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The Effect of Two Doses of Aspirin in Prevention of Preeclampsia in High-Risk Pregnant Women: A Clinical Trial

Masoumeh Mirzamoradi[1], Hoda Etemadzadeh[1*], Marzieh Jamali[2], Razieh Jamali[2], Zahra Salehi[1], Kyana Jafarabady[3], Saeed Sohrabpour[4]

1. *Department of Obstetrics and Gynecology, Mahdieh Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran*
2. *Department of Medicine, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran*
3. *Department of Medicine, School of Medicine, Alborz University of Medical Sciences, Karaj, Iran*
4. *Department of Otolaryngology, Otorhinolaryngology Research Center, Tehran University of Medical Sciences, Tehran, Iran*

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Corresponding Information:
Hoda Etemadzadeh,
Department of Obstetrics and Gynecology, Mahdieh Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran
Email: hodaetemadzad@yahoo.com

ABSTRACT

Background & Objective: Nowadays, low-dose aspirin is frequently used to prevent preeclampsia, which is a serious risk factor for adverse maternal and neonatal outcomes. However, the optimal dosage remains unclear. This study was conducted with aim to compare the effect of 80 mg and 120 mg daily doses of aspirin in prevention of preeclampsia in high-risk pregnant women.

Materials & Methods: This open-labeled randomized clinical trial was conducted on high-risk pregnant women at 12-16 weeks of gestation. They were assigned to three groups: control, aspirin 80 mg, and aspirin 120 mg. Treatment continued until 36 weeks of gestation and adverse pregnancy outcomes were monitored until delivery.

Results: The incidence of preeclampsia in the control group (33%) was significantly (P<0.001) higher than in the aspirin 80 mg (22%) and aspirin 120 mg (17%) groups. However, there was a significantly higher proportion of severe preeclampsia cases with aspirin 120 mg. The frequency of intrauterine growth restriction and preterm labor did not differ significantly among the groups. The most common causes of preterm labor were multiple gestation and spontaneous delivery, with severe preeclampsia accounting for only 11% of cases. There were no significant differences in maternal and neonatal measurements upon delivery. Side effects associated with the use of aspirin were negligible.

Conclusion: Daily use of aspirin with doses of 80 mg or 120 mg before the 16th week of gestation in high-risk women reduces the incidence of preeclampsia to a similar extent. As such, 80 mg daily aspirin appear to be sufficient for prevention of preeclampsia in high-risk women.

Keywords: Pre-eclampsia, Prevention, Aspirin, Pregnancy

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1. Introduction

Preeclampsia is one of the concerning pregnancy complications, which is characterized by high blood pressure and proteinuria typically after 20th week of gestation **(1,2)**. Prevalence of preeclampsia varies widely between different countries. In the United States, the reported prevalence is 3.4% **(3)**, while in Iran, it is reported to be 5% **(4)**. The disorder poses a significant risk to maternal and child health, with more than 70,000 maternal deaths per year worldwide **(5)**.

Currently, there is no definitive treatment for preeclampsia and termination of pregnancy is often the only option. However, in cases of preterm preeclampsia, expectant therapy may lead to better maternal and fetal outcomes **(6)**. Since there is no definitive treatment for preeclampsia other than pregnancy termination, the use of preventive measures is emphasized. Low-dose aspirin has been found to be effective to prevent preeclampsia in high-risk women **(7-12)**, and various doses ranging from 50-150 mg have been investigated in previous studies. The American college of obstetrics and gynecology (ACOG) currently recommends the administration of low-dose aspirin (81 mg) daily for high-risk patients with preeclampsia **(13)**. However, according to some studies, higher doses are associated with stronger effects in reducing the incidence of preeclampsia **(10,12,14,15)**. Therefore, the proper dose used for this

purpose is still controversial. Since a small number of studies have investigated the effects of different doses of aspirin, the present study was conducted with aim to compare the effectiveness of two different doses of aspirin (80 mg and 120 mg daily) in the prevention of preeclampsia in high-risk pregnant women.

2. Materials and Methods

This open-labeled randomized clinical trial study was conducted on high-risk pregnant women with a gestational age between 12 and 16 weeks who were referred to an academic tertiary care hospital (Mahdieh) in Tehran in 2018-2019. The inclusion criteria were pregnant women aged≥18 years with a high risk of developing preeclampsia **(13)** due to multiple gestation, chronic hypertension, type one or two diabetes mellitus, chronic kidney disease, antiphospholipid syndrome, systemic lupus erythematosus, and/or a history of preeclampsia with adverse outcomes in previous pregnancies. Additionally, a viable fetus had to be present at the time of enrollment. Patients were excluded if they had coexisting heart, liver, or thyroid diseases, coagulopathies, peptic ulcer, asthma, aspirin allergy, major fetal disorders detected during referral, or if they were long-term nonsteroidal anti-inflammatory drug (NSAID) users.

All participants were informed about the objectives of the design and of the study, and written consent was obtained.

Using the random number table, the eligible pregnant women were assigned into one of three groups: the control group who did not receive aspirin, and two treatment groups that received either 80 mg or 120 mg of aspirin daily. Patients were advised to take the medication regularly at bedtime. Treatment continued until the 36th week of gestation.

Patients were monitored monthly until the 28th week of gestation, and then every two weeks until delivery. During each visit, blood pressure was measured, and patients were asked about medication use and side effects, including gastrointestinal symptoms such as heartburn, nausea, gastritis, gastrointestinal bleeding, and rash, as well as vaginal bleeding. Adverse outcomes including preeclampsia, intrauterine growth retardation (IUGR), and preterm labor were documented and treated. At delivery, data regarding gestational age, delivery mode, and neonatal characteristics such as gender, weight, and 5-minute Apgar score were also recorded.

The patients' demographic characteristics, including maternal age, race, education, Body Mass Index (BMI), obstetric history (primiparous or multiparous), and risk factors for preeclampsia (e.g., multiple gestation, hypertension, diabetes, autoimmune disease, chronic kidney disease) were collected using paper-based questionnaires at the beginning of the study. Systolic and diastolic blood pressure were also recorded.

Data was analyzed using SPSS software (version 24.0). Data were primarily assessed using descriptive statistics, including frequency, percentage, mean, and standard deviation. Incidence of preeclampsia throughout the pregnancy among the study groups was further analyzed using logistic regression models adjusted for risk factors of preeclampsia and confounding effects. Time-to-event analysis and its results are presented as Kaplan-Meier time-to-failure graphs. $P<0.05$ was considered statistically significant.

3. Results

The study enrolled a total of 780 women, of whom 16 in the control group, 17 in the aspirin 80 mg group, and 13 in the aspirin 120 mg group gave birth in another center at the end of the study. Additionally, two cases of Intrauterine Fetal Death (IUFD) were observed in the control and aspirin 80 mg groups and one case in the aspirin 120 mg group, all of whom were excluded from the study. Therefore, 729 participants (243 in each group) were included in the statistical analysis (Figure 1).

The mean age of the women was 32±6 years, with a range of 18 to 50 years. Most of the participants (67%) were of Iranian origin, while the rest (33%) were of Afghan descent. Moreover, 61% of the participants had a high school diploma or higher degree and 58% had obesity grades I to III (BMI>30 Kg/m^2). Primiparity was found in 30% of the women. The mean systolic and diastolic blood pressure at baseline were 125±10 mmHg and 79±6 mmHg, respectively. There were no significant differences among the groups regarding demographic characteristics, primiparity (P=0.672), and systolic (P=0.420) and diastolic (P=0.329) blood pressure at baseline (Table 1).

The type of delivery was cesarean section in 585 women (80%) and the most common cause was repeated cesarean section. Concerning gestational age at delivery, most of the deliveries occurred at≥37th week of gestation. There was no significant difference among the studied groups regarding type of delivery (P=0.834), cause of cesarean section (P=0.420), and gestational age at delivery (P=0.807). Overall, 877 neonates were born, including 462 boys (53%) and 415 (47%) girls. The mean weight of neonates was 2705±740 gr; also, 776 neonates (89%) had a fifth minute Apgar score of 9 out of 10. There was no significant (P>0.005) difference between the studied groups in terms of neonatal characteristics (Table 1).

IUGR occurred in 90 patients (12%), which was not significantly (P=0.078) difference between the groups. Preterm labor occurred in 254 women (35%), of which 60 cases (25%) were early (less than 34 weeks). The most common causes of preterm labor were multiple gestation and spontaneous delivery. There was no

significant difference between the groups in terms of the frequency of preterm labor (P>0.679) and its timing (P>0.505). However, concerning the cause of preterm labor, the frequency of severe preeclampsia and multiple gestations were significantly higher in the control group than in the two aspirin groups (Table 2).

Incidence of preeclampsia in the control group (33%) was significantly (P<0.001) higher than in the aspirin 80 mg (22%) and aspirin 120 mg (17%) groups. The frequency of preeclampsia was significantly higher in the control group compared to the two aspirin groups, corresponding to lower odds of developing preeclampsia in 80 mg (OR:0.47, 95%CI:0.30-0.75) and 120 mg (OR:0.44, 95%CI:0.28-0.71) aspirin groups (Table 3).

However, there was no difference between 80 mg and 120 mg aspirin for prevention of preeclampsia (OR: 0.94, 95CI:0.57-1.55, P=0.820). Furthermore, there was a significantly higher proportion of severe cases in the 120 mg aspirin group (OR: 3.59, 95%CI:1.31-9.87) (Figure 2).

Table 1. Baseline data and Delivery and Neonatal characteristics

Parameters	Control group (n=243)	Aspirin 80 group (n=243)	Aspirin 120 group (n=243)	P-value
Age, year	30±6	32±6	32±6	0.104
Iranian Race	158(65%)	154(63%)	173(71%)	0.157
BMI, Kg/m2				
18.5-25	28(12%)	23(10%)	38(16%)	0.115
>25	215(88%)	220(90%)	205(84%)	
Primiparous	69(28%)	73(30%)	78(32%)	0.672
Systolic blood pressure	125±10	124±9	125±10	0.420
Diastolic blood pressure	80±6	79±5	79±7	0.329
Gestational age at delivery				
< 37 weeks	18(8%)	20(8%)	23(10%)	0.807
37 week or higher	161(66%)	154(64%)	161(66%)	
Cesarean section	194(80%)	193(79%)	198(82%)	0.834
CS due to Fetal distress	26(13%)	35(18%)	30(15%)	0.420
Male Neonatal sex	161(53%)	154(54%)	147(50%)	0.609
Neonatal Weight, g	2729±716	2681±765	2704±743	0.739
5th minute Apgar score of 9 out of 10	278(92%)	250(88%)	248(85%)	0.170

Table 2. Crude report of pregnancy endpoints

Pregnancy endpoints		Control group (n=243)	Aspirin 80 group (n=243)	Aspirin 120 group (n=243)	P-value
Preeclampsia		81(33%)	53(22%)	41(17%)	<0.001
Severity	Mild	70(86%)	40(76%)	29(71%)	0.089
	Severe	11(14%)	13(24%)	12(29%)	
Time	Early (<34w)	8(10%)	8(15%)	10(24%)	0.104
	Late (>=34w)	73(90%)	45(85%)	31(76%)	
IUGR		28(12%)	39(16%)	23(10%)	0.078
Preterm labor		82(34%)	90(37%)	82(34%)	0.679
Time	Early (<34w)	17(21%)	20(22%)	23(28%)	0.505
	Late (>=34w)	65(79%)	70(78%)	59(72%)	
Cause	Multiple gestation	38(46%)	29(33%)	31(38%)	0.014
	Spontaneous	16(20%)	34(38%)	21(25%)	
	Vaginal leak	14(17%)	18(20%)	22(27%)	
	Severe preeclampsia	13(16%)	7(7%)	8(10%)	
	Others	1(1%)	2(2%)	0(0%)	

Table 3. Multivariate adjusted analysis for incidence and severity of preeclampsia

Incidence of preeclampsia (n=175)			Severity of preeclampsia (n=36)		
Model variables	**Odds ratio and 95% CI**	**P-value**	**Model variables**	**Odds ratio and 95% CI**	**P-value**
Group allocation			**Group allocation**		
80mg Aspirin	0.47(0.30-0.75)	0.001	80mg Aspirin	2.05(0.80-5.26)	0.131
120mg Aspirin	0.44(0.28-0.71)	0.001	120mg Aspirin	3.59(1.31-9.87)	0.013
120mg vs 80mg Aspirin	0.94(0.57-1.55)	0.820	BMI	1.03(0.96-1.10)	0.430
Age	1.05(1.02-1.09)	0.001	HTN	2.95(0.48-18.06)	0.241
BMI	1.04(1.00-1.08)	0.014	DM	3.71(0.36-37.78)	0.269
Gravity	0.94(0.76-1.17)	0.580	Multiple pregnancy	3.09(0.69-13.80)	0.140
Parity	0.94(0.69-1.28)	0.708	Nulliparity	3.34(1.40-7.97)	0.007
Abortion	1.40(0.93-2.11)	0.106			
HTN	3.95(1.62-9.62)	0.002			
Multiple pregnancy	1.42(0.61-3.29)	0.414			
Diabetes mellitus	0.76(0.27-2.18)	0.615			
Autoimmune disease	1.35(0.26-7.11)	0.723			
History of preeclampsia	1.87(1.22-2.86)	0.004			

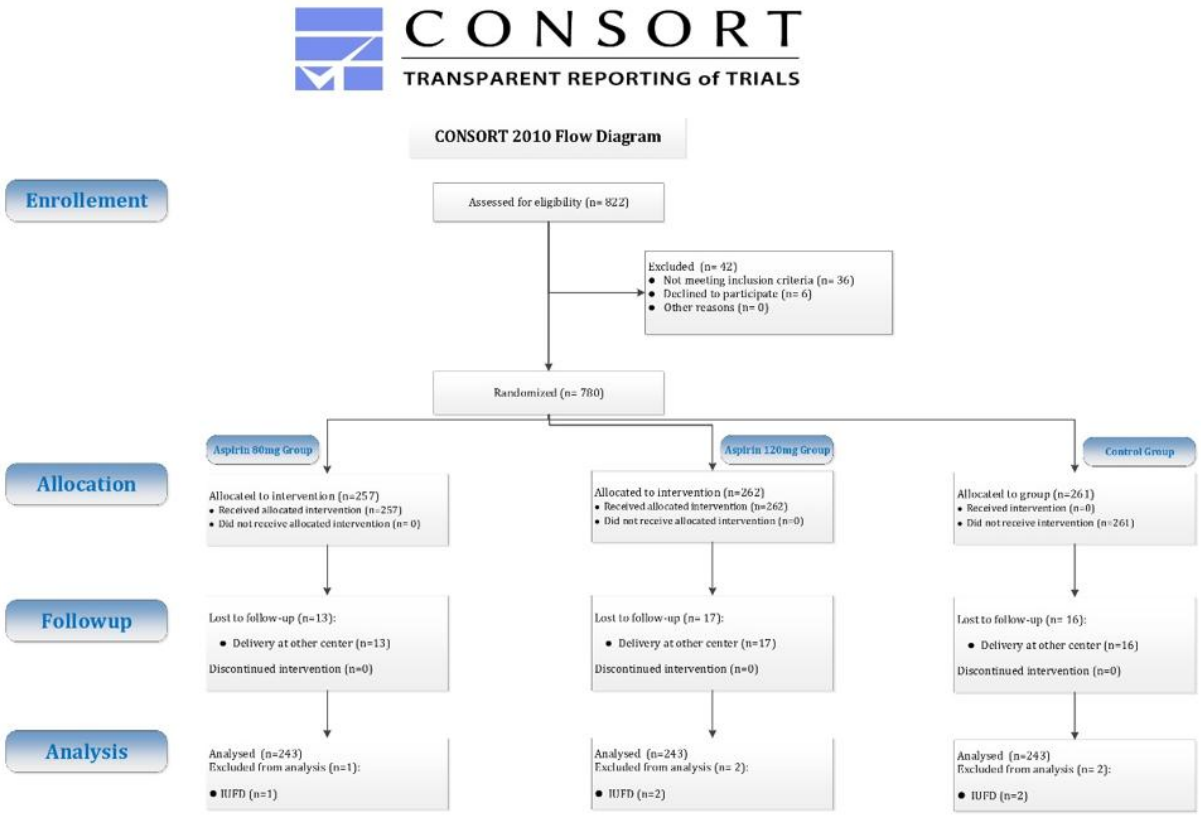


Figure 1. **Study consort algorithm**

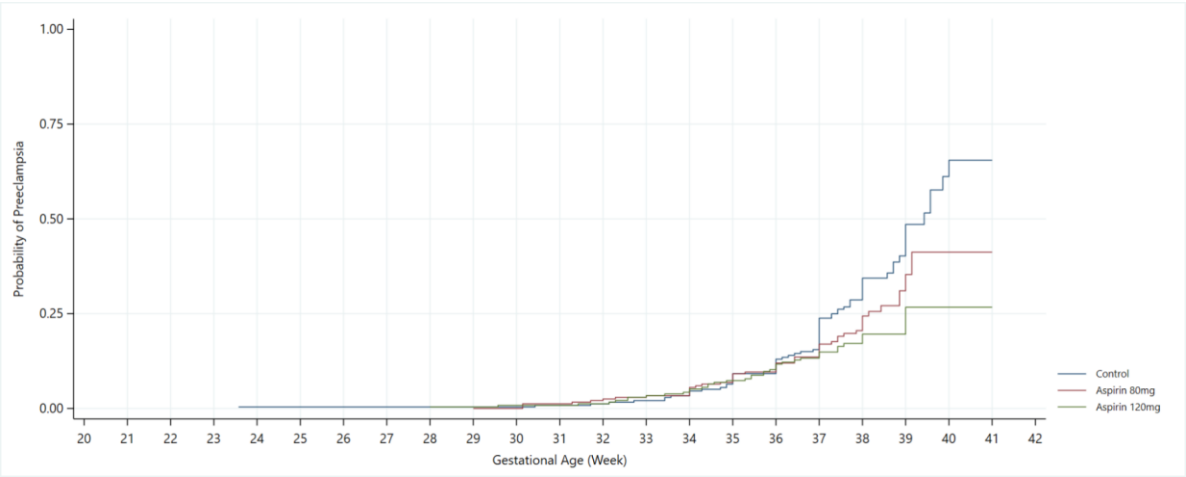


Figure 2. **Kaplan-Meier failure curve demonstrating time-to-development of preeclampsia in each study group**

Moreover, 13 cases (3%) of aspirin-related side effects occurred in the two aspirin groups, all of which were mild gastrointestinal discomfort that improved without specialized treatment. Of these, 8 cases (3%) occurred in the aspirin 80 mg group and 5 cases (2%) in the aspirin 120 mg group, and there was no significant difference between the two groups (P=0.339). Overall, mild vaginal spotting occurred in 26 cases (4%), all in the second trimester, which did not lead to preterm labor and only improved with supportive care. Of these, 19 cases (8%) occurred in the aspirin 80 mg group, 5 cases (2%) in the aspirin 120 mg group, and 2 cases (1%) in the control group. The incidence of mild vaginal spotting was significantly higher in the aspirin 80 mg group (P=0.003). There were no cases of severe bleeding or placental abruption

4. Discussion

As evidenced by the results of the present study, the prevalence of preeclampsia in all the studied women was 24%, and it was severe in 36 patients (21%) and early in 26 patients (15%). The prevalence of preeclampsia in the control group was higher than that in the aspirin 80 mg and aspirin 120 mg groups, but there was no difference between the groups in terms of severity and timing. The frequency of preterm labor and IUGR did not differ significantly between the studied groups. The side effects of aspirin were also minor.

Numerous studies have investigated the effect of low-dose aspirin on the incidence of preeclampsia in high-risk women, and most of them have noted its beneficial effects. Our study also showed that aspirin use was associated with a reduction in preeclampsia. However, the appropriate dose is still controversial. Chiaffarino et al., reported that a brief desirable effect on the prevention of preeclampsia or IUGR was achieved after the administration of aspirin 100 mg in pregnant women at risk of gestational hypertension. However, only 16 patients received aspirin and preeclampsia occurred in five cases (31%), which was not significantly different from the control group **(16)**. Ruano et al., studied the prevention of preeclampsia using low-dose aspirin in a systematic review of 22 studies (5 trials in low-risk women and 17 trials in high-risk women). Different doses of aspirin ranging from 50-60 mg to 150 mg had been used in the reviewed studies. They reported that the prevalence of preeclampsia was 3.75% in the low-risk group, 0.91% in the high-risk group, and 6.40% in all the patients. Moreover, low-dose aspirin did not have a significant effect on the incidence of preeclampsia in the low risk group, but it had a small positive effect in the high risk group. They also stated that the different doses had no relationship with the incidence of preeclampsia **(17)**.

Bakhti and Vaiman in 2011 reported the desirable effect of aspirin at a daily dose of 100 mg on improving the outcome of blood pressure disorders in pregnant women. As they reported, aspirin use increased gestational period by an average of 12 days and resulted in more weight gain in neonates. However, most women were experiencing their first pregnancy, and the patient and the researcher were not blinded **(7)**.

Ayala et al., in 2013 reported that low-dose aspirin not only had a small effect on the incidence of preeclampsia but also reduced the incidence of preterm labor and IUGR. In addition, aspirin at a daily dose of 100 mg should be used before the 16th week of gestation as a minimum dose to prevent hypertensive pregnancy complications **(18)**. Henderson et al., in a review study in 2014 reported that daily low-dose aspirin started early in the second trimester can prevent the negative consequences of pregnancy and, depending on underlying risks in patients, it can reduce the risk of preeclampsia by 24%, IUGR by 20% and preterm labor by 14% **(19)**. The present study also showed a reduction in the incidence of preeclampsia as

the result of the administration of aspirin, but there was no significant difference between the studied groups in terms of IUGR or preterm labor. The observed difference may be attributed to the differences in the method of selecting the patients. For example, in our study, about one-fifth of the patients had multiple gestations, which accounted for one-third of all cases of preterm birth.

In a review and meta-analysis in 2016, Bergeron et al., reported the effect of low-dose aspirin on the prevention of preeclampsia in women with multiple gestations; apparently, the administration of low doses aspirin in women with multiple gestations reduced the risk of preeclampsia in general and mild forms but not in severe forms **(11)**. This result was also reflected our results with significantly higher proportion of severe preeclampsia cases with 120 mg aspirin.

In a review study in 2017, Roberge et al., studied the relationship between aspirin dose and the time of prescription and their effect on the prevention of preeclampsia in 45 clinical trials with a sample size of 20,909 pregnant women who were taking aspirin at a daily dose of 50-150 mg. Their results showed that prescribing aspirin before the 16th week of gestation had a dose-dependent reduction in the incidence of preeclampsia and its severe form, which was present even in low-risk groups. However, aspirin was less effective after 16th week of gestation and was not dose-dependent **(12)**. According to Rolnik et al., administration of aspirin at a dose of 150 mg was effective in preventing preeclampsia, but they did not report a significant difference between the studied women in terms of other outcomes of pregnancy **(15)**. In a systematic review and meta-analysis in 2018, Roberg et al., reported that aspirin was associated with a decrease in preterm preeclampsia, not a term preeclampsia; it was observed only in patients taking a dose of more than 100 mg which was started before the 16th week of gestation **(10)**.

Based on the current recommendation of the ACOG, low-dose aspirin should be prescribed in the first trimester for women with a history of preterm preeclampsia and preterm labor at a gestational age of less than 37 weeks, or in women with a history of preeclampsia in previous pregnancies. Low-dose aspirin daily is a safe medication and is associated with a low risk of maternal or fetal complications. The recommended dose is 81 mg per day, which should be started in high-risk women with preeclampsia at 12th-28th week of gestation (preferably before 16th week). High-risk women are characterized by the presence of one or more major risk factors for preeclampsia including history of preeclampsia, multiple gestation, kidney disease, autoimmune disease, type I or II diabetes, and chronic hypertension; or the presence of more than one moderate risk factor such as first pregnancy, age over 35 years, BMI>30 kg/m^2, and family history of preeclampsia **(13)**.

In general, according to previous studies, there are several points regarding the effect of aspirin on preeclampsia, which are currently recommended by ACOG **(13)**. First, low-dose aspirin is effective in preventing preeclampsia and reducing its severity in high-risk women and has few side effects. However, its routine use is not recommended for all women. Second, the recommended dose in various studies is 60-150 mg and the appropriate (optimal) dose has not yet been determined. Concerning the prescription time, it is recommended to prescribe aspirin for high-risk cases before 16th week of gestation. Finally, unlike some studies that have recommended doses higher than 100 mg, the results of our study showed no difference between the effects of aspirin 80 mg and 120 mg on preeclampsia or its severity. ACOG currently recommends to use a daily dose of 81 mg **(13)**. Since our study was conducted in a center which was a third-party patient referral center, the prevalence of preeclampsia in our study was higher than that in other studies.

5. Conclusion

Findings of the present study showed that daily aspirin use at a dose of 80 mg or 120 mg in high-risk women before 16th week of gestation was associated with a reduction in the incidence of preeclampsia without serious side effects. As there was no significant difference between aspirin 80 mg and 120 mg doses in terms of pregnancy outcomes and side effects, 80 mg dose appears to properly reduce the incidence of preeclampsia in high-risk women without higher risk of severe preeclampsia.

6. Declarations

Acknowledgments

None.

Ethical Considerations

This study was approved by the ethics committee of Shahid Beheshti University of Medical Sciences (ethical code: IR.SBMU.MSP.REC.1397.531). The study was registered on the Iranian Registry of Clinical Trials (code: IRCT20120918010876N6).

Authors' Contributions

All authors contributed in designing and writing the manuscript, data collection and statistical analysis.

Conflict of Interest

The authors declare no conflict of interest.

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