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Original Research Article

Efficacy of oral nifedipine versus intravenous isoxsuprine hydrochloride in prevention of preterm labour: a prospective randomized parallel group open-label study

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ABSTRACT

Background: Preterm labour is a leading cause of perinatal morbidity and mortality. Tocolytics delay delivery to allow corticosteroid administration, but the optimal agent remains debated. Thus, we compared the tocolytic efficacy of oral Nifedipine and intravenous Isoxsuprine hydrochloride in prevention of preterm labour.
Methods: This prospective randomized parallel group open-label study was conducted over 18 months (June 2024 to November 2025) in the labour ward of S.N.R District Hospital, Kolar, Karnataka. Pregnant women at 28-37 weeks with preterm labour, intact membranes, cervical dilatation<3 cm, and no prior tocolytics were randomized into Group 1 (intravenous Isoxsuprine) or Group 2 (oral Nifedipine). Primary outcomes were tocolytic success and prolongation of pregnancy; secondary outcomes included Bishop score, mode of delivery, birth weight, APGAR scores, NICU admission, maternal adverse events (AEs) and hemodynamic changes.
Results: Pregnancy prolongation was significantly longer with Nifedipine than Isoxsuprine (24.29±8.64 vs 20.20±9.61 days; p=0.027). Bishop score was higher in the isoxsuprine group (5.56±2.81 vs. 4.42±2.56; p=0.036). Tocolytic success was higher with nifedipine (94.00% vs 78.00%; p=0.040). APGAR scores at 5 minutes were significantly higher (8.04±0.66 vs 7.19±1.51.; p<0.001) and NICU admissions lower (36.00% vs. 16.00%; p=0.040) with Nifedipine. Mode of delivery, birth weight, APGAR at 1-minute, maternal AEs, and hemodynamic changes were comparable.
Conclusions: Oral Nifedipine is more effective than intravenous Isoxsuprine for preventing preterm labour, with better pregnancy prolongation, success rates, and neonatal outcomes.

Keywords: Obstetric Labor, Premature, Nifedipine, Isoxsuprine, Tocolytic agents, Pregnancy outcome

INTRODUCTION

Preterm labour (PTL) remains the leading cause of perinatal morbidity and mortality worldwide.[1] Globally, around 13.4 million babies are born preterm each year, accounting for over 10% of all live births, with over one million succumbing to complications of prematurity annually.[2] India bears a disproportionate burden and ranks first globally, accounting for 23% of all preterm births worldwide, with an estimated 3.02 million preterm deliveries annually.[2] The prevalence of preterm birth in India ranges from 6.1% to 28.25% across different regions.[3]

Preterm infants are at increased risks of various short- and long-term complication.[4,5] In developing countries, these complications are compounded by limited access to neonatal intensive care, making effective tocolysis

critical to allow antenatal corticosteroid administration and transfer to higher-level care facilities.[5] Clinical practice guidelines recommend short-term tocolysis to improve outcomes of preterm birth.[6] Beta-adrenergic agonists such as isoxsuprine hydrochloride and calcium channel blockers such as nifedipine are frequently used tocolytics.[5] Isoxsuprine delays delivery for 48 hours to 7 days, but its use is limited by maternal tachycardia, hypotension, and rare pulmonary oedema, with a reported incidence of 0.5% over a 7-year interval.[7,8] Nifedipine inhibits uterine contractility by blocking calcium influx through L-type channels and is widely used as a first-line tocolytic agent because of its oral route and favourable safety profile.[9,10] A meta-analysis demonstrated that nifedipine was more effective than beta-agonists in delaying delivery at least 48 hours and was interrupted significantly less often because of adverse events (AEs).[11]

In a randomised study, Ray and Kshirsagar reported that nifedipine achieved an overall success rate of 86.8% compared with 80% for isoxsuprine, with significantly greater pregnancy prolongation, higher neonatal birth weight, and fewer maternal AEs.[12] Rayamajhi and Pratap found successful tocolysis in 81.25% (nifedipine) versus 70% (isoxsuprine) of patients, with mean pregnancy prolongation of 25.19 days and 19.18 days, respectively.[13] Other studies from India have reported similar findings with nifedipine consistently demonstrating higher success rate, greater prolongation of pregnancy, and lower AEs than isoxsuprine.[7,14-17] However, these studies are from tertiary care institutes and their findings cannot be generalised to district-level Indian settings and studies from southern part of India are scarce. Thus, this study compared the tocolytic effect of oral nifedipine and intravenous isoxsuprine hydrochloride in the prevention of preterm labour.

METHODS

Study design and ethics

This prospective randomized parallel group study was conducted over a period of 18 months (June 2024 to November 2025) at the Department of Obstetrics and Gynaecology of S.N.R District Hospital, Kolar, Karnataka. The study was approved by the Institutional Ethics Committee and written informed was obtained from the patients.

Study population

The study included hemodynamically stable, singleton pregnant women with gestational age between 28 and 37 weeks, presence of intact membranes, uterine contractions (at least one contraction every 10 minutes) and cervical changes with cervical dilatation<3 cm, no prior administration of tocolytics in the preceding 7 days and absence of foetal distress. While women with advanced cervical dilatation (>3 cm) with strong uterine contractions; multiple gestations; complications, including pre-eclampsia, eclampsia, chorioamnionitis, antepartum haemorrhage, polyhydramnios and premature preterm rupture of membranes (PPROM); associated medical disorders such as thyroid disorders, diabetes mellitus in pregnancy, heart disease, chronic obstructive pulmonary disease, bronchial asthma, and renal disorders; maternal contraindications to tocolysis (drug-specific); as well as intrauterine growth restriction (IUGR), intrauterine foetal demise (IUFD), congenital anomalies, or foetal distress were excluded.

Data collection

Patient data on demographic characteristics, including maternal age, parity, gestational age, educational status, and occupation; and clinical characteristics, including presenting symptoms, obstetric history, risk factors for preterm labour, Bishop score, and baseline maternal and foetal hemodynamic parameters were recorded. Participants were followed until delivery and outcomes, both maternal and neonatal, including duration of pregnancy prolongation, gestational age at delivery, mode of delivery, neonatal birth weight, APGAR scores, NICU admission, neonatal morbidity, and mortality, were recorded.

Study protocol

Following enrolment, a detailed history was taken and vital parameters were recorded. Subsequently, general physical examination followed by cardiovascular system and respiratory system examination was performed. Per abdomen examination was done to note the uterine height, presentation, position, lie of the foetus, liquor volume, foetal heart rate. Uterine contractions were assessed clinically by abdominal palpation for 20 minutes initially and subsequently for 10 minutes every 30 minutes for 2 hours. Per speculum examination was performed to assess vaginal discharge, bleeding, or leakage of liquor. Per vaginal examination was conducted to evaluate cervical dilatation, effacement, consistency, position, membrane status and station of the presenting part.

Routine laboratory investigations including complete hemogram, blood grouping and Rh typing, random blood sugar, renal function tests, HIV, HBsAg and VDRL were performed. Women with gestational age<34 weeks received two doses of intramuscular betamethasone 12 mg, 24 hours apart. Maternal pulse rate, blood pressure, foetal heart rate, uterine contractions, and AEs were monitored half-hourly. Treatment was discontinued if maternal tachycardia (>120 bpm), hypotension (drop in diastolic BP ≥15 mmHg), fever (>100°F) or rupture of membranes occurred.

Randomisation and blinding

Patients were randomly allocated in a 1:1 ratio into two either of the treatment groups using a computer-generated random number. Patients and surgeon were not blinded to

study treatment. Patients in the Isoxsuprine group received Isoxsuprine infusion (40 mg in 500 ml crystalloid) starting at 0.04 mg/min and titrated up to 0.24 mg/min based on uterine activity and maternal tolerance. Once uterine quiescence was achieved, oral isoxsuprine 10 mg was continued 8-hourly for 7 days. Patients in the Nifedipine group received a loading dose of oral Nifedipine 20 mg was administered, followed by 20 mg every 6 hours for at least 48 hours or until cessation of contractions. Maintenance therapy consisted of Nifedipine 10 mg orally every 8 hours for 7 days.

Study outcomes

Primary outcome was treatment success and duration of pregnancy prolongation, with success defined as abolition of uterine contractions, no progression of cervical dilatation and absence of recurrent contractions within 48 hours of cessation of therapy. While failure was defined as persistence of contractions despite maximum dosage or occurrence of significant maternal or foetal AEs necessitating discontinuation. Secondary outcomes were gestational age at delivery, mode of delivery, neonatal birth weight, APGAR scores, NICU admission, as well as neonatal morbidity and mortality. Moreover, active surveillance was performed to noted anticipated AEs.

Sample size calculation

Sample size was calculated based on the difference in success rates between isoxsuprine (75%) and nifedipine (96%) reported by Nagendrappa et al.[15] With a power of 80% and a confidence level of 95%, the calculated sample size was 45 patients per group. Considering a 10% nonresponse or loss to follow-up, 50 patients were included in each group.

Statistical analysis

Data was analysed using SPSS version 23.0. Continuous variables were expressed as mean±standard deviation, and categorical variables as frequency and percentage. Independent t-test and Chi-square test were used for comparison between groups. A $p<0.05$ was considered statistically significant.

RESULTS

Women in the Isoxsuprine and Nifedipine groups had a men age of 25.66±2.88 and 25.16±2.93 years and gestational age of 31.9±2.42 and 31.22±2.36 weeks, respectively.

Table 1. Baseline demographic and clinical characteristics.

Characteristics	Isoxsuprine (n=50)	Nifedipine (n=50)	P value
Age, years, Mean±SD	25.66±2.88	25.16±2.93	0.392
Parity, N (%)			
Multiparous	27 (54.00%)	23 (46.00%)	0.549
Nulliparous	23 (46.00%)	27 (54.00%)	
Educational status, n (%)			
Graduate/Postgraduate	21 (42.00%)	21 (42.00%)	0.966
Secondary/SSC	17 (34.00%)	16 (32.00%)	
Elementary	12 (24.00%)	13 (26.00%)	
Occupation, N (%)			
Housewife	35 (70.00%)	37 (74.00%)	0.824
Working	15 (30.00%)	13 (26.00%)	
Symptoms, N (%)			
Abdominal pain	50 (100.00%)	50 (100.00%)	0.829
Associated complaints	7 (14.00%)	5 (10.00%)	
Risk factors, N (%)			
Infections	16 (32.00%)	15 (30.00%)	0.821
Substance abuse	12 (24.00%)	9 (18.00%)	
Anaemia	9 (18.00%)	6 (12.00%)	
Previous preterm	7 (14.00%)	4 (8.00%)	
Abortion	7 (14.00%)	10 (20.00%)	
Multiple pregnancies	5 (10.00%)	4 (8.00%)	
Cervical incompetence	5 (10.00%)	4 (8.00%)	
Uterine malformation	3 (6.00%)	2 (4.00%)	
Previous suction and evacuation	2 (4.00%)	6 (12.00%)	
Gestational age, weeks, Mean±SD	31.9±2.42	31.22±2.36	0.158

Majority of the patients in the Isoxsuprine and Nifedipine groups were multiparous and nulliparous (each 54.00%), had graduate/post-graduate education (each 42.00%), were housewives (70.00% and 74.00%, respectively), abdominal pain (each 42.00%), infection as the risk factor (32.00% and 30.00%, respectively). The groups were comparable in age (25.66±2.88 vs. 25.16±2.93 years; p=0.392), parity (p=0.549), education (p=0.966), occupation (p=0.824), gestational age (p=0.158), presenting symptoms (p=0.829), and risk factors (p=0.821; Table 1 above)

Prolongation of pregnancy was significantly shorter in the Isoxsuprine group compared to the Nifedipine group (20.20±9.61 vs. 24.29±8.64 days; p=0.027). Bishop score was significantly higher in the Isoxsuprine group than the Nifedipine group (5.56±2.81 vs. 4.42±2.56; p=0.036). The overall success rate was significantly lower in the Isoxsuprine group (78.00% vs. 94.00%; p=0.040; Table 2).

Table 2: Comparison of obstetric outcomes.

Outcome	Isoxsuprine (n=50)	Nifedipine (n=50)	P
Prolongation of pregnancy, days, Mean±SD	20.20±9.61	24.29±8.64	0.027
Bishop score, Mean±SD	5.56±2.81	4.42±2.56	0.036
Overall rate, n (%)			
Success	39 (78.00%)	47 (94.00%)	0.040
Failure	11 (22.00%)	3 (6.00%)	

Table 3: Comparison of delivery and neonatal outcomes.

Outcome	Isoxsuprine (n=50)	Nifedipine (n=50)	P
Mode of delivery, n (%)			
Vaginal	36 (72.00%)	32 (64.00%)	0.776
LSCS	14 (28.00%)	18 (36.00%)	
Birth weight (kg), Mean±SD	2.22±0.55	2.22±0.57	1.000
APGAR score, Mean±SD			
1 min	5.43±0.93	5.14±1.01	0.139
5 min	7.19±1.51	8.04±0.66	<0.001

Table 4: Comparison between hemodynamic variables pre- and post-drug administration.

Hemodynamic parameters	Pre-administration (n=50)	Post-administration (n=50)	P
Isoxsuprine			
SBP (mmHg)	121.96±6.67	112.72±6.67	<0.001
DBP (mmHg)	77.16±4.77	69.56±4.75	<0.001
Maternal pulse rate (bpm)	86.56±3.15	111.76±8.29	<0.001
Foetal pulse rate (bpm)	134.5±3.16	140.02±4.74	<0.001
Nifedipine			
SBP (mmHg)	121.96±6.67	113.64±11.80	<0.001
DBP (mmHg)	77.16±4.77	67.92±5.22	<0.001
Maternal pulse rate (bpm)	86.56±3.15	112.34±7.63	<0.001
Foetal pulse rate (bpm)	134.5±3.16	139.92±5.05	<0.001

SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure

Majority of the patients in the Isoxsuprine and the Nifedipine groups had vaginal delivery (72.00% and 64.00%, respectively), with no significant difference between the groups (p=0.776). Moreover, the Isoxsuprine and the Nifedipine groups had comparable birth weight (2.22±0.55 vs. 2.22±0.57 kg, respectively; p=1.000) and APGAR score at 1-minute (5.43±0.93 and 5.14±1.01, respectively; p=0.139), while APGAR score at 5-minute was significantly higher in the Nifedipine group than the Isoxsuprine group (8.04±0.66 vs 7.19±1.51.; p<0.001; Table 3).

Administration of Isoxsuprine and Nifedipine resulted in significant fall in SBP and DBP (both p<0.001) with

significant rise in maternal and foetal pulse rate (both p<0.001; Table 4).

Change in the hemodynamic variables before and after administration of Isoxsuprine and Nifedipine revealed that both the groups were comparable regarding SBP (p=0.585), DBP (p=0.097), maternal pulse rate (p=0.622) and foetal pulse rate (p=0.893; Table 5).

NICU admissions were significantly higher in the Isoxsuprine group compared to the Nifedipine group (36.00% vs. 16.00%; p=0.040). Maternal AEs were comparable between the Isoxsuprine and the Nifedipine groups (p=0.987), with facial flushing (32.00% vs. 22.00%) and palpitations (16.00% vs. 10.00%) being most common (Table 6).

Table 5: Changes in the hemodynamic variables pre- and post-drug administration.

Hemodynamic parameters	Isoxsuprine (n=50)	Nifedipine (n=50)	P
SBP (mmHg)	-9.24±3.82	-8.32±11.23	0.585
DBP (mmHg)	-7.6±4.58	-9.24±5.18	0.097
Maternal pulse rate (bpm)	25.2±5.96	25.78±5.76	0.622
Foetal pulse rate (bpm)	5.52±2.40	5.42±4.63	0.893

SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure

Table 6: Neonatal intensive care admission and maternal adverse effects.

Outcome	Isoxsuprine (n=50)	Nifedipine (n=50)	P
NICU admission, N (%)	18 (36.00%)	8 (16.00%)	0.040
Adverse events, N (%)			
Facial flushing	16 (32.00%)	11 (22.00%)	0.987
Palpitations	8 (16.00%)	5 (10.00%)	
Tachycardia	3 (6.00%)	2 (4.00%)	
Nausea	3 (6.00%)	1 (2.00%)	
Hypotension	2 (4.00%)	1 (2.00%)	
Vomiting	2 (4.00%)	1 (2.00%)	
Headache	1 (2.00%)	2 (4.00%)	

NICU: Neonatal Intensive Care Unit

DISCUSSION

Preterm labour remains the leading cause of perinatal morbidity and mortality, and tocolytic agents are the cornerstone of acute management; however, the optimal agent continues to be debated, particularly in resource-limited settings where beta-agonists such as isoxsuprine is widely used.[9] The principal findings of the study suggest that oral Nifedipine is superior to intravenous Isoxsuprine in prolongation of pregnancy (24.29±8.64 vs. 20.20±9.61 days; p=0.027) and overall tocolytic success (94.00% vs. 78.00%; p=0.040), with significantly higher 5-minute APGAR score and lower NICU admissions in the Nifedipine group.

These findings are consistent with various Indian studies. Ray and Kshirsagar reported pregnancy prolongation of 24.89±13.66 days with nifedipine versus 19.92±11.66 days with isoxsuprine, with a success rate of 86.8% versus 80.0%.[12] Seema and Pujar observed mean prolongation of 31.68 days with nifedipine versus 27.54 days with isoxsuprine, and success rates of 96% versus 75%, closely consistent with the present results. Singh et al demonstrated that nifedipine was twice as effective as isoxsuprine as a tocolytic agent (p=0.006), with greater efficacy in early-diagnosed preterm labour.[17,18] In the present study, higher Bishop score in the Isoxsuprine group (5.56±2.81 vs. 4.42; p=0.036) likely reflects a more advanced cervical state at presentation, contributing to the lower success rate observed; this is consistent with evidence that nifedipine exerts superior efficacy when initiated early.

Regarding maternal haemodynamic effects, the present study found that both agents significantly reduced systolic and diastolic blood pressure and increased maternal and foetal pulse rates, with no significant intergroup differences in the magnitude of change. Similarly, Ray and Kshirsagar reported that Isoxsuprine caused greater lowering of SBP and DBP and higher foetal pulse rate compared with nifedipine (p<0.05).[12] This haemodynamic profile is attributable to the beta-2 adrenergic agonist action of isoxsuprine, which causes vasodilation and reflex tachycardia, whereas nifedipine, as a calcium channel blocker, primarily inhibits smooth muscle contraction with a comparatively milder chronotropic effect.[19,10] A Cochrane review of calcium channel blockers for inhibiting preterm labour concluded that nifedipine is associated with fewer maternal side effects than beta-mimetics.[20] Though greater proportion of patients in the Isoxsuprine group had facial flushing, palpitations, tachycardia, nausea and hypotension, the differences did not reach statistical significance, consistent with the findings of Jain et al who reported similar maternal side-

effect profiles in both groups with hypotension and tachycardia being the commonest.[14]

Neonatal outcomes, in the present study, favoured Nifedipine, with significantly higher APGAR scores at 5 minutes (8.04±0.66 vs. 7.19±1.51; p<0.001) and lower NICU admissions (16.00% vs. 36.00%; p=0.040). Similarly, Ray et al found that none (0.0%) of the neonates in the nifedipine group had an abnormal APGAR score (<7) at 5 minutes, compared with the isoxsuprine group (10.0%), and reported lower rates of tachycardia and respiratory distress syndrome in the nifedipine group.[12] A systematic review and meta-analysis comparing nifedipine with other tocolytics found that nifedipine was superior to ritodrine (beta-2 adrenergic agonist) for prolongation of pregnancy and was associated with better neonatal outcomes.[21,22] The lower NICU admission rate with nifedipine may be attributed to the longer pregnancy prolongation achieved, allowing greater foetal maturation. However, a network meta-analysis by Wilson et al. reported that all tocolytics are probably effective in delaying preterm birth compared with placebo, with calcium channel blockers showing a favourable safety profile.[23]

The comparable mode of delivery and birth weight between groups in the present study is consistent with the findings of Gupta et al., who reported no significant differences in birth weight, APGAR scores at 5 minutes, or NICU admission between Nifedipine and Isoxsuprine groups.[24] The lack of significant difference in APGAR scores at 1 minute, in the present study, may reflect the acute transition period at birth, which is influenced by multiple intrapartum factors beyond tocolytic therapy.

Limitations

This study has certain limitations. It was conducted at a single centre, limiting generalizability. The sample size was relatively small, reducing statistical power to detect minor differences. The open-label design may have introduced performance and detection bias, particularly for subjective outcomes such as AEs and assessment of Bishop score. Duration of maintenance therapy and dosing protocols differed between groups, which may have influenced outcomes. Long-term neurodevelopmental outcomes were not assessed. Additionally, the follow-up period was limited to the immediate neonatal period, and potential confounding factors such as socioeconomic status and access to antenatal care were not fully controlled.

CONCLUSION

Oral Nifedipine was more effective than intravenous Isoxsuprine hydrochloride in preventing preterm labour, achieving significantly longer pregnancy prolongation, higher success rates, and better APGAR scores at 5 minutes with fewer NICU admission. Maternal haemodynamic changes and AE profiles were comparable between groups. These findings support Nifedipine as a safer and more efficacious first-line tocolytic agent in resource-limited settings, though larger multicentre trials with long-term neonatal follow-up are warranted to confirm these findings.

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