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Mycophenolate mofetil as initial immunosuppressive therapy in Behçet's uveitis: a retrospective cohort study

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Abstract

Background:
Behçet’s disease is a chronic multisystem inflammatory disorder in which uveitis represents a major cause of visual morbidity. While corticosteroids remain central for acute control, their prolonged use is associated with significant adverse effects, necessitating effective steroid-sparing strategies. Mycophenolate mofetil (MMF) has shown benefit in noninfectious uveitis; however, data regarding its use in Behçet’s uveitis remain limited. This study evaluates the real-world efficacy, steroid-sparing potential, and adverse reactions of MMF when used as the initial immunosuppressive agent.

Methods:
A retrospective cohort study was conducted at King Khaled Eye Specialist Hospital, Riyadh, including patients who initiated MMF as the primary immunosuppressive agent between 2013 and 2025. Concomitant corticosteroids were permitted during the induction phase, and escalation to biologic therapy was allowed per the treating physician judgment. Patients receiving biologics or multiple immunosuppressants at baseline were excluded.

Results:
Among 287 Behçet’s disease patients identified, 15 met the inclusion criteria. Panuveitis was the predominant presentation (86.7%). Steroid tapering was achieved in 80%, with complete steroid discontinuation in 13.3%. However, Relapse occurred in 10 patients (66.7%), most commonly as recurrent anterior chamber inflammation with a ≥2-step increase in cell grade.

MMF was discontinued in 33.3% of patients, primarily due to lack of efficacy.

Conclusion:
MMF demonstrated a steroid-sparing effect within an MMF-initiated treatment strategy for Behçet's uveitis, though relapse and discontinuation rates were high. Corticosteroid reduction reflects the overall treatment employed during follow-up rather than the isolated effect of MMF alone. These findings reflect a real-world approach and suggest MMF may be better positioned as a maintenance or adjunctive agent rather than sole initial therapy for patients with severe posterior segment involvement.

Introduction

Behçet's disease is a chronic, multisystem inflammatory disorder characterized by recurrent oral and genital ulcers, skin lesions, and uveitis (1). Uveitis, an inflammation of the uveal tract of the eye, is a significant cause of morbidity in Behçet's disease, potentially leading to severe visual impairment or blindness if not adequately managed (2). Despite the lack of population-based prevalence data, Saudi studies have shown that Behçet’s uveitis is the third most common cause of uveitis in tertiary care hospitals, following idiopathic uveitis and Vogt-Koyanagi-Harada (VKH) disease (3–5). Traditional treatment strategies have primarily involved systemic corticosteroids and immunosuppressive agents to control ocular inflammation (6). However, long-term corticosteroid use is associated with substantial

adverse effects, necessitating the early introduction of effective steroid-sparing therapies (7). The European League Against Rheumatism (EULAR) 2018 guidelines recommend close coordination between ophthalmologists and rheumatologists to induce and maintain remission. While posterior segment involvement warrants systemic therapy with agents such as azathioprine, cyclosporine A, interferon-α, or anti-TNF antibodies. (8) the role of MMF in this context remains relatively limited and was not included in the 2024 living guidelines for Behçet's disease. (9) However, some evidence suggests that MMF may be effective in treating certain skin manifestations of Behçet's disease, and it has therefore been included in the British Society for Rheumatology (BSR) guidelines as a secondary treatment option for skin involvement, though not for ocular involvement. (9) MMF exhibits its action by selective inhibition of inosine monophosphate dehydrogenase, leading to suppression of lymphocyte proliferation (10)

It has long been recognized as a promising immunosuppressive agent for the treatment of various autoimmune disorders including skin manifestations of behcet (9), pemphigus (11), connective tissue diseases like lupus erythematosus (12), inflammatory myopathies (13), and systemic sclerosis (14), as well as atopic dermatitis and chronic actinic dermatitis (15, 16). However, in the context of Behçet's disease-related uveitis, the experience with MMF remains relatively limited. Two recent studies — Ucar et al. (19) and Kerim et al. (18) — have examined MMF specifically in Behçet's uveitis, reporting that it may serve a role as a maintenance agent and demonstrating an acceptable safety profile, respectively. Therefore, this study aims to evaluate the real-world efficacy of MMF when used as the initial immunosuppressive strategy in behcet related uveitis.

Methodology

Study Design and Setting

This is a retrospective cohort study conducted at King Khaled Eye Specialist Hospital (KKESH) in Riyadh, Saudi Arabia. The study examines the efficacy, steroid-sparing effects, and adverse reactions of mycophenolate mofetil (MMF) as the initial immunosuppressive strategy in patients with Behçet's disease-related uveitis.

Participants and Eligibility Criteria

Inclusion Criteria included: patients with a confirmed diagnosis of Behçet's disease based on the International Criteria for Behçet's Disease (ICBD), which assigns points for oral aphthosis (2 points), genital aphthosis (2 points), ocular lesions (2 points), skin lesions (1 point), neurological manifestations (1 point), vascular manifestations (1 point), and a positive pathergy test (1 point), with a score ≥ 4 required for diagnosis, patients diagnosed with uveitis associated with Behçet's disease, and patients who initiated MMF as the primary immunosuppressive agent for Behçet-related uveitis. Exclusion

Criteria included patients who initiated triple therapy upfront, including biologics, and incomplete medical records preventing assessment of outcomes.

Data Collection and Patient Selection

Data were extracted from the hospital's electronic medical records system for patients meeting the inclusion criteria from 2013–2025. Of the 287 patients correctly identified in the TrakCare Hospital electronic system using diagnosis codes M35.2 (“Behçet’s disease”) and M35.2X0 (“Behçet’s disease with uveitis”), 63 did not meet the International Criteria for Behçet’s Disease (ICBD), 4 had incomplete medical records that prevented outcome assessment, 9 were lost to follow-up, and 196 did not initiate mycophenolate mofetil as their first-line treatment. This resulted in a final sample size of 15 patients, reflecting the relative rarity of Behçet’s uveitis patients meeting strict first-line MMF eligibility criteria. It is noteworthy that not all patients 15 completed the full 24 month follow-up; 6 patients were lost to follow-up before 24 months.

Outcome Measures and Ethical Considerations

The primary outcome was the rate of relapse over a 24-month follow-up period. Relapse was defined as a ≥ 2-step increase in anterior chamber cell grade or vitreous haze (per Standardization of Uveitis Nomenclature [SUN] criteria), new or worsening retinal vasculitis on fluorescein angiography, or the need for escalation of corticosteroid dose or addition of a new immunosuppressive or biologic agent, following a documented period of clinical quiescence.

Secondary outcomes included the ability to taper oral prednisolone. Steroid tapering was defined as any reduction in systemic corticosteroid dose from baseline during follow-up. Complete corticosteroid withdrawal was defined as full discontinuation of systemic corticosteroids.

As this was a retrospective study, corticosteroid treatment and tapering were not governed by a standardized protocol but were performed at the discretion of the treating physician based on clinical response and disease activity. Intravenous pulse methylprednisolone was used at the treating physician's discretion for acute severe flares; no standardized induction regimen was applied uniformly.

The study adhered to ethical standards for research involving human subjects. Ethical approval for this study was approved by the Institutional Review Board (IRB) of King Khaled Eye Specialist Hospital, Riyadh, Saudi Arabia (Approval No. RD/26001/IRB/0226 – 25). The study was conducted in accordance with the principles of the Declaration of Helsinki. The requirement for informed consent was waived due to the retrospective nature of the study and the use of anonymized data. Data was anonymized to ensure patient confidentiality.

Statistical Plan

All statistical analyses were performed using the IBM SPSS (29.0.0). The descriptive statistics were summarized for the demographic and clinical characteristics. The continuous variables are expressed as mean and the standard deviation (SD) or the median (IQR) where appropriate. The categorical variables are presented as the frequencies (N) and percentages (%). The differences between groups were analyzed using the Student's t-test or Mann–Whitney U test for continuous variables, and the chi-square or Fisher's exact test for categorical variables. A p-value < 0.05 was considered statistically significant.

Results

Out of 287 BD patients identified, 15 patients (30 eyes) met the inclusion criteria. The majority were males (13, 86.7%). The mean (SD) age of the participants was 36.4 (10.1) years, and ranged from 17 to 54 years. Oral ulcers were the most common systemic manifestation (86.7%), followed by genital ulcers (53.3%). HLA-B51 positivity was documented in 8 of the 15 patients (53.3%). ***(Table 1)***

Panuveitis was the predominant presentation (86.7%), highlighting the severity of ocular disease in this cohort. Occlusive retinal vasculitis and retinitis were common. 60.0% and 73.3% respectively.(***Figure 1***)

MMF was discontinued in 5 patients (33.3%). Among those who discontinued the therapy, the main reasons were the failure of the therapy; defined as inability to achieve and maintain clinical remission despite adequate dosing and adherence (3, 20.0%), followed by the adverse effects (1, 6.7%) in the form of gastrointestinal upset.

Corticosteroid tapering up to 7.5mg was achieved in most patients (12, 80.0%), and complete discontinuation of steroids occurred in 2 (13.3%). Overall, the MMF demonstrated a good steroid-sparing potential. (***Table 2)***

Regarding post-treatment inflammatory status, the majority of patients were stable with only trace anterior chamber inflammation (11, 73.33%). Only 4 patients (26.7%) had persistent panuveitis activity indicating that MMF achieved partial disease control. (***Table 3)***

The relapse rate as per SUN criteria was common, with only 5 patients (33.3%) remaining relapse-free. Relapse occurred in 10 patients (66.7%), most commonly as recurrent anterior chamber inflammation with ≥2-step increase in cell grade. (***Table 4)***

The baseline mean steroid dose was 41.9 mg (SD 9.2), which declined markedly over the time of 24 months to a mean of 7.5mg (SD2.7). representing an overall 82.1% reduction compared to baseline. However, it is important to note that this corticosteroid reduction cannot be attributed solely to MMF, as 40% of patients required escalation to biologic therapy during the same follow-up window. Corticosteroid reduction therefore reflects the overall treatment employed during follow-up rather than the isolated effect of MMF alone. These findings highlight the steroid-sparing potential within an MMF-initiated treatment strategy. ***(Figure 2)***

Discussion

Our findings add to the limited body of evidence evaluating the role of MMF as an initial immunosuppressive treatment in Behçet's uveitis. While MMF has shown efficacy in various autoimmune and noninfectious uveitis entities, its role in Behçet's disease remains less well defined. This study highlights several important clinical implications. It is important to acknowledge that the present cohort does not represent a strict monotherapy population. The majority of patients (93.3%) received concurrent oral corticosteroids from the outset, and 40% required escalation to biologic therapy during the follow-up period. Accordingly, the 24-month outcomes reported herein reflect the results of an MMF-initiated, rather than the isolated efficacy of MMF.

Because most patients had posterior segment involvement and retinal vasculitis, many would currently be considered candidates for early biologic therapy according to contemporary EULAR recommendations. (8). Therefore, our findings should be interpreted as reflecting real-world outcomes of MMF use rather than as evidence supporting MMF as the optimal first-line treatment strategy for such patients.

Limited Efficacy of MMF as initial therapy

MMF was introduced as a first-line immunosuppressive therapy in our cohort. The majority experienced recurrent inflammatory episodes post-treatment. A retrospective data from Ucar et al reported that MMF may serve better as a maintenance agent rather than as an induction therapy, particularly when combined with biologics (19). Similar findings were described by Durrani et al and Daniel et al, who observed that MMF as initial therapy often results in partial control but rarely induces long-term remission in noninfectious uveitis (16, 21). Furthermore, Taylor et al highlighted that Behçet's posterior uveitis is especially resistant to conventional immunosuppressants compared with other uveitic entities (20). Taken together, these findings emphasize the limitations of MMF when used alone in severe posterior segment involvement, where stronger immunosuppression is typically required.

Steroid-Sparing Effect

Despite the limited efficacy as initial therapy, MMF demonstrated a clear steroid-sparing effect in our cohort. Two patients achieved complete steroid withdrawal, and the majority experienced substantial tapering. This aligns with prior multicentre study demonstrating that MMF facilitates significant reductions in corticosteroid burden (16). Additionally, Teoh et al. and Rodriguez et al. observed high probabilities (> 80%) of tapering prednisone to ≤ 10 mg by 1 year when using MMF for noninfectious uveitis (21, 22). Given the well-recognized toxicity of long-term corticosteroids, including osteoporosis, diabetes, hypertension, glaucoma, and cataract formation (23). This steroid-sparing property remains an important clinical benefit.

Discontinuation and Relapse Rates

Drug survival with MMF was suboptimal. One-third of our patients discontinued MMF, primarily due to lack of efficacy or adverse events. The primary outcome of this study is the relapse rate among Behçet's uveitis patients who received MMF as their initial therapy during a 24-month follow-up period. We found that relapses were frequent, with panuveitis reactivation being the most common pattern. These discontinuation and relapse rates are consistent with prior reports that MMF is less durable in Behçet's compared with other uveitic entities (16, 19).

Positioning of MMF Relative to Biologics

The emergence of biologics, particularly anti-TNF agents such as infliximab and adalimumab, has transformed the management of Behçet's uveitis. Both agents have demonstrated superior efficacy in achieving rapid control of posterior segment inflammation and in reducing relapse rates. (2, 8). In our cohort, escalation to biologics was required in 40% of patients within two years, reflecting their necessity in cases refractory to MMF as stated by EULAR guidelines (8). MMF may best be positioned as adjunctive agent for maintenance in patients requiring a steroid-sparing bridge while initiating biologic therapy. Its role as initial therapy in severe Behçet's uveitis appears limited. The decision to initiate MMF as the primary immunosuppressive agent in this cohort, despite a severe baseline disease profile, was guided by its availability, physician's preference, and institutional practice patterns that employed sequential escalation. This reflects real-world access constraints and treatment sequencing

Limitations

The main limitations of this study include its retrospective design, small sample size, and lack of a control group, which limit the generalizability of the findings. Nonetheless, its strength lies in being among the first analyses to assess MMF as the initial immunosuppressive strategy in Behçet's uveitis with two-year follow-up data, offering valuable real-world insights into treatment dynamics and steroid-sparing potential.

Conclusion

In summary, MMF in Behçet's uveitis provides meaningful steroid-sparing benefits but demonstrates limited efficacy as initial therapy, relatively high discontinuation rates, and frequent relapses. While it remains a potential option for maintenance therapy or as a bridge to biologics, its use as a standalone agent in patients with severe posterior segment involvement should be undertaken with caution, given the high relapse and biologic escalation rates observed in this cohort. MMF may be better suited for patients with mild-to-moderate disease activity, or as part of a combination maintenance regimen following biologic induction. The current study is the first to describe safety, relapse rate, and its steroid-sparing effect. Future prospective studies are needed to define the most effective integration of MMF into the treatment algorithms for Behçet's uveitis.

Abbreviations

BD

Behçet’s disease
BCVA
Best-corrected visual acuity
BSR
British Society for Rheumatology
CME
Cystoid macular edema
CRAO
Central retinal artery occlusion
CRVO
Central retinal vein occlusion
EDI-OCT
Enhanced depth imaging optical coherence tomography
EULAR
European League Against Rheumatism
HLA
Human leukocyte antigen
ICBD
International Criteria for Behçet’s Disease
IQR
Interquartile range
IRB
Institutional Review Board
KKESH
King Khaled Eye Specialist Hospital
LogMAR
Logarithm of the minimum angle of resolution
MMF
Mycophenolate mofetil
NVG
Neovascular glaucoma
OCT
Optical coherence tomography
PVD
Posterior vitreous detachment
SD
Standard deviation
SPSS
Statistical Package for the Social Sciences
SUN

Standardization of Uveitis Nomenclature

Declarations

Ethics approval and consent to participate

This retrospective study was approved by the Institutional Review Board (IRB) of King Khaled Eye Specialist Hospital, Riyadh, Saudi Arabia (Approval No. RD/26001/IRB/0226-25), and was conducted in accordance with the Declaration of Helsinki. The requirement for informed consent was waived by the Institutional Review Board due to the retrospective nature of the study. Data was anonymized to ensure patient confidentiality.

Consent for publication Not applicable.

Availability of data and materials Available upon request.

Competing interests Not applicable.

Funding Not applicable.

Authors' contributions H.S. and H.A.A. contributed equally to the conception and design of the study. H.S. collected the data and drafted the manuscript. H.A.A. and M.A.O. contributed to data interpretation and critically revised the manuscript. R.A., A.M.A., N.A., and S.A. assisted in data collection and manuscript review. All authors read and approved the final manuscript.

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Tables

Table 1: Demographic Parameters, Extra-ocular Clinical Manifestations, and HLA-B51 Lab Results in Behçet's Disease Patients (n=15)

		Frequency N (%)
Male Gender		13 (86.7%)
Age (Years)	Mean (SD)	36.4 (10.1)
	Range	17-54
Smoker		2 (13.3%)
Oral Ulcers		13 (86.7)
Genital Ulcers		8 (53.3)
Arthritis		3 (20.0)
Cutaneous Involvement		4 (26.7)
Gastrointestinal Involvement		2 (13.3)
Thromboembolic Events		0
Neurological Involvement		0
HLAB51		8 (53.3%)

(N) Frequency, (%) Percentages

Table 2: Treatment Outcomes, Steroid-Sparing Effect, Drug Survival, and Reasons for Discontinuation of MMF in Behçet's Uveitis (n=15)

		Frequency N (%)
MMF Discontinuation	Yes	5 (33.3)
Reason for Discontinuation of MMF	Adverse effect*	1 (6.7)
	Failure of therapy	3 (20.0)
Steroids Tapered	Yes	12 (80.0)

**Adverse effect in the form of gastrointestinal upset.*

Table 3: Post-Treatment Inflammatory Status, and Relapse Patterns in Behçet's Uveitis Patients Treated with MMF (n=15)

Severity of Inflammation Post MMF Treatment	**Frequency N (%)**
Trace anterior activity	11 (73.33)
+1 Anterior activity	4 (26.7)
+1 Intermediate activity	2 (13.3)
Posterior activity	3 (20.0)
Panuveitis	4 (26.7)
Systemic activity	2 (13.3)

Table 4: Post-Treatment Relapse Patterns in Behçet's Uveitis Patients Treated with MMF as initial immunosuppressants therapy (n=15)

		Frequency N (%)
Relapse*	No	5 (33.3%)
	≥2-step increase in anterior chamber cell grade	7 (46.7%)
	≥2-step increase in vitreous haze	1 (6.7%)
	New or worsening retinal vasculitis on fluorescein angiography	0 (0.00%)
	Escalation of corticosteroid dose or addition of a new immunosuppressive or biologic agent	6 (40.0%)

* Per Standardization of Uveitis Nomenclature [SUN] criteria

Figures

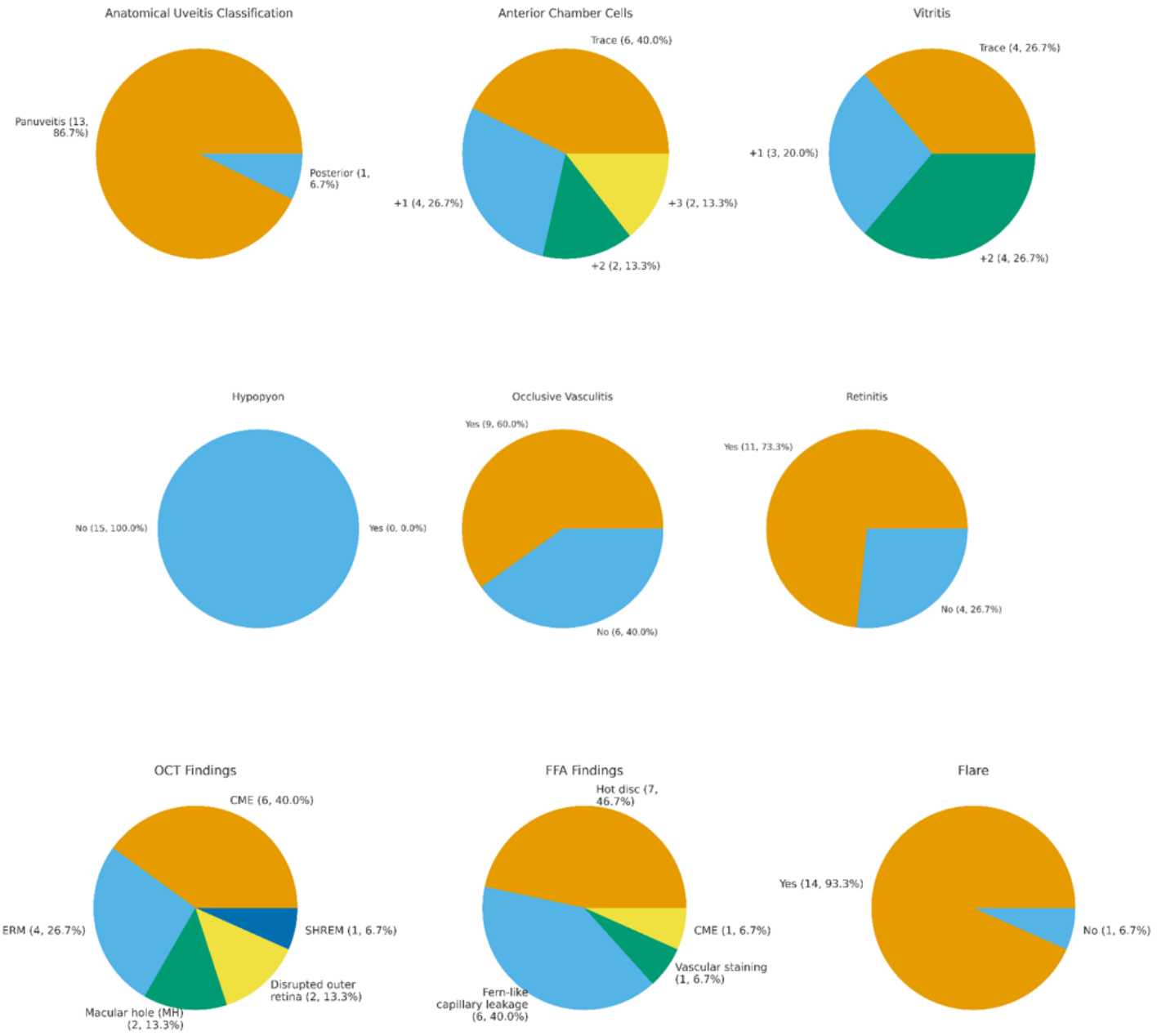


Figure 1

Ocular Characteristics and Imaging Findings of Behçet's Uveitis Among Participants (n=15)

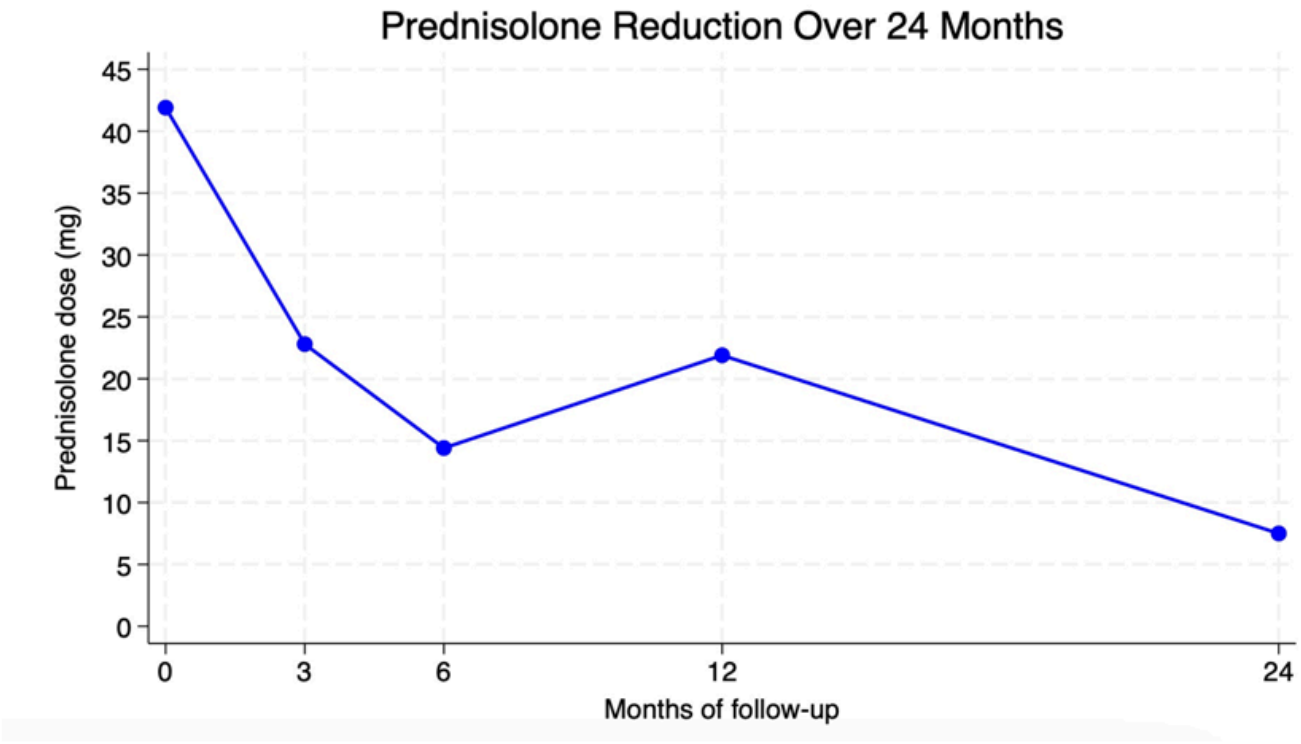


Figure 2

Reduction in Oral Prednisolone Dose Among Behçet's Uveitis Patients Treated with MMF (n=15)