International Journal of Cardiology 275 (2019) 65–69

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Transcatheter aortic valve implantation utilizing a non-occlusive balloon for predilatation☆

Yvonne Schneeberger [a,*,1], Andreas Schaefer [a,1], Niklas Schofer [b,1], Miriam Silaschi [c,1], Florian Deuschl [b,1], Stefan Blankenberg [b,1], Hermann Reichenspurner [a,1], Hendrik Treede [c,1], Ulrich Schäfer [b,1], Efstratios I. Charitos [c,1], Lenard Conradi [a,1]

[a] Department of Cardiovascular Surgery, University Heart Center Hamburg, Germany
[b] Department of General and Interventional Cardiology, University Heart Center Hamburg, Germany
[c] Department of Cardiac Surgery, University Hospital Halle (Saale), Germany

ARTICLE INFO

Article history:
Received 11 May 2018
Received in revised form 3 October 2018
Accepted 17 October 2018
Available online 18 October 2018

Keywords:
TAVI
Balloon valvuloplasty
Depressed left ventricular function
Aortic stenosis

ABSTRACT

Background: Balloon aortic valvuloplasty (BAV) is routinely performed preceding transcatheter aortic valve implantation (TAVI). Among risks inherent in BAV is low cardiac output due to rapid ventricular pacing (RVP), especially in patients with severely impaired left ventricular function. We herein report early experience utilizing a non-occlusive balloon for BAV (TrueFlow™, BARD, Peripheral Vascular, Tempe, AZ, US), which does not require RVP.

Methods: Between 11/2016 and 10/2017, 27 consecutive patients received TAVI using a non-occlusive balloon valvuloplasty catheter for predilatation and a self-expandable transcatheter heart valve (77.8% female, 81.7 ± 6.6 years, logEuroSCORE I 15.8 ± 10.3%, STS Prom Score 2.5 ± 0.5%). Hemodynamic measurements and acute outcome data were analyzed according to updated Valve Academic Research Consortium definitions.

Results: Procedure time, fluoroscopy time and amount of contrast agent were 74.5 ± 17.4 min, 16.7 ± 6.9 min and 156.9 ± 92.7 ml. Device success and early combined safety were 100% and 92.6% (25/27). Effective BAV without RVP after the first inflation was achieved in 92.6% of the patients (25/27). Continuous recording of hemodynamics documented no relevant systemic pressure drop during BAV. Postdilatation with a regular balloon was required in 10/27 patients. No death was observed during 30-day follow-up. Resultant mean transvalvular gradient was 6.0 ± 3.5 mm Hg. In one patient a moderate paravalvular leakage was seen.

Conclusions: In this series of TAVI utilizing a novel non-occlusive balloon, safety and efficacy were demonstrated. Adequate predilatation was achieved in all cases without need for RVP and with stable hemodynamics. These results will have to be confirmed in larger patient cohorts.

1. Introduction

Transcatheter aortic valve implantation (TAVI) is an established therapy for severe aortic valve stenosis (AS) in patients with an intermediate or high-risk profile for surgical aortic valve replacement [1–3] and has therefore been incorporated in international guidelines [4,5]. Commonly, balloon aortic valvuloplasty (BAV) is considered a mandatory prerequisite prior to transfemoral (TF) or transapical (TA)-TAVI in order to facilitate subsequent retrograde insertion of delivery catheter and crimped transcatheter heart valves (THV) into the native aortic annulus, to promote adequate apposition of the THV stent to the annulus with optimal stent expansion, prevent paravalvular leakage (PVL) and predict displacement of coronary leaflets during TAVI [6,7].

On the other hand, specific risks inherent in BAV have been described [8–10]. Besides cerebral ischemia due to distal embolization of calcific particles, aggravation of aortic regurgitation (AR) or conduction

Abbreviations: AS, Aortic valve stenosis; AVB, Atrioventricular block; BAV, Balloon aortic valvuloplasty; BE, Balloon-expandable; EOA, Effective orifice area; LV, Left ventricular; LVEF, Left ventricular ejection fraction; LVOT, Left ventricular outflow tract; MSCT, Multislice computed tomography; PPM, Permanent Pacemaker; PVL, Paravalvular leakage; RVP, Rapid ventricular pacing; SE, Self-expandable; TA, Transapical; TAVI, Transcatheter aortic valve implantation; TEE, Transesophageal echocardiography; TF, Transfemoral; THV, Transcatheter heart valve; TTE, Transthoracic echocardiography; VARC, Valve Academic Research Consortium.

☆ **Acknowledgement of grant support:** No grant support was received regarding this work.

* Corresponding author at: University Heart Center Hamburg, Martinistraße 52, D-20246 Hamburg, Germany.
E-mail address: y.schneeberger@uke.de (Y. Schneeberger).

[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

https://doi.org/10.1016/j.ijcard.2018.10.059
0167-5273/

disturbances, low cardiac output as consequence of rapid ventricular pacing (RVP) during BAV is of particular interest. Especially in patients with an impaired left ventricular (LV) function, microcirculatory arrest during BAV with RVP has the potential to further deteriorate LV function [11]. For most THV types, implantation series without the utilization of BAV are described today [12–14]. Furthermore, next generation self-expandable (SE) devices are implantable without the use of RVP, which theoretically allows TAVI procedures with complete absence of RVP [15,16]. To date BAV is only feasible under RVP, therefore a trade-off between advantages of BAV against possible drawbacks of BAV and RVP has to be conducted for patients undergoing TAVI procedures.

We herein report first experience with the TrueFlow™ balloon valvuloplasty catheter (Bard Peripheral Vascular Inc., Tempe, AZ, US), which allows BAV in absence of RVP. This potentially combines the advantages of balloon-predilatation with the absence of RVP during TAVI. The system consists of a palisade-like balloon structure including eight individual balloon chambers and a central culvert with an open inner lumen encapsulated in a fiber-based non-compliant shell providing continuous blood flow during every step of inflation. When utilizing the described device for BAV, the LV is capable of ejecting blood into the ascending aorta due to the low hemodynamic resistance during BAV, and therefore RVP is unnecessary. The balloon is of 3.5 cm in length and available in 5 sizes covering an annulus range between 18 and 26 mm with a sheath size range of 11 Fr. to 16 Fr.

2. Methods

2.1. Patients

Between 11/2016 and 10/2017 a consecutive series of 27 patients received TF- or TA-TAVI with preceding BAV utilizing the TrueFlow™ balloon valvuloplasty catheter for treatment of severe symptomatic calcified AS as determined by transthoracic (TTE) and transesophageal echocardiography (TEE). Allocation of patients to TAVI followed current international recommendations [4] after consensus of the local dedicated heart team at two heart centers. Informed consent was obtained from each patient.

2.2. Diagnostic work-up and study procedure

The preprocedural diagnostic work-up followed institutional standards and was described before [17]: by routine, all patients received preoperative TTE and TEE. Furthermore, diagnostic work-up included contrast-enhanced, electrocardiogram-gated multislice computed tomography (MSCT). Datasets were analyzed using the 3mensio Medical Imaging Software (3mensio, Medical Imaging, Bilthoven, Netherlands).

In all patients the Acurate neo (Boston Scientific Corporation, Marlborough, MS, US) THV was implanted. Both, TF and TA implantation procedures were already characterized in detail [18]. Procedures were generally performed under analgosedation (TA cases in general anesthesia), in a specially equipped hybrid operating suite by a dedicated team of cardiologists, cardiac surgeons and anesthesiologists.

To prove hemodynamic efficacy of this non-occlusive balloon for BAV in all procedures invasive hemodynamic measurements were performed. This included determination of pre- and post-implantation systolic/diastolic LV pressures, systolic/mean/diastolic aortic pressures as well as peak to peak and mean pressure gradients (LV to ascending aorta). Furthermore, in the first ten patients, additional similar measurements were performed post-BAV. Moreover, final THV function was assessed by aortic root angiography and TTE.

2.3. MSCT analysis

Analysis of MSCT was described before [19]. In brief the aortic annulus was defined as the virtual basal plane containing the basal attachment of the three aortic cusps. Asymmetry of calcium distribution was calculated as maximum absolute difference in calcium volume between leaflet sectors for both aortic valve complex and left ventricular outflow tract (LVOT).

Calcium quantification was performed utilizing an automated volume-scoring tool with an empiric threshold of 500 Hounsfield units. Two regions were evaluated for calcium load: the aortic valve complex including the basal plane to coronary ostia (zone 1) and the LVOT including the subannular region from 10 mm inferior to basal plane (zone 2). Calcium distribution within the aortic valve and the LVOT was sectioned according to left-, right-, and non-coronary cusps. To mitigate interobserver variability, all MSCT were analyzed by one investigator.

2.4. Statistics

Baseline, intraprocedural and acute follow-up data up to 30 days were prospectively collected and entered into a standardized database and retrospectively analyzed. Clinical endpoints were adjudicated in accordance with the updated standardized VARC-2 definitions [20]. Data are presented as absolute numbers and percentages for categorical variables and mean values and standard deviation for continuous variables unless stated otherwise. Dichotomous variables were compared by Fisher's exact test and continuous variables by *t*-tests. *p*-Values were reported without correction for multiple testing. A level of significance was set to two-tailed $p < 0.05$.

3. Results

3.1. Baseline demographics

A total of 27 consecutive patients eligible for Acurate neo THV implantation received TF- (n = 26) or TA- (n = 1) TAVI using the non-occlusive balloon valvuloplasty catheter for predilatation (77.8% female, 81.7 ± 6.6 years, logEuroSCORE I 15.8 ± 10.3%, logEuroSCORE II 5.7 ± 2.8%, STS Prom Score 2.5 ± 0.5%). Preinterventional evaluation presented a highly symptomatic patient cohort (NYHA ≥III: 23/27, 85.2%) with comorbidities including a high proportion of coronary artery disease (17/27, 70.4%) and previous percutaneous coronary intervention (12/27, 44.4%). Detailed patient demographics are summarized in Table 1.

Table 1
Baseline demographics and preprocedural MSCT imaging[e].

	True-Flow™ (n = 27)
Age, years	81.7 ± 6.6
Female gender, % (n)	77.8 (21)
BMI, kg/m^2	28.4 ± 8
logEuroSCORE I (%)	15.8 ± 10.3
logEuroSCORE II (%)	5.7 ± 2.8
STS PROM Score (%)	2.5 ± 0.5
Diabetes mellitus, % (n)	59.3 (16)
Arterial hypertension, % (n)	96.3 (26)
Left ventricular ejection fraction (%)	55.4 ± 9.3
Stroke, % (n)	3.7 (1)
Coronary artery disease, % (n)	70.4 (19)
Previous cardiac surgery, % (n)	7.4 (2)
Previous PCI, % (n)	44.4 (12)
Extracardiac atheropathy[f], % (n)	7.4 (2)
Arrhythmia, % (n)	25.9 (7)
Pacemaker, % (n)	3.7 (1)
COPD >Gold II[f], % (n)	14.8 (4)
Pulmonary hypertension >60 mm Hg[f], % (n)	3.7 (1)
Creatinine, mg/dl	1.6 ± 1.5
Dialysis, % (n)	7.4 (2)
NYHA ≥III, % (n)	85.2 (23)
Calcium load zone 1[a], mm^3	
Right-coronary cusp	170.9 ± 139.6
Left-coronary cusp	146.9 ± 132.9
Non-coronary cusp	359.1 ± 284.5
Total calcium load Zone 1	676.7 ± 453.6
Calcium load zone 2[b], mm^3	
Right-coronary cusp^{LVOT}	9.1 ± 26.9
Left-coronary cusp^{LVOT}	14.9 ± 32.9
Non-coronary cusp^{LVOT}	11.1 ± 24.2
Total calcium load zone 2	34.9 ± 80.1
Asymmetry calcium load[c], mm^3	
Zone 1 asymmetry	261.5 ± 260.7
Zone 2 asymmetry	20.3 ± 21.2
Annulus diameter, mm	24.1 ± 1.1
Eccentricity Index[d]	0.22 ± 0.06
Cover index[&]	3.2 ± 4.5

BMI Body mass index; logEuroSCORE logistic European System for Cardiac Operative Risk Evaluation, STS-PROM Society of Thoracic Surgeons Predicted Risk of Mortality; PCI percutaneous coronary intervention; COPD chronic obstructive pulmonary disease, NYHA New York Heart Association; MSCT multi-slice computed tomography; LVOT left ventricular outflow tract; RCA right coronary artery; LCA left coronary artery.

[a] From AA to coronary ostia.

[b] subannular, from AA 10 mm in left ventricular outflow tract.

[c] Calculated by maximum absolute difference in calcium volume between leaflet sectors for aortic valve complex/LVOT.

[d] Calculated by 1 − (minimum diameter / maximum diameter), & ([nominal THV diameter − measured diameter] / nominal THV diameter) * 100.

[e] Threshold 500–600 HU.

[f] Extracardiac atheropathy, COPD and pulmonary hypertension according to EuroSCORE definitions.

3.2. Preprocedural MSCT imaging

The study group showed the following calcium loads of both predefined zones of the aortic annulus: zone 1 (aortic annulus to coronary ostia) showed a mean total calcium load of 676.7 ± 453.6 mm^3 and zone 2 (subannular from AA 10 mm in LVOT) a mean total calcium load of 34.9 ± 80.1 mm^3. Mean asymmetry values were 261.5 ± 260.7 mm^3 for zone 1 and 20.3 ± 21.2 mm^3 for zone 2, indicating inhomogeneous calcium distribution patterns. Regarding cover index (3.2 ± 4.5) and eccentricity (0.22 ± 0.06) no outliers were found. Detailed MSCT data are summarized in Table 1.

3.3. Periprocedural data

Procedure, fluoroscopy times and contrast agent used were 74.5 ± 17.4 min, 16.7 ± 6.9 min and 156.9 ± 92.7 ml. The majority of patients were treated via TF approach (26/27, 96.3%), in 25/27 patients (92.6%) conscious sedation was utilized. All patients received balloon predilatation and were subsequently implanted with a Symetis valve. In 2 patients balloon migration necessitated a second inflation, in 4 patients minor balloon movement was noted. In 10/27 patients (37.0%) postdilatation with a regular balloon subsequent to THV implantation was performed due to residual significant PVL. In one patient (3.7%) a

Table 2
Periprocedural data, clinical outcome and echocardiographic results at discharge and hemodynamic measurements pre- and post-dilatation.

	True-Flow™ (n = 27)
Periprocedural data	
Baseline EOA, cm^2	0.8 ± 0.1
Baseline peak gradient, mm Hg	55.7 ± 17.8
Baseline mean gradient, mm Hg	32.3 ± 10.7
Procedure time, min	74.5 ± 17.4
Fluoroscopy time, min	16.7 ± 6.9
Contrast agent, ml	156.9 ± 92.7
Access, % (n)	
Transfemoral	96.3 (26)
Transapical	3.7 (1)
Valve size (Acurate neo), % (n)	100 (27)
S	14.8 (4)
M	63.0 (17)
L	22.2 (6)
Predilatation, % (n)	100 (27)
Postdilatation, % (n)	37.0 (10)
Cerebral protection, % (n)	3.7 (1)
Anesthesia, % (n)	
General anesthesia	7.4 (2)
Conscious sedation	92.6 (25)
Clinical outcome and echocardiographic results at discharge	
All-cause mortality (30 days), % (n)	0 (0)
Cardiovascular or unknown, % (n)	0 (0)
Stroke (disabling), % (n)	0 (0)
Myocardial infarction, % (n)	3.7 (1)
Bleeding (major/life threatening), % (n)	0 (0)
Access site complications (major), % (n)	3.7 (1)
Acute kidney injury (AKIN 2, 3)*, % (n)	3.7 (1)
Pacemaker implantation, % (n)	7.4 (2)
Device success†, % (n)	100 (27)
Early safety‡, % (n)	92.6 (25)
EOA§, cm^2	2.1 ± 0.2
Peak/mean gradient∂, mm Hg	11.3 ± 6.0/6.0 ± 3.5
Paravalvular leakage∂, % (n)	
None/trace	66.7 (18)
Mild	33.3 (9)
≥Moderate	3.7 (1)
Transvalvular leakage∂, % (n)	0 (0)
Intensive care unit stay, days	3.9 ± 5.1
Hospital stay, days	11.3 ± 9.7

Hemodynamic measurements pre- and post-dilatation	Pre-BAV (n = 27)	Post-BAV* (n = 10)	THV implantation (n = 27)
Left ventricle, mm Hg			
Systolic	156.5 ± 29.6	157.3 ± 23.7	129.3 ± 31.9
Diastolic	21.5 ± 37.3	15.2 ± 35.8	14.6 ± 5.7
Ascending aorta, mm Hg			
Systolic	120.0 ± 33.0	156.8 ± 45.3	116.1 ± 55.4
Diastolic	54.8 ± 14.9	15.8 ± 12.6	47.4 ± 9.9
Mean	77.4 ± 15.4	128.2 ± 20.3	65.7 ± 40.6
Peak to peak gradient, mm Hg	40.5 ± 19.1	22.1 ± 15.3	3.3 ± 2.7
Mean gradient, mm Hg	38.8 ± 15.8	24.9 ± 17.3	8.6 ± 4.2
Heart rate, bpm	69.6 ± 13.6	76.2 ± 13.4	72.0 ± 12.7

EOA Effective orifice area, BAV balloon aortic valvuloplasty; THV transcatheter heart valve; syst. Systolic; diast. diastolic; bpm beats per minute; *post-BAV invasive measurements performed in first ten patients to proof hemodynamic efficacy, *AKIN Acute Kidney Injury Network; VARC-2 definitions: †device success: absence of procedural mortality, correct positioning of a single prosthetic heart valve into the proper anatomical position, intended performance of the prosthetic heart valve (no prosthesis-patient mismatch and mean aortic valve gradient <20 mm Hg or peak velocity < 3 m/s and no moderate or severe prosthetic valve regurgitation). ‡early safety at 30 days: all-cause mortality (at 30 days), all stroke (disabling and non-disabling), life-threatening bleeding, acute kidney injury stage 2 or 3 (including renal replacement therapy), coronary artery obstruction requiring intervention, major vascular complication, valve-related dysfunction requiring repeat procedure (BAV, TAVI, or SAVR); §intraprocedural TEE; ∂TTE at discharge.

cerebral protection device (Claret Sentinel, Claret Medical, Santa Rosa, CA, US) was used. Detailed periprocedural data are summarized in Table 2.

3.4. Intraprocedural invasive hemodynamic measurements

Invasive baseline hemodynamics confirmed severe AS with a peak to peak pressure gradient of 40.5 ± 19.1 mm Hg and a mean pressure gradient of 38.8 ± 15.8 mm Hg. Subsequent to BAV no relevant pressure drop of the LV was detected with simultaneous increase of aortic systolic and mean pressure. Furthermore, pressure gradients decreased to 22.1 ± 15.3 mm Hg (peak to peak, $p = 0.009$ for comparison with baseline value) and 24.9 ± 17.3 mm Hg (mean, $p = 0.03$ for comparison with baseline value). After TAVI, further decrease of transvalvular pressure gradients and increase of aortic pressure was documented. Detailed invasive measurements are shown in Table 2. Hemodynamic course is depicted in Fig. 1.

3.5. Echocardiographic outcome data

TTE prior to discharge showed decrease of peak and mean transvalvular gradients from 55.7 ± 17.8 to 11.3 ± 6.0 mm Hg and 32.3 ± 10.7 to 6.0 ± 3.5 mm Hg (both $p < 0.01$). Effective orifice area (EOA) increased from 0.8 ± 0.1 to 2.1 ± 0.2 cm^2 ($p < 0.01$). Postinterventionally, moderate PVL was found in one patient (3.7%). In 9/27 patients (33.3%) mild PVL was documented. No transvalvular leakage was found during 30-day follow-up. Echocardiographic parameters are documented in Table 2.

3.6. Clinical outcome data

All-cause 30-day mortality or disabling stroke occurred in 0% (0/27) of the patients. In one patient (3.7%) myocardial infarction became apparent due to dissection of the left anterior descending with unclear pathological mechanism. Acute kidney injury (AKIN 2) and major access site complications occurred in one patient (3.7%) respectively. Postprocedural PPM implantation due to atrioventricular blockade (AVB) was indicated in 7.4% of the patients (2/27).

Device success according to VARC-2 definitions was achieved in all cases (27/27, 100%). Early safety was reached in 92.6% of the cases (25/27). Failure to obtain this composite endpoint was due to periprocedural myocardial infarction in one patient and due to acute renal failure necessitating renal replacement therapy in another. Intensive care unit and hospital stay were 3.9 ± 5.1 and 11.3 ± 9.7 days, respectively. Detailed clinical outcome data are summarized in Table 2.

4. Discussion

4.1. Main findings

Main findings of the study are (I) TAVI with predilatation utilizing a non-occlusive balloon without concomitant RVP is feasible and safe, (II) despite high calcium loads of aortic valves treated with SE-THV in this series, adequate hemodynamic results were obtained post-BAV as well as after THV deployment, (III) although in few cases balloon migration occurred during BAV, no increase in procedure time or amount of contrast agent was seen and (IV) clinical outcomes in this small patient series were excellent with achievement of device success in all cases.

Since BAV is considered to carry certain risks, by now series of TAVI without the utilization of predilatation are reported for almost all latest generation devices [21,22]. Nevertheless, omission of BAV is not recommendable in all cases: especially patients with bulky calcium formations of the aortic annulus, bicuspid aortic valves or unclear valve size, highly benefit from BAV since subsequent insertion of the delivery catheter and the THV are more likely to succeed and THV size can be determined. Also, in patients with horizontal aorta BAV should be taken into consideration [23,24]. When BAV is considered necessary due to anatomical reasons, it may be poorly tolerated by patients with systolic dysfunction or pulmonary hypertension. Frequently, this observation is attributed to RVP. This hemodynamic deterioration potentially results in cerebral, renal and myocardial malperfusion, further impairing left ventricular function [11,25].

This non-occlusive balloon system for BAV without use of RVP, may overcome some of the aforementioned potential risks. Nevertheless, invasive hemodynamic measurements indicated adequate and effective BAV with a statistical significant drop of peak-to-peak and mean pressure gradients despite relatively high calcium loads of both the annular and sub-annular aortic valve zones. Furthermore, left ventricular and aortic systolic pressures remained stable subsequent to predilatation, suggesting hemodynamic stability during BAV. Efficacy of BAV using this novel type of predilatation balloon was further substantiated by adequate hemodynamic outcomes after THV insertion with low postprocedural transvalvular pressure gradients and only one case of moderate PVL.

By combining this novel balloon with a latest-generation SE-THV, like the herein used Acurate neo THV, TAVI procedures with complete absence of RVP are possible, especially when post-dilatation is not necessary. Additional administration of conscious sedation has the potential to perform TAVI with minimal interference with hemodynamics during the procedure, as performed in the majority of the cases in this series. It is likely that patients with reduced systolic function and/or pulmonary hypertension may benefit from this strategy. Therefore, patients with an aortic valve anatomy suggesting application of aortic

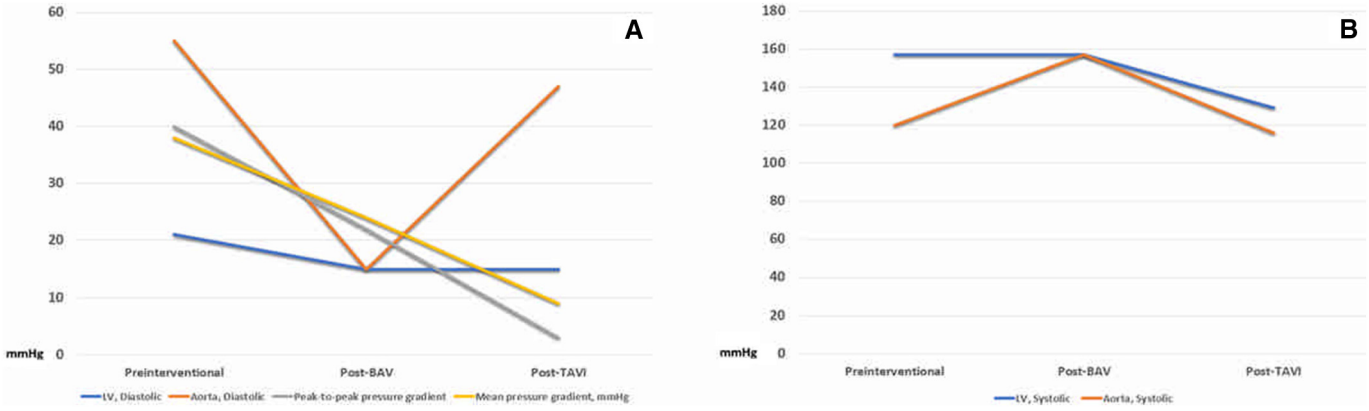

Fig. 1. Invasive measurements of hemodynamic course during TAVI utilizing a non-occlusive balloon for BAV. Diastolic LV, aortal pressure and peak-to-peak/mean pressure gradients are shown preinterventional, post-BAV and post-THV deployment (A), same course is shown for systolic LV and aortal pressure (B). TAVI transcatheter aortic valve implantation; BAV balloon aortic valvuloplasty; LV left ventricle; THV transcatheter heart valve.

valve dilatation prior to TAVI and impaired LV function are most likely to benefit from this novel balloon system. These findings have to be confirmed in larger patient cohorts and especially by comparison of patients with and without reduced systolic LV function.

4.2. Study limitations

Due to the retrospective nature of the herein conducted study, limitations are inherent in the two-center study design with limited patient numbers: patients were not randomized to a specific treatment, therefore patient preselection with hidden confounders may apply.

5. Conclusions

In this series of TAVI utilizing a non-occlusive balloon, safety and efficacy were demonstrated. Adequate predilatation was achieved in all cases without the need of RVP and with stable hemodynamics. Only one moderate PVL was observed. In ten patients post-dilatation was necessary. These results will have to be confirmed in larger patient cohorts.

Conflict of interest

LC is proctor for Boston Scientific; US is a consultant and proctor for Symetis SA, has received travel support and speakers honoraria, as well as grant support; AS has received travel support from Symetis SA. All other authors have nothing to disclose.

Acknowledgements

N/A.

References

[1] C.R. Smith, M.B. Leon, M.J. Mack, et al., Transcatheter versus surgical aortic-valve replacement in high-risk patients, N. Engl. J. Med. 364 (2011) 2187–2198.
[2] M.J. Reardon, N.M. Van Mieghem, J.J. Popma, et al., Surgical or transcatheter aortic-valve replacement in intermediate-risk patients, N. Engl. J. Med. 376 (2017) 1321–1331.
[3] M.B. Leon, C.R. Smith, M.J. Mack, et al., Transcatheter or surgical aortic-valve replacement in intermediate-risk patients, N. Engl. J. Med. 374 (2016) 1609–1620.
[4] H. Baumgartner, V. Falk, J.J. Bax, et al., ESC Scientific Document Group, 2017 ESC/EACTS guidelines for the management of valvular heart disease, Eur. Heart J. 38 (36) (2017 Sep 21) 2739–2791.
[5] R.A. Nishimura, C.M. Otto, R.O. Bonow, et al., 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, J. Am. Coll. Cardiol. 70 (2) (2017) 252–289.
[6] A. Vahanian, D. Himbert, Transcatheter aortic valve implantation: could it be done without prior balloon valvuloplasty? J. Am. Coll. Cardiol. Intv. 4 (2011) 758–759.
[7] P.C. Patsalis, F. Al-Rashid, T. Neumann, et al., Preparatory balloon aortic valvuloplasty during transcatheter aortic valve implantation for improved valve sizing, J. Am. Coll. Cardiol. Intv. 6 (2013) 965–971.
[8] I. Ben-Dor, A.D. Pichard, L.F. Satler, et al., Complications and outcome of balloon aortic valvuloplasty in high-risk or inoperable patients, J. Am. Coll. Cardiol. Intv. 3 (2010) 1150–1156.
[9] C.M. Tissot, D. Attias, D. Himbert, et al., Reappraisal of percutaneous aortic balloon valvuloplasty as a preliminary treatment strategy in the transcatheter aortic valve implantation era, EuroIntervention 7 (2011) 49–56.
[10] P. Kahlert, F. Al-Rashid, P. Döttger, et al., Cerebral embolization during transcatheter aortic valve implantation: a transcranial Doppler study, Circulation 126 (2011) 1245–1255.
[11] A. Selle, H.R. Figulla, M. Ferrari, et al., Impact of rapid ventricular pacing during TAVI on microvascular tissue perfusion, Clin. Res. Cardiol. 103 (11) (2014 Nov) 902–911.
[12] A. Schaefer, E. Harmel, M. Seiffert, et al., First experience with transfemoral transcatheter aortic valve implantation without prior balloon pre-dilatation using a latest generation repositionable and retrievable transcatheter heart valve, Interact. Cardiovasc. Thorac. Surg. 24 (5) (2017 May 1) 659–662.
[13] L. Conradi, A. Schaefer, M. Seiffert, et al., Transfemoral TAVI without pre-dilatation using balloon-expandable devices: a case-matched analysis, Clin. Res. Cardiol. 104 (9) (2015 Sep) 735–742.
[14] G.P. Martin, M. Sperrin, R. Bagur, et al., Pre-implantation balloon aortic valvuloplasty and clinical outcomes following transcatheter aortic valve implantation: a propensity score analysis of the UK registry, J. Am. Heart Assoc. 6 (2) (2017 Feb 18).
[15] H. Möllmann, C. Hengstenberg, M. Hilker, et al., Real-world experience using the ACURATE neo prosthesis: 30-day outcomes of 1,000 patients enrolled in the SAVI TF registry, EuroIntervention 13 (15) (2018 Feb 2) e1764–e1770.
[16] H. Möllmann, A. Linke, D.M. Holzhey, et al., Implantation and 30-day follow-up on all 4 valve sizes within the portico transcatheter aortic bioprosthetic family, J. Am. Coll. Cardiol. Intv. 10 (15) (2017 Aug 14) 1538–1547.
[17] A. Schaefer, M. Linder, H. Treede, et al., Applicability of next generation balloon-expandable transcatheter heart valves in aortic annuli exceeding formally approved dimensions, Clin. Res. Cardiol. 105 (7) (2016 Jul) 585–591.
[18] U. Schäfer, L. Conradi, P. Diemert, et al., Symetis ACURATE TAVI: review of the technology, developments and current data with this self-expanding transcatheter heart valve, Minerva Cardioangiol. 63 (5) (2015 Oct) 359–369.
[19] M. Seiffert, B. Fujita, M. Avanesov, et al., Device landing zone calcification and its impact on residual regurgitation after transcatheter aortic valve implantation with different devices, Eur. Heart J. Cardiovasc. Imaging 17 (5) (2016 May) 576–584.
[20] A.P. Kappetein, S.J. Head, P. Généreux, et al., Valve Academic Research Consortium-2, Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document, J. Thorac. Cardiovasc. Surg. 145 (1) (2013 Jan) 6–23.
[21] W.K. Kim, F. Praz, J. Blumenstein, et al., Transfemoral aortic valve implantation of Edwards SAPIEN 3 without predilatation, Catheter. Cardiovasc. Interv. 89 (1) (2017 Jan) E38–E43.
[22] S. Noble, S. Stortecky, D. Heg, et al., Comparison of procedural and clinical outcomes with Evolut R versus Medtronic CoreValve: a Swiss TAVI registry analysis, EuroIntervention 12 (18) (2017 Apr 7) e2170–e2176.
[23] P.H. Chan, C.D. Mario, N. Moat, Transcatheter aortic valve implantation without balloon predilatation: not always feasible, Catheter. Cardiovasc. Interv. 82 (2) (2013 Aug 1) 328–332.
[24] M. Spaziano, F. Sawaya, B. Chevalier, et al., Comparison of systematic predilation, selective predilation, and direct transcatheter aortic valve implantation with the SAPIEN S3 valve, Can J Cardiol. 33 (2) (2017 Feb) 260–268.
[25] R. Bagur, C.S. Kwok, L. Nombela-Franco, et al., Transcatheter aortic valve implantation with or without preimplantation balloon aortic valvuloplasty: a systematic review and meta-analysis, J. Am. Heart Assoc. 5 (6) (2016 Jun 13).