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Rashmi verma



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## RESEARCH ARTICLE

# COMPARISON OF INTRAMUSCULAR AND INTRAVENOUS MAGNESIUM SULPHATE FOR CONTROL OF ECLAMPTIC FITS

**Rashmi verma**

Department of Obstetrics and Gynaecology, Katihar Medical College and Hospital, Bihar, India

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### ABSTRACT

Eclampsia is defined as the occurrence of a tonic-clonic seizure in association with a diagnosis of preeclampsia. It is an obstetric emergency and occurs in 1 in 2000 pregnancies and alone accounts for 50,000 maternal deaths worldwide, annually. 50% cases occur postpartum, 25% after 48 hours but it may occur up to 10 days after delivery. Magnesium Sulphate is the drug of choice both for control of fits and preventing further seizures. Commonly used regimens are the IM MgSO<sub>4</sub> regimen by Pritchard and, the IV MgSO<sub>4</sub> regimen by Zuspan. The present study was done with an aim to compare the efficacy of IM Magnesium Sulphate regimen with IV Magnesium Sulphate regimen for prevention of recurrence of seizure and maternal and fetal outcome.

#### Material and Methods

The present study was carried out in Katihar medical college and hospital. 100 patients presenting with eclamptic fits were included in the study and were randomly allocated to one of the following groups.

Group A: A loading dose of 4 gm IV MgSO<sub>4</sub> was given over 5-10 minutes followed by 5 gm MgSO<sub>4</sub> deep intramuscular injection in each buttock and a maintenance dose of 5 gm MgSO<sub>4</sub> deep intramuscular injection in alternate buttock every 4 hourly.

Group B: A loading dose of MgSO<sub>4</sub> 4gm slow IV was given over 5-10 minutes followed by 1 gm MgSO<sub>4</sub> per hour as continuous intravenous maintenance infusion.

#### Results

The recurrence of convulsions was comparable in both the groups. 4 patients in Group IM and 2 patients in Group IV developed convulsions after initiation of treatment. Incidence of loss of knee jerk was significantly higher in Group IM as compared to group IV. 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 reflex. Both IM and IV regimen are equally effective but IM Magnesium Sulphate is associated with a higher incidence of toxicity.

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## INTRODUCTION

Eclampsia is a multisystem disorder originating in the placenta as a result of failure of developing trophoblast to invade the spiral arteries during the second trimester. These arterial walls fail to distend to accommodate the required increase in blood flow, an increase in the maternal blood pressure acting as a compensatory mechanism. The maternal sequelae are a result of the abnormal behaviour of the vascular endothelium.

Eclampsia occurs in 1 in 2000 pregnancies characterized by the occurrence of convulsions not attributable to other cerebral causes and occurs in association with the signs and symptoms of preeclampsia. 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. Eclampsia alone accounts for 50,000 maternal deaths worldwide annually. Anticonvulsants have been advocated for prevention of eclampsia in pre-eclamptic patients. Diazepam being cheap and readily available is still being used for the

\*Corresponding author: **Rashmi verma**

Department of Obstetrics and Gynaecology, Katihar Medical College and Hospital, Bihar, India

control of convulsions. Phenytoin had the advantage of controlling convulsions while avoiding sedation. But now -a - days, magnesium sulphate is the preferred drug for the treatment of eclamptic fits 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<sub>4</sub> slow IV over 5-10 minutes + 10 gm MgSO<sub>4</sub> deep intramuscular injection (5 gm in each buttock) and a maintenance dose of 5 gm MgSO<sub>4</sub> in alternate buttock at every 4 hour interval. In the Zuspan regimen, the loading dose consists of 4 gm MgSO<sub>4</sub> slow IV bolus over 5-10 minutes followed by a maintenance dose of 1gm/hr MgSO<sub>4</sub> through continuous IV infusion. This is the standard IV regimen. Another IV regimen suggested by Sibai consists of a loading dose of 6 gm MgSO<sub>4</sub> slow IV followed by maintenance dose of 2 gm/hr MgSO<sub>4</sub> through IV infusion. The concept of using a single loading dose of MgSO<sub>4</sub> to control and prevent fits in eclampsia was suggested by Boyd & Browse. We followed Pritchard regimen at our institution to study the efficacy of intravenous magnesium sulphate over intramuscular magnesium sulphate.

**MATERIALS AND METHODS**

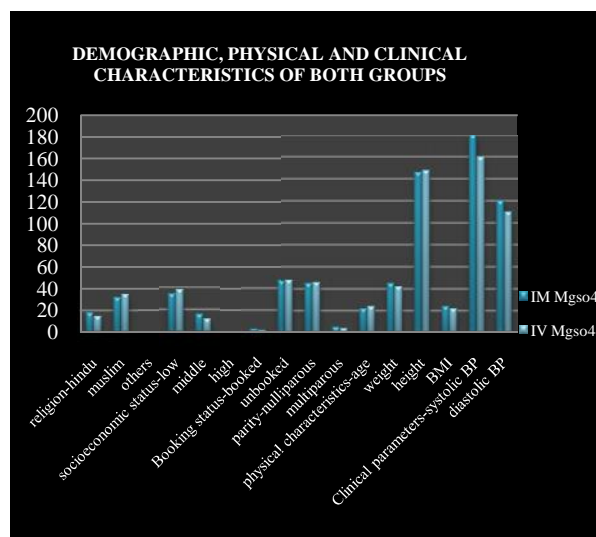
A prospective randomized clinical trial was carried out on 100 pregnant patients presenting with eclampsia at katihar medical college and hospital .Pregnant patients with convulsions due to epilepsy or from other causes, known contraindication to MgSO<sub>4</sub> (e.g. Myaesthesia Gravis) and those who received any form of treatment for eclamptic fits outside were excluded from the study.100 patients were randomly allocated in two groups. Group A: received a loading dose of 4 gm IV MgSO<sub>4</sub> over 5-10 minutes+10 gm MgSO<sub>4</sub> deep intramascular injection (5 gm in each buttock) and a maintenance dose of 5 gm MgSO<sub>4</sub> deep intramuscular injection in alternate buttock every 4 Hourly. Group B: Received MgSO<sub>4</sub> 4 gm slow IV over 5-10 minutes as loading dose and 1 gm MgSO<sub>4</sub> per hour as continuous intravenous maintenance infusion.

In both the groups, MgSO<sub>4</sub> 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<sub>4</sub> 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 not given 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. Detailed history was taken and all records of antenatal visits were thoroughly examined. 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

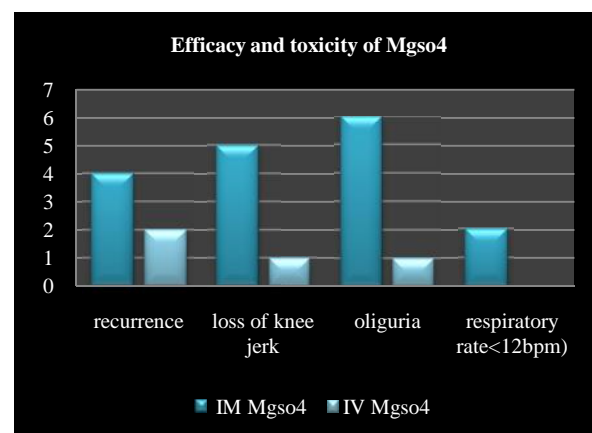
20 mg i.v. and repeated when required. Routine investigation included complete blood count, liver function test, renal function test, serum electrolytes(Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>).

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.

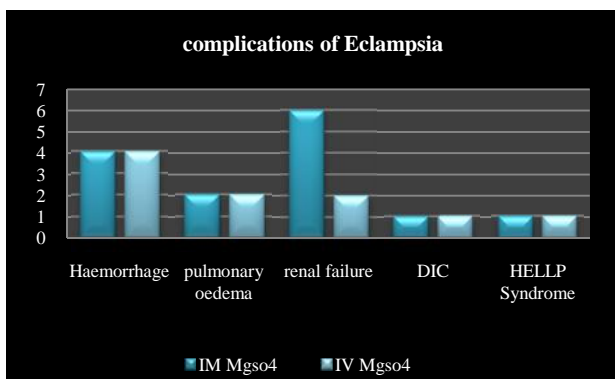
parameters	IM Mgso4	IV Mgso4
religion-hindu	18	15
muslim	32	35
others	0	0
socioeconomic status-low	34	38
middle	16	12
high	0	0
Booking status-booked	3	2
unbooked	47	48
parity-nulliparous	45	46
multiparous	5	4
physical characteristics-age	22	24
weight	45	42
height	146	148
BMI	24	22
Clinical parameters-systolic BP	180	160
diastolic BP	120	110



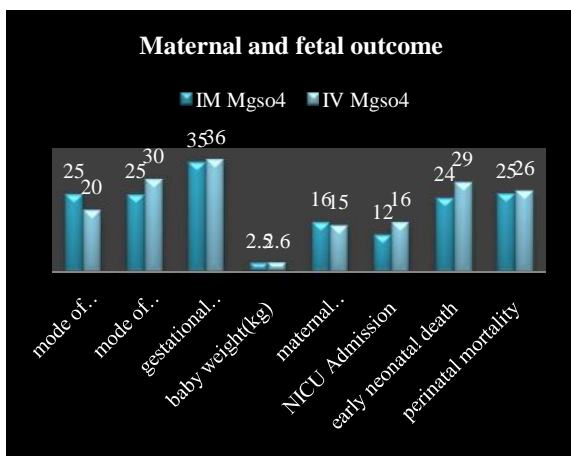
parameters	IM Mgso4	IV Mgso4
recurrence	4	2
loss of knee jerk	5	1
oliguria	6	1
respiratory rate<12bpm)	2	0



complications	IM Mgso4	IV Mgso4
Haemorrhage	4	4
pulmonary oedema	2	2
renal failure	6	2
DIC	1	1
HELLP Syndrome	1	1



Parameters	IM Mgso4	IV Mgso4
mode of delivery(vaginal)	25	20
mode of delivery(lscs)	25	30
gestational age(weeks)	35	36
baby weight(kg)	2.5	2.6
maternal mortality(IUD+still birth)	16	15
NICU Admission	12	16
early neonatal death	24	29
perinatal mortality	25	26



## RESULTS

The patients in both groups were comparable with regard to age 22 years in Group IM versus 24 years in Group IV, weight 45 kg in Group IM versus 42 kg in Group IV, height 146cm in Group IM versus 148 cm in Group IV, BMI 24 in Group IM versus 22, SBP 180mm Hg in Group IM versus 160mm Hg in Group IV and DBP 120 mm Hg in Group IM versus 110mm of Hg in group IV. There were 18 Hindu and 32 Muslim patients in Group IM versus 15 Hindu and 35 Muslim patients in Group IV. Most of the patients in both groups were from low socio-economic strata. In Group IM, 34 patients were of low income group and 16 patients were of middle income group, whereas in Group IV, 38 patients were of low income group and 12 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. 47 and 48 patients were admitted as unbooked cases in IM and IV groups respectively. Both the treatment regimens were

comparable with regards to recurrence of convulsion. 4 patients in Group IM and 2 patients in Group IV developed recurrence. Patients were monitored clinically for toxicity by monitoring knee jerk, urinary output and respiratory rate. 5 patients in Group IM developed loss of knee jerk whereas only 1 patient in Group IV developed loss of loss of knee jerk. This difference was found to be significant. 6 patients in Group IM and 1 patient in Group IV developed oliguria. 2 patients in Group IM developed respiratory depression, while none in Group IV developed respiratory depression. These differences were not found to be significant. Patients developed various complications in both the groups. 2 patients in Group IM and 2 patients in Group IV developed hemorrhage. 2 patients in Group IM and 2 patients in Group IV developed pulmonary edema. 6 patients in Group IM and 2 patients in Group IV developed renal failure. 1 patient in Group IM and 1 patient in Group IV developed Disseminated Intravascular Coagulation (DIC). 1 patient in Group IM and 1 patient in Group IV developed HELLP (Hemolysis Elevated Liver Enzyme and Low Platelets). Incidences of all the complications were comparable and no significant difference was observed between the groups. Delivery of baby was expedited in both the groups, either by augmentation of labor or by LSCS. LSCS was done for obstetric indications. 25 in Group IM and 20 patients in Group IV delivered babies by vaginal route. 25 patients in Group IM and 30 women in Group IV delivered babies by LSCS. Deliveries of babies by different modes in two groups were comparable. Maternal mortality was quite high in both the groups. 16 patients in Group IM and 15 patients in Group IV died during treatment. With regard to maternal mortality, no significant differences were seen between the groups. Body weight of fetus was 2.5 kg in Group IM and 2.6kg in Group IV respectively. These differences were found to be insignificant. Outcome of babies was poor in both the groups. 16 patients in Group IM and 15 patients in Group IV had the outcome of babies in the form of IUD or still births. Out of the live born babies 12 babies in Group IM and 16 babies in Group IV were admitted in NICU. 24 babies in Group IM and 29 babies in Group IV died in the early neonatal period. Total perinatal fetal loss was 40 (15 IUD/stillbirth + 24 deaths in early neonatal period) in Group IM and 44 (15 IUD/stillbirth + 29 deaths in early neonatal period) in Group IV. These data were comparable and no significant differences were observed.

## DISCUSSION

High maternal mortality is still a harsh reality in almost all developing countries including India. The incidence of eclampsia was quite high as compared to overall data from developing countries due to the fact that 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%. Begum MR and Begum M reported the incidence as high as 9% in their study at a tertiary care centre in Bangladesh.

Most of the patients in both the groups in our study were Muslims because the area 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 because most of the

people residing in this area are very poor due to rare employment opportunities. Jamila M Naib in her study also found that 100% cases of eclampsia belonged to low socio-economic group. Majority of women in both groups were unbooked because lack of antenatal care is a risk factor for eclampsia. Similar percentage of unbooked eclampsia was reported by Agarwal (92%) and Sahu L (84-92%). 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.

Most of the patients 45 in Group IM and 46 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%..

4 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. 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<sub>4</sub>.

Toxicity of MgSO<sub>4</sub> was assessed clinically using knee jerk reflex, urinary output and respiratory rate. 5 patients in Group IM developed loss of knee jerk whereas only 1 patient in Group IV developed loss of knee jerk. This difference was found to be significant. 6 patients in Group IM and 1 patient in Group IV developed oliguria. 2 patients in Group IM developed respiratory depression 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. Serum Magnesium is a costly test and not readily available at all centers.

16 patients in Group IM and 15 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 and DJ Tuffnel, et al. Singh S. and Bahera A. has reported maternal mortality of 10.44%, whereas A. Pal, et al has reported maternal mortality as high as 27.85%. Choudhary, et al reported maternal mortality of 5% in IM MgSO<sub>4</sub> and 3.3% in IV MgSO<sub>4</sub> group. 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 30 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. The incidence of stillbirths and intrauterine deaths was 16 in Group IM and 15 in

Group IV. Out of 36 live births in Group IM, 10 babies required NICU admission and 8 died in neonatal period. Out of 33 live births in Group IV, 12 required NICU admission and 16 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. Chissel S described 1/8 and 1/9 still birth in IV and IM MgSO<sub>4</sub> 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<sub>4</sub> 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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