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Case Report

A case report of refractory advanced-stage mycosis fungoides: successful treatment and improved patient quality of life with mogamulizumab

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***Abstract*:** Mycosis fungoides (MF), the most common form of cutaneous T-cell lymphoma, is characterized by patches, plaques, and, in advanced stages, tumors and erythroderma. Early-stage MF may progress to advanced-stage disease in up to one-third of patients, conferring a worse prognosis and typically requiring systemic treatment for extracutaneous involvement. The most frequently reported signs and symptoms are pain, pruritus, scaling, and skin redness, with pruritus, the most bothersome symptom, exerting a profound impact on patients' health-related quality of life (HRQoL). These dermatologic signs and symptoms can overlap with those of other benign inflammatory dermatoses, such as eczema and psoriasis, and therefore, diagnostic delay is common in patients with MF. Moreover, identifying patients with features adversely affecting prognosis (e.g. large-cell transformation or folliculotropic variant) is a significant challenge. We report the case of a 75-year-old female patient who was misdiagnosed with eczema and then pityriasis rubra pilaris and consequently did not receive treatment for MF for 4 years. The patient was eventually correctly diagnosed with MF [stage IIIB (T4 N1 M0 B1)] in September 2018. The patient received several systemic treatments; however, she did not respond to or tolerate the treatments. Due to lack of treatment response, in July 2021, she was initiated on mogamulizumab, an anti-CC chemokine receptor 4 antibody with demonstrated effectiveness and licensed approval for adults with MF/Sézary syndrome who have received one or more prior systemic therapies. Treatment rapidly led to a complete response in blood after 1 week and in skin after 4 months. Mogamulizumab was well tolerated by the patient, who also reported a significant improvement in her HRQoL. After 1 year in complete response, mogamulizumab was discontinued. This case highlights the need for accurate and early diagnosis of MF to initiate disease-specific treatment and the importance of considering patient HRQoL when treating this condition.

Keywords: case report, diagnosis, eczema, misdiagnosis, mogamulizumab, mycosis fungoides, quality of life, refractory

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Background

Cutaneous T-cell lymphomas (CTCLs) are a heterogeneous collection of non-Hodgkin lymphomas that present in skin and involve malignant populations of T lymphocytes.[1,2] Mycosis fungoides (MF) is the most prevalent form of CTCL, accounting for approximately 60% of cases,[3,4] and its incidence increases with age.[5] Diagnosis of MF is based on the correlation of clinicopathologic and clinical signs with the pathology.[2,6,7] Clinically, MF is characterized by erythematous patches or thin, scaly plaques of

variable size and shape in early disease stages.[1,6,8] The disease progresses in up to approximately one-third of patients, evolving to include erythroderma, tumors of the skin, or extracutaneous disease.[4,6,8–12] The primary histologic hallmark of MF is the presence of T cells in the epidermis, and this is accompanied by superficial dermal lymphoid infiltrate.[4,6]

Delayed diagnosis of MF is a problem that can pose a challenge to timely and effective management.[12,13] MF may be commonly misdiagnosed as eczema, psoriasis, or other common benign inflammatory skin illnesses, especially at early disease stages as the nonspecific skin presentation overlaps with other conditions.[12,13] The frequency of misdiagnosis is unknown, but one study found 72% of patients with CTCL ($n = 18$) experienced delays in receiving the correct diagnosis, with the majority of these delays being attributed to misdiagnosis[14]; delays in accurate diagnosis were estimated to be a median duration of 32 months in the PROCLIPI study.[12]

Here, we present the case of a patient who was misdiagnosed with eczema and pityriasis rubra pilaris and received a series of treatments for eczema. When diagnosed with MF in 2018 at an advanced stage (IIIB), the disease was refractory to multiple treatments. After treatment with mogamulizumab, a rapid response was observed, with response in the blood within 1 week and complete remission in the skin within 4 months. The response has persisted, and the patient reported improvement in her health-related quality of life (HRQoL). The reporting of this study conforms to the CARE guidelines.[15]

Patient information

A Caucasian female patient presented with pruritus and was subsequently diagnosed with severe eczema in 2014 at 67 years of age (her treatment history is summarized in Supplemental Figure S1 and Supplemental Table S1). She had an unremarkable family history. The patient had sleep disturbances, mental stress, and negative effects on her daily life due to presenting pruritus. She was prescribed trazodone (from January 2017; 150 mg daily) and gabapentin (from February 2017; starting dose of 300 mg daily, slowly increased to a maximum of 2400 mg daily) for pruritus and neuropathic pain and the associated mental stress; all medications were well tolerated. Systemic steroids (dose and regimen unknown) were prescribed for eczema in 2014, 2015, and 2017. From October 2014, the patient received omalizumab, an anti-immunoglobulin E antibody, 300 mg every 2 weeks, but it was discontinued in December 2014 because the skin symptoms did not respond to treatment. A biopsy was conducted in January 2015 in an attempt to understand the lack of response to treatment thus far; the findings supported the initial diagnosis of eczema due to the absence of any histologic and immunohistochemical signs typical of MF, such as cluster of differentiation (CD)3/CD5 loss, epidermotropism, and lymphoid atypia. The biopsy showed spongiosis in the epidermis and a perivascular infiltrate of lymphocytes and macrophages in the superficial dermis [Figure 1(a)]. Following a lack of response to treatments initiated between March and December 2015 (Supplemental Figure S1 and Supplemental Table S1), another skin biopsy was conducted.

In December 2015, the patient was diagnosed with the rare skin disease pityriasis rubra pilaris based on the clinical observation of erythroderma and pathology demonstrating a prominent stratum granulosum, focal parakeratosis with neutrophils, and superficial perivascular dermal infiltrates of lymphocytes and macrophages. The patient started combination treatment with methotrexate 10 mg weekly plus acitretin, a retinoid, at 25–30 mg daily in January 2016, but acitretin was discontinued at the patient's request (reason not known) and single-treatment methotrexate was continued from July 2016 onward. However, methotrexate was also discontinued in February 2017 because of elevated liver enzyme levels and a lack of response. In March 2017, ongoing treatment failure prompted another biopsy, and the diagnosis reverted to eczema based on the lack of clinical response to treatment and the histology. Histology showed hyperparakeratosis, acanthosis, spongiosis in the epidermis, superficial perivascular dermal infiltrates of lymphocytes and macrophages, but without epidermotropism, lymphoid atypia, or CD7/CD3/CD5 loss [Figure 1(b)]. At this time (March 2017), blood and flow cytometry (FC) testing revealed a hemoglobin (Hb) level of 137 g/L (reference: 120–157 g/L), lactate dehydrogenase (LDH) level of 290 U/L (reference: 100–250 U/L), 13.6% lymphocytes (reference: 20–40%), 0.2% eosinophils (reference: 1.0–5.0%), CD4:CD8

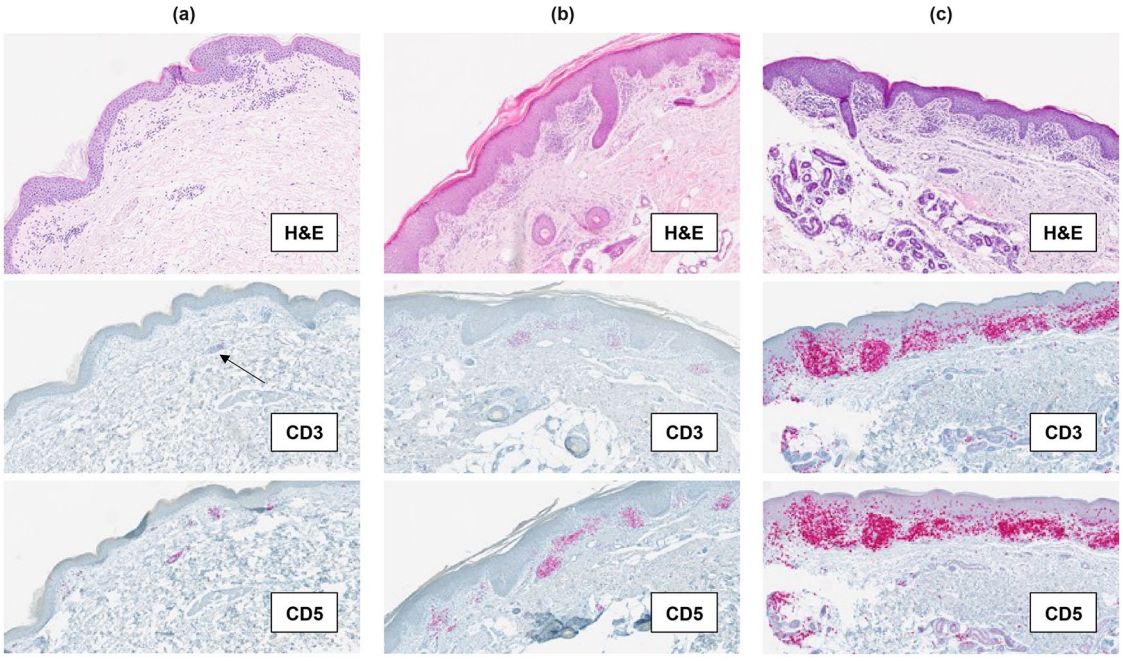

Figure 1. Immunohistochemical analysis of skin biopsies at (a) initial diagnosis of eczema in January 2015 (arrow indicates presence of CD3+ cells), (b) reversion of the eczema diagnosis in March 2017, and (c) confirmation of MF in September 2018.
CD, cluster of differentiation; H&E, hematoxylin and eosin; MF, mycosis fungoides.

ratio 2:3, and 100 CD4+/CD7− cells/μL (6%). From February 2017 to February 2018, the patient was also receiving extracorporeal photopheresis (ECP) once every 4 weeks. In March 2018, dupilumab, an interleukin-4 receptor-α and interleukin-13 antagonist, was initiated, dosed at 300 mg subcutaneously every other week. After 5 months, dupilumab was discontinued because eczema did not respond to treatment and pruritus continued.

Diagnosis of MF

In September 2018, another skin biopsy was conducted as the patient was still not responding to systemic treatment for eczema. The biopsy results and histology findings showed CD30+ cells <10% with no large cell transformation and the presence of hyperkeratosis, acanthosis, superficial lichenoid lymphoid infiltrate, epidermotropism, and no CD7/CD3/CD5 loss [Figure 1(c)]. As per local protocols, FC was used to identify clonal CD7− T cells (CD4:CD8 ratio of 2:4), with 20% lymphocytes (reference: 20–40%), 5% eosinophils (reference: 1.0–5.0%), LDH level of 225 U/L (reference: 100–250 U/L), and a Hb level of 111 g/L (reference: 120–157 g/L) demonstrated on blood analysis, also in September 2018. A clonality assessment was conducted which detected the presence of the T-cell-gamma receptor clone. A positron emission tomography/computed tomography scan showed clinically abnormal peripheral lymph nodes, although the results of a lymph node biopsy from the left axilla showed no histologic evidence of MF. Clinical assessment indicated that the patient was erythrodermic. These findings supported the final diagnosis of erythrodermic MF, stage IIIB T4 N1 M0 B1.

Initial management of MF

Following the diagnosis of MF in September 2018, the patient started combination treatment with ECP (4-week intervals) plus bexarotene 300 mg/m^2 per day in November 2018. After 1 month, the patient was found to have developed hypertriglyceridemia, measured as triglyceride levels of 1690 mg/dL, during routine blood testing. Consequently, the dose of bexarotene was reduced to 150 mg/m^2 per day. In January

2019, although pruritus improved, bexarotene at the reduced dose was discontinued due to unmanageable hypertriglyceridemia (measured at 666 mg/dL). The hypertriglyceridemia subsequently resolved. ECP was continued, and concurrent subcutaneous interferon-α was initiated at a dosage of 3 million units three times a week from May 2019. After 2 months, interferon-α was discontinued because of the occurrence of interferon-α-associated fever and seizures; the patient did not experience infection or febrile neutropenia. Ultraviolet B therapy was used again in January 2020, but the treatment was discontinued in February 2020 because of a phototoxic reaction. Following this, ECP monotherapy was continued at 4-week intervals until May 2021, when it was discontinued because of lack of efficacy in skin (skin symptoms worsened) and blood. The level of clonal T cells in the blood was increased, with an increase in the number of clonal CD7− T cells in the blood (700 cells/μL, 52% CD7− T cells, CD4:CD8 ratio of 7.2).

Therapeutic intervention with mogamulizumab

In July 2021, following discussion with the healthcare team, mogamulizumab treatment was initiated at a dosage of 1 mg/kg weekly on Days 1, 8, 15, and 22 of the first 28-day cycle, followed by 1 mg/kg every 2 weeks in subsequent cycles.

Follow-up and outcomes

Mogamulizumab was associated with resolution of pruritus within 2 weeks of initiation, and by 14 July 2021, after only 9 days of mogamulizumab treatment, the number of clonal T cells (CD3+/CD4+/CD7− T cells) in the blood had significantly reduced from 692 to 14 cells/μL, as measured by FC (Figure 2). In July 2021, because of improvement in pruritis symptoms after mogamulizumab initiation, the dose of daily gabapentin was slowly reduced from 2400 mg daily. The patient went on to achieve a partial response in the skin by September 2021 and a complete response in the skin in November 2021 (Figure 3), defined by 100% clearance of skin lesions. No adverse effects of mogamulizumab were reported, with the treatment continuing to produce a complete response in the skin and blood from November 2021, alongside an absence of

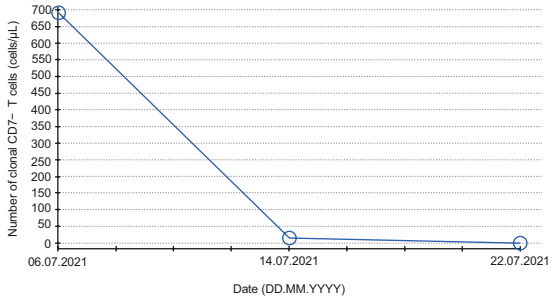

Figure 2. Flow cytometry analysis of clonal CD7− T cells (cells/μL) in the blood on Day 1, Day 9, and Day 17 of mogamulizumab treatment.
CD, cluster of differentiation.

pruritus. The patient noted improvement based on her own observations and clinical assessment following complete response with mogamulizumab. In particular, the patient described meaningful improvement in pruritus considering the prior significant negative effects on sleep and everyday activities. As a result, in December 2021, the dose of gabapentin was reduced to 600 mg daily; treatment with gabapentin (600 mg daily) and trazodone (150 mg daily) are ongoing to date. The patient last received mogamulizumab in November 2022, 14 months after first achieving a clinical response (partial response in the skin). Regular clinical monitoring and blood tests have shown no indication of relapse, and complete remission is ongoing 17 months after mogamulizumab discontinuation (last visit in April 2024). Mogamulizumab rechallenge may be considered should disease relapse occur.

Discussion

We report here the case of a patient with multiple comorbidities for whom it took 4 years to be correctly diagnosed with stage IIIB MF. Furthermore, numerous treatments had failed both before and after the patient was diagnosed with MF. Once mogamulizumab was initiated, a rapid complete response was observed in both the blood (within 1 week) and skin (after 4 months) of the patient. Mogamulizumab was well tolerated by the patient, especially considering the side effects and tolerability issues experienced with prior therapies (see Supplemental Table S1).

The patient experienced a delay in correct diagnosis and treatment because of misdiagnosis of her skin symptoms as other conditions, such as

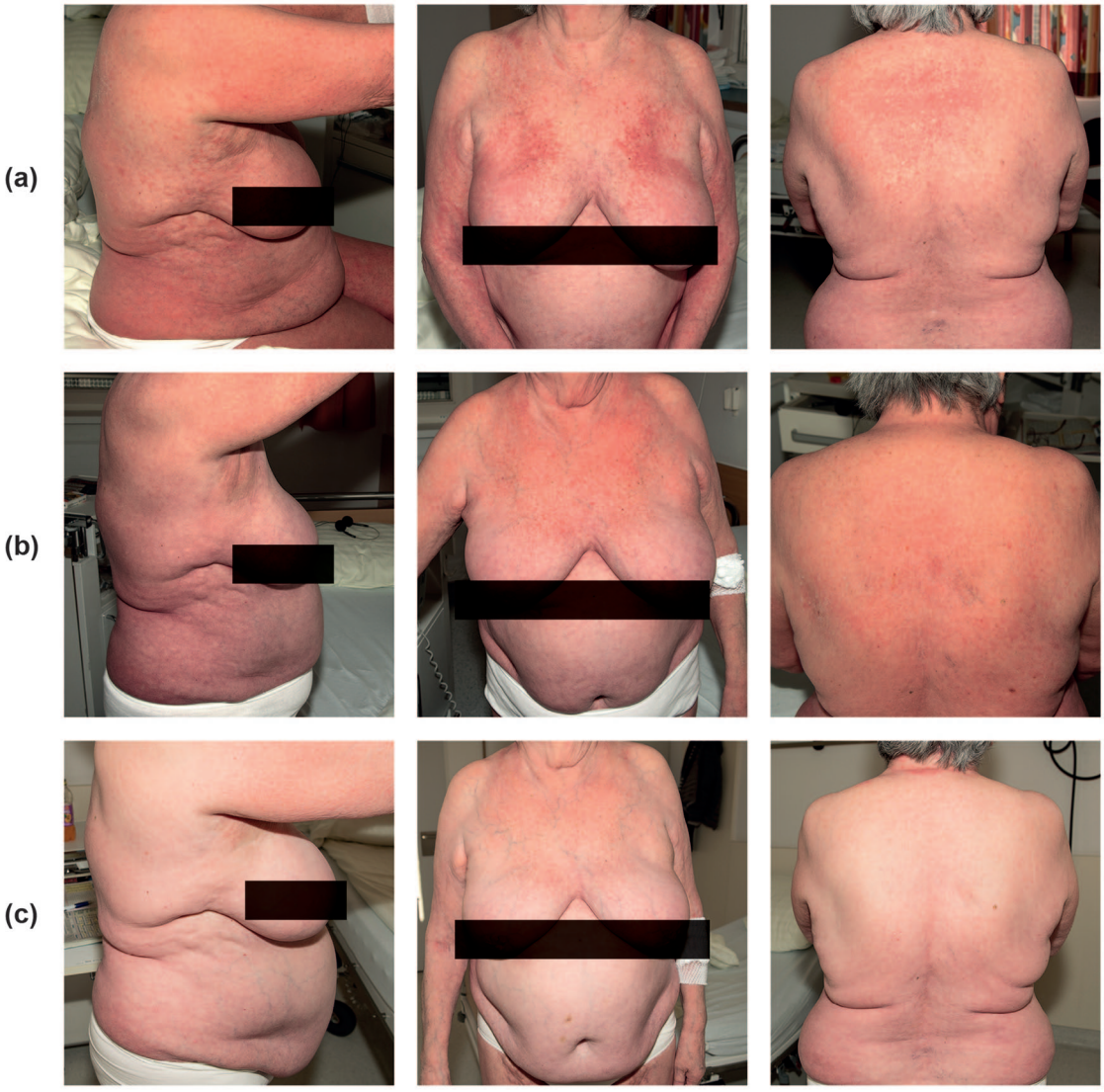

Figure 3. Clinical images (a) before mogamulizumab treatment, (b) after 2 months of mogamulizumab treatment (partial response), and (c) after 4 months of mogamulizumab treatment (complete response).

eczema. Indeed, the clinicopathologic findings of benign inflammatory dermatoses, such as eczema, overlap with the features of early-stage MF.[6,12,13] Eventually, the clinicopathologic picture, with results from biopsies where needed, should lead to a diagnosis of MF.[6,7,13,16] This case highlights the value of performing multiple biopsies to assist accurate diagnosis. Furthermore, histopathologic diagnosis of early MF is one of the most debated issues in dermatopathology,[6] as the presentation varies from patient to patient over time, and even between different sites in the same patient, and may lack features that support the diagnosis of MF.[1,16,17]

In terms of treatment, outcomes, and the treatment options available for patients with MF will differ from patients with other inflammatory disease; therefore, accurate and early diagnosis of MF is essential to avoid unnecessary prescribing of medications such as interleukin-4 receptor-α and programmed death-1 inhibitors, which have been reported to lead to progression of MF.[13,18,19] Therefore, failure to diagnose MF early can result in delayed treatment and potentially progression to advanced disease.

In the reported case, the patient experienced ongoing disease progression with worsening skin

involvement and blood tumor burden until treatment with mogamulizumab between July 2021 and November 2022, which to date has been associated with a sustained complete response in the skin and blood and resolution of pruritus that previously negatively impacted the patient's sleep and everyday activities.

The MAVORIC trial was a phase III, open-label, randomized, controlled, comparative study in which a cohort of patients with relapsed or refractory MF or SS received mogamulizumab (1.0 mg/kg intravenously weekly for the first 28-day cycle, then on Days 1 and 15 of subsequent cycles; $n = 186$) or vorinostat (400 mg daily; $n = 186$).[20] Mogamulizumab increased progression-free survival (PFS) and the proportion of patients with an overall response (the proportion of patients with an overall response or compartmental response is the percentage of patients with confirmed complete response or confirmed partial response) compared with vorinostat; investigator-assessed median PFS was 7.7 months [95% confidence interval (CI), 5.7–10.3] with mogamulizumab compared with 3.1 months (95% CI, 2.9–4.1) with vorinostat ($p < 0.0001$).[20] Compartmental response rate was reported as 68% in the blood and as 42% in the skin for mogamulizumab in MAVORIC, with a median time to compartmental response of 1.1 months [interquartile range (IQR): 1.0–1.2] in the blood and 3.0 months (IQR: 1.9–4.7) in the skin.[20,21] However, *post hoc* analyses have since shown that time to global response can be more variable in patients with MF treated with mogamulizumab than in patients with SS.[22] Indeed, for the patient in this case report, a rapid response following mogamulizumab treatment was observed with respect to blood within 1 week and subsequently in skin after 4 months of treatment.

HRQoL is another important aspect of managing patients with MF/SS, and patients with late-stage disease have poorer quality of life (QoL) outcomes than patients at earlier disease stages according to a variety of HRQoL questionnaires.[23] Patients with late-stage disease (Stage IIB–IVB) often have significant impairments in functional, emotional, and physical aspects of HRQoL.[23] In a validation study of a new European Organisation for the Research and Treatment of Cancer (EORTC)/Cutaneous Lymphoma Task Force HRQoL questionnaire, a number of skin symptoms associated with MF and SS were identified as being detrimental to patient HRQoL, including pruritis, skin pain, sensitivity, redness, scaling, and irritation.[24] Indeed, pruritus was among the most important signs and symptoms highlighted as troublesome or bothersome by both patients and healthcare professionals in this survey.[24] Additionally, a systematic review evaluated the HRQoL of patients with MF and SS and reported that pruritus was the most frequently reported and most bothersome symptom.[23] Similarly, a cross-sectional cohort study demonstrated that pruritus levels of patients with MF or SS are strongly correlated with QoL.[25]

Following initiation of mogamulizumab, the patient discussed in this case reported improved HRQoL due to the resolution of pruritus, a symptom that had caused major discomfort and resulted in limited activities of daily living and impaired sleep. The patient's symptoms improved sufficiently to enable a reduction in the gabapentin dose; daily trazodone treatment was maintained. The mogamulizumab-related benefits for pruritus and patient-reported HRQoL are consistent with the favorable HRQoL (assessed using Skindex-29, FACT-G, and EQ-5D-3L) associated with mogamulizumab treatment, assessed as a secondary endpoint of the MAVORIC trial.[26] Further evaluations of mogamulizumab treatment effects are warranted once the real-world validity of novel disease-specific measures of HRQoL, such as the cutaneous lymphoma module of the EORTC-quality of life questionnaire, has been established in patients with CTCL.[24,27]

In summary, this case demonstrates the importance of considering the possibility of CTCL in patients with nonspecific skin symptoms to achieve a correct diagnosis of MF as early as possible. Advanced-stage MF is often difficult to treat, especially when the patient has been misdiagnosed and thus received multiple inappropriate treatments that do not produce a response, which may result in toxicity and potential disease progression. In these situations, patient HRQoL will likely be compromised. Collectively, our observations contribute to the growing evidence showing that mogamulizumab may be an effective treatment option for reducing symptom burden and improving response rates and HRQoL outcomes in patients with MF after previous treatments have failed.

Declarations

Ethics approval and consent to participate
Due to the retrospective nature of the reported case study, ethics approval was not required.

Consent for treatment
The patient provided their written informed consent for treatment.

Consent for publication
The patient provided written informed consent for this case to be published.

Author contributions
Nina Frischhut: Formal analysis; Methodology; Resources; Software; Validation; Writing – review & editing.

Van Anh Nguyen: Data curation; Supervision; Writing – review & editing.

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VAN has previously received honoraria from Kyowa Kirin. NF declares no conflict of interest.

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Supplemental material
Supplemental material for this article is available online.

Supplemental Figure S1. Treatment timeline. The timeline of interventions and outcomes of the case.

Supplemental Table S1. Overview of treatments administered to the patient prior to and after MF diagnosis.

CARE checklist

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