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Research Article

Expectant Management of Severe Preeclampsia Remote from Term: A Hospital-Based Survey

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- Timing of delivery
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Abstract

Introduction: The management of severe preeclampsia remote from term is one of the most difficult challenges in obstetrics. Delivery at a very low gestational age increases the risk for adverse neonatal outcomes, and the attempt to prolong pregnancy in order to improve neonatal outcomes is suggested in selected cases. We aimed to assess the real feasibility and effectiveness of expectant management of early onset severe preeclampsia in a routine clinical setting.

Materials and methods: The study included 194 patients with severe preeclampsia between 24-34 weeks' gestation; the primary outcome measure was perinatal outcome according to management.

Results: Sixty-four women were delivered during or immediately after stabilization and 130 patients underwent expectant management. Median gestational age at onset was significantly lower in patients who underwent expectant management (29 vs. 31 weeks; $p<0.001$). Median gestational age at delivery in both groups was 31 weeks' gestation. Mean prolongation of pregnancy in the expectant management group was 7 days (range 4-19). The longest prolongation of pregnancy was recorded in patients with the lowest gestational age. The perinatal/neonatal outcomes between the two groups were similar. The most common indications for delivery in both groups were uncontrolled maternal hypertension and HELLP syndrome.

Conclusions: Expectant management of severe preeclampsia remote from term is feasible in a routine clinical setting, and it is effective particularly at the lowest gestational ages. The definition of the proper length of prolongation of pregnancy and the target gestational age to reach require further investigation.

ABBREVIATIONS

HELLP: Haemolysis Elevated Liver enzymes and Low Platelets syndrome; IQR: Inter Quartile Range

INTRODUCTION

Management of severe preeclampsia remote from term remains one of the most difficult challenges in obstetric practice. Although the mother would benefit from prompt delivery to avoid severe complications, prolongation of pregnancy may be useful to reduce neonatal complications resulting from preterm birth [1-4]. According to the evidence from two randomized trials [5,6], several observational studies [3], and a meta-analysis [7], international guidelines and expert committees suggest that expectant management of early onset severe preeclampsia is appropriate in selected cases and is associated with improved neonatal outcomes [2-4, 8-13]. On the contrary, a recent randomized trial did not demonstrate neonatal benefit with expectant management of severe preeclampsia from 28 to 34 weeks, and suggested that a conservative approach may increase the risk of abruption and small for gestational age newborns [14]. There are no randomized controlled trials on

expectant management of severe preeclampsia below 28 weeks gestation. The aim of this study was to assess the feasibility and effectiveness of expectant management of severe preeclampsia remote from term in a routine clinical setting and to analyze perinatal outcomes according to management.

MATERIALS AND METHODS

A retrospective cohort study was performed at the Department of Obstetrics and Gynecology, Sant'Anna University Hospital, Turin, Italy, which is a regional tertiary referral center. Data were obtained from the hospital's computerized obstetric database. The database includes information on maternal demographics, obstetric history, pregnancy complications, labor and delivery events, and short-term maternal and neonatal outcome.

Inclusion criteria were severe preeclampsia remote from term (24-34 weeks' gestation) and singleton pregnancy. Only patients who delivered at our hospital from January 2010 to December 2014 were included. Exclusion criteria were severe preeclampsia at less than 24 or beyond 34 weeks' gestation and twin pregnancy. Patients with uncertain diagnosis or incomplete clinical record were also excluded. A chart review of each patient was performed and data were extracted for maternal age, gravidity, parity, gestational age at delivery, mode of delivery, birth weight, admission to the neonatal intensive care unit, and maternal and neonatal complications.

The diagnosis of severe preeclampsia and HELLP syndrome (hemolysis, elevated liver enzymes and low platelet) was made according to the definition of the American College of Obstetricians and Gynecologists [11]. The following perinatal complications were recorded: fetal growth restriction, small for gestational age, severe respiratory distress syndrome, necrotizing enterocolitis, intra ventricular hemorrhage, perinatal death, and admission in the neonatal intensive care unit. The diagnosis of respiratory distress syndrome, necrotizing enterocolitis and intra ventricular hemorrhage was made according to the Vermont Oxford Network Manual of Operations [15]. Indications for delivery and short term maternal complications were also recorded. The study was approved during the meeting of the ethical review committee on June 10th, 2011, n. 27352/c 28.2..

Under the standardized protocol at our hospital, patients with severe preeclampsia remote from term should undergo clinical stabilization (i.e., control of hypertension and intravenous magnesium sulfate administration for 24 hours to prevent eclamptic seizures), and corticosteroids prophylaxis for fetal lung maturity) before delivery, except in emergencies such as severe placental abruption. MgSO4 is repeated during labor or cesarean section and for 24 hours after delivery. After stabilization is achieved, usually within 48 hours, an attempt to prolong pregnancy should be made whenever possible (expectant management), unless maternal or fetal conditions require prompt delivery. The choice of clinical management is left to the discretion of a senior obstetrician. All patients with severe preeclampsia included in the survey underwent clinical and laboratory examination at admission (symptoms of concern, complete blood cell count with platelet count, serum creatinine, liver enzymes, serum fibrinogen, prothrombin time, partial thrombin time, serum bilirubin, lactate dehydrogenase, urine collection for diuresis quantification and 24-hours proteinuria). Fetal condition was assessed by fetal heart rate monitoring and ultrasound to evaluate fetal growth and amniotic fluid volume. Fetal-placental Doppler ultrasound was performed in growth-restricted fetuses.

Continuous data were expressed as the median with inter quartile range as a measure of variability, and categorical variables were given as counts and percentages. Comparison between treatment groups was made using the Mann-Whitney U test for continuous variables and the Chi-square test for categorical variables. The effect of treatment on several neonatal outcome variables (respiratory distress syndrome, necrotizing enterocolitis, intra ventricular hemorrhage, fetal growth restriction, small for gestational age newborn, admission in the neonatal intensive care unit, and mortality) was evaluated by logistic regression models adjusting for maternal age, parity, and gestational age at the onset of preeclampsia and at delivery. Firth's correction was applied to reduce bias in the estimates due to the small number of events [16].All analyses were carried out using R version 2.15 [17].

RESULTS AND DISCUSSION

Over the 5-year study period, 521 patients were admitted to the hospital with the diagnosis of severe preeclampsia, 283 of which had late onset preeclampsia (beyond 34 weeks' gestation) and underwent delivery immediately after stabilization. Four cases of severe preeclampsia occurred at less than 24 weeks' gestation and underwent termination of pregnancy. Twenty-eight of the 222cases of severe preeclampsia remote from term (24-34 weeks' gestation) were twin pregnancies and were not included in the survey to avoid perinatal confounding factors due to multiples. 12 patients were excluded because of uncertain diagnosis or incomplete clinical record. In all, 194 women with severe preeclampsia remote from term and singleton pregnancy were included in the survey. In 38 patients (19.6%) preeclampsia occurred between 24 and 28 completed weeks of pregnancy. The demographic and clinical characteristics of the patients according to management are reported in (Table 1).

Sixty-four patients (32.9%) underwent prompt delivery during or immediately after stabilization. Median gestational age at onset (and delivery) was 31 weeks (interquartile range [IQR] 29-32 weeks; range 24-33).Ten patients were at less than 28 weeks' gestation. Admission to delivery time was 0-12 hours in 21patients (32.8%), 12-24 hours in 25 (39.0%), and 24-48 hours in 18 (28.2%).The remaining 130 patients (67.1%) underwent expectant management. Twenty-eight patients were at less than 28 weeks' gestation. Median gestational age at onset was 29 weeks (IQR 27-32 weeks; range 24-33), significantly lower than in patients who underwent prompt delivery ($p<0.001$). Median gestational age at delivery was 31 weeks (IQR 29-33 weeks; range 25-33). Median prolongation of pregnancy after stabilization was 7 days (IQR of prolongation 4-14 days; range: 4-19). A longer prolongation of pregnancy (range 13-19 days) was recorded in patients with the lowest gestational age at onset (24-27 completed weeks).The blood pressure levels of the two groups at admission did not differ significantly (mean + SD: 158/99 + 13/8 mmHg in the prompt delivery group; 156/98 + 14/9 mmHg in the expectant management group).

Table 1: Demographic and clinical characteristics of the patients included in the study, stratified by prompt delivery or expectant management. The median and I quartile-III quartile for continuous variables are reported.

Characteristics of the patients	Prompt delivery N=64	Expectant management N=130	P value
Age, years	33.5; 30-37	35.0; 30-38	0.271
White Caucasian, %; N	93.7%; 60	96.1%; 125	0.545
Nulliparity, %; N	64.0%; 41	71.5%; 93	0.745
Smoking, %; N	3.1%; 2	9.2%; 12	0.122
Gestational age at onset, weeks	31; 29-32	29; 27-32	<0.001
Gestational age at delivery, weeks	31; 29-32	31; 29-33	0.618
Birth weight, grams	1400; 1032-1760	1327; 1010-1629	0.515
NICU admission, %; N	70.3%; 45	71.5%; 93	0.745

P-value was calculated using Chi-square test or Fisher's exact test (when low expected frequency was < 5) for categorical variables, and Mann-Whitney test for continuous variables. NICU: neonatal intensive care unit.

Table 2 presents the perinatal/neonatal outcomes according to management. No significant differences were observed between the two groups, after adjusting for maternal age, parity, and gestational age at onset of preeclampsia and at delivery. Twenty-two patients in the prompt delivery group were delivered before completion of the corticosteroid course for fetal lung maturity (i.e. none or only one dose of beta methasone), and the incidence of severe neonatal respiratory distress syndrome was 31.8% (7/22), p=0.037 versus 9.5% (4/42) of patients who completed the corticosteroid course.

Two intrauterine deaths were recorded, one in each management group, both involving severely growth restricted fetuses at less than 26 weeks' gestation. Six neonatal deaths occurred (one in the prompt delivery, five in the expectant management group); all were in patients who were delivered for severe HELLP syndrome at less than 27 weeks' gestation.

Table 3 lists the indications for delivery according to management, as reported on the clinical records. Composite indications (e.g., maternal and fetal indications) were present in some cases. Maternal indications were significantly more frequent than fetal indications in both groups (p < 0.001 in each group).

The most common maternal indications for delivery in both groups were: uncontrolled hypertension (persistent or recurrent severe hypertension despite treatment), HELLP syndrome, significant renal dysfunction (persistent oliguria, increased creatinine), and persistent warning symptoms (symptoms of impending eclampsia such as severe headache, epigastric pain, hyper reflexia, cerebral and visual symptoms). The HELLP syndrome was overt at admission in nine patients and developed during stabilization in three patients in the prompt delivery group. Of the two patients with eclampsia in the prompt delivery group, one case of eclampsia occurred at home before admission and the other during stabilization despite magnesium sulfate therapy. Pulmonary edema indicated delivery in two patients (one in each group).

No significant differences in fetal indications for delivery were observed between the two groups.

In the 46 patients who underwent prompt delivery during stabilization within 24 hours of admission, maternal indications for delivery (33/46, 71.7%) were significantly (p< 0.001) more frequent than fetal indications (13/46, 28.3%) (Table 4). The most common indications were uncontrolled hypertension and HELLP syndrome.

Two cases of HELLP syndrome and one case of pulmonary edema developed after delivery in each treatment group. Transient acute renal failure occurred after delivery in one patient in the prompt delivery group. Post-partum hemorrhage requiring blood transfusion occurred in two patients in the prompt delivery group and in three patients in the expectant management group. Two cases of placental abruption occurred in the prompt delivery group during induction of labor (one case with severe HELLP syndrome and one with intrauterine fetal death). No maternal deaths were recorded.

International guidelines, randomized trials, and observational studies on the management of preeclampsia suggest that expectant management of selected cases of early onset severe preeclampsia (<34 weeks' gestation) can improve neonatal outcomes [2-7,11]. The criteria for patient selection and the indications for delivery are clearly defined [4,11,12]; however, clinicians often face a multifaceted situation, and in the clinical practice the decision of prolonging pregnancy may be very difficult and controversial.

One weakness of our study is its retrospective design; nonetheless, it reflects real clinical practice in a hospital setting where a specific protocol for the management of severe preeclampsia remote from term based on international guidelines has long been in place. In line with guidelines indications, our results suggest that two-thirds of patients with severe preeclampsia at 24-34 weeks' gestation can undergo expectant management. As expected the median gestational age at onset was significantly lower in the expectant management group. It is reasonable that the efforts to prolong pregnancy were greater in the patients at very low gestational age at onset. Not surprisingly, a longer prolongation of pregnancy was achieved in patients with the lowest gestational age at onset (24-27 completed weeks). Nonetheless, randomized trials on type of management of severe

Table 2: Perinatal/neonatal outcomes according to management.

Outcomes	Prompt delivery N=64	Expectant Management N=130	P-value	Adj OR	95%CI
RDS	17.1%;n.11	23.8%;n.31	0.382	0.48	0.17-1.32
IVH	3.1%;n.2	6.1%;n.8	0.581	1.73	0.46-9.30
SGA	3.1%;n.2	7.7%;n.10	0.353	0.38	0.08-1.82
Neonatal sepsis	3.1%;n.2	12.3%;n.16	0.070	0.24	0.05-1.08
Perinatal Death	3.1%;n.2	4.6%;n.6	0.924	1.84	0.36-18.37

P-value was calculated using Chi-square test or Fisher's exact test (when a low expected frequency was < 5) for categorical variables, and Mann-Whitney test for continuous variables. Odds ratios (OR) were adjusted (Adj) for maternal age, parity, gestational age at onset of preeclampsia, and gestational age at delivery. CI: confidence interval. RDS: respiratory distress syndrome.
IVH: Intra Ventricular Hemorrhage (3rd-4th degree). SGA: small for gestational age.

Table 3: Maternal and fetal indications for delivery in the two groups of subjects were according to the management. Composite indications were reported on the clinical record in some cases.

Indications	Prompt delivery N=64	Expectant management N=130	P value
Maternal indications	**89.1%; n.57**	**77.6%;n.101**	**0.086**
Uncontrolled hypertension	17.2%;n.11	21.5%;n.28	0.605
HELLP syndrome	18.7%;n.12	10.7%;n.14	0.194
Warning symptoms	25.0%;n.16	10.0%;n.13	0.018
Persistent oliguria	17.2%;n.11	6.1%;n.8	0.032
Eclampsia	3.1%;n.2	0	n.a.
Low platelet count	7.8%;n.5	7.7%;n.10	0.790
High liver enzymes	6.2%;n.4	5.3%;n.7	0.932
Hemolysis	0	2.3%;n.3	n.a.
Increased creatinine	7.8%;n.5	0.8%;n.1	0.026
Pulmonary edema	1.6%;n.1	0.8%;n.1	0.807
Fetal indications	**21.8%;n.14**	**34.6%;n.45**	**0.099**
Abnormal FHR	12.5%;n.8	14.6%;n.19	0.861
Abnormal UA Doppler	9.3%;n.6	19.2%;n.25	0.122
FGR< 5th centile	9.3%;n.6	6.9%;n.9	0.754

P value was calculated by Chi-square test or Fisher's exact test (when low expected frequencies were < 5%). Warning symptoms (at least one): headache, visual or cerebral disturbances, hyper reflexia, epigastric pain. N.a.: not applicable. FHR: fetal heart rate. UA: umbilical artery. FGR: fetal growth restriction.

Table 4: Maternal and fetal indications for delivery in patients of prompt delivery group who underwent immediate delivery (within 24 hours from admission) before completion of stabilization and of corticosteroids course (N=46).

Maternal indications	N=33*
Uncontrolled hypertension	36.4%; n.12
HELLP syndrome	27.2%; n.9
Warning symptoms	18.2%;n.6
Eclampsia	3.0%;n.1
Increased creatinine/oliguria	6.1%;n.2
Pulmonary edema	3.0%;n.1
Fetal indications	**N=13**
Abnormal FHR	46.1%; n.6
Abnormal UA Doppler	23.1%;n.3
FGR < 5th centile	23.1%;n.3
Intrauterine fetal death	7.7%;n.1

*: $p < 0.001$ vs. fetal indications
Warning symptoms (at least one): headache, visual or cerebral disturbances, hyper reflexia, epigastric pain. FHR: fetal heart rate. UA: umbilical artery. FGR: fetal growth restriction.

preeclampsia at less than 28 weeks' gestation are still lacking. The median gestational age at delivery in both groups was the same, 31 weeks' gestation, which means that delivery was necessary and performed in most patients at around 31 weeks.

We did not observe significant differences in perinatal outcomes between the two groups, even after adjusting for gestational age at onset and at delivery. Since the gestational age at onset was lower in the expectant management group (29 weeks vs 31 weeks in the prompt delivery group), and the longest prolongation of pregnancy was achieved in patients with the lowest gestational age at onset (13-19 days in patients at less than 28 weeks), the finding of similar perinatal outcomes in the two groups may suggest that expectant management effectively improves outcomes. This result is in agreement with those reported by Odendaal et al. [5], and Sibai et al. [6], but it contrasts those observed by Vigil-De Gracia et al. [13], and Suzuki et al.[18]. Although our study covered a wider range of gestational age at onset (24-34 weeks) than the randomized studies mentioned above (28-33 weeks) [5,6,13], the incidence of the most severe neonatal complications according to treatment was similar. The

most common complication was severe respiratory distress syndrome. A very low frequency of other adverse outcomes (necrotizing enterocolitis, intra ventricular hemorrhage, sepsis, and newborns small for gestational age) was observed. The reasons for the higher, although it is not significantly, incidence of sepsis that we observed in the newborns of the expectant management group is unknown. Corticosteroids prophylaxis seems to be the major determinant factor in preventing adverse neonatal outcomes. In our series, 22 patients in the prompt delivery group were delivered before completion of the corticosteroid course and the incidence of severe neonatal respiratory distress syndrome was three times greater than in patients who completed the course.

The indications for delivery in both groups were similar to those reported in three randomized trials [5,6,13] and two observational studies [3,18], and were mainly maternal. The most common indications were uncontrolled hypertension, HELLP syndrome, and warning symptoms (severe headache, epigastric pain, hyper reflexia, cerebral and visual disturbances). Uncontrolled hypertension was the indication for delivery in 20% of cases, with no significant difference between groups according to management. In our series, the HELLP syndrome indicated delivery in 13% of cases, with no significant difference between the two groups. The most severe maternal complications (acute pulmonary edema, acute renal failure, post-partum hemorrhage, and placental abruption) occurred in patients with the HELLP syndrome. Moreover, 6 neonatal deaths occurred in severely preterm newborns (<27 weeks' gestation) from mothers with the HELLP syndrome. These data indicate that a conservative approach for the HELLP syndrome is still impossible. International guidelines and published evidence suggest that women with the HELLP syndrome should not be managed expectantly because of the high risk of maternal and perinatal complications [3,4,9,14]. Corticosteroids may improve maternal platelet counts and may be useful after delivery to accelerate recovery, but a recent meta-analysis found no evidence of improvements in maternal mortality, severe maternal morbidities, or perinatal deaths after corticosteroid treatment [19].

Persistent warning symptoms indicated delivery in 25% of the patients during stabilization and in 10% of patients during expectant management. This probably reflects the fear of impending life-threatening complications such as eclampsia and the HELLP syndrome. For the same reason, isolated low platelet count, elevated liver enzymes or signs of hemolysis alone indicated delivery in 9 cases of prompt delivery and in 20 cases of expectant management. It is questionable whether isolated features of the HELLP syndrome require delivery; however, they may be signs of the impending development of the HELLP syndrome. Furthermore, the risk of surgical complications in the setting of isolated thrombocytopenia not responding to corticosteroids should be considered, and decreasing low platelet count may be properly regarded as an indication for delivery [4,12].

CONCLUSION

In conclusion, our data suggest that expectant management of selected cases of early onset severe preeclampsia is feasible in a routine clinical setting, and it is effective particularly at the lowest gestational age. The proper length of prolongation of pregnancy and the target gestational age to reach are still under investigation, and randomized trials on preeclamptic patients at less than 28 weeks' gestation are needed. Effective control of blood pressure and conservative treatment of HELLP syndrome remain two major areas of investigation and management improvement.

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