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Original article

The standing of percutaneous pulmonary valve implantation compared to surgery in a non-preselected cohort with dysfunctional right ventricular outflow tract – Reasons for failure and contraindications

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ABSTRACT

Background: Percutaneous pulmonary valve implantation (PPVI) numbers are rising but are still minor compared to surgery due to several contraindications. We sought to analyze the impact of PPVI compared to standard surgery in an unselected cohort with dysfunctional right ventricular outflow tract (RVOT). Reasons for PPVI failure and possible contraindications were explored.

Methods: Between 2010 and 2015 all consecutive patients who underwent surgery or intervention for a dysfunctional RVOT were investigated.

Results: A total of 382 cases was identified – 246 patients underwent successful valve insertion: 166 surgeries (166/246 = 67.4%) with 55/166 homografts (33.1%), 106 Contegra® grafts (63.8%), 5 Hancock valves (3.0%). Overall, 70/246 patients presented a priori with an enlarged RVOT > 28 mm (28.5%) not appropriate for PPVI and 14/246 (5.7%) had additional defects necessitating surgery. Some 31/246 patients had surgery for initial repair of congenital defects or were too small (<20 kg) for PPVI (12.6%). 80 underwent successful PPVI (32.5% of 246 valves implanted) [51 Edwards Sapien® valves (63.7%), 29 Melody valves (36.3%)]. The RVOT was too large for PPVI in 22/246 patients (8.9%). A total 20/246 patients (8.1%) showed coronary compression after balloon interrogation. In 4/246 patients PPVI was not possible due to technical issues (1.4%).

Conclusion: PPVI could be performed successfully in 80/382 patients (20.9%). An enlarged RVOT, small patient size, and coronary compression were the major obstacles for interventional management. Future developments for larger RVOTs and smaller body weight may expand the indication for PPVI.

Introduction

Malfunctioning, dysplasia, or absence of the pulmonary valve or the right ventricular outflow tract (RVOT) is one of the major components of the cardiac physiology in many congenital heart defects [1–4]. Surgical correction thereby includes some form of repair or replacement of the native RVOT by biological valves such as homograft, bioprosthesis or xenografts (i.e. Contegra®-conduits; Medtronic Inc., Minneapolis, MN, USA) [5]. The repaired or replaced pulmonary valve often becomes dysfunctional later on and surgical revisions of the RVOT with pulmonary valve replacement usually within 10 years after the primary intervention are necessary [6]. Various valved conduits are available for the restoration of right ventricle-to-pulmonary artery (RV-PA) continuity with inherent advantages and limitations [5].

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Percutaneous pulmonary valve implantation (PPVI) is a relatively new procedure introduced in 2000 as a less invasive procedure for RVOT dysfunction with the aim to replace or postpone surgical conduit exchange with the potential to avoid or delay a further sternotomy and its associated morbidity and mortality [7–9]. It became commonly available in Europe, the USA, and other countries since 2010 [10–12]. Traditionally, the Melody®-valve (Medtronic Inc., Minneapolis, MN, USA) was used offering diameters of 18–22 mm to replace the dysfunctional RVOT [10–14]. The Edwards SAPIEN valves (i.e. Sapien®™, SAPIEN® XT, and Sapien® S3 valve, Edwards Lifesciences, LLC, Irvine, CA, USA) were initially used for aortic valve replacement and reached initial CE certification for PPVI at the end of 2010 [15–18].

In most of the reports presenting the results of PPVI, a careful preselection was performed for patients who ultimately were scheduled for PPVI [10–13]. Patients after patch reconstruction of the RVOT, or with dilated native RVOTs, have been successfully treated with PPVI technology, however they are the exception rather than the rule [19,20]. Conduits <16-mm diameter may also represent relatively poor candidates for PPVI [21]. In addition endocarditis with active infection, coronary compression during RVOT balloon inflation, and occluded central veins are considered contraindications to PPVI [22,23]. Multimodality cardiac imaging using echocardiography (ECHO), dual source computer tomography (CT) imaging, or magnetic resonance imaging (MRI) therefore plays a central role in ensuring optimal selection of patients scheduled for this treatment option [24]. The objective of this study was to assess the impact of PPVI compared to surgery in a non-preselected group of patients and analyze reasons for implantation failure and possible contraindications for PPVI.

Methods

Patient acquisition and data analysis

During the period of 1st of January 2010 until 31st of December 2015 we performed a single center retrospective cohort analysis of all consecutive patients who had a surgical pulmonary valve implantation or reconstruction of the RVOT with the use of a valved conduit or a PPVI by catheter techniques at the Herz und Diabetes Zentrum NRW, Bad Oeynhausen, Germany. Patient data (sex, age, weight, height), the underlying diagnosis (tetralogy of Fallot, pulmonary atresia with ventricular septal defect, double outlet right ventricle, truncus arteriosus communis, Ross-surgery, pulmonary stenosis, others), the surgical as well as interventional catheter reports were analyzed with regard to the implanted valve and size in mm (Contegra® graft, homograft, Melody® valve, Edwards® valve, others). Informed and written consent for the procedure was obtained from the parents at the time of the procedure. The retrospective analysis was approved by the local ethical committee (Ref. No.: 26/2015) and additional consent was waived due to the retrospective character of the analysis.

Patient selection for valve implantation

All patients were discussed in a multidisciplinary team consisting of pediatric cardiac surgeons, pediatric cardiologists, Adults with congenital heart disease (ACHD) – cardiologists, and imaging specialists before the procedures and indications for replacement were consented according to current guidelines [1–3].

Patients scheduled for primary surgical intervention were patients for primary repair of congenital defects (i.e. truncus, etc.) or with other cardiac defects requiring surgical repair at the same time, those with active endocarditis, patients that were deemed too small for PPVI at the time (i.e. <20 kg), and those who had an RVOT >28 mm in diameter as assessed by MRI or echocardiography. Valves were implanted surgically by using cardiopulmonary bypass without cardioplegic arrest whenever possible. If surgical correction of additional intracardiac defects was required during the surgical procedure cardioplegic arrest was performed according to the underlying physiology.

In patients scheduled for catheter interventions a diagnostic procedure was performed initially and the patients classified in three groups as mainly obstruction [gradient > 20 mmHg, pulmonary insufficiency (PI) less than grade II], mainly regurgitation (gradient < 20 mmHg, PI > grade II) or mixed lesions (gradient > 20 mmHg and PI > grade II). Patients with a dedicated treatment of a right or left pulmonary artery lesion (i.e. left pulmonary artery or right pulmonary artery stent implantation, etc.) are not included in this analysis. In all patients with significant stenosis, a balloon dilatation using high pressure balloons was performed as primary intervention and the hemodynamic situation reassessed thereafter. Whenever necessary a stent implantation was performed aiming for valve sparing supravalvular or infravalvular position. In patients with a significant regurgitation or after a transvalvular stent implantation a PPVI was attempted. Initially a balloon interrogation of the RVOT was performed using a maximum diameter balloon. In patients with a primary pulmonary regurgitation, a 30 mm × 40 mm balloon was used; if this balloon could not be stabilized in the RVOT, the procedure was aborted and the patients referred to surgery. In all other patients, the maximal balloon diameter was chosen according to the diameter of the RVOT beneath the valve and the bifurcation in order to achieve a maximal diameter of the RVOT for PPVI. A high pressure balloon was used for maximal predilation and at a second inflation selective coronary angiography or ascendogram was performed simultaneously with the maximal balloon inflation to assess coronary impairment. If coronary compression occurred the patients were transferred to surgery. We excluded patients at risk for coronary compression and did not use coronary wire protection techniques to enable PPVI [25]. The anatomy of the coronary arteries was independently assessed by two investigators for the analysis of this paper. Prestenting of the RVOT was performed using predominantly large caliber bare metal stents [4,14,15]. Covered stents were used only if the primary balloon dilatation resulted in rupture of the high-pressure balloons. All catheter procedures were performed under sedation and without general anesthesia as per institutional protocol [26].

Statistics

The results are documented in tables in a descriptive manner and the values are expressed as percentage, mean, standard deviation, and median in a descriptive manner where applicable.

Table 1
Characteristics of the inserted valves.

Time frame	01.01.2010 – 31.12.2015	
Patients	$n = 246$	(100%)
Surgery	$n = 166$	(67.4%)
Homografts	$n = 55$	(22.4%)
Contegra® grafts	$n = 106$	(43.1%)
Hancock®	$n = 5$	(2.0%)
Intervention	$n = 80$	(32.6%)
Melody® valve	$n = 29$	(11.8%)
Edwards Sapien®	$n = 51$	(20.8%)

Numbers are indicated as absolute numbers and percentages.
Contegra indicates treatment with a Contegra® graft, Homograft with a human homograft, Hankock with Hankock® bioprosthesis, Edwards with an Edwards Sapien®, Edwards Sapien® XT, or Edwards Sapien® S3 valve, and Melody with a Medtronic Melody® valve.

Table 2
Reasons for surgical valve implantation.

Surgery	*n* = 166/246	(67.5%)
Primary repair	*n* = 15	(6.1%)
Patient too small for PPVI (<20 kg)	*n* = 16	(6.5%)
RVOT too large for PPVI (>28 mm)	*n* = 92	(37.4%)
After ECHO/MRI measurements	*n* = 70	(28.5%)
After catheter investigation	*n* = 22	(8.9%)
Additional cardiac defects	*n* = 14	(5.7%)
Acute endocarditis	*n* = 4	(1.6%)
Failed intervention	*n* = 24	(9.8%)
Coronary compression	*n* = 20	(8.1%)
Technical failure	*n* = 4	(1.6%)
Patients personal choice	*n* = 1	(0.4%)

RVOT, right ventricular outflow tract; PPVI, percutaneous pulmonary valve implantation; ECHO, echocardiography; MRI, magnetic resonance imaging.

Results

Patient selection

The patient selection toward surgical and interventional valve replacement is documented in Fig. 1.

Over the 6-year period a total number of 2512 surgeries for congenital heart defects was performed and implantation or replacement of a valved RVOT with a biological valve was used in 166. During the same time 2719 catheter investigations were performed, 216 for a dysfunctional RVOT; patients with treatment of a left or right pulmonary artery stenosis only were not included in this analysis. In 126 patients a PPVI was judged necessary and possible in 80 (for details of the implanted valves see Table 1).

Surgical patients

The predominant reason for surgery (see Table 2) included those patients with primary repair (*n* = 15/246; 6.1%), those who were too small for PPVI (<20 kg) (*n* = 16/246; 6.5%), those with additional cardiac defects (*n* = 14/246; 5.7%) and those where the RVOT was a priori too large for PPVI (>28 mm) (*n* = 70/246; 28.5%). Minor reasons included acute endocarditis (*n* = 4/246; 1.6%) and patients' personal choice (*n* = 1; 0.4%). A total 46/246 patients were initially scheduled for intervention, but were then found not suitable due to an enlarged RVOT (*n* = 22; 8.9%), coronary compression during balloon interrogation (*n* = 20; 8.1%), or technical failure (*n* = 4; 1.6%). In one patient a stent/balloon malfunction occurred that ultimately resulted in perforation and the patient's death at surgical rescue operation.

Catheter investigations

A total of 216 catheter procedures were performed in patients with predominantly RVOT obstruction (*n* = 72, 33.3%), mainly regurgitation (*n* = 99, 45.8%), or mixed lesions (*n* = 45, 20.8%) (Table 3). Interventional treatment was successful in 161 (74.5%), in 90 no PPVI was necessary due to adequate pressure gradient relief by balloon dilatation or stent implantation. The characteristics of the RVOT scheduled for catheter investigation and the patients' underlying diagnoses are described in Table 4.

Coronary anatomy

In all 216 patients in whom catheter investigations were performed the coronary anatomy could be assessed (Table 5). Normal coronary anatomy was diagnosed in *n* = 145 (67.2%) and abnormal coronary anatomy in the resulting 71 (32.8%). Selective coronary angiography or aortic root injection was however not performed simultaneously in all patients together with balloon interrogation, especially when additional defects existed or the RVOT was too large for PPVI. Coronary compression resulted in 27% of all patients with coronary abnormalities. In the patients with successful PPVI, in *n* = 21/80 (26%) PPVI was possible despite coronary abnormalities. For details of the coronary anatomy see Table 6.

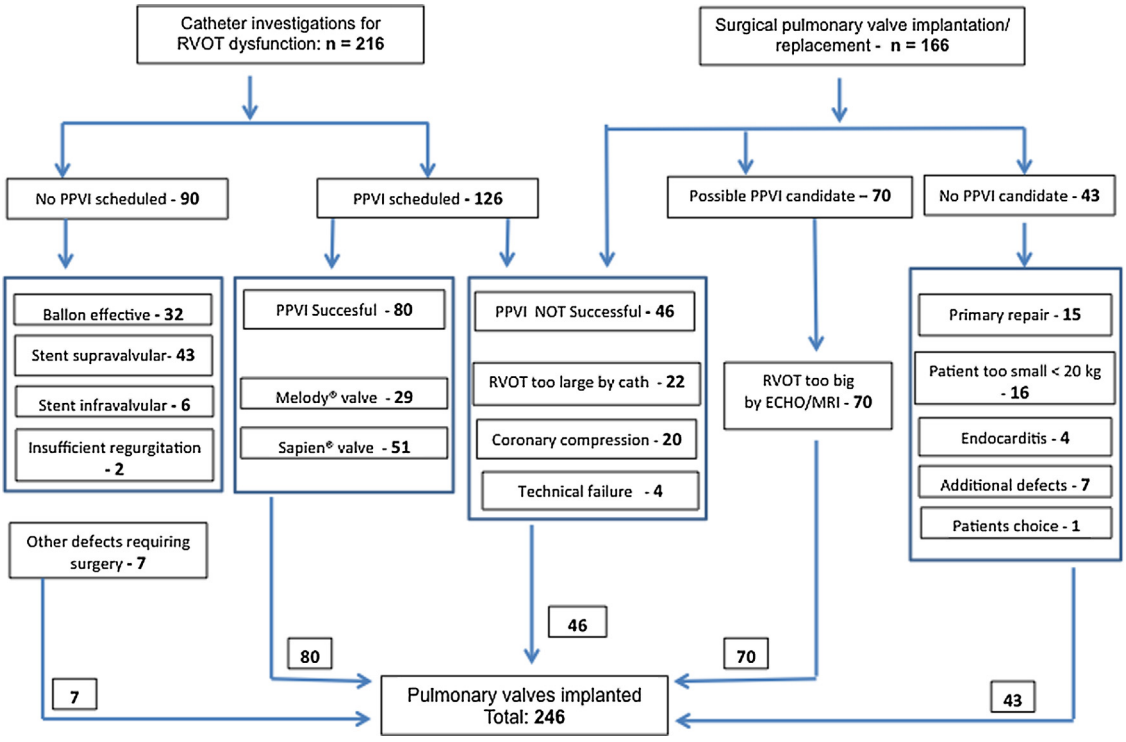

Fig. 1. Detailed patient distribution between each sub-groups. A total of 246 patients underwent pulmonary valve implantation, of these *n* = 80 had a percutaneous pulmonary valve implantation. ECHO, echocardiography; PPVI, percutaneous pulmonary valve implantation; RVOT, right ventricular outflow tract; MRI, magnetic resonance imaging.

Table 3
Results of the catheter investigations.

Catheter investigations	$n = 216$	(100%)
Indications		
Mainly RVOTO	$n = 72$	(33.3%)
Mainly regurgitation	$n = 99$	(45.8%)
Mixed lesions	$n = 45$	(20.8%)
Successful intervention	$n = 161$	(74.5%)
Balloon dilatation effective	$n = 32$	(14.8%)
Stent supravalvular	$n = 43$	(19.9%)
Stent infravalvular	$n = 6$	(2.8%)
Successful PPVI	$n = 80$	(37.0%)
Melody® valve	$n = 29$	(13.4%)
Edwards® valve	$n = 51$	(23.6%)
Failed intervention	$n = 46$	(21.3%)
RVOT too big after balloon sizing	$n = 22$	(10.2%)
Coronary compression	$n = 20$	(9.3%)
Valve dislocation	$n = 2$	(0.9%)
Stent dislocation	$n = 1$	(0.5%)
Inability to advance sheath to RVOT	$n = 1$	(0.5%)
Others	$n = 9$	(4.2%)
Insufficient regurgitation	$n = 2$	(0.9%)
Other defects requiring surgery	$n = 7$	(3.2%)

RVOT, right ventricular outflow tract; PPVI, percutaneous pulmonary valve implantation; RVOTO, RVOT obstruction.

Table 4
Patient characteristics for catheterization.

Characteristics of the RVOT	216	(100%)
Contegra grafts	82	(39.9%)
Homografts	21	(9.7%)
Transanular patch	89	(41.2%)
Native pulmonary valve	18	(8.3%)
Other	6	(2.7%)
Diagnoses of the patients	216	(100%)
Tetrology of Fallot	101	(46.7%)
Double outlet right ventricle	29	(13.4%)
Truncus arteriosus	22	(10.2%)
Pulmonary atresia with VSD	16	(7.4%)
Ross surgery for AS	13	(6.0%)
Pulmonary stenosis	6	(2.8%)
Rastelli repair	8	(3.7%)
Arterial switch for d-TGA	9	(4.2%)
Others	12	(5.6%)

VSD, ventricular septal defect; AS, aortic stenosis; d-TGA, dextro transposition of the great arteries; RVOT, right ventricular outflow tract.

Discussion

In most of the early and actual reports presenting the results of PPVI, a careful preselection was performed for patients with suitable RVOT who ultimately were scheduled for PPVI [10–13]. Most authors exclude patients below a certain age (i.e. 5 years) or a specific weight (i.e. 20 or 30 kg) according to the instructions for use of the PPVI devices [13,27]. Other exclusion criteria usually are pregnancy, occluded central veins, active infection, and outflow tracts with "unfavorable" morphology. These predefined anatomical reasons may vary, ranging from the initial surgical implant diameter (i.e. conduits < 16 mm in diameter at surgical insertion) or the actually measured diameters (i.e. narrowest RVOT diameter > 22 mm on angiography) [22,23,27]. These patients usually are those after patch reconstruction of the RVOT or those with dilated native RVOTs and successful PPVI is the exception rather than the rule [19,20]. As most of the patients are assessed by a variable preselection process, the actual number of patients excluded by applying this process is unclear or not reported [10,28].

Table 5
Results of the coronary anatomy.

Catheter investigations	$n = 216$	(100%)
Normal coronary anatomy	$n = 145$	(67.1%)
Abnormal coronary anatomy	$n = 71$	(32.8%)
Large RCA branch across RVOT	$n = 33$	(15.3%)
LAD from RCA	$n = 7$	(3.2%)
s/p arterial switch for d-TGA	$n = 9$	(4.2%)
s/p ALCAPA repair	$n = 2$	(0.9%)
single ostium	$n = 6$	(2.8%)
others	$n = 14$	(6.5%)

RCA, right coronary artery; LAD, left anterior descending coronary artery; RVOT, right ventricular outflow tract; d-TGA, dextro-transposition of the great arteries; ALCAPA, anomalous left coronary artery arising from the pulmonary artery.

Our study includes a single center cohort of subsequent patients where all types of patients who underwent PPVI with the Edwards Sapien® valve were analyzed to assess the reasons for implantation failure and possible contraindications in a not preselected group of patients. Overall, there seems to be a relatively high number of patients potentially suitable for PPVI; these include in our series 126 patients scheduled for PPVI and 70 with a RVOT too big as assessed by imaging techniques alone (196/246 = 79%). In addition an extension of the body weight to 13–15 kg body weight could increase the number of potential PPVI candidates to about 85%. The final success rate in this unselected group, however, is less than half of the candidates and reached 80/246 (32.5%) only.

Heart team approach

During the past ten years, the novel "heart team approach" has brought the traditional competition between adult interventionists and surgeons to an end and nowadays enables both sides to work together to determine what is the best strategy for a patient – interventional or surgical. Like in structural heart disease, this approach is also applied and highly appreciated in the field of congenital heart disease. In a co-working process an interdisciplinary team of interventionists, surgeons, and imaging specialists is selecting patients for either surgical or interventional pulmonary valve replacement on a case-to-case basis and according to current guidelines. The heart team approach concept has been shown to effectively improve the quality of evidence-based medicine, to lower costs, and, most importantly, to improve patients' (long-term) outcomes [29].

Preprocedural imaging techniques

In order to optimize preselection and improve the success for PPVI, cardiac imaging techniques such as echocardiography, dual source CT imaging, or MRI are used [24,30]. In addition 3-D modeling was able to delineate the actual anatomy of the RVOT and the coronary arteries [31]. It has been stated that a position of the coronary arteries directly contacting the conduit without any intervening tissue may predict coronary artery compression during PPVI [30]. As conduit calcification could increase the risk of PPVI-associated conduit injury, these patients are excluded by some authors [32]. In our study only patients with a RVOT clearly exceeding the potential size of the largest valve available for PPVI (i.e. >28 mm) were excluded; all other patients were referred for catheter investigations and balloon interrogation irrespective of the actual size of the RVOT or the level of calcification. We could not confirm that the amount of calcification or the position of the coronary arteries predicted the suitability for PPVI at balloon interrogation.

Table 6
Coronary anatomy and coronary compression during balloon interrogation.

		Compression during balloon interrogation		No compression during balloon interrogation		Successful Implantation	
Normal coronary anatomy	$n=145$	4/128	(3%)	124/128	(97%)	59/80	(74%)
Abnormal coronary anatomy	$n=71$	16/59	(27%)	43/59	(73%)	21/80	(26%)
	216	20/187	(10.7%)	167/187	(88.3%)		
Large RCA branch across RVOT	$n=33$	1/16		29/43		13	(16%)
LAD from RCA	$n=7$	3/16		4/43		1	(1.3%)
s/p arterial switch for d-TGA	$n=9$	1/16		5/43		2	(2.5%)
s/p ALCAPA repair	$n=2$	2/16		0/43		0/2	(0%)
Single ostium	$n=6$	4/16		0/43		0/4	(0%)
Others	$n=14$	7/16		7/43		5	(6.3%)
RCA ostium posteriorly	$n=2$	0/16		2		1	(1.3%)
RCA ostium far left	$n=4$	3/16		1		1	(1.3%)
Branch from RCA anteriorly	$n=2$	1/16		1		1	(1.3%)
RCA from RCX, LAD separate	$n=2$	0/16		1		1	(1.3%)
RCA from LCA	$n=4$	3/16		1		1	(1.3%)

RCA, right coronary artery; LAD, left anterior descending coronary artery; RVOT, right ventricular outflow tract; d-TGA, dextro transposition of the great arteries; RCX, circumflex coronayr artery; ALCAPA, anomalous left coronary artery arising from the pulmonary artery.

Coronary compression

Coronary compression has been reported by many authors as a potential cofounder for PPVI and careful balloon interrogation is therefore recommended as assessment of choice to prevent this potentially lethal complication [10,13,15,25]. Patients with congenital heart defects often show a great variability of the coronary arteries both with unusual origin as well as the anatomical course of major branches across the RVOT [33]. In our patient cohort we identified a high rate of coronary abnormalities (27%) and these variations accounted for the majority of coronary compressions during balloon interrogation (see Table 6). This is in accordance with Fraisse et al. who reported a higher risk for coronary compression in patients with abnormal coronary anatomy [34]. Preprocedural imaging was however not useful to predict coronary compression and PPVI was successful even with abnormal coronary arteries in 26%.

Small children

In our study we excluded patients with a body weight <20 kg a priori from PPVI; this assumption was based on the technical equipment available at this time (i.e. 22 F introducer sheath for the Melody® valve, 20–22 F for the Sapien®, and 16–20 F for the Sapien® XT valve). Martin et al. presented their results of the use of the Melody® valve in children below 20 kg bw [35]. They reported a large proportion of vascular injury, patient exclusion due to inappropriate vessel size, and therefore used the internal jugular vein for access in about half of the patients. They concluded that access site complications may be more frequent in this population, and consideration should be given to using the internal jugular vein as a default access site in the smallest patients. With the availability of the new Sapien® S3 introducer system (14 F) we have currently reduced this weight limitation for PPVI to 13 kg bw as this sheath size has been used for stent implantation in many patients with excellent success and low complication rate.

Small conduits

Current instructions for use recommend PPVI in conduits above 16 mm diameter only; in addition balloon dilatation of a conduit to a diameter >110% of the original implant size is also not recommended [12,13]. Many authors however have shown that despite these cautious recommendations PPVI is feasible in small conduits based on an individual assessment of the actual anatomy and careful selection of patients [15,21]. In our study the actual size of the RVOT or the diameter of the original implant did not influence the strategy for PPVI.

Large RVOT

Based on the absolute size of an enlarged RVOT, current catheter-based pulmonary valve replacement strategies are inadequate for the treatment of most patients with postoperative pulmonary valve regurgitation. Considering the current available balloon-expandable stent-valves, transvenous pulmonary valve implantation is however feasible to treat even an incompetent conduit-free RVOT. Preparation of the RVOT by pre-stenting, in most patients with more than two stents in telescope technique remains challenging [15,20]. New valve designs such as the Medtronic Harmony® transcatheter pulmonary valve (TPV) are developed to be securely anchored in the oversized, dilated, and distorted RVOT [36,37]. Nevertheless, a careful preselection is still warranted and may exclude a high proportion of patients [38]. These new valve designs may have been suitable for at least a part of the 92 patients in our study and increase the rate of successful PPVI.

Technical failure

In our study there was a relatively low rate of technical failure (<2%) that is in consistence with other reports [20,27]. Smaller and more flexible introducer sheaths (i.e. Sapien® S3 valve equipment) as well as improved operator-specific experience may overcome most of the technical issues.

Study limitations

The retrospective analysis of the study may be regarded as a limitation; as we were able to receive complete perioperative as well as periinterventional datasets and we could provide a 100% follow-up of the clinical course and status of all patients, this limitation is only minimal. Whereas other centers have used the Melody® valve first and the Sapien® valves with a relevant time delay thereafter, we introduced both valves in the year 2010 into our management portfolio; thereby the potential chronological bias could be avoided, too.

Conclusion

In an unselected cohort with dysfunctional RVOT, PPVI could be performed successfully in $n = 80/246$ patients (32.5%). In $n = 92/246$ the RVOT was found too large for PPVI (37.4%). Patients were too small in $n = 16/246$ (6.5%). Coronary compression occurred in $n = 20/246$ patients scheduled for PPVI (8.1%) and technical failure occurred in $n = 4/246$ (1.6%). Future developments for larger RVOTs as well as the extension of the technique to smaller body weight may expand the indication and increase positive results for PPVI.

Authors' statement

All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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Conflict of interest

There is no conflict of interest by any of the authors regarding this report.

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