

IV LABETALOL VS ORAL NIFEDIPINE IN ACUTE SEVERE HYPERTENSION IN

PREGNANCY – A RANDOMIZED CONTROLLED TRIAL

BY

REG NO. BJ0121006

DISSERTATION

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IN

OBSTETRICS AND GYNAECOLOGY

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

JAWAHARLAL NEHRU MEDICAL COLLEGE, NEHRU NAGAR BELAGAVI,

KARNATAKA JUNE/JULY - 2024

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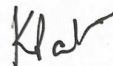
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LIST OF ABBREVIATIONS

IV	:	Intravenous
IM	:	Intramuscular
SBP	:	Systolic Blood Pressure
DBP	:	Diastolic Blood Pressure
HELLP	:	Hemolysis, Elevated Liver enzyme and Low Platelets
HTN	:	Hypertension
PE	:	Pre-eclampsia
Sflt	:	Soluble FMS like Tyrosine kinase
P	:	Probability value
Mg	:	Milligrams
mmHg	:	Millimeters of mercury
β Bs	:	Beta blockers
Mgso4	:	Magnesium sulfate
APGAR	:	Appearance, Pulse, Grimace, Activity and Respiration
ADR	:	Adverse reaction

Abstract

Objectives:

Primary objective is to compare the efficacy of IV labetalol vs oral Nifedipine in controlling acute severe hypertension in pregnancy to achieve a target blood pressure of $\leq 150/100$ mmhg. Secondary objective is to assess the time taken and number of dosages required to achieve the target blood pressure.

Methods:

A randomized clinical trial for a duration of 1-year 2 months with a sample size of 45 in each group was conducted at university teaching hospital. The patients were randomized either to Group A – IV Labetalol or B - oral Nifedipine. Group A received IV Labetalol 20mg initially followed by escalating dose of 40,80,80 and 80mg every 10 minutes while Group B received oral Nifedipine of 10mg with repeated doses of 20mg every 20 minutes until blood pressure systolic ≤ 150 mmhg and diastolic ≤ 100 mmhg. Following outcomes were noted to assess the time taken and number of dosages required to achieve the target blood pressure, side effects, maternal and fetal outcome. Descriptive statistics, chi-square tests, and independent t-tests were used for statistical analysis, with data evaluated using IBM SPSS Statistics for Windows, Version 26.0.

Results

The mean age of patients was similar in both groups ($P = 0.753$). Group A (IV Labetalol) had more primigravida patients (57.78%) compared to Group B (oral Nifedipine) with 46.67% (p value 0.018). The mean SBP for all patients was significantly higher in Group A was 168.4 ± 8.83 mmhg compared to Group B was 163.42 ± 5.07 mmhg, with a P value of 0.001. The mean DBP was 103.91 ± 7.05 mmhg for Group A and 100.36 ± 6.4 mmhg for Group B, with a statistically significant difference of $P = 0.015$. In Group

A, 22.22% of patients and a significant 92.89% of patients in group B achieved the target at 20 minutes. Regarding the number of doses, 57.78% of patients in Group A required only one dose, compared to 93.33% in Group B. Patients in Group A required higher doses and more time take to achieve to manage blood pressure. There was no significant difference in the 1-minute APGAR scores between the two groups ($P = 0.196$). However, the 5-minute APGAR scores are significantly higher in the Nifedipine group compared to the Labetalol group ($P = 0.039$).

Conclusion

Oral Nifedipine is more effective in achieving target blood pressure faster and with fewer doses than IV Labetalol.

Keywords

Hypertension emergencies, Labetalol, Nifedipine, pregnancy.

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INTRODUCTION

Hypertensive disorders are a prevalent pregnancy complication that increases the likelihood of further difficulties and lifelong consequences for both the foetus and the mother. Pregnancy-related hypertension is a prevalent medical condition among expectant mothers. They cause substantial morbidity and mortality in mothers, foetuses, and new-borns, they impact 10-15% of pregnancies. Pregnancy-related hypertension is the second most common cause of maternal death globally. The most prevalent medical condition that pregnant women experience is hypertension, which complicates one in every ten pregnancies.

The National Institute for Health and Clinical Excellence defines severe hypertension as having a systolic blood pressure of 160mmhg or higher and a diastolic blood pressure of 110mmhg or higher.¹ The prevalence of hypertension during pregnancy is still rising¹. Pregnancy-related high blood pressure raises the risk of end organ damage, eclampsia, cerebral haemorrhage, pulmonary oedema, placental abruption, and hypertensive encephalopathy. It also raises the possibility of a difficult pregnancy outcome. Reducing the blood pressure below 150/100mmhg or less can help with these problems.

In the event of a hypertensive emergency during pregnancy, a number of medications can assist quickly drop blood pressure. The treatment of hypertension involves the use of injectable and oral medications. The majority of guidelines recommend Nifedipine, Labetalol, and Hydralazine as first-line options for treating acute hypertension in pregnant women. Previously, hydralazine was the recommended medication; however, oral Nifedipine and IV Labetalol have become more popular options⁵. The recommended antihypertensive drug in the US for treating severe hypertension that develops during pregnancy is Hydralazine.

In this instance, it should take a few minutes to many hours to actively drop the blood pressure. Therefore, during the late third trimester of pregnancy, quick yet safe blood

pressure management can often reduce the chance of a delivery delay.

Because the level of placental blood flow self-regulation is unknown, it is crucial to prevent hypotension. Additionally, abrupt, significant drops in blood pressure might result in foetal hypoxia³.

The pharmacokinetics and pharmacodynamics of the medications will be impacted differently by the pathophysiology of pregnancy-related hypertension diseases. The National Institute for Health and Clinical Excellence in the United Kingdom suggests using oral or IV Labetalol, IV Hydralazine, or oral Nifedipine as the first line alternative antihypertensive in the critical care setting for the inpatient treatment of severe hypertension in pregnancy.

Hydralazine was associated with a higher incidence of hypotension, placental abruption, caesarean delivery, oliguria, adverse effects on foetal heart rate, and low Apgar score at one minute compared to other antihypertensives. This was found in studies comparing the treatment of severe hypertension with Hydralazine, Nifedipine, and Labetalol³. Since beta-adrenergic receptor blocking agents are non-selective, Labetalol causes dose-related drops in blood pressure without appreciably lowering heart rate. IV Labetalol starts to work after five minutes. The activity lasts from 45 minutes to six hours, with the peak effect happening between 10 and 15 minutes. IV labetalol has the benefit of effectively treating severe hypertension during pregnancy, even in patients who are unconscious.

One calcium channel blocker is Nifedipine. The duration of effect following oral ingestion ranges from 1.5 to 4.5 hours. The half-life of the pill after administration is roughly 6 to 12 hours. Nifedipine's pharmacological effects can last for up to 12 hours following tablet administration⁴. It is inexpensive, convenient to store, and effective when ingested. One side effect of Nifedipine is an increase in coronary blood flow as well as heart rate. Comparing the time frames to target blood pressure, dosage

requirements, adverse effects, and perinatal and maternal outcomes, an additional side effect is increased frequency of urine.

Problems including high blood pressure during pregnancy, severe bleeding during and after childbirth, and infections following childbirth account for two thirds of maternal mortality.

IV Labetalol, injectable Hydralazine, and oral Nifedipine are the first-line medications for PIH. Since hydralazine is not commonly accessible and also causes maternal hypotension, we made the decision to compare the effectiveness of IV labetalol with oral Nifedipine and its outcome.

OBJECTIVES

“Primary Objective: Compare the efficacy of IV Labetalol vs Oral Nifedipine in controlling acute severe hypertension in pregnancy to achieve a target blood pressure of $\leq 150/100$ mmhg.

Secondary objective: To assess the time taken and number of dosages required to achieve the target blood pressure”

The present study, hence, centred on hypothesis in pregnant women experiencing hypertensive crisis, oral Nifedipine is more effective than IV Labetalol in terms of achieving target blood pressure.

REVIEW OF LITERATURE

Background :

Hypertension is the most prevalent medical problem seen by pregnant women, complicating one in every ten pregnancies. This pregnancy condition is the world's second largest cause of maternal death. The condition has a wide range, from mild hypertension to preeclampsia and eclampsia. Pregnancy-induced hypertension can be managed, and problems such as preeclampsia, eclampsia, and HELLP syndrome can be avoided throughout the antenatal period.

Hypertension may predate conception or increase throughout pregnancy or the early puerperium. It is frequently accompanied with oedema and proteinuria, either alone or simultaneously, and can occasionally result in convulsions and a coma.

As per ISSHP hypertension disorders in pregnancy are classified as

1.GESTATIONAL HYPERTENSION

According to ACOG recommendations, gestational hypertension is defined as a blood pressure reading of 140 mm Hg systolic or 90 mm Hg diastolic, taken at least four hours apart, after the first 20 weeks of pregnancy, in cases where the patient's blood pressure was previously normal.^{8,9}

2. PRE-ECLAMPSIA

Presence of hypertension and proteinuria occurring after 20weeks of gestation in a previously normotensive patient with significant proportion of women develop systemic manifestations such as low platelets or elevated liver enzymes before the hallmark of proteinuria is detected.

3. ECLAMPSIA

Pre-eclampsia associated with seizures (Generalized tonic clonic convulsion)

4. PREEXISTING HYPERTENSION

HTN diagnosis before pregnancy, early in pregnancy (before 20 weeks of gestation), or HTN continues after six weeks post-partum.

Pre-existing hypertension plus superimposed PE with new onset proteinuria

5. White-coat HTN

Refers to elevated office/clinic BP >140/90 mm hg, but normal BP measured at home or work which is <135/85 mm hg.

6. Antenatally unclassifiable hypertension

This term is used when HTN is first diagnosed after 20 weeks of gestation and it is unclear if hypertension was pre-existing. Reassessment six weeks post-partum will help distinguish pre-existing from gestational hypertension.

Hypertensive emergency

Condition characterized by a severe elevation in blood pressure, specifically with a systolic blood pressure of 180 mmHg or higher, or a diastolic blood pressure of 120 mmHg or higher. The critical distinction in a hypertensive emergency is the presence of acute target organ damage, such as encephalopathy, myocardial infarction, acute left ventricular failure with pulmonary oedema, aortic dissection, or acute renal failure. This condition requires immediate medical attention to prevent potentially life-threatening complications.

Hypertensive urgency

Elevation in blood pressure without evidence of acute target organ damage, such as pulmonary oedema, cardiac ischemia, neurologic deficits, or acute renal failure. Specific cut-offs have been proposed, such as systolic blood pressure greater than 180 mmHg or diastolic blood pressure greater than 110 mmHg.

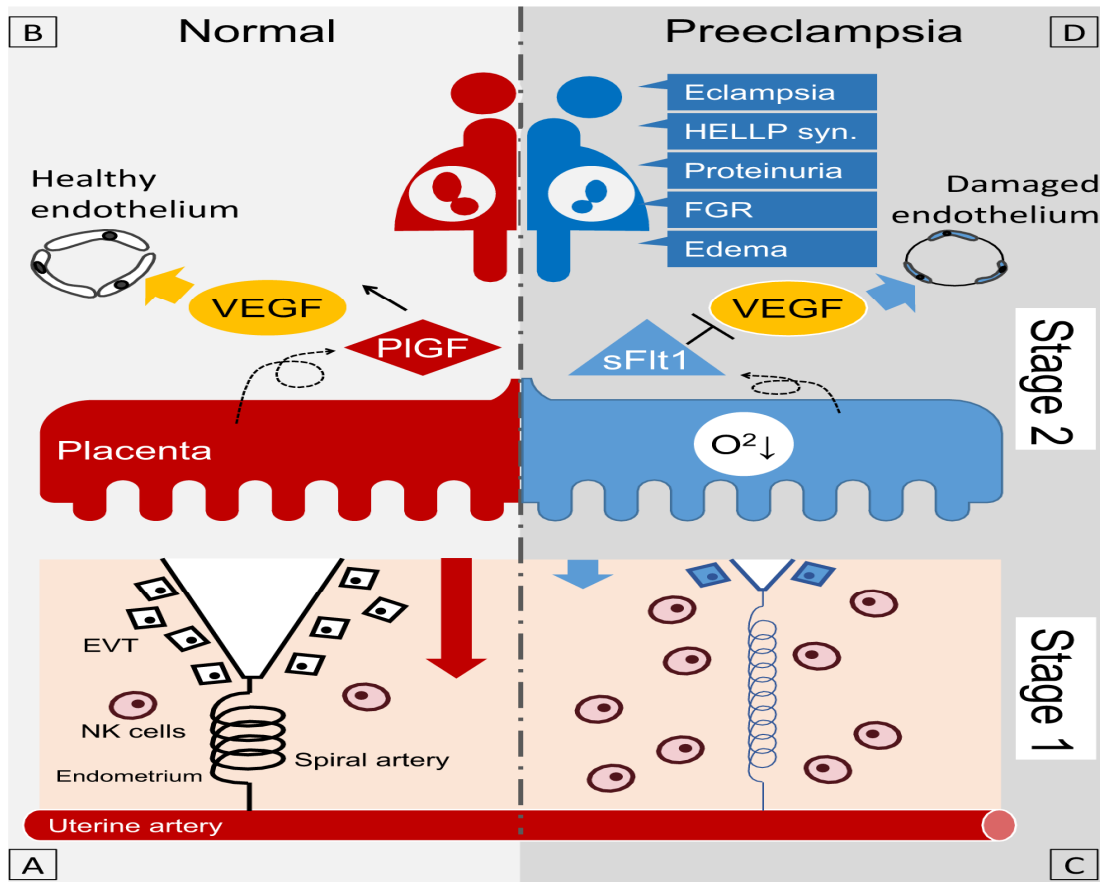
PATHOPHYSIOLOGY

We still don't fully understand the pathogenesis of hypertension during pregnancy. "Research conducted recently highlights the importance of the mis-regulation and/or overproduction of cytokines, adhesion molecules, major histocompatibility complex molecules, and metalloproteinases during endothelial invasion in the development of gestational hypertensive disease." Spiral arteries in the deep myometrial tissues grow and remodel abnormally when these molecules are not regulated or produced properly. The result is ischemia and hypoperfusion of the placenta. Recent studies have shown that placental tissue releases antiangiogenic factors, which can lead to systemic endothelial dysfunction and, ultimately, systemic hypertension. The peripheral vasculature, eyes, lungs, liver, and kidneys are the most typical organs to experience hypoperfusion due to endothelial dysfunction. In general, the majority of specialists concur that there are multiple factors at play. ⁸

Theories¹⁰

These are various theories of pathogenesis of pre-eclampsia. The most popular theory is immunologic. During a normal pregnancy, foetal syncytial trophoblasts penetrate and remodel maternal spiral arteries, causing them to dilate into large, flaccid vessels. This remodelling accommodates the vast, increased maternal circulation needed for adequate placental perfusion. This remodelling is somehow prevented in preeclamptic

pregnancies: the placenta is unable to properly bur- row into the maternal blood vessels, leading to intrauterine growth restriction and other foetal manifestations of the disorder. Investigators speculate that this incomplete placentation is due to maternal immunologic intolerance of foreign foetal genes. Evidence in support of this theory is that the risk of preeclampsia is highest in a first pregnancy and decreases with the length of time a woman has lived with the father before becoming pregnant. Furthermore, risk is also increased in multi- parous women who are pregnant by a new partner. Others theories of pathogenesis of preeclampsia are angiogenic factors (increased sflt-decreased placental growth factor levels) cardiovascular maladaptation and vasoconstriction, genetic predisposition (maternal, paternal, thrombophilia's) (immunologic intolerance between fetoplacental and maternal tissue, platelet activation, vascular endothelial damage or dysfunction. Several factors are associated with preeclampsia and they are antiphospholipid antibody syndrome, chronic hypertension, chronic renal disease, elevated body mass index, maternal age older than 40 years, multiple gestation, nulliparity, preeclampsia in a previous pregnancy (particularly if severe or before 32 weeks of gestation), pregestational diabetes mellitus. Prevention through routine supplementation with calcium, magnesium, omega-3 fatty acids, or antioxidant vitamins is ineffective calcium supplementation reduces the risk of developing preeclampsia in high-risk women and those with low dietary calcium in- takes.



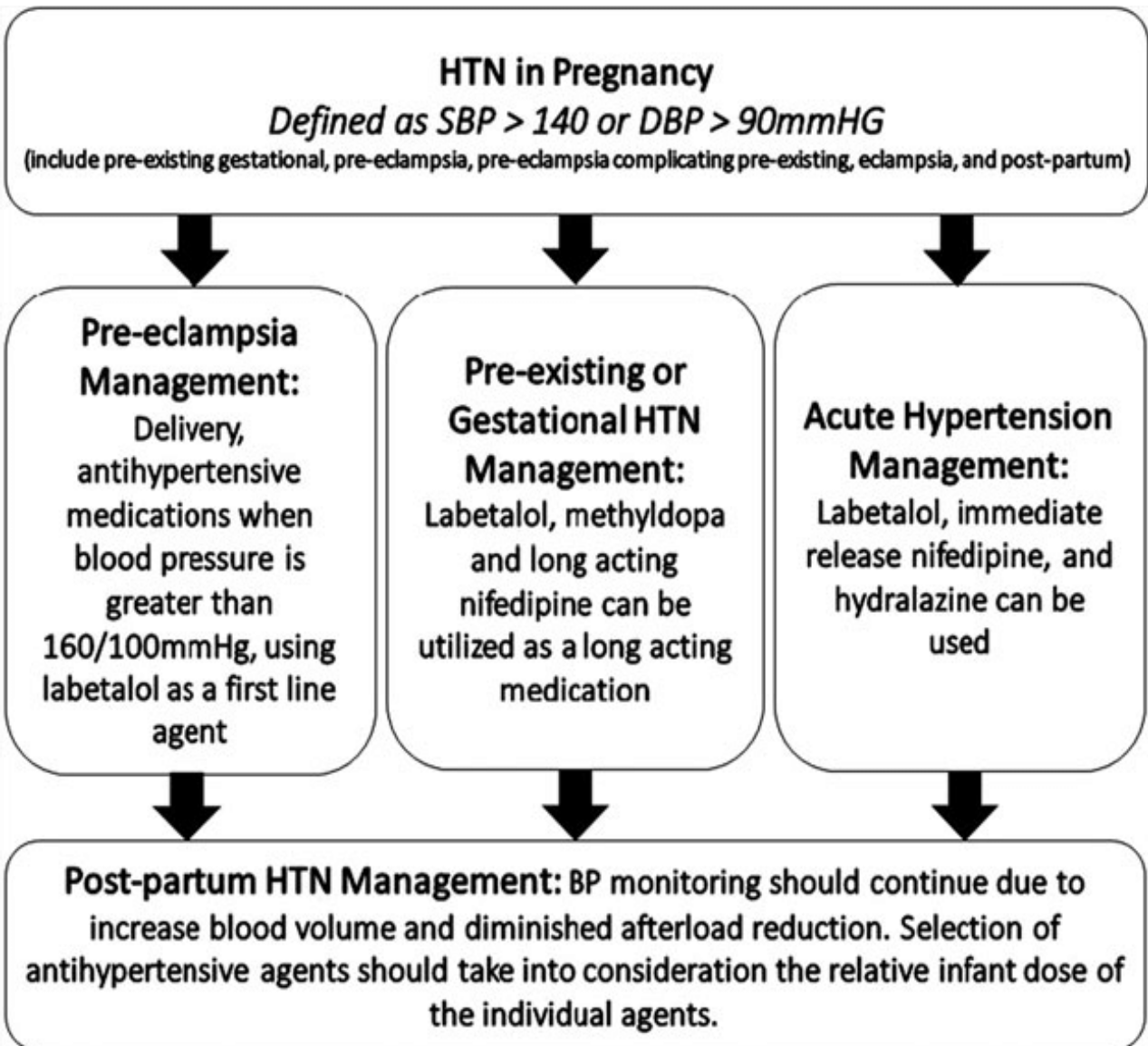
https://media.springernature.com/full/springer-static/image/art%3A10.1038%2Fs41440-022-00965-6/mediaobjects/41440_2022_965_Figa_HTML.png

Placental circulation

The placental circulation is a combination of the maternal and foetal circulatory systems. Despite the near proximity of these two, the placental barrier ensures that they will remain distinct from one another. This group prevents the mother's immune system from labelling the developing baby as an alien invader. Blood pressure, medicine, hormones, uterine contractions, and other variables can affect these two separate blood flows. Nutrients, gasses, waste products, and hormones can change systems (from fetal to maternal or vice versa) via diffusion as they travel through various circulations. As a

result of diffusion, particles move from more densely populated regions to less densely populated ones. ¹²

These nutrient particles, gases, hormones and wastes can cross directly through the placental membrane by diffusion in either direction to alter foetal or maternal blood concentrations. The flow of blood to the unborn child The placenta, the umbilical cord, and the developing foetus all work together to form the circulatory system. Through the two umbilical arteries, the foetal capillaries in the placenta get deoxygenated blood, which is blood with a reduced oxygen level. Here, the placenta is emptied of waste and carbon dioxide (CO₂) by means of the maternal circulation, which carries the gases out of the foetus. The mother's blood flow blood flows via the mother and the placenta's intervillous region. To accommodate the developing embryo, this circulation is in a perpetual state of flux. The placenta receives oxygenated blood, which has a high oxygen concentration, via the maternal arteries into the intervillous space. It is via these capillaries that the new born receives oxygen, nutrients, and hormones via the umbilical vein after diffusing into the villi. ¹²



<https://www.researchgate.net/publication/328816992/figure/fig3/AS:807087592448001@1569436085493/Simplified-algorithm-for-management-of-hypertension-in-pregnancy-DBP-diastolic-blood.ppm>

DRUGS FOR MILD HTN

BETA-BLOCKERS

Pregnant women and nursing mothers should begin treatment with beta-blockers (BBS) as soon as possible. A common medicine used in HDP is Labetalol. In cases of severe hypertension, it can be administered intravenously. Proper monitoring of the foetus is required since BB can cause foetal bradycardia or intrauterine growth retardation. It is recommended that pregnant women not take atenolol.¹⁷

ALPHA METHYLDOPA

“The effects on both the central nervous system (CNS) and the peripheral nervous system can be felt by using this α 2-adrenergic agonist. It has been used for almost 40 years without major negative effects on the mother or the foetus, making it one of the safest medications during pregnancy. However, Labetalol has essentially replaced it as the first-line treatment of choice for most patients. There should be two to four doses of 0.5-3.0 g of methyldopa taken daily. You may experience side symptoms such as drowsiness, dry mouth, general malaise, hemolytic anemia, and hepatopathy.”¹⁸

CALCIUM CHANNEL BLOCKERS

“Calcium channel blockers (CCBS) are among the recommended antihypertensive drugs during pregnancy. Both dihydropyridines and non-dihydropyridines are allowed [2]. One class of antihypertensive medications that is advised to be used during pregnancy is calcium channel blockers (CCBS). There is no restriction on either dihydropyridines or non-dihydropyridines.”¹⁷

RENIN-ANGIOTENSIN-ALDOSTERONE SYSTEM INHIBITORS

Included in the class of drugs known as renin-angiotensin-aldosterone system (RAAS) inhibitors are ACE inhibitors, ARBs, renin inhibitors, and aldosterone antagonists, both selective (eplerenone) and non-selective (spironolactone). Exposure during organogenesis in the early stages of pregnancy does not appear to raise the incidence of abnormalities, according to recent research.³⁴ Results from both animal and human studies point to an increased risk of problems, including as renal dysplasia, pulmonary hypoplasia, and growth limitation, when RAAS inhibitors are used in the second and third trimesters.¹⁹

The use of RAAS inhibitor medicines during pregnancy and lactation is discouraged according to the guidelines (Class III recommendations). When younger hypertensive women are going to become mothers, beta-blockers are prescribed instead of ACE inhibitors and arbs.¹⁷

DRUGS FOR SEVERE HTN

The criteria for a drug emergency in hypertension is a blood pressure reading of 170/110 mm Hg or above. It calls for a quick trip to the emergency room and some antihypertensive medicine administered intravenously.¹⁷ Possible administration methods include intravenous Nicardipine and Labetalol, oral Methyldopa, and CCB. In light of its elevated risk of perinatal side effects, Hydralazine is currently reserved for cases where other medications have failed to manage hypertension.²⁰

A daily aspirin dose of 100–150 mg should be recommended to pregnant women at risk of preeclampsia during weeks 12–36 of gestation.²¹ Both pre-eclampsia and premature delivery can be reduced by 14% and 12%, respectively, with the use of aspirin.²² If hypertension medicine has not been administered to a woman before her diagnosis of pre-eclampsia, she should be admitted and given the medication. However, there is a risk about foetal bradycardia when using IV labetalol and Nicardipine to reduce the blood pressure. Nitro-glycerine infusion is advised in cases of pulmonary oedema. Everyone agrees that blood pressure should be lowered below 160/105mmhg.

When treating eclampsia fits, intravenous magnesium sulfate is recommended. Although the only way to treat pre-eclampsia is to have the placenta (and the baby, of course!) Delivered, it is possible to postpone delivery until the 37th week of pregnancy in individuals who do not have any symptoms.

Labetalol

When it comes to anti-hypertensives, Labetalol is among the most popular choices for pregnant women with hypertension. Labetalol injection is an adrenergic receptor-blocking agent that has both selective alpha 1-adrenergic and non-selective beta-adrenergic receptor blocking actions in a single substance.

Labetalol produce dose-related falls in BP without reflex tachycardia and without significant reduction in heart rate.

Following IV infusion of labetalol, the elimination half-life is about 5 and half hours and the total body clearance is 33ml/min/kg. Plasma half-life is 6-8hours.



Mechanism of Action

One of the reasons Labetalol is so beneficial is that it acts as an antagonist to alpha1-adrenergic receptors while simultaneously blocking beta-adrenergic receptors (B1 and B2) without being selective. Laboratory analysis of alpha to beta-blockade after oral treatment has shown an activity ratio of around 1 to 3, whereas intravenous (IV) administration has shown an activity ratio of about 1 to 7.²⁹

Administration

An intravenous (IV) push of 10–20 mg is recommended for the treatment of acute hypertension episodes (emergent/urgent), with subsequent boluses given every 10 minutes until the systolic blood pressure falls within the target range or 300 mg is reached in 24 hours. An 80-kilogram patient would take around 0.25 mg/kg of 20 mg. Alternately, you could think about a continuous infusion that starts at 0.5 to 2 mg/min and can be adjusted up to 10 mg/min.²⁵

ADVERSE EFFECTS

The majority of people have no problems tolerating Labetalol. The majority of side effects are usually minor and short-lived. As mentioned earlier, patients may experience symptomatic postural hypotension if they are tilted or permitted to go from a seated or supine posture to standing too rapidly. In the post-operative period (PACU or ward), this becomes even more crucial when caring for hypertensive patients on Labetalol who are otherwise able to walk to the restroom. Some users have experienced flushing and increased perspiration when using Labetalol. It appears that

the occurrence of side effects following Labetalol administration appears to be dose-dependent.^{30,31}

CONTRAINDICATIONS

“The use of Labetalol is highly discouraged in patients suffering from bronchial asthma, overt cardiac failure, greater-than-first degree heart block, cardiogenic shock, severe bradycardia, or any other condition linked to severe and prolonged hypotension. This is due to Labetalol's classification as a beta-blocker. It goes without saying that anyone who have ever had a severe allergic reaction to any part of the medication should not take it”.^{32,33}

TOXICITY

In cases of beta-blocker overdose, glucagon produces a number of significant therapeutic effects. It enhances atrioventricular conduction and myocardial contractility in addition to increasing HR. It appears that its mode of action (MOA) is effective even when bound to beta-adrenergic receptors. In order to reverse severe symptomatic beta-blockade, the suggested starting dose of glucagon is 50 mcg/kg intravenously (IV). Then, the dosage should be adjusted to 1 to 15 mg per hour IV, depending on the patient's response and improvement.³⁴

LABOR AND DELIVERY

Labetalol given to pregnant women with hypertension did not affect the course of labour and delivery.

ACOG Protocol for IV Labetalol Algorithm

If Blood Pressure (BP) \geq 160/110 mmhg:

Initial Dose Administer 20 mg IV bolus, followed by record BP every 10 minutes. If BP is still not controlled (\geq 160/110mmhg) , Increase the dose to 40 mg IV, Record BP again after 10 minutes. If BP is still not controlled (\geq 160/110mmhg), Increase the dose to 80 mg IV every 10 minutes.

Continue increasing the dose up to a maximum of 300 mg/day.

If BP remains uncontrolled after the maximum dose: Switch to oral nifedipine.

NIFEDIPINE

Nifedipine is a calcium channel blocker that belongs to the dihydropyridine subclass. It is primarily used as an antihypertensive . Nifedipine capsules are formulated as soft gelatin capsules for oral administration each containing 10mg nifedipine.

The drug is detectable in serum 10mins after oral administration and reaches peak blood level in 30mintes.

MECHANISM OF ACTION

When smooth muscle cells are depolarizing, calcium ions flood in via voltage-gated channels. In order to prevent calcium ions from entering vascular smooth muscle and cardiac cells, Nifedipine blocks these voltage-dependent L-type calcium channels. Systemic blood pressure drops and oxygen supply to the heart muscle is enhanced when intracellular calcium levels drop because the coronary arteries dilate and peripheral artery vascular resistance drops. Thus, Nifedipine is hypotensive and antianginal.

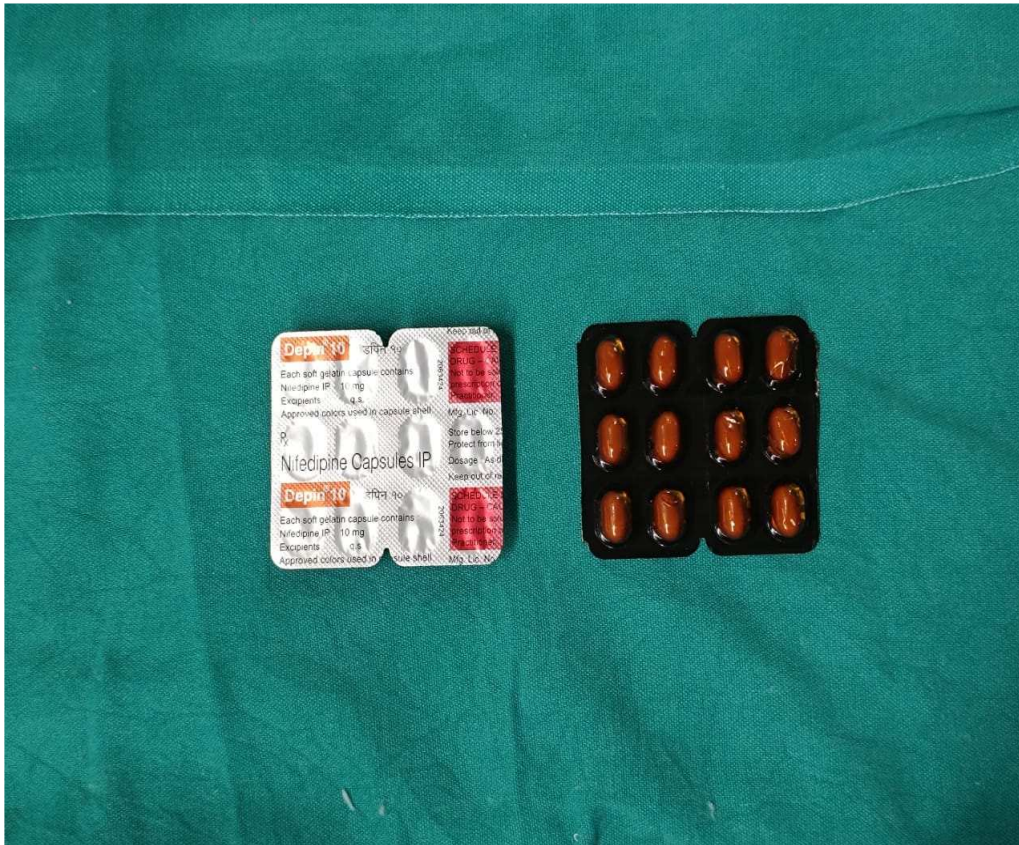
“RECOMMENDED DOSAGES”³⁹

Hypertension

- Extended-release: 30 or 60 mg daily; maximum dose of 120 mg per day

Hypertensive Emergency During Pregnancy or Postpartum Period

- Immediate-release: 10 mg; may repeat with a 20 mg dose in 20 minutes



ADVERSE EFFECTS

About 20% to 30% of people who use Nifedipine will experience some kind of side effect. The main cause of these is the vasodilatory effects of Nifedipine. Side symptoms such as flushing, peripheral oedema, vertigo, and headache are rather prevalent. When comparing extended-release and immediate-release Nifedipine formulations, tolerance is better with the latter. Urticaria, bronchospasms, pruritus, and other hypersensitivity events are uncommon. When the medicine is suddenly stopped after a lengthy period of use, it can cause rebound hypertension or angina. ³⁸⁻⁴⁰

CONTRA-INDICATIONS :

Absolute Contraindication

- Hypersensitivity to Nifedipine or its components
- ST-elevation myocardial infarction⁴¹

Relative Contraindication

- Severe aortic stenosis
- Unstable angina
- Hypotension
- Heart failure
- Moderate to severe hepatic impairment

Patients experiencing hypertensive emergencies or urgencies should not be given immediate-release formulations of Nifedipine, whether sublingually or orally, because these preparations are not only ineffective but also pose safety risks.⁴³ By blocking the entry of calcium ions into cardiac cells, cardiogenic shock is made worse, making the heart's inability to pump blood efficiently.⁴²

ACOG Protocol for Oral Nifedipine Algorithm

If Blood Pressure (BP) \geq 160/110 mmhg:

Initial Dose Administer 10 mg orally, followed by record BP every 20 minutes. If BP is still not controlled (\geq 160/110mmhg), Increase the dose to 20 mg orally, Record BP every 20 minutes. If BP is still not controlled (\geq 160/110mmhg), 20 mg orally can be repeated every 20 minutes.

Continue increasing the dose up to a maximum of 90-120 mg per day.

If BP remains uncontrolled after the maximum dose: Switch to IV labetalol.

Hospital management protocol for Pre-eclampsia :

When patient comes to hospital with BP \geq 160 / 110 mm hg with imminent sign (Headache, blurring of vision, epigastric pain , vomiting)

1. At gestational age < 24 weeks

- Antihypertensive
- Prophylactic Mgso4
- Immediate delivery

2. At gestational age 24-28 weeks

Initial assessment to rule out – HELLP , IUGR, Oligohydrannios , Abruption placentae

Absent

1. Antihypertension treatment
2. Best rest , Daily weight gain.
3. Daily input / output charting.
4. Daily NST(32weeks).
5. Daily fetal kick count.
6. Steroids to be given.
7. PIH profile every alternate day.
8. AFI biweekly
9. Umbilical and MNA doppler biweekly
10. Ultrasound for growth every 2 weeks

Present

1. Antihypertension treatment
2. Prophylactic Mgso4
3. Steroids
(Betamethasone 12mg 2 doses 24hrs apart)
4. Delivery in 48 – 72 hrs

If not worsening – Continue expectancy till 34 weeks and terminate.

3. At gestational age > 34 weeks

- Antihypertensives
- Prophylactic mgso₄
- Immediate delivery

Convulsion management protocol :

CONTROL OF CONVULSIONS

Mgso₄ regimens

I.M regimen (Pritchard)

Loading dose of 4 gm, 20 ml of 20% mgso₄, solution given I.V. over 15-20 min and 5 gm of 50% mgso₄, along with 1 ml of 2% lignocaine deep I.M. in each buttock.

Maintenance dose : Every 4 hours thereafter give 5 gm of 50% mgso₄, along with 1 ml of 2% lignocaine deep.

I.M. alternatively in each buttock.

IV regimen (Zuspan)

Loading dose of 4 gm, 20 ml of 20% mgso₄, solution given I.V. over 15-20 min.

Maintenance dose : 1 to 2g/h by controlled infusion pump for 24 hrs after last seizure.

ICMR low dose regimen preferred in Indian women with low BMI

Loading dose of 3 gm, 15 ml of 20% mgso₄, solution given I. V. Over 15-20 min and 2.5 gm of 50% mgso₄, with 1 ml of 2% lignocaine deep I.M. in each buttock.

Every 4 hours thereafter give 2.5 gm of 50% mgso₄, with 1 ml of 2% lignocaine deep I.M. alternatively in each buttock.

*** Magnesium sulphate is continued for 24 hours after delivery or up to 24 hours after the last convulsion .**

MONITORING OF PATIENTS ON MGSO, REGIMEN

- I. Patellar reflex should be present
- II. RR > 16/min
- III. Urine output > 30 ml/hour or 100 ml in last 4 hours Maintenance doses to be given only if all above are present
- IV. Serum magnesium levels to be monitored when
 - I.V. mgso₄, regimen is given
 - Oliguria and/or serum creatinine of > 1 mg/dl
 - Recurrent convulsions
 - There are other signs of magnesium toxicity
- V. For signs and serum levels of magnesium toxicity,
- VI. Antidote for magnesium sulphate toxicity
 - 10 ml of 10% calcium gluconate I.V. over 10 minutes. Also withhold further dose of magnesium sulphate. This reverses mild to moderate respiratory depression.
 - For severe respiratory depression and arrest, prompt tracheal intubation and mechanical ventilation are required.
 - If mgso₄, is contraindicated

Phenytoin: 10-15 mg/kg body weight, slow I.V. infusion @ 50 mg/min

Followed by 100 mg slow I.V. bolus every 6-8 hours.

Caution: ECG monitoring is required with I.V. administration of phenytoin due to the risk of cardiac arrhythmias / heart block.

From the Literature

The Double blind study conducted by Vermillion et al. found that oral Nifedipine reduced blood pressure more rapidly than the other medicine, while both are useful in the management of severe hypertension.⁴³ Dhali B et al. found that Nifedipine reached the therapeutic objective blood pressure ($\leq 150/100$ mmhg) faster than IV labetalol.⁴⁴ Raheem IA et al. found that both treatments successfully reduced maternal hypertension.⁴⁵ When compared to IV Labetalol, oral Nifedipine is equally safe and effective, and it may even be more efficient in settings with limited resources, according to a meta-analysis conducted by S. Shekhar and colleagues.⁴⁵

According to the studies done by Vermillion et al. And Gavit Y et al., both drugs were able to achieve the target blood pressure level absolutely every time.^{43,47} A larger volume of urine was detected in the Nifedipine group in both the Barton et al. And Dhali et al. Investigations.⁴⁴ out of Labetalol and Nifedipine have evidently become alternative drugs due to the change in their use patterns during the last decade. An online survey of medical professionals recently found that IV Labetalol was the preferred medication by 57% of respondents, followed by Hydralazine at 33%, and Nifedipine at 9%.⁴⁸

“Research conducted by Raheem et al., Shekhar et al., Anjuman et al., and Yogita et al. Demonstrated that oral Nifedipine was more effective than IV Labetalol in bringing

blood pressure levels under control, and that fewer doses were required.⁴⁹⁻⁵¹ The study conducted by Sujit et al.⁵² found that the mean time to attain target blood pressure differed significantly (p value < 0.01) between IV Labetalol group (71.00 ± 66.60 minutes) and oral Nifedipine group (25.20 ± 14.03 minutes)”.

“Thirty minutes (interquartile range 22.5 to 67.5 minutes) and forty-five minutes (interquartile range 30-60 minutes) were the median time frames to target blood pressure levels for oral Nifedipine and IV Labetalol, respectively, according to the research by Raheem et al. ($p=0.59$).⁴⁹ In the trial conducted by Shekhar et al., the median time to target blood pressure was 40 minutes for the Nifedipine group and 60 minutes for the Labetalol group”.⁵³

The average time needed in the Labetalol group was 47.2 ± 13.5 minutes, while in the Nifedipine group it was 45.6 ± 14.5 minutes, according to a related study by Swapan et al. Their research did not find a significant difference between the two groups, with a p -value of 0.511.⁵⁴

“In the study conducted by Vermillion et al., the mean timings to achieve goal blood pressure for the Nifedipine group were 25 minutes, and for the Labetalol group, 43.6 minutes. In present experiment, the median time frames to accomplish target blood pressure were 40 minutes and 60 minutes, respectively. Researchers Gavit Y et al.

Found that Nifedipine significantly reduces the amount of time it takes to reach the target blood pressure”.^{43,47}

Most patients (17 out of 38.1%) were able to get their symptoms under control with the first oral dose of Nifedipine (Group B). Two doses of IV Labetalol were sufficient to bring the condition under control in a maximum of fourteen patients (26.4% of the total) in Group A. Reducing the number of doses needed to regulate increased blood pressure in preeclampsia, oral Nifedipine is preferable to IV Labetalol, according to the data in the table. Present findings showed that oral Nifedipine shortened treatment time to the required systolic and diastolic blood pressure values more quickly than IV Labetalol. Still, with a p-value of only 0.590, the discrepancy never even approached statistical significance. The oral Nifedipine group required 2(1.5-4.5) doses of total antihypertensive medicine to meet the goal blood pressure, but IV Labetalol group required 3(2-4) doses, with a p-value of 0.60, according to Raheem et al.⁴⁹ Dhali B et al.⁴⁴ found that compared to IV Labetalol, oral Nifedipine reduced blood pressure more rapidly and with fewer dosages.

Researchers Sathya Lakshmi et al.⁵⁵ observed that among 100 preeclampsia patients, 22% achieved their target blood pressure with a single dose of IV Labetalol, compared to 7% following the first oral dose of Nifedipine ($p= 0.002$). The study conducted by Sujit et al. found that the aim blood pressure (BP) was achieved with an average of $1.12\pm.32$ doses of Nifedipine and 2.04 ± 1.37 doses of Labetalol.⁵² According to statistical analysis, this difference is extremely significant ('P' value <0.01). The

number of dosages needed to achieve target blood pressure with oral Nifedipine was significantly lower than with IV Labetalol, according to research by Shekhar et al.⁵³ Tests performed by Vermillion et al.⁴³ and Gavit Y et al.⁴⁷ shown that both drugs had a 100% success rate in obtaining the goal blood pressure. According to Vermillion et al.^{43, 47}, there was a 100% success rate in reaching the target BP with both medications, in contrast to Raheem et al.⁴⁹, who discovered a 20% failure rate and required crossover treatment. Compared to the IV Labetalol group, oral Nifedipine group achieved the target blood pressure more quickly.

From the collective findings of multiple studies comparing oral Nifedipine and IV Labetalol in the management of severe hypertension and preeclampsia, several consistent conclusions emerge. Oral Nifedipine consistently demonstrates a faster onset of action in lowering blood pressure compared to IV Labetalol, achieving target levels in approximately 30-45 minutes versus 40-60 minutes for Labetalol. Moreover, oral Nifedipine often requires fewer doses to achieve therapeutic objectives, indicating a more efficient and rapid response in controlling hypertension. Studies also highlight Nifedipine's effectiveness in diverse settings, including scenarios where IV access may be limited, suggesting it as a viable alternative particularly in resource-constrained environments. Overall, these findings underscore Nifedipine's favourable profile in terms of efficacy and speed of action compared to Labetalol in the acute management of hypertension.

MATERIAL AND METHODS

Study Design: Randomized clinical trial.

Duration of study: 1 year 2 months (March 2023 to April 2024)

Place of study: KAHERS' Dr. Prabhakar kore Hospital, and MRC Belagavi.

Source of data: Pregnant women of 20 weeks pregnancy or more with acute severe hypertension presented to the labour room were included

Sample size

According to Kumari et al study⁵⁶ considering the mean and standard deviation of Mean SBP after IV Labetalol as 108.1 ± 7.64 , mean and standard deviation of Mean SBP after oral Nifedipine after 45mins as 112.73 ± 8.1 at 95% confidence interval with 80% power, the sample size is calculated as

$$N = (r+1/r) \times (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times \sigma^2 / (\mu_1 - \mu_2)^2$$

$$N = (r+1/r) \times (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times \sigma^2 / (\mu_1 - \mu_2)^2$$

$Z_{1-\alpha/2}$ - two tailed probability for 95% confidence interval = 1.96

$Z_{1-\beta}$ - two tailed probability for 80% power = 0.84

M_1 - mean of Mean SBP after labetalol = 108.1

M_2 - mean of Mean SBP after Nifedipine = 112.73

Σ - average standard deviation of Mean SBP after labetalol & Mean SBP after Nifedipine = 7.87

$$N = (1 + 1/1) / (1.96 + 0.84)^2 * 2 * 7.87336014672262^2 / (108.1 - 112.73)^2$$

$$N = 45.39$$

Thus the sample size required for each group is 45 and the total sample size is 90

“ Ethical clearance obtained from Institutional Ethics committee of Jawaharlal Nehru Medical College, Belagavi. A thorough detailed history was been obtained from the

women regarding age, parity, socio economic status, booking history and gestational age and presenting history . Past history for hypertension and other medical disorders was obtained. A detailed general examination and obstetric examination and blood pressure measurement was done.”

Inclusion criteria

“All Singleton pregnant women of 20 weeks’ gestation or more with acute severe hypertension [Gestation hypertension , Pre-eclampsia, Eclampsia & HELLP syndrome]. Systolic blood pressure ≥ 160 mmhg and diastolic blood pressure ≥ 110 mmhg. Or a mean arterial pressure of >125 mmhg lasting for 15 minutes or more.”

Exclusion criteria:

Chronic hypertension

Multiple pregnancy

Hypersensitivity to Nifedipine or Labetalol

Contraindication to Labetalol (Bronchial asthma, Cardiac failure, Cardiac rhythm abnormalities, Heart failure , Heart block.)

Pregnant women who presented to the delivery room with a high blood pressure of 160/110 mmHg were randomised to either Group A (IV Labetalol) or Group B (oral Nifedipine) using the envelope method. IV Labetalol (20 mg) was administered to Group A initially, with subsequent doses of 40, 80, 80, and 80 mg increasing to a maximum of 300 mg every 10 minutes. Group B was given oral Nifedipine (10 mg) with repeated doses of 20 mg to a maximum of 80 mg every 20 minutes until the target blood pressure of systolic <150 mmhg and diastolic <100 mmhg was reached. The time it took and the number of doses needed to reach the desired blood pressure, as well as

the side effects, maternal, and foetal outcomes, were observed. Anticonvulsant medication was given to every patient. Data were gathered and recorded in proforma. If the gestational age was less than 34 weeks, patients received two doses of 12 mg of injection betamethasone administered 24 hours apart. Obstetrics care was provided based on the patients' overall status.

Statistical Analysis

Descriptive statistics were reported as mean(SD) continuous variables, frequencies (percentage) for categorical variables. Chi square was used to find the association between categorical variables. Independent t test was used to find the association between the continuous variables of two groups. Data were statistically evaluated with IBM SPSS Statistics for Windows, Version 26.0., IBM Corp., Chicago, IL.

Results

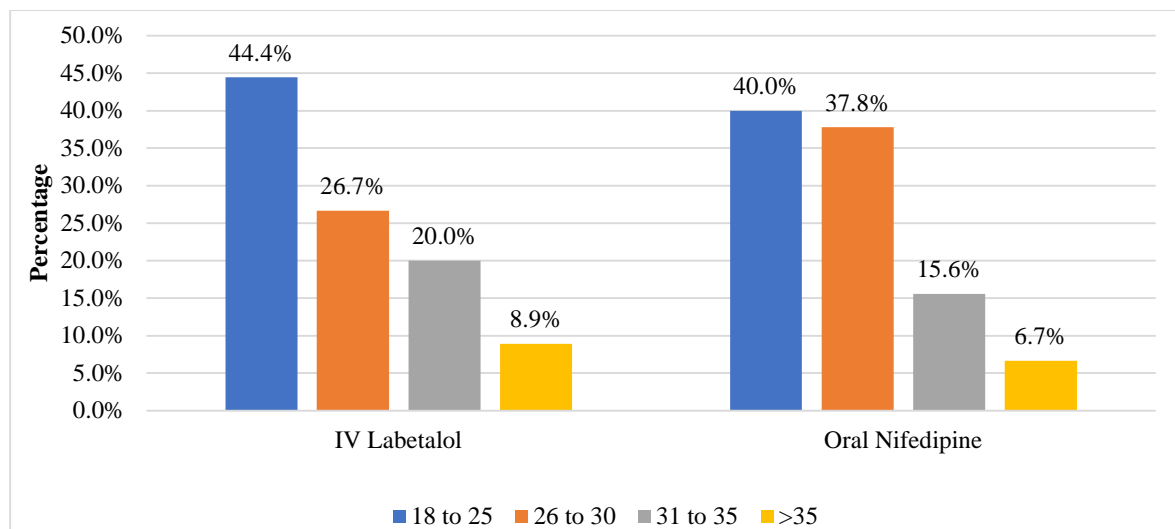
This study involved the screening of 200 patients in total. A total of 130 patients underwent eligibility assessments using predetermined inclusion and exclusion criteria. The following criteria led to the exclusion of forty patients: Thirty had chronic hypertension, five had heart problems, five had had multiple pregnancies, and nil declined to participate. After that, 90 patients remained eligible, and they were randomly divided into two groups using the envelope method..

Group A comprised 45 patients who received IV Labetalol, while Group B included 45 patients who received oral Nifedipine. By using the envelope method, the randomization procedure made sure that each group had an equal number of participants for the comparison study.

Table 1: Age distribution (in years) between two study groups (N=90)

Parameter	Intervention (Study groups) (Mean± SD)		P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)	
Age (in years)	27.73 ± 6.02	27.36 ± 5.32	0.753
Age Distribution			
18 To 25	20 (44.44%)	18 (40%)	0.715
26 To 30	12 (26.67%)	17 (37.78%)	
31 To 35	9 (20%)	7 (15.56%)	
>35	4 (8.89%)	3 (6.67%)	

Graph 1: Cluster bar chart of comparison of age distribution between intervention groups



In this study, two groups of patients were compared: Group A, treated with IV Labetalol (n=45), and Group B, treated with oral Nifedipine (n=45). The mean age of patients in Group A was 27.73 ± 6.02 years, while the mean age in Group B was 27.36 ± 5.32 years, with no statistically significant difference between the groups ($P = 0.753$). When examining age distribution, 44.44% of patients in Group A were between 18 to 25 years old compared to 40% in Group B. In the 26 to 30 years age range, 26.67% of patients were in Group A, while 37.78% were in Group B. For the 31 to 35 years age range, Group A had 20% of patients, and Group B had 15.56%. Finally, in the age group above 35 years, Group A had 8.89% of patients, whereas Group B had 6.67%. The age distribution did not show any statistically significant difference between the groups ($P = 0.715$).

Table 2 :Comparison of Obstetric scores between intervention study groups (N=90)

Obstetric scores	Intervention (Study Groups)		Chi square	P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)		
Primigravida	26 (57.78%)	21 (46.67%)	1.113	0.291
Multigravida	19 (42.22%)	24 (53.33%)		

In Group A, 57.78% of patients were primigravida, whereas 46.67% of patients in Group B were primigravida. Conversely, 42.22% of patients in Group A were multigravida compared to 53.33% in Group B. The chi-square test result was 1.113, and the P value was 0.291, indicating no statistically significant difference in obstetric scores between the two groups.

Graph 2: Cluster bar chart of comparison of obstetric scores between intervention (study group) (N=90)

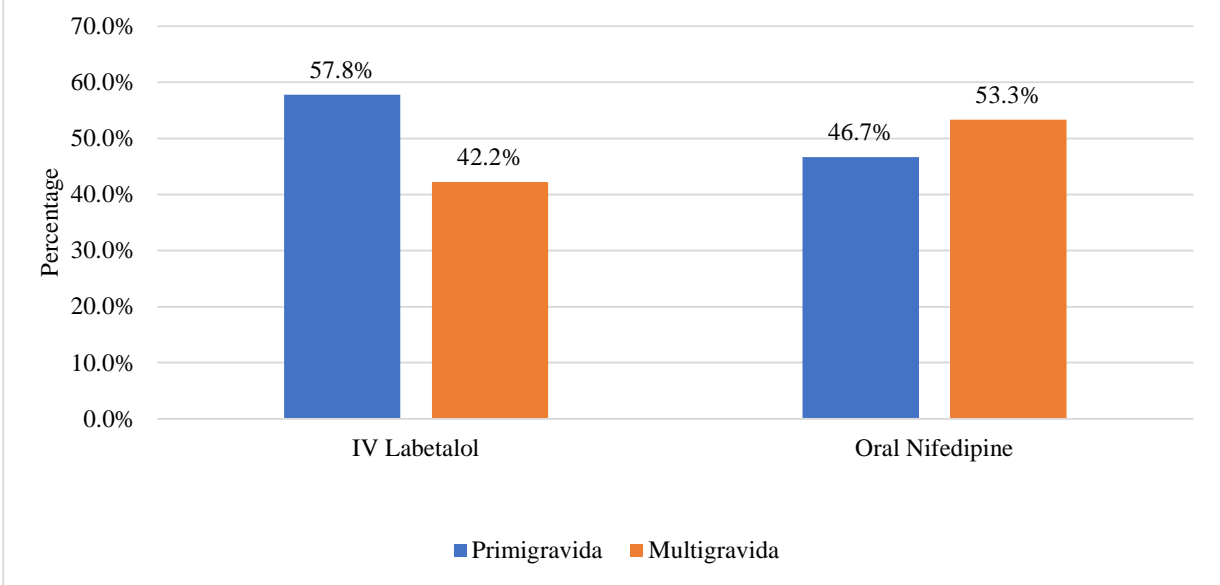


Table 3: Gestational age (in weeks) between two study groups (N=90)

Gestational Age (In Weeks)	Intervention (Study Groups)		Chi square	P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)		
20-33 Weeks	14 (31.11%)	6 (13.33%)	7.403	0.060
34-36 Weeks	16 (35.56%)	12 (26.67%)		
37-40 Weeks	14 (31.11%)	24 (53.33%)		
>40 Weeks	1 (2.22%)	3 (6.67%)		
Mean Gestational Age (In Weeks)	34.79 ± 3.62	36.63 ± 3.62	*	0.018

In Group A, 31.11% of patients were at or below 33 weeks of gestation, while 13.33% of patients in Group B fell into this category. For the gestational age range of 34 to 36 weeks, 35.56% of patients were in Group A compared to 26.67% in Group B. Between 37 to 40 weeks of gestation, 31.11% of patients in Group A and 53.33% in Group B were represented. Lastly, 2.22% of patients in Group A and 6.67% of patients in Group B were over 40 weeks of gestation.

The chi-square test yielded a result of 7.403 with a P value of 0.060, suggesting that there is no statistically significant difference in gestational ages between the two groups. The difference in gestational age between the two groups is statistically significant (p value 0.018).

Graph 3: Cluster bar chart of comparison of gestational age (in weeks) between intervention (study groups) (N=90)

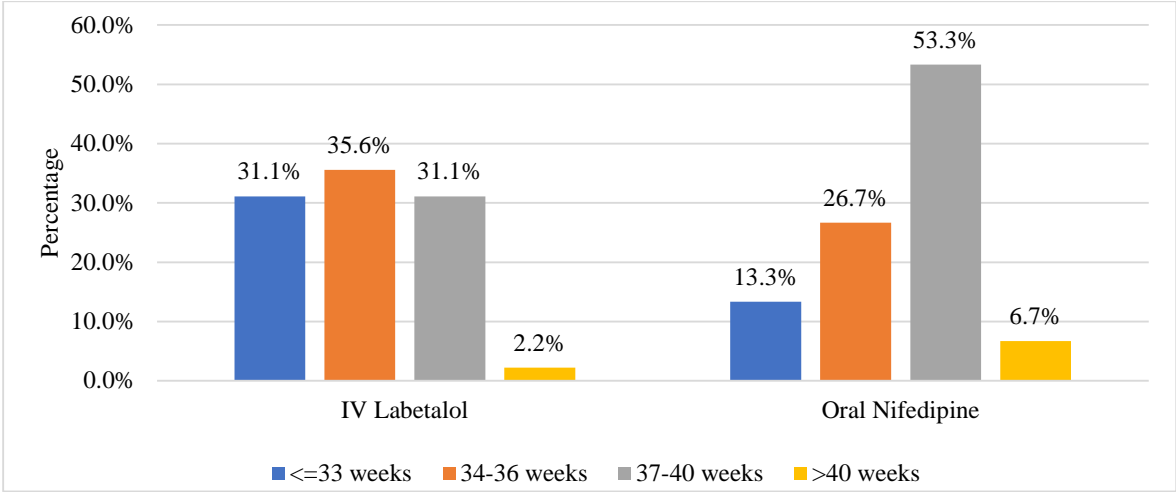
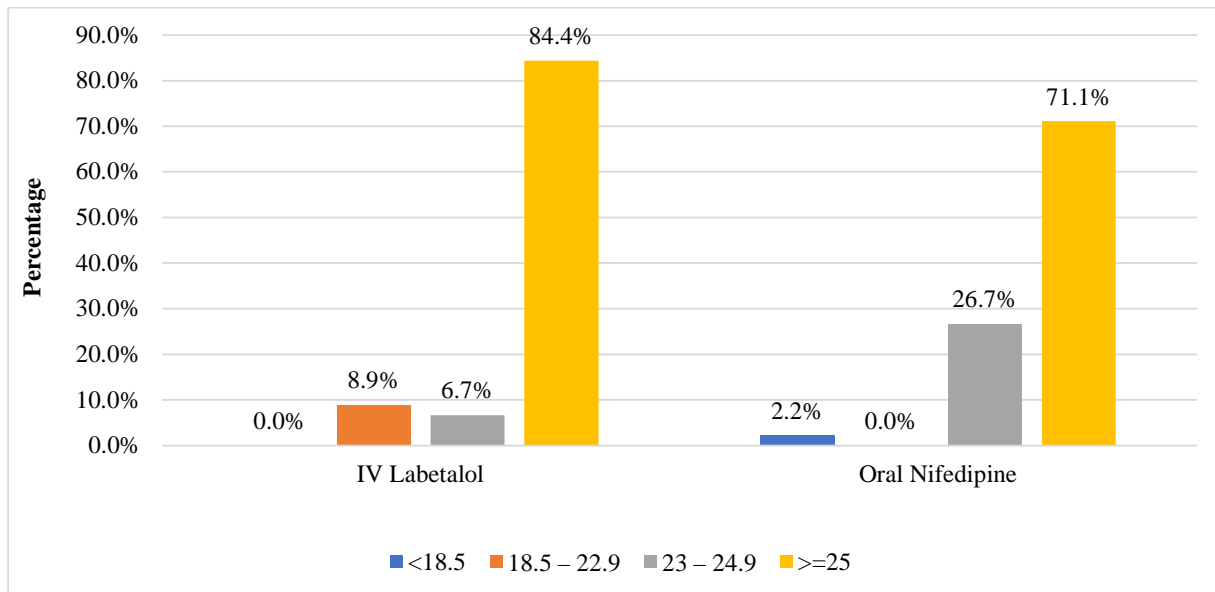


Table 4: BMI distribution between two study groups (N=90)

BMI	Intervention (Study Groups)	
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)
<18.5	0 (0%)	1 (2.22%)
18.5 – 22.9	4 (8.89%)	0 (0%)
23 – 24.9	3 (6.67%)	12 (26.67%)
>=25	38 (84.44%)	32 (71.11%)
Mean	27.91 ± 4.44	26.4 ± 3.76

Graph 4: Cluster bar chart of comparison of BMI between intervention (study groups) (N=90)

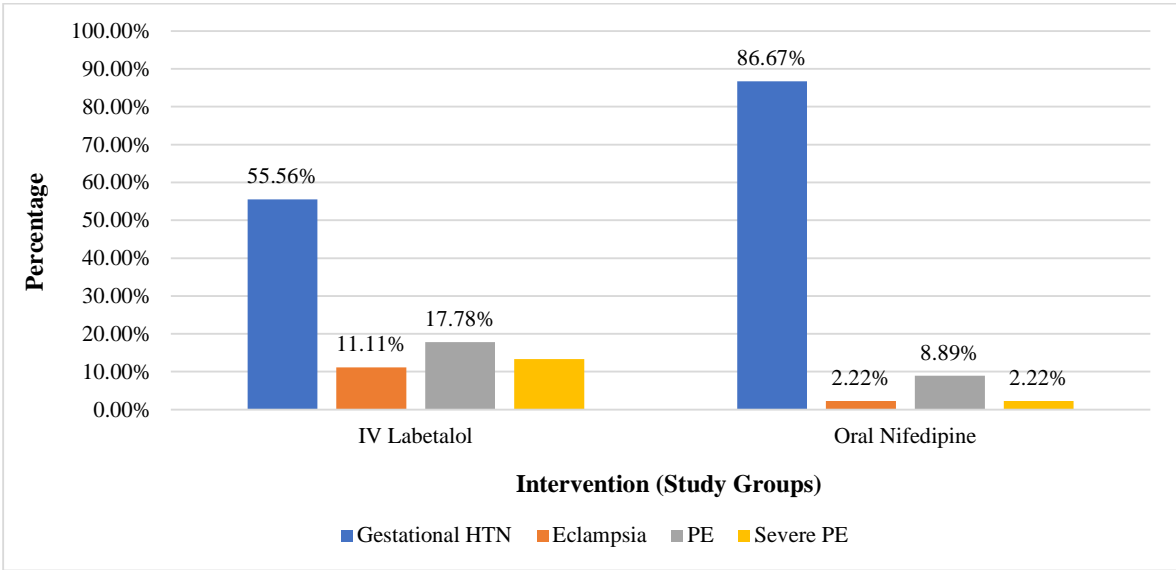


In Group A, none of the patients had a BMI less than 18.5, whereas 2.22% of patients in Group B fell into this category. For the BMI range of 18.5 to 22.9, 8.89% of patients in Group A were represented, while there were no patients in this category in Group B. In the BMI range of 23 to 24.9, 6.67% of patients were in Group A compared to 26.67% in Group B. The majority of patients in both groups had a BMI of 25 or higher, with 84.44% in Group A and 71.11% in Group B. The mean BMI for Group A was 27.91 ± 4.44 , while the mean BMI for Group B was slightly lower at 26.4 ± 3.76 . This data indicates that the majority of patients in both groups fell into the higher BMI categories, with Group A having a slightly higher mean BMI than Group B.

Table 5: Comparison of hypertensive emergency disorders between the two study groups (N=90)

Diagnosis	Intervention (Study Groups)		P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)	
Gestational HTN	25 (55.56%)	39 (86.67%)	0.005
Eclampsia	5 (11.11%)	1 (2.22%)	
Severe PE	15 (33.33%)	5 (11.11%)	

Graph 5: Clustered bar chart of hypertensive emergency disorders between the two study groups (N=90)



In Group A, 55.56% of patients were diagnosed with gestational hypertension, while this condition was present in 86.67% of patients in Group B. Eclampsia was diagnosed in 11.11% of patients in Group A, compared to 2.22% in Group B. Severe pre-eclampsia (Severe PE) was present in 33.33% of patients in Group A, whereas only 11.11% of patients in Group B had this diagnosis. This data shows a higher prevalence of gestational hypertension in Group B compared to Group A, while Group A had higher percentages of eclampsia, pre-eclampsia, severe pre-eclampsia compared to Group B.

Table 6: Distribution according to SBP at Admission between two study groups (N=90)

SBP Admission	Intervention (Study groups)		P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)	
160-178 (mmhg)	35 (77.78%)	43 (95.56%)	0.013
179-199 (mmhg)	10 (22.22%)	2 (4.44%)	
Mean SBP (N=90)	168.4 ± 8.83	163.42 ± 5.07	0.001

In Group A, 77.78% of patients had an SBP ranging from 160 to 178 mmHg, whereas 95.56% of patients in Group B fell into this category, with a statistically significant difference (P = 0.013). Conversely, 22.22% of patients in Group A had an SBP ranging from 179 to 199 mmHg, compared to only 4.44% of patients in Group B. The mean SBP for all patients (N=90) was significantly higher in Group A (168.4 ± 8.83 mmHg) compared to Group B (163.42 ± 5.07 mmHg), with a P value of 0.001. These results indicate that patients in Group A had higher initial systolic blood pressure levels than those in Group B, suggesting a statistically significant difference in the severity of hypertension at admission between the two groups.

Graph 6: Cluster bar chart of comparison of SBP at admission between intervention (study group) (N=90)

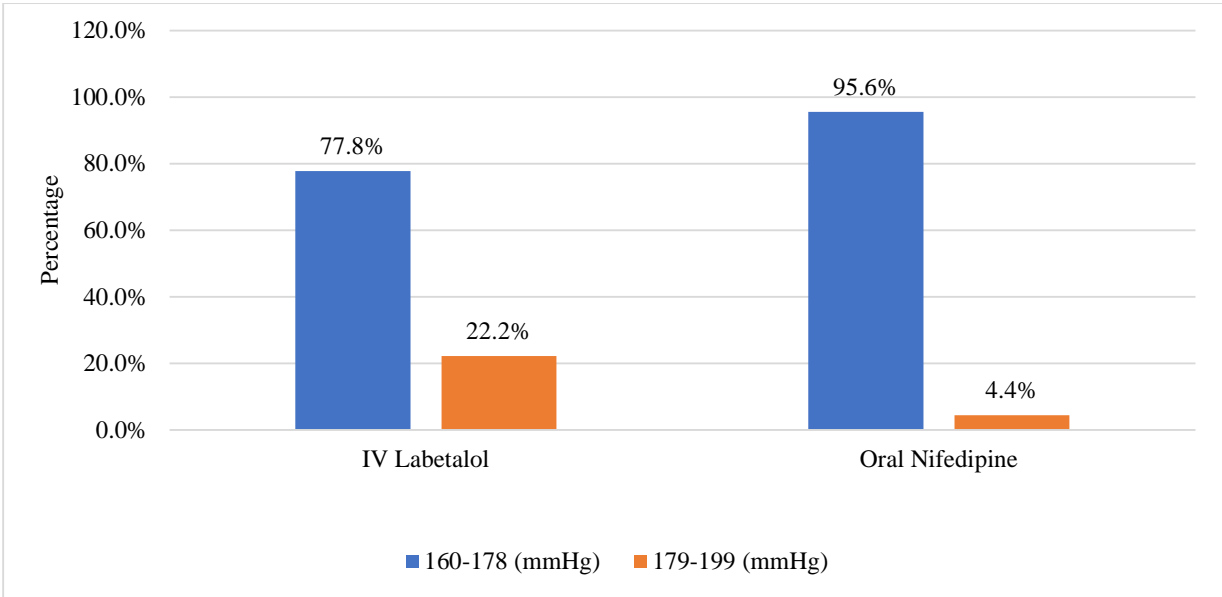


Table 7: Distribution according to DBP at Admission between two study groups (N=90)

DBP Admission	Intervention (Study groups) (Mean± SD)		P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)	
<110 (mmhg)	25 (55.56%)	35 (77.78%)	0.065
110-119 (mmhg)	19 (42.22%)	10 (22.22%)	
≥120 (mmhg)	1 (2.22%)	0 (0%)	
Mean DBP (N=90)	103.91 ± 7.05	100.36 ± 6.4	0.015

In Group A, 55.56% of patients had a DBP below 110 mmHg, compared to 77.78% of patients in Group B, with a P value of 0.065, indicating no statistically significant difference. For the DBP range of 110 to 119 mmHg, 42.22% of patients in Group A and 22.22% in Group B were represented. Only 2.22% of patients in Group A had a DBP of 120 mmhg or higher, with no patients in Group B falling into this category. The mean DBP at admission was 103.91 ± 7.05 mmHg for Group A and 100.36 ± 6.4 mmHg for Group B, with a statistically significant difference (P = 0.015). These findings suggest that, on average, patients in Group A had higher diastolic blood pressure levels at admission compared to those in Group B, with the difference being statistically significant.

Graph 7: Cluster bar chart of comparison of dbp at admission between intervention (study group) (N=90)

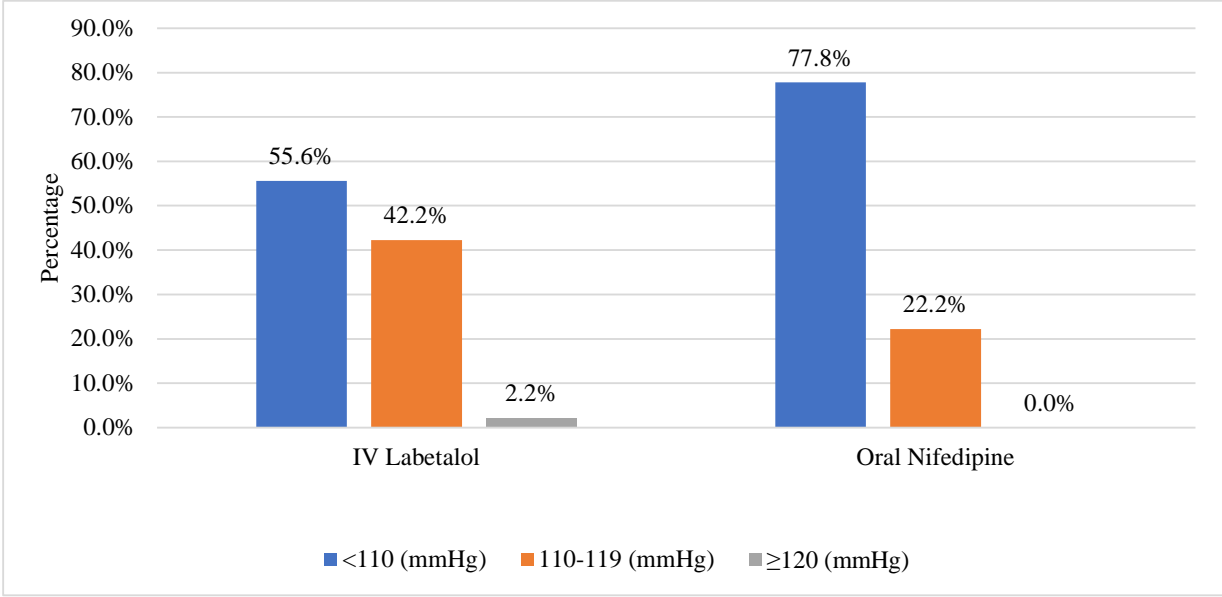


Table 8: Distribution according to the time taken to achieve target BP between two study groups (N=90)

Time taken To achieve target BP (in minutes)	Intervention (Study Groups)		Chi square	P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)		
10	26 (57.78%)	Not done according to protocol	45.771	<0.001
20	10 (22.22%)	42 (92.89%)		
30	7 (15.56%)	Not done according to protocol		
40	2 (4.44%)	3 (6.67%)		

In Group A, 57.78% of patients achieved the target blood pressure within 10 minutes, whereas Group B BP not measured according to protocol. At 20 minutes, 22.22% of patients in Group A and a significant 92.89% of patients in Group B achieved the target. By 30 minutes, 15.56% of patients in Group A reached the target, while in Group B, BP not measured according to protocol. At 40 minutes, 4.44% of patients in Group A and 6.67% of patients in Group B achieved the target blood pressure. At every 20 minutes, 40 minutes, 60 minutes BP monitored.

The chi-square test result was 45.771 with a P value of <0.001, indicating a highly significant difference in the time taken to achieve the target blood pressure between the

two groups. This data demonstrates that oral Nifedipine in Group B achieved the target blood pressure significantly faster than IV Labetalol in Group A

Table 9: Distribution according to number of doses to achieve target BP between two study groups (N=90)

No of Dose to achieve target BP	Intervention (Study Groups)		P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)	
1	26 (57.78%)	42 (93.33%)	<0.001
2	12 (26.67%)	3 (6.67%)	
3	7 (15.56%)	0 (0%)	

In terms of dosage, none of the patients in Group A received a 10 mg dose, whereas 93.33% of patients in Group B were administered this dose. In Group A, 57.78% of patients received a 20 mg dose, compared to none in Group B. No patients in Group A received a 30 mg dose, while 6.67% of patients in Group B did. For the 60 mg dose, 22.2% of patients in Group A were treated, with no patients in Group B receiving this dose. Additionally, 20% of patients in Group A received a 140 mg dose, while none in Group B were administered this amount. The P value for dose differences was <0.001, indicating a highly significant difference between the two groups. Regarding the number of doses, 57.78% of patients in Group A required only one dose, compared to 93.33% in Group B. In Group A, 26.67% of patients needed two doses, whereas only 6.67% in Group B required two doses. Additionally, 15.56% of patients in Group A needed three doses, with none in Group B requiring this number of doses. The P value for the number of doses was also <0.001, demonstrating a significant difference between the groups. These results indicate that patients in Group A, treated with IV Labetalol, required higher doses and a greater number of doses to manage their blood pressure compared to those in Group B, treated with oral Nifedipine

Graph 9: Cluster bar chart of comparison of no of dose to achieve target bp between intervention (study group) (N=90)

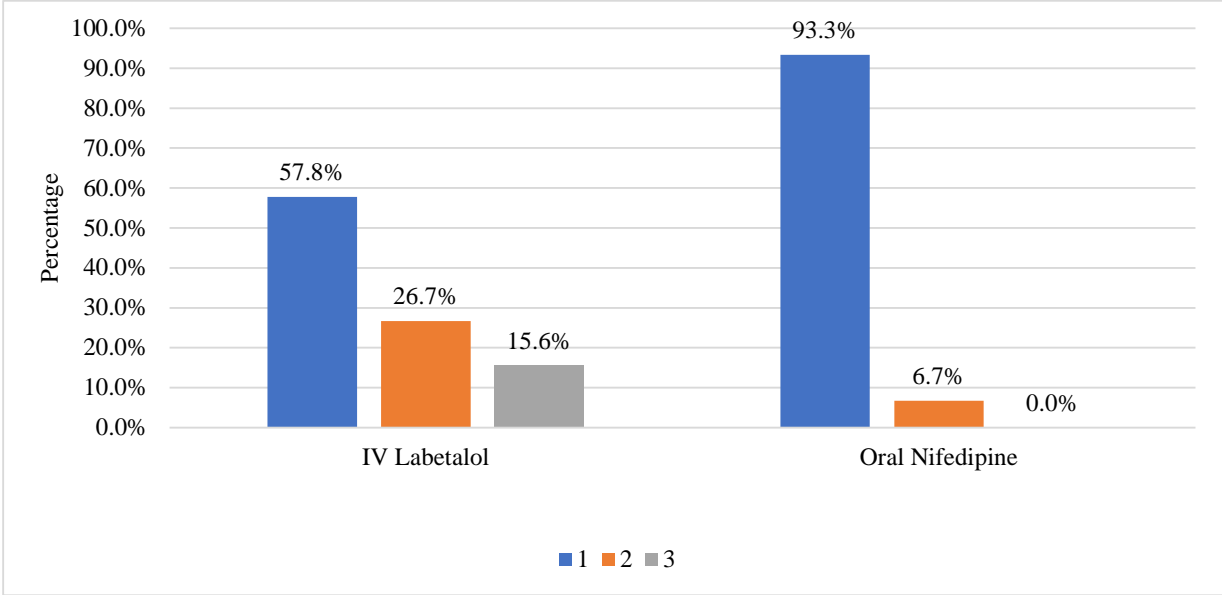
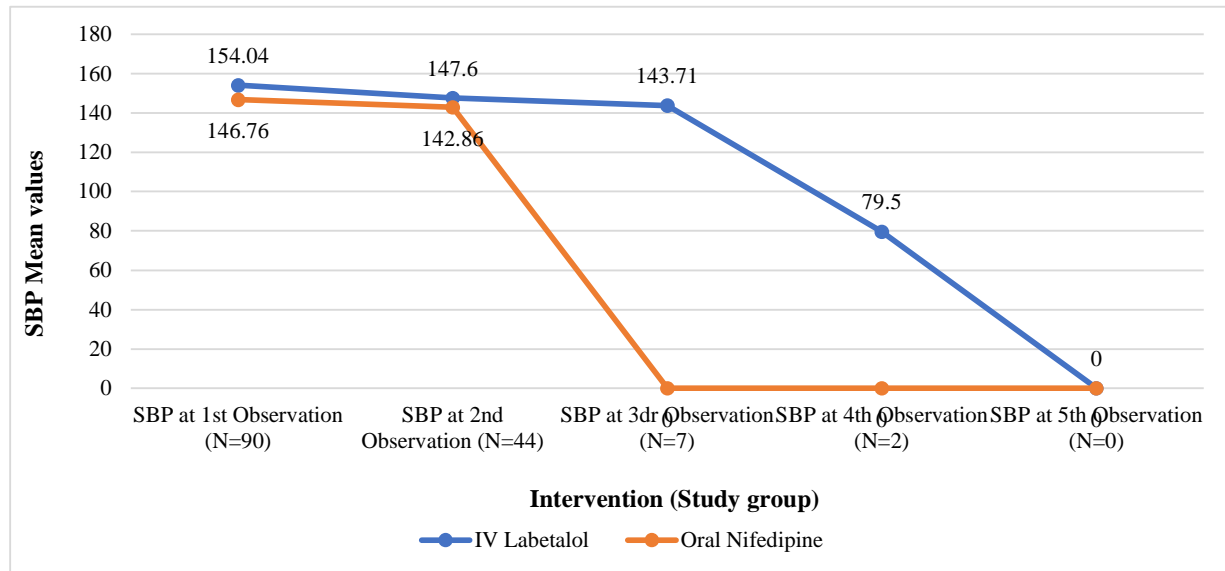


Table 10: Comparison of mean of SBP between two study groups at different follow up periods (N=90)

Parameter (N=90)	Intervention (Study groups) (Mean± SD)		P value
	Group A IV Labetalol (10mins)	Group B Oral Nifedipine (20mins)	
SBP at 1st Observation(N=90)	154.04 ± 10.82	146.76 ± 8.69	<0.001
SBP at 2nd Observation (N=44)	147.6 ± 8.48	142.86 ± 5.53	0.063
SBP at 3 rd Observation (N=7)	143.71 ± 4.680	0	*
SBP at 4 th Observation (N=2)	79.50 ± 99.702	0	*
SBP at 5 th Observation (N=0)	0	0	*

Graph 10: Comparative line chart of mean of SBP between two study groups at different follow up periods(N=90)



At the first observation, the mean SBP for Group A was 154.04 ± 10.82 mmhg, while for Group B, it was significantly lower at 146.76 ± 8.69 mmhg ($P < 0.001$). This indicates a significant difference in SBP between the groups at the initial observation. At the second observation, the mean SBP for Group A was 147.6 ± 8.48 mmhg, and for Group B, it was 142.86 ± 5.53 mmhg, with a P value of 0.063, indicating no significant difference at this time point. For the third observation, the mean SBP in Group A was 143.71 ± 4.68 mmhg, while no data was available for Group B. Similarly, at the fourth observation, the mean SBP for Group A was 79.50 ± 99.702 mmhg, with no corresponding data for Group B. There were no observations for either group at the fifth observation point. These results suggest that Group A, treated with IV Labetalol, had higher SBP readings initially compared to Group B, treated with oral Nifedipine.

Table 11: Comparison of mean of DBP between two study groups at different follow up periods :

Parameter	Intervention (Study groups) (Mean± SD)		P value
	Group A IV Labetalol (10mins)	Group B Oral Nifedipine (20mins)	
DBP at 1st Observation	95.51 ± 6.73	91.02 ± 5.92	0.001
DBP at 2nd Observation	93.83 ± 5.29	90.67 ± 4.39	0.054
DBP at 3rd Observation (N=9)	92.25 ±5.064	80.00	
DBP at 4th Observation (N=1)	98.00	0	*
DBP at 5th Observation	0	0	*

At the first observation, the mean DBP for the IV Labetalol group was 95.51 ± 6.73 mmhg, while the mean DBP for the oral Nifedipine group was significantly lower at 91.02 ± 5.92 mmhg ($P = 0.001$). This indicates a statistically significant difference in DBP between the groups at the initial observation. At the second observation, the mean DBP for the IV Labetalol group was 93.83 ± 5.29 mmhg, and for the oral Nifedipine group, it was 90.67 ± 4.39 mmhg. The P value was 0.054, indicating that the difference in DBP between the groups at this time point was not statistically significant. For the third observation, the mean DBP in the IV Labetalol group (N=9) was 92.25 ± 5.064 mmhg, while the mean DBP for the oral Nifedipine group was 80.00 mmHg. There was no statistical analysis provided for this observation due to the small sample size. At the

fourth observation, the mean DBP for the IV Labetalol group (N=1) was 98.00 mmHg, with no corresponding data for the oral Nifedipine group. There were no observations for either group at the fifth observation point.

Graph 11: Comparative line chart of mean of DBP between two study groups at different follow up periods (N=90)

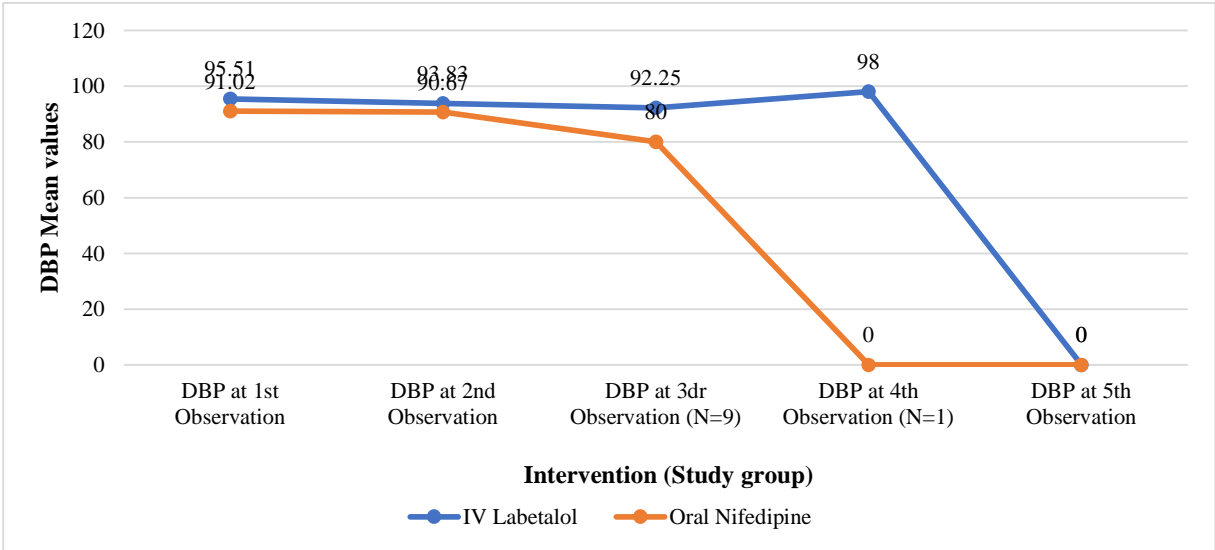
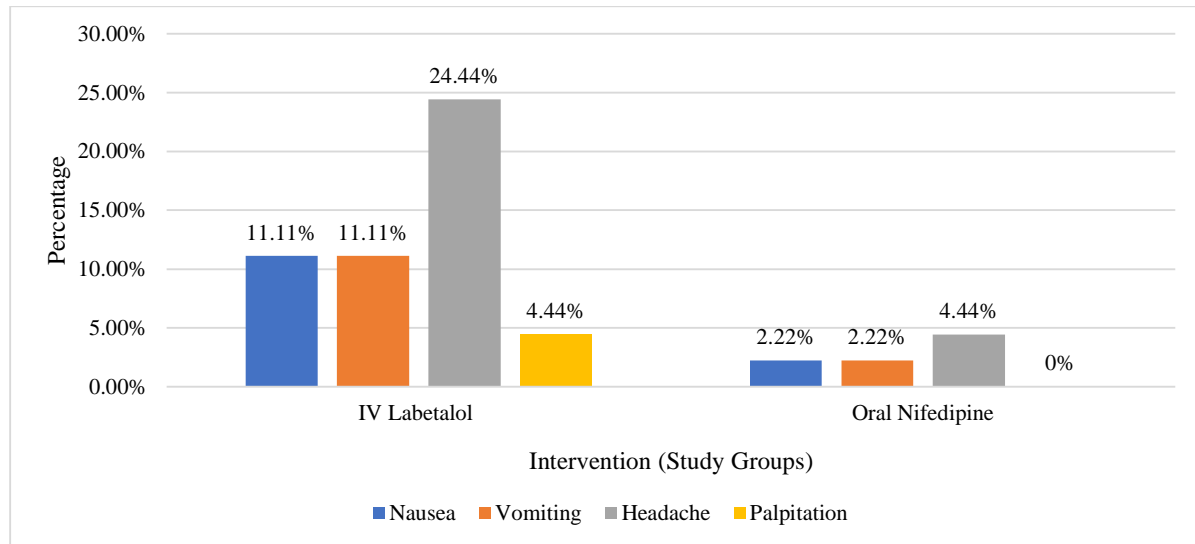


Table 12: Comparison of Side effects between intervention (study groups) (N=90)

Complications	Intervention (Study Groups)		P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)	
Nausea	5 (11.11%)	1 (2.22%)	0.203
Vomiting	5 (11.11%)	1 (2.22%)	0.203
Headache	11 (24.44%)	2 (4.44%)	0.007
Palpitation	2 (4.44%)	0 (0%)	*
Blurring of vision (No)	0 (0%)	0 (0%)	*
Sweating (No)	0 (0%)	0 (0%)	*
Flushing (No)	0 (0%)	0 (0%)	*
Chills (No)	0 (0%)	0 (0%)	*
Tingling sensation (No)	0 (0%)	0 (0%)	*
Shortness of breath (No)	0 (0%)	0 (0%)	*

Graph 12: Clustered bar chart of complications (Side effects) between intervention (study groups) (N=90)



In Group A, 11.11% of patients experienced nausea and vomiting, compared to 2.22% in Group B, with a P value of 0.203, indicating no statistically significant difference between the groups for these complications. Headache was reported by 24.44% of patients in Group A, while only 4.44% of patients in Group B experienced this complication, with a P value of 0.007, indicating a statistically significant difference. Palpitations were reported by 4.44% of patients in Group A, with no patients in Group B reporting this issue. There were no instances of blurring of vision, sweating, flushing, chills, tingling sensation, or shortness of breath reported in either group.

Table 13: Comparison of mode of delivery between intervention (study groups) (N=90)

Mode of delivery	Intervention (Study Groups)		Chi square	P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)		
Vaginal	12 (26.67%)	18 (40%)	1.843	0.398
LSCS	31 (68.89%)	25 (55.56%)		
Instrumental	2 (4.44%)	2 (4.44%)		

There was no statistically significant difference in the modes of delivery between the two treatment groups. (p value 0.398)

Graph 13: Cluster bar chart of comparison of mode of delivery between intervention (study groups) (N=90)

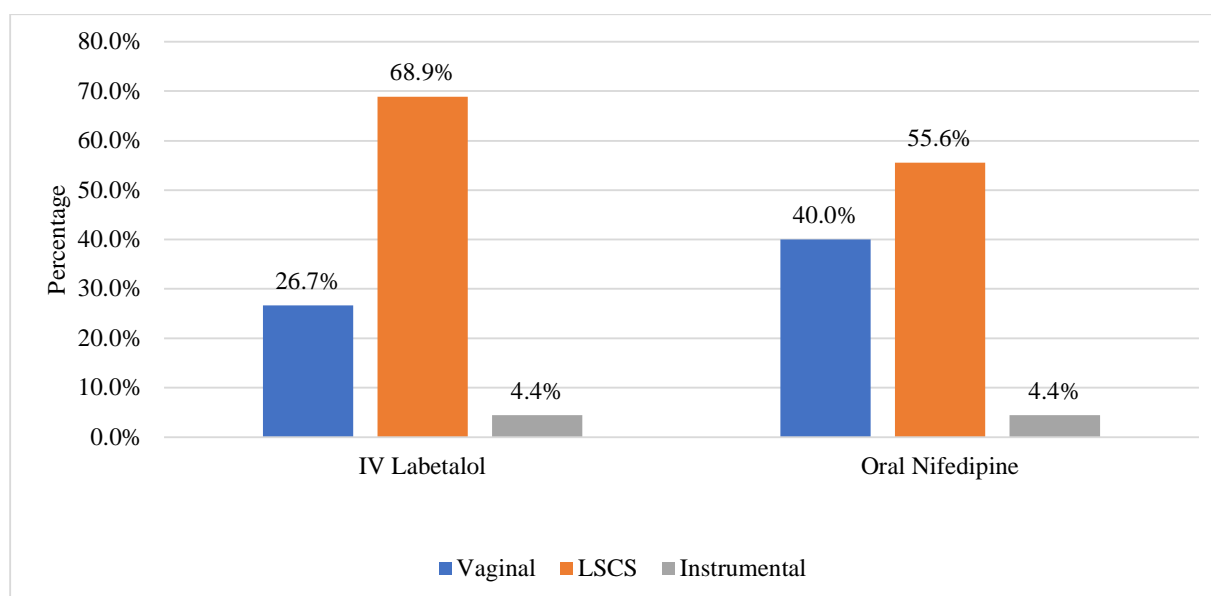


Table 14: Comparison of birth weight (in kg) between intervention (study groups) (N=90)

Birth Weight (In Kg)	Intervention (Study Groups)		Chi square	P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)		
<=1 Kg	5 (11.11%)	2 (4.44%)	13.780	0.017
1.1 To 1.5 Kg	11 (24.44%)	3 (6.67%)		
1.6 To 2 Kg	13 (28.89%)	7 (15.56%)		
2.01 To 2.5 Kg	7 (15.56%)	16 (35.56%)		
2.6 To 3 Kg	7 (15.56%)	12 (26.67%)		
>3 Kg	2 (4.44%)	5 (11.11%)		

The birth weight distributions between the two groups showed a statistically significant difference. (p value 0.017)

Graph 14: Cluster bar chart of comparison of birth weight (in kg) between intervention (study groups) (N=90)

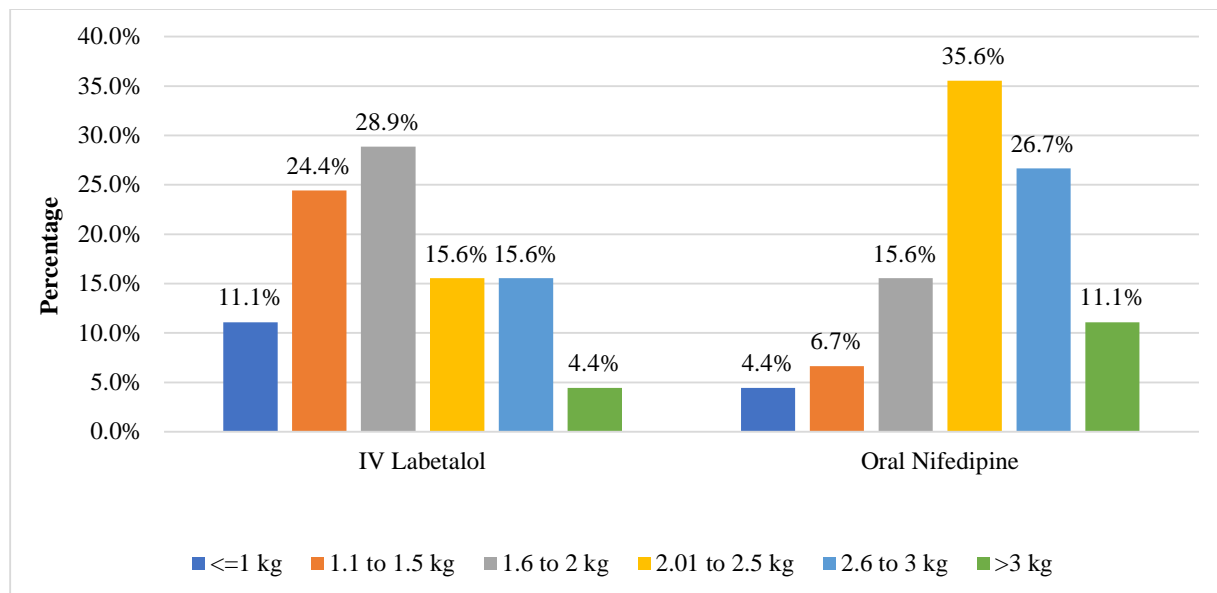


Table 15: Comparison of mean of APGAR at 1 mint and 5 mints between intervention (study groups) (N=90)

Parameter	Intervention (Study groups) (Mean± SD)		P value
	Group A IV Labetalol (N=39)	Group B Oral Nifedipine (N=44)	
APGAR 1 Min	6.72 ± 1.02	7.05 ± 1.24	0.196
APGAR 5 Min	7.95 ± 1.1	8.41 ± 0.9	0.039

The table compares the effects of IV Labetalol and oral Nifedipine on newborns' APGAR scores at 1 and 5 minutes. There was no significant difference in the 1-minute APGAR scores between the two groups (P = 0.196). However, the 5-minute APGAR scores are significantly higher in oral Nifedipine group compared to IV Labetalol group (P = 0.039)

Graph 15: Comparative bar chart of mean of APGAR at 1 mint and 5 mints between intervention (study groups) (N=90)

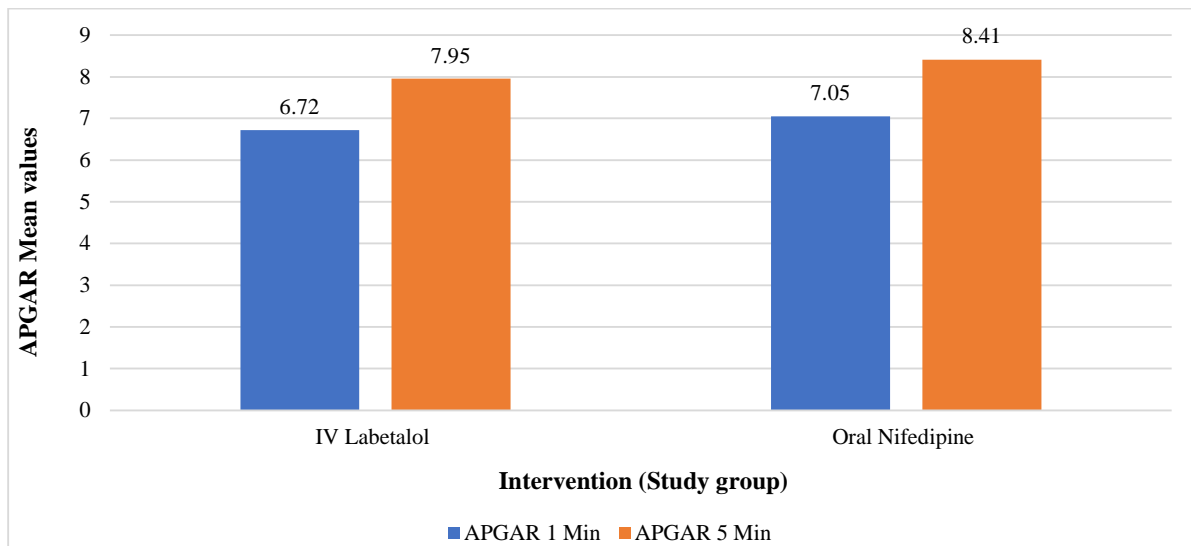
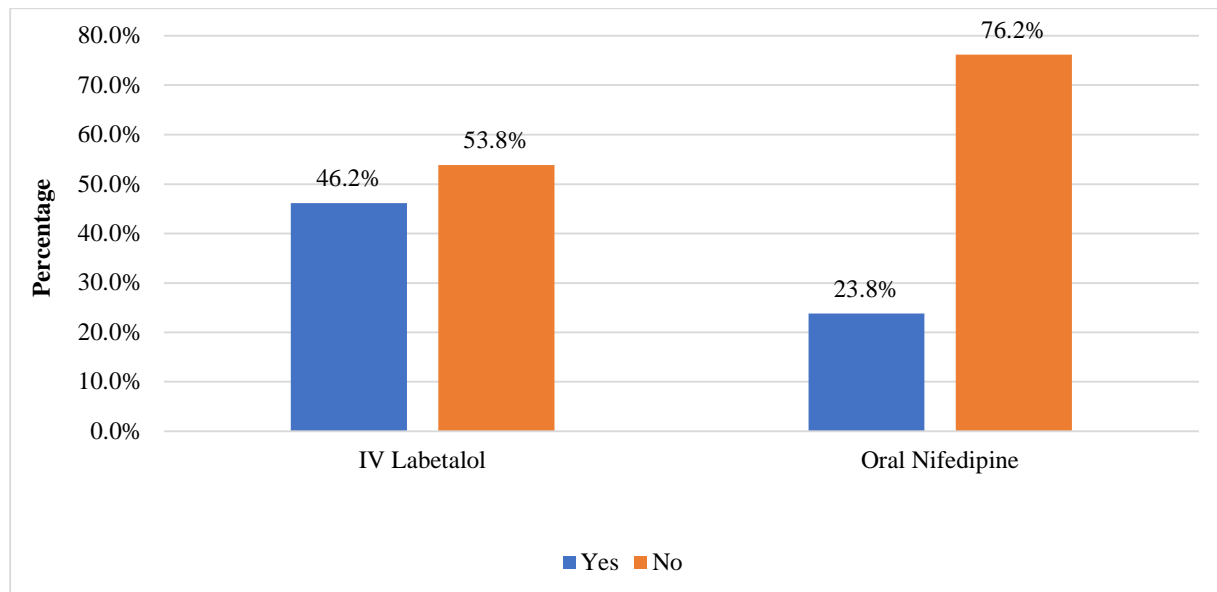


Table 16: Comparison of NICU admission between intervention (study groups) (N=81)

NICU Admission	Intervention (Study Groups)		Chi square	P value
	Group A IV Labetalol (N=39)	Group B Oral Nifedipine (N=42)		
Yes	18 (46.15%)	10 (23.81%)	4.464	0.035
No	21 (53.85%)	32 (76.19%)		

Graph 16: Cluster bar chart of comparison of NICU admission between intervention (study groups) (N=81)



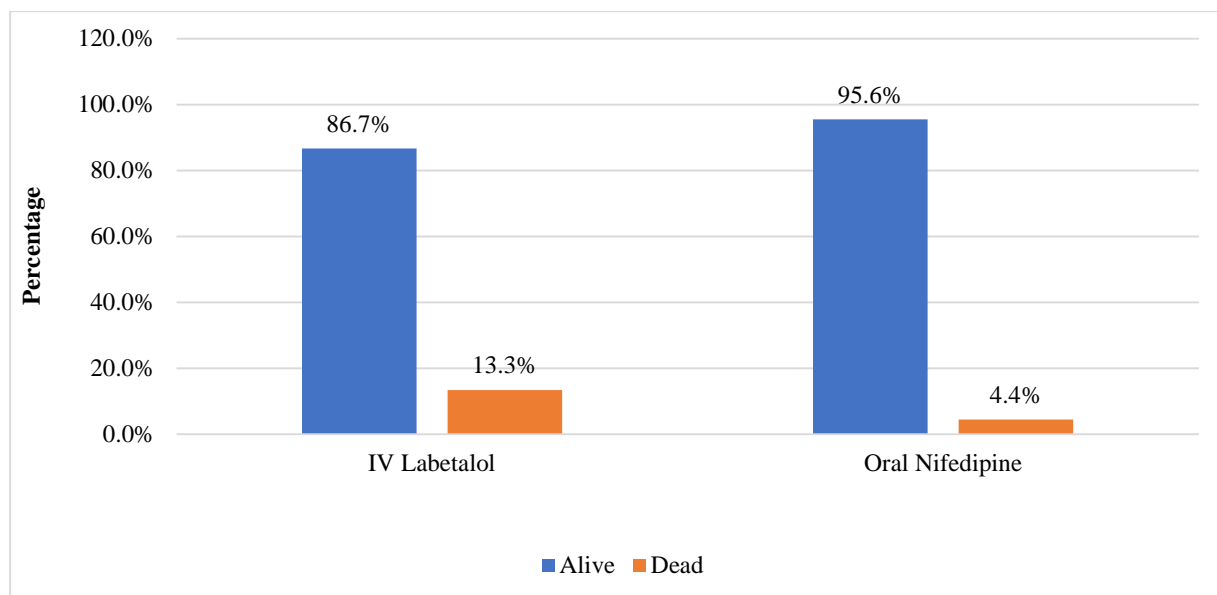
The table showed the rates of NICU admission for newborns whose mothers were treated with IV labetalol versus oral nifedipine. NICU admission was significantly higher in IV Labetalol group (46.15%) compared to oral Nifedipine group (23.81%), with a chi-square value of 4.464 and a P value of 0.035 .

Table 17: Comparison of birth outcome between intervention (study groups) (N=90)

Birth Outcome	Intervention (Study Groups)		Fisher exact P value
	Group A IV Labetalol (N=45)	Group B Oral Nifedipine (N=45)	
Alive	39 (86.67%)	43 (95.56%)	0.266
FSB	2(4.44%)	0	
MSB	4 (8.89%)	2 (4.44%)	

The table compares birth outcomes between newborns whose mothers were treated with IV Labetalol and those treated with oral Nifedipine. The percentage of live births was slightly lower in IV labetalol group (86.67%) compared to oral Nifedipine group (95.56%). The percentage of deaths was higher in IV labetalol group (13.33%) compared to oral Nifedipine group (4.44%). However, the fisher exact P value is 0.266, The difference in birth outcomes between the two groups was not statistically significant.

Graph 17: Cluster bar chart of comparison of birth outcome between intervention (study groups) (N=90)



DISCUSSION

Present study conducted at KAHERS' DR. Prabhakar Kore hospital and MRC. A randomized clinical trial done by envelop method with 45 participants in each group involving 90 participants over 1 year and 2 months aimed to compare oral Nifedipine and IV Labetalol in managing acute severe hypertension in pregnant women.

In terms of maternal age, present study showed no significant difference between IV Labetalol group (27.73 ± 6.02 years) and the oral Nifedipine group (27.36 ± 5.32 years) with a P value of 0.753. This finding aligns with those of Raheem et al⁶². And Zulfeen et al⁷⁸., who also reported no significant difference in maternal age between the treatment groups (P = 0.54 for both studies). However, Dalhi et al⁶¹. reported a significant difference in maternal age between their study groups, with IV Labetalol group having a slightly older maternal age compared to oral Nifedipine group (P = 0.024).

Regarding obstetric scores, Present study found no significant difference in the distribution of primigravida and multigravida between the IV Labetalol and oral Nifedipine groups (P = 0.291). This finding is consistent with the results from Raheem et al⁶². And Zulfeen et al⁷⁸., who found no significant differences in gravidity (P = 0.12) and parity (P = 0.25) between their study groups.

Present study showed a significant difference in the diagnosis of gestational hypertension, with a higher rate observed in the oral Nifedipine group (86.67%) compared to the IV Labetalol group (55.56%). This particular comparison was not directly made in the studies by Raheem et al⁶². And Zulfeen et al⁷⁸. However, Present

study also revealed higher incidences of pre-eclampsia and eclampsia in the IV Labetalol group, which were not the focus of the other studies.

In terms of systolic blood pressure (SBP) at admission, Present study found significant differences between the groups, with a higher mean SBP in the IV Labetalol group (168.4 ± 8.83 mmhg) compared to the oral Nifedipine group (163.42 ± 5.07 mmhg), with a P value of 0.001. This trend is consistent with the observations in the studies by Raheem et al⁶². And Zulfeen et al⁷⁸., although Raheem et al⁶². Reported no significant difference in SBP between their groups ($P = 0.25$).

Diastolic blood pressure (DBP) at admission in present study was significantly higher in the IV Labetalol group (103.91 ± 7.05 mmhg) compared to the oral Nifedipine group (100.36 ± 6.4 mmhg), with a P value of 0.015. This finding is similar to the significant difference in DBP reported by both Raheem et al⁶². ($P = 0.012$) and Zulfeen et al⁷⁸. ($P = 0.012$). In contrast, Dalhi et al⁶¹. Did not find a significant difference in DBP between their treatment groups ($P = 0.124$).

In present study, the majority of patients in Group B, treated with oral Nifedipine, required a 10 mg dose, with 93.33% achieving the target blood pressure with just one dose. Conversely, in Group A, treated with IV Labetalol, no patients received a 10 mg dose. Instead, 57.78% of patients in Group A required a 20 mg dose, 22.2% required a 60 mg dose, and 20% required a 140 mg dose. Additionally, 57.78% of patients in Group A achieved the target blood pressure with one dose, 26.67% required two doses, and 15.56% needed three doses.

In contrast, Raheem et al⁶². reported that patients randomized to oral Nifedipine required a median of 2 doses (ranging from 1.5 to 4.5) to achieve the target blood pressure, while those randomized to IV Labetalol required a median of 3 doses (ranging from 2 to 4). The P value for the difference in the number of doses required between the two groups was 0.60, indicating no statistically significant difference.

Overall, present study demonstrates a significant difference in the dosing regimen between IV Labetalol and oral Nifedipine, with a higher proportion of patients in the Nifedipine group achieving the target blood pressure with fewer doses. In contrast, Raheem et al⁶².’s study did not find a significant difference in the number of doses required between the two groups. This discrepancy may be attributed to differences in study design, patient populations, or specific dosing protocols used in the respective studies

Comparing the side effects observed in present study with those reported by Raheem et al⁶². And Zulfeen et al⁷⁸., we find several points of interest. In present study, nausea was reported in 11.11% of patients in the IV Labetalol group and 2.22% in the oral Nifedipine group (P = 0.203). Similarly, Raheem et al⁶². Found no cases of nausea in the Nifedipine group, while 16% of patients in the Labetalol group experienced this side effect (P = 0.11). Zulfeen et al⁷⁸. Did not report specific percentages for nausea alone but combined it with other adverse drug reactions . Vomiting was observed in 11.11% of patients in present study IV Labetalol group and 2.22% in the oral Nifedipine group (P = 0.203), while Raheem et al⁶². Reported vomiting in 8% of the Labetalol group and none in the Nifedipine group (P = 0.49). Headaches were significantly more common in present IV Labetalol group (24.44%) compared to oral Nifedipine group (4.44%) with a P value of 0.007, whereas Raheem et al⁶². Reported equal headache incidences of 12% in both groups (P = 1.00). Palpitations in present study were noted in 4.44% of IV Labetalol group and none in oral Nifedipine group, while Raheem et al⁶². Observed palpitations in 4% of oral Nifedipine group and none in IV Labetalol group (P = 1.00). Present study found no reports of blurring of vision, sweating, flushing, chills, tingling sensation, or shortness of breath in either group, a finding partially echoed by Raheem et al., who reported shortness of breath in 4% of patients in both groups, with no cases of other specific side effects. Zulfeen et al⁷⁸. Did not provide a breakdown of these specific side effects but included them in general adverse drug reactions.

Both present study and Raheem et al⁶².’s findings highlight a higher prevalence of headache and nausea in IV Labetalol group, with present study showing significant differences for headache. These results underscore the tolerability differences between IV Labetalol and oral Nifedipine, revealing some overlapping trends in side effect profiles across the studies.

The distribution of birth weights of infants born to moms receiving IV labetalol versus oral nifedipine showed notable variances, according to the study. While infants in the Nifedipine group displayed larger proportions in higher birth weight categories (2.01 to 2.5 Kg, 2.6 to 3 Kg, >3 Kg), infants in the Labetalol group showed higher proportions in lower birth weight categories (≤ 1 Kg, 1.1 to 1.5 Kg, and 1.6 to 2 Kg). This pattern is consistent with previous research indicating possible effects of antihypertensive drugs on foetal development and growth.⁶¹

APGAR scores at 1 minute did not differ significantly between IV Labetalol and oral Nifedipine groups. However, at 5 minutes, neonates exposed to oral Nifedipine had significantly higher APGAR scores compared to those exposed to IV Labetalol. This difference at 5 minutes may indicate a transient effect or a differing impact of the medications on neonatal adaptation post-birth, possibly related to pharmacokinetic differences.⁶²

The study found a significantly higher rate of NICU admissions among neonates born to mothers treated with IV Labetalol compared to those treated with Oral Nifedipine. This suggests a potential association between the type of antihypertensive medication used during pregnancy and neonatal health outcomes requiring intensive care support, which warrants further investigation into underlying mechanisms⁶³.

While there was a slightly lower percentage of live births in the IV Labetalol group compared to the oral Nifedipine group, the difference was not statistically significant. However, the incidence of foetal and neonatal deaths appeared numerically higher in IV Labetalol group, although not reaching statistical significance in this sample size. This highlights the importance of larger studies to better understand the safety profiles of these medications in pregnancy⁶⁴.

Limitations

It is important to recognise the limitations of the current study. First off, the findings' generalizability can be impacted by the sample size, which was somewhat small. Furthermore, the research was carried out exclusively at one location, thus restricting the generalizability of the results to alternative contexts with distinct patient demographics and medical procedures. A further drawback is the little follow-up period, which makes it impossible to evaluate the treatments' long-term effects and possibility for delayed unfavourable results.

Strength of the study

The study's comparative design with randomized groups provide a robust evaluation of IV Labetalol and oral Nifedipine for managing hypertension in pregnancy. Clear inclusion and exclusion criteria, comprehensive data collection, and appropriate statistical analysis enhance its validity. Detailed reporting on side effects and consistency with previous studies add clinical relevance. The findings have direct practical implications for optimizing treatment protocols and improving outcomes for hypertensive pregnant women.

CONCLUSION

This study shows that in patients with hypertensive crises during pregnancy, oral Nifedipine is more effective than IV Labetalol in reaching target blood pressure quickly and using fewer doses. The current study's findings have significant therapeutic implications for the handling of hypertensive crises during pregnancy. Because oral Nifedipine is more effective and more tolerable, it needs to be taken into consideration as a first-line therapy choice in this situation. Its usage as a first-line therapy option is further supported by the lower occurrence of side effects. These results imply that oral Nifedipine should be given preference for treating acute hypertension episodes in pregnant women, which has important therapeutic implications. Prospective investigations need to concentrate on confirming these findings in more extensive and diverse populations and examining long-lasting effects linked to various therapeutic alternatives.

SUMMARY

A randomized clinical trial with 45 participants in each group involving 90 participants over a year and 2 months aimed to compare oral Nifedipine and IV Labetalol in managing acute severe hypertension in pregnant women.

The study included pregnant women of 20 weeks' gestation or more presenting to the tertiary hospital at KAHERS' Dr. Prabakar Kore hospital and MRC with acute severe hypertension. Inclusion criteria comprised singleton pregnancies of 20 weeks or more with hypertension (gestational hypertension, pre-eclampsia, eclampsia) with specified blood pressure thresholds or mean arterial pressure criteria lasting 15 minutes or more. Exclusion criteria involved chronic hypertension, multiple pregnancies, hypersensitivity to Nifedipine or Labetalol, and Labetalol contraindications such as bronchial asthma, cardiac failure, rhythm abnormalities, and heart block.

There was no significant difference in maternal age between the IV Labetalol group (27.73 ± 6.02 years) and the oral Nifedipine group (27.36 ± 5.32 years), with a P value of 0.753. No significant difference was found in the distribution of primigravida and multigravida between the IV Labetalol and oral Nifedipine groups ($P = 0.291$).

A significantly higher rate of gestational hypertension was observed in the oral Nifedipine group (86.67%) compared to the IV Labetalol group (55.56%).

The mean SBP at admission was significantly higher in the IV Labetalol group (168.4 ± 8.83 mmhg) compared to the oral Nifedipine group (163.42 ± 5.07 mmhg), with a P value of 0.001.

The mean DBP at admission was significantly higher in the IV Labetalol group (103.91 ± 7.05 mmhg) compared to the oral Nifedipine group (100.36 ± 6.4 mmhg), with a P value of 0.015.

Total number of doses in the oral Nifedipine group, 93.33% of patients achieved the target blood pressure with a 10 mg dose, whereas in the IV Labetalol group 57.78% achieved the target blood pressure with one dose, 26.67% required two doses, 15.56% needed three doses.

Although not statistically significant ($P = 0.203$), nausea and vomiting were common in Group A (11.11% vs. 2.22%).

Headache was significantly frequent in Group A (24.44% vs. 4.44%, $P = 0.007$).

Patients in Group A required higher doses and frequent dosing to manage blood pressure, with significant differences in dose distribution and number of doses required ($P < 0.001$).

APGAR scores at 1 minute did not differ significantly between IV Labetalol and oral Nifedipine groups. However, at 5 minutes, neonates exposed to oral Nifedipine had significantly higher APGAR scores compared to those exposed to IV Labetalol.

The study found a significantly higher rate of NICU admissions among neonates born to mothers treated with IV Labetalol compared to those treated with Oral Nifedipine.

The present study concluded that oral nifedipine is more effective in achieving target blood pressure rapidly with fewer doses compared to IV labetalol in pregnant women with hypertensive crisis.

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“TITLE OF THE PROJECT/STUDY”

Name of Student/Principal Investigator:

Name of Guide/Co Investigators:

Objective:

Introduction:

Explanation of procedure:

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact: “Name of student/PI, mobile number, email ID” If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study “**I/V Labetalol vs Oral Nifedipine in Acute Severe Hypertension of Pregnancy – A Randomized controlled trial**”. My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant: Name of the witness:

Signature or left thumb impression of the witness: Name of the investigator:

Signature of the investigator:

OBSTETRIC HISTORY:

Married life –

Consanguineous marriage - yes no

If yes – degree

OBSTETRIC SCORE:

GRAVIDA PARA LIVE ABORTION

MENSTRUAL HISTORY:

Cycles: regular irregular

LMP:

EDD:

POG:

PAST HISTORY:

YES NO IF YES, TREATMENT

1.Diabetes

2.Hypertension

3.Hypothyroidism

4.Bronchial asthma

5.Epilepsy

6.TB

7.Cardiac disease

8.H/o blood transfusion

9.H/o drug allergy

COMORBIDITIES:

MATERNAL

NONE

GEST HTN

ANEMIA

GDM

HYPOTHYROID

OTHER_____

FETAL

NONE

FGR

MACROSOMIA

OTHERS_____

GENERAL EXAMINATION:

Height

Weight

BMI

Pallor

Icterus

Pedal edema

Thyroid / breast/ spine

SYSTEMIC EXAMINATION:

CVS-

RS -

Vitals:

	On admission	Min	Min	Min	Min	Min
SBP						
DBP						
RR						
HR						

Urine output: _____ml/Hour

Mg So4

YES

NO

If given

Dose

No of dose Route

If Toxicity noted

Urine output Knee jerk

RR: _____

Others : _____ Treated

Antihypertensive

LABETOTOL NIFEDIPINE

Route IM IV ORAL

- Dose
- No of dose

Time to achieve desire level of BP (in mins)

• MOD -Vaginal LSCS INSTRUMENT

ICU ADMISSION YES NO

- Complications-

Nausea/ vomiting

Headache

Palpitation

Eclampsia

Abruption

HELLP syndrome

Pulmonary oedema

Renal failure

PPH

FETAL OUTCOME:

APGAR AT 1MIN

APGAR AT 5MIN

Birth weight in kg

CORD blood ph DONE If yes, ph ____

NICU ADMISSION INDICATION FOR ADMISSION

YES

NO

Complication :

YES

NO

Birth asphyxia

HMD

Sepsis

Final outcome –

Alive

Death

