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Comparative study of safety and efficacy of labetalol and nifedipine in the management of hypertensive disorders of pregnancy: A prospective observational study

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Abstract: *Background:* Hypertensive disorders of pregnancy is a leading cause of maternal and fetal morbidity and mortality. Antihypertensive agents such as labetalol and nifedipine are commonly used, but comparative data on their effectiveness and safety are still being evaluated. *Objectives:* To compare the efficacy and safety of labetalol and nifedipine in the management of hypertensive disorders in pregnancy. *Methods:* This prospective observational study included 120 pregnant women with hypertensive disorders of pregnancy divided into two groups: group A (n=60) received oral labetalol, and group B (n=60) received oral nifedipine. Blood pressure, maternal outcomes, and fetal outcomes were monitored over 7 days and until delivery. *Results:* Both drugs significantly reduced systolic and diastolic blood pressure. labetalol showed slightly faster control (mean BP normalization in 3.2 days vs 3.6 days for nifedipine,$p<0.05$). Maternal side effects were minimal and similar in both groups. Fetal outcomes (birth weight, Apgar scores, NICU admissions) were comparable. *Conclusion:* Both labetalol and nifedipine are effective and safe in managing hypertensive disorders of pregnancy. Labetalol provides slightly faster control of blood pressure with comparable maternal-fetal outcomes.

Keywords: Pregnancy-induced hypertension, Labetalol, Nifedipine, Antihypertensives, Maternal outcomes.

Introduction

Hypertensive disorders of pregnancy, defined as new-onset hypertension after 20 weeks of gestation without proteinuria, affects approximately 6-10% of pregnancies and is a major contributor to maternal and fetal complications [1, 2]. It remains one of the leading preventable causes of maternal morbidity and mortality globally [3]. Effective management of blood pressure reduces the risk of eclampsia, placental abruption, and adverse neonatal outcomes [4-5].

Labetalol, a mixed alpha- and beta-blocker, and nifedipine, a calcium channel blocker, are recommended first-line oral antihypertensives for use during pregnancy by several national and international guidelines [6-9]. However, their comparative performance in clinical settings, especially in low-resource environments, continues to be of research interest.

This study aims to compare labetalol and nifedipine in terms of blood pressure control, onset of action, and maternal-fetal outcomes in pregnant women diagnosed with hypertensive disorders of pregnancy.

Material and Methods

Study Design and Setting: This was a prospective observational study conducted in the department of obstetrics and gynaecology at Al ameen medical college hospital, Vijayapur Karnataka over a period of 12 months (January 2024–December 2024). Ethical approval was obtained from the institutional ethics committee.

Inclusion Criteria:

- Singleton pregnancy
- Gestational age >20 weeks
- Systolic BP ≥140 mmHg and/or diastolic BP ≥90 mmHg

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- No proteinuria(to exclude pre-eclampsia) [10]

Exclusion Criteria:

- Chronic hypertension
- Pre-eclampsia/eclampsia
- Multiple gestation
- Cardiac disorders
- Contraindications to labetalol or nifedipine

Study Population: 120 women were enrolled and divided into:

- *Group A (n=60):* Received oral labetalol (initial dose 100 mg twice daily, titrated up to 300 mg/day based on response).
- *Group B (n=60):* Received oral nifedipine extended-release (initial dose 20 mg once daily, titrated up to 60 mg/day).

Outcome Measures:

- *Primary:* Time to achieve target BP (<140/90 mmHg)
- *Secondary:* Maternal adverse effects, fetal outcomes (birth weight, Apgar score, NICU admission)

Statistical Analysis:

- Data were analyzed using SPSS v26.
- Continuous variables were expressed as mean ± SD and compared using t-tests.
- Categorical variables were analyzed using Chi-square test.
- A p-value <0.05 was considered significant.

Results

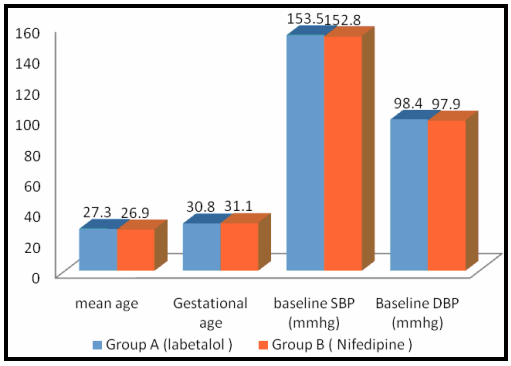
The baseline characteristics of the two groups were comparable. The mean age of participants in Group A (Labetalol) was 27 years, while in Group B (Nifedipine) it was 26.9 years, with no statistically significant difference (p = 0.52). The mean gestational age was 30.8 weeks in Group A and 31.1 weeks in Group B, which was also not statistically significant (p = 0.38). The baseline systolic blood pressure (SBP) was 153.5 mmHg in Group A and 152.8 mmHg in Group B, with no significant difference between the groups (p = 0.61) (Table-1).

Interpretation: The two groups were well-matched at baseline, minimizing confounding and supporting the validity of the outcome comparisons (Fig-1).

Table-1: Baseline Characteristics

Parameters	Group A (labetalol)	Group B (nifedipine)	P-value
Mean age	27	26.9	0.52
Gestational age	30.8	31.1	0.38
Baseline SBP (mmhg)	153.5	152.8	0.61
Baseline DBP (mmhg)	98.4	97.9	0.44

Fig-1: Comparison of baseline parameters



The mean time to achieve target blood pressure was significantly shorter in Group A (Labetalol) at 3.2 days, compared to 3.6 days in Group B (Nifedipine), and this difference was statistically significant (p=0.01). However, the percentage of participants achieving blood pressure control within 5 days was similar in both groups 93.3% in Group A and 91.7% in Group B with no statistically significant difference (p = 0.76) Table-2.

Table-2: Blood Pressure Control

Parameter	Group A labetolol	Group B nifedipine	p-value
Time to target BP (days)	3.2	3.6	0.01*
% achieving control in 5 days	93.3%	91.7%	0.76

Interpretation: Labetalol demonstrated a significantly faster onset of antihypertensive effect. Despite differences in time to control, the overall effectiveness within 5 days was comparable between the two drugs (Fig-2).

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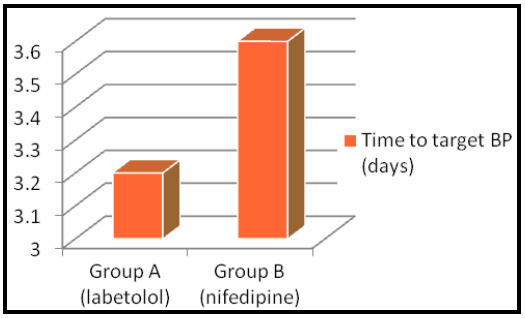
Fig-2: Time to target BP (days)



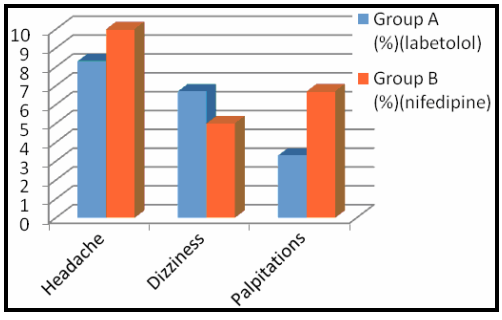
Maternal adverse effects were reported in both groups, with slight variations in incidence (Tab-3:

- Headache was reported in 8.3% of participants in Group A (Labetalol) and 10.0% in Group B (Nifedipine)**.**
- Dizziness occurred in 6.7% of Group A and 5.0% of Group B.
- Palpitations were observed in 3.3% of Group A and 6.7% of Group B.

Table-3: Maternal Adverse Effects			
Side Effect	**Group A (%) (labetolol)**	**Group B (%) (nifedipine)**	**p-value**
Headache	8.3	10.0	
Dizziness	6.7	5.0	
Palpitations	3.3	6.7	

Reported adverse effects (headache, dizziness, palpitations) were slightly more frequent in Group B (Nifedipine), but *no p-values are provided,* suggesting either non-significant differences or not statistically analyzed (Table-3).

Fig-3: Maternal Adverse Effects



Interpretation: Both medications were generally well-tolerated, with no clear pattern of significantly more adverse effects in either group (Fig-3).

Fetal outcomes were comparable between the two groups (Table-4):

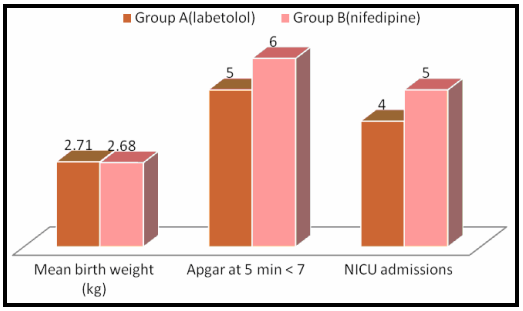
- The mean birth weight was 2.71 kg in Group A (Labetalol) and 2.68 kg in Group B (Nifedipine), with no statistically significant difference (p = 0.57).
- An Apgar score at 5 minutes less than 7 was observed in 8.3% of newborns in Group A and 10% in Group B (p = 0.75).
- NICU admissions occurred in 6.7% of cases in Group A and 8.3% in Group B (p = 0.73).

Table-4: Fetal Outcomes			
Outcome	**Group A labetolol**	**Group B nifedipine**	**p-value**
Mean birth weight (kg)	2.71	2.68	0.57
Apgar at 5 min < 7	5 (8.3%)	6 (10%)	0.75
NICU admissions	4 (6.7%)	5 (8.3%)	0.73

Mean birth weight, Apgar score at 5 minutes < 7, and NICU admissions were similar in both groups (all p-values > 0.05) (Table-4).

Interpretation: Both medications appear safe in terms of fetal outcomes, with no significant differences observed (Fig-4).

Fig-4: Fetal outcomes



Discussion

This study demonstrates that both labetalol and nifedipine are effective in managing hypertensive disorders of pregnancy. Labetalol achieved faster BP normalization compared to nifedipine (p=0.01), in line with earlier randomized trials [6-7, 11]. However, maternal and fetal outcomes were comparable between the groups, supporting findings from similar observational studies [12-13].

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Guideline-based reviews and meta-analyses confirm both drugs are equally safe for fetal development and maternal hemodynamic stability [8-9, 14]. Although nifedipine has the advantage of simpler oral dosing and fewer contraindications, labetalol appears slightly more potent in acute BP control [7, 11]. The exclusion of pre-eclampsia in this study aligns with recommendations that it represents a separate clinical entity with unique pathophysiology [4, 10]. This study contributes to real-world evidence especially relevant for developing countries where hypertensive disoreders of preganancy prevalence and complications remain high [5, 15].

Limitations include the single centre design and relatively small sample size. Larger multicentric studies could further validate these findings.

Conclusion

Both labetalol and nifedipine are safe and effective in managing hypertensive disorders of pregnancy. Labetalol offers faster blood pressure control, though maternal and fetal outcomes are similar. Either drug may be used depending on patient profile and resource availability.

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