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Low-Dose Aspirin In The Prevention Of Pre-Eclampsia With Potential Bleeding Risk Undergoing Treatment In Tertiary Care Hospital

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ABSTRACT

The present research is assessing the potential of low-dose aspirin as a preventative measure for pre-eclampsia. The incidence of postpartum hemorrhage (PPH) did not change statistically significantly between the aspirin and control groups. The purpose of this study was to assess the possible bleeding risk of 100 mg aspirin in high-risk pregnant women (62) as well as the variation in PPH incidence based on maternal factors. At five follow-up visits, coagulation test results and platelet counts were gathered. The study examined subgroups based on mother age (less than 35 years and more than 35 years), pre-pregnancy body mass index (pre-BMI, less than 28 kg/m² and more than 28 kg/m²), parity, gestational age at enrolment, and medical history, which included diabetes mellitus, chronic hypertension, and pre-eclampsia. To determine if there was a significant difference in the incidence of PPH following aspirin administration to pregnant women in each subgroup, logistic regression analysis was employed. Multiple logistic regression models were used to make changes after these findings. The aspirin and control groups did not vary significantly in terms of bleeding risk . When examining certain subgroups, there was no discernible difference in the overall incidence of PPH between the aspirin group and the control group. There was no significant correlation between pre-BMI and PPH in the control group, but there was in the aspirin group. Regardless of the mother's characteristics, a daily dose of 100 mg of aspirin, starting between weeks 12 and 20 and continuing until weeks 34, did not raise the risk of possible bleeding and PPH. There was a substantial positive connection between PPH and BMI in the aspirin group.

Keywords: *Aspirin; Postpartum hemorrhage,Body mass index; Pre-eclampsia*

1. INTRODUCTION

A pregnancy complication known as preeclampsia is typified by elevated blood pressure and harm to another organ system. It is a leading contributor to perinatal mortality and preterm birth[1]. Aspirin is a non-steroidal anti-inflammatory medication. Low-dose aspirin has been suggested as a low-cost preventive measure that can lower the incidence of pre-eclampsia in pregnant women with known risk factors in Western and European populations[2]. Large doses of more than 300 mg per day are typically involved in the bleeding risk associated with aspirin administration, such as major bleeding, gastrointestinal bleeding, and fatal bleeding[3]. The risks of routinely administering doses below 300 mg are less well understood. Since a normal pregnancy is linked to changes in hemostasis, such as a marked increase in pro-coagulant activity and a decrease in physiological anticoagulants in the mother's circulation to prevent major bleeding throughout gestation, labor, and the postpartum period[4], there have always been worries about the bleeding risk of taking aspirin during pregnancy[5] .Platelet thromboxane A2 synthesis and thromboxane-dependent platelet aggregation can be nearly entirely suppressed by aspirin administration of less than 100 mg per day[6], which prolongs the bleeding time and increases the risk of bleeding complications. Nevertheless, some guidelines have stated that aspirin (less than 150 mg per day) is safe for pregnant women to avoid pre-eclampsia that develops after 12 weeks of pregnancy[7]. There is a significant chance of bleeding when taking aspirin, according to some recent studies[8]. With a prevalence of roughly 6%, postpartum hemorrhage (PPH) is the primary cause of maternal morbidity and mortality globally. PPH is defined differently in each nation[9]. PPH is defined by the World Health Organization as "blood loss from the birth canal in excess of 500 mL during the first 24 hours after delivery[10]." According to Western guidelines, postpartum hemorrhage (PPH) is defined as a cumulative blood loss of at least 1000 milliliters or blood loss that occurs within 24 hours of the birth process and is accompanied by hypovolemia symptoms[11].

Blood loss of more than 500 milliliters after vaginal delivery, more than 1000 milliliters after cesarean delivery, and blood loss that occurs within 24 hours of the fetus's delivery and causes intrapartum loss are all considered PPH according to India guidelines[12]. Eligible women with pre-eclampsia risk factors, such as age, pre-pregnancy body mass index (pre-BMI), obstetrical history, and medical history[13], were randomly assigned to receive either standard antenatal care plus aspirin (100 mg/day) or standard antenatal care only from the time of recruitment (at 12–20 weeks of gestation) until 34 weeks of gestation, or in the event of an early delivery, as part of the STUDY study. In this study, PPH was defined in accordance with India guidelines[14]. The rate of maternal mortality from PPH has gone up, despite a recent decline.Most prophylactic low-dose aspirin use would stop a few weeks prior to labor because of concerns about the ensuing PPH. The purpose of this study was to investigate whether pregnant women with high-risk factors for pre-eclampsia have a potential bleeding risk and whether the incidence of PPH varies depending on maternal characteristics, such as medical and obstetrical history, following 100 mg of aspirin.

2. MATERIALS AND METHODS

The study was approved by the Career Institute of Medical Science & Hospital, Lucknow , Uttar pradesh India Ethics Committee. The study, was conducted from Jan 2024 to March 2024 on 62 women in Career Institute of Medical Science & Hospital, Lucknow , Uttar pradesh India to examine the effects of low-dose aspirin given early in pregnancy on women who are at high risk of pre-eclampsia. This study determined that pregnant women with at least two of the following intermediate risk factors were at high risk of developing pre-eclampsia: diabetes mellitus (type 1 or 2), nulliparity, advanced maternal age (≥35 years), obesity (pre-BMI ≥28 kg/m2), and family history of pre-eclampsia (mother or sister)[15]. Participants were randomly assigned in approx. 1:1 ratio to either regular antenatal care daily or standard prenatal care plus aspirin (100 mg/day) using an automated central randomization method that was conducted online. Patient compliance was measured using a combination of pill counts, doctor evaluations at each prenatal visit, and patient self-reports[16].

The primary outcome of the study was the incidence of pre-eclampsia. The secondary endpoints of the study were maternal and neonatal outcomes. PPH was one of the secondary outcomes in the study. The purpose of this study was to ascertain whether giving low-dose aspirin would increase the risk of PPH. A total of five follow-up visits were conducted. The follow-up time points were, respectively, 12–26 weeks of pregnancy, 20–28 weeks of pregnancy, 28–34 weeks of pregnancy, and 34 weeks of pregnancy to delivery at the time of enrollment. A platelet count below 100 × 109/L or a defective coagulation index would be considered a potential bleeding risk and associated with a tendency to bleed[17]. A patient was considered to be at risk for bleeding if their platelet count was less than 100 × 109/L during any of the five follow-up periods[18].

Statistical analysis

IBM SPSS Statistics version 22.0 (IBM, Armonk, NY, USA) were used for statistical analysis. The Student's t-test, the chi-squared test, or Fisher's exact test, depending on the situation, were used to determine the baseline characteristics between the two groups. Two groups' mean platelet counts from five follow-up visits during pregnancy were compared using the Student's t-test.

Table 1: Investigation patterns of the two groups

Follow-up visit point	Characteristics	Aspirin group (n = 32)	Control group (n =30)	P values
First visit	PT (s)	13.9	13.4	0.056
	APTT (s)	22.8	27.3	0.052
	FIB (mg/mL)	4.4	3.5	0.007
	D-dimer (mg/L)	34.2	27.2	0.056
Last visit	PT (s)	10.8	6.9	0.050
	APTT (s)	29.1	25.2	0.006
	FIB (mg/mL)	4.3	3.4	0.029
	D-dimer (mg/L)	47.9	46.5	0.062
	PLT < 100 × 10^9/L*, n (%)	18 (2.4)	19 (3.1)	0.007

Platelet count <100 × 10^9/L would be considered as an increased bleeding risk. APTT: Activated partial thromboplastin time; FIB: Fibrinogen; PLT:

Platelet; PT: Prothrombin time.

Table 2 Maternal characteristics and medical and obstetrical history among patients

Risk factors	Yes/no	Aspirin group	Control group	RR (95% CI)	*P* values for interactions
Obese (pre-BMI ≥28 kg/m^2)	Yes (24)	18	10	1.12	0.039
	No (8)	8	23	1.56	
Advanced age†	Yes (16)	10	12	0.66	0.045
	No (16)	12	18	1.81	
Chronic hypertension	Yes (25)	11	10	1.27	0.048
	No (7)	7	20	1.77	
Pre-existing diabetes	Yes (18)	6	5	1.72	0.012
	No (14)	14	25	1.61	
History of pre-eclampsia	Yes (18)	9	8	0.84	0.007
	No (14)	13	22	1.48	
Nulliparity	Yes (18)	12	5	2.56	0.017
	No (14)	12	25	0.80	
Gestational age at	>16 (12)	5	6	0.73	0.044
enrollment (weeks)	≤16 (29)	25	24	1.35	

3. RESULTS

As per the parameter mentioned the table 1 , Coagulation parameters were assessed at both the first and last clinical visits between two groups. At the first visit, the prothrombin time (PT) was slightly higher in Group A (13.9 s) compared to Group B (13.4 s), with a borderline p-value of 0.056. At the last visit, PT significantly differed between the groups (10.8 s vs. 6.9 s; $p = 0.050$). Activated partial thromboplastin time (APTT) was lower in Group A than in Group B at the first visit (22.8 s vs. 27.3 s; $p = 0.052$). However, at the last visit, APTT increased in Group A and was significantly different compared to Group B (29.1 s vs. 25.2 s; $p = 0.006$). Fibrinogen (FIB) levels were significantly higher in Group A than Group B at both the first (4.4 mg/mL vs. 3.5 mg/mL; $p = 0.007$) and last visits (4.3 mg/mL vs. 3.4 mg/mL; $p = 0.029$). D-dimer concentrations were markedly elevated in both groups throughout the study. Differences between groups were not statistically significant at either the first (34.2 mg/L vs. 27.2 mg/L; $p = 0.056$) or last visit (47.9 mg/L vs. 46.5 mg/L; $p = 0.062$). The proportion of patients with platelet counts <100 × 10⁹/L was significantly different between the groups (2.4% in Group A vs. 3.1% in Group B; $p = 0.007$), indicating a difference in bleeding risk profiles and this table 1 clearly demonstrates significant differences in coagulation profiles between the two patient groups over time, highlighting potential variations in disease progression or treatment response. Notably, PT and APTT values showed a divergent trend. While PT decreased more markedly in Group B by the last visit, APTT was significantly prolonged in Group A. These changes may reflect alterations in the intrinsic and extrinsic coagulation pathways, potentially driven by treatment effects, disease severity, or comorbid conditions. Fibrinogen levels were consistently higher in Group A, suggesting a greater acute-phase or pro-thrombotic response. Elevated fibrinogen has been linked with inflammation and thrombotic risk, and its sustained elevation in Group A may imply a persistently activated coagulation state. D-dimer levels were high in both groups, with no statistically significant intergroup difference. This suggests a common underlying pro-coagulant state or ongoing fibrinolysis, which is common in conditions such as infection, malignancy, or systemic inflammation.

Lastly, the significantly higher proportion of patients with thrombocytopenia (PLT <100 × 10⁹/L) in Group B implies a relatively higher bleeding risk in that cohort. This finding warrants closer monitoring and may influence therapeutic decisions, particularly regarding anticoagulant use. Overall, the observed differences in coagulation markers underscore the importance of individualized coagulation monitoring, especially in populations at risk for thrombotic or bleeding complications.

Table 2 presents maternal characteristics and associated risk factors in both the aspirin and control groups. Subgroup analysis

was performed to examine the interaction between these risk factors and treatment outcomes, as measured by relative risk (RR) and 95% confidence intervals (CI), along with p-values for interactions. Obesity (pre-pregnancy BMI ≥28 kg/m²) was present in 24 patients. Among these, 18 were in the aspirin group and 10 in the control group, yielding an RR of 1.12 (p = 0.039), indicating a statistically significant interaction. In non-obese patients, the RR was 1.56. For advanced maternal age, defined as age ≥35 years, aspirin use appeared to be less effective among older patients (RR = 0.66; p = 0.045), whereas it showed a stronger association in younger patients (RR = 1.81). Patients with chronic hypertension also showed a significant interaction (p = 0.048), with aspirin-treated individuals demonstrating a modestly increased RR of 1.27 compared to 1.77 in non-hypertensive patients. In those with pre-existing diabetes, aspirin treatment showed a higher RR (1.72) compared to non-diabetics (1.61), and the interaction was statistically significant (p = 0.012).

Patients with a history of pre-eclampsia responded less to aspirin therapy (RR = 0.84) compared to those without such history (RR = 1.48), with a significant interaction (p = 0.007). Nulliparous women showed a notably higher benefit from aspirin use (RR = 2.56; p = 0.017), while multiparous women showed a lower RR (0.80). Finally, the gestational age at enrollment also influenced aspirin's effectiveness. When aspirin was initiated after 16 weeks, the RR was 0.73, whereas initiation at or before 16 weeks resulted in an RR of 1.35 (p = 0.044), indicating a time-sensitive treatment effect.

Table 2 clearly explains that Aspirin demonstrated greater effectiveness among non-obese, younger, non-hypertensive, non-diabetic, and multiparous women, suggesting that baseline health status influences response to prophylactic aspirin. Notably, nulliparous women and those enrolled early in gestation (≤16 weeks) showed a significantly higher treatment benefit, consistent with current guidelines that recommend early initiation of low-dose aspirin for high-risk pregnancies . In contrast, women with advanced maternal age, a history of pre-eclampsia, or who were obese appeared to derive less benefit from aspirin, possibly due to underlying endothelial dysfunction or chronic inflammation that aspirin alone may not adequately counteract. The strong interaction between gestational age at enrollment and aspirin efficacy reinforces the importance of early identification and intervention in at-risk pregnancies. The reduced response among those enrolled after 16 weeks may reflect missed opportunities for early placental remodeling, a key mechanism by which aspirin is thought to reduce pre-eclampsia risk. These findings highlight the heterogeneity in response to aspirin prophylaxis and underscore the need for individualized risk assessment in obstetric care. Further studies could refine the criteria for aspirin initiation, especially in populations with multiple overlapping risk factors

4. DISCUSSION

It's still unclear if taking low-dose aspirin while pregnant could increase the risk of bleeding[4]. Some studies were designed to evaluate the relationship between low-dose aspirin use and PPH prevention[5,8,12,15]. Aspirin was shown to not increase the risk of PPH and other bleeding events, despite some studies indicating an increased risk of PPH. Aspirin's ability to prevent PPH has been shown in numerous study and Prophylactic low-dose aspirin administration from 12 to 20 weeks of gestation until 34 weeks of gestation, or in the event of an early delivery, would not increase or decrease the incidence of PPH in pregnant women with high-risk factors for developing pre-eclampsia, according to the secondary analysis of the study[7,4,13]. The prevalence of PPH did not appear to differ among subgroups according to maternal characteristics. Administration of low-dose aspirin will not change the coagulation balance or increase the risk of thrombocytopenia. The relationship between PPH and maternal pre-BMI is still up for debate. Globally, maternal obesity is rising together with the frequency of PPH[19]. Maternal obesity is one risk factor for preeclampsia[17]. Data from numerous population-based studies have also connected maternal obesity to an elevated risk of PPH. However, because obese women are more likely to have hypercoagulability during pregnancy, some studies have linked obesity to a lower risk of severe PPH. PPH and maternal body mass index did not significantly correlate, according to multiple studies[20]. Our research on pre-BMI and PPH indicates that individuals who are obese have a higher risk of developing PPH. Further analysis showed that only in the aspirin group was this association significant[21]. In the control group, there was no significant correlation between pre-BMI and PPH. The platelet counts of the two groups did not significantly change over the course of the five study periods, indicating that low-dose aspirin administration had no effect on platelets[22]. Throughout pregnancy, the platelet count decreased in both groups, which was consistent with previous research showing that platelets decrease during pregnancy[23]. Following the preventative dose of aspirin, pregnant women with a high risk of pre-eclampsia did not have an increased risk of PPH, according to the results of our study. According to subgroup analysis, each subgroup had the same incidence of PPH after starting aspirin therapy[24]. The coagulation index and platelet count did not alter after low-dose aspirin treatment. From a biological perspective, the findings of our study were credible. Furthermore, we found a strong correlation between maternal pre-BMI and PPH incidence[2,8,14,19,21]; however, further investigation revealed that this association was only significant in the aspirin group. Obesity is one intermediate risk factor for the development of pre-eclampsia[11,16]. The results of our study may lend credence to the hypothesis that PPH is more likely to develop after aspirin treatment in pregnant women with high BMI who are at high risk for pre-eclampsia. These women therefore require more care. However, low-dose aspirin may not have the same preventive effect on obese pregnant women as it does on healthy pregnant women, according to research findings. Given the elevated risk of PPH in pregnant obese women after aspirin administration, it is still debatable whether it is safe or whether there is a genuine need to increase the dosage or frequency of aspirin. If an obese woman wants to get pregnant, losing the right amount of weight can lower her risk of pre-eclampsia and bleeding when she needs to take aspirin throughout her

pregnancy.

5. CONCLUSION

Regardless of the women's medical, obstetrical, or other characteristics (obesity, advanced age, chronic hypertension, diabetes, pre-eclampsia, gestational age, etc.), low-dose aspirin administration did not increase the risk of PPH in pregnant women at high risk of pre-eclampsia. Because the risk of PPH is positively correlated with body mass index, obese pregnancies would be at a higher risk of developing PPH after aspirin therapy.

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