Original Article

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Internal Medicine Section

Percutaneous Pulmonary Valvuloplasty by JOMIVA Balloon in Adults: Long Term Retrospective Study from a Tertiary Care Hospital of Eastern India

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ABSTRACT

Introduction: Isolated pulmonary valve stenosis with intact ventricular septum constitutes the third most common congenital heart disease apart from Ventricular Septal Defect (VSD) and Atrial Septal Defect (ASD). Percutaneous balloon pulmonary valvuloplasty is an effective therapeutic alternative procedure of choice in severe valvular PS. Conventionally, the Mansfield balloon is being used worldwide for pulmonary valvuloplasty. Joseph Mitral Valvuloplasty (JOMIVA) balloon offers advantages of longer size, lower cost and its familiarity to use this balloon for mitral valvuloplasty in this institution since long.

Aim: To assess the immediate and long term results of Joseph Mitral Valvuloplasty (JOMIVA) balloon for Pulmonary valvuloplasty in isolated severe Pulmonary Stenosis (PS).

Materials and Methods: This was a long term retrospective study conducted at the Cardiology Department of SCB Medical College and Hospital, Cuttack, Odisha, India, where pulmonary valvuloplasty was performed using single JOMIVA balloon in 21 adults and adolescent patients. Clinical and Echocardiography (Echo) Doppler evaluation for restenosis and Pulmonary Regurgitation (PR) were assessed. All the cases were followed-up serially in Outpatient Department (OPD) for 12 years in retrospect manner.

Results: Data of total 21 participants (15 males and six females; mean age was 18.3±6.8 years) were analysed in the study. After pulmonary valvuloplasty, the median transvalvular gradient significantly decreased from 115 mmHg (interquartile range (IQR) 101-128 mmHg) to 46 mmHg (IQR 37-51 mmHg) (p-value <0.0001). Also, the right ventricular systolic pressure reduced significantly from 136 mmHg (IQR 122-148 mmHg) to 67 mmHg (IQR 57-71 mmHg) (p-value <0.0001). Catheterisation Laboratory (Cath Lab) complications were transient and self-limiting. Mild to moderate (PR) was noted in all cases i.e., Grade I in 12 cases (57.1%) and Grade II in 9 cases (42.8%) which showed evidence of regression on follow-up. Neither significant restenosis nor significant PR (Grade III/IV) was observed during follow-up period of 12 years.

Conclusion: Percutaneous valvuloplasty using JOMIVA Balloon, in case of severe valvular PS in adults, is a cost-effective procedure. It has excellent immediate results, and long term incremental benefits was observed in the present 12-year follow-up study.

Keywords: Immediate results, Joseph mitral valvuloplasty, Pulmonary regurgitation, Pulmonary stenosis, Pulmonary valve balloon dilatation

INTRODUCTION

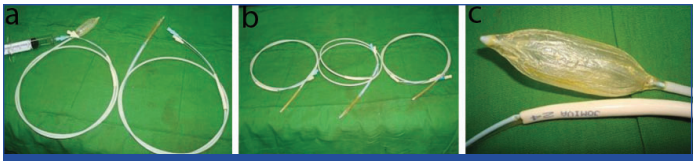
Congenital isolated pulmonary valve stenosis (PS) with intact ventricular septum, constitutes the third most common and comprises 8% to 10% [1] of all congenital heart diseases and can also occur in up to 50% [2] of patients with other congenital cardiac defects. This condition may be broadly divided in to three categories i.e., neonatal critical stenosis, dome-shaped and dysplastic (10%-15% of cases) [2] stenosis. Now a days, percutaneous balloon pulmonary valvuloplasty is an effective and well-established therapeutic procedure of choice in dome-shaped severe valvular pulmonary stenosis in neonates and adults [2]. In case of dome-shaped pulmonary valvular stenosis, the commissures are fused with the three resultant fibrous raphes extending from the level of sino-tubular junction, over the surface of valve to a central orifice, where valvular tissue is not thickened, the arterial walls are normal, and pulmonary annulus is usually within normal size. Splitting of commissural fusion is the mechanism involved in balloon dilatation in case of dome-shaped severe pulmonary stenosis. Even in critical neonatal pulmonary stenosis, a simple efficacious balloon dilation by experienced interventionalist, can provide a definite solution and avoid the need for future medical intervention. However, in dysplastic valve which commonly associated with genetic anomaly like Noonan's syndrome has unsatisfactory and variable results from balloon valvuloplasty because of its severely thickened myxomatous valve leaflets with "cauliflower" like changes affecting the distal tips and hypoplastic annulus [2].

This procedure has been extensively reported in a wide range of patients (3 months to 56 years) [3-5] and even in a neonate [6] with satisfactory immediate [7,8] and long term results [9,10] using a single balloon (Inoue) [11] and double balloon [12] techniques. Need for re-intervention (surgical or transcatheter) for residual or recurrent pulmonary valvular stenosis is about 5-10% of patients within 10 years of the initial intervention [13].

Conventionally, the Mansfield balloon is being used worldwide as the percutaneous procedure to relieve obstruction in the case of PS [14]. Joseph Mitral Valvuloplasty (JOMIVA) balloon [Table/Fig-1] was used for mitral valvuloplasty [15] in this Institution since long. As the JOMIVA balloon offers advantages of longer size, lower cost and its user-friendly characterstics, the present study was planned to evaluate its utility in severe PS. The primary objective was to assess the immediate and long term results of JOMIVA balloon for pulmonary valvuloplasty in case of isolated severe PS. Secondary objectives were changes in relation to the New York Heart Association (NYHA) class [16], transvalvular gradient, restenosis, reintervention, and pulmonary regurgitation following procedure.

MATERIALS AND METHODS

It was a retrospective record-based study, at the Cardiology Department of SCB Medical college and Hospital at Cuttack in Odisha, India, on patients underwent pulmonary valvuloplasty using



[Table/Fig-1]: Joseph Mitral Valvuloplasty (JOMIVA) Balloon. (a) Inflated balloon; (b) Deflated balloon; (c) Preparation of JOMIVA balloon.

JOMIVA balloon. The follow-up effects on the patients were recorded. All patients that underwent the procedure at the Department of Cardiology, between December 2002 and June 2006, and were followed-up serially in the OPD were included in the present study. The last follow-up visit was documented in June 2018. The record room and the records of the Cardiology Department are in the custody of office of the Professor and Head of Department of Cardiology. Necessary permission for performing the record-based study (and perusing the records) were obtained from the office of the HOD Cardiology by November 2019 and the analysis of collected data was done from November 2020-April 2021. ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants were followed.

The relevant patient records were retrieved from the filing unit of the Department and perused for the present study. All patient identifiers were removed during data extraction to maintain patient confidentiality and data handling was done as per the National Ethical Guidelines for Biomedical and Health Research involving Human participants of Indian Council for Medical Research (ICMR).

Inclusion criteria: Patients with isolated severe valvular pulmonary stenosis admitted to this tertiary care hospital for pulmonary valvuloplasty, Peak Transvalvular Gradient (TVG) of 64 mmHg or more across pulmonary valve, by echo Doppler study, irrespective of symptoms.

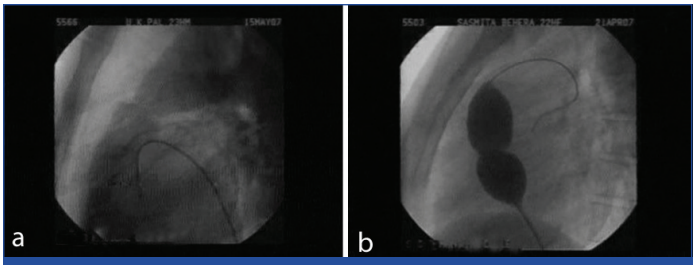
Exclusion criteria: Patients associated with Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD), tetralogy physiology, sub and supra-valvular PS and mild to moderate PS were excluded.

Study Procedure

Twenty-three consecutive cases which met the inclusion and exclusion criteria were subjected for pulmonary valvuloplasty procedure. In two patients, neither wire nor catheter could cross the pulmonary valve and the procedure were abandoned, hence, these two patients were excluded from the analysis. Rest 21 patients underwent pulmonary valvuloplasty using JOMIVA balloon [Table/Fig-1] that were included for analysis. Procedural success was defined as a 50% deduction in the transvalvular gradient across pulmonary valve following valvuloplasty.

After right heart catheterisation, an Right Ventricular (RV) angiogram was performed either in the left lateral view [Table/Fig-2a] or Antero-posterior (AP) view with cranial angulation for the creation of a reference image and measurement of the pulmonary valve annulus. An exchange stiff guide wire (0.035) was placed distally either in the pulmonary artery or mostly on the distal left lower lobe pulmonary artery.

After proper sizing of JOMIVA balloon i.e., 20% to 40% higher than annulus, a deflated balloon was inserted through a short 14-F sheath over exchange wire and positioned across the Pulmonary Valve (PV), so that waist remains at the center of the balloon. The balloon was fully inflated until the complete disappearance of waist [Table/Fig-2b] and then quickly deflated in 20 sec. If required, subsequent two or more re-dilatations were undertaken to achieve satisfactory results. The balloon was advanced to the Pulmonary Artery (PA) and pulled back to measure RV pressure and transvalvular gradient across pulmonary valve. All these 21 study subjects were followed-up for immediate haemodynamic parameters and subsequent evaluation of symptoms related to restenosis along with Echocardiography



[Table/Fig-2]: (a) Right Ventricular (RV) Angiogram left lateral view shows domed pulmonary valve and dilatation of main pulmonary artery; (b) Partially inflated JOMIVA balloon catheter (Waist) across stenotic pulmonary valve.

(Echo) doppler evaluation of transvalvular pulmonary gradient and Pulmonary Regurgitation (PR) at discharge, at 1 year, 3 yearly thereafter, till, 12 years. The degree of PR was semi-quantitated by the criteria adopted by Cooper J et al., [17].

STATISTICAL ANALYSIS

Statistical Package for Social Sciences (SPSS) version 21.0 was used to test the hypothesis for comparing the distribution of variables among different follow-ups using medians, Interquartile Range (IQR), and Friedman's test. The comparison between pair-wise follow-up was done by the Wilcoxon-Signed Rank test. Box plot has been used to see the comparison of the distribution of pressure gradient over different follow-ups. The cut-off for p-value was 0.05.

RESULTS

Out of 21 study subjects, 15 were males (71.4%), age of patients varied from 12-29 years, and the mean age was 18.3±6.8 years. The most common symptoms were Shortness of Breath (SOB) class II/III (18, 85.7%). Peak Transvalvular Gradient (TVG) across pulmonary valve was in the range of 76-126 mmHg with mean 102.6±15.8 mmHg as per echocardiography. TR was found in two-thirds of cases and only one case had a dysplastic valve and another one was associated with right pulmonary artery branch stenosis (PAS). The main pulmonary artery (MPA) was dilated in 20 cases (95.3%). The median annular size was 20 mm (IQR,18-21 mm). The median balloon size was 24 mm (IQR,23-26). The median balloon to annulus ratio was 1.3 (IQR,1.2-1.3) [Table/Fig-3].

Parameter	Variable	n (%)
Sex	Male	15 (71.4)
	Female	6 (28.6)
Predominant symptom	SOB-CI-II/III	18 (85.7)
	Angina	5 (23.8)
	Presyncope/Syncope	3 (14.28)
	HF	2 (9.52)
ECG	RAD	14 (66.66)
	RVH	21 (100.0)
	RVH with strain	8 (38.09)
	QR Pattern	4 (19.0)
Chest x-ray and echocardiography	MPA dilated	20 (95.3)
	CE (CTR 55%-65%)	10 (47.61)
	RAE	10 (47.61)
	Gradient across PV #(mean)*	76-26 mmHg (102.6±15.8)
	Tricuspid Regurgitation	14 (66.6%)
	PAS (RPA)	1 (4.76%)
	PFO	5 (23.8%)
	Dysplastic Valve	1 (4.76%)
Annular size (n=21)	Range	16-22 mm
	Median (IQR)	20 (18,21)

Balloon size (n=21)	Range	20-26 mm
	Median (IQR)	24 (23,26) mm
Ratio (n=21)	Range	1.2-1.4
	Median (IQR)	1.3 (1.2,1.3)
No. of dilatation	Single	1 (4.8%)
	2 times	10 (47.6%)
	3 times	9 (42.9%)
	4 times	1 (4.8%)

[Table/Fig-3]: Baseline characteristics.
*Mean±SD; N: Number of cases; the value in parentheses represents the percentage; #Range; SOB: Shortness of breath; HF: Heart failure; RAD: Right axis deviation; RVH: Right ventricle hypotrophy, MPA: Main pulmonary artery; CE: Cardiac enlargement; RAE: Right arterial enlargement; PAS: Pulmonary artery stenosis; RPA: Right pulmonary artery; PFO: Patent foramen ovale; IQR: Inter quartile range

Immediate results: Procedural success was achieved in 19 cases (90.4%) with significant reduction of median peak TVG from 115 mmHg (IQR,101-128 mmHg) to 46 mmHg (IQR,37-51 mmHg) p-value <0.001. Similarly, median RVSP significantly reduced from 136 mmHg (IQR, 122-148 mmHg) to 66 mmHg (IQR, 57-71 mmHg) p-value <0.001 [Table/Fig-4]. In one patient with dysplastic valve, there was also a non significant reduction of TVG from 110 mmHg to 78 mmHg, and Right Ventricular Systolic Pressure (RVSP) from 130 mmHg to 96 mmHg, even though it does not meet the criteria of procedural success.

Parameters	Pre-PVBD (n=21)		Post-PVBD (n=21)		p-value
	Minimum-maximum	Median (IQR)	Minimum-maximum	Median (IQR)	
Peak TVG across PV (mmHg)	88-140	115 (101,128)	36-78	46 (37,51)	<0.001
RVSP (mmHg)	106-160	136 (122,148)	54-96	66 (57,71)	<0.001

[Table/Fig-4]: Immediate results: Haemodynamics Parameters in Catheterisation Laboratory (Cath Lab).
RVSP: Right ventricular systolic pressure; TVG: Transvalvular gradient; PV: Pulmonary valve; PVBD: Pulmonary valve balloon dilatation (Wilcoxon-Signed Rank test)

Repeated dilatation i.e., two and more times were required in the majority of the patients (20 cases, 95%) to achieve procedural success, of which 10 patients required 2 times (46.6%), nine patients required 3 times (43%), and one required 4 times (4%) i.e., in dysplastic valve [Table/Fig-3].

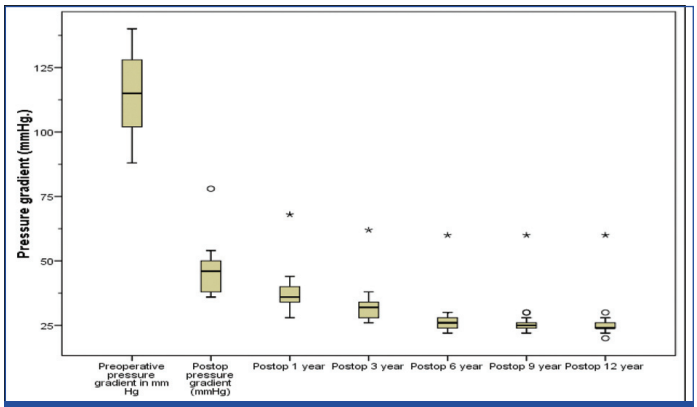
Long term results: The comparison of pressure gradient for pair-wise follow-ups at different intervals revealed that at every follow-up there was a significant reduction in pressure gradient p-value <0.05 [Table/Fig-5]. But there was no significant difference between 9-year and 12-year follow-ups as seen in the box plot in [Table/Fig-6]. This showed the reduction in the central value (median) and variation (IQR) of pressure gradient over the follow-ups until nine years and maintained for 12 years. Seven patients had high immediate postoperative residual gradient of more than 50 mmHg of which, the mean pressure gradient reduced from 55.4 mmHg to 31.1 mmHg, at the end of 12 years. There was one patient (dysplastic valve) with a higher-pressure gradient at post-intervention and different follow-ups [Table/Fig-6]. Nevertheless, this patient was maintained at around 60 mmHg from 1 year to 12 years follow-up.

[Table/Fig-7] depicts the percentage reduction in pressure gradient over different follow-up. At immediate postoperative, 12 out of 21 patients had reduction of 60-70% and 7 had reduction of 50-60%. In subsequent follow-up, a higher range of reduction in pressure gradient was observed i.e., 5 patients had 80-90% reduction, 15 had 70-80% reduction at the end of 12 years. This shows high stability of pressure gradient following pulmonary valvuloplasty in long term follow-up.

Complications: Transient bradycardia and hypotension during balloon dilatation was seen in all patients [Table/Fig-8]. Benign

Pressure gradient (mmHg) in different follow-up	All ages (n=21)		12-18 year (n=8)		19-29 year (n=13)	
	Median (IQR)	Minimum-Maximum	Median (IQR)	Minimum-Maximum	Median (IQR)	Minimum-Maximum
Preoperative	115 (101, 128)	88-140	103 (91.5, 115.8)	90-120	126 (109, 133)	88-140
Immediate Postoperative	46 (37, 51)	36-78	37 (36, 41.5)	36-50	48 (44, 52)	36-78
Postoperative 1 year	36 (33, 40)	28-68	33 (30.5, 37)	28-44	38 (36, 40)	30-68
Postoperative 3 year	32 (28, 35)	26-62	29 (26, 31.5)	26-36	32 (30, 36)	28-62
Postoperative 6 year	26 (24, 28)	22-60	24 (24, 26)	22-28	26 (26, 29)	24-60
Postoperative 9 year	25 (24, 27)	22-60	24 (22, 25)	22-26	26 (24, 29)	22-60
Postoperative 12 year	24 (24, 27)	20-60	24 (22.5, 24)	20-25	26 (24, 28)	24-60
Friedman's test p-value	0.001		0.001		0.001	

[Table/Fig-5]: Comparison of pressure gradient in different follow-up by age group.
Wilcoxon-Signed Rank test: Postop pressure gradient vs Preoperative pressure gradient 'p' value=0.001; Wilcoxon-Signed Rank Test: Postop 1-year vs Postop pressure gradient mmHg 'p' value=0.001; Wilcoxon-Signed Rank Test: Postop 3-year vs Postop 1 year 'p' value=0.001; Wilcoxon-Signed Rank Test: Postop 6-year vs Postop 3 year 'p' value=0.001; Wilcoxon-Signed Rank test: Postop 9-year vs Postop 6 year 'p' value=0.023; Wilcoxon-Signed Rank Test: Postop 12-year vs Postop 9-year 'p' value=0.450.



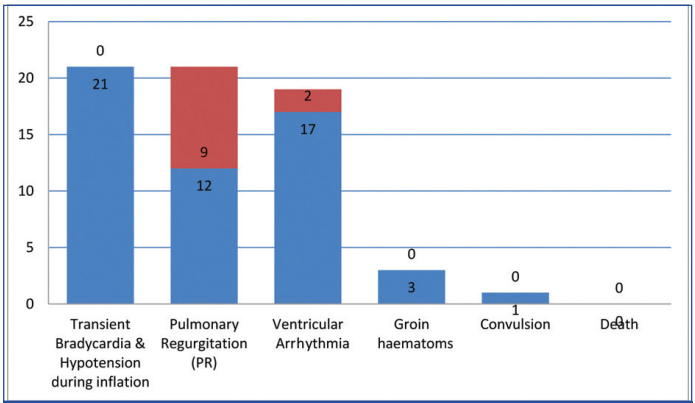
[Table/Fig-6]: Comparison of pressure gradient over different follow-ups.
Post-op: Postoperative

Range of reduction in %	Postoperative immediate n (%)	1 year n (%)	3 years n (%)	6 years n (%)	9 years n (%)	12 years n (%)
20-30	1 (4.8%)	0	0	0	0	0
>30-40	0	1 (4.8%)	0	0	0	0
>40-50	1 (4.8%)	0	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)
>50-60	7 (33.3%)	1 (4.8%)	0	0	0	0
>60-70	12 (57.1%)	11 (52.4%)	5 (23.8%)	0	0	0
>70-80	0	8 (38.1%)	15 (71.4%)	17 (81%)	16 (76.2%)	15 (71.4%)
>80-90	0	0	0	3 (14.3%)	4 (19%)	5 (23.8%)

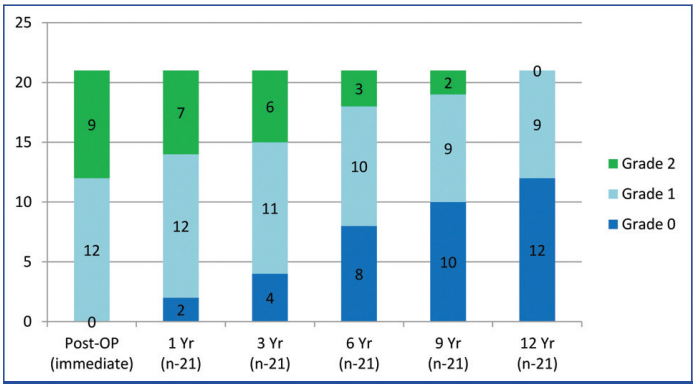
[Table/Fig-7]: Percentage reduction in pressure gradient by different follow-ups (n=21).

ventricular arrhythmia such as multiple Ventricular Premature Complexes (VPC), Non sustained Ventricular Tachycardia (NSVT) were seen in 19 patients (90.4%), which were self-limiting. No death was observed during valvuloplasty or follow-up period. Vascular complications like groin haematoma seen in 3 (14.3%), that recovered with a pressure bandage. The patient with dysplastic value had prolonged VT with convulsion, and recovered with Direct Current (DC) shock. Only minor grades (Grade I and II) of pulmonary regurgitation (PR) were observed in all patients, following valvuloplasty of which Grade I, were 12 cases and Grade II,

nine cases which showed significant reduction over different follow-up periods. At 12 years, there were only 9 patients (42%) of Grade I pulmonary regurgitation [Table/Fig-9].



[Table/Fig-8]: Catheterisation laboratory (Cath Lab) complication.
Pulmonary regurgitation (PR): Blue colour indicates number of grade-I PR (n=12); red colour indicates number of grade-II PR (n=9). Ventricular arrhythmia: Blue colour indicates number of multiple VPC and NSVT (n=17); red colour indicates number of VT (n=2)



[Table/Fig-9]: Degree of pulmonary regurgitation on follow-up.
Yr: Year

DISCUSSION

Percutaneous balloon valvuloplasty, after Kan's [14] report in 1982, has been so successful that, in recent years it has largely replaced surgical valvotomy except in patients with dysplastic valve [18].

Present study represents one of the largest series of pulmonary valvuloplasty with the JOMIVA balloon in adults and adolescents. It was found effective procedure irrespective of age and sex, as with earlier reports using Mansfield balloon or Inoue balloon [11] in severe PS. Procedural success in this series was achieved in 90.4% of cases with excellent haemodynamic and symptomatic improvement, which is comparable with the previous series [Table/Fig-10], even though there were higher initial transvalvular gradient and supra systemic RV pressure in the present series i.e. median value were 115 mmHg and 136 mmHg respectively [11,14,20,22,23]. However repeated dilatation (>2 times) was required in the majority of cases to achieve good results because of the cylindrical shape of the balloon without a pre-defined waist, liable for slippage during inflation. One case of the dysplastic valve had also shown significant reduction of gradient following balloon dilatation with development of grade-II PR and it did not show significant reduction of gradient on subsequent follow-up. This lesser reduction of gradient could be due to its dysplastic nature, immobility of valve without commissural fusion. Its success rate varies from 0-75% in different series [18,19].

Author	Year	No. of patients (n)	PSG (mmHg)		Mean follow-up (in yrs)	PSG at end of follow-up (Mean mmHg)
			Pre	Post		
Sievert H et al., [20]	1989	24	92±36	43±19	1	30±7
Fawzy ME et al., [23]	1990	22	111±33	37±26	1	18.4±10
Kan JS et al., [14]	1989	46	70±36	23±14	4.6	20±13
Kaul UA et al., [22]	1993	40	107±29	37±25	2.5	31±13
Chen CR et al., [11]	1996	53	91±46	38±32	6.9	19±8
Present study	2018	21	Median 115 (IQR 101-128)	Median 46 (IQR 37-51)	12	Median 24 (IQR 24-25)

[Table/Fig-10]: Comparison of different studies (adults, single Balloon PVBD) [11,14,20,22,23].

It was noted that even significant immediate post-intervention residual gradient could resolve spontaneously on follow-up. Assessing sub-valvular pressure gradient after valvuloplasty is often technically difficult [20]. Infundibular obstruction is dynamic and it occurs at the end of systole and is the result of forceful contraction of crista supraventricularis, septal, parietal muscle bands, and ventricular walls [21]. In the present series, seven patients had a high immediate postoperative residual gradient of which, the mean pressure gradient was significantly reduced from 50.5 mmHg to 21.1 mmHg at the end of 12 years follow-up. This could be due to regression of sub-valvular hypertrophy and obstruction, as observed in Kaul UA et al., [22]. Hence, an apparently poor immediate result from balloon pulmonary valvuloplasty doesn't preclude a good result latter.

Procedural complications [Table/Fig-8] observed in this series were transient, and self-limiting, without much alteration of cardiac haemodynamics, which amounting to safe procedure and better immediate results. In the patient with dysplastic valve, the convulsion could be due to anoxic encephalopathy following prolonged and repeated dilatation. However, the patient recovered completely without any residual neurological deficit. Ventricular arrhythmia i.e., multiple VPC, NSVT, were observed in almost all cases related to catheter manipulation in RV and RVOT, but were self-limiting. Neither restenosis nor reintervention was observed on follow-up. Significant PR (grade III and IV), causing haemodynamic alteration, was not observed, in contrast to surgical valvotomy. Both residual transvalvular gradient (TVG) and non significant PR (grade I and II) following pulmonary valvuloplasty showed a gradual reduction in a mean follow-up 12 years [Table/Fig-5,6,9]. This could be due to regression of infundibular hypertrophy and obstructions, as observed by Fawzy ME et al., [23]. It suggests that gradient immediately after valvuloplasty probably underestimates the long term efficacy of balloon dilatation.

Limitation(s)

The study was conducted in a single centre and the sample was small. The study did not compare the results with other balloons, and therefore, it is difficult to provide comparable results. The study highlights JOMIVA balloon may still be useful in resource-limited settings. Also, the authors did not identify the characteristics of patients where the procedure was failed and thus selection bias can't be ruled out.

CONCLUSION(S)

To the best of authors' knowledge, the present study is the first study to describe the use of JOMIVA balloon in pulmonary valvuloplasty. Pulmonary valvuloplasty using JOMIVA balloon is an effective technique for severe valvular PS in adults and adolescents. It is associated with excellent immediate results with long term incremental benefits in the terms of regression of infundibular hypertrophy and narrowing was observed in this longest follow-up period of 12 years. Using JOMIVA balloon in severe pulmonary stenosis offers a cost-effective approach in developing countries like India. However, a prospective study with a larger sample involving a wide range of age groups is required to validate these findings.

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