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Original Research Article

A study on the effect of a low-dose magnesium sulfate regimen for the management of eclampsia

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ABSTRACT

Background: Magnesium sulfate is the anticonvulsant of choice for eclampsia, but the standard Pritchard regimen uses repeated intramuscular injections and requires careful toxicity monitoring. This study compared a half-dose regimen with the standard Pritchard regimen.
Methods: In this prospective randomized study, 50 women with eclampsia were allocated equally to a low-dose group or a standard Pritchard group. The low-dose regimen comprised 2 g intravenous and 5 g intramuscular loading doses, followed by 2.5 g intramuscularly every four hours for 24 hours after delivery or the last seizure. The primary outcome was control of convulsions. Repeat dosing, treatment failure, clinical toxicity, perinatal outcome, injection-site discomfort, ambulation, magnesium sulfate use, and cost were assessed. Categorical data were compared using Fisher's exact test or the chi-square test.
Results: Convulsions were controlled in 25/25 women (100%) in the low-dose group and 24/25 (96%) in the Pritchard group (p=1.000). Repeat doses were required in 3/25 (12%) and 2/25 (8%), respectively (p=1.000). No treatment failure occurred with the low-dose regimen; one failure occurred in the Pritchard group in a woman with hepatic capsule rupture. No clinical evidence of magnesium toxicity was observed in the low-dose group. Live-birth rates were 88% and 92%, respectively (p=1.000). The low-dose regimen used half the magnesium sulfate and reduced the calculated drug cost by 50%.
Conclusions: The low-dose regimen achieved seizure control comparable to the standard regimen in this small study and reduced drug use and cost. Larger multicentre non-inferiority trials are required before routine substitution.

Keywords: Eclampsia, Magnesium sulfate, Low-dose regimen, Pritchard regimen, Seizure control, Maternal outcome

INTRODUCTION

Hypertensive disorders complicate approximately 5-10% of pregnancies and remain important causes of maternal and perinatal morbidity and mortality.[1] Pre-eclampsia is a multisystem pregnancy-specific disorder characterised by new-onset hypertension after 20 weeks of gestation, with proteinuria and/or maternal organ dysfunction, while eclampsia is the occurrence of generalized tonic-clonic seizures that cannot be attributed to another cause.[1,2] Magnesium sulfate is the recommended anticonvulsant for the treatment of eclampsia and prevention of recurrent seizures.[2-5] The traditional Pritchard regimen consists of a 4g intravenous loading dose, followed by 10g intramuscularly and a 5g intramuscular maintenance dose every four hours for 24 hours after delivery or the last convulsion.[3] Although effective, the regimen requires repeated painful injections and careful clinical monitoring for loss of patellar reflexes, respiratory depression, and oliguria.[2,3] Several lower-dose regimens have been evaluated, particularly in South Asian populations, on the premise that women with lower body weight may achieve seizure control with a smaller total dose.[6-10] However, the available regimens differ in loading dose, maintenance schedule, patient selection, and outcome definitions, and reduced-dose treatment should not be assumed to be

universally equivalent to the full Pritchard regimen.[6-10] The present study compared a regimen using half the Pritchard dose with the standard Pritchard regimen in women with eclampsia.

Aim and objectives

The primary objective was to compare control of convulsions with a low-dose magnesium sulfate regimen and the standard Pritchard regimen. Secondary objectives were to compare the need for repeat dosing, treatment failure, clinical evidence of magnesium toxicity, maternal and perinatal outcomes, injection-site discomfort, ambulation, magnesium sulfate requirement, and treatment cost.

METHODS

Study design and setting

This prospective randomized comparative study was conducted in the Department of Obstetrics and Gynaecology at Dr. D. Y. Patil Hospital, Navi Mumbai, from April 2022 to April 2023. Fifty eligible women provided informed consent and were allocated in a 1:1 ratio to the low-dose group (n=25) or the standard Pritchard group (n=25).

Eligibility criteria

Pregnant women presenting after 20 weeks of gestation with eclampsia, blood pressure greater than 140/90 mmHg, proteinuria of at least 1+ on qualitative urine examination, no previous seizure disorder, and no anticonvulsant treatment before admission were eligible. Women with renal failure, pulmonary oedema with respiratory failure, cerebrovascular accident, HELLP syndrome, disseminated intravascular coagulation, or refusal to participate were excluded.

Interventions

Women in the low-dose group received 2 g of 20% magnesium sulfate intravenously over 3-5 minutes, followed by 5g of 50% magnesium sulfate intramuscularly (2.5 g in each buttock). The maintenance dose was 2.5g of 50% magnesium sulfate intramuscularly every four hours in alternate buttocks for 24 hours after delivery or the last convulsion. Women in the standard group received the conventional Pritchard regimen: 4g intravenously, followed by 10g intramuscularly (5g in each buttock), and 5g intramuscularly every four hours for 24 hours after delivery or the last convulsion.[3]

Outcome assessment and monitoring

The primary outcome was control of convulsions. Secondary outcomes included the need for a repeat dose, failure of the assigned regimen, maternal outcome, live birth or stillbirth, clinical evidence of magnesium toxicity, injection-site discomfort, time to ambulation, total magnesium sulfate requirement, and drug cost. Before each maintenance dose, the patellar reflex, respiratory rate, and urinary output were assessed; maintenance treatment was withheld when clinical safety criteria were not met.[2,3]

Statistical analysis

Data were reanalysed using Python version 3.13.5 with SciPy version 1.17.0. Categorical variables were summarised as frequency and percentage. Fisher's exact test was used for 2×2 comparisons because of the small sample and expected cell counts, while Pearson's chi-square test was used for the three-category gestational-age comparison. All tests were two-sided, and $p<0.05$ was considered statistically significant. Because no a priori non-inferiority margin or sample-size calculation was available, the analysis was interpreted as exploratory and was not considered proof of equivalence.

RESULTS

Approximately 80% of participants were referrals from other healthcare facilities. The treatment groups were similar with respect to age, parity, booking status, gestational age, and timing of eclampsia; none of the observed baseline differences was statistically significant (Table 1 and Figures 1-4).

Table 1: Baseline and clinical characteristics.

Characteristics	Low-dose group (n=25)	Pritchard group (n=25)	P value
Age <25 years	18 (72%)	20 (80%)	0.742
Age ≥25 years	7 (28%)	5 (20%)	
Primigravida	19 (76%)	18 (72%)	1.000
Multigravida	6 (24%)	7 (28%)	
Booked	7 (28%)	9 (36%)	0.762
Unbooked	18 (72%)	16 (64%)	
Gestational age >37 weeks	6 (24%)	7 (28%)	0.838*
Gestational age 28-37 weeks	16 (64%)	14 (56%)	
Gestational age <28 weeks	3 (12%)	4 (16%)	
Antepartum eclampsia	22 (88%)	21 (84%)	1.000
Postpartum eclampsia	3 (12%)	4 (16%)	

*Pearson chi-square test; all other p values are from Fisher's exact test

Table 2. Perinatal outcome.

Outcome	Low-dose group (n=25)	Pritchard group (n=25)	P value
Live birth	22 (88%)	23 (92%)	1.000
Stillbirth/IUFD	3 (12%)	2 (8%)	

Table 3. Treatment efficacy and resource use

Observation	Low-dose group (n=25)	Pritchard group (n=25)	P value
Control of convulsions	25 (100%)	24 (96%)	1.000
Need for repeat dose	3 (12%)	2 (8%)	1.000
Failure of regimen	0	1 (4%)	1.000
Number of 1 g ampoules required by protocol	22	44	-
Calculated magnesium sulfate cost	Rs. 242	Rs. 484	-

Convulsions were controlled in all 25 women (100%) in the low-dose group and in 24 of 25 women (96%) in the Pritchard group (Fisher's exact p=1.000). A repeat dose was required in three women (12%) and two women (8%), respectively (p=1.000). There was no treatment failure in the low-dose group; one failure occurred in the Pritchard group in a woman with hepatic capsule rupture and haemorrhage who subsequently died. The fatal outcome was related to the underlying hepatic complication and cannot be interpreted as evidence of a regimen effect.

No loss of patellar reflex, respiratory depression, or oliguria was documented in the low-dose group. Women receiving the low-dose regimen reported less injection-site discomfort and earlier ambulation, although these outcomes were recorded descriptively without a validated scale. The protocol-based magnesium sulfate requirement was 22 one-gram ampoules in the low-dose group and 44 in the standard group, corresponding to calculated drug costs of Rs.242 and Rs.484, respectively. Live births occurred in 22 women (88%) in the low-dose group and 23 women (92%) in the Pritchard group; the difference was not statistically significant (p=1.000).

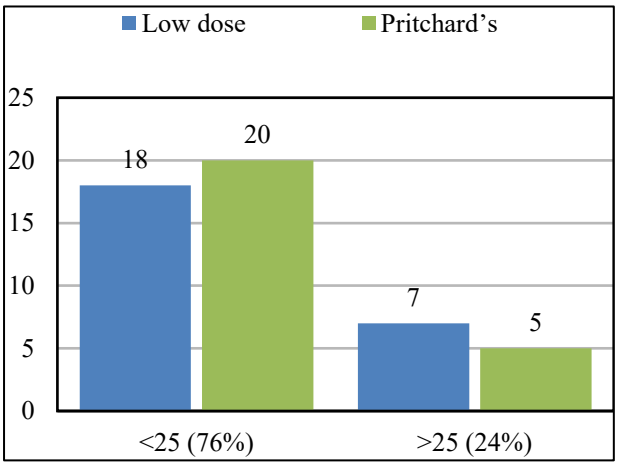

Figure 1: Distribution of maternal age by treatment group.

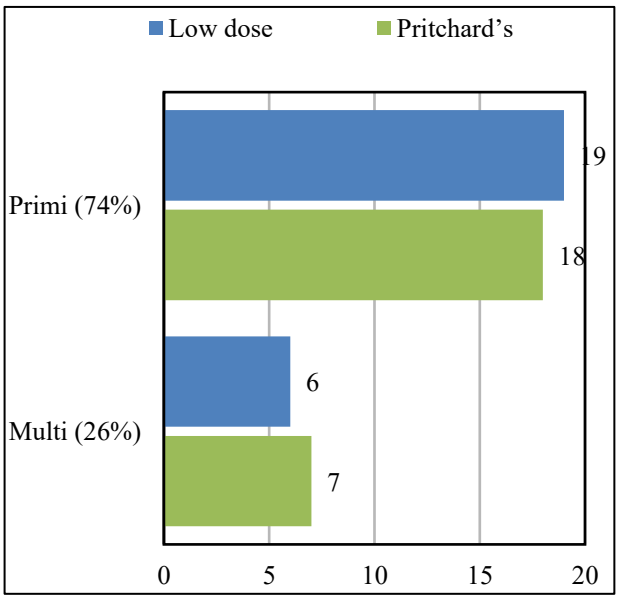

Figure 2: Distribution of parity by treatment group.

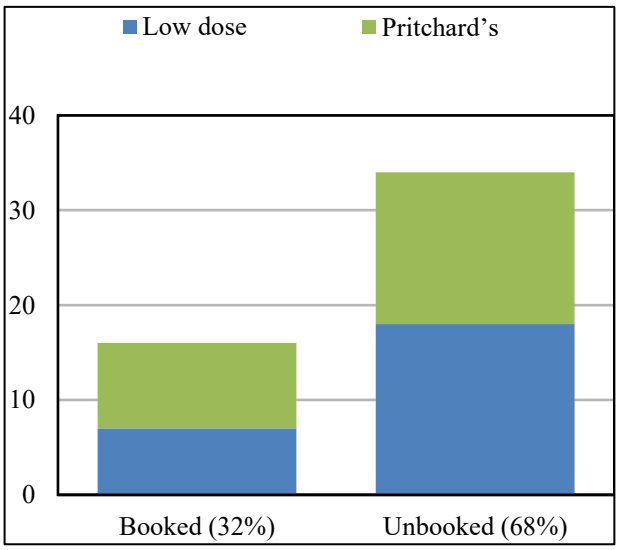

Figure 3: Distribution of booking status by treatment group.

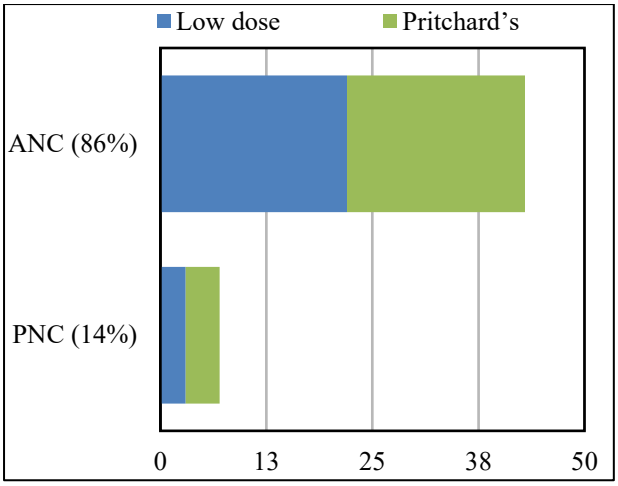

Figure 4: Timing of eclampsia in relation to delivery.

DISCUSSION

In this prospective randomized study, the half-dose regimen-controlled convulsions in 100% of women compared with 96% in the standard Pritchard group. The observed differences in seizure control, repeat dosing, treatment failure, and live-birth rate were not statistically significant. The low-dose protocol halved magnesium sulfate use and calculated drug cost and was associated with less injection-site discomfort and earlier ambulation. These findings are clinically relevant in resource-constrained settings, but the small sample does not establish therapeutic equivalence or non-inferiority.

The full Pritchard regimen remains a well-established standard for eclampsia.[3] The collaborative eclampsia trial demonstrated that magnesium sulfate was superior to diazepam and phenytoin for preventing recurrent convulsions, while the magpie trial established its benefit for seizure prevention in women with pre-eclampsia.[4,5] The world health organization therefore recommends full intravenous or intramuscular magnesium sulfate regimens for eclampsia and reserves loading-dose-only treatment for circumstances in which complete administration is not feasible before urgent referral.[2] Any reduced-dose protocol should consequently be evaluated against this evidence base rather than considered automatically interchangeable with standard therapy.

Low-dose magnesium sulfate regimens were developed largely in South Asian settings to reduce drug exposure, injection burden, toxicity risk, and cost.[6-10] Begum and colleagues described the Dhaka regimen and subsequently reported similar recurrence rates with a loading-dose-only strategy and the standard regimen, although the loading-dose approach required careful selection and monitoring.[6,7] Sardesai et al reported seizure control in 91.93% of women using a regimen tailored for Indian women, with recurrent convulsions in 7.89%.[8] Other early studies likewise suggested that lower-dose regimens could provide acceptable seizure control, but the dosing schedules and inclusion criteria were heterogeneous.[9,10] The seizure-control rate in the present study is consistent with subsequent comparative Indian studies. Sahu et al reported 96% seizure control with a low-dose regimen in a randomized comparison, and Sharma et al found no significant difference between Dhaka and Pritchard regimens.[12,13] Patil et al observed recurrent convulsions in 7.5% of women receiving a low-dose regimen and 13.75% receiving Pritchard treatment, with lower clinical toxicity in the reduced-dose group.[14] Bhagat et al reported seizure control of 97.5% with the Dhaka regimen and 100% with the Pritchard regimen, while the total magnesium dose was significantly lower with Dhaka treatment.[16] Rani et al similarly found no statistically significant difference in recurrent seizures between Pritchard and Dhaka regimens.[18]

More recent studies continue to report broadly comparable seizure outcomes with reduced-dose protocols. Akhtar et al found effective seizure control with a lower total magnesium exposure, and Perhar et al reported comparable recurrence with fewer adverse clinical findings in the low-dose group.[19,20] Nevertheless, these studies should be interpreted cautiously because many are single-centre trials with modest samples and different definitions of recurrence, toxicity, and regimen failure. The current half-Pritchard protocol is also not identical to the Dhaka regimen: it uses a smaller 2 g intravenous component and 5 g intramuscular loading dose, whereas the Dhaka regimen generally employs a larger loading dose.[6] Direct extrapolation from Dhaka-regimen studies is therefore limited.

No clinical evidence of magnesium toxicity was documented in the low-dose group, supporting the biological plausibility that lower exposure may reduce dose-related adverse effects. However, the absence of toxicity in 25 women cannot demonstrate safety, and clinical monitoring of reflexes, respiration, and urine output remains mandatory with any magnesium sulfate regimen.[2,3] Studies of alternative reduced-dose schedules have still reported absent reflexes and other adverse findings, illustrating that dose reduction does not eliminate toxicity risk.[10,17]

Live-birth rates were similar in both groups (88% versus 92%). Perinatal outcome in eclampsia is influenced strongly by gestational age, disease severity, fetal condition at presentation, referral delay, and timing of delivery; a small anticonvulsant trial is unlikely to isolate the independent effect of magnesium dose on neonatal outcome. Accordingly, the perinatal findings should be regarded as descriptive rather than evidence of equivalent fetal safety.

The 50% reduction in protocol-based drug use and cost is a practical advantage where procurement and out-of-pocket expenditure are important barriers. Reduced intramuscular volume may also explain the reported decrease in injection-site discomfort and earlier

ambulation. These patient-centred benefits were not measured with validated scales in the present study and should be quantified prospectively in future trials.

Strengths

The prospective randomized design, concurrent standard-regimen comparison, and assessment of efficacy, safety, perinatal outcome, and resource use are strengths of the study.

Limitations

The principal limitations are the small single-centre sample, absence of a documented sample-size calculation or non-inferiority margin, lack of blinding, exclusion of women with major eclampsia-related complications, and absence of serum magnesium measurements. The source records did not provide a detailed method of sequence generation or allocation concealment, and injection discomfort and ambulation were recorded qualitatively. These limitations restrict generalisability and preclude a definitive claim that the half-dose regimen is equivalent to standard Pritchard treatment.

CONCLUSION

In this small prospective randomized study, a half-dose magnesium sulfate regimen achieved high seizure-control rates without documented clinical toxicity and reduced magnesium sulfate use and calculated cost. The outcomes did not differ significantly from those observed with the standard Pritchard regimen, but the study was not powered to establish non-inferiority. The regimen may be considered a promising option for carefully selected women in settings with strict clinical monitoring and resource limitations; larger multicentre non-inferiority trials are required before routine replacement of the standard regimen.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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