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

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Background—Self-expandable percutaneous pulmonary valve implantation (PPVI) for native right ventricular outflow tract lesions is still in the clinical trial phase. The aim of this study is to present the result of feasibility study of a novel self-expandable knitted nitinol wire stent mounted with a treated trileaflet α-Gal–free porcine pericardial valve for PPVI.

Methods and Results—A feasibility study using Pulsta valve (TaeWoong Medical Co, Gyeonggi-do, South Korea) was designed for patients with severe pulmonary regurgitation in the native right ventricular outflow tract, and 6-month follow-up outcomes were reviewed. Ten tetralogy of Fallot patients were enrolled. Before PPVI, severe pulmonary regurgitation (mean pulmonary regurgitation fraction, 45.5%±7.2%; range, 34.9%–56%) and enlarged right ventricular volume (mean indexed right ventricular end-diastolic volume, 176.7±14.3 mL/m^2; range, 158.9–205.9 mL/m^2) were present. The median age at PPVI was 21.7±6.5 years (range, 13–36 years). Five patients were successfully implanted with 28 mm and the other 5 with 26 mm valves loaded on the 18F delivery cable. No significant periprocedural complications were noted in any patient. At the 6-month follow-up, indexed right ventricular end-diastolic volume was dramatically decreased to 126.3±20.3 mL/m^2 (range, 99–164.2 mL/m^2), and the mean value of peak instantaneous pressure gradient between the right ventricle and the pulmonary artery decreased from 6.8±3.5 mm Hg (range, 2–12 mm Hg) before PPVI to 5.7±6.7 mm Hg (range, 2–12 mm Hg) without significant pulmonary regurgitation. There was no adverse event associated with the valve.

Conclusions—A feasibility study of the Pulsta valve for native right ventricular outflow tract lesions was completed successfully with planned Pulsta valve implantation and demonstrated good short-term effectiveness without serious adverse events.

Clinical Trial Registration—URL: https://www.clinicaltrials.gov. Unique identifier: NCT02555319.

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Key Words: feasibility study ■ heart diseases ■ nitinol ■ pulmonary valve ■ stent

Various congenital heart diseases involving the right ventricular outflow tract (RVOT) lesion, such as tetralogy of Fallot (TOF) with or without pulmonary atresia, transposition of the great arteries with pulmonary stenosis, and so on, require implantation of a prosthetic valve with or without a conduit between the right ventricle (RV) and the pulmonary artery (PA) because of significant pulmonary stenosis or pulmonary regurgitation (PR) and after RV failure.[1] These prosthetic valves and conduits need repeated operations because of inevitable degeneration of artificial tissue and clinically significant pulmonary stenosis and PR. Repeated operations carry the risk of significant morbidity and mortality.[2,3] Balloon-expandable percutaneous pulmonary valve implantation (PPVI) using Melody and Edwards SAPIEN valves have been replacing surgically implanted RV to PA valves[4–8]; however, balloon-expandable PPVI has unavoidable limitations in case of native RVOT lesions with variable geometry and significant PR.[9] Therefore, larger valve of a self-expandable nature has been suggested as the next generation of percutaneous valves in these native RVOT lesions.[9–11] Pulsta valve (TaeWoong Medical Co, Gyeonggi-do, South Korea) is a self-expandable valve with flared-ends to adapt to the larger native RVOT and is using a relatively low profile delivery catheter from knitted nitinol wire backbone and trileaflets made from treated porcine pericardial tissue.[12,13] This valve

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WHAT IS KNOWN

- Various congenital heart diseases involving the right ventricular outflow tract lesions require implantation of a prosthetic valve with or without a conduit between the right ventricle and the pulmonary artery because of significant pulmonary stenosis or regurgitation.
- Because 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, a single self-expandable delivery system to implant pulmonary valve have been developed as a next-generation percutaneous pulmonary valve.

WHAT THE STUDY ADDS

- This is the first successful human feasibility study for the native right ventricular outflow tract lesion after tetralogy of Fallot repair using Pulsta valve, a newly made knitted nitinol wire stent with treated trileaflet α-Gal–free porcine pericardial valve.
- A feasibility study of the Pulsta valve up to 28 mm valve diameter for native right ventricular outflow tract lesions was completed successfully with planned Pulsta valve implantation and demonstrated good short-term effectiveness without serious adverse events.

was approved as an orphan device and permitted for a feasibility study on 10 patients with RVOT lesions by the Korean Ministry of Food and Drug Safety. We, hereby, report the results of this feasibility study of the Pulsta valve, completed in South Korea.

Methods

The data, analytic methods, and study materials will be made available to other researchers for purposes of reproducing the results or replicating the procedure on request to be addressed at the corresponding author's email.

We planned to implant a self-expandable valve with knitted nitinol wire backbone and trileaflet porcine pericardial valve newly developed by our research team in the Seoul National University Hospital with the cooperation of the TaeWoong Medical company for a feasibility study. This feasibility study was completed at the Seoul National University Hospital. The primary goal was to evaluate procedural success, procedure- or device-related serious adverse events, and hemodynamic functional improvement at 6-month follow-up. Data will be collected every year for 5 years in each patient after PPVI.

Pulsta Valve

Pulsta valve is made by using knitted double-strand nitinol wire with 0.0115-inch thickness, and the stent wall is covered by treated porcine pericardium. The valve diameter ranges from 18 to 28 mm with 2 mm increments. Both ends of the valve are flared to 4 mm wider than the outer diameter for stable valve adaptation to various RVOT geometries. The total length of the valve is 28 to 38 mm according to outer diameter (Figure 1). The trileaflet valve is made using treated porcine pericardium for maximal tissue preservation, reduction in calcification, and prevention of early tissue degeneration by the following methods as we previously published: decellularization, α-galactosidase treatment to remove the α-gal xenoantigen, space filler treatment, glutaraldehyde fixation, organic solvent treatment, and finally detoxification.[13–17] This treated porcine pericardium was tightly hand sewn to the stent wall with 5–0 braided polyester to allow good valve coaptation as tricuspid leaflets. Before this feasibility study, we had to complete stent fatigue test for 400 000 000× and valve accelerated wear test for 200 000 000× to get approval of the Korean Ministry of Food and Drug Safety for a human clinical trial.

Delivery Cable

We developed a transcatheter delivery system as shown in Figure 2. The total usable length of the catheter is 110 cm (Figure 2A) with a conical tapered tip, 17 mm in length for smooth vessel introduction (Figure 2B). The diameter of the outer sheath in the valve loading zone is 18F (5.9 mm), and the diameter of the catheter shaft is 12F (Figure 2C). We made a hook block at the proximal part of the valve loading area for controlled deployment and to prevent abrupt valve jumping during valve deployment (Figure 2B). By simply hooking the proximal end of the nitinol wires at the hook block, controlled deployment and subsequent good positioning of the valve at the target area are possible. The valve is easily loaded into the delivery cable just before catheter exchange using commercialized Heart Valve Crimper (Model RVS, Blockwise Engineering LLC, AZ) in several minutes.

Patient Selection

Patients with native RVOT after TOF total repair with more than moderate PR and dilated RV diagnosed by transthoracic echocardiography and cardiac magnetic resonance image (MRI) were enrolled in this study. The essential inclusion criteria for enrollment were as follows: (1) age >10 years and body weight >30 kg, (2) patients with more than moderate PR and indexed RV end-diastolic volume >150 mL/m^2, and (3) patients with anatomic suitability for Pulsta valve implantation with narrowest diameter <28 mm from transthoracic echocardiography or cardiac computed tomography. Basic demographics are described in Table 1.

This feasibility study complies with the Declaration of Helsinki and was approved by the Institutional Review Board of the Seoul National University Hospital (Institutional Review Board number: 1412-011-630). Written consent was obtained from all the patients or parents.

Valve Size Selection

Valve size selection was basically based on all the images of transthoracic echocardiography, cardiac computed tomography, cardiac MRI

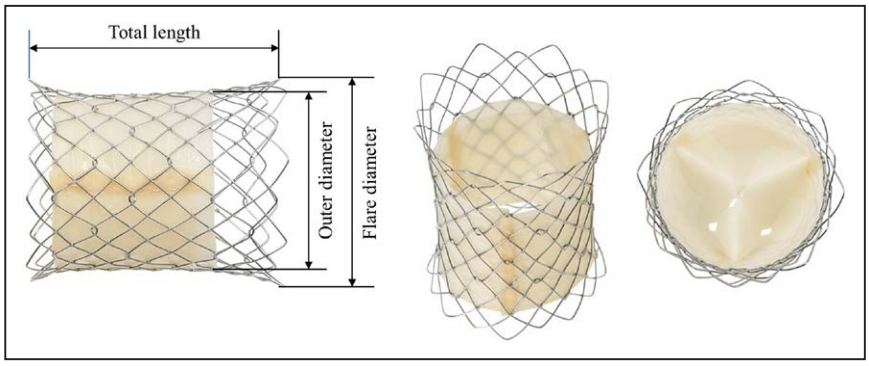

Figure 1. Pulsta valve profile. The outer diameter of valve ranged from 18 to 28 mm with 2 mm increase with knitted nitinol wire backbone. Total length was 38 mm. Both ends of the valve were flared to 4 mm wider than the valve diameter itself. We covered the wall of the stent by treated porcine pericardium and tightly stitched treated porcine pericardium to the stent wall to allow good valve coaptation as tricuspid leaflets.

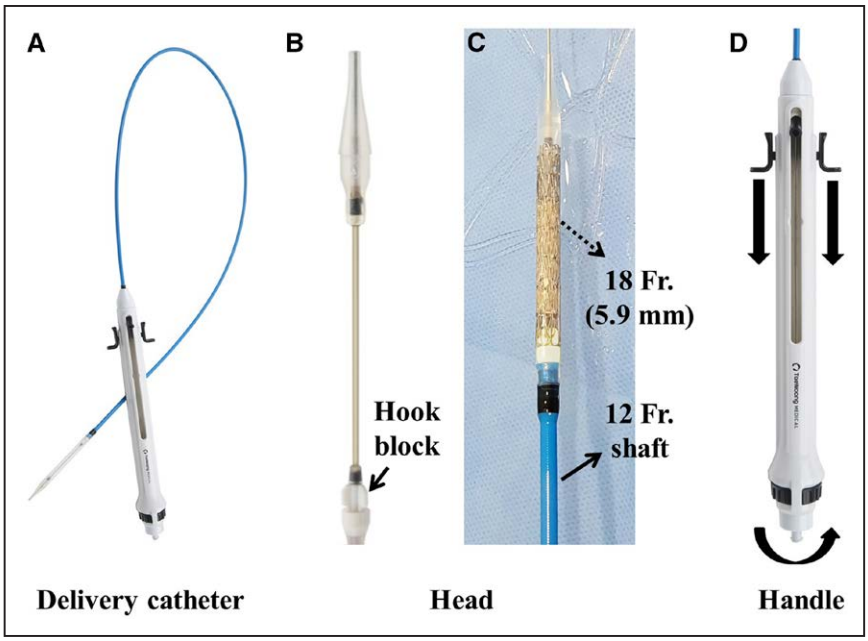

Figure 2. Delivery catheter profile. The total usable length of delivery cable is 110 cm (**A**). Head portion of valve loading has a 17-mm conical tapered tip and hook block to perform controlled deployment at the target area (**B**). The outer diameter of valve loading area is 18F for 28 mm valve and shaft of delivery cable is 12F (**C**). Valve is half unloaded by turning the knob clockwise (curved **arrow**) and deployed fully by pulling the slider (straight **arrows**; **D**).

before the procedure, and sizing balloon during the procedure. The target RVOT area for PPVI is the main PA in practice (Figure 3A and 3C). We selected valve size 2 to 4 mm larger than the narrowest area of the main PA and equal or slightly larger than the mean main PA size. Table 2 shows each patient's target main PA measurements (proximal to PA annulus, narrowest and distal bifurcation site diameter, and the length) during the most dilated phase. We measured main PA by transthoracic echocardiography at the parasternal short axis view mostly during end-systolic phase (most dilated phase of main PA) and also measured main PA by angiography at the mostly left anterior oblique and true lateral view. The main PA length was measured from the PA annulus level up to the PA bifurcation site (Figure 3B).

Valve Implantation

Under general anesthesia and mechanical ventilation, 2 femoral veins (we used right internal jugular vein for PPVI in the third patient as the main route because of inferior vena cava interruption) and 1 femoral artery access was made. After routine hemodynamic study, main PA angiography was done. Balloon sizing and coronary angiography were done at the same time to predict coronary artery compression by the valve. After deciding the valve size, we carefully inserted the valve loaded on the 18F delivery cable through an Amplatzer super stiff wire (Boston Scientific, Heredia, CostaRica) into the targeted main PA area. After careful positioning with serial RV angiograms, we finally deployed the valve safely at the target area similar to our previous published report.[12] By rolling the knob (curved arrow) clockwise, the outer sheath is pulled back, and half of the valve can be expanded, and the valve is completely deployed at the target RVOT area by pulling the slider (straight arrow; Figure 2D). After valve implantation, the RV and PA pressures were measured again to check the pressure gradient across the implanted valve, and final main PA angiogram was carefully performed.

Data Analysis and Monitoring

For this feasibility study, we recorded patients' clinical findings at baseline, discharge, and at follow-up periods of 1 month±1 week, 3 months±2 weeks, and 6 months±4 weeks and will follow-up annually for 5 years±8 weeks after PPVI. Especially, we performed cardiac catheterization and MRI at 6-month follow-up to evaluate hemodynamic functional improvement. We also noted any adverse events experienced by patients during the follow-up period after PPVI. A Data Safety and Monitoring Board comprising of a pediatric cardiologist

Table 1. Patients' Baseline Characteristics Before Procedure

	Age, y	Weight, kg	TAP	LPA Stenosis	RVOT Aneurysm	RVEDVi, mL/m^2	RVESVi, mL/m^2	PRF, %
1	20	39.2	+			186.5	89.7	38.4
2	19	41.75	+			161	76.6	56
3	25	61.7		+	+	205.9	97.8	49.8
4	26	60.9	+		+	179	95.6	42.5
5	22	81.3	+			189.7	110	40
6	23	70.7	+		+	158.9	100.5	49.5
7	18	56.8	+		+	172.3	103.1	34.9
8	13	47.6	+	+	+	172.7	100.6	42.9
9	36	69.4			+	175.1	94.5	56
10	15	66.95	+	+	+	165.5	79.4	45.4
Mean±SD	21.7±6.5	59.6±13.5				176.7±14.3	94.8±9.8	45.5±7.2

LPA indicates left pulmonary artery; PRF, pulmonary regurgitation fraction; RVEDVi, indexed right ventricular end-diastolic volume; RVESVi, indexed right ventricular end-systolic volume; RVOT, right ventricular outflow tract; and TAP, transannular patch.

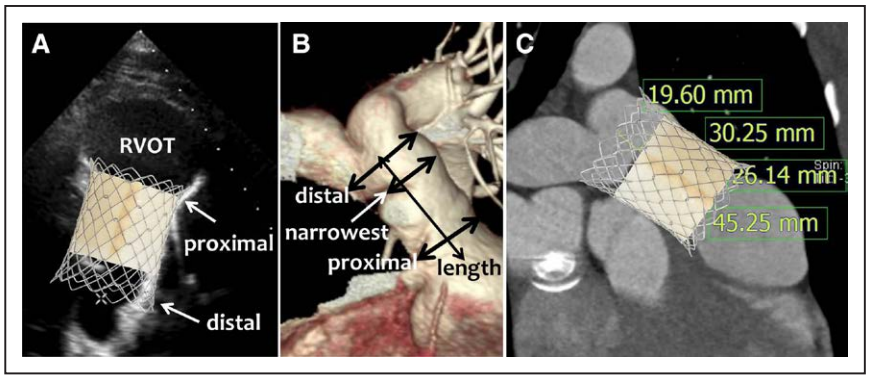

Figure 3. Target main pulmonary artery (PA) measurement for valve implantation. Largest diameter of target main PA, including the proximal, narrowest, and distal diameter, was measured (**A**–**C**). Main PA length was measured from the PA annulus level to near PA bifurcation site (**B**). RVOT indicates right ventricular outflow tract.

and a congenital cardiothoracic surgeon from another hospital independent of our study reviewed data quality and adverse events of enrolled patients.

Statistical Analysis

SPSS version 21.0 (IBM, Armonk, NY) was used for data analysis. For the descriptive analysis, continuous variables are described as mean±SD, and categorical variables are presented as frequencies and percentage. The Wilcoxon signed-rank test was used to compare variables between baseline and 6 months after PPVI. Statistical significance was defined as $P<0.05$.

Results

Ten patients with significant PR and enlarged RV after TOF total correction were screened and enrolled for this PPVI feasibility trial. Patients' baseline characteristics before procedure are described in Table 1. Mean age was 21.7±6.5 years (range, 13–36 years), and mean body weight was 59.6±13.5 kg (range, 39.2–81.3 kg). Among them, 5 patients were men (50%). Eight patients (80%) underwent transannular RVOT patch angioplasty at the time of TOF total correction. All patients showed severe PR with mean PR fraction 45.5%±7.2% (range, 34.9%–56%). Mean indexed RV end-diastolic volume was 176.7±14.3 mL/m^2 (range, 158.9–205.9 mL/m^2) on cardiac MRI. There was no RVOT stenosis except in 3 patients with left PA stenosis. The mean value of peak pressure gradient between RVOT and main PA was 17.3±6.3 mm Hg (range, 9–27 mm Hg) by pulse wave Doppler examination of RVOT forward flow on transthoracic echocardiography. Seven patients (70%) had an RVOT aneurysm below the pulmonary valve annulus. All the patients showed mild to moderate exercise intolerance with mean peak oxygen consumption 25.3±6.6 mL/kg per minute (range, 14.9–36.8 mL/kg per minute) on cardiopulmonary exercise testing.

Valve Implantation

We selected each patient's valve size after measuring the largest diameter of target main PA's proximal, narrowest, and distal part and length using the images of cardiac computed tomography, MRI, echocardiography, and balloon sizing during procedure as described in Table 2. We implanted 26 mm diameter valve in 5 patients and 28 mm diameter valve in 5 patients successfully. The mean procedural time was 78.7±14.5 minutes (range, 57–103 minutes), and mean fluoroscopy time was 30.0±5.6 minutes (range, 14.5–31.9 minutes). After implantation of valve (Figure 4), all patients were transferred to the general ward without any acute complication, and intravenous heparin was infused overnight. We started the patients on clopidogrel 75 mg and aspirin 100 mg

Table 2. Pulsta Valve Selection Criteria

	TTE				CT							Balloon Sizing			Pulsta Valve	
	MPA Proximal	MPA Narrowest	MPA Distal	MPA Length	MPA Proximal Axial View	MPA Narrowest Axial View	MPA Distal Axial View	MPA Proximal Sagittal View	MPA Narrowest Sagittal View	MPA Distal Sagittal View	MPA Length	MPA Proximal	MPA Narrowest	MPA Distal	Diameter	Length
1	26.9	21.1	31.1	41.4	31	25.1	25	30	26.7	29.2	40.9	30.3	23	24.7	28	38
2	22.4	22.6	24.6	34.5	24.7	22.5	23.4	28.2	24.2	26.2	40.3	24	23.2	29.1	26	38
3	27.6	23.3	23.3	44	33	24.5	16.6	27.4	20.7	25.4	43.4	24.7	21.3	25.1	26	38
4	26.6	20.9	20.5	41.9	29.2	20.8	18.9	29.3	22.1	31.2	42.6	29.6	18.1	23	26	38
5	30.1	22.6	29.5	40.8	26.5	25.3	28.2	29.9	26.4	35.8	48.3	27.4	24	29.1	28	38
6	30.1	23.4	28.2	35.9	29.7	23.7	26.2	29.9	24.7	24.2	38.1	29.4	22.9	30.5	28	38
7	28.8	25.3	30.9	39.5	28.6	24.9	29.6	30.5	26.8	35.3	40.4	28.9	22.7	30.3	28	38
8	24.6	19.5	28.1	37.4	25.2	23.6	30.8	27.5	24	33.3	39.9	25.5	24.1	30.3	26	38
9	25.7	20.9	25.8	37.9	24	18.7	20.1	27.6	20.1	21.2	39.4	25.7	23.2	27	26	38
10	24.7	22.4	26.5	42.4	32.6	24.6	28.9	24.2	21.9	30.8	41.8	24.9	24.4	27.9	28	38

All numbers have same unit (mm). CT indicates computed tomography; MPA, main pulmonary artery; and TTE, transthoracic echocardiography.

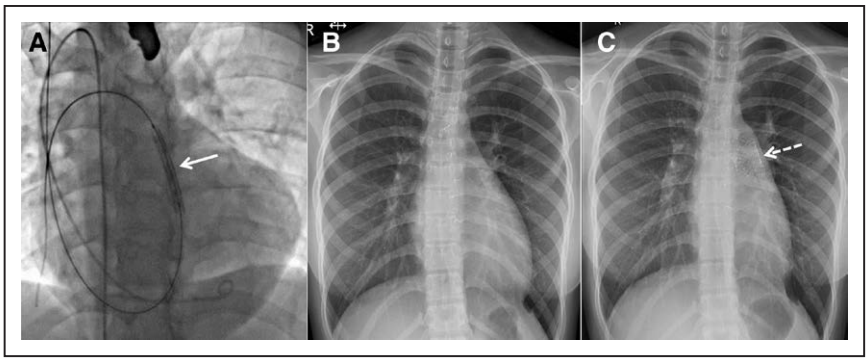

Figure 4. Pulsta valve on chest x-ray. In the third patient with inferior vena cava interruption, Pulsta valve could be introduced by internal jugular vein smoothly (**A**). In the second patient, just 10 days after valve implantation, cardiac size decreased significantly (**B** and **C**).

daily for 3 months followed by aspirin 100 mg daily life-long. All patients were discharged from the hospital without any serious adverse event. Echocardiogram just before discharge revealed trivial PR in 4 patients and trivial paravalvular leak in 5 patients. Four patients during the early phase of the clinical trial complained of mild chest discomfort on the procedure day and 1 day after PPVI, which was relieved in 2 days after procedure. Oral furosemide and spironolactone were given for 2 days after PPVI to reduce pulmonary overflow because of significantly reduced PR after PPVI. During the trial, we started to give oral furosemide and spironolactone 2 days before PPVI and gave intravenous furosemide on the day of procedure to prevent sudden pulmonary overflow after PPVI. After this preload reduction policy, patients did not complain of chest discomfort or dyspnea after PPVI. Other procedure-related adverse events were minor problems, such as mild fever in 5 patients at procedure day, transient premature ventricular contractions in 5 patients on electrocardiography monitoring during admission period, nausea and vomiting in 6 patients at procedure day, headache in 5 patients at procedure day, and urticaria in 2 patients at procedure day.

Follow-Up Data

We completed a planned 6-month follow-up evaluation of all the patients. New York Heart Association functional class of the patients improved in 9 patients and peak oxygen consumption also significantly improved from 25.3±6.6 to 30.3±5.4 mL/kg per minute (P=0.017) on cardiopulmonary exercise testing (Table 3). Echocardiography at 6-month follow-up revealed that all the patients showed trivial PR, and trivial paravalvular leak was seen in 3 patients. The mean value of peak pressure gradient between RVOT and main PA after PPVI decreased to 10.9±2.6 mm Hg (range, 7–14 mm Hg) by pulse wave Doppler examination of RVOT forward flow. Follow-up cardiac MRI at 6-month follow-up revealed that the mean indexed RV end-diastolic volume had significantly decreased to 126.3±20.3 mL/m^2 (range, 99–164.2 mL/m^2) than the data (176.7±14.3 mL/m^2) before PPVI (P=0.005; Figure 5; Table 3). The mean value of peak instantaneous pressure gradient between RV and main PA at 6-month follow-up decreased from 6.8±3.5 mm Hg (range, 2–12 mm Hg) to 5.7±6.7 mm Hg (range, 2–12 mm Hg) on cardiac catheterization (Table 3). There was no stent fracture on fluoroscopy examination at 6-month follow-up during catheterization. We experienced 1 serious adverse event in a 15-year-old boy. He showed vomiting and hematemesis 1 month after PPVI. After admission, gastrofiberscopy revealed *Helicobacter pylori*–induced duodenal ulcer in that patient. With medication for eradication of *Helicobacter pylori* and ulcer treatment, patient was discharged uneventfully. During follow-up after PPVI, there was no other device-related adverse event in any patient.

Table 3. Hemodynamic and Clinical Improvements After Pulsta Valve Implantation

	RVEDVi, mL/m^2		Peak RV-PA PG, mm Hg		Max. Vo_2, mL/kg per minute		NYHA Fc Class	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	186.5	139	6	3	14.9	25.8	3	1
2	161	112.6	5	3	16.9	26.9	3	1
3	205.9	164.2	6	5	33.1	36.3	2	2
4	179	99	13	7	30.9	28	2	1
5	189.7	99.1	12	2	27.3	34.7	2	1
6	158.9	124.3	3	2	21	22.8	2	1
7	172.3	126.8	9	4	23.6	24	2	1
8	172.7	119	6	4	23.4	35.7	2	1
9	175.1	143.1	4	12	25.2	31.8	2	1
10	165.5	135.7	6	12	36.8	37.1	2	1
Mean±SD	176.7±14.3	126.3±20.3	6.80±3.49	5.70±6.65	25.3±6.6	30.3±5.4		

Max. Vo_2 indicates maximal oxygen consumption; NYHA Fc, New York Heart Association functional; PA, pulmonary artery; PG, pressure gradient; RV, right ventricle; and RVEDVi, indexed right ventricular end-diastolic volume.

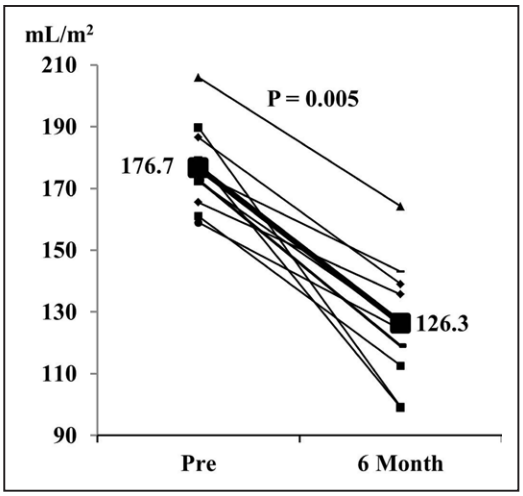

Figure 5. The changes of right ventricular (RV) volume before and 6 months after valve implantation. The mean indexed RV end-diastolic volume was statistically significantly decreased to 126.3±20.3 mL/m² than before valve implantation (176.7±14.3 mL/m²) on cardiac magnetic resonance imaging (*P*=0.005).

Discussion

In this first human feasibility study for the native RVOT lesion after TOF repair using Pulsta valve, a newly made knitted nitinol wire stent with treated trileaflet porcine pericardial valve,[13] we successfully completed valve implantation in all the patients without any device-related adverse event. Six-month follow-up cardiac MRI and catheterization also revealed significantly improved hemodynamic status in every patient without any device-related problem, including fracture, infection, etc.

Balloon-expandable Melody and SAPIEN valves have been used in the selective native RVOT lesions using various technical modifications, such as off-pump surgical main PA banding and Melody valve implantation or RVOT prestenting and large SAPIEN valve implantation, and so on.[18–21] Especially, Edwards SAPIEN XT valve with 29 mm diameter is being implanted for native RVOT lesions with good procedural success rate and hemodynamic improvement. However, most patients with dilated native RVOT 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 PPVI have been developed and are undergoing human clinical trials as a next-generation percutaneous pulmonary valve.

First successful implantation of a single self-expandable valve in a patient with a dilated pulmonary trunk was reported by Schievano et al,[22] and the feasibility study has just been completed in the United States and Canada by Medtronic, Inc. This Harmony feasibility trial to implant Harmony valve for 20 patients revealed high procedural success and safety, with a favorable acute device performance.[10,23] Venus P valve (Venus Medtech, Shanghai, China) 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.[11,24] These 2 self-expandable valves have shown high procedural success and good short-term efficacy in the selected patients with native RVOT lesions.

Pulsta valve has several merits for native RVOT lesions. First, we have performed multiple steps of specific tissue treatment, including decellularization, α-galactosidase treatment to remove the α-gal xenoantigen, space filler treatment, glutaraldehyde fixation, organic solvent treatment, and detoxification to reduce immunogenicity, as described in our previous articles.[13–17] This is the first human clinical study with α-Gal–free porcine pericardial valve, and we hope good valve durability through these multiple steps of specific tissue treatment. Second, because Pulsta valve was made by knitted nitinol wire stent with a maximal length of only 38 mm, it is not bulky. Because of this unique structure, we could load the valve in the delivery cable and advance it into the target RVOT area easily using only an 18F delivery catheter for a 28-mm valve. We could implant Pulsta valve in patients with branch PA stenosis and even in a triangular shaped main PA. As illustrated in Figure 3, this Pulsta valve is fit for the target RVOT area (main PA in practice). Third, the knitted wire backbone of Pulsta valve has the potential to prevent stent fracture at the dynamic RVOT area as seen in this trial, and we have also performed stent fatigue test for 400 000 000× before the feasibility trial to estimate the risk of stent fracture.

In this feasibility trial, we implanted 26 mm valves in 5 patients and 28 mm valves in 5 patients. The shape of native RVOT lesions with mainly significant PR is diverse, and many patients have a larger pulmonary trunk than 28 mm. Therefore, we have already finished the bench test up to 32 mm valves and will try to implant larger Pulsta valves up to 32 mm in the next human trial. Because Pulsta valve is fit for various dynamic native RVOT lesions with mainly significant PR with low profile delivery system and softer device nature than other types of self-expandable pulmonic valve, we think that Pulsta valve could be the next-generation self-expandable valve for PPVI to minimize reintervention rates and redo PPVI.[7]

Study Limitations

This Pulsta feasibility study has a limitation because of the small patient number. However, because this valve was approved as an orphan device and permitted for a feasibility study for 10 patients with RVOT lesions by the Korean Ministry of Food and Drug Safety, we completed this study under this regulation. As a next step, we started a Korean multicenter clinical trial since March 2017. Second limitation is still small diameter of Pulsta valve considering various large-size native RVOT lesions. In this feasibility trial, we implanted valves up to 28 mm because we had finished bench test up to 28 mm and acquired permission to implant up to 28 mm by the Korean Ministry of Food and Drug Safety. However, we already finished bench test up to 32 mm valve, and we will start valve implantation up to 32 mm diameter for the patients with larger RVOT lesions after approval of the Korean Ministry of Food and Drug Safety.

Conclusions

A feasibility study to evaluate short-term (6 months) effectiveness using a new knitted nitinol-based self-expandable α-Gal–free valve (Pulsta valve) for native RVOT lesions with significant PR was completed without any device-related adverse event. All patients showed significantly improved

hemodynamic status, and there was no adverse event associated with Pulsta valve itself. A larger, multicenter study is now on-going in South Korea.

Sources of Funding

The study was partially funded by the sponsor, TaeWoong medical Co (Gyeonggi-do, South Korea).

Disclosures

None.

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