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The Role of Low-Dose Acetylsalicylic Acid in the Prevention of Preeclampsia: A Prospective Cohort Study Among At-Risk Women at the Nabeul Regional Hospital, Tunisia

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Abstract **Original Research Article**

***Background*:** Preeclampsia, a hypertensive complication affecting 5–10% of pregnancies in Tunisia, remains a major cause of maternal and neonatal morbidity. Low-dose aspirin is a recommended preventive strategy but has been little studied locally. The aim of this study is to describe the effectiveness of treatment in at-risk women monitored at the Nabeul Regional Hospital. ***Methods*:** This was a prospective, descriptive observational study conducted between 2022 and 2024. Two hundred fifty patients with at least one risk factor for preeclampsia were included after providing informed consent. They received low-dose aspirin (75–150 mg/day) in accordance with international guidelines. Data were collected in real time during prenatal visits and at delivery. The primary endpoint was the incidence of preeclampsia; secondary endpoints included prematurity, birth weight, and the occurrence of aspirin-related adverse effects. The data were analyzed using SPSS 26. ***Results*:** Among the 250 patients included, the overall incidence of preeclampsia was 14%, including 10% mild cases and 4% severe cases, which was lower than the 20–25% reported in untreated women at risk. Initiation of aspirin before 16 weeks of amenorrhea was associated with a significant reduction in risk, with preeclampsia observed in 9% of patients compared to 27.1% for later initiation (OR = 3.12). Good treatment compliance also reduced the incidence of preeclampsia (11% vs. 26%; OR = 2.85). In multivariate analysis, chronic hypertension (OR = 2.98), history of preeclampsia (OR = 3.45), and nulliparity (OR = 2.15) were identified as independent predictors of preeclampsia despite prevention. Prematurity was observed in 20% of cases and birth weight below the 10th percentile in 16% of newborns, mainly in patients who developed severe preeclampsia. Hemorrhages, including postpartum hemorrhages, were reported in 6% of patients, 2% of which were potentially related to aspirin. Complications specific to preeclampsia were rare: eclampsia (1.2%) and HELLP syndrome (1.6%), with no maternal deaths. ***Conclusion*:** This prospective study confirms that low-dose aspirin effectively reduces the incidence of preeclampsia in at-risk women in Tunisia, provided that treatment is initiated before 16 weeks of amenorrhea and accompanied by good adherence.

Keywords: Aspirin, Preeclampsia, Prevention, Tunisia.

1. INTRODUCTION AND OBJECTIVE

Preeclampsia is a serious hypertensive complication of pregnancy, defined by the onset of hypertension (≥ 140/90 mmHg) associated with proteinuria or organ dysfunction after 20 weeks of gestation [1, 2]. In Tunisia, its incidence is estimated at between 5% and 10% in certain regions, with significant maternal and neonatal morbidity and mortality [3, 4]. Low-dose aspirin (75–150 mg/day) has demonstrated its preventive efficacy in international trials (ASPRE, CNGOF, WHO) [5,6], but local data remain limited.

Primary Objective:

To evaluate the efficacy of low-dose aspirin in preventing preeclampsia in at-risk pregnant women prospectively followed at the Nabeul Regional Hospital.

Secondary Objectives:

- Identify factors associated with the onset of preeclampsia (dose, timing of initiation, adherence, comorbidities).
- Describe obstetric outcomes (preterm birth, birth weight, mode of delivery, maternal and neonatal complications).

- Assess aspirin tolerance.

2. MATERIALS AND METHODS

2.1. Study Design and Setting

We conducted an observational, descriptive, prospective study at a single centre: the Department of Obstetrics and Gynaecology at the Mohamed Tlatli Regional Hospital in Nabeul, Tunisia. This is a Level 2 maternity hospital.

2.2. Study Period: The study ran for three years, from 1 January 2022 to 31 December 2024.

2.3. Study Population

Inclusion Criteria

We included pregnant women who: received low-dose aspirin (75–150 mg/day) to prevent preeclampsia; had at least one recognised risk factor (history of preeclampsia, multiple pregnancy, chronic hypertension, diabetes, obesity with BMI ≥ 30 kg/m², kidney disease, or thrombophilia); planned to give birth at Nabeul Hospital; and gave written informed consent.

Exclusion Criteria Before Enrolment

Women were excluded if they had: an allergy or contraindication to aspirin (such as an active gastric ulcer or a severe bleeding disorder); or a history of severe preeclampsia that occurred despite aspirin treatment in a previous pregnancy.

Exclusion Criteria After Enrolment

Women were also excluded if they: were lost to follow-up before delivery; or had incomplete medical records or missing data.

In total, we recruited 310 patients. Of these, 22 were not included (did not meet inclusion criteria) and a further 38 were excluded after enrolment due to incomplete data or loss to follow-up. This left 250 patients for analysis.

2.4. Data Collection

A trained team collected data in real time during prenatal visits and at delivery, with double-checking for accuracy. We recorded the following variables:

Demographic and Obstetric Data: age, parity, BMI, and obstetric history.

Risk Factors: chronic hypertension, diabetes, multiple pregnancy, smoking, and family history.

Therapeutic Data:

Prescribed aspirin dose (75, 100 or 150 mg/day), week of treatment initiation, duration of treatment, and adherence (self-reported and checked by counting returned pills at each visit).

Obstetric Outcomes:

Incidence of preeclampsia (using ACOG criteria), gestational age at delivery, mode of delivery, and maternal complications (haemorrhage, eclampsia, HELLP syndrome, placental abruption).

Neonatal Outcomes:

Preterm birth (< 37 weeks), low birth weight (< 10th percentile), 5-minute Apgar score, admission to the neonatal unit, and early neonatal death.

2.5. Outcome Measures

Our primary outcome was the incidence of preeclampsia in the treated cohort. Secondary outcomes were preterm birth, birth weight below the 10th percentile, and side effects of aspirin.

2.6. Controlling for Bias

We took several steps to minimise bias:

Selection Bias: We recruited all eligible patients consecutively, without selective inclusion.

3. RESULTS

We analysed data from 250 patients who met the inclusion criteria and completed follow-up. Below we present their characteristics, treatment details, obstetric and neonatal outcomes, and the results of univariate and multivariate analyses.

3.1. Descriptive Characteristics of the Cohort (n = 250)

Table 1 summarises the baseline characteristics of the 250 women included in the study. The women had a mean age of 31.2 ± 5.7 years (range 18–42 years). More than half were nulliparous (130, 52%). Regarding obstetric history, 45 women (18%) had experienced preeclampsia in a previous pregnancy, 60 (24%) had a history of miscarriages, and 35 (14%) had previously given birth prematurely.

The most common comorbidities were obesity (80 women, 32%), diabetes (60, 24%), and chronic hypertension (50, 20%). Kidney disease was present in 15 women (6%) and autoimmune diseases in 10 (4%). Twenty-five women (10%) had multiple pregnancies. Smoking was reported by 20 women (8%), and a family history of preeclampsia was noted in 40 (16%).

3.2. Treatment Data

Regarding aspirin dosing, 90 women (36%) received 75 mg daily, 120 (48%) received 100 mg daily, and 40 (16%) received 150 mg daily.

The timing of treatment initiation varied: 70 women (28%) started aspirin before 12 weeks of gestation, 110 (44%) started between 12 and 16 weeks, and 70 (28%) started after 16 weeks. The average duration of treatment was 22.5 ± 5.2 weeks (range 8–30 weeks).

Adherence was defined as good when women took at least 90% of the prescribed doses. By this definition, 200 patients (80%) had good adherence, while 50 (20%) had poor adherence.

3.3. Obstetric and Neonatal Outcomes

Preeclampsia occurred in 35 patients (14%). Of these, 10% had mild preeclampsia and 4% had severe forms.

Preterm birth (before 37 weeks) occurred in 50 women (20%). Among these, 8% were attributed to preeclampsia and 12% to other causes.

Birth weight averaged 3,050 ± 550 g. Forty newborns (16%) had a birth weight below the 10th percentile for gestational age.

Mode of delivery: 150 women (60%) delivered vaginally, while 100 (40%) delivered by caesarean section. Of the caesarean sections, 12% were related to preeclampsia.

Maternal complications were relatively uncommon. Haemorrhage occurred in 15 women (6%); of these, 2% were potentially related to aspirin use. Three women (1.2%) developed eclampsia, four (1.6%) developed HELLP syndrome, and three (1.2%) had placental abruption. Overall, 222 women (88.8%) had no complications. There were no maternal deaths.

Neonatal complications included a 5-minute Apgar score below 7 in 15 newborns (6%), admission to the neonatal unit in 40 (16%), and early neonatal death in 4 (1.6%).

3.4. Univariate Analysis

We first examined factors associated with preeclampsia, preterm birth, low birth weight, and side effects using univariate tests. Table 2 summarises the results of the univariate analysis of factors associated with preeclampsia.

Factors Associated with Preeclampsia:

- Aspirin dose was associated with preeclampsia incidence: 20% among those on 75 mg, 10% on 100 mg, and 12.5% on 150 mg (p = 0.048).
- Timing of initiation mattered strongly: preeclampsia occurred in 8.6% of women who started before 12 weeks, 9.1% of those who started at 12–16 weeks, but 27.1% of those who started after 16 weeks (p = 0.002).
- Poor adherence was linked to a higher rate of preeclampsia (26% vs. 11%, p = 0.006).
- Several risk factors were also associated: chronic hypertension (p = 0.001), diabetes (p = 0.047), nulliparity (p = 0.038), and multiple pregnancy (p = 0.049).

Factors Associated with Preterm Birth:

Table 3 summarises the univariate analysis of factors associated with prematurity.

Preterm birth was significantly more frequent among women with late treatment initiation (p = 0.016), poor adherence (p = 0.015), multiple pregnancies (p = 0.008), and chronic hypertension (p = 0.048).

Factors associated with birth weight below the 10th percentile:

Table 4 summarises the univariate analysis of factors associated with birth weight below the 10th percentile.

Low birth weight was associated with late treatment initiation (p = 0.009), chronic hypertension (p = 0.042), diabetes (p = 0.049), and multiple pregnancies (p = 0.016).

Side Effects (Minor Bleeding):

Minor bleeding events were not related to aspirin dose (p = 0.876) or to treatment duration (p = 0.412).

3.5. Multivariate Analysis

We then performed logistic regression (and linear regression for continuous birth weight) to adjust for potential confounders.

Table 5 summarises the logistic regression analysis for predictors of preeclampsia.

Predictors of preeclampsia (logistic regression):

After adjustment, the following factors remained independently associated with preeclampsia:

- Starting aspirin after 16 weeks (compared with before 12 weeks): odds ratio (OR) = 3.12, 95% confidence interval (CI) [1.45–6.72], p = 0.004
- Poor adherence: OR = 2.85 [1.32–6.15], p = 0.008
- Chronic hypertension: OR = 2.98 [1.39–6.41], p = 0.005
- Nulliparity: OR = 2.15 [1.02–4.53], p = 0.045
- History of preeclampsia: OR = 3.45 [1.62–7.34], p = 0.001

The aspirin dose was no longer significant after adjustment for other factors.

Predictors of preterm birth (logistic regression):

Table 6 summarises the logistic regression analysis for predictors of prematurity.

- Initiation after 16 weeks: OR = 2.67 [1.28–5.57], p = 0.009
- Poor adherence: OR = 2.42 [1.12–5.23], p = 0.025
- Multiple pregnancy: OR = 3.15 [1.32–7.52], p = 0.010
- Chronic hypertension: OR = 2.08 [1.01–4.29], p = 0.047

- Preeclampsia itself: OR = 4.12 [1.89–8.97], p < 0.001

Predictors of birth weight below the 10th percentile (logistic regression):

Table 7 summarises the regression analysis for predictors of birth weight below the 10th percentile.

- Initiation after 16 weeks: OR = 2.89 [1.22–6.85], p = 0.016
- Chronic hypertension: OR = 2.35 [1.05–5.26], p = 0.038
- Multiple pregnancy: OR = 2.78 [1.10–7.02], p = 0.031
- Preeclampsia: OR = 3.65 [1.62–8.22], p = 0.002

Predictors of continuous birth weight (linear regression):

We also examined birth weight as a continuous variable. After adjustment:

- Initiation after 16 weeks was associated with a mean reduction of 210 grams (β = –210 g, 95% CI [–350, –70], p = 0.003)
- Preeclampsia was associated with a reduction of 280 grams (β = –280 g, 95% CI [–420, –140], p < 0.001)
- Chronic hypertension was associated with a reduction of 150 grams (β = –150 g, 95% CI [–290, –10], p = 0.036)
- Multiple pregnancy was associated with a reduction of 200 grams (β = –200 g, 95% CI [–360, –40], p = 0.015)

The model explained about 22% of the variance in birth weight (adjusted $R^2 = 0.22$).

Table 1: Baseline characteristics of the study cohort

Caractéristique	**Valeur**
Age (years), mean ± standard deviation (min–max)	31,2 ± 5,7 (18–42)
Nulliparity, n (%)	130 (52%)
Obstetric history, n (%)	
Previous preeclampsia	45 (18%)
Miscarriages	60 (24%)
Previous preterm delivery	35 (14%)
Comorbidities, n (%)	
Chronic hypertension	50 (20%)
Diabetes	60 (24%)
Obesity (BMI ≥ 30 kg/m²)	80 (32%)
Kidney disease	15 (6%)
Autoimmune disease	10 (4%)
Multiple pregnancy, n (%)	25 (10%)
Smoking, n (%)	20 (8%)
Family history of preeclampsia, n (%)	40 (16%)

Table 2: Univariate analysis of factors associated with preeclampsia.

Variable	**Preeclampsia (n, %)**	**No preeclampsia (n, %)**	**p-value**
Aspirin dose			**0,048**
75 mg (n=90)	18 (20,0)	72 (80,0)	
100 mg (n=120)	12 (10,0)	108 (90,0)	
150 mg (n=40)	5 (12,5)	35 (87,5)	
Time of initiation			**0,002**
<12 weeks (n=70)	6 (8,6)	64 (91,4)	
12–16 weeks (n=110)	10 (9,1)	100 (90,9)	
>16 weeks (n=70)	19 (27,1)	51 (72,9)	
Risk factors			
Chronic hypertension	15/50 (30,0)	35/50 (70,0)	**0,001**
Yes	12/60 (20,0)	48/60 (80,0)	**0,047**
No	24/130 (18,5)	106/130 (81,5)	**0,038**
Diabetes	13/80 (16,3)	67/80 (83,7)	**0,482**
Nulliparity	6/25 (24,0)	19/25 (76,0)	**0,049**
Obesity			**0,006**
Good (n=200)	22 (11,0)	178 (89,0)	
Insufficient (n=50)	13 (26,0)	37 (74,0)	

Table 3: Univariate Analysis Results for Prematurity

Variable	Prematurity (n, %)	No Prematurity (n, %)	p-value
Aspirin dose			0.374
75 mg	22/90 (24.4)	68/90 (75.6)	
100 mg	20/120 (16.7)	100/120 (83.3)	
150 mg	8/40 (20.0)	32/40 (80.0)	
Time of initiation			0.016
<12 weeks	10/70 (14.3)	60/70 (85.7)	
12–16 weeks	18/110 (16.4)	92/110 (83.6)	
>16 weeks	22/70 (31.4)	48/70 (68.6)	
Adherence			0.015
Good	34/200 (17.0)	166/200 (83.0)	
Insufficient	16/50 (32.0)	34/50 (68.0)	
Risk factors			
Multiple pregnancies	10/25 (40.0)	15/25 (60.0)	0.008
Chronic hypertension	15/50 (30.0)	35/50 (70.0)	0.048
Diabetes	14/60 (23.3)	46/60 (76.7)	0.454

Table 4 : Univariate Analysis Results for Birth Weight

Variable	Birth Weight <10th Percentile (n, %)	Birth Weight ≥10th Percentile (n, %)	p-value
Aspirin dose			0.362
75 mg	18/90 (20.0)	72/90 (80.0)	
100 mg	16/120 (13.3)	104/120 (86.7)	
150 mg	6/40 (15.0)	34/40 (85.0)	
Time of initiation			0.009
<12 weeks	7/70 (10.0)	63/70 (90.0)	
12–16 weeks	14/110 (12.7)	96/110 (87.3)	
>16 weeks	19/70 (27.1)	51/70 (72.9)	
Adherence			–
Good	–	–	
Insufficient	–	–	
Risk factors			
Multiple pregnancies	8/25 (32.0)	17/25 (68.0)	0.016
Chronic hypertension	12/50 (24.0)	38/50 (76.0)	0.042
Diabetes	13/60 (21.7)	47/60 (78.3)	0.049

Table 5: Logistic Regression Results for the Incidence of Preeclampsia

Variable	Adjusted OR	95% CI	p-value
Time of initiation >16 weeks / <12 weeks	3.12	1.45–6.72	0.004
Insufficient vs. good adherence	2.85	1.32–6.15	0.008
Chronic hypertension	2.98	1.39–6.41	0.005
Nulliparity	2.15	1.02–4.53	0.045
Previous history of preeclampsia	3.45	1.62–7.34	0.001

Table 6 : Logistic Regression Results for Prematurity

Variable	Adjusted OR	95% CI	p-value
>16 weeks / 12 weeks	2.67	1.28–5.57	0.009
Insufficient vs. good adherence	2.42	1.12–5.23	0.025
Multiple pregnancies	3.15	1.32–7.52	0.010
Chronic hypertension	2.08	1.01–4.29	0.047
Occurrence of preeclampsia	4.12	1.89–8.97	<0.001

Table 7: Regression Results for Birth Weight

Variable	Logistic Regression (<10th Percentile)	95% CI
>16 weeks / 12 weeks	2.89	1.22–6.85
Chronic hypertension	2.35	1.05–5.26
Multiple pregnancies	2.78	1.10–7.02
Occurrence of preeclampsia	3.65	1.62–8.22

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4. DISCUSSION

4.1. Principal Findings

In this prospective cohort of 250 high-risk pregnant women receiving low-dose aspirin for preeclampsia prevention, we found that the incidence of preeclampsia was 14%. This is lower than the expected rates of 5–10% reported in the general Tunisian pregnant population, noting that our cohort was exclusively composed of women with at least one recognised risk factor. The key factors associated with preeclampsia were late initiation of aspirin (after 16 weeks of gestation), poor adherence, chronic hypertension, nulliparity, and a history of preeclampsia. Interestingly, the aspirin dose itself (75, 100 or 150 mg/day) did not independently predict outcomes after adjusting for other factors.

4.2. Results in the Context of Existing Literature

Our findings align well with the broader body of evidence on aspirin for preeclampsia prevention. The landmark ASPRE trial (Rolnik *et al*., 2017) demonstrated that 150 mg of aspirin initiated before 16 weeks significantly reduced preterm preeclampsia [5-7]. Similarly, a large meta-analysis by Roberge *et al.,* (2017) concluded that aspirin is effective only when started at or before 16 weeks, with no clear benefit for later initiation [8]. Our observation that late initiation (after 16 weeks) was associated with a three-fold increased risk of preeclampsia (OR = 3.12) is consistent with these findings [9].

Regarding adherence, our results echo those of previous studies showing that poor adherence substantially diminishes the protective effect of aspirin [10, 11]. For example, the ECLIPSE trial and several real-world cohorts have reported that adherence below 80–90% is associated with preeclampsia rates approaching those of untreated populations. In our study, poor adherence more than doubled the risk (OR = 2.85), highlighting that prescribing aspirin is insufficient without supporting patients to take it consistently.

The absence of an independent dose effect after adjustment is also consistent with the literature [12]. Most guidelines (including ACOG and WHO) recommend a range of 75–150 mg, noting that while higher doses may offer slightly greater protection, the benefit is primarily driven by early initiation and adherence rather than by dose escalation beyond 100 mg [5-7].

Our observed incidence of preeclampsia (14%) is higher than the 5–10% reported for the general Tunisian pregnant population, but this is expected given that our cohort was selected precisely for having risk factors. Compared with untreated high-risk populations, where preeclampsia rates can reach 20–30%, our 14% suggests a meaningful protective effect of aspirin, though the lack of a concurrent control group prevents a definitive conclusion [13].

4.3. Strengths and Limitations

Strengths

This study has several strengths. First, it provides prospective, real-world data on low-dose aspirin use in a Tunisian setting, where local evidence has been scarce. Second, we used strict, standardised diagnostic criteria for preeclampsia (ACOG) and applied consistent data collection procedures [14]. Third, we assessed adherence using both self-report and pill counts, which is more robust than relying on prescription records alone. Fourth, we adjusted for multiple confounders using multivariate regression, reducing the risk of spurious associations.

Limitations

We acknowledge several important limitations. The single-centre design limits generalisability to other settings, such as Level 3 maternity hospitals, private clinics, or other regions of Tunisia. The absence of a concurrent control group (untreated or placebo) means we cannot make direct causal claims about aspirin's effectiveness; we can only describe associations and compare indirectly with historical data. Adherence was measured by self-report and pill count, which may overestimate true adherence; we did not perform biochemical validation (e.g., salicylate levels). Residual confounding is possible despite multivariate adjustment, as unmeasured factors (socioeconomic status, diet, physical activity) could influence outcomes. We did not perform a formal sample size calculation, as this was a convenience sample based on recruitment over the study period. Finally, our adherence questionnaire has not been formally validated, which we have acknowledged in the Methods section and addressed by providing the questionnaire as Extended data.

4.4. Clinical Implications

Our findings have several practical implications for clinical practice in Tunisia and similar settings. First, they support systematic early screening for preeclampsia risk factors during the first trimester, allowing aspirin to be initiated before 16 weeks of gestation. Second, they reinforce that simply prescribing aspirin is not enough; healthcare teams should actively monitor and support adherence, for example through patient education, simplified dosing regimens, and regular reinforcement at prenatal visits. Third, the lack of a clear dose effect suggests that the more accessible and lower 75 mg or 100 mg doses may be sufficient when started early and taken consistently, which is particularly relevant in resource-limited settings.

4.5. Future Research Directions

Future work should address the limitations of this study. Large, multicentre prospective studies are needed across different Tunisian regions (urban and rural, public and private sectors) to assess

generalisability. Randomised controlled trials or well-designed pragmatic trials with concurrent control groups would provide stronger evidence for causality. Research is also needed on implementation strategies to improve adherence, such as text message reminders, community health worker support, or fixed-dose combination pills. Finally, future studies should validate simple, culturally adapted adherence questionnaires for use in North African populations, or consider biochemical adherence markers in a subset of patients.

5. CONCLUSIONS

This prospective study, conducted among 250 pregnant women at risk for preeclampsia at the Nabeul Regional Hospital, confirms that low-dose aspirin is effective in reducing the incidence of preeclampsia (14% vs. the expected 20–25%), provided it is initiated before 16 weeks of amenorrhea (ideally before 12 weeks of gestation) and is well adhered to (≥ 90%). Classic risk factors (chronic hypertension, history of PE, nulliparity, multiple pregnancies) remain independent predictors despite treatment. Aspirin is well tolerated, with very few serious side effects. These results support the widespread implementation of early screening and the standardization of the dosage to 100 mg/day in Tunisian maternity wards.

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