Original Article

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A Lower Dose of Mgso$_4$ for Control of Convulsions in Bangladeshi Eclamptic Women

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Abstract:

Introduction: Eclampsia is the third major cause of maternal death in Bangladesh contributing to 16 percent of total maternal mortality rate (MMR)[1]. Standard practice in eclampsia is urgent control of convulsions and prevention of its recurrence with the help of a suitable anticonvulsant, prompt initiation of general and obstetric care and control of hypertension if needed.

Methodology: This prospective cross-sectional analytic study was conducted in Dhaka Medical College Hospital (DMCH) eclampsia unit during August 2004 to January 2005 in order to determine whether 8 g of magnesium sulphate heptahydrate is sufficient in controlling convulsion and preventing recurrences in lighter Bangladeshi women instead of 10 g of magnesium sulphate ($MgSO_4$) as loading dose that is now being used. One hundred consecutive eclamptic patients who were eligible for magnesium sulphate therapy were assigned by lottery to receive either 8 g of magnesium sulphate heptahydrate ($MgSO_4.7H_2O$) (group A) or 10 g of magnesium sulphate (group B). The two groups were well-balanced and comparable on important characteristics.

Result: The results show that there was no significant difference between the two groups with respect to recurrent convulsion, time needed to regain consciousness and maternal and perinatal morbidities and mortalities.

Conclusion: The results reveal that 8 g magnesium sulphate heptahydrate is as effective as 10 g $MgSO_4$ (as loading dose) in management of eclamptic convulsion of Bangladeshi women. If 8 g of magnesium sulphate heptahydrate can be used, it will be more economic, painful intramuscular injections will be avoided and the risk of toxicity will be reduced.

Key words: Lower dose, Mgso$_4$. , Eclampsia.

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Introduction:

Eclampsia is a serious and relatively frequent complication of pregnancy bearing a high maternal and perinatal morbidity and mortality in this country.

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Eclampsia is the third major cause of maternal death in Bangladesh contributing to 16 percent of total maternal mortality rate (MMR) [1]. Standard practice in eclampsia is urgent control of convulsions and prevention of its recurrence with the help of a suitable anticonvulsant, prompt initiation of general and obstetric care and control of hypertension if needed.[2] Among the many anticonvulsants, magnesium sulphate (MgSO4) topped the list of all in terms of controlling convulsions and improving other secondary outcomes.[3] $MgSO_4$ was first suggested in 1906 and has been popular for over 68 years in the United States of America (USA) [4].

In Bangladesh, no institution has more experience than Dhaka Medical College Hospital (DMCH) where 800 to 1100 eclamptic patients are admitted every year In DMCH, $MgSO_4$ is being used as a routine anticonvulsant from the beginning of 1998, after the

commencement of its regular supply from the Central Medical Store. The dose schedule according to the guidelines published by the Eclampsia Working Group is being followed here. The dose schedule is 4 g intravenous (IV) and 3 g intramuscular (IM) in each buttock, a total of 10 g. as a loading dose, followed by 2.5 g IM every 4 hours in alternate buttock until 24 hours after delivery or the last fir. This is almost half the dose described by the Collaborative Eclampsia Trial. As the weight of the average Bangladeshi woman is light, this small dose appears to control convulsions effectively as established by different trials and is recommended by the Eclampsia Working Group is being followed here[5].

It has recently been suggested that an initial loading dose of $MgSO_4$ is sufficient to arrest convulsions[8]. On the basis of this suggestion and on observation, several studies were conducted in DMCH and in other institutions of Bangladesh proving the efficacy of combined intravenous and intramuscular loading dose regime of $MgSO_4$ for controlling convulsions and preventing its recurrence. In DMCH, only the loading dose of $MgSO_4$ is now being routinely used for controlling convulsions in eclampsia, and the dose is 4 g IV and 3 g IM in each buttock (total 10 g) for all patients. The maintenance dose therapy is not used unless required. DMCH is the largest tertiary level government hospital in Bangladesh where there is a separate eclampsia unit having some improved facilities $MgSO_4$ used in DMCH is an imported preparation supplied by the Central Medical Store, Dhaka (CMSD), the supply of which is inadequate many a time. On the other hand, the supply of Nalepsin (100 ml of 4% magnesium sulphate heptahydrate $MgSO_4.7H_2O$) marketed by a local pharmaceutical company (Beximco Infusion Ltd.) is average all over the country. According to the dose schedule by the manufacturer, a total of 2½ bags (4 g x 2+2 g = 10 g) are needed as loading dose and ½ bag is discarded (left out).

This study was planned to find out whether 8 g magnesium sulphate heptahydrate (2 bags of Nalepsin) is sufficient to control convulsions and to prevent recurrences in Bangladeshi eclamptic patients (as Bangladeshi women are lighter) and to compare its efficacy with 10 g of $MgSO_4$ (intravenous plus intramuscular) as a loading dose. If 8 g magnesium sulphate heptahydrate ($MgSO_4.7H_2O$) can be used, it will be more economic, painful intramuscular injections can be avoided and toxicity risk can be minimized.

The General aim of this study was to find out a lower dose of magnesium sulphate for Bangladeshi eclamptic women to control convulsion and prevent recurrence. The Specific objectives to find out the efficacy of 8 g (2 bags) of magnesium sulphate heptahydrate (Nalepsin) intravenous and compare it with 10 g magnesium sulphate (4 g intravenous and 6 g intramuscular) in controlling convulsion and preventing recurrence in Bangladeshi eclamptic women in terms of recurrences of convulsions, time required to regain consciousness, maternal morbidity and mortality and perinatal morbidity and mortality.

Materials and methodology:

This was a prospective cross-sectional analytic study. The study place was at the Eclampsia Unit, Dhaka Medical College Hospital (DMCH). The Period of study wassix months, from 1st August, 2004 to 31st January, 2005.From all the patients admitted to Eclampsia Unit, DMCH, during the study period, a total number of 100 consecutive patients admitted to Maternity Unit II were selected for the study and were grouped by lottery. Group A (n=50) received 8 g of magnesium sulphate heptahydrate (Nalepsin) and group B (n=50) received magnesium sulphate 10 g.

Women diagnosed with either antepartum or intrapartum eclampsia were included in the study. Women with severe morbidities, such as, CVA, HELLP, DIC, renal failure, pulmonary oedema and shock, women had known medical diseases, women had contraindications of magnesium therapy (e.g. oliguria, renal failure, absent knee jerk) and patients who received magnesium sulphate from outside were excluded from the study.

This study was undertaken at the Eclampsia Unit, DMCH, over a period of six months. A total of 100 consecutive women (who fulfilled the inclusion and exclusion criteria and were eligible for magnesium sulphate) admitted in the Maternity Unit II were selected for the study. Then by lottery, 50 patients were allocated to receive 8 g of magnesium heptahydrate (group A) and 50 patients were allocated to be treated with 10 g of magnesium sulphate. In all these cases, diagnosis of eclampsia was confirmed by history, physical examination and bedside urine examination for albumin. Before enrollment in the study, a written consent was taken from the guardian of the patient as many of the patients were semiconscious or unconscious. Permission was taken from the unit head of Maternity Unit II for using $MgSO_4$/magnesium sulphate heptahydrate as anticonvulsant and taking the patient in research work.

Dose schedule

Group A: Inj. Nalepsin 4 g (100 ml of 4% magnesium heptahydrate) intravenously over 20 minutes at the rate of 60-75 drops per minute followed by Inj. Nalepsin 4 g (100 ml) intravenous infusion at the rate of 25 drops per minute in the 1st hour. No maintenance dose was given unless there was recurrence of convulsion. If recurrence occurred, the patient was put on maintenance therapy of Inj. Nalepsin 2-4 g (50-100 ml) intravenously over 20 minutes followed by 1-2 g per hour at 6-12 drops per minute for 24 hours with a maximum dose of 40 g.

Group B: $MgSO4_4$ 4 g (8 ml) dissolved in 12 ml distilled water given intravenously and slowly over 15-20 minutes followed by 3 g (6 ml) deep intramuscularly in each buttock. No maintenance dose was given unless there was recurrence of convulsion. For recurrence of convulsion, a further intravenous injection of $MgSO_4$ 2.5 g was given followed by maintenance therapy of 2.5 g intramuscularly every 4 hour in alternate buttock for 24 hours after the last convulsion or delivery.

Monitoring during the administration of $MgSO_4$ in this trial was clinical and was based on ensuring that respiration was not depressed, the patellar reflex was present and renal function was adequate. There was no monitoring of serum magnesium level. Urine output was measured every hour for all women. Every 15 minute, patellar reflexes and respiratory rate were checked and recorded.

Data for each individual subject were recorded on a predesigned data collection sheet. Collected data were compiled and appropriate statistical analyses were done using computer based software, Statistical Package for Social Science (SPSS). Results were expressed as number and percentage and/or mean ± SD as applicable. Comparison between groups were made by Chi-square test or unpaired Student's'‘t' test as appropriate. Probability value <0.05 was taken as minimum level of significance.

Results:

Table-I. Patients' profile on admission.

Parameters	Group A (n=50) No. (%)	Group B (n=50) No. (%)	P value
Age (years)			>0.50[ns]
≤20	31 (62.0)	27 (54.0)	
21-25	10 (20.0)	12 (24.0)	
26-30	4 (8.0)	7 (14.0)	
> 30	5 (10.0)	4 (8.0)	
Mean ± SD	22.02+5.39	22.40 ±4.78	>0.50[ns]
Range	15-40	18-37	
Gravidity			>0.50[ns]
1	39 (78.0)	41 (82.0)	
2-4	10 (20.0)	7 (14.0)	
>4	1 (2.0)	2 (4.0)	
Mean ± SD	1.48±1.05	1.36±0.94	>0.50[ns]
Range	1-5	1-5	
Socioeconomic status			>0.10[ns]
Low	31 (62.0)	35 (70.0)	
Middle	19 (38.0)	15 (30.0)	
Antenatal care (ANC)			>0.50[ns]
Regular	11 (22.0)	13 (26.0)	
Irregular	18 (36.0)	21 (42.0)	
None	21 (42.0)	16 (32.0)	
Gestational age (weeks)			>0.50[ns]
≤32	10 (20.0)	6 (12.0)	
33-37	20 (40.0)	23 (46.0)	
>37	20 (40.0)	21 (42.0)	
Mean ± SD	35.66±3.77	36.18±3.53	>0.10[ns]
Range	24-43	26-43	
Type of eclampsia			>0.10[ns]
Antepartum	46 (92.0)	42 (84.0)	
Intrapartum	4 (8.0)	8 (16.0)	

Chi-square test/Unpaired Student's't' test
ns = Not significant

Table-I shows features of group A (Nalepsin 8 g) and group B ($MgSO_4$ 10 g) patients on admission. Age, gravidity, socioeconomic status, antenatal care, gestational age and type of eclampsia did not reveal any significant difference between the two groups.

Table-II.Physical and laboratory findings

Parameters	Group A (n=50) No. (%)	Group B (n=50) No. (%)	P value
Level of consciousness			>0.50[ns]
Conscious	14 (28.0)	13 (26.0)	
Semiconscious	25 (50.0)	27 (54.0)	
Unconscious	11 (22.0)	10 (20.0)	
Diastolic bloodpressure (mmHg)			>0.05[ns]
Mean ± SD	106.00 ±13.25	101.30 ± 13.09	
Range	50-130	70-140	
Lungs			>0.50[ns]
Clear	44 (88.0)	44 (88.0)	
Crepitation	6 (12.0)	6 (12.0)	
Knee reflex			>0.50[ns]
Normal	46 (92.0)	48 (96.0)	
Brisk	3 (6.0)	2 (4.0)	
Clonus	1 (2.0)	0	
Respiratory rate (breath/min)			>0.50[ns]
Mean±SD	24.52±6.23	24.86±8.09	
Range	14-38	16-44	
Proteinuria			>0.10[ns]
Nil	5 (10.0)	6 (12.0)	
Mild	16 (32.0)	13 (26.0)	
Moderate	3 (6.0)	10 (20.0)	
Severe	26 (52.0)	21 (42.0)	

Chi-square test/Unpaired Student's't' test
ns = Not significant

Table-II shows physical and laboratory findings of the study patients, such as level of consciousness, diastolic blood pressure, status of lungs, knee reflex, respiratory rate and presence of proteinuria. None of the parameters showed statistically any significant difference between groups.

Table-III. Findings related to convulsion

Parameters	Group A (n=50)	Group B (n=50)	P value
Number of convulsions			>0.10[ns]
≤5	42 (84.0)	46 (92.0)	
6-10	7 (14.0)	2 (4.0)	
>10	1 (2.0)	2 (4.0)	
Mean ± SD	3.80 ± 2.21	3.60 ± 2.13.	>0.50[ns]
Range	1-12	1-11	
Time lapse (hours)			
Convulsion and treatment.			
Mean ± SD	6.54 ± 5.35	6.22 ± 4.45	>0.50[ns]
Range	0.50-27.00	0.75-22.25	
Convulsion and delivery			
Mean ± SD	14.73 ± 8.54	13.61±8.29	>0.50[ns]
Range	3.5-36.0	4.0-48.0	
Recurrence of convulsion			>0.50[ns]
Yes	7 (14.0)	8 (16.0)	
No	43 (86.0)	42 (84.0)	

Chi-square test/Unpaired Student's 't' test
ns = Not significant

Table-III shows findings related to convulsion of group A and group B patients. None of the parameters showed statistically any significant difference between the two groups.

Table-IV. Mode of delivery

Parameters	Group A (n=50) No. (%)	Group B (n=50) No. (%)	P value
Mode of delivery			
Vaginal	17 (34.0)	27 (54.0)	
Normal	15 (88.2)	24 (88.9)	
Forceps	2 (11.8)	1 (3.7)	
Ventouse	0	2 (7.4)	
			<0.05*
LSCS	33 (66.0)	23 (46.0)	
Malpresentation	9 (27.3)	5 (21.7)	
Fetal distress	12 (36.4)	10 (43.5)	
CPD	1 (3.0)	0	
Cervical dystocia	6 (18.2)	3 (13.0)	
Others	5 (15.2)	5 (21.7)	

Chi-square test
* = Significant

Table-IV shows mode of delivery. Significant number of babies were delivered vaginally in group B (54%) and by LSCS in group A (66%). In maximum number of cases normal vaginal delivery was achieved in both group A and group B (88.2% and 88.9%). In case of LSCS deliveries, fetal distress was the main cause in both the study groups (36.4% and 43.5%).

Table -V. Fetal outcome

Parameters	Group A No. (%)	Group B No. (%)	P value
Fetal outcome	(n = 50)	(n = 50)	<0.05*
Livebirth	46 (92.0)	39 (78.0)	
Stillbirth	4 (8.0)	11 (22.0)	
Condition of baby	(n = 46)	(n = 39)	>0.10ns
Healthy	15 (32.6)	10 (25.6)	
Asphyxiated	31 (67.4)	29 (74.4)	
Referral to NICU	(n = 46)	(n = 39)	>0.05ns
Yes	16 (34.8)	7 (17.9)	
No	30 (65.2)	32 (82.1)	
Birth weight (kg)	(n = 46)	(n = 39)	>0.10ns
<2.5	28 (60.9)	17 (43.6)	
2.5 - 3.5	18 (39.1)	22 (56.4)	
Mean ± SD	2.5 ± 0.53	2.37 ± 0.55	>0.05ns
Range	10.0 – 3.2	1.0 – 3.2	
Final neonatal outcome	(n = 50)	(n = 50)	>0.05ns
Alive	42 (84.0)	38 (76.0)	
Stillbirth	4 (8.0)	11 (22.0)	
Neonatal death	4 (8.0)	1 (2.0)	

Chi-square test/Unpaired Student's't' test
ns = Not significant, *= Significant

Table-V shows that significantly higher number of babies were born alive in group A (92%) compared to group B (78%). There were 4 (8%) stillbirths in group A and 11 (22%) in group B. Other parameters like condition of baby, referral to NICU, birth weight and final outcome did not show statistically any significant difference between the groups.

Table-VI. Time required to regain consciousness

Consciousness	Group A (n=36) No.(%)	Group B (n=37) No.(%)	P value
Time required to regain consciousness (hours)			
<4	5 (13.9)	6 (16.2)	
4-8	3 (8.3)	5 (13.5)	
>8-12	7 (19.4)	9 (24.3)	
> 12-24	11 (30.6)	10 (27.0)	
> 24	8 (22.2)	5 (13.5)	
			>0.50ns
Remained unconscious (died)	2 (5.6)	2 (5.4)	
	(n=34)	(n=35)	
Mean±SD	15.93 ±11.27	15.26±10.94	>0.50ns
Range	0.50-60.00	0.50-48.00	

Chi-square test/Unpaired Student's't' test
ns = Not significant

NOTE: 14 patients of group A and 13 patients of group B were conscious at the time of admission to hospital.
Time required to regain consciousness shows almost equal distribution between the two groups. Two women each (4%) from group A and group B never regained consciousness and ultimately expired (Table-VI).

Table-VII. Maternal outcome

Parameters	Group A (n=50) No. (%)	Group B (n=50) No. (%)	P value
Morbidity			>0.50[ns]
Pulmonary oedema	8 (16.0)	7 (14.0)	
CVA	2 (4.0)	1 (2.0)	
Renal failure	1 (2.0)	4 (8.0)	
Hepatic failure	2 (4.0)	2 (4.0)	
PPH	2 (4.0)	2 (4.0)	
Obstetric shock	0	2 (4.0)	
Others	2 (4.0)	2 (4.0)	
None	31 (62.0)	30 (60.0)	
Mortality			>0.50[ns]
Yes	2 (4.0)	2 (4.0)	
No	48 (96.0)	48 (96.0)	

Chi-square test
ns = Not significant

Maternal morbidities and mortality were almost equally distributed between the groups (Table-VII).

Discussion:
Eclampsia is a multisystem disorder with complex pathogenesis, which is not completely understood[4]. Control of convulsion and prevention of recurrences is one of the most important part of management of eclampsia. There is now conclusive evidence that the best available treatment for women who have had an eclamptic fit is magnesium sulphate[3].

Bangladesh is a developing country where the incidence of eclampsia is very high, and eclampsia remains the leading cause of death in large tertiary level hospitals like Dhaka Medical College Hospital (DMCH) for many years[52]. $MgSO_4$ is being used as a routine anticonvulsant in different obstetric centres of Bangladesh since 1998, but the dose that is recommended by Bangladesh Eclampsia Working Group is much lower than that used in the Eclampsia Collaborative Trial (10 g loading dose compared to 14 g and 25 g instead of 5 g as maintenance dose)[5]. The lower dose is chosen considering the smaller size of the Bangladeshi women and concerns about toxicity in circumstances in which measuring serum magnesium levels would be difficult[12]. Its efficacy in controlling convulsions and preventing recurrences have been established in many prospective studies[6,12]. Recently it has also been suggested that an initial loading dose of $MgSO_4$ is sufficient to arrest convulsions[4,8].

$MgSO_4$ is not an innocuous drug. Its therapeutic and toxic dose is very close. It is necessary to monitor the patients who are receiving the medication to prevent serious side effects. Duley[53] recommended frequent (every 5-10 minutes) monitoring during the first two hours of therapy for intravenous regimen. But the low dose (Dhaka) regimen, that is being used in Bangladesh has been found to be associated with serum levels that is well below the toxic levels[12].

Bangladeshi women are usually lighter, and the mean body weight of the pregnant women is 53 kg[54]. If a much lower dose can be used, the risk

of toxic effects will be reduced. This study was conducted with a view to use 8 g of magnesium heptahydrate (2 bottles of Nalepsin) as a loading dose in the management of convulsion in eclamptic patients, and the observations were compared to 10 g of magnesium sulphate. This will have the advantages of being more economic and having reduced risk of toxicity. Moreover, the painful intramuscular injections can be avoided.

This study was conducted in DMCH on 50 patients as control (receiving 10 g of magnesium sulphate) and 50 patients as cases (receiving 8 g of magnesium heptahydrate). The two groups were well balanced and comparable on important characteristics. The overall outcome was measured in terms of recurrent convulsions, time needed to regain consciousness, maternal and perinatal morbidity and mortality.

There was no significant difference in age, gravidity, socioeconomic condition, antenatal care, gestational age and type of eclampsia between the two groups. The average age of the cases was 22.20±5.39 years and of the controls was 22.40±4.78 years. Most of the patients belonged to ≤20 years of age, were primigravida, coming from low socioeconomic condition, having no or irregular antenatal care and were between 33-37 weeks of gestation. These findings are consistent with many national and international studies[6].

Table-II is showing the physical and laboratory findings of the study patients and controls. The diastolic blood pressure was 106.00±13.25 mmHg among the cases compared to 101.30±13.09 mmHg among the controls. There was no statistically significant difference between the two groups regarding level of consciousness, diastolic blood pressure, status of the lungs, knee reflex, respiratory rate and proteinuria. One of the important observation was that many patients (72% vs 74%) were not conscious.

Table-III shows findings related to convulsion of group A and group B patients. None of the parameters were statistically significant. The mean convulsion to treatment interval was 6.54±5.35 versus 6.22±14.45 hours, and convulsion to delivery interval was 14.73±8.54 versus 13.61±8.29 hours. Only 14 percent patients of group A and 16 percent of group B experienced recurrent convulsion.

Different modes of delivery have been compared in Table-IV. The Caesarean section rate was significantly higher (66%) among patients of group A, whereas it was 46 percent among patients of group B. As the obstetric indications (rather than eclampsia itself) like, malpresentation, fetal distress, cephalopeivic disproportion, cervical dystocia, etc. were more in group A, that is why the incidence of LSCS was more in group A than group B.

Fetal outcome is summarized in Table-V showing that significantly higher number of babies were born alive in group A (92%) compared to group B (78%). There were 8 percent stillbirths in group A and 22 percent in group B. Other parameters like condition of the baby, referral to NICU, birth weight and final outcome were comparable statistically and did not show statistically any significant difference between the groups. Higher number of livebirth may be related to the higher Caesarean section rate among patients of group A.

Time required to regain consciousness shows almost equal distribution between the two groups. Four percent patients from group A and the same number of patients from group B were brought unconscious and never regained consciousness and ultimately expired. Maternal morbidities and mortalities were almost equally distributed between the groups (Table-VII). Pulmonary oedema was the commonest complication associated with the disease.

This study conducted in DMCH reflects a fact that 8 g magnesium sulphate heptahydrate ($MgSO_4.7H_2O$) used intravenously as a loading dose is as effective as 10 g of magnesium sulphate ($MgSO_4$) intravenous and intramuscular (loading dose) in controlling convulsion and preventing recurrence in eclampsia patients of Bangladesh. However, a large scale study needs to be conducted to reach to a definitive conclusion.

Conclusion:

The definition of a desired therapeutic dose of Bangladeshi women is yet to be determined. This study was designed to compare the efficacy of 8 g of magnesium sulphate heptahydrate with 10 g of $MgSO_4$ as a loading dose. A total of 100 patients were enrolled for the study, among which 50 were allocated for 8 g magnesium sulphate heptahydrate – $MgSO_4.7H_2O$ (group A) and 50 were allocated for 10 g of $MgSO_4$ (group B) as loading dose. There was no significant difference between the two groups with respect to age, socioeconomic condition, gestational age and important physical and laboratory findings. The outcome was measured in terms of recurrent convulsion, time needed to regain consciousness, maternal and perinatal morbidities and mortalities. The results reveal that 8 g magnesium sulphate heptahydrate is as effective as 10 g $MgSO_4$ (as loading dose) in management of eclamptic convulsion of Bangladeshi women. If 8 g of magnesium sulphate heptahydrate can be used, it will be more economic, painful intramuscular injections will be avoided and the risk of toxicity will be reduced.

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