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Efficacy of Nifedipine in Suspension of Preterm Labour

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ABSTRACT

Objective:
To evaluate the efficacy and safety of oral nifedipine compared with standard tocolytic therapy in women presenting with threatened preterm labour.

Study Design and Setting:
A randomized controlled trial conducted at the Department of Obstetrics and Gynaecology, PAF Hospital Mushaf, Sargodha, over a period of six months following ethical approval.

Methodology:
Eighty-four women with singleton pregnancies between 24+0 and 34+0 weeks of gestation diagnosed with threatened preterm labour were enrolled and randomly allocated into two equal groups. Group A received oral nifedipine, while Group B received standard β-agonist therapy. The primary outcome was successful tocolysis, defined as no delivery within 48 hours of therapy. Secondary outcomes included prolongation of pregnancy beyond seven days, maternal adverse effects, and neonatal outcomes such as Apgar score, birthweight, and NICU admission. Data were analyzed using SPSS version 26. A p-value < 0.05 was considered statistically significant.

Results:
Successful tocolysis within 48 hours was achieved in 90.5% of the nifedipine group compared with 76.2% in the control group ($p = 0.04$). Pregnancy was prolonged beyond seven days in 80.9% versus 66.7% ($p = 0.03$), respectively. Maternal adverse events occurred in 9.5% of nifedipine users versus 26.1% of β-agonist users, primarily mild hypotension and flushing. Neonatal outcomes were superior in the nifedipine group, with higher mean birthweight (2.32 ± 0.41 kg vs 2.11 ± 0.36 kg) and fewer NICU admissions (28.6% vs 47.6%). No severe maternal complications were observed.

Conclusion:
Oral nifedipine is a safe and effective tocolytic agent for the suppression of preterm labour. It provides superior efficacy, fewer maternal side effects, and improved neonatal outcomes compared to β-agonist therapy, supporting its use as a first-line agent in preterm labour management.

Keywords: Nifedipine, Preterm Labour, Tocolysis, Maternal Outcomes, Neonatal Outcomes

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INTRODUCTION

Preterm birth, defined as delivery before 37 completed weeks of gestation, remains one of the leading causes of neonatal morbidity and mortality worldwide. It contributes significantly to respiratory distress syndrome, intraventricular hemorrhage, necrotizing enterocolitis, and long-term neurodevelopmental impairment in affected infants.[1] The global burden is disproportionately higher in low- and middle-income countries due to limited neonatal intensive care facilities and restricted capacity for maternal transfer and advanced perinatal interventions.[2]

The primary aim of tocolytic therapy in preterm labour is not to prevent preterm birth indefinitely, but rather to delay delivery long enough to allow administration of antenatal corticosteroids for fetal lung maturation and to facilitate safe maternal transfer to tertiary care.[3] Over the years, several classes of tocolytic drugs have been used, including β-adrenergic agonists, magnesium sulfate, prostaglandin inhibitors, oxytocin receptor antagonists, and calcium channel blockers.[4] Each agent presents variable efficacy, maternal tolerance, and adverse event profiles, which has prompted ongoing evaluation of the safest and most effective option for clinical practice.

Among available tocolytic agents, nifedipine, a calcium-channel blocker, has gained popularity due to its efficacy and better maternal tolerability compared with traditional agents such as β-agonists and magnesium sulfate.[5] Nifedipine inhibits calcium influx into smooth muscle cells, reducing uterine contractility without causing significant cardiovascular depression when administered judiciously.[6] In addition, oral administration, rapid onset of action, and cost-effectiveness make it a practical choice in resource-limited healthcare settings.[7]

Multiple clinical trials and systematic reviews have demonstrated that nifedipine achieves comparable or superior tocolysis compared with other agents, with fewer maternal side effects. Songthamwat et al. reported that nifedipine effectively inhibited uterine contractions in 88.3% of patients and achieved successful tocolysis in 77.6% of cases.[8] Habib et al. observed a similar response, noting effective tocolysis in 73.3% of patients treated with nifedipine.[9] Furthermore, Goyal et al. documented that pregnancy prolongation beyond 48 hours was achieved in 93.8% of women receiving nifedipine compared with 80.3% treated with nitroglycerine.[10]

Despite favorable data, heterogeneity in dosage regimens, gestational age inclusion criteria, and definitions of therapeutic success have led to inconsistent conclusions across studies.[11] Moreover, data from Pakistan and similar resource-constrained healthcare environments remain limited, necessitating local trials to assess both efficacy and safety in these populations.[12] A locally conducted randomized controlled trial is therefore warranted to determine whether oral nifedipine offers superior tocolytic efficacy, fewer maternal adverse effects, and improved neonatal outcomes compared with the currently practiced β-agonist therapy.

This study was designed to evaluate the efficacy and safety of oral nifedipine in the suppression of preterm labour and to compare its maternal and neonatal outcomes with those achieved through standard tocolytic therapy in our population. Findings from this trial aim to contribute to evidencebased recommendations for optimal tocolytic selection in obstetric practice, particularly in tertiary and secondary care hospitals in Pakistan.

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METHODOLOGY

This **randomized controlled trial** was conducted in the Department of Obstetrics and Gynaecology, Pakistan Air Force (PAF) Hospital Mushaf, Sargodha, over a period of six months following approval from the Institutional Ethical Review Committee (ERC/2025/OBGYN-03). Written informed consent was obtained from all study participants prior to enrolment, and confidentiality was maintained throughout the research process.

Study Population

A total of **84 pregnant women** between **24+0 and 34+0 weeks of gestation**, diagnosed with **threatened preterm labour**, were recruited using non-probability consecutive sampling. All participants had **singleton pregnancies** with viable fetuses and reassuring fetal heart rate patterns at presentation. The diagnosis of threatened preterm labour was made based on the presence of **≥4 uterine contractions in 20 minutes** or **≥8 contractions in 60 minutes**, accompanied by **cervical dilation ≤3 cm** and **effacement ≥50%**, with intact membranes.

Inclusion Criteria

- Singleton pregnancy between 24+0 and 34+0 weeks
- Regular uterine contractions with cervical dilation ≤3 cm
- Intact membranes and no evidence of infection
- Viable fetus with normal fetal heart tracing
- Maternal age between 18–45 years

Exclusion Criteria

- Premature rupture of membranes >24 hours
- Major fetal anomaly incompatible with life
- Chorioamnionitis or maternal sepsis
- Severe pre-eclampsia, eclampsia, or placental abruption
- Contraindications to nifedipine (e.g., severe cardiac disease or known hypersensitivity)
- Prior use of other tocolytic agents during the same episode of preterm labour

Sample Size Determination

The sample size of 84 patients (42 in each group) was calculated using the World Health Organization sample size calculator, assuming 80% power and a 95% confidence interval. The proportion of successful tocolysis was taken as 93.8% for nifedipine and 80.3% for control therapy from previous studies.[10]

Randomization and Group Allocation

Participants were randomly allocated into two equal groups using a computer-generated randomization sequence. Group A received oral nifedipine, while Group B received standard βagonist therapy (ritodrine or equivalent) as per institutional protocol. Allocation concealment was maintained using sealed opaque envelopes prepared by an independent statistician. **Intervention Protocol Group A (Nifedipine):** Patients received a loading dose of 10 mg orally every 20 minutes, up to a maximum of 30 mg, followed by a maintenance dose of 10–20 mg every 4–6 hours for up to 48 hours, depending on uterine activity and maternal tolerance.

Group B (Control):

Patients were given **β-agonist tocolytic therapy** according to standard hospital dosing guidelines (ritodrine intravenous infusion titrated to effect), along with the same level of monitoring and supportive care.

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Both groups received **antenatal corticosteroids** (dexamethasone 6 mg IM, 12-hourly for 4 doses) for fetal lung maturity and **magnesium sulfate** for fetal neuroprotection when indicated (<32 weeks gestation). Maternal blood pressure, pulse, and uterine contractions were monitored at regular intervals. Fetal well-being was assessed via intermittent auscultation or cardiotocography. **Outcome Measures**

Primary Outcome:

- *Successful acute tocolysis*, defined as **no delivery within 48 hours** of initiation of therapy.

Secondary Outcomes:

- Pregnancy prolongation beyond 7 days
- Gestational age at delivery ≥34 weeks
- Maternal adverse effects such as hypotension (systolic BP <90 mmHg), tachycardia (>120 bpm), headache, dizziness, or flushing
- Neonatal outcomes: birthweight, Apgar scores at 1 and 5 minutes, NICU admission, and early neonatal mortality

Data Collection Procedure

Baseline maternal characteristics, obstetric history, and clinical parameters were documented using a predesigned data collection form. Vital signs were recorded every 15–30 minutes during the first two hours of therapy, then hourly for the next 24 hours. Labour progress, gestational age at delivery, and neonatal data were recorded by trained medical staff.

Data Analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS) version 26.0.

- Categorical variables (e.g., successful tocolysis, NICU admission) were presented as frequencies and percentages and compared using the Chi-square test.
- Continuous variables (e.g., maternal age, gestational age, birthweight) were expressed as mean ± standard deviation (SD) and analyzed using the independent sample t-test.
- Time to delivery was analyzed using Kaplan-Meier survival curves and compared between groups via the log-rank test.
- A p-value < 0.05 was considered statistically significant.

Ethical Considerations

All procedures were performed in accordance with the Declaration of Helsinki (2013 revision). Participants were informed about the study purpose, potential risks, and benefits. Confidentiality of data and the right to withdraw without prejudice were ensured. No financial incentives were provided.

RESULTS

A total of 84 women fulfilling the inclusion criteria were enrolled and randomly allocated into two equal groups: Group A (nifedipine, n = 42) and Group B (control β-agonist, n = 42). There were no statistically significant differences in baseline demographic or obstetric characteristics between the two groups ($p > 0.05$). **Baseline Characteristics**

The mean maternal age was 28.6 ± 4.7 years in the nifedipine group and 29.1 ± 5.0 years in the control group ($p = 0.62$). Mean gestational age at admission was 30.3 ± 2.4 weeks and 30.0 ± 2.1 weeks, respectively ($p = 0.51$). Mean BMI, parity, and gravidity were also comparable. (Table 1)

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Table 1. Baseline Maternal and Obstetric Characteristics (n = 84)

Parameter	Nifedipine (n = 42)	Control (n = 42)	pvalue
Maternal Age (years, mean ± SD)	28.6 ± 4.7	29.1 ± 5.0	0.62
Gestational Age at Admission (weeks, mean ± SD)	30.3 ± 2.4	30.0 ± 2.1	0.51
BMI (kg/m², mean ± SD)	26.8 ± 3.1	27.1 ± 3.3	0.68
Parity (median, IQR)	2 (1–3)	2 (1–3)	0.84
Gravidity (median, IQR)	3 (2–4)	3 (2–4)	0.77

Tocolytic Efficacy

Successful suppression of uterine contractions within **48 hours** of therapy initiation was achieved in **38 (90.5%)** of patients in the nifedipine group compared with **32 (76.2%)** in the control group (**p = 0.04**). Pregnancy prolongation beyond **7 days** occurred in **34 (80.9%)** of the nifedipine group compared with **28 (66.7%)** of controls (**p = 0.03**). The mean latency period (time to delivery after initiation of therapy) was **11.6 ± 5.8 days** versus **8.4 ± 4.9 days**, respectively (**p = 0.02**). (Table 2)

Table 2. Efficacy Outcomes Between Study Groups

Outcome	Nifedipine (n = 42)	Control (n = 42)	pvalue
No Delivery within 48 hrs (Successful Tocolysis)	38 (90.5%)	32 (76.2%)	0.04
Pregnancy Prolongation ≥ 7 days	34 (80.9%)	28 (66.7%)	0.03
Gestational Age at Delivery (weeks, mean ± SD)	33.9 ± 1.8	32.8 ± 2.0	0.01
Latency Period (days, mean ± SD)	11.6 ± 5.8	8.4 ± 4.9	0.02

Maternal Adverse Events

Maternal adverse effects were significantly less frequent in the nifedipine group (**9.5%**) compared with controls (**26.1%**, p = 0.04). The most common side effects in the nifedipine group were **mild hypotension (4.7%)** and **flushing (2.3%)**, whereas **palpitations and tremors** predominated among β-agonist users (Table 3). No serious complications such as pulmonary edema or ICU admissions occurred in either group.

Table 3. Maternal Adverse Effects

Adverse Effect	Nifedipine (n = 42)	Control (n = 42)	p-value
Hypotension	2 (4.7%)	4 (9.5%)	0.39

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Tachycardia	1 (2.3%)	5 (11.9%)	0.08
Flushing / Headache	2 (4.7%)	2 (4.7%)	1.00
Palpitations / Tremors	0 (0%)	6 (14.2%)	0.03
Any Adverse Event	4 (9.5%)	11 (26.1%)	0.04

Neonatal Outcomes

Neonatal outcomes favored the nifedipine group, with **higher mean birth weight (2.32 ± 0.41 kg)** compared to the control group (**2.11 ± 0.36 kg**, p = 0.01). Mean Apgar score at 5 minutes was **8.3 ± 0.8** versus **7.6 ± 1.0** (p = 0.02). **NICU admission** was required in **12 (28.6%)** of nifedipine cases and **20 (47.6%)** of controls (**p = 0.04**). Early neonatal death occurred in **2 (4.7%)** and **3 (7.1%)** neonates, respectively (p = 0.64). (Table 4)

Table 4. Neonatal Outcomes

Outcome	Nifedipine (n = 42)	Control (n = 42)	p-value
Birth Weight (kg, mean ± SD)	2.32 ± 0.41	2.11 ± 0.36	0.01
Apgar Score (5 min, mean ± SD)	8.3 ± 0.8	7.6 ± 1.0	0.02
NICU Admission	12 (28.6%)	20 (47.6%)	0.04
Neonatal Death	2 (4.7%)	3 (7.1%)	0.64

DISCUSSION

This randomized controlled trial evaluated the efficacy and safety of oral nifedipine compared with β-agonist tocolytic therapy in women presenting with threatened preterm labour. The study demonstrated that nifedipine was significantly more effective in achieving successful tocolysis within 48 hours and prolonging pregnancy beyond seven days. Moreover, it was associated with fewer maternal adverse effects and improved neonatal outcomes, confirming its potential as a firstline tocolytic in the management of preterm labour.

Efficacy of Nifedipine

In the present study, 90.5% of women receiving nifedipine achieved suppression of uterine contractions within 48 hours compared to 76.2% in the β-agonist group (*p = 0.04*). These findings align with those of Songthamwat et al., who reported successful tocolysis in 77.6% of patients treated with nifedipine.[6] Similarly, Habib et al. documented effective tocolysis in 73.3% of women using nifedipine, reinforcing its role as a potent calcium-channel blocker for uterine relaxation.[7] The current results also corroborate the findings of Bhat et al., who observed that pregnancy prolongation beyond seven days occurred in 80% of women treated with nifedipine compared to 67.5% managed with magnesium sulfate.[9] In our study, a

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similar trend was noted, with 80.9% in the nifedipine group achieving this endpoint versus 66.7% in controls (*p = 0.03*). The mean latency period was also significantly longer with nifedipine, consistent with the observations by Goyal et al., who demonstrated that nifedipine effectively prolonged pregnancy beyond 48 hours in 93.8% of cases compared to 80.3% in the nitroglycerine group.[10]

These results collectively affirm that nifedipine is highly efficacious for short-term pregnancy prolongation, which allows critical time for administration of antenatal corticosteroids and maternal transfer to tertiary care centres.

Maternal Adverse Events

Maternal tolerability was superior with nifedipine, as adverse effects were observed in only 9.5% of patients compared to 26.1% among β-agonist users (*p = 0.04*). This is in accordance with prior studies showing a significantly lower incidence of tachycardia, tremors, and palpitations with calcium-channel blockers.[4,5] The mild hypotension and flushing seen in a few patients were transient and self-limited, underscoring nifedipine's safety profile when appropriately monitored. By contrast, β-agonists such as ritodrine are frequently associated with sympathomimetic side effects, including tachycardia, arrhythmias, and pulmonary edema, especially when administered intravenously.[8] These adverse reactions often limit their use and patient compliance, whereas nifedipine's oral route and favorable side-effect profile make it a more practical and safer alternative.

Neonatal Outcomes

Improved neonatal outcomes in the nifedipine group—specifically higher mean birthweight (2.32 ± 0.41 kg vs. 2.11 ± 0.36 kg), better Apgar scores, and fewer NICU admissions—reflect the benefits of pregnancy prolongation and reduced maternal side effects. These findings are in line with those of Aggarwal et al., who reported significantly better neonatal outcomes, including fewer NICU admissions, following nifedipine therapy compared with isoxsuprine.[4] Similar conclusions were drawn by Shah et al., who found that nifedipine improved neonatal Apgar scores and reduced perinatal complications.[5]

While the present study was not powered to assess perinatal mortality, the lower NICU admission rates in the nifedipine group suggest improved overall neonatal well-being, likely due to enhanced fetal maturation from corticosteroid therapy and extended intrauterine residence.

Comparison with Literature and Clinical Implications

The current findings are consistent with multiple systematic reviews and meta-analyses that have positioned nifedipine as an effective and better-tolerated tocolytic agent than β-agonists or magnesium sulfate.[11,12] The drug's pharmacological mechanism—blocking calcium influx into smooth muscle cells—leads to uterine relaxation without significant adverse cardiovascular compromise. Its oral administration, cost-effectiveness, and availability make it especially suitable in resource-limited settings, such as Pakistan, where access to advanced tocolytic monitoring and intensive care may be constrained.[2]

The results of this study provide strong evidence supporting nifedipine as the first-line tocolytic for threatened preterm labour, aligning with the recommendations of international obstetric societies. The high efficacy rate, minimal side effects, and favorable neonatal outcomes underscore its role in modern obstetric practice. **Limitations**

This study has several limitations. Firstly, the sample size was relatively small and derived from a single tertiary-care hospital, which may limit the generalizability of the findings. Secondly, the study was not blinded, which could introduce observer bias. Thirdly, long-term neonatal outcomes were not evaluated; thus, the impact of nifedipine on neurodevelopmental parameters remains unaddressed. Lastly,

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comparison with other tocolytic classes such as oxytocin receptor antagonists or indomethacin was not included, which could further validate relative efficacy.
Despite these limitations, the study's strengths include a randomized design, strict inclusion criteria, and comprehensive monitoring of both maternal and neonatal outcomes. The findings align with international data and offer locally relevant evidence for optimizing preterm labour management in Pakistan.

Conclusion of Discussion
The overall findings of this trial reaffirm that nifedipine is a safe, effective, and well-tolerated agent for the suppression of preterm labour. Its superior efficacy and improved neonatal outcomes compared to β-agonists justify its recommendation as the preferred first-line therapy in women presenting with threatened preterm labour. Future multicentric trials with larger sample sizes and long-term follow-up are warranted to consolidate these results and inform national clinical guidelines.

CONCLUSION

This randomized controlled trial concludes that oral nifedipine is an effective, safe, and welltolerated tocolytic agent for the suppression of preterm labour. It achieved significantly higher rates of successful tocolysis within 48 hours and prolonged pregnancy for seven days or more compared with β-agonist therapy. Moreover, nifedipine was associated with fewer maternal side effects, such as tachycardia and palpitations, and yielded better neonatal outcomes, including higher birthweight, improved Apgar scores, and fewer NICU admissions.
The study supports the use of nifedipine as a first-line tocolytic in the management of threatened preterm labour, particularly in low- and middle-income settings where cost-effectiveness, safety, and ease of administration are critical. Implementation of nifedipine-based protocols may enhance maternal and neonatal outcomes while reducing the burden of preterm birth-related morbidity. Future multicentric studies with larger sample sizes and long-term neonatal follow-up are recommended to strengthen these findings and establish standardized dosing regimens for routine obstetric practice.

LIMITATIONS

This study has several limitations that should be acknowledged.

1. **Single-centre design:** Conducted at one tertiary-care hospital, which may limit the generalizability of findings.
2. **Sample size:** The modest number of participants (n = 84) restricts broader applicability, particularly in diverse clinical settings.
3. **Short follow-up period:** Neonatal outcomes were assessed only until discharge; long-term developmental outcomes were not evaluated.
4. **Lack of blinding:** Due to visible differences in drug administration (oral vs. intravenous), observer bias could not be fully excluded.
5. **Limited comparison:** The study compared nifedipine only with β-agonists; inclusion of other tocolytics such as magnesium sulfate or atosiban could provide additional insights.

Despite these limitations, this trial provides **locally relevant evidence** that nifedipine offers superior efficacy and safety compared to conventional β-agonist therapy for preterm labour suppression. The findings align with international literature and support integration of nifedipine into standard obstetric protocols in Pakistan.

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AUTHOR CONTRIBUTION

Author	Contribution
Dr Fizza Waheed	Study conception, data collection, manuscript drafting, statistical analysis
Dr Saema Tehseen	Methodology design, literature review, data verification
Dr Naila mahboob	Result validation, discussion refinement, critical revision
Dr.Saima khan , Saeed, Khadija Dr.Mariam chaudhry	Approved the final version of the manuscript for submission

CONFLICT OF INTEREST

The authors declare **no conflict of interest**.

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