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Original Research Article

Efficacy of antenatal magnesium sulfate for preterm neuroprotection administered in preterm labour: a retrospective comparative observational study

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ABSTRACT

Background: Preterm birth before 32 weeks is associated with a high morbidity burden of neonatal mortality and neurodisability. The use of magnesium sulfate ($MgSO_4$) for fetal neuroprotection is very common, however, its effect on short term neonatal outcome in the Indian population remains poorly investigated.
Methods: This Retrospective Comparative Observational study was carried out for 15 months at Smt. Kashibai Navale Medical College and General Hospital, Pune, Maharashtra, India. Sixty-five singleton neonatal infants born before 32 weeks were enrolled. Mothers were categorized retrospectively into one of two groups based on documented antenatal treatment: Group A, who had received antenatal $MgSO_4$ (4 g intravenous loading in 20 min and then 1 g/h for a maximum of 24 h) and Group B, who had not received $MgSO_4$. The chi-square test was used to compare maternal demographics, mode of delivery, birth weight category and respiratory support by $p<0.05$.
Results: There was no difference between both groups at baseline. Caesarean section rates in two groups were 25.0% for Group A and 41.5% for Group B ($p=0.20$). No significant differences were seen in birth weight distribution between ELBW, VLBW and LBW ($p=0.86$). The need for respiratory assistance (mechanical ventilation, CPAP, oxygen by a hood or not) was also comparable among groups ($p=0.95$).
Conclusions: No detrimental effects of antenatal $MgSO_4$ were found on any of the short-term neonatal outcomes measured, thus supporting its safety in clinical practice. The advantage is its long-term neuroprotection and larger prospective studies with neurodevelopmental follow-up is required in the Indian context.

Keywords: Extreme prematurity, Magnesium sulfate, Neonatal outcomes, Neuroprotection, Preterm birth, Respiratory support

INTRODUCTION

Neonatal morbidity and mortality are one of the primary causes of preterm birth, which is defined as delivery before 37 weeks of gestation, a condition that affects the world at large. While neonatal intensive care (NICU) has contributed to increasing the survival rate of these infants, prevention of brain injury is a challenge.[1,2] Magnesium sulfate (MgSO4) has a known use in obstetric practice for treating preeclampsia and eclampsia as an anticonvulsant. Its protective properties of the preterm fetal brain have been extensively studied over the last 20 years.[3,4] The FIGO Working Group for Preterm Birth (2021) has made a formal recommendation to use $MgSO_4$ for neuroprotection in all women at risk of imminent preterm birth<30 weeks gestation and recommended consideration of its use up to 32–34 weeks.[5] The Cochrane systematic review of randomised trials and by subsequent meta-analysis.[6,7] However, despite this guidance from an international arena, the routine use of $MgSO_4$ for neuroprotection in the Indian tertiary centres is stable. Additionally, studies that are unique to the Indian

population and focus specifically on short-term neonatal outcomes like birth weight, delivery mode and immediate adaptation to the respiratory system are scarce. $MgSO_4$ is sometimes not added to complex antenatal regimens because of a lack of local safety data. This study was done to fill this gap by comparing the short-term neonatal outcome of $MgSO_4$ exposed and unexposed preterm neonates in a tertiary centre in Pune.

METHODS

Study design and setting

This was a retrospective comparative observational study in the Departments of Obstetrics and Gynaecology and Neonatology at Smt. Kashibai Navale Medical College and General Hospital (SKN-GH), Pune, is a tertiary level care teaching hospital in Maharashtra, India. Data has been gathered from October 2023 to March 2025 (around 15 months).

Ethical approval

The study was approved by the Institutional Ethics Committee before enrolment (IEC Ref: SKNMC/Ethics/App/2025/366). As this was a retrospective study based on review of existing case records, the requirement for individual patient consent was waived by the Institutional Ethics Committee. Patient confidentiality was maintained throughout by anonymizing all data.

Study population

These 65 preterm neonates were enrolled serially who were born at less than 32 weeks of gestation. The mothers were categorized retrospectively according to whether they received $MgSO_4$ in their antenatal period or not. Group A (n=24) comprised mothers who received antenatal $MgSO_4$ for fetal neuroprotection and Group B (n=41) comprised mothers who did not receive $MgSO_4$.

Inclusion criteria

Neonates born less than 32 weeks gestation from singleton pregnancies at risk of preterm delivery, who were born alive and admitted to the NICU, were included in the study.

Exclusion criteria

Mothers with contraindications to the use $MgSO_4$, such as renal failure, myasthenia gravis or cardiac conduction defects, women with multiple gestations and neonates with major congenital anomalies were excluded from the study.

Drug protocol

Mothers in Group A were treated with intravenous $MgSO_4$ as per the institutional protocol based on the guidelines of FIGO-2021: 4 g as loading dose over 20 minutes followed by 1 g/h infusion up to delivery or for maximum of 24 hours. The maternal monitoring comprised pulse rate, blood pressure, respiratory rate, patellar reflexes and urine output, all of which were monitored at least every four hours. At the bed-side an antidote, calcium gluconate, was available. In Group B, mothers were provided with routine antenatal care, but without $MgSO_4$.

Data collection

For each mother-neonate pair, the following variables were recorded in a retrospective manner: maternal age, gravida/parity and gestational age at delivery; mode of delivery categorised as preterm lower segment caesarean section (PT-LSCS) or preterm vaginal delivery (PTVD); neonatal sex and birthweight category classified as ELBW (≤1,000 g), VLBW (1,001–1,500 g), LBW (1,501–2,500 g); and respiratory support at birth and in the NICU, categorised as intubation and mechanical ventilation (MV), CPAP, oxygen via hood or none.

Statistical analysis

Data were recorded in a structured proforma and analysed using the program IBM SPSS Statistics for windows, Version 26.0, Medcalc Software ltd. All data that are continuous are presented as means±SDs and were compared between groups using the Student's t-test. Categorical variables are presented in terms of frequencies and percentages and were compared using the Chi-square test. A p value less than 0.05 (two-tailed) was considered to be statistically significant.

RESULTS

A total of 65 preterm neonates were enrolled in the study period; 24 in Group A ($MgSO_4$ exposed) and 41 in Group B (not exposed). Short-term outcomes (from all four domains) are summarized. The two groups were evenly balanced. The mean maternal age was similar (27.95±5.85 years in Group A vs. 26.22±3.93 years in Group B). Both groups were nearly equally represented by multiparous women and the ratio of males to females (sex ratio) of neonates was similar. The distribution of gestational age was comparable across each group and about 1/4 of the neonates in each group were born prematurely (before 30 weeks gestation).

More women had a vaginal delivery in both groups (Table 2, Figure 1). This difference was not statistically significant (χ^2=1.62, p=0.20), albeit the rates of CS were higher in Group B (41.5%) than in Group A (25.0%). Furthermore, there was no effect of $MgSO_4$ on mode of delivery.

Both groups were comparable with regard to birth weight distribution. Around 12% of the neonates in each group were categorized in the ELBW group. Most were either VLBW or LBW and there was no significant intergroup difference (p=0.86).

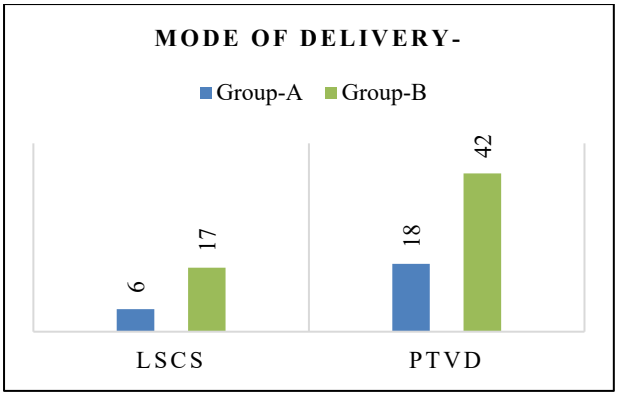


Figure 1: Mode of delivery in Group A ($MgSO_4$ exposed) and Group B ($MgSO_4$ not exposed).

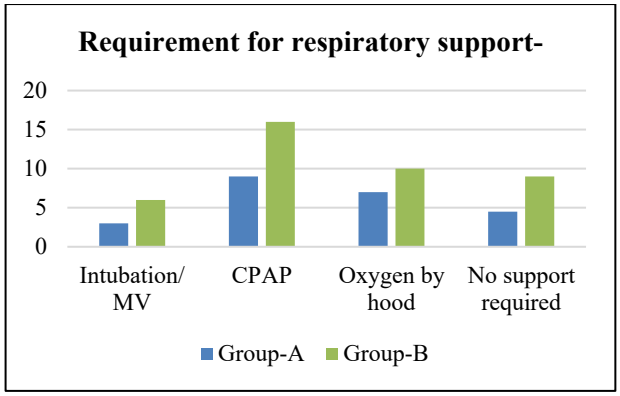


Figure 2: Requirements for respiratory support in Group A ($MgSO_4$ exposed) and Group B ($MgSO_4$ not exposed).

Table 1: Maternal and neonatal baseline characteristics.

Variables	Group A (N=24)	Group B (N=41)	Total (N=65)
Maternal age (in years) mean±SD	27.95±5.85	26.22±3.93	—
Male neonates n (%)	11 (45.8%)	20 (48.8%)	31 (47.7%)
Female neonates n (%)	13 (54.2%)	21 (51.2%)	34 (52.3%)
Nulliparous n (%)	9 (37.5%)	15 (36.6%)	24 (36.9%)
Multiparous n (%)	15 (62.5%)	26 (63.4%)	41 (63.1%)
GA <30 weeks n (%)	6 (25.0%)	9 (22.0%)	15 (23.1%)
GA 30.1–32 weeks n (%)	10 (41.7%)	18 (43.9%)	28 (43.1%)
GA >32 weeks n (%)	8 (33.3%)	14 (34.1%)	22 (33.8%)

Table 2: Mode of delivery.

Mode of delivery	Group A, N (%)	Group B, N (%)	Total n (%)	χ^2	P value
LSCS	6 (25.0)	17 (41.5)	23 (35.4)	1.62	0.20 (NS)
Preterm vaginal delivery	18 (75.0)	24 (58.5)	42 (64.6)	—	—

Table 3: Distribution of Neonatal Birth Weight.

Birthweight category	Group A N (%)	Group B N (%)	Total N (%)	χ^2	P value
ELBW (≤1,000 g)	3 (12.5)	5 (12.2)	8 (12.3)	0.29	0.86 (NS)
VLBW (1,001–1,500 g)	11 (45.8)	16 (39.0)	27 (41.5)	—	—
LBW (1,501–2,500 g)	10 (41.7)	20 (48.8)	30 (46.2)	—	—

Table 4: Requirement for Respiratory Support.

Respiratory support	Group A, N (%)	Group B, N (%)	Total n (%)	χ^2	P value
Intubation/MV	3 (12.5)	6 (14.6)	9 (13.8%)	0.31	0.95 (NS)
CPAP	9 (37.5)	16 (39.0)	25 (38.5%)	—	—
Oxygen by hood	7 (29.2)	10 (24.4)	17 (26.2%)	—	—
No support required	5 (20.8)	9 (22.0)	14 (21.5%)	—	—

Approximately 38–39% of people used CPAP, which was the most common type of respiratory support in both groups (Table 4, Figure 2). The rates of intubation, hood oxygen use and no support were comparable. There was no significant difference between the groups (χ^2=0.31, p=0.95).

DISCUSSION

The purpose of this study was to assess the immediate neonatal outcomes in the infants born before 32 weeks gestation and exposed to $MgSO_4$ for fetal neuroprotection versus the unexposed group. There were no statistically

significant differences between the $MgSO_4$ exposed and unexposed groups on any of the four parameters assessed (baseline demographics, mode of delivery, birth weight category and requirement for respiratory support). This is good news for safety reasons and is consistent with results from bigger international studies. It is important that both groups are comparable at baseline because if they were not, there would be a greater risk that any difference in outcomes (if there was one) was due to the confounding. The mean maternal age, parity, neonatal sex distribution and gestational age profiles were comparable. In the randomised ACTO$MgSO_4$ trial by Crowther et al similar baseline characteristics were observed between the $MgSO_4$-exposed and control groups.[8] This is comparable with the observational study conducted by Bansal and Desai at tertiary centre, India, that also found similar baseline characteristics between $MgSO_4$-exposed and control groups.[9]

In our group, delivery mode was not affected by $MgSO_4$ exposure. This is physiologically plausible because $MgSO_4$ does not affect uterine contractility or pelvic mechanics, but rather the fetal central nervous system. This is supported by two trials (BEAM by Rouse et al PREMAG by Marret et al) which found no significant difference in operative delivery rates with $MgSO_4$.[10,11] FIGO 2021 guidelines confirm this and suggest that $MgSO_4$ should be given irrespective of the delivery plan.[5] The fact that there was no effect on birth weight was not surprising. No influence on placental function or fetal growth is known for $MgSO_4$, which does cross the placenta, but has no influence on the delivery of nutrients or oxygen. In a much smaller number of infants, we found no difference in birthweight between treated and untreated neonates, in agreement with our results from the Cochrane review by Doyle et al which included 5 RCTs with more than 6000 neonates.[6]

The respiratory support requirements were also comparable between groups. The differences might be because of the smaller number of patients in the two groups or because of the difference in gestational age distribution and the intubation thresholds for the units. In either case, this is clinically relevant because it has been suggested that neonatal magnesium toxicity will lead to respiratory depression, which was not seen here with the neonates exposed to $MgSO_4$ compared to unexposed neonates.

Other data recorded in the institutional database included APGAR score, IVH grading, NEC, hyperbilirubinemia, surfactant use and NICU length of stay. In neonates exposed to $MgSO_4$, most of the IVH events graded as 1-2; the lower grades of the Papile classification. This is a positive trend, but this is a non-randomized sample of additional data and the results do not permit causal statements to be made. These secondary outcomes will require a well-powered prospective study with long term neurodevelopmental follow up.

There were a few important limitations of this study. It was an observational, single-centre study which limits its generalizability. The sample size (n=65) was small and some real differences might not have been captured because of lack of power. As this was a retrospective study, group allocation was based on documented antenatal treatment decisions made as part of routine clinical care, rather than investigator-controlled randomisation. This introduces the possibility of selection bias, as the decision to administer $MgSO_4$ may have been influenced by clinical factors not captured in this analysis.

Reliance on existing case records may have introduced missing or incompletely documented data, particularly for secondary outcomes such as APGAR score and NICU length of stay. Primary endpoints of interest in the field of neuroprotection (long-term outcomes, including cerebral palsy and developmental delay) were not evaluated. A neurodevelopmental follow-up (structured at 18–24 months) is recommended to complete the clinical picture in future studies and has been done for the ACTO$MgSO_4$ trial cohort, which was followed up to school age.[12]

CONCLUSION

In this study, 65 preterm neonates born before 32 weeks were studied and no significant differences were found with regard to distribution of birthweight, mode of delivery or requirement for respiratory support between $MgSO_4$ and non-$MgSO_4$ groups. The results of the study have been consistent with the safety of use of $MgSO_4$ in a tertiary care center for fetal neuroprotection in India. The main benefit (reduction in risk of cerebral palsy and long term neurodisability) needs to be evaluated in the Indian context with larger, well-designed prospective studies with longer follow up.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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