

COMPARISON OF INTRAVENOUS LABETALOL AND ORAL NIFEDIPINE IN MANAGEMENT OF BLOOD PRESSURE IN PATIENTS WITH SEVERE PREGNANCY INDUCED HYPERTENSION

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ABSTRACT:

It is estimated that 6-12% of all the pregnancies are complicated by hypertension and even all improvements pre eclampsia is a significant reason of maternal and perinatal morbidity and mortality worldwide. Nifedipine, Labetalol and hydralazine are mostly being used in acute management of hypertension in pregnancy but so far there is no evidence that anyone drug is more effective.

OBJECTIVE: To compare the mean time to achieve blood pressure control of oral Nifedipine with intravenous Labetalol for management of severe pregnancy induced hypertension.

METHODOLOGY: This randomized control trial was done in Obstetrics and Gynaecology department of Hilal-e-Ahmer hospital, Faisalabad over a period of 6 months from 01-07-2016 to 31-12-2016. Total 100 patients (group-A and group-B having 50 in each) were included in study. In group A, females were given 40mg oral Nifedipine and in group, females were given 20ml intravenous Labetalol. Time at administration was followed in the ward for assessment of blood pressure control. Blood pressure was noted after every 10 min. The total donation time to achieve B.P was noted (as per operational definition).The collected data was analyzed by using SPSS version 17.0. Baseline blood pressure were presented in the form of mean \pm SD. Both groups were compared for mean time to achieve blood pressure control by applying t- test and consider significant at p value \leq 5%.

RESULTS: Patients were ranged between 20-40 years. Mean age of the patients was calculated as 26.98 \pm 4.54 and 27.36 \pm 4.43 years in group-A and B respectively. Gestational age shows that 64%(n=32) in Group-A 74%(37%) in Group-B were between 20-30 weeks of gestation while 36%(n=18) in Group-A were between 31-40 weeks of gestation mean \pm SD was calculated as 28.92 \pm 4.91 and 28.94 \pm 4.72 weeks in Group-A and B respectively. Mean time to achieve B.P control in group A was 31.24 \pm 5.62 and in group B 45.5 \pm 4.63 with p value <0.05.

CONCLUSION: Mean time to achieve blood pressure control was shorter with oral Nifedipine when compared to I/V Labetalol for management of female presenting with severe pregnancy induced hypertension.

KEYWORDS: Severe pregnancy induced hypertension, Nifedipine, Labetalol.

INTRODUCTION:

Severe pregnancy induced hypertension according to guideline is systolic blood pressure \geq 160 mmHg and/or diastolic blood pressure \geq 110 mmHg on two separate occasions 4 hours apart, after 20 weeks of pregnancy^[2]. Hypertensive conditions during pregnancy contribute greatly to maternal morbidity and

mortality around the world and in UK, despite improvement in recent years, severe PIH is a

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leading cause of direct maternal death, six in latest triennial report^[3]. The complications of uncontrolled high blood pressure during pregnancy affects multiple organ systems and can be detrimental to both mother and fetus like pre-eclampsia, eclampsia and stroke^[4]. Antihypertensive therapy should be for severe hypertension women's to low down for blood pressure^[5]. Recently mostly used drugs suggested from literature including Nifedipine & labetalol hydrochloride. Both Nifedipine & labetalol have demonstrated comparable efficacy & a lower risk of overshoot hypotension & fetal distress when compared with hydralazine in randomized controlled trials^[6]. The use of anti-hypertensive drugs in pregnancy is controversial^[7]. It has been expressed that antihypertensive treatment in pregnancy with labetalol may can possibly hinder fetal conduct in lower degree hypertensive malady of pregnancy when contrasted with Nifedipine. Prime attention must balance the possibly inconsistent risks and assistances to mother and fetus^[8]. Recent guidelines also listed hydralazine, Nifedipine and labetalol as first-line alternatives for reducing blood pressure in pregnancy induced hypertension^[9]. Pregnant women needed severe control on their blood pressure under case of severe pregnancy induced hypertension to avoid life threats like eclampsia, HELLP syndrome, shock etc. Oral Nifedipine is more effective for safely reducing the blood pressure to target levels compared with intravenous labetalol. Therefore oral Nifedipine can be an alternative to intravenous labetalol for lowering blood pressure during hypertensive emergencies in pregnancy. Oral may also be preferable because of its ease of oral administration, lower price and a smooth treating schedule.

Rationale of this is to identify a safe, easy to use and cost effective regimen to control hypertensive crises especially in developing countries like Pakistan. Results of this study may escort the concerned professionals towards a better management of PIH leading to prevention of associated morbidity and mortality.

METHODOLOGY:

This randomized control trial was conducted in department of obstetrics and gynaecology, Hilal-e-Ahmer hospital, Faisalabad over a period of 6 months from 01-07-2016 to 31-12-2016. Sample size of 100 cases, 50 in each group was calculated with 80 % power of test and 5% level of significance. Non-probability, consecutive sampling was used. Females of ages 20-40 years of parity <7 presenting with severe pregnancy induced hypertension (as per operational definition). Females having multiple gestation on ultra sonography and females with other systemic problems i.e. chronic or gestational diabetes (BSR > 140mg/dl), abnormal RFT, s (creatinine >1.2mg/dl), abnormal LFT.s (AST>40IU, ALT>40IU), cardiovascular disease (abnormal ECG and medical record) were excluded from study. Approval of hospital ethical committee was taken. One hundred patients who fulfill the selection criteria were enrolled in the study after taking informed consent. Their demographic data (name, age, gestational age, parity, baseline blood pressure) was recorded. The females were divided in two groups by using random number table. In group A, females were given 40mg oral Nifedipine and in group B, females were given 20ml intravenous labetalol. Time of administration of trial drugs noted. Then females were followed in the ward for assessment of blood pressure control. Blood pressure was noted after every 10 minutes. The total duration of time to achieve BP control was noted (as per operational definition). All the information was in the Pro forma (attached). SPSS 17.0 version was for data analysis. Quantitative variables like age, gestational age and total time to achieve control were presented as mean and standard deviation. Independent sample t-test was used to compare the mean time to achieve BP control in both groups. P value ≤ 0.05 was considered statistically significant.

RESULTS:

In this study 100 patients were included and further divided in two groups (50 in each group). There is 76%(n=38) patients lies in

Group-A and 74% (n=37) patients lies in Group-B between age group 20-30 years while 24% (n=12) patients lies in Group-A and 26% (n=13) patients lies in Group-B between age group 31-40 years. Mean±SD is 26.98±4.54 and 27.36±4.43 years in Group-A and B respectively (Table-I).

Parity distribution shows that 62% (n=31) in Group-A and 62% (n=31) in Group-B were between 1-3 Para while 38% (n=19) in Group-A

and 38% (n=19) in Group-B were between 4-6 Para; mean±SD was calculated as 3.26±1.55 and 3.3±1.63 paras in Group-A and B respectively (Table-II).

Independent sample t-test shows mean time to achieve BP control in both groups was recorded as 31.24±5.62 minutes in Group-A and 45.5±4.63 minutes in Group-B, it shows significant mean difference between both groups at p value 0.001 (Table -III).

Table-I: Comparison between two groups regarding age.

Age (in years)	Group-A (n=50)		Group-B (n=50)	
	No. of patients	%	No. of Patients	%
20-30	38	76	37	74
31-40	12	24	13	26
Total	50	100	50	100
Mean±SD	26.98±4.54		27.36±4.43	

Table-II: Comparison between two groups regarding parity.

Parity	Group-A (n=50)		Group-B (n=50)	
	No. of patients	%	No. of patients	%
1-3	31	62	31	62
4-6	19	38	19	38
Total	50	100	50	100

Table-III: Mean time to achieve bp control in both groups (n=100).

Mean time	Group-A		Group-B	
	Mean	SD	Mean	SD
	31.24	5.62	45.5	4.63
Mean±SD	3.26±1.55		3.3±1.63	

P-value=0.001

DISCUSSION:

Most of the authorities recommend labetalol, hydralazine and Nifedipine as first line alternative for the treatment of severe hypertension in pregnancy. Labetalol and Nifedipine have fast emerged as alternative drugs and can be judged in usage pattern of these drugs in the past decade. Nifedipine is a 2nd type calcium channel blocker that prevents inner movement of calcium across the L-type slow channel at cellular level. The capacity of Nifedipine to vasodilate the foundational and

pneumonic vasculature with full reversibility on halting the medication and its absence of tachyphylaxis has come about it, turning into a broadly utilized specialist in the treatment of intense and perpetual hypertension. Sibai et al^[11] compared pre-eclampsia between 26-36 weeks of gestation bed rest with oral Nifedipine in 200 women and find out significant reduction occurred in the diastolic and systolic blood pressures with Nifedipine, also reduce the numbers of severe hypertension deliveries. Current study demonstrated that mean time to achieve blood pressure control significantly

shorter with oral Nifedipine when compared with intravenous labetalol ($p < 0.05$). We compared our results with a randomized control trial where the study reported that time taken to achieve blood pressure control was 35 vs. 42 min for oral Nifedipine and intravenous labetalol respectively ($p = 0.37$)^[12]. Another pooled analysis of seven trials also showed that oral Nifedipine is as efficacious and safe as labetalol and may have less reported maternal side effects^[13]. S Shekhar *et al.*^[14] determined the efficacy and safety of oral Nifedipine for treatment of severe hypertension of pregnancy compared with intravenous labetalol and concluded with oral Nifedipine is as efficacious and safe as intravenous labetalol and may have an edge in low resource settings.

Going forward, the ability of Nifedipine need to be tested in multi-centers so that racial and ethnic differences may also be controlled. The other aspect need to be evaluated, is the preference of oral Nifedipine use in multiple gestation and patients with systemic disorders i.e. gestational diabetes, cardiovascular disorders.

CONCLUSION:

We concluded that the mean time to achieve blood pressure control was shorter with oral Nifedipine when compared to intravenous labetalol for the management of severe PIH.

CONFLICT OF INTEREST:

There is no declared conflict of interest.



ETHICAL REVIEW COMMITTEE:

Ethical review committee of the said institute has reviewed and approved this article.

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Value of a man depends upon his courage; his veracity depends upon his self-respect and his chastity depends upon his sense of honor.

Hazrat Ali (Karmulha Wajhay)