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PERIPARTUM CARDIOMYOPATHY IN PREGNANT WOMEN PRESENTING WITH DYSPNEA

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ABSTRACT

Aims and Background: Peripartum cardiomyopathy (PPCM) is a rare but potentially life threatening form of cardiac failure with a high degree of morbidity and mortality. This study was aimed to screen the pregnant women for PPCM, to ascertain the role of two dimensional (2D) echocardiography in the diagnosis of PPCM and to identify important risk factors. **Methods:** This hospital based crosssectional study was done in the Department of Obstetrics and gynaecology, Sri Siddhartha Medical College and Hospital, Tumakuru, Karnataka, India for the period of 18 months from June 2022 to December 2023. A total of 116 women presenting with shortness of breath or other symptoms of PPCM were studied. **Results:** Three women (2.59%) were diagnosed with PPCM among them, one women (0.86%) had peripartum and two women (1.72%) had postpartum cardiomyopathy. Electrocardiogram (ECG) findings revealed ST changes in two women (1.72%) and one women (0.86%) had ST changes with T and V2 inversion. The 2D echo findings revealed dilated left atrium/left ventricle (LV) and left ventricular dysfunction (LVD), LV ejection fraction (LVEF)<45% in all the three women.During the study period there were a total of 1381 live births and incidence of PPCM was one per 460 live births.The mean age was 25.18±2.12 years. Most of the women were housewives(63.79%), from rural locality (61.21%),had singleton pregnancy (99.14%), consumed mixed diet (69.83%),belonged to lower middle class socioeconomic strata(37.07%), primi para (56.90%). **Conclusion:** Considerable number of women are at risk of PPCM. Two dimensional echocardiography helps in early diagnosis of high-risk cases of PPCM. Further, maternal age, fatigue, chest pain, gestational age and respiratory rate as important risk factors leading to PPCM.

KEYWORDS : Dyspnoea; Maternal heart disease; Peripartum cardiomyopathy

INTRODUCTION

Heart diseases are the most important non obstetrical causes of maternal deaths during pregnancy, accounting for almost 10% of maternal deaths. They complicate 1-3% of all pregnancies with congenital defects in 70-80% of the cases.[1] In western countries, maternal heart disease complicates one to three percent of pregnancies and is the third common cause of maternal death during pregnancy.[2,3] Heart disease is now the leading cause of maternal mortality in the United Kingdom with a mortality rate of 2.27 per 100,000 maternities; double that reported in 1990.[4]

Increased cardiac demands during the course of pregnancy potentially increase morbidity and mortality in women with underlying heart disease. Valvular heart disease is often recognized for the first time during pregnancy, when the pregnancy associated cardiovascular changes increase the demand on the heart and exacerbate the symptoms and signs of valvular lesion.[5]

Pregnancy-associated cardiocirculatory changes primarily, increase in heart rate, stroke volume, and cardiac output, as well as reduction in systemic vascular resistance may threaten maternal outcome: which in turn holds foetal implications. Whereas pregnancy is associated with high maternal morbidity under some conditions (cyanosis), others such as valve insufficiencies generally follow a benign course during gestation if myocardial function is not compromised.[6]

The functional capacity of the heart is assessed by investigations as electrocardiography (ECG) echocardiography, oxygen saturation and complete blood examination.[7] Close liaison between obstetrician and cardiologist is required throughout pregnancy. If possible pregnancy should not be allowed in patients with uncorrected severe valvular lesion or those requiring anticoagulation. This is due to increased maternal and foetal morbidity and mortality. Medical therapy and balloon valvuloplasty have greatly improved the outcome and now term gestation is possible.[8]

Among the more severe pregnancy associated cardiovascular complications, peripartum cardiomyopathy (PPCM) is a life-threatening heart disease.[9] It usually occurs in pregnant women during peripartum and postpartum period. It is generally considered as idiopathic primary myocardial disease associated with pregnancy.Peripartum cardiomyopathy presents clinically as left ventricular dysfunction and heart failure.The symptoms and signs progress rapidly in PPCM when compared to dilated cardiomyopathy.[10]

The incidence of PPCM in India is 1 in 1340.[5]The risk factors associated with PPCM are multiparity, advanced maternal age, anemia, twin pregnancy, pre-eclampsia, gestational hypertension, gestational diabetes, smoking.[11,12]

Most of the cases present in puerperium with signs of heart failure like shortness of breath, dizziness, pedal edema, and orthopnea, which are seen even in normal pregnancy too. Difficulty in diagnosing and distinguish it from other pathological conditions in pregnancy may explain why PPCM is still undervalued. A crucial challenge is to differentiate the peripartum discomforts like shortness of breath, edema, and fatigue in healthy women from pathological symptoms of PPCM.[10]

Foetal outcome depends on the degree of maternal wellbeing. Foetal mortality is not exceptionally high in patients with New York Heart Association (NYHA)[13] class I and II, however if there is associated pulmonary hypertension there is a risk of abortions, intrauterine growth retardation, preterm delivery

and early neonatal death.[14]

Hemodynamic changes of pregnancy in women with preexisting cardiovascular disease may complicate the course of pregnancy. However, the literature regarding cardiovascular complications of pregnancy is replete with numerous case reports and expanded case reports. At best there are very small series of patients which makes it difficult to quantify the incidence or prevalence of the complication. Also, it is necessary that whenever there is an etiological factor present in a women or when clinical suspicion arises, diagnostic methods like 2D Echocardiogram is advised to diagnose PPCM, which helps in early diagnosis, further reducing morbidity and mortality associated with PPCM.[10]This present study was undertaken to screen pregnant women presenting with shortness of breath in peripartum and postpartum period to identify PPCM, to determine the usefulness of 2D echocardiogram in the early diagnosis of PPCM and to find the risk factors leading to PPCM.

Methodology

This hospital based Cross-sectional study was conducted for the period of 18 months from June 2022 to December 2023in the Department of Obstetrics and gynaecology from a tertiary care hospital situated in Karnataka, South India. Prior to the commencement, ethical clearance was obtained from the Institutional Ethics committee. Considering prevalence of PPCM as 0.2207 based on the study by Kanakasabapathy RA and Annamalai N.[71] (2022), the minimum sample size required to determine primary outcome was 116. Hence, a total of 116 Women in peripartum and postpartum period within three months, presenting with shortness of breath or other symptoms of PPCM were included in the study. Antenatal women with bronchial asthma, chronic obstructive pulmonary disease (COPD), tuberculosis, congenital and rheumatic heart diseases, deep vein thrombosis, venous thromboembolism and Coronavirus disease 2019 (COVID-19) with dyspnea were excluded from the study (Figure 1).Prior to the commencement, the study was approved by the Ethical and Research Committee. The pregnant women who fulfilled the selection criterion were explained about the nature of the study in their vernacular language and a written informed consent was obtained prior to the enrollment.

Eligible women who fulfilled the selection criterion were interviewed and information regarding demographic data, obstetric and medical history, clinical presentation were obtained. General physical examination including vitals and clinical signs and symptoms was done. All these findings were noted on a predesigned proforma. The selection women were classified for socio economic status according to Modified Kuppuswamy socioeconomic scale 2023: stratification and updates.[15]

All the women underwent investigations including hemoglobin, blood sugar levels, were obtained. In women with suspected PPCM, ECG and 2D Echocardiogram were done to diagnose or rule out PPCM. Two dimensional and colour Doppler echocardiography was done using a Vingmed flex scan T 561 and a 2.5 MHz transducer. The LV dimensions were measured in all patients as per the standard guidelines. The LV ejection fraction (EF) as a mean of more than three beats was obtained and the end diastolic dimension (EDD) and end systolic dimension (ESD) were defined as maximum and minimum dimension during diastole and systole. All patients diagnosed with PPCM were managed by an interdisciplinary team approach consisting of obstetricians, cardiologists, anesthesiologists, neonatologists, and chest physicians in the high dependency unit (HDU).

The women were evaluated for the diagnosis of PPCM based on Demakis and colleagues criterion for PPCM.[10,16,17]The women with PPCM were also investigated risk factors including maternal age,occupation, socioeconomic status, diet, place of residence (locality), parity, gestation, gestational age, antenatal care, history of hypertension and History of diabetes mellitus and family history of congenital heart disease.

Statistical Analysis

Thedataobtained was coded and entered into Microsoft Excel Worksheet (Annexure III). The data was analysed using statistical software SPSS version 20.0. Continuous variables were analyzed for normality by the Kolmogorov Smirnov test. The data was expressed in terms of mean±standard deviation (SD) for the data that followed normal distribution and the data which followed skewed distribution was expressed as median and interquartile range (IQR). The association between Cardiotocography (CTG) findings with perinatal outcome and other parameters was determined using either Chi-square test or Fisher's exact test. The comparison of continuous data was done using independent sample t test. At 95% confidence interval (CI), a probability value ('p' value) of less than or equal to 0.050 was considered to be statistically significant.

RESULTS

Three women (2.59%) were diagnosed with PPCM (Graph 1). Further, during the study period there were a total of 1381 live births and the incidence of PPCM was one per 460 live births. Out of the three women (2.59%) with PPCM, one women (0.86%) had peripartum and two women (1.72%) had post-partum cardiomyopathy.ECG findings revealed ST changes in two women (1.72%) and one women (0.86%) had ST changes with T and V2 inversion (Graph 2).2D echo findings revealed Dilated LA/LV with LVD, PCME with LVD and LVD alone in one women each (0.86%) and LVEF < 45 percent in all the three women (2.59%) (Graph 3).With regard to demographic characteristics, 58.62% of the women were aged from 21 to 25 years, 63.79% were housewives, 37.07% belonged to lower middle class socioeconomic strata and 61.21% were from rural locality (61.21%) and 69.83% of the women consumed mixed diet (Table 1 and 3). With regard to obstetric history, 41.38% had four ANC visits, 99.14% had singleton pregnancy and 56.90% belonged to primi para (Table 2).Cough at presentation was noted in 6.90% of the women (Table 2). On examination, pallor was noted in 25.86% of the women.On systemic examination CVS abnormalities were noted in 4.31% of the women (Table 4).Statistically significant difference was noted with respect to age, gestational age, pulse rate and respiratory rate ($p<0.050$) (Table 1 to 4). Further, maternal age, fetal distress, fatigue, chest pain, gestational age and respiratory rate as important risk factors leading to PPCM (Table 5).All the three women (2.59%) with PPCM underwent LSCS and none of them developed complications.

DISCUSSION

The present study showed that, although rare, considerable number of women are at risk of PPCM within the study area during both peri and postpartum period with LVD at the same time maternal age, fetal distress, fatigue, chest pain, gestational age and respiratory rate as important risk factors leading to PPCM.

In the present study three women were diagnosed with PPCM and the frequency of PPCM was 2.59% during the study period in the study area. of the three women (2.59%) with PPCM, one women (0.86%) had peri-partum and two women (1.72%) had post-partum cardiomyopathy. This observations was consistent with previous studies which suggest that, PPCM is more common during the postpartum period. Lampert et al. reported 78% of cases that occurred during the postpartum period. It is also in accordance with an Indian study done by Pandit V et al.[18] (2009) where all of the patients of PPCM presented postpartum. A systemic review by Albakri A.[19] (2018)

concluded that 78% of the patients present postpartum. The cardiovascular changes occurring in pregnancy like the increased cardiac output, increased stroke volume, and decreased peripheral vascular resistance, could contribute to the development of cardiomyopathy. The ECG finding revealed ST changes in two women (1.72%) and one women (0.86%) had ST changes with T and V2 inversion. Further the 2D echocardiography findings showed dilated LA/LV with LVD, PCME with LVD and LVD in one women each (0.86%) with LVEF < 45 percent in all the three women (2.59%). These observations were comparable with the observations reported by Khade SA et al.[20] (2022) who reported that, electrocardiographic findings in cases of PPCM included sinus tachycardia and non-specific ST-T alterations with a mean EF of 34% on 2D echo. Hence, the present study demonstrates the usefulness of routine 2D-echocardiography in early diagnosis of high-risk cases of PPCM, in relation to EF taken as a vital parameter and these patients can be monitored in a high-risk pregnancy unit by senior 54 obstetrician/internist/cardiologist to decrease the maternal mortality rate and improve pregnancy outcome. Hence, pregnant women presenting with risk factors of PPCM may be monitored with 2D echocardiography routinely as obstetric ultrasound in the third trimester so that early identification, prompt monitoring and management can be done with multidisciplinary approach and may help in reducing the maternal morbidity and mortality.

In the present study during the study period there were a total of 1381 live births and the incidence of PPCM was one per 460 live births. The incidence of PPCM varies very widely across the world, ranging from 1:15,000 to as common as 1:100.[21] The incidence of PPCM noted in the present study was well within the reported range in the literature. Minimal studies have been conducted mainly in developing and underdeveloped countries, due to the low prevalence.

The comparison of incidence of PPCM noted in the present study with other studies is as shown in the table 6. It is evident that, the incidence of PPCM within India is also variable and is reported between 1 per 1541 by Binu AJ et al.[21](2019) from Vellore India to as high as 1 in 453 by Kanakasabapathy RA.[22](2022) from, Chidambaram, India. The incidence of PPCM noted in the present study that is one per 460 was well within this reported range by Indian studies. However, incidence of PPCM noted in the present study was high compared to a study by Chaitra S. et al.[23] (2009) from Bangaluru, Karanataka.

In the current study age of the women ranged from 19 to 32 years with mean and median values being 25.18±2.12 and 25.00 (IQR 2.00) years respectively. Further, most of the women (58.62%) were aged from 21 to 25 years. Followed by 26 to 30 years (38.79%). Significantly higher number of women aged from 26 to 30 (two out of 45; 4.44%) and 31 to 35 years (one women; 100%) had PPCM (p=0.005). Also, the mean maternal age in women with PPCM was significantly high (29.00±3.00 vs 25.08±2.01 years; p=0.001). These observations suggest that, advanced maternal age is an important risk factor for PPCM. The age distribution pattern noted in the present study was comparable with the results of Chaitra S. et al.[23] (2009) from Bangaluru, Karanataka where, maximum women were aged between 21 to 25 years (38.09%). A study by Binu AJ et al.[21](2019) from Vellore India reported mean age of the women as 25.50 years which sharply corroborates with the present study. Elkayam U. et al.[81] (2005) had previously demonstrated that PPCM can occur at any age but a higher incidence was noted in women aged 30 years or more.[21]

In the present study with regard to other demographic characteristics, majority of the women were housewives (63.79%), belonged to lower middle class socioeconomic strata (37.07%) according to Modified Kuppuswamy socioeconomic scale 2023[15] and majority of them reside in rural area (61.21%) However, no statistically significant association was found between these characteristics and PPCM (p>0.050) suggesting that, PPCM is independent of occupation, place of residence/locality and socio economic status.

In this study with regard to obstetric history, most of the women (56.90%) reported primi para. However, no statistically significant association was found between parity and PPCM (p=0.604) suggesting that, PPCM is independent of parity status. Twin Gestation was found to be a significant risk factor for the development off PPCM as evidenced by the findings in study by Elkayam U. et al.[24] (2001) but the same was not true in the present study. Previous studies suggests that multiparity is a risk factor for developing PPCM and a study done by Pandit V et al.[18](2009) in India had a mean parity of 2.3±1. However such an association was not seen in the present study.

In the present study with regard to history of current pregnancy, most of the women (41.38%) four ANC visits, majority of the women had singleton pregnancy (99.14%). However no statistically significant association was found between number of ANC visits and gestation with PPCM (p>0.050). one important aspect worth discussion is that on FHR examination, fetal distress was noted 5.17% of the women and significantly higher number of women (two out six, 33.33%; p=0.007) had PPCM demonstrating fetal distress as one of the significant risk factor for the development of PPCM. Similarly, of the women with PPCM was significantly low (36.97±5.17 vs 39.20±5.17 weeks; p=0.002) suggesting that PPCM is common in women with lower gestational age at delivery.

PPCM is known to have a variable clinical course and remains a diagnostic and therapeutic challenge. Clinical features are similar to those observed in any other form of DCM and include exertional dyspnoea, fatigue, syncope and oedema.[21,] In the present study cough was the common clinical presentation which was noted in 6.90% of the women. However, all the women with PPCM had breathlessness and significantly higher number of women with fatigue (two out of seven; 28.57%; p=0.009) and chest pain (one women; 100%; p=0.026) were significantly associated with PPCM (p<0.050) suggesting that, women with fatigue and chest pain are at high risk of PPCM and need prompt care. Chaitra S. et al.[23] (2009) in their study reported that, the commonest symptoms of cardiac failure with which the patient presented was breathlessness (57.1%), chest pain and tachycardia 6 (28.5%) postnatally. Khade SA et al.[20] (2022) in their study reported that, all cases invariably had breathlessness which was consistent with the present study.

In this study other risk factors including history of mixed diet, preeclampsia, diabetes mellitus and Covid 19 were not associated with PPCM (p>0.050). Further, none of the women presented with thyrotoxicosis, COPD and family history of CHD. Also, on examination, clinical signs including, pallor pedal oedema and cyanosis were not associated with PPCM (p>0.050) and none of the women had signs of icterus and clubbing but pulse (84.00±6.00 vs 74.83±5.31 per minute; p=0.004) and respiratory rate (29.33±10.07 vs 22.27±2.71 per minute; p<0.001) in women with PPCM were significantly high compared to their counterparts. On systemic examination significant association was found between CVS and respiratory system abnormalities with PPCM (p<0.050). These observations were comparable with the results of a study by Binu AJ et al.[21](2019) where, no significant association was determined with regard to gestational hypertension or diabetes mellitus and hypothyroidism. In contrast, a study done by Deb Nath J et al.[25] (2019) reported preeclampsia in 12.9% patients with PPCM. A meta analytic study by Bello et al.[26] (2013) found that 22% of the patients with PPCM had a

history of pre-eclampsia.

With regard to pregnancy outcome all the women with PPCM underwent LSCS and none of them developed complications. These observations were comparable with the results of a study by Kanakasabapathy RA and Annamalai N.[22] (2022) who reported that, majority of the cases with PPCM (81.3%) were delivered by caesarean section. Similar observations were reported in another study by Binu AJ et al.[21](2019) who reported that with regard to obstetric management, vaginal delivery is preferred in women with compensated HF, while LSCS is reserved for women who are decompensated or in cases of fetal distress and 59.3% of our women underwent an LSCS, 9.3% underwent operative vaginal deliveries.

Overall, the present studdemonstrates that, considerable number of women are at risk of PPCM in the study area during both peri and postpartum period with LVD. Two dimensional echocardiography helps in early diagnosis of high-risk cases of PPCM, in relation to EF taken as a vital parameter. Further, maternal age, fetal distress, fatigue, chest pain, gestational age and respiratory rate as important risk factors leading to PPCM.

The strengths of the study were that, the results of the study were based on detailed analysis on a carefully selected study population after excluding confounders. Also, the detailed analysis of risk factors of the study population makes the findings of this study highly reliable and valid. The limitations of the study were that, the findings in this study were based on the data having relatively smaller sample size from a single centre. Also owing to the smaller subset of patients with different risk factors, subgroup analysis could not be done. Further, the women with PPCM were not available for long term follow. Hence long term effects of PPCM remain unknown although, these parameters were beyond the scope of this study. Further, multicentric studies involving large sample size with age, sex and risk factor specific study population with long term follow up may further provide the useful insights on the epidemiology of PPCM.

Table 1. Distribution Of Women According To The Demographic Characteristics And Its Association With PPCM

Parameters	Sub groups	PPCM				Total (n=205)		P value
		Absent		Present				
		No.	%	No.	%	No.	%	
Age group (Years)	18 to 20	2	100.00	0	0.00	2	1.72	0.005
	21 to 25	68	100.00	0	0.00	68	58.62	
	26 to 30	43	95.56	2	4.44	45	38.79	
	31 to 35	0	0.00	1	100.00	1	0.86	
Occupation	Housewife	71	95.95	3	4.05	74	63.79	1.000
	Unskilled labour	21	100.00	0	0.00	21	18.10	
	Service	15	100.00	0	0.00	15	12.93	
	Professional	6	100.00	0	0.00	6	5.17	
	Lower class	22	100.00	0	0.00	22	18.97	
Socio economic strata	Lower middle class	42	97.67	1	2.33	43	37.07	0.067
	Middle class	8	88.89	1	11.11	9	7.76	
	Upper class	3	75.00	1	25.00	4	3.45	
	Upper lower class	8	100.00	0	0.00	8	6.90	
	Upper middle class	30	100.00	0	0.00	30	25.86	
Place of residence (Locality)	Rural	70	98.59	1	1.41	71	61.21	0.333
	Urban	43	95.56	2	4.44	45	38.79	

Table 2. Distribution Of Women According To The Obstetrics History And Its Association With PPCM

Parameters	Sub groups	PPCM				Total (n=205)		P value
		Absent		Present				
		No.	%	No.	%	No.	%	
Number of ANC visits	2	5	100.00	0	0.00	5	4.31	0.294
	3	23	95.83	1	4.17	24	20.69	
	4	48	100.00	0	0.00	48	41.38	
	5	25	92.59	2	7.41	27	23.28	
	6	12	100.00	0	0.00	12	10.34	
Gestation	Singleton	112	97.39	3	2.61	115	99.14	0.974
	Twins	1	100.00	0	0.00	1	0.86	
Parity	Primi	64	96.97	2	3.03	66	56.90	0.604
	Multi	49	98.00	1	2.00	50	43.10	
Fetal heart sounds	Fetal distress	4	66.67	2	33.33	6	5.17	0.007
	No abnormality detected	109	99.09	1	0.91	110	94.83	

Table 3. Distribution Of Women According To The Risk Factors And Its Association With PPCM

Risk factors	PPCM				Total (n=205)		P value
	Absent		Present				
	No.	%	No.	%	No.	%	
Mixed diet	78	96.30	3	3.70	81	69.83	0.337
Preeclampsia	16	100.00	0	0.00	16	13.79	0.638
Diabetes mellitus	10	90.91	1	9.09	11	9.48	0.260
Covid 19	1	100.00	0	0.00	1	0.86	0.974
Thyrotoxicosis	0	0.00	0	0.00	0	0.00	-
COPD	0	0.00	0	0.00	0	0.00	-
Family history of CHD	0	0.00	0	0.00	0	0.00	-

Table 4. Distribution Of Women According To The Clinical And Systemic Examination Findings And Its Association With PPCM

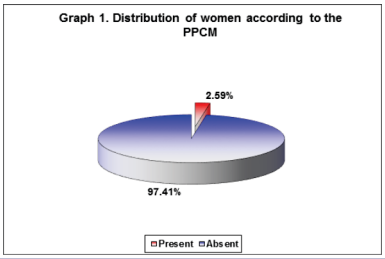
Parameters	Sub groups	PPCM				Total (n=205)		P value
		Absent		Present				
		No.	%	No.	%	No.	%	
Clinical presentation	Cough	8	100.00	0	0.00	8	6.90	0.805
	Fatigue	5	71.43	2	28.57	7	6.03	0.009
	Chest pain	0	0.00	1	100.00	1	0.86	0.026
	Orthopnoea	0	0.00	0	0.00	0	0.00	-
	Palpitation	0	0.00	0	0.00	0	0.00	-
	Syncope	0	0.00	0	0.00	0	0.00	-
Clinical examination findings	Pallor	28	93.33	2	6.67	30	25.86	0.164
	Pedal oedema	9	90.00	1	10.00	10	8.62	0.239
	Cyanosis	1	100.00	0	0.00	1	0.86	0.974
	Icterus	0	0.00	0	0.00	0	0.00	-
	Clubbing	0	0.00	0	0.00	0	0.00	-
Systemic examination findings	Cardiovascular system abnormalities	0	0.00	0	0.00	0	0.00	-
	CVS abnormalities	0	0.00	1	100.00	1	0.86	0.026
	Respiratory system abnormalities	3	60.00	2	40.00	5	4.31	0.004

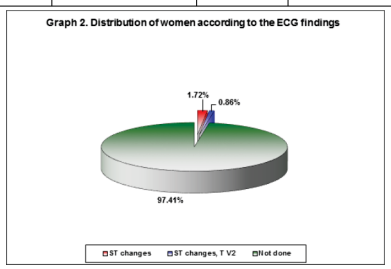
Table 5. Comparison Of Clinical Data With Respect To PPCM

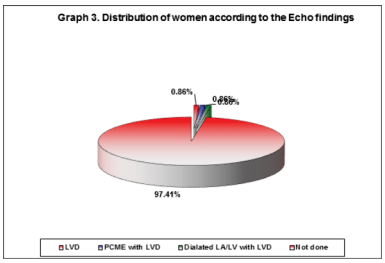
Findings	PPCM				p value
	Absent (n=113)		Present (n=3)		
	Mean	SD	Mean	SD	
Age (Years)	25.08	2.01	29.00	3.00	0.001
ANC care (Number of checkups)	4.14	1.01	4.33	1.15	0.746
Gestational age (Weeks)	39.20	1.02	36.97	5.17	0.002
Pulse rate (per minute)	74.83	5.31	84.00	6.00	0.004
Systolic blood pressure (mm Hg)	124.04	13.29	126.67	15.28	0.736
Diastolic blood pressure (mm Hg)	80.60	7.18	73.33	5.77	0.085
Respiratory rate (per minute)	22.27	2.71	29.33	10.07	<0.001
Temperature (0F)	98.66	0.49	98.57	0.51	0.757

Table 6. Comparison Of Incidence Of PPCM Noted In The Present Study With Other Studies

Author	Year	Country	Duration	Sample size	Incidence
Chaitra S. et al.23	2009	India	5 years	16866	0.07%; 1 per 804
Pandit V. et al.18	2009	India	10 years	12369	1 per 1374
Joshi AV et al.27	2017	India	2 years	10279	1 per 468
Binu AJ et al.21	2019	India	5 years	-	1 per 1541
Khade SA et al.20	2022	India	2 years	12880	0.07% 1 per 1398
Kanakasabapathy RA.22	2022	India	4 years	14505	1 in 453
Sarkar S. et al.28	2022	India	5 years	76000	0.09% 1 per 1118
Present Study	2024	India	18 months	1381	1 per 460







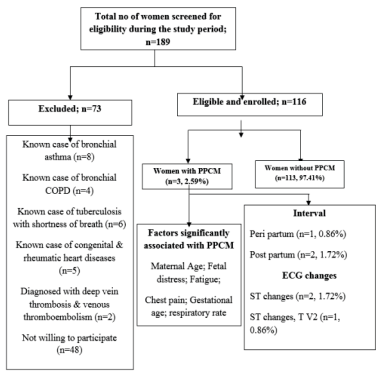


Figure 1. Selection And Enrolment Of Patients

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