

Comparison of Efficacy and Safety of Magnesium Sulphate in 12 Hours Versus 24 Hours After Last Fit in Eclamptic Patients

Effect of Mg.
Sulphate in
Eclampsia

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ABSTRACT

Objective: To compare the efficacy & safety of magnesium sulphate in 12 hours regime versus 24 hours regime after last fit in eclamptic patients.

Study Design: Randomized controlled trial study

Place and Duration of Study: This randomized controlled trial was carried out at Department of Obstetrics and Gynaecology, Unit-III, Nishtar Medical College/Hospital Multan from 01.06.2013 to 31.05.2014.

Materials and Methods: Total 120 patients with eclampsia were included. All patients were given 4g of magnesium sulphate (20% solution) intravenously slowly (15 mins) as loading dose. After receiving the loading dose randomization was performed by block design. So 60 patients for 12 hour regime while 60 patients for 24 hour regime (control group). In 12 hour regime group magnesium sulphate maintenance dose of 1g (20% solution) was given 1 hourly intravenously for 12 hours after last fit. In 24 hour regime group magnesium sulphate maintenance dose of 1g (20% solution) was given 1 hourly intravenously for 24 hours after last fit. Efficacy in shape of recurrence of fits, number of fits and safety in shape of pulmonary oedema, oliguria and loss of knee jerk reflex, Nausea and flushing was noted.

Results: Total 120 patients were studied falling in age group of 20 to 40 years. Eclampsia was most commonly occurring in young and primigravida patients. Majority of eclamptic patient had diastolic B.P 110 or > 110mmHg. None of patients in either group had eclamptic fit. Loss of knee jerk reflex seen in 5 patients in 24hrs regime group. Minor side effects were more commonly observed in 24hrs regime group.

(n=38) of the students were underweight and 36 % (n=21) were obese.

Conclusion: Twelve hours regime is equally effective as 24hours regime but with lesser side effects & so more cost effective. 12hours regime was observed to promote shorter hospital stay decreasing work load.

Key Words: Magnesium Sulphate, Eclampsia, Efficacy, Safety

Citation of article: Rao SI, Shaheen U, Hussna S. Comparison of Efficacy and Safety Of Magnesium Sulphate in 12 Hours Versus 24 Hours After Last Fit in Eclamptic Patients. Med Forum 2015;26(8):

INTRODUCTION

Eclampsia is a greek word meaning "To shine forth" or "flash of lightning".¹ Eclampsia is defined as the occurrence of fits in association with other clinical features of pre-eclampsia, excluding convulsions of co incidental neurological disorder such as epilepsy or metabolic & other organic causes.^{2,3}

Eclampsia is an important modifiable cause of maternal mortality and morbidity worldwide and in particular in countries of low socioeconomic conditions.^{4,5}

Eclampsia has become rare in developed countries but in low & middle socioeconomic countries where appropriate or prompt intervention are not available delay in seizer treatment results in hypoxic brain damage resulting in maternal and neonatal mortality and morbidity. According to world health organization

pre-eclampsia and eclampsia is the second leading direct cause of maternal morbidity and mortality following postpartum haemorrhage in under developed countries.⁶

In 1925 MgSO₄ was introduced into clinical practice to control fits in cases of eclampsia.⁷ It is an anti convulsion drug, approved by the WHO as cost effective and safe drug available for management of severe pre-eclampsia and eclampsia.⁸

Its exact mechanism of action is unclear. It is thought to treat eclampsia by producing cardiovascular and neurological effects, which are induced by its interaction with calcium homeostasis.⁹ According to some studies magnesium sulphate causes vasodilatation, protects blood brain barrier by decreasing cerebral edema so acts as cerebral anticonvulsant.¹⁰

MgSO₄ is generally administered parenterally in a loading dose by intravenous route or intramuscular route. It is followed by maintenance dose (by continuous IV infusion or intermittent IM injections). The two most commonly used regimens are the Zuspan

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regimen (a loading dose of 4 g IV, and maintenance dose of 1 g/hr IV) and the Pritchard regimen (loading doses of 4 g IV and 10 g IM or maintenance dose of 5 g IM/4hr).^{11,12}

Despite the strong evidence for the efficacy of magnesium sulphate, its safety is still questionable, particularly in clinical environments where the facilities for patient monitoring are limited. These concerns can limit the initiation and maintenance of MgSO₄ therapy for all women where indicated.^{13,14}

Ekele and his associates¹⁵ has reported in a study that a short dosage therapy of magnesium sulphate was effective in controlling fits in 92.6%. Sahu and his associates¹⁶ has also reported in a recent study that 12 hours therapy had almost same results like that of treatment with MgSO₄ 24 hours after last convulsion in terms efficacy and safety.

Tasnim and her associates¹⁷ has reported in a recent comparative study comparing 12 hours therapy versus 24 hour therapy that there was no recurrence of fits in both therapies while no difference was found regarding pulmonary edema and oliguria.¹⁷ The various studies performed on different dosage regimes have shown that 12 hours MgSO₄ therapy is equally effective versus 24 hours regime with simultaneous reduction in side effects. Our study was planned on basis of existing data with a hope that 12 hours regime will reduce the work load of tertiary care hospital and will prove more safe.

MATERIALS AND METHODS

This randomized controlled trial was conducted at Department of Obstetrics and Gynaecology, Unit-III, Nishtar Medical College/Hospital Multan. Total 120 patients with eclampsia were enrolled in study. All patients were given 4g of magnesium sulphate (20% solution) intravenously slowly (15 mins) as loading dose. After receiving the loading dose randomization was performed by block design. So 60 patients for 12 hour regime while 60 patients for 24 hour regime (control group). In 12 hour regime group MgSO₄ maintenance dose of 1g (20% solution) was given 1 hourly intravenously for 12 hours after last fit. In 24 hour regime group it was given as a maintenance dose of 1g (20% solution) per hour intravenously for 24 hours after last fit. Efficacy in shape of recurrence of fits, number of fits and safety in shape of pulmonary oedema, oliguria and loss of knee jerk reflex, Nausea and flushing was noted.

RESULTS

Of 120 patients 60 patients were assigned to each group, It was found eclampsia occurring more commonly in young (Table 1), nulliparous woman with first pregnancy and least frequent in multipara woman (Table 2). Moreover it was more common in antepartum patient as compared to intrapartum or post partum patient (Table 3). Majority of these patients had

diastolic B.P 110 or >110 mmHg (Table 4). Regarding maternal outcome in terms of recurrence of fits No patient in either group has fit. 5 patients in 24 hours group developed loss of knee jerk reflex. No patient in either group had respiratory or renal failure. Regarding minor side effects nausea and flushing was observed more commonly in group having 24 hrs regime of MgSO₄.

Table No.1: Percentage of patients according to age

Age (years)	12 Hours Group A	24 Hours Group B
20-24	33 (55%)	35(58.3%)
25-29	14(23.3%)	10(16.6%)
30-40	13(21.6%)	15(25%)

Table No.2: Frequency and percentage of gravidity & parity

Gravidity & parity	12 Hours Group A	24 Hours Group B
G ₁ P ₀	46(76.6%)	44(73.3%)
G ₂ P ₁	05(8.3%)	4(6.6%)
G ₃ P ₂ or more	09(15%)	12(20%)

Table No.3: Percentage of type of eclampsia

Type of eclampsia	12 Hours Group A	24 Hours Group B
Ante Partum	43(71.6%)	41(68.3%)
Intra Partum	03(5%)	2(3.3%)
Post Partum	14(23.3%)	17(28.3%)

Table No. 4: Percentage of blood pressure

Blood pressure	12 Hours Group A	24 Hours Group B
90 or Less	06(10%)	04(6.6%)
91-100	07(11.6%)	09(15%)
101-110	13(21.6%)	15(25%)
>110	34(56.6%)	32(53.3%)

Table No.5: Frequency of recurrent fits

Recurrent fits	12 Hours Group A	24 Hours Group B
Recurrent of Fits	0(%)	0(%)
No of fits	0(%)	0(%)

Table No.6: Frequency of major and minor side effects

Major side effects	12 Hours Group A	24 Hours Group B
Loss of Knee Jerk Reflex	0(%)	05(8.3%)
Respiratory Failure (Pulmonary Oedema)	0	0
Renal Failure (Oliguria)	0	0
Minor		

Table No.7: Frequency of minor side effects

Minor side effects	12 Hours Group A	24 Hours Group B
Nausea	1 (1.6)	7 (11.6%)
Flushing	3 (5%)	11 (18.3%)

DISCUSSION

Efficacy & Safety of magnesium sulphate in eclamptic women is time tested & supported by various studies. Eclampsia was found to be particularly common in young pregnant patients, in age range of 20-24 years (55-58.3%).¹⁸ It was found predominately a disease of primigravidas (73.3-76.6%). Our study also showed similar results.

Most of the patient with eclampsia developed fits in antepartum period (71.6%)¹⁹. The study contradicting to these finding was by Douglas.²⁰ Mostly patients (53.3 - 56.6%) had very high blood pressure at the time of their presentation suggesting it is a risk factor for development of fits but convulsions can also occur without previous history of hypertension.¹⁸ As Ekele and his colleagues¹⁵ reported that ultrashort regime of MgSO₄ was effective in controlling recurrent of fits in considerably high proportion of patients while in our study it is effective in 100% of cases. Regarding toxicity our study showed loss of knee jerk reflex in 5 patients (8.3%) and nausea in 7 (11.6%) and flushing in 11(18.3%) patients in group receiving 24hrs regime. No patient had loss of knee jerk reflex in 12 hours group. Nausea & flushing was seen only in 1 (1.6%) and 3 (5%) patients respectively in 12hours group. These results are supported by a study in india in 2010 in which low dose magnesium sulphate was associated with lower toxicity.²¹

CONCLUSION

Twelve hours regime is equally effective as 24hours regime but with lesser side effects & so more cost effective. 12hours regime was observed to promote shorter hospital stay decreasing work load.

Conflict of Interest: The study has no conflict of interest to declare by any author.

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