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A Study to Compare the Risks and Benefits of Aggressive Management with the Expectant Management for Women With Severe Preeclampsia between 28 and 36 Weeks Admitted in Burdwan Medical College and Hospital.

[1]Debdut Banerjee, [2]Priyankar Kanrar, [3]Amitava Das, [4]Dr. Arunima Chaudhuri, [5]Deepteemayee Sahoo, [6]Sisir Kumar Biswas

[1]MS G&O, Assistant Professor G&O, Burdwan MedicalCollege and Hospital, West Bengal, India.
[2]MS G&O RMO cum Clinical Tutor,G&O BMCH BurdwanMedical College and Hospital, West Bengal, India.
[2]MS G&O, Medical Officer, Jangipur Super SpecialityHospital, Murshidabad.
[4]Associate Professor Department ofPhysiology, Rampur hat Government Medical College and Hospital, West Bengal, India.
[5]MS trainee resident,G&O Burdwan Medical College and Hospital, West Bengal, India.
[6]MS trainee resident G&O, Burdwan Medical College and Hospital, West Bengal, India.
**Corresponding Author: Priyankar Kanrar,*

ABSTRACT:
Background: There is an ongoing debate on the mode of management of patients with severe preeclampsia before term.
Aims: To compare the risks and benefits of aggressive management with the expectant management for women with severe preeclampsia between 28 and 36 weeks.
Materials and methods: This study was conducted in the Gynaecology & Obstetrics department of Burdwan Medical College & Hospital in a time span of one year on hundredpregnant women admitted with severe preeclampsia before term. Institutional ethical clearance and informed consent was taken before conduction of the study. All the patients were counseled for expectant management. 56patients were managed aggressively because of refusal of expectant management either by the patient or due to the development of signs & symptoms of progression to impending Eclampsia, DIC or Acute Renal Failure or develops HELLP SYNDROME or Abruptio placentae. The other 44 patients were managed expectantly. Both the groups were followed-up and carefully monitored till discharge.
Results: Most of the subjects were primipara (66%). Among the study populations 9 patients in the aggressive group and 3 patients in the expectant group were found to have deranged liver function test but the difference was not statistically significant. However, during follow up 14 mothers in the aggressive group and 5 mothers in the expectant group were found to have deranged liver function test and the difference became significant with a p value of 0.042.During the study of renal function test it was observed that during admission 7 mothers in aggressive management group and 2 mothers in expectant management group had deranged renal function test but the difference was not significant. However significant difference was observed during follow up where 12 mothers in the aggressive group and 4 mothers in the expectant group were found to have deranged renal function test; p value being 0.039.62 mothers had undergone caesarean section out of which 39 mothers were in the aggressive management group (69.64%) and 23 mothers were in the expectant management group (52.27%). The duration of NICU admission was more in the babies born to aggressively managed mothers (6.38±2.03 days) than the babies born to expectantly managed mothers (4.41±2.54 days).19 babies born to aggressively managed mothers and 8 babies born to expectantly managed mothers had APGAR score < 7 at 1 minute. This was a significant difference with p value being 0.039. Statistically significant difference was also found at 5 minute with 14 babies from aggressive management group and 5 babies from expectant management group had APGAR score < 7; p value being 0.042.Among the neonatal parameters statistically significant difference was found in Respiratory distress syndrome (27 vs 12), Early onset sepsis (<72 hrs) (9 vs 2), Neonatal death (9 vs 2) and Necrotising enterocolitis (7 vs 1) which were more in the babies from aggressive management group than the babies from expectant management group; p value being 0.016, 0.033, 0.033 & 0.033 respectively.
Among the maternal outcomes only pulmonary edema, which was more in aggressive group (n=7) than expectant group (n=1), had statistically significant difference; p value =0.033. The frequency of Eclampsia (04 vs 03), Disseminated intravascular coagulation (03 vs 01), HELLP syndrome (05 vs 04), Cerebrovascular accident (04 vs 01) and maternal mortality (03 vs 01) were more in the mothers from aggressively managed

group than the expectantly managed group. But Abruptio placentae was seen only in expectant group (n=2) though not significant.
Conclusions: Maternal and fetal outcomes are better in the expectant management than the aggressive management for severe preeclampsia before term, so expectant management should be carried out in a selected group of mothers with severe preeclampsia before term with the aim to improve baby outcome without compromising the safety of the mothers and with careful monitoring.

Keywords: Pre-eclampsia, management protocol, outcome.

I. INTRODUCTION

Preeclampsia is a multisystem disorder unique to human pregnancy and the exact pathology is still unknown [1]. There are various hypotheses about its causes and risk factors. It is one of the major causes of maternal morbidity & mortality in developed country more so in a developing country like us. It is also associated with high perinatal morbidity and mortality mainly due to iatrogenic pre-maturity [2]. In India, incidence of preeclampsia ranges from 5%-15%; 5% in multigravida and 15% in primigravida [3].
The signs and symptoms of preeclampsia becomes apparent relatively late in pregnancy usually during the third trimester [4]. Severe preeclampsia occurring preterm can result in both acute [5-7]and long term complications for both the mother and her newborn [8,9]. The only known cure for pre-eclampsia is delivery of the baby and placenta. However prematurely born babies have many complications and morbidity and mortality rate is high [10, 11].

There is an ongoing debate on the mode of management of patients with severe preeclampsia before term. Some advocate early delivery, which has been referred to as 'aggressive management' [10]. This means delivery by either induction of labor or cesarean section after giving corticosteroids for lung maturation [12]. But early delivery resulting in a very pre-mature baby could lead to more neonatal complications such as respiratory distress, neonatal sepsis, perinatal death etc. Others prefer to give corticosteroids, stabilize the woman's condition and then, if possible, aim to delay delivery. This is known as 'expectant management [13]. But delaying the delivery in an attempt to allow fetal maturation could place the mother in jeopardy and at risk of multi-system organ failure.

Although delivery is curative for mother it may not be good for the health of the baby. In the past, it was believed that premature infants born to severely preeclamptic women had lower rates of neonatal mortality and morbidity than infants of similar gestational age born to non-preeclamptic women as chronic stress factor matures the lung early. However recent studies have shown that premature infants born to severe preeclamptic mother have neonatal complications similar to those of other premature infants of similar gestational age and have higher rates of admission to neonatal intensive care units [14]. It has been also seen that babies of preeclamptic mothers do not exhibit accelerated lung or neurological maturation [14]. Most of the maternal deaths occur postpartum. A hurried delivery in an unstable patient probably worsens her condition rather than curing it. On the other hand, delay in an unstable patient may be dangerous [15].

The present study was conducted to compare the risks and benefits of aggressive management with the expectant management for women with severe preeclampsia between 28 and 36 weeks.

II. MATERIALS AND METHODS

This study was conducted in the Gynaecology & Obstetrics department of Burdwan Medical College & Hospital in a time span of one year on hundredpregnant women admitted with severe preeclampsia before term.Institutional ethical clearance and informed consent was taken before conduction of the study.

Inclusion criteria: Pregnant women beyond 28th completed weeks but less than 36th completed weeks of pregnancy admitted with severe preeclampsia.
Exclusion criteria:
1. All pregnant women with multifetal gestation.
2. All chronic hypertensive cases.
3. All pregnant women with severe systemic diseases, like- heart disease, renal failure.

All the patients were counseled for expectant management. 56patients were managed aggressively because of refusal of expectant management either by the patient or due to the development of signs & symptoms of progression to impending Eclampsia, DIC or Acute Renal Failure or develops HELLP

SYNDROME or Abruptio placentae. The other 44 patients were managed expectantly. Both the groups were followed-up and carefully monitored till discharge.

Aggressive management

All mothers in this group were prepared for delivery after administration of corticosteroid. Mode of delivery was determined according to the state of cervix and condition of the mother. If the mother was stable then the induction for vaginal delivery started either by ARM & Oxytocin infusion, if cervix was favorable, or by PGE_2 gel if cervix was unfavorable. If the maternal condition was poor or deteriorating caesarean section was done immediately. $MgSo_4$ was given according to the Pritchard's regimen wherever needed.

Expectant management

Criteria

Maternal – 1 or more of following

- Controlled hypertension
- Oliguria (< 30 ml/hr) which resolves with routine fluid intake.
- No increased AST / ALT (2 x upper limit of normal) or epigastric pains /RUQ tenderness.

Fetal – All of the following

- USG – EFW > 5th percentile for that gestational age.
- Doppler – Normal.
- AFI > 2 cm.
- BPP ≥ 6.

Guidelines

- Those patients who fulfilled the above criteria were observed round the clock in the labour and delivery unit.
- Antihypertensives drugs were administered as needed.
- Investigations – Hematocrit, platelets, S. creatinine, S-Uric acid, Blood-urea, creatinine clearance, 24 hr urine protein, LDH, AST / ALT.
- 4th hourly BP, daily platelets, daily urine albumin, output, alternate day AST, creatinine (once severe preeclasmpsia was documented, 24 hour urine protein was repeated).
- USG with Doppler every week (IUGR, AFV).
- Glucocorticoid administered & repeated weekly.
- Prophylaxis $MgSo_4$ was given according to Pritchard's regimen if needed.

Criteria for termination of pregnancy:

Maternal:

- Uncontrolled hypertension (BP Persistently ≥ 160/110 mmHg despite recommended maximum doses of 2 antihypertensives medications)
- Eclampsia
- Persistent Platelet count < 1,00,000/cumm.
- Pulmonary edema.
- Oliguria <500ml/24hr or serum creatinine ≥1.5mg/dl
- Suspected abruption
- ruptured membranes
- Increase AST / ALT with epigastric pain / RUQ tenderness.

Fetal:

- Severe IUGR (5^{th} percentile)
- Persistent severe oligohydramnios (AFI < 5 cm)
- Biophysical profile score ≤ 4 done 6 hrs apart
- Reversed end diastolic umbilical artery flow
- Fetal death

Mode of delivery: It was determined by state of cervix and fetal condition. If the condition of cervix was favorable, then induction was done by ARM and oxytocin infusion. If cervix was unfavorable then either PGE_2 gel was used for cervical ripening or caesarean section done according to the condition of fetus. Also in

presence of any obstetrical complications or rapidly deteriorating maternal condition caesarean section was preferred.

Parameters assessed post-delivery:
New born:

a. Birth weight and APGAR score of the baby.
b. Oxygen requirement at 24hrs.
c. Clinical signs of early onset (<72 hours) septicemia with positive laboratory tests.
d. Number of days hospitalized in NICU.
e. Number of Intra uterine fetal death or still born and necrotizing enterocolitis.
f. Death of the baby within 28 days of delivery.

III. MATERNAL

a) Occurrence of pulmonary edema, convulsion, prolonged PT & aPTT and presence of oliguria in association with elevated serum urea & creatinine levels.
b) Positive laboratory test for Hemolysis, Low platelet & Elevated liver enzyme; clinical signs for abruption placentae and positive radiological findings for CVA.
c) Death of the mother during pregnancy or within 42 days of delivery.

IV. RESULTS

Among the study population most of the subjects were in the age group of 16 to 20-year: 42 mothers; followed by 21 to 25-year group:34 mothers;26 to 30-year age group: 21 mothers; 31 and more age group:3 mothers. There was no significant difference in age distribution between the two groups in respect of maternal age.

Most of the subjects were primipara (66%). Among the primipara 38 mothers were in the aggressive management group (67.86%) and 28 mothers were in the expectant management group (63.64%). Among the multiparas, 18 mothers were in the first study group (32.14%) while 16 mothers were in the second study group (36.36%).

Majority of the mothers were of 31 to 33 weeks of pregnancy (48%) during the time of admission followed by 34 to 36 weeks of pregnancy (32%) and 28 to 30 weeks of pregnancy (20%). All these three groups the study populations were almost similarly distributed between the aggressive and expectant management group.

Among the study populations 9 patients in the aggressive group and 3 patients in the expectant group were found to have deranged liver function test but the difference was not statistically significant. However, during follow up 14 mothers in the aggressive group and 5 mothers in the expectant group were found to have deranged liver function test and the difference became significant with a p value of 0.042 (Table1).

Table 1: Comparison of the Study of LFT in between Aggressively & Expectantly Managed Groups

	Aggressive Management (n=56)		**Expectant Management (n=44)**		**P Value**
	Normal	**Deranged**	**Normal**	**Deranged**	
LFT status on Admission	47	09	41	03	>0.05
LFT status on follow up	42	14	39	05	**0.042***

P-value <0.05 (*significant)
P-value <0.01 (highly significant)**

During the study of renal function test it was observed that during admission 7 mothers in aggressive management group and 2 mothers in expectant management group had deranged renal function test but the difference was not significant. However significant difference was observed during follow up where 12 mothers in the aggressive group and 4 mothers in the expectant group were found to have deranged renal function test; p value being 0.039 (Table 2).

Table 2: Comparison of the Study of Renal Function Test between Aggressively & Expectantly Managed Groups

	Aggressive Management (n=56)		Expectant Management (n=44)		P Value
	Normal	Deranged	Normal	Deranged	
RFT status on Admission	**49**	**07**	**42**	**02**	**>0.05**
RFT status on follow up	**44**	**12**	**40**	**04**	**0.039***

P-value <0.05 (*significant)
P-value <0.01 (highly significant)**

During the study of platelet count it was observed that 11 mothers in the aggressive management group (19.64%) and 9 mothers in the expectant management group (20.45%) had thrombocytopenia though the difference was not statistically significant.
62 mothers had undergone caesarean section out of which 39 mothers were in the aggressive management group (69.64%) and 23 mothers were in the expectant management group (52.27%). The other 38 mothers had vaginal delivery. Frequency of caesarean section was more than the vaginal delivery in both the groups.

Babies born to the mothers of expectantly managed group had more birth weight than the babies born to the mothers of aggressively managed group; mean birth weight being 2.118±0.361 kg and 1.854±0.413 kg respectively. However, the duration of NICU admission was more in the babies born to aggressively managed mothers (6.38±2.03 days) than the babies born to expectantly managed mothers (4.41±2.54 days).

In this study 19 babies born to aggressively managed mothers and 8 babies born to expectantly managed mothers had APGAR score < 7 at 1 minute. This was a significant difference with p value being 0.039. Statistically significant difference was also found at 5 minute with 14 babies from aggressive management group and 5 babies from expectant management group had APGAR score < 7; p value being 0.042 (Table3).

Table 3: Comparison of APGAR score < 7

APGAR Score < 7	Aggressive Management (n=56)	Expectant Management (n=44)	P Value
At 1 min	19	08	0.039
At 5 min	14	05	0.042

P-value <0.05 (*significant)
P-value <0.01 (highly significant)**

Among the neonatal parameters statistically significant difference was found in Respiratory distress syndrome (27 vs 12), Early onset sepsis (<72 hrs) (9 vs 2), Neonatal death (9 vs 2) and Necrotising enterocolitis (7 vs 1) which were more in the babies from aggressive management group than the babies from expectant management group; p value being 0.016, 0.033, 0.033 & 0.033 respectively. IUFD/Still Born were more in aggressive group (n=03) than expectant group (n=1) but not significant (Table 4**)**.

Table 4: Comparison of Neonatal Outcomes

Neonatal Outcome	Aggressive Management (%)	Expectant Management (%)	P Value
RDS	27(48.21%)	12(27.27%)	**0.016***
Early onset Sepsis	09(16.07%)	02(4.55%)	**0.033***
IUFD/SB	03(5.36%)	01(2.27%)	>0.05
Neonatal death	09(16.07%)	02(4.55%)	**0.033***
NEC	07(12.5%)	01(2.27%)	**0.033***

P-value <0.05 (*significant)
P-value <0.01 (highly significant)**

Among the maternal outcomes only pulmonary edema, which was more in aggressive group (n=7) than expectant group (n=1), had statistically significant difference; p value =0.033. The frequency of Eclampsia (04 vs 03), Disseminated intravascular coagulation (03 vs 01), HELLP syndrome (05 vs 04), Cerebrovascular accident (04 vs 01) and maternal mortality (03 vs 01) were more in the mothers from aggressively managed

group than the expectantly managed group. Acute renal failure has similar frequency in both the groups. But Abruptio placentae was seen only in expectant group (n=2) though not significant(Table 5).

Table 5: Comparison of Maternal Outcomes

Maternal Outcomes	Aggressive Management (%)	Expectant Management (%)	p Value
Pulmonary Edema	07(12.5%)	01(2.27%)	**0.033***
Eclampsia	04(7.14%)	03(6.82%)	>0.05
ARF	02(3.57%)	02(4.55%)	>0.05
DIC	03(5.36%)	01(2.27%)	>0.05
Abruptio Placentae	00	02(4.55%)	>0.05
HELLP Syndrome	05(8.93%)	04(9.09%)	>0.05
CVA	04(7.14%)	01(2.27%)	>0.05
Mortality	03(5.36%)	01(2.27%)	>0.05

P-value <0.05 (*significant)
P-value <0.01 (highly significant)**

Mothers of the expectant management group had increased duration of hospital stay than the mothers of aggressive management group; mean days of hospital stay were 9.636±2.598 days and 4.786±2.006 days respectively. However, the admission to delivery interval was also more among the mothers of expectant group than the mothers of aggressive group; mean days of interval were 10.386±4.765 days and 0.645±0.265 days respectively.

V. DISCUSSION

Severe pre-eclampsia is a multifactorial condition that has a number of adverse effects affecting both the health status of mother and fetus. Various studies have demonstrated its effect on mother resulting in eclampsia, deranged liver and renal function status, decreased platelet count, pulmonary edema, acute renal failure, disseminated intravascular coagulation, abruption placentae, cerebrovascular accident, HELLP syndrome and finally maternal death. Similarly, low birth weight, low apgar score, neonatal sepsis, respiratory distress syndrome, increased NICU admission and increased number of IUFD /still birth have been mentioned as its poor impact on fetal or neonatal health in different literatures[1-15]. Ideal management of this grave condition remains a matter of controversy till now because of lack of adequate evidences.

The present prospective, observational study was conducted to determine the optimal management of patients with pre-eclampsia. A total of 100 singleton pregnant women were included in this study.

Most of the mothers belonged to the age group of 16 to 20 years in both expectant (40.91%) and aggressive (42.86%) groups. In this study majority of the mothers with preeclampsia were primi para (66%). Similar findings have been reported by Misra DP et al [16], they found that primiparas are more likely to develop preeclampsia. However, in another study Hall DR et al [17] reported that preeclampsia occurs more commonly in multiparas. Most of the mothers in the study were admitted between 31 to 33 weeks of gestation.

Deranged liver function test was found to be more but not statistically significant in the aggressively managed group during admission, whereas statistically significant difference was found during follow up; p value = 0.042. During renal function test analysis, it was found that deranged renal function test was more in the aggressive group than expectant group both during the admission and follow up. The difference was not statistically significant during admission but significant difference was observed during follow up, p value = 0.039.

Alteration of platelet count was almost similar in between the aggressive group (19.64%) and the expectant group (20.45%). Frequency of caesarean section was more than vaginal delivery in both the study groups. In the aggressively managed group caesarean section was done for 69.64% of the mothers. In a study from Iraq, Sarsam DS et al [18] reported similar rate of caesarean section for the aggressive management group.
Birth weight of the newborns were higher in the expectant management group (2.118±0.361 kg) than the aggressive management group (1.854± 0.413 kg), similar results have been reported by Sarsam DS et al [18] and Sibai BM et al [19]. Duration of NICU admission for the babies was less in the expectant management group than the aggressive management group (4.41± 2.54 vs 6.38±2.03 days). Magee LA et al [20], Sibai BM et al [19] and Sarsam DS et al [18] et al reported similar findings in their studies.

In this study statistically significant difference was found for APGAR score < 7 both at 1minute and at 5minute; p value being 0.039 and 0.042 respectively. More number of babies with APGAR score < 7 were in the aggressive management group both at 1 minute and at 5 minute. Similar findings have been reported by Odendall et al [21], Hall et al [17]and Sarsam DS et al [18].

Among the neonatal outcomes, occurrence of respiratory distress syndrome was significantly less in the expectant group (27.27%) than the aggressive group (48.21%); p value=0.016. Sibai BM et al [19], Odendall et al [21] and Sarsam DS et al. [18] et al reported similar findings in their studies. In this study the early onset sepsis rate and neonatal death rate are significantly less in the expectant management group, p value being 0.033 in both the outcomes. This finding is similar to that of Hall et al [17.] Frequency of IUFD/Still Born was more in the aggressive group (5.36% vs 2.27%) but not statistically significant. Occurrence of necrotizing enterocolitis was significantly more in the aggressively managed group [12.5% vs 2.27%; p value=0.033] which was at par with Sibai BM et al [19].

Among the maternal outcomes pulmonary edema was significantly less in the expectantly managed group than the aggressively managed group (2.27% vs 12.5%; p value=0.033). This finding was similar to that of Haddad B et al [22] and Sarsam DS et al [18]. Among others rate of Eclampsia (7.14% vs 6.82%), Acute renal failure (3.57% vs 4.55%) and disseminated intravascular coagulation (5.365 vs 2.27%) were similar between the aggressively managed and expectantly managed groups. There was no incidence of abruptio placentae in the aggressive management group but 2 mothers (4.55%) had abruptio placentae in the expectant management group. Similar rates have been reported by Haddad B et al [22] and Shear RM et al [23]. But Hall DRet al [17] reported much higher rate (20.2%) of abruption placentae in the expectant management. HELLP syndrome rate was similar in between the two groups (8.93% vs 9.09%). Similar rates were reported by Bombrys AE et al [24] and Vigil-De Gracia P et al [25] but rates reported by Shear RM et al [23] and Haddad B et al [22] are much higher. Cerebrovascular accident rate was more in the aggressive group (7.14%) than expectant group (2.27%) but the difference was not significant. There were three mortalities in the aggressively managed group against one in the expectantly managed group.

Duration of hospital stay of the mothers was more in the expectant management group (9.636±2.598 days) than the aggressive management group (4.786±2.006 days). Admission to delivery interval was 10.386±4.765 days in the expectantly managed group which was similar to the studies of Sarsam DS et al [18], Sibai BM et al [19] and Odendaal HJ et al [21]. They demonstrated significant prolongation of pregnancy of a mean of 9.2 days, two weeks and 7.1 days respectively in their studies.

The present study thus demonstrates that the expectant management had better maternal and fetal outcome than the aggressive management for severe preeclampsia before term.

VI. CONCLUSIONS

Maternal and fetal outcomes are better in the expectant management than the aggressive management for severe preeclampsia before term, so expectant management should be carried out in a selected group of mothers with severe preeclampsia before term with the aim to improve baby outcome without compromising the safety of the mothers and with careful monitoring.

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Corresponding Author: Priyankar Kanrar,
[2]MS G&O RMO cum Clinical Tutor, G&O BMCH Burdwan Medical College and Hospital, West Bengal, India.