

COMPARISON OF EFFICACY OF INTRAVENOUS LABETALOL AND INTRAVENOUS HYDRALAZINE IN THE MANAGEMENT OF PREECLAMPSIA IN OBSTETRIC PATIENTS.

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Abstract

Objectives: To compare the efficacy of intravenous Labetalol and intravenous Hydralazine in the management of preeclampsia in obstetric patients.

Methodology: This comparative study was conducted at the Department of Obstetrics and Gynecology at Shaikh Zayed Women Hospital, Larkana during the period of January to June, 2023. The study involved a total of 301 pregnant women with severe pre-eclampsia (systolic pressure ≥ 160 mmHg and diastolic pressure ≥ 110 mmHg). A was given I/V Labetalol in Group A. Hydralazine was given I/V to Group B. The reduction in blood pressure and the number of dosages given were indicators of medication effectiveness. SPSS version 26 was used to analyze the data.

Results: Systolic blood pressure reduction in Labetalol group was significantly lower than in hydralazine group (105.5 ± 11.3 vs. 115.8 ± 17.1 , $p < 0.001$). Diastolic blood pressure reduction was also lower in labetalol group than in hydralazine group ($p = 0.03$). Number of dosage of drugs in Group A (Labetalol) was 3.2 ± 1.2 vs. Group B (Hydralazine) was 4.4 ± 1.4 , $p = 0.006$.

Conclusion: According to the study's findings, Labetalol is more effective than Hydralazine in lowering systolic and diastolic blood pressure as well as the number of doses needed to treat patients with severe preeclampsia.

Introduction:

Pre-eclampsia is a condition that affects pregnant women, usually in the second trimester, and if left untreated, progresses to eclampsia. One of the primary causes of maternal, foetal, and neonatal illness and mortality worldwide is pre-eclampsia in pregnant women¹. Pre-eclampsia occurs 3–8% frequently in wealthy nations and 1–21% frequently in underdeveloped nations². There are several different types of pre-eclampsia, including gestational hypertension, pre-eclampsia, chronic hypertension, and pre-eclampsia on top of chronic hypertension³. Three to five percent of all pregnancies are complicated by pre-eclampsia, which results in

placental and vascular dysfunction and poor consequences include severe hypertension, stroke, eclampsia, renal and hepatic damage, intrauterine foetal growth limitation, and even death⁴. Pregnancy-related progression from mild to severe hypertension is unpredictable and even sudden. Pregnancies with severe hypertension require hospital admission if the systolic and diastolic blood pressures are both greater than 160mmHg⁵. Labetalol (oral or intravenous), intravenous hydralazine hydrochloride, or oral nifedipine are available as first-line anti-hypertensive therapies in critical care settings for severe pregnancy-related hypertension. An arterial vasodilator, hydralazine hydrochloride

takes 20 to 30 minutes to start working and takes 30 to 60 minutes to reach its peak⁶.

Labetalol starts to work in 5–10 minutes and peaks in 5–15 minutes⁷. In contrast to other antihypertensive medications like intravenous (I/V) labetalol and nifedipine, intravenous hydralazine hydrochloride was found to have significant side effects, including maternal hypotension, a higher rate of Caesarean section, and irregular foetal heart rate⁸. In terms of acute blood pressure control, the trial found no differences between intravenous labetalol and oral hydralazine hydrochloride (5% in each group), but maternal hypotension was more common in hydralazine hydrochloride-treated women (2/100) than in labetalol-treated women (0/100)⁹. Since maternal hypotension and other side effects are less common with labetalol (non-selective alpha and beta blocker), it is preferred over hydralazine¹⁰.

Due to limited data from the local population, the debate is still ongoing in our setting. Hence, the aim of the current study was to compare the efficacy of Labetalol and Hydralazine for the treatment of hypertension in patients with preeclampsia. As most of the previous studies reported mean reduction in blood pressure in severe pre-eclampsia, we wanted to confirm if this is true for our population. Only a few studies focused on assessing the efficacy. This study will provide current & local magnitude of efficacy in comparison of labetalol and hydralazine which will help in making strategies to overcome the pregnancy related complications & morbidity.

Methodology:

This comparative study was conducted at the Department of Obstetrics and Gynecology at Shaikh Zayed Women Hospital, Larkana during the period of January to June, 2023. Total 302 pregnant women with 20–35 years of age, gestational age ≥ 20 weeks (determined by dating scan (9–13 weeks) having severe pre-eclampsia (systolic pressure ≥ 160 mmHg and diastolic pressure ≥ 110 mmHg), admitted and fulfilling the criteria were included in study via non-

probability consecutive sampling technique. Hypertension prior to pregnancy, women with renal disease, known allergy to hydralazine/labetalol, deranged LFT'S due to any other cause, were excluded from the study.

By using OPENEPI calculator, taking efficacy of labetalol 86.5%¹¹ and hydralazine 96.2%¹¹. Power of test 80%, level of significance 5%, then the estimated sample size was at least $n=151$ in each group and total sample size were at least $n=302$.

The eligible patients were randomly divided into two groups using lottery methods. Group A was given 20mg bolus dose of labetalol in 2 minutes, and blood pressure was checked after 20 minutes, if not effective, then 40mg dose of labetalol was given. If still no effect was seen, then 80 mg were given every 20 minutes up to a maximum dose of 300mg and every time blood pressure was checked after 20 minutes. Group B were given I/V hydralazine 5mg in blouse dose then were repeated every 20 minutes in needed up to five doses, maximum 25mg were given. Target Blood pressure was 130/90mmHg. Throughout this period vitals were taken. Fetal hearts were closely monitored. Time taken to reduce the blood pressure up to desired level was noted on predesigned proforma. Final outcomes were measured after six hours in terms of efficacy.

Results:

In this study the age range was 18–45 years. In Group A (Labetalol), the mean age (SD) was 27.3 ± 5.0 years and in Group B (Hydralazine), the mean age was 26.9 ± 5.4 years. The mean gestational age in Group A was 37.4 ± 2.3 weeks and in group, it was 37.0 ± 3.1 weeks. In group-A, booked patients were 144 (95.3%) and multigravida was 107 (71%) and in Group-B, booked patients were 143 (94.7%) and multigravida was 110 (59%). In Group A, 130 (86%) patients had no history of miscarriage, while in Group B, 127 (84%) patients had no history of miscarriage, as shown in Table #1.

Table#1: Demographic data of the patients

Characteristics	Group-A (n=151)	Group-B (n=151)
	n(%) / mean $\pm$ SD	n(%) / mean $\pm$ SD

Age (mean $\pm$ SD)	27.3 $\pm$ 5.0	26.9 $\pm$ 5.4
Gestational Age (mean $\pm$ SD)	37.4 $\pm$ 2.3	37.0 $\pm$ 3.1
Booking status		
• Booked	144(95.3%)	143 (94.7%)
• Un-booked	07 (4.6%)	08 (5.3%)
Obstetric characteristics		
• Primigravida	44 (29%)	41 (27%)
• Multigravida	107 (71%)	110 (59%)
Miscarriages		
• No miscarriage	130 (86%)	127 (84%)
• ≥ 1 miscarriage	21 (14%)	24 (16%)

Efficacy of Intravenous Labetalol Versus Hydralazine for Management of Preeclampsia was compared and Labetalol was found to be effective in 91 (60%) cases and Hydralazine was

found effective in 77 (51%), however, no significance difference was observed as p-value was 0.104, as shown in Table #2.

Table#2: Comparison of Efficacy of Intravenous Labetalol Versus Hydralazine for Management of Preeclampsia.

Intravenous Drugs Group	Efficacy		P-value
	Yes	No	
Labetalol (A)	91 (60%)	60 (40%)	0.104
Hydralazine (B)	77 (51%)	74 (49%)	

Mean, Standard deviation of Systolic blood pressure reduction in Group A (Labetalol) was 105.5 $\pm$ 11.3 vs. Group B (Hydralazine) was 115.8 $\pm$ 17.1, value of 'p' being 0.000 which is significant. Diastolic blood pressure reduction Mean, Standard deviation in Group A (Labetalol) was 69.5 $\pm$ 9.2 vs. Group B (Hydralazine) was 78.9 $\pm$ 11.2, value of 'p' being

0.000 which is statistically significantly high. Number of dosage of drugs in Group A (Labetalol) was 3.2 $\pm$ 1.2 (Mean, S.D) vs. Group B (Hydralazine) was 4.4 $\pm$ 1.4, the P value was more than 0.05 (P value 0.000) was significantly high, as shown in Table#3.

Table#3 Mean differences in Number of doses, systolic and diastolic Blood Pressure in both Pre-eclamptic pregnant women in both groups

Variables	Labetalol (A) (n=151)	Hydralazine (B) (n=151)	P-value
Systolic Pressure	105.5 $\pm$ 11.3	115.8 $\pm$ 17.1	0.000
Diastolic Pressure	69.5 $\pm$ 9.2	78.9 $\pm$ 11.2	0.000
Number of Doses	3.2 $\pm$ 1.2	4.4 $\pm$ 1.4	0.000

Discussion:

One of the main causes of maternal death in the postpartum period is pre-eclampsia. The effectiveness of hydralazine for the treatment of preeclampsia in comparison to labetalol was assessed in the current study. In patients with preeclampsia, we discovered that both medications were successful at lowering blood pressure; however, labetalol was more effective than hydralazine (p 0.000). Additionally,

compared to labetalol, hydralazine required considerably more dosages to manage blood pressure (P value 0.000). This shows that despite both medications' equivalent effectiveness, labetalol takes a smaller dosage to treat preeclampsia-related hypertension in pregnant individuals, which lowers the risk of peripartum or postpartum side effects. These results are consistent with earlier work. Labetalol and hydralazine were found to be equally effective for

treating severe hypertension in preeclampsia patients in research by Nombur¹². There were no statistically significant variations in systolic, diastolic, or mean blood pressure between the Hydralazine and Labetalol groups in a study of a similar nature by Delgado De Pasquale¹³.

In another study, the effectiveness and safety of intravenous hydralazine and labetalol for treating pregnancy-related hypertension were assessed¹⁴. Both labetalol and hydralazine were found to be efficient at lowering blood pressure in expectant women. Mothers' palpitations and tachycardia were the most typical hydralazine side effects. When compared to the hydralazine group, the labetalol group had much more pronounced neonatal bradycardia and hypotension. However, in our study, participants only reported minor headaches. The patients did not disclose any additional difficulties.

The best effective medications for treating hypertension during pregnancy were examined using network meta-analysis and trial sequential analysis in 2018¹⁵. 46 of the 51 studies analyzed for the systematic review were qualified for meta-analysis. It was determined that the efficacy and safety profiles of nifedipine, hydralazine, and labetalol in the treatment of hypertension in pregnancy were comparable. In contrast to the results described above, a prior study examining the effectiveness of hydralazine and labetalol for the treatment of severe hypertension in pregnancy found that these medications had respective efficacy rates of 96.2% and 86.5%¹⁶. This could be because of the different routes of administration of drugs or the different number of doses administered to patients. The patients with multiple comorbidities may have different experiences with these drugs. Vigil de Gracia reported that both labetalol and hydralazine were effective in controlling the blood pressure in women in the postpartum period as well¹⁴.

Both medications work well to treat severe pregnancy-related hypertension, but mild to moderate hypertension requires careful dose monitoring to prevent consequences for both the mother and the baby¹⁷. Another medication, nifedipine, is frequently prescribed to pregnant patients with severe preeclampsia who are experiencing hypertensive crises. Shi DD et al.¹⁸ found that oral nifedipine controlled blood

pressure in pregnant women more quickly than intravenous labetalol.

Despite the study's many strengths, there are some drawbacks. First, the patients were not monitored in order to document any long-term pharmacological negative effects. Second, the study only involved one centre. A more comprehensive investigation might shed light on several important socio-demographic and racial elements at work. There were no immediate problems found in the current investigation. To assess the long-term negative effects of these antihypertensive medications on pregnant women with preeclampsia, additional longitudinal studies need to be done.

Preeclampsia and pregnancy-induced hypertension are dangerous but treatable pregnancy problems that happen frequently in our environment. To reduce the risk of problems in pregnant or postpartum hypertensive women, adequate pharmaceutical intervention is required. Our research indicates that both labetalol and hydralazine have positive outcomes. Labetalol is thought to be more effective, nevertheless, because to its higher efficacy rate and lower dosage requirement.

Conclusion

According to the study's findings, Labetalol is more efficient than Hydralazine at lowering systolic and diastolic blood pressure as well as the number of dosages needed to treat preeclampsia patients.

CONFLICT OF INTEREST

None to declare

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None

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