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Original Research Article

Comparative Study of the Standard Pritchard Regimen and Low Dose Dhaka Regimen of Magnesium Sulphate in the Management of Severe Preeclampsia and Eclampsia

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Abstract:

Background: Pre eclampsia and eclampsia are responsible for more than 50,000 maternal fatalities worldwide. Controlling convulsions is the first rule in the treatment of eclampsia. Magnesium sulphate is the anticonvulsant medication of choice for both preventing and treating eclampsia, but its toxicities are dose-related, which is a serious issue. In many low-income nations, the medicine is only sometimes used due to unwarranted concern over these risks. Reducing the toxicity of magnesium sulphate without sacrificing its effectiveness in preventing seizures and reducing mortality rates is still a difficult task.

Aim of the study: To study the effectiveness of low dose Magnesium sulphate Regimen- Dhaka Regimen in Eclampsia and to compare the effects of Standard regimen (Pritchard) to low dose regimen (Dhaka).

Materials & Methods: This was a Prospective Clinical Study, Government Maternity Hospital attached to SVMC, Tirupati done in 200 pregnant women with severe pre-eclampsia, imminent eclampsia & eclampsia attending to Govt Maternity Hospital, Tirupati for a period of one year.

Results: Unbooked cases of Pritchard regimen group were 94% and Dhaka regimen were 89%. Most of the cases were primigravida (67.5%). 44% were above 37 weeks. Level of consciousness of the patients in the 2 groups not differs significantly. No significant differences between 2 groups in number of convulsions before admission. Majority of the cases in both groups have SBP >160 mm Hg and Majority of the cases have DBP of 100-110 mm Hg. Out of 100 cases in Dhaka regimen group, 17 cases were augmented with oxytocin, 19 cases with PGE2, 57 cases with misoprostol.

Conclusion: In women with eclampsia, magnesium sulphate is the anticonvulsant medication of choice. For smaller women, the Dhaka Regimen at a low dose appears to effectively regulate and avoid seizures. The current study offers more convincing evidence in favor of using magnesium sulphate frequently to treat eclampsia convulsions. Clinical surveillance seems suitable as long as there is enough urine output. There is no difference between the two magnesium sulphate regimens in terms of maternal mortality, perinatal death, maternal morbidity, or caesarean section rates.

Keywords: Eclampsia, Pre eclampsia, Prichard Regimen, Dhaka Regimen.

Introduction

Women with Gestational Hypertension have blood pressures that reach 140/90mm of Hg or greater on 2 occasions at least 4 hours apart for the first time after 20 weeks of gestational age but lack proteinuria and returns to normal by 12 weeks post-partum.

Preeclampsia is best described as pregnancy specific syndrome that can affect virtually every organ system. Although preeclampsia is more than simply gestational hypertension with proteinuria, the appearance of protein remains a primary diagnostic criterion. It is an objective marker and reflects the system wide endothelial leak that characterizes the preeclampsia syndrome.

Eclampsia is preeclampsia exacerbated with convulsions. Eclampsia is classified as antepartum, intrapartum, or postpartum according on when the symptoms develop before, during, or after delivery. One of the most frequent obstetrical catastrophes, eclampsia significantly increases maternal and

perinatal morbidity. According to studies, it is responsible for more than 50,000 maternal fatalities worldwide. The majority of these fatalities take place in low-income nations, when maternal care is frequently of poor quality. [1,2,3]

Controlling convulsions is the first rule in the treatment of eclampsia. Magnesium sulphate is the anticonvulsant medication of choice for both preventing and treating eclampsia, but its toxicities are dose-related, which is a serious issue. Potential risks include respiratory depression, respiratory arrest, and maternal hypotension (cardiac arrest is rare). In many low-income nations, the medicine is only sometimes used due to unwarranted concern over these risks.

Reducing the toxicity of magnesium sulphate without sacrificing its effectiveness in preventing seizures and reducing mortality rates is still a difficult task. Women from 27 centers in 10 countries participated in the Collaborative Eclampsia Trial, which is still the largest study of magnesium sulphate for the treatment of eclampsia. Despite the fact that maternal weight is significantly higher in high-income nations than in low income ones, no dose modifications were performed for maternal weight in this trial (65 kg vs 45kg). [4] The conventional Pritchard regimen used in the trial was modified by small observational studies from India and Bangladesh, and these alterations seemed to lessen medication toxicity. To lessen the toxicity associated with magnesium, a low dose regimen is required.

Aim of the study:

- To study the effectiveness of low dose Dhaka Regimen in Eclampsia.
- To compare the effects of Standard regimen (Pritchard) to low dose regimen (Dhaka).
- To compare the Effectiveness in controlling of convulsions in eclampsia
- To compare the magnesium related toxicity in both the regimens.

Materials & Methods:

This was a Prospective Clinical Study, Government Maternity Hospital attached to SVMC, Tirupati done in 200 pregnant women with severe pre-eclampsia, imminent eclampsia & eclampsia attending to Govt Maternity Hospital, Tirupati for a period of one year.

Methodology:

Details of study protocol explained to subjects and Informed consent is obtained. In case of any complications for the study subject during the period of study the subject will be dropped out of the study and the subsequent doses will be stopped. In case of patient developing any toxicity related symptoms like decreased urine output, respiratory depression, absent patellar reflex then serum magnesium levels will be evaluated. Under aseptic condition 2cc venous sample from ante cubital fossa will be collected and evaluated for serum magnesium.

Pritchard Regimen (Standard): Loading Dose: 4g of 20% MgSo4 IV at a rate not exceeding 1 g / min. 10g of 50% MgSo4 deep IM in Buttocks. Total loading dose -14grams. If convulsions persist after 15 minutes, give 2 g of 20% MgSo4 at a rate not exceeding 1 gm / minute

Maintenance Dose: Every 4hrs 5gm of 50% MgSo4 as IM on alternate Buttocks after assuring Patellar reflex is present, Respiration are not depressed >16/min, Urine output>100ml in preceding 4 hours. MgSo4 discontinued 24 hours after delivery.

Dhaka Regimen of Magnesium Sulphate Regimen:

Loading Dose: 4gm of 20% magnesium sulphate given intravenously slowly over15 minutes. 3gm of 50% magnesium sulphate given intramuscularly in each buttock. Total loading dose-10gms

Maintenance Dose: 2.5gm 50% magnesium sulphate every 4hours given intramuscularly in alternate buttocks, until 24hrs after administration of the first dose. Monitored with urine output knee jerks, and respiratory rate.

In comparison to the standard dose regimen the toxicity of loading dose and maintenance dose in low dose regimen has been reduced by 28.4% and 50% respectively.

Results

Table 1: Age Distribution

	Group A		Group B		Total	
Age Group	**No**	**%**	**N**	**%**	**N**	**%**
18–24	73	73%	71	72%	144	72%
25–30	20	20%	17	17%	37	18.5%
>30	7	7%	12	12%	19	9.5%
Total	100	100%	100	100%	200	100%
Mean Age	22.94±3.68		23.45±4.12		23.19±3.90	
Chi square test=1.58,p=0.45, Not statistically significant						

Table 2: Booking Status

Booking status	Group A		Group B		Total	
	No	%	No	%	No	%
Booked	11	11%	6	6%	17	8.5%
Unbooked	89	89%	94	94%	183	91.5%
Total	100	100%	100	100%	200	100%
Chisquare test =1.59,p=0.20, Not statistically significant						

Table 3: Parity

Parity	Group A		Group B		Total	
	No	%	No	%	No	%
Primi	58	58%	77	77%	135	67.5%
Multi	42	42%	23	23%	65	32.5%
Total	100	100%	100	100%	200	100%
Chisquare test=8.18,p=0.004*, statistically significant						

Table 4: Gestational Age in Weeks

Gestational age in weeks	Group A		Group B		Total	
	No	%	No	%	No	%
24–28	5	5%	14	14%	19	9.5%
29–32	14	14%	10	10%	24	12%
33–36	33	33%	36	36%	69	34.5%
>37	48	48%	40	40%	88	44%
Total	100	100%	100	100%	200	100%
Chisquare test = 5.78, p=0.12, Not statistically significant						

Table 5: Conscious Level at Admission

Level of consciousness	Group A		Group B		Total	
	No	%	No	%	No	%
Conscious	92	92%	91	91%	183	91.5%
Semiconscious	8	8%	8	8%	16	8%
Unconscious	0	0%	1	1%	1	0.5%
Total	100	100%	100	100%	200	100%
Chisquare test=2.07, p=0.55, Not statistically significant						

Table 6: Number of Fits before Admission

Number of fits Before Admission	Group A		Group B		Total	
	No	%	No	%	No	%
0	12	12%	7	7%	19	9.5%
1	42	42%	50	50%	92	46%
2	27	27%	22	22%	49	24.5%
3	9	9%	9	9%	18	9%
4	9	9%	8	8%	17	8.5%
5	1	1%	1	1%	2	1%
>6	0	0%	3	3%	3	1.5%
Total	100	100%	100	100%	200	100%
Chisquare test =7.26, p=0.40, Not statistically significant						

Table 7: SBP

SBP	Group A		Group B		Total	
	No	%	No	%	No	%
120-140	1	1%	8	8%	9	4.5%
140–160	38	38%	44	44%	82	41%
>160	61	61%	48	48%	109	54.5%
Total	100	100%	100	100%	200	100%
Chisquare test=7.43,p=0.02*, statistically significant						

Table 8: DBP

DBP	Group A		Group B		Total	
	No	%	No	%	No	%
80–90	15	15%	12	12%	27	13.5%
90–100	16	16%	19	19%	35	17.5%
100-110	47	47%	46	46%	93	46.5%
>110	22	22%	23	23%	45	22.5%
Total	100	100%	100	100%	200	100%
Chisquare test=0.03,p=0.98, Not statistically significant						

Table 9: Mode of Induction

MOI	Group A		Group B		Total	
	No	%	No	%	No	%
Augmentation(Oxytocin)	17	18.3%	7	7.4%	24	12.8%
GEL(PGE2)	19	20.4%	22	23.2%	41	21.8%
Misoprostol	57	61.3%	65	68.4%	122	64.9%
Prior LSCS	0	0.0%	1	1.1%	1	0.5%
Total	93	100%	95	100%	200	100%
Chisquare test = 5.89,p=0.011, Not statistically significant						

Table 10: Mode of Delivery

Mode of delivery	Group A		Group B		Total	
	No	%	No	%	No	%
FORCEPS	5	5%	4	4%	9	4.5%
LSCS	21	21%	28	28%	49	24.5%
VACCUM	4	4%	3	3%	7	3.5%
VAGINAL DELIVERY	70	70%	65	65%	135	67.5%
Total	100	100%	100	100%	200	100%
Chisquare test =1.43,p=0.69, Not statistically significant						

Table 11: Admission Delivery Interval in Hours

	Minimum	Maximum	Mean ± SD	P value
Group A	1	22	13.45±6.03	
Group B	2	22	11.81±4.85	0.03*

Table 12: Recurrence of Convulsions after Starting the Regimen

	Group A		Group B	
	No	Percentage	No	Percentage
Recurrence of convulsions after starting the regimen	0	0%	2	2%

Table 13: Condition of Mother after Delivery

	Group A		Group B		Total	
	No	%	No	%	No	%
Alive	100	100%	99	99%	199	99.5%
Dead	0	0%	1	1%	1	0.5%
Total	100	100%	100	100%	200	100%
Chisquare test=1,p=0.31, Not statistically significant						

Table 14: Condition of Baby after Delivery

	Group A		Group B		Total	
	No	%	No	%	No	%
Alive	75	75%	69	69%	144	72%
IUD	2	2%	2	2%	4	2%
Neonatal death	18	18%	22	22%	40	20%
Still birth	5	5%	7	7%	12	6%
Total	100	100%	100	100%	200	100%
Chisquare test = 4.28, p=0.50, Not statistically significant						

Table 15: Birth Weight In Kgs

Birth Weight in kgs	Group A		Group B		Total	
	No	%	No	%	No	%
<1.5	19	19%	14	14%	33	16.5%
1.5– 2.5	40	40%	53	53%	93	46.5%
>2.5	41	41%	33	33%	74	37%
Total	100	100%	100	100%	200	100%
Mean Birth weight in Kg	2.30± 0.70		2.20± 0.65		2.25±0.68	
Chisquare test =3.44,p=0.17,Not statistically significant						

Table 16: Number of Fits after Delivery

Number of fits	Group A		Group B		Total	
	No	%	No	%	No	%
0	98	98%	95	95%	193	96.5%
1	2	2%	4	4%	6	3%
2	0	0%	1	1%	1	0.5%
Total	100	100%	100	100%	200	100%
Chisquare test=1.71, p=0.42, Not statistically significant						

Discussion

Over the years, treatment of eclampsia has undergone a significant change. Eclampsia is one of the most common obstetrical emergencies that cause significant maternal and perinatal morbidity and mortality especially in the developing world. The first principal in the management of Eclampsia is the control of convulsions. Magnesium sulphate is the anticonvulsant drug of choice which prevents and controls eclamptic convulsions and hence reduces maternal and neonatal morbidity but its dose related toxicity is a major concern particularly in clinical environments where the capacity for patient monitoring is limited and when recipients are of small built. [5,6,7] Different magnesium sulphate dose protocols have been used in treating Eclampsia, amongst which Pritchard regime is widely used.

Women in India, especially from rural areas or from low socio- economic Strata, tend to have smaller weights. Administrating Pritchard regime might prove to be hazardous in these low weight women and there is possibility of most dreadful respiratory failure. [10] With this in mind, many studies have been conducted to determine the lowest effective dose and these modifications have shown promise in terms of decreased side effects and comparable efficacy. Mean age, gender and BMI were comparable between the two groups and there was no significant difference in distribution of patients on the basis of presenting complaints or co morbidities or previous surgery between two groups. In our current study, Age of women in 2 groups does not differ. In this study 144 cases (72%) were between 18-24 years, 31 cases (18.5%) were between 25-30, 19 cases (9.6%) were more than 30 years, mean age for Pritchard regimen was 23.45 ± 4.13 years and Dhaka regimen was 22.9 ± 3.6years. In a study done by Dr. Himadri Nayek et al, the mean ages were 23.59 years and 23.65 years in Group L and Group S respectively. In a study done by Ranjana et al compared two groups of severe preeclamptic women by instituting low dose MgSO4 (Dhaka regime) in one group and standard Pritchard regime in other group. The mean age of both the groups was 25.8 and 25.7 years respectively. [5] In a study done by Hall et al the mean maternal age was 26.9 years. In a study done by Coetzee et al the mean maternal age in Magnesium Sulfate group was 24 years and in placebo group was 25 years. [10]

In our present study, In Pritchard regimen the booked classes were 6%. In Dhaka regimen the booked cases were 11%. Unbooked cases of Pritchard regimen were 94% and Dhaka regimen was 89%. P-value is 0.20 which is not statistically significant. In a study done by Anjali rani et al various parameters are compared between Pritchard and Dhaka regimen group. [11] Maximum patients were from rural background (79.16% in Pritchard regimen and 83.3% in Dhaka regimen and Most of the patients were un-booked in both the groups (88%) in Pritchard regimen and (91.7%) in Dhaka regimen. In a study done by Bangal V et al., 90% cases were unbooked. In a study done by Ranjana et al 75% of cases in group A and 65% of cases in group B were unbooked and had no antenatal records at the time of admission to our hospital. [5]

In our current study 135 cases were primigravida (67.5%) (Primigravida > multigravidas) and 65 cases (32%) were multigravidas. In a study done by Dr. Himadri Nayek et al, 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. [7] In a study done by Ranjana et al, Majority of patients were primigravida (70% and 75% in group A and group B respectively). Ante partum eclampsia was the most common followed by impending eclampsia in both the groups. In this

study, 19 cases were 24-28 weeks (9.5%), 24 cases were 29-32 weeks, 69 cases (34.5%) were between 33-36 weeks. Most of the cases i.e 88 cases (44%) were above 37 weeks. In a study done by Dr. Himadri Nayek et al, found that the gestational age were at term (60% and 61%) in Group L and Group S respectively. [7] In a study done by Ranjana et al Mean gestational age in Group A was 34.5 ± 2.88 weeks and in Group B was 34.8±2.71 weeks. [7] In a study done by Hall et al recruited women in their study with mean gestational age of 31 completed weeks. Coetzee et al recruited the same with mean gestational age of 34.3 and 34.8 weeks respectively in Magnesium Sulfate and placebo group respectively.

In our current study, Level of consciousness of the patients in the 2 groups not differs significantly. Conscious patients on both regimen were 191 cases (91.5%). semiconscious were 16% in both the groups. 1 case was unconscious that is with Pritchard regimen. P-value is 0.55 which is not statistically significant. There were no similar studies regarding level of consciousness.

In our present study no significant differences was noted between 2 groups in the number of convulsions before admission. P- Value was 0.40 which was not statistically significant. In a study done by Ranjana et al majority of patients were having number of convulsions between 1-5 in both the group (67.5% in group A and 57.5% in group B). [5] Only one patient experienced more than 10 convulsions in group B.

In our current study, Majority of the cases have SBP (>160). Dhaka regimen 61% and Pritchard 48% and p-value is 0.02 was statistically significant. In our present study, Majority of the cases have DBP of 100-110. P value was 0.98 which is statistically not significant.

In our current study, out of 100 cases Group A (Dhaka regimen) 17 cases were augmented with oxytocin, 19 cases with PGE2, 57 cases with misoprostol. Out of 100 cases in group B (Pritchard), 7 cases were augmented with oxytocin, 22casses with PGE2, 65 cases with misoprostol. P-Value was 0.011 which was statistically not significant.

In our study, out of 100 cases of Dhaka regimen 71 cases delivered vaginally, 5 cases forceps, 21 delivered C-section. Out of 100 cases of Pritchard regimen 65 cases were vaginal deliveries, 4 cases by forceps, 1 case by vacuum, 2 by C section. P-value was 0.69 which was statistically insignificant. In a study done by Dr. HimadriNayek et al It was found that 55 (73.33%) women in Group L and 58 (77.33%) women in Group S had spontaneous vaginal delivery.7 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). In a study done by Ranjana et al shows 57.5% and 67.5% LSCS in both groups Dhaka (Begum R) regimen and Pritchard regime respectively. In a study done by Duley et al also reported a little higher (5%) Cesarean section rate in Magnesium Sulfate group than in those allocated placebo or no anticonvulsant (RR 1.05, 95% CI 1.01 to1.10).10 In patients treated with Dhaka regime 23 (57.5%) patients underwent LSCS, 13 (32.5%) patients had spontaneous vaginal deliveries while in 2(5%) patients outlet forceps and in 1 patient ventouse was applied for foetal distress. In patients treated with Pritchard regime 27 (67.5%) underwent LSCS, 10 (25%) patients delivered naturally while 2 (5%) had assisted vaginal deliveries. One patient in both the group underwent hysterectomy due to uncontrolled PPH during caesarean section.

In current study, mean duration of ADI for Dhaka regimen is 13.45 hours and Pritchard was 11.81 hours. P-value was statistically insignificant. In our present study, in Pritchard regimen only 2 % had 1 convulsion. In Dhaka regimen 5% had convulsions. P-value was 0.42 which was not statistically significant. There was one maternal mortality with Pritchard regimen. The cause of death was renal failure. Recurrence of convulsions was observed in group -B after starting the regime. In a study done by Sardesai SP et al.,(2000) Used low dose MgSO4 in Indian women and found safe and effective Convulsion control was 97.5% in Group 1 (Dhaka) and 100% in Group 2 (Pritchard) with comparable results ($\chi 2$ =1.013; p=0.314). In a study done by Bhagat N et al., Convulsions controlled 97.5% with Dhaka regimen and 100% with Pritchard regimen. MgSO4 toxicity was seen in 10% cases in Dhaka regimen and 32.5% cases in Pritchard. Overall 4.2% recurrence of convulsions was recorded. [11]

In our study, there were no signs of magnesium toxicity seen in both the groups. In a study done by Dr. Himadri Nayek et al, 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. From the meta-analytic study of Duley et al [2] toxicity related to Magnesium Sulfate (absent or reduced tendon reflexes and/or respiratory depression) was uncommon, occurring only in around 1% of women receiving Magnesium Sulfate. 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).

In a study done by Nagaria T et al., (2017) Control of convulsion was 97.6% in low dose group. The mean serum Mg2+ levels were significantly lower in the low dose regimen at 30 minutes as well as at four hours of therapy. In a study done by Anjali rani et al, Magnesium sulfate toxicity was seen in

three cases in Pritchard regimen and in Dhaka regimen no case shows toxicity. It was not statistically significant. The study done by Bhagat N et al. also had shown the same results. A Study by Sahu L et al., also found no case of magnesium sulphate toxicity in Dhaka regimen. The present study shows that low dose Dhaka regimen is as effective and safer as standard Pritchard regimen. A study by Begum R et al., in also shows that low dose magnesium sulfate is as effective as standard Pritchard. Similar statements are also made by Bera P et al. So, our study has also added to the existing facts that Dhaka regimen is as good as Pritchard. So many studies had shown similar results.

In a study done by Ranjana et al, The mean amount of magnesium sulphate received was 22.5 gms and 39 gms in Group A and Group B. One patient died in Group A due to cerebrovascular accident and 2 patients in group B due to DIC and cerebrovascular accident respectively.

In our current study, In Dhaka regimen there were no maternal deaths (100%). In Pritchard regimen 99 cases (99.5%) were alive and only 1 case died (0.5%) due to renal failure. P- value was 0.31 which was not statistically significant. In our present study, Out of 200 cases, 144 (72%) were alive, IUD were 4 cases (2%), neonatal deaths were 40 (20%) and still births were 12 (6%). There was no major difference between 2 groups. P-value was not statistically significant.

In our study, Most of the neonates were in range of 1.5-2.5 kgs. P - value was 0.17 which was not statistically significant. In a study done by Dr. Himadri Nayek et al, 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 (p0.05). 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) in a study done by Kansa VM et al., (2019) Neonatal deaths were 5% in low dose group and 6.7% in Pritchard group. In a study done by Anjali rani et al, Deaths due to preeclampsia/eclampsia was 30.50% (18/59×100). There were total 59 maternal deaths and deaths due to preeclampsia and eclampsia was 18 In Pritchard groups there were 6.25% early neonatal deaths and in Dhaka regimen there were 5.55% early neonatal deaths.

In a study done by Ranjana et al, Six (15%) cases in Group A and 10 (25%) cases in Group B were already had IUD at the time of admission. Mean birth weight in Group A and Group B was 2.03 kg and 2.13 kg respectively [5]. APGAR score, neonatal death rate and overall perinatal death were comparable in both the groups. Neonatal mortalities were mainly due to birth asphyxia, respiratory syndrome and septicemia

Conclusion

In women with eclampsia, magnesium sulphate is the anticonvulsant medication of choice. For smaller women, the Dhaka Regimen at a low dose appears to effectively regulate and avoid seizures. The current study offers more convincing evidence in favour of using magnesium sulphate frequently to treat eclampsia convulsions. Clinical surveillance seems suitable as long as there is enough urine output. There is no difference between the two magnesium sulphate regimens in terms of maternal mortality, perinatal death, maternal morbidity, or caesarean section rates. The research amply demonstrates that the Dhaka regimen is nearly similar to Pritchard protocol for the prevention and management of convulsions.

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