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COMPARATIVE STUDY OF INTRAVENOUS MAGNESIUM SULFATE VERSUS INTRAMUSCULAR MAGNESIUM SULFATE REGIMEN IN THE MANAGEMENT OF ECLAMPSIA

Shipra Misra[1], Shubham Surve[2], S.P. Singh[3], Ashima Das[4]

[1]*Associate Professor, Department of Obstetrics and Gynaecology, SHKM Government Medical College and Hospital, Nuh, Haryana, India.*
[2]*Secondary DNB, Department of Obstetrics and Gynaecology, SHKM Government Medical College and Hospital, Nuh, Haryana, India.*
[3]*Professor, Department of Obstetrics and Gynaecology, SHKM Government Medical College and Hospital, Nuh, Haryana, India.*
[4]*Professor, Department of Anatomy, SHKM Government Medical College and Hospital, Nuh, Haryana, India.*

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Corresponding Author:
Dr Shipra Misra,
Associate Professor, Department of Obstetrics and Gynaecology, SHKM Government Medical College and Hospital, Nuh, Haryana, India.
Email: doctorshipramisra@gmail.com

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A B S T R A

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. Magnesium sulphate is the ideal drug (recommended by WHO) for the prevention and treatment of eclampsia. Never the less, the best regimen for protection against eclampsia with minimal side effects remains to be established. Hence this study was designed to compare the efficacy and side effects of intravenous magnesium sulfate (Zuspan regimen) versus intramuscular magnesium sulfate (Pritchard regimen) in Eclampsia patients.

Materials and Methods: A prospective study was conducted on 120 patients of Eclampsia from December 2023 to December 2024.Included patients were allocated to IV group(Group A) and IM group(Group B) on alternate basis. IV group of patients received magnesium sulphate as per Zuspan regimen and the IM group received magnesium sulphate according to Pritchard regimen.

Results: The majority (41.7%) of study participants belonged to the age group of 21-25 years with the mean age of 25.68. There was no significant difference between the study groups (p = 0.49). Registration of pregnancy was done only in 34.2% cases while majority of the remaining 65.8% cases were unbooked, with no statistical significant difference (p-0.83). Most participants belonged to the rural areas (78.3%).The majority of participants were nulliparous (67.5%) with no significant difference between study groups (p = 0.19). Weight, height, and BMI were comparable between the two groups (p>0.05). The mean gestational age was similar in both the study groups, with no significant difference (p = 0.98). Convulsions were controlled with standard dose in 100% cases of IV regimen and in 90% cases of IM regimen. A statistical significant difference (p-0.03) was observed among the study groups in terms of control of convulsions. The prevalent mode of delivery was caesarean section noted in 56.7% cases of IV regimen and in 51.6% cases of IM regimen without statistical significant difference (p-0.09). Serum Magnesium levels were significantly higher in the IV group at all measured time points compared to the IM group (p<0.01). This indicates that IV regimen maintains higher and steadier magnesium levels in the blood compared to the IM regimen. Incidence of magnesium toxicity was observed to be slightly higher with IV dose. Loss of knee jerk was seen in 8.3% cases in IV group as compared to none in IM group, however this difference was not statistically significant (p-0.074). Local site complications like pain and discolouration were exclusively associated with IM injections with statistical significant difference (16.7% vs 0%; p<0.01). Though,

Feto-Maternal outcomes were poor but there was no significant difference between the two study groups.
Conclusion: IV regimen was significantly more efficacious in preventing recurrence of seizures in Eclampsia than IM regimen. If the facilities for IV infusion and frequent serum magnesium monitoring exists then Intravenous Magnesium Sulphate should be the preferred mode of treatment in Eclampsia patients. Though, IM regimen holds the disadvantage of painful intramuscular injections, but it has the advantage of great convenience in resource deficient setups, where pumps for IV infusion are not readily available and frequent monitoring of magnesium levels is not practical. However, multicentre studies are needed to reach a definitive conclusion regarding the most effective regimen for the treatment of eclampsia.
Keywords: Eclampsia, Zuspan, Pritchard, Magnesium sulphate.

INTRODUCTION

Incidence of eclampsia is one in 2000 deliveries in developed countries and one in 50 to 500 deliveries in developing countries.[1] Eclampsia accounts for about 12% of maternal deaths in the world and 8% of maternal deaths in India.[2,3] The World Health Organization recommends a 24-hour intravenous/intramuscular regimen of magnesium sulfate consisting of a loading dose and maintenance doses as the best medication for extreme pre-eclampsia and eclampsia prevention and management.[4,5,6,7] Collaborative trial in 1995 conclusively proved that Magnesium Sulphate is the preferred treatment for eclamptic fits.[8] Commonly used regimens are the IM MgSO4 (Pritchard regimen) and the IV MgSO4 (Zuspan regimen).Administration of MgSO4 to women should only take place in healthcare facilities that have sufficient personnel and clinical resources to monitor them for symptoms of magnesium toxicity in between doses.[9] Majority health centres in the world administer MgSO4 by continuous IV infusion because IV route for MgSO4 administration holds advantages in terms of easy administration, less painful, good compliance and well controlled mean magnesium levels. But in India most medical centers prefer IM administration as described by Pritchard because in resource deficient sets ups giving IV magnesium sulphate is not feasible due to non-availability of IV infusion sets and frequent monitoring of serum magnesium levels. Although magnesium sulphate is useful in preventing and treating eclamptic seizures, the ideal maintenance medication and therapeutic regimen remain uncertain.Hence, this study was conducted to assess the efficacy and safety of intravenous magnesium sulfate versus intramuscular magnesium sulfate in eclampsia cases attending the tertiary care hospital at one of the most backward district (Nuh) of India.

MATERIALS AND METHODS

A hospital based Prospective Comparative study was conducted from December 2023 to December 2024 to compare the efficacy and safety of intravenous versus intramuscular magnesium sulphate in Eclampsia cases.Secondary objective was to assess the fetal and maternal outcome. Inclusion Criteria: Women who had antepartum eclampsia /Intrapartum eclampsia/Postpartum eclampsia. Exclusion Criteria: Patient with Renal, Hepatic, Cardiovascular, Neurological disorder, Hypersensitivity to MgSO4 and Patient not responding to magnesium sulphate (recurrent convulsions). All women fulfilling the inclusion and exclusion criteria were alternately taken into group A followed by group B and so on till the desired sample size of 120 (60 patients in each group)was reached. All the patients included in the study were subjected to detailed history and thorough clinical examination including general physical, systemic and obstetrical examination. Investigations like ABO and Rh type, complete hemogram including peripheral smear, liver function tests, kidney function tests, coagulation profile, Fundus examination and urine analysis for proteinuria were done. Women in group A received Magnesium sulfate by Zuspen regimen with infusion pump:- Loading Dose 4 g of 20% MgSo4 IV over 20 minutes, Maintenance Dose: 1g/hour by controlled infusion pump till 24 hours after delivery or last convulsion whichever occurred last. Women in group B received MgSO4 by Pritchard regimen (IM) Loading Dose: 4 g of 20% MgSo4 slow IV over 10 minutes,10 g of 50% MgSo4 deep IM in buttocks followed by Maintenance Dose: 5 gm of 50% MgSo4 IM on alternate buttocks every 4 hrs, till 24 hours after delivery or last convulsion whichever has occurred last. In patients having recurrent convulsion within 30 min of MgSO4 administration, additional 2 gm of 20% MgSO4 IV dose was repeated. If the convulsion re-occurred and Antiepileptic's were started then these subjects were eliminated from the study. Patients were strictly monitored for MgSO4 toxicity by checking clinical parameters (Patellar reflex, Respiratory Rate, Urine output) every 4 hourly and by measuring serum Magnesium levels through ABG- baseline (before administration of magnesium sulfate) and at 4hrs, 8 hours,12hours,16hrs,20hrs and 24hrs.Obstetric management was done as per the departmental protocol. The definitive treatment of Eclampsia is termination of Pregnancy so delivery of baby was expedited by augmentation of labour or by emergency caesarean section. Caesarean section was performed only for obstetrical indications. Primary

Outcome Measures: Recurrence of convulsions, Signs of MgSO4 toxicity (Loss of deep tendon reflex, Decreased respiratory rate (<12/min), Urine output < 30 ml /hr). Serum magnesium levels. Secondary Outcome Measures: Feto-maternal outcomes- Antepartum Haemorrhage, Postpartum haemorrhage, HELLP syndrome, Disseminated Intravascular Coagulopathy, Maternal death, Low Apgar Score, NICU Admission, Neonatal mortality. Maternal and Fetal outcome measures were recorded on the structured data collecting proforma.

RESULTS

The IV Magnesium sulfate and IM Magnesium sulfate study groups showed no significant differences in Age, Residence, Booking status, Parity, ,Gestational age, providing a balanced foundation for evaluating the drug efficacy.

The majority of participants were in the age group of 21-25 years (41.7%). There was no significant difference between study groups (p = 0.49). Mean age of the females in the study was 25.68 years. Most participants were from rural areas (78.3%). The difference between the two groups was not statistically significant (p = 0.22).Registration of pregnancy was done in 34.2% cases while majority of the remaining 65.8% cases were unbooked (p-0.83). The majority of study participants were nulliparous (67.5%). There was no significant difference between study groups (p = 0.19).The mean gestational age was similar in both groups, with no significant difference (p = 0.98). There was no significant difference in the incidence of anaemia between groups (70% vs 65%; p = 0.697).

Table 1: Comparison of study groups as per mean anthropometry parameters.

Anthropometry	Group	N	Mean	SD	p- value
Weight in Kg	IM	60	56.52	7.63	0.10
	IV	60	58.78	7.33	
Height in cm	IM	60	154.28	5.14	0.85
	IV	60	154.13	3.81	
BMI in Kg/m2	IM	60	23.86	3.42	0.09
	IV	60	24.83	2.82	

Weight, height, and BMI were comparable between the two groups. No significant differences were observed (p>0.05).

Table 2: Comparison of study groups as per control of convulsions with standard dose.

Convulsion Controlled with Standard Dose	Regimen		Total
	IM	IV	
No	6	0	6
	10.0%	0.0%	5.0%
Yes	54	60	114
	90.0%	100.0%	95.0%
Total	60	60	120
	100.0%	100.0%	100.0%
p- Value - 0. 03			

Convulsions were controlled with standard dose in 90% cases of IM regimen and 100% cases of IV regimen. A significant difference was observed among study groups in terms of control of convulsion (p-0.03).

Table 3: Comparison of study groups as per mean magnesium levels.

Serum Magnesium Levels	Group	N	Mean	SD	p- value
Baseline	IM	50	1.89	0.30	0.91
	IV	50	1.88	0.29	
4 hrs	IM	50	5.43	0.78	<0.01
	IV	50	7.49	1.01	
8 hrs	IM	50	5.33	0.79	<0.01
	IV	50	7.33	1.00	
12 hrs	IM	50	5.23	0.81	<0.01
	IV	50	7.18	1.00	
16 hrs	IM	50	5.14	0.85	<0.01
	IV	50	7.04	1.01	
20 hrs	IM	50	5.05	0.89	<0.01
	IV	50	6.90	1.03	
24 hrs	IM	50	4.96	0.93	<0.01
	IV	50	6.76	1.05	

Before administration, both groups had similar magnesium levels. Serum magnesium levels were recorded for 24 hours after the initial dose. Magnesium levels were significantly higher in the IV group at all measured time points compared to the IM group (p<0.01). This indicates that IV regimen

maintains higher and steadier magnesium levels in the blood compared to the IM regimen.

Table 4: Comparison of study groups as per incidence of magnesium toxicity.

Magnesium Toxicity	Regimen		Total	p-value
	IM	IV		
Loss of Knee Jerk	0	5	5	0.074
	0.0%	8.3%	4.2%	
Oligouria	3	8	11	0.204
	5.0%	13.3%	9.2%	
RR< 12/ min	0	0	0	NA
	0.0%	0.0%	0.0%	
Local Site Complications (Pain/ Discolouration)	10	0	10	<0.01
	16.7%	0.0%	8.3%	

Incidence of magnesium toxicity was observed to be slightly higher with IV dose. Loss of knee jerk was seen in 8.3% cases in IV group as compared to none in IM group (p-0.074). Oliguria was seen in 13.3% cases and 5% cases of IV and IM group respectively (p-0.11). Local site complications like pain and discolouration were exclusively associated with IM injections (16.7% vs 0%; p<0.01).

Mode of delivery as caesarean section was noted in 51.6% cases of IM regimen and 56.7% cases of IV regimen. The difference was statistically non-significant (p-0.09).

Table 5: Comparison of study groups as per incidence of maternal complications.

Maternal Complications	Regimen		Total	p-value
	IM	IV		
APH	1	4	5	0.36
	1.7%	5%	3.3%	
PPH	6	8	14	0.77
	10.0%	13.3%	11.7%	
HEELP	3	4	7	0.13
	5.0%	6.7%	5.83%	
Pedal Edema	5	8	13	0.11
	8.3%	13.3.0%	10.83%	
DIC	2	3	5	0.27
	3.3%	5%	4.2%	
Mortality	0	2	2	0.48
	0.0%	3.3%	1.7%	

No difference was observed among study groups in terms of maternal morbidities like PPH (10% vs 13.3%), APH (1.7% vs 5%), HELLP (5% vs 6.7%) and DIC (3.3% vs 5%) and maternal mortality (0% vs 3.3%) in IM and IV group respectively.

Table 6: Comparison of study groups as per fetal complications.

Fetal Complications	Regimen		Total	p-value
	IM	IV		
APGAR < 5 (at 5 mins)	26	29	48	0.54
	43.3%	48.3%	37.5%	
NICU Admission	19	22	41	0.32
	38.8%	36.7%	34.2%	

No difference was observed among IM and IV study groups in terms of low APGAR at 5 min (43.3% vs 48.3%) and requirement of NICU admissions (38.8% vs 36.7%).

Table 7: Comparison of study groups as per prevalence of neonatal mortality.

Neonatal Mortality (NND, Still birth & IUD)	Regimen		Total
	IM	IV	
No	49	46	95
	81.7%	76.7%	79.2%
Yes	11	13	24
	18.3%	21.7%	20.0%
Total	60	60	120
	100.0%	100.0%	100.0%
p- value - 0.69			

No statistical significant difference was observed between IM and IV groups in terms of neonatal mortality (18.3% vs 21.7%; p-0.69).

DISCUSSION

Eclampsia is a major cause of maternal and perinatal mortality and morbidity. During our study period, 2041 deliveries were conducted at our institute. Total number of patients presenting with eclampsia were 200. The incidence of eclampsia was 9.8% in our study. The higher incidence of Eclampsia could be attributed to lack of access to healthcare facility, lack of resources, inappropriate diagnosis and delayed referral to higher centre in the rural settings of developing countries. The majority of study participants (41.7%) were in the age group of 21-25 years with no significant difference between the study groups (p = 0.49). This low age is indicative of the fact that the girls are still married at an early age particularly in low socioeconomic status due to illiteracy and lack of health awareness. In the study done by Kanti et al, the mean age in i.m.group and i.v.group was 25.7±4.24 years and 25.8±3.72 years respectively (p value=0.934).[10] Nautiyal et al. and Sharma et al.in their study too observed the mean age of the patients of eclampsia/ preeclampsia as 25.5 years and 25.9 years respectively in their study group.[11,12] In our study registration of pregnancy was done in 34.2% cases while remaining 65.8% cases were unregistered (p-0.83). Studies done by Agarwal et al and SahuL et al reported a higher percentage of unbooked cases 92% and 84% respectively.[13,14] In our study, majority of the patients were found to be primigravida (67.5%). This finding is close to the observation of study done by Ekel et al which reported a higher incidence 89% of nulliparity.[15] In our study the mean gestational age was similar in both the groups 35.69 vs 35.70, with no significant difference (p = 0.98).This finding is in concordance with the study done by Singh et al, which observed the mean gestational age in i.m.group and i.v.group as 35.92±1.65 weeks and 36.18±1.73 weeks respectively.[16] Similarly in a study done by Verma et al, the mean gestational age in i.m.group and i.v.group was 35 weeks and 36 weeks respectively.[17]

Singh S et al. in their study observed that 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.[16] Rashmi Verma et al also observed that incidence of recurrence of convulsions was comparable in both the groups, 8% patients in Group IM and 4% patients in Group IV developed convulsions after initiation of treatment.[17] These findings are not in agreement with the observations of our study which reported that recurrence of convulsions after standard dose of magnesium sulfate was among 10% and 0% cases of IM and IV regimen respectively.

The results of our study revealed that the IV group consistently exhibited significantly higher serum magnesium levels compared to the IM group at multiple time intervals post-treatment. Notably, at the 4-hour mark, the IV regimen resulted in a mean serum magnesium level of 7.49 mg/dL, while the IM group showed only 5.43 mg/dL ($p < 0.01$). This trend continued, with the IV group maintaining higher magnesium levels at 8, 12, 16, 20, and 24 hours post administration. A study done by Magee et al. demonstrated that IV magnesium sulfate administration leads to more effective serum magnesium levels and quicker achievement of therapeutic levels compared to IM administration, supporting its clinical efficacy in controlling seizures.[18] Similarly, the work of Sukumar et al. found that patients receiving MgSO4 intravenously had significantly higher magnesium levels at all measured intervals, which correlated with better control of seizures compared to those receiving the IM method.[19] The IV administration allows for immediate systemic distribution and absorption, resulting in faster therapeutic levels. In contrast, the IM route delays peak serum levels due to the variability in absorption rates from the muscle tissue. Kafle et al.discussed that intraintravenous magnesium administration leads to faster onset of action, which is particularly crucial in emergency settings such as eclampsia.[20] This perspective is supported by the study done by Bansal et al which concluded that IV regimen maintained significantly higher magnesium levels at all measured time points compared to the IM regimen leading to better convulsion control.[21]

In our study the incidence of magnesium toxicity was observed to be slightly higher with IV regimen. Loss of knee jerk was seen in 8.3% cases in IV group as compared to none in IM group (p-0.074). Oliguria was seen in 13.3% cases and 5% cases of IV and IM group respectively (p-0.11).However oliguria is an element of disease process and not an adverse effect of the magnesium use. Our findings are not in agreement with the study done by Vaibhav et al, which reported that the signs of impending toxicity were more common in IM group compared to IV group (39.02%IM/12.19% IV) but difference was not statistically significant.[10] Sipra et al also reported that (14%) patients in Group IM developed loss of knee jerk whereas only 1 (2%) patient in Group IV developed loss of knee jerk.[22] Shweta et al reported that loss of deep tendon reflex was present in 10/40 (25%) subjects of IM group and only in 4/40(10%) in IV group and this was statistically significant. P = (0.02298).[23] Local site complications like pain and discolouration was exclusively associated with IM regimen (16.7% vs 0%; p<0.01) during our study. Vaibhav et al also reported local site abscess in one case of eclampsia (IM group).[10] In our study mode of delivery as caesarean section was noted in 51.6% cases of IM regimen and 56.7% cases of IV regimen. Relatively, the high caesarean rate observed in our study was due to the fact that most of the high risk cases were late referrals due to lack of health awareness and resources. On the contrary, Vaibhav et al reported that the common mode of delivery was by

vaginal route (68.29%) in IV group and (75.60%) in IM group.[10]

In our study no statistical significant difference was observed among study groups in terms of maternal morbidities like PPH (10% vs 13.3%), APH (1.7% vs 5%), HELLP (5% vs 6.7%), DIC (3.3% vs 5%) and maternal mortality (0% vs 3.3%). Singh S et al. in their study observed that maternal outcome were poor in both the groups but were comparable and no significant differences were observed between the groups.[16] Chissell S et al.in a similar study observed no significant differences between groups with regard to clinical outcome of mothers.[25] Vaibhav Kanti et al. also observed that there was statistically no significant difference in maternal morbidities between the two groups.[10] During our study no significant difference was observed among IM and IV study groups in terms of neonatal findings like low APGAR at 5 min (43.3% vs 48.3%), requirement of NICU admissions (38.8% vs 36.7%) and neonatal mortality (18.3% vs 21.7%; p-0.69).These findings are in close agreement with the study done by Singh S et al. which reported that fetal outcome were poor in both the groups but were comparable and no significant differences were observed between the groups.[16] Chissell S et al.in their study also observed no significant differences between study groups with regard to clinical outcome of neonates.[24]

CONCLUSION

In the present study, we observed that in Eclampsia patients, IV route was able to maintain good therapeutic serum levels of magnesium and was significantly more efficacious in preventing recurrence of seizures than IM regimen. Local complications like pain and discolouration were exclusively present in IM group as compared to IV group. Maternal and fetal outcome were comparable in both the regimens. We thus conclude that Intravenous Magnesium Sulphate (Zuspan regimen) should be the preferred mode of treatment in Eclampsia, if facilities for IV infusion and frequent serum magnesium monitoring exists. However, in resource deficient setups where pumps for IV infusion are not readily available and frequent monitoring of magnesium levels is not practical, IM MgSO4 (Pritchard regimen) can be used.

Limitations: The study was conducted in a single hospital setting and included only 120 participants, which may limit generalizability. Multicentric studies are needed to reach a definitive conclusion regarding the most effective regimen for the treatment of eclampsia.

Ethical approval was obtained from the Institutional Ethical Committee before the commencement of study. Confidentiality of the data was maintained.

No conflict of interest.

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