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Original Research Article

Comparative Study of the Standard Pritchard Regimen and Low Dose Dhaka Regimen of Magnesium Sulphate in the Management of Severe Pre-Eclampsia and Eclampsia

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Conflict of interest: Nil

Abstract:

Background: We wanted to evaluate the Standard Pritchard Regimen and Low Dose Dhaka Regimen of Magnesium Sulphate in the management of severe pre-eclampsia and eclampsia, assess the effects of magnesium sulphate regimens and investigate the efficacy of the Dhaka Regimen (a low dosage regimen), in eclampsia, compare Standard regimen (PRITCHARD) with low dose regimen (DHAKA) with regard to the effectiveness in controlling of convulsions in eclampsia, and compare the magnesium related toxicity in both the regimens in this study.

Methods: This was a hospital based prospective randomized clinical study conducted among 200 pregnant women with severe pre-eclampsia, imminent eclampsia & eclampsia attending the Government Maternity Hospital attached to SVMC, Tirupati, for 1 year after obtaining clearance from the institutional ethics committee and written informed consent from the study participants.

Results: In parity study, 135 cases were primigravida (67.5%) (Primigravidas >multigravidas). 65 cases (32%) were multigravida. Majority of the cases were primigravida in both the regimens. P- value was 0.004 which was statistically significant. In SBP, majority of the cases had SBP(>160) in DHAKA regimen i.e. 61% and in Pritchard regimen 48%. P-value was 0.02 which was statistically significant. In admission delivery interval in hours, it showed that mean duration of ADI for DHAKA regimen was 13.45 hours and Pritchard was 11.81 hours. Majority of the cases in DHAKA regimen had more delivery interval in hours. P-value was statistically insignificant.

Conclusion: The current study offers more convincing evidence in favour of using magnesium sulphate frequently to treat eclampsia convulsions. Clinical surveillance seems suitable as long as there is enough urine output. There is no difference between the two magnesium sulphate regimens in terms of maternal mortality, perinatal death, maternal morbidity, or caesarean section rates. The research amply demonstrates that the Dhaka regimen is nearly similar to Pritchard protocol for the prevention and management of convulsions.

Keywords: Standard Pritchard Regimen, Low Dose Dhaka Regimen, Magnesium Sulphate, Management, Pre-eclampsia, Eclampsia

Introduction

Women with gestational hypertension have blood pressures that reach 140/90 mm of Hg or greater on 2 occasions at least 4 hours apart for the first time after 20 weeks of gestational age but lack proteinuria and return to normal by 12 weeks' post-partum.

Preeclampsia is best described as pregnancy specific syndrome that can affect virtually every organ system. Although preeclampsia is simply more than gestational hypertension with proteinuria, the appearance of protein remains a primary diagnostic criterion. It is an objective marker and reflectsthe system-wide endothelial leak that characterises the preeclampsia syndrome.

Eclampsia is preeclampsia exacerbated with

convulsions. Eclampsia is classified as antepartum, intrapartum, or postpartum according to when the symptoms develop before, during, or after delivery. One of the most frequent obstetrical catastrophes, eclampsia significantly increases maternal and perinatal morbidity. According to studies, it is responsible for more than 50,000 maternal fatalities worldwide. The majority of these fatalities take placein low-income nations, when maternal care is frequently of poor quality. [1-2] Controlling convulsions is the first rule in the treatment of eclampsia. Magnesium sulphate is the anticonvulsant medication of choice for both preventing and treating eclampsia, but its toxicities are dose-related, which is a serious issue. Potential risks include respiratory depression, respiratory arrest, and maternal hypotension (cardiac arrest is rare). In many low-income nations, the medicine is only sometimes used due to unwarranted concern over these risks. Reducing the toxicity of magnesium sulphate without sacrificing its effectiveness in preventing seizures and reducing mortality rates is still a difficult task. Women from 27 centres in 10 countries participated in theCollaborative Eclampsia Trial, which is still the largest study of magnesium sulphate for the treatment of eclampsia. Despite the fact that maternal weight is significantly higher in high-income nations than in low-income ones, no dose modifications were performed for maternal weight in this trial (65 kg vs 45 kg). [3] The conventional Pritchard regimen used in the trial was modified by small observational studies from India and Bangladesh, and these alterations seemed to lessen medication toxicity. To lessen the toxicity associated with magnesium, a low dose regimen is required.

Aims and Objectives

- Comparative Study of the Standard Pritchard Regimen and Low Dose Dhaka Regimen of Magnesium Sulphate in the Management of Severe Pre-Eclampsia and Eclampsia
- To investigate the efficacy of the Dhaka Regimen, a low-dose magnesium sulphate regimen in eclampsia.
- To assess the differences between the Standard regimen (PRITCHARD) and low dosage regimen (DHAKA) for magnesium sulphate. To compare the effectiveness in controlling of convulsions in eclampsia
- To compare the magnesium related toxicity in both the regimens.

Methods

This was a hospital based prospective randomized clinical study conducted among 200 pregnant women with severe pre-eclampsia, imminent eclampsia & eclampsia attending the Government Maternity Hospital attached to SVMC, Tirupati, for 1 year after obtaining clearance from the institutional ethics committee and written informed consent from the study participants.

Inclusion Criteria

1. Pregnant women with severe eclampsia, imminent eclampsia,antepartum eclampsia, intrapartum, postpartum eclampsia.
2. Those who were willing to give written and informed consent
3. BMI <30
4. Irrespective of age and parity.

Exclusion Criteria

1. Any contraindication to magnesium sulphate like myasthenia gravis or pre-existing renal failure.
2. Known epileptics.
3. Chronic Hypertensives.

Statistical Methods

Data was entered in MS Excel and analysed using SPSS software. Results were resented as tables.

Results

Table 1: Age distribution

Age Group(yrs.)	Group A		Group-B		Total	
	No	%	No	%	No	%
18 – 24	73	73%	71	72%	144	72%
25 – 30	20	20%	17	17%	37	18.5%
>30	7	7%	12	12%	19	9.5%
Total	100	100%	100	100%	200	100%
Mean Age	22.94 ± 3.68		23.45 ± 4.12		23.19 ± 3.90	
Chi square test= 1.58, p=0.45, Not statistically significant						

The distribution of ages is seen below. The two groups' women's ages are identical. In this study, 144 cases (72%) are between 18-24 years, 31 cases (18.5%) are between 25-30, 19 cases (9.6%) are more than 30 years, mean age for Pritchard regimen is 23.45 ±4.13 years and DHAKA regimen is 22.9±3.6 years. In both the regimens, the majority of cases fall between the 18–24 age range. P-value is 0.45, where it is not statistically significant.

Table 2: Parity

Parity	Group A		Group B		Total	
	No	%	No	%	No	%
Primi	58	58%	77	77%	135	67.5%
Multi	42	42%	23	23%	65	32.5%
Total	100	100%	100	100%	200	100%
Chi square test= 8.18, p=0.004*, statistically significant						

This shows parity. In this study, 135 cases were primigravida (67.5%) (primigravidas >multigravidas) and 65 cases (32%) were multigravida. Majority of the cases were primigravida in both the regimens. P- value is 0.004 which is statistically significant.

Table 3: SBP

SBP	Group A		Group B		Total	
	No	%	No	%	No	%
120- 140	1	1%	8	8%	9	4.5%
140 – 160	38	38%	44	44%	82	41%
>160	61	61%	48	48%	109	54.5%
Total	100	100%	100	100%	200	100%
Chi square test= 7.43, p=0.02*, statistically significant						

This shows SBP. Majority of the cases have SBP(>160) in DHAKA regimen i.e. 61% and in Pritchard regimen 48%. P-value is 0.02 which is statistically significant.

Table 4: Admission delivery interval in hours

	Minimum	Maximum	Mean ± SD	P-value
Group A	1	22	13.45 ±6.03	0.03*
Group B	2	22	11.81 ±4.85	

This shows admission delivery interval in hours. Mean duration of ADI for DHAKA regimen is 13.45 hours and Pritchard is 11.81 hours. The majority of cases in DHAKA regimen had more delivery interval in hours. P-value is statistically insignificant.

Discussion

The management of eclampsia has changed significantly throughout time. One of the most frequent obstetrical crises, eclampsia significantly increases maternal and neonatal morbidity and death, particularly in underdeveloped nations. Controlling convulsions is the primary goal in the treatment of eclampsia. The preferred anticonvulsant medication is magnesium sulphate, which prevents and regulates eclamptic convulsions and thereby lowers morbidity for both mothers and newborns. However, dose-related toxicity is a serious concern, especially in clinical settings where patient monitoring is restricted and when patients are small in stature. [4-5] A variety of magnesium sulphate dosage regimens have been employed to treat eclampsia; the Pritchard regimen is one such regimen.

In India, women tend to weigh less, particularly those from lower socioeconomic strata or those from rural regions. Giving these underweight ladies the Pritchard regimen might be dangerous, and there's a serious risk of severe respiratory collapse. [6] In light of this, several investigations have been carried out to ascertain the lowest effective dosage, and these adjustments have demonstrated potential in terms of reduced adverse effects and equivalent efficacy.

In this study, magnesium-related toxicity was evaluated, the effectiveness of the low-dose MgSO4 regime (also known as the Dhaka regime) for controlling seizures in eclampsia and preventing convulsions in impending eclampsia was assessed, and the maternal and perinatal outcomes were compared to the standard Pritchard regime.

With the institutional ethical committee clearance, this randomised control trial was conducted from March 2020 to March 2022 at the obstetrics and gynaecology department of Sri Venkateshwara Medical College and Hospital, Tirupati.

Based on the defined inclusion and exclusion criteria, 200 patients withpre-eclampsia and eclampsia enrolled in the study, among which 100 underwent Pritchard regimen and remaining 100 underwent Dhaka regimen.

Demographic Characters

Mean age, gender and BMI were comparable between the two groups and there was no significant difference in distribution of patients on the basis of presenting complaints or comorbidities or previous surgery between two groups.

In our current study, the age of women in 2 groups did not differ. In this study, 144 cases (72%) were between 18-24 years, 31 cases (18.5%) were between 25-30, 19 cases (9.6%) were more than 30 years, mean age for Pritchard regimen was 23.45 ± 4.13 years and Dhaka regimen was 22.9 ± 3.6 years.

Dr. Himadri Nayek et al. conducted a study in which the mean ages of Group L and Group S were 23.59 and 23.65 years, respectively.

Ranjana et al. conducted a research wherein two groups of severe preeclamptic women were compared. One group was administered low dosage MgSO4 (Dhaka regime), while the other group was given the usual Pritchard regime. The two groups' respective means were 25.8 and 25.7 years old.

Magnesium sulphate was instituted in one group and nicodipine in another in a research by Hall et al. titled Comparative Research Of Low Dose Magnesium Sulphate Versus Standard Regime In Severe Preeclampsia Women. The average mother's age was 26.9 years old there.

A research conducted by Coetzee et al. [7] (2014) examined the effects of magnesium sulphate vs placebo treatment on two groups of preeclamptic women. There, the mean mother's age was 25 years for the placebo group and 24 years for the magnesium sulphate group.

Booking Status

In the current trial, 6% of the scheduled lessons in the Pritchard regimen were filled. 94% of Pritchard regimen cases and 89% of DHAKA regimen cases were unbooked. P- value was 0.20 which was not statistically significant.

Anjali Rani et al. evaluated a number of parameters between the Pritchard and Dhaka regimen groups in their study. [8] The majority of patients in both groups-88% in the Pritchard regimen and 91.7% in the Dhaka regimen—were not scheduled, with the majority of patients coming from rural backgrounds (79.16% in the Pritchard regimen and 83.3% in the Dhaka regimen).

Ninety percent of the cases in a research by Bangal V et al. (2009) were not booked. In a research by Ranjana et al., upon admission to our hospital, 75% of patients in group A and 65% of cases in group B were unbooked and lacked prenatal data.

Parity

In this study, 135 cases were primigravida (67.5%) (primigravidas > multigravidas) and 65 cases (32%) were multigravida.

According to a research by Dr. Himadri Nayek et al., a majority of the women in both groups, accounting for 48% and 53.33% of the populations in Group L and Group S, respectively, were primigravidas.

The majority of patients in a research by Ranjana et al. were primigravidas (70% in group A and 75% in group B, respectively). In all groups, antepartum eclampsia was the most prevalent, followed by imminent eclampsia.

Gestational Age

In this study, 19 cases were between 24-28 weeks (9.5%), 24 cases were between 29-32 weeks, and 69 cases (34.5%) were between 33-36 weeks. Most of the cases i.e. 88 cases (44%) were above 37 weeks.

The distribution of women in both groups with respect to gestational age was determined in a research conducted by Dr. Himadri Nayek and colleagues. In Group L and Group S, the majority of enrolled women (60% and 61%, respectively) were at term.

In the research conducted by Ranjana et al., Group B's mean gestational age was 34.8±2.71 weeks, whereas Group A's was 34.5±2.88 weeks. When they were admitted, most of the patients in both groups (57.5% in group B and 67.5% in group A) had between one and five convulsions.

Hall et al. selected women with a mean gestational age of 31 completed weeks for their research. The magnesium sulphate group and the placebo group were recruited by Coetzee et al. with mean gestational ages of 34.3 and 34.8 weeks, respectively.

Level of Consciousness

The patients' level of consciousness in the two groups did not differ substantially in our current investigation. 191 instances (91.5%) of conscious patients were on both regimens. Semiconscious were 16% in both the groups. 1 case was unconscious that is with Pritchard regimen. P-value was 0.55 which was not statistically significant. There were no similar studies regarding level of consciousness.

Convulsions

With regard to the number of convulsions before admission, no significant differences were found between the 2 groups. P- value was 0.40 which was not statistically significant.

According to a research conducted at the time of admission by Ranjana et al., the majority of patients (67.5% in group A and 57.5% in group B) had between one and five convulsions. In group B, just one patient had more than ten convulsions.

Blood Pressure

In our current study, majority of the cases had SBP (>160). DHAKA regimen 61% and Pritchard 48%. P-value was 0.02 and statistically significant. In our present study, majority of the cases had DBP of 100-110. P-value was 0.98 which is statistically not significant.

Type of Labour

In our current study, out of 100 cases in group A (DHAKA regimen), 17 cases were augmented with oxytocin, 19 cases with PGE2, and 57 cases with misoprostol. Out of 100 cases in group B (Pritchard), 7 cases were augmented with oxytocin, 22 cases with PGE2, and 65 cases with misoprostol. P-value was 0.011 which is statistically not significant.

Mode of Delivery

In our present study, out of 100 cases of DHAKA regimen, 71 cases delivered vaginally, 5 cases with forceps, and 21 delivered through C-section. Out of 100 cases of Pritchard regimen, 65 cases delivered vaginally, 4 cases by forceps, and 2 by C- section. P-value was 0.69 which is statistically insignificant.

According to a research by Dr. Himadri Nayek et al colleagues, spontaneous vaginal deliveries occurred in 55 (73.33%) of Group L's women and 58 (77.33%) of Group S's women.

Group S had 17 (22.66%) and Group L had 20 (26.66%) caesarean sections performed. The statistical significance of this difference was P>0.05. Maternal outcomes were found to be the same in both groups: 3 (4%) of Group L's cases of eclampsia and 4 (5.33%) of Group S' cases.

A research by Ranjana et al. demonstrates that the Dhaka (Begum R) regimen and the Pritchard regimen, respectively, showed 57.5% and 67.5% LSCS in both groups.

A little greater (5% increase) Caesarean section rate was seen in the magnesium sulphate group compared to the placebo or no anticonvulsant groups (RR 1.05, 95% CI 1.01 to 1.10) in a research conducted by Duley et al. [9]

Among the patients treated under the Dhaka protocol, 23 (57.5%) had LSCS, 13 (32.5%) had spontaneous vaginal births, 2 (5%) had forceps placed in their exit, and 1 patient had a ventouse placed in response to foetal distress.

Out of the patients who received the Pritchard protocol, 27 (67.5%) had LSCS, 10 (25%) had spontaneous births, and 2 (5%) had aided vaginal deliveries. Due to uncontrollable high preterm labour during the caesarean surgery, one patient in each group had a hysterectomy.

According to a research by Shoaib et al., the incidence of caesarean sections was 12% in the group receiving only loading doses but was 30% in the group receiving normal regimens. Similarly, in our study, Group L had a 20% incidence of caesarean sections, but Group S had a 17% incidence-slightly higher than Group L. However, statistical analysis did not support it.

Mean Duration of Regimen

In our current study, mean duration of ADI for DHAKA regimen was 13.45 hours and Pritchard was 11.81 hours. P-value is statistically insignificant.

Treatment Response

In our study in Pritchard regimen, 98% of the cases had no convulsions and only 2 % had 1 convulsion. In DHAKA regimen, 95% of the cases had no convulsions and 5% had convulsions. P-value was 0.42 which is not statistically significant.

In our present study, recurrence of convulsions was seen after starting the regimen. There was 1 maternal mortality with Pritchard regimen. The causeof death was renal failure. Recurrence of convulsions was observed in group -B after starting the regime.

In a research conducted by Sardesai SP et al. (2000), low dosage MgSO4 was shown to be safe and effective in controlling seizures in Indian women. The results showed that convulsion control was 100% in Group 2 (Pritchard) and 97.5% in Group 1 (Dhaka), with similar results ($\chi 2 = 1.013$; $p = 0.314$).

In a study done by Begum R et al., (2001) 98% convulsions were controlled with Dhaka regimen. [10]

Convulsions were managed 97.5% with the Dhaka regimen and 100% with the Pritchard regimen in a research by Bhagat N et al. MgSO4 toxicity was seen in 32.5% of the Pritchard patients and 10% of Dhaka regimen cases. Convulsions recurred 4.2% of the time overall. [11]

In a research by Sahu L et al. (2014), 96% of patients in the low dosage group had convulsion control. In this trial, unbooked patients made up 84% of the standard dosage group and 92% of the low dose group. In Dhaka and Pritchard regimens, the mean systolic blood pressure (SBP) was 159±17.2 and 164±14.14 mmHg, respectively. [12]

Convulsion control was 95% with the Dhaka regimen and 97.5% with the Pritchard regimen, according to a research by Ranjana et al. (2017). In 95% of instances under the Dhaka regime and 97.5% under the Pritchard regime, convulsions were under control.

Two instances of low dosage magnesium sulphate (the Dhaka regime) and one case of the Pritchard regime had recurrence of convulsion, which was attempted to be controlled with a single extra IV dose of two grams of 20% MgSO4. One patient was resolved, while another under the Dhaka regime had more convulsions.

This was deemed a sign of regime failure, and the case was promptly transferred to the regular Pritchard regime. Further convulsions occurred in the Pritchard regime group following intravenous

administration of 2 grams of 20% MgSO4 and IV phenytoin.

Recurrence of seizures in the Pritchard regimen was 2.1%, but in the Dhaka regimen it was 5.6%, according to a research by Anjali et al.

Safety Profile

Neither group in our investigation showed any indications of magnesium toxicity. In our present study, 5.55% of women in Group L and 8.45% of women in Group S got haematuria, and 2.81% of women in Group S lost their ability to knee-jerk, according to a study by Dr. Himadri Nayek et al. There was statistical insignificance for all these characteristics. The higher cumulative blood concentration of magnesium in these women due to the large dosages of magnesium sulphate could have accounted for the increased reduction of knee jerk in Group S. The Pritchard protocol, which was first designed for Western women who are often stout and heavier-built than Indian women, may be the cause of this toxicity, which is mostly unreported because all patients on this medication do not have their serum magnesium levels monitored. According to the Duley et al. 20 meta-analysis, magnesium sulphate-related toxicity-which manifested as diminished or absent tendon reflexes and/or respiratory depression-occurred in only around 1% of women who took the supplement. Maternal outcomes were found to be the same in both groups: 3 (4%) of Group L's cases of eclampsia and 4 cases (5.33%) of Group S. P>0.05 indicated that there was no statistically significant difference. This is the main result of the investigation. [13]

It was discovered that when comparing the secondary result and neonatal effects in both groups, the women who had experienced eclampsia-three in Group L and four in Group S-were excluded. Thus, the total number of cases in Groups L and S were 72 and 71, respectively. They discovered that the secondary outcomes between the two groups revealed that Group S experienced more nausea and vomiting (7.04% in Group S vs. 4.16% in Group L), respiratory depression (9.85% in Group S vs. 8.33% in Group L), blurred vision (7.04% in Group S vs. 5.55% in Group L), and haematuria (8.45% in Group S vs. 5.55% in L). However, these results did not meet statistical significance (P>0.05). Nonetheless, they discovered that Group L had higher levels of oliguria (8.33% in Group L vs. 5.63% in Group S). P<0.05 indicated that these issues were statistically significant.

In a research by Nagaria T et al. (2017), [13] the low dosage group had 97.6% control over seizures. Both at 30 minutes and four hours into treatment, the low dosage regimen's mean blood Mg2+ levels were noticeably lower.

According to a research by Anjali Rani et al., there were three incidences of magnesium sulphate toxicity in the Pritchard regimen and none in the Dhaka regimen. The results lacked statistical significance. The findings of Bhagat N et al.'s investigation were likewise consistent. There were no cases of magnesium sulphate toxicity in the Dhaka regimen, according to a study by Sahu L et al. [12] The current investigation demonstrates that the low-dosage Dhaka regimen is safer and equally effective as the traditional Pritchard regimen. According to a research by Begum R et al., magnesium sulphate at low doses works just as well as regular Pritchard. Bera P. et al. also make similar claims. [14] The evidence that the Dhaka regimen is just as effective as Pritchard has therefore been strengthened by our research. Numerous investigations have yielded comparable findings.

In a research by Ranjana et al., the mean dosage of magnesium sulphate given to the patients with imminent eclampsia and eclampsia was 22.5 gm and 39 gm, respectively, and was statistically significant with a p-value.

Maternal complications did not differ significantly between the two groups. Due to a cerebrovascular accident, one patient in Group A and two patients in Group B, respectively, passed away from DIC and a cerebrovascular accident.

Perinatal Mortality

In our current study, in DHAKA regimen, there were no maternal deaths(100%) but in Pritchard regimen, 99 cases (99.5%) were alive and only 1 case died (0.5%) due to renal failure. P- value was 0.31 which is not statistically significant.

In our present study, out of 200 cases, 144(72%) were alive, IUD were 4cases (2%), neonatal deaths were 40 (20%) and still births were 12(6%).

There is no major difference between the 2 groups. P-value is not statistically significant.

In our current study, most of the neonates were in the range of 1.5 -2.5 kgs. P - value was 0.17 which is not statistically significant.

In a research by Dr. Himadri Nayek et al., it was discovered that the newborn outcomes in both groups were as follows: at five minutes, 89.33% of neonates in Group L had an Apgar score of 7–10, whereas 93.33% of neonates in Group S had a score that was statistically significant (p0.05). Neonates in Groups L and S were admitted to the Neonatal Intensive Care Unit (NICU) for 48 hours in 22.22% and 40% of the cases, respectively, and for 72 hours in Groups L and S (66.66% and 60% of the cases). Additionally, this was not statistically significant (P>0.05).

Neonatal mortality was 6.7% in the Pritchard group and 5% in the low dosage group in a Kansa VM et al. (2019) research.

Anjali Rani et al. conducted a research in which the death rate from preeclampsia/eclampsia was 30.50% (18/59×100). In all, 59 maternal fatalities occurred, of which 18 were attributable to preeclampsia or eclampsia. There were 5.55% of early neonatal fatalities in the Dhaka regimen and 6.25% in the Pritchard group.

Six (15%) of the patients in Group A and ten (25%) of the cases in Group B in a research by Ranjana et al. had IUDs at the time of admission. Groups A and B had mean birth weights of 2.03 kg and 2.13 kg, respectively. The two groups' Apgar scores, rate of neonatal deaths, and total perinatal deaths were similar. The primary causes of newborn deaths were septicaemia, respiratory syndrome, and birth asphyxia.

Conclusion

In our study in Pritchard regimen group, 98% of the cases had no convulsions and only 2 % had 1 convulsion. In DHAKA regimen group, 95% of the cases had no convulsions and 5% had convulsions suggesting more recurrence in Dhaka regimen group. In women with eclampsia, magnesium sulphate is the anticonvulsant medication of choice. For smaller women, the Dhaka Regimen at a low dose appears to effectively regulate and avoid seizures. The current study offers more convincing evidence in favour of using magnesium sulphate frequently to treat eclampsia convulsions. Clinical surveillance seems suitable as long as there is enough urine output. There is no difference between the two magnesium sulphate regimens in terms of maternal mortality, perinatal death, maternal morbidity, or caesarean section rates. The research amply demonstrates that the Dhaka regimen is nearly similar to Pritchard protocol for the prevention and management of convulsions.

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