# European Journal of Clinical Pharmacy

**Print ISSN:** 2385-409X **Online ISSN**: 3105-0409

Website: https://farmclin.com/


*Original Research Article*

# Comparison of Frequency of Intrauterine Growth Retardation in Preeclampsia in Primigravida Treated with Nifedipine Versus Labetalol


***Article History:***



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***Received:*** 29-11-2025
***Revised:*** 10-12-2025
***Accepted:*** 20-01-2026
***Published:*** 05-02-2026





***Abstract***: ***Introduction***: Pre-eclampsia remains one of the largest causes of mortality and morbidity among maternal and neonatal deaths. It is a pregnancy-specific disease expressing in the de novo onset of concomitant proteinuria and hypertension that can even develop into a multi-organ complex involving diverse clinical manifestations. Hydralazine, nifedipine and labetalol are the most common drugs used for the treatment of preeclampsia. Intrauterine growth restriction (IUGR) is one of the common complications in such females on these therapies. ***Objective***: To compare the frequency of IUGR in pre-eclamptic primigravida managed with nifedipine versus labetalol. ***Methods***: It Randomized Controlled Trial was done at department of Gynae and Obs Combine Military Hospital, Lahore. The study was done in 6 months from August 5, 2017 till Feb 5, 2018. A total of 90 patients (45 patients in each group) were recruited from outpatient department of Obstetrics and gynaecology, Combine Military Hospital, Lahore after hospital ethical review committee approval. Informed consent was obtained and every case was asked to provide their detailed history. After then cases were randomly divided into 2 groups as per lottery method, i.e. Group A: Labetalol Treatment (45 cases) and Group-B: Nifedipine Treatment (45 cases). Nifedipine 20 mg or labetalol 100 mg was given through oral route twice daily 12 hours apart. Weight of the neonate was measured with in 1 hour of birth by a trained nurse after correcting zero error. Neonates with birth weight less than 10 percentile of the gestational age was labeled as IUGR. SPSS version 20 was utilized to analyzed and record all the collected data. ***Results***: The mean age of all cases was 26.38 ± 4.28 years while mean age in Labetalol and nifedipine group was 25.73 ± 4.02 years and 27.02 ± 4.47 years. In nifedipine group there 6(13.3%) cases who had IUGR while 39(86.7%) did not have IUGR while in labetalol group 19(42.2%) neonates had IUGR while 26(57.8%) did not have IUGR. The frequency of IUGR was significantly lower in nifedipine as compare to labetalol group, p-value = 0.002 (< 0.05). ***Conclusion***: Through the findings of this study we conclude that the frequency of IUGR was significantly less in females treated by nifedipine as compared to labetalol.



**Keywords**: Hypertensive disorder, preeclampsia, antihypertensive therapy, complication, IUGR.


## INTRODUCTION

High blood pressure is a complication during pregnancy related to an increase in maternal morbidity and mortality and complicate about 5 to

10%. This is arranged into gestational hypertension, and pre-eclampsia, an association of hypertension coupled with maternal multi-organ and/or uteroplacental involvement [1]. During pregnancy, hypertension is linked to poor maternal outcomes, such as cerebrovascular, renal and cardiovascular diseases and with acute and chronic uteroplacental insufficiency that may result in ante or intrapartum anoxia, intrauterine growth restriction (IUGR) and intrauterine death (IUD) both preterm and after birth [2].

A recent study demonstrates 64.7% prevalence of IUGR in expecting women with hypertension, and this is in support of close monitoring of the foetuses [3]. In this respect, the use of antihypertensive medications during pregnancy still remain debatable. However, labetalol, hydralazine and nifedipine can be taken as safe in treating severe preeclampsia [4]. Labetalol is a 3rd generation alpha 1 receptor blocker and non-selective beta blocker which decrease the blood pressure through vasodilation induction. And it also protects the risk of preeclampsia, blood pressure regulation and even decreases the foetal mortality rate in pregnancy [5]. The dominant effect of nifedipine inhibit smooth muscle contraction to reduce high blood pressure [6].

These two agents have demonstrated similar cost-effectiveness weekly doses and their comparable success in quickly reducing blood pressure in case of severe preeclampsia [7]. Although favorable maternal outcome is linked to nifedipine or labetalol, however a recent study showed a relatively high rate of IUGR, 35.7 %, in acute cases of pregnant women treated with nifedipine, and this justifies the demand of constant fetal monitoring [8]. In contrast, a retrospective cohort study of 210 hypertensive pregnancies reported that 16.7 % of the patients receiving the labetalol developed IUGR, particularly with preeclampsia or co-administered antihypertensive therapy [9]. A later prospective trial identified labetalol to have improved foetal outcomes with similar efficacy; the total rate of IUGR was 1.5 % in labetalol and 3.5 % with nifedipine [10]. However, in another local RCT, a markedly reduced occurrence of IUGR (6.9 %) was shown in the nifedipine group compared to the labetalol group (22.4 %) that suggest a possible benefit of nifedipine in promoting fetal growth [11].

Therefore, it is problematic to make clear conclusions on the effect of labetalol and nifedipine on IUGR. Because the labetalol-associated IUGR rates reported in the published literature are 1.5 - 22.4 % [10,11], the nifedipine-associated IUGR rates reported in the published literature are 3.5 - 35.7 % [8,10], in various demographic and study design scenarios. Hence, there is inconsistence in data regarding IUGR rate by using these two drugs. So the aim of the current study is to compare the incidence of IUGR in preeclamptic primigravida women using either labetalol or nifedipine as their antihypertensive medications, hence providing an explanation on whether or not the use of medication to treat hypertension will result into better foetal growth.

## MATERIAL AND METHODS

**Study design:** Randomized Controlled Trial.

**Settings:** Department of Gynae and Obs Combine Military Hospital, Lahore.

**Study Duration:** Six months from August 5, 2017 till Feb 5, 2018 after the acceptance of the synopsis

**Sample Size:** While taking expected frequency of IUGR in primigravida with preeclampsia is 15.5% with nifedipine and 38.8% with labetalol, a sample size of 90 (45 in each group) is determined using 80% test power and a 95% confidence interval. [12]

**Sampling Technique:** Non probability, Consecutive sampling.

**Sample Selection:**

***Inclusion criteria:***

1. Primigravida aged 18 to 35 years having preeclampsia presenting at 20-24 weeks of gestation (as per dating scan) according to operational definition.
2. Participants in the research who provide written informed permission

***Exclusion criteria:*** (Risk factors of IUGR)

1. Those with foetal anomalies or twins as revealed by the obstetric ultrasound
2. The patients having liver diseases (bilirubin greater than or equal to 1.2 mg/dl) or renal diseases (serum creatinine greater than or equal to 1.2 mg/dl), based on their history and clinical record.
3. The anaemic patients who have (haemoglobin level 9g/dl and below), based on their clinical documentation.
4. Patients with diabetes (fasting blood glucose level 110 mg/dl or more) or cardiac diseases (ejection fraction 40 percent or less).

### DATA COLLECTION PROCEDURE

A total of 90 patients (45 on each group) who present to the outpatient department of Obstetrics and Gynaecology at the Combine Military Hospital, Lahore and similarly fit the aforementioned criteria were counselled and provided with an explanation of the study detail after obtaining the clearance of the ethics review committee at the hospital. The written informed permission was given by each patient and complete medical history was taken. These patients were randomly divided into the following two groups,

as per the lottery method.

- Group A: Labetalol Treatment (45 cases)
- Group-B: Nifedipine Treatment (45 cases)

Nifedipine 20 mg or labetalol 100 mg was recommended orally in B.D. 12 hours apart. Weight of the neonate was measured with in 1 hour of birth by a trained nurse after correcting zero error. Neonates with birth weight less than 10 percentile of the gestational age were labeled as IUGR. All the data, duration of the therapy and birth weight of the neonate along with demographic details of the patient were documented and written in an attached proforma. Hospital Lab was used for clinical investigations and all the pregnant mothers were given nifedipine or labetalol of the same brand (depending on the group they were placed) to remove bias and confounders. All the recorded data was computed and analysed using SPSS version 20. All the numerical variables, (age, birth weight, treatment duration, height, weight, and BMI) were presented as the mean ± standard deviation and the range. The frequency and percentage were used to present categorical variables, e.g. intrauterine growth retardation. Chi-square test was employed to compare the IUGR of the groups whereby, $p<0.05$ was taken as statistically significant. The data was stratified according to age, duration of treatment and BMI so as to account the effect modifiers. The post-stratification Chi-square was utilized to indicate that the p-value was less than 0.05 and that it was significant.

## RESULTS

The baseline maternal and neonatal characteristics were comparable between the Nifedipine and Labetalol groups (Table 1). The participants mean age in the Nifedipine group was 27.02 ± 4.47 years, while in the Labetalol group it was slightly lower at 25.73 ± 4.02 years. This difference fell short of the traditional criterion of $p < 0.05$, even though it was close to statistical significance ($p = 0.06$), indicating that the age distribution between groups was not significantly different.

Regarding body mass index (BMI), both groups were similar with mean values of 26.71 ± 5.70 kg/m² in the Nifedipine group and 26.37 ± 5.01 kg/m² in the Labetalol group ($p = 0.74$). Likewise, neonatal birth weight did not differ significantly in 2 groups, with mean weights of 2.83 ± 0.65 kg in the Nifedipine group and 2.89 ± 0.66 kg in the Labetalol group ($p = 0.41$). The average duration of therapy was also comparable: 13.33 ± 4.40 days for Nifedipine and 13.38 ± 4.69 days for Labetalol ($p = 0.29$). These results suggest no statistically significant differences in maternal baseline metrics or neonatal birth outcomes between the two treatment groups.

Despite the similarities in baseline characteristics, a significant difference was noted in the IUGR incidence between the groups (Table 2). In the Nifedipine group, 6 out of 45 participants (13.3%) experienced IUGR, whereas in the Labetalol group, this proportion was significantly higher at 19 out of 45 (42.2%). This was statistically significant difference having chi-square value of 9.36 and a p-value of 0.002, indicating that IUGR was more frequently associated with Labetalol use.

Subgroup analysis further revealed important patterns (Table 3). Among younger participants aged 18–27 years, IUGR occurred in 13.3% of those on Nifedipine compared to 40.0% in the Labetalol group ($p = 0.024$). A similar trend was noted in the 28–35 age group, where 13.3% in the Nifedipine group had IUGR compared to 45.0% in the Labetalol group ($p = 0.046$). These findings suggest that the risk of IUGR associated with Labetalol may be independent of maternal age.

When stratified by duration of therapy, patients treated for less than 10 weeks with Labetalol had a significantly higher incidence of IUGR (66.7%) compared to only 15.4% in the Nifedipine group ($p = 0.009$). Among those treated for 10–20 weeks, the trend persisted, with 12.5% in the Nifedipine group and 33.3% in the Labetalol group developing IUGR ($p = 0.046$). This indicates that the association between Labetalol use and IUGR may be more pronounced with shorter therapy durations.

BMI stratification also revealed noteworthy differences. Among obese women, 7.7% of those in the Nifedipine group experienced IUGR compared to 41.7% in the Labetalol group ($p = 0.047$). In non-obese women, IUGR occurred in 15.6% of Nifedipine users and 42.4% of Labetalol users ($p = 0.018$). These results suggest that the higher risk of IUGR with Labetalol persists regardless of maternal BMI status.

**Table -1: Descriptive Statistics of Maternal and Neonatal Parameters in Nifedipine and Labetalol Groups (n = 90)**

| Parameter | Group | Mean | S.D. | Minimum | Maximum | p-value |
|---|---|---|---|---|---|---|
| **Age (years)** | Nifedipine (n=45) | 27.02 | 4.47 | 20.00 | 35.00 | 0.06 |
| | Labetalol (n=45) | 25.73 | 4.02 | 18.00 | 35.00 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **BMI (kg/m²)** | Nifedipine (n=45) | 26.71 | 5.70 | 19.19 | 37.04 | 0.74 |
| | Labetalol (n=45) | 26.37 | 5.01 | 18.81 | 35.55 | |
| **Birth Weight (kg)** | Nifedipine (n=45) | 2.83 | 0.65 | 1.82 | 3.88 | 0.41 |
| | Labetalol (n=45) | 2.89 | 0.66 | 1.81 | 3.90 | |
| **Duration of Therapy (days)** | Nifedipine (n=45) | 13.33 | 4.40 | 6.00 | 20.00 | 0.29 |
| | Labetalol (n=45) | 13.38 | 4.69 | 6.00 | 20.00 | |

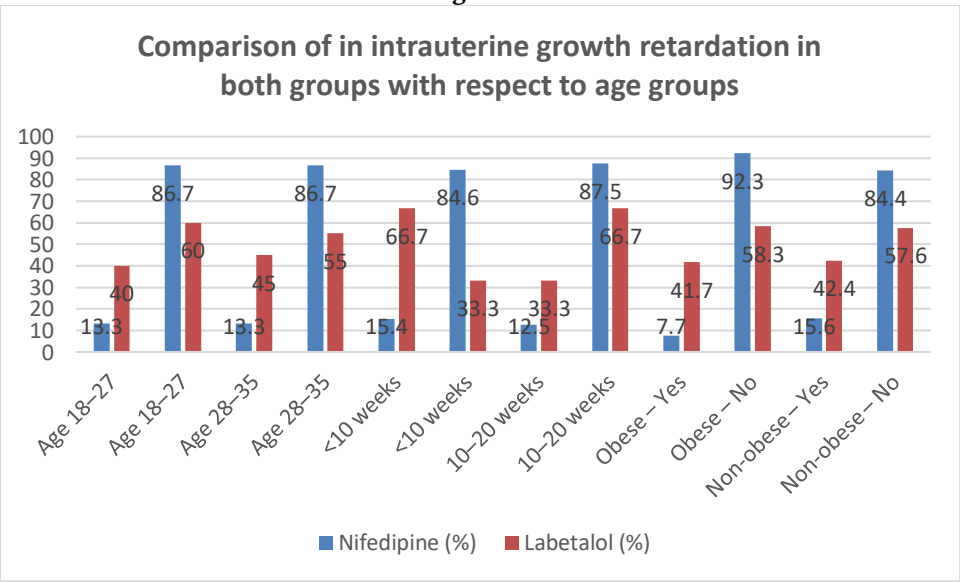
**Table -2: Comparison of in intrauterine growth retardation in both groups**

| | | Study groups | | *Chi-square, p-value* |
|---|---|---|---|---|
| | | **Nifedipine** | **Labetalol** | |
| ***Intrauterine growth retardation*** | ***Yes*** | 6(13.3%) | 19(42.2%) | *9.36, 0.002* |
| | ***No*** | 39(86.7%) | 26(57.8%) | |
| ***Total*** | | 45(100.0%) | 45(100.0%) | |

**Table -3: Comparison of in intrauterine growth retardation in both groups with respect to age groups**

| | | *Intrauterine growth retardation* | Study groups | | p-value |
|---|---|---|---|---|---|
| | | | **Nifedipine** | **Labetalol** | |
| **Age groups *(years)*** | ***18-27*** | ***Yes*** | 4(13.3%) | 10(40%) | 0.024 |
| | | ***No*** | 26(86.7%) | 15(60%) | |
| | ***28-35*** | ***Yes*** | 2(13.3%) | 9(45%) | 0.046 |
| | | ***No*** | 13(86.7%) | 11(55%) | |
| **Duration of therapy *(weeks)*** | ***< 10*** | ***Yes*** | 2(15.4%) | 8(66.7%) | 0.009 |
| | | ***No*** | 11(84.6%) | 4(33.3%) | |
| | ***10-20*** | ***Yes*** | 4(12.5%) | 11(33.3%) | 0.046 |
| | | ***No*** | 28(87.5%) | 22(66.7%) | |
| **BMI** | ***Obese*** | ***Yes*** | 1(7.7%) | 5(41.7%) | 0.047 |
| | | ***No*** | 12(92.3%) | 7(58.3%) | |
| | ***Non-obese*** | ***Yes*** | 5(15.6%) | 14(42.4%) | 0.018 |
| | | ***No*** | 27(84.4%) | 19(57.6%) | |

**Figure: 1**




## DISCUSSION

Maternal hypertensive disorders are one of the dominant causes of morbidities and mortality during the pregnancy. First-line treatments for severe HDP are the intravenous hydralazine or labetalol as the

international guidelines recommend [13]. Latest studies revealed that both labetol and nifedipine have a better efficacy and safety profile rate compared to methyldopa or iv hydralazine in the treatment of preeclampsia while considering the stable Blood pressure after having received therapy [14]. Nifedipine has performed equally well and has been proven to lessen the cases of overshoot hypotension and foetal distress compared to hydralazine, as has labetalol in randomised controlled trials. However, there is an association between the use of labetalol in moderate hypertension and adverse fetal perfusion in a number of observational studies [15]. To determine whether antihypertensive drugs affect fetal growth, this study randomly assigned primagravida women with gestational hypertension and the outcomes were assessed on frequency of intrauterine growth retardation (IUGR). Baseline maternal characteristics (age, weight, height and body mass index) were comparable among both groups with only maternal age 0.19 years greater in the nifedipine arm (27.02 +/- 4.47 years) than in the labetalol arm (25.73 +/- 4.02 years), though this difference was not statistically significant.

A key finding in our study was the significantly lower incidence of IUGR in the nifedipine group (13.3%) compared to the labetalol group (42.2%), with a p-value of 0.002. This reinforces the evidence that nifedipine may be more protective of fetal growth in hypertensive pregnancies. These findings are aligned with a recent prospective comparative study conducted in India, which evaluated oral nifedipine versus intravenous labetalol in cases of severe preeclampsia and showed that nifedipine has accelerated action onset, a lower adverse-effect profile, and even better adaption to resources limited settings despite the fact that both agents are equally capable of reducing the blood pressure. Of note, the risk of IUGR was slightly lower in the nifedipine group than in the labetalol group (12 % versus 15 %), but this difference was not significant (p = 0.50). On the other hand, our research denotes nifedipine to have some tangible protective roles in foetal development hence justifying its clinical value in prenatal hypertension [16]. The results of these are further supported by a double blind randomised controlled trial comparing oral nifedipine with intravenous labetalol used in severe pregnancy hypertension. In the nifedipine group, systolic blood pressure and diastolic blood pressure reduced more rapidly, fewer doses were given out and more urine was excreted without affecting maternal safety. Whereas the prevalence of IUGR in the nifedipine arm was lower (6.7 %), as compared to that of the labetalol arm (13.3 %), the difference was not significant (p = 0.389) [17].

Similarly, another prospective trial compared the two pharmacological regimen on the efficacy and safety of severe hypertensive disorders of pregnancy. The study population was a group of 100 women with preeclampsia diagnosed beyond the 20$^{th}$ week of pregnancy, 50 of which were treated with oral nifedipine and the remaining 50 with intravenous labetalol. IUGR occurred in 24% of the nifedipine group and 30% of the labetalol group, with no statistically significant difference (p=0.50) [16]. Results of the current randomised controlled trial differ with those of a prospective observational study conducted at Chigateri District Hospital in India that demonstrated that the infants of mothers who were given prenatal oral nifedipine had high incidence of IUGR (44.4%) and low birth weight (88.9%) compared to the infants of mothers who received antepartum labetalol where the incidence of IUGR was 14.3%. The researchers hence hypothesized that nifedipine could be left to be used postnatally where the outcomes of the fetus are taken into consideration and labetalol could be used in prenatal setting although both drugs possess high dose efficacy in decreasing hypertension in pregnant mothers. These variation in results between the two studies can be because of the study design, timing of initiation of treatment and policies of monitoring. Both studies however conclude that nifedipine has great cost-effectiveness thus making it effective in the management of hypertensive pregnancy in low-resource settings with use based on established guideline [18].

Nimbark et al. conducted another prospective study to determine the efficacy and safety of nifedipine and labetalol in 200 pregnant women having hypertension. The participants were randomly allocated to have their treatment to either labetalol (Group A) or nifedipine (Group B) and their outcomes that involved the analysis of side effects, complications during their pregnancy and their birth patterns. IUGR was observed in 1% of labetalol users and 3% of nifedipine users, with no statistically significant difference. Both agents were equally effective in reducing blood pressure, but labetalol was usually well tolerated and with fewer side effects as compared to nifedipine [19].

In our current cohort study, the mean birth weight of the labetalol group of 2.89 +/- 0.66 kg was slightly higher than that of the nifedipine group of 2.83 +/- 0.65 kg but this difference was not significant and could not be attributed to the more major and clinically significant difference in the prevalence of IUGR. This conclusion has some discrepancy to that of a local randomised controlled trial conducted in Lahore, which demonstrated that the average birth weight of nifedipine group was significantly higher than that of labetalol group (2.6 0.3 kg vs. 2.3 0.3 kg, p < 0.01) [11].
These two cohorts had the same mean antihypertensive treatment times, about 13.3 weeks,

and it is possible that it was a result of choice of medication and not the length of exposure that produced the differences in these cohorts. The protection by nifedipine was consistent across all groups of maternal age, BMIs, and categories of treatment duration as shown by subgroup analysis. As an example, the IUGR rate of the nifedipine group was significantly lower (13.3% vs. 40) in the study group ages between 18 and 27 years. Similarly, similar trends were observed in the subgroups who got less than 10 weeks, 10 to 20 weeks of therapy or more than 20 weeks of therapy, older age group, in obese and non-obese women. These results support the suitability and effectiveness of nifedipine, which proves that its positive effects are not limited to any particular subgroup.

In our study, the findings have an important clinical implication. Despite the fact that both nifedipine and labetalol belong to the first-line antihypertensive drugs in the context of pregnant women (according to NICE and ACOG guidelines), we revealed very different foetal development patterns when both drugs were used [20]. Moreover, the higher cost-effectiveness, widespread distribution, and convenience of dosing (with nifedipine, two or one time daily), as well as their administration (oral administration), favours nifedipine in a particular environment with low resources. Another benefit that nifedipine possesses is the prevention of hospitalisation linked with the intravenous use of labetalol in some cases of treatment [21].

Despite these comments, our study has certain limitations as it is single-centred, the sample size is relatively small, and the parameters of neonatal outcomes are narrow (that is, intrauterine growth restriction and birth weight), which makes the data interpretation overall less interpretable. Such depth of knowledge may be achieved by using longitudinal follow-up data, which carry beyond the domain of neurodevelopmental outcomes. In that regard, it is recommended that future multicentre studies with larger cohorts are used.

## CONCLUSION

Coming to the conclusion of the study, we can state that the IUGR frequency in cases who had used nifedipine was very little as compared to labetalol. So, the antihypertensive drug like labetalol can influence fetal behavior in cases of low-grade pregnancy hypertension disorders. The risks and benefits to the mother as well as the fetus have to be weighed out to best benefit.

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