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Research Article

Midterm Experience with the Self-Expandable Venus P-Valve™ for Percutaneous Pulmonary Valve Replacement in Large Right Ventricular Outflow Tracts

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Background. Preliminary results with the recently certified self-expandable Venus P-Valve™ designed for percutaneous pulmonary valve implantation in patients with dilated right ventricular outflow tracts are encouraging, but experience is limited. We therefore assessed our early and midterm outcomes with the Venus P-Valve™. *Methods*. Twenty patients who underwent Venus P-Valve™ implantation in our institution were included in this retrospective study. Procedural data and clinical, imaging, and hemodynamic data at baseline and last follow-up were recorded and analyzed. *Results*. Mean patient age was 35.0 ± 16.8 years, and five patients were <18 years of age. Procedural success was 100%, and there was no major valve-related procedural complication. At last follow-up (median 0.5 (range 0.1–6.6) years), valve function was excellent in all patients. Two patients had mild regurgitation after 6.2 and 6.6 years, respectively, while all other patients had no or only trace regurgitation. Flow was unobstructed with a mean gradient estimated by echocardiography of 12 ± 4 mmHg. NYHA functional class improved significantly ($p = 0.009$), and right ventricular dimensions significantly decreased (right ventricular end-diastolic diameter 56±9 mm vs. 44±8 mm) ($p < 0.001$). Transient benign ventricular arrhythmias were frequent. One patient experienced a severe arrhythmia with sustained ventricular tachycardia during follow-up. *Conclusions*. Early and midterm results with the Venus P-Valve™ are excellent. It considerably extends the interventional options and offers a safe and effective alternative to surgery in patients with large right ventricular outflow tracts. Larger multi-institutional studies with longer follow-up duration are required to reliably assess the long-term performance and possible long-term complications of the Venus P-Valve™.

1. Introduction

Residual or reoccurring right ventricular outflow tract (RVOT) dysfunction after the repair of congenital heart disease results in significant morbidity and mortality and represents one of the most frequent causes of reoperation [1, 2]. Owing to the pioneering work of Bonhoeffer and colleagues, the concept of transcatheter pulmonary valve replacement (PPVI) has been established as a safe and effective minimally invasive alternative option by now [3–5]. PPVI has become an integral element of the lifetime management of patients with RVOT lesions. It reduces the number of required open heart surgeries in affected patients and has excellent results comparable to surgical valve replacement while showing lower complication and mortality rates and favourable cost-effectiveness [4–8].

To date, the Melody® transcatheter pulmonary valve (Medtronic Inc., Minneapolis, MN, USA) and the Edwards SAPIEN™ Valve (Edwards Lifesciences, Irvine, CA, USA) have been the most commonly percutaneously implanted

valves in the pulmonary position [9, 10]. Both are balloon-expandable and intended for the treatment of dysfunctional RVOT conduits or bioprosthetic valves [4]. The available range of sizes is limited, and it has become evident that there are a considerable number of patients with RVOT dysfunction having unsuitably large dimensions for PPVI with balloon-expandable valves, in particular patients with native outflow tracts and predominant pulmonary valve regurgitation, as frequently observed in patients after tetralogy of Fallot repair [11, 12]. Moreover, in combination with large diameters and highly variable morphology, outflow tracts in these patients often are very distensible and compliant, precluding the safe implantation of balloon-expandable valves [13].

To address these limitations, the concept of using large-diameter self-expanding stents for PPVI stimulated the development of a new generation of devices. Several self-expanding devices have been introduced such as the Harmony™ Valve (Medtronic Inc., Minneapolis, USA), the Venus P-Valve™ (Venus MedTech Inc., Hangzhou, China), and the Pulsta™ Valve (Taewoong Medical Co., Ltd., Gyeonggi-do, South Korea) as self-expanding valves for PPVI or the Alterra Adaptive Prestent™ (Edwards Lifesciences, Irvine, USA), designed to serve as a self-expanding landing zone within the ROVT to accommodate the SAPIEN™ Valve [14–17]. While the Harmony™ Valve and Alterra™ devices received Food and Drug Administration approval in the USA in 2021, the Venus P-Valve™ is the first and currently only CE-marked valve designed for PPVI in large-dimension native RVOT.

Worldwide, a considerable number of patients have been successfully treated with the Venus P-Valve™ during the past years, with encouraging early and midterm results [18–21]. Nevertheless, the clinical experience is still limited as marketing and increasing use in Europe only began recently after CE certification in 2022. We therefore sought to summarize our initial experience and early and midterm outcomes with the self-expandable Venus P-Valve™ for PPVI in patients with large RVOT.

2. Materials and Methods

2.1. Study Cohort. We performed a retrospective study including all patients who had received PPVI with a Venus P-Valve™ in our institution. Demographic, clinical, imaging, and hemodynamic and procedural data were retrieved from electronic medical charts. If available, data from the last follow-up examinations were also recorded. The study was approved by the institutional ethics committee (decision number EA2/009/21); the requirement of individual informed consent was waived due to the retrospective study design. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki and its subsequent amendments.

2.2. Patient Eligibility. Patients were considered eligible for PPVI with the Venus P-Valve™ if they had no pulmonary valve stenosis and RVOT dimensions with landing zones considered borderline or too large for balloon-expandable valves. Preprocedural assessment includes imaging with magnetic resonance imaging and/or computed tomography. Indications for pulmonary valve replacement were based on recommended guideline criteria including moderate-to-severe regurgitation (regurgitation fraction ≥30–40%) with indexed right ventricular end-diastolic volume ≥160 ml/m^2 and/or indexed right ventricular end-systolic volume ≥80 ml/m^2, compromised systolic right ventricular function with ejection fraction ≤45%, or heart failure symptoms corresponding to NYHA functional class ≥II [22].

2.3. Preprocedural Imaging. Preimplantation imaging was submitted to a screening process conducted by the core facility to assess the feasibility of using Venus P-Valve™ according to RVOT morphology and dimensions (Figures 1(a) and 1(b)). Diameters were measured on multiple cine slides (6–8 mm thick, 1 mm overlapping) of the RVOT, up to three separate orthogonal planes (bifurcation, parasagittal, and right ventricle inflows to outflows) at various levels during systole and diastole. Measurements were kept perpendicular to the long axis of the proximal pulmonary artery/RVOT (at the level of the landing zone), to account for the straightening effect of the valve on the pulmonary artery (Figure 1(b)). In most cases, this is akin to measurements derived from the centre line method. The landing zone is defined as 25 or 30 mm distal to the valve annulus. The valve size recommendation was based on the diameter of at least compliant segments and matched close to the maximal diameter of the remaining main pulmonary artery. Factors additionally evaluated included main pulmonary artery length (valve to bifurcation), branch pulmonary artery anatomy, and coronary artery proximity to the landing zone.

2.4. Percutaneous Pulmonary Valve Implantation. Cardiac catheterization was generally performed under sedation/analgesia with spontaneous breathing according to our routine institutional protocol. Two patients were submitted to general anaesthesia: one had severe scoliosis with restrictive lung function and one had a history of relevant allergic reactions during previous analgosedation, respectively. Vascular access was femoral in all cases and included two venous sheaths (6-7F) and one arterial sheath (5-6F). Heparin was administered to achieve an activated clotting time of 200–220 seconds; cefazolin (30 mg/kg) was administered as antibiotic prophylaxis. In addition to angiography (Figure 1(c)), the RVOT was sized with a 34 mm Amplatzer™ sizing balloon (Abbott, Plymouth, USA) or occasionally with a Z-MED II™ balloon (28–30 mmm; Numed Inc., Hopkinton, USA). Stop flow was ascertained by pressure recordings documenting arterial pressure drop and right ventricular angiography (Figure 1(d)). Coronary compression or displacement was ruled out by simultaneous angiography of the left coronary artery. The valve diameter (28–36 mm) was chosen to comply with a safety margin of at least 1–2 mm of oversizing the valve in relation to the smallest waist diameter determined by balloon sizing, and length was chosen according to distance from the annular

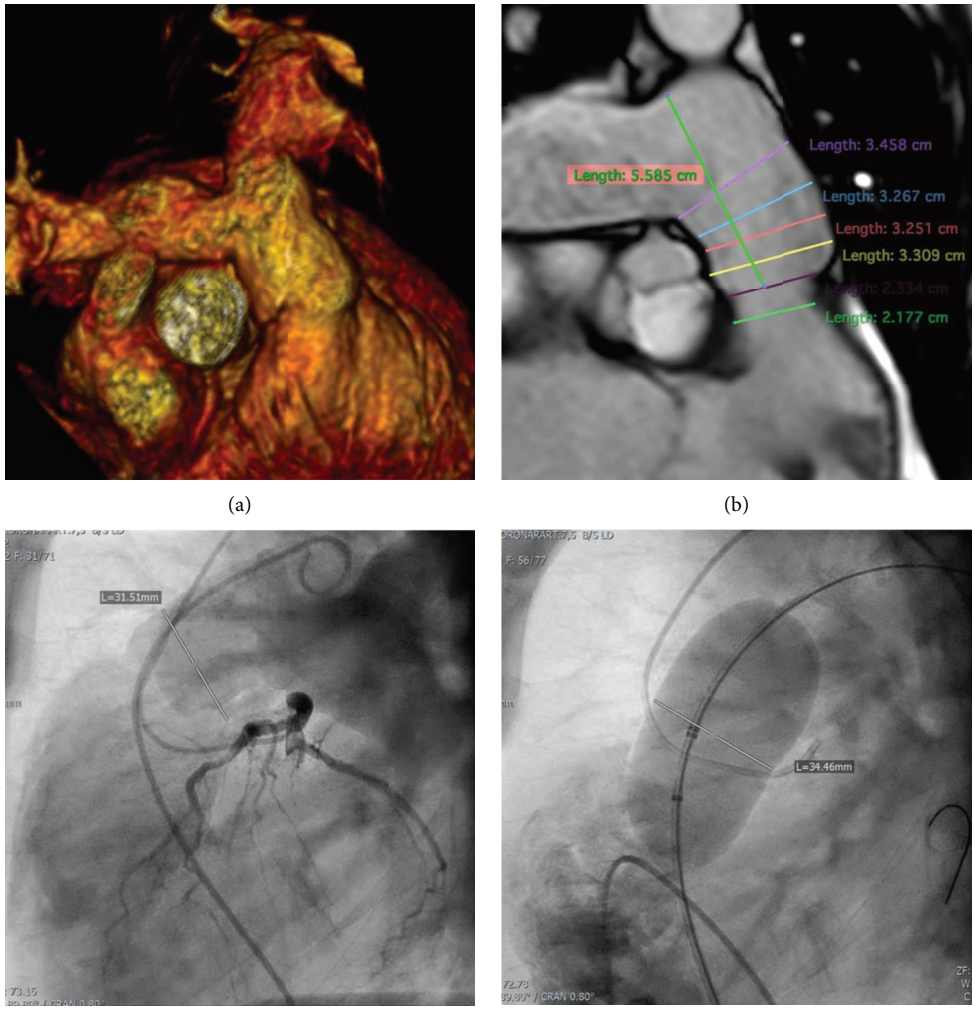

Figure 1: Preprocedural imaging and measurements in a patient with subsequent Venus P-Valve™ implantation. 3D reconstruction (a) and assessment of RVOT dimensions (b) from preprocedural MRI. (c) Angiography of the pulmonary artery/RVOT with simultaneous coronary angiogram of the left coronary artery. (d) Balloon sizing of the RVOT with simultaneous RV angiogram demonstrating complete occlusion. MRI: magnetic resonance imaging; RV: right ventricle; RVOT: right ventricular outflow tract.

level to the bifurcation. While in the early experience the longer 30 mm valve length was often preferred due to concerns of stable positioning, currently the shorter 25 mm valve is generally favoured to minimise the protrusion of the valve's proximal flared end into the RVOT. For valve implantation, an extra-stiff guidewire (Lunderquist®; Cook Medical, Bloomington, USA; or E-Wire; Artivion, Kennesaw, USA) was placed in the peripheral pulmonary artery and a 24F–26F GORE® DrySeal Flex Introducer Sheath (W. L. Gore & Associates, Inc., Flagstaff, USA) was advanced. The Venus P-Valve™ (Figures 2(a) and 2(b)) was crimped and mounted to the delivery catheter according to the manufacturer's instructions. The delivery catheter was then advanced through the sheath into the proximal branch of the pulmonary artery, where valve deployment was initiated (Figure 2(c)). During slow and controlled deployment with gradual release of the valve, the delivery system was gently pulled back to the designated landing zone, controlled by repeated RVOT angiograms (Figure 2(d)). After the release of the valve (Figure 2(e)) and extraction of the delivery system, pressure recordings and final angiograms were performed to document valve function and position (Figure 2(f)).

Dual antiplatelet inhibition was initiated on the second postprocedural day and maintained for 6 months followed by continuous antiplatelet therapy with aspirin alone.

2.5. Statistics. Statistical analyses were performed using SPSS (version 25; IBM Corp., Armonk, USA). Data distribution was tested using the D'Agostino–Pearson test, and most variables displayed normal distribution. Categorical variables are expressed as figures (percentages); continuous variables are expressed as the mean ± standard deviation for normal distribution or median (interquartile range, IQR) for non-normal distribution, respectively. Comparisons between baseline and follow-up parameters were performed with the paired t-test. P values <0.05 were considered statistically significant.

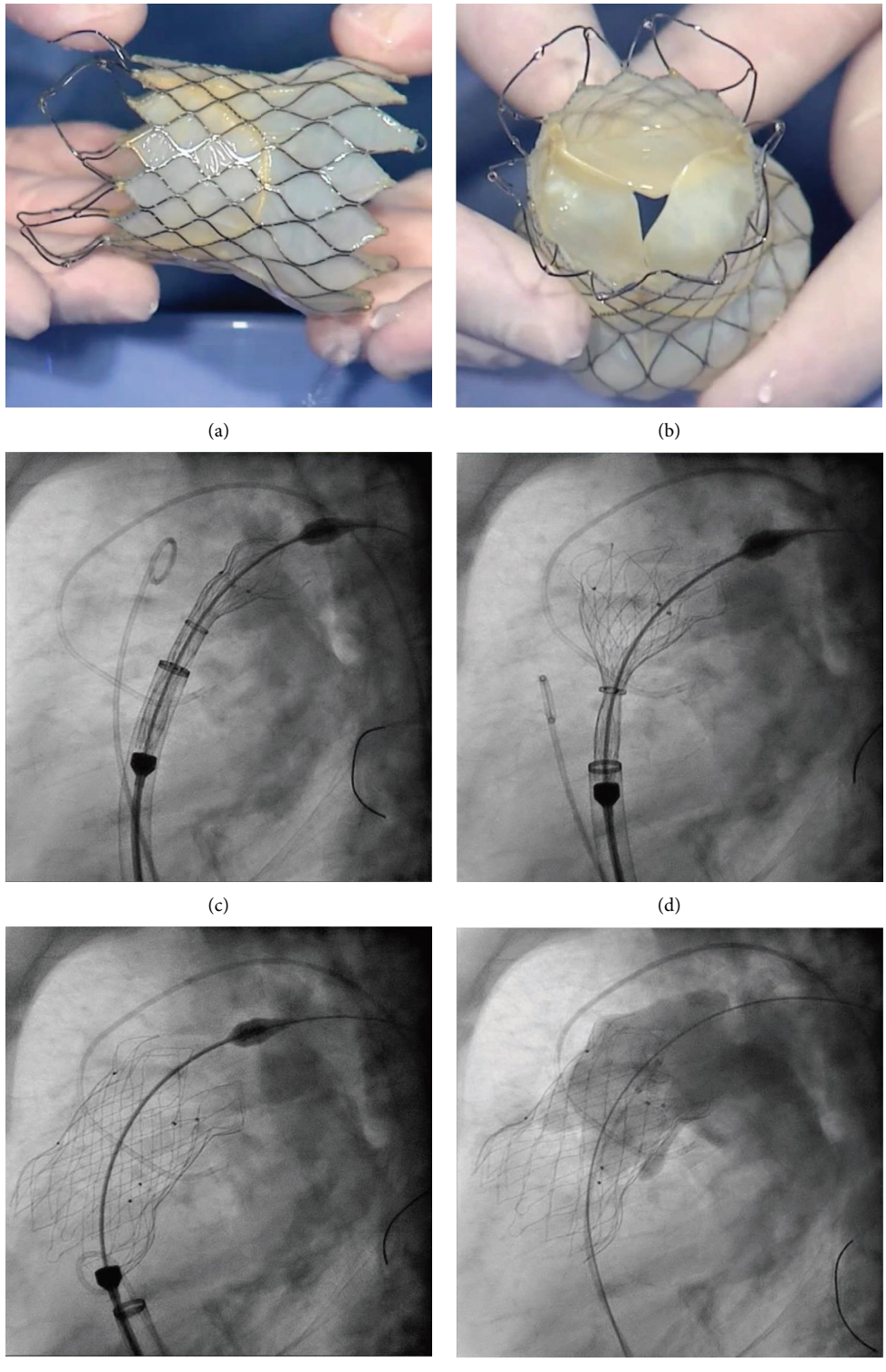

Figure 2: (a, b) Design of the Venus P-Valve™. (c–f) Implantation of the Venus P-Valve™ (same patient as Figure 1). Slow and controlled deployment with gradual release of the valve and gentle pullback of the delivery system and the valve to the designated landing zone (c, d). Final valve configuration after release (e) and final angiography after removal of the delivery system (f) showing excellent valve function.

3. Results

3.1. Patients. Patient characteristics are displayed in Table 1. A total of 20 patients underwent PPVI with a Venus P-Valve™ in our institution. Five of these procedures were performed between 2017 and 2018 within the CE certification study (EUDAMED CIV-15-04–013524); 15 patients were treated after certification and market release in 2022.

The majority of the patients were adults, while five were children of 13–17 years of age, respectively. All patients had moderate-to-severe pulmonary valve regurgitation and RV dilatation documented by magnetic resonance imaging and angiography. No relevant pressure gradient across the RVOT was observed. There was a fair overall concordance of the smallest RVOT dimensions assessed by magnetic resonance imaging and angiography (Tables 1 and 2); individually, however, differences of up to 6 mm were noted. Patients displayed considerable compliance of the RVOT with a mean difference of 2.8 ± 1.5 mm of the smallest dimensions between angiography and balloon sizing (Table 2).

All patients reported reduced physical capacity to some extent; however, advanced heart failure was uncommon and most patients were in NYHA functional class ≤II. Several patients had a history of arrhythmias prior to PPVI (Table 1). A history of ventricular tachycardia (VT) was noted in three patients (15%). Of these, two had electrophysiological studies with successful ablation prior to PPVI due to recurrent nonsustained VT. One patient had experienced a single episode of torsades de pointes tachycardia thought to be medication-induced during chemotherapy for colon cancer, and she had no further documented VT after the conclusion of chemotherapy.

Table 1: Patient characteristics.

Age (years)	35.0 ± 16.8
Weight (kg)	73 ± 19
Height (cm)	175 ± 10
Sex (female/male)	6 (30%)/14 (70%)
Diagnosis	
Repaired TOF	15 (75%)
Repaired PV stenosis	4 (20%)
Ross' procedure with PVR	1 (5%)
NYHA functional class	
I	7 (35%)
II	12 (60%)
III	1 (6%)
QRS duration (ms)	150 ± 34
History of arrhythmia*	11 (55%)
Sinus node dysfunction	1 (5%)
Permanent atrial fibrillation	1 (5%)
Recurrent atrial fibrillation	3 (15%)
Paroxysmal atrial flutter	1 (5%)
Nonsustained ventricular tachycardia	2 (10%)
Torsades de pointes tachycardia	1 (5%)
Low-burden polymorphic PVC	2 (10%)
Low-burden monomorphic PVC	5 (25%)
RVEDVi (ml/m^2)	165 ± 26
RVESVi (ml/m^2)	91 ± 23
RVEF (%)	48 ± 6
PV RF (%)	47 ± 12
RVOT diameter (mm)	27.2 ± 3.3
RVEDD (mm)	55 ± 9

Data are presented as the mean ± standard deviation or frequencies (percentages). Right ventricular functional parameters and minimum RVOT diameter were analyzed from MRI, and RVEDD was analyzed from echocardiography. RVEDD was measured as a maximal transversal dimension in the basal part of RV inflow at the end diastole in the four-chamber view. *More than one type of arrhythmia has been observed in some patients. TOF: tetralogy of Fallot; PV: pulmonary valve; PVC: premature ventricular complex; PVR: pulmonary valve replacement; RVEDD: right ventricular end-diastolic diameter; RVEDVi: indexed right ventricular end-diastolic volume; RVEF: right ventricular ejection fraction, RF: regurgitation fraction; RVOT: right ventricular outflow tract; RVESVi: indexed right ventricular end-systolic volume.

3.2. Immediate Outcome. All procedures were successful, and procedural details are presented in Table 2. All valves were implanted in an annular position. Valves were deployed via the left pulmonary artery in the majority of cases, and only in one patient, deployment was performed via the right pulmonary artery. Deployment was uneventful in all but one patient. A partial infolding of the distal aspect of the valve limited control of deployment and placement in that patient. During the deployment of the last third of the valve, it eventually unfolded and slid distally towards the bifurcation, well beyond the intended implantation site. As it was still partially hooked to the delivery catheter, it could be successfully repositioned by traction.

Final intraprocedural angiograms showed excellent valve function in all patients, and there were no valvar regurgitations or paravalvular leakages. Invasive pressure recordings documented unobstructed flow after PPVI. No compromise of coronary perfusion was observed.

One major procedural complication occurred, which, however, was unrelated to the Venus P-Valve™. The patient experienced a presumable perforation of the peripheral pulmonary artery by the stiff guidewire during balloon sizing. He showed acute haemoptysis during the procedure and was intubated. No extravasation was observed in the pulmonary angiography, and intrabronchial bleeding seemed to have stopped; therefore, the procedure was continued with successful PPVI. On the first post-interventional day, a significant haematothorax was noted requiring thoracotomy for evacuation.

The majority of patients had a transiently increased burden of premature ventricular complexes (PVCs) observed by telemetry, which had generally ceased until discharge. In 5 patients, short episodes of nonsustained VT were detected by telemetry during the first 2–3 days after PPVI. At discharge, Holter monitoring showed a low burden of PVC in 8 patients and short nonsustained VT in three patients. A new antiarrhythmic medication was initiated in four patients with either ß-blocker ($n = 2$) or amiodarone ($n = 2$). One patient with frequent short episodes of VT and preexisting sinus node dysfunction became symptomatically bradycardic with the initiated antiarrhythmic; a dual-chamber implantable cardioverter-defibrillator (ICD) was implanted before discharge as he displayed additional risk factors for ventricular arrhythmias such as advanced age and reduced systolic RV function.

Table 2: Procedural details.

Fluoroscopy time (min)	19.5 ± 8.6
DAP (mGy*cm^2)	49,672 ± 31,951
mPAP (mmHg)	15 ± 5
RVOT gradient (mmHg)	3 ± 3
RVOT diameter, native (mm)	
a.p./lateral	26.5 ± 3.5/26.3 ± 3.3
RVOT diameter, sizing (mm)	
a.p./lateral	28.8 ± 3.3/29.4 ± 3.2
Implanted valve sizes	
28–25 mm	2 (10%)
30–30 mm	2 (10%)
32–25 mm	3 (15%)
32–30 mm	3 (15%)
34–25 mm	1 (5%)
34–30 mm	1 (5%)
36–25 mm	4 (20%)
36–30 mm	4 (20%)
Valve diameter (mm)	
a.p./lateral	29.7 ± 3.6/27.9 ± 3.0

Data are presented as the mean ± standard deviation or frequencies (percentages). Diameters refer to the smallest diameters measured across the RVOT in systole or along implanted valves, respectively. Valve sizes are specified in diameter length of the central tubular valve part. a.p.: anterior-posterior; DAP: dose area product; mPAP: mean pulmonary artery pressure; RVOT: right ventricular outflow tract.

One patient complained of severe chest pain after PPVI and possible causes such as coronary artery compression or pulmonary artery dissection were ruled out by a computed tomography scan and laboratory analyses. Chest pain resolved with analgesic medication within a few days. The hospital course was uneventful in all other patients.

3.3. Midterm Outcome. Median follow-up was 0.5 (IQR 0.1–4.1) years. Valve function was excellent in all patients. Two patients showed mild pulmonary valve regurgitation in echocardiography after 6.2 and 6.6 years of follow-up, respectively, while all the other patients had no or only trivial regurgitation. No relevant valve stenosis was observed with a mean gradient of 12 ± 4 mmHg in echocardiography. Right ventricular dimensions had significantly decreased (Table 3). Symptoms and physical capacity improved significantly, and the majority were in NYHA functional class I at the last follow-up (Table 3). Eleven patients had chest radiograms after a median of 0.6 (IQR 0.5–3.1) years of follow-up, and only one patient showed a stent fracture of a single strut without compromise of stent integrity or valve function.

In two patients, relevant ventricular dysrhythmias occurred during follow-up. One patient experienced a sustained VT one month after PPVI. It degenerated to ventricular fibrillation while being treated in an emergency department; he was defibrillated to sinus rhythm after a short episode of cardiopulmonary resuscitation. After a subsequent electrophysiological study with ablation, he underwent ICD implantation. The second patient had sinus bradycardia and recurrent episodes of nonsustained VT during follow-up Holter monitoring despite antiarrhythmic therapy; therefore, implantation of an ICD was decided. No relevant ventricular arrhythmias were observed in the remaining patients. Of the four patients with newly initiated antiarrhythmic treatment, medication could be discontinued during follow-up in two and switched from amiodarone to ß-blocker in one patient, respectively. In one additional patient, discontinuation of ß-blocker is intended after repeated Holter.

A haemodynamically relevant femoral arteriovenous fistula requiring surgical treatment was diagnosed in one patient during follow-up. No further complications were observed.

Table 3: Comparison of baseline and follow-up data.

Parameter	Baseline	Last follow-up*	p
NYHA functional class			
I	6 (40%)	11 (73%)	
II	8 (53%)	4 (27%)	**p = 0.009**
III	1 (7%)	0 (0%)	
RVEDVi (ml/m^2)#	161 ± 32	115 ± 23	**p = 0.001**
RVEF (%)#	47 ± 6	46 ± 5	$p = 0.063$
PV RF (%)#	43 ± 11	6 ± 6	**p < 0.001**
RVEDD (mm)	56 ± 9	44 ± 8	**p < 0.001**

Data are presented as the mean ± standard deviation or frequencies (percentages). Right ventricular functional parameters were analyzed from MRI, and RVEDD was analyzed from echocardiography. Statistically significant p values are highlighted in bold. *Only 15/20 patients with available follow-up were analyzed in comparative analyses. #Only 8/20 patients with available follow-up MRI were analyzed in comparative analyses. MRI: magnetic resonance imaging; PV: pulmonary valve; RVEDD: right ventricular end-diastolic diameter; RVEDVi: indexed right ventricular end-diastolic volume; RVEF: right ventricular ejection fraction, RF: regurgitation fraction; RVOT: right ventricular outflow tract; RVESVi: indexed right ventricular end-systolic volume.

4. Discussion

Here, we report excellent results from our initial experience with the Venus P-Valve™ for PPVI in patients with large RVOT. Procedural success in our cohort was 100%, and implanted valves showed excellent function without relevant regurgitation or stenosis during follow-up of up to 6.6 years.

The development of PPVI has revolutionized the treatment of a huge number of patients with RVOT dysfunction after the repair of congenital heart disease. Balloon-expandable valves for PPVI valves have shown very good short- and long-term results; however, their limitations in size exclude a substantial number of patients with unsuitably large RVOT dimensions from treatment [9, 10, 12]. Currently, the Venus P-Valve™ is the only CE-certified valve intended for PPVI in large-dimension native RVOT available in Europe. It covers a wide size range of 28–36 mm diameter in 2 mm increments and allows percutaneous treatment of RVOT dimensions up to 33–34 mm, considering a safety margin for required oversizing. Thus, the Venus P-Valve™ considerably expands the options of PPVI providing a feasible alternative for patients not amenable to PPVI with hitherto available valves. Of note, critical evaluation of the RVOT morphology, comparable to PPVI with balloon-expandable valves, is paramount for the successful implantation of the Venus P-Valve™. While preprocedural magnetic resonance imaging is crucial in assessing RVOT

morphology for suitability of PPVI with the Venus P-Valve™, size measurements may differ substantially between imaging and angiography, as also seen in some patients in our cohort. Moreover, the dilated RVOT may be unpredictably compliant [13]. For the ultimate decision on PPVI and appropriate selection of valve size, balloon sizing of the RVOT is therefore to be recommended.

Deployment and implantation of the valve were safe and generally uneventful in our cohort and in previous studies [18–21]. Only in one case, we experienced a partial infolding of the self-expandable stent limiting controlled deployment. Complete infolding of the valve stent, requiring balloon dilatation, has been previously described but seems to be a rare phenomenon [23]. No particular device-related procedural complications were observed in our cohort. One major complication occurred; however, this was caused by guidewire perforation of the pulmonary artery during balloon sizing and was not related to the valve.

We did observe one case of stent fracture during follow-up (9% of patients with follow-up chest radiograms). Interestingly, stent fractures were found in up to 27% of the patients in a previous report after a mean follow-up of 25 months [18]. These, however, did not compromise valve function. Concordant with our findings, stent fractures were infrequent in various other studies [19–21]. Additional long-term follow-up data will be required to determine the causes and significance of stent fractures of the Venus P-Valve™.

Consistent with the limited previous experience with the Venus P-Valve™, patients in our cohort improved in the NYHA functional class and experienced marked right ventricular remodeling [18, 21]. The systolic right ventricular function did not improve in our patients, but was in general only mildly impaired before PPVI. Various studies reported no improvement in right ventricular ejection fraction despite remodeling after pulmonary valve replacement, suggesting that regurgitation should be remediated before relevant deterioration of function becomes evident [24]. However, the optimal time point for pulmonary valve replacement in patients with moderate-to-severe regurgitation is still a matter of controversy. Inconsistent results from studies and meta-analyses foremost indicate essential knowledge gaps [24–27].

One particular concern of self-expandable valves and devices for PPVI is the possible increase in the risk of ventricular arrhythmias. In addition to the overall increased risk in patients with tetralogy of Fallot, mechanical irritation by the foreign body protruding into the RVOT might facilitate the provocation of malignant arrhythmias such as VT. Moreover, arrhythmogenic substrates in the RVOT might become inaccessible after PPVI [28]. However, while a transient increase in the burden of PVC was observed in the majority of our patients, only a few showed persisting relevant ventricular arrhythmias at discharge. Nonetheless, one of our patients experienced a serious arrhythmic event with a sustained VT subsequently deteriorating to ventricular fibrillation; he had shown no relevant arrhythmias prior to discharge. Ventricular arrhythmias including VT have also been documented after PPVI with other self-expanding devices such as the Harmony™ and the Alterra™ but also with balloon-expandable valves [16, 29, 30]. While regular monitoring for arrhythmias is the standard of care in these patients and particularly essential before and after PPVI, there are currently no guildeline recommendations concerning preemptive electrophysiological studies to detect and ablate latent arrhythmogenic substrates, as recently advocated [28]. In the hitherto reported experience with the Venus P-Valve™, no overt risk of significant ventricular arrhythmias has been observed [18–21]. Appropriate risk stratification to guide arrhythmia screening and possible preemptive treatment will be an objective for future studies.

4.1. Limitations. Limitations of this study are inherent to its retrospective design, for which consistency of follow-up examinations and data acquisition is not given. Our study is restricted to a single institution, and results may not be generalizable. Moreover, our cohort is small and rare procedural complications may not have been detected. Importantly, our follow-up is limited and does not allow confident conclusions concerning the long-term performance of the valve or late complications such as infective endocarditis.

5. Conclusions

Early and midterm results with the Venus P-Valve™ are excellent. The self-expandable valve considerably extends the interventional options for PPVI and provides an alternative to surgical valve replacement in patients with large RVOT not amenable to PPVI with balloon-expandable valves. Larger multi-institutional studies with longer follow-up duration are required to reliably assess the long-term performance and possible long-term complications of the Venus P-Valve™.

Abbreviations

ICD: Implantable cardioverter-defibrillator
RVOT: Right ventricular outflow tract
PPVI: Percutaneous pulmonary valve implantation
PVC: Premature ventricular complex
VT: Ventricular tachycardia.

Data Availability

The data supporting the findings of this study are available on reasonable request from the corresponding author in accordance with applying data protection legislation. The data are not publicly available due to privacy or ethical restrictions.

Disclosure

Employers were not involved in the research, manuscript preparation, editing approval, or decision to publish.

Conflicts of Interest

F.B. and P.D. declare financial activities unrelated to the submitted work with several commercial entities. F.B. has received consulting fees and travel expenses from

Medtronic; consulting fees, travel expenses, and research support from Abbott; and consulting fees from Venus MedTech Europe. P.D. has received consulting fees and travel expenses from Venus MedTech Europe. None of the other authors have conflicts of interest to declare.

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