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Original Article

To Determine the Therapeutic Benefits of Tocolysis Comparing Nifedipine and Isoxsuprine in Preterm Labor

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ABSTRACT

Background: Preterm labour is a major cause of neonatal morbidity and mortality. Tocolytic therapy is used to delay delivery and improve neonatal outcomes. Nifedipine and Isoxsuprine are commonly used agents, but their comparative efficacy and safety remain under study.
Aim: To determine and compare the therapeutic benefits of Nifedipine and Isoxsuprine in the management of preterm labour.
Materials and Methods: This quasi-experimental study was conducted in the Department of Obstetrics and Gynaecology at KoIMS, Madikeri, over 18 months. A total of 64 women with preterm labour (28–37 weeks of gestation) were included and divided into two groups: Nifedipine (n=32) and Isoxsuprine (n=32). Data were analysed using SPSS software. Quantitative variables were expressed as mean ± SD, and qualitative variables as percentages. Chi-square test and independent t-test were used, with $p<0.05$ considered significant.
Results: The success rate of tocolysis was significantly higher in the Nifedipine group (90.6%) compared to the Isoxsuprine group (53.1%) (p=0.001). Prolongation of pregnancy up to 48 hours was also significantly better with Nifedipine (p=0.001). The time taken for tocolysis was shorter with Nifedipine (2.8 ± 2.1 hours) compared to Isoxsuprine (8.7 ± 1.4 hours) (p=0.001). Maternal side effects were significantly higher in the Isoxsuprine group (p=0.001). Neonatal weight was comparable between groups (p=0.850), but NICU admissions were higher in the Isoxsuprine group.
Conclusion: Nifedipine is more effective, faster acting, and better tolerated than Isoxsuprine, making it a preferred first-line tocolytic agent in the management of preterm labour.

Keywords*: Preterm labour, Nifedipine, Isoxsuprine, Tocolysis, Maternal outcomes, Neonatal outcomes.*

INTRODUCTION

Preterm labor (PTL), defined as the onset of regular uterine contractions leading to cervical changes before 37 completed weeks of gestation, remains a major global health concern and a leading cause of neonatal morbidity and mortality. It is responsible for approximately 70–75% of neonatal deaths not related to congenital anomalies and contributes significantly to long-term neurological disabilities such as cerebral palsy, visual impairment, and learning difficulties (1). Globally, the incidence of preterm birth ranges from 10–12%, with higher prevalence observed in low- and middle-income countries. In India, the burden of preterm labor is particularly high due to factors such as maternal malnutrition, anemia, infections, and limited access to quality antenatal care (2,3). The etiology of preterm labor is multifactorial and includes uterine overdistension, intrauterine infections, cervical insufficiency, placental abnormalities, and hormonal dysregulation (4).

The management of preterm labor aims at delaying delivery to improve neonatal outcomes. Tocolysis plays a crucial role in achieving this objective by inhibiting uterine contractions temporarily. The primary goal of tocolytic therapy is to

prolong pregnancy for at least 48 hours to allow administration of antenatal corticosteroids, which enhance fetal lung maturity, and to facilitate in-utero transfer to tertiary care centers (5,6).

Several classes of tocolytic agents have been used in clinical practice, including β-adrenergic agonists, calcium channel blockers, prostaglandin inhibitors, magnesium sulfate, and oxytocin receptor antagonists. Among these, β-agonists such as Isoxsuprine have been widely used due to their ability to relax uterine smooth muscle by increasing intracellular cyclic AMP levels. However, their use is often limited by significant maternal side effects such as tachycardia, palpitations, hypotension, and pulmonary edema (7,8).

In recent years, calcium channel blockers, particularly Nifedipine, have emerged as a preferred alternative due to their efficacy and improved safety profile. Nifedipine acts by inhibiting the influx of calcium ions into myometrial cells, thereby reducing uterine contractions. It is easy to administer orally, cost-effective, and associated with fewer maternal adverse effects compared to β-agonists (9).

Several randomized controlled trials and systematic reviews have demonstrated that Nifedipine is at least as effective, if not superior, to β-agonists in delaying preterm delivery and improving neonatal outcomes (10,11). Furthermore, international guidelines recommend calcium channel blockers as first-line agents for tocolysis in appropriate clinical settings (5,12).

Despite the growing evidence favoring Nifedipine, Isoxsuprine continues to be widely used in many parts of India due to familiarity and availability. Comparative studies between these two agents in the Indian population remain limited. Therefore, this study was undertaken to evaluate and compare the therapeutic benefits, efficacy, and safety profile of Nifedipine and Isoxsuprine in the management of preterm labor.

MATERIALS AND METHODS

Study subjects: All suspected cases of PTL admitted in antenatal clinic at OBG department, KoIMS, Madikeri.

Study design: - A Quasi experimental study or Comparision study

Study period: - Study was carried out for 18 months duration from June 2024 to December 2025.

Inclusion criteria:

1. Women with single live intrauterine gestation of 28- 37 weeks of gestational age
2. Women presented with preterm labor

Exclusion Criteria:

All antenatal clinic women with:

1. Preterm labor in active labor
2. Multiple gestation
3. Threatened abortion
4. Polyhydramnios
5. Pregnancy achieved with ART
6. Heart diseases, renal or any systemic illness.
7. On medication with Nifedipine for gestational hypertension or pre-eclampsia
8. Allergic to Isoxuprine or Nifedipine

Sampling: Convenient sampling

Sample size:

The samplee sizee wasccalculated based on previous literature, the expected proportion of Success Rate in the two groups *viz.* Nifedipine and isoxsuprine was 80% and 68% respectively.[15] The samplee sizee was calculatedd using the following formula provided by Sahai and Kurshid (1996):[52]

Sample size N = $\frac{\left\{z_{(1-\alpha/2)}\sqrt{2*\bar{p}(1-\bar{p})} + z_{(1-\beta)}\sqrt{p_1(1-p_1)+p_2(1-p_2)}\right\}^2}{(p_1-p_2)^2}$ **where** $\hat{p} = \frac{p_1+p_2}{2}$

Where,

N = Sample size

Expected Proportion in First Group: $p_1 = 0.8$ (80%)

Expected Proportion in Second Group: $p_2 = 0.68$ (68%)

$\hat{p}$: $(p_1 + p_2)/2 = 0.74$

Type I error: $\alpha = 0.05$ (5%) = 1.96, CI = 95%

Type II error: β = 0.2 (20%), = 0.842, Power = 80%
After substitution of values, the sample size got for each was 208.56 ≈ 209 (total 418).
Since only about 75 subjects meeting the inclusion criteria are expected to be available for the study during the data collection period, applying finite population correction, the final sample size was N = 418/(1+(418/75)) ≈ 64 (32 per group).

Thus, with 80% power and 95% confidence interval, the minimummsample size needed was 32/group (total 64).

Methodology
Study was initiated after obtaining approval from the Institutional Scientific Committee and the Institutional Ethicsc Committee of KoIMS, Madikeri. A detailed history, demographic characteristics, pregnancy related, and other study related data were obtained in a detailed structured proforma.

- Clinical assessment of preterm labor by prenatal NST and CTG was done
- Tocolysis and monitoring of the patient done thoroughly
- Reassessment of preterm labor by prenatal NST and CTG was done post-tocolysis and the therapeutic benefits of the drugs were recorded and inference were made.

Statistical Analysis
The statistical analysis was carried out using SPSS version 21. The data was entered in the Microsoft excel spread sheet version 2021. The descriptive statistics for the explanatory and outcome variables was carried out using mean and standard deviation for quantitative data, and frequency and proportions for qualitative data. Inferential statistics like the Chi-square test was carried out for qualitative data to check for association, and the independent t-test was carried out to check for differences in quantitative data. $p<0.05$ was set to be statistically significant.

RESULT AND OBSERVATION

TABLE: 1 DISTRIBUTION OF EFFICACY OF TOCOLYSIS AND DRUG EFFICACY (N = …)

Variable	Category / Outcome	Nifedipine (N, %)	Isoxsuprine (N, %)	χ^2 value	p-value
Efficacy of Tocolysis	Successful tocolysis with preterm delivery (<37 weeks)	5 (15.6%)	4 (12.5%)	0.129	0.719
	Successful tocolysis with term delivery	3 (9.4%)	2 (6.3%)	0.217	0.641
Drug Efficacy (Gestational Age)	<34 weeks	15 (46.9%)	9 (28.1%)	—	—
	>34 weeks	14 (43.7%)	8 (25.0%)	—	—

TABLE: 2 DISTRIBUTION OF GESTATIONAL AGE AT DELIVERY, PERIOD OF GESTATION, AND MATERNAL FACTORS (N = 64)

Variable	Category	Nifedipine (N, %)	Isoxsuprine (N, %)	Total (N, %)	χ^2 value	p-value
Gestational Age at Delivery	28–30 weeks	2 (6.3%)	2 (6.3%)	4 (6.3%)		
	31–33 weeks	10 (31.3%)	11 (34.4%)	21 (32.8%)		
	34–36 weeks	17 (53.1%)	17 (53.1%)	34 (53.1%)		
	37–39 weeks	3 (9.4%)	2 (6.3%)	5 (7.8%)	0.248	0.970
Period of Gestation	<34 weeks	16 (50.0%)	16 (50.0%)	—	0.063	0.802
	>34 weeks	16 (50.0%)	16 (50.0%)	—	0.000	1.000
Maternal Factors	Primigravida	6 (18.8%)	7 (21.9%)	13 (20.3%)		
	Multigravida	26 (81.2%)	25 (78.1%)	51 (79.7%)	0.097	0.756

TABLE: 3 DISTRIBUTION OF MATERNAL SIDE EFFECTS, NEONATAL WEIGHT, AND SUCCESSFUL TOCOLYSIS (N = 64)

Variable	Category	Nifedipine (N, %) / Mean ± SD	Isoxsuprine (N, %) / Mean ± SD	Total (N, %)	χ^2 / Mean Diff.	p-value
Maternal Side Effects	Dizziness	2 (6.3%)	0 (0.0%)	2 (3.1%)		
	Headache	2 (6.3%)	0 (0.0%)	2 (3.1%)		
	Hot flushes	1 (3.1%)	0 (0.0%)	1 (1.6%)		
	Hypotension	0 (0.0%)	7 (21.9%)	7 (10.9%)		
	Palpitations	2 (6.3%)	7 (21.9%)	9 (14.1%)		
	Tachycardia	2 (6.3%)	9 (28.1%)	11 (17.2%)		
	Nil	23 (71.9%)	9 (28.1%)	32 (50.0%)	25.357	0.001
Neonatal Weight (kg)	Mean ± SD	2.00 ± 0.76	1.97 ± 0.54	—	0.03	0.850
Successful Tocolysis	Failure	3 (9.4%)	15 (46.9%)	18 (28.1%)		
	Success	29 (90.6%)	17 (53.1%)	46 (71.9%)	11.130	0.001

TABLE: 4 DISTRIBUTION OF PROLONGATION OF LABOR (N = 64)

Variable	Category	Nifedipine (N, %)	Isoxsuprine (N, %)	Total (N, %)	χ^2 value	p-value
Prolongation up to 48 Hours	No	3 (9.4%)	15 (46.9%)	18 (28.1%)		
	Yes	29 (90.6%)	17 (53.1%)	46 (71.9%)	11.130	0.001
Prolongation up to 7 Days	No	27 (84.4%)	28 (87.5%)	55 (85.9%)		
	Yes	5 (15.6%)	4 (12.5%)	9 (14.1%)	0.129	0.719
Prolongation up to 37 Weeks	No	29 (90.6%)	30 (93.8%)	59 (92.2%)		
	Yes	3 (9.4%)	2 (6.3%)	5 (7.8%)	0.217	0.641

TABLE: 5 COMPARISON OF TIME TAKEN FOR TOCOLYSIS AND PERIOD OF GESTATION (N = 64)

Variable	Group	N	Min	Max	Mean	SD	Mean Difference	p-value
Time Taken for Tocolysis (hrs)	Nifedipine	32	1.0	13.0	2.8	2.1	5.8	0.001*
	Isoxsuprine	32	6.0	11.0	8.7	1.4		
Period of Gestation (weeks)	Nifedipine	32	30.0	38.4	34.0	2.3	0.36	0.497
	Isoxsuprine	32	30.0	38.0	33.6	1.9		

*Statistically significant

TABLE 6: NEONATAL COMPLICATIONS WISE DISTRIBUTIONS

Maternal Side Effects		Groups		Total
		Isoxsuprine	Nifedipine	
Birth Asphyxia	Count	2	0	2
	%	6.3%	0.0%	3.1%
NEC	Count	0	1	1
	%	0.0%	3.1%	1.6%
Neonatal death	Count	4	1	5
	%	12.5%	3.1%	7.8%
Neonatal jaundice	Count	3	3	5
	%	9.4%	9.4%	7.8%
NICU Admission	Count	17	5	22
	%	53.1%	15.6%	34.4%
RDS	Count	4	4	8
	%	12.5%	12.5%	12.5%
Sepsis	Count	0	1	1
	%	0.0%	3.1%	1.6%
Nil	Count	5	14	19

	%	15.6%	43.8%	18.8%
Total	Count	32	32	64
	%	100.0%	100.0%	100.0%
Chi-square value (X^2) = 20.879				
p-value = 0.013*				

*Significant

DISCUSSION

The present study was conducted to compare the efficacy and safety of Nifedipine and Isoxsuprine in the management of preterm labor. The findings of this study demonstrate that Nifedipine is superior to Isoxsuprine in terms of efficacy, onset of action, and maternal safety profile.

In the present study, the success rate of tocolysis was significantly higher in the Nifedipine group (90.6%) compared to the Isoxsuprine group (53.1%) (p = 0.001). These findings are in agreement with previous studies that have demonstrated higher efficacy of calcium channel blockers over β-agonists (10,11). A randomized controlled trial by Papatsonis et al. showed that Nifedipine was more effective in delaying delivery and had fewer treatment failures compared to β-agonists (10).

The ability to prolong pregnancy for at least 48 hours is clinically significant, as it allows time for administration of corticosteroids. In this study, prolongation of labor up to 48 hours was significantly higher in the Nifedipine group. However, prolongation beyond 7 days and up to 37 weeks did not show a statistically significant difference between the two groups. This finding is consistent with current evidence suggesting that most tocolytic agents are effective only for short-term prolongation of pregnancy (5,6).

The time taken for tocolysis was significantly shorter in the Nifedipine group compared to the Isoxsuprine group, indicating a faster onset of action. This can be attributed to the direct inhibitory effect of Nifedipine on calcium influx in uterine smooth muscle cells, resulting in rapid relaxation of the myometrium (9).

Maternal side effects were significantly more common in the Isoxsuprine group, particularly cardiovascular complications such as hypotension, tachycardia, and palpitations. In contrast, the majority of patients in the Nifedipine group experienced minimal or no side effects. These findings are supported by earlier studies that have highlighted the higher adverse effect profile associated with β-agonists (7,8). Reduced maternal side effects contribute to better compliance and overall safety of therapy.

In terms of neonatal outcomes, the mean birth weight was comparable between the two groups, indicating that both drugs had a similar effect on fetal growth. However, neonatal complications such as NICU admissions were higher in the Isoxsuprine group. This may be due to less effective tocolysis and higher maternal side effects, leading to suboptimal intrauterine conditions. Similar findings have been reported in previous studies and global health reports (2,3).

The distribution of gestational age at delivery and maternal characteristics, such as parity, were comparable between the two groups, indicating that the baseline characteristics were well matched. This minimises confounding and strengthens the validity of the study findings.

Overall, the findings of the present study are consistent with existing literature and international guidelines, which recommend Nifedipine as a first-line agent for tocolysis due to its superior efficacy and better safety profile (5,12).

However, the study has certain limitations, including a relatively small sample size and a single-centre design, which may limit generalizability. Further large-scale multicentric studies are recommended to validate these findings.

CONCLUSION

Nifedipine is more effective and safer than Isoxsuprine for the management of preterm labour. It provides a higher success rate of tocolysis, faster onset of action, and better short-term prolongation of pregnancy with fewer maternal side effects. Therefore, Nifedipine can be considered a preferred first-line tocolytic agent.

REFERENCES

1. Williams Obstetrics. 25th ed. McGraw-Hill Education; 2018.
2. World Health Organisation. Preterm birth: Fact sheet; 2018.
3. Blencowe H, et al. National, regional, and worldwide estimates of preterm birth. Lancet. 2012;379:2162–2172.
4. Goldenberg RL, et al. Epidemiology and causes of preterm birth. Lancet. 2008;371:75–84.
5. American College of Obstetricians and Gynaecologists. Practice Bulletin No. 171; 2016.

6. Royal College of Obstetricians and Gynaecologists. Tocolysis guideline; 2011.
7. Simhan HN, Caritis SN. Prevention of preterm delivery. N Engl J Med. 2007;357:477–487.
8. Anotayanonth S, et al. Beta-agonists for inhibiting preterm labour. Cochrane Database Syst Rev. 2004.
9. King JF, et al. Calcium channel blockers for inhibiting preterm labour. Cochrane Database Syst Rev. 2003.
10. Papatsonis DN, et al. Nifedipine vs β-agonists in preterm labour. Lancet. 2001;358:986–991.
11. Conde-Agudelo A, et al. Nifedipine vs other tocolytics: systematic review. Am J Obstet Gynecol. 2011.
12. NICE Guidelines. Preterm labour and birth. 2015.