

ORIGINAL ARTICLE

A Comparative Study of Dosage of MgSO₄ in Indian Women with Eclampsia.

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KEY WORDS : : Eclampsia, Low dose magnesium sulphate, Pritchard regimen

ABSTRACT

Objective To assess the safety and efficacy of a low dose magnesium sulfate regimen for the management of eclampsia in Indian women. **Aims & Objectives:** 1) To identify the cases of eclampsia who come to dept. Of obstetrics & gynaecology of C.U.Shah medical college, surendranagar. 2) To treat some cases with Pritchard regimen & study the efficacy & safety profile. 3) To treat some cases with Low-dose regimen & study the efficacy & safety profile. 4) To compare the efficacy & safety profile of the two regimens. **Methods:** A loading dose consisting of 4 gram of magnesium sulfate intravenously plus 6 gram intramuscularly (3 gram in each buttock) was followed by 4 gram intramuscularly every 4 hours, for 24 hours beyond the last seizure. This regimen was evaluated prospectively with 50 women with eclampsia and the results were compared with Pritchard regimen which was used in 50 women with eclampsia. **Results:** **Conclusion:** The low dose regimen was associated with a lower seizure recurrence and a slightly lower maternal mortality. This study confirm that Low-dose regime is as effective and safer than Prichard regime.

INTRODUCTION

Hypertensive disorders remain among the most significant and intriguing unsolved problems in obstetrics. Hypertensive disorders complicate 5 to 10 percent of all pregnancies, and together they are one member of the deadly triad along with hemorrhage and infection that contributes greatly to maternal morbidity and mortality. Pre-eclampsia is identified in 3.9% of all pregnancies¹. The World Health Organization (WHO) systematically reviews maternal mortality worldwide, and in developed countries, 16% of maternal deaths were reported to be due to hypertensive disorders². Together preeclampsia – eclampsia account for 40,000 maternal deaths every year with most of the mortalities occurring in the developing countries. In India, they account for 5% of all maternal deaths with most of them occurring due to eclampsia. Eclampsia is derived from the Greek word meaning flash of lightning, to shine forth. Eclampsia is defined as the occurrence of generalized tonic-clonic convulsion in women with pre-eclampsia not caused by any other neurological or medical disorders. The major breakthrough in the management of eclampsia came when Dr. J A Prichard published his standard protocol in 1984³. Currently the most commonly used regimens of magnesium sulfate administration is the standard regimen of Pritchard^{3,4,5,6}. Pritchard regime sometimes

ends up with toxicity, due to its high dosage (34 g) because the women Pritchard studied were obese and well-nourished from developed country, the same dosage may not apply to the lean and malnourished of developing countries like India. Pritchard himself stated that “If a woman is known to be or appear to be small, the dose should probably be limited.” - J. A. Pritchard, American Journal of Obst. & gyn vary according to the patient's weight or body mass index. However this has never been adequately evaluated⁷. With this background Low-dose protocol (26 g) has been formulated to suit our Indian women with eclampsia to reducing magnesium sulfate toxicity without compromising its efficacy in controlling seizures. This study is to compare the efficacy and safety profile of two different regime, Pritchard regime and low dose regime in Indian women with eclampsia.

MATERIALS AND METHODS

A prospective study was conducted at a tertiary care teaching hospital from December 2014 to October 2016 in 100 patients with eclampsia. A written informed consent was taken from patient and/or relative for participation in this study. All cases of Eclampsia (Antepartum / Intrapartum / Postpartum) were included in the study. Other cases of convulsions like Epilepsy, meningitis, encephalitis, cerebrovascular accidents, rupture of aneurysm were excluded. Eclampsia with severe

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complication such as CVA, HELLP Syndrome, Renal failure, Oliguria, Pulmonary oedema, massive hemorrhage and shock and suffering from known medical diseases like Diabetes mellitus, Heart disease, Jaundice, Blood dyscrasia were also excluded. Out of the 100 patients, 50 patients were randomly selected for Pritchard regimen and given intravenous Loading dose of 4 g mgso4 (20 ml of 20%) iv f/b intramuscular loading dose of 5 g mgso4 (10 ml of 50%) im in each buttock, Maintenance dose of 5 g mgso4 (10 ml of 50%) im was given 6 hrly on alternate buttock. Total dose of magnesium sulfate was 34 g. Other 50 patients were given Low-dose regimen with intravenous Loading dose of 4 g mgso4 (20 ml of 20%) iv f/b intramuscular loading dose of 3 g mgso4 (6 ml of 50%) im in each buttock, Maintenance dose of 4 g mgso4 (8 ml of 50%) im was given 6 hrly on alternate buttock. Total dose of magnesium sulfate was 26 g, 23.53% less than Pritchard regime. Detail history was elicited and examination was carried out. Weight of the patient was obtained from antenatal card for booked patients and mamta card for unbooked ones. Abdominal examination was also carried out, height of fundus, presentation of the fetus and Uterine contractility was assessed by palpation. FHS were ausculted using a doppler. Per vaginum examination was carried out at the time of admission and repeated every 4 hourly and then according to progress of labor. All patients were monitored hourly by pulse, BP, respiratory rate, Spo2, level of consciousness, knee jerk, auscultation of lungs, urine output. Maintenance dose was given as per schedule if their urine output > 30ml/hour, deep tendon reflexes present, respiratory rate > 14/min and pulse oximetry \geq 96%. Evidence of magnesium toxicity was detected by absence of deep tendon reflexes, respiratory rate and pulse oximetry. Continuous catheterization and I.V fluid was given very cautiously. If convulsions persisted after start of therapy additional 2gm mgso4 (20% solution) given intravenously. All necessary investigations like CBC, urinary protein, blood group, RBS, serum creatinine, SGPT, serum electrolyte, serum bilirubin, blood coagulation profile, HIV, HBsAg, test were done. The additional antihypertensives used were oral nifedipine, oral labetalol and intravenous labetalol as per the management protocol practiced in our hospital. Patients under study were either induced, allowed to deliver spontaneously or if indicated cesarean section was performed. Progress of labor was monitored. Mothers were kept under close observation at least for 72 hours post-partum.

OBSERVATION

From the prospective study was conducted from December 2014 to October 2016 in 100 patients with

Eclampsia, Following observations were recorded incidence of eclampsia is more in unbooked cases than that of booked cases. Majority of patients with eclampsia were in the age-group of 21-30 years 72%, 20% were in the age-group of 20 years and below, whereas 8% patients were 31 years and above. Incidence of eclampsia is more in primi para than that of multi para. 61% patients were primi para and 39% patients were multi para. In this study, 55% of patients were had 3-5 convulsions, 36% of patients were had 1-2 convulsion and 9% of patients were had more than 5 convulsions before starting of treatment. In this study, 68% of patients were conscious, 27% of patients were semi-conscious and 5% of patients were unconscious at the time of admission. Patients with weight of 45-49 kg 23 (46%) patients received Pritchard regime and 22 (44%) patients received Low-dose regime. Patients with weight of 50-55 kg 27 (54%) patients received Pritchard regime and 28 (56%) patients received Low-dose regime. In this study, incidence of eclampsia is more in 36 wks of gestation and above, 52% of patients were had gestational age of 36 wks and above, 35% of patients were had gestational age of 30-34 wks and 13% of patients were had gestational age of 28 wks and below. Ante partum eclampsia is much more common. 86% of patients were of Ante partum eclampsia, 10% patients were of Post partum eclampsia and 4% of patients were of Intra partum eclampsia. 54% of patients were had systolic blood pressure 150-159 mm Hg and diastolic blood pressure 100-109 mm Hg and 46% of patients were had blood pressure \geq 160/110 mm Hg on admission. Patients who were treated with low-dose regime from them 8 (16%) patients had 1 episode of recurrence of convulsion and patients who were treated with Pritchard regime from them 2 (4%) patients had 1 episode of recurrence of convulsion. Patients who were treated with Pritchard regime had developed much more toxicity, 8 (16%) had absent DTR and 2 (4%) had respiratory depression. Patients who were treated with low-dose regime had developed very less toxicity, 2 (4%) had absent DTR and no any patient developed respiratory depression. Patients with body weight of 45-49 kg, 23 patients who received pritchard regime, 6 of them developed toxicity, and patients with body weight of 50-55 kg, 27 patients who received Pritchard regime, 4 of them developed toxicity. Patients with 45-49 kg, 22 patients received Low-dose regime, 2 patients developed toxicity, and no patient developed toxicity with body weight of 50-55 kg. Patients who treated for eclampsia, 19% were delivered FTND (full term vaginal delivery), 3% were vacuum delivery, 43% were PTVD (preterm vaginal delivery) and 35% were delivered by cesarean section. Patients who treated with Pritchard regime, 34 (68%) had good perinatal outcome, 10 (20%) poor and 6 (12%) had

IUD (intra-uterine death). With low-dose regime 41 (82%) had good perinatal outcome, 3 (6%) poor and 6 (12%) had IUD (intra-uterine death). Patients who were treated with Pritchard regime, 41 (82%) had systolic blood pressure 120-129 mm Hg and diastolic blood pressure 90-99 mm Hg, 9 (18%) had blood pressure of $\geq 130/90$ mm Hg on discharge. With low-dose regime, 38 (76%) had systolic blood pressure 120-129 mm Hg and diastolic blood pressure 90-99 mm Hg, 12 (24%) had blood pressure of $\geq 130/90$ mm Hg on discharge.

DISCUSSION

In this study, 100 cases of eclampsia, who came to the Dept. of Obstetrics and Gynaecology of a tertiary care teaching hospital, have been studied during the period of December 2014 to October 2016. Detailed analysis has been done and the results have been compared with the statistics available from Indian authors and other authors around the world. As is evident from this study correlates

with the study done by other authors, incidence of eclampsia is higher among the age group of 21-30 years. In Prosunbera et al⁸ study it is 87.6%, in Cherukuri karuna el at⁹ study it is 82%, Nautiyal el at¹⁰ study it is 88% and in present study it is 72%

Eclampsia is much more common, in primi para, it is correlates with the study done by other authors from India and around the world. Present study showing 61% of patients with eclampsia were primi para and 39 % were multi para. Sultana N¹¹ reported 73 % patients were primi para, Cherukuri karuna el at⁹ reported 78% and Ruchiranauiyal el at¹⁰ reported 72% patients were primi para in their study. As is evident from this study ante partum eclampsia is most common type of eclampsia, it is correlates with the study done by other authors from India. Present study showing 86% had ante partum eclampsia, 10% had post partum eclampsia and 4 % had intra partum eclampsia. R sasikala el at¹² reported 83% ante partum eclampsia, jayatinath el at¹³ reported 74% ante partum

Efficacy of Low-dose regime in different study

Study	Total no. Of patients	Control of convulsion
Cherukuri karuna el at ⁹	50	94%
Jayatinath el at ¹³	50	86%
Present study	50	84%

Statistical study for Comparison of safety profile of two regimes

Regimen	Total no. of patients	No. of patients developed toxicity	No. of patients not developed toxicity	Statistical Study
Pritchard regime	50	10	40	$\chi^2 = 6.061$ $df = 2$ $p < 0.05$ (0.048291)
Low -dose regime	50	2	48	

Statistical study for Comparison of efficacy of two regime

Regimen	Total no. of patients	No. of patients with recurrence of convulsion	No. of patients without recurrence of convulsion	Statistical Study
Pritchard regime	50	2	48	$\chi^2 = 4$ $df = 2$ $p > 0.05$ (0.135335)
Low -dose regime	50	8	42	

eclampsia and Cherukuri karuna el at9 reported 76% antepartum eclampsia in their study.

As is evident from above table Low-dose regime is efficient to control convulsions in Indian women. As shown in table, Cherukuri karuna el at9 study 94% patients were control convulsions, another study Jayatinath el at13 shows 86% of patients were control convulsions and present study shown 84% of patients were control convulsions.

Statistical study for Comparison of safety profile of two regimes

Above Table shows whether safety profile of Low-dose regime is more than Pritchard regime on basis of development of toxicity. The Chi-square test was applied and its value came to be 6.061. The p-value for the above table for degree of freedom (df) = 2 is 0.048291 i.e. p-value < 0.05. This means that the difference between the two groups is statistically significant.

This shows that patients with eclampsia if they receive Low-dose regime, they having less chances of development of toxicity. This Statistical study shows that Low-dose regime is more safer than Pritchard regime in Indian women with eclampsia.

Above table shows whether efficacy of Low-dose regime and Pritchard regime are equal on basis of recurrence of convulsion. The Chi-square test was applied and its value came to be 4. The p-value for the above table for degree of freedom (df) = 2 is 0.135335 i.e. p-value > 0.05.

This Statistical study shows that efficacy of Low-dose regime and Pritchard regime is same.

CONCLUS

From the above observations and discussion, following conclusion has been drawn:

- ✓ Present study concludes that Low-dose of Magnesium Sulfate is as effective as Standard Pritchard regime in the control and prevention of recurrent convulsions.
- ✓ Low-dose Magnesium Sulfate is sufficient to prevent recurrence of convulsion in 84% of cases.
- ✓ Dose required for control of convulsion with Low-dose Magnesium Sulfate is 23.53% less than that of Pritchard regime.
- ✓ Present study conclude that Pritchard regime end up with more magnesium sulfate related toxicity on clinical monitoring, 20% cases developed toxicity.
- ✓ There was minimum Magnesium Sulfate related toxicity on clinical monitoring with Low-dose regime as compared to Pritchard regime.

- ✓ As the Low-dose regimen lowered the drug dose for each patient, it substantially lowered the overall cost of treatment.
- ✓ The results of present comparative study of both regimes confirm that the Low-dose is adequate for Indian women with eclampsia who weigh less than the western counterparts.
- ✓ The present comparative study of both regime confirm that Low-dose regime is as effective and more safer than Pritchard regime.

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