Transcatheter aortic valve implantation for bicuspid aortic valve stenosis: Acute and intermediate-term outcomes in a high volume institution

Transkatetrska vstavitev aortne zaklopke pri bolnikih s stenozo bikuspidne aortne zaklopke: kratko- in srednjeročni rezultati v ustanovi z velikim obratom bolnikov

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Izvleček

Izhodišče: Prikazujemo rezultate naše skupine bolnikov z bikuspidno aortno (BAV) stenozo, ki smo jim perkutano vstavili umetno aortno zaklopko.

Metode: Retrospektivno smo analizirali perioperativne podatke in podatke s kontrolnih pregledov. Vsi bolniki so bili zdravljeni z metodo transkatetrske vstavitve aortne zaklopke (*angl.* transcatheter aortic valve implantation, TAVI) v centru z velikim številom posegov.

Rezultati: 33 bolnikov z bikuspidno aortno zaklopko (55–87 let) smo zdravili z metodo transkatetrske zamenjave aortne zaklopke. Srednji logistični EuroSCORE (*angl.* European System for Cardiac Operative Risk Evaluation) je bil 23,2 ± 19,3. Večini pacientov smo vstavili zaklopko Edwards Sapien® s transapikalnim pristopom (87,9 %). 9 bolnikom (27,3 %) smo morali dodatno balonsko razširiti zaklopko zaradi zmerne do hude paravalvularne regurgitacije, 3 bolnikom (9 %) smo morali vstaviti drugo zaklopko zaradi vztrajajoče hude paravalvularne regurgitacije, 2 bolnika (6 %) pa smo morali nato še klasično operirati s pristopom preko mediane sternotomije. Po posegu je bila blaga aortna regurgitacija prisotna pri 12 bolnikih (36,4%), zmerna AR pri 3 %, regurgitacije večje kot stopnja 2, pa nismo zabeležili. Uspešnost delovanja aortne zaklopke po perkutani metodi smo glede na merilo VARC (*angl.* Valve Academic Research Consortium) ocenili na 82 %. Med bolniki z in bolniki brez paravalvularne regurgitacije po posegu ni bilo pomembnih razlik v anatomiji BAV, razporeditvi kalcija in velikosti ter tipu vgrajene umetne zaklopke. 30-dnevno preživetje je bilo 100 %, 2-letno pa 70 % (CI: 52.7–93.1), kar je podobno pri bolnikih s paravalvularno regurgitacijo po posegu ali brez nje.

Zaključki: Transkatetrska zamenjava aortne zaklopke je izvedljiva pri bolnikih s stenozo bikuspidne aortne zaklopke. Tudi v izkušenih centrih je tehnično zahteven poseg povezan z večjim številom dodatnih balonskih dilatacij, vstavitvijo dodatne druge zaklopke ali potrebo po klasični kardiokirurški operaciji. Zanimivo bo videti, ali bodo rezultati podobni tudi pri novejši drugi generaciji perkutanih aortnih zaklopk.

Abstract

Background: We report our experience with transcatheter aortic valve implantation (TAVI) in patients with bicuspid aortic valve (BAV) stenosis.

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Methods: Perioperative and intermediate-term follow-up data were retrospectively analysed. All procedures were performed within the premises of an experienced high-volume TAVI centre.

Results: Thirty-three consecutive BAV patients (age 55 to 87 years) underwent TAVI. Mean logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) was 23,2 ± 19,3. Transapical Edwards Sapien® valve was implanted in the majority of patients (87.9 %). Nine patients (27.3 %) required post-ballooning of the implanted valve for moderate to severe paravalvular leak, 3 patients (9 %) required a second valve implantation for persistent severe paravalvular leak, and 2 (6 %) required conversion to conventional surgery. Post-operative mild aortic regurgitation (AR) was presented in 12 patients (36.4%) and AR = 2 in 3 %. No AR > 2 was observed. The device success rate according to the valve academic research consortium (VARC) criteria was 82 %. Similar BAV anatomy, calcium distribution, type and size of implanted valve were noticed in patients with and without residual AR. There was no thirty-day mortality. Two-year estimated survival was 70 % (CI: 52.7–93.1) and was similar in patients with and without post-procedural residual paravalvular leak.

Conclusions: TAVI in BAV stenosis is feasible but, even in experienced centres, is technically more challenging and is associated with a higher rate of post-dilatation, re-valving, and conversion to conventional surgery. Results should be re-tested in light of the recent introduction of second-generation TAVI prostheses.

1. Introduction

Bicuspid aortic valve (BAV) has been considered a relative contraindication for transcatheter aortic valve implantation (TAVI) mainly because of the theoretical risk for uneven and incomplete prosthesis expansion and wall apposition, resulting from calcium asymmetric distribution in the annulus, commissures, and aortic valve leaflets, which will eventually lead to consequent increased rate of prosthesis malfunction and paravalvular regurgitation.

Although there are reports describing the feasibility of TAVI in patients with BAV, experience remains restricted, often referred to multicentre cohorts, and with limited mid-term follow-up information (1-8). We present our experience focusing on preoperative BAV anatomical data, perioperative findings, and intermediate-term clinical results.

2. Methods

Perioperative and intermediate-term follow-up data of all patients with BAV treated consecutively with TAVI from May 2008 to April 2014 at the Deutsches Herzzentrum Berlin, Berlin, Germany, were retrospectively analysed. Type of BAV, annular geometry, calcium distribution, and calcium amount were all recorded. All patients had signed consent to the procedure and to the processing of their data for medical and scientific purposes.

2.1 BAV Classification

Aortic valves were classified as bicuspid according to preoperative multislice computed tomography and transoesophageal echocardiography and were arranged in 3 groups (9). Fusion of two of the three aortic leaflets was observed in all patients. If the fusion occurred between the right and the left coronary cusps, the BAV was classified as type 1. Similarly, type 2 BAV included fusion of the right- and non-coronary leaflets, whereas fusion of the left- and non-coronary cusps was classified as type 3 BAV. Moreover, the presence or absence of a raphe was marked with a "+" or a "-" , respectively (placed next to the valve type).

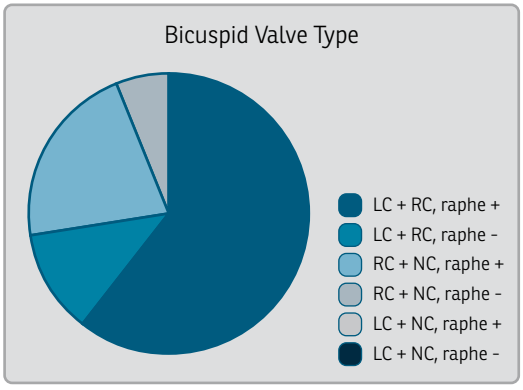


Figure 1: Percentage of different BAV morphological types as observed in our patient group.

2.2 Geometrical Annular Data

Geometrical annular information was analysed using multi-slice cardiac computed tomography. Measures included: aortic valve (AV) annulus at the insertion of the aortic cusps (perimeter derived diameter, major and minor axis), native AV area, LVOT, aortic root, sinotubular junction and ascending aorta maximal diameters. The annular ellipticity index (EI) was calculated as the ratio between the semi-minor and the semi-major aortic annulus axis (EI = b/a, where a is semi-major and b is semi-minor axis). We also calculated linear and numeric eccentricity, as previously described by our group (10).

2.3. Aortic Unit Calcification

Information about calcification score were obtained from multi-slice computed tomography and expressed as the AV and LVOT calcified volumes. Moreover, the calcification area and distribution on each of the cusps was also evaluated. Measurements were performed automatically using the dedicated planning workflow from the software 3mensio Valves® (Pie Medical Imaging BV, Maastricht, the Netherlands).

2.4 Implantation Technique

Two different prostheses were implanted: transapical Edwards SAPIEN® valve (Edwards Lifesciences, Inc., Irvine, California) and transfemoral Medtronic CoreValve® (Medtronic, Inc., Minneapolis, Minnesota). All procedures were performed under general anaesthesia and following previously described and established protocols (11-13). Rules for prostheses sizing did not differ from those normally applied for TAVI in tricuspid AV stenosis (14).

2.5 Perioperative and Follow-up Evaluation

Perioperative results were collected and procedural success/complications were classified following the Valve Academic Research Consortium (VARC) recommendations. Intraoperative trans-oesaphageal and pre-discharge trans-thoracic echocardiography were performed. Paravalvular and valvular regurgitation was calculated and classified as mild (I), moderate (II), and severe (III) according to semiquantitative and quantitative parameters (15).

Trans-prosthetic gradients were calculated together with indexed effective orifice areas (EOAi) and eventual patient prosthesis mismatch (PPM) (16).

Clinical follow-up through outpatient visits (one month after discharge) and telephone contacts (after rehabilitation and one year after the procedure) was performed.

2.5 Statistical Analysis

Data are presented as absolute numbers, percentages, and mean ± standard deviation.

Patients without and with residual paravalvular leak ≥ 1 at the end of TAVI were compared.

Comparisons were also performed with patients that required prosthesis re-ballooning, second valve implanta-

Table 1: Patients Baseline Data.

	BAV (n = 33)
Age (yrs)	73.0 ± 7.3
Men	20 (60.6 %)
Body surface area (m^2)	1.97 ± 0.24
Aortic annulus size (mm)	24.99 ± 3.01
Aortic valve area (cm^2)	0.50 ± 0.11
Ellipticity index	0.84 ± 0.10
Linear eccentricity	7.04 ± 2.71
Numeric eccentricity	0.51 ± 0.18
Max. diameter (mm)	
LVOT	40.47 ± 7.02
aortic root	36.64 ± 3.93
sinotubular junction	32.12 ± 4.36
ascending aorta	38.48 ± 5.78
Bicuspid valve type	
LC + RC, raphe +	20 (60.6 %)
LC + RC, raphe -	4 (12.1 %)
RC + NC, raphe +	7 (21.2 %)
RC + NC, raphe -	2 (6.1 %)
LC + NC, raphe +	0
LC + NC, raphe -	0
Calcium score (mm^3)	
total	5716.34 ± 4989.95
LVOT	1636.94 ± 2275.24
valve	4061.22 ± 3027.96
non-coronary leaflet	1303.30 ± 1026.77
right-coronary leaflet	1446.72 ± 1077.01
left-coronary leaflet	1311.18 ± 1081.87
Calcium mass total (g)	8.87 ± 7.71
Logistic EuroSCORE	23.2 ± 19.3
EuroSCORE II	10.3 ± 11.6
STS score	8.0 ± 9.2
LVEF	48.61 ± 15.33

Data presented as n (%) or mean ± standard deviation. LVOT, left ventricular outflow tract; LC, left-coronary; RC, right-coronary; NC, non-coronary; EuroSCORE, European System for Cardiac Operative Risk Evaluation; STS, Society of Thoracic Surgeons; LVEF, left ventricular ejection fraction.

tion, and conversion to conventional surgery.

Differences between continuous variables were tested by means of unpaired Student t-test, Mann-Withney test, chi-square and Fischer exact test whenever appropriate. Kaplan-Meier survival curves were built and the equality of survival distribution between patients with and without paravalvular leak was tested (Mantel-Cox, Breslow, Tarone-Ware).

3. Results

3.1 Perioperative

A total of 33 patients (13 females and 20 males) were treated. Preoperative patients and AVs data are reported in Table 1 and Figures 1–2. Moreover, Table 2 summarizes intraoperative data. The majority of patients were treated by means of transapical Edwards SAPIEN® valve. Nine patients (27.3 %) required post- ballooning of an implanted valve for moderate to severe paravalvular leak occurrence. Three patients required a second valve implantation (9 %) for persistent severe paravalvular leak that became mild after re-valving. Two conversions (6 %) to conventional surgery were necessary. One patient had malpositioning of a self-expandable valve with structural damage of the prosthesis during implantation. The second patient experienced annular rupture during implantation of a balloon expandable valve.

Table 3 includes the intraoperative echocardiography together with the clinical outcome data. At the end of the procedure, mild paravalvular leak was noticed in 12 patients (36.4 %) and moderate paravalvular leak in one patient (3 %). Central AV regurgitation was reported in one patient (3 %). PPM was moderate in 5 patients (15 %) and no patient developed severe PPM. The device

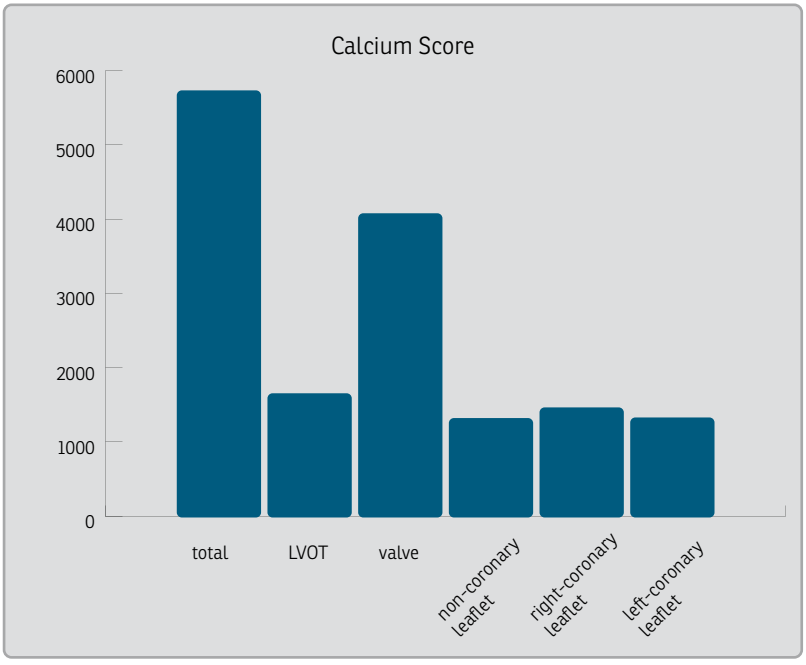
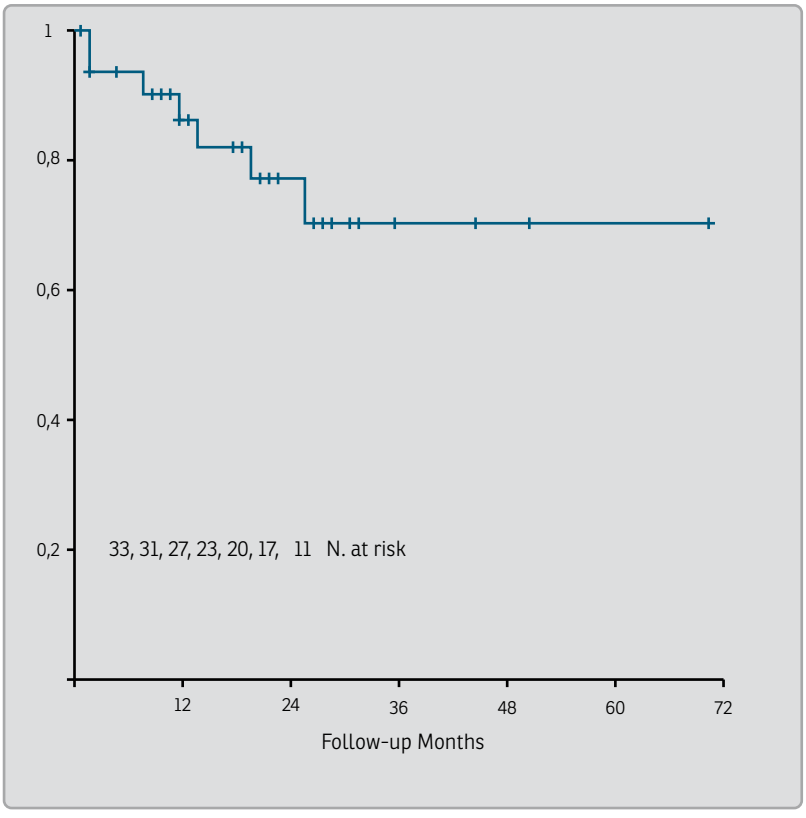


Figure 2: Respective calcium scores for different parts of the aortic valve apparatus as observed in our patient group.

Figure 3: K-M survival curve in patients undergoing TAVI for bicuspid aortic valve stenosis. Estimated survivals: at 6 months 90.1% (CI: 80.0-100.0); at 1 year 82.0% (CI: 68.5-97.8); at 2 years 70.0% (CI: 52.7-93.1).



success rate according to VARC criteria was 82 %.

No patient died in the first 30 days after the procedure. Two patients (6 %) died in a different institution because of pneumonia and sepsis during the post-surgical rehabilitation, both 6 weeks after discharge.

When comparing anatomical variables of patients without and with ≥ 1 residual paravalvular leak at the end of the procedure, there was a trend for larger aortic annular diameter and valve area in patients that developed paravalvular leak (Table 4). Moreover, a trend for higher valve calcium volume with higher distribution in the right and left coronary leaflets was noticed in patients that developed paravalvular leak. Operative time was significantly longer in patients that developed paravalvular leak. Prosthesis performance, in terms of transvalvular gradient, effective orifice area and eventual PPM, was similar in both groups (Table 4).

Moreover, a sub-analysis of patients that required re-ballooning (9 patients), re-valving (3 patients), and conversion to conventional surgery (2 patients) was performed. Although there were no significant differences in terms of valve anatomy, ellipticity, calcium distribution, and calcium content, these patients had significantly larger native annular area, perimeter, and perimeter derived diameter when compared to the remaining patients (27.6 ± 2.1 mm vs. 24.8 ± 3.0 mm; p = 0.01).

3.2 Follow-up

Clinical follow-up was complete in all patients and average duration was 20 ± 15 months (1–70 months). Overall two-year estimated survival was 70 % (CI: 52.7–93.1) (Figure 3). There were no reported cardiac deaths. No patient re-

Table 2: Procedural Data.

Variable	BAV (n = 33)
Valve type	
Edwards	29 (87.9 %)
CoreValve	4 (12.1 %)
Access	
Edwards	
Transfemoral	0
Transapical	29 (100 %)
Transaxillary	0
Transaortic	0
CoreValve	
Transfemoral	3 (75 %)
Transapical	0
Transaxillary	1 (25 %)
Transaortic	0
Valve size (mm)	
Edwards	
23	5 (17.2 %)
26	9 (31 %)
29	15 (51.7 %)
CoreValve	
23	1 (25 %)
26	1 (25 %)
29	2 (50 %)
Procedure duration (min)	97.89 ± 36.40
Amount of contrast dye used (mL)	133.81 ± 73.27

Data presented as n (%) or mean ± standard deviation.

quired reoperation for AV dysfunction and/or degeneration or any sort of additional cardiac surgery. No significant difference (p = 0.5) in terms of estimated survival was noticed between patients without (66.2 %; CI: 42.4–100.0) and with (68.6 %; CI: 45.0–100.0) residual paravalvular leak ≥ 1 after TAVI.

Discussion

The occurrence of BAV in patients with severe AV stenosis may represent a theoretical challenge for TAVI. In fact, this anatomic variation that is present in at least 50 % of patients submitted to conventional AV replacement (17) has been considered, *per se*, an exclusion criterion for TAVI (18).

In patients with BAV, a potential risk of TAVI is mainly in an uneven expansion of the prosthesis, resulting from the heterogeneous pliability of the native valve and the particular stiffness of the leaflet where a raphe is present.

Zegdi et al. (19) have proven these important theoretical drawbacks of TAVI in a group of 16 BAV patients where a self-expandable stent, specifically designed for stented valves, was deployed intraoperatively inside the aortic valve before undergoing AV resection for conventional surgical aortic valve replacement. Elliptic stent deployment and under-deployment were the rule in BAV. In a second phase, the authors performed an *ex vivo* study of a "homemade" stented valve to confirm that the regularity of the coaptation line was dependent on the quality of stent deployment (20).

Zegdi report, although of seminal importance, presents some differences from the daily TAVI practice. First, it does not include a phase of balloon valvuloplasty before stent deployment within the native AV annulus. Secondly, it is focused on the anatomical adaptation of a self-expandable stent and does not take into consideration the dynamics of balloon expandable stents. Finally, it considers the *ex vivo* behavior of a "homemade" stented AV prosthesis that may differ greatly from the *in vivo* performance of the TAVI prostheses currently available on the market.

Table 3: Postprocedural Data.

Variable	BAV (n = 33)
Effective orifice area (cm^2)	2.25 ± 0.55
Indexed effective orifice area (cm^2/m^2)	1.13 ± 0.29
Max. aortic valve gradient (mm Hg)	7.95 ± 4.09
Mean aortic valve gradient (mm Hg)	3.99 ± 2.09
Paravalvular Leak	
= 1	12 (36.4 %)
= 2	1 (3 %)
> 2	0
30-Day mortality	0
Complications	
Conversion To Conventional Surgery	2 (6 %)
Re-Valving	3 (9 %)
Bleeding	3 (9 %) (1 annular rupture and 2 apical bleeding)
AKIN 0	27 (81.8 %)
AKIN 1	2 (6 %)
AKIN 2	0
AKIN 3	1 (3 %)
TIA	1 (3 %)
Stroke	0
Myocardial infarction	0
Pacemaker implantation	1 (3 %)

Data presented as n (%) or mean ± standard deviation. AKIN, acute kidney injury; TIA, transient ischemic attack.

In fact, despite the described important theoretical drawbacks, TAVI has been applied, although in limited numbers, in BAV patients at prohibitive risk for conventional surgery. Published experiences have mainly described acute and mid-term results with both balloon expandable and self-expandable TAVI prostheses. In these patients, occurrence of more than moderate aortic regurgitation ranges from 0 to 32 % with mean trans-valve pressure gradients always below 15 mmHg (1-8).

Mylotte et al. have reported the multicenter results of TAVI in BAV. In a total of 139 patients procedural mortality was 3.6 %, with valve embolization in 2.2 % and conversion to surgery in 2.2 %. Post-implantation aortic regurgitation grade ≥ 2 occurred in 28.4 % but was prevalent in only 17.4 % when CT-based TAVI sizing was performed. One-year mortality was 17.5 % (7).

Bauer et al. evaluated 38 patients with BAV within the German TAVI registry, and have compared them with a cohort group of 1357 tricuspid aortic valve patients. Although TAVI outcomes were satisfactory in both groups, the occurrence of ≥ grade 2 AR was significantly more common in BAV (25 % vs. 15 %). Thirty-day mortality rate was similar in both cohorts and BAV was not associated with higher 1-year mortality rate (6). In a case-match study, Kochman et al. compared 28 BAV with 84 tricuspid valve patients (1:3 ratio), implanted with both balloon expandable and self-expandable prostheses. There was a statistically insignificant trend for higher post-procedural mean pressure gradient (11.5 ± 6.4 vs. 10.4 ± 4.5 mm Hg) and aortic regurgitation grade ≥ 2 (32 % vs. 23 %) in the BAV patients that did not result in an increased 30-day and 1-year all-cause mortality (5).

More recently Costopoulos et al. have shown more concerning results in a multicenter experience. When comparing TAVI in 21 BAV versus 447 tricuspid AV patients, the authors noticed a trend toward a lower device success rate (85.7 % vs. 94.4 %) and significantly higher 30-day mortality rate (14.2 % vs. 3.6 %) in the BAV group (4).

Finally, in the most recent multicenter evaluation proposed by Yousef et al. (8), the authors present results in 108 patients with BAV treated by TAVI within the premises of 21 centres. The

Table 4: Comparison of patients with AR versus patients without AR after TAVI.

Characteristic	BAV with AR ≥ 1 (n = 12)	BAV without AR (n = 21)	p Value
Age (yrs)	70.5 ± 8.32	74.38 ± 5.96	0.1
Gender			
male	10 (83.3 %)	10 (47.6 %)	0.04*
Body surface area (m^2)	1.97 ± 0.24	1.97 ± 0.25	0.9
Aortic annulus size (mm)	26.34 ± 2.38	24.28 ± 3.07	0.07
Aortic valve area (cm^2)	0.55 ± 0.09	0.47 ± 0.11	0.07
Ellipticity index	0.82 ± 0.09	0.84 ± 0.11	0.6
Linear eccentricity	7.92 ± 2.2	6.53 ± 2.94	0.3
Numeric eccentricity	0.55 ± 0.13	0.49 ± 0.2	0.6
Max. diameter (mm)			
LVOT	39.94 ± 6.72	40.77 ± 6.99	0.8
aortic root	37.38 ± 3.48	36.22 ± 4.01	0.4
sinotubular junction	32.76 ± 4.66	31.76 ± 4.03	0.8
ascending aorta	37.71 ± 4.82	38.91 ± 6.09	0.5
Bicuspid valve type			
LC + RC, raphe +	8 (66.7 %)	12 (57.1 %)	NS
LC + RC, raphe -	2 (16.7 %)	2 (9.5 %)	NS
RC + NC, raphe +	1 (8.3 %)	6 (28.6 %)	NS
RC + NC, raphe -	1 (8.3 %)	1 (4.8 %)	NS
Valve type			
Edwards	10 (83.3 %)	19 (90.5 %)	NS
CoreValve	2 (16.7 %)	2 (9.5 %)	NS
Calcium score (mm3)			
total	5571.83 ± 3313.14	5798.92 ± 5625.93	0.5
LVOT	1289.29 ± 1229.66	1835.60 ± 2629.79	0.6
valve	4232.53 ± 2349.76	3963.33 ± 3284.77	0.6
non-coronary leaflet	1121.73 ± 750.40	1407.06 ± 1120.32	0.8
right-coronary leaflet	1587.04 ± 953.81	1366.54 ± 1109.05	0.7
left-coronary leaflet	1523.71 ± 840.33	1189.73 ± 1157.35	0.2
Calcium mass total (g)	8.73 ± 5.06	8.96 ± 8.72	0.5
Procedure duration (min)	124.22 ± 37.75	86.05 ± 26.03	0.01*
Amount of contrast dye used (mL)	141.42 ± 40.83	131.43 ± 83.75	0.08
Effective orifice area (cm^2)	2.48 ± 0.54	2.17 ± 0.51	0.3

Characteristic	BAV with AR ≥ 1 (n = 12)	BAV without AR (n = 21)	p Value
Indexed effective orifice area (cm^2/m^2)	1.23 ± 0.39	1.10 ± 0.22	0.6
Max. aortic valve gradient (mm Hg)	8.76 ± 3.60	7.59 ± 4.13	0.4
Mean aortic valve gradient (mm Hg)	4.91 ± 2.70	3.81 ± 1.84	0.3

Data presented as n (%) or mean ± standard deviation. *LVOT*, left ventricular outflow tract; *LC*, left-coronary; *RC*, right-coronary; *NC*, non-coronary.

composite primary outcome, according to VARC criteria, occurred in one quarter of patients (26.9 %) and was mainly driven by re-intervention for valve malposition (9.3 %).

Although the topic TAVI in BAV has been already analyzed in details, the present manuscript presents the largest single center experience with an extended follow-up. All cases were performed within the premises of a facility that has had a consistent exposure to TAVI since its very early introduction. Our results confirm what has been previously shown by others and clearly demonstrate that, although TAVI for BAV has become a standard procedure, challenges should be expected, even in most experienced centres.

We have recently reported our 5-year experience with trans-apical TAVI, including over 700 patients. In our global experience, conversion to surgical aortic valve implantation due to rupture of the device landing zone or coronary artery obstruction was reported in 1.1 % of the cases (6 % in the BAV series), prosthesis re-dilatation for more than mild paravalvular leak in 7.5 % (27 % in the BAV series), and re-valving in 2.2 % (9 % in the BAV series) (13).

Valve hemodynamics in BAV patients were also quite different, when compared to those reported in our overall experience. At the end of the procedure, mild regurgitation was present in 19.2 %, and moderate regurgitation in 0.8 % of the patients included in our overall experience (13). In our sub-group of BAV patients, mild and moderate paravalvular leaks occurred in a slightly higher rate (36 % and 3 % respectively).

Although the presence of residual paravalvular leak ≥ 1 did not impact upon acute and intermediate-term (2-year) survival, these findings may be biased by the very limited sample size. In fact, there is emerging and consistent evidence that even the presence of mild prosthetic regurgitation after TAVI may impact significantly upon long-term clinical outcomes (21).

From an inferential standpoint, we were not able to identify any specific anatomical reason that could have increased the risk of TAVI failure in BAV patients. In particular, calcification distribution and calcification amount did not seem to differ significantly in patients that had residual paravalvular leak and/or required further intervention. Furthermore, although "ellipticity" was not found to be a predictor of outcome, the sample size and the contained number of valves that were truly elliptic should be considered as a major limitation of the present study.

Interestingly, we have noticed a trend for larger annular anatomy in patients developing mild paravalvular leak. Moreover, we have reported significantly larger native annuli in patients requiring further intervention (re-ballooning, re-

valving, and conversion) for persistent moderate to severe paravalvular leak.

Finally, some comments should be given concerning the risk of inappropriate prosthesis expansion with consequent valve malfunction in patients with BAV undergoing TAVI.

In this context, some authors have described a PPM rate after TAVI for tricuspid AV stenosis ranging from 40 to 60 % (22,23). In our experience, moderate and severe PPMs occurred respectively in approximately 27 % and 8 % of patients undergoing TAVI for severe stenosis of a tricuspid AV (24). In the present series of BAV patients moderate PPM was present in only 15 % of patients and no patient experienced severe PPM.

One should take into account also the limitations of our article: this was a single-centre retrospective analysis of a relatively small cohort of patients whose BAV have had different, morphological types. Prospective studies are needed and cooperation between institutions with large numbers would be required to enlarge the study population numbers.

In conclusion, although TAVI in BAV is feasible, it is associated with an increased rate of implantation failures and caution should be advised when treating these patients, even in the premises of very experienced centres. The present manuscript presents results achieved with balloon expandable and self-expandable prostheses belonging to an earlier generation of devices. Outcomes may be different once new generation TAVI prostheses, including those that are fully retrievable and repositionable, are tested consistently in this challenging aortic anatomical scenario.

Disclosure

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The authors have no other conflicts of interest to declare.

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