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A comparative study between low dose magnesium sulphate regimen and standard pritchard regimen in management of eclampsia and imminent eclampsia

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Abstract
Background: Eclampsia remains a leading cause of maternal morbidity and mortality, and magnesium sulphate is the anticonvulsant of choice. Debate persists regarding the optimal dosing regimen, particularly in resource-limited settings.
Aim: To compare the efficacy and safety of the low-dose Solapur magnesium sulphate regimen with the standard Pritchard regimen in managing eclampsia and imminent eclampsia.
Material and Methods: A prospective comparative study of 70 women allocated to either regimen assessed seizure control, maternal outcomes, toxicity, and perinatal results. Data were analyzed using SPSS, with $p < 0.05$ considered significant.
Results: Both regimens achieved comparable seizure control and perinatal outcomes. The Pritchard regimen produced significantly higher serum magnesium levels and more toxicity events.
Conclusion: The Solapur regimen is equally effective and associated with fewer adverse effects, making it a safe alternative in resource-constrained environments.

Keywords: Eclampsia, Magnesium sulphate, Solapur regimen, Pritchard regimen

Introduction

Eclampsia and imminent eclampsia continue to be major causes of maternal morbidity and mortality, especially in low- and middle-income countries where timely access to critical care remains limited [1]. Magnesium sulphate ($MgSO_4$) is internationally regarded as the anticonvulsant of choice, demonstrating superior efficacy and safety when compared with diazepam, phenytoin, and other agents historically used to prevent and treat seizures in hypertensive disorders of pregnancy [2]. The widely used Pritchard regimen, consisting of an intramuscular loading dose followed by 4-hourly maintenance injections, has remained the standard of care for decades; however, concerns about toxicity — particularly respiratory depression, loss of reflexes, and reduced urine output — persist in populations with lower body mass and limited monitoring resources [3].

In response to these challenges, several low-dose magnesium sulphate regimens have been proposed over the last two decades. Among them, the Solapur low-dose regimen has gained attention due to its comparable anticonvulsant effect, reduced total magnesium exposure, and lower incidence of toxicity, making it particularly suitable for resource-constrained settings [4]. Early large-scale clinical experiences in India showed that low-dose regimens effectively controlled convulsions in the majority of eclampsia patients while significantly reducing adverse effects associated with high serum magnesium levels [5].

Subsequent prospective and randomized controlled trials have provided further evidence supporting reduced-dose therapy. Studies evaluating single-loading-dose $MgSO_4$ protocols demonstrated that seizure prophylaxis and control were comparable to the standard Pritchard protocol in women with severe preeclampsia and eclampsia [6]. More recent randomized trials have confirmed non-inferiority of low-dose or loading-dose-only regimens in preventing recurrent seizures, with the added benefits of decreased drug burden, easier administration, and fewer treatment-related complications [7].

Emerging research has also explored reducing the *duration* of postpartum $MgSO_4$ therapy. Evidence from non-inferiority trials suggests that 12-hour regimens may be as effective as traditional 24-hour maintenance therapy, supporting the broader trend toward individualized and

minimally necessary dosing strategies [8]. Additionally, observational studies highlight that difficulties in protocol adherence, shortages of trained staff, and variable monitoring capacities in low-resource regions often limit the safe application of high-dose regimens, further reinforcing the need for simplified protocols [9].

Furthermore, comparative studies evaluating modified low-dose regimens against standard protocols have consistently reported similar maternal and neonatal outcomes, with the reduced-dose groups showing fewer side effects and improved patient tolerance [10]. Collectively, these findings underscore the growing clinical rationale for reassessing traditional dosing strategies and adopting safer, equally effective alternatives tailored to local populations.

Given this evolving evidence, a direct comparison between the Solapur low-dose magnesium sulphate regimen and the standard Pritchard regimen is clinically significant. Such evaluation may offer valuable insights into optimizing anticonvulsant therapy, balancing efficacy with safety, and guiding future practice in the management of eclampsia and imminent eclampsia.

Materials and Methods

This study was designed as a prospective, comparative interventional investigation aimed at evaluating the efficacy of two magnesium sulphate regimens in the management of eclampsia and imminent eclampsia. A prospective approach was selected to ensure systematic real-time observation of participants over an 18-month period, minimizing recall bias while allowing continuous monitoring of maternal and perinatal outcomes. The comparative nature of the study enabled a direct assessment of the low-dose Solapur regimen against the standard Pritchard regimen. Participants were allocated into two predetermined groups, allowing the effects of each treatment protocol to be assessed independently while controlling for critical confounders such as gestational age, severity of hypertension, and pre-existing comorbidities. Due to the practical constraints associated with emergency obstetric care and predefined clinical protocols, blinding was not feasible; however, strict standardization of treatment administration and data recording procedures was employed to minimize observer bias.

The study was conducted in the Department of Obstetrics and Gynecology at Zydus Medical College and Hospital (ZMCH), Dahod, Gujarat, India. The hospital caters predominantly to women from low-to-middle socioeconomic backgrounds, many of whom have limited access to regular antenatal care. This demographic profile made the setting ideal for evaluating magnesium sulphate regimens that are particularly relevant in resource-constrained regions. The total study duration was 18 months, beginning with a preparatory period from October 2023 to March 2024, during which ethical approval was obtained and the research team received training to ensure uniformity in patient enrolment, magnesium sulphate administration, and data documentation. Participant recruitment and prospective data collection were carried out from April 2024 to July 2025. The final phase, from July 2025 to January 2026, was dedicated to data cleaning, statistical analysis, and report preparation.

Eligible participants included pregnant women aged above 18 years with gestational age greater than 28 weeks who were diagnosed with antepartum, intrapartum, or postpartum eclampsia, defined by generalized tonic-clonic seizures associated with preeclampsia. Women exhibiting features of imminent eclampsia, such as severe hypertension accompanied by headache, visual disturbances, or epigastric pain, were also included. Informed written consent was obtained from all conscious participants, while consent for comatose patients was secured from their relatives. Women with seizures not attributable to eclampsia, those presenting more than seven days postpartum, and individuals with pre-existing medical conditions such as renal disease, cardiac disorders, or diabetes were excluded. Patients who had received anticonvulsants prior to admission or who declined participation were also excluded.

Participant recruitment followed a purposive sampling strategy from the antenatal ward and labour room. Eligible women were randomized into the two study groups using a computer-generated sequence prepared by an independent statistician. Allocation was concealed using sealed opaque envelopes to reduce selection bias. Stratification based on gestational age (28-34 weeks versus ≥35 weeks) was implemented to ensure balanced representation in both groups. A total of 35 participants were included in each group within the study time frame.

Participants in Group A received the standard Pritchard regimen, consisting of a loading dose of 4 g intravenous magnesium sulphate administered over 10-15 minutes, followed by 10 g intramuscularly with 5 g injected into each buttock. Maintenance therapy consisted of 5 g intramuscular doses every four hours for 24 hours after the last convulsion or after delivery, whichever occurred later. Group B received the Solapur regimen, which included a loading dose of 4 g intravenous magnesium sulphate diluted in 20 ml and administered over 15-20 minutes, followed by 2 g intravenous doses every three hours for 24 hours following the last convulsion or delivery. Both groups received standardized antihypertensive therapy, most commonly labetalol, and delivery was expedited whenever clinically appropriate.

Study parameters included maternal, perinatal, and safety-related outcomes. Maternal assessments comprised convulsion control within 24 hours, development of complications such as HELLP syndrome or postpartum haemorrhage, renal dysfunction, maternal mortality, and serum magnesium levels obtained before treatment and four hours after the initial loading dose. Neurological findings were evaluated using MRI, interpreted by a radiologist blinded to group allocation. Perinatal outcomes included gestational age at delivery, birth weight, Apgar scores at one and five minutes, NICU admission, and perinatal mortality. Monitoring for magnesium sulphate toxicity—manifested by respiratory depression, loss of reflexes, and altered sensorium—was conducted throughout treatment, and dose adjustments were made whenever necessary.

Upon enrolment, detailed demographic information, obstetric history, vital signs, laboratory parameters, and urine protein levels were recorded. Randomization was followed by prompt initiation of the assigned regimen. Additional 2 g intravenous magnesium sulphate was administered to Group B patients in the event of convulsion recurrence. Delivery was facilitated through induction, augmentation, or caesarean section as warranted. Postpartum monitoring continued for 24 hours, and newborn assessments were carried out immediately after birth by the attending paediatric team. All clinical observations and outcomes were documented in electronic case-report forms, with regular audits ensuring data completeness and accuracy.

Data collection utilized structured proformas and electronic hospital records. Serum magnesium levels were measured using atomic absorption spectroscopy, and MRI evaluations were conducted following standard neuroimaging protocols. Missing data were reconciled through cross-verification with clinical notes. Statistical analysis was performed using SPSS version 26. Continuous variables such as serum magnesium concentration

and birth weight were expressed as mean ± standard deviation and compared using the Student's t-test. Categorical variables, including convulsion recurrence and maternal or perinatal mortality, were expressed as frequencies and percentages and analyzed using Chi-square or Fisher's exact test as appropriate. Logistic regression models adjusted for confounders including gestational age and baseline blood pressure. A p-value of less than 0.05 was considered statistically significant. Subgroup analyses were undertaken to compare outcomes between preterm and term pregnancies, and multiple imputation methods were applied for sensitivity analysis of missing data.

Ethical approval for the study was granted by the Institutional Ethics Committee of ZMCH (Ref: IEC/ZMCH/2023/OBG-45). Written informed consent procedures ensured participant autonomy, and confidentiality was upheld through anonymized data storage with access restricted to authorized research personnel. Adverse events were managed according to hospital guidelines and promptly reported to the ethics committee. The study adhered to the principles outlined in the Declaration of Helsinki, ensuring that all research activities were conducted with integrity, respect, and full protection of participant rights.

Results

Table 1 presents the baseline demographic and clinical characteristics of participants. Both groups were comparable in age, gestational age, parity, blood pressure levels, and degree of proteinuria at the time of admission. The proportion of women presenting with eclampsia and imminent eclampsia was also similar in both groups. The lack of statistically significant differences ($p > 0.05$) confirms that the study groups were well matched at baseline, ensuring that outcome comparisons reflect the effect of the magnesium sulphate regimen rather than pre-existing disparities.

Table 2 shows the presenting symptoms and initial maternal neurological findings. The prevalence of headache, visual disturbances, epigastric pain, hyperreflexia, and clonus did not differ significantly between the two regimens. This indicates that both groups had similar clinical severity at admission, supporting the comparability of maternal condition prior to initiation of treatment.

Table 3 summarises the primary efficacy outcomes related to convulsion control. Both the Pritchard and Solapur regimens demonstrated high effectiveness, with similar proportions achieving seizure control after the loading dose. Seizure recurrence within 24 hours was low and comparable in both groups. Although the Solapur group showed a higher need for additional magnesium sulphate, the difference was not statistically significant. Time to cessation of convulsions was also similar, indicating that both regimens are equally effective in immediate seizure management.

Table 4 outlines maternal outcomes following treatment. Rates of postpartum haemorrhage, HELLP syndrome, acute kidney injury, ICU admission, and maternal mortality were comparable between the two groups, with no significant differences. However, serum magnesium levels measured four hours post-dose were significantly higher in the Pritchard group, reflecting its higher dosing protocol and indicating increased exposure to potential toxicity.

Table 5 details the toxicity profile of magnesium sulphate administration. Adverse effects such as loss of deep tendon reflexes, respiratory depression, oliguria, and the need to skip or discontinue doses were more frequently observed in the Pritchard group. Notably, the loss of reflexes was significantly higher, suggesting that the higher-dose regimen carries a greater risk of magnesium-related toxicity compared with the low-dose Solapur regimen.

Table 6 provides a direct comparative overview of efficacy and maternal outcomes. Both regimens were similarly effective in seizure control and prevention of recurrence. However, serum magnesium levels and toxicity indicators were consistently higher in the Pritchard group, reflecting its more intensive dosing schedule. Despite these differences, ICU admission rates and maternal mortality did not differ significantly, indicating that both regimens offer comparable maternal safety outcomes overall.

Table 7 compares perinatal outcomes between the two groups. Birth weight, preterm delivery rates, Apgar scores at one and five minutes, NICU admission rates, and perinatal mortality were similar in both regimens. No parameter demonstrated statistical significance, suggesting that the choice of magnesium sulphate regimen does not adversely affect neonatal outcomes. Both regimens appear equally safe for the fetus.

Table 1: Baseline Characteristics of Study Participants (n = 70)

Parameter	Group A: Pritchard (n=35)	Group B: Solapur (n=35)	p-value
Mean maternal age (years)	23.8 ± 3.4	24.1 ± 3.1	0.64
Gestational age (weeks)	35.2 ± 2.6	35.0 ± 2.8	0.78
Primigravida (%)	68.5%	65.7%	0.79
Systolic BP (mmHg)	166 ± 12	164 ± 11	0.42
Diastolic BP (mmHg)	108 ± 9	107 ± 10	0.68
Proteinuria ≥ +2 (%)	74.2%	71.4%	0.81
Presentation type			
• Eclampsia	22 (62.8%)	21 (60.0%)	0.81
• Imminent eclampsia	13 (37.2%)	14 (40.0%)	0.79

Table 2: Clinical Presentation and Initial Maternal Status

Parameter	Group A: Pritchard	Group B: Solapur	p-value
Headache (%)	22 (62.8%)	24 (68.5%)	0.62
Visual disturbances (%)	15 (42.8%)	13 (37.1%)	0.63
Epigastric pain (%)	10 (28.5%)	12 (34.2%)	0.60
Hyperreflexia (%)	28 (80.0%)	27 (77.1%)	0.77
Clonus present (%)	18 (51.4%)	17 (48.5%)	0.82

Table 3: Comparison of Convulsion Control (Primary Outcome)

Outcome	Pritchard (n=35)	Solapur (n=35)	p-value
Seizure control after loading dose	30 (85.7%)	29 (82.8%)	0.74
Seizure recurrence (<24 hours)	3 (8.5%)	4 (11.4%)	0.68
Additional $MgSO_4$ required	5 (14.2%)	9 (25.7%)	0.21
Time to stop seizures (min)	12.4 ± 4.3	13.1 ± 5.1	0.51

Table 4: Maternal Outcomes in Both Groups

Maternal Outcome	Pritchard	Solapur	p-value
Postpartum hemorrhage	3 (8.5%)	2 (5.7%)	0.64
HELLP syndrome	4 (11.4%)	3 (8.5%)	0.69
Acute kidney injury	2 (5.7%)	1 (2.8%)	0.55
ICU admission	6 (17.1%)	4 (11.4%)	0.49
Maternal mortality	1 (2.8%)	0 (0%)	0.31
Serum Mg (4-hour post-dose)	5.9 ± 0.7	4.3 ± 0.5	<0.001

Table 5: Magnesium Sulphate Toxicity Profile

Toxicity Parameter	Pritchard	Solapur	p-value
Loss of deep tendon reflexes	6 (17.1%)	1 (2.8%)	0.03
Respiratory depression	2 (5.7%)	0 (0%)	0.15
Oliguria (<25 mL/hr)	4 (11.4%)	1 (2.8%)	0.16
Need to skip dose	5 (14.2%)	2 (5.7%)	0.24
Discontinuation due to toxicity	1 (2.8%)	0 (0%)	0.31

Table 6: Comparative efficacy and maternal outcomes between pritchard and solapur regimens

Outcome Parameter	Pritchard (n=35)	Solapur (n=35)	p-value
Seizure control after loading dose	85.7%	82.8%	0.74
Seizure recurrence (<24 hours)	8.5%	11.4%	0.68
Additional $MgSO_4$ needed	14.2%	25.7%	0.21
Serum magnesium (mEq/L)	5.9 ± 0.7	4.3 ± 0.5	<0.001
Loss of reflexes	17.1%	2.8%	0.03
Respiratory depression	5.7%	0%	0.15
ICU admission	17.1%	11.4%	0.49
Maternal mortality	2.8%	0%	0.31

Table 7: Comparative perinatal outcomes between pritchard and solapur regimens

Perinatal Outcome	Pritchard (n=35)	Solapur (n=35)	p-value
Mean birth weight (kg)	2.32 ± 0.48	2.38 ± 0.44	0.52
Preterm delivery	51.4%	48.5%	0.82
Apgar score <7 at 1 min	34.2%	28.5%	0.61
Apgar score <7 at 5 min	14.2%	11.4%	0.72
NICU admission	40.0%	31.4%	0.46
Perinatal mortality	8.5%	5.7%	0.64

Discussion

The findings of the present study demonstrate that both the Solapur low-dose regimen and the standard Pritchard regimen are effective in controlling eclamptic seizures, with comparable rates of seizure recurrence and similar perinatal outcomes. However, the significantly higher incidence of magnesium-related toxicity in the Pritchard group reinforces the growing evidence advocating for dose-minimizing strategies in resource-limited settings. Recent clinical investigations further support this shift toward simplified and safer magnesium sulphate regimens. A randomized crossover evaluation in India comparing modified low-dose schedules with standard protocols reported similar efficacy in seizure prophylaxis, while highlighting a substantial reduction in adverse effects among women treated with reduced dosing strategies [11]. These findings align well with the current study, where toxicity indicators such as loss of reflexes and respiratory depression were notably reduced in the Solapur regimen group.

Emerging global data also suggest that shorter postpartum durations of magnesium sulphate therapy may offer additional benefits without compromising seizure prevention. A 2024 non-inferiority trial evaluating 12-hour versus 24-hour postpartum magnesium sulphate regimens demonstrated equal effectiveness, with lower drug exposure and improved maternal comfort in the shorter-duration group [12]. These results mirror the pharmacological rationale behind the Solapur regimen, which prioritizes minimal effective dosing while maintaining anticonvulsant protection.

Moreover, comparative analyses from low-resource obstetric centres reveal that the feasibility of magnesium sulphate administration is strongly influenced by staffing, monitoring capacity, and drug availability. A multicentric observational study reported that simplified dosing regimens reduced nursing workload and improved adherence to treatment protocols, ultimately resulting in better quality of care for women with eclampsia [13]. This operational advantage supports the applicability of the Solapur regimen in settings similar to the study centre, where personnel limitations and high patient turnover challenge the sustained use of intensive monitoring required for the Pritchard regimen.

Further, recent neuroimaging-based investigations have shown that magnesium sulphate regimens do not significantly differ in preventing radiological abnormalities associated with eclampsia, such as PRES, irrespective of dosage variations [14]. This reinforces that seizure prevention—not supratherapeutic serum magnesium levels—is the primary determinant of neurological protection, supporting the safety and suitability of low-dose strategies.

Finally, a contemporary systematic review comparing multiple magnesium sulphate dosing protocols concluded that low-dose regimens—including the Solapur and Dhaka modifications—achieve seizure control rates equivalent to standard Western protocols while significantly reducing the frequency of maternal side effects [15]. The consistency of these global findings with the present study underscores the clinical relevance of adopting low-dose regimens, particularly in regions where maternal nutritional status, body mass, and monitoring limitations pose additional risks with higher-dose therapies. Collectively, the evidence supports the broader implementation of low-dose magnesium sulphate regimens as effective, safe, and context-appropriate alternatives for managing eclampsia and imminent eclampsia.

Conclusion

The present study demonstrates that the Solapur low-dose magnesium sulphate regimen is as effective as the standard Pritchard regimen in controlling convulsions associated with eclampsia and imminent eclampsia, with the added advantage of significantly reduced magnesium-related toxicity. Maternal and perinatal outcomes were comparable between the two regimens, supporting the use of simplified dosing strategies in resource-constrained settings. Based on these findings, the Solapur regimen represents a safe, feasible, and clinically effective alternative to the conventional Pritchard protocol.

Conflict of Interest

Not available.

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Not available.

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