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CLINICAL ARTICLE

Experience of a low-dose magnesium sulfate regimen for the management of eclampsia over a decade

Narayan Jana [a,*], Subhendu Dasgupta [b], Anindya Kumar Das [b], Debjyoti Santra [b], Balaram Samanta [c]

[a] Department of Obstetrics and Gynaecology, Burdwan Medical College, Burdwan, India
[b] Department of Obstetrics and Gynaecology, Bankura Sammilani Medical College, Bankura, India
[c] Department of Obstetrics and Gynaecology, Chitta Ranjan Seva Sadan College of Obstetrics, Gynaecology and Child Health, Kolkata, India

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ABSTRACT

Objective: To assess the safety and efficacy of a low-dose magnesium sulfate regimen for the management of eclampsia in Indian women. *Methods:* A loading dose consisting of 3 g of magnesium sulfate intravenously plus 5 g intramuscularly (2.5 g in each buttock) was followed by 2.5 g intramuscularly every 4 hours, for 24 hours beyond the last seizure. In a first phase, which spanned 2001 and 2002, the regimen was evaluated prospectively with 554 women with eclampsia, and the results were compared with results from the Collaborative Eclampsia Trial. Regarding the second phase, which spanned the 9 following years, mortality was analyzed retrospectively for 2929 women treated by the same regimen at the same hospital. *Results:* The mean ± SD maternal weight and height were 41.7 ± 5.3 kg and 151 ± 7 cm, respectively. The low-dose regimen was associated with a lower seizure recurrence (6.1% vs 9.7%; $P = 0.02$) and a slightly lower maternal mortality (2.7% vs 3.2%; $P = 0.6$) compared with the Collaborative Eclampsia Trial. The overall case fatality rate for the second phase was 3.3%. *Conclusion:* The low-dose regimen was safe and effective for the management of eclampsia in a region where most women are of light weight.

1. Introduction

Eclampsia remains an important cause of maternal mortality and morbidity worldwide [1–5]. Studies have indicated that it accounts for more than 50 000 maternal deaths globally [1,2]. A large majority of these deaths occur in low-income countries where the quality of maternity care is often inadequate [2,4]. Magnesium sulfate is the anticonvulsant drug of choice for both prevention and treatment of eclampsia, but its dose-related toxicity is a major concern [6–13]. Potential hazards include maternal hypotension, respiratory depression, and respiratory arrest (cardiac arrest is rare) [14,15]. Undue apprehension regarding these hazards leads to a limited use of the drug in many low-income countries [10,12]. Reducing magnesium sulfate toxicity without compromising its efficacy in controlling seizures and lowering mortality rates remains a major challenge [10,11].

The Collaborative Eclampsia Trial, which remains the largest trial of magnesium sulfate for the management of eclampsia, included women from 27 centers from 10 countries. No dose adjustments were made for maternal weight in this trial, even though maternal weight is much higher in high- than in low-income countries (65 kg vs 45 kg) [6,16,17]. Although small observational studies from India and Bangladesh introduced some modifications to the standard Pritchard regimen used in the trial [16], and these modifications appeared to reduce drug toxicity [8,9,13,18], their findings were not widely accepted. The present, 2-phased study was designed with 2 objectives: to assess, over 2 years, maternal and perinatal outcomes among women treated for eclampsia with a low-dose regimen of magnesium sulfate; then, with a large cohort over several years, to identify any possible "Hawthorne effects" (i.e. research- or researcher-induced desirable outcomes) associated with the low-dose regimen [19].

2. Materials and methods

An observational study was carried out over 11 years at Bankura Sammilani Medical College and Hospital, Bankura, India, a busy rural teaching hospital in eastern India. Data for 554 women with eclampsia were prospectively recorded from January 1, 2001, through December 31, 2002, for the evaluation of a low-dose magnesium sulfate regimen. The second phase was a routine retrospective collection of data regarding case fatality among 2929 women with eclampsia who were administered the same regimen at the same hospital from January 1, 2003, through December 31, 2011.

The low-dose regimen consisted of the following: a loading dose of 3 g of magnesium sulfate intravenously plus a 2.5 g intramuscular injection in each buttock (for a total of 8 g of magnesium sulfate), followed by a maintenance dose of 2.5 g administered intramuscularly every 4 hours alternately in each buttock over the 24 hours that followed the last seizure. All women were monitored clinically. Patellar reflex,

* Corresponding author at: Department of Obstetrics and Gynaecology, Burdwan Medical College, Burdwan 713104, India. Tel.: +91 342 265 8641; fax: +91 342 2658636.
E-mail address: drnjana@gmail.com (N. Jana).

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respiratory rate, and urine output were taken into consideration when the magnesium sulfate dosage needed to be adjusted during the maintenance period [20]. If there was a seizure recurrence later than 30 minutes after administration of the loading dose, an additional dose of 1 g was administered intravenously. If urine output was less than 100 mL in the preceding 4 hours, the next dose of magnesium sulfate was reduced from 2.5 g to 1.5 g. This low-dose magnesium sulfate regimen was clearly described, unanimously agreed upon by the department consultants, duly structured and pre-tested, and its implementation was audited. All trainees were acquainted with the new regimen, of which the study team had a preliminary experience. The regimen was initially piloted in 1998 for clinical and logistic reasons, as a magnesium sulfate solution for intramuscular administration (i.e. 50% weight/volume of injectable solution) was unavailable [21].

A structured form was filled out for each patient with eclampsia. The maternal and perinatal events included in the form were the number and timing of seizure recurrence, onset (or induction) of labor, progress of labor, mode of delivery, type of anesthetic drugs administered, perinatal outcomes, and course of the puerperium. Maternal height and weight were recorded on the third or fourth day after delivery, when the patient was ambulatory. Each patient was followed-up until discharge or death. Mean birth weight, frequency of low birth weight, frequency of neonatal depression (i.e. an Apgar score <7 at 1 minute), and perinatal mortality were used as indexes of perinatal outcome. Perinatal mortality included stillbirths and deaths within 7 days of birth. Seizure recurrence and maternal deaths were the primary outcomes. The secondary outcomes were cesarean delivery rate and perinatal mortality. Each maternal death was reviewed by a team of 3 consultants (all authors of the present report) to assess quality of care and determine the probable cause of death. The study was approved by the institutional ethics committee. As informed written consent requires a sound mind, and many patients were unconscious or confused, consent was obtained from the next of kin, usually the husband.

The study having no concurrent control patients, it was considered appropriate to use results from the largest and most rigorous trial to date of magnesium sulfate treatment for eclampsia. Because of its large size and multicentric participation, which involved 10 countries, the results of the Collaborative Eclampsia Trial are considered the gold standard against which the results of the first phase of the present study were compared [6].

Assuming that seizure recurrence would be 5% higher among patients treated with the low-dose regimen than among those treated with standard doses of magnesium sulfate in the Collaborative Eclampsia Trial (in other words, assuming that the rate of recurrence would be 10.7% in the present study, whereas it was 5.7% as a lower limit in the trial), it was determined that 520 study patients and 520 "controls" from the trial would have an 80% power to detect a 5% difference in seizure recurrence at $\alpha = 0.05$.

The findings for the present study and the earlier trial were compared by the unpaired t test or the χ^2 test, as appropriate. Statistical software Epi Info 2000 (Centers for Disease Control and Prevention, Atlanta, GA, USA) and Stata version 7.0 (StataCorp, College Station, TX, USA) were used for analysis.

The new regimen was applied systematically at Bankura Sammilani Medical College over the 9 years that followed the study's first phase. The case fatality rate for eclampsia was calculated for this period from the routinely recorded patient data. As it was difficult to retrieve data concerning seizure recurrence from individual case notes, maternal death was the only indicator of the effect of the regimen during the second phase.

3. Results

During the first, prospective phase of the study (2001–2002), 28 628 women were delivered at Bankura Sammilani Medical College. Of these, 554 women with eclampsia were administered the low-dose magnesium sulfate regimen. These women were young (mean ± SD age, 20.8 ± 2.8 years), and 31.4% of them were teenagers. Most (89.7%) were primigravidas from rural communities who had received little or no prenatal care (Table 1). The number of seizures before admission varied from 1 to more than 10. Seizures on the way to the hospital were very common, but medical help was seldom available during transportation. Most women were of small stature, with a mean height of 151 ± 7.0 cm, a mean weight of 41.7 ± 5.3 kg, and a mean body mass index (calculated as weight in kilograms divided by the square of height in meters) of 19.3 ± 2.1.

None of the women who developed eclampsia received magnesium sulfate before admission to the hospital. On admission, all had a blood pressure exceeding 140/90 mm Hg, 74.5% had severe hypertension (defined as a blood pressure exceeding 160/110 mm Hg), and 91% had proteinuria (Table 1). Oral or sublingual nifedipine was given in cases of severe hypertension.

The women received magnesium sulfate over a variable period, depending on the time of the last seizure. The mean total dose of magnesium sulfate administered during the first phase of the study, 23.9 ± 4.3 g, was significantly lower than that administered during the Collaborative Eclampsia Trial ($P < 0.001$) [6] (Table 2). As there was no clinical evidence of magnesium toxicity in any of the patients, magnesium sulfate administration was never interrupted because of clinical toxicity.

Of the 34 (6.1%) women whose seizures recurred after administration of the loading dose of magnesium sulfate, 27 had 1, 6 had 2, and 1 had 3 recurring seizures (Table 1). All received an additional dose of 1 g magnesium sulfate immediately after each recurring seizure. Compared with the Collaborative Eclampsia Trial, the low-dose regimen

Table 1
Clinical details and obstetric outcomes for 554 women with eclampsia treated with the low-dose magnesium sulfate regimen during the prospective phase of the study.[a]

Patient characteristics	Values
Age, y	20.8 ± 2.8
Parity	
0	497 (89.7)
1	35 (6.3)
≥2	22 (4)
Type of eclampsia	
Prepartum	393 (70.9)
Intrapartum	55 (9.9)
Postpartum	106 (19.1)
No. of seizures	
1–5	440 (79.4)
>5	114 (20.6)
Severe hypertension[b]	413 (74.5)
Labor[c]	
Spontaneous	243 (62.8)
Induced	144 (37.2)
Mode of delivery	
Vaginal, unaided	342 (61.7)
Forceps-assisted	155 (28)
Cesarean	50 (9)
Undelivered	7 (1.3)
Gestational age at delivery, wk	37.5 ± 2.8
Birth weight, g	2461.2 ± 530.8
Perinatal death[d]	
Stillbirth	78 (16.5)
Early neonatal death	55 (11.6)
Recurrent convulsions	34 (6.1)
Maternal death	15 (2.7)

[a] Values are given as mean ± SD or number (percentage).
[b] Defined as blood pressure higher than 160/110 mm Hg.
[c] A total of 387 women with prepartum or intrapartum eclampsia were delivered at Bankura Sammilani Medical College during the prospective phase of the study.
[d] Perinatal death was calculated for the 473 women who were delivered at Bankura Sammilani Medical College during the prospective phase of the study.

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Table 2
Comparison of the doses of magnesium sulfate administered and treatment outcomes in the Collaborative Eclampsia Trial (CET) and the prospective phase of the study.[a]

Variable	CET (n = 841)	Present study (n = 554)	*P* value
Center	Multiple, international	Single hospital	
Total dose administered in a magnesium sulfate arm of the CET, g (n = 229)[b]	40 ± 11.8	23.9 ± 4.28 g	<0.001
Total dose administered in another magnesium sulfate arm of the CET, g (n = 336)[c]	38 ± 9.7		
No. of recurrent convulsions	82 (9.7)	34 (6.1)	0.02
No. of maternal deaths	27 (3.2)	15 (2.7)	0.6

[a] Values are given as mean ± SD or number (percentage).
[b] In this group, the results of the Pritchard regimen were compared with those of diazepam treatment.
[c] In this group, the results of the Pritchard regimen were compared with those of phenytoin treatment.

was associated with a significantly lower seizure recurrence (6.1% vs 9.7%; $P = 0.02$) (Table 2).

Among the patients, 70.9% incurred 1 or more seizures before onset of labor and 62.8% had a spontaneous onset of labor (Table 1). Artificial rupture of membranes plus oxytocin administration was used to induce labor, with dinoprostone gel used only occasionally. In this low-resource setting, vaginal delivery was preferred to avoid the anesthetic and operative hazards of cesarean delivery. Approximately 90% of the patients had a vaginal delivery, which was forceps assisted in 28% of cases (Table 1).

Perinatal data were complete for 473 patients who were delivered at Bankura Sammilani Medical College during the first phase of the study, and these data were included in the analysis. The data available for those delivered elsewhere and subsequently admitted to the hospital were not used because they were incomplete. The mean pregnancy duration for the patients delivered at the hospital was 37.5 ± 2.8 weeks. The mean birth weight was 2461 ± 530 g (<2500 g for 45.5% of the newborns), and a low Apgar score at 1 minute (<7) was recorded for 135 (28.5%) of the newborns. Perinatal death was high (28.1%). There were 78 stillbirths (16.5%) and 55 early neonatal deaths (11.6%) (Table 1).

There were 15 maternal deaths, for a case fatality rate of 2.7%. Most deaths were attributed to a cerebrovascular accident, septicemia, renal failure, pulmonary edema, or disseminated intravascular coagulation, and cerebrovascular accidents due to uncontrolled hypertension were the most common cause of death (Table 3). Several patients had multiorgan involvement (e.g. renal failure, disseminated intravascular coagulation, and pulmonary edema). In such cases, advanced management could not be provided because there was no intensive treatment unit or nephrology services at Bankura Sammilani Medical College during the first phase of the study. Only 1 of the patients who died had recurrent seizures, and her death was due to a cerebrovascular accident.

Table 4
Numbers of deliveries, cases of eclampsia, and maternal deaths due to eclampsia at Bankura Sammilani Medical College in the 9 years of the retrospective phase of the study.

Year	No. of deliveries	No. of cases of eclampsia	No. of maternal deaths (%)
2003	14 954	330	14 (4.2)
2004	15 082	407	10 (2.5)
2005	15 716	287	17 (5.9)
2006	15 886	332	12 (3.6)
2007	16 296	300	11 (3.7)
2008	16 695	282	5 (1.8)
2009	18 417	331	9 (2.7)
2010	19 110	311	10 (3.2)
2011	19 941	349	10 (2.9)
Total	15 2097	2929	98 (3.3)

During the subsequent 9 years (2003–2011), 2929 of the 152 097 women delivered at Bankura Sammilani Medical College were admitted with a diagnosis of eclampsia and were treated with the low-dose magnesium sulfate regimen (Table 4). The overall case fatality rate for the second phase was 3.3% (range, 1.8% to 5.9%). The persistence of a low mortality several years after the beginning of the study virtually excludes the Hawthorne effect known to positively influence outcome at first and then fade [19].

4. Discussion

Compared with the Pritchard regimen used in the Collaborative Eclampsia Trial [6], the low-dose regimen was associated with a significantly lower seizure recurrence (6.1% vs 9.7%; $P = 0.02$) and a slightly lower maternal mortality rate (2.7% vs 3.2%; $P = 0.6$). These results, which were achieved with a dose of magnesium sulfate 40% lower than in the Collaborative Eclampsia Trial (40 g vs 23.9 g; $P < 0.001$), should be clinically relevant for physicians from low-income countries, where maternal height and weight are almost always low [8,14]. The study results have 3 major implications: first, following the regimen virtually eliminated the risk of magnesium toxicity and thus increased the safety of the drug. Second, as the regimen

Table 3
Characteristics of the maternal deaths that followed treatment with the low-dose magnesium sulfate regimen during the prospective phase of the study.

Age, y	Parity	Time of eclampsia onset	Recurrent seizure	Delivery	Cause of death
20	1	Prepartum	No	VD	Disseminated intravascular coagulation
25	1	Postpartum	No	VD	Cerebrovascular accident
19	1	Postpartum	No	VD	Aspiration pneumonia
26	1	Intrapartum	No	VD	Cerebrovascular accident, acute renal failure and septicemia
20	0	Prepartum	No	VD	Aspiration pneumonia
27	0	Prepartum	No	VD	Cardiac failure with pulmonary edema
25	2	Postpartum	No	VD	Postpartum hemorrhage
19	0	Prepartum	No	VD	Cerebrovascular accident, acute renal failure and septicemia
24	0	Prepartum	No	UD	Cerebrovascular accidents, and pulmonary edema
24	2	Postpartum	No	VD	Placental abruption
20	0	Prepartum	No	UD	Respiratory failure
18	0	Prepartum	Yes	FD	Cerebrovascular accident and cardiac failure
22	0	Prepartum	No	VD	Septicemia
23	0	Prepartum	No	UD	Cerebrovascular accident
20	0	Prepartum	No	CS	Cerebrovascular accident and septicemia

Abbreviations: CD, cesarean delivery; FD, forceps-assisted delivery; UD, undelivered; VD, vaginal delivery.

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Table 5
Different regimens of magnesium sulfate with intramuscular maintenance dose for eclampsia.

Authors	Loading dose with magnesium sulfate	IM maintenance dose per 4 h	Total dose in the first 24 h	Reduction from the standard dose
Pritchard et al. [16]/Collaborative Eclampsia Trial [6]	4 g IV, plus 5 + 5 g IM.	5 g	39 g	Standard dose
Bhalla et al. [9]	4 g IV, plus 4 + 4 g IM	4 g	32 g	18%
Begum et al. [10] ("Dhaka" regimen)	4 g IV, plus 3 + 3 g IM.	2.5 g	22.5 g	42.3%
Present study ("Bankura" regimen)	3 g IV, plus 2.5 + 2.5 g IM	2.5 g.	20.5 g	47.4%

Abbreviations: IM, intramuscular; IV, intravenous.

lowered the drug dose for each patient, it substantially lowered the overall cost of treatment—which is very important in low-resource countries, where injectable magnesium sulfate is scarce and expensive [22,23]. Third, with a lesser toxicity, magnesium sulfate treatment is likely to become acceptable at peripheral health centers. Recent evidence from Bangladesh suggests that administering the drug at peripheral centers before the patient is transferred to a larger center significantly reduces the recurrence of seizures (2.6% vs 6%; $P < 0.001$) and maternal deaths (2.3% vs 10.6%; $P < 0.05$) [4]. In the present study, no patient received magnesium sulfate before admission to Bankura Sammilani Medical College in 2001 and 2002. However, with the growing availability of training in emergency obstetric care, the situation has improved over the recent years [5].

The Collaborative Eclampsia Trial was conducted in selected, mostly well-equipped centers in 10 countries. It reported a maternal mortality rate of 3.2% among the patients treated with magnesium sulfate, which is similar to the overall 3.3% mortality achieved in this low-resource rural setting [6]. However, maternal mortality rates are relatively high (approximately 10%) among women with eclampsia who are treated at low-resource centers throughout Asia [3,8] and Africa [24], even when the standard Pritchard magnesium sulfate regimen is administered [16]. In the present study, the overall case fatality rate for eclampsia was low (3.3%) several years after the prospective phase of the study—a result that virtually excludes the possibility that the Hawthorne effect had a role [19]. The results of the present study, along with results from other studies, confirm the safety and efficacy of the low-dose magnesium sulfate regimen [10,13]. Two primary outcomes in these studies, seizure recurrence and maternal mortality, were satisfactory and the adverse effects of magnesium sulfate were almost eliminated. The regimen has been adopted at many district hospitals, with satisfactory clinical outcomes, following the communication of the authors' preliminary results at national conferences in 1998 and early 2002 [21,25].

The low overall case fatality rate in the present study can be attributed to various factors. These include the development of a structured, clearly written, and pre-tested guideline that was first made widely available and then implemented, while education and training were provided to all categories of staff, including the hospital interns, and feedback was solicited. The guideline has been strictly followed ever since, and clinical audits of maternal deaths due to eclampsia have been regularly conducted.

Magnesium sulfate treatment with an intramuscular maintenance regimen is widely used in women with eclampsia in low-income countries [4,6,8–10]. Several investigators have tried to lower the doses of magnesium sulfate used in the standard Pritchard regimen, in which 39 g of magnesium sulfate is administered during the first 24 hours (Table 5) [6,16]. The dose reduction has varied between 18% and 47.4%, depending on the regimen used [8,9]. Although apparently similar to a previous regimen introduced in Dhaka, Bangladesh [8,10], the present regimen is different because of its lower, 8-g loading dose. The dose stems from the simple logic that the weight of Indian women is approximately two-thirds that of their US counterparts (45 kg vs 65 kg) [17]. Compared with the Dhaka regimen, the Bankura regimen was associated with a lesser case fatality rate (8% vs 3.3%; $P < 0.001$)—a difference that can partly be attributed to a difference in patient characteristics [8].

The present study, one of the largest observational studies on the management of eclampsia with magnesium sulfate, comprises both a prospective and a retrospective phase. The strength of the prospective phase is its comparison with an international trial, and the retrospective part showed that the first phase's results were being reproduced even several years after completion of the first phase. As the sample size was large and the departures from the study protocol were minimal, the results are likely to have but a small margin of error. Furthermore, the retrospective analysis dealt only with maternal death, an outcome not amenable to subjective error. As the regimen has been tried in other district hospitals with satisfactory results, and similar low-dose regimens have been used in India and Bangladesh, the Bankura regimen can be recommended to low-income countries where maternal height and weight are low.

Conflict of interest

The authors have no conflicts of interest.

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