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Long-term outcome after treatment of isolated pulmonary valve stenosis

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ABSTRACT

Background: Few data are available on very long-term follow-up after treatment for isolated pulmonary valve stenosis (PVS), either surgically or by percutaneous balloon angioplasty (PBA).
Methods and results: All patients with isolated PVS were selected from our database of congenital heart defects. Their records were reviewed systematically. We identified 79 surgically treated patients with a median follow-up of 22.5 years (range 0–45 years) and 139 PBA patients with median follow-up of 6.0 years (range 0–21 years). Echocardiographic and catheterization parameters indicate excellent results of both techniques in relieving the transpulmonary gradient. However, after initial surgery 20.3% of patients needed a cardiac re-intervention: 81% for severe pulmonary valve regurgitation, but none for residual pulmonary stenosis. After initial PBA a cardiac re-intervention was needed in 9.4% of patients. In 85% the indication was residual pulmonary stenosis, in none of them pulmonary regurgitation, although almost all patients developed a mild pulmonary regurgitation. Freedom of re-intervention after surgery was 98.4%, 93.5%, 87.7%, 70.9% and 55.7% at 5, 10, 20, 30 and 40 years postoperatively. Freedom of re-intervention in the PBA group was 95.1%, 87.5% and 84.4% at 5, 10 and 20 years post-procedure.
Conclusions: Both surgery and PBA are safe and successful in relieving the acute transpulmonary gradient. Long-term results of surgery are worse than previously thought due to severe PR. After PBA re-interventions for residual stenosis are frequently needed and the incidence of mild PR is high. Very long-term results of PBA are still unknown.

1. Introduction

Pulmonary valve stenosis (PVS) is a common disorder and accounts for up to 10% of all congenital heart defects. Until a few decades ago, surgical intervention was the treatment of choice for a moderate to severe PVS. However, since the first balloon valvuloplasty has been performed in 1982 by Kan [1], it has been further established as a valuable alternative. Although isolated PVS is relatively common, few data are available on very long-term follow-up after treatment, either surgically or by balloon angioplasty. Therefore, we aimed at evaluating retrospectively the outcome of both PVS treatment choices in our centre.

2. Methods

2.1. Patients' selection

An automatic search in the database of all patients with congenital heart disease followed in our centre was performed. After looking for every case of PVS, those patients with isolated PVS were selected. Patients with associated anomalies (Table 1) were not considered for further analysis. Patients found to have a PVS in combination with a patent foramen ovale or atrial septal defect (ASD) without any further anomalies, were not excluded. Patients with Noonan syndrome were selected for analysis if there was no associated hypertrophic cardiomyopathy or other congenital defect. The presence of an associated infundibular pulmonary stenosis or supravalvular pulmonary stenosis was not used as an exclusion criterion. The selection and reviewing process were approved by the institutional ethics committee.

2.2. Review of patients' records

Demographic data as well as electrocardiographic, echocardiographic and cardiac catheterization parameters were collected. Demographic data included gender and age at the time of PVS treatment. A standard 12-lead surface electrocardiogram (ECG) was used to evaluate the presence of sinus rhythm, atrio-ventricular conduction disturbances (AV block), right ventricular bundle branch block (RBBB) and the presence of a rightward axis of the QRS complex. Echocardiographic data included peak instantaneous gradient (PIG) over the pulmonary valve and the degree of pulmonary regurgitation (PR) and tricuspid regurgitation (TR) on a scale from 0 to 4. Cardiac catheterization data were limited to peak to peak gradients (PTP) over the pulmonary valve. For patients who underwent percutaneous balloon pulmonary angioplasty (PBA) the balloon diameter was also noted.

2.3. Statistical analysis

Continuous variables were reported as mean ± standard deviation (SD), except when the data set was not normally distributed, then median and range (minimum and maximum) were used. Proportions were reported as percentages. Descriptive statistics

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Table 1
Exclusion criteria and number of excluded patients in each group.

	Surgery	PBA
Ventricular septal defect	11	14
Atrio-ventricular septal defect	0	1
Univentricular heart	0	8
Monoatrium	1	0
Transposition of the great arteries	1	16
Tetralogy of Fallot	1	11
Patent ductus arteriosus	5	15
Right ventricular abnormality	0	6
Aortic abnormality	1	0
Hypoplasia of pulmonary trunk	0	1
Ebstein's anomaly	1	3
Tricuspid valve stenosis	1	6
Aortic valve stenosis	1	4
Mitral valve dysplasia	1	2
Mitral valve prolapse	2	1
Fetal hydrops	0	1
Kawasaki syndrome	0	1
Noonan syndrome with cardiomyopathy	1	4
Total	27	94

were applied where applicable. Kaplan–Meier curves were plotted for freedom of re-intervention in both the group of patients with surgical repair and the group with balloon angioplasty. Freedom of re-intervention was defined as survival without any additional treatment aimed at the correction of residual PVS or PR or any other cardiac re-intervention. A *P*-value less than 0.05 was considered statistically significant. We analyzed the data using SPSS for Windows (version 16.0).

3. Results

3.1. Selection of patients

In our centre's database, 120 patients underwent surgical repair for PVS between 1960 and 2009. Twenty-seven patients were excluded from further analysis because of associated anomalies, as listed in Table 1. The patient with mitral valve dysplasia also had a problem of left ventricular non-compaction. One patient had first undergone balloon angioplasty and in thirteen patients, no follow-up data were available. Subsequently, a total of 79 surgically treated patients were eligible for further analysis.

Initially, 252 patients who underwent percutaneous balloon pulmonary angioplasty (PBA) between 1987 and 2009 were identified. Ninety-four patients were excluded because of associated anomalies (Table 1). Out of fourteen patients with ventricular septal defect, one also had a patent ductus arteriosus. From the sixteen patients with transposition of the great arteries, ten had ventricular septal defects, three had atrio-ventricular septal defects and another three had univentricular hearts. One patient had first undergone pulmonary valvotomy and in eighteen patients no follow-up data were available. Subsequently, a total of 139 patients were included in the group of PBA.

As stated earlier, the presence of a patent foramen ovale, atrial septal defect, Noonan syndrome without hypertrophic cardiomyopathy, infundibular pulmonary stenosis or suprapulmonary stenosis was not considered as an exclusion criterion. Their prevalence is noted in Table 2.

3.2. Patients' characteristics and duration of follow-up

In the surgically treated group, 79 patients were included of whom 43 patients (54%) were men. The age at the time of surgical repair ranged between 0 and 39 years, with a median of 5.0 years. The baseline characteristics of the thirteen patients lost in follow-up were not different from those in the selected group. Surgical repair, routinely performed until 1986, consisted of open valvectomy or valvotomy, sometimes in combination with the insertion of a transannular patch. Since 1987, only three patients with isolated PVS were treated surgically, in 1989, 1994, and 2008. The patient operated in 2008 was first planned for balloon angioplasty but had an associated atrial septal defect with small rim that needed surgery. In the group of 23 surgically treated patients with a concomitant atrial septal defect, this defect was closed immediately in 17 patients and later on in three additional patients (one surgical, two transcatheter device closures). In 23 (29.1%) surgically treated patients an infundibulectomy was performed during the initial surgery. The duration of the follow-up period of this group varied considerably between 0 and 45 years, with a mean follow-up duration of 19.4 years and a median of 22.5 years.

In the group of 139 patients treated with balloon angioplasty, 61 patients (44%) were men. The age at the time of PBA ranged between 0 and 61 years, with a median age of 3.0 years. The baseline characteristics of the eighteen patients lost in follow-up were not different from those in the selected group. Twenty patients who underwent PBA had an atrial septal defect, which was closed by a transcatheter device in two patients during the same procedure. Another seven patients in the PBA group had an ASD closure later on (three surgical, four transcatheter device closures). The duration of follow-up in the group treated by PBA was between 0 and 21 years, with a mean of 7.8 years and a median of 6 years.

Table 2
Demographic data and prevalence of associated congenital problems.

	Surgery	PBA
Men/women	43/36 (54%/46%)	61/78 (44%/56%)
Age at time of PVS repair		
Median age	5.0 years	3.0 years
Range	0–39 years	0–61 years
Associated problems		
Atrial septal defect	29.1%	14.4%
Patent foramen ovale	10.1%	12.2%
Noonan syndrome	6.3%	5.8%
Infundibular pulmonary stenosis	16.5%	6.5%
Suprapulmonary stenosis	1.3%	7.9%

PBA: percutaneous balloon angioplasty; PVS: pulmonary valve stenosis.

3.3. Changes in electrocardiographic parameters

The ECG parameters are listed in Table 3. All patients were in sinus rhythm at the moment of the initial procedure and at latest follow-up, although some patients suffered from transient arrhythmias during follow-up. In the surgical group one patient had atrial fibrillation, two patients had atrial flutter and one patient was treated for ventricular arrhythmia. After PBA one patient had atrial fibrillation and one patient had atrial flutter. The atrio-ventricular blocks noted were only first degree blocks which needed no further treatment.

In the surgically treated group, the prevalence of rightward axis of the QRS complex diminished from 80.6% before to 13.2% after surgery. About 32.3% of patients had a pre-existing RBBB, which increased to 60.3% after surgery. In the group who underwent PBA, a decrease of the prevalence of rightward QRS axis from 63.7% before PBA to 22.9% at latest follow-up and an increase of the prevalence of RBBB from 16.9% to 38.9% were observed.

3.4. Changes in echocardiographic parameters

In the surgically treated patients, almost no pre-procedural echocardiographic parameters were available because these patients were treated before the introduction of echocardiography into daily practice. At latest follow-up, echo parameters were available in 56 surgically treated patients (70.9%) (Table 4). The mean PIG over the pulmonary valve after surgical correction of PVS was 9.7 mmHg with a range from 0 to 31 mmHg. PR occurred frequently (92.9%) but was only mild to moderate in 58.9% of patients. However, 28.6% of patients had severe PR and 5.4% were classified with very severe PR. TR was mild to moderate in 76.8% of patients and severe in only 5.4%.

In the group treated with PBA, echocardiographic parameters were available for most patients both before and after the procedure, in 92.8% and 96.4% of patients, respectively. The mean PIG decreased from 79.5 mmHg before to 24.5 mmHg after the procedure. There were no patients with severe PR before the procedure, but 6.7% developed severe PR after the procedure. The percentage of patients with mild to moderate PR increased from 54.3% to 85.8%. TR was mild to moderate in 22.5% before and in 50.0% of patients after the procedure. There were no patients with severe TR before PBA, but 1.5% of them developed it after the procedure.

3.5. Cardiac catheterization data

Table 5 shows the available catheterization parameters. The mean PTP gradient across the pulmonary valve before surgery was 97.4 ± 48.5 mmHg. Data about the PTP gradient after surgery were not available because repeated cardiac catheterizations were not routinely performed.

In the group of patients treated by PBA, the PTP gradient across the pulmonary valve decreased from a mean of 50.4 ± 26.2 mmHg to a mean of 18.1 ± 14.4 mmHg. The PTP gradient after PBA was measured immediately after the PBA procedure. New

Table 3
ECG parameters.

	Surgery	PBA
	Before/after	Before/after
AV block	0%/0%	0.8%/2.3%
Rightward QRS axis	80.6%/13.2%	63.7%/22.9%
RBBB	32.3%/60.3%	16.9%/38.9%

PBA: percutaneous balloon angioplasty, AV: atrio-ventricular; RBBB: right bundle branch block.

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Table 4
Echocardiographic parameters.

	After surgery	Before PBA	After PBA
Peak instantaneous gradient			
Mean	9.7 mmHg	79.5 mmHg	24.5 mmHg
Standard deviation	6.1 mmHg	24.5 mmHg	20.8 mmHg
Pulmonary regurgitation			
None (0/4)	7.1%	45.7%	7.5%
Mild (1/4)	33.9%	51.2%	56.7%
Moderate (2/4)	25.0%	3.1%	29.1%
Severe (3/4)	28.6%	0%	6.7%
Very severe (4/4)	5.4%	0%	0%
Tricuspid regurgitation			
None (0/4)	17.9%	77.5%	48.5%
Mild (1/4)	50.0%	14.7%	39.6%
Moderate (2/4)	26.8%	7.8%	10.4%
Severe (3/4)	5.4%	0%	1.5%
Very severe (4/4)	0%	0%	0%

PBA: percutaneous balloon angioplasty.

cardiac catheterization was not routinely performed at latest follow-up. The median diameter of the balloons used for dilatation was 16 mm with a range from 1 to 32 mm.

3.6. Outcome and mortality

In the surgically treated group, three patients died during follow-up. One was a newborn in distress who died the same day she was born during urgent surgery. The second was a girl of 12 months old who died the day after surgery due to surgery related complications. The third case was a 27-year old female who died suddenly during a sports competition, 19 years after surgery. Autopsy revealed the presence of myocarditis. In the group of patients with PBA, two patients died during follow-up. One patient died during PBA at the age of six months due to rupture of the pulmonary trunk. The other was a 61-year old female who developed an infected haematoma in the groin and eventually died of septic shock one month after the PBA. She suffered from morbid obesity (170 kg, 161 cm, body mass index 65.6) and diabetes.

3.7. Outcome, cardiac re-interventions and event-free survival

In the surgically treated group, there were 16 cardiac re-interventions. In one patient a suspected atrial mass, which turned out to be an atrial haematoma, was removed 34.5 years after the initial surgery. In another patient fibrous tissue was removed underneath the pulmonary valve and an ASD was closed 26.0 years after the initial surgery. All fourteen other interventions included pulmonary valve replacement by a homograft, sometimes in combination with other interventions as listed in Table 6. In thirteen of fourteen patients, the indication for the pulmonary valve replacement was moderate to very severe PR. These homografts were inserted 6.3 to 42.7 years after the initial procedure, with a median of 21.3 years after the procedure. None of these patients had a high gradient over the pulmonary valve before re-intervention. Using the Kaplan–Meier method, we calculated that 87.7% of patients were free of re-intervention at 20 years postoperatively. However, their number declined to 78.6%, 70.9% and 55.7% at 25, 30 and 40 years respectively.

In the PBA group, 13 cardiac re-interventions were performed after a median time of 2.4 years. In eight patients this re-intervention consisted in a repeat PBA procedure. In three other patients surgery on the pulmonary valve or right ventricular outflow tract was performed because of residual pulmonary stenosis. In two other patients the re-intervention consisted in an ablation of atrial flutter or pericardial fluid drainage. Only three of these thirteen patients suffered from a more than moderate PR, which was not the reason for re-intervention in any of these patients. The re-intervention-free survival was calculated 95.1%, 87.5% and 84.4% at 5, 10 and 20 years respectively. Kaplan–Meier curves were plotted for both groups as shown in Figs. 1 and 2. Some re-re-interventions were carried out in both groups. These are listed in Table 6.

3.8. Other complications

In the surgically treated group in one patient a ventricular septal defect was accidentally created during surgery and closed immediately. This patient developed an episode of ventricular tachycardia 31 years later. In another patient a sternal dehiscence was reported.

Table 5
Catheterization parameters.

Peak to peak gradient	Before surgery	Before PBA	After PBA
Mean	97.4 mmHg	50.4 mmHg	18.1 mmHg
Standard deviation	48.5 mmHg	26.2 mmHg	14.4 mmHg

PBA: percutaneous balloon angioplasty.

Table 6
Cardiac re-interventions.

Time after surgery (years)	Type of re-intervention after surgery
6.3	Pulmonary valve replacement
8.5	Pulmonary valve replacement
9.9	Pulmonary valve replacement
10.6	Pulmonary valve replacement and surgery on tricuspid valve Followed by PBA 2.9 years later Followed by pulmonary artery stenting 2.1 years later
15.0	Pulmonary valve replacement
19.4	Pulmonary valve replacement
19.8	Pulmonary valve replacement
22.2	Percutaneous flutter ablation Followed by pulmonary valve replacement 2.0 years later
22.8	Pulmonary valve replacement
22.9	Pulmonary valve replacement
24.6	Pulmonary valve replacement
26.0	Resection of fibrotic pulmonary valve and surgical ASD closure Followed by percutaneous flutter ablation 10.8 years later
29.9	Pulmonary valve replacement
31.7	Pulmonary valve replacement
34.5	Resection of atrial haematoma Followed by atrial fibrillation ablation and pacemaker 1.0 year later
42.7	Pulmonary valve replacement and coronary artery bypass grafting
Time after PBA (years)	**Type of re-intervention after PBA**
0.1	Repeat PBA
0.1	Pulmonary valvotomy, surgery on tricuspid valve and ASD closure
0.5	Repeat PBA
0.8	Surgical repair of suprapulmonary stenosis and ASD closure
0.9	Surgical reconstruction of RVOT
2.2	Repeat PBA Followed by repeat PBA 2.7 years later Followed by repeat PBA 8.6 years later
2.4	Repeat PBA
3.8	Surgery on tricuspid valve and ASD closure Followed by repeat PBA 1.3 years later
5.7	Repeat PBA
5.9	Repeat PBA
6.9	Percutaneous ablation of atrial flutter
7.7	Repeat PBA
15.5	Drainage of pericardial fluid

In the PBA group, one patient developed a transient atrial fibrillation during the procedure. Another patient suffered from acute pulmonary oedema and in a third patient a chordal rupture caused an important TR.

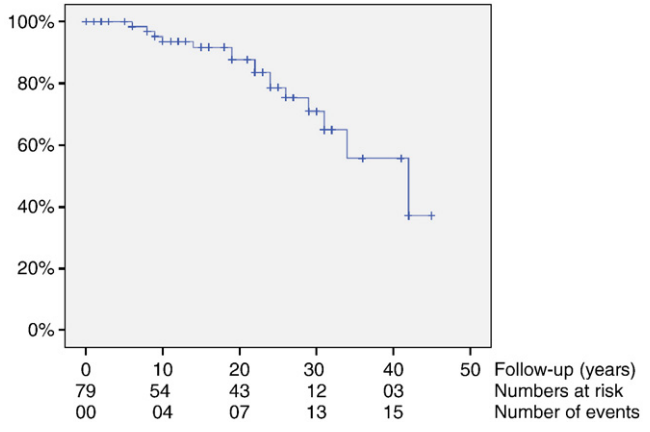

Fig. 1. Kaplan–Meier curve indicating event-free survival in the surgically treated patients.

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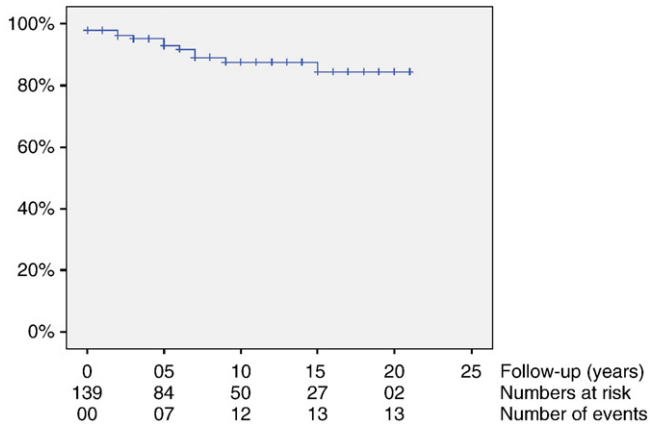

Fig. 2. Kaplan–Meier curve indicating event-free survival in the patients treated by percutaneous balloon pulmonary angioplasty.

4. Discussion

4.1. Surgery

Survival data after surgical repair for isolated PVS are excellent. In our series of 79 patients we reported two in-hospital fatal cases and one late death due to myocarditis, unrelated to the preceding surgical intervention. These results confirm the data found in the literature. In a series of 191 patients with a follow-up time between 20 and 30 years, a survival (excluding hospital mortality) of 90% was reported at 25 years postoperatively [2]. Life expectancy was normal in patients who underwent surgical repair before the third decade of life. Others reported an even lower mortality rate of 5% and 7% at 25 years after surgery [3,4].

Less information is available regarding the need for re-intervention on the long term. In our series we reported 16 cardiac re-interventions at a median interval of 22.5 years postoperatively. Fourteen patients required pulmonary valve replacement, almost exclusively for PR. In 59% of patients a moderate to severe PR was found at latest follow-up, and only 7.1% had no PR. No re-intervention was needed for residual PVS, indicating the success of surgery in relieving the transpulmonary gradient. In older studies, the incidence of re-operation for PVS or regurgitation was estimated 3 to 5%, again indicating excellent results after surgery [2,5]. However, later studies have shown data more similar to our results. The re-intervention rate after a follow-up of 22–33 years in 90 patients by Roos-Hesselink was 15% [4]. The series with the longest follow-up until now was published in 2005 by Earing et al., who reported the results of 53 patients with a mean follow-up of 33 years [6]. They also used the Kaplan–Meier method to calculate the percentage of patients not needing cardiac re-intervention at a certain time during follow-up. Re-intervention-free survival at 30 years postoperatively was 67% in their study, compared to 70.9% in ours. This number declined to 50% in their population and to 56.7% in our patients at 40 years postoperatively. Therefore, we do agree that a life-long cardiac follow-up is needed in all patients after surgical pulmonary valve replacement as pulmonary valve repair is commonly executed in infants and children and the results on the long term appear to be worse than previously thought.

4.2. Percutaneous balloon pulmonary angioplasty

Since its introduction by Kan et al. [1] in 1982 numerous reports have pointed out the safety and efficacy of PBA. The largest registry reported a mortality rate of 0.2%, other major complications in 0.4% and minor complications in 1.3% of patients [7]. In our series of 139 patients, one patient died during the PBA procedure and another one died one month later because of septic shock caused by a groin haematoma. Given the important risk factors of the latter patient (morbid obesity and diabetes), we do still consider PBA a safe treatment for isolated PVS.

The acute success rate of PBA has been illustrated in multiple studies and was estimated around 92% in 196 patients in the VACA registry and around 80% by McCrindle et al. who reviewed the data of 353 patients in 15 studies [7,8]. In our study the PTP gradients across the pulmonary valve decreased significantly from a mean of 50.4 mmHg to a mean of 18.1 mmHg, confirming the good immediate results of PBA. This gradient relief probably even underestimates the efficacy of PBA, since it has been well established that during the first year after PBA there is spontaneous reduction of the infundibular gradient [8–11].

Our echocardiographic data show that the mean PIG decreased from 79.5 mmHg before PBA to 24.5 mmHg at latest follow-up, indicating the overall efficacy of PBA on the longer term. However, in eight patients at least one additional PBA procedure was performed and three other patients underwent surgery for residual pulmonary stenosis. This means that after a median follow-up of 6 years, 7.9% of patients had already needed a re-intervention for PVS. In several studies, the re-intervention rate for pulmonary stenosis was reported between 4.8% and 16%, with the mean follow-up time varying between 4.6 and 10 years [8,9,12]. Rao et al. calculated a re-intervention-free rate 84% after 10 years, comparable to our results [13]. The freedom of re-intervention in our study was 95.1%, 87.5% and 84.4% at 5, 10 and 20 years respectively. We conclude that the efficacy of PBA is good but not excellent. We should continue monitoring these patients to obtain more definitive results on the very long term.

In addition, after PBA 85.8% of patients had mild to moderate PR, 6.7% had severe PR and 51.5% had TR. In the literature the incidence of PR after PBA varies greatly between 13 and 89%, but re-interventions for PR are absent or rare [8–10,12–14]. However, we emphasize that these valvular regurgitations may well become more important with time and lead to interventions in the future.

4.3. Surgery versus PBA

We realize that we cannot make a reliable direct comparison between the results of our surgical and PBA groups for different reasons. Surgery, apart from three exceptions, was performed between 1960 and 1986, while PBA was executed after 1987. Not only have treatment possibilities changed, but also the duration of follow-up is completely different. All studies written about the so-called 'long-term' efficacy of PBA should be placed in this perspective. Our freedom of re-intervention rate at 20 years after PBA was 84.4% which we consider good but not excellent. As we know that in the surgical group after a re-intervention-free rate of 87.7% at 20 years, this rate declined to 56.7% at 40 years, we realize that life-long follow-up of all patients after PBA is warranted and that conclusions cannot yet be made.

Three authors have tried to compare the results of surgery with those of PBA [15–17]. They all concluded that there is a higher prevalence of restenosis after PBA, which appears to be confirmed by our own results. They also concluded that there is a higher prevalence of PR in patients treated with surgery, which is confirmed by our results as well. However, our results are not in agreement with Peterson et al. who state that surgically treated patients have longer freedom from re-intervention [15].

4.4. Limitations of the study

First of all it is a retrospective study. Second, there might be a referral bias because only patients with treatment or follow-up in our tertiary referral centre were considered.

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5. Conclusions

Both surgery and PBA have low mortality rates and appear to be successful in relieving the acute transpulmonary gradient. Life-long follow-up after surgery is warranted because long-term results are worse than previously thought, due to severe PR. After PBA re-interventions for pulmonary stenosis are more frequently needed and the incidence of mild PR is high. Long-term results of PBA are still unknown.

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The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology [18].

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