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A Comparative Study of Oral Nifedipine and Intravenous Labetalol for Acute Hypertensive Management in Pregnancy: Assessing Feto-Maternal Outcomes in a Hospital-based Randomized Control Trial

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ABSTRACT

Background and Objective: Hypertension is one of the most common medical complications during pregnancy and a leading cause of maternal mortality and morbidity. Severe preeclampsia is defined as blood pressure (BP) >160/110 mmHg with warning signs such as headache, blurring of vision, and epigastric pain. Nifedipine ($C_{17}H_{18}N_2O_6$), labetalol ($C_{19}H_{24}N_2O_3$), and hydralazine ($C_8H_8N_4$) are commonly used drugs, and all are recommended as first-line agents. Hydralazine is associated with a higher incidence of adverse outcomes, so oral nifedipine has been proposed as a first-line alternative to intravenous labetalol. Consequently, this study aims to compare the efficacy and safety of oral nifedipine with that of intravenous labetalol. The objective is to compare the ability/effectiveness of oral nifedipine and intravenous labetalol to normalize acute hypertension in severe preeclampsia and to assess the birth outcome. Relations between different factors were established by appropriate statistical tests. The p-value <0.05 was considered statistically significant.

Methods: The study was conducted on 120 antenatal women with blood pressure ≥160/110 mmHg admitted to our hospital, a tertiary care center, from January 1st, 2020 to June 30th, 2021. Patients were randomized by a single blinding method to receive intravenous labetalol and oral nifedipine. The primary outcome measures were the time taken to control the blood pressure and the number of doses of drugs required. The secondary outcome measures were the birth outcome like a method of delivery, side effect profile, and the number of admissions in the neonatal intensive care unit.

Results: A total of 120 patients were included with 60 patients in each group. The labetalol group took 48.67 ± 17.80 minutes and the nifedipine group took 64.33 ± 9.81 minutes to achieve a target BP of <=140/90 mmHg ($p < 0.05$). No side effects were seen in 70% of patients in the labetalol group and 71.67% in the nifedipine group ($p > 0.05$).

Conclusion and Global Health Implications: Intravenous labetalol is faster in restoring blood pressure in pregnant women with preeclampsia than oral nifedipine and may be used as a first-line drug in the acute control of blood pressure in a hypertensive emergency during pregnancy. More studies are needed in order to evaluate the findings from this pilot study in a large sample of patients.

Keywords: Severe Preeclampsia, Labetalol, Nifedipine, Hypertension, Pregnancy, Comparison

INTRODUCTION

Hypertension is one of the most common medical complications during pregnancy, and it is a leading cause of maternal mortality and morbidity.[1] Hypertension with hemorrhage and infection

forms the deadly triad that increases the risk of morbidity and mortality during pregnancy and childbirth.[2] The incidence of hypertensive disorders in pregnancy varies between 5% and 10% contributing to 22% of perinatal and 30% of maternal deaths.[3] The incidence of hypertensive disorders is on the rise due to factors such as women postponing their first pregnancy and an increase in pre-pregnancy weight. On the other hand, the adverse outcomes due to eclampsia are declining in industrialized and affluent societies due to better antenatal care and management of preeclampsia. Hypertensive disorders of pregnancy are classified as gestational hypertension, preeclampsia, eclampsia, chronic hypertension, and chronic hypertension with superimposed preeclampsia.

Hypertension during pregnancy is diagnosed when the systolic pressure is ≥140 mmHg and/or a diastolic pressure of ≥90 mmHg and is measured on two occasions at least 4 hours apart.[4,5] Gestational hypertension is defined as new-onset hypertension developing after 20 weeks of gestation, during labor or in the first 24 hours postpartum, without proteinuria or any other systemic features of preeclampsia, in a previously normotensive nonproteinuric woman and the blood pressure resolves within 12 weeks postpartum. Preeclampsia is defined as hypertension associated with proteinuria greater than 0.3 g/L in a 24-hour urine collection or +1 by qualitative estimation using reagent strips, after 20 weeks of gestation. Eclampsia is defined as preeclampsia with seizure. Chronic hypertension is defined as hypertension present before the 20th week of pregnancy and persists beyond 12 weeks postpartum. Preeclampsia superimposed on chronic hypertension is diagnosed when one or more features of preeclampsia (e.g., elevated liver enzymes, low platelets, proteinuria) develop for the first time during pregnancy after 20 weeks, in a woman with pre-existing chronic hypertension.

Hypertensive disorders can result in several maternal complications including eclampsia, cerebrovascular accidents, placental abruption, HELLP (hemolysis, elevated liver enzymes, low platelet count) syndrome, pulmonary edema, acute renal failure, and microangiopathic hemolytic anemia. Hypertensive disorders also carry a risk for the baby. Preeclampsia is strongly associated with fetal growth restriction, low birth weight, spontaneous or iatrogenic preterm delivery, respiratory distress syndrome, and admission to neonatal intensive care.[6]

For the purpose of management, preeclampsia is divided into non-severe and severe forms based on the level of blood pressure (BP) and the presence of signs and symptoms of end-organ damage. Non-severe preeclampsia is defined as BP >140/90 mmHg but <160/110 mmHg without warning signs. Severe preeclampsia is defined as BP ≥160/110 mmHg with warning signs like headache, blurring of vision, and epigastric pain.

The basic management objective for any pregnancy complicated by severe preeclampsia is the termination of pregnancy with the least possible trauma to the mother and fetus, the birth of a healthy baby, and the restoration of the health of the mother. Treating hypertension does not alter the progress of the disease, but the reduction of BP is necessary to reduce complications like placental abruption, pulmonary edema, hypertensive encephalopathy, intracranial hemorrhage, eclampsia, and end-organ damage.[7] Several drugs are available to rapidly lower the BP in hypertensive emergencies of pregnancy. The most common drugs are nifedipine, labetalol, and hydralazine. All three of these are recommended as first-line agents.[8] Nifedipine has now been safely used in several obstetric trials for the treatment of hypertensive emergencies.[9-12] It is orally effective, cheap, and easy to administer and store. Nifedipine increases cardiac output and coronary blood flow and also increases urine output. Intravenous labetalol is equally effective in controlling severe hypertension in pregnancy and has the advantage of administering it in unconscious patients. An intravenous drug like injectable labetalol is mainly used to rapidly lower BP in case of acute hypertensive crisis. Injectable medications necessitate venous access and thorough fetal monitoring, which may not be feasible in resource-limited or busy settings. In contrast, oral medications can be distributed across various healthcare settings, require no cold storage, need only basic drug administration training, and are widely available in both low- and middle-income countries. Studies comparing hydralazine to labetalol and nifedipine to control BP in severe preeclampsia showed that hydralazine was associated with a higher incidence of adverse outcomes like hypotension, placental abruption, oliguria, cesarean section, adverse effect on fetal heart rate, and low Apgar score at 1 min, when compared to other hypertensives.[13] Oral nifedipine has been proposed as a first-line alternative to IV labetalol.[14] The purpose of this study therefore was to compare the effectiveness and safety of oral nifedipine and intravenous labetalol to normalize acute hypertension in severe preeclampsia.

METHODS

This study was conducted on 120 antenatal women admitted to the obstetrics and gynecology department at a tertiary care hospital from January 1st, 2020 to June 30th, 2021 for a period of 18 months. This was a hospital-based randomized controlled trial. The study was approved by the ethical committee of Uttar Pradesh University of Medical Science, Saifai, Etawah. This study was not registered with any clinical

trial registry, as this study sample size was small and is a pilot study. This is the limitation of this study.

Sample Size Determination

Sample size calculated using the formula:

$$N \geq (Z_{1-\alpha/2} + Z_{1-\beta})^{2} (\sigma_1^2 + \sigma_2^2/r)/(\mu_1 \mu_2)^2$$

Z-score = Value's relationship to the mean

N = Sample size

α = Type 1 error rate

β = Type 2 error rate

μ_1 = Expected mean of the outcome in group 1

μ_2 = Expected mean of the outcome in group 2

σ_1 = Expected standard deviation of the outcome in group 1

σ_2 = Expected standard deviation of the outcome in group 2

r = Sample size ratio group 2/1

μ_1 = 32.62

μ_2 = 26.25

σ_1 = 12.19

σ_2 = 12.60

So, the sample size was calculated using the above formula = 60 samples per group.

Hence, the total sample size was 60 patients in the Injectable labetalol group and 60 patients in the oral nifedipine group.

The study included pregnant women aged 18–40 years with a gestational age of over 34 weeks and a blood pressure of ≥160/110 mmHg, all of whom were admitted to the obstetrics and gynecology department of our institution. Informed written consent was sought from pregnant women, who fulfilled the criteria for inclusion. Group 1 included 60 patients on the injectable labetalol and Group 2 included 60 patients on oral nifedipine. Patients with essential hypertension, eclampsia, previous history of cardiac disease, bronchial asthma, hematological disorder, diabetes mellitus I and II, liver disorders, history of allergy to labetalol or nifedipine, gestational diabetes mellitus, maternal tachycardia, or bradycardia (PR >120/min and PR < 60/min) were excluded from the study. A detailed history from the patients regarding age, parity, gestational age, socio-economic status, booking history, and history suggestive of imminent symptoms, past, personal, and family history was taken to exclude the above-mentioned exclusion criteria. Obstetrical history was taken with special reference to any complications like recurrent abortions, intrauterine death, intrauterine growth restriction (IUGR), preeclampsia, and multiple pregnancies in previous pregnancies. A proper general examination and obstetric examination were done with special attention to pallor, icterus, edema, blood pressure, and weight of the patient at the beginning of the study. Systemic examination of the cardiovascular system, central nervous system, and respiratory system was done to exclude the presence of any systemic disease. Assessment of fetal well-being was carried out by clinical (fetal heart rate) and ultrasound evaluation. Patients were catheterized with Foley's catheter to measure urine output. Necessary laboratory investigations like complete blood count (CBC), random blood sugar, blood grouping and cross matching, liver and renal function tests, serum lactate dehydrogenase (LDH) and uric acid, urine albumin, and ultrasonography were performed. Patients were randomly allocated to one of two groups, each comprising 60 subjects using a computerized random number table. Group 1 received an injection of labetalol and group 2 received oral nifedipine.

Group 1 (labetalol group): After taking the initial BP, 20 mg of labetalol was administered slowly intravenously over 2 min. The BP was measured after 20 min of the labetalol administration. If BP was uncontrolled, we repeated with slow 40 mg labetalol IV administration in escalating doses of 80 mg, 80 mg, and 80 mg till the target blood pressure of ≤ 140/90 mmHg was achieved. A maximum of five doses of intravenous labetalol were given.

Group 2 (nifedipine group): After taking the initial BP, 10 mg of nifedipine was administered orally, and BP was measured after 20 min. For uncontrolled BP, we repeated 20 mg nifedipine orally and measured BP after 20 min. If BP was further uncontrolled, we repeated 20 mg nifedipine orally till the target blood pressure of ≤140/90 mmHg was achieved. A maximum of five doses of oral nifedipine were given.

No cross-over treatment was given in the study. After the successful control of blood pressure, further antihypertensive therapy and delivery of the baby as the definitive treatment for severe pregnancy-induced hypertension was done for participants at or near term as a standard practice. The primary outcome measures were the time taken to control blood pressure and the number of drug doses needed to achieve this control. Secondary outcome measures were the maternal outcome, method of delivery and side effect profile, and neonatal outcomes in the form of the number of admissions in the neonatal intensive care unit.

Statistical Analysis

Data was compiled using MS Excel and analyzed using Statistical Package for the Social Sciences software (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.). Data was grouped and

presented as frequency and percentage whereas numerical data was expressed as mean ± standard deviation. Data was represented as tables and graphs. Relations between different factors were established by Chi-square test. The *p*-value <0.05 was considered statistically significant.

RESULTS

A total of 120 patients were recruited in this randomized control trial and later divided into two groups randomly by a single blinding technique. Group 1 and group 2 consisted of 60 patients each, who were managed with injection labetalol and oral nifedipine tablets, respectively. Patient characteristics are shown in Table 1. The mean age of patients was 25.85±3.10 years and 24.92±3.12 in group 1 and group 2, respectively. As well, 78.33% (47/60) and 56.67% (34/60) primigravida were found in groups 1 and 2, respectively (p=0.071). The majority of patients had a gestational age ranging from 34 to 36 weeks. The average gestational ages for group 1 and group 2 were 36.43±1.48 and 36.10±1.68, respectively. In group 1, 51.67% (31/60) of the patients were booked while in group 2, 53.33% (32/60) patients were booked (p=0.855). About 68.33% in group 1 and 66.67% in group 2 had BMI ≥30 kg/m^2. The mean BMI in the labetalol and nifedipine groups was 31.01±2.34 and 30.92±2.08 kg/m^2, respectively. The primary outcome of the study is the time taken to achieve blood pressure control is shown in Table 2. The average time taken to control the BP was 48.67±17.80 min for group 1 and 64.33±9.81 min for group 2 ($p \leq 0.0001$). About 78.33% of patients in group 1 reached a target blood pressure of ≤140/90 mmHg after two doses of antihypertensive. Also, 81.67% of patients enrolled in group 2 reached the target blood pressure of ≤140/90 mmHg after three doses of antihypertensive (p-value ≤ 0.0001). A total of 81 patients comprising 66.67% of group 1 and 68.33% of group 2 were delivered vaginally. The remaining patients delivered their babies using cesarean section (p-value = 0.845). The mean birth weights of babies in group 1 and 2 were 2.41±0.46 kg and 2.36±0.53 kg, respectively. Ten percent of mothers in group 1 and 18.33% of mothers in group 2 had their newborns admitted to the intensive care unit, respectively (p = 0.191). In group 1, out of 10% of intensive care admissions, 6.67% (4/60) of the babies died. In group 2, out of 18.33% of intensive care admissions, 11.67 % (7/60) of the babies died (p = 0.342). No major adverse effects were reported in the majority of the recruited patients. In group 1, the common adverse effects were dizziness (11.67%), headache (6.67%), and nausea (5.00%). The common adverse effects in patients recruited in group 2 were nausea (10%), headache, and dizziness (8.33%). Overall, there was no significant difference in adverse effects in both groups (p-value = 0.580).

Table 1: Maternal characteristics.

Maternal characteristics	Group-1 Labetalol (n = 60)	Group-2 Nifedipine (n = 60)	*p* value
Maternal age (years)	25.85±3.10	24.92±3.12	0.222
Primigravida	47 (78.33%)	34 (56.67%)	0.071
Gestational age (weeks)	36.43±1.48	36.10±1.68	0.358
Booking status Booked Unbooked	 31 (51.67%) 29 (48.33%)	 32 (53.33%) 28 (46.67%)	0.855
BMI	31.01±2.34	30.92±2.08	0.845

BMI: Body mass index

Table 2: Fetomaternal outcome.

Fetomaternal outcome	Group-1 Labetalol	Group-2 Nifedipine	*p* value
Time (min) taken to achieve target blood pressure	48.67 ± 17.80	64.33 ± 9.81	<0.0001
Total antihypertensive doses to achieve target blood pressure	78.33% in 2 doses	81.67% in 3 doses	<0.0001
Mode of delivery Vaginal Cesarean	 40 (66.67%) 20 (33.33%)	 41 (68.33%) 19 (31.67%)	0.845
Birth weight (kg)	2.41 ± 0.46	2.36 ± 0.53	0.557
NICU admission YES NO	 6 (10%) 54 (90%)	 11 (18.33%) 49 (81.67%)	0.191
Neonatal outcome Alive Dead	 56 (93.33%) 4 (6.67%)	 53 (88.33%) 7 (11.67%)	0.342
Adverse drug reactions No ADR Dizziness Headache Palpitations Nausea Tremor	 42 (70%) 7 (11.67%) 4 (6.67%) 2 (3.33%) 3 (5.00%) 2 (3.33%)	 43 (71.67%) 5 (8.33%) 5 (8.33%) 1 (1.67%) 6 (10%) 0 (0.00%)	0.580

NICU: Neonatal intensive care unit, ADR: Adverse drug reaction.

DISCUSSION

Hypertensive emergency in pregnancy is associated with morbidity and mortality in both maternal and neonatal populations. The primary aim of this study is to compare the efficacy and safety of oral nifedipine with intravenous labetalol in the control of acute hypertension in severe preeclampsia. In the present study, the mean age of the patients enrolled in this study was 25.85 and 24.92 years in the labetalol and nifedipine groups, respectively. These findings are similar to the study done by Afreen *et al.* (2018).[15] In the present study,

78.33% of patients in the labetalol group and 56.67% in the nifedipine group were primigravida. A similar observation was made in the study by Duckitt *et al.* (2005), which showed that primiparity is one of the risk factors for preeclampsia.[16] In the present study, 51.67% in the labetalol group and 60% in the nifedipine group belonged to gestational age of 34–36 weeks. This is similar to a study conducted by Ramprasad Dey *et al.* (2017).[17] In the present study, 68.33% in the labetalol group and 66.67% in the nifedipine group have a body mass index (BMI) ≥30 kg/m^2. The mean BMI in the labetalol group and nifedipine group are 31.01±2.34 and 30.92±2.08 kg/m^2, respectively. Most of the patients enrolled in the labetalol and nifedipine groups fell under the category of obesity. These findings are similar to the study by Sibai and others (1997).[18] In the present study, out of the 60 patients enrolled in the labetalol group, 47 patients, constituting 78.33% of the study population achieved the target blood pressure of ≤ 140/90 mmHg in 40 min of commencement of the treatment, requiring two incremental doses of intravenous labetalol. In the nifedipine group, 81.67% of the enrolled patients required three doses of oral nifedipine. On statistical analysis, there was a significant difference in the time taken for both drugs to act for reduction in systolic blood pressure. This is in contrast with a double-blind randomized trial by Raheem *et al.* (2012), which showed that both labetalol and nifedipine are equally efficacious in controlling blood pressure.[19] A study conducted by Vermilion *et al.* (1999), showed that oral nifedipine is superior when compared to labetalol in blood pressure control.[20] The present study's findings were in contrast with that of Shekhar *et al.* (2016), which compared oral nifedipine and intravenous labetalol for severe hypertension during pregnancy. This study included 363 women and concluded that oral nifedipine is as efficacious and safe as intravenous labetalol.[21] All the patients enrolled in the study received prophylactic magnesium sulfate therapy. None of the patients developed eclampsia in antepartum or post-partum periods. In the present study, none of the patients receiving either drug developed hypotension or neuromuscular blockade. This is similar to the Magpie trial in 2002, which recruited 10,141 women with preeclampsia and showed that there was no significant interaction between nifedipine and magnesium sulfate.[22] All group 1 patients (injection labetalol) were given oral labetalol and all group 2 patients (oral nifedipine) were given oral nifedipine as a maintenance dose after achieving a target blood pressure of ≤140/90 mmHg. Among the patients enrolled, 66.67% delivered vaginally and 33.33% delivered by cesarean section in group 1 while in group 2, 68.33% delivered vaginally and 31.67% delivered by cesarean section.

There was no significant difference in birth weight in both groups. In the present study, 10% of the newborns from the labetalol group and 18.33% of the newborns from the nifedipine group were admitted for intensive care. A study conducted by Tayyiba Wasim *et al.* (2020), to compare oral nifedipine and intravenous labetalol in terms of rapidity of BP control in severe preeclampsia, showed that in the labetalol group, 22.54% of babies and in nifedipine group 29.40% of babies were admitted in neonatal intensive care unit (NICU).[23] The causes of admission were extreme prematurity and respiratory distress syndrome. The outcome was similar in both groups. None of the newborns had neonatal hypoglycemia or hypotension after birth.

In the present study, 6.67% of the newborns from the labetalol group and 11.67% of admitted newborns from the nifedipine group died due to extreme prematurity. In a study by Tayyiba Wasim *et al.* (2020), 20.5% of babies in group A and 18.6% of babies in group B showed perinatal deaths.[23]

The majority of the patients enrolled in the study did not report any notable adverse effects. The most commonly reported adverse effect in the labetalol group was dizziness and that in the nifedipine group was headache and nausea. 3.33% of the patients in the labetalol group had palpitations, though 1.67% of patients in the nifedipine group had complained of the same. 3.33% of the patients enrolled in the labetalol group complained of tremors. On the whole, there was no statistically significant difference in adverse effects between both groups. This is in comparison to the study conducted by Vermillion *et al.* (1999), which showed that adverse effects were infrequent.[20]

Limitations

One limitation of our study is the small sample size. Given that this was a pilot study, the sample size was small in order to evaluate the study outcomes in a small sample. Given this small sample size, this study was not required to be registered with a clinical trial registry.

CONCLUSION AND GLOBAL HEALTH IMPLICATIONS

Both oral nifedipine and intravenous labetalol demonstrated safety and efficacy in reducing blood pressure. None of the drugs were associated with any detrimental maternal or fetal outcomes with respect to the anti-hypertensive usage. Intravenous labetalol proved more efficacious than oral nifedipine, suggesting its suitability as a first-line treatment for hypertensive emergencies due to its rapid blood pressure-lowering effect and the need for fewer doses.

Key Messages

- Preeclampsia can lead to complications in the liver, kidneys, brain, and the clotting system. Fetal risks are poor growth and prematurity. Although the outcome

is often good, preeclampsia can be devastating and life-threatening.
- In low and middle-income countries many public hospitals have limited access to neonatal intensive care, so mortality and morbidity are likely to be higher in these settings.
- Antihypertensive drugs are mandatory for high blood pressure.

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COMPLIANCE WITH ETHICAL STANDARDS

Conflicts of Interest

There are no conflicts of interest.

Financial Disclosure

Nothing to declare.

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Ethics Approval

This is an Original Article study. Approval/clearance for undertaking the proposed research study was obtained from the Institutional Ethics Committee, UPUMS, Saifai, Etawah-206130, Uttar Pradesh, India. The ethical clearance number is 125/2019-20.

Declaration of Patient Consent

Patient's consent is not required as the patient's identity is not disclosed or compromised.

Use of Artificial Intelligence (AI)-Assisted Technology for Manuscript Preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

Disclaimer

None.

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