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Original Article

The Efficacy of Oral Labetalol Versus Oral Methyldopa for the Management of Pregnancy-Induced Hypertension: A Quasi-Experimental Study

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ABSTRACT

Hypertensive disorders of pregnancy are a common complaint faced by obstetricians in routine clinical practice. Careful monitoring of both the mother and fetus is a crucial part of treatment. Numerous anti-hypertensive drugs are available in the market. **Objectives:** To compare the efficacy and safety of oral labetalol versus oral methyldopa in the management of pregnancy-induced hypertension during the third trimester. **Methods:** This quasi-experimental comparative study was carried out in the Department of Obstetrics and Gynecology, Avicenna Hospital, Lahore. Hundred females were enrolled and divided into two groups. Half of the females were prescribed labetalol (Group A), and half were prescribed methyldopa (Group B). After 5 days, the efficacy and safety of the drugs were noted. Data were analyzed in SPSS version 26.0. **Results:** The mean age of females was 28.62 ± 6.91 years in the labetalol group, while 29.86 ± 6.69 years in the methyldopa group. The mean SBP was reduced from 148.50 ± 4.43 mmHg to 122.00 ± 9.26 mmHg with labetalol and from 148.40 ± 4.99 mmHg to 127.50 ± 14.44 mmHg with methyldopa. Likewise, mean DBP was reduced from 98.10 ± 4.62 mmHg to 73.10 ± 12.37 mmHg with labetalol and from 98.20 ± 4.71 mmHg to 78.60 ± 11.56 mmHg with methyldopa. Target BP was achieved in 42 (84%) with labetalol, while in 30 (60%) females with methyldopa ($p<0.05$). Hypotension was noted in 4 (8%) females in the methyldopa group only ($p<0.05$). **Conclusion:** Labetalol has been proven to be more efficient in controlling blood pressure than methyldopa.

INTRODUCTION

One of the most fascinating and unresolved issues in obstetrics is hypertensive disorders during pregnancy. It is a significant contributor to morbidity and death among mothers and perinatal [1]. Hemorrhage, hypertensive disorders of pregnancy, and infection are the "lethal trifecta of pregnancy," according to the World Health Organization (WHO). These conditions considerably increase maternal mortality and morbidity and take the lives of at least one woman every seven minutes [2]. Up to 5%–10% of pregnancies globally are complicated by these. Recent global estimates indicate a rising trend in hypertensive disorders of pregnancy over recent decades, highlighting an increasing burden on maternal health worldwide [3, 4]. Hemorrhage, hypertensive disorders of pregnancy, and infection are the "lethal trifecta of pregnancy," according to the World Health Organization (WHO). These conditions considerably increase maternal mortality and morbidity and take the lives of at least one woman every seven minutes [5]. Close monitoring of the mother and fetus is part of treatment. If a pregnancy-safe antihypertensive medication is required, prescribe it. Optimal treatment includes keeping blood pressure between 110/70 and 140/85 mmHg, regularly screening for pre-eclampsia, and continuously monitoring fetal

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development and health [5]. Antihypertensive medication usage during pregnancy is debatable [6]. The sickness can be treated with several first- and second-line drugs. Labetalol lowers blood pressure by blocking both α and β adrenergic receptors. It effectively maintains uteroplacental blood flow [7]. By inhibiting α and β adrenergic receptors, labetalol lowers blood pressure (BP). Compared to other β-blockers, it can better maintain uteroplacental circulation. Compared to methyldopa, labetalol has a quicker onset of effect. Treatment for hypertension should be titrated to avoid abrupt drops in blood pressure and should not negatively impact the fetus [8, 9]. Methyldopa is one of the most popular medications for managing pregnancy-induced hypertension because it has long been shown to be safe during pregnancy. However, it takes about 4 to 6 hours to control blood pressure, and at high doses, it can cause excessive sedation and impaired mental focus [10]. A smaller study by Nahar *et al.* conducted in a different patient population also reported a favorable blood pressure response with labetalol compared with methyldopa [11].

But limited data have been reported earlier that labetalol is more effective than any other drug. But still, methyldopa is currently used in many clinical settings. Therefore, to confirm the above-stated evidence, this study aimed to compare the efficacy and safety of oral labetalol versus oral methyldopa in the management of pregnancy-induced hypertension during the third trimester.

METHODS

This quasi-experimental comparative study was carried out from November 2024 to April 2025 in the Department of Obstetrics and Gynecology, Avicenna Hospital, Lahore, after approval from the ethical review board (Ref No: IRB/Avic/Obs & Gynae/2024/113; dated 7th October 2024). The sample size of 100 females (50 in each group) was calculated using the WHO sample size calculator based on 90% power, 5% level of significance, and expected efficacy rates of 91.8% with labetalol and 62.9% with methyldopa, as reported in a previous study [6]. The formula used for comparison of two proportions was: $n = [(Z\alpha/2 + Z\beta)^2 \times \{p1(1-p1) + p2(1-p2)\}] / (p1-p2)^2$. However, the observed efficacy rates in the current study were 84% and 60%, respectively, yielding a smaller effect size (24% absolute difference) compared to the anticipated 28.9% difference. Consequently, the achieved power for detecting the observed difference was approximately 78%, which is below the conventional 80% threshold. This reduced power should be considered when interpreting the non-significant findings in subgroup analyses. The study may have been underpowered to detect smaller but clinically meaningful differences between the two treatment groups. All the females who fulfilled the following criteria were enrolled by using a non-probability, consecutive sampling technique. Pregnant females aged 18-40 years, presenting at gestational age >20 weeks with PIH, were enrolled. PIH was defined as the presence of BP ≥140/90 mmHg on two occasions at least 4 hours apart after 20 weeks of gestation (assessed on the last menstrual period date) [2]. Females already on anti-hypertensive medication for chronic hypertension, females with severe proteinuria or HELLP syndrome, or severe hypertension (BP≥160/110 mmHg), were not included in the study. Females with abnormal placenta, abruptio placenta, or notching in the umbilical artery on Doppler were also excluded. Informed consent was taken. Demographics like age, BMI, gestational age, parity, medical history, occupation, residence, life style of females were recorded. Then, the baseline blood pressure was recorded and participants were allocated to two treatment groups using a non-randomized approach.

In Group A, females were prescribed to take one 100 mg tablet of labetalol orally twice daily. In Group B, females were prescribed to take one 250 mg tablet of methyldopa orally thrice daily. All the females were followed up in the OPD and were asked to present after 5 days of initiation of treatment. Females were advised to monitor blood pressure at home on a daily basis, three times a day, and record the value. If the target blood pressure (<130/90 mmHg) was achieved, then efficacy was confirmed. If there was any episode of blood pressure <100/60 mmHg, then hypotension was also noted. All the data were recorded in a proforma. The patient flow diagram is shown in figure 1.

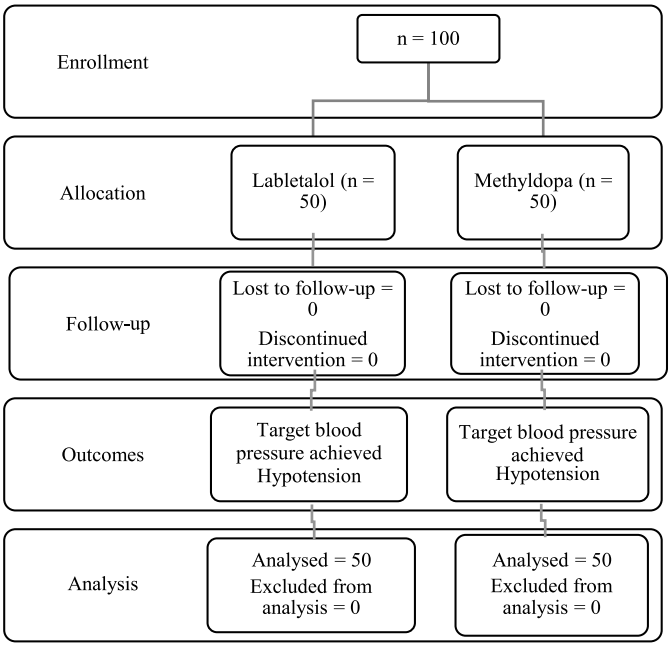


Figure 1: Patient Flow Diagram (n=100)

Data were entered and analyzed in SPSS version 26. Numeric variables (age, BMI, gestational age, and blood

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pressure) were presented as mean ± SD. Categorical variables (history, residence, occupation, lifestyle, target BP achieved, and hypotension) were presented as frequency and percentage. Both groups were compared for mean blood pressure using an independent samples t-test. Within-group comparisons (baseline vs. after 5 days of treatment) were performed using a paired t-test. The normality assumption was assessed using the Shapiro-Wilk test. For systolic blood pressure, the Shapiro-Wilk statistic was 0.974 (p=0.213) at baseline and 0.965 (p=0.089) at follow-up. For diastolic blood pressure, the Shapiro-Wilk statistic was 0.979 (p=0.341) at baseline and 0.961 (p=0.054) at follow-up. These results confirmed that the data did not significantly deviate from normality (p>0.05 for all comparisons), justifying the use of parametric tests.

RESULTS

In this study, a total of 100 pregnant females with pregnancy-induced hypertension were enrolled and divided them in two equal-sized groups of equal number. The mean age of females was 28.62 ± 6.91 years in the labetalol group, while 29.86 ± 6.69 years in the methyldopa group. The mean gestational age at presentation was 30.26 ± 3.63 weeks in the labetalol group and 30.00 ± 3.98 weeks in the methyldopa group. Females were age, gestational age, BMI, parity, and history matched to prevent bias. Mostly females had a sedentary lifestyle (>60%). Detailed baseline characteristics are shown in table 1.

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants in Both Groups (n=100)

Variables	Labetalol, n (%) / Mean ± SD	Methyldopa, n (%) / Mean ± SD
	(n=50)	
Age (years)	28.62 ± 6.91	29.86 ± 6.69
Gestational Age at Presentation, in Weeks	30.26 ± 3.63	30.00 ± 3.98
BMI, in kg/m^2	24.66 ± 5.01	23.54 ± 5.07
Parity		
Primigravida	17 (34%)	14 (28%)
Primiparous	10 (20%)	12 (42%)
Multiparous	23 (46%)	24 (48%)
History		
Diabetes	16 (32%)	22 (44%)
Anemia	25 (50%)	27 (54%)
Occupation		
Housewife	37 (74%)	44 (88%)
Working Lady	13 (26%)	6 (12%)
Residence		
Urban	25 (50%)	27 (54%)
Rural	25 (50%)	23 (46%)
Lifestyle		
Sedentary	29 (58%)	33 (66%)
Active	21 (42%)	17 (34%)

At baseline, the mean systolic blood pressure was 148.50 ± 4.43 mmHg in the labetalol group, which was reduced to 122.00 ± 9.26 mmHg after five days of treatment. Similarly, in the methyldopa group, the mean systolic blood pressure at baseline was 148.40 ± 4.99 mmHg, which was reduced to 127.50 ± 14.44 mmHg after five days of cure. The distinction in both groups was insignificant at baseline, showing a homogenous distribution of females in both groups. But after five days of cure, the difference in systolic pressure of blood was significant, and the labetalol group showed better reduction in systolic blood pressure (p<0.05). Likewise, at baseline, the mean diastolic pressure of blood was 98.10 ± 4.62 mmHg in the labetalol group, which was reduced to 73.10 ± 12.37 mmHg after five days of treatment. Similarly, in the methyldopa group, the mean diastolic blood pressure at baseline was 98.20 ± 4.71 mmHg, which was reduced to 78.60 ± 11.56 mmHg after five days of treatment. Difference in both groups was insignificant at baseline, showing a homogenous distribution of females in both groups. After 5 days of treatment, the reduction in both systolic and diastolic blood pressure was significantly greater in the labetalol group compared to the methyldopa group (p<0.05), as shown in table 2.

Table 2: Comparison of Mean Systolic and Diastolic Blood Pressure at Baseline and After 5 Days of Treatment in Both Groups

Variables	Labetalol, (n=50)	Methyldopa, (n=50)	p-value
	Mean ± SD		
Systolic Blood Pressure at Baseline	148.50 ± 4.43	148.40 ± 4.99	0.916[a]
Systolic Blood Pressure After 5 Days	122.00 ± 9.26	127.50 ± 14.44	0.026[a*]
Diastolic Blood Pressure at Baseline	98.10 ± 4.62	98.20 ± 4.71	0.915[a]
Diastolic Blood Pressure After 5 Days	73.10 ± 12.37	78.60 ± 11.56	0.024[a*]

[a]Independent samples t-test. *Indicates statistical significance at p ≤ 0.005

A significant reduction in systolic blood pressure over time was observed in both groups; however, the reduction was more pronounced in the labetalol group compared to the methyldopa group (Repeated measures ANOVA, p<0.001), as shown in figure 2.

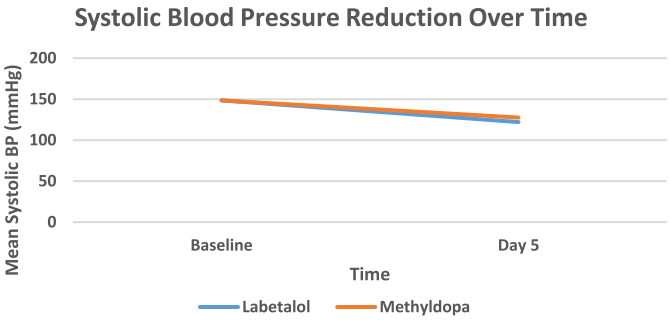


Figure 2: Trend of Reduction in Mean Systolic Blood Pressure Over 5 Days in Labetalol and Methyldopa Groups

After 5 days of treatment, the target blood pressure was achieved in 42 (84%) females in the labetalol group

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compared to 30 (60%) in the methyldopa group, showing a statistically significant difference (p<0.05). Hypotension was observed in 4 (8%) females in the methyldopa group, while no cases were reported in the labetalol group (p<0.05), as shown in table 3.

Table 3: Comparison of Treatment Efficacy (Target Blood Pressure Achieved) and Safety (Hypotension) Between Labetalol and Methyldopa Groups

Variables	Labetalol, n (%)	Methyldopa, n (%)	p-value
Target Blood Pressure Achieved	42 (84%)	30 (60%)	0.008*
Hypotension	0 (0%)	4 (8%)	0.041*

*Indicates statistical significance at p ≤ 0.005

The study split or stratified data for effect modifiers and observed that among females of the younger age group, the efficacy of labetalol was significantly better than methyldopa (89.3% vs. 63%, p<0.05). While in the older age group, the efficacy of labetalol was better, although the findings were insignificant (77.3% vs. 56.5%, p>0.05). In underweight, overweight, and obese females, labetalol showed better control in achieving target blood pressure than methyldopa, but the difference was insignificant (p>0.05). While among females with normal BMI, labetalol achieved target blood pressure in more than 90% females than methyldopa (28.6%, p<0.001). Among primigravida females, labetalol was effective in 88.2%, while methyldopa was effective in 64.3% cases (p>0.05). Among multigravida females, labetalol was effective in 81.8% while methyldopa was effective in 58.3% cases (p<0.05). Among females with a sedentary lifestyle, labetalol significantly affects blood pressure more than methyldopa (86.2% vs. 54.5%, p<0.05). But among females with an active lifestyle, efficacy was achieved in 81% females with labetalol and in 70.6% with methyldopa (p>0.05), as shown in table 4.

Table 4: Stratified Analysis of Efficacy (Target Blood Pressure Achieved) Across Different Effect Modifiers in Both Groups

Target Blood Pressure Achieved	Labetalol, n (%)	Methyldopa, n (%)	p-value
Age 18-29 Years	25 (89.3%)	17 (63%)	0.022*
Age 30-40 Years	17 (77.3%)	13 (56.5%)	0.140*
Underweight Females	6 (85.7%)	7 (58.3%)	0.216*
Normal	13 (92.9%)	4 (28.6%)	<0.001*
Overweight Or Obese	23 (79.3%)	19 (79.2%)	0.990*
Primigravida	15 (88.2%)	9 (64.3%)	0.112*
Multigravida	27 (81.8%)	21 (58.3%)	0.034*
Sedentary Lifestyle	25 (86.2%)	18 (54.5%)	0.007*
Active Lifestyle	17 (81%)	12 (70.6%)	0.455*

*Indicates statistical significance at p ≤ 0.05

DISCUSSION

In this study, we observed that with labetalol, the systolic blood pressure of females was reduced from 148.50 ± 4.43 mmHg to 122.00 ± 9.26 mmHg, with labetalol while with methyldopa, systolic blood pressure was reduced from 148.40 ± 4.99 mmHg to 127.50 ± 14.44 mmHg. Similarly, the mean diastolic pressure of blood was reduced from 98.10 ± 4.62 mmHg to 73.10 ± 12.37 mmHg with labetalol and from 98.20 ± 4.71 mmHg to 78.60 ± 11.56 mmHg with methyldopa. Thus, the target blood pressure was achieved in 42 (84%) with labetalol, while in 30 (60%) females with methyldopa (p<0.05). A study was conducted on 97 pregnant females with pregnancy-induced hypertension and compared the mean arterial pressure with labetalol versus methyldopa. Researchers observed that pressures were significantly better among females who received labetalol than methyldopa (92.85 ± 8.95 vs. 99.58 ± 7.73, p=0.005) [6]. Another study was conducted on 350 pregnant females and divided them into two groups. Half of the females received oral labetalol and half received methyldopa. Continuous blood pressure monitoring was done. In the labetalol group, 70.3% of ladies in the methyldopa group and 84.6% of females in the other group had their blood pressure under control (p<0.05). Labetalol is more effective than methyldopa for treating hypertension brought on by pregnancy [12]. Similarly, in a study, compared to methyldopa, labetalol was shown to be more effective and to have fewer adverse effects on both the mother and the fetus. The systolic and diastolic blood pressure of females treated with labetalol were 150 ± 9 mmHg and 100 ± 8 mmHg on the first day, respectively, and were regulated to 123 ± 9 mmHg and 79 ± 7 mmHg at the conclusion of therapy. On the first day, the methyldopa-treated group's systolic and diastolic blood pressure were 148 ± 8 mmHg and 102 ± 9 mmHg, respectively, but at the conclusion of the therapy, they had dropped to 125 ± 10 mmHg and 82 ± 6 mmHg. Additionally, labetalol was the preferred medication for pregnancy-induced hypertension and had superior antihypertensive activity with fewer adverse effects on the mother and fetus than the methyldopa-treated group [13]. A study was carried out in Rawalpindi and found that the labetalol and methyldopa groups had similar mean systolic and diastolic blood pressures (152.33 ± 6.53/100.33 ± 4.54 mmHg against 151.17 ± 5.83/99.50 ± 4.01 mmHg, respectively). The mean drop in systolic blood pressure was 15.50 ± 4.80 mmHg for the labetalol group and 7.33 ± 2.86 mmHg for the methyldopa group (p-value<0.0001). The mean drop in diastolic blood pressure was 13.17 ± 5.80 mmHg for the labetalol group and 5.50 ± 4.22 mmHg for the methyldopa group (p-value<0.001). Based on the results of this study, researchers also supported labetalol to be a more effective and safer drug in reducing blood pressure

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for females with Pregnancy-Induced Hypertension [14]. A comparative study of 120 women with pregnancy-induced hypertension reported a significantly greater reduction in mean arterial pressure among patients receiving labetalol compared with those receiving methyldopa. The labetalol group also required less time to achieve blood pressure control than the methyldopa group, supporting the greater short-term antihypertensive efficacy of labetalol [15]. Numerous studies have demonstrated the beneficial effects of labetalol in pregnancy-induced hypertension and validated its usage with minimal adverse effects on both the mother and the fetus. In this study, one complication (hypotension) was observed in 4 (8%) females with methyldopa, while no female in the labetalol group had any episode of hypotension ($p<0.05$). This also supports labetalol as a safe and effective drug of choice for pregnancy-induced hypertension in the third trimester. Treatments for pre-existing hypertension include methyldopa, labetalol, slow-release nifedipine, beta-blockers (apart from atenolol), and a diuretic [16-18]. Except for angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers, a woman may continue taking a medication if her blood pressure is properly managed before becoming pregnant [9, 18]. Methyldopa is advised as first-line treatment for women with persistent hypertension who are starting medication therapy again. Labetalol and nifedipine can be used as emergency treatments for preeclampsia. Because it inhibits vascular beta-1 receptors, labetalol, a non-selective beta-blocking medication, is frequently used during pregnancy [19, 20].

There are some limitations that can be raised in this study. As a quasi-experimental, single-center study, where the sampling was non-probability consecutive, the results might not represent the results in other environments and populations. Because treatment allocation was non-randomized, selection bias cannot be excluded, and the observed differences should not be interpreted as definitive evidence of a causal treatment effect. The 5-day follow-up allowed assessment of short-term blood pressure control but was insufficient to evaluate sustained efficacy or long-term maternal and fetal safety. No blinding was done, which could have also created observer or performance bias. Home-based blood pressure monitoring may have introduced measurement variability and reporting bias because readings were obtained outside direct clinical supervision. The fixed dosing regimens were not pharmacologically equipotent, and differences in dose intensity may have influenced the comparative blood pressure response. Therefore, the observed treatment difference should be interpreted cautiously. Moreover, other key outcomes, such as fetal results and biochemical parameters, were not measured, and the sample size, though adequate to measure major outcomes, could have been insufficient to measure adverse effects that are not common. These findings are suggested to be proven by additional multicenter randomized controlled trials that will have a longer follow-up. Future larger multicenter randomized trials using standardized dose-titration protocols and longer follow-up are needed to provide a more robust comparison of the two agents and to further determine their long-term maternal and fetal outcomes. Subgroup analyses were performed to explore potential effect modification by age, BMI, parity, and lifestyle. However, these analyses should be interpreted with caution due to the limited sample sizes in certain subgroups, particularly the underweight category (n=7 in labetalol group, n=12 in methyldopa group) and normal BMI category (n=14 in labetalol group, n=14 in methyldopa group). The small subgroup sizes reduced the statistical power for detecting differences and increased the likelihood of unstable estimates. These stratified analyses were considered exploratory rather than confirmatory. Future studies with larger sample sizes are needed to adequately assess the influence of these effect modifiers on treatment response. The primary conclusions of this study are based on the overall comparison of the two treatment groups, which had adequate statistical power.

CONCLUSIONS

Oral labetalol was associated with greater short-term reduction in blood pressure and a higher proportion of participants achieving target blood pressure than methyldopa over 5 days. Although hypotension was observed only in the methyldopa group, the short follow-up and limited safety assessment do not permit definitive conclusions regarding comparative safety.

Authors' Contribution

Conceptualization: IM
Methodology: IM, GW
Formal analysis: IM, SN
Writing and Drafting: IM, GW, SN, BS
Review and Editing: IM, GW, SN, BS

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflict of Interest

All the authors declare no conflict of interest.

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