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Comparative Study of Oral Nifedipine and Intravenous Labetalol for Control of Blood Pressure in Severe Preeclampsia

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Abstract

Background-Hypertensive disorders complicates 5-10 % of all pregnancies and is the third common cause of maternal mortality and morbidity next to haemorrhage and infections.

Methods- This longitudinal interventional study was conducted in the department of Obstetrics and Gynaecology, P.B.M and Associated Group of Hospitals, attached to Sardar Patel Medical College, Bikaner from February 2017 to January 2018.

Results- The mean age of women in Group A was 24.16±4.40 while in Group B it was 24.60±4.92. Both drugs were approximately similar efficacious in reduction of blood pressure. Mean time duration to achieve desired blood pressure was less in group B than in group A and it was statistically significant. The significant difference was observed between mean doses given in both groups to control blood pressure.

Conclusion- The choice of antihypertensive agent in severe hypertension in pregnancy should depend on the clinician's experience, familiarity, drug availability and cost of the drugs. This study has shown that both Nifedipine and Labetalol fulfill the criteria required for an antihypertensive drug to treat severe hypertension in pregnancy with adequate efficacy and safety. Both the drugs are equally effective for the same.

Keywords: Hypertension, Pregnancy, Labetalol, Nifedipine.

Introduction

Hypertensive disorders of pregnancy including preeclampsia complicates about 10% of pregnancies worldwide[1]. The spectrum of hypertensive diseases that can complicate pregnancy are broad ranging from gestational hypertension, preeclampsia, chronic hypertension and chronic hypertension with superimposed preeclampsia. Preeclampsia is a multi system disorder defined as hypertension of 140/90 mmHg or more associated with significant proteinuria usually develops after 20 weeks of gestational. Sever preeclampsia is characterized by systolic blood pressure ≥ 160 mmHg and diastolic blood pressure ≥ 110 mmHg. The definitive treatment of preeclampsia is delivery but the immediate delivery is not recommended if the fetus is preterm. Early intervention in managing preeclampsia can significantly reduce the maternal and fetal complications.

The most commonly used antihypertensive agents for hypertensive emergencies in pregnancy are oral short acting Nifedipine, parental 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 distress caused by placental hypo perfusion, palpitation and transient neuromuscular weakness

when used concomitant with magnesium sulphate. 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 n some trials and is not as cost effective as Nifedipine.

In India, Nifedipine is the most commonly used antihypertensive for blood pressure control in severe hypertension because of its easy availability, rapid onset of action, cause of oral administration and satisfactory reduction in blood pressure. An interaction between Nifedipine and Magnesium Sulphate may be associated with profound muscle weakness and hypotension Nifedipine and Magnesium Sulphate both have tocolytic effect and can prolong the duration of labour. 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, safety profile and adverse effect of the drug and also to observe the fetomaternal outcomes[2,3].

Material and Methods

This longitudinal interventional study was conducted in the department of Obstetrics and Gynaecology, P.B.M and Associated Group of Hospitals, attached to Sardar Patel Medical College, Bikaner from February 2017 to January 2018. The aim was to enroll 100 hemodynamically stable pregnant patients at ≥20 weeks of gestation with severe hypertension ≥160/110 mmHg. Enrolled subjects was randomized into two groups A & B using computerized generated table to either oral Nifedipine or IV Labetalol. Exclusion criteria were patients with an essential hypertension, bronchial asthma, Hematological disorder, Cardiac disease, hemodynamically unstable patients and allergic to Labetalol or Nifedipine.

All the demographic data and an appropriate laboratory tests were done at the time of admission. Patients were randomized into either group 'A' (oral Nifedipine) or group 'B' (IV Labetalol) until target blood pressure ≤ 150/ 100 mmHg was achieved. The cross treatment was given if the initial treatment regimen is a failure. In group A Nifedipine 10 mg stat dose (not slow release) was given. It could be repeated in every 30 minutes until target BP was achieved with maximum doses of 50 mg. At the same time, slow release preparation twice daily could be commenced until desired BP is obtained in group B Labetalol injection 20 mg was given slow IV over a period of 2 minutes. An additional injections of 40 to 80 mg could be given at 20 minutes interval until a desired blood pressure was obtained. The maximum doses to be used was 220 mg.

During the study, the maternal blood pressure and heart rate was monitored every fifteen minute intervals till first 30 minutes after achieving the target blood pressure of ≤ 150/100 mmHg, thereafter, every 30 minutes for next two hours and after that every hourly.

The primary outcome of our study was the time interval required to achieve the desired blood pressure of ≤150/100 mmHg. secondary outcomes analyzed included number of drug doses administered, adverse maternal like eclampsia, oliguria, headache, hypotension, palpitation, dizziness, nausea and vomiting were noted. Perinatal outcome was analyzed by low APGAR score, presence of meconium, birth weight, signs of prematurity and admission to neonatal intensive care unit.

Observation

Table 1: Distribution Of Cases According To Age Group

Age in years	Group A (Nifedipine)	Group B (Labetalol)
Mean±SD	24.16±4.40	24.60±4.92

t = 0.471
p value= 0.628

The mean age of women in Group A was 24.16±4.40 while in Group B it was 24.60±4.92.Both the groups were statistically comparable in relation to age group (p value=0.628).

TABLE 2: Mean Arterial BP

Group	Before Treatment (Mean± SD)	After Treatment (Mean± SD)	Mean Difference (Mean± SD)
Group A (Nifedipine)	131.93±11.07	111.52±5.74	20.41±5.33
Group B (Labetalol)	134.20±9.59	112.63±6.07	21.57±3.52
t=1.28			
p-value=0.202			

MAP = [(DBP) x(2)+SBP)]/3

Above table shows that no significant difference was observed in mean arterial blood pressure in both groups (p-value=0.202). Both drugs were approximately similar efficacious in reduction of blood pressure.

TABLE 3: Distribution of cases according to total duration needed to control BP

Total Duration (in minutes)	Group A (Nifedipine)		Group B (Labetalol)	
	No	%	No	%
10	0	0	0	0
15	0	0	0	0
20	0	0	12	24
25	0	0	0	0
30	20	40	0	0
35	0	0	0	0
40	0	0	29	58
45	11	22	0	0
60	18	36	7	14
90	1	2	0	0
Not control	0	0	2	4
Total	50	100	50	100
Mean±Sd	45.30±14.69		37.92±12.54	
t =2.70				
P value= 0.008				

In group A 20 (40%) patients achieved desired BP in 30 minutes, 11 (22%) patients in 45 minutes, 18(36%) patients in 60 minutes and 1(2%) patient achieved desired BP in 90 minutes.

In group B 12 (24%) patients in 20 minutes and 29(58%) patients in 40 minutes achieved desired blood pressure. In 2 patients BP was not controlled with Labetalol.

Mean time duration to achieve desired blood pressure was less in group B than in group A and it was statistically significant (p value = 0.008).

TABLE 4: Distribution of cases according to total doses given to control BP

No. of Doses	Group A (Nifedipine)		Group B (Labetalol)	
	No	%	No	%
1	19	38	12	24
2	30	60	29	58
3	1	2	7	14
≥4	0	0	2	4
Total	50	100	50	100
Mean±SD	1.64±0.53		1.98±0.74	
t=2.64				
P value=0.01				

In group A 19 (38%) patients responded to single dose and 30(60%) patients needed 2 doses for control of BP. In

group B 12 (24%) patients needed single dose, 29 (58%) patients needed 2 doses and in 2(4%) patients BP was not controlled with maximum dose.

The significant difference was observed between mean doses given in both groups to control blood pressure (p =0.01).

TABLE 5: Distribution of cases according to treatment outcome

Treatment Outcome	Group A (Nifedipine)		Group B (Labetalol)	
	No	%	No	%
Failure	0	0	2	4
Success	50	100	48	96
Total	50	100	50	100
χ^2 =0.510				
P value= <0.475 (Non Significant)				

According to our study all patients in Group A and 48 (98%) patients in Group B achieved target BP ≤150/100 mmHg and the treatment outcome was considered successful. Two (4%) patients in Group B failed to achieve target BP after treatment. The outcome was considered as treatment failure. However it was not statistically significant between two groups (p value=0.475).

Discussion

Hypertension affects up to 10% of pregnant women worldwide. National high blood pressure education program working group (2000) recommended intimation of drug therapy in women with BP ≥160/105mmHg. Short acting oral Nifedipine, parenteral Labetalol and Hydralazine are the most commonly used drugs to control acute severe hypertension in pregnant women. This randomized clinical trial for the treatment of severe hypertension in pregnancy shows that short acting oral Nifedipine and IV Labetalol are safe and effective drugs. This finding collobrate earlier studies including Cochrane review on the efficacy of both drugs in hypertensive emergency in pregnancy[4].

The average time taken to achieve desired BP control in Nifedipine group was 45.30± 14.69 minutes in Nifedipine group and 37.92 ± 12.54 minutes in Labetalol group and this was statistically significant. (P value = 0.008). Similar results found in the study of Shobha Mukherjee (2015)[5] where mean time required to achieve the target BP was 43± 16.74 minutes for Nifedipine group and 38.67 ± 19.43 minutes for Labetalol group.

As far as number of repeat doses were concerned, the Nifedipine group required an average of 1.64 ± 0.53 doses as compared with Labetalol group which required an average of 1.98 ± 0.74 doses. In a study conducted by Sujit Das et al [6]average doses required for desired action were 1.12 ± 0.32 in Nifedipine group and 2.04 ± 1.37 Labetalol group. Another study conducted by Shobha Mukherjee[5] et al showed similar results where Nifedipine group required an average of 1.67± 0.61 doses and Labetalol required an average of 1.77 ± 0.63 doses.

Conclusion

The choice of antihypertensive agent in severe hypertension in pregnancy should depend on the clinician's experience, familiarity, drug availability and cost of the drugs. This study has shown that both Nifedipine and Labetalol fulfill the criteria required for an antihypertensive drug to treat severe hypertension in pregnancy with adequate efficacy and safety. Both the drugs are equally effective for the same.

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