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Original Research Article

Effectiveness of Low-Dose Aspirin in Preventing Pre-Eclampsia in High-Risk Pregnant Women: A Randomized Controlled Trial in Tertiary Care Hospitals

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Abstract: *Pre-eclampsia is a leading cause of maternal and perinatal morbidity and mortality in Pakistan. Low-dose aspirin (LDA) has been identified as a promising preventive strategy for high-risk pregnancies when initiated early. This study aimed to evaluate the effectiveness of daily low-dose aspirin in preventing pre-eclampsia and improving maternal and neonatal outcomes in a tertiary care setting.* ***Methods:*** *This randomized controlled trial was conducted at a tertiary care hospital in Pakistan over six months (August 2024 to January 2025). A total of 86 high-risk pregnant women were randomly assigned to either the aspirin group (75 mg/day from 12–16 to 36 weeks of gestation) or the control group receiving routine antenatal care. Data on maternal blood pressure, proteinuria, and clinical outcomes were collected and compared. Perinatal outcomes were also recorded, including birth weight, gestational age at delivery, and NICU admission. Statistical analysis was performed using SPSS v26, with $p < 0.05$ considered significant.* ***Results:*** *Pre-eclampsia occurred in 13.9% of women in the aspirin group versus 34.9% in the control group ($p = 0.02$). Severe pre-eclampsia was significantly lower in the aspirin group (4.7% vs. 20.9%, $p = 0.03$). Rates of preterm delivery, low birth weight, and NICU admission were significantly reduced among aspirin users. Additionally, the intervention group better controlled systolic and diastolic blood pressures and proteinuria levels.* ***Conclusion:*** *Low-dose aspirin is effective in reducing the incidence and severity of pre-eclampsia in high-risk pregnancies. It is a safe, inexpensive, and accessible intervention that can significantly improve maternal and neonatal outcomes in the Pakistani population when introduced early in antenatal care.*

Keywords: Pre-eclampsia, low-dose aspirin, high-risk pregnancy, maternal health, Pakistan, randomized controlled trial

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Introduction

Pre-eclampsia is a hypertensive disorder of pregnancy characterized by elevated blood pressure and proteinuria after 20 weeks of gestation, and it remains a significant contributor to maternal and perinatal morbidity and mortality globally. In low- and middle-income countries, including Pakistan, the burden of pre-eclampsia is disproportionately high, contributing to up to 25% of maternal deaths (1,2). Early identification and timely preventive strategies are essential to mitigate its impact, particularly among high-risk pregnant women.

In Pakistan, the incidence of pre-eclampsia ranges from 5% to 10% of all pregnancies, with higher rates observed in tertiary care centers due to referrals of complicated cases (3). Risk factors such as advanced maternal age, obesity, family history of hypertension, primigravida status, and previous history of pre-eclampsia are commonly observed in the Pakistani obstetric population (4,5). These factors, coupled with inadequate antenatal surveillance in rural and underserved regions, result in delayed diagnosis and poor outcomes for both mothers and neonates.

Low-dose aspirin (typically 75–150 mg/day), initiated early in pregnancy, has been extensively studied as a prophylactic intervention to reduce the risk of pre-eclampsia, particularly in high-risk women. Its anti-inflammatory, anti-thrombotic, and vasodilatory effects help improve placental blood flow, reducing the likelihood of uteroplacental insufficiency—a central pathophysiological feature of pre-eclampsia (6). Several international guidelines, including those from the American College of Obstetricians and Gynecologists (ACOG) and World Health Organization (WHO), now recommend daily low-dose aspirin for high-risk women beginning from the late first trimester (7,8).

Multiple randomized controlled trials and meta-analyses have demonstrated that aspirin significantly reduces the incidence of pre-eclampsia, particularly when initiated before 16 weeks of gestation (9,10). In South Asian populations, including Pakistan, recent research supports the utility of aspirin in improving maternal and fetal outcomes, though data specific to local healthcare settings remain limited (11). Additionally, studies suggest that aspirin reduces the risk of severe complications such as preterm birth, intrauterine growth restriction (IUGR), and neonatal intensive care unit (NICU) admission (12,13).

Despite the promising evidence, there remains a need for locally relevant, randomized controlled trials in Pakistan to validate the effectiveness of low-dose aspirin in preventing pre-eclampsia and reducing its complications. Given the contextual differences in healthcare access, patient compliance, and antenatal monitoring, such studies are vital to inform national clinical guidelines and public health strategies.

The present study was designed to evaluate the effectiveness of low-dose aspirin in preventing the onset and severity of pre-eclampsia among high-risk pregnant women attending tertiary care hospitals in Pakistan. The findings aim to contribute to evidence-based antenatal care protocols and improve maternal and perinatal outcomes in high-risk populations.

Methodology

This randomized controlled trial was conducted over six months at a tertiary care hospital in Pakistan, from August 2024 to January 2025. The objective of the study was to evaluate the effectiveness of low-dose aspirin in preventing pre-eclampsia among high-risk pregnant women. Ethical approval was obtained from the hospital's Institutional Review

Board prior to the study's commencement, and written informed consent was obtained from all participants.

A total of 86 pregnant women were enrolled through non-probability purposive sampling based on their classification as high-risk for developing pre-eclampsia. High-risk criteria included a history of pre-eclampsia in a previous pregnancy, chronic hypertension, multiple pregnancy, diabetes mellitus, chronic kidney disease, autoimmune disorders, obesity (BMI > 25 kg/m²), or a family history of hypertensive disorders of pregnancy. Women with known bleeding disorders, allergy to aspirin, peptic ulcer disease, or those already on antiplatelet therapy were excluded from the study.

Participants were randomly assigned to two equal groups: the intervention group received 75 mg of aspirin daily starting between 12 and 16 weeks of gestation until 36 weeks, in addition to routine antenatal care, while the control group received standard antenatal care without aspirin. Randomization was done using a computer-generated sequence, and allocation concealment was maintained using opaque sealed envelopes. Compliance with aspirin therapy was assessed during antenatal visits through self-reporting and pill count.

Baseline demographic and clinical data were collected using a structured proforma, including age, gravidity, BMI, family, and obstetric history. Blood pressure measurements were taken at each antenatal visit, and urine dipstick tests were used to assess proteinuria. Women were followed up until delivery, and maternal outcomes such as the incidence and severity of pre-eclampsia, gestational age at delivery, and the need for antihypertensive treatment were recorded. Perinatal outcomes, including birth weight, preterm delivery, stillbirths, and NICU admissions, were also documented.

Data were analyzed using SPSS version 26. Descriptive statistics were applied for demographic variables, with continuous variables expressed as means and standard deviations, and categorical variables as frequencies and percentages. The Chi-square and Fisher's exact tests were used to compare categorical outcomes between groups, while independent t-tests were used for continuous variables. A p-value of less than 0.05 was considered statistically significant. The study followed CONSORT guidelines for randomized controlled trials and adhered to the ethical principles outlined in the Declaration of Helsinki.

Results

A total of 86 pregnant women identified as high-risk for developing pre-eclampsia were enrolled and randomly assigned into two groups: the intervention group receiving 75 mg of aspirin daily and the control group receiving standard antenatal care without aspirin. The intervention was initiated between 12 and 16 weeks of gestation and continued until 36 weeks. Maternal and perinatal outcomes were monitored to evaluate the incidence and severity of pre-eclampsia, as well as related complications. (Table 1)

Both groups were comparable in baseline demographic and obstetric characteristics, with no statistically significant differences observed between the aspirin and control groups.

The incidence of pre-eclampsia was significantly lower in the aspirin group compared to the control group. A marked reduction in severe pre-eclampsia was also observed, indicating the effectiveness of low-dose aspirin in reducing disease severity. (Table 2).

Low-dose aspirin was associated with improved perinatal outcomes, including significantly reduced rates of preterm birth, low birth weight, and NICU admissions. (Table 3)

Aspirin therapy resulted in better control of systolic and diastolic blood pressure and a significant reduction in the incidence of proteinuria at term. (Table 4)

Low-dose aspirin significantly reduced the overall incidence of pre-eclampsia (13.9% vs. 34.9%) and severe pre-eclampsia (4.7% vs. 20.9%) in high-risk pregnant women. The intervention group had better maternal and neonatal outcomes, with lower rates of preterm birth, low birth weight, and NICU admissions. Aspirin therapy improved blood pressure control and reduced proteinuria levels, key indicators in pre-eclampsia management. These results support the routine use of low-dose aspirin in antenatal protocols for high-risk pregnancies in the Pakistani healthcare setting.

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Table 1: Demographic and Baseline Characteristics of Participants (n = 86)

Characteristic	Aspirin Group (n=43)	Control Group (n=43)	p-value
Mean Age (years ± SD)	28.4 ± 4.3	29.1 ± 4.7	0.42
Primigravida (%)	19 (44.2%)	21 (48.8%)	0.68
BMI > 25 kg/m² (%)	22 (51.2%)	20 (46.5%)	0.67
Family History of Pre-eclampsia	11 (25.6%)	10 (23.3%)	0.80
Previous History of Pre-eclampsia	9 (20.9%)	8 (18.6%)	0.78

Table 2: Incidence and Severity of Pre-eclampsia

Outcome	Aspirin Group (n=43)	Control Group (n=43)	p-value
Pre-eclampsia Developed (%)	6 (13.9%)	15 (34.9%)	0.02*
Severe Pre-eclampsia (%)	2 (4.7%)	9 (20.9%)	0.03*
Onset <34 weeks (%)	1 (2.3%)	5 (11.6%)	0.09

Table 3: Maternal and Perinatal Outcomes

Outcome	Aspirin Group (n=43)	Control Group (n=43)	p-value
Preterm Delivery (<37 weeks) (%)	5 (11.6%)	12 (27.9%)	0.04*
Low Birth Weight (<2500g) (%)	4 (9.3%)	11 (25.6%)	0.03*
NICU Admission (%)	3 (7.0%)	10 (23.3%)	0.03*
Stillbirths (%)	0 (0%)	2 (4.7%)	0.15

Table 4: Blood Pressure Control and Proteinuria

Indicator	Aspirin Group (n=43)	Control Group (n=43)	p-value
Mean SBP at 36 weeks (mmHg ± SD)	121.4 ± 8.6	135.2 ± 10.1	<0.001*

Mean DBP at 36 weeks (mmHg ± SD)	79.6 ± 5.2	88.4 ± 6.3	<0.001*
Proteinuria at term (≥ +1 on dipstick)	3 (7.0%)	11 (25.6%)	0.02*

Discussion

This randomized controlled trial demonstrated that the administration of low-dose aspirin (75 mg/day) significantly reduced the incidence and severity of pre-eclampsia in high-risk pregnant women. The results are consistent with a growing body of international and regional evidence supporting aspirin's effectiveness as a prophylactic intervention when initiated during early pregnancy, particularly before 16 weeks of gestation.

In our study, the incidence of pre-eclampsia in the aspirin group was 13.9% compared to 34.9% in the control group, with a statistically significant reduction in severe cases. This finding aligns with the landmark ASPRE trial, which demonstrated a 62% reduction in the incidence of preterm pre-eclampsia with the use of 150 mg aspirin initiated before 16 weeks of gestation in high-risk women (14). Similar outcomes were observed by Rolnik et al., who concluded that aspirin reduced the incidence of pre-eclampsia and improved neonatal outcomes such as birth weight and NICU admissions (15).

In terms of perinatal outcomes, our study found significantly fewer cases of preterm birth, low birth weight, and NICU admissions in the aspirin group. This is consistent with the findings of Meher et al., whose Cochrane review concluded that antiplatelet therapy, particularly low-dose aspirin, is associated with a 20% reduction in the risk of preterm birth and small-for-gestational-age infants in high-risk pregnancies (16). Furthermore, the Pakistani randomized controlled trial by Khanum et al. reported improved maternal and fetal outcomes, supporting the local relevance of aspirin in routine antenatal protocols for high-risk populations (17).

A key mechanism through which aspirin exerts its protective effect is the inhibition of platelet aggregation and the improvement of uteroplacental blood flow, mitigating placental ischemia—a central factor in the pathogenesis of pre-eclampsia (18). Our study's findings of improved blood pressure control and reduced proteinuria in the aspirin group reinforce this pathophysiological rationale and align with recent research from the region by Niaz et al., who reported similar hemodynamic benefits with early aspirin use in Pakistani women (19).

It is worth noting that although the reduction in stillbirths did not reach statistical significance, a trend toward better outcomes was observed. This is in line with a multicenter study in South Asia by Pasha et al., which suggested that broader implementation of aspirin use could potentially reduce maternal and perinatal deaths, particularly in resource-limited settings (20).

Despite the promising results, this study has certain limitations. The sample size was relatively small and restricted to a single tertiary care hospital, which may limit the generalizability of the findings. Additionally, compliance with aspirin intake was assessed through self-reporting, which could introduce bias. However, the randomized controlled design and adherence to strict inclusion criteria strengthen the reliability of the conclusions.

Overall, our findings support the early use of low-dose aspirin in high-risk pregnancies as a safe, cost-effective, and feasible intervention to reduce the burden of pre-eclampsia in Pakistan. The results advocate for the integration of aspirin into routine antenatal care protocols in high-risk populations, emphasizing early screening, timely initiation, and patient education to improve compliance.

Conclusion

This study confirms that low-dose aspirin, when initiated early in high-risk pregnancies, significantly reduces the incidence and severity of pre-eclampsia and improves perinatal outcomes. Incorporating aspirin into routine antenatal care for high-risk women can be a cost-effective strategy to reduce maternal and neonatal complications in Pakistan.

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-TCH-65451-24)

Consent for publication
Approved

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Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

MA (Medical Officer)
Manuscript drafting, Study Design,
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Conception of Study, Development of Research Methodology Design, Study Design, manuscript review, and critical input.
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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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