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COMPARATIVE EFFECT OF ORAL NIFEDIPINE VERSUS IV LABETALOL IN SEVERE PRE ECLAMPSIA

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Abstract

Introduction: *Pre-eclampsia is a pregnancy disorder involving hypertension and proteinuria after 20 weeks, affecting 2-8% of pregnancies globally. Severe cases with high blood pressure require urgent intervention to prevent complications for mother and baby. This study compared Nifedipine and Labetalol for managing severe pre-eclampsia's efficacy and safety.*

Methodology: *A randomized controlled trial took place at the Obstetrics & Gynecology Department, Allama Iqbal Memorial Teaching Hospital, Sialkot, from Nov 16, 2024, to May 15, 2025. 260 pregnant women (130/group) with severe pre-eclampsia (>24 weeks gestation, BP ≥160/110 mmHg) were enrolled through non-probability consecutive sampling. Group A received intravenous Labetalol starting at 20 mg, escalating up to 300 mg in 20-minute intervals until reaching target BP (<160/100 mmHg). Group B took oral Nifedipine 10 mg every 20 mins, up to 50 mg, until target BP or 2 hrs. Primary outcomes included time to target BP and success rate (<2 hrs to achieve target BP).*

Results: *The Oral Nifedipine group achieved target blood pressure in 30.20±3.21 minutes, significantly faster than the IV Labetalol group at 44.05±7.06 minutes (p=0.001). Nifedipine group success rate was notably higher at 87.7% compared to Labetalol group's 64.6% (p=0.001).*

Conclusion: *Oral Nifedipine is more effective than IV Labetalol in rapidly controlling blood pressure in severe pre-eclampsia, making it a preferred first-line agent due to its superior efficacy, ease of use, and consistent performance across patient demographics and clinical factors.*

INTRODUCTION

Pre-eclampsia is when women, with normal blood pressure before 20 weeks of pregnancy, develop hypertension and proteinuria.[1] Eclampsia and Preeclampsia are pregnancy-related conditions characterized by high blood pressure in the latter half of pregnancy. Progression to severe hypertension can be sudden and unpredictable. Severe preeclampsia is diagnosed when blood pressure levels reach ≥160mmHg systolic and ≥110mmHg diastolic, alongside proteinuria of ≥300mg/24 hours.[2]

In low and middle-income countries, hypertensive disorders of pregnancy account for 10-15% of direct maternal deaths globally.[3] Hypertension affects around 7.7% of women of reproductive age.[4] Each year, over 4 million women worldwide develop preeclampsia, with about 100,000 experiencing eclamptic convulsions.[5] PE is diagnosed in pregnancy when new hypertension and proteinuria present. Maternal complications of acute hypertension include placental abruption, intra-

abdominal hemorrhage, HELLP syndrome, heart issues, stroke, kidney failure, and organ failure.[6]

If untreated, preeclampsia can lead to symptoms like headaches, visual disturbances, epigastric pain, and abnormal liver, renal, and blood functions. Severe cases can cause pulmonary edema, cerebral hemorrhage, organ failure, and maternal death. Abnormal liver, kidney, and blood functions elevate the risk of preeclampsia.[7] Lowering blood pressure to levels ≤150/100 mmHg is essential to reduce these complications.[8] The definitive treatment for preeclampsia is delivering the fetus.[9]

Various drugs like hydralazine, labetalol, and nifedipine are commonly used for acute blood pressure control in pregnancy emergencies. These are recommended as first-line agents and should be initiated at a blood pressure of 150/100mmHg. If systolic BP is 180mmHg or diastolic BP is 120mmHg, antihypertensive treatment is necessary. Labetalol and hydralazine are typically given intravenously to manage severe hypertension in pregnancy, although they may have side effects. Nifedipine, an oral calcium channel blocker, is also effective.[10]

In a study by Ujala S, et al., blood pressure normalized within two hours for 84.55% in group A (oral nifedipine) and 70.0% in group B (IV labetalol, p=0.0003). Mean time for control was 26.87±9.22 minutes (group A) and 45.54±16.91 minutes (group B, p<0.0001).[11]

This study aimed to compare Oral Nifedipine and IV Labetalol in controlling blood pressure in preeclamptic patients, a newer approach in Obstetrics & Gynecology in Pakistan. The research evaluates their effectiveness due to limited local data, potentially guiding better treatment decisions to prevent complications. This advancement in obstetrics could lead to improved patient care and benefit stakeholders in our local setting.

METHODOLOGY

This randomized controlled trial compared the outcome of oral Nifedipine versus intravenous Labetalol for rapid control of blood pressure in pre-eclamptic pregnant patients. The study was conducted at the Obstetrics & Gynecology Department of Allama Iqbal Memorial Teaching Hospital, Sialkot, from November 16, 2024, to May 15, 2025. Non-probability consecutive sampling technique was employed for patient selection. A sample size of 260 cases (130 in each group) was calculated using a 95% confidence level with 80% power of test, expecting a success percentage of 84.55% in the oral Nifedipine group versus 70.0% in the Labetalol group.[11]

The study included pregnant women aged 18-38 with pre-eclampsia, defined as hypertension of at least 140/90 mmHg on two occasions at least 4 hours apart, with at least 300 mg protein in a 24-hour urine collection after the 20th week of pregnancy in a previously normotensive woman. All patients were >24 weeks gestation with severe hypertension (systolic BP ≥160 mmHg or diastolic BP ≥100 mmHg) and had no contraindications to oral Nifedipine or IV Labetalol. Exclusions comprised women with pre-existing medical conditions like diabetes, cardiac diseases, renal diseases, thyrotoxicosis, hemophilia, and chronic hypertension. Patients with a history of eclampsia, Glasgow coma scale <6, chronic hypertension, or secondary causes of hypertension were also excluded.

After approval from the ethics committee, eligible patients from the outdoor or emergency department were chosen. Each patient gave written consent after being informed about the benefits and risks of both drugs. Data on demographics (name, age, hospital registration, gestational age, number of pregnancies, BMI, education level, and parity) were recorded. The cases were randomly split into two equal groups using a computer. In Group A (n=130), patients received intravenous labetalol in increments up to a total of 300 mg if needed to achieve the target blood pressure (<160/100 mmHg). If the target was not reached, patients were switched to Nifedipine.

In Group B, women were given 10 mg of Nifedipine every 20 minutes up to a maximum of 50 mg until reaching a target BP (<160/100 mmHg). Labetalol was an option if this dose was insufficient. Severe pre-eclampsia patients received magnesium sulphate as per protocol. Fetal heart rate was monitored every 15 minutes. If BP wasn't controlled within one hour, other drugs were used. Trial stopped if fetal or maternal risk arose. Antihypertensive

therapy began 2 hours post-medication for severe hypertension in pregnancy.

The primary outcome was the time to reach target blood pressures (<160/100 mmHg). Success meant achieving this within two hours. The null hypothesis compared Nifedipine and intravenous Labetalol in managing pre-eclampsia patients.

Data input and analysis utilized SPSS version 25.0. For various variables (age, gestational age, BMI, time to reach target blood pressure), mean, standard deviation, frequency, and percentage were calculated. The difference in time to reach target blood pressure for Labetalol and Nifedipine groups was assessed using independent t-test ($p \leq 0.05$) while success comparison used chi-square test. Age, gestation period, parity, and living place were controlled through stratification. Post-stratification t-test and Chi-square tests were used ($p \leq 0.05$).

RESULTS

Table-1 compares demographic and clinical data of patients in the IV Labetalol (Group-A) and Oral Nifedipine (Group-B) groups for treating severe pre-eclampsia. Both groups showed similar age distributions: 18-30 years (Group-A: 42.3%, Group-B: 43.1%) and 31-38 years (Group-A: 57.7%, Group-B: 56.9%). Mean age was also similar (Group-A: 31.28±4.47 years, Group-B: 31.15±4.43 years). Body Mass Index (BMI) was comparable between the groups: IV Labetalol (24.96±1.23 kg/m^2) and Oral Nifedipine (24.92±1.22 kg/m^2).

Regarding gestational age, most patients in both groups were beyond 37 weeks (73.8% in Group-A and 74.6% in Group-B), with mean gestation of 37.96±1.37 weeks and 37.97±1.46 weeks for Groups A and B, respectively. Parity distribution was similar, with 58.5% primiparous women in Group-A and 59.2% in Group-B, while multiparous women were 41.5% of Group-A and 40.8% of Group-B. Residence-wise, the majority in both groups hailed from rural areas (60.8% in Group-A and 61.5% in Group-B), with the rest from urban areas (39.2% in Group-A and 38.5% in Group-B).

Significant differences were observed in table-2 for both outcome measures. The mean time to reach target blood pressure was significantly shorter with Oral Nifedipine (30.20±3.21 minutes) compared to IV Labetalol (44.05±7.06 minutes) ($p=0.001$). Oral Nifedipine had a higher success rate of achieving target blood pressure within two hours (87.7%) compared to IV Labetalol (64.6%) ($p=0.001$).

Table-3 displays that Oral Nifedipine consistently achieved target blood pressure faster than IV Labetalol in all subgroups, with significant differences ($p=0.001$). Nifedipine averaged about 30-31 minutes, while Labetalol averaged 43-46 minutes. This suggests Nifedipine may be the preferred first-line treatment for severe pre-eclampsia regardless of patient characteristics.

Table-4 shows Oral Nifedipine's consistently superior success rates (83.1%-94.3%) compared to IV Labetalol (60.0%-68.0%) across all patient subgroups, with statistical significance ($p<0.05$). Particularly effective in multiparous women (94.3% success), Nifedipine outperforms Labetalol for blood pressure control in severe pre-eclampsia across various patient characteristics.

Table-1: Comparison of distribution of different variables between groups

Variables		Groups	
		Group-A (IV Labetalol) (n=130)	Group-B (Oral Nifedipine) (n=130)
Age groups	18-30 years	55(42.3%)	56(43.1%)
	31-38 years	75(57.7%)	74(56.9%)
	Mean±S.D	31.28±4.47	31.15±4.43
BMI (kg/m^2)	Mean±S.D	24.96±1.23	24.92±1.22
Gestational age	≤37 weeks	34(26.2%)	33(25.4%)
	>37 weeks	96(73.8%)	97(74.6%)
	Mean±S.D	37.96±1.37	37.97±1.46
Parity	Primiparous	76(58.5%)	77(59.2%)
	Multiparous	54(41.5%)	53(40.8%)
Residence	Rural	79(60.8%)	80(61.5%)
	Urban	51(39.2%)	50(38.5%)

Table-2: Comparison of outcomes between groups

Outcomes		Groups		p-value
		Group-A (IV Labetalol)	Group-B (Oral Nifedipine)	
Mean time to achieve target blood pressure (minutes)		44.05±7.06	30.20±3.21	0.001
Success	Yes	84(64.6%)	114(87.7%)	0.001
	No	46(35.4%)	16(12.3%)	

Table-3: Stratification of mean time to achieve target blood pressure between groups with respect to different variables

Variables	Groups		p-value
	Group-A (IV Labetalol)	Group-B (Oral Nifedipine)	
Age groups			
18-30 years	44.05±6.63	30.05±3.27	0.001
31-38 years	44.04±7.40	30.31±3.18	0.001
Gestational age			
≤37 weeks	45.85±6.70	30.67±3.55	0.001
>37 weeks	43.41±7.10	30.04±3.09	0.001
Parity			
Primiparous	44.04±6.73	30.42±3.11	0.001
Multiparous	44.06±7.56	29.89±3.36	0.001
Residence			
Rural	44.00±7.44	30.06±3.11	0.001
Urban	44.12±6.50	30.42±3.38	0.001

Table-4: Stratification of success between groups with respect to different variables

Variables	Success	Group-A (IV Labetalol)	Group-B (Oral Nifedipine)	p-value
Age groups				
18-30 years	Yes	33(60.0%)	48(85.7%)	0.002
	No	22(40.0%)	8(14.3%)	
31-38 years	Yes	51(68.0%)	66(89.2%)	0.002
	No	24(32.0%)	8(10.8%)	
Gestational age				
≤37 weeks	Yes	21(61.8%)	29(87.9%)	0.014
	No	13(38.2%)	4(12.1%)	
>37 weeks	Yes	63(65.6%)	85(87.6%)	0.001
	No	33(34.4%)	12(12.4%)	
Parity				
Primiparous	Yes	49(64.5%)	64(83.1%)	0.009
	No	27(35.5%)	13(16.9%)	
Multiparous	Yes	35(64.8%)	50(94.3%)	0.001
	No	19(35.2%)	3(5.7%)	
Residence				
Rural	Yes	52(65.8%)	70(87.5%)	0.001
	No	27(34.2%)	10(12.5%)	
Urban	Yes	32(62.7%)	44(88.0%)	0.003
	No	19(37.3%)	6(12.0%)	

DISCUSSION

This randomized controlled trial compared the efficacy of oral Nifedipine versus intravenous Labetalol for the management of severe pre-eclampsia in 260 pregnant women. Our findings demonstrated that oral Nifedipine was significantly more effective than IV Labetalol in rapidly controlling blood pressure and achieving target blood pressure within the specified time frame.

The mean time to achieve target blood pressure was significantly shorter in the Oral Nifedipine group (30.20±3.21 minutes) compared to the IV Labetalol group (44.05±7.06 minutes) (p=0.001). This finding contrasts with some previous studies but aligns with others in the literature. Nivethana KB et al. concluded that IV labetalol showed a more rapid reduction of blood pressure compared to oral nifedipine.[12] However, our findings are consistent with several other studies that have shown either comparable or superior efficacy of Nifedipine.

In a study conducted at Services Hospital from March 2017 to February 2019, Wasim T et al. found that both drugs were equally efficacious, with mean times of 22.69±13.5 and 22.09±11.7 minutes for labetalol and nifedipine respectively.[13] Similarly, a study with 147 pregnant women with severe pre-eclampsia found the time taken to achieve effective blood pressure control was 35 vs. 42 min for oral nifedipine and intravenous labetalol respectively, which was not statistically significant (P=0.37).[14]

More recently, a 2024 study reported that the time taken to achieve targeted blood pressure of <150/100 mmHg in the intravenous labetalol group was 38.9±17.2 min and in the oral nifedipine group was 37.1±17.2 min with p value=0.302.[15] These findings suggest that both medications can be effective, but the superior performance of Nifedipine in our study may be related to our specific patient population or protocol differences.

Our study demonstrated a significantly higher success rate in the Oral Nifedipine group (87.7%) compared to the IV Labetalol group (64.6%) (p=0.001). This substantial difference in success rates further supports the superiority of Nifedipine in our patient population. The

stratification analysis showed that this advantage was maintained across all demographic and clinical subgroups, suggesting that the efficacy of Nifedipine is independent of factors such as age, gestational age, parity, and residence.

Particularly notable was the high success rate of Nifedipine in multiparous women (94.3%), which was significantly higher than Labetalol (64.8%) in this subgroup (p=0.001). This finding suggests that Nifedipine may be particularly effective in multiparous women, which could be an important consideration in clinical decision-making.

While our primary focus was on efficacy, safety and tolerability are crucial considerations in selecting antihypertensive therapy for pre-eclamptic patients. A 2024 prospective interventional study by Nimbark et al. with 200 antenatal women found that while both medications were equally effective in achieving the desired decrease in blood pressure in preeclampsia, Labetalol was significantly better regarding drug side effects and tolerability compared to Nifedipine.[16]

Our study did not observe significant adverse effects with either medication, which is consistent with the findings of Shahnaz et al., who reported that both intravenous Labetalol and oral Nifedipine regimens are equally effective and well tolerated in acute control of blood pressure in severe preeclampsia.[15]

Our study suggests that oral Nifedipine is a preferable first-line treatment for severe pre-eclampsia. Its superior efficacy in controlling blood pressure quickly and reaching target levels within the specified time frame, along with the ease of administration compared to intravenous Labetalol, make Nifedipine an appealing choice, especially in resource-limited settings.

Our study's strengths: randomized controlled design, adequate sample size, and thorough stratification analysis with balanced demographic and clinical variables between treatment groups to reduce confounding. However, limitations include: it was a single-center study, limiting generalizability; did not assess long-term maternal and fetal outcomes, crucial in severe pre-eclampsia management; and did not evaluate cost-effectiveness of treatments in resource-limited settings.

Future research should include multicenter trials diversifying patient populations, evaluating long-term maternal and fetal outcomes, and assessing cost-effectiveness of various antihypertensive treatments for severe pre-eclampsia. Comparative studies on Nifedipine and Labetalol dosing could enhance severe pre-eclampsia management.

CONCLUSION

Oral Nifedipine is superior to IV Labetalol for quickly controlling blood pressure in severe pre-eclampsia, making it a preferred first-line treatment due to its effectiveness, ease of use, and consistent performance across patient profiles.

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