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Frequency of Recurrence of Seizures with Intravenous Versus Intramuscular Magnesium Sulphate in Women with Eclampsia

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ABSTRACT

Magnesium sulphate is increasingly being utilized in women with eclampsia. But there is still debate on the ideal route of administration. **Objectives:** To compare the recurrence of seizures between intravenous (IV) and intramuscular (IM) magnesium sulphate (MgSO4) in women with eclampsia. **Methods:** This open-label, parallel-group, randomized controlled trial was conducted at the Department of OBG, Nishtar Hospital, Multan, from 13th May to 12th November 2025. A total of 200 women aged 18–45 years, admitted with eclampsia, were enrolled after informed consent and demographic data were collected. Women with intracranial bleeding or prior use of anticonvulsants were excluded. Participants were randomly divided to receive either IV (4g IV bolus then 1g/hour infusion) or IM MgSO4 (4g IV+6g IM loading dose, followed by 2.5g IM, 4 hourly). $MgSO_4$ was continued for 24 hours post-seizure or delivery. The primary outcome was seizure recurrence within 48 hours. Data were analyzed using SPSS version 25.0 with the chi-square test. **Results:** The mean age was 24.5 ± 4.9 years, and the mean gestational age was 29.0 ± 3.1 weeks. Most participants were ≤25 years (67%), <30 weeks of gestation (60.5%), and obese (64%). Baseline characteristics were comparable across both groups. Seizure recurrence was higher in the IM group (70%) compared to the IV group (30%), with no statistically significant difference (p=0.059). No significant predictors of seizure recurrence were identified after stratification. **Conclusions:** Although seizure recurrence was high in the intramuscular $MgSO_4$ group, this was not statistically significant. The intramuscular route can be considered an alternative to the intravenous route.

INTRODUCTION

During childbirth and the puerperium, eclampsia is a significant source of morbidity and mortality. Every year, eclampsia alone causes almost 50,000 maternal fatalities globally [1]. In industrialized nations, eclampsia occurs in one out of every 2000 deliveries; in underdeveloped regions, it occurs in one out of every 50 to 500 deliveries [2]. Eclampsia is linked to a higher risk of placental abruption, cardiovascular and cerebrovascular problems, disseminated intravascular coagulation, and maternal death; it is only exceeded by hemorrhage [3]. The first and most important concept in eclampsia management is seizure control [4]. According to findings from a collaborative eclampsia trial, magnesium sulphate (MgSO4) is more effective than diazepam and phenytoin for routine anticonvulsant treatment of eclamptic women [5]. It was reported that toxicity-related issues might be avoided by administering MgSO4 intravenously [6]. It also has the advantage of being simple to administer, causing less pain to the patient, and allowing for easy control of the magnesium level [7]. However, because infusion sets are scarce, nursing personnel are inadequate, and frequent serum magnesium levels are expensive, most medical centers in low-resource countries prefer intramuscular (IM) delivery. Improper dosing, renal or underlying metabolic

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disorders (hypoglycemia or hypocalcemia), or refractory or severe eclampsia may cause recurrence of seizures despite treatment [6]. Bagariya et al. studied a total of 80 patients with eclampsia (40 in each intravenous or intramuscular group). They found that 3 out of 40 patients (7.5%) who received MgSO4 IM experienced recurrence of fits, while none of the patients who received an IV dose experienced either a recurrence or an onset of seizures. In the IM group, 25% cases, while in the IV group, 10% cases had loss of deep tendon reflexes (DTR) [7]. Saha et al. studied 41 women who presented with eclampsia, randomly splitting them into 2 groups: IV magnesium was used in group I, whereas IM MgSO4 was given in group II. Seizure recurrence and loss of DTR were observed in 10% and 65% of group I, while 4.8% and 14.3% of group II cases, respectively [8]. So, keeping in view the controversy regarding the better efficacy of various routes of administration of magnesium sulphate, we have planned this study in patients with eclampsia presenting to our local setting.

Although magnesium sulphate is the standard treatment of eclampsia, there still remains confusion about the best mode of administration, especially in a low-resource environment where data collection and human expertise might not be consistent. However, the prior investigations showed mixed results on the issue of seizure control by intravenous and intramuscular regimens, and it is necessary to directly compare them in a standardized clinical environment. The study aimed to compare the incidence of recurrence of seizures in IV and IM magnesium sulphate in women with eclampsia, with the hypothesis that there is a significant difference between the two routes to inform the practice and resource planning of evidence-based clinical practice.

METHODS

This open-label, parallel-group, randomized controlled trial (Reg. No. NCT06997575, https://clinicaltrials.gov/study/NCT06997575) was conducted at the Department of Obstetrics and Gynaecology, Nishtar Medical University and Hospital, Multan, over a period of six months from 13th May 2025 to 12th November 2025 after approval from the institutional ethics review committee (ERC # 8995/NMU). A total of 200 women, 18 – 45 years of age, admitted in labour room due to eclampsia were consecutively included in the study after informed consent. Women having intracranial bleeding (on CT-scan brain), already receiving MgSO4, phenytoin, or diazepam in the last 72 hours, were excluded from the study. Participants' age, gestational age, parity, and obesity (obtained on interview at enrollment) were documented. Through simple random sampling using the lottery method, the participants were assigned to intramuscular magnesium sulphate (intervention group) or intravenous magnesium sulphate (comparison group) groups in a 1:1 ratio. Allocation codes were placed in sequentially numbered, sealed opaque envelopes. At the time of enrollment, the recruiting surgeon opened the envelope in sequence to assign the participant in allocated group. Pregnant women, ≥ 20-weeks of gestation (using LMP), having blood pressure of ≥ 160/110 mm of Hg plus protein (+3 or +4) in spot urine examination, now presenting with new onset of grand mal seizure activity and/or unexplained coma were labelled as eclampsia positive cases. Seizure recurrence was labelled if the seizure episode (clinical tonic-clonic motor seizure activity) occurred within 48-hours of treatment. In the active comparator group, participants received a 20% solution bolus of 4 g of IV MgSO4 and a continuous IV infusion of 1 g per hour. A 10 g loading dose of MgSO4 (4 g IV as 20% solution, 6 g IM 50% solution, and 3 g in each buttock with 1% of 1 ml of lidocaine) was administered to the intervention group, whereas 2.5 g IM every 4 hours was administered as maintenance therapy. For 24 hours following the last seizure or 24 hours following birth, whichever came first, MgSO4 medication was maintained. A minimum sample size of 200 participants was calculated using OpenEpi online software through the formula for a randomized controlled trial (https://www.openepi.com/PDFDocs/SSCohortDoc.pdf. $n=(Z\alpha/2+Z1-\beta)2\,\bar{p}\bar{q}(r+1)/r(p1-p2)2$. Seizure recurrence of 10% in the intravenous magnesium sulphate group was used [8], seizure recurrence risk ratio of 2.5 in the intramuscular magnesium sulphate group, with a power of 80% and significance level of 5%. Normality of continuous data was assessed through the Shapiro-Wilk test at 5% significance level. Normally distributed numerical data were presented as mean ± SD, and categorical data as frequency and percentages. Data were analyzed using SPSS version 25.0. Seizure recurrence between the groups is compared through a chi-square test, and a p-value < 0.05 is taken as significant. The study followed Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting of randomized controlled trials [9].

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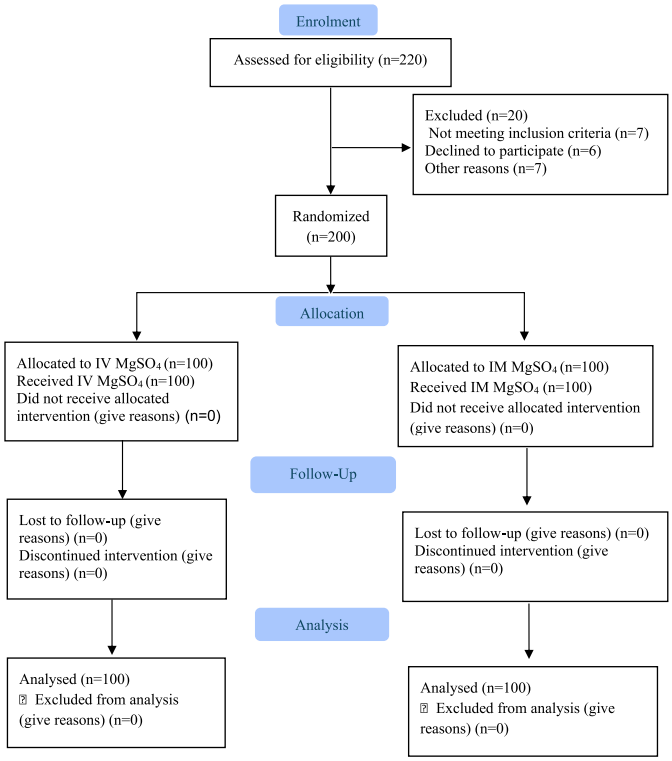

Figure 1: CONSORT 2010 Flow Diagram

RESULTS

The mean age of the women was 24.5 ± 4.9 years, with 134 (67%) ≤ 25-years of age. The mean gestational age was 29.0 ± 3.1 weeks, including 121 (60.5%) below 30-weeks. The median parity was one (IQR – 1) that included 125 (62.5%) para one women. Obesity was identified in 128 (64%) of the women. All the demographic characteristics were comparable between the intravenous and intramuscular magnesium sulphate treatment groups (Table 1).

Table 1: Characteristics of pregnant women presenting with eclampsia (n=200)

Characteristics	All (n=200)	Magnesium Sulphate		p-value*
		Intravenous	Intramuscular	
Age (Years)	24.5 ± 4.9	24.4 ± 4.2	24.6 ± 5.6	0.810
⩽ 25-Years	134 (67%)	66 (49.3%)	68 (50.7%)	0.881
> 25-Years	66 (33%)	34 (51.5%)	32 (48.5%)	
Gestational Age (Weeks)	29.0 ± 3.1	29.0 ± 3.1	29.0 ± 3.2	0.964
< 30 Weeks	121 (60.5%)	61 (50.4%)	60 (49.6%)	0.885
⩾ 30-Weeks	79 (39.5%)	39 (49.4%)	40 (50.6%)	
Parity	1 (1%)	1 (1%)	1 (1%)	1.000
Para 1	125 (62.5%)	63 (50.4%)	62 (49.6%)	0.884
Para ≥ 2	75 (37.5%)	37 (49.3%)	38 (50.7%)	
Obesity – Yes	128 (64%)	63 (49.2%)	65 (50.8%)	0.768

*chi-square test; categorical comparison, t-test for means comparison, and Mann-Whitney U test for median comparison

Seizure recurrence was high in the intramuscular compared to the intravenous magnesium sulphate group (70% vs. 30%), but this did not achieve statistical significance (Table 2).

Table 2: Seizure recurrence after treatment in pregnant women presenting with eclampsia (n=200)

Seizure Recurrence	All (n=200)	Magnesium Sulphate		p-value*
		Intravenous	Intramuscular	
Yes	20 (10)	6 (30)	14 (70)	0.059
No	180 (90)	94 (52.2)	86 (47.8)	

No significant determinant of seizure recurrence in the intramuscular compared to the intravenous magnesium sulphate group was identified after stratification of demographic characteristics (Table 3).

Table 3: Determinants of seizure recurrence in pregnant women presenting with eclampsia (n=200)

Characteristics		Magnesium Sulphate	Seizure Recurrence		p-value*
			Yes	No	
Age Groups	⩽ 25-Years	Intravenous	3 (4.5%)	63 (95.5%)	0.128
		Intramuscular	9 (13.2%)	59 (86.8%)	
	> 25-Years	Intravenous	3 (8.8%)	31 (91.2%)	0.469
		Intramuscular	5 (15.6%)	27 (84.4%)	
Gestational Age	< 30 Weeks	Intravenous	2 (3.3%)	59 (96.7%)	0.163
		Intramuscular	6 (10%)	54 (90%)	
	⩾ 30-Weeks	Intravenous	4 (10.3%)	35 (89.7%)	0.348
		Intramuscular	8 (20%)	32 (80%)	
Parity	Para 1	Intravenous	3 (4.8%)	60 (95.2%)	0.126
		Intramuscular	8 (12.9%)	54 (87.1%)	
	Para ≥ 2	Intravenous	3 (8.1%)	34 (91.9%)	0.480
		Intramuscular	6 (15.8%)	32 (84.2%)	
Obesity	Yes	Intravenous	3 (4.8%)	60 (95.2%)	0.206
		Intramuscular	8 (12.3%)	57 (87.7%)	
	No	Intravenous	3 (8.1%)	34 (91.9%)	0.301
		Intramuscular	6 (17.1%)	29 (82.9%)	

*Fischer's exact test

DISCUSSION

One of the main reasons for maternal morbidity and death is eclampsia. In industrialized countries, this disease affects 1 in 2,000 to 4,000 deliveries; in poorer countries, the rate is several times higher [10]. Eclampsia is a serious obstetric emergency that needs to be managed promptly and effectively to prevent disastrous results [11]. The preferred medication for preventing and treating eclamptic convulsions is magnesium sulphate [12]. The majority of the women in our study were under 25, and their mean age was 24.5 ± 4.9 years, highlighting the tendency of eclampsia in our population to affect younger mothers. This is consistent with research from Sukkur, Pakistan, which showed that women with pre-eclampsia/eclampsia were 23 ± 5 years old on average [13]. From Abbottabad, a cohort showed similar age patterns, with a mean age of 30 ± 10.9 years and 72% of eclamptic patients being between the ages of 18 and 27 [14]. A cross-sectional study conducted in Pakistan in 2022 found that 160 eclamptic primigravida had an average age of 26.4 ± 2.4 years,

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highlighting the continued vulnerability of younger mothers [15]. When taken as a whole, these recent studies demonstrate the necessity for focused prenatal surveillance in this age range and emphasize how susceptible younger mothers are to eclampsia. We found that the majority of pregnant women had gestational ages below 30 weeks, and the mean gestational age of eclamptic patients was 29.0 ± 3.1 weeks, indicating that eclampsia is common in the early third trimester. This result is in line with several previous studies that highlight early onset in comparable contexts. For instance, early-onset pre-eclampsia/eclampsia primarily occurs before 34 weeks and is linked to worse maternal outcomes and increased illness severity, according to a 2021 retrospective cohort study conducted in Ethiopia [16]. Furthermore, the median gestational age at intervention was approximately 29 weeks, which reflects the clinical threshold when eclampsia or severe symptoms appear, according to an expectant management study of severe pre-eclampsia among women at 24-34 weeks [17]. Another study emphasized the greater risks associated with early-onset hypertensive disorders of pregnancy, which often call for earlier intervention and closer monitoring if they appear before 32 weeks [18]. Together, these findings confirm our finding that eclampsia often appears before 30 weeks and emphasize the importance of prompt management and heightened prenatal care during this crucial gestational period. Although it was shown in our study that the intramuscular group experienced a higher rate of seizure recurrence than the intravenous magnesium sulphate group, this difference was not statistically significant. This pattern can be a result of the more stable serum magnesium levels attained by intravenous delivery, which enables a better titration of therapeutic levels and a quicker onset. The authors of a randomized controlled trial from Rawalpindi, in 2022, found that 92.5% of women treated with IM did not experience seizure recurrence compared to 97.5% of women getting IV medication (p=0.147) [19]. Despite not substantially impairing overall seizure control, recent pharmacokinetic analyses have shown that IM regimens (like the Pritchard protocol) produce more variable serum magnesium levels than IV protocols, possibly resulting in brief intervals of subtherapeutic concentrations that could predispose to breakthrough seizures [20]. Similar to our findings, a recent study published in 2024 found that two IV patients and four IM patients had recurrent convulsions, a non-significant difference, while the IM group showed more frequent symptoms of magnesium toxicity, including decreased deep tendon reflexes [21]. According to Kanti et al. 1/17 (5.88%) of eclamptic patients in the IV group and 1/17 (5.88%) in the IM group experienced a convulsion recurrence, which is statistically not significant (P=1) [22]. Fits were controlled in 62 (93.94%) of the women treated with the conventional Pritchard regimen, and only 4 (6.06%) experienced recurrences of convulsions, according to the research by Ali *et al.* Eight (12.12%) women in the loading (intravenous) dose group experienced another convulsion, while 58 (87.87%) women did not have another one. A single loading dose worked just as well as a typical Pritchard regimen [23]. Furthermore, because of its more predictable pharmacodynamics, revised clinical guidelines still support IV magnesium sulphate as a first-line seizure prophylactic; nevertheless, they also confirm that intramuscular administration is still a feasible option in cases where IV access or infusion pumps are not accessible [24]. When combined, these findings support the idea that, under strict monitoring and adherence to established protocols, IM delivery may show a tendency towards increased seizure recurrence, but this does not translate into a statistically or clinically significant difference when compared to IV administration. The benefits of intramuscular magnesium sulphate are; it can be used in circumstances when there is a lack of intravenous access, severe circulatory collapse, risk of rapid infusion toxicity, and limited monitoring facilities [24].

The current study's strengths were that it was a randomized controlled trial, which is the gold standard for comparing therapies, and lowering selection bias to increase the dependability of the results. Comparing seizure recurrence between two routes of magnesium sulphate delivery in eclamptic women was the study's specific and clinically relevant goal. For a single-center study, the sample size was comparatively big, which enhanced the study's power and generalizability to comparable contexts. The fact that this study was limited to a single institution may have limited its generalizability to different demographics or healthcare environments. Another limitation is that magnesium levels were not measured before and after magnesium sulphate treatment in study participants. Recurrence of seizures was only tracked for 48 hours. For a more thorough evaluation of therapy effectiveness, longer follow-up may be required. In particular, while evaluating results, a lack of blinding may increase observer and performance bias.

CONCLUSIONS

To summarize, though seizure recurrence was high in the intramuscular MgSO4 group, this was not statistically significant. The intramuscular route can be considered an alternative to the intravenous route, particularly in situations where IV access is restricted.

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Authors' Contribution

Conceptualization: LI
Methodology: LI, IA, MK, FK
Formal analysis: LI, IA, MK, FK
Writing and Drafting: LI, MK
Review and Editing: LI, IA, MK, FK

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflicts of Interest

All the authors declare no conflict of interest.

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