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Original Research Article

Prospective observational study to evaluate the efficacy of labetalol versus nifedipine in the management of preeclampsia

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ABSTRACT

Background: Hypertensive disorders of pregnancy are the common medical disorders in pregnancy. It has effects both on expectant mother and fetus. Pre-eclampsia is a pregnancy specific multisystem disorder of unknown etiology, and accounts for 12-18% of maternal mortality. There is general consensus that maternal risk is decreased by antihypertensive treatment that lowers very high blood pressure. Objective of this study was to study the efficacy of oral labetalol versus oral Nifedipine in the management of preeclampsia in the antepartum and intrapartum period.

Methods: The present study was conducted in a tertiary care centre, Chennai from October 2013 to September 2014. It was a prospective observational study done in antenatal ward and labor ward. All antenatal women diagnosed to have pre-eclampsia, irrespective of gestation are included in this study.

Results: Age distribution of PIH patients and the maximum number of patients were 20-25 years of age. maximum patients of severe preeclampsia were primigravida. Both systolic and diastolic BP in the two groups (oral labetalol and oral Nifedipine groups) were not statistically significant as the p value is >0.005.

Conclusions: From this study, authors found that both oral labetalol and oral nifedipine are effective and well tolerated when used for rapid control of blood pressure in severe hypertension of pregnancy.

Keywords: Labetalol, Nifedipine, Preeclampsia

INTRODUCTION

Hypertensive disorders of pregnancy are the common medical disorders in pregnancy. It has effects both on expectant mother and fetus.¹⁻³ This impact due to hypertensive disorders in pregnancy on maternal and neonatal mortality and morbidity is very high in India and other developing countries.^{4,5} Pregnancy induced hypertension complicates about 10% of pregnancies. Preeclampsia is a pregnancy specific multisystem disorder of unknown etiology, and accounts for 12-18% of maternal mortality. The incidence of eclampsia greatly varies

between settings being higher in developing countries where it affects between 1/100 and 1/1700 deliveries while in industrialized/developed countries it affects about 1/2000 deliveries.⁶ Among the pregnancy complicating hypertensive disorders, pre-eclampsia and eclampsia are the major causes of maternal and perinatal morbidity and mortality.⁷

There is general consensus that maternal risk is decreased by antihypertensive treatment that lowers very high blood pressure. The control of acutely raised blood pressure has become central for women with severe hypertension,

particularly that of pre-eclampsia. The aim of treatment is to quickly bring about a smooth reduction in blood pressure to levels that are safe for both mother and baby.⁸ On the other hand the above therapy is both a medical and obstetric challenge.⁹ The objective of the study was to study the efficacy of oral Labetalol vs oral Nifedipine in the management of preeclampsia in the antepartum and intrapartum period.

METHODS

The present study was conducted in a tertiary care centre, Chennai. It was a prospective observational study done in antenatal ward and labor ward. The study was carried out over a period of 12 months from October 2013 to September 2014. All antenatal women diagnosed to have pre-eclampsia, irrespective of gestation are included in this study. Patient with k/c of bronchial asthma, diabetes, thyroid disorder and k/c of heart diseases are excluded from the study. Total of 150 antenatal patients, with 75 patients in each group.

- Group 1: Labetalol
- Group 2: Nifedipine were included in this study.

All pregnant women irrespective of gestation diagnosed as pre-eclampsia by clinical parameter are subjected to pharmacological therapy. A total of 150 antenatal patients who attended the antenatal clinic and labor ward of the department of obstetrics and gynecology, Government Kilpauk Medical College, were selected based on inclusion and exclusion criteria after obtaining their consent. All selected women were subjected to a detailed history comprising of age, parity, body weight and height, LMP, medical history, drug history, previous obstetric history, previous H/o pre-eclampsia. They were subjected to clinical examination and BP was recorded. Routine laboratory investigations were done. These patients were regularly followed up in the antenatal OP once in 4 weeks till 28 weeks then once in two weeks till their delivery and thorough clinical examination were done focusing their blood pressure and urine albumin. All details were entered.

Definitions used for the diagnosis of pre-eclampsia was according to International Society for the Study of Hypertension in Pregnancy (ISSHP), hypertension is defined as systolic blood pressure of >140 or diastolic blood pressure of >90 mmHg.

A rise in the systolic blood pressure of 30 mmHg or rise in the diastolic blood pressure of 15 mmHg at least 4 hours apart associated with proteinuria of at least 1+ or 1g/l on dipstick.

RESULTS

Table 1 shows the age distribution of PIH patients and the maximum number of patients were 20-25 years of age

followed by 26-30 years age group. Above analysis for age distribution in both groups found no significance.

Table 1: Comparison of age distribution of the two groups.

Age (years)	Oral labetalol		Oral nifedipine		P value
	No.	%	No.	%	
< 20	10	13.3%	8	10.7%	0.723
20-25	35	46.7%	42	56.0%	
26-30	20	26.7%	17	22.6%	
> 30	10	13.3%	8	10.7%	
Total	75	100%	75	100%	

Table 2: Gravida distribution of two groups.

Gravida	Oral labetalol		Oral nifedipine	
	No.	%	No.	%
1 st Gravida	48	64%	49	64%
2 nd Gravida	27	36%	26	36%
Total	75	100%	75	100%

Table 2 shows the gravida distribution of patients studied in each group; maximum patients of severe preeclampsia were primigravida.

Table 3: Comparison of gestational age between the groups.

GA	Oral labetalol		Oral nifedipine	
	No.	%	No.	%
Term	59	78.7%	62	82.7%
Preterm	10	21.3%	13	17.3%
Total	75	100%	75	100%

Table 3 shows the comparison of gestational age at presentation of the two groups. Most patients with preeclampsia belonged to term pregnancy. Severe preeclampsia condition often seen in late trimester of pregnancy.

Table 4: Comparison of mode of delivery between the groups.

Mode of delivery	Labetalol		Nifedipine	
	No.	%	No.	%
Vaginal delivery	26	34.7%	34	45.3%
LSCS	49	65.3%	41	54.7%
Total	75	100%	75	100%

Table 4 shows comparison of systolic and diastolic BP of the two groups. Both systolic and diastolic BP in the two groups (oral Labetalol and oral Nifedipine groups) were not statistically significant as the p value is >0.005.

Table 5 shows mode of delivery of the two groups. Vaginal delivery rate in the oral Labetalol group 34.7%

while in oral Nifedipine 45.3%. Caesareans section rate was 65.3% and 54.7% in the oral Labetalol and oral Nifedipine group respectively.

Table 5: Comparison of blood pressure between the groups.

Variables	Labetalol (n = 40) Mean±SD	Nifedipine (n = 40) Mean±SD	P value
Systolic BP in mmHg	176.05±12.87	171.75±12.45	0.133
Diastolic BP in mmHg	112.35±5.10	112.85±5.29	0.668

DISCUSSION

In this study the maximum number of patients were in the age group of 20-25 years followed by 26-30 years which is similar to study conducted by Raheem et al.¹⁰ In this study high incidence of preeclampsia was found in primigravida, which is similar to other studies conducted by Raheem et al which showed 36 out of 50 patients were primigravida.¹⁰ Other studies done by Shelter et al (58 out of 60 patients) and Swapan et al, (49 out of 100 patients) were primigravida respectively.^{6,7} Hence, severe preeclampsia condition often seen in late trimester of pregnancy.¹⁴⁻¹⁶ Mean systolic and diastolic BP in both groups in this study was found to be statistically insignificant.

In this study, more caesarean section (54.7%) compared to vaginal delivery in both groups. This finding is similar to the studies conducted by Raheem et al, Shekhar et al, and Swapan et al, the percentage of vaginal delivery and caesarean section in oral labetalol group was 48% and 52%, 66.6% and 33.3%, 54% and 46% while in oral Nifedipine 36% and 64%, 56.6% and 43.3%, 46% and 54% respectively. In contrast to this study the studies conducted by Gavit Y et al, and in Shekhar et al, caesarean section rates were low.

CONCLUSION

From this study, found that both oral Labetalol and oral Nifedipine are effective and well tolerated when used for rapid control of blood pressure in severe hypertension of pregnancy.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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