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Outcome of expectant management of severe preeclampsia between 28 to 34 weeks of gestation at tertiary care hospital

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Abstract
Objective: The objective of the study was to study to evaluate the maternal and perinatal outcome of expectant management in early onset of severe preeclampsia in a tertiary care hospital.
Material and Methods: This was a observational study performed in tertiary hospitals. All eligible pregnant women with gestational age between 28 and 34 weeks and diagnosis of severe preeclampsia (ACOG 2013 guidelines) were included in study for expectant management. On admission; cases were monitored vigilantly and treated with antihypertensives, magnesium sulphate seizure prophylaxis and termination of pregnancy ether at 34 weeks or earlier in case of complication. Appropriate statistical analysis was done.
Results: A total of 96 cases were enrolled in study. Mean prolongation of pregnancy was 8 days with range between 1-27.Only 26.04% were able to attain 34 weeks of gestation. Maternal complications were noted in 12.5% of cases. There was no maternal mortality. There were 2.08% stillbirths, 32.29% perinatal death and 67.70% babies were alive. The association between days prolonged was not significant that means increase in number of days of pregnancy prolongation, does not increase maternal complications. At the same time, the association between number of days prolonged and perinatal survival was found to be statistically significant that means improved perinatal outcome was noted with increasing number of days of pregnancy prolongation.
Conclusion: This study concluded that an expectant management of women with early onset severe preeclampsia in selected situation is associated with improved perinatal survival without increasing maternal complications.

Keywords: Early onset severe preeclampsia, maternal mortality and morbidity, expectant management

Introduction

Preeclampsia refers to the new onset of hypertension and proteinuria or end-organ dysfunction with or without proteinuria after 20 weeks of gestation in a previously normotensive woman. In 2013, the American College of Obstetricians and Gynaecologists replaced the term “severe preeclampsia” with the term “preeclampsia with severe features. The studies published before the change in terminology used different features to characterize the severe end of the preeclampsia spectrum [1]. For example, the diagnosis of "severe preeclampsia" in these studies may have been based on hypertension with fetal growth restriction or proteinuria >5 grams/day, which are no longer considered features of severe disease. Women with preeclampsia with severe features are usually delivered promptly to prevent maternal and fetal complications. Since the disease is progressive and there is no medical treatment, delivery is always in the best interest of the mother. However, preterm delivery is not always in the best interest of the fetus; therefore, a decision to delay delivery can be considered under certain circumstances. The rationale for delaying delivery in these pregnancies is to reduce perinatal morbidity and mortality by delivery of a more mature fetus and, to a lesser degree, to achieve a more favourable cervix for vaginal birth. The risk of prolonging pregnancy is worsening maternal endothelial dysfunction and continued poor perfusion of major maternal organs with the potential for severe end organ damage to the brain, liver, kidneys, placenta/fetus, and hematologic and vascular systems.

Cochrane review published in 2013 recommended that an expectant approach to the management of women with severe preeclampsia may be associated with decreased morbidity for the baby [2]. This evidence was based on data of only four trials and recommended that

further large trials are needed to confirm or refute these findings. The outcome of severe features of preeclampsia remote from term in a developing country would not be the same as that in developed countries where the expertise and resources are far better. Keeping this in mind, we conducted a study to evaluate the maternal and perinatal outcome of expectant management in early onset of severe preeclampsia in a tertiary care hospital.

Materials & Methods

This was hospital based observational study conducted in Department of Obstetrics & Gynaecology, Government Medical College & Hospital, Aurangabad between study period January 2017 to December 2017.

Inclusion Criteria: All pregnant women of gestational age between 28 and 34 weeks and diagnosis of severe features preeclampsia was made according to the criteria put forward by American College of Obstetrics and Gynaecology (ACOG) having any of these findings

1. Systolic blood pressure of 160 mm of Hg or higher or diastolic blood pressure 110 m of Hg on two occasions at least 4 hrs apart while the woman is on bed rest (unless antihypertensive therapy is initiated before this time)
2. Thrombocytopenia (platelet count < 1,00,000 / mm3)
3. Impaired liver function as indicated by abnormally elevated blood concentrations of liver enzymes. (to twice normal concentration), severe persistent right upper quadrant or epigastric pain unresponsive to medication and not accounted for by alternative diagnoses, or both.
4. Progressive renal insufficiency (serum creatinine concentration > 1.1 mg/dl or a doubling of serum creatinine concentration in the absence of other renal disease)
5. Pulmonary edema
6. New onset cerebral or visual disturbances [1].

Exclusion criteria: Eclampsia, severe uncontrolled hypertension, significant renal dysfunction (oliguria), abruptio placenta, disseminated Intravascular coagulation (DIC), non-reassuring CTG, reverse end diastolic flow in the umbilical artery, severe oligohydramnios, foetal distress/intrauterine foetal demise, HELLP syndrome, participants already on antihypertensive medication, pregnant women having systemic disease like atherosclerosis, cardiovascular disease, renal disease, vascular disease, thyroid disorder, diabetes in pregnancy, pregnant women having other related or unrelated high risk factors, pregnant women having malformed fetus, pregnant women with multiple gestation, lost to follow up cases.

All pregnant women presenting or referred to tertiary care hospital with severe pre-eclampsia were enrolled after applying inclusion and exclusion criteria and after obtaining written consent for providing expectant management till any of complications of severe preeclampsia appeared warranting termination of expectant management or completion of 34 weeks the study was. Approved by institutional ethics committee.

Recruited women were admitted to labour room for intensive, non invasive monitoring of maternal and fetal status. Gestational age was determined by means of last menstrual period or obstetric ultrasonography or both. Detailed history was obtained. Participants were also questioned about warning symptoms such as headache, vomiting, blurring of vision, epigastric pain.

Participants were admitted and provided expectant management as; bed rest, daily maternal weight record, monitoring of maternal blood pressure and urine output every 6 hourly. Participants were questioned frequently about warning symptoms such as headache, visual disturbance, & right upper quadrant pain.

Antihypertensive drugs were administered to keep the systolic blood pressure at 130-150 mm of Hg and the diastolic blood pressure at 80-100 mm of Hg. We used two antihypertensive agents in stepwise approach (Tab. Labetolol 200 TDS, maximum 1200 mg/day and if required Tab. Nifedepine 10mg TDS, maximum 30 mg/day). Inj. Labetolol 20 mg IV was given to control hypertensive crisis and second dose of Inj. Labetolol 40mg was repeated after 10 minutes if blood pressure did not come down to desired level maximum Upto 220 mg/treatment cycle. Inj. Dexamethasone 6 mg intramuscularly 4 doses were given 12 hours apart to enhance fetal lung maturity.

Inj. Magnesium sulphate prophylaxis according to Pritchard`s regime was given to all admitted women for 24 hours. A full blood count, renal function tests, liver function tests, urine routine examination, fundoscopy and coagulation profile were obtained. Fetal condition on admission was assessed by means of ultrasound for the estimation of fetal growth and amniotic fluid volume, non stress test and the study of the umbilical artery Doppler waveform if required.

Maternal monitoring included blood pressure measurement every 4 hourly and participants were questioned frequently about headache, visual disturbance & right upper quadrant pain. Blood tests included haemoglobin, packed cell volume, platelet count, liver enzymes, urea, creatinine, serum LDH and uric acid. These tests were performed biweekly. Urine albumin, 24 hour urine volume and maternal weight were assessed every day. Daily fetal movement, biweekly non stress test, weekly obstetric ultrasound and umbilical artery Doppler in case of intrauterine growth restriction was used for antepartum fetal surveillance. Failure to control blood pressure or the development of major maternal or fetal complications was an indication of delivery. Women reaching a minimum gestation of 34 weeks without complications were delivered electively. Decision of mode of delivery was taken by attending obstetrician.

Fetal indications for delivery during expectant management were abnormal fetal heart rate monitoring (repeated late decelerations, prolonged decelerations > 3 min, short term variability < 5 beats/min over 60 min), severe IUGR (estimated fetal weight < 5^{th} percentile) or severe oligohydramnios (amniotic fluid index < 5 cm).

Maternal indications for delivery during expectant management were eclampsia, HELLP syndrome. Abruption, DIC, acute kidney injury, severe uncontrolled hypertension, persistent headache or visual disturbances, persistent epigastric pain or right upper quadrant tenderness.

The main objective was to study maternal and perinatal outcome after expectant management of severe pre eclampsia. Maternal outcome and pregnancy prolongation were analyzed according to the gestational age at the time of admission, and perinatal outcome was analyzed according to the gestational age at delivery. Maternal outcome included maternal death and complications like eclampsia, stroke, HELLP syndrome, abruption, DIC, pulmonary edema, acute renal failure, liver failure, cardiac arrest. Perinatal outcome included stillbirth, neonatal death, respiratory distress syndrome (RDS), necrotizing enter colitis, intraventricular haemorrhage, sepsis, convulsions, hyperbilirubinemia and small for gestational age.

Statistical analysis was done by using SPSS (version 19) for windows and data were presented as median with range, mean or percentage as appropriate. Chi square test was used for qualitative analysis; p value of <0.05 was considered to be significant.

Results

Table 1: Baseline Characteristics of Study Participants

Characteristics		Study Participants (n=96)	
		Frequency	%
Age (In years)	≤ 19	04	4.1
	20-24	47	49.0
	25-29	36	37.5
	≥30	09	9.4
Gravidity	Primigravida	72	75.0
	Multigravida	24	25.0
Gestational age in weeks at the time of admission	28.1-30	29	30.2
	30.1-32	38	39.6
	32.1-34	29	30.2

Table 2: Distribution according to prolongation of number of days

Gestational age in weeks at the time of admission	Number of participants n=96	Mean number of days prolonged	Median	Range in days
28.1-30	29	10.41	9	2-27
30.1-32	38	07.11	5	1-25
32.1-34	29	5.55	5.5	1-11
Total	96	7.69	6.5	1-27

Table 3: Distribution according to Maternal Outcome

Maternal Outcome			Gestational age in weeks at the time of admission (n=96)		
			28.1-30 (n=29)	30.1-32 (n=38)	32.1-34 (n=29)
Mode of delivery		Vaginal	22	21	16
		Caesarean section	07	17	13
		Total	29	38	29
Maternal complications	No complications n=84		21	36	27
	Complications* n=12	HELLP	04	01	01
		Abruption	00	01	02
		DIC	00	00	03
		Acute Kidney Injury	00	01	00

*More than one complication was seen in some women.

Table 4: Distribution according to Perinatal Outcome

Perinatal Outcome (n=96)		Gestational age in weeks at the time of delivery		
		28.1-30 (n=13)	30.1-32 (n=39)	32.1-34 (n=44)
Birth Weight in Kg.	1-1.5	12	27	21
	>1.5-2	01	12	21
	>2-2.5	00	00	02
	Total	13	39	44
Apgar at 5 minutes**	<7	11	26	11
	7-10	00	13	33
	Total	11	39	44
Perinatal outcome	Still birth	02	00	00
	Perinatal	10	15	06
	Alive	01	24	38
	Total	13	39	44
Perinatal Complication** n=31	Hyaline membrane disease	6	4	2
	Sepsis	8	3	0
	Hyperbilirubinemia	3	3	3
	Convulsions	3	3	2
	Necrotising enterocolitis	3	1	1
	Intraventricular haemorrhage	2	2	2
	Pneumonia	1	1	1
	Hypothermia	1	2	1

*For Apgar score, n=94

**More than one perinatal complications was noted in some neonates.

Table 5: Distribution according to days Prolonged with maternal complication & perinatal outcome

Gestational age at time of admission in weeks	Mean Number of days prolonged	Maternal Complications (n=96)		Test of significance	Perinatal outcome (n=96)			Test of significance
		Yes	No		Still birth	Perinatal Death	Alive	
28.1-30	11.07	08	21	χ^2=2.2442	02	10	01	χ^2=8.5644
30.1-32	6.95	02	36	df=1	00	15	24	df=1
32.1-34	5.55	02	27	p=0.13412	03	06	38	p=0.003428

Results

During the study period, 17934 women delivered in this hospital. There were 1686 (9.4%) cases of hypertensive disorders in pregnancy. A total 96 eligible and willing cases were recruited for expectant management of severe preeclampsia.

Around 86.5% participant were in the age group of 20-29 years.75% were primigravida and 39.6% participants were in gestational age group of 30 -32weeks. (Table 1)

The mean prolongation of pregnancy was around 8 days with range of 1-27. It was noted that the mean days gained were maximum (10.41days) in gestational age between 28.1 - 30 weeks. (Table 2)

Out of total 96 cases, Only 25(26.04%) cases reached 34weeks of gestation and remaining 71(73.95%) cases required pregnancy termination. The most common reason for termination of pregnancy was uncontrolled hypertension in 27(28.12%) followed by reappearance of warning symptoms in 15(15.62%) cases followed by other maternal or fetal complications. Mode of delivery was vaginal in 59 cases (61.45 %) and caesarean section in 37 cases (38.54 %). Life threatening maternal complications were noted in 12(12.5%) cases. Out of 3 cases complicated by abruptio placenta, one case required dialysis for acute kidney injury and recovered after 3 weeks. HELLP syndrome was the commonest complication (6 cases) requiring medical management and blood and component therapy. Two cases of DIC were noted following abruption and one after HELLP syndrome. There was no maternal mortality. (Table 3**)**

A total 94 (97.91%) newborns were having birth weight less than 2kg. There were only 2 babies with birth weight >2 kg. Apgar score at 5minutes was <7 in 48 (51.06%) newborns. There were 2 (2.08%) still birth between 28.1-30 weeks. Perinatal death was noted in 31(32.29%) and 65 (67.70%) neonates were alive. The perinatal death was noted in 10 (10.41%) neonates between 28 to 30 weeks, 15 (15.62%) neonates of 30.1 to 32 weeks and 6 (6.25%) neonates of 32.1 to 34 weeks.

A total 70 newborns required NICU admission and 31 of them developed serious perinatal complication leading to death. The birth weight was between 1 to 1.5kg in 19 (19.79%) and between 1.5 to 2 kg in 12 (12.5%) neonates who developed serious complications. Out of 31 perinatal deaths, major causes for perinatal death include HMD (38.70%), sepsis (35.48%), and hyper billirubinemia (29.03%). (Table 4)

The association between number of days prolonged (average 8 days) and maternal complication was not significant that means increase in number of days of pregnancy prolongation, does not increase maternal complications. At the same time, the association between number of days prolonged and neonatal survival was found to be statistically significant that means improved perinatal outcome was noted with increasing number of days of pregnancy prolongation. (Table 5)

Discussion

In India, the incidence of preeclampsia is reported to be 8-10% among pregnant women. According to study, the prevalence of hypertensive disorders of pregnancy was 7.8% with preeclampsia in 5.4% of the study population in India (3). Close supervision of mother and fetus is crucial, as it is impossible to predict the clinical course of the disease after admission, and clinical deterioration can occur rapidly. After initial assessment and stabilization in the labour room, these cases were monitored and medically managed in an antenatal wards.

The first attempts at expectant management were aimed at providing brief pregnancy prolongation to allow for antenatal corticosteroid administration, but the potential for longer expectant management was entertained because some patients remained stable or improved during initial observation. Further study has shown that median latency with expectant management ranges from 7–14 days [4]. There were hardly any studies after ACOG 2013 guidelines to demonstrate the effectiveness of expectant management of severe preeclampsia.

In present study, pregnancies were prolonged by a mean 8 days and median of 5 days with a significantly greater period gained at earlier gestations as similarly observed Swamy M K *et al* who reported pregnancy prolongation of median 5 days [5]. In present study, there were no instances of maternal mortality, cerebrovascular accidents or major complications requiring adult intensive care admission due to continuous monitoring of maternal and fetal condition. This observation is in agreement with other studies [5, 6]. There was no case of eclampsia in present study as compared to other studies. This is due to prophylactic use of Magnesium sulphate as per Pritchard's regimen in all cases of severe preeclampsia. Other studies reported use of magnesium sulphate either in cases of eclampsia or in cases of imminent eclampsia only [5, 6]. Present study reported one case of acute kidney injury requiring dialysis and all cases recovered well.

Perinatal morbidity & mortality is clearly less in cases delivered between 32.1-34 weeks of gestation. Perinatal death was noted in 32.29% in present study. Our perinatal mortality was consistent with Ragini M *et al* [7] but higher than Swamy *et al*. [5]. This may be due to the fact that nearly 54% women delivered before 32 weeks in present study which was in contrast to Swamy *et al* where only 26.59% delivered before 32 weeks of pregnancy.

Present study reported significant prolongation of pregnancy and improvement in perineal outcome with expectant management, with no increase in the rate of maternal complications. This observations in agreement with other study. [6]. A larger randomized trial (MEXPRE Latin Study) reported that expectant management resulted in prolongation of pregnancy but this did not result in significant neonatal benefit. The lack of newborn benefit from expectant management may have been due to selection of patients' at the most severe end of disease spectrum [8].

Overall expectant management in severe preeclampsia with proper control of hypertension, starting prophylactic magnesium sulphate therapy for prevention of convulsion at the time of admission and timely termination of pregnancy with vigilant monitoring improves perinatal outcome without increasing maternal complications.

Conclusion

This study concluded that an expectant management of women with early onset severe preeclampsia in selected situation is associated with improved perinatal survival without increasing maternal complications.

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