Implantation of the Edwards SAPIEN XT and SAPIEN 3 valves for pulmonary position in enlarged native right ventricular outflow tract

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Abstract

Objective: Percutaneous pulmonary valve implantation (PPVI) into right ventricle–to–pulmonary artery conduits is increasingly being performed, but a few options are available for patients with a dilated native right ventricular outflow tract (RVOT), among which is the off-label use of Edwards SAPIEN® valves. This study reviews the results of the SAPIEN XT and SAPIEN 3 (S3) valve implantations in the pulmonary position in patients with a dilated native RVOT.

Methods: Between January 2015 and March 2020, PPVI procedures were performed on 129 patients. Among them, 103 (80%) had dilated native RVOT, 86 of whom were eligible for PPVI prestenting and valve implantation. Retrospective analysis was performed on 84 patients who have undergone successful PPVI implantation using the SAPIEN XT or S3 valves with dilated native RVOT.

Results: The procedural success rate was 84/86 (98%). The median age was 18.7 years (8–46 years), and the median weight was 57 kg (22–102 kg). The primary underlying diagnosis was tetralogy of Fallot (n=77/84). Stenting was performed simultaneously with valve implantation in 50/84 (60%) cases-six of which were hybrid procedures-whereas prestenting was performed 3 to 14 weeks earlier in 34/84 cases. Before valve implantation, the median right anterior oblique and lateral diameters of the stents were 26 mm (20–32 mm) and 28 mm (21–32 mm). Valve sizes were 26 mm (n=13) and 29 mm (n=64) for XT and 29 mm (n=7) for S3. In 59 patients, an additional 1–5 ml (median 2 ml) volume was added to the valves' balloons for stabilization. In all hybrid procedures, the stent and valve were implanted in the same session. During follow-ups of 1 to 59 months (median 14 months), no deaths were reported, 3 patients developed tricuspid regurgitation secondary to the procedure, and valves continued to function in all patients.

Conclusion: The Edwards SAPIEN XT and S3 valves may be an alternative to PPVI in patients with dilated native RVOT.

Keywords: dilated native right ventricular outflow tract, percutaneous pulmonary valve implantation, pulmonary valve, Edwards SAPIEN

Cite this article as:*Güzeltaş A, Tanıdır İC, 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.*

Introduction

Right ventricular outflow tract (RVOT) reconstruction is commonly performed in patients with congenital heart disease. The restoration of pulmonary valve function by valvuloplasty has been attempted because the native leaflet tissue can continue to grow after transannular patching. The number of suitable candidates for these procedures is relatively small, given the need for pliable valve tissue, integrity of the anterior leaflet, and the absence of pulmonary stenosis. Furthermore, these procedures are not curative, and most patients will be required valve implantation later in life to address a dysfunctional valve or conduit (1, 2). Percutaneous pulmonary valve implantation (PPVI) has emerged as a safe and effective option for patients that need pulmonary valve replacement after surgical repair (3, 4). Two valves are currently available commercially in our country, the Melody transcatheter pulmonary valve (Medtronic, Minneapolis, MN) and the Edwards SAPIEN transcatheter heart valve system (Edwards Lifesciences, Irvine, CA, USA) (5, 6).

Previously, when valve protection could not be performed and valve sparing surgery was still uncommon, complications due to both RVOT dilatation and free pulmonary regurgitation

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Accepted Date: 05.08.2020 **Available Online Date:** 04.01.2021

DOI:10.14744/AnatolJCardiol.2020.46024

HIGHLIGHTS

- CHD patients with previous RVOT surgery require re-intervention later in life secondary to pulmonary regurgitation.
- PPVI can be performed in patients with native RVOT as well as in patients with pulmonary conduit.
- Adding 5ml extra to the recommended balloon volume does not adversely affect the valve functions.
- Thanks to the new technologies, available valve sizes for patients with native RVOT increase, and the need for surgery is decreasing over time.

were frequently observed. Few options remain for patients with a significantly enlarged RVOT, the most prevalent of which is the implantation of the Edwards SAPIEN valve system (maximum available size, 29 mm) (5, 7, 8). Other methods are still being developed, which reduce the RVOT diameter using the Alterra Adaptive Prestent and subsequent valve replacement (9), Pulsta Pulmonary Valve implantation (TaeWoong Medical Co., Gyeonggi-do, South Korea; maximum available size, 28 mm) (10, 11), and Venus P-valve implantation (MedTech, Shanghai, China) (3, 12-14). Additional treatment options are as follows: surgically reducing the RVOT and implanting a transcatheter valve (15, 16), implanting valves on both pulmonary arteries, and "Russian doll" and "pulmonary jailing" techniques (17). Moreover, development studies for the harmony transcatheter pulmonary valve (Medtronic, Minneapolis, MN, USA) are in progress (18).

In this study, we present the results of SAPIEN XT and SAPIEN 3 (S3) valve implantations in patients with an enlarged native RVOT and free pulmonary regurgitation due to a transannular patch.

Methods

Between January 2015 and March 2020, among 129 patients (both native and conduits) who underwent the PPVI implantation procedure, 112 successful PPVI procedures were (both native and Conduits) performed. Among the 112 successful PPVI, 84 patients had native RVOTs.

Indications and patient selection

Indications for PPVI were based mostly on assessments using cardiac magnetic resonance imaging. Patients were considered candidates for PPVI if they meet at least two of the following criteria: moderate-to-severe pulmonary regurgitation with a pulmonary regurgitant fraction of >25%, a right ventricular end-diastolic volume index of >150 ml/m^2, a right ventricular end-systolic volume index of >80 ml/m^2, a right ventricular ejection fraction of <40%, and New York Heart Association class II or III symptoms (19).

Transthoracic echocardiography was performed on all patients to assess right ventricular size and function, tricuspid regurgitation, right ventricular systolic pressure, RVOT gradient, and the degree of pulmonary regurgitation. In particular, a short axis view measured the diameters of the pulmonary valve annulus, the main pulmonary artery (MPA), and the pulmonary artery branches, as well as the MPA length, which is particularly useful in selecting the length of the valve to implant.

Echocardiography, MRI, and/or computed tomography angiography (CTA) were performed on all patients before the procedure, and catheter angiography was performed on patients with a native RVOT diameter <28 mm in echocardiography and <30 mm in either MRI or CTA (Fig. 1).

All candidates for PPVI were evaluated using a 24-hour Holter electrocardiogram (ECG) monitor and exercise stress test before the procedure. The patients with frequent ventricular extrasystole (>10% of total heartbeats), polymorphic ventricular extrasystole, ventricular tachycardia, or syncope history (12 patients) underwent electrophysiological study and if necessary catheter ablation or ICD implantation before the PPVI procedure, and they were re-evaluated after 6–12 months only if no arrhythmia was recorded by the 24-hour Holter ECG monitor.

Hybrid PPVI was indicated in patients weighing <25 kg with a concomitant permanent pacemaker implantation (n=2), concomitant partial anomalous pulmonary venous return surgery (n=1), jugular and femoral vein occlusion or inadequate vein diameter (n=1), life-threatening arrhythmias after advancing the long sheaths into the distal pulmonary artery (n=1), and abnormal RVOT anatomy, preventing the advancement of the long sheaths into the pulmonary artery (n=1) (20).

Procedure

All procedures were performed under general anesthesia (with either intubation or laryngeal mask) in a catheter laboratory

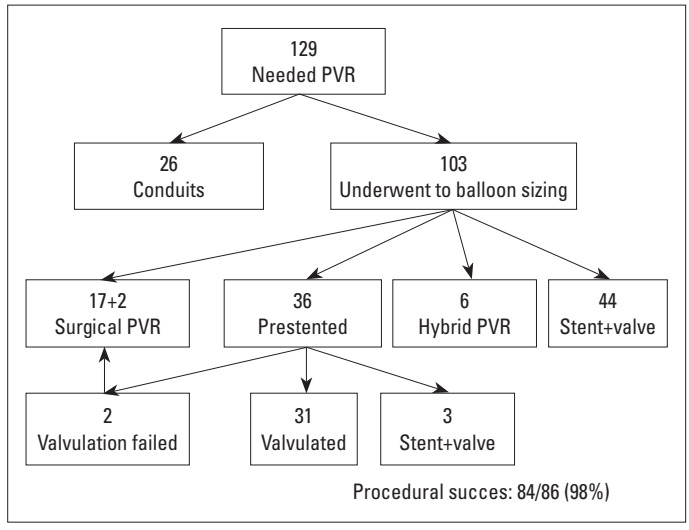

Figure 1. Flow chart of percutaneous pulmonary valve implantation procedure
PVR - pulmonary valve replacement

Anatol J Cardiol 2021; 25: 96-103
DOI:10.14744/AnatolJCardiol.2020.46024

equipped with the Philips Allura Xper FD20/10® biplane angiography system (Philips Medical Systems, Eindhoven, Netherlands). Heparin (100 IU/kg) was routinely used as an anticoagulant at the beginning of the procedure, and additional heparin was administered for the activated clotting time to remain above 200 s throughout the procedure. Cefazolin (25 mg/kg) (max dose of 1 g) was delivered intravenously at the onset of catheterization.

After the administration of a local anesthetic, the interventions were initiated with the cannulation of the right femoral vein and the left femoral artery. Following a hemodynamic assessment, angiograms were performed in the RVOT and MPA to delineate the anatomy of the RVOT and pulmonary artery bifurcation. Angiograms were commonly performed in the left anterior oblique or right anterior oblique with cranial angulation and lateral projections for better visualization of the pulmonary artery bifurcation, since understanding of the anatomy is the key to valve implantation. Measurements were made of the maximum diameters of the RVOT and the medial aspect of the MPA and its bifurcation, maximum systolic diameter of the proximal and distal pulmonary artery branches, and the length from the RVOT to the pulmonary artery bifurcation. In patients with peripheral pulmonary artery stenosis, the distal stenosis was treated first (stent, n=3; balloon angioplasty, n=2).

The balloon size for test occlusion is selected according to the narrowest section of the RVOT and the size of the valve that will be implanted. According to our clinical protocol, we used either a 28 mm or 30 mm sizing balloon for a 29 mm valve, 23 mm or 25 mm for a 26 mm valve, and 20 mm or 22 mm for a 23 mm valve.

After measuring, a non-compliant balloon with a 30 mm maximum diameter (TyShak balloon) was advanced across the RVOT over a 0.035 inch Lunderquist wire (Cook; Bjaeverskov, Denmark) and stabilized in the proper position at full inflation. Thereafter, we evaluated the following criteria:

- a significant drop in systemic blood pressure (BP) (<40 mm Hg),
- any clear waist on the balloon,
- any residual leak to the MPA after contrast injection into the RV,
- balloon stabilization by checking with tagging.

If the patient's anatomy was accepted for a PPVI procedure (an average balloon waist diameter of ≤ 28 mm with a significant systemic BP drop and no contrast passage to the pulmonary artery), the procedure was continued to check the coronary artery compression using the same balloon. If there was none, the procedure was then continued with prestenting.

If the assessments were semi-suitable for a PPVI procedure (no clear waist on the TyShak balloon but also little contrast passage to the pulmonary artery and/or mild systemic BP dropping), we continued testing with a non-compliant balloon, but this time we inflate the balloon up to burst pressure (1.5–2 barr) and perform tests again. If the results were appropriate (no contrast passage to the pulmonary artery and/or significant systemic BP dropping), then we proceeded to PPVI (Fig. 2).

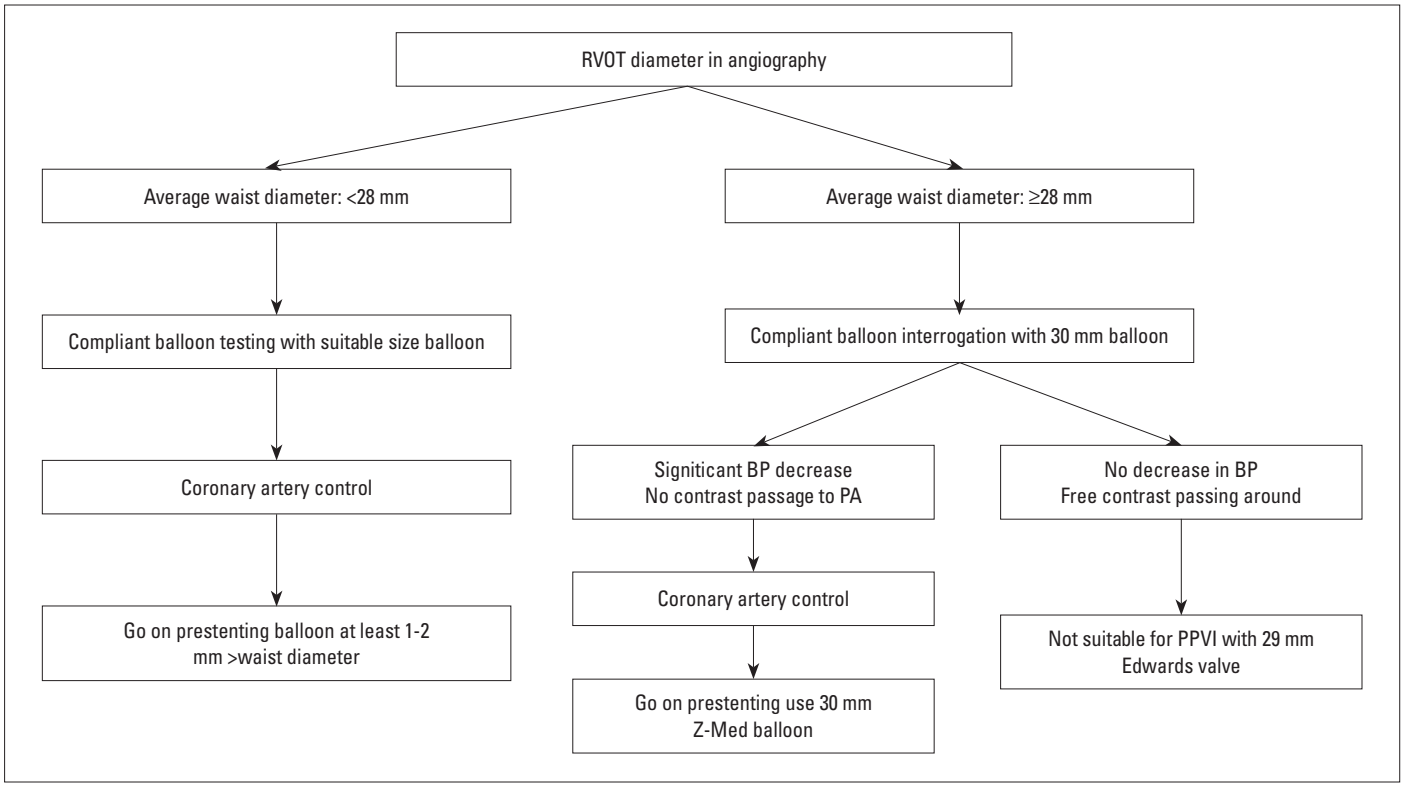

Figure 2. Patient selection algorithm
RVOT - right ventricular outflow tract; BP - blood pressure; PA - pulmonary artery; PPVI - percutaneous pulmonary valve implantation

Table 1. Patient and procedural characteristics

Age (years)	18.7 (15.7-21.7)*
Gender (Female/Male)	38/46
Weight (kg)	57 (50-68)*
Height (cm)	165 (158-175)*
Underlying diagnosis, n (%)	
Tetralogy of Fallot	77/84 (92%)
Pulmonary stenosis	5/84 (6%)
DORV	1/84 (1%)
Ebstein anomaly	1/84 (1%)
Implanted valve sizes, n (%)	
XT, 26 mm	13/84 (16%)
XT, 29 mm	64/84 (76%)
S3, 29 mm	7/84 (8%)
Procedure time (min)	
Prestented patients	35 (25-75)*
Stent+valve	70 (60-120)*
Hybrid	100 (60-200)*
Fluoroscopy time (min)	
Prestented patients	11 (8.1-32.1)*
Stent+valve	17.3 (11-28)*
Hybrid	10.1 (8-13.2)*

The results are among the successful procedures. *Numbers given as median [interquartile range (25%–75%)]. DORV - double outlet right ventricle

An Andra XXL stent (Andramed®, Reutlingen, Germany) (39 mm, 43 mm, 48 mm, or 57 mm) mounted over the Z-Med-II balloon (Braun Interventional Systems Inc., Bethlehem, PA, USA) was used for prestenting. If a PPVI with a 26 mm valve was performed on the patient or testing for prestenting was performed with a 28 mm balloon (in these patients, 29 mm valves were used), then we proceeded to PPVI in the same session. Also, if a hybrid procedure was performed on the patient, both prestenting and PPVI were also performed in the same session. However, if a 30 mm balloon was used for testing, then waiting for 6–12 weeks after the prestenting procedure before performing PPVI was preferred for our initial patients. After gaining some experience, we tended to implant the valve during the same session (the last 30 cases) as long as there was a significant systemic BP dropping and no contrast passage to the pulmonary artery with balloon testing. To avoid complications, an additional volume of 1 to 5 cc was added for these patients.

Both stenting and pulmonary valve implantation procedure (SAPIEN XT or S3 transcatheter heart valve) were reported in the literature (21).

The day after the procedure, cefazolin (100 mg/kg/day) (four doses, maximum 1 gr/dose) was given intravenously. For 6 months, all patients received aspirin (100 mg) daily.

Follow-up

The patients were assessed on day 1 after the procedure and were scheduled for outpatient visits at 1, 3, and 6 months- and yearly thereafter-which included clinical evaluation, ECG, chest x-ray, 24-hour Holter monitoring, and transthoracic echocardiography.

Statistical analysis

The Statistical Package for the Social Sciences (SPSS) for Windows version 15 (SPSS, Chicago, IL, USA) was used for the statistical analyses. As this study was purely descriptive, standard descriptive statistics were used for the procedural and demographic data sets. Qualitative variables were expressed as frequencies and percentages, and quantitative variables were expressed as median values and interquartile range (25%–75%) when appropriate.

Results

Between January 2015 and March 2020, PPVI was performed on 129 patients, 26 of whom had previously placed right ventricle–to–pulmonary artery (RV-PA) conduits and were excluded from the study. Among the 103 patients with dilated native RVOT, 17 were not appropriate for PPVI implantation according to the evaluation with balloon testing, leaving 86 appropriate ones, 84 of whom had a successful PPVI. The patients with a failed PPVI (in one patient, the stent crashed and could not be fixed with another stent, and the other patient's valve could not be advanced to the MPA) underwent surgical valve implantation.

The previously mentioned 84 patients were enrolled in this study. Retrospective analyses of the pre- and post-procedural data and clinical follow-up were gathered from the hospital database (Fig. 1).

All patients had undergone patch annuloplasty repair without conduits during childhood. None of them had pulmonary stenosis before the PPVI, mainly indicated by severe pulmonary regurgitation. The primary diagnosis was tetralogy of Fallot in 77 cases, pulmonary stenosis in 5, double outlet right ventricle in 1, and Ebstein anomaly in another. The median age was 18.7 (8–46), and the median weight was 57 kg (22–102 kg). Some of the demographic data are presented in Table 1.

Among 86 patients, 50 underwent both stent and valve implantation during the same session, 6 of whom underwent hybrid PPVI (with left anterior thoracotomy), as described in the literature (19). Thirty-six patients underwent valve implantation in a second session, among whom three needed a second stent before valve implantation (due to a fracture in the previously implanted stent) and four needed balloon dilatation of the stent since ventricular edges of the stent prevented valve propagation during PPVI.

The procedure was a success in 84 out of 86 patients (98%) (Fig. 1). In one patient, the long sheath crushed the stent in the RVOT during manipulations, with the procedure ending in elective surgery, as we could not fix it with a second stent. In another patient, the valve was embolized back to the RVOT during valve

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DOI:10.14744/AnatolJCardiol.2020.46024

opening and therefore could not be further advanced, making him undergo urgent surgical PVI.

In 59 patients, the valve was overexpanded by an additional volume [median 2 ml (range 1–5 ml)] to increase stabilization.

Complications

Major complications: Arrhythmias [ventricular tachycardia (n=1) and ventricular fibrillation (n=1); both patients were defibrillated] and severe tricuspid regurgitation (n=1) were the major complications. One patient experienced hemoptysis following the procedure, and rupture of the peripheral pulmonary artery was detected in the right lower lobe secondary to stiff wire injury that was embolized with a vascular plug.

Minor complications: Stent enfolding during pulmonary valve advancement into the pulmonary artery (after the valve was implanted, enfolding was fixed), femoral hematoma (n=2), moderate tricuspid regurgitation (n=2), mild paravalvular leak (n=4), transient hemoptysis (n=2), and blood transfusion due to the extensive hemorrhage during the procedure (n=1) were the minor complications.

Follow-up

During follow-ups of 1 to 59 months (median 14 months), no deaths were reported, valve function was preserved in all patients, and no stent fractures were seen in x-rays. One of the patients with severe tricuspid regurgitation secondary to PPVI underwent tricuspid valve repair 2 years after the first intervention. The remaining patients are still on follow-up.

Discussion

The main finding of this study is that PPVI can be feasible and safe in selected patient groups with dilated native RVOT. To select the right patients, besides routine examination tools (echocardiography, CT, and MRI), a rational angiogram will help interventionalists in the successful implantation of pulmonary valves.

Progressive dilation of the RVOT and pulmonary regurgitation usually occur in patients with tetralogy of Fallot after previous surgeries with a transannular patch (4). PPVI is an interventional method for patients with RV-PA conduits to avoid surgery. Extending the PPVI indications to include conduit-free native RVOTs may have a significant impact on the management of many patients. Either Melody or Edwards SAPIEN valves can be used to treat these patients (17, 21).

The maximum diameter of the Melody transcatheter pulmonary valve is 24 mm (2, 3, 7). Therefore, in patients with RVOTs larger than 26 mm, the Melody valve is not an option. The Edwards SAPIEN XT or S3 valves are available in diameters of 26 mm and 29 mm, but neither device can be used in patients with native RVOT (2). Newer valves like Pulsta (10, 11), Venus P (3, 12-14), and Harmony (18) are still being tested but show promising results for patients with large native RVOTs. There are two types of Edwards valves available: SAPIEN XT and the newer S3 and S3 Ultra. According to Guccione et al. (22), the first Edwards valve implanted in the native RVOT had a 26 mm diameter.

Demkow et al. (23) (10 patients, 1 failed procedure), Haas et al. (24) (11 patients), Georgiev et al. (17) (18 patients, 10 with pulmonary stenosis), and Esmaeili et al. (5) (7 patients) reported on PPVI procedures using Edwards SAPIEN XT. There were no major complications during or after the procedures. Levi et al. (25) reported that the main problem was the advancement of the XT system but could be overcome with different manipulations. Subsequently, Hascoet et al. (26) stated that the new delivery system was more easily advanced and reduced complication rates.

The Edwards S3 valve was first used in the pulmonary position by Rockefeller et al. (1), which was reported by Riahi et al. (27) and Suntharos and Prieto (8). In a retrospective study involving eight centers, the Edwards S3 valve was implanted in 82 patients, which was unsuccessful in only 1 of them. Among them, 13 patients (16%) had native/pulmonary stenosis, and 21 patients (26%) had transannular patch repair. In 26 patients, 29 mm Edwards S3 valves were implanted. No complications were detected except for the development of pulmonary valve thrombosis in two patients within a 201-day median follow-up period (26). In a multicentric retrospective study including 50 patients-38 with native RVOT-Edwards S3 valves were successfully implanted with no procedural deaths but with major complications including severe aortic compression (n=1) and tricuspid valve injury (n=3). Two patients with tricuspid regurgitation underwent surgery after 1 month and 6 months. In our series, one patient underwent tricuspid plasty 2 years after the procedure due to the severe tricuspid regurgitation.

Sinha et al. (28) reported a patient with mild-to-moderate central pulmonary regurgitation after implanting an overexpanded 29 mm S3 valve (40 ml volume in dilation balloon) to a dilated RVOT, remaining unchanged at a 12-month follow-up. Also, they reported another patient with a persistent, mild paravalvular leak after placement of a second Edwards S3 valve to treat larger paravalvular leaks associated with proximal malposition of the first S3 valve (28). During the median follow-up at 3 months, neither stenosis nor valve insufficiency was detected (28).

For dilated RVOTs, creating a stable landing zone with a diameter less than the largest available valve (currently 29 mm) is crucial for the technical success of the procedure (17). In our study, even though RVOT and MPA were significantly dilated, we did not need an anchoring technique to implant valves, attributing to the success of landing zone selection in advance of the stent implantation. If an indentation is seen when a non-compliant balloon is fully inflated at nominal pressure in the presumed stent zone, and if there is no contrast passage to the MPA during simultaneous RV injection, a stent can be implanted with a 30 mm balloon. If the patient has an atrial septal defect or a residual ventricular septal defect, there will be no BP decrease. Therefore, BP decrease should not be a criterion in these patients.

In this study, stent placement was successfully performed in all patients that fulfilled these criteria.

Prestenting of the RVOT is the most crucial step of the procedure since it creates an artificial conduit, allowing safe positioning of the valve stent, may prevent or reduce the chance of stent/valve fracture or migration, and may also prevent paravalvular leak (22, 29). Prestenting can also provide a well-defined radiopaque outline of the RVOT, allowing very precise measurements of the RVOT (29). For most patients undergoing Melody valve implantation, prestenting is required to reduce the incidence of stent fracture. On the other hand, Edwards SAPIEN valves have a high radial force frame, which is very likely to resist the frame fractures seen in pulmonic Melody valve implantation. Prestenting was utilized prestenting to test, outline, and potentially stabilize the landing zone and decrease paravalvular leaks in the SAPIEN valves (19, 25, 29). Prestenting, but it had a number of disadvantages, such as stent crush or enfolding during PPVI procedures, additional radiation exposure, prolonged procedure time, difficulties in advancing the valve, and increased costs. Consequently, in a multicenter retrospective study including 41 patients with dilated native RVOT, patients underwent percutaneous placement of the SAPIEN XT and S3 valves in the pulmonary position without prestenting. There were no reports of significant obstruction or regurgitation around the valve, and no frame fractures were reported during follow-up (29). Also, in another study including 11 patients with dilated native RVOT, Edwards S3 valve implantation was performed with prestenting. Operators mentioned that, in these two centers, they abandoned the use of prestenting as their experience increased (28), demonstrating the possibility to implant the Edwards SAPIEN valve without a prior stent in the landing zone with a non-significant rate of valve embolization, frame fracture, or paravalvular leak (29). In our study, none of the patients underwent PPVI without prestenting; therefore, we do not have any experience with PPVI in patients without prestenting. However, observing long-term outcomes in patients with and without prestenting is still needed to decide which is better, and the best way to do so is by analyzing each patient individually. As the stability of the first stent is of paramount importance, the next interventional step (PPVI) is delayed for a few months to allow stent integration (17). In our study, we performed stenting and PPVI in the same procedure if the RVOT diameter was less than 28 mm. If the RVOT diameter was in the borderline range, we preferred to perform prestenting at the beginning of our learning curve. After our experience increased, if an indentation was seen with a fully inflated non-compliant balloon in the presumed stent zone, and there was no contrast passage to the MPA in simultaneous RV injection, we proceeded to valve implantation in the same session. In these patients, an additional 2–5 cc was added for overexpansion.

Additional volume for valve balloons is essential for a successful procedure. Edwards SAPIEN XT and S3 valves are designed for the aortic position; thus, aortic regurgitation is a significant problem. The manufacturer suggests inflating the valve with appropriate volumes to prevent this complication, but pulmonary insufficiency is not as important as aortic insufficiency and patients can easily tolerate mild insufficiency. Using additional volumes, we can overexpand the valve and use it in borderline dilated RVOTs. In a study with 50 patients who underwent PPVI with the Edwards S3 valve, in 28 of them (56%), the valve was overexpanded beyond its nominal volume by as much as 5 ml, allowing the 29 mm S3 valves' outer diameters to reach up to 31 mm. In addition, overexpansion of the 29 mm S3 valve can provide extra safety in patients that have large and compliant RVOT, reducing the risk of malposition, embolization, or paravalvular leak. In this study, no significant paravalvular leaks that required intervention were noted. Most centers now routinely prepare the balloon with extra volume in case overexpansion is needed during valve implantation (28). In cases where the substrate was a native RVOT with measurements at the upper limit of feasibility for a 29 mm valve, operators tended to "over dilate" the valve, particularly where an S3 valve was being implanted, which usually involves putting an additional 3–9 cc (mean 5 cc) of volumes into the inflation device, maximizing the dilation of the valve to decrease the risk of an unstable deployment and valve embolization (29). Also, Ghobrial et al. implanted Edwards SAPIEN 29 mm valves without prestenting, but they could stabilize the valve only after the addition of 9 ml of volume (30). In our study, we added 1–5 ml (median 3 ml) to the valve's balloon to stabilize the valve in 31/50 (62%) patients; most of their valves were Edwards SAPIEN XT. None of the patients had more than trace pulmonary insufficiency.

There are several transcatheter valve implantation options for dilated native RVOT, and clinical trials are still ongoing for these valves. There were three alternative self-expandable valves for PPVI: the Venus Pulmonary Valve [currently available up to a maximum diameter of 34 mm, which is suitable up to 30–32 mm RVOT diameter (3, 12)], Pulsta valve [28 mm maximum size, but clinical trials are ongoing with a 32 mm valve (10, 11)], and harmony transcatheter pulmonary valve (another self-expandable valve implanted in RVOTs up to 29 mm) (18, 31). But the new valve options are beyond the scope of this article. Furthermore, some of these valves do not have a CE mark or FDA approval. Also, Alterra Adaptive Prestent is a self-expanding, partially covered stent that was designed to internally reconfigure these types of RVOTs, making them suitable for implantation of a commercially available balloon-expandable heart valves. But it still requires more clinical research (9).

Study limitations

This study reports our initial experience with PPVI in patients with "dilated native RVOT" and has some limitations, such as the procedure being technically demanding. Although our patient number is small and the follow-up period is relatively short, to our knowledge, this is one of the largest cohorts treated by PPVI

Anatol J Cardiol 2021; 25: 96-103
DOI:10.14744/AnatolJCardiol.2020.46024

for this indication. However, only limited conclusions can be drawn so far and further studies are needed.

Conclusion

The Edwards SAPIEN XT and S3 valves can be safely implanted in patients with dilated native RVOT. Pre-procedural patient selection and carefully performed angiography were crucial steps in this procedure. In borderline dilated RVOTs, additional volume can be added to the valve's balloon to reduce the risk of malposition, embolization, or paravalvular leak. Patients' midterm follow-ups were excellent, but further studies should have more patients with dilated native RVOTs for more definite conclusions.

Conflict of interest: None declared.

Peer-review: Externally peer-reviewed.

Authorship contributions: Concept – A.G., İ.C.T.; Design – A.G., İ.C.T.; Supervision – A.G., S.G.; Fundings – A.G., M.Ş.; Materials – A.G., İ.C.T., M.Ş.; Data collection and/or processing – İ.C.T., S.G., M.A.T., M.Ş.; Analysis and/or interpretation – A.G., S.G.; Literature search – S.G., M.A.T., M.Ş.; Writing – A.G., İ.C.T., M.Ş.; Critical review – A.G., İ.C.T., M.Ş.; Revision – Y.E.

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