COMPARISON OF IM MAGNESIUM SULFATE AND IV MAGNESIUM SULFATE FOR CONTROL OF CONVULSION IN ECLAMPTIC PATIENTS

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ABSTRACT

BACKGROUND

Hypertensive disorder of pregnancy is the foremost cause of maternal deaths in developed countries and the third most common cause of death in developing countries. Eclampsia alone accounts for 50,000 maternal deaths worldwide, annually. Collaborative trial in 1995 conclusively proved that Magnesium Sulphate is the preferred treatment for eclamptic fits. Commonly used regimens are the IM $MgSO_4$ regimen popularized by Pritchard and, the IV $MgSO_4$ regimen popularized by Zuspan. The present study was done with an aim to compare IM Magnesium Sulphate regimen with IV Magnesium Sulphate regimen with regard to prevention of recurrence of seizure and maternal and fetal outcome.

MATERIAL AND METHODS

After institutional ethical committee approval and obtaining informed consent from patients, 100 patients presenting with eclamptic fits reporting to our centre were included in the study and were randomly allocated to one of the following groups.
Group I. M.: Received a loading dose of 4 gm IV $MgSO_4$ over 5-10 minutes +5 gm $MgSO_4$ deep intramuscular injection in each buttock and a maintenance dose of 5 gm $MgSO_4$ deep intramuscular injection in alternate buttock every 4 hourly.
Group I.V.: Received $MgSO_4$ 4gm slow IV over 5-10 minutes as loading dose and 1 gm $MgSO_4$ per hour as continuous intravenous maintenance infusion.

RESULTS

Both the treatment regimens were comparable with regard to recurrence of convulsions. 3 (6%) patients in Group IM and 2 (4%) patients in Group IV developed convulsions after initiation of treatment, p value 0.646. Incidence of loss of knee jerk was significantly higher in Group IM as compared to group IV; 7 (14%) in Group IM versus 1 (2%) in Group IV, p value 0.027. Incidence of other parameters of toxicity were comparable between the groups. Maternal and fetal outcome were poor in both the groups but were comparable and no significant differences were observed between the groups.

CONCLUSION

Both IM and IV regimen are equally effective in controlling the recurrence of eclamptic fits. IM Magnesium Sulphate is associated with a higher incidence of toxicity as evidenced by significantly higher incidence of loss of knee jerk reflux.

KEYWORDS

Eclampsia, IM Manesium Sulphate, IV Magnesium Sulphate.

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INTRODUCTION: High maternal mortality is still a harsh reality of obstetric care in almost all developing countries including India. Approximately, 5,00,000 or more women die of complications due to pregnancy every year and 95% of these women are from Asia & Africa.[1] Hypertensive disorder of pregnancy is the foremost cause of maternal deaths in developed countries and the third most common cause of maternal deaths in developing countries. Due to public unawareness, many pregnancies are not supervised and they reach the tertiary care centre in serious condition, resulting in high maternal mortality. Eclampsia alone accounts for 50,000 maternal deaths worldwide annually.[2] Eclampsia is estimated to complicate 1 in 2,000 deliveries in Europe and other high income countries[3] and, from 1 in 100 to 1700 deliveries in low and middle income countries.[4] Anticonvulsants have been used since long with the assumption that controlling the convulsions will improve the outcome. More recently, anticonvulsants have been advocated for prevention of eclampsia in pre-eclamptic patients.[5] Diazepam being cheap and readily available is still being used for the control of convulsions. In the 1980s, Phenytoin was found to have theoretical advantage of controlling convulsions while avoiding sedation.[6] However, collaborative eclamptic trial in 1995 conclusively proved that Magnesium Sulphate is the preferred treatment for

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eclamptic fits rather than Diazepam or Phenytoin. The use of this drug reduced the incidence of maternal death from 7% to 4% and the recurrence rate of convulsions was found to be reduced by 52% and 67% when compared to Diazepam and Pheytoin, respectively.[7]

Two widely used regimens for pre-eclampsia and eclampsia are the Pritchard regimen and the Zuspan regimen. Pritchard regimen consists of a loading dose of 4 gm $MgSO_4$ slow IV over 5-10 minutes + 10 gm $MgSO_4$ deep intramuscular injection (5 gm in each buttock) and a maintenance dose of 5 gm $MgSO_4$ in alternate buttock at every 4 hour interval.[8] In the Zuspan regimen, the loading dose consists of 4 gm $MgSO_4$ slow IV bolus over 5-10 minutes followed by a maintenance dose of 1gm/hr $MgSO_4$ through continuous IV infusion.[9] This is the standard IV regimen. Another IV regimen suggested by Sibai consists of a loading dose of 6 gm $MgSO_4$ slow IV followed by maintenance dose of 2 gm/hr $MgSO_4$ through IV infusion.[10,11] The concept of using a single loading dose of $MgSO_4$ to control and prevent fits in eclampsia was suggested by Boyd & Browse.[12,13]

Among the various regimens, the standard regime practiced at our institution is the Pritchard regimen. Various reasons for hindrance in accepting the IV regimen are; lack of trained staff for monitoring, lack of equipments, concern regarding toxicity with IV $MgSO_4$ and non familiarity with IV dosing regimen.

This present study was done to assess the efficacy and safety of intravenous $MgSO_4$ regimen in comparison to commonly practiced intramuscular regimen. Primary aim of the study was to compare the recurrence rate between the two regimens of $MgSO_4$. Secondary aim of the study was to compare the safety profile, maternal and fetal outcome of the two treatment regimens.

MATERIAL AND METHODS: After obtaining Institutional Ethical Committee approval and informed consents from all the patients, 100 pregnant patients presenting with eclampsia were included in this prospective randomized clinical trial during the period April 2013 to March 2015. 100 patients were randomly allocated into two groups using a random number table. Allocation concealment was done using a sealed opaque envelop technique. Blinding was not possible because of obvious difference in route of administration of drugs.

Inclusion Criteria: Pregnant patients presenting with eclamptic fits and coming to our institution during the study period.

Exclusion Criteria: Pregnant patients with convulsions due to epilepsy or from other causes, known contraindication to $MgSO_4$ (e.g. Myaesthenia Gravis) and those who received any form of treatment for eclamptic fits outside.

Statistical analyses were done using Statistical Package for Social Studies (SPSS) version 20. Continuous variables were analyzed using independent sample T test. Categorical variables were analyzed using Chi Squared test. P value less than 0.05 was taken as significant.

Participants were divided into two groups of 50 patients each.

Group IM: received a loading dose of 4 gm IV $MgSO_4$ over 5-10 minutes+10 gm $MgSO_4$ deep intramascular injection (5 gm in each buttock) and a maintenance dose of 5 gm $MgSO_4$ deep intramuscular injection in alternate buttock every 4 hourly.

Group IV: Received $MgSO_4$ 4 gm slow IV over 5-10 minutes as loading dose and 1 gm $MgSO_4$ per hour as continuous intravenous maintenance infusion.

In both the groups, $MgSO_4$ was given till 24 hours after delivery or 24 hours after last convulsion whichever occurred later. If convulsion occurred after commencement of treatment in any group, it was considered recurrence and was treated with additional bolus of 2 gm intravenous $MgSO_4$ stat. Monitoring of toxicity was done clinically by observing knee jerk reflex, urinary output and respiratory rate at intervals of 1 hour each. Maintenance dose was differed if knee jerk was absent or urinary output was less than 100 ml in 4 hours or respiratory rate was less than 12 breaths per minute.

On arrival of the patients in eclampsia ward, detailed history was obtained and all records of antenatal visits were thoroughly examined. Prescriptions regarding any antihypertensive treatment were thoroughly checked. History of blurring of vision, epigastric pain, number of convulsions at home or on the way to the hospital, pre-eclampsia in previous and present pregnancy was thoroughly asked. General examination included pulse, blood pressure, pallor, icterus and edema. Systemic examination included respiratory system examination, cardiovascular system examination, obstetric pelvic examination, neurological examination and fundal examination. If systolic blood pressure more than 160 mm of Hg or diastolic blood pressure more than 110 mm of Hg were observed, it was treated with Inj. Labetalol 20 mg i.v. and repeated when required. Routine investigation included complete blood count, liver function test, renal function test, serum electrolytes(Na^+, K^+, Ca^{++}).

Delivery of baby was expedited by augmentation of labor or by emergency caesarean section. Caesarean section was performed on obstetrical indications. Weight of the baby, APGAR score and neonatal outcome were recorded.

Results:

The participants in both groups were comparable with regard to age 20.38±2.2 years in Group IM versus 20.16±1.43 years in Group IV; p value 0.533, weight 46.84±4.84 kg in Group IM versus 45.66±5.42 kg in Group IV; p value 0.288, height 144.72±5.78 cm in Group IM versus 142.86±5.42 cm in Group IV; p value 0.100, BMI 22.50±3.09 in Group IM versus 22.49±3.10; p value 0.996, SBP 174±11.24 mm Hg in Group IM versus 170.68±9.83 mm Hg in Group IV and DBP 108.84±6.08 in Group IM versus 110.28 ±6.59 mm of Hg in group IV (Table 1).

Parameters		I.M $MgSO_4$	I.V $MgSo_4$	Λ^2/t value	P value
Religion	Hindu	10(20%)	11(22%)	0.060	0.806 NS
	Muslim	40(80%)	39(78%)		
	Others	0	0		
Socio-economic status	Low income gr	39(78%)	40(80%)	0.060	0.086 NS
	Middle Inc. gr	11(22%)	10(20%)		
	High Inc. gr	0	0		
Booking status	Booked	2(4%)	2(4%)	0.000	1.000 NS
	Un-booked	48(96%)	48(96%)		
Parity	Nulliparous	41(82%)	43(86%)	0.298	0.588 NS
	Multiparous	9(18%)	7(14%)		
Physical parameters	Age (Yrs)	20.38± 2.02	20.16± 1.43	0.626	0.533 (N.S)
	Weight (Kgs)	46.84 ±4.84	45.66 ±4.88	1.213	0.228 (NS)
	Height (cms)	144.72 ±5.78	142.86 ±5.42	1.658	0.100 (N.S)
	BMI	22.50 ±3.09	22.49 ±3.09	0.005	0.99 (NS)
Clinical parameter	SBP	17400± 11.24	170.68± 9.83	1.57	7.51 NS
	DBP	108.84 ±6.68	110.28± 6.59	- 1.084	0.281 NS

Table 1: Demographic, physical and clinical characteristics in two groups

Religion, socio-economic status, booking status, parity presented as frequency (% in the group).

Physical and clinical parameters presented as mean ± standard deviation.

Λ^2 for categorical variables, t value for continuous variables. NS= not significant.

Patient population comprised of 10 (20%) Hindu and 40 (80%) Muslim patients in Group IM versus 11 (22%) Hindu and 39 (78%) Muslim patients in Group IV. Most of the patients in both groups were from low socio-economic strata. In Group IM, 39 (78%) patients were of low income group and 11 (22%) patients were of middle income group, whereas in Group IV, 40 (80%) patients were of low income group and 10 (20%) patients were of middle income group. No patient in any group was from high socio-economic strata. Most of the patients in both groups never availed any antenatal check up facility. 48 (96%) patients were admitted as unbooked cases in both the groups (Table 1).

Parameters	I.M $MgSO_4$	I.V MgSo4	Λ^2	P value
Recurrence	3 (6%)	2 (4%)	0.211	0.646 (NS)
Loss of knee jerk	7(14%)	1(2%)	4.891	0.027 Significant
Oliguria	5(10%)	2(4%)	1.382	0.240(NS)
Respiratory rate<12 bpm	2(4%)	0	2.041	0.153(NS)

Table 2: Efficacy and toxicity of $MgSo_4$

Both the treatment regimens were comparable with regards to recurrence of convulsion. 3 (6%) patients in Group IM and 2 patients in Group IV developed convulsion after initiation of treatment, p value 0.646. (Table 2)

Patients were monitored clinically for toxicity by monitoring knee jerk, urinary output and respiratory rate. 7 (14%) patients in Group IM developed loss of knee jerk whereas only 1 (2%) patient in Group IV developed loss of loss of knee jerk. This difference was found to be significant, p value 0.027. 5 (10%) patients in Group IM and 2 (4%) patients in Group IV developed oliguria, p=0.240. 2 (4%) patients in Group IM developed respiratory depression, while none in Group IV developed respiratory depression, p value 0.153. These differences were not found to be significant (Table 2).

Parameters	I.M $MgSO_4$	I.V $MgSo_4$	Λ^2	P value
Hemorrhage	3(6%)	4 (8%)	0.154	0.695 (NS)
Pulmonary edema	8(16%)	3(6%)	2.554	0.110 (NS)
Renal failure	3(6%)	2(4%)	0.211	0.646 (NS)
DIC	2(4%)	1(2 %)	0.344	0.558 (NS)
HELLP	2(4%)	1(2%)	0.344	0.558 (NS)

Table 3: Complications of Eclampsia

DIC= Disseminated Intravascular Coagulation.
HELLP= Hemolysis Elevated Liver Enzyme and Low platelet.
NS= Not Significant.

Patients developed various complications in both the groups. 3 (6%) patients in Group IM and 2(4%) patients in Group IV developed hemorrhage λ^2=0.154 p=0.695. 8(16%) patients in Group IM and 3(6%) patients in Group IV developed pulmonary edema; λ^2=2-554, p=0.110. 3(6%) patients in Group IM and 2 (4%) patients in Group IV developed renal failure λ^2=0.211, p= 0.646. 2 (4%) patients in Group IM and 1 (2%) patient in Group IV developed Disseminated Intravascular Coagulation (DIC); λ^2=0.344, p= 0.533. 2 (4%) patients in Group IM and 1 (2%) patient in Group IV developed HELLP (Hemolysis Elevated Liver Enzyme and Low Platelets); λ^2=0.344, p=0.558. Incidences of all the complications were comparable and no significant difference was observed between the groups (Table 3).

Parameters	I.M. $MgSO_4$	I.V $MgSO_4$	Λ^2/t value	P value
Mode of delivery Vaginal LSCS	Vaginal 25(50%) LSCS 25(50%)	Vaginal 21(42%) LSCS 29(58%)	0.644	0.422 (NS)
Gestational age (weeks)	35.92±1.65	36.18±1.73	t=- 0.768	0.445 (NS)
Baby weight (kg)	2.38±0.24	2.38±0.21	t=0.065	0.942 (NS)
Maternal mortality	12(24%)	10(20%)	0.233	0.629 (NS)
IUD + Still birth	18(36%)	17(34%)	0.044	0.834 (NS)
NICU admission	10	14	0.271	0.603 (NS)
Early neonatal death	8	10	0.271	0.603 (NS)
Perinatal mortality	26	27	-040	0.741 (NS)

Table 4: Maternal and fetal outcome

Λ^2 for categorical variables, t value for continuous variables. NS= not significant.

Delivery of baby was expedited in both the groups, either by augmentation of labor or by LSCS. LSCS was done for obstetric indications. 25 (50%) in Group IM and 21 (42%) patients in Group IV delivered babies by vaginal route. 25 (50%) patients in Group IM and 29 (58%) women in Group IV delivered babies by LSCS ; $\lambda^2 = 0.644$, p= 0.422. Deliveries of babies by different modes in two groups were comparable. (Table 4).

Maternal mortality was quite high in both the groups. 14 (28%) patients in Group IM and 10 (20%) patients in Group IV died during treatment. With regard to maternal mortality, no significant differences were seen between the groups $\lambda^2 = 0.233$, p value= 0.029 (Table 4).

Mean body weight of fetus was 2.38±0.24 kg in Group IM and 2.38±0.21 kg in Group IV respectively; t=-0.065, p= 0.947. These differences were found to be insignificant.

Outcome of babies was poor in both the groups. 18 patients in Group IM and 17 patients in Group IV had the outcome of babies in the form of IUD or still births; λ^2 =0.44 p=0.834. Out of the live born babies 10 babies in Group IM and 8 babies in Group IV were admitted in NICU. 8 babies in Group IM and 10 babies in Group IV died in the early neonatal period. Total perinatal fetal loss was 26 (18 IUD/stillbirth + 8 deaths in early neonatal period) in Group IM and 27 (17 IUD/stillbirth + 10 deaths in early neonatal period) in Group IV. These data were comparable and no significant differences were observed (Table 4).

DISCUSSION: High maternal mortality is still a harsh reality in almost all developing countries including India. During the study period, 6286 deliveries were conducted at our institute. Total number of patients presenting with eclamptic fits were 292. The incidence of eclampsia was 4.64% in our study. Out of 292 patients, only 100 patients were included in this study and others were excluded on the basis of exclusion criteria. Most of the patients who were excluded had already received $MgSO_4$ at referring centres. Incidence of 4.64% is quite high as compared to overall data from developing countries but this is due to the fact that Katihar Medical College serves to the people of Koshi region of the state Bihar, western part of the state Bengal and border area of the neighboring country, Nepal. Most of the cases reaching our centre were referred cases resulting in high incidence of eclampsia. Singh S & Bahera A in their study on eclampsia in eastern India reported an incidence of 3.2%.[12] Begum MR and Begum M reported the incidence as high as 9% in their study at a tertiary care centre in Bangladesh.[13]

Most of the patients in both the groups in our study were Muslims. This is because of the fact that the area to which this centre caters has a large proportion of native and immigrant Muslims from the neighbouring country, Bangladesh.

In our study, almost all the patients belonged to low or middle socio-economic status. This is the reflection of economic status of this part of India. Most of the people residing in this area are very poor because employment opportunities are very rare and most of the immigrant Muslims are very poor. Jamila M Naib in her study also found that 100% cases of eclampsia belonged to low socio-economic group.[14]

Majority of women in both groups were unbooked. This is not surprising because lack of antenatal care is a risk factor for ecalmpsia. Similar percentage of unbooked eclampsia was reported by Agarwal (92%) and Sahu L (84-92%).[15,16]

Age range in both the groups was 16-24 years with mean age of 20.38±2.02 years in Group IM and 20.16±1.43 in Group IV. This low age is indicative of the fact that the girls are still married at an early age particularly in low socio-economic status. The difference between the groups is insignificant. Sibai reported mean age of 18.5 years.[17]

Most of the patients, 41 (82%) in Group IM and 43 (86%) in Group IV, were nulliparous. Both groups were comparable. Ekel reported incidence of nulliparous in eclampsia to be 89%, while Seth, et al found incidence of eclampsia in primigravida to be 74.2%.[18]

Mean gestational age was 35.92±1.65 in Group IM and 36.18±1.73 in Group IV. Difference was found to be insignificant.

There were 17 (34%) preterm deliveries in Group IM and 16 (32%) preterm deliveries in Group IV supporting other studies which underscore the fact that the cure for eclampsia is stabilization and termination of pregnancy.[19]

3 patients in Group IM and 2 patients in Group IV had recurrence of convulsions after initiation of the treatment. These differences were found to be insignificant; λ^2=0.211, p= 0.646. Pritchard and Sibai have reported recurrence rates of 11% and 16%, respectively. Coetzee, et al found occurrence of convulsion rate as 0.3% in severe eclampsia group after intravenous $MgSO_4$.[20]

Toxicity of $MgSO_4$ was assessed clinically using knee jerk reflex, urinary output and respiratory rate. 7(14%) patients in Group IM developed loss of knee jerk whereas only 1 (2%) patient in Group IV developed loss of knee jerk. This difference was found to be significant; λ^2= 4.891 p= 0.027. 5 (10%) patients in Group IM and 2 (4%) patients in Group IV developed oliguria, $\lambda^2 = 1.302$, p = 0.240. 2 (4%) patients in Group IM developed respiratory differences as compared to none in Group IV. These differences between the groups were found to be insignificant. Chinayon P. and Ekele suggested that the monitoring of toxicity is possible with clinical monitoring of knee jerk, urinary output and respiratory rate obviating the need of serial serum magnesium monitoring.[21,22] Serum Magnesium is a costly test and not readily available at all centers.

12 (24%) patients in Group IM and 10 (20%) patients in Group IV expired during the treatment. There is wide variation in reporting of maternal mortality from different parts of world. In developed world, no maternal death was reported in the studies of Sibai, et al, Lee E. et al[23] and DJ Tuffnel, et al[24]. Singh S. and Bahera A. has reported maternal mortality of 10.44%, whereas A. Pal, et al[25] has reported maternal mortality as high as 27.85%. Choudhary,

et al reported maternal mortality of 5% in IM $MgSO_4$ and 3.3% in IV $MgSO_4$ group[26]. High mortality rate in our study was due to the fact that most of the patients came to our centre at a very late stage and already had had many episodes of convulsions at home or on the way to the hospital.

Most common mode of delivery in both the groups was LSCS. 25 (50%) patients in Group IM and 29 (58%) patients in Group IV underwent LSCS. Comparatively, the high incidence rate was due to the fact that most cases were of failed induction by untrained dais or quacks at home. Caesarean section rate in collaborative eclampsia trial was 66 to 72% using Standard Pritchard Regimen. Chissel S. reported 33% Caesarean Section rate in IV Group and 50% rate in IM group.[27]

The incidence of stillbirths and intrauterine deaths was 18 (36%) in Group IM and 17 (34%) in Group IM. Out of 32 live births in Group IM, 10 babies required NICU admission and 8 died in neonatal period. Out of 33 live births in Group IV, 14 required NICU admission and 10 babies died in early neonatal period. The high incidence of intrauterine deaths, stillbirths and early neonatal deaths was due to the fact that most of the cases were handled outside by untrained *dais* and quacks and expected fetal outcome was very poor by the time they reached the hospital. Sardesai and Pritchard reported 20-22% and 33-83% peri-natal mortality, respectively[28]. Chissel S described 1/8 and 1/9 still birth in IV and IM $MgSO_4$ regimen, respectively.

CONCLUSION: From the above study, we may conclude that the awareness regarding antenatal checkup among poor population is still very low resulting in poor maternal and fetal outcome. Both IM and IV regimens are equally effective in controlling recurrence of convulsions. IM Magnesium Sulphate regimen is associated with high incidence of magnesium toxicity as evidenced by significant higher incidence of loss of knee jerk. Careful monitoring may obviate the need for serum magnesium estimation. Maternal and fetal outcome are comparable with both the regimens. Intravenous Magnesium Sulphate will be a preferred mode if facilities of IV infusion and frequent monitoring exist, otherwise in resource deficient setups, IM $MgSO_4$ can be used safely.

LIMITATION OF THE STUDY: This study was done on a very small sample size of 50 patients in each group. A multicentric study is needed to come to a final conclusion.

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