

Intravenous Magnesium Sulphate versus Oral Nifedipine for Tocolysis: Maternal and Neonatal Outcomes

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Abstract:

Background: Preterm labour is a major cause of neonatal morbidity and mortality. Tocolytic therapy aims to delay delivery to allow corticosteroid administration and improve neonatal outcomes. This study compared the efficacy and safety of magnesium sulphate and nifedipine in managing preterm labour.

Methods: A prospective observational study was conducted at Government Maternity Hospital, Hanamakonda, from July 2023 to December 2024. A total of 100 women with preterm labour were enrolled, with 50 receiving intravenous magnesium sulphate and 50 receiving oral nifedipine. Baseline characteristics, tocolytic efficacy, maternal adverse effects, and neonatal outcomes were systematically recorded and analysed.

Results: Baseline demographics were comparable between groups. Nifedipine achieved a significantly greater mean delay in delivery (6.1 ± 3.2 days) compared with magnesium sulphate (4.6 ± 2.4 days). Prolongation of pregnancy beyond 48 hours and 7 days was higher in the nifedipine group. Maternal adverse effects were mild; nifedipine produced more headache and flushing, while magnesium sulphate showed occasional hypotension and reduced reflexes. Neonatal outcomes, including birth weight, APGAR scores, and NICU admissions, were similar between groups.

Conclusion: Nifedipine demonstrated superior tocolytic efficacy with good maternal tolerability, making it a preferable first-line agent for preterm labour.

Keywords: Preterm labour, magnesium sulphate, nifedipine, tocolysis, neonatal outcomes.

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Introduction

Preterm labour, defined as the onset of regular uterine contractions leading to cervical change before 37 completed weeks of gestation, remains a leading cause of perinatal morbidity and mortality, with an estimated 13–14 million preterm births annually worldwide [1]. Despite advances in neonatal care, preterm birth contributes substantially to long-term neurodevelopmental impairment and health-system burden, especially in low- and middle-income countries [1]. Tocolytic therapy is primarily used to delay delivery long enough to allow administration of antenatal corticosteroids, in-utero transfer, and optimisation of neonatal care. Among available agents, magnesium sulphate (MS) has been widely used both as a tocolytic and for fetal neuroprotection, although evidence suggests it does not consistently reduce early preterm birth or improve neonatal outcomes when used solely for tocolysis [2]. Calcium channel blockers, particularly

nifedipine, have emerged as effective alternatives with favourable maternal tolerability profiles [3].

Randomised trials directly comparing MS and nifedipine demonstrate comparable efficacy in delaying delivery beyond 48 hours and 7 days, with variable differences in maternal side-effects and neonatal outcomes [4, 5]. However, most studies differ in dosing regimens, routes of administration, gestational age (GA) windows, and monitoring protocols, and data from Indian and other resource-limited settings remain limited [3–5]. In this context, the present study is designed to compare the intravenous efficacy of MS with oral nifedipine in arresting preterm labour, while systematically documenting maternal haemodynamic changes, drug-related adverse effects, and immediate fetal/neonatal outcomes. The specific objectives are: (1) to evaluate the effect of intravenous MS on the mother and fetus; and (2) to evaluate the effect of

oral nifedipine on the mother and fetus, thereby generating locally relevant evidence to inform rational selection of first-line tocolytic therapy in women with threatened preterm labour.

Methods

This prospective observational study was conducted in the department of Obstetrics and Gynecology at Government Maternity Hospital, Hanumakonda, from July 2023 to December 2024. All pregnant women presenting with symptoms of threatened preterm labour between 28 and 36+6 weeks of gestation were screened for eligibility. Preterm labour was defined as the presence of regular uterine contractions occurring at least once every 10 minutes, accompanied by cervical dilatation of ≥ 2 cm or cervical effacement of $\geq 80\%$. Women carrying singleton pregnancies, with intact membranes and no contraindication to tocolysis, were included. Exclusion criteria consisted of multiple gestation, antepartum haemorrhage, chorioamnionitis, major fetal anomalies, severe preeclampsia or eclampsia, maternal cardiac disease, and known hypersensitivity to either MS or nifedipine. After obtaining informed written consent, eligible participants were enrolled consecutively to avoid sampling bias. Demographic information, obstetric history, GA (confirmed by first-trimester ultrasonography), and baseline vital parameters were documented using a pretested structured proforma.

Management was provided as per the institutional protocol for tocolysis. Women who were clinically assessed to receive intravenous MS were administered a loading dose of 4 g given over 20 minutes, followed by a maintenance infusion of 1–2 g/hour for 24 hours or until contractions subsided. Maternal monitoring included serial assessments of respiratory rate, deep tendon reflexes, urine output, heart rate, and blood pressure at predetermined intervals. Fetal well-being was monitored using intermittent cardiotocography and serial fetal heart rate auscultation. For women who were initiated on nifedipine therapy, a dosage of 10 mg orally every 15 minutes for three doses was given, followed by maintenance dosing of 10–20 mg every 6–8 hours depending on clinical response. Maternal monitoring included evaluation of pulse rate, blood pressure, respiratory status, and adverse reactions such as headache, flushing, hypotension, or palpitations. All participants received standard obstetric care, including hydration, antenatal corticosteroids for fetal lung maturity, and antibiotic prophylaxis when indicated.

Outcome assessment included evaluation of tocolytic efficacy, defined as the ability to delay delivery for ≥ 48 hours and ≥ 7 days from the onset of therapy. Secondary outcomes included maternal adverse effects, need for rescue tocolysis, progression to active labour, mode of delivery, and neonatal outcomes such as birth weight, APGAR scores, need for NICU admission, and early neonatal complications. Data were collected prospectively by trained staff nurses and postgraduate residents under supervision of senior obstetricians. All clinical findings were recorded immediately to minimise recall bias. Data completeness and quality were reviewed weekly by the principal investigator. Statistical analysis was performed after completion of data collection. Continuous variables such as age, GA, and time gained in pregnancy were summarised as mean \pm standard deviation, while categorical variables such as maternal side-effects and neonatal outcomes were expressed as frequencies and percentages. The comparative performance of MS and nifedipine was analysed using the chi-square test or Fisher's exact test for categorical variables and the independent t-test for continuous variables. A p-value < 0.05 was considered statistically significant.

Results

A total of 100 women with preterm labour were studied, with 50 receiving intravenous MS and 50 receiving oral nifedipine. As shown in Table 1, both groups were comparable in baseline maternal characteristics, including age, GA at admission, and parity, ensuring valid comparison of outcomes. Evaluation of tocolytic efficacy (Table 2) showed that nifedipine achieved a higher proportion of pregnancies prolonged beyond 48 hours (84% vs. 72%) and 7 days (60% vs. 44%), although the differences were not statistically significant; however, the mean delay in delivery was significantly greater with nifedipine (6.1 ± 3.2 days) than with MS (4.6 ± 2.4 days), indicating better overall efficacy. Maternal side-effect profiles differed as expected, with nifedipine producing more headache, flushing, and tachycardia, while MS caused occasional hypotension and decreased deep tendon reflexes, as presented in Table 3. Most adverse effects were mild and controllable. Neonatal outcomes (Table 4) were similar between groups, with no significant differences in birth weight, APGAR scores, NICU admissions, or early neonatal complications. Although MS provided additional fetal neuroprotective benefits, nifedipine demonstrated superior tolerability and greater prolongation of pregnancy, making it a more favourable tocolytic option in this cohort.

Table 1: Baseline maternal characteristics of the study population

Parameter	MS	Nifedipine	p-value
Mean age (years)	25.8 ± 4.1	26.2 ± 4.4	0.62
GA at admission in weeks	32.1 ± 2.1	32.4 ± 2.3	0.48
Primigravida; n (%)	28 (56)	26 (52)	0.69
Previous preterm birth; n (%)	6 (12)	5 (10)	0.74

Table 2: Tocolytic efficacy outcomes among the study members

Outcome	MS	Nifedipine	p-value
Pregnancy prolonged ≥ 48 hours	36 (72%)	42 (84%)	0.15
Pregnancy prolonged ≥ 7 days	22 (44%)	30 (60%)	0.11
Mean delay in delivery (days)	4.6 ± 2.4	6.1 ± 3.2	0.01*
Need for rescue tocolysis	12 (24%)	7 (14%)	0.21

Table 3: Maternal adverse effects among the study members

Adverse events	MS	Nifedipine	p-value
Hypotension	4 (8%)	10 (20%)	0.09
Headache/flushing	2 (4%)	14 (28%)	0.001*
Tachycardia	1 (2%)	9 (18%)	0.008*
Loss of deep tendon reflexes	3 (6%)	0	0.08
Nausea/vomiting	5 (10%)	6 (12%)	0.75

Table 4: Neonatal outcomes in the study

Neonatal Parameter	MS	Nifedipine	p-value
Mean birth weight (kg)	2.18 ± 0.34	2.24 ± 0.38	0.34
APGAR <7 at 1 min	8 (16%)	5 (10%)	0.37
NICU admission	12 (24%)	9 (18%)	0.48
Early neonatal complications	10 (20%)	7 (14%)	0.42

Discussion

Preterm labour continues to be a major contributor to neonatal morbidity and mortality worldwide, particularly in low- and middle-income countries where access to advanced neonatal care remains limited. In this prospective observational study, the comparative evaluation of intravenous MS and oral nifedipine provided valuable insights into their clinical performance as tocolytic agents. The baseline maternal characteristics were comparable between both groups, ensuring the internal validity of findings. Our results demonstrated that nifedipine offered superior prolongation of pregnancy, achieving a significantly greater mean delay in delivery than MS. These findings align with global evidence suggesting that calcium channel blockers have become preferred first-line agents due to their efficacy and favorable maternal tolerance [6, 7]. The prolongation of pregnancy is clinically important because it enables the administration of antenatal corticosteroids and maternal transfer to higher-level care, both of which substantially reduce neonatal complications [8].

The greater tocolytic efficacy of nifedipine observed in this study is consistent with prior randomized controlled trials and meta-analyses. Lyell et al. reported significantly improved success in delaying preterm birth with nifedipine compared with MS, similar to our findings [9]. Conde-Agudelo and Romero also showed that nifedipine significantly

reduced the risk of delivery within 7 days and improved neonatal outcomes compared with β -agonists and MS [3]. The pharmacological mechanism of action of nifedipine blocking calcium influx into myometrial cells may contribute to a more sustained uterine relaxation, explaining the longer latency period observed in this study [10]. Meanwhile, MS, although historically used as a tocolytic, has shown inconsistent efficacy as a primary agent for preventing preterm birth, which is reflected in our results [11]. The requirement for rescue tocolysis was also higher in the MS group, reinforcing the relative advantage of nifedipine for sustained suppression of uterine contractions.

Maternal side-effect profiles in this study were consistent with established drug characteristics. Nifedipine was associated with significantly higher incidence of flushing, headache, and tachycardia, which aligns with previous clinical data describing the vasodilatory nature of the drug [12]. However, these effects were largely mild and manageable, underscoring the safety of nifedipine in carefully monitored settings. In contrast, MS demonstrated fewer hemodynamic side effects, but isolated cases of diminished deep tendon reflexes highlighted the need for vigilant monitoring due to risk of toxicity. Previous research has emphasized the importance of monitoring respiratory rate, reflexes, and urine output during magnesium therapy, as toxicity can be life-threatening if undetected [13]. Our findings support the notion that while MS remains safe when

used appropriately, it demands more intensive clinical supervision than nifedipine. Overall, the adverse event profiles observed in this study were mild and did not necessitate discontinuation of therapy.

Neonatal outcomes between the two groups were largely comparable, demonstrating no significant differences in birth weight, APGAR scores, NICU admission, or early neonatal complications. These findings are consistent with the meta-analysis by King et al., which reported no major differences in neonatal outcomes between tocolytic agents except when MS was used for neuroprotection rather than tocolysis [14]. Importantly, while MS is not consistently effective as a tocolytic, its proven role in reducing the risk of cerebral palsy in preterm infants remains crucial [11]. In our study, the similarity in neonatal outcomes between groups suggests that prolongation of pregnancy rather than drug class may play the dominant role in improving immediate neonatal health. However, nifedipine's ability to extend gestation longer than MS potentially enhances fetal maturity, resulting in overall favourable neonatal outcomes. Considering all aspects efficacy, safety, and neonatal impact our findings support the increasing global trend of preferring nifedipine as a first-line tocolytic agent in the management of threatened preterm labour.

Conclusion:

This study demonstrated that oral nifedipine was more effective than intravenous magnesium sulphate in prolonging pregnancy among women presenting with preterm labour, offering a significantly greater delay in delivery while maintaining an acceptable maternal safety profile. Although magnesium sulphate remains valuable for fetal neuroprotection, its efficacy as a primary tocolytic was comparatively lower and required more intensive maternal monitoring. Neonatal outcomes were similar between groups, indicating that both drugs are safe for fetal wellbeing. Taken together, nifedipine appears to be a superior and more practical first-line tocolytic for managing preterm labour in routine clinical settings.

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