

## STUDY OF SINGLE DOSE MAGNESIUM SULPHATE VERSUS PRITCHARD'S REGIME IN MANAGEMENT OF ECLAMPSIA

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### Abstract

**Background:** Eclampsia/ Pre-eclampsia are leading causes for maternal and fetal mortality and morbidity. It has been established that Magnesium sulphate is the anticonvulsant of choice for both prevention and treatment of eclampsia. Various MgSO<sub>4</sub> regimens are used to control convulsions but modifications are made considering various aspects for the prevention and treatment of eclampsia. In developing countries like India with low resources need a simpler and low dose regime of Magnesium sulphate for the treatment of eclampsia because Indian women have less weight compared to western women. The objective is to study the efficacy and outcome of 'single dose' Magnesium sulphate versus Pritchard's regimen in the treatment of eclamptic convulsions. 2. To study maternal and fetal outcome in both regimens. **Materials and Methods:** The study was conducted in a setting of tertiary care center on pregnant women admitted to Eclampsia labour room, Department of Obstetrics and Gynecology in MCH & HQH VIMS Bellary with diagnosis of Eclampsia. A total of 100 eclamptic women were enrolled in the study who meet the inclusion criteria. They were assigned to either single dose regimen (Group A) or the Pritchard regimen (Group B) group randomly (50 in each group) The single dose group patients received Inj MgSO<sub>4</sub> (20%) - 4gm IV and Inj MgSO<sub>4</sub> 4gm (50%) IM (2 gm in each buttock) The Pritchard regimen group received – Loading dose: Inj MgSO<sub>4</sub> 4g (20 ml of 20%) IV over not less than 10-15 minutes immediately to be followed by 10g (20 ml of 50%) IM - 5g in each buttock. The maintenance dose in the Pritchard regimen group was – Inj MgSO<sub>4</sub> 5g (10 ml of 50%) is given every 4 hours at alternate sites after assuring no signs of magnesium toxicity. Comprehensive obstetric care was given to all patients. The fetal maternal outcome and the adverse effects of MgSO<sub>4</sub> were assessed and analyzed. **Result:** There was no statistically significant difference in maternal and fetal outcome among both the groups. The recurrence rate of convulsion among both the groups was also statistically not significant, indicating equal efficacy of both the regimens. In 20 patients the maintenance dose of the MgSO<sub>4</sub> was skipped in Pritchard regimen group due to clinical signs of magnesium toxicity supported by lab evidence of serum magnesium levels higher than therapeutic levels. **Conclusion:** Single dose regimen is a better option for management of eclampsia in our set up compared to Pritchard's regimen.

## INTRODUCTION

Eclampsia is a cause of 10-15% direct maternal deaths and is associated with high perinatal morbidity and mortality.<sup>[1]</sup> Greater numbers of convulsions prior to care may be due to lack of reachable facilities. Time spent in access to care is crucial and may alter maternal and fetal outcome Magnesium sulphate is the anticonvulsant of choice for treating eclampsia, known to be more effective than diazepam, phenytoin, or lytic cocktail. <sup>[2-6]</sup> Although it is a low-cost effective treatment, magnesium

sulphate is not available in all low and middle income countries; scaling up its use for eclampsia and severe preeclampsia will contribute to achieving the millennium development goals. A major concern in the use of magnesium sulphate has been its safety especially regarding respiratory depression. Vigilance in the use of magnesium sulphate is essential for women's safety. As per Sibai: "More patients die of Magnesium sulphate toxicity than from the seizures especially in the developing countries, where disciplined use is hard to achieve there is definitely a transnational difference in response to magnesium

sulphate in the third world with racial characteristics being important in determining the response, there is danger in applying the results of the trails as such in different countries” [7] Convulsions post admissions indicate a lack of standardized care protocol for eclampsia which is mandatory Various studies have been done to define the optimal regimens, achieving maximal effectiveness with minimal adverse effects Our study is an effort to compare the efficacy and safety of the Pritchard regimen which is time tested but which was devised for the western women and the Single dose regimen which has been tailor made for the Indian women who are smaller in the body mass.

**OBJECTIVE OF THE STUDY** 1. To study the efficacy and outcome of ‘single dose’ Magnesium sulphate versus Pritchard’s regimen in the treatment of eclamptic convulsions. 2. To study maternal and fetal outcome in both regimens.

## MATERIALS AND METHODS

**SOURCE OF DATA:** All patients admitted with eclamptic convulsions to the labour room of MCH and HQH , combined group of hospitals VIMS Bellary **INCLUSION CRITERIA:** All proved case of eclampsia. **EXCLUSION CRITERIA** 1. Known epileptic. 2. Eclamptic who are put on other regimens. 3. Women in whom hypertension is detected earlier to 20 weeks **STUDY DESIGN:** Randomized controlled trial (Block randomization method) **STUDY SETTING:** The study was conducted in a setting of tertiary care center on pregnant women admitted to Eclampsia labour room in Department of Obstetrics and Gynecology in VIMS Bellary with diagnosis of Eclampsia. The study period is from December 1st 2013 to November 30th 2014

**METHOD:** The study done on eclamptic patients admitted to the labour room of MCH and HQH combined groups of hospitals of VIMS Bellary. The patients admitted in eclampsia labour room were selected for the study and after explaining in detail about the study design a written consent was taken from the patient and attenders & were included in the study. A thorough history was elicited from those women chosen for study. All the study subjects were analyzed in full details regarding age, literacy, socioeconomic status, parity, etc. Pregnancy details regarding ANC, significant past and family history, the other complications associated with eclampsia were noted. Subjects were followed further by a thorough General physical, Systemic and obstetric examinations. Total of 100 eclamptic women included in the study were randomly allocated into a group – treated with Single dose regimen (50 cases) i.e. group A- loading dose of 4gm of 50% w/v I.V. Magnesium sulphate diluted with 5% of dextrose over 10-15 minutes, and administration of 2 gm of Magnesium sulphate intramuscularly, in each buttock and group B treated with, Pritchard Regime(50 cases)- 4 g Magnesium sulphate diluted IV over not

less than 10-15 minutes to be followed by 10g IM i.e. 5 g in each buttock and a maintenance dose of 5g Magnesium sulphate is given every 4 hours at alternate buttocks up to 24 hours after last eclamptic fit or 24hours postdelivery. The patient is monitored with adequate hydration, antihypertensives and immediate termination of pregnancy. If recurrence of convulsions occurs then patient is switched over to other regimens like low dose Magnesium sulphate regime or Phenytoin regime. Serum Magnesium levels soon after admission to the hospital and 24 hours after the last dose of MgSO4 were measured in both the groups. Maintenance dose of MgSO4 in Pritchard regimen i.e. 5gm MgSO4 every 4th hourly is given only after ensuring presence of knee jerk, urine output of more than 30ml/hour, and respiratory rate of more than 14cycles/min. Whenever MgSO4 dose was skipped(absent knee jerk, urine output< 14cycles per min) serum Mg levels were checked. Other investigations carried out along with serum Magnesium levels were 1. Basic investigations: Complete blood count, Blood grouping, HIV, HBsAg 2. Blood urea, serum creatinine, serum uric acid, RBS, SGOT, SGPT, LDH, S.Bilirubin, Total proteins & Albumin. 3. Urine for proteinuria. 4. Fundoscopy. The data collected is plotted on excel sheet and statistically analyzed.

## RESULTS

This randomised controlled trial was conducted in department of Obstetrics and Gynaecology, VIMS, Bellary after approval of institutional ethical committee clearance. A total of 100 patients admitted to eclampsia labour room were allocated in to two groups, Group A- Single dose MgSO4 regime and Group B- Pritchard’ s MgSO4 regime by block randomisation technique. The observations made and the statistical analysis of these observations; depicted below in the tabular and graphical form. T test was used in the analysis of the observations.

**Table 1: Comparison of Obstetric profile of the patients among the two groups**

Variable	Single dose regimen (n=50)		Pritchard regimen (n=50)		p value
	Frequency	Percent	Frequency	Percent	
<b>Age group</b>					
< 20 yrs	11	22.0	6	12.0	0.086
20 - 25 yrs	32	64.0	38	76.0	
26 - 30 yrs	7	14.0	3	6.0	
> 30 yrs	0	0.0	3	6.0	
Mean ± SD	22.26 ± 3.36		22.18 ± 3.54		
<b>Obstetric score</b>					
Multigravida	13	26.0	10	20.0	0.476
Primigravida	37	74.0	40	80.0	
<b>Gestation in weeks</b>					
< 28 wks	0	0.0	1	2.0	0.702
28 - 36 wks	26	52.0	24	48.0	
≥ 37 wks	23	46.0	23	46.0	
NA	1	2.0	2	4.0	
Mean ± SD	35.18 ± 4.20		35.27 ± 3.52		

The obstetric profile of the patients in both the groups was similar. There was no statistically significant difference among the various parameters. Incidence of eclampsia was more common in 20-25 years age group. Single dose group 64% and in Pritchard's regime group 76% (p value 0.086). In both the groups the incidence of eclampsia was seen more in primi gravida. In single dose group it was 74% and in Pritchard group it was 80% in primi gravida. (p value 0.476). The incidence was seen more in the gestational age of 28-36 wks; in single dose group it was 52% and in Pritchard group it was 48% (p value 0.702).

**Table 2: Comparison of clinical profile of two groups**

Comparison of clinical profile of the patients among the two groups					
Variable	Single dose regimen (n=50)		Pritchard regimen (n=50)		p value
	Frequency	Percent	Frequency	Percent	
<b>Episodes of convulsions</b>					
< 4 episodes	31	62.0	33	66.0	0.911
4 - 7 episodes	17	34.0	15	30.0	
> 7 episodes	2	4.0	2	4.0	
Mean ± SD	3.24 ± 1.76		3.30 ± 1.72		0.131*
<b>GCS</b>					
GCS: < 9	0	0.0	0	0.0	0.317
GCS: 9 - 12	25	50.0	30	60.0	
GCS: 13 - 15	25	50.0	20	40.0	
Mean ± SD	12.16 ± 1.96		11.10 ± 1.39		0.109
<b>Systolic BP in mmHg</b>					
Mean ± SD	159.48 ± 21.06		149.96 ± 15.47		0.267*
<b>Diastolic BP in mmHg</b>					
Mean ± SD	105.08 ± 16.17		98.60 ± 11.61		0.432*
<b>AntiHTN drugs</b>					
Given	48	96.0	50	100.0	0.495
Not given	2	4.0	0	0.0	

\*T test is applied

**Table 3: Comparison of hematological profile of two groups**

Comparison of haematological profile of the patients among the two groups					
Variable	Single dose regimen (n=50)		Pritchard regimen (n=50)		p value
	Frequency	Percent	Frequency	Percent	
<b>Haemoglobin</b>					
< 11 gm%	1	2.0	2	4.0	0.681
11 - 14 gm%	30	60.0	32	64.0	
15 - 18 gm%	20	40.0	18	36.0	
Mean ± SD	10.45 ± 1.85		10.38 ± 1.32		0.587*
<b>Platelet count</b>					
< 1.5 L/mm <sup>3</sup>	12	24.0	11	22.0	0.812
1.5 - 4 L/mm <sup>3</sup>	38	76.0	39	78.0	
Mean ± SD	1.96 ± 0.78		2.17 ± 0.84		0.452*
<b>Bleeding time</b>					
> 4 min	10	20.0	4	8.0	0.126
2 - 4 min	40	80.0	46	92.0	
Mean ± SD	3.41 ± 1.56		3.02 ± 0.99		0.771*
<b>Clotting time</b>					
> 8 min	1	2.0	0	0.0	0.513
2 - 8 min	49	98.0	50	100.0	
Mean ± SD	4.38 ± 1.77		3.97 ± 0.95		0.453*
<b>LDH levels</b>					
< 600 IU/dl	17	34.0	12	24.0	0.271
> 600 IU/dl	33	66.0	38	76.0	
Mean ± SD	850.48 ± 492.05		936.38 ± 593.15		0.917*

\*T test is applied

There was no statistically significant difference in the clinical profile of both groups. Maximum patients in both the groups presented with less than 4 episodes

of convulsions (in single dose group 62% and Pritchard group 66%) (p value 0.911). The average number convulsions was around 3 in both the groups. All the patients enrolled in the study had GCS of more than 9 at admission (p value 0.317).

The mean systolic BP at admission in single dose group was around 160 mmHg, the mean diastolic BP at admission was around 106 mmHg. (p value 0.267). The mean systolic BP at admission in Pritchard group was around 150 mmHg, the mean diastolic BP at admission was around 99 mmHg. (p value 0.432). 96% of patients in the single group received antihypertensives, all the patients in the Pritchard's group received antihypertensives. (p value 0.495).

The haematological parameters of both the groups were statistically same. There was no statistically significant difference between two groups. The average Hb was 10.45 gm% in single dose group and 10.38 gm% in Pritchard group. The average platelet count in the single dose group was 1.96 L/mm<sup>3</sup> and in the Pritchard group it was 2.17 L/mm<sup>3</sup>. The BT and CT were normal in both the groups. The LDH levels were more than 600 IU/L in 66% of patients in the single dose group and 76% of patients in the Pritchard group.

## DISCUSSION

Eclampsia has been a major obstetric problem mainly in the low resource set up countries. The magnesium sulphate is proven to be the drug of choice in the treatment of convulsions due to eclampsia but the availability of this drug is still a major problem in the developing countries. The optimal dosage of magnesium sulphate is still a debatable question. There is no uniformly agreed dose and schedule for the magnesium sulphate in eclampsia. Various studies have been conducted to ascertain the optimal dose giving better fetomaternal outcome with minimal side effects. Few of the studies are discussed below. [8] K Shail, and G Harleen conducted study in Department of Obstetrics and Gynaecology, Punjab Institute of Medical Sciences, Jalandhar, Punjab, India with an objective to compare the efficacy of single dose magnesium sulphate to Pritchard regime in controlling eclamptic fits. [9] The authors had following results: the age group of the patients in both the groups was mainly in 20 - 30 yrs (100% in Pritchard group and 83.3% in the low dose group). The incidence of eclampsia was found mainly in the Primigravida - 76.7% in both the groups.

The eclampsia was seen mainly in the group with the gestational age more than 36 wks 43.3% in Pritchard group and 40% in low dose regimen group.

Fetomaternal outcome: There was no statistically significant difference in the APGAR score in either group.

The occurrence of hypertonia, need for oxygen, and neonatal Intensive Care Unit (NICU) admission were more in Pritchard group (36.67 vs. 10%) which was significant (P = 0.0303).

The maternal side effects were seen more in the Pritchard group but it was not statistically significant.

## CONCLUSION

The authors concluded - The effectiveness of single regimen of magnesium sulphate appeared comparable to the “standard dose regimen.” Single dose regimen may guarantee more safety and in an environment where cost is an important determinant of accessibility to qualitative health services, it is certainly attractive. More studies are needed to establish the place of single dose regimen of magnesium sulphate in the management of eclampsia.

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