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Comparison of Efficacy of Nifedipine Alone Versus Nifedipine and Progesterone in the Treatment of Threatened Preterm Labour

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ABSTRACT

Background: Preterm birth is one of the leading causes of infant morbidity and mortality, and it is considered to be a child born before the 37 weeks of gestation. Tocolytic therapy is needed in order to delay delivery so that corticosteroid could be administered to achieve fetal lung maturation. Nifedipine is a useful tocolytic and progesterone could increase uterine quiescence. This study compared the effectiveness of nifedipine alone versus nifedipine plus progesterone in suppressing uterine contractions within 48 hours in threatened preterm labor.

Methods: This prospective comparative study was carried out in Shifa International Hospital, Islamabad from May to October 2025. One hundred and thirty singleton pregnant women between 24-37 weeks were recruited through consecutive sampling and allocated to treatment groups based on clinical management plan. Group A received oral nifedipine alone (10 mg loading dose, repeatable up to 3 times, then 10 mg every 8 hours). Group B received the same nifedipine regimen plus progesterone (250 mg IM on admission, then 200 mg vaginally every 12 hours if needed). Uterine contractions and maternal side effects were observed. The data were analyzed with the help of SPSS v22 where chi-square and t-tests were used, p less than 0.05 was taken as the significant level.

Results: Cessation of contractions within 48 hours occurred in 31 (47.7%) participants of Group A and 47 (72.3%) of Group B (χ^2=8.56, p=0.003). Mean time to cessation was shorter in Group B (21.7 ± 7.0 hours) than Group A (29.4 ± 8.2 hours, t=3.38, p=0.001). Maternal side effects were mild; vaginal discomfort occurred only in the 5 patients from combination group (7.7%, p=0.03). Stratification by age, parity, and gestational age did not alter these outcomes

Conclusion: Nifedipine with progesterone proved better than only nifedipine in the case of threatened preterm labor with few side effects implying that it is a safe and an effective method of enhancing maternal and neonatal outcomes.

Keywords: Preterm labour, Nifedipine, Progesterone, Tocolysis, Uterine contractions

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INTRODUCTION

A major worldwide health concern, preterm birth is defined as delivery before 37 weeks of gestation and is linked to high rates of infant morbidity, mortality, and long-term consequences [1]. Approximately 14.48 million infants are born preterm annually, with the highest burden in low- and

middle-income countries [2]. Regular uterine contractions leading to cervical changes are the earliest signs of preterm labor, making timely intervention critical for improving neonatal outcomes [3].

By delaying preterm delivery, tocolytic therapy makes it possible to administer magnesium sulfate for neuroprotection, corticosteroids for fetal lung development, and transfer to higher-level care facilities [4]. Various agents, including beta-adrenergic agonists, calcium channel blockers, prostaglandin inhibitors, and oxytocin receptor antagonists, have been used [5]. However, an ideal tocolytic with maximum efficacy and minimal maternal-fetal side effects is yet to be identified [6].

Nifedipine, a calcium channel blocker, inhibits calcium influx in myometrial cells, effectively suppressing contractions with fewer maternal side effects compared to beta-agonists [7]. Progesterone supports myometrial structure and minimizes contractions to assist sustain pregnancy [8]. Studies indicate that combining progesterone with nifedipine may enhance efficacy; one study in Lahore reported 71.74% success with combination therapy versus 47.83% with nifedipine alone [9].

The efficacy of nifedipine-progesterone combination therapy in local settings is under researched, thus necessitating a study in this group. The research was undertaken to determine whether nifedipine alone was effective or nifedipine in association with progesterone in curbing the occurrence of uterine contractions in the next 48 hours in threatened preterm labor.

This study offers comparative evidence to assess the use of nifedipine monotherapy versus combined nifedipine and progesterone therapy for acute tocolysis in threatened preterm labor. Unlike previous studies that primarily investigated progesterone as maintenance therapy following successful nifedipine tocolysis, this study evaluates simultaneous initiation of combination therapy from the outset of acute tocolysis. Specifically, we administered intramuscular progesterone (250 mg) concurrently with nifedipine loading dose, followed by vaginal progesterone (200 mg every 12 hours) if contractions persisted—differing from protocols where progesterone was added only after successful nifedipine tocolysis. This design allows assessment of acute tocolytic efficacy during the initial 48 hours, a critically important clinical window for corticosteroid administration and fetal lung maturation. Additionally, the study measures time to uterine contraction cessation and maternal side-effect profiles, providing practical evidence to optimize tocolytic protocols in resource-constrained healthcare settings.

METHODS

It was a prospective comparative study conducted in 6 months (May to October 2025) in the department of obstetrics and gynecology, Shifa International Hospital, Islamabad (IRB & EC Shifa

International Hospitals IRB No. 131-25). The sample size was calculated using the WHO sample size calculator[10] that was applied with a level of significance of 5%, power of 80%, population proportion of Group A (nifedipine alone) of 47.83% and pop proportion of Group B (nifedipine plus progesterone) of 71.74%.

$$n = \frac{(Z\alpha/2 + Z\beta)^2 \times [p1(1-p1) + p2(1-p2)]}{(p1-p2)^2}$$

Where $Z\alpha/2$ = 1.96 (for 5% significance level, two-sided); $Z\beta$ = 0.84 (for 80% power); $p1$ = 0.4783 (47.83% - Group A proportion); and $p2$ = 0.7174 (71.74% - Group B proportion). The effective size found was 130 participants.

Eligible patients were recruited on a first come first served basis and treatment groups were decided according to the clinical management plan as opposed to being randomly selected. The women of childbearing age 18-35 years old diagnosed with an impending preterm birth, having singleton pregnancies, and a gestational age of 24-37 weeks were included. Threatened preterm labor was considered the development of regular Uterine contractions (≥2 contractions within 10 minutes, ≤20 seconds) with cervical dilation ≤4 cm, which were confirmed with either clinical examination or cardiotocography. The exclusion criteria were normal pregnancies with no palpable contractions, gestational age below <24 weeks, multiple pregnancies, premature membrane rupture, the presence of chorioamnionitis, congenital malformations of the fetus, non-reassuring fetal heart rates, and allergy to nifedipine or progesterone.

Written informed permission and ethical approval were obtained and a comprehensive history and physical examination were performed. All the patients were admitted as inpatients. Group A was given a loading dose of 10 mg of nifedipine orally. Its dosage was repeated after every 15 minutes to a maximum of three times in cases of persistence of contractions and then 10 mg every 8 hours as a maintenance dose. On admission, Group B received 250 mg intramuscular progesterone on top of the same regimen of nifedipine. In case of contractions further, dosage of nifedipine was repeated as above and vaginal progesterone 200 mg was used every 12 hours.

The blood pressure of the mother was measured after every fifteen minutes of the loading dose and subsequently after every five minutes until normalcy was achieved. The side effects of the nifedipine (transient hypotension, tachycardia, flushing, headache, dizziness, nausea) and progesterone (bloating, diarrhea, vaginal discomfort) were identified and managed. To achieve fetal lung maturation, every participant of the two groups was given four 12 hour intervals of 6 mg dexamethasone intramuscularly. Sounds of the fetal heart and uterine contractions were manually

monitored as per standard protocols of preterm labor. A predetermined questionnaire was used to record the data in terms of demographic variables, obstetric history, clinical findings, and treatment outcomes. At least four hours of no measurable uterine contractions during 48 hrs after treatment initiation was an indication of effective treatment.

The data collected was entered and assessed using SPSS 22. Quantitative data such as age, gestational age and parity were represented using the mean ± standard deviation, and qualitative factors such as the side effects and the effectiveness of the treatment were represented using frequencies and percentages. Effect modifiers such as age, parity and gestational age were controlled using stratification. The two groups were compared using chi square and t-tests after stratification. The statistical significance was set at less than 0.05 p-value.

Ethical approval was given by the Institutional review board of Shifa international hospital, Islamabad. Each subject was informed of the study by signing a written agreement, and confidentiality was observed in accordance with the Declaration of Helsinki.

RESULTS

Table 1: Baseline Demographic and Obstetric Characteristics

Variable		Group A (n=65)	Group B (n=65)	Statistical Test	p-value
Maternal Age (years)	Mean ± SD	28.1 ± 4.2	27.8 ± 4.0	t = 0.49	0.62
	Range	20–35	19–35	—	—
	<25 years, n (%)	14 (21.5%)	16 (24.6%)	$\chi^2 = 0.18$	0.67
	25–30 years, n (%)	28 (43.1%)	29 (44.6%)	—	—
	>30 years, n (%)	23 (35.4%)	20 (30.8%)	—	—
Gestational Age (weeks)	Mean ± SD	31.5 ± 3.1	31.7 ± 3.0	t = 0.37	0.71
	Range	24–36	24–37	—	—
	24–28 weeks, n (%)	12 (18.5%)	10 (15.4%)	$\chi^2 = 0.55$	0.76
	29–32 weeks, n (%)	26 (40.0%)	29 (44.6%)	—	—

	33–37 weeks, n (%)	27 (41.5%)	26 (40.0%)	—	—
Parity	Primipara, n (%)	29 (44.6%)	31 (47.7%)	$\chi^2 = 0.15$	0.70
	Multipara, n (%)	36 (55.4%)	34 (52.3%)	—	—
Previous Preterm Birth, n (%)		8 (12.3%)	9 (13.8%)	$\chi^2 = 0.07$	0.79
Cervical Dilation (cm)	Mean ± SD	2.4 ± 0.8	2.5 ± 0.9	t = 0.68	0.50
	≤2 cm, n (%)	28 (43.1%)	26 (40.0%)	$\chi^2 = 0.14$	0.71
	>2–4 cm, n (%)	37 (56.9%)	39 (60.0%)	—	—
BMI (kg/m²), Mean ± SD		26.8 ± 3.4	27.1 ± 3.6	t = 0.50	0.62

t = Independent Student's t-test; χ^2 = Chi-square test; SD = Standard Deviation; BMI = Body Mass Index. p-value <0.05 was considered statistically significant.

The total number of participants was 130 (including 65 in Group A (nifedipine only) and 65 in Group B (nifedipine plus progesterone). The similarity to be compared using the observational method was supported by the baseline variables, which included the mean age, gestational age, and parity, which were comparable between the groups (p>0.05). The mean age of Group A was 28.1 ± 4.2 years and the mean gestational age was 31.5 ± 3.1 weeks as shown in **Table 1**. The mean age of Group B was 27.8 ± 4.0 years and the mean gestational age was 31.7 ± 3.0 weeks. The rest was multipara with 44.6% percent in Group A and 47.7% percent in Group B. There were no apparent differences between these baseline variables and this ensures comparability.

One hundred and thirty-one participants were used with 65 in Group A (nifedipine) and 65 in Group B (nifedipine + progesterone). There were no differences in baseline characteristics, such as mean age, gestational age, and parity (p>0.05). As illustrated in **Figure 1**, overall, cessation of uterine contractions within 48 hours was achieved in 31 participants (47.7%) in Group A and 47 participants (72.3%) in Group B ($\chi^2 = 8.56$, p = 0.003). Stratified analysis by parity showed similar trends, with combination therapy more effective in primipara (48.3% vs 74.2%, $\chi^2 = 4.29$, p = 0.038) and multipara participants (47.2% vs 70.6%, $\chi^2 = 3.43$, p = 0.064), confirming that adding progesterone improves tocolytic effectiveness across all parity groups.

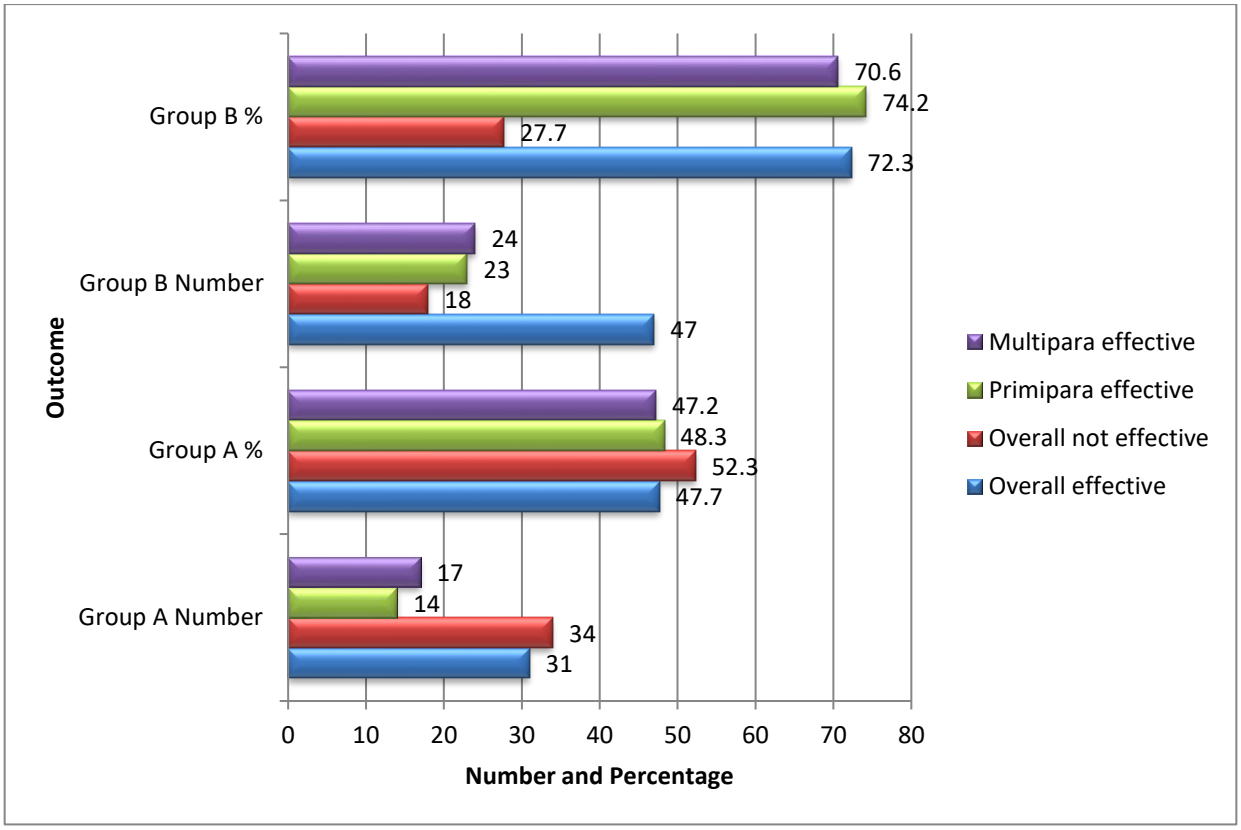

Figure 1: Effectiveness of Treatment (Cessation of Contractions within 48 Hours, Stratified by Parity)

Table 2: Effectiveness of Treatment (Cessation of Uterine Contractions within 48 Hours)

Outcome		Group A (n=65)	Group B (n=65)	Statistical Test	P-value	Effect Size (OR, 95% CI)
Overall Effectiveness	Cessation achieved, n (%)	31 (47.7%)	47 (72.3%)	$\chi^2 = 8.56$	0.003	2.85 (1.40–5.80)
	Cessation not achieved, n (%)	34 (52.3%)	18 (27.7%)	—	—	—
By Parity	*Primipara*					
	Effective, n/N (%)	14/29 (48.3%)	23/31 (74.2%)	$\chi^2 = 4.29$	0.038	3.07 (1.05–8.96)
	Multipara					
	Effective, n/N (%)	17/36 (47.2%)	24/34 (70.6%)	$\chi^2 = 3.43$	0.064	2.67 (0.94–7.58)
	24–32 weeks					

By Gestational Age	Effective, n/N (%)	16/38 (42.1%)	27/39 (69.2%)	$\chi^2 = 5.78$	0.016	3.04 (1.21–7.65)
	33–37 weeks					
	Effective, n/N (%)	15/27 (55.6%)	20/26 (76.9%)	$\chi^2 = 2.71$	0.10	2.67 (0.82–8.71)
By Cervical Dilation	*≤2 cm*					
	Effective, n/N (%)	16/28 (57.1%)	22/26 (84.6%)	$\chi^2 = 4.89$	0.027	4.13 (1.12–15.21)
	>2–4 cm					
	Effective, n/N (%)	15/37 (40.5%)	25/39 (64.1%)	$\chi^2 = 4.32$	0.038	2.61 (1.05–6.48)

χ^2 = Chi-square test; OR = Odds Ratio; CI = Confidence Interval. Bold p-values indicate statistical significance (<0.05).

The mean time to cessation of uterine contractions was significantly shorter in the combination therapy group. As shown in **Table 2**, combination therapy demonstrated a markedly superior success rate compared to nifedipine alone. Cessation of uterine contractions within 48 hours was achieved in 72.3% (47/65) of women in Group B versus 47.7% (31/65) in Group A (p = 0.003), with nearly threefold higher odds of success (OR 2.85, 95% CI 1.40–5.80). The benefit was especially evident among primiparous women (74.2% [23/31] vs 48.3% [14/29], p = 0.038; OR 3.07) and those at 24–32 weeks of gestation (69.2% [27/39] vs 42.1% [16/38], p = 0.016; OR 3.04). Women with cervical dilation ≤2 cm showed the most pronounced response, with success rates of 84.6% (22/26) vs 57.1% (16/28), p = 0.027; OR 4.13. Interaction p-values were non-significant, indicating a consistent treatment effect across subgroups.

Table 3: Time to Cessation of Uterine Contractions

Parameter	Group A (n=31)	Group B (n=47)	Statistical Test	p-value
Time to Cessation (hours)				
Mean ± SD	29.4 ± 8.2	21.7 ± 7.0	t = 3.38	**0.001**
Median (IQR)	30 (24–36)	21 (16–28)	—	—
Range	12–48	8–42	—	—
Time Categories, n (%)			$\chi^2 = 8.92$	**0.012**

<18 hours	4 (12.9%)	16 (34.0%)	—	—
18–24 hours	6 (19.4%)	14 (29.8%)	—	—
25–36 hours	12 (38.7%)	12 (25.5%)	—	—
>36 hours	9 (29.0%)	5 (10.6%)	—	—
Mean Difference (95% CI)	—	−7.7 (−12.2 to −3.2)	—	—

t = Independent Student's t-test; χ^2 = Chi-square test; IQR = Interquartile Range; CI = Confidence Interval. A p-value < 0.05 was considered statistically significant. Analysis includes only participants who achieved cessation within 48 hours.

Beyond higher success rates, combination therapy achieved a significantly faster clinical response (**Table 3**). The mean time to cessation was reduced from 29.4 ± 8.2 hours (median 30, IQR 24–36) in Group A to 21.7 ± 7.0 hours (median 21, IQR 16–28) in Group B (p = 0.001), with a mean difference of −7.7 hours (95% CI −12.2 to −3.2). Early response (<18 hours) was notably more frequent with combination therapy (34.0% [16/47] vs 12.9% [4/31]), while prolonged cessation times (>36 hours) were less common (10.6% [5/47] vs 29.0% [9/31], p = 0.012). These results highlight not only improved effectiveness but also a substantially faster therapeutic action with the addition of progesterone.

Maternal side effects were generally mild in both groups. As illustrated in **Figure 2**, In Group A (nifedipine alone), 7 participants (10.8%) experienced hypotension ($\chi^2 = 0.31$, p = 0.57), 6 (9.2%) headaches ($\chi^2 = 0.12$, p = 0.73), and 5 (7.7%) flushing ($\chi^2 = 0.11$, p = 0.74). In Group B (nifedipine + progesterone), 9 participants (13.8%) had hypotension, 7 (10.8%) headache, 6 (9.2%) flushing, and 5 (7.7%) vaginal discomfort ($\chi^2 = 5.00$, p = 0.03). Chi-square analysis confirmed that only vaginal discomfort was significantly higher in the combination group, while other side effects were comparable between groups. No serious adverse events occurred in either group.

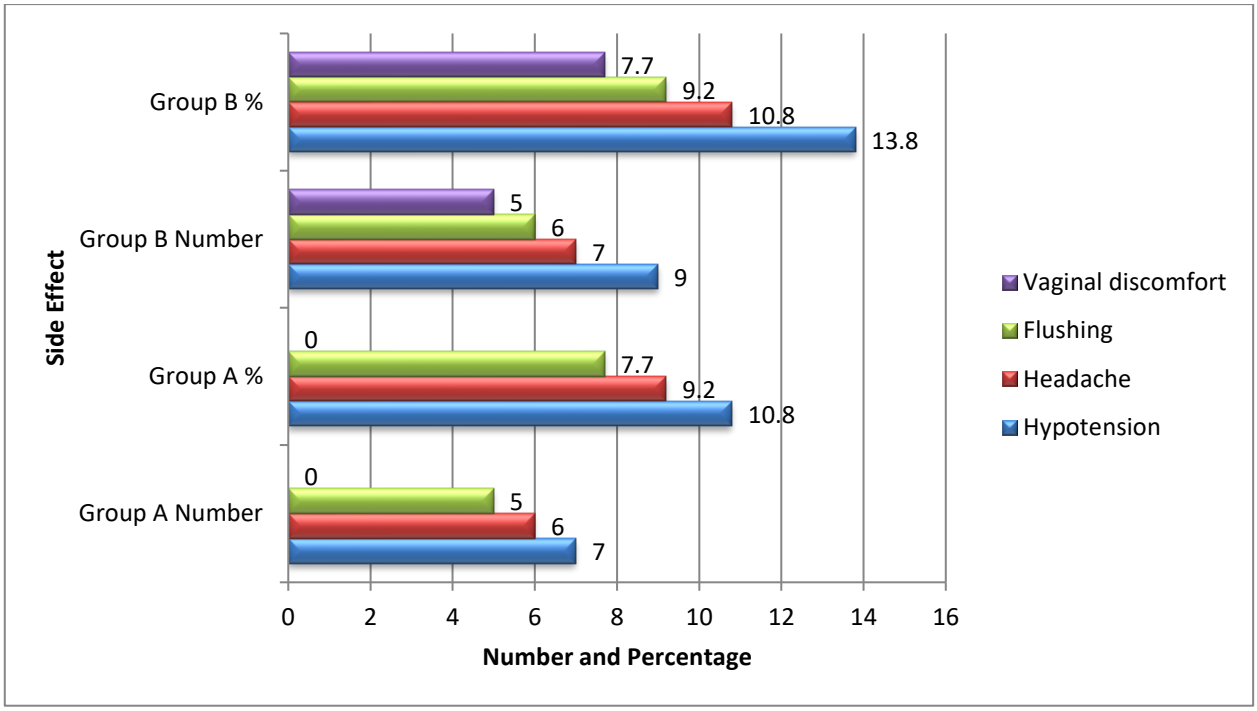

Figure 2: Maternal Side Effects

Table 4: Maternal Side Effects Profile

Side Effect		Group A (n=65)	Group B (n=65)	Statistical Test	p-value	Relative Risk (95% CI)
Nifedipine-Related Effects	Hypotension	7 (10.8%)	9 (13.8%)	$\chi^2 = 0.31$	0.58	1.28 (0.50–3.28)
	Tachycardia	4 (6.2%)	5 (7.7%)	$\chi^2 = 0.15$	0.70	1.25 (0.35–4.44)
	Headache	6 (9.2%)	7 (10.8%)	$\chi^2 = 0.12$	0.73	1.17 (0.40–3.42)
	Flushing	5 (7.7%)	6 (9.2%)	$\chi^2 = 0.11$	0.74	1.20 (0.38–3.79)
	Dizziness	3 (4.6%)	4 (6.2%)	$\chi^2 = 0.18$	0.67	1.33 (0.30–5.87)
	Nausea	2 (3.1%)	3 (4.6%)	$\chi^2 = 0.21$	0.65	1.50 (0.26–8.68)
Progesterone-Related Effects	Vaginal discomfort	0 (0%)	5 (7.7%)	$\chi^2 = 5.00$	0.026	—
	Bloating	1 (1.5%)	4 (6.2%)	$\chi^2 = 1.87$	0.17	4.00 (0.46–34.94)

	Diarrhea	0 (0%)	2 (3.1%)	$\chi^2 = 2.03$	0.16	—
Any Side Effect		18 (27.7%)	28 (43.1%)	$\chi^2 = 3.42$	0.064	1.56 (0.97–2.50)
Multiple Side Effects (≥2)		5 (7.7%)	8 (12.3%)	$\chi^2 = 0.82$	0.37	1.60 (0.54–4.73)
Serious Adverse Events		0 (0%)	0 (0%)	—	—	—
Treatment Discontinuation Due to Side Effects		1 (1.5%)	2 (3.1%)	$\chi^2 = 0.34$	0.56	2.00 (0.18–21.90)

χ^2 = Chi-square test; RR = Relative risk; CI = Confidence interval. A p-value < 0.05 was considered statistically significant.

The combination therapy was generally well tolerated. The overall incidence of any side effect was slightly higher in Group B (43.1%, 28/65) compared to Group A (27.7%, 18/65), but this difference did not reach statistical significance (p = 0.064; RR 1.56, 95% CI 0.97–2.50; **Table 4**). Notably, vaginal discomfort related to progesterone was reported in 7.7% (5/65) of women in Group B and was absent in Group A (0/65, p = 0.026), representing the only statistically significant adverse effect. Other nifedipine-related effects such as hypotension (13.8%, 9/65), headache (10.8%, 7/65), and tachycardia (7.7%, 5/65) were mild and comparable between groups. No serious adverse events occurred, and treatment discontinuation due to side effects was rare (1.5% in Group A vs 3.1% in Group B).

Table 5: Secondary Maternal and Neonatal Outcomes (n = 130)

Outcome	Group A (n=65)	Group B (n=65)	Statistical Test	p-value
Need for Rescue Tocolysis, n (%)	15 (23.1%)	8 (12.3%)	$\chi^2 = 2.78$	0.095
Delivery within 7 days, n (%)	22 (33.8%)	14 (21.5%)	$\chi^2 = 2.51$	0.11
Delivery within 48 hours, n (%)	8 (12.3%)	3 (4.6%)	$\chi^2 = 2.45$	0.12
Prolongation of Pregnancy (days), Mean ± SD	18.5 ± 12.3	24.2 ± 14.1	t = 2.51	0.013
Birth weight (grams), Mean ± SD	2450 ± 420	2680 ± 380	t = 3.28	0.001
NICU admission, n (%)	19 (29.2%)	12 (18.5%)	$\chi^2 = 2.14$	0.14
Respiratory distress syndrome, n (%)	8 (12.3%)	5 (7.7%)	$\chi^2 = 0.91$	0.34

Neonatal sepsis, n (%)	3 (4.6%)	2 (3.1%)	$\chi^2 = 0.21$	0.65
Neonatal death, n (%)	1 (1.5%)	0 (0%)	$\chi^2 = 1.01$	0.32

t = Student's t-test; χ^2 = Chi-square test; SD = Standard deviation; NICU = Neonatal Intensive Care Unit. A p-value < 0.05 was considered statistically significant.

Combination therapy resulted in significant prolongation of pregnancy, with Group B having a mean extension of 24.2 ± 14.1 days versus 18.5 ± 12.3 days in Group A (p = 0.013). Correspondingly, neonates in Group B had higher birth weights (2680 ± 380 g vs 2450 ± 420 g, p = 0.001). Other outcomes such as the need for rescue tocolysis (12.3%, 8/65 vs 23.1%, 15/65, p = 0.095) and NICU admission (18.5%, 12/65 vs 29.2%, 19/65, p = 0.14) favored combination therapy numerically, but differences were not statistically significant. Rates of respiratory distress syndrome, neonatal sepsis, and neonatal death were low and comparable across groups (**Table 5**).

Table 6: Stratified Analysis by Risk Factors

Subgroup		Group A Success Rate	Group B Success Rate	p-value	Interaction p-value
Age	<25 years	42.9% (6/14)	68.8% (11/16)	0.18	0.89
	25–30 years	50.0% (14/28)	72.4% (21/29)	0.085	
	>30 years	47.8% (11/23)	75.0% (15/20)	0.074	
Previous Preterm Birth	Yes	37.5% (3/8)	66.7% (6/9)	0.22	0.76
	No	49.1% (28/57)	73.2% (41/56)	0.006	
Cervical Dilation	≤2 cm	57.1% (16/28)	84.6% (22/26)	0.027	0.42
	>2–4 cm	40.5% (15/37)	64.1% (25/39)	0.038	

p-values from Chi-square test or Fisher's exact test where appropriate. Interaction p-values test for effect modification between subgroups.

Subgroup analyses confirmed that the superiority of combination therapy was consistent across maternal age, parity, and cervical dilation categories (**Table 6**). Women without previous preterm birth had markedly higher success with combination therapy (73.2%, 41/56 vs 49.1%, 28/57, p = 0.006). Participants with cervical dilation ≤2 cm benefited the most, achieving success in 84.6%

(22/26) of Group B vs 57.1% (16/28) of Group A, p = 0.027. Interaction p-values were all non-significant, indicating that these baseline characteristics did not modify the treatment effect.

DISCUSSION

The proportion of contraction cessation of the uterus in 48 hours was higher in women who were treated with nifedipine and progesterone in this research than when they were treated with nifedipine on its own. The combination group also showed shorter mean time to cessation and hence a faster clinical response. The side effects of the maternal were mostly mild and vaginal discomfort was the only side effect that was more pronounced in the combination group because of vaginal progesterone. Parity and gestational age stratification did not significantly change overall results, which reinforced the consistency of the results.

These results support the data indicating a beneficial effect of calcium channel blockers as tocolytics that have lower maternal side effects than the beta-adrenergic agonists [11,12]. Progesterone appears to enhance uterine quiescence and reduce preterm contractions, likely due to its dual role in inhibiting contractility and supporting myometrial structural integrity [13,14]. Studies evaluating combination therapy have reported higher success rates and shorter time to cessation of contractions compared to monotherapy, aligning with the present study's observations [15]. Combination therapy may also reduce the need for rescue tocolytics and allow timely administration of corticosteroids for fetal lung maturation [16].

Furthermore, by extending gestation and lowering the rate of low birth weight and neonatal intensive care admissions, combination treatment has been shown in several studies to improve newborn outcomes [17-19]. Observational data also suggest that using progesterone with nifedipine may decrease the frequency of recurrent preterm labor episodes in high-risk pregnancies [20]. Furthermore, combination therapy has been associated with better maternal tolerance and fewer dose adjustments of nifedipine compared to monotherapy [21,22].

While nifedipine alone is effective, its combination with progesterone was associated with improved outcomes without substantial increases in serious maternal adverse events [23]. Mild side effects, such as transient hypotension, headache, or vaginal discomfort, were consistent with known pharmacological profiles [23, 24]. These results indicate that progesterone supplement to baseline nifedipine therapy could maximize the clinical outcomes and even decrease the rates of preterm births [25].

The generalizability of the study was limited by the fact that this study was conducted in only one tertiary care facility. The follow-up was immediate with a follow-up of the contraction stoppage within 48 hours and no evaluation of the long-term maternal or neonatal outcome. Several gestations and preterm membrane rupture were not covered and could only be used in these populations. It is recommended that in the future multicentric studies be carried out with larger samples and longer follow-ups to determine the effect on the maternal safety, pregnancy duration, and postnatal outcomes. The study might also look into the best strategies of dosing and alternative formulations of progesterone with tocolytics.

CONCLUSION

Nifedipine combined with progesterone was more effective than nifedipine when used on women who were at risk of preterm labor to stop uterine contractions in a quick manner. It reduced the time to cessation of contraction and enhanced the overall treatment efficacy and unfavorable maternal side effects were also very mild and manageable. These results indicate that the combination therapy can be taken as a safe and effective method in order to optimize the management of preterm labor and enhance the maternal and neonatal outcomes.

LIST OF ABBREVIATIONS

BMI Body Mass Index

CI Confidence Interval

CTG Cardiotocography

h Hour(s)

IM Intramuscular

IQR Interquartile Range

NICU Neonatal Intensive Care Unit

OR Odds Ratio

PTL Preterm Labor

RDS Respiratory Distress Syndrome

RR Relative Risk

SD Standard Deviation

Zα/2 Z-score for significance level

Zβ Z-score for statistical power

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None.

CONFLICT OF INTEREST

None.

ETHICAL APPROVAL

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board and Ethics Committee (IRB&EC) of Shifa International Hospitals (Approval No. 131-25). Written informed consent was obtained from all participants prior to enrollment. All patient data were de-identified and maintained with strict confidentiality in compliance with institutional data protection policies.

AUTHORS' CONTRIBUTION

All authors contributed equally as per ICMJE.

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