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Loading Dose Only Vs Standard 24 Hrs Pritchard's Regimen of Magnesium Sulphate in Severe Pre-Eclampsia - A Randomised Trial

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Introduction

Hypertensive disorders of pregnancy affect about 10% of all pregnant women around the world. The pre-eclampsia affects 2-8% of all pregnancies worldwide. The primary aim of treatment in severe pre-eclampsia is to prevent eclamptic seizures & resultant morbidity & mortality. Magnesium sulphate is drug of choice for prevention of seizures in pre-eclampsia as well as treatment of seizures in eclampsia.

PRITCHARD REGIME recommends giving 4gms Inj MgSO4 IV over 5 minutes followed immediately by 10 gms IM and 5 gms IM every 4 hours. It has recently been suggested that an initial dose of inj MgSO4 is sufficient to arrest convulsion. We also observed that most of the patient did not receive maintenance therapy due to suspicion of toxicity & they did not convulse further. On the basis of these observations, a study was done to compare the efficacy of loading only & standard regime.

Aims and Objective

To determine the efficacy & safety of only loading dose of Pritchard regimen of MgSO4 therapy in patients of severe pre-eclampsia.

Material and Methods

This randomized trial was undertaken at Katihar Medical College, Katihar, Bihar between April 2018 to March 2019 after obtaining institutional ethical approval. All the women who had severe pre-eclampsia were included in study. The women who received Magnesium sulphate outside our hospital were excluded from the study. After giving standard loading dose, patients were divided in Group A (Loading & maintenance dose) or Group B (loading dose only). In event of recurrent convulsions further Magnesium sulphate was given intravenous and maintenance regimen continued as usual. In Group B, when patient had recurrent seizures they were switched to maintenance protocol. The patients were followed up till discharge from the obstetric unit of the hospital. Any complications and need of intensive care were noted.

The categorial data was analysed using the chisquare test & normally distributed continuous variables were analysed with student's t test. A probability value of <0.05 was considered significant.

Results

During the study period of 12 months, 50 patients

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of severe pre-eclampsia under control group received the conventional 24 hrs regime of magnesium sulphate and 50 patients of severe preeclampsia under study group received only loading dose of magnesium sulphate. The total no of patients enrolled & their details is depicted in the flow diagram.

Table 1 Baseline patient characteristics

Categorical	Pritchard's	Loading dose only	P-value
variables	Regimen		
Age group (Years)			0.956
19 – 20	04(8)	04(8)	
21 – 30	39(78)	40(80)	
31 – 40	07(14)	6(12)	
Mean age	25.60 +/-3.67	25.76 +/- 4.86	0.853
Gravida-Status			0.374
Primigravida	29-(58)	32-(64)	
Gravida-II	14-(28)	14-(28)	
Gravida-III	04-(8)	04-(8)	
Gravida-IV	Nil	Nil	
Gestation in Weeks		,	
26-28		2-(4)	
28-32		11-(22)	
33-36	24-(48)	19-(38)	
≥=37	10-(20)	18-(36)	
Mean gestation	31.56±3.27	31.28±3.47	0.533

Table 2: Maximum systolic and diastolic blood pressure

Maximum systolic	Pritchard's	Loading dose only	p-
BP in mm of Hg	(n=50)(%)	(n=50)(%)	value
= 160</td <td>26 (52)</td> <td>38 (77.6)</td> <td>0.008</td>	26 (52)	38 (77.6)	0.008
> 160	24 (48)	11 (22.4)	

Maximum diastolic	Pritchard's	Loading dose	p- value
BP in mm of Hg	(n=50)(%)	only (n=50)(%)	
= 110</td <td>32 (64)</td> <td>36 (73.5)</td> <td>0.310</td>	32 (64)	36 (73.5)	0.310
> 110	18 (36)	13 (26.5)	

Table 3: Albuminuria

Grading of urine albumin	Pritchard"s	Loading dose only
	(n=50)(%)	(n=50)(%)
1+	5 (10)	6 (12)
2+	12 (24)	12 (24)
3+	11(22)	10 (20)
4+	22 (44)	20 (40)

p value - 0.693

Table 4: Maternal morbidity

	Pritchard's	Loading dose only (n=50)(%)
		Loading dose only (11–30)(%)
	(n=50)(%)	
OCCURENCE OF FIT (primary outcome)	01(2)	01(2)
Conversion to control regime	01(2)	0
Anaesthesia complications	01(2)	01(2)
Postpartum psychosis	0.00	01(2)
Switch over to Phenytoin	0.00	01(2)
Placental abruption	02(4)	06(12)
Post partum haemorrhage	02(4)	03(6)
HELLP syndrome	01(2)	02(4)

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Table 5: Morbidity due to use of magnesium sulphate

Morbidity	Pritchard's (n=50)(%)	Loading dose only	<i>p</i> -value
		(n=50)	_
Absent knee jerk	6(12)	0	0.012
Oliguria	5(10)	0	0.022

Table 6: Perinatal outcome

	Pritchard's (n=52)(%)	Loading dose only (n=52)	<i>p</i> -value
		(%)	•
Live born	43 (82.69)	47 (90.38)	0.566
Fresh still born	6 (11.53)	4 (7.69)	
Cause of still birth	LBW - 3	Prematurity – 1	
	Abruption – 1		
	Congenital heart	Associated abruption in 2	
	block - 1		
	Unknown cause – 1		
Macerated still born	3 (5.76)	1 (0.01)	
Mean POG at birth (weeks)	34.5+/-3.3	34.4+/-3.1	
Apgar < 7 at 1mt	17(33.3)	12(22.6)	
Apgar < 7 at 5 mt	11 (21.50)	10 (19.23)	0.544
Respiratory depression requiring	11 (21.50)	8 (15.38)	0.393
intubation			
Birth weight < -2 SD	9 (17.30)	6 (11.53)	
Admission to special neonatal care unit	10 (19.23)	17 (32.69)	0.224
Hypoxic ischemic encephalopathy	6 (11.53)	3 (5.76)	0.268
Mortality	7 (13.46)	2 (3.84)	0.071
	HIE – 4	Sepsis - 3	
	Sepsis - 3	_	

(n=52) - There were 2 cases of twins in each group, HIE - Hypoxic Ischemic Encephalopathy, LBW - Low birth weight

Discussion

All 100 subjects in present study are randomised in two groups. Each group consisting 50 patients. Study group encompasses subjects ,where only loading dose was given & control group includes subjects where standard Pritchard's regimen (loading & maintenance both) was given. Patients in both the groups are comparable in terms of age, number of previous pregnancies, period of gestation, blood pressure, albuminuria, maternal morbidity & perinatal outcome. In present study, risk of occurence of seizures are similar in both the groups.

This study shows a significant reduction in toxicity (knee jerk & oliguria) associated with injection MgSO4 in study group in comparison to control group. Neonatal outcome in present study with a still birth rate of 7.69 percent & neonatal death rate 3.84 percent, which are lesser than in control group.

Conclusion

The present study demonstrates that loading dose only is equally effective as standard dose (Pritchard's regimen) of magnesium sulphate in seizure prophylaxis with better maternal and fetal outcome and less toxicity in severe preeclampsia.

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