

Original Research

Assessment of incidence of preeclampsia among pregnant women reporting to tertiary hospital in Nepal and evaluation of safety of alternative method to standard Pritchard's regime for prophylaxis of eclampsia

¹Rajkishor Pandit, ²Ruby Singh, ³Brijmohan Kumar Rajak

¹Senior Consultant and Head of Department, Department of Obstetric and Gynecology, MIHS, Provincial Hospital, Janakpur, Madhesh Pradesh, Nepal;

^{2,3}Consultant Obstetrician and Gynecologist, MIHS, Provincial Hospital, Janakpur, Madhesh Pradesh, Nepal

ABSTRACT:

Introduction: Pregnancy is a state of hypomagnesemia. Thus, it is obvious that Mg²⁺ depletion may be one of the aetiologies for preeclampsia syndrome. Hence, the present study was undertaken to find the incidence of preeclampsia among pregnant women reporting to tertiary hospital in Nepal and evaluation of safety of alternative method to standard Pritchard's regime for prophylaxis of eclampsia. **Materials and Method:** There were total 60 cases of severe preeclampsia fulfilling inclusion criteria, out of them 30 cases (group A) received only single loading dose of magnesium sulphate and other 30 cases (group B) received 24hour standard Pritchard's regime of magnesium sulphate. In group A, only loading dose magnesium sulphate was given. In group B, complete standard Pritchard regime was given, for 24 hours. Primary outcome measure was occurrence of eclamptic seizure(s) after enrollment in the study. Differences between categorical variables were analyzed using chi-square test. P value was considered significant if it was <0.05. : During the study period of six months duration, there were total 12043 obstetrics admission. Among all, patients with gestational hypertension were 796 (6.6%), preeclampsia 196 (1.6%), and severe preeclampsia 60(0.5%). The study showed that the loading dose of magnesium sulphate was comparable to standard regime for prophylaxis of eclampsia as there was no statistically significant difference w.r.to parity, mode of delivery and side effects between loading dose group and standard dose. **Conclusion:** This study concludes that the use of single loading dose of magnesium sulphate is as effective as standard Pritchard's regime for prophylaxis of eclampsia as there was no convulsion reported in either group. Therefore, the study found that the loading dose of magnesium sulphate was comparable to standard regime for prophylaxis of eclampsia.

Keywords: Gestational hypertension; Magnesium sulphate; Preeclampsia; Pritchard's regime

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Corresponding author: Rajkishor Pandit, Senior Consultant and Head of Department, Department of Obstetric and Gynecology, MIHS, Provincial Hospital, Janakpur, Madhesh Pradesh, Nepal

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INTRODUCTION

Hypertensive disorders in pregnancy are among the common medical complications of pregnancy and are among the three leading causes of maternal mortality worldwide. The spectrum of these disorders ranges from chronic hypertension, gestational hypertension, preeclampsia, and superimposed preeclampsia in the setting of chronic hypertension.¹Preeclampsia is a pregnancy specific multi organ disease process characterized by de novo development of hypertension and proteinuria after 20 weeks of

gestation. Preeclampsia complicates 2-8% of pregnancies.²

Interventions targeting maternal deaths need to address pre-eclampsia and eclampsia as it is the second leading direct cause of maternal mortality, second only to haemorrhage. Also, these conditions can result in major morbidity and residual complications which affect the quality of life of the woman and her family and significant economic burden.³

Pregnancy is a state of hypomagnesemia. The total and ionized serum magnesium levels are not only

significantly lower compared to non-pregnant women, but also tend to fall with advancing gestation, with further decrease in those who develop PES. Mg²⁺ affects contractility and tone of blood vessels thereby regulating Blood Pressure (BP). So, it is obvious that Mg²⁺ depletion may be one of the aetiologies for PES.⁴ Hence, the present study was undertaken to find the incidence of preeclampsia among pregnant women reporting to tertiary hospital in Nepal and evaluation of safety of alternative method to standard Pritchard's regime for prophylaxis of eclampsia.

MATERIAL AND METHODS

The present hospital based, cross-sectional comparative study was conducted among 60 patients with severe pre-eclampsia either in labor or those requiring delivery admitted in the Department of Obstetrics and Gynaecology at Paropakar Maternity and Women's Hospital, Thapathali, Kathmandu, a tertiary centre of the country. The study was carried over a period of 6 months.

The study population consisted of singleton pregnancy of 28 weeks to 42 weeks of gestation with severe preeclampsia. The permission was taken from ethical committee before initiation of study.

Inclusion criteria comprised of patients with systolic blood pressure ≥ 160 mm Hg and diastolic ≥ 110 mmHg with proteinuria (≥ 300 mg/dl or $\geq 2+$ on dipstick), systolic blood pressure ≥ 140 mm Hg and diastolic blood pressure ≥ 90 mm Hg with at least one of the following

- a) proteinuria ($\geq 2+$ on dipstick or ≥ 5 g/24 hour urine collection)
- b) persistent frontal headache
- c) visual or cerebral disturbances,
- d) epigustre or right upper quadrant pain.
- e) HELLP syndrome - Hemolysis, elevated liver enzymes (LDH ≥ 600 U/l, AST ≥ 70 U/l), low platelet ($< 100 \times 10^9/l$) or partial HELLP syndrome consisting of only one or two elements of the above triad.

Exclusion criteria comprised of patients who already had eclamptic fit, deranged renal functions (urine output < 100 ml/4 hour, urea > 10 mmol/l), already on magnesium sulfate, known hypersensitivity to magnesium and refusal or inability to obtain informed consent.

The cases were selected from emergency room, high risk wards, out-patient department and from labor room. There were total 60 cases of severe preeclampsia fulfilling inclusion criteria, out of them 30 cases (group A) received only single loading dose of magnesium sulphate and other 30 cases (group B)

received 24 hour standard pritchard's regime of magnesium sulphate.

In group A, only loading dose magnesium sulphate was given. 4gms of magnesium sulphate was given intravenously as a bolus dose over 5-10 min and 5 grams (gms) of MgSO₄ deep intramuscular injection was given in upper outer quadrant of both buttocks i.e., total 14gms of MgSO₄. Injection lignocaine 1 ml 2% solution was added in intramuscular dose to minimize pain caused by intramuscular dose of magnesium sulphate. Injection site was cleaned with spirit swab. While giving the loading dose of magnesium sulphate, subjective and objective side effects of magnesium sulphate was recorded.

In group B, complete standard Pritchard regime i.e., 14gms of loading dose (4gms by intravenous route and 10 gms intramuscular route) followed by 5 gms intramuscularly every 4 hours, in alternate buttocks was given, for 24 hour, ensuring patellar reflex was present, respiratory rate > 16 breaths/min and urine output in previous 4 hours exceeded 120 ml.

In each dose of intramuscular injection of MgSO₄. 1 ml of 2% xylocaine solution was added to minimize pain caused by magnesium sulphate. While giving loading and maintenance dose of magnesium sulphate, subjective and objective side effects of magnesium sulphate was noted and recorded in proforma.

In case of occurrence of convulsion, if in group A patient if convulsion could had occurred then complete Pritchard's regime of magnesium sulphate would had been be given to control the convulsion and to treat the eclampsia.

Primary outcome measure was occurrence of eclamptic seizure(s) after enrollment in the study.

Pre-testing the data collection tools was performed and analyzed in the first 10 cases and results discussed with the guide. Data were collected and entered in a master chart as well as in a SPSS excel spread sheet. Data analysis was made manually as well as with the help of the computer using SPSS program and was depicted as tables, diagrams, or as charts. An interim analysis was done after finishing 25% of the data collection to have an idea of expected result and necessary adjustment. Regular meeting with the preceptor was held for discussion and to clear up the confusion. Differences between categorical variables were analyzed using chi-square test. P value was considered significant if it was < 0.05 . Biostatistician's help was also taken for data management. At the end, a conclusion was drawn depending upon the findings after well discussion.

RESULTS

Table 1: Incidence of preeclampsia among pregnant women reporting to tertiary hospital

| Total number of patients over a period of 6 months | Gestational hypertension | Preeclampsia | Severe Preeclampsia |
|--|--------------------------|--------------|---------------------|
| 12043 | 796 (6.6%) | 196 (1.6%) | 60 (0.5%) |

During the study period of six months duration, there were total 12043 obstetrics admission. Among all, patients with gestational hypertension were 796 (6.6%). preeclampsia 196 (1.6%), and severe preeclampsia 60 (0.5%) (table 1).

Table 2: Severe preeclampsia according to parity

| Parity | Regimen of MgSO ₄ | | Total | p-value |
|--------|------------------------------|-----------------|-------|---------|
| | Loading Dose | Standard regime | | |
| 0 | 16 | 20 | 36 | 0.069 |
| | 53.3% | 66.7% | 60.0% | |
| 1 | 1 | 2 | 3 | 5.0% |
| | 3.3% | 6.7% | 5.0% | |
| 2 | 12 | 5 | 17 | 28.3% |
| | 40.0% | 16.7% | 28.3% | |
| 3 | 0 | 3 | 3 | 5.0% |
| | 0.0% | 10.0% | 5.0% | |
| 4 | 1 | 0 | 1 | 1.7% |
| | 3.3% | 0.0% | 1.7% | |
| Total | 30 | 30 | 60 | |

Most of the patient were primipara in both the groups, 16 cases (53.3%) in loading dose group and 20 cases (66.7%) in standard regime group (table 2). This was statistically not significant as p-value is more than 0.05.

Table 3: Mode of delivery

| Mode of delivery | Regimen of MgSO ₄ | | Total | p-value |
|-------------------------|------------------------------|-----------------|-------|---------|
| | Loading Dose | Standard regime | | |
| Normal vaginal delivery | 8 | 9 | 17 | 0.774 |
| | 26.7% | 30.0% | 28.3% | |
| Vaccum delivery | 1 | 0 | 1 | 1.0 |
| | 3.3% | 0.0% | 1.7% | |
| Forceps delivery | 0 | 1 | 1 | 1.0 |
| | 0.0 | 3.3% | 1.7% | |
| LSCS | 21 | 20 | 41 | 0.781 |
| | 70.0% | 66.7% | 68.3% | |
| Total | 30 | 30 | 60 | |

Most common mode of delivery was cesarean section in both groups. There were 21cases (70.0%) of caesarean section in loading dose group vs 20 cases (66.7%) in standard dose regime but this is statistically not significant as the p-value is 0.781. There was 1 case (3.3%) of forceps delivery in

standard regime group, 1 case (3.39) of vacuum delivery in loading dose group and 8 cases (26.7%) of normal vaginal delivery in loading dose group vs 9 cases (30.0%) in standard regime group (table 3). This was statistically not significant as p-value was more than 0.05.

Table 4: Side effects of Magnesium sulphate

| Side effects | Regimen of MgSO ₄ | | Total | p-value |
|--------------------------------|------------------------------|-----------------|-------|---------|
| | Loading Dose | Standard regime | | |
| Dizziness | 2 | 2 | 4 | 1.0 |
| | 6.7% | 6.7% | 6.7% | |
| Feeling of warmth and flushing | 9 | 9 | 18 | 1.0 |
| | 30.0% | 30.0% | 30.0% | |
| Irritation at injection site | 2 | 5 | 7 | 0.421 |
| | 6.7% | 16.7% | 11.7% | |
| Nausea | 1 | 1 | 2 | 1.0 |
| | 3.3% | 3.3% | 3.3% | |
| Nausea & vomiting | 3 | 2 | 5 | 1.0 |
| | 10% | 6.7% | 8.3% | |
| Total | 30 | 30 | 60 | |

The side effects between loading dose group and standard dose group were statically not significant as the p-value for each variables was more than 0.05.

Dizziness and feeling of warmth & flushing were present in 2 (6.7%) and 9 (30.0%) cases in each group. Irritation at injection site was more in standard

regime group, 5 (16.7%) vs 2 (6.7%) in loading dose group. 3 cases (10.0%) of nausea and vomiting in loading dose group vs 1 case (0.3%) in standard regime group (table 4).

DISCUSSION

In the present study, there were total 60 cases of severe preeclampsia fulfilling inclusion criteria, out of them 30 cases (group A) received only single loading dose of magnesium sulphate and other 30 cases (group B) received 24 hours standard pritchard's regime of magnesium sulphate. The study showed that the loading dose of magnesium sulphate was comparable to standard regime for prophylaxis of eclampsia as there was no statistically significant difference w.r.t to parity, mode of delivery and side effects between loading dose group and standard dose. In a similar study, Sravani P et al⁵ found that the occurrence of eclampsia was more common in the age range of 20 to 26 years among the primigravida and with previous history of PIH and reported that low dose regimen is better alternative to control seizures in eclamptic patients. Obanimoh AA et al¹ suggested the effectiveness of the loading dose of magnesium sulfate in the prevention of seizure among women with severe preeclampsia when compared with the standardized Pritchard regimen as well as also demonstrated safety and similarity in fetal-maternal outcome. In another study by Nagaria T et al,⁴ the single loading low dose regimen was equally efficacious in prevention (96.6% vs 100%, $p = 0.934$) and control (97.6% vs 97.8%, $p = 0.358$) of eclamptic fits as compared to the Pritchard's regimen. In another study by Unwaha EA et al,⁶ no case of eclampsia and maternal death was recorded. Keepanasseril A et al⁷ also reported that the loading dose only regime may be considered an effective alternative regime for the prevention of eclampsia in women with severe preeclampsia. Similarly, Malek-Mellouli M et al⁸ assessed the validity of a service protocol in the management of severe pre-eclampsia all specifying the benefits, complications and side effects of magnesium sulfate and found that the use of magnesium sulfate in practice does not appear to increase the risk of complications or major side effects in the mother and fetus.

Ranganna H et al⁹ reported that the efficacy of a single loading dose of magnesium sulphate in prevention of seizures was similar to the conventional 24 hour regime though not superior to it and there was a trend towards decreased side effects of magnesium sulphate in the group which received only the loading dose, hence, it would be useful in peripheral health centers without good monitoring facility. For further safety profile of patients, expert committees of regional and national societies need to identify regimens for use in patients at a greater risk of magnesium toxicity, including women with acute or chronic kidney disease, instead of blindly applying the most popular regimens such as Pritchard's and

Zuspan's regimens. Apart from logistic constraints, paucity of trained staff for meticulous clinical monitoring of patients receiving parenteral magnesium (like respiratory rate, deep tendon reflexes and urine output), and lack of availability of serum magnesium monitoring at the level of PHCs pose a challenge.¹⁰

This study had some limitations. It was a hospital based study conducted in a small sample size in a short duration of time. A larger sample size would have been ideal to generate more accurate and statistically significant conclusions.

CONCLUSION

This study concludes that the use of single loading dose of magnesium sulphate is as effective as standard Pritchard's regime for prophylaxis of eclampsia as there was no convulsion in either group. The study found that the loading dose of magnesium sulphate was comparable to standard regime for prophylaxis of eclampsia.

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