Original Research Article

Postpartum $MgSO_4$ prophylaxis regime (8 hours) vs traditional postpartum $MgSO_4$ prophylaxis regime (24 hours) in pre-eclampsia patients: A randomised control trial study

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Abstract

Background: Preeclampsia is a common complication during pregnancy and is also a cause of 10%–15% of cases of maternal morbidity and mortality, such as those involving cardiovascular and cerebrovascular diseases, liver and kidney failure, placental abruption, disseminated intravascular coagulation, and hemolysis, elevated liver enzyme levels, and low platelet levels (HELLP) syndrome. **Methods:** It was randomised control trial study. Pregnant Patients admitted in the Department of Obstetrics and Gynaecology at Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, between March 2019 to April 2020 was included in the study. Total 96Patients previously diagnosed and on treatment was also included. **Results:** Difference of mean PP Uric Acid in two groups was not statistically significant (p=0.034). PP Creatinine in two groups was not statistically significant (p=0.476).Distribution between MgSO4 toxicity in two groups was not statistically significant (p=0.558). Hospital stay in two groups was statistically significant (p Value - 0.04). **Conclusion**: The study therefore concludes that the use of short duration postpartum MgSO4 therapy for 8 hours instead of 24 hours with continued hourly maternal monitoring of vital signs and symptoms till 24 hours may be more reasonable recommendation. However, multicentric placebo controlled randomized trials in a larger population is needed to recommend it universally.

Key Words: pre-eclampsia, PP Uric Acid, PP Creatinine, MgSO4 toxicity,

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INTRODUCTION

The global incidence of hypertensive disorders in pregnant women during 2002–2012 was 4.6%, a figure that varied from 2.7%–8.2% by region,[1] and the worldwide incidence rate of preeclampsia was 2.16%.[2] These numbers vary according to differences in population characteristics, definitions, and criteria of diagnosis. In 2013, The American College of Obstetricians and Gynecologists (ACOG) changed the standard diagnostic criteria and definitions of preeclampsia with or without severe features.[3] These changes in criteria may result in changes to the incidence rates, perinatal outcomes, and magnitude of difference between preeclampsia with or without severe features. Preeclampsia is defined as the presence of (1) a systolic blood pressure (SBP) greater than or equal to 140 mm Hg or a diastolic blood pressure (DBP) greater than or equal to 90 mm Hg or higher, on two occasions at least 4 hours apart in a previously normotensive patient, OR (2)

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an SBP greater than or equal to 160 mm Hg or a DBP greater than or equal to 110 mm Hg or higher [4] In addition to the blood pressure criteria, proteinuria of greater than or equal to 0.3 grams in a 24-hour urine specimen, a protein (mg/dL)/creatinine (mg/dL) ratio of 0.3 or higher, or a urine dipstick protein of 1+ is required to diagnose preeclampsia. [4]

Preeclampsia with severe features is defined as the presence of one of the following symptoms or signs in the presence of preeclampsia [8]:

- SBP of 160 mm Hg or higher or DBP of 110 mm Hg or higher, on two occasions at least 4 hours apart while the patient is on bed rest.
- Impaired hepatic function as indicated by abnormally elevated blood concentrations of liver enzymes, severe persistent upper quadrant or epigastric pain that does not respond to pharmacotherapy and is not accounted for by alternative diagnoses, or both.
- Progressive renal insufficiency (serum creatinine concentration >1.1 mg/dL or a doubling of the serum creatinine concentration in the absence of other renal disease)
- New onset cerebral or visual disturbances
- Pulmonary edema
- Thrombocytopenia (platelet count < 100,000/µL)

In a patient with new-onset hypertension without proteinuria, the new onset of any of the following is diagnostic of preeclampsia:

- Platelet count below 100,000/µL
- Serum creatinine level above 1.1 mg/dL or doubling of serum creatinine in the absence of other renal disease
- Liver transaminase levels at least twice the normal concentrations
- Pulmonary edema
- Cerebral or visual symptoms

Eclampsia is defined as seizures that cannot be attributable to other causes in a woman with preeclampsia. HELLP syndrome (hemolysis, elevated liver enzyme, low platelets) may complicate severe preeclampsia.

MATERIALS AND METHODS

Pregnant Patients admitted in the Department of Obstetrics and Gynaecology at Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, between March 2019 to April 2020 was included in the study. Total 96Patients previously diagnosed and on treatment was also included. It was randomised control trial study.

Pregnant women attending ANC and those are admitted in Labor Room or ward with severe pre-eclampsia and Eclampsia.

Inclusion criteria:

- Antepartum, intra partum, or postpartum severe pre-eclampsia with a blood pressure of 160/110 mm Hg or higher after 20 weeks of pregnancy; proteinuria with a dipstick value of 2 +or higher;
- Antepartum, intrapartum, postpartum eclampsia
- And seizures not attributed to other causes among women with PIH

Methodology:

The study was approved by the Ethical Committee of the institution, and patients were provided informed consent before the administration of MgSO4. Patients with eclampsia who were admitted during the study period was randomly assigned to either the **study group (8 hours MgSO4)** or the **control group (24 hours MgSO4)**. Participants were not told in which group they have been assigned to, but because the groups receive treatments for different lengths of time, full masking was not be possible. Investigators and data analysts were not masked to group assignment. All women were examined at the time of admission and a detail history was taken. Complete blood counts, coagulograms, liver and renal function tests, and urine protein measurements was performed. Women in the study group was given a loading dose of 4 g of intravenous MgSO4 (20%), followed by a maintenance dose of 5g MgSO4 (50%) 4 hourly deep intramuscularly in alternate buttocks for 8 hours after the last fit or delivery (whichever was later). Those in the control group was given a loading dose of 4 g of intravenous MgSO4(20%), followed by a maintenance dose 5g MgSO4 (50%) 4 hourly deep intramuscularly in alternate buttocks for 24 hours after the last fit or delivery. All women were monitored for the entire duration of MgSO4 infusion by trained obstetricians and gynecologists for blood pressure, patellar reflexes, respiratory rate, urine output, and reoccurrence of convulsions. In the case of MgSO4 toxic effects, the plan of management was stopped and further infusions of MgSO4, to inject 1 g of calcium gluconate (10 mL of 10% solution) intravenously, and to switch the therapy to another anticonvulsant. These patients was considered to have treatment failure. After completion of the MgSO4 infusion, patients was monitored every 4 hours until normalization of blood pressure, and then every 12 hours until discharge. Labetalol was used as an antihypertensive drug as per the management protocol of the study institute. The participants was induced, allowed to undergo spontaneous labor, or undergo cesarean delivery depending on the obstetric indication and the patient's general condition. The primary outcome was recurrent convulsions once the MgSO4 therapy was completed. If a repeat convulsion occurs before completion of therapy, the patient was infused with a 2 g loading dose of MgSO4, and women in the study group was switched to a maintenance

dose of MgSO4 for 24 hours. If a second convulsion was observed during the therapy, the treatment was switched from MgSO4 to phenytoin and consider as an MgSO4 failure. Secondary outcomes was related to patient recovery, which was analyzed in terms of total dose of MgSO4 given, duration of hospital stay any deterioration of maternal renal, liver and coagulation system and duration of Foley catheterization. The patients were followed up until discharge from hospital. The study data was analyzed by SPSS software. The study and control groups was compared by student t test and $\chi 2$ test as appropriate and P value less than 0.05 was considered significant.

Intervention Group A – was receiving MgSO4 for 24 hrs postpartum.

Intervention Group B – was receiving MgSO4 for 8 hrs postpartum.

RESULTS

Table: 1: Distribution of mean Age among two groups

Age Distribution	Group	Number	Mean	SD	p-value
	Group-A	46	25.087	±4.35	0.804
	Group-B	52	23.711	±4.08	

Difference of mean age in two groups was not statistically significant. There was no statistically significant difference in age distribution between the groups. Thus age matched patients selected in two groups Numerical variables between groups compared by t-test; (p=0.804).

Table 2: Distribution of mean and SD value of Admission SBP and DBP among two groups

Distribution of Admission SBP	Group	Number	Mean	SD	p-value
	Group-A	46	168.065	±10.64	0.375
	Group-B	52	168.269	±10.25	
Distribution of Admission DBP	Group-A	46	119.173	±11.36	0.876
	Group-B	52	116.423	±11.96	

Difference of mean SBP and DBP at admission in two groups was not statistically significant p value was p=0.375 and 0.876 respectively.

Table 3: Distribution of Mean and SD Value of APand PP Uric Acid among two groups

AP Uric Acid	Group	Number	Mean	SD	p-value
	Group-A	46	5.571	±0.75	**0.776**
	Group-B	52	5.603	±0.71	
PP Uric Acid	Group-A	46	5.813	±0.84	0.034
	Group-B	52	5.686	±0.51	

Table 4: 3B2Distribution of Mean and SD Value of AP and PP Creatinine among two groups

AP Creatinine	Group	Number	Mean	SD	p-value
	Group-A	46	0.663	±0.13	**0.505**
	Group-B	52	0.646	±0.12	
PP Creatinine	Group-A	46	0.750	±0.21	**0.476**
	Group-B	52	0.732	±0.17	

Table 5: Distribution of Delivery outcome in two groups

Delivery outcome	Group-A		Group- B		Total	
	No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage
LSCS	42	91.3	44	84.6	86	87.7
VD	04	8.7	08	15.4	12	12.2
Total	46	100	52	100	98	98

Chi-square value: 1.016; p-value: 0.31

Table 6: Distribution of MgSO4 toxicity in two groups

MgSO4 toxicity	Group-A		Group- B		Total	
	No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage
Nil	43	93.5	50	96.1	93	94.9
Oliguria	02	4.3	02	3.8	04	4.1
Resp. Depression	01	2.2	00	00	01	1.0
Total	**46**	**100**	**52**	**100**	**98**	**100**

Chi-square value: 1.163; p-value: 0.558

Distribution between MgSO4 toxicity in two groups was not statistically significant (p=0.558).

Table 7: Distribution of NICU Admission in two groups

NICU Admission	Group-A		Group- B		Total	
	No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage
Nil	41	89.1	47	90.4	88	89.8
Yes	05	10.9	05	9.6	10	10.2
Total	56	100	52	100	98	100

Chi-square value: 0.419 ; p-value: 0.837

Distribution between NICU Admission in two groups was not statistically significant (p=0.837).

Table 8: Distribution of Mean and SD Value of Hospital stay among two groups

Hospital stay	Group	Number	Mean	SD	p-value
	Group-A	46	5.869	±1.08	0.04
	Group-B	52	5.346	±1.42	

Difference of mean Hospital stay in two groups was statistically significant (p Value - 0.04).

Table 9: Distribution of Birth asphyxia in two groups

Birth asphyxia	Group-A		Group- B		Total	
	No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage
No	44	95.7	51	98.1	95	96.9
Yes	02	4.3	01	1.9	03	3.1
Total	46	100	52	98	98	100

Chi-square value: 0.483 ; p-value: 0.486

Distribution between Birth asphyxia in two groups was not statistically significant (p=0.486).

DISCUSSION

In modern obstetrics treatment of choice is mgso4 in severe pre eclampsia and eclampsia and several regimen are used like pict. Traditionally mgso4 (pict) is given for 24 hours following delivery or last fit whichever is later on. Recently 12 hours mgso4 therapy comes in attention because of their low toxicity which has been proved by different clinical studies. In woman with severe pre eclampsia and eclampsia shorter (8 hours) MgSO4 therapy was associated with lesser duration of drug exposure and toxicity with clinical outcomes were comparable to the control group who received 24 hours MgSO4 therapy. There are several studies found in the literature who has compared shorter duration of 8 hours MgSO4 therapy versus 24 hours MgSO4 therapy with equal efficacy with lesser toxicity in 8 hours MgSO4 therapy. In my study I had taken total 98 cases of severe pre eclampsia and eclampsia among them 46 cases for 24 hours MgSO4 therapy (GROUP-A) and 52 cases for 8 hours MgSO4 therapy (GROUP-B) who had fulfil the eligibility criteria. Distribution of mean age of Group-A is 25.08 yrs vs Group-B 23.711 yrs and P value is 0.804 which is statistically non significance. Distribution of mean BMI of Group-A is 23.913 kg/m. sq vs Group-B 24.538 and P value is 0.257 which is statistically non significance. Distribution of mean gestational age of Group A -37.804 weeks vs Group B 38.115 weeks and the P value is 0.728 which is not reach the level of statistically significance. Distribution of mean SBP of Group A -168.065 vs Group B 168.269 and the P value is 0.375 which has got no importance without reaching statistically significance. Distribution of mean DBP of Group A -119.173 vs Group B 116.423 and the P value is 0.876 which has got no importance without reaching statistically significance. All patient had proteinuria. Distribution of mean uric acid of Group-A is 5.571 mg/dl vs Group-B 5.603 and P value is 0.776 which is statistically non significance. Distribution of mean Creatinine level of Group-A is 0.663 vs Group-B 0.646 and P value is 0.505 which is statistically non significance. Distribution of delivery outcome LSCS of Group A was 42 and Group B 44, Vaginal Group A 4 and Group B 8 and the P value is 0.31 which is not reach the level of statistically significance. Distribution of postpartum uric acid of Group-A is 5.813 vs Group-B 5.686 and P value is 0.03 which is statistically significance. Distribution of postpartum Serum Creatinine of Group A 0.750 mg/dl vs Group B 0.732 mg/dl and the P value is 0.476 which is not reach the level of statistically significance. Distribution of MgSO4 toxicity of Group A 4 vs Group B 2 and the P value is 0.558 which has got no importance without reaching statistically significance. In MgSO4 toxicity distribution was Oliguria 2 case in Group B, Oliguria with 2 case in Group A, Oliguria with respiratory depression in Group A 1 and Group B 0, Respiratory depression in Group A and P value is 0.558 which is statistically non significance. Distribution of Apgar score after 5 minutes of birth is 0 in Group A 1, 4-1,6-3, 8-41 case in Group A and Group B, 4-2, 6-3, 8-47. Distribution of mean hospital stay of mother of Group A -5.869 days vs Group B 5.346 and the P value is < 0.04

which has got importance with reaching statistically significance. Distribution of birth asphyxia of Group A -2 vs Group B 1 and the P value is 0.486 which has got no importance without reaching statistically significance. According to the results of randomized clinical studies, receiving Mg leads to an eclampsia frequency of 0.6%, with a range from 0.3 to 0.9%.[5] That is, in patients with severe pre-eclampsia in hospitals, receiving Mg represents a seizure risk ranging from 0.3 to 0.9%. All the studies reviewed administered Mg beginning at diagnosis in the antepartum period and maintained treatment for 24 h postpartum; most studies start Mg during labor. Our study shows that after starting infusion and receiving treatment with Mg (4 g on average) for less than 8 h prior to birth, continuing the Mg for 24 h postpartum is no better than just maintaining it for 6 h postpartum. Interestingly, the current study does not report any cases of eclampsia, contrary to expectations. In patients treated with Mg ante- and postpartum, we expected at least two cases of eclampsia among 280 cases of severe pre-eclampsia, according to the results of the MAGPIE study.[6] Approximately 80% of cases of eclampsia occur during pregnancy or intrapartum, and only an average of 20% of cases occur postpartum.[7] This timing means that our main strategy for avoiding eclampsia should focus on the pregnant woman and the moment of birth. Therefore, delivery of the fetus is the main strategy to treat eclampsia.[8] The two known strategies for preventing eclampsia are pregnancy discontinuation and the use of Mg.[9] Thus it seems that if we have used the minimum effective dose of Mg and we interrupt the pregnancy, then the administration of Mg postpartum is not justified. In addition, any postpartum strategy would be focused on preventing only approximately 20% of cases of eclampsia. We do not know the effective minimum dose of Mg; however, our study shows that a 4 g infusion plus an average of 4 g before birth and 6 g postpartum (14 g total) is sufficient to avoid eclampsia; 32 g of Mg was used in the control group.

CONCLUSION

In the light of above observations the present study indicates that the MgSO4 therapy can be safely reduced from 24 hours to shorter duration of 8 hours. In has been found that 8 hours MgSO4 have almost same efficacy compare to 24 hours MgSO4 therapy. Moreover 8 hours MgSO4 therapy has less Magnesium toxicity like oliguria, respiratory depression, diminish knee jerk as compared to 24 hours MgSO4 therapy. Again hospital stay is obviously less in 8 hours MgSO4 therapy. Although frequency of postpartum eclamptic fits are marginally more in 8 hours MgSO4 therapy as compared to 24 hours MgSO4 therapy but the value is not statistically significant. The study therefore concludes that the use of short duration postpartum MgSO4 therapy for 8 hours instead of 24 hours with continued hourly maternal monitoring of vital signs and symptoms till 24 hours may be more reasonable recommendation. However, multicentric placebo controlled randomized trials in a larger population is needed to recommend it universally.

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