

# TREATMENT ADHERENCE IN FAMILIAL MEDITERRANEAN FEVER PATIENTS: REAL-LIFE DATA FROM CENTRAL ANATOLIA

FMF Hastalarında Tedaviye Uyum: Orta Anadolu'dan Gerçek Yaşam Verileri

Özlem KARAKAŞ<sup>1</sup> , Sualp Mete SEVİL<sup>2</sup> , Dudu ÇELİK TAM<sup>3</sup>

#### Afiliasyon / Affiliation:

<sup>1</sup>Kırıkkale University Faculty of Medicine, Department of Internal Medicine, Division of Rheumatology, Kırıkkale, Türkiye.

<sup>2</sup>Kırıkkale University Faculty of Medicine, Department of Internal Medicine, Kırıkkale, Türkiye.

<sup>3</sup>Bilkent City Hospital, Department of Rheumatology, Ankara, Türkiye.

# Sorumlu Yazar / Correspondence:

Dudu Çelik Tam, MD Ankara Bilkent City Hospital, Division of Rheumatology Ankara, Türkiye. E-mail:duduceliktam@gmail. com

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### **ABSTRACT**

Objective: Familial Mediterranean Fever (FMF) is a hereditary autoinflammatory disorder characterized by recurrent febrile episodes and serosal inflammation. Colchicine remains the cornerstone of FMF treatment, and adherence to therapy is critical to prevent disease flares and long-term complications such as amyloidosis. However, studies on treatment adherence in FMF are limited and report varying rates. This study aimed to evaluate treatment adherence in FMF patients and its association with clinical variables using real-life data from Central Anatolia. Methods: This retrospective cross-sectional study included FMF patients aged 18 years and older who were followed at a tertiary rheumatology outpatient clinic and met the Tel-Hashomer diagnostic criteria. Demographic and clinical data were collected through structured interviews and medical record reviews. Treatment adherence was assessed via self-report. Associations between adherence and variables such as attack frequency, disease duration, drug adverse events, and follow-up visits were analyzed using Mann-Whitney U, Chi-square, and Spearman correlation tests as appropriate. Results: 70 patients (64.3% female, median age 33.5 years) were included. The majority (89.2%) reported regular adherence to treatment. Colchicine was the most commonly used drug, with a median dose of 1.5 mg/day. A weak, non-significant positive correlation was found between colchicine dose and the number of attacks in the last 6 months ( $\rho = 0.229$ , p = 0.071). There was no statistically significant association between treatment adherence and attack frequency (p = 0.622), disease duration (p = 0.134), follow-up frequency (p = 0.779), side effects (p = 0.582), proteinuria (p = 1.000), or marital status (p = 0.105). Discussion: Despite high levels of reported adherence to colchicine among FMF patients, this did not consistently correlate with improved clinical outcomes. These findings highlight the complex nature of treatment adherence and underscore the need for individualized support strategies and objective adherence assessment tools in FMF management.

Keywords: Attack frequency, Colchicin, Familial mediterranean fever, Treatment adherence

#### ÖZET

Amaç: Ailevi Akdeniz Ateşi (AAA), tekrarlayan ateş atakları ve serozal inflamasyon ile karakterize, kalıtsal bir otoinflamatuar hastalıktır. Kolşisin, AAA tedavisinin temelini oluşturur ve tedaviye uyum, atakları önlemek ve amiloidoz gibi uzun vadeli komplikasyonları engellemek açısından kritik öneme sahiptir. Ancak, AAA hastalarında tedaviye uyum oranlarıyla ilgili veriler sınırlıdır ve literatürde değişken sonuçlar bildirilmiştir. Bu çalışmada, Orta Anadolu bölgesinden elde edilen gerçek yaşam verileri kullanılarak, AAA hastalarında tedaviye uyum ve bunun klinik değişkenlerle ilişkisi değerlendirilmiştir. Yöntem: Bu retrospektif kesitsel çalışma, Tel-Hashomer tanı kriterlerini karşılayan ve bir üçüncü basamak romatoloji polikliniğinde takip edilen 18 yaş ve üzeri AAA hastalarını içermektedir. Demografik ve klinik veriler yapılandırılmış görüşmeler ve tıbbi kayıt incelemeleri yoluyla toplanmıştır. Tedaviye uyum, hastaların kendi beyanına dayalı olarak değerlendirilmiştir. Uyum ile atak sıklığı, hastalık süresi, ilaç yan etkileri ve takip sıklığı gibi değişkenler arasındaki ilişkiler Mann-Whitney U, Ki-kare ve Spearman korelasyon testleri ile analiz edilmistir. **Bulgular:** Calısmaya 70 hasta (kadın oranı %64,3; medyan yas: 33,5 yıl) dahil edilmiştir. Hastaların büyük çoğunluğu (%89,2), tedaviye düzenli olarak uyum sağladığını bildirmiştir. En sık kullanılan ilaç kolşisin olup, medyan günlük doz 1,5 mg'dır. Kolşisin dozu ile son 6 aydaki atak sayısı arasında zayıf, istatistiksel olarak anlamlı olmayan pozitif bir korelasyon saptanmıştır (p = 0.229; p = 0.071). Tedaviye uyum ile atak sıklığı (p = 0.622), hastalık süresi (p = 0.134), takip sıklığı (p = 0.779), yan etkiler (p = 0.582), proteinüri (p = 1.000) veya medeni durum (p = 0.105) arasında anlamlı bir ilişki bulunmamıştır. Tartışma: AAA hastalarının büyük çoğunluğu kolşisin tedavisine yüksek oranda uyum gösterdiğini belirtse de, bu durum klinik sonuçlarda belirgin bir iyileşme ile ilişkilendirilmemiştir. Bulgular, kronik hastalıklarda tedaviye uyumun karmaşık doğasını vurgulamakta ve AAA yönetiminde bireyselleştirilmiş destek stratejilerine ve objektif uyum değerlendirme araçlarına duyulan ihtiyacı ortaya koymaktadır.

Anahtar Kelimeler: Ailevi akdeniz ateşi, Atak sıklığı, Kolşisin, Tedaviye uyum

## INTRODUCTION

Mediterranean Fever Familial (FMF) is hereditary, monogenic autoinflammatory disease characterized by recurrent episodes of fever and/ or serosal inflammation, and it is the most common autoinflammatory disorder worldwide & Lachmann, 2020). The disease is particularly prevalent among Turks, Armenians, and Arabs, with a reported prevalence of 0.093% in Turkey (Ozen et al., 1998). Most patients experience their first attack during early childhood, with approximately 65% of cases having their initial episode before the age of 10 and 90% before the age of 20 (Majeed et al., 1999). The main goals of FMF treatment are to improve quality of life (QoL), reduce the frequency, severity, and duration of attacks, and minimize chronic/ subclinical inflammation in order to prevent longterm complications—most notably AA amyloidosis. There is considerable interindividual variability in the frequency, type, and severity of attacks. Therefore, treatment should be individualized based on monitoring of clinical episodes and inflammatory markers (Knieper et al., 2017). Inflammation in FMF patients can be effectively controlled with treatments targeting interleukin (IL)-1β, such as colchicine, the recombinant human IL-1 receptor antagonist anakinra, the fully human IgG1 monoclonal antibody directed against IL-1β canakinumab, or the fully human dimeric fusion protein rilonacept (Jesenak et al., 2018; Sönmez, Batu, & Özen, 2016). Colchicine remains the cornerstone of FMF treatment. However, up to 5% of patients fail to respond to colchicine despite receiving the maximum tolerable dose. One of the most important factors contributing to colchicine resistance is poor treatment compliance (Padeh, Gerstein, & Berkun, 2012). Treatment resistance can not only lead to disease-related complications but also negatively impact patients' quality of life. In the literature, treatment adherence in FMF and other rheumatic diseases has been evaluated using various tools such as the Compliance Questionnaire-Rheumatology (CQR), the Morisky Medication Adherence Scale, electronic medication monitoring devices, and pharmacy refill records. Although these

methods are considered objective, their widespread use is limited due to disadvantages such as recall and social desirability bias, cultural adaptation difficulties, high cost, technical challenges, and the inability to confirm actual medication intake. Studies investigating treatment adherence in FMF are limited and have shown variable results. In one study evaluating adherence to colchicine treatment, adherence rates were reported as 73% in adults and 96% in children (Padeh, Gerstein, & Berkun, 2012). In another study conducted in Turkey involving 96 FMF patients, 35.5% of the patients reported that they did not use colchicine regularly (Karaaslan et al., 2015). This study aims to evaluate treatment adherence in FMF patients and, by presenting reallife data from Central Anatolia where the disease is highly prevalent, to contribute to the limited body of adherence research in Turkey and to a better understanding of its impact on disease course.

# **METHODS**

# **Study Design and Patient Selection**

This study was designed as a retrospective crosssectional analysis. Patients aged 18 years and older who were diagnosed with FMF based on the Tel-Hashomer criteria and followed at the rheumatology outpatient clinic of Ankara City Hospital were included. To be eligible, participants were required to be under regular follow-up and treatment for at least 6 months. Exclusion criteria included patients with additional autoimmune diseases (e.g., overlap syndromes, Sjögren's syndrome, systemic sclerosis, inflammatory myositis), individuals under 18 years of age, and those not fulfilling the Tel-Hashomer diagnostic criteria. A total of 123 patients were initially assessed, of whom 43 were excluded due to irregular follow-up or incomplete medical records. Consequently, 70 patients were included in the final analysis. Ethical approval for the study was obtained from the Ankara City Hospital Ethics Committee (Date: 30.07.2025, Approval No: 1-25-1544), and the study was conducted in accordance with the ethical standards of the Declaration of Helsinki (1964) and its later amendments.

#### Treatment Adherence in Familial Mediterranean Fever

## **Data Collection**

Demographic and clinical data were obtained through structured interviews and review of medical records. Collected variables included age, sex, disease duration, family history of FMF, number of attacks in the last 6 months, treatment type, colchicine dosage, side effects, proteinuria status, marital status, and annual follow-up visit frequency. Treatment adherence was determined based on patients' self-report of regular medication use.

# **Statistical Analysis**

Statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize the demographic and clinical characteristics of the patients. Categorical variables were presented as frequencies and percentages, while continuous variables were expressed as medians and ranges due to non-normal distribution. To evaluate the association between treatment adherence and attack frequency, the Mann-Whitney U test was applied. This test was also used to compare disease duration and the number of annual follow-up visits between patients with and without regular treatment adherence. The relationship between colchicine dosage and attack count was assessed using Spearman's correlation coefficient. Associations between categorical variables such as treatment adherence and side effects, proteinuria status, and marital status were evaluated using Pearson's Chi-square test or Fisher's Exact test where appropriate.

# **RESULTS**

# **Demographic Characteristics**

A total of 70 patients were included in the study, with a median age of 33.5 years (range: 19–77). Of these patients, 45 (64.3%) were female and 25 (35.7%) were male. The median disease duration was 10 years (range: 0–30). At least one comorbidity was present in 27 patients (40.3%) (Table 1). Among 37 patients who were aware of their family history, 27 (72.9%) reported a positive family history of FMF.

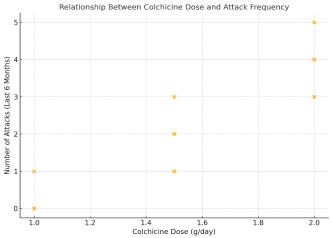
Table 1. Demographic Characteristics of FMF Patients

| Median age (years) (min-max)             | 33.5 (19-77) |
|--|--------------|
| Gender, n, %                             | '            |
| Female                                   | 45 (64.3%)   |
| Male                                     | 25 (35.7%)   |
| Disease duration, median years (min-max) | 10 (0-30)    |
| At least one comorbidity, n, %           | 27 (40.3%)   |
| Hypertension                             | 6 (22.2%)    |
| Diabetes Mellitus                        | 5 (18.5%)    |
| Treatment, n, %                          | '            |
| Colchicine                               | 67 (95.71%)  |
| Anakinra                                 | 1 (1.42%)    |
| Canakinumab                              | 1 (1.42%)    |
| No current treatment                     | 1 (1.42%)    |

FMF: Familial Mediterrean Fever

# **Disease Characteristics and Quality of Life**

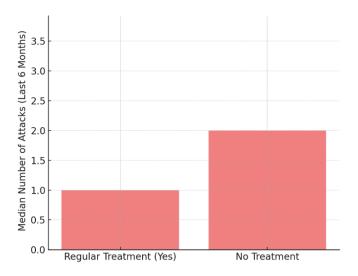
The median disease duration was 10 years (range: 0-30). The median age at FMF symptom onset was 23 years (range: 3-71). A majority of patients (97.1%) were receiving active treatment. Colchicine was the most commonly used medication, reported by 67 patients (95.71%), followed by anakinra and canakinumab in 1 patient each (1.42%). The median daily colchicine dose was 1.5 mg (range: 1-2). The median number of attacks within the past 6 months was 1 (range: 0-12). Although a weak positive correlation was found between colchicine dose and the number of attacks, this relationship was not statistically significant ( $\rho = 0.229$ ,  $\rho = 0.071$ ) (Figure 1).



**Figure 1.** The relationship between colchicine dose and number of attacks in the last 6 months

Colchicine-related adverse events were reported by 9.9% of patients. The most common adverse event was diarrhea, observed in 85.8% of those reporting adverse events. One patient experienced

liver function abnormalities after colchicine use. Among patients receiving IL-1 antagonists, only one developed an allergic reaction following anakinra administration. A total of 89.2% of patients reported regular adherence to their treatment regimens. Among those receiving colchicine, 87.1% also reported consistent follow-up visits. The median frequency of outpatient follow-up visits in the past year was 2 (range: 1–8). There was no statistically significant difference in annual follow-up frequency between those with and without regular treatment adherence (p = 0.779). No significant association was found between experiencing drug-related side effects and adherence to regular treatment (p = 0.582). Similarly, no statistically significant difference was found between treatment adherence and disease duration (p = 0.134). When assessing the relationship between treatment adherence and attack frequency, no statistically significant difference was observed between regularly treated and nonregularly treated patients regarding the number of attacks in the past 6 months (p = 0.622) (Figure 2).



**Figure 2.** Comparison of Median Attack Frequency by Treatment Adherence

Proteinuria was observed in 11.1% of patients. There was no significant relationship between the presence of proteinuria and regular treatment adherence (p = 1.000). Regarding the impact of marital status on treatment adherence, no significant difference was found in treatment compliance between married and single patients (p = 0.105).

## **DISCUSSION**

In this study, treatment adherence and related clinical factors were investigated in patients with FMF, and the majority of patients (89.2%) reported that they adhered to their treatment regimen regularly. However, no statistically significant relationship was found between regular treatment adherence and the number of attacks in the past 6 months (p = 0.622), disease duration (p = 0.134), or the frequency of annual outpatient visits (p = 0.779). Additionally, no significant association was observed between treatment adherence and variables such as the presence of drug-related side effects (p = 0.582), presence of proteinuria (p = 1.000), or marital status (p = 0.105). Although the majority of patients in our study reported regular adherence to colchicine therapy, this adherence did not result in significant improvements in clinical outcomes such as attack frequency or disease duration. This discrepancy may be explained by several interacting factors. First, adherence was assessed solely via patient self-report, a method prone to recall and social desirability bias. Recent European Alliance of Associations for Rheumatology EULAR) guidelines (Özen et al., 2024) emphasize the importance of using objective methods for adherence assessment, including pharmacy refill records and validated adherence questionnaires, to ensure accurate monitoring. Treatment adherence was assessed by patient self-report. Although self-report is practical and commonly used in real-life clinical settings, it may be subject to recall and social desirability bias. The main advantage of using self-report is feasibility and accessibility in routine practice, while its limitations include potential overestimation of adherence compared to objective methods such as electronic monitoring or pharmacy refill data. Familial Mediterranean Fever is a hereditary monogenic autoinflammatory disease characterized by recurrent fever attacks accompanied by sterile peritonitis, pleuritis, arthritis, and/or erysipelaslike erythema (Masters et al., 2009). Although the attacks are self-limiting, patients are at risk of developing secondary amyloidosis, which can lead to renal failure and premature death due to chronic

inflammation and reduced quality of life (Ozen et al., 2016). The primary goals of FMF treatment are to prevent attacks and reduce chronic inflammation and its consequences. Regular monitoring of disease activity, complications, and inflammatory burden is essential for a comprehensive approach to FMF management (Bilici Salman et al., 2022). Colchicine is the mainstay of FMF treatment and has been proven effective in preventing attacks and secondary amyloidosis (Ozen, Kone-Paut, & Gül, 2017). Reported adherence rates to colchicine therapy vary between 58% and 73% in the literature (Corsia et al., 2017). In our study, this rate was found to be 87.1%. The recommended colchicine dose in adults is generally 1.0-1.5 mg/day (Demirkaya et al., 2016), and the median dose used by our patients was 1.5 mg/day, consistent with literature data. At recommended doses, oral colchicine is generally safe and well tolerated. Gastrointestinal side effects such as diarrhea, cramps, and abdominal pain may occur even at therapeutic doses (COLCRYSTM, 2009). In our patient group, the rate of side effects was 9.9%, with diarrhea being the most common (85.8%). According to the EULAR, FMF patients should ideally be evaluated every six months or more frequently by a rheumatologist (Özen et al., 2016). In our study, the median annual number of follow-up visits was two, which aligns with these recommendations. Previous studies have reported poor adherence to follow-up visits among FMF patients (Bilici Salman et al., 2022, Babaoglu et al., 2019); however, our findings indicate a relatively high rate of regular treatment adherence (89.2%). Although the treatment adherence rate in our FMF cohort was higher than expected, no significant association was found between regular adherence and clinical parameters such as attack frequency, disease duration, or follow-up visit frequency. This suggests that treatment adherence may be influenced by multifactorial aspects including individual awareness, patient education, and access to healthcare, in addition to clinical indicators. Multidisciplinary approaches aimed at improving adherence are crucial for both preventing complications and enhancing quality of life. These findings support the development of individualized follow-up strategies in FMF management.

Limitations: This study has several limitations. Firstly, its cross-sectional design precludes causal inferences between treatment adherence and clinical outcomes. Secondly, adherence was based solely on patient self-report, which may be subject to recall and social desirability bias. The absence of objective adherence measures (e.g., pharmacy records, electronic monitoring) may have led to overestimation. Additionally, genetic variability (e.g., MEFV mutations), treatment duration, and dose optimization were not analyzed—factors that could significantly influence response to therapy. Finally, the single-center setting, small sample size, and generally low attack rates may have reduced statistical power and limited generalizability. Despite these constraints, this study contributes meaningful real-world data and highlights the need for future prospective, multicenter research incorporating objective and individualized metrics.

Conclusion: In our study, although the majority of patients reported regular adherence to colchicine therapy, this was not found to be significantly associated with improvements in clinical parameters. This finding suggests that the relationship between treatment adherence and clinical outcomes is multifactorial and cannot be explained solely by the frequency of medication use.

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**Author Contributions:** Ö.K. contributed to the conception and design of the study, planning, and final approval of the manuscript. S.M.S. contributed to data collection, preparation of data for analysis, and final review of the manuscript. D.Ç.T. contributed to manuscript revision, data analysis and interpretation, and literature review.

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