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Balloon post-dilation of the mechanically expanded LOTUS transcatheter aortic valve

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KEYWORDS

- aortic stenosis
- balloon valvuloplasty
- miscellaneous
- transcatheter aortic valve replacement (TAVR)

Abstract

Aims: The aim of this study was to describe the technique and assess the feasibility of balloon post-dilation (BPD) within the mechanically expanded LOTUS transcatheter aortic valve.

Methods and results: Consecutive patients with severe aortic stenosis who underwent LOTUS valve implantation at a single centre were prospectively followed with pre-discharge and 30-day echocardiography. BPD was performed in limited cases of significant procedural paravalvular aortic regurgitation (AR) where mitigation by initial device repositioning had been unsuccessful. BPD success was defined as a reduction of paravalvular AR to a severity of mild or less. Safety was determined by 30-day occurrence of major adverse events defined according to VARC-2 criteria. BPD was performed in four patients for significant post-implant paravalvular AR (n=4) and/or prosthesis frame deformation (n=2). BPD was successful in achieving a reduction of procedural paravalvular AR in three out of four patients and in pre-discharge AR in all patients. There were no 30-day deaths, cerebrovascular events or new pacemaker requirement in patients who received BPD.

Conclusions: This is the first study to describe the technique of BPD within the mechanically expanded LOTUS transcatheter aortic valve. An acceptable success rate with no complications was observed with the use of BPD in a small number of LOTUS valve recipients.

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Abbreviations

AR aortic regurgitation
BPD balloon post-dilation
CHB complete heart block
LBBB left bundle branch block
LVOT left ventricular outflow tract
MDCT multidetector computed tomography
STS Society of Thoracic Surgeons
TAVR transcatheter aortic valve replacement
TOE transoesophageal echocardiography

Introduction

Residual significant paravalvular aortic regurgitation (AR) occurs in approximately 5-17% of all transcatheter aortic valve replacement (TAVR) recipients, and has been linked to poorer outcomes[1]. Patients found to have significant periprocedural paravalvular AR following TAVR can undergo balloon post-dilation (BPD) to expand the valve better and improve sealing of the paravalvular space. The potential risks of BPD include damage to the valve prosthesis leaflets, annulus rupture and increased risk of conduction abnormalities or cerebrovascular events.

In recipients of the balloon-expandable Edwards SAPIEN valve (Edwards Lifesciences Inc., Irvine, CA, USA) and the self-expanding CoreValve® (Medtronic, Minneapolis, MN, USA), BPD is utilised in approximately one quarter of patients[2-4]. In contrast, BPD has been discouraged in the mechanically expanded LOTUS™ valve system (Boston Scientific, Marlborough, MA, USA) and is generally only recommended to mitigate significant residual transprosthetic gradients due to severe frame distortion. The LOTUS valve's adaptive seal and fully repositionable and retrievable nature generally result in extremely low rates of moderate to severe paravalvular AR[5,6]. While the proportion of LOTUS recipients who develop AR remains small, increasing implantation rates worldwide will result in this complication being encountered more frequently. This is the first case series to describe the technique and preliminary efficacy of BPD following implantation of the LOTUS valve system.

Methods

Consecutive patients with severe AS at high or extreme surgical risk underwent TAVR with the LOTUS valve system at a single centre from April 2012 to October 2015. All patients underwent standard preprocedural TAVR work-up including transthoracic echocardiography, multidetector computed tomography (MDCT) and coronary angiography, as previously described[7]. Baseline, procedural, in-hospital and 30-day follow-up was prospectively collected for all patients and entered into a dedicated TAVR database. This was pre-approved by the institutional human research ethics committee and complies with the Declaration of Helsinki. Balloon predilation was routinely performed before valve implantation. After valve deployment, the presence, location and severity of AR were carefully assessed using aortography and/or transoesophageal echocardiography (TOE). Residual AR was defined as non-significant (none, trivial or mild) or significant (mild-to-moderate, moderate, moderate-to-severe, or severe).

BPD was performed in cases of significant paravalvular AR (defined as a severity of mild-to-moderate or higher) despite, where appropriate, an initial attempt to mitigate this by device repositioning being unsuccessful. Sizing of the post-dilatation balloon was at the operator's discretion; however, in keeping with the manufacturer's recommendation, the balloon did not exceed 3 mm less than the prosthesis diameter in order to avoid damaging the locking mechanisms. In addition, the left ventricular outflow tract (LVOT) dimensions and degree of calcification were considered in order to minimise the risk of annular injury. After BPD, the presence and severity of periprocedural AR was again carefully assessed using aortography or TOE. The BPD was considered successful if the degree of residual paravalvular AR was reduced to a severity of mild or less. Safety was determined by occurrence of procedural, in-hospital or 30-day major adverse events defined according to the Valve Academic Research Consortium-2 criteria[8]. Thirty-day echocardiography was also used to assess prosthesis valve leaflet deterioration or the haemodynamic impact of BPD.

Results

BPD was performed in a total of four (out of 104) patients during the time period stated above. The four patients who received BPD all received a 25 mm LOTUS valve via the transfemoral approach. The baseline and procedural characteristics for these four patients are shown in **Table 1** and **Table 2**, respectively. Cases 1, 3 and 4 underwent TAVR under conscious sedation and in case 2 general anaesthesia (GA) with TOE was utilised. Post-dilation was

Table 1. Baseline characteristics.

Variable	Case 1	Case 2	Case 3	Case 4
Age	87	80	89	98
Baseline creatinine (µmol/L)	73	421	136	115
STS Plus score	2.1	7.8	5.1	7.6
STS morbidity score	14.7	35.9	22.4	28.9
Echocardiographic			Bicuspid*	
Valve area (cm^2)	0.6	0.7	0.7	0.8
Peak/mean gradient (mmHg)	160/98	61/35	87/48	107/63
LVEF (%)	65	59	15	55
Baseline AR	mild	trivial	trivial-mild	mild
Annulus				
Min/max diameter (mm)	22/30	22/27	24/35	23/26
Perimeter (mm)/area (mm^2)	81/489	77/456	93/648	77/472
Left ventricular outflow tract				
Perimeter (mm)/area (mm^2)	82/481	79/479	103/813	74/426
Sinus of Valsalva				
Perimeter (mm)/area (mm^2)	99/769	100/747	129/1,244	102/775
Valve calcification	severe	mild	severe	severe

*Case 3 had a bicuspid native aortic valve. AR: aortic regurgitation; LVEF: left ventricular ejection fraction; STS: Society of Thoracic Surgeons

Table 2. Procedural characteristics.

Variable		Case 1	Case 2	Case 3	Case 4
Device size (mm)		25	25	25	25
Device/annulus perimeter ratio		0.97	1.02	0.84	1.02
Predilation balloon (mm)		18	18	22	18
Number of re-sheathings and repositioning		1	2	2	0
Pre balloon post-dilation	Severity of AR	Moderate	Moderate	Mild-mod	Moderate
	AR index	0.35	0.17	0.22	0.11
Size of post-dilation balloon		20	18	22	20
Post balloon post-dilation	Severity of AR	Mild	Mild	Mild-mod	Mild
	AR index	0.38	0.18	0.24	0.19
Periprocedural CHB		No	N/A*	Yes	Yes
New or worsened LBBB		Yes	Yes	Yes	No

*Case 2 had a pre-existing permanent pacemaker. AR: aortic regurgitation; CHB: complete heart block; LBBB: left bundle branch block

performed in each patient after the deployed prosthetic valve was crossed with a pigtail catheter and a super stiff wire positioned in the left ventricle (Amplatz Super Stiff™ 0.035 wire; Boston Scientific). In accordance with the manufacturer's recommendation, the BPD balloon was undersized by at least 3 mm to avoid damage to the prosthesis locking mechanism. The post-dilation balloon was filled with dilute contrast and expanded within the prosthetic valve under rapid ventricular pacing. Each case procedure is illustrated in **Figure 1**-**Figure 4**.

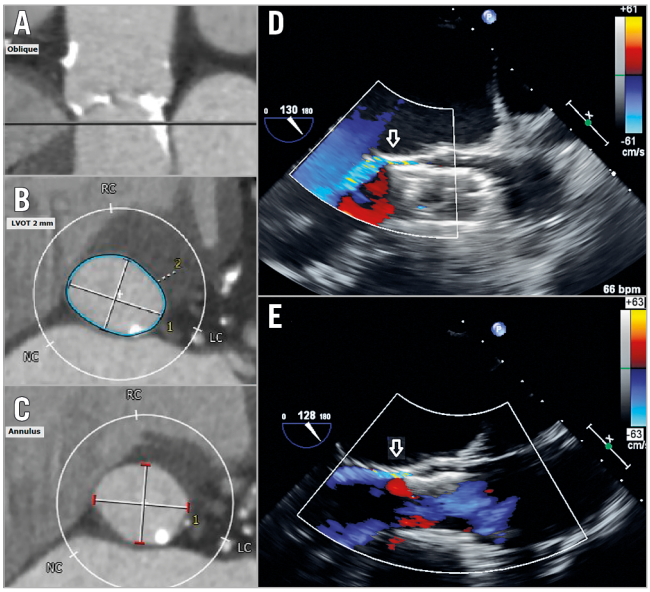

Figure 2. *Case 2. Transoesophageal imaging pre and post balloon post-dilation of the LOTUS valve. MDCT imaging demonstrates calcification of the native aortic valve, particularly at the site of the left coronary cusp (A-C). Transoesophageal echocardiogram shows moderate paravalvular AR immediately after LOTUS valve implantation, along the area of calcification, seen on long-axis view (D). The LOTUS valve was post-dilated with an 18×40 mm NuCLEUS-X™ balloon (B. Braun Interventional Systems, Bethlehem, PA, USA) with improvement in paravalvular AR to mild (E). Arrows indicate the paravalvular leak.*

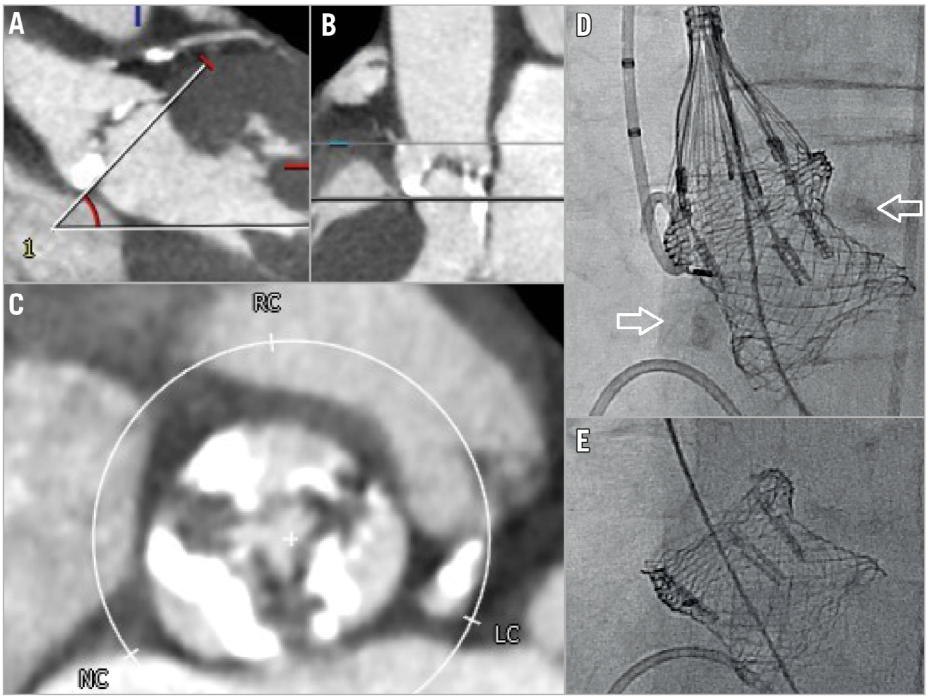

Figure 1. *Case 1. Severe native valve calcification with resultant device frame deformation and underexpansion. Severe native valve calcification is seen on MDCT and fluoroscopy (A-D). Following deployment of a 25 mm LOTUS valve system, deformation of the frame at the site of heavy calcification is seen (D, arrows). This patient underwent post-dilation with a 20×45 mm Cristal balloon (Balt Extrusion, Montmorency, France) with mildly improved frame expansion (E).*

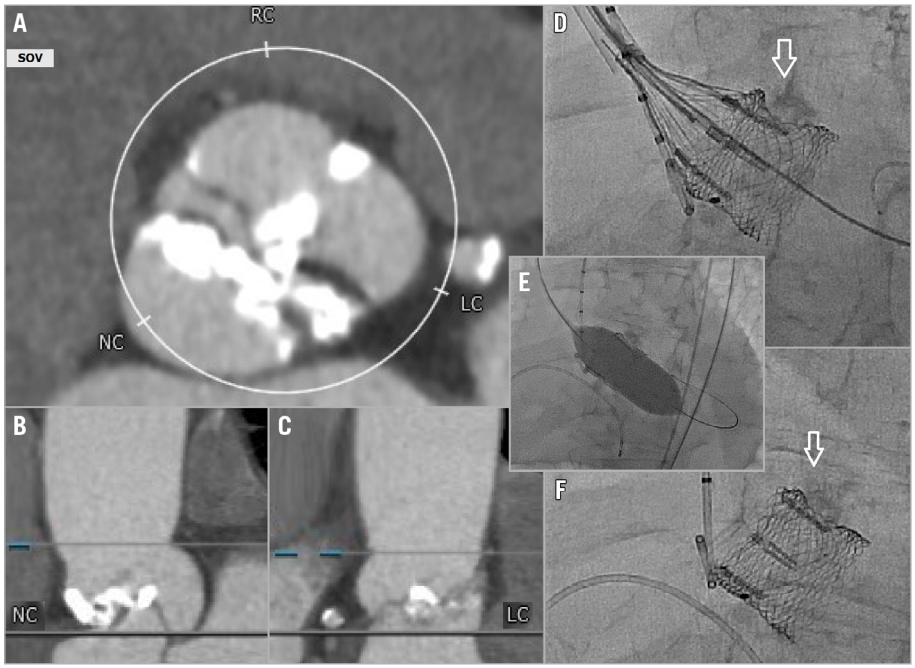

Figure 3. *Case 3. Severe native bicuspid valve calcification with resultant device frame deformation responding to BPD. Severe native valve calcification is seen on MDCT in a functionally bicuspid aortic valve (A-C). Following deployment of a 25 mm LOTUS valve system, deformation of the frame at the site of heavy calcification is seen (D, arrow) with mild-moderate paravalvular AR. This patient underwent post-dilation with a 23×40 mm Z-MED II-X™ balloon (B. Braun Interventional Systems) with improved frame expansion (E & F) but no reduction in severity of AR.*

There were no major procedural or in-hospital complications, including no annular rupture, strokes, myocardial infarction, major vascular or major bleeding events in the four patients who underwent BPD. No patients required new pacemaker implantation within 30 days. All four patients were alive at 30-day follow-up without any major cerebrovascular events. The echocardiographic outcomes are shown in **Table 3**.

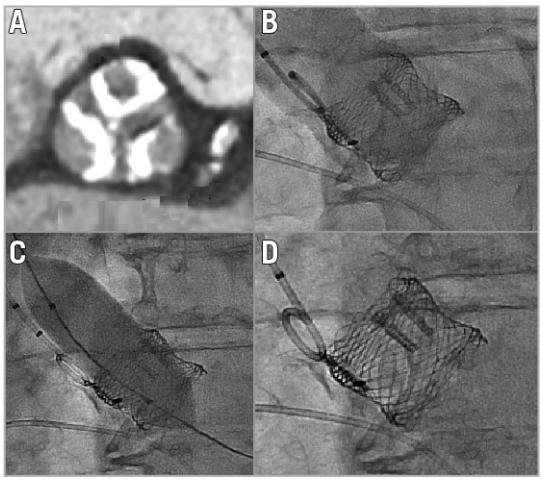

Figure 4. *Case 4. Severe native valvular calcification with deployment of a 25 mm LOTUS valve system (A & B). Following valve deployment, moderate paravalvular AR was seen on the aortogram. This patient underwent post-dilation with a 20×40 mm Z-MED II-X balloon under rapid ventricular pacing (C). Aortogram demonstrated AR improvement to mild with improvement in the AR index (D).*

Discussion

In the mechanically expanded LOTUS valve, use of BPD has typically been discouraged. This is due to the LOTUS valve's adaptive seal and fully repositionable nature, designed to minimise significant paravalvular AR[5]. As such, BPD has generally been reserved for cases of severe frame distortion with a high residual transprosthetic gradient.

Table 3. Echocardiographic results.

Echocardiogram	Case 1	Case 2	Case 3	Case 4
Pre-discharge				
Mean gradient (mmHg)	16	7	9	7
Aortic regurgitation	Trivial	Mild	Mild	Trivial-mild
Dimensionless index	0.40	0.59	0.36	0.55
LVEF	70	60	15	50
30-day				
Mean gradient (mmHg)	21	6	Not performed*	10
Aortic regurgitation	Trivial	Mild		Trivial-mild
Dimensionless index	0.48	0.55		0.49
LVEF	70	60		50

*Patient was re-admitted to another facility for an unrelated small bowel obstruction treated surgically with resultant missed 30-day echocardiographic follow-up. LVEF: left ventricular ejection fraction

This first case series describes BPD in four patients with mild-to-moderate or greater severity paravalvular AR immediately following LOTUS valve implantation. A reduction of paravalvular AR to mild or lesser severity was seen in three out of four patients. This success rate is similar to that seen following BPD within the Edwards SAPIEN or CoreValve, both prostheses that commonly require BPD to treat periprocedural AR[2,4]. Therefore, while BPD is rarely required following LOTUS valve implantation, it appears to be reasonably successful in the treatment of paravalvular AR.

In the current case series, two out of four patients undergoing BPD for significant AR had associated prosthesis frame underexpansion or deformation. This was related to the presence of significant native valve calcification. The successful use of BPD in this clinical scenario has been described in a single case study where underexpansion of the LOTUS valve was associated with a significant residual transaortic gradient[9]. In the current case series, BPD was utilised to treat frame deformation in two patients. This resulted in marked improvement of valve frame underexpansion in one patient and a mild improvement in the second patient **(Figure 1, Figure 3)**.

The presence of a heavily calcified aortic valve probably prevents complete sealing of the paravalvular space, and has been seen to predict paravalvular AR and the need for BPD[3,5,10]. The degree of valve calcification has also been seen to be the only independent predictor of BPD success[2]. In the current study, all patients requiring BPD had calcification of the native aortic valve. In addition, in the patient where BPD did not result in a reduction of periprocedural AR, severe valvular calcification was present.

Prosthesis-to-annulus undersizing is another factor associated with paravalvular leak and hence the need for BPD[4,11]. The LOTUS valve is sized according to the MDCT-derived annulus measurements, as well as consideration of the entire aortoventricular interface anatomy, degree of calcification and valve morphology. In cases 1, 2 and 4, the device to annulus ratio was 1:1 and the presence of severe prosthesis deformation and/or adequate waisting of the device supported adequate sizing. In these cases, upsizing the device was felt unlikely to result in improvement in AR while increasing the risk of annular injury; hence BPD was performed instead. In case 3 the presence of a bicuspid aortic valve resulted in the appearance of apparent device undersizing when basal plane dimensions were considered in isolation. However, as this was a bicuspid valve, further factors including the specific bicuspid morphology, intercommissural dimension and potential for supra-annular sealing were considered. While there are no specific sizing algorithms universally available for bicuspid valves, utilisation of a combination of these factors is widely accepted; however, it does result in apparent undersizing of the chosen prosthesis.

No studies have yet evaluated the safety of BPD following TAVR with the LOTUS valve. A safety concern with performing BPD is that further manipulation or expansion of the prosthesis in the annulus may be associated with higher rates of cerebral embolisation and new conduction abnormalities[2]. In our small case series, no cerebrovascular events or conduction abnormalities were observed following BPD. Another safety concern with BPD includes potential damage to the annulus or prosthesis leaflets, resulting in escalated deterioration of prosthetic valve function. In this small case series, we demonstrated no adverse impact of BPD on the prosthesis leaflets, with no deterioration of valve haemodynamics or occurrence of central AR at 30-day echocardiography. Due to the known increased mortality associated with residual AR[1], BPD could be considered in LOTUS valve recipients with significant residual AR.

Limitations

The main limitation of this study is the small patient number. Whilst patients were recruited from a high-volume TAVR centre, due to very low rates of paravalvular AR following LOTUS valve implantation, BPD was considered after valve repositioning in only a minority of patients. Further studies are required to evaluate the long-term efficacy and safety of BPD within the LOTUS valve. A further limitation is the use of aortography instead of TOE to assess periprocedural AR. However, routine use of conscious sedation for TAVR procedures with a resultant decline in TOE-guided TAVR probably reflects real-world practice.

Conclusions

This case series of four patients is the first to describe the technical feasibility of BPD for treatment of paravalvular AR and/or prosthesis frame underexpansion following implantation with the LOTUS valve system.

Impact on daily practice

Whilst BPD is rarely needed for the mechanically expanded LOTUS valve, this study demonstrates that it can be safely performed with acceptable success rates. In cases where repositioning or retrieval are not viable options, BPD allows an alternative management step to correct paravalvular AR or prosthesis frame deformation within the LOTUS valve.

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Conflict of interest statement

I. Meredith has received consultant fees and honoraria from Boston Scientific and Medtronic and proctor fees from Boston Scientific. R. Gooley has received proctor fees from Boston Scientific. The other authors have no conflicts of interest to declare.

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