

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20263985>

Original Research Article

Effectiveness and safety of labetalol with magnesium sulfate in preeclampsia patients and its effect on maternal and fetal outcomes: a prospective observational study at a tertiary care teaching hospital in central India

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Received: 10 August 2026

Revised: 30 September 2026

Accepted: 02 October 2026

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ABSTRACT

Background: Preeclampsia is a major contributor to maternal and neonatal morbidity and mortality, particularly in developing countries. Labetalol and magnesium sulfate are commonly used for blood pressure control and seizure prophylaxis, respectively. However, evidence regarding their combined effectiveness in routine clinical practice in Central India remains limited.

Methods: A prospective observational study was conducted from October to December 2025, including 50 women with preeclampsia and 50 women without preeclampsia. Blood pressure in preeclampsia patients was recorded at baseline, 1 hour, and 4 hours after combined therapy, along with serum total protein levels measured before and after treatment. Maternal and fetal outcomes, along with adverse drug reactions, were assessed up to 48 hours postpartum.

Results: Among the preeclampsia group, systolic and diastolic blood pressure decreased significantly ($p < 0.0001$) following treatment, and total serum protein levels increased after treatment. Compared to the non-preeclampsia group, the preeclampsia group exhibited higher rates of low birth weight (82% versus 36%), preterm birth (68% versus 18%) and cesarean delivery was more frequent (76% versus 66%) but not significant ($p = 0.378$). Adverse drug reactions were mild.

Conclusions: Combined therapy was associated with effective short-term blood pressure control; however, adverse maternal and fetal outcomes were observed in women with preeclampsia.

Keywords: Preeclampsia, Labetalol, Magnesium sulfate, Maternal outcome, Fetal outcome

INTRODUCTION

Preeclampsia is a severe pregnancy-associated hypertensive disorder that contributes to maternal and neonatal morbidity and mortality.¹ It manifests after 20 weeks' gestation as new-onset hypertension (systolic blood

pressure ≥ 140 mmHg or diastolic ≥ 90 mmHg on two measurements ≥ 4 hours apart), with or without proteinuria (≥ 300 mg/24 h) or end-organ dysfunction.^{1,2} It is estimated to affect 2–10% of pregnancies globally, with a reported incidence of 1.8–16.7% in developing countries.³

Preeclampsia is associated with significant maternal and fetal complications.¹ Maternal complications may include progression to eclampsia, which has been reported in approximately 1–2% of cases, as well as HELLP syndrome (syndrome of hemolysis, elevated liver enzymes, and low platelets), placental abruption, renal failure, and multi-organ dysfunction, contributing substantially to severe maternal morbidity and mortality.^{1,3} Fetal and perinatal complications may include preterm birth, fetal growth restriction, low birth weight, fetal distress, and perinatal mortality.³

The pathogenesis of preeclampsia is associated with abnormal placental development and impaired vascular adaptation.^{1,2} These abnormalities lead to uteroplacental ischemia and the release of circulating factors that disrupt endothelial function.^{1,2} Additional contributing mechanisms include immune maladaptation, genetic predisposition, and increased necrotic trophoblastic debris, all of which can induce systemic inflammation.¹ Clinical features of preeclampsia include headache, visual disturbances, epigastric pain, and edema.^{1,2}

The main goals of preeclampsia treatment are blood pressure management and prevention of seizures. Labetalol, a dual α - and β -adrenergic receptor blocker, is frequently used as a first-line antihypertensive drug. This is due to its ability to reduce systemic vascular resistance while maintaining uteroplacental blood flow. The drug may be administered orally, initiated at 100 mg twice daily, or intravenously in acute cases, beginning at 20 mg bolus, up to 300 mg/day or 1–2 mg/min constant infusion.¹

Magnesium sulfate is the preferred medication for preventing seizures in preeclampsia.¹ It acts as an antagonist of N-methyl-D-aspartate receptors (NMDA) and produces cerebral vasodilatory and anticonvulsant effects.⁵ The widely used regimens for magnesium sulfate are Pritchard and Zuspan. The Pritchard regimen consists of a 4 g intravenous loading dose of magnesium sulfate followed by 10 g intramuscularly with 5 g intramuscular maintenance doses every 4 hours. The Zuspan regimen involves a 4 g intravenous loading dose followed by continuous intravenous infusion of 1–2 g/hour.⁴

Variations in treatment response and pregnancy outcomes continue to be observed across various healthcare settings despite the wide spread usage of these medications.^{6–9} There is limited information from Central India, especially from real-world hospital-based studies. Thus, the current study was conducted to analyze maternal and fetal outcomes as well as the efficacy and safety of combined therapy.

METHODS

Study design and setting

This prospective observational study was conducted over a three-month period from October 2025 to December

2025 at a tertiary care teaching hospital in Central India. During this period, a total of 50 consecutive pregnant women (gestational age ≥ 20 weeks) with newly diagnosed preeclampsia and 50 consecutive women without preeclampsia (≥ 20 weeks gestation) attending the same obstetrics unit were included after obtaining written informed consent. Ethical approval was obtained from the Institutional Ethics Committee of the tertiary care teaching hospital in Central India. (Reference ID: 3840/EC/Pharma).

Eligibility criteria

Pregnant women ≥ 20 weeks of gestation diagnosed with preeclampsia (blood pressure $\geq 140/90$ mmHg and proteinuria of at least 1+ on dipstick urine examination), with no history of chronic hypertension, pre-existing renal or cardiac disease, gestational diabetes mellitus, known drug hypersensitivity, or those presenting with eclampsia at the time of admission.

Treatment

All patients received standard institutional treatment, viz., oral labetalol (initiated at 100 mg twice daily and titrated up to 200 mg twice daily if required), and magnesium sulfate was administered according to the Pritchard regimen.^{1,4}

Blood pressure was measured in the sitting position using a calibrated sphygmomanometer at baseline and 1 and 4 hours following treatment initiation.⁷ Serum total protein was observed before and after initiation of treatment. The adverse drug reactions with maternal and fetal outcomes were assessed until 48 hours post-delivery.

Outcome assessment

The primary outcome was change in mean systolic and diastolic blood pressure from baseline to 1 hour and 4 hours after initiation of therapy. Secondary outcomes included change in serum total protein levels, assessment of maternal and fetal outcomes, and adverse drug reaction until 48 hours post-delivery. Maternal outcomes included mode of delivery and complications such as eclampsia, impending eclampsia, oligohydramnios, polyhydramnios, placental abruption, HELLP syndrome (syndrome of hemolysis, elevated liver enzymes, and low platelets), and multiple organ dysfunction. Fetal outcomes included low birth weight, preterm birth, fetal growth restriction, fetal distress and fetal death. Adverse drug reactions included nausea, vomiting, reduced tendon reflexes, and headache.

Statistical analysis

Data were analyzed using GraphPad Prism version 8.4.2.679. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were presented as frequencies and percentages. Comparisons within the preeclampsia women were performed using

repeated measures analysis of variance (ANOVA) and paired t-tests. Between-group comparisons were conducted using an independent t-test, a chi-square or Fisher's exact test as appropriate. A $p < 0.05$ was considered statistically significant.

RESULTS

A total of 100 pregnant women were included in the study, comprising 50 women with preeclampsia and 50 non-

preeclampsia women admitted to the Obstetrics and Gynecology Department at a tertiary care teaching hospital in Central India from October 2025 to December 2025.

The demographic characteristics of patients are shown in Table 1. Most women belonged to the 20–30 years age group, with a higher proportion of preterm pregnancies in the preeclampsia group compared to the non-preeclampsia group. Most of the patients were multigravida, and resided in urban areas.

Table 1: Demographic characteristics of patients in the preeclampsia and non-preeclampsia groups.

Variables	Preeclampsia (n=50)	Non-preeclampsia (n=50)	P value
Age (years)			
<20	2 (4%)	–	0.128
20–24	9 (18%)	17 (34%)	
25–29	20 (40%)	23 (46%)	
30–34	11 (22%)	9 (18%)	
≥35	8 (16%)	1 (2%)	
Gestation age			
Term (≥37 weeks)	16 (32%)	41 (82%)	<0.0001*
Moderate/late preterm (32–<37 weeks)	22 (44%)	9 (18%)	
Very preterm/extremely preterm (<32 weeks)	12 (24%)	–	
Parity			
Primigravida	14 (28%)	18 (36%)	0.5205
Multigravida	36 (72%)	32 (64%)	
Residence			
Rural	19 (38%)	24 (48%)	0.4193
Urban	31 (62%)	26 (52%)	

* $p < 0.05$ is considered statistically significant.

Baseline clinical parameters are shown in Table 2. The mean maternal weights were 54.78 ± 9.19 kg in the preeclampsia group and 54.96 ± 8.53 kg in the non-preeclampsia group. Hemoglobin averaged 10.83 ± 1.95 g/dl versus 10.61 ± 1.19 g/dl in the preeclampsia and non-

preeclampsia groups, respectively. Mean systolic blood pressure was 150.36 ± 12.46 mmHg in preeclampsia versus 113.50 ± 9.83 mmHg in non-preeclampsia ($p < 0.0001$); similarly, diastolic blood pressure was 96.36 ± 11.85 mmHg and 74.86 ± 8.07 mmHg, respectively ($p < 0.0001$).

Table 2: Baseline clinical parameters of patients in the preeclampsia and non-preeclampsia groups.

Clinical parameters	Preeclampsia	Non-preeclampsia	P value
Weight (kg)	54.78 ± 9.19	54.96 ± 8.53	0.919
Hemoglobin (g/dl)	10.83 ± 1.95	10.61 ± 1.19	0.495
SBP (mmHg)	150.36 ± 12.46	113.50 ± 9.83	<0.0001*
DBP (mmHg)	96.36 ± 11.85	74.86 ± 8.07	<0.0001*

* $p < 0.05$ is considered statistically significant; Data are expressed as mean $\pm$ standard deviation. SBP, Systolic blood pressure, DBP, Diastolic blood pressure.

There was a significant reduction in both SBP and DBP among the preeclampsia patients after administration of oral labetalol and magnesium sulfate, as shown in Table 3. SBP declined from baseline 150.36 ± 12.46 mmHg to 139.28 ± 11.61 mmHg at 1 hour and 129.44 ± 11.37 mmHg at 4 hours. Diastolic blood pressure similarly decreased from 96.36 ± 11.85 mmHg to 91.64 ± 10.91 mmHg, and 85.35 ± 10.23 mmHg, respectively. Total serum protein

levels, as shown in Table 4, increased significantly after treatment compared to baseline values.

Maternal outcomes of the patients are shown in Table 5. Most patients underwent cesarean section, with (76%) in preeclampsia patients compared to (66%) of non-preeclampsia patients. Maternal complications, viz,

impending eclampsia, HELLP syndrome (syndrome of hemolysis, elevated liver enzymes, and low platelets), placental abruption, and multi-organ dysfunction, were observed more frequently in the preeclampsia group.

Oligohydramnios and polyhydramnios were observed in (4%) patients each in the preeclampsia group; however, oligohydramnios was reported in (6%) patients of the non-preeclampsia group.

Table 3: Change in blood pressure from baseline to 1 and 4 hours after treatment with oral labetalol and magnesium sulfate in patients with preeclampsia.

Blood pressure	Before treatment	After treatment (1 hour)	After treatment (4 hours)	P value
SBP (mmHg)	150.36±12.46	139.28±11.61	129.44±11.37	<0.0001*
DBP (mmHg)	96.36±11.85	91.64±10.91	85.35±10.23	<0.0001*

*p<0.05 is considered statistically significant; Data are expressed in Mean±standard deviation, SBP, Systolic blood pressure, DBP, Diastolic blood pressure.

Table 4: Pre- and post-treatment total serum protein levels in patients with preeclampsia.

Parameter	Before treatment	After treatment	P value
Total serum protein (g/dl)	5.368±0.69	5.994±0.64	0.0001*

*p<0.05 is considered statistically significant; Data are expressed in Mean±standard deviation.

Table 5: Maternal outcomes observed in the preeclampsia and non-preeclampsia groups.

Maternal outcomes	Preeclampsia (n=50)	Non-preeclampsia (n=50)	P value
Vaginal delivery	12 (24%)	17 (34%)	0.378
Cesarean delivery	38 (76%)	33 (66%)	0.378
Impending eclampsia	5 (10%)	—	0.0563
HELLP syndrome	3 (6%)	—	0.2424
Oligohydramnios	2 (4%)	3 (6%)	>0.999
Polyhydramnios	2 (4%)	—	0.4949
Placental abruption	3 (6%)	—	0.2424
Multi-organ dysfunction	4 (8%)	1 (2%)	0.3622

*p<0.05 is considered statistically significant. HELLP Syndrome, Syndrome of hemolysis, elevated liver enzymes, and low platelets.

Table 6: Fetal outcomes observed in the preeclampsia and non-preeclampsia groups.

Fetal outcomes	Preeclampsia (n=50)	Non-preeclampsia (n=50)	P value
Low birth weight	41 (82%)	18 (36%)	<0.0001*
Preterm birth	34 (68%)	9 (18 %)	<0.0001*
Fetal distress	22 (44%)	15 (30%)	0.2137
FGR	7 (14%)	6 (12%)	>0.999
IUFD	2 (4%)	—	0.4949

*p<0.05 is considered statistically significant. FGR, Fetal growth restriction, IUFD, Fetal intrauterine death.

Table 7: Adverse drug reaction observed with oral labetalol and magnesium sulfate in the preeclampsia group (n=50).

Adverse drug reaction	Number (N)	Percentage (%)
Nausea	1	2
Vomiting	1	2
Headache	7	14

Fetal outcomes are shown in Table 6. High rates of low birth weight (82%) and premature birth (68%) were reported in neonates of preeclampsia patients compared to (36%) and (18%) in non-preeclampsia patients, respectively. Fetal distress, fetal growth restriction (FGR),

and fetal intrauterine death (IUFD) occurred more frequently in the preeclampsia group.

Adverse drug reactions observed with oral labetalol and magnesium sulfate among the 50 preeclampsia patients are

shown in Table 7. Headache was observed in (14%) and nausea or vomiting (2% each).

DISCUSSION

Preeclampsia remains a major contributor to maternal and neonatal morbidity and mortality, especially in developing countries. Its key pathophysiological features include endothelial dysfunction and impaired placental perfusion. Management primarily focuses on controlling blood pressure and preventing seizures. The present study assessed the short-term effects of combined oral labetalol and magnesium sulfate therapy on blood pressure control, safety, and maternal and fetal outcomes in women with preeclampsia.

Almost all the women in both groups were aged 25–29 years (40% in the preeclampsia and 46% in the non-preeclampsia group). Although preeclampsia is often associated with extremes of maternal age, this finding is consistent with Ganesh SK et al possibly due to the higher frequency of pregnancies in this age group.¹⁰ A higher proportion of women were multigravida in both the preeclampsia (72%) and non-preeclampsia (64%) groups, aligning with Kolluru et al.¹¹ This difference may be due to differences in demographic and obstetric characteristics across study populations.

The majority of the women with preeclampsia (44%) were in the moderate-to-late pre-term gestational age group (32–<37 weeks). Similar observations have been reported by Gomathy et al who noted that preeclampsia commonly presents in the late second and third trimesters.¹²

Urban women constituted a higher proportion of the preeclampsia group (62%) compared with the non-preeclampsia group (52%), similar findings were reported by Yadav et al.¹³

The present study demonstrated a significant reduction in systolic and diastolic blood pressure at 1 and 4 hours following initiation of combined therapy with oral labetalol and magnesium sulfate. These findings are consistent with those of Wu et al, Wang et al, and Gu et al, who also reported a significant reduction in blood pressure following combination therapy.^{6,8,9} However, the magnitude of blood pressure reduction observed in the present study was lower than that reported in the above-mentioned studies as shown in Table 8. This difference may be attributed to the lower baseline blood pressure of the present study population, variation in disease severity, treatment protocols, dosage regimens, and the timing of blood pressure assessment, which may have contributed to the differences observed across different studies.

Table 8: Comparison of blood pressure reduction reported in different studies of preeclampsia.

Blood pressure	Time point	Present study	Wu et al (2024) ⁶	Wang et al (2020) ⁸	Gu et al (2024) ⁹
SBP (mmHg)	Before treatment	150.36±12.46	154.88±10.81	176.35±15.28	167.29±10.45
	After treatment	139.28±11.61	125.98±5.99	138.43±14.52	134.81±12.25
	Mean Reduction	11.08	28.90	37.92	32.48
DBP (mmHg)	Before treatment	96.36±11.85	96.65±9.51	117.28±16.24	98.28±6.14
	After treatment	91.64±10.91	80.15±5.30	95.13±11.68	82.03±5.77
	Mean Reduction	4.72	16.50	22.15	16.25

In the present study, despite significant blood pressure reduction, maternal outcomes showed a higher rate of cesarean deliveries in the preeclampsia group (76%) compared to the non-preeclampsia group (66%), likely due to increased maternal and fetal complications associated with the disease. Other maternal complications included impending eclampsia (10%), HELLP syndrome (6%), placental abruption (6%), oligohydramnios (4%), polyhydramnios (4%), and multi-organ dysfunction (8%). These findings contrast with the improved maternal outcomes reported by Gu et al who observed higher spontaneous vaginal delivery and lower rates of cesarean sections. However, similar findings have been reported by studies like Priyamvadhya et al, Jain et al, and Aabidha et al.^{9,14-16}

Fetal outcomes showed higher rates of low birth weight (82% versus 36%) and preterm delivery (68% versus 18%) in the preeclampsia group compared to the non-preeclampsia group. These findings may be related to uteroplacental insufficiency and the greater burden of preterm gestation among women with preeclampsia.

Fetal distress (44% versus 30%), fetal growth restriction (14% versus 12%), and fetal intrauterine death (4%) were also more frequent in the preeclampsia group, consistent with the finding of observational studies by Kolluru et al. and Jain et al., whereas Gu et al. observed improved fetal outcomes.^{9,11,15} These findings highlight the importance of close antenatal surveillance and effective neonatal care in reducing perinatal morbidity and mortality.

The adverse fetomaternal outcomes observed in the present study may be attributed to a higher proportion of women with moderate-to-late preterm gestational age, in whom placental insufficiency and disease severity are often more advanced. Additionally, the tertiary care setting likely included a higher proportion of high-risk patients, including referred complicated cases, those with inadequate antenatal care, and severe disease manifestations, which may also have further contributed to the outcomes. The adverse drug reactions were mild including headache (14%) and nausea and vomiting (2% each).

This study had certain limitations. The study had a relatively small sample size and was conducted at a single tertiary care center, which may limit generalizability. It did not include an untreated or alternative treatment preeclampsia comparator group. The follow-up period was limited to 48 hours post-delivery, and long-term maternal and neonatal outcomes were not assessed.

CONCLUSION

The present study demonstrates that combined oral labetalol and magnesium sulfate therapy significantly lowers blood pressure. However, pharmacological blood pressure control provides primarily short-term stabilization, and adverse maternal and fetal outcomes may persist despite medical management. These persistent pregnancy outcomes reflect the outcome of combined therapy's role in acute management of preeclampsia.

Therefore, enhancing antenatal care services, increasing patient awareness, ensuring timely referral, and developing therapies that target endothelial and placental dysfunction are essential steps toward reducing fetomaternal morbidity and mortality. Further multicentric studies with larger sample sizes and longer follow-up periods are recommended for future management strategies.

ACKNOWLEDGEMENTS

The authors sincerely thank all participants and supporting clinical staff for their cooperation and assistance in the successful completion of this study.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Meshram AR, Kerketta RR, Shamkuwar CA. Effectiveness and safety of labetalol with magnesium sulfate in preeclampsia patients and its effect on maternal and fetal outcomes: a prospective observational study at a tertiary care teaching hospital in central India. *Int J Reprod Contracept Obstet Gynecol* 2026;15:4404-10