TO COMPARE THE ORAL LABETALOL VERSUS NIFEDIPINE IN SEVERE HYPERTENSION IN PREGNANCY

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ABSTRACT

Background: Pregnancy related hypertension is one of the common medical disorders in pregnancy which affect the mortality and morbidity related to foetus and mother. There is no proper protocol for selection of drugs among nifedipine and labetalol for severe hypertension in pregnancy

Objective: To find out the number of doses of labetalol and nifedipine required to decrease the severe hypertension of pregnancy by 25%.

Method: 40 patients in each group with sever pregnancy hypertension of greater than 28 weeks of gestation were included in the study. Nifedipine of 30 mg, 30mg, 30mg, 30mg and 30mg (after 30 minutes) were given in first group gradually unless the target BP is achieved. Labetalol intravenous was preceded from 20mg, to 40mg, to 80mg and to 80mg were given with each half hour apart with BP monitoring and when the target BP was achieved no further doses were given. Any side effect was also noted.

Result: there was no significant difference in the baseline between the two groups. The 4 (10%) patients in nifedipine group and 16 (40%) patients in group L achieved the blood pressure goal with the first dose this was significantly higher patients in labetalol group ($p=0.04$). During second dose 8 (20%) patient in nifedipine group and 10 (25%) patients in labetalol group achieved the required blood pressure goal, this difference was not significant ($p=0.15$). With the third dose 13 (32.5%) patients in group N and 9 (22.5%) patients in group L achieved the blood pressure goal ($p=0.43$), with 4th dose 11 (27.5%) patient in N group and 5 (12.5%) patients in L group achieved blood pressure goal ($p=0.71$). increasing the dose to 5th one 4 (10%) group in N group and 0(0%) in L group achieved blood pressure.

Conclusion: Both the drug is effective in controlling the severe hypertension in pregnancy. Labetalol were rapid in while nifedipine took time for BP controlling. Further randomization studies are recommended to further strength these effects.

INTRODUCTION

Pregnancy related hypertension is one of the common medical disorder in pregnancy which effect the mortality and morbidity related to foetus and mother[1]. The worldwide complicated hypertension in pregnancy is from 7% to 10%[2]. The maternal mortality due to pregnancy related hypertension has been reported to be up to 30% of all maternal deaths[3]. Severe preeclampsia is one the pregnancy related hypertensive disease which is included in these.

The severe pregnancy related hypertension is consider, according to American college of obstetrics and Gynaecologists (ACOG), when the systolic blood pressure is equal to or greater than 160 mmHg and/or the diastolic blood pressure is equal to or greater than 110mmHg and is acute onset[4]. This usually occurs from the 20 weeks of gestation onward. The risk factors for such hypertension include familial history, maternal smoking, advancing age, pre-existing diabetes or hypertensions, anti phospholipid syndrome etc[5].

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The management of such hypertension is pregnancy is still a major challenge face by many gynaecologists and general physicians. The initiation of proper medical therapy and the choice of drug, for mild or moderate blood pressure in pregnancy is still a major problem. For severe hypertension in pregnancy the smooth and safely lowered of the BP is necessary for the sake of mother as well as for foetus. Recants studies have proposed the Hydralazine, Nifedipine and Labetalol for the treatment of severe hypertension in pregnancy[6]. Up to now the hydralazine was used as first choice for severe pregnancy hypertension, however a meta-analysis did not agree with this first choice of hydralazine[7] because of the risk of causing severe hypotension and other complication to mother and fetus. Another study did not showed any difference between nifedipine or labetalol with hydralazine.

The choice of drug by the clinician is depend upon the clinician experience, familiarity with drug and the cost of drug. Currently there is proper guideline to support the use of one or any metanalysis study.

This study will compare the effect of the labetalol with nifedipine in patient with hypertension in severe preeclampsia patients. The result of my study will be used for the superiority of one drug in the management of sever hypertension in pregnancy.

METHODOLOGY

This study was conducted in lady reading hospital from 1-3-2019 to 31-8-2019. All the patient with hypertension in severe preeclampsia presenting to the Gynae department for the management of this hypertension, with gestation age greater than 28 weeks up to the delivery, without end organ damage and singleton pregnancy on ultrasound were included in the study. Severe pregnancy induced hypertension was defined as when the patient has no past history of chronic hypertension presents with a systolic blood pressure of equal to or greater than 160 mmHg and/or the diastolic blood pressure is equal to or greater than 110mmHg and is acute onset[4]. Those entire patients with bronchial asthma, congestive heart failure, any type of heart block, previous ischemic heart diseases, chronic kidney failure congenital heart anomalies and those with diabetes were excluded from the study.

A total of 80 patients fulfilling the selection criteria were admitted for management of her hypertension. This was divided into two equal groups (40 in each) one group of Nifedipine (group N) and another group with Labetalol (Group L). Detail history and detail examination were done for proper selection. BP was check after one hour of admission to gynea unit. The BP reduction was not more than 25% of the baseline BPS. Group N patients received tablet Nifedipine 10mg orally and were repeated after every 30 minutes (no more than 50mg total) until the target blood pressure of 25% reduction in the mean arterial pressure at baseline. Group L patient received intravenous labetalol 20mg proceeding to 40mg after half hour and 80mg (not more than 220mg total dose) after every half hour. Once the BP was in controlled the patient was prescribed oral labetalol 100mg BD for control of BP when discharging.

The outcome was the number of doses which gain the 25% decrease in the baseline BP of patient. The patients BP, Pulse, any symptom of headache, nausea was recorded. Fetal heart rate was monitored. And any sided effect experiences by the patient were noted in the proforma.

RESULT

In our 80 patients with 40 in each group, mean age was 26.41±5.30 in group N and 25.31±4.18 in group L (p=0.093), average gestational age was 34 in group N and 35 in group L (p=0.748), the average systolic blood pressure was 172.3± 14.32 mmHg in N group and 173.01±10.69 in group L (p=0.235), mean diastolic blood pressure was 110±9.02 in group N and 112±8.13 in group L (p=0.430) and the mean arterial blood pressure was 130±7.61 mmHg in group N and 131±7.42 in group L (p=0.860). All these difference were not significant (Table 1).

The 4 (10%) patients in nifedipine group and 16 (40%) patients in group L achieved the blood pressure goal with the first dose this was significantly higher patients in labetalol group (p=0.04). During second dose 8 (20%) patient in nifedipine group and 10 (25%) patients in labetalol group achieved the required blood pressure

Table 1 Baseline Characteristics

	Nafidipin group	Labetalol group	P value
Age	26.41±5.30	25.31±4.18	0.093
Gestational age	34	35	0.748
SBP (mmHg)	172.3± 14.32	173.01± 10.69	0.235
DBP (mmHg)	110±9.02	112±8.13	0.430
MAP (mmHg)	130±7.61	131±7.42	0.860

Table 2 Comparison of the two groups

No of doses required	Nifedipine group (40)	Labetalol group (40)	P value
1	4 (10%)	16 (40%)	0.04
2	8 (20%)	10 (25%)	0.15
3	13 (32.5%)	9 (22.5%)	0.43
4	11 (27.5%)	5 (12.5%)	0.71
5	4 (10%)	0 (0%)	-
Adverse events			
Headache	0 (0%)	2 (5%)	1.03
Dizziness	0 (0%)	1 (2.5%)	
Mother tachycardia	2 (5%)	1 (2.5%)	
Fetal tachycardia	1 (2.5%)	2 (5%)	

goal, this difference was not significant (p=0.15). With the third dose 13 (32.5%) patients in group N and 9 (22.5%) patients in group L achieved the blood pressure goal (p=0.43), with 4th dose 11 (27.5%) patient in N group and 5 (12.5%) patients in L group achieved blood pressure goal (p=0.71), increasing the dose to 5th one 4 (10%) group in N group and 0(0%) in L group achieved blood pressure (Table 2).

With respected to adverse events headache was experience in 2 (5%) patients dizziness was in 1 (2.5%) patient, mother tachycardia in 1 (2.5%) patients and fetal tachycardia in 2 (5%) patients in labetalol group. In nifedipine group mother tachycardia was experience in 2 (5%) patient and fetal tachycardia in 2 (5%) patient. There was no significant difference in both groups (p =1.03) (Table 2).

DISCUSSION

The use of nifedipine and labetalol has been studied in a number of studies. In our study 80 patients with 40 in each group, mean age was 26.41±5.30 years in group Nifedipine and 25.31±4.18 years in group Labetalol (p=0.093) this result was similar to those obtained by Sathya et al. who showed the means age of presentation 23.4 ± 3.8 years in nifedipine group and 24.6 ± 3.3 years in labetalol group[8] there was no difference in both group in baselines in both groups also shown by Shekar et al.[9] and Stephen et al[10].

In our study both drugs showed reduction in BP, so both were effective. This result consistent with the previous studies[8,11-13] the number of doses indirectly shows the time taken by the drugs to decrease the BP, 30% of patients showed reduction in BP in nifedipine group with just 2 doses of 30mg and 30 mg 30 minutes apart and 65% of patients showed decrease in the BP with just 2 doses of labetalol of 20 mg and 40mg. in all patients the in labetalol group the require target BP was achieved in labetalol group before reaching to 5th dose of labetalol i.e. before 220mg dose. The reduction in Blood pressure in our study was more with the first dose in labetalol group as compared to nifedipine group, this is because of the rapid onset action of labetalol, our study result consistent with result of Sathya[8], however significant lowered number of dose of nifedipine for achieving the target goal of blood pressure was reported by metanalysis[14].

Some adverse event was experience by small amount of patient like tachycardia, headache nausea and vomiting, there was no significant difference in both these, and also the number of patient experiences these symptoms very low. So there is no significance difference in according both drugs or in other words in term of these symptoms both drugs are safe. This result is also shown in many other studies[8, 15, 16].

Limitation of the study includes the non-randomization of the patients, as this was just the comparison of the two medicines for pregnancy related severe hypertension. The adverse events are small and may be coincidence.

CONCLUSION

Both the drug is effective in controlling the severe hypertension in pregnancy. Labetolol were rapid in while nifedipine took time for BP controlling. Further randomization studies are recommended to further strength these effects.

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