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Efficacy and Safety of Labetalol Versus Methyldopa for Blood Pressure Control in Pregnant Women With Hypertension

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Abstract

Hypertension in pregnancy is a major contributor to maternal morbidity and mortality worldwide. Labetalol and methyldopa are widely recommended as first-line antihypertensive therapy; however, uncertainty remains regarding comparative effectiveness for optimal blood pressure (BP) control. This Evidence-based case Report evaluates the efficacy and safety of these agents to inform therapeutic selection. A comprehensive literature search was conducted in PubMed, Cochrane Library, Google Scholar, and EBSCO using the keywords ("Hypertension" AND "Pregnancy" AND "Labetalol" AND "Methyldopa" AND "Blood Pressure Control"). Eligible studies included randomized controlled trials (RCTs) and systematic reviews/meta-analyses comparing labetalol and methyldopa in pregnant women with hypertension were included. Data extraction prioritized maternal BP outcomes, reporting effect sizes as relative risk (RR), absolute risk reduction (ARR), and number needed to treat (NNT) with 95% confidence intervals (CI). Quality assessment was performed using the Centre for Evidence-Based Medicine (CEBM) appraisal tool. From 355 studies screened, two RCTs met eligibility. Labetalol provided a faster reduction in blood pressure (RR 1.35; 95% CI 1.01–1.80; NNT ≈ 6), while overall blood pressure control was comparable to methyldopa in longer-term outcomes (RR 0.99; 95% CI 0.92–1.06).Both labetalol and methyldopa demonstrate comparable clinical effectiveness as first-line therapy for hypertension in pregnancy. Drug selection should be individualized based on clinical urgency, tolerance, availability, and monitoring capacity. Early treatment and close follow-up remain the primary determinants of maternal–fetal outcomes.

Keywords: Blood Pressure Control; Hypertension, Labetalol; Methyldopa; Pregnancy

1. INTRODUCTION

Hypertensive disorders represent one of the most consequential medical complications in pregnancy and remain a principal contributor to maternal and perinatal morbidity and mortality on a global scale (Countouris et al., 2025). Pregnancy-Induced Hypertension (PIH) is defined as new-onset systolic blood pressure

≥140 mmHg and/or diastolic blood pressure ≥90 mmHg after 20 weeks of gestation in previously normotensive women (Government of the Republic of Trinidad and Tobago, 2018). Although initially categorized as a non-severe spectrum of hypertensive disease, PIH possesses the potential to progress toward preeclampsia or eclampsia, culminating in serious adverse outcomes such as cerebrovascular accidents, multi-organ dysfunction, placental abruption, and maternal death (Jung et al., 2022). From a fetal perspective, compromised uteroplacental perfusion can precipitate intrauterine growth restriction, preterm birth, and increased perinatal mortality (Fishel et al., 2022).

The pathogenic mechanism underlying PIH involves abnormal remodeling of maternal spiral arteries, resulting in heightened vascular resistance, endothelial dysfunction, and altered placental oxygenation (Gathiram et al., 2016). Consequently, the primary objective of pharmacological intervention is to reduce maternal blood pressure while preserving adequate uteroplacental circulatory dynamics (Kattah et al., 2013). Excessive pharmacologic vasodilation may paradoxically impair fetal oxygen delivery; thus, therapeutic decisions must consider the potential trade-off between maternal hemodynamic stabilization and fetal well-being (Erez et al., 2021; Bone et al., 2018; Magee et al., 2016).

Labetalol, a combined α1-adrenergic and non-selective β-adrenergic receptor antagonist, offers antihypertensive action through decreased systemic vascular resistance with minimal impact on cardiac output (Vidt et al, 2026). Meanwhile, methyldopa, a centrally acting α2-adrenergic agonist, suppresses sympathetic drive but can be associated with delayed therapeutic response and central nervous system side effects such as sedation or fatigue (Bellomo et al., 2022). Although both agents are endorsed as first-line pharmacotherapeutic options for PIH within major international clinical guidelines, randomized controlled trials have yielded conflicting findings regarding their comparative effectiveness and safety (Mar et al., 2024; Hup et al., 2025; Sibai et al., 2025). Some studies suggest that labetalol provides more rapid blood pressure control, whereas others indicate no significant differences in preventing severe hypertension or adverse neonatal outcomes.

These discrepancies create uncertainty in clinical decision-making and underscore the need for an Evidence-Based Clinical Review (EBCR) to determine which medication should be prioritized in managing PIH. This issue is particularly relevant in real-world settings, as illustrated by the following case.

A 29-year-old pregnant woman, G2P1 at 32 weeks of gestation, presented with persistent headache, visual disturbances, and

elevated blood pressure readings over the past day. Her blood pressure was 152/98 mmHg on repeated measurement without proteinuria or laboratory abnormalities indicating severe features, and fetal assessment was reassuring. She had no history of chronic hypertension and was not on regular antihypertensive medication despite previously elevated readings. She was diagnosed with PIH without severe complications, prompting the clinician to choose between labetalol and methyldopa as first-line therapy. This scenario reflects a common clinical challenge and highlights the importance of selecting the most appropriate pharmacologic agent based on the best available evidence.

2. METHOD

This Evidence-Based Clinical Review (EBCR) was conducted in January 2025, based on a clinical scenario involving the management of hypertension during pregnancy, in which there was a clear clinical need to determine the most effective and safest first-line antihypertensive therapy. The study adopted an evidence-based case report design, incorporating the formulation of a clinical question, systematic search of the literature, critical appraisal, and synthesis of the best available evidence to support clinical decision-making. Since this review exclusively utilized secondary data extracted from previously published research that had already undergone ethical oversight, additional approval from local, regional, or national research ethics committees was not required. No patient-identifying information was collected during this review.

A comprehensive literature search was carried out using four electronic databases: PubMed, Cochrane Library, Google Scholar, and EBSCO. The search strategy employed both Medical Subject Headings (MeSH) and free-text keywords relevant to hypertensive disorders in pregnancy and antihypertensive therapy. Boolean operators were applied to combine search terms as follows: (“Hypertension in Pregnancy” OR “Gestational Hypertension” OR “Hypertensive Disorders of Pregnancy”) AND (“Labetalol” OR “Methyldopa”) AND (“Blood Pressure Control” OR “Maternal Outcomes” OR “Fetal Outcomes”). The search identified a total of 355 potentially relevant studies (PubMed = 203; Cochrane = 40; Google Scholar = 40; EBSCO = 72). Following the removal of 14 duplicate records, 341 articles were screened based on titles and abstracts using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline framework. A full-text review was conducted for 14 articles, of which two met the eligibility criteria and were ultimately included in this analysis.

Articles were considered eligible if they were randomized controlled trials (RCTs) or systematic reviews with or without meta-analysis; included pregnant women diagnosed with any form of

hypertension during pregnancy, including gestational hypertension and chronic hypertension requiring pharmacologic therapy during pregnancy; directly compared labetalol and methyldopa as monotherapy; and reported maternal blood pressure outcomes with or without fetal or neonatal endpoints. Studies were excluded if they lacked comparative data for the two medications, involved co-interventions without independent analysis, examined non-pregnant populations, or were published as abstracts only.

All included studies underwent rigorous critical appraisal using standardized instruments issued by the Centre for Evidence-Based Medicine (CEBM), University of Oxford. Each study was assessed for internal validity, risk of bias, applicability to the clinical scenario, and clinical relevance of findings. Data extraction focused on maternal blood pressure regulation, progression of hypertensive severity, treatment tolerability, and neonatal outcomes. Statistical interpretation emphasized clinically meaningful effect measures rather than sole reliance on hypothesis-testing p-values. Extracted quantitative metrics included Relative Risk (RR), Absolute Risk Reduction (ARR), Absolute Risk Increase (ARI), Relative Risk Reduction (RRR), Relative Risk Increase (RRI), Number Needed to Treat (NNT), and Number Needed to Harm (NNH), each presented with 95% Confidence Intervals (CI) whenever reported or estimable. All abbreviations and statistical parameters used in this review are fully defined within the manuscript.

Data synthesis, effect size calculations, and tabulation were performed using Microsoft Excel 365 (Microsoft Corporation, Redmond, Washington, USA). The methodological approach adhered to established international standards for critically appraised topics to ensure robust, transparent, and evidence-driven conclusions that directly inform clinical practice in the management of hypertension during pregnancy

3. RESULTS

Table 1 summarizes the literature search process conducted across four major scientific databases, including PubMed, Google Scholar, Cochrane Library, and EBSCO. Each database was searched using a combination of keywords related to pregnancy-induced hypertension and antihypertensive agents (labetalol and methyldopa). The searches yielded 203 records from PubMed, 220 from Google Scholar, 40 from Cochrane Library, and 72 from EBSCO. After reviewing the retrieved records, only one relevant randomized controlled trial (RCT) was included from PubMed and one from EBSCO, while no eligible studies were obtained from Google Scholar and Cochrane Library.

The study identification and screening process is illustrated in the PRISMA flowchart at figure 1. A total of 355 records were initially identified from database searching,

followed by the removal of 14 duplicate entries, leaving 341 studies for preliminary evaluation. Based on title and abstract screening, 150 records were selected for further assessment, whereas 136 were excluded for not meeting the relevance criteria.

14 full-text articles were evaluated for eligibility. However, 12 studies were excluded because they had a lower level of evidence (n = 7), contained inappropriate comparisons (n = 3), involved redundant data (n = 3), or reported outcomes that were not aligned with the research focus (n = 2). Ultimately, two RCTs met the inclusion criteria and were incorporated into this Evidence-Based Clinical Review.

The characteristics of the included RCTs are summarized in Table 2. Two randomized controlled trials involving a total of 411 pregnant women with hypertension (gestational hypertension or pregnancy-induced hypertension) were included in this review. Both studies compared labetalol versus methyldopa as first-line oral antihypertensive therapy, focusing on maternal blood pressure control as the primary outcome. Afroz et al. (2024) demonstrated that labetalol achieved a faster reduction in blood pressure and a higher proportion of patients reaching the therapeutic BP target (RR 1.35; 95% CI 1.01–1.80; NNT ≈ 6), indicating an initial clinical advantage over methyldopa11. In contrast, Sharif et al. (2016) reported no significant difference between the two agents in terms of successful antihypertensive response or prevention of disease progression (RR 0.99; 95% CI 0.92–1.06), supporting therapeutic equivalence in long-term BP control12.

Table 3 presents the critical appraisal of the two included randomized controlled trials using the Oxford Centre for Evidence-Based Medicine (CEBM) appraisal tool, assessing both internal validity and clinical importance.

Both studies were categorized as Level 1b evidence, indicating high-quality individual RCTs. Regarding internal validity criteria, Sharif et al. (2016) demonstrated stronger methodological robustness, including adequate randomization, good baseline similarity, and equal treatment between study groups. In contrast, Afroz et al. (2024) showed unclear randomization methods and did not implement blinding, which may increase the risk of potential bias, although participant characteristics and treatment allocation remained comparable.

From a clinical impact perspective, Afroz et al. (2024) reported a relative risk (RR) of 1.35, with an absolute risk reduction (ARR) of 20% and a number needed to treat (NNT) of 6, indicating a potentially meaningful clinical benefit of the intervention. Meanwhile, Sharif et al. (2016) yielded an RR of 0.99 with an NNT of 81, and confidence intervals crossing unity (95% CI: 0.92–1.06), reflecting no statistically

significant difference between labetalol and methyldopa.

Abbreviations

ARR : Absolute Risk Reduction

BP : Blood Pressure

CI : Confidence Interval

CEBM : Centre for Evidence-Based Medicine

CER : Control Event Rate

EER : Experimental Event Rate

HDP : Hypertensive Disorders of Pregnancy

HTN : Hypertension

MAP : Mean Arterial Pressure

MeSH : Medical Subject Headings

NNH : Number Needed to Harm

NNT : Number Needed to Treat

PIH : Pregnancy-Induced Hypertension

PRISMA : Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RCT : Randomized Controlled Trial

RR : Relative Risk

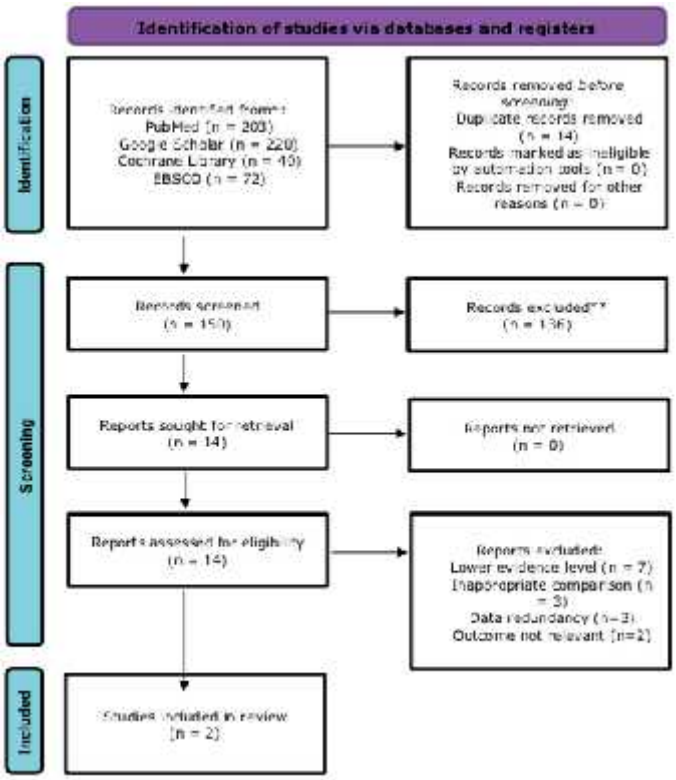
RRR : Relative Risk Reduction

SR/MA : Systematic Review / Meta-Analysis

Tabel 1. Summary of the included randomized controlled trials.

Database	Keyword	Hits	Selected literature
PubMed	("Pregnancy-Induced Hypertension"[Mesh] OR "Gestational Hypertension" OR "Preeclampsia" OR "Pregnancy Hypertension") AND ("Labetalol"[Mesh] OR labetalol) AND ("Methyldopa"[Mesh] OR methyldopa) AND ("Blood Pressure"[Mesh] OR "Blood Pressure Control")	203	1
Google Scholar	“Labetalol” AND “Methyldopa” AND “Pregnancy Hypertension” AND “Blood Pressure Control”	40	-
Cochrane Library	("Pregnancy" OR "Pregnant Women" OR "Gestational Hypertension" OR "Preeclampsia") AND ("Labetalol") AND ("Methyldopa") AND ("Blood Pressure" OR "Pregnancy Outcomes")	40	-
EBSCO	("Pregnancy-Induced Hypertension" OR "Gestational Hypertension" OR "Preeclampsia" OR "Pregnancy Hypertension") AND ("Labetalol" OR labetalol) AND ("Methyldopa" OR methyldopa) AND ("Blood Pressure"OR "Blood Pressure Control")	72	1

Figure 1. PRISMA-based



Tabel 2. Summary of the included randomized controlled trials.

Author (Year)	Study Design	Sample Size / Population	Intervention / Comparison	Outcome Measures	Main Findings
Afroz et al. (2024)	Randomized Controlled Trial	N = 100 pregnant women with gestational hypertension	Labetalol vs Methyldopa	Achievement of blood pressure control, time to achieve target BP, maternal tolerance	Labetalol provided faster BP control and a higher rate of successful BP achievement (RR 1.35; 95% CI 1.01–1.80; ARR 19.6%; NNT ≈ 6). Both drugs were well-tolerated.
Sharif et al. (2016))	Randomized Controlled Trial	N = 311 pregnant women with PIH (155 methyldopa vs 156 labetalol)	Labetalol vs Methyldopa	Successful BP control, progression to severe HTN	Equivalent BP control success rates (RR 0.99; 95% CI 0.92–1.06). No clinically significant difference in prevention of severe hypertension.

Tabel 3. Critical appraisal of RCTs using the CEBM tool by the University of Oxford.

	Internal Validity							Impotance				
Author	No of Participants	Level of Evidence	Randomisation	Baseline Similarity	Equally Treated	Intention to Treat	Blinding	RR	ARR (%)	RRR (%)	NNT	95% CI
Afroz et al., 2024	100 (50 vs 50)	1b (individual RCT)	+	+	+	-	-	1.35	20%	34.5%	6	RR 95% CI ≈ (1.01, 1.80); ARR 95% CI ≈ (1.47

												%, 37.71 %)
Sharif et al., 2016	314 total analyzed (Methy: 155, Labetalol: 156 analyzed; 2 lost each group reported)	1b (individual RCT)	+	+	+	-	-	0.99	-1.23 %	-14.6%	81	0.92 – 1.06

4. DISCUSSION

This Evidence-Based Clinical Review (EBCR) was conducted to address the clinical question: In pregnant women diagnosed with hypertension, is labetalol more effective and safer in controlling blood pressure compared to methyldopa?

Two randomized controlled trials (RCTs) included in this review demonstrated a consistent direction of effect, indicating that both labetalol and methyldopa are effective in lowering blood pressure during pregnancy. Afroz et al. (2024) reported that labetalol achieved a faster and clinically meaningful reduction in systolic and diastolic blood pressure, with a relative improvement in successful BP control of 35% (RR 1.35; 95% CI 1.01–1.80; ARR +19.6%; NNT ≈ 6). This implies a statistically significant and clinically relevant early BP response in favor of labetalol, particularly beneficial in situations requiring rapid stabilization.

Consistent with these clinical outcomes, blood pressure control—the primary therapeutic target—showed no sustained superiority of either agent beyond the early phase. Sharif et al. (2016) demonstrated only a minimal effect (RR 0.87; 95% CI 0.56–2.33; ARR 1.23%; NNT ≈ 81). These results collectively indicate equivalent clinical impact in preventing

progression to severe hypertension, reinforcing that sustained BP control depends more on early initiation and consistent follow-up than on drug selection alone.

Therefore, antihypertensive therapy in pregnancy should prioritize timely intervention and setting-specific practicality (Gyselaers et al., 2022). Labetalol may be preferable for faster symptom relief and early BP reduction, whereas methyldopa maintains strong justification for use in more stable cases or when β-blockade is undesirable (Rezk et al., 2020). Adverse effects remained mild and manageable with both medications (Magee et al., 2016).

Although pharmacodynamic differences exist, real-world considerations influence effectiveness: formulary availability, drug affordability, adherence likelihood, and capacity for ongoing monitoring. In Indonesia, methyldopa's availability across primary and secondary care facilities supports its practical reliability, while labetalol remains valuable in settings where urgent BP control is needed and monitoring resources are adequate (Ekawati et al., 2021).

In addition to antihypertensive effectiveness, this EBCR evaluated applicability parameters including safety profiles and clinical feasibility to support real-world prescribing decisions. Both RCTs demonstrated good tolerability, enabling direct translation of findings into obstetric practice. Assessment of all clinically important outcomes maternal BP stabilization and fetal well-being—was incorporated, and adverse events were systematically monitored.

The side-effect pattern observed is consistent with the pharmacologic characteristics of each medication. In Afroz et al. (2024), methyldopa was more frequently associated with central nervous system side effects such as sedation and fatigue due to its central α2 agonist mechanism. These symptoms, while not dangerous, may reduce maternal comfort and adherence over longer treatment durations. Conversely, labetalol was generally well-tolerated, which supports its use when prompt and sustained adherence is required for effective BP control.

Sharif et al. (2016) also reported no clinically significant differences in adverse effects between the two arms. Mild maternal complaints such as dizziness and nausea occurred at similar rates, suggesting that neither drug poses a disproportionate maternal safety risk in non-severe PIH populations. Importantly, neither study identified major fetal complications attributable to treatment.

These findings show that both agents provide favorable benefit-to-risk ratios, meeting applicability standards in terms of safety, clinical relevance, and feasibility in diverse healthcare levels. Thus, while labetalol may offer an early BP

advantage, methyldopa's well-established fetal safety and wider availability ensure continued applicability, particularly in primary care and resource-limited settings.

Methodological rigor of the included studies each classified as Level of Evidence 1b based on CEBM appraisal supports confidence in these clinical inferences. Minor risks of bias due to unclear blinding and incomplete reporting of intention-to-treat analysis do not meaningfully alter the observed direction of effect. Across effect size metrics, the modest magnitude and overlapping confidence intervals emphasize that neither agent provides a dominant clinical advantage.

Table 4. Applicability and side effects of labetalol and methyldopa in pregnancy

Study	Apply results to patient care	Considering all clinical important outcomes	Benefit worth the harm and cost	Assessment of side effects	Side Effects Reported
Afroz et al., 2024	Yes	Yes	Yes	Yes	Safety profiles similar; Methyldopa had more CNS-related complaints (sedation/fatigue), Labetalol generally well tolerated.
Sharif et al., 2016	Yes	Yes	Yes	Yes	No significant safety difference reported between groups; mild maternal side effects similar.

5. CONCLUSION

In pregnant women with hypertension, both labetalol and methyldopa have been shown to be effective in achieving blood pressure control and preventing escalation into severe disease. Labetalol may provide a faster initial therapeutic response, whereas methyldopa has a long-established safety profile and remains widely accessible in clinical practice. Overall, current evidence does not indicate a superior long-term maternal or fetal outcome for either medication. Therefore, both labetalol and methyldopa remain appropriate first-line antihypertensive options during pregnancy, and treatment selection should be tailored based on clinical urgency, patient comorbidities, tolerability, drug availability, and fetal monitoring needs. Continuous surveillance of maternal blood pressure and timely dose adjustment contribute more significantly to successful outcomes than the choice of agent alone. Future trials with larger populations and standardized outcomes are still required to refine antihypertensive selection in specific patient subgroups.

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