



Early Outcomes of Self-expanding VenusP-valve Implantation in Dysfunctional Right Ventricular Outflow Tracts in Pediatric Patients: A Single-Center Evolving Experience

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Abstract

Recent introduction into clinical practice of large self-expanding valves addresses the issue of dilated dysfunctional right ventricular outflow tracts (RVOTs). The purpose of this study was to determine the safety and short-term efficacy of the VenusP-valve (Venus MedTech) implantation in the pulmonary position in the pediatric group of patients with emphasis on the evolving qualification criteria and implantation techniques. Over a 14-month period, 15 patients < 18 years-old with severe pulmonary regurgitation underwent successful PPVI with the self-expanding VenusP-valve. All types of RVOT anatomies were represented in the study group. Desired valve position during the first attempt was achieved in 13 patients (87%). When compared between the first and second half of the study period, there was a significant difference toward less oversizing: 3.3 ± 1.4 mm versus 1.8 ± 0.7 mm, $p = 0.039$. On final angiography, trivial pulmonary regurgitation was present in 9 patients (60%). In the remaining 6 patients (40%), the valve was competent. Adverse events were limited to two patients (13.3%) with transient rhythm disturbances without any clinical sequelae. During a median follow-up of 11.5 months (range 7.9–21 months), all the valves remained normally functioning with no need for reinterventions and no episodes of infective endocarditis. The VenusP-valve implantation was safely and effectively performed in pediatric patients with all types of large dysfunctional RVOTs. With modified techniques of implantation, limited femoral vein access or stented pulmonary artery branches, the valves can be successfully implanted.

Keywords Pulmonary regurgitation · Precautious pulmonary valve implantation · Transcatheter pulmonary valve implantation

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Introduction

Despite the improvements in surgical techniques and introduction of biocompatible materials, dysfunctional right ventricular outflow tracts (RVOT) remain a major therapeutic challenge over longer-term follow-up after treatment of various congenital heart defects [1, 2]. Introduction into clinical practice of percutaneous pulmonary valve implantation (PPVI) added a valuable therapeutic option that enabled reduction of open-heart surgeries throughout the patient's lifetime [3, 4]. PPVI was pioneered with the initial introduction of Melody valve (Medtronic) followed by the Sapien valve (Edwards Lifesciences). The major limitation of the balloon-expandable valves is the maximum size of the RVOT that can be addressed with these valves: 22–24 mm for the Melody valve and 29–30 mm for the Sapien valve. Relatively recent introduction into clinical

practice of large self-expanding valves addresses the issue of dilated dysfunctional RVOTs [5]. One of the examples is the VenusP-valve (Venus Medtech, Hangzhou China) designed for implantation into surgically patched RVOT [6, 7]. The maximum available valve diameter is 36 mm with distal flares up to 46 mm. These features make the valve a valuable tool in the treatment of RVOTs not amenable to the balloon-expandable valves. The VenusP-valve clinical studies, conducted primarily in adult populations, have shown satisfactory results with excellent short and mid-term performance [6–8]. The valve gained CE marking in 2022, and shortly afterward, the first implantations in Poland were performed [9, 10].

The purpose of this study was to determine the safety and short-term efficacy of the VenusP-valve implantation in the pulmonary position in the pediatric group of patients with emphasis on the evolving qualification criteria and implantation techniques.

Methods

Study Design and Participants

This is a single-center, observational, retrospective study. Preprocedural imaging included transthoracic echocardiography (TTE) and cardiovascular magnetic resonance (CMR) or cardiovascular computed tomography (CCT). Patient selection and indications for PPVI procedure were conducted in compliance with the latest guidelines and were discussed at “heart team” meetings. The inclusion criteria required patients to be ≤ 18 years of age at the time of the procedure and have a minimum body weight of 30 kg. All patients underwent professional dental clearance before the PPVI.

Cross-sectional imaging was evaluated by an external imaging specialist to assess the suitability of the patients for PPVI with the VenusP-valve. Based on initial experiences patients were assigned to one of the following categories: green—not anticipating major challenges, amber 1—suitable anatomy, borderline size/stability of valve, amber 2—borderline anatomy, unusual maneuver anticipated, and finally red—unsuitable anatomy, or size, and will need surgery or hybrid approach.

The study protocol was approved by the Institutional Review Board. Written informed consent was obtained from the legal representatives and patient if ≥ 16 years-old. The risks and benefits of the procedure and relative novelty of the valve were emphasized.

Valve Implantation

All the procedures were performed under general anesthesia with endotracheal intubation and standard antibiotic prophylaxis. After establishment of ultrasound-guided vascular access, a dose of 100 IU/kg heparin was given. Initial hemodynamic assessment included right ventricular (RV), aortic (Ao) and pulmonary arterial (PAs) pressures. Angiograms were performed in the main pulmonary artery (MPA) and RVOT in two projections: the right anterior oblique with cranial angulation and left lateral. An exchange length 0.035" Lunderquist extra-stiff guidewire (Cook Medical) was positioned in one of the PAs, and RVOT distensibility was tested with a compliant, low-pressure 34 mm Amplatzer sizing balloon (St. Jude Medical), or 40 mm PTS-X balloon (NuMED) or a non-compliant Atlas balloon (Bard). Simultaneous aortography was performed to evaluate the presence of aortic regurgitation and the proximity of the coronary arteries to the potential landing zone of the valve. Initially valve selection was based on the manufacturer recommendations: 2–4 mm larger than the balloon waist. After rinsing, the valve was manually crimped on the delivery system and introduced into the RVOT through a 24 or 26 Fr DrySeal introducer sheath (Gore). Angiograms were performed during valve positioning and deployment via a pigtail catheter placed in the main pulmonary artery or a side-arm of the DrySeal sheath [11]. After the implantation, final angiographies and hemodynamic measurements were performed. Hemostasis of the femoral venous access site was achieved with a “z” suture, which was removed within 24 h post-procedure.

Post-procedure Management

Low molecular heparin in prophylactic dose was administered over the first 24 h, and oral aspirin (2–3 mg/kg/day) was started on the evening after the PPVI procedure and continued indefinitely. Rhythm monitoring consisted of bedside monitoring after the procedure and a pre-discharge 12-lead electrocardiogram (ECG). A TTE was performed on the evening of the procedure and before discharge. Patients were strongly advised to maintain excellent oral hygiene, avoid nail biting, piercing, and tattooing.

Follow-up

Follow-up visits were scheduled one month after PPVI and 3-, 6-, and 12-months post-procedure thereafter. Fluoroscopy to assess framework of the valve was performed on

3- and 12-months follow-up visits. Holter ECG monitoring was performed during the first or second check-up.

Statistical Analysis

Continuous variables were presented as mean $\pm$ SD when normally distributed, and as median and range when not normally distributed. Categorical variables were expressed as numbers and percentages. Comparisons were conducted with a two-sided unpaired Student's *t* test or nonparametric Wilcoxon test. *p* values < 0.05 were considered significant.

Results

Baseline Characteristics

Over a 14-month period, 15 patients < 18 years-old with severe pulmonary regurgitation underwent successful PPVI with the self-expanding VenusP-valve. Table 1 shows baseline patients characteristics. The majority were male (9 patients, 60%) and were diagnosed with tetralogy of Fallot (12 patients, 80%). All patients underwent surgical reconstruction of the RVOT with either a transannular patch repair (12 patients, 80%) or a monocusp valve tailored from homograft (3 patients, 20%). Four patients (25%) had undergone branch pulmonary artery stenting. Fourteen patients (93.3%) were classified as New York Heart Association (NYHA) class I or II and one was in class III.

Cross-sectional Imaging and Anatomy Type

In the 7 patients (46.7%) who underwent CMR study, all had significant degree of RV dilation with indexed end-diastolic volume ranging from 156 to 191 mL/m² (median 166 mL/m²) and pulmonary regurgitation fraction between 34 and 43% (median 40%) with preserved RV ejection fraction ranging from 51 to 59% (median 53%) (Table 1).

All types of RVOT anatomies as described by Schievano et al. were represented in the study group [12]. The most common types were pyramidal (4, 26.7%) and tubular (4, 26.7%), followed by reversed pyramid (3, 20%), convex type (3, 20%), and hourglass type (1, 6.7%). Two patients had coronary artery anomaly—dual anterior interventricular—in one patient coming from the left main branch and in another from the right coronary artery and crossing the proximal RVOT.

VenusP-valve Suitability

Based on the cross-sectional imaging, most patients (7, 46.7%) were assigned to the amber category including 6 with borderline anatomy (amber 2) and one with suitable

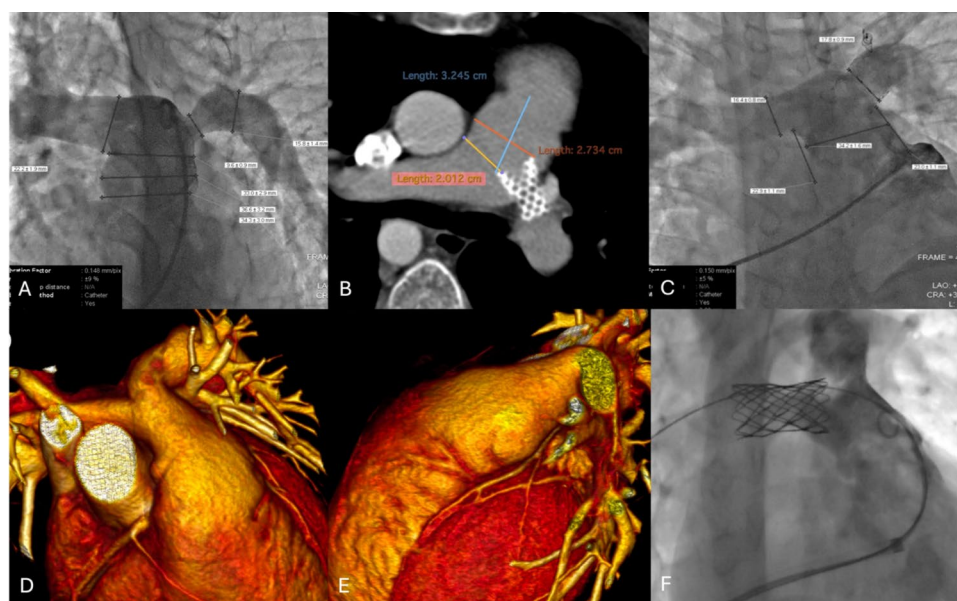
Table 1 Patients baseline characteristics

	N=15
Age, years	14.9 $\pm$ 2.3
Weight, kg	49.7 $\pm$ 11
Male	10 (62.5)
Diagnosis	
Tetralogy of Fallot	9 (60)
Tetralogy of Fallot, absent pulmonary valve	2 (13.3)
Pulmonary stenosis	2 (13.3)
Tetralogy of Fallot, pulmonary atresia	1 (6.7)
Pulmonary atresia, intact ventricular septum	1 (6.7)
Comorbidities	6 (40)
Intellectual disability	2 (13.3)
DiGeorge syndrome	1 (6.7)
Cantrell pentalogy	1 (6.7)
Pectus excavatum	1 (6.7)
Severe scoliosis	1 (6.7)
Right ventricular outflow tract treatment	
Transannular patch	12 (80)
Homograft monocusp	3 (20)
Stents in pulmonary arteries	4 (25)
Right pulmonary artery	2 (12.5)
Left pulmonary artery	2 (12.5)
New York Heart Association functional class	
I	7 (46.7)
II	7 (46.7)
III	1 (6.7)
Cross-sectional imaging	
Cardiac magnetic resonance	7 (46.7)
Computed tomography	6 (40)
Recent cardiac catheterization	2 (13.4)
Cardiac magnetic resonance data	
Indexed right ventricular end-diastolic volume, mL/m ²	169.4 $\pm$ 16
Pulmonary regurgitation fraction, %	38.8 $\pm$ 3.4
Right ventricular ejection fraction, %	54 $\pm$ 3.2
Right ventricular outflow tract type ¹²	
I	4 (26.7)
II	4 (26.7)
III	3 (20)
IV	3 (20)
V	1 (6.7)
Suitability category	
Green	5 (33.3)
Amber	7 (46.7)
Red	3 (20)

Values are mean $\pm$ SD, number and %

anatomy but borderline size (amber 1). Five patients (33.3%) were classified as green as no major challenges were anticipated. Twenty percent of patients (*n* = 3) were assigned to the red category. One patient had a very short (30 mm)

Fig. 1 Examples of patients initially deemed unsuitable for the VenusP-valve due to short and wide main pulmonary artery and a protruding stent in the left pulmonary artery (A–C), pyramidal shape right ventricular outflow tract with insufficient support at the proximal end (D, E), and a large stent in the right pulmonary artery protruding into the main pulmonary artery and limiting access to the left pulmonary artery (F)



and wide (min 33–36 mm on angiography) tubular RVOT with a stent at the origin of the left pulmonary artery (LPA, Fig. 1A–C). One patient had a wide pyramidal RVOT with anticipated insufficient anchoring for the valve at the proximal end together with a short distance from the level of the pulmonary valve to the PA bifurcation (Fig. 1D, E). Another patient had a tubular, short MPA (30 mm) with a large caliber stent in the proximal right pulmonary artery (RPA) limiting space at the bifurcation for expansion of the distal flare (Fig. 1F).

Vascular Access

A femoral artery and bilateral femoral venous access were obtained in 11 patients (Table 2). Due to unilateral stenosis or occlusion of the femoral veins, the procedure was performed using a single femoral vein approach in 3 patients (Fig. 2A). One patient had a complete occlusion of the right femoral vein and significant stenosis of the contralateral femoral vein; hence, PPVI was performed via the right internal jugular vein (Fig. 2B).

RVOT Balloon Interrogation

Compliant balloons were almost exclusively used for interrogation of the RVOT. In one patient with a reversed pyramid type RVOT and minimum angiographic measurements of 22–24 mm, a non-compliant balloon was utilized.

Aortography was performed in all but one patient in whom additionally selective left main coronary artery contrast injection was performed. There was no compromise to the coronary blood flow. Flattening of the aortic bulbus during RVOT balloon inflation occurred in 3 patients and led

to a significant regurgitation in 2 (13.4%). In one patient, a 34 mm AGA sizing balloon was inflated over a wire in the LPA, and in another, a 40 mm PTS-X balloon over a wire in the RPA (Fig. 2C). In one patient, RVOT interrogation with a non-compliant high-pressure balloon caused flattening of the left aortic sinus without aortic regurgitation. Control aortograms after valve implantation showed competent aortic valve in all 3 patients (Fig. 2D). Simultaneous RV contrast injection and RVOT balloon inflation were performed in 3 patients (20%). Minimal balloon waist diameter in any projection varied from 25 to 36 mm (median 30.6 mm).

Valve Selection

All available valve diameters were implanted with 30 mm being the most common (33.3%). In most patients (87%), the length of the middle part was 25 mm with only 2 (13%) receiving the longer valve. Overall, the diameter of the tubular segment of the valve was larger than the balloon waist diameter by mean of 2.5 mm (± 1.3 mm). When compared between the first and second half of the study period, there was a significant difference toward less oversizing: 3.3 ± 1.4 mm versus 1.8 ± 0.7 mm, $p = 0.039$.

Valve Delivery and Deployment

For valve deployment, a stiff guidewire was positioned in the distal lower lobe of LPA in 3 patients (20%) and in RPA in 11 patients (73.3%). In a single patient, valve implantation was initiated with the wire in the LPA, but due to oblique orientation of the distal flare at the PA bifurcation, the valve was recaptured and eventually implanted over the guidewire repositioned in RPA (Fig. 3). The tip of the DrySeal sheath

Table 2 Procedural characteristics

	N=15
Venous access (%)	
Bilateral femoral	11 (73.3)
Single femoral	3 (20)
Jugular	1 (6.7)
Pulmonary artery approach (%)	
Right pulmonary artery	11 (73.3)
Left pulmonary artery	3 (20)
Left, then right pulmonary artery	1 (6.7)
Sizing balloon type (%)	
34 mm compliant balloon	8 (53.4)
40 mm compliant balloon	6 (40)
26 mm non-compliant balloon	1 (6.7)
Min right ventricular outflow tract size on balloon	30.2 ± 3.2
Position of the DrySeal sheath	
Main pulmonary artery	6 (40)
Right pulmonary artery	7 (46.7)
Left pulmonary artery	2 (13.3)
Valve diameter, mm (%)	
28	1 (6.7)
30	5 (33.3)
32	3 (20)
34	3 (20)
36	3 (20)
Valve oversizing, mm	
Overall	2.5 ± 1.3
First half of the study period	3.3 ± 1.4
Second half of the study period	1.8 ± 0.7
Valve length, mm (%)	
25	13 (87)
30	2 (13)
Fluoroscopy time, min	23.4 (15–45.1)
Procedural time, min	137.5 (110–197)
Dose area product, uGy × m ²	197.6 (64.2–459.7)
Air Kerma, mGy	2154.0 (812–4061.4)

Values: number and %, mean ± SD, median and range

was placed either in the RPA (46.7%) or MPA (40%) and less often in the LPA (13.3%). Desired valve position during the first attempt was achieved in 13 patients (87%). The valve was successfully recaptured with assistance of the DrySeal sheath in two patients (13.3%) including the one described above and another with an hourglass RVOT in whom valve deployment from the LPA resulted in the distal flare migrating proximally below the narrowest part of the MPA. The situation recurred during the second deployment; however, due to stable distal flare position and unobstructed flow to the PAs, the valve was completely deployed leading to a stable position and good function.

In all patients, either proximal tubular segment or the proximal flare was implanted at the pulmonary annulus.

Additional Interventions

Of 4 patients with previously implanted branch PA stents, in 2 cases further stent dilation was performed prior to PPVI. In 2 patients (13.4%), adaptation of valve flares was performed with the same compliant balloon as used for RVOT interrogation. In one patient, control angiography after uneventful deployment of a 30 mm valve showed moderate pulmonary regurgitation. In the antero-posterior projection, a typical valve shape was noticed; however, in the lateral view, the distal flare was under expanded. Inflation of a 40 mm PTS-X balloon in the MPA/RPA led to further distal flare expansion and mild regurgitation. In another patient, the distal flare and mid-portion of a 34 mm valve expanded to a typical configuration; however, the proximal flare positioned at the pulmonary annulus was only partially outwardly orientated. A 34 mm AGA balloon was inflated in the mid and proximal part of the valve leading to partial reconfiguration of the proximal flare (Fig. 4).

Final Outcomes

On final angiography, trivial pulmonary regurgitation was present in 9 patients. In the remaining 6 patients, the valve was competent. Invasive pressure measurements did not show any significant gradients through the valve. Median fluoroscopy and procedural times were 23.4 and 137.5 min, respectively.

All the implantation procedures were successful, without any major complications. Adverse events were limited to two patients with transient rhythm disturbances without any clinical sequelae. One patient had ventricular bigeminy and couplets immediately after the procedure. Arrhythmia was successfully managed by intravenous Esmolol infusion.

Further Course

One patient had palpitations the same day after PPVI procedure. The ECG revealed monomorphic premature ventricular contractions (PVCs). Both patients remained hemodynamically stable and were discharged on prophylactic beta-blocker. Follow-up Holter ECGs did not show any significant arrhythmia, and the treatment was discontinued after 6 months.

Thirteen patients were transferred to an observation unit for a short period after PPVI procedure and then to the cardiology ward the same day. Two patients were sent for an overnight observation to the intensive care unit including the previously described patient, who presented with ventricular arrhythmia immediately after the procedure without

Fig. 2 Examples of VenusP-valve implantation in patients with limited venous access: through the single femoral venous access (**A**, white arrow) and the right internal jugular vein (**B**, black arrow). Example of aortic sinus compression and aortic regurgitation during balloon interrogation of the right ventricular outflow tract (**C**) and a competent aortic valve after VenusP-valve implantation (**D**)

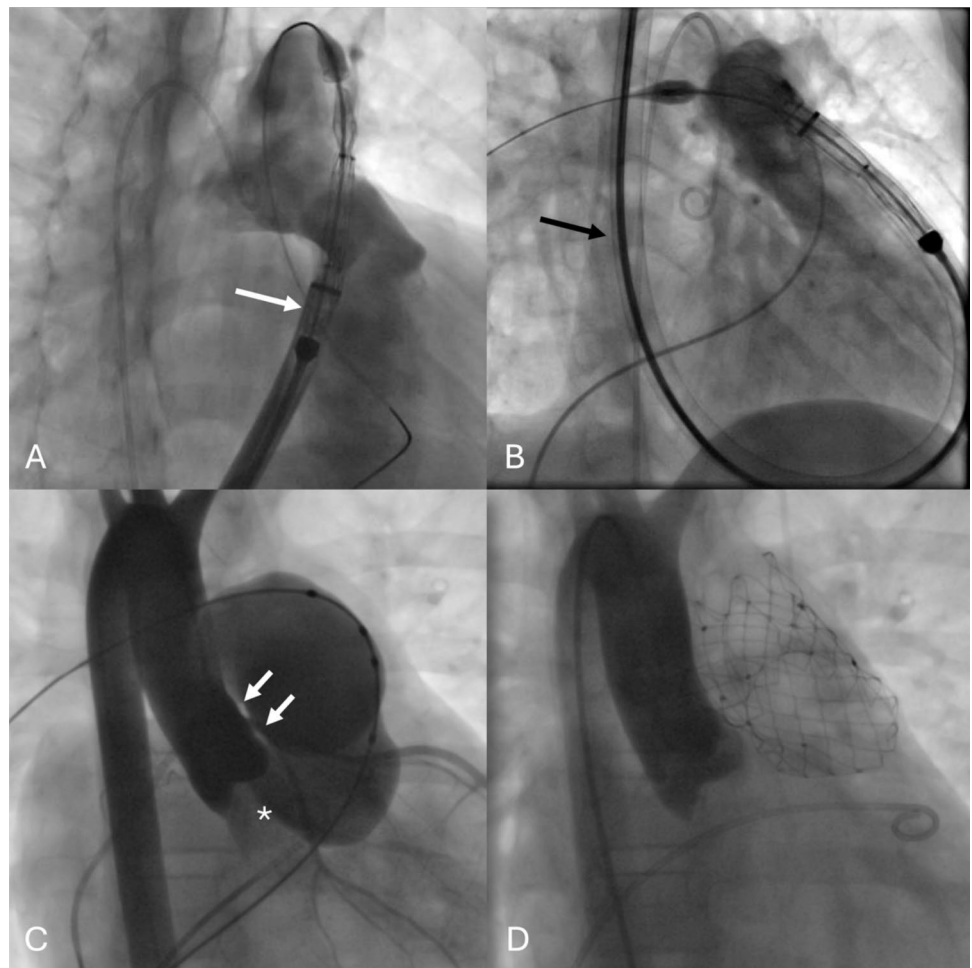


Fig. 3 Examples of alignment of the VenusP-valve (white dashed line) with the right ventricular outflow tract (black dashed lines) during implantation from the left pulmonary artery (**A**, **B**), recapturing with the DrySeal (Gore) sheath (black arrow, **C**) and successful deployment from the right pulmonary artery (**D**, **E**)

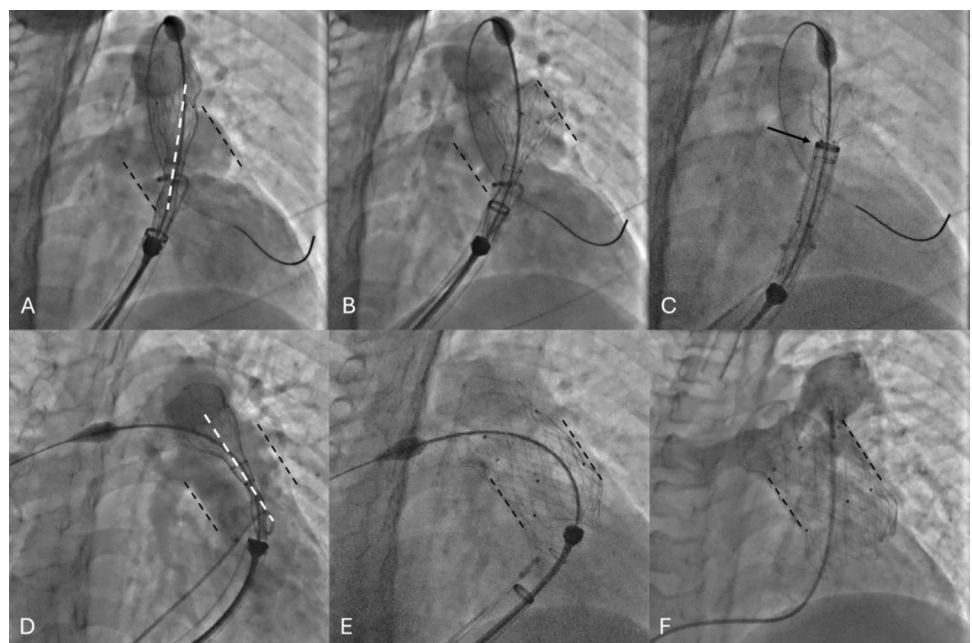
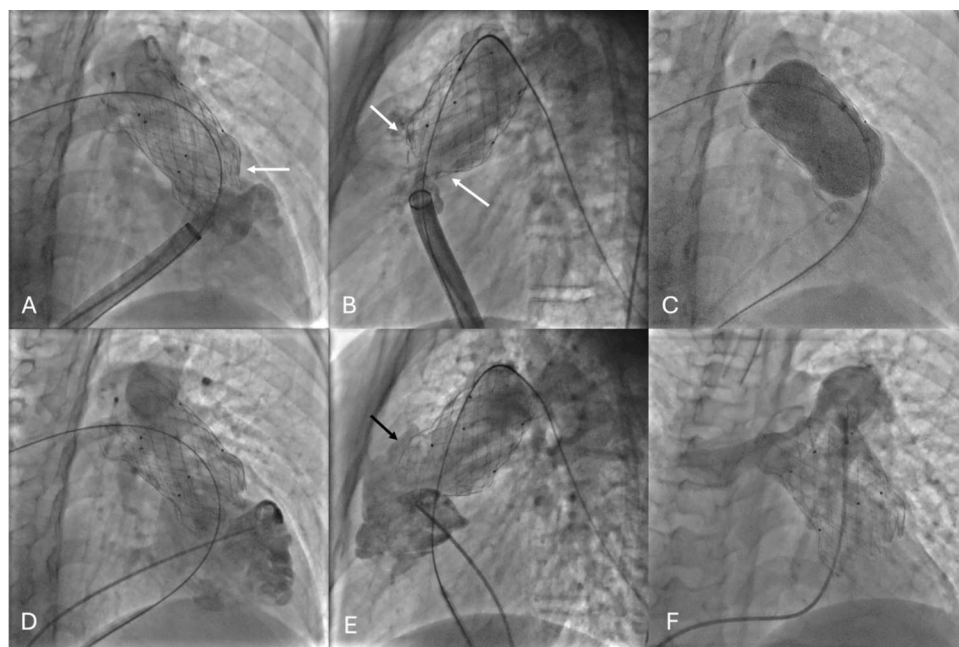


Fig. 4 Balloon adaptation of the proximal flare of the VenusP-valve. A control angiography (A, B) after deployment of a 34 mm valve implanted high in the right ventricular outflow tract shows the distal flare and mid-portion expanded to a typical configuration and constrained proximal flare (white arrows). A 34 mm AGA balloon was inflated in the mid and proximal part of the valve (C) leading to partial reconfiguration of the proximal flare (D, E; black arrow). Final angiography (F) shows unobstructed flow to pulmonary arteries with central trace of regurgitation



hemodynamic consequences and another patient with autistic spectrum disorder who required sedation due to lack of cooperation. Both patients were transferred to the cardiac ward the next morning.

Transthoracic echocardiography at discharge showed none or trace of pulmonary regurgitation in 10 patients and mild central regurgitation in the remainder. There was no worsening of preexisting tricuspid regurgitation, de-novo aortic regurgitation, regional wall motion abnormalities, pericardial effusion or paravalvar leak.

Overall median hospital stay was 4 days (2–6 days).

Follow-up

During a median follow-up of 11.5 months (range 7.9–21 months), all the valves remained normally functioning with no need for reinterventions and no episodes of infective endocarditis. Fourteen patients had improvement in exercise tolerance capacity of whom 13 patients were in functional NYHA class I at the latest follow-up. In one patient, NYHA classification was not possible to assess reliably due to lack of cooperation and difficulties in verbal communication.

There were no relevant rhythm or conduction disturbances on follow-up ECGs and Holter ECGs monitoring, nonetheless two patients remained on prophylactic beta-blocker therapy during the initial 6 months after the procedure. The most recent TTE showed none or trace of valve regurgitation in 6 patients and mild central regurgitation in 9 patients. There was no difference in maximum RVOT velocity between the predischARGE and the latest follow-up: 1.89 ± 0.3 m/s versus 1.96 ± 0.3 m/s; $p = 0.41$. Fluoroscopy

confirmed integrity of the nitinol frame of the valve in all cases.

Discussion

Our study reports good short-term outcomes of VenusP-valve implantation into all types of RVOTs in a pediatric cohort. The valve was successfully implanted in all attempted patients with preserved function, no reinterventions, and no infective endocarditis in up to 21 months of follow-up.

While the median age and weight of our cohort approach adult thresholds, this study remains distinct in that all participants were managed within pediatric cardiology settings. This pediatric designation is clinically meaningful, as younger patients require unique procedural considerations, tailored valve selection strategies, and long-term planning that accounts for somatic growth, future valve-in-valve interventions, and the eventual transition to adult congenital heart disease care. To date, there are limited data specifically addressing the implantation of self-expanding pulmonary valves in pediatric cohorts. Our experience provides novel insights into the performance and suitability of the VenusP-valve in this unique population.

The VenusP-valve's self-expanding nitinol frame, featuring three potential anchoring mechanisms—proximal flare, distal flare, or the tubular mid-section—offers conformability to the irregular RVOT anatomies commonly observed in congenital heart disease. Additionally, the absence of covering on the distal stent struts helps reduce the risk of obstructing the branch pulmonary arteries.

Importantly, the valve is available in a wide range of sizes, including larger diameters with shorter lengths, allowing for a more tailored fit to individual anatomies without excessive extension into the pulmonary artery branches or right ventricle. However, in patients with a particularly short RVOT, even the shortest available valve may pose a challenge, emphasizing the need for precise pre-procedural imaging and careful case selection.

The valve suitability reports generated from pre-procedural imaging provide a three-category assessment of potential valve suitability, offering recommendations on the optimal size range, pulmonary access route, and proposed landing zone. While these reports are helpful in the initial planning phase, they do not replace balloon sizing, which remains the gold standard for evaluating dynamic RVOT dimensions and identifying appropriate anchoring points.

With growing experience, we have widened the qualification criteria and modified the implantation procedure. Three patients in the study group were initially categorized as not suitable for the valve including two with stented PAs—a contraindication for PPVI with VenusP-valve at the time of submission of data for the external evaluation [7]. D'Aiello et al. reported successful VenusP-valve implantation in 3 adult patients just below the LPA stents [13]. We hypothesized that the unique design of the valve could also be advantageous in the setting of stented pulmonary arteries. If the distal uncovered cells of the valve were deployed at the level of the stent, there would be no threat of PAs being jailed. In our experience, PA stents in teenage patients did not preclude successful implantation of the valve, although they required sufficient predilation with high-pressure balloons [14].

Uni- or bilateral femoral vein occlusion is not uncommon in patients evaluated for PPVI. For those with limited femoral venous access, we successfully introduced a single vein approach with the DrySeal sheath used for the valve delivery and angiography during the valve positioning [11]. In case of the lack of adequate femoral veins, implantation of a large self-expanding pulmonary valve using the jugular vein approach was also technically feasible in one of our patients [15].

Unlike some other self-expanding pulmonary platforms, balloon interrogation of the RVOT is a part of routine patient evaluation prior to the VenusP-valve implantation [16, 17]. It does not add much to the complexity of the procedure but provides pertinent and important information. The primary benefit of balloon interrogation is the assessment of RVOT distensibility and the identification of potential choke points, as well as the evaluation of possible compression of adjacent structures such as the coronary arteries or the ascending aorta [18]. This information is essential for selecting the optimal valve size and determining the safest and most effective landing zone for implantation. For this purpose,

we almost exclusively used non-compliant balloons. In three patients, balloon inflation in the RVOT led to flattening of aortic bulbus and significant regurgitation in two—each with a different balloon inflated over a wire in the opposite PA. Another compression occurred with a high-pressure balloon, but without aortic regurgitation. The mechanism for compression was most likely a combination of pulling of the balloon to counteract the RV output pushing it distally and balloon overexpansion. Underfilling of the ascending aorta and change of the geometry of the aortic bulbus due to temporarily significant reduction of cardiac output during balloon occlusion of the RVOT might be another factor. All these patients showed no aortic regurgitation on final aortograms after valve implantation, nor on TTE during follow-up.

Initially valve deployment over a wire parked in the LPA was part of the implantation protocol [7–9]. Early in our experience we utilized this approach; however, in the only two patients in whom we had to recapture the distal flare of the valve, the implantation was initiated in the LPA. Although introduction of the valve over a wire in the LPA might be easier than with the wire in the RPA due to a smoother course, this advantage might be offset during deployment of the distal flare not aligning with the desired landing zone and forcing additional maneuvers. In the most recent patients, we preferred valve implantation over a wire in the RPA.

Although the valve has its own delivery system, a long, large caliber sheath was used to facilitate delivery, positioning, and recapturing, if required, similar to the experience with other valves [19]. Hydrophilic coating of the sheath allowed easy introduction to either femoral or jugular veins with no postprocedural complications in our pediatric patients. The latter might also be attributed to meticulous use of ultrasound guidance to select the optimal puncture site, serial vessel dilation with increasing dilator size, and careful manual hemostasis. Initially the sheath was introduced at least beyond the origin of the PA and followed with the delivery system. With this technique, the distal flare of the valve was mostly opened in one of the branches and then retracted toward the PA bifurcation. In the more recent patients, we introduced the sheath more proximally, just to the PA bifurcation, where subsequent uncovering of the distal flare was performed. This approach enabled reduced manipulation of a large caliber sheath in branch PAs yet provided enough support for smooth valve delivery and steady deployment.

In the early patients, we applied 2–4 mm oversizing in relation to the balloon waist diameter [7–9]. However, with more experience and better understanding of multiple anchoring mechanisms of the valve, we have aimed to oversize by up to 2 mm, and in 2 patients, we even used valves smaller than the balloon waist diameter. This approach

is reflected by significantly reduction of mean oversizing between the early and more recent patients (mean of 3.3 vs. 1.8 mm).

The relatively long frame of the valve might raise concerns regarding significant protrusion of the proximal flare toward the body of the RV in pediatric population. That was not the case in our experience. To avoid this situation in all but 2 patients, we selected the shorter (25 mm body) valve, and we attempted as distal implantation as possible. However, even with this approach, a total supra-annular implantation was not possible in this patient population.

The adverse effects were limited to transient rhythm disturbances without hemodynamic implications. Rhythm disturbances in the early postprocedural period following percutaneous implantation of self-expandable valves of other types, such as Pulsta (Company), Harmony (Medtronic Inc.), and the Alterra (Edwards Lifesciences), have been previously reported [17, 18, 20]. These are believed to be secondary to contraction-excitation feedback induced by myocardial stretching during repeated ballooning or certain degree of stent protrusion into the muscle of the sub-pulmonary outflow tract. This arrhythmia burden is usually self-limiting, as was the case in our two patients.

Although the VenusP-valve offers an effective percutaneous treatment for pulmonary regurgitation in pediatric patients, long-term planning must consider the possibility of future valve-in-valve procedures, as valve degeneration over time may necessitate reintervention [21]. The large stent housing of the VenusP-valve can typically accommodate one or more additional valves, minimizing the risk of a significant reduction in the effective valve orifice (*own unpublished experience*). Moreover, unlike RVOT-reducing devices, valve-in-valve implantation within the VenusP-valve does not require further expansion of the existing frame, thereby lowering the risk of compression on surrounding structures. While the valve's design facilitates future valve-in-valve procedures in most cases, some patients may ultimately require surgical replacement, particularly as they grow older or develop additional comorbidities.

Although these findings are promising, continued data collection and larger studies are warranted to confirm our results.

Conclusions

The VenusP-valve implantation was safely and effectively performed in pediatric patients with all types of large dysfunctional RVOTs. With modified techniques of implantation, limited femoral vein access, or stented pulmonary artery branches, the valves can be successfully implanted.

Author Contributions Conceptualization and methodology: S.G.; Original draft and figures preparation: S.G., M.L.; Resources: M.L.; Conceptual supervision: MG, SQ; Writing—review and editing: [MS, AR, RB, PD, MW]; guidance on study design and final approval of the manuscript: S.G, MG, SQ. All authors have read and agreed to the published version of the manuscript.

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Data Availability No datasets were generated or analysed during the current study.

Declarations

Competing Interests SG, MG, SQ are consultants and proctors for Venus Medtech. RB is an employee of Venus Medtech.

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