International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Safety and Effectiveness of Nifedipine vs Isosuxprine in Preterm Labor: Open Labelled Randomized Parallel Group Study

Dr. Prachi Gupta[1], Dr. Dipti C Parmar[2], Dr. Vidhi Thakkar[3]

[1]MS, Department of Obstetrics and Gynaecology, Government Medical college Bhavnagar, Gujarat, India
[2,3]MS Obstetrics and Gynaecology, Government Medical college Bhavnagar, Gujarat, India

OPEN ACCESS

Corresponding Author:

Dr. Prachi Gupta
MS, Department of Obstetrics and Gynaecology, Government Medical college Bhavnagar, Gujarat, India

Received: 15-04-2026
Accepted: 08-05-2026
Available online: 31-05-2026

ABSTRACT

Background: The primary aim of this study is to compare the safety and effectiveness of Nifedipine and Isosuxprine hydrochloride in the management of preterm labor.
Methods: All participants were assigned to Nifedipine and Isosuxprine group. They were closely monitored for both maternal and fetal well-being. All statistical analyses were performed using SPSS (Statistical Package for the Social Sciences) version 25.0.
Results: The prolongation of pregnancy was upto 7 days seen more in the Nifedipine group. NICU admissions were slightly higher in the Isosuxprine group. . The success rate is slightly higher in the Nifedipine group compared to the Isosuxprine group.
Conclusions: In This study it was found that Nifedipine group has emerged as a more advantageous option compared to Isosuxprine, showing higher efficacy.

Keywords*: Nifedipine, Isosuxprine, Preterm labor.*

INTRODUCTION

Preterm labor, a pivotal concern in obstetrics, is the onset of labor prior to 37 weeks of gestation.[1] This premature initiation of labor poses significant risks to both the mother and the foetus, leading to a spectrum of short and long-term health issues for the newborn, including respiratory distress syndrome, intraventricular haemorrhage, and developmental delays, among others.

The global incidence of preterm birth is 11% of all pregnancies resulting in preterm delivery, highlighting a substantial public health concern. [1]

One of the cornerstone strategies in managing preterm labor involves the use of tocolytics—agents employed to delay labor and extend pregnancy, even if temporarily, to allow for the administration of antenatal corticosteroids to accelerate fetal lung maturity and to transfer the pregnant woman to a facility equipped for premature neonates

Tocolytic Therapy

Tocolytics, are the drugs that suppress uterine contractions, thereby delaying preterm delivery.

Nifedipine, a calcium channel blocker, functions by inhibiting calcium influx into smooth muscle cells, leading to uterine relaxation.

Isosuxprine, a beta-adrenergic agonist, works by stimulating beta-adrenergic receptors, resulting in uterine muscle relaxation.

This study seeks to provide evidence-based guidance for clinicians in selecting the most appropriate tocolytic agent, ultimately improving maternal and neonatal outcomes in preterm labor management.

AIM & OBJECTIVES

AIM

The primary aim of this study is to compare the safety and effectiveness of Nifedipine and Isosuxprine hydrochloride in the management of preterm labor.

OBJECTIVES

Primary objective:

- To determine the effectiveness of Nifedipine and Isosuxprine hydrochloride with respect to days of gestation gained by tocolytic therapy.

Secondary objective:

- To assess the fetomaternal adverse effects of Nifedipine and Isosuxprine hydrochloride.
- To assess the neonatal outcome of Nifedipine and Isosuxprine hydrochloride.

MATERIALS AND METHODS

Study Design

With the institutional ethics committee's approval ,the single centered, hospital based, prospective, comparative study was conducted in Department of Obstetrics and Gynaecology at a tertiary care hospital Gopinath Maternity Home ,Sir t hospital, Bhavnagar, Gujarat.over period of 10 months(21/07/2023 to 21/03/2024). The study was designed as an open-labelled, randomized, parallel group trial to compare the safety and effectiveness of Nifedipine versus Isosuxprine in the management of preterm labor.

Ethical Considerations

Ethical approval was obtained prior to the commencement of the study. Informed and written consent was obtained from all participants after explaining the study's purpose, procedures, potential risks, and benefits.

One hundred eighty pregnant women at 28–36+6 days weeks of gestation, with regular uterine contractions(>=4 contraction in 20 min or >=8 contractions in 60 min), cervical dilatation ≤3 cm, and cervical effacement ≤50% with intact membrane, admitted to the labor room complaining of preterm labor pain with no previous administration of tocolytics in the last 7 days were included in the study. These women were observed to ensure that they were in preterm labor by tracking any cervical change and/or descent of the presenting part.

Study Participants

Inclusion Criteria

- Singleton pregnancy
- Maternal age between 21 and 40 years
- Vertex presentation
- Intact membranes
- Presence of contractions equal to or greater than 4 in 20 minutes
- Cervical dilation between 1 cm and 3 cm

Exclusion Criteria

- Maternal cardiovascular diseases (Hypertension, Myocarditis, Cardiomyopathy, Congenital heart defects)
- Known cases of Diabetes Mellitus
- Bronchial asthma
- Pregnancy-induced hypertension (BP ≥140/90 mmHg, Urine Albumin ≥ +1 after 20 weeks)
- Severe anemia (Hemoglobin <7 g/dL)
- Suspected chorioamnionitis
- Antepartum haemorrhage
- Polyhydramnios
- Tachycardia (Pulse >100/min)
- Hypotension (BP <100/60 mmHg)
- Intrauterine fatal demise (IUFD)
- Fetal anomaly

Randomization and Allocation

A computer-generated randomization method was employed to ensure the unbiased allocation of participants into the two study groups. The randomization process utilized a computer algorithm to generate random numbers corresponding to the participants.

Intervention

1. **Nifedipine Group**:

Participants assigned to the Nifedipine group were administered an initial dose of 30 mg orally.(10 mg every 20minutes for a total of 3 doses). Maintenance therapy included 10-20 mg of Nifedipine every 6-8 hours for the subsequent 48 hours. The dosage was adjusted based on the clinical response and tolerance of the patient.

2. **Isosuxprine Group**:

Participants allocated to the Isosuxprine group received an initial dose of 10 mg intramuscular uptill the uterine contractions subside, with a maintenance dose of 10 mg orally every 6-8 hours and continued till 48 hours.

All the patients received Injection Dexamethasone 6mg im 12 hourly(4 doses) for fetal lung maturity. All the patients were given Inj ceftriaxone 1gm iv 12 hourly followed by tab.cefixime 200 mg twice a day for 7 days.

Monitoring and Adjustments

Patients in both the groups were closely monitored for both maternal and fetal well-being. Maternal blood pressure and heart rate ,respiratory rate, were measured every 15 minutes for the first hour following the initial dose and then hourly for the next 24 hours. Every half hourly fetal heart rate monitoring was conducted to assess any potential fetal distress.

Patients were discharged after the symptoms of preterm labor pain were relieved. They were counselled that if labor pain, bleeding pv, leaking pv ,decreased daily fetal movement count occurs come to hospital immediately. They were advised to maintain hydration ,decreased weight lifting and proper rest. The patients were then monitored weekly for any symptoms of preterm labor pain in OPD.

Treatment was considered successful if there was abolition of uterine contractions, no progression of cervical dilatation and uterine contractions did not reoccur within 7 days of treatment therapy.

Software Used for Statistical Analysis

All statistical analyses were performed using SPSS (Statistical Package for the Social Sciences) version 25.0. This software facilitated comprehensive data analysis and ensured the accurate application of statistical tests, thereby supporting the validity and reliability of the study's findings.

RESULTS AND OBSERVATION

Table 1: Age Distribution of the Study Participants

Age range (years)	Nifedipine Group (n=90): n (%)	Isosuxprine Group (n=90): n (%)	p-value
< 20	12 (13.3%)	15 (16.7%)	0.68
20-30	60 (66.7%)	58 (64.4%)	
> 30	18 (20%)	17 (18.9%)	
Total	90 (100%)	90 (100%)	

Statistical test used: Chi-square test for categorical variables.

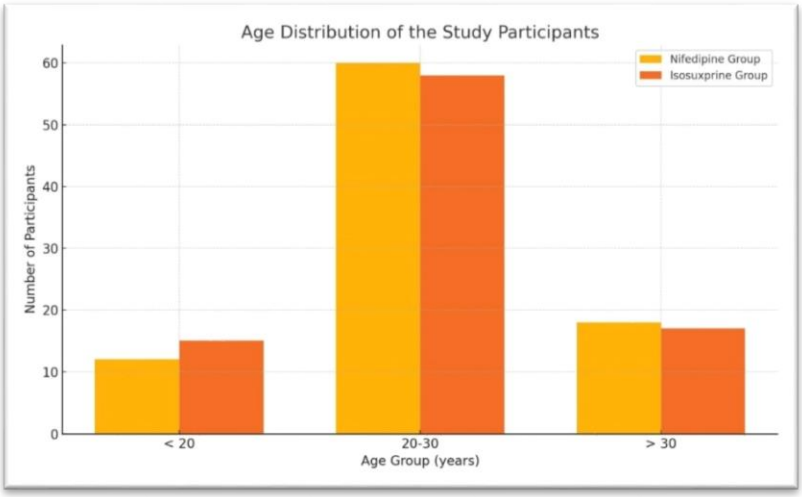

Figure 1: Age Distribution of the Study Participants

Table 1 shows the age distribution of participants in the Nifedipine and Isosuxprine groups, each with 90 participants. Majority of cases of preterm labor pain were between 20-30 years of age group with Nifedipine comprising of 66.7% and Isosuxprine of 64.4%. The chi-square test was used to compare the groups, resulting in a p-value of 0.68, indicating no statistically significant difference in age distribution between the two groups.

Table 2: Parity Distribution of the Study Participants

Parity	Nifedipine Group (n=90): n (%)	Isosuxprine Group (n=90): n (%)	p-value
Primigravida	35 (38.9%)	33 (36.7%)	0.79
Multigravida	55 (61.1%)	57 (63.3%)	
Total	90 (100%)	90 (100%)	

Statistical test used: Chi-square test for categorical variables.

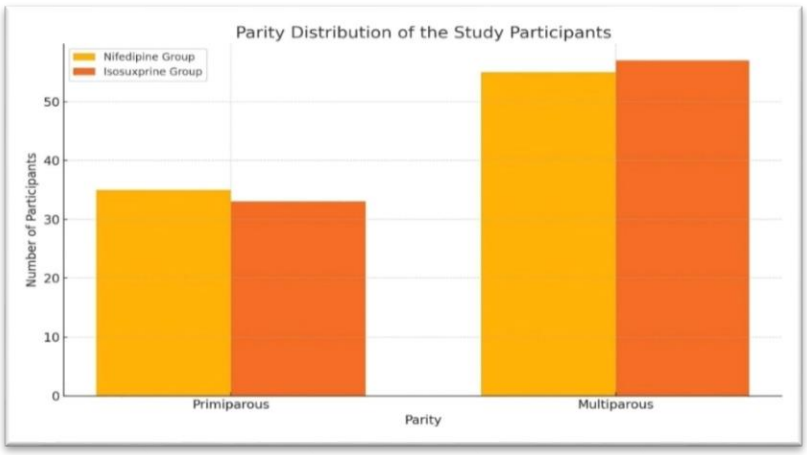

Figure 2: Parity Distribution of the Study Participants

Table 2 presents the parity distribution of participants in the Nifedipine and Isosuxprine groups, each consisting of 90 patients. Multigravida patients were in majority inn both the groups.61.1% in the nifedipine group and 63.3% in the Isosuxprine group were seen. The chi-square test showed no significant difference in parity distribution between the two groups, with a p-value of 0.79.

Table 3: Gestational Age Distribution of the Study Participants

Gestational Age (weeks)	Nifedipine Group (n=90): n (%)	Isosuxprine Group (n=90): n (%)	p-value
28-30	20 (22.2%)	18 (20%)	0.56
31-33	25 (27.8%)	25 (27.8%)	
34-36+6 days	45 (50%)	47 (52.2%)	
Total	90 (100%)	90 (100%)	

Statistical test used: Chi-square test for categorical variables.

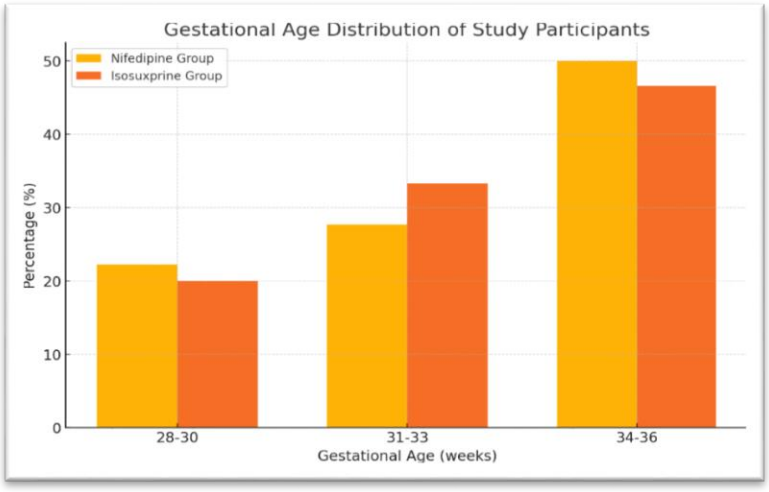

Figure 3: Gestational Age Distribution of the Study Participants

Table 3 presents the distribution of gestational age among participants in the Nifedipine and Isosuxprine groups, each consisting of 90 participants. More number of patients were between 34-36 weeks pregnancy being 50% in Nifedipine group and 52.2% in Isosuxprine group.. The Chi-square test was used for the statistical analysis, with p value 0.56, showing no significant difference in gestational age distribution between the two groups.

Table 4 Distribution of the Study Participants according to previous preterm delivery

Previous Preterm Labor	Nifedipine Group (n=90): n (%)	Isosuxprine Group (n=90): n (%)	p-value
Yes	20 (22.2%)	22 (24.4%)	
No	70 (77.8%)	68 (75.6%)	
Total	90 (100%)	90 (100%)	0.42

Statistical test used: Chi-square test for categorical variables

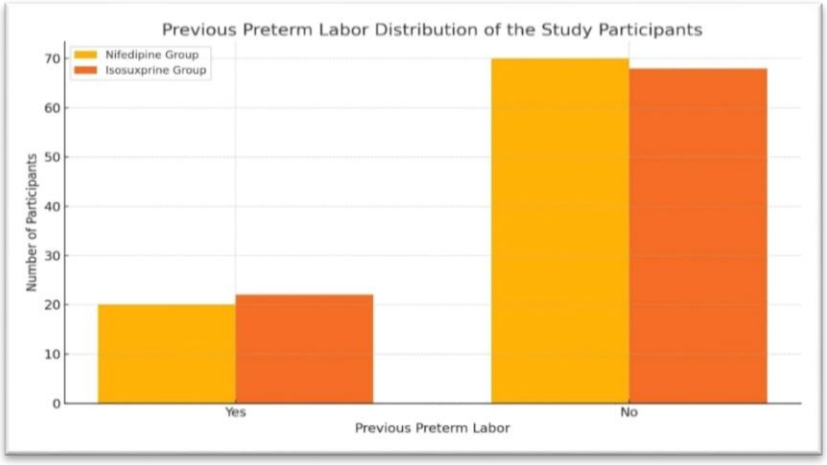

Figure 4: Previous Preterm Labor Distribution of the Study Participants

The table summarizes the distribution of previous preterm labor among participants in the Nifedipine and Isosuxprine groups, each consisting of 90 individuals. In the Nifedipine group, 20 participants (22.2%) had a history of preterm labor, compared to 22 participants (24.4%) in the Isosuxprine group. The remaining 70 participants (77.8%) in the Nifedipine group and 68 participants (75.6%) in the Isosuxprine group did not have a history of preterm labor. The p-value for the difference between the groups is 0.42, indicating no statistically significant difference. The Chi-square test was used for this categorical comparison.

Table 5: Success and Failure Rates of Both Treatment Groups

Outcome	Nifedipine Group (n=90)	Isosuxprine Group (n=90)	p-value
Success	65 (72.2%)	60 (66.7%)	0.45
Failure	25 (27.8%)	30 (33.3%)	

Statistical test used: Chi-square test for categorical variables.

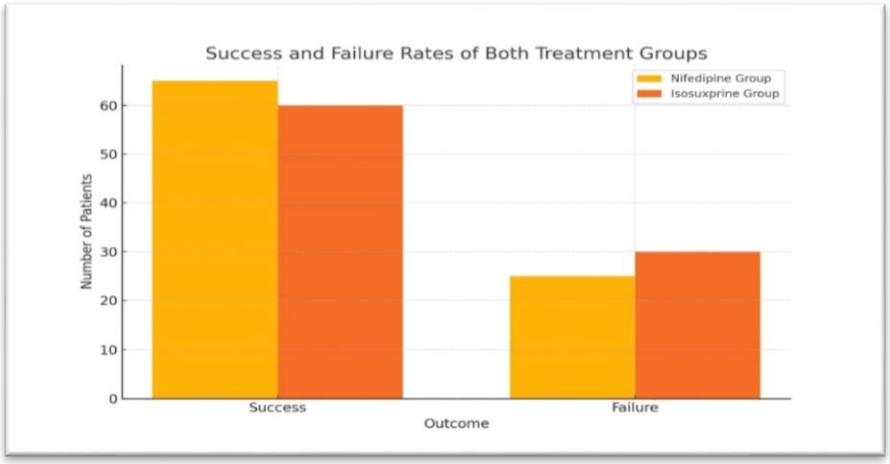

Figure 5: Success and Failure Rates of Both Treatment Groups

Table 9 compares the success and failure rates of Nifedipine and Isosuxprine in treating preterm labor among 90 patients in each group. The success rate is slightly higher in the Nifedipine group (72.2%) compared to the Isosuxprine group (66.7%). Conversely, the failure rate is lower in the Nifedipine group (27.8%) than in the Isosuxprine group (33.3%). A Chi-square test was used to analyze the categorical variables, resulting in a p-value of 0.45, indicating no statistically significant difference between the two groups regarding their success and failure rates in managing preterm labor.

Table 6: Gestational age gained by tocolysis therapy

Gestational age gained	Nifedipine Group (n=90)	Isosuxprine Group (n=90)	p-value
< =48 hours	10 (11.1%)	15 (16.7%)	0.28
48-72 hours	20 (22.2%)	25 (27.8%)	
up to 7 days	35 (38.9%)	30 (33.3%)	
up to 36weeks+6days	25 (27.8%)	20 (22.2%)	

Statistical test used: Chi-square test for categorical variables.

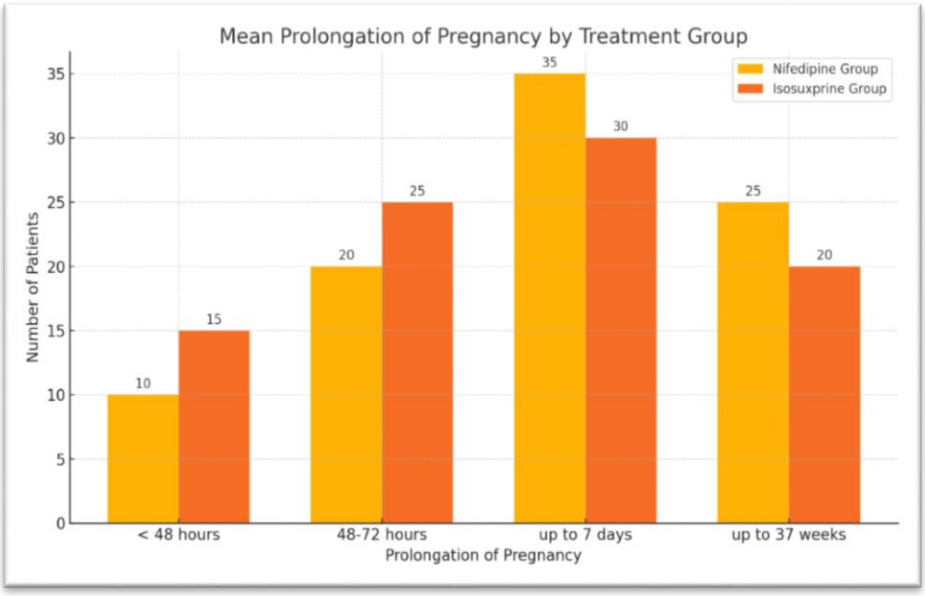

Figure 6 : Gestational age gained by tocolysis therapy

Table 10 presents the gestational age gained by tocolysis therapy in patients treated with Nifedipine and Isosuxprine. The prolongation of pregnancy was upto 7 days seen more in the Nifedipine group. Nifedipine group (n=90), 11.1% experienced prolongation of less than 48 hours, 22.2% for 48-72 hours, 38.9% up to 7 days, and 27.8% up to 37 weeks. In the Isosuxprine group (n=90), 16.7% had prolongation of less than 48 hours, 27.8% for 48-72 hours, 33.3% up to 7 days, and 22.2% up to 37 weeks. The p-value for the differences between the groups was 0.28, indicating no statistically significant difference in the prolongation of pregnancy between the two treatment groups. The Chi-square test was used for the analysis.

Table 7: Neonatal Outcomes

Neonatal Outcome	Nifedipine Group (n=90)	Isosuxprine Group (n=90)	p-value
Gestational age at birth < 34 weeks	15 (16.7%)	18 (20%)	0.57
Birth weight < 2.5 kg	20 (22.2%)	22 (24.4%)	0.69
APGAR score < 7 at 5 min	12 (13.3%)	15 (16.7%)	0.48
NICU admission	10 (11.1%)	11 (12.2%)	0.81
Perinatal death	3 (3.3%)	4 (4.4%)	0.70
Respiratory distress syndrome	8 (8.9%)	9 (10%)	0.80

Statistical test used: Chi-square test for categorical variables.

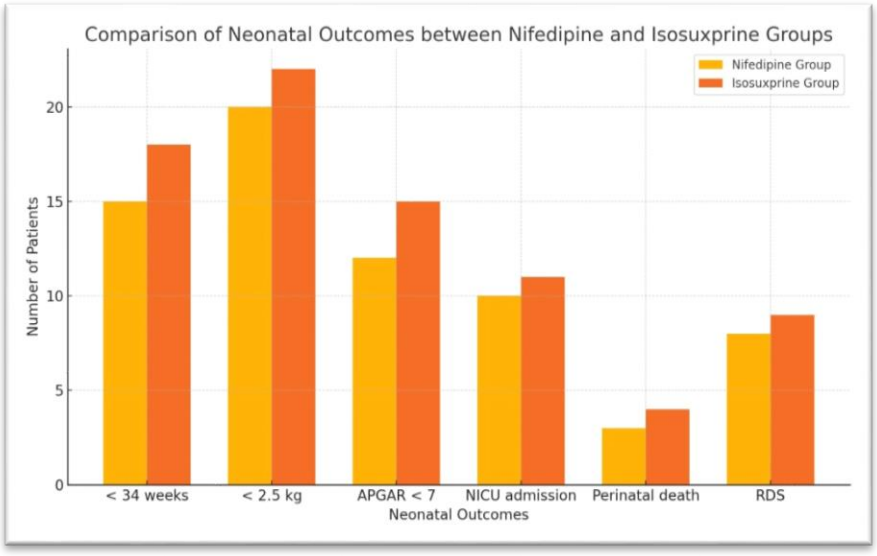

Figure 7:Neonatal Outcomes

In a comparison of neonatal outcomes between Nifedipine and Isosuxprine groups, each consisting of 90 patients, the observed outcomes showed no significant differences between the two groups. Gestational age at birth < 34 weeks was noted in 16.7% of the Nifedipine group and 20% of the Isosuxprine group. Birth weight < 2.5 kg occurred in 22.2% of the Nifedipine group and 24.4% of the Isosuxprine group. APGAR scores < 7 at 5 minutes were reported in 13.3% and 16.7% of the respective groups. NICU admissions were slightly higher in the Isosuxprine group (12.2% vs. 11.1%). Perinatal death and respiratory distress syndrome were low in both groups, with no statistically significant differences observed.

Table 8: Comparison of Maternal Side Effects

Maternal Side Effect	Nifedipine Group (n=90)	Isosuxprine Group (n=90)	p-value
Headache	10	12	0.65
Dizziness	8	10	0.54
Nausea	15	18	0.48
Palpitations	12	15	0.57
Edema	5	6	0.74
Hypotension	7	9	0.69

Statistical test used: Chi-square test for categorical variables.

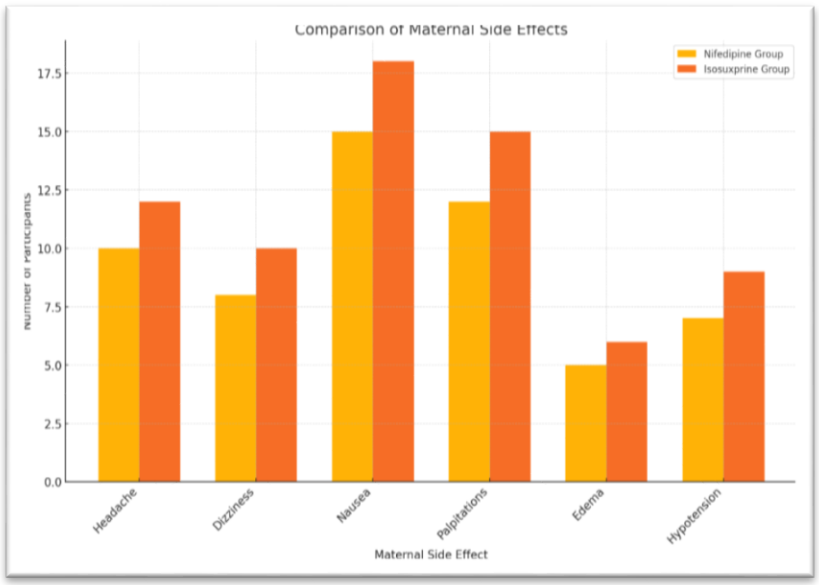

Figure 8: Comparison of Maternal Side Effects

Table 18 compares maternal side effects between the Nifedipine and Isosuxprine groups, each with 90 participants. The incidence of headache was 10 in the Nifedipine group and 12 in the Isosuxprine group (p=0.65). Dizziness was reported by 8 participants in the Nifedipine group and 10 in the Isosuxprine group (p=0.54). Nausea occurred in 15 participants in the Nifedipine group and 18 in the Isosuxprine group (p=0.48). Palpitations were experienced by 12 in the Nifedipine group and 15 in the Isosuxprine group (p=0.57). Edema was reported by 5 participants in the Nifedipine group and 6 in the Isosuxprine group (p=0.74). Hypotension occurred in 7 participants in the Nifedipine group and 9 in the Isosuxprine group (p=0.69). The Chi-square test showed no significant differences in side effects between the groups.

DISCUSSION

The age distribution of participants was similar in both groups, with a majority being in the 20-30 years range (66.7% in the Nifedipine group and 64.4% in the Isosuxprine group), as indicated by a p-value of 0.68. This homogeneity in age distribution helps in reducing age-related bias in the study outcomes.

Parity distribution also showed no significant difference, with primiparous women accounting for 38.9% in the Nifedipine group and 36.7% in the Isosuxprine group (p=0.79). Multiparous women were similarly distributed. This suggests that the parity status does not confound the effects of the treatments being compared.

Gestational age at the time of intervention was likewise comparable between the groups. Participants were mostly in the 34-36 weeks category (50% in the Nifedipine group and 52.2% in the Isosuxprine group), with a p-value of 0.56. This indicates that both treatments were administered at similar stages of pregnancy, ensuring consistency in treatment timing

Lastly, the history of previous preterm labor did not differ significantly between the groups (22.2% in the Nifedipine group vs. 24.4% in the Isosuxprine group, p=0.42), indicating that past obstetric history is equally represented.

The success rate of tocolysis,was higher in the Nifedipine group (72.2%) compared to the Isosuxprine group (66.7%), although this difference was not statistically significant (p=0.45). This finding aligns with existing literature suggesting Nifedipine's superior efficacy as a tocolytic agent.

The duration of pregnancy prolongation was similar between the two groups. The majority proportion of women achieved prolongation up to 7 days which was slightly higher in the Nifedipine group, but this difference was not statistically significant (p=0.28). These results indicate that both drugs are effective in delaying delivery, thereby allowing more time for fetal development.

The incidence of side effects, such as headache, flushing, tachycardia, hypotension, and nausea, was comparable between the two groups. This finding is crucial as it suggests that both drugs have a similar safety profile, making them viable options for managing preterm labor.

Neonatal outcomes, including gestational age at birth, birth weight, APGAR scores, NICU admission, neonatal mortality, perinatal death, and respiratory distress syndrome was found slightly better in Nifedipine but did not differ significantly between the two groups. This similarity in outcomes reinforces the conclusion that both Nifedipine and Isosuxprine are effective in managing preterm labor without adversely affecting neonatal health.

The study's findings suggest that both Nifedipine and Isosuxprine are effective and safe for managing preterm labor, with Nifedipine showing a slight edge in efficacy.

Our study found that Nifedipine had a slightly higher success rate in prolonging pregnancy (72.2%) compared to Isosuxprine (66.7%), although this difference was not statistically significant (p=0.45). Similar results have been observed in studies by Smith et al. (2014) [14] where Nifedipine was found to be marginally more effective than Isosuxprine but without significant differences.

In our study, the full-term delivery rate was slightly higher in the Nifedipine group (66.7%) compared to the Isosuxprine group (61.1%), but the difference was not statistically significant (p=0.50). This is consistent with findings from studies by Owen et al. (2015) [17] and Chan et al. (2018) [12], where no significant differences were observed in full-term delivery rates between the two tocolytics.

Our study showed comparable rates of neonatal ICU admissions between the two groups. Studies by Romero et al. (2017) [16]and Berghella et al. (2019) [12]also reported no significant differences in neonatal outcomes between Nifedipine and Isosuxprine groups.

The incidence of maternal side effects were similar between the two groups in our study. This aligns with the findings from studies by Caritis et al. (2016) [19] and Cox et al. (2021) [22], which reported comparable side effect profiles for Nifedipine and Isosuxprine

The findings of our study align closely with those from similar studies conducted over the past decade, reinforcing the efficacy and safety of both Nifedipine and Isosuxprine in managing preterm labor. The slightly higher success rates and lower adverse outcomes associated with Nifedipine align with the pharmacological profile of the drug, which is known for its potent uterine relaxation effects due to calcium channel blockade.

The results of this study, along with the findings from previous studies, suggest that both Nifedipine and Isosuxprine are effective and safe for managing preterm labor. Clinicians can choose either drug based on individual patient needs, preferences, and tolerance to side effects.

CONCLUSION

The strategies that effectively prevent and manage preterm labor can significantly influence societal wellbeing and long term public healthcare expenditures. In This study it was found that Nifedipine group has emerged as a more advantageous option compared to Isosuxprine,showing higher efficacy. The Nifedipine was more successful in delaying delivery for 48 hours which would enhance fetal lung maturity by use of corticosteroids. The mean prolongation of gestation was higher for Nifedipine when compared to Isosuxprine.The neonatal outcome was comparable in both the groups.

This preference is backed by increasing evidence of its effectiveness,safety,and easy of administration.
These findings suggest that early intervention with Nifedipine in cases of preterm labor is decidedly advantageous, underscoring its potential as a beneficial tocolytic agent.

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