Original Article

Comparison of Mean Arterial Pressure in Oral Labetalol versus Methyldopa in Pregnancy Induced Hypertension

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Abstract

Objective: To compare mean arterial pressure (MAP) on day 7 following oral labetalol versus methyldopa therapy in women with pregnancy-induced hypertension (PIH).

Methodology: This randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, Recep Tayyip Erdogan Hospital, Muzaffargarh, from 6 November 2023 to 6 May 2024. A total of 194 patients, equally divided into labetalol and methyldopa groups, who fulfilled the inclusion criteria were enrolled. Eligible participants were women aged 18–35 years with a gestational age of ≥20 weeks diagnosed with pregnancy-induced hypertension as per the operational definition and classified as American Society of Anesthesiologists (ASA) physical status I or II. After recording demographic information, patients were observed for the first 24 hours to achieve the target controlled blood pressure range. Mean arterial pressure was assessed on the 7th day after initiation of medication. Data analysis was performed using SPSS version 23.

Results: The mean age of women with PIH was 28.7 ± 4.2 years. The mean systolic blood pressure (SBP), diastolic blood pressure (DBP), and MAP on day 7 after treatment were 143.1 ± 3.6 mmHg, 87.4 ± 4.2 mmHg, and 105.9 ± 2.8 mmHg, respectively. Overall, mean diastolic blood pressure and MAP were lower in the labetalol group compared to the methyldopa group (86.3 ± 4.1 vs. 88.4 ± 3.9 mmHg, and 105.2 ± 2.8 vs. 106.7 ± 2.7 mmHg, respectively).

Conclusion: Labetalol was found to be more effective than methyldopa in achieving better blood pressure control during pregnancy.

Keywords: Labetalol, Methyldopa, Hypertension, Pregnancy-Induced.

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Introduction

Pregnancy-induced hypertension remains a major contributor to both maternal and fetal morbidity and mortality throughout the world.[1] It is measured as one of the three major life-threatening situations, along with hemorrhage and the infection. Worldwide, it is causative factor for estimated 7–10% of the perinatal deaths in industrialized nations, with the rising proportion around 20% in the developing nations.[1] PIH if goes untreated, risks the feto-maternal life with chronic hypertension, preterm delivery, fetal growth retardation, Antepartum hemorrhage, pre-eclampsia and eclampsia etc.[2] At the start of the pregnancy maternal blood pressure decreases due to relaxation of the vessel's musculature and with further progression in pregnancy gravid uterus becomes a cause. But this normal phenomenon can be altered rather reversed leading to higher blood pressures in pregnancy (PIH) with the presence of different risk factors like, chronic hypertension previous PIH history, increasing maternal age, multi parity, high BMI, chronic renal disease and Diabetes mellitus etc[3].

Perinatal mortality linked with mild hypertension in pregnancy is lower but in cases of moderate to severe PIH with proteinuria the rate of mortality is higher[4]. Although the definitive management of the pregnancy related hypertensive issues is the delivery of the fetus but as the prime goal remains the combined feto-maternal outcome, so different medicines like, nifedipine, methyldopa, atenolol, labetalol and

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metoprolol etc. are used to control the blood pressure and prolong duration of pregnancy.[5]

Methyldopa is a centrally acting drug, it is transformed to methyl norepinephrine to limit the adrenergic discharge by alpha-2 function from central nervous system, thereby leading to decrease in systemic vascular resistance and lowering the blood pressure. Newer studies show that Methyldopa is associated with reduced cerebral blood flow, increases prolactin release, impairs neuron function leading to postpartum depression[6]. Labetalol is generally well tolerated. It is a non-selective alpha and beta- adrenergic receptor antagonist, this blocking effect leads to lowering of heart rate, cardiac work strain and blood pressure. Due to its non-selective nature of blockade, it is used in pheochromocytoma and hypertensive emergencies[7].

A study on 180 patients, 90 patients in each group (Methyldopa/Labetalol) with mean age 24.41 and 24.85 years respectively, as per the parity status 58.89% and 54.44% females were primigravida respectively, their overall control is presented in terms of means of mean arterial pressure (MAP) for methyldopa group 98.15 ± 3.44 mm of Hg and 96.90 ± 2.70 mm of Hg for labetalol group at the end of 7th day.[8] Similarly, another study on 161 patients including multi and primigravida with no record of percentage in this aspect showed MAP was better in women who were treated with Labetalol as compared to Methyldopa 92.85±8.95 versus 99.58±7.73 at the end of 14th day respectively.[9] An acceptable agent in this regard must have characteristics like, early and sustained control, better tolerability in terms of maternal side effects and fetus friendly. For more clarification of this important topic, we designed to run the present study to evaluate the comparative efficacy of the oral labetalol and methyldopa in controlling pregnancy induced hypertension.

Methodology

The present study was a randomized controlled trial conducted at the Department of Obstetrics and Gynecology, Recep Tayyip Erdogan Hospital, Muzaffargarh. The study duration was six months, following approval of the synopsis, from 6 November 2023 to 6 May 2024.

Women aged 18–35 years with a gestational age of ≥20 weeks, singleton pregnancy, and newly diagnosed pregnancy-induced hypertension (PIH), classified as American Society of Anesthesiologists (ASA) physical status I or II, were included in the study. Women with a body mass index (BMI) ≥30 kg/m², parity ≥4, known diabetes mellitus or chronic hypertension (based on history and medical records), a history of cardiac or renal disease, or placental abnormalities (e.g., placenta previa) were excluded.

A sample size of 194 patients was calculated using the WHO sample size calculator. The mean MAP was 98.15 ± 3.44 mmHg for the methyldopa group and 96.90 ± 2.70 mmHg for the labetalol group. With a two-sided confidence interval of 95% and study power of 80%, the sample size was equally divided into 97 patients per group.

The study was conducted after obtaining ethical approval from the Institutional Ethical Review Committee (ERC) (Ref No. IHHN_IRB_2024_04_009). Prior to data collection, written informed consent was obtained from each participant, and strict confidentiality of participant information was maintained throughout the study.

Pregnancy-induced hypertension was defined as systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg on two occasions at least four hours apart in a previously normotensive pregnant woman after 20 weeks of gestation, with or without proteinuria.

After enrollment, patients were randomly allocated in equal numbers into two treatment groups using the lottery method with sealed opaque envelopes. Patients in Group A received oral labetalol at an initial dose of 100 mg twice daily, while patients in Group B received oral methyldopa at an initial dose of 250 mg three times daily. Dose adjustments were made according to blood pressure response and institutional protocol.

All women with PIH were closely monitored during the first 24 hours after initiation of antihypertensive therapy for blood pressure control and potential adverse drug effects. Participants were followed up regularly, and MAP was reassessed on the 7th day after starting antihypertensive treatment. All relevant data were recorded on a predesigned proforma.

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 23. Data normality was assessed using the Shapiro–Wilk test. Numerical variables were expressed as mean ±

standard deviation, while categorical variables were presented as frequencies and percentages. Mean arterial pressure between the two groups was compared. Effect modifiers such as age, gestational age, parity, obesity, and ASA status were controlled

through stratification, and post-stratification independent sample *t*-tests were applied. A *p*-value ≤0.05 was considered statistically significant.

Results

The mean age of the women with pregnancy induced hypertension was 28.7 ± 4.2 years and mean gestational age was 31.4 ± 2.3 weeks. There were 44.3% women were obese, 80.4% had with ASA-I status and 56.2% were multiparous. The mean gestational age was high in labetalol group compared to methyldopa group (31.8 ± 2.3 vs. 30.9 ± 2.2 weeks, p-value =0.011). The mean baseline measurements of blood pressures and MAP were 150.1 ± 4.2, 92.7 ± 4.3 and 111.8 ± 3.3 mm of Hg respectively. The mean systolic blood pressure was high in labetalol group compared to Methyldopa group (151.6 ± 4.0 vs. 148.7 ± 3.8 mm of Hg). Likewise, MAP was insignificantly higher in women of labetalol group compared to the methyldopa group (112.7 ± 3.3 versus 110.9 ± 2.9 mmHg), p= >0.05. Table I.

On the 7th day assessment, the mean SBP was lower in labetalol group compared to the methyldopa (128.9 ± 3.5 mmHg vs 143.3 ± 3.6 mmHg), p=0.001, and DBP was significantly lower in the labetalol group compared to the methyldopa group (81.3 ± 4.1 mmHg versus 88.4 ± 3.9 mmHg) p=0.001. Similarly, MAP on Day 7 was significantly reduced among women who received labetalol compared to those on methyldopa (102.2 ± 2.8 versus 108.7 ± 2.7 mmHg (p =0.001), indicating that both medications were effective in controlling systolic blood pressure, labetalol was superior in lowering diastolic blood pressure and mean arterial pressure after 7 days of treatment. Table II.

Based on stratification. in most subgroups the mean MAP was statistically significant, like women <30 years, gestational age 31–36 weeks, ASA I patients, both obese and non-obese women, and multiparous women (p ≤ 0.05), whereas no significant differences were observed in women ≥30 years, gestational age 22–30 weeks, ASA II patients, and nulliparous women (p > 0.05). Table III

Table III: Effect of Maternal age on post-treatment Mean arterial pressure in women with pregnancy induced hypertension. (n=194)

Effect modifiers	Labetalol Group	Methyldopa Group	p-value*
Age groups			
<30-year	104.7 ± 2.8	106.7 ± 2.7	0.001
≥30-year	105.7 ± 2.8	106.7 ± 2.7	0.059
Gestational age groups			
22 – 30 weeks	105.5 ± 2.6	106.5 ± 2.5	0.066
31 – 36 weeks	105.1 ± 2.9	106.9 ± 2.9	0.001
ASA status			
I	104.8 ± 2.9	106.7 ± 2.7	< 0.001
II	106.4 ± 2.1	106.7 ± 2.6	0.706
Obesity			
Yes	105.6 ± 2.8	107.3 ± 3.1	0.009
No	104.8 ± 2.8	106.3 ± 2.3	0.006
Parity			
Nulliparous	105.4 ± 2.8	106.5 ± 3.1	0.077
Multiparous	105.1 ± 2.8	106.9 ± 2.4	< 0.001

*Independent sample t-test

Discussion

Pregnancy-induced hypertension (PIH) is a life-threatening medical condition that is directly linked to maternal morbidity and mortality.[10] In addition to these immediate risks, PIH is also associated with the development of long-term chronic hypertension.[10] Several medications, including both first- and second-

Table I: Characteristics of women with pregnancy induced hypertension. (n=194)

Variables		All (n=194)	Labetalol Group (n=97)	Methyldopa Group (n=97)	p-value*
Age (years)		28.7 ± 4.2	28.8 ± 4.2	28.6 ± 4.3	0.736
Gestational Age (weeks)		31.4 ± 2.3	31.8 ± 2.3	30.9 ± 2.2	0.011
Obesity	Yes	86 (44.3)	44 (51.2)	42 (48.8)	0.773
	No	108 (55.7)	53 (49.1)	55 (50.9)	
ASA Status	I	156 (80.4)	75 (48.1)	81 (51.9)	0.278
	II	38 (19.6)	22 (57.9)	16 (42.1)	
Parity	Nulliparous	85 (43.8)	42 (49.4)	43 (50.6)	0.885
	multiparous	109 (56.2)	55 (50.5)	54 (49.5)	
Baseline measurements					
Systolic BP		150.1 ± 4.2	151.6 ± 4.0	150.7 ± 3.8	>0.05
Diastolic BBP		92.7 ± 4.3	92.3 ± 4.6	93.1 ± 3.9	>0.05
MAP		111.8 ± 3.3	112.7 ± 3.3	110.9 ± 2.9	>0.05

Table II: Post-treatment blood pressure measurements in women with PIH. (n=194)

Post-treatment Measurements (mm of HG)	All (n=194)	Labetalol Group (n=97)	Methyldopa Group (n=97)	p-value*
Systolic Blood Pressure	143.1 ± 3.6	128.9 ± 3.5	143.3 ± 3.6	0.001
Diastolic Blood Pressure	87.4 ± 4.2	81.3 ± 4.1	88.4 ± 3.9	0.001
Mean Arterial Pressure	105.9 ± 2.8	102.2 ± 2.8	108.7 ± 2.7	0.001

*Independent sample t-test

line agents, have been used for the treatment of this condition.

The present study compared mean arterial pressure (MAP) following oral administration of labetalol versus methyldopa among women with PIH. We found that oral labetalol was superior in reducing MAP by Day 7 compared to methyldopa (MAP = 102.2 ± 2.8 mmHg vs. 108.7 ± 2.7 mmHg; diastolic BP = 86.3 ± 4.1 mmHg vs. 88.4 ± 3.9 mmHg), consistent with a growing consensus in the obstetric hypertension literature that labetalol often provides more effective blood pressure control in this population.

These findings are strongly supported by Sultana et al.,[11] who compared labetalol and methyldopa among women with PIH and demonstrated that labetalol produced significantly greater reductions in both systolic and diastolic blood pressure (130.4/85.6 mmHg vs. 136.1/89.7 mmHg for methyldopa) and achieved target blood pressure more rapidly (3.6 ± 1.0 days vs. 4.8 ± 1.2 days, *p* = 0.0005). They also observed a more pronounced effect of labetalol on MAP, particularly in the early days of therapy.

Similarly, Arshad et al.[12] reported that labetalol resulted in a significantly greater reduction in systolic and diastolic blood pressure compared to methyldopa, with systolic BP decreasing from 143.5 ± 7.3 mmHg to 126.1 ± 5.49 mmHg and diastolic BP from 101.3 ± 3.9 mmHg to 87.4 ± 5.62 mmHg over 7 days. MAP in the labetalol group dropped from 115.23 ± 4.17 mmHg to 100.17 ± 4.43 mmHg, whereas in the methyldopa group, it decreased from 115.99 ± 4.38 mmHg to 103.27 ± 2.99 mmHg, with better maternal hemodynamic stability. These findings correspond closely with the post-treatment differences observed in our study (*p* = 0.001).

In alignment with our findings, Afroz et al.[13] reported that labetalol not only achieved faster blood pressure normalization but was also well tolerated, with no significant adverse maternal or fetal effects. Their results further support the clinical relevance of superior MAP control by labetalol, consistent with our subgroup analyses showing a consistent advantage across diverse maternal characteristics.

Similarly, Biswas and Biswas[14] observed that labetalol was associated with better maternal outcomes and a lower progression to severe hypertension compared to methyldopa, indicating that improved MAP reduction translates into meaningful clinical benefits beyond mere numerical changes. Comparatively, methyldopa, although historically recognized as a first-line agent due to its long-standing safety record, has demonstrated relatively weaker antihypertensive effects. For example, Nahar et al.[15] showed that while both drugs effectively lowered blood pressure, labetalol was superior in reducing diastolic BP and achieving hemodynamic stability with fewer dose adjustments.

This pattern likely reflects the pharmacologic differences between the drugs: the combined alpha- and beta-adrenergic blockade of labetalol produces more comprehensive vasodilation and heart rate modulation, whereas the central alpha-agonist action of methyldopa results in a less pronounced reduction in blood pressure, particularly in MAP. Supporting this pharmacologic rationale, Kumari et al.[16] compared labetalol with various antihypertensives and consistently observed its superiority in controlling MAP across different maternal risk profiles. Moreover, in agreement with the subgroup analyses of our study, they suggested that the hemodynamic effects of labetalol are relatively independent of demographic factors such as BMI or parity, reinforcing its utility as an effective option for managing PIH.

Demographically in this study the average age was almost similar between the labetalol and methyldopa groups (28.8 ± 4.2 versus 28.6 ± 4.3 years), without significant difference (p = 0.736), whereas the average gestational age was slightly higher in the labetalol group compared to the methyldopa group (31.8 ± 2.3 versus 30.9 ± 2.2 weeks respectively), (p = 0.011). The findings were comparable to findings by Pentareddy et al[17] where the mean age was 22.3 years in the methyldopa group and 23.2 years in the labetalol group, p=0.369. Additionally, almost equivalent findings were demonstrated in few other studies by Verma et al[18] and Qasim A et al.[19]

However, in aligns to our findings many other studies have also reported comparable findings, presenting that labetalol provides more effective and consistent control of MAP and produces better overall outcomes among patients with pregnancy-induced hypertension.[20-23] On viewing in the context of existing confirmation, the overall findings of the studies underscore the important clinical implications: successful reduction of MAP is important for decreasing the complications, and the reliable benefits observed across maternal characteristics indicate that labetalol offers reliable antihypertensive control irrespective of demographic characteristics, thereby improving its generalizability to various clinical populations. However, the such evidence

does not invalidate the methyldopa utility, specifically in contexts where labetalol may not be tolerated or contraindicated. Though, the trend across recent studies constantly favors labetalol for more effective and faster MAP decease, potentially reducing the risk of maternal adverse outcomes. However future larger randomized trials with prolonged and safety measure maternal and neonatal follow-up are recommended for further clarification whether such short-term advantages interpret into progressive perinatal outcomes.

Conclusion

The study concludes that labetalol is more effective than methyldopa in achieving better blood pressure control in women with pregnancy-induced hypertension. Due to its potent antihypertensive effect and the associated improvement in perinatal outcomes—particularly in a condition often accompanied by high fetal loss—labetalol is recommended for use in the management of PIH.

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