

Original Research

Evaluation of efficacy of Oral Labetalol and Oral Nifedipine in hypertensive disorders of pregnancy: A comparative study

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ABSTRACT:

Background: Hypertensive disorders are the most common medical disorders encountered during pregnancy and are responsible for 31% of the maternal deaths in India. Hence; the present study was undertaken for evaluation of efficacy of Oral Labetalol and Oral Nifedipine in hypertensive disorders of pregnancy. **Materials & methods:** A total of 60 patients were enrolled. Only those patients were enrolled which were prescribed with either Labetalol or Nifedipine were selected and included in the study. Preterm or term pregnant women with severe preeclampsia/ eclampsia and BP \geq 160/100 mm Hg were included in the study. Complete demographic and clinical details of all the patients were obtained. Patients were divided into 2 groups of 30 each. Group A patients were given oral labetalol and group B were given oral 10 mg Nifedipine. Maternal blood pressure was measured. Neonatal outcome was assessed. **Results:** Among the patients of group A, 15 patients were of primi gravida while 10 patients were of G2. Among the patients of group B, 16 patients were of primi gravida while 9 patients were of G2. Mean Prolongation in duration among subjects of group A and group B was 126.5 hours and 153.2 hours respectively. Among the patients of Nifedipine group, death occurred in 1 patient while among the patients of the labetalol group, death occurred in 2 patients. **Conclusion:** From the above results, the authors conclude that Oral Nifedipine was better in comparison to labetalol.

Key words: Oral Labetalol, Nifedipine

Received: 27 January 2018

Revised: 19 March 2018

Accepted: 27 March 2018

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This article may be cited as: Gupta AA, Goen A. Evaluation of efficacy of Oral Labetalol and Oral Nifedipine in hypertensive disorders of pregnancy: A comparative study. J Adv Med Dent Sci Res 2018;6(5):87-89.

INTRODUCTION

Hypertensive disorders are the most common medical disorders encountered during pregnancy and are responsible for 31% of the maternal deaths in India. The main causes of mortality are severe pre-eclampsia, hypertensive crisis, cerebrovascular accidents and HELLP (Haemolysis, Elevated Liver enzymes, Low Platelet count) syndrome. A retrospective analysis of maternal deaths due to hypertensive disorders at our own institute revealed hypertensive crisis as the main cause of mortality. There is still controversy regarding the initiation of antihypertensive therapy in mild and moderate hypertension as well as about the choice of antihypertensive therapy in hypertensive emergencies and urgencies. According to the American College of

Obstetricians and Gynecologists (ACOG) committee opinion (2011), acute onset, severe systolic (\geq 160 mmHg) or diastolic hypertension (\geq 110 mmHg) or both in pregnant or postpartum patients constitutes hypertensive emergency.³ National Institute for Health and Clinical Excellence guidelines from 2010 recommend the use of intravenous hydralazine, oral nifedipine and intravenous labetalol for the treatment of severe hypertension in pregnancy which is defined as a systolic blood pressure (SBP) \geq 160 mmHg and/or a diastolic blood pressure (DBP) \geq 110 mmHg.¹⁻⁴ Hence; the present study was undertaken for evaluation of efficacy of Oral Labetalol and Oral Nifedipine in hypertensive disorders of pregnancy: A comparative study

MATERIALS & METHODS

The present study was undertaken for evaluation of efficacy of Oral Labetalol and Oral Nifedipine in hypertensive disorders of pregnancy. A total of 60 patients were enrolled. Only those patients were enrolled which were prescribed with either Labetalol or Nifedipine were selected and included in the study. Preterm or term pregnant women with severe preeclampsia/ eclampsia and BP $\geq 160/100$ mm Hg were included in the study. Complete demographic and clinical details of all the patients were obtained. Patients were divided into 2 groups of 30 each. Group A patients were given oral labetalol and group B were given oral 10 mg Nifedipine. Maternal blood pressure was measured. Neonatal outcome was assessed. The

data was collected and entered into the patient proforma. SPSS software was used for assessment of level of significance.

RESULTS

Among the patients of group A, 15 patients were of primi gravida while 10 patients were of G2. Among the patients of group B, 16 patients were of primi gravida while 9 patients were of G2. Mean Prolongation in duration among subjects of group A and group B was 126.5 hours and 153.2 hours respectively. Among the patients of Nifedipine group, death occurred in 1 patient while among the patients of the labetalol group, death occurred in 2 patients.

Table 1: Distribution of patients

Gravida	Group A	Group B	P value
Primi	15	16	0.12
G2	10	9	
G3	3	2	
G4	2	3	

Table 2: Comparison of efficacy of labetalol and nifedipine

Drug name	Nifedipine (n=30)	Labetalol (n=30)
Mean Prolongation in duration (hours)	126.5	153.2
SD	23.8	43.8

Table 3: Neonatal outcome

Drug name	Nifedipine (n=30)	Labetalol (n=30)	p-value
Survived	29	28	0.177
Expired	1	2	

DISCUSSION

International guidelines define severe pregnancy hypertension as systolic blood pressure (sBP) ≥ 160 –170 mmHg and/or diastolic BP (dBP) ≥ 110 mmHg. Severe hypertension is the only modifiable end-organ complication of pre-eclampsia, the most dangerous of the hypertensive disorders of pregnancy (HDP). However, severe hypertension may occur in association with any of the HDP, and either antenatally, intrapartum or postpartum.^{4, 6} It is widely accepted that women with severe hypertension are at increased risk of stroke and, as such, must have their BP lowered. In the latest report from the Centre for Maternal and Child Enquiries (CMACE) in the UK (2006–08), failure to treat sustained severe hypertension was identified as the most common cause of substandard care of women with pre-eclampsia who die in the UK; 12 of the 18 women who died from pre-eclampsia suffered from severe hypertension-related intracerebral haemorrhage or cerebral infarction.^{6- 9} All international pregnancy hypertension guidelines recommend immediate treatment of severe pregnancy hypertension, a recommendation endorsed as ‘strong’ by the World Health Organization (WHO).⁶ While severe pregnancy hypertension is a ‘hypertensive urgency’ that requires treatment, it is appropriate to lower BP

over hours (and certainly within 24 hours) and this could be achieved with oral or parenteral antihypertensive therapy.^{6- 9} Hence; the present study was undertaken for evaluation of efficacy of Oral Labetalol and Oral Nifedipine in hypertensive disorders of pregnancy: A comparative study. In the present study, among the patients of group A, 15 patients were of primi gravida while 10 patients were of G2. Among the patients of group B, 16 patients were of primi gravida while 9 patients were of G2. Shi DD et al compared the efficacy and safety of oral nifedipine and intravenous labetalol for severe pre-eclampsia therapy. Eligible pregnant women with severe pre-eclampsia (n = 147) were allocated to receive either oral nifedipine or intravenous labetalol. The primary endpoint of the study was the time needed to achieve target blood pressure. Secondary outcomes were the time interval before a new hypertensive crisis following effective blood pressure control, number of doses and adverse effects. They found that the time taken to achieve effective blood pressure control was 35 vs. 42 min for oral nifedipine and intravenous labetalol, respectively (P = 0.37). Compared with labetalol group, no significant difference was observed regarding time interval and drug dosages in nifedipine arm. Moreover, no serious side effects on maternal or perinatal were observed in

either group. These findings suggested that both oral nifedipine and intravenous labetalol are effective for safely reducing blood pressure to target levels in patients with severe pre-eclampsia.¹¹

In the present study, mean Prolongation in duration among subjects of group A and group B was 126.5 hours and 153.2 hours respectively. Among the patients of Nifedipine group, death occurred in 1 patient while among the patients of the labetalol group, death occurred in 2 patients. Shekhar S et al compared the effectiveness of orally administered nifedipine and intravenously administered labetalol for acute blood pressure control in hypertensive emergency of pregnancy. Pregnant women with sustained increase in systolic blood pressure of 160 mm Hg or higher or diastolic blood pressure of 110 mm Hg or higher were randomized to receive nifedipine (10 mg tablet orally up to five doses) and intravenous placebo saline injection or intravenous labetalol injection in escalating doses of 20, 40, 80, 80, and 80 mg and a placebo tablet every 20 minutes until the target blood pressure of 150 mm Hg systolic and 100 mm Hg diastolic, or lower, was achieved. They enrolled 60 patients. The median time taken to achieve target blood pressure was 40 minutes (interquartile range, 20-60 minutes) compared with 60 minutes (interquartile range 40-85 minutes) for nifedipine and labetalol, respectively (P=.008). The median dose required was two (interquartile range 1-3) compared with three (interquartile range 2-4.25) for nifedipine and labetalol, respectively (P=.008). No serious adverse maternal or perinatal side effects were witnessed in either group. As administered in this trial, oral nifedipine lowered blood pressure more quickly than did intravenous labetalol during hypertensive emergency in pregnancy.¹²

CONCLUSION

From the above results, the author conclude that Oral Nifedipine was better in comparison to labetalol. However; further exploratory studies are recommended.

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