Postpartum Twelve-hour Magnesium Sulphate for Preeclamptic Patients versus Twenty four-hour: A Randomized Controlled Trial

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Abstract

Background& aim: Eclampsia is one of the major complications for patients with severe pre-eclampsia. Magnesium sulphate has been used as gold standard preventive treatment for a long time. Currently there is no consensus on the optimum duration of administration with maximum efficacy and less adverse events. In postpartum women with severe pre-eclampsia, the effectiveness of taking magnesium sulphate for 12 hours versus 24 hours was compared in this research. The objective was to maximize anticonvulsant action effectiveness while reducing magnesium sulphate adverse effect exposure.

Patients and Methods: A total of 280 women with severe preeclampsia were enrolled in the study. Those patients were randomly subdivided into group 1): received Mgso4 12- hour after delivery maintained at 1g per hour for 12 h and group 2): received Mgso4 24-hour after delivery maintained at 1g per hour for 24 h. All participants were subjected to thorough evaluation with recording demographic, obstetric and peripartum data.

Results: Both groups had insignificant differences as regard demographic, obstetric, clinical, laboratory, antepartum and intrapartum data. Administration of 12-hour magnesium sulfate as much as 24-hour magnesium sulfate was effective regard occurrence of eclampsia. Postpartum 12 hours group had significantly shorter duration of urinary catheter insertion (15.07 ± 11.01 vs. 28.11 ± 11.49 (h); $p< 0.001$) and length of hospital stay (2.52 ± 1.57 vs. 3.56 ± 1.69 (day); $p< 0.001$). Only one woman in 12 hours group had oliguria. There were three women in 12 hours group required prolongation of magnesium sulphate intake beyond the planned time.

Conclusion: twelve hours postpartum magnesium sulphate intake could be beneficial in women with severe preeclampsia as regard prevention of eclampsia with fewer side effects.

Keyword: preeclampsia, magnesium sulphate, postpartum seizure, eclampsia, fits.

Introduction

Preeclampsia, a pathological condition of pregnancy, is typified by the onset of hypertension that typically arises after the 20th week of gestation and often near term (1). The advent of eclampsia represents a perilous outcome of preeclampsia. For the prevention of eclampsia, the utilization of magnesium sulphate has been deemed the quintessential method (2).

Although it is recommended to administer magnesium sulphate to women with severe preeclampsia, there no consensus regarding the optimal duration of preventive postpartum anticonvulsant treatment. A proposition has been put forth suggesting the administration of magnesium sulphate for a period of 24 hours after childbirth, as this timeframe is believed to encompass the highest vulnerability period for the onset of eclampsia (3).

There are multiple protocols, including 12-hour and 6-hour regimens, for the administration of magnesium sulphate therapy. However, it is crucial to acknowledge that prolonged usage of this therapy may lead to adverse effects, particularly magnesium toxicity, which can manifest as respiratory depression, renal impairment, and neuromuscular dysfunction (4).Given the inherent risks associated with these complications, constant monitoring becomes a necessity. Consequently, it becomes imperative to ascertain the minimum duration of therapy that is both effective and safe (5).

At women Health Hospital, Assiut University, Egypt our policy is using magnesium sulphate as first line but there is paucity in the literature about comparison between the different regimens of magnesium sulphate. The present study conducted a comparison between the utilization of magnesium sulphate for a duration of 12 hours as opposed to 24 hours in postpartum women with severe pre-eclampsia. This was done to ensure the attainment of optimal efficacy in terms of anticonvulsant activity, while simultaneously minimizing the potential adverse effects associated with magnesium sulphate exposure.

Patients and Methods

Study design and setting

A prospective Randomized controlled trial study was conducted at The Department of Obstetrics and Gynecology (Women's Health Hospital), Assiut University, Assiut, Egypt. It was performed in the period between October 2020 to November 2022

Ethical approval

The study protocol was approved by Assiut School Ethical Review Board (IRB No17101300). Informed written consent was obtained from all participants according to the declaration of Helsinki. The study protocol is registered at Clinicaltrails.gov with NCT04576364.

Inclusion criteria:

Any patient who clinically diagnosed as antepartum or intrapartum pre-eclampsia with severe features as classified by ACOG guidelines (6) and accepted to participate the study was recruited.

Exclusion criteria:

Any patient with one or more of the following criteria was excluded; eclampsia, nervous system disorders as epilepsy or convulsions due to metabolic disturbances, neurological lesions, intracranial neoplasia or intra cerebral infections and comorbidities as chronic kidney or cardiac diseases.

Sample Size Calculation

Sample size based on the outcome of number of patients needed to prolong treatment duration in both groups. The total number of scheduled patients to be recruited was 280 patients 140 in each group. (Sample size was calculated using Epi-info 7 Version 3) with confidence level 95 % and power of 85%, alpha error 0.05, based on expected difference of 5.4% need to prolong treatment (7).

Randomization and allocation:

Randomization was conducted using a computer-generated table of random numbers with allocation concealment.

Allocation concealment: the details of the series were contained in a set of sequentially numbered, opaque sealed envelopes, each bearing on the outside only the name of the hospital and a number. The envelope wasn't opened till the moment of assignment.

Blinding: both medical service provider & patient couldn't be blinded because there was difference in duration of treatment of both groups.

Methodology

All enrolled women were diagnosed based on diagnostic criteria for preeclampsia defined by ACOG 2019(6). All women were subjected to;

- Complete history taking and clinical evaluation.
- Clinical examination: pulse, blood pressure measurement (two blood pressure readings at least 4 h apart were obtained).
- Chest examination to exclude pulmonary edema, heart examination to exclude cardiac problems.
- The following investigations were done; complete blood count, coagulation profile, liver function tests, renal function tests and urine analysis.in addition to, ultrasound evaluation to assess state of the fetus and placenta.

Intervention

All recruited participants received a loading dose of 4 g of intravenous drip MgSO4 over 30 minutes, followed by a maintenance dose of 1g per hour before and during delivery. After delivery patients were Randomly assigned to one of two groups:

- Group (1): received IV drip of Mgso4 after delivery maintained at 1g per hour for 12 hours.
- Group (2): received IV drip of Mgso4 after delivery maintained at 1g per hour for 24 hours.

Follow up as following:

Patients of both groups assessed hourly for;

- pulse and blood pressure
- urine output, tendon reflexes in form of knee jerk and respiratory rate for early detection of symptoms of magnesium sulphate toxicity

As a safety measure, need to prolong treatment was considered if there were signs of imminent eclampsia as defined by RCOG 2019 (ongoing or recurring severe headaches, visual scotomata, nausea or vomiting, epigastric pain), And /or, she had very high blood pressure (systolic blood pressure of 180 mm Hg or more and/or a diastolic blood pressure of 120 mm after completion of sulphate. These patients were managed according to local protocol.

Complication and toxicity of MgSO4 are considered as loss of the patellar reflex at concentrations between 3.5 and 5 mmol/L. Respiratory paralysis and cardiac arrest may occur at supratherapeutic concentrations beyond 5 mmol/L (8). Patients were managed based on local hospital protocol. Patients of both groups were assessed for their neonatal outcomes including gestational age at delivery, fetal birth weight, Apgar score and neonatal ICU admission.

Outcome of study:

- **Primary outcome:** compare efficacy of 12-hour vs 24-hour postpartum Mgso4 patients who needed to prolong treatment in each group.
- **Secondary (subsidiary):**

  a. to compare efficacy of 12-hour vs 24-hour postpartum Mgso4 to prevent occurrence of eclampsia.

  b. Duration of Hospital stay.

  c. Time from delivery to beginning of Ambulation.

  d. Maternal and fetal outcomes.

Statistical analysis

Data was collected and analyzed through the utilization of SPSS (Statistical Package for the Social Science), version 20, developed by IBM and headquartered in Armonk, New York. The Shapiro test was employed to ascertain the adherence of the data to a normal distribution. For quantitative data that exhibited a normal distribution, the mean ± standard deviation (SD) was employed as a means of expression and subsequently compared using the Student t test. On the other hand, quantitative data that deviated from a normal distribution were expressed as the median (minimum-maximum) and compared using the Mann-Whitney U test.

Nominal data were presented as a number (n) and percentage (%), and the Chi2 test was performed on such data. The level of confidence was set at 95%, and therefore, a P value of less than 0.05 was considered to be significant.

Results

Baseline data of the studied groups (table 1)

Both groups had insignificant differences as regard baseline data (p> 0.5).

Risk factors for preeclampsia among the studied groups (table 2):

Both groups had insignificant differences as regard risk factors for preeclampsia either as regard previous obstetric and medical history or during the current pregnancy (p> 0.05). The most frequent risk factors in previous obstetric and medical history were miscarriage and preeclampsia followed by chronic hypertension. Meanwhile, the most frequent risk factors in the current pregnancy were, first pregnancy followed by gestational hypertension.

Clinical and laboratory assessment of the studied groups (table 3):

Both studied groups had insignificant differences as regard clinical and laboratory data (p> 0.05).

Intrapartum and antepartum data among the studied groups (table 4):

Antepartum MgSo4 was used in most patients (92.1% vs. 97.1%; p= 0.06) with mean dose (16.74 ± 2.45 vs. 14.57 ± 4.87 (mg); p= 0.11) and mean duration was (12.85 ± 9.77 vs. 10.86 ± 8.77 (h); p= 0.19).

Postpartum follow up among studied groups (table 5):

No case developed eclampsia in both groups. Postpartum magnesium 12-hours group had significantly shorter duration of urinary catheter insertion (15.07 ± 11.01 vs. 28.11 ± 11.49 (h); p< 0.001) and length of hospital stay (2.52 ± 1.57 vs. 3.56 ± 1.69 (day); p< 0.001).

Only one patient developed MgSo4 toxicity in the form of oliguria in the 24 hours group. Three women, from the 12-hours group; required prolongation of MgSo4 versus none in 24 hours group secondary to nausea and vomiting (one patient), epigastric pain (3 patients), systolic blood pressure≥ 180 mmHg (3 patients) and diastolic blood pressure ≥ 120 mmHg (2patients).

Discussion

Preeclampsia associated with maternal and fetal morbidities. Eclampsia is one of the risky complications. Mgso4 is the gold standard preventive measure for occurrence of eclampsia in patients with preeclampsia. In our study we compare shortened protocol versus 24-hour protocol for intravenous MGSO4 administration. 280 participants were enrolled in this study, 140 in each group.

In the current study, no patient in the studied groups developed eclampsia. This finding goes in accordance with many authors (7-17) who also compare 12 hours versus 24 hours with different patient samples with zero incidence of eclampsia,

while maintaining a high safety margin. in addition to being safe and cost-effective, short term administration was as effective as long-term administration of this drug(17).

In the other hand many studies reported insignificant difference between both groups; Yifu et al., observed that only two eclampsia episodes were documented across the seven trials, both in the shorter regimen arm (risk difference 0.00, 95% CI -0.01-0.01, P = 0.49) (18). Titus K Beyuo and colleagues, no distinct disparity was observed in the incidence of seizures following the completion of the designated regimen in the 24-hour group (n = 5, 0.9%) as opposed to the 12-hour group (n = 2, 0.3%), yielding a p-value of 0.29 (19).

The contrasting findings between the current study and Beyuo et al.'s study regarding the development of eclampsia can be attributed to several factors. These include differences in sample size (1176 participants) and differences in treatment regimens. Also, Kashanian et al. stated that one out of 79 patients had convulsions, and that to avoid this one incident of convulsion, they gave MgSO4 to 78 women for an extra 12 hours with no apparent effect. To avert one occurrence of convulsion, 78 women must be given MgSO4 for 24 hours (20). Moreover, Quist-Nelson et al. reported a negligible elevation in the occurrence of eclampsia within the early cessation cohort (5 out of 1,088 compared to 2 out of 1,095) (0.5% versus 0.2%) in the 24-hour group. Utilizing this proportion (with an absolute risk reduction of 0.0027) to determine the needed number to treat(NNT), it is estimated that 370 women would need to undergo the conventional 24-hour regimen to avert a single case of eclampsia (21).

In our study, three women, from the 12-hours groups; required prolongation of MgSo4 usage secondary to nausea vomiting (one patient), epigastric pain (3 patients), systolic blood pressure ≥ 180 mmHg (3 patients) and diastolic blood pressure ≥ 120 mmHg (2 patients).

In Ehrenberg and colleagues' study, the application of magnesium sulphate treatment was prolonged in seven individuals (6.9%) within the 12-hour group due to a progress of their condition to a severe features, whereas only one individual (1.1%) within the 24-hour group experienced a similar progression (P=.07) (24). In contrast, Maia et al. and Leal et al. reported that, there was no need to re-initiate treatment after completing the scheduled magnesium sulfate therapy in either group (7, 22).

In our study, 12-hours group had significantly shorter duration of urinary catheter insertion. This is supported by many studies with similar shorter duration of bladder indwelling (16,19,22,24). With less risk for urinary tract infection, less patient discomfort, and early ambulation.

In our study, there is no significant difference in the time it takes for women to ambulate or have contact with their baby, regardless of whether they receive magnesium sulfate therapy for 12 hours or 24 hours.

Maia et al. revealed that the length of postpartum magnesium sulfate medication may be reduced, reducing the time for ambulation. The time between delivery and engaging with the infant was shortened

in the 12 hours group as women had been discharged from the intensive care unit and immediately placed in a rooming-in arrangement after discontinuing their anticonvulsant medication(7). Also, (Leal et al., 2014) reported that, in the 12-hour group, significant time reductions were found concerning time until the start of deambulation, and the interval between delivery and the mother's contact with her newborn.

In our study, 12-hours group had significantly shorter length of hospital stay, This agrees with previous studies (16,19,24) that is explained by early ambulation and discharge from intensive care unit.

In our study, in 24-hours group only one patient developed suspected MgSo4 toxicity in form of oliguria that was managed according to local protocol. In general there is no significant difference between both groups regarding side effects and toxicity which cope with previous studies (7,9,19)

The study had some limitations, it was conducted at a single site, which might confine the applicability of the findings to other localities and demographic cohorts.

The study did not examine long term outcomes for mothers or newborns, rather it concentrated on immediate consequences and adverse reactions. As well as the study did not evaluate the impact of MgSO4 regimens on the initiation and success of breastfeeding.

In conclusion, compared to continuation of magnesium for 24-hour postpartum, 12-hours magnesium postpartum therapy does not significantly increase the rate of prolongation of magnesium therapy or postpartum eclampsia. Additional benefits of shorter postpartum regimen may include reduction of the risk of drug toxicity, and side effects of more injections.

Recommendation for Further Studies:

The cost-benefit analysis of such medication should be conducted, and it should be noted that this number of convulsions can also occur within 24 h following MgSO4 delivery.

Larger sample sizes, multi-center settings, and longer-term follow-up are required to validate our findings and provide more comprehensive data regarding the appropriate duration of MgSO4 treatment in postpartum women with severe pre-eclampsia.

Ethics approval:

The study was approved by the ethical committee of faculty.

Availability and data material:

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interests:

The authors report there are no competing interests to declare.

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Table 1: Baseline data of the studied groups

	12 hours group (n= 140)	**24 hours group (n= 140)**	**P value**
Age (years)	28.29 ± 6.38	29.31 ± 6.51	0.18
Residence Rural Urban	 125 (89.3%) 15 (10.7%)	 126 (90%) 14 (10%)	0.50
Gestational age (week)	34.80 ± 3.06	34.90 ± 3.09	0.35
Number of deliveries	2 (0-8)	1 (0-9)	0.07
Number of abortions	1 (0-4)	2 (0-6)	0.90
Number of living children	2 (0-8)	1 (0-9)	0.10

Data expressed as frequency (percentage), mean (SD), median (range). P value was significant if < 0.05.

Table 2: Risk factors for preeclampsia among the studied groups

	12 hours group (n= 140)	24 hours group (n= 140)	P value
Previous obstetric and medical history			
Preeclampsia	22 (15.7%)	29 (20.7%)	0.17
Preterm labour	3 (2.1%)	6 (4.3%)	0.25
IUFD	6 (4.3%)	6 (4.3%)	0.61
Chronic HTN	16 (11.4%)	21 (15%)	0.24
Pregestational DM	5 (3.6%)	4 (2.9%)	0.50
Current pregnancy			
Multiple pregnancy	7 (5%)	18 (12.9%)	0.17
Pgda	44 (31.4%)	37 (26.4%)	0.21
Assisted reproductive technique	7 (5%)	6 (4.3%)	0.50
Inter-pregnancy interval > 10 years	5 (3.6%)	6 (4.3%)	0.50
Overweight/obese	120 (85.7%)	132 (94.3%)	0.05
Vaginal bleeding in early pregnancy	5 (3.6%)	4 (2.9%)	0.50
Gestational HTN	20 (14.3%)	18 (12.9%)	0.43

Data expressed as frequency (percentage). P value was significant if < 0.05. IUFD: intrauterine fetal death; HTN: hypertension; DM: diabetes mellitus

Table 3: Clinical and laboratory data of the studied groups

	12 hours group (n= 140)	24 hours group (n= 140)	P value
Systolic blood pressure (mmHg)			
1st measure	155.87 ± 10.19	158.89 ± 9.87	0.65
2nd measure	160.11 ± 16.56	159.89 ± 6.78	0.39
Diastolic blood pressure (mmHg)			
1st measure	89.11 ± 8.01	88.88 ± 8.17	0.09
2nd measure	90.17 ± 10.10	89.12 ± 5.44	0.33
Hemoglobin (g/dl)	11.52 ± 1.78	11.38 ± 1.60	0.48
Hematocrit value (%)	34.85 ± 4.69	34.22 ± 4.51	0.24
Platelets (10^3/ul)	211.89 ± 7.60	201.56 ± 6.87	0.34
Prothrombin time (s)	11.37 ± 1.58	11.31 ± 1.58	0.70
Prothrombin concentration (%)	111.44 ± 19.01	110.45 ± 19.85	0.67
INR	0.96 ± 0.13	0.96 ± 0.10	0.93
Urea (mg/dl)	4.47 ± 2.67	5.11 ± 2.47	0.27
Creatinine (mg/dl)	0.52 ± 0.12	0.56 ± 0.23	0.21
AST (u/l)	58.11 ± 23.87	60.68 ± 22.19	0.07
ALT (u/l)	60.88 ± 12.98	62.87 ± 13.87	0.07
Bilirubin (mg/dl)	1.24 ± 0.13	1.23 ± 0.12	0.40
Albumin (mg/dl)	3.22 ± 0.98	3.30 ± 0.45	0.50

Data expressed as frequency (percentage), mean (SD). P value was significant if < 0.05. INR: international randomized ratio; AST: alanine transaminase; ALT: alanine transaminase.

Table 4: Intrapartum and antepartum data among the studied groups

	12 hours group (n= 140)	24 hours group (n= 140)	P value
Usage of antepartum $MgSo_4$	129 (92.1%)	136 (97.1%)	0.06
Dose (gm)	16.74 ± 2.45	14.57 ± 4.87	0.11
Duration (h)	12.85 ± 9.77	10.86 ± 8.77	0.19
Mode of delivery			0.50
Cesarean section	129 (92.1%)	128 (91.4%)	
Vaginal delivery	11 (7.9%)	12 (8.6%)	
Intraoperative complications	0	2 (1.5%)	0.24
Fetal outcome			
One-minute Apgar score	5.87 ± 2.22	6.01 ± 1.98	0.11
Five-minutes Apgar score	8.12 ± 2.45	8 ± 2.01	0.13
Fetal weight (kg)	2.22 ± 0.63	2.09 ± 0.54	0.10
Respiratory distress	74 (52.8%)	76 (54.3%)	0.33
Need to Ambu	11 (7.9%)	12 (8.6%)	0.42
Need to MV	4 (2.9%)	1 (0.70%)	0.18
Admission to NICU	16 (11.4%)	11 (11.4%)	0.61

Data expressed as frequency (percentage), mean (SD). P value was significant if < 0.05.
MV: mechanical ventilation; NICU: neonatal intensive care unit

Table 5: Postpartum follow up among studied groups.

	12 hours group (n= 140)	24 hours group (n= 140)	P value
Development of eclampsia	0	0	---
$MgSo_4$ toxicity	0	1 (0.70)	0.50
Prolongation of $MgSo_4$ usage	3 (2.1%)	0	0.12
Causes of prolongation			
Nausea/vomiting	1 (0.70)	0	0.50
Epigastric pain	3 (2.1%)	0	0.12
SBP ≥ 180 mmHg	3 (2.1%)	0	0.12
DBP ≥ 120 mmHg	2 (1.4%)	0	0.24
Duration of urinary catheter (h)	15.07 ± 11.01	28.11 ± 11.49	**< 0.001**
Duration till ambulation	7.64 ± 1.36	8.10 ± 1.48	0.10
Length of hospital stay (day)	2.52 ± 1.57	3.56 ± 1.69	**< 0.001**

Data expressed as frequency (percentage), mean (SD). P value was significant if < 0.05.SBP: systolic blood pressure; DBP: diastolic blood pressure