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Comparative Study of Low Dose Magnesium Sulphate Versus Standard Regime In Severe Preeclampsia

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Abstract:*In this study a comparison was made between two different dosing schedules of Magnesium Sulfate with respect to prevention of fits primarily, when applied to two groups of severely preeclamptic women.*

We conducted the study on 150 severely preeclamptic women at third trimester carrying singleton pregnancy, and were randomly allocated into two groups, Group L and Group S. Group L received only 5 gm I.M. loading dose with 2.5 gm I.M. maintenance dose of Magnesium Sulfate, whereas Group S received the standard Prichard regime.

This study revealed the incidence of eclampsia to be 3% and 4% in Group L and Group S respectively. Spontaneous vaginal delivery was the outcome in 73.33% and 77.33% in Group L and Group S respectively. Twenty (20) women (26.66%) and 17 women (22.66%) were delivered by Cesarean section in Group L and Group S respectively. These outcomes were statistically insignificant. Non progress of labour was the major indication of LSCS in both Group L and Group S. This outcome is also statistically insignificant.

Among the maternal side effects, hematuria, blurred vision, nausea & vomiting, oliguria, respiratory depression and loss of knee jerk were noticed in both Group L and Group S and appeared to be statistically insignificant.Apgar score at 5 minutes and duration of stay in NICU were considered as two parameters to compare neonatal outcome between the two groups. 89.33% neonate in Group L and only 93.33% in Group S had Apgar score more than 7. This appeared statistically insignificant. 10.66% neonates in Group L and 6.66% in Group S had Apgar score less than 7. This also appeared statistically insignificant. Duration of stay in hours in NICU appeared more in Group L than Group S but appeared statistically insignificant.

Thus from the above results, low dose of Magnesium Sulfate appeared equally effective in preventing eclampsia in severely preeclamptic women in comparison to the Pritchard regime. Feto-maternal side effects were noticed less in low dose group, thus favoring its use in clinical practice.

Keywords:*Magnesium Sulphate, Severe Preeclampsia, Pritchard Regime, Feto-Maternal Outcome*

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I. Introduction

Preeclampsia and eclampsia account for about 9% of maternal deaths in Africa and Asia and about 25% of maternal deaths in Latin America and the Caribbean[1]. In some parts of northern Nigeria, eclampsia contributes to almost one third of maternal mortality[2,3,4].

When there is severe preeclampsia, it can also involve the liver, kidneys, clotting system or brain. The placenta can be affected too, leading to an increased risk of placental abruption, poor growth and preterm labor. These medical complications that can strike anytime and affect all the organs relentlessly can occur at any time during the second half of pregnancy or the first few weeks after delivery. Only about 5% of women present for the first time following delivery[5].

On the global scale, eclampsia ranks as the 3th most common cause of maternal mortality, being

responsible for about 12% of maternal death[6]. Recent institutional reports from developing countries alluded to this fact with eclampsia being responsible for 5.3% and 11.6% ofdeaths[7,8].

The goal of treatment in preeclampsia is to prevent eclamptic seizures and their resultant morbidity whereas, in eclamptic patients, the goal is to treat and prevent recurrent seizures. The use of Magnesium Sulfate (MgSO4) in obstetrics has controversy despite many years of experience with its use. Magnesium Sulfate was first used to prevent eclamptic seizures in 1906 by Horn in Germany, who injected it intrathecally. An intramuscular regimen was used

in 1926 to prevent recurrent seizures in women with eclampsia and the drug was given intravenously in 1933 to women with preeclampsia and eclampsia[9].

The disagreement regarding the type of prophylactic dosage schedule as well as the duration also created confusion. The prophylactic dosing schdules of multicentric Magpie trialinvolved either intramuscular (Pritchard) or intravenous (Zuspan) regime in 5070 preeclamptic women for 24 hours following delivery[10,11]. In practicing fields, these recommendations appeared to the clinicians as overtly generalized, nonspecific and unreasonably prolonged. Thus, though agreed with the rationality of administration of prophylactic Magnesium Sulfate in preeclamptic women for preventing first fit; debates are still going on regarding the target candidates as well as ideal dosage and duration of prophylactic Magnesium Sulfate therapy. Herein lays the importance of this study. We have chosen two cohorts of randomly allocated 150 severly preeclamptic women for study purpose.

We have statistically compared the outcome of populations receiving two different prophylactic Magnesium Sulfate regimens. Our study has considered only severely preeclamptic women for cohort, excluding the mild preclamptics.

1. To compare statistically the efficacy of the two different regimes of prophylactic Magnesium Sulfate therapy in preventing eclampsia when administered to randomly allocated 150 severely preeclamptic women. This is considered as the primary objective.
2. To compare the two regimes in light of their safety profile by comparing the adverse feto-maternal effects when used in severe preeclampsia. This should be considered as the secondary objective of the study.

II. Materials & Methods

This study was a randomized controlled trial including 150 severely preeclamptic antenatal women either receiving prophylactic low dose MgSO4 or standard Pritchard regimen. The intervention and data collection was intentionally minimalist to concentrate on achieving the primary objective of the study.All the women in this study had been selected from the antenatal ward and the labor room of Midnapore Medical College and Hospital, West Bengal.

Inclusion Criteria

Antenatal severely preeclamptic women having blood pressure 160/110 mm of Hg or above carrying singleton pregnancy in the third trimester were recruited as subjects in the study.

Exclusion Criteria

i) Women with eclampsia, carrying multiple pregnancies, malpresentation.
ii) Women with other obstetric complications like post caesarean section pregnancy, ante partum hemorrhage, premature rupture of membrances.
iii) Women with moderate and severe anemia, heart disease, diabetes mellitus, renal disease, epilepsy or any other medical disorders including chronic hypertension.
iv)Women

Sample Design

We had enrolled consecutive 150 antenatal women, and they were randomly allocated into two equal groups designated as Group L and Group S with the help of computer generated random number for 75 in each group out of 150.

Group L- Received only low dose of Magnesium Sulfate.A total dose of 5 gm. of Magnesium Sulfate 50% solution is administered over one buttock intramuscular route, and 2.5 gm. Magnesium Sulfate 50% administered intramuscularly in alternate buttock 4 hourly. This regime was continued until 24 hrs. after delivery

Group S-Standard Pritchard regime was given.Injection Magnesium Sulfate 4 gm. (20%) intravenous slowly, then 5 gm. intramuscular simultaneously in each buttock followed by5 gm. intramuscular

inalternate buttock four hourly was given. This regimewas continued until 24 hrs after delivery.
This is a double blind study as here both the patients who received the drug and the person who observed the effect of the drug were unaware of the study protocol.

Data Analysis &Statistical Methods

All data were collected in a prescribed proforma (a copy attached at the end of the thesis) and tabulated in excel sheet (Microsoft office 2010). Parametric data were presented as mean and standard deviation and nonparametric data as median and range. Student *t*-test was used for the comparison of mean values and Mann-Whitney *U* test for the comparison of median values. Differences between groups were analyzed using x^2 test with Yates correction. P values <0.05 were considered as statistically significant. All data were calculated by IBM-SPSS version 22. All data were analyzed on an intention-to-treat basis.

III. Result And Analysis

We found that age group wise distribution of women. Majority of women (68% and 78.66%) in both groups were in the age range of 20-25 years.It was found that gravida wise distribution of women in both groups, majority were primigravida women accounting 48% and 53.33% in Group L and Group S respectively.We found that describes the gestational age wise distribution of women in both groups. Majority of women enrolled in the study were at term (60% and 61%) in Group L and Group S respectively.It was found that distribution of women according to body weight. 49(65.33%) and 51(68%) women in Group L and Group S respectively, were having body weight in the range of 50 to 60kg. They constituted the major proportion in both groups.

We found that there were no statistically significant difference between the two groups in respect to age, gestational age at delivery, maternal weight, birth weight and duration of hypertension prior to randomization, SBP, DBP (Independent samples t-test) (P >0.05). So both the groups were comparable in respect to above background parameters.It was found that admission-delivery interval in both groups, there was no significant prolongation of labor, as the admission-delivery interval was comparable in respect to both groups (P>0.05).

It was found that 55 (73.33%) women in Group L and 58 (77.33%) women in Group S had spontaneous vaginal delivery. The incidence of Cesarean section in Group L was 20 (26.66%) and in Group S it was 17 (22.66%). This difference was statistically insignificant (P>0.05).

It was found that maternal outcome in both groups, in Group L occurrence of eclampsia was 3 (4%) and Group S it was 4 (5.33%). This difference was statistically not significant (P>0.05). This is the primary outcome of this study.It was found that as 3 mothers had developed eclampsia in Group L and 4 in Group S, they were not included while comparing secondary outcome and neonatal effects in both groups. So total numbers of cases were 72 and 71 in Group L and Group S respectively.

We found that the secondary outcomes in between two groups, it shows that blurred vision (7.04% in Group S vs. 5.55% in Group L), hematuria (8.45% in Group S vs. 5.55% in L), respiratory depression (9.85% in Group S vs. 8.33% in Group L), loss of knee jerk (2% in Group S vs. 0% in Group L)and nausea and vomiting(7.04% in Group S vs. 4.16% in Group L) were more in Group S than Group L. But these outcome were statistically not significant (P>0.05).We found that on the other hand oliguria (8.33% in Group L vs. 5.63% in Group S), more in Group L compared to Group S. These complications were statistically significant (P<0.05).

It was found that neonatal outcome in both groups as per Apgar score, in Group L, 89.33% neonate had Apgar score 7-10 at 5 minutes, while in Group S it was 93.33% and was statistically significant (p<0.05). In Group L, 10.66 % had Apgar score <7 and in Group S it was 6.66%. This was also statistically significant (P<0.05).We found that duration of stay in neonatal intensive care unit, stay in NICU for 24 hours in Group L was 11.11% and in Group S was 0% among the neonates requiring NICU care. It was statistically not significant (P>0.05). 22.22% and 40% neonate in Group L and Group S were stayed in Neonatal intensive care unit for 48 hours and 66.66% and 60% neonate in Group L and Group S were stayed in NICU for 72 hours. This was also statistically not significant (P>0.05).

IV. Discussion

In our current study, we had selected severely preeclampsia women and randomly allocated them into two groups.

In our current study, the mean ages were 23.59 years and 23.65 years in Group L and Group S respectively. Ranjana et al [12] compared two groups of severe preeclamptic women by instituting low dose MgSO4 (Dhaka regime) in one group and standard Pitchard regime in other group. The mean age of both the groups were 25.8 and 25.7 years respectively. Hall et al [13] compared two groups of

preeclampsiawomen by instituting Magnesium Sulfate in one group and Nimodipine in another group. There, the mean maternal age was 26.9 years. Coetzee et al [14] compared two groups of preeclamptic women by Magnesium Sulfate vs. placebo therapy. There, the mean maternal age inMagnesium Sulfate group was 24 years and in placebo group was 25years.

Primigravida women constitute the major portion of both Group L and Group S (48% vs. 53.33% respectively). Mean gestational age in Group L and Group S of our study were 37.81 and 37.87 weeks respectively. The study of Ranjana et al [15] shows the mean gestational age were 34.5 and 34.8 weeks respectively. Hall et al [13] recruited women in their study with mean gestational age of 31 completed weeks. Coetzee et al [14] recruited the same with mean gestational age of 34.3 and 34.8 weeks respectively in Magnesium Sulfate and placebo group respectively. Since we recruited women mostly when they arrived in labor room, most of whom were oblivious of their hypertensive status due to inadequate antenatal care, we had to recruit women in the later weeks of gestation. But this parameter is statistically comparable with respect to both the groups.

The four large randomized trials discussed by Sibai BM[15] shows a lower rate of eclampsia in those assigned to prophylactic Magnesium Sulfate (0.6% versus 2.0%). Thus the number of women needed to be treated to prevent one case of eclampsia is too large. Thus wehave enrolled only severely preeclampsia women in our study to compare the prophylactic efficacy of two different regimes of Magnesium Sulfate.

Hall et al[13] recruited all preeclampsia women but Coetzee et al[14] enrolled only severely preeclampsia women. Shoaib et al[16] performed the similar study after recruiting 100 severely preeclampsia women.

Our current study revealed mean admission-delivery intervals are 5.44 hrs and 6.19 hrs. in Group L and Group S respectively. This lag apparently could be attributed to Magnesium Sulfate as the second group of women received the same for a longer period of time and thus might have led to some instances of uterine inertia. However other study results do not corroborate our views Stallworth et al[17] found a transient mild decrease in frequency of uterine contraction during the Magnesium Sulfate loading does but no significant change in intensity of uterine contraction. Fang-Ping Chen et al[18] in this regard experienced reverse outcome. They conducted the almost similar study comparing prophylactic Magnesium Sulfate with placebo and found admission delivery interval to be more in the placebo group.

Shoaib et al[16] reported that the incidence of Cesarean section in only loading dose group was 12%, but much higher in standard regime group that is, 30%. In our study, likewise, the incidence of Cesarean section in Group L was 20% and in Group S was 17%; slightly higher than Group L. But it was statistically not significant. The study of Ranjana et al78 shows 57.5% and 67.5% LSCSin both groups Dhaka (Begum R)[19] regimen and Pitchard regime respectively. Duley et al[20] also reported a little higher (5% increase) Cesarean section rate in Magnesium Sulfate group than in those allocated placebo or no anticonvulsant (RR 1.05, 95% CI 1.01 to1.10).

In our study, theincidence of eclampsia appeared a bit higher in both groups, in comparison to other studies. But this outcome, with respect to both groups, was statistically not significant. Enrollment of only the severely preeclamptics and a smaller sample size might have resulted in this apparently increased incidence of this adverse outcome. Also it is an accepted fact that the incidence of eclampsia is higher in the Indian subcontinent that in the western world.

As the difference in the incidence of eclampsia was statistically insignificant between both the groups, it could be inferred that low dose was equipotent to standard Prichard regime as regards prevention of eclamptic fits in preeclamptics.

In our current study, 5.55% women in Group L and 8.45% women in Group S developed hematuria, 2.81% experienced loss of knee jerk in Group S. All these parameters were statistically insignificant. Increased loss of knee jerk in Group S could be explained by the high doses of Magnesium Sulfate leading to a higher cumulative serum concentration of magnesium in these women. Pritchard regime, originally planned on the western women who have a stouter and heavier build than the average Indian women, may account for this toxicity which is largely under reported due to lack of monitoring of serum Magnesium levels in all patients who are given this drug. From the meta-analytic study of Duley et al [20] toxicity related to Magnesium Sulfate (absent or reduced tendonreflexes and/or respiratory depression) was uncommon, occurring only in around 1% of women receiving Magnesium Sulfate.

In our current study, most of the neonates (89.33% in Group L and 93.33% in Group S) had Apgar score more than 7 and this was statistically insignificant 10.66% neonate in Group L and 6.66% in Group S had Apgar score less than 7. It was also statistically insignificant.

There were no still born babies in both groups and this was statistically not significant. Shoaib et al[16] reported 82% live birth in loading dose group and 72% in standard regime group. Crowther CA et al[21] reported that use of Magnesium Sulfate was associated with increased rates of fetal, neonatal, and infant mortality. This increased risk particularly limited to women receiving relatively high maintenance doses of Magnesium Sulfate (> 2g/hour). Coetzee et al[14] reported 11% still born in Magnesium Sulfate

group and 8% still born in placebo group.

In the Magpie trial, there were 11 maternal deaths in the Magnesium Sulfate group and 20 deaths in the placebo group (RR = 0.55; CI.26-1.14). However, 3 or the deaths in the placebo group were the results of renal failure, 3 were attributed to pulmonary embolism, and 2 to infection.In our study there was no maternal death in both Group L and Group S. Thus maternal mortality was not statistically different in the two groups.

V. Conclusion

In a developing country like India where maternal mortality is still very high, our prime endeavor should be aimed at prevention of obstetric complications that claim lives in addition to their timely management.

Using the low dose MgSO4, results in significantly lower maternal side effects, without compromising on the efficacy of the drug. The advantage of lowereconomic burdento the patient and subsequently of that to the nation is too great to ignore. As long as preeclampsia and eclampsia continues to take its toll over our mothers, we have to strive relentless to find its remedy. More trials are needed to be done using the low dose to the preeclampsia women before this regime can be established as the ideal prophylaxis for severe preeclampsia.

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Table: Distribution of parameters in two groups

		Group L (n=75)	Group S (n=75)	P value
Age group (in years)	<20	7(9.33%)	3(4%)	NS
	20-25	51(68%)	59(78.66%)	
	>25	17(22.66%)	13(17.33%)	
Gravida	G1	36(48%)	40(53.33%)	NS
	G2	27(36%)	25(33.33%)	
	G3	12(16%)	10(13.33%)	
Gestational age (in weeks)	<37 wks	30(40%)	29(38.66%)	NS
	37-40 wks	44(58.66%)	45(60%)	
	>40 wks	01(1.33%)	01(1.33%)	
Body weight (in kg)	<50	6(8%)	5(6.66%)	NS
	50-60	49(65.33%)	51(68%)	
	>60	20(26.66%)	19(25.33%)	
Mode of delivery	Spontaneous	55 (73.33%)	58 (77.33%)	0.57
	Cesarean section	20 (26.66%)	17 (22.66%)	
Eclampsia	Yes	3 (4%)	4 (5.33%)	0.699
	No	72 (96%)	71 (94.66%)	
Apgar score at 5 minutes	7-10	67 (89.33%)	70 (93.33%)	0.384
	<7	8 (10.66%)	5 (6.66%)	

Table: Difference of mean in two groups

	Group L (Mean±SD)	Group S (Mean±SD)	P value
Age(in years)	23.59±2.584	23.65±2.096	0.862
Gestational age (in weeks)	37.81±1.205	37.87±1.166	0.783
Maternal weight (in kg)	57.56±5.269	57.63±5.09	0.937
Birth weight of baby (in kg)	2.841±0.219	2.852±0.23	0.769
Duration of Hypertension (in weeks)	4.73±1.489	4.29±0.756	0.481
SBP	170.80±7.986	170.88±7.947	0.951
DBP	110.77±4.831	110.72±4.795	0.946
Admission-delivery interval (in hours)	5.44±2.406	6.19±2.323	0.55

Table: Distribution of Indications of Cesarean Section, Maternal effects and Stay in NICU(hours) in two groups

		Group L(n=20)	Group S(n=17)	P value
Indications of Cesarean Section	Eclampsia	3 (15%)	3 (17.64%)	0.840
	Non progress of labor	5 (20%)	5 (%)	
	Fetal distress	4 (20%)	4 (23.52%)	
	Severe preeclampsia with unfavourable cervix	4 (20%)	4 (23.52%)	
	Cephalopelvic Disproportion	1 (5%)	1 (5.88%)	
		Group L(n=72)	**Group S(n=71)**	
Maternal effects	Blurred vision	4 (5.55%)	5 (7.04%)	0.32
	Hematuria	4 (5.55%)	6 (8.45%)	
	Oliguria	6 (8.33%)	4 (5.63%)	
	Respiratory Depression	6 (8.33%)	7 (9.85%)	
	Loss of knee jerk	0 (0%)	2 (2.81%)	
	Nausea, vomiting	3(4.16%)	5(7.04%)	
		Group L(n=9)	**Group S(n=5)**	
Stay in NICU(hours)	24	1 (11.11%)	0 (%)	0.627
	48	2 (22.22%)	2 (40%)	
	72	6 (66.66%)	3 (60%)	

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