

Maternal and Fetal Outcomes Following Percutaneous Transluminal Mitral Commissurotomy in Pregnant Women with Critical Mitral Stenosis: An Experience of a Tertiary Care Center from Northern India

ORIGINAL INVESTIGATION

ABSTRACT

Background: Rheumatic mitral stenosis is the common valvular heart disease seen during pregnancy. Percutaneous transvenous mitral commissurotomy is an effective, safe, and recommended treatment for critical mitral stenosis during pregnancy. We hereby report the maternal and fetal outcomes of pregnant women subjected to percutaneous transvenous mitral commissurotomy at our institute.

Methods: Seventy consecutive pregnant women with critical mitral stenosis, who underwent PTMC during the last 10 years, were retrospectively analyzed. All patients had a detailed clinical and obstetric evaluation and were optimally managed with drugs, before the intervention. A comprehensive pre- and post-percutaneous transvenous mitral commissurotomy transthoracic echocardiographic evaluation was performed. Detailed obstetric and fetal outcomes were noted at the time of delivery. Six weeks of post-partum follow-up was noted in all patients.

Results: The mean gestational age at the time of percutaneous transvenous mitral commissurotomy was 29.5 ± 6.68 weeks. Percutaneous transvenous mitral commissurotomy was successful in 97% of patients. Post-percutaneous transvenous mitral commissurotomy New York Heart Association functional class, mitral valve area, trans-mitral pressure gradient, and left atrial pressure had a significant improvement ($P < .001$). The mean gestational age at the time of delivery was 36.92 ± 3.02 weeks. The mean birth weight of live newborn was 2.29 ± 0.55 kg. The fetal complications include growth restriction in 62.85%, preterm delivery in 34.37%, and low birth weight in 67.21%. A delayed percutaneous transvenous mitral commissurotomy at about 30 weeks of gestation did not affect the maternal and fetal outcomes.

Conclusion: Percutaneous transvenous mitral commissurotomy is safe and efficacious in managing pregnant women with critical mitral stenosis. There was a significant improvement in clinical symptoms and echocardiographic parameters following percutaneous transvenous mitral commissurotomy.

Keywords: Balloon mitral valvuloplasty, mitral stenosis, Percutaneous transvenous mitral commissurotomy, pregnancy, valvular heart disease

INTRODUCTION

Chronic rheumatic heart disease (RHD) is the most common valvular heart disease during pregnancy in developing countries like India. The mitral valve is the commonly affected valve in RHD.¹⁻³ Though both mitral stenosis (MS) and mitral regurgitation (MR) can clinically manifest for the first time during pregnancy, it is MS that is more symptomatic due to pregnancy-related hemodynamic changes. Pregnancy increases blood volume, cardiac output, and heart rate and decreases peripheral vascular resistance. These changes exaggerate the stenotic physiology, cardiac decompensation, and pulmonary edema.^{4,5} Critical MS is associated with increased maternal and fetal morbidity and mortality.² According to the modified World Health Organization classification, critical MS with pulmonary artery hypertension and New York Heart Association (NYHA) functional class II is

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Table 1. Baseline Characteristics of Pregnant Women Who Underwent Percutaneous Transluminal Mitral Commissurotomy (PTMC) (n = 70)

	Value	Median (Range)
Age (years)	25.71 ± 3.6*	25 (19-35)
Period of Gestation at the time of PTMC (weeks)	29.5 ± 6.68*	32 (16-38)
Primigravida [number (%)]	46 (65.71%)	–
Mitral regurgitation [number (%)] Absent	52 (74.29%)	–
Mild	18 (25.71%)	–
2-Dimensional mitral valve area (cm ²)	0.73 ± 0.12*	0.7 (0.5-1.1)
Atrial fibrillation [number (%)]	4 (5.71%)	–
Wilkins echocardiographic score (number)	6.64 ± 0.93*	6 (6-9)

Data given as Mean ± 1 SD*.

associated with high maternal morbidity and mortality, having a cardiac event rate from 40% to 100%.⁵ Medical treatment which includes β -blockers and diuretics can control the symptoms in mild-to-moderate cases; however, those with critical MS with decompensation and pulmonary edema need mechanical dilatation of the mitral valve. Surgical mitral commissurotomy is associated with significant maternal and fetal mortality.^{6,7} Percutaneous transvenous mitral commissurotomy (PTMC) is an effective, safe, and recommended treatment for critical MS during pregnancy. We hereby report our experience of 70 consecutive pregnant women with critical MS, who underwent PTMC at our institute during the last 10 years.

METHODS

We had 99 pregnant women with critical MS, out of a total of 398 RHD patients seen in the cardio-obstetric clinic during the last 10 years, from the year 2009 to 2018. Seventy patients had undergone PTMC and were retrospectively analyzed. Twenty-nine patients with critical MS did not have PTMC because of the reasons such as delayed presentation with active labor (n=15), left atrial or left atrial appendage clot (n=9), and refusal for the intervention (n=5). Patients with MS having mitral valve area (MVA) of <1.2 cm² in NYHA functional class III or IV or a recent worsening of functional class without

any precipitating factors were intervened. These patients did not have any previous medical consultation for underlying RHD, hence were not intervened before the current pregnancy. Patients with associated moderate-to-severe MR and significant aortic valve disease were excluded from the study. All patients had a detailed clinical and obstetric evaluation and were optimally managed with drugs, before the intervention. They had a comprehensive transthoracic 2-dimensional echocardiography before PTMC to assess the mitral valve morphology, commissural calcification, severity of subvalvular pathology, and severity of MS. The MVA was calculated by 2-dimensional echocardiography in the para-sternal short-axis view. The trans-mitral gradient was assessed using a continuous-wave Doppler technique. None of the patients had trans-esophageal echocardiography. All patients received an injection of 17-alpha-hydroxyprogesterone caproate 250 mg intra-muscularly, before PTMC to prevent preterm labor. Percutaneous transvenous mitral commissurotomy was performed using an Inoue balloon and a standard trans-septal antegrade approach. Right-side heart catheterization was not performed to avoid excess radiation in pregnant women. A lead apron was wrapped circumferentially around the abdomen of the patient to avoid fetal irradiation. Repeat echocardiography was performed within 24-h of PTMC to assess MVA, trans-mitral gradient, and severity of MR. PTMC was considered successful when MVA had >50% increase or ≥ 1.5 cm², and without severe MR. The functional class of patients was also assessed following the intervention and during follow-up. All women had obstetric evaluation on the same day after PTMC and were followed regularly at the cardio-obstetric clinic. Any maternal or fetal complications of pregnancy were noted. Informed consent was obtained from all the study participants. The study was approved by the Institute Ethics Committee for retrospective analysis of the database, vide no. SPL-1304, dated November 24, 2020. The study conforms to the ethical guidelines of the Declaration of Helsinki.

Statistical Analysis

Descriptive statistics are used to summarize the data. Continuous variables are presented as mean \pm standard deviation (normally distributed data) or median (interquartile range [IQR], skewed data). Categorical variables are expressed in percentages. The normality of the data was analyzed by Kolmogorov–Smirnov test. Inferential

HIGHLIGHTS

- Percutaneous transvenous mitral commissurotomy (PTMC) is an effective, safe, and recommended treatment for rheumatic mitral stenosis (MS) during pregnancy.
- Seventy consecutive pregnant women of critical MS, who underwent PTMC during the last 10-years were retrospectively analysed.
- The mean gestational age at the time of PTMC was 29.5 \pm 6.68 weeks.
- PTMC was successful in 97% of patients. Post PTMC NYHA functional class, mitral valve area, trans-mitral pressure gradient, and left atrial pressure had significant improvement (P < .001).
- The mean gestational age at the time of delivery was 36.92 \pm 3.02 weeks.

Table 2. Pre- and Post-percutaneous Transluminal Mitral Commissurotomy (PTMC) Echocardiographic and Hemodynamic Data in 70 Pregnant Women

Parameters	Pre-PTMC		Post-PTMC		P
	Mean ± 1SD	Median (Range)	Mean ± 1SD	Median (Range)	
Mitral valve area (cm ²)	0.73 ± 0.12	0.7 (0.5-1.1)	1.61 ± 0.20	1.6 (1.1-2.2)	<.001 [#]
Peak trans-mitral gradient (mm Hg) on echocardiography	30.96 ± 8.40	29.50 (15-54)	13.66 ± 3.60	13.50 (5-28)	<.001 [#]
Mean trans-mitral gradient (mm Hg) on echocardiography	19.11 ± 5.84	18 (11-39)	5.67 ± 2.28	5 (1-14)	<.001 [#]
Mean trans-mitral gradient (mm Hg) on catheterization	18.14 ± 6.38	18.5 (4-33)	1.71 ± 2.16	1.5 (0-8)	<.001 [#]
Mean left atrial pressure (mm Hg) on catheterization	28.34 ± 7.60	29.5 (12-45)	13.60 ± 5.93	14[3-27]	<.001 [#]
NYHA class [number (%)]	I-0 (0%) II-4 (5.71%) III-38 (54.28%) IV-28 (40.00%)		I-54 (77.14%) II-14 (20.00%) III-1 (1.42%) IV-1 (1.42%)		<.001 [*]

[#]Paired t-test and ^{*}marginal homogeneity test were used for statistical analysis.

statistics was used to analyze pre- and post-procedure data. A Marginal Homogeneity test (Stuart–Maxwell test) was used to assess the improvement in NYHA functional class following the intervention. A paired t-test was used to analyze the pre- and post-procedure improvement in MVA and trans-mitral gradient. All statistical analyses were performed with IBM SPSS software version 23.

RESULTS

Seventy consecutive pregnant females of age 25.71 ± 3.6 years were enrolled in the study. Baseline characteristics were shown in Table 1. The mean gestational age at the time of PTMC was 29.5 ± 6.68 weeks (range: 16-38 weeks).

Twenty-eight (40%) patients were in NYHA class IV, 38 (54.28%) were in class III, and 4 (5.72%) were in NYHA class II, before PTMC (Table 2). Four patients presented with significant hemoptysis at the time of the presentation. Four patients were in atrial fibrillation, while the rest were in normal sinus rhythm. Eighteen patients had associated mild MR, while the rest did not have any MR. The median Wilkins echocardiographic score of the mitral valve was 6 (range: 6-9). There was significant improvement in MVA (0.73 ± 0.12 cm² to 1.61 ± 0.20 cm², P ≤ .001) and trans-mitral gradient (19.11 ± 5.84 to 5.67 ± 2.28 mm Hg, P < .001), following PTMC (Table 2). Mean fluoroscopy time for PTMC was 4.44 ± 3.33 minutes (range: 1.18-20.10 minutes). Percutaneous transvenous mitral commissurotomy

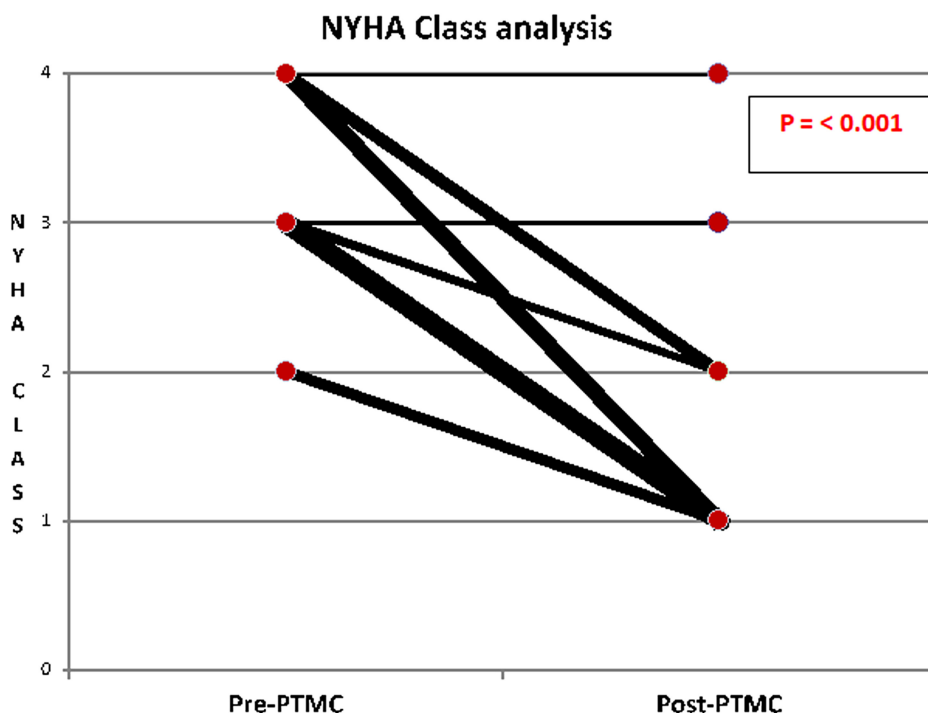


Figure 1. A pair graph analysis showed a significant improvement of the NYHA functional class following PTMC. PTMC, percutaneous transluminal mitral commissurotomy; NYHA, New York Heart Association.

was successful in 68 out of 70 patients (97.14%) and showed a significant transition from higher to lower NYHA class (Marginal Homogeneity statistic—7.965, $P < .001$) (Figure 1). Among the 2 unsuccessful patients, 1 patient had severe MR, while the other had a failed procedure as Inoue balloon could not cross the mitral valve despite repeated attempts. Both the patients were managed with optimal medical treatment and had uneventful delivery without any further intervention, during peri-partum period. The patient with severe MR had spontaneous labor at 38 weeks and delivered a healthy baby of 2.8 kg weight. Another patient of failed PTMC delivered a 1.7 kg baby at 34 weeks of gestation. Six (8.57%) patients developed moderate MR. One patient had an inadvertent puncture of ascending aorta during transseptal puncture. She remained hemodynamically stable, without any pericardial effusion, and had cesarean-assisted

delivery of a healthy child a week later. Two patients developed hemodynamically unstable supra-ventricular tachycardia during PTMC, one responded with adenosine, while the other required direct-current cardioversion after failed adenosine injection. One patient presented with acute pulmonary edema, cardiogenic shock, and severe metabolic acidosis at 30 weeks of gestation. Though she had a successful emergency PTMC but died of cardiac arrest after an hour of intervention. Another patient had transient right upper limb and facial paresis following PTMC, which was completely resolved within 24 hours of heparin infusion. None of the patients developed any local vascular complication, cardiac perforation, or tamponade.

Obstetric Outcomes

Forty-six (65.71%) patients were primigravida. There were 2 maternal deaths, 1 patient with cardiogenic shock and severe metabolic acidosis died following PTMC, while another patient died of puerperal sepsis following a cesarean section at 37 weeks of gestation. Obstetric data were available for 64 patients (Table 3), as 5 patients had delivered at a nearby local hospital, while 1 patient died following PTMC. Those 5 patients had uneventful delivery and had favorable maternal and neonatal outcomes at local hospitals, as per telephonic conversation. Common obstetric complications were intrauterine growth restriction (<10 percentile for gestational age) in 44 (62.85%) patients and prematurity (<37 weeks of gestational age at the time of delivery) in 22 (34.37%) patients (Table 3). Other complications included anemia, gestational hypertension, stillbirth, second-trimester abortion, and severe preeclampsia/eclampsia (Table 3). The average period of gestation at the time of delivery was 36.92 ± 3.02 weeks. Fifty-one patients had a normal vaginal delivery, 12 had a cesarean section, while 1 had a second-trimester abortion for intra-uterine death of the fetus.

Newborn Outcomes

The average weight of 61 live newborns was 2.29 ± 0.55 kg. Low birth weight (<2.5 kg) was seen in 41 out of 61 live birth (67.21%). There were three intra-uterine deaths, one in the second trimester and two in the third trimester (Table 3). All 61 newborns had an Apgar score of more than 7 at 5 minutes

Table 3. Obstetric and Fetal Outcomes in the Cohort

Period of Gestation at Delivery (Weeks)	36.92 ± 3.02 (Mean ± 1 SD) 37.5 (Median), (Range 30-42)
Maternal complications during pregnancy (n = 70) [number (%)]	Anemia-13 (18.57%) Gestational hypertension-3 (4.28%) Eclampsia/preeclampsia-2 (2.85%) Post PTMC severe MR-1 (1.42%) Transient ischemic attack/paralysis-1 (1.42%) Maternal Death-2 (2.85%)
Fetal complications (n = 70) [number (%)]	Abortion: 1 (1.42%) Still birth: 3 (4.28 %) Growth restriction (IUGR): 44 (62.85%)
Mode of delivery (n = 64) [number (%)]	Vaginal delivery: 51 (79.68%) Caesarean section: 12 (18.75%) Abortion: 1 (1.56%)
Newborn Outcomes	
Preterm (n = 64) [number (%)]	22 (34.37%)
Live newborn birth weight (kg) (n = 61)	2.29 ± 0.55 (mean ± 1SD) 2.34 (median), (range 0.8-2.95)
Low birth weight (≤ 2.5 kg) [number (%)]	41 out of 61 live birth (67.21%)

IUGR, intrauterine growth retardation; MR, mitral regurgitation; PTMC, percutaneous transluminal mitral commissurotomy.

Table 4. Relationship of Obstetric Outcomes with Timing of Percutaneous Transluminal Mitral Commissurotomy (PTMC)

	PTMC ≤24 weeks (n = 23)	PTMC >24 weeks (n = 47)	P
Period of gestation at delivery (weeks)	36.80 ± 3.29 (mean ± 1 SD) 37 (median) (range 31-41)	36.83 ± 5.99 (mean ± 1 SD) 37.28 (median) (range 29-42)	.980
Fetal Complications (n = 70)			
Abortion (n = 1)	1	0	.150
Still birth (n = 3)	1	2	.980
Growth restriction (IUGR) (n = 44)	13	31	.440
Newborn Outcomes			
Preterm (n = 22)	10	12	.120
Birth weight (kg) (n = 61)	2.22 ± 0.75 (mean ± 1SD) 2.3 (median), (range 1.33-3.25) (n = 19)	2.26 ± 0.54 (mean ± 1SD) 2.3 (median), (ange 0.8-3.16) (n = 42)	.810
Low birth weight (n = 41)	12	29	.450

IUGR, intrauterine growth restriction.

Table 5. Published Case Series of Percutaneous Transluminal Mitral Commissurotomy (PTMC) in Pregnant Women and Their Comparison with the Index Study

Authors	No of Patients	Maternal Age in Years	Gestational Age in Weeks at the Time of PTMC	Gestational Age in Weeks at Delivery	Pre-PTMC				Post-PTMC			
					Mean Pressure		Mean Pressure		Mean Pressure		Mean Pressure	
					Mitral Valve Area in cm ²	Gradient in mm Hg	Mitral Valve Area in cm ²	Gradient in mm Hg	Mitral Valve Area in cm ²	Gradient in mm Hg	Mitral Valve Area in cm ²	Gradient in mm Hg
Abdi ¹⁰	33	31.55 ± 6.3	21.85 ± 5.8	-	0.83 ± 0.13	15.5 ± 7.4	1.38 ± 0.29	2.3 ± 2.3	97	-	-	-
deSouza ⁷	21	24.6 ± 4.8	25.2 ± 7.2	-	0.96 ± 0.15	15.9 ± 8.6	1.84 ± 0.30	4.7 ± 3.3	95	-	-	-
Esteves ¹¹	71	27 ± 6	24 ± 7	38.0 ± 1.2	0.9 ± 0.2	18 ± 7	2.0 ± 0.3	3.9 ± 3.1	94	-	-	-
Ben Farhat ²	44	29 ± 6	26 ± 6	-	1.07 ± 0.21	22 ± 8	2.32 ± 0.36	5 ± 3	90.9	16 ± 7	-	-
Kalra ¹³	27	24.9 ± 3.14	22.2 ± 4.3	-	0.78 ± 0.19	30.5 ± 7.6	2.2 ± 0.12	6.1 ± 2.6	96.3	5.6 ± 2.2	-	-
Vinayakumar ¹⁴	49	25.7 ± 3.1	23.5 ± 5.2	-	0.93 ± 0.17	-	1.75 ± 0.27	-	95.9	6.4 ± 1.2	-	-
Gupta ¹⁵	40	24 ± 6.5	21 ± 11	-	0.8 ± 0.2	26 ± 7	1.7 ± 0.2	9 ± 5	97.5	7.8 ± 1.9	-	-
Salehi R. ¹⁶	24	29.45 ± 5.05	83% in second trimester	-	0.92 ± 0.15	11.03 ± 3.61	1.57 ± 0.16	5 ± 1.39	100	-	-	-
Joshi ¹⁷	30	24.80 ± 4.34	25.3 ± 3.93	-	0.85 ± 0.16	-----	1.60 ± 0.27	-	100	3.97	-	-
Ananthakrishna Pillai ¹⁸	96	26.7 ± 7.2	23.4 ± 10.9	-	0.98 ± 0.12	26.7 ± 1.3	1.32 ± 0.06	9.6 ± 1.12	82.2	-	-	-
Rathakrisnan ¹⁹	38	25 ± 6	90% in second trimester	-	0.8 ± 0.3	16 ± 4	1.7 ± 0.4	4 ± 3	95	-	-	-
Routray ²⁰	40	23.4 ± 4.8	24.2 ± 4.6	-	0.82 ± 0.34	27.8 ± 9.6	1.9 ± 0.4	6.8 ± 4.2	100	5.5 ± 3.8	-	-
Mishra S ²¹	85	22.7 ± 4.1	24.8 ± 4.7	-	0.75 ± 0.5	29.1 ± 91	2.0 ± 0.5	7.2 ± 4.1	94	3.6 ± 3.2	-	-
Nercolini ²²	44	28 ± 6	23 ± 6	-	1.17 ± 0.26	16.22 ± 5.55	2.06 ± 41	7.94 ± 3.75	95	-	-	-
Sharma ²³	10	25.7 ± 3.5	18.4	39.2	0.8 ± 0.2	-	1.75 ± 0.27	-	100	-	-	-
Present Study	70	25.71 ± 3.6	29.5 ± 6.6	36.92 ± 3.0	0.73 ± 0.12	19.11 ± 5.84	1.61 ± 0.20	5.67 ± 2.28	97.14	4.44 ± 3.33	-	-

and none required any special care following delivery and during 6 weeks of follow-up.

Sub-Group Analysis

We had a sub-group analysis of maternal and fetal outcomes in patients for early (≤ 24 weeks of gestation) versus late (>24 weeks of gestation) PTMC during pregnancy. There was no significant difference in the period of gestation at the time of delivery and birth weight of the newborn between the two groups. Intrauterine growth restriction and low birth weight were also equally distributed in the two groups (Table 4).

DISCUSSION

Chronic RHD is primarily restricted to developing countries and some poor, indigenous populations of developed countries.⁸ Due to high prevalence and lack of screening during childhood, chronic RHD is frequently diagnosed during adulthood when there is a progression of the disease or an increase in hemodynamic stress.^{4,5,9} Pregnancy-associated hemodynamic stress decompensates these asymptomatic patients, especially those with critical MS.^{4,5} Though the medical treatment which includes β -blockers and diuretics can initially improve the symptoms, later in the due course of pregnancy, the clinical deterioration would require mechanical dilatation of stenotic mitral valve.^{1,4,5} Table 5 describes the demographic and PTMC details of various published series of pregnant patients.^{7,10-23} The mean age of pregnant women in the present study was similar to the other studies. The mean gestational age at the time of PTMC was 29.5 ± 6.68 weeks, which was higher compared to previously published studies having a range of 21-25 weeks (Table 5). The possible reason for the late PTMC at our institute was delayed referrals from peripheral centers. Two of the largest case series by Ananthakrishna Pillai et al¹⁸ (n=96) and Mishra et al²¹ (n=85) demonstrated a technical success rate of PTMC in 82% and 94% patients, respectively, while we had a success rate of 97%. There was a significant improvement of MVA and trans-mitral gradient following PTMC, as reported by other authors.^{7,10-23} Post-PTMC severe MR had been reported in 1.1-6.5% of pregnant women.^{10,11-14,18,19,21} We had one patient (1.4%) with severe MR, who was medically managed and had an uneventful delivery. Similar to our experience of transient ischemic attack (n=1), three other authors had also reported one patient each in their series of PTMC.^{11,20,23} Cardiac tamponade^{14,21} and vascular access site complications^{11,12,18,19} as reported by others were not experienced by us. Certain patients with poor pre-procedural hemodynamics such as intractable pulmonary edema, cardiogenic shock, post-cardio-pulmonary resuscitation, and disseminated intravascular coagulation had high mortality despite successful PTMC,¹⁸ as observed in one of our patients. The reported mean fluoroscopy time for PTMC ranged from 3.6 to 16.0 minutes,^{12-15,17,20,21} which was 4.44 ± 3.33 minutes in the index study. The gestational age at the time of delivery in the present study (36.92 ± 3.02 weeks) was lower compared to other studies.^{12,23}

We observed cesarean section in 18.75% and stillbirth in 4.28%, which was comparable with our earlier published

data of a similar trend in pregnant women with chronic RHD.^{3,24} Two of the South Asian series had reported 14%¹⁵ and 17%¹⁴ rate of cesarean section in post-PTMC patients. The average birth weight of the newborn in the present study (i.e., 2.29 ± 0.55 kg) was lower compared to the reported birth weight by 4 case series from the South Asian region (2.32-2.64 kg).^{15-17,23} Certain Western series had reported even higher birth weight ranging from 2.8 kg to 3.2 kg in post-PTMC patients.^{11,12,20} The reasons for low birth weight in this geographical region are multifactorial including delayed referral, poor socioeconomic status, NYHA classes III and IV, anemia, severe valvular heart disease, and gestational hypertension.^{1,5,24} We had reported a lower mean birth weight of 2.4-2.5 kg in pregnant women suffering from chronic RHD.^{3,24} A higher rate of intrauterine growth restriction and preterm labor as observed by us is also reported by other authors^{1,5} and by our team.^{3,24} The limitation of the present study includes a retrospective analysis and lack of long-term follow-up of mother and child following the intervention.

CONCLUSION

We demonstrated the safety and efficacy of PTMC in managing pregnant women with critical MS. There was a significant improvement in functional status and echocardiographic parameters following PTMC. A delayed PTMC at about 30 weeks of gestation did not affect the fetal and maternal outcomes in limited number of patients.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of Post Graduate Institute of Medical Education & Research (PGIMER) (approval No: SPL - 1304 dated 24th Nov. 2020).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer Review: Externally peer-reviewed.

Author Contributions: Concept – R.V., V.S., P.S., G. K., A.G., N.K., S.S., N.A., S.C.; Design – R.V., V.S., P.S., G. K., A.G., N.K., S.S., N.A., S.C.; Supervision – R.V., V.S., P.S., G. K., A.G., N.K., S.S., N.A., S.C.; Fundings – None; Materials – R.V., V.S., P.S., G. K., A.G., N.K., S.S., N.A., S.C.; Data collection &/or processing – R.V., V.S., P.S., G. K., A.G., N.K., S.S., N.A., S.C.; Analysis &/or interpretation – R.V., V.S., P.S., G. K., A.G., N.K., S.S., N.A., S.C.; Literature search – R.V., V.S., P.S., G. K., A.G., N.K., S.S., N.A., S.C.; Writing – R.V., V.S., P.S., G. K., A.G., N.K., S.S., N.A., S.C.; Critical review – R.V., V.S., P.S., G. K., A.G., N.K., S.S., N.A., S.C.

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