

# Impact of colchicine on inflammatory markers and pregnancy outcomes in familial Mediterranean fever patients

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## ABSTRACT

**Objectives:** The aim of this study is to evaluate the effect of colchicine use on maternal inflammatory markers and pregnancy outcomes in pregnant women diagnosed with Familial Mediterranean Fever (FMF) and receiving colchicine therapy.

**Methods:** This retrospective analysis included 42 pregnant women diagnosed with FMF who underwent colchicine treatment and 126 healthy pregnant controls. Neutrophil/Lymphocyte Ratio (NLR), Platelet/Lymphocyte Ratio (PLR), and Monocyte/Lymphocyte Ratio (MLR) rates in the blood of the groups in the first trimester, obstetric morbidities and pregnancy outcomes were compared.

**Results:** The patient cohort had markedly reduced hemoglobin levels ( $12.15 \pm 1.36$  vs.  $12.80 \pm 1.02$  g/dL,  $P=0.001$ ), an elevated prevalence of anemia (19% vs. 3%,  $P=0.002$ ), and diminished monocyte counts ( $0.55$  vs.  $0.61 \times 10^9/L$ ,  $P=0.022$ ) as well as decreased MLR values ( $0.27$  vs.  $0.29$ ,  $P=0.020$ ) in comparison to the control group. Other inflammatory markers, pregnancy complications, and neonatal outcomes were similar between the groups ( $P>0.05$ ).

**Conclusions:** Colchicine seems to be useful in managing inflammation during FMF pregnancies without negatively affecting pregnancy or neonatal outcomes. Thorough prenatal care, encompassing anemia monitoring, is crucial for enhancing mother and fetal health.

**Keywords:** Familial Mediterranean fever, colchicine, inflammation, pregnancy

Familial Mediterranean Fever (FMF) is an autoinflammatory disorder characterized by autosomal recessive inheritance, predominantly observed in individuals of Mediterranean descent [1]. FMF is marked by repeated episodes of fever, abdominal pain, pleuritis, and arthritis [2]. Pregnancy may frequently occur during the condition, as women of reproductive age are impacted by it. The implications

and management of FMF during gestation can significantly impact both the mother and the fetus. FMF is recognized to elevate the risk of spontaneous abortion and preterm delivery [3, 4].

Colchicine is an efficacious anti-inflammatory agent that inhibits microtubule polymerization and modulates inflammatory pathways [5]. Colchicine is extensively utilized in autoinflammatory disorders

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since it alleviates aphthous ulcers, modulates inflammation, and diminishes the severity and frequency of relapses [6]. Colchicine is thought to be safe and effective during pregnancy to control and prevent flares in patients with FMF [7].

Although the inflammatory characteristics of FMF are well-documented, limited research has investigated the significance of hematologic markers in FMF pregnancies or their potential association with pregnancy outcomes [8]. Comprehending the correlation among FMF, systemic inflammation, and obstetric outcomes may enhance our capacity to anticipate and address issues in this high-risk population. In recent years, the utilization of straightforward and cost-effective biomarkers for quantitatively evaluating systemic inflammation has risen [9]. Blood-based markers of inflammation such as Neutrophil/Lymphocyte Ratio (NLR), Platelet/Lymphocyte Ratio (PLR), and Monocyte/Lymphocyte Ratio (MLR) are used as practical tools in the evaluation of different inflammatory conditions [10]. These markers are gaining increasing interest in predicting pregnancy-related complications and inflammatory diseases [11-13].

This study aims to evaluate NLR, PLR, and MLR values in pregnant women taking colchicine with FMF and investigate their association with pregnancy outcomes. Our secondary aim is to investigate pregnancy complications and neonatal outcomes in pregnant women with FMF taking colchicine. We hope to contribute to the understanding of inflammatory mechanisms in FMF pregnancies and their impact on maternal-fetal health.

## METHODS

This retrospective study was conducted at the Perinatology clinic of Ankara Etlik City Hospital between October 2022 and November 2024. Approval was obtained from the hospital's ethics committee before starting the study (Decision no: AEŞH-BADEK-2025-0060, date: 08.01.2025). Due to the retrospective nature of the study, informed consent was not required, as approved by the ethics committee.

The study included pregnant women who had previously been diagnosed with FMF and were taking colchicine. Patients whose blood samples from the first trimester were not available and whose birth data

could not be accessed were excluded from the study. In addition, patients who had an abortion and patients with chronic diseases were excluded from the study.

After 42 individuals who met the inclusion and exclusion criteria were selected for the patient group, a control group was formed consisting of pregnant women of similar age and body mass index (BMI) in a 1:3 ratio. The following clinical and demographic data were obtained by reviewing the patient's medical records: Maternal age, body mass index, number of pregnancies, number of parities, and number of abortions. Laboratory data of the patients were obtained from the hospital data system. First-trimester complete blood parameters, including hemogram, complete blood count, lymphocyte level, neutrophil level, monocyte level, platelet count, as well as NLR, PLR, MLR rates, were calculated. Whether the patients had gestational hypertension, gestational diabetes, intrauterine growth retardation, abnormal amniotic fluid (polyhydramnios or oligohydramnios), preterm labor, preterm premature rupture of membranes diagnosis during pregnancy, and neonatal outcomes (neonatal weight, APGAR 1st and 5th-minute scores, need for neonatal intensive care or neonatal death) were recorded. Laboratory data and neonatal outcome differences between the groups were compared.

## Statistical Analysis

The statistical analysis was conducted using IBM Corporation SPSS (version: 30.0.0.172). The adherence to the normal distribution was assessed utilizing the Kolmogorov-Smirnov test. For continuous variables with a normal distribution, descriptive statistics are presented as "mean±standard deviation"; for those without, they are presented as "median (interquartile range)". Fisher's exact test or the chi-squared test was employed to compare categorical variables. The Student T-test and the Mann-Whitney U test were employed to examine continuous variables with and without normal distribution.

## RESULTS

Table 1 compares the demographic and obstetric characteristics of the patient (n=42) and control groups (n=126). No significant differences were observed in age, BMI, weight gain during pregnancy, or gravida

**Table 1. Demographic data of the study population**

Parameter	Patient group (n=42)	Control group (n=126)	P value
Age (years)	29 (24-32)	29 (26-34)	0.689 <sup>a</sup>
BMI (kg/m <sup>2</sup> )	28.9 (25.3-32.8)	29.6 (26.9-33.7)	0.350 <sup>a</sup>
Weight gain during pregnancy (kg)	10 (8-12)	10 (8-15)	0.893 <sup>a</sup>
Gravida	2 (1-3)	2 (1-3)	0.565 <sup>a</sup>
Primipar	16 (35.7%)	22 (17.5%)	<b>0.007<sup>b</sup></b>
Two or more consecutive spontaneous abortions	2 (4.7%)	3 (2.3%)	0.367 <sup>c</sup>
IVF	2 (4%)	1 (0.7%)	0.155 <sup>c</sup>

Data are shown as median (Q1-Q3) or n (%) where appropriate. BMI=Body mass index, IVF= In vitro fertilization

<sup>a</sup>Mann-Whitney U Test, <sup>b</sup>Chi-Square Test, <sup>c</sup>Fisher Exact Test.

( $P>0.05$ ). However, the patient group had a significantly higher proportion of primiparous individuals compared to the control group (35.7% vs. 17.5%,  $P=0.007$ ). Other parameters, such as spontaneous abortion rates and in vitro fertilization (IVF) conception, were similar between the groups ( $P>0.05$ ). However, there was a significant difference in the distribution of primiparous and multiparous participants between the groups.

The patient group had a higher proportion of primiparous individuals (35.7% vs. 17.5%,  $P=0.007$ ). Other parameters, such as two or more consecutive spontaneous abortions (4.7% vs. 2.3%,  $P=0.367$ ) and IVF conception rates (4% vs. 0.7%,  $P=0.155$ ), did not show statistically significant differences. Table 2 presents the laboratory data of the patients. The blood sampling week was similar between the groups ( $P=0.514$ ). Hemogram levels were significantly lower in the patient group ( $12.15\pm 1.36$  g/dL) compared to the control group ( $12.80\pm 1.02$  g/dL) ( $P=0.001$ ). Anemia prevalence was higher in the patient group (19%) compared to the control group (3%) ( $P=0.002$ ). Monocyte levels were also significantly lower in the patient group ( $0.55$  vs.  $0.61 \times 10^9/L$ ,  $P=0.022$ ). Similarly, the MLR was significantly lower in the patient group (0.27 vs. 0.29,  $P=0.020$ ). Other parameters, including whole blood cell count, lymphocyte, neutrophil, platelet levels, NLR, PLR, systemic immune-inflammation index (SII), pregnancy-associated plasma protein-A (PAPP-A) multiples of the median (MoM), beta human chorionic gonadotropin (beta-hCG) MoM, and nuchal

translucency (NT) MoM, did not show significant differences between the groups ( $P>0.05$ ).

When the FMF and control groups were compared in terms of birth outcomes, no statistically significant differences were observed in gestational age at delivery, birth weight, preterm birth rates, primary cesarean section rates, 1st and 5th minute APGAR scores, neonatal intensive care unit admission rates, or composite adverse perinatal outcomes ( $P>0.05$ ) (Table 3). Pregnancy outcomes showed no significant differences between the groups. Fetal growth restriction (16% vs. 7%,  $P=0.069$ ), preterm labor (14% vs. 12%,  $P=0.725$ ), and gestational diabetes (2.4% vs. 10%,  $P=0.193$ ) were slightly more frequent in the patient group. Rates of polyhydramnios, oligohydramnios, and gestational hypertensive disease were comparable (Table 4).

## DISCUSSION

In this study, we compared the first-trimester laboratory data and neonatal outcomes of pregnant women with FMF who used colchicine. We found no significant difference except for lower monocyte levels and MLR. In addition, pregnancy complications and neonatal outcomes in the FMF group were comparable to the general population. To our knowledge, this is the first study comparing the first-trimester blood analysis results of pregnant women using colchicine with those of normal pregnant women.

**Table 2. Second trimester laboratory findings of the study population**

Parameter	Patient group (n=42)	Control group (n=126)	P value
Blood sampling week	11 (8-12)	11 (9-12)	0.514 <sup>a</sup>
Hemogram (g/dL)	12.15±1.36	12.80±1.02	<b>0.001<sup>b</sup></b>
Anemia	8 (19%)	4 (3%)	<b>0.002<sup>c</sup></b>
Whole blood cells ( $\times 10^9/L$ ),	8.68 (7.40-10.14)	8.55(7.44-9.75)	0.870 <sup>a</sup>
Lymphocyte ( $\times 10^9/L$ )	2.09 (1.74-2.47)	1.94 (1.72-3.27)	0.486 <sup>a</sup>
Neutrophil ( $\times 10^9/L$ )	5.94 (4.68-7.40)	5.60 (4.93-6.83)	0.737 <sup>a</sup>
Monocyte ( $\times 10^9/L$ )	0.55 (0.42-0.62)	0.61 (0.52-0.71)	<b>0.022<sup>a</sup></b>
Platelet ( $\times 10^9/L$ )	262 (206-303)	260 (231-311)	0.303 <sup>a</sup>
NLR	2.76 (2.02-3.65)	2.85 (2.23-3.66)	0.695 <sup>a</sup>
PLR	123 (98-156)	133 (109-163)	0.097 <sup>a</sup>
MLR	0.27 (0.23-0.31)	0.29 (0.25-0.37)	<b>0.020</b>
SII	721 (488-936)	770 (575-995)	0.354 <sup>a</sup>
PAPP-A MoM	0.97 (0.54-1.19)	1.00 (0.66-1.43)	0.262 <sup>a</sup>
bhCG MoM	0.85 (0.45-1.20)	0.84 (0.48-1.37)	0.861 <sup>a</sup>
NT MoM	0.77 (0.69-0.86)	0.74 (0.59-0.92)	0.760 <sup>a</sup>

Data are shown as mean±standard deviation or median (Q1-Q3) or n (%) where appropriate. bhCG=Beta-human chorionic gonadotropin, MoM=Multiple of the median, NLR=Neutrophil-to-lymphocyte ratio, NT=Nuchal translucency, PAPP-A=Pregnancy-associated plasma protein A, PLR=Platelet-to-lymphocyte ratio, SII=Systemic immune-inflammation index.

<sup>a</sup>Mann-Whitney U Test, <sup>b</sup>Student-T Test, <sup>c</sup>Fisher-Exact Test

**Table 3. Comparison of birth outcomes between FMF and control groups**

Parameter	Patient group (n=42)	Control group (n=126)	P value
Gestational age at delivery (week)	38 (37-39)	39 (37-40)	0.101 <sup>a</sup>
Birth weight (gram)	3145 (2720-3400)	3270 (2980-3480)	0.123 <sup>a</sup>
Preterm birth (<37 weeks)	5 (11%)	14 (11%)	0.888 <sup>b</sup>
Primary cesarean section	10 (23%)	27 (21%)	0.934 <sup>b</sup>
Fetal distress	4 (9%)	11 (8%)	0.544 <sup>c</sup>
APGAR score at 1st minute	9 (8-9)	9 (8-9)	0.056 <sup>a</sup>
APGAR score at 5th minute	1 (9-10)	10 (9-10)	0.164 <sup>a</sup>
NICU admission	5 (11%)	20 (15%)	0.566 <sup>b</sup>
Intrauterine ex	1 (2%)	0	0.250 <sup>c</sup>
CAPO	5 (11%)	20 (15%)	0.566 <sup>b</sup>

Data are shown as median (Q1-Q3) or n (%) where appropriate. CAPO=Composite adverse perinatal outcome, FMF=Familial Mediterranean fever, NICU=Neonatal intensive care unit.

<sup>a</sup>Mann-Whitney U Test; <sup>b</sup>Chi-Square Test; <sup>c</sup>Fisher-Exact Test

**Table 4. Comparison of pregnancy complications in patients with FMF and control group**

Parameters	Patient group (n=42)	Control group (n=126)	P value
Preterm labor	6 (14%)	15 (12%)	0.725 <sup>a</sup>
Preterm premature rupture of membranes	2 (4.9%)	0 (0%)	0.061 <sup>b</sup>
Gestational hypertensive disease	1 (2.4%)	2 (1.6%)	1 <sup>b</sup>
Gestational diabetes	1 (2.4)	13 (10%)	0.193 <sup>b</sup>
Fetal growth restriction	7 (16 %)	9 (7%)	0.069 <sup>a</sup>
Polyhydramnios	3 (7.3%)	4 (3.2%)	0.368 <sup>b</sup>
Oligohydramnios	3 (7.3%)	7 (5.6%)	0.712 <sup>b</sup>

FMF=Familial Mediterranean fever

<sup>a</sup>Chi-Square Test, <sup>b</sup>Fisher-Exact Test

Individuals with FMF possess mutations in the Mediterranean fever gene, which encodes the pyrin protein involved in the synthesis of interleukin-1 $\beta$  (IL-1 $\beta$ ) [14]. Colchicine, used to prevent acute attacks in FMF, suppresses inflammatory processes by inhibiting microtubule polymerization [15]. It is also thought that colchicine causes changes at the transcriptional level by altering gene expression in human umbilical vein endothelial cell line cells [16]. We analyzed systemic inflammatory markers, including NLR, MLR, and PLR, which are frequently utilized in cancer, rheumatic disorders, and numerous pregnancy issues, during the first-trimester complete blood study of pregnant women using this inflammatory medication [11, 17, 18]. Our findings show that colchicine treatment regulates the inflammatory response in pregnant women and keeps inflammatory levels at a level comparable to normal pregnant women. However, in our study, we observed that monocyte levels and MLR were lower in the patient group. It is known that colchicine reduces monocyte activation [19]. In addition, it is thought that the use of colchicine in Behçet's disease decreases the number of classical monocytes while increasing the number of non-classical monocytes [20]. In this context, our findings are consistent with the literature.

Anemia is common in FMF patients. This finding is also consistent with the study by Hirahara *et al.* [3], who reported an increased prevalence of anemia in FMF patients during pregnancy. In addition, in one study, anemia was detected in 63.4% of FMF patients [21]. Although the same study suggested that colchicine treatment improved anemia in FMF patients, our findings suggest that pregnant women with FMF who use colchicine should still be carefully mon-

itored for anemia.

Although there are older studies advocating routine amniocentesis in pregnant women using colchicine [22, 23], colchicine treatment during pregnancy in FMF patients is currently considered safe and amniocentesis is not routinely recommended [24].

Additionally, a study comparing pregnant women treated with colchicine during pregnancy and those not treated showed no significant difference in malformation rates [7]. In our study, the rate of chromosomal anomalies was not increased in the patient group, consistent with the literature. Furthermore, pregnancy-related biomarkers like PAPP-A MoM,  $\beta$ -hCG MoM, and NT MoM were similar among the groups, indicating that FMF does not substantially affect these first-trimester screening indicators. This discovery corroborates the findings of Sotskiy *et al.* [25], who similarly indicated no substantial disparities in biochemical markers between FMF patients and controls.

One of the main findings of our study is that the perinatal outcomes of FMF patients are similar to the general population. Although Ofir *et al.* [26] argued that FMF is a risk factor for preterm birth, they emphasized in their study that the perinatal outcomes were the same as those of pregnant women without FMF. However, unlike our study, only 66 percent of the patients in this study were using colchicine. In our study, there was no difference in pregnancy complications or birth outcomes between the pregnant women using colchicine and the control group. From this, it can be concluded that FMF pregnant women whose inflammatory pathways are regulated under colchicine treatment can be followed up similarly to the general population.

While our study offers significant insights, the

limited sample size may restrict the generalizability of the results. The other limitation of the study is the retrospective design of the study. Additionally, colchicine, which is frequently used in FMF patients, may influence immune mechanisms, blood parameters, and their functions, potentially affecting our findings. Subsequent research including larger cohorts and prospective methodologies is crucial to enhance our comprehension of FMF's effects on pregnancy and to corroborate our results.

## CONCLUSION

In conclusion, our study highlights changes in monocyte levels in pregnant women with FMF who use colchicine, while pregnancy outcomes remain largely comparable to controls. These results highlight the importance of comprehensive prenatal care and continued use of colchicine to optimize maternal and fetal health in FMF patients. Attention should also be paid to the prevalence of anemia in pregnant women with FMF to optimize both maternal and fetal health in this population.

### *Ethical Statement*

This study was approved by the Ankara Etlik City Hospital Scientific Research Evaluation and Ethics Committee (Decision no: AEŞH-BADEK-2025-0060, and date: 08.01.2025).

### *Authors' Contribution*

Study Conception: BTÇ; Study Design: BTÇ, GA; Supervision: ZŞ, NVT; Funding: N/A; Materials: BTÇ, FA, SNA; Data Collection and/or Processing: GA, GK, FA, SNA; Statistical Analysis and/or Data Interpretation: ZŞ, NVT; Literature Review: GA, GK; Manuscript Preparation: BTÇ, GA, ŞÇ; and Critical Review: BTÇ, ŞÇ.

### *Conflict of interest*

The authors disclosed no conflict of interest during the preparation or publication of this manuscript.

### *Financing*

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