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Original Research Article

## A comparative study of intramuscular sulfate versus intravenous magnesium injection among eclampsia patients in Eastern, Uttar Pradesh, India

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### ABSTRACT

**Background:** Hypertensive in pregnancy is the second most common cause of maternal mortality in India. Among the hypertensive disorders that complicate pregnancy, pre-eclampsia and eclampsia stand out as major causes of maternal and perinatal mortality and morbidity. The majority of deaths due to pre-eclampsia and eclampsia are avoidable through the provision of timely and effective care to the women presenting with these complications. Objectives of this study were to find out the effectiveness of intravascular and intramuscular magnesium sulfate in management of eclampsia. To compare the side effects and complications of intravascular and intramuscular magnesium sulfate in management of eclampsia.

**Methods:** A total 100 patients presenting with eclamptic fits reporting to the center that has been included in the study. The study has been conducted in the labor room of Nehru Chikitsalaya of B. R. D. Medical College, Gorakhpur, Uttar Pradesh for 12 months duration period. Statistical analysis of observations has been done by Chi-square test with p-value <0.05 has been considered in the study.

**Results:** Majority of eclampsia patients belonged to 20-25 years age group (63%) followed by above 30 years of age (22%). Nearly 16% patients in IM MgSO<sub>4</sub> group and 12% patients in IV MgSO<sub>4</sub> received recurrence of seizure after starting of treatment (p value >0.5). About 26% patients in IM MgSO<sub>4</sub> group and 18% patients in IV MgSO<sub>4</sub> group had mild side effects of MgSO<sub>4</sub> but no patients in both the group had major side effects of MgSO<sub>4</sub>.

**Conclusions:** The study concludes that intramuscular injection of MgSO<sub>4</sub> is painful and the chances of abscess formation that's why compliance of intramuscular MgSO<sub>4</sub> is not very good in compared to intravascular infusion of MgSO<sub>4</sub>. The chances of Mg toxicity are more MgSO<sub>4</sub> regimen because of the dose required in IM MgSO<sub>4</sub> regimen is more (44gm) that of IV MgSO<sub>4</sub> (28 gm).

**Keywords:** Eclampsia, Maternal morbidity, Maternal mortality, Pregnancy complication

### INTRODUCTION

Hypertensive disorders of pregnancy are an important cause of severe morbidity, long-term disability and death among both mothers and their babies. Worldwide, they account for approximately 14% of all maternal deaths, whereas in Latin America and the Caribbean, they contribute to approximately 22% of all maternal deaths.<sup>1</sup>

Among the hypertensive disorders that complicate pregnancy, pre-eclampsia and eclampsia stand out as major causes of maternal and perinatal mortality and morbidity. The majority of deaths due to pre-eclampsia and eclampsia are avoidable through the provision of timely and effective care to the women presenting with these complications. An estimated 0.5 million or more women die each year from complications of pregnancy

and 95% of these women are in Africa and Asia.<sup>2</sup> Eclampsia accounts for about 12% of maternal deaths in the world and 8% of maternal deaths in India.<sup>3,4</sup> Magnesium sulfate has been used for the treatment of eclampsia since 1906 and has been popular for over 70 years in the USA.<sup>5,6</sup> It has not been widely used in many countries, however, including India. In eastern India, magnesium sulfate was introduced in the treatment of eclampsia in the late 1990s following the publication of the multi-centric collaborative eclampsia Trial in 1995.<sup>7-9</sup> The collaborative eclampsia trial conclusively proved that magnesium sulfate is the drug of choice for the anticonvulsant management of women with eclampsia, rather than diazepam or phenytoin. The use of this drug reduced maternal deaths to 4.0% and the recurrence rate of convulsion was reduced by 52% and 67% when compared with diazepam and phenytoin, respectively.<sup>6</sup>

The use and apparent success of the magnesium sulfate regimen in the treatment of eclampsia is empirical, however.<sup>10,11</sup> The two most widely used regimens of magnesium sulfate administration are the intramuscular IM regimen popularized by Pritchard and the continuous IV regimen recommended by Zuspan.<sup>10,12</sup> Magnesium sulfate therapy has been associated with increased length of labor, an increased caesarean delivery rate, increased postpartum bleeding, increased respiratory depression, decreased neuromuscular transmission and maternal death from overdose.<sup>13</sup> Since 1998, the IM magnesium sulfate regimen has been popular in this hospital for the treatment of women with eclampsia.

### **Objectives**

- To find out the effectiveness of intravenous and intramuscular magnesium sulfate in management of eclampsia.
- To compare the side effects and complications of intravenous and intramuscular magnesium sulfate in management of eclampsia.

### **METHODS**

A total 100 eclampsia patients admitted in obstetrics and gynecology department of Nehru Chikitsalaya of B. R. D. Medical College, Gorakhpur, Uttar Pradesh, India. A total duration of this study was 12 months (from 1<sup>st</sup> August 2017 to 31<sup>st</sup> July 2018).

### **Inclusion criteria**

- Eclampsia patients admitted in B. R. D. Medical College, Gorakhpur with exception in that magnesium sulfate is contraindicated.

### **Exclusion criteria**

- Patients with known case of epilepsy
- In those where magnesium sulfate is contraindicated.

### **Methodology of the data collection**

After institutional ethical committee approval and obtaining informed consent from patients, 100 patients presenting with eclamptic fits reporting to the center that has been included in the study. The study has been conducted in the labor room of Nehru Chikitsalaya of B. R. D. Medical College, Gorakhpur, Uttar Pradesh for 12 months duration period. Patients who had been admitted with eclampsia in the labor room, a complete history, general examination, central nervous system, cardiovascular system, respiratory system and obstetrical examination has been done. Also, those patients who presented with history of previous seizure disorders and patients in whom magnesium sulfate was contraindicated (oliguria or renal failure, hypocalcaemia states, myasthenia gravis, cardiac conditions in particular conduction disorders or myocardial damage) which has been excluded and rest of patients were recruited for the study after informed written consent. Then, the recruited patients were randomly selected for intravenous or intramuscular regimen of magnesium sulfate.

### **Continuous intravenous infusion**

- 4 gm of loading dose of magnesium sulfate diluted in 100 ml of intravenous fluid (normal saline) administered over 15-20 minutes.
- 12 ampule magnesium sulfate in 1 L of normal saline solutions at 28 drops/ minute (total 24 hours), after 12 hours similar bottle of magnesium sulfate infusion. This provides MgSO<sub>4</sub>, at 1 gm/hr.
- Monitoring for magnesium toxicity:
  - Asses deep tendon reflexes periodically (4 hourly)
  - Measure urine output hourly
  - Respiratory rate hourly.
- Magnesium sulfate is discontinued for 24 hours after delivery or last convulsion which one is later.

### **Intermittent intramuscular injections**

- 4 mg of magnesium sulfate has been given as 20% solution intravenously at the rate not exceed 1 gm/minute.
- Follow promptly with 10 gm of 50% magnesium sulfate solution, one half (5 gm) injected deeply in the upper outer quadrant of both buttocks through the 3-inch-long gauge needle, if convulsion persists after 15 minutes which has been given 1 gm/minute.
- Every four hours there after 5gm of 50% solution of magnesium sulfate has been given deeply in outer upper quadrant of alternate buttocks but only after ensuring that:
  - Patellar reflex was present
  - Respiration were not depressed
  - Urine output of the previous 4 hours exceeded 100 ml.

- Magnesium sulfate discontinued in 24 hours after the delivery.

**Examination of patients**

- Abdominal examination, per vaginal examination (p/v) has been done and BISHOP score has been recorded and completed the investigations (ABG, ABO/Rh, Hb, TLC, DLC, HIV, HBsAg, HCV, CDRL, LFT, KFT, RBS, LDH, GBP with platelets count, prothrombin time and INR has been also taken. The patient has been chosen for caesarean section or induction of labor depending on maternal, fetal conditions and Bishop score.
- The patient who has been selected for induction of labor, continuous fetal monitoring by CTG and progression of labor has been recorded by partogram as per World Health Organization (WHO) guidelines.

- The vitals of all patients have been recorded continuously by multichannel monitor (pulse rate, blood pressure, respiratory rate, temperature, saturation, urine output).

**Statistical analysis**

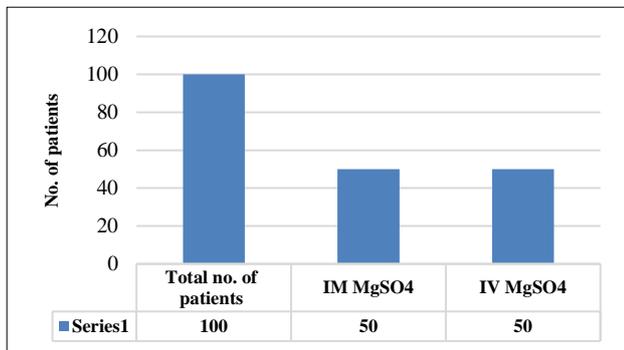
Statistical analysis of observations has been done by Chi-square test with p-value <0.05 has been considered in the study.

**RESULTS**

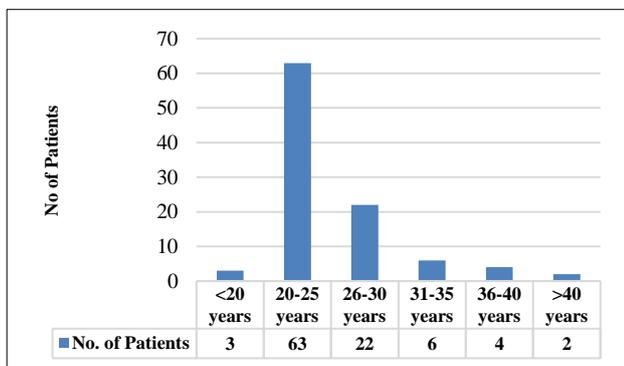
During the study period, the total number of deliveries was 3294 and total number of eclampsia was 328. Therefore, the incidence of eclampsia was 9.95% (Table 1). The total eclampsia patients have been selected in the present study and divided into two sub-groups, i.e. IM MgSO<sub>4</sub> groups and IV MgSO<sub>4</sub> groups (Figure 1).

**Table 1: Incidence of eclampsia during the study period.**

Time period	Total number of deliveries	Total number of eclampsia	Incidence of eclampsia
1 <sup>st</sup> August 2017 to 31 <sup>st</sup> July 2018	3294	328	9.95%



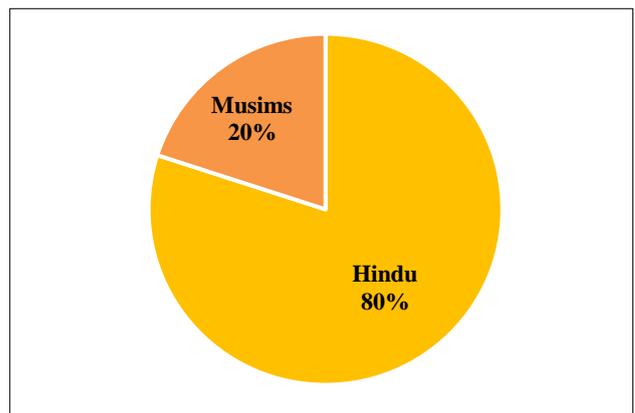
**Figure 1: Total patients of eclampsia selected in the study.**



**Figure 2: Age-wise distribution of patients presenting with eclampsia.**

The Figure 2 indicates the distribution of age groups among eclampsia patients. The maximum number of eclampsia patients (63%) among 20-25 years age groups.

Around 22% eclampsia patients were above 30 years of age and only 3% patients were accounted for the age group below 20 years.

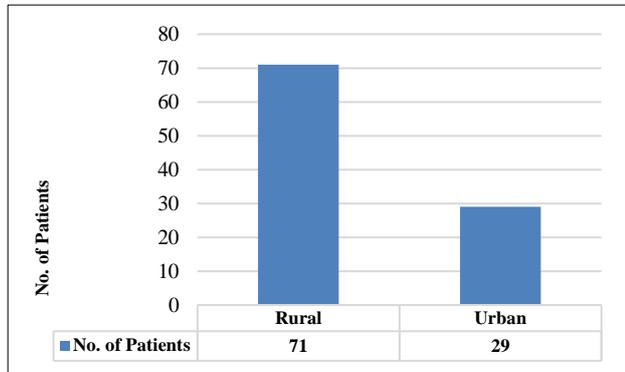


**Figure 3: Religion wise distribution of patients presenting with eclampsia.**

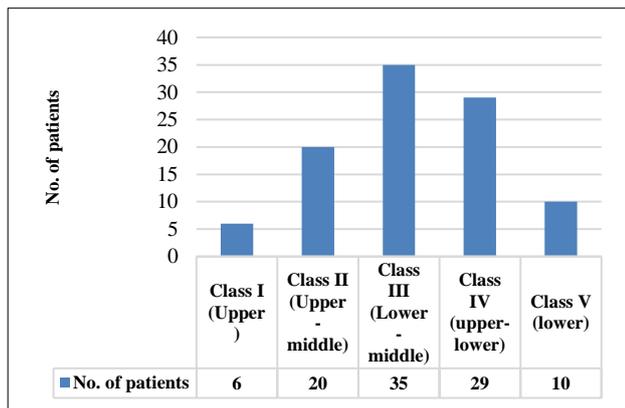
The Figure 3 explains the religion compositions among eclampsia patients. This shows that majority of eclampsia patients were Hindus that have been accounted for 80% whereas Muslims were accounted for only 20%.

The Figure 4 shows that the majority of eclampsia patients were belong to rural areas which have been accounted for 71% whereas remaining 26% belonged to urban areas.

The Figure 5 shows that the majority of eclampsia patients belonged to lower middle socio-economic status.

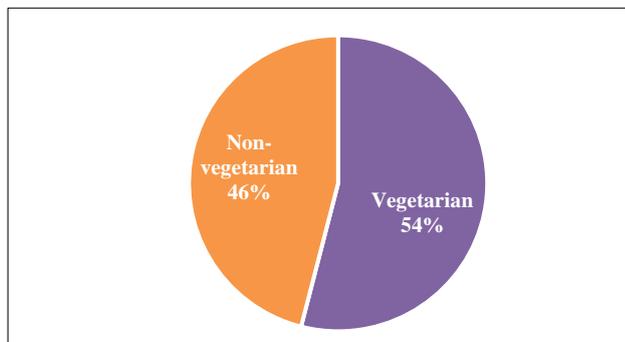


**Figure 4: Distribution of eclampsia patients by place of residence.**



**Figure 5: Distribution of patients presenting with eclampsia according to their socio-economic status (Kuppuswamy's classification).**

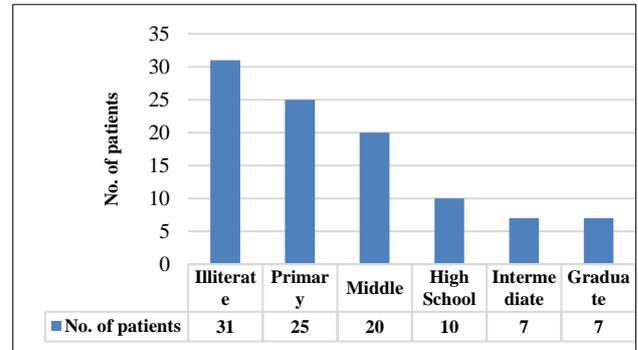
Around 35% belonged to class III and 29% belonged to class IV.



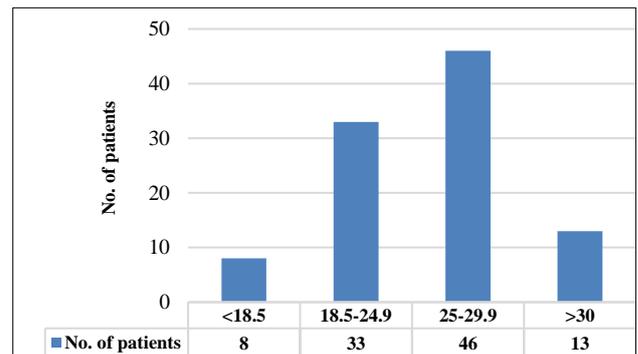
**Figure 6: Distribution of patients presenting with eclampsia according to their dietary habit.**

The Figure 6 shows that the majority of eclampsia patients were vegetarian which have been accounted for 54% whereas rest 46% were non-vegetarian.

The Figure 7 shows that the majority 31% eclampsia patients were illiterate, rest were educated up to primary 25%, middle class 20%, high school 10%, intermediate 7%, graduation 7%.

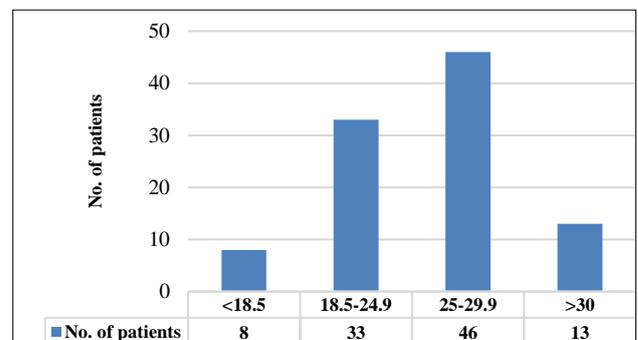


**Figure 7: Distribution of patients presenting with eclampsia according to education level.**



**Figure 8: Distribution of patients presenting with eclampsia according to their body mass index (BMI) taken days after delivery).**

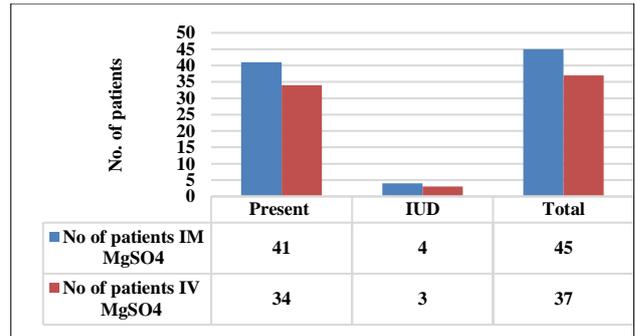
The Figure 8 shows the distribution of patients presenting with eclampsia according to their BMI. There were 59% eclampsia patients who had BMI >25 and rest 41% has BMI <25.



**Figure 9: Distribution of patients presenting with eclampsia according to the type of eclampsia.**

The Figure 9 represents that the majority of patients were 54%, presented as antepartum eclampsia, 28% as intrapartum and only 18% presented with post-partum eclampsia. The Figure 10 represents that the majority of patients 91.11% in IM group and 91.89% in IV MgSO<sub>4</sub> group presented with fetal heart sound and rest patients presented with intrauterine death.

Table 2 shows 16% patients in IM MgSO<sub>4</sub> group and 12% patients in IV MgSO<sub>4</sub> received recurrence of seizure after starting of treatment with p value 0.564, which is insignificant. Table 3 shows 26% patients in IM MgSO<sub>4</sub> group and 18% patients in IV MgSO<sub>4</sub> group had mild side effect of MgSO<sub>4</sub> but no patients in both the group had major side effects of MgSO<sub>4</sub>.



**Figure 10: Distribution of patients in IM MgSO<sub>4</sub> and IV MgSO<sub>4</sub> group patients according to fetal heart present during admission.**

**Table 2: Incidence of repeat seizure in IM MgSO<sub>4</sub> and IV MgSO<sub>4</sub> group in eclampsia patients after starting of treatment.**

	IM MgSO <sub>4</sub>		IV MgSO <sub>4</sub>		p-value
	No. of patients	Percentage	No. of patients	Percentage	
Repeated seizures	8	16%	6	12%	0.564
Total	50	100%	50	100%	

**Table 3: Comparison of IM MgSO<sub>4</sub> and IV MgSO<sub>4</sub> regimen according to their side effect of MgSO<sub>4</sub> in eclampsia patients.**

Side effects of MgSO <sub>4</sub>	IM MgSO <sub>4</sub>		IV MgSO <sub>4</sub>	
	No. of patients	Percentage	No. of patients	Percentage
Mild (flushing of skin, sensation of pain or warmth in arms nausea)	13	26%	9	18%
Severe (loss of reflexes, respiratory depression, muscles paralysis, blurred or double vision, slurred speech, cardiac conduction changes, cardiac arrest).	0	0%	0	0%
Total	50	100%	50	100%

**DISCUSSION**

Eclampsia is a life-threatening complication of hypertensive disorders of pregnancy. It is a major cause of maternal mortality, perinatal mortality and morbidity. They study has shown that incidence rate is very high as this medical institute is a tertiary center and the referral cases are higher. During the study period from 1<sup>st</sup> August 2017 to 31<sup>st</sup> July 2018, out of total 3294 deliveries, there was 241 cases were antepartum eclampsia and 87 cases were postpartum eclampsia (total eclampsia cases were 328). Thus, incidence of eclampsia is 9.95%. The study shown that incidence of eclampsia in eastern India has been reported with 3.2%.<sup>14</sup> Study has reported that incidence as high as 9% in their study at a tertiary center in Bangladesh.<sup>15,16</sup> In a study, there were 44 cases of eclampsia in the University hospital Institute of medical sciences of BHU (Varanasi), the incidence was reported

as 22/1000.<sup>17</sup> The total 100 eclampsia patients have been selected in the present study and divided into two sub-groups, i.e. IM MgSO<sub>4</sub> groups and IV MgSO<sub>4</sub> groups. The present study shown that the maximum number of patients belongs to 20-25 years age group where 22% eclampsia patients belonged to the age group 26-30 years and there were only 12% patients above 30 years and only 3% patients were below 20 years age. This low age is indicative of the fact that girls are still married at an early age particularly in low socio-economic status. Another study has reported that the mean age of eclampsia incidence is 18.5 years.<sup>13</sup>

The present study revealed that majority of eclampsia patients were Hindus that have been accounted for 80% whereas Muslims were accounted for only 20%. And the majority of eclampsia patients were belonging to rural areas which have been accounted for 71% whereas remaining 26% belonged to urban areas. The study also

explained that the majority of eclampsia patients belonged to lower middle socio-economic status. Around 35% belonged to class III and 29% belonged to class IV. Previous study has found that 100% cases of eclampsia belonged to low socio-economic status.<sup>18</sup> The majority 31% eclampsia patients were illiterate, rest were educated up to primary 25%, middle class 20%, high school 10%, intermediate 7%, graduation 7%. Previous study observed that maximum cases of eclampsia is illiterate group (37.61%) followed by primary education (27.08%) and high school (31.19%).

The distribution of patients presenting with eclampsia according to their BMI. There were 59% eclampsia patients who had BMI >25 and rest 41% has BMI <25. The present study revealed that majority of patients 91.11% in IM group and 91.89% in IV MgSO<sub>4</sub> group presented with fetal heart sound and rest patients presented with intrauterine death. This shows 16% patients in IM MgSO<sub>4</sub> group and 12% patients in IV MgSO<sub>4</sub> received recurrence of seizure after starting of treatment with p value 0.564, which is insignificant. The study revealed that there are 26% patients in IM MgSO<sub>4</sub> group and 18% patients in IV MgSO<sub>4</sub> group had mild side effect of MgSO<sub>4</sub> but no patients in both the group had major side effects of MgSO<sub>4</sub>.

## CONCLUSION

The study concludes that the pritchard regimen and IV continuous MgSO<sub>4</sub> regimen (Zuspan regimen) are equally effective in controlling maternal and fetal side effects which were equally low. Intramuscular injection of MgSO<sub>4</sub> is painful and the chances of abscess formation that's why compliance of intramuscular MgSO<sub>4</sub> is not very good in compared to intravenous infusion of MgSO<sub>4</sub>. The chances of Mg toxicity are more MgSO<sub>4</sub> regimen because of the dose required in IM MgSO<sub>4</sub> regimen is more (44 gm) that of IV MgSO<sub>4</sub> (28 gm).

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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