Original Research Article

Study of maternal outcome in women receiving low dose magnesium sulphate

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Abstract

Background: Eclampsia is the second most common cause of maternal mortality in India. Pritchard's regimen is the most popular regimen but has dose related side effects. There was a need for modification of magnesium sulphate dose especially in women with low body weight. **Aim:** To study the maternal outcome of low dose magnesium sulphate in women with eclampsia. Material and Methods: A total of 240 pre-eclamptic women complicated by eclampsia were divided into two groups as: Low dose regimen -received MgSO4 according to low dose MgSO4 regimen and Pritchard regimen-received MgSO4 according to Pritchard regimen. Maternal complications and mortality was observed in both groups. **Results:** Abruption and HELLP syndrome were leading complication of eclampsia observed in both groups. CVA occurs in one patient in Low dose group and one patient in Pritchard group. Maternal mortality in Low dose regime was 2.4% and in Pritchard regime was 4.8%. **Conclusion:** Low dose magnesium sulphate regime is equally efficacious as Pritchard's regimen. Low dose regime can be suggested for Indian women who were having less BMI as compare to their counterparts in western world.

Key Word: Eclampsia, Magnesium sulphate, low dose regime, Pritchard's regimen, maternal mortality

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INTRODUCTION

Eclampsia is the second most common cause of maternal mortality in India. The pathophysiology of eclampsia is poorly understood and treatment controversial. Prevention of seizure activity in preeclampsia and recurrent seizures in eclampsia is the essential aspect of management of eclampsia. Numbers of different anticonvulsants are in use to control eclamptic fits and to prevent future seizures. Magnesium sulphate (MgSO4) is the anticonvulsant of choice as it controls and prevents recurrence of eclamptic convulsions more effectively, in addition to reducing feto-maternal morbidity and mortality.[1,2] Pritchard's regimen is the most popular time-tested regimen used. But this 'high dose' regimen, which is standardized for Western women, showed multiple dose-related and potentially life-threatening toxicities like respiratory, renal and neuromuscular dysfunction in lean and malnourished women from low and middle income countries.[3,4] There was a need for modification of dose in management of eclampsia and to formulate a regimen of women of tropical world physique. Indian women especially are from low socio-economic strata, weighing much smaller than their counterparts in the World. In India, Pritchard's regimen has been modified at many places due to concerns over availability, safety, cost and religious monitoring.[3-6] With this in mind the dose of $MgSO_4$ was modified and standardized protocol has been formulated to suit our Indian women weighing around 40-60 kg. The present study was conducted to study the maternal outcome of low dose magnesium sulphate in women with eclampsia.

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MATERIAL AND METHODS

This prospective randomized case control clinical trial was conducted at our tertiary care institute over a period of two years. A total of 240 cases calculated according to prevalence of eclampsia at our institute. The study was started after approval from Institutional Ethical Committee.

Inclusion criteria

- All women diagnosed with eclampsia

Exclusion criteria

- Hypersensitivity to Magnesium.
- Hepatic coma with risk of renal failure.
- Myasthenia gravis
- Other causes of convulsions apart from pre-eclampsia and eclampsia such as cerebral malaria, epilepsy, hepatic encephalopathy.
- Cases who had received anticonvulsant treatment before admission to hospital and those who presented with complications like CVA, renal failure and aspiration pneumonitis.

Definitions

- Eclampsia: The onset of convulsion in a woman with preeclampsia that cannot be attributed to other causes is termed eclampsia.
- Mild preeclampsia: When systolic BP greater than or equal to 140 and less than 160 and/or diastolic BP equal to or greater than 90 but less than 110 mmHg and proteinuria of 1+ and not associated with frontal headache, clonus, visual disturbances, epigastric pain, pain in right upper abdominal quadrant, oligouria (urine output <50ml/24 hours), pulmonary edema, elevated liver enzymes AST, ALT>40IU/L, increased Serum creatinine >1.5 mg/dl.
- Severe preeclampsia: When systolic BP greater than equal to 160 mmHg and diastolic BP greater than equal to 110 mmHg and or persistent proteinuria of 2+ and above associated with any of above mentioned criteria.

All pre-eclamptic women complicated by convulsion called eclampsia were divided into two groups as:

- **Low dose regimen:** Those women who received $MgSO_4$ according to low dose $MgSO_4$ regimen.
- **Pritchard regimen:** Those women who received $MgSO_4$ according to Pritchard regimen.

Low dose $MgSO_4$ regimen

Loading dose: 4 gm $MgSO_4$ I.V. diluted in 20 cc of 5% dextrose slowly over 15-20 minutes. **Maintenance dose:** 2 gm 50% $MgSO_4$ I.M. given 3 hourly till 24 hours after delivery or after last convulsion whichever was later. If urine output was above 30 ml/hour, deep tendon reflexes were intact and respiration rate was adequate (i.e.>14-16/minute). If $MgSO_4$ toxicity developed, it can be reversed by slow I.V. administration of 10% calcium gluconate solution and nasal administration of O2.

Recurrence: In case of recurrence of convulsion, after half an hour of the $MgSO_4$ dose, an additional dose of 2 gm 20% diluted in 20cc of 5% Dextrose I.V. was given and previous schedule of 3 hourly was continued. If again recurrence occurred, 2 gm $MgSO_4$ I.V. was given and previous schedule of 3 hourly was continued. If again recurrence occurred, then other anticonvulsant like phenytoin sodium was used.

Failure: Recurrence of more than 2 convulsions and in case of use of other anticonvulsant like phenytoin sodium.

Successful: Control of convulsions without using any other anticonvulsant except Magnesium sulphate.

Pritchard regimen

Loading dose: 4 gm $MgSO_4$ as a 20% solution I.V. was given at the rate of not to exceed 1 gram/ minute the diluents may be 5% dextrose or 0.9% normal saline, followed by 10 gm of 50% $MgSO_4$ solution. 5 gm injected deeply in upper outer quadrant (superolateral) quadrant of both buttocks through a 3 inch, 20 guage needle.

Maintenance dose: Every 4 hours there after 5 gm of 50% solution of $MgSO_4$ injection deeply I.M. given in outer upper quadrant of alternate buttocks only if patellar reflex present, respiratory rate between 14-16/minute and urine output of previous 4 hours >100ml. $MgSO_4$ prophylaxis was given 24 hrs after delivery or last convulsion whichever was later. If $MgSO_4$ toxicity developed, it can be reversed by slow I.V. administration of 10% calcium gluconate solution and nasal administration of O2.

Recurrence: If convulsion occurred during treatment after 30 min of loading dose then 2 gm of 20% $MgSO_4$ given I.V. not exceeds 1 gm/min. And previous schedule continued, if still convulsion occurred, then again 2 gm $MgSO_4$ was repeated and previous schedule continued. If again recurrence occurred, then other anticonvulsant like phenytoin sodium was used.

Failure: Recurrence of more than 2 convulsions and in case of use of other anticonvulsant like phenytoin sodium.

Successful: Control of convulsions without using any other anticonvulsant except Magnesium sulphate.

Methodology

Detailed history was obtained, age and parity noted, chief complaints were noted. History in detail of previous pregnancies, if applicable their outcome was elicited. General and systemic examination was followed to rule out any systemic or medical disorder complicating pregnancy. Hydration was maintained by Ringer lactate 75cc/hour over 24 hours and I.V. fluids restricted to prevent circulatory overload. Patient encouraged to take orally as soon as they recovered. Nifedipine 10 mg was given either

orally as an adjuvant therapy in patient who had systolic BP>160 mmHg and/or diastolic BP>110 mmHg stat and every 4-6 hours maximum upto 120 mg. If the BP remains uncontrolled, then Inj Labetalol 20 mg IV bolus was given. Watch for 10 min. If BP did not come down to expected range (80-100 mmHg) in 10 minutes, 2nd dose of IV Labetalol bolus 40 mg was given maximum upto 300 mg. Once BP controlled, oral Labetalol 200-400 mg every 12 hourly was started. If LDH was above 600 IU, then Inj. Dexamethasone 10 mg I.V. 12 hourly was given till LDH level came to normal. Investigation done were blood grouping and Rh typing with cross matching, bedsides test like urine albumin by dipstick method, bleeding time and clotting time estimation, Complete blood count, liver function test, kidney function tests, serum lactate dehydrogenase level (for hemolysis). Peripheral smear to detect intravascular hemolysis and coagulation profile, fundoscopy, NCCT brain, if intracranial haemorrhage or infarct were done whenever needed. Serum Magnesium level was not done in present study but women was monitored clinically for MgSO4 intoxication. All women were observed in eclampsia room for adverse or side effects of Magnesium sulphate till discharge from hospital. All these patients were remained in hospitalized for a minimum of 5 days postpartum and they were discharged after this period depending on their clinical condition.

Statistical analysis

Data analysis was done by Chi-square test and statistically significance was calculated.

RESULTS

Mean age in low dose regime was 22.41±3.48 years. Mean age in Pritchard regime was 22.65±2.89 years. A youngest age woman in present study was 16 years and eldest of 35 years. 84 (70%) women in Low dose regime and 68 (56.67%) women in Pritchard regime were in age group of 20- 24 yrs. Only 1 woman in Low dose regime and 2 women in Pritchard regime were above 30 years.

Table 1: Characteristics of study population

Characteristics	Low dose regime (n=120)	Pritchard regime (n=120)	P value
Age (in years)			
≤19	13 (10.83%)	20 (16.66%)	X^2=4.73; p=0.19 (Not significant)
20-24	84 (70%)	68 (56.67%)	
25-29	22 (18.33%)	30 (25%)	
>30	1 (0.83%)	2 (1.66%)	
Parity			
P0	76 (63.33%)	74 (61.67%)	X^2=4.95; P=0.08 (Not significant)
P1	32 (26.67%)	23 (19.17%)	
P2-P4	12 (10%)	23 (19.17%)	
BMI			
<19	34 (28.32%)	30 (25%)	X^2=0.56; P=0.75 (Not significant)
19-24	63 (51.5%)	61 (50.83%)	
>24	25 (20.72%)	29 (24.17%)	
Type of eclampsia			
Antepartum	94 (78.33%)	102 (85%)	X^2=1.78; P=0.18 (Not significant
Postpartum	26 (21.67%)	18 (15%)	
No. of convulsions			
≤3	34 (28.33%)	36 (30%)	X^2=0.88; P=0.64 (Not significant
4-6	74 (61.67%)	68 (56.67%)	
7-10	12 (10%)	16 (13.33%)	

In present study, 76 (63.33%) women in Low dose group and 74(61.67%) women in Pritchard regime were nulliparous. In Low dose regimen, 63 (51.50%) women were of normal BMI. In Pritchard regimen, 61 (50.83%) women were of normal BMI. Mean BMI in low dose regime was 22.5 kg/m^2 and Pritchard regime was 22.13 kg/m^2. 94 (78.33%) women in Low dose regime and 102 (85.00%) women in Pritchard regime had ante partum and intrapartum eclampsia. 74 (61.67%) women in Low dose group and 68 (56.67%) women in Pritchard group had 4-6 convulsions. 34 (28.33%) women in Low dose group and 36 (30%) women in Pritchard group had ≤3 convulsions. 12 (10%) women in Low dose group and 16 (13.33%) women in Pritchard group had 7-10 convulsions. In both groups, not a single woman was suffering from status eclampticus. In present study 60 (63.82%) women in Low dose regimen and 65 (63.72%) women in Pritchard regimen were above gestational age 33 wks. In present study all women delivered within 24 hours of admission. 72 (76.59%) women in Low dose regime and 71(69.60%) women in Pritchard regime delivered within 2-12 hours. In Low dose regime 62 (65.96%)

women and in Pritchard regimen 68 (66.67%) women delivered vaginally. In Low dose regime 8 (8.85%) women required instrumental delivery. Out of whom 7 were term and one was pre-term. Out of 102 women who received Pritchard regimen 6 women required instrumental delivery. Out of whom 3 were term and 3 were preterm. 24 women in Low dose group delivered with LSCS and 28 women in Pritchard group delivered by LSCS.

Table 2: Maternal characteristics

Characteristics	Low dose regime (n=120)	Pritchard regime (n=120)	P value
Gestational age			
≤28 weeks	11 (11.7%)	12 (11.76%)	X^2=1.38; P=0.71 (Not significant
29-32 weeks	23 (24.46%)	25 (24.5%)	
33-36 weeks	34 (36.17%)	30 (29.41%)	
37-40 weeks	26 (27.65%)	35 (34.31%)	
Labour duration			
<2 hours	12 (%)	17 (16.67%)	X^2=0.85; P=0.65 (Not significant
2-12 hours	72 (%)	71 (69.6%)	
13-24 hours	10 (%)	14 (13.73%)	
Mode of delivery			
Vaginal	62 (65.96%)	68 (66.67%)	X^2=0.5; P=0.76 (Not significant
Instrumental	8 (8.51%)	6 (5.88%)	
LSCS	24 (25.53%)	28 (27.45%)	

In Low dose regimen mean dose requirement was 21.25 grams. In Pritchard regimen mean dose requirement was 40.59 grams.

Table 3: Control of convulsion

Recurrence of convulsion	Low dose regime (n=120)	Pritchard regime (n=120)
Without Recurrence	109 (90.83%)	116 (96.66%)
With one recurrence	3 (2.5%)	2 (1.6%)
With two recurrence	4 (3.3%)	2 (1.6%)
More than 2 recurrence	4 (3.3%)	0 (0%)

[X^2=0.54; P=0.76 (Not significant)]

In present study 109 (90.83%) women were managed with low dose $MgSO_4$ without any recurrence. In Pritchard regimen 116 (96.66%) women were managed without any recurrence.

Table 4: Side effects of $MgSO_4$

Side Effect	Low dose regime (n=120)	Pritchard regime (n=120)
Flushing	23 (19.16%)	34 (28.33%)
Hypotension	5 (4.17%)	9 (7.5%)
Respiratory depression	0 (0%)	2 (1.66%)
Absent reflex	0 (0%)	1 (0.83%)
Injection Abscess formation	1 (0.83%)	3 (2.5%)

[X^2=2.28; P=0.6 (not Significant)]

Flushing was observed in 23 (19.16%) women in Low dose regimen and 34 (28.33%) women in Pritchard regimen. Hypotension was observed in 5(4.17%) women in Low dose regime and 9 (7.5%) women in Pritchard regime. Not a single woman in Low dose regimen had absent reflex or respiratory depression while in Pritchard regimen 2 (1.66%) women had respiratory depression and 1 (0.83%) women had absent reflex.

Table 5: Maternal complications of eclampsia

Complication	Low dose regime (n=120)	Pritchard regime (n=120)
CVA	1 (0.83%)	1 (0.83%)
Renal failure	0 (0%)	3 (2.5%)
HELLP Syndrome	9 (7.5%)	10 (8.33%)
Abruption	9 (7.5%)	12 (10%)
DIC	7 (5.83%)	9 (7.5%)
PPH	2 (1.67%)	3 (2.5%)

[X^2=5.34; P=0.25 (Not significant)]
In Low dose regimen, 9 (7.50%) women were having HELLP syndrome and 9 (7.50%) women were having abruption, 7(5.83%) were having DIC and 2 (1.67%) women were having PPH. In Pritchard regimen 12 (10%) women were having abruption and 10 (8.33%) women were having HELLP syndrome,9 (7.5%) were having DIC, 3 (2.5%) were having renal failure and 3 (2.5%) were having PPH. In both groups one woman had CVA.

Table 6: Distribution of cause of maternal mortality

Cause	Low dose (n=120)	Pritchard regime (n=120)
Acute renal failure	0 (0%)	2 (1.6%)
Pulmonary oedema	1 (0.8%)	1 (0.8%)
CVA	1 (0.8%)	1 (0.8%)
DIC	1 (0.8%)	2 (1.6%)

[X^2=1.50; P=0.68 (Not significant)]
In present study, cause of maternal mortality in Low dose group was pulmonary oedema in 1 (0.8%), CVA in 1 (0.8%) and DIC in 1 (0.8%). In Pritchard group cause of maternal mortality was acute renal failure in 2 (1.6%) women and DIC in 2 (1.6%) and 2 of maternal mortality were due to pulmonary oedema and CVA. Maternal mortality in Low dose regime was 2.4% and in Pritchard regimen was 4.8%.

DISCUSSION

Eclampsia is one of the commonest cause of convulsions in pregnancy. Eclampsia is continuing problem in developing country.[7] The incidence of eclampsia in developing countries varies from 1:100 to 1:1700.[8] Like other developing countries, eclampsia is still a major problem in India. Eclampsia is a life threatening emergency that continues to be major cause of maternal morbidity and mortality. Eclampsia accounts for 12% of maternal deaths in world and 8% maternal death in India.[9] 99.16% women in Low dose regime and 98.33% women in Pritchard regime were in the age group <30 years. In Sardesai *et al* study, 95.79% women were <30 years. This finding was consistent with Sardesai *et al* study.[10] This is because in Indian scenario, many women complete their family by the age of 30 years. Eclampsia is found to be common in early age group. In present study 63.33% women in Low dose regime and 61.67% women in Pritchard regime were nulliparas. In present study also nullipara were predominate over multipara. In Sardesai *et al* study,[10] 74.03% women were nulliparas and 25.97% women were multiparas. In Chowdhury *et al* study,[11] 85.00% women in I.M (Pritchard regime) group and 81.06% women in I.V. (Low dose) group were nulliparas. In Ekele *et al* study[12] 83.00% women were nulliparas. In present study mean BMI was 22.5 kg/m2 in Low dose regime and 22.13 kg/m2 in Pritchard regime. This was slightly higher than Sardesai *et al* study. In Sardesai *et al* study, mean BMI was 20.45 kg/m2.[10] In present study, 90% of women had less than 7 convulsion and 10% of women had >7 convulsions in Low dose group. In Pritchard regime, 86.67% women had less than 7 convulsions and 13.33% had >7 convulsions. These findings were consistent with Sardesai *et al* study and Chowdhury *et al* study.[10,11] In present study, gestational age in Low dose group >36 weeks was 27.7% and ≤ 36 weeks was 72.3%. In Pritchard group, ≤ 36 weeks was 65.68% and >36 weeks was 34.32%. In Chowdhury *et al* study,[11] 30.00% women were ≤36 weeks and 70.00% women were >36 weeks of gestation. In Seth *et al*[13] study 53.00% women were ≤36 weeks and 47.00% women were >36 weeks of gestation. This finding was not consistent with Chowdhury *et al*[11] and Seth *et al*.[13] This might be due to the fact that our hospital is a tertiary care centre catering people from different areas. In present study, recurrence of convulsions was 9.1% Low dose regime which was consistent with Sardesai *et al*[10] study in which recurrence rate was 8%. Lowest recurrence rate was observed in Chowdhury *et al*[11] study which was 3.3% and other in R Begum *et al*[14] study which was 3.9%. In Low dose regime, flushing was observed in 19.16% which was consistent with Magpie trial.[15] Flushing in present study in control group i.e. Pritchard regime was 28.33% which was higher that Magpie trial.[15] This disparity may be due to underweight Indian women. Hypotension in present study was noted in 4.17% in Low dose and 7.5% in Pritchard Regime which was much higher than Magpie trial.[15] This might be due to simultaneous administration of $MgSO_4$ and nifedipine (whether this hypotension was due to Magnesium sulphate or due to nifedipine was not certain) and can be avoided if both drugs not given simultaneously. Respiratory depression was not observed in Low dose group and 1.66% in Pritchard regime which was consistent with Magpie trial.[15] Absent reflex was not observed in Low dose group and 0.83% in Pritchard group which was lower than that observed in Magpie trial.[15] Abscess at site of intramuscular injection was noted in 0.83% low dose group and 2.5% in Pritchard group which was much higher than Magpie trial.[15] This might be due to high dose and in some

cases faulty technique of $MgSO_4$ administration by staff. In present study, CVA was observed only in 0.8% in Low dose regime and 0.83% in Pritchard regime which was much lower than Chowdhury *et al* study.[11] Renal Failure wasn't seen in Low dose group. In Pritchard regime 5.8% had renal failure which was slightly greater than Sardesai *et al*[10] and Chowdhury *et al*.[11] HELLP Syndrome and abruption were observed in 7.5% each respectively in Low dose regime and 8.3% and 10% in Pritchard regime respectively which was much more than Sardesai *et al*.[10] In present study, DIC was 5.8% in Low dose and 7.5% in Pritchard which was also greater than Sardesai *et al*.[10] PPH was observed in 1.67% in Low dose regime and 2.5% in Pritchard regime, which was higher than Sardesai *et al*.[10] i.e. 0.5%. In Chowdhury *et al*[11] study, PPH was observed in 8.3% in I.M group and 6% in I.V. group. This was much higher than present study. This might be due to practice of active management of third stage of labour at our tertiary care institute. In present study, maternal mortality in Low dose regime was 2.4% which was comparable to Sardesai *et al*[10] study which was 2.63% and Seth *et al*[13] study which was 2.98%. In control group i.e. Pritchard regime maternal mortality rate was 4.8%. This was much less than Ekele *et al*[12] where maternal mortality was 9.9%.

CONCLUSION

There was no significant difference observed regarding maternal complications and maternal mortality in both groups. Low dose regime can be suggested for Indian women who were having less BMI as compare to their counterparts in western world. Hence, we conclude that low dose magnesium sulphate was equally efficacious and was relatively more safe than Pritchard regime.

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