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ORAL NIFEDIPINE VERSUS TRANSDERMAL NITROGLYCERIN FOR TOCOLYSIS IN PRETERM LABOUR: A SINGLE-CENTRE RANDOMIZED COMPARATIVE STUDY

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ABSTRACT

Background: Acute tocolysis aims to delay preterm delivery long enough to administer antenatal corticosteroids and arrange appropriate perinatal care. Oral nifedipine and transdermal nitroglycerin act through different pathways, and comparative studies have reported varying results. The objective is to compare the efficacy, maternal tolerability and immediate neonatal outcomes of transdermal nitroglycerin and oral nifedipine in women with preterm labour.

Materials and Methods: This prospective randomized study enrolled 114 women with singleton pregnancies in preterm labour at 24–34 weeks. Participants received transdermal nitroglycerin (10 mg/24 hours, up to two applications; n=57) or oral nifedipine (20 mg loading dose, repeatable after 60 minutes, then 10 mg every six hours for up to 48 hours; n=57). Successful tocolysis required contraction suppression without cervical progression, corticosteroid-course completion and no recurrence within 48 hours after treatment cessation. Additional outcomes were time to delivery, gestational age at birth, maternal adverse events and immediate neonatal outcomes.

Results: Successful tocolysis occurred in 44/57 (77.2%) women receiving nitroglycerin and 51/57 (89.5%) receiving nifedipine (p=0.0785; absolute difference 12.3 percentage points, 95% CI -1.6 to 25.9). Mean time from treatment to delivery was 21.36 ± 13.89 and 32.85 ± 20.69 days, respectively (p=0.0007). Mean gestational age at delivery was 34.88 ± 1.83 versus 36.46 ± 2.07 weeks (p<0.0001). Headache was documented in 17/57 (29.8%) and 8/57 (14.0%) women. Mean neonatal birth weight was 2.25 ± 0.31 versus 2.74 ± 0.39 kg, and five-minute Apgar score was 8.37 ± 1.23 versus 8.86 ± 0.91, respectively.

Conclusion: Both treatments met the study-defined response criteria in most participants. The response rate was higher with nifedipine, but the difference was not statistically significant. Deliveries occurred at a later gestational age in the nifedipine group, whereas headache was more common with nitroglycerin.

Keywords: Preterm Birth; Tocolysis; Nifedipine; Nitroglycerin; Pregnancy Outcome; Randomized Controlled Trial.

INTRODUCTION

Preterm birth is a major cause of perinatal illness and death, particularly where access to neonatal intensive care is constrained. An estimated 13.4 million babies were born before 37 completed weeks worldwide in 2020.[1] The consequences extend beyond survival: respiratory disease, intracranial complications, feeding difficulties and later neurodevelopmental impairment place substantial demands on families and health services. Because neonatal risk changes markedly with gestational age, even a short delay in delivery may be important when it permits an intervention with established benefit.

Tocolytic treatment is intended chiefly to defer delivery long enough for antenatal corticosteroids to be administered and, where indicated, for transfer to a suitable perinatal facility. Suppression of contractions does not necessarily correct the process responsible for preterm labour, and prolonged maintenance treatment is not synonymous with improved neonatal outcome. The World Health Organization recommends nifedipine for appropriately selected women at risk of imminent preterm birth when conditions for safe use are met.[2] National guidance similarly supports nifedipine in selected cases with intact membranes.[3] A Cochrane review found that several drug classes may postpone birth, but estimates vary across efficacy and maternal safety outcomes.[4]

Nifedipine inhibits transmembrane calcium influx into myometrial cells and thereby reduces contractility. It is administered orally and has an established place in contemporary practice, although maternal hypotension, flushing and tachycardia remain relevant considerations.[5] Nitroglycerin releases nitric oxide, increases intracellular cyclic guanosine monophosphate and relaxes smooth muscle. The transdermal system avoids repeated oral dosing but is associated with vasodilator effects, particularly headache. In a systematic review, evidence for transdermal nitroglycerin did not support its routine use as the preferred tocolytic agent.[6]

Randomized head-to-head trials have produced differing results. Amorim and colleagues found similar short-term suppression of preterm labour with both drugs.[7] Dhawle and colleagues reported fewer deliveries within 48 hours among women receiving nifedipine.[8] Kashanian and colleagues observed a longer delay to delivery with nitroglycerin.[9] Ghomian and colleagues reported favourable maternal and neonatal findings with nitroglycerin for selected outcomes.[10] Kaur and colleagues favoured nifedipine for some delivery and neonatal measures.[11] Sharma and colleagues reported comparable rates of early treatment failure.[12] A 2025 meta-analysis found no clear overall difference in pregnancy prolongation or neonatal outcomes, while maternal adverse-effect profiles varied between treatments.[13]

This study compared acute treatment response, subsequent delivery outcomes, maternal adverse effects and immediate neonatal outcomes among women presenting with preterm labour at 24–34 weeks.

Aim: To compare the efficacy and maternal safety of transdermal nitroglycerin and oral nifedipine in the management of preterm labour.

Objectives

- To compare the proportion of women achieving the study-defined composite outcome of successful tocolysis.
- To compare pregnancy prolongation and gestational age at delivery between the two treatment groups.
- To document maternal adverse events associated with each tocolytic regimen.
- To assess neonatal outcomes, including birth weight, five-minute Apgar score, resuscitation, respiratory distress syndrome, neonatal intensive care unit (NICU) admission and ventilatory support.

MATERIALS AND METHODS

Study design and setting: This prospective, parallel-group randomized comparison was conducted in the Department of Obstetrics and Gynaecology at a tertiary care hospital in Jharkhand, India, from 1 January 2018 to 1 June 2019. Women admitted with preterm uterine contractions were assessed for eligibility. Both groups received active tocolytic treatment.

Inclusion criteria

- Singleton pregnancy at 24–34 weeks of gestation.
- At least four uterine contractions in 20 minutes or eight contractions in one hour.
- Progressive cervical change.
- Cervical dilatation greater than 1 cm and no more than 4 cm at enrolment.

The clinical records also listed a separate cervical measurement of more than 1 cm and less than 3 cm under the term 'effacement', expressed in centimetres rather than as a percentage.

Exclusion criteria

- Active labour with cervical dilatation greater than 4 cm.
- Diabetes mellitus or significant cardiac, hepatic or renal illness.
- Pre-eclampsia, eclampsia or antepartum haemorrhage.
- Abnormal amniotic fluid volume, hyperthyroidism or preterm prelabour rupture of membranes.
- Suspected chorioamnionitis.
- Fetal growth restriction, fetal anomaly, fetal compromise or intrauterine fetal death.
- Multiple gestation.
- Systolic blood pressure below 90 mmHg.

- Completion of antenatal corticosteroid treatment before entry.
- Contraindication or known sensitivity to either tocolytic.

Recruitment, randomization and sample size: Participants were randomized 1:1 to transdermal nitroglycerin or oral nifedipine (57 per group) using a computer-generated sequence prepared with Research Randomizer. The sample-size plan cited event proportions of 17.85% and 44.64%, a two-sided significance level of 5% and 90% power, with a target of 57 women per group.

Baseline assessment: After written consent, maternal age, menstrual and obstetric history, antenatal care, relevant comorbidities and family history were recorded. Clinical assessment included vital signs, abdominal examination, contraction frequency, fetal lie and presentation, and fetal heart rate. Ultrasound assessed gestation, amniotic fluid and cervical characteristics. Pelvic examination included cervical dilatation, the additional recorded cervical measurement, Bishop score and membrane status. Gestational age was estimated from menstrual history and obstetric assessment.

Study interventions: The nitroglycerin group received an abdominal transdermal patch designed to deliver 10 mg over 24 hours. Up to two patch applications were permitted until contractions subsided. The nifedipine group received an initial oral dose of 20 mg; if contractions continued after 60 minutes, a second 20-mg dose was given. Following suppression of contractions, nifedipine 10 mg was administered six-hourly for up to 48 hours. Completion of maternal antenatal corticosteroid treatment was included in the definition of response.

Monitoring and follow-up: Maternal blood pressure, pulse and fetal heart rate were assessed every 15 minutes in the first hour, every 30 minutes in the second hour and four-hourly thereafter. Headache, nausea, vomiting, flushing, dizziness, palpitations, tachycardia, hypotension and local irritation were recorded during treatment. Adverse events were counted separately by symptom, allowing more than one event to be recorded for an individual woman. Women were followed to delivery for pregnancy prolongation, gestational age at birth, neonatal weight, five-minute Apgar score, resuscitation, respiratory distress syndrome, NICU admission and requirement for ventilatory support.

Outcome definitions: Successful tocolysis required cessation of uterine contractions without further cervical dilatation, completion of the antenatal corticosteroid course and no recurrence of contractions during the 48 hours after treatment stopped. Treatment failure included persistent contractions, incomplete corticosteroid treatment or a maternal or fetal event requiring treatment withdrawal. The recorded time from treatment to delivery was evaluated in days as a mean interval and in the categories 1–7, 8–14 and >14 days; gestational age at delivery was analysed separately. The composite success measure did not simply represent remaining undelivered for 48 hours after randomization.

Statistical methods: Continuous outcomes were summarized as mean ± standard deviation (SD) and categorical outcomes as n (%), with 57 participants in each arm. Two-sided independent-samples t tests compared continuous measures; Pearson chi-square tests compared categorical measures, with Fisher exact tests used when expected cell counts were small. Age and gravidity categories were compared individually against the other categories of the same variable. Statistical significance was set at $p<0.05$. The absolute difference in successful tocolysis rates was accompanied by a 95% confidence interval calculated using the Newcombe method, and mean differences were summarized with t-based 95% confidence intervals. Analyses were reported to use Microsoft Excel and SPSS version 20. Comparisons were unadjusted, with no correction for multiple secondary tests.

Ethical considerations: Approval was obtained from the Institutional Ethics Committee. Written informed consent was obtained from participating women, and consent documents were available in English and Hindi.

RESULTS

Study population and baseline findings: The study enrolled 114 women, equally divided between the nitroglycerin and nifedipine groups. Each reported group-level analysis was based on 57 women. Mean maternal ages were 23.21 ± 4.29 and 23.88 ± 4.21 years, respectively ($p=0.4018$). Primigravidae numbered 31 (54.4%) and 33 (57.9%). Mean gestational ages at admission were 31.11 ± 2.85 and 30.84 ± 2.90 weeks ($p=0.6171$); mean cervical dilatation was 1.92 ± 0.53 and 1.85 ± 0.44 cm. Baseline characteristics are presented in Table 1.

Tocolytic efficacy and pregnancy prolongation: Successful tocolysis occurred in 44 of 57 women (77.2%) assigned to nitroglycerin and 51 of 57 (89.5%) assigned to nifedipine ($p=0.0785$). The absolute difference was 12.3 percentage points in favour of nifedipine (95% CI -1.6 to 25.9), and did not reach the prespecified significance threshold. Treatment failed in 13 (22.8%) and six (10.5%) women, respectively. Overall, 95 of 114 participants (83.3%) met the composite success criteria (Figure 1B). Mean time from treatment to delivery was 21.36 ± 13.89 days in the nitroglycerin group and 32.85 ± 20.69 days in the nifedipine group ($p=0.0007$). Delivery occurred more than 14 days after treatment in 33 (57.9%) and 36 (63.2%) women, respectively. Treatment response is shown in Figure 1A; delivery intervals are summarized in [Table 2 and Figure 2A].

Gestational age at delivery: Mean gestational age at delivery was 34.88 ± 1.83 weeks in the nitroglycerin arm and 36.46 ± 2.07 weeks in the nifedipine arm ($p<0.0001$); the unadjusted mean difference was 1.58

weeks (95% CI 0.86 to 2.31 weeks). Delivery in the recorded >36-week category occurred in 16 of 57 (28.1%) and 34 of 57 (59.6%) women, respectively. In the 32-34-week category, the corresponding numbers were 22 (38.6%) and 11 (19.3%). The complete distribution is shown in Table 2 and Figure 2B. The >36-week category includes women who may still have delivered before 37 completed weeks.

Maternal adverse events: Headache occurred in 17 women (29.8%) receiving nitroglycerin and eight (14.0%) receiving nifedipine [Table 3, Figure 3]. Palpitations occurred in four (7.0%) and one (1.8%) women, nausea in two (3.5%) and six (10.5%), and flushing in one (1.8%) and five (8.8%), respectively. One woman in the nitroglycerin group experienced hypotension; no hypotension was recorded in the nifedipine group. Individual participants may have experienced more than one symptom.

Neonatal outcomes: Mean neonatal birth weight was 2.25 ± 0.31 kg after nitroglycerin exposure and 2.74 ± 0.39 kg after nifedipine exposure (p<0.0001); the unadjusted mean difference was 0.49 kg (95% CI 0.36 to 0.62 kg). Mean five-minute Apgar scores were 8.37 ± 1.23 and 8.86 ± 0.91, respectively (p=0.0172). Resuscitation was required for ten (17.5%) and four (7.0%) neonates, while NICU admission occurred in 16 (28.1%) and 11 (19.3%), respectively. Respiratory distress syndrome occurred in four (7.0%) and two (3.5%) neonates; three neonates (5.3%) in each group received ventilatory support. These outcomes were evaluated separately and were not adjusted for gestational age at delivery [Table 4; Figure 4].

Table 1: Baseline characteristics of the randomized groups

Characteristic	Nitroglycerin (n=57)	Nifedipine (n=57)	p value
Age, years, mean ± SD	23.21 ± 4.29	23.88 ± 4.21	0.4018
Age 18–20 years, n (%)	19 (33.3)	14 (24.6)	0.3018
Age 21–25 years, n (%)	26 (45.6)	28 (49.1)	0.7075
Age 26–30 years, n (%)	8 (14.0)	10 (17.5)	0.6075
Age 31–35 years, n (%)	3 (5.3)	4 (7.0)	1.0000
Age >35 years, n (%)	1 (1.8)	1 (1.8)	1.0000
Primigravida, n (%)	31 (54.4)	33 (57.9)	0.7058
Gravida 2, n (%)	20 (35.1)	15 (26.3)	0.3100
Gravida ≥3, n (%)	6 (10.5)	9 (15.8)	0.4059
Gestation at admission, weeks	31.11 ± 2.85	30.84 ± 2.90	0.6171
Cervical dilatation, cm	1.92 ± 0.53	1.85 ± 0.44	0.4446
Recorded cervical measurement, cm	2.38 ± 0.21	2.36 ± 0.19	0.5949

Data are mean ± SD or n (%) (57 women per arm). Age and gravidity p values compare each category against all others.

Table 2: Efficacy and delivery outcomes

Outcome	Nitroglycerin (n=57)	Nifedipine (n=57)	p value
Successful tocolysis, n (%)	44 (77.2)	51 (89.5)	0.0785
Treatment failure, n (%)	13 (22.8)	6 (10.5)	0.0785
Reported interval to delivery, days, mean ± SD	21.36 ± 13.89	32.85 ± 20.69	0.0007
Delivery 1-7 days after treatment, n (%)	13 (22.8)	10 (17.5)	0.4838
Delivery 8-14 days after treatment, n (%)	11 (19.3)	11 (19.3)	1.0000
Delivery >14 days after treatment, n (%)	33 (57.9)	36 (63.2)	0.5654
Gestational age at delivery, weeks, mean ± SD	34.88 ± 1.83	36.46 ± 2.07	<0.0001
Delivery at 30-32 weeks, n (%)	5 (8.8)	1 (1.8)	0.2062
Delivery at 32-34 weeks, n (%)	22 (38.6)	11 (19.3)	0.0231
Delivery at 34-36 weeks, n (%)	14 (24.6)	11 (19.3)	0.4971
Delivery >36 weeks, n (%)	16 (28.1)	34 (59.6)	0.0007

Values are mean ± SD or n (%) (57 per arm). Successful tocolysis also required completion of antenatal corticosteroids and no recurrence within 48 hours of stopping treatment. The pregnancy-prolongation p value was calculated from group summary statistics.

Table 3: Maternal adverse events recorded during treatment

Event	Nitroglycerin, n (%)	Nifedipine, n (%)	p value
Headache	17 (29.8)	8 (14.0)	0.0416
Nausea	2 (3.5)	6 (10.5)	0.2712
Tachycardia	1 (1.8)	3 (5.3)	0.6183
Palpitations	4 (7.0)	1 (1.8)	0.3638
Flushing	1 (1.8)	5 (8.8)	0.2062
Vomiting	1 (1.8)	4 (7.0)	0.3638
Dizziness	2 (3.5)	1 (1.8)	1.0000
Local irritation	0 (0.0)	2 (3.5)	0.4956
Hypotension	1 (1.8)	0 (0.0)	1.0000

Events are n (%) of 57 women per arm and may overlap within a participant. P values are unadjusted.

Table 4: Neonatal outcomes by maternal treatment group

Outcome	Nitroglycerin (n=57)	Nifedipine (n=57)	p value
Birth weight, kg, mean ± SD	2.25 ± 0.31	2.74 ± 0.39	<0.0001
Apgar score at 5 min, mean ± SD	8.37 ± 1.23	8.86 ± 0.91	0.0172
Resuscitation, n (%)	10 (17.5)	4 (7.0)	0.0869
NICU admission, n (%)	16 (28.1)	11 (19.3)	0.2707
Respiratory distress syndrome, n (%)	4 (7.0)	2 (3.5)	0.6790
Ventilatory support, n (%)	3 (5.3)	3 (5.3)	1.0000

Data are mean ± SD or n (%) (57 neonates per arm). A neonate could have more than one listed outcome. NICU, neonatal intensive care unit; SD, standard deviation. P values are unadjusted; statistical tests are described in Methods.

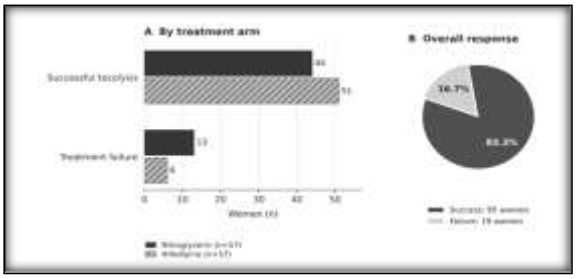

Figure 1: Tocolytic treatment response: (A) successful tocolysis and treatment failure in each treatment group; (B) overall composite response among all randomized women.

Each treatment group included 57 women. Overall, 95 of 114 participants (83.3%) fulfilled the composite success criteria and 19 (16.7%) did not.

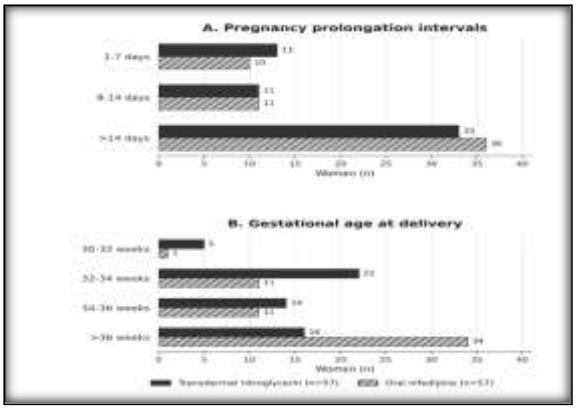

Figure 2: Pregnancy and delivery outcomes: (A) recorded time from treatment to delivery, grouped as 1-7, 8-14 and >14 days; (B) gestational age category at delivery.

Each arm included 57 women. Delivery after 36 weeks does not necessarily indicate term birth.



Figure 3: Recorded maternal adverse events during tocolytic treatment in the nitroglycerin and nifedipine groups (57 women per arm).

Adverse-event categories are not mutually exclusive.

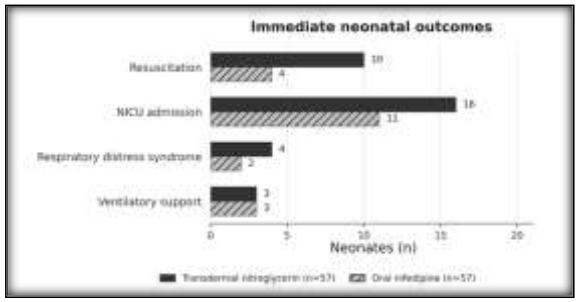

Figure 4: Recorded neonatal outcomes by maternal tocolytic agent (57 neonates per arm).

Neonatal outcomes may overlap within the same infant.

DISCUSSION

Among the 114 women allocated to the two regimens, successful tocolysis was recorded in 77.2% of the nitroglycerin group and 89.5% of the nifedipine group. The difference did not reach statistical significance (p=0.0785). Women receiving nifedipine had a longer reported interval to delivery and gave birth at a later mean gestational age. Headache was more frequent after nitroglycerin. Neonates in the nifedipine group also had higher mean birth weights and five-minute Apgar scores, although these differences must be considered alongside the later gestational age at delivery.

The composite endpoint measured more than the immediate suppression of contractions: it also required cervical stability, completion of the corticosteroid course and no recurrence of contractions during the 48 hours after treatment ended. It therefore differs from the rate of delivery within 48 hours of randomization. More than half the women in each arm delivered over 14 days after starting treatment.

The direction of the treatment-response findings is similar to that reported by Dhawle and colleagues, who observed fewer early tocolytic failures with nifedipine.[8] Kaur and colleagues also described more favourable results with nifedipine for selected maternal or neonatal measures.[11] By contrast, Sharma and colleagues reported comparable early failure rates.[12] Differences in gestational age at enrolment, cervical status, dosing schedules and outcome definitions may account for some of this variation.

Other randomized studies have reported similar efficacy or findings favouring nitroglycerin. Amorim

and colleagues observed comparable short-term contraction suppression. Kashanian and colleagues found a longer delay to delivery with nitroglycerin. Ghomian and colleagues reported more favourable outcomes with nitroglycerin for selected measures. The 2025 systematic review and meta-analysis found no consistent advantage for either agent in pregnancy prolongation or neonatal outcomes.[13] A placebo-controlled trial of transdermal nitroglycerin also reported more maternal side effects in the active-treatment group.[14] Differences in comparator treatment, eligibility and outcome definitions complicate direct comparisons between studies.

Headache was more common with nitroglycerin (29.8% versus 14.0%), in keeping with its vasodilator effects. The 2025 meta-analysis also identified more headache with nitroglycerin and more tachycardia or palpitations with nifedipine across the included trials. In the present study, adverse events were counted by symptom, so the proportion of women experiencing any adverse effect cannot be determined from those counts. Maternal surveillance remains important during tocolytic therapy.[15]

Mean birth weight and five-minute Apgar score were higher among neonates whose mothers received nifedipine, but those pregnancies also ended at a later gestational age. Greater maturity at birth may partly explain the differences. Resuscitation and NICU admission were more frequent after nitroglycerin exposure, whereas respiratory distress syndrome and ventilatory support were uncommon in both groups. These unadjusted comparisons do not establish a direct neonatal effect of either drug.

Acute tocolysis is intended primarily to create a window for antenatal corticosteroid administration and transfer to an appropriate facility when required.[16] A recent network meta-analysis ranked calcium-channel blockers favourably when efficacy and safety were considered together.[17] Earlier comparative evidence also showed that tocolytic agents can delay preterm birth, although delivery postponement alone does not establish a neonatal benefit.[18] Drug selection should therefore account for maternal haemodynamic status, fetal condition and contraindications.

Prospective enrolment, defined treatment schedules and follow-up to delivery allowed assessment of both acute tocolysis and perinatal outcomes. Although randomization used a computer-generated sequence, allocation concealment and blinding were not described.[19]

CONCLUSION

Oral nifedipine and transdermal nitroglycerin each achieved the study-defined composite response in most women with preterm labour. The higher response proportion with nifedipine was not statistically significant. Mean gestational age at delivery and neonatal birth weight were greater with nifedipine, whereas headache occurred more frequently with nitroglycerin. Because neonatal comparisons were unadjusted, these findings do not establish the superiority of either treatment.

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