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Original Research Article

The Role of Magnesium Sulfate as a Tocolytic Agent in Preterm Labor and its Impact on Maternal Health: A Cohort Study

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Abstract:

Background: Preterm labor, classified as labor occurring before 37 completed weeks of gestation, poses significant risks to neonatal health, including intraventricular hemorrhage, respiratory distress syndrome, and long-term neurodevelopmental disabilities. Magnesium sulfate, traditionally used for eclampsia management, has gained attention as a tocolytic agent to delay preterm delivery and improve newborn outcomes. This study aimed to evaluate the effectiveness and safety of magnesium sulfate as a tocolytic agent in preterm labor and its impact on maternal health.

Methods: The cohort study included 100 pregnant women experiencing preterm labor who received magnesium sulfate. Data on demographic characteristics, clinical outcomes, maternal side effects, and neonatal health indicators were collected and analyzed using SPSS version 19. Statistical significance was determined at a p-value of less than 0.05.

Results: The mean duration of pregnancy prolongation was 14.5 ± 5.2 days. Mild to moderate side effects were observed in 35% of participants, while 2% experienced severe side effects. The cesarean section rate was 45%, and maternal morbidity rates included 5% for preeclampsia and 8% for postpartum hemorrhage. Neonatal outcomes were favorable, with a mean birth weight of 2300 grams and Apgar scores of 7.5 at 1 minute and 8.5 at 5 minutes. Comparative analysis showed a statistically substantial increase in pregnancy duration compared to historical controls ($p < 0.05$).

Conclusion: Magnesium sulfate effectively prolonged pregnancy in preterm labor with an acceptable safety profile. The treatment was associated with favorable maternal and neonatal outcomes, indicating its utility as a tocolytic agent.

Recommendations: Further research with larger sample sizes and diverse populations is recommended to confirm these findings. Tailored dosing regimens based on individual patient characteristics should be considered to optimize outcomes.

Keywords: Preterm Labor, Magnesium Sulfate, Tocolytic Agent, Maternal Health, Neonatal Outcomes.

Introduction

Preterm labor, classified as labor that arises before 37 completed weeks of gestation, is a significant obstetric complication associated with increased neonatal morbidity and mortality. It contributes substantially to long-term adverse health outcomes, comprising intraventricular hemorrhage, respiratory distress syndrome, and neurodevelopmental disabilities in surviving infants [1]. The management of preterm labor remains a challenge in obstetrics, necessitating the use of effective tocolytic agents to delay delivery and allow for fetal maturation and the administration of corticosteroids to enhance fetal lung development [2].

Magnesium sulfate ($MgSO_4$) has long been used in obstetrics, primarily for the prevention and treatment of eclampsia. However, its role as a tocolytic agent to suppress preterm labor has garnered increasing interest. Magnesium sulfate functions by competing with calcium at the cellular level, leading to the relaxation of smooth muscle cells, including those in the uterus [3]. This mechanism of action positions magnesium sulfate as a potential agent to halt uterine contractions and delay preterm birth.

Previous studies have demonstrated varying degrees of efficacy of magnesium sulfate in prolonging pregnancy and improving neonatal outcomes [4, 5]. Additionally, its safety profile has

been extensively studied, with most side effects being mild and manageable, such as flushing, nausea, and headache. Severe side effects, though rare, include respiratory depression and cardiovascular complications [6]. Given these considerations, magnesium sulfate presents a dual benefit in preterm labor management: delaying delivery and potentially improving neonatal outcomes.

The study aim was to evaluate the role of $MgSO_4$ as a tocolytic agent in preterm labor and its impact on maternal health. The study focused on determining the efficacy of $MgSO_4$ in prolonging pregnancy and assessing maternal and neonatal outcomes associated with its use.

Methodology

Study Design: A retrospective cohort study.

Study Setting: The study was carried out at Jawaharlal Nehru Medical College Hospital, Bhagalpur, India, from 1st April 2022 to 31st March 2023, spanning a period of one year.

Participants: A total of 100 pregnant women experiencing preterm labor were encompassed in the study.

Inclusion Criteria:

- Pregnant women diagnosed with preterm labor between 28 and 34 weeks of gestation.

- Singleton pregnancies.

- Women who received $MgSO_4$ as a tocolytic agent.

- Willingness to participate and provide informed consent.

Exclusion Criteria:

- Women with multiple pregnancies.

- Presence of maternal contraindications to magnesium sulfate.

- Women with severe preeclampsia or eclampsia.

- Women with known fetal anomalies.

Sample size:

To calculate the sample size for this study, the following formula was used for estimating a proportion in a population:

$$n = \frac{Z^2 \times p \times (1-p)}{E^2}$$

Where:

- n = sample size

- Z = Z-score corresponding to the desired level of confidence

- p = estimated proportion in the population

- E = margin of error

Bias: To minimize selection bias, participants were consecutively selected based on the inclusion criteria. Information bias was reduced by using standardized data collection forms and ensuring that all data collectors were trained uniformly.

Variables: Variables included administration of $MgSO_4$, maternal health outcomes, including adverse effects and pregnancy prolongation, maternal age, gestational age at administration, and baseline health status.

Data Collection: Data were collected retrospectively from medical records of the participants. Information regarding demographic details, clinical characteristics, treatment details, and maternal health outcomes were documented.

Procedure: The administration protocol for magnesium sulfate followed the standard guidelines practiced at Jawaharlal Nehru Medical College Hospital. The dosage and administration were recorded along with any observed maternal side effects and outcomes. The effectiveness of the tocolytic therapy was assessed by the duration of pregnancy prolongation and maternal health indicators.

Statistical Analysis: The analysis of the data was done with SPSS 19. For continuous variables, descriptive statistics like mean and standard deviation were employed, but for categorical variables, frequencies and percentages were utilised. Inferential statistics were utilised to ascertain the significance of variations among groups, such as t-tests and chi-square tests. Statistical significance was attained when the p-value was less than 0.05.

Ethical Considerations: The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

Result

A total of one hundred pregnant women who were treated with MgSO4as a tocolytic drug to control preterm labour were included in the study. To evaluate the treatment's efficacy and influence on maternal health, the data were examined.

Table 1 provides an overview of the study participants' clinical and demographic characteristics. The participants' ages ranged from 28.4 years, on average, to 4.6 years, on standard. With a standard deviation of 1.8 weeks, the mean gestational age at the time of MgSO4 injection was 31.2 weeks.

Table 1: Demographic and Clinical Characteristics of Participants

Characteristic	Value (Mean ± SD or %)
Age (years)	28.4 ± 4.6
Gestational Age (weeks)	31.2 ± 1.8
Parity	
Primiparous	40%
Multiparous	60%
Previous Preterm Birth	12%
Baseline Health Status	
Hypertension	10%
Diabetes	8%
No Comorbidities	82%

The effectiveness of magnesium sulfate in prolonging pregnancy and improving maternal outcomes was evaluated. The mean duration of pregnancy prolongation was 14.5 ± 5.2 days. The maternal health outcomes are presented in Table 2. Additionally, the neonatal outcomes, such as birth weight and Apgar scores, were assessed and summarized in Table 3.

Table 2: Maternal Health Outcomes Post Magnesium Sulfate Administration

Outcome	Value (Mean ± SD or %)
Duration of Pregnancy Prolongation (days)	14.5 ± 5.2
Maternal Side Effects	
Mild (Nausea, Flushing)	25%
Moderate (Headache, Dizziness)	10%
Severe (Respiratory Distress)	2%
No Side Effects	63%
Mode of Delivery	
Vaginal Delivery	55%
Cesarean Section	45%
Maternal Morbidity	
Preeclampsia	5%
Postpartum Hemorrhage	8%
No Morbidity	87%

Table 3: Neonatal Outcomes

Outcome	Value (Mean ± SD or %)
Birth Weight (grams)	2300 ± 500
Apgar Score at 1 minute	7.5 ± 1.2
Apgar Score at 5 minutes	8.5 ± 0.8
NICU Admission	20%
Neonatal Mortality	2%

The impact of magnesium sulfate on the duration of pregnancy prolongation was analyzed using a t-test, and the results indicated a statistically substantial increase ($p < 0.05$) in the duration of pregnancy compared to historical controls who did not receive tocolytic treatment.

Table 4: Comparison of Pregnancy Prolongation with Historical Controls

Group	Mean Duration (days)	p-value
Magnesium Sulfate Group	14.5 ± 5.2	< 0.05
Historical Controls	7.8 ± 3.6	

The maternal morbidity rates, including preeclampsia and postpartum hemorrhage, were also compared with historical data. The occurrence of these complications did not show a statistically significant increase, indicating that magnesium sulfate did not adversely affect maternal health.

The rate of NICU admissions among neonates was 20%, and the neonatal mortality rate was 2%. The average birth weight of the neonates was 2300 grams, and the mean Apgar scores at 1 minute and 5 minutes were 7.5 and 8.5, respectively.

Discussion

The study included 100 pregnant women who received magnesium sulfate. The participants' mean age was 28.4 years, and the mean gestational age at administration was 31.2 weeks. Among the participants, 40% were primiparous, and 60% were multiparous, with 12% having a history of previous

preterm birth. Additionally, 18% had comorbid conditions such as hypertension and diabetes.

The treatment's effectiveness was evident as it resulted in an average prolongation of pregnancy by 14.5 days, a statistically significant improvement compared to historical controls who experienced an average prolongation of 7.8 days ($p < 0.05$). Most participants (63%) did not experience any side effects, while 35% had mild to moderate side effects, and only 2% encountered severe side effects. These findings suggest that magnesium sulfate effectively delays preterm labor with a manageable side effect profile.

In terms of maternal health outcomes, 55% of the deliveries were vaginal, and 45% were cesarean sections. Maternal morbidity rates, including preeclampsia (5%) and postpartum hemorrhage (8%), did not show a significant increase compared to historical data. This indicates that magnesium sulfate did not adversely affect maternal health, maintaining acceptable safety levels for use in preterm labor management.

Neonatal outcomes were also favorable. The mean birth weight of the neonates was 2300 grams, and the mean Apgar scores were 7.5 at 1 minute and 8.5 at 5 minutes, indicating generally healthy newborns. The NICU admission rate was 20%, and the neonatal mortality rate was 2%, which are within expected ranges for preterm births. These results further support the safety and effectiveness of magnesium sulfate in this clinical setting.

Overall, the study demonstrates that magnesium sulfate is an effective tocolytic agent for managing preterm labor, significantly prolonging pregnancy and offering additional time for fetal development. The treatment's safety profile is acceptable, with manageable side effects and no significant increase in maternal morbidity. Favorable neonatal outcomes also support its use, making magnesium sulfate a valuable tool in preterm labor management, benefiting both maternal and neonatal health outcomes.

Recent research continues to shed light on the effectiveness and safety of $MgSO_4$ as a tocolytic agent for managing preterm labor, highlighting its role in prolonging pregnancy and improving maternal and neonatal outcomes. A review examined the comparative efficacy of various tocolytic agents, including $MgSO_4$, nifedipine, and ritodrine. This analysis included 40 trials published between 1991 and 2023, with a total sample size of 4336 participants. The study found that while nifedipine was generally more effective in preventing preterm labor within the first 48 hours (risk difference, RD: -0.06; 95% CI: -0.10 to -0.01; I^2: 73.2%), magnesium sulfate remained significant in specific clinical scenarios [7]. This study highlighted that magnesium sulfate effectively prolonged pregnancy with minimal side effects, though its efficacy in patients with ruptured membranes remained a point of discussion. The study emphasized the importance of careful patient selection and monitoring to maximize benefits and minimize risks.

A randomized clinical trial focused on the efficacy and safety of high versus low dose $MgSO_4$ regimens in patients with symptomatic placenta previa and preterm labor. The study included 100 pregnant women randomized into two groups. The high-dose group showed a significantly longer cervical length at 48 hours ($p<0.001$) and achieved therapeutic magnesium levels more effectively in non-obese women compared to the low-dose group (4.80 ± 0.91 vs. 3.98 ± 0.60; $p<0.001$). These findings suggest that higher doses of $MgSO_4$ may be more beneficial for certain subgroups of patients [8].

In a different trial, scientists looked into using $MgSO_4$ in addition to ritodrine as a second-line tocolytic drug. The combination therapy considerably reduced the prevalence of inefficiency compared to MgSO4alone, according to a randomised controlled trial that was carried out on Kyushu Island and involved 33 women (relative risk, RR: 0.06; 95% CI: 0.006 to 0.54). When ritodrine by itself was unable to stop uterine contractions, 90% of the research participants postponed giving birth for more than 48 hours [9].

Conclusion

In conclusion, magnesium sulfate proved to be an effective tocolytic agent in prolonging pregnancy in preterm labor without significantly increasing the risk of adverse maternal health outcomes. Neonatal outcomes were also favorable, supporting the use of $MgSO_4$ in managing preterm labor.

Limitations: The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of comparison group also poses a limitation for this study's findings.

Recommendation: Further research with larger sample sizes and diverse populations is recommended to confirm these findings. Tailored dosing regimens based on individual patient characteristics should be considered to optimize outcomes.

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List of abbreviations:

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