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Original Research Article.

A Study to Determine the Maternal and Fetal Outcome After Single Loading Dose of Magnesium Sulphate for Eclampsia

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ABSTRACT

Introduction: Eclamptic seizures are a medical emergency and can arise after 20 weeks of gestation, either antepartum, intrapartum, or postpartum. They require urgent intervention to prevent death in the mother and fetus. Magnesium sulphate is the anticonvulsant of choice in prevention and control of eclamptic convulsions. Therefore, the present study was undertaken to determine the maternal and fetal outcome after single loading dose of Magnesium sulphate in comparison to standard Pritchard's regime for prophylaxis of eclampsia.

Materials and Methods: The present cross-sectional hospital based comparative study was conducted among 60 pregnant women 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. Patients were categorized in two groups - one group A that received only loading dose of magnesium sulphate and other group B that received standard Pritchard's regime of magnesium sulphate. Primary outcome measured were maternal complications, fetal and neonatal outcome that consist of 5 min Apgar score and neonatal admission in baby unit. Data were collected and analysed by SPSS -20 software. Differences between categorical variables were analyzed using chi-square test and *p* value of <0.05 was considered significant.

Results: The fetal outcome in terms of apgar scores 27 at 5 minutes of birth was better in loading dose group i.e., 21 cases (70.0%) versus 15 case (50.0%) in standard regime group but this was statistically not significant as p-value was 0.114. Among 30 cases in each loading dose and standard regime group, there were total 5 neonates (16.7%) in loading dose group and 8 neonates (26.7%) in standard regime got admitted in neonatology and this was statistically not significant as the p-value is 0.347.

Conclusion: The results this study showed that the loading dose of magnesium sulphate is comparable to standard Prichard's regime for prophylaxis of eclampsia. This study also concludes that there is statistically no significant difference in maternal and fetal outcome between loading dose group and standard Pritchard's regime group.

Keywords: Eclampsia; Magnesium sulphate; Prichard's regime; Seizures.

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INTRODUCTION

Pre-eclampsia-Eclampsia Syndrome (PES) has remained a major global public health threat in contributing significantly to maternal and perinatal morbidity and mortality.[1] Eclamptic seizures are a medical emergency and can arise after 20 weeks of gestation, either antepartum, intrapartum, or postpartum. They require urgent intervention to prevent death in the mother and fetus.[2] It is a multi-system disorder with complex pathogenesis, which is not completely understood. Cerebral involvement causing convulsions can kill the mother and fetus unless expertly managed. Over the centuries, many diverse therapies have been employed (rightly or wrongly) to both prevent and cure this condition. These include systemic (sedation with morphine and chloral hydrate, phlebotomy, gastric lavage, mastectomy, and renal decapsulation) as well as hormonal (oophorectomy) and neuronal (spinal tap) interventions.[3]

Magnesium sulphate is the anticonvulsant of choice in prevention and control of eclamptic convulsions. Pritchard's regimen is the most popular time - tested regimen used. However, owing to

concerns of toxicity, several low dose regimens have been introduced considering the lower body mass index of Asian women.[1] Furthermore, when magnesium sulphate was introduced for management of eclamptic convulsions, it was given according to Pritchard regime. However, it was observed that many patients did not receive maintenance therapy due to suspicion of toxicity, but they did not convulse any further. It was observed that none of the patients with pre-eclampsia developed seizure even after the single bolus dose.[4] Therefore, the present study was undertaken to determine the maternal and fetal outcome after single loading dose of Magnesium sulphate in comparison to standard Pritchard's regime for prophylaxis of eclampsia.

MATERIALS AND METHODS

The present cross-sectional hospital based comparative study was conducted among 60 pregnant women 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. The permission was taken from ethical committee before initiation of study.

Inclusion criteria comprised of patients with singleton pregnancy of 28 weeks to 42 weeks of gestation with severe preeclampsia, patients with systolic blood pressure ≥160mm Hg and diastolic 2110mmHg with proteinuria (≥300mg/di or ≥2+ on dipstick), systolic blood pressure ≥140 mm Hg and diastolic blood pressure ≥90 mm Hg with at least one of proteinuria (≥2+ on dipstick or ≥5 g/24 hour urine collection) or persistent frontal headache or visual or cerebral disturbances or epigastrium or right upper quadrant pain or HELLP syndrome - hemolysis, elevated liver enzymes (LDH ≥600 U/l, AST ≥70U/l), low platelet (<100 x 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/), already on magnesium sulfate, known hypersensitivity to magnesium and refusal or inability to obtain informed consent.

All admitted cases were categorized according to standard classification of hypertensive disorder of pregnancy. Among these admitted cases, patients with diagnosis of severe preeclampsia, fulfilling inclusion criteria, were enrolled in the study.

The cases were selected from emergency room, high risk wards, out-patient department and from labor room. The patient enrolled in the study was counselled about maternal and perinatal risks. Written informed consent for the study was taken from every patient. Data was collected according to the proforma.

History of patient was taken in regard to age, gravid, party, previous obstetrical complications like previous pregnancy complication as hypertensive disorder of pregnancy, twin pregnancy, history of chronic hypertension, any medical illness presenting as hypertension, any surgical illness, about risk factor, ethnicity, socioeconomic class, menstrual history, contraceptive history and history of any drug intake. The symptoms of patients were recorded specially headache, blurring of vision, epigastric pain, hemorrhagic manifestation (per vaginal bleeding, gum bleeding, upper GI bleeding, petechiae etc.), respiratory difficulties, edema, convulsion and other complaints.

Patients were examined in emergency room. Blood pressure and other vital signs were recorded at admission and monitored 6 hourly. Chest examination, cardiovascular system examination, abdominal and per vaginal examination were done. Foley catheterization was done, and input and output charting were maintained. Urine albumin was measured on admission then twice daily and other relevant investigation including hemoglobin, total count, differential count, platelets count, liver function test, renal function test, random blood sugar, serum uric acid, coagulation profile, serum lactate dehydrogenase. Obstetrics ultrasound was done to see fetal viability, gestational age, placental localization, retroplacental clots. Patients were shifted to maternal intensive care unit and managed according to hospital protocol. Patients were categorized in two groups - one group A that received only loading dose of magnesium sulphate and other group B that received standard Pritchard's regime of magnesium sulphate. First case was selected by lottery method either as group A or B and then each subsequent case was taken as either A or B.

Patients received magnesium sulphate under monitoring of vital signs. There was 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 $MgSO_4$ deep intramuscular injection was given in upper outer quadrant of both buttocks i.e., total 14gms of $MgSO_4$. 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 hours, 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 $MgSO_4$. 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 given to control the convulsion and to treat the eclampsia.

Patients were immediately managed in emergency for lowering blood pressure and other emergency situation. Observations of patients were done during hospital stay till discharge. Patients were observed in maternal intensive care unit for any development of signs of impending eclampsia, pulmonary edema, visual disturbances, signs of HELLP (Hemolysis, Elevated liver enzymes, Low platelets counts) syndrome, oliguria and signs of acute renal failure. Mode of delivery was recorded. After delivery, fetal outcome was recorded in terms of baby's birth weight, Apgar score, maturity, still birth and neonatal death. Patients and their babies followed up in hospital till discharge. After collecting above information's, all needed data was entered in tables.

Primary outcome measured were maternal complications, fetal and neonatal outcome that consist of 5 min Apgar score and neonatal admission in baby unit. Data were collected and analysed by SPSS -20 software. Differences between categorical variables were analyzed using chi-square test and *p* value of <0.05 was considered significant.

RESULTS

Among total 30 cases in each loading dose and standard regime group, 1 case (3.33%) in loading dose group and 4 cases (13.33%) in standard regimen group lost the knee jerk after giving magnesium sulphate but this was statistically not significant as the p-value is 0350. Similarly, there was statistically no significant difference between respiratory rate and urinary output between loading dose and standard regimen group (table 1). Majority of patients in both groups had normal conditions throughout the treatment Period. There were 4 cases (13.33%) of abruptio placentae, I case (3.3%) of HELLP syndrome, 1 case (3.3%) of impaired renal function test, and 1 case of PPH (3.3%) in loading dose group, whereas there were I case (3.3%) of pulmonary edema and 1 case (B3%) of apruptio placentae in standard regime group but these findings between the groups are statistically not significant (table 2).

Apgar score at 5 minutes of birth was better in loading dose group but that was statistically not significant. More than 2/3rd of the neonates had > 7 apgar score at 5 minutes in both loading dose and standard Prichard's regime groups. Among 30 cases in loading dose group, 21 babies (70.0%) had apgar score > 7 at 5 min of births and among 30 cases in loading dose group, 15 babies (50.0%) had apgar score ≥ 7 at 5 min of births. As the p-value is 0.114, apgar score at 5 min in two groups was statistically not significant (table 3).

Among 30 cases in each loading dose and standard regime group, there were total 5 neonates (16.7%) in loading dose group and 8 neonates (26.7%) in standard regime got admitted in neonatology and this was statistically not significant as the p-value is 0.347 (table 4). All other babies were admitted to special baby care unit for observation as the mothers were admitted in maternal intensive care unit and no need to admit in neonatal intensive care.

Table 1: Maternal Monitoring of effects of Magnesium Sulphate

Effects of Mgso4	Regimen of MgSo4		P-value
	Loading dose	Standard dose	
Knee Jerk (Absent)	1	4	0.350
Respiratory rate (Mean breath/min)	22.6	23.33	0.516
Urine outcome (Mean ml/4hr)	161.60	307.00	0.983

Table 2: Maternal Complications

Maternal Complications	Regimen of $MgSO_4$		Total	P-value
	Loading dose	Standard dose		
Abruptio Placentae	4	1	5	0.117
	13.33%	3.3%	16.66%	
Headache	2	2	4	1.000
	6.7%	6.7%	13.33	
HELLP Syndrome	1	0	1	1.000
	3.3%	0.0%	1.7%	
Impaired LFT	1	0	1	1.000
	3.3%	0.0%	1.7%	
PPH	1	0	1	1.000
	3.3%	0.0%	1.7%	
Pulmonary Oedema on 1st POD	0	1	1	1.000
	0.0%	3.3%	1.7%	

Table 3: Apgar score at 5 min of birth

Apgar score at 5 min of birth	Regimen of MgSo4		Total	P-value
	Loading dose	Standard dose		
<7	9	15	24	
	30.0%	50.0%	40.0%	0.114
>=7	21	15	36	
	70.0%	50.0%	60.0%	
Total	30	30	60	
	100.00%	100.00%	100.00%	

Table 4: Neonates needing admission in neonatal intensive care unit

Regimen of MgSo4	No. Babies of admitted in neonatal intensive care unit	P-value
Loading dose	5(16.7%)	0.347
Standard dose	8 (26.7%)	

DISCUSSION

Eclampsia remains a common cause of maternal death.[5] The present study found that among total 30 cases in each loading dose and standard regime group, 1 case (3.33%) in loading dose group and 4 cases (13.33%) in standard regimen group lost the knee jerk after giving magnesium sulphate but this was statistically not significant as the p-value is 0350. Similarly, there was statistically no significant difference between respiratory rate and urinary output between loading dose and standard regimen group. As well as the p-value was 0.114 for apgar score at 5 min in two groups which was statistically not significant.

In another study by Anjum S et al,[6] no convulsions were recorded after either $MgSO_4$ infusion for 12 hours or 24 hours after delivery or the last seizure (whichever occurred later) among women with eclampsia. Regmi MC et al[3] also observed that most of the patients did not receive maintenance therapy due to suspicion of toxicity and they did not convulse further. Keepanasseril A et al[7] compared the efficacy and safety of 'low-dose Dhaka' regime with 'Loading dose only' regime for seizure prophylaxis in severe preeclampsia using a randomised controlled trial in 402 women. The Dhaka regimen utilizes a 10 mg loading dose of $MgSO_4$, followed by 2.5 mg given four hours. This is approximately half the dose of the Pritchard regimen and has been found to be equally effective in reducing recurrent seizures. Neonatal outcomes such as Apgar score at 5 minutes (5.0% vs. 8.05% $p = .251$) and perinatal mortality (20.4% vs. 21.9%, $p = .724$) were similar in both groups.

Nagaria T et al[1] reported that single loading LDR is an equally efficacious, safer, cheaper and more body-friendly alternative to the Pritchard's regimen for both prophylaxis and therapy of eclamptic fits even at subtherapeutic serum concentrations with similar feto-maternal outcomes. In developing countries where the maternal morbidity and mortality due to pre-eclampsia-eclampsia is relatively higher, resorting to such shorter low dose courses of $MgSO_4$ therapy with minimal monitoring would be a welcome sea-change in the peripheral health centres with limited resources and high patient turnover.

Dixit P et al[8] found that magnesium sulphate for 24hrs is the drug of choice for seizure prophylaxis in patients with severe preeclampsia and eclampsia but benefits of magnesium sulphate should outweigh its adverse effects. But there was increase in the feeling of wellbeing in shorter regimens with early ambulation, lesser duration of indwelling catheter and early breastfeeding leading to better capability of the mother to take care of newborn.[8]

The potential concern for magnesium sulphate therapy is the risk of side effects which could increase with the duration of treatment especially if there are challenges in clinical monitoring of the patients. Similarly, the cost of therapy would inevitably increase with the duration of treatment. For example with the standard Pritchard regimen in which 5 grams of magnesium sulphate is administered four-hourly for 24 hours after loading with 14 grams; a patient would require at least 44 grams of the drug to complete a course.[9] In the present study, 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 $MgSO_4$ deep intramuscular injection was given in upper outer quadrant of both buttocks i.e., total 14gms of $MgSO_4$. 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 hours, ensuring patellar reflex was present, respiratory rate >16 breaths/min and urine output in previous 4 hours exceeded 120 ml.

Lower-dose and loading dose-only regimens could be as safe and efficacious as standard regimens.[10] Various low dose magnesium sulphate regimens have been described principally because of small size of Indian women & concern about toxicity in circumstances where facility for measurement of serum level of magnesium is not available. Low dose magnesium sulphate regimen has shown promise in terms of decrease in side effects without a significant decrease in its therapeutic benefits. In India, Pritchard's regimen has been modified in various places and found that low dose regimen was as efficacious as standard dose regimen in convulsion control with less of magnesium toxicity but neither a long-term statistical data has been reported nor standardisation of protocol has been framed.[11] Furthermore, Magnesium sulphate for pre-eclampsia costs less and prevents more eclampsia in low gross national income (GNI) than in high GNI countries. Cost-effectiveness substantially improves if it is used only for severe pre-eclampsia, or the purchase price is reduced in low GNI countries.[12]

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. Also, this study was a single center-based study. Cases from multiple centers would have better results. Several confounding factors like age, maternal BMI, ethnicity, socioeconomic status, number of antenatal visits, exposure to tobacco and alcohol were not included in this study. So, the impact of these factors in the development of eclampsia could not be studied.

CONCLUSION

The results this study showed that the loading dose of magnesium sulphate is comparable to standard Prichard's regime for prophylaxis of eclampsia. This study also concludes that there is statistically no significant difference in maternal and fetal outcome between loading dose group and standard Pritchard's regime group.

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