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Original Research Article

Efficacy and Feto-Maternal Outcome with Low Dose Dhaka Regimen Vs Conventional Dose Pritchard's Regimen of Magnesium Sulphate in the Management of Eclampsia: A Comparative Study

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Conflict of interest: Nil

Abstract:

Background & Objectives: Worldwide with the introduction of magnesium sulphate, the morbidity and mortality associated with eclampsia has been reduced significantly. Inspite of its excellent anticonvulsant property, it is still underutilized because of lack of proper training among the health staff as well as over the concern of potential adverse effects. In spite of having numerous regimens to administer Magnesium Sulphate, Pritchard regimen remains the most popular regimen till date. However, magnesium toxicity has limited its use especially in the low resource setting. The current study was undertaken to find out whether lowering the dose than conventional Pritchard regimen's dose can produce desired effect.

Methods: Observational comparative study conducted on 64 eclampsia patients from January 2019 to June 2020 at Agartala Government Medical College, Tripura, India. The patients under study were divided into two equal groups, each group comprising of 32 numbers of patients. One group received low dosage regimen and another Pritchard regimen. The analysis was done for ascertaining the optimum dose of MgSO4 required to control seizure's as well as recurrence of seizure after the loading dose, magnesium toxicity and feto-maternal outcomes.

Results: The mean dosage of MgSO4 to control seizures and its difference in both the groups was statistically significant (P value <0.05). After loading dose seizures were controlled in 96.88% of the cases receiving low dose regimen and 100% in Pritchard regimen. Only 3.13%cases of low dose regimen group had recurrence of seizure. The Feto-maternal outcome was comparable in both the groups.

Interpretation and Conclusion: In this study, the dose required to control seizures was 40% lower than the standard Pritchard regimen. Low-dose MgSO4 therapy had similar efficacy as Pritchard therapy in controlling the convulsive episodes and in prevention of repeat convulsions, with minimal side effects, especially in rural women of lower socioeconomic status and lower bodyweight.

Keywords: Eclampsia, low-dose, Magnesium sulphate, Pritchard's regime, Recurrent convulsion, Toxicity.

Introduction

Eclampsia is a severe life-threatening complication of the hypertensive disorder of pregnancy. Worldwide approximately 50,000 deaths occur per year due to eclampsia.[1]According to WHO,12% of all maternal deaths results from eclampsia.[2]Prevalence of eclampsia in India is10.3%.[3]The emergent treatment in eclampsia is to control seizures using anticonvulsant and also to prevent the recurrences. The only definitive treatment is termination of pregnancy. In 1955, Dr. J. A. Pritchard at Parkland Hospital, USA, used magnesium sulphate to arrest convulsions in cases of eclampsia.[4]There is reduction of endplate sensitivity to acetylcholine in peripheral myoneural junction which reduces the neuromuscular irritability. It also blocks N. methyl D aspartate and Calcium channels thus preventing seizure genesis and cerebral vasospasm respectively.[5] The narrow therapeutic index of magnesium sulphate demands critical withholding of the drug to prevent possible detrimental side effects like maternal hypotension, renal, neuromuscular dysfunction,

respiratory depression, respiratory arrest. [6] Disproportionate anxiety of these adverse effect leads to constrained use of the drug in many poverty–stricken nations. In many studies it has been proposed that the dosage of MgSO4 can be decreased in women with a low BMI. [7]To get the desired response with lesser dose of magnesium sulphate for controlling the convulsion in eclamptic patient without life threatening adverse effects is a major challenge. The suitable dose of magnesium sulphate and its therapeutic range have always been debated. As the average bodyweight of the women of Indian subcontinent is much lower than their western counterparts, many low-dose magnesium sulphate treatments were reported appropriate for the patient's profile.[8]

In the recent past a handful of studies were done in the Indian subcontinent to formulize the best magnesium sulphate regimen in the treatment of eclampsia.[9,10]Therefore, in the above line of research, this study was outlined to compare the efficacy between the low dose regimen and conventional Pritchard regimen with comparable feto-maternal outcome following the respective treatments.

Objectives

1) To compare the optimum dosage of magnesium sulphate required to control the seizures in eclampsia among subjects distributed in two separate groups receiving either the conventional or low dose regimen.
1. To estimate and compare the number of subjects developed recurrence (convulsion after 30 minutes of loading dose)
2. To assess and compare the fetal outcome (Still birth, Apgar score, NICU admission) when the eclamptic mother received either of the both regimens
3. To assess and compare the maternal outcome between these two groups of subjects by identifying and comparing number of subjects experienced adverse effects of magnesium sulphate (Respiratory depression, loss of deep tendon reflex and cardiac arrhythmia, Post-partum hemorrhage and death).

Materials & Methods:

From January 2019 to June 2020, this observational comparative study was conducted in the Department of Obstetrics & Gynaecology of Agartala Government Medical College, India.

Eclampsia was diagnosed when generalized tonic-clonic seizures with or without raised blood pressure and proteinuria (by dipstick) occurred after 20 weeks' gestation without pre-existing seizure disorder. All consecutive patients with eclampsia (antepartum/ Intrapartum/postpartum) admitted to the labor room and/or wards were included in the study after consent. Consent for unconscious patients was obtained from the patient's relatives. Patients with a history of epilepsy, heart block, kidney disease, or other seizures disorder, patients already received magnesium sulphate or other anticonvulsants prior to hospital admission were excluded. Those with eclampsia were kept in the eclampsia room and primary supportive care provided.

After stabilization, booking history of the antenatal period following the days to the convulsion has been noted. Careful general and physical examination, systemic examination, abdominal and pelvic examination, Bishop's scoring, laboratory tests, fundoscopy were performed.

Dosage, Regimen:

Group 1 (Control) Pritchard regimen: Loading dose - MgSO4 4gm intravenous (20% solution) for 4-5 minutes and 10gm (50% solution) intramuscular (5gm in each buttock).

Maintenance dose: 5gm intramuscular alternate buttock every 4 hours for the next 24 hours after delivery or the last seizure, whichever occurs later.[11]

Group 2 (study) Loading dose - MgSO4 4gm intravenous diluted (as above) over 4-5 minutes and 6gm intramuscular (3gm in each buttock). Maintenance dose: 2.5gm in alternate buttock every 4 hours for the next24 hours after delivery or the last seizure, whichever occurs later.[12]

Recurrent or repeat seizures: If seizures occurred 30 minutes after the initial dose, this was referred to as seizure recurrence.[13]

Rescue therapy: - The recurrence of the convulsion was treated with half of the initial intravenous loading dose i.e.,2 gm 20% MgSO4 and rest of the dosage continued as of routine regimen.[14]

Failure of Regimen: If recurrent seizures were not controlled after two additional 2 gm of 20% MgSO4 intravenously, the cases were labeled as a failure of low dose regimen and the case was transferred to the conventional regimen.[14]Input & urine output chart was maintained for each patient by an indwelling catheter. The absence of deep tendon reflexes (knee jerk), urine output, and respiratory rate were checked each time before the maintenance dose is administered. Maintenance doses were withheld if there was absent deep tendon reflex or decreased urine output (<100 mL in the last 4 hours) and shallow breathing (respiratory rate< 16/min). If magnesium sulphate toxicity was found, rest of the regimen were withheld and 10 mL of 10% calcium gluconate administered intravenously slowly over 10 minutes as an antidote. The ventilator support was given in cases with respiratory failure.

Study Design: Observational cross-sectional study.

Study Population:

All cases of eclampsia admitted via emergency in the Department of Obstetrics and Gynecology, Agartala Govt. Medical College fulfilling the inclusion criteria of the study.

Sample Size Calculation:

n= required sample size.
$\mathbf{Z_{\alpha/2}}$= Value of the standard normal variate at 5% of type 1 error (P <0.05). So $\mathbf{Z_{\alpha/2}}$ is 1.96
p=Expected proportion in population based on previous studies.
Seizure recurrence rate=2% (p=0.02) [15]
d=Absolute margin of error or precision =5% (0.05)

Calculation of sample size done with precision/ absolute error 5% and at type 1 error of 5%.

$n = Z_{\alpha/2}^2 . p(1-p)d^2$
$n=(3.84 \times 0.02 \times 0.98) \div 0.0025$
$n= 0.075264 \div 0.0025 = 30.10$

Thus, n comes out as 30 in each group. For two groups (1:1), n=30x2=60 eclamptic patients. Now with a minimum sample size of 60 people, the study was conducted on 64 patients with eclampsia.

Inclusion Criteria:

All cases of eclampsia both inpatient and outpatient category, irrespective of their delivery status was included in the study after their consent.

Exclusion criteria:

- Diagnosed cases of epilepsy
- History of heart block or kidney disease
- Other causes of seizure such as cerebrovascular accident, meningitis, encephalitis, brain tumors, metabolic disorders, septic shock.
- Patients who have already received magnesium sulphate or another anticonvulsant before entering the hospital.

Statistical Analysis

Data entry and analysis were performed on a computer using SPSS software version 20.0. Data were expressed as mean, SD or 2x2 tables and presented using, tables, bar graphs. Continuous variables were expressed as mean ± standard deviation.

Categorical parameters were expressed as percentages. An unpaired t test was used to compare continuous variables.

The chi-square test was used to compare categorical variables. A P value of less than 0.05 is considered statistically significant.

Table 1: Distribution of cases according to their Demographic profile

	Group-D (Dhaka regime) n=32(%)	Group-P (Pritchard regime) n=32(%)	P-Value	Remarks
Age(Mean±SD)	21.66 ± 4.63	21.72 ± 5.11	0.96	Not significant
Primigravida	25(78.13%)	23(71.88%)	0.26	
Booking status(booked)	(34.38%)	(34.38%)	1	
Unbooked	65.63%	65.63%	1	
Mean period of gestation	37.18 ± 2.34 weeks	36.90 ± 3.11weeks	0.68	
Antepartum Eclampsia	25(78.13%)	21(65.63%)	0.53	
Intrapartum Eclampsia	1(3.13%)	2(6.25%)		
Postpartum eclampsia	6(18.75%)	9(28.13%)		
Proteinuria			0.74	
1+	13(40.63%)	10(31.255)		
2+	13(40.63%)	16(50%)		
3+	5(15.63%)	5(15.63%)		
BMI (Mean±SD)	22.57 ± 1.87	23.14 ± 2.62	0.32	
BP				
Systolic BP (Mean ± S.D)	172.81 ± 20.86	169.81 ± 17.42	0.53	
Diastolic BP (Mean ± S.D)	112.88 ± 14.11	114.5 ± 14.42	0.65	
Bishop's score			0.59	
Favorable (1-5)	9(28.13%)	12(37.50%)		
Unfavorable (6-13)	23(71.88%)	20(62.50%)		
Mode of delivery			0.57	
Spontaneous Vaginal	6(18.75%)	7(21.88%)		
Induction of Labor	2(6.25%	5(15.63%)		
Instrumental Forceps /Ventose	2(6.25%)	1(3.13%)		
LSCS	22(68.75%)	19(59.38%)		

Table 2: Total dose of Magnesium Sulphate Received.

Total Dose(gms)	Group-D	%	Group-P	%	Statistical Significance		
					t-value	P-Value	Remarks
Less than 15	3	9.38	0	0	-7.85	< 0.05	**Significant**
16-20	23	71.88	6	18.75			
21-29	5	15.63	5	15.625			
30-39	0	0.00	15	46.875			
40-49	1	3.13	5	15.625			
50-59	0	0.00	1	3.125			
Grand Total	**32**	**100**	**32**	**100**			
Mean ± S.D	**26.00 ± 6.11**		**43.06 ± 10.66**				

Table 3: Efficacy of low dose regime and conventional regime to control convulsions

Outcome	Group-D low dose	%	Group-P conventional dose	%	Statistical Significance		
					Chi-square	P-Value	Remarks
Convulsion Controlled	31	96.88	32	100	0	1	Not Significant
Recurrence of Convulsion	1	3.13	0	0.00			
Grand Total	32	100	32	100			
	-						
3 convulsion after loading dose	1	3.13	0	0.00			
1 convulsion after 2 times rescue dose	1	3.13	0	0.00			
Failure of regimen	1	3.13	0	0.00			

Table 4: Magnesium sulphate toxicity profile in both groups

Magnesium Sulphate toxicity	Group-D low dose	%	Group-P conventional dose	%	Statistical Significance		
					Chi-square	P-Value	Remarks
Oliguria	1	3.13	2	6.25	4.66	0.32	Not Significant
Absent DTR(Knee Jerk)	7	21.88	11	34.38			
Respiratory Depression	0	0.00	1	3.13			
No Toxicity	24	75.00	18	56.25			

Table 5: Maternal Complications in Both Groups

Maternal Complication	Group-D low dose	%	Group-P conventional dose	%	Statistical Significance		
					Chi-square	P-Value	Remarks
No Complication	26	81.25	21	65.63	9.53	0.22	Not Significant
Abruptio Syndrome	2	6.25	0	0.00			
HELLP Syndrome	1	3.13	0	0.00			
Pulmonary Edema	1	3.13	1	3.13			
PPH	2	6.25	6	18.75			
DIC	0	0.00	2	6.25			
AKI	0	0.00	1	3.13			
PRES	0	0.00	1	3.13			
Grand Total	32	100	32	100			

Table 6: Neonatal outcome in both the groups

Birth Weight (Kg)	Group -D low dose group	%	Group-P convention al dose	%	Statistical Significance		
					t-value	P-Value	Remarks
Less than 1500 gm	1	3.13	1	3.13	-0.89	0.38	Not Significant
1500-2500	14	43.75	12	37.50			
More than 2500 gm	17	53.13	19	59.38			
Grand Total	32	100	32	100			
Mean ± S.D	2.52 ± 0.51		2.65 ± 0.62				
Live Birth	30	93.75	26	81.25	-		
Still birth	2	6.25	6	18.75			
APGAR Score 8-10(Normal)	22	73.33	17	65.38			
APGAR Score6-7(Mild asphyxia)	6	20	5	19.23			
APGAR Score 4-5(Moderate asphyxia)	2	6.66	4	15.38			
APGAR Score 0-3(severe asphyxia)	0	0.00	0	0.00			
NICU admission	5	16.66	7	26.92			
Neonatal Mortality	0	00.00	1	3.84			
	Mean	**SD**	**Mean**	**SD**	**t-value**	**P-Value**	**Remarks**
APGAR Score at 1 min	6.93	2.50	5.87	3.26	1.46	0.05	
APGAR Score at 5 min	7.97	2.69	6.75	3.60	1.53	0.04	

Results

After analysis of 64 patients' demographic characteristics following observation were made. Table number 1 presented data are (%)N=64, maximum number of patients were from 18 to 25 years of age. It has been observed that eclampsia was more in teenage pregnancy. In the current study proportion of teenage pregnancy was 37.5%. Most of the eclampsia patients (65.63%) were from rural background and were unbooked. Majority of eclampsia patients were Primigravida (75%). Most of the patient presented in the third trimester between 37-39weeks 6 days. Average gestational age observed in the study was 37.18 ± 2.34 weeks in the low dose group and 36.90 ± 3.11 weeks in the conventional dose group., majority patients presented with antepartum eclampsia. In both the groups majority patients were with low to normal BMI. Mean systolic BP in low dose group is 172.81±20.86 and mean diastolic BP was 112.88± 14.11.Mean systolic BP in conventional dose group was 169.81±17.42 and mean diastolic BP 114.5±14.42. Majority of patients had proteinuria 2+ in both low dose group (40.63%) and conventional dose group (50%). Total 23 patients in low dose group and 20 patients in conventional dose group had unfavourable cervix. Induction of labor was done 10.94% patients, 35.94%of patients undergo vaginal delivery and 64.06% delivered by cesarean section.

The proportion of instrumental delivery was 4.69% in the present study. Table number 2 presenting the mean amount of magnesium sulphate received was 26±6.11grams in low dose group and 43.06±10.66grams in conventional dose. There has statistically significant difference in average dose of Magnesium Sulphate received in both groups (P value <0.05). Table number 3 demonstrated the effectiveness of low dose vs conventional group. Convulsions were controlled after receiving loading dose in 96.88% of cases with low dose regime and 100% of cases with conventional regime. Recurrence of convulsion was seen in 1 patient (3.13%) of low dose regime. The difference was statistically not significant. Table number 4 representing the proportion of maternal magnesium toxicity in either group. Absent Deep Tendon Reflex (Absent Knee jerk) was seen in 21.88% in low dose regimen and 34.38% in conventional dose regimen. One patient in conventional dose regimen developed respiratory depression needed Calcium gluconate supplementation. Oliguria seen in 1 patient in low dose regime and 2 patients in conventional dose regime. Maternal complications are shown in Table number 5.HELLP syndrome seen in 1 patient with low dose regime. Pulmonary edema developed in 1 patient in both groups. PPH rate was 3 times higher in conventional regime (18.75%)compared to low regime (6.25%). AKI (Acute Kidney Injury) developed in 1 patient &disseminated intravascular coagulation (DIC) developed in 2 patients in conventional dose group. Posterior reversible encephalopathy syndrome (PRES) developed in 1 patient in conventional dose group. Table number 6 deals with neonatal outcome. Majority of newborns were in the above 7 Apgar score at 5 min (in 73.33% in low dose group

and 65.38% in conventional dose group). The Apgar score below 7 at 5 min was 26.66% and 34.61% in the low dose and conventional dose group respectively. NICU admission is done 16.66% in low dose group and 26.92% in conventional dose group. There was 1 neonatal mortality in conventional dose group. There was no statistically significant difference in respect to maternal and neonatal outcome in both the groups.

Discussion

It has been observed that eclampsia is more in teenage pregnancy. In the current study proportion of teenage pregnancy was 37.5%, in their study Sardesai et al. has reported 45.79% were below 20 years.[16]The demographic figures in the current study shows 65.63% patients belongs to rural, unbooked, unsupervised group but it was much less compared to the study by Bangal et al where 90% of cases were unbooked or unregistered.[17] Eclampsia is more common in primigravida. In the present study 75% of the eclampsia observed were in Primigravida which is in concurrence to the findings by Nath J et al.[18]The average gestational age observed in the study was 37.18 ± 2.34 weeks in the low dose group and 36.90 ± 3.11 weeks in the conventional dose group. The distribution was comparable to the findings in the study done by Chamkuri et al. The mean gestational age documented by Chamkuri et al was 35 weeks and 36 weeks, in the conventional and low-dose group respectively.[19]Majority of patient had antepartum eclampsia in our study. The mode of delivery in our study was 35.94%vaginal delivery and 64.06% delivered by cesarean section. Induction of labor was done in 10.94%patients. The proportion of instrumental delivery was 4.69% in the present study. Kathawadia KK et al observed vaginal delivery 67.39%and LSCS 28.26%, instrumental delivery 4.34%. [20] In this study, the mean dose required to control convulsion in low dose group was 26±6.11gram, and in conventional dose it was 43.06±10.66gram.Hence the dose required to control seizures was 40% lower than with the conventional (Pritchard)regimen. Our findings in the study significantly suggest that the low dose of MgSO4 needed to control the seizures in eclampsia is equally therapeutic with less adverse effect in comparison to conventional dosage (P value <0.05). This observation is consistent with another study by Ranjana et al, where the mean total dose of MgSO4 in low dose regimen was significantly lower than the Pritchard regimen with P value <0.001.[21] Sharafat Z etal. concluded that total dose of MgSO4 required for seizure control was 54.5% less than the conventional dose regime with no MgSO4 related toxicity.[22]The standard measurement of the effectiveness of magnesium sulphate was the number of seizures that occurred after the patient received the loading dose. The seizures after loading dose were controlled in 96.88% of cases receiving low dose regimen and 100% in the conventional dosage regimen group. Recurrence of seizures was observed in only one patient 2 hours after the initial dose of low dose regimen which was attempted to be controlled with an additional dose of 2gm of MgSO4. After the administration of two such rescue doses, the convulsions were not controlled and were labeled as a failure of low dose regimen and that case was immediately transferred to the conventional regimen.

The difference was not statistically significant. In the present study, the proportion of recurrence with low dose regimen was3.13%.Overall 4.2% recurrence seizure rate was documented in a study done by MA Abdul et al.[23]In eclampsia collaborative trial (1995) recurrence rate was 5.7%,[24] Kumari KC et al documented recurrence rate 6% in low dose group and 4% in conventional dose group.[25] Whereas Mohanapu S et al observed recurrence rate with low dose 10%.[26]The proportion of patients with absent knee jerk in the present study was21.88% and 34.38% respectively in the low dose regimen and the conventional dose regimen. Due to absent knee jerk maintenance dose of MgSO4 was withdrawn in 8 cases receiving low dose regimen and in 14 cases receiving conventional dose. In the present study in conventional dose regimen 3.13% patients developed respiratory depression and needed Calcium gluconate supplementation. Similar observation was made by Murthy OK et al, they found 2% of patient in the conventional dose regimen developed respiratory depression.[27]The proportion of cases developing oliguria was 3.13% and 6.25% with low dose and conventional dose regimen respectively whereas Chowdhury et al documented oliguria in 3.2% cases.[28] The occurrence of atonic PPH was3 times higher in the conventional dose regimen (18.75%) in comparison to the low dose regime (6.25%). There is a relation between magnesium sulphate therapy and atonic PPH. [29] Sultana F et al observed 2% cases in the low- dose group and 4% cases in the conventional dose group had Atonic PPH. [30]The Apgar score below 7 at 5 min was 26.66% and 34.61% in the low dose and conventional dose group respectively. Findings has been observed by Garg R et al in regard to the APGAR scoring such as Apgar score below 7 at 5 min in low dose group was 8.57% and in conventional group it was 17.14%.[31]The proportion of neonates admitted in NICU was 16.66% and 26.92% with the low dose and conventional dose regimen respectively. The most common indication for NICU admission were IUGR and prematurity. The only neonatal mortality observed in the present study was from conventional dose group. Present study results have major implications in the treatment of eclampsia.

Factors found associated with eclampsia are -young maternal age, primigravida, and lack of antenatal care.

Conclusions

In this study, the mean dose required to control convulsion in low dose group was 26±6.11gram, and in conventional dose it was 43.06±10. 66gram. Hence the dose required to control seizures was 40% lesser than with the conventional (Pritchard) regimen. Magnesium sulphate toxicity was significantly greater with the conventional regimen in comparison to low dose (Dhaka) regimen. The fetal and maternal outcome was equivalent in both the groups. Because of its low toxicity profile and efficacy comparable to Pritchard regimen, low-dose regimen can be safely administered even by primary health workers without worrying the risk of inducing respiratory failure. In the near future, this may become an established practice in India and is a foremost step towards safe motherhood.

Limitations

The sample size was smaller because we had to exclude those cases that had already received magnesium sulfate before arriving this institution. The observations of this study need validation from a large-scale randomized control trial. Larger studies with multiple healthcare facilities may be needed to find out the lowest effective dose of magnesium sulphate for seizure control.

Ethical approval:

The present study was approved by the Institutional Ethics Committee of Agartala Govt Medical College. Ref .No. 4(6-11)-AGMC/Medical Education/Ethics Com:/2018/15124(Registration No. ECR/937/Inst/TR/2017 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945 under Govt of India).

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