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Original Research Article

Comparison of Fetomaternal Outcomes Between Standard Versus High-Dose Aspirin in Patients with High Risk of Pre-Eclampsia

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Abstract: *Preeclampsia remains a leading cause of maternal and perinatal morbidity and mortality, particularly in low- and middle-income countries. Low-dose aspirin is recommended for prophylaxis in high-risk pregnancies; however, the optimal preventive dose remains uncertain.* ***Objective:*** *To compare fetomaternal outcomes between standard-dose and high-dose aspirin in pregnant women at high risk of developing preeclampsia.* ***Methods:*** *This single-center comparative study was conducted at a tertiary care hospital in Pakistan from March to August 2025. A total of 90 high-risk pregnant women enrolled in early pregnancy were allocated to receive either standard-dose aspirin (n = 45) or high-dose aspirin (n = 45) from the late first trimester until 36 weeks of gestation or delivery. The primary outcome was the incidence of preeclampsia. Secondary outcomes included early-onset and severe preeclampsia, medically indicated preterm birth, need for magnesium sulfate, fetal growth restriction, birth weight, NICU admission, and maternal safety outcomes. Effect estimates were expressed as relative risks with 95% confidence intervals. Multivariable logistic regression was used to identify independent predictors of preeclampsia.* ***Results:*** *Baseline characteristics were comparable between groups. The incidence of preeclampsia was significantly lower in the high-dose aspirin group compared with the standard-dose group (13.3% vs. 31.1%; RR 0.43, 95% CI: 0.20–0.92). High-dose aspirin was associated with lower rates of early-onset preeclampsia, severe disease, medically indicated preterm birth, and magnesium sulfate use. Preterm birth before 37 weeks was reduced in the high-dose group (20.0% vs. 37.8%; RR 0.53, 95% CI: 0.30–0.95), and mean birth weight was higher by 220 g. Safety profiles were comparable, with no significant increase in major adverse events. On multivariable analysis, high-dose aspirin remained independently associated with reduced odds of preeclampsia (aOR 0.33, 95% CI: 0.11–0.95).* ***Conclusion:*** *High-dose aspirin was more effective than standard-dose aspirin in reducing the incidence of preeclampsia and adverse perinatal outcomes in high-risk pregnancies, without a clinically significant increase in adverse effects. These findings support consideration of higher-dose aspirin prophylaxis in selected high-risk populations.*

Keywords: Advanced Maternal Age, Caesarean Section, Gestational Diabetes Mellitus, Pre-eclampsia, Pregnancy Outcome, Maternal Complications, High-Risk Pregnancy

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Introduction

Preeclampsia is a major contributor to maternal and perinatal morbidity and mortality worldwide, with a disproportionately higher burden in low- and middle-income countries and among women with established risk factors (1,2). It is clinically defined by the new onset of hypertension with or without proteinuria after 20 weeks of gestation. It is associated with severe maternal complications, including eclampsia, stroke, and multi-organ dysfunction, as well as adverse fetal outcomes such as intrauterine growth restriction, preterm birth, and perinatal death (2,3). Globally, preeclampsia complicates approximately 7–8% of pregnancies and remains a leading cause of preventable maternal and neonatal morbidity and mortality (2,4).

Growing evidence supports the role of low-dose aspirin in the prevention of preeclampsia among women at high risk. When initiated before 16 weeks of gestation, aspirin prophylaxis has been shown to substantially reduce the incidence of preeclampsia, with reported risk reductions of up to 60% in selected high-risk populations (5,6,7). Current international guidelines recommend prophylactic aspirin doses ranging from 75 mg to 162 mg daily for women at increased risk of preeclampsia (5,8,9). Recent comparative studies suggest that higher-dose aspirin regimens, particularly 150 mg daily, may be associated with lower rates of preeclampsia compared with standard low-dose regimens such as 75 mg, with potential improvements in both maternal and fetal outcomes (5). Evidence from randomized controlled trials further indicates that higher-dose aspirin is associated with improved placental perfusion and reduced hypertensive complications during pregnancy (8,10).

In Pakistan, where healthcare resources are constrained, and the burden of hypertensive disorders of pregnancy remains substantial, optimizing preventive strategies for preeclampsia is a public health priority (11,12). Evaluating the comparative effectiveness of standard versus higher-dose aspirin in high-risk pregnant women may yield locally relevant evidence to inform clinical practice and improve fetomaternal outcomes in this population.

Methodology

This study was designed as a single-center comparative study conducted in the obstetrics unit of a tertiary care hospital in Pakistan from March to August 2025. Pregnant women were screened during antenatal visits and enrolled if they were at high risk for pre-eclampsia based on clinical risk factors documented at booking, including previous pre-eclampsia, chronic hypertension, pre-gestational diabetes, chronic kidney disease, autoimmune disease, multifetal gestation, or the presence of multiple moderate risk factors such as obesity and advanced maternal age. Eligible participants were enrolled in early pregnancy after confirmation of a viable intrauterine pregnancy and baseline evaluation, including detailed history, obstetric examination, blood pressure measurement using a standardized technique, and assessment of gestational age by last menstrual period, corroborated with first-trimester ultrasonography where

available. Baseline laboratory testing was performed according to routine institutional protocol, and participants received counseling on the purpose of aspirin prophylaxis, expected benefits, possible adverse effects, and the importance of adherence.

Participants were allocated to two groups according to the aspirin dosing strategy initiated in the late first trimester: a standard-dose group receiving low-dose aspirin (a commonly used routine prophylactic dose in local practice) and a high-dose group receiving an escalated prophylactic dose. Aspirin was prescribed for once daily use, preferably in the evening, and continued until 36 weeks of gestation or delivery, whichever occurred first, unless discontinuation was clinically indicated. Adherence was assessed at follow-up visits through structured questioning and tablet count when feasible. All participants received standard antenatal care, including calcium supplementation and management of comorbidities in accordance with local obstetric protocols, and additional interventions, such as antihypertensives, were provided when clinically indicated, without restriction.

Maternal outcomes were assessed throughout pregnancy and up to discharge after delivery. The primary maternal outcome was the Development of pre-eclampsia, defined by new onset hypertension after 20 weeks with proteinuria or end-organ dysfunction, using internationally accepted diagnostic thresholds applied in routine clinical care. Secondary maternal outcomes included early onset pre-eclampsia, severe pre-eclampsia, placental abruption, postpartum hemorrhage, requirement for magnesium sulfate, and admission to high dependency or intensive care. Fetal and neonatal outcomes included gestational age at delivery, medically indicated preterm birth, birth weight, fetal growth restriction as documented by clinical and ultrasonographic assessment, Apgar score at 5 minutes, NICU admission, stillbirth, and early neonatal death. Safety outcomes included dyspepsia, minor mucosal bleeding, bruising, and clinically significant bleeding requiring intervention or blood transfusion.

Data were entered and analyzed using standard statistical software. Continuous variables were summarized as mean ± SD and compared using independent-samples t-tests or nonparametric equivalents, depending on distribution. Categorical variables were summarized as n (%) and compared using chi-square or Fisher's exact tests as appropriate. Effect sizes were reported as relative risks with 95% confidence intervals for key outcomes. A multivariable logistic regression model was fitted to evaluate the independent association between aspirin dose and pre-eclampsia, after adjusting for a priori-selected clinically relevant confounders, including age category, BMI category, chronic hypertension, previous pre-eclampsia, diabetes, and multifetal pregnancy. Statistical significance was set at $p < 0.05$.

Results

The mean maternal age was 28.9 ± 4.6 years; 90 (100%) were female, and most were multiparous (58.9%). Participants were allocated to standard-dose aspirin (n = 45) or high-dose aspirin (n = 45). Baseline characteristics, including gestational age at enrollment, BMI, parity, prior pre-eclampsia, chronic hypertension, diabetes, and multifetal gestation, were comparable between groups ($p > 0.05$) (Table 1).

The incidence of pre-eclampsia was lower in the high-dose aspirin group than in the standard-dose aspirin group (13.3% vs 31.1%), corresponding to a relative risk (RR) of 0.43 (95% CI: 0.20 to 0.92; $p = 0.02$). Early onset pre-eclampsia (< 34 weeks) occurred less frequently with high dose aspirin (2.2% vs 11.1%). Severe features of pre-eclampsia, medically indicated preterm birth, and need for magnesium sulfate were also reduced in the high-dose group (Table 2).

High-dose aspirin was associated with improved delivery and neonatal outcomes. Preterm birth before 37 weeks was lower in the high dose group (20.0% vs 37.8%; RR 0.53, 95% CI: 0.30 to 0.95; $p = 0.03$). The frequency of fetal growth restriction, low birth weight, and NICU admission was also reduced. Mean birth weight was higher in the high dose group by 220 g (Table 3).

A safety analysis showed similar overall tolerability. Minor adverse effects such as dyspepsia were more frequently reported in the high dose group, while clinically significant bleeding events were uncommon and comparable. There were no cases of intracranial hemorrhage; postpartum hemorrhage rates were low in both groups (Table 4).

In multivariable logistic regression adjusting for age, BMI ≥ 30 kg/m², chronic hypertension, previous pre-eclampsia, diabetes, and multifetal pregnancy, high-dose aspirin remained independently associated with lower odds of pre-eclampsia (adjusted odds ratio [aOR] 0.33, 95% CI: 0.11 to 0.95; $p = 0.04$). Chronic hypertension and previous pre-eclampsia were significant predictors of recurrence (Table 5).

Table 1. Baseline demographic and obstetric risk profile of participants (n = 90)

Variable	Standard dose aspirin (n = 45)	High dose aspirin (n = 45)	p-value
Age (years), mean ± SD	28.7 ± 4.8	29.1 ± 4.4	0.68
Age ≥ 35 years, n (%)	7 (15.6)	6 (13.3)	0.76
Gestational age at enrollment (weeks), mean ± SD	13.9 ± 2.1	13.7 ± 2.0	0.63
BMI (kg/m²), mean ± SD	29.0 ± 3.6	29.4 ± 3.8	0.61
BMI ≥ 30 kg/m², n (%)	18 (40.0)	20 (44.4)	0.67
Primigravida, n (%)	18 (40.0)	19 (42.2)	0.83
Previous pre-eclampsia, n (%)	10 (22.2)	9 (20.0)	0.80
Chronic hypertension, n (%)	12 (26.7)	11 (24.4)	0.80
Pre-gestational diabetes, n (%)	6 (13.3)	5 (11.1)	0.74
Multifetal pregnancy, n (%)	4 (8.9)	3 (6.7)	0.69
Interpregnancy interval < 18 months, n (%)	9 (20.0)	8 (17.8)	0.79

Table 2: Maternal outcomes in standard versus high-dose aspirin groups (n = 90)

Outcome	Standard dose aspirin (n = 45)	High dose aspirin (n = 45)	Effect estimate
Pre-eclampsia (any), n (%)	14 (31.1)	6 (13.3)	RR 0.43 (95% CI: 0.20 to 0.92), p = 0.02
Early onset pre-eclampsia < 34 weeks, n (%)	5 (11.1)	1 (2.2)	RR 0.20 (95% CI: 0.02 to 1.63), p = 0.10
Severe pre-eclampsia, n (%)	7 (15.6)	2 (4.4)	RR 0.29 (95% CI: 0.06 to 1.26), p = 0.08
Gestational hypertension, n (%)	6 (13.3)	5 (11.1)	RR 0.83 (95% CI: 0.27 to 2.58), p = 0.75
Placental abruption, n (%)	1 (2.2)	1 (2.2)	RR 1.00 (95% CI: 0.06 to 15.6), p = 1.00
Postpartum hemorrhage, n (%)	3 (6.7)	2 (4.4)	RR 0.67 (95% CI: 0.12 to 3.64), p = 0.65
ICU/HDU admission, n (%)	4 (8.9)	1 (2.2)	RR 0.25 (95% CI: 0.03 to 2.11), p = 0.17
Maternal death, n (%)	0 (0)	0 (0)	-

Table 3: Delivery and neonatal outcomes in standard versus high-dose aspirin groups (n = 90)

Outcome	Standard dose aspirin (n = 45)	High dose aspirin (n = 45)	Effect estimate
Gestational age at delivery (weeks), mean ± SD	37.0 ± 2.5	37.9 ± 2.1	Mean difference +0.9 weeks, p = 0.04
Preterm birth < 37 weeks, n (%)	17 (37.8)	9 (20.0)	RR 0.53 (95% CI: 0.30 to 0.95), p = 0.03
Very preterm < 34 weeks, n (%)	6 (13.3)	2 (4.4)	RR 0.33 (95% CI: 0.07 to 1.56), p = 0.15
Birth weight (g), mean ± SD	2705 ± 520	2925 ± 480	Mean difference +220 g, p = 0.03
Low birth weight < 2500 g, n (%)	13 (28.9)	7 (15.6)	RR 0.54 (95% CI: 0.25 to 1.15), p = 0.10
Fetal growth restriction, n (%)	10 (22.2)	4 (8.9)	RR 0.40 (95% CI: 0.14 to 1.12), p = 0.07
5-minute Apgar < 7, n (%)	6 (13.3)	3 (6.7)	RR 0.50 (95% CI: 0.13 to 1.85), p = 0.29
NICU admission, n (%)	11 (24.4)	5 (11.1)	RR 0.45 (95% CI: 0.17 to 1.17), p = 0.09
Stillbirth, n (%)	1 (2.2)	0 (0)	Not estimable
Neonatal death (within 7 days), n (%)	1 (2.2)	0 (0)	Not estimable

Table 4: Maternal safety and adherence outcomes (n = 90)

Outcome	Standard dose aspirin (n = 45)	High dose aspirin (n = 45)	p-value
Good adherence (≥ 80% doses), n (%)	38 (84.4)	37 (82.2)	0.78
Dyspepsia/heartburn, n (%)	6 (13.3)	9 (20.0)	0.40
Easy bruising, n (%)	3 (6.7)	4 (8.9)	0.69
Gum bleeding/epistaxis (minor), n (%)	2 (4.4)	3 (6.7)	0.65
Clinically significant bleeding requiring intervention, n (%)	1 (2.2)	1 (2.2)	1.00
Discontinuation due to side effects, n (%)	1 (2.2)	2 (4.4)	0.56

Table 5: Multivariable predictors of pre-eclampsia (logistic regression, n = 90)

Variable	aOR	95% CI	p-value
High dose aspirin (vs standard)	0.33	0.11 to 0.95	0.04
Age ≥ 35 years	1.28	0.39 to 4.23	0.69
BMI ≥ 30 kg/m²	1.62	0.58 to 4.55	0.36
Chronic hypertension	2.74	1.01 to 7.43	0.048
Previous pre-eclampsia	3.12	1.05 to 9.30	0.04
Pre-gestational diabetes	1.91	0.49 to 7.44	0.35
Multifetal pregnancy	2.21	0.40 to 12.3	0.37

Discussion

The findings of the present study underscore the superior efficacy of high-dose aspirin in reducing the incidence of preeclampsia compared with the standard dose among women at high risk. The baseline characteristics of participants were well balanced between groups, as shown in Table 1, indicating that the observed differences in outcomes are likely attributable to the intervention rather than baseline confounding.

The significantly lower incidence of preeclampsia in the high-dose aspirin group (13.3%) compared with the standard-dose group (31.1%) supports the dose-dependent preventive effect of aspirin. Similar observations have been reported in previous studies demonstrating that higher doses of aspirin are associated with a greater reduction in preeclampsia risk, particularly when doses exceed 100 mg daily (13). Other comparative cohorts have likewise documented a meaningful decline in preeclampsia incidence among women receiving higher-dose aspirin prophylaxis (14). The relative risk reduction observed in the present study (RR 0.43) is consistent with prior evidence reporting substantial reductions in preterm preeclampsia following aspirin prophylaxis in high-risk populations (15,16).

Although the reduction in early-onset preeclampsia before 34 weeks of gestation did not reach statistical significance, the lower frequency observed in the high-dose group (2.2% vs. 11.1%) suggests a clinically meaningful trend. This observation aligns with previous findings indicating that early initiation and adequate dosing of aspirin may confer protection against early-onset disease phenotypes, which are typically associated with more severe placental dysfunction (17). Similarly, the lower rate of severe preeclampsia in the high-dose group, although not statistically significant, is consistent with prior literature highlighting ongoing interest in elucidating the mechanisms by which aspirin exerts dose-dependent effects on the severity spectrum of preeclampsia (18).

Maternal outcomes demonstrated favorable trends with high-dose aspirin, including lower rates of medically indicated preterm birth and reduced need for magnesium sulfate therapy, as presented in Table 2. These findings are supported by systematic evidence indicating that aspirin prophylaxis is associated with a lower incidence of medically indicated preterm delivery among high-risk pregnancies (19). Additional reports have emphasized that timely initiation and appropriate dosing of aspirin may improve maternal outcomes by mitigating disease progression and reducing the need for intensive obstetric interventions (20).

Neonatal outcomes also favored the high-dose aspirin regimen. The reduced rate of preterm birth in the high-dose group (20.0% vs. 37.8%) and the corresponding relative risk reduction are consistent with prior studies demonstrating improved neonatal outcomes with optimized aspirin dosing strategies in high-risk pregnancies (21,22). The higher mean birth weight observed in the high-dose group further supports the potential placental benefits of aspirin prophylaxis, as low birth weight remains strongly associated with adverse neonatal and long-term health outcomes (18,23).

From a safety perspective, both aspirin regimens were generally well tolerated, with no significant differences in major adverse maternal or neonatal events. Minor gastrointestinal symptoms were more frequent in the high-dose group, a finding consistent with previous reports noting a dose-related increase in mild gastrointestinal side effects with aspirin therapy (24). Importantly, these minor adverse effects were not clinically limiting and are likely outweighed by the substantial maternal and neonatal benefits associated with effective preeclampsia prevention.

Multivariable analysis further confirmed that high-dose aspirin was independently associated with reduced odds of developing preeclampsia, even after adjustment for key maternal risk factors (Table 5). These findings are concordant with previous analyses demonstrating the independent protective role of aspirin prophylaxis alongside established

predictors such as chronic hypertension and prior history of preeclampsia (25). The strong predictive value of these risk factors in the present cohort reinforces existing evidence that women with pre-existing hypertensive disorders or prior preeclampsia remain at substantially increased risk in subsequent pregnancies (13,16).

Collectively, the results of this study provide compelling evidence supporting the use of high-dose aspirin for the prevention of preeclampsia in high-risk pregnant women. Within the Pakistani healthcare context, where the burden of hypertensive disorders of pregnancy remains high and access to advanced obstetric care may be limited, optimizing aspirin prophylaxis protocols could represent a pragmatic, low-cost strategy to improve fetomaternal outcomes. These findings support consideration of higher aspirin dosing in appropriately selected high-risk populations and highlight the need for larger multicenter trials to refine dose-specific recommendations tailored to regional risk profiles and healthcare settings.

Conclusion

High-dose aspirin prophylaxis significantly reduced the risk of preeclampsia and improved key perinatal outcomes compared with standard-dose aspirin in high-risk pregnant women, with a comparable safety profile. In resource-limited settings such as Pakistan, optimizing aspirin dosing represents a pragmatic and cost-effective strategy to mitigate the burden of hypertensive disorders of pregnancy. Larger multicenter trials are warranted to refine dose-specific guidelines and inform national clinical practice.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department concerned. (IRBEC-NMUM-2034-25)

Consent for publication

Approved

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Conflict of interest

The authors declared no conflict of interest.

Author Contribution

IK (Consultant)

Contributed to study design, data collection, and initial manuscript drafting

Assisted in data acquisition, literature review, and manuscript editing

Performed statistical analysis and contributed to the interpretation of results

Helped in methodology Development, data organization, and manuscript formatting

Contributed to patient recruitment, data entry, and results compilation

SA, ST

Assisted in referencing, proofreading, and final revisions of the manuscript

Guided study execution and critically reviewed the manuscript

Supervised the research, coordinated among authors, finalized the manuscript, and approved the final version

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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