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Maternal and perinatal outcomes in early versus late onset pre-eclampsia – A comparative study

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ABSTRACT

Background: Hypertensive disorders are the most common medical complications of pregnancy and complicate up to 10% of pregnancies. **Aims and Objectives:** This prospective study examined the effects of early-onset pre-eclampsia (EO-PE) and late-onset pre-eclampsia (LO-PE) on composite maternal and perinatal outcomes. **Materials and Methods:** Pregnant women booked, unbooked or referred having pre-eclampsia admitted in Department of Obstetrics and Gynaecology at RG Kar Medical College and Hospital from march 2023 to february 2024 were included in the study. **Results:** The most common complications were eclampsia (16.7% vs. 13.3%; P = 0.609), HELLP syndrome (P = 0.018), and abruptio placentae (21.7% vs. 6.7%; P = 0.018). Although all these complications were more in the EO-PE group, the difference did not gain statistical significance. EO-PE is more strongly linked to small for gestational age births, stillbirths, and birth asphyxia. **Conclusion:** LO-PE was more prevalent among primigravida patients. The adverse maternal outcomes were more in mothers of the EO-PE group than the LO-PE group but in most cases, the difference did not reach statistical significance. Adverse neonatal complications were significantly more common in EO-PE.

Key words: Maternal mortality ratio; Hypertensive disorder of pregnancy; Pre-eclampsia; Eclampsia; Proteinuria; Perinatal mortality rate; Low birth weight baby; Stillbirth; Apgar score

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INTRODUCTION

According to the special bulletin on maternal mortality ratio (MMR) released by the Registrar General of India March 14, 2022, India's MMR has improved to 103 in 2017–2019. According to the sustainable development goals, the target is to reduce the global MMR to <70/1,00,000 live births by 2030. Hypertensive disorders are among the most common medical complications of pregnancy and complicate up to 10% of pregnancies and forms one of the deadly triad along with hemorrhage and infection. Pre-eclampsia is defined as the new onset hypertension and either proteinuria or end-organ dysfunction after 20 weeks of gestation in previously normotensive women.[1] Pre-eclampsia can affect both the mother and the fetus and affect between 5 and 8% of healthy pregnancies.[2] It is clear that pathological processes at the interface of the fetal and maternal circulation leading to generalized endothelial cell dysfunction contribute to the spectrum of the disease.[3]

However, in recent years, pre-eclampsia is classified based on the timing of the disease onset: (a) Early onset pre-eclampsia (EO-PE) occurring before 34 weeks of gestation (b) late-onset pre-eclampsia (LO-PE) occurring at or beyond 34 weeks of gestation.[4,5] The diagnostic criteria are the same for the EO-PE and LO-PE; in fact this simple division has better prognostic implication than mild versus severe terminology.[6] It has been suggested that

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the maternal and perinatal morbidities and mortalities of the two subgroups are different.[7-9]

The diagnostic criteria for severe pre-eclampsia are: (a) Blood pressure ≥160 mmHg systolic or ≥110 mmHg diastolic on two occasions >6 h apart (b) Significant proteinuria (protein excretion ≥3+ on a dipstick random sample) (c) Oliguria (urinary output <400 mL/24 h). In addition any patient with cerebral or visual disturbances, pulmonary edema or cyanosis, impaired liver function or thrombocytopenia (platelet count <1,00,000/mL) are included in severe pre-eclampsia. We compared the effects of maternal and perinatal outcomes as well as the similarities and differences in laboratory parameters in two groups.

There are retrospective studies that have defined the outcomes of the EO-PE and LO-PE and have compared them with the outcomes of pregnancies without pre-eclampsia whereas studies comparing the clinical trends, laboratory parameters, and composite outcomes of the maternal and fetal health in the two groups are limited. This prospective study examined the effects of EO-PE and LO-PE on composite maternal and perinatal outcomes and identified the similarities and differences in the laboratory parameters and clinical presentations of the two groups.

Aims and objectives

General objectives

The purpose of the proposed study was to examine the effects of early onset and LO-PE on composite maternal and perinatal outcomes.

Specific objectives

(1) To compare the adverse maternal outcomes between EO-PE and LO-PE groups (a) HELLP syndrome (Complete/Partial HELLP) (b) abruptio placentae (c) post-partum hemorrhage (PPH) (d) acute kidney injury (AKI) (e) eclampsia (f) cerebrovascular accidents (CVA) (g) pulmonary edema (h) oligohydramnios (2) To compare the adverse perinatal outcomes between EO-PE and LO-PE groups: (a) small for gestational age (SGA) (b) low birth weight (LBW) (c) stillborn (d) 5 min Apgar score.

MATERIALS AND METHODS

Study design

This was a prospective, observational, and comparative study.

Place of study

This study was conducted by R G Kar Medical College and Hospital.

Period of study

The study period was from March 2023 to February 2024.

Study population

According to the inclusion and exclusion criteria of our study, antenatal mothers booked at antenatal clinic, unbooked/referred pregnant women having pre-eclampsia, admitted and delivered in the department of obstetrics and gynecology at RG Kar Medical College and Hospital.

Sample size

Wadhwani et al., in their study, showed that the stillbirth rate in two groups, that is, early onset versus LO-PE was significantly higher in EO-PE group (21.0% vs. 1.9%; P<0.001) Taking this result as a guidance data and 90% power of the study with a level of significance as 5% a sample size of 53 will be required in each group which is rounded off to 60 in each group.

Inclusion criteria

Singleton pregnancy, both cephalic and non-cephalic presentation between 24 and 41 weeks of gestation without any systemic medical illness with confirmed gestational age and disease onset timing.

Exclusion criteria

- Multifetal pregnancy
- Pregnancies conceived by *in vitro* fertilization
- Teenage pregnancy
- Severe anemia (Hb <7.0 g/dL)
- Pregnancies complicated by known medical illness
  - Chronic hypertension
  - Pre-gestational diabetes
  - Chronic kidney disease
  - Liver disease
  - Anti-phospholipid antibody syndrome/any other autoimmune disease
- Patient with a history of drug abuse patients with systemic medical illness may alter clinical and laboratory findings as well as maternal and perinatal outcomes and hence were excluded from the study.

Outcome parameters and definition

(a) Maternal outcomes:
   (i) HELLP syndrome
   (ii) Abruptio placentae
   (iii) PPH
   (iv) AKI
   (v) Pulmonary edema
   (vi) CVAs
   (vii) Eclampsia
   (viii) Oligohydramnios

(b) Perinatal outcomes:
   (i) LBW
   (ii) Stillborn
   (iii) Apgar score at 5 min <7
   (iv) Neonatal death
   (v) Composite neonatal outcomes
   (vi) SGA.

Data collection and interpretation

- On admission day all the booked cases from the outpatient department as well un-booked/referred cases admitted in the department were selected. Out of this who gave consent were selected after matching the inclusion and exclusion criteria.
- Group A patients – EO-PE: Patients developing pre-eclampsia before 34 weeks of gestation. Group B patients – LO-PE: Patients developing pre-eclampsia at or beyond 34 weeks gestation. Gestational age will be determined based on the last menstrual period and/or crown-rump length at the first-trimester ultrasound.
- Maternal and fetal monitoring was performed according to the standard guidelines. All patients with severe pre-eclampsia will be admitted to the hospital and women with mild pre-eclampsia were admitted only if fetal indications were present. Fetal surveillance in the form of biophysical profile, non-stress test, and Doppler ultrasonography was performed.

Management

Magnesium sulfate, antihypertensive therapy (labetalol or nifedipine), and corticosteroid therapy for fetal lung maturity <34 weeks gestation were administered to women with severe PE. Maternal blood pressure was monitored regularly, and laboratory testing was done at regular intervals depending on disease severity. Fetal assessment was performed by daily fetal heart rate monitoring and Doppler at least every 3 days. Cardiotocography (CTG) and biophysical profile were done as needed. Indications for delivery: (1) Severe PE or uncontrollable blood pressure (2) Primary fetal distress diagnosed by CTG (3) Abnormal umbilical artery Doppler.

Laboratory investigations

- Complete hemogram including platelet count
- Liver function test (alanine transaminase, aspartate transaminase, total bilirubin, direct bilirubin)
- Serum urea
- Serum creatinine
- Urine protein
- Ultrasound for FPP+amniotic fluid index with Doppler velocimetry of umbilical artery and middle cerebral artery.

Ethical approval

This study was approved by Institutional Ethics Committee.

Statistical analysis

The data are tabulated in Microsoft Excel. The continuous variables are presented with mean and standard deviation. The categorical variables are presented with frequency and percentage. The normality of the quantitative data was checked by the Kolmogorov–Smirnov test of normality. Independent t-test was used for quantitative test and Chi-square was used for qualitative variables for the statistical analysis. The statistical tests were 2-sided and performed at a significance level of α=0.05 (P<0.05). The analyses were conducted using JAMOVI version 2.3.

RESULTS

Out of 120 patients included in the study, 60 (50%) were EO-PE and 60 (50%) were late onset eclampsia. Out of EO-PE, 61.7% had severe features and 38.3% did not have severe features. Out of LO-PE, 41.7% had severe features.

Table 1 shows that the Chi-square test statistic of 4.81 with 1° of freedom and a P=0.028 indicates a statistically significant association between the occurrence of severe features in pre-eclampsia and the type of pre-eclampsia (EO-PE vs. LO-PE). Women with EO-PE are more likely to experience severe features compared to those with LO-PE.

Table 2 shows that HELLP syndrome (either partial or complete), the EO-PE subgroup comprises 12 individuals, making up 10.0%. Moreover, in the LO-PE, subgroup includes 14 individuals, representing 11.7%. Together, the group with HELLP syndrome accounts for 21.7%.

Table 3 shows that in the EO-PE group 13 individuals, making up 10.8% of the sample, and in the LO-PE group 4 individuals, representing 3.3% of the sample developed placental abruption. The cumulative percentages show that 85.8% of the sample did not experience placental abruption as a complication, while 14.2% did.

Table 4 shows that for individuals with eclampsia, the EO-PE group comprises 10 individuals, making up 8.3% of the sample compared to eight individuals, representing 6.7% of the sample in LO-PE subgroup. Thus, 15.0% of the total sample developed eclampsia as a complication. The data indicate a modest prevalence of eclampsia among the participants, with slightly higher proportions in the EO-PE subgroup (8.3%) compared to the LO-PE subgroup (6.7%).

Table 5 shows that in the EO-PE group, 24 infants did experience adverse outcomes, while in the LO-PE group, 7 infants had adverse outcomes. Across both groups, out of

Table 1: Pre-eclampsia with severe features

Parameters	Group (%)		Total (%)	X^2, DF, P value
	EO-PE	LO-PE		
Pre-eclampsia with severe				
No				
N	23	35	58	4.81, 1, 0.028
%	38.3	58.3	48.3	
Features				
Yes				
N	37	25	62	
%	61.7	41.7	51.7	
Total				
N	60	60	120	
%	100	100	100	

EO-PE: Early onset pre-eclampsia, LO-PE: Late-onset pre-eclampsia

Table 2: Distribution of total no of patients with HELLP (complete/partial)

Total no. of patients with HELLP (complete/partial)	Group	N	% of total	Cumulative %
No	EO-PE	48	40.0	40.0
	LO-PE	46	38.3	78.3
Yes	EO-PE	12	10.0	88.3
	LO-PE	14	11.7	100.0

EO-PE: Early onset pre-eclampsia, LO-PE: Late-onset pre-eclampsia

Table 3: Distribution of abruptio placentae

Abruption	Group	N	% of total	Cumulative
No	EO-PE	47	39.2	39.2
	LO-PE	56	46.7	85.8
Yes	EO-PE	13	10.8	96.7
	LO-PE	4	3.3	100

EO-PE: Early onset pre-eclampsia, LO-PE: Late-onset pre-eclampsia

Table 4: Distribution of eclampsia

Eclampsia	Group	N	% of total	Cumulative
No	EO-PE	50	41.7	41.7
	LO-PE	52	43.3	85.0
Yes	EO-PE	10	8.3	93.3
	LO-PE	8	6.7	100

EO-PE: Early onset pre-eclampsia, LO-PE: Late-onset pre-eclampsia

Table 5: Composite neonatal outcome

Parameter	Group		Total	X^2, DF, P value
	EO-PE	LO-PE		
Neonates with complications				
No				
N	36	53	89	12.6, 1, <0.001
%	60	88.3	74.2	
Yes				
N	24	7	31	
%	40	11.7	25.8	
Total				
N	60	60	120	
%	100	100	100	

EO-PE: Early onset pre-eclampsia, LO-PE: Late-onset pre-eclampsia

120 infants, 89 experienced no adverse neonatal outcomes, and 31 experienced adverse outcomes. The calculated Chi-squared (χ^2) is 12.6 with 1 degree of freedom (df), and the associated P<0.001. This low P-value indicates a highly statistically significant association between the type of pregnancy complication and the occurrence of adverse neonatal outcomes.

DISCUSSION

Pre-eclampsia, defined as the new onset hypertension and either proteinuria or end-organ dysfunction developing after 20 weeks of gestation, is a major concern as it can complicate 2–10% of pregnancies and one of the most common causes of maternal mortality and severe maternal morbidity. Mehta et al.,[9-10] in his study found an incidence of hypertensive disorders of pregnancy of 6.9% in the Indian population. The incidence of pre-eclampsia in hospital practice in India varies from 5% to 15%, and that of eclampsia is about 1.5%. Like hypertensive disorders, the incidence of pre-eclampsia is five correlated to ethnicity and race, most prevalent among African-American and Hispanic patients, making up around 26% of maternal death among this population.[10] It has been estimated that pre-eclampsia complicates 4.6% of pregnancies globally and is a significant cause of maternal and perinatal death.[11] About 0.5% of women with pre-eclampsia without severe features, and as many as 2–3% of patients with severe pre-eclampsia who are not receiving antiseizure prophylaxis, will develop eclampsia.[12] However, for a better understanding of this complex entity, pre-eclampsia in recent years is classified into EO-PE occurring before 34 weeks of gestation and LO-PE occurring at or after 34 weeks of gestation.[13,14] This prospective observational study was conducted to find and compare the various maternal and perinatal outcomes between the EO-PE and the LO-PE group. The association of the various maternal demographic characteristics was studied and it was found that for age, there was no statistically significant difference between the groups (t=−1.213, P=0.228), with a small effect size (Cohen's d=−0.2214). Mean age in EO-PE group was 25.75±3.85 years and mean age in LO-PE group was 26.61±3.97 years. This represents age distribution was independent of EO-PE or LO-PE occurrence. Similarly, socioeconomic status (P=0.689) showed no significant associations, suggesting these factors did not influence pre-eclampsia timing However, body mass index (BMI) showed a significant difference (P=0.002), with a medium effect size (Cohen's d=−0.5685), indicating that LO-PE group (mean=22.9±1.99) had higher BMI compared to EO-PE group (mean=24.1±2.21). Nulliparity is considered an overall risk factor for pre-eclampsia. In our study, 48.3% of women in the EO-PE group and 71.7% of women in

the LO-PE group were primigravida. Conversely, there were more multiparous women in the EO-PE group. A significant association between the gravida and the time of disease onset was seen (P=0.009). A history of pre-eclampsia in previous pregnancies is considered a risk factor for pre-eclampsia in the subsequent pregnancies. In the present study, a significant association (P=0.006) between the history of pre-eclampsia in previous pregnancies and the type of pre-eclampsia (EO-PE vs. LO-PE) was observed. This risk factor was seen to be more commonly associated with the EO-PE. The hematological parameters and the laboratory parameters were comparable between the two groups and showed no significant difference except for serum creatinine (P=0.009) and urine protein (P<0.001) values. The data suggests that the kidney function is affected more in the EO-PE which may be due to glomerular endotheliosis which results in a lower glomerular filtration rate and effective renal plasma flow. Interestingly, it was observed in the study that although the EO-PE group had higher serum levels of renal biomarkers than the LO-PE group, no significant differences (P=0.309) were found between the groups in terms of adverse renal conditions, for example, AKI. Various other maternal complications were studied. The most common complications were eclampsia (16.7% vs. 13.3%; P=0.609), HELLP syndrome (P=0.018), and abruptio placentae (21.7% vs. 6.7%; P=0.018). Although all these complications were more in the EO-PE group, the difference did not gain statistical significance. Other complications studied were PPH (P=0.088), pulmonary edema (P=0.559), and CVA (P=0.315) which showed similar results between the two groups. Oligohydramnios is a condition characterized by reduced amniotic fluid levels, which can complicate pregnancy and delivery. In the present study, oligohydramnios was seen in 33.3% of women in EO-PE group and 15% in the LO-PE group. Thus, a significantly greater (P=0.019) number of women with EO-PE were more likely to have oligohydramnios compared to those with LO-PE. Gestational age at diagnosis and delivery varied significantly between EO-PE and LO-PE groups, with EO-PE diagnosed and delivering earlier on average compared to LO-PE, indicating distinct patterns in disease onset and progression. The gestational age at diagnosis in the EO-PE group was 30.6±1.56 and in the LO-PE group was 36.4±1.2. The gestational age at delivery in the EO-PE group was 32.3±1.44 and in the LO-PE group was 37.1±0.941. The mean duration of hypertension (onset to delivery) was 12.8±9.53 days in the EO-PE group and 12.8±9.53 days in the LO-PE group. Significant differences were found in gestational age at diagnosis (t=−22.808, P<0.001), gestational age at delivery (t=−21.400, P<0.001), duration of hypertension (t=5.060, P<0.001) The severity of the disease, that is, development of the severe features and the use of $MgSO_4$ therapy was compared and it was observed that women belonging to EO-PE group developed more severe disease than the LO-PE group (61.7% vs. 41.7%; P=0.028). Similarly, the use of $MgSO_4$ therapy was significantly higher in the EO-PE group (56.7% vs. 36.7%; P=0.028). However, no statistically significant association was found between the mode of delivery (assisted vaginal delivery, cesarean sections [CS]) and the type of pre-eclampsia (EO-PE vs. LO-PE) (χ^2=0.772, df=2, P=0.680). The distribution of delivery modes was similar across both groups, suggesting that factors other than the type of pre-eclampsia influence the choice of delivery method. The substantial use of CS in managing pregnancies complicated by pre-eclampsia, was slightly higher in early-onset cases, although the data failed to reach statistical significance (P=0.583). EO-PE showed a statistically significant association with umbilical artery Doppler abnormalities (χ^2=4.66, df=1, P=0.031), suggesting that these abnormalities are more prevalent in cases of EO-PE compared to LO-PE. Significant associations were observed between the time of onset of pre-eclampsia (EO-PE or LO-PE) and perinatal outcomes. There was a highly significant correlation between EO-PE and a higher incidence of SGA neonates (χ^2=7.76, df=1, P=0.005). This indicates that EO-PE is more strongly linked to SGA births compared to LO-PE. Furthermore, EO-PE was significantly associated with a higher risk of stillbirth (χ^2=11.6, df=1, P<0.001) and lower birth weights (<0.001), highlighting the increased adverse fetal outcomes in these pregnancies compared to LO-PE. In contrast, there was no significant association between the type of pre-eclampsia and neonatal acidosis (χ^2=0.342, df=1, P=0.559), indicating that the occurrence of neonatal acidosis is not influenced by whether pre-eclampsia onset is early or late. Neonates with 5 min APGAR score <7 were higher in the EO-PE (11.67%) than the neonates of the LO-PE (3.3%) but the difference were not statistical significance (P=0.083). The need for respiratory support was also significantly higher in the neonates of the EO-PE group (P<0.001) compared to those born to mothers with LO-PE. Finally, there was no significant difference in the incidence of neonatal death between infants born to mothers with EO-PE versus LO-PE (χ^2=1.37, df=1, P=0.243), suggesting similar risks of neonatal mortality regardless of pre-eclampsia onset timing.

Limitation of the study

- Small sample size
- Short follow-up period (until discharge)
- Women with chronic hypertension and diabetes were not included in the study which itself if considered a risk factor for developing pre-eclampsia
- Women with multifetal pregnancy, teenage pregnancy, and *in vitro* fertilization were not included in the study.

CONCLUSION

This comparative prospective observational study was conducted on singleton pregnancy between 24 and 41 weeks of gestation without any systemic medical illness to observe and compare the various maternal and perinatal outcomes in the EO-PE (before 34 weeks) and LO-PE (at or beyond 34 weeks). LO-PE was more prevalent among primigravida patients. The adverse maternal outcomes were more in mothers of the EO-PE group than the LO-PE group but in most cases, the difference did not reach statistical significance. There were no maternal deaths in either group. The most common maternal complications were HELLP syndrome, eclampsia, and abruptio placentae. There was a significant difference noted between the two groups in terms of gestational age at diagnosis, gestational age at delivery, and duration of hypertension. The EO-PE group has a significant early gestational age at diagnosis and delivery. A significantly higher number of women with EO-PE than those with LO-PE developed severe features during their disease course and most of these women required $MgSO_4$ therapy. Adverse neonatal complications were significantly more common in babies born to mothers of EO-PE. The greater number of the adverse perinatal outcomes in the EO-PE group might have been due to prematurity itself than the severity of pre-eclampsia. Thus, we conclude that adverse maternal and perinatal outcomes were more in the EO-PE than the LO-PE group highlighting that EO-PE is a more severe form of the disease.

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NS- Concept and design statistical analysis; **SS**- Interpretation of result, manuscript preparation, coordination; **LA**- Preparation of manuscript, statistical analysis; **RM**- Manuscript preparation; **DG**- Concept and design.

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