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Original Research Article

Comparison of low dose magnesium sulphate regime with standard Pritchard regime in severe preeclampsia and eclampsia: a tertiary centre experience

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ABSTRACT

Background: We tried to see if omitting the intravenous (IV) loading dose of magnesium sulphate ($MgSo_4$) would result in similar outcome in comparison to the standard loading dose (intravenous+intramuscular) in eclampsia in preventing convulsions.
Methods: Patients were randomized into 2 groups. In group A (modified Pritchard regimen), IV loading dose of $MgSo_4$ was omitted (only IM loading dose was given) and maintenance dose was given for 12 hours. In group B, standard Pritchard regimen was followed, both IV and IM given as loading dose and maintenance dose was given for 24 hours. Our aim was to see if modified Pritchard regimen was as effective as the standard Pritchard regimen.
Results: There was no difference in age, parity, gestational age at presentation, mode of child birth between both regimens. After 1 hour of loading dose, in both pre-eclampsia (PE) and eclampsia patients, in both groups A and B, therapeutic range of $MgSo_4$ was reached with added benefit of less propensity of toxicity in group A (as IV dose was omitted). Out of 64 women with eclampsia, recurrent convulsions were seen in 6 women (20.68%) of group A and 11 women (31.4%) of group B (p=0.333). None of the women of severe PE had convulsion after loading dose of $MgSO_4$ in either of the two groups.
Conclusions: We conclude that efficacy of reduced loading dose regimen (omitting IV loading dose) and 12 hour maintenance dose of $MgSo_4$ is similar to standard Pritchard regimen (which employs full loading dose and 24 hour maintenance dose) in both prophylaxis of convulsion in severe preeclampsia and controlling convulsion and preventing recurrent convulsion in eclampsia with the obvious lower propensity for $MgSo_4$ toxicity.

Keywords: Eclampsia, Pre-eclampsia, Magnesium sulphate, Convulsions, Pritchard regimen

INTRODUCTION

The incidence of hypertensive disorders of pregnancy including PE and eclampsia is high in developing countries due to hypoproteinemia, malnutrition and poor obstetric facilities. $MgSO_4$ is the mainstay of preeclampsia and eclampsia treatment and Pritchard regime is the most commonly employed regimen.[1] But use of $MgSO_4$ in community is limited because of apprehension among healthcare workers about its safety. Low doctor to patient ratio, limited provider knowledge and training and fear due to lack of ventilatory support in case of respiratory depression are responsible for underutilization of $MgSO_4$.[2,3] A common scenario is when cases of severe preeclampsia/eclampsia are sent from some remote place and throw a convulsion or have recurrent convulsions on the way which poses grave consequences to maternal life, simply because $MgSO_4$ particularly IV appears scary to be given at primary health centres. The present study was planned to evaluate a modified loading dose of $MgSO_4$

omitting the IV component so that women may receive the loading dose prior to referral.

METHODS

This was a prospective study, conducted in department of obstetrics and gynaecology, Military hospital, Meerut conducted over a period of four years from August 2017 to July 2021.

All consecutive women admitted in the department with eclampsia/severe PE were enrolled in the study after taking informed consent.

Hypertension was managed with IV labetalol if systolic blood pressure was ≥160 mmHg or diastolic blood pressure was 110 mmHg and subsequently by oral labetalol and nifedipine accordingly, only if they were fit enough for oral intake.

Patients with other causes of convulsions like epilepsy, cerebrovascular accidents, ruptured aneurysm, meningitis, encephalitis, cerebral tumors, metabolic abnormalities, women already treated outside with $MgSO_4$ were excluded from the study.

Sample size was calculated according to the study done in 2012 by Okusanya et al in which 7% of women who had only 10 gm IM loading dose had repeat convulsions, while no repeat convulsions occurred in those with 14 gm (4 gm intravenous and 10 gm intramuscular) loading dose.[15] Taking this into consideration sample size was 105 in each group by following formula,

$$n=C+\frac{P_1q_1+P_2q_2}{d^2}+\frac{2}{d}+2,$$

where,

P1=0.07 (7%),

q1=1-P1=0.93,

P2=0.0 (0%),

q2=1-P2=1.0,

d=P1-P2=0.07,

C=7.8=105 for each group.

Cases were further divided into two groups: group A (study group/receiving modified dose $MgSO_4$ as given below); group B (receiving standard Pritchard's regime of $MgSO_4$).

Group A was given only 10 gm IM $MgSO_4$ (5 gm in each buttock) loading dose followed by maintenance dose 5 gm IM in alternate buttock every 4 hours for 12 hours after delivery/last convulsion whichever was later.

Group B was given standard Pritchard regime, 4 gm IV and 10 gm IM of $MgSO_4$ (5 gm in each buttock) loading dose followed by 5 g maintenance dose 4 hourly in alternate buttock for 24 hours after delivery or last convulsion whichever was later.

If the patient in the study or control group had convulsion after administration of loading dose then 2 g IV $MgSO_4$ was given. This additional dose was given upto a maximum of 2 times and if they had recurrent convulsions then other regimen was given as per protocol. The additional doses, when given, were given after one hour of the loading dose in all the cases, so the additional doses of $MgSO_4$ did not have impact on the serum magnesium levels which were seen at 15 minutes and then at one hour after the loading dose. Number of cases requiring this additional dose in the two groups was compared.

Randomization

By computer generated random number in blocks of 4 were selected.

Allocation concealment

Allocation concealment was done by SNOSE-sequentially numbered opaque sealed envelopes.

Blinding

Of participants (study group) was done by giving 20 ml normal saline slow IV over.

Signs of magnesium toxicity were respiratory rate; knee jerk reflex and hourly urinary output estimation were monitored in both groups. $MgSO_4$ toxicity was ruled out if the women had respiration 16 cycles per min and knee jerk reflex was present. 30 ml per hour urine output was ensured before giving next dose in all cases. 10 ml of 10% calcium gluconate was given if any woman had respiratory depression.

Outcome measures were occurrence of convulsion in severe PE, recurrence of convulsions in eclampsia and serum levels of magnesium before administering $MgSO_4$ and at 15 min and 1 hour after giving $MgSO_4$. Recurrent eclampsia was defined in our study as seizures occurring after administration of loading dose.

Statistical analysis

Statistical analysis was done using SPSS (statistical package for social sciences) version 21.0 statistical analysis software. Continuous variables were expressed in Mean±SD. Categorical variables were expressed as

frequency and percentage. Nominal categorical data were compared using Chi square test or Fischer's exact test as appropriate. Quantitative data were compared using paired t test. For all statistical purposes, confidence interval was set at 95% and p value <0.05 was considered significant.

RESULTS

Table 1 shows group wise distribution of study population and Table 2 shows distribution of cases according to various parameters. Table 3 shows that among women with severe PE, mean serum magnesium levels of women of both groups were comparable prior to loading dose 1.99±0.33 mg/dl and 2.07±0.52 mg/dl in group A and group B respectively (p=0.281).

After loading dose there were statistically significant higher levels of serum magnesium in group B at both 15 min and 1 hour.

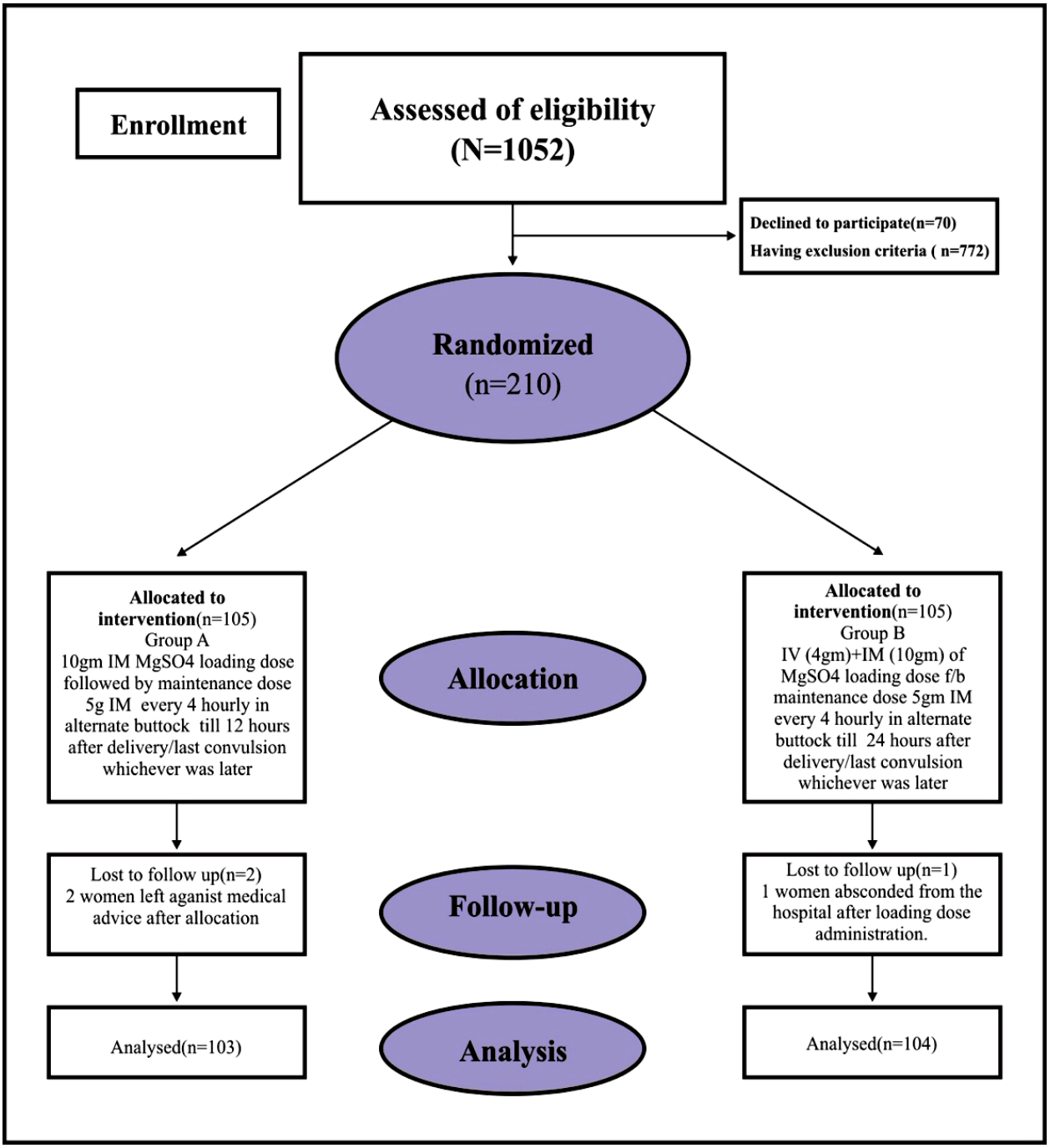

Figure 1: Consort flow diagram.

Table 1: Group wise distribution of study population.

Groups	Description	No. of subjects	Severe PE	APE	Percentage
Group A	Study group	105	76	29	50.00
Group B	Control group (standard Pritchard's regimen)	105	70	35	50.00
Total		210	146	64	100.00

Table 2: Distribution of cases according to various parameters.

Parameters		Group A (n=103)		Group B (n=104)		Total (n=207)		χ^2	P
		No.	%	No.	%	No.	%		
Severe PE or antepartum eclampsia	Severe PE	74	71.84	69	66.35	143	69.08	0.733	0.392
	Eclampsia	29	28.16	35	33.65	64	30.92		
Age group (in years)	≤20	6	5.83	5	4.81	11	5.31	0.336	0.846
	21-30	80	77.67	79	75.96	159	76.81		
	>30	17	16.50	20	19.23	37	17.87		
Religion	Hindu	74	71.84	64	61.54	138	66.67	2.143	0.143
	Muslim	29	28.16	40	38.46	69	33.33		
Place of residence	Urban	60	58.25	55	52.88	115	55.56	0.604	0.437
	Rural	43	41.75	49	47.12	92	44.44		
Educational status	Illiterate	34	33.01	36	34.62	70	33.82	0.060	0.807
	Literate (>standard 8)	69	66.99	68	65.38	137	66.18		
Number of antenatal care visits	≤4 visits (unbooked)	79	76.70	79	75.96	158	76.33	0.016	0.901
	>4 visits (booked)	24	23.30	25	24.04	49	23.67		
Parity	0	60	58.25	56	53.85	116	56.04	0.408	0.523
	1	23	22.33	22	21.15	45	21.74		
	2	13	12.62	15	14.42	28	13.53		
	≥3	7	6.80	11	10.58	18	8.70		
History of hypertension/PE/ eclampsia	Yes	6	5.83	4	3.85	10	4.83	0.441	0.507
	No	97	94.17	100	96.15	197	95.17		
Mode of delivery	Vaginal	44	42.72	39	37.50	83	40.10	2.428	0.297
	LSCS	59	57.28	63	60.58	122	58.94		
	Not delivered	0	0.00	2	1.92	2	0.97		
Perinatal outcomes	Live	73	70.87	74	72.55	147	71.71	0.071	0.790
	Stillborn	30	29.13	28	27.45	58	28.29		
Maternal outcomes	Improved	101	98.06	101	97.12	202	97.58	0.195	0.659
	Expired	2	1.94	3	2.88	5	2.42		

Table 3: Comparison of serum magnesium levels (mg/dl) in two groups.

Time period	Group A			Group B			Statistical significance	
	N	Serum magnesium level in mg/dl		N	Serum magnesium level in mg/dl		t	P
		Mean	SD		Mean	SD		
Severe PE (n=143)								
Before loading dose	74	1.99	0.33	69	2.07	0.52	-1.083	0.281
15 min after dose	74	3.86	0.98	69	6.10	0.98	-13.665	<0.001
1 hr after dose	74	4.84	0.84	69	5.29	1.07	-2.980	0.006
Antepartum eclampsia (n=63)								
Before loading dose	29	2.17	0.46	34	2.37	0.71	-1.292	0.201
15 min after loading dose	29	4.47	0.80	34	6.48	1.19	-7.724	<0.001
1 hr after loading dose	29	4.93	0.68	34	5.68	1.11	-3.165	0.002

Table 4: Comparison of recurrence of convulsions in cases of antepartum eclampsia in two groups.

After treatment	Group A (n=29)		Group B (n=35)		Total (n=64)		χ^2	P
	No.	%	No.	%	No.	%		
No repeated episodes	23	79.32	24	68.57	47	73.44	0.938	0.333
Repeated episodes	6	20.68	11	31.43	17	26.56		

Table 5: Comparison of timing of recurrence of convulsions among cases of antepartum eclampsia in the two groups.

Time of recurrent convulsion (interval after loading dose)	Group A (n=6)		Group B (n=11)		Total (n=17)		χ^2	P
	No.	%	No.	%	No.	%		
Within 5 min	2	33.33	2	18.18	4	23.53	0.892	0.827
Within 15 min	2	33.33	5	45.45	7	41.18		
Within 1 hr	1	16.67	3	27.27	4	23.53		
Within 4 hr	1	16.67	1	9.09	2	11.76		

Table 6: Comparison of recurrent convulsions and maternal mortality in different studies in women of antepartum eclampsia.

Study		Present study (%)	Begum et al (%)	Okusanya et al (%)
Recurrence of convulsions	Study group	20.68	3.96	7
	Control group	31.43	3.52	0
Maternal mortality	Study group	1.94	4.45	4.42
	Control group	2.88	5.02	0

The serum magnesium levels achieved therapeutic level after 15 minutes of loading dose in eclampsia but not in severe PE cases. This may be due to increased third space loss in patients with severe PE due to which there was delay in serum magnesium level to attain therapeutic levels.

Among women with antepartum eclampsia, mean serum magnesium levels of women of both groups were comparable prior to loading dose, 2.17±0.46 mg/dl and 2.37±0.71 mg/dl in group A and group B respectively (p=0.201). After loading dose there were statistically significant higher levels of serum magnesium in group B at both 15 min and 1 hour.

We can infer from the above table that after 1 hour of loading dose, in both PE and eclampsia patients, in both groups, therapeutic range of $MgSO_4$ is reached with added benefit of less propensity of toxicity in group A (as IV dose was omitted). In fact, we may one day in future, see a new world where IV dose was permanently omitted and only IM loading dose would be the standard loading dose recommendation.

Table 4 shows that out of 64 women with antepartum eclampsia, recurrence of convulsions (occurrence of convulsions after loading dose) was seen in 6 women (20.68%) of group A and 11 women (31.4%) of group B (p=0.333). In our study group patients, maintenance dose was given for 12 hours and in control group patients, maintenance dose was given for 24 hours. Still recurrent convulsions were more in the control group. These findings may be due to larger sample size in group B patients. Although the relation was statistically not significant, we at least can say that propensity of recurrent convulsion was not raised in patients in whom IV loading dose is omitted. These findings justified our study that low loading dose was sufficient to manage eclampsia.

Table 5 shows the time of recurrence of convulsions in the 17 patients in whom there were recurrent convulsions. The timing of recurrent convulsions was not significant.

None of the 64 patients had thrombocytopenia precluding the use of $MgSO_4$. Severe local site pain and occurrence of gluteal abscess with use of IM $MgSO_4$ was not observed in any of our patients.

DISCUSSION

Hypertensive disorders of pregnancy including PE and eclampsia complicate around 5-10% of pregnancies worldwide and together they were a member of the deadly triad, along with hemorrhage and infection that contributed to maternal morbidity and mortality.[4,5] The incidence was high in developing countries due to hypoproteinemia, malnutrition and poor obstetric facilities. Overall, 10-15% of maternal deaths were directly associated with PE and eclampsia.[2]

The collaborative eclamptic trials in 1995 conclusively proved that $MgSO_4$ was the drug of choice for the anticonvulsant management of eclampsia rather than diazepam or phenytoin.[6] The use of this drug reduced maternal deaths from 7% to 4% and the recurrence rate of convulsion was reduced by 52% and 67% when compared with diazepam and phenytoin respectively.[7,8]

Since the introduction of Pritchard's regimen of $MgSO_4$ there had been a constant discussion regarding the dose of $MgSO_4$ and therapeutic serum magnesium levels.

Phuapradit et al and Witlin in their study, observed that $MgSO_4$ dosing should vary according to women's weight or body mass index.[9,10] Based on these observations various low dose regimens have been introduced in Asian countries.

The present study was a comparison between modified low dose regime of $MgSO_4$ (10 gm only IM loading dose omitting IV dose and continuing maintenance dose for 12 hours after delivery/last convulsion whichever was later as compared to 24 hours in Pritchard regime) and standard Pritchard regime of $MgSO_4$ (4 gm IV+10 gm IM of $MgSO_4$ loading dose), in terms of occurrence of convulsion in severe PE, recurrence of convulsion in eclampsia and serum levels of magnesium.

The relevance of our study lied in the fact that $MgSO_4$ was not an innocuous drug. It was necessary to monitor the patients who were receiving the medication to prevent serious side-effects. It was recommended that frequent monitoring (every 5-10 min) should be undertaken during the first 2 hour of therapy when the intravenous regimen was being used. Where the number of patients was high in relation to attending doctor and health care workers frequent monitoring was sometimes difficult. $MgSO_4$ particularly IV appeared scary to be given at all places considering this; IM regime appeared to be most suitable.

As mentioned in literature serum magnesium levels of 2.0 to 3.5 mmol/l or 4.8 to 8.4 mg/dl or 4 to 7 mEq/l had been suggested for treatment and prevention of eclamptic convulsions.[11]

In present study serum magnesium levels were measured prior, after 15 min and 1 hour of loading dose of $MgSO_4$, which showed low level of serum magnesium (but still in therapeutic range) in study group as compared to control group. In severe PE women, therapeutic serum magnesium levels were not reached after 15 min of loading dose administration but were in therapeutic range at 1 hour post loading dose. In eclampsia women serum magnesium level were within therapeutic range after 15 min and 1 hour both in study group and control group.

On comparing with another study in 2015 by Savitha et al assessed the effectiveness of low dose $MgSO_4$ regime for the prevention of convulsion in severe PE and eclampsia and compared the therapeutic levels of serum magnesium at 1 hour, 6 hour and 12 hours after administration of loading dose.[12] In study group, low dose $MgSO_4$, loading dose 4 gm IV, maintenance dose 2 gm/4 hr IV infusion and in control group loading dose 4 gm IV, maintenance dose of 2 gm/hr IV infusion was given serum magnesium levels prior to loading dose were not measured either in study group or in control group. There was statistically significant difference between serum magnesium levels at 1 hour, 6 hour and 12 hour between the two groups ($p<0.01$) but levels in both groups were in therapeutic range at all time intervals at which they were measured.

Recurrence of convulsions in eclampsia

In present study, recurrence of convulsions among antepartum eclampsia (APE) women was 31.43% in group B and 20.68% in group A; this was in variance to the results described in standard literature of western population. This can be explained by poor health awareness among Indian women leading to late arrival at heath care centres. So that by the time they arrive they have already had many convulsions (5.30±3.32 in group A and 4.63± 3.19 in group B in women who did not have repeat convulsions and 6.67±3.78 in group A and 6.18±4.36 in group B in women who had repeat convulsions) and were in a low condition.

In their study, Samoriski et al observed that generalized clonic seizures resulted in a progressive decrease in both the generalized seizure threshold and caused hypoxic brain injury.[13] So it was postulated that the high number of seizures prior to admission resulted in lower seizure threshold and hypoxic brain injury accounting for the high incidence of recurrent seizures after $MgSO_4$ loading dose in both groups.

It was shown in Table 3 that in present study it was found that convulsions did not occur after giving $MgSO_4$ in women of severe PE in both groups. However, in APE repeated episodes of convulsions were observed in 20.68% and 31.43% women in group A and group B respectively and the difference was not found to be statistically significant ($p=0.333$).

In group A, recurrent convulsions occurred in 6 women (20.68%) and in all of them serum magnesium levels were not in therapeutic range. In group B, 11 women had recurrent convulsions in whom 9 women had serum magnesium levels in therapeutic range, in only 1 woman therapeutic levels were not reached and sample of one woman could not be sent as she expired within 15 min of admission.

Begum et al 2002 in their study, used only loading dose consisting of 4 gm intravenously and 6 gm intramuscularly in each buttock in study group and 4 gm intravenously and 6 gm intramuscularly as loading followed by 2.5 gm intramuscularly every 4 hourly in each alternate buttock for 24 hourly in control group and the difference in recurrence rate of convulsion in both the groups was not

significant.[14] So they concluded that only a reduced loading dose of 10 gm (4 gm IV+6 gm IM) was sufficient for preventing recurrent convulsions in eclampsia in Bangladeshi women.

Okusanya et al 2012 in their study, used loading dose of 10 gm MgSO4 via IM route in study group and 14 gm loading dose (10 gm IM and 4 gm IV) of Pritchard regimen was given to control group in women with severe PE/eclampsia and there was no significant difference in rate of recurrent convulsion (p=0.1948).[15]

Maternal outcome

Present study showed that maternal outcome of majority of women was good with 101 women of each group being discharged well (97.58% overall; 98.06% group A and 97.12% group B). Maternal death occurred in 2 women (1.94%) in group A and 3 women (2.88%) in group B. This difference was not found to be statistically significant (p=0.659). Cause of death of 2 women of group A was pulmonary edema and pulmonary embolism each. 3 women expired in group B and the cause of death of 3 women in group B was pulmonary edema, pulmonary embolism and DIC with pulmonary embolism in each case.

Table 6 shows that maternal deaths in present study were lower as compared to observations by Begum et al and Okusanya et al in their studies.[14,15]

The reported maternal mortality ranged from 0.4% to 4% depending on the condition of the women on admission and hospital facilities.

CONCLUSION

The present study indicates that a reduced loading dose (only 10 gm IM) and shortened period of maintenance dose (12 hours after delivery/convulsion whichever is later) of $MgSO_4$ alone is as effective in controlling and preventing the recurrence of convulsions in eclampsia as that of Pritchard regime in Indian women. It also has the added advantage of being less expensive and in reducing the number of painful IM injections. The introduction of only IM $MgSO_4$ to primary health facilities would make available an evidence-based treatment at the first point of contact for women with eclampsia as in present study 44.34% women had been referred without being given loading dose of $MgSO_4$. This study suggests that many lives may be saved by this intervention and demonstrates the prospects for its use at this level of care. The adverse maternal and perinatal outcome in this study is still unacceptably high due to poor antenatal care received by the patients; however, based on the findings from this study, consideration should be given to the use of low dose $MgSO_4$ in the management of eclampsia as there is no significant difference between it and the standard Pritchard regime. The key issue in developing countries like India is transport and high patient to staff ratio, especially in rural areas. After women start getting convulsions they need to be transported to a tertiary referral center. In such situations, the intramuscular regime can be initiated and then they can be transported without fear of convulsion during transit. The dose we propose is small and very easy to administer.

A larger study, preferably a randomized control trial is recommended to further evaluate the feasibility and efficacy of the use of only MgSO4 intramuscular loading dose in cases of eclampsia and severe preeclampsia.

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