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Performance of the Labcor Dokimos Plus pericardial aortic prosthesis: a single-centre experience

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Abstract

OBJECTIVES: In patients with a small aortic annulus, aortic valve replacement (AVR) is frequently associated with high residual pressure gradients. Supra-annular pericardial aortic prostheses are gaining popularity due to the increased effective orifice areas (EOA) and resulting lower gradients. This study reports the clinical and echocardiographic results following implantation of the new supra-annular pericardial aortic prosthesis Dokimos Plus (Labcor, Belo Horizonte, Brazil).

METHODS: Between October 2013 and July 2015, 137 patients (41% women, mean age: 74 years) underwent supra-annular AVR with or without concomitant procedures using the Dokimos Plus prosthesis in our department. Transthoracic echocardiography was performed pre- and postoperatively on all patients to assess haemodynamic parameters (gradients, acceleration time [AT], Doppler velocity indices [DVIs] and indexed EOA [EOAI]) and to detect paravalvular leakage (PVL). Data were collected retrospectively from our hospital databases.

RESULTS: Patients were grouped by prosthesis size: Most patients received 23-mm (57.6%), followed by 21-mm (19%), 25-mm (15.4%) and 27-mm (8%) prostheses. The mean EOAI in all groups was 1.1 ± 0.26 cm^2/m^2. Pressure gradients were low in all groups (mean: 8.9 ± 4.4 mmHg; peak: 18.8 ± 6.8 mmHg); AT and DVI were in the normal range according to American Society of Echocardiography/European Association of Cardiovascular Imaging recommendations (mean AT 73.3 ± 29 ms; mean DVI 0.5 ± 0.2). One patient had severe PVL and one presented with central regurgitation, both requiring re-intervention. The mortality rate was 5.1% ($n = 7$); none of the cases was associated with valve insufficiency.

CONCLUSIONS: The Dokimos prosthesis showed a satisfactory overall performance, presenting low gradients and DVIs as well as high EOAI. Further investigations are needed to analyse the cases of regurgitation and monitor long-term performance.

Keywords: Labcor Dokimos Plus prosthesis • Aortic valve replacement • Supra-annular aortic valve bioprosthesis

INTRODUCTION

Bioprostheses are recommended for patients older than 65 years who require valve replacement and for young patients who are not suited for lifelong systemic anticoagulation because of medical contraindications or lifestyle considerations [1]. Aortic valve replacement (AVR) has been shown to prolong survival, provide symptom relief and preserve left ventricular function in patients with severe aortic valve disease [2]. However, in patients with a small aortic annulus requiring a small prosthesis, high transprosthetic gradients, low effective orifice area (EOA) and low left ventricular mass regression may occur [3]. Prosthesis–patient mismatch (PPM) is a frequent problem in patients undergoing AVR, especially in those with a small aortic annulus, and is associated with worse outcomes and higher mortality rates [4, 5]. Supra-annular prostheses emerged as an alternative to optimize haemodynamic performance and overcome the residual pressure gradient seen with traditional prostheses [6, 7].

The aim of this single-centre, retrospective study was to investigate the efficacy and early haemodynamic performance of the supra-annular stented pericardial Dokimos Plus aortic valve prosthesis (Labcor, Belo Horizonte, Brazil).

MATERIALS AND METHODS

Data collection

From October 2013 until July 2015, a retrospective search of patient information was performed. Data from all patients with aortic valve disease who had supra-annular AVR with the Dokimos Plus

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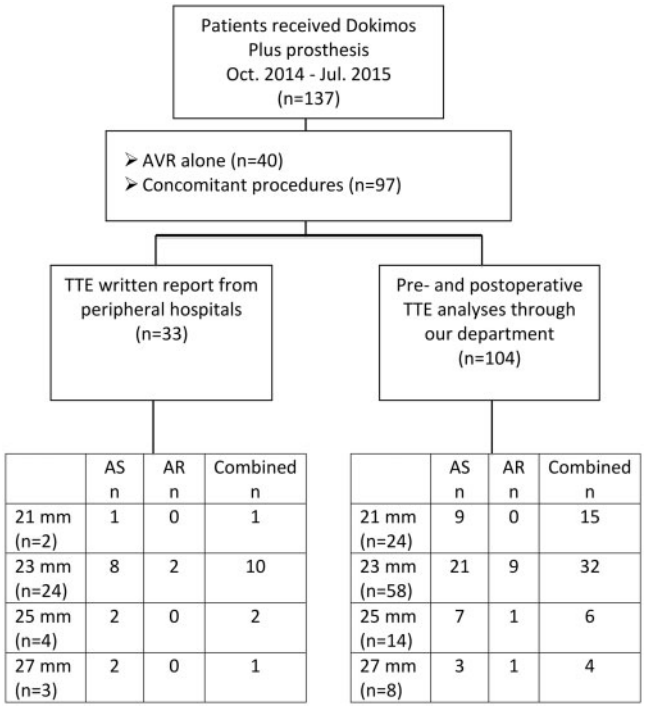

	AS n	AR n	Combined n
21 mm (n=2)	1	0	1
23 mm (n=24)	8	2	10
25 mm (n=4)	2	0	2
27 mm (n=3)	2	0	1

	AS n	AR n	Combined n
21 mm (n=24)	9	0	15
23 mm (n=58)	21	9	32
25 mm (n=14)	7	1	6
27 mm (n=8)	3	1	4

Figure 1: Study design. AR: aortic regurgitation; AVR: aortic valve replacement; AS: aortic stenosis; Comb.: combined aortic valve vitium; concomitant procedures: includes AVR + coronary artery bypass graft surgery, AVR + mitral valve reconstruction or replacement, AVR + tricuspid valve reconstruction, AVR + repair of patent forman ovale, AVR + myoectomy; postop: postoperative; TTE: transthoracic echocardiography

prosthesis, with or without concomitant procedures in our department, were analysed. Informed consent was waved by our ethics committee due to the retrospective nature of the study.

Data from a total of 137 patients were retrieved (Fig. 1). In 20 patients, transthoracic echocardiograms (TTEs) were not performed through our department postoperatively because of early referral to peripheral hospitals or cardiac rehabilitation units ($n = 20$). In 13 patients, early post-operative TTE performed in our department were of insufficient quality to measure all of the evaluated parameters ($n = 13$). Only written postoperative TTE reports were available from 33 patients, for whom the TTE was performed in peripheral hospitals after 15 postoperative days (POD). The written TTE reports included information about paravalvular leakage (PVL), aortic regurgitation, pressure gradients and effective orifice areas indexed (EOAI); the acceleration time (AT) and Doppler velocity indices (DVIs) were not measured.

The European System for Cardiac Operative Risk Evaluation II (EuroSCORE II) and the Society of Thoracic Surgeons risk calculator (STS score) were used for patient risk assessment. The demographic data are shown in Table 1.

Echocardiographic measurement

All patients were routinely evaluated pre- and postoperatively using TTE performed according to the guidelines of the European Association of Cardiovascular Imaging and the American Society of Echocardiography (ASE) [8]. TTE measurements performed at rest included transvalvular flow velocity with continuous-wave Doppler scanning and left ventricular outflow tract (LVOT) flow velocity with pulse-wave Doppler scanning. LVOT diameter was assessed from a parasternal long-axis view. The transvalvular pressure gradient was calculated using the Bernoulli equation with inclusion of subvalvular velocity and the EOA using the standard continuity equation. The EOA was indexed to body surface area (EOAI) [9, 10]. Besides evaluation of left ventricular function, assessment of the aortic valve included the following parameters: EOAI, mean pressure gradient (MPG), peak pressure gradient (PPG), flow AT and DVI ratio (DVI: V_{max} LVOT/V_{max} AV) [10]. All echocardiographic studies were performed using the Vivid E9 (GE Vingmed Ultrasound AS, Horten, Norway), and the measurements were done with EchoPAC version 113 (GE Vingmed Ultrasound AS, Horten, Norway).

Figure 2: Dokimos Plus bioprosthesis

Description of the implanted bioprostheses

The stented pericardial heart valve Dokimos Plus, aortic model is a low-profile, tri-composite valve. The low-profile scalloped design facilities implantation in the aortic intra-annular or supra-annular position. The valve is made from 3 precut bovine pericardial leaflets. The bovine pericardial leaflets are fixed in buffered glutaraldehyde solution at zero pressure to preserve the integrity of the collagen fibres. The leaflets are mounted on a scalloped, flexible polymer stent that is covered with polyester fabric, coated on the inner surface of the stent with a thin pericardial strip to avoid contact between the leaflets and the fabric, which minimizes the risk of abrasion due to repeated impact with the synthetic material. The flexibility of the stent permits motion at the commissural level, thus reducing the closing stress of the commissures. The sewing cuff is composed of a silicone rubber suture covered with the same polyester fabric [11] (Fig. 2).

Surgical procedure

In all patients, AVR was performed via a median sternotomy using standard cardiopulmonary bypass at mild hypothermia with cold cristalloid cardioplegia (Custodiol, Köhler Chemie, Germany).

The aorta was opened with a transverse incision; the native aortic valve was removed to ensure complete annular decalcification. The appropriate prosthesis valve size was determined using the original sizers provided by the manufacturer. The valve prosthesis was implanted in supra-annular position using pledged interrupted non-inverting mattress sutures. Intraoperative transoesophageal echocardiography was performed to evaluate valve function.

Statistical analysis

Continuous variables are expressed as mean ± SD and categorical variables, as absolute numbers and percentages. Data analysis

Table 1: Demographics and peri- and postoperative data

Variable	21-mm valve (*n* = 26)	23-mm valve (*n* = 82)	25-mm valve (*n* = 18)	27-mm valve (*n* = 11)
Age, years	76.2 ± 7.1	74.1 ± 7.1	75.2 ± 7.1	67.8 ± 7.9
Women, *n* (%)	21 (80.7)	33 (40.2)	2 (11.1)	0
Preoperative risk factors				
Ejection fraction, %	58.8 ± 8.2	53.2 ± 9.5	51.7 ± 13.8	53.1 ± 9.4
NYHA I, *n* (%)	0	0	2 (11.15)	1 (9.1)
NYHA II, *n* (%)	14 (53.8)	57 (69.5)	9 (50)	4 (36.3)
NYHA III, *n* (%)	11 (42.3)	25 (30.5)	6 (33.3)	5 (45.4)
NYHA IV, *n* (%)	1 (3.9)	0	1 (5.55)	1 (9.1)
Hyperlipoproteinemia, *n* (%)	18 (69.2)	55 (67.1)	10 (55.5)	3 (27.3)
COPD, *n* (%)	4 (15.3)	18 (21.9)	2 (11.1)	1 (9.1)
BMI, kg/m^2	25.4 ± 3.7	27.2 ± 4.6	30.6 ± 6.2	28.6 ± 6.9
IDDM, *n* (%)	10 (38.4)	31 (37.8)	7 (38.8)	2 (18.2)
Renal insufficiency, *n* (%)	4 (15.3)	10 (12.2)	6 (33.3)	1 (9.1)
Atrial fibrillation, *n* (%)	10 (38.4)	23 (28.04)	5 (27.77)	3 (27.2)
Apoplexy, *n* (%)	2 (7.69)	11 (13.4)	1 (5.55)	3 (27.2)
CAD, *n* (%)	20 (76.9)	51 (62.2)	11 (61.1)	4 (36.3)
EuroSCORE II, %	7.32 ± 5.62	5.68 ± 5.23	5.89 ± 4.59	4.73 ± 3.38
STS mortality, %	5.35 ± 4.15	5.01 ± 5.92	4.14 ± 4.33	2.50 ± 1.96
STS re-operation, %	10.14 ± 3.41	9.97 ± 3.82	9.64 ± 4.40	8.49 ± 2.69
Peri- and postoperative data				
Heart-lung machine time, min	145.6 ± 59.3	132.3 ± 58.8	127.9 ± 49.1	100.2 ± 35.6
Cross-clamp time, min	91.1 ± 37.6	88.4 ± 37.5	86.3 ± 34.4	68.7 ± 27.1
Atrial fibrillation, *n* (%)	6 (23.1)	18 (21.9)	8 (44.4)	5 (45.4)
Atrioventricular block, *n* (%)	4 (15.4)	7 (8.5)	0	0
Arrhythmia, *n* (%)	0	3 (3.65)	0	1 (9.1)
Re-thoracotomy, *n* (%)	2 (7.7)	10 (12.2)	0	1 (9.1)
Pneumonia, *n* (%)	7 (26.9)	23 (28.1)	9 (50)	1 (9.1)
Delirium, *n* (%)	2 (7.7)	25 (30.5)	8 (44.4)	2 (18.2)
Renal insufficiency, *n* (%)	2 (7.7)	5 (6.1)	2 (11.1)	1 (9.1)
Apoplexy, *n* (%)	1 (3.8)	0	0	0
30 POD mortality, *n* (%)	0	4 (4.9)	0	1 (9.1)
>30 POD mortality, *n* (%)	1 (3.8)	1 (1.2)	0	0

BMI: body mass index; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; IDDM: insulin-dependent diabetes mellitus; NYHA: New York Heart Association; POD: postoperative day; STS: Society of Thoracic Surgeons; Re-thoracotomy: reoperation due to bleeding.

was performed with SPSS 23 (IBM, Chicago, IL, USA). Due to non-normal distribution of the data, continuous variables were analysed using the Wilcoxon signed ranks test. The boxes of the box-and-whiskers plots contain the middle 50% of the values. The upper and lower quartiles represent the 25th and 75th percentiles, respectively. The horizontal line inside the box marks the median. The whiskers indicate the largest and smallest values, excluding extreme outliers. Categorical variables were analysed with a Chi-square test or, if appropriate, the Fisher exact test. *P*-values were reported as 3-digit numbers or with at least one non-zero digit. A *P*-value <0.05 was considered statistically significant.

RESULTS

Baseline

Between October 2013 and July 2015, 137 patients (81 men, 59%) with a mean age of 74 (range: 40–85) years who had aortic valve disease (aortic stenosis [*n* = 53], aortic regurgitation [*n* = 13] and combined aortic valve disease [*n* = 71]) (Fig. 1) received AVR with the Dokimos Plus bioprosthesis. Most patients (*n* = 80) were between 71- and 80-years old. The mean BMI was 27.5 ± 5.1. The most important comorbidities were dyslipidaemia (*n* = 86), diabetes mellitus (*n* = 50), atrial fibrillation (*n* = 41), chronic obstructive pulmonary disease (*n* = 25), renal insufficiency (*n* = 21) and a previous stroke (*n* = 17). Associated coronary artery disease was present in 86 patients. Three patients presented with NYHA I; 83 with NYHA II; 48 with NYHA III and 3 with NYHA IV. The mean EuroSCORE II was 5.89 ± 4.58% (range, 1.4–21.5%); the mean STS risk of mortality was 3.36 ± 2.19% (Table 1).

Clinical results

The majority of patients received 23-mm valves (*n* = 82), followed by 21-mm valves (*n* = 26), 25-mm valves (*n* = 18) and 27-mm valves (*n* = 11). All patients survived surgery. Concomitant surgical procedures included coronary artery bypass graft (*n* = 71), closure of persistent foramen ovale (*n* = 9), mitral valve repair (*n* = 8), aortic arch replacement (*n* = 4), septal myectomy (*n* = 4) and implantation of a left ventricular assist device (*n* = 1). The mean bypass time was 128 ± 58 min, and the mean cross-clamp time was 89 ± 36 min. Postoperative complications included pneumonia (*n* = 40), atrial fibrillation (*n* = 37), delirium (*n* = 37), re-thoracotomy due to bleeding

Table 2: Pre- and postoperative echocardiographic parameters

Valve size	21 mm (*n* = 26)	23 mm (*n* = 82)	25 mm (*n* = 18)	27 mm (*n* = 11)
Mean pressure gradient, mmHg				
Preoperative	39.8 ± 9.2	40.2 ± 9.8	43.2 ± 7.2	44.4 ± 7.1
Postoperative	11.8 ± 4.9	9.9 ± 4.1	9.6 ± 3.4	9.2 ± 3.8
P-values	**<0.0001**	**<0.0001**	**0.001**	**0.012**
Peak pressure gradient, mmHg				
Preoperative	51.4 ± 17.9	61.8 ± 16.9	65.2 ± 9.4	70.4 ± 4.8
Postoperative	22.4 ± 8.2	17.2 ± 8.1	17.8 ± 4.7	17.2 ± 4.9
P-values	**<0.0001**	**<0.0001**	**0.001**	**0.012**
EAOI, cm^2/m^2				
Preoperative	0.42 ± 0.18	0.47 ± 0.32	0.40 ± 0.24	0.50 ± 0.19
Postoperative	0.90 ± 0.35	0.96 ± 0.32	1.1 ± 0.23	1.1 ± 0.18
P-values	**<0.0001**	**<0.0001**	**0.001**	**0.012**
Doppler velocity index[a]				
Preoperative	0.27 ± 0.07	0.29 ± 0.11	0.28 ± 0.06	0.27 ± 0.03
Postoperative	0.49 ± 0.16	0.52 ± 0.16	0.61 ± 0.09	0.51 ± 0.11
P-values	**<0.0001**	**<0.0001**	**0.001**	**0.012**
Ejection fraction, %				
Preoperative	60 ± 7.8	55.11 ± 7.8	54.8 ± 5.4	54.1 ± 9.3
Postoperative	54.8 ± 6.8	54.3 ± 7.4	56.8 ± 5.8	51.6 ± 10.8
P-values	**0.002**	0.320	0.674	0.091
TAPSE, mm				
Preoperative	17.6 ± 5.8	19.8 ± 3.6	18.1 ± 3.2	19.9 ± 4.2
Postoperative	14.4 ± 3.6	13.9 ± 3.4	15.8 ± 3.9	18.9 ± 7.8
P-values	**0.026**	**0.0001**	0.151	0.380
Acceleration time, ms[a]				
Preoperative	111.7 ± 24.2	100.2 ± 22.5	104 ± 25.4	114.9 ± 24.2
Postoperative	72.7 ± 14.03	68.5 ± 28.2	73.5 ± 12.9	91.2 ± 23
P-values	**<0.0001**	**<0.0001**	**0.001**	0.093

EOAI: effective orifice area indexed to the body surface area; PPG: peak pressure gradient; TAPSE: tricuspid annular plane systolic excursion. **Bold** type indicates values that are statistically significant.
[a]Missing values from 33 patients.

(*n* = 13), atrioventricular block that required pacemaker implantation (*n* = 11), PVL (*n* = 3) and central regurgitation (*n* = 1). The mean hospital stay was 16.7 ± 10.9 days.

Haemodynamic results

An overview of the pre- and postoperative TTE results grouped by Dokimos Plus bioprosthesis size is depicted in Table 2. No improvement was detected in both left and right ventricular systolic function in the first 10 days postoperatively compared with the preoperative measurement. The mean value of the MPG decreased significantly postoperatively (38.2 ± 11.4 vs 8.9 ± 4.4 mmHg; $P < 0.0001$); the EOAI increased significantly postoperatively (0.48 ± 0.29 vs 1.1 ± 0.26 cm^2/m^2; $P < 0.0001$); and the postoperative mean values of AT and DVI were in the normal range according to the European Association of Cardiovascular Imaging/ASE recommendations on the evaluation of prosthetic valves [9, 10] (AT: 73.3 ± 29 ms; DVI: 0.53 ± 0.16). Detailed information about all measured TTE parameters is presented in Table 2 and Figure 3.

PVL and central aortic regurgitation

PVL was recognized in 3 patients. One out of 26 patients receiving the 21-mm prosthesis had PVL (3.8%). Two out of 82 patients with the 23-mm valve had PVL (2.4%). In 1 patient with a 25-mm prosthesis, echocardiography detected central aortic regurgitation. Patients who developed PVL had a significantly higher EuroSCORE II (8.57 ± 9.11% vs 5.91 ± 1.06%, $P = 0.0064$), higher STS risk of mortality (5.93 ± 2.26% vs 4.25 ± 1.275, $P = 0.0135$) and higher STS risk of reoperation (23.37 ± 8.6% vs 9.56 ± 0.74%, $P = 0.0001$) compared with the rest of the patients. There was no relationship between heart and lung machine/cross-clamp time and PVL. Table 3 shows the characteristics and clinical factors of patients with PVL and central regurgitation.

The echocardiographic follow-up of patients with PVL showed moderate leakage in 2 patients and severe leakage in one patient; the latter required re-intervention and underwent a valve-in-valve transcatheter aortic valve implant through a transfemoral approach.

One patient had severe aortic valve regurgitation with signs of ventricular overload and required re-intervention; the patient also had a valve-in-valve transcatheter aortic valve implant.

The 2 patients who underwent re-intervention had satisfactory echocardiographic parameters during follow-up. The patients with moderate PVL did not show echocardiographic changes in gradients or left ventricular overload before hospital discharge. Table 4 shows the echocardiographic follow-up data of patients with PVL.

Prosthesis-patient mismatch

PPM occurs when the EOA of the prosthesis is too small in relation to the patient's body size, resulting in abnormally high

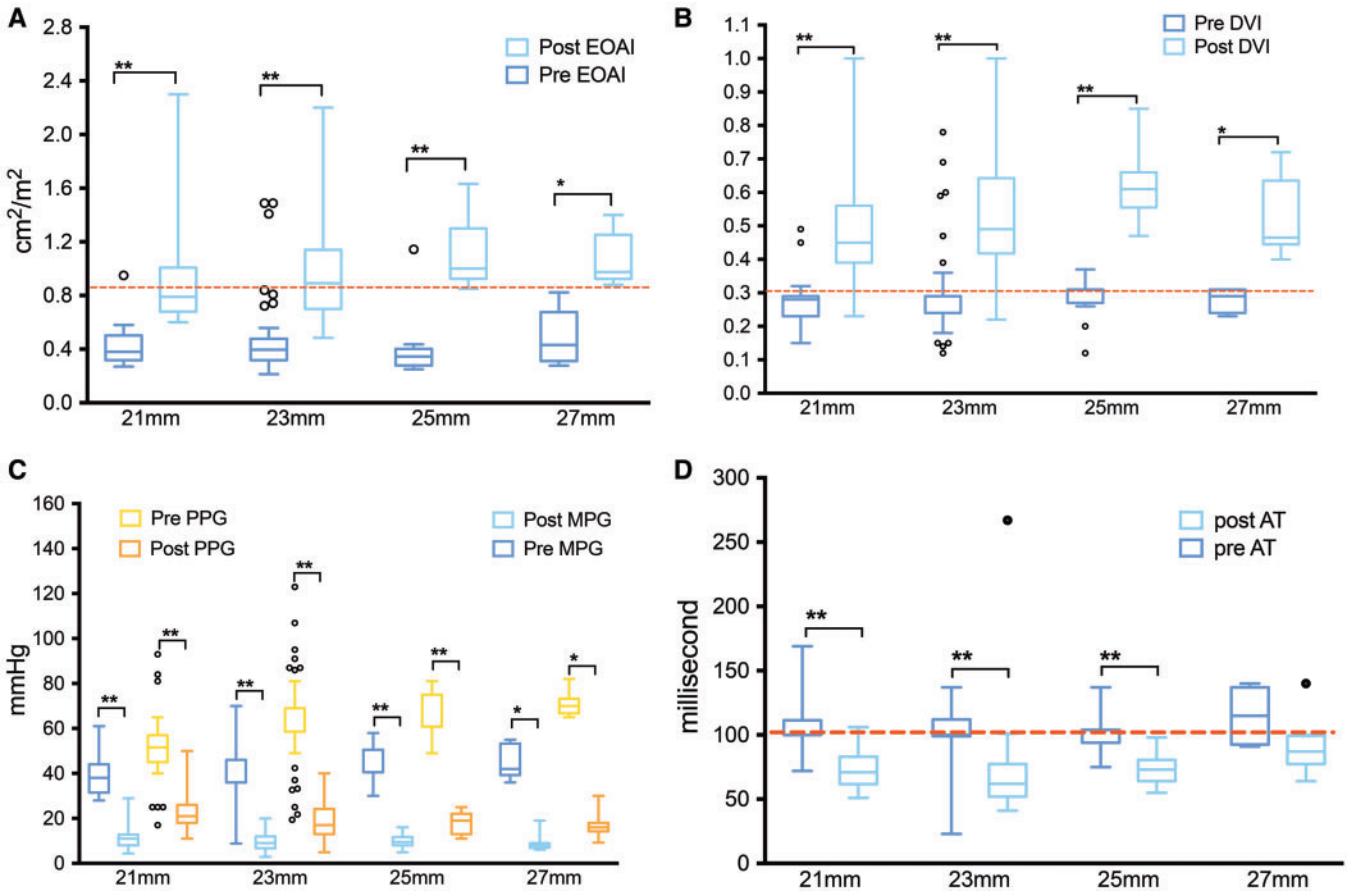

Figure 3: Comparison of pre- and postoperative echocardiographic parameters. **(A)** Comparison of pre- and postoperative EOAI; **(B)** comparison of pre- and postoperative DVI; **(C)** comparison of pre- and postoperative MPG and PPG; **(D)** comparison of pre- and postoperative AT. AT: acceleration time (ms); DVI: Doppler velocity index; EOAI: effective orifice area indexed to the body surface area (cm^2/m^2); MPG: mean pressure gradient (mmHg); PPG: peak pressure gradient (mmHg); $^{**}P \leq 0.001$; $^{*}P < 0.05$; *P*-values were determined using the Wilcoxon signed-rank test.

Table 3: Characteristics and clinical factors in patients with PVL and central regurgitation

Variable	Absent PVL (*n* = 133)	Moderate or severe PVL/CR (*n* = 4)	*P*-values
Age, years	74.5 ± 6.1	76.7 ± 8.8	0.473
BMI, kg/m^2	27.5 ± 5.1	25.9 ± 2.8	0.538
NYHA I, *n* (%)	3 (2.2)	0	1.000
NYHA II, *n* (%)	83 (62.4)	1 (25)	0.093
NYHA III, *n* (%)	45 (33.8)	2 (50)	0.577
NYHA IV, *n* (%)	2 (1.5)	1 (25)	0.075
Ejection fraction, %	55.2 ± 12.1	52.7 ± 3.2	0.681
Heart-lung machine, min	130.8 ± 56.7	131.9 ± 71	0.969
Cross-clamp, min	86.9 ± 36.4	85 ± 39.7	0.931
EuroSCORE II,%	5.87 ± 1.97	8.57 ± 9.11	**0.026**
STS risk of mortality, %	4.76 ± 5.30	5.93 ± 2.26	0.661
STS risk of morbidity or mortality, %	24.56 ± 15.85	35.47 ± 12.25	0.175
STS risk of reoperation, %	9.77 ± 3.76	12.07 ± 2.27	0.239

BMI: body mass index; NYHA: New York Heart Association; POD: postoperative day; STS: Society of Thoracic Surgeons.

postoperative gradients [5, 10, 12]. PPM is considered haemodynamically insignificant if the indexed EOA (EOAI) is >0.85 cm^2/m^2, moderate if between 0.65 and 0.85 cm^2/m^2 and severe if <0.65 cm^2/m^2 [5, 10]. In our study, according to the above definition, 10 out of 26 patients who received the 21-mm Dokimos Plus bioprosthesis, 19 out of 82 patients who received the 23-mm prosthesis and 1 out of 18 patients who received the 25-mm prosthesis had a moderate PPM. But in all of these patients, MPG, AT and DVI were in the normal range (Table 5).

Table 4: Echocardiographic follow-up of patients with PVL and central regurgitation

Valve size	21 mm (*n* = 1)	23 mm (*n* = 1)	25 mm (*n* = 1)	27 mm (*n* = 1)
Sex	Male	Male	Male	Male
BMI, kg/m^2	26	29	23	29
Concomitant procedure	No	No	AVR+CABG	No
Bypass time, min	128	91	101	75
Cross-clamp time, min	89	75	77	49
TTE	Moderate PVL	Severe PVL	Moderate PVL	Aortic CR III
Left ventricular overload	No	Yes	No	Yes
Treatment	No re-op	Re-op: TAVI	No re-op	Re-op: TAVI
TTE follow-up	Without any changes	Postop improvement	Without any changes	Postop improvement
LOS, days	22	21	21	20

AVR: aortic valve replacement; BMI: body mass index; CABG: coronary artery bypass graft; CR: central regurgitation; LOS: length of stay; postop: postoperative; PVL: paravalvular leakage; Re-op: reoperation; STS: Society of Thoracic Surgeons; TAVI: transcatheter aortic valve implantation; TTE: transthoracic echocardiography.

Table 5: Echocardiographic parameters of patients with PPM

Valve size	21 mm (*n* = 26)	23 mm (*n* = 82)	25 mm (*n* = 18)	27 mm (*n* = 11)
0.9 ≥ EOAI ≥ 0.85, *n* (%)	3 (11.5)	4 (4.9)	1 (5.5)	1 (9.1)
Mean pressure gradient, mmHg	14 ± 3.7	9.8 ± 1.9	11	7
Peak pressure gradient, mmHg	29.3 ± 7.7	17.2 ± 3.4	19	17
Acceleration time, ms	66.3 ± 10.6	66.7 ± 17.3	72	78
Doppler velocity index	0.49 ± 0.03	0.53 ± 0.07	0.5	0.46
0.65 ≥ EOAI ≤ 0.85, *n* (%)	10 (38.5)	19 (23.2)	1 (5.5)	0
Mean pressure gradient, mmHg	12.9 ± 5.5	10.3 ± 3.2	16	
Peak pressure gradient, mmHG	23.9 ± 9.1	20.8 ± 5.9	20	
Acceleration time, ms	76.5 ± 15.5	74.1 ± 47.2	55	
Doppler velocity index	0.46 ± 0.18	0.42 ± 0.07	0.66	
EOAI ≤ 0.65, *n* (%)	0	0	0	0

EOAI: effective orifice area indexed to the body surface area.

Mortality

A total of 7 patients (5.1%) died following the AVR, 5 of these within 30 days after surgery. For these 7 patients, the mean STS risk score of mortality was 22.99 ± 6.11% and the STS risk score of morbidity or mortality was 72.62 ± 5.07, whereas the mean EuroSCORE II was 14.44 ± 11.35%. Combined surgery had been performed in 4 of these 7 patients. One patient had a history of a previous aortic valve operation. Six of the 7 deceased presented with NYHA III or higher. The length of extracorporeal circulation ranged from 67 to 270 min (cross-clamp time: 52–211 min). The most common postoperative complications seen in the patients who died were pneumonia in 6 and renal failure in 4. Furthermore, all of the deceased had postoperative cardiac arrhythmia resistant to pharmacological treatment in the early postoperative phase, and 2 required a pacemaker because of atrioventricular block. For detailed information, please refer to Supplementary Table 1.

DISCUSSION

In our study we demonstrated that the supra-annular pericardial aortic bioprosthesis Dokimos Plus provides normal pressure gradients and low rate of prolapse and leakage, particularly in patients with a small aortic annulus that would otherwise only allow implantation of small prostheses, which often leads to high trans-prosthetic gradients, low EOAI and low ventricular mass regression [13].

Postoperatively, echocardiographic parameters such as reduction in pressure gradients and increase in EAOI improved significantly. Pressure gradients were low in all groups, and AT and DVI were in the normal range according to American Society of Echocardiography and European Association of Cardiovascular Imaging (ASE/EACVI) recommendations. EOAI was well above 0.85 cm^2/m^2 in all groups.

It must be taken into account that we only performed TTE follow-up 10 days postoperatively and only in 33 patients, TTE was performed after 15 POD in peripheral hospitals. Otherwise, factors like haemoglobin levels, haematocrit and volume status directly affect the parameters in the early postoperative period [14, 15]. To be able to determine the functional outcome with more certainty, mid- and long-term follow-up studies with echocardiography should be performed.

Various clinical studies have been conducted to compare the performance of different types of aortic valve bioprostheses. In a study by Bach and colleagues, the Trifecta valve demonstrated

superior haemodynamic results in comparison to the Magna Ease and Freestyle valves [16, 17]. Similarly, another study comparing the Trifecta valves with the Mitroflow and Perimount Magna valves found better haemodynamic performance in Trifecta valves [18]. Taken together, the results of our study show that the haemodynamic profile of pressure gradients and the percentage of patients with postoperative PVL are comparable to those reported for the Trifecta aortic valve bioprosthesis.

The clinical results with the Dokimos Plus bioprosthesis were satisfactory. The length of hospital stay and the incidence of complications did not differ significantly in comparison to those of other types of valves reported in the literature [18, 19].

Previous studies have reported a 5% mortality rate after AVR procedures [6, 18, 19]. Although there were 7 (5.1%) reported deaths in our study, none of them was associated with valve insufficiency. All patients who died had cardiac arrhythmias in the postoperative period, the most common being atrial fibrillation and atrioventricular block, the latter requiring pacemaker implantation in 2 patients. As described in other studies, there seems to be a direct relationship between advanced age and atrial fibrillation, possibly attributable to limited cardiac denervation during the surgical intervention [20]. Atrioventricular block, in turn, is not a rare complication and is associated with the surgical procedure due to the proximity to the electrical conduction system of the heart, occasionally requiring implantation of a pacemaker [21].

In this study, most of patients who died had advanced age, associated cardiovascular risk factors and NYHA class III. A high incidence of complications was also found to be associated with longer times of extracorporeal circulation, for example in cases of combined operations. This finding is consistent with known factors associated with early death reported in the literature such as advanced age, coronary artery disease, NYHA classes III–IV, intraoperative blood use, low left ventricular ejection fraction <33%, long cardiopulmonary bypass time and aortic insufficiency [22, 23].

Prosthesis-patient mismatch

Many previous studies reported an incidence of moderate PPM of between 20 and 70%, whereas that of severe PPM was between 2 and 11% [5, 24, 25]. In our study, in the group with the smallest valve size (21mm), 38.5% and in the group with the 23-mm valve, 32.2% of the patients had moderate PPM, whereas all of the other TTE values, such as MPG, AT and DVI, were in the normal range in these patients. In the groups with 25-mm and 27-mm valves, no moderate PPM could be detected. No cases of severe PPM were observed in any of the groups.

Paravalvular leakage

PVL is one of the complications following AVR, mostly without haemodynamic repercussions. A large leak can lead to left ventricular volume overload; in small valves intravascular haemolysis leading to anaemia is frequently documented [26]. The incidence of PVL increases with increased annulus diameter because of insufficient contact between the prosthesis and the aortic annulus [27].

Known risk factors for PVL include presence of calcifications, low ejection fraction (<30%), NYHA IV, bicuspid aortic valves and the lower or higher position of the implanted valve [28].

In our study, 3 patients had PVL, all of whom had a small aortic annulus. However, it must be noted that 78.83% of the patients in this study received a small-annulus AVR; therefore, we were unable to compare the incidence of PVL with different sizes of the Dokimos Plus valve. Only one of the 3 patients with PVL and one patient with central regurgitation required re-intervention because of left ventricular overload (Tables 3 and 4). Echocardiographic follow-up showed improvement in valve gradients. Those patients had a significantly higher EuroSCORE II, higher STS risk of mortality and higher STS risk of reoperation (Table 3). There was no evidence of a prolonged hospital stay in comparison to those patients who received conservative treatment. There was no association between combined surgery or prolonged extracorporeal circulation and development of PVL.

Limitations of the study

The limitations of this study include a non-randomized design resulting in patient and valve selection by the surgeon. The fact that echocardiographic follow-up was performed in the early postoperative period when the parameters measured were still subject to change (e.g. left ventricular systolic and diastolic function, the patient's volume status, function of the mitral valve, blood pressure and heart rate) and the fact that some patients had to be excluded from the study due to incomplete echocardiographic data are also limitations of the study.

CONCLUSION

The Dokimos Plus supra-annular aortic bioprosthesis showed a promising overall performance, presenting low gradients and DVIs as well as high EOAI. Further investigations are needed to analyse long-term performance, left ventricular mass regression and patient outcome. The Dokimos Plus bioprosthesis should be considered as an alternative for the treatment of patients with aortic valve disease and a small aortic annulus.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

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