

OUTCOME OF BALLOON PULMONIC VALVULOPLASTY WITH 18 MONTHS FOLLOW UP

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Objective: To determine the immediate and intermediate term outcome of balloon pulmonic valvuloplasty by echocardiography. **Methods:** This study was conducted in the Department of Cardiology Postgraduate Medical Institute Lady Reading Hospital (LRH), Peshawar from July 1999 to January 2003. Patients with severe pulmonic valve stenosis who underwent balloon pulmonic valvuloplasty during this period were included in the study. Forty Patients fulfilling the study inclusion criteria were followed up to 18 months by two dimensional and Doppler echocardiographic examinations at 6 months interval. Patients with dysplastic valve leaflets or for whom 18 months follow up data was not available were excluded from the study. Echocardiographic data was collected prospectively. Echocardiographic hemodynamic data was analysed initially and at all three follow up visits, using descriptive statistics and paired *t*-test. **Results:** Total 64 balloon pulmonic valvuloplasty procedures were performed during this period. Forty patients fulfilled the study inclusion criteria and the remaining 24 patients were excluded from the study. Mean age of the patients was 13.05±8.22 years, ranging from 1–33 years. Pre-peak pulmonic valve gradient reduced from 100.9±29.20 mmHg to 31.38±15.99 mmHg ($p<0.0001$) immediately after balloon pulmonic valvuloplasty. Pulmonic valve gradient at day 1 (31.38±15.99) reduced significantly at 18 months (18.88±10.24) ($p<0.0001$). Complication encountered during the procedure was transient ventricular tachycardia or multiple premature ventricular contractions. **Conclusion:** Balloon pulmonic valvuloplasty is safe and effective in reducing pulmonic valve gradient acutely and the benefit persists till 18 months. Further fall in pulmonic valve gradient is seen in intermediate term follow up.

Keywords: Pulmonic valve stenosis, balloon pulmonic valvuloplasty

INTRODUCTION

Pulmonary valve or pulmonic stenosis (PS), is the second most common form of congenital heart diseases in the adult.¹ Because the pulmonary valve is the least likely valve to be affected by the acquired heart diseases, virtually all cases of pulmonary valve stenosis are congenital in origin.²

Symptoms are unusual in children or adolescents with pulmonary valve stenosis even when severe. Adults with long standing severe obstruction may have dyspnea and fatigue secondary to an inability to increase cardiac output adequately with exercise. Exertional syncope or presyncope may occur in severe pulmonic stenosis with systemic or suprasystemic right ventricular (RV) pressure, with decrease preload or dehydration, or with a low systemic vascular resistance state (such as pregnancy). Eventually, long standing untreated patients developed tricuspid regurgitation (TR) and RV failure.²

The traditional method of treatment for congenital pulmonic stenosis was surgical valvotomy until 1982, when Kan *et al* introduced the technique of percutaneous balloon pulmonic valvuloplasty (BPV).³ Since then balloon pulmonic valvuloplasty has established its role in the field of interventional cardiology and is the treatment of choice for typical pulmonary valve stenosis.⁴ This technique has been applied with varying success for the dilatation of many other congenital and acquired cardiovascular lesions.⁵

The procedure continues to be performed as originally described with few modifications, including the use of double balloon or oversized balloon.^{6,7}

The short-term results of the procedure are so encouraging that nowadays it has become the preferred method of therapy for moderate to severe pulmonic stenosis in children and adults except in patients with dysplastic pulmonic valve. However, data documenting the midterm and long term results of this procedure is scanty. We started doing BPV in cardiology unit postgraduate medical institute Lady Reading Hospital (PGMI LRH) Peshawar in 1990, but there are no published data regarding the immediate and long term results of these patients.

We conducted this prospective study in the department of cardiology PGMI LHR Peshawar from July 1999 to January 2003. Patients who underwent BPV during this period were included in the study. The purpose of this study is to determine the immediate and intermediate term outcome of BPV by Echocardiography. To the best of our knowledge, no local data on the outcome of BPV is available in Pakistan, so this will be a useful and informative study on the said subject.

MATERIAL AND METHODS

All patients underwent balloon dilatation of pulmonic valve in Cath-Lab of Cardiology Unit, Postgraduate Medical Institute, LRH, Peshawar.

All patients who presented with typical severe pulmonic valve stenosis and underwent balloon dilatation of pulmonic valve between July 1999 and January 2003 were included in the study. Among 64 patients who underwent balloon dilatation of pulmonic valve during this period, only 40 patients were selected for the study. Other patients were excluded from the study because they did not fulfil the inclusion criteria.

Inclusion Criteria:

- All patients with severe pulmonic valve stenosis who underwent balloon dilatation of pulmonic valve between July 1999 and January 2003.
- Patients for whom informed consent to participate in study is available.

Exclusion Criteria:

- Patients for whom follow-up data of one year is not available were excluded from the study group.
- Patients were excluded from the study upon whom procedure could not be performed because of age less than one year and inability to advance the balloon dilatation catheter across the pulmonic valve.
- Those patients having pulmonary valve dysplasia were excluded from the study.

Study Design: Prospective study.

Data Collection Procedure:

Case notes of all the patients meeting specific inclusion and exclusion criteria were reviewed. Data on each patient were collected at 5 times:

- Before balloon pulmonic valvuloplasty
- Immediately after balloon pulmonic valvuloplasty (day 1)
- At six months
- At one year
- And 18 months after balloon pulmonic valvuloplasty.

The case notes of each patient were examined. Echocardiographic, haemodynamic data consisting of right ventricular to pulmonary artery peak systolic pressure gradient were analysed at all 4 follow-up visits. Doppler estimate gradient were calculated by application of modified Bernoulli equation to maximum continuous wave Doppler systolic peak flow velocities across right ventricular out flow tract and main pulmonary artery obtained from parasternal short axis position. Short and intermediate term follow up data were collected by investigator blinded to the results of patients' initial balloon pulmonic valvuloplasty results.

Follow up

Patients were scheduled for echocardiographic follow-up in the echocardiographic section of Postgraduate Medical Institute, Lady Reading Hospital, Peshawar. Patients were asked to come for follow-up at: Day 1, immediately after balloon dilatation of pulmonic valve, 6 months, 1 year, and 18 months after initial balloon dilatation of pulmonic valve.

Patient was considered lost if he or she did not come for their last visit at least 18 months after balloon dilatation of pulmonic valve.

The data were collected and analysed with the help of statistical programme software SPSS Version 8. The descriptive statistics were used to measure the frequencies of different outcomes. Mean and SD was compared for quantitative variable like age, pre peak pulmonic valve gradient, pre mean pulmonic valve gradient for base line at day 1, 6 months 12 months and 18 months.

We compared the pre balloon pulmonic valvuloplastic value with immediate post balloon pulmonic valvuloplastic value (Day 1). The immediate post balloon pulmonic valvuloplastic value (Day 1) was compared with values at 6, 12, 18 month after balloon pulmonic valvuloplasty.

In order to calculate significant fall in the gradient across the pulmonic valve paired *t*-test was used to compare the values pre balloon dilatation of pulmonic valve peak and mean gradient with immediate post balloon dilatation of pulmonic valve peak and post mean gradient on echocardiography. Immediate post balloon dilatation of pulmonic valve mean and peak gradient was compared with 6, 12, 18 months follow up peak and mean gradient.

OPERATIONAL DEFINITIONS:

Successful procedure:

Pulmonic valve gradient reduced to <36 mm Hg, after balloon dilatation of pulmonic valve. This cut point value was chosen because it corresponded to a continuous wave Doppler peak velocity of 3 m/sec and represented a reasonable gradient above which repeat balloon pulmonic valvuloplasty or surgical intervention might be considered.

Unsuccessful:

Pulmonic valve gradient of more than 36 mm Hg after the balloon dilatation of pulmonic valve.

Major events:

Major events were non-cardiac death, cardiac death, surgery, repeat balloon dilatation of pulmonic valve, functional impairment, i.e., in New York Heart Association Class III or IV.

Pulmonary valve dysplasia:

The presence of thick, immobile valve leaflets with the absence of poststenotic pulmonary artery dilatation.

RESULTS

A total of 40 consecutive patients with congenital pulmonic stenosis underwent balloon dilatation of pulmonic valve at Cardiology department Lady Reading Hospital Peshawar. There were no associated cardiac defects in any of the patients. The mean age of the patients was 13.05±8.22 years; range was 1–33 years. Out of the 40 patients 15 were females (37.3%), 25 were

males (62.5%). Balloon dilatation of pulmonic valve was successful in all the study patients (Table-1, 2).

Table-1: Gender-wise distribution of the patients with severe pulmonic stenosis

Gender	No	Percentage
MALE	25	62.5%
FEMALE	15	37.5%
TOTAL	40	100%

Table-2: Baseline demographic features of patients with severe pulmonic stenosis of all 40 patients

Variable	Mean±SD
Age (years)	13.05±8.22
Pre peak pulmonic valve gradient.	100.90±29.20 mmHg
Pre mean pulmonic valve gradient.	53.38±15.99 mmHg

Complications

Except for the transient arrhythmia (ventricular tachycardia or multiple premature ventricular contraction), there were no complications and no immediate or late deaths associated with the procedure.

Pulmonic valve gradient at day 1

All the patients who went for balloon dilatation of the pulmonic valve had transthoracic echocardiogram done before the procedure. The peak pulmonic valve gradient on echocardiogram before the balloon dilatation of the pulmonic valve was 100.93±29.20. The mean pre dilatation gradient was 53.38±15.99. The minimum pre peak gradient was 71 mmHg and maximum was 210 mmHg (Table-2). The minimum mean pre gradient was 30 mmHg and maximum pre mean gradient was 110 mmHg. Trans-thoracic echocardiography was done on the next day after balloon dilatation of the pulmonic valve. At day 1 peak gradient was 31.38±15.99 mmHg, minimum was 10 mmHg and maximum was 90 mm Hg. The mean gradient at day 1 was 17.90±8.99, minimum was 7 mmHg and maximum was 45 mmHg. (Table-3)

Pulmonic valve gradient at 6 months

The peak gradient at 6 months at echocardiographic follow up was significantly reduced to 25.50±11.5 mm Hg ($p=0.0001$), minimum was 8 mmHg and max was 60 mm Hg. The mean gradient decreased significantly to 15.45±7.56 mmHg ($p=0.0001$), minimum was 6 mmHg and maximum was 36 mm Hg (Table-3).

Pulmonic valve gradient at 12 months

The peak gradient at 12 month at echocardiographic follow up was 21.00±10.47 mm Hg ($p=0.0001$), minimum was 8mmHg and maximum was 60 mm Hg. The mean gradient dropped down to 12.65±6.44 mmHg ($p=0.0001$), minimum was 6 mmHg and maximum was 37 mm Hg recorded (Table-3).

Pulmonic valve gradient at 18 months

The peak gradient at 18 months after successful balloon dilatation of pulmonic valve was 18.88±10.24 mm Hg ($p=0.0001$), minimum was 8 mmHg and maximum was

58 mmHg. The mean gradient was 11.70±6.79 mmHg ($p=0.0001$), minimum was 5 mmHg and maximum was 35 mmHg (Table-3).

Table-3: Post balloon pulmonic valvuloplasty gradient over 18 months follow-up of 40 patients.

Follow-up	Peak PV gradient Mean±SD	p value	Mean PV gradient Mean±SD	p value
Day1	31.38±15.99	0.0001	17.90±8.99	0.0001
6months	25.50±11.58	0.0001	15.45±7.56	0.01
12months	21.00± 10.47	0.0001	12.65±6.44	0.0001
18months	18.88±10.24	0.0001	11.70±6.79	0.0001

PV: Pulmonic valve

DISCUSSION

Stenosis of the pulmonic valve is one of the more common forms of congenital heart diseases. Most of the patients diagnosed and subsequently treated for stenosis are children. Not infrequently, however, patients with congenital pulmonic stenosis may come to medical attention during adolescence or adulthood. In these cases decision about treatment, surgical or non-surgical, may not be easy.^{8,22}

The traditional method of treatment for congenital pulmonic stenosis was surgical valvotomy until 1982, when Kane *et al*, introduced the technique of percutaneous balloon pulmonic valvuloplasty.³ The results of the procedure have been so successful that in recent years it has largely replaced surgical valvotomy except in patients with dysplastic valves. The mobility of a dysplastic valve is so impaired that surgery is usually preferred.^{4,8}

The current study clearly demonstrates that balloon pulmonic valvuloplasty provides long term relief of obstruction in the majority of patients with severe pulmonic stenosis. When criteria used for defining successful procedure (i.e., a gradient of less than 36 mmHg after balloon pulmonic valvuloplasty), 72.5% (29 patients) had successful balloon dilatation of pulmonic valve in our study. While literature review shows success rate of 37% to 100%. Our results are comparable to those reported internationally.^{8-10,22}

Our patient population was similar to that of most other institutions that have reported acute and intermediate results with comparable distributions regarding patient demography and haemodynamics parameter before balloon pulmonic valvuloplasty.^{6,11,12}

The persistent stenosis after the procedure on day 1 was present in 11 patients (27.5%). The only significant factors predictive of poor acute results were haemodynamic indicators of more severe degree of obstruction. Results from the large valvuloplasty and angioplasty of congenital anomalies registry (VACA) suggest that the majority of these significant residual gradient are at the infundibular level and that the higher the degree of total obstruction before balloon pulmonic

valvuloplasty the higher the infundibular gradient immediately after balloon pulmonic valvuloplasty.^{5,22}

This subgroup of patients showed regression of pressure gradient with passage of time. The number decreased from 11 at day 1 to 2 (2.9%) at 18 months of follow-up. In some patients with immediate significant infundibular gradient, a long delay is probably necessary for its regression. Rao *et al* re-studied 29 patients by catheterisation at a mean follow-up of 10 months; 8% had residual infundibular gradient that subsequently disappeared in only 4 of them.^{13,24} As demonstrated by Gupta *et al*, the long-term course of patients following balloon pulmonic valvuloplasty depends upon the site and magnitude of the residual gradients.¹⁴ Even high residual infundibular gradients show marked reductions at follow-up.¹⁴ In most studies, beta-blocker were given to patients with infundibular obstruction.^{15,16} Infundibular obstruction following balloon pulmonic valvuloplasty disappeared in about 50% of the patients in the follow up study and this is in part responsible for fall in pulmonary valve gradient on follow up due to reduction in the infundibular stenosis. Although suprasystemic pressure (102 mmHg) in the right ventricle immediately following balloon pulmonic valvuloplasty has been noted in our study which reduced to 30 mmHg at 12 months of follow up. The infundibular obstruction has been expected to regress with time, as has been observed following surgical pulmonary valvotomy and balloon pulmonic valvuloplasty.^{17,24} There has been a debate about the gradient cutpoint to determine candidacy to balloon pulmonic valvuloplasty.^{2,18} It is noteworthy that before balloon pulmonic valvuloplasty all of our patients had a gradient of ≥ 75 mmHg which is higher than reported in literature. The success rate was 72.5% on day 1 on transthoracic echocardiography report, which gradually reduced and at 18 months of follow-up only, 2 patients had peak gradient more than 35 mmHg. There was no re-dilatation required for pulmonic valve at 18 months.

Another factor responsible for successful outcome of balloon pulmonic valvuloplasty is Balloon Annulus Ratio (BAR). However, the ideal balloon ratio for this procedure remain unclear.

Narang *et al* studied 71 procedures (balloon pulmonic valvuloplasty) where BAR of 1.0–1.5 were used, that showed that a ratio of <1 is less effective and that of >1.5 produced more complications. A curvilinear relation was found between BAR and the fractional fall in haemodynamic parameters reflecting stenosis severity, both immediately after dilatation and at follow up. Best result were observed with balloon annulus ratio of 1.25 with progressive worsening on either side of this ratio. The relationship remained significant in multiple regression analysis involving age, sex and baseline haemodynamic variables. The data showed that a balloon annulus ratio of 1.25 is probably the ideal ratio

for balloon pulmonic valvuloplasty, as we have used balloon annulus ratio of 1.1–1.2 in our study.¹⁹

Mourad Jarrar *et al* suggested that a balloon to annulus ratio of more than 1.5 may be justified for the patients whose immediate valvular gradient is more than 35 mmHg. It is note worthy that the use of large balloon was uneventful in their study.²⁰

Our medium term outcome is very favourable and comparable in term of re-stenosis with other reports.^{21–24}

Re-stenosis was reported in one study in 5 patients out of 90 study patients had developed re-stenosis (6%) and underwent repeat valvotomy using larger balloon, all with satisfactory outcome.¹⁶ In the present study there were transient arrhythmias which are usually associated with balloon pulmonic valvuloplasty. There was no death or any emergency requiring operation although balloon pulmonic valvuloplasty carries a high risk of complication as in the other reports.^{23,24} The reported mortality with balloon pulmonic valvuloplasty is 3% to 7% reported in literature.^{23,24} The reason for no mortality in our study could be the older age group of patients and more stable patient selected for balloon pulmonic valvuloplasty.

Study Limitation

There are some limitations to the present study. Only echocardiographic data was collected. Follow-up data was not correlated with symptoms of the patients.

Several possible inaccuracies of pressure data before and after balloon pulmonic valvuloplasty may have introduced small errors in the measurement of gradients. The estimate of pulmonary valve regurgitation was not studied in the present study.

CONCLUSION

Balloon pulmonic valvuloplasty is safe and effective for both immediate and intermediate term relief of obstruction caused by pulmonary valve stenosis. Increased severity of obstruction before balloon pulmonic valvuloplasty is associated with significant immediate residual gradient that resolve over time with regression of infundibular hypertrophy and narrowing. Balloon pulmonic valvuloplasty performed in patients with obstruction at the valvular level result in significant reduction of gradient with passage of time at 18 months of follow-up.

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