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Original Research Article

Comparative Study between the Efficacies of 75 Mg Vs 150 Mg of Aspirin in Prevention of Preeclampsia in High-Risk Patients in GMCH

Manisha Paul[1], Tanma Saikia Das[2], Saswati Sanyal Choudhury[3]

[1]Post Graduate Trainee, Department of Obstetrics and Gynecology, Gauhati Medical College, Guwahati, Assam 781006

[2]Associate Professor, Department of Obstetrics and Gynecology, Gauhati Medical College, Guwahati, Assam 781006

[3]Professor, Department of Obstetrics and Gynecology, Gauhati Medical College, Guwahati, Assam 781006

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Corresponding Author: Dr. Manisha Paul

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Abstract:

Background: Preeclampsia is a significant complication of pregnancy characterized by hypertension and proteinuria, posing risks to both maternal and foetal health. Studies suggest that aspirin may play a preventive role in high-risk populations, particularly in women with a history of obstetric complications.

Objective: This study aims to compare the efficacy of two different doses of aspirin (75 mg vs. 150 mg) in the prevention of preeclampsia among high-risk pregnant women attending the Antenatal Outpatient Department at Guwahati Medical College and Hospital.

Methodology: A single-blind, two-armed, parallel randomized controlled trial was conducted over 18 months. The study enrolled 200 pregnant women, aged 18-43 years, in their 12 to 18 weeks of gestation, identified as high-risk through the Gestosis score, which evaluates 27 risk factors for hypertensive disorders. Participants were randomly assigned to receive either 75 mg or 150 mg of aspirin daily. Demographic data, obstetric history, and pre-pregnancy weight were collected, and mean arterial pressure was measured at baseline.

Results: 74% of people taking 75 mg prevented preeclampsia from developing compared to 86% in the 150 mg group, according to the study, with a statistically significant p-value of 0.034. The maximum incidence of preeclampsia was observed among primigravidae, with age extremes contributing to higher risk. The findings corroborate previous research on the comparative efficacy of aspirin dosages.

Conclusion: Both doses of aspirin demonstrated a preventive effect against preeclampsia, with the higher dosage exhibiting greater efficacy. These results support the use of aspirin as a preventative measure in high-risk pregnancies, emphasizing the importance of early intervention and tailored therapeutic approaches to improve maternal and fetal outcomes. Further studies are warranted to solidify these findings and refine dosage recommendations.

Keywords: Aspirin, Preeclampsia, High-risk pregnancy. Low-dose aspirin

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Introduction

Hypertensive disorders during pregnancy are a significant global contributor to maternal and newborn mortality. Preeclampsia is a pregnancy-related condition characterized by the onset of hypertension, which may occur with or without proteinuria. It typically arises after the 20th week of gestation and is often observed close to the delivery date. This condition includes a spectrum of hypertensive diseases in pregnancy, starting with gestational hypertension and progressing to more severe forms. [1] This condition leads to around 50,000 maternal fatalities, over 500,000 fetal fatalities, and contributes to 2% to 8% of pregnancy-related complications on a global scale [2] As of right now, it is thought that pregnancy-induced hypertension (PIH) progresses as follows: gestational hypertension with new onset of hypertension worsening with severe types of hypertensions with particular laboratory and clinical criteria. [3–5] However, rather than being founded on original research, the most current definitions supported by regulatory organizations like ACOG have mostly relied on expert opinion and consensus. [4,6] Preeclampsia is divided into two key subtypes: early-onset preeclampsia, which is placental in nature, and late-onset preeclampsia, which is maternal in nature. Both subtypes exhibit unique phenotypes and different underlying causes. [7] In terms of the early-onset variety, preeclampsia is thought to have developed as a result of a malfunctioning placenta.

Vascular sclerosis and several placental infarcts are seen upon examination of the preeclamptic placenta. Placental ischemia and hypoperfusion are associated with this because of altered trophoblast invasion. [8] In the second type a healthy placenta and maternal factors interact to induce maternal preeclampsia, which in turn causes microvascular damage. This could be due to endothelial dysfunction in mothers. The final stages of pregnancy are marked by maternal preeclampsia, which results in little to maintain the blood supply of the placenta and does not alter arterial conversion. [9]

The antiplatelet drug aspirin has been thoroughly investigated for its possible function in averting preeclampsia, especially in those who are at high risk. Its capacity to prevent the synthesis of thromboxane A2, which lowers platelet aggregation and increases uteroplacental blood flow, is thought to be the mechanism of action. [10] Several worldwide guidelines, such as those from NICE and ACOG, have suggested using aspirin at a modest dose to avoid preeclampsia. [11] [12]

Numerous research works have looked into the best aspirin dosage to avoid preeclampsia. Roberge et al. revealed that aspirin doses more than 100 mg/day were superior to lesser doses in terms of lowering the risk of preeclampsia, particularly when started prior to 16 weeks of gestation. [13]

The ideal dosage is still up for debate, though, as some research indicates that smaller doses-like 75 mg-might work as well as larger ones-like 150mg. [14]

There is still disagreement over the ideal dosage and when to start taking aspirin to prevent preeclampsia, despite the increasing amount of evidence in favor of this approach. This comparison study's objective is to ascertain which dose of aspirin is more beneficial in avoiding preeclampsia in high-risk individuals.

Materials and Methods

This study was a single-blind, two-armed, parallel randomized controlled trial conducted over a period of 1-and-a-half-year period starting from October 2022 to April 2024 at the Antenatal Outpatient Department (ANOPD) of Guwahati Medical College and Hospital (GMCH), Assam, India. The study enrolled 200 pregnant women aged 18-43 years attending ANOPD at GMCH.

Inclusion Criteria

The Gestosis score, a validated tool for assessing preeclampsia risk, was central to the study's inclusion criteria. This score comprises 27 risk factors for hypertensive disorders in pregnancy. Each factor is assigned a weighted score based on its relative importance. The scoring system was divided into mild risk factor (score 1), moderate risk factor (score 2) and severe risk factor (score 3).

Women with a Gestosis score > 3 were considered high-risk and included in the study. This cutoff was chosen based on previous research indicating a significantly increased risk of preeclampsia above this threshold.

Table 1: Gestosis Score

Gestosis Score (> Or =3 High Risk for Hypertensive Disorders of Pregnancy
Mild Risk Factors (Score 1)
1.Age older than 35yrs
2.Age younger than 19yrs
3.Maternal Anemia
4.Obesity (BMI >30)
5.Primigravida
6.Short duration of paternity(cohabitation)
7. Woman born as small for Gestational age
8. PCOS
9.Interpregnancy interval >5yrs
10.Conceived with ART(IVF/ICSI)
11.MAP>85
12.Chronic vascular disease (Dyslipidemia)
13.Execessive weight gain during pregnancy
14. Family history of cardiovascular disease
MODERATE RISK FACTORS(SCORE2)
1.Maternal hypothyroidism
2. Family h/o preeclampsia
3. GDM
4.Multiple pregnancy
5.Obesity (BMI>35)
6. Hypertensive disease during previous pregnancy
SEVERE RISK FACTORS(SCORE3)

1.Pregestational DM
2.Chronic Hypertension
3.Mental disorder
4.Inherited/acquired Thrombophilia
5.Maternal chronic kidney disease
6. Autoimmune disease (SLE/APLAS/RA)
7.Pregnancy with ART (OD or Surrogacy)

Procedure

Eligible participants were assigned at random to either 150 mg or 75 mg of aspirin every day using a computer-generated sequence. The intervention began at 12-18weeks of gestation and lasted until the 36th week of pregnancy. Following enrolment, the women were randomly assigned to two groups each containing 100 patients: one group was given 150 mg of aspirin daily at bedtime, while the other group received 75 mg. Opaque sealed envelopes with sequential numbers (SNOSE) were used for allocation concealment. Participants were instructed to select an envelope in the order of enrolment after a unique code was put in the SNOSE, and the appropriate dosage of aspirin was then administered. During the 36- week period beginning with enrolment, at bedtime, each patient was instructed to consume one capsule. Up to delivery, patients were observed, and the outcomes were recorded.

Baseline demographic and clinical data were collected at enrolment. Regular follow-ups were conducted throughout pregnancy. The institutional ethics committee at GMCH gave its approval to the study protocol. Written informed permission was acquired by each subject.

Table 2: Characteristics of included women in the present study

	150 mg aspirin (n=100)	**75 mg aspirin (n=100)**
Age (mean ± SD)	30.68 ± 5.5	29.72 ± 6.7
Weight of body (mean ±SD)	60.88 ± 7.9	60.74 ± 9.3
Methods of conception		
Spontaneous	83	88
IVF	17	12
Obstetrics history		
Nullipara	38	35
Multipara	62	65

Study outcome

Preeclampsia and its frequency in each of the two groups was the main outcome. The development of proteinuria (urine protein 2+ by dipstick technique) and gestational hypertension (BP more than or equal ʊ140/90 mm Hg) at more than or equal to 20 weeks was used to diagnose preeclampsia in the vulnerable group. A comparison of the feto-maternal outcomes in the form of IUGR babies, stillborn at two different dosages, age distribution versus development of preeclampsia, parity with the highest incidence of preeclampsia were the secondary results.

Statistical analysis

After being coded, the collected data was input into a Microsoft Excel worksheet (version 2021). Frequency and proportion (percentage) were used to express categorical data. Mean and standard deviation represented numerical data. The Fisher/ Chi-square test was used for data analysis. IBM-SPSS version 25 was used to do the analysis for the variables.

For statistical significance, a p-value of less than 0.05 was used. The treatment effect was quantified as the relative risk (RR) with a 95% confidence interval (CI).

Results

In my study, a total of 200 pregnant patients of 12 to 18 weeks of gestation were selected randomly and were splitted equally into two halves, each containing 100 patients. Each group received 75mg and 150mg of aspirin respectively.

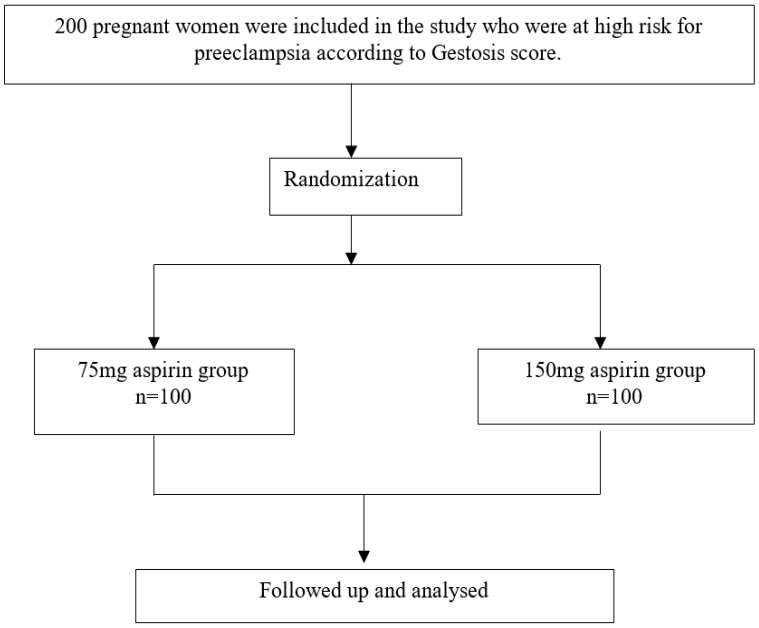

Figure 1: Flow chart of randomization

Data were analyzed as mean, standard deviation (SD), frequency and percentage whenever appropriate. Comparison of the different variables between the study groups was done using t test (for independent samples in case of continuous data) and $\chi 2$-test. For smaller values, Fisher's exact test was used. There were no significant differences between the 75mg and 150 mg aspirin group in regard to the characteristics at the baseline as shown in the table no 3.

Table 3: Characteristics of the study population at baseline and their distribution

	75mg aspirin group	150mg aspirin group	p-value
Age (mean±SD) in years	30.86±6.82	31.24 ±5.54	0.66
Obstetric history			
Nullipara	35	38	0.94
Multipara	65	62	
Pre pregnant bodyweight (mean±SD) in kg	60.65±9.31	60.97± 8.02	0.79
Haemoglobin level (mean±SD) in g/dl	9.70± 0.91	9.75± 0.78	0.70
Diabetes mellitus			0.81

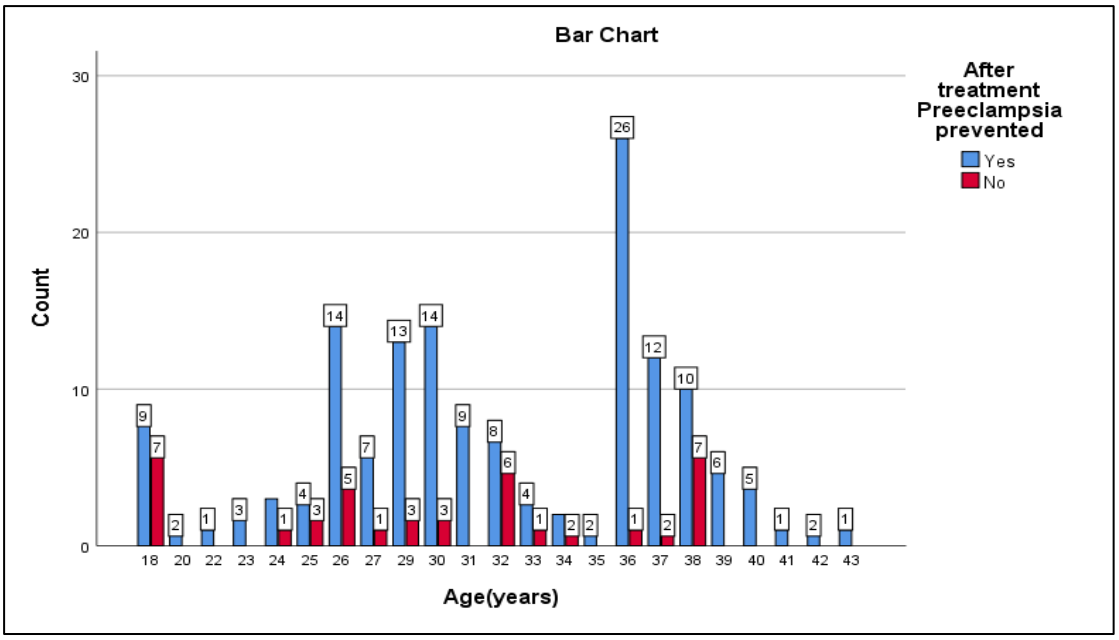

Figure 2: Bar Diagram showing the distribution of the preeclampsia cases in relation to various age.

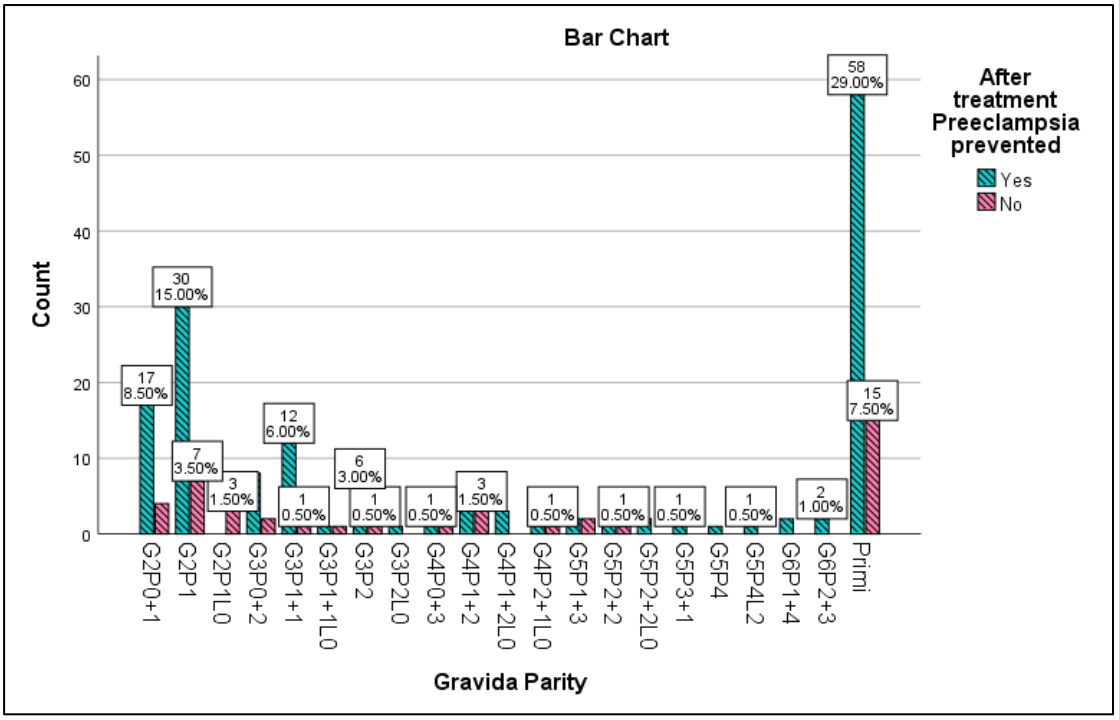

Figure 3: The distribution of the study population in relation to various obstetric history and Prevention of preeclampsia

Table 4: The distribution of the study population in relation to various obstetric history and Prevention of preeclampsia

Development of preeclampsia	75mg aspirin group	150mg aspirin group	p-value
	26%	14%	0.034
Mild preeclampsia	2%	8%	0.0001
Severe preeclampsia	24%	6%	

The incidence of preeclampsia among the individuals of 75mg aspirin study group was 26% and that among the 150mg aspirin group was 14%. The incidence of mild preeclampsia was 2% in the group receiving 75mg aspirin and it was 8% in the group receiving 150mg aspirin. The incidence of severe preeclampsia was 24% among the individuals receiving 75mg aspirin and it was 6% among the individuals receiving 150mg aspirin.

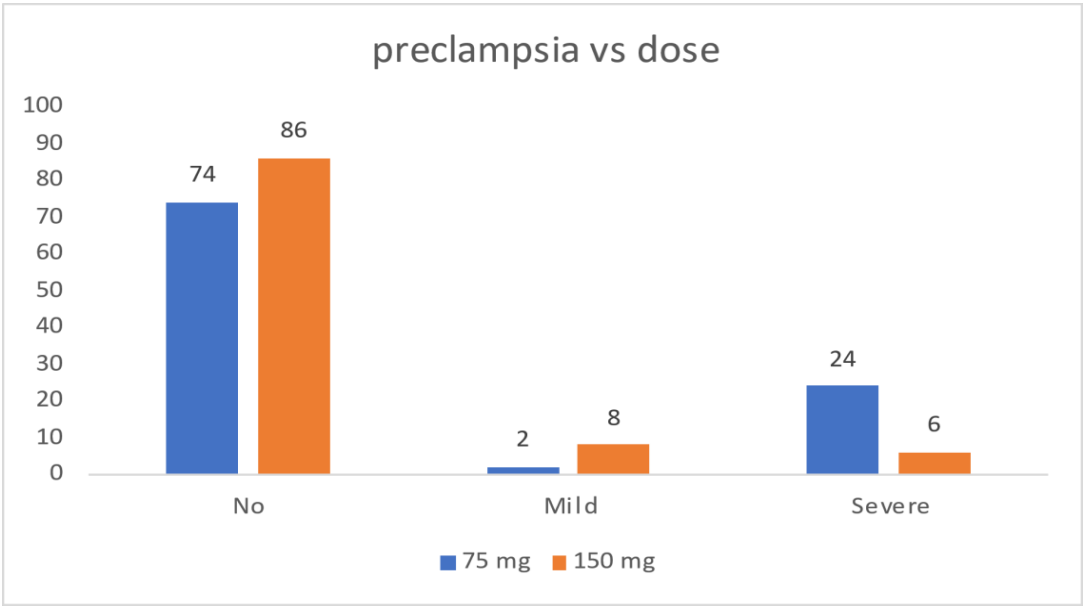

Figure 4: Shows the distribution of mild and severe preeclampsia in 75mg and 150 mg aspirin group

There were significantly higher values of MAP in those women who developed preeclampsia eventually as compared to those who did not in both the study groups.

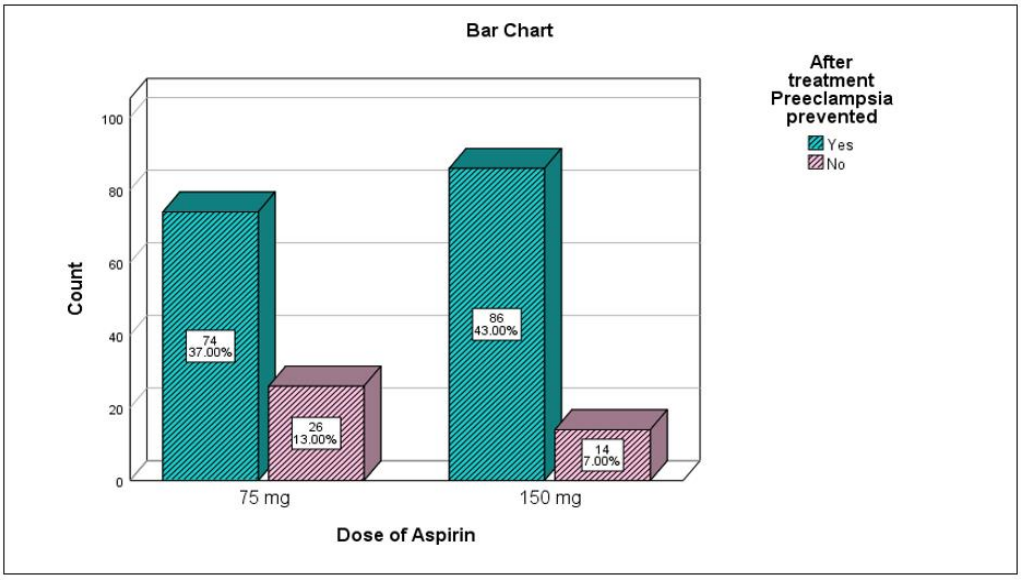

Figure 5: Doses of aspirin and their efficacies in preeclampsia prevention

Table 5: Comparison of fetal outcomes between the study groups

	75mg aspirin group	150mg aspirin group	p-value
Preeclampsia			
Healthy baby	2	0	<0.05
IUGR	13	5	
Stillborn	1	1	
NICU admission	10	8	
No Preeclampsia			
Healthy baby	54	47	<0.05
IUGR	13	29	
Stillborn	0	0	
NICU admission	7	10	

Fetal outcomes were observed in both the groups of women, and there was statistically significant difference between the two study groups as shown in the table mentioned above.

Discussion

The present study aimed to evaluate the efficacy of two different dosages of aspirin (75 mg and 150 mg) in the prevention of preeclampsia in high-risk pregnancies determined by Gestosis score. The results indicated that 74% of participants in the 75 mg group and 86% in the 150 mg group were able to prevent the development of preeclampsia, with a statistically significant p-value of 0.034. These findings align with previous studies that highlight the benefits of higher aspirin doses in mitigating the risks of preeclampsia. For instance, Bushra et al. (2019) reported an efficacy of 78.3% for the 75 mg group and 90% for the 150 mg group (p-value = 0.013), demonstrating similar trends [15]. Kumar et al. (2020) found that 66.7% of participants in the 75 mg group and 90.2% in the 150 mg group were protected against preeclampsia, with a highly significant p-value (<0.001) [16]. These results collectively suggest a consistent advantage of the 150 mg dosage over 75 mg in preventing preeclampsia.

Additionally, the current findings mirror those of Abdi et al. (2020), who observed notable differences in diastolic blood pressure (DBP) pre- and post-treatment among those receiving different doses of aspirin [17]. The present study also noted that the incidence of severe preeclampsia was significantly lower in the 150 mg group (6%) compared to the 75 mg group (24%) with a p-value of 0.0001, reinforcing the notion that higher doses are linked to better maternal outcomes. This aligns with prior evidence suggesting an increased efficacy of higher aspirin doses, particularly in women with risk factors for preeclampsia.

Furthermore, the study identified that most patients who developed preeclampsia were primigravidae, consistent with findings from Faiza et al. (2023), where primigravidae constituted 76% of eclampsia cases [18]. This highlights an important demographic trend that may warrant targeted interven-

tions in future clinical practice. The ASPRE trial focused on the effect of low-dose aspirin in high-risk pregnant individuals to prevent preeclampsia. Preterm preeclampsia occurred in 1.6% of participants in the aspirin group compared to 4.3% in the placebo group. It indicated that aspirin could significantly reduce the incidence of preterm preeclampsia, especially among nulliparous women. The ASPRE trial supports the present study's findings regarding aspirin dosage, affirming the effectiveness of 150 mg daily to reduce preeclampsia risk, particularly in higher-risk groups [19].

Rahmawati Hamzah et al. found that primiparous women aged between 14 and 28 were at significantly higher risk for preeclampsia (1.581 times more likely), while older mothers presented a different risk profile. In line with findings in the current study, the analysis showed prevalence linked to ages and primiparity which aligned with previous findings from other studies [20].

U.S. Preventive Services Task Force (USPSTF) study, the 2021 recommendation stated that low-dose aspirin is effective in reducing the risks of preeclampsia and its associated morbidities and mortalities in women identified as being at high risk [21]. This underscores the importance of aspirin as a preventive measure, aligning with findings from various studies, including the present one that emphasizes early and tailored therapeutic approaches to enhance maternal and fetal health.

Both studies advocate for the utility of low-dose aspirin in high-risk pregnancies, demonstrating similar outcomes in improving fetal health and reducing complications like preeclampsia. The findings encourage further research to refine dosage recommendations and treatment protocols to optimize health outcomes for mothers and their babies.

Comparison with Other Studies

In summary, the efficacy of aspirin in preventing preeclampsia, as demonstrated in this study, is consistent with the literature:

75 mg Aspirin Group

- Present Study: 74% efficacy (p = 0.034)
- Bushra et al. (2019): 78.3% efficacy (p = 0.013)[15]
- Kumar et al. (2020): 66.7% efficacy (<0.001)[16]

150 mg Aspirin Group

- Present Study: 86% efficacy (p = 0.034)
- Bushra et al. (2019): 90% efficacy (p = 0.013) [15]
- Kumar et al. (2020): 90.2% efficacy (<0.001)[16]

Severe Preeclampsia Rates

- Present Study: 24% (75 mg), 6% (150 mg); p = 0.0001

- Kumar et al. (2020): 10.3% (75 mg), 2.1% (150 mg); p = 0.051[16]

These comparative analyses substantiate the advantages of aspirin, especially in higher doses, for patients at risk of preeclampsia. Future research should seek to expand sample sizes and explore the long-term implications of these treatment regimens.

Conclusion

In conclusion, this comparative study evaluated the efficacy of two aspirin dosages, 75 mg and 150 mg, in preventing preeclampsia among high-risk pregnant women at Gauhati Medical College and Hospital. Our findings affirm that higher doses of aspirins, particularly 150 mg, significantly reduce the incidence of preeclampsia compared to the lower dosage. The results demonstrated a clear advantage for the 150 mg group, with a notable improvement in maternal outcomes alongside comparable safety profiles. The study highlights the critical role of early intervention in high-risk pregnancies and supports the growing body of evidence advocating for targeted aspirin therapy. The mechanism by which aspirin may mitigate the risk of preeclampsia through enhanced uteroplacental blood flow reinforces the need for ongoing research to optimize prophylactic strategies.

These findings contribute to existing guidelines and clinical practices concerning preeclampsia prevention and underscore the importance of individualized care based on risk assessment. Future studies with larger populations and diverse demographics are recommended to validate these findings and further elucidate the optimal dosage and timing for aspirin administration in pregnant women at risk of developing preeclampsia.

Limitations

While the results are promising, it is pertinent to note certain limitations, such as the study's modest sample size, single centered study and the lack of long-term follow-up after delivery, which would be critical for assessing the prolonged effects of aspirin treatment.

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