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ORIGINAL ARTICLE

Eight Hours Versus twenty four hours Postpartum Magnesium Sulphate for Prophylaxis in Women with Pre-Eclampsia

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ABSTRACT

Aim: To compare the outcome of 8 hours versus 24 hours postpartum magnesium sulphate for eclampsia prophylaxis in women with moderate to severe pre-eclampsia.
Study design: Randomized control trial
Place and duration of study: The study was conducted in Gynecology and Obstetrics Department, MCH -1, PIMS Hospital, Islamabad from August 2020- Jan 2021
Methodology: After getting approval from hospital ethical committee and informed consent from patients the randomized controlled trial was conducted. The sample size was calculated by using WHO sample size calculator and total sample size was 108 patients that were selected after fulfilling of selection criteria. Complete history, physical examination, laboratory investigations and sonographical evaluation was performed for the selected women. The selected women were randomly assigned to either group A or B using a random list developed by lottery method. Group A received $MgSO_4$ for 8 hour (8micro drops/min) and Group B received $MgSO_4$ for 24 hours only (8micro drops/min). The primary outcome was occurrence of eclamptic fits and secondary outcomes were ambulation time, initiation of breast feeding, patient's hospital stay and patient satisfaction in both groups. Data was analyzed by using SPSS version 21.0. P-value <0.05 was considered significant
Results: Women in both groups had similar demographic profile. Baseline patients' characteristics (systolic BP, diastolic BP, Hb, ALT and uric acid, urinary protein) were also similar in both groups. Main symptoms were headache, blurred vision and epigastric pain in both groups Eclamptic fits in the first 72 hours were not observed in both groups. In group A patients, mean ambulation time was 10.6±1.1 hours and in group B it was 18.8±7.5 hours (P=0.001). In group A patients, mean time to initiate breast feeding was 14.6 ± 1.9 hours and in group B it was 24.3±8.3 hours (P=0.001). In group A patients, mean duration of hospital stay was 2.8±0.43 days and in group B it was 3.4±0.49 days (P=0.001). In group A patients, mean patient satisfaction score was 8.9±1.1 and in group B it was 4.5±1.8 (P=0.001).
Clinical implication:Less risk of side effects observed and less monitoring required.
Conclusion: Both the dosing regimens were equally effective and eclamptic fits in the first 72 hours were not observed in both groups. Mean ambulation time, mean time to initiate breastfeeding and mean duration of hospital stay was significantly shorter in patient treated with MgSO4 for 8 hours compared to those treated with MgSO4 for 24 hours. Patients treated with MgSO4 for 8 hours demonstrated better satisfaction when compared to those treated with MgSO4 for 24 hours.
Keywords: Postpartum magnesium sulphate, eclampsia, prophylaxis, pre-eclampsia. Ambulation time, Breastfeeding

INTRODUCTION

Preeclampsia is multisystem disorder that affects the pregnancy after 20 weeks of the gestation and characterized by the hypertension and proteinuria. Preeclampsia affects 2-8% of all births. The most feared consequence of serious preeclampsia is eclampsia, which can happen during pregnancy and can have a variety of negative effects on both the mother and the fetus[1].

Pre-eclampsia, which can result in serious multisystem problems like brain bleeding, liver and kidney failure, and breathing impairment, affects up to 5% of pregnant women in their first pregnancy. Pre-eclampsia is caused by pathophysiology that begins in the placenta and only goes away after the placenta is delivered[2,3].

In individuals with serious preeclampsia, magnesium sulphate is medication of preference for preventing eclampsia, and its use enhances outcome. When used wisely in preeclampsia, MgSO4 lowers the chance of seizures and maternal death by 50%, but the optimal duration of $MgSO_4$ treatment has not yet been determined. MgSO4 has traditionally been used for 24 hours after birth to avoid eclampsia[4-6].

$MgSO_4$ is vasodilating agent and contribute to reduction of the cerebral perfusion pressure and it is a membrane stabilizer too. It is given intravenously as a 4g loading dose over 5 mins followed by an infusion of 1g/hr maintained for 24 hour. Recent studies suggest that postpartum magnesium sulphate can be omitted when women with severe pre-eclampsia received >8 hour of magnesium sulphate before birth. However, women receiving magnesium sulphate for less than 8 hour before birth were continued on magnesium sulphate for 24 hour postnatally[7,8].

Women receiving postpartum $MgSO_4$ are kept under observation in HDU (high dependency unit) with resultant delay in breastfeeding and ambulation. In developing countries like Pakistan with limited resources, overburdened facilities and limited number of beds, shorter regimen with equal efficacy should be considered, as some studies validate the efficacy of magnesium sulphate for 8 hour postpartum. Timing of the drug discontinuation has been arbitrary; there are no quality data to guide therapy[9,10].

In some non-randomized trials[11,12], the duration of $MgSO_4$ treatment for preeclamptic women has been decided based on clinical factors. Early postpartum ambulation, less frequent healthcare worker surveillance, and improved infant care may be aided by $MgSO_4$ treatment that is administered for a shorter period of time[13]. In economically underdeveloped nations like Pakistan, the use of $MgSO_4$ for the avoidance of eclampsia 24 hours after delivery in preeclamptic women is costly to the healthcare system.

In the present study we compared the outcome of 8 hours versus 24 hours postpartum magnesium sulphate for eclampsia prophylaxis in women with moderate to severe pre-eclampsia. If shorter duration regimen would found to be equally effective with satisfactory patients acceptability, it can be adopted in future

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practice. This would save time and result in optimal utilization of available resources. The aim of current study was to compare the outcome of 8 hours versus 24 hours postpartum magnesium sulphate for eclampsia prophylaxis in women with moderate to severe pre-eclampsia.

METHODOLOGY

This randomized controlled trial was conduct in Gynecology and Obstetrics Department, MCH -1, PIMS Hospital, Islamabad from August 2020- Jan 2021. The sample size was calculated by using WHO sample size calculator with parameter: level of significance = 5% and power of test = 80%. The sample size was 54 patients in each group and a total of 108 patients were included in the study by using non probability consecutive sampling: population: pregnant women with moderate to severe pre-eclampsia, age 18-45 years and gestational age 28-42 weeks

Exclusion criteria: antepartum eclampsia, epilepsy, all diabetics with pre-eclampsia and pre-eclampsia with other additional pathology like hypertensive encephalopathy, autoimmune diseases, acute pulmonary edema and renal failure. Data collection procedure: After getting approval from hospital ethical committee and informed consent from patients the randomized controlled trial was conducted at the Complete history, physical examination, laboratory investigations and sonographical evaluation was performed for the selected women.

Sampling: The selected women were randomly assigned to either group A or B using a random list developed by lottery method.

Group A received $MgSO_4$ for 8 hour (8micro drops/min)

Group B received $MgSO_4$ for 24 hours only (8micro drops/min)

The primary outcome was occurrence of eclamptic fits and secondary outcomeswere ambulation time, initiation of breast feeding, patient's hospital stay and patient satisfaction in both groups.

Data analysis: Data was analyzed by using SPSS version 21.0. P-value <0.05 was considered significant

RESULTS

A total of one hundred and eight (n=108) pregnant women with moderate to severe pre-eclampsia were recruited in the present trial. Women in both groups had similar demographic profile. Mean age and gestational age was similar in both groups (P>0.05, Table-1).

Baseline patients' characteristics (systolic BP, diastolic BP, Hb, ALT and uric acid, urinary protein) were also similar in both groups (P>0.05, Table-1). Main symptoms were headache, blurred vision and epigastric pain in both groups (P=0.853, table 5). Edema was present in 37% (n=20/54) females in group A, while it was observed in 38.9% (n=21/54) females in group B (P=0.843, Table-2).

Eclamptic fits in the first 72 hours were not observed in both groups. In group A patients, mean ambulation time was 10.6±1.1 hours and in group B it was 18.8±7.5 hours (P=0.001). In group A patients, mean time to initiate breast feeding was 14.6±1.9 hours and in group B it was 24.3±8.3 hours (P=0.001). In group A patients, mean duration of hospital stay was 2.8±0.43 days and in group B it was 3.4±0.49 days (P=0.001).

Mean ambulation time, time to initiate breastfeeding and duration of hospital stay were significantly (p<0.05) shorter in patient treated with $MgSO_4$ for 8 hours compared to those treated with $MgSO^4$ for 24 hours. In group A patients, mean patient satisfaction score was 8.9±1.1 and in group B it was 4.5±1.8 (P=0.001). Patients treated with $MgSO_4$ for 8 hours demonstrated better satisfaction when compared to those treated with $MgSO_4$ for 24 hours.

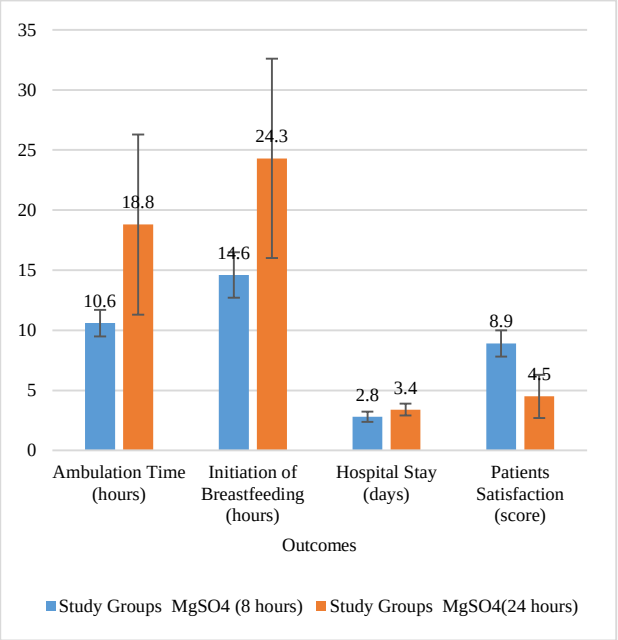
Table-1: Results of demographic and baseline clinical variables in study groups

Variables	Study Groups		p-value
	$MgSO_4$ (8 hours)	$MgSO_4$ (24 hours)	
Age (Years)	27.5 ± 5.1	26.1 ± 4.3	0.114
Gestational Age (Weeks)	36.5 ± 2.7	37.3 ± 2.3	0.101
Systolic Blood Pressure (mmHg)	176.9±10.4	174.3±10.7	0.206
Diastolic Blood Pressure (mmHg)	116.9±4.7	114.4±6.6	0.132
HB (g/dL)	10.6±0.73	11.2±1.3	0.102
ALT (U/L)	39.0±9.7	41.6±6.4	0.115
Uric Acid (mg/dL)	6.4±0.43	6.1±0.37	0.254
Urinary Protein (mg)	630.2±160.1	588.6±178.3	0.207
Platelets (/mm^3)	258537.1±98117.1	267814.8±73975.5	0.580
AST (U/L)	42.3±10.3	39.4±6.5	0.109

Table-2: Results of baseline symptoms in study groups

Variables		Study Groups		Total	p-value
		$MgSO_4$ (8 hours)	$MgSO_4$ (24 hours)		
Symptoms	Headache	32(59.3%)	31(57.4%	63(58.3%	0.853
	Blurred vision	1(1.9%)	0(0.0%)	1(0.9%)	
	Headache + Blurred vision	13(24.1%)	13(24.1%)	26(24.1%)	
	Headache + Epigastric pain	3(5.6%)	3(5.6%)	6(5.6%)	
	Headache + Blurred vision +Epigastric pain	5(9.3%)	7(13.0%)	12(11.1%)	
Edema	Present	20(37.0%)	21(38.9%)	41(38.0%)	0.843
	Absent	34(63.0%)	33(61.1%)	67(62.0%)	
Reflexes	Normal	53(98.1%)	54(100.0%)	107(99.1%)	0.315
	Abnormal	1(1.9%)	0(0.0%)	1(0.9%)	

Figure 1: Comparison of Results of different outcomes in study groups



DISCUSSION

Magnesium sulphate ($MgSO_4$) has been found effective in the management of moderate to severe pre-eclampsia. In current study no difference was found in baseline variables like age, gestational age between both groups. Also no difference was found in clinical variables like blood pressure, Hb levels, ALT, uric acid, urinary protein, platelets and AST between both groups.

Also no eclamptic fits were observed in both the groups. The mean ambulation time, time to initiate breastfeeding and duration of hospital stay were significantly shorter in patient treated with $MgSO_4$ for 8 hours compared to those treated with $MgSO^4$ for 24 hours. Also Patients treated with $MgSO_4$ for 8 hours demonstrated better satisfaction when compared to those treated with $MgSO^4$ for 24 hours. The study by Paulino Vigil-De Gracia[7] also showed similar results like current study findings. 7.6% of the 503 women who participated in the research by Isler et al used perinatal clinical signs as a guidance to restart $MgSO_4$ treatment[14]. In a more recent randomised controlled study, Ehrenberg et al investigated disease development in moderate preeclampsia patients treated with $MgSO_4$ for 12 and 24 hours postoperatively. They found that 6.9% of the women in the 12-hour group required longer $MgSO_4$ treatment[15].

In a randomized trial by Darngawn L et al., comparing a shortened 6 hours $MgSO_4$ prophylaxis regime versus 24 hours in preeclamptic women at low risk of eclampsia, only 1.3% women in 6 hours intervention group needed to continue $MgSO_4$ due to increased blood pressure nine hours following delivery[16]. This is consistent with the results of the current research.

Greater than 8-hour duration therapy with magnesium sulfate carries the risk of magnesium toxicity, which can cause respiratory depression, renal dysfunction, and neuromuscular dysfunction. The least effective length of therapy is especially essential to determine because the risks of these consequences necessitate ongoing monitoring[17].

Patients getting postpartum magnesium are typically confined in bed for 24 hours in many hospitals around the globe. Additionally, this limitation makes nursing during this period challenging or impossible[18]. The postpartum Mg group (8 hours) in this research began to ambulate considerably earlier and began nursing earlier, as was to be anticipated, shorter hospital stay and better satisfaction. These results point to a significant advantage for the woman and her child. Additionally, maintaining Mg for an extended period of time is more costly and calls for more employees for monitoring.

Anjum et al also reported that women with the eclampsia, 12 hours of magnesium sulfate might effectively prevent the recurrent convulsions[19]. He also reported that hospital stay was shorter in 12 hours groups (5.3±0.8 days) than 24 hours group (7.5±1.5 days) with p value (p=0.001).

Sadia et al also reported that in individuals with eclampsia, the 12-hour $MgSO_4$ protocol effectively lowers the chance of repeated seizures. A 12-hour $MgSO_4$ dose permits for early patient movement and needs less time for tracking. Additionally, it results in the patient's early release from the hospital[20].

In summary, results of present study and evidence available in the literature highlighted that $MgSO_4$ when given prophylactically in pregnant women with features of severe preelampsia results in effective prevention seizures. Bulk of available evidence as well as results of present study suggest that a shorter duration (8 hours) postpartum $MgSO_4$ is effective.

It is probably reasonable to shorten the duration of therapy in women who are clearly improving clinically. The duration of magnesium sulfate therapy may be extended in women whose disease has not begun to improve postpartum with a caution in mind for women with persistent renal impairment postpartum, since these patients are at increased risk for magnesium toxicity and need close monitoring.

Moreover, women receiving postpartum $MgSO_4$ are kept under observation in HDU (high dependency unit) with resultant delay in breastfeeding and ambulation. In developing countries like Pakistan with limited resources, overburdened facilities and limited number of beds, shorter regimen with equal efficacy should be considered. Present study has some limitations. Firstly, the sample was relatively smaller, when compared with other large scale trials cited in the literature, yet sufficient enough for interpretation propose. Secondly, we did not take into account maternal side effects and neonatal outcomes as our outcome variable. Thirdly, we did not measure serum magnesium levels in the present study. We suggest future studies addressing these limitations taking larger sample size, using different durations of postpartum $MgSO_4$ therapy and taking into account other outcome variables like maternal side effects of therapy and neonatal outcomes.

CONCLUSION

Both the dosing regimens were equally effective and eclamptic fits in the first 72 hours were not observed in both groups. Mean ambulation time, mean time to initiate breastfeeding and mean duration of hospital stay was significantly shorter in patient treated with MgSO4 for 8 hours compared to those treated with MgSO4 for 24 hours. Patients treated with MgSO4 for 8 hours demonstrated better satisfaction when compared to those treated with MgSO4 for 24 hours.

Conflict of interest: Nil

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