that the final outcome of balloon dilation mainly depends on the severity of the underlying pathological abnormalities in the valve and the extent of the injury created by the balloon. BAV causes injury to the aortic valve which leads to the development, organisation and collagenisation of young scar tissue in the tears and fractures in the valve which ultimately leads to progressive reduced leaflet mobility and restenosis.¹⁷

HAEMODYNAMIC OUTCOMES

The National Heart Lung and Blood Institute (NHLBI) balloon valvuloplasty registry collected data on patients undergoing BAV in the USA and Canada between 1987 and 1989, and forms the most comprehensive early outcome data set.¹⁸ In 1991 the group published 30-day follow-up on a cohort of 674 patients. Haemodynamically post-BAV, aortic valve area increased from 0.5 to 0.8 cm² (p<0.0001), with a concomitant decrease in peak aortic gradient from 65 to 31 mm Hg (p<0.0001), associated with a small but significant increase in cardiac output. Similar results were reported from the Mansfield Scientific Aortic Valvuloplasty Registry of 492 patients between 1986 and 1987 where an increase in aortic valve area from 0.5 to 0.8 cm², a decrease in peak aortic gradient from 60 to 30 mm Hg and an increase in cardiac output from 3.86 to 4.05 L/min was observed.¹⁹

The Mansfield registry assessed the impact of procedure-related variables on acute valvuloplasty and postvalvuloplasty haemodynamic changes. The only variable associated with a significant difference was balloon inflation time whereby an inflation time between 30 and 60 s resulted in a larger final aortic valve area, but no difference in aortic valve gradient when compared with inflation times of <30 s. They concluded that short inflation times (<30 s) should be avoided.¹⁹ The size of largest balloon used, the number of balloons, the number of balloon exchanges and the use of single or double balloons made no significant difference to post-procedure haemodynamics. A summary of haemodynamic outcomes from different studies during the pre-TAVI era can be found in [table 3](#).

Outcome data from the 'pre-TAVI era'

Procedural complications include systemic embolisation, acute AR, ventricular perforations, local arterial trauma,

Table 3 Reported changes in aortic gradient and aortic valve area following BAV procedures in series reported prior to and after the introduction of TAVI in 2002

Era	Author	Year	Study design	Patients	Change in aortic gradient (mm Hg)	Change in aortic valve area (cm ²)
No TAVI (pre-2002)	Lababidi <i>et al</i> ²⁹	1984	SC, P	23	81	NA
	Walls <i>et al</i> ³⁰	1984	SC, P	27	90	NA
	Block and Palacios ³¹	1987	SC	35	45	0.44
	Dorros <i>et al</i> ³²	1987	SC	10	38	0.30
	Schneider <i>et al</i> ³³	1987	SC	6	27	0.39
	Isner <i>et al</i> ³⁴	1987	SC	9	15	0.26
	McKay <i>et al</i> ³⁵	1987	SC, P	9	36	0.47
	Cribier <i>et al</i> ³⁶	1987	SC	92	33	0.30
	Letac <i>et al</i> ³⁷	1988	SC	218	35	0.30
	Nishimura <i>et al</i> ³⁸	1988	SC, P	25	26	0.20
	Litvack <i>et al</i> ³⁹	1988	SC	25	15	0.31
	Safian <i>et al</i> ⁴⁰	1988	SC	170	43	0.41
	NHLBI Registry ¹⁸	1991	MC, R	674	34	0.30
	Mansfield Registry ¹⁹	1991	MC, P	492	30	0.32
	Lieberman <i>et al</i> ⁴¹	1995	SC	165	30	0.20
TAVI (2002 to current)	Agarwal <i>et al</i> ⁴²	2005	SC, R	212	26	0.59
	Klein <i>et al</i> ⁴³	2006	SC, R	78	21	0.38
	Tissot <i>et al</i> ²¹	2011	SC, P	253	16	0.21
	Khawaja <i>et al</i> ¹⁵	2013	MC	423	50	0.22
	Ben-Dor <i>et al</i> ²²	2013	SC, P	472	23	0.40
	Saia <i>et al</i> ¹⁰	2013	SC, R	415	30	0.30
	Eltchaninoff <i>et al</i> ⁴⁴	2014	SC, R	323	23	0.44
	Moretti <i>et al</i> ²³	2015	MC, R	811	21	0.19

BAV, balloon aortic valvuloplasty; MC, multicentre; NA, not available; NHLBI, National Heart Lung and Blood Institute; P, prospective; R, retrospective; SC, single-centre; TAVI, transcatheter aortic valve implantation.

Table 4 Reported complications from series of patients undergoing BAV prior to and after the introduction of TAVI in 2002

Era	Author	Subgroup	Year	Study design	Patients	Total complication	Acute				
							CVA	CT	AI	MI	Vascular*
No TAVI (pre-2002)	NHLBI Registry ¹⁸	NA	1991	MC, R	674	25%	2%	1%	1%	NA	34%
	Mansfield Registry ^{19, 20}	NA	1991	MC, P	492	21%	2%	2%	1%	NA	NA
	Lieberman <i>et al</i> ⁴¹	NA	1995	SC	165	NA	0.4%	NA	1.1%	NA	NA
TAVI (2002 to current)	Agarwal <i>et al</i> ⁴²	NA	2005	SC, R	212	NA	0.4%	NA	1.1%	NA	13.5%
	Klein <i>et al</i> ⁴³	NA	2006	SC, R	78	22%	1%	1%	0%	1%	NA
	Tissot <i>et al</i> ²¹	NA	2011	SC, P	253	4%	0%	NA	0%	0%	1%
	Khawaja <i>et al</i> ¹⁵	NA	2013	MC	423	6.3%	1%	1%	NA	1%	2.2%
	Ben-Dor <i>et al</i> ²²	NA	2013	SC, P	472	NA	2%	1%	1%	0%	11%
	Saia <i>et al</i> ¹⁰	NA	2013	SC, R	415	NA	1%	NA	2.6%	0%	5.6%
	Eltchaninoff <i>et al</i> ⁴⁴	NA	2014	SC, R	323	7%	2%	0%	2%	0%	2.5%
	Moretti <i>et al</i> ²³	Dest.	2015	MC, R	416	NA	0.8%	NA	NA	2.4%	11%†
	B-TAVI			320	NA	0.7%	NA	NA	0.8%	7.7%†	
	B-AVR			75	NA	0%	NA	NA	0%	12%†	

*Includes both major and minor vascular complications as well as requirement for blood transfusions.

†According to VARC criteria.

AI, aortic insufficiency; BAV, balloon aortic valvuloplasty; B-AVR, bridge to aortic valve; B-TAVI, bridge to TAVI; CT, cardiac tamponade; CVA, cerebrovascular accident; Dest, destination therapy; MC, multicentre; MI, myocardial infarction; NA, not available; NHLBI, National Heart Lung and Blood Institute; P, prospective; R, retrospective; SC, single-centre; TAVI, transcatheter aortic valve implantation; VARC, Valve Academic Research Consortium Definitions.

arrhythmias and cardiac arrest. Data from the NHLBI and Mansfield registries as well as other studies are summarised in [table 4](#) below.

Additional complications included the need for blood transfusion (23%), vascular surgery (7%), cerebrovascular accident myocardial infarction (MI; 2%) and cardiac surgery (1%). Severe AR is relatively uncommon following BAV, and occurred in only 11 (1%) patients across both cohorts, leading to surgery in 8 (including 3 patients emergently) and death in 2. The Mansfield study demonstrated an increased propensity towards acute AR in women in whom a dual balloon technique was used.²⁰

In the NHLBI study, by 30 days there were 92 deaths (14%), 71 due to cardiovascular-related causes. Unsurprisingly, death was more common in those patients with preprocedural poor LV systolic function, low cardiac output (<3 l/min), hypotension, New York Heart Association (NYHA) IV cardiac failure and multi-organ failure.

Of the survivors (86%) at 30 days, symptomatic improvement was generally seen, with 75% experiencing at least one functional class improvement in overall NYHA score.¹⁸

BAV in the 'TAVI era'

With the advent of TAVI, the clinical status and baseline characteristics of patients undergoing BAV has changed substantially over the past 10 years. Advances in technology coupled to improved patient selection has led to improvements in procedural outcomes and complication rates. These are described in detail below and are compared with historical pre-TAVI data in [tables 3–5](#) below.

Tissot *et al*²¹ describe a cohort of 253 patients referred to their centre for TAVI between 2006 and 2009. Forty-one patients (16%) were considered transiently unsuitable for either AVR or TAVI and underwent BAV as a bridge to intervention (half of which were in cardiogenic shock). Of the other patients, TAVI/AVR was performed in 140 cases and medical therapy alone in 72 cases. Within the BAV treated group, there were no Percutaneous Aortic Balloon Valvuloplasty (PABV)-related deaths. Of these 41 patients, 23 went on to have TAVI (n=19), or AVR (n=4), while 18 patients did not undergo further intervention. In those who underwent definitive aortic valve intervention with TAVI or AVR, the 1-year and 2-year survival rates were 94±5% and 85±10%, respectively. One-year and 2-year survival rates of 33±11% and 6±5% after BAV alone were similar to those who were managed medically.^{2 21} Thus, the Tissot *et al*'s paper supports the concept of patients undergoing BAV to improve haemodynamics and clinical status at relatively low procedural risk, with a view to more definitive treatment based on their clinical response and comorbid conditions.

Saia *et al*¹⁰ reported on a series of 415 consecutive patients who underwent BAV between 2000 and 2010 in

Italy. Of the 415 patients, 23 were in cardiogenic shock and 133 were treated for symptom palliation alone, the remaining 259 were treated with a view to subsequently being considered for AVR or TAVI. Saia *et al* described only occasional requirement for right ventricular pacing and at least three dilations with complete pulse abrogation was achieved in 79.8% of patients. In terms of overall procedure success as measured by reduction in peak LV to aortic pressure gradient, the following was reported: >50% gradient reduction was achieved in 215 patients (51.8%), 30–49% reduction in 105 (25.3%) and <30% in 95 patients (22.9%). Acute AR occurred in 11 patients (2.6%), but it was successfully managed in 8 patients in the catheter laboratory, using a pigtail catheter, reinforced with a stiff wire to mobilise a locked cusp. The in-hospital mortality of the entire cohort was 5.1% and occurred predominantly in patients with cardiogenic shock (56.5% vs around 2% in other subgroups). The incidence of stroke was 0.5% (two patients, one with complete functional recovery), while life-threatening bleeding occurred in 1.5% and major vascular complications in 2.2%. Postprocedure, acute kidney injury was seen in 18% of cases, with an at least 50% increase in creatinine reported in 10% of cases.^{10 22} The 1-year and 2-year mortality rates were 33.2% and 57.4%, respectively, with the highest incidence in the shock group (70.7% and 80.4%). Those who underwent BAV for symptom palliation alone had 1-year and 2-year mortality rates of 44.3% and 67%. Repeat BAV procedures were performed in 30.8% within 2 years of the index procedure. The clinical outcomes in those who underwent TAVI were good, with a 1-year mortality of 13.1% and of 19.4% at 2 years. Patients who underwent AVR had corresponding mortalities of 0% and 33.7%.¹⁰ In those patients presenting with cardiogenic shock, 11% underwent AVR with nobody undergoing a TAVI.¹⁰ Given that the outcomes for those treated with BAV alone are poor, patients being bridged should have minimal delay prior to their destination therapy on improvement of clinical status.

Recently, the largest published series reported on 811 consecutive patients undergoing BAV across seven centres in Europe between 2006 and 2013.²³ Nearly half the cohort underwent BAV with the intention of bridging to TAVI (n=320, 40%) or AVR (n=75, 9%), with the remainder being treated as destination therapy. Of those being bridged to TAVI or AVR, 65.1% and 68.4%, respectively, did not have any further intervention, percutaneous or surgical, after their BAV procedure. Those undergoing BAV as a bridge to AVR were younger and had a reduced burden of comorbidities, but there were no significant difference in the echocardiographic features of AS between the three groups. 30-day all-cause mortality (6.5% vs 6.2% vs 7.4%; p=0.56) and cardiovascular mortality (4.9% vs 4.9% vs 2.9%; p=0.98) was not statistically different among the three groups of destination therapy versus TAVI versus AVR, respectively. After a median follow-up of 318 days (IQR 116–500 days) no

Table 5 Cumulative all-cause mortality following BAV in series reported prior to and after the introduction of TAVI in 2002

Era	Author	Subgroup	Year	Study							
				design	Patients	Hospital*	30-day	6-month	1-year	5-year	
No TAVI (pre-2002)	Lababidi <i>et al</i> ²⁹	NA	1984	SC, P	23	NA	NA	NA	NA	NA	
	Walls <i>et al</i> ³⁰	NA	1984	SC, P	27	4%	NA	NA	NA	NA	
	Block and Palacios ³¹	NA	1987	SC	35	6%	NA	NA	NA	NA	
	Dorros <i>et al</i> ³²	NA	1987	SC	10	NA	NA	NA	NA	NA	
	Schneider <i>et al</i> ³³	NA	1987	SC	6	0%	NA	NA	NA	NA	
	Isner <i>et al</i> ³⁴	NA	1987	SC	9	NA	NA	NA	NA	NA	
	McKay <i>et al</i> ³⁵	NA	1987	SC	32	10%	NA	NA	NA	NA	
	Cribier <i>et al</i> ³⁶	NA	1987	SC	92	3%	NA	NA	NA	NA	
	Letac <i>et al</i> ³⁷	NA	1988	SC	218	5%	NA	NA	NA	NA	
	Nishimura <i>et al</i> ³⁸	NA	1988	SC, P	25	1%	16%	48%	NA	NA	
	Litvack <i>et al</i> ³⁹	NA	1988	SC	25	1%	NA	NA	NA	NA	
	Safian <i>et al</i> ⁴⁰	NA	1988	SC	170	4%	NA	18%	26%	NA	
	NHLBI Registry ¹⁸	NA	1991	MC, R	674	3%	14%	NA	36%	NA	
	Mansfield Registry ^{19 45}	NA	1991	MC, P	492	5%	NA	23%	36%	NA	
	Lieberman <i>et al</i> ⁴¹	NA	1995	SC	165	NA	NA	NA	40%	NA	
	TAVI (2002 to current)	Agarwal <i>et al</i> ⁴²	NA	2005	SC, R	212	8%	10%	NA	36%	86%
		Klein <i>et al</i> ⁴³	NA	2006	SC, R	78	1%	NA	NA	62%	86%
BAV alone			2011	SC, P	41	NA	NA	NA	67%	NA	
Tissot <i>et al</i> ²¹		BAV			140	NA	NA	NA	6%	NA	
		bridge									
Khawaja <i>et al</i> ¹²		NA	2013	MC	423	2.4%	14%	NA	36%	NA	
Ben-Dor <i>et al</i> ²²		NA	2013	SC, P	472	2.5%	NA	NA	NA	NA	
Saia <i>et al</i> ¹⁰		B-TAVI	2013	SC, R	162	NA	NA	NA	21%	NA	
		B-AVR			197	NA	NA	NA	22%	NA	
		Shock			23	NA	NA	NA	71%	NA	
		Pall.			133	NA	NA	NA	44%	NA	
Eltchaninoff <i>et al</i> ⁴⁴		BAV	2014	SC, R	238	NA	NA	NA	54%	99%	
		B-TAVI			54	NA	NA	NA	26%	91%	
	B-AVR			31	NA	NA	NA	23%	81%		
Moretti <i>et al</i> ²³	Dest.	2015	MC, R	416	NA	6.5%	NA	NA	NA		
	B-TAVI			320	NA	6.2%	NA	NA	NA		
	B-AVR			75	NA	7.4%	NA	NA	NA		

*Hospital: mortality rate during procedure, after 24 hours and at time of discharge combined.

BAV, balloon aortic valvuloplasty; B-AVR, bridge to AVR; B-TAVI, bridge to TAVI; Dest., destination therapy; MC, multicentre; NHLBI, National Heart Lung and Blood Institute; P, prospective; Pall., palliation; R, retrospective; SC, single-centre; TAVI, transcatheter aortic valve implantation.

statistical difference in all-cause mortality was seen between the three groups, but cardiovascular deaths were reduced for patients undergoing AVR (11% vs 11% vs 3%; $p=0.04$). Life-threatening and major bleeding (8% vs 5.7% vs 6%) and vascular complication (3% vs 2% vs 6%) rates were higher than reported in Saia *et al*'s cohort but MI (1.6% vs 0.8% vs 0%) and stroke rates (0.8% vs 0.7% vs 0%) were comparable.²³ For all complications, the Valve Academic Research Consortium Definitions (VARC) criteria were used.²⁴

The trend towards reduced complication rates observed during the TAVI era was also observed in a cross-sectional study of all BAVs performed in the USA between 1998 and 2010. In-hospital mortality rates fell from 11.5% in 1998 to 8.8% in 2009–2010, with similar improvements seen in complication rates in comparison to date from the Mansfield and NHLBI registries.²⁵

These trends could be explained by improvements in the technology of the balloons, catheters and vascular closure devices, as well as the increased screening of the peripheral arterial system.^{26 27} Additionally, more procedures are now being undertaken in high-volume centres by increasingly experienced operators following an MDT discussion highlighting the importance of appropriate selection of patient based on characteristics and comorbidities.²⁵ Use of novel clinical risk prediction scores, may lead to further improvements in the future.²⁸

Combined BAV and PCI

Given the rising incidence of coronary artery disease and severe AS, around 65% of patients referred for TAVI are found to have coexisting coronary artery disease.⁴⁶ Studies comparing patients undergoing concomitant BAV and percutaneous coronary intervention (PCI)

against those undergoing BAV alone have not demonstrated any difference in hospital mortality or complication rates between both groups, although an increased length of stay was seen for those undergoing both procedures simultaneously.^{47 48} Furthermore, no difference was observed in the efficacy of the valvuloplasty, leading to Ben-Dor *et al*⁴⁸ to postulate that the added benefit of revascularisation protects against LV ischaemia, particularly during rapid right ventricular pacing.

Balloon postdilation in TAVI

One of the complications of percutaneous aortic valve implantation is that of paravalvular AR or paravalvular leak (PVL). This acute regurgitant volume is poorly tolerated and the LV is not able to adapt resulting in deleterious progressive dilation, a rapid increase in the LV end diastolic pressure and the onset of pulmonary oedema.⁴⁹ In the original PARTNER trial, 12% of TAVI cases had postprocedural moderate-to-severe AR despite procedural intervention at 30-day follow-up and 7% of cases had persistent AR at 1-year follow-up.⁶ Owing to the resultant worse outcomes in patients with significant PVL, the presence and severity of AR is checked for judiciously intraprocedurally by means of transthoracic/transoesophageal echocardiography, aortography and invasive haemodynamic assessment.⁵⁰ Paravalvular AR is most often only mild or mild-to-moderate in severity post-TAVI. These patients do not require any specific further intervention and often have ongoing echocardiographic surveillance of the AR severity in the post-operative phase and on discharge. At 1-year follow-up post-TAVI, 80% of patients had trace or mild AR and 13% of patients had no AR.⁶ A recent literature review on TAVI, self-expanding THV valves (Corevalve, Medtronic) were associated with higher rates (9–21%) of haemodynamically important (moderate-to-severe) AR compared with balloon-expandable (Edwards Sapien XT) valves (6–13.9%).⁵⁰

Several causative factors have been implicated in contributing to the incidence of PVL in patients post-TAVI. This includes the presence of significant valvular annular and LVOT calcification, valve underexpansion, THV undersizing and suboptimal positioning of THV (either too low in the LVOT or too highly positioned). Attempts have been made to reduce the influence of these factors by improving TAVI technology with balloon predilation of the native aortic valve prior to valve deployment intraprocedurally, development of THV cuffs that reduce the degree of PVL, the presence of repositionable valves and the increasing use of CT to accurately assess annulus area to improve decision-making in THV sizing.

Haemodynamic assessment of PVL

Haemodynamic assessment can be undertaken to assess the severity of PVL. The Aortic Regurgitation Index (ARI) is calculated by subtracting the Left Ventricular End-Diastolic Pressure (LVEDP) from the aortic diastolic

blood pressure and dividing this by the aortic systolic blood pressure. An ARI of 25 is used as the cut-off value for the predictor of 1-year mortality and a score of ≥ 25 is suggestive of non-significant PVL.⁵¹ This haemodynamic assessment should be undertaken at least 10 min post-THV deployment to allow recovery of the myocardium from the impact of burst pacing influencing haemodynamic parameters.⁵²

The treatment of moderate significant AR post-TAVI depends on the cause. If the mechanism of AR is due to valve underdeployment or due to eccentric annular calcification then balloon postdilation may be used to expand the valve further (in self-expanding and balloon-expandable THVs) and reduce any paravalvular AR.⁵³ Postdilation of THV can be safely undertaken with an oversized balloon without causing significant damage to the THV prosthesis. This is the initial therapeutic strategy to reduce the severity of postprocedural paravalvular AR.⁵³ Postdilation reduces the severity of AR in a significant proportion of patients.⁵⁴

In a cohort of patients with self-expanding THV implant (Corevalve), independent predictors of moderate+ AR ($AR \geq 2+$) were peripheral vascular disease, larger aortic annulus dimensions and low implantation depth of THV. In this study, 32 out of 79 patients (40.5%) had postprocedural $AR \geq 2+$. In 10 patients, the AR was conservatively managed. In the remainder AR patients, 21 underwent BAV with a majority of them improving in AR severity (17/21 or 81%). In the remaining four patients, AR severity failed to improve with BAV and two required a valve-in-valve implantation and in one case the original THV was pulled more proximally via a snare technique. This shows that postdilation is an effective measure to reduce the severity of AR.⁵⁵

Postdilation has been shown to increase the minimum diameter of the THV on average by 1.9 mm. Postdilation also improves the circularity of the THV and improves apposition of the aortic valve annulus and THV cuff.^{54 56} Different operators will use a variety of balloons for THV postdilation based on their experience, the degree of paravalvular AR, percentage of THV oversizing or undersizing, severity of calcification of native valves and LVOT and the initial deployment pressure (if a balloon-expandable valve is used). Frequently in balloon-expandable valves, the deployment balloon may be reused based on the relevant manufacturer. A semi-compliant balloon could be used to postdilute the valve in a 1:1 ratio to the mean annulus size. If a non-compliant balloon is used, then this is usually at least 1 mm smaller than the mean aortic annulus to achieve satisfactory postdilation while balancing against the risk of annular rupture. The advantage of using the same inflation balloon for postdilation as used for THV deployment (if it was used in balloon-expandable valves) is that it avoids transit of another balloon across the aortic arch/descending aorta to minimise the risk of aortic plaque disruption or dislodgement. In a study by Hahn *et al*,⁵⁷ balloon postdilation was undertaken under

rapid pacing with the same inflation volume as the initial deployment volume or in some cases with 0.5–2 mL extra in the inflation syringe as per operator discretion. In their cohort, the postdilation balloon was usually placed in a slightly more apical position to help better THV deployment around the aortic annulus to seal any cuffs.

In summary, paravalvular AR is associated with increased morbidity and mortality. The newer iterations of the THV including the Edward Sapien S3 and Corevalve Evolut-R are associated with reduced incidence of paravalvular AR. When paravalvular AR is present it is important to assess the haemodynamic impact of the AR and mechanism of AR to determine the best possible solution which may include valve repositioning, THV postdilation or valve-in-valve implantation.

CONCLUSION

In the TAVI era, BAV has an important role to play in the management of patients with severe symptomatic AS deemed too high risk for AVR either because of comorbidities or clinical instability. It has been used for symptom palliation and as a salvage procedure in the context of cardiogenic shock since it was first performed in 1986, but over the past 10 years, it has been used with increasing frequency as a bridge to definitive aortic valve intervention, usually TAVI but also AVR. In those with heart failure and severe impairment of LV function, BAV can improve clinical status to reduce the risk of subsequent TAVI/AVR and has also proved useful in patients where the benefits of definitive aortic valve intervention are unclear due to comorbidities such as COPD or other frailty. Although BAV procedural risks and complications remain, these have improved since the advent of TAVI programmes due to improvements in technology, operator experience and more careful patient selection.

The advent of increased technology in the TAVI era has resulted in improved range of devices that can be used for the BAV procedure. Prior to the TAVI era most LV superstiff guidewires required shaping by the operator to ensure a rounded edge in the left ventricle to reduce the risk of chamber perforation. Now the presence of confida and safari wires used during TAVI procedures can also be used for BAV and provide a safe, atraumatic and less arrhythmogenic support guidewire for BAV. Improvement in CT techniques and availability of this resource means that better assessments of aortic annular diameter and peripheral vascular assessment can be made prior to the BAV procedure. As well as this, improvement in balloon shapes with ‘hour glass’ shape means more accurate balloon positioning, reduced risk of annular rupture due to a narrowed balloon waist and improved aortic valve areas due to leaflet hyperextension.

Limitations into the efficacy of BAV include that the data reviewed are predominantly retrospective and

observational in nature. Given the patient population, there is a heterogeneous range of comorbidities or characteristics that can affect outcome including mortality. Further controlled or randomised studies as well as data on cost-effectiveness would equip both physicians and policymakers with a greater understanding of the treatment risks, benefits and economic costs in relation to the natural history of the disease.

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