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Low Dose Magnesium Sulphate Versus Standard Pritchard Regimen in Management of Severe Preeclampsia / Eclampsia at Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Ebonyi State, Nigeria

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Abstract

Introduction: Preeclampsia/eclampsia is a pregnancy-specific multi-systemic disease associated with considerable maternal and perinatal morbidity and mortality. Prevention and/or treatment of eclampsia with magnesium sulphate, among others, has been shown to be life-saving. However, despite efforts made in adjusting the dosage, the minimum effective dose of $MgSO_4$ for the prevention and treatment of eclampsia has not been determined. The objective of this study is to compare the efficacy of low dose magnesium sulphate with that of Pritchard regimen in prevention and treatment of eclampsia.

Methods: It was a prospective, single-blinded, randomised controlled study of the low-dose (Dhaka) regimen of $MgSO_4$ versus the Pritchard regimen at Alex Ekwueme Federal University Teaching Hospital, Abakaliki. Consenting patients were assigned to either arm of the study using computer-generated random numbers. Data were collated, tabulated and then statistically analysed using the statistical package for social sciences (IBM SPSS) software (version 22, Chicago, USA). Continuous variables were presented as mean and standard deviation, while categorical variables were presented as numbers and percentages. A difference with a P value <0.05 was considered statistically significant

Results: The low-dose regimen of $MgSO_4$ was as effective as the Pritchard regimen in the prevention of eclampsia in patients with severe preeclampsia and the prevention of further convulsion in patients with eclampsia. Except for primary postpartum haemorrhage, other side effects of the drug were comparable in both groups**. Low-**dose $MgSO_4$ was as effective as the Pritchard regimen in the prevention and treatment of eclampsia. The Pritchard regimen was associated with a higher risk of PPH.

Keywords: Severe preeclampsia, eclampsia, $MgSO_4$, Pritchard, PPH

Background

Pre-eclampsia (PE) is a pregnancy-specific multi-systemic disease, which is associated with significant maternal and perinatal morbidity and mortality. [1, 2] It is defined as new-onset hypertension presenting after 20 weeks of pregnancy, associated with significant proteinuria, in a previously normotensive and non-proteinuric woman, which resolves before the end of the 6th week postpartum.[3,4] Severe pre-eclampsia occurs when there is severe hypertension with proteinuria or other symptoms of severity and/or biochemical/haematological derangements.[3] Eclampsia represents the most severe end of the spectrum and it is defined as generalised tonic-clonic seizures in a woman with preeclampsia which cannot be attributed to any other cause.[5]

Preeclampsia complicates about 5–7% of all pregnancies globally. However, hospital-based studies in Nigeria have reported rates ranging between 1.2% and 6.3%,[6-9] while a study in Abakaliki reported 0.99% for severe preeclampsia and 0.76% for eclampsia.10 Preeclampsia is more common in first pregnancies, occurring in more than 10% of such pregnancies.[1,8] Severe preeclampsia and eclampsia are associated with increased maternal and perinatal morbidity and mortality. The World Health Organisation (W.H.O.) estimates that about 63,000 maternal deaths occur annually from preeclampsia/eclampsia and associated complications, with 98% of these deaths occurring in developing countries[1] such as Nigeria. Perinatal adverse outcomes are usually due to prematurity associated with preterm delivery, as well as intrauterine foetal death from intrauterine growth restriction and placental abruption.[11] Early recognitions, therefore, combined with prompt management, is often required for good maternal and perinatal outcomes.

The definitive treatment for severe preeclampsia or eclampsia is delivery of the placenta.[1,4,5] In affected women, positive maternal and perinatal outcomes depend on the woman having timely access to expert obstetric care, with effective utilisation of anticonvulsant therapy, in addition to other essential care. [12]. Of all the anticonvulsants that have been tried, $MgSO_4$ has been established as the anticonvulsant of choice both for prevention and treatment of convulsions in severe preeclampsia and eclampsia respectively.[12-14] It has been shown to be superior to diazepam, phenytoin, and the lytic cocktail (a mixture of chlorpromazine, promethazine and pethidine) in reducing the occurrence of eclamptic convulsions and the associated maternal morbidity and mortality.[14,15] It also has beneficial effects on foetuses, reducing the risks of birth asphyxia and cerebral haemorrhage, as well as admission into newborn intensive care units. [5,14]

In an attempt to arrive at the minimum effective dose, different $MgSO_4$ regimens have been tried. The most commonly used $MgSO_4$ regimens are those given intramuscularly and/orintravenously from the diagnosis of severe preeclampsia and eclampsia to 24 hours post-delivery or post the last seizure episode, whichever occurs later.[15-19] Though these regimens have been found to be effective, they involve administering large doses of the drug. This usually leads to high costs of treatment as well as difficulties in monitoring such patients for drug toxicity, especially in developing countries where manpower and facilities are limited.[15] Therefore, several attempts have been made either to shorten the duration of administration or reduce the dosage of $MgSO_4$ while still achieving optimal efficacy but reducing the side effects of the drug and the cost of management.[14,16,20,21] Despite several of these regimens proving effective, none of them has been generally adopted as the minimum effective dose.[14] However, the effectiveness of these dosages is an indication that large doses of $MgSO_4$, as given in the Pritchard regimen, may not be needed either as prophylaxis for patients with severe preeclampsia or as treatment for those with eclampsia.[14]

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The Dhaka regimen is one of the low-dose regimens of $MgSO_4$ that have been found to be effective in the management of severe preeclampsia and eclampsia. Though the reason for the success recorded with the low-dose regimen used in Dhaka was attributed to the low body mass index of the population of women in Bangladesh, several other studies in other places with varying dosages and different weight distributions have also recorded varying degrees of success [14-16]. This suggests that a small body mass index (B.M.I.) alone may not be enough to explain the whole phenomenon. Some authorities have also shown that there is no association between treatment failures and patients' B.M.I. or with serum magnesium levels.[14] Different systematic reviews have recommended further studies to identify the minimum effective dose of $MgSO_4$ for the management of severe preeclampsia/eclampsia; [22, 23] thus, the need for this study. The aim of this study was to compare the efficacy of a low-dose regimen of $MgSO_4$ with that of the Pritchard regimen in preventing eclamptic convulsions in patients with severe preeclampsia and preventing further fits in patients with eclampsia.

Method

Study Design

This was a single-blinded randomised controlled trial comparing the efficacy of low-dose $MgSO_4$ with that of the Pritchard regimen in preventing eclamptic fits in patients with severe preeclampsia and preventing recurrent convulsions in those with eclampsia at Alex Ekwueme Federal University Teaching Hospital, Abakaliki (AEFUTHA), Ebonyi State. The low dose of $MgSO_4$ employed in this study was the Dhaka regimen. A non-inferiority study design was used. The study took place between 18th May 2017 and 27th December 2017.

Study Population

Participants who were included in this study were patients with severe preeclampsia and eclampsia admitted and managed at AEFUTHA who met the inclusion criteria. Detailed history was obtained and clinical examination was carried out on all patients. Relevant investigations, which included blood group and Rhesus type, complete blood count, platelet count, liver function test, kidney function test, coagulation profile and urine analysis for proteinuria, were carried out.

Diagnosis of Severe Preeclampsia

For the purpose of this study, the diagnosis of severe preeclampsia was made when a blood pressure of 160 mmHg or more systolic and/or 110 mmHg or more diastolic was obtained, with proteinuria, in a pregnant woman at a gestational age of 28 weeks or more, who was previously normotensive and non-proteinuric. Other symptoms signifying severity, such as severe headache, epigastric pain and blurring of vision (when present), were considered for the diagnosis, whether or not there was proteinuria. Blood pressure was measured using a mercury sphygmomanometer, while urinalysis was done using a urinalysis strip (Combi 2), dipped in midstream urine.

Diagnosis of Eclampsia

Eclampsia was also diagnosed in pregnant women who presented with generalised convulsion after 28 weeks of pregnancy, having ruled out other causes of convulsion such as epilepsy, head injury, hypoglycaemia, cerebral malaria and meningitis.

Inclusion Criteria

Patients included in this study were pregnant women with singleton pregnancies at a gestational age of 28 weeks and above, on admission with a diagnosis of severe

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preeclampsia and eclampsia who consented to the study following proper counselling.

Exclusion Criteria

Patients excluded from the study included those who:

1. Had received $MgSO_4$ before admission.

2. Had received any other anticonvulsant, such as diazepam or phenytoin, before admission.

3. Had complications such as disseminated intravascular coagulation, cerebrovascular accident, renal disease and aspiration pneumonitis.

4. Had multiple gestations.

5. Presented at gestational ages below 28 weeks

6. Had postpartum eclampsia

Patients' selection One hundred and twenty (120) patients with severe preeclampsia or eclampsia were recruited, but only 114 completed the study. They were randomised by means of a computer-generated random number, using the software Research Randomiser®. Using this software, 60 numbers were randomly generated from a pool of 120 numbers (1-120), and these were assigned to group A (low dose), while the remaining 60 random numbers were automatically assigned to group B (Pritchard).

Group A: received 4 g of 20% intravenous (I.V.) $MgSO_4$ (Magphate®) given over 10 minutes, followed by 3 g of 50% intramuscular (I.M.) $MgSO_4$ in each buttock statim (total = 10 g). Then, maintenance doses were given as 2.5 g of 50% $MgSO_4$ administered intramuscularly 4-hourly in alternate buttocks. (low-dose regimen).

Group B: received a loading dose of 4 g of 20% $MgSO_4$ I.V. over 10 minutes, followed by 5 g of 50% $MgSO_4$ I.M. in each buttock (total = 14 g). Maintenance doses were given as 5 g of 50% $MgSO_4$ I.M. 4-hourly in alternate buttocks (Pritchard regimen).

In both groups, the $MgSO_4$ regimen was continued until 24 hours for patients with severe preeclampsia or 24 hours after delivery/last fit, whichever occurred later, for patients with eclampsia.

Concealment

The numbers generated (60 on each side) were inscribed on brown envelopes and a piece of paper with the inscription 'low dose' or 'Pritchard' was inserted into the respective envelope, along with the respective drug and sealed. The envelopes were then arranged from 1 to 120 and kept in a locker that was made accessible to all members of the research team. Patients were made to know what the drug was meant to do for them during the counselling session and the possible side effects but did not know which arm of the study they belonged to.

Participants, who met the inclusion criteria, having consented to the study, were given sequential study numbers and the corresponding numbered opaque sealed envelope was allocated to the patient. The drug was given according to the group the patient belonged to, as inscribed on the paper inserted into the envelope.

Patients' vital signs were checked before $MgSO_4$ administration. Signs of toxicity (loss of deep tendon reflex, respiratory rate less than 16 cycles per minute or urine output less than 30 ml per hour) were also checked before administration of maintenance doses. The next maintenance dose was to be suspended if found contraindicated in any of the patients based on her clinical status or presence of sign(s) of toxicity.

Fitting by Patients on Magnesium Sulphate

Arrangements were made for patients who might convulse during the administration of $MgSO_4$, using either regimen. For any of the patients, 2 g of 20% $MgSO_4$ was to be administered intravenously over 10 minutes. Those on a low-dose regimen were to be converted to the Pritchard regimen while re-evaluating them for other possible causes of convulsion.

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Outcome Measures

All patients were followed up until discharge. The primary outcome measure was the occurrence of convulsion for patients with severe preeclampsia and recurrent convulsions for patients with eclampsia. Secondary outcome measures were adverse effects of magnesium sulphate and maternal and foetal complications.

Statistical Analysis

Data were collated, tabulated and then statistically analysed using the Statistical Package for Social Sciences (SPSS) (IBM) software (version 22, Chicago, USA). Continuous variables were presented as mean and standard deviation (mean ± 2SD), while categorical variables were presented as numbers and percentages. A difference with a p-value <0.05 was considered statistically significant.

Results

Over the study duration, 132 patients were assessed for randomisation into the study; twelve patients were excluded while 120 were allocated to receive either the low dose (60) or the Pritchard regimen (60) of $MgSO_4$. . Only 56 patients in the study (low-dose regimen) group and 58 in the control (Pritchard regimen) group were eligible for the final analysis

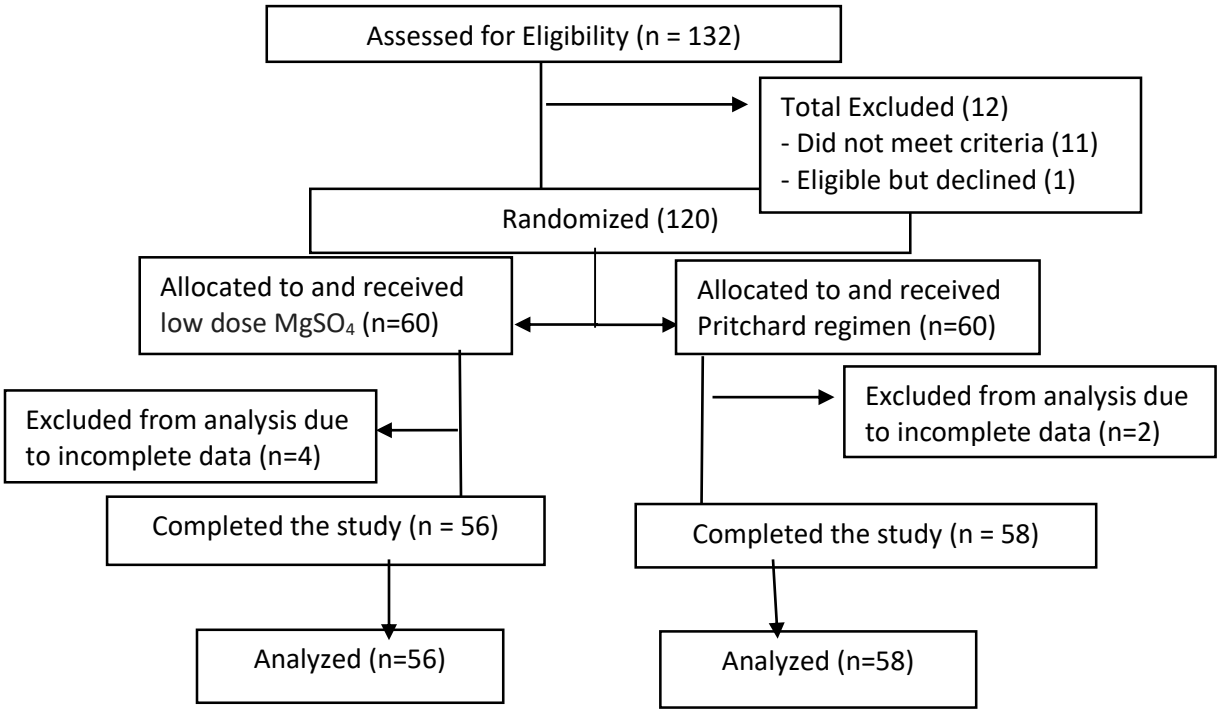

Figure 1: the flow of patients through the study

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Table 1: Socio-demographic Characteristics of Patients

Socio-demographic Variables	Low dose regimen (%)	Pritchard regimen(%)	P value
Age (years)			
≤20	5 {8.93}	3 {5.17}	
21-34	44 {78.57}	45 {77.59}	
≥35	7 {12.50}	10 {17.24}	0.4030
Mean age	2 8.39 ± 5.50	29.55 ± 4.78	0.23155
Parity			
	29 {51.79}	21{36.21}	
Primigravida	18 {32.14}	28{48.27)	
Para 2-4	9 {16.07}	9 {15.52}	0.8296
≥Para 5			
Gestational age at delivery (weeks)			
	8 {14.29}	12 {20.69}	
	12 {21.43}	10 {17.24)	
28-33^{+6}	36 {64.28)	36 {62.07}	0.7922
34-36^{+6}			
≥37 – 41^{+6}			
Highest level of education			
	10 {17.86}	9 {15.52}	
	31 {55.36}	24 {41.38)	
None/Primary	15 {26.78}	25 {43.10}	0.5152
Secondary			
Tertiary			
Booking status			
	32 {57.14}	27 {46.55}	
Booked	24 {42.86}	31 {53.45}	
Unbooked			0.42885
Mean weight on admission	81.93 ± 11.09	81.52 ± 11.70	0.84765
Diagnosis on admission			
Severe PE	45 {80.36}	43 {74.14}	
Eclampsia	11 {19.64}	15 {25.86}	0.4288

Table 1 shows some important demographic characteristics. There was no statistically significant difference in the demography of the participants. The majority of the women in both groups were between ages 20 and 34 years. Expectedly, primigravid women form the largest group, followed by multiparous women, while grand-multiparous women form the least of the parity group. The majority of the women (63.16%) delivered at term. There were slightly more booked than unbooked patients, with women having severe preeclampsia accounting for the larger proportion of the study population.

Table 2: Mean blood pressure on admission

Variables	Low dose reg. Mean ± SD	Pritchard reg. Mean ± SD	P value Mean ± SD
Systolic BP			
Severe	180.89±20.87	183.49±21.37	0.5652
Preeclampsia	194.55±25.44	181.33±18.84	0.1406
Eclampsia			
Diastolic BP			
Severe	112.86 ± 14.49	112.56±13.82	0.9704
preeclampsia	114.55±13.68	112.00±13.73	0.6443
Eclampsia			

BP – blood pressure

As shown in table 2, there was no statistically significant difference in the mean blood pressure (both systolic and diastolic) between the two groups at presentation.

Table 3: Maternal outcome

Parameters	Low dose	Pritchard	P value
Recurrence of fits in Ecl	0	1	0.324
Additional dose of $MgSO_4$	0	1	0.324
Placental abruption	2	3	0.678
Post-partum haemorrhage	1	7	0.032*
Admission into ICU	8	5	0.344
Mortality	1	0	0.309

Ecl – eclampsia; ICU – intensive care unit; *significant

As shown in Table 3, only one patient had a recurrent convulsion among those who received the Pritchard regimen and was managed

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according to the study protocol. There was no significant difference in abruptio placentae or the rate of admission into ICU. Seven patients among those who received the Pritchard regimen had primary postpartum haemorrhage (1o PPH) as against one of those who received a low dose, and this was statistically significant (p = 0.032). None of the patients, who presented with severe preeclampsia and were treated with either regimen, developed eclampsia. There was no sign of magnesium toxicity detected among women in this study. One eclamptic patient in the low-dose group died during the study. The cause of death was suspected to be a cerebrovascular accident (autopsy was not done).

Table 4: Route of delivery

Mode of delivery	Low dose/ (%)	Pritchard/ (%)	P value
Caesarean section	19 {33.93}	26 {44.83}	0.1766
	24 {42.86}	18 {31.03}	0.1668
Vaginal delivery	13 {23.21}	14 {24.14}	0.6266
Vacuum			

Table 4 shows the route of delivery. Caesarean section was more common among women who received Pritchard compared to the low-dose regimen, though the difference was not statistically significant.

Table 5: Foetal Status on Admission and Neonatal Outcome

	Low dose Regimen		Pritchard regimen	P value
Status				
Alive	50		54	
Dead	6	4	4	0.4734
				0.4866
Apgar Score	**Low dose**		**Pritchard**	**P value**
Birth weight (kg)	18		20	
1-2.4	36		37	0.785
2.5-3.9	2		1	
≥4				0.846
				0.525
1st minute Apgar	1		0	
0	7		12	0.317
<7	41		42	
≥7				0.221
				0.325
5th minute Apgar	1		0	
0	-		-	0.969
<7	49	5	54	-
≥7				0.314
Admission into Special care baby unit (SCBU)	9		12	0.569

As shown in Table 5, ten patients presented with intrauterine foetal death (six among the low-dose group and four among the Pritchard regimen group). One woman had an intrapartum foetal death due to abruptio placenta among the low-dose regimen group. Both 1st and 5th minute Apgar scores were comparable between the groups. The rate of admission into (SCBU) was comparable between the groups.

Discussion

Preeclampsia and eclampsia are common complications of pregnancy and result in significant maternal and perinatal morbidity and mortality if not promptly and effectively managed. Magnesium sulphate ($MgSO_4$) is the recommended anticonvulsant for prevention and treatment of eclampsia. The Pritchard regimen is the most commonly used regimen for patients with severe preeclampsia and eclampsia.[16,17] Several studies have reported the efficacy of lower-dose regimens of $MgSO_4$ in the prevention and treatment of eclampsia.[24-30]

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The majority of patients in this study were booked, which probably accounted for their detection before progression to eclampsia, as there were more severe preeclamptic than eclamptic patients in both arms of the study. This is contrary to findings in studies comprising entirely eclamptic women, which usually have unbooked women in larger proportion.[24-29, 31] This emphasises the role of antenatal care in the prevention of eclampsia, as elevated blood pressure may be promptly detected and treated or delivery expedited if the risks of prolongation of the pregnancy outweigh the benefits. Primigravidae form the largest group of patients in this study. This supports the disease being essentially that of first pregnancies,[1-3] as found in similar studies.[25-33]

In this study, none of the women with severe preeclampsia developed convulsion. This supports the efficacy of $MgSO_4$ in the prevention of eclampsia in women with severe preeclampsia, as shown by the Magpie trial [13] and the fact that lower doses might be enough to achieve this29-33. This finding agrees with that of Murthy et al. and Shoaib et al. who did not find a statistically significant difference in the risk of progression to eclampsia in patients with severe preeclampsia treated with either low dose or Pritchard regimen33,34. These findings support the fact that $MgSO_4$ in lower doses (than the Pritchard regimen) may be enough to prevent eclampsia in women with severe preeclampsia.

Only one eclamptic woman (1.7%) in the Pritchard regimen group had a repeat convulsion; none in the other group. This finding supports the efficacy of $MgSO_4$ in the treatment of eclampsia in lower doses than Pritchard regimen35,36. This is a huge advantage, especially in poor countries, where treatment is out-of-pocket and adequate personnel for patients' monitoring may not be available. This finding agrees with that of Murthy et al. and Bera et al., both in India24,34, despite the differences in demographic and environmental characteristics of the populations studied, thus supporting the efficacy of the low-dose MgSO4 regimen37,38. However, these findings contrasted with those of Sharma et al., who reported a significant difference in the rate of recurrent convulsion between women on lower doses and those on Pritchard regimen.28 . They attributed this to the delay in achievement of serum therapeutic concentration of $MgSO_4$ in patients who received a low-dose regimen.

There was no clinical feature of magnesium toxicity observed in this study. This could be due to the large volume of distribution of $MgSO_4$[3][9] in pregnancy in addition to the fact that the therapeutic level is far lower than the level at which toxicity occurs [40]. This observation was similar to that obtained by Imaralu et al. in Ile-Ife Nigeria and Murthy et al. in India, who recorded no sign of toxicity among the patients studied 18, 34. This corroborates the large therapeutic index of $MgSO_4$. . However, Bera et al. and Sharma et al. reported a significant difference in the rate of exhibiting $MgSO_4$ toxicity among patients who received Pritchard as compared with those on a low-dose regimen24,28. This was attributed to the low weight of Indian women which results in low volume of distribution of $MgSO_4$24.

Primary postpartum haemorrhage (PPH) in this study was significantly higher in Pritchard group than in the low-dose regimen group. This might be due to the calcium channel blocking effect of magnesium, leading to vasodilatation and decreased uterine contraction, which are dose-related39. A similar observation was made by Sharma et al. 28 and Imaralu et al. 18 These findings are in agreement with $MgSO_4$ being a smooth muscle relaxant through calcium channel blockade39. Nautiyal et al., however, did not report a significant difference in primary PPH between the low-dose and Pritchard regimen groups.26 . This might be due to the difference between the parity of women in their study and

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the present one, as about 67% of their patients (in both arms of the study) comprised primigravidae, as opposed to the present study, where primigravidae made up about 43% of the total study population. This agrees with parity being a major consideration in an atonic PPH1.

Foetal outcomes in this study were comparable on both arms. One intrapartum death (due to abruptio placenta) occurred among the low-dose regimen group, but none among Pritchard group. This finding agrees with the study conducted by Nautiyal et al. and Bera et al. who did not record any significant difference in neonatal outcomes between the two arms of their studies24, 26. Sharma et al., however, reported a higher number of fresh stillbirths among patients who received Pritchard regimen as opposed to the low-dose regimen.28 . This was attributed to increased foetal serum levels of magnesium with higher doses of $MgSO_4$, leading to neonatal respiratory depression. This finding, however, has not been supported by any other study.

One of the eclamptic patients in the low-dose regimen group (1.8%) died two days after delivery. Though an autopsy was not done due to refusal by her relatives, the cause of death was suspected to be cerebrovascular accident (a known complication of eclampsia). In a similar study, Nautiyal et al. recorded one death on the Pritchard arm of their study due to disseminated intravascular coagulopathy (DIC), while none occurred among women on a low-dose regimen.26 . Bai also recorded two deaths out of 100 patients (2%) recruited for their study, one on Pritchard regimen due to intracranial haemorrhage, while the one on low dose was due to pulmonary oedema,25 which are both complications of the disease1,8. Sharma et al. did not record any mortality in their study28. These findings support the safety profile of $MgSO_4$ 39.

Conclusion

From this study, magnesium sulphate given in low dosage was found to be equally effective as the Pritchard regimen. Reduced risk of primary PPH in patients given low doses, as compared to Pritchard regimen, makes it more suitable in low-resource settings where resources and personnel for PPH treatment may not be easily available. It does obviate the needless cause of a new problem by solving the old one. Considering its efficacy, lower risk of PPH and relatively lower cost to patients, a low-dose regimen of $MgSO_4$ may need to be considered for the prevention and treatment of eclampsia. Considering the efficacy, lower cost and lower risk of side effects of the low-dose $MgSO_4$ regime in patients with severe preeclampsia and eclampsia, a large-scale multicentre study is recommended in order to consider reducing the therapeutic dosage of the $MgSO_4$ regimen used in the prevention and treatment of eclampsia.

Limitation of the Study

This is a single-centre study, which may therefore affect the generalisation of the result of the study. A multicentre study may give a better representation of the outcome.Severe preeclampsia and eclampsia were studied together, which might have limited the number of each group included in the study. The result may be more valid for each group if they are studied separately.The gross imbalance between the preeclampsia and eclampsia cases in this study might have had an effect on the outcome recorded in the study. Similar studies in the future may address this by recruiting a fairly equal number of cases in each group in order to compare the effect of the drugs on both sides.

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