

A COMPARATIVE STUDY ON EFFICACY OF INTRAVENOUS LABETALOL AND ORAL NIFEDIPINE FOR CONTROL OF BLOOD PRESSURE IN SEVERE PRE-ECLAMPSIA IN A TERTIARY CARE HOSPITAL

Ishba Shahnaz¹, Erum Ali², Soumen Das³, Injamam Ul Hoque²

Received : 27/06/2024
Received in revised form : 06/08/2024
Accepted : 22/08/2024

Keywords:
Hypertension, pregnancy, Labetalol, Nifedipine, preeclampsia.

Corresponding Author:
Dr. Injamam Ul Hoque,
Email: dr.injamam34@gmail.com

DOI: 10.47009/jamp.2024.6.4.185

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2024; 6 (4); 945-951



¹Senior Resident, Department of Obstetrics & Gynaecology, Midnapore Medical College and Hospital, Vidyasagar Road, West Midnapore, West Bengal, India

²3rd Year Post Graduate Trainee, Department of Obstetrics & Gynaecology, Midnapore Medical College and Hospital, Vidyasagar Road, West Midnapore, West Bengal, India

³RMO Cum Clinical Tutor, Department of Obstetrics & Gynaecology, Midnapore Medical College and Hospital, Vidyasagar Road, West Midnapore, West Bengal, India.

Abstract

Background: Hypertension is the most common medical disorder in pregnancy, complicating 6-10% pregnancies. Treatment of severely increased blood pressure is widely recommended to reduce the risk of maternal and fetal complications. Regimens for acute treatment of severe hypertension in pre-eclampsia include intravenous medications. Although effective, these drugs require venous access and careful fetal monitoring and might not be feasible in busy or low resource environments. Therefore, this study aimed to compare the efficacy of intravenous labetalol and oral nifedipine for control of hypertension in severe pre-eclampsia. The aims and objectives were to compare efficacy of labetalol and nifedipine when used rapidly to lower high blood pressure in severe pre-eclampsia mothers. **Materials and Methods:** This was a hospital based prospective randomized interventional comparative trial, conducted at Midnapore Medical College and Hospital of West Bengal from April '2022 to Sep '2023. The study had a sample size of 100 patients divided into two groups randomly, group A received intravenous labetalol injection (in escalating dose of 20,40, 80 and 80 mg every 30 mins, maximum dose of 220mg) and group B received oral nifedipine (10mg tablet orally upto 5 doses) every 30 mins. Target BP was $\leq 150/90$ mm of Hg. **Result:** 100 patients were randomized using computer generated random tables with fifty patients in each group. The study was conducted to evaluate and compare the efficacy of intravenous labetalol and oral nifedipine in the treatment of hypertension in severe preeclampsia. Group A (n=50) received intravenous Labetalol 20 mg i.v stat followed by incremental doses of 40,80 and 80 mg with 30 min intervals upto a maximum dose of 220 mg. After target blood pressure was achieved, patients were put on an oral maintenance dose of the respective drug. Group B (n=50) received oral nifedipine 10 mg stat followed by 10 mg every 30 min till target BP was achieved upto a maximum dose of 80 mg. Mean SBPR (SBP reduction) after 30 mins of drug administration in Labetalol group was 6.04 ± 7.38 mm of Hg and in Nifedipine group was 4.32 ± 4.22 mm Hg of Hg. P value is 0.154 which is non significant. Mean DBPR (DBP reduction) after 30 mins of drug administration in Labetalol group was 6.88 ± 4.8 mm of Hg and in Nifedipine group was 5.12 ± 3.9 mm of Hg with a non significant P value of 0.469. Mean MAPR (MAP reduction) after 30 mins of drug administration in Labetalol group was 7.63 ± 6.0 mm of Hg and in Nifedipine group was 7.68 ± 6.02 mm of Hg with P value 0.969 which stands non significant. In the labetalol group 36% of patients achieved target blood pressure reading with 1 dose, 20% with 2 doses, 28% with 3 doses and 16% with 4 doses. Whereas, in nifedipine group 32% of patients achieved target blood pressure reading with 1 dose, 24% with 2 doses, 20% with 3 doses and 16% with 4 doses and 8% with 5 doses. P value was 0.29 which is non significant. One patient in the labetalol group failed to achieve target BP with the maximum allocated dose of 220 mg necessitating a cross over and was controlled by 2 doses of nifedipine. Mean time required to achieve target BP in

labetalol group was 67.2 ± 33.168 mins and nifedipine group was 73.2 ± 38.475 mins. P value was 0.405 which is non significant. **Conclusion:** Intravenous Labetalol and oral Nifedipine regimen are equally effective and well tolerated in acute control of the blood pressure in severe preeclampsia.

INTRODUCTION

Severe Pre-eclampsia is a Hypertensive disorder in pregnancy which is characterized by a systolic blood pressure of ≥ 160 mm of Hg and a diastolic blood pressure of ≥ 110 mm of Hg with or without proteinuria >300 mg in 24 hours urine.^[1]

Hypertensive disorders of pregnancy are common disorders contributing significantly to maternal and perinatal mortality and morbidity, It is responsible for 14% maternal deaths worldwide including India. Pre-eclampsia or superimposed on pre-existing hypertension presents the major risk for women causing maternal and fetal serious morbidity and mortality. Hypertensive disorders represents the most common medical complications of pregnancy with a reported incidence between 5-10%,^[1] and this hypertension which develops de-novo in pregnancy appears to be unique to human.^[2]

Severe hypertension in pregnancy accounts for most maternal risk of target organ damage, HELLP syndrome, DIC, hypertensive retinopathy, hypertensive encephalopathy and maternal deaths. The risk for the fetus includes perinatal death, intrauterine growth restriction, hypoxia and preterm delivery, the latter often iatrogenic due to concerns regarding maternal safety. Acute fetal compromise overall accounts for nearly 45% of urgent deliveries. There is general consensus that maternal and fetal risks are decreased by antihypertensive treatment that acutely lowers severely elevated BP.

The main goal of treatment is to safeguard the mother from the development of acute complications like cerebrovascular accidents, eclampsia, target organ damage and maternal mortality while delivering a healthy infant. There is a consensus that due to these risks the patient should be treated with anti-hypertensive agents as an inpatient.^[3]

The most commonly used hypertensive agents for hypertensive emergencies in pregnancy are Nifedipine, Labetalol and hydralazine. Nifedipine has the advantage of being cost effective, rapid onset of action, long duration of action and can be administered orally, however it is known to cause sudden maternal hypotension and fetal distress caused by placental hypoperfusion, palpitation and transient neuromuscular weakness when used concomitant with magnesium sulphate.^[4] Intravenous Labetalol is considered to control severe hypertension in pregnancy. Its advantages include little placental transfer, less palpitation and less maternal tachycardia, however neonatal hypotension and neonatal bradycardia has been observed in some trials and is not as cost effective as Nifedipine.^[4]

A meta analysis of randomized clinical trials using Hydralazine for the treatment of severe hypertension

in pregnancy concluded that the evidence does not support the use of these agents as first line drug when compared with Labetalol and Nifedipine.^[5] Hence, the aim of the present study is to compare the two most commonly used drug in India, i.e. oral Nifedipine and IV Labetalol in terms of efficacy, time required and doses required to achieve desired level of blood pressure in severe pre-eclampsia patient.

Aims and Objectives

To compare intravenous labetalol with oral nifedipine in the following aspects:

1. Efficacy in terms of rapidity in controlling hypertension.
2. Efficacy in terms of number of doses required and drug crossover

MATERIALS AND METHODS

Study Design: This study was a hospital based prospective randomized interventional comparative trial to compare the efficacy of intravenous labetalol and oral nifedipine in control of high blood pressure in patients with severe pre-eclampsia.

Place of Study: Department of Obstetrics and Gynecology, Midnapore Medical College and Hospital, Paschim Medinipur, West Bengal, India .

Period of Study: 18 months (1st April 2022 to 30th September 2023)

Study Population: Pregnant women reporting to department of obstetrics and gynecology in MMCH during the study period and fulfilling the eligibility criteria (according to inclusion and exclusion criteria) were recruited for this study after obtaining informed consent.

Sample Size: A total of 100 women fulfilling eligibility criteria according to inclusion and exclusion criteria.

Case Control Required or Not: not required.

Inclusion Criteria

1. Patient's age 19 years and above and below 35 years.
2. Gestational age of atleast 24 weeks.
3. Patients having symptoms like Headache, visual disturbances, nausea or epigastric pain.
4. SBP ≥ 160 mm of Hg and DBP ≥ 110 mm of Hg
5. Proteinuria of 300mg or more per 24 hours of urine collection or Urine dipstick reading 2+.
6. Any of the following:
 - a) Platelet count $<100,000/\mu\text{L}$.
 - b) Creatinine level $> 1.1\text{mg/dL}$
 - c) Serum AST or ALT twice the normal value.

Exclusion Criteria

1. Patient's age less than 18 years and more than 35 years.
2. Patients with cardiovascular disorders.
3. History of asthma, COPD.

4. Patients with uncontrolled diabetes.
5. Patients with thyroid disorder.
6. Chronic hypertension with history of other pre pregnancy antihypertensive medication intake.
7. Patients with liver diseases.
8. Patients allergic to labetalol or nifedipine.
9. Patients not consenting to participate in the study

Study Tools: Blood pressure monitoring, lab investigations like routine blood complete hemogram, renal and liver function tests, serum lactate dehydrogenase, serum uric acid, and urine examination. Other individual parameters like LMP, booked or unbooked to MMCH, whether referred from peripheral hospitals were taken into account, OPD ticket, OT/OPD register, bed head tickets, labour room log book records.

Data Collection And Interpretation:

After obtaining necessary clearance from the Institutional Ethics Committee and informed written consents from all the women who participated in the study, they were randomized equally into two groups: Group A (n=50) and Group B (n=50). A detailed history regarding antenatal care, past medical, surgical, family and obstetric history was taken.

A general, physical and systemic examination was done. Investigations included were urine protein, complete hemogram, renal and liver function tests, serum lactate dehydrogenase, serum uric acid, ultra sonogram for fetal growth and liquor and fundoscopy.

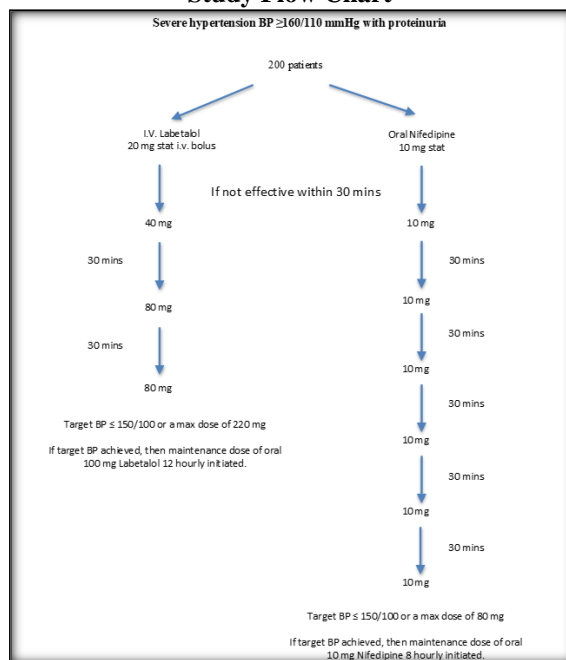
Group A patients were administered 20 mg labetalol intra venous stat; repeat 20–80 mg intra venous every 30 minutes to a maximum of 220 mg till target blood pressure is achieved (then switch to oral 100 mg 12th hourly). Group B patients received oral capsule nifedipine 10 mg stat followed by 10 mg every 30 minutes up to a maximum of 80 mg till the desired BP was achieved. Once the target BP was achieved, patients received a maintenance dose of nifedipine 10 mg sixth or eighth hourly.

The dosing regimens are in accordance with that of ACOG recommendations except that labetalol was given every 30 min in order to compare with that of nifedipine. All patients with imminent eclampsia received prophylactic dose and those with eclampsia received therapeutic dose of magnesium sulphate. Success was defined as a decrease in mean arterial blood pressure (MAP) by 25%. Uncontrolled hypertension was defined as failure to achieve target

blood pressure after the maximum dose. The point of BP control was taken as a systolic BP between 140-150 mmHg diastolic BP between 90-100 mm Hg in both the groups. Number of doses required to achieve target BP and time required to reduce the MAP by 25% was assessed.

Statistical Analysis: The statistical analysis were done for the collected raw data after it was coded, computed by using SPSS Inc. version 21. Data were presented as frequency and percentages (qualitative variables) and mean ± SD (quantitative continuous variables). Chi square was used for comparison of categorical variables. The difference was considered significant at P<0.05.

Study Flow Chart



RESULTS

A total of 100 patients were enrolled in this study from April,2022 to September,2023, these pregnant women with severe pre-eclampsia were divided into 2 groups.

Group A- (N=50) – received intravenous labetalol, Group B – (N=50) – received oral nifedipine.

Observation made had been summarized in the following tables:

Table 1: Age Wise Distribution.

AGES	GROUP		Total
	Group A N (%)	Group B N (%)	
<20	8 (16.0%)	12(24.0%)	20 (20.0%)
21-25	29 (58.0%)	23 (46.0%)	52 (52.0%)
26-30	10 (20.0%)	9 (18.0%)	19 (19.0%)
31-35	3(6.0%)	6(12.0%)	9(9.0%)
Total	50 (100.0%)	50 (100.0%)	100(100.0%)

Analysis of age in group A, showed a mean age of 23.28 years, whereas in group B it was 23.55 years. P value is 0.46 which is not significant.

Table 2: Gravid Index of the Study

GRAVID index	GROUP		Total
	Group A N (%)	Group B N (%)	
G1	30 (60.0%)	29 (58.0%)	59(59.0%)
G2	14 (28.0%)	15 (30.0%)	29 (29.0%)
G3	6 (12.0%)	6 (12.0%)	12(12.0%)
Total	50 (100.0%)	50 (100.0%)	100 (100.0%)

Table 3: Gestational Age in Weeks

GAW	GROUP		Total
	Group A N (%)	Group B N (%)	
28-32	5 (10.0%)	2(4.0%)	7 (7.0%)
32-36	5 (10.0%)	7 (14.0%)	12(12.0%)
36+	40 (80.0%)	41 (82.0%)	81 (81.0%)
Total	50(100.0%)	50(100.0%)	100(100.0%)

[Table 2 and 3] showed that the percentages of different gravidities and gestational ages of current pregnancy were nearly close in both groups with no significant differences. (p.0.05)

Table 4: Systolic, Diastolic and Mean Arterial Pressure Reading in mm of Hg at Admission

	Group A (mm Hg)	Group B (mm Hg)
SBP_0	161.60	160.00
DBP_0	111.92	108.96
MAP_0	130.90	129.78

The mean systolic blood pressure at admission was 161.60 mmHg in the Labetalol group and 160.00 mmHg in Nifedipine group. Mean diastolic blood pressure at admission was 111.92 mmHg in Labetalol group and 108.96 mmHg in Nifedipine group. The Mean MAP at admission in Labetalol group was 130.90 mmHg, and in Nifedipine group was 129.78 mmHg.

Table 5: Systolic, diastolic and mean arterial pressure reading after 30 min of drug administration

	Group A (mm Hg)	Group B (mm Hg)
SBP_30	155.32	155.68
DBP-30	101.04	104.08
MAP_30	122.05	121.59

The mean SBP after 30 mins of drug administration in Labetalol group was 155.32 mmHg and in the Nifedipine group was 155.68 mmHg with a P value 0.852 which stands non-significant.

The mean DBP after 30 mins of drug administration in Labetalol group was 101.04 mmHg and in the Nifedipine group was 104.08 mmHg. The calculated P value was 0.45 which is non significant.

The mean MAP after 30 mins of drug administration in Labetalol group was 122.05 mmHg and in the Nifedipine group was 121.59 mmHg with a non-significant P value of 0.796.

Table 6: Reduction in systolic, diastolic and mean arterial pressure after 30 mins of drug administration in mm of Hg

	Group A (mm Hg)	Group B (mm Hg)
SBPR_30	6.04	4.32
DBPR-30	6.88	5.12
MAPR_30	7.63	7.68

Mean SBPR (SBP reduction) after 30 mins of drug administration in Labetalol group was 6.04±7.38 mmHg and in Nifedipine group was 4.32±4.22 mmHg. P value is 0.154 which is non significant.

Mean DBPR (DBP reduction) after 30 mins of drug administration in Labetalol group was 6.88±4.8 mmHg and in Nifedipine group was 5.12±3.9 mmHg with a non significant P value of 0.469. Mean MAPR (MAP reduction) after 30 mins of drug administration in Labetalol group was 7.63±6.0 mmHg and in Nifedipine group was 7.68±6.02 mmHg with P value 0.969 which stands non significant.

Table 7: Number of Doses Required to Achieve Target Blood Pressure

		GROUP		Total
		Group A N (%)	Group B N (%)	
NOD	1	18 (36.0%)	16 (32.0%)	34 (34.0%)
	2	10 (20.0%)	12 (24.0%)	22(22.0%)
	3	14 (28.0%)	10 (20.0%)	24 (24.0%)
	4	8 (16.0%)	8 (16.0%)	16 (16.0%)
	5	0 (0.0%)	4 (8.0%)	4 (4.0%)
Total		50 (100.0%)	50 (100.0%)	100 (100.0%)

In the labetalol group 36% of patients achieved target blood pressure reading with 1 dose, 20% with 2 doses, 28% with 3 doses and 16% with 4 doses.

Whereas, in nifedipine group 32% of patients achieved target blood pressure reading with 1 dose 24% with 2 doses, 20% with 3 doses and 16% with 4 doses and 8% with 5 doses. P value is 0.29 which is non significant.

One patient in the labetalol group failed to achieve target BP with the maximum allocated dose of 220 mg necessitating a cross over and was controlled by 2 doses of nifedipine.

Table 8: Time Required to Achieve Target BP in Minutes

	Group	N	Mean	Std. Deviation	Std. Error Mean
TIME	Group A	50	67.200	33.168	4.690
	Group B	50	73.200	38.475	5.441

Mean time required to achieve target BP in labetalol group was 67.2±33.168 mins and nifedipine group was 73.2±38.475 mins. P value is 0.405 which is non-significant.

Table 9: Randomized Studies of Antihypertensive Drugs for Severe Hypertension in Pregnancy

Author	Sample size	Type of hypertension	Drugs used	Dosage schedule	Result
1.Vermillion et al. ^[10] (1999) South Carolina	n=50	Hypertensive emergencies of pregnancy	Oral nifedipine (n) vs. Intravenous labetalol (L)	N=10,20, 20,20,20 (mg) L=20,40,80, 80mg	Nifedipine controlled hypertension more rapidly than labetalol and is associated with a significant increase in urine output. Adverse effects were infrequent.
2.Scardo JA et al. ^[7] (1999) South Carolina	n=12	Preeclamptic hypertensive emergencies	Oral nifedipine (n) vs. Intravenous labetalol (L)	N(mg)10,20,20,20 L(mg) 20,40,80,80,80	There was a 43% increase in the cardiac index and a significant decrease in the systemic vascular resistance index after nifedipine administration but no significant effect in the labetalol group. The mean arterial pressure was significantly affected. An insignificant increase in heart rate with nifedipine and a significant decrease with labetalol were noted.
3.Aali BS et al. ^[11] (2002) Scandinavia	n=12 6	Severe preeclampsia	Sublingual nifedipine (N) vs. Intravenous hydralazine (H)	N(mg) 8mg H(mg) 5-10 mg	Both effective in control of BP. Nifedipine more effective in preventing further hypertensive crises. Fever drug administration required and increased urine output in nifedipine group. Nifedipine is cheap, easy to administer
4.Gracia PVD et al. ^[12] (2006) Europe	n=20 0	Severe hypertension in pregnancy	Intravenous labetalol (L) vs. Intravenous hydralazine (H)	L(mg) 20,40,80,80,80 H(mg) 5,5,5,5,5	Both effective in control of BP. palpitations and maternal tachycardia occurred more in the hydralazine group. Neonatal hypertension and bradycardia were significantly more frequent in the labetalol group.
5. Raheem et al. ^[6] 2011 Malaysia.	n=50	Hypertensive emergencies of Pregnancy	Oral nifedipine (N) vs. Intravenous labetalol(L)	N(mg) 10,10,10,10,10 (mg) L(mg) 20,40,80,80,80	Oral nifedipine and i.v. labetalol regimens are similarly effective in the acute control of severe hypertension in pregnancy.
6. Sathya Lakshmi B and Dasari P. ^[8] 2012 Puducherry, India.	n=10 0	Hypertensive urgencies and emergencies of pregnancy	Oral nifedipine (N) vs. Intravenous labetalol(L)	N(mg) 10,10,10, 10, 10(mg) L(mg) 20,40,80,80	Both oral nifedipine and i.v. labetalol are effective in the treatment of hypertensive crisis. i.v labetalol may have benefits because it is more effective in reducing the SBP, DBP and MAP to target levels with a lower number of doses.
Present study	n=1 00	Severe preeclampsia	Oral nifedipine (N) vs. Intravenous labetalol(L)	N(mg) 10,10, 10, 10, 10, 10, 10, 10(mg) L(mg) 20,40,80,80	Both oral nifedipine and i.v. labetalol equally effective in the rapid control of hypertension in severe preeclampsia

DISCUSSION

In the present study titled “A Comparative study on efficacy of intra venous Labetalol and oral nifedipine for management of hypertension in severe pre-eclampsia in a tertiary care hospital”, 100 patients were randomized using computer generated random tables with fifty patients in each group. The study was conducted to evaluate and compare the efficacy of intravenous labetalol and oral nifedipine in the treatment of hypertension in severe preeclampsia.

Group A (N=50) received intravenous Labetalol 20 mg i.v stat followed by incremental doses of 40,80 and 80 mg with 30 min intervals upto a maximum dose of 220 mg. After target blood pressure was achieved, patients were put on an oral maintenance dose of the respective drug. Group B (n=50) received oral nifedipine 10 mg stat followed by 10 mg every 30 min till target BP was achieved upto a maximum dose of 80 mg.

Analysis of age in group A, showed a mean age of 23.28 years, whereas in group B it was 23.55 years. P value is 0.46 which is not significant.

30 patients (60%) of Group A were Nulliparous and 29 patients (58%) of the Group B were nulliparous.

The mean systolic blood pressure at admission was 161.60 mm Hg in the Labetalol group and 160.00 mmHg in Nifedipine group. Mean diastolic blood pressure at admission was 111.92 mmHg in Labetalol group and 108.96 in Nifedipine group. The Mean MAP at admission at Labetalol group was 130.90 mmHg, and in Nifedipine group was 129.78 mmHg. The mean SBP after 30 mins of drug administration in Labetalol group was 155.32 mmHg and in the Nifedipine group was 155.68 mmHg with a P value 0.852 which stands non-significant. The mean DBP after 30 mins of drug administration in Labetalol group was 101.04 mmHg and in the Nifedipine group was 104.08 mmHg. The calculated P value is 0.45 which is non-significant. The mean MAP after 30 mins of drug administration in Labetalol group was 122.05 mmHg and in the Nifedipine group was 121.59 mmHg with a non-significant P value of 0.796.

Mean SBPR after 30 mins of drug administration in Labetalol group was 6.04 ± 7.38 mmHg and in Nifedipine group was 4.32 ± 4.22 mmHg with P value 0.154 which is non-significant. Mean DBPR after 30 mins of drug administration in Labetalol group was 6.88 ± 4.8 mmHg and in Nifedipine group was 5.12 ± 3.9 mmHg with a non-significant P value of 0.469. Mean MAPR after 30 mins of drug administration in Labetalol group was 7.63 ± 6.0 mmHg and in Nifedipine group was 7.68 ± 6.02 mmHg with P value 0.969 which stands non-significant.

In the labetalol group 36% of patients achieved target blood pressure reading with 1 dose, 20% with 2 doses, 28% with 3 doses and 16% with 4 doses. Whereas, in nifedipine group 32% of patients achieved target blood pressure reading with 1 dose

24% with 2 doses, 20% with 3 doses and 16% with 4 doses and 8% with 5 doses. P value was 0.29 which is non-significant. One patient in the labetalol group failed to achieve target BP with the maximum allocated dose of 220 mg necessitating a cross over and was controlled by 2 doses of nifedipine.

Mean time required to achieve target BP in labetalol group was 67.2 ± 33.168 mins and nifedipine group was 73.2 ± 38.475 mins. P value was 0.405 which is non-significant.

The mean systolic blood pressure at admission was 161.60 mm Hg in the Labetalol group and 160.00 mmHg in Nifedipine group. Mean diastolic blood pressure at admission was 111.92 mmHg in Labetalol group and 108.96 in Nifedipine group. The Mean MAP at admission at Labetalol group was 130.90 mmHg, and in Nifedipine group was 129.78 mmHg. While in the study of Raheem et al,^[6] the mean systolic BP was 175 (170-180) mm of Hg in Nifedipine group and 170 (165-180) mm of Hg in Labetalol group with ‘P value 0.25. Raheem et al,^[6] showed that the mean diastolic BP was 110 (110-116) mm of Hg in Nifedipine group and 108 (100-112) mm of Hg in Labetalol group with a P value of 0.012. The present study showed no significant difference between the labetalol and nifedipine groups with reduction in systolic, diastolic and MAP values after 30 minutes of drug administration. A study by Raheem et al.^[6] concluded that repeated measure analysis of variants for the first hour indicated that both SBP and DBP decreased significantly overtime and there was no significant difference in comparison of the Nifedipine and Labetalol groups. Scardo et al.^[7] had also the opinion that both Nifedipine and Labetalol had an equally significant effect on MAP and this effect was evident at 60 mins in post test analysis. Sathya Lakshmi B and Dasari P.^[8] summarised that Magnitude of fall in SBP, DBP and MAP was greater in Labetalol group compared to nifedipine group (P value < 0.05) in their study.

In our study, 18 patients in labetalol group and 16 patients in nifedipine group achieved target BP with a single dose of respective drug with a non-significant P value of 0.29. One patient in our labetalol group failed to achieve target BP with the maximum allocated dose of 220 mg necessitating a crossover after which BP was controlled with two more doses of nifedipine. Raheem et al.^[6] concluded in their study that target BP was achieved with one dose in 6 cases of nifedipine group and in 5 cases in the labetalol group with a non-significant p value. In their trial they also observed 5 cases of cross over in the nifedipine group and 6 cases in labetalol group. Sathya Lakshmi B and Dasari P.^[8] in their study concluded that 22 patients in Labetalol group and 7 Patients in Nifedipine group achieved target BP with a single dose with a significant P value of less than 0.002. One patient in their labetalol group did not achieve target BP with the maximum allocated dose and was treated with a Nitroglycerine Patch.

In our study, the average time required to achieve target Blood pressure in minutes was 67.2 ± 33.168 in

labetalol group and 73.2 ± 38.475 in nifedipine group with a non significant P value of 0.405. Raheem et al.^[6] found in their study that there was no significant difference between the groups with respects to time taken to achieve target BP. However, Sathya Lakshmi B and Dasari P.^[8] concluded that the time required to achieve target BP was significantly lower in the labetalol group as compared to the nifedipine group with a significant P value of 0.002.

The principal finding of study conducted by Vermillion et al.^[10] is that to achieve target blood pressure the oral nifedipine regimen is more rapidly effective and requires fewer drug doses as compared to IV labetalol regimen. However, our study showed similar rapidity in antihypertensive action and similar number of doses required to achieve blood pressure control. This difference can be explained by the drug regimen used in a study by Vermillion et al.^[10]. They used higher oral nifedipine dose (10mg stat followed by 20mg for further 4 doses) as compared to using a flat 10 mg dose throughout in our regimen.

Limitations of the Study

1. This was a single center study. As a study was performed in a tertiary care center, the findings cannot be projected to a general population. For that community based study to be done.
2. The sample size of this study was small. Hence, the result obtained cannot be applied to a larger population.
3. The study period was short (18 months only)
4. All patients were from rural area. Hence, patients from urban area were missed.

CONCLUSION

Pre-eclampsia is one of the most important cause of maternal and fetal morbidity and mortality. The need for appropriate management by regular ante-natal care, stratification of high risk groups, adequate control of blood pressure, prevention of eclampsia and its comorbidities should be taken into consideration. The present study concluded intravenous labetalol and oral nifedipine are equally efficacious for acute and rapid control of hypertension in severe pre eclampsia.

Labetalol is expensive, needs intravenous administration, has the advantage of use in an acute

setting of concurrent eclampsia and in delirious or comatose patients. However, the lack of availability and trained personnel for drug administration in low resource and peripheral settings works to its disadvantage.

Nifedipine on the other hand is cheap, easily available, orally administrable drug which makes it ideal for use even in low resource and peripheral settings, but not suitable in an acute setting of concurrent eclampsia or comatose patients.

REFERENCES

1. Cunningham FG, Leveno KJ, Bloom SL, Hauth JC, Rouse DJ, Spong CY. Pregnancy Hypertension. Text Book of Williams Obstetrics. 23rd Edition.2010 New York, McGraw Hill. 706-757 pp.
2. McCarthy FP, Kingdom JC, Kenny LC, et al. Placenta 2011; 32(6): 413-9.
3. Magee L A, Ornstein M P, Von Dadelszen P. Management of hypertension in pregnancy. BMJ; 1999;318 1332 – 1336.
4. Duley L, Henderson-Smart DJ: Drugs for treatment of very high blood pressure during pregnancy (Cochrane Review). Cochrane Database Syst Rev 2006, CD001449.
5. Magee LA, Cham C, Waterman EJ, et al. BMJ 2003; 327(7421): 955-60.
6. Raheem IA, Saaid R, Omar SZ, Tan PC. Br J Obstet Gynaecol 2012; 119: 78-85.
7. Scardo JA, Vermillion ST, Hogg BB, Newman RB: Hemodynamic effects of oral nifedipine in preeclamptic hypertensive emergencies. Am J Obstet Gynecol 1996, 175:336–340.
8. Sathya Lakshmi B, Dasari P. Oral nifedipine versus intravenous labetalol in hypertensive urgencies and emergencies of pregnancy: a randomized clinical trial. Obstetric Medicine. 2012 Dec;5(4):171-5.
9. ACOG.Diagnosis and management of pre eclampsia and eclampsia.ACOG practice bulletin 33. American college of obstetricians and gynaecologists.Obstet Gynecol 2002;99:159-67.
10. Vermillion ST, Scardo JA, Newsman RB, Chauhan SP. A Randomised double blind trial of oral nifedipine and intravenous labetalol in hypertensive emergencies of pregnancy. Am J Obstet Gynecol.1999; 181:858-61.
11. Aali BS, Nejad SS: Nifedipine or hydralazine as a first-line agent to control hypertension in severe preeclampsia. Acta Obstet Gynecol Scand 2002, 81:25–30.
12. Gracia PVD, Lasso M, Ruiz E. Severe hypertension in pregnancy: hydralazine or labetalol.A randomized clinical trial. Eur J Obstet Gynecol Reprod Biol. 2006 Sep- Oct;128(1-2):157-62.