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Early results of Pulsta® transcatheter heart valve in patients with enlarged right ventricular outflow tract and severe pulmonary regurgitation due to transannular patch*

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Abstract

Objective: The purpose of this study is to assess the feasibility, effectivity, and safety of a novel self-expandable valve system, Pulsta® transcatheter heart valve in patients with tetralogy of fallot and severe pulmonary regurgitation after transannular patch repair. *Background:* Severe pulmonary regurgitation after tetralogy of fallot repair is a life-threatening problem and should be treated by pulmonary valve implantation. Although percutaneous pulmonary valve implantation has been ever increasingly used for this purpose, available balloon-expandable valves have limitations and cannot be used by most patients. Pulsta® transcatheter heart valve is a new self-expandable valve system and offers a new solution to be used in patients with different types of native right ventricular outflow tract geometry. *Patients and Methods:* Ten patients with severe regurgitation after tetralogy of fallot repair with a transannular patch have been enrolled in the study according to echocardiographic examination. MRI was used in asymptomatic patients to delineate the indication and the right ventricular outflow tract geometry. Pulsta® transcatheter heart valve implantation was performed in ten patients, and preprocedural, procedure, and 6 months follow-up findings of the patients were evaluated. *Results:* Pulsta® pulmonary valve implantation was performed in ten patients successfully without any severe complications. Valve functions were perfect in six of ten patients, while the others had insignificant regurgitation by echocardiographic examination at the end of 6 months follow-up. *Conclusions:* This study showed that Pulsta® transcatheter heart valve is a feasible, effective, and safe method in the treatment of severe pulmonary regurgitation due to transannular patch repair in patients with tetralogy of fallot.

Severe pulmonary valve regurgitation is a life-threatening condition, which often emerges in long-term follow-up of tetralogy of fallot surgical repair.[1] Severe pulmonary regurgitation causes right ventricular failure and eventually ends up with exercise intolerance, dyspnoea, and ventricular arrhythmias.[2] Subsequently, percutaneous pulmonary valve implantation has been developed as an alternative to surgery in recent years but has limitations.[3] Although in certain cases balloon-expandable valves could be useful, they do not fulfill the wide spectrum of patient requirements due to variability of the right ventricular outflow tract morphology and technical difficulties in a large right ventricular outflow tract.[4] There are limited ongoing clinical trials regarding self-expandable valves for the pulmonic position, yet this area is still attractive for cardiologists since optimisation is needed.[4,5] A new self-expandable valve Pulsta® (TaeWoong Medical Co., Gyeonggi-do, South Korea) provides a new opportunity for pulmonary valve implantation, yet the data are limited by Korean publications.[6–8] Herein, we present early results of our experiences with Pulsta® valve in native right ventricular outflow tracts.

Patients and methods

Patient selection

The patients with a history of total repair of tetralogy of fallot with a transannular patch were recruited for the study. Inclusion criteria are based on previously defined indication criteria for pulmonary valve replacement in patients with moderate or severe pulmonary regurgitation.[9] In patient 1 although volume criteria did not fulfil the pulmonary valve implantation criteria, he had right bundle branch block with QRS prolongation over 160 msn and moderate tricuspid regurgitation in echocardiographic examination. Patients were enrolled with a diameter of the main pulmonary artery with transthoracic echocardiography larger than 16 and smaller than 30 mm.

The informed consent and follow-up requirements were explained, dated, and signed with the approval of the faculty ethical committee. The patients with pre-existing mechanical heart

Table 1. Demographic and clinical data of the patients

Patient	Age (year)	Gender	Weight (kg)	Diagnosis	Lesion
1	13	Male	53	TOF	Pulmonary insufficiency
2	38	Female	64	TOF	Pulmonary insufficiency
3	11	Male	33,5	TOF	Pulmonary insufficiency
4	12	Male	45,5	TOF	Pulmonary insufficiency
5	19	Female	58	TOF	Pulmonary insufficiency
6	8	Male	33	TOF	Pulmonary insufficiency
7	14	Male	68	TOF	Pulmonary insufficiency
8	33	Female	53	TOF	Pulmonary insufficiency
9	12	Male	39	TOF	Pulmonary insufficiency
10	9	Male	28	TOF	Pulmonary insufficiency

valve in any position, obstruction of the central veins, coronary artery compression, known hypersensitivity to aspirin or heparin, immunosuppressive disease, active infectious disease, estimated survival less than 6 months, child-bearing potential, or are currently breastfeeding an infant were excluded. Demographic and clinical data of the patients are presented in Table 1.

The patients with severe pulmonary regurgitation and dilatation of the right ventricle were evaluated in terms of the main pulmonary artery diameters, flow velocity throughout the right ventricular outflow tract, pulmonary artery branch peak velocity, and tricuspid valve functions. Screening for feasibility was performed by measuring the colour Doppler diameter size of the main pulmonary artery at the end of systole in a short axis view. Echocardiographic measurements were not considered the final decision-making parameters for valve size choosing. Additionally, at least three measurements were made from the main pulmonary artery in systole, and an average diameter was accepted. Since we need a landing zone, the smallest diameters of the MPA are considered appropriate (Fig 1).

Ten patients were considered candidates for the Pulsta® valve implantation. Cardiac MRI angiography was performed in all asymptomatic patients. MRI is used as inclusion criteria and for the evaluation of the detailed anatomy of the right ventricle, right ventricular outflow tract, pulmonary artery, and branches. MRI images from the axial and sagittal sections were also measured, and the mean main pulmonary artery diameter was taken as the diameter of the main pulmonary artery.

Product

Pulsta® Valve

Pulsta® Valve is composed of nitinol wire self-expandable stent frame and decellularized anti calcification treated porcine pericardium leaflets which are sewn to the nitinol stent wall. Available valve diameters start from 18 to 32 mm with 2 mm increments. Both sides of the valve are flared and 4 mm wider than the outer diameter. The total length options of the valve are 28, 31, 33, and 38 mm according to right ventricular outflow tract length.

Valve leaflet is made of the porcine pericardium and treated with decellularisation, α galactosidase treatment to remove the α-gal xenoantigen, space filler treatment, glutaraldehyde fixation, organic solvent treatment, and finally detoxification (Fig 2).[6,7]

Delivery catheter system

The transcatheter delivery with a total length of 110 mm system is shown in Figure 3. A conical tapered tip of 17 mm in length provides smooth vessel introduction. The diameter of the outer sheath in the valve loading zone is 18 F, and the diameter of the catheter shaft is 12 F. A hook block is designed to provide controlled release of the device. The valve is easily loaded into the delivery cable just before catheter exchange using a commercialised Heart Valve Crimper (Model right ventricles (RVs), Blockwise Engineering LLC, AZ).[6–8]

Valve implantation procedure

Before the procedure cephazolin, 50 mg/kg was given intravenously as prophylaxis and repeated 6 hours after the procedure.

All procedures were performed under general anaesthesia and a biplane angiography machine. Introducers were placed right and left femoral vein and left femoral artery. Patients heparinised 50 Unit/kg and the dose has determined according to the activated clotting time, which should be between 150 and 250 seconds. Right heart catheterisation was performed, and right ventricle, pulmonary artery, and aorta pressures were measured. Table 2 depicts the angiographic data of the procedure. Then the angiograms were completed on cranial-right anterior oblique and 90-degree left lateral positions. The narrowest part and the length of the main pulmonary artery were measured (Fig 4). A sizing balloon advanced to the main pulmonary artery and inflated; simultaneously aortic root angiogram also was done to interrogate coronary artery compression. Another injection was performed in the right ventricle by using a pigtail catheter advanced, which is advanced from the contralateral femoral vein and total occlusion of the right ventricle flow by sizing balloon (Fig 5). Pulsta® valve size was selected according to measurements of the sizing balloon. Generally, the device which is 2–4 mm larger from the narrowest area of the main pulmonary artery during the balloon occlusion test was selected. After diagnostic steps are completed, a stiff wire such as Backup Meier® (Boston Scientific) or Lunderquist® Extra-stiff wire (Cook Medical Inc., Bloomington, IN) was placed into the distal pulmonary artery. Pulsta® valve loaded on the 18 or 20 F delivery catheters and advanced into the main pulmonary artery. The position of the valve was checked with control angiography using a pigtail catheter placed in the right ventricle. Deployment started by rolling the knob clockwise, the distal part of the valve is uncovered by pulling back the outer sheath and can be expanded, and the valve is completely deployed at the target right ventricular outflow tract area by pulling the slider slowly (Fig 6). After valve implantation, the right ventricle and PA, pressures were measured again to check the pressure gradient across the implanted Pulsta®, and a final main pulmonary artery angiogram was carefully performed (Fig 7).

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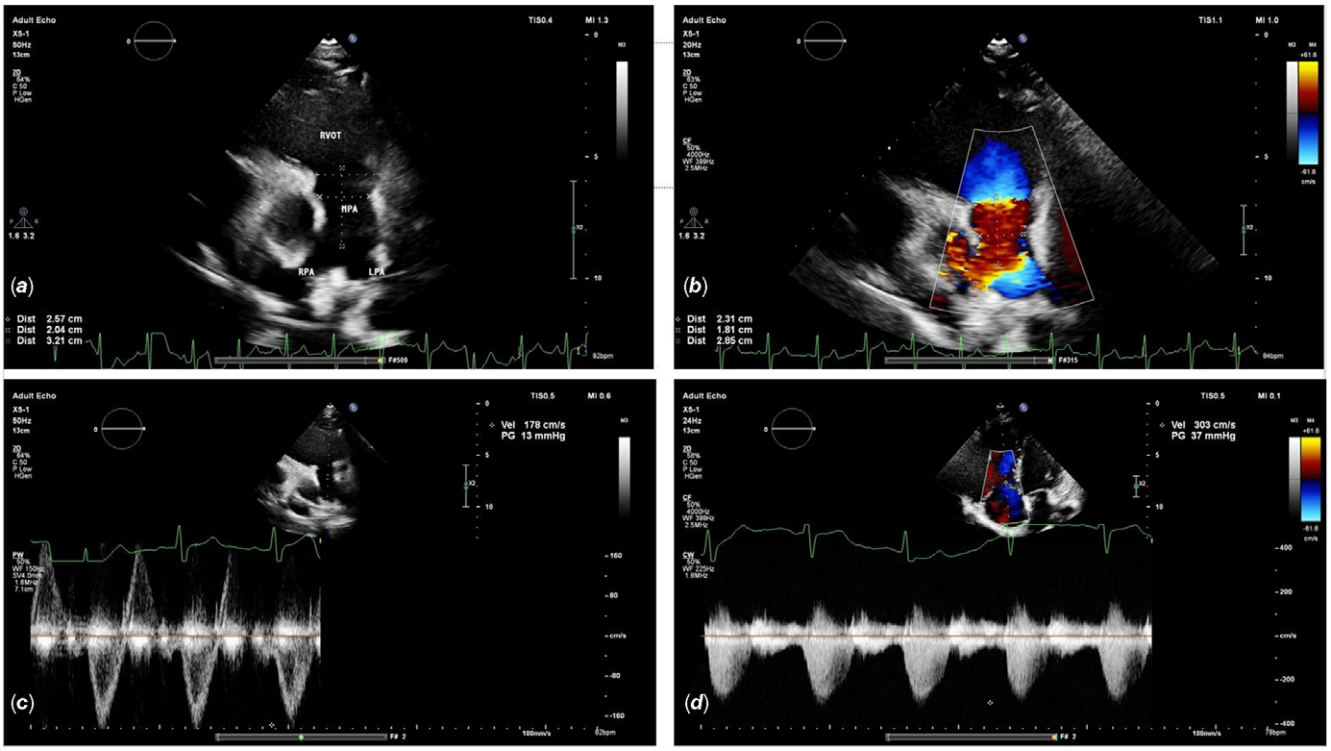

Figure 1. Detailed echocardiographic assessment of the heart before the procedure: Measurement of the pulmonary annulus, main pulmonary artery, and the length of the aimed implantation region in short axis view with 2D (***a***) and colour Doppler (***b***). Peak velocity with Continuous Wave Doppler throughout the right ventricle outflow tract (***c***). Tricuspid regurgitation velocity measurement (***d***).

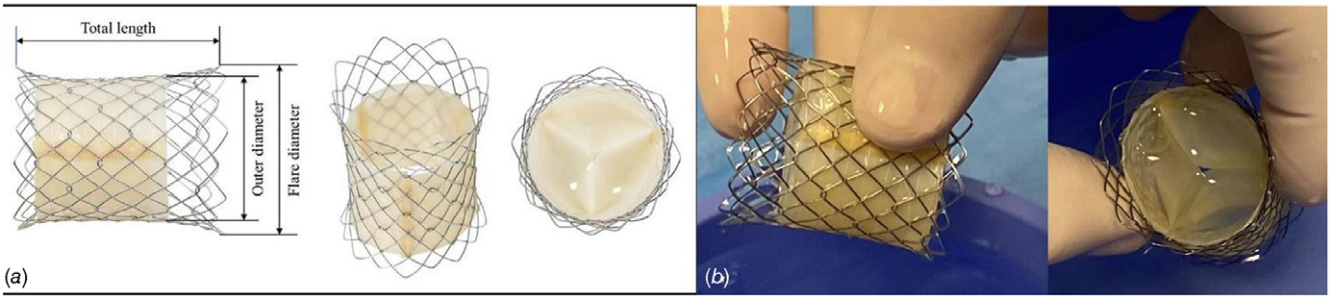

Figure 2. Picture of the Pulsta ® valve in the catalog (***a***) and outer appearance from our procedures (***b***). The tissue-covered main body and perfect coaptation of the valve leaflets are seen.

Patient follow-up

Patients followed up in the ward and were discharged 48 hours after the procedure. Acetylsalicylic acid was begun at 100 mg per day. Patients were examined before discharge, on the 1st, 3rd, 6th months. Transthoracic echocardiography and electrocardiogram were performed.

Results

All of the patients were diagnosed with tetralogy of fallot and repaired with a transannular patch. The mean age was 16 years (range: 8–38 years), and the mean body weight was 44.6 kg (range: 28–68). Among them, seven patients were male (70%). The MRI imaging was performed in eight patients before the procedure. In two patients, MRI was not obtained. One of those patients who were not performed did not give consent since he had an autistic disorder. The other patient was already symptomatic and did not require MRI for percutaneous pulmonary valve implantation indication. Severe regurgitation was detected in eight patients and moderate in two patients. On MRI imaging, mean pulmonary regurgitation (PR) fraction was 5.75 (range: 26–59). Mean indexed RV end-diastolic volume of 152.5 ml/m^2 (range: 98–192 ml/m^2), mean end-systolic volume of 79.08 ml/m^2 (range 43.7–103 ml/m^2), mean right ventricle ejection fraction of % 49.8 (range: 42–55.3) were calculated by MRI. MRI findings of the patients are summarised in Table 2.

We have successfully implanted Pulsta® valve in all patients without any major complications Valve sizes of those 10 patients were 28 mm for 3, 30 mm for 4, and 32 mm for 3 patients. The mean time was 98.1 minutes (range: 55–130) for the procedure and 23.7 (range: 14–46) minutes for fluoroscopy. Whereas all patients had severe PR before the implantation, mild PR in one patient, and trace PR in three patients were detected on

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Figure 3. The delivery system of the valve in the catalog (***a***) and from our procedures (***b***). Handle (for partial deployment) and slider (for full deployment) are seen. The valve is completely covered by a transparent sheath before being inserted into the vein.

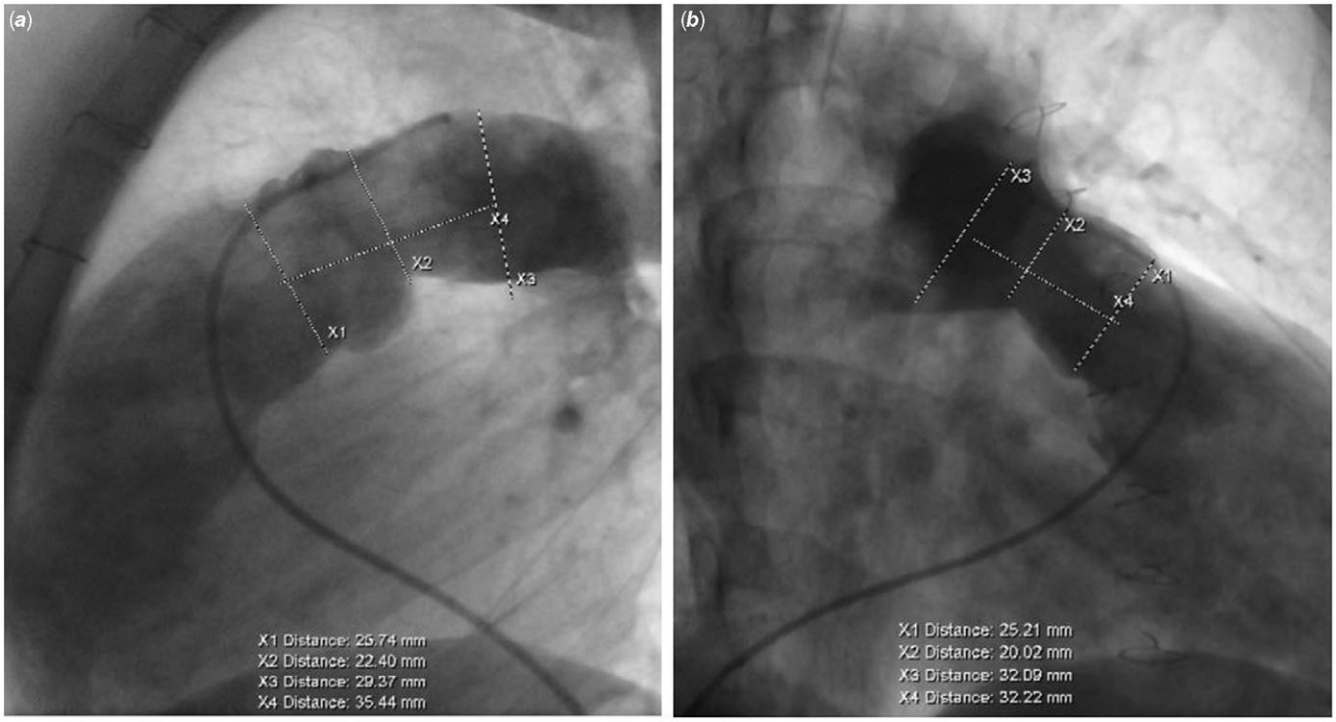

Figure 4. The narrowest part of the pulmonary annulus, the main pulmonary artery, and bifurcation were measured from the left lateral view (***a***) and right anterior oblique and cranial view (***b***).

echocardiographic examination just after the procedure. Echocardiographic examination on the first day revealed mild valve insufficiency in four patients. No regurgitation was detected in six patients. Echocardiographic examination findings of the patients during six months follow-up are summarised in Table 3.

The patients were discharged under treatment of acetylsalicylic acid at a dose of 5 mg/kg/day. An echocardiographic examination after 6 months was performed for all patients. Mild valve insufficiency was visualised in four patients. There was no valve insufficiency in six patients which is similar to the first echocardiographic findings after the implantation. No arrhythmia was observed at the end of the 6-month follow-up in any patient.

In one patient, (number 6) valve was partially exposed in the right pulmonary artery and pulled back slightly to the bifurcation as a routine procedure. However, since guidewire support was not enough, it dislodged to the right ventricular outflow tract. The valve was partially uncovered at that moment. Therefore, we turned the handle to the opposite (counterclockwise) side and recovered the valve by a sheath in the right ventricular outflow tract. Then we pulled it back gently and remained part of the valve

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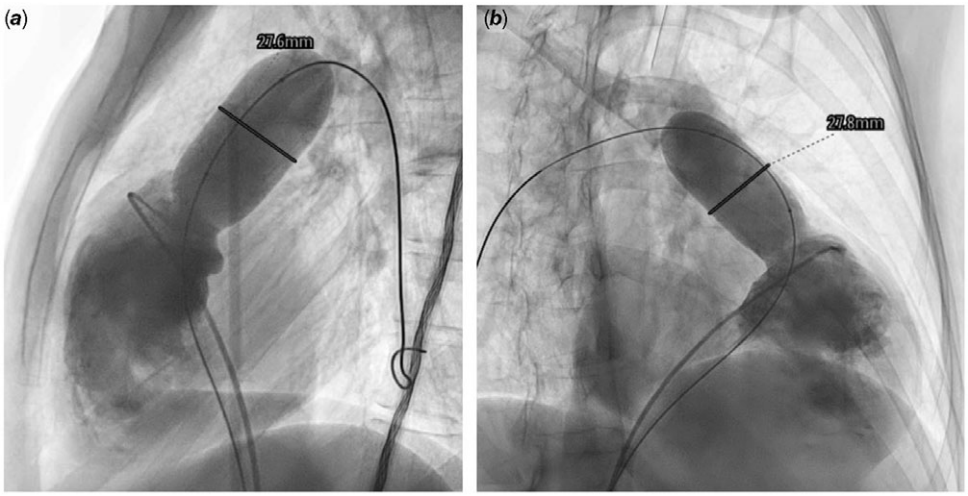

Figure 5. Balloon Occlusion test: A sizing balloon or thysack II balloon was inflated in the main pulmonary artery and simultaneous injection was performed to test complete blocking of the passage throughout RVOT. The diameter of the balloon at the complete occlusion level was measured from two views.

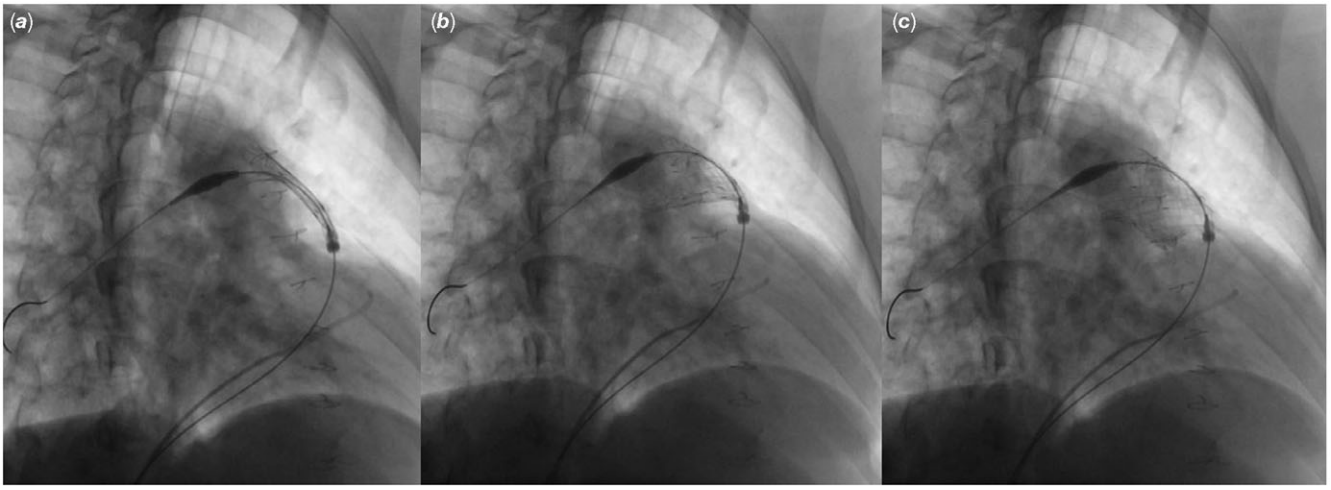

Figure 6. Deployment steps of the valve. (***a***) Partially deployment of the valve in the bifurcation. (***b***) Just before total deployment of the valve. (***c***) Totally deployed valve in pulmonary artery.

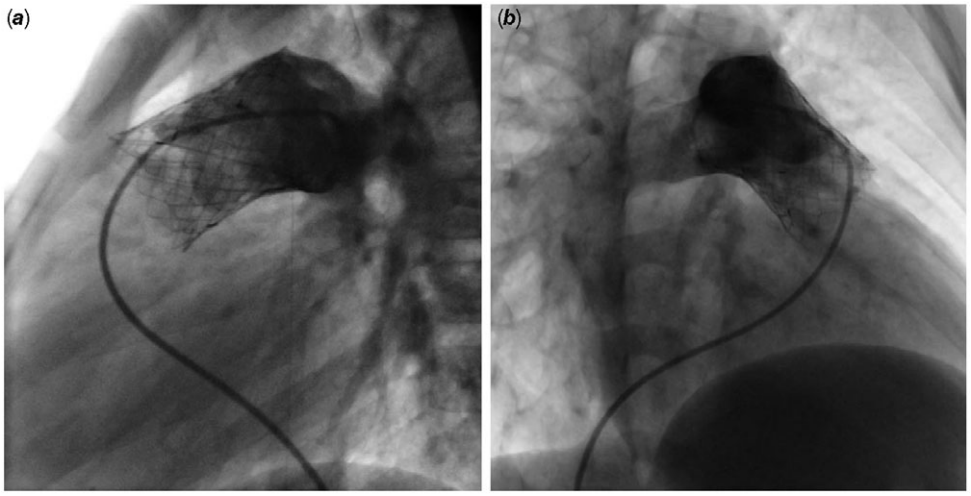

Figure 7. A control angiogram shows no pulmonary regurgitation throughout the valve in lateral view (***a***) and right cranial oblique valve (***b***).

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Table 2. Radiologic and angiographic analysis

Patient	MRI findings	Angiographic measurements				
		MPA diameter (mm)	Balloon stretch Diameter (mm)	Valve size (mm)	Procedure time (minute)	Flouroscopy time (minute)
1	PRF: %42 RVEDVi: 102 ml/m^2 RVESVi: 61.9 ml/m^2 RVEF: %39.2	25.92	26.3	28	55	14
2	PRF: %23 RVEDVi: 100.8 ml/m^2 RVESVi: 43.7 ml/m^2 RVEF: %56.6	25	26.7	30	80	19
3	PRF: %46 RVEDVi: 166 ml/m^2 RVESVi: 79.7 ml/m^2 RVEF: %52	25	26.4	30	110	21
4	PRF: %26 RVEDVi: 124 ml/m^2 RVESVi: 60.8 ml/m^2 RVEF: %51	21	24.6	28	100	20
5	PRF: %57 RVEDVi: 151 ml/m^2 RVESVi: 85.8 ml/m^2 RVEF: %51.9	26	27.96	32	105	18.2
6	PRF: %59 RVEDVi: 176 ml/m^2 RVESVi: 101 ml/m^2 RVEF: %42	25.9	27.6	30	130	46
7	No MRI	25.3	28.3	32	95	29.9
8	No MRI	22.5	27.8	30	97	28.6
9	PRF: %50 RVEDVi: 192 ml/m^2 RVESVi: 103 ml/m^2 RVEF: %46	27	30.3	32	118	22.5
10	PRF: %52 RVEDVi: 188 ml/m^2 RVESVi: 102 ml/m^2 RVEF: %46	25	26.1	28	90	25.5

PRF = pulmonary regurgitation fraction; RV = right ventricle; RVEDVi = right ventricle end diastolic volume index; RVEF = right ventricle ejection fraction; RVESVi = right ventricle endsystolic volume index.

that could be covered totally and retrieved without any vascular or valvular complication. The valve was crimped again and successfully implanted in the second attempt.

Three patients have suffered from unspecific chest pain after implantation. Electrocardiogram and cardiac troponin levels were normal, and the pain is relieved by using paracetamol and disappeared after 24 hours.

Vascular complications, dysrhythmia, coronary compression, fever, or infective endocarditis was observed in none of the patients.

Discussion

Pulmonary regurgitation is a life-threatening condition after tetralogy of fallot repair. Most of the patients were admitted to the hospital with the symptoms of right heart failure due to chronic volume overload.[10] Percutaneous pulmonary valve implantation is a promising alternative to surgery which has been increasingly used in patients with native right ventricular outflow tract with established good outcomes.[11–16] However, balloon-expandable valves have important limitations such as lack of large size valves and variable right ventricular outflow tract geometry which is not suitable for balloon-expandable valve implantation. The prestenting to create a landing zone is also required for most of the patients before valve implantation which increases the risk of complications such as stent migration or embolisation.[17] The endothelisation of the stent to avert embolisation or migration lasts at least two months after implantation. Therefore, patients need to undergo cardiac catheterisation twice.

Some technical modifications such as off-pump surgical main pulmonary artery banding and valve implantation or right ventricular outflow tract prestenting and large SAPIEN valve implantation were reported to use the balloon-expandable valves for the solving of severe pulmonary insufficiency problems in certain selected cases.[18–21]

Although Edwards SAPIEN XT and S3 valve with 29 mm diameter have been implanted since its larger diameter offers an advantage for native right ventricular outflow tract lesions with good procedural success rate and haemodynamic improvement.[22] We also demonstrated the usefulness of the Meryl Myval in native right

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Table 3. Evaluation of patients after transcatheter pulmonary valve implantation

Patient	Pulmonary regurgitation before valve implantation	Pulmonary regurgitation after valve implantation	ECHO on the day after the procedure	ECHO after 6 months	Complication
1	Severe	Trace	Mild	Trace	0
2	Moderate	No PR	Mild	No PR	0
3	Severe	No PR	No PR	No PR	0
4	Moderate	No PR	No PR	No PR	0
5	Severe	Mild	No PR	Mild	0
6	Severe	Trace	Mild	No PR	Valve dislodgement and retrievel
7	Severe	Trace	No PR	Mild	0
8	Severe	No PR	Mild	No PR	0
9	Severe	No PR	No PR	No PR	0
10	Severe	No PR	No PR	Trace	0

ventricular outflow tract.[23] However, most patients with dilated native right ventricular outflow tract need a larger diameter valve than the balloon-expandable valve to have a stable valve position. For these reasons, several single self-expandable systems for percutaneous pulmonary valve implantation are promising and offer superiority to the balloon-expandable valves.

Additionally, available balloon-expandable valve delivery systems are particularly designed for the aortic position. Therefore, they are not proper for the pulmonary position, especially in a curved right ventricular outflow tract course. Advancement of the valve on the balloon to the pulmonic position is almost always tricky. In some cases, a larger sheath which is Gore® Dryseal Flex Introducer has been used to cope with this problem.[24] However, percutaneous pulmonary valve implantation in native and large right ventricular outflow tracts is still one of the most challenging procedures due to difficulties in the delivery of the valve to the pulmonic position. Therefore, interventional cardiologists already have been seeking new solutions.

Clinical trials on self-expandable devices, including the Venus p-valve® (Venus Medtech, Shanghai, China), Harmony® (Medtronic), and Alterra Pre-stent® (with SAPIEN S3) valves, have been carried out.[25–27] The first successful implantation of a single self-expandable valve in a patient with a dilated pulmonary trunk was reported by Schievano et al, and the feasibility study has just been completed in the United States and Canada by Medtronic, Inc.[28,29] After a clinical trial of the harmony valve, high procedural success, and safety, with a favourable acute device performance were revealed. The harmony valve is now the solely self-expandable valve that has food and drug administration approval.[30] Venus p valve ® is another self-expandable valve for insertion into a dilated pulmonary trunk and on the Conformité Européenne mark trial across Europe. Early clinical experience revealed good functioning of the implanted valve on short-term follow-up.[31] These two self-expandable valves have shown high procedural success and good short-term efficacy in the selected patients with native right ventricular outflow tract lesions.

In this study, we report our first experiences of the utilisation of the self-expandable Pulsta® valve for the treatment of right ventricular outflow tract dysfunction even has paediatric patients. We achieved valve implantation in all patients without any device-related complications. The valve functions were monitored in followed-up and any abnormalities are detected.

The first report on the Pulsta® valve was established by Kim et al. in 2018 and since then the valve has been increasingly used with good outcomes.[8] Since the first implementation of Pulsta® Valve started in Korea and relatively late in other western countries, our Pulsta® valve experience in this study contributes to the literature in terms of feasibility, effectivity, and short-term safety of the Pulsta® Valve.[6–8]

Lee et al also reported their mid-term results with the Pulsta® THV system and depicted the mid-term safety and efficiency without any adverse events and also improving in the RV indexes.[32] Unlike the other self-expandable systems, Pulsta® has some specific advantages such as a lower profile of delivery system due to nitinol wire knitted stent despite having 32 mm maximal size and 38 mm in length. Nitinol wire mesh provides a reasonable stent size without bulkiness.[6–8] Therefore, advancing the large size of valves throughout curved right ventricular outflow tract to the implantation position is quite easier compared to the other self-expandable devices and also balloon-expandable valve systems.

Since the main intended implantation area of the Pulsta® Valve is the main pulmonary artery, it can be implanted in patients with branch pulmonary arterial stenosis, which is a considerable advantage, if we take into account that many of the patients have branch pulmonary arterial stenosis.

Pulsta® valve delivery sheath is comparable to small size, for instance, 18 F sheath is for 28 mm valve and 20 F sheath for 32 mm valve.[9] This low profile offers to be the ability to use this valve in smaller size children. The patient with the lowest weight in our serial is a 28 kg 9 years old age boy.

We did not encounter any advancement problems with the delivery catheter and valve throughout the right ventricular outflow tract, and we did not need any extra manoeuvre such as using buddy wire, excessive curving in the right atrium, or the necessity of larger sheath such as Gore® Dryseal Flex Introducer. In all the patients Pulsta® valve could be advanced very smoothly to the implantation area without any trouble.

The only tricky point of the implantation is releasing the hook block from the stent frame after the device is deployed. In some cases, we experienced that the hook block may entangle the frame and if the implanter pulls back the system carelessly it may be because of dislodgement or even embolisation of the device.

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Therefore, we strongly recommend checking the position of the hook block and making sure that it is released from the stent.

The Pulsta valve can be deployed partially, and the position of the valve can be adjusted before totally releasing the device. The Pulsta® valve is a retrievable device. In one patient, even though around one-third of the valve was already exposed, we could easily retrieve the device without any embolisation and vascular damage. Being recaptured and retrievable feature of the device is an unignorable advantage over the balloon-expandable valves.

We did not observe any major complications during the procedure and no dysrhythmia occurred in all patients. Nonspecific chest pain in three patients was interpreted as caused by the self-expandable property of the valve which may result in stretching over the pulmonary arterial wall even after implantation. We also encountered very similar symptoms after balloon-expandable valve implantation procedures. Since ECG, cardiac troponin levels were normal, and the pain is relieved by using paracetamol and disappeared after 24 hours we did not interpret this symptom as related to coronary compression or other severe cardiac causes of the chest pain.

Aortic distortion due to compression of the pulmonic valve onto the aorta is another concern during percutaneous pulmonary valve implantation procedures.[33] However, we did not encounter any problem resulting from pressure onto the aorta which may cause distortion. In our opinion, this complication is very unlikely with the Pulsta® valve due to its self-expandable property which has very low radial force compared to balloon-expandable valves. All the patients completed 6 months followed up and there is no echocardiographic increase detected in the gradient and the pulmonary regurgitation throughout the implanted Pulsta® valves.

Although valve competency is excellent in six patients, we interpreted the increase of the regurgitation from trace to mild in three patients as lower blood pressure during the procedure because of the haemodynamic suppression of anaesthesia.

Besides the advantages, we have still some concerns regarding the feasibility of Pulsta® Valve, especially in patients with mixed lesions which is stenosis accompanied by severe regurgitation. Because the Pulsta® valve is self-expandable and has not had enough radial force to relieve the stenosis, the valve does no't seem proper for use in patients with stenosis. Prestenting should be performed before Pulsta® valve implantation and this will turn into a disadvantage for the valve. Even with prestenting data regarding effectivity and durability of Pulsta® valve is not enough in the stenotic conduits compared to balloon-expandable valves. We excluded the patients with more than 40 mmHg gradient throughout right ventricular outflow tract in this study. Thus, this study doesn't evaluate the effectiveness of the Pulsta® valve in patients with mixed lesions which consist of a considerable percentage of the patients after TOF repair.

Conclusion

Our early results revealed that Pulsta® valve implantation in native and large right ventricular outflow tracts is a feasible, effective, and safe treatment modality. Pulsa® valve is a promising solution for patients with unsuitable right ventricular outflow tract geometry for the balloon-expandable valves. Our study is the first clinical report from Europe about Pulsta® Valve contributes to the literature which has limited data. We still need long-term follow-up results to depict more data including the effectivity on right ventricular volumes, functions, safety, and durability of the valve.

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Conflict of interest. None.

Ethical standards. The informed consent form was obtained from all the patients or their parents. Ethical committee approval was achieved from the Koc University Faculty of Medicine.

References

1. Cheung MMH, Konstantinov IE, Redington AN. Late complications of repair of tetralogy of Fallot and indications for pulmonary valve replacement. In Seminars in thoracic and cardiovascular surgery. vol. 17, WB Saunders, 2005.
2. Bouzas B, Kilner PJ, Gatzoulis MA. Pulmonary regurgitation: not a benign lesion. Eur Heart J 2005; 26: 433–439.
3. Ansari MM, Cardoso R, Garcia D, et al. Percutaneous pulmonary valve implantation: present status and evolving future. J Am Coll Cardiol 2015; 66: 2246–2255.
4. Zahn Evan M, et al. First human implant of the Alterra Adaptive Prestent™: a new self-expanding device designed to remodel the right ventricular outflow tract. Catheter Cardio Inte 2018; 91: 1125–1129.
5. Alkashkari W, Alsubei A, Hijazi ZM. Transcatheter pulmonary valve replacement: current state of art. Curr Cardiol Rep 2018; 20: 1–13.
6. Kim GB, Song MK, Bae EJ, et al. Successful feasibility human trial of a new self-expandable percutaneous pulmonary valve (Pulsta valve) implantation using knitted nitinol wire backbone and trileaflet α-Gal-free porcine pericardial valve in the native right ventricular outflow tract. Circ Cardiovasc Interv 2018; 11: e006494.
7. Giugno L, Faccini A, Carminati M. Percutaneous pulmonary valve implantation. Korean Circ J 2020; 50: 302–316.
8. Kim AY, Jung JW, Jung SY, et al. Early outcomes of percutaneous pulmonary valve implantation with pulsta and melody valves: the first report from Korea. J Clin Med 2020; 9: 2769.
9. Geva T. Indications and timing of pulmonary valve replacement after tetralogy of Fallot repair. In Seminars in Thoracic and Cardiovascular Surgery: Pediatric Cardiac Surgery Annual. vol. 9, WB Saunders, 2006.
10. Van der Ven JPG, Bosch E, Bogers JCC, Helbing WA. Current outcomes and treatment of tetralogy of Fallot. F1000Res 2019; 8.
11. Giugno L, Faccini A, Carminati M. Percutaneous pulmonary valve implantation. Korean Circ J 2020; 50: 302–316.
12. Georgiev S, Tanase D, Ewert P, et al. Percutaneous pulmonary valve implantation in patients with dysfunction of a "native" right ventricular outflow tract - mid-term results. Int J Cardiol 2018; 258: 31–35.
13. Esmaeili A, Bollmann S, Khalil M, et al. Percutaneous pulmonary valve implantation for reconstruction of a patch-repaired right ventricular outflow tract. J Interv Cardiol 2018; 31: 106–111.
14. Guccione P, Milanesi O, Hijazi ZM, Pongiglione G. Transcatheter pulmonary valve implantation in native pulmonary outflow tract using the Edwards SAPIENTM transcatheter heart valve. Eur J Cardiothorac Surg 2012; 41: 1192–1194.
15. Malekzadeh-Milani S, Ladouceur M, Cohen S, Iserin L, Boudjemline Y. Results of transcatheter pulmonary valvulation in native or patched right ventricular outflow tracts. Arch Cardiovasc Dis 2014; 107: 592–598.
16. Boshoff DE, Cools BL, Heying R, et al. Off-label use of percutaneous pulmonary valved stents in the right ventricular outflow tract: time to rewrite the label? Catheter Cardiovasc Interv 2013; 81: 987–995.
17. Kostolny M, Tsang V, Nordmeyer J, et al. Rescue surgery following percutaneous pulmonary valve implantation. Eur J Cardio-Thorac Surg 2008; 33: 607–612.
18. Boudjemline Y, Schievano S, Bonnet C, et al. Off-pump replacement of the pulmonary valve in large right ventricular outflow tracts: a hybrid approach. J Thorac Cardiovasc Surg. 2005; 129: 831–837.

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19. Porras D, Gurvitz M, Marshall AC, Emani SM. Hybrid approach for off-pump pulmonary valve replacement in patients with a dilated right ventricular outflow tract. Ann Thorac Surg 2015; 100: e99–e101.
20. Godart F, Bouzguenda I, Juthier F. Experimental off-pump transventricular pulmonary valve replacement using a self-expandable valved stent: a new approach for pulmonary incompetence after repaired tetralogy of Fallot? J Thorac Cardiovasc Surg 2009; 137: 1141–1145.
21. Demkow M, Rużyłło W, Biernacka Eżbieta K, et al. Percutaneous edwards SAPIENTM valve implantation for significant pulmonary regurgitation after previous surgical repair with a right ventricular outflow patch. Catheter Cardiovasc Interven 2014; 83: 474–481.
22. Güzeltaş A, Tanıdır IC, Gökalp S, Topkarcı MA, Şahin M, Ergül Y. Implantation of the Edwards SAPIEN XT and SAPIEN 3 valves for pulmonary position in enlarged native right ventricular outflow tract. Anatol J Cardiol 2021; 25: 96–103.
23. Odemis E, Yenidogan I. First experiences with Myval Transcatheter Heart Valve System in the treatment of severe pulmonary regurgitation in native right ventricular outflow tract and conduit dysfunction. Cardiol Young 2021; 32: 1–7.
24. Jones MI, Murphy M, Rosenthal E, et al. Use of the GOREÒ dryseal flex introducer sheath to facilitate implantation of the transcatheter venus P-valve. Congenit Heart Dis 2021; 16: 197–203.
25. Zablah JE, Morgan GJ. Current treatment options for catheter-Based pulmonary valve replacement in children. Curr Treatm Options Pediatr 2020; 6: 1–9.
26. Gales J, Krasuski RA, Fleming GA. Transcatheter valve replacement for right-sided valve disease in congenital heart patients. Prog Cardiovasc Dis 2018; 61: 347–359.
27. Alkashkari W, Albugami S, Abbadi M, Niyazi A, Alsubei A, Hijazi ZM. Transcatheter pulmonary valve replacement in pediatric patients. Expert Rev Med Devic 2020; 17: 541–554.
28. Schievano S, Taylor A, Capelli C, et al. First-in-man implantation of a novel percutaneous valve: a new approach to medical device development. EuroIntervention 2010; 5: 745–750.
29. Bergersen L, Benson LN, Gillespie MJ. Harmony feasibility trial: acute and short-term outcomes with a self-expanding transcatheter pulmonary valve. JACC: Cardiovasc Interv 2017; 10: 1763–1773.
30. Gillespie MJ, Bergersen L, Benson LN, Weng S, Cheatham JP. 5 year outcomes from the Harmony Native Outflow Tract early Feasibility Study. JACC Cardiovasc Interv 2021; 14: 816–817.
31. Morgan G, Prachasilchai P, Promphan W, et al. Medium-term results of percutaneous pulmonary valve implantation using the Venus P-valve: international experience. EuroIntervention 2019; 14: 1363–1370.
32. Lee SY, Kim GB, Kim SH, et al. Mid-term outcomes of the pulsta transcatheter pulmonaryvalve for the native right ventricular outflow tract. Catheter Cardiovasc Interv 2021; 98: E724–E732.
33. Morgan GJ, Sadeghi S, Salem MM, et al. SAPIEN valve for percutaneous transcatheter pulmonary valve replacement without "pre-stenting. Catheter Cardio Inte 2019; 93: 324–329.

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