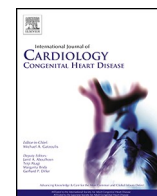




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Percutaneous implantation of self-expanding pulmonary valves: results from real-life experience of the Venus-P valve Registry of the Italian Society of Pediatric Cardiology (SICPED)[☆]

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ABSTRACT

Background: Self-expandable valves may have a significant impact on the feasibility of transcatheter treatments of RVOT dysfunction. Venus P valve is the first autoexpandable Valve that received CE mark in 2022. Here, we are reporting on a multicenter data collection about patients undergoing Venus P valve implantation in Italy.

Materials: Seven Italian centers were included in the study. Data were collected from patients treated with a Venus P valve between July 2022 and May 2024. Indication for percutaneous valve implantation were in accordance with published guidelines.

Results: During the study period, a total of 65 patients were considered eligible for percutaneous implantation of a Venus P valve. Median age at procedure was 35 years (IQR 12–63 years) median weight 63 Kg (IQR 33–103 Kg). Indication for PPVI was severe regurgitation in all subjects but one where ventricular pressure was increased because of stenosis on a homograft conduit and pulmonary arteries which needed previous bilateral stenting. Venus P valve was implanted successfully in 61/65 (94 %) patients. Four procedural complications occurred (6 %): 1 artero-venous fistula, 1 pulmonary bleeding, 1 hemothorax and a pulmonary oedema. During follow up (median 13 months, 1–20 months), all patients experienced a significant improvement of functional class. Neither deaths or re-intervention occurred. CT Scan showed hypoattenuating leaflet thickness (HALT) in 4 patients and one of them experienced endocarditis 12 months after the procedure.

Conclusions: Our study shows that Venus P valve implantation is safe and results are stable during a short-to-medium term follow-up. Endocarditis and HALT are inducing some concern and larger studies are needed.

1. Background

Percutaneous pulmonary valve implantation (PPVI) is a valid alternative to surgery in patients with dysfunctional right ventricular outflow

tract (RVOT) [1].

Until recently, balloon-expandable valves, as the Melody (Medtronic Inc., Minneapolis, MN, United States of America) and the Edwards-Sapien (Edwards Lifesciences, Irvine, CA, United States of America),

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have been the only options available for PPVI in those patients. However, these valves can treat RVOTs up to 29–30 mm in size and therefore 15–20 % of the patients with dysfunctional RVOTs can be treated percutaneously.

In order to overcome this limitation, self-expandable valves have been developed. Venus P valve (MedTech, Hangzhou, China) is the first self-expandable valve that obtained CE mark in 2022 and since then it has been used in clinical practice [2,3].

However, after CE mark, only a single case series from China [4] has been published. In order to collect data and monitor results, we have set a registry in Italy including results from 7 centers under the auspices of the Italian Society of Pediatric Cardiology (SICPED).

2. Methods

This is a multicenter, national, prospective study evaluating patients who underwent Venus P valve implantation. This Italian Registry, that involved 7 institutions, aimed to analyze the efficacy and safety of Venus P valve implantation as primary objectives.

Procedural success was defined as no more than trivial regurgitation on post-implantation angiography and a post implantation systolic peak to peak gradient <20 mmHg. Safety was intended as freedom from periprocedural early complications, including PPVI related death. Secondary objectives were success rate of auto-expandable valve implantation after two years from implantation and frequency of medium-term complications related to valve implantation.

The study was approved by the ethics committee of the participating centers.

3. Inclusion criteria

The study included patients with congenital heart disease, RVOT dysfunction and pulmonary insufficiency with an indication to percutaneous pulmonary valve implantation.

Current guidelines for PPVI have been used [5]. Exclusion criteria were: weight <30 kg, clinical or biological signs of infection, known allergy to aspirin, other antiplatelet agents or heparin and pregnancy. All patients underwent cardiac MRI and cardiac CT before the procedure and the images were sent to a review board of the manufacturer company in order to evaluate eligibility to PPVI with Venus P valve.

4. Venus P valve

Venus P valve is the first self-expandable valve approved in Europe in 2022. It is a self-expanding nitinol stent with inside a tri-leaflet porcine pericardial tissue valve preserved in a low-concentration solution of buffered glutaraldehyde and hand-sewn inside of the nitinol frame. The stent has a proximal and a distal flare to anchor the valve in the RVOT. The proximal flare is covered by pericardial tissue, whereas the distal flare is an open cell wire frame to avoid obstruction of the pulmonary artery branches. The middle part is fully covered by pericardium.

The diameters of the middle part ranges from 28 mm to 36 mm with 2 mm increments and the lengths are 25 and 30 mm. The proximal and distal flare are 10 mm larger than the middle segment.

The delivery system consists of a 16 Fr-100 cm long shaft catheter with a 20–22 Fr capsule and a handle rotating mechanism for deployment of the valve. It is advanced through a 22–24 Fr sheath.

The valved stent is crimped and loaded into the delivery system under sterile cold saline solution which helps to reduce the memory property of nitinol.

5. Procedure

The procedure was extensively described in previous reports [6]. Briefly, valve implantation was performed under general anesthesia and from the femoral vein in all the patients.

After angiograms performed in different projections in order to obtain the best visualization of the main pulmonary trunk (MPT) and pulmonary branches, a sizing balloon was carried out over a stiff guidewire placed in a pulmonary branch, in order to obtain a precise measurement of the MPT (waist diameter) and to exclude coronary compression. Valve diameter was decided by measuring the balloon waist and the maximum angiographic systolic diameter of the mid and distal MPA and then oversizing by 2–4 mm. Length of the valve was chosen on the basis of the distance from the pulmonary valve annulus and PA bifurcation.

The valve was advanced into the right heart through a distally placed Lunderquist guidewire (Cook Medical, Bloomington, IN, USA) and through a DrySeal 26 Fr (W.L. Gore and Associates, Flagstaff, Ariz). The distal flare of the valve was opened into the pulmonary artery (usually the left) and the rest of the valve was then deployed slowly, whilst carefully withdrawing the system to allow the distal flare to slide out the PA origin into the MPT.

Frequent check angiograms with a pigtail placed into the right ventricle were frequently performed during valve positioning and deployment.

Antibiotic prophylaxis was administered on the basis of single hospital protocols. The patients were discharged on different antithrombotic or antiaggregant therapies.

6. Follow up

The patients were evaluated the day after the procedure and then at one, three and six months, then yearly thereafter. Every evaluation included clinical assessment, electrocardiogram and transthoracic Echocardiogram (TTE). According to local hospital protocols some patients underwent a CT scan after 3–6 months and a MRI after one year. A Holter EKG was applied in 12 patients one month after the procedure.

7. Statistical analysis

Categorical variables were expressed as frequency and percentage, continuous variables as median and interquartile range. The comparison of the continuous variables was carried out by independent Student T test or one-way analysis of variance whichever was appropriate based on the distribution of data. A p Value less than 0.05 was considered statistically significant.

8. Results

8.1. Population

From July 2022 to April 2024, in 7 Italian centers, 396 patients underwent pulmonary valve replacement for a dysfunctional RVOT. Two hundred and thirty-one patients (58 %) were treated surgically while 168 (42 %) percutaneously: 101 with a balloon expandable valve and 64 with an auto expandable valve (61 with a Venus P valve and 3 with an Alterra and Sapien Valve for compassionate use). We analyzed the impact of the time-period on the adoption of the self-expandable technology and the impact of PPVI on percentage of patients treatable by a percutaneous approach instead of surgery.

We defined a period 1, between July 1, 2022 and April 30, 2023, and period 2, between May 1, 2023 and May 30, 2024.

In period 1, 123 pts underwent surgery while 63 pts received a PPVI (balloon expandable in 40; self-expandable in 23). In period 2, 108 pts underwent surgery while 103 pts received a PPVI (balloon expandable in 62; self-expandable in 41) (Fig. 1). This difference showed a statistically significant difference ($p < 0.05$).

A total of 65 patients were considered eligible for Venus P valve implantation in the period from 01.07.22 to 30.05.24, median age at procedure was 35 years (IQR 12–63 years) median weight 63 Kg (IQR 33–103 Kg). Forty-seven patients (72 %) had a diagnosis of Tetralogy of

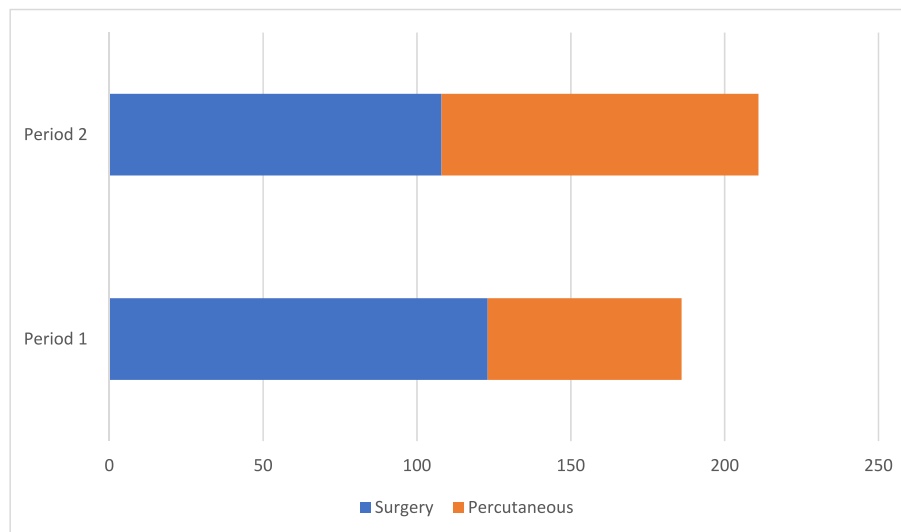


Fig. 1. Percentage of percutaneous (blue) and surgical (orange) pulmonary valve implantation divided in two periods (period 1: 01/07/22–30/04/23; period 2: 30/04/23–30.05.24).

Fallot, 16 patients (25 %) of pulmonary stenosis, one patients of pulmonary atresia and VSD and one had transposition of great arteries. Four subjects had also a Trisomy 21 syndrome.

Fifty-nine patients (91 %) underwent previous surgical procedures (57 a transannular patch, 1 with a conduit interposition and one a switch operation), 6 patients were treated with a percutaneous valvuloplasty. Six patients had previous PA stenting.

Indication for PPVI was regurgitation in all subjects but one where ventricular pressure was increased because of stenosis on a homograft conduit and pulmonary arteries which needed previous bilateral stenting.

At MRI, all the patients had a severe pulmonary regurgitation (median RF 42 %, IQR 35–49 %), with a severely dilated right ventricle RV (median VTDRV 165 mL/m², IQR 142–197 mL/m²) and a median RV ejection fraction of 43 % (IQR 37–51 %). At CT-Scan, diameters of MPT ranged from 21 mm to 44 mm, 35 patients (53 %) had a MPT diameter >30 mm. All the patients complained reduced functional capacity. Twenty-three patients (35 %) had a past history of arrhythmias: 11 patients had isolated ventricular ectopic beats, 4 patients suffered of ventricular tachycardia and underwent ICD implantation and 8 patients had events of supraventricular arrhythmias (Fig. 2). Seven patients

underwent an electrophysiological study and of them, 4 were ablated before the procedure.

8.2. Procedure

All the procedures were performed under general anesthesia from the femoral vein. At catheterization all the patients presented a normal RV pressure, except one, corrected with a homograft and stenting of both pulmonary arteries, who showed an increased RV pressure.

A sizing testing was carried out in all the patients in order to confirm PPVI eligibility, to choose valve size and to exclude coronary compression: in 53 patients a sizing balloon (Abbott Vascular, California, US) was used, in 10 a PTS-X sizing balloon (Braun Interventional Systems Inc., Bethlehem, PA) and in 2 a BIB balloon (NuMED, Hallenweg, Netherlands). In 4 patients a sizing balloon and a BIB balloon were successively used.

Venus P valve was implanted successfully in almost all the patients (61/65, 94 %). In four patients the procedure failed: in two because of an under over arrangement of PAs, in one because of coronary compression at sizing test and one patient with TGA had a main pulmonary artery which was short to accommodate even a 25 mm long Valve.

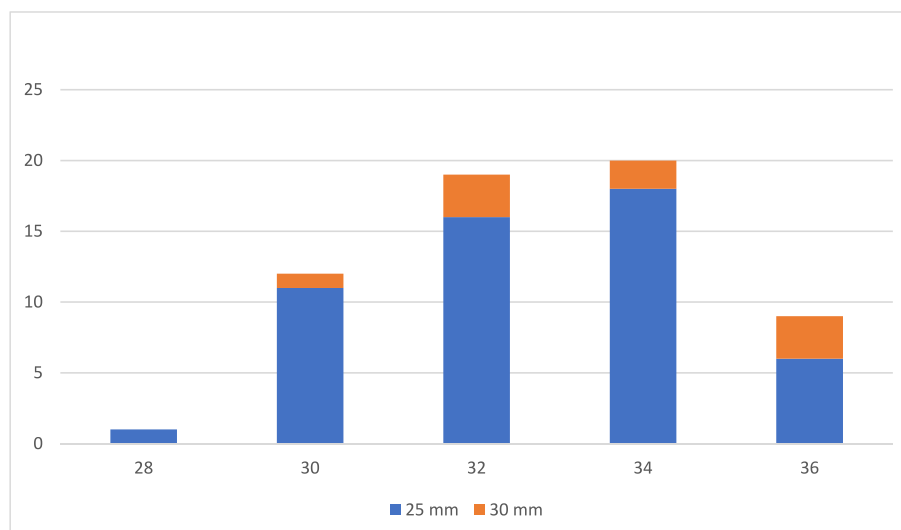


Fig. 2. Venus P valve sizes.

Implanted valve sizes were listed in Fig. 2. In total a shorter valve was implanted in the large majority of patients (52/61; 85 %).

Median procedural time was 170 min (IQR 98–240 min) and median fluoroscopic time was 37 min (IQR 22–49 min).

Four procedural complications occurred (6 %): 1 artero-venous fistula that sealed spontaneously after 2 months, 1 pulmonary bleeding that required some days of intensive care unit stay and one hemothorax requiring a percutaneous drainage and coil occlusion of a distal pulmonary branch perforated by the lunderquist guidewire used for PPVI and a pulmonary oedema.

Post procedural recovery time was uneventful for almost all the patients except for 2 who experienced fever without signs or laboratory markers of infection and 12 (19 %) who suffered of frequent ventricular ectopic beats necessitating beta blockers therapy.

All the patients were discharged after 3 or 4 days on antiaggregation or anticoagulation therapy according to local protocols.

8.3. Follow up

Median follow up was 13 months (IQR 1–20months). All the patients experienced an improvement of the functional class (Fig. 3). In 12 patients, who suffered of ventricular ectopic beats, an Holter EKG was performed and showed a significant reduction of the ectopic beats. No event of TV or sudden death occurred.

At Echocardiogram performed at 1, 6 and 12 months all the valves were normally functioning without significant gradient or paravalvular leaks.

Ten patients underwent a CT scan in the first three months after the procedure and in 4 patients a thickening of the leaflets with a reduced movement (HALT) was detected. HALT was clinically silent in all the patients. Echocardiogram of these patients showed no gradient, only in 3 patients a mild central pulmonary valvar insufficiency was described. Three patients were treated with anticoagulation with a net reduction of leaflet thickening at CT scan performed after 3 months (Fig. 4). One of the patients with HALT experienced more than 12 months after the procedure an endocarditis on Venus P valve related to *Enterococcus faecalis* and is actually on antibiotics therapy.

The valve has a mild regurgitation and a mild systolic gradient of about 30 mmhg.

9. Discussion

Until few years ago, experience with PPVI was limited to balloon expandable valves (Sapien and Melody). Several trials [7,8] have been published showing good clinical results for both valves with a good durability over a period of at least 5 years. Both valves were used not

only in conduits but also in native outflow tracts [9,10] with an exclusion rate of more than 60–70 %, related to the limited diameters of both valves.

In the last years many efforts have been concentrated on self-expanding systems to provide valve competence despite significant dilatation of the RVOT.

The Medtronic Harmony valve is the first FDA-approved self-expanding valve designed specifically for the treatment of regurgitation in native malfunctioning RVOTs [11]. The Harmony valve design utilizes a wire frame knitted into a polymer cloth, a previously utilized technology in self-expanding stent grafts. The valve housing contain a 22 or 25 mm pulmonary valve but, if needed a balloon expandable valve can be placed inside the Harmony frame rate. The Alterra Adaptive Prentest (Edwards Lifesciences) was designed with the scope to create a landing zone suitable for a Edwards 29 mm valve implantation. The FDA has approved its use in 2021 [12].

In Europe, the first self-expandable valve That received the CE Mark was the Venus P Valve. Since its first implantation in 2014 [13] some reports described the use of this self-expanding prosthesis in enlarged RVOT with a high success rate.

Zhou et al. [14] reported the Chinese experience with the description of 55 implants, showing a success rate of 98 %. In the only failure, the patient experienced a valve dislodgement in the right ventricle two days after the procedure and underwent surgical intervention. The CT scan of this patient showed a cone inverted shaped RVOT that is a very challenging anatomy for valve implantation.

Morgan G et al. [3] published the pre-CE mark international experience with the Venus P Valve, describing 38 implants. Their success rate was 97 %. There was one failure related to a break in the sheath covering of the valve during manipulation across PA bifurcation for the presence of a stent in the left PA and one patient needed a surgical stabilization of the valve.

In our registry success rate was 94 % and failure to implant was due to challenging anatomy of pulmonary arteries, shortness of main PA in transposition of the great arteries and coronary compression at balloon sizing.

Furthermore, in our registry, the introduction of autoexpandable valves has increased the number of patients cadidable to PPVI, reducing therefore the number of patients undergoing surgical procedure. Infact, while in the first period 34 % of patients were suitable to PPVI, their percentage increased up to 49 % in the second year of experience.

At the beginning of the experience with the Venus P Valve anatomy of the pulmonary arteries and in particular the presence of a stent was a relative contraindication because of the risk of interference of the stent during valve deployment. However, probably due to improvement in deployment technique, in Italian Registry six successfully implanted patients (10 %) had a previous PA stenting. As a further result, the large majority of patients (85 %) received a 25 mm long Venus-P valve.

In line with other reported experiences, in our registry procedural complication rate was low (4/61; 6 %) and all were minor or mild. In particular, we reported no cases of embolization or need of emergent surgery. In other studies [3,7] the rate of valve embolization ranged from 1 % to 5 % and usually it was related to a challenging MPT anatomy or to an incomplete detachment of the valve form the delivery system. In the case of an auto-expandable system, incomplete detachment is of particular concern [2]. During the procedure attention must be paid to the appearance of the proximal flare in two different fluoroscopic views checking the release from the proximal hooks, moreover delivery catheter pull back must be very careful and under fluoroscopic guide in order to rule out a valve engagement with this.

Twelve patients (19 %) showed the days after the procedure frequent ectopic ventricular beats also organized in short runs of non-sustained ventricular tachycardia. All these arrhythmias resolved at Holter EKG performed after one month. We speculated that the reason of the ectopic beats could be the position of the proximal flare of the valve into the muscular part of RVOT. In presence of a very long MPT, one option is to

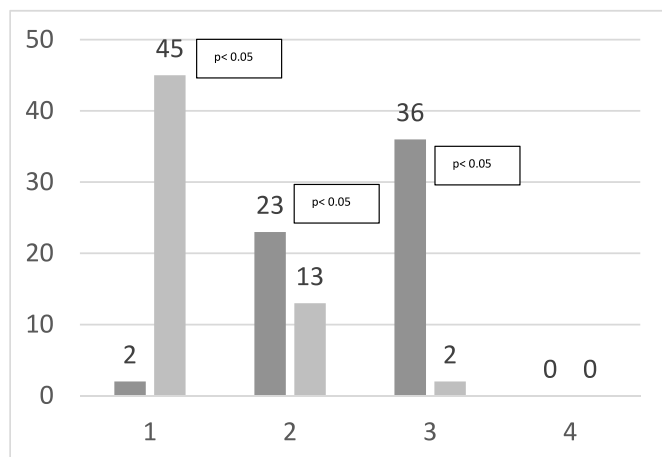


Fig. 3. NYHA Class improvement.

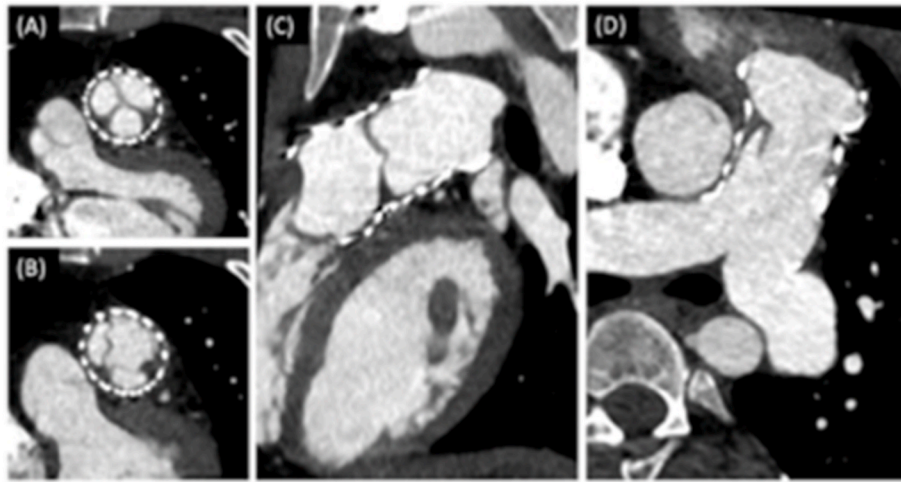


Fig. 4. Contrast-enhanced CT images of three orthogonal multiplanar reconstruction views of Patient 1 after Venus-P valve implantation, showing hypoattenuating leaflet thickening of the valve cusps towards the annulus (A,C), with reduced leaflet systolic excursion of the right and inferior facing leaflets (B,D).

implant the valve in supra-annular position with some advantages: avoiding ectopic ventricular beats and eventual frame fracture and making moreover the RVOT approachable in the future for potential electrophysiological procedures.

The median follow-up of our study was 13 months with the longest follow up of 20 months. During this period all the valves were well functioning at echocardiogram without any gradient, significant insufficiency or paravalvular leaks. There were no deaths or need for reintervention and all the patients experienced a subjective improvement of symptoms and effort tolerance. Antiplatelets were not discontinued in any patient.

Endocarditis is an important issue after PPVI with an annual incidence of 2.4 % [15,16] in patients with balloon expandable valves. In our Registry one case of endocarditis was described. The patient had at a previous CT scan a subclinical leaflet thrombosis in presence of a normally functioning Venus P valve and he was not treated with anticoagulation. Sivakumar et al. [2] described 1 case of endocarditis among 29 implanted patients at 4 years after implantation that was treated medically. In the Chinese Registry [4], with the longest published follow up of 5 years for the Venus P valve, endocarditis occurred in 5 Patients out of 55 (9 %).

One of these patients died and one needed surgery, showing a survival rate after infection (intendetragliinfetti) of 91 %. Authors attributed this complication to the lack of strict clinical practice in performing antibiotic prophylaxis following surgery and percutaneous procedures.

Nine of our patients underwent a CT scan after Venus P Valve implantation and in 4 of them a subclinical leaflet thrombosis (HALT) was detected [17]. This event has been widely described in TAVI [18], however, its clinical significance has not been well understood. In some studies, it seems to be related to follow up valve malfunctioning [19].

Only one report described HALT in biological pulmonary valves [20]. At CT scan performed in 12 patients after Edwards valve implantation in pulmonary position, HALT incidence was about 57 % with no evidence at echocardiogram of valve dysfunction.

Causes of leaflet thrombosis are yet not completely known and are probably multifactorial such as consequences. Three of our patients underwent anticoagulation therapy with thrombosis resolution. Other registries about Venus P Valve did not describe any case of HALT but CT scan was not routinely performed in those studies.

Even if the clinical significance is still unclear, we think that it may have an impact on valve durability and potentially also on the risk of valve endocarditis as showed by the fact that the only patient experiencing infection in this registry had HALT. Strict surveillance is mandatory after valve implantation and any signs of malfunctioning

needs to be deeply investigated.

10. Limitations

This study has some limitations. First of all, population size and follow up duration are relatively small. Moreover, procedural approaches and follow-up protocols may vary among institutions, affecting partially the uniformity of data.

11. Conclusions

Our study shows that Venus P valve implantation is safe and results are stable during a short-to-medium term follow-up. Further follow-up and larger studies will be needed to further clarify several issues.

12. Impact on daily practice

We have shown that autoexpandable pulmonary valves are increasing the number of patients eligible for PPVI. Preliminary results of the use of Venus P Valve are promising even if larger studies with longer follow up are needed.

CRediT authorship contribution statement

M. Pilati: Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **F.A. D'Aiello:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation, Conceptualization. **M. Chessa:** Writing – review & editing, Visualization, Validation, Supervision, Conceptualization. **G. Santoro:** Writing – review & editing, Validation, Supervision, Data curation. **A. Donti:** Writing – review & editing, Data curation. **E. Mariucci:** Writing – review & editing, Data curation. **C. Marrone:** Writing – review & editing, Data curation. **G. Annoni:** Writing – review & editing, Data curation. **G. Gaio:** Writing – review & editing, Data curation. **M. Rebonato:** Writing – review & editing, Data curation. **E. Piccinelli:** Writing – review & editing, Data curation. **M. Cheli:** Writing – review & editing, Data curation. **R. Formigari:** Writing – review & editing, Data curation. **G. Butera:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial

interests or personal relationships that could have appeared to influence the work reported in this paper.

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